

Picasso II | Picasso Perio | Picasso Lite

Operating Instructions Manual



ISO 13485



For EU only

Canada Only - This device should be installed and operated in accordance with CAN/CSA-Z386-92: Laser Safety in Health Care Facilities

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DEVICES WITH WIRELESS FOOT CONTROL 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:

Caution:

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

15.105:

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

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved 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.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner uniquement avec une antenne d'un certain type et d'un gain maximal (ou inférieur), approuvé pour l'émetteur, par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain, de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

7.1.3 User Manual

This device complies with Industry Canada licence-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.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts d'une licence. L'exploitation est autorisée si les deux conditions suivantes sont respectées : (1) l'appareil ne doit pas produire de brouillage et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

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Introduction & Safety

INTRODUCTION

The Picasso line of soft tissue dental lasers is designed for a wide variety of oral soft tissue and teeth whitening procedures. Picasso II | Picasso Perio | 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 II | Picasso Perio | Picasso Lite lasers are intended for use by Dentists, Hygienists and/or authorized dental professionals in oral soft tissue and 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 II | Picasso Perio | Picasso Lite lasers will prove to be a valuable addition to your practice. Please contact your authorized representative or AMD LASERS®, LLC if you have any questions or require assistance.

SAFETY

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

SAFETY PRECAUTIONS

The user should read and be thoroughly familiar with this manual before operating the instrument. The equipment should be routinely inspected and maintained in accordance with the instructions given in the maintenance section of this manual.

All clinical procedures performed with Picasso II | Picasso Perio | 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.

Nominal Ocular Hazard Distance (NOHD) is 2m 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.

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

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

WARNINGS

Eyewear

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 are 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 II | Picasso Perio | Picasso Lite Picasso is designed to remove soft tissue. Therefore, always be aware of adjacent structures and substructures during treatment. 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 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 II | Picasso Perio | 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®, LLC 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, canulas, and the handpieces may become hot during use. Avoid unnecessary contact with tissue.

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 (810nm) 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 800-820nm range 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®, LLC.

- **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 (Standby button) 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.**

Safety Classification

The following safety classifications are applicable to the Picasso II | Picasso Perio | 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
- Not protected against water ingress – Ordinary Equipment
- Not suitable for use in the presence of flammable anesthetic mixtures
- Operation Mode – Continuous Operation

Safety Questions

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

SAFETY FEATURES

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. 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.

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

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.

Equipment & Control Panels

EQUIPMENT DESCRIPTION

MAIN UNITS: PICASSO II | PICASSO PERIO | PICASSO LITE



Item#	Item	Item Description
1	HANDLE	For carrying the unit
2	EMERGENCY STOP BUTTON	Disables the unit in the event of an emergency.
3	CONTROL PANEL	Displays and controls the parameters, such as power output, presets, aiming beam intensity, and speaker volume.
4	KEYSWITCH	Turns display of the unit ON and OFF
5	HANDPIECE, DISPOSABLE TIP & HANDPIECE HOLDER	Multi-tip handpiece/fiber with fiber spool, holder and disposable tip
6	FIBER SPOOL	Stores fiber
7	COOLING VENTS	Cooling vents
8	CIRCUIT BREAKER	Master ON/OFF switch
9	REMOTE INTERLOCK CONNECTOR	Connects interlock to the unit
10	AC POWER CONNECTOR	Connects power supply to the unit
11	WIRED FOOT CONTROL CONNECTOR PORT	Connects wired foot control to the unit
12	FIBER CONNECTOR PORT	Connects fiber to the unit
13	TRANSPORTATION BOX	Transportation Box – Picasso II/Picasso Perio
14	TRANSPORTATION BOX KEYS	Transportation Box Keys – Picasso II/Picasso Perio
15	LASER EYEWEAR PROTECTIVE GOGGLES CASE	Protective case
16	LASER EYEWEAR PROTECTIVE GOGGLES (3)	ANSI Z87, 800-820 nm, Optical Density (OD) 5+ Protective eyewear goggles
17	WIRED FOOT CONTROL	Wired foot control Std Picasso Lite
19	WIRELESS FOOT CONTROL	Wireless foot control Std Picasso II / Picasso Perio
19	REMOTE INTERLOCK	Remote interlock
20	AC ADAPTER	Connects the unit and net power supply Input: 100-240 V 50-60Hz Output: 9V--3A
21	POWER CORD	Power cord
22	INITIATION CORK	Initiation Cork
23	LASER DANGER SIGN	Danger sign for operatory
24	KEYS	Unit Keys
25	QSG	QUICK START GUIDE
26	MANUAL	Operations Manual
27	PERIO MANUAL	Perio manual
28	SETUP DVD	Setup DVD
29	TRAINING/CERTIFICATION DVDS	ICLE training/certification DVDs

CONTROL PANEL PICASSO II

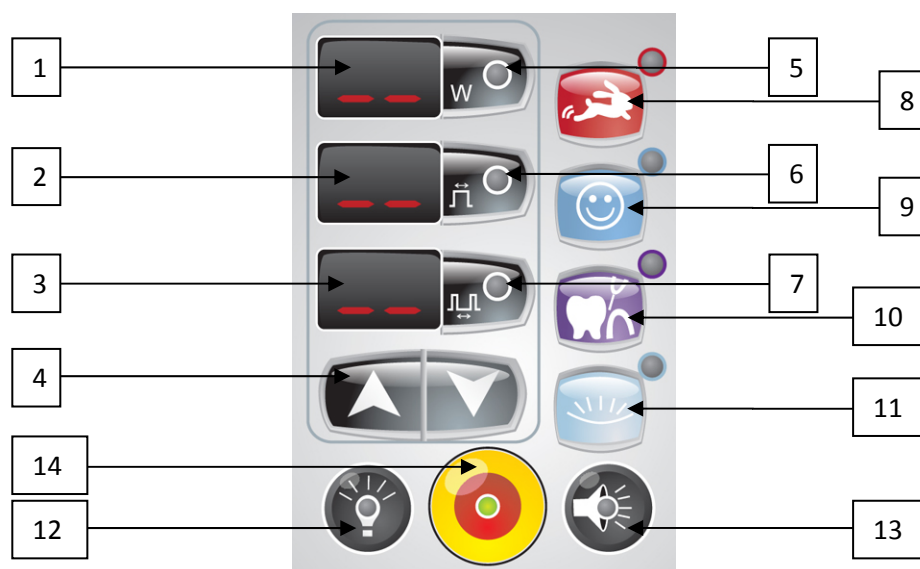


FIGURE 1

1. POWER DISPLAY
2. DURATION DISPLAY
3. INTERVAL DISPLAY
4. UP/DOWN ADJUSTMENT BUTTONS
5. POWER SELECTION
6. DURATION SELECTION
7. INTERVAL SELECTION
8. SPEED MODE
9. COMFORT MODE
10. PERIO MODE
11. BLEACHING/THERAPEUTIC MODE
12. AIMING BEAM SETTING: 3 steps:
13. VOLUME SETTING: 3 steps:
14. STANDBY / READY

Off-> Low->High
Off-> Low->High



CONTROL PANEL - PICASSO PERIO

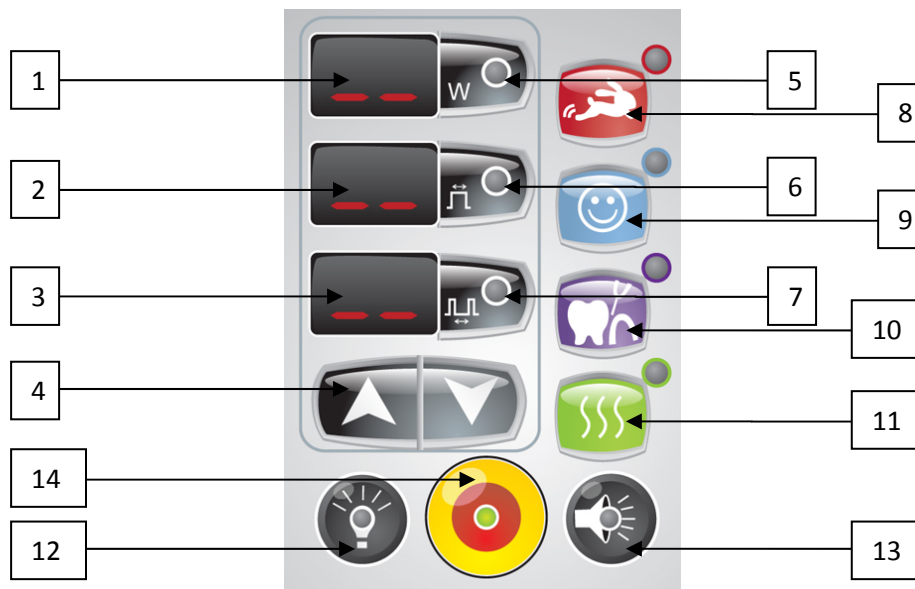


FIGURE 2

1. POWER DISPLAY
2. DURATION DISPLAY
3. INTERVAL DISPLAY
4. UP/DOWN ADJUSTMENT BUTTONS
5. POWER SELECTION
6. DURATION SELECTION
7. INTERVAL SELECTION
8. SPEED MODE
9. COMFORT MODE
10. PERIO MODE
11. THERAPEUTIC MODE
12. AIMING BEAM SETTING: 3 steps: Off-> Low->High
13. VOLUME SETTING: 3 steps: Off-> Low->High
14. STANDBY / READY



CONTROL PANEL - PICASSO LITE

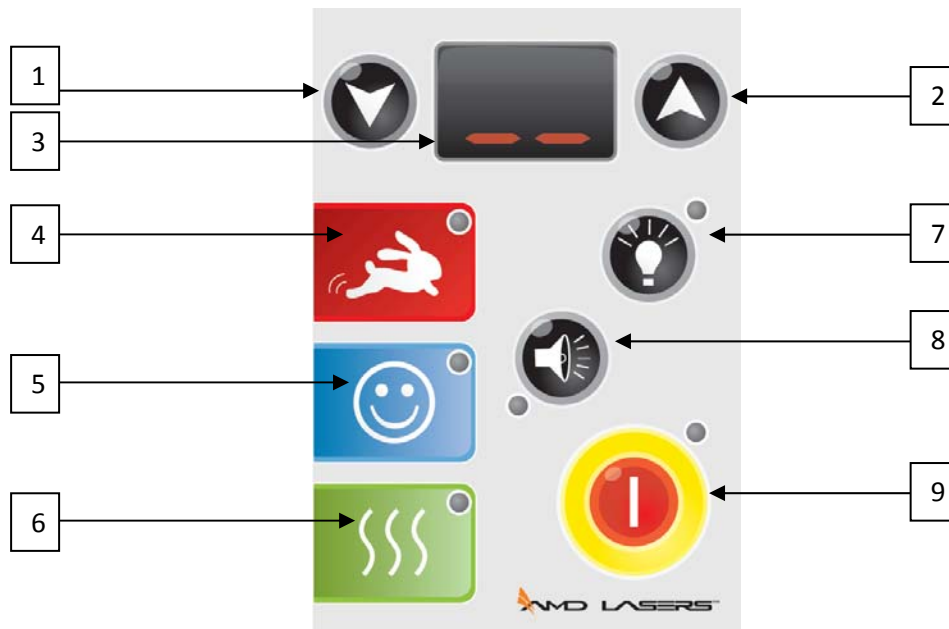


FIGURE 3

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



Set-up, Operations & Troubleshooting

Set-up

PICASSO II | PICASSO PERIO | PICASSO LITE SET-UP

For details refer to "Quick Start Guide" (FIGURE 4). See page 11/12 for identification of components.

1. Place unit in a clean, dry, and well ventilated area.
2. Verify circuit breaker is in OFF position.
3. Insert 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. Insert fiber into fiber connection port.
9. Set up Delivery System handpiece and fiber (see Page 25).



FIGURE 4

OPERATION INSTRUCTIONS

TURN ON PICASSO II | PICASSO PERIO | PICASSO LITE

- Verify Red Emergency button (Page 14, Item # 2) is pushed in.
- Turn circuit breaker to ON position. See Page 11 for Circuit Breaker location.
- Rotate key clockwise to ON position.
- Select a PRESET
- Press STAND-BY to place unit in READY Mode.
- Press foot control switch to fire laser and release to stop.

TURN OFF PICASSO II | PICASSO PERIO | PICASSO LITE

- 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.

NOTE: Do not leave the system in an uncontrolled environment where the temperature could drop below 41°F (5°C) (i.e., 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 II 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:

1. Press the READY button.
2. Press and hold the footswitch.
3. 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.
4. 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.

TROUBLESHOOTING

TROUBLESHOOTING – PICASSO II | PICASSO PERIO | PICASSO LITE

QUICK SOLUTIONS		
Symptom	Possible Causes	Solution
Unit will not turn on	<ul style="list-style-type: none"> No power to the laser One or more of the safety devices are not in the ON position 	<ul style="list-style-type: none"> Verify that the unit is plugged in and the green LED on the AC adapter is on. Verify that the Circuit Breaker Switch on the back of the unit is ON, the Keyswitch is in the ON position, and the red Emergency Stop button is pushed in.
No laser output when stepping on the foot control	<ul style="list-style-type: none"> Laser is not in the READY mode Optical fiber not connected properly 	<ul style="list-style-type: none"> Press the STANDBY /READY button Verify that the optical fiber is tightened all the way at the fiber connection port on the back of the unit.
Laser will not cut or cuts poorly	<ul style="list-style-type: none"> Fiber has not been initiated Disposable tip not inserted all the way onto the multi-tip handpiece Fiber cleave poor Power too low 	<ul style="list-style-type: none"> Follow the steps on initiating the optical fiber Insert the disposable tip all the way onto the multi-tip handpiece Cleave fiber and verify that the aiming beam “dot” is circular Increase power
Laser beeps continuously	<ul style="list-style-type: none"> Remote interlock or foot control not connected or connected improperly 	<ul style="list-style-type: none"> See the following instructions



FIGURE 5

REMOTE INTERLOCK ERROR (FIGURE 5) - 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.



FIGURE 6

FOOTSWITCH ERROR (FIGURE 6) - 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.

Delivery Systems

**Multi-Tip Fiber
Disposable Tips
Strippable Fiber
Stripping/Cleaving
Maintenance**

DELIVERY SYSTEMS

MULTI-TIP HANDPIECE WITH PERMANENT FIBER

NOTE: Tips are not autoclavable.

The delivery system used in conjunction with removable and disposable tips consists of the Multi-Tip Handpiece/fiber assembly (FIGURES 7 (200 μm) and 8 (400 μm)):



FIGURE 7

Fiber Spool



FIGURE 8

Multi-Tip Fiber

- 400 μm Picasso II (orange); 200 μm Picasso Perio, Picasso Lite (black)
- 2 meters in length
- FC connector

The disposable tips (FIGURE 9) 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 9

THE QUADRA TIP

The Quadra Tip (FIGURE 10) 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 10

STRIPPABLE FIBER WITH STANDARD HANDPIECE



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 400 μm fiber. Other sizes are available upon request.

- Handpiece
- Accessories: Adapter (To be used with Disposable/Bendable Tip)
- Picasso II | Picasso Perio | 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 30). Fiber optic cable is not autoclavable unless labeled as “autoclavable.”

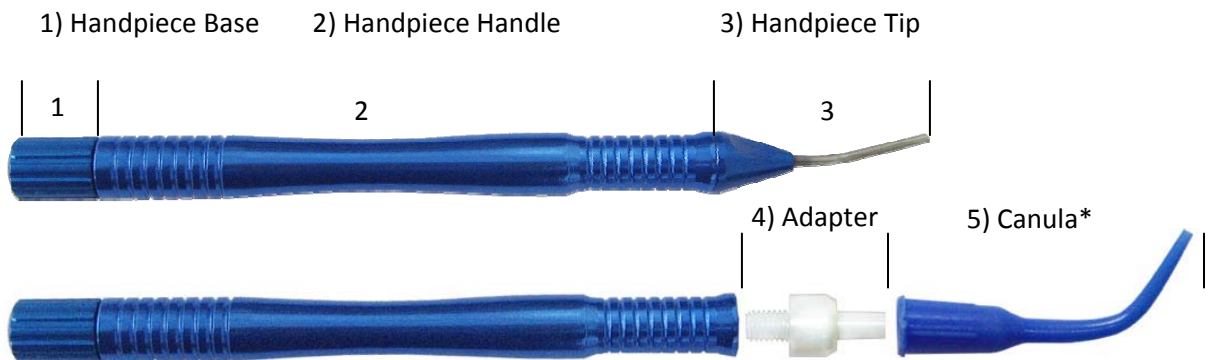


FIGURE 11

* Customer supplied disposable tip (18 gauge or larger)



FIGURE 12

DIRECTIONS FOR STRIPPING AND CLEAVING PICASSO II | PICASSO PERIO | PICASSO LITE FIBER

Strippable fiber should be cleaved/scribed after each procedure.

To cleave/scribe the fiber:

1. Loosen the proximal end of the handpiece by unscrewing the handpiece base (FIGURE 12).
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 13).
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 14), 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 15).
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.

To connect handpiece to fiber optic assembly:

1. Loosen handpiece base (FIGURE 12)
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 13 and 14)
5. Adjust to desired length
6. Gently tighten handpiece base to secure the fiber

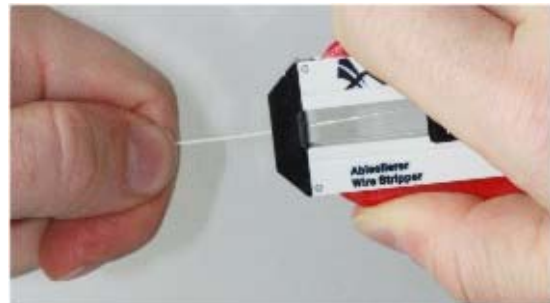


FIGURE 13



FIGURE 14

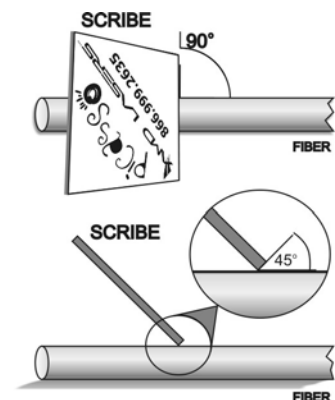


FIGURE 15

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.

CONTAMINATION CONTROL PROCEDURES

The contamination control suggested for fiber optic cable, handpiece, and interchangeable tips is the system sterilization method. However, before sterilization, Picasso II | Picasso Perio | 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 II | PICASSO PERIO | PICASSO LITE STANDARD HANDPIECE AND THE STRIPPABLE FIBER OPTIC CABLE



FIGURE 16

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 II | Picasso Perio | Picasso Lite Fiber Optic Delivery System.

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

HIGH-LEVEL 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 (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 a CAVICIDE equivalent 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 equivalent disinfecting solution, please follow the manufacturer's instructions.

STEAM STERILIZATION FOR PICASSO II | PICASSO PERIO | 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(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.

MAINTENANCE

MAINTENANCE - DENTAL LASER UNIT AND PLASTIC BARRIERS

This unit requires little operator maintenance. Wipe down the system with a cloth dampened with a mild antiseptic or cleaning solution. 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 II | Picasso Perio | 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.

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.

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 II | Picasso Perio | 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 transportation box. If you have any questions regarding transportation, please call your authorized representative or AMD LASERS®, LLC.

STORAGE

Picasso II | Picasso Perio | Picasso Lite should be stored at room temperature in dry conditions when not in use. Cover the unit when not in use for extended periods of time. Care should be taken to ensure the system is stored in a place where it will be protected from accidental mishandling.

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

CLINICAL APPLICATIONS

CLINICAL APPLICATIONS

INTRODUCTION

To efficiently remove tissue, it is imperative to understand the nature of the Picasso II | Picasso Perio | 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. 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. A cork is supplied with each laser for initiation. This initiation focuses laser energy to the tip. Non-initiated tips are used for procedures like decontamination and for therapeutic reasons.



SOFT TISSUE SURGERY – CONTACT MODE

Cutting and coagulating soft tissue procedures can be utilized with either the surgical handpiece or the multitip 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. 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 WATTS to 2.5 WATTS with either CONTINUOUS or PULSED MODES. Operator should try to use the least amount of power (WATTS) to achieve desired results. Consult the accessories index for a complete listing of fibers and tips. Indications for use are: 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 papillertomies, Reduction of gingival hypertrophy, Soft tissue crown lengthening, Vestibuloplasty

INITIATING

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



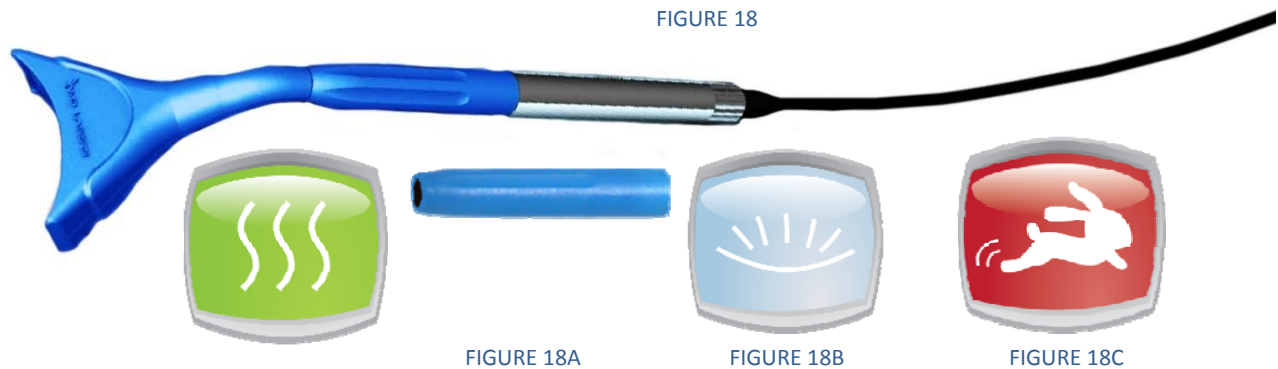
FIGURE 17

A cork is included with each Picasso laser, waxed based articulating paper is also widely used. Select the SPEED MODE preset (figure 18c) and insert tip into the cork or onto the articulating paper while firing the laser. A good ignition will cover 3-4 mm of the tip with a dark carbonization (figure 17). For

more information on initiation please consult the Quick Reference Guide or training DVDs included with your laser.

THERAPEUTIC USE – NON CONTACT MODE

The treatment of tissue in a biostimulation mode requires training. It is recommended that only personnel who have adequate training utilize the Picasso line of lasers for therapeutic treatments. Laser energy is applied to the target area in the form of heat. Two methods are widely used. The first is by applying low power for a long duration, the second by applying high power for a short duration. Using a smaller spot size (400 microns) that is close to target tissue can cause burning.



It is recommended that 400 micron fibers be used at a distance of 10mm and only moved closer as the individual patient can tolerate for a maximum of 2 minutes in the THERAPEUTIC MODE (figure 18a).

Common treatments are aphthous ulcers and TMJ. Subsequently when larger spot size tips are used such as the 6mm or the Quadra Tip (figure 18) the operator must increase the power using the BLEACHING/THERAPEUTIC MODE preset (figure 18b) and move the distance to target to direct contact or 1-2 mm.

TEETH WHITENING (PICASSO II ONLY)

Picasso II teeth whitening should be performed only by trained personal and as allowed by local, state and federal authorities. Picasso II is design for fast, efficient laser bleaching with an unique laser diffuser – The Quadra Tip. Consult with the gel manufacturer on their recommended settings. Most bleaching is performed by first cleaning, pumicing the teeth, protecting the gingival and soft tissue mucosa with a liquid rubber dam and applying the manufacturers bleach to the teeth with 2-3 mm of coverage. Picasso II has a built in bleaching mode. Prior to usage the operator must use the multitip fiber and Quadra Tip as seen in figure 18. The tip is non-disposable and must be wrapped in dental plastic to protect the lens from contact with the bleach. Depress the BLEACHING/THERAPEUTIC MODE Preset (Figure 18b) and hold the Quadra tip 2 mm from target area. Picasso II has a 30 second timer built into the preset. After the cycle is complete the laser will cease firing. The operator must let go and depress the foot control again to reactivate the laser. The operator may stop the laser from firing during the 30 second cycle by simply releasing the foot control. Most bleaches require 4 - 6 passes per quadrant with the Quadra handpiece and also require 4 -6 applications of the bleach to be effective. Picasso II is used for laser assisted whitening/bleaching of teeth. Light activation for bleaching materials for teeth whitening.

PERIO TREATMENT



See separate Picasso Perio Treatment Manual for instructions included with Picasso II and Picasso Perio.

DESCRIPTION OF LASER OPERATION MODES

FIGURE 19



Picasso II, Picasso Perio and Picasso Lite have two modes of operation, CONTINUOUS and 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 repeated pulse mode, the laser will deliver output radiation at the power level specified by the user in a pulse format defined by the user. In this section, the operation of the laser in each of these modes is described.

SPEED MODE

PICASSO II, PICASSO PERIO, PICASSO LITE

To select the SPEED MODE of operation, the user simply presses the key marked with the Rabbit 🐰 symbol representing SPEED MODE. In this mode, the mode is preset from the factory at 1.8 watts, 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 power shown in watts by pressing the corresponding up/down keys.

To operate the laser in CONTINUOUS MODE, the user presses 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

PICASSO II, PICASSO PERIO, PICASSO LITE


To select the COMFORT MODE of operation, the user simply presses the key marked with the HAPPY FACE 😊 symbol representing the COMFORT MODE. In this mode, the mode is preset from the factory at 1.8 watts, 30 ms on time and 30 ms off time. This is a PULSED MODE of operation. The user may modify all three of these parameters and save them into the laser as a customized preset. These are the POWER (Figure 19-1), PULSE ON TIME (Figure 19-2), and PULSE OFF TIME (Figure 19-3). To select each of the variable parameters, the user simply presses the key that corresponds to that parameter. For example, to modify the value of Watts the user presses the button shown as a "W" (Figure 19-1) and then uses the corresponding up/down keys to adjust (Figure 19-4). To modify the PULSE ON TIME, the user presses the key marked with the symbol  (Figure 19-2) and then uses the corresponding up/down keys to adjust. To modify the PULSE OFF TIME, the user presses the key marked with the symbol  figure (Figure 19-3) and then uses the corresponding up/down keys to adjust.



Once the user has set the desired pulse format and number of pulses, the unit may be enabled by pressing the READY/STANDBY key. After the READY/STANDBY key 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 equal to the pulse ON TIME. An audible signal will be sounded while the laser is active and the ready light will be flash. At the end of the ON PULSE, the laser will pause for a period equal to the OFF TIME. 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.



The user may lock this new set of parameters into the Comfort Mode setting by first selecting desired parameters for power, pulse on time and pulse off time and then by pushing and holding down for approximately four secs the Happy Face comfort mode button. The system will momentarily blink off and then on again symbolizing the new parameter has been set.

PERIO MODE

PICASSO II & PICASSO PERIO


To select the PERIO MODE of operation, the user simply presses the key marked with the Perio Treatment symbol  representing PERIO MODE. This is a pulsed mode of operation. In this mode, the mode is preset from the factory at 0.7 watts, 670 ms on time and 28 ms off time. The laser will fire for 30 seconds while the foot control is depressed. Releasing the foot control will interrupt the 30 second cycle. The only variable parameter is the output power. The user can increase power shown in watts by pressing the corresponding up/down keys.


To operate the laser in  PERIO MODE, the user presses 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.



 PERIO MODE output power can be changed at any time using the up/down arrow buttons. The user may lock this new parameter into the  PERIO MODE setting by first selecting desired parameter for power and then by pushing and holding down the PERIO button for approximately four seconds. The system will momentarily blink off and then on again symbolizing the new parameter has been set.


BLEACHING MODE/ THERAPUETIC TREATMENT

PICASSO II

To select the BLEACHING/THERAPEUTIC MODE of operation, the user simply presses the key marked with the symbol . This is a continuous mode of operation. In this mode, the mode is preset from the factory at 7.0 watts continuously for 30 seconds while the foot control is depressed. Releasing the foot control will interrupt the 30 second cycle. The only variable parameter is the output power. The user can increase power shown in watts by pressing the corresponding up/down keys.


To operate the laser in the  BLEACHING / THERAPEUTIC MODE, the user presses the READY/STANDBY 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.



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


holding down the  button for approximately four seconds. The system will momentarily blink off and then on again symbolizing the new parameter has been set.

THERAPUETIC TREATMENT MODE

PICASSO PERIO, PICASSO LITE

To select the THERAPEUTIC MODE of operation, the user simply presses the key marked with the symbol . This is a continuous mode of operation. In this mode, the mode is preset from the factory at 1.0 Watts. And can be activated while the foot control is depressed. The only variable parameter is the output power. The user can increase power shown in Watts by pressing the corresponding up/down keys (Figure 19-4).

To operate the laser in the  THERAPEUTIC MODE, the user presses 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.

THERAPEUTIC MODE output power can be changed at any time using the up/down arrow buttons (Figure 19-4). The user may lock this new parameter into the THERAPUETIC TREATMENT MODE mode setting by first selecting desired parameter for power and then by pushing and holding down the  button for approximately four seconds. The system will momentarily blink off and then on again symbolizing the new parameter has been set.

Indications for Use

INDICATIONS OF USE

Use of Picasso II | Picasso Perio | 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 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
- Picasso assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium).

TEETH WHITENING INDICATIONS (PICASSO ONLY)

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

THERAPEUTIC

The Picasso II | Picasso Perio | Picasso Lite is intended to provide biostimulation therapy by emitting energy in the near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; and the temporary relaxation of muscle.

Specifications & Calibration Schedule

Picasso II | Picasso Perio | Picasso Lite SPECIFICATIONS

GENERAL – PICASSO II | PICASSO PERIO | 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) \pm 20%

ELECTRICAL – PICASSO II | PICASSO PERIO | PICASSO LITE

- Operating Voltage AC 110/230V \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 – PICASSO II

- Laser Classification IV (4)
- Medium GaAlAs
- Wavelength 810 \pm 10 nm
- Power Accuracy \pm 20%
- Power Modes Continuous, Repeat Pulse
- Adjustable Pulse Duration 10 ms – 90 ms,
- Pulse Interval 10 ms – 90 ms
- Delivery Fiber Diameter 200 - 1000mn
- Mode Speed, Comfort, Perio, Bleaching/ Therapeutic
- Speed Mode Preset to 1.8 Watts continuous, adjustable from 0.2 – 7.0 watts
- Comfort Mode Preset to 1.8 Watts pulsed, 30 ms on time (duration), 30 ms off time (interval). Adjustable 0.2 – 7.0 watts, 10 -90ms duration, 10 -90 ms interval
- Bleaching/Therapeutic Mode Preset to 7.0 Watts, Continuous, 30 sec cycle
- Perio Mode Preset to 0.8 Watts, 670 ms pulse duration, 28 ms interval, 30 sec cycle. Adjustable 0.2 – 2.5 Watts
- Output Range 0.2 – 7.0 Watts \pm 20%

LASER – PICASSO PERIO

- Laser Classification IV (4)
- Medium GaAlAs
- Wavelength 810 ± 10 nm
- Power Accuracy $\pm 20\%$
- Power Modes Continuous, Repeat Pulse
- Adjustable Pulse Duration 10 ms – 90 ms,
- Pulse Interval 10 ms – 90 ms
- Delivery Fiber Diameter 200 – 1000 mn
- Modes Speed, Comfort, Perio, Therapeutic
- Speed Mode Preset to 1.8 Watts continuous, adjustable from 0.2 – 2.5 watts
- Comfort Mode Preset to 1.8 Watts pulsed, 30 ms on time (duration), 30 ms off time (interval). Adjustable 0.2 – 2.5 watts, 20 -90ms duration, 20 -90 ms interval
- Perio Mode Preset to 0.8 watts pulsed 670 ms pulse width, 28 ms interval, 30 second cycle time. Adjustable 0.2 – 2.5 Watts.
- Therapeutic Mode 1.0 Watts, continuous, 30 sec cycle. Adjustable 0.2 – 2.5 watts
- Output Range 0.2 - 2.5 Watts $\pm 20\%$ output

LASER – PICASSO LITE

- Laser Classification IV (4)
- Medium GaAlAs
- Wavelength 810 ± 10 nm
- Power Accuracy $\pm 20\%$
- Power Modes Continuous, Repeat Pulse
- Adjustable Pulse Duration 30 ms
- Pulse Interval 30 ms
- Delivery Fiber Diameter 200 – 1000 nm
- Mode Speed, Comfort, Therapeutic
- Speed Mode Preset to 1.8 Watts continuous, adjustable from 0.2 – 2.5 watts
- Comfort Mode Preset to 1.8 Watts pulsed, 30 ms on time (duration), 30 ms off time (interval). Adjustable 0.2 – 2.5 watts, 20 -90ms duration, 20 -90 ms interval
- Therapeutic Mode 1.0 Watts, continuous, 30 sec cycle. Adjustable 0.2 – 2.5 Watts
- Output Range 0.2 - 2.5 Watts $\pm 20\%$ output

OTHER LIGHT SOURCES – PICASSO II | PICASSO PERIO | PICASSO LITE

- Aiming Beam $632\text{nm} \pm 20\%$, max 5 mW
- Medium Laser Diode

CALIBRATION PROCEDURE

Picasso II | Picasso Perio | 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.

It is highly recommended that the customer contact AMD LASERS, rather than performing the procedure itself. Utilizing these procedures requires certain technical expertise and improper calibration could lead to damage and failure to calibrate the laser.

EQUIPMENT NEEDED: PC with Windows XP or better and a serial (RS-232) port. Laser power/energy display such as 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%, for example, Ophir power meter P/N 7z02637 or equivalent. AMD LASERS Calibration Software. AMD LASERS Calibration Data Cable. #1 Philips Head Screw Driver.

PICASSO II

TURN LASER OFF and UNPLUG PRIOR TO CALIBRATION 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 this process until all fields have been properly adjusted.

PICASSO LITE / PICASSO PERIO

TURN LASER OFF AND UNPLUG PRIOR TO TESTING

Remove front panel

- 1: Move and place the jumper 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)

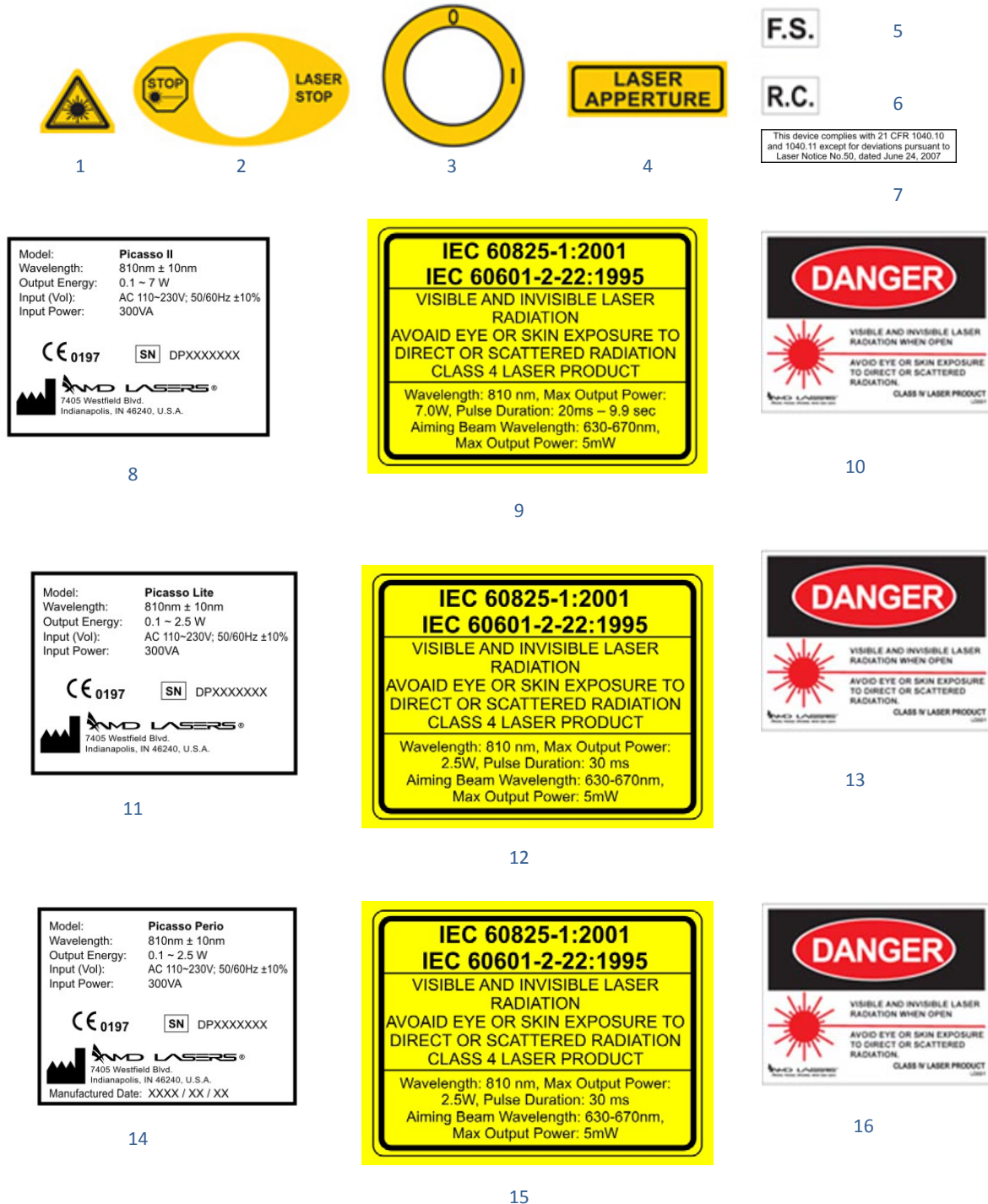
Calibration 6 ____//____//____
(72 months after purchase date)

*This procedure is intended for reference only. All service to your laser (including calibration) is to be performed by an AMD LASERS trained service technician. The warranty will be null and void if service is performed by an unauthorized technician.

Appendices

APPENDIX A – LABELS & DESCRIPTIONS

FIGURE 19

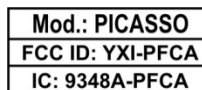




17



18

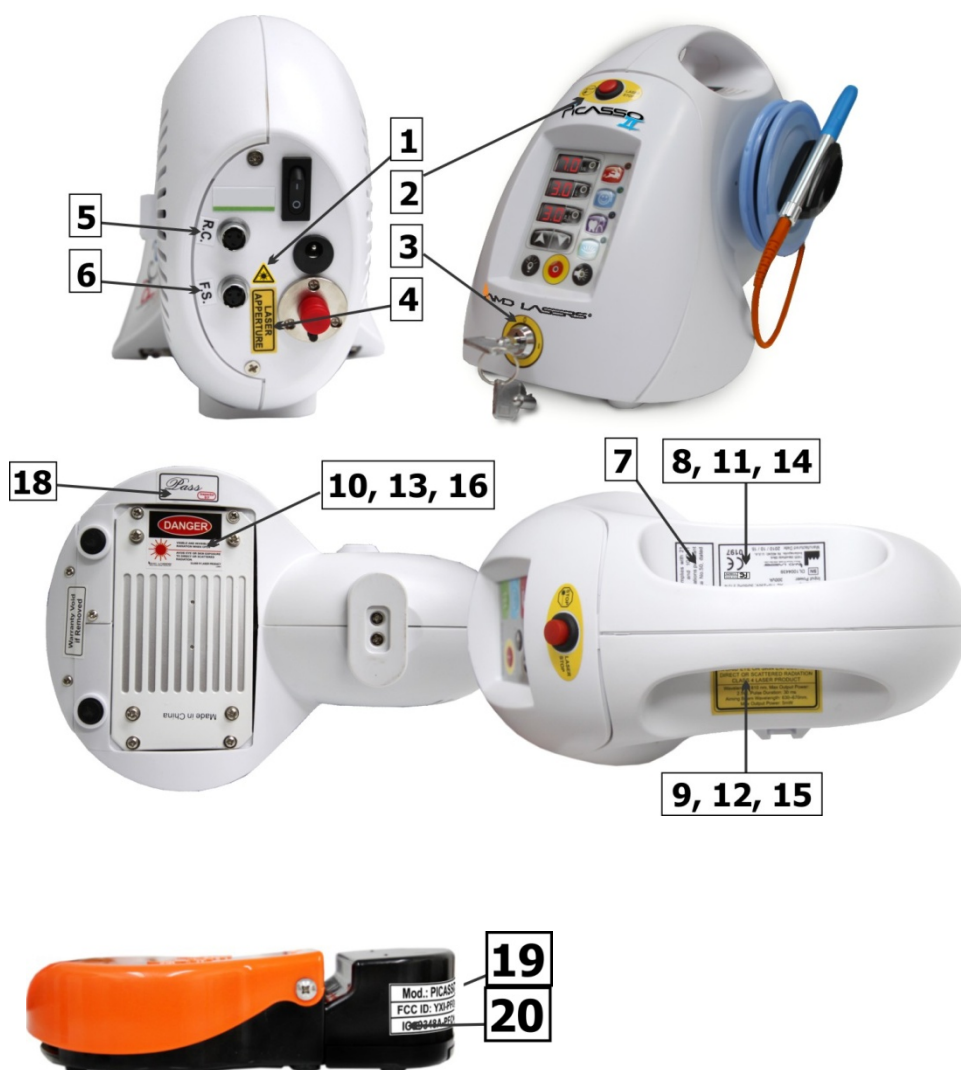


19

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.

20

LABEL POSITIONS



LABEL DESCRIPTIONS

- 1. Warning for Laser Aperture Port**
 - a. Located on back of unit next to the laser output port
- 2. Emergency Laser Stop**
 - a. Located on the front of unit surrounding the emergency off red button
- 3. Laser Off – 0, Laser On – I**
 - a. Located on the front of the unit surrounding the key switch
- 4. Laser Aperture label**
 - a. Located on back of unit next to the laser output port
- 5. Foot Switch (F.S.)**
 - a. 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 (R.C.)**
 - a. Located on the back on the unit next to the remote interlock connection port
- 7. CDRH Laser Notice 50 Compliance label**
 - a. Located on top of the unit
- 8, 11, 14. Manufacturer label**
 - a. Located on the top of the unit
- 9, 12, 15. IEC Explanatory label**
 - a. Located on the top of the unit
- 10, 13, 16. Laser Danger label**
 - a. Located on the bottom of the unit
- 18. Fragile Keep Dry**
 - a. Located on both ends of the shipping box
- 19. FCC Compliance label**
 - a. Located on the back of the wireless footcontrol
- 20. FCC and IC Identification label**
 - a. Located on the back of the wireless footcontrol

APPENDIX B – PARTS AND ACCESSORIES

Part Number	Description
Manuals/Reference/Training	
EMN002	Picasso Picasso Lite Owners Manual rev. OIM_v5_5-10_r3
EMN003	Picasso II Picasso Perio Picasso Lite Owners Manual rev. OIMv6_8-10_r5
EMN003P	Picasso II & Picasso Perio Instructions Manual (PMv1.10-10)
CS01	Quick Reference Sheet Picasso rev. 1.0
STQ01	Quick Start Guide - Picasso v4_4-10
STQL01	Quick Start Guide - Picasso II Picasso Perio Picasso Lite
QSG200	Quick Start Guide - 200um kit v2_4-10
CS01L	Quick Reference Sheet / Laminated - Picasso Lite rev. 1.0
CS01PP	Quick Reference Sheet / Laminated Picasso Perio rev. 1.0
CS02	Quick Reference Sheet / Laminated - Picasso II rev. 1.0
STD01	Picasso Picasso Lite Setup DVD
STD02	Picasso II Picasso Perio Picasso Lite Setup DVD
PB01	Patient Brochure - Canker Sores - Pack of 50 v2_4-10
PB02	Patient Brochure - Teeth Whitening - Pack of 50 v2_4-10
PB03	Patient Brochure - Smile Design - Pack of 50 v2_4-10
PB04	Patient Brochure - Periodontal Disease - Pack of 50 v2_4-10
LD001	Laser Danger Sign
ICLEDVD01	ICLE Diode Laser Certification DVD (3 Disc Set)
Disposable Tips	
DT0010400	25 Disposable Tips 0 deg 10mm 400um
DT01A	Disposable Tips - Assortment of..25 tips: 5 tips 0 deg 10mm 400um, 5 tips 45 deg 5mm 400um, 5 tips 45 deg 10mm 400um, 5 tips 90 deg 5mm 400um, 5 tips 90 deg 10mm 400um
DT25LT	25 Solo Disposable Tips
DT4505400	25 Disposable Tips 45 deg 5mm 400um
DT4510400	25 Disposable Tips 45 deg 10mm 400um
DT9005400	25 Disposable Tips 90 deg 5mm 400um
DT9010400	25 Disposable Tips 90 deg 10mm 400um
Optical Fibers	
STF02	200 Micron Fiber - SMA 905 Connector
STF04	400 Micron Fiber - FC Connection
STF200	200 Micron Optical Fiber with Multi-Tip Handpiece - FC Connection - Black - Picasso Lite Picasso Perio Only
STF400	400 Micron Optical Fiber with Multi-Tip Handpiece - FC Connection - Orange - Picasso Picasso II Only
STFA02FC	200 Micron Fiber Adapter for Picasso Picasso II lasers with FC fiber connection
STFA02ST	200 Micron Fiber Adapter for Picasso lasers with ST fiber connection
STFST04	400 Micron Fiber - Connection for Picasso Lasers with ST fiber connection
STP200	Multi-Tip Handpiece Kit Picasso Lite - FC Connection (includes optical fiber (black), spool, protective dust cap)
STP400	Multi-Tip Handpiece Picasso - FC Connection (includes optical fiber (orange), spool, protective dust cap)
STP400ST	Multi-Tip Handpiece Picasso - ST Connection (includes optical fiber (orange), spool, protective dust cap)
Protective Eyewear	
STGY001	Yellow Adult Protective Goggles (CE Certified) ANSI Z87+ 800-820 nm OD 5+

STGYF01	Yellow Adult Protective Fitover Goggles (CE Certified) 800-820 nm OD 5+
Fiber Accessories	
MS112S21FS	Fiber Stripper - Blue for 200um kit- Inner Clad Stripper
MS116S70FS	Fiber Stripper - Blue for 200um kit- Outer Jacket Stripper
STST010	Fiber Stripper - Red - 400 um
STCL010	Cleaver Stone
SP001	Picasso Removable Fiber Spool - Blue
SP001-PF	Picasso Removable Fiber Spool - Blue for use with Multi-Tip Handpiece
STHP004	Surgical Handpiece (400 um) (Blue)
STHPC004	Surgical Handpiece Case
STHP200	200um Fiber Handpiece
STHPA004	Handpiece Adapter for Disposable Canulas
STBH01	Quadra Tip for use with the Multi-Tip Handpiece
STAK200FC	200um kit - FC connector (One 200um fiber, one adapter, one handpiece, two fiber strippers, one cleaver, instruction manual, case, spool).
STAK200ST	200um kit - ST connector (One 200um fiber, one adapter, one handpiece, two fiber strippers, one cleaver, instruction manual, case, spool).
STAP013	Accessory Package (Two Fibers, One Handpiece)
STAP100	Strippable Fiber Accessory Package (One 400um FC fiber, two handpieces, one fiber stripper, one cleaver, handpiece case, blue spool for strippable fiber)
Other	
CK001	Cork for initiating the fiber
STBK01	Laser Teeth Whitening Gel Kit (5 Single Packs) for use with Picasso Picasso II lasers
STTC005	Transportation Case
STCCK005	Transportation Case Keys
STIL012	Remote Interlock
STPS006	9V Power Adapter (110V-240V 50-60 Hz)
STPS007	5V Picasso Lite Power Adapter (110V-240V 50-60 Hz) for Picasso Lite Lots 1-15
STFP011	Wired Foot Control Pedal with Cover
STFP02	Wireless Foot Control Pedal with Integrated Cover and back-up wired connection

APPENDIX C – (LIMITED WARRANTY)

AMD LASERS®, LLC warrants for a period of twenty-four (24) months for the Picasso II | Picasso Perio | Picasso Lite from shipment to the original purchaser/user Picasso II | Picasso Perio | 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 it was originally shipped by AMD LASERS®, LLC or by its authorized distributor.

Accessories included with the unit but not limited to: optical fiber(s), handpiece(s), Quadra Tip, cleaver, and stripper are warranted for ninety (90) days against defects in materials and workmanship. Disposable or consumable items are not covered by this warranty, and it does not cover the cost of the annual calibration of unit.

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. 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 packaging.

In order to receive warranty service, Picasso II | Picasso Perio | Picasso Lite lasers must be shipped to AMD LASERS® in the original transportation case and proper shipping box with the foam packaging. **The user is responsible for all shipping cost.**

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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