Cynergy™

OPERATOR MANUAL

850-1065-000, Rev. 6

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Table of Contents

Glossary of Symbols and Abbreviations

The following symbols and abbreviations may be used on the Cynergy laser and/or in this manual.

Symbols

CE	Declaration of Conformity to Medical Device Directive 93/42/EEC CE Mark to Directive 93/465/EEC
	Type B applied part per EN60601-1: 1990
	Attention, consult accompanying documents
	Laser Hazard Warning
	Dangerous Voltage
	Non-ionizing Radiation
	Remote Interlock Connector per EN60601-2-22: 1996
	Optical Fiber Applicator per EN60601-2-22: 1996
STOP	Emergency Laser Stop per EN60601-2-22: 1996
	Off—power disconnection from mains
	On—power connection to mains
	Foot Switch
	WEEE symbol per EN50419
Other Symbols	
	Hand Switch

Abbreviations

°C	Degrees Celsius	V	Volts
A	Amperes	DVM	Digital Voltmeter
mA	Milliamp	Hz	Hertz
µA	Microamp	J	Joule
AC	Alternating Current	J/cm²	Joule per square centimeter
cm	Centimeter	kW	Kilowatt
mm	Millimeter	ms	Millisecond
nm	Nanometer	Ω	Ohms
CW	Continuous Wave	mΩ	Milliohms

About the Lasers

The Cynergy laser combines two lasers—a high-powered pulse dye laser (PDL) and a Nd:YAG laser—into one unit with a common delivery system. The result is a multi-application dermatological laser that treats small red vessels, scars, rosacea, vascular lesions and sun-damaged skin using the pulse dye wavelength, as well as treating larger facial and leg veins, vascular lesions, and unwanted hair on all skin types using the YAG wavelength. The laser is also available with the Cynergy MultiPlex option that combines both wavelengths in a single pulse offering improved clinical outcome. This manual addresses both lasers including the MultiPlex option.

The laser is designed to effectively couple the laser energy directly to the target while leaving the surrounding tissue unharmed. This principle is known as Selective Photothermolysis (SPT). By careful selection of the wavelength, pulse width, spot size, energy and cooling method, the effectiveness of the laser on the target is maximized, while any heating to surrounding tissue is minimized. Thermokinetic Selectivity®, or TKS®, is a corollary of SPT. It uses a laser pulse width that is much longer than the thermal relaxation time of small surrounding structures, yet less than the thermal relaxation time of the large target. This allows the small surrounding structures to remain cool while the larger target heats up to the destruction point.

The Cynergy with Multiplex™ Option, which allows treatment with both PDL and YAG in a single pulse, further exploits the principles of SPT and TKS for maximum efficacy in the treatment of cutaneous vascular lesions.

About the Manual

The *Cynergy Operator Manual* provides the following information about the laser:

- Equipment Safety
- Site Preparation
- Laser Operation
- Maintenance
- Customer Support
- Storage and Transport

Although the manual provides useful information on the use and maintenance of the laser, it is not intended to be a complete guide. Cynosure suggests that all health care professionals who plan to use the laser seek further training in its proper use. The custodian of the laser shall take steps to prevent its unauthorized use.

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

® Thermokinetic Selectivity and TKS are registered trademarks of Cynosure, Inc. / Cynergy with Multiplex is a trademark of Cynosure, Inc.

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Potential Hazards

As with any equipment, there are potential hazards. Before using the laser, operators should be aware of the following types of hazards: optical, electrical and combustible. This section of the manual describes these potential hazards and suggests precautions. This section also describes safety features designed to minimize potential hazards.

Optical Hazard

The laser emits an intense energy beam of invisible and visible laser light radiation that can cause serious eye damage with direct or even indirect optical contact.

WARNING: Always wear the protective eyewear supplied with the laser system. Failure to wear the appropriate protective eyewear can result in serious eye injury.

Please follow these precautions to avoid optical damage to laser operators, assisting personnel and patients.

- All persons in the room during treatment must wear the protective eyewear recommended by Cynosure. See "System Specifications" starting on page 34 for recommendations.
- Never look directly into the handpiece, fiber or fiber opening, even while wearing protective eyewear.
- Mark treatment rooms with the laser warning signs to avoid unnecessary personnel entering room during treatment.
- Limit entry to the treatment room only to personnel who are assisting in treatment and are trained in the use of the equipment.
- Cover windows and other openings in the treatment room to avoid the inadvertent escape of laser light.
- Direct the activated laser only at the intended area of treatment.
- Place one person in charge of the laser system's controls during the treatment.
- Cover reflective objects, such as jewelry or mirrors, which could deflect the laser beam to an area other than the intended treatment area.
- Put the laser into Standby Mode when the laser is not in use. When in Standby Mode, the laser beam cannot be inadvertently activated.
- Ensure that all appropriate staff members are trained to shut off the laser in the case of an emergency.
- Keep the laser start-up key in a safe place outside of the treatment room when the laser is not in use.

Electrical Hazard

The laser system uses high voltage. Do not open the protective panels unless you are trained and authorized to do so.

Chemical Hazard

The Cynergy laser uses a dye medium. Handle the dye with care, both to protect against toxicity and against staining. Operators should follow these precautions:

- Wear rubber or plastic gloves when handling the dye.
- Do not dispose of dye down drains.
- Return empty dye bottles and used filters to Cynosure.
- Avoid spillage on fabrics or on any porous material.

Potential Chemical Accidents and Appropriate Responses

The following table lists potential chemical accidents and their appropriate emergency responses.

Chemical Accident	*Appropriate Emergency Response*
Ingestion of dye or solvent	Drink water, induce vomiting, and seek immediate medical attention.
Excessive inhalation of dye or solvent	Go outdoors and inhale fresh air. Seek medical attention if symptoms appear.
Eyes exposed to dye or dye solvent	Rinse eyes with water. Seek medical attention if symptoms appear.
Skin exposed to dye or dye solvent	Immediately wash the exposed skin area with plain water, then with soap and water.

Hot Water Hazard

The laser uses water cooling to maintain the system at its proper operating temperature. This water can become very hot (greater than 50 ºC) and could scald. Do not perform any maintenance on the water system while hot. Always let the system cool down before changing the deionizing filter or adding deionized or distilled water.

Laser-Induced Fire Hazard

When the laser beam contacts an exterior surface, that surface can absorb the laser energy. This raises the surface temperature, whether the surface is skin, hair, clothes or any flammable substance. Operators should take the following precautions to prevent a laser-induced fire:

- Use non-flammable substances for uses such as anesthesia, skin preparation, and cleaning or disinfecting instruments.
- Be especially careful with the use of oxygen. Oxygen accelerates both the severity and the extent of a fire.
- Keep a minimum of combustible materials (e.g., alcohol) in the treatment room. If treatment requires the use of gauze, first soak it in water.
- Always keep a small fire extinguisher and water in the treatment room.

Electromagnetic Compatibility Hazards

The Cynergy laser has special precautions regarding electromagnetic compatibility hazards (EMC), and need to be installed and operated according to the EMC information provided in Appendix B, starting on page 73 of this manual.

CAUTION: Portable and mobile radio frequency (RF) communication equipment can affect the Cynergy laser.

CAUTION: The Cynergy laser should not be used adjacent to, or stacked with, other equipment other than the Cynergy PL system. If the laser must be used adjacent to, or stacked with other equipment, then observe the laser in its configuration to verify that operation is normal.

Laser Safety Features

The laser offers several safety features to prevent its misuse or unintentional activation. All personnel who operate the laser or assist in the operation should be familiar with these safety features.

Key Switch

The Key Switch controls the electrical activation of the laser system. Only those authorized personnel who have access to the key can start the laser system. Keep the laser start key in a secure location to prevent use by unauthorized personnel.

Emergency Laser Stop

The Emergency Laser Stop is a dedicated override switch for immediate shut down of the laser system.

Standby Mode

Standby Mode is designed to prevent unintentional or accidental activation of the laser. The system enters Standby Mode when the operator presses the Standby Key on the touch screen, or when laser is selected from the Home screen at start up. The laser status is displayed on the upper-left part of the screen.

When the laser is in Standby Mode, the system is on but the operator cannot activate the laser beam without first pressing the Ready Key on the touch panel.

Delayed Ready Mode

From Standby Mode, press the Ready Key to activate the laser. As required by the Center for Devices and Radiological Health of the U.S. Food and Drug Administration and International Standards (IEC601-2-22 and 825-1), there is a 3-second delay from the time the Ready Key is pressed until the laser can be activated. This delay, during which there is an audible beep and the ready key is lit, provides time for personnel to prepare before the beginning of treatment.

Automatic Shutdown Feature

When certain faults occur, the laser automatically shuts down and a fault code, message and corrective action is displayed. For a complete list of faults and failure analysis information, see "Troubleshooting," starting on page 59.

Remote Interlock

Cynosure provides a remote interlock circuit that can connect to a door switch of a treatment room. When the remote interlock is wired in series with a door switch, the laser automatically shuts down if anyone enters the treatment room. Contact Cynosure for detailed instructions on how to implement this function.

Audible Tone

Laser emission is indicated by a pulsed tone for the period of the emission.

Laser Warning Sign

Cynosure supplies a laser warning sign with each laser system. We recommend posting the sign at all entrances to rooms with an operating laser. Please check the policy of your hospital or clinic.

Locking Casters

The front casters of the laser may be locked into place. On the top of the front casters is a locking lever. To lock the casters, press down on the front of the lever. To release the casters, lift the lever into the original horizontal position.

Device Labels

The Cynergy laser comes with a series of required safety labels. Be sure that all personnel are familiar with these labels and their meanings**.**

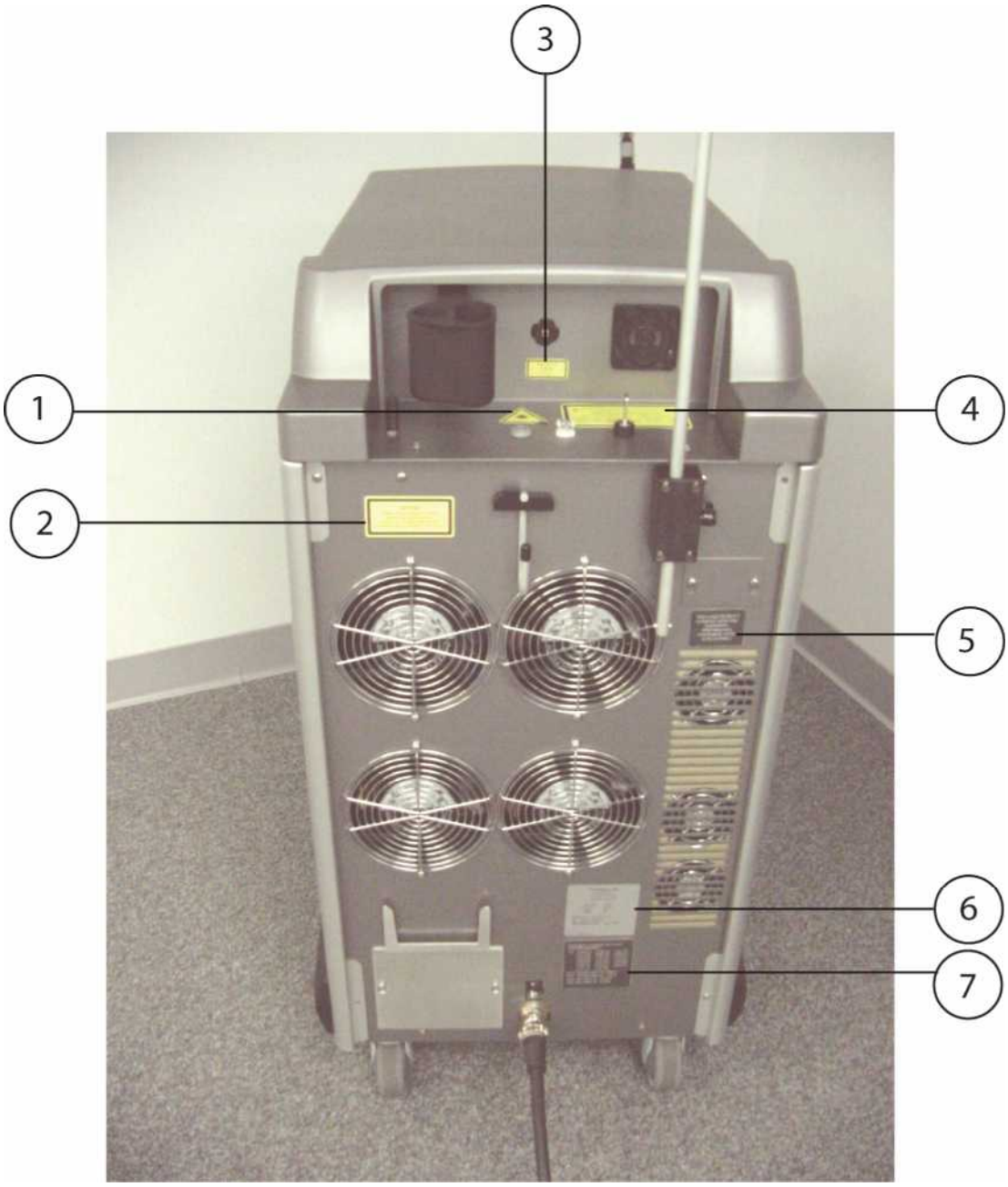

Figure 1A–Device Labels in Position

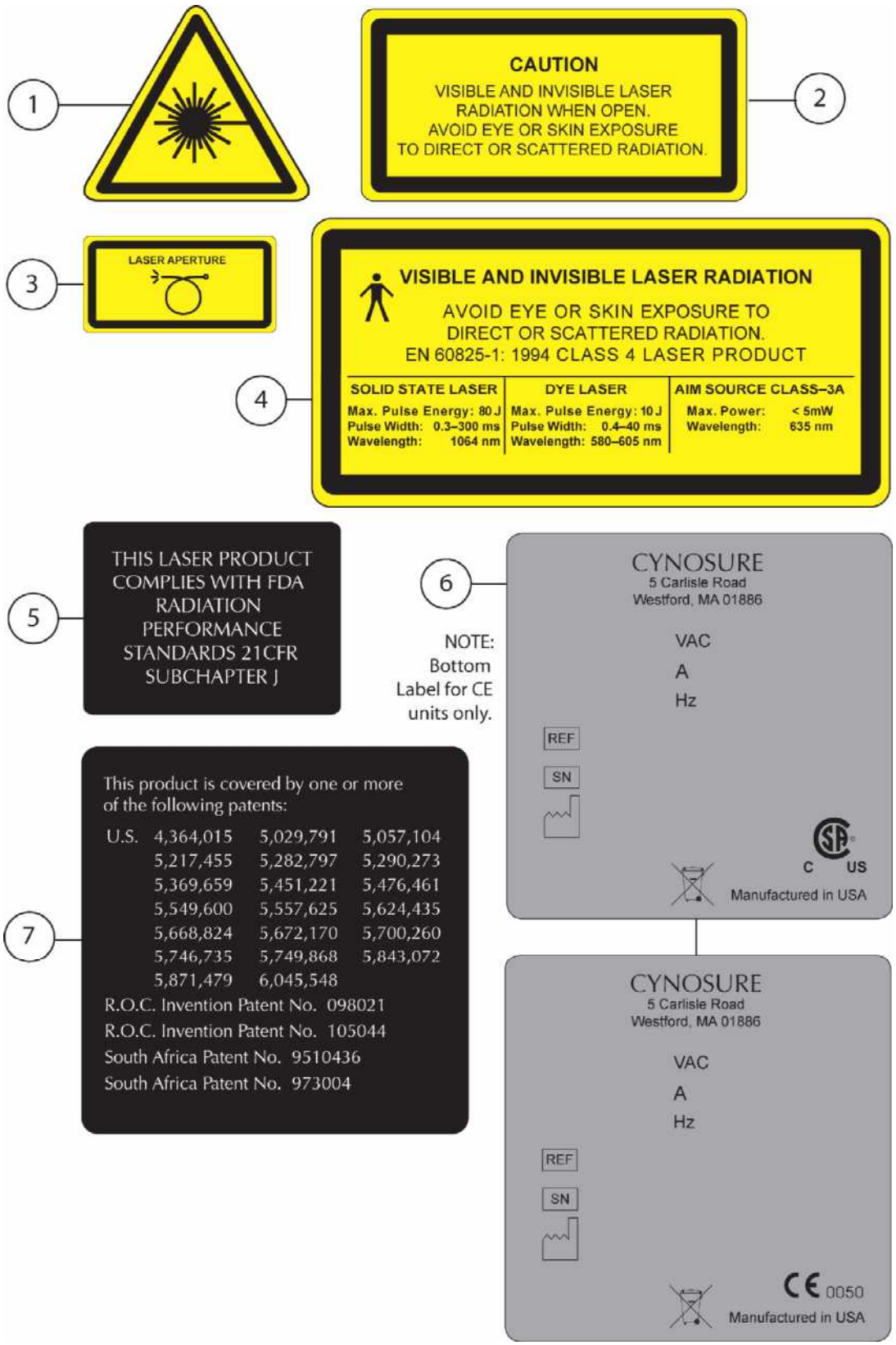

Figure 1B–Device Labels Used

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When preparing the laser site, operators should consider the spatial, electrical, environmental, transportation and storage requirements of the laser unit.

Spatial Requirements

The Cynergy and Cynergy III systems, which include the Cynergy Pulse Light (PL) system, have the following dimensions:

	Cynergy Laser	Cynergy III Cynergy w/Cynergy PL
Height:	40" (101 cm)	48" (121 cm)
Width:	18" (46 cm)	19" (48 cm)
Depth	31" (79 cm)	31" (79 cm)
Weight	270 lbs (123 kg)	310 lbs (141 kg)

For more information on the pulse light system, please refer to the *Cynosure PL Operator Manual*.

Electrical Requirements

Please consider the following electrical requirements before installing the laser unit:

- The AC line power requirements for the laser are:
  200-240 VAC, Single Phase
  30 Amps
  50-60 Hz
- The plug is NEMA L6-30.
- Power receptacles must be within 15 feet of the laser site.
- The power receptacle must be grounded.
- The laser should not share a power line with other heavy power-load equipment such as air conditioners or elevators. Ideally, the laser unit should be on a separate power line with a separate circuit breaker.

Environmental Requirements

Follow these environmental requirements to properly maintain the laser system.

- Keep the air free of corrosive substances, such as salts and acids. These pollutants may damage electrical wiring and optical surfaces.
- Keep dust and hair particles to a minimum. Shave patient's skin in a separate room. Dust and hair particles can cause permanent damage to optical components.
- Keep humidity in the laser room at 20% to 80%, non-condensing.
- Keep the laser room temperature from 50° to 80° F (10° to 27°C).
- Do not place laser unit near heating vents or other sources of temperature variation. **NOTE:** Most of the heat that is dissipated by the laser exits the rear panel.

Storage and Transport Requirements

To maintain the laser system properly during storage and transport, follow these requirements.

- Keep the ambient temperature between 40° and 110° F (4° to 43° C).
- Keep the laser system in a location where the humidity is between 10% and 90%, non-condensing.
- Lift only with suitable and appropriate equipment.
- Minimize shock and vibration.
- Do not drop.
- Store the laser system where the air is free of corrosive substances, such as salts or acids.
- Store the laser system where there is a minimum of dust particles.
- When storing or transporting the laser in temperatures less than 40° F (4° C), the laser coolant system must be drained. This is a highly complex process and should be performed by a trained service technician. Please contact Cynosure Customer Service, as detailed on page 66 to arrange for a service call.

Disposal of Waste Electrical and Electronic Equipment

To comply with European Commission Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) and other country and state regulations, please DO NOT dispose of this laser equipment in any location other than designated locations.

This section of the manual gives a general description of the laser including the system's specifications.

Main Components

Refer to **Figures 2A and 2B** to identify the main components of the laser system.

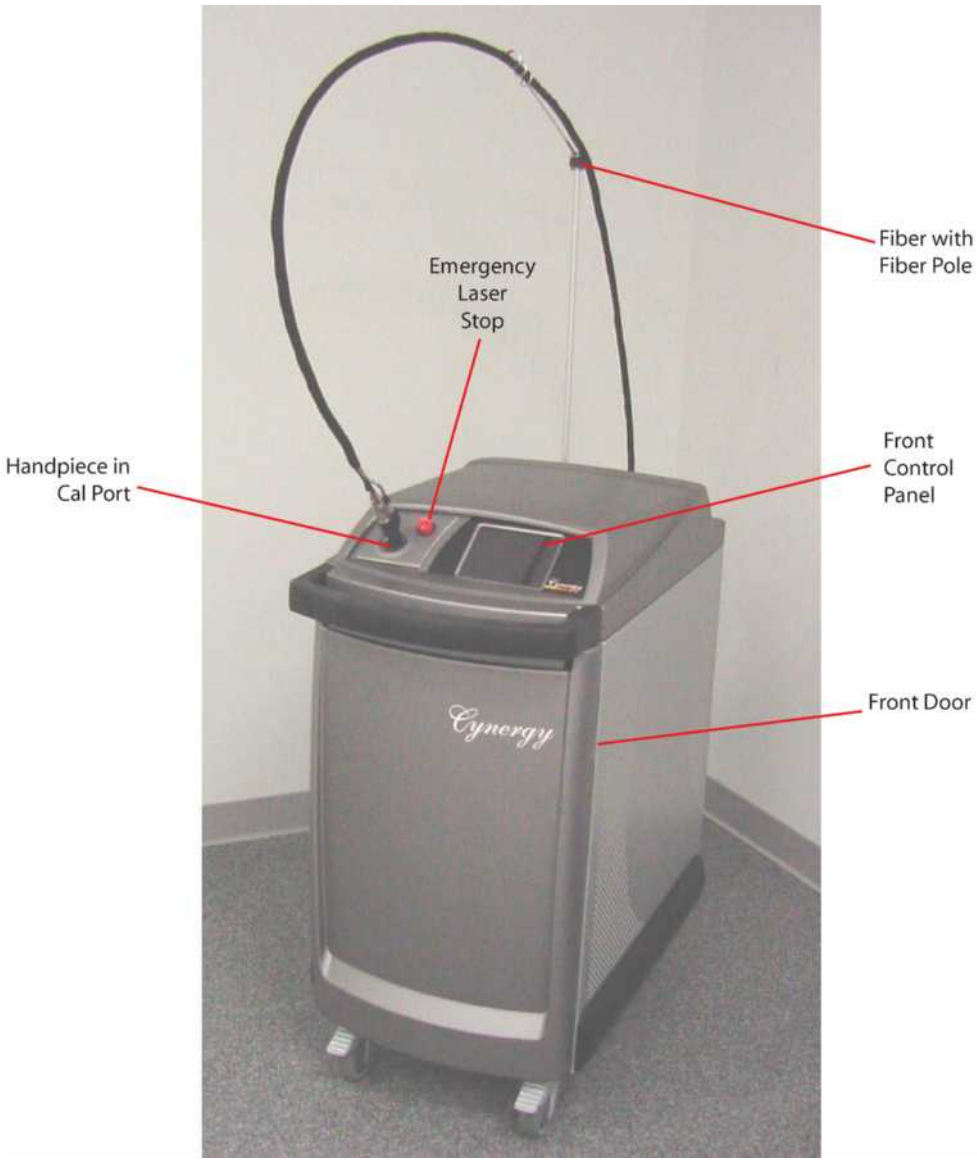

Figure 2A–Main Components, Front

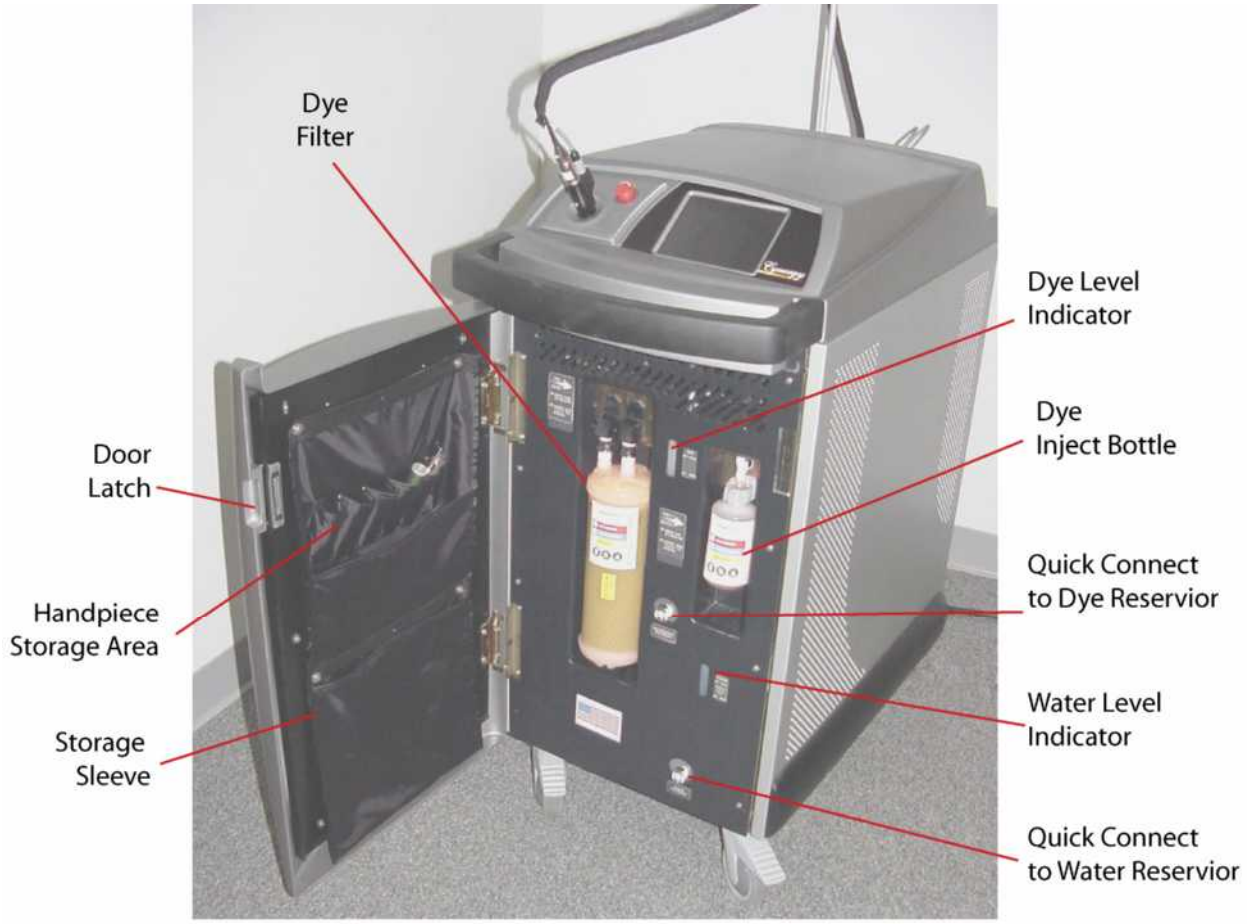

Figure 2B–Main Components, Inside Front Door

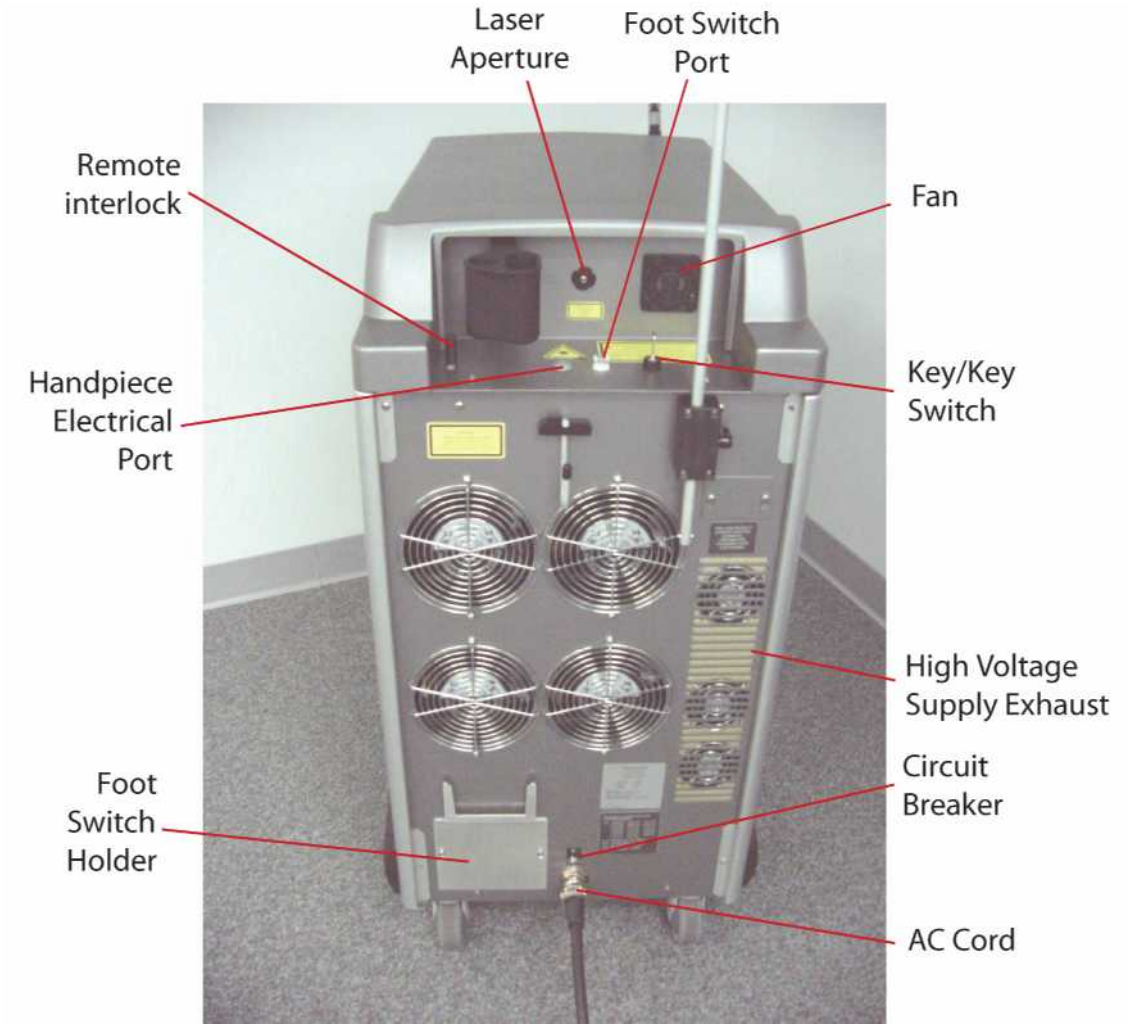

Figure 2C–Main Components, Rear View

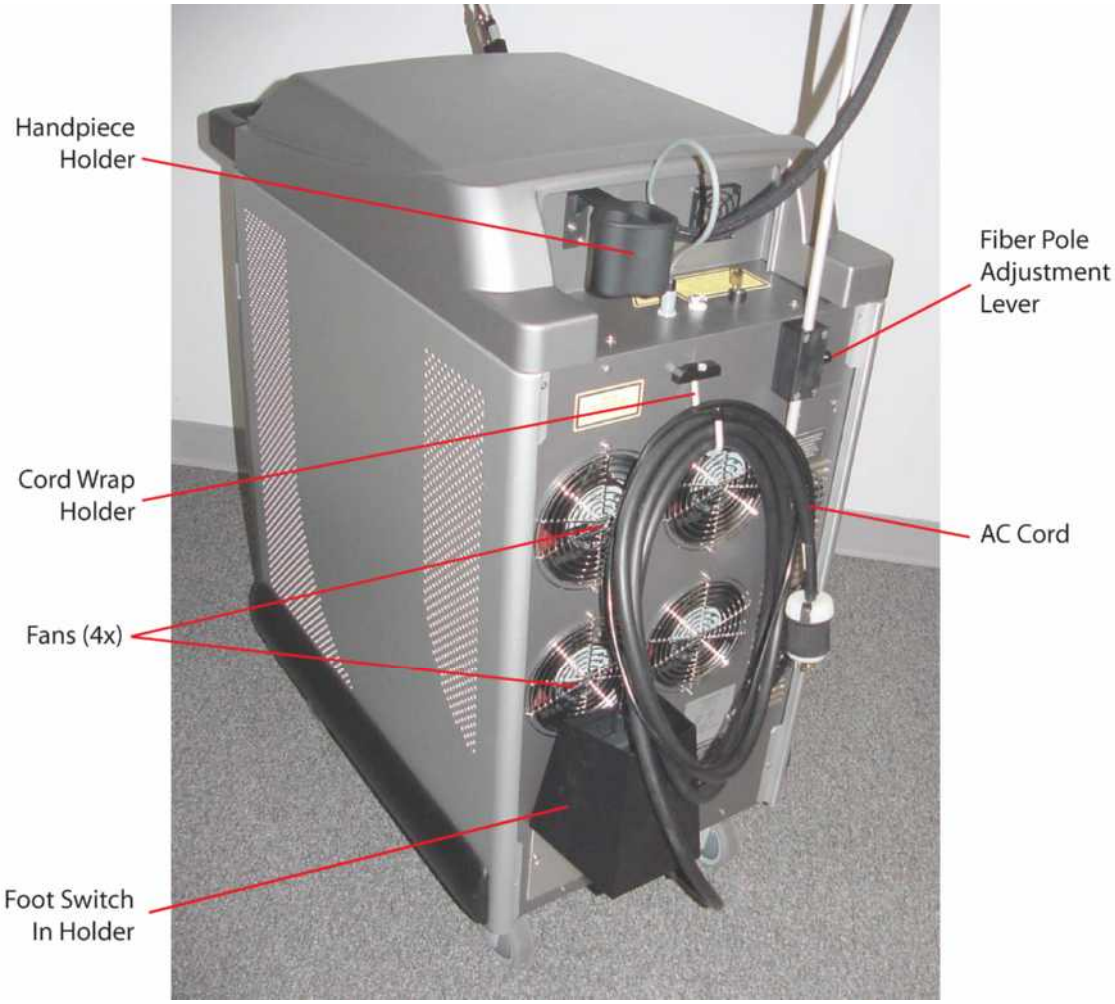

Figure 2D–Main Components, Right Side from Rear

Key Switch

The key switch and key turn the system on and off. There are two positions on the switch: ON (|) and OFF (○). To turn the laser on, insert the key and turn the key switch to the start position. Always remove the key after use to prevent access by unauthorized users.

Handpieces and Delivery Optical Fiber

The delivery system of the laser consists of a fused silica optical fiber that attaches to a handpiece. The optical fiber is 1.5 mm in diameter and 3 meters long. From the laser head, a lens couples the treatment and aiming source into the delivery optical fiber. The optical fiber delivers the laser beam through the handpiece to the treatment area. To initiate treatment, position the handpiece tip against the target site.

WARNING: There is a potential hazard when inserting, steeply bending, or inadequately tightening the proximal end of the fiber optic cable. Always follow the recommendations in this manual to avoid damaging the fiber or delivery system and/or harming the patient or user.

If the aiming beam is not present at the distal end of the delivery system, its intensity is reduced, or it looks diffused, this indicates a possible problem with the delivery system. Refer to the "Troubleshooting Chart," starting on page 62 for more information.

Connecting the Optical Fiber

Refer to **Figures 2C and 3** for an illustration of the fiber assembly and handpiece.

WARNING: Using cables other than provided may result in increased emissions or decreased immunity of the equipment. Inspect the fiber ends to verify that they are clean and free of all dust.

1. Screw the fiber connector into the laser aperture on the rear of the laser. See **Figure 2C** for laser aperture location. Firmly tighten by hand.
2. Firmly seat the electrical connector into the handpiece electrical port on the rear of the laser. See **Figure 2C** for the location of handpiece electrical port.
3. Attach the optical fiber connector to the handpiece.
4. Connect the handpiece electrical cable to the handpiece.
5. Wind the fiber onto the fiber pole's pigtail end. Adjust the position of the fiber by sliding the fiber assembly through the pigtail. Secure the assembly to the fiber pole with Velcro. If the fiber pole needs to be raised or lowered, use the fiber pole adjustment level on the rear of the laser.
6. Verify that all connections are tight.
7. Place the handpiece into the handpiece holder or calibration port.

Changing Handpieces

To change handpieces, remove the optical fiber connector to disconnect the fiber from the handpiece, see **Figure 3**. Then disconnect the handpiece electrical cable by pulling it from the handpiece. Connect the new handpiece, and then reconnect the handpiece electrical cable. Be sure to calibrate the laser before initiating treatment with a new handpiece.

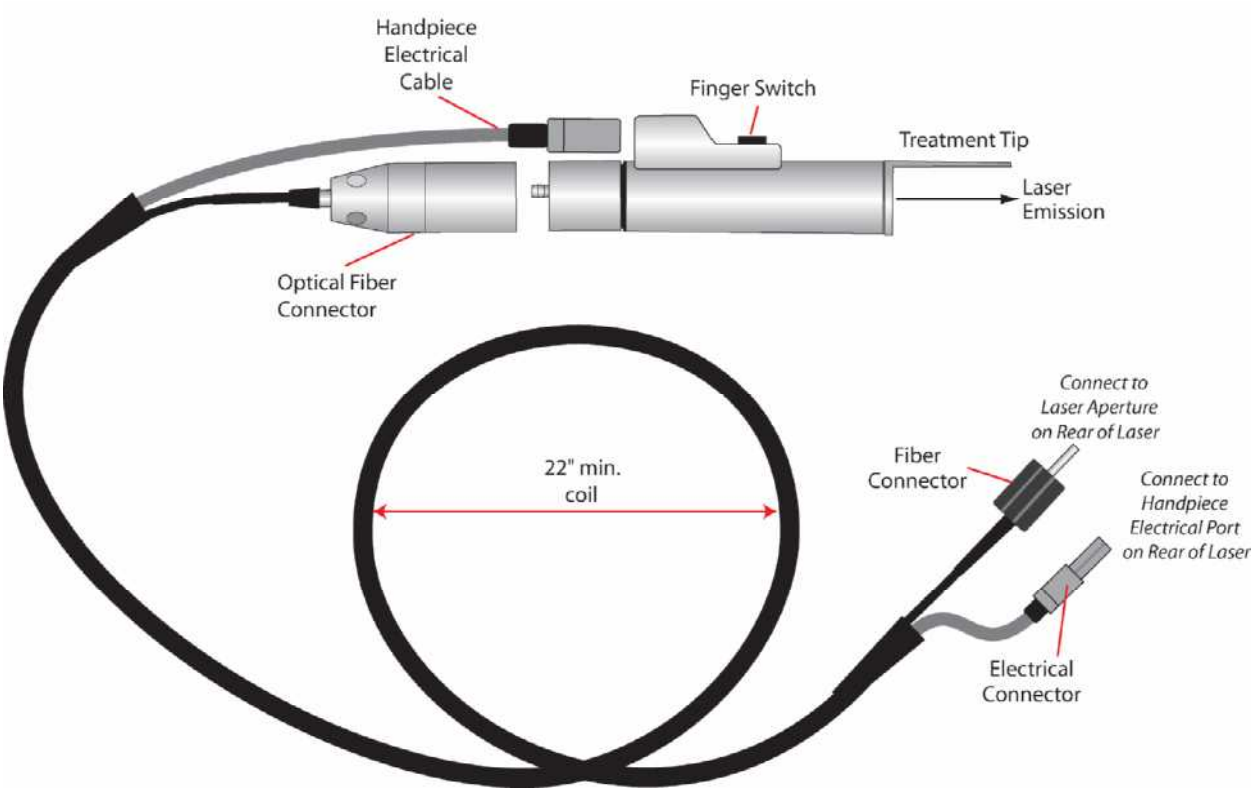

Figure 3–Handpiece

Trigger Switches

When the laser system is in the Ready Mode and the three-second delay has passed, the operator can activate the laser beam by pressing either of the following switches:

- The Finger Switch, an electrical switch located on the handpiece, as shown in **Figure 3.**
- The Foot Switch, a pneumatic switch that reduces the chance of electrical hazard in a wet environment. To connect the foot switch, insert the foot switch into the footswitch port on the rear of the laser. See **Figure 2C**.

Front Control Panel

The Front Control Panel, **Figure 4**, contains the controls and displays for operating and monitoring the laser. It is essential that operators understand and use these controls properly.

Figure 4–Front Control Panel

Emergency Laser Stop

The Laser Stop shuts down the system immediately, and should be reserved for emergency use only. Use the Key Switch to routinely shut down the laser.

Cal Port

The Cal Port is where the handpiece (distal end) is placed during calibration. As the handpiece fires laser light into the Cal Port, a sensor measures the energy of the beam and, by knowing which handpiece is inserted, displays the fluence (energy per unit area, J/cm^2) on the display.

The window in the Cal Port must be kept clean to ensure proper calibration. Clean the window with a tissue or soft cloth weekly or whenever debris or smudges are present.

WARNING: Failure to keep the Cal Port window clean may result in incorrect fluence leading to patient injury.

Display

The display is at the center of the user interface and consists of a high-resolution color display with a touch screen.

Display Screens

Home Screen

After the laser is turned on, the computer initializes and displays the Cynosure logo. After the system completes a diagnostic routine, the Home Screen is displayed. From the Home Screen menu, the user can choose the PDL laser, the YAG laser, the Cynosure MultiPlex function, a Utility program or a Database of laser treatment parameters. These screens and functions are discussed in detail in the following pages.

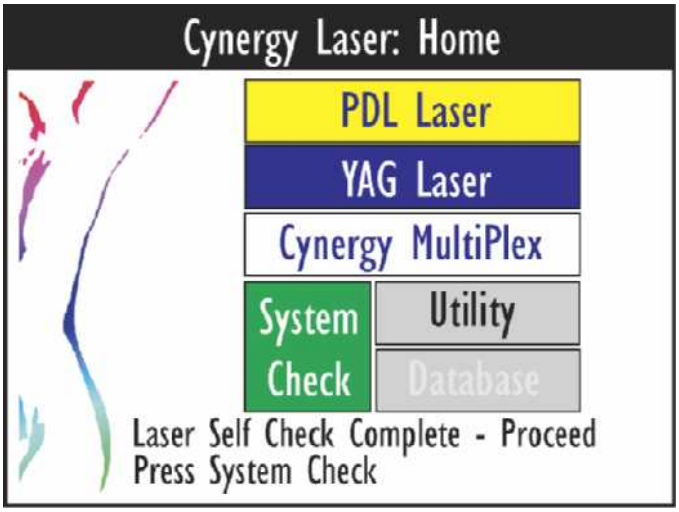

Figure 5A–Home Screen

After the laser has warmed up and before the user can begin treatment, the user is prompted to press System Check. System check is performed with the delivery system connected and the handpiece seated firmly into the calibration port. System check initiates a sequence in which the PDL and YAG lasers fire automatically and evaluate the basic performance level of the system. This check also includes the delivery systems. Following the system check, the user is instructed to take some action based on its results.

Treatment Screens

If the PDL is chosen, the screen shown in **Figure 5B** will appear that allows the user to set the parameters of the PDL. When the appropriate values are chosen for fluence (for a given handpiece), pulse width and repetition rate, the user can begin treatment by pressing Ready. The laser status is displayed along the top row and the user messages along the bottom rows.

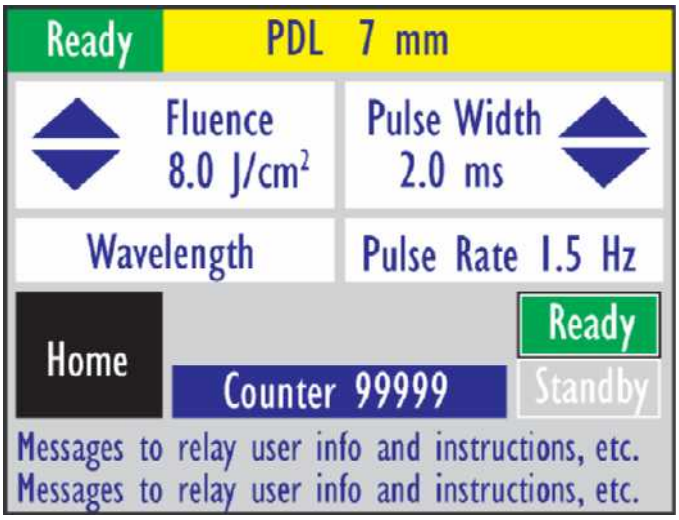

Figure 5B–PDL Screen

The treatment screens are designed so that the user can see at a glance which wavelength has been chosen. For example the YAG screen, **Figure 5C**, uses blue fields with white text, while the PDL screen uses the opposite—white fields with blue text.

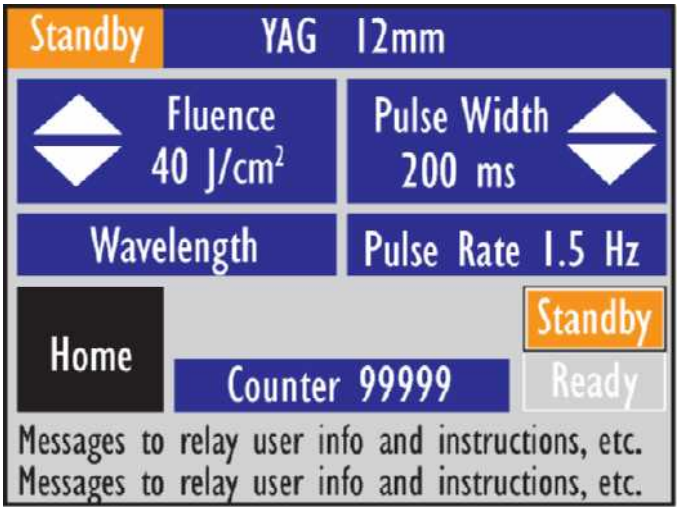

Figure 5C–YAG Screen

Treatment Screen Elements

1–Laser Status Bar

At the top left of the status bar, the status of the laser is displayed, i.e., Ready mode, Standby mode or Calibration (Cal) mode. At the center of the status bar, the type of laser and the spot size chosen are displayed.

2–Fluence

The Fluence Display shows the selected fluence from the handpiece. The units are expressed in joules per square centimeter (J/cm^2). Before or after calibration, press the (▲) key to increase the fluence, or press the (▼) key to decrease the fluence. After the correct fluence is achieved and the system is calibrated, the handpiece can be removed from the Cal Port.

3–Pulse Width

Pulse Width indicates the period for one laser pulse. The pulse width can be set from 0.3 ms to 300 ms depending on the laser. See, "System Specifications," starting on page 34 for further information. To increase the pulse width, press the (▲) key. To decrease the pulse width, press the (▼) key.

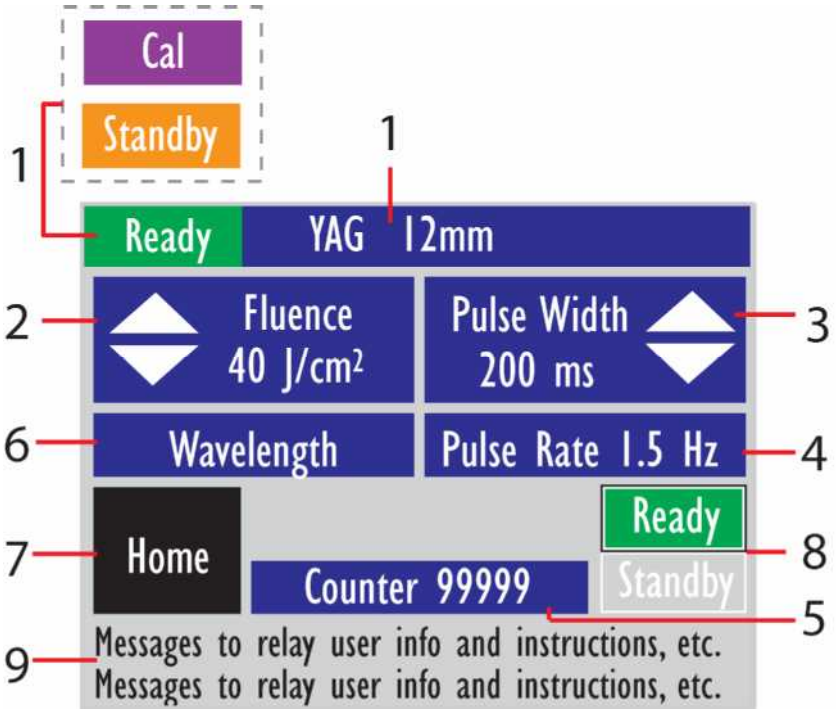

Figure 5D–Laser Screen Elements

4–Pulse Rate

Pulse Rate indicates the selected frequency of laser pulses. Depending on the laser and spot size, pulse rate can be adjusted from ‘single’ (one pulse at a time) to ‘5 Hz’ (five pulses per second). See, “System Specifications,” starting on page 34 for further information. Press the display box to toggle through the available pulse rates.

5–Counter

The counter displays a count of the treatment pulses as they occur (since the last reset). To reset the counter to zero, press the counter box. Each wavelength, as well as the MultiPlex option, has a separate counter.

6–Wavelength

The wavelength box allows the user to toggle between the PDL and YAG lasers. When changing wavelengths, the system prompts the user to verify the change by pressing wavelength again to confirm, or by pressing the text message area to cancel. To enter the Cynergy MultiPlex screen, exit to the Home Screen and access the MultiPlex screen from there.

7–Home

Press the Home key box to access the Home screen.

8–Ready/Standby

This button changes the status of the laser to either Standby mode or Ready mode. Press the display box directly to change the laser status.

9–Text Message Area

The text message area is where helpful information is provided for the user, such as instructions or error messages.

MultiPlex Treatment Screen

The basic format of the MultiPlex Screen, see **Figure 5E**, is the same as the other treatment screens. The MultiPlex Screen has a laser status bar, home key, a reset counter, standby and ready keys, as well as a text message area. Unlike the other treatment screens, the MultiPlex screen can only be accessed from the Home Screen. Where the MultiPlex Screen differs in both look and function is in the way treatment parameters can be changed.

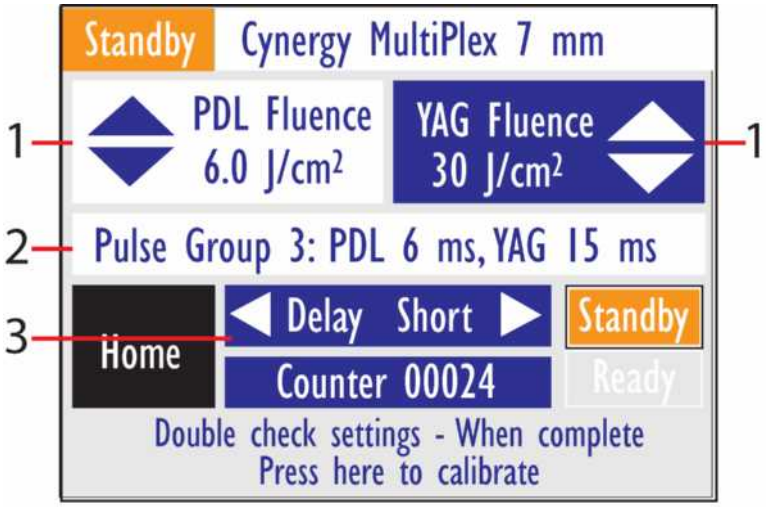

Figure 5E–MultiPlex Laser Screen

1–Fluence

The fluence settings for the PDL and YAG now appear side-by-side, since the Multiplex option delivers light from both wavelengths in one pulse. **NOTE:** Currently, one Multiplex configuration is available consisting of a PDL followed by the YAG. The fluence settings can still be changed by pressing the up (▲) and down (▼) keys.

2–Pulse Groups

There are eight pulse groups that can be selected in Multiplex mode. Each pulse group has a fixed pulse width for each of the lasers, a range of acceptable fluence parameters, and an appropriate range in which the delay can be set. See, “Cynergy MultiPlex Option,” table on page 37 for specific settings.

3–Delay

There is no repetition rate adjustment for the MultiPlex option since the laser uses only the one shot per second (1 Hz) repetition rate. The delay between multiplex pulses is adjusted by using the left/right arrows in the display window. The delay can be short, medium, long or extended depending on the pulse group and handpiece selected.

Utility Screen

The Utility Screen, see **Figure 5F**, displays helpful diagnostic information about the status of the laser, such as the number of shots on the flashlamps. Additionally, it provides access to system control parameters that can be changed, e.g., LCD brightness.

1–Software Version

The type of laser is displayed and the version number of the software installed on the unit.

2–Home

This field allows the user to exit the utility screen and return to the home screen.

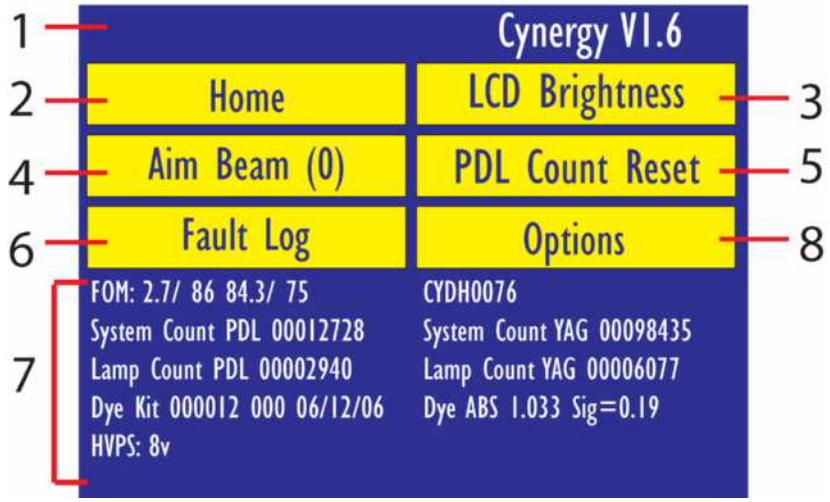

Figure 5F–Utility Screen

3–Brightness

Brightness allows the screen brightness to be adjusted. Press the touch key to increase or decrease the brightness.

4–Aim Beam

Aim allows the red treatment aim beam intensity to be adjusted. Press the touch key to adjust the beam intensity from (0), where aim beam is off, to (5), where aim beam intensity is maximized.

5–PDL Count Reset

When a dye kit is changed, the dye counter is reset. This is analogous to a trip odometer for the dye kit. The total number of shots is still recorded in addition to the dye kit count, which equals the shots delivered for that dye kit. See “Dye Kit” under “7–System Status Area,” on page 32 for more information.

6–Fault Log

The fault log enters a new page that displays the fault history of the laser. This is useful for diagnostic purposes.

7–System Status Area

Field	Description	Field	Description
FOM	This field generates a number used for diagnostic purposes only. It is an indication of the general health of both lasers and their associated delivery transmission system. NOTE: PDL info is followed by YAG laser info.	CYDH9876 (Serial Number)	This field is the serial number: a four-character alphanumeric product code, followed by a sequential number. The number used here is only an example.
System Count PDL	The total number of laser pulses for the PDL is displayed.	System Count YAG	The total number of laser pulses for the YAG laser is displayed.
Lamp Count PDL	The total number of flashlamp pulses since the last flashlamp change is displayed for the PDL.	Lamp Count YAG	The total number of flashlamp pulses since the last flashlamp change is displayed for the YAG laser.
Dye Kit/Days Used Since Reset/Date of Reset	The total number of pulses delivered since the PDL count reset button was pressed, usually the number of shots on a dye kit. Additionally the number of days the laser has been used since reset was pressed is displayed, as well the date it was reset.	DYE ABS/Sig	The dye absorbance is displayed. The normal range is from 0.7 to 1.1. Sig is the signal level of the dye concentration monitor and is used only by service personnel for diagnostics purposes.
HVPS	The voltage on the capacitor is displayed. This voltage is used only by service personnel. It normally is observed to drop near zero from the operating voltage of 400 to 1200 VDC.		

8–Options

The options field, when pressed, provides access to the option screen where additional user functions can be performed.

Option Screen

1–Home

This field allows the user to exit the utility screen and return to the home screen.

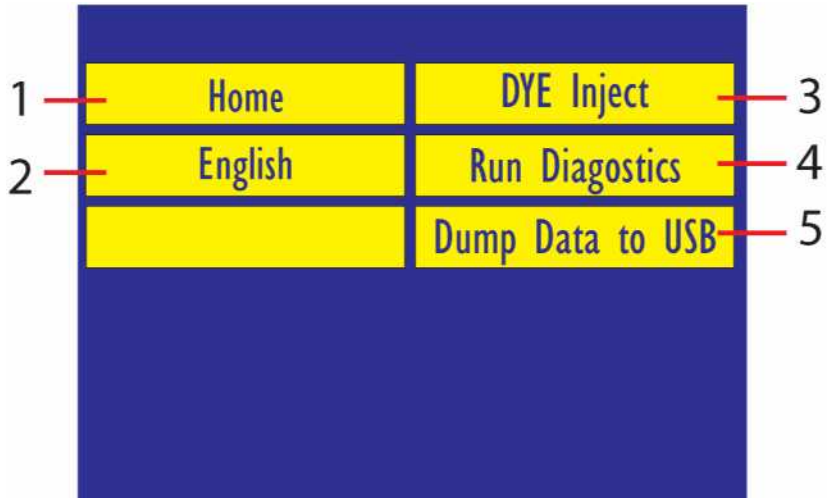

Figure 5G–Option Screen

2–Language

Press the language field to change the display language to German, Spanish or French. The default language is set to English.

3–Dye Inject

By pressing the dye inject field, the normal sequence of adjusting the dye concentration is initiated manually. See, “Dye Injection,” on page 56 for more information. **IMPORTANT:** This function should only be pressed on the advisement of Cynosure Service personnel.

4–Run Diagnostics

Pressing display diagnostics generates a report of pertinent laser diagnostic information.

5–Display Dump to USB

This field allows users and service personnel to transfer diagnostic information to a USB stick for transfer and further analysis by Cynosure. For more information refer to “Transferring Diagnostic Data,” in the Troubleshooting section starting on page 63.

System Specifications

General Specifications

Cynergy		
Specification	**Pulse Dye Laser (PDL)**	**YAG Laser**
Type (Flashlamp-excited):	Pulse Dye	YAG laser
Wavelength:	585nm +/- 2%	1064 nm
Method of Optical Output:	Fused silica optical fiber	
Cooling Method:	Water, internally circulated with heat exchanger to air	
Protective Safety Eyewear (min):	> 5.4 O.D. at 585 nm	> 5.8 O.D. at 1064 nm
Nominal Ocular Hazard Distance (NOHD):	100 meters	
Electrical Power:	200-240 VAC	
	4.5 kVA	
	50/60 Hz	
	Single phase	
Electrical Service Requirement:	30 Amp dedicated outlet	
Aiming Beam Source and Wavelength:	red diode laser (635 nm)	
Max. Delivered Output Power:	< 5.0 mW	
Handpiece Characteristics		
Handpiece Type	*Spot Size:*	*Beam Divergence:*
3 mm	3 mm ± 0.5 mm	½ angle, 1.9°
5 mm	5 mm ± 0.5 mm	½ angle, 2.2°
7 mm	7 mm ± 0.5 mm	½ angle, 2.1°
10 mm	10 mm ± 0.5 mm	½ angle, 2.1°
12 mm	12 mm ± 1.0 mm	½ angle, 2.6°
15 mm	15 mm ± 2.0 mm	½ angle, 2.2°

Fluence Specifications

Cynergy PDL

Handpiece (mm)	Rep Rate (Hz)	Maximum Rep Rate (Hz)	Minimum Fluence (J/cm²)	Maximum Fluence (J/cm²)	Max Power (W)	Pulse Width (ms)	Starting Fluence (J/cm²)	Fluence Increment (J/cm²)
5	1, 1.5, 2	2	10	40	15.7	0.5	10	1
5	1, 1.5	1.5	10	40	11.8	2-40	10	1
7	1, 1.5, 2	2	5	20	15.4	0.5	5	0.5
7	1, 1.5	1.5	5	20	11.5	2-40	5	0.5
10	1, 1.5, 2	2	2.5	10	15.7	0.5	2.5	0.5
10	1, 1.5	1.5	2.5	10	11.8	2-40	2.5	0.5
12	1, 1.5, 2	2	2	7	15.8	0.5	2	0.5
12	1, 1.5	1.5	2	7	11.9	2-40	2	0.5
Pulse Widths: 0.5, 2, 6, 10, 20, 40 ms								

Key	Yellow = PDL	Blue = YAG

Cynergy YAG

Handpiece (mm)	Rep Rate (Hz)	Maximum Rep Rate (Hz)	Minimum Fluence (J/cm²)	Maximum Fluence (J/cm²)	Max Power (W)	Pulse Width (ms)	Starting Fluence (J/cm²)	Fluence Increment (J/cm²)
3	1	1	50	300	21.2	5-300	50	5
3	1.5	1.5	50	300	31.8	5-300	50	5
3	2	2	50	300	42.4	5-300	50	5
5	1, 1.5, 2, 5	5	10	25	24.5	0.3	10	5
5	1	1	15	240	47.1	5-300	15	5
5	1.5	1.5	15	240	70.7	5-300	15	5
5	2	2	15	150	58.9	5-300	15	5
7	1, 1.5, 2, 5	5	10	17	32.7	0.3	10	5
7	1	1	15	160	61.6	5-300	15	5
7	1.5	1.5	15	120	69.3	5-300	15	5
7	2	2	15	75	57.7	5-300	15	5
10	1	1	15	80	62.8	5-300	15	5
10	1.5	1.5	15	60	70.7	5-300	15	5
12	1	1	15	50	56.5	5-300	15	5
12	1.5	1.5	15	40	67.9	5-300	15	5
15	1	1	15	35	61.9	5-300	15	5
15	1.5	1.5	15	25	66.3	5-300	15	5
Pulse Widths: 0.3, 5, 10, 15, 20, 25, 30, 40, 50, 100, 150, 200, 250, 300 ms								

Cynergy MultiPlex Option

Pulse Group	Fixed Pulse Width Settings		Fluence Range		Delay Range	
	PDL (ms)	YAG (ms)	PDL (J/cm²)	YAG (J/cm²)	7-mm HP	10-mm HP
1	0.5	15	4–8	20–60	Med–Ext	Long–Ext
2	2	15	4–8	20–60	Med–Ext	Long–Ext
3	6	15	6–12	20–60	Short–Ext	Long–Ext
4	10	15	6–12	20–70	Short–Ext	Long–Ext
5	20	20	7–12	20–80	Short–Ext	Long–Ext
6	40	40	8–15	20–80	Short–Ext	Long–Ext
7	0.5	40	4–8	20–60	Med–Ext	Long–Ext
8	10	40	6–12	20–60	Short–Ext	Long–Ext

Key	Yellow = PDL	Blue = YAG

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This section of the manual explains how to start the laser, calibrate the laser energy output, correct an out of range fault, and turn the laser off.

Laser Start-Up

WARNING: Always wear the protective eyewear supplied with the laser system. Failure to wear the appropriate protective eyewear can result in serious eye injury.

WARNING: Failure to keep the cal port window clean may result in incorrect energy leading to patient injury.

1. Make sure that the handpiece is connected and in the cal port.
2. Insert the key into the key switch and turn it to ON.
3. Verify that the front panel display comes on and displays the Cynosure logo.
4. Verify that the system completes its diagnostic routine, and displays the Home screen.
5. When the system is warmed up, press System Check. The system check sequence takes about fifteen seconds. The system will automatically begin firing into the cal port during this period.
6. When all interlock conditions are met (the fiber is connected, the laser panels are closed, etc.), the Standby key is activated.

   NOTE: If any interlock conditions are not met, or if any faults occur refer to, "Troubleshooting," starting on page 58 for information on correcting the problem.

   If "ADD WATER" appears on start up or at any time during operation, please refer to "Adding Water to the Reservoir" on page 55. The "ADD WATER" fault will not occur in Ready Mode.

Laser Shutdown

1. To shut down the laser, press the Standby Key, to place the laser in Standby Mode.
2. Turn the key OFF.
3. Remove the key to prevent access by unauthorized users.

IMPORTANT: At any time, press the emergency laser stop to shut down the laser immediately.

Laser Calibration

Calibrate the laser according to the procedure below each time you turn on the laser, change fibers, handpieces, fluence, pulse width and pulse rate.

The window in the Cal Port must be kept clean to ensure proper calibration. Clean the window with a tissue or soft cloth weekly or whenever debris or smudges are present.

1. With the system on, place the distal end of the handpiece in the cal port.
2. Select the desired laser and laser settings.
3. Check the status of the laser in the upper left corner. If the laser has just been started, the laser will default to Standby. Press Ready to change the laser to Ready mode.
4. After the system is Ready, the output must be verified. Press the front panel as instructed to initiate the CAL sequence, which is the laser adjusting and verifying the settings measured into the cal port.

   NOTE: If the handpiece is not in the cal port, the operator is instructed to do so from the text message display before proceeding.
5. When calibration is complete, a message is displayed on the screen. The handpiece can be removed from the cal port and treatment may begin.

   NOTE: At any time the laser can be calibrated again by simply returning the handpiece to the cal port, and repeating the steps above.

Energy Regulation During Treatment

During treatment, an automatic internal adjustment occurs to maintain a constant level of energy output determined during calibration.

If during treatment, the energy increases or decreases by more than 20% of the calibrated energy output, an energy “Out of Range” fault occurs, and is displayed on the touch screen. This fault causes the laser to exit Ready Mode. To activate the laser again and begin treatment, follow the steps below.

1. Press the Ready Key to return to the Ready Mode.
2. Place the handpiece into the Cal Port, and then fire the laser until “FLUENCE VERIFIED” appears on the display.
3. The laser will return to the selected energy output level, and then treatment can continue.

Laser Operation

1. Select the desired fluence, pulse width, wavelength and pulse rate (repetition rate). If using the Cynergy MultiPlex option, select pulse group, fluence and delay. Calibrate the setting.
2. Press the Ready Key to place the laser in Ready Mode. **NOTE:** In Ready Mode, no laser light is generated until the finger switch or foot switch is depressed.
3. Place the handpiece over the treatment site, contacting the handpiece tip to the treatment area.
4. Press either the finger switch or the foot switch to deliver laser pulses. **NOTE:** After each laser pulse, the counter increments displaying treatment pulses.

   WARNING: If the foot switch or handpiece switch malfunctions and remains on unintentionally while the laser is firing, quickly aim the handpiece at a wet sponge to absorb the laser energy. Press the Emergency Laser Stop immediately.
5. To check energy during treatment, place the handpiece, without the treatment tip, into the Cal Port and press the foot switch to verify fluence. In accordance with federal regulations, energy is maintained within a narrow range.

Changing Treatment Parameters

When a setting change is made during treatment, it may be necessary to return the handpiece to the cal port for a calibration.

1. Check the status of the laser in the upper left corner. If the laser status reads, Cal, the system must be calibrated.
2. Place the handpiece into the cal port and press the text message area. The system will automatically calibrate the output at the current setting, and then return the laser status to Ready mode.

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The section covers training requirements, indications, contraindications, possible adverse effects, patient selection and treatment recommendations for the Cynergy YAG laser only.

Refer to Section 7 starting on page 47 for clinical information regarding the pulse dye laser. If using the MultiPlex option, see Section 8 starting on page 51.

Laser Operator Training Requirements–YAG

This manual is not intended to be a complete guide to laser use. Cynosure recommends that all qualified personnel who operate the laser system first seek training that includes, but is not limited to, the following aspects of laser operation:

- Basic Laser Physics
- Laser Safety
- Soft Tissue Interaction
- Laser Operating Procedures
- Laser Set-up Procedures
- Potential Hazards
- Hands-on Experience

Indications, Contraindications and Adverse Effects–YAG

Indications

The Cynergy YAG laser is indicated for hair removal, leg and facial veins, vascular lesions, pigmented lesions, and wrinkle reduction.

Contraindications

Therapy using the Cynergy YAG laser is contraindicated for those patients who:

- Are hypersensitive to light in the 1064-nm wavelength region
- Take medication which is known to increase sensitivity to sunlight
- Take anticoagulants
- Have seizure disorders triggered by light
- Are pregnant

Adverse Effects

Adverse effects such as blistering, scarring, hypopigmentation or hyperpigmentation may result from the use of excessive energy levels.

Pretreatment Recommendations–YAG

At the time of the initial visit, the physician should determine the suitability of the laser treatment, inform patients about the treatment, and take photographs of the target site.

Determine Suitability

In determining suitability, physicians should consider the following factors for each individual case.

- Patient's age
- Patient's skin type
- Family history of the patient
- Current medications
- Reason patient is seeking treatment
- Patient's expectations

Inform Patient About the Treatment

After determining suitability, the physician should inform the patient of the following:

- The expected outcome of the treatment versus other possible outcomes
- The probable number of treatments needed to achieve the desired outcome
- Possible side effects resulting from laser treatment

Photographs

It is helpful to have photographs of the pretreatment area to assess precisely the success and progression of the treatment.

Treatment Recommendations–YAG

The operator should be able to determine the appropriate energy level of the laser, number of treatment sessions, size of treatment area at each session, and when no further treatment is warranted. At the time of treatment, the laser operator should also take precautions to prevent fire, see "Laser-Induced Fire Hazard," page 11.

Minimizing Adverse Effects

Adverse effects, such as erythema, blistering, burns and scarring may be reduced by air-cooling or coolant gel. Prior to treatment, remove all make up, lotions or creams from the area to be treated. Apply cooled, clear gel to freshly prepared clean areas.

Setting Energy Level

Depending on the patient's skin color, different energy levels are needed. Generating test spots prior to treatment is recommended.

Number and Length of Treatment Sessions

The number and length of treatment sessions depends on the size of the treatment area, the success rate of the treatment, and the patient's tolerance of the treatment.

Determining End of Treatment

The physician should determine the end of treatment by the acceptable success of treatment, non-compliance on the part of the patient, or adverse effects of the treatment.

Posttreatment Recommendations–YAG

After each treatment session, physicians should advise their patients on the proper care of the treated area.

- Wash the treatment area gently with soap and water. Do not soak.
- Do not shave the treated area if crusting is evident.
- Avoid contact sports or any other activity that could cause bruising of the treated area.

The section covers training requirements, indications, contraindications, possible adverse effects, patient selection and treatment recommendations for the Pulse Dye Laser (PDL) only.

Refer to Section 6, starting on page 42, for clinical information regarding the YAG laser. If using the MultiPlex option, see Section 8 starting on page 51.

Laser Operator Training Requirements–PDL

This manual is not intended to be a complete guide to laser use. Cynosure recommends that all qualified personnel who operate the laser system first seek training that includes, but is not limited to, the following aspects of laser operation:

- Basic Laser Physics
- Laser Safety
- Soft Tissue Interaction
- Laser Operating Procedures
- Laser Set-up Procedures
- Potential Hazards
- Hands-on Experience

Indications, Contraindications and Adverse Effects–PDL

Indications

The Cynergy pulse dye laser is indicated for the treatment of benign cutaneous vascular or vascular dependent lesions.

Contraindications

Therapy using the Cynergy pulse dye laser is contraindicated for those patients who:

- Are hypersensitive to light in the 580–605 nm wavelength region
- Have a personal or family history of skin cancer
- Are pregnant

Adverse Effects

Adverse effects, such as scarring, hypopigmentation and hyperpigmentation, may result from the use of excessive energy levels.

The recently tanned (skin types of III or greater) are more prone to adverse effects.

Patient Selection–PDL

The best candidates for treatment with the PDL of the Cynergy laser are the following:

- Patients with cutaneous vascular lesions such as port wine stains, verruca, hemangiomas, telangiectasia, scars with vascular components, vascular related gynecological disorders and other vascular dependent lesions.
- Patients who have previously undergone unsuccessful alternative treatment for vascular lesions, providing that the previous treatment did not cause excessive damage or scarring.

Pretreatment Recommendations–PDL

At the time of the initial visit, the physician should determine the suitability of the laser treatment, inform patients about the treatment, and take photographs of the vascular lesion.

Determine Suitability

In determining suitability, physicians should consider the following factors for each individual case:

- Type of lesion
- Color of lesion
- Patient's age
- Location of lesion
- Patient's skin type
- Family history of the patient
- Reason patient is seeking treatment
- Patient's expectations

Inform Patient About the Treatment

After determining suitability, the physician should inform the patient of the following:

- The expected outcome of the treatment vs. other possible outcomes
- The number of treatments it is likely to take to achieve the desired outcome
- Possible side effects resulting from laser treatment.
- The gradual clearing of the lesion

Photographs

It is helpful to have photographs of the pre-treated lesions in order to precisely assess the success and progression of the treatment.

Treatment Recommendations–PDL

The operator should be able to determine the appropriate energy level of the laser, number of treatment sessions, size of treatment area at each session, and when no further treatment is warranted. At the time of treatment, the laser operator should also take precautions to prevent fire, see "Laser-Induced Fire Hazard," page 11.

Minimizing Adverse Effects

Air cooling with the SmartCool™ air-cooling system is recommended before and after treatment. Adverse effects, such as erythema, blistering, burns and scarring may be reduced by air-cooling or coolant gel. Prior to treatment, remove all make up, lotions or creams from the area to be treated. Apply cooled, clear gel to freshly prepared clean areas.

Setting Energy Level

Depending on the patient's skin color, different energy levels are needed. Generating test spots prior to treatment is recommended.

Number and Length of Treatment Sessions

The number and length of treatment sessions depends on the size of the treatment area, the success rate of the treatment, and the patient's tolerance of the treatment.

Determining End of Treatment

The physician should determine the end of treatment by the acceptable success of treatment, noncompliance on the part of the patient, or adverse effects of the treatment.

Posttreatment Recommendations–PDL

After each treatment session, physicians should advise their patients on the proper care of the treated area.

- No rubbing or scratching treated area. No picking crusted area. Keep moist and let it fall off on its own.
- No shaving treated area if crusting is evident.
- No swimming or using a whirlpool while discoloration is present.
- Apply antibiotic ointment twice a day while discoloration is present
- Applying make-up is permitted if no crusting is present.
- Discomfort may be relieved by ice packs or acetaminophen.
- Avoid contact sports or any other activity that could cause bruising of the treated area.
- Use a sunblock with an SPF of 30+ when treated area is exposed to the sun.

™SmartCool is a trademark of Cynosure, Inc.

The section covers training requirements, indications, contraindications, possible adverse effects, patient selection and treatment recommendations when using the Cynergy with MultiPlex option.

Refer to Section 6, starting on page 42, for clinical information regarding the YAG laser. If using the PDL refer to Section 7 starting on page 47.

Laser Operator Training Requirements–MultiPlex

This manual is not intended to be a complete guide to laser use. Cynosure recommends that all qualified personnel who operate the laser system first seek training that includes, but is not limited to, the following aspects of laser operation:

- Basic Laser Physics
- Laser Safety
- Soft Tissue Interaction
- Laser Operating Procedures
- Laser Set-up Procedures
- Potential Hazards
- Hands-on Experience

Indications, Contraindications and Adverse Effects–MultiPlex

Indications

The Cynergy with MultiPlex option is indicated for the treatment of benign cutaneous vascular or vascular dependent lesions.

Contraindications

Therapy using the Cynergy with MultiPlex option is contraindicated for those patients who:

- Are hypersensitive to light in the 580–605 nm or the 1064-nm wavelength region
- Have a personal or family history of skin cancer
- Are pregnant

Adverse Effects

Adverse effects, such as scarring, hypopigmentation and hyperpigmentation, may result from the use of excessive energy levels.

The recently tanned (skin types of III or greater) are more prone to adverse effects.

Patient Selection–MultiPlex

The best candidates for treatment with the Cynergy with MultiPlex option are the following:

- Patients with cutaneous vascular lesions such as port wine stains, verruca, hemangiomas, telangiectasia, scars with vascular components, vascular related gynecological disorders and other vascular dependent lesions.
- Patients who have previously undergone unsuccessful alternative treatment for vascular lesions, providing that the previous treatment did not cause excessive damage or scarring.

IMPORTANT: The Cynergy PDL remains the first choice for treatment of uncomplicated vascular birthmarks.

Pretreatment Recommendations–MultiPlex

At the time of the initial visit, the physician should determine the suitability of the laser treatment, inform patients about the treatment, and take photographs of the vascular lesion.

Determine Suitability

In determining suitability, physicians should consider the following factors for each individual case:

- Type of lesion
- Color of lesion
- Patient's age
- Location of lesion
- Patient's skin type
- Family history of the patient
- Reason patient is seeking treatment
- Patient's expectations

Inform Patient About the Treatment

After determining suitability, the physician should inform the patient of the following:

- The expected outcome of the treatment vs. other possible outcomes
- The number of treatments it is likely to take to achieve the desired outcome
- Possible side effects resulting from laser treatment.
- The gradual clearing of the lesion

Photographs

It is helpful to have photographs of the pretreated lesions in order to precisely assess the success and progression of the treatment.

Treatment Recommendations–MultiPlex

The operator should be able to determine the appropriate energy level of the laser, number of treatment sessions, size of treatment area at each session, and when no further treatment is warranted. At the time of treatment, the laser operator should also take precautions to prevent fire, see "Laser-Induced Fire Hazard," page 11.

Minimizing Adverse Effects

Aggressive air cooling with the SmartCool air-cooling system is highly recommended before and after treatment. Adverse effects, such as erythema, blistering, burns and scarring may be reduced by air-cooling or coolant gel. Prior to treatment, remove all make up, lotions or creams from the area to be treated. Apply cooled, clear gel to freshly prepared clean areas.

Setting Energy Level

Depending on the patient's skin color, different energy levels are needed. Generating test spots prior to treatment is recommended.

Number and Length of Treatment Sessions

The number and length of treatment sessions depends on the size of the treatment area, the success rate of the treatment, and the patient's tolerance of the treatment.

Determining End of Treatment

The physician should determine the end of treatment by the acceptable success of treatment, non-compliance on the part of the patient, or adverse effects of the treatment.

Posttreatment Recommendations–MultiPlex

After each treatment session, physicians should advise their patients on the proper care of the treated area.

- No rubbing or scratching treated area. No picking crusted area. Keep moist and let it fall off on its own.
- No shaving treated area if crusting is evident.
- No swimming or using a whirlpool while discoloration is present.
- Apply antibiotic ointment twice a day while discoloration is present
- Applying make-up is permitted if no crusting is present.
- Discomfort may be relieved by ice packs or acetaminophen.
- Avoid contact sports or any other activity that could cause bruising of the treated area.
- Use a sunblock with an SPF of 30+ when treated area is exposed to the sun.

This section of the manual discusses maintenance practices, such as cleaning and disinfecting equipment. The section also provides a troubleshooting chart with fault codes.

Cleaning and Disinfecting Equipment

Cynosure suggests that operators periodically clean and disinfect the exterior of the laser system. Always turn off the system before cleaning. The handpiece and tip should be cleaned and disinfected after each treatment session in the following manner:

1. Clean the exterior of the laser system with a mild soap and water.
2. When necessary, disinfect the exterior parts of the equipment with a hospital-grade disinfectant.
3. Use a soft cloth for both cleaning and disinfecting.
4. Be careful not to contaminate the optics with soap or disinfectant.

Disinfect the handpiece by wiping the exterior surfaces, especially the tip, with hospital-grade disinfectant. Be careful not to allow the disinfectant to have contact with the internal optics or seep into the finger switch.

Adding Water to the Reservoir

During normal operation, fill the reservoir when “ADD WATER” is indicated on the text message area of the display.

The water level can be checked by opening the front door and locating the water level indicator on the lower right side.

WARNING: The water is very hot and could scald. Do not perform any maintenance on the water system while it remains hot. Always let the system cool down before adding deionized or distilled water.

1. After a cool down period, turn the laser ON
2. Connect the Filler Tube and Funnel Assembly to the Quick Connect Fitting located inside the front door marked Water Fill/Drain, see **Figure 2B.**
3. Fill the reservoir with distilled or de-ionized water until the water level reads “FULL.” Be careful not to overfill the laser, or water will pool under the laser system.

   CAUTION: Use distilled or de-ionized water only when filling the reservoir; tap water can damage the system.
4. Remove the Filler Tube and Funnel Assembly.

Dye Kit Methodology

The dye laser uses an organic dye suspended in a solvent as the lasing media. The dye filter and the inject bottle serve as reservoirs to maintain an acceptable concentration of fresh dye.

As the dye laser pulses, the dye undergoes a chemical transformation after each pulse and must pass through the dye filter to be rejuvenated. This process can continue so long as the dye filter is less than 12 months old or the filter has less than 100,000 shots after its last change. If either of these conditions is met, the dye kit (dye filter and inject bottle) should be replaced, see page 57.

The dye concentration is maintained by a monitoring system that will inject more dye as needed. This additional supply of dye is pulled from the inject bottle.

Dye Injection

At startup, the system must warm up in order for the dye solvent to reach and maintain its operating temperature. One the system is warm, the dye concentration is checked. Normally, the dye concentration is correct and the system will complete the startup process. Occasionally, however, additional dye concentrate may be required. When this occurs, the system will automatically add more dye concentrate through a series of inject and mix cycles. This process usually takes only a few minutes, but in extreme cases may take up to thirty minutes. Once the process has finished, the laser will go to the Home Screen and the user may proceed as normal. The system will continue to monitor the dye concentration level, but will not require another injection cycle unless the laser is restarted. If the laser is not started for more than a week, it is more likely that additional dye concentrate will be required.

Replacing the Dye Kit

CAUTION: Dye easily stains. Always wear gloves for protection and proceed careful to avoid spilling or dripping dye.

1. Turn off the laser.
2. Open the front door.
3. Disconnect the dye filter by squeezing the tab of the quick-connect, and then sliding the fitting up toward the top of the laser. See left side of **Figure 6A**. Repeat for the other dye filter connector.

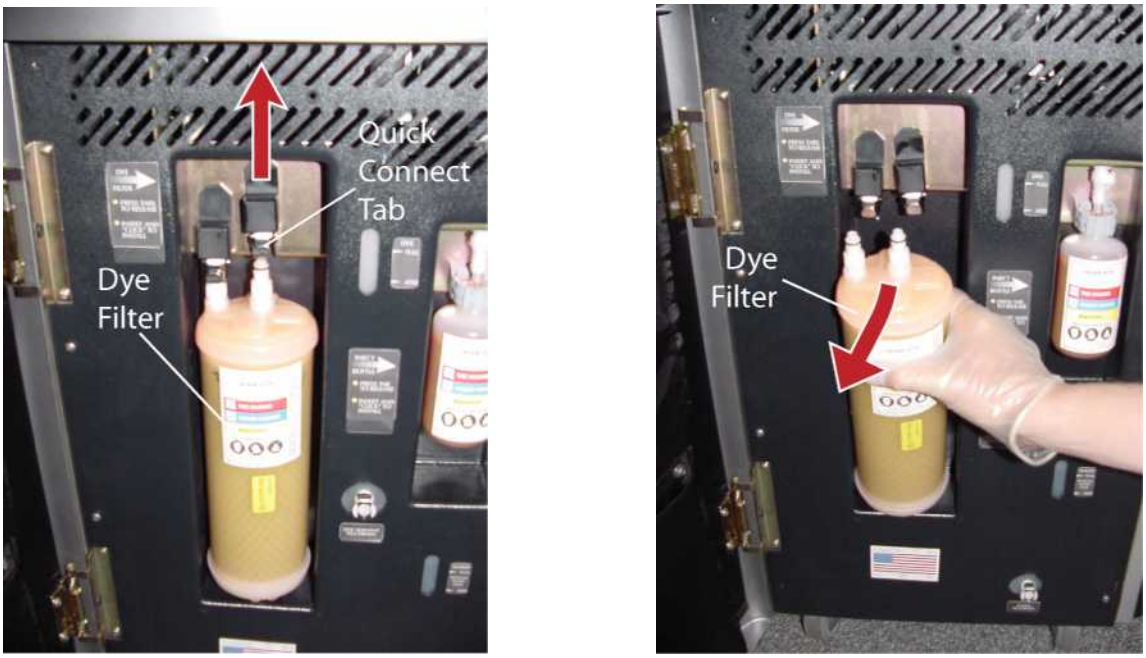

Figure 6A–Disconnecting and Removing Dye Filter

4. Once the dye filter connectors are disengaged from the fittings, slide the dye filter down and away from the laser, as shown in right side of **Figure 6A**.
5. Reverse steps 3-4 to install a new filter. Be sure that the two quick-disconnects are fully seated and “click” in place.

6. Remove the dye inject bottle by squeezing the tab of the quick-disconnect, and then pulling the bottle down and away from the fitting. See left side of **Figure 6B**.

Figure 6B–Detaching/Inserting Dye Inject Bottle

7. Unsnap the gray clamp to loosen.
8. Reverse steps 6-7 to install a new dye filter bottle. Once the fluid connections are made, squeeze the gray clamp to fasten. See right side of **Figure 6B**.
9. Turn on the laser.
10. Reset the PDL count reset button located on the Utility screen, as detailed on page 31. The dye kit count in the system status area of the Utility screen should read zero.

Troubleshooting

Faults

The user may encounter faults while operating the laser system. When a fault occurs a fault code appears on the display followed by a brief text message. There are two types of faults: 1) errors, or 2) warnings.

Errors faults are critical and will cause the laser to stop operating. These faults codes begin with the prefix 'E' meaning error. Some of these errors require that you contact the Cynosure Service Department.

Warnings are faults that indicate an improper laser state or operator error. These fault codes begin with the prefix 'W' meaning warning. For example, an attempt to fire the laser without a fiber present causes a warning fault to occur. The operator can usually correct these faults.

All faults codes and messages are listed in the following table, along with the probable cause and corrective action if applicable.

Fault Code Table

Fault Code and Text Message		Probable Cause/Corrective Action
E01	Water Flow Fault; Cycle Power	Broken water pump or blown fuse. Needs service.
E02	Open Shutter Fault	Safety shutter stuck closed. Do not use laser until serviced.
E03	Close Shutter Fault	Safety shutter stuck open. Do not use laser until serviced.
E04	Fuse Open; Call Service	Blown capacitor bank fuse or shorted dump circuit. Needs service.
E05	Checksum Error; Call Service	Computer program memory error. Needs service.
E07	IGBT Fault - YAG	YAG IGBT overload sensed. Cycle power to continue.
E08	Heater Fault; Call Service	Open thermostat or heater. Blown heater fuse. Needs service.
E09	Coolant Sensor Fault; Call Service	Open thermistor sensor or unplugged. Needs service.
E10	No High Voltage	Capacitor bank or HVPS wire shorted. No read back voltage. Needs service.
E13	No Simmer YAG	Broken lamp or blown fuse. Needs service.
E14	HVPS Fault	HVPS over-temperature.
E15	Dump Fault; Call Service	Fuse fault at power up. Needs service.
E16	Dump Fault; Call Service	Dump always on. Needs service. Dump shorted. Failed dump TX. HVPS failed.
E17	Dump Fault; Call Service	Dump not working. Needs service. Fiber connections broken to cap bank. HVPS disconnected or failed.
E18	H2o Flowmeter	Defective water flow sensor. Needs service.
E19	HVPS Fault	HVPS over-voltage or open-circuit.
E23	Low Trans; Replace Fiber/Handpiece	Damaged fiber, handpiece or focus lens, needs replacement.
E24	YAG Calibration Error; Call Service	Incorrect Resonator Port or Cal Port sensor calibration. Needs service.
E25	YAG Cal Failed, Energy Low; Call	YAG cal port energy too low to use. Needs service.

Fault Code and Text Message		Probable Cause/Corrective Action
	Service	
E26	No Energy; Check Fiber/Handpiece	Broken fiber or severely damaged focus lens. Needs replacement.
E27	DYE Flow Fault	No dye filter or it is not installed properly. Broken pump. Blown fuse
E28	IGBT Fault - Dye	Dye IGBT overload sensed. Cycle power to continue.
E29	IGBT Fault - Pulse Simmer	Pulse simmer IGBT overload sensed. Cycle power to continue.
E30	No Simmer PDL	Broken lamp or blown fuse. Needs service.
E32	Flow Switch DYE	Broken dye pump or blown fuse. Needs service.
E33	PDL Calibration Error, Call Service	Transmission too high. Miscalibrated resonator or cal port sensor. Needs service.
E34	PDL Cal Failed, Energy Low; Call Service	Low delivered dye energy. Needs service
E35	PDL Misfire	Possible dye simmer fault. Service if problem reoccurs.
E36	YAG Misfire	Possible yag simmer fault. Service if problem reoccurs.
E37	Simmer Sensor PDL	Failed dye simmer control module. Needs service.
E38	Simmer Sensor YAG	Failed YAG simmer control module. Needs service.
E39	HVPS Adjust Error	HVPS readback incorrect. Defective HVPS. Needs service.
E40	PDL and YAG Cal Failed, Call Service	Fiber, handpiece, or focus lens damaged. Needs service.
E41	Display Fault; Call Service	Corrupted internal display files. Needs service.
E42	Blocking Diode; Call Service	Shorted blocking diodes. Needs service.
E43	Ext Shutter	Shutter positioning failure on power-up. Retry. If continued failure, do not use laser until serviced.
E44	Keypad	Object on touchscreen. Broken touchscreen.
E45	File Open Error; Call Service	Defective compact flash memory card. Corrupted internal files. Needs service.
E46	PDL Temp Sensor Fault; Call Service	Open dye thermostat or heater. Blown heater fuse. Needs service.
E47	Internal Math Error; Call Service	Corrupted program or data file. Needs service.
E48	Checksum Error; Call Service	Computer calibration data error. Needs service.
W50	Open Interlock; Check Interlock	Install remote interlock connector or, if using interlock, close laser room door.
W51	No Fiber; Connect Fiber	Install delivery fiber and handpiece.
W52	Wavelength Unavailable	Wavelength use disabled. See second line message for the reason.
W53	Low Water; Add Water	Water is low. Add water to reservoir.
W54	HVPS EOC Warning	High fluence when using 120 VAC. Press standby to continue using laser.
W56	Invalid Handpiece; Change Handpiece	Handpiece from another laser model or handpiece not allowed for selected wavelength. Install correct handpiece.
W57	No Handpiece; Install Handpiece	Install handpiece.
W58	Handpiece Changed	Handpiece changed. Press screen message box to continue.
W59	Low Trans; Check Fiber and	Fiber, handpiece, or focus lens damaged but still

Fault Code and Text Message		Probable Cause/Corrective Action
	Handpiece	useable.
W60	YAG Cal Failed, Energy Low; Call Service	Low delivered yag energy. Needs service
W61	PDL Cal Failed, Energy Low; Call Service	Low delivered dye energy. Needs service
W63	Fluence Meter Error; Call Service	Miscalibrated cal port meter. Defective cal port. Needs service.
W64	Internal Meter Error; Call Service	Miscalibrated res port meter. Defective res port. Needs service.
W65	Energy Out of Range, YAG	Capacitor bank did not recharge properly or overcharged. Retry operation.
W66	Handpiece Removed	Handpiece removed from cal port during system check or calibration.
W67	Unable to Reach Fluence; Decrease	Max fluence reached for handpiece and/or treatment settings. Lamps near end-of life.
W68	Schedule Lamp Change, PDL	Lamps for dye laser approaching end-of-life. Schedule lamp replacement.
W69	Schedule Lamp Change, YAG	Lamps for Nd:YAG laser approaching end-of-life. Schedule lamp replacement.
W70	Coolant Over Temp; Let Laser Cool	Water is too hot for continued operation. Fans are on to cool laser. Let laser cool.
W71	Add Water Soon	Water level low - refill water reservoir.
W72	Energy Out of Range, PDL	Capacitor bank did not recharge properly or overcharged. Retry operation.
W73	PDL Over Temp; Let Laser Cool	Dye is too hot for continued operation. Fans are on to cool laser. Let laser cool.
W74	Warning: Purge Dye Concentrate Bottle	Air in dye line, squeeze bottle
W75	Dye Mix Warning; Call Service	<ABS 0.85 after 30 min cycle (30 injects)

Self Test

During startup, the laser runs a self test. If the fault occurs during this process, consult the fault code chart above for information on resolving the fault.

Troubleshooting Chart

Problem	Possible Cause	Solution
Laser does not turn on.	Power lines are not properly connected.	Check and secure power cables.
	Laser circuit breaker is in OFF position.	Turn on circuit breaker (near power cord in back.
	Main panel circuit breaker of wall service is in OFF position.	Turn circuit breaker on at panel.
	Key switch is not in the ON position.	Turn the key switch to the ON position.
Laser turns on (display lights and pumps on), but does not stay running.	Multiple causes: Self check failure displayed	Follow prompt on text message area to resolve. If unable to resolve, call Cynosure Service Dept.
Laser does not go into the PDL mode.	Dye solvent is not warmed up to 40 °C	Wait for warm up.
Laser unable to inject dye during warm-up mix cycle	Extremely low dye concentration Inject bottle depleted	Check dye inject bottle is properly connected and that the dye inject bottle is not empty.
	Air in inject lines	Turn system off, gently squeeze inject bottle for approximately 5 seconds to remove air bubbles. Check ABS reading. Manually press dye inject button via the Option screen to speed up process. If unable to resolve, call Cynosure Service Dept.
Laser does not enter Ready or Standby modes.	The delivery optical fiber or handpiece is disconnected.	Connect the optical fiber and the electrical connector to the handpiece.
The laser does not fire from Ready mode.	Foot switch is not connected or hand switch wires are broken.	Fully seat foot switch connection and make sure hose is not kinked or crushed by equipment. Replace handpiece to try another.
Laser will not enter Ready mode from Standby mode	Foot switch or hand switch is depressed	Release switch.

NOTE: If any problems occur that are not covered in the troubleshooting chart, or the suggested solutions do not work, call the Cynosure Service Department, see page 66 for contact information.

Transferring Diagnostic Data

During a live troubleshooting event, you may be asked to download data from the laser via a USB stick (use only a SanDisk USP flash drive with a minimum of 128 MB storage) and forward that data to Cynosure service personnel for analysis. This data helps service personnel to diagnose the condition of the laser and be prepared should a service call be necessary. To access the USB slot and download data, follow these steps.

1. Open the front door of the laser, and locate the access panel that covers the USB slot, see **Figure 7A**.
2. Using a flathead screwdriver or a coin, turn the access panel screw one quarter turn to the right. Take off the panel and place aside.

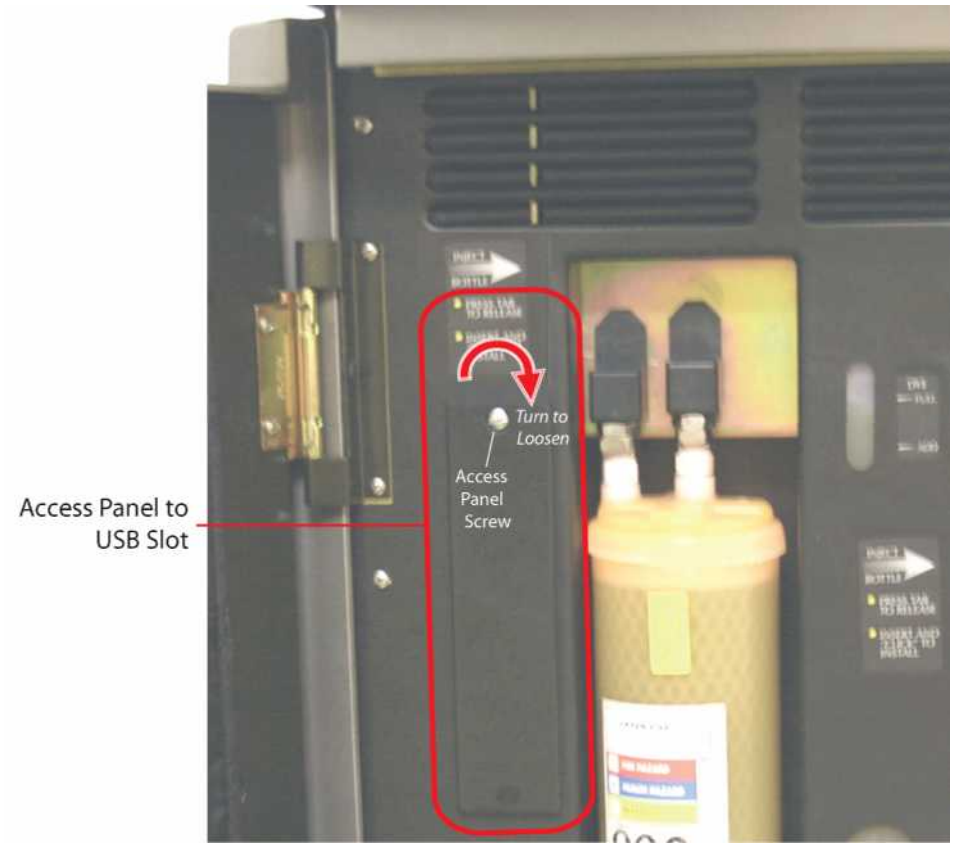

Figure 7A–USB Access Panel Location

3. Once the panel is off, locate the USB slot, and then insert the USB stick into the slot. See **Figure 7B**. Make sure the LED is illuminated on the USB stick.

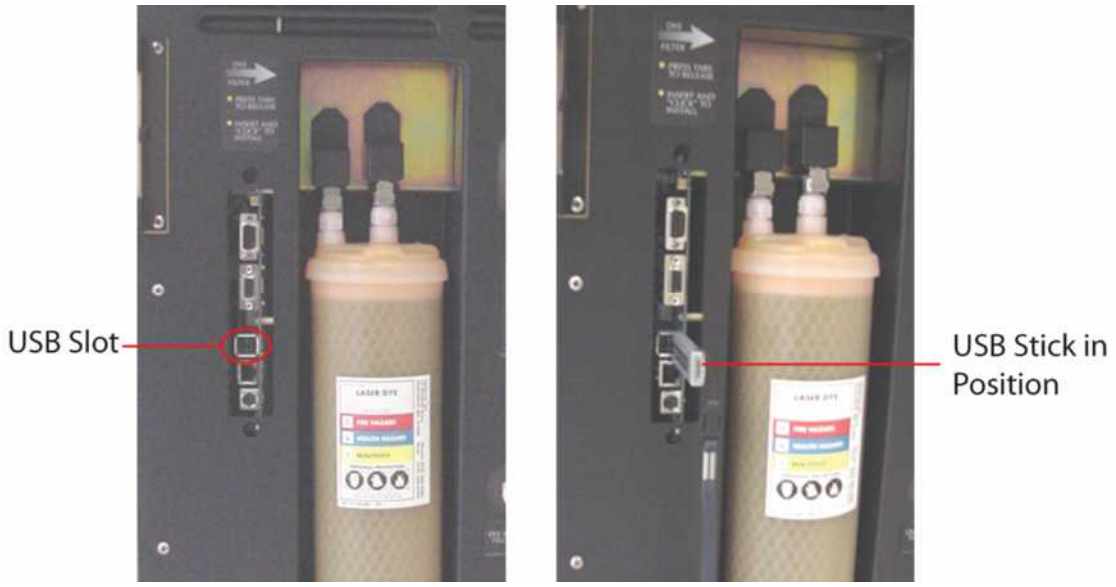

Figure 7B–USB Slot Location

4. Verify that the laser is on and the handpiece is in the Cal Port.
5. Initiate and complete a System Check.
6. Access the Option Screen from the Utility Screen from the Home Screen. Press Diagnostic on the Option Screen. This initiates a test sequence lasting several minutes where the laser fires into the cal port.
7. When the report is complete a summary will appear on the screen. Press Dump Data to USB to download results to USB stick.
8. Remove the USB stick from the slot, and then email the data files electronically as directed by Cynosure service personnel.
9. Replace the panel, and then tighten the screw in place by turning it in the opposite direction.

This section of the manual provides information regarding customer support, such as Warranty, Warranty Claims, Installation, Customer Service and a list of laser accessories.

Direct-Purchase Warranty

Please refer to the signed Warranty information detailed in the Terms and Conditions of your Sales Contract.

Distributor-Purchased Warranty

Since exact terms and periods may vary when a laser system is purchased through a distributor, contact your distributor for warranty information.

Warranty Claims

If merchandise is damaged and you want to return the merchandise for repair or replacement, please be aware of the following:

- You should make the claim as soon as possible.
- Before returning merchandise, obtain prior approval from Cynosure.
- Cynosure will provide shipping instructions.
- Returned merchandise must be sent insured and prepaid.
- The cost of shipping is the responsibility of the customer.
- Cynosure has the sole responsibility to determine the cause of merchandise defect.

Installation

Cynosure or its authorized personnel installs the laser, gives a demonstration of operation, and provides a basic training service for each new customer.

Customer Service

Scope of Service

Cynosure's Customer Service Policy includes the following support for customers:

- On-site customer training for operating the laser
- On-site repair and maintenance of laser
- Telephone troubleshooting

Service personnel make periodic safety checks and functional evaluations as a part of maintenance.

Contacting Customer Service

If there is a technical problem with the laser, contact the Cynosure Service Department.

Normal Business Hours	Monday–Friday, 7:30 am–7:00 pm EST Call: 1-888-523-2233; or fax to (978) 256-6556 or (978) 256-4888.
After Hours and Weekends	Call: 1-888-692-2966.

If there is a question regarding clinical information call Cynosure.

Normal Business Hours	Monday–Friday, 9:00 am–5:00 pm EST Call: 1-800-886-2966 ext. 443

CAUTION: This procedure should be performed by authorized service personnel only. See, "Laser Calibration," on page 40 for laser calibration performed by the operator.

Schedule for Calibration

Cynosure calibrates the laser's energy meter at the factory prior to shipment. The energy meter should be calibrated once a year by authorized service personnel. Call your local Cynosure representative to arrange for annual calibration by authorized personnel. The energy meter is calibrated by checking that the displayed fluence value corresponds to the actual laser pulse energy as measured by an independent energy meter of known accuracy.

Overview

The laser is provided with a built-in energy meter that allows the laser to be calibrated by measuring the actual energy delivered from the handpiece. Energy measurements are obtained by inserting the handpiece into the cal port, and then firing the laser. The front panel display indicates the energy per unit area (or fluence in joules per square centimeter, J/cm^2), taking into account the area of the laser focal spot for the handpiece in use.

The energy meter consists of these main components:

- The cal port built into the front panel. The cal port includes an internal switch to sense the presence of the handpiece, which allows the laser to fire while in calibration mode only if a handpiece is inserted.
- A sapphire window that protects the internals of the cal port and is damage resistant. It should be cleaned frequently using a tissue or cloth.
- A pinhole within the cal port that allows only a small fraction of the incident light through a fiber optic cable to an optical sensor.
- An optical sensor that receives the laser light incident on it, and produces an electrical signal proportional to the absorbed optical pulse energy. The signal is amplified and calibrated at the Laser Control PCB.
- A front panel display that shows the selected fluence in joules/cm^2.

Required Equipment

CAUTION: The accuracy of the calibration depends completely upon the measurement of laser pulse energy using a separate instrument as an independent calibration standard. If the calibration standard is inaccurate or not used correctly, then the built-in energy meter will also be inaccurate after calibration.

- An accurate, NIST-traceable, laser power meter for use as a calibration standard. The selected calibration standard must be accurate for the appropriate wavelength and range of pulse energies. The meter's sensor element or input attenuator must withstand, without damage, the range of fluence and peak power per unit area typical of the laser.
- Laptop computer with RS-232 interface

Calibration Procedures

There are three detectors in the system: 1) a resonator port that samples the full energy of the beam prior to coupling into the optical fiber, 2) a calibration port that samples the full energy leaving the handpiece, and, 3) the internal monitor for monitoring pulse-to-pulse stability of the dye laser. All three detectors must be calibrated as part of a complete service calibration. These calibration procedures are detailed in the following pages.

Before starting the calibration, however, verify that these preparatory steps are taken.

- Verify that the cal port window is clean.

  WARNING: Failure to keep the cal port window clean may result in incorrect calibration.
- Be sure that the fiber optic is properly routed and secured.
- Install a 7-mm handpiece.

Calibrating the Resonator Port, YAG

1. Remove the SMA focusing mount from the rail assembly.
2. Type ‘CV’ from the C:\ prompt**.**
3. Set laser to the following settings

   Wavelength = YAG

   CV Voltage = 450

   Pulse Width = 5 ms

   Rep Rate = 1 Hz
4. Set NOVA II power meter to the following settings:

   Laser type = “NIR”

   Average = 3 seconds
5. Connect NOVA II power meter analog out to laser J2.
6. Align the Ophir detector so it is facing toward the beam combiner output within 14 to 16 inches.
7. Fire the laser one shot, and then verify the energy pulse is not clipping on the Ophir detector head.
8. Set the CV Voltage to approximately 750V.
9. Continue to fire the laser adjusting the laser voltage until the NOVA II power meter reads from 44W to 46W. Make note of the NOVA II power meter reading.
10. Make note of the laser voltage setting.
11. Press lowercase ‘d’ to keep the external shutter closed while firing the laser.
12. Set laser resonator gain to 7.
13. Fire the laser six shots and read the resonator voltage from the CV screen.
14. Verify the voltage is from 0.5 to 1.25 volts.

    If the voltage is too low, increase the gain number (press uppercase ‘M’).

    If the voltage is too high, decrease the gain number (press lowercase ‘m’).
15. Fire the laser six shots again, and read the resonator voltage from the CV screen.
16. Make note of the resonator voltage.
17. Make note of the resonator gain.
18. Press lowercase ‘u’, and then enter the NOVA II power meter reading from step 9.
19. Fire the laser again into the resonator port, and then verify that the resonator energy measures from 43W to 47W.
20. Press lowercase ‘e’ to return the external shutter to normal function.

Calibrating the Resonator Port, PDL

1. Remove the SMA focusing mount from the rail assembly.
2. Type ‘CV’ from the C:\ prompt.
3. Set laser to the following settings

   Wavelength = PDL

   CV Voltage = 600

   Pulse Width = .5 ms

   Rep Rate = 1 Hz
4. Set NOVA II power meter to the following settings:

   Laser type = “VIS”

   Average = 3 seconds
5. Verify that NOVA II power meter analog out is connected to laser J2.
6. Align the Ophir detector so it is facing toward the beam combiner output within 14 to 16 inches.
7. Fire the laser one shot, and then verify the energy pulse is not clipping on the Ophir detector head.
8. Set the CV Voltage to approximately 700V.
9. Fire the laser adjusting the laser voltage until the NOVA II power meter reads from 7.5W to 8.5 W. Make note of the NOVAII power meter reading.
10. Make note of the laser voltage setting.
11. Press lowercase ‘d’ to keep the external shutter closed while firing the laser.
12. Set laser resonator gain to 2.
13. Fire the laser six shots and read the resonator voltage from the CV screen.
14. Verify the resonator voltage is from 0.5 to 1.25 volts.

    If the resonator voltage is too low, increase the gain number (press uppercase ‘M’).

    If the resonator voltage is too high, decrease the gain number (press lowercase ‘m’).
15. Fire the laser six shots again, and read the resonator voltage from the CV screen.
16. Make note of the resonator voltage.
17. Make note of the resonator gain.
18. Press lowercase ‘u’, and then enter the NOVA II power meter reading from step 9.
19. Fire the laser again into the resonator port, and then verify that the resonator energy measures from 7W to 9W.
20. Press lowercase ‘e’ to return the external shutter to normal function.

Calibrating the Cal Port, YAG

1. Remove the SMA focusing mount from the rail assembly.
2. Type ‘CV’ from the C:\ prompt.
3. Set laser to the following settings

   Wavelength = YAG

   CV Voltage = 700

   Pulse Width = 5 ms

   Rep Rate = 1 Hz
4. Set NOVA II power meter to the following settings:

   Range = “AUTO”

   Laser type = “NIR”

   Average = 3 seconds
5. Verify that NOVA II power meter analog out is connected to laser J2.
6. Position the handpiece, so that is facing the Ophir detector head.
7. Press lowercase ‘e’ to allow the external shutter to open when the laser is fired.
8. Fire the laser adjusting the laser voltage until the NOVA II power meter reads from 34W to 36W. Make note of the NOVA II power meter reading.
9. Make note of the laser voltage setting.
10. Move the handpiece to the cal port.
11. Set YAG cal port gain to 10.
12. Fire six shots into the cal port.
13. Verify cal port voltage reads from 0.50 to 1.25 volts.

    If the cal port voltage is too low, increase the gain number (press uppercase ‘C’).

    If the cal port voltage is too high, decrease the gain number (press lowercase ‘c’).

    NOTE: Most gain is 0; least gain is 15.
14. Fire the laser six shots again, and read the cal port voltage from the CV screen.
15. Make note of the cal port voltage.
16. Make note of the cal port gain.
17. Press uppercase ‘U’, and then enter the NOVA II power meter reading from step 8.
18. Fire the laser again into the cal port, and then verify that the cal port energy measures from 34W to 36W.

Calibrating the Cal Port, PDL

NOTE: Before this calibration is performed, the dye temperature should be approximately 39 °C.

1. Remove the SMA focusing mount from the rail assembly.
2. Type 'CV' from the C:\ prompt.
3. Set laser to the following settings

   Wavelength = PDL
   CV Voltage = 700
   Pulse Width = 5 ms
   Rep Rate = 1 Hz
4. Set NOVA II power meter to the following settings:

   Range = 30W
   Laser type = "VIS"
   Average = 3 seconds
5. Verify that NOVA II power meter analog out is connected to laser J2.
6. Position the handpiece, so that is facing the Ophir detector head.
7. Press lowercase 'e' to allow the external shutter to open when the laser is fired.
8. Fire the laser adjusting the laser voltage until the NOVA II power meter reads from 5W to 7W. Make note of the NOVA II power meter reading.
9. Make note of the laser voltage setting.
10. Move the handpiece to the cal port.
11. Set YAG cal port gain to 3.
12. Fire six shots into the cal port.
13. Verify cal port voltage reads from 0.50 to 1.25 volts.

    If the cal port voltage is too low, increase the gain number (press lowercase 'C').

    If the cal port voltage is too high, decrease the gain number (press uppercase 'c').

    NOTE: Most gain is 0; least gain is 15.
14. Fire the laser six shots again, and read the cal port voltage from the CV screen.
15. Make note of the cal port voltage.
16. Make note of the cal port gain.
17. Press uppercase 'U', and then enter the NOVA II power meter reading from step 8.
18. Fire the laser again into the cal port, and then verify that the cal port energy measures from 5.5W to 6.5W.

Guidance and Manufacturer's Declaration—Electromagnetic Emissions The *Cynergy* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Cynergy* should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment—Guidance**
RF emissions CISPR 11	Group 1	The *Cynergy* uses RF energy only for its internal function. Therefore, its RF emission is very low and is not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The *Cynergy* is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations / Flicker emissions IEC61000-3-3	Not Applicable	

Guidance and Manufacturer's Declaration—Electromagnetic Immunity The *Cynergy* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Cynergy* should assure that it is used in such an environment.			
Immunity Test	**IEC60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	± 1kV Line-to-Line ± 2kV Line-to-Earth	± 1kV ± 2kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC61000-4-11	< 5% U_t (> 95% dip in U_t) for 0.5 cycle 40% U_t (60% dip in U_t) for 5 cycles 70% U_t (30% dip in U_t) for 25 cycles < 5% U_t (> 95% dip in U_t) for 5 sec	Not Applicable Not Applicable Not Applicable < 5% U_t (> 95% dip in U_t) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *Cynergy* requires continued operation during power mains interruptions, it is recommended that the *Cynergy* be powered from an interruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_t is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The *Cynergy* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Cynergy* should assure that it is used in such an environment.			
Immunity Test	IEC60601 test level	Compliance level	Electromagnetic Environment—Guidance
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHZ to 2.5GHZ	3Vrms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the *Cynergy*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance d = 1.17*√(p) 150kHz to 80MHz d = 1.17*√(p) 80MHz to 800MHz d = 2.33*√(p) 800MHz to 2.5GHz where (p) is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol. 
NOTE 1: At 80MHz and 800MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *Cynergy* is used exceeds the applicable RF compliance level above, the *Cynergy* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *Cynergy*. [b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.			

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Cynergy

The *Cynergy* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Cynergy* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Cynergy,* as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter (m)**		
	150kHz to 80MHz d = 1.17*√(p)	**80MHz to 800MHz d = 1.17*√(p)**	**800MHz to 2.5GHz d = 2.33*√(p)**
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where (P) is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

NOTE 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CE 0050

Declaration of Conformity

We,

Cynosure, Inc., 5 Carlisle Road, Westford, MA, USA 01886
declare under our sole responsibility that the product

Type of equipment: Pulsed Dye Laser and Long Pulse Infrared Laser
Model designation: Cynergy
Model number: 105-0065-004
to which this declaration applies,
is in conformity with the following European, harmonized, and published standards:
Standards: EN60601-1, EN60601-1-2, EN60601-1-4, EN60601-2-22, EN60825-1

following the provisions of the Directives:
EMC Directive 89/336/EEC
Medical Device Directive 93/42/EEC

Cynosure's applied quality and design systems have been examined and certified per Registration No. MD19.2613 by the notified body, NSAI.

The name, address and phone number of the authorized EU representative is:

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