CardioGenesis®

SolarGen 2100s
Holmium:YAG Laser for TMR

Part of the **CardioGenesis TMR Holmium:YAG Laser System**

INSTRUCTIONS FOR USE

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INTRODUCTION

These Instructions For Use provide information required to operate the CardioGenesis SolarGen 2100s Laser System in a safe and proper manner. It is recommended that all equipment operators and personnel familiarize themselves with the information in these Instructions For Use prior to operating the laser system. No attempt is made to teach the medical procedures involved.

A trained physician who has prescribed its use according to and in compliance with FDA regulations must operate this system.

CAUTIONS:

United States Federal law restricts this device to sale by or on the order of a physician (applies to U.S. sales only).

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

Using, or attempting to use, optical fibers and/or other delivery systems not supplied by CryoLife® may result in radiation exposure, injury to patient and/or user and damage to the laser.

This laser product complies with the requirements of the following established standards:

1) 21 CFR 1040 (U.S. FDA Performance Standards for Light-Emitting Products);
2) EN 55011:1998 + A1:1999 (Radiated and Conducted Emissions);
3) ISO/IEC 12207:1995 + A1:2002 (Software Life Cycle Processes);
4) IEC 60601-1:1988 + A1:1994 + A2:1994 (Medical Electrical Equipment Part 1: General Requirements for Safety - Second Edition);
5) IEC 60601-1-1:2000 (General Requirements for Safety: Medical Electrical Systems);
6) IEC 60601-1-2:2001 + A1:2004 (General Requirements for Safety: Electromagnetic Compatibility);
7) IEC 60601-1-4:2000 (Medical Electrical Equipment: General Requirements for Safety; Collateral Standard: Programmable Electrical Medical Systems);
8) IEC 60601-2-22:1995 (Particular Requirements for the Safety of Diagnostic and Therapeutic Laser Equipment);
9) IEC 60825-1:1993 + A1:1997 + A2:2001 (Safety of Laser Products: Equipment Classification, Requirements, and User's Guide).

1.0 INSTRUCTIONS FOR USE

Refer to the CardioGenesis TMR Holmium:YAG Laser System Handpiece Delivery System Instructions For Use for all indications, warnings, precautions, and instructional details regarding the clinical use of the system.

CAUTIONS:

Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner). Federal law further restricts the use of this device to practitioners who have been trained in laser heart surgery including laser operation.

Use of this device is restricted to patients who have signed a procedure-specific consent form to ensure that the risks associated with TMR have been fully explained and understood (United States only).

2.0 SYSTEM DESCRIPTION AND SPECIFICATIONS

2.1 INTRODUCTION AND GENERAL DESCRIPTION

1) The CardioGenesis SolarGen 2100s Holmium:YAG Laser is a Class IV, pulsed, solid-state laser and designed and validated for use with CardioGenesis Handpiece Delivery Systems.

2) The CardioGenesis SolarGen 2100s laser console is specifically designed to be easy to install, simple to operate, user-friendly, convenient and reliable.

Major components include:

- Control Panel;
- Laser Emission Aperture;
- Footswitch;
- Laser Head (includes optics and interlocked laser safety shutters)*;
- Cooling System*;
- Laser Controller and Power Supply*;
- Isolation Transformer*;
- Light-tight Covers*.

** These are internal components and do not require direct user interface.*

2.2 SITE PREPARATION PRIOR TO DELIVERY OF EQUIPMENT

No special preparations or modifications to the operating room are required for use of the SolarGen 2100s CardioGenesis laser console. The console is internally cooled and requires no running water or water hoses.

Working environmental range is a temperature of 14 to 30ºC (57 to 86ºF) ambient, humidity (non-condensing) of 10-80%.

ELECTRICAL POWER

The 2100s is available in two configurations. The configuration is identified on the manufacturers label located on the rear panel above the power input. Power requirement for the 115 volt configuration is a 115 ± 10% VAC, 50-60 Hz, single-phase Dedicated outlet rated at 15 amps. Power requirement for the 230 volt configuration is a 230 ± 10% VAC, 50-60 Hz, single-phase Dedicated outlet rated at 15 amps. A built-in isolation transformer meets UL 544 requirements, with patient connections isolated from ground, 2.5MΩ, 135 VAC, 60 Hz.

Note: A Dedicated outlet is required for the proper operation of the laser console. DO NOT plug the laser console into a power strip!

EYE PROTECTION

Laser Safety Eyewear

As with all lasers, suitable protective laser eyewear (properly-filtered goggles or glasses) is required. The CardioGenesis laser console is shipped with four pairs of appropriate eyewear. Additional pairs of eyewear may be obtained from CryoLife.

When ordering laser safety eyewear from another vendor, specify that the eyewear have effective protection for the following laser wavelengths: 2000 to 2200 nanometers (equivalent to 2.0 to 2.2 microns). Minimum optical density should be at least 4. The Nominal Hazard Zone for the laser is approximately 31 inches and the laser type is Holmium:YAG (or CTH:YAG). It is the sole responsibility of the hospital to determine that the correct laser safety eyewear is received from the vendor.

Laser Warning Signs

Laser warning signs should be displayed prominently at each access door to the treatment area (two signs are provided with the laser shipment).

2.3 DELIVERY, TRAINING AND CLINICAL SUPPORT

The CardioGenesis laser console is delivered to the hospital in a protective shipping box. An authorized representative will unbox, test and install the laser. The laser console will then be ready for clinical use. Comprehensive on-site physician and staff in-service training will be scheduled prior to the first clinical cases.

One copy of these Instructions For Use is delivered with the laser console and the contents are fully explained during in-service training.

For more information, contact 1-800-741-7062 (United States and Canada) and +1-770-419-3355 (International).

2.4 USER MAINTENANCE AND DAILY USE

The CardioGenesis SolarGen 2100s laser is a self-contained, mobile laser console engineered for reliability and intended for extended daily use.

It is suggested that the outside panels of the laser console be wiped down periodically with a slightly damp cloth.

It is recommended that the laser console be covered when stored.

Non-routine maintenance and all servicing of the SolarGen 2100s laser, such as installation, calibration, and repair should only be performed by an authorized representative. It is recommended that maintenance of the SolarGen 2100s laser console, including system calibration, be performed at least twice annually.

2.5 SERVICE

Only an authorized representative can install, maintain or service the CardioGenesis laser console. Service can be requested or more information obtained by contacting 1-800-741-7062 (United States and Canada) and +1-770-419-3355 (International).

2.6 SYSTEM SPECIFICATIONS

Model:	CardioGenesis SolarGen 2100s
Laser type:	Pulsed, solid-state Holmium:YAG
Wavelength:	2.1 microns, mid-infrared
Therapeutic energy:	1.4 Joules average energy
Power:	7 Watts
Pulse width:	200 microseconds
Frequency rate:	5 Hertz (pulses per second)
Electrical service:	115 or 230 ± 10% VAC, 15 amp, **Dedicated** single phase outlet
Cooling:	Water to Air Heat Exchanger, self-contained
Dimensions:	21”L x 14”W x 36”H
Weight:	120 lbs. 58 (kg) Mobile, on wheels.
User maintenance:	None. Preventive maintenance by an authorized representative is recommended at least twice yearly.
Classification:	Class IV laser system per 21 CFR 1040.10(b)(11)
Delivery systems:	CardioGenesis Handpiece Delivery Systems
Temperature:	14 to 30ºC (57 to 86ºF) ambient
Humidity:	10-80% (non-condensing)
Altitude:	6,000 feet above sea level or less

3.0 OPERATION

3.1 MODES OF OPERATION

The CardioGenesis SolarGen 2100s laser console is designed to be simple and user-friendly. It features a single security keyswitch for start-up, requires standard **Dedicated** 115 or 230 ± 10% VAC single-phase electrical service, depending on configuration, and is internally cooled.

Note: A Dedicated outlet is required for the proper operation of the laser console. DO NOT plug the laser console into a power strip!

The CardioGenesis laser operates at a fixed repetition rate of 5 Hertz and a fixed pulsewidth of 200 microseconds ± 25%.

When turned on, the CardioGenesis laser console has two basic modes: “Standby” and “Laser Ready”. The “Standby” mode prevents accidental firing of the laser beam if the footswitch is inadvertently activated. The laser transmits energy through the CardioGenesis Handpiece Delivery System only when:

1) No safety interlocks or other problems are detected;
2) A CardioGenesis Handpiece Delivery System is properly installed in the laser aperture;
3) A calibration factor is entered on the user panel;
4) The laser is in “Laser Ready” mode; and
5) The footswitch is activated.

The status of the laser (either “Laser Ready” or “Standby”) is indicated on the console Display Panel.

3.2 USER CONTROL PANEL

SolarGen 2100s Display Panel:

“Laser Stop” button (red) – located on the front of the laser console
Immediate one-button power shut down of laser in case of emergency.

On/Off Key Switch and Power indicator lamp (orange) – located on the front of the laser console
Main on/off power control requires a key. “0” position is off. “I” position is on. When in the on position, the orange power indicator lamp will be illuminated.

Reset Button and Pulse Counter Display
This button is pressed to clear the Pulse Counter Display. The Pulse Counter Display performs three functions.

1. During warm-up, the Pulse Counter Display counts down to “0” to indicate the laser console is ready for use.

2. During use, the Pulse Counter Display provides a continuous read-out of the number of pulses of laser energy that have been transmitted through the Handpiece Delivery System. The Pulse Counter may be reset at anytime.

> **Note: The Reset button may be continuously pushed for more than one second to recall the last reading on the Pulse Counter Display.**

3. In the event of a problem, it will display an error message. This can be used to help determine the nature of a system problem. See the Troubleshooting section for more details.

Calibration Increase and Decrease buttons and Calibration display
These buttons adjust the calibration setting of the laser output power to match the handpiece delivery system being used. The “INC” button increases the setting. The “DEC” button decreases the setting. Possible settings are 43-55% in one step increments. The setting appears on the calibration display. When no CardioGenesis Handpiece is attached, the setting will always read “00” and no adjustments can be made to the calibration setting. Once a handpiece is attached, the calibration setting on the laser must be set to match the calibration factor recorded on the handpiece package.

WARNING: THE CALIBRATION SETTING AFFECTS HOW MUCH LASER ENERGY WILL BE EMITTED FROM THE HANDPIECE DELIVERY SYSTEM. NEVER SET THE CALIBRATION SETTING TO ANY NUMBER OTHER THAN THE VALUE IMPRINTED ON THE HANDPIECE PACKAGE.

“Standby” Button
Press to place laser in “Standby” mode. Laser energy **cannot** be transmitted through the attached delivery system while in “Standby” mode.

“Laser Ready” and “Laser Emission Enabled” indicator (red)
Press the “Laser Ready” button to place the laser in “Laser Ready” mode. The red “Laser Emission Enabled” indicator will illuminate only when the console is in “Ready” mode. Laser energy **will** be transmitted when the laser is in “Laser Ready” mode, handpiece has been properly installed, a calibration value has been entered, and the footswitch is activated.

3.3 TURNING ON THE LASER

1. Attach the power cord to an appropriate 115 or 230 ± 10% VAC, depending on configuration, 50-60 Hz, single-phase, Dedicated 15 amp power outlet.
2. If not already attached, attach the footswitch to laser console. Do not connect a handpiece to the laser aperture at this time.
3. Turn the Key Switch to the “Start” position. Hold the key there for approximately one second. The orange power indicator lamp should illuminate. The console will perform internal power-on self tests for approximately 15-20 seconds. The cooling system will also turn on at this time. In the event of a problem during these tests, the console will display an error message.
4. After the self tests have been completed, the control panel buttons and displays will become active. The default settings for the laser are as follows:

DISPLAY OR INDICATOR	DEFAULT SETTING
POWER ON	Illuminated
PULSE COUNTER	00000
CALIBRATION	00
OUTPUT (WATTS)	7.0
LASER MODE, “Standby”	“Standby” Mode
“LASER EMISSION ENABLED”	Not Illuminated

3.4 PERFORMING OPERATIONAL TEST OF LASER CONSOLE

CAUTION: ***The laser must be tested prior to preparing the patient for the procedure.***

1. Remove the CardioGenesis laser test fiber from the package remove the plastic end caps and inspect the fiber connectors for damage or debris before use.
2. Turn on CardioGenesis laser console. Attach test fiber connector to laser aperture and ensure the fiber is tightened completely.
3. Fill a small non-metallic water basin with water approximately half full. Note: usage of too little water or a metal basin could result in damage to the test fiber or injury to the user.
4. **Set laser console to the calibration factor listed on handpiece package.**
5. Put on appropriate laser protective eyewear.
6. Put laser in “Laser Ready” mode.

Place the distal end of the test fiber so it just touches the surface of the water and activate the footswitch. Laser energy from the test fiber should cause a snapping sound. If no sound is heard or an error code is displayed on the Pulse Counter, contact customer service at 1-800-741-7062 (United States and Canada) and +1-770-419-3355 (International). Failure to test the fiber in water or testing the fiber in open air may result in device failure or injury to the user.

7. Disconnect test fiber and dry the distal end of fiber. Replace both end caps and store the test fiber in its original packaging.

3.5 INSTALLING CARDIOGENESIS HANDPIECE DELIVERY SYSTEM AND DELIVERING LASER ENERGY

CAUTIONS: ***Using or attempting to use optical fibers and/or other delivery systems not supplied by CryoLife may result in hazardous radiation exposure, injury to patient and/or user and damage to laser.***

All personnel within the treatment room must wear safety eyewear before placing laser in “Laser Ready” mode. Refer to Section 2.2 for proper selection of protective eyewear.

Laser energy will be transmitted through the handpiece delivery system while the laser console is in “Laser Ready” mode whenever the footswitch is activated.

1. The circulating nurse should peel open the CardioGenesis Handpiece Delivery System outer pouch to expose the inner sealed tray to the scrub nurse.
2. The scrub nurse should peel the Tyvek® lid from the tray and pass off the fiberoptic connector to the circulating nurse for connection to the laser console. Refer to the CardioGenesis Handpiece Delivery System Instructions For Use.
3. Make sure the coupler is threaded all the way into the laser aperture
4. Using the Calibration Increase (INC) and Decrease (DEC) buttons, match the calibration setting on the laser display with the calibration factor listed on the CardioGenesis Handpiece Delivery System package.

Representation of CardioGenesis Handpiece Delivery System Label

5. Refer to the Handpiece Delivery System Instructions For Use for instructions on how to functionally test and inspect the handpiece to ensure proper delivery of laser energy through the distal tip during the TMR surgical procedure.

CAUTION: ***The laser console should be placed in "Standby" mode during the inspection.***

NOTE: If a test fiber or handpiece is not installed, the console will not go to "Laser Ready" mode and will display "Install Fiber". To resume use, a handpiece must be connected to the laser aperture, ensure the fiber is tightened completely, **and its calibration setting entered using the calibration buttons**.

6. When the CardioGenesis Handpiece Delivery System has been positioned over the epicardium, place laser console in "Laser Ready" mode.
7. The console will perform a self test, if all is operating to specifications.
8. The red Laser Emission Enabled indicator should illuminate. With the laser in "Laser Ready" mode, the laser console will fire whenever the footswitch is activated.

CAUTION: ***Whenever the laser is in the "Laser Ready" mode, activating the footswitch will transmit laser energy through the handpiece.***

9. When laser treatment is complete, or between a series of treatment pulses, place the laser console in "Standby" mode by pressing the "Standby" button. The laser cannot be fired while in "Standby".

Note: As an added safety feature, if the laser is not used for a period of five minutes while the laser console is in "Laser Ready" mode, it will automatically change from "Laser Ready" to "Standby" mode. Press the "Laser Ready" button to switch the laser console back to "Laser Ready" mode to resume treatment.

3.6 TURNING OFF THE LASER

1. Place laser system in “Standby” mode.
2. Record the pulse data from the pulse counter display, if desired.
3. Turn Key Switch to “Off” (O) position.

IMPORTANT: IN CASE OF EMERGENCY, press the red “Laser Stop” button.
The system is immediately disabled when the red “Laser Stop” button is pressed.

If red “Laser Stop” button was pressed to turn off laser console, before restarting laser console make sure to:

- Turn key switch to “Off” (O) position, and
- Reset the “Laser Stop” button by twisting it to the right (button should “pop up” so that it is again ready for use in an emergency).

4.0 LASER SAFETY AND LABELING

4.1 SAFETY REGULATIONS AND REFERENCE DOCUMENTS

DANGER: Invisible Laser Radiation. Avoid eye or skin exposure to direct or scattered radiation.

The light output from the laser console is capable of inflicting permanent eye damage which could result in total blindness, burning skin tissues or causing spontaneous ignition of combustible chemicals or gases.

It is recommended that the user become familiar with the following safety and health regulations and guidelines:

Laser Institute of America (LIA), “Safe Use of Lasers in Health Care Facilities”, LIA Standard Z136.3, 2005;

Laser Institute of America (LIA), “Safe Use of Lasers”, LIA Standard Z136.1, 2007;

U.S. Department of Labor, Occupational Safety and Health Administration (OSHA), Code of Federal Regulations, 20 CFR 1518.54, and Federal Register 37, (243), pp. 27611 and 27512 (December 16, 1975);

American Conference of Governmental Industrial Hygienists (ACGIH), “Guide for Control of Laser Hazards”, ACGIH 0165, 1990;

U.S. Department of the Army, “Control of Hazards to Health from Laser Radiation”, Technical Bulletin TB MED 524, Washington, D.C., January 2006;

U.S. Department of the Air Force, “Laser Health Hazards Control”, AFM 161-8, 1980, Washington, D.C;

U.S. Food and Drug Administration, Code of Federal Regulations, 21 CFR Subpart J (Radiological Health) – Parts 1000 (General Information), 1002 (Records & Reports), & 1040 (Performance Standards for Light-Emitting Products).

4.2 OPTICAL SAFETY CONSIDERATIONS

Observe the following safety precautions:

1. Keep a basin of sterile water or saline available in case of fire.
2. During procedure keep laser console in “Standby” mode when not actively creating channels.
3. Protect the patient’s eyes by covering them with wet gauze or protective eyewear.

All personnel in the operating room must wear ANSI-approved protective glasses or goggles with an optical density of at least 4 to filter out the radiated wavelength of 2000nm-2200nm.

Note: The Nominal Hazard Zone for the CardioGenesis laser is approximately 31 inches, however, safety precautions should be observed in all areas of the OR when the laser is in use.

4. Do not look directly into laser beam, even with laser safety eyewear on.

5. DO NOT REMOVE OUTSIDE LIGHT-TIGHT COVERS FROM LASER CONSOLE.

NOTE: ***It is recommended that the safety precautions set forth in the American National Standard for the Safe Use of Lasers in Health Care Facilities (ANSI Z136.1 & Z136.3) be followed. The Nominal Hazard Zone (NHZ) for the CardioGenesis SolarGen 2100s Laser is approximately 31 inches.***

4.3 ELECTRICAL SAFETY CONSIDERATIONS

High voltage capable of causing death is used in this equipment. **DO NOT REMOVE OUTSIDE LIGHT-TIGHT COVERS**.

Only authorized representatives should perform maintenance or service operations.

4.4 ELECTROMAGNETIC RADIATION SAFETY CONSIDERATIONS

The SolarGen 2100s laser has been successfully tested for electromagnetic conformity with IEC 60601 (international standard for medical laser systems), as indicated in the tables included in this section. The user of the SolarGen 2100s laser console should read and refer to this information to ensure the laser is used in the proper environment.

CAUTION: ***Despite demonstrated conformity with all applicable electromagnetic compatibility requirements, the influence of the laser and other electronic devices upon each other cannot be completely ruled out.***

CAUTION: ***The use of any kind of radiofrequency transmitting device, including but not necessarily limited to, portable and mobile radiofrequency communication devices, in the vicinity of the laser or the treatment room is not allowed.***

Guidance and manufacturer's declaration – electromagnetic emissions		
The SolarGen 2100s laser system is intended for use in the electromagnetic environment specified below. The customer or user of the SolarGen 2100s laser system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The SolarGen 2100s laser system uses RF energy only for its internal function. There, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The SolarGen 2100s laser system is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The SolarGen 2100s laser system is intended for use in the electromagnetic environment specified below. The customer or user of the SolarGen 2100s laser system 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	±6 kV contact ±8 kV air	±6 kV contact ±8 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	±1 kV for power supply lines Not applicable	Mains power quality should be that of a typical hospital environment.
Surge IEC61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical 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)	Passed Level 0 Compliance	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Passed Level 2 Compliance	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical 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 SolarGen 2100s laser system is intended for use in the electromagnetic environment specified below. The customer or user of the SolarGen 2100s laser system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC61000-4-6	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 SolarGen 2100s laser system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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 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 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 SolarGen 2100s laser system is used exceeds the applicable RF compliance level above, the SolarGen 2100s laser system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SolarGen 2100s laser system.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the SolarGen 2100s laser system			
The SolarGen 2100s laser system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SolarGen 2100s laser system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SolarGen 2100s laser system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum power output of transmitter W	**Separation distance according to frequency of transmitter** M		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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 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.			

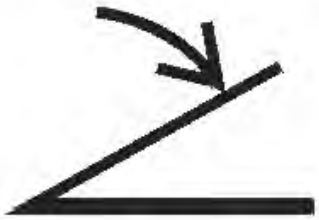
4.5 INTERLOCK SYSTEMS

The SolarGen 2100s laser features a Remote Interlock System which allows the hospital to wire the laser console to a remote door switch. This would only be desirable if the hospital desires the laser console to shut down anytime someone opens the door into the treatment room. Since most surgical procedures require some traffic in and out of the room, this Remote Interlock system is rarely used. To bypass an external door switch, a Remote Interlock Connector is provided which plugs into the Remote Interlock receptacle located next to the Footswitch Connector on the rear panel. The Remote Interlock Connector has been wired to bypass the interlock.

Contact customer service at 1-800-741-7062 (United States and Canada) and +1-770-419-3355 (International) for information on how to modify the Remote Interlock Connector to shut down the laser console using a door interlock system.

The following symbols identify the interlock systems:

Remote Interlock Symbol
Located on rear electrical panel



Footswitch Symbol
Located on rear electrical panel

4.6 LABELING

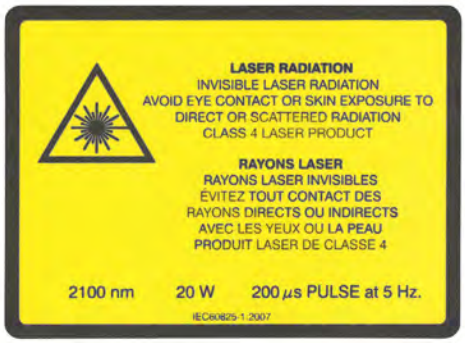
FDA Compliance Safety Labels that are mounted on the laser console in accordance with 21 CFR 1040 are pictured below.

Laser Aperture Label
Located on front of laser console below laser aperture

Laser Warning Symbol
Located on front of laser above laser aperture, also internally on laser head assembly four places

Explosion Hazard Label
Located on rear panel below power input

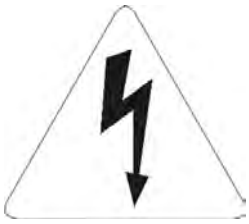
Cover Warning Label
Located on both side edges of top cover



Laser Warning Label
Located in top center of rear panel

Equipotential Label
Located on rear panel below
equipotential connector

Emergency Stop Label
Located on front panel above
emergency off switch



High Voltage Symbol
Located internally on laser head assembly, main discharge capacitor, PFN inductor,
and digital controller/discharge PCB assembly.

Resonator Cover Label
Located internally on laser head assembly, three places

Rail Cover label
Located internally on laser head cover

The Manufacturer's Label contains the following information and is located on rear panel above power input:

Manufacturer name and address;

Catalog Number REF;

Serial Number SN;

Manufacturing Date ;

Voltage, Amperage, and Frequency;

Type CF Applied Part Designation ;

CE Mark Designation;

Notice to Consult the Instructions for Use ;

US Regulatory Compliance Statement.

5.0 TROUBLESHOOTING

In the unlikely event that the laser system fails to operate properly, this troubleshooting guide will help locate and correct the problem. For major malfunctions, an authorized representative must be contacted at 1-800-741-7062 (United States and Canada) and +1-770-419-3355 (International).

BEFORE PROCEEDING, PLEASE CHECK FOR THE FOLLOWING ITEMS:

1. Verify that the console electrical cord is plugged into a **Dedicated** power source and the footswitch and remote interlock are both plugged into the appropriate receptacles.
2. Verify that the console circuit breakers are not tripped or shut off. If a circuit breaker is off, it will be extended out or the Main Line Power rocker switch will be in the down position. The circuit breaker(s) should then be reset.
3. If a SYSTEM FAULT has been observed, the system should be reset. Reset the system in the following manner. Turn the key switch counterclockwise to the OFF position, wait a few seconds and then turn the key switch clockwise to the START position. Hold the key in this position for one second and then release. The keyswitch will automatically spring back to the ON position. If the system fault repeats, call customer service at 1-800-741-7062 (United States and Canada) and +1-770-419-3355 (International).
4. Check to make sure that the CardioGenesis Handpiece Delivery System is securely and tightly connected to the laser console.

TROUBLESHOOTING GUIDE

DIFFICULTY	POSSIBLE CAUSE	SOLUTION
Key switch turned on, console does not turn on. No display.	Power cable not plugged in.	Connect power cable.
	No power at wall plug.	Check facility circuit breaker.
	Circuit breaker(s) tripped off (back panel).	Reset tripped breaker(s).
	Key not turned fully to START position.	Rotate key fully clockwise and hold for one second.
Console turns on, display flashes “INTERLOCK OPEN” continuously.	Remote Interlock not correctly installed on back panel.	Install Remote Interlock Jumper Plug or Remote Interlock Connector from door switch.
	If Remote Interlock used, door is open.	Close door to close interlock switch.
	If Remote Interlock is used, circuit is incorrectly installed.	Contact customer service.
Console turns on, display flashes “FOOTSWITCH NOT INSTALLED” continuously.	Footswitch is not connected.	Install the footswitch or check for proper connection of plug to the console.
	Footswitch is defective.	Contact customer service.
Console turns on, operates OK but sometimes reverts to STANDBY.	Console has been idle for 5 minutes while in READY mode.	Normal safety action.
	Fiber interlock system.	Contact customer service.
Laser does not fire when footswitch is activated.	Console is not on.	Turn console on.
	Console is in STANDBY.	Select READY mode.
	Faulty footswitch.	Contact customer service.
Console shuts down and shows no message.	Wall outlet circuit breakers tripped off.	Check facility wall circuit breakers and reset.
	Circuit breaker(s) tripped off.	Check laser circuit breakers and reset.
	Major system fault occurred.	Contact customer service.
After several test fire attempts, laser console display indicates “TEST FIRE FAILED” and reverts to STANDBY.	Proper laser energy level is not within the specified range after three attempts to correct internally.	Contact customer service.
Console shuts down, laser console display flashes “SHUTTER FAIL”.	Safety shutter detected in wrong position causing safety shutdown.	Do not rapidly press and release the footswitch.
		Turn console OFF, then ON again to reset console.
		If problem persists, contact customer service.
When key switch is turned to START and released, the laser begins to turn on, and shuts off immediately.	EMERGENCY OFF switch may be in the OPEN position.	Twist the EMERGENCY OFF switch clockwise to reset to the CLOSED position, and restart the laser.
	Cable connection is loose or disconnected inside the laser console	Contact customer service.
	Insufficient water in Coolant Reservoir.	Contact customer service.

6.0 DISPOSAL OF LASER CONSOLE

Consult national, state, and local regulations regarding disposal of this unit.

7.0 GLOSSARY

Ablative Surgery ..... The removal of tissue, vaporization.

Amplitude ..... Magnitude or height of a wave.

Attenuation ..... The decrease in energy as a beam passes through an absorbing or scattering medium.

Beam ..... A collection of rays that may be parallel, convergent, or divergent (ANS).

Continuous Mode ..... The duration of laser exposure is controlled by the user (by foot or hand switch); exposure is maintained as long as the switch is activated.

Divergence ..... Angle of spread of the outer edges of the laser beam from the tip of the delivery system.

Emission ..... Act of giving off radiant energy by an atom

Energy ..... Power (watts) times duration (seconds). One watt second = one joule.

Energy Source ..... High Voltage electricity, radiowave, flashes of light, or another laser used to excite the laser medium.

Fiberoptics ..... Thin, flexible devices used to carry optical energy.

Focal Length ..... Distance between the focusing lens and the point at which you achieve the smallest spot size (focus).

Focus (Focal Point) ..... The point at which light rays converge to form the smallest possible beam diameter thus achieving the greatest power density.

Frequency ..... The number of waves per time unit.

Irradiance ..... Power density incident on tissue during a single exposure.

Joule ..... A unit of energy equaling one watt-second.

Laser ..... An acronym for Light Amplification by the Stimulated Emission of Radiation, a device which produces an intense beam of light with the unique properties of coherency, collimation, and monochromaticity**.**

Micron (μ) ..... Unit of measurement, 1,000 nanometers.

Monochromatic ..... All waves of a specific laser type are of the same length and energy, causing an identical tissue effect.

Nanometer (nm) ..... Unit of measurement, one billionth of a meter.

Optically Pumped Laser ..... Laser in which the medium's electrons are excited by absorption of light from an auxiliary source (flash lamps).

Output Coupler ..... Partially reflective mirror in laser cavity that allows emission of laser light.

Photon ..... Energy in the form of light, given off when excited electrons decay to a ground or resting state.

Power Density ..... Measurement of power concentration within the laser spot as it impacts on tissue in units of Watts/unit area:

Power (watts) x 100/(spot size in mm)^2

Pulsed Laser ..... Laser which delivers energy in the form of a single or train of pulses of a duration less than .25 seconds.

Radiation ..... In the context of optics, electromagnetic energy is released; the process of releasing in extremely high peak power output.

Spontaneous Emission ..... Decay of an excited atom to a ground or resting state causing the emission of one photon.

Spot Size ..... Diameter of the laser beam spot as it impacts on a surface.

Stimulated Emission ..... Process of accelerating the decay of an atom to its ground state, causing two photons to travel in the same direction with the same wavelength and in phase.

Transmission ..... Passage of electromagnetic radiation through a medium.

Vaporization ..... Conversion of a solid or liquid into a vapor.

Watt ..... A unit of power used to express laser power. Power is equivalent to current times voltage. 1 watt = 1 amp-volt.

Wavelength ..... Distance from one wave peak to the next.

8.0 SYMBOLS

=Consult Instructions for Use

REF =Catalogue Number

SN =Serial Number

= Manufacture Date

=Type CF Applied Part

EC REP

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