

Model: Picasso™ by AMD LASERS™, LLC
Dental Diode Laser System

Operating Instructions Manual



PLEASE READ THIS OPERATION INSTRUCTIONS MANUAL
CAREFULLY BEFORE USE AND KEEP IT FOR REFERENCES

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INTRODUCTION

PICASSO Dental Soft Tissue Laser is a surgical device at the cutting edge of technology, designed for a wide variety of oral soft tissue and tooth whitening procedures. PICASSO utilizes a solid state diode 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 is intended for use by dentists in oral soft tissue and tooth whitening procedures. The use of this device requires proper clinical and technical training. This manual provides instructions for professionals that have completed the appropriate training.

When used and maintained properly, PICASSO 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: This unit has 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”. 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, 1 = 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. The text display will indicate the type of error. Operation will not resume until the error is cleared, and the text once again displays “PICASSO”.

Keyswitch

The unit can only be switched ON (key in horizontal position) with the proper key. The key cannot be removed while in the ON position. 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 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. To reset the Emergency Stop button, simply press RESET. 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). This feature may be overridden by inserting the remote interlock plug.

Functional Display

The System Text Display 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 device:

- Laser Radiation – Class 4
- Type of protections against electrical shock – Class 1
- 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)



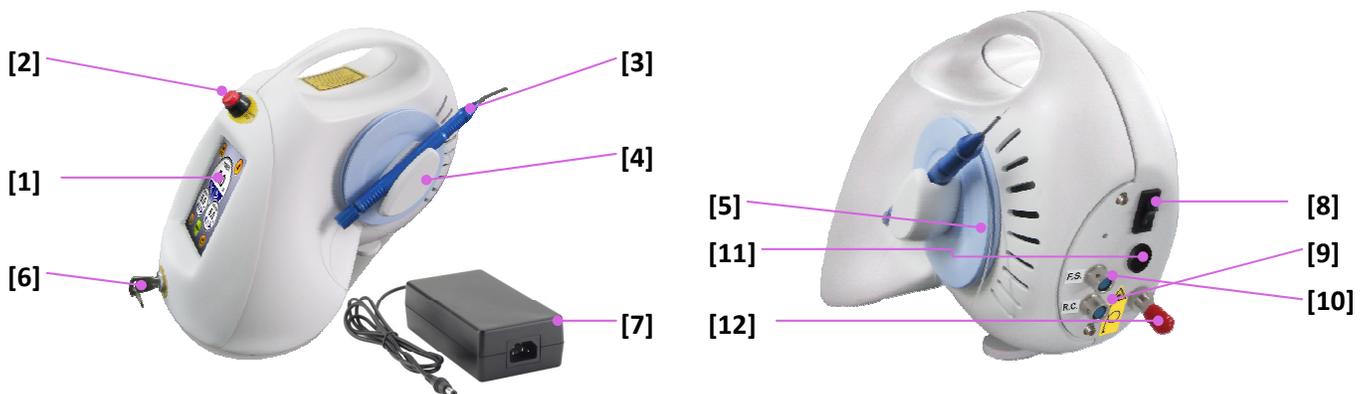
FIGURE 1



FIGURE 2

Item#	Item	Item Description
1	LCD COLOR TOUCH SCREEN	Displays and controls the parameters, such as working status of the system, operation mode, pulse duration, output energy, etc.
2	EMERGENCY STOP BUTTON	Disables the unit in the event of an emergency. Push once to disable Picasso. 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 Setup

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 9).
10. Set up Delivery System handpiece and fiber (see page 10).
11. See Operation Instructions on page 12.

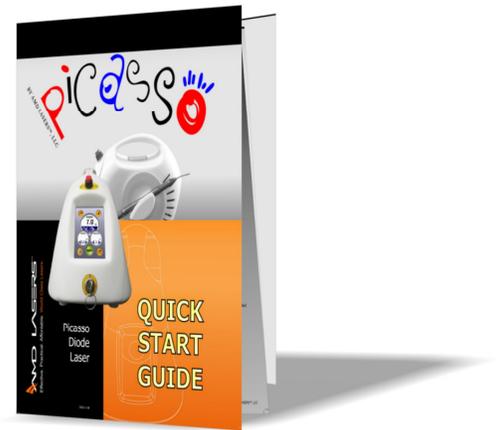


FIGURE 4

Control Panel

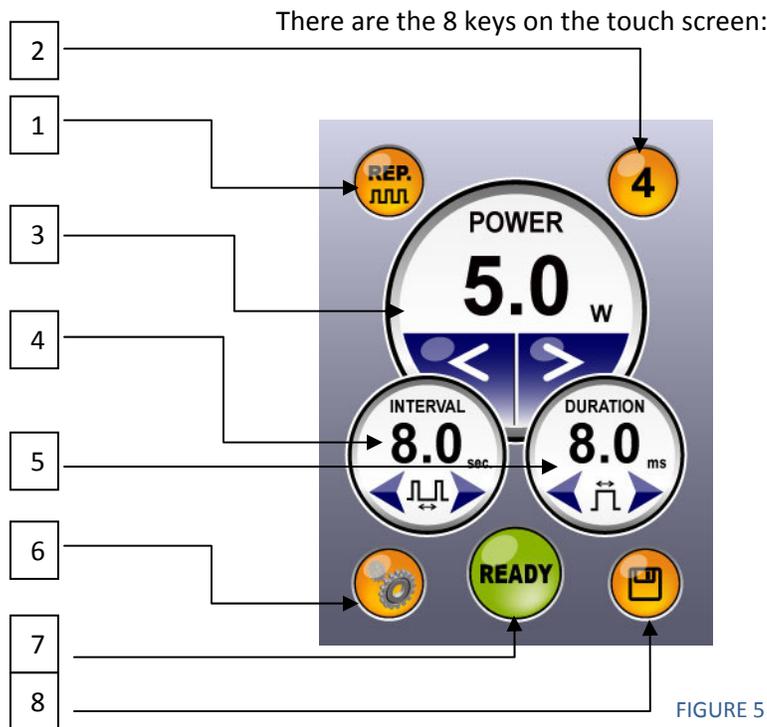


FIGURE 5

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. AIMING BEAM: 5 steps: Off->Weakest->Weak->Strong->Strongest
7. STANDBY/READY:  Standby/  Ready button
8. SAVE: Save button

Language selection

Seven languages can be selected (Figure 6):



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

English is the default language.

FIGURE 6

To select another language, press  button then the system will 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

PICASSO IS PRESET TO THE FOLLOWING PARAMETERS:

Custom presets

The user is able to select parameters as POWER, INTERVAL, DURATION, CONT or REP modes according to the operation. Then, press the SAVE button to store 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 Repeating .

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) are able to be selected as a preset. Use the  and  buttons (Figure 5, #4 and #5) to select desired interval and duration from 20ms to 9.9 secs.

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 emit laser.

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

POWER SETTINGS AND USE

CUTTING 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 5.0 WATTS on either REPEAT or CONTINUOUS MODES. Operator should try to use the least amount of power (WATTS) to achieve desired results.



TOOTH-WHITENING

Tooth whitening should be performed on single teeth at a distance of 10 mm at 7.0 WATTS in the CONTINUOUS MODE for 30 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

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 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 17). Fiber optic cable is not autoclaveable unless labeled as “autoclaveable”.

PICASSO Handpiece



FIGURE 7

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 2 inches (5cm) should protrude
4. Strip and cleave fiber (FIGURES 9 AND 10) See Directions Page 12
5. Adjust to desired length
6. Gently tighten Handpiece Base to secure Handpiece and the Fiber Optic Assembly

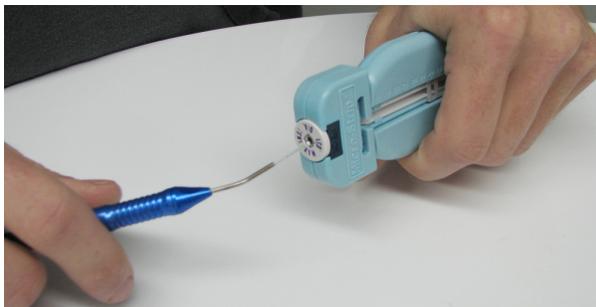


FIGURE 9



FIGURE 10

Directions for Stripping and Cleaving PICASSO Fiber

PICASSO fiber should be cleaved after each procedure.

To cleave 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. 2-3 inches (5-6 cm) out of the tip.
3. Select a fiber stripper that corresponds to the fiber diameter size.
4. Insert approximately 1 inch (25 mm) of the fiber optic cable into the stripper. Squeeze the stripper handles to get a firm grasp on the fiber optic cable. While keeping a firm grip on the fiber optic cable, pull the stripper away from the handpiece in a smooth motion to ensure that the jacket is cleanly removed (Figure 9).
5. Use a diamond/carbide cleaver to cut the end of the fiber. Place the fiber against a flat surface. Position the edge of the cleaver approximately $\frac{1}{4}$ inch (7mm) from the end of the fiber, and make a scratch around half the circumference of the fiber (Figure 10). Make sure that the edge of the cleaver is always perpendicular to the fiber during scratching.
6. Hold the end of the fiber above the scratch 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.

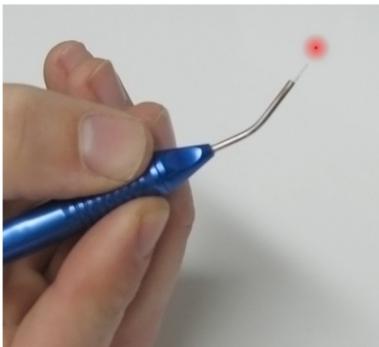


FIGURE 11

fiber optic cable at the proximal end (Figure 11).

7. Verify the 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 cleaving procedure presented in steps 5 and 6 until you obtain a perfect circle 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 not loose by pulling lightly on the

OPERATION INSTRUCTIONS

Turn ON PICASSO

- Turn circuit breaker to ON position. See Set-UP Page 8 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 12).
- Select PRESET 1 – 4 or select custom power, interval and duration settings
- Press STAND-BY to place unit in READY Mode (See page 8)
- Depress foot control switch to fire laser and release to stop

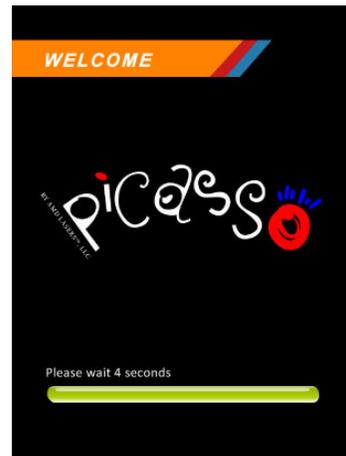


FIGURE 12

Turn OFF PICASSO

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

CAUTION: Verify that fiber optic tubing 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.

1. Press the READY key.
2. Press and hold the footswitch until the system stops.
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.

NOTE: While output power is negligible, wear protective glasses during the warm-up. The warm-up mode will not function at temperatures below 41°F (5°C), as a “Thermistor Error” will appear on the display. 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 in a controlled environment for ten to fifteen minutes before the warm-up mode is activated.

PICASSO SPECIFICATIONS

General

- Dimensions L x W x H -> 9.5" x 6" x 6.2" (240 x 150 x 160mm)
- Weight 6.6 lbs (3 kg)

Electrical

- Operating Voltage AC 110/230V 50/60 Hz \pm 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

- Laser Classification IV (4)
- Medium GaAlAs
- Wavelength 810 ± 10 nm
- Power Accuracy \pm 10%
- Power Modes Continuous, Repeat Pulse
- Pulse Duration 20 ms – 9.9 sec
- Pulse Interval 20 ms – 9.9 sec
- Delivery Fiber Diameter 200 - 1000 μ m
- Mode Multimode
- Max Output
Power Range 7 watts output 600 μ m or 400 μ m fiber

Other Light sources

- Aiming Beam LED, max 5 mW, 630-670nm

CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

Contraindications

- All clinical procedures performed with PICASSO 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 others in the operatory must wear appropriate laser eyewear protection for the diode laser wavelength of 810 ± 10 nm.

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 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 energy towards hard tissues, such as tooth or bone. Do not direct energy towards amalgam, gold or other metallic surfaces. Do not direct energy toward any filling material.

Suction

Use high-speed suction as required to maintain a clear field of vision during treatment. Do not use PICASSO if you cannot clearly see the treatment site.

Training

Only licensed professionals who have successfully completed a PICASSO training seminar 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 operates unlike traditional devices. The techniques mentioned below must be practiced and perfected to ensure efficient operation. Please study this section carefully, practice on model tissues, and attend a quality diode laser-training seminar before using this device in a clinical situation.

Indications of Use:

Use of PICASSO 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 should be serviced annually by a qualified, trained, and certified technician.

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

Daily Maintenance

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

Contamination Control Procedures

The contamination control suggested for PICASSO fiber optic cable, handpiece, and interchangeable tips is the system sterilization method. However, before sterilization, PICASSO 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 Surgical Handpiece and the Fiber Optic Cable



FIGURE 13

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 quality 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 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 "Equipment Description" section (see page 6).

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 inches (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 CAVIVIDE disinfecting solution, please follow the manufacture's instructions.

Steam Sterilization for PICASSO 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, fiber optic cable, and interchangeable tips 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 is 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 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 is shipped inside a custom shipping box. Please save and store the box in a cool, dry place.

CALIBRATION

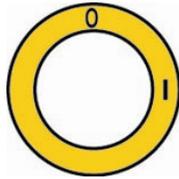
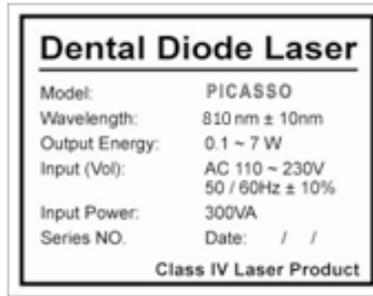
PICASSO is factory calibrated and certified for use. Recalibration of the unit should be performed every 12 months and should be performed only by authorized personnel. To calibrate the unit, contact your authorized representative or AMD LASERS™, LLC at 1.866.999.2635. You must obtain an RMA before returning the unit for calibration. Calibration generally takes 1-2 business days (excluding holidays).

Calibration schedule

Dates:	Authorized by:
--------	----------------

Purchase Date ____//____//_____	
Calibration 1 ____//____//_____	_____
(12 month after purchase date)	
Calibration 2 ____//____//_____	_____
(24 month after purchase date)	
Calibration 3 ____//____//_____	_____
(36 month after purchase date)	
Calibration 4 ____//____//_____	_____
(48 month after purchase date)	
Calibration 5 ____//____//_____	_____
(60 month after purchase date)	
Calibration 6 ____//____//_____	_____
(72 month after purchase date)	

APPENDIX A – LABELS



APPENDIX B – PARTS AND ACCESSORIES

PICASSO DESCRIPTION

- Handpiece
- Fiber Optic Assembly
- 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

APPENDIX C – (LIMITED WARRANTY)

AMD LASERS™, LLC warrants for a period of thirty-six (36) months from the shipment to the original purchaser/user PICASSO Laser system serial number _____. It is warranted to be free from defects in materials and workmanship under normal use and service and fit for ordinary use for which designed, if operated by a trained and competent operator and 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 it 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 is satisfied that 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 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.

APPENDIX D – (LIMITED LIABILITY)

AMD LASERS™, LLC WILL NOT BE LIABLE FOR INCIDENTAL, CONSEQUENTIAL, INDIRECT, OR SPECIAL DAMAGES OF ANY KIND INCLUDING, BY 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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