



NICO. myriad-LX™

(Patent 9,772,094)

Xenon Illuminator with Digital Dimming Control Operator Manual



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1. INTRODUCTION

Congratulations on the purchase of your new MyriadLX™ Xenon Illuminator!

The Myriad-LX light source is a high-intensity 300W Xenon Illuminator with touch screen and digital dimming controls. The light source is fitted with a proprietary connector to ensure usage is reserved for the NICO Myriad NOVUS™ system. For setup and instructions related to other components of the Myriad NOVUS, refer to their respective labeling or manuals.


The Myriad-LX is a high efficiency light source utilizing state-of-the-art illumination technology. It offers a variety of features such as:


- 5600 K color temperature provides daylight brightness for perfect color definition
- Quiet operation
- Compact and light weight
- Autoshutter turret
- Air filter to mitigate dust/lint buildup inside the cabinet
- Digital dimming
- Easy lamp replacement


This Operator's Manual provides instruction for use of the illuminator and how to keep it clean. It includes maintenance and service guidelines as well as recommendations for best performance results.


1.1 INDICATIONS FOR USE: The intended use of this device is to provide light for fiberoptic cables and instruments – providing light for instrumentation via fiberoptic cables for use in surgical fields.


2. WARNINGS/ CAUTIONS


 **WARNING** The illuminator produces a highly concentrated (luminous energy per unit area) light beam and this high energy density is retained through any connected lightguides and instruments. The output of a connected instrument left in close proximity or contact with tissue or flammable materials presents a risk of injury or fire. Qualified personnel must determine a safe working distance and intensity setting for each application. The illuminator should never be left on unattended.

 **Caution** Rx only. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

 **Caution** To prevent fire or electric shock, do not open or expose the illuminator unit to rain or moisture. Refer all servicing to qualified personnel only.

 **Caution** Not suitable for use in presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.


 **Caution** This equipment is suitable for use in hospital and clinical settings. Avoid placement near other high RF equipment; user should determine proper placement and confirm normal operation of equipment when stacked or used near or with other RF equipment.


 **Caution** This product should be used only with type BF endoscopic instruments which have been certified according to IEC 60601-1 for medical equipment and IEC 60601-2-18 for endoscopic equipment.





This symbol indicates type BF equipment.


 **Caution** User must not alter this device in any fashion. Doing so voids all warranties and statements of suitability for any purpose.


 **Caution** All devices connecting to the Illuminator must be classified as medical equipment. Additional information processing equipment connected to the Illuminator, a Medical System and the operator must determine that all equipment complies with the appropriate end-product standards (such as IEC 60950 or IEC 60065 and the Standard for Medical System, IEC 60601-1-1).


 **Caution** Always set the intensity control to the minimum level and insert the fiberoptic cable into the unit before turning **on** the power. When light is not required at the surgical site, the intensity control should be set to the fully dimmed position. If it becomes necessary to remove the fiberoptic cable without turning the unit **off**, turn the intensity control to the fully dimmed position.


 **Caution** **The fiberoptic cable used with this illuminator must be electrically NON-CONDUCTIVE.** It should not have conductive shielding or any other conductive connection between the patient and equipment. Such connection will impair safety of the equipment. Ensure the optical surface is clean before connecting the cable to the illuminator.


 **Caution** When using high intensity illuminators at full output, the recommended from working distance to the patient is not less than 12 inches (30.5 cm). If using less than 12 inches from the patient, the light intensity must be reduced.


 **Caution** This equipment is intended to illuminate a surgical site; user is responsible for determining if interruption of light output, including due to effects from electromagnetic disturbances, will create an unacceptable risk. If such a determination is made, alternate arrangements (such as a standby illuminator) should be made by the user to reduce the risk.


 **Caution** Use of this illuminator with accessories or attachments requires that the end-user follow all accessory or attachment instructions which could affect illuminator setup, usage and/or settings.


 **Caution** This device contains stored electrical energy, follow operating instructions when changing lamp.


 **Caution** Do not remove lamp immediately after operation. Allow lamp to cool 10 minutes.


 **Caution** To prevent overheating, replace only with the same type and rating of lamp. Read instructions before replacing lamp.


 **Caution** Do not operate illuminator without lamp in place.


 **Caution** For grounding reliability, use only hospital grade marked power cord and receptacle.

 **Caution** Disconnect power supply cord before servicing to avoid electrical shock.

 **Caution** To reduce risk of electrical shock, do not remove cover. Refer servicing to qualified personnel.

 **Caution** Illuminator can cause permanent eye damage if viewed directly with unprotected eye.

 **Caution** Do not reach hand inside unit due to risk of shock hazard.

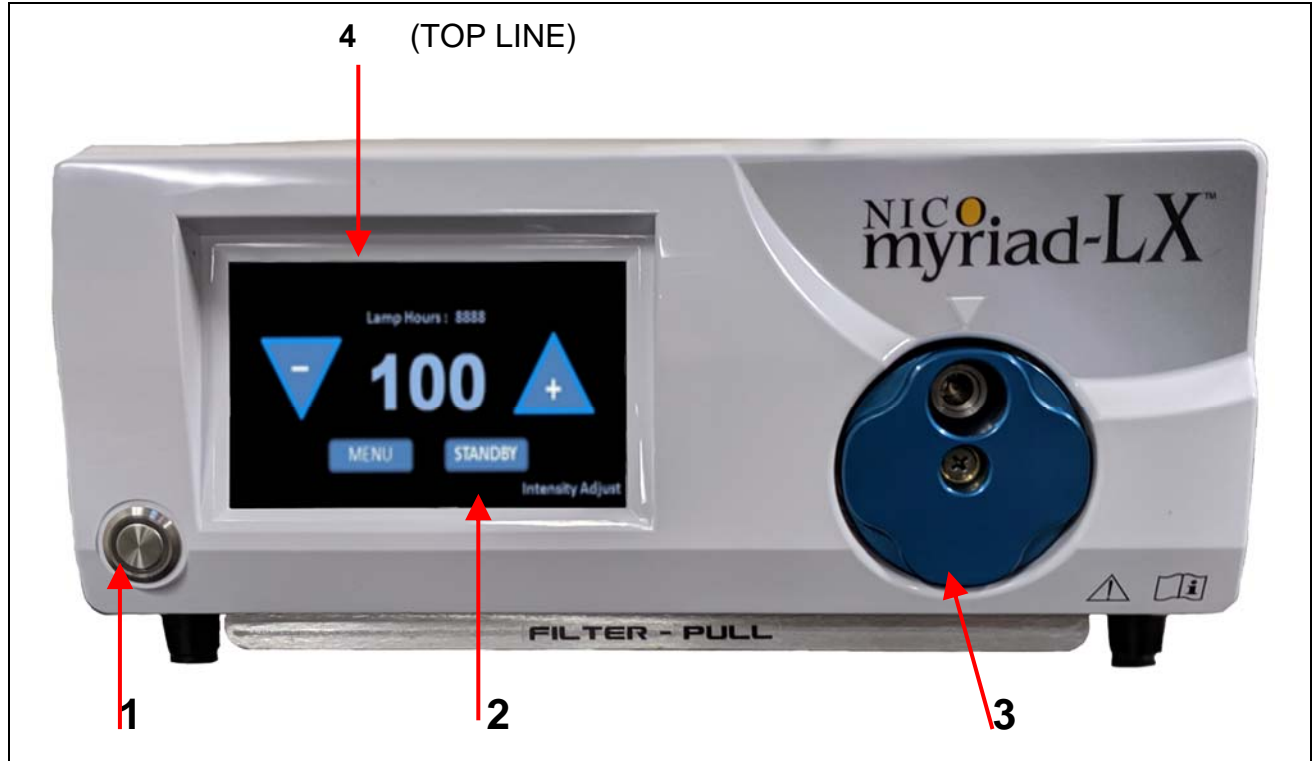
 **Caution** Use only approved manufacturer accessories and power cables. For more information, contact your distributor.

3. SPECIFICATIONS

Item	Specification
Lamp type	Ceramic type 300 watt Xenon
Power	300 Watt
Color temperature	5600 K
Lamp life	1000 hours (typical)
Lamp replacement	Cartridge replacement from the side of the unit
Light guide adapter	NICO proprietary
Brightness control	Mechanical progressive shutter control from the front panel
Input voltage	100-120 V AC, 50/60 Hz 220-240 V AC, 50 Hz
Power consumption	750 watt max
Regulatory Approvals	UL60601, EN 60601-1, EN 60601-1-2, CAN/CSA, C22.2, No 601.1-M90
Equipment Class	BF-type, Conforms to CISPR 11 Class A
Mode of Operation	Continuous operation
Water Resistant	Not Protected Equipment, IPX0
Operating Environment Temperature Relative Humidity Air Pressure	+20° to +40° C (68° to 104° F) 30 to 85% 700 to 1060 hPa
Storage Environment Temperature Relative Humidity Air Pressure	-20° to +60° C (-4° to 140° F) 0 to 95% 700 to 1060 hPa
Dimensions, mm (inch)	338 (13.3) Width x 155 (6.1) Height x 457 (18) Depth front-to-back
Weight, kg (lb)	10kg (22lb)

4. OPERATING ELEMENTS, SYMBOLS AND FUNCTIONS

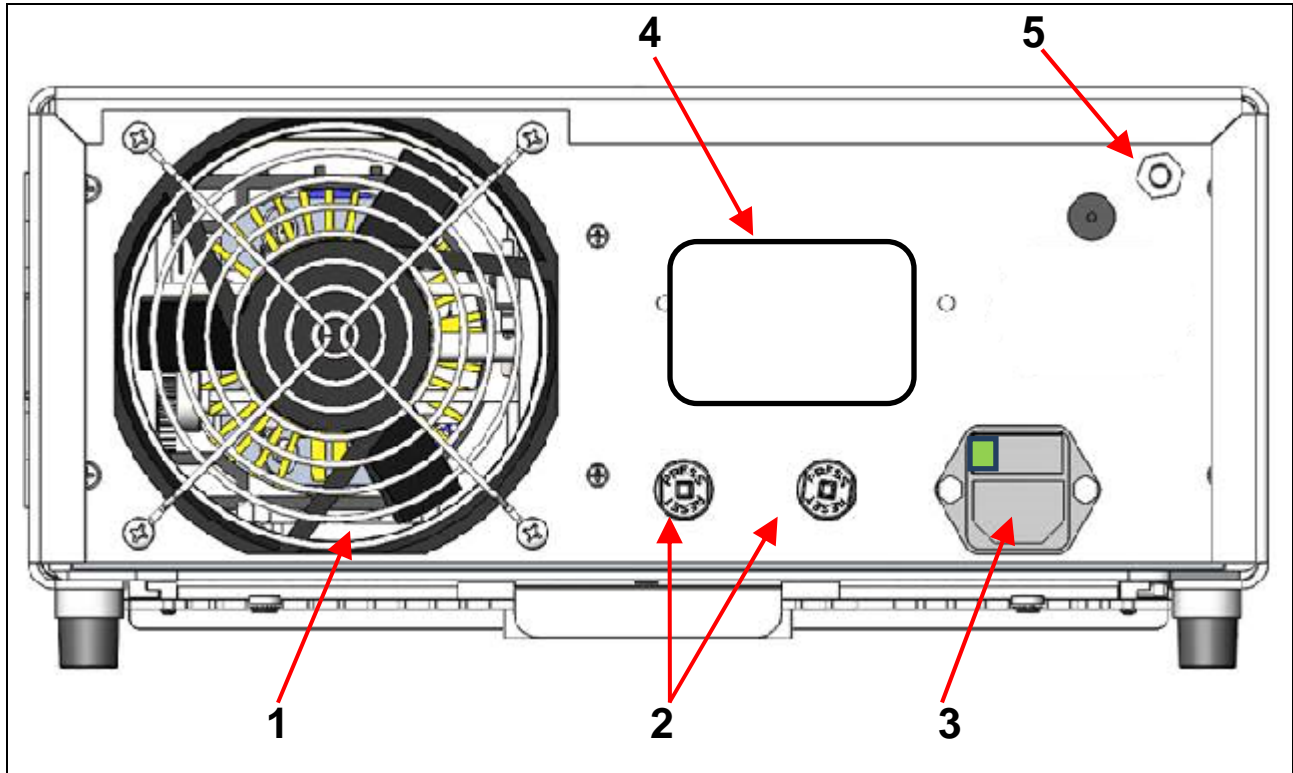
4.1 FRONT PANEL



Illuminator Front Panel

No.	Name	Function
1.	Lamp switch	Turns the illuminator on and off; illuminates blue when turned on
2.	Touch screen	Controls light intensity, displays notices and accesses data
3.	Turret	Autoshutter turret accepts end tip of fiber optic cable; light is shuttered off when no cable is inserted
4.	Lamp Hours Display	Displays total hours of lamp use

4.2 REAR PANEL



Illuminator Rear Panel

No.	Name	Function
1.	Fan	Fan 12V DC, airflow for cooling of unit
2.	Circuit breaker	Over current protection
3.	AC mains power switch and input module	Accepts AC Power cord and switches on AC power (Green light indicates "on")
4.	Product label	Product Label containing: Model Number, Serial Number, Electrical Ratings, Manufacturer Name, Regulatory Marks and FDA "Rx Only" Symbol
5.	Grounding Connector	For electric potential equalization

5. INSTALLATION

5.1 SETTING UP THE ILLUMINATOR

Place the illuminator within the low on shelf of the supplied NICO Myriad NOVUS cart.

NOTE If used without the required NOVUS cart, avoid locations where the illuminator may be splashed with liquid.

DO NOT use in any environment with explosive or flammable gases.

This illuminator pulls cooling air into its cabinet through a filtered grille in the bottom panel underneath the front portion and exhausts warm air from the fan in the rear.

DO NOT block the space in front or below the front of the illuminator or impede exhaust air flow behind or above the cabinet.

If used without the required NOVUS cart a clear space minimum of 5"/12.7cm behind and above the cabinet is required.

The illuminator should not be placed where its exhaust will influence other devices, nor where exhaust from other devices will influence the illuminator.

Ensure the rear power switch is in OFF position.

Ensure that the lamp is properly positioned for use. Open the lamp compartment door. Move the lamp positioning lever (found to the right of the lamp) clockwise, from horizontal to vertical. As the positioning cones disengage the lamp should drop about 3mm. Move the lamp positioning lever counterclockwise to reengage the positioning cones and observe that the lamp rises about 3mm as it returns to operating position.

Close the lamp compartment door.

Connect AC power cord to the power inlet located on the rear panel of the illuminator.

Ensure the power cord is completely seated into the power inlet and engage the cord retainer if so equipped.

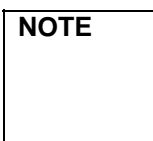


Use only power cords provided with the illuminator.

Plug the AC power cord into a wall outlet using the three (3) prong plug supplied with the unit.



To prevent electric shock, connect power cords of peripheral equipment through medical isolation transformers.



When using medical isolation transformer, be sure to check the transformer power ratings. Ensure that the power cord is connected to the main power with three prong plug (USA use UL2601-1 rated isolation transformers and/or power strips only).



Nearby radio or TV units may subject this equipment to radio interference.

To avoid adverse electromagnetic effects, **DO NOT** operate this equipment near RF energy equipment.

5.2 CONNECTING THE Myriad-LX FIBER

Connect the Myriad-LX Illumination fiber to the Myriad Handpiece per the relevant IFU. Insert the Illumination Fiber's proximal connector into the port of the turret on the front panel.

You may notice a very slight **normal** resistance to insertion as the tip opens the auto shutter. Push the tip all the way in.

6. OPERATION

6.1 POWERING UP THE ILLUMINATOR

To operate the illuminator: First attach the fiber to the ILLUMINATOR. Turn on the rear power switch. Turn on the front lamp switch.

The lamp switch will light up and the fan will start. The touch screen will display



for three seconds, followed by the **normal operating display**:

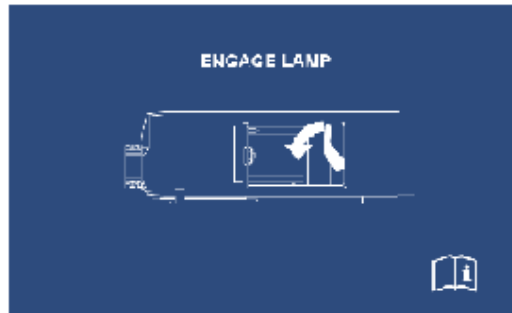


6.2 TOUCH SCREEN FUNCTIONS

6.2.1 FAULT CONDITION NOTICES

There are twelve fault conditions detectable by sensors that will render the illuminator inoperable until they are corrected. A fault condition notice will appear on the screen identifying the fault and how to correct it.

6.2.1.1 ENGAGE LAMP



(Refer to **8.1 LAMP REPLACEMENT**) Disconnect power. Open the door. The lamp positioning lever should be completely down (horizontal) to properly engage the lamp and completely up (vertical) to release it. Raise the lever completely if not already raised and firmly push the lamp to assure full engagement to the power connectors. Lower the lamp engagement lever counter-clockwise, from vertical to horizontal, and observe that the lamp rises slightly as it is engaged into proper operating position.

6.2.1.2 CLOSE DOOR



Close the door completely. (Fan will continue to run with door open.)

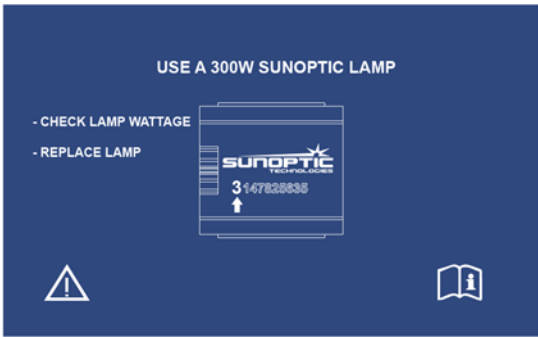
6.2.1.3 INCOMPATIBLE LAMP MODULE INSTALLED



Install correct STX0350 lamp.

The digital control system communicates with Sunoptic Technologies® lamps designed for it. Only Sunoptic Technologies® lamps can be engaged by the positioning mechanism.

6.2.1.4 INCORRECT WATTAGE LAMP INSTALLED



Install correct STX0350 lamp.
Installed lamp does not match the intended power (watts). Tx350 units require a 300-watt lamp.

6.2.1.5 LAMP HAS EXCEEDED USEABLE LIFE



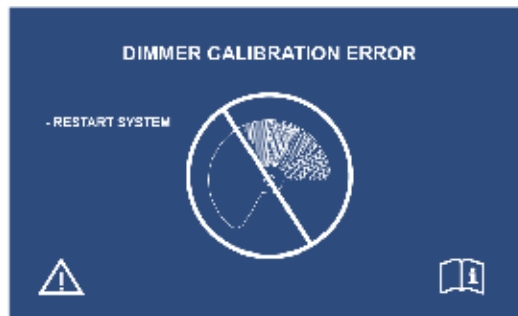
Lamp has been used more than 1000 hours. Install new STX0350 lamp or one used less than 1000 hours. The main screen always displays lamp hours, and notices are displayed when a lamp is approaching the end of its useful lamp life. This screen is displayed when the lamp has exceeded its usable lifetime.

6.2.1.6 FAN FAULT



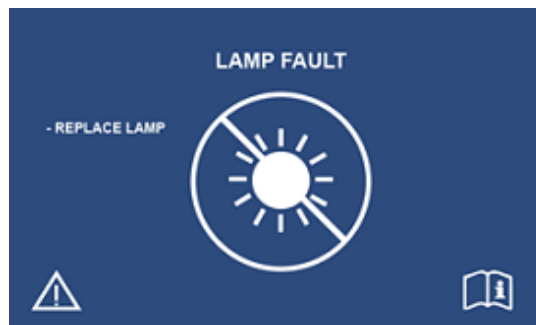
In the event of a fan problem the unit will turn off the lamp and display this screen. Turn off and restart the illuminator. If the fault persists the unit needs servicing.

6.2.1.7 DIMMER CALIBRATION ERROR



On start-up the system calibrates the dimmer plate position. If the process fails, this screen will display and the lamp will not ignite. Turn off and restart the illuminator. If the fault persists the unit needs servicing.

6.2.1.8 LAMP FAULT



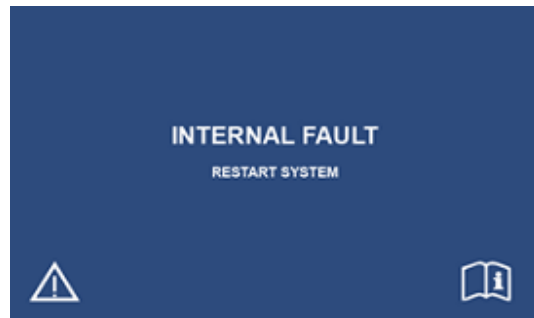
Lamp will not strike or stay lit. Replace the lamp. If the fault persists the unit needs servicing.

6.2.1.9 LAMP COMMUNICATION FAULT



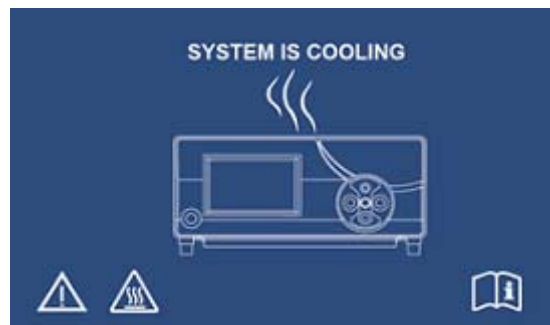
This screen is displayed when the control system does not get a response from the lamp during startup. Turn off and restart the illuminator. If the fault persists the unit needs servicing.

6.2.1.10 INTERNAL FAULT



This screen is displayed whenever the control systems detect a fault between its two processors. Turn off and restart the illuminator. If the fault persists the unit needs servicing.

6.2.1.11 SYSTEM IS COOLING



If the lamp temperature exceeds preset limits the lamp will go off and this screen will display. The fan will run to reduce the temperature. If acceptable reductions achieved within ten seconds, the lamp will turn back on to resume normal operation.

6.2.1.12 COOLING SHUTDOWN

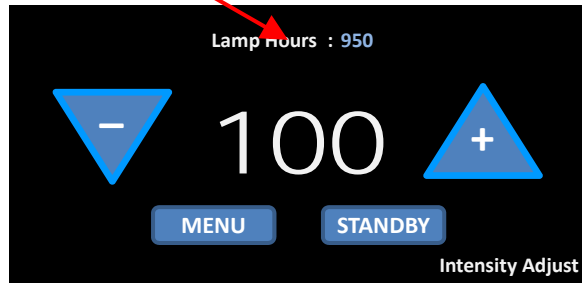


If cooling pauses are unable to acceptably restore acceptable operating temperature the lamp will go off and this screen will display. Follow the instructions (check the air filter, restart, check for obstructions that would impede intake air flow under the front of the unit or exhaust air flow from the rear of the unit). If the fault persists the unit needs servicing.



6.2.2 NORMAL OPERATING DISPLAY

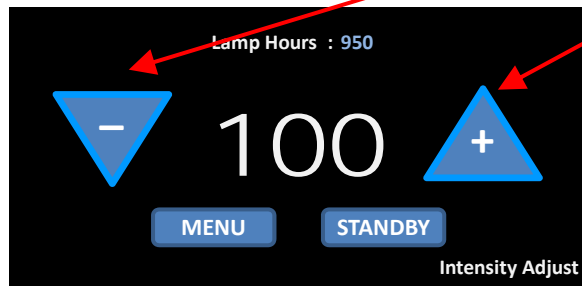
6.2.2.1 LAMP HOURS

Shows total lamp on hours.



6.2.2.2 LIGHT BRIGHTNESS CONTROL

The user may adjust the light brightness by touching the minus  or plus  controls on the normal operating display touch screen.

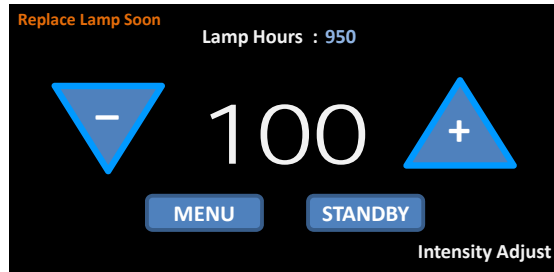


NOTE The brightness control operates a progressive electro-mechanical shutter. The lamp is running at full power if the power switch is on no matter where the brightness control is set.

6.2.2.3 STANDBY

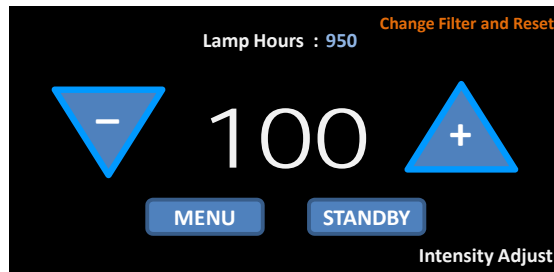
Touching **STANDBY** dims, the light by moving the shutter to fully occlude it and “softly” (not strobe) flashes the word “STANDBY” on/off in one second Intervals. Touching **STANDBY** again while in STANDBY mode will restore the light to the preset brightness value showing on the screen.

6.2.2.4 REPLACE LAMP SOON



The **Replace Lamp Soon** message is an information warning and does not require any action from the user. This message displays whenever the currently installed lamp has reached 950 hours of usage. This message begins to flash whenever the lamp reaches 975 hours of usage. This warning is shown because the lamp will no longer turn on when the lamps usage reaches 1000 hours.

6.2.2.5 CHANGE FILTER AND RESET

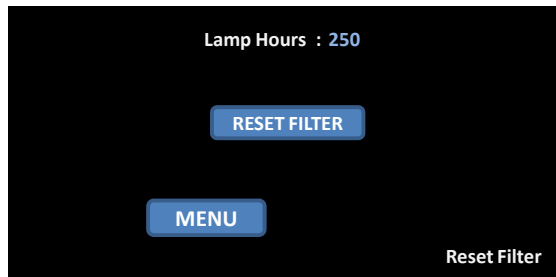


The **Change Filter and Reset** message is displayed flashing whenever the unit runtime hours an increment of 250 hours (250, 500, 750, 1000, 1250, etc.). Every 250 hours the unit filter is supposed to be replaced in order to keep the unit, and the lamp, cool enough to avoid damage. After replacing the filter, the user must go into the Filter Reset menu and press the Reset Filter button in order to clear this warning.

6.2.2.6 MENU

The **MENU** button gives the operator access to five functions of information and control. Repeatedly touching the **MENU** button will cycle through the five MENU functions, as follows:

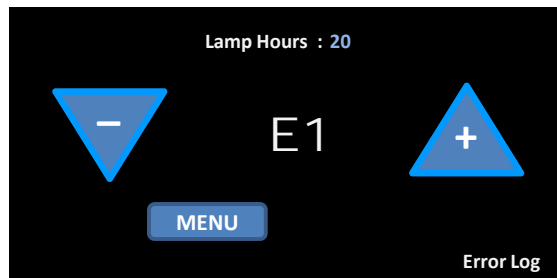
6.2.2.6.1 RESET FILTER





This screen will advise if the air filter is due for replacement. Air filter replacement every 250 hours of unit operation is advised. When air filter replacement is due there will be a flashing signal to the left of **CHANGE FILTER AND RESET**.

After installing a new filter, touch **RESET FILTER** to turn off the flashing signal for the next 250 hours of unit operation.

6.2.2.6.2 ERROR LOG



The error log function displays error codes useful for repair service. The minus  or plus  controls will cycle through the error codes logged.



6.2.2.6.3 TOTAL UNIT HOURS



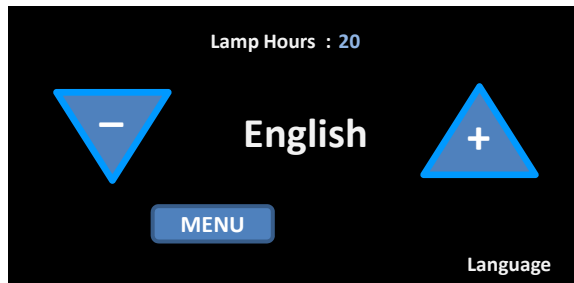
Displays total hours of unit powered up operation (rear panel mains power switch **on**.)

6.2.2.6.4 FIRMWARE VERSIONS



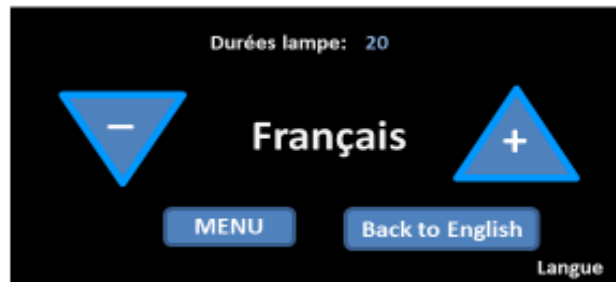
Displays the firmware dates of the two processors (K70 and PIC.) The minus  or plus  controls will cycle between them.

6.2.2.6.5 LANGUAGE



The minus  or plus  controls will cycle through the choices of variation languages.

- Press menu to enter desired language.
- To get back to default English language press menu to cycle thru functions until back to English language button shows up; as per example below:



7. CLEANING AND DISINFECTION

NOTE

Always disconnect the power cord before cleaning the system and while unit is drying if wet-wiped.

Disinfection agents should be commercially available cleansers commonly used for disinfection of electronic equipment in hospitals, such as ethyl or isopropyl alcohols, or disinfecting sprays containing quaternary ammonium compounds or hydrogen peroxide.

Do not use strongly caustic or acidic cleansers such as “Clorox” hypochlorite bleach, ammonia, muriatic acid or similar products. Do not use acetone, methyl ethyl ketone or halogenated / chlorinated hydrocarbon solvents or cleaners containing any of these restricted compounds.

Apply cleaning agents by light spray or dampened towels. Do not pour liquids over the cabinet.

Do not allow liquids to enter the cabinet seams or ventilation openings.

8. MAINTENANCE, SERVICING AND REPAIR, WARRANTY

Performance of routine maintenance is essential to proper operation of the illuminator. Follow the steps below for replacing filters and lamps.

Regular diagnostics can contribute to identifying potential problems before they become serious; thus, enhancing the instrument’s reliability and extending its useful operating life. Diagnostic services can be obtained from your local representative.

Defective items or equipment are to be serviced and repaired exclusively by persons authorized by the manufacturer. All repair work shall employ original manufacturer’s parts only.

8.1 Filter Replacement

Every 250 operating hours the air filter must be replaced. The time for replacement is notified by the system software (see paragraph 6.2.2.4.2). To replace the filter:





- Slide open the filter drawer located under the lightsource (it is labeled FILTER – PULL)
- Remove and dispose of old filter
- Obtain a new filter from the accessories kit and place into filter drawer
- Close filter drawer
- Reset filter message per paragraph 6.2.2.4.3

8.2 Lamp Replacement

WARNING!

CERAMIC lamps are at high internal pressure when cold and at operating temperature; therefore, CERAMIC lamps may unexpectedly rupture resulting in discharge of hot *fragments of quartz and/or glass and metal*.

Only handle lamps with protective covers in place. Do not handle lamps without their protective covers unless government approved safety glasses, facemasks (with neck protector, chest protector and gauntlets) are worn.

 CAUTION	<i>Always disconnect power cord and turn main switch off before lamp replacement.</i>
 CAUTION	<i>Take utmost care not to hit gas-seal edge of lamp; it may cause gas lamp failure.</i>
 CAUTION	<i>Do not touch the lamp and patient simultaneously when changing the lamp.</i>
 CAUTION	<i>Lamp power connection pins at the back of the lamp compartment may retain stored energy. Do not contact the lamp power connectors in the back of the lamp compartment.</i>

This illuminator is designed to use Sunoptic Technologies® p/n STX0350 lamp module ONLY. Use of any other lamp may void the warranty.

To replace the lamp:

- Open the lamp compartment door.
- Move the lamp positioning lever (found to the right of the lamp) clockwise, from horizontal to vertical, and pull the lamp cartridge out. Grasp only the horizontal top and bottom grip flanges of the plastic housing of the lamp, pull straight out to remove the lamp.
- Insert a new lamp, pushing firmly to assure full engagement to the power connectors. Lower the lamp engagement lever counter-clockwise, from vertical to horizontal, and observe that the lamp rises about 3mm as it moves to its proper operating position.
- Close the lamp compartment door.
- Re-connect the power cord and turn the light source on according to 6.1. to verify that the new lamp works and is properly installed.

NOTE	If the tamper seal on the illuminator is broken, the WARRANTY WILL BE VOIDED. There are no other user serviceable parts in the unit.
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8.3 Replacement Components

Three replacement filters are provided with the illuminator. They should be kept in an accessible location. Replacement lamps come with four replacement filters and can be ordered from NICO Corporation by calling 317-660-7118 and asking for part number STX0350. **Use only OEM STX0350 lamps and filters when performing routine maintenance.**

8.4 LIMITED WARRANTY

Your MyriadLX™ carries a one-year warranty from the date of shipment on workmanship and all defects of material. Should your product prove to have such defects within one years of the shipment, **NICO Corporation** will repair or replace the product or components without charge. Should your illumination product(s) need servicing under this warranty, please contact **NICO Corporation** to initiate the return process. Warranty does not cover equipment subject to misuse, accidental damage, normal wear and tear or if transferred to a new owner without authorization from **NICO Corporation**. This warranty gives you specific legal rights and you may also have other rights that vary from state to state.

POST WARRANTY REPAIRS: Please contact NICO Corporation to initiate the process.

In the US call: 317-660-7118 (toll free)

9. END OF PRODUCT LIFE

In accordance with the European Waste from Electrical and Electronic Equipment (WEEE) directive, we encourage our customers to recycle this product whenever possible. Disposal of this unit must be performed in accordance with the applicable local environmental regulations.

In the US a list of recyclers in your area can be found at: <http://www.eiae.org/>.

Please contact customer service to issue a return authorization to return product to manufacturer at the end of product life.



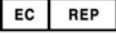











10. TROUBLESHOOTING







<u>Problem</u>	<u>Solution</u>
Power indicator (refer to 4.2) is not lit.	<ul style="list-style-type: none">• Check that the AC power cord is properly connected.• Check power input switch position.• Check the circuit breakers. If necessary, reset.
Power indicator is lit, but Xenon lamp will not ignite.	If any inoperable fault condition is displayed on the screen, correct the condition shown per section 6.2.1 .

11. CHART OF MEDICAL AND ELECTRICAL DEVICE SYMBOLS USED

11.1 Chart of Medical Device Symbols Used

	Manufacturer
	Date of manufacture (YYYY-MM-DD)
	“Authorized Representative” in the European Community
	Caution
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	Consult Instructions for Use
	CE mark
	Not disposable in general waste,
	Caution: Hot Surface
	Caution: Dangerous Voltage
	Product Safety Mark
	Do not use if package is damaged

11.2 Chart of Electrical Symbols Used

	AC Current
	Equipotentiality
	Power on
	Power off
	Type BF
	Protective Earth (Ground)