**CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

**WARNING!**
This laser device is sold solely for HUMAN purposes only.

# PINNACLE PRO
MEDICAL DIODE LASER SYSTEM

<table>
<thead>
<tr>
<th>1. Model:</th>
<th>Pinnacle Pro: 980nm, 30W</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Serial Number:</td>
<td></td>
</tr>
<tr>
<td>3. Software Version:</td>
<td></td>
</tr>
<tr>
<td>4. Date of Sale:</td>
<td></td>
</tr>
<tr>
<td>5. Manufacturer:</td>
<td>Aspen Laser Systems, LLC</td>
</tr>
</tbody>
</table>
<pre><code>                | Dominion Towers          |
                | 600 17th Street #2800    |
                | Denver, CO USA 80202     |
                | Phone: 877-817-0365      |
                | Fax: 877-817-0366        |
                | aspenlasers.com • info@aspenlasers.com |
</code></pre>
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1. INTRODUCTION

1.1 Corporate Contact Information

Thank you for choosing the Aspen Pinnacle Pro Medical Diode Laser System.

The Pinnacle Pro is a Class IV laser. Care is required to avoid hazards or injuries. Please read this manual carefully before operating. If you have further questions not answered in this manual regarding safety, application or operations of the device, please contact your local distributor or:

Aspen Laser Systems, LLC
Dominion Towers, 600 17th Street #2800
Denver, CO USA 80202
Phone: 877-817-0365
Fax: 877-817-0366
Web: aspenlasers.com
Email: info@aspenlasers.com

1.2 Copyright Notice

The appearance, the fiber-coupled technology, control software and other related parts are part of the Aspen Laser System copyright with all rights reserved. Attempts at counterfeiting by any person or company will result in legal liability.

Under copyright laws, this manual cannot be copied in whole or in part without the express written consent of Aspen Laser Systems. Permitted copies must carry the same Proprietary and copyright notices as were affixed to the original.

The manual will be updated with the modifications and upgrades to the device.
1.3 Overview of Conventions Used in Manual

Various precautions, warnings, recommendations and notes are presented throughout this document. Explanations and examples of each follow.

A describes specific measures that if properly followed beforehand will prevent harm.

⚠️ **CAUTION!**

Never allow untrained person to operate this device unless directly supervised by a properly trained and experienced individual.

A calls the reader’s attention to a specific or potential danger in advance. If ignored or compromised, the situation could result in serious, irreversible personal injury or production damage.

⚠️ **WARNING!**

Never direct the laser beam at anything other than the area to be treated.

A offers guidance that may be worthy of acceptance or trial within a specific area of Aspen application and may serve to optimize overall Aspen utilization.

⚠️ **RECOMMENDATION**

Designate at least one person at each facility that utilizes this device as laser safety supervisor, responsible for providing training on all operating and safety procedures.

A describes the conditions or exceptions that may apply to the subject matter presented.

⚠️ **NOTE**

The optical fiber must be properly inserted and secured into the laser emission port before the device’s operational mode can change from standby to ready.
1.4 Overview of General Precautions

- Never allow untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual.
- The protective eyewear supplied with this device has an optical density rating >5 in the 980 nm region. All personnel present during device operation must wear this eyewear.

Contact Aspen Laser Systems at 1-877-817-0365 to purchase additional sets of protective eyewear for this device.

- Select a secure, properly equipped, and well-ventilated location in which to install and operate the laser.
- Place “Laser in use” signs at location entrances where people will use the Aspen Laser System.
- Always put the laser in Standby mode or switch the device off prior to adjusting or preparing the hand or piece of fiber optic.
- Never leave this device in the READY mode unattended. See the STANDBY to READY Mode in the Operations section of this manual.
- Remove the key from the device’s key switch when not in use to prevent unauthorized and/or unqualified use of the device as well as inadvertent laser emissions.
- Turn the device off before relocating equipment in the same vicinity.
- Never press the foot panel without first verifying the safe orientation and proper positioning of the hand piece and distal end of the optical fiber and ensuring compliance to all safety precautions.
- During any laser procedure, do not allow any nonessential personnel into the treatment area.
- Never allow the untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual.
- ALWAYS clean the small fiber tip before inserting into the SMA emission port. A dirty tip could result in damage to the unit.
1.5 Overview of General Safety Warnings

- This laser device is sold solely for HUMAN purposes only!
- This laser device produces 980-nanometer near infrared laser energy that is invisible and can be an extreme hazard to the eyes of any living being. Irreparable corneal and/or retinal damage may occur if a person exposes one or both eyes to direct or indirect (reflected) laser energy.
- IMPROPER USE OF SYSTEM CONTROLS or performance of procedures other than those specified in this manual may result in hazardous radiation exposure.
- FAILURE TO COMPLY with all safety instructions and warnings may expose all participants to harmful levels of laser radiation and/or dangerous levels of electrical current.
- NEVER direct the laser beam at anything other than the area to be treated.
- NEVER allow the eyes of any living being to look directly into the distal end of the optical fiber connected to an active laser device - WITH or WITHOUT wearing appropriate laser-emission protective eyewear.
- DO NOT allow any reflective object to fall into or obstruct the path of the laser energy produced by this device. Scattered or reflected laser energy can cause serious damage to eyes and skin. The operator, all assistants, and the patient must remove all reflective objects (such as rings, metal watchbands, and jewelry) prior to treatment with this device.
- THERE ARE NO USER-SERVICEABLE COMPONENTS inside this laser device. Therefore, do not attempt to gain access to any internal device component. Doing so may cause serious and/or irreversible injury.
- DO NOT remove protective eyewear until the operator returns the laser device to Standby mode. To do this, the operator release the foot switch, touches the Ready screen button on the display panel, and visually observes the laser device returning to Standby.
- AVOID THE USE of flammable anesthetics or oxidizing gases such as nitrous oxide (N₂O) and oxygen. The high temperatures produced in normal use of the laser equipment may ignite some material, for example cotton or wool, when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Attention should also be drawn to the danger of ignition of endogenous gases.

If the laser fails to operate properly, immediately contact Aspen Laser Systems at 1-877-817-0365.

1.6. Recommendation of Laser Safety Officer

Designate at least one person at each facility that utilizes this device as laser safety supervisor, responsible for providing training on all operating and safety procedures.
2. THEORY AND TECHNICAL INFORMATION

Diode laser is a one with a semiconductor as its working material. It consists of working material, cavity resonator and power source.

The diode laser for this unit is a GaAlAs diode bar, and the wavelength is 980nm. It features impact structure, high efficiency and long lifetime. Generally the beam shall be emitted as the big beam divergence of the laser from the diode. With the Aspen Laser Systems, LLC’s unique fiber-coupling technology, the laser beam can be coupled efficiently into the fiber.
3. TRANSPORTATION AND STORAGE

3.1 Packaging Information

NOTE: Please keep the original packaging, it should be used if you need to return the product for service or repair.

The transportation and storage symbols printed on the outside of the box mean:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Upwards Arrow]</td>
<td>This end up</td>
</tr>
<tr>
<td>![Umbrella]</td>
<td>Keep away from moisture</td>
</tr>
<tr>
<td>![Do Not Turn Over]</td>
<td>Don’t turn over</td>
</tr>
<tr>
<td>![Temperature Extremes]</td>
<td>Temperature extremes</td>
</tr>
<tr>
<td>![Fragile Glass]</td>
<td>Fragile – handle with care</td>
</tr>
<tr>
<td>![Not Stowed]</td>
<td>Not to be stowed under other cargo</td>
</tr>
</tbody>
</table>

The Pinnacle Pro should be transported and stored in its original container to prevent damage. Rough handling during the transportation should be avoided.

Avoid any contamination by acid, alkali or caustic material. Protect from direct exposure to sun or rain.

3.2 Transportation and Storage Conditions

Ambient Air: Less than 80% humidity.
Temperature: 0° to 55°
Atmospheric Pressure: 500hPa to 1060hPa.
4. USAGE PREREQUISITES

Every facility or institution utilizing this device is encouraged to adopt an ongoing training and safety program.

4.1 Safety Information

Safety information must be located at all entrances, exits, including windows, where the laser light or laser radiation could escape.

4.2 Treatment Room Requirements

The use of a medical Class IV Laser requires warnings on the unit itself and clear markings at the entrances to the treatment room. Refer to the information below for further instructions.

4.2.1 Labeling The Entrance

All entrance doors to the treatment room must be clearly marked on the outside warning of the presence of the laser and include wavelength information.

Each entrance door must be equipped with a warning light. When the laser is switched on the warning light should illuminated on the outside.

Entering the room is strictly prohibited while the laser is in use.

4.2.2 Laser Protection of Windows

During surgery, it is important that no laser light escape from the room. All openings to the exterior including windows must be properly secured to prohibit the escape of laser beams.

If you need information or help designing the room, please contact Aspen Laser Systems or your local distributor.

4.2.3 Protection Against Highly Reflective Surfaces

To avoid any direct or indirect scattered radiation from the laser beam, no highly reflective material should located in the treatment room. This includes mirrors, picture frames, polished chromium surfaces and windows. These surfaces should be removed or protected by non-reflective material.

4.3 Environmental Protection

The laser device is air-cooled and designed for use in a well-ventilated clinical office environment that maintains relative humidity and temperature conditions conducive to conventional human productivity.

4.4 Unpacking

In most of the cases the device should be unpacked and installed by Aspen Laser Systems or one of the representatives who will test and inspect the unit.

The product is well-packed for transportation. Please check the package and device carefully to determine any damage occurred in transit.

When unpacking, check all the items listed on the packing list are received. If you have any questions, please contact Aspen Laser Systems or authorized distributor immediately.
5. SAFETY

This section provides a collection of safety guidelines and safety-related statements relevant to the safe and effective operation of the Aspen Laser System. Additional statements and protocols regarding safety appear elsewhere in this document. Use this laser device according to all printed guidelines cautionary statement, and protocols.

5.1 Laser Classification

The Aspen Laser System is for medical application only. The system has been thoroughly developed and tested before shipment. To protect personnel from laser radiation, please read this chapter very carefully. Persons operating the unit should receive training before use.

The Aspen Laser System is classified as a Class IV Laser.

5.1.1 Class IV Lasers and Laser Systems

Output: 500mW and greater, continuous wave
Wavelength: Infrared spectrum (non-visible)

Class IV Lasers are high power lasers or laser systems that can produce a hazard not only from direct or specular reflections, but also from a diffuse reflection. In addition, such lasers may produce fire and skin hazards. Class IV lasers include all lasers in excess of Class III limitations.

In addition to the control measures described for Class III B, Class IV lasers should be operated by trained individuals in areas dedicated to their use. Fail-safe interlocks should be used to prevent unexpected entry into the controlled area, and access should be limited by the laser operator to persons who have been instructed as to the safety procedures and who are wearing proper laser protection eyewear when the laser is capable of emission.

Laser operators are responsible for providing information and safety protection to untrained personnel who may enter the laser controlled areas as visitors.

The laser area should be:
• Restricted to authorized personnel only
• Designed to allow for rapid emergency egress
• Equipped with a device that allows for deactivation of the laser or reduction of the output to below the MPE
• Designed to fulfill Class III B controlled area requirements
• Designed with entry safe controls
• Designed such that the laser may be monitored and fired from a remote location (for pulsed systems) have interlocks designed to prevent firing of the laser by dumping the stored energy into a dummy load (for continuous wave systems) have interlocks designed to turn off the power supply or interrupt the beam by means of shutters.
• The beam path must be free of specularly reflective surfaces and combustible objects and the beam terminated in a non-combustible, non-reflective barrier or beam stop.

⚠️ CAUTION!

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
5.2 Laser Safety

5.2.1 Safety Program

Laser therapy is extremely safe when basic protocols are followed by the laser operator and support staff.

As with all therapeutic procedures, some element of risk is present through negligence or accident. These hazards are easily prevented or reduced with safety protocols for each application.

5.2.2 Laser Safety Officer

Every clinic using a laser should have an individual trained in safe operation of laser therapy and regularly use a safety checklist. This individual (often the doctor), is the Laser Safety Officer (LSO).

5.2.3 Eye Protection

Class IV Therapy Lasers emit both visible and invisible radiation. Protective eyewear is necessary for both Class III and Class IV lasers where irradiation of the eye is possible.

5.2.4 Required Users of Safety Goggles

1. Administrator of the laser therapy treatment
2. Patient
3. Any other individuals in the room

5.2.5 Importance of Wearing Safety Goggles

Laser beam focused by the lens on the retina or fovea

An incident laser beam striking directly inline with the lens is very dangerous. The beam is magnified over 100,000 times by the lens of the eye. The more divergence of the beam the less light strikes the eye. The more the mean is focused or collimated the greater the fluence of the beam and potential for injury
5.2.6 Safety Goggles

Not all Safety Goggles are the same. The protective eyewear that came with your laser is manufactured specifically for the wavelengths emitted by the laser. Do not use protective eyewear from other manufacturers as they may not provide the appropriate level of protection.

Technical Specifications for proper usage include:
- Wavelength Specific
- Blocks 980nm (and also 810nm)
- Meets ANSI Safety Standards

CAUTION!

DO NOT remove protective eyewear until the operator returns the laser device to STANDBY mode. To do this, the operator must release the foot switch, touch the READY screen button on the display panel, and visually observe the laser device returning to STANDBY.

5.2.7 Using Safety Goggles Correctly

Laser Safety Goggles are vital for eye protection in the presence of laser radiation. Since accidental laser radiation exposure can cause irreversible damage to the human eye, protective measures must not be taken lightly.

1. Ensure that the eyewear has appropriate optical density for the wavelength of operation.
2. Remove all reflective objects (such as rings, metal watchbands, and jewelry) prior to treatment with the laser. Indirect or direct eye contact with the laser beam or with scattered laser light from any reflective surfaces will cause serious damage, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes.
3. Do not allow any reflective object to fall into, or obstruct the path of the laser beam.
4. Always wear protective eyewear. Any person present during the laser operation must wear protective eyewear.
5. Never look directly into the end of any therapy hand piece.
6. Never direct the laser light directly into the eyes, or direct the laser beam at anything other than the area to be treated with or without the correct Safety Goggles.
7. Do not remove the Safety Goggles until the administrator of the laser has turned off the laser or notified the patient that it is safe to remove them.
5.2.8 Laser Safety Warning Signs

Lasers require the use of specific Warning signs for the safe operations of each laser system.

Warning signs must be in view outside and inside the room where the laser treatment is being performed.

Warning signs must meet ANSI recommendations.

![DANGER Warning Sign](image)

**CAUTION!**

Place LASER WARNING SIGN at location entrance where people will use the Aspen Laser System.

5.3 Environmental and Electrical

The laser device is air-cooled and designed for use in a well-ventilated office environment that maintains relative humidity and temperature conditions conducive to conventional human productivity.

5.4 Federal Regulation Compliance

Aspen Laser System's user information is in compliance with section 1040.10 of Title 21 of the code of Federal Regulations, Chapter1, Subchapter J of Health and Human Services, Food and Drug Administration, and Center for the Devices and Radiological Health.

5.5 Laser Safety Supervision

Designate at least one person at each facility that utilizes this device as laser safety supervisor, responsible for providing training on all operating safety procedures.
5.6 Warnings

Please read and adhere to the following warnings:

- Improper use of system controls or performance of procedures other than those specified in this menu may result in hazardous radiation exposure.

- Failure to comply with all safety instructions and warnings may expose all participants to harmful levels of laser radiation and/or dangerous levels of electrical currents.

- NEVER direct the laser beam at anything other than the area to be treated.

- NEVER allow the eyes of any living being to look directly into the distal and of the optical fiber connected to an active laser device, WITH or WITHOUT wearing appropriated laser-emission protective eyewear.

- DO NOT ALLOW any reflective object to fall into or obstruct the path of the laser energy produced by this device. Scattered or reflected laser energy can cause serious damage to eyes and skin. The operator, all assistants, and patient must remove all reflective objects (such as rings, metal watchbands, and jewelry) prior to treatment with this device.

- There are no user-serviceable components inside this laser device. Therefore, do not attempt to gain access to any internal device component. Doing so may cause serious and/or irreversible injury.

- DO NOT remove protective eyewear until the operator returns the laser device to STANDBY mode. To do this, the operator releases the foot switch, touches the READY screen button on the display panel, and visually observes the laser device returning to STANDBY.

- The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N₂O) and oxygen should be avoided. High temperatures produced in normal use of the laser equipment may ignite some materials, for example cotton or wool, when saturated with oxygen. The solvents of adhesives and flammable solution used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Attention should be drawn to the danger of ignition of endogenous gases.
5.7 Precautions

Please read and adhere to the following precautions:

- NEVER let untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual.

- This laser device produces 980-nanometer near-infrared laser energy that can be an extreme hazard to the eyes of any living being. Irreparable corneal and/or retinal damage may occur if a person exposes one or both eyes to direct or indirect (reflected) laser energy.

- The Protective eyewear supplied with this device has an optical density rating > 5.0 for 980 nm laser emission. All personnel present during device operation must wear this eyewear. Contact Aspen Laser Systems at 1-877-817-0365 to purchase additional sets of protective eyewear for this device.

- DO NOT remove protective eyewear until the operator returns the laser device to STANDBY mode. To do this, the operator releases the foot switch, touches the READY screen button on the display panel, and visually observes the laser device returning to STANDBY.

- Select a secure, properly equipped, and well-ventilated location in which to install and operate the laser.

- Place LASER IN USE signs at location entrances where people will use the Aspen Laser System. Please contact Aspen Laser Systems at 1-877-817-0365 for more information regarding these signs.

- Always put laser in STANDBY mode or switch the device off prior to adjusting or preparing the hand piece or fiber optic.

- Never leave this device in the Emission-enable mode unattended.

- Remove the key from device’s key switch when not in use to prevent unauthorized and/or unqualified use of the device as well as inadvertent laser emissions.

- Turn the device off before relocating equipment in the same vicinity.

- Never press the foot pedal/switch without first verifying the safe orientation and proper positioning of the hand piece and distal end of the optical fiber and ensuring compliance to all safety precautions.

- During any laser procedure, do not allow any nonessential personnel into the treatment area.

- Never allow untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual.

- If the laser fails to operate properly, immediately contact Aspen Laser Systems at 1-877-817-0365.
5.8 Labels and Symbols

The following labels appear on the Aspen Laser System.

MANUFACTURER’S GENERAL IDENTIFICATION LABEL – Located on the top of the device. The label displays the manufacturer, model number, serial number, date of manufacture of the Aspen Laser System. This label also presents various regulatory compliance declarations.

GENERAL SAFETY DECLARATION LABEL – Located on the side of the device, this label indicates the laser classification. It warns of the radiation exposure hazard potential to eyes and skin.

LASER EMISSION (APERTURE) LABEL – Located on the front of the device, the laser emission label indicates that the laser energy emission occurs at the distal end of a properly connected optical fiber.

NOTE

The laser WILL NOT enable unless the fiber is inserted into the emission port.
**Warranty Seal Label** – These labels are positioned on the underside of the laser device in such a way that any attempt to open the panels of this device will break this seal.

**Other Safety Signs**

- **Laser Danger**
- **Laser Output Window**
- **External Interlock Connector On**
- **Pay Attention to Fiber Connector**

- **STOP**
- **Interlock**
- **Fiber**

- **B Type Device**
- **Refer to Operating Manual**
- **Production Date**

- **Manufacturer**
- **Safety Mark**
5.9 Safety Features on Device

The following component devices have specific safety-related features. All individuals who use this laser device should be familiar with the purpose and the operation of these components.

**EMERGENCY POWER OFF SWITCH** – This switch is located on the front panel of the Aspen Laser System. Pushing the switch in terminates all electrical power to the laser device’s microprocessor and laser-emitting components. Resetting the switch restores power. To reset the EMERGENCY POWER OFF SWITCH, the user must press, twist, and rotate in the direction indicated by the arrows, then release it as the switch pops out, returning it to its normal position.

**KEY ACTIVATED POWER SWITCH** – This switch is located on the rear panel of the Aspen Laser System. A key is required to activate the Aspen Laser System. The user inserts the supplied key into the keyswitch and turns it 90 degrees clockwise. When the key switch is in this position, it cannot be removed.

After powering OFF the device using the key switch (a 90-degree, counter-clockwise turn), the user should remove the key and store it properly to prevent unauthorized or unexpected laser system operation.

**SAFETY INTERLOCK** – This device is equipped with a safety interlock located at the rear of the device. If the interlock is not inserted into the DB9 connector, all electrical power to the controls and laser components is terminated. The safety interlock MUST be inserted before the device can power on.

**POWER ON/OFF VISUAL INDICATOR** – Located on the front of the laser device, the LCD panel is illuminated continuously whenever the user activates the key switch and the emergency power off switch is disabled.

**LASER-EMISSION INDICATOR** The laser device emits an optional continuous alert tone whenever the treatment laser emits energy. The device also emits an optional beeping tone during the laser emission enabling notification sequence. The laser is also equipped with a visual indicator. The LCD touchscreen panel will display and blink “EMISSION” during the emission mode.

**NOTE**

The operator can intentionally disable the alert tone using the setup display screen. To enable the alert tone when it has been disabled, select the appropriate alert tone operating parameter on the setup display (refer to the Operation Section).

**INTERNAL LASER ENERGY MONITOR** – This is an internal device that monitors the intensity of laser energy generated whenever laser emission occurs. This monitor aborts laser emission if the laser device is unable to maintain the laser energy output set by the user.

**MANUAL RESET** – To reset the system the user is required to manually power off then on the system or press the RESET button on the touchscreen when the LASER EMISSION ABORTED message is displayed.
5.10 Laser Safety Checklist

Check List for the Laser Operator and Laser Safety Officer

✔ Appropriate warning signs posted
✔ Access to laser and treatment area is secure and controlled
✔ Visually inspect and clean all optical connectors for dirt, debris, etc.
✔ Inspect laser for proper function
✔ Visually inspect and clean all safety goggles
✔ Goggles available for all persons in Nominal Hazard Zone
✔ Extra goggles placed outside treatment room if necessary
✔ Sources of potential laser beam reflection and scatter controlled
✔ Treatment protocol established for patient
✔ Laser injury management protocol in place for accidental injury
✔ Document laser treatment and post-treatment outcomes

5.11 Sources for Additional Information and Assistance on Laser Safety

Center for Devices and Radiological Health
Office of Compliance
2098 Gaither Rd.
Rockville, MD 20850
Tel: 301-594-4654
Fax: 301-594-4672
http://www.fda.gov/cdrh/index.html

Laser Institute of America
12424 Research Parkway, Suite 125
Orlando, FL 32826
Tel: 407 380 1553
Fax: 407 380 5588
http://www.laserinstitute.org/
6. CLINICAL INDICATIONS

The unit can realize vaporization, incision and coagulation of the tissues with a high power beam laser from the fiber. It is widely applied in gynecology: vaporization and coagulation of endometriosis, endometrial polyps cutting, coagulation and incision of uterine myoma / cervical erosion.

The physician should be aware of the clinical applications for the laser when the exact therapy of the diode laser in each clinical case cannot be known clearly.

Application prohibited in patients who have: heart trouble, psychosis, hypertensive diseases or any patient who has been proved to be unsuitable for laser therapy.
## 7. PRODUCT DESCRIPTION
### 7.1 SPECIFICATIONS
Temperature is 5°-40°, relative humidity is less than 80%, and atmospheric pressure is 860hPa-1060hPa.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser Type</td>
<td>GaAlAs diode laser</td>
</tr>
<tr>
<td>Model</td>
<td>Pinnacle Pro</td>
</tr>
<tr>
<td>Wavelength</td>
<td>980nm±10nm</td>
</tr>
<tr>
<td>Output Power</td>
<td>1-30W</td>
</tr>
<tr>
<td>Operation Mode</td>
<td>CW, Single Pulse, Repeat Pulse</td>
</tr>
<tr>
<td>Pulse Width</td>
<td>10µs-3s</td>
</tr>
<tr>
<td>Pulse Repetition Rate</td>
<td>0.2 Hz-20 KHz</td>
</tr>
<tr>
<td>Transmission System</td>
<td>Fibers of 200µm, 400µm and 600µm with SMA905 connector</td>
</tr>
<tr>
<td>Aiming Beam</td>
<td>Diode laser of 650nm, power 5mW, adjustable brightness</td>
</tr>
<tr>
<td>Operation Interface</td>
<td>True Color Touch Screen</td>
</tr>
<tr>
<td>Power Supply</td>
<td>110/220VAC, 5A, 50/60Hz</td>
</tr>
<tr>
<td>Laser Class</td>
<td>4</td>
</tr>
<tr>
<td>Safety Classification</td>
<td>Class IV – Type B</td>
</tr>
<tr>
<td>Cooling</td>
<td>Air</td>
</tr>
<tr>
<td>FUSE</td>
<td>F 250V 5A</td>
</tr>
<tr>
<td>Dimensions</td>
<td>400 (W) x 385 (L) x 200 (H) mm</td>
</tr>
<tr>
<td>Weight</td>
<td>47 kg.</td>
</tr>
<tr>
<td>Waterproof Level</td>
<td>IPX1</td>
</tr>
<tr>
<td>Foot Switch Waterproof Level</td>
<td>IPX8</td>
</tr>
<tr>
<td>Safety Compliance</td>
<td>CE 0197</td>
</tr>
</tbody>
</table>
7.1 General Overview

The Pinnacle Pro consists of five main components:
1. Laser System
2. Color Touch Screen
3. Fiber and the Hand Piece
4. Foot Switch
5. Power System and Control Device

The Laser System consists of the fiber-coupled diode laser module, power supply, control panel, safety shutter, and the embedded computer control system.

7.2 Front

On the front of the unit you will find:
1. Caster
2. Emergency Stop
3. Alarm Indicator (RED)
4. Laser Emission Indicator (YELLOW)
5. Power Indicator (GREEN)
6. Fiber Holder
7. Fiber
8. Color Touch Screen
9. Encode Knob
10. Hand Piece
11. Hand Piece Holder
7.2.1 Casters

There are four CASTERS. Each can rotate 360 degrees. The device can be easily moved by pushing.

7.2.2 Emergency Stop

The EMERGENCY STOP connects to the system's power supply. In the event of an emergency, pressing the Emergency Stop will immediately cease laser emission. Before restarting, turn so the arrow shows at the knob to bring up the emergency stop.

7.2.3 Alarm Indicator

The Pinnacle Pro offers an ALARM INDICATOR for system errors. The Alarm Indicator will be red when system alarms. For example, if the indicator is on and the system alarms, the screen will show information, as long as the Fiber is removed. The foot switch cannot control the output of the laser.

7.2.4 Laser Emission Indicator

The LASER EMISSION INDICATOR will be yellow when the laser is emitting. The action of the indicator synchronizes with the laser.

The Laser Emission Indicator will be on if the system is in an emergency or a non-normal state. At that time the system will stop all the output and the touch screen will show error information, and the system will alarm.

ATTENTION!

Press the EMERGENCY STOP to terminate laser emission if the emission indicator light is on constantly.

7.2.5 Power Indicator

The POWER INDICATOR will be green if the power supply of the laser is operating normally.
7.2.6 Fiber Holder

Wrap the fiber into a circle. Use the top clip to clamp the fiber bundle and the lower hook to secure the bottom.

7.2.7 Fiber

FIBER CORE DIAMETER: 200µm, 400µm, 600µm.

FIBER CONTACT TIPS: flat, spherical, pyramidal, side emitted.

The output power of the unit is calibrated by 400µm fiber. The actual output power will be 2 to 3 watts higher if 600µm or 1000µm is selected.

7.2.8 Color Touch Screen

The high resolution LCD COLOR TOUCH SCREEN is very sensitive. Use fingers or a pointing device to touch the icons to open the programs.

ATTENTION!

Do not put heavy objects or apply excessive pressure to the touch screen to prevent display distortion. Avoid touching the screen with sharp objects to prevent scratching the surface.

Caution must be taken to prevent liquids from contacting the surface of the touch screen.

7.2.9 Encode Knob

The ENCODE knob is used for adjusting the parameter value. In different conditions, the step is not the same.
7.2.10 Hand Piece

The **HAND PIECE** is gynecology LVR hand piece which is used for vaporization and coagulation of endometriosis, endometrial polyps cutting, coagulation and incision of uterine myoma, cervical erosion etc.

The Hand Piece can be placed in the Hand Piece Holder when not in use.

7.2.11 Hand Piece Holder

The **HAND PIECE HOLDER** protects the Hand Piece from contamination when not in use.
7.3 Rear Panel

1. Usb Port – For Update Program
2. Remote Interlock
3. Ground
4. Power Outlet
5. Main Switch
6. Rs232 Port – For Computer Control
7. Foot Switch Outlet

ATTENTION!
Take care while inserting and removing the Foot Switch and the Interlock.
There is a red dot on the connector. Insert the Foot Switch or Interlock with the red dot facing upward as shown above.

When removing the Foot Switch or Interlock grasp the textured area.
8. OPERATING THE LASER DEVICE

ATTENTION!
The Pinnacle Pro should only be operated by a physician who has been instructed in the use of the instrument during installation.

This part of the manual only describes the technical use of the instrument without detailing the medical use.

8.1 Introduction

To guarantee a faultless operation of the device during surgery the following requirements have to be met:
> The device has already been plugged into electricity.
> The safety goggles are available for the people in the room.
> The fiber has already been fixed to the laser aperture (Connect the Hand Piece when necessary).
> The remote interlock connector has been used.
> The footswitch has already been connected.
> The emergency stop has already been popped out.
8.2 Starting the Laser Device

To start the laser unit, turn the main switch ON and the key clockwise to the ON position (↑). The power indicator will turn green and the system fans will be working. At the same time, the LCD screen lights up.

The system will perform a Diagnostic Self Check. If there are problems during startup, the system will display them. The system takes 90 seconds or less to start up. For more information, please see Section 9 – TROUBLESHOOTING.
8.3 Main Menu Screen

1. Footswitch Alarm
2. Interlock Alarm
3. Fiber Alarm
4. Timer on
5. Sound on
6. Aiming Beam on
7. Wavelength
8. Parameter area, not as a touch area
9. Reset Energy
10. Help or Alarm Message
11. Total Energy
12. Menu
13. Pre-Set Proposals
14. Pulse count
15. Standby/Ready
16. Set Laser Power
17. Set Ton Time – at Ton the laser is emitting.
18. Set Toff Time – at Toff the laser is paused.
19. Laser Emission Modes:
   - CW – Continuous Laser Output
   - Single – Press the footswitch, one laser pulse
   - Repeat – Press the footswitch, multiple laser pulses
20. Aiming Beam Intensity
21. Timer Setting – shown in seconds
8.4 Setting Laser Operations

8.4.1 Set Laser Output Power

There are two ways to change or adjust the power level:

1. Pressing the peak power is the output MAX power when laser is emitting. The range is 1W to 30W. Pressing + or – adjusts the laser output power.
2. This can also be done using the ENCODE button. When finished, the Pinnacle Pro will save the parameter into the proposal.

8.4.2 Select Laser Emission Mode

There are altogether 3 LASER EMISSION MODES. When selected, the corresponding button turns green:

1. CW – In this mode, the laser will emit continuously unless you release the footswitch.

   **ATTENTION!**
   
   For safety in this mode, after emitting 5 minutes (when peak power is above 12W), the laser should be stopped for at least one minute.

2. Single
   In this mode, the laser will emit one pulse when the footswitch is engaged.

3. Repeat
   In this mode, the laser will emit by pulse when the footswitch is engaged.
8.4.3 Set Laser Ton Time

The Ton TIME is the laser emission time during one pulse period. It ranges from 10µs-10s. Pressing + or − adjusts the value. This can also be done using the ENCODE button. When finished, the Pinnacle Pro will save the parameter into the Proposal.

8.4.4 Set Laser Toff Time

The Toff TIME is the laser emission off time during one pulse period. It ranges from 25µs to 10s. Pressing + or − adjusts the value. This can also be done using the ENCODE button. When finished, the Pinnacle Pro will save the parameter into the Proposal.
8.4.5 Adjust Aiming Beam

Adjust density of the Aiming Beam. Pressing + increases the density. Pressing – decreases it.

The Aiming Beam has 7 levels, from 0 to 6. When the level is selected, it turns green, otherwise it is black. When the Aiming Beam level is at 0, it is closed.

At the Main Menu, item 6 is active (see Section 8.3) only when the value is more than 0.

ATTENTION!

Only in Ready status, is the density of the aiming beam displayed. In Stand-by the density can be adjusted but is not displayed.

8.4.6 Save The Parameter

When finished setting a parameter, press the SAVE button to enter the current parameters to current Proposal.

8.4.7 Reset The Total Energy (Joules)

As the laser is in complete operation mode, the number of joules displayed will increase to reflect the total number of joules being administered, until the laser operation is paused or stopped.

The total energy ranges from 0 to 99999J. If you want to reset the total energy, press the RESET button. If the total energy is more than 99999J, it will automatically reset back to 0.

Count: Pulse count

Single: Total count of footswitch presses

Repeat: Total count of footswitch presses and releases. If the footswitch is depressed again, the count will be suspended.
8.4.8 Menu and Proposal

Pressing the MENU button enters the Menu Interface. The PROPOSALS button enters the Proposals Interface. For details please refer to section 8.4.10 and 8.4.11.

8.4.9 Standby and Ready

Pressing the READY or STANDBY buttons, changes from one status to another.

STANDBY: In this mode, the laser power supply is disabled.

READY: In this mode, the laser power supply is enabled. Pressing the Foot Switch sends out the laser.

Pressing the On / Off Switch on the Hand Piece or Foot Switch if used instead, will activate the Laser beam (infrared)
8.4.10 Menu Interface

8.4.10.1 Settings

In main interface press SETTINGS to access the following user settings:

1. **SPEAKER SOUND** – You can adjust the Sound of the Intermittent Beeping from ZERO Sound to High Sound

2. **LCD BACK LIGHT** – You can adjust the back light from light to dark to compensate for the ambient light in the room, to make the screen more visible

3. **TIMER** – You can enable and disable the timer. The timer value can be set when it is enabled.

Press the BACK icon to return to the main menu.
8.4.10.2 System Information

To display **SYSTEM INFORMATION** press the **SETTINGS** icon in menu interface.
8.4.10.3 Testing Laser Power

Pressing the **TEST POWER** icon enters the test power interface.

**SET POWER:** The power to be tested.

**TEST POWER:** The value of the tested power.

**TESTING STEPS:**
1. Open the Laser Power Detect Aperture
2. Fix the Fiber
3. Wear safety goggles
4. Press **TEST POWER**. The button will turn yellow and the Aiming Beam turns on
5. Press the Foot Switch, and hold it
8.4.10.3 Testing Laser Power (continued)

6. When the process is finished release the Foot Switch. The value of the laser power is displayed.

ATTENTION!
The test value may be different from the set value. A difference of 20% is normal.
8.4.10.4 Calibrating Laser Power

ATTENTION!
Before calibration, make sure to have an accurate power meter. When the testing result is near the power meter reading, calibration can begin.

Pressing CALIBRATION will display the interface above.

TEST POWER: Before laser test, this power is the MAX power of the Pinnacle Pro.

MAX POWER: The value of the tested power.

SAVED: After you make sure the Pinnacle Pro testing power is near to the power meter testing result, save the result to the memory and finish the calibration.

RESET FACTORY SETTING: Restore the laser power setting as the factory setting, don’t keep the calibration result.

CALIBRATION STEPS:
2. Fix the Fiber.
3. Wear the safety goggles.
4. Press TEST POWER. The button will turn yellow and the Aiming Beam turns on.
5. Press the Foot Switch and hold it.
6. When the process is finished release the Foot Switch. The value of the laser power is displayed.
7. Use the power meter to test the laser power again.
8. If the test results are close, the test result is correct. Press **SAVE** to retain the test result.

**ATTENTION!**

1. If the test power is too low (<50%), calibration will not occur.
2. After calibration, Pinnacle Pro MAX power will change. If the new calibration power is lower than the old, you can save only the lower value as the MAX power.
8.4.11 Proposals Interface

Up to 16 options can be stored in the PROPOSALS interface. To change a Proposal parameter:

1. Select the Proposal to be changed.
2. The previous parameter will be displayed at the bottom of the screen.
3. Press OK to return to the Main Menu.
4. Change the parameter in the main interface.

8.5 Laser Emission

When finished setting the parameters, press READY. The system will remind you to wear safety goggles (protection wavelength from 800nm to 1100nm). When you press one time the On / Off Switch to turn on; or depress the Foot Switch, the laser will begin emitting.
## 9. TROUBLESHOOTING

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>POSSIBLE CAUSE</th>
<th>SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main switch is turned on but the unit does not start and the power</td>
<td>1. EMERGENCY STOP button is pressed</td>
<td>1. Turn the EMERGENCY STOP button to the normal position</td>
</tr>
<tr>
<td>indicator is off</td>
<td>2. The fuse is burned out</td>
<td>2. Unplug the power line and check the fuse.</td>
</tr>
<tr>
<td>Alarm information on the screen</td>
<td>1. The Fiber is not plugged in or plugged improperly</td>
<td>1. Plug the Fiber in tightly</td>
</tr>
<tr>
<td></td>
<td>2. Safety Interlock switch is on</td>
<td>2. Connect the Safety Interlock switch.</td>
</tr>
<tr>
<td></td>
<td>3. Foot Switch does not operate</td>
<td>3. Connect the Foot Switch</td>
</tr>
<tr>
<td>Temperature too high</td>
<td>Temperature more than 35°</td>
<td>Turn off the laser for a few minutes</td>
</tr>
<tr>
<td>Temperature too low</td>
<td>Temperature less than 10°</td>
<td>Raise room temperature</td>
</tr>
<tr>
<td>Power Supply error</td>
<td>Laser current too high</td>
<td>Adjust laser current</td>
</tr>
<tr>
<td>Remote Interlock does not operate</td>
<td>Interlock is disconnected</td>
<td>Re-connect the Interlock</td>
</tr>
<tr>
<td>Fiber does not operate</td>
<td>Fiber is disconnected</td>
<td>Re-connect the Fiber</td>
</tr>
<tr>
<td>Foot Switch does not operate</td>
<td>Foot Switch is disconnected</td>
<td>Re-connect Foot Switch</td>
</tr>
<tr>
<td>Fiber temperature is high</td>
<td>The Fiber Tip or laser output lens may be dirty.</td>
<td>Clean the Fiber tip and the laser output lens.</td>
</tr>
<tr>
<td>MOSFET temperature is high</td>
<td>MOSFET temperature is high</td>
<td>Stop laser output</td>
</tr>
<tr>
<td>No power when starting laser</td>
<td>1. Power cord unplugged</td>
<td>1. Plug in power cord</td>
</tr>
<tr>
<td></td>
<td>2. Emergency stop switch is depressed</td>
<td>2. Turn clockwise to pop-up the emergency stop switch</td>
</tr>
<tr>
<td></td>
<td>3. Pressure mistake</td>
<td>3. Check the supplied pressure and required pressures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Power supply may be faulty, contact Aspen Laser Systems</td>
</tr>
<tr>
<td>Cannot start up, no display</td>
<td>1. Screen wire or data wire is broken or disconnected.</td>
<td>1. Take machine apart to check the screen and data wires</td>
</tr>
<tr>
<td></td>
<td>2. Control board can not output</td>
<td>2. Control board may be faulty, contact Aspen Laser Systems</td>
</tr>
</tbody>
</table>
## 9. TROUBLESHOOTING (continued)

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>POSSIBLE CAUSE</th>
<th>SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Red Aiming Beam Light</td>
<td>1. Fiber not connected</td>
<td>1. Check Fiber connection</td>
</tr>
<tr>
<td></td>
<td>2. The intensity too low</td>
<td>2. Take Aim Light may be faulty, contact Aspen Laser Systems</td>
</tr>
<tr>
<td></td>
<td>3. Laser stays in STANDBY</td>
<td>3. The laser is in the preparative situation, the light can be seen</td>
</tr>
<tr>
<td></td>
<td>4. Fiber or optic problem</td>
<td>4. Change the Fiber and/or the Hand Piece</td>
</tr>
<tr>
<td></td>
<td>6. Aim beam is OFF</td>
<td>6. Turn ON aim beam</td>
</tr>
<tr>
<td></td>
<td>7. Diode laser output lens in the SMA connector is faulty</td>
<td>7. Contact Aspen Laser Systems</td>
</tr>
<tr>
<td>The Red Aiming Beam is visible, but the</td>
<td>1. Foot switch not connected</td>
<td>1. Check foot switch connection and foot switch wire</td>
</tr>
<tr>
<td>Infrared Treatment Beam is not</td>
<td>2. Foot switch or Fiber may be faulty</td>
<td>2. Contact Aspen Laser Systems</td>
</tr>
<tr>
<td>the Infrared Treatment Beam is not working</td>
<td>3. Power is set too low or the diode laser have</td>
<td>3. Increase power and re-test</td>
</tr>
<tr>
<td>The Red Aiming Beam AND the Infrared</td>
<td>1. Fiber not connected to laser</td>
<td>1. Check the Fiber connection</td>
</tr>
<tr>
<td>Treatment Beam are both not working</td>
<td>2. Foot switch not connected</td>
<td>2. Check Foot Switch connection</td>
</tr>
<tr>
<td></td>
<td>3. Foot switch or Fiber may be faulty</td>
<td>3. Contact Aspen Laser Systems</td>
</tr>
<tr>
<td>The Alarm status is indicated</td>
<td>Check temporary failures</td>
<td>Restart the laser. If alarm info remains, record it and contact Aspen Laser Systems</td>
</tr>
</tbody>
</table>
## 10. MAINTENANCE

### 10.1 Fiber Maintenance and Cleaning

1. The Fiber end which connects to the SMA905 connector is the output to the fiber-coupled diode laser.
   
   | Any dirt or material on the end can burn or damage the diode laser. |

2. If the Fiber end face is not flat or contaminated, the output power of laser will be affected. When the laser releases high power, the end face can melt or carbonize which can lower the output power of the laser drastically.

3. During clinical use, end of the Therapy Hand Piece may come into direct contact with patients. The Therapy Hand Piece can be contaminated and become a means of disease transmission. The Therapy Hand Piece should be cleaned and disinfected after each patient use.

4. Use ethylene oxide sterilization. Please note the SMA905 connector can not be immersed into liquids or the Fiber can be damaged or the laser destroyed.

   | IMPORTANT: |
   | The Fiber should not be bent more than a 90 degree angle to avoid breakage. |

   | NOTE: |
   | The SMA905 connector should never be immersed in liquid when cleaning the optical fiber. The Fiber Protective Hat should not be removed when the Fiber is disconnected. |

### 10.2 Main Unit Maintenance

Aspen Laser System is a precise therapy instrument and should only be maintained by personnel authorized by the Company to ensure compliance with all Warranty Requirements.

1. When the Fiber is removed, cover the Aperture with the Protective Hat. The Hat should be cleaned with alcohol prior to replacement.

2. Do not touch the screen with hard or sharp objects or scrub the screen with reagent. Clean with a soft material.

3. Avoid shaking or hitting the laser device during transportation.
11. SERVICE

For any Service issue, contact your distributor or the company directly regarding any issues or concern, including:

1. Laser training
2. Regular maintenance and technical support
3. Accessories and equipment

Aspen Laser Systems, LLC
Dominion Towers
600 17th Street #2800
Denver, CO USA 80202
Phone: 877-817-0365
Fax: 877-817-0366
Web: aspenlasers.com
Email: info@aspenlasers.com
12. LASER THEORY AND LASER TERMS

12.1 Laser Theory

All light is composed of photons. Photons are small packets of light energy – in the form of waves – with a defined wavelength and frequency. Photon energy is able to more effectively penetrate the skin and underlying structures, therefore accelerating the healing process. Light travels at a constant speed and oscillate up and down as it moves forward.

However, all light is not the same. It is measured in wavelengths, with each wavelength of light representing a different color of the spectrum. The number of oscillations per second represents the frequency of each wavelength; shorter waves have a greater frequency than longer waves. Laser energy is coherent (well-ordered photons), monochromatic (single-color) light energy. When produced as a narrow, bright beam. Laser light holds its intensity until it is absorbed by a medium (the body). When applied to an organism, Laser light, tuned to specific wavelengths and frequencies, stimulates metabolic processes at the cellular level.

Photo-Chemical Action

Studies have shown that when tissue cultures are irradiated by Lasers, enzymes within cells absorb energy from laser light. Visible (red) light and Near Infrared (NIR) are absorbed within the mitochondria and the cell membrane. This produces higher ATP levels and boosts DNA production, leading to an increase in cellular health and energy. When applied as treatment, therefore, Lasers have been shown to reduce pain and inflammation as well as stimulate nerve regeneration, muscle relaxation and immune system response.

Lasers have no effect on normal tissues, as photons of light are only absorbed and utilized by the cells that need them.

Role of Chromophores

Chromophores are components of various cells and sub-cellular organelles which absorb light. The stimulation of Chromophores on mitochondrial membranes incites the production of ATP resulting in:

- Increases cellular energy levels
- Allows pain relief
- Accelerates cellular healing

Summary of the Photochemical Process:

- Photons
- Absorbed in Mitochondria and Cell Membrane within cytochromes and Porphyry’s
- Singlet Oxygen is Produced
- Changes in Membrane Permeability
- ATP Synthesized and DNA Produced
- Increase in Cell Metabolism from a Depressed Rate to a Normal Level
  - Selective Bio-Stimulatory Effect on Impaired Cells
  (Note cells and tissues functioning normally are not affected)
Analgesia – How Does Laser Therapy Reduce Pain?

Increase In Beta Endorphins
The localized and systemic increase of this endogenous peptide, after laser therapy irradiation has been clinically reported in multiple studies, to promote pain reduction.

Increased Nitric Oxide Production
Nitric oxide has both a direct and indirect impact on pain sensation. As a neurotransmitter, it is essential for normal nerve cell action potential in impulse transmission activity.
And indirectly, the vasodilation effect of nitric oxide can enhance nerve cell perfusion and oxygenation.

Decreased Bradykinin Levels
Since Bradykinsins elicit pain by stimulating nociceptive afferents in the skin and viscera, mitigation of elevated levels through laser therapy can result in pain reduction.

Ion Channel Normalization
Photobiomodulation promotes normalization in Ca++, NA+ and K+ concentrations, resulting in pain reduction as a result of these ion concentration shifts.

Blocked Depolarization of C-fiber Afferent Nerves
The pain blocking effect of therapeutic lasers can be pronounced, particularly in low velocity neural pathways, such as non-myelinated afferent axons from nociceptors.
Laser irradiation suppresses the excitation of these fibers in the afferent sensory pathway.

Increased Nerve Cell Action Potentials
Healthy nerve cells tend to operate at about -70 mV, and fire at about -20 mV. Compromised cell membranes have a lowered threshold as their resting potentials average around this -20 mV range.
That means that normal non-noxious activities produce pain.
Laser therapy can help restore the action potential closer to the normal -70 mV range.

Increased Release of Acetylcholine
By increasing the available acetylcholine, Laser Therapy helps in normalizing nerve signal transmission in the autonomic, somatic and sensory neural pathways.

Axonal Sprouting and Nerve Cell Regeneration
Several studies have documented the ability of laser therapy to induce axonal sprouting and some nerve regeneration in damaged nerve tissues.
Where pain sensation is being magnified due to nerve structure damage, cell regeneration and sprouting may assist in reducing pain.
12.2 Laser Terms

**Accessible Exposure Limit (AEL)** is the maximum permissible power level for the appropriate class of laser as defined in ANSI Z136.1.


**Aperture** is an opening through which laser radiation can pass.

**Aversion Response** is closing the eye and moving the head away to avoid exposure to laser light.

**Biological Amplification** – When photobiomodulation occurs, the photon activates a chromophore, amino acid, nucleic acid, or molecule. Activation of a single enzyme molecule rapidly catalyzes thousands of other chemical reactions amplifying the signal to the cell. This is similar to the calcium regulated 2nd messenger camp cascade. Biological amplification explains how systemic, cellular, and clinical effects can occur almost instantaneously after exposure to light therapies.

**Biomodulation** is the process of changing the natural biochemical response of a cell or tissue within the normal range of its function, stimulating the cell’s innate metabolic capacity to respond to a stimulus. a cell can heal itself by this stimulation mechanism.

**Chromophores** – Literally means, “Color lover” (L. chromo = color; L. phore = to seek out, to have an affinity for, to love). Chromophores are generally pigmented molecules that accept photons within living tissue. When the chromophore accepts a photon, it causes a biochemical change within an atom, molecule, cell or tissue. if this change increases cellular function, it is said to have activated the tissue. if this change decreased cellular function it is said to have inhibited the tissue. Biomodulation occurs in both cases.

**Coherence** – The photons within a laser beam are extremely well organized and directional. This means that all of the photons (energy) have waves that travel in unison – they are highly parallel with a specific wavelength. true laser systems focus all of their energy in one direction in a very concentrated line. a super-luminous diode, on the other hand, diffuses its energy in all directions with only a small percentage of the energy traveling in the direction of the treatment. a true laser system will deliver 90% more power to the treatment area than a super-luminous diode system of exactly the same power rating.

**Collimation** – A property of light commonly associated with lasers and accomplished with focusing lenses where all the photons are traveling in the same direction.

**Continuous Wave (CW) Laser** – A laser with a continuous output of laser radiation for a duration that is greater than or equal to 0.25 seconds.

**Diffuse Reflection** – When a laser beam is reflected in many directions by a surface reducing its intensity.

**Dose** – The term dose is an estimate of a therapy which produces a desired therapeutic action without harmful side effects. The therapeutic dose (safe and effective) range is defined by clinical evaluation of the response of a sufficient number of patients, generally 50 percent who improve without toxicity. The most important parameter in laser therapy is always the dose, often referred to as “fluence”. By dose (d) is meant the energy (e) of the light directed at a given unit of area (a) during a given session of therapy. The energy is measured in joules (j), the area in cm² and consequently, the dose in j/cm².

**Duty Cycle** – Relates to the amount of time the light source is active, usually from 10% to 100%. a laser operating in continuous wave is running at 100% duty cycle.

**Energy Density** – The energy density expresses the total amount of energy delivered per unit area, in joules per square centimeter, j/cm². The energy is measured in joules, and is calculated by multiplying the power output of the laser times the amount of time elapsed during the laser treatment. (energy = power x time, and the units are joules = watts x seconds.) a 4 watt continuous wave laser would deliver 240 joules in one minute. (4 watts x 60 seconds = 240 joules) then simply divide the total energy by the area to arrive at the energy density in joules per centimeter squared.

**Frequency** – The frequency of light is inversely proportional to its wavelength, and is dependent upon the energy value of the individual photons being emitted. The higher the frequency, the higher the energy, and the shorter the wavelength.
12.2 Laser Terms (continued)

Infrared Radiation (IR) – This is invisible radiation of wavelengths from 700nm-1mm. This part of the electromagnetic spectrum is broken down into 3 bands: near infrared (IR-A) 700nm-1400nm, mid infrared (IR-B) 1400nm-3,000nm, and far infrared (IR-C) 3,000nm-1mm.

Intrabeam Viewing – Direct viewing of a point source laser beam on axis.

Irradiance – The power per unit area expressed in watts per square centimeter (w/cm²). It is also referred to as power density and applies to cw lasers.

Laser Diode – A semiconducting device which emits monochromatic non-ionizing radiation by a process of stimulated emission. A laser beam has a number of unique properties, such as coherence, polarization and directionality. Beams emitted by laser diodes are not, as is often stated, ‘straight’ and/or ‘parallel’. Unless manipulated with additional optical devices such as lenses, a laser diode’s beam is broadly divergent along one plane and narrowly divergent along the perpendicular plane, producing an elliptical cross-section.

Laser Safety Officer (LSO) – The LSO is responsible for monitoring the control of laser use and implementing the laser safety program.

Laser – Light Amplification by Stimulated Emission of Radiation – Refers to the specific qualities and methods by which lasers produce light. Originally theorized and defined by Albert Einstein in 1917, it was not produced until the 1950s. Laser light is coherent, has a monochromatic wavelength, is collimated, and polarized. These four characteristics differentiate lasers from LED & SLD light sources.

Light is a small spectrum of electromagnetic energy with wavelengths between 380 nanometers (nm) and 760nm in length. This spectrum of energy is visible to the naked eye.

Maximum Permissible Exposure (MPE) – The maximum level of laser radiation to which a human can be exposed without harmful effects to the eye or skin. MPE values for eye exposure to direct beam viewing can be found in table 5 of ANSI Z136.1 Standard.

Monochromatic – Contains one specific wavelength of light (one specific color). It is an exclusive property of laser light, setting them apart from all other light sources. Because the wavelength of laser light determines its effect on tissue, the monochromatic property of laser light allows energy to be delivered to specific tissues in specific ways. Non-laser therapies such as LED’s (light emitting diodes) are sufficient for superficial treatment (wounds), but are questionable on penetration for musculoskeletal conditions. Lasers penetrate deeper.

Nominal Hazard Zone (NHZ) – An area where the MPE is exceeded for the laser radiation emitted.

Optical Density (OD) is the base ten logarithm of the reciprocal of the transmittance. The OD is calculated for protective eyewear to reduce the transmission density to the safe MPE level.

Penetration – Refers to the distance an energy wave travels into the tissue before it is absorbed and dissipated as heat or molecular vibration. Penetration is a physical and thermal phenomenon, not a therapeutic phenomenon. Penetration of laser light is dependent on the wavelength of the light. Lower wavelengths are absorbed by hemoglobin and melanin, and higher wavelengths are absorbed by water in the tissues.

Photobiomodulation – When biomodulation occurs from a photon transferring its energy to a chromophore it is referred to as photobiomodulation.

Physiological Dose of Therapy – A physiological dose of any therapy is designed to stimulate production of, or provide to the body what it needs to normalize and heal itself through biomodulation. The symptomatic response to a physiological dose of therapy is dependent of the capacity of the patient’s body to respond to the therapy. The physiological dose of any treatment has specific advantages. A physiological dose represents the body’s own response to a stimulus. A physiological dose generally improves the patient’s health.

Power Density is amount of power delivered per unit area. Power density indicates the degree of concentration of the laser output. It is expressed in watts per square centimeter, or milliwatts per square centimeter, w/cm² or mw/cm². Some studies have concluded that the power density may be of even greater significance than the dose. Example: a laser’s output is 4 watts, and it is illuminating a circle of 3 centimeter diameter. First find the area of the circle, 3.14 x 1.5 x 1.5 = 7 cm². Then divide the power by the area, 4w / 7cm² = 0.6 w/cm².
12.2 Laser Terms (continued)

**Power** = energy / time 1 watt = 1 joule / second. It is important not to confuse power and energy, although they are closely related. Power is the rate at which energy is delivered, not an amount of energy itself.

**Pulsed (Simulated)** – In most modern therapeutic lasers, the pulsing is simulated by mechanically or electronically interrupting the output of a continuous beam laser. The pulse rate may be adjusted up or down without significantly affecting treatment time. This is accomplished by modulating pulse duration and/or the space between pulses.

**Pulsed Laser** – A laser that delivers energy in single or multiple pulses which are less than or equal to 0.25 seconds in duration.

**Radiant Exposure** – Radiant energy per unit area expressed in joules per square centimeter (j/cm²). Radiant exposure applies to pulsed lasers.

**Retracing** – From time to time, a patient will experience an increase in pain following treatment. It is not an adverse reaction, but indicates that the laser treatment is working. Patients will frequently observe improvement once this pain subsides which is usually within 24 hours.

**Specular Reflection** is a mirror-like reflection of the beam in which most of the power is retained in the reflected beam. Therapeutic energy = power (watts) or joules/sec x time(sec).

**Ultraviolet Radiation (UV)** – Invisible radiation that has wavelengths from 180nm-400nm. UV radiation is broken down into 3 regions; near ultraviolet (UV-A) 315nm-400nm, mid ultraviolet (UV-B) 280nm-315nm, and far ultraviolet (UV-C) 100nm-280nm.

**Visible Radiation** is radiation that is visible to the human eye. The wavelengths are from 400nm – 700nm. At these wavelengths the eye can focus the light onto the retina increasing the radiant exposure by 100,000 times.

**Wavelength** – the property that differentiates different spectrums of energy within the electromagnetic spectrum of energy is wavelength. The wavelength of light is measured in billionths of a meter, or nanometers (nm). The energy of a wave is inversely proportional to its wavelength. In other words, the greater the energy, the shorter (smaller) the wavelength. Light of shorter wavelength carries greater the energy of the light. As wavelength becomes longer, the energy carried is less. Some wavelengths work better than others for therapy.

Wavelength is the prime determinant of tissue penetration. The wavelength is very specific for cell absorption. In the infrared (IR) spectrum, the longer wavelengths penetrate deeper and a greater percentage of the laser light will be transmitted in a forward direction. This means less scatter and better results. Each photon contains energy and just as energy of the ocean comes to shore in waves of high and low energy, the same is true of photons. Only with photons the energy is not measured by the height of the wave but the number of waves the photon carries. These waves are measured in two ways, the number of waves that will pass a given point in one second, or wavelength, the distance between one wave and the next.
13. WARRANTY CERTIFICATE

Name: ________________________________

Purchase Date: _______________ Serial Number: __________________

STANDARD WARRANTY TERMS

A) LASER DEVICES. The Company warrants each ASPEN LASER SYSTEMS, LLC laser device to be free from defects in workmanship and materials for the period of THREE (3) YEARS from the date of shipment and under normal use and service. B) ACCESSORIES. ASPEN LASER SYSTEMS, LLC accessories are warranted for a period of ONE (1) YEAR from the date of shipment, and include the fiber optic cable, treatment hand piece and safety goggles.

The Company’s obligation under this warranty is limited to providing any and all necessary product repairs upon the Company’s examination and final determination as to cause or existence of defect and, at its option to repair or replace the products, which prove to be defective during the warranty period.

Products replaced under warranty will be warranted only for the balance of the warranty period from the original supplied equipment.

This warranty extends only to the original purchaser of the equipment from ASPEN LASER SYSTEMS, LLC or its authorized distributor.

Any transfer of warranty must be approved in writing from the Company.

STANDARD WARRANTY CONDITIONS

This Standard Warranty will not apply to those products which have been:

(i) repaired or altered other than in accordance with the terms of this Agreement, or
(ii) abused, misused, improper handling in use, or storage, or used in an unauthorized or improper manner or without following written procedures supplied by ASPEN LASER SYSTEMS, LLC, or
(iii) original identification markings or labels have been removed, defaced or altered, or
(iv) any other claims not arising directly from material defects in material or workmanship.

This Standard Warranty is the exclusive warranty made by ASPEN LASER SYSTEMS, LLC and is in lieu of all other warranties, whether written, oral, or implied, including any warranty of merchantability or fitness for a particular purpose, and shall be owner’s sole remedy and ASPEN LASER SYSTEMS, LLC’s sole liability on contract or warranty of otherwise for the products. This warranty shall not be modified or amended without the written approval of an officer of ASPEN LASER SYSTEMS, LLC.

EXTENDED WARRANTIES

ASPN LASER SYSTEMS, LLC may make available an extended warranty(s) for additional years beyond the Standard Warranty Plan. Please contact the Company for specific details regarding the costs for Extended Warranty Plans.

In no event shall ASPEN LASER SYSTEMS, LLC be liable for any indirect, special, incidental or consequential damages resulting from the failure to perform or use or improper use of any goods or services sold pursuant hereto, whether due to breach of contract, breach of warranty, negligence or otherwise.

ASPN LASER SYSTEMS, LLC
600 17th Street #2800 | Denver, CO 80202
Phone: 877-817-0365 | Fax: 877-817-0366
info@aspenlasers.com | AspenLasers.com
14. WARRANTY REGISTRATION

AS P E N L AS E R S Y S T E M S, LLC

PLEASE COMPLETE AND RETURN THIS CARD

ORIGINAL PURCHASER: ____________________________________________

ADDRESS: ______________________________________________________

PHONE: ____________________ FAX: ________________________________

EMAIL: ____________________

LASER MODEL: ______________

SERIAL NUMBER: ____________________

DATE PURCHASED: ____________________

AS P E N L AS E R S Y S T E M S, LLC
Dominion Towers, 600 17th Street #2800
Denver, CO USA 80202
Phone: 877-817-0365 • Fax: 877-817-0366
Web: aspenlasers.com • Email: info@aspenlasers.com

AS P E N L AS E R S Y S T E M S, LLC
Dominion Towers
600 17th Street #2800
Denver, CO USA 80202
15. ASPEN LASER SYSTEMS PRODUCT RETURNS & REPAIRS

Return Materials Authorization (RMA) Required and Issuance of RMA Number

The customer agrees that any product to be serviced, repaired or returned to the Company shall maintain the following procedures:

1. Notification
   The customer must notify the Company within 15 days of first noticing the defect and promptly return the defective product upon receipt of RMA number(s) before expiration of the warranty period.

2. Prior Approval
   Contact the Company directly to obtain a Return Materials Authorization (RMA) number for shipping purposes:
   Aspen Laser Systems Customer Service at 1-877-817-0365

3. Proper Labeling
   The RMA number must appear on the outside of the shipping container. Return shipments will not be accepted if the RMA number is not clearly visible.

4. Written Description
   Please provide a written statement indicating the model number, serial number, and a brief description of the reason for return.

5. Shipping Address
   Send returns to:
   ASPIEN LASER SYSTEMS AUTHORIZED REPAIR CENTER
   Dominion Towers
   600 17th Street #2800
   Denver, CO USA 80202
   Phone: 877-817-0365
   Fax: 877-817-0366
   Web: aspenlasers.com
   Email: info@aspenlasers.com

Shipping Instructions and Charges

1. Packaging
   The unit must be shipped to Aspen Laser Systems, LLC in either its original package or similar package affording an equal degree of protection. Failure to provide this may result in voiding the warranty.

2. Customer Return Address
   Instructions must be provided indicating an address to which the repaired unit must be returned.

3. Shipping Charges Under Warranty
   The Company is responsible for the freight and insurance charges for any product that is being repaired or replaced that is under the warranty.

4. Shipping Charges Out of Warranty
   For any product that is not covered under the warranty, the customer is responsible for any freight and insurance charges.