



CVX-300 in-service checklist

Purpose

This checklist will be used by the Sales and Field Service teams when providing in-service training to our customers that use the CVX-300 laser systems. The CVX-300 Operator's Manual, 7030-0068, provides detailed information and should be referenced as needed.

Checklist safety

- ☐ Controlled Environment
 - Post laser "Danger" warning signs on all entrances to the room where the laser system is being used
 - Signs have the following information:
 - Visible and invisible laser radiation.
 - Avoid eye or skin exposure.
 - Eye protection required.
 - 308 nm Excimer Laser - Class IV Laser.
 - 670nm Diode Laser – Class IIIa/3R (International and Europe) Laser(not on older signs, rev05 or lower).
 - Signs can be ordered from Customer Service.

Footer information heading

Footer information such as disclaimer and copyright text, references, part number, etc.



☐ Eye Protection

- Protective laser safety eyewear will always have the Optical Density (OD) rating at a specific wavelength or range of wavelengths printed on the lens or frame.
 - An OD rating of at least 5 at 308nm is required when operating the CVX-300.
 - Spectranetics laser eyewear has an OD rating of 9+ and can be ordered from Customer Service, part number 4110-0223.
- Everyone in the room including the patient must wear the appropriate laser safety eyewear at all times when in the operating room or cath lab.
- The red aiming laser is a class IIIa/3R (International and Europe) laser and does not require any additional eye protection.

☐ Moving the CVX-300

- The CVX-300 is heavy. Use caution when moving the system to avoid injury to you and others around you.
- Use the rear handle and/or front hand inserts when moving the CVX-300.
- Do not attempt to lift the system with the rear handle.
- Avoid slopes when moving the CVX-300 otherwise use two people to move the system, one on the front and one on the rear of the laser system.
- Avoid jarring the CVX-300 or running it into walls or other equipment. Move the laser system slowly over bumps such as elevator thresholds.
- Always disconnect and store the footswitch when moving the CVX-300.
- Always ensure the power cord is disconnected from the wall and properly stored before moving the CVX-300.
- Once the CVX-300 is in the required location lock the front wheels using the foot brake located in the front of the laser system.





☐ Practical Safety

- Only trained clinicians and operators should utilize the CVX-300.
- Never look directly into the laser beam, even with proper eye protection.
- Do not allow direct or reflected laser radiation to go beyond the laser operating area.

Set-up

☐ Position the CVX-300

- Move the CVX-300 into a position where the power cord will reach the wall receptacle, the catheter will reach the patient and the operator can easily access the display panel and energy detector.
- Lock the front wheels of the CVX-300 by pushing down on the brake bar located in the front of the laser system using your foot.

☐ CVX-300 Power-Up

- Power cord connected to wall receptacle, main circuit breaker in ON position, interlock plug installed.
 - Ensure the power cord strain relief on the CVX-300 is locked into position.
 - Safely route the power cord to eliminate tripping hazards.
- On initial power up the CVX-300's display panel will:
 - Complete a lamp test.
 - Indicate the software version in the display window.
 - Complete a self-test (approx. 30 seconds).
 - Enter the 5:00 minute warm-up mode.

☐ Footswitch Connection

- Connect the footswitch to the connector located at the rear of the CVX-300.
 - Align the red dot on the footswitch connector and the red dot on the footswitch receptacle then insert.
- Safely route the footswitch cable to eliminate tripping hazards.



☐ Warm-Up Mode

- The CVX-300 requires a 5:00 minute warm-up in order to operate properly.
- If the laser system is accidentally turned off the warm-up mode can be by-passed if the laser system has already completed an initial 5:00 minute warm-up and was without power for less than 30 seconds before power was turned back on.
 - To by-pass the warm-up mode allow the system to complete the self- test mode and re-enter the 5:00 minute warm-up then simultaneously depress the Standby and Reset buttons. The Warm-Up lamp will turn out.



Warning: Not following the warm-up and by-pass instructions as outlined above can result in *Power Errors, Fault codes* and damage internal components which will prevent the use of the CVX-300.

Catheter calibration

- ☐ Clean the front surface of the energy detector using an alcohol prep. Allow the alcohol to completely evaporate.
- ☐ Catheter Connection
 - Open the catheter connection door. Raise the energy detector if using a CVX-300-P.
 - Insert the proximal end of the catheter completely.
- ☐ CVX-300 Operation Verification (Reference Catheter)
 - Proper operation of the CVX-300 should be verified by calibrating the Reference Catheter prior to calibration of a clinical catheter(s). Follow the instructions in step 4.3.4 to calibrate all catheters.
 - If the CVX-300 is moved from one location to another proper operation should be verified again using the Reference Catheter.



☐ Catheter Calibration

- Upon connection of a catheter the Fluence and Rate settings are automatically set-up by the CVX-300's control system.
- Depress the Calibrate button then aim the distal tip of the catheter at the center of the energy detector. Use the red aiming beam for centering.
- Using the catheter alignment guide label distance the tip of the catheter between the min and max lines. Catheter should be pointed directly at the center of the detector and not at an angle.
- Depress the footswitch and hold it down until the CVX-300 automatically stops lasing and the Cal OK lamp illuminates.



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.

Operation

- ☐ Adjust the Fluence and Rate settings per the physician's instructions.
- ☐ Depress the Ready button.
 - Depressing the footswitch will cause the CVX-300 to operate for a period of time as described in the catheter's Instructions For Use (IFU).
 - A wait period may be imposed at the end of a lasing train depending on the type of catheter, refer to the IFU. The footswitch must be released during the wait period.
 - An audible beep will be heard at the end of the wait period indicating the CVX-300 is ready to complete another lasing train.





☐ Pulses Delivered Counter.

- Depressing the Pulses Delivered button will display the total number of pulses delivered during the procedure.
 - The total pulses will be stored in memory until a catheter is calibrated again or the system is turned off.
- The counter can be reset by simultaneously depressing the Pulses Delivered and Reset buttons.

☐ Treatment Time Counter.

- Depressing the Treatment Time button will display the total lasing time delivered during the procedure.
 - The treatment time will be stored in memory until a catheter is calibrated again or the system is turned off.
- The counter can be reset by simultaneously depressing the Treatment Time and Reset buttons.

☐ Read Energy Mode.

- Depressing the Read Energy button enables the catheter output energy read by the energy detector to be visible in the display window.
 - The distal tip of the catheter must be properly aimed at the energy detector as described in section 4.3 to correctly read energy.
 - The footswitch must be depressed in order to read the catheter's output energy.

Troubleshooting

☐ CVX-300 will not turn on.

- Verify the power cord is properly connected to the CVX-300 and the wall receptacle.
- Verify the main circuit breaker on the CVX-300 is in the ON position.
- Verify the interlock plug is installed.
- Have the facilities bio-med department verify there is power at the wall receptacle.



- ☐ CVX-300 buzzes when plugged in and will not turn on.
 - Release the red emergency button located on the rear of the CVX-300 by turning it clockwise.
- ☐ Fault Codes 1 – 4.
 - Ensure the energy detector face is clean. Use an alcohol prep to clean.
 - Ensure the distal tip of the catheter is clean and dry.
 - Try to re-calibrate again.
 - If calibration is unsuccessful attempt to calibrate the catheter at a lower Fluence setting (40 Fluence for VI catheters or 50 Fluence for LM catheters).
 - If calibration is successful proceed. Record the Fault Code and report the incident to Spectranetics Customer Service.
 - If calibration is un-successful, turn the CVX-300 OFF and then ON again, by-pass warm-up and then attempt to calibrate the Reference Catheter. If successful open a new clinical catheter. Record the Fault Code and report incident to Spectranetics Customer Service.
 - If calibration of the Reference Catheter is unsuccessful, record the Fault Code and report the incident to Spectranetics Customer Service.
- ☐ Fault Codes 5.
 - Remove the proximal end of the catheter from the CVX-300 and firmly reinsert.
 - If Fault occurs again report incident to Spectranetics Customer Service.
- ☐ Fault Codes 10 – 50.
 - Turn the CVX-300 OFF and then ON again, by-pass warm-up and then attempt to calibrate the catheter. If calibration is successful proceed.
 - Record the Fault Code and report the incident to Spectranetics Customer Service.
- ☐ Service lamp turns on.
 - If Reference Catheter calibrates OK proceed.
 - Report incident to Spectranetics Customer Service so a service call can be scheduled.





- ☐ Power Error lamp flashing or on continuously.
 - Ensure that the 5:00 minute warm-up has been completed.
 - Stop use of the CVX-300 and call Spectranetics Customer Service so a service call can be scheduled.

CVX-300 shutdown and storage

- ☐ Press the Standby button.
- ☐ Turn the keyswitch to the OFF position
- ☐ Disconnect the catheter from the CVX-300.
- ☐ Disconnect the power cord from the wall receptacle.
 - Wrap power cord around cord wrap on located at the rear of the CVX-300.
- ☐ Disconnect and store the footswitch in the front storage compartment.
- ☐ Clean the energy detector face with a alcohol prep.
- ☐ Lower the energy detector on a CVX-300-P. Close the catheter connector door
- ☐ When not in use, the laser system should be protected from unqualified use by removing the key.
- ☐ Cover the laser system.



FOR INTERNAL USE ONLY

Developed from Spectranetics Work Instruction 7010-0657-07