

**NMD LASERS®**  
Effective. Practical. Affordable. World Class Lasers.

ENGLISH

**PICASSO**  
*clarío™*





















## OPERATING INSTRUCTION MANUAL

PICASSO CLARIO™

version 1.1

**PICASSO CLARIO  
OPERATING INSTRUCTIONS  
MANUAL**

SYMBOL	DESCRIPTION
 <b>Do Not Throw Away</b>	Do Not Throw Away Consult with local laws with respect to medical equipment disposal.
	Laser Danger
 Non-autoclavable	Do Not Autoclave
 Single Use Only	Single Use Only
 Consult Instructions For Use	Consult Instruction For Use
 Exp Date	Expiration Date
	Manufactured for AMD LASERS 4628 W. Skyhawk Dr., West Jordan, UT 84084 USA
	Fragile, handle with care
	Only Applicable for USA

SYMBOL	DESCRIPTION
 Type B Applied Part	Type B Applied Part
	Warning Label
 Class II Equipment	Class II Equipment
	Must Read Manual Prior to Use
	Battery Direction
	Nonreturnable if Seal Is Broken
	Optical Fiber
	Manufactured Date
	Standby/Ready Button



LS34; DPG DVHUV1D 001 kw 4hnhxhg1

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## INTRODUCTION

Picasso Clario laser utilizes a solid-state diode as a laser energy source. The energy is delivered to the target 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 wireless footswitch.

Picasso Clario Laser is intended for use by dental hygienists and other authorized dental professionals on oral soft tissue as defined by the "Indications for Use". 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 Clario laser will prove to be a valuable addition to your practice. Please contact your authorized representative or AMD LASERS® if you have any questions or require assistance.

## SAFETY INFORMATION

### SAFETY PRECAUTIONS

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

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

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

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

**WARNING: Nominal Ocular Hazard Distance (NOHD) is 1 m from the distal end of the fiber.**

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

Note: Opening this unit or adjusting components inside the unit will void the warranty since such actions may compromise the performance of the laser system.

**WARNING: To prevent device damage, use only the power supply provided with the system or provided by AMD LASERS.**

Failure to comply with the stated precautions and warnings may lead to exposure to electrical shock and/or exposure to radiation sources. Please comply with all safety instructions and warnings.

Picasso Clario has been tested and have been found to be compliant with the latest electrical safety standard (IEC60601-1 3<sup>rd</sup> Edition).

## SAFETY INSTRUCTIONS

Follow these safety instructions before and during treatments:

- All operatory entrances must be marked with the appropriate danger warning sign.
- Do not operate the laser in the presence of explosive or flammable materials.
- Do not operate the laser without a laser tip in place.
- 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 range of 800–820nm during all procedures.
- Do not position the laser such that it is difficult to disconnect the electrical plug from the wall or disconnect the power input connector from the back of the unit.

**CAUTION: PERIODICALLY INSPECT EYEWEAR FOR PITTING AND CRACKING.**

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

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

## Safety Classification

The following safety classifications are applicable to the Picasso Clario device:

- Laser Radiation: Class 4 (US classification)
- Type of electrical shock protection: Class 2 (US classification)
- Degree of electrical shock protection: Type B Applied Part
- Laser not protected against water ingress: Ordinary Equipment
- Not suitable for use in the presence of flammable anesthetic mixtures
- Operation Mode: See Specifications

## Safety Questions

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

## SAFETY FEATURES

### Power Switch

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

### System Monitor

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

### Key switch

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

### STANDBY/READY Button

Once the power switch and key switch are set to the ON position, the STANDBY/READY button on the keypad must be pressed to enable the footswitch. One beep will sound to indicate that the system is ready for use. The STANDBY/READY button on the Picasso Clario will turn green.

### 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. Once pressed, 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

If the laser is not connected to a remote interlock, the laser is designed to function normally without any plug inserted into the interlock. If an interlock is connected, the laser will show a Remote Interlock error

if the plug is not fully inserted, the remote interlock switch is open (i.e. the operatory room door is open), or the interlock loop is not wired correctly.


**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 by the user. The visual display may not be turned off.

**Functional Display**

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

**WIRELESS FOOT CONTROL COMPLIANCE**

	P r g l = S I F D V V R	I u h t x h q f   = 5 I 7 J K }
	I F F I G = R X U 0 [ E H H 2 F E O 3 < 5 8	Y r o d j h = < Y r o w G F
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**FCC:**

**15.19(a) (3):**

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

**15.21:**

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

**15.105:**

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

**NOTE:**

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

- Reorient or relocate the receiving antenna.



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

## IC: RSS-GEN:

### 7.1.2 Transmitter Antenna

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

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

Information in this document is subject to change without notice. ©2018 AMD LASERS. All rights reserved. User manuals for transmitters shall display the following notice in a conspicuous location:

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approval for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

### 7.1.3 User Manual

User manuals for license-exempt radio apparatus shall contain the following or equivalent notice in a conspicuous location in the user manual or alternatively on the device or both.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

[1] This device may not cause interference, and [2] this device must accept any interference, including interference that may cause undesired operation of the device.

## CONTENTS OF PICASSO CLARIO KIT

#	ITEM	DESCRIPTION
1	Fiber Connector Port	Connects Fiber to the Unit
2	Control Panel	Displays&ControlstheParameters(e.g.PowerOutput,Presets,AimingBeam&Intensity, &Speaker Volume)
3	Emergency Stop Button	Disables the Unit In the Event of an Emergency
4	Handle	For Transporting the Unit
5	Handpiece & Holder, Disposable Tip	Multi-Tip Handpiece/Fiber with Fiber Spool, Holder,& Disposable Tip
6	Fiber Spool	Stores Fiber
7	Remote Interlock Port	Connects Interlock to the Unit
8	AC Power Connector	Connects Power Supply to the Unit
9	Cooling Vents	Cooling Vents
10	Power Switch	Master ON/OFF Switch
11	Key Switch	Turns Display of the Unit ON & OFF
12	Quick Start Guide (QSG)	Quick Start Guide (QSG)
13	Transportation Box	Transportation Box
14	Unit Keys	Used to Turn Machine Off/On
15	Laser Eyewear Protective Goggles (2)	ANSI Z87, 800–820 nm, Optical Density (OD), includes Protective Case
16	Wireless Foot Control	Wireless Foot Control Standard Picasso Clario
17	AC Adapter	Connects the Unit & Net Power Supply Input: 100–240 V 50/60 Hz, Output: 12V, 5A AC/DC adapter is specified as a part of ME EQUIPMENT.
18	Power Cord	Power Cord 9.5 Feet (2.89 meters)
19	Articulating Paper	Sample of Paper to Be Used for Laser Tip Initiation
20	Laser Danger Sign	Danger Sign for Operatory (Included at End of Manual)

## Contents of Picasso Clario Kit



## INDICATIONS FOR USE

Picasso Clario is indicated for incision, excision, vaporization, ablation and coagulation of oral soft tissues including the following:

- Gingivectomy
- Gingivoplasty
- Hemostasis and coagulation
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa

## LASER PERIODONTAL PROCEDURES

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

## SET-UP INFORMATION

### PICASSO CLARIO SET UP

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

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

## OPERATION INSTRUCTIONS

### Turn ON Picasso Clario

- Verify Red Emergency button (FIGURE 1, Item #3) is pushed in.

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

#### Turn OFF Picasso Clario

- Press the STANDBY/READY button to place unit in STANDBY Mode.
- Place handpiece back on handpiece holder.
- Switch power switch to OFF position.
- Turnoff and remove key from the unit, and place in a secure area.

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


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

#### LANGUAGE Selection


English is the default language. French and Spanish are also available.

To select a language, press the SETTINGS button. The system will then enter into the language selection display. Press desired language for two seconds, and the system will restart in the chosen language.

#### AIMING BEAM brightness settings

To select the brightness for aiming beam, first press the SETTINGS button. Then press the  button to change the brightness settings. There are three levels for Picasso Clario: Off/Medium/Bright.

#### VOLUME settings

To select the volume, press the SETTINGS button. Then press the  button to change the volume settings. There are three levels: Soft / Normal / Loud.

#### Operating Picasso Clario

**STEP 1:** Attach Disposable Tip onto the Multi-Tip Handpiece

**STEP 2:** Select Mode

**STEP 3:** Select STANDBY/READY button and step on the foot control to activate the laser.

## WIRELESS FOOT CONTROL

### Instruction for Use

**STEP 1:** Place wireless foot control on the floor.

**STEP 2:** To operate the wireless foot control, apply pressure to enclosed foot switch with your foot. The green LED Indicator light blinks to indicate that the foot control is operating when you step on the pedal to fire laser.



## WARNINGS

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

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

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

### Eyewear

Post appropriate warnings in operatories where the lasers are to be used, so that appropriate eyewear can be donned before entry into the operatory. The doctor, patient, assistant, and any other persons in the operatory during laser procedures must wear the appropriate laser eyewear protection for the diode laser wavelength of  $810 \pm 10$  nm with an optical density (OD) of at least +5. Class 4 laser radiation is hazardous to the eye from the direct beam and diffuse reflections. It also represents a significant skin and fire hazard. Safety eyewear not designed to this specification is not suitable for use with Picasso lasers. Laser protective eyewear is available from your AMD LASERS representative.

### Anesthesia

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

### Adjacent Structures

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

### Suction

Use high-speed suction as required to maintain a clear field of vision during treatment. Do not use Picasso Clario if you cannot clearly see the treatment site. It is recommended that a smoke evacuator or

in-line filter be used to capture the plume during the treatment of herpetic lesions, oral papillomas, and whenever possible. It is recommended that personnel wear a half face respirator/clinical mask with proper HEPA™ filtration. The plume should be regarded as a source of active biological material as it may contain viable tissue particulates.

### Training

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

### Heat Generation

The end of the fiber optic cable, disposable tips, and non-disposable tips, cannulas, and handpieces may become hot during use. Avoid unnecessary contact with tissue. Portions of the housing such as the air vents also may become hot during use. The user should be cautious when touching these areas.

### Disposable Tips

Disposable Tips provide the aperture for laser emissions. It is this portion of the device that contacts the patient.

The disposable tips are designed and labeled for SINGLE USE only. These tips are not meant to be bent more than one time, nor bent more than 90°. They are designed to be bent once to the preferred angle, used on a single patient, and then disposed of properly. Bending the disposable tip more than once in an unintended manner is a risk to the fiber optic cable inside the cannula, leading to potentially lowered power output.

When the handpiece is not in use, place protective cap over the tip to prevent contamination of tip and to prevent dust or debris from coming in contact with the fiber optic.

Additionally, bending the metal cannula in the Disposable Tip in an unintended manner can lead to a breakage resulting in a potential sharp point which could puncture the skin of the patient or office personnel. Care should be taken to not bend the metal cannula multiple times.

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

## PRECAUTIONS

AMD Picasso Clario Laser System is for Dental Use Only according to the Indications for Use in this OIM Version of the manual. The laser is to be used under the supervision of a Dental professional.

Periodic cleaning of the tip during procedures is required to keep the efficiency of the heat transfer. If removing coagulum, use CaviCide™ or other equivalent solution following manufacturer's instructions. If using any product containing alcohol, make sure to allow tip to air dry fully prior to re-initiating the tip. When placing the handpiece in the holder, make sure to have the tip pointing away from all plastic articles to avoid damage to the plastic and/or the tip.

While the unit is on, it will retain the last settings selected for a particular application. When the unit is shut down and powered back up, it will return to the default settings for power and duration for each application.

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



## STEP-BY-STEP INSTRUCTIONS

### MULTI-TIP HANDPIECE WITH FIBER

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



#### Multi-Tip Handpiece & Fiber

- Length: 2 meters
  - S.T. Connector and Handpiece
- NOTE: Tips are not autoclavable.

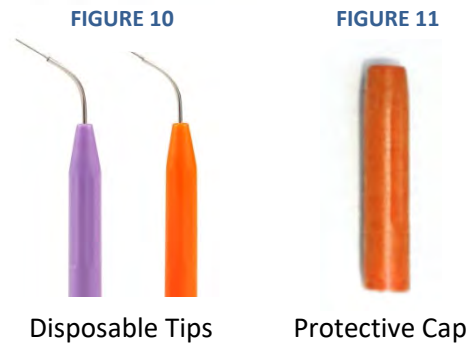


#### Disposable Tips & Protective Cap

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

#### Using Disposable Tips:

- Assorted bendable tips are available for use with Picasso Clario.
- Disposable tips are not sterile, and must be cleaned with a disinfectant wipe prior to use. If alcohol wipes are used, air dry prior to installing the tip on the Multi-Tip Handpiece and initiating the tip for use.
- Orange tips are 400 µm in size, available in 5 mm and 10 mm length.



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

To install a disposable tip, remove the orange protective cap (Figure 11) and slide the tip over the handpiece until the tip is fully seated.

You should hear and feel a slight 'click' when the tip snaps into place. To remove, pull gently on the tip and dispose of properly.

These tips have a bendable steel cannula allowing the user to customize the angle of each tip for a specific application. The tip can be bent from 0° to a maximum of 90°. To bend the tip, pressure should be applied only in the middle of the metal cannula to form a smooth curve. See the Quick Start Guide for additional information.

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

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

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

### **CLEANING INSTRUCTIONS FOR THE MULTI-TIP HANDPIECE**

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

- Transport the delivery system to a decontamination/sterilization work area.

### **DISPOSAL OF USED DISPOSABLE TIPS**

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

### **CLINICAL APPLICATIONS**

To efficiently remove tissue, it is imperative to understand the nature of the Picasso Clario. Each laser operates unlike traditional devices. The techniques mentioned below must be practiced and perfected to ensure efficient operation. Please study this section carefully, practice on sample tissues, and attend a quality diode laser training seminar before using this device in a clinical situation. The Picasso line of soft tissue lasers are designed for a number of surgical and non-surgical procedures. (See "Indications for Use").

Only licensed professionals, who have successfully completed Picasso training and are certified in the use of Class 4 lasers, have read and understand this manual, and know how to correctly operate the system, should use this device.

Every state dental board sets the parameters for dental hygiene duties. While hygienists may use a diode laser in a majority of states, the guidelines vary. It is your responsibility to know your state practice act.

## LASER OPERATION MODES INTERFACE



### UTILITIES

Select language, adjust volume, adjust aiming beam, go to home screen.



### GINGIVITIS

Default Power: 0.5 Watts  
Default Duration: 4.0 Sec.



### PERIO

Default Power: 0.6 Watts  
Default Duration: 6.0 Sec.



### PERIO+

Default Power: 0.8 Watts  
Default Duration: 8.0 Sec.



### TISSUE

Default Power: 1.0 Watt  
Duration: Counter



### DEBRIDEMENT

Default Power: 0.8 Watts.  
Duration: Counter

## DESCRIPTION OF LASER OPERATION MODES

The Home Screen of Picasso Clario displays the Gingivitis Treatment Mode. When the right arrow on the Treatment button is pressed, the display scrolls through Perio, Perio+, Tissue, and Debridement Treatment screens. From any other screen, press the right or left arrow on the TREATMENT button until desired mode is displayed.

### GINGIVITIS

The GINGIVITIS Treatment Mode is indicated for GINGIVITIS, for which the clinical criteria is pocket depth of 0-4mm with localized or generalized inflammation. The GINGIVITIS Treatment Mode is the home screen of the Picasso Clario unit. From any other screen, press the right or left arrow on the TREATMENT button until GINGIVITIS Mode is on screen. In this mode, the laser default is 0.5w with a duration of 4.0 seconds. Power and duration can be increased or decreased by pressing the corresponding right (increase) or left (decrease) arrow buttons.

To operate the laser in GINGIVITIS Mode, press the STANDBY/READY button. The laser will be activated when the footswitch is pressed and will deliver output radiation for 5.0 seconds (or the adjusted duration) unless the foot switch is released. An audible signal will be sounded while the laser is active and the ready button will flash.

Output power or duration can be changed at any time using the increase/decrease arrow buttons.

### PERIO

The PERIO Treatment Mode is indicated for Slight Perio, for which the clinical criteria is pocket depth of 4-5mm with possible signs of inflammation<sup>1</sup>.

To select the PERIO Treatment Mode from the Home Screen, press the right arrow once. In this mode, the laser default is 0.6w with a duration of 6.0 seconds. Power and duration can be increased or decreased by pressing the corresponding right (increase) or left (decrease) arrow buttons.

To operate the laser in PERIO Mode, press the STANDBY/READY button. The laser will be activated when the footswitch is pressed and will deliver output radiation for 6.0 seconds (or the adjusted duration) unless the foot switch is released. An audible signal will be sounded while the laser is active and the ready button will flash. Output power or duration can be changed at any time using the increase/decrease arrow buttons.

### PERIO+

The PERIO+ Treatment Mode is indicated for Moderate Periodontitis, for which the clinical criteria is pocket depth of 5-6mm with possible signs of inflammation.

To select the PERIO+ Treatment Mode from the Home Screen, press the right arrow twice. In this mode, the laser default is 0.8W with a duration of 8.0 seconds. Power and duration can be increased or decreased by pressing the corresponding right (increase) or left (decrease) arrow buttons.

To operate the laser in PERIO+ Mode, press the STANDBY/READY button. The laser will be activated when the footswitch is pressed and will deliver output radiation for 8.0 seconds (or the adjusted duration) unless the foot switch is released. An audible signal will be sounded while the laser is active and the ready button will flash. Output power or duration can be changed at any time using the increase/decrease arrow buttons.

## TISSUE

The TISSUE Treatment Mode is indicated for lesion management in cases of oral mucosal lesions or cold sores.

To select the TISSUE Treatment Mode from the Home Screen, press the right arrow three times. In this mode, the laser default is 1.0w. Power can be increased or decreased by pressing the corresponding right (increase) or left (decrease) arrow buttons.

To operate the laser in TISSUE Mode, press the STANDBY/READY button. The laser will be activated when the footswitch is pressed, and remains activated until the foot switch is released. An audible signal will be sounded while the laser is active and the ready button will flash. Output power can be changed at any time using the increase/decrease arrow buttons.

## DEBRIDEMENT

The DEBRIDEMENT Treatment Mode is indicated for severe chronic periodontitis or aggressive periodontitis in patients with necrotic tissue needing treatment.

To select the DEBRIDEMENT Treatment Mode from the Home Screen, press the right arrow four times. In this mode, the laser default is 0.8 watts. Power can be increased or decreased by pressing the corresponding right (increase) or left (decrease) arrow buttons.

To operate the laser in Debridement Mode, press the STANDBY/READY button. The laser will be activated when the footswitch is pressed, and remains activated until the foot switch is released. An audible signal will be sounded while the laser is active and the ready button will flash. Output power can be changed at any time using the increase/decrease arrow buttons.

## PRODUCT SPECIFICATION

### GENERAL

- Model Number CL810
- Dimensions L x W x H 9.5" x 6" x 6.2" (240 mm x 150 mm x 160 mm)
- Weight: 2.0 lbs (1 kg) ± 20%
- Working Environment: Temperature 60°F/15°C–90°F/32°C, Humidity 25%–85% , Pressure 700 hpa–1060 hpa
- Storage: Temperature 50°F/10°C–122°F/50°C, Humidity 25%–85% , Pressure 700 hpa–1060 hpa

### ELECTRICAL

- Output Voltage: +12.0 V DC
- Output Current: 5.0 AMPS
- Output Power Range: 60 Watts MAX
- External Fuses: None
- Main Control: Power switch
- On/Off Controls: Key switch, Power switch, Emergency Stop

### LASER

- Laser Classification IV (4)
- Medium GaAlAs
- Wavelength 810 ± 10 nm
- Power Accuracy ± 20%
- Power Modes Continuous
- Delivery Fiber Diameter 400 µm
- Output Range 0.5–1.2 W ± 20

### OTHER LIGHT SOURCES

- Aiming Beam 632 nm ± 20, max 5 mW, Class 2 laser
- Medium Laser Diode

## INSTRUCTION FOR ACCESSORIES MAINTENANCE

### DENTAL LASER UNIT AND PLASTIC BARRIERS MAINTENANCE

This unit requires little operator maintenance. Wipe down the system with a cloth dampened with a mild antiseptic or cleaning solution—we recommend the use of CaviWipes™. Never use solvents or abrasive cleaners, which can damage the finish. Never pour or spray any liquid on or directly over the control console.

Protective plastic barriers can be used to protect the carrying handle, touch pad, handpieces, and goggles and are customer supplied.

### ANNUAL MAINTENANCE

Picasso Clario should be calibrated and serviced annually by a qualified, AMD LASERS' trained technician. Please contact your authorized representative or AMD LASERS® to discuss annual maintenance options.

To maintain compliance with the applicable IEC and CDRH regulations, all systems must be checked and verified that they are functioning properly in the event the unit has been subjected to adverse environmental conditions such as fire, flood, mechanical abrasion, solvent spillage, etc.

Calibration is required to maintain your laser in good operating condition. By regulation, power is allowed to vary a total of +/- 20% from the established rated power. (21 CFR 1040.10).

If calibration shows a variation of more than +/- 20%, the laser needs to be returned to the AMD Laser Repair Center for repair.

The following safety checks shall be carried out:

- Verify all labels are firmly in place.
- Verify 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 Clario lasers are susceptible to misalignment if not handled properly. The unit should ALWAYS be handled carefully and never banged, jarred, jolted, dropped, or hit. Do not transport the laser unless it is completely packaged inside of its transportation box. Failure to properly package the laser can result in damage to the laser and accessories. When transporting or shipping your laser you must always disconnect the keys, the AC Power Adapter, and fiber, from the laser. Then, you must place the protective cap on the Fiber Connector Port and replace the white and orange protective caps on the fiber. If you have any questions regarding transportation, please call your authorized representative or AMD LASERS®.

## CALIBRATION PROCEDURE

**In order to ensure that your laser is operating at factory specifications for power output, it must be calibrated annually.** Picasso Clario comes factory calibrated and certified for use. For accurate treatment results, the unit(s) should be calibrated every 12 months following the date of first use. 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® at (866) 999-2635 to obtain an RMA.

### CALIBRATION SCHEDULE

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

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



## ERRORS AND WARNINGS

The Picasso Plus and Picasso Lite Plus lasers have an ability to provide operator with warnings and errors. Please see the error description with suggested steps to resolve it.

### Remote Interlock Error



**REMOTE INTERLOCK**

This error appears on screen when the remote interlock connection has been opened. The laser shall immediately go into Standby mode and error shall disappear from the screen only upon closing remote interlock connection and placing the laser into Ready Mode by the operator.

### Low Foot Switch Battery Error



**LOW FOOT  
SWITCH BATTERY**

This warning appears when the wireless foot switch battery is low which is under 7V. You can clear the message from the screen by tapping the triangle area as long as the foot switch battery voltage is greater than 6.5V and continue using the laser. If the popup is cleared successfully, you can operate the laser without popup appearing again until laser is turned off and on again. Under 6V, the warning message changes to an error, laser goes and remains in Standby mode and all controls are disabled and persists on the screen until battery is replaced and the unit is turned off and on to clear the popup message and error.

### Internal Fault – Service Required Error



This is a hard error, which means that you cannot erase it and continue using the unit. You can attempt to clear the error by turning unit off and back on but if the error persists, the laser unit must be sent in for service. The cause of the error can be: laser output outside tolerance limits, software fault, diode current or voltage limit outside limits. Upon this pop-up error, laser will go and remain in Standby mode and all controls are disabled.

## High Laser Module Temperature Error



**HIGH LASER MODULE  
TEMPERATURE**

This pop-up Error shall occur if the diode laser module temperature exceeds 42°C. The pop-up shall remain on the screen until the temperature falls below 40°C. When this Error occurs, the system will go from the Firing or Ready state to the Standby state. No device settings or controls shall be available until the pop-up disappears.

## Check Optical Fiber Connection Error



**CHECK OPTICAL  
FIBER CONNECTION**

This error appears when the optical fiber connection in the front of the unit is not made (the micro-switch is not pressed-in). Laser shall go into Standby mode and remain in Standby mode until this error is rectified. Please check optical fiber attachment and ensure that the optical fiber is tightened on the laser output aperture and closing the electrical connection on the micro-switch. The error message cannot be “erased” or ignored by the user.

## Calibration Required Error



This pop-up will remain in place regardless of whether the error automatically corrects itself. You will be required to turn the unit off and then on again to attempt to clear the error. When the error occurs, the system will go from the Firing or Ready state to the Standby state. No device settings or controls shall be available. You should send the laser for calibration to AMD LASERS or nearest Authorized Service Center as soon as possible.

## ELECTROMAGNETIC COMPATIBILITY (EMC)

Picasso® Clario™ Soft Tissue Diode Laser needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.


**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the laser, including cables attached to the laser. Otherwise, degradation of the performance of this equipment could result.

**WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

**WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Guidance and manufacturer's declaration – electromagnetic emissions		
Picasso Clario is intended for use in the electromagnetic environment specified below. The customer or the user of the Picasso Clario should assure that it is used in such an environment.		
Emissions Test	Compliance	
RF emissions CISPR 11	Group 1	Picasso Clario uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not available	
Voltage Fluctuations/ Flicker emissions	Not available	
Picasso Clario is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.		

Guidance and manufacturer's declaration – electromagnetic emissions			
Picasso Clario is intended for use in the electromagnetic environment specified below. The customer or the user of the Picasso Clario should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst	±2 kV common mode	±2 kV for power supply	Main power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-4	±1 kV for input/ output lines	Lines Not Applicable	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 5 sec	
(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	





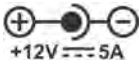




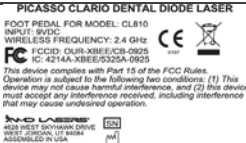
Guidance and manufacturer’s declaration – electromagnetic emissions			
Picasso Clario is intended for use in the electromagnetic environment specified below. The customer or the user of the Picasso Clario should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Picasso Clario, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000 4-6	6 Vrms 150 kHz to 80 MHz	8 Vrms	Recommended separation distance $d = [3.5/V1] \sqrt{P}$
Radiated RF IEC 61000-4-3	7 V/m 80 MHz to 2,5 GHz	3 V/m	$d = [3.5/E1] \sqrt{P}$ 80 MHz to 800MHz
			$d = [7/E1] \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Picasso Clario is used exceeds the applicable RF compliance level above, Picasso Clario should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Picasso Clario. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

## ANNEX A: LABELS

FIGURE 22





ITEM	SYMBOL	DESCRIPTION
1		Emergency Laser Stop
2		Picasso Clario Logo
3		AMD LASER Logo
4		Label for Optical Fiber and Warning for Laser Aperture Port
5		SPEC for DC Input
6		Laser Key Switch
7		Manufacture Label
8		Laser Danger
9		IEC Explanatory Label
10		FCC and IC Identification Label

## ANNEX B: ACCESSORIES

<b>DISPOSABLE TIPS</b>	
Disposable Bendable Tip, 300µm, 60 degree, 5mm	TIP3006005
Disposable Bendable Tip, 300µm, 60 degree, 10mm	TIP3006010
Disposable Bendable Tip, 400µm, 60 degree, 5mm	TIP4006005
Disposable Bendable Tip, 400µm, 60 degree, 10mm	TIP4006010
<b>FIBERS</b>	
300µm Fiber With Multi Tip Handpiece, FC	Plus MTHP-P
<b>EYE PROTECTION</b>	
Goggles - Adult Fit-Over Style	EYEF
Goggles – Adult	EYE
<b>POWER</b>	
Universal Power Cord (North America)	PCNA
European Style Power Cord	PCEU
12V Universal Medical Grade Power Adapter for Picasso Clario	PS
<b>MISCELLANEOUS</b>	
Articulating Paper	AP

## AMD LASERS: TERMS AND CONDITIONS OF SALE

### SHIPPING AND HANDLING

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

### GOVERNING LAW, CONSENT TO JURISDICTION AND VENUE OF LITIGATION

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

### ELECTRONIC SIGNATURES

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

### RETURNS

IF YOU ARE NOT SATISFIED WITH THE [PRODUCT], AMD LASERS EXTENDS THE OPPORTUNITY TO OBTAIN A FULL REFUND OF THE PURCHASE PRICE OF THE PRODUCT (NOT INCLUDING FEES, SHIPPING, ETC.) WHEN **ALL** OF THE FOLLOWING CONDITIONS ARE MET:

- THE PRODUCT IS RETURNED TO AND ARRIVES AT AMD LASERS WITHIN 30 CALENDAR DAYS FROM THE DATE OF PURCHASE;
- THE PRODUCT IS RETURNED WITH ALL ACCESSORIES AND PACKAGING ORIGINALLY SHIPPED WITH THE PRODUCT (MINUS CONSUMABLES THAT MAY HAVE BEEN USED); AND
- ALL ASPECTS OF THE PRODUCT, INCLUDING ACCESSORIES, DOCUMENTATION, AND PACKAGING ARE FREE FROM ANY DAMAGE;

IF SLIGHT DAMAGES OR A SIGNIFICANT REDUCTION IN CONSUMABLE ITEMS ARE IDENTIFIED, A REFUND MAY BE PROVIDED FOR THE PURCHASE PRICE DISCOUNTED BY 15% TO COVER RECONDITIONING, REPLENISHMENT OF CONSUMABLES, REPLACEMENT OF DAMAGED ITEMS AND RESTOCKING. IF EXTENSIVE DAMAGE IS IDENTIFIED, THE REFUND MAY BE FURTHER DISCOUNTED TO OFFSET THE COST OF DAMAGES.

NOTWITHSTANDING, NO REFUND IS OFFERED IF MORE THAN 30 DAYS HAS PASSED SINCE THE DATE OF PURCHASE.

ALL PRODUCT RETURNS MUST BE ACCOMPANIED BY A RETURN MATERIAL AUTHORIZATION (RMA) NUMBER ISSUED BY AMD LASERS WHICH CAN BE OBTAINED BY CALLING AMD LASERS AT (866) 999-2635. IN SOME CASES, AMD LASERS WILL REPLACE AN ACCESSORY OR PART UNDER THE LIMITED

WARRANTY, BUT WILL REQUIRE THE RETURN OF THE DEFECTIVE PART. A CREDIT CARD WILL BE NEEDED TO SECURE THE VALUE OF THE DEFECTIVE UNIT AND WILL BE CHARGED IF DEFECTIVE PART IS NOT RETURNED TO AMD LASERS IN A TIMELY MANNER OR IF, UPON INSPECTION, AMD LASERS DETERMINES THAT THE RETURNED PRODUCT IS DEFECTIVE DUE TO MISUSE OR HANDLING AS OUTLINED IN THE LIMITED WARRANTY.

## LIMITED WARRANTY

AMD LASERS HEREBY WARRANTS AGAINST DEFECTS IN MATERIALS AND WORKMANSHIP OF THE FOLLOWING PORTIONS/ASPECTS OF THE PICASSO CLARIO DIODE LASER ALONG WITH ITS COMPONENTS AND ACCESSORIES (COLLECTIVELY REFERRED TO HEREIN AS PRODUCT):

- 24 MONTHS FOR THE LASER UNIT, FOOT PEDAL, AND EXTERNAL POWER SUPPLY;
- 6 MONTHS FOR THE OPTICAL FIBER CABLE.

THIS WARRANTY SHALL BE IN EFFECT AS OF THE DATE OF PURCHASE ONLY BY THE ORIGINAL END USER OF THE RESPECTIVE ITEMS. THIS WARRANTY SHALL INCLUDE THE COST OF LABOR ASSOCIATED WITH ADDRESSING THE DEFECT IN MATERIALS OR WORKMANSHIP.

THIS WARRANTY DOES NOT INCLUDE, COVER, OR APPLY TO THE FOLLOWING:

- ALL OTHER ACCESSORIES AND SINGLE-USE, CONSUMABLE, OR DISPOSABLE ACCESSORIES OR ASPECTS OF THE PRODUCT;
- THE COST OF FREIGHT/POSTAGE ASSOCIATED WITH MOVEMENT OF THE PRODUCT FOR THE PURPOSES OF FULFILLING THIS WARRANTY;
- DAMAGE TO THE PRODUCT RESULTING FROM ACCIDENT, MISUSE, ALTERATION, OR FAILURE TO FOLLOW THE INSTRUCTIONS CONTAINED WITHIN THIS DOCUMENT;
- COURTESY REVIEW, EXAMINATION, OR CALIBRATION OF THE PRODUCT NOT RELATED TO A DECLARED DEFECT;
- ORDINARY WEAR TO THE PRODUCT CONSISTENT WITH NATURAL AGING, USE AND HANDLING, AND/OR AS A RESULT OF FOLLOWING THE CLEANING, CARE AND MAINTENANCE INSTRUCTIONS OF THIS DOCUMENT;
- DAMAGE INCURRED IN TRANSIT DUE TO FAILURE TO PACKAGE THE PRODUCT IN ITS ORIGINAL FACTORY PACKAGING;

THIS WARRANTY DOES NOT COVER, AND AMD LASERS IS NOT LIABLE FOR, ANY LOSS OF REVENUE INCURRED DUE TO THE PRODUCT REQUIRING REPLACEMENT, REPAIR, OR SERVICING. THE OWNER/USER OF THE PRODUCT IS REQUIRED TO READ THIS DOCUMENT IN FULL PRIOR TO USE OF THE PRODUCT, AND THE OWNER/USER ACCEPTS ALL LIABILITIES AND RISKS ASSOCIATED WITH USE OF THE PRODUCT. THIS WARRANTY IS VALID ONLY TO THE ORIGINAL END-USE PURCHASE AND IS NOT TRANSFERRABLE.

IF UPON EXAMINATION OF THE PRODUCT, WITHIN THE TIMEFRAMES SPECIFIED ABOVE, THE PRODUCT IS FOUND TO BE DEFECTIVE IN MATERIALS OR WORKMANSHIP, AMD LASERS SHALL REPAIR OR REPLACE AT ITS DISCRETION SUCH DEFECTS IN MATERIALS OR WORKMANSHIP AND SHALL NOT CHARGE THE OWNER/USER ONLY FOR MATERIALS ASSOCIATED WITH SUCH REPAIR OR REPLACEMENT. AMD LASERS RESERVES THE RIGHT TO MAKE CHANGES IN DESIGN OR TO MODIFY THE PRODUCT SUBSEQUENT TO ITS ORIGINAL MANUFACTURE. IF UPON EXAMINATION THE PRODUCT IS FOUND TO BE FREE OF THE CLAIMED DEFECTS IN MATERIALS OR WORKMANSHIP TO WHICH APPLICATION UNDER THIS WARRANTY IS LODGED, THE USER/OWNER SHALL BE CHARGED FOR THE LABOR NECESSARY TO PERFORM THE EXAMINATION OF THE PRODUCT. THIS WARRANTY IS VOIDED IF ANYONE OTHER THAN A AMD LASERS AUTHORIZED SERVICE CENTER PERFORMS SERVICE, CALIBRATION, OR REPAIR OF THE PRODUCT NOT DESCRIBED IN THIS DOCUMENT.

IN THE EVENT THAT THE OWNER/USER INFORMS AMD LASERS OF PRODUCT DEFECTS AND THE OWNER/USER OF THE PRODUCT DOES NOT COOPERATE WITH AMD LASERS TO ACCOMMODATE REPAIR, SERVICING, OR REPLACEMENT OF THE DEFECTS, THIS WARRANTY SHALL BE VOIDED RELATIVE TO SUCH ORIGINAL DEFECTS AND TO ALL SUBSEQUENT DEFECTS RESULTING FROM THE CONTINUED PRESENCE OF THE ORIGINAL DEFECTS OR CONTINUED USE OF THE PRODUCT WITH THE ORIGINAL OR NEW DEFECTS. ADDITIONALLY, AMD LASERS IS NOT LIABLE FOR ANY DEATH, INJURY, OR PROPERTY DAMAGE DUE TO CONTINUED USE OF THE PRODUCT WITH A DEFECT PRESENT THAT IS KNOWINGLY UNADDRESSED BY THE OWNER/USER. THIS WARRANTY HOLDS SUPREMACY TO ANY OTHER AGREEMENT, GUARANTEE OR WARRANTY, ORAL OR WRITTEN, EXPRESSED OR IMPLIED, EXCEPT SUCH WRITTEN AGREEMENTS ISSUED DIRECTLY BY THE AMD LASERS AND MUTUALLY ENTERED INTO BETWEEN THE AMD LASERS AND THE ULTIMATE OWNER/USER OF THE PRODUCT.

## OTHER

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

## LIMITED LIABILITY

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

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U.S Patents 7,485,116; 8,834,457; 8,834,457; 8,961,040; 8,967,883;  
EU: 2118971; JP: 5631594; CH: 201630566833.4  
Other U.S and International patents pending