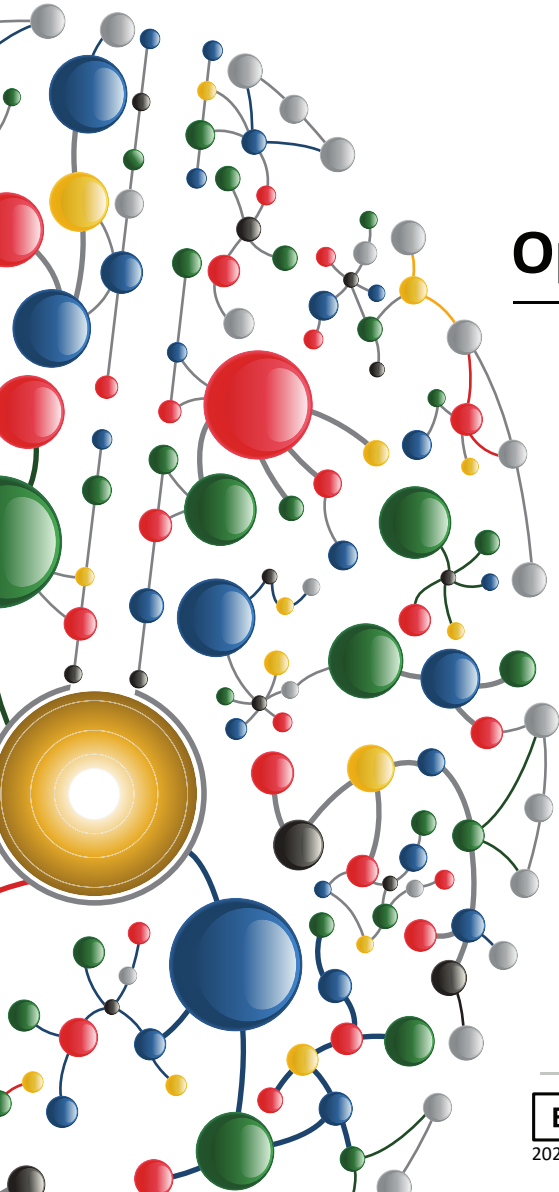


**NICO**  
CORPORATION

NICO MYRIAD  
**SPECTRA™**

**Light Source  
Operator's Manual**

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EC REP

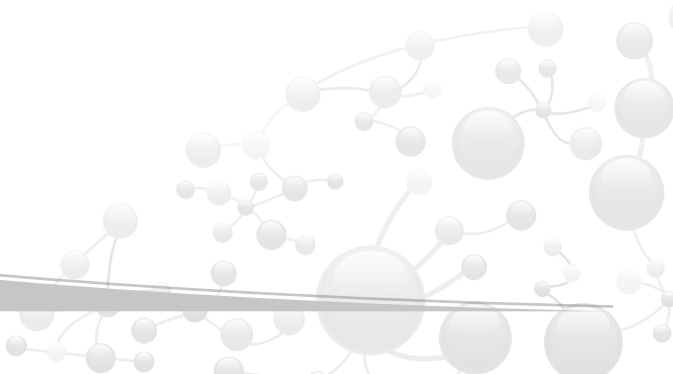
Atlantico Systems, Ltd.  
34 Oldfield, Kingston, Galway Ireland

CE

2023-12-01

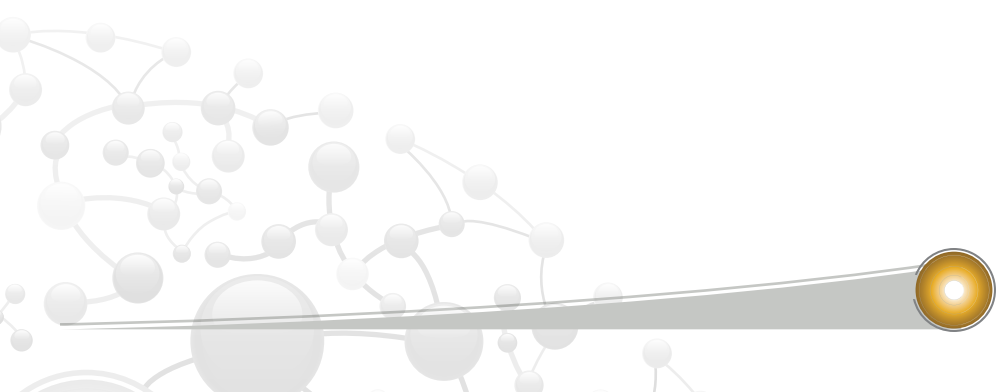
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# ENGLISH



# Table of Contents

<b>1</b>	<b>OVERVIEW.....</b>	<b>1</b>
<b>2</b>	<b>WARNINGS AND CAUTIONS .....</b>	<b>2</b>
<b>3</b>	<b>SPECTRA LIGHT SOURCE INTRODUCTION.....</b>	<b>4</b>
3.1	COMPONENTS.....	4
3.2	FUNCTIONS AND SYMBOLS .....	4
<b>4</b>	<b>SETUP AND ASSEMBLY.....</b>	<b>7</b>
<b>5</b>	<b>SYSTEM OPERATION .....</b>	<b>8</b>
5.1	POWERING UP THE DEVICE .....	8
5.2	TOUCH SCREEN FUNCTIONS.....	8
5.3	OPERATING INSTRUCTIONS.....	12
<b>6</b>	<b>USE WITH OTHER DEVICES .....</b>	<b>14</b>
<b>7</b>	<b>CLEANING AND MAINTENANCE .....</b>	<b>14</b>
<b>8</b>	<b>TROUBLESHOOTING/SERVICE .....</b>	<b>14</b>
8.1	INQUIRIES AND SERVICE .....	15
8.2	MAINTENANCE SCHEDULE .....	15
<b>9</b>	<b>TECHNICAL SPECIFICATION.....</b>	<b>15</b>
9.1	405NM EXCITATION LIGHT .....	15
9.2	NICO MYRIAD SPECTRA LIGHT SOURCE .....	16
9.3	NICO SPECTRA FOOT PEDAL .....	16
9.4	CLASSIFICATION.....	16
9.5	LIGHT SOURCE EQUIPMENT ENVIRONMENTAL CONDITIONS.....	16
9.6	ENVIRONMENTAL .....	16
9.7	SYSTEM ELECTROMAGNETIC EMISSIONS AND IMMUNITY DECLARATION .....	17
<b>10</b>	<b>GENERAL INFORMATION .....</b>	<b>21</b>



# 1 Overview

This manual is written for the medical personnel who will be responsible for operating the Myriad SPECTRA™ Light Source. It is extremely important that the operator read and thoroughly understand the contents of this manual and follow the instructions contained herein for reliable, safe and efficient operation of the light source.

This manual is for the SPECTRA Light Source only. For more details on the illumination accessories used with the SPECTRA Light Source, refer to the specific IFU provided with the accessories.

## **Product Description**

The SPECTRA Light Source is an LED illuminator with a touch screen that delivers various light outputs at user-defined intensities.



The LED light engine within the light source is capable of outputting white light, 405nm light, and 492nm light. The end user chooses the desired output as well as the intensity for the output. The user can deliver either a single output (e.g., white light) or can toggle between two outputs (e.g., white light or 405nm light). Selection of the desired output and corresponding intensity are controlled using the digital touchscreen (outside the sterile field). Toggling between two outputs during use is possible using either the touchscreen (outside the sterile field) or using a foot pedal that connects to the source (inside the sterile field). Additionally, light output can be interrupted by using the standby feature.

## **Indication for Use**

The Myriad SPECTRA Light Source is an accessory to the Myriad System and delivers white light as well as excitation light for spectral ranges of 399 - 411 nm and 486 – 498 nm for use with an appropriate surgical microscope and fluorophore during fluorescence-guided surgery.

## **Contraindications**

None

### **Special Facilities, Training, or Qualifications for Users**

The SPECTRA Light Source is prescription-use-only and intended to be used by a licensed surgeon. There are no special facility, training, or user qualifications.

## **2 Warnings and Cautions**



### **CAUTION**

- Federal law restricts this device to sale by or on the order of a licensed practitioner.
- To prevent electric shock, do not use the polarized plug with an extension cord, receptacle, or other outlet unless the blades can be fully inserted to prevent blade exposure.
- Not suitable for use in presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- 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.
- This product is not provided as sterile.
- The SPECTRA Light Source can cause permanent eye damage if viewed directly with unprotected eye. To reduce the chance of eye damage, place the light source in standby mode when light is not required.



### **WARNINGS**

- The SPECTRA Light Source should only be used with fluorophores approved for use within the specified spectral ranges.



### **WARNINGS**

- The SPECTRA Light Source is not a standalone diagnostic device.



### **WARNINGS**

- To prevent fire or shock hazard, do not expose the light source to rain or moisture.
- Use only components with this product that are manufactured by NICO Corporation (NICO) and intended for use with the SPECTRA Light Source. Use of any other systems' components will void all warranties and may result in system damage.
- To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAINS with protective earth.
- Risk of electric shock - do not open the light source. To reduce the risk of electric shock, do not remove cover. No user serviceable parts inside. Refer servicing to your distributor or to NICO Customer Service (CS@niconeuro.com).
- No modification of this equipment is allowed.
- The SPECTRA Light Source is a highly concentrated light source (luminous

power per area) and this high energy density is retained through a connected illumination fiber. The output of the light source through the fiber left in close proximity to tissue or flammable materials presents a risk of patient injury or fire. Qualified personnel must determine a safe working distance and intensity setting for each application. The output should never be left on unattended. Turn the light source off or place it in standby if it will not be required.

- Do not position the equipment such that it is difficult to unplug the power cord from the back of the light source.
- The SPECTRA Light Source requires special precautions concerning EMC and needs to be installed and put into service according to the EMC information provided in this document.
- Portable and mobile RF communications equipment can affect the SPECTRA Light Source.
- 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 SPECTRA Light Source, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The SPECTRA Light Source is intended for use by healthcare professionals only. The light source may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the light source or shielding its location.
- Use of accessories other than those specified by NICO, may result in increased emissions or decreased immunity of the equipment and may cause the light source to be non-compliant with the requirements of IEC 60601-1-2.
- The SPECTRA Light Source should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
- This light source should be used only by physicians trained in open or corridor tissue removal procedures.
- Products manufactured or distributed by companies not authorized by NICO Corporation may not be compatible with the SPECTRA Light Source. Use of such products may lead to unanticipated results and possible injury to the user or patient.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Dispose of all single patient use instruments whether used or unused. Do Not Re-sterilize any NICO device or accessory if its labeling indicates that it is for single use only. Re-sterilization of any single use disposable device may compromise the integrity and mechanical function of the instrument or accessory which may result in unintended injury or unacceptable clinical result.
- Should any object or liquid fall into the light source, unplug it and have it checked by qualified personnel before further operation.
- Allow adequate air circulation to prevent internal heat build-up. Do not place the light source on surfaces or near materials that may prevent proper ventilation.
- Do not install the light source in a location near heat sources such as radiators or air ducts, and do not place the light source in direct sunlight. Isolate light source from excessive dust, mechanical vibration or shock.
- Do not place the light source on any unstable surfaces which may not properly support it. The light source may fall resulting in injury and/or product damage.

Use only with a cart, stand or table recommended by the manufacturer or sold with the light source. The light source and cart combination should be moved with care. Quick stops, excessive force and uneven surfaces may cause the light source and cart combination to overturn.

- Grounding reliability can only be achieved when this equipment is connected to an equivalent receptacle marked “Hospital Grade.”
- This product is for use only by qualified medical personnel trained for its use.
- If the unit has been subjected to a sudden temperature change, moisture may form on the metal inside the unit. If such a temperature change has occurred, allow the unit to achieve room temperature prior turning the unit on.
- Do not damage or modify the power cord. Damage to the power cord may cause a fire or shock hazard. When unplugging the power cord, always hold by the plug and remove it carefully.
- When not in use, unplug the light source from the electrical outlet.
- When the light source is not being used, store it in a location where it will not be damaged.
- Only ship the light source in packaging that has been approved by NICO. Alternate packaging will not guarantee the protection of the device during shipping.
- Consult your distributor or NICO Customer Service if you can’t correct a problem using this operator’s manual.

**DANGER:** Risk of explosion if used in the presence of flammable anesthetics.

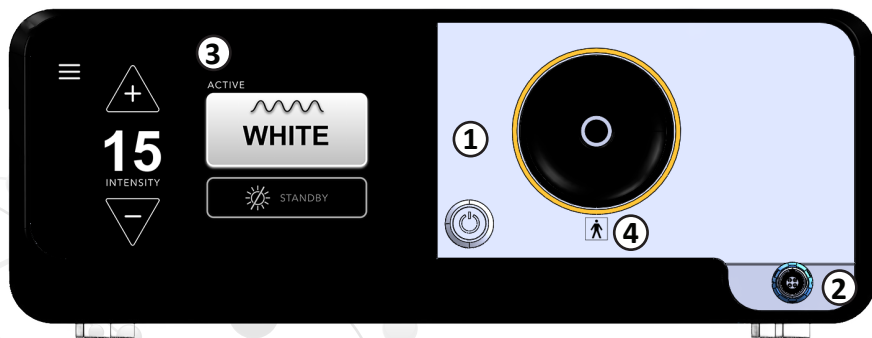
## 3 SPECTRA Light Source Introduction


### 3.1 Components

- Foot Pedal
- Power Cord
- SPECTRA Light Source

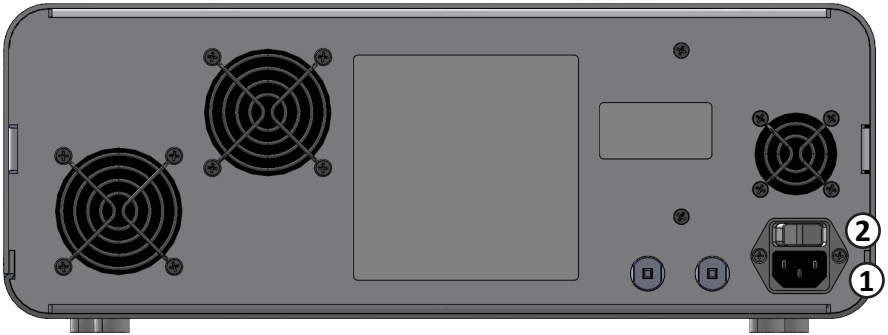
### 3.2 Functions and Symbols

Front Panel




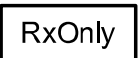


1. Screen Power -  Depress the power button on the front panel (Blue when ON)
2. Foot Pedal - Attachment site for the foot pedal cord to the Light Source.
3. Touch Screen - The interface which allows you to control the operation of the device.
4. Port - The Illumination Fiber, which is the Type BF applied part, is connected to the light source using this port

## Rear Panel













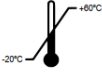





1. Power Cord Receptacle - Attachment site for detachable hospital grade power cord (IEC320C13).
2. System Power - Toggle to turn power to the system on or off. I=ON, O=OFF

## Symbols

	Screen Power - Depress the power button on the front panel (Blue when ON)
	Prescription Use Only
	Caution
	Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol.



	Symbol for the Waste Electrical and Electronic Equipment Directive (WEEE Directive), European Community directive 2002/96/EC on waste electrical and electronic equipment (WEEE)
	Symbol indicating the catalog number for the device.
	Symbol indicating the serial number for the device.
	Symbol indicating the unique device identifier (UDI) for the device.
	Symbol indicating a Type BF applied part. The Illumination Fiber is the applied part for the Light Source.
	Symbol which specifies contact information for the European Authorized Representative.
	Symbol indicating the manufacturer of the equipment.
	Symbol indicating the date of manufacture of the equipment.
	Frequency Range
	AC Voltage
	Current Max
	Indicates item is a Medical Device
	Indicates the higher and lower limits for the storage and transport temperature
	Indicates the higher and lower limits for the storage and transport humidity
	Indicates the need for the user to consult the instructions for use.
	Medical – General Medical Equipment as To Electrical Shock, Fire And Mechanical Hazards Only In Accordance With AAMI ES60601-1:2005/(R)2012 and A1:2012/(R)2012 and A2:2021, CSA-C22.2 No. 60601-1 (2008, 2014 or Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14)



Indicates a medical device that has not been subjected to a sterilization process.

## 4 Setup and Assembly

The SPECTRA Light Source is placed on the cart along with the Myriad System.



### SPECTRA Light Source Connections

This section provides information for making all connections necessary to set up the light source. The following connections will be covered:

- Power Cord
- Illumination fiber
- Foot Pedal

#### Power Cord Connection

The power cord connects the light source to the building power supply. Insert the hospital grade power cord into the power cord receptacle on the rear panel. The power cord is to be used for mains disconnection.

**NOTE:** Ensure that the power cord is in good condition. A damaged power cord poses an electrical shock hazard. When unplugging the unit, always grasp the plug and pull gently. NEVER pull on the cord.

#### Illumination Fiber

To connect the Illumination fiber to the port on the light source, insert the proximal connector in the port marked on the front of the light source. Position the pin as the arrows align with each other and push until it clicks into position. (NOTE: the illumination fiber connector is keyed and will only connect to the light source in one orientation). Only NICO Illumination fibers are compatible and provide the best output for the Light Source.

### Foot Pedal Connection

To connect the foot pedal to the light source, insert the gray foot pedal connector into the gray receptacle on the light source until it clicks into position (NOTE: the foot pedal connector is keyed and will only connect to the light source in one orientation). To remove the connector, pull back on outer sleeve with one hand while securing connector with other hand, then withdraw from light source receptacle.

To safely terminate operation of this equipment, power off the Light Source.

## 5 System Operation

### 5.1 Powering up the device

To turn on the SPECTRA Light Source, toggle the rear power switch to the ON position, then depress the power button on the front panel (Blue when ON).

The lamp switch will light up and the fan will start. The touch screen will display the following image for three seconds:



NICO Logo Display

Next, the normal operating display will appear:



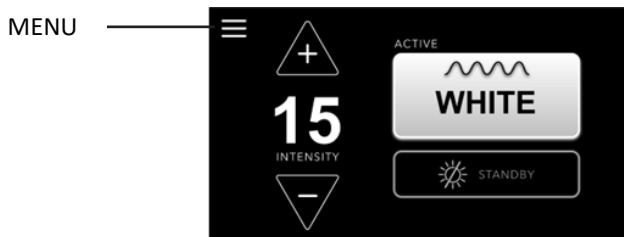
### 5.2 Touch screen functions

The touch screen is the primary interface to control the device. The touch screen allows the user to switch between different wavelengths and to adjust the intensity of the wavelengths emitting from the device. The touch screen also allows the user to access other settings associated with the light source.

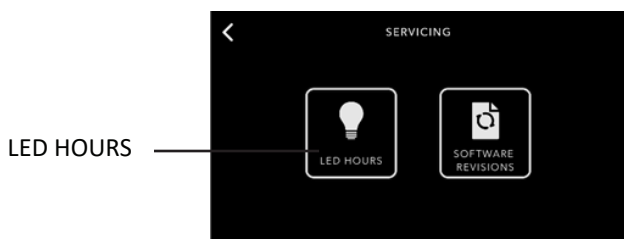
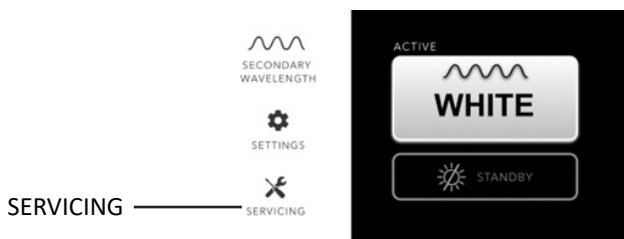
### 5.2.1 Lamp hours

The touch screen menu has an option to display the number of hours each of the LEDs has been in use.

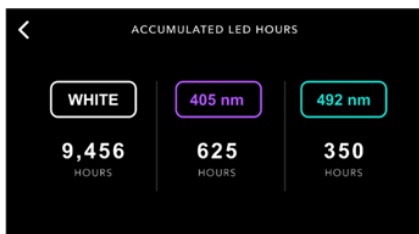
- Select the menu icon on the top left corner of the screen.



- Select SERVICING, then select LED HOURS.



- This screen displays the total accumulated hours for each of the LED (White, 405nm, 492nm).



## 5.2.2 Screen Brightness control

The default setting for screen brightness is 100%. The brightness can be adjusted based on the user's preference by following the steps below:

- Select the menu icon on the top left corner of the screen.



- Select SETTINGS to access SCREEN BRIGHTNESS

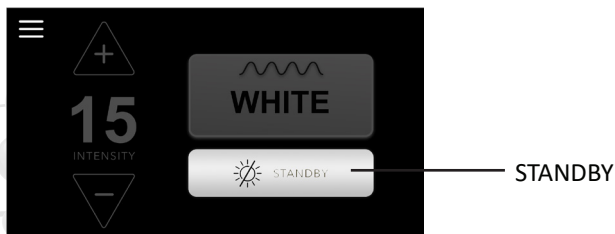


- Adjust screen brightness to the desired level by sliding the white button



## 5.2.3 Standby

The standby feature may be used to temporarily disable output from the light source. To enable/disable standby, simply press the STANDBY icon on the touch screen. The standby button blinks when activated.



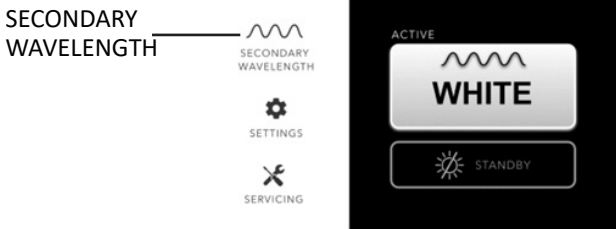
### 5.2.4 Secondary Wavelength

The menu option is used to select the secondary wavelength required during the procedure.

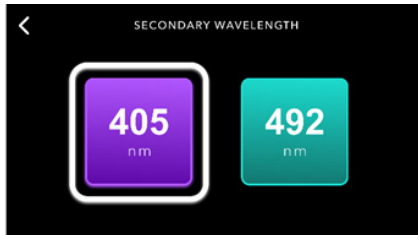
- Select the menu icon on the top left corner of the screen.



- Select the SECONDARY WAVELENGTH



This screen will then display the available wavelengths. Choose the desired wavelength by pressing the 405 nm or the 492 nm icon.



### 5.2.5 Software revisions

The software revisions for the controller and light engine are accessible for servicing purposes.

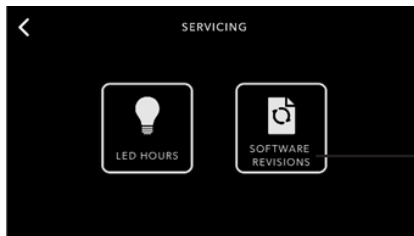
- Select the menu icon on the top left corner of the screen.

MENU



- Select SERVICING, then select SOFTWARE REVISIONS.

SERVICING



SOFTWARE REVISIONS

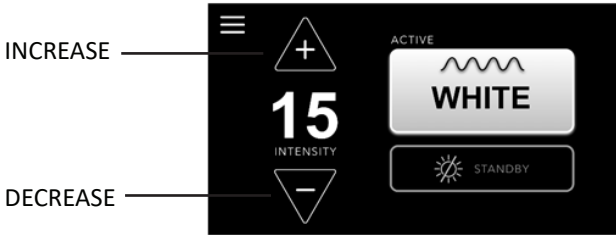
- This screen displays the software revisions for the light engine and controller.



## 5.3 Operating Instructions

- Ensure that the illumination fiber and the foot pedal (optional) are properly connected to the light source as outlined within Section 4 above.
- Ensure the touchscreen is working by navigating the menu.
- Increase/decrease the intensity of the white light as desired by toggling the

up or down arrows on the touchscreen (the system defaults to white light as the “Active” output at 15% intensity).



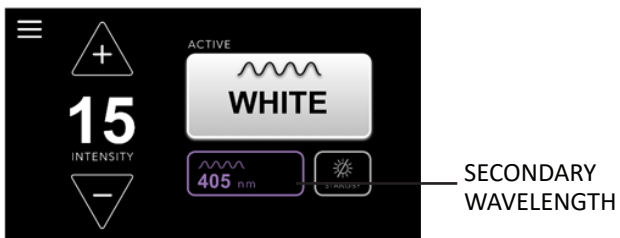
d. Select the desired secondary wavelength by using the menu icon (refer to section 5.2.4. above). The secondary wavelength defaults to 100% intensity.

e. Increase/decrease the intensity of the secondary wavelength as desired by toggling the up or down arrows on the touchscreen.



f. Illuminate tissue as desired. Toggle between white light and the secondary wavelength as desired during illumination.

- To toggle using the touch screen, simply press the icon corresponding to the desired output.



- To toggle using the foot pedal, simply depress and release the foot pedal one time





- g. Adjust intensities of white light and/or secondary wavelength as desired during procedure (see steps 5.3.c and 5.3.e above).
- h. When finished illuminating tissue, power off the device by depressing the power button on the front of the light source.
- i. Disconnect the Illumination Fiber from the light source and discard all disposable components in accordance with the applicable IFU.
- j. Disinfect the SPECTRA Light Source and Foot Pedal per the instructions within section 7 of this manual.

## 6 Use with other devices

This light source should only be used with the NICO Illumination Packs. Using incompatible equipment/devices can result in patient or operator injury and/or equipment damage as well as malfunction.

The SPECTRA Light Source may be used with an appropriate surgical microscope and fluorophore during fluorescence-guided surgery.

This light source complies with EMC standard for medical electrical equipment edition 4 (IEC 60601-1-2: 2020).

## 7 Cleaning and maintenance

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

Wipe off the light source and foot pedal with a clean towel moistened with isopropyl alcohol (60% - 90%) or Cavicide.

## 8 Troubleshooting/Service

This section provides guidance if problems are encountered when operating the light source. Please consult the following information before contacting NICO to ensure the problem is not a misunderstanding of the operation of the system. If after reading this section the problem still cannot be resolved, please contact NICO for technical support.

## Minimum Requirements for Hardware, IT Networks and Security Measures

There are no special requirements for hardware, IT networks or cyber-security. The device does not connect to a network and the firmware is inaccessible to the end-user.

### 8.1 Inquiries and Service

Direct inquiries to your distributor or to NICO Corporation:

NICO Corporation  
Customer Service Department  
250 East 96th Street, Suite 125  
Indianapolis, IN 46240  
Phone: 317-660-7118 ext.100

If your system requires service, contact your distributor or NICO Corporation Customer Service at 317-660-7118 ext.100. Your distributor or NICO Customer Service will provide you with all necessary information for returning and repairing your Light Source.

### 8.2 Maintenance Schedule

Activity	Occurrence	Action
Wipe off Light Source	As needed	Wipe off light source with a clean towel moistened with isopropyl alcohol (60% - 90%) or Cavicide.
Wipe off foot pedal	As needed	Wipe off foot pedal with a clean towel moistened with isopropyl alcohol (60% - 90%) or Cavicide.
Inspect foot pedal cord	Annually	Check for cuts and damage to outside cover and strain reliefs
Inspect power cord	Annually	Check for cuts and damage to outside cover
Inspect markings for legibility	Annually	View markings and confirm they are still legible (free from excessive fading, etc.)

## 9 Technical Specifications

### 9.1 405 nm Excitation Light

Fluorescence Excitation ..... 405 nm +/- 6 nm (Violet-blue light)  
Minimum Working Distance ..... 3 cm  
Minimum Irradiance @ 3 cm ..... 5.2 mW/cm<sup>2</sup>

## 9.2 NICO Myriad SPECTRA™ Light Source

Width.....	12.5 in. (318 mm)
Height.....	4.10 in. (104 mm)
Length.....	14.75 in. (375 mm)
Weight.....	16.50 Lbs. (7.0 kg)
AC Voltage Range .....	100-240 V
Frequency Range.....	50-60 Hertz
Max Current .....	1.25 Amps
Power Cord Length.....	15 feet (4.5 m) min.

## 9.3 NICO Myriad SPECTRA™ Foot Pedal

Width.....	4.75 in. (121 mm)
Height.....	3.75 in. (95 mm)
Length.....	11.875 in. (302 mm)
Weight.....	6.7 lbs. (3.0 kg)
Cord Length .....	17 feet (5.2 m)

## 9.4 Classification

Class I, Type BF Applied Part  
Continuous Mode of Operation  
Light source: IP20 (Ordinary)  
Foot Pedal: IPX6

## 9.5 Light Source Equipment Environmental Conditions

Temperature range within 10°C to 35°C  
Relative humidity range within 30% to 85%  
Operating altitude less than or equal to 3,000 meters above sea level

Storage Temperature : -20°C to 60°C  
Storage Humidity : 10% to 95%  
Transport Temperature : -20°C to 60°C  
Transport Humidity : 10% to 95%

## 9.6 Environmental

Comply with all local codes when disposing of packaging, equipment or any other portion of this product.

## 9.7 System Electromagnetic Emissions and Immunity Declarations

**IEC 60601-1-2:2020 Table 1 Requirements**

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the Equipment should assure that it is used in such an environment.

Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Class A	The equipment is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the equipment or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A (Harmonics)	Class A (Harmonics)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	10 Min	10 Min	

IEC 60601-1-2:2020 Table 4 Requirements			
Phenomenon Basic EMC standard or test method	Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	$\pm 8$ kV contact $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ kV air	$\pm 8$ kV contact $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated RF electromagnetic field IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	
Proximity fields from RF wireless communications Equipment IEC 61000-4-3	See Table 9	See Table 9	
Power frequency (50 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic Fields IEC 61000-4-39	65 A/m at 134,2 kHz 7,5 A/m 13,56 MHz	65 A/m at 134,2 kHz 7,5 A/m 13,56 MHz	

IEC 60601-1-2:2020 Table 5 Requirements

Phenomenon Basic EMC standard or test method	Test level	Compliance level	Electromagnetic environment – guidance
Electrical fast transient/burst IEC 61000-4-4	$\pm 2$ kV 100 kHz repetition frequency SIP/SOPS (if applicable) $\pm 1$ kV 100 kHz repetition frequency	$\pm 2$ kV 100 kHz repetition frequency SIP/SOPS (if applicable) $\pm 1$ kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\pm 0,5$ kV, $\pm 1$ kV line(s) to line $\pm 0,5$ kV, $\pm 1$ kV, $\pm 2$ kV line(s) to ground	$\pm 0,5$ kV, $\pm 1$ kV line(s) to line $\pm 0,5$ kV, $\pm 1$ kV, $\pm 2$ kV line(s) to ground	Mains power quality should be that of a typical commercial or hospital environment.
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 UT = 230 Vac	Voltage Dips: 0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle And 70 % UT; 25/30 cycles Single phase: at 0° Voltage Interruptions: 0 % UT; 250/300 cycle	Voltage Dips: 0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle And 70 % UT; 25/30 cycles Single phase: at 0° Voltage Interruptions: 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.

**IEC 60601-1-2:2020 Table 9 Requirements**

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation	Immunity Test Level
385	380 to 390	TRTRA 400	Pulse Modulation <sup>b)</sup> 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM <sup>c)</sup> ±5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse Modulation <sup>b)</sup> 217 Hz	9
745				
780				
810	800 to 960	GMS 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation <sup>b)</sup> 18 Hz	28
870				
930				
1720				
1845	1700 to 1990	GMS 1800; CDMA 1900; GMS 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation <sup>b)</sup> 217 Hz	28
1970				
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation <sup>b)</sup> 217 Hz	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse Modulation <sup>b)</sup> 217 Hz	9
5500				
5785				

If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

# 10 General Information

## **Special Storage or Handling Conditions**

There are no special storage or handling conditions.

## **Device Related Serious Incident Reporting**

Any serious incident or serious adverse event involving these products should be reported to NICO or the local Distribution Partner immediately. Serious incidents may also need to be reported to the local Regulatory Authority (e.g., Competent Authority of the Member State in EU). To report a serious incident, contact the local Representative or the Customer Service at 317-660-7118 ext.100.

## **Basic-UDIs:**

SPECTRA Light Source	00816744027469
SPECTRA Foot Pedal	00816744027483

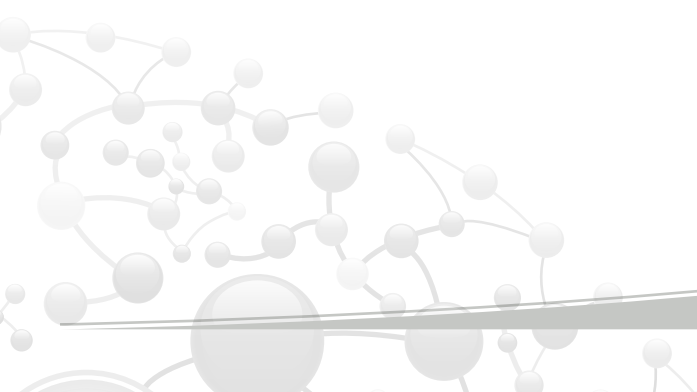
## **For More Information**

For more information on the SPECTRA Light Source, contact your NICO representative or NICO Customer Service at 317-660-7118 ext.100. Additional information may be found at [www.niconeuro.com](http://www.niconeuro.com). Additional information may be found at [www.niconeuro.com](http://www.niconeuro.com), including electronic versions of the labelling: [www.niconeuro.com/labeling](http://www.niconeuro.com/labeling)

Patent: [www.niconeuro.com/patents](http://www.niconeuro.com/patents)

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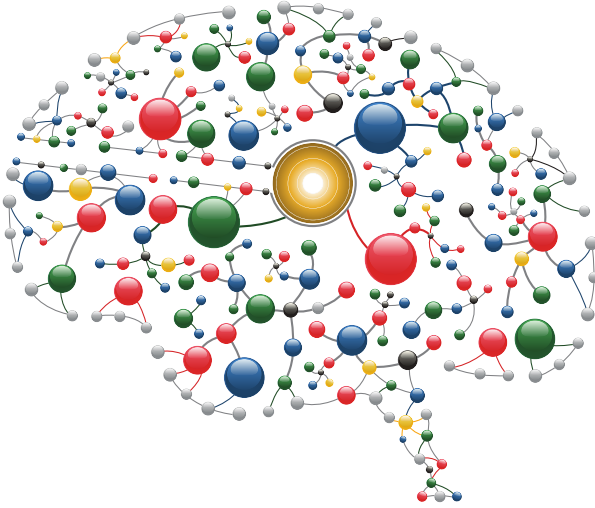




### Owner's Record


The model ("REF") and serial number ("SN") are located on the rear panel of the Light Source. Record these numbers in the spaces provided below. Refer to them whenever you call your distributor or NICO Customer Service regarding this product.

Model (REF): \_\_\_\_\_ Serial Number (SN): \_\_\_\_\_



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