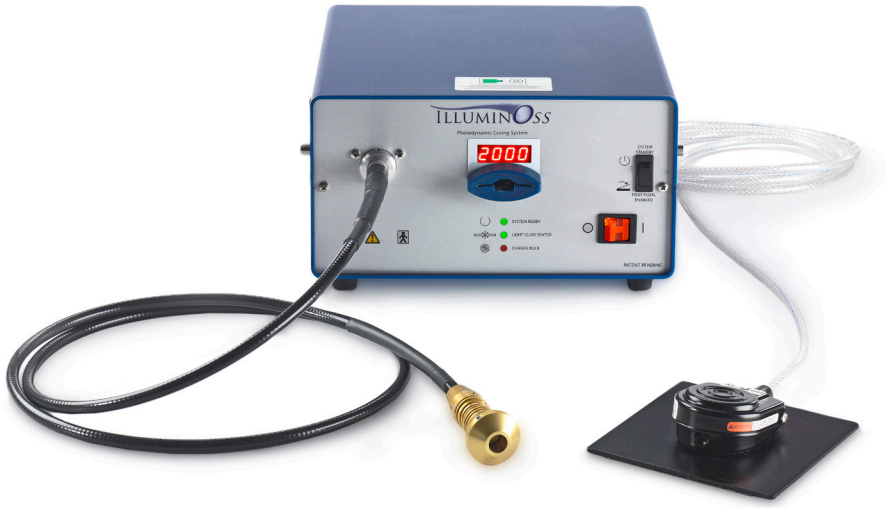
ILLUMINOSS®

PHOTODYNAMIC LIGHT CURING SYSTEM

INSTRUCTIONS FOR USE

SY-2000-01



ILLUMINOSS MEDICAL INC
993 WATERMAN AVENUE
EAST PROVIDENCE, RI 02914
+1 (401) 714-0008

CONTENTS

The proper set up and operation of this photodynamic curing system will maximize safety and performance. Please read and follow all safety and operating instructions compiled in this and other instructions prior to setting up and operating the photodynamic light source or its individual components. Set-up and activate the Photodynamic Curing System prior to the start of any surgical procedure using the IlluminOss implant to ensure proper equipment operation as described in this manual. Do not use the system or implant if any of its components are damaged or not operating properly and contact IlluminOss Medical for service or replacement.

1. Intended Use

The intended use of the Photodynamic Light Curing System is to deliver visible light to the IlluminOss Photodynamic Bone Stabilization System implant to polymerize and harden the photodynamic liquid monomer contained within the balloon portion of the implant.

2. Indications For Use / Contraindications

Please refer to the implant instructions for use for indications and contraindications.

3. Warnings, Precautions, And Safety Considerations

The words WARNING, CAUTION, and NOTE carry special meanings and should be carefully Reviewed.

Warning: The personal safety of the patient and health professional may be involved. Disregard-ing this information could result in injury to the patient.

Caution: Special service procedures or precautions must be followed to avoid damaging the instrument.

Note: Special information to make maintenance easier or important information clearer.

Warnings and Cautions

WARNING:	To avoid eye injury, do not look directly into the light beam emitted by the light guide assembly or light pipe. Extreme long term exposure to bright light may cause eye injury. Avoid direct exposure to light. The bulb utilized in this system emits UV.
WARNING:	The end of the light guide assembly, without the light pipe adapter, may be hot after use and may be harmful to skin if touched. Do not operate without light pipe adapter in place.
WARNING:	The photodynamic curing system is not suitable for use in the presence of a flammable or anesthetic mixture. It should not be used in an oxygen enriched environment.
WARNING:	Disconnect power supply from power outlet prior to any maintenance.
WARNING:	The photodynamic curing system and all associated accessories are for use exclusively with the IlluminOss Medical Inc Photodynamic Bone Stabilization System. Do not use the Photodynamic Curing Console, Light Guide, or associated accessories for any other use.
WARNING:	If any component failure is observed during use or unexpected light is visible, power down unit and contact customer service immediately
CAUTION:	Use only the cleaning methods described in this manual.
CAUTION:	There are no User-serviceable parts inside the device. Contact IlluminOss Medical Inc for any service needs.
CAUTION:	Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in this manual.
CAUTION:	Portable and mobile RF communications equipment can affect medical electrical equipment.
CAUTION:	U.S. Federal Law restricts this device for sale by or on the order of a physician.

4. Unpacking and Inspection

Upon receipt of the unit, carefully remove the contents from the boxes and check for damage. IlluminOss Medical Inc is not responsible for damage from shipping – all claims for shipping damage should be made with carrier.

Check all boxes for contents and record any serial numbers with table included in this manual for future reference. You may wish to retain original shipping cartons in the event of repackaging for return.
If you observe or experience any problems with your equipment, notify Illuminoss Medical Inc customer service immediately.
The light source console is shipped with the bulb/reflector installed.
Before continuing with unpacking and installation, please read the following chapters of this operation manual for safety recommendations and installation, running, and troubleshooting instructions.

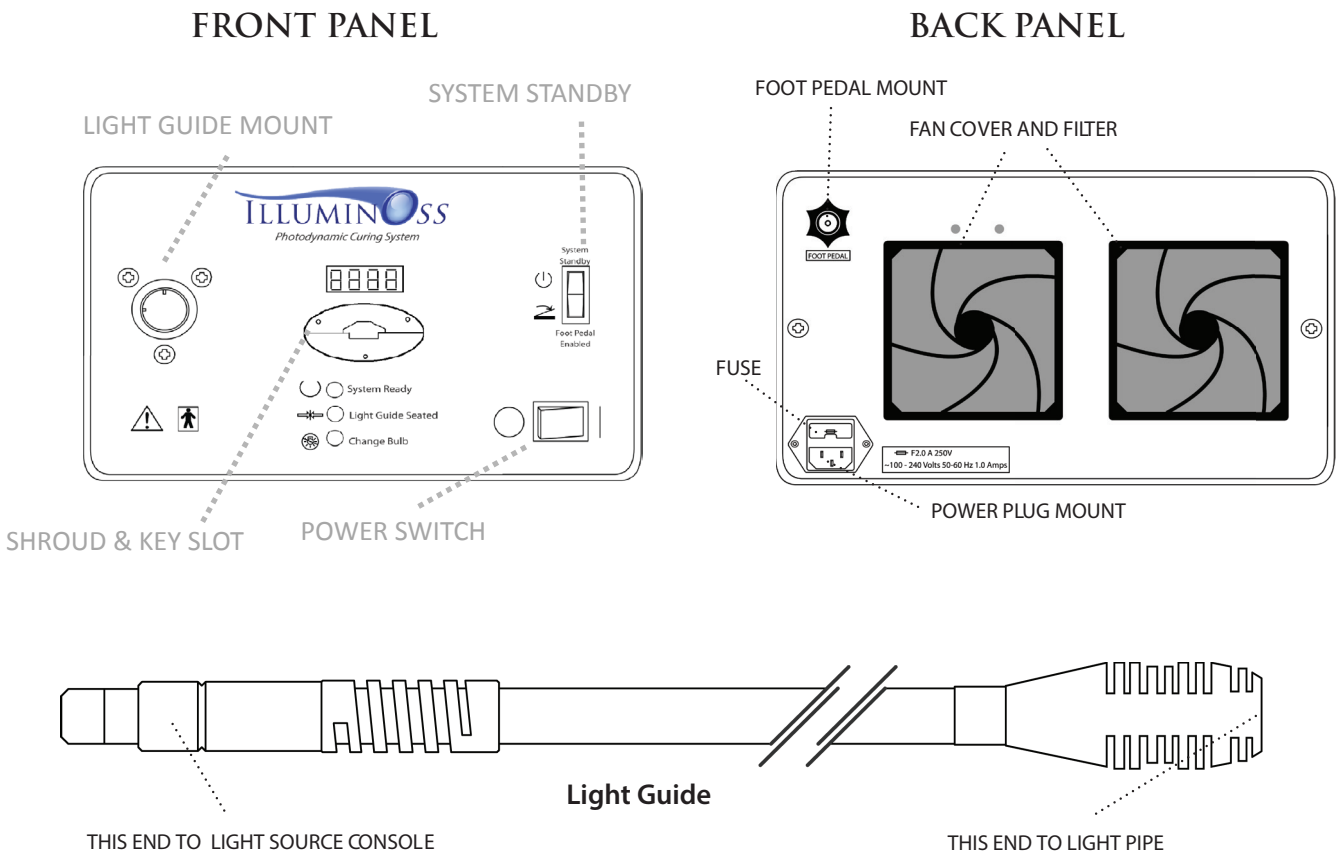
5. System Overview

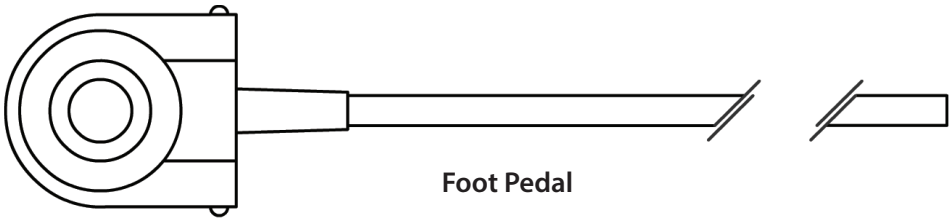
The Light Source Console is a special purpose light source for the curing of Photodynamic Monomer in the IlluminOss Medical Inc Photodynamic Bone Stabilization System. It emits a specific spectral output from the Light Guide to effect curing.

The unit consists of aluminum housing containing a 75W power module, lamp and lamp mount, an internal UV light band pass filter, a shutter system, and a programmable timer control board with a timer key interface. The shutter is supplied with "Foot Pedal Enabled" and "System Standby" operation modes. The Light Guide plugs into the Light Guide Mount.

The power supply operates on universal line voltages from 100-240VAC, 50-60Hz and is an auto-ranging power supply specially designed to provide properly rated voltage and current to the 75W lamp.

A cooling fan with a control loop is provided to keep the lamp housing and internal components of the power supply at the optimum operating temperature. The fan must not be covered or otherwise blocked. The light source is a 75W, medium pressure arc metal halide lamp mounted in a reflector and focused to provide optimum light output. The console is rated for continuous operation.
The bulbs used to power the system all degrade with repeated use. Intensity, therefore, decreases as the bulb ages. A "Change Bulb" light illuminates when bulb replacement is required.





Foot Pedal

The anodized aluminum housing contains an electronic power supply, circuit protection, bulb/reflector assembly, internal light filter for extended light guide life, thermostatically controlled cooling fan, light guide mount, bulb and unit status indicator lights, and a shutter system. A thermal shutdown sensor is provided for internal temperature control of the unit. A cover closed switch and light guide sensing switch add to the safety of the unit. Fan filters should be changed or cleaned frequently to prevent blockage and reduced ventilation airflow. The electric shutter is supplied with foot pedal enabled and system standby operating modes. The light guide is separate and plugs into the light guide holder.

⚠	WARNING:	Engage the light guide in the mount before the light is turned on, and remove the light guide from the bezel only after the light is turned off to avoid the accidental possibility of exposure to the light.
⚠	WARNING:	UV emitted from this product.

The power supply operates on line voltage between 100-240 VAC and frequencies between 50-60 Hz. If the bulb extinguishes due to a momentary power failure, the unit must be turned off, allowed to cool, and then turned on again in order to reignite the bulb. A cooling fan is provided to keep the bulb housing and internal components of the power supply at the optimum operating temperature. The fan must not be covered or otherwise blocked. The light source is a 75-Watt short arc mercury vapor bulb mounted in a reflector and pre-focused to provide optimum light output. The unit is rated for continuous operation.

The system is designed to operate in conjunction with the IlluminOss Variable Timer Keys which will be supplied with each IlluminOss Photodynamic Bone Stabilization System. The keys contain specific resistor circuitry which, when connected to the light box, will program a specific timer countdown cycle which is optimized for the specific IlluminOss implant.

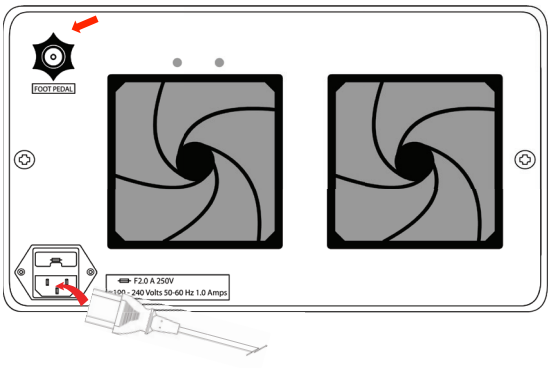
Front Panel Light Display

Testing confirms a minimum acceptable intensity provided by the lamp bulb. A "Change Bulb" Indicator light is provided to alert the operator to check bulb operation or to contact customer service if maintenance is required.

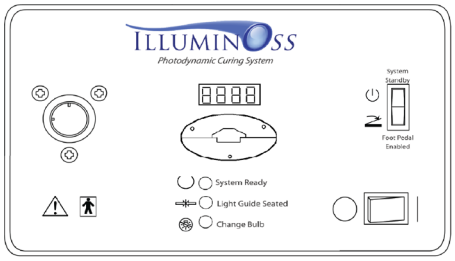
◯	●	SYSTEM READY
⟷	●	LIGHT GUIDE SEATED
☼	●	CHANGE BULB

6. System Setup

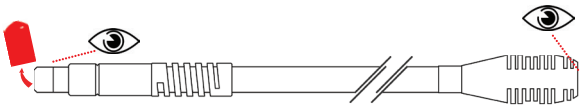
1. Connect power cord and foot pedal to rear of the light source console and plug the power cord into a grounded wall outlet.



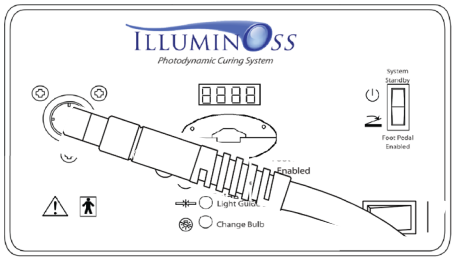
2. Remove the protective cover from the light guide mount.



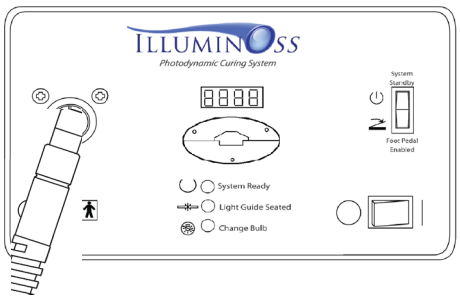
3. Remove the protective cover from the light guide. Visually inspect both ends to verify no foreign material is present. The light guide ends may be cleaned with 70% IPA as required.



4. Insert Light Guide into Light Guide Mount until it snaps in place. The GREEN "Light Guide Seated" indicator will illuminate when the light guide is properly seated and the unit is turned on.



5. The Light Guide is now installed and ready for use. The ends of the Light Guide should be cleaned periodically with 70% IPA.



7. Operation

The Photodynamic Curing System will arrive almost fully assembled. The system should be positioned in a dry location that will not obstruct the rear of the unit. Adequate ventilation is essential for proper operation.

CAUTION: TO ENSURE PROPER OPERATION OF THE SHUTTER, BE SURE TO COMPLETELY INSERT THE LIGHT GUIDE INTO THE CONSOLE. ENSURE THAT THE LIGHT GUIDE REMAINS IN PLACE DURING USE.

To power the system, turn the Power Switch to the ON position; the fan, timer, and 75W lamp should begin to function. The operator should confirm proper start up before commencing with surgery by checking for an audible fan system and visually confirming a green light shining out the back of the box. Before operating the unit, allow the 75W lamp to complete the warm up cycle, approximately five minutes.

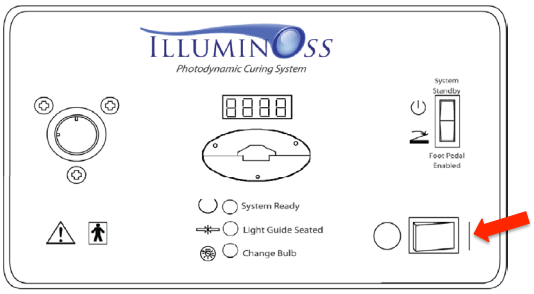
CAUTION: NEVER LOOK DIRECTLY AT LIGHT EXITING THE LIGHT GUIDE OR THE LIGHT PIPE.

CAUTION: IF POWER TO THE CONSOLE IS DISTRUPTED DURING A CURING CYCLE, TO ENSURE PROPER CURING HAS BEEN ACHIEVED, IT IS RECOMMENDED THAT A FULL REPEAT CYCLE IS PERFORMED FOLLOWING THE RESUMPTION OF POWER AND A FULL SYSTEM RESTART. THE CYCLE TIME IS AUTOMATICALLY SET BY THE TIMER KEY INCLUDED IN THE CATHETER PACKAGE.

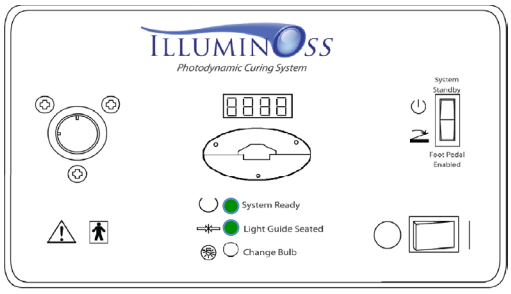
CAUTION: WHEN THE "CHANGE BULB" LIGHT ILLUMINATES, THE UNIT WILL NOT OPERATE UNTIL A NEW BULB IS INSTALLED AS DESCRIBED IN THE BULB REPLACEMENT PROCEDURE.

Bulb life is reduced each time it is started. To avoid premature lamp deterioration, leave the unit on throughout breaks and short shutdowns. These light sources are designed for continuous operation. If the power is lost momentarily, shut the unit off to allow the unit to cool down for 5 -10 minutes, then restart the console.

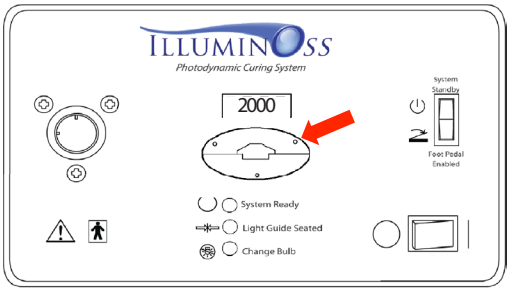
1. Turn the power switch to "ON." The LED display should run through a power up sequence and end on 2000 seconds.



2. Allow the bulb to warm up (3-5 minutes). The bulb is warmed up when the GREEN "System-Ready" indicating light is illuminated. The shutter is inoperable until the warm up period is complete and the Light Guide is installed.

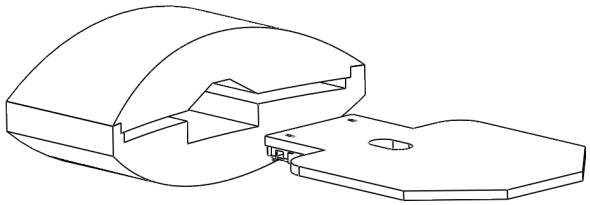


③ Ensure that the LED display shows 2000 seconds, then insert the Variable Timer Key contained in the package of the catheter being used in the procedure. Confirm that the LED display changes within 2 seconds after insertion and displays the correct time value corresponding to the key inserted.

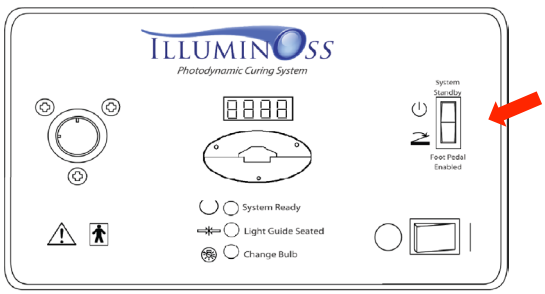


CAUTION: FAILURE TO USE THE PROPER VARIABLE TIMER KEY CAN RESULT IN INADEQUATE CURING OF THE ILLUMINOSS MONOMER. ENSURE YOU ARE USING THE CORRECT TIMER KEY CORRESPONDING TO THE IMPLANT SELECTED FOR SURGERY.

NOTE: There is a protective shroud protruding from the faceplate which prevents improper insertion of the Variable Timer Keys. See image below for help with insertion.



④ Ensure that the STANDBY TOGGLE SWITCH is in the "Foot Pedal Enabled" position, then operate the Light Source Console by depressing the Foot Pedal. The Light Source Console will operate for the prescribed number of seconds. With the STANDBY TOGGLE SWITCH in the "System Standby Mode," the Foot Pedal is inoperable and the user will hear an audible beep when the foot pedal is depressed.



CAUTION: DO NOT REMOVE TIMER KEY DURING COUNTDOWN!

CAUTION: If STANDBY TOGGLE SWITCH is changed to "System Standby Mode" during operation, wait for time cycle to expire, remove key and reinsert, then reinitiate full cure cycle.

CAUTION: This is an arc, not a filament bulb. Avoid turning the console off and on. It is recommended that the console is turned on at the beginning of the procedure and remains in operation until the end of the procedure.

CAUTION: The bulb must be cool before it can be reignited. Turn the unit off and allow 5 – 10 minutes for it to cool down. If the bulb fails to reignite, refer to the "Troubleshooting" section of this manual. Bulb life is reduced each time the unit is switched on and off. Avoid repeated cycles that shorten bulb life by leaving the unit on throughout the procedure.

8. Warranty and Maintenance

Warranty

IlluminOss Medical Inc offers a one year warranty against defects in material and workmanship on all system components, except the bulb. Unauthorized repair, modification, or improper use of equipment will void the warranty. The use of aftermarket replacement parts not supplied or approved by IlluminOss Medical Inc will void any effective warranties and may result in damage to the equipment.

Maintenance

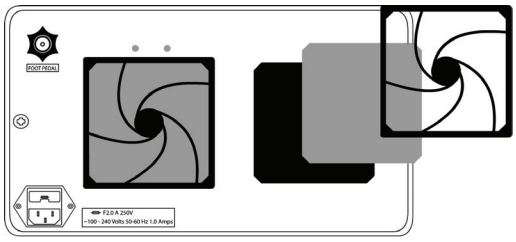
The IlluminOss Medical Inc Light Source console was designed to operate with minimal maintenance. Follow the listing below to assure top unit performance. In addition, examine cords, connections, and transformer case for wear or damage monthly. After every use, clean the Light Source Console, Light Guide, Foot Pedal, and power cord according to the Cleaning and Sterilization section of this manual.

LightGuide Assembly

Clean the Light Guide ends monthly or as required according to the Cleaning and Sterilization section of this manual. The ends of the Guide should be kept clean to transmit as much light as possible. Handle the Light Guide with care, as sharp bends will reduce light output and cause permanent damage.

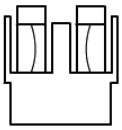
Fan Filters

The external fan filters should be inspected and cleaned periodically to prevent dust buildup from affecting airflow through the unit. Spare filters are provided with each unit and with replacement bulbs. The fan filters are washable and may be reused. Replace the fan filter by removing the snap-on cover from the rear of each grill.



Fuse Replacement

Contact IlluminOss for servicing.



Bulb Replacement

The bulb requires replacement after 500 hours of use. After 450 hours of use, the red "Change Bulb" indicator light on the front panel of the box will flash to warn the user of the impending need to replace the bulb. The unit will be operational while the light is flashing. After 500 hours, the red "Change Bulb" light will permanently illuminate, there will be an audible beeping sound and the unit will be inoperable. Return the unit to IlluminOss for bulb replacement when the indicator light starts flashing.

Cleaning

Clean the Photodynamic Curing system immediately after each use by following the cleaning procedure described. These procedures require the use of a low-level disinfectant (LLD) wipe and solution that includes the following claims on its labeling – that it does not cause adverse effects (corrosion) to plastics, rubbers, and metals.
Users of the Photodynamic Curing System must also observe site-specific governing regulations for protection of personnel and for effective handling and disposal of LLD waste by-products.

CAUTION: DO NOT IMMERSE THE LIGHT SOURCE CONSOLE, LIGHT GUIDE, POWER CORD, OR FOOT PEDAL IN ANY SOLUTION, OR CLEAN WITH STEAM, AUTOCLAVE OR ETHYLENE OXIDE.

9. Trouble Shooting

WARNING: ONLY QUALIFIED MAINTENANCE PERSONNEL SHOULD ATTEMPT THE FOLLOWING PROCEDURES.

Problem: Bulb Will not ignite or Change Bulb light is on

Possible Cause	Testing	Corrective Action
Improper connections	Visually inspect all input / output connections (i.e. power cord, bulb)	Secure all connections
Bulb beyond useful life of 500 hours	Replace with a new bulb / reflector assembly	Contact IlluminOss Medical or your distributor for bulb replacement
Main line fuse blown (no power to unit)	Remove fuse from power recepticle and check with an ohmmeter	Replace fuse if defective

10. Customer Service

If you encounter a problem, have any questions, or would like to help us with your suggestions or recommendations, please contact our Customer Service departments at:

993 Waterman Avenue
East Providence, RI 02914
United States of America
+1 (401) 714-0008

Product Information Table

The table below has been provided for recording product serial / lot numbers for reference.

Item	Part Number	Serial / Lot Number
Photodynamic Light Curing System	SY-2000-01	
Light Guide Pole Clamp	CT-0164	

Maintenance Log

Instigating Issue	Performed by / Date	Action Taken

IlluminOss Medical Inc.
993 Waterman Avenue
East Providence, RI 02914
United States of America

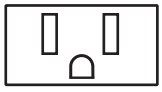
+1 401 714 0008 TEL
+1 401 714 0009 FAX

11. Specifications

Power Supply

The Illuminoss Medical Inc Photodynamic Curing System's power supply provides power from an appropriate wall outlet to the system.

Outlet Types

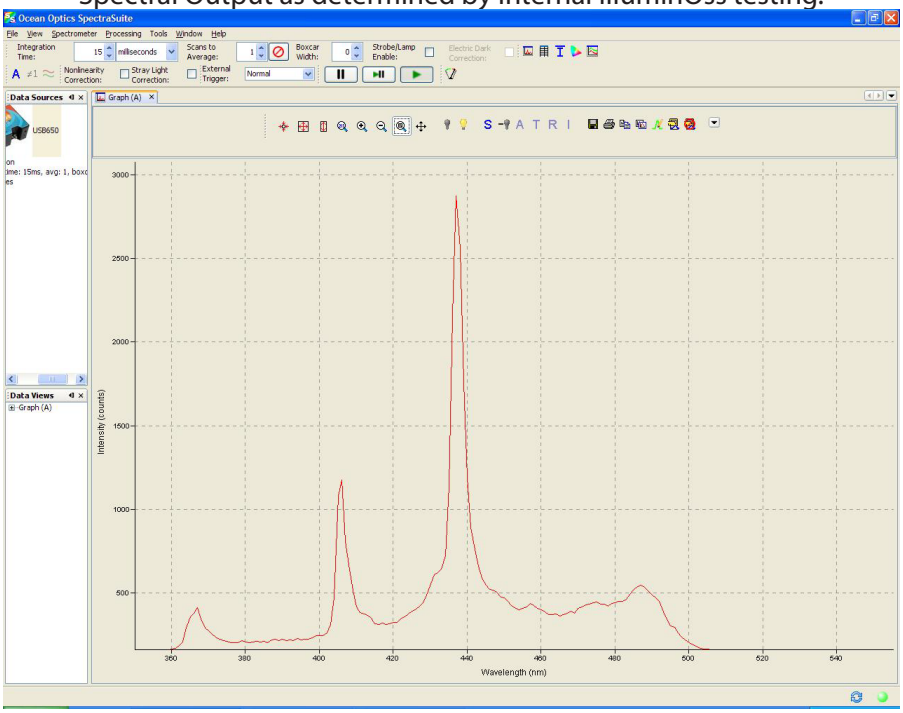
A

USA
NEMA 1-15P

Verify that the power supply will connect to the appropriate outlet and that the power supplied to the outlet is within the range specified in the table provided.	
Plug P/N Codes	Plug Style
01-9007-US	A

Frequency	300 - 500nm (~85% Visible, > 400nm)
Power Requirements	100 - 240 VAC, 50-60HZ, 1.1 AMP
Bulb	75 Watt Mercury Bulb included
Reflector	Elliptical Glass with Dichroic Coating
Shutter Timer	Digital LCD Timer, Timed Shutter
Shutter Activation	Foot Switch, IP68
Cooling	Filtered, Single Fan Arrangement, Thermally Controlled to Maintain Proper Lamp Temperature
Operating Conditions	50°F-86°F (10°C-30°C), 30% to 75% relative humidity, atmospheric pressure 700hPA to 1060hPA
Housing Dimensions	12.0" x 12.25" x 6.5" (30.5c, x 31.1cm x 16.5cm)
Weight	14.0 lbs (6.0 kg)
System Warranty	1 Year from Purchase
Type of Applied Part	BF
Protection Class in Accordance with EN / IEC 60601-1; (UL 60601-1 / CSA C22.2 No. 061.1 for USA / Canada)	Class I
Degree of Protection Against Foreign Solids	IPX0
Mode of Operation / Duty Factor	Continuous Operation
Degree of Protection when Flammable Gases are Present	Not Category AP or Category APG Equipment
Storage, Transportation and Shipping Conditions	32°F-122°F (0°C-50°C), 30% to 75% relative humidity, atmospheric pressure 700hPA to 1060hPA

Spectral Output Information

Spectral Output as determined by internal IlluminOss testing.



12. SYMBOL DESCRIPTIONS

Symbol	Description
	Attention, Warning, Caution Attention, consult accompanying documents
	Caution, high temperatures
	Caution, high-intensity light
	Type BF Applied Part
	Equipotential Ground
	System Ready
	Light Guide Connected
	Change Bulb
	Direct Current
	Alternating Current
IPXO	PHOTODYNAMIC CURING SYSTEM not protected from the ingress of water
IP68	FOOT PEDAL dust and liquid rating
	Risk of Electrical Shock when cover is removed
	System Stand-by
	"Foot Pedal" Enabled
WARNING: UV emitted from this product	The bulb utilized in this system is in excess of the Exempt Group as per IEC 62471-2. Viewer-related risk is dependant upon how the users install and use the product.

13. GUIDANCE AND MANUFACTURERS DECLARATION

CERTIFIED TO: CAN / CSA STD C22.2 NO. 601.1-M90:2003
CAN / CSA STD C22.2 NO. 601.1-10-92

CONFORMS TO: EN 60601-1-2/A1:2007
EN 55011/A2:2007
IEC 60601-1:A2:1995 + 2005 (3rd)
IEC 60601- 2-18:2009

RoHS Compliant

Calibration of Light Curing System is not required

ILLUMINOSS MEDICAL INC.
993 Waterman Avenue
East Providence, RI 02914
U.S.A.
+1 (401) 714-0008

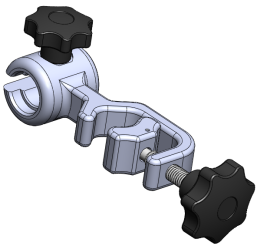
EMISSIONS FOR ALL EQUIPMENT AND SYSTEMS

The Photodynamic Curing System and its powering accessories are intended for use in the electromagnetic environment specified below. The customer or user of the Photodynamic Curing System and its powering accessories should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Photodynamic Curing Console and its powering accessories use RF energy for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Photodynamic Curing Console and its powering accessories are suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 31000-3-3	Complies	

OPTIONAL ACCESSORIES

LIGHT GUIDE POLE CLAMP
(CT-0164)



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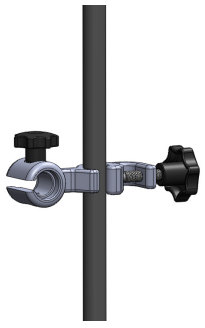

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