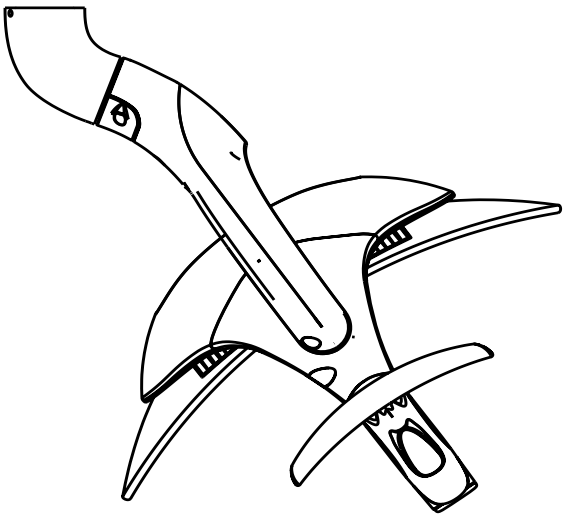
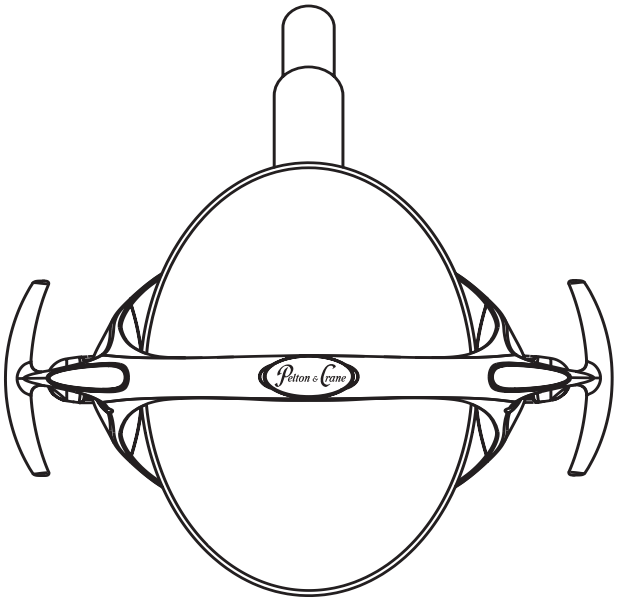
Pelton & Crane





Helios Light

Use & Care Manual

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Technical Support

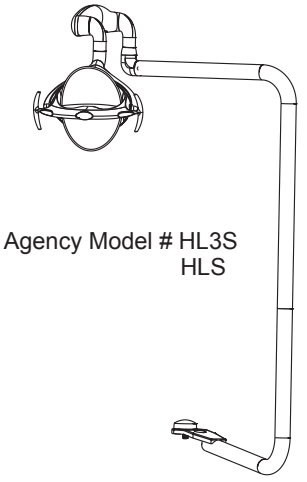
Technical assistance is available Monday through Friday, 8:00 am to 6:00 pm (Eastern Standard Time).

Phone: 800-659-5922
Fax: 704-583-8506
Customer Service: 800-659-6560

SYSTEM OVERVIEW

The Helios dental light uses LEDs to create a beam of light that is reflected and creates a shadow reduced pattern suitable for dentistry. The low voltage light source is mounted in various ways for allowing the user to adjust the position to illuminate the oral cavity. The Helios Dental light is intended for use by dental professionals to illuminate the oral cavity while performing examinations and dental procedures.

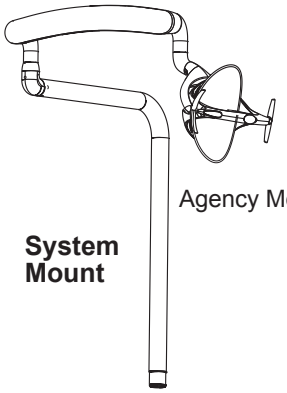
The dental light is classified as Class 1 device under rule FDA CFR 21, Class I device under Health Canada guidelines, and a Class I device under rule 11 of the MDD 93/42/EEC of Annex IX.



Agency Model # HL3S
HLS

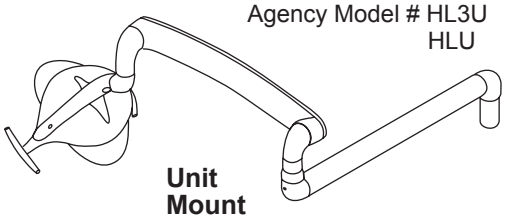
System Ellipse Mount

--OR--



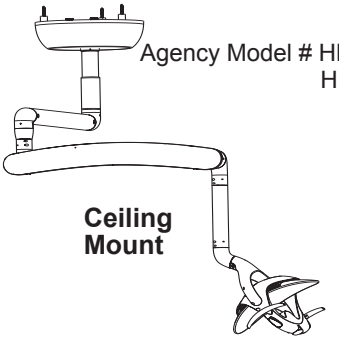
Agency Model # HL3S
HLS

System Mount



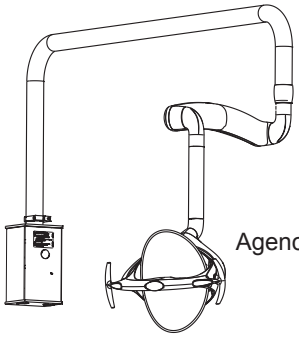
Agency Model # HL3U
HLU

Unit Mount



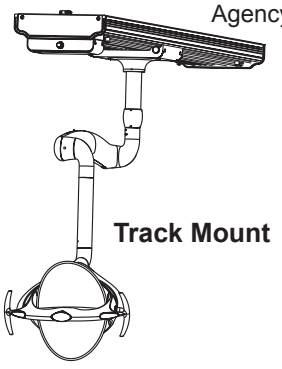
Agency Model # HL3C
HLC

Ceiling Mount



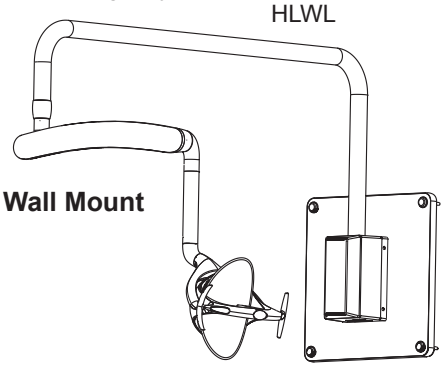
Agency Model # HL3CB
HLCB

Cabinet Mount



Agency Model # HL3T
HLT

Track Mount



Agency Model # HL3WL
HLWL

Wall Mount

GENERAL INFORMATION

DEFINITION OF SYMBOLS

The following symbols and terms may be used throughout this manual:

WARNING. Failure to carefully follow the described procedure may result in damage to the equipment and/or operator/patient injury.

Risk of electrical shock present. Ensure power is disconnected before attempting this procedure.

See operating instructions.

(AC) Alternating current.

Protective earth (Ground)

Manufacturing Date

Waste Electrical and Electronic Equipment.

Type B Applied part.

Conforms with the Essential Requirements of the European Medical Device Directive 93/42/EEC for Class I Devices.

0473 Conforms with the Essential Requirements of the European Medical Device Directive 93/42/EEC for Class IIa Devices.

Indicates conformity to General Requirements for Safety is certified by Intertek Testing Services.

General mandatory action required, important to follow instruction. Not a caution.

Warning, strong magnetic field.

Off

On

Light Switch

WARNING: This product must be disinfected before use.

WARNING: Only authorized service technicians should attempt to service this equipment. Use of other than authorized technicians will void the warranty.

Product Disposal

Contact your local authorized dealer for proper disposal of the device to ensure compliance with your local environmental regulations.

Interference with Electromedical Devices

To guarantee the operational safety of electromedical devices, it is recommended that the operation of mobile radio telephones in the medical practice or hospital be prohibited.

Strong EMI sources such as electro surgery units or x-ray units may effect performance. If performance problems occur, move the light to another electrical circuit or physical location.

Incompatible Units or Accessories

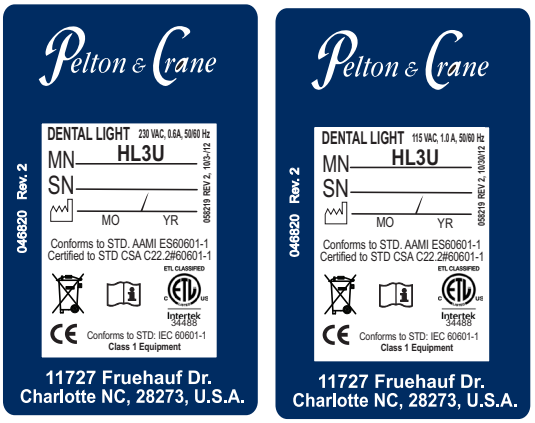
For reasons of product safety, only original Pelton & Crane accessories approved for this product, or accessories from third parties which have been released by Pelton & Crane may be used. It is the user's risk when using non-released accessories are used.

Obtaining Technical Literature

The manufacturer will make available on request circuit diagrams, component parts lists, descriptions, calibration instructions or other information that will assist technical personnel to repair and replace serviceable items.

Product Identification

This dental light can be identified by its product label, located on product. This label states the light model and serial number, electrical specifications, manufacture date and safety classification. Note the **SAMPLE** labels shown below.



WARNING: Use only Pelton & Crane replacement parts. All repairs should be performed by an authorized Pelton & Crane dealer and/or their representatives.

SAFETY NOTES

The pre-installation must be performed according to the requirements in our 'Pre-installation Instructions'.

As manufacturers of electro-medical products we can assume responsibility for safety-related performance of the equipment only if maintenance, repair and modifications are carried out only by us or agencies we have authorized for this purpose, and if components affecting safe operation of the unit that may be needed are replaced with original parts.

We suggest that you request a certificate showing the nature and extent of the work performed, from those who carry out such work, and specify that the certificate show any changes in rated parameters or working ranges, as well as the date, the name of the firm and a signature.

Storage Conditions:
-55°C to +50°C
10% to 90% Relative Humidity

WARNING: Rotational stops are designed for a maximum force limit of 25 lbs. If rotational stops are broken immediately take the equipment out of use and have the equipment serviced. Operation of damaged equipment could result in injury to the operator and/ or patient.

WARNING: Failure to install set screws & roll pin per Installation Instructions could result in injury or damage to equipment.

WARNING: The Helios light is not to be used in rooms where an explosion hazard exists.

Electrical Specifications

Volts	Cycles	Amps
115 VAC	60 HZ	1 A ~
230 VAC	50 HZ	.6 A ~

All fuses are labeled at point of use. Replace fuses only with type and rating as indicated.

IEC Medical Device Classification

Classification:	1
Operation Mode:	Continuous
Splash Protection:	IPX0

WARNING: Power cords and their associated parts cannot be substituted without increase risk of electric shock or fire. we recommend the use of Pelton & Crane replacement parts only! Power cords must be installed by qualified personnel. Make sure all service loops, strain reliefs, and cord guards are in place and that line, neutral and ground wires are secured.

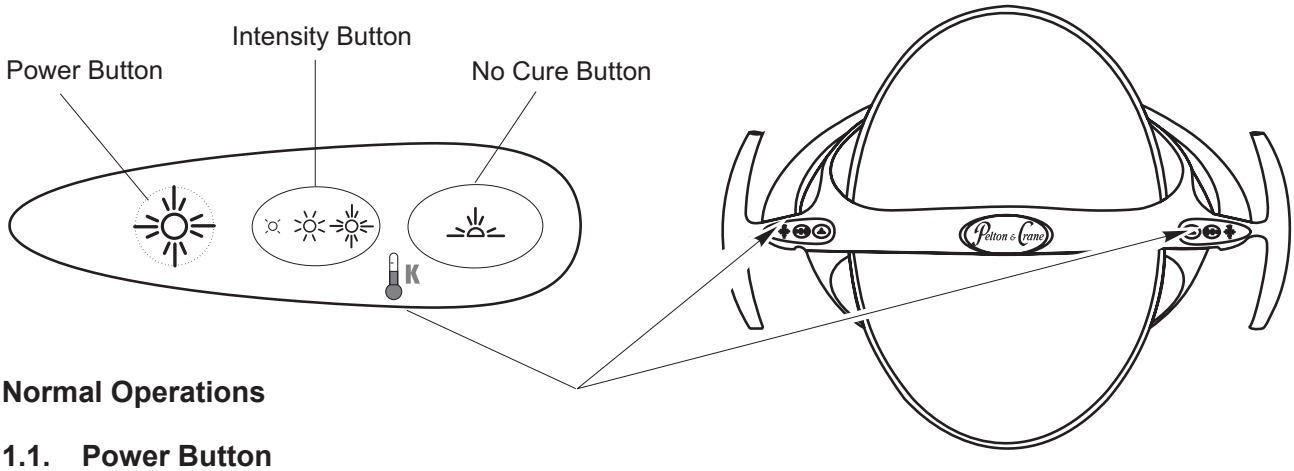
WARNING: Failure to disinfect the dental operating light between patients could expose user/patient to cross contamination and bio-burden/bio-contamination.

WARNING: No modification of this equipment is allowed.

WARNING: Use a licensed electrician for all wiring.

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

OPERATION OF LIGHT — TOUCHPAD FOR HELIOS 3000



Normal Operations

1.1. Power Button
Press the “Power” Button and release to turn the lights ON/OFF.

1.2. Intensity Button
Pressing and releasing the “Intensity” Button will toggle the light between High/Medium/Low settings.

1.3. No Cure Button
Pressing and releasing the “No Cure” Button will toggle the light between “No Cure” mode and “Normal” mode. The “No Cure” mode will display a light with a yellow tint.

1.4. Color Temperature Setting (4200K & 5000K)
When the light is ON, press the “No Cure” Button for 3 seconds. This will toggle the light between color temperatures of 4200K and 5000K.
The light will flash BLUE before changing to 5000K.
The light will flash YELLOW before changing to 4200K.

1.5. Automatic Light Shutoff
The Optical switch (located in the Flex Arm) is used to turn the light OFF when the light head is in parked position (raised high) and to turn the light ON when the light head is pulled down.

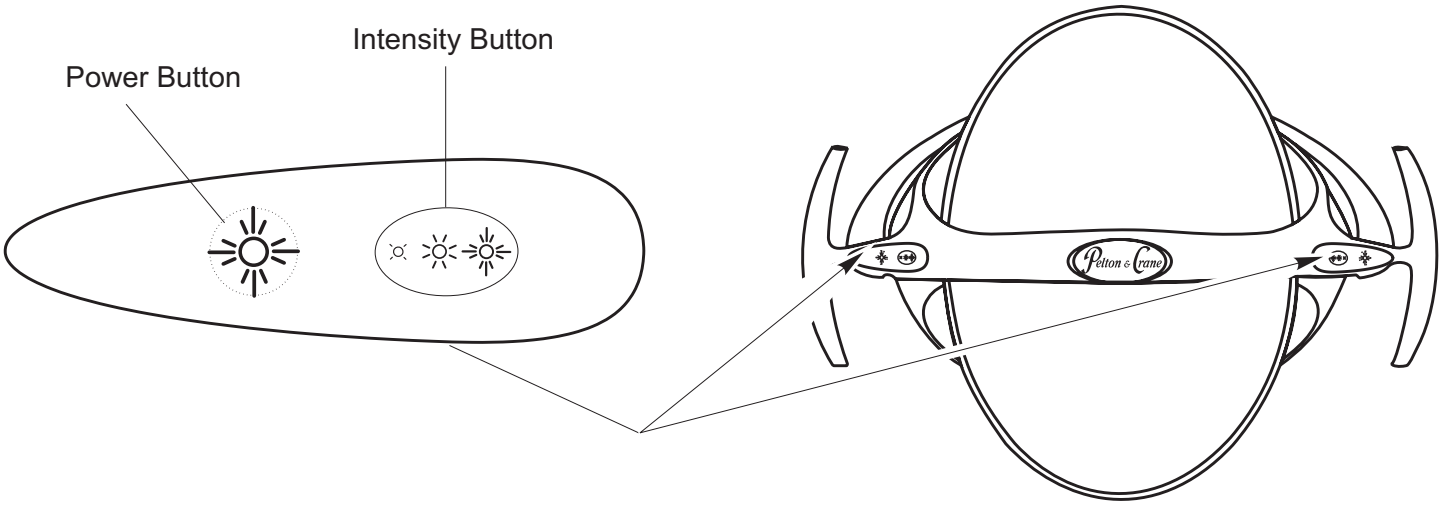
Enable/Disable optical switch
When the light is ON, press the Power Button for 5 seconds. This will disable/enable the optical switch. A very short flicker of the light indicates that the optical switch has been Enabled/Disabled.

1.6. Diagnostics and Error handling
Button Stuck Indication: When AC power is applied, if the light flashes the RED LED three times, it indicates that a button is stuck.

Changing from Hi - Medium - Low
When changing light intensity, you will hear a change in fan speed**.** This is normal and by design.

The **System Lights** may be operated (ON/OFF) via chair activation when used in conjunction with a Pelton & Crane Spirit Series Chair.

OPERATION OF LIGHT — TOUCHPAD FOR HELIOS 1800



Normal Operations

1.1. Position the light head approximately 17” (432 mm) to 36” (914 mm) from the oral cavity. Reposition the light head as required during the dental procedure.

1.2. Power Button
Press the “Power” Button and release to turn the lights ON/OFF.

1.3. Intensity Button
Pressing and releasing the “Intensity” Button will toggle the light between High/Medium/Low settings.

1.4. Automatic Light Shutoff
The Optical switch (located in the Flex Arm) is used to turn the light OFF when the light head is in parked position (raised high) and to turn the light ON when the light head is pulled down.

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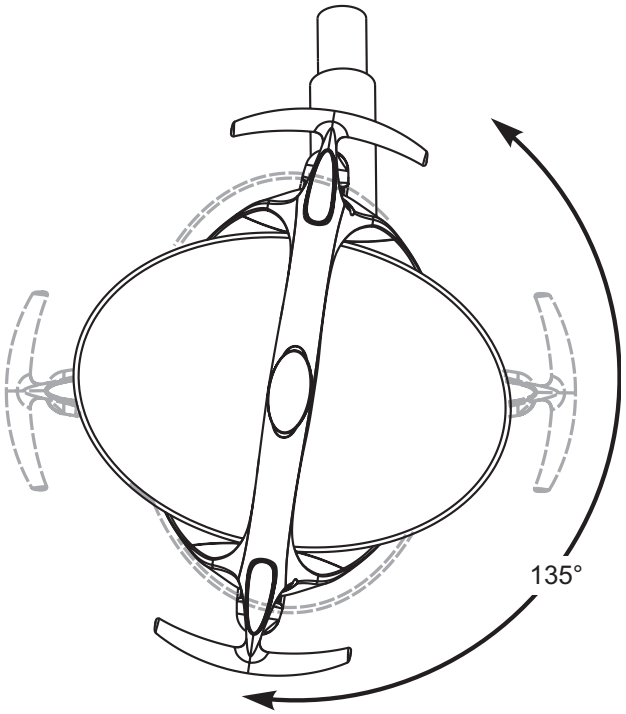
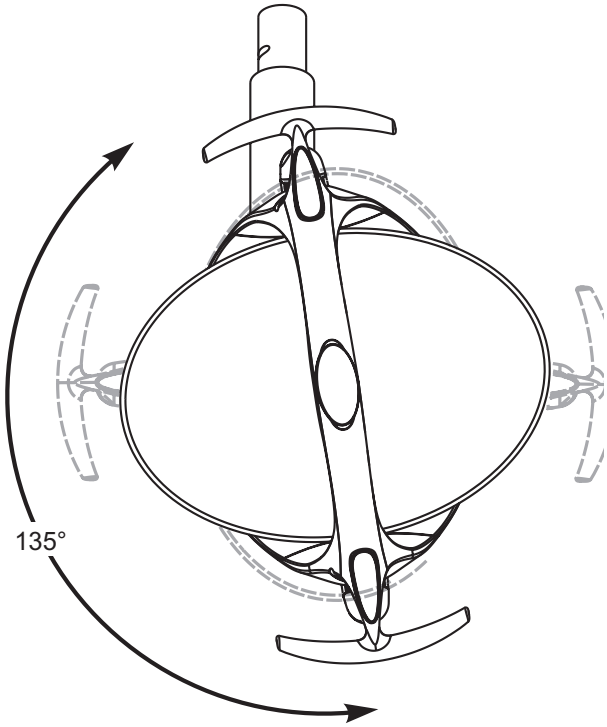
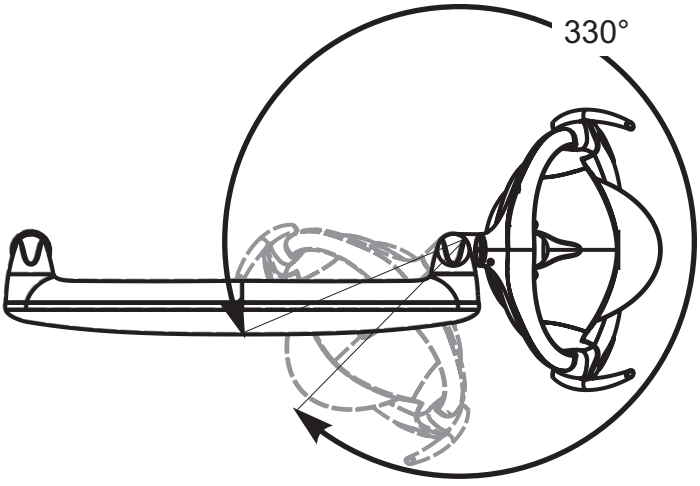
The **System Lights** may be operated (on/off) via chair activation when used in conjunction with a Pelton & Crane Spirit Series Chair.

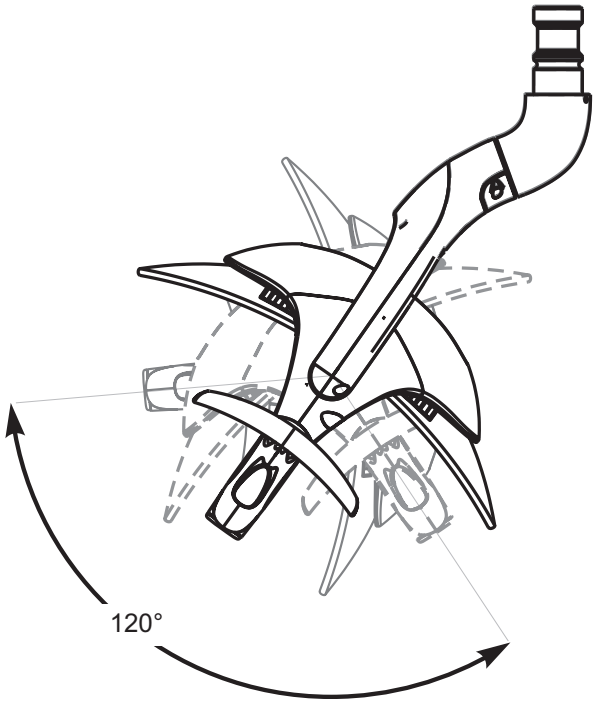
The Helios is designed for use in an indoor temperature controlled office environment.

OPERATION OF LIGHT — HELIOS LIGHT HEAD RANGE OF MOTION









CLEANING THE HELIOS LIGHT

The equipment can be cleaned with a solution of mild detergent and warm water. A variety of surface disinfectants are available for use in dental treatment rooms. Some of these can cause discoloration of painted, plated or anodized surfaces with repeated use. This can be minimized by careful adherence to the disinfectant manufacturer's instructions and by frequent washing with soap and water.

If you use an iodophor, it is especially important that you follow up with an iodophor neutralizer.

IMPORTANT: Do not use powdered cleansers, scouring pads or abrasive scrubbers or any of the painted, plastic or metal surfaces of this light. To remove dried-on material, use a soft bristled brush and a solution of mild detergent.

WARNINGS, DISINFECTING & STERILIZATION - LIGHTS

Infection control in the dental office continues to be a high priority for our customers and end users. OSHA, the ADA and the CDC are also involved in this complex issue. The Manufacturer will not attempt to specify the required intervals for disinfection nor can it recommend the overall best surface disinfectant. Please refer to the:

Infection Control

Recommendations published by the American Dental Association for further information. The question is often asked, "What should I use to disinfect my dental unit, chair and light?" This question is more complex than it seems because of the wide variety of products on the market as well as formulations of the products changing to meet the needs of increased asepsis.

Barrier Technique

The Manufacturer strongly advocates the barrier technique be used whenever possible to preserve the finish and appearance of the equipment. Wherever possible disposable barriers should be used and changed between patients. The barrier technique will ensure maximum long term durability of the surfaces and finishes of the equipment.

Chemical Disinfection

Regardless of the chemical disinfectant used, it is imperative that the equipment be thoroughly washed with mild soap and warm water at least once per day. This wash down will minimize the harmful effects of chemical disinfectant residues being allowed to accumulate on the equipment. When using chemical disinfectants, always pay strict attention to the manufacturer's disinfectant directions. When using concentrated disinfectants, measure the concentrate carefully and mix according to package directions. Disinfectant solutions that are relatively harmless to surfaces at their recommended strengths can be corrosive at higher than recommended dilution ratios.

Unacceptable Disinfectants

These disinfectants will harm the surface finishes of dental equipment and are not recommended. Use of these products will void your warranty.

Chemical Composition
Strong Phenols/Phenol Alcohol combinations
Sodium Hypochlorite/Household Bleach
Sodium Bromide
Strong Alcohol
Household Cleaners (Dental Equipment Only)
Citric Acids
Iodophors**
Ammonium Chloride
Accelerated Hydrogen Peroxide (0.5%)

⚠ WARNING

Only disinfect by wiping, no spray disinfection. Please be aware that Pelton & Crane expressly rejects any claims for warranty or damages when using other cleaning and disinfections solutions.

*The Manufacturer makes no representation as to the disinfectant efficacy of these products. We make no warranty expressed or implied that these disinfectants will not damage the surface finishes. Damage and discoloration of the surface finishes are not covered under the warranty.

Conditionally Acceptable Disinfectants*

These disinfectants have been found to be the least harmful to the equipment surfaces by our test methods.

Chemical Composition
Phthalaldehyde
Quaternary Ammonium
Glutaraldehyde

**Iodophor-based disinfectants will cause yellow staining on many surfaces.

CLEANING & DISINFECTING OF REFLECTOR

Note: The instructions below come attached to the Helios Light. The card should be kept for reference and not discarded.

Operator Only to remove this card!

HELIOS

LED DENTAL LIGHTS

WARNING!

DO NOT USE ABRASIVES WHEN CLEANING THE REFLECTOR.

DO NOT SOAK THE REFLECTOR IN CLEANING SOLUTION.

DO NOT RUB HEAVILY.

The Helios reflector is a precise optical instrument and when properly cared for will provide years of trouble-free operation. The reflector should only be cleaned according to these instructions.

DISINFECT THE REFLECTOR

The following disinfectants are conditionally acceptable for use with the Helios reflector:
1) Caviwipes
2) Banicide
3) Coecide

If using wipes, wipe the reflector in a lengthwise (vertical) direction.

DO NOT USE STRONG ALCOHOL SOLUTIONS AS THESE WILL DAMAGE THE PROTECTIVE COATING

After disinfecting, clean the reflector following the directions below:

CLEANING THE REFLECTOR

1. Saturate a clean, soft, lint-free cloth using mild detergent and warm distilled quality water.
2. Wipe the reflector in a lengthwise (vertical) direction.
3. Use clean, dry, soft, lint free cloth to dry the reflector.

Pelton & Crane

PN 055381 Rev2 06/11

An appropriate cleaning cloth has been provided with your Helios light (P/N 062476) Additional cleaning cloths are available from Pelton & Crane in a 1-pack (P/N 062476) and a 4-pack (P/N 062477). Please contact Pelton & Crane Customer Service to place and order.

ELECTROMAGNETIC COMPATIBILITY

MEDICAL ELECTRICAL EQUIPMENT ELECTROMAGNETIC COMPATIBILITY
(Instructions for use)

ELECTROMAGNETIC COMPATIBILITY
Electrical medical devices are subject to special EMC safety measurements and as a result the equipment must be installed according to the Pelton and Crane installation instruction manual.

PORTABLE ELECTRONIC DEVICES
Portable and mobile high frequency electronic communications equipment may interfere with electronic medical devices.

STATIC SENSITIVE DEVICES
Where labeled this equipment contains static sensitive devices that require special precautions when handling. At a minimum a grounded wrist strap that is connected to ground stud should be worn to reduce the possibility of damage to the light.

MEDICAL ELECTRICAL EQUIPMENT
ELECTROMAGNETIC COMPATIBILITY
(TECHNICAL DESCRIPTION)

ELECTROMAGNETIC COMPATIBILITY testing has been done for the Helios (HL) light and track.

ACCESSORY USE
Using accessory devices not specified by Pelton and Crane for use with their equipment may results in an increase of electromagnetic emissions and/or a decrease in electromagnetic immunity of the system.

INTERFERENCE FROM OTHER EQUIPMENT
If other equipment is used adjacent to or stacked with the Pelton and Crane equipment the system must be observed to verify normal operation.

ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration-electromagnetic immunity

The Models Helios Dental Lights are intended for use in the electromagnetic environment specified below. The customer or the user of the Helios Light should ensure that it is used in such an environment.

IMMUNITY TEST	IEC60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
ELECTROSTATIC DISCHARGE (ESD) IEC 61000-4-2 61000-4-2	+/-6 kV contact +/-8 kV air	+/-6 kV contact +/-8 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%. Where labeled, a ground strap (connected to ground lug) should be worn to reduce the possibility of damaged to the unit when servicing.
ELECTRICAL FAST TRANSIENT/BURST IEC 61000-4-4	+/-2 kV for power supply lines +/-1 kV for input/output lines	+/-2 kV for power supply lines Not applicable, No I/O lines	Mains power quality should be that of typical commercial or hospital environment.
SURGE IEC 61000-4-5	+/-1 kV for power supply lines +/-2 kV line(s) to earth	+/-1 kV line(s) to line(s) +/-2 kV line(s) to earth	Mains power quality should be that of typical commercial or hospital environment.
VOLTAGE DIPS, SHORT INTERRUPTIONS AND VOLTAGE VARIATIONS ON POWER SUPPLY INPUT LINES IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 seconds	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 seconds	Mains power quality should be that of typical commercial or hospital environment. If the user of the Helios Light requires continued operation during power mains interruptions, it is recommended that the Helios Light be powered by an uninterrupted power supply or battery.
POWER FREQUENCY (50/60 HZ) MAGNETIC FIELD IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

U_T is the AC. mains voltage prior to application of the test level.

ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration-electromagnetic immunity

The Helios Dental Lights are intended for use in the electromagnetic environment specified below. The customer or the user of the Helios Light should assure that it is used in such an environment.

Immunity Test	IEC60601 Test Level	Compliance Level	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
			Portable and mobile RF communications equipment should be used no closer to any part of the Helios Light, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	**3 Vrms 150 kHz to 80 MHz**	**3 Vrms**	Recommended separation distance: $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	**3 V/m 80 kHz to 2.5 MHz**	**3 V/m**	$d = 1.2 \sqrt{P}$ 80 MHz 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz 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, (a) should be less than the compliance level in each frequency range. (b) - Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz to 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.

a) 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 assess 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 Model HL3 is used exceeds the applicable RF compliance level above, Helios Light should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Helios Light.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3/Vm.

ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration-electromagnetic emissions		
The Helios Dental Lights are intended for use in the electromagnetic environment specified below. The customer or the user of the HL should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment guidance**
RF emissions CISPR-11	**Group 1**	The Helios Dental Lights use RF energy only for its internal function. Therefore, their emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR-11	**Class B**	The Helios Dental Lights are suitable for use in all establishments, including domestic establishments 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**	
Voltage Fluctuations / flicker Emissions IEC 61000-3-3	**Complies**	

Recommended separation distances between portable and mobile RF communications equipment and the Helios Dental Light			
The Models Helios Dental Lights are intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Helios Dental Light can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Helios Dental Light as recommended below, according to the maximum output of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d= 1.2\sqrt{P}$	80 MHz to 800 MHz $d= 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d= 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation 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 to 800 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 structures, objects and people.			

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We reserve the right to make any alterations which may be due to any technical improvements.

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