Specifications:

Weight: 5.5 lbs.

Dimensions: 6 1/4"(W) X 8 3/4"(L) X 5 1/2"(H)

Power Range:
- 100 mW to 5.0 Watts in 100 mW increments
- Aiming Beam (3 mW)

IEC Laser Classification:
- Laser Diode: Class 4 Laser Device
- Aiming Beam: Class 3R Laser Device

Wavelength:
- Laser: 810 nm ± 20 nm
- Aiming Beam: 630 nm – 660 nm ±15 nm
- Beam Divergence: 9 degrees ± 1 degree

Cordless Foot Switch:
- Frequency: 2.4 GHz
- 9 volt DC

Modes:
- Continuous Wave or Pulse
- Hertz Rate in Pulse Mode – fixed: 1.0 Hz
- Pulse Duration: fixed: 0.5 seconds
- Duty Cycle (pulsed mode): 50%

Audible Notification: Yes

Visual Notification: Yes

Power Requirements: 110 - 120 VAC @ 60 Hertz

Amperage: 1.5 Amps @ 110 - 115 VAC

Complies with:
IEC 60601-2-22
IEC 60825-1
21 CFR 1040.10 and 1040.11
IEC 60601-1
CAN/CSA - C22.2

Ordering Information

XXXXXX Odyssey Laser with Accessories
Contents:
(1) Odyssey Laser Unit
(1) Fiber Cleaver
(1) Fiber Stripper
(1) Protective Glasses - Black
(1) Protective Glasses - White
(1) Protective Glasses - White Frame Slim
(1) 400 Micron Fiber Cartridge System
(1) Package of (50) Hand Piece Tips
(1) Hand piece (autoclavable)
(1) Cordless Foot Switch
(1) Cordless Foot Switch Receiver
(1) 9 volt Alkaline Battery
(1) Power Cord
(1) Owner's Manual
(1) Procedure Guide
(1) Warranty Card
(1) Key
(1) Laser Safety Sign
(1) Training DVD

Accessories:

579032 Fiber Cleaver
579031 Fiber Stripper
579033 Protective Glasses - Black
579034 Protective Glasses - White
579035 Protective Glasses - White Slim
579036 400 Micron Fiber Cartridge System
579039 Package of (50) Hand Piece Tips
579038 Hand Piece
XXXXX Cordless Foot Switch
XXXXX Cordless Foot Switch Receiver
579041 Power Cord

UNITED STATES
175 Pineview Drive
Amherst, New York 14228
716-691-0010
800-533-6825
Fax: 716-691-2285
www.ivoclarvivadent.us.com

CANADA
Ivoclar Vivadent, Inc
2785 Skymark Ave., Unit 1
Mississauga, ON L4W 4Y3
905-238-5700
800-263-8182
Fax: 905-238-5711
www.ivoclarvivadent.ca

EUROPEAN AUTHORIZED REPRESENTATIVE
Ivoclar Vivadent, AG
Bendererstrasse 2, FL-9494,
Schaan, Liechtenstein
+423-235-3535

Learn more about the Odyssey at
www.GetOdysseyLaser.com

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.

100% CUSTOMER SATISFACTION
GUARANTEED!

Odyssey™ 2.4G
DIODE LASER

ivoclar vivadent®

French Language version of the Odyssey 2.4G Owner's Manual is available upon request.

© 2005 Ivoclar Vivadent, Inc. Odyssey is a trademark of Ivoclar Vivadent, Inc.

XXXXXXXX Rev. 0, May 2005

FC ID: TFIODYSSEY24G
Model No.: 595126

Odyssey™ 2.4G
DIODE LASER

Owner's Manual

ivoclar vivadent

Table of Contents

Section 1 - Introduction 1

Section 2 -Specifications
2.0 Laser Specifications 2
2.1 Delivery System Specifications 2
2.2 Warranty 2
2.3 Parts List 2

Section 3 – Laser Assembly Instructions
3.0 Removing the Laser from the Packaging 3
3.0.1 Instructions on Unpacking & Dealer Assistance .3
3.0.2 Shipping Container Information 3
3.0.3 Contents of the Shipping Container 3
3.1 Assembling the Laser 3
3.1.1 The Laser Chassis 3
3.1.2 Power Cord Installation 3
3.1.3 Power/Fan Switch - Check
Checking the Laser Key Switch 3
3.1.4 Laser Key Switch – Check 3
3.1.5 Foot Switch Installation 3
3.1.6 Odyssey Remote Interlock 3
3.1.7 Emergency Shutdown Switch 4
3.1.8 Installing the Disposable Fiber Cassette 4
3.1.9 Review of Installation Procedures 4

Visual Assembly Aides
Figure 3.0 Back Panel of the Laser 5
Figure 3.1 Front Panel of the Laser 5
Figure 3.1a Key Switch Activation 5
Figure 3.2 Laser Control Pad 6
Figure 3.2a Laser Display Indicators 6
Figure 3.3 Cordless Foot Switch Input Port 6
Figure 3.4 Cordless Foot Switch 6
Figure 3.5 Emergency Shutdown Button - Activating . .7
Figure 3.6 Emergency Shutdown Button - Releasing . .7
Figure 3.7 Top View - Emergency Shutdown
Button and Fiber Retraction Switch 7
Figure 3.7a Advance and Retraction
Switch Activation 7
Figure 3.8 Laser Aperture and Cassette Power
Receiver Location on the Chassis 7
Figure 3.9 Disposable Fiber Cassette Base
with a 15 Pin Power Coupler 8
Figure 3.10 Removable End Cap on the Cassette 8
Figure 3.11 Disposable Fiber Cassette without
an End Cap 8
Figure 3.12 Proximal End of the Fiber
as it Exits the Cassette 8
Figure 3.13 Locking Hub 8
Figure 3.14 Alignment Slot 8
3.2 Facility Requirements 9
3.2.1 Electrical Requirements 9
3.2.2 Heating and Ventilation 9
3.2.3 Lighting 9
3.2.4 Combustible Chemicals and Gases 9
3.2.5 High Speed Vacuum Systems 9
3.2.6 Access and Visual 9

Section 4 - Safety Considerations

4.0 Food and Drug Administration 9
4.1 Wireless Technology 9
4.2 Statutory Licensure 9
4.3 OSHA and its Provisions 9
4.4 Laser Safety Officer (LSO) 10
4.5 Continuing Education 10
4.6 In-office Safety Issues 10
4.6.1 Lighting 10
4.6.2 Safety Eyewear 10
4.6.3 Test Firing the Laser 10
4.6.4 Power Changes with Fiber Changes 10
4.6.5 Fiber Preparations 10
4.6.6 Danger – Laser in Use Signage 11
4.6.7 Sharps Disposal 11
4.6.8 Plume Evacuation 11
4.6.9 Key Switch and Mode Selection 11
4.6.10 Safety Education 11
4.6.11 Laser Security 11
4.6.12 Emergency Shutdown Options 11
4.6.13 Hard Tissue Procedures 11
4.7 ANSI Standards 11

Section 5 – Operating the Laser

5.0 Standby and Ready Status 11
5.1 Continuous Wave Mode 11
5.2 Pulsed Energy Mode 11
5.3 Tissue Responses to Laser Energy 12
Figure 5.1 Poor Cleave on the Fiber 12
5.4 Fiber and Hand Piece Care 12
5.5 Warning (Fiber Cassette Care) 12
5.6 System Procedures 12
5.6.1 Selecting the Treatment Center 12
5.6.2 Checking Foot Switch Installation 12
5.6.3 Checking the Disposable Fiber Cassette Installation 12
5.6.4 Checking Fiber Preparation 12
5.6.5 Checking the Emergency Shutdown Button - Release Instructions 13
5.6.6 Checking the Key Activation and Control Panel Display 13
5.6.7 Setting Mode Parameters 13
5.6.8 Setting Power Parameters 13
5.6.9 Aiming Beam – Switching On and Off 13
5.6.10 Avoiding Use of a Defective Fiber Tip (Shards) 13
5.6.11 Aiming Beam Activation 13
5.6.12 Test Firing the Laser Before Beginning Procedures 13
5.6.13 Using Quick/Short Strokes with the Fiber Tip .13
5.6.14 Cleaning the Fiber Tip During a Procedure . . .13
5.6.15 Preventive Measure – Placing the Laser in Standby 13
5.6.16 Cleave used fiber tip and discard 13
5.6.17 Preventive Measure - Cleaning the Fiber Before Retracting It. 13
5.6.18 Preventive Measure – Turning the Key Off Between Procedures 13
5.6.19 Recording Power, Mode and Time Parameters in the Patients Chart. 13
5.6.20 Self Diagnostic and Monitoring 13

Section 6.0 Systems Components: Preparation, Care and Maintenance

6.0 Disposable Fiber Cassette 14
6.0.1 Replacing the Fiber Cassette 14
6.1 Fiber Preparation 14
6.1.1 Jacket 14
6.1.2 Cladding 14
6.1.3 Quartz/Silica Fiber 15
6.1.4 Stripping the Fiber 15
6.1.5 Cleaving the Fiber 15
6.1.6 Initiating the Fiber 15
6.1.7 Fiber Disinfection 15
6.2 Maintenance 16
6.2.1 Laser Chassis Disinfection 16
6.2.2 Calibration 16
6.3 Hand Piece Preparation 16
6.3.1 Preparation for Autoclaving 16
6.3.2 Components of the Hand Piece 16
6.3.3 Providing Adequate Fiber to Cleave, Strip and Initiate 16
6.3.4 Disposable Tips 16
6.3.5 Using the Stripper 16
6.3.6 Mounting the Disposable Tip 16

Section 7.0 Labels, Signs, Warnings and Information

7.1 Federal Compliance 17
7.2 Danger – Laser in Use Signage 17
7.3 Laser Classification – Aiming Beam 17
7.4 Laser Classification – Treatment Laser 17
7.5 Caution – Changes Not Approved 17
7.6 Caution – Avoid Skin and Eye Contact 17
7.7 Caution – No User Serviceable Parts Within the Chassis 17
7.8 Caution – Sale or Use of a Laser by Other than a Physician or Dentist 17
7.9 WARNING – Do Not Use Eyewear for Other than the 810 nm Wavelength 17
7.10 Manufacturer's General Information 17
7.11 Nominal Ocular Hazard Distance 18

Section 8.0 Warranty Policy

8.1 Loaner Policy 18
8.2 Repairs 18
8.3 Customer Service Address 18

Section 9.0 Glossary of Laser Terminology 18

Section 10.0 Selected References on Laser Dentistry 19

Section 11.0 Troubleshooting 20

Section 1 - Introduction

As dentists strive to create the perfect smile, they are often compromised by the technology they use in their practice. Respected leaders from the dental profession and dental equipment manufacturers have sought to identify the most practical and least invasive technology available to deliver restorative and preventive care. Today, thanks to continuing efforts by these industry leaders, we have seen the introduction of many new devices that have advanced the dentist's ability to perform at the highest standards. The ODYSSEY 2.4G DIODE LASER from Ivoclar Vivadent, Inc. represents the latest solid state diode laser technology available for soft tissue modification and preventative care.

Unlike solid state lasers that utilize a man-made rod of elements such as yttrium, aluminum, and garnet, doped with a rare earth compound like Erbium, the diode has components that have become known for their durability, dependability and longevity. We are, of course, referring to semi-conductor crystal technology like that found in televisions, DVD players, telephones and many more of those household products that we have learned to rely on each day.

The major components of the Odyssey 2.4G are semi-conductor "chips" made from Aluminum, Gallium and Arsenide, together commonly referred to as AlGaAs. They are activated or "pumped" by passing an electrical current through the diode to produce an elliptical shaped display of monochromatic light that can be focused into a very small point and placed into the delivery fiber. The wave length produced by the diode is approximately 810 nanometers (nm) and produces invisible non-ionizing thermal radiation that does not create changes in cellular DNA. The diode is air cooled and highly efficient when used correctly. For safety, the diode features several ways to stop energy flow if the operator wishes to deactivate the laser. The safety system includes a choice of an emergency shutoff switch, a key, a power switch, a power cord or an electrical plug. Any of these items can be used to shut down the laser.

The design and technology used in the Odyssey 2.4G allows the dentist or hygienist (in states where the Dental Practice Act doesn't prohibit hygienists from using a laser) to transport the laser between different operatories. It has a light weight and durable chassis that is designed to use 110 – 120 V electricity found in most dental offices.

Training is recommended and opportunities for such are available through such outlets as the Academy of Laser Dentistry and many of the dental schools. You should ask your authorized representative for the names of dentists in your area who have a laser and who could help you in a mentoring capacity. There are many applications for using this laser system and you will be proud of the results you attain when you use the Odyssey 2.4G regularly.

Laser safety is paramount in importance and each office should quickly develop and implement a laser safety program and appoint a "laser safety officer" to be responsible for the laser. Their duties include management of the laser and all accessories as well as training office personnel in all aspects of laser safety. More duties are outlined in Section 4, subsection 4.3 of this manual.

Remember: Always test fire the laser outside the mouth before using it on a patient. The doctor, the patient and any staff member present in the operatory should be wearing the appropriate safety eyewear whenever the laser is being operated. Strict adherence to protocols for safe laser use is essential.

Section 2 – Specifications

2.0 Laser Specifications

Weight	5.5 lbs
Dimension in inches (H X W X L)	5.5” X 6.25” X 8.75”
Laser Classification (Per 60825)	
Laser Diode	Class 4 Laser Device
Aiming Beam	Class 3R Laser Device
Wavelength	
Laser	810 nm ±20 nm
Aiming Beam	630 nm – 660 nm ±15 nm
Beam Divergence	9 degrees ± 1 degree
Power Range	100 mw to 5 Watts
Hertz Rate in Pulsed Mode - fixed	1.0 Hz
Pulse Duration - fixed	0.5 seconds
Duty Cycle	
pulsed mode	50%
continuous wave	100%
Aiming Beam (3 mW)	Yes
Audible Notification	Yes
Visual Notification	Yes
Power Requirements	110 - 120 VAC @ 60 Hertz 220 - 240 VAC @ 50 Hertz
Amperage	1.5 Amps @ 110-115 V AC 0.75 Amps @ 210-230 V AC
Cordless Foot Switch	
Frequency	2.4 GHz
Battery	9 volt DC Alkaline

2.1 Delivery System Specifications

2.1.1 Quartz silica fiber	
1 cassette – approximately 20’ each (6 meters)	
Fiber Diameter	400 microns
Autoclavable	No
Retractable fiber delivery cassette (non-autoclavable)	1
2.2.2 Hand Piece - Autoclavable	1
2.2.3 Tips for the Hand Piece	
Autoclavable and disposable	50 per box
2.2.4 Laser Aperture -ST Adapter Type	Yes

2.2 Warranty (See also Section 8)

Laser	1 year Parts and Labor
Fiber and Cassette	90 days Parts and Labor

2.3 Parts List

	Part Identification number
Cordless Foot Switch	XXXXXX
Cordless Foot Switch Receiver	XXXXXX
Power Cord	579041
Disposable Fiber Cassette with a 400 micron fiber	570936
Disposable Fiber Cassette with a 600 micron fiber	579037
Laser Safety Eyewear (appropriate for 810 nm protection)	
Black	579033
White	579034
White Slim	579035
Hand Piece (autoclavable)	579038
Disposable Handpiece Tips (50 quantity)	XXXXXX
Fiber Cleaver	579032
Fiber Stripper	579031
Owner’s Manual	XXXXXX
Danger Sign	580280
Procedure Guide	579347

Section 3 - Laser Assembly Instructions

3.0 Removing the Laser from the Packaging

3.0.1 - Your local authorized dealer can provide a representative to assist you when you are ready to remove the laser from its shipping container. You may remove it yourself if you wish to get a head start on the set-up, but please do not attempt to unpack the laser and install the various components without reading this section first. If you are unsure about any aspect of the assembly, call your authorized dealer representative for assistance.

3.0.2 - Please do not destroy or throw away your shipping container. Though highly unlikely, you may need to return the laser for service or repair and the shipping container you received with your laser has been designed to transport the laser.

3.0.3. - The contents of the shipping container should include the following:

a. Laser chassis
b. 3 pairs of protective eyewear
   - optical density of 4+ at 810 nm
c. 1 laser fiber cassette with approximately
   20 feet (6 meters) of 400µm fiber optics
d. 1 cordless foot switch
e. 1 cordless foot switch receiver
f. 1 9 volt Alkaline battery
g. 1 power cord
h. 1 cleaver
i. 1 fiber stripper
j. 1 autoclavable hand piece
k. 1 owner's manual
l. 1 key
m. Laser in use warning sign
n. 1 procedure guide
o. 1 pack of 50 - hand piece tips

Please check all items sent with your laser to insure that all components are accounted for.

3.1 Assembling the Laser

Each of the following items should be inspected, inserted into the appropriate receptacle, and when applicable, locked using the locking hub.

3.1.1 Laser Chassis: After the laser chassis and all accessories have been removed from the shipping packaging, inventory all parts using the parts list (section 3.0.3). Refer to the customer service number on the last page of this manual and file a damaged or missing part report. You will receive information regarding the return of the damaged part and also a tentative schedule date for receiving the replacement.

3.1.2 Power Cord: Remove the power cord from the Odyssey accessory package and plug the power cord into the appropriate receptacle on the back of the laser. See Figure 3.0 on page 4. To prevent power surges due to electrical storms or spikes in line voltage, you should use a power strip with a circuit breaker or unplug the laser when you are not present. Plug the power cord into a 110 Volt AC outlet rated at 60Hz.

3.1.3 Power/Fan Switch: The power/fan switch for the laser and fan is the first item you turn on each day. The switch is located on the rear panel of the laser near the lower right hand corner. See Figure 3.0 on page 4.

3.1.4 Laser Key Switch: The laser key switch is the major circuit breaker for your laser. It will be the second item you turn on when activating the laser each day. Place the laser key into the key receptacle located near the lower right corner on the front of the laser. See Figure 3.1 and Figure 3.1a on page 5. Check the key switch by turning the key clockwise approximately 1/4 of a turn. This is the (ON) operating position for the key. The fan will start when the power/fan switch is on and the key is turned. Prior to leaving the office, the laser safety officer should check to see that the key switch has been turned off and the key removed and stored in a safe place.

3.1.5 Foot Switch: Locate the foot switch receptacle on the back of the laser and insert the wireless transmitter adapter into the marked receptacle on the back of the laser. Then check to see if it is securely locked. See Figure 3.0 on page 4 and Figure 3.3 and 3.4 on page 6. Remove the battery cover from the underneath side of the foot switch. Insert the enclosed 9 volt battery. Replace the battery cover. The foot switch is now ready for operation. **NOTE: An extra 9 volt alkaline battery should be kept in your office inventory as the battery should be changed every 90 days.**

3.1.6 Odyssey Remote Interlock: The Odyssey Laser is equipped with a Remote Interlock Jack. The Remote Interlock Jack is provided so that a clinician may install the laser in a dedicated laser treatment room such that the laser will be interlocked with the entrance door of the room. In such an interlocked installation, the laser would shut off anytime the door is opened, hypothetically, to protect the person's eyes who is entering the room. It is recognized that such installment is not facilitated nor required in many operatories or clinics. To that end, the Remote Interlock is available to any practitioner that requires it. The Remote Interlock Jack is located and clearly labeled on the rear of the laser. The miniphono

jack is wired in the normally closed position; meaning that no further action is required to operate the laser without the interlock loop. If the interlock loop is desired you may purchase the loop as an accessory or you may purchase a loop from a local electronics store. You need only inform the local electronics store that you require a mini (1/8") mono-phono jack wired into a normally closed momentary switch and select the switch design that best suits your needs. To install the loop, install the switch on the door and simply plug the mini phono jack into the Remote Interlock Jack on the rear of the laser.

3.1.7 Emergency Shutdown Switch: Before you can activate the laser, you must first check to see if the emergency shutdown switch has been depressed prior to shipment and locked in the off position. The switch is the red button located on the top of the laser. To release, depress the switch by grasping it between your thumb and index finger, and gently depress it as you turn the button 1/4 turn to the right. You will feel it "click" or release and the spring loaded button will pop back up. The display on the control panel should now be lighted. If the cartridge lock plate is not fully engaged, this will prevent the display from lighting up. If you find that the display is still not operational, check all attachments, keys and switches to see that they are securely installed and that you have an active wall plug for electricity. (See Troubleshooting Section pg. 19). If the laser can not be activated, please contact your authorized distributor who can help you to get a replacement. If the control panel does light up when you release the shutdown switch, you should test the switch again by depressing it to turn the laser off. If the shutdown switch is locked down, the laser will not turn on. See Figure 3.5 and Figure 3.6 on page 7.

3.1.8 Installing the Disposable Fiber Cassette: To install a new cassette, carefully remove the fiber cassette from the packing. Remove the end cap from the old cassette and remove the cassette (do not dispose of the end cap). To install the new cassette, locate the end of the new fiber. **Avoid placing your finger on the proximal end of the new fiber.** See Figure 3.12. Human oils on the fiber can burn and diminish the effective transmission of radiant energy once the fiber is installed. While opening the door on the laser aperture with one hand, insert the proximal end of the new fiber into the laser aperture. See Figure 3.13. Be careful to align the slot on the fiber end with locking hub of the aperture. See Figure 3.14. Once inserted, turn the fiber locking hub to the right (clockwise) to lock the fiber securely into the ST connection . Once the fiber is connected, align the dove tail of the cassette with the dove tail receiver on the chassis wall. See Figure 3.8. This will help assure that the power coupler(a serial port) on the underside of the fiber cassette will be aligned with the receiver on the laser chassis. Slowly press the cassette into place. See Figures 3.8, 3.9 & 3.11 on pages 7-8. Once connected, replace the end cap to secure the fiber cassette. The laser will not operate without the end cap firmly in place. Turn the key switch and power/fan switch to the "on" position. Test your power connection by advancing the fiber, using the rocker switch on the top of the cassette. Depress the switch at its most anterior point to see if it moves the fiber forward.

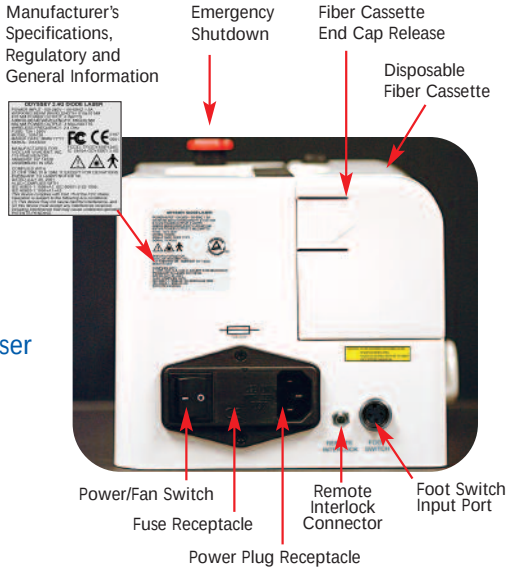
Next, select a low power to check transmission of energy (1 Watt – 1.5 Watt). Put on the safety eyewear to protect your eyes. Place the laser in ready mode and depress the foot pedal to activate the laser while holding the fiber approximately 2-4 mm away from a piece of paper with printing on it. Aim at the printing, the paper will begin to burn in 1-2 seconds. See 4.5.2 and 6.1.6. You should be able to see the aiming beam on the paper and the fiber tip should produce enough heat to let you know it is installed properly and the fiber is sound. You do not want to use an initiated fiber (see page 15) for this check because the energy would stop at the tip.

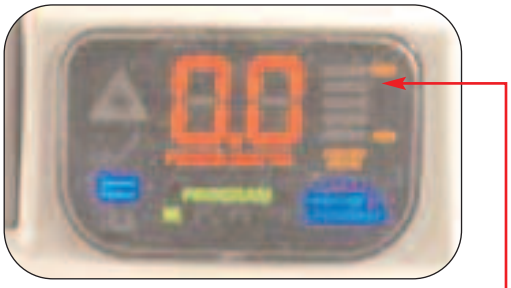
3.1.9 Review: Laser Assembly Instructions

1. Attach the laser's power cord and place the plug into the wall receptacle.
2. Attach the foot switch and lock the locking hub.
3. Attach remote interlock, if desired (not required).
4. Check the emergency shutdown switch to see that is has been released.
5. Install the fiber cassette and attach the fiber to the ST connector.
6. Place the key into the key switch receptacle (see Figure 3.1a on page 5) and turn the key to the right.
   The control console should light up.
7. The light on the console indicating the operating status should be in the standby mode.

NOTE: When the power cord is plugged in, the fan/power motor switched on, the cordless foot switch receiver attached and the emergency shutdown released, the key will turn the laser on.

Figure 3.0
Back Panel of the Laser





Odyssey 2.4G Digital Display

Figure 3.1 - Front Panel of the Laser

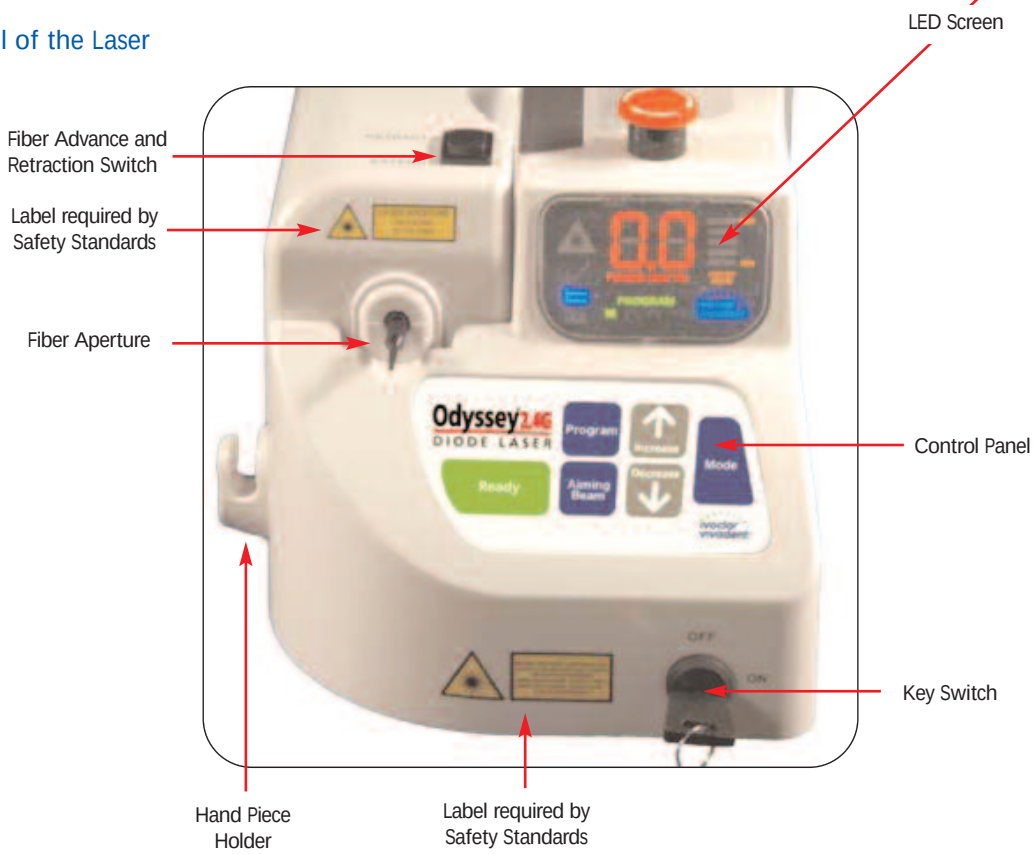


Figure 3.1a Key Switch Activation

Turn the key 1/4 of a turn to the right to turn on the laser

Figure 3.2 - Control Pad Settings

Mode: Press this key to toggle between Continuous and Pulse mode.

Increase and Decrease: Use these to adjust the working beam power. Hold the key to rapidly change the value.

Program: Press this key to select either manual (M) or one of three user saved programs (P1, P2, P3). Each program will save all of the parameters - working beam, aiming beam and mode.

The settings can be changed as desired for any of the program modes. To set the user defined program modes, choose either P1, P2 or P3, set your preferred settings and push the ready button. Upon activating the ready button, the new settings will be retained.

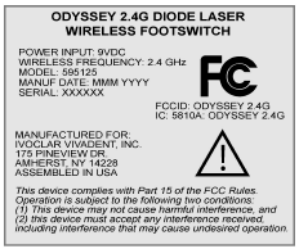
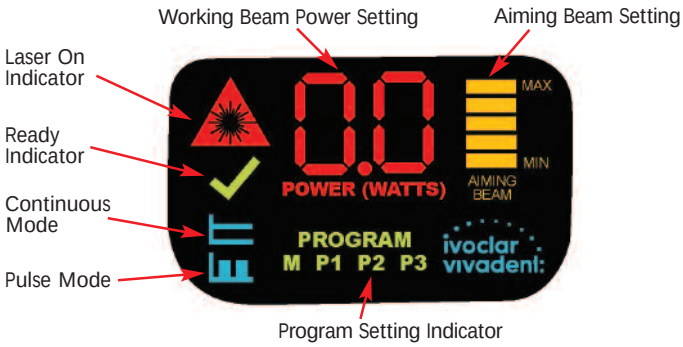


Figure 3.3 Cordless Foot Switch Input Port & Receiver

Align the lip on the proximal end of the cordless receiver with the notch at the top of the input port.

Figure 3.2a - Display Indicators



Laser On: This illuminates when the foot pedal is depressed. This indicates that the working beam (810nm) energy is being emitted.

Ready Indicator: This illuminates when the READY key is pressed. It will blink for 3 seconds, then remain steady. Once it is steady on, the aiming beam will be activated.

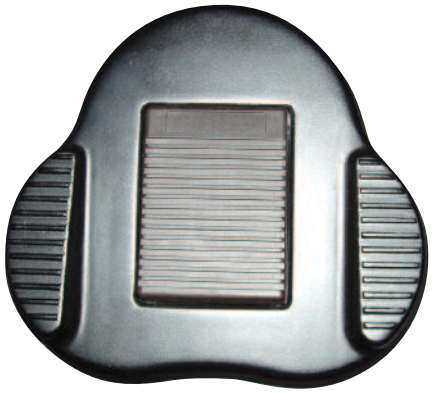
Continuous and Pulse Mode: This illuminates when the unit is in continuous mode. Use the MODE key to toggle back and forth between Continuous and Pulse.

Working Beam Setting: Indicates the working beam power output setting.

Aiming Beam Setting: Indicates the aiming beam setting. Each bar represents about 20% of maximum capacity. Thus 0 bars means the aiming beam is shut off.

Program Setting Indicator: Shows the current program mode that is selected. Pressing the PROGRAM key will cycle through the programs left to right, then back to "M".

Figure 3.4 Cordless Foot Switch



Check of the Emergency Shutdown System

1. Depress to shutdown (feel the click) Power is OFF in the down position Emergency Shutdown Switch

2. Depress slightly and turn right 1/4 of a turn turn to release. The emergency stop will pop up and the LED screen will light.

Figure 3.5

Figure 3.6

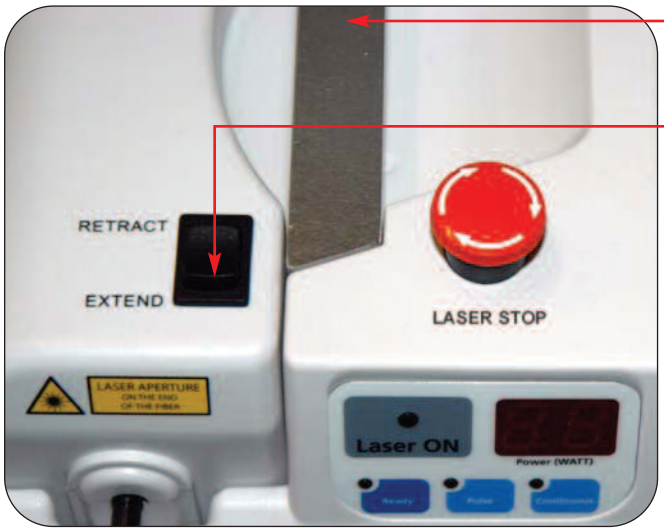


Figure 3.7

Aluminum handle

Fiber advance and retract rocker switch (See below)

Depress the OUT or IN rocker switch to advance or retract the fiber

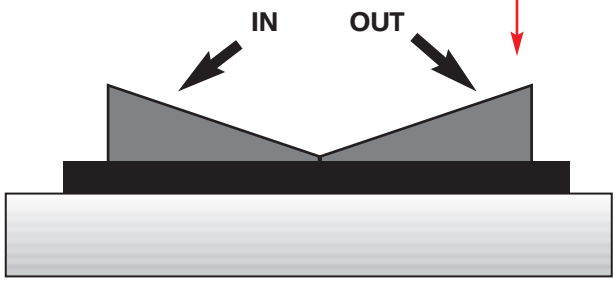
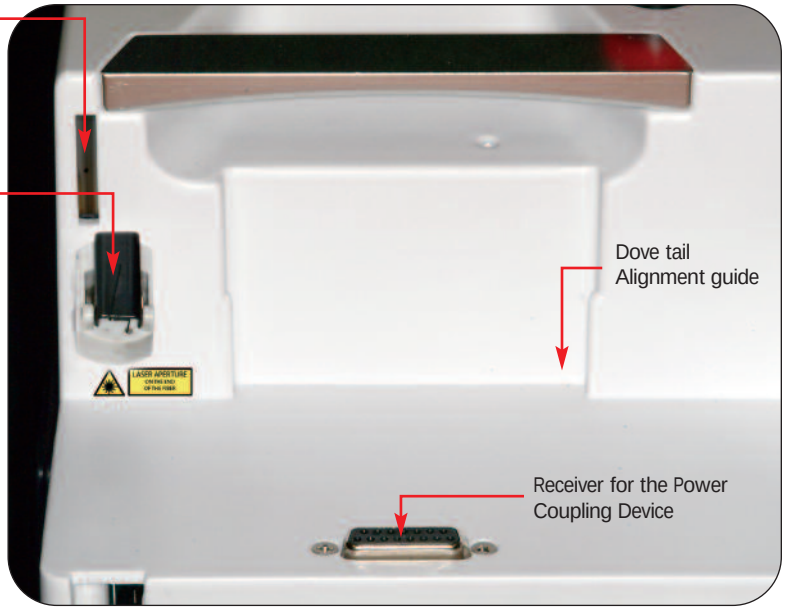


Figure 3.7a Rocker Switch Activation

Receiver for the Fiber Cassette end cap locking device

Laser Aperture with ST Connection:

The proximal end of the fiber inserts here and is locked by turning the locking hub to the right



Dove tail Alignment guide

Receiver for the Power Coupling Device

Figure 3.8 Laser Aperture (ST adapter) and power receiver for the power coupling device on the base of the cassette.

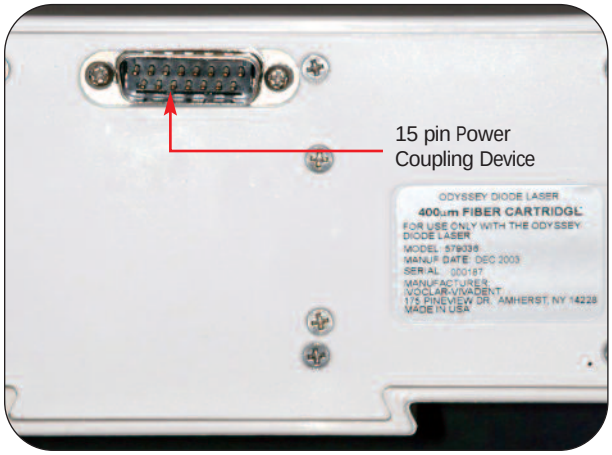


Figure 3.9 Base of the Fiber Cassette and the 15 Pin Power Coupling Device

Figure 3.10 Removable End Cap of the Fiber Cassette

Figure 3.11 Disposable Fiber Cassette without the End Cap

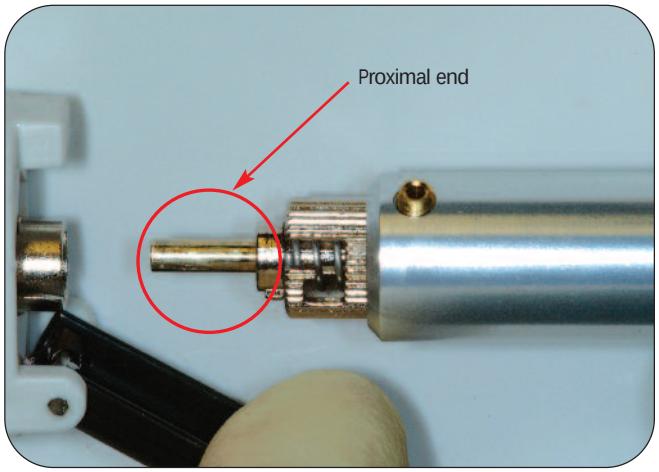


Figure 3.12 Fiber exit from the Disposable Fiber Cassette

The proximal end of the fiber extends from the internal wall of the fiber cassette and must be attached to the laser by inserting it into the Laser Aperture (ST adapter).

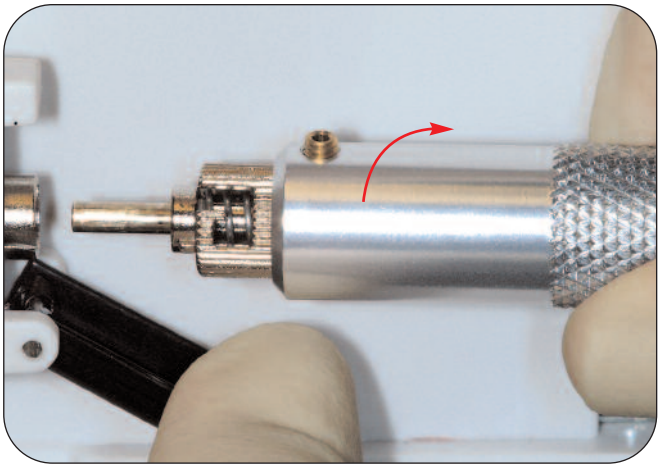


Figure 3.13 Locking Hub

Once it is inserted into place, it is locked by turning the locking hub approximately 1/8 turn to the right.

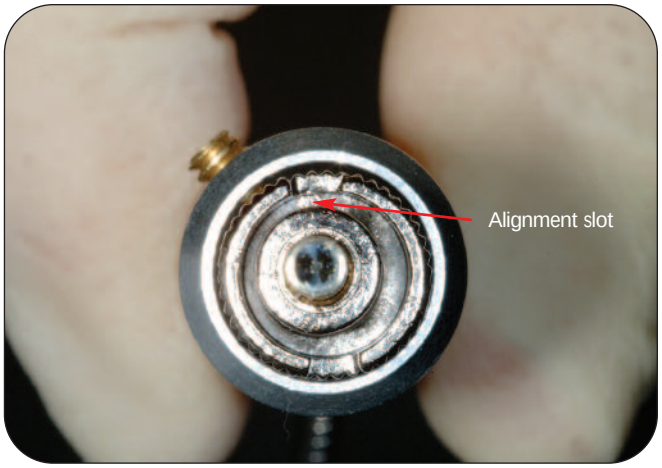


Figure 3.14 Alignment Slot

3.2 Evaluating the Facility and Environmental Considerations (United States)

In order to insure the safe use of the laser in your facility, please check to make sure that the proposed location has the following:

3.2.1 Electrical Requirements

110 -120 V AC ±10 % at 60 Hz
3 Amps
Frequency range 45 - 63 Hz
9 volt DC Alkaline battery

3.2.2 Heating and Ventilation

The room where the laser is used should have good cooling and heating system so that the laser can be operated within the optimum range of 20º - 30ºC (68º - 86º F). Avoid storing or transporting the laser in temperatures below 0º Celsius (32º F).

3.2.3 Lighting

Overhead lighting and or dental unit light should provide enough illumination to allow good operator vision when activating the laser intra-orally.

3.2.4 Combustible Chemicals and Gases

All gases that are combustible or support combustion and are used in the operatory area where the laser is in use must be turned off during the procedure. Cleaning supplies or other flammable chemical compounds should be stored in an area away from the surgical site in order to avoid possible combustion.

3.2.5 High Speed Vacuum Systems

Plume evacuation is a priority when vaporizing tissues. The doctor and their chair-side assistants should keep themselves and the patient safe by using a high volume vacuum system and high filtration masks that are suitable for virus and bacterial control.

3.2.6 Access and Visual

Access to the treatment area should allow the dental team to restrict entry while the laser is in use. There should be a Laser In Use warning sign placed in a designated area adjacent to the entry into the treatment area. See Figure 7.0 on page 16.

4. Safety Considerations

The safe use of the Odyssey is the responsibility of the entire dental team including the doctor, the laser safety officer appointed from the doctor's staff, and the dental team of auxiliary personnel. Protocols for the safe use of lasers have been developed by a combination of medical and dental professionals working in concert with educators at the university level, scientists and laser manufacturers. Dental professionals have had to develop protocols and guidelines for using the laser on oral soft tissues. Sound judgment and the concern for patient safety should be the basis of all laser care. The following entities have influence over laser use.

4.0 Food and Drug Administration

Manufacturers of products subject to performance standards under the Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C - Electronic Product Radiation Control are required to certify compliance with the regulations and furnish various reports to the Center for Devices and Radiological Health (CDRH)). For medical laser manufacturers, additional review by the FDA of the safety and effectiveness of the device is required. Companies who intend to market a medical laser today must receive authorization from the FDA to permit the device into commercial distribution. There are two forms of premarket clearance procedures. The premarket notification (510(k)) procedure is principally used for those devices that are documented to be substantially equivalent to legally marketed Class I and Class II devices. For new devices not equivalent to legally marketed devices, a more complex PMA is required.

4.1 Wireless Technology

In order to promote efficient use of the radio spectrum in various global markets the US FCC (Federal Communications Commission) and other international government agencies have developed technical standards for devices that are capable of emitting radiofrequency energy when in use – such as wireless data cards. These products need to receive certain identification numbers in accordance with the Commission Equipment Authorization rules prior to marketing in US markets. The FCC certification is similar to the CE certificate for the European markets.

The Code of Federal Regulations, Title 47 (47 CFR), Part 15 covers the rules for the operation of unintentional, intentional or incidental radiators. Any electrical or electronic devices incorporating a digital circuitry and operating with an oscillator or clock speed of greater than 9kHz requires approval to this rule. There are various types of FCC Part 15 approvals, pending on the nature of the product and its intended use.
In Canada, IC-RSS 210 (Radio Standards Specification) sets out the requirements for license exempt low-power intentional radiators. This standard is very closely harmonized in terms of permitted frequencies, types of operation, and other technical requirements to the FCC requirements, but a sepa-

rate certification application is required for Canada.
In the European Community, compliance with several safety directives and testing to EN 300 328, EN 60950 and EN 301 489 is required for this type of device. The manufacturer is required to provide a Declaration of Conformity as evidence of its compliance with the various regulatory requirements.

4.2 Statutory Licensure

Usually, states do not have a specific licensure requirement for use of a laser by a dentist. Most states require a hygienists to attend licensure training that includes both a lecture and hands-on training. Prior to using the laser, the hygiene applicants are required to pass a proficiency test for certification. These courses are usually taught by members of the Academy of Laser Dentistry who possess instructor credentials.

4.3 OSHA and its Provisions

Worker safety is the responsibility of the employer and is regulated by OSHA (Occupational Safety and Health Administration), a division of the U.S. Department of Labor. OSHA has issued no specific standard for safe use of lasers but recognizes ANSI standard Z136.1 as a source for analyzing safety with respect to medical lasers. For more information see OSHA Technical Manual (TED 1-0.15A) Section III, Chapter 6, 1999. Ivoclar Vivadent Inc. recommends implementation of a Laser Safety Program for the safety of your patients and office staff in connection with the use of the Odyssey Diode Laser.

4.4 Laser Safety Program

We recommend implementation of a Laser Safety Program appropriate for your dental office. The plan may include the following:

- Delegation of authority and responsibility for supervision and control of the laser to a Laser Safety Officer;
- Minimum Training requirements for users of the laser
- Laser security against unauthorized use of the laser
- Standard operating procedures to regulate the work environment in order to protect the patient and office staff from laser hazards.

The safe use of a laser is the responsibility of the Laser Safety Officer (LSO) who can be a full or part-time employee, or the laser operator. It is their responsibility to train the staff, maintain records concerning training and the laser's performance, perform safety checks and prepare the laser for use on a daily basis. The LSO must keep records of any incidents that relate to the failure of the laser or any adverse effects related to laser therapy and report such incidents as prescribed by law. The laser safety officer assures that a medical follow-up has been sought or has occurred following any adverse incident during treatment. The LSO is responsible for the training of all office personnel who are involved with the laser preparation and use. Daily checks of the facility and equipment are also the LSO's responsibility. The LSO should test fire the laser each day prior to beginning each treatment procedure. For more information on the contents of a Laser Safety Plan, you can review ANSI Standard Z136.3 for *Safe User of Lasers in Health Care Facilities or TR IEC 60825-8 Guidelines for the Safe Use of Medical Laser Equipment.*

4.5 Continuing Education

The laser safety officer should insure that the operator and staff attend laser courses taught by qualified laser educators. Ongoing reviews of laser safety procedures should be a part of normal office routine.

4.6 In-office Safety Issues

4.6.1 Lighting: Always use the Odyssey in a well lighted and ventilated area. Make certain that chemicals or gases capable of supporting or causing combustion are not present when using the laser. Use high volume vacuum to remove the laser "plume" and provide a high filtration masks for all people present in the treatment area during lasing.

4.6.2 Safety Eyewear: While using the Odyssey laser, doctors, auxiliary staff, patients, and anyone attending them in the operatory must wear the appropriate safety eyewear that has been designed for use with the 810 nm wavelength. Never point the laser tip directly at the face, eyes or skin of anyone while emitting energy. The aiming beam is also capable of causing eye damage

4.6.3 Test Firing the Laser: Always test-fire the Odyssey prior to using it intra-orally. Using a power of 1 Watt continuous wave or less, place the laser in the ready mode. Then, activate the laser for 1-2 seconds while aiming the fiber onto a 2X2 gauze sponge wetted with water. Do not use alcohol or any other combustible material to wet the 2X2 sponge as it may ignite.

4.6.4 Power Changes With Fiber Changes: Switching to a smaller diameter fiber will increase the density of the power at the fiber tip. As a result, you may need to adjust your power downward. Increasing the power may be required when switching to a larger diameter fiber. In order to achieve the same rate of work after changing fiber diameters, remember this: a smaller diameter fiber will require less power and conversely, a larger diameter will require more power.

4.6.5 Fiber Preparations: After cleaving and stripping the fiber, photo-initiation of the fiber tip will allow the operator to remove tissue more rapidly. Gingival debris on the tip will retain the heat and it should be removed. The tip will also begin to blacken and deteriorate as it retains the heated debris and can break if not removed by cleaving it. Clean the tip often using a 2 X 2 gauze sponge moistened with water. Do not use combustible liquids to moisten the 2 X 2.

4.6.6 Danger - Laser In Use Signage: Each operatory where the Odyssey is used should have a "laser in use" sign placed at the operatory entrance when a procedure is in progress. This signage will help to eliminate eye damage caused by inadvertent exposure to laser energy. See Figure 7.0 on page 30.

4.6.7 Sharps Disposal and Sponge Removal: Remove cleaved fiber remnants and place them into a sharps container for disposal. All sponges used for cleanup of lasers and fibers should be disposed of in a bag for contaminated soft products.

4.6.8 Plume Evacuation: Use high volume evacuation suction during procedures to remove laser smoke or 'plume'. debris. Use masks suitable for viral filtration. Caution - laser plume may contain viable tissue particulates.

4.6.9 Key Switch and Mode Selection: When the key switch is in the ON position (turn to the right), the laser has been enabled and can be activated while in the READY status. When not in use, insure that the key has been turned off or that the laser is placed in the STANDBY status.

4.6.10 Safety Education: Provide comprehensive safety procedure training for all office personnel and include the staff in all outside laser courses you attend when possible. Be certain that all members of the dental team understand how the laser works and can advise patients as to their safety and advantages over conventional procedures.

4.6.11 Laser Security: To prevent the unauthorized use of the laser while not in use, the key should be removed from the unit and maintained by the Laser Safety Officer.

4.6.12 Emergency Shutdown Options: Any of these mechanisms can be used to shut down the emission of laser energy in a real or perceived emergency.

1. Depress the emergency shutdown button
2. Foot switch – remove your foot to stop lasing
3. Key – turn off the key
4. Switch the Power/Fan to the off position (O)
5. Power Cord – unplug from the wall outlet

4.6.13 Hard Tissue Procedures: The Odyssey diode is not an appropriate laser for hard tissue procedures. The laser is attracted to melanin, hemoglobin and to some extent to water and oxygenated hemoglobin. Avoid prolonged exposure of the energy when working in and around the cervical areas of the tooth. Due to the thin layer of enamel in this area, the laser's energy may be absorbed by the hemoglobin in the pulp and pulpal hyperemia may occur. Extended exposure to laser energy could lead to pain and possible pulpal necrosis.

4.7 American National Standards Institute (ANSI) - Safety Standards

ANSI is a non-governmental, non-profit agency that has established guidelines and safety standards for the use of lasers and other electro-optics. The provisions of ANSI Z 136.3 outlines standards for lasers used in dentistry and the assessment of laser risks. ANSI also establishes guidelines for safety eyewear and classifies all lasers based on their potential for damage to eyes or tissue.

5. Operating the Laser

The Odyssey will deliver energy in either a Continuous Wave (CW) mode or in a pulsed mode which are called temporal emission modes (time related modes). Selecting the appropriate mode is a factor of controlling target tissue temperatures and the efficiency of energy delivered. The pulse duration (.5 seconds) and the number of pulses per second (1) have been fixed by the manufacturer using a 50 % duty cycle and you will therefore need only to change the power and mode.

5.0 Standby and Ready Status

Once you have turned on the power /fan switch on the back of the laser and the key switch on the front, you will see the laser LED screen light up. The status of the laser will be in Standby which is a non-active status. The laser will not emit energy while in Standby, even if you depress the foot switch. On the left of the control panel you will see the ready button. See Figure 3.2. Press this key to place the unit into the ready status. When this key is pressed whatever settings are displayed on the unit will be saved into the unit's memory for the program setting shown. The settings saved into the three programmable modes will be retained even if the laser is turned off. Any adjustments to the settings after the laser is in the ready status will not be saved to memory. The laser will now be ready to emit energy as you depress the foot switch.

5.1 Continuous Wave Mode

In setting up the laser while in the CW mode, you will deliver the amount of power in one second that you have set the laser for. i.e. Set the laser for 2 Watts CW and while in the ready mode, the laser will deliver 2 Watts per second as long as you have the foot switch depressed. The CW mode is generally the fastest way to ablate tissues but heat can build up and cause collateral damage to the target and adjacent tissues. Cool the tissues being lased by using periodic blast of air from a triplex syringe. You may use water to cool in areas where there is prolonged exposure to the laser's beam. Avoid using the air syringe when you have an opening in soft tissue adjacent to or within the surgery site. An air embolism may occur as a result of air captured within the tissue during the cooling process.

5.2 Pulsed Energy Mode

Pulsing the laser energy will allow some cooling of the tissue in between emissions of energy. The "duty cycle" is the percentage of the time in each second that the laser is emitting ener-

gy. The pulses per second, the duty cycle and the energy intensity per pulse will determine your average power. In the pulsed mode, the Odyssey is programmed to deliver 1.0 pulse per second with each pulse lasting for 0.5 seconds. The duty cycle is set for 50% so you will have 1 energy pulse with 1 period of rest with no energy between each pulse.

If the laser is producing energy at 1 time per second for 0.5 seconds per pulse, you will be producing energy for a total of 0.5 seconds. The result will be an average power per second that will be 0.5 of what you have set the laser for. Therefore, when using pulsed energy, you will have to adjust your power upward in order to achieve the same rate of work as the same power set in CW. 2 Watts of Pulsed energy will be the same average power output as 1 Watt CW.

5.3 Tissue Responses to Laser Energy

Maximum results will be achieved by regulating the power and the speed that the operator moves the fiber tip. Tissue Charring is an undesirable after effect of too much power or the tip moving too slowly. Always use the least amount of power necessary to complete your procedure. The ideal tissue response will show little or no discoloration after lasing and there will be less residual damage and faster healing. Avoid penetrating or damaging the periosteum, and do not use the laser on alveolar bone. Because the laser energy is attracted to melanin and hemoglobin, power must be reduced when treating patients with dark skin. Always begin lasing with the lowest power you can use to remove or modify the target tissues.

Avoid damage to the gingival sulcus by moving the fiber tip quickly and using a power below 1.5 Watts. Check to make sure you have a good cleave of the fiber so that no shard is present on the tip. A shard may act as a miniature scalpel and damage the small blood vessels, thus preventing hemostasis and coagulation. (See Fig. 5.1)

Fiber with a shard (a bad cleave)

Figure 5.1

5.4 Fiber and Hand Piece Care

Do not continue to use the fiber tip once you have observed that the tip has a blackened appearance that is greater in length than 2-4 mm from the previous cleave spot. See (Figure 6.1) The protein debris of gingival tissue accumulates on the tip during surgery and retains extreme heat that can cause rapid tip deterioration and subsequent breakage. This is especially important when using the laser for periodontal pocket debridement. During surgery, clean the tip often using a 2 X 2 sponge moistened with water. Do not use alcohol or other combustible liquids to moisten the 2 X 2 gauze sponge and do not use the sponge while the tip is hot. Always use a cold disinfectant solution like BIREX to wipe off the fiber jacket before retracting the fiber. The fiber can be advanced or retracted by using the "rocker switch" on the top of the fiber cassette. The hand piece should be autoclaved after each patient and a new disposable tip applied. Dispose of the cleaved tip in a "Sharps" waste receptacle.

Be advised about the potential hazards when inserting, steeply bending or improperly securing the fiberoptics to the chassis. Radiation exposure may occur in these instances which could be harmful to yourself, your staff and your patient. Special care should be taken not to break or snap the fiber.

As the aiming beam passes down the same delivery system as the Working Beam, it provides a good method of checking for integrity of the delivery system. If the aiming beam spot is not present at the distal end of the delivery system, its intensity is reduced or it looks diffused, this is a possible indication of a damaged or not properly working delivery system.

5.5 WARNING- !!!! DO NOT PLACE THE FIBER AND FIBER CASSETTE IN THE AUTOCLAVE TO STERILIZE THE SYSTEM. USE COLD DISINFECTING SOLUTIONS TO WIPE DOWN THE FIBER AND THE EXTERIOR OF THE LASER FIBER CASSETTE.

5.6 Systems Procedures

5.6.1 Treatment Area Requirements The laser should be placed in an area with good ventilation and lighting. The electrical service required is a 110 Volt AC outlet - 60 Hz. The area where the laser is placed should be free of standing water. Combustible gases or those that support combustion should be turned off and all flammable materials or chemicals stored in the area should be removed.

5.6.2 Foot Switch. Check to see that the foot switch receiver is installed properly and locked. **Be sure to replace your battery every 90 days or whenever the foot switch fails to respond.**

5.6.3 Fiber Cassette. Before using the laser, check the fiber cassette to see that it is firmly seated. Depress the extend/retract rocker switch on the cassette to see that it is functioning properly. After Checking the Fiber Cassette Power, expel some fiber from the cassette.

5.6.4 Fiber Preparation. You will want to have approximately 3 feet (1 meter) of fiber available to strip the fiber, cleave the fiber, initiate the fiber and disinfect the fiber (See Section 6.1). When the fiber is prepared, the hand piece and tip should be attached (See Section 6.3). Once prepared place the hand piece into the holder on the side of the laser. See Figure 3.2 on page 6 and Figures 3.7 and 3.7a on page 7. The rocker switch for fiber cassette operation should not be depressed during laser operation.

5.6.5 Emergency Shutdown Button. Check the Emergency Shutdown Button to see that it has not been depressed. If it

has, release it by depressing it slightly as you turn it 1/4 turn to the right.

5.6.6 Key Switch. Turn the Key Switch on the front of the laser to the "on" position by turning it approximately 1/4 turn to the right (clockwise). The control panel should light up and show the laser is in Standby Mode.

5.6.7 Setting Parameters. Review your power and mode requirements and then depress the mode button to select either CW or pulsed mode. The mode you have selected will be displayed just below the LED screen and will be designated by a small light in the corner of either the pulse or CW panel display. See Figure 3.2 on page 6.

5.6.8 Select Your Power by pressing the up or down arrow until you have reached the desired Wattage. Beginning with a low of 0.1 Watts, the power increases in increments of 100 mW up to a maximum of 5.0 Watts (CW). By holding the up or down arrow, you can have an un-interrupted increase until you reach your desired power. See Figure 3.2 on page 6.

5.6.9 Aiming Beam The aiming beam can be turned on and off by pressing the aiming beam button on the laser control panel. Press this key to progressively increase the aiming beam intensity from 0 (off) to full intensity. Press the key once more to cycle back to 0. Each bar represents approximately 20% of the aiming beam output. output.

Note that adjusting the intensity of the aiming beam, has no effect on the output power of the primary laser.

5.6.10 Examine the Fiber Tip to insure that you have not created a fiber tip shard during the cleaving process. The shard can act like a miniature scalpel and cause damage while diffusing the light beam and lowering the laser's power. See Figure 5.1 on page 11. See Section 6.1 for fiber preparation.

5.6.11 Depress the Ready Button and the aiming beam should light after 2 seconds. Review your power and mode requirements and then depress the mode button to select either CW or pulsed mode. See Figure 3.2 page 6.

5.6.12 Test Fire the Laser outside the mouth by activating the laser into a 2 X 2 gauze sponge that has been wetted with water to prevent combustion. Do not use flammable liquids to wet the sponge.

5.6.13 Depress the Foot Switch and make short quick strokes at the lowest power that you can to remove the target tissues while lightly contacting it.

5.6.14 Remove Your Foot from the foot switch and use a clean 2 X 2 gauze sponge wetted with water to remove debris from the fiber tip. Do not use flammable liquids to wet the sponge.

5.6.15 Place the Laser in Standby Mode until you are ready to start another procedure.

5.6.16 Cleave used fiber tip and discard in suitable biowaste disposal.

5.6.17 Wipe the Outside of the Fiber using a disinfectant or sterilization solution and then retract the fiber by depressing the back of the rocker switch. Do not retract the distal end of the fiber into the cassette.

5.6.18 Turn the Key Off if you are not going to be starting another procedure.

5.6.19 Record the Powers and total lasing times used for each procedure in the patient's chart. Example:

Name: Mary Jones
Procedure: Gingivectomy # 6 and # 7
#6 Lasing time 90 seconds @ 2.2 Watts CW air cooled
#7 Lasing time 60 seconds @ 1.5 Watts CW air / water spray

5.6.20 Odyssey Self Diagnostic and Monitoring: When the Odyssey Laser's microprocessor detects an issue with performance it will immediately notify you by way of an audible beep. There are two different ways in which the Odyssey will alert you to any issues:

1. Continuous audible beep when footswitch is engaged.
If you are operating the Odyssey with the footswitch engaged and the Odyssey emits a constant audible beep and stops the beep when you release the footswitch, the microprocessor has determined that the laser power output has fallen below the set level. In this event the Odyssey Laser should be turned off and allowed to sit for 5 minutes then turned on again. If the Odyssey then performs without beeping, the microprocessor has been able to make operational adjustments to the laser and the unit will perform its functions. If, however, upon restart the unit continues to beep when the footswitch is engaged, the microprocessor was unable to adjust the unit enough and the unit will need to be sent in for adjustment by a qualified service center.

2. Continuous audible beep when the unit is turned on.
If you are operating the Odyssey and the Odyssey emits a constant audible beep whether or not the footswitch is engaged, the microprocessor has determined that the laser has either low power or a general fault has occurred. In this event the Odyssey Laser should be turned off allowed to sit for 5 minutes and turned on again. If the Odyssey then performs without beeping the microprocessor has been able to make operational adjustments to the laser and the unit will perform its functions. If, however, upon restart the unit continues to beep, the microprocessor was unable to adjust the unit enough and the unit will need to be sent in for adjustment by a qualified service center.

6. System Components: Preparations and Care

The fiber optic element of a laser is responsible for carrying the light from the diode array to the tissue being treated. The dental laser fibers are usually made of quartz, sapphire, silica or a combination of those elements. Quartz/silica is the most popular product used in diode lasers.

Be advised about the potential hazards when inserting, steeply bending or improperly securing the fiberoptics to the chassis. Radiation exposure may occur in these instances which could be harmful to yourself, your staff and your patient. Special care should be taken not to break or snap the fiber.

As the aiming beam passes down the same delivery system as the Working Beam, it provides a good method of checking for integrity of the delivery system. If the aiming beam spot is not present at the distal end of the delivery system, its intensity is reduced or it looks diffused, this is a possible indication of a damaged or not properly working delivery system.

6.0 Disposable Fiber Cassette

The fiber cassette is a removable assembly with a plug-in capability that provides power for the internal retraction device. This cassette is disposable after all fiber has been used. This cassette is ***not*** autoclavable.

6.0.1 Replacing the Fiber Cassette: A black mark on the fiber indicates 6' of fiber remaining on the cassette. At this point, a new fiber cassette should be ordered. When the cassette is empty, it should be released from the laser aperture and gently removed. Slowly lift the cassette up using the dove tail as a guide. The fiber cartridge can be thrown away. Note: Retain the end cap, do not discard the end cap. Review the installation procedure again on page 8.

6.1 Fiber Preparation

The fiber cassette contains approximately 20' (6 meters +) and is wound onto a spool. The fiber itself has three components:

- Jacket
- Cladding
- 400 micron quartz/silica fiber

6.1.1 Jacket: This is the protective cover for the fiber system and usually is made of a synthetic material that is clear or white in color. There can be other colors used but there are no standardized color systems to denote the diameter of the fiber or its use.

6.1.2 Cladding: This is the material on the outside of the quartz/silica fiber that is used to block the lateral escape of laser energy as it traverses the fiber. During stripping, you may "nick" the cladding and you will likely see the red aiming beam light as it escape the site of the damage. This is not a danger if all people in the area have the appropriate safety eyewear.

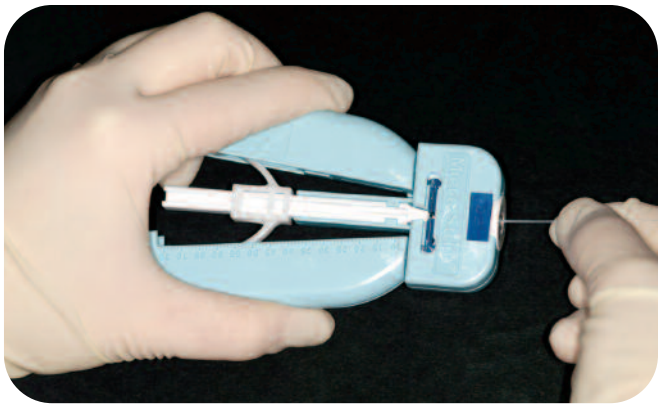


Figure 6.0 Adjustable Fiber Strippers

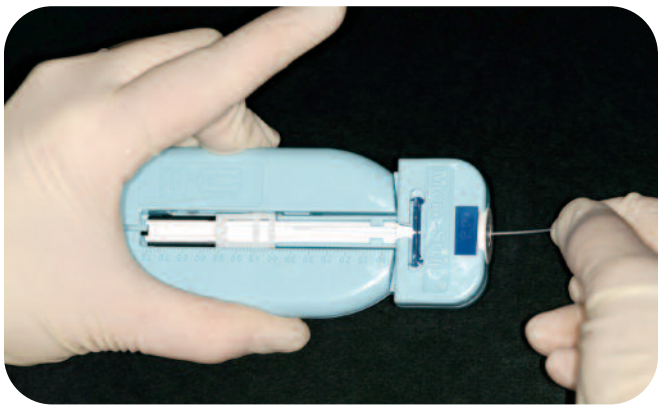


Figure 6.1

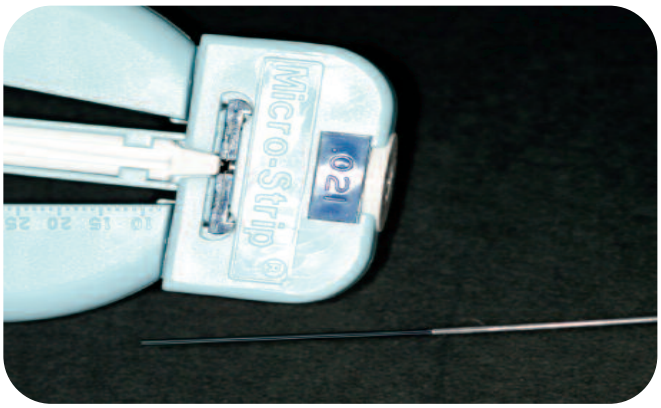


Figure 6.1.1

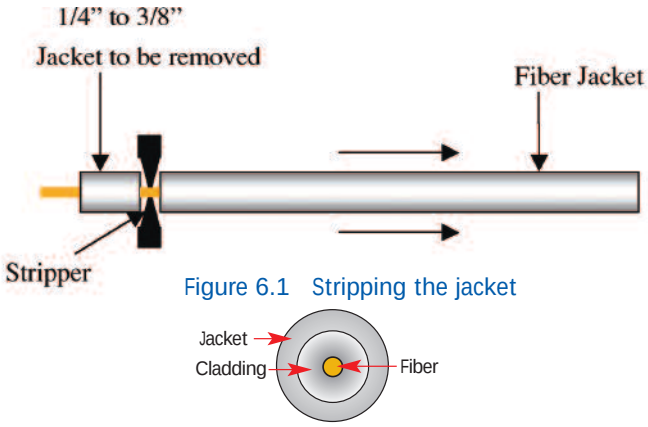


Figure 6.1 Stripping the jacket

Figure 6.2 Scoring & Cleaving

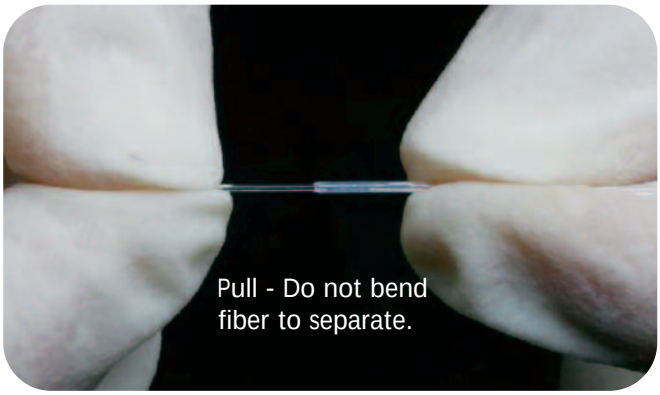


Figure 6.2.1

Figure 6.3

Figure 6.4

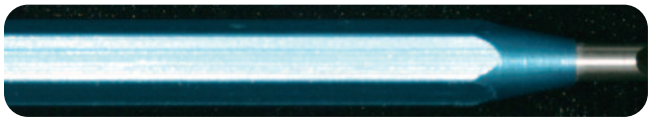
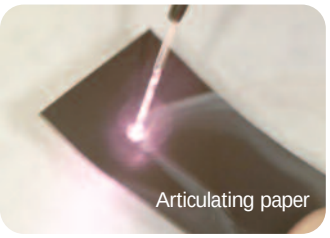


Figure 6.5 Fiber Cleaver (Scribe)

6.1.3 Quartz/Silica fiber: The fiber is fairly flexible but can be broken if bent into a small circle or bent at an angle of 90 degrees. The cladding will burn as protein from the gingiva accumulates on the fiber and will deteriorate the tip. It can fracture if not cleaved once the blackened area has reached 3-4 mm. Stop lasing and wipe off the tip regularly as you work to avoid accumulation of protein debris. Use water on a 2X2 gauze sponge to clean the tip. Do not use flammable materials like alcohol products when cleaning a hot tip.
Dispose of all small fiber remnants after you have cleaved the fiber. They should be kept in a small box with a lid until they can be properly disposed of in the "sharps" container.



Move the tip left or right while lightly touching the paper.

Warning: Using too much power can start a fire on the articulating paper.

Figure 6.5.1

6.1.4 Stripping the Fiber: The fiber's jacket is removed using a "stripper". Once a fiber tip is initiated and begins retaining debris from the tissues during lasing, you will get a deterioration of the fiber tip. When you have a blackened tip that extends 3-4 mm up the fiber shaft, it is time to cleave the fiber and strip the jacket to prepare for the next procedure. Begin by selecting enough jacket so that when it is removed, you will have approximately 3/8" of bare fiber exposed. Place the fiber in the stripper and grasp that portion of the fiber that will have the jacket removed between your thumb nail and index finger. See Figure 6.0. Grasp the fiber with the stripper by applying pressure to the handles. With a slow steady force, remove the jacket by pulling the fiber away from the stripper. See Figure 6.1

6.1.5 Cleaving the Fiber. As the tip deteriorates, it is more likely to fracture and could fall into the sulcus or a deep periodontal pocket. To avoid this problem, it is prudent to periodically "cleave" the burned tip. The cleave is made after stripping off the jacket to expose approximately 1-4" - 3/8" of bare fiber. The cleave should be made at a point approximately 1/2" (8-10 mm) from the site of the previous cleave so that there is no visible discoloration of the tip. The operator should place their index finger at the spot of the proposed cleave so as to stabilize the fiber. Using the pen style cleaver, draw the cleave blade across the top of the fiber with enough pressure to "score" the fiber. See Figure 6.2. With the thumb and index finger of each hand holding the fiber at a spot approximately 1/2" on either side of the cleave mark, pull the fiber in opposite directions. See Figure 6.2.1. Do not bend the fiber to separate it because you will develop a poor cleave and possible shard. After you have cleaved the fiber, point it perpendicular to a white piece of paper and place the laser in READY mode. Hold the tip approximately 1/2" from the paper and you should see a near perfect circle of red light. If you have a large comet effect radiating from the circle, you have not obtained a good cleave. If the circle has just a small comet effect, it will probably work. See Figures 6.3 and 6.4.

WARNING:
Always dispose of the fiber tip remnants in the "Sharps" container immediately after cleaving the fiber.

6.1.6 Initiating the fiber: The tip of the fiber should be cleaved to provide a flat surface that can be prepared to retain heat by introducing it to a dark material like ink, blood or water color paints. The easiest way to prepare the tip is to lightly move the flat surface of the tip across a piece of articulating

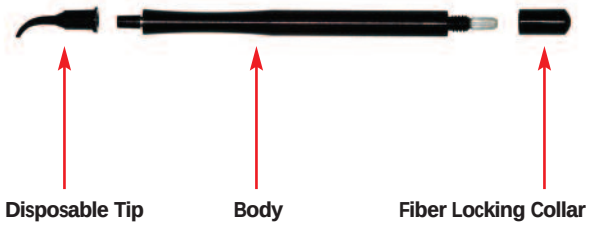


Figure 6.6 Hand Piece with disposable tip and fiber locking collar

paper at powers of about 1 Watt CW. The tip will retain the ink and the ink will make the tip glow if you exceed 1-2 seconds while in contact with the paper. Prolonged heating will accelerate the deterioration of the tip. See Figure 6.5.

6.1.7 Fiber Disinfection: The fiber and spool remain in the fiber cassette and are not autoclaved while in the cassette. Once stripped, cleaved and initiated, the tip will reach temperatures of several hundred degrees centigrade, thus, as the laser emits energy, it will rid the tip of pathogens. Additionally, the tip can transfer heat up the shaft of the fiber to the edge of the jacket which may melt slightly. After your procedure, always cleave the blackened tip and strip the damaged jacket. Wipe the jacket down using BIREX™, CIDEX® or a comparable product that can disinfect the jacket. Dry the jacket using a clean 2X2 sponge prior to retracting the fiber into the fiber cassette.

6.2 Laser Maintenance

6.2.1 Laser Chassis Disinfection: The exterior of the laser should be cleaned using a liquid disinfectant similar to BIREX™ or CIDEX®. Do not spray the disinfectant directly on the chassis. Apply with a gauze sponge or wipe. Do not use abrasive materials to clean the system. Place a barrier material similar to cellophane over the control panel and LED screen prior to treating the next patient

6.2.2 Calibration: The Odyssey Laser uses solid-state circuitry to continuously monitor the power output, and adjusts the power supplied to the laser module to keep the output consistent with the user defined setting. If output levels are more than ± 20% of the set value, the unit is designed to shut down power to the laser, and an audible alarm will sound. If this happens, the unit should be turned off and allowed to sit for 5 minutes and turned on again. If the laser then performs without beeping, the microprocessor has been able to make operational adjustments and the unit will perform its functions. If, upon restart, the unit continues to beep, the unit will need to be sent in for adjustment by a qualified service center. We suggest that your practice establish an internal calibration program for your laser. Recalibration is recommended a minimum of once per year based on average useage. Recalibration may be performed by the manufacturer by returning the unit. In the alternative, you may purchase a calibrated hand held power meter approved for use with 810nm devices to check power output. The laser should be set at 1, 3 and 5 Watts with output checked at each level. The output display should be within 20% of the meter reading. If not, recleave the fiber and re-check. If the output display is still outside the 20% tolerance, return the unit to the manufacturer for recalibration. There are no methods available for the user to adjust the calibration of the unit and the unit chassis must not be removed by the user for any reason.

6.3 Hand Piece Preparation

6.3.1 Autoclavable. The hand piece for the Odyssey is an autoclavable material that should be cleaned with warm soapy water, rinsed, bagged and autoclaved after each patient.

6.3.2 Hand Piece Components. The hand piece has three (3) components:

a. Body
b. Disposable Tip
c. Fiber locking collar see Figure 6.6 below

6.3.3 Rocker Switch. Using the rocker switch on the top of the fiber cassette, press the switch at its most anterior position (toward the front of the laser). Express 3-4 feet of fiber and feed it through the fiber locking collar after you have loosened the collar. The fiber should extend about 1 foot beyond the distal end of the hand piece so that you can strip the fiber and place the disposable tip.

6.3.4 Disposable Tips. The disposable tips can be shaped to provide the clinician any degree of access required.

6.3.5 Prepare Fiber. Using your stripper, remove approximately 1/4 - 3/8 inch of jacket from the distal end of the fiber. Cleave the fiber and examine the results by turning the laser to the Ready status. The aiming beam should create a near perfect circle when directed onto a white surface from about 1/4 - 3/8 inch above the paper. See Figures 6.3 and 6.4 on page 14. Once cleaved, the fiber tip should be disinfected (See Section 6.1.7).

6.3.6 Mounting the Tip. After selecting your tip, straighten it using your thumb and index finger. Begin at the proximal end of the tip and feed the stripped end of the fiber through the straightened tip until only bare fiber is extending beyond the disposable tip. Gentle slide the disposable tip onto the distal end of the hand piece and pull the fiber from the proximal end until the disposable tip is almost seated on the hand piece body. Seat the disposable tip securely on the hand piece body and tighten the locking collar. You may now shape the disposable tip to the desired form. Press the rocker switch to make sure the fiber moves freely. You should now initiate the fiber tip if your procedure calls for it.

7.0 Labels, Signs, Warnings and Manufacturer's Information

7.1 Federal Compliance. The Odyssey Diode Laser has been certified to the latest safety standards applicable to medical lasers in the US and Canada including IEC 60825, IEC 60601-2-22, IEC 60601-1 and the Food and Drug Administration's Laser Performance Standard (21 CFR 1040.10 and 1040.11). The laser has also been certified and tested according to the telecommunications regulations for the US (FCC Part 15) , Canada (IC RSS 210) and the European Community (EN 300 328, EN 60950 and EN 301 489). Various labels are included on the laser and the wireless foot switch as evidence of conformity to these requirements. The labels on the units are required under these standards for safety purposes and should not be removed. Please review all labels prior to using the laser. See Figures 7.0.1, 7.0.2, 7.0.3 and 7.0.4.

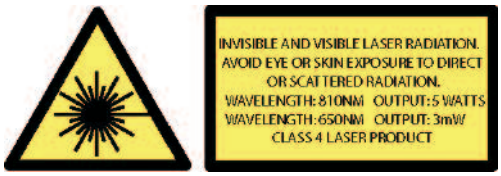


Figure 7.0.1 Label required under FDA Laser Notice 50

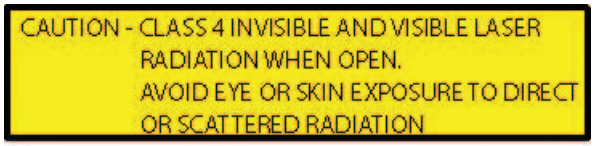


Figure 7.0.2 Label required under FDA Laser Notice 50

Figure 7.0.3 Laser Aperture Label

Figure 7.0.4 Rating Label with Serial Number

7.2 Danger Laser in Use – Each treatment area should have a "laser in use" warning sign posted at the entrance to the treatment area. This signage serves to warn people to not enter the treatment area without proper safety eyewear an protective clothing when the laser is in use. See Figure 7.1.

Figure 7.1 Label to be posted at entrance to treatment area

7.3 Class 2 Laser Product - (Aiming Beam laser)
630 - 660 nm 3 mW

7.4 Class 4 Laser Product - (Treatment laser)
810 nm 5 W

7.5 **CAUTION**
Changes or modifications not expressly approved by Ivoclar Vivadent, Inc. could void the user's authority to operate the equipment.

7.6 **CAUTION**
Laser Radiation - Avoid exposure to the eyes or skin from direct or scattered radiation

7.7 **CAUTION**
This product contains no user serviceable components within the chassis. Visible and invisible radiation may be present when the cover is removed.

7.8 **CAUTION**
US Federal law restricts this device to sale by or on the order of a licensed dentist.

7.9 **CAUTION**
Eyewear that protects your eyes from wave lengths other than 810 nm do not provide proper protection for use with this laser. Damage to the retina or corneal may be irreparable if exposed to direct, reflected or scattered radiation.

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

7.11 Nominal Ocular Hazard Distance (NOHD)

The NOHD is the distance beyond which the exposure during normal operation is not to exceed the appropriate Maximum Permissible Exposure (MPE). The NOHD for persons wearing safety glasses is shown in Table 1 below. The Nominal Hazard Zone (NHZ) is the area where the laser source within which exposure levels exceeds the MPE (which is the highest level of laser radiation to which a person may be exposed without hazardous effects or adverse biological changes in the eyes or skin). The outer limit of the NHZ is the NOHD. Eye Protection within the NHZ is mandatory.

Source of Radiation	MPE (mW/cm²)	Divergence angle (degrees)	NOHD (inches)	
			No Eye wear inch/cm	With Eye wear (OD=4) inch/cm
Fiber optic devices	1.66	9	60.63/154	0.6087/1.546
Reflection from Tissue	1.66	N/A	0.37/0.96	0.00378/0.0096

Assumptions: Maximum Laser Power = 5 Watts Direct viewing angle=0°, reflectance viewing angle=20°, reflectance coefficient of tissue=0.001

Table 1 - Nominal Ocular Hazard Distance (NOHD) for various viewing conditions while wearing eye protection.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

8.0 Servicing

8.1 Warranty Policy

The Odyssey soft tissue laser is fully guaranteed against defective materials and workmanship for a period of (1) year from the date of purchase and will be repaired or replaced at our discretion, if returned prepaid to our factory. This warranty does not cover damage of the Odyssey unit or components caused by accident, misuse, or being tampered with. This warranty does not include labor, postage, or delivery charges. This warranty does not apply to the external finish of the console, handpiece, fiber, power cord, foot pedal, or foot pedal cord. Ivoclar Vivadent reserves the right to make changes in design or to make additions to or improvements upon this product without incurring any obligations to modify such previously manufactured products. Your Odyssey warranty does not become effective unless the attached registration card is mailed to us within ten (10) days of purchase with a copy of the dated dealer invoice as proof of purchase.

The fiber cassette and fiber, the cleaver, the stripper, the safety eyewear and the hand piece have ninety (90) day warranty coverage for replacement if defective. Abuse or improper cleaning will void the warranty.

8.2 Repairs

Should the laser fail to work correctly and your local dealer representative is unable to assist you, please call Ivoclar Vivadent Customer Service at (800) 533-6825 in the U.S. or at (800) 263-8162 in Canada to obtain a Return Goods Authorization (RGA) number for shipping purposes. Please insure that the RGA number is clearly marked on the box used to return the laser.

CAUTION ! Do not attempt to remove the cover from the laser chassis for the purpose of repairing the laser. Serious

UNITED STATES
Ivoclar Vivadent, Inc
Attn: Warranty Department
8683 South 700 West
Sandy, UT 84070

CANADA
Ivoclar Vivadent, Inc
Attn: Warranty Department
2785 Skymark Ave., Unit 1
Mississauga, ON L4W 4Y3

Injury from an electrical shock or laser radiation could occur. Removing the cover on the laser chassis will void the warranty.

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

8.3 Repair Returns to Ivoclar Vivadent, Inc

9.0: Glossary of Laser Terminology

Activate - The action that prepares the laser to emit energy.

Active Medium - The core material of a laser that is responsible for producing a source of electromagnetic energy when activated by a power supply. They can be a gas, liquid dye, semi-conductor chip or a man made rod of Yttrium, Aluminum Garnet, Scandium or Gallium, or some combination of those elements.

Amplitude - The height of an electromagnetic wave as measured from the top of one wave to the lowest point on the next wave.

Articulating arm - A device used to deliver radiant energy from a CO^2 or Erbium laser using a series of mirrors located within a jointed arm.

Atom - The smallest particle of an element. It can exist alone or in combination with other atoms.

Biopsy - A tissue sample removed from an area of questionable health. Used for examination and diagnosis of a disease.

Cleave - An act of scoring an optical fiber so that it separates into two pieces

Coherent - A property of electromagnetic waves in which every wave is of the same wave length and is in phase with the other identical waves.

Collagen - The fibrous protein that is prevalent in bone, tendons, cartilage, and connective tissue.

Collimated - A characteristic of laser wave lengths where they travel in a parallel bundle and are slow to deviate.
Continuous Wave - A temporal mode where radiant laser energy is emitted constantly for one second without interruption. Also known as (CW).

Electromagnetic components of Energy - Radiation consisting of electromagnetic waves where the vertical of the wave is the electrical phase and the lateral component is a magnetic phase. Laser light is electromagnetic energy.

Electromagnetic Waves - Time varying electric and magnetic fields propagating through space. They vary in their wave lengths and frequency.

Electromagnetic Spectrum - A combination of all electromagnetic radiation arranged by wave length and frequency. Light as we know it is from the visible portion of the spectrum.

Exposure - Introducing a tissue to laser energy as measured by the intensity of the power, the frequency and time.

Frequency - The number of complete oscillations per second of an electromagnetic wave.

Joule - A unit of energy. Expressed as milliJoules when used in dental lasers operating in the pulsed mode.1000 MilliJoules per second equal 1 Watt.

LASER - An acronym for light amplification by stimulated emission of radiation. Lasers are devices that utilize standard electricity from a wall outlet to stimulate an active medium which will produce electromagnetic energy that is collimated, coherent and monochromatic.

Micron - One millionth of a meter. It can also be stated as 10^{-6} meter.

Mode - A stable condition of oscillation in a laser. Lasers can operate is one or more modes.

Molecule - The smallest particle of a substance that retains the property of that substance. It is composed of one or more atoms.

Nanometer - A billionth of a meter and can also be expressed as 10^{-9}. Nanometers and microns are the primary measures of a wave length used in dental lasers.

Photon - A quantum (unit) of radiant energy. A particle of light.

Power (output power) - Expressed as Watts where1 Joule per second equals 1 Watt.

Power Density - A measure of exposure of the power in Watts delivered per square millimeter or square centimeter.

Pulsed - A temporal emission of laser energy that is distributed among periods where the laser is actively emitting (on) and periods of no emission (off). The time period when the laser is not emitting energy (off) is referred to as period of thermal relaxation and is designed to allow the tissue to cool between bursts of energy.

Quantum - The smallest unit of measure for radiant (light) energy.

Radiant energy - The vertical component of electromagnetic waves as they travel through space. It is measured in Joules or milliJoules.

Spontaneous Emission - As an electron accumulates incident energy, it is elevated to a higher energy orbit where it will become unstable and most emit a photon.

Stimulated Emission - An external source of energy from a power supply stimulates the unstable electron to return to a more stable energy level by emitting an additional photon.

Velocity - The rate of speed of an electromagnetic wave as it travels through space

Watt - The measure of power is Watts. As used in lasers, 1 Joule per second is equal to 1 Watt.

10.0 Selected References on Laser Dentistry

Leo Meserindino, D.D.S. and Robert Pick, D.D.S., *Lasers in Dentistry*, 1995 by Quintessence Books

Jeffrey G. Manni, Dental Applications of Advanced Lasers. JGM Associates, Burlington MA Contact at (781) 272-6692

The Institute for Advanced Dental Technologies, Southfield, MI: *" Lasers Dentistry: Clinical Training Seminars"* copyright in 1966

D.J.Coluzzi, *" An overview of laser wave lengths used in dentistry"*. Chapter in The Dental Clinics of North American: Convissar, Robert A. editor, *"Lasers and Light Amplification in Dentistry"*, W.B. Saunders Company, 44(4): 753-765, October 2000

Andreas Moritz, et.al. *"Treatment of periodontal pockets with a diode laser"*. Lasers in Surgery and Medicine, volume 22, pages 302- 311. 1998

M. Kreisler, et.al., *"Effects of Diode Laser Irradiation on the Survival Rate of Gingival Fibroblast Cell Cultures"*, Lasers Surg Med, vol 28(5): 445-450, 2001

P. Spencer et.al. *"Change of temperature in subjacent bone during soft tissue laser ablation"*, Journal of Periodontology, volume 69 (11) 1998

Nora Raffetto and Terri Gutierrez, *"Lasers in periodontal therapy, a five year retrospective"*, California Dental Hygiene Association Journal, volume 16 (2) pages 17-20 Redondo Beach, CA 2001

American National Standard Institute Standard Z136.3. *Safe use of Lasers in Health Care Facilities*.

11.0 Troubleshooting

Problem: Laser has no response.

Corrective Action: Check that the power cord is securely plugged into back of the laser unit. See pages 3-4

Corrective Action: Check that the power switch on the back panel is turned to the on position. See page 4

Corrective Action: Check that the key switch is turned to the on position. See page 5

Corrective Action: Check that the Emergency button is in the up position. If not, turn the button 1/4 turn to the right to release the button. See page 7

Corrective Action: Check the fiber cartridge and verify that it is properly engaged. See pages 7-8

Problem: Laser has power but no LED display.

Corrective Action: Check to see that the End Cap of the fiber cassette is securely engaged.

Problem: Laser has power but no output.

Corrective Action: Check the foot pedal is connected. See page 6

Corrective Action: Remove the fiber cartridge and check if the fiber connector is attached.

Problem: Measured power output on a power meter is different from the LED display.

Corrective Action: Make sure the power meter is calibrated for use with 810 nm wavelength devises.

Corrective Action: Review the fiber tip for a good cleave.

Problem: Fiber does not move from the cartridge.

Corrective Action: Make sure the fiber cartridge is seated properly.

Problem: Audible beep on Laser will not stop when laser is on.

Corrective Action: Turn laser off for 5 minutes. Turn laser back on. If beep stops, the unit was able to make operational adjustmenets and the laser should perform its function. If the beep continues, the laser must be sent in for adjustment by a qualified service center.

Problem: Audible beep on Laser will not stop when foot pedal is depressed.

Corrective Action: Turn laser off for 5 minutes. Turn laser back on. If beep stops, the unit was able to make operational adjustmenets and the laser should perform its function. If the beep continues, the laser must be sent in for adjustment by a qualified service center.