# IlluminOss Photodynamic LED Light Curing System

## Instructions for Use

### SY-2100-01


For detailed procedural information including Indications, Warnings, Cautions, Risks & Contraindications, visit www.illuminoss.com/ifu-us

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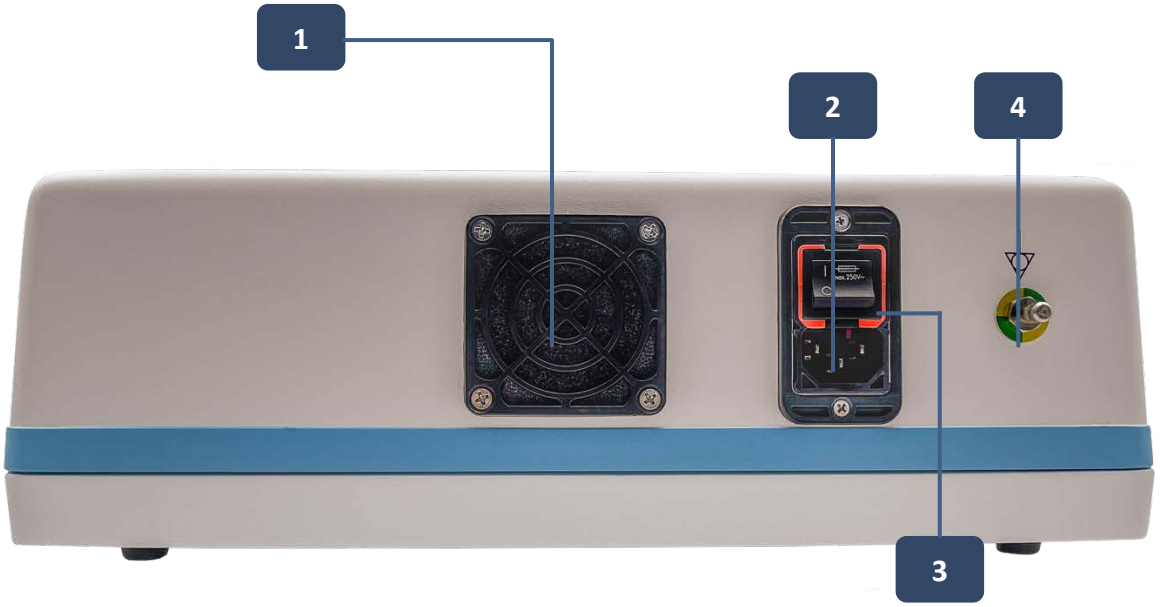
| 3 | (LCD) Touchscreen |
| 4 | Light Fiber Insert / Release Button |
| 5 | Nosecone |

## DESCRIPTION OF PARTS | LED CONSOLE

### LED Console Rear View




| Description of Parts | |
|---|---|
| 1 | Fan |
| 2 | Main Power Switch |
| 3 | Power Cord Attachment and 10 ft length Power Cord (not pictured) |
| 4 | Earth Ground |

## Additional Parts (Contained Within the Sterile Implant Kit)


| Description of Parts | |
|---|---|
| 1 | Timer Card |
| 2 | Light Fiber Hub |

## DESCRIPTION OF PARTS | TOUCHSCREEN

### (LCD) Touchscreen

The organization of the Touchscreen on the LED Console is designed to provide the user with details about the status of the system as well as understanding the stages of system setup.


| Description of Parts | |
|---|---|
| 1 | Timer Duration |
| 2 | Status |
| 3 | Light Fiber Status |
| 4 | User Actions |


| Touchscreen Status Definitions | |
|---|---|
| Setup | Time being set and Light Fiber being attached |
| Standby | All systems programmed, timer set, Light Fiber attached and waiting for user |
| Enabled | System moved from Standby – awaiting user activation |
| Curing | Activation of light source, light delivered to the implant – timer counting down |
| Done | Curing process completed – light delivery process terminated |

## SYMBOLS

| Symbols | Description |
|---|---|
|  | Warning |
|  | Caution |
|  | Read Instructions For Use |
|  | Catalog Number |
|  | Medical Device |
|  | Serial Number |
|  | LOT Number |
|  | UDI code |
|  | Manufacturer |
|  | Date of Manufacture |
|  | CE mark for product compliance |
|  | FCC symbol |
|  | Operating Temperature |
|  | Operating Humidity |

| | |
|---|---|
|  | Fuse information |
|   | National Recognized Test Laboratory Safety Mark |
|  | Electrical waste and electronic equipment |
|  | Type BF Applied Part |
|  | Equipotential Ground |
| IPX0 | Ordinary equipment, no protection against ingress of particulate or water |
|   | Radio Frequency Identification (RFID) |
|  | Caution Optical Radiation |

## SYSTEM OVERVIEW

### LED Console

The IlluminOss LED Console is a special purpose light source for the curing of Photodynamic Monomer in the IlluminOss Photodynamic Bone Stabilization System Implant Kit, which are provided to the user as a sterile EtO packaged implant.

The LED Console emits a specific spectral output of 435 nm from an LED which is delivered to the Light Fiber positioned within the implant to affect curing of the implant.

The unit consists of a composite outer housing containing an LED power module; LED and focusing optics; an optical shutter system; an RFID Timer Card reader; and a timer control board with an interface that manages the duration of visible light provided which is specific for each of the implants.

The Shutter permits either “Active” or “System Standby” operation modes, precluding the emission of light to the Light Fiber until the user defines the activation step.

The Light Fiber plugs into the Nosecone which detects the insertion of the Light Fiber, ensuring that it is attached to the LED Console prior to the delivery of light as well as ensuring the Light Fiber is connected to the system for the entire duration of the curing process. The system shall not operate without the Light Fiber inserted into the Nosecone.

Do not use any other components or parts other than those supplied with the LED Console.

**Warning:**

**The LED Console may not be used with the predicate implant kit.**

### System

The system user architecture has multiple safeties built into each process. Any active processes, initiation of curing, powering the system off, or stopping of the curing process, requires two discrete actions to prevent inadvertent activation by the user.

Each individual stage of the system setup has a “Back” button permitting modification or alteration to the process. Curing times are embedded into the system during setup, and any duration of curing less than that programmed (e.g., user-initiated stop or Light Fiber disconnection) reads as a system fault on the screen. The Nosecone continually monitors for the presence of the Light Fiber using microswitches, and any removal of the fiber during the curing process also reads as a fault. All faults associated with shortened cure times resets the timer to the originally designated cure time to prevent potential of shortened cures times.

### Power Supply

The power supply operates on universal line voltages from 100-240VAC, 50-60Hz with a fixed power supply specially designed to provide properly rated voltage and current to the LED. An external cooling fan is provided to keep the LED lamp housing and internal components of the power supply at optimum operating temperature. The fan must not be covered or otherwise blocked.

The IlluminOss Photodynamic LED Light Console SY 2100-01 is provided with a 10 ft medical grade power cord. There are no other parts nor accessories required for its use. Should the 10ft power cord become lost or damaged, contact IlluminOss Medical Inc. for a replacement.

### Light Source

The light source is a specific wavelength and power LED, with an integrated optical barrel, focused to provide optimum light output to the plastic optical Light Fiber. The LED Console is rated for continuous operation.

### RFID Timer Cards

The system is designed to operate in conjunction with the IlluminOss RFID Timer cards, which will be supplied with each IlluminOss Photodynamic Bone Stabilization System implant Kit.

The cards contain specific RFID programming, which when read by the RFID antennae will program a specific timer countdown cycle optimized for that specific IlluminOss implant. Once the RFID card has been read by the LED Console, the RFID reader process is terminated, preventing the reading of another card. Curing time can then only be adjusted by the user actively navigating backwards through the setup process and resetting the timer system with a new timer card.

## Maintenance

All LEDs degrade over time, and the LEDs used to power the LED Console are no different, as they degrade to some extent after extensive and repeated use. Although the amount determined by testing was shown to be minimal, nonetheless a “Change LED” light illuminates when the LED has achieved 4950 hours, reminding the user to have the unit serviced. The unit shall continue to operate normally up through 5000 hours of use, where the system shall finish the last curing cycle and no longer function, requiring a replacement of the illumination system by authorized IlluminOss parties. There are no self-serviceable components on the LED Console and all repairs must be performed by IlluminOss.

## INTENDED USE, INDICATIONS & CONTRAINDICATIONS

| Intended Use, Indications & Contraindications | |
|---|---|
| Precautions | • Read instructions prior to use.<br>• Prior to using the IlluminOss Photodynamic Bone Stabilization system, surgeons should, through specific training and experience, be thoroughly familiar with the properties, handling characteristics, and application of the system.<br>• Strict adherence to good surgical principles and technique are required during the use of the IlluminOss Photodynamic Bone Stabilization System.<br>• The monomer in liquid form may cause sensitization by skin contact. In case of contact with skin, wash immediately with soap and water.<br>• In the tibia and femur, the IlluminOss implant is intended only as a means of providing supplemental fixation for FDA-cleared fracture fixation devices. In the tibia and femur, IlluminOss cannot be used as a stand-alone implant. |
| Intended Purpose | The intended purpose of the Photodynamic LED 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 sterile ( EtO sterilized ) packaged balloon implant portion of the product. |
| Intended Users & Environment of Use  | The intended users of the LED Console are orthopedic surgeons, nurses and surgical technicians working within the environment of the Operating Room, in the repair and stabilization of fractures. As with any surgical equipment, the user is required to read and understand the operating manual of the system that they are using.<br><br>**WARNING:** The Photodynamic LED Light 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. |
| Intended Patient Populations | The Photodynamic LED Light Curing System is intended for use in skeletally mature patients in the treatment of traumatic, fragility, pathological, and impending pathological fractures of the humerus, radius, ulna, clavicle, pelvis, fibula, metacarpals, metatarsals, and phalanges. It may also be used in the femur and tibia to provide supplemental fixation to an anatomically appropriate FDA-cleared fracture fixation system. |

| Intended Use, Indications & Contraindications | |
|---|---|
| Indications / Medical Condition(s) | The Photodynamic LED Light Curing System is used only in conjunction with the curing of the IlluminOss Photodynamic Bone Stabilization Implants, and therefore the indications that govern its use are those of the implant.<br><br>The IlluminOss Photodynamic Bone Stabilization System is indicated for use in skeletally mature patients in the treatment of traumatic, fragility, pathological, and impending pathological fractures of the humerus, radius, ulna, clavicle, pelvis, fibula, metacarpals, metatarsals, and phalanges. The IlluminOss Photodynamic Bone Stabilization System can also be used in conjunction with FDA-cleared fracture fixation systems to provide supplemental fixation in these anatomic sites. The IlluminOss System may be used in the femur and tibia to provide supplemental fixation to an anatomically appropriate FDA-cleared fracture fixation system. |
| Contraindications | There are no specific contraindications for the IlluminOss LED Console.<br><br>The IlluminOss Photodynamic LED Light Curing System is used only in conjunction with the IlluminOss Photodynamic Bone Stabilization System, and therefore the contraindications that govern its use are those of the implant.<br><br>The warnings for the IlluminOss Photodynamic Bone Stabilization System are:<br><br>• This device has not been studied in patients who are skeletally immature.<br>• Do not reuse or attempt to re-sterilize the disposable components.<br>• Discard and do not use opened or damaged packages. Do not use if there is a loss of sterility of the monomer or other kit components.<br>• Do not utilize any component after the expiration date.<br>• Correct selection of the implant diameter and length is extremely important, and should be determined before implantation:<br>• Ensure the implant is long enough to span the fracture, and is not longer than the canal<br>• Ensure that the implant diameter is large enough to ensure cortical contact.<br>• Ensure the separation instrument can reach the balloon.<br>• The polymerization (curing cycle of implant) is a short term exothermic reaction.<br>• Do not insert or affix sutures, K-wires, or other hardware to or |

through the stabilization balloon until after it has cured.

- Do not attempt to inflate the balloon catheter by use of any ancillary inflation equipment. Properly sized inflation syringes and the amount of monomer necessary to accomplish the appropriate inflation are provided. The balloon is made of a non-compliant, thin walled PET and does not expand larger than its prescribed size.
- Do not add any material or fluids to the monomer.
- Do not expose monomer to any light source other than the IlluminOss Photodynamic Curing System, shield the monomer from light after removal from vial.
- If, upon fluoroscopic examination, the user determines that the inflated balloon is not in contact with the intramedullary canal of the bone, the user should remove the balloon prior to curing the monomer, reassess sizing, and replace it with the appropriately sized balloon.
- Do not activate the light source until the balloon catheter is in the appropriate position and the bone fracture is reduced and ready for stabilization. Activation of the light source in the presence of the monomer will initiate polymerization, an irreversible process.
- The monomer must be exposed to the IlluminOss Photodynamic Curing System for a specific amount of time in order to activate and fully cure the implant. A partially cured implant cannot be used to complete a procedure. If an uncured, or partially cured implant is suspected, or if a curing cycle is interrupted, additional curing cycles should be completed
- Inadequate postoperative fixation or unanticipated postoperative events may affect the interface between the bone and stabilization balloon, which may lead to micro-motion of the implanted balloon and balloon surface. Periodic follow up examinations and radiographs are advised for all patients.
- Deep wound infection is a serious postoperative complication and may require total removal of the stabilization system and embedded polymer. Deep wound infection may be latent and not manifest itself for several years post- operatively. Vascular insufficiency.

| Intended Use, Indications & Contraindications | |
|---|---|
| | **Risks**<br>As with any IM fixation system or rod the following can occur:<br>• loosening, bending, cracking, fracture, or mechanical failure of the components or loss of or inadequate fixation in bone attributable to delayed union, nonunion, insufficient quantity or quality of bone, markedly unstable comminuted fractures, or insufficient initial fixation<br>• loss of anatomic position with nonunion or malunion with rotation or angulation<br>• adverse tissue reaction<br>• infection, including wound complications<br>• thromboembolic event or fat embolism (blood clot, fat, or other material that could<br>• result in organ damage or failure)<br>• implantation-related bone fracture<br>• soft tissue damage<br>• pain and/or loss of function<br>• revision<br>• inability to properly deploy or remove device<br>Risks specific to a photodynamic curing system can include:<br>• malfunction of photodynamic process<br>• lack of electrical safety or electromagnetic compatibility<br>• unacceptable exothermic reaction<br>• balloon leakage |

## INITIAL SYSTEM SETUP

The proper set up and operation of the IlluminOss photodynamic Light Console 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 light source.

**Intended User and Environment of Use:**

The intended users of the LED Console are orthopedic surgeons, nurses and surgical technicians working within the environment of the Operating Room, in the repair and stabilization of fractures. As with any surgical equipment, the user is required to read and understand the operating manual of the system that they are using.

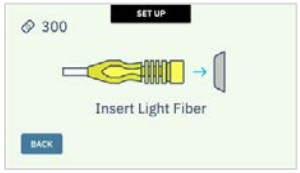
**Note**: This manual is only designed to provide information on the use and set up of the IlluminOss LED Console, however it does reference the materials and components contained within the IlluminOss Photodynamic Bone Stabilization System Implant Kit.

These items are packaged sterile, single patient contact, separately from the LED Console. The user should refer to the specific Surgical Technique guide, or instructions for use towards the correct preparation and use of the catheter and light fiber. Items contained within the IlluminOss Bone Stabilization System Implant Kit are sterilized by ETO.

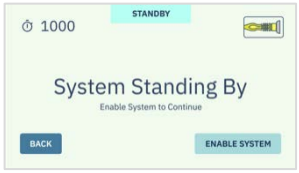
### Process at a Glance


1. Setup

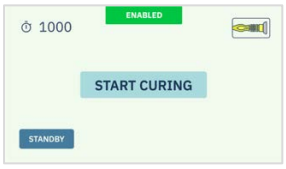

2. Set Curing Timer



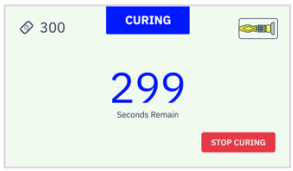

3. Insert Light Fiber




4. System Standing By




5. Enable Curing




6. Curing Cycle


7. Finish Curing

## DEVICE USE GUIDE | INITIAL SYSTEM SETUP

**Initial System Setup** | **Step 1: Unbox & Setup**

### 1.1 Unbox

Unpack the LED Console from the shipping container and place it on a stable table.

### 1.2 Inspect

Carefully remove the contents from the boxes and check for any damage. Check the Nosecone label to verify the LED Console has not been tampered with. If you observe or experience any problems with your equipment, notify IlluminOss Medical Inc. Customer Service immediately. Before continuing with unpacking and installation, please read the following operation manual for safety recommendations and installation, running, and troubleshooting instructions.

## Initial System Setup | Step 2: Power & Activate Device

### 2.1 Attach the Power Cord

Attach the Power Cord to the Power Cord Attachment on the rear of the LED Console, immediately below the Main Power Switch. Connect the plug to a wall power supply outlet.

**Warning:**

**To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.**

**Note**: From a safety perspective, as with any wall powered electrical system, do not position the plug and receptacle powering the LED Console in a manner where disconnection of the power source is not readily accessible should it be required. The LED Console is rated for 120 voltage.

### 2.2 Power On Device

Turn on the Main Power Switch on the rear side of the LED Console. This switch controls power delivery to the entire LED Console. **The Main Power Switch must be on for the unit to operate**.


### 2.3 Confirm Power On

When the plug is inserted into the wall and the Main Power Switch is turned on, the Activation Button at the front of the unit shall blink with a blue light to indicate the system has power.

### 2.4 Activate Device

To activate the system, depress the blinking Activation Button on the front of the LED Console once. When activation is successful, the button will illuminate solid blue.


### 3.1 Self Diagnostics Cycle

The unit will now turn on and begin a short self-diagnosis. The screen will display “Performing Self Diagnostics.”

When complete and all systems and components are functioning according to specification, the screen shall display, “Diagnostic Check Complete System Ready.” The system is now ready for clinical use.

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**Note**: For Self-Diagnostics troubleshooting, see Troubleshooting section, p.46




### 4.1 Locate Change Language Button

Once the System Ready screen has been initiated, the user has the opportunity to set the local language from the screen by depressing the Change Language Button on the Touchscreen and picking one of the available options.

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**Note:** The default language is always English and the Change Language Button is presented in English irrespective of the set language.


### 5.1 Deactivate Device

Deactivate off the system by depressing the solid blue Activation Button on the front of the LED Console.

### 5.2 Confirm Deactivation

Press the Activation Button a second time to confirm.

The Activation Button shall blink with a blue light to indicate the device is still powered by the Main Power Switch.

**Note**: The Activation button has a safety against the user inadvertently turning off the system by a single depression of the button, and a second action depressing the Activate Button is required.

### 5.3 Power Off Device

After deactivation, turn off power to the entire device by pressing the Main Power Switch on the rear of the device. Unplug the LED Console, remove the Power Cord, and place the instrument in an appropriate storage location.

# DEVICE USE GUIDE | CLINICAL USE

**Important Pre-Operative Setup Note**

With the setup of any equipment brought into the hospital for use, it is important to Set-up and activate the LED Light Console light prior to the start of the clinical procedure to ensure the correct operation and functionality of the unit.

Conformation of functionality of the LED Light console prior to the start of the clinical procedure reduces risk, ensures that wall power connections are functional, negates potential extended procedural times and permits the exchange or of equipment or alteration of clinical treatment methods should it be deemed necessary.

**The LED Light Console should be turned on and functional prior to the start of the surgical procedure.**

This device complies with Part 18 of the FCC Rules however
**Do Not Stack the LED Light Console with Other Equipment**

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**Warning:**  **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**

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**Warning:**  **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**

**Clinical Use** | **Step 1: Console Setup**

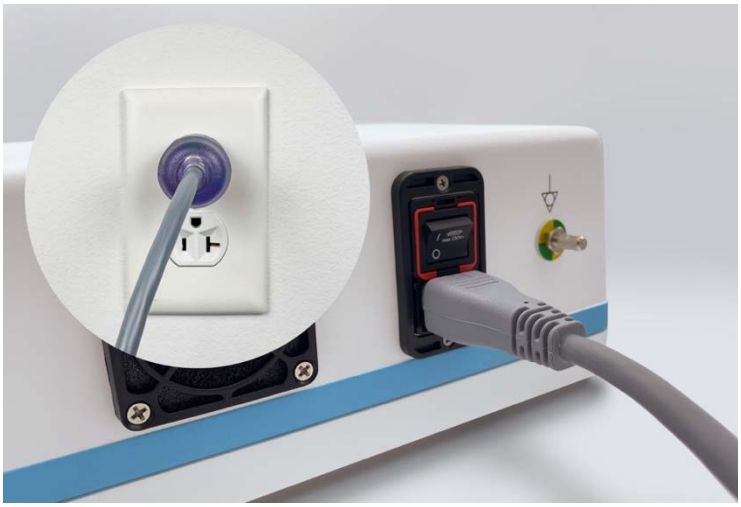

### 1.1 Place LED Console in OR

Place the LED Console on a stand in the Operating Room, outside of the sterile field. Determine an appropriate position for the LED Console, making certain that it is placed in a position convenient to the operating table and that it is on the same side as the surgical site.

Ensure that the distance from the LED Console is not further than ~6 ft to the surgical site as the Light Fiber from the implant needs to comfortably reach the LED Console.

**Warning:** The Photodynamic LED Light 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.

**Note:** Do not block or cover the fan or place the LED Console in a location where the fan may be covered.



### 2.1 Attach the Power Cord

Attach the Power Cord to the Power Cord Attachment on the rear of the LED Console, immediately below the Main Power Switch. Connect the plug to a wall power supply outlet.

**Warning:**

**To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.**

**Note**: From a safety perspective, as with any wall powered electrical system, do not position the plug and receptacle powering the LED Console in a manner where disconnection of the power source is not readily accessible should it be required. The LED Console is rated for 120 voltages.

### 2.2 Power On Device

Turn on the Main Power Switch on the rear side of the LED Console. This switch controls power delivery to the entire LED Console. **The Main Power Switch must be on for the unit to operate**.

**Note**: When the plug is inserted into the wall and the Main Power Switch is turned on, the Standby Button shall blink with a blue light to indicate the system has power.


### 2.3 Confirm Power On

When the plug is inserted into the wall and the Main Power Switch is turned on, the Activation Button at the front of the unit shall blink with a blue light to indicate the system has power.

### 2.4 Activate Device

To activate the system, depress the blinking Activation Button on the front of the LED Console once. When activation is successful, the button will illuminate solid blue.


### 3.1 Self Diagnostics Cycle

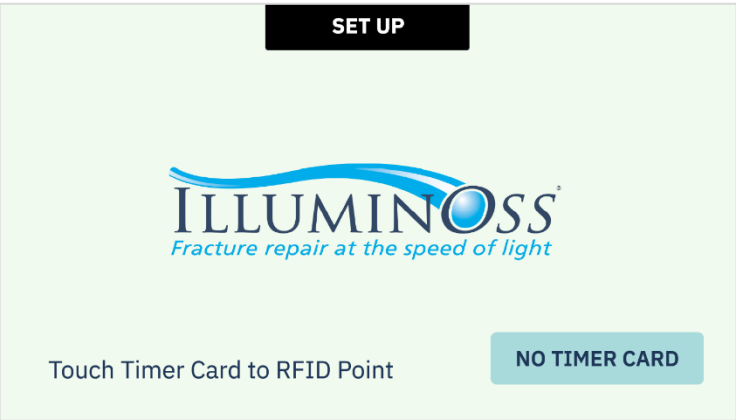
The unit will now turn on and begin a short self-diagnosis. The screen will display “Performing Self Diagnostics.”

The self-diagnosis process ensures that all aspects of the system are functional and performing according to design specifications. This program is run each time the unit is powered on.

**Note**: For Self-Diagnostics troubleshooting, see Troubleshooting section, p. 46.


### 3.2 Ready for Setup

When the system, has completed Self Diagnostics and all systems and components are functioning according to specification, the Touchscreen shall display, “System Ready.” The system is now ready for use and further setup in the curing of an implant.




### 4.1 System Ready for Setup

A “System Ready” screen shows up for ~5 seconds and then automatically changes to “System Set Up,” alternating between the IlluminOss logo and a “Touch Timer Card to RFID Point” message.


### 4.2 Obtain Timer Card

The Timer Card is located within the IlluminOss Photodynamic Bone Stabilization System Implant Kit in a non-sterile package.

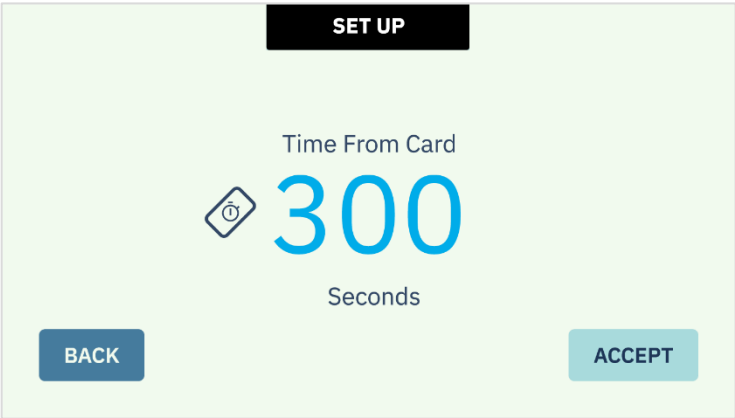
**Warning:**

**The Timer Card is not sterile and should not be placed on the sterile field.**


### 4.3 Hold Card to Target

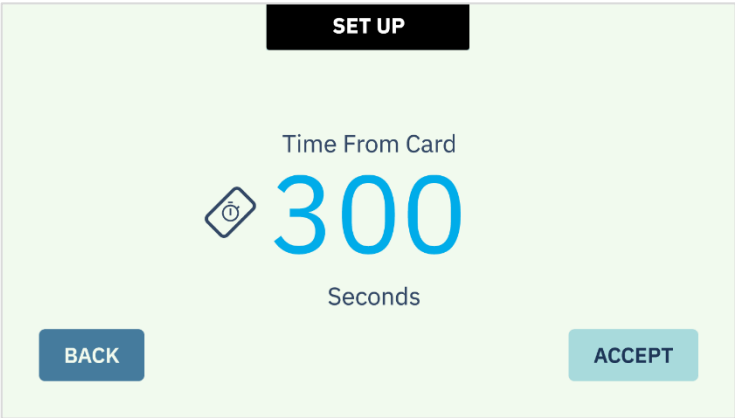
Bring the Timer Card into contact with the Timer Card Target on the LED Console to the left of the Touchscreen.

**Note**: The Timer Card Target blinks green while searching for the Timer Card to read.




### 4.4 Timer Card Read

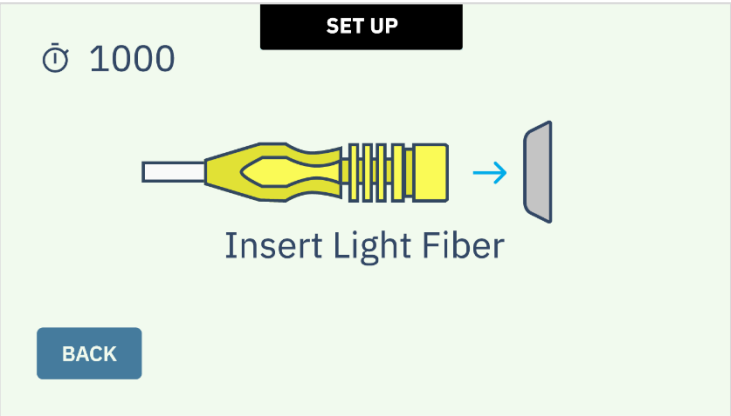
When the Timer Card is successfully read by the system, the screen changes to “Time From Card,” and the time in seconds is now displayed at the center of the Touchscreen.




### 4.5 Accept (or Reject) Timer

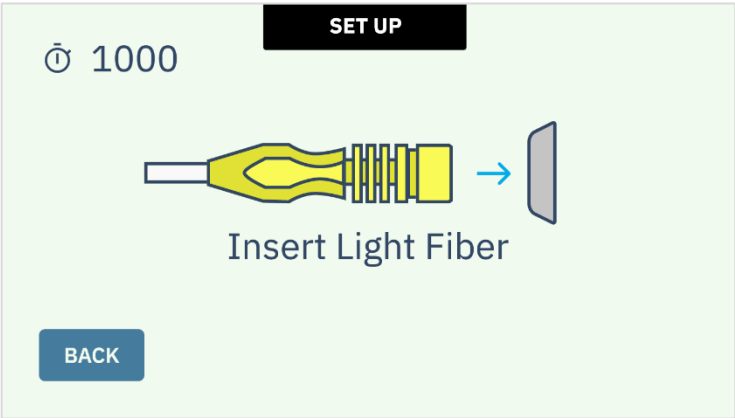
The user must either confirm the time set by pressing the “Accept” button on the lower right hand of the screen, or the “Back” button to return to the timer programming stage of Curing Setup.

**Note:** The system shall not proceed to the next step in Curing Setup without the user making a timer set choice.




### 4.6 Complete Timer Setup

With the time accepted into the system, the time set from the Timer Card is displayed on the upper left portion of the screen.




### 5.1 Insert Light Fiber Prompt

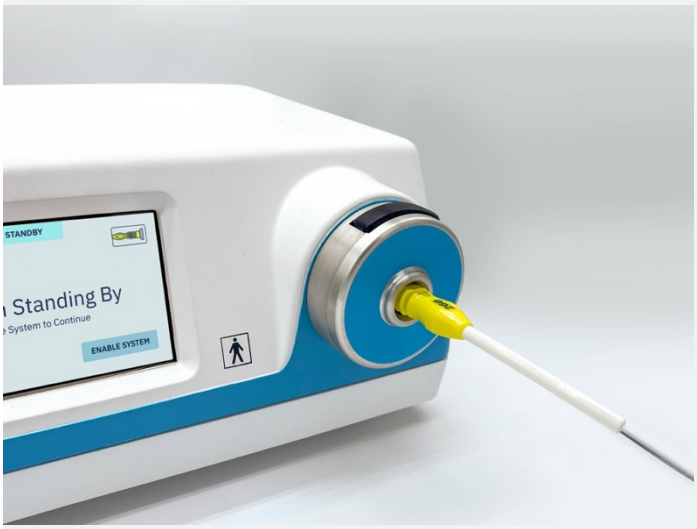
The screen automatically changes to displaying an image of the Hub of the Light Fiber, indicating it needs to be inserted into the round insertion point on the front of the Nosecone of the LED Console.

### 5.2 Press to Insert

With one hand, press down on the Light Fiber Insert / Release Button on the top of the Nosecone and with the other hand, insert the Light Fiber Hub into the Nosecone.

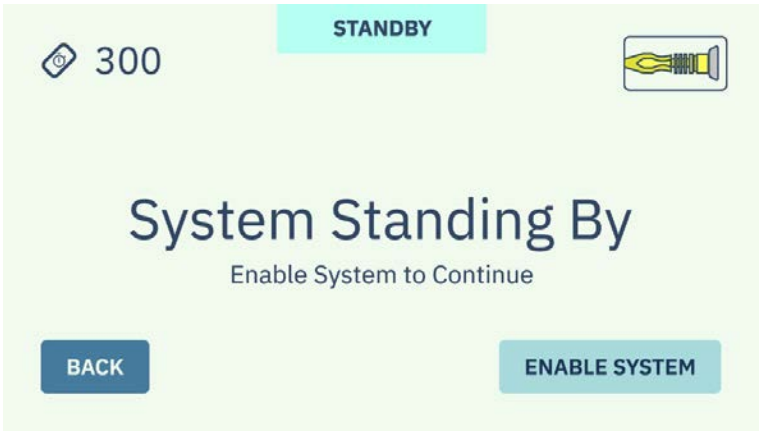
### 5.3 Push to the Back

While still holding the Light Fiber Insert / Release button, grasp the Light Fiber Hub with two fingers and insert it all the way to the rear of the receptable. The user should feel solid resistance from the back wall of the Nosecone.




### 5.4 Release Button

Release the Light Fiber Insert / Release button. The Light Fiber is now seated and securely retained in the Nosecone




### 5.5 Light Fiber in Place

When the Light Fiber is positioned correctly, a symbol of the Light Fiber Hub shall appear on the upper right side of the screen.

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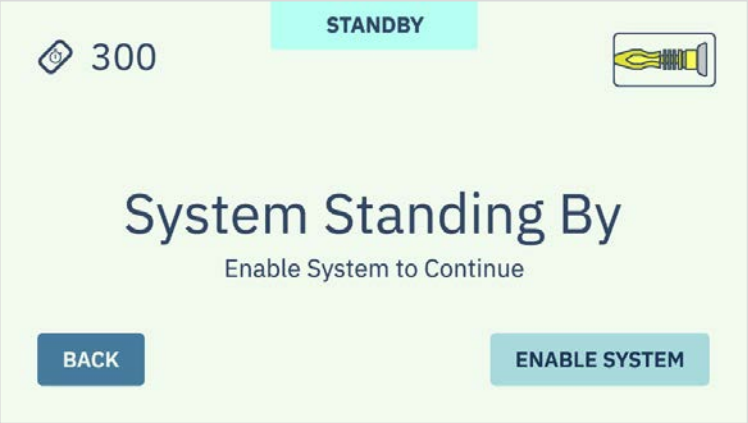
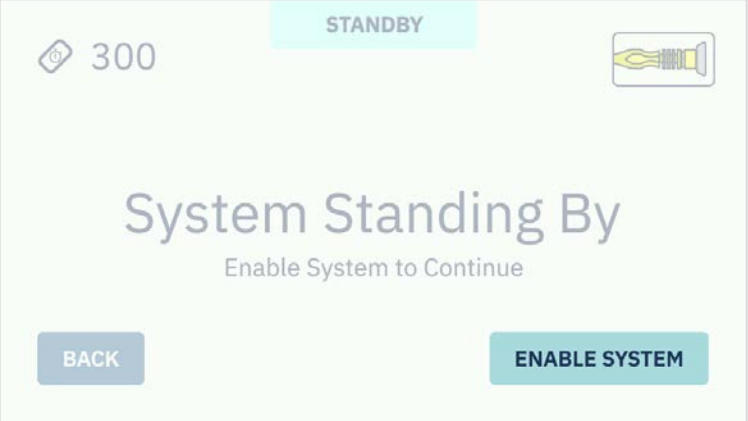
**Note**: The Nosecone has two microswitches that continually sense the position of the Light Fiber Hub, ensuring that it is in place and in the correct position. These sensors confirm that there is a Light Fiber in place while the system is delivering optical power to the implant (and immediately stops the curing process, warns the user if the Light Fiber has been removed).




### 6.1 System Standing By

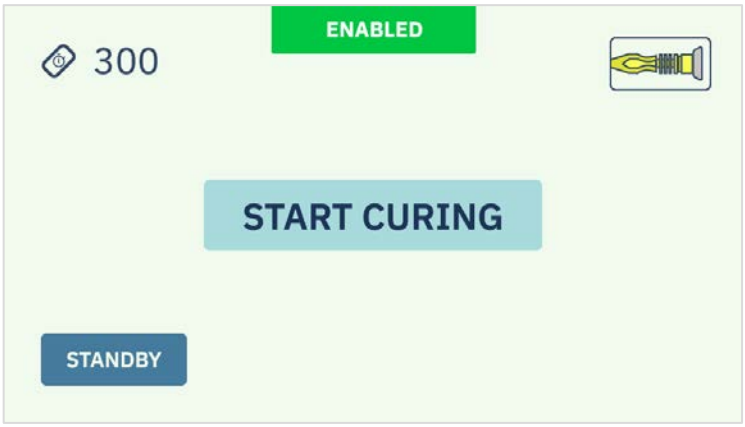
When the correct curing time is loaded into the system and the Light Fiber has been properly seated in the Nosecone, the screen shall display, “System Standing By,” and the set time and the Light Fiber Hub shall appear along the top of the Touchscreen.




### 6.2 Enable System

Depressing the “Enable System” button advances the screen to the “Start Curing” screen.

**Note:** As with all major active controls or actions that the user shall take on the LED Console, a confirmatory secondary step or second depression of a button is required to initiate any major process. No single button depression initiates an action step.

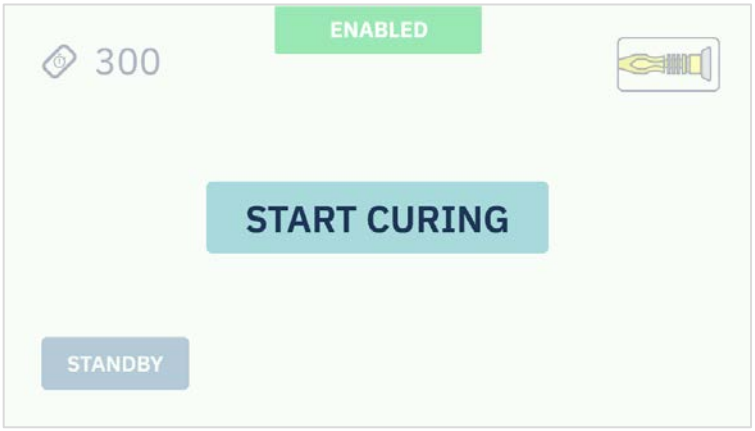



### 6.3 Ready for Curing

The system is now ready and awaiting activation from the user to initiate the curing process.

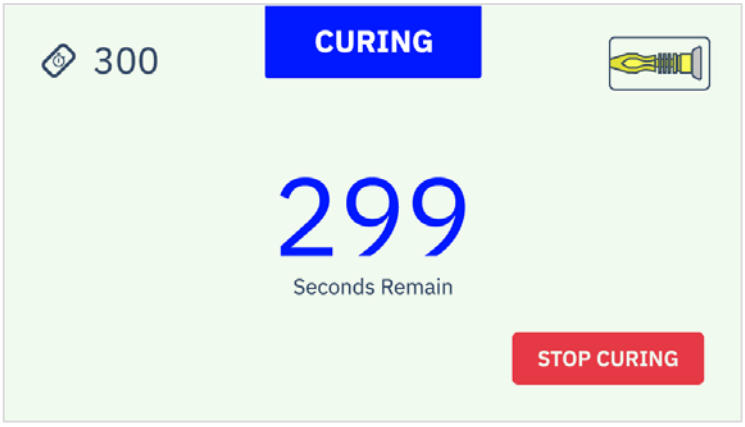
---

**Note:** The user can go backwards by pressing the “Back” button and revert to a Standby stage.




### 7.1 Start Curing

Depressing the “Start Curing” button initiates the curing process. The Shutter is activated and opened, light is delivered to the Light Fiber and the timer counts down.

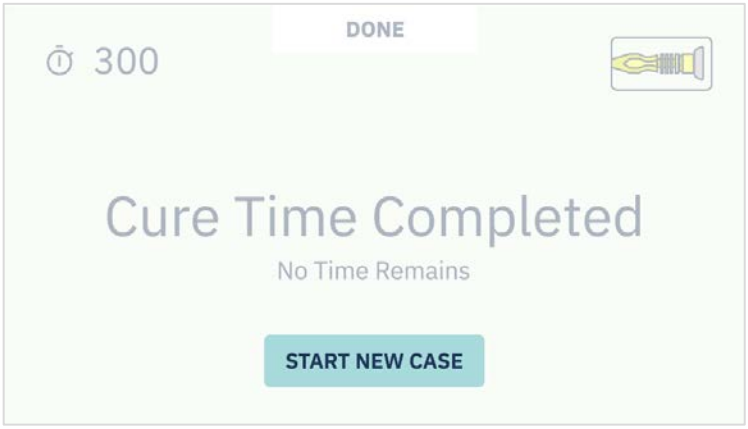



### 7.2 Curing

The status across the top of the screen automatically changes from “Enabled” to “Curing” and the time in seconds remaining in the curing process is displayed at the center of the screen.


### 7.3 Curing Completed

When the required curing time has been completed and the timer countdown has reached zero, the light delivered to the Light Fiber shall turn off and the status across the top of the screen displays “Cure Time Completed.”




### 7.4 Start New Case (Optional)

When finished, a “Start New Case” button appears on the lower left of the screen, enabling the user to start the programming process of the system for another implant, should it be required.

### 8.1 Press & Hold Release Button

To remove the Light Fiber after completion of a case, with one hand press and hold the Light Fiber Insert / Release button on the top of the Nosecone

### 8.2 Remove Light Fiber

Grasp the Light Fiber Hub with the other hand, removing it from the Nosecone. Release the Light Fiber Insert / Release button.


### 9.1 Deactivate Device

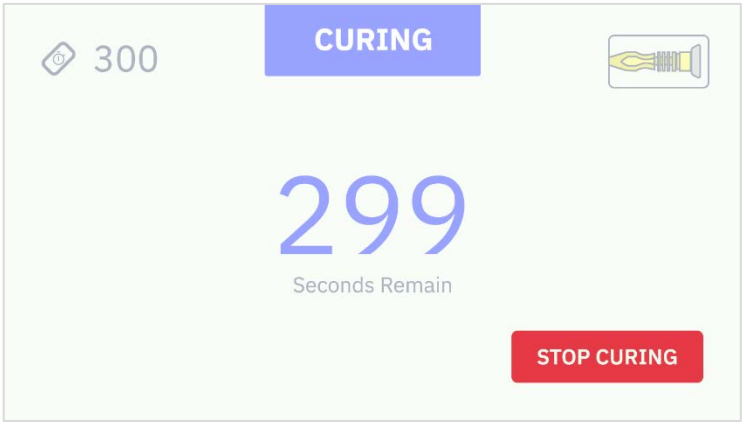
When finished with clinical use of the LED Console, press the blue illuminated Activation Button to deactivate the system.

Press the Activation Button a second time to confirm

**Note:** The Activation Button shall blink with a blue light to indicate the device is still powered by the Main Power Switch.

### 9.3 Power Off Device

After deactivation, turn off power to the entire device by pressing the Main Power Switch on the rear of the device. Unplug the LED Console, remove the Power Cord, and place the instrument in an appropriate storage location.




### 1. Confirm Cancel

If during the curing process, the red “Stop Curing” button is depressed, the system asks the user to confirm cancellation by depressing it a second time.


### 2. Curing Canceled

At this point the curing system is stopped, light delivery to the Light Fiber and implant terminated, and the Touchscreen indicates that the system has been stopped as a result of a user-initiated Stop.

The System reverts to Standby Mode, and the Touchscreen indicates that the Implant was not fully cured, and that the system needs to be run again to complete curing.


### 3. Enable System

Depressing the “Enable System” button takes the system back to the “Start Curing” stage.


### 4. Curing Timer Reset

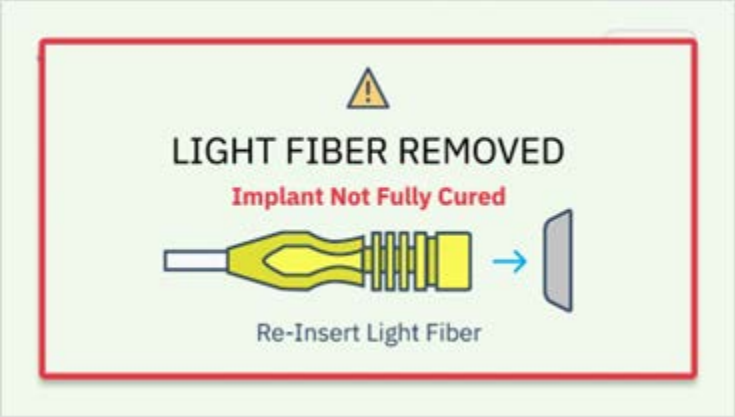
Now the original programmed time has been reset and the full cure time shall be run again, as the implant has not had the entire amount of programmed illumination and no assurance can be made that the implant is fully cured.


### 5. Restart Curing

Depressing the “Start Curing” button initiates curing, and the system countdown is displayed, proceeding as per a normal curing process.

Note: In all cases when the curing process has been terminated early, the reset process of the system reverts the curing cycle to the stated length of a full implant cure.






**1. Light Fiber Removed**

If the Light Fiber is removed from the system, the illumination process and timer are terminated, and a warning stating, “Light Fiber Removed - Implant Not Fully Cured,” is displayed on the Touchscreen.

**Note**: The LED Console will immediately stop the delivery of illumination if the Light Fiber is removed from its correct position in the Nosecone during the curing process.

**2. Reinsert Light Fiber**

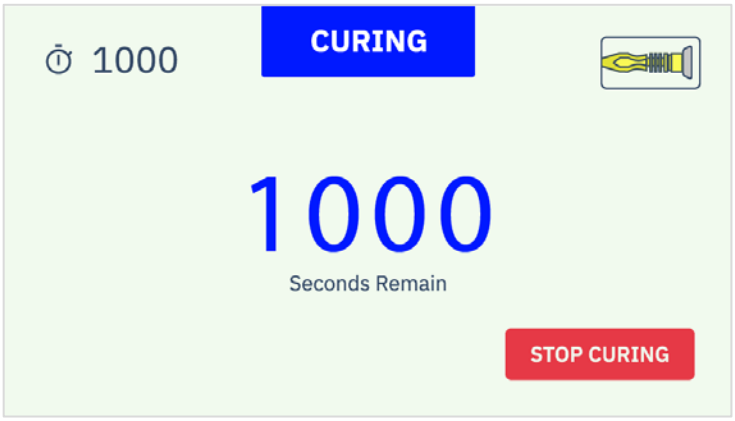
Reinsert the Light Fiber into the Nosecone in the same manner that it was originally placed (see p. 31, Clinical Use | Step 5: Light Fiber Insertion).


### 3. Curing Timer Reset

Once the Light Fiber is reinserted, the original programmed curing time is reset and the full cure time shall be run again, as the implant has not had the entire amount of programmed illumination and no assurance can be made that the implant is fully cured.


### 4. Restart Curing

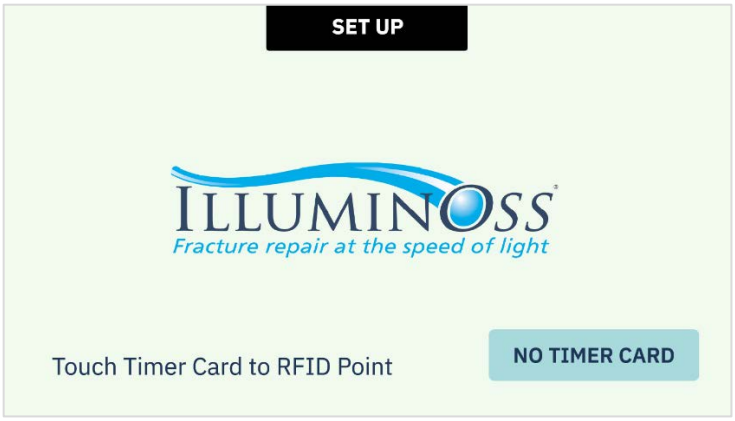
Depressing the “Start Curing” button initiates curing, and the system countdown is displayed, proceeding as per a normal curing process.




### 1. System Default Timer

In the unusual event that the user does not have a Timer Card or that the provided Timer Card is not capable of being read by the system, the LED Console can be utilized through a pre-programmed timer setting.

The pre-programmed timer is set to a default time of 1,000 seconds, which is the longest cure time of any of the implants provided.




### 2. No Timer Card

When the “No Timer Card” button is depressed, the default system time of 1,000 seconds is initiated.

## No Timer Card

**Note 1:** If the Timer Card is located prior to the initiation of the curing process, the user can go backwards in the Timer Setup by depressing the “Back” button and enter the correct time through the steps outlined in Clinical Use | Step 4: Set Timer (p. 28).

**Note 2**: There is no means to enter any times other than with the Timer Card or by using the system default time.



## Self Diagnosis Failure


### 1. Re-Run Self Diagnostics

If aspects of the system do not function according to specification, the system with re-attempt to conduct the Self Diagnostics tests again.

### 2. System Failure

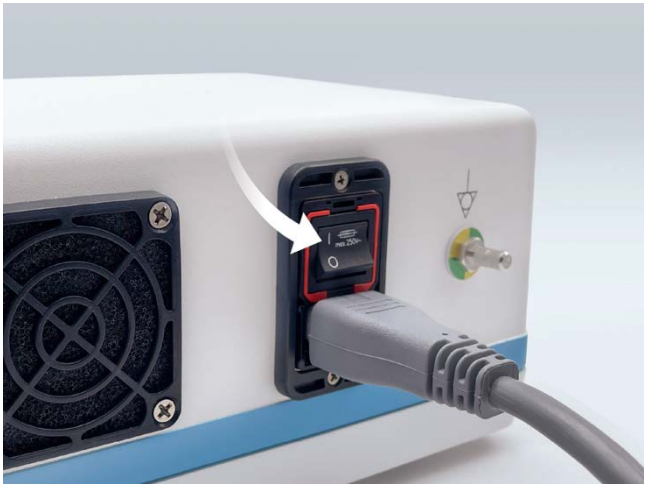
If after repeated attempts, the system has not been able to achieve successful functional specifications in the Self Diagnostics mode, the result shall be a System Failure Mode displayed on the Touchscreen, and the unit shall have to be returned to IlluminOss Medical Inc. under an RMA for repair.

---

**Note:** There are no user serviceable parts on the LED Console.

### 1. Check Connections

Visually inspect all input and output connections, such as the Power Cord Attachment on the rear side of the LED Console, and Power Cord plug connection at the wall outlet.



### 2. Check Main Power Switch

Check that the Main Power Switch on the rear side of the LED Console is in the "on" position.

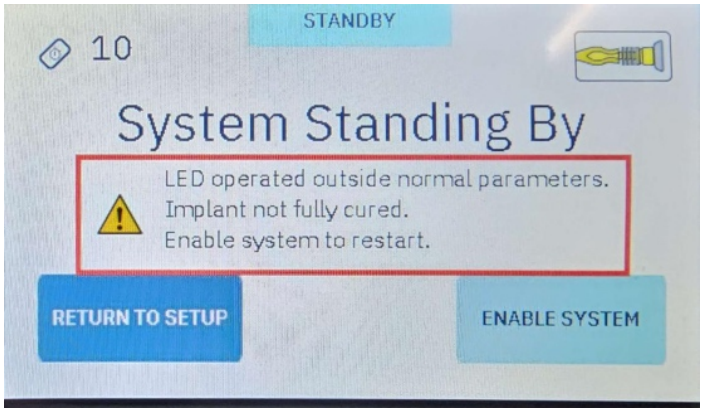


**Error Messages Applicable to Users**

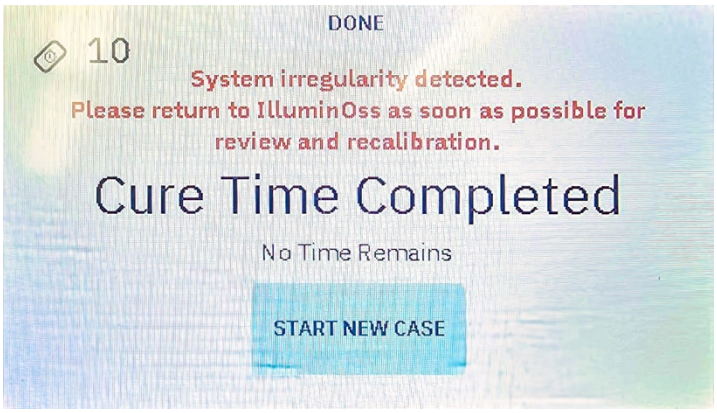
The LED Console is continually running Self Diagnostics to ensure that the system is performing according to the designed specifications. **There are the error messages that are applicable to a user during the use of the Console and means to remediate the issue; the residual error messages are applicable only to IlluminOss repair facilities.**

Critical Error messages displayed on the Touchscreen shall indicate that the system has suffered an internal electrical or software fault, that the system needs to be returned to IlluminOss under an RMA and that these can only be rectified by Authorized IlluminOss Repair Facilities.

**During the curing process, should the LED Light Console detect a minor system anomaly, at the conclusion of the curing process the system shall display a screen indicating that the one unit operated outside of normal parameters, and that the implant may not be fully cured, a repeat cycle of curing is required.**




Upon completion of the second curing cycle, the system shall indicate that the LED Console had experienced a system irregularity, and that the unit should be returned to IlluminOss for review and recalibration as soon as possible.

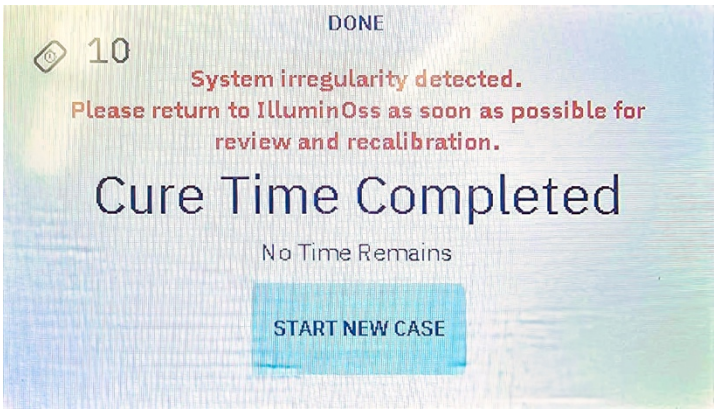



To ensure that a user is aware that a LED Console had experienced a minor System Irregularity, the notification of that irregularity shall remain active on the unit, requesting that the unit be returned to IlluminOss for review.
This notification shall remain present until IlluminOss technical staff reviews the system and clears the fault. It cannot be cleared by a user.


## Troubleshooting — Minor System Faults in the Standby State

Should the LED Console indicate a minor error while the system is in the standby state, eg the LED is operating, but indicated not to be within it's normal operating parameters, the user should restart the LED Console System via the rear Main Power Switch.

At the completion of use, send device to IlluminOss for servicing per the notification on the final screen.




NOTE : Any minor system faults that occur during the curing cycle shall automatically generate the warning that the system operated outside of it's established parameters and that a second curing cycle is required.

**Minor Faults of the LED System that if were to occur during a curing cycle might impact the implant and require a second curing cycle are as follows:**

### 0x00000008 LED under-current, but not shorted LED OPERATING OUTSIDE NORMAL PARAMETERS

The LED is operating, but not within normal operating parameters. A fault experienced prior to use, restart the LED Console via the rear Main Power Switch. At the completion of use, send device to IlluminOss for servicing. If the fault occurs during a curing cycle, at the completion of that cycle, **the user needs to repeat the curing cycle,** and then send device to IlluminOss for servicing

### 0x00000010 LED over-current, but not shorted LED OPERATING OUTSIDE NORMAL PARAMETERS

The LED is operating, but not within normal operating parameters. A fault experienced prior to use, restart the LED Console via the rear Main Power Switch. At the completion of use, send device to IlluminOss for servicing. If the fault occurs during a curing cycle, at the completion of that cycle, **the user needs to repeat the curing cycle,** and then send device to IlluminOss for servicing

### 0x00000020 LED current sensors mismatch LED OUTSIDE NORMAL PARAMETERS

There are redundant LED current measuring circuits that are not consistent compared to each other. If the error presents prior to a curing cycle, restart the Console via the rear main power switch. If it occurs during curing , at the completion of a curing cycle, **the user needs to repeat the curing cycle**, and then send device to IlluminOss for servicing.

### 0x00000080 Supply failure, low threshold LED OUTSIDE NORMAL PARAMETERS

The AC/DC power supply is operating, but not within normal operating parameters. If the error presents prior to a curing cycle, restart the Console via the rear main power switch. If it occurs during curing at the completion of a curing cycle, **the user needs to repeat the curing cycle**, and then send device to IlluminOss for servicing.

Other minor faults such as fan failure or temperature anomaly do not impact the curing process

**The above are the error messages that are applicable to a user during the use of the Console; the residual error messages are applicable only to IlluminOss repair facilities.**

All Error messages displayed on the Touchscreen shall indicate that the system has suffered an internal electrical or software fault, that the system needs to be returned to IlluminOss under an RMA and that these can only be rectified by Authorized IlluminOss Repair Facilities.

| Error Code | Error Message | Cause | Resolution |
|---|---|---|---|
| N/A | LED-expiration warning | The LED is within 50 hours of reaching the useful life limit. | Can use the device until the LED is expired per line below. |
| 0x00000001 | LED expired | The LED has reached the useful life of 5,000 hours. | Send device to IlluminOss for service |
| N/A | Light Fiber Removed | Light Fiber removed from the Nosecone during curing process | Reinsert the Light Fiber into the Nosecone, repeat curing cycle. |
| 0x00000008 | LED under-current, but not short | The LED is operating, but not within normal operating parameters. | If the error presents prior to a curing cycle, restart the Console via the rear main power switch. If it occurs during curing, at the completion of a curing cycle, the user needs to repeat the curing cycle, and then send device to IlluminOss for servicing. |
| 0x00000010 | LED over-current, but not short | The LED is operating, but not within normal operating parameters. | Prior to use, restart the LED Console via the rear Main Power Switch. At the completion of use, send device to IlluminOss for servicing. |
| 0x00000020 | LED current sensors mismatch | There are redundant LED current measuring circuits that are not consistent compared to each other | If the error presents prior to a curing cycle, restart the Console via the rear main power switch. If it occurs during curing , at the completion of a curing cycle, the user needs to repeat the curing cycle, and then send device to IlluminOss for servicing. |
| 0x00000080 | Supply failure, low threshold | The AC/DC power supply is operating, but not within normal operating parameters. | If the error presents prior to a curing cycle, restart the Console via the rear main power switch. If it occurs during curing at the completion of a curing cycle, the user needs to repeat the curing cycle, and then send device to IlluminOss for servicing. |
| 0x00000800 | Fan failure | The fan is not operating properly | If the error presents prior to a curing cycle, restart the Console via the rear main power switch. Upon |

| | | | |
|---|---|---|---|
| | | | the completion of use, send device back for service. |
| N/A | Temperature failure | Incorrect operating temperature has been detected | If the error presents prior to a curing cycle, restart the Console via the rear main power switch. Upon the completion of use, send device back for service. |
| 0x00000040 | LED open circuit | The LED is not functioning properly | Send device to IlluminOss for servicing. |
| 0x00000004 | LED short circuit | The LED is not functioning properly | Send device to IlluminOss for servicing. |
| 0x00000100 | Supply failure, high threshold | The AC/DC power supply is not functioning properly | Send device to IlluminOss for servicing. |
| N/A | LCD backlight current failure | The LCD Touchscreen backlight is not within expected operating range | Restart the Console via the rear main power switch. Send device to IlluminOss for servicing. |
| 0x00000400 | Shutter failure | The mechanism that controls the optical power to the Light Fiber is not in the proper position | If the error presents prior to a curing cycle, restart the Console via the rear main power switch. If it occurs during curing, at the completion of a curing cycle, the user needs to repeat the curing cycle and send device to IlluminOss for servicing. |
| 0x00002000 | Cover open | The top cover has been moved from its normal position | Send device back to IlluminOss for service |
| N/A | SD-card cannot be read | The memory device used to log data cannot be communicated with | Restart the Console via the rear main power switch. After use, send device to IlluminOss for servicing. |

The words “Warning,” “Caution,” and “Note” carry special meanings and should be carefully reviewed.

### Alert Definitions

| Symbol | Definition |
|---|---|
| Warning  | The personal safety of the patient and health professional may be involved. Disregarding 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. |

### Alert Messages

| Symbol | Definition |
|---|---|
| Warning  | To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth. |
| Warning  | The Photodynamic LED Light 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 LED Light Curing System and all associated accessories are for use exclusively with the IlluminOss Medical Inc. Photodynamic Bone Stabilization System Implant Kit. Do not use the system for any other purpose. |
| Warning  | If any component failure is observed during use or unexpected light is visible, power down the unit and contact customer service immediately. |
| Warning  | Do not attempt to open or gain access to the IlluminOss LED Console. There are no user serviceable items, and entry to the system may result in damage to the optical systems and overall function to the system. |

| Symbol | Definition |
|---|---|
| Warning  | Do not use the LED Console if the tamper proof decal on the side of the unit of on the front nose cone has been removed, altered or broken. Do not use the LED Console if the system appears to have been opened or tampered with. Return the LED Console immediately to IlluminOss Medical for replacement. |
| Warning  | The LED Console may not be used with the predicate implant kit. |
| Caution  | There are no User-serviceable parts inside the device. Contact IlluminOss Medical Inc. for any service needs. |
| Caution  | Risk Group 2; CAUTION: Possibly hazardous optical radiation emitted from this product. Do not stare at the operating lamp. Maybe harmful to the eye. |
| Caution  | Portable and mobile RF communications equipment can affect medical electrical equipment. |
| 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  | Never look directly at light exciting the active portions of the Light Fiber. |
| Note | Do not repeatedly turn the LED Console on and off as it will eventually shorten the life of the LED. |
| Note | Change LED" light illuminates when the LED has achieved 4950 hours, reminding the user to have the unit serviced. The unit shall continue to operate normally up through 5000 hours of use, where the system shall finish the last curing cycle and no longer function, requiring a replacement of the illumination system by authorized IlluminOss parties. |

## WARRANTY & MAINTENANCE

### Warranty

IlluminOss Medical Inc. offers a one-year warranty against defects in material and workmanship on all system components. 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 LED Console was designed to operate with minimal maintenance. Examine exterior of cords and console, including labels and markings, for wear or damage after use. Should any damage be observed to the 10 ft Power Cord, a new Power Cord should be requested from IlluminOss Medical Inc. Do not use any power cords other than those supplied with the IlluminOss Photodynamic LED Bone Stabilization System.

The IlluminOss Light Console SY 2100- 01 is provided with a 10 ft medical grade power cord. Should the 10ft power cord become lost or damaged, contact IlluminOss Medical Inc. for a replacement.

**Servicing**

The IlluminOss Photodynamic LED Light Curing System is **NOT** user serviceable. There are no user serviced components. Do not tamper with the device's hardware or software. If you encounter a problem or have any questions, please contact the IlluminOss Medical Inc. Customer Service Department at:

IlluminOss Medical Inc.
993 Waterman Avenue
East Providence, RI 02914
+1 (401) 714-0008
www.illuminoss.com

**Security Maintenance and Reporting**

To ensure the prolonged cybersecurity of the device, IlluminOss continually monitors available resources to remain apprised of the device's security. In the event, a vulnerability is identified, or a security compromise has been detected the device will need to be returned to the manufacturer for remediation.
For any security-related inquiries or issues, please contact customerservice@illuminoss.com

**SBOM Request**

The FDA has issued guidance that requires medical device manufacturers to create and maintain a software bill of materials (SBOM). SBOM ensures the security and compliance of software products by listing all the components and dependencies of a software product.
To request an SBOM, send an email to customerservice@illuminoss.com

## PRODUCT CLEANING & DISPOSAL

### LED Console Cleaning

**CAUTION:**

**Do not immerse the LED Console or Power Cord in any solution or clean with steam, autoclave, or ethylene oxide.**

After every use, clean the LED Console and Power Cord according to the cleaning instructions below or standards that are prescribed according to hospital policy.

Use of a low-level disinfectant (LLD) wipe and solution that includes the following claims on its labeling: “does not cause adverse effects (corrosion) to plastics, rubbers, and metals.” Enclosure, labeling and LCD materials shall be compatible with cleaning with the use of 70% Isopropyl Alcohol Wipes.

Users of the Photodynamic LED Light Curing System must also observe site-specific governing regulations for protection of personnel and for effective handling and disposal of LLD waste by-products.

### Light Fiber Insertion Point Cleaning

Inspect and clean the Light Fiber insertion point on the front Nosecone after each use or as required according to the Cleaning & Sterilization standards according to hospital policy.

**Note**: Do not insert anything into the optical pathway of the system as damage to the optical pathway may occur.

### Disposal

At the end of the LED Console's service life, please return the LED Console to IlluminOss for proper disposal.

## TECHNICAL SPECIFICATIONS

| System Technical Specifications | |
|---|---|
| Light Frequency | 435 nm delivered by LED |
| Power Requirements | 100 – 240 VAC, 50-60 HZ, 1.1 AMP |
| LED | 435 peak, width 17.83 |
| Shutter Timer | Digital LCD timer, timed shutter |
| Shutter Activation | LCD Touchscreen Button |
| Cooling | Filtered, single fan arrangement, thermally controlled to maintain proper lamp temperature |
| Operating Conditions | The LED Console shall operate in an ambient environment of 50 – 86 °F (10 – 30 °C) with 30 - 75% relative humidity (noncondensing) |
| Housing Dimensions | 14.0” x 9.0” x 5.0” |
| Weight | 8.5 lbs. |
| System Warranty | 1 year from date of purchase |
| Electrical Protection Classifications in accordance with EN / IEC 60601-1; (UL 60601-1 / CSA C22.2 No. 061.1 for USA / Canada) | Class I, type BF applied part (Light Fiber) |
| Degree of Protection Against Ingress of Particulates and Fluid | IPX0 (Ordinary Operation) |
| Mode of Operation / Duty Factor | Continuous Operation |
| Degree of Protection when Flammable Gases are Present | Not to be used in flammable gas environment. It should not be used in an oxygen enriched environment. |
| Storage, Transportation and Shipping Conditions | 32°F – 122°F (0°C – 50°C), 30 – 75% relative humidity, atmospheric pressure 700 hPA - 1060 hPa |

<table>
<tr><th colspan="3">System Technical Specifications</th></tr>
<tr><td>Essential Performance</td><td colspan="2">The IlluminOss Photodynamic Led Light Console shall maintain an essential performance of the optical output power of > 185 mw/cm$^2$ during the curing cycle, measured by the light output of the system at the bulkhead fitting, and the duration shall be within -1% of the total desired cure cycle time. If the Essential Performance is not maintained during the curing cycle, a potential exists that the implant shall not be fully cured, and a second curing cycle of the implant is<br><br>When a curing cycle is interrupted due to an error, LCD screen blackout, LED shutdown, or reset, the device must come back up into a normal state to allow curing to be restarted. If the device is unable to restart the cure cycle, it will be considered a failure. User intervention to restart the console via the rear main power switch is allowed.</td></tr>
<tr><td>Power Supply</td><td colspan="2">The IlluminOss Medical Inc. Photodynamic LED Light Curing System’s power supply provides power from an appropriate wall outlet to the system:<br><br>USA: NEMA 1-15P<br>Europe: CEE 7/16</td></tr>
<tr><td rowspan="3">Power Supply</td><td colspan="2">The IlluminOss Medical Inc. Photodynamic LED Light Curing System’s power supply provides power from an appropriate wall outlet to the system:</td></tr>
<tr><td>USA</td><td>Europe</td></tr>
<tr><td>NEMA 1-15P</td><td>Europe: CEE 7/16</td></tr>
<tr><td rowspan="4">Outlet & Plug</td><td colspan="2">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.</td></tr>
<tr><td>Plug Style</td><td>Plug P/N Codes</td></tr>
<tr><td>A</td><td>01-9007-US</td></tr>
<tr><td>B</td><td>01-9007-EU</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
</table>

## System Technical Specifications

**Warning:** **Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**

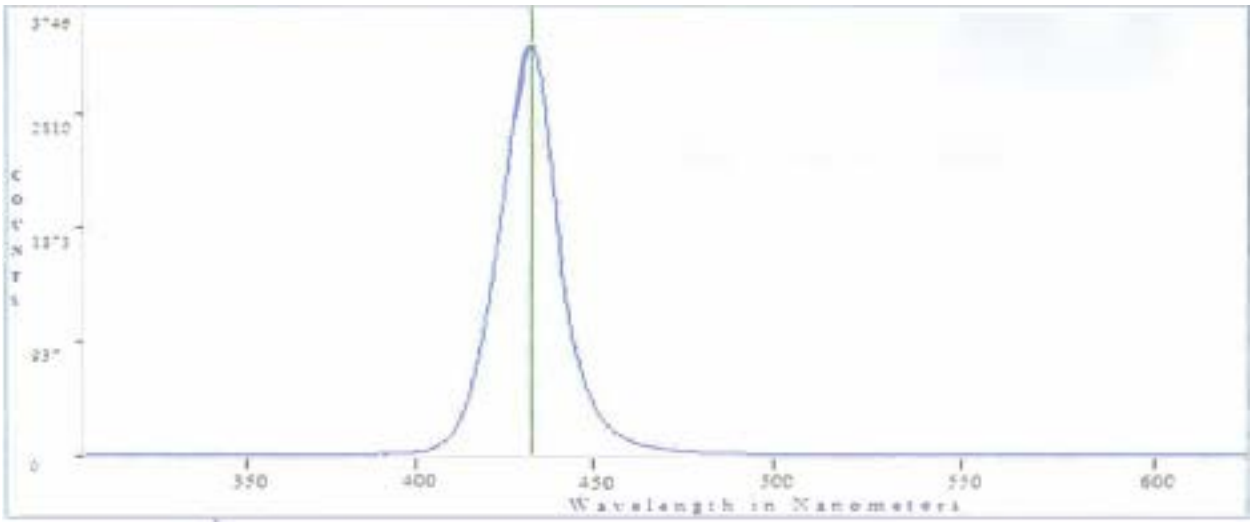
This device complies with Part 18 of the FCC Rules however

**Do Not Stack the LED Light Console with Other Equipment**

**Warning:** **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**

**Warning:** **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**

### Spectral Output




### Medical Electrical Equipment Safety and Essential Performance Testing

IEC 60601-1:2005 + A1:2012 + A2:2020 Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance

IEC 60601-1-2:2014 + A1:2020
Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Test

IEC 60601-1-6:2010 + A1:2013 + A2:2020
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

IEC 62471:2006 Photobiological safety of lamps and lamp systems
The IlluminOss LED Light Console emits a bright blue visible light @ 433 nm. As with any source of intense light, the user should not stare directly at the source.

Risk Group 2 CAUTION Possibly hazardous optical radiation emitted from this product. Do not stare at the operating lamp. May be harmful to the eye.

## FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

Reorient or relocate the receiving antenna.
Increase the separation between the equipment and receiver.
Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment

RADIATION EXPOSURE STATEMENT: The device has been found to be compliant to the requirements set forth in CFR 47 Sections 2.1091 for an uncontrolled environment. The antenna(s) used for this transmitter must be installed to **provide a separation distance of at least 20 cm from** all persons and must not be co-located or operating
in conjunction with any other antenna or transmitter.

### Emissions for all Equipment and Systems

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

| Emissions Test | Compliance | Electromagnetic Environment Guidance |
|---|---|---|
| RF Emissions CISPR 11 | Group 1 | The LED 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 A | The LED Console is suitable for use in all establishments connected to the US power grid. |
| Harmonics IEC 61000-3-2 | Class A | |
| Flicker IEC 31000-3-3 | Complies | |

**NOTE**: The **Emissions Characteristics** of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A).

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications.

If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

### EMC standards Compliance

The IlluminOss Photodynamic LED Light Curing System was tested and found compliant with the following standards. The device is suitable for use in a professional healthcare facility environment.

| Standard | Version | Test Type | Limits |
|---|---|---|---|
| CISPR 11<br>A1<br>A2 | 2015<br>2016<br>2019 | Emissions | Group 1, Class A |
| IEC 61000-3-2<br>A1 | 2018<br>2020 | Harmonic Distortion | NA |

| | | | |
|---|---|---|---|
| IEC 61000-3-3<br>A1<br>A2 | 2013<br>2017<br>2021 | Voltage Flicker | NA |
| IEC 61000-4-2 | 2008 | ESD | Contact Level 3 (8KV)<br>Air Discharge Levels 1-4 (2KV, 4KV, 8KV, 15KV) |
| IEC 61000-4-3<br>A1<br>A2 | 2006<br>2007<br>2010 | Radiated Immunity | Professional Healthcare Facility Environment:<br>3 V/m<br>80 MHz – 2,7 GHz<br>80 % AM at 1 kHz |
| IEC 61000-4-4 | 2012 | EFT | ± 2 kV<br>100 kHz repetition frequency |
| IEC 61000-4-5<br>A1 | 2014<br>2017 | Surge | Line to line: ± 0,5 kV, ± 1 kV<br>Line to ground: ± 0,5 kV, ± 1 kV, ± 2 kV |
| IEC 61000-4-6 | 2023 | Conducted Immunity | Professional Healthcare Facility Environment:<br>3 V<br>0,15 MHz – 80 MHz<br>6 V in ISM bands between<br>0,15 MHz and 80 MHz<br>80 % AM at 1 kHz |
| IEC 61000-4-8 | 2009 | Magnetic Field | 30 A/m g)<br>50 Hz or 60 Hz |
| IEC 61000-4-11 | 2020 | Voltage Dips/Interruptions | Dips: 0 % UT; 0,5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0 % UT; 1 cycle<br>And 70 % UT; 25/30 cycles<br>Single phase: at 0°<br>Interruptions: 0 % UT; 250/300 cycle |

| | | | |
|---|---|---|---|
| IEC 61000-4-39 | 2017 | Magnetic Field Proximity | See table below |
| Immunity to proximity fields from RF wireless communication equipment as defined in Table 9 of IEC 60601-1-2 Proximity Fields | 2014<br>2020 | EMC Table 9 | See table below |

**Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields**

| Test Frequency | Modulation | Immunity Test Level (A/m) |
|---|---|---|
| 30 kHz | CW | 8 |
| 134.2kHz | Pulse Modulation 2.1kHz | 65 |
| 13.56MHz | Pulse Modulation 50kHz | 7.5 |

**Immunity to proximity fields from RF wireless communication equipment as defined in Table 9 of IEC 60601-1-2 Proximity Fields**

| Test Frequency (MHz) | Band (MHz) | Service | Modulation | Immunity Test Level (V/m) |
|---|---|---|---|---|
| 385 | 380 to 390 | TETRA 400 | Pulse Modulation 18Hz | 27 |
| 450 | 430 to 470 | GMRS 460, FRS 460 | FM<br>± 5 kHz deviation<br>1kHz sine | 28 |
| 710 | 704 to 787 | LTE Band 13, 17 | Pulse Modulation<br>217Hz | 9 |
| 745 | | | | |
| 780 | | | | |
| 810 | 800 to 960 | GSM 800/900, TETRA 800,<br>iDEN 820, CDMA 850,<br>LTE Band 5 | Pulse Modulation 18Hz | 28 |
| 870 | | | | |
| 930 | | | | |
| 1720 | 1700 to 1990 | GSM 1800; CDMA 1900;<br>GSM 1900; DECT; LTE Band<br>1, 3, 4, 25; UMTS | Pulse Modulation<br>217Hz | 28 |
| 1845 | | | | |
| 1970 | | | | |
| 2450 | 2400 to 2750 | Bluetooth, WLAN,<br>802.11 b/g/n, RFID 2450,<br>LTE Band 7 | Pulse Modulation<br>217Hz | 28 |
| 5240 | 5100 to 5800 | WLAN 802.11 a/n | Pulse Modulation<br>217Hz | 9 |
| 5500 | | | | |
| 5785 | | | | |

### RoHS Compliance

The IlluminOss Photodynamic LED Light Curing System complies with the substance restriction requirements of the RoHS Recast Directive 2011/65/EU including the amendment to Annex II described in Commission Delegated Directive (EU) 2015/863.

### LED Replacement

The LED requires replacement after 5000 hours of use. After 4950 hours of use, the system shall display a blinking "Change LED" indicator on the Touchscreen of the LED Console will flash to warn the user of the impending need to replace the LED. The unit will be operational while the light is flashing.

After 5000 hours, the "Change LED" light will permanently illuminate, there will be an audible beeping sound and the unit will be inoperable. Return the unit to IlluminOss for LED replacement when the indicator light starts flashing.

### Calibration

Calibration of the system is not required. The system utilizes frequency stable and non-adjustable microprocessor design for all timing sequence controls and is not adjustable. The timer circuit uses a digital program card to input time duration settings and is read from program card to the controller memory. The controller is based on a Microchip Technologies PIC microprocessor which interprets the data from the program card and manages timing. There is no hardware in the unit that can be calibrated or requires calibration.

### Implants

The Implants of the IlluminOss Photodynamic Bone Stabilization System are comprised of an EtO sterilized, single use disposable procedure pack

- Do not expose or attempt to cure the monomer by any light source other than the IlluminOss Photodynamic Curing System,
- The Sterile Implant Kit contains:

Balloon Stabilization Catheter Tray and Lid

| QTY. | Description |
|---|---|
| (1) | Balloon Stabilization Catheter (with Sheath & Lightfiber) |
| (1) | Introducer Sheath with Dilator |
| (1) | Protective Tube |
| (0) or (1) | 10 ml Syringes Ring handle |
| (1) (2) or (3) | 20 ml Syringes |
| (1) | Vented Transfer Spike |
| (1) | 20 ml Air Evacuation Syringe |

Photodynamic Monomer Pouch – Sterile Packaged separately

| QTY. | Description |
|---|---|
| (1) (2) (3) or (4) | 20ml Photodynamic Monomer Vials in Multipack with tray |

Additional Item

| | |
|---|---|
| (1) | Non-Sterile RFID Timer Card |

**NOTE: The IlluminOss Photodynamic Bone Stabilization Procedure Pack, its container, and any packaging is not made with natural rubber latex.**

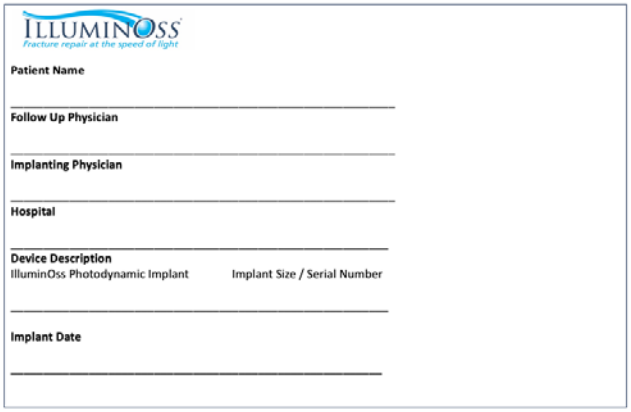

**MRI Safety Information MR Conditional**

MRI modeling and physical testing were performed to consider the entire family of the IlluminOss Photodynamic Bone Stabilization System (4-mm to 22-mm in diameter and lengths from 30- to 280-mm). Every version of the IlluminOss Photodynamic Bone Stabilization System is MR Conditional. A patient with the IlluminOss Photodynamic Implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

| ***Parameter*** | ***Condition of Use/Information*** |
|---|---|
| **Nominal Values of Static Magnetic Field (T)** | 1.5-Tesla or 3.0-Tesla |
| **Maximum Spatial Field Gradient (T/m and gauss/cm)** | 20-T/m (2,000-gauss/cm) |
| **Type of RF Excitation** | Circularly Polarized (CP) (i.e., Quadrature-Transmission) |
| **Transmit RF Coil Information** | Any transmit RF coil may be used. |
| **Receive RF Coil Information** | Any receive RF coil may be used. |
| **Operating Mode of MR System** | Normal Operating Mode |
| **Maximum Whole Body Averaged SAR** | 2-W/kg (Normal Operating Mode) |
| **Limits on Scan Duration** | Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks). |
| **MR Image Artifact** | The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest. |
| **Additional Information** | This MR Conditional labeling is only applicable for the IlluminOss Photodynamic Bone Stabilization System. The use of this implant with any supplemental screw fixation has not been evaluated for MRI-related issues. This MR Conditional labeling is only applicable for the IlluminOss Photodynamic Implant. The use of this implant with any supplemental screw fixation has not been evaluated for MRI-related issues.<br><br>Patients who have other MR Conditional devices can be scanned as long all the MR Conditional scan parameters for each of the devices are met. Do not conduct an MRI scan if any conditions for safe scanning for any device cannot be met.<br><br>If information about a specific parameter is not included, there are no conditions associated with that parameter. |

Patient Implant Card

To improve patient safety in the MR environment, as well as MRI patient workflow a “Patient Implant Card” that provides the conditions for safe use for the implanted device has been provided. Without a “ Patient Implant Card” many MR imaging services are not equipped to quickly obtain the necessary implant information to safely conduct MR imaging. Please fill out the form and provide it to the patient.


ILLUMINOSS
Fracture repair at the speed of light

**Patient Name**

_____

**Follow Up Physician**

_____

**Implanting Physician**

_____

**Hospital**

_____

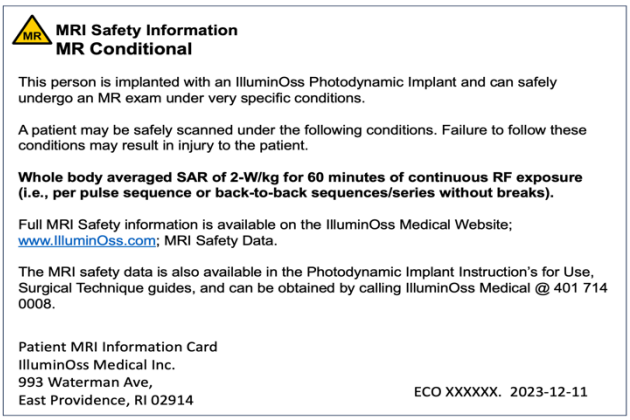
**Device Description**

IlluminOss Photodynamic Implant  Implant Size / Serial Number

_____

**Implant Date**

_____


**MRI Safety Information**
**MR Conditional**

This person is implanted with an IlluminOss Photodynamic Implant and can safely undergo an MR exam under very specific conditions.

A patient may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

**Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks).**

Full MRI Safety information is available on the IlluminOss Medical Website; www.IlluminOss.com; MRI Safety Data.

The MRI safety data is also available in the Photodynamic Implant Instruction's for Use, Surgical Technique guides, and can be obtained by calling IlluminOss Medical @ 401 714 0008.

Patient MRI Information Card
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ECO XXXXXX. 2023-12-11

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