Hatteras™

LED Light Source
Operating Manual

BFW™
www.bfwinc.com

Long Island Technology Group

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Symbol Description

These important symbols may appear on your Long Island Technology Group Optic light source. Please note their meaning.

Attention: Read this owner's manual for all warnings, precautions and instructions for use.

CE marking of conformity indicates this device complies with Regulation (EU) 2017/745 on medical devices and Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The UL mark indicates this product has been tested to, and conforms to applicable standards.

More information for this product can be found in this operating manual.

AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IEC 60601-1 Edition 4 (2014), IEC 60601-1-2 Edition 3 (2007),
ANSI/AAMI E-S60601-1 (2005), CAN/CSA-C22.2 No. 60601-1 (2008)

Warnings and Cautions

Users of this product should be thoroughly trained in the appropriate medical procedures. Also they should read and understand this owner's manual for this light source and all equipment used with it.

DO NOT shine light into eyes. Eye injury may result.

DO NOT use in the presence of flammable anesthetics or other flammable mixtures. Explosion or Fire may result.

DO NOT use if packaging is damaged.

Service must be performed only by Long Island Technology Group or properly trained biomedical technicians.

DO NOT operate light closer then 3 inches to tissue. Tissue Damage may result.

DO NOT use non-approved fiber optic cables. Damage to the Hatteras™ or fiber optic cable may result.

DO NOT block the light emission by turning the turret to cover the opening. Fire or damage to the Hatteras™ may result.

DO NOT plug or unplug AC cord with wet hands. Electrical shock may result.

DO NOT stack the Hatteras™ or obstruct the vents. Damage to the Hatteras™ or Fire may result.

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put in service according to the EMC information in the Electromagnetic Capability of this manual.

DB9 Serial port located in the rear is for Manufacturer use only. Use of unauthorized accessories may negatively affect EMC performance and result in non-compliance. Do not use a DB9 cable longer than 3 m (9.84 ft).

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.

Warnings and Cautions

WARNING Use only components and accessories listed on page 5 and 8 of this manual. Failure to do so may decrease system performance, may lead to unsafe operation, may negatively affect EMC performance, and could result in non-compliance and could void the warranty.

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 Hatteras™, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Warnings and Cautions

Package Content

1 - Hatteras™ LED Light Source
1 - Operating Manual Card
1 - Medical Grade Power Cable

Intended Use

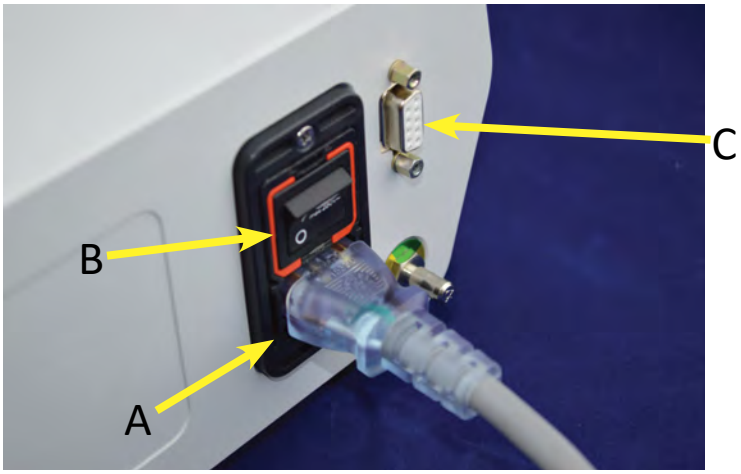
The Hatteras™ Light Source is a LED light source designed to be a replacement for similar halogen light sources. The device is intended to be used with a fiber optic cable and an optic system. A rotating turret accommodates fiber optic cables from Wolf, Storz, Olympus and ACMI/BFW products. The light is an excellent supplementary light source for examinations and procedure. The advantage of the Hatteras™ system is that it uses an LED light engine which runs cooler then halogen light engine. The intended environment for use is for Professional Health Care except for near active HF Surgical Equipment and the RF shielded room of an ME System for magnetic resonance imaging. Please follow the maintenance instructions on p7 in order to maintain basic safety.

Operation

Light Source

1. Plug AC cable from the AC cable receptacle (A) into a medical grade power supply.
2. Flip the main power switch (B) to the on position.

A. AC Cable Receptacle
B. Main Power Switch
C. DB9 Serial Port- Manufacturer use only
D. Power Button
E. Dim Button
F. Display
G. Standby Button
H. Increase Button
I. Decrease Button
J. Active Port Indicator



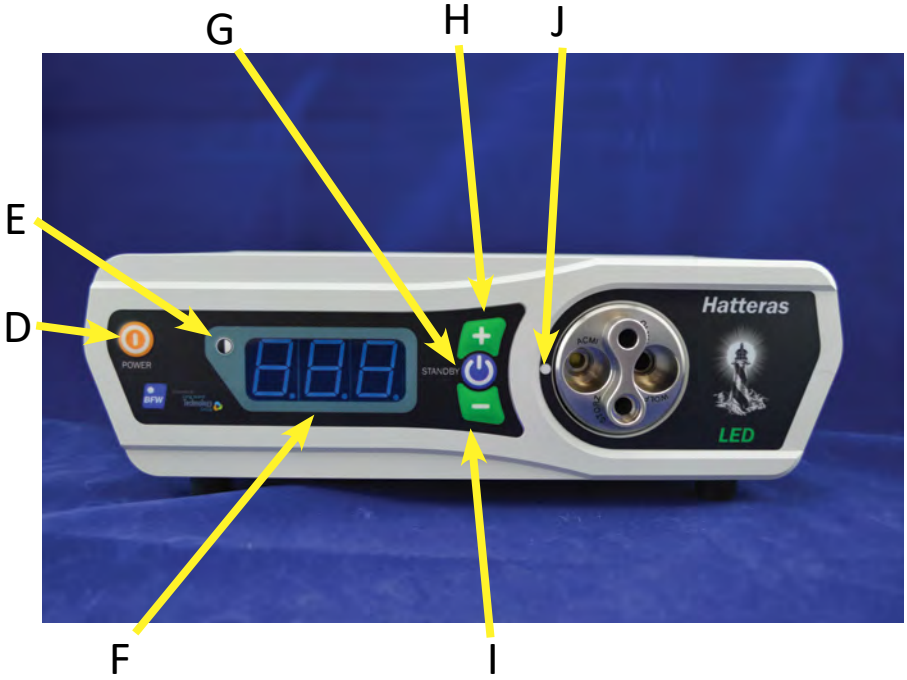
3. Press the Power button (D) to turn the system to standby.

If you see an error on the display (F) please consult the Troubleshooting section on page 11.

4. Insert your fiber optic cable into the active port as indicated by the white dot (J).
5. Press the standby button (G) to turn the light on at the most recent brightness or 80% brightness, shown on the display (F).

The light will not come on or remain on if there is no fiber in place the active port. Press and hold the standby button for 3 seconds to turn the LED on with no fiber present.

6. Pressing the + (H) or – (I) buttons to increase or decrease the light brightness by 10%.
7. Pressing the standby button (G) again will turn the light off.
8. Pressing the dim button (E) will change the brightness level of the display (F).



Cleaning and Maintenance

Light Source

1. Clean the Hatteras™ with an alcohol wipe.
2. Use a can of compressed air to clean out any dust accumulations.

DO NOT pour cleaning solution directly on the surface of the Hatteras™

DO NOT use any sterilization process or cleaning process using excessive heat or humidity as it will damage the device

NEVER immerse the light source in any type of liquid

NOTE. Damaging any part of the system with the use of an improper cleaning agent or cleaning process will void all warranties.

Specifications

Classification	
Classification & Type	FDA Class II: Medical Electrical Equipment per IEC 60601-1/CAN/CSA C22.2 No. 60601-1
Safety , EMC, and Regulatory Compliance	IEC 60601-1 Edition 3 (2008) IEC 60601-1-2 Edition 4 (2014) AAMI ES60601-1 Edition 1 (2005) CSA C22.2 NO 60601-1:08 Edition 2 (2008)

Mechanical	
LxWxH	14.0” x 5.0” x 8.0”
Indicators	7-segment display
Weight	9.6 lbs

Electrical	
Input Voltage	100-240 VAC, 50/60 Hz @ 1 Ampere
Line Cord (IEC 60320 - Hospital Grade)	Maximum Length 10ft
Fuse	5 mm x 20 mm, 4A, 250VAC, high breaking capacity, slow blow fuse

Environment	
Operation Temperature	50 Degrees F (10 C) to 104 Degrees F (40 C)
Operating Humidity	20% to 80% RH non-condensing
Storage Temperature	14 Degrees F (-10 C) to 140 Degrees F (60 C)
Storage Humidity	10% to 95% RH non-condensing

Performance	
Lamp Type	LED
Lamp Life	10,000+ hours
Over-Temperature	Protection device automatically shuts down to prevent overheating. Fans will remain on during Over-Temperature Protection. Power OFF and power unit On to relight lamp.

Electromagnetic Compatibility

Portable and mobile RF communications equipment can affect medical electrical equipment.

Guidance and manufacturer's declaration-electromagnetic emissions			
The Hatteras™ is intended for use in the electromagnetic environment specified below. The customer or the user of the Hatteras™ should assure that it is used in such an environment			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz - 80 MHz 3V/meter 80 MHz - 2.5 GHz	3 Vrms 3V/m from 30MHz to 1GHz, 3V/m for 1 GHz to 25GHz; (1000 Hz 80% Modulated Test Signal)	Portable and mobile RF communications equipment should be used no closer to any part of the Hatteras™, including cables, than the recommended separation distance calculated from the equation application to the frequency of the transmitter. Recommended Separation Distance: Battery Operated Device $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.23\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (1), should be less than the compliance level in each frequency range (2). Interference may occur in the vicinity of equipment marked with the following symbol: 

Electromagnetic Compatibility

NOTE 1: At 80 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from surfaces, objects, and people.

(1) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy to asses the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Hatteras™ is used exceeds the applicable RF compliance level above, the Hatteras™ should be observed to verify normal operation. IF abnormal performance is observed, additional measure may be necessary, such as re-orienting or relocating the Hatteras™.
(2) Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Hatteras™

The Hatteras™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Hatteras™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Hatteras™ as recommended below, according to the maximum output power of the communications equipment.

Rate maximum output power of transmitter	Separation distance according to frequency of transmitter in meters		
W	150 kHz to 80 MHz d = 1.17 P	80 MHz to 800 MHz d = 1.17 P	800 MHz to 2.5 GHz d = 2.23 P
.01	0.12	0.12	0.23
.1	0.37	0.37	0.737
1	1.17	1.17	2.33
10	3.0	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separate distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
NOTE 3: An additional factor of 10/3 has been incorporated into the formulae used in calculated the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.
NOTE 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from surfaces, objects, and people.

Electromagnetic Compatibility

Guidance and manufacturer's declaration - electromagnetic immunity			
The Hatteras™ is intended for use in the electromagnetic environment specified below. The customer or the end user of the Hatteras™ should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF electromagnetic field & Proximity fields from RF wireless communications equipment	IEC 61000-4-3 Radiated: 80MHz to 2700MHz at 3V/m	IEC 61000-4-3 Radiated: 80MHz to 2700MHz at 3V/m	Radiated RF levels should be that of a typical commercial or hospital environment
Conducted Disturbances induced by RF fields	IEC 61000-4-6 Conducted: 150kHz to 80MHz at 3Vrms outside the ISM band, 6Vrms in the ISM band	IEC 61000-4-6 Conducted: 150kHz to 80MHz at 3Vrms outside the ISM band, 6Vrms in the ISM band	Mains power quality should be that of a typical commercial or hospital environment.
Electrostatic discharge (ESD)	IEC 61000-4-2 ± 8 kV contact ± 15 kV air	IEC 61000-4-2 ± 8 kV contact ± 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 %. The user of the (Hatteras™) should avoid situations that could result in excess electrostatic discharge.
Electrical Fast Transient/burst	IEC 61000-4-4 ± 2 kV for power supply lines 100kHz repetition frequency	IEC 61000-4-4 ± 2 kV for power supply lines 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge	IEC 61000-4-5 ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	IEC 61000-4-5 ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines	IEC 61000-4-11 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° 0 % UT; 250/300 cycle	IEC 61000-4-11 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° 0 % UT; 250/300 cycle h)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Hatteras™ requires continued operation during power mains interruptions, it is recommended that the Hatteras™ be powered from an uninterruptible power supply or a battery.
Proximity fields from RF wireless communications equipment	IEC 61000-4-3 See Table 9 on p12.	IEC 61000-4-3 See Table 9 on p12.	RF wireless communications equipment should be used no closer than 30 cm to the Hatteras™.
Power frequency (50/60 Hz) magnetic field	IEC 61000-4-8 30A/m	IEC 61000-4-8 30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic Capability

Guidance and manufacturer's declaration - Electromagnetic Emissions			
The Hatteras™ is intended for use in the electromagnetic environment specified below. The customer or the end user of the Hatteras™ should assure that it is used in such an environment.			
Emissions Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Group 1	The Hatteras™ 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 Hatteras™ is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	Complies	

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). 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.

Table 9 - Test specifications for Enclosure Port Immunity to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5Hz deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0,3	28
870						
930						
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9
5500						
5785						

Troubleshooting and Service

Troubleshooting

Symptom	Possible Issue	Solution
No Power	Main power cord not plugged into socket	Plug in cord
	Fuse is blown	Return Hatteras™ to manufacturer for service
	Main power switch is not fully engaged	Toggle ON/OFF switch
	Internal component is not functioning	Return Hatteras™ to manufacturer for service
Light Does not Illuminate	Fiber is not fully inserted into the active port	Push fiber into the active port until it clicks
	Internal component is not functioning	Return Hatteras™ to manufacturer for service
Low Light Output	LED is nearing end of life	Return Hatteras™ to manufacturer for service
	Fiber optic cable is damaged	Replace Fiber optic cable
Fans running full speed/ loud	LED is operating warmer than normal	Remove objects around the Hatteras™ that may be blocking the vents or producing heat
"Er1" appears in the display	LED has reached a critical temperature and has shut its self off for safety	Remove objects around the Hatteras™ that may be blocking the vents or producing heat
"Er2" appears in the display	One or more of the fans has stalled	Remove obstructions in the vents

Troubleshooting and Service

Warranty and Service

Warranty against manufacturer's defects applies to the following components of the Hatteras™ under normal use for one (1) year from the date of sale from Long Island Technology Group (includes parts and labor).

- LED Optics and Controller
- Cables and Connectors

The warranty does not cover products damaged by the following:

- Accident, misuse, abuse, or alteration
- Servicing by unauthorized persons
- Use with unauthorized accessories
- Connection to incorrect current or voltage

In all cases Long Island Technology Group, reserves the right to determine the cause of all malfunctions and at its sole discretion will determine the damage and/or repairs that are covered under this warranty.

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Contents are fragile, Handle with care.

Conforms to:
IEC 60601-1 Edition 3, IEC 60601-1-2 Edition 4
AAMI ES60601-1 Edition 1, CSA C22.2 NO 60601-1:08 Edition 2

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