CVX-300®
CVX-300®-P

Excimer Laser System

Operator's Manual
Version A

Patent: www.spnc.com/patents

Preface

The CVX-300 is an excimer laser system approved for use in minimally invasive interventional procedures within the cardiovascular system, and for the removal of problematic pacemaker and defibrillator cardiac leads. The CVX-300 produces pulsed excimer radiation which is delivered to the target site with proprietary fiber optic catheter technology, or other approved instruments or accessories, to complete the system.

Notice

THE CVX-300 CONTAINS NO USER SERVICEABLE PARTS OR ASSEMBLIES.

SERVICE OF THE SPECTRANETICS CVX-300 LASER SYSTEM MUST BE PERFORMED ONLY BY A SPECTRANETICS CERTIFIED FIELD SERVICE ENGINEER IN ORDER TO AVOID RISKS TO INDIVIDUALS, CUSTOMERS AND/OR PATIENTS. SERVICE OF THE SPECTRANETICS CVX-300 REQUIRES SPECIAL TOOLS, EQUIPMENT AND/OR GASES, SOME OF WHICH MAY NOT BE COMMERCIALLY AVAILABLE, OR MAY ONLY BE AVAILABLE TO OR FROM THE SPECTRANETICS CORPORATION.

SPECTRANETICS ASSUMES NO RESPONSIBILITY OR LIABILITY FOR ANY SERVICE PROVIDED BY NON-CERTIFIED REPRESENTATIVES. SERVICE PERFORMED BY ANYONE OTHER THAN A SPECTRANETICS CERTIFIED FIELD SERVICE ENGINEER VOIDS ALL WARRANTIES (IF ANY) TO THE LASER SYSTEM AND/OR THE DISPOSABLE LASER CATHETER DELIVERY DEVICES.

SPECTRANETICS RESERVES THE RIGHT TO REFUSE TO SELL PRODUCTS OR SERVICES TO ANY CUSTOMER NOT IN COMPLIANCE WITH MANUFACTURERS RECOMMENDED SERVICE REQUIREMENTS.

Contents

Warranty

The Spectranetics Corporation ("Spectranetics") warrants that the CVX-300® Excimer Laser ("Laser") will meet the written specifications for the period described in the agreement between Spectranetics and the entity acquiring the Laser ("Customer"). This warranty will become immediately void in the event that any of the following conditions are not met or cease to be true:

(i) The Laser must be installed by a Spectranetics Certified Field Service Engineer;
(ii) The Laser must be operated and stored in accordance with the Operator's Manual;
(iii) All required and recommended maintenance must be performed on time by Spectranetics Certified Field Service Engineers using authorized parts, components, and gases;
(iv) The Laser must be kept in the proper operating environment and site requirements; and
(v) The Laser must be operated by trained personnel according to approved clinical guidelines using authorized disposable devices.

Spectranetics' sole obligation under this warranty shall be to provide all parts and labor required to cause the Laser to operate in accordance with the specifications during the warranty period.

Spectranetics will perform all warranty service and repairs during the normal business hours of 8:00 am to 5:00 pm at Customer's facility, Monday through Friday, excluding holidays. Customer is responsible for assuring that the Laser is accessible to Certified Field Service Engineers at the scheduled time. Customer will pay Spectranetics at its standard billing rates for: Warranty repairs requested outside of normal business hours; waiting time if the Laser is not available for scheduled maintenance; service made necessary as a result of Customer's failure to follow the requirements in the Operator's Manual; or service that is required due to any damage to the Laser from outside causes.

This warranty extends only to the entity that acquires the Laser from Spectranetics and will not extend to any successor of that entity.

Spectranetics makes no other warranties, expressed or implied. **Spectranetics specifically disclaims any implied warranty of merchantability or fitness for a particular purpose.**

In no event will Spectranetics be liable for any indirect, special, incidental, punitive, or consequential damages, including, but not limited to, loss of profits and/or loss of business, arising out of or resulting from use of the Laser or its failure to meet the terms of this warranty, even if Spectranetics has been advised of the possibility of such damages.

This limited warranty covers only the Laser. Information on Spectranetics' warranty relating to disposable items used with the Laser can be found in the documentation relating to those products.

Warnings and Responsibility

IMPORTANT

Read the Operator's Manual thoroughly before operating the Excimer Laser System CVX-300. Pay particular attention to the NOTES, CAUTIONS, and WARNINGS throughout this manual to ensure safe operating conditions at all times.
Also refer to the Instructions for Use which accompanies Spectranetics fiber optic catheters. Indications and contraindications are included in individual instructions for use for the CVX-300 disposables.

WARNING

The CVX-300 is a Class III medical device which contains a Class IV laser that produces an invisible beam of high-energy ultraviolet radiation. Improper use of the CVX-300 could result in serious personal injury. Observe all safety precautions for use of Class IV laser equipment.

WARNING

The CVX-300 contains high voltages which are potentially lethal. To avoid electrical shock, do not open the CVX-300 cabinet. Internal maintenance must be performed solely by a Spectranetics Certified Field Service Engineer.

WARNING

Laser system is not intended to be used during a defibrillation event.

DANGER

Possible explosion hazard if used in the presence of flammable anesthetics.

WARNING

Skin exposure to excimer radiation should be avoided.

WARNING

Move the Excimer Laser System carefully, and avoid jarring or sudden impacts. Disconnect and store the footswitch before moving the laser system. Do not run over power cables with the system. Depress the brake bar to lock the wheels when the Excimer Laser System is positioned for use. Lift up on the brake bar to release wheels.

CAUTION

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

WARNING

Use only fibers and catheters approved by Spectranetics in the CVX-300 system. The Spectranetics laser fiber optic catheters are supplied sterile. Sterility is guaranteed only if the package is unopened and undamaged.

WARNING

Use care when handling the fiber optic catheter to ensure the distal or proximal fibers are not chipped or scratched.

WARNING

Bypassing the warm-up period if the system has been off for longer than 30 seconds may damage internal components and render the CVX-300 Excimer Laser System inoperable.

NOTICE

The CVX-300 is intended for use only by licensed physicians. All persons who operate and service this equipment must be properly trained.

CAUTION

The CVX-300 is designed for continuous operation with intermittent loading. In procedures which exceed 50,000 laser pulses, the CVX-300 must be allowed to idle in Standby Mode for a minimum of one (1) hour.

NOTICE

The CVX-300 contains a gas mixture that is 0.05% HCl, a respiratory irritant. To avoid injury, only a trained and certified Spectranetics Field Service Engineer should handle the laser gas.

CAUTION

Federal Law restricts this device to the sale or on the order of a physician.

RESPONSIBILITY

Spectranetics is not responsible for injury or damage resulting from improper use of the CVX-300 equipment. If there is any doubt concerning the use of the CVX-300 or the Operator's Manual, contact Spectranetics immediately for assistance.

CUSTOMER understands that the Equipment is manufactured with substances that are considered hazardous to the environment and cannot be disposed of directly. In the unlikely event that CUSTOMER wishes to remove the Equipment from service, they may elect to return the system (at their expense) to SPECTRANETICS. Once the Equipment is received, Spectranetics will bear the cost of properly disposing of and/or recycling the raw components according to law.

Specifications

The excimer laser is a pulsed laser with the following nominal specifications.

Active Medium	XeCl
Wavelength	308 nm
Catheter Output Fluence*	30 - 80 mJ/mm^2
Repetition Rate Range*	25 - 80 Hz
Pulse Width	125-200 ns, FWHM
Weight	750 lbs / 340 kg
Length	49 in / 125 cm
Height	35 in / 89 cm - unit
	7-9 in / 18-23 cm - control panel
Width	25 in / 62 cm
	(All Dimensions Approximate)
Power Requirements	200 – 230 V ~ - Single Phase
	50/60 Hz
	16 Amp

Environmental Specifications
- Operating temperature: 12 °C to 30 °C (54 °F to 86 °F)
- Storage temperature: 12 °C to 30 °C (54 °F to 86 °F)
- Operating humidity: 20 to 95% relative humidity, non-condensing
- Storage humidity: 20 to 95% relative humidity, non-condensing

System footswitch is IPX8 rated.

Accessories: power cord, footswitch, interlock plug, safety glasses, and Spectranetics approved fiber optic catheters.

Environment: Avoid exposing the laser system to extreme temperatures (below 54 °F or 12 °C, above 86 °F or 30 °C). If the system is exposed to conditions outside of the listed ranges, a service visit may be required to perform maintenance prior to returning the system to use.

*** Dependent on fiber optic catheter in use and the CVX-300 software installed; see the Instructions for Use documentation supplied with each fiber optic catheter for specific information.**

Safety Precautions

1. The laser must be operated only by trained personnel.
2. Establish a controlled-access laser operating area to limit access to persons instructed in the safe operation of lasers.
3. Post "LASER IN OPERATION" warning signs at all entries to the laser operating area.
4. Persons in the laser operating area including doctors, nurses, observers and the patient must wear the appropriate protective eyewear and protective gloves. Protective eyewear of 5 or greater at a 308 nanometer (nm) wave-length must be worn when operating the laser system. The laser safety glasses must state the OD rating and wavelength on the lens or on the side shields. Spectranetics offers safety glasses that may be purchased by calling Customer Service. Sources of information about eye protection include: Rockwell Laser Institute (rli.com) and Ultra-Violet Products (uvex.com).
5. Never look directly into the laser beam.
6. Avoid uncontrolled reflections of the laser beam.
7. Skin exposure to excimer laser radiation should be avoided.
8. Do not allow direct or reflected laser radiation to go beyond the laser operating area.
9. When not in use, the laser system should be protected against unauthorized use by removing the key.

Nominal Ocular Hazard Distance (NOHD)

The nominal ocular hazard distance (NOHD) is defined by the American National Standard (ANSI®) Z136.1 as the distance along the axis of the unobstructed beam from a laser, fiber end, or connector to the human eye beyond which the irradiance or radiant exposure is not expected to exceed the applicable maximum permissible exposure (MPE) limits.

All laser energy produced by the CVX-300 Excimer Laser System, when operated in accordance with this manual, is enclosed within the CVX-300, the Spectranetics Fiber Optic Device or within the body except during the calibration of the fiber optic device (refer to the CVX-300 Excimer Laser System Operating Instructions and precautions in this manual).

During these short calibration periods, the energy output from the laser is not contained and the operator should be aware of the NOHD from the tip of the fiber. A 2.5 mm fiber optic device emits the highest amount of energy during calibration.

The Fiber NOHD was calculated with the system in the Normal Operating Mode during Calibration utilizing the following values;

Exposure time	20 seconds
Energy at tip of catheter	76.5 mJ
Fiber Tip Diameter	2.5 mm
Repetition Rate (calibration)	25 Hz
Numerical Aperture of the fiber optic	0.22
Wavelength	308 nM
Pulse Width	135 nS
Repetitively Pulsed	Yes

Using the ANSI® Z136.1 standard, the fiber NOHD can be calculated as **1.35 meters** (53.1 inches) from the distal tip of the 2.5 mm Reference Catheter device during calibration.

Always wear the appropriate laser safety glasses when using this equipment and follow all safety precautions as outlined within this manual.

EMC Precautions

Special precautions are required regarding the Electromagnetic Compatibility (EMC) of the CVX-300. The CVX-300 needs to be installed and put into service according the EMC information provided in this manual.

Portable and Mobile Radio Frequency (RF) communications equipment can affect any medical electrical equipment including the CVX-300.

Only cables and accessories provided by Spectranetics may be used with the CVX-300. The use of any other cable or accessories may have an adverse effect on the Electromagnetic Compatibility of the CVX-300 such as increased emissions or decreased immunity.

The CVX-300 should not be used adjacent to or stacked with other equipment. Should use adjacent to other equipment become necessary, the CVX-300 should be observed to verify normal operation in that configuration.

Table 201 (EN 60601-1-2)

<table>
<tr><th colspan="3">Guidance and Manufacturer's Declaration- Electromagnetic Emissions</th></tr>
<tr><td colspan="3">The CVX-300 is intended for use in the electromagnetic environment specified below. The customer or the user of the CVX-300 should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The CVX-300 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The CVX-300 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.</td></tr>
<tr><td>Harmonic Emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage Fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Table 202 (EN 60601-1-2)

Guidance and Manufacturer's Declaration- Electromagnetic Emissions			
The CVX-300 is intended for use in the electromagnetic environment specified below. The customer or the user of the CVX-300 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment- guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2 IEC 60601-1-2 4.0 2014-02	± 6 kV contact ± 8 kV air ± 8 kV contact ± 15 kV air	± 6 kV contact ± 8 kV air ± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	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. IEC 61000-4-11	<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.	100% dip for 0.5 cycles 60% dip for 5 cycles 30% dip for 25 cycles 100% dip for 5 seconds	Mains power quality should be that of a typical commercial of hospital environment. If the user of the CVX-300 requires continued operation during power mains interruptions, it is recommended that the CVX-300 be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) magnetic field IEC 61000-4-8 IEC 60601-1-2 4.0 2014-02	3 A/m 30 A/m	3 A/m 30 A/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.			

Table 204 (EN 60601-1-2)

Guidance and manufacturer's declaration – Electromagnetic Immunity			
The CVX-300 is intended for use in the electromagnetic environment specified below. The customer or the user of the CVX-300 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment- guidance**
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	3 V rms	Portable and mobile RF communications equipment should be used no closer to any part of the CVX-300 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = (3.5/3)\sqrt{P}$ $d = (3.5/3)\sqrt{P}$ 80 MHz to 800 MHz $d = (7/3)\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	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).
IEC 60601-1-2 4.0 2014-02	3 V/m 80 MHz to 2.7 GHz		Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol. 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, 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 CVX-300 is used exceeds the applicable RF compliance level above, the CVX-300 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CVX-300. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 206 (EN 60601-1-2)

Recommended separation distances between portable and mobile RF communications equipment and the CVX-300			
The CVX-300 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CVX-300 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CVX-300 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**		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.0
10	3.7	3.7	7.4
100	12	12	12
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 80 MHz and 800 MHz, 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.			

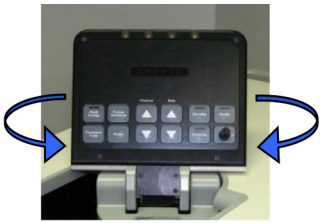
Stowable Control Panel / Energy Detector

Some CVX-300 Excimer Laser Systems have a control panel and an energy detector that can be stowed when not in use. This section will describe how these features are used.

Stowable Control Panel

When the laser system is not in use, the control panel may be folded flat.

To raise the control panel, lift up on the handle.



When the control panel is raised, it may be rotated 90° left or right for easy access.

NOTICE

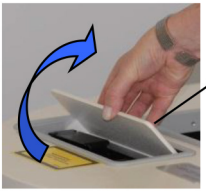
The control panel may only be stowed when the panel is rotated to face the front of the unit.

Do not attempt to rotate the control panel beyond its stops.

When stowing the control panel, keep fingers and hands out of the way.

Stowable Energy Detector

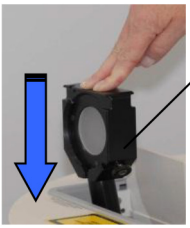
The Energy Detector is located to the left of the laser/catheter coupler. The Energy Detector is used to calibrate fiber optic catheters prior to use, and must be pulled up into position to facilitate system calibration.



Open Protective Cover

Extend the Energy Detector to the fully up position

Return the Energy Detector to the storage position by pushing it back into the unit and closing the protective cover.



Push Energy Detector back into the unit and close the Protective Cover

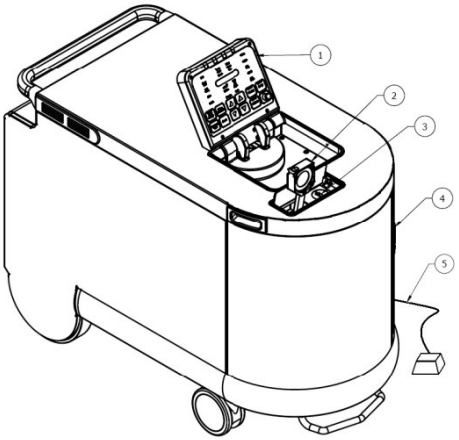
NOTICE

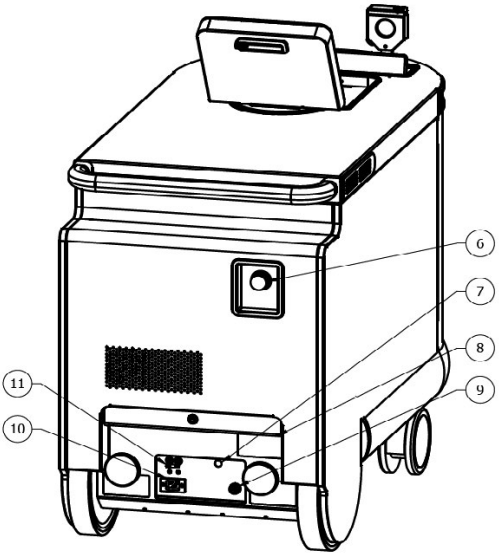
At no time should the energy detector or its mounting pole be used in an attempt to move the CVX-300.

As with all CVX-300 units, it is necessary to keep the area around the Catheter Connector, Energy Detector, and Control Panel clean, dry and free of contaminants.

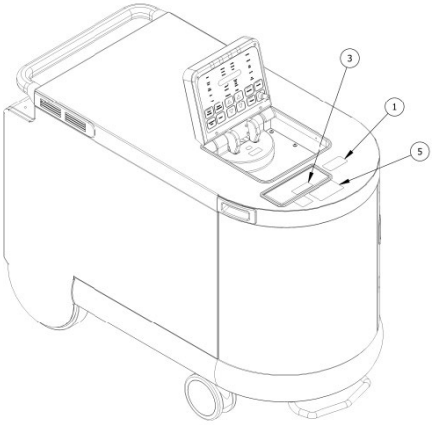
CVX-300-P Components

1. Control Panel
2. Energy Detector
3. Catheter Connector
4. Front Storage Compartment
5. Footswitch (IPX8 rated)
6. Emergency Button
7. Footswitch Connector
8. Interlock Plug
9. Potential Equalization (PE)
   (Optional PE cable provided based on destination country)
10. Power Connector
11. Main Circuit Breaker





CVX-300-P Labeling



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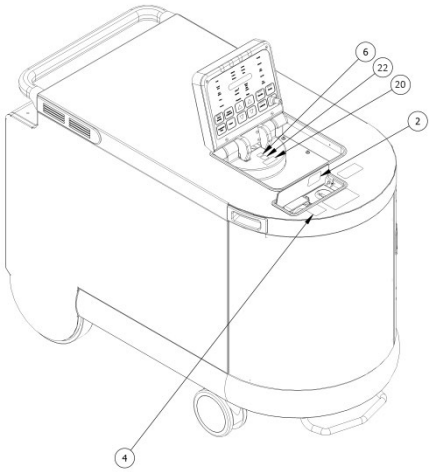
CUSTOMER SERVICE
FIELD SERVICE
SALES
1-800-231-0978
Spectranetics

2

LASER APERTURE
VISIBLE AND/OR INVISIBLE RADIATION EMITTED AT DISTAL END OF CATHETER
CAUTION
DIRT AND LIQUIDS MAY DAMAGE OPTICAL SYSTEM, KEEP FREE OF CONTAMINATION

3

CVX-300®
3.818
MAXIMUM REPETITION RATE
80 Hz



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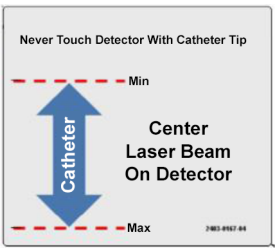

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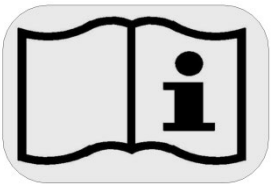

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(Follow Instructions for Use)

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Operators Manual at:
www.spnc.com/ifulibrary

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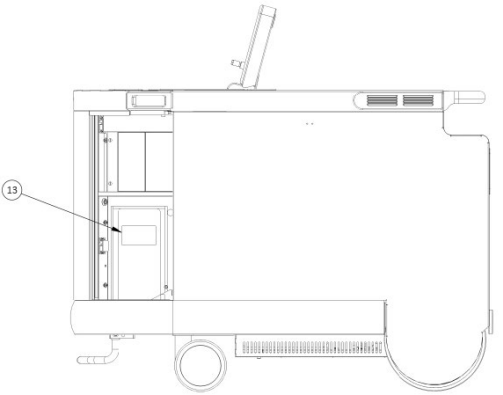
Catheter Output Fluence: 30-80 mJ/mm²
(dependent on device)
Pulse Width: 125 nS – 200 nS
Wavelength: 308 nm
Class 4 Laser per EN 60825-1:2007-03



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DANGER

VISIBLE AND INVISIBLE LASER RADIATION
AVOID EYE OR SKIN EXPOSURE
TO DIRECT OR SCATTERED
RADIATION

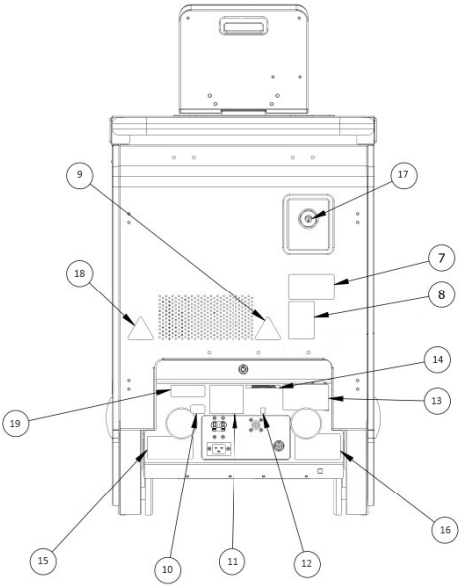
INVISIBLE OUTPUT

MAX AVG. POWER 20 WATTS
MAX ENERGY 400 mJ / PULSE
PULSE DURATION 125 – 200 NSEC
WAVELENGTH 308 NM

VISIBLE OUTPUT

MAX POWER 4 MW
WAVELENGH 670 NM
CLASS IV LASER PRODUCT
PER EN 60825-1:2007-03

POSSIBLE EXPLOSION
HAZARD IF USED IN THE
PRESENCE OF FLAMMABLE
ANESTHETICS

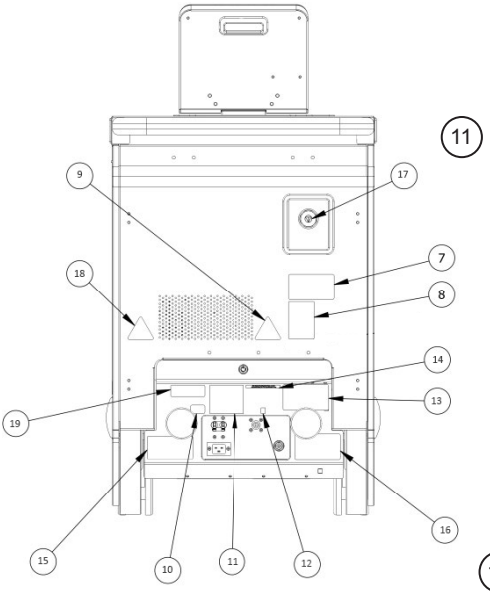


9

(Laser Radiation)

10

(Robert A. Golobic Memorial Label –
Spectranetics Founder)



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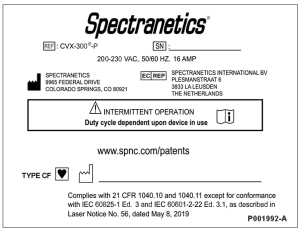

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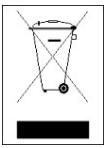

(WEEE)

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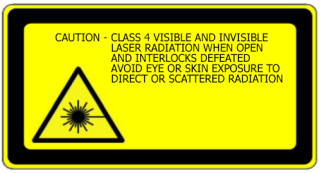

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This Device Has Received Class A Level Remanufacturing By The Spectranetics Corp.

(Label on Remanufactured CVX-300 Only)

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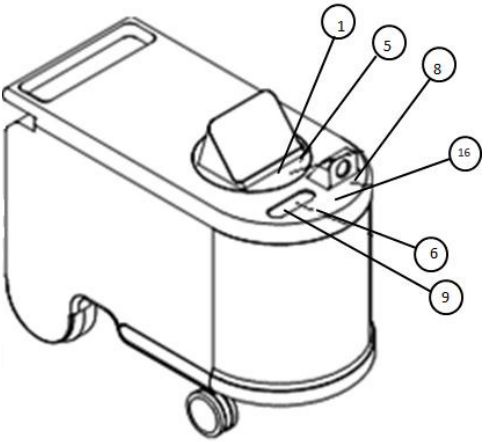
(Emergency Stop)

18

(Non-Ionizing Radiation)

19

CVX-300 Labeling



1

CUSTOMER SERVICE
FIELD SERVICE
SALES

1-800-231-0978

Spectranetics

2

Spectranetics

REF: CVX-300® SN:

200-230 VAC, 50/60 HZ. 16 AMP

SPECTRANETICS
6060 FEDERAL DRIVE
COLORADO SPRINGS, CO 80921

EC REP SPECTRANETICS INTERNATIONAL BV
PLESMANSTRAAT 6
3833 LA LEUSDEN
THE NETHERLANDS

INTERMITTENT OPERATION
Duty cycle dependent upon device in use

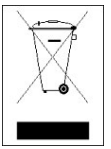
www.spnc.com/patents

TYPE CF

CERTIFIED AS REQUIRED BY 21 CFR
CHAPTER 1, SUB CHAPTER J (1040.10, 1040.11)
(U.S. ONLY)

2403-0425-A

3



(WEEE)

6

AVOID EXPOSURE -
LASER RADIATION IS
EMITTED FROM THIS APERTURE

4

(Robert A. Golobic Memorial Label – Spectranetics Founder)

7

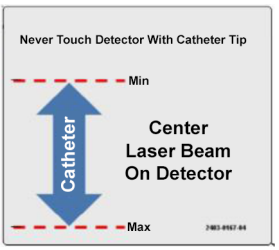
CAUTION - VISIBLE AND INVISIBLE LASER RADIATION WHEN OPEN

CAUTION - CLASS 4 VISIBLE AND INVISIBLE LASER RADIATION WHEN OPEN AND INTERLOCKS DEFEATED AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION

5

(Operating Instructions)

8



9

LASER APERTURE
VISIBLE AND/OR INVISIBLE RADIATION EMITTED AT DISTAL END OF CATHETER

CAUTION
DIRT AND LIQUIDS MAY DAMAGE OPTICAL SYSTEM, KEEP FREE OF CONTAMINATION

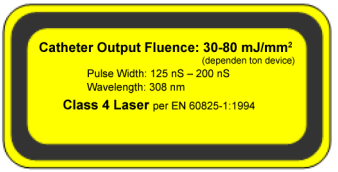
10

(Emergency Stop)

12

(Laser Radiation)

11



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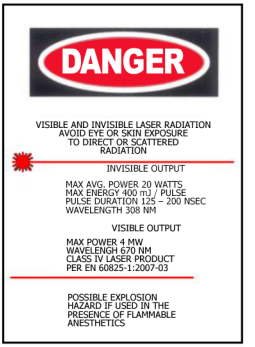

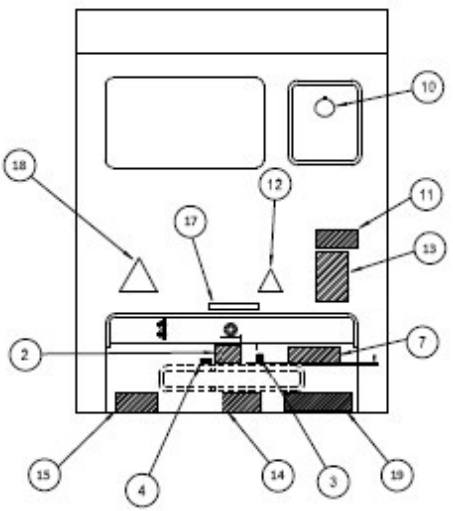

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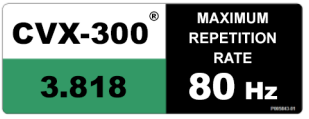


15

17

This Device Has Received Class A Level Remanufacturing By The Spectranetics Corp.

18

19

CVX-300 Markings

Outside:

Equipotentiality

FOOTSWITCH

Footswitch Connector

MAINS (16A) (US/CANADA/EU)

Main Circuit Breaker

Laser Radiation

Warning, Danger, Caution

Follow Operating Instructions

WEEE
(Waste from Electrical and Electronic Equipment)

Type CF

Emergency Stop

Follow Instructions for Use

Non-Ionizing Radiation

Operators Manual at:
www.spnc.com/ifulibrary

World Wide Web Address

UDI Label

Manufacturer

Date of Manufacture

EC REP

Authorized Representative in the European Community

REF

Catalogue Number

SN

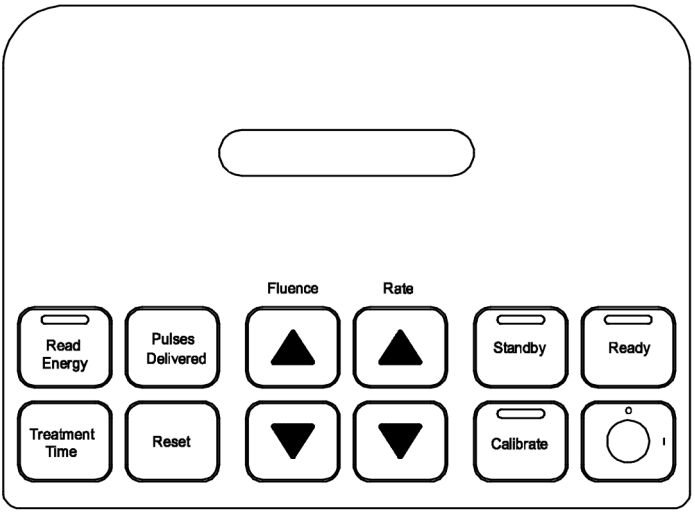
Serial Number

Inside:

Protective Earth (ground)

Dangerous Voltage

Control Buttons



Calibrate: Depressing the **Calibrate** button places the Excimer Laser System in **Calibrate** mode. The **Calibrate** button is illuminated.

Fluence: The **Fluence** button adjusts the output energy of the Excimer Laser System. The fluence value is increased or decreased by depressing the appropriate **Fluence** button. The current fluence value is visible in the display window and the **mJ/mm²** indicator light is illuminated. A brief press of either the increase or decrease **Fluence** button while in other operating modes shows the current fluence value. Depressing either the increase or decrease **Fluence** buttons for one second or longer changes the fluence value accordingly.

Pulses Delivered: Depressing the **Pulses Delivered** button enables the total number of pulses during a procedure to be visible in the display window.

Rate: The **Rate** button adjusts the pulse repetition rate of the Excimer Laser System. The rate is increased or decreased by depressing the appropriate **Rate** button. The repetition rate is visible in the display window and the **Pulses/Second** indicator light is illuminated. A brief press of either the increase or decrease **Rate** button while in other operating modes shows the current repetition rate. Depressing either the increase or decrease **Rate** button for one second or longer changes the repetition rate accordingly.

Read Energy: Depressing the **Read Energy** button enables the fiber output energy read by the calibration detector to be visible in the display window. The **Read Energy** button will be illuminated.

Ready: Depressing the **Ready** button places the Excimer Laser System in **Ready** mode. If the Excimer Laser System has not been calibrated, the **Ready** button is not active.

Reset: The **Reset** button is used in combination with the **Standby** button, **Pulses Delivered** and **Treatment Time** buttons.

Standby: If the system is in either **Ready** or **Calibrate** mode, depressing the **Standby** buttons places the Excimer Laser System in **Standby** mode. The **Standby** button and the green status light are illuminated.

Keyswitch: The keyswitch is the power control for the Excimer Laser System.

In case of emergency, the Excimer Laser System can be powered down by depressing the **Emergency Shutoff** located on the back panel. Caution should be taken not to activate the **Emergency Button** accidentally. To reactivate the system, rotate the Emergency Shutoff clockwise until it ascends and turn the keyswitch to the OFF (◯) position and then to the ON (|) position. Refer to the **Reset and Standby** and **Warning** below to bypass the CVX-300 Excimer Laser warm-up.

Treatment Time: Depressing the **Treatment Time** button enables the total lasing time of the procedure to be visible in the display window.

Reset and Pulses Delivered: The **Reset** and **Pulses Delivered** buttons are depressed simultaneously to reset the total pulses delivered during the procedure.

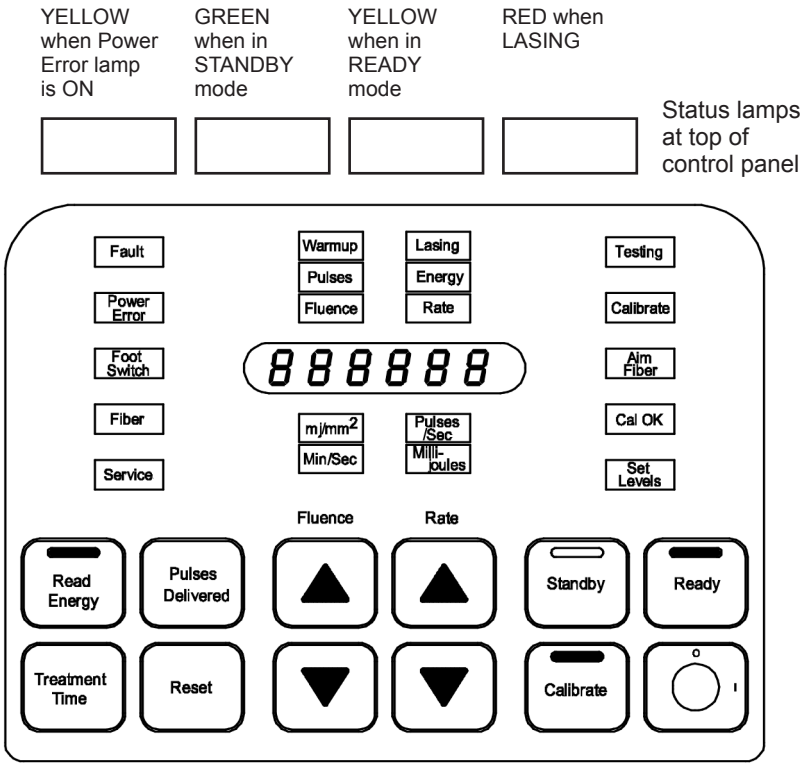
Reset and Standby: The **Standby** and **Reset** buttons are depressed simultaneously to bypass the five minute warm-up phase if the Excimer Laser System parameters, fluence and rate, are set. The CVX-300 must not be off for longer than 30 seconds in order to use this feature. See Warning below.

Reset and Treatment Time: The **Reset** and **Treatment Time** buttons are depressed simultaneously to reset the total lasing time of the procedure.

Warning

Bypassing the warm-up period may damage components in the Excimer Laser System if the system has been off for longer than 30 seconds.

Advisory, Indicator and Status Lights



Aim Fiber Energy and Millijoules: The **Aim Fiber** advisory light and the **Energy** and **Millijoules** indicator lights illuminate simultaneously indicating the system is in the **Calibrate** mode or **Read Energy** has been selected in the **Ready** mode. To begin calibration, aim the fiber tip at the calibration detector head and depress the footswitch. The system reads and displays the fiber output energy after each laser pulse.

Calibrate Button: The **Calibrate** button illuminates indicating the Excimer Laser System is operating in **Calibrate** mode.

Calibrate Light: The **Calibrate** advisory light indicates the Excimer Laser System needs to be calibrated.

Cal OK: The **Cal OK** advisory light indicates the Excimer Laser System has successfully completed calibration.

Fault: If the **Fault** advisory light illuminates with a **fault code** in the display window, it indicates a malfunction. Record the fault code and notify Spectranetics for service.

Fiber: The **Fiber** advisory light indicates the fiber is not connected or properly inserted into the fiber adapter.

Fluence and mJ/mm²: The Fluence and mJ/mm² indicator lights illuminate simultaneously when the fluence setting is visible in the display window.

Footswitch: The **Footswitch** advisory light indicates the footswitch is not connected, not operating properly or is depressed during the **Warm-up** or **Standby** mode.

Lasing: The **Lasing** status light indicates the footswitch is being depressed and the Excimer Laser System is lasing. The red status light on the top of the control panel also illuminates when the system is lasing.

Min-Sec: The **Min-Sec** indicator light is illuminated when the warm-up time or treatment time is visible in the display window.

Power Error: The **Power Error** advisory light indicates the laser energy is out of range and the Safety Power Monitor has disabled the laser beam. An audible tone will be heard whenever the Power Error lamp is illuminated. During normal operation, this light may flicker as the laser energy varies within the acceptable range. The CVX-300 will continue to lase as the unit is working to correct the condition. The shutter will remain closed while Power Error is illuminated, preventing energy delivery through the fiber. Refer to the Troubleshooting section in this manual. If the Power Error and yellow advisory light on top of the control panel illuminate constantly, this indicates a problem with the Excimer Laser System. Call Spectranetics Customer Service for assistance.

Pulses: The **Pulses** indicator light illuminates when the **Pulses Delivered** button is depressed and the number of laser pulses delivered is visible in the display window.

Rate and Pulses/Second: The **Rate** and **Pulses/Second** indicator lights illuminate simultaneously when the laser pulse repetition rate is visible in the display window.

Ready: The **Ready** button illuminates indicating the Excimer Laser System is operating in **Ready** mode. The yellow status light on top of the control panel also illuminates when the system is in **Ready** mode.

Service: The **Service** advisory light indicates that the laser is near its maximum energy output and requires service. The Excimer Laser System is still operational and safe. Call Spectranetics immediately to schedule service.

Standby: The **Standby** button illuminates indicating the Excimer Laser System is operating in **Standby** mode. The green status light on top of the control panel also illuminates when the system is in **Standby** mode.

Testing: The **Testing** status light indicates the Excimer Laser System is checking the internal operation of the control circuitry.

Warm-up: The **Warm-up** status light indicates the Excimer Laser System is operating in **Warm-up** mode.

Operational Modes

Setup Mode

1. Remove the footswitch from the front storage compartment. Close the storage door prior to operating the laser. Connect the footswitch plug into the receptacle located on the rear panel.
2. Connect the end of the power cord into the receptacle located on the lower back panel of the CVX-300. Ensure power cord is fully seated into the power receptacle. Insert the other end of the power cord into a wall receptacle with the proper output voltage.

   Note: Anytime an extension cord is used to power the CVX-300 on a temporary basis, it must be a minimum 12 AWG cord of type SJO, SJT, SJOOW or equivalent. The power cord should be routed to avoid all tripping hazards and damage from other equipment. Any temporary extension cord must be disconnected and removed immediately upon completion of the task for which it was installed.
3. Insert the key in the keyswitch on the control panel. Turn the keyswitch clockwise to activate the system.
4. When the system is activated, it enters **Testing** mode.
5. Clean the surface of the energy detector with an alcohol prep before and after each use.

Testing Mode

1. The system executes an internal test which takes approximately 30 seconds.
2. The first part of self-test is a control panel lamp test in which all status buttons and advisory lights, except standby, and green status light on top of the control panel are illuminated simultaneously for approximately 5-7 seconds. Six number eights (8) are visible in the display window. (Figure 1)

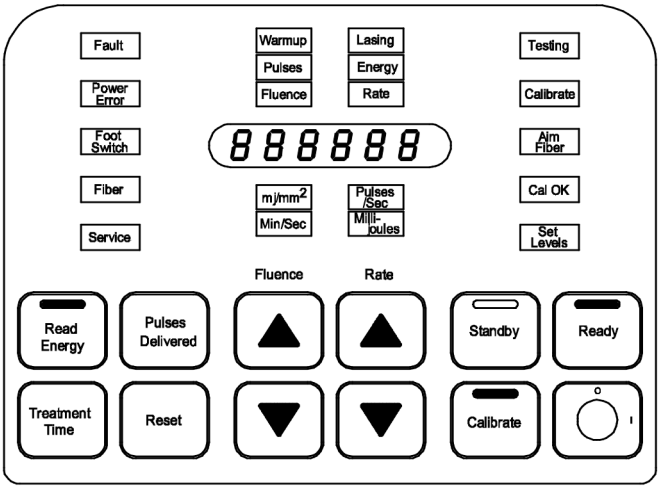


Figure 1
Lamp Test

3. At the end of the lamp test, **Standby** and **Testing** are illuminated (Figure 2). The software version number will displayed following the lamp test.

   During the test cycle, it is normal to hear a "clicking" sound inside the unit as the safety shutter is tested. The Power Error lamp will also flash several times during this test.

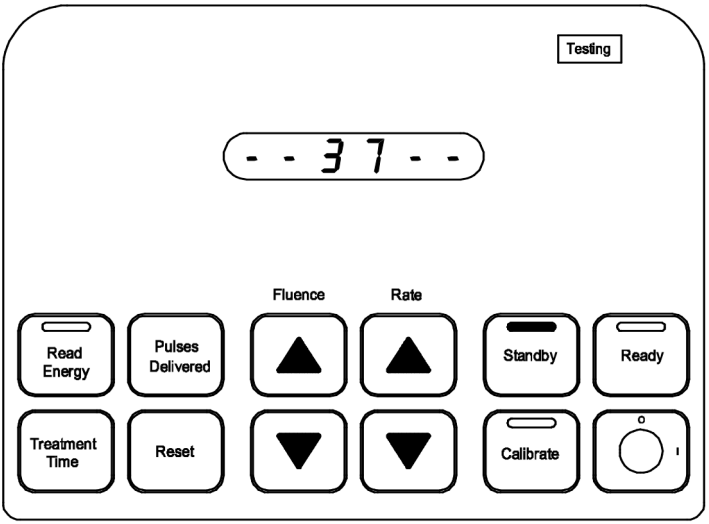


Figure 2
Self Test

4. If a malfunction is detected by the internal test, a fault code will be visible in the display window and the Excimer Laser System locks in a non-operational mode. The malfunction must be corrected by Spectranetics service personnel before the system can be restored to an operational mode. Refer to the Fault Codes section. The operator may turn the laser to the OFF (◯) position for 5 seconds and then to the ON (|) position to attempt restarting the system.
5. When the internal test is complete, the Excimer Laser System enters **Warm-up** mode. A 5 minute countdown timer indicates warm-up time remaining.

Warm-up Mode

1. When the system is in **Warm-up** mode, the **Warm-up** advisory light will be illuminated. The **Standby** button and green status light on the top of the control panel are also illuminated. (Figure 3)

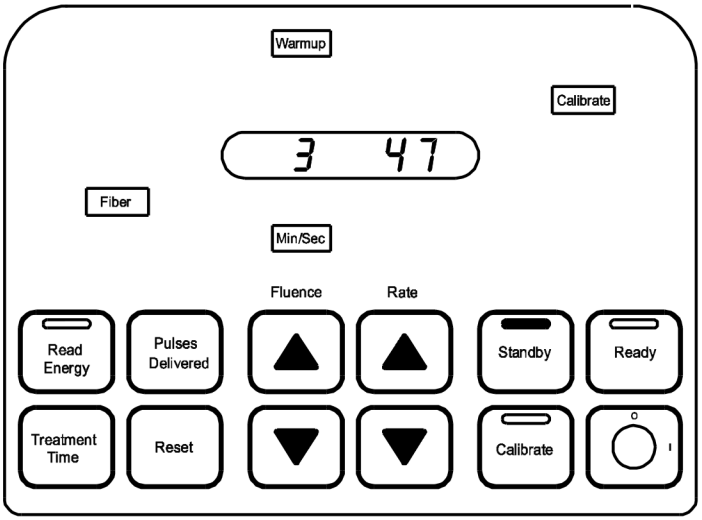


Figure 3
Warm-up

2. The **Warm-up** mode continues for five minutes. The display window shows the remaining time in the **Warm-up** mode. The warm-up period allows various components inside the unit to reach normal operating temperatures.
3. The Excimer Laser System automatically checks for proper connection of both the footswitch and the fiber optic catheter. If either component is improperly connected or not connected at all, the appropriate advisory light, **Fiber** or **Footswitch**, illuminates.
4. The recommended calibration settings will automatically appear in the display when the fiber optic catheter is inserted. (Some devices may have different Calibration settings than are displayed – always verify these settings with the recommended settings in the device's Instructions for Use documentation.) The remaining warm-up time is normally visible in the display window. Briefly depressing a **Fluence** or **Rate** increment or decrement button enables the fluence value and pulse repetition rate to be visible on the display window. Four seconds after releasing the button, the display reverts to the warm-up timer. A brief push of either button will not cause a change in the values, but will display the current setting.
5. When the five minute warm-up period is complete, the system enters **Standby** mode.

Standby Mode

1. The **Standby** button and the green status light on the top of the control panel are illuminated.
2. Depressing a **Fluence** or **Rate** button causes the fluence value or pulse repetition rate to change.

If a fiber optic catheter is not installed, the Fluence and Rate can only be set to their minimum values, 30mJ/mm^2 and 25 Hz respectively, and the Fiber light will remain illuminated. (Figure 4)

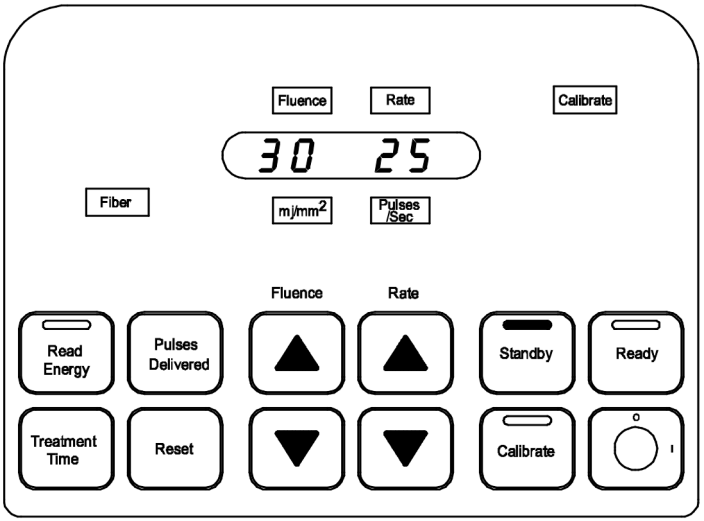


Figure 4
Standby

3. When the Excimer Laser System is in Standby mode for the first time after being powered up or a fiber optic catheter is changed, depressing the Calibrate button causes the system to enter Calibrate mode.

Calibrate Mode

1. Insert the coupler, on the proximal end of the fiber optic catheter, into the center of the connector on the CVX-300.
2. The appropriate calibration values will be displayed for the device in use. (Figure 5)

   Note: Calibration settings may vary between devices. The recommended settings are located in the device's Instruction for Use.

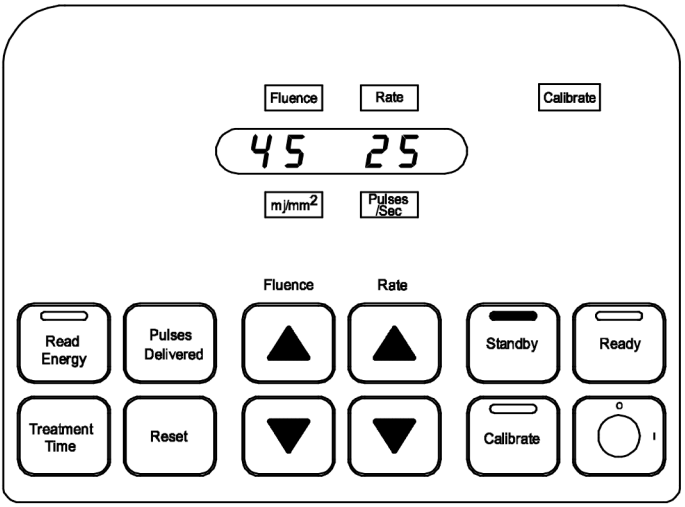


Figure 5
Calibrate

3. Allow the CVX-300 time to complete the five-minute warm-up period and enter the **Standby** mode.
4. Clean the face of the energy detector with an alcohol prep before and after each use.
5. Depress the **Calibrate** button to enter **Calibrate** mode.
6. The yellow Ready status on the top of the control panel, **Aim Fiber**, **Energy**, **Millijoules**, **Calibrate**, **Calibrate** button, and **Ready** button lights are illuminated. The display window shows 00.0 on the three rightmost digits. (Figure 6)

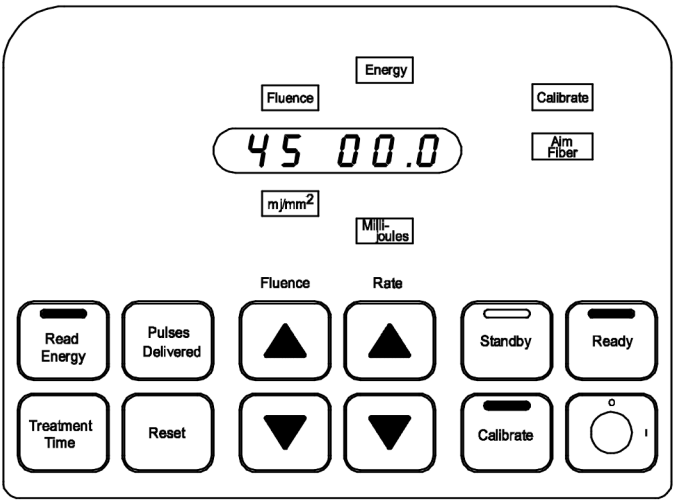


Figure 6
Calibrate –Read Energy

7. Point the distal tip of the fiber optic catheter directly at the center of the energy detector. Ensure that the catheter is no less than one inch (2.5 cm) and no more than two inches (5 cm) away from the front surface. The red visible beam must be in the center of the detector when calibrating.

Warning: **System faults may occur during the procedure if the catheter is not perpendicular to and/or at the proper distance from the detector surface during calibration.**

8. **Depress and hold** the footswitch down until lasing stops. The **Lasing** light and red lasing status light on the top of the control panel illuminates and the CVX-300 begins lasing.

   Note: the Power Error lamp may flicker momentarily during the Calibration cycle as the laser adjusts energy output (an audible tone will be heard when the Power Error lamp illuminates.)

9. During the calibration, the display window shows, in the three rightmost digits, the energy out of the fiber optic catheter. As the CVX-300 calibrates, the energy out of the distal tip of the fiber optic catheter increases or decreases until the energy corresponding to the fluence setting for that fiber optic catheter is reached. When the calibration is completed, the CVX-300 stops lasing, displays the final calibration energy value for approximately five seconds, then returns to the **Standby** mode, and the **Cal OK** advisory light illuminates. When the calibration is complete, **the final calibration energy value is visible in the display window**.

10. Compare the calibration energy reading displayed with the energy range for the fiber optic catheter selected. (See catheter package for appropriate ranges.)

    NOTE: If the calibration energy at the end of the calibration step was not read, or if an energy reading is desired at any other time during the operation of the CVX-300, check the energy out of the fiber optic catheter by selecting the **Ready** mode, depress the **Read Energy** button, aim the distal tip of the fiber optic catheter at the energy detector, and depress the footswitch. After reading the energy, depress the **Standby** button to return the CVX-300 to the **Standby** mode. (Figure 7)

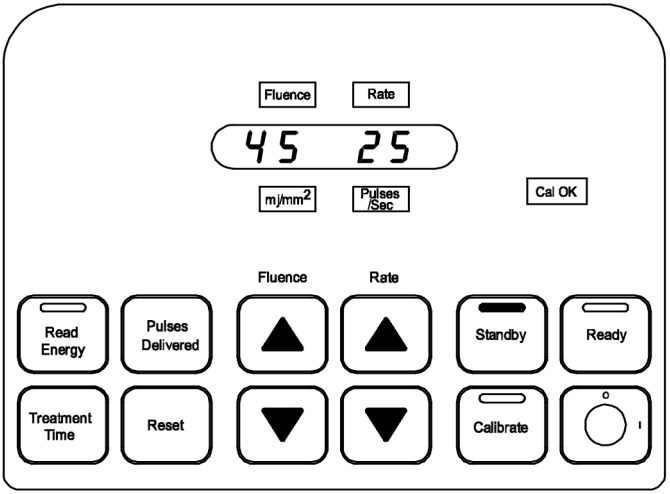


Figure 7
Standby

11. If the calibration energy value indicated in the display window does not compare properly with the energy range listed on the pouch, repeat the calibration of the fiber optic catheter at its recommended fluence setting. If the energy values do not compare after the second calibration, the fiber optic catheter should not be used and a new fiber optic catheter should be obtained.
12. If a problem occurs during the calibration process, the CVX-300 will return to the Standby mode and the fault light will be illuminated. A numeric code will also appear in the display. Refer to the Troubleshooting section of this manual.
13. If a second calibration attempt is unsuccessful, call Spectranetics Customer Service for assistance.
14. The CVX-300 returns to the Standby mode if calibration is not completed within one minute.
15. If the Fault advisory light illuminates and a numerical fault code is displayed, refer to the Troubleshooting section of this manual. Always record the fault code number and report it to Spectranetics Customer Service.

Standby Mode (Returning from Calibrate Mode)

The **Standby** mode is automatically entered a few seconds after the **Cal OK** lamp is illuminated.

1. **Standby** mode is entered from the **Calibrate** mode by depressing the **Standby** button. (Figure 8)
2. The **Standby** button and green status light on the top of the control panel are illuminated.
3. The fluence value and pulse repetition rate appear in the display window.
4. The **Cal OK** advisory light remains illuminated.

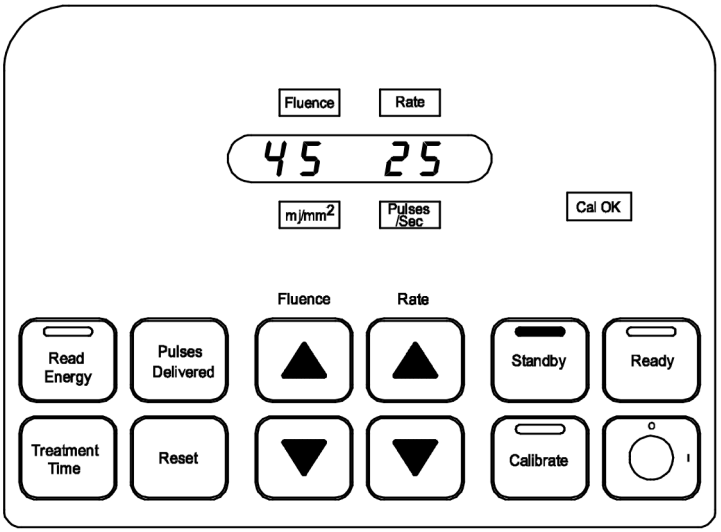


Figure 8
Standby

Standby Mode (Returning from Ready Mode)

1. **Standby** mode is entered from **Ready** mode by depressing the **Standby** button.
2. The **Standby** button and green status light on the top of the control panel are illuminated.
3. The fluence value and pulse repetition rate appear in the display window.
4. The **Cal OK** advisory light remains illuminated. (Figure 8)

Ready Mode

1. **Ready** mode is entered from **Standby** mode by depressing the Ready button. (Figure 9)
2. The **Ready** button, **Cal OK** light and yellow status light on the top of the control panel are illuminated.
3. The fluence value and pulse repetition rate may be changed by depressing a **Fluence** or **Rate** button. **After a change to either value, it is not necessary to re-calibrate.**

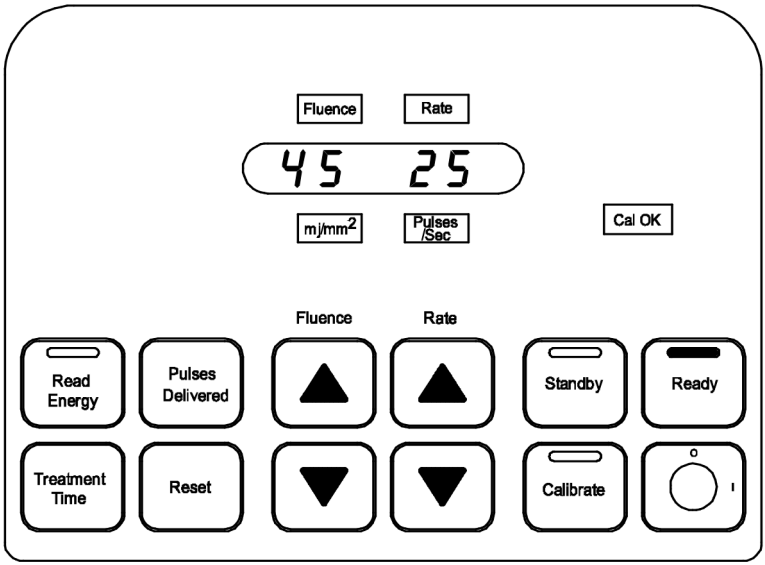


Figure 9
Ready

4. The Excimer Laser System is now ready to use in a procedure.
5. Depressing the footswitch causes the red **Lasing** light and red status light on the top of the control panel to illuminate. (Figure 10)
6. The Excimer Laser System begins to lase at the specified pulse repetition rate. Releasing the footswitch stops lasing, the red **Lasing** light and red status light on the top of the control panel go out.

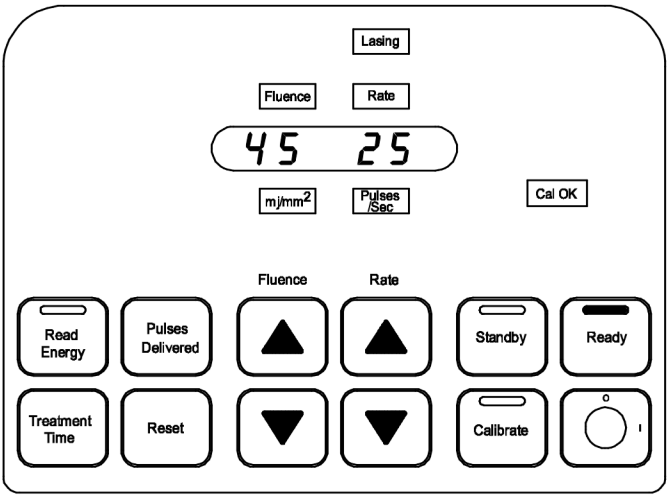


Figure 10
Lasing

7. While the Excimer Laser System is lasing, the total treatment time is stored. To retrieve the treatment time, stop lasing and depress the **Treatment Time** button. The **Min/Sec** indicator light illuminates and the total treatment time is visible in the display window. (Figure 11)
8. To reset the treatment time counter, depress the **Reset** and **Treatment Time** buttons simultaneously.
9. While the Excimer Laser System is lasing, the number of pulses delivered during a procedure is accumulated. To retrieve the total number of pulses delivered, stop lasing and depress the **Pulses Delivered** button. The count is visible in the display window. (Figure 12)
10. To reset the pulses delivered counter, depress the **Reset** and **Pulses Delivered** buttons simultaneously.

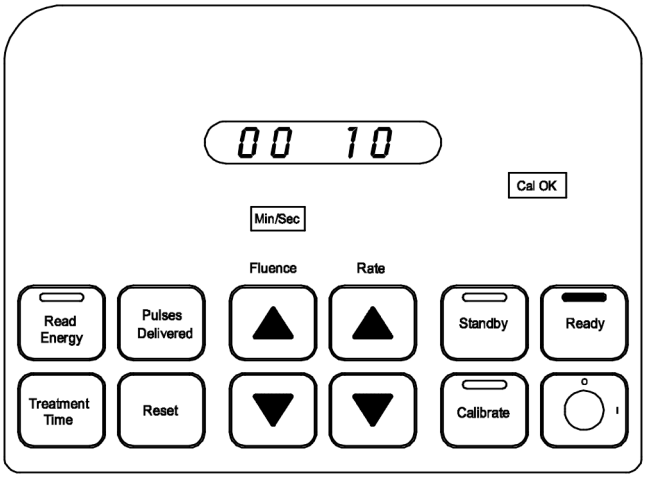


Figure 11
Treatment Time

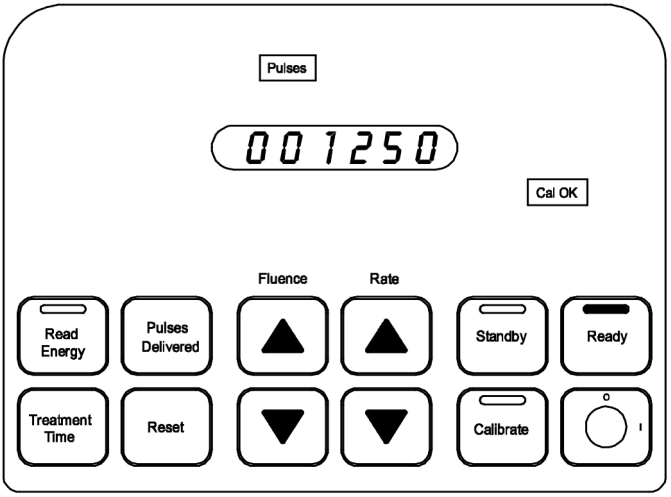


Figure 12
Pulses Delivered

11. Pressing the **Read Energy** button causes the fiber output energy to be visible in the display window. To read the energy coming from the fiber, aim the fiber at the calibration detector and depress the footswitch. (Figure 13)

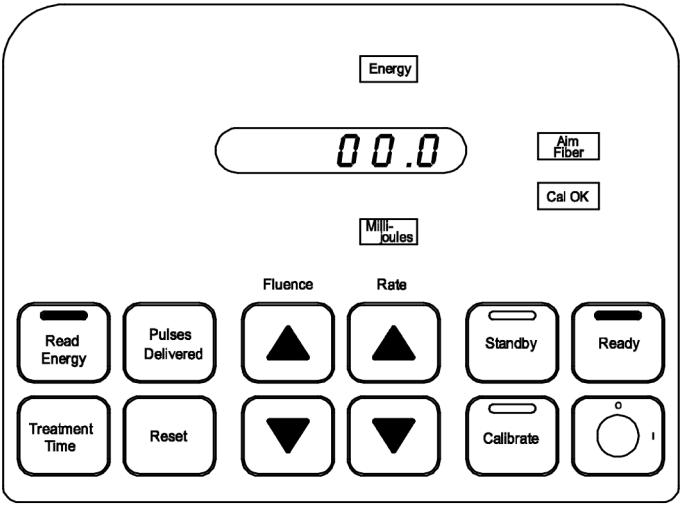


Figure 13
Read Energy

12. If the system has been in the **Ready** mode for five minutes without lasing, it returns to **Standby** mode.

Power Down

1. Press the **Standby** button.
2. Turn the keyswitch to the OFF (◯) position.
3. Disconnect the power cord from the power source.
4. Disconnect and store the Footswitch in the front storage compartment.
5. Close the catheter connector door.
6. Clean detector face with alcohol prep.
7. When not in use, the laser system should be protected from unqualified use by removing the key.
8. Cover the laser system.

Fault Codes

When a fault is detected by the system, a code number is displayed in the middle of the display window corresponding to the appropriate fault. Refer to the Troubleshooting Section of this manual. Always record the fault code number and report it to Spectranetics Customer Service.

Maintenance

Clean and disinfect the external surfaces of the CVX-300 Excimer Laser System after each use with Super Sani-Cloth® wipes or product with equivalent active ingredients and concentration *.

Cleaning:
Wipe the system with Super Sani-Cloth® wipes for 2 minutes to remove any visible soil, using additional wipes as needed. Special attention should be given to cracks, crevices, seams, and hard to reach areas. Dry the system by wiping with a clean, dry, lint-free cloth for 30 seconds.

Disinfection:
Using fresh Super Sani-Cloth® wipes, ensure the system stays wet for 2 minutes, using additional wipes as needed.

*If using an equivalent product, determine equivalency and follow the manufacturer's recommendations for use.

Clean the face of the energy detector with an alcohol prep before and after each use.
The system should be stored in a secure place, protected from freezing or extremely high temperatures, and draped with a protective cover when not in use. Never store the laser system in areas that may be below 54 °F (12 °C) or above 86 °F (30 °C). **Relative humidity must be between 20% and 95% non-condensing.** The same conditions should be observed when transporting the laser system. If the system is exposed to conditions outside of the listed ranges, a service visit may be required to perform maintenance prior to returning the system to use.
When moving the laser system, avoid traversing large bumps or extremely rough surfaces.
The Spectranetics CVX-300 system requires regular maintenance and calibration to ensure problem-free operation. Spectranetics recommends that preventive maintenance be performed on the unit every three to six months. Preventive Maintenance is required annually at a minimum. Internal maintenance must be solely performed by a Spectranetics Certified Field Service Engineer. Internally, the CVX-300 contains no user serviceable parts. Product safety tests in the form of current leakage and ground testing should be performed by a Biomedical Engineer according to generally recognized technical rules.

Only cables and power cords supplied by Spectranetics should be used on the CVX-300. Use of alternate parts may affect EMC compliance.

Prior to use, the operator should perform the following checks on the laser system:

1) Visually inspect the system for damage of the laser covers.
2) Visually inspect the power cord to insure connections on both ends are not damaged.
3) Visually inspect the power cord jacket to insure the insulation is not damaged.
4) Visually inspect the ground connection to insure it is intact.
5) Clean the face of the energy detector with an alcohol prep.
6) Turn the CVX-300 on, warm it up, and calibrate the laser with a Reference Catheter.

If any of the above do not pass visual inspection or the Reference Catheter does not calibrate, contact Spectranetics prior to using the laser.

CAUTION

Anytime an extension cord is used to power the CVX-300 on a temporary basis, it must be a minimum 12 AWG cord of type SJO, SJT, SJOOW or equivalent. The power cord should be routed to avoid all tripping hazards and damage from other equipment. Any temporary extension cord must be disconnected and removed immediately upon completion of the task for which it was installed.

WARNING

The CVX-300 contains a Class IV laser that produces an invisible beam. Potentially lethal high voltages are present inside the system. The gas mixture utilized inside the laser contains 0.05% HCl, a respiratory irritant.

WARNING

Failure to service the equipment properly may result in personal injury or death. Service should only be completed by a Spectranetics Certified Field Service Engineer.

In the event that the laser has exceeded its useful life, contact Spectranetics to return the laser or for information regarding disposal of the equipment. See Instructions for Use for each single-use device for disposal of these CVX-300 accessories.

Verification of Calibration

CVX-300 Energy Detector Circuit

The energy monitor on the CVX-300 Excimer Laser System requires verification of calibration annually at a minimum to ensure that the laser radiation output is within specification. This procedure may be performed more frequently if desired. Always wear the appropriate laser safety glasses when using this equipment and follow the safety precautions as outlined within this manual.

Safety glasses specific to the CVX-300 Excimer Laser System are available for purchase from Spectranetics by calling our Customer Service Department.

Equipment required

- Spectranetics Laser Safety Glasses
- CVX-300 Excimer Laser System
- A commercially available National Institute of Standards and Technology (NIST) calibrated Joule Meter and Energy Detector rated at 308 nM, 120 nS, 0-100 mJ, and directions for use
- Spectranetics Reference Catheter

This procedure requires that the CVX-300 Excimer Laser System is operational and functions properly and that the operator has been trained by Spectranetics on the proper use, safety and operation of the CVX-300. This procedure also requires that the operator has been trained on the use, safety and operation of the NIST calibrated Joule Meter.

Energy Monitor Verification Procedure

1. Connect the power cord to the rear panel of the laser system. Ensure power cord is fully seated into the power receptacle. Insert the other end of the power cord into the appropriate receptacle with the proper output voltage.
2. Insert the key in the switch located on the control panel and rotate it clockwise to turn the system ON (|). The system will energize and enter the self test mode.
3. Remove the Footswitch from the front storage compartment and connect it to the receptacle located on the rear panel of the system.
4. Allow the laser system to complete the warm-up period.
5. Insert the Reference Catheter's proximal end into the CVX-300 connector. The appropriate calibration Fluence and Rate will automatically be displayed when the 2.5 mm Reference Catheter is inserted into the connector.
6. Ensure that all personnel in the room are wearing the appropriate laser safety glasses.
7. Aim the distal end of the Reference Catheter directly at the center and one to two inches away from the front surface of the Energy Detector on the front of the CVX-300.
8. Depress the Calibrate button on the CVX-300 display panel.

9. **Depress and hold** the Footswitch down until the laser stops and the "Cal OK' light is illuminated.
10. Record the energy reading in mJ shown on the CVX-300 display panel.
11. Depress the Ready button on the CVX-300 display panel.
12. Aim the Reference Catheter directly at the center of the NIST Detector and Joule Meter.
13. Depress the Footswitch and record the energy.
14. Compare the recorded energy value in step 10 with the recorded energy value in step 13.
15. The difference in the two recorded energy values should be less than 20% (CFR 21 1040.11 Section 1) when using the following equation

(energy value in step 10 – energy value in step 13)
/ energy value in step 13

16. Notify the Spectranetics Customer Service Department immediately if the difference in the recorded energy values are greater than or equal to 20%.
17. Press the Standby button, turn the key switch to the OFF (◯) position, remove the key and store it in a safe place, disconnect the Footswitch and store it in the front compartment, disconnect the power cord from the power source and the laser, close the catheter connector door, cover the laser system with the protective cover.

Troubleshooting

The keyswitch will not turn ON (|) the CVX-300.	• Ensure the CVX-300 power cord is connected to the proper source.
	• Ensure the main circuit breaker, located on the lower back panel, is in the ON (|) position.
	• Ensure the interlock plug is inserted into the receptacle located on the lower back panel.
The buzzer sounds when CVX-300 power cord is plugged in.	• Release the emergency button by turning it in a clockwise direction.
The CVX-300 will not enter the Calibrate mode.	• Allow the CVX-300 time to complete the warm-up mode.
	• Insert a fiber optic catheter into the coupler.
	• Plug in the footswitch.
	• Set the fluence and pulse repetition rate.
Alarm sounds when the ready button is depressed.	• Calibrate the system.
The CVX-300 does not complete calibration.	• **Depress and hold** the footswitch down until lasing stops and the Cal OK indication is illuminated.
Keyswitch is ON (|) but the CVX-300 will not come on after the emergency button has been reset.	• Turn the keyswitch to the OFF (◯) position and then to the ON (**|**) position to reset the system.
Fiber indicator is illuminated.	• Ensure the fiber optic catheter handle is fully inserted into the coupler.
Service indicator is illuminated.	• Call Spectranetics Customer Service for assistance.

Power error indicator is illuminated constantly.	• Call Spectranetics Customer Service for assistance.
A fault occurs during Warm-up or Calibration, the fault indicator is illuminated and a fault code number is shown in the middle of the display window.	• Refer to the Fault Code Table at the end of this section.
The laser gives an odor of HCl gas (like bleach).	• Place the laser in a well-ventilated, yet isolated room. Call Spectranetics Customer Service to schedule an emergency service visit.

Troubleshooting: CVX-300 Fault Codes & Error Lamps

Fault Code	Problem Description	Try this…
		Clean the fiber optic catheter tip and re-calibrate at the recommended settings (45/25 for ELCA devices; 60/40 for SLS devices.) Ensure the device is pointed at the center of the energy detector, one to two inches away. If calibration is unsuccessful, attempt to calibrate with the Reference Catheter. If successful, try a new fiber optic catheter.
1	No energy detected at detector head	If calibration of the Reference Catheter is unsuccessful, record the Fault code and call Spectranetics Customer Service.
2	Calibration did not occur within the unit's pre-set pulse limit	Clean the Energy Detector Surface with an alcohol prep. Clean the fiber optic catheter tip and re-calibrate at the recommended settings (45/25 for ELCA devices; 60/40 for SLS devices.) Ensure the device is pointed at the center of the energy detector, one to two inches away. If calibration is unsuccessful, attempt to re-calibrate the device at a lower fluence setting (40/25 for ELCA devices; 50/40 for SLS devices.) If calibration is successful, proceed. Report the incident to Spectranetics after the case is complete. If calibration is unsuccessful, turn the system OFF (◯), then back ON (|). Attempt to calibrate with the Reference Catheter. If successful, try a new fiber optic catheter. If calibration of the Reference Catheter is unsuccessful, record the Fault code and call Spectranetics Customer Service.
3	Beam attenuator at maximum opening	
4	Fiber Power Monitor test error	
5	Fiber optic catheter handle improperly inserted	Remove the fiber optic catheter and reinsert. If the fault is repeated, call Spectranetics Customer Service.
10-50	System Error detected	Record the Fault Code and call Spectranetics Customer Service.

Error Lamp	*Problem Description*	*Try this…*
Power Error Lamp	Internal energy deviation detected	Remove the fiber from the treatment area. Aim fiber at the center of the detector. Ensure the device is pointed at the center of the energy detector, one to two inches away. Depress the footswitch and continue to lase for up to 10 seconds. If the Power Error indicator turns off and remains off, reintroduce the fiber device and continue. Report the incident to Spectranetics after the case is complete. If the Power Error indicator remains illuminated, turn the unit OFF (◯), then back ON (**|**). Bypass the warm-up period by pressing the RESET and STANDBY buttons simultaneously *(in order to bypass the warm-up period, the system must not be OFF* (◯) *for longer than 30 seconds.)* Attempt to calibrate with the Reference Catheter. If successful, attempt to calibrate the fiber optic catheter to be used in the patient. Proceed if successful. Report the incident to Spectranetics after the case is complete. If the Power Error lamp continues to illuminate, either steadily or intermittently, call Spectranetics Customer Service.
Service Lamp	System has reached 95% of maximum energy output	System operation is typically not affected when this indicator is initially illuminated. **Call Spectranetics immediately to schedule service.** Test the system using the Reference Catheter. If the unit operates normally and calibration is completed successfully, continue with the desired fiber optic catheter. If calibration is unsuccessful, record the Fault Code and call Spectranetics Customer Service.

Glossary

Align

To adjust the components of a system for proper interrelationship.

Circuit breaker

An electromagnetic device which opens a circuit automatically when the current exceeds a pre-determined value.

Distal

Located away from the point of origin or attachment.

Energy

The capacity for doing work and overcoming resistance. Heat, light, and electricity are examples of energy. Energy is measured in joules.

Excimer

Contraction of **EXCI**ted and di**MER**.

Excimer laser

A pulsed, gas laser which lases when two atoms form a temporary excited molecule.

Excimer radiation

Electromagnetic radiation emitted from the **CVX-300** which includes all reflected radiation and any other form of energy resulting from the primary beam.

Excitation

The addition of energy to a particle or system of particles to produce an excited state.

FDA

The Food and Drug Administration.

Fiber optic

Transparent, glass or quartz fibers used for conducting light.

Fluence

Fiber optic catheter output energy density usually expressed in millijoules/square millimeter.

Hydrogen Chloride (HCl)

A gaseous compound which is the source of the excimer laser chlorine atom.

Hertz

One cycle per second; a unit of frequency. Abbreviated Hz.

IPX8

The degree of protection rating given the footswitch which means it is enclosed such that it is usable under water.

Joule

One Watt second; a unit of energy.

Laser

(An acronym) **L**ight **A**mplification by **S**timulated **E**mission of **R**adiation: a device which amplifies light, then releases it in a coherent powerful beam.

Non-Ionizing Radiation

Electromagnetic radiation that does not have sufficient energy to remove electrons from the outer shells of atoms. Types of non-ionizing radiation are: ultraviolet (UV), visible light, infrared (IR), microwave, radio (and television), and extremely low frequency (ELF, sometimes referred to as EMF or ELF-EMF).

Neon (Ne)

A rare, inert gas occurring in the atmosphere. It is colorless, but glows reddish-orange in an electrical discharge.

Proximal

Nearest to the point of attachment or origin.

Pulsed laser

A laser which delivers energy in short bursts.

Repetition rate

The rate at which the laser delivers pulses, usually expressed as pulses per second.

Type CF

Classification indicating direct conductive contact with the heart.

Ultraviolet

Pertains to electromagnetic radiation at wavelengths shorter than visible light.

Watt

One joule per second; a unit of power.

Wavelength

The distance between corresponding points on two successive waves.

WEEE (Waste from Electrical & Electronic Equipment)

Directive that mandates the collection and treatment of electronic and electrical equipment at end-of-life.

Xenon (Xe)

A noble gas.

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