STERIS®



ALYON™ Surgical Lighting System

Operator Manual

en
11062964
Revision A

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Published: 2025-3-25

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A Word from STERIS

1.1 Introduction

This manual contains important information on proper use and care of this surgical lighting system. All operators and department heads are urged to carefully review and become familiar with the warnings, cautions and instructions contained herein. Your new surgical lighting fixture features an advanced, state-of-the-art design, with cool, shadow-reduced light and ease of maneuverability. It produces light of a quality necessary for the most demanding and complex of surgical procedures.

A thorough preventive maintenance program is essential for safe and proper operation of your surgical light. You are encouraged to contact STERIS concerning annual maintenance agreements. Under the terms of this agreement, preventive maintenance, adjustments and replacement of worn parts are done on a scheduled basis to verify lighting fixture performance according to its specifications and to help avoid untimely or costly downtime. STERIS maintains a nationwide staff of well-equipped, factory-trained technicians to provide this service, as well as expert repair services. Contact STERIS for details.

1.2 Intended Purpose

The surgical lighting system is a fixed or variable pattern, variable intensity surgical lighting fixture designed to provide visible illumination of the surgical field or the patient for the operating room staff.

1.3 Advisory

The following is an important message from STERIS about the advantages and limitations associated with the use of high intensity surgical lighting systems.

Because of the variety of surgical procedures performed and the wide range of individual preferences of surgical staffs, it is desirable that a surgical lighting system be capable of selective control across a wide range of illumination intensities. The Illuminating Engineering Society (IES) stresses that in addition to providing control of intensity, surgical lighting systems should provide shadow control, correct color rendition, and a suitable depth of field to provide sharp, consistent lighting into deep body cavities. As illumination levels increase, however, radiant heat also increases. Therefore, the IES cautions that for most operations, radiant heat should be kept to a minimum. The user of surgical lights should utilize the lowest possible illumination level suitable for the procedure, especially in certain neurological or intestinal procedures on delicate, thin, dry or abnormal tissue. Furthermore, for the protection of surgically exposed tissues and for the comfort and efficiency of the surgeon and assistants, radiant energy can be effectively controlled by limiting the time of exposure at higher illumination levels. Extra care must be taken when the light fields from multiple lightheads are overlapped on the surgical site, since this condition creates a risk of too much heat.

An international standard for the safety of surgical lights established by the International Electrotechnical Commission (IEC) sets minimum and maximum levels of illumination and maximum levels of radiant heat that can be emitted from a single surgical luminaire. The system has been designed to comply with this international standard and to provide a wide range of illumination levels while minimizing the potentially damaging infrared heat in the surgical field.

The illumination level of surgical lights can be adjusted through several intensity settings via conveniently located controls on either the wall mounted control center or the lighthead handle. The illumination level also decreases as the pattern size increases. Maximum illuminance can reach 160 klx for the smallest pattern size of the lighthead and can be adjusted by intensity control or pattern size control throughout the entire range specified by the IEC.

Serious incidents that have occurred in relation to this medical device should be reported to the manufacturer and competent authority in the country where the incident occurred.

1.4 Addresses

EC REP

STERIS Ireland Limited
IDA Business and Technology Park
Tullamore
County Offaly

R35 X865 ■ Ireland

STERIS Corporation
2720 Gunter Park East
Montgomery, AL 36109 ▪ USA
334-277-6660/800-444-9009
www.steris.com

CH REP

STERIS GmbH
c/o BDO AG Längfeldweg 116A
CH-2504 Biel-Bienne
Switzerland

UK REP

STERIS Solutions Limited
Chancery House, Rayns Way
Watermead Business Park, Syston
Leicester
LE7 1PF
United Kingdom

Class 1 Equipment

Ordinary Equipment (enclosed equipment without protection from ingress of water)

Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.

Suitable for continuous operation.

The base language of this document is ENGLISH. Any translations must be made from the base language document.

Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste. It must be collected separately and must be disposed as per local regulations. Contact your authorized representative for information concerning the decommissioning of your equipment.

1.5 Associated Publications

Equipment Drawing Number	Equipment Drawing Title
11041489	HarmonyAIR ALYON Surgical Lighting System Installation Instructions
11062964	HarmonyAIR ALYON Surgical Lighting System Operator Manual
P764340522	HarmonyAIR ALYON Surgical Lighting System Maintenance Manual
11050193	HarmonyAIR ALYON Surgical Lighting System Tech Data
11042426	Harmony ConnectPoint (Model ALYON) Installation Instructions
11042427	Harmony ConnectPoint (Model ALYON) Operator Manual

1.6 Waste Disposal Guidelines

WARNING

DISPOSAL HAZARD:

⚠ This product contains materials which may require disposal through appropriately licensed and permitted hazardous waste management firms. The materials listed in this manual are contained within the system. When disposing of the lighting fixture or its parts, ensure proper disposal of hazardous and other regulated waste in compliance with national, state, and local WEEE/RoHs regulations.

Electronic and Electrical Parts–not known to require special disposal methods at date of this manual.

Metal Parts–made from aluminum (Al), steel (Fe), cast iron (Fe), copper (Cu), and copper alloys (Cu/x), plastic, synthetic rubber, plating (Cr, Ni, Zn, Au), and adhesives not known to require special disposal methods at date of this manual.

Safety Precautions

2.1 Introduction

The following *Safety Precautions* must be observed when operating or servicing this equipment.

WARNING indicates the potential for personal injury.

CAUTION indicates the potential for damage to equipment.

For emphasis, certain *Safety Precautions* are repeated throughout the manual. It is important to review all *Safety Precautions* before operating or servicing the unit.

Strictly following these *Safety Precautions* enhances your ability to safely and effectively use the unit and helps to avoid improper maintenance methods which may damage the unit or render it unsafe. It is important to understand that these Safety Precautions are not exhaustive; Customers are encouraged to develop their own safety policies and procedures to enhance and complement these *Safety Precautions.*

2.2 WARNING – PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD

WARNING

PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD

⚠ Safe and reliable operation of this equipment requires regularly scheduled preventive maintenance, in addition to the regular performance of routine maintenance. Contact STERIS Service Engineering to schedule preventive maintenance.

⚠ Repairs and adjustments to this equipment should be made only by fully qualified service personnel. Maintenance performed by inexperienced, unqualified personnel or installation of unauthorized parts could cause personal injury, invalidate the warranty or result in costly equipment damage. Contact STERIS Service regarding service options.

⚠ Do not attempt to clean lighthead/monitor unless power is turned off and the lighthead/monitor has cooled sufficiently.

⚠ Do not attempt to adjust suspension system. Refer servicing to qualified service personnel.

⚠ No part of this system shall be serviced while in use with a patient.

⚠ Flat Panel Monitor spring arm uses adjustable tension force to support monitor weight. Do not remove monitor from the arm unless the arm has been locked in place by a trained and authorized technician.

⚠ Lighthead arm uses adjustable tension force to support lighthead weight. Do not remove lighthead from the arm unless the arm has been locked in place by a trained and authorized technician.

⚠ Do not modify this equipment without authorization of the manufacturer.

⚠ If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of operation.

⚠ Use of this equipment adjacent to other equipment should be avoided due to risk of improper operation of the powered device. Observe equipment used adjacent to this equipment for proper operation prior to use.

⚠ Portable RF communications equipment, including peripherals such as antenna cables and external antennas, should be used no closer than 12" (305 mm) to any part of the surgical lighting system, including cables specified by STERIS. Degradation of equipment performance could result.

⚠ Portable and mobile RF communications equipment used in close proximity to the wall control or canopy controls units may temporarily affect the operation of the equipment.

⚠ Use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of this device as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the system. Accessories or replacement parts not listed in the Operator or Maintenance Manuals should not be used.

⚠ Avoid potential EMISSIONS interference. The system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

⚠ Accessories or replacement parts not listed in the Operator Manual or Maintenance Manual should not be used as it may affect EMC or result in equipment damage.

⚠ Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

Monitor mount may fall down if the max. load capacity is exceeded. Exceeding the maximum approved load capacity can cause the monitor mount or its components to become loose and fall.

⚠
- Do not exceed the maximum load capacity of the monitor mount.
- Do not hang or mount further loads on the spindle arm, spring arm, adaption, or monitor mount.

Avoid damage after collisions. The monitor mount may become damaged and fail if it collides with other objects, walls, or ceilings.

⚠
- Check the monitor mount for potential damage after collisions.
- Inform the operator if in doubt.

⚠ The ON/OFF switch under the canopy only removes power from the load side of the system. Any system wiring located between this switch and the utility junction box is still energized. To ensure complete system zero-energy state, lockout-tagout junction box and perform system energy check.

⚠ Arms may move when package is lowered.

⚠ Avoid sudden release of spring arm: The height limit of the monitor spring arm must only be adjusted with equipment installed.

⚠ Risk of the spindle arm set dropping. The collapse of the spindle arm set may cause serious injury. Make sure that no one is standing underneath the spindle arm set while it is being installed.

⚠ Risk of the spindle arm set dropping. The spindle arm set can drop if the fastening elements have not been properly tightened. Tighten the countersunk screws M4 x 7 mm – 8.8 – ISO 14581 (alternative: M4 x 8 mm) to 2 N▪m.

Avoid risk of the product dropping. The product can drop if the fastening elements have not been properly tightened:

⚠
- Tighten the countersunk screw M4 x 6 mm– 8.8 – ISO 10642 (alternative: ISO 14581) to 2 N▪m.
- Tighten the Allen cylinder screw M6 x 5 mm – 8.8 – ISO 4762 to 10 N▪m.

Avoid risk of the spring arm with adaption and end device dropping. If the spring arm pivot and the securing segments are not mounted correctly, there is a risk of the spring arm with the adaption and the end device dropping and causing severe injury. When mounting the spring arm, make sure that it sits correctly on the extension arm and follow the instructions provided in this manual.

⚠

Avoid risk of the spring arm with adaption and end device dropping. If the spring arm pivot and the securing segments are not mounted correctly, there is a risk of the spring arm with the adaption and the end device dropping and causing severe injury.

⚠
- When installing the spring arm, verify spring arm sits correctly on the spindle arm.

Avoid risk of the adaption with end device dropping. If the two securing segments are not properly mounted, there is a risk of the adaption and the end device dropping and causing serious injury. Verify the two securing segments are securely in place.

⚠
- The adaption/end device must be inserted into the spring arm up to the end stop.
- The two securing segments must be inserted into the spring arm up to the end stop such that they protrude into the groove on the pivot of the adaption/end device.

Avoid risk of the product dropping. The overall system and the product are an adapted system with regard to the maximum load bearing capacity and maximum loading capacity (payload). If the maximum loading capacity (maximum payload) is exceeded, there is a risk that the product or components thereof may disengage from the fastening device and drop.

⚠
- Before installing the product, check that the permissible loading capacity (payload) on the product and on the overall system are not exceeded.

Avoid risk of the product dropping. The overall system and the product are an adapted system with regard to the maximum load bearing capacity and maximum loading capacity (payload). Alterations to the product can result in exceeding the permissible, total or maximum loading capacity of individual components. In this case, there is a risk of the product or components thereof disengaging from the fastening product and dropping.

⚠
- No structural alterations are made to the product. Unauthorized modifications or conversions to the product are not permitted for safety reasons.
- Only genuine spare parts or accessories and those specified and approved by STERIS are used. The use of other parts may involve unknown risks and must be avoided in all cases.
- Inspections and maintenance are carried out at the specified time intervals.

Avoid risk of the product dropping. The product or components thereof can drop if the fastening elements have not been properly tightened.

⚠
- Tighten the countersunk screws M5 x 16 – 10.9 – ISO 10642 to 6 N▪m.
- Tighten the cylinder screws M5 x 8 – 8.8 – DIN 7984 to 6 N▪m.
- Tighten the cross recessed head screws M5 x 16 – 10.9 – ISO 7380-2 to 6 N▪m.

Avoid risk of the end stop dropping. The end stop or components thereof can drop if the fastening elements have not been securely tightened.

⚠
- Tighten the countersunk screw M5 x 20 – 8.8 – ISO 10642 to 6 N▪m.
- Tighten the countersunk screw M5 x 25 – 8.8 – ISO 10642 to 6 N▪m.
- Tighten the cap nut M5 – DIN 986 to 2 N▪m.

Avoid risk of the monitor dropping. If the screws are not screwed in deeply enough, there is a risk of the monitor dropping. If the screws are screwed in too deeply, there is a risk of the monitor becoming damaged and unusable.

⚠
- Observe the monitor manufacturer's instructions for the correct fastening of the monitor.
- Observe and check the screwing depth even if a deep thread insert is available.

Avoid risk of the monitor dropping. The monitor can drop if the fastening elements have not been properly tightened.

⚠

- Tighten the countersunk screws M4 ISO 10642 to 4 N▪m.
- Note that the tightening torque depends on the individual monitor and observe the monitor manufacturer’s instructions.

Avoid risk of the monitor dropping. Make sure that the monitor is correctly aligned with the rail and securely fastened. The monitor can drop if the fastening elements have not been properly tightened.

⚠

- Tighten two setscrews M5 x 20– ISO 4026 such that the monitor is securely fastened.

Avoid risk of the monitor dropping. If the screws are not screwed in deeply enough, there is a risk of the monitor dropping. If the screws are screwed in too deeply, there is a risk of the monitor becoming damaged and unusable.

⚠

- Observe the monitor manufacturer's instructions for the correct fastening of the monitor.
- Observe and check the screwing depth even if a deep thread insert is being used.

Avoid risk of the monitor dropping. The monitor can drop if the fastening elements have not been properly tightened:

⚠

- Tighten the cylinder screws M4 to 4 N▪m.
- Note the tightening torque depends on the individual monitor and observe the monitor manufacturer’s instructions.

Avoid risk of the handle dropping. The handle or components thereof can drop if the fastening elements have not been securely tightened:

⚠

- Tighten the countersunk screws M4 x 8 – 8.8 – ISO 10642 to 3 N▪m.
- Tighten two cross recessed head screws M4 x 12 – A2-70 – ISO 7380-2 to 3 N▪m.
- Tighten two cross recessed head screws M5 x 10 – 10.9 – ISO 7380-1 to 3 N▪m.

Avoid risk of the box dropping. The box can drop if the fixing elements have not been securely tightened:

⚠

- Tighten countersunk screws M5 x 16 – A2-70 – ISO 10642 to 6 N▪m.

⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12”) to any part of the HarmonyAIR ALYON Surgical Lighting System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ A risk of increased emissions or decreased immunity may result if any additional cables are attached.

⚠ This device has not been tested for compatibility with all other potential RF Emitters such as X-ray, Metal Detectors, Electrosurgical Equipment, Diathermy Equipment, 5G Cellular, NFC, WPT, or Electronic Article Surveillance (EAS) devices. Caution should be used if such emitters are present within the use environment.

⚠ 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.

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

2.3 WARNING – PERSONAL INJURY HAZARD

WARNING

PERSONAL INJURY HAZARD

Harm due to contraindication. The product may cause harm in case of the following contraindications:

⚠
- The monitor mount may move by itself in strong magnet fields and must not be used in their proximity.
- Application parts of type BF or CF according to IEC 60601-1 must not be connected directly to monitor mount.

⚠ Avoid looking directly at high-intensity light from the lighthead. Eye injury may result.

Sudden release of spring arm. When uninstalling the end device from the product, the spring arm can suddenly jump up and may cause serious injury.

⚠
- Uninstalling work of any kind may only be performed by qualified personnel who have been authorized and instructed by the operator.
- Avoid risk of parts falling off. During all installation work, it must be ensured that nobody is located in the area underneath the components of the product.

Avoid risk of bruising. To adjust the tilting angle and friction, the bracket holding the monitor in place must be moved. Note that there is a risk of bruising fingers and limbs between the holding bracket and the connecting plate.

⚠
- Make sure you keep your fingers and limbs out of the gap whilst carrying out adjustment work.

2.4 WARNING – POSSIBLE PATIENT INJURY HAZARD

WARNING

POSSIBLE PATIENT INJURY HAZARD

⚠ Failure to engage the disposable light handle cover completely may result in cover falling from lighthead during the procedure.

⚠ Cables or accessories other than those supplied by STERIS may affect EMC performance.

2.5 WARNING – STERILITY ASSURANCE HAZARD

WARNING

STERILITY ASSURANCE HAZARD

⚠ Do not use the surgeon's control buttons when the plastic light handle is being used unless a sterile cover is installed. If the plastic light handle is used without a disposable cover, the sterility of the surgical environment may be compromised.

⚠ Do not use disposable handle covers if the packaging has been damaged, torn or opened, as the sterility of the cover may be compromised.

2.6 WARNING – BIOHAZARD

WARNING

BIOHAZARD

⚠ Sterile disposable covers for handles and camera are intended for single use only.

⚠ Reusable sterilizable covers must be properly cleaned and sterilized between uses.

⚠ Universal precautions must be observed when disposing of any single use disposable item.

2.7 WARNING – DISPOSAL HAZARD

WARNING

DISPOSAL HAZARD

⚠ This product contains materials which may require disposal through appropriately licensed and permitted hazardous waste management firms. The materials listed in this manual are contained within the system. When disposing of the lighting fixture or its parts, ensure proper disposal of hazardous and other regulated waste in compliance with national, state and local WEEE/RoHs regulations.

2.8 WARNING – EXPLOSION HAZARD

WARNING

EXPLOSION HAZARD

⚠ Do not use this lighting system in the presence of flammable anesthetics.

2.9 WARNING – ELECTRIC SHOCK HAZARD

WARNING

ELECTRIC SHOCK HAZARD

⚠ Disconnect all utilities to lighting fixture before servicing. Do not install the lighting fixture unless all utilities have been properly locked out. Always follow OSHA Lockout-Tagout and electrical safety-related work practice standards.

⚠ Do not remove covers or perform service other than as described in this manual. Refer servicing to qualified service personnel.

⚠ Do not remove wall control covers. Servicing must be performed by qualified service personnel.

⚠ The ON/OFF switch under the canopy only removes power from the load side of the system. Any system wiring located between this switch and the utility junction box is still energized.

Avoid electric shock hazard. The monitor mount may be live when connected to a supply network without protective ground conductor.

⚠
- To avoid the risk of electric shock, the monitor mount may only be connected to a supply network with protective ground conductor.
- If in doubt, ask the operator whether the monitor mount has been installed properly.

Avoid electric shock hazard. The monitor mount may be live and must be treated carefully during cleaning and disinfection:

- If a mains plug is present, please disconnect it.

⚠
- Do not use spray cleaning and/or disinfecting agents sprays.
- Do not spray fluid into sockets or monitor mount openings. Do not allow fluid to penetrate them.

⚠ Do not cut and abandon the alternating current (ac) wiring leads, as this is an electrical hazard.

⚠ Do not apply alternating current (ac) to the lighting system until all control and power interconnections have been completed.

⚠ To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective ground.

The supply cables are not included in the scope of delivery:

- The installer carrying out the installation is responsible for selecting suitable cables for supplying the end device (e.g., medical device, etc.) with electric power.

⚠

- Observe the maximum cable routing aperture of approximately 23 x 16 mm on the supply helix.
- The maximum cable cross section of Ø10 mm per cable must not be exceeded.

Power supply cables are laid inside the product. Contact with energized components presents a danger to life from electric shock. Disconnect the product from the mains before any adjustment work:

⚠

- Disconnect all the poles from the mains and prevent the product from being switched back on again.
- Verify all the devices connected are de-energized.

⚠ Electric shock caused by defective insulation. Damaged insulation can energize the product. Always ground the ceiling plate to building ground.

The spring arm with cables must be fitted with an end stop (twist protection) which restricts the swivel range of the spring arm. If the end stop is not mounted, the cables are twisted off and the pendant system is energized. Contact with energized components presents a danger to life from electric shock:

⚠

- Verify end stop is mounted to the standard accessory spring arm.
- For the advanced accessory spring arm, end stop included in the accessories must be mounted.
- The spring arm must not be mounted without an end stop.

The spring arm with cables must be fitted with an end stop (twist protection) which restricts the swivel range of the spring arm. If the end stop is not installed, the cables are twisted off and the system is energized. Contact with energized components presents a danger to life from electric shock.

⚠

- For a spring arm with cables, mount the end stop from the accessories.
- The spring arm must not be mounted without an end stop.

For the spring arm with cables, the end stop (twist protection) must be mounted in order to restrict the swivel range of the spring arm. If the end stop is not mounted, the cables are twisted off and the system is energized. Contact with energized components presents a danger to life from electric shock.

⚠
- Place the end stop ring onto the pivot of the adaption/end device.
- Adaption/end device used must be fitted with an end stop.
- Spring arm with cables must not be mounted without an end stop on the adaption/end device.

If the external cables are not laid next to each other and without twisting or if the external cables are damaged, the system is energized. Contact with energized components presents a danger to life from electric shock.

⚠
- Be sure to lay the external cables next to each other and without twisting.
- Do not damage the cable insulations.

Damaged external cables can energize the system with a voltage of 230 V (120 V):

⚠
- Check all external cables for damage. Make sure to insert them with great care without cables/hoses crossing each other, without loops and without twisting.
- Do not damage the cable insulation.

Damaged external cables can energize the system with a voltage of 230 V (120 V).

- Lay the external cables in the spring arm in such a way that they are not exposed to tensile stress in any position.

⚠
- Do not damage the cable insulation.
- When inserting or laying external cables, the permissible minimum deflection and bending radii and the permissible maximum tensile stress values must be observed. The specifications of the corresponding cable manufacturer must be observed.

To prevent the risk of electric shock, the product may only be connected to a supply network equipped with a protective conductor.

⚠
- The product must be connected in such a way that it can be disconnected from the mains at all poles and at the same time.

Power supply cables are laid inside the product. Contact with energized components presents a danger to life from electric shock. Prior to any installation/dismantling and setting up work, the product must be disconnected from the mains.

⚠

- Disconnect all the poles from the mains and prevent the product from being switched back on again.
- Check whether the monitor is de-energized.

Electric shock hazard In the event of damage to supply cables, the entire system will be energized. Contact with energized components presents a danger to life from electric shock.

⚠

- Make sure to pull back the supply cables without twisting.
- Do not damage the cable insulation.

If no suitable end stop is installed, there is a risk of damaging or squeezing the cables in the area of the holding bracket. In the event of damage to supply cables, the entire system will be energized. Contact with energized components presents a danger to life from electric shock.

⚠

- Select an end stop which matches the cable harness cross section.
- Make sure to always mount an end stop.

In the event of damage to supply cables, the entire system will be energized. Contact with energized components presents a danger to life from electric shock.

- Prior to performing any installation and adjustment work, disconnect the product from the mains at all poles and prevent it from being switched back on again.

⚠

- Verify supply cables are laid in a way to prevent twisting.
- Do not damage the cable insulation.

If the grounding cables are damaged, the overall system can be energized in the case of a system fault. Contact with energized components presents a danger to life from electric shock.

⚠

- The grounding cables may only be installed by STERIS technical service team or STERIS-trained and authorized service personnel.

There is a risk that certain parts are not properly connected to ground if the fastening elements have not been securely tightened:

⚠

- Tighten the flat fillister head screws M4 x 16– 10.9 – ISO 7380-1 to 4 N▪m.
- Tighten the cross recessed head screws M4 x 6– A2-70 – ISO 7380-2 to 4 N▪m.

There is a risk that certain parts are not properly connected to ground if the fastening elements have not been securely tightened:

⚠

- Tighten the screws CM-4x8-Z – DIN 7500 to 3 N▪m.

There is a risk that certain parts are not properly connected to ground if the fastening elements have not been securely tightened:

⚠

- Tighten the countersunk screw M4 x 12 – 8.8 – ISO 10642 to 3 N▪m.

There is a risk that certain parts are not properly connected to ground if the fastening elements have not been securely tightened:

⚠

- Tighten two countersunk screws M4 x 10 – 8.8 – ISO 10642 to 3 N▪m.
- Tighten the hexagon nuts M4 – ISO 10511 to 3 N▪m.

2.10 WARNING – PINCHING HAZARD

WARNING

PINCHING HAZARD

⚠ Pinch points are created during extreme articulation of the suspension system. Do not place hands on or near the suspension knuckle during lighthead articulations.

2.11 CAUTION – POSSIBLE EQUIPMENT DAMAGE

CAUTION

POSSIBLE EQUIPMENT DAMAGE

⚠ Appropriate components of this lighting system have been tested and found in compliance with IEC 60601-1-2:2014/AMD1:2020 , Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility (EMC). There is, however, a potential for electromagnetic or other interference between this equipment and other devices. Should you experience interference, relocate this device or minimize the use of the affected equipment while this device is in operation.

⚠ Portable and mobile RF communications equipment used in close proximity to the wall control or canopy controls units may temporarily affect the operation of the equipment.

⚠ Use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the EQUIPMENT or SYSTEM as replacement parts for internal components, may result in increased emissions or decreased immunity of the system.

⚠ Accessories or replacement parts not listed in the Operator or Maintenance Manuals should not be used adjacent to or stacked with the system. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

⚠ Accessories or replacement parts not listed in the Operator or Maintenance Manuals should not be used as it may affect EMC or result in equipment damage.

⚠ Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

⚠ When installing or removing the video camera, be careful to place it in a secure location to prevent it from rolling, dropping and breaking. Also, to avoid scratching the lens surface, do not stand camera up with lens side facing down.

Use of any disinfectant solution OTHER than those listed here may cause discoloration or deformation on the lens surface:

- Coverage® Plus Germicidal Surface Wipes Disinfecting/Deodorizing/Cleaning Wipes
- Quaternary Ammonium Compound (Quats) with Ethanol solvent
- Quaternary Ammonium Compound (Quats) with Isopropyl Alcohol (IPA) solvent
- Quaternary Ammonium Compound (Quats) with IPA + 2-Butoxyethanol solvent
- Quaternary Ammonium Compound (Quats) + Biguanide
- H2O2 (Hydrogen Peroxide)
- Neutral Cleaners

⚠ The use of H2O2 + PAA (Hydrogen Peroxide + Peracetic Acid) is strongly discouraged for use on all STERIS products.

⚠ Always follow manufacturer instructions for concentrations and use of cleaning products.

⚠ Avoid discoloration of the wall control. Do not clean wall control with povidoneiodine solutions or allow such solutions to contact bezel, bezel label and display surfaces.

⚠ Prevent leakage of fluids into interior of lighthead, monitor, or wall control. Ensure no excess fluids remain on lighthead, monitor, or panel during and after cleaning.

⚠ Cleaning and disinfecting agents used on this lighting system must be certified by their manufacturer to be compatible with the following materials: polycarbonate, polyetherimide, santoprene.

⚠ DO NOT SPRAY any cleaning product directly onto the lighthead, monitor, wall control, or any system components. Clean wall control with a clean, lint-free cloth dampened with 90% isopropyl alcohol. For other system components, dampen a clean, soft cloth with the cleaning solution and wring out the excess moisture.

⚠ Do not use floor cleaners on this equipment.

⚠ Do not scratch the lens when cleaning; always wear rubber gloves and use only a clean, white, lint-free cloth when wiping external surfaces.

⚠ Do not attempt to replace LED modules on the lighthead. Refer servicing to qualified service personnel.

⚠ Prevent leakage of fluids into interior of lighthead, monitor, or wall control. Any such leakage could impair or damage the lighting system.

⚠ Avoid discoloration of control center keypad and display. Do not clean control center with povidone-iodine solutions or allow such solutions to contact keypad and display surfaces.

⚠ Do not bump lightheads into walls or other equipment.

⚠ To avoid inadequate balancing, load added to single monitor yoke or dual monitor yoke must not exceed 15 kg (33 lb) per monitor.

⚠ Avoid damage to the monitor mount. To avoid damage to the monitor mount:

- Do not use force when moving the monitor mount into the limit positions.
- Avoid collisions with other components.

⚠ During all mounting steps, verify wires are not pinched between mechanical components of suspension, spring arms, canopy controls enclosures or lightheads.

⚠ Do not attempt to replace LED modules on the ighthead. Refer servicing to qualified service personnel.

⚠ Tape over Molex connectors before pulling through conduit to avoid damaging connectors.

⚠ Do not pinch or scrape wiring. Tape wires together for better control.

If spindle binds in vertical tube:

⚠
- Twist vertical tube.
- Lower system pack slightly.

⚠ To avoid inadequate balancing, load added to single monitor yoke or dual monitor yoke must not exceed 33 lb (15 kg) per monitor.

⚠ Avoid damage to the decorative caps. The installation steps must be performed in the correct order.

⚠ Avoid risk of destroying the end stop. When swivelling the product, hitting the internal end stop hard can destroy the end stop. The product becomes unusable.

- Do not hit the end stops of the product hard.

⚠ Avoid damage to Single Flat Panel Monitor (SFPM) hinge covers. Use only M4 x 20 (P/N 10056254) or M4 x 16 (P/N 10056255) flat head screws supplied with SFPM yoke assembly. DO NOT use screws supplied with monitors.

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 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-orientating the equipment.

Symbols and Labels

3.1 Symbols

The following symbols may appear on the system.

Table 3-1. Symbol Definitions

Symbol	Definition
	Standby
	Settings Control. Press button to access System Menu for system configuration or information
	Lighthead (Designation and Intensity) Symbol Definitions
	Camera Control
	Do not operate system unless optical fiber cables are fully connected
	Caution, Indicates Control Fault. Refer situation to qualified, trained service technician.
	Increase Intensity (Surgeon's Control Buttons)[1]
	Decrease Intensity (Surgeon's Control Buttons)[1]
	Control Fault
	Pinch Point Label
	Hazardous Voltage
	Direct Current
	Protective Earth (Ground)
 or 	Attention, consult manual for further instructions

1. *Symbol is a fingertip "contour" molded into the handle. or yoke.*

Table 3-1. Symbol Definitions (continued)

Symbol	Definition
	Consult instructions before use
	Potential Impact Hazard
	Maximum Load Hazard (maximum load limit given on label)
SN	Serial Number of Unit
REF	Equipment or Reorder Number
LOT	Batch Code
	Symbol Indicating the Legal Manufacturer Name and Address
	Symbol Indicating the Date of Manufacture (YYYY-MM-DD)
	Date and Place of Manufacture
V~	Voltage Rating of Unit, Alternating Current
A	Amperage Rating of Unit, Alternating Current
Hz	Frequency Rating of Unit, Alternating Current
MD	Medical Device
UDI	Unique Device Identifier
	CE Mark with Notified Body Reference Number
EC REP	Authorized Representative in the European Community
	UKCA Marked (UK Conformity Assessed)
UK REP	UK Authorized Representative
CH REP	Swiss Authorized Representative
	This Way Up
	Keep Dry
	Fragile, Handle with Care

Table 3-1. Symbol Definitions (continued)

Symbol	Definition
	Handle with Care
	Do Not Stack
	3R Laser (Video Only)
	Storage Humidity Range
	Atmospheric Pressure
	Temperature Limit
	Single Use
	Do Not Use If Packaging Damaged
	Keep From Sunlight
	Use By Date
	Product Is Not Made With Natural Rubber Latex
	Sterilized Using Ethylene Oxide
	Single Sterile Barrier System
	Single Sterile Barrier System with Protective Packaging Outside
	WEEE Directive: Product Must Be Recycled
	Symbol Indicating the Legal Manufacturer Name and Address

Specifications and Requirements

4.1 Application Specification

The surgical lighting system is sold for use in operating rooms, trauma rooms, exam rooms and critical care areas in major metropolitan hospitals, community hospitals, clinics, physician offices and outpatient surgery centers. The product is well suited to specialty and general-purpose operating rooms, exam and trauma bays along with critical care rooms, and is intended to cover all of the surgical lighting needs within a hospital and surgery center.

Intended Medical Indication:

The surgical lighting system can be used in a variety of applications, including diagnostic procedures performed in outpatient surgery centers, operating rooms, intensive care units, and major acute care suites.

Intended Patient Population:

There are no restrictions on patient populations.

Intended part of the body or type of tissue applied to or interacted with:

This device does not directly interact with the patient but interacts with the caregiver. The hands, arms, and torso may be used to operate the lighthead and/or camera controls or to adjust the lightheads.

Intended user profiles:

Surgical staff members are the intended operators of this device. The Operator Manual is written at a level consistent with this intended user.

Intended conditions of use:

This equipment is designed to be used in operating rooms, trauma rooms, exam rooms, and critical care areas of hospitals, clinics, physician offices and outpatient surgery centers that meets the environment requirements of the operator manual. This equipment is suitable for continuous operation.

Operating principle:

Illumination is provided via high intensity LEDs. The pattern size of the LEDs can be adjusted by rotating the spring loaded lighthead handle.

The illumination level of surgical lights can be adjusted through several intensity settings via controls on either the wall-mounted control center or the light head handle. Increasing the pattern size can also decrease the luminance level.

4.2 Camera Performance

Table 4-1. Wireless Camera Characteristics

Number of effective pixels	Up to 8,294,400 (4K, 3840x2160)
Video signal	4K: 2160p/30
Optical zoom	20x
Digital zoom	12x
Recommended lighting levels	100 to 100,000 lux
Signal/noise ratio	50dB
Focus	Automatic/manual

Table 4-1. Wireless Camera Characteristics (continued)

White balance	Automatic/manual
Brightness	Automatic/manual
Gamma	Standard/gamma correction
Video output	HDMI: V1.4 Type-A (output present on the receiver included in the ALYWRK kit)
Wireless video transmission frequency	5.150 Ghz to 5.850 Ghz
Bandwidth	20MHz/40MHz
Number of receivers connected simultaneously to the camera	Up to 4
Connection distance between camera and receiver	From 1 to 10 meters
Storage temperature/humidity	-20 to 60°C (-4 to 140°F)/15 to 90%
Operating temperature/humidity	0 to 40°C (32 to 104°F)/25 to 75%

4.3 Electrical Characteristics

Electrical characteristics power supply	**Value**
Protection	Class I
Fuse	Mains input: F1, F2: F5A, 5x20, 250VV BC1500A (master card)
Use	Continuous

Electrical characteristics battery backup	**Value**
Mains	100–240 VAC 50–60 Hz 480 VA max
Protection	Class I
Fuse	1xT10A, 500V, 10 3x38mm/0.40x1.4in, BC 120kA (external)
Batteries	2x12V 17Ah lead sealed
Standalone operation	Minimum 1 hour
Charge/discharge indicator	Indicators on wall control screen and/or yoke touch screen

4.4 Environmental Conditions

Table 4-2. Three Lighthead System (System Running)

For sealed-ceiling applications	Control Center Ambient = 60°C (140°F) Maximum Room Ambient = 20 to 25°C (68 to 77°F)
Interstitial space temperature has minimal effect on the canopy ambient in a completely sealed ceiling application.	
For vented-ceiling applications (1/4" [6 mm] minimum gap between ceiling and ceiling plate)	Control Center Ambient = 60°C (140°F) Maximum Room Ambient = 20 to 25°C (68 to 77°F)
To avoid adverse thermal effects on canopy control electronics, thermal contributions from interstitial space and room ambient temperatures must NOT result in canopy ambient temperatures exceeding 60°C (140°F).	
Recommended Transport/Storage Temperature (not exceeding 15 weeks)	2 to 38°C (36 to 100°F)
Recommended Relative Humidity	20 to 75%
Atmospheric Pressure	500 to 1060 hPascals
RPC: Interstitial space temperature when RPC is mounted above ceiling	40°C (104°F)

4.5 Essential Performance

Essential Performance (EP) for surgical luminaires:

1. Peak central illuminance (measured at 1m from the luminaire) within the range from 40 klx to 160 klx.
2. Peak central irradiance (measured at any distance along the beam axis) less than 1000 W/m^2.
3. Provide white light to illuminate the operating field. (The apparent whiteness of the light can be verified by visual observation.)
4. Loss of illumination could result in delay of surgical procedure.
5. In extreme cases of electromagnetic interference, the operator may experience temporary loss of light function or camera operation. This can be corrected by removing the source of interference and power cycling the light if necessary.

4.6 Lighthead Optical Performance

Table 4-3. Lighthead Optical Performance

Feature	**Lighthead**
Light Field Safety Information, Step 10, at D_{MI}*	
Central Illuminance $E_{C, MI}$ (0/-10%), 3500K, 4000K, 4500K, 5000K, Small Pattern	160,000 Lux
Maximum Total energy Irradiance E_{Total} (+/-10%)	540 W/m2

Table 4-3. Lighthead Optical Performance (continued)

Feature	Lighthead
Light Field Performance Information, Step 10, at DREF*	
Central Illuminance $E_{C, REF}$ (+/-10%), 3500K, 4000K, 4500K, 5000K, Small Pattern	140,000 Lux
Color Temperature (+/6%)	Variable Color Temperature Lightheads: 3500 – 4000 – 4500 – 5000K Fixed Color Lightheads: 4500K
Color Rendering Index Ra (+/-6 %)**, 3500K, 4000K, 4500K, 5000K	98
Color Rendering Index R_9 (+/-10%)** 3500K, 4000K, 4500K	97
Color Rendering Index R_9 (+/-10%) 5000K	89
D_{50} Light Field Diameter at 50% $E_{C, REF}$ (+/-10%), 4500K	Small Pattern: 10.5 cm Large Pattern: 14.9 cm
D_{10} Light Field Diameter at 10% $E_{C, REF}$ (+/-10%), 4500K	Small Pattern: 17 cm Large pattern: 28 cm
Ratio D_{50} / D_{10}	Small pattern: 0.62 Large pattern:0.53
Depth of Illumination (L1 + L2 at 60% $E_{C, REF}$) (+/-10%), 4500K, Large Pattern	75 cm
Depth of Illumination (L1 + L2 at 20% $E_{C, REF}$) (+/-10%), 4500K, Large Pattern	130 cm
Shadow Dilution*** with 1 mask (+/-10%%), 4500K, Small Pattern	58%
Shadow Dilution with 1 mask (+/-10%), 4500K, Large Pattern	58%
Shadow Dilution with 2 masks (+/-10%), 4500K, Small Pattern	55%
Shadow Dilution with 2 masks (+/-10%), 4500K, Large Pattern	55%
Shadow Dilution with Simulated Cavity (+/-10%), 4500K, Small Pattern	90%

Table 4-3. Lighthead Optical Performance (continued)

Feature	Lighthead
Shadow Dilution with Simulated Cavity (+/-10%), 4500K, Large Pattern	88%
Shadow Dilution with Simulated Cavity and 1 mask (+/-10%), 4500K, Small Pattern	45%
Shadow Dilution with Simulated Cavity and 1 mask (+/-10%), 4500K, Large Pattern	45%
Shadow Dilution with Simulated Cavity and 2 masks (+/-10%), 4500K; Small Pattern	50%
Shadow Dilution with Simulated Cavity and 2 masks (+/-10%), 4500K, Large Pattern	45%
Life Span (L70 up to 30% Loss of Illumination)	60,000 hrs
* D_{MI}=0,89m, D_{REF}=1m	
** Maximum 100	

4.7 Power Requirements

Table 4-4. Power Requirements

Three Lighthead System with Camera	100 – 240 Vac, 50/60 Hz 4-2A 320 Watts
Typical Lighthead Wattage	40 Watts (Nominal) 100 Watts (Maximum)

Component Identification

5.1 Component Identification

Figure 5-1

Standard System Components

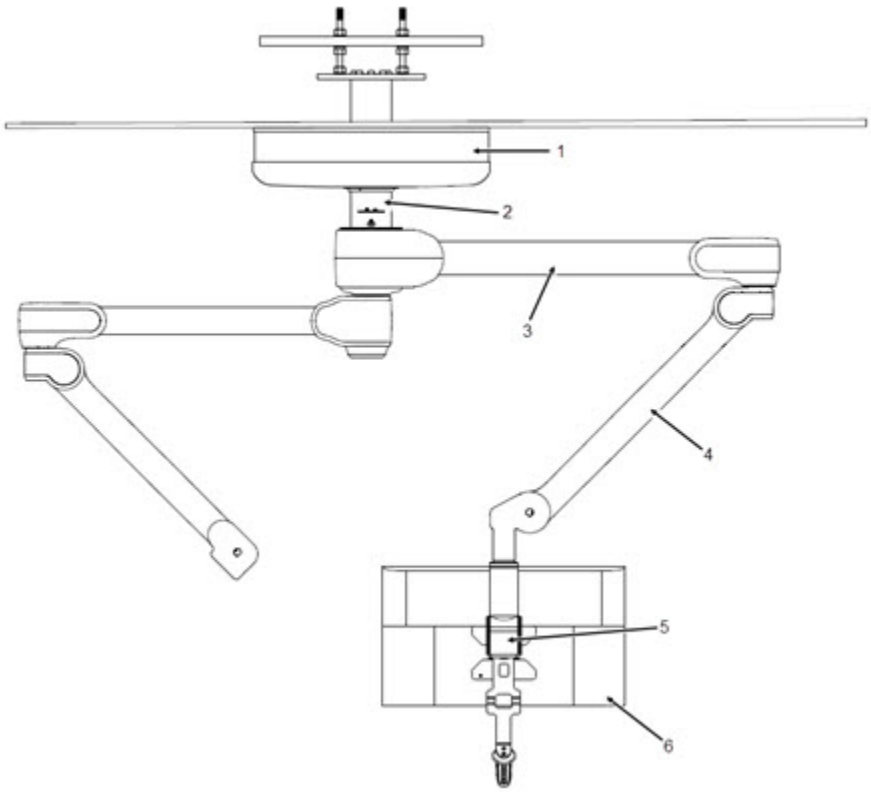
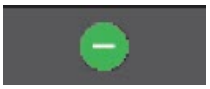
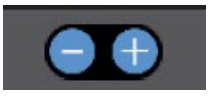
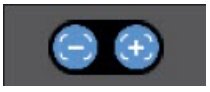


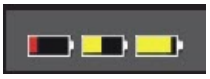
Figure 5-1. Standard System Components

1. Canopy
2. Down tube
3. Spindle arm
4. Spring arm
5. Attachment yoke
6. End device (e.g., monitor)

5.2 Operator Controls

The following symbols may appear on the touch screen.

Lighting Tab		Increase Level of Selected Function
		Decrease Level of Selected Function
		Identification of Light(S) (1, 2 or 3) On Suspension
		Adjust Color Temperature (if ordered)
		On/Off
		Indicates Level of Selected Camera Function (Zoom, Brightness, Focus) or Lighting (Intensity)
		Activate/Deactivate Ambient Lighting
		Light Intensity Adjustment
		On/Off for All Lights
		Light Intensity Adjustment and Setting (Yoke Touchscreen)
Camera Tab		Set Focus/Auto Focus
		Set Gamma (Pre-Set 1/Pre-Set 2)
		Rotate Camera
		Set Zoom

		Set Image Brightness
		Identification of Camera(S) (1, 2 Or 3) on Suspension
		Automatic Light Intensity
		Pre-Configuration
		On/Off
Settings Tab		System Fault
		Backup Battery-Powered Operation
		Mains-Powered Operation
		Display Brightness Adjustment
		Enable/Disable ASC Mode
		Light Pattern Size Adjustment
		Freeze Image
		Set White Balance (Automatic/Manual)
		Saving Current Configuration In One Of the Two Memories
		Recall One of the Two Memorized Configurations
		Ambient Lighting Automatic Mode

		Backup Battery Switch Test (International Only)
		Backup Battery Standalone Operation Test (International Only)
		Ambient Light Color Setting

Operating Instructions

6.1 Pre-operation Checklist

Equipment Drawings showing all of the space and utility requirements were sent to the purchaser after the order for this surgical light was received. The clearance space shown on the drawing is necessary for proper installation, operation and maintenance of this fixture.

Installation Instructions were furnished with the system.

If any of these documents are missing or misplaced, contact STERIS, giving the serial and model numbers of the equipment. Replacement copies will be sent to you promptly.

WARNING

WARNING–ELECTRIC SHOCK HAZARD

⚠ Do not remove covers or perform service other than as described in this operator manual. Refer servicing to qualified service personnel.

1. **Check Suspension Movement** — Check all suspension joints for compromised integrity, such as loose fasteners or components.

   WARNING

   PINCHING HAZARD

   ⚠ Pinch points are created during extreme articulation of the suspension system. Do not place hands on or near the suspension knuckle during lighthead articulations.

   ☐ Verify that suspension system moves through all articulations smoothly without binding. Lightheads and monitors should move smoothly and easily. When positioned, the lighthead support arms (or monitor support arms) should not drift. If binding or drifting is present in suspension movements, call your STERIS service representative to make adjustments.

2. **Check System Operation** — Verify that electrical power to the control center is on.

WARNING

ELECTRIC SHOCK HAZARD

⚠ The OFF position on the system ON/OFF touch pad of the wall control turns OFF control to camera and lightheads, but system remains energized. This mode is referred to as STANDBY.

☐ Turn control ON by pressing wall control ON/OFF touch pad. Verify that wall control touch pads function. Check intensity levels for each system lighthead. If optional camera module is installed, check camera controls.

NOTE: Turn power OFF to each lighthead using intensity controls, and to optional camera (if installed) when testing is complete.

☐ **Check Module Failure Indicators:** If LED Module(s) Requires Service graphic on wall control display is lit, one or more modules may require service.

☐ **Check Module Failure LED:** If the LED on any of the lightheads is blinking, one or more LED modules may require service. Check lighthead status LED.

☐ **Check Intensity Controls at Each Surgeon's Control:** Verify that the intensity level can be increased and decreased at each lighthead using the surgeon's control buttons.

3. **Check Optional Video Camera Operation** — Turn the surgical lighting system ON. Install video camera in light handle. Press the Camera Control button on the touch pad to turn on the camera.

☐ **Video:** Verify that a clear signal is reaching the video display device (monitor) from the camera. (Check cable connection between video output connector at suspension and monitor, if necessary.)

☐ **Wall Control:** Verify zoom, rotation and focus functions with the control center switches.

4. **Check Optional Monitor Support Arms**

☐ The system can include up to three lightheads and up to two monitor arms or Harmony® ConnectPoint® (Model ALYON) with three other arms with lightheads or flat panel monitors.

6.2 Light Control Center – Control Screen

See *Figure 6-1*.

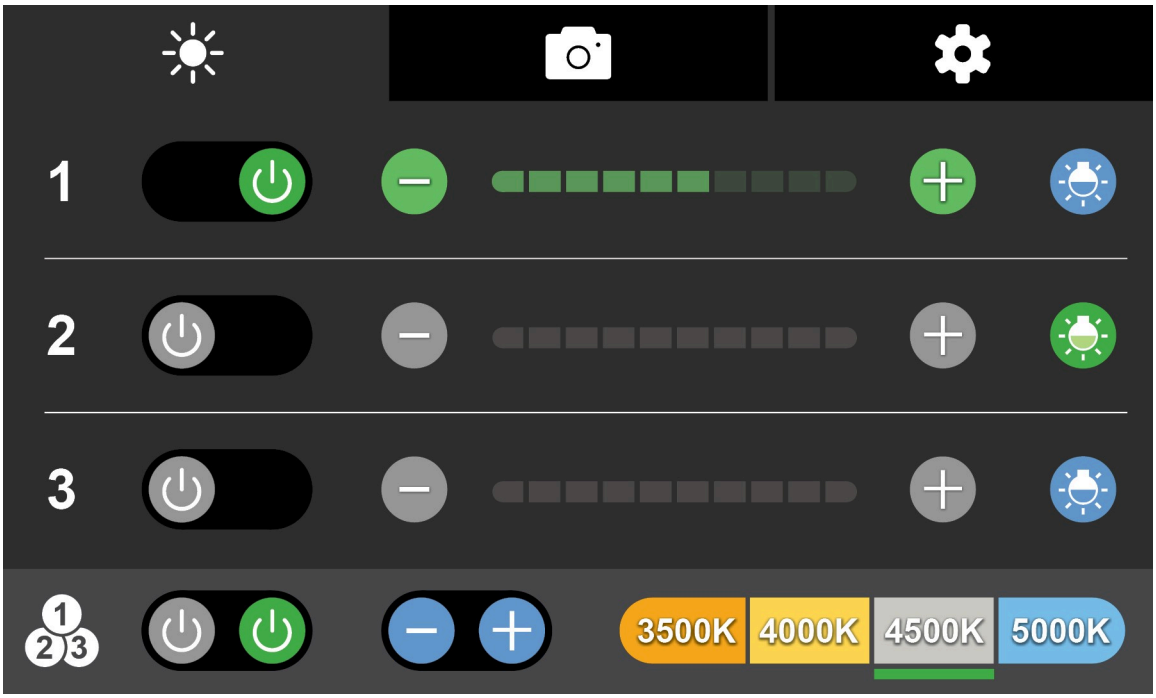


Figure 6-1. Wall Control Light Control Screen

6.3 Intensity Controls

Wall Control

The wall control allows the user to adjust the lighthead intensity level (brightness) by pressing a touch screen button. Each lighthead has a numbered cover that corresponds to a numbered control on the wall control. Each lighthead can be controlled by control buttons. Buttons on the lighthead handle can be used by sterile personnel. To use light handle buttons in a sterile manner, the handle must be properly sterilized or properly covered by a disposable cover. Buttons located on an optional camera may only be operated by sterile personnel when covered with a disposable sterile cover. Buttons located on the lighthead yoke are not designed for sterile use and may be controlled by non-sterile personnel.

WARNING

EXPLOSION HAZARD

⚠ Do not use lighting fixture in the presence of flammable anesthetics.

To Adjust Lighthead Intensity Levels:

- Lightheads may be turned on and off individually or all lights connected to a system simultaneously (up to four lightheads).



Figure 6-2. On/Off Button (Off Position Displayed)

To turn lightheads on, slide On/Off button to the right. On/Off button lights up on display.

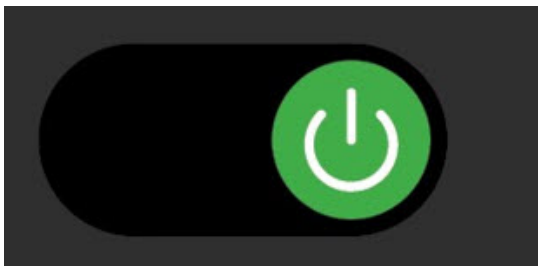


Figure 6-3. On/Off Toggle Button (On Position Displayed)

Each lighthead may be adjusted from intensity 0 (Off) to intensity 10 (brightest) by using (-) and (+) buttons. These buttons may be used to step through intensities in order.

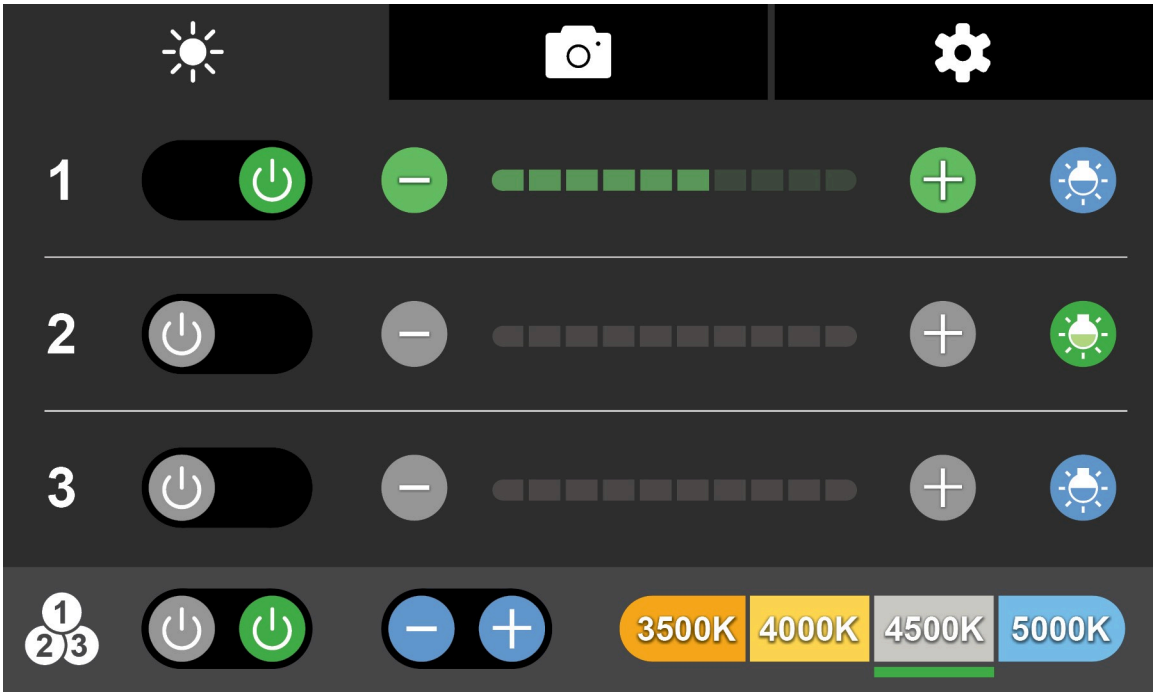


Figure 6-4. Increase or Decrease Light Intensity Using - and + Buttons

- All lightheads connected to a system can be simultaneously stepped up or down in intensity by using the (-) and (+) buttons located at the bottom of the screen.

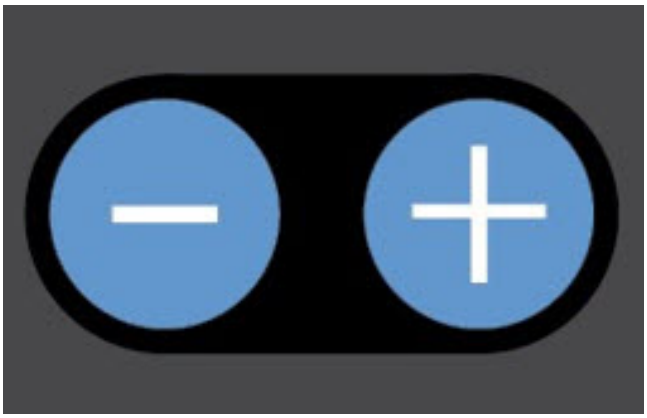


Figure 6-5. Increase or Decrease Light Intensity for All Lightheads Simultaneously

- Each lighthead may be put into Task mode. This mode offers a very dim light output below the lowest setting on the slider. Task mode is often used for low illumination for support personnel during laproscopic cases. Task mode may also be enabled for all lights connected to a system simultaneously by pressing Task button below All Lights heading.
- Intensity levels for up to three lightheads can be controlled from one wall control. A lighthead's surgeon's control buttons can also be used to adjust the intensity level for that lighthead.

NOTE: For longer LED module life, and decreased energy delivered to the surgeon/patient, use lowest intensity level suitable for surgical procedure.

6.4 Color Temperature Controls

The apparent color of white light can be specified using a metric known as color temperature. Color temperature is typically measured in units of Kelvin (K). White light sources with lower color temperatures are referred to as “warm white” and have a yellower appearance. White light sources with higher color temperatures are referred to as "cool white" and have a bluer appearance. The wall control allows the user to change the lighthead color temperature by pressing the color temperature buttons. These buttons allow the color temperature of all connected lightheads to be simultaneously adjusted to 3500K, 4000K, 4500K, or 5000K.

To Adjust Lighthead Color Temperature

Press button with desired color temperature.

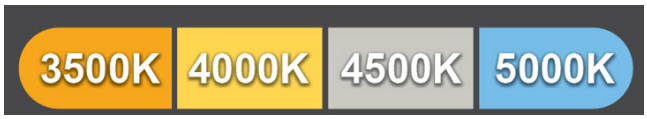


Figure 6-6. Color Temperature Buttons

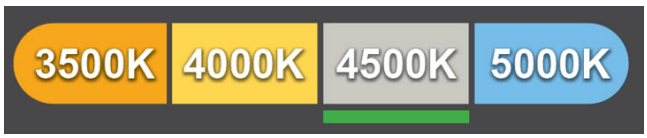


Figure 6-7. Color Temperature Control with 4500K Selected

6.5 Controlling Lights at Lighthead

Introduction

Lights are equipped with controls on each lighthead. Controls are listed below.

The surgeon's light handle comes standard with lightheads. The surgeon's light handle may be replaced with optional camera or basic (universal) handle.

- Light Handle (standard): This may also be referred to as the Standard Handle. The body has two pairs of (+) and (-) rubber buttons. The light handle may be used to control lighthead intensity and light spot size. The buttons are accessible by sterile personnel when the handle is used with a disposable sterile cover.
- Camera (optional): The camera has four pairs of illuminated (+) and (-) buttons similar to the surgeon's light handle. When installed, the camera can control lighthead intensity and spot size.
- Basic Handle (optional): This may also be referred to as the Universal Handle. The basic handle does NOT have control buttons. Using the basic handle removes the ability for sterile personnel to control lighthead intensity. The basic handle only controls light spot size. Refer to documentation included with the basic handle for additional information and installation instructions.

Turning Light On

1. Grasp handle of appropriate lighthead. Each handle has membrane buttons located toward the top of the handle.

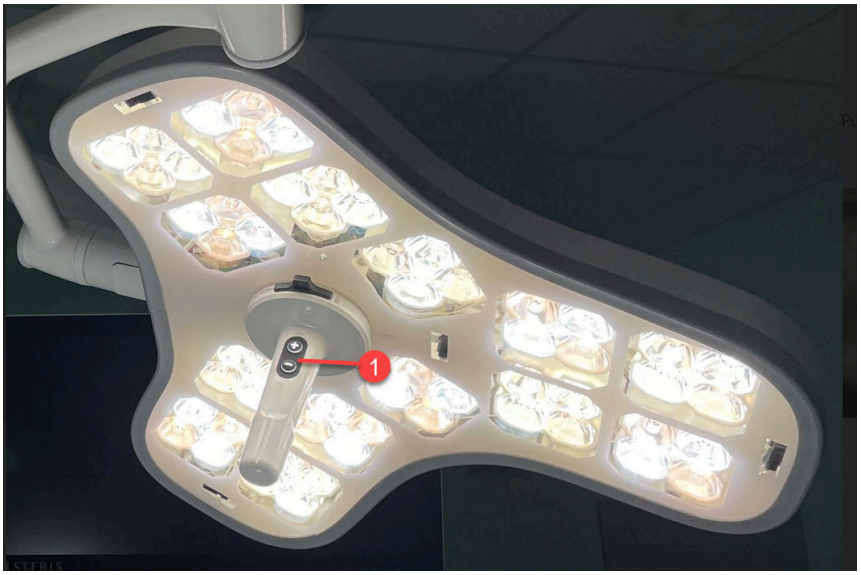


Figure 6-8. Lighthead Surgeon's Control Buttons

Legend
1. Lighthead Surgeon's Control Buttons

2. Press any (+) or (-) button to turn surgical light on to intensity setting 7.

   Press and hold (+) button for greater than one second to turn all surgical lights connected to the system to intensity setting 7.

Adjusting Light Intensity

1. Press (+) button to increase lighthead intensity.
2. Press (-) button to decrease lighthead intensity.

Lights have 10 intensities and task lighting.

Task Lighting

Press (-) button while lighthead is set to intensity 1 to turn task light on.

Task light is a low intensity setting often used by support personnel during laporoscopic procedures when room lighting is low.

Turning Light Off

Press (-) button for greater than one second to turn light off. Continue pressing (-) button for a total of 1.5 seconds to turn off all surgical lights connected to the system.

6.6 Lighthead Features

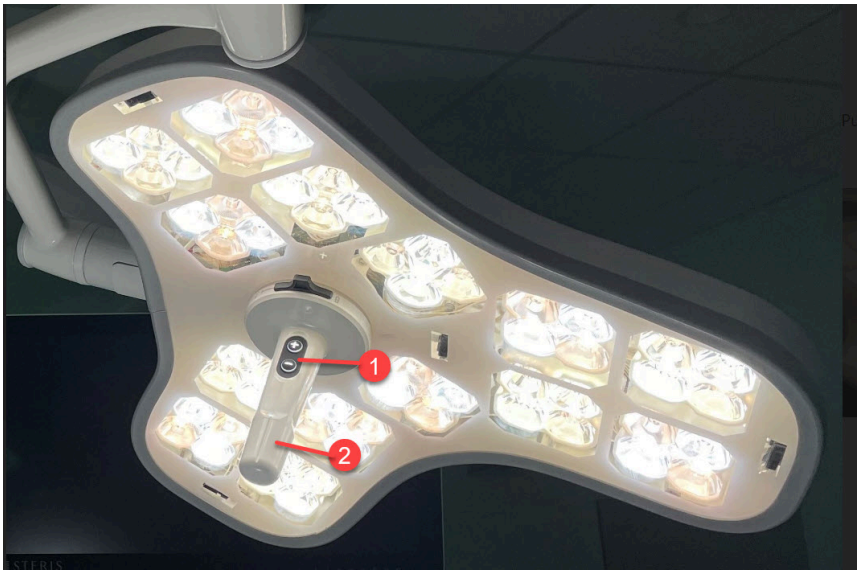


Figure 6-9. Lighthead

Legend
1. Surgeon's Control Buttons
2. Rotate Central Light Handle to Adjust Pattern Size

Table 6-1. Sterile Covers

Description	Part Number
Sterile Light Handle Cover	11010168
Sterile Light Handle Covers (Case)	11010162 (LB83)
Sterile Universal Handle Cover (Basic)	11010173
Sterile Universal Handle Covers (Case) (Basic)	11010164 (LB82)
Sterile HD Camera Handle Cover	11010169
Sterile HD Camera Handle Covers (Case)	11010163 (LB84)

6.7 Lighthead Positioning

Lightheads can be positioned by using either the sterile handle, or by grasping the non-sterile handle around the lighthead housing. Each lighthead can be positioned as listed from outside or from within the sterile field. To optimize shadow control, position the lighthead as appropriate before starting the intended surgical procedure.

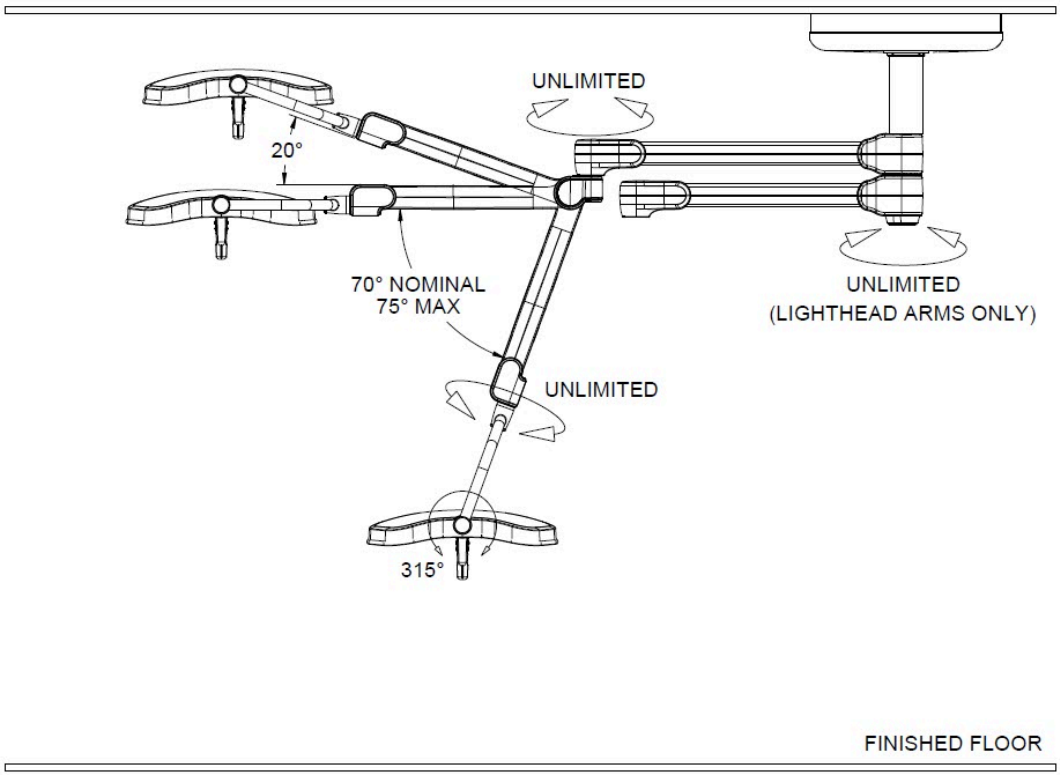


Figure 6-10. Lighthead Positioning

Surgical lighting system Lighthead/Spring Arm Assemblies may:

See *Figure 6-10* .

1. Rotate continuously around central hub;
2. Rotate continuously at horizontal suspension arm/spring arm connection;

3. Rotate continuously at spring arm/yoke connection;
4. Tilt forward or backward in yoke approximately 315°; and
5. Move up or down by pivoting at suspension elbow 20° up, and 75° down (total range: 95°).

6.8 Lighthead Pattern Adjustment

CAUTION

POSSIBLE EQUIPMENT DAMAGE HAZARD

⚠ Do not bump lightheads into walls or other equipment.

The lighthead is available in fixed or adjustable pattern size. For adjustable pattern size, the illumination pattern can be adjusted to any size between the maximum diameter and minimum diameter.

- Rotate light handle clockwise to increase pattern size.



Figure 6-11. Increase Pattern Size

- Rotate light handle counterclockwise to decrease pattern size.

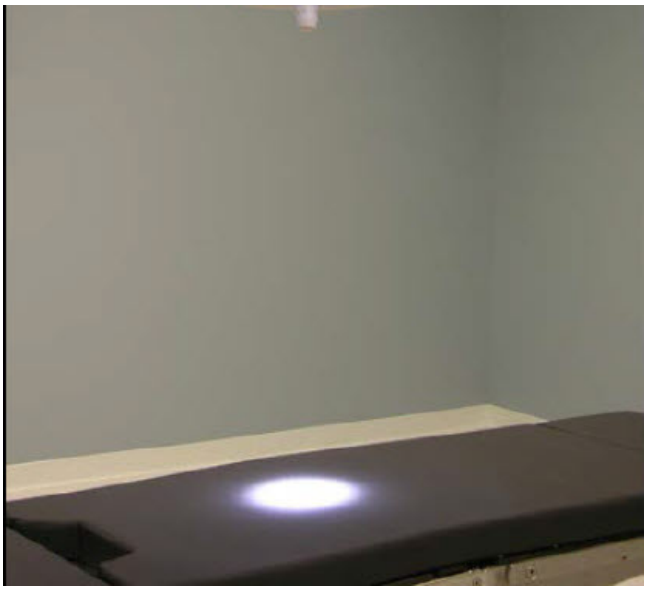


Figure 6-12. Decrease Pattern Size

6.9 Light Handle

Introduction

Light handles are used to position the lightheads, allow access to intensity control on each lighthead, and to adjust lighthead pattern size.

If the light handle is not installed, refer to *Installing Light Handle*.

A sterilizable handle may be used in place of a plastic handle and disposable sterile light handle cover. See Installing Sterilizable Light Handle.

The plastic light handle can be removed for cleaning. Do not use the lighthead during a sterile procedure unless a disposable cover is installed on the light handle.

1. Prior to starting a procedure, ensure light handle is in place.
2. Remove sterile light handle cover from its packaging and install onto light handle.

   NOTE: Sterile light handle covers, STERIS catalog #LB53, have been sterilized by the use of ethylene oxide per ANSI/AAMI/ISO 11135:2014.

Installing Light Handle

1. Install light handle by aligning connection bolts with holes on top of light handle.

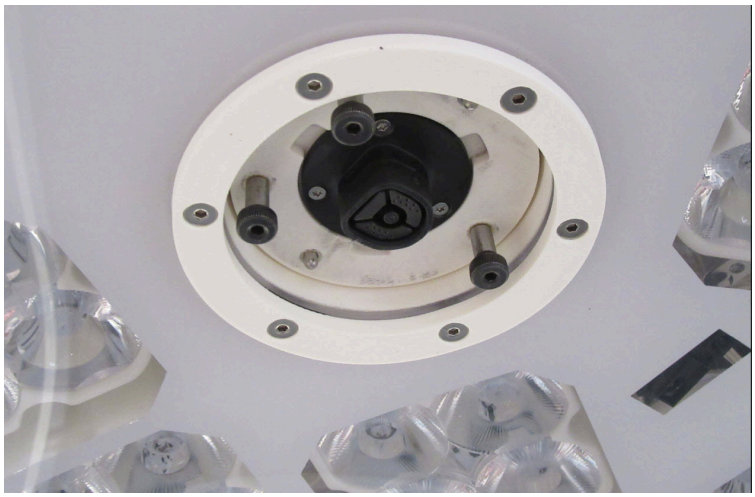


Figure 6-13. Lighthead Connection Bolts

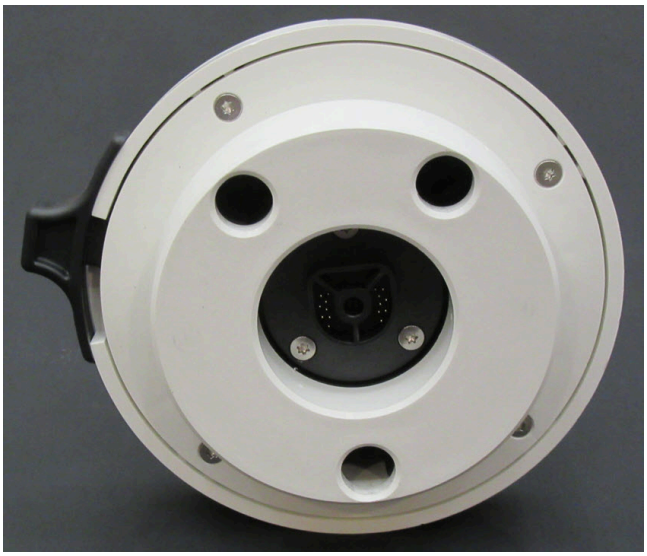


Figure 6-14. Holes on Top of Light Handle



Figure 6-15. Install Light Handle

2. Once light handle is aligned and seated on lighthead accessory port, rotate the switch at the top of light handle in the locked direction.

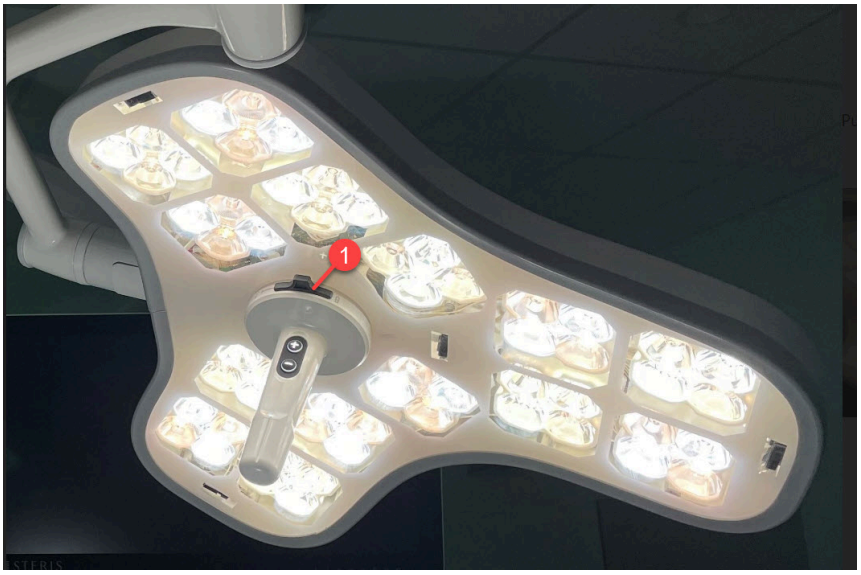


Figure 6-16. Light Handle Locking Switch

Legend
1. Light Handle Lock

NOTE: The light handle only attaches to the lighthead in one orientation.

NOTE: The light handle should be rocked and rotated to ensure it is properly connected.

Uninstalling Light Handle

1. Remove light handle by rotating lock slide at top of light handle.

Installing Sterilizable Light Handle (XHAND5 and ALYHAND Adapter)

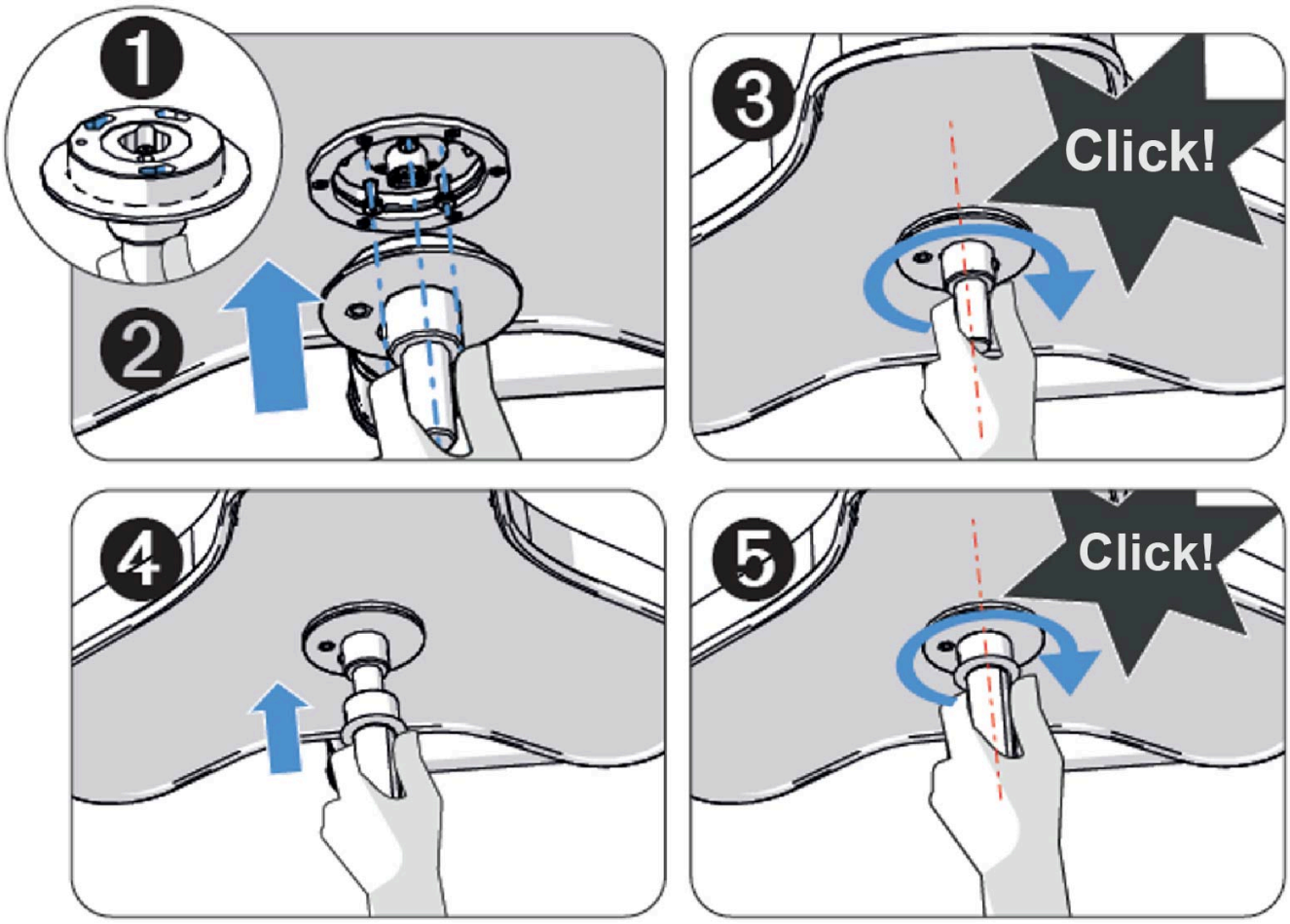


Figure 6-17. Installing the Sterilizable Light Handle

1. Align the 3 connection points of the ALYHAND adapter with those on the light.
2. Push the adapter in and hold.
3. Rotate the adapter clockwise until a click sounds, indicating the adapter is locked in place.
4. Fully attach the XHAND5 sterilizable handle to the support.
5. Turn the handle until a click sounds, indicating the handle is locked in place.

Uninstalling Sterilizable Light Handle (XHAND5 and ALYHAND Adapter)

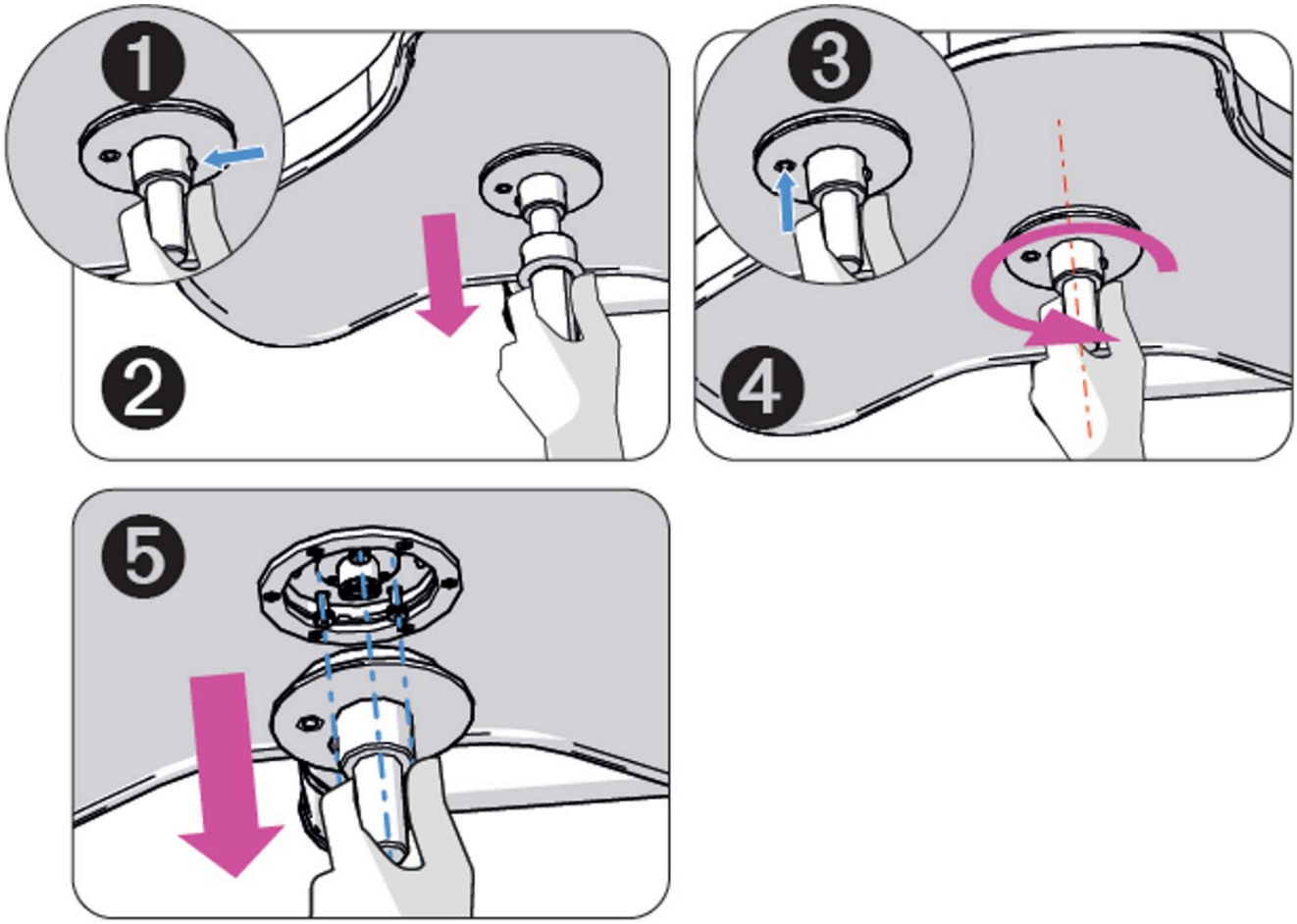


Figure 6-18. Uninstalling the Sterilizable Light Handle

1. Press the button on the XHAND5 sterilizable handle.
2. While holding the button down, pull the handle away to remove it from the adapter.
3. Press the button on the adapter.
4. While holding the button down, rotate the adapter counter-clockwise.
5. Remove the adapter from the lighthead.

Sterilizable Cover Surgeon Control Handle

Prior to starting a procedure, install a clean, sterilized handle cover by pushing it onto the handle until positive engagement is felt. Ensure handle cover is fully engaged prior to use.



Figure 6-19. Sterilizable Cover Surgeon Control Handle

Cleaning Recommendations

1. Remove visible debris by means of manual or automated cleaning using an enzymatic or neutral PH cleaner/detergent and water. Any cleaner used must be compatible with aluminum and silicone.
   - Remove silicone cover from Surgeon Control Handle before cleaning.
   - Follow instructions supplied with the cleaning agent regarding temperature and dilution rates.
   - Use a brush or cloth if needed.
2. Rinse thoroughly.

Sterilization Recommendation

1. Silicone sterilizable cover be sterilized before use in any surgical procedure.
2. When placing cover in the sterilizer for processing, the best practice is to orient all objects with openings downward, as if to allow water (or air) to flow out.
3. Sterilize handle cover using a cycle with either of the following parameters:
   - Prevacuum
     - **Temperature:** 270°F (132°C)
     - **Exposure Time:** 4 minutes
   - Gravity
     - **Temperature:** 270°F (132°C)
     - **Exposure Time:** 10 minutes

     NOTE:

     Before using silicone cover, note the following:

     1. Reuse limit is 500 cycles.
     2. Replace ring if yellowing, deformation, cracking or other signs of deterioration are present.

Installing Disposable Light Handle Cover

NOTE:

Wrinkles in the cover are normal. The appearance of wrinkles in the cover does not compromise the integrity of the cover.

1. Place sterile cover on light handle. See *Figure 6-20*.



Figure 6-20. Place Sterile Cover On Light Handle

2. Push sterile cover completely onto light handle. See *Figure 6-21*.



Figure 6-21. Installed Disposable Sterile Light Handle Cover

6.10 Yoke Touchscreen Controls

Lightheads are equipped with touchscreens mounted on the yoke. The yoke touchscreen provides many of the same controls as the wall control touchscreen. The non-sterile user is able to adjust lighthead intensity, pattern size, color temperature, ambient light color, and turn lightheads on and off, as well as control camera settings (if equipped). Controls are listed below.



Figure 6-22. Yoke Touchscreen

Lighting Controls

The lighting tab displays the functions for the lighthead on which the touchscreen is fitted. Swipe left on the screen to display more functions.

- To turn the lighthead on, slide the On/Off button to the right. The On/Off button lights up on the display. By default, the light will be set to intensity level 6, small light pattern, and 4500K.



Figure 6-23. On/Off Button (On Position Displayed)

- To adjust lighthead intensity, use the plus and minus buttons to increase or decrease the brightness of the light from intensity 0 (non-surgical task lighting, indicated by a central blue ring on the display) to intensity 10 (brightest).



Figure 6-24. Increase or Decrease Light Intensity

- To adjust the size of the light pattern, use the plus and minus buttons to increase or decrease the diameter of the light output.



Figure 6-25. Increase or Decrease Light Pattern Diameter

- To switch to ambient lighting mode, press the ambient light button. Press again to return to the previous intensity level.



Figure 6-26. Ambient Light Mode

- If the light is operating on battery power, a battery icon will be displayed that indicates the charge status of the battery unit.



Figure 6-27. Battery Power Indicator

- If any issues occur, the fault icon will appear. Press on the icon for more details about the fault.



Figure 6-28. Fault Indicator

- To turn on/off all connected lights, swipe to the second page in the lighting tab and select On or Off.



Figure 6-29. All Lights On/Off Toggle Button

- To change the color temperature for all connected lights, swipe to the second page in the lighting tab and select the color temperature. The selected option is displayed with a green underline.

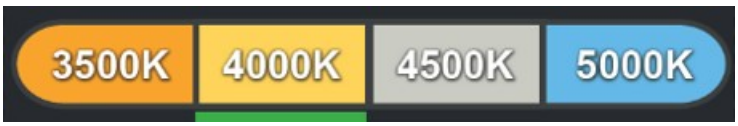


Figure 6-30. Color Temperature Buttons

Camera Controls

When a camera is fitted on the lighthead, all camera control functions are displayed.



Figure 6-31. Camera Options

- Camera power: Toggle to turn the camera on and off.
- Zoom: Use this function for determining the level of detail visible in the image field. The zoom function adjusts the image field continuously between two extremes:

  NOTE: Overall distance between the object and the camera, plus the length of zoom, affects the camera's ability to achieve a sharp focus. The greater the zoom length, the less capability the camera has to establish a sharp focus.

  – Telephoto: At extreme telephoto, the camera captures an image showing great detail in a small area.

    NOTE: At extreme telephoto, any motion of the lighthead/camera may be exaggerated (jerky). The field of focus has little depth at this extreme, forcing the Auto Focus function (if enabled) to refocus the camera when any object (such as a hand) enters the image field, or if camera position is adjusted. The camera is also sensitive to light level changes at extreme telephoto.

  – Wide Angle: At extreme wide angle, the camera captures a large image with less detail than telephoto.

    NOTE: At extreme wide angle, the image field possesses a greater depth of focus and less sensitivity to light level changes.
- Freeze: Press to freeze the camera image.
- All Auto: Press to set brightness, focus, and white balance to the default levels.
- Rotate: Use this function to change orientation of the video field. Image field can be rotated in either clockwise or counterclockwise directions.



Figure 6-32. Swipe for More Camera Options

- Brightness: Use this function to affect the overall brightness (or darkness) of the video image. The Bright control can be set to adjust itself automatically. When the brightness Auto mode is selected, the Auto text is white and the brightness adjustment controls are inactive. When Manual mode is selected, the Manual text is white and the brightness adjustment controls are active.
- Auto Brightness: When auto brightness is on, auto button turns green to show that it is in an automatic state and the two sun buttons turn grey to indicate they are inactive.
- Focus: Use this function to manually set the focus. The Auto Focus function must be toggled off to enable manual focusing. Adjust the clarity of focus by pressing the brightness increase button or brightness decrease button.

- Auto Focus: Use this function to toggle Auto Focus on or off. When Auto Focus is ON, the camera automatically focuses on the object in the image field closest to the camera lens. The focus adjustment arrows are inactive. When Auto Focus is turned OFF and Manual Focus is on, the Manual Focus text is white. The focus adjustment arrows are active. The camera maintains focus on the last object upon which it was focused, until Auto Focus is turned back on.



Figure 6-33. Swipe for More Camera Options

- Gamma: Press the left button to decrease gamma; press the right button to increase gamma.
- White Balance: Press the left button to readjust fixed white balance mode.

  NOTE: This is a fixed white balance mode that may be automatically readjusted by pressing this button, assuming that a white subject, in correct lighting conditions, and occupying more than 1/2 of the image, is submitted to the camera. This data is lost when the power is turned off and must be reset.

  Press the auto button to reset white balance to the default.
- Load: Press to load previously saved camera settings.
- Save: Press to save the current camera settings.

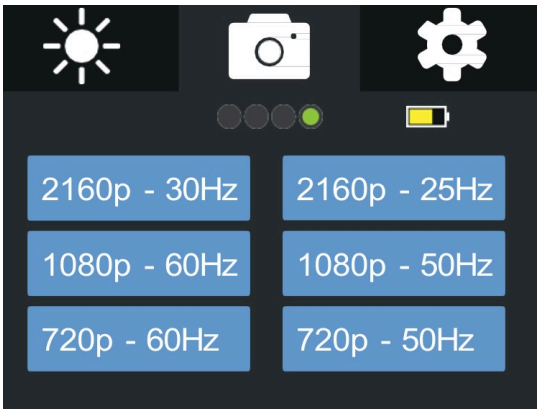


Figure 6-34. Video Format

- Select the desired camera video format from the available options.

Settings

The settings tab provides quick access to several settings options. Swipe left or right to see all available settings.

- To activate or deactivate automatic ambient lighting, toggle the AUTO button. When activated, turning off the lighthead will switch all lights to ambient light mode. There are several color options to select.



Figure 6-35. Ambient Light Settings

- To activate or deactivate the ability to turn lights on and off from the sterilizable light handle, toggle the on/off button. When activated, rotating the sterilizable light handle will allow you to turn the light on and off.



Figure 6-36. Toggle the Ability to Turn All Lights On/Off from the Handle (On Position Displayed)

- To activate or deactivate Adaptive Shadow Control, toggle the on/off button.



Figure 6-37. Toggle Adaptive Shadow Control (On Position Displayed)

- To test the battery backup, press the battery backup button. The system will switch to battery backup power and the button will turn green. Press the button again to return to mains power.



Figure 6-38. Test Battery Backup

- To test the switch to the battery backup, press the check battery button. This will switch to battery backup mode for 5 seconds, then return to normal mode.



Figure 6-39. Test Switch to Battery Backup

- To change the system language, select the desired language from the list.

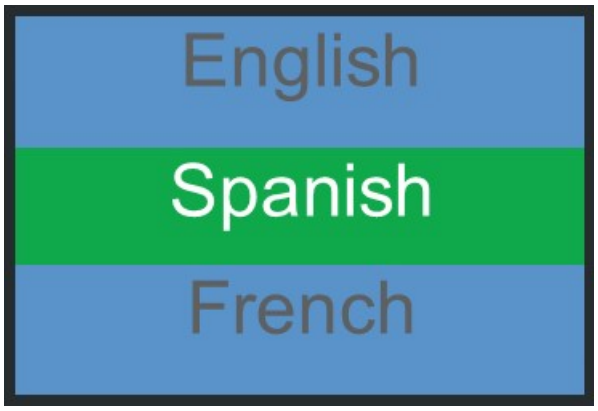


Figure 6-40. Language Options

- To view the Information screen, select the Info button. This will show information about how the system is configured, and may be requested by a technician for remote troubleshooting.



Figure 6-41. Information

- To view any faults, press the Defaults button. This will show a list of active faults.

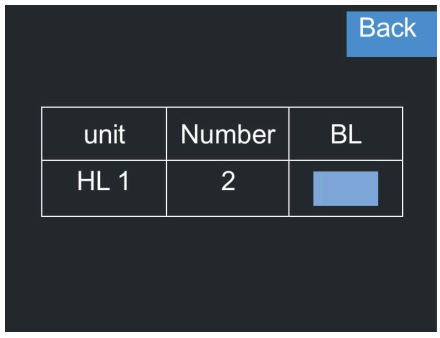


Figure 6-42. Faults

6.11 Monitor Arms

The system can be equipped with one or two monitor support arms.

NOTE: Central Tandem systems only allow for support of one (1) single flat panel monitor.

WARNING

PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD

⚠ Flat Panel Monitor arm uses adjustable tension force to support equipment weight. Do not remove monitor from the arm unless the arm has been locked in place by a trained and authorized technician.

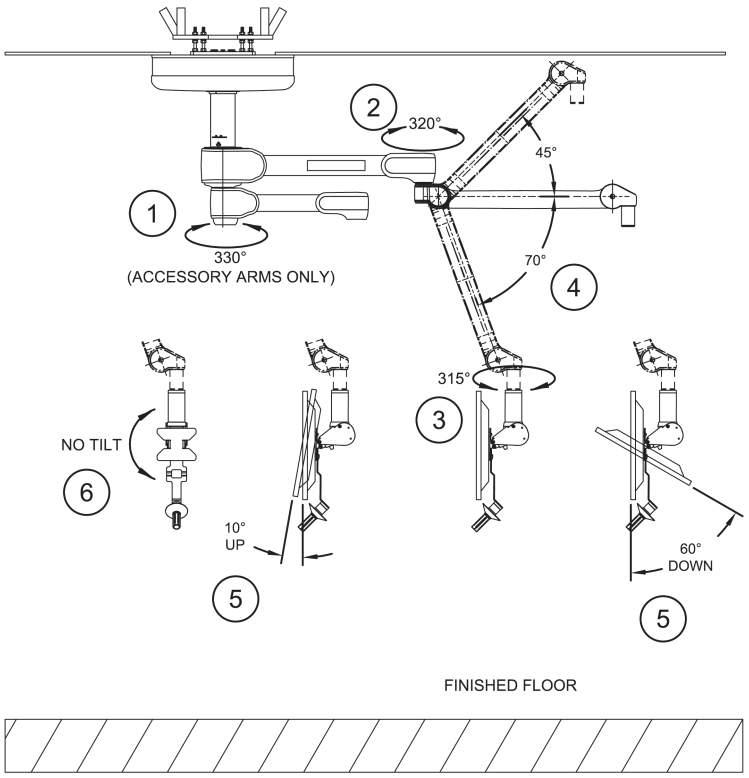


Figure 6-43. Surgical Lighting System Monitor Arm

Monitor arms can be included in the system either as the uppermost arm on the central spindle, or upper- and lower-most arms on the central spindle.

Monitor arms are capable of the following articulations: (1) rotate 330° at the central spindle; (2) rotate 320° at the horizontal extension arm; (3) rotate 315° at the yoke transition; (4) move up by pivoting at spring arm knuckle 45° up; move down by pivoting at spring arm knuckle 70° down. Flat panel monitor (FPM) yoke tilts (5) forward 10° or backward 60° in yoke. See *Figure 6-43*.

- Refer to separate operating instructions supplied with the monitor.
- Input signals to monitors can be routed through the suspension wiring from an external video source (not provided by STERIS).

6.12 Monitor Mount

WARNING

PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD

Monitor mount may fall down if the max. load capacity is exceeded. Exceeding the maximum approved load capacity can cause the monitor mount or its components to become loose and fall.

- Do not exceed the maximum load capacity of the monitor mount.
- Do not hang or mount further loads on the spindle arm, spring arm, adaption or monitor mount.

Avoid damage after collisions. The monitor mount may become damaged and fail if it collides with other objects, walls, or ceilings.

- Check the monitor mount for potential damage after collisions.
- Inform the operator if in doubt.

WARNING

ELECTRIC SHOCK HAZARD

Avoid electric shock hazard. The monitor mount may be live when connected to a supply network without protective ground conductor.

- To avoid the risk of electric shock, the monitor mount may only be connected to a supply network with protective ground conductor.
- If in doubt, ask the operator whether the monitor mount has been installed properly.

WARNING

PERSONAL INJURY HAZARD

Harm due to contraindication The product may cause harm in case of the following contraindications:

- The monitor mount may move by itself in strong magnet fields and must not be used in their proximity.
- Application parts of type BF or CF according to IEC 60601-1 must not be connected directly to monitor mount.

Monitor Mount Description

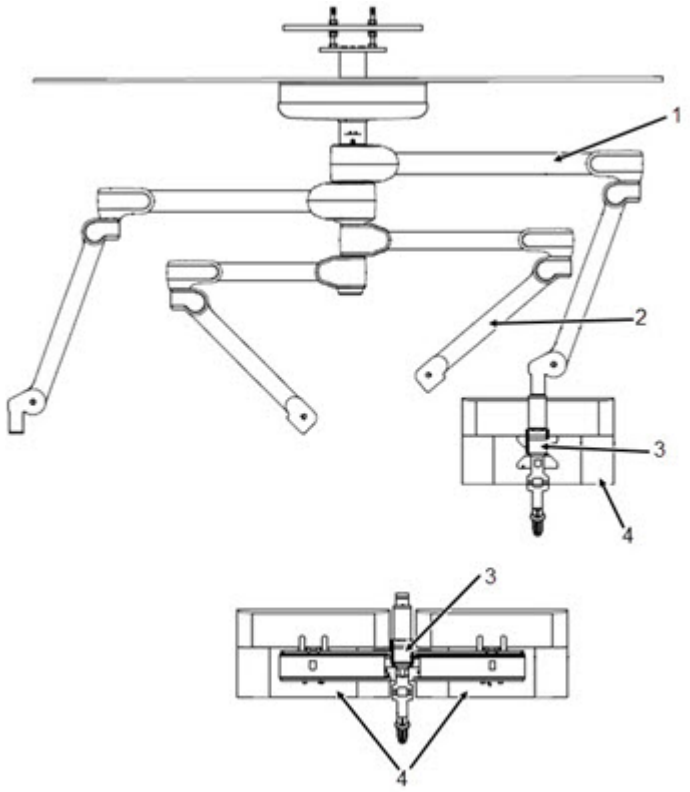


Figure 6-44. Monitor Mount Description

1. Extension arm
2. Spring arm
3. Adaption
4. End device (e.g., monitor mount)

NOTE: Central Tandem systems only allow for support of one (1) single flat panel monitor.

Operating Monitor Mount

CAUTION

POSSIBLE EQUIPMENT DAMAGE

Avoid damage to the monitor mount. To avoid damage to the monitor mount:

- Do not use force when moving the monitor mount into the limit positions.
- Avoid collisions with other components.

The monitor mount may collide with other components when it is moved.

- Check the environment for potential collision hazards before swivelling, adjusting the height or tilting.

1. Hold monitor mount on optional handles or on monitor and slowly move it into desired position to swivel or tilt the monitor mount or adjust its height.

   The rotation range and height limit ends – depending on the variant – at the internal limit stops of the spindle arm, spring arm, and adaption.

   If spindle arm, spring arm, adaption, or monitor mount do not remain stationary in set position, spring force, brake force, or possibly the friction must be adjusted by a service technician. Contact STERIS.

6.13 Installing HD Video Camera

Installation

NOTE: The camera physically connects to any lighthead, but only functions on video ready suspension arms.

CAUTION

POSSIBLE EQUIPMENT DAMAGE

⚠ When installing or removing the video camera be careful to place it in a secure location to prevent it from rolling, dropping and breaking. Also, to avoid scratching the lens surface, do not stand camera up with lens side facing down.

---

1. Rotate lighthead until lighthead lens faces the room ceiling.
2. Remove light handle by rotating the switch at the top of light handle in the locked direction.

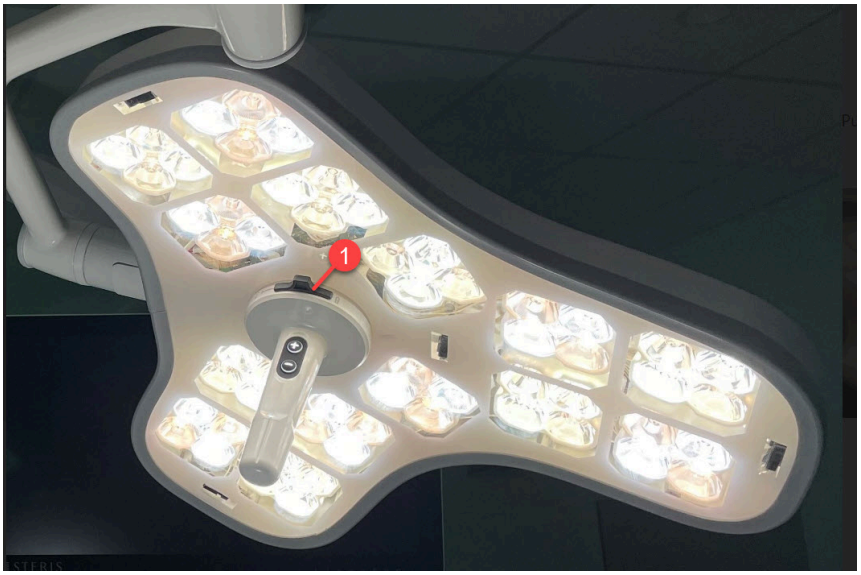


Figure 6-45. Install Light Handle

Legend
1. Light Handle Lock

3. Camera transmits signals over a cable. Camera shall be handled with care to avoid dust, dirt, debris, and fingerprints from impacting the signal.
4. Once light handle is removed, camera may be installed. The camera is installed by aligning connection bolts with holes on top of camera.



Figure 6-46. Install Camera

5. Once camera is aligned and seated on lighthead accessory port, rotate the switch at the top of camera housing in the locked direction.



Figure 6-47. Camera Module Lock

Legend
1. Camera Module Lock

NOTE: The camera only attaches to the lighthead in one orientation.

NOTE: The camera should be rocked and rotated to ensure it is properly connected.

6. Select Camera Menu on wall control.
7. Verify all functions of the camera operate correctly using wall control.

8. Once camera module functions are verified, press the lighthead symbol on the navigation pane.

6.14 Installing 4K Wireless Video Camera

Installation

CAUTION

POSSIBLE EQUIPMENT DAMAGE

⚠ When installing or removing the video camera be careful to place it in a secure location to prevent it from rolling, dropping and breaking. Also, to avoid scratching the lens surface, do not stand camera up with lens side facing down.

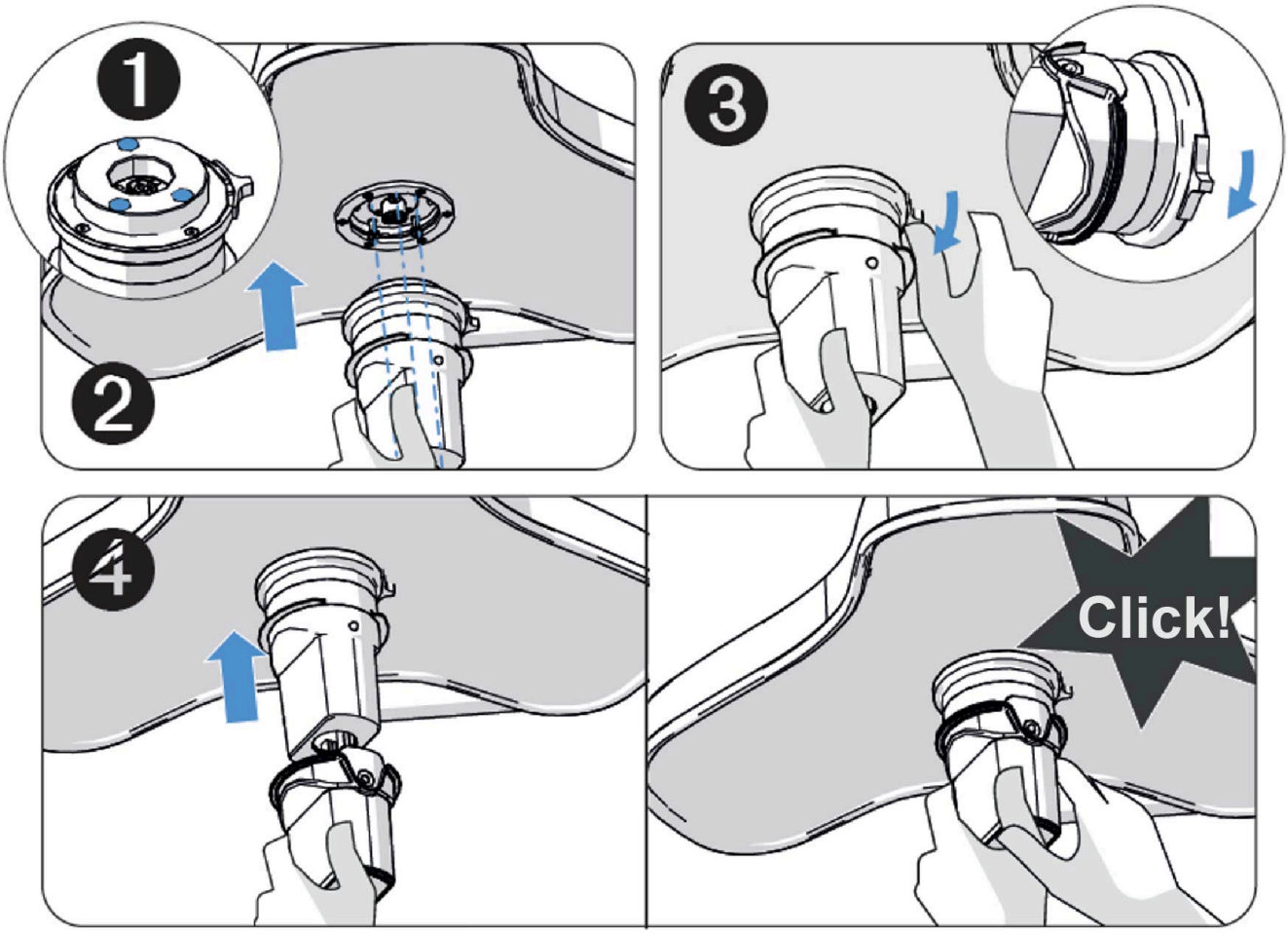


Figure 6-48. Installing the 4K Wireless Video Camera

1. Align the 3 connection points of the camera handle with those on the lighthead.
2. Push the camera handle in and hold.
3. Rotate the catch clockwise until a click is heard, indicating it's locked in place.

4. Fully attach the ALYWSH sterilizable case onto the camera handle until a click is heard, indicating it's locked in place.

Pairing

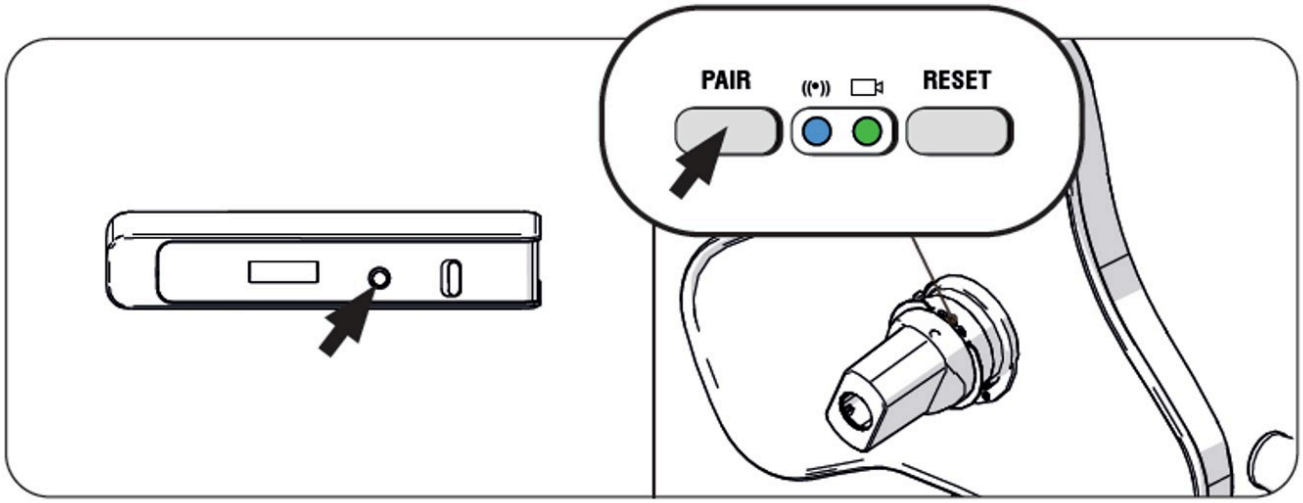


Figure 6-49. Pairing the 4K Wireless Video Camera

1. In any order, press the pairing button on both the camera and the receiver.
2. The LED will rapidly flash to indicate that pairing is in progress. The camera is successfully paired when the blue LED remains on. The LED will turn solid green when the image is sent to the receiver.

6.15 Uninstalling HD Video Camera

1. Rotate lighthead so lens is aimed toward the ceiling.
2. Remove camera by rotating lock slide at top of camera housing.
3. Install Enhanced handle (or basic handle if optioned).

6.16 Uninstalling the 4K Wireless Video Camera

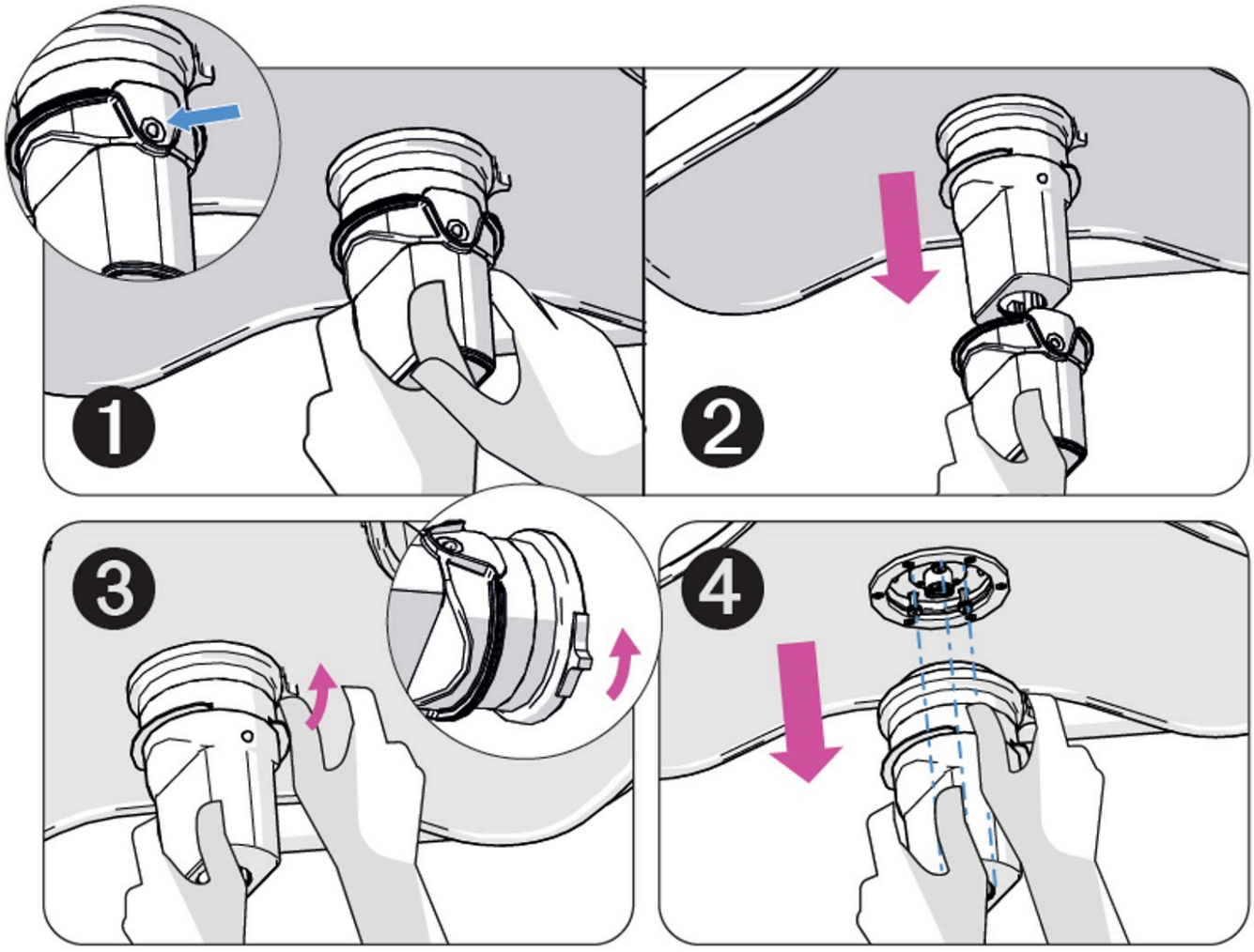


Figure 6-50. Uninstalling the 4K Wireless Video Camera

1. Press the button that locks the sterilizable handle in position.
2. While holding the button, pull the handle away to remove it from the camera handle.
3. Rotate the camera handle catch counter-clockwise to remove it from the mount.
4. Remove the camera handle.

6.17 Installing Disposable Sterile Camera Cover

NOTE: Wrinkles in the cover are normal. The appearance of wrinkles in the cover does not compromise the integrity of the cover.

When the lighthead is used with a camera, a disposable sterile cover shall be placed over the camera housing if it is to be used by sterile personnel. (Disposable sterile covers are available from STERIS.)

WARNING

BIOHAZARD

⚠ Sterile disposable covers are intended for single use only.

WARNING

STERILITY ASSURANCE HAZARD

⚠ Do not use disposable handle covers if its packaging has been damaged, torn or opened; as the sterility of the cover may be compromised.

1. Place sterile cover on camera module.



Figure 6-51. Install Disposable Sterile Camera Cover

2. Push sterile cover completely onto camera module.



Figure 6-52. Disposable Sterile Camera Cover Installed

6.18 Video Camera

Optional video camera is integrated into a removable, modular handle that can be fitted into a camera-ready lighthead. The camera only functions in a camera ready suspension arm. For most systems, this is the bottom arm.

The camera transmits video signal via a cable connection. Treat camera with care; dirt, dust, and debris may affect camera signal quality.

- Harmony Standard Definition (SD) in-light camera is not compatible with HarmonyAIR ALYON Surgical Lighting System.
- The camera includes four pairs of +/- buttons. These buttons, when properly covered with a disposable sterile cover, may be used by sterile personnel to adjust the intensity on the light. The buttons perform the same function as the buttons on the light handle.
- The camera may be gripped to adjust the lighthead position.
- The camera may be rotated to change the spot size of the light.

Whenever video option is used, a separate sterile disposable cover must be fitted over the camera before each procedure. This cover allows the camera to be grasped and used in the same way as an Enhanced handle, including positioning the lighthead for optimal illumination, adjusting lighthead intensity and pattern size, as well as positioning video image field for the best view of the procedure.

The sterile cover must be removed from the camera and discarded after each procedure.

NOTE: Two camera modules may be used per surgical lighting system (if optioned and appropriately provisioned – two video ready arms).

Once the video camera module has been installed in the lighthead, the camera may be turned on at the wall control by selecting the camera menu and then pressing camera On button. Once the camera is initialized, control of camera functions is available through menus on the wall control.

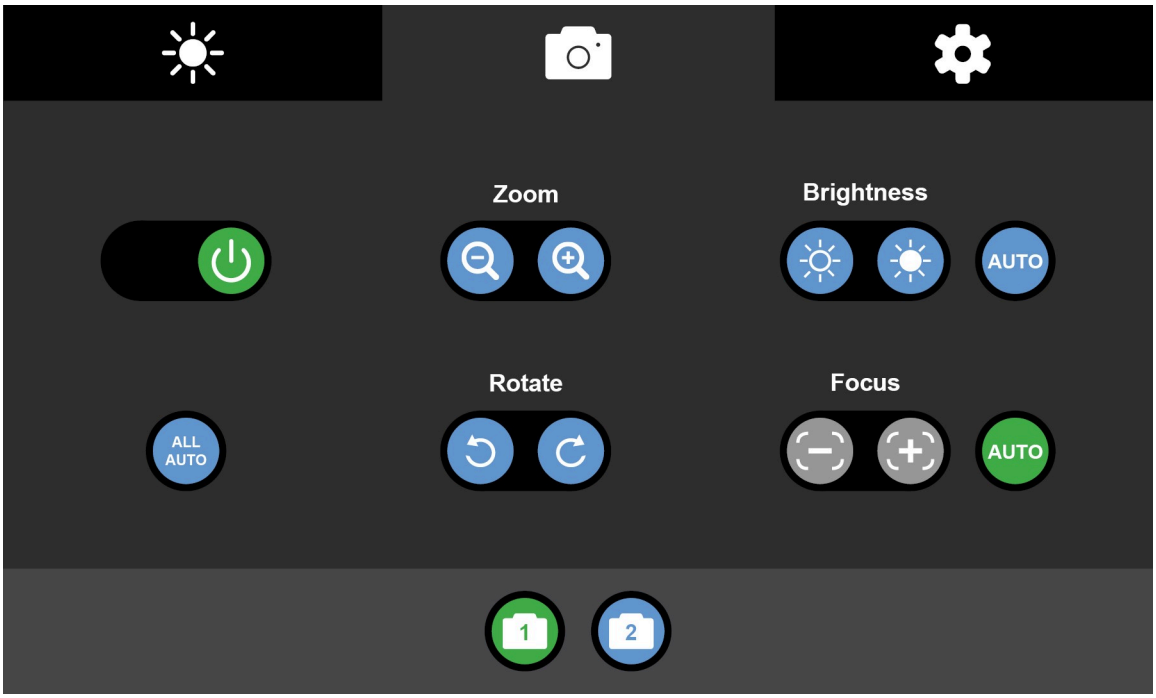


Figure 6-53. Camera Screen

The wall control functions by transmitting signals via a control cable to the camera located in the lighthead.

To initiate camera functions, press Camera icon on the wall control.

6.19 Video Camera Operation

The wall control is used to control the following camera functions:

- **Camera Power** – Turns camera on and off.
- **Zoom** — Use this function for determining the level of detail visible in the image field. The Zoom function adjusts the image field continuously between two extremes:

  NOTE:

  Overall distance between the object and the camera, plus the length of zoom, affects the camera's ability to achieve a sharp focus. The greater the zoom length, the less capability the camera has to establish a sharp focus.

- **Telephoto** — At extreme telephoto, the camera captures an image showing great detail in a small area.

  NOTE:

  At extreme telephoto, any motion of the lighthead/camera may be exaggerated (jerky). The field of focus has little depth at this extreme, forcing the Auto Focus function (if enabled) to refocus the camera when any object (such as a hand) enters the image field, or if camera position is adjusted. The camera is also sensitive to light level changes at extreme telephoto.

- **Wide Angle** — At extreme wide angle, the camera captures a large image with less detail than telephoto.

  NOTE:

  At extreme wide angle, the image field possesses a greater depth of focus and less sensitivity to light level changes.

- **Rotate** — Use this function to change orientation of the video field. Image field can be rotated in either **clockwise** or **counterclockwise** directions.

  NOTE: Rotate is not available for the 4K wireless camera.

- **Manual Focus** — Use this function to manually set the focus. The Auto Focus function must be toggled off to enable manual focusing. Adjust the clarity of focus by pressing the brightness increase button or brightness decrease button.

  NOTE:

  As instruments are introduced to and removed from the surgical field, the auto focus attempts to focus on the nearest object, possibly causing the image to blur intermittently. To prevent this effect, once the camera has been positioned and focused onto the surgical site, the manual focus mode may be engaged to maintain image clarity during the procedure.

  NOTE:

  For deep cavity illumination, it may be necessary to engage the manual focus to focus beyond the nearest object (i. e., the surface area surrounding the incision) so that the desired image can be viewed clearly.

- **Auto Focus** — Use this function to toggle Auto Focus on or off. When Auto Focus is ON, the camera automatically focuses on the object in the image field closest to the camera lens. The focus adjustment arrows are inactive. When Auto Focus is turned OFF and Manual Focus is on, the Manual Focus text is white. The focus adjustment arrows are active. The camera maintains focus on the last object upon which it was focused, until Auto Focus is turned back on.

  NOTE:

  It may be necessary to toggle Auto Focus OFF when using the camera at extreme telephoto (close up), to prevent the camera from refocusing on hands and other objects introduced into the image field while video imaging procedures.

- **Brightness** — Use this function to affect the overall brightness (or darkness) of the video image. The Bright control can be set to adjust itself automatically. When the brightness Auto mode is selected, the Auto text is white and the brightness adjustment controls are inactive. When Manual mode is selected, the Manual text is white and the brightness adjustment controls are active.
- **Auto Brightness** – When auto brightness is on, auto button turns green to show that it is in an automatic state and the two sun buttons turn grey to indicate they are inactive.
- **Camera Selection** — Pressing camera 1&2 buttons switch which camera being controlled. The button that is green shows the camera being actively controlled.

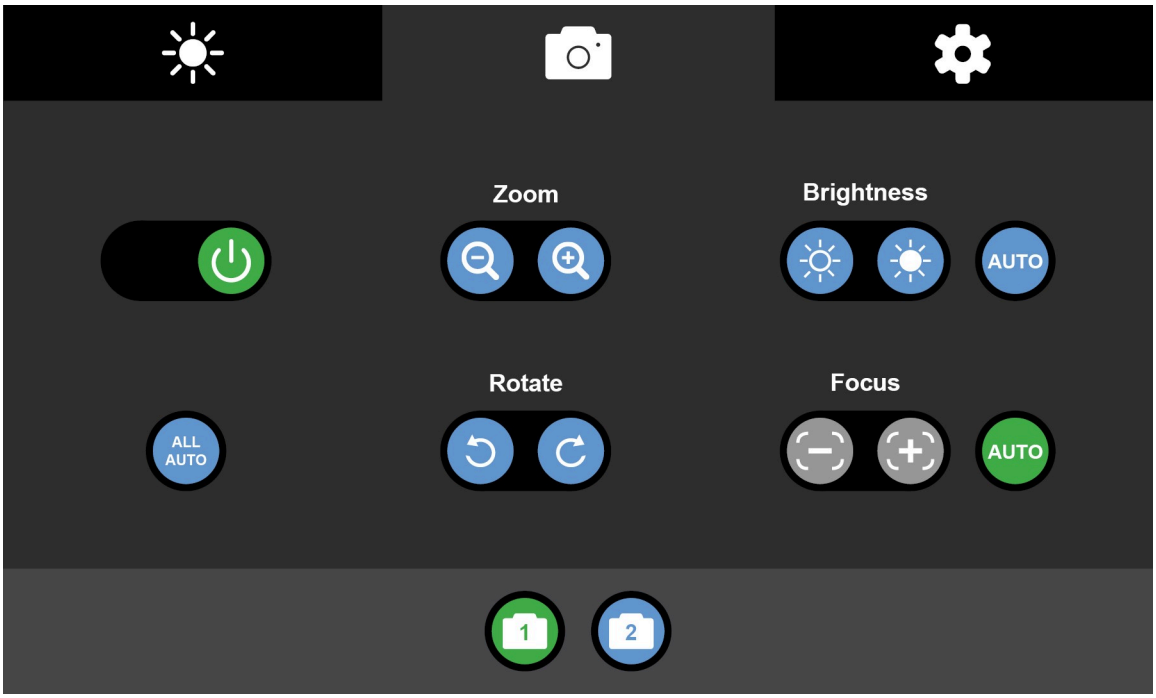


Figure 6-54. Camera Screen

6.20 Settings Screen

Introduction – Settings Screen

The Settings screen has the following functions:

- General – (Includes settings for Language, Screen Brightness, On/Off By Rotating Handle, Screen Saver, Time, and Date)
- Lighting – (Includes settings for Spot Size, Adaptive Shadow Control, Ambient Lighting and Auto Intensity)
- Camera – (Includes settings for Video Format, Gamma, White Balance, Freeze, Save, and Load)
- Service – (Allows service technicians to access service mode)

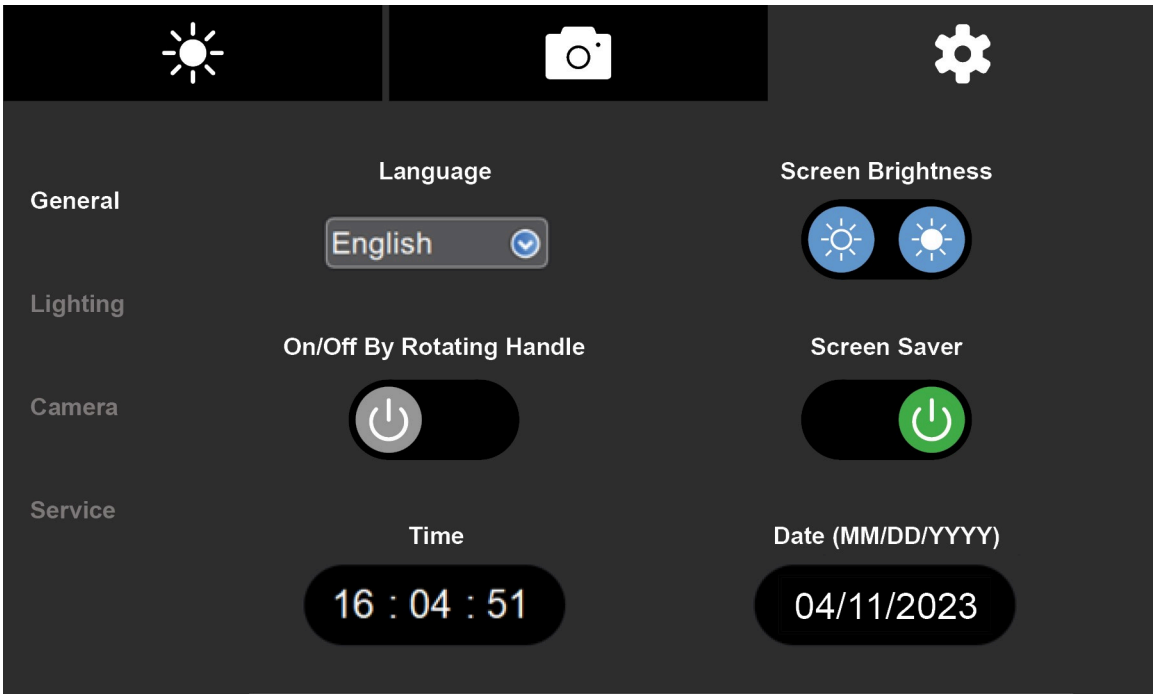


Figure 6-55. Settings Screen

Setting the Language

1. Press Settings button on wall control.
2. Press General.
3. Select language from drop-down menu.

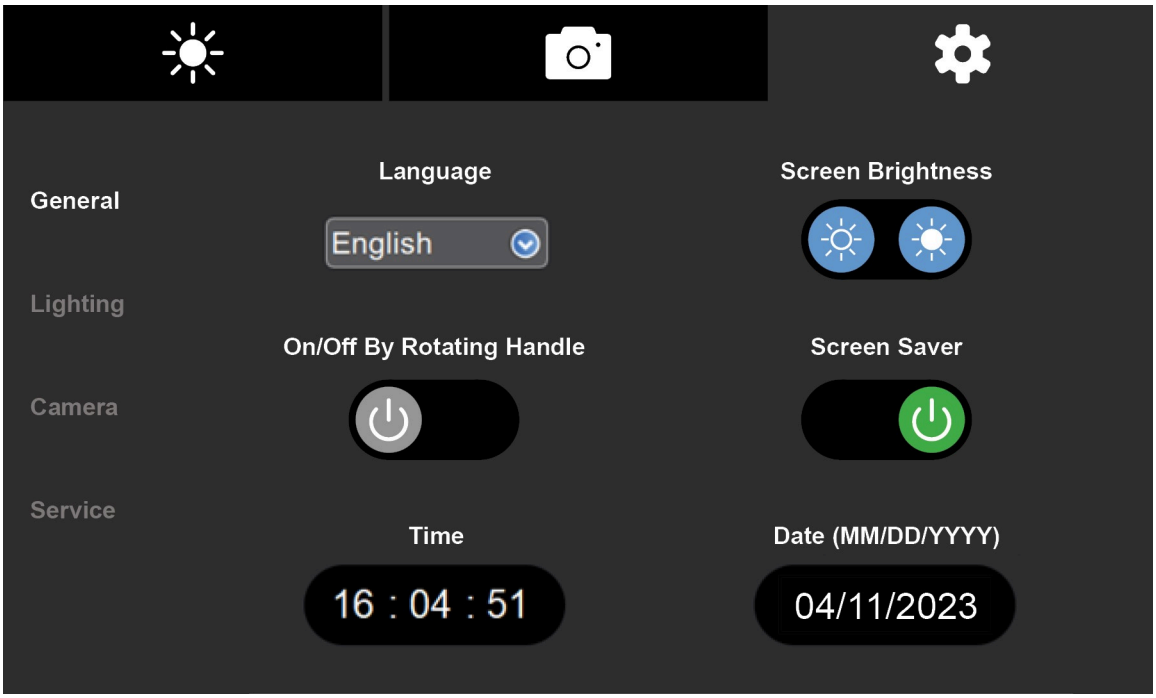


Figure 6-56. Select Language

Setting Screen Brightness

1. Press Settings button on wall control.
2. Press General.
3. Under Screen Brightness, press left button to decrease screen brightness.
4. Under Screen Brightness, press right button to increase screen brightness.

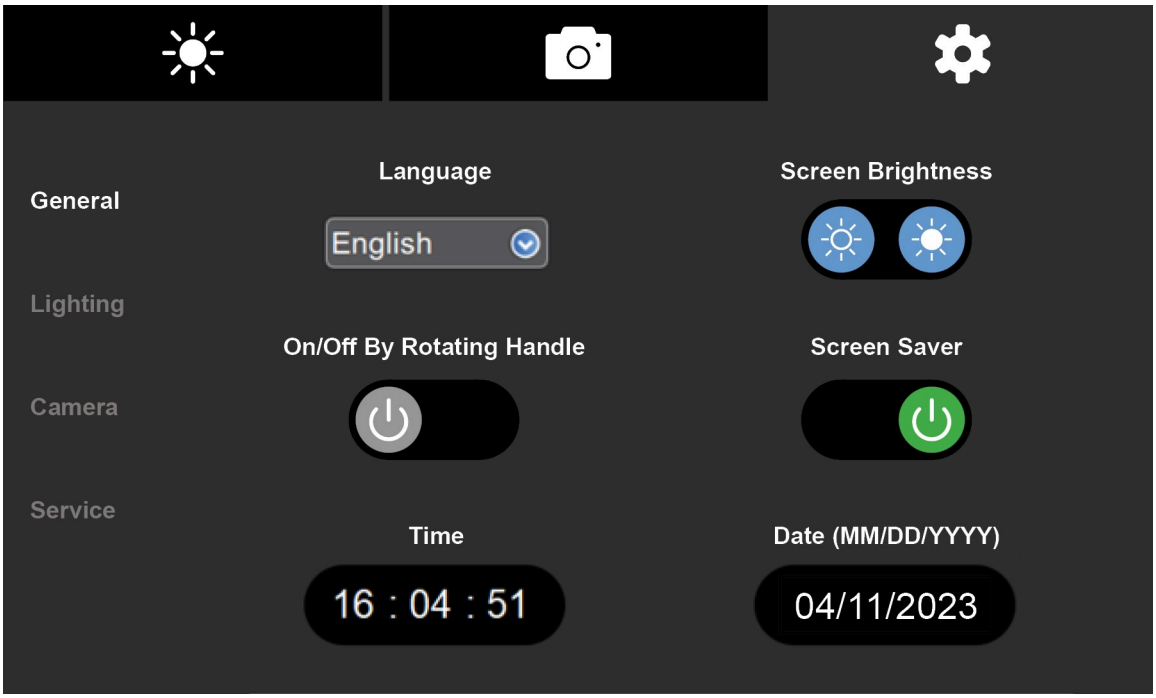


Figure 6-57. Screen Brightness

Setting Screen Saver

1. Press Settings button on wall control.
2. Press General.
3. Under Screen Saver, slide button to the right to enable screen saver.
4. Under Screen Saver, slide button to the left to disable screen saver.

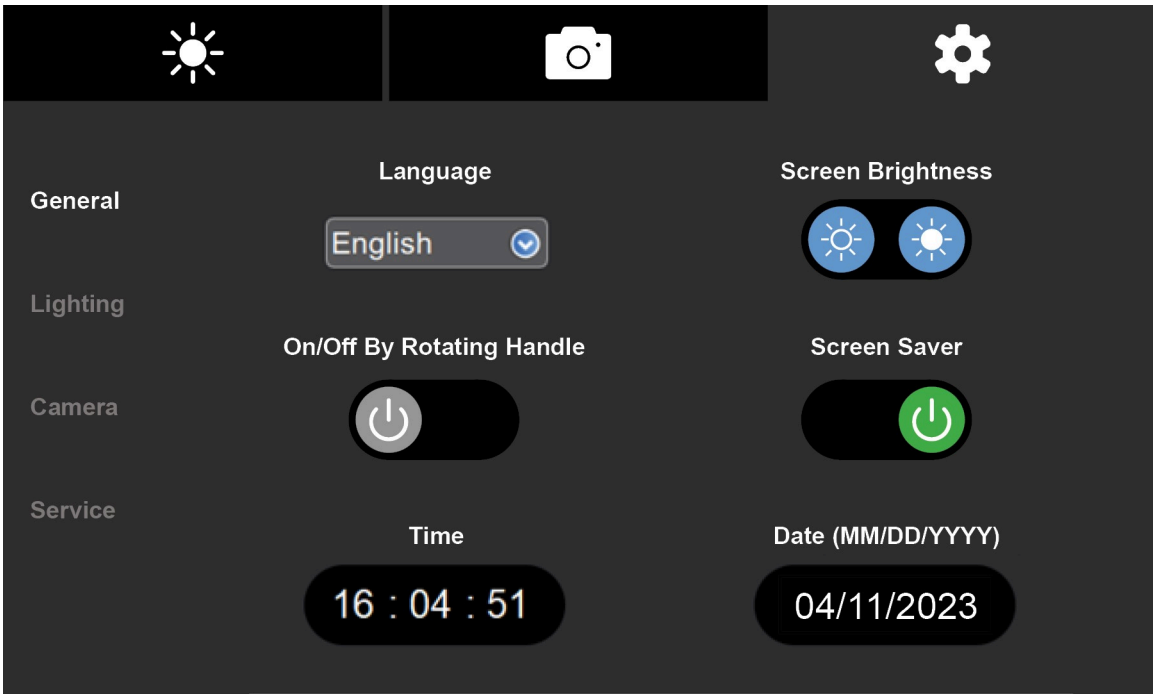


Figure 6-58. Screen Saver

Setting Time

1. Press Settings button on wall control.
2. Under Time, press time button to change time.

Setting Date

1. Press Settings button on wall control.
2. Under Date, press date button to change date.

Spot Size

1. Press Settings button on wall control.
2. Press Lighting.
3. Under Spot Size, press (-) button to decrease spot size.
4. Under Spot Size, press (+) button to increase spot size.

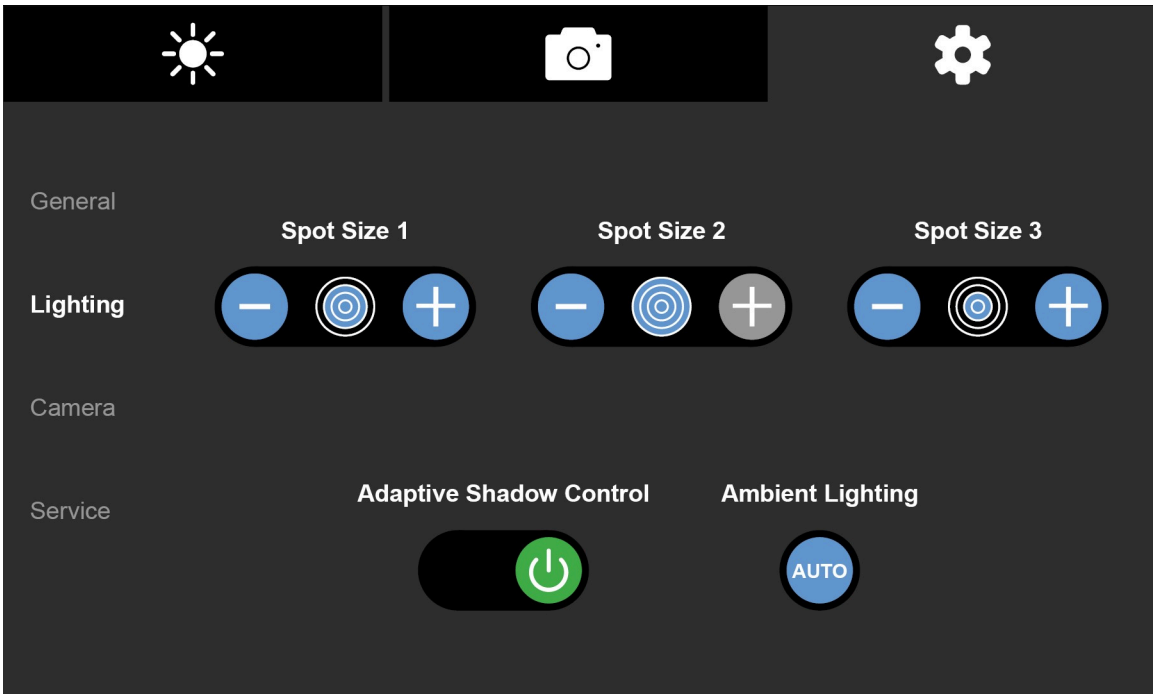


Figure 6-59. Spot Size

Adaptive Shadow Control

1. Press Settings button on wall control.
2. Press Lighting.
3. Under Adaptive Shadow Control, slide button to the right to enable adaptive shadow control.
4. Under Adaptive Shadow Control, slide button to the left to disable adaptive shadow control.

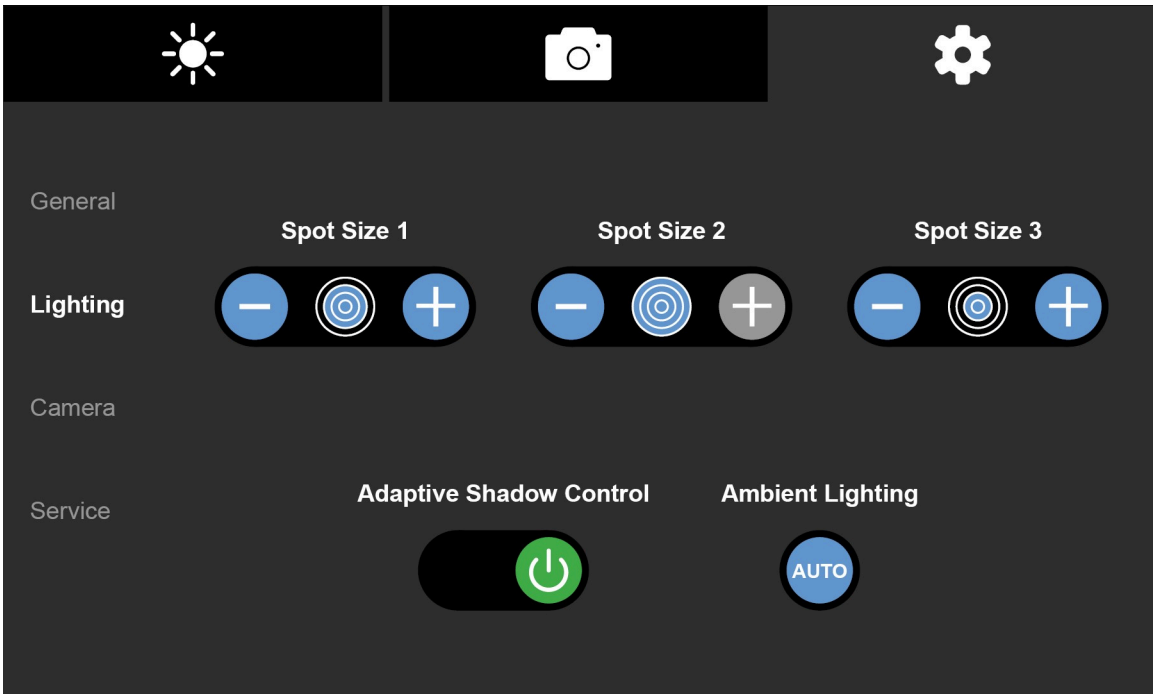


Figure 6-60. Adaptive Shadow Control

Ambient Lighting

1. Press Settings button on wall control.
2. Press Lighting.
3. Under Ambient Lighting, press AUTO button to enable ambient lighting.
4. Under Ambient Lighting, press AUTO button to disable ambient lighting.

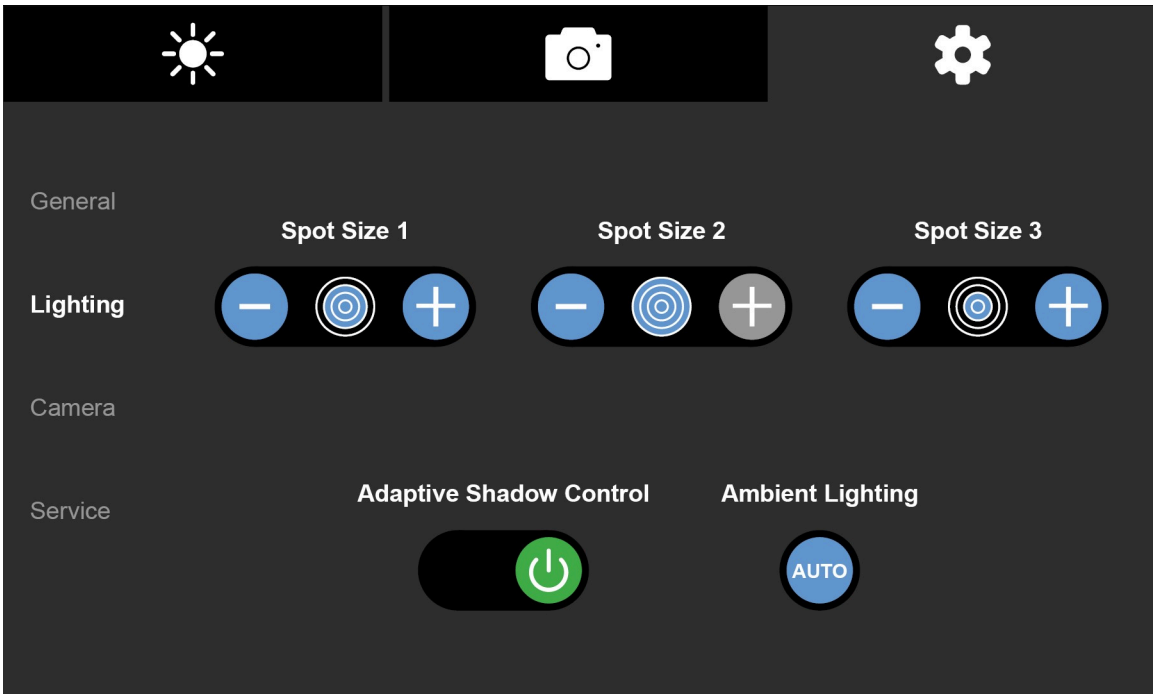


Figure 6-61. Ambient Lighting

Setting Camera Video Format

1. Press Settings button on wall control.
2. Press Camera.
3. Under Camera Video Format, click drop-down menu.
4. Press desired camera video format from drop-down menu.

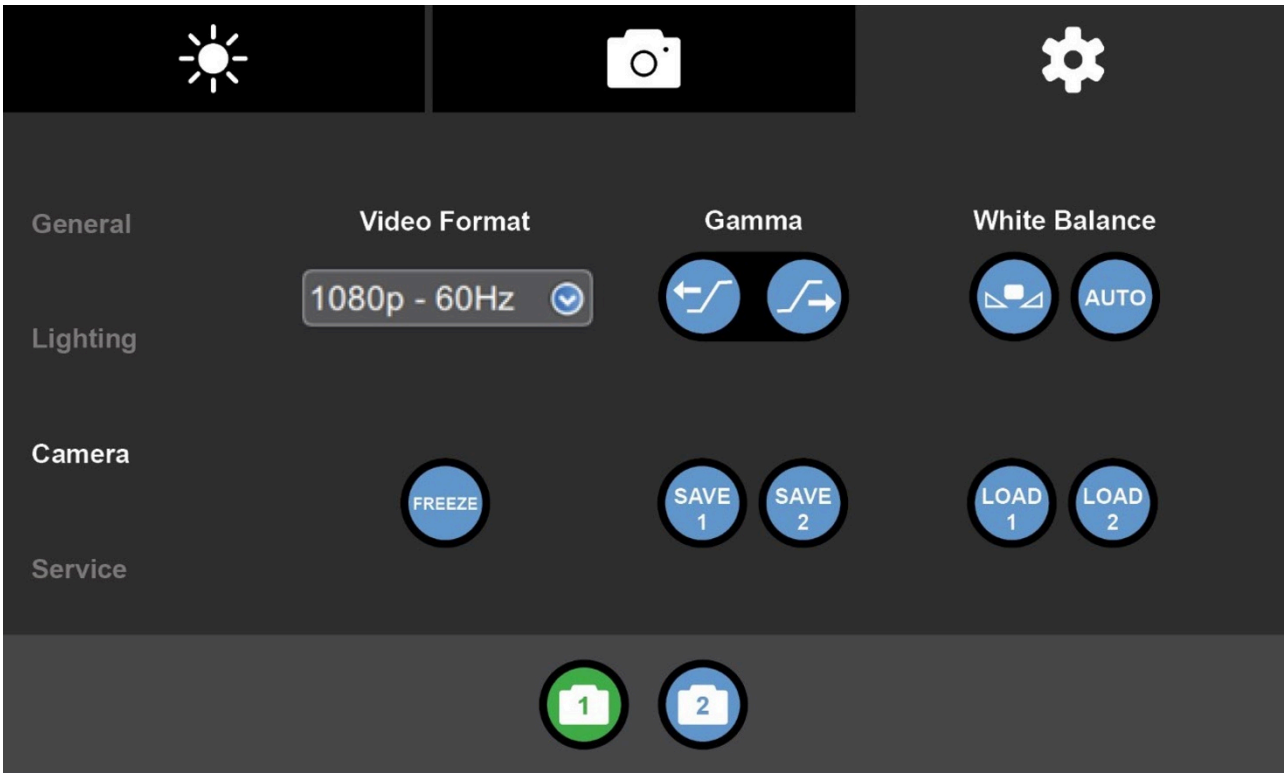


Figure 6-62. Camera Video Format

Gamma

1. Press Settings button on wall control.
2. Press Camera.
3. Press left button to decrease gamma for selected camera.
4. Press right button to increase gamma for selected camera.

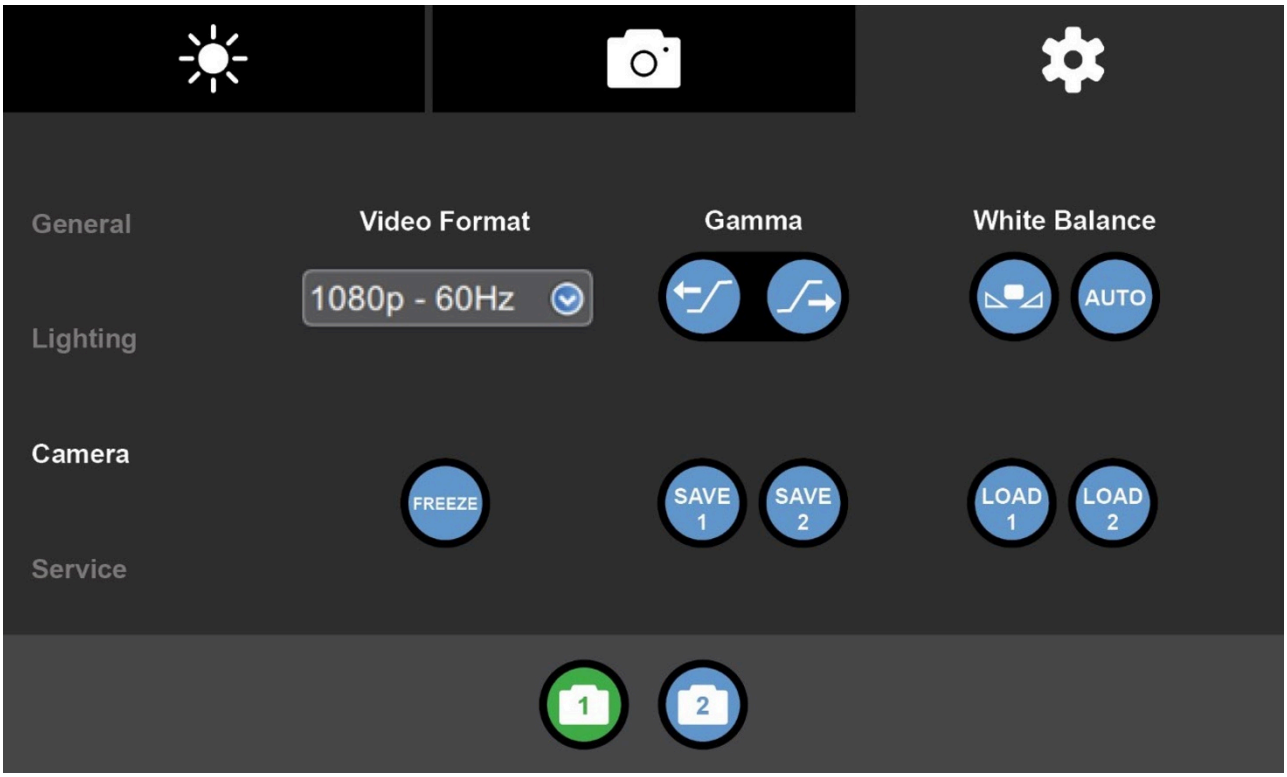


Figure 6-63. Gamma

White Balance

1. Press Settings button on wall control.
2. Press Camera.
3. Press left button to automatically readjust fixed white balance mode.

   NOTE: This is a fixed white balance mode that may be automatically readjusted by pressing this button, assuming that a white subject, in correct lighting conditions, and occupying more than 1/2 of the image, is submitted to the camera. This data is lost when the power is turned off and must be reset.
4. Press auto button to invoke auto white balance for selected camera.

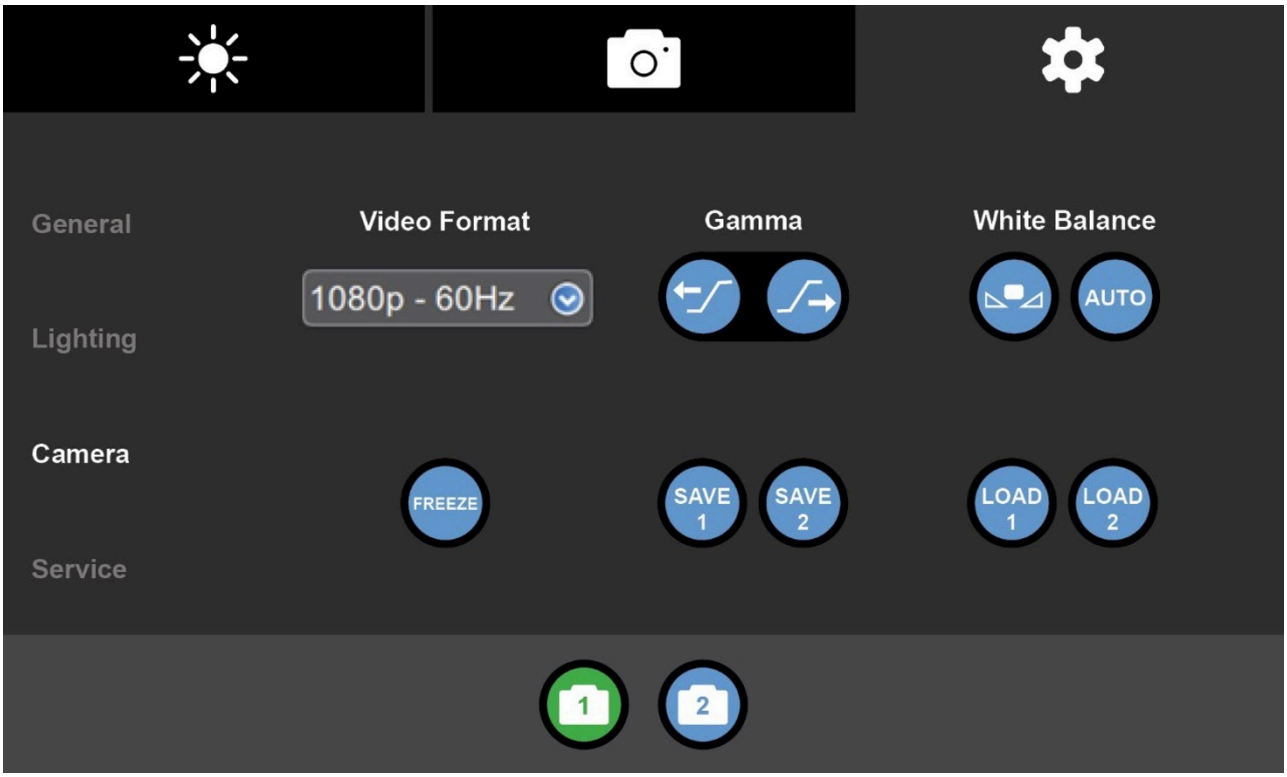


Figure 6-64. White Balance

Freeze

1. Press Settings button on wall control.
2. Press Camera.
3. Press freeze button to freeze image from selected camera.

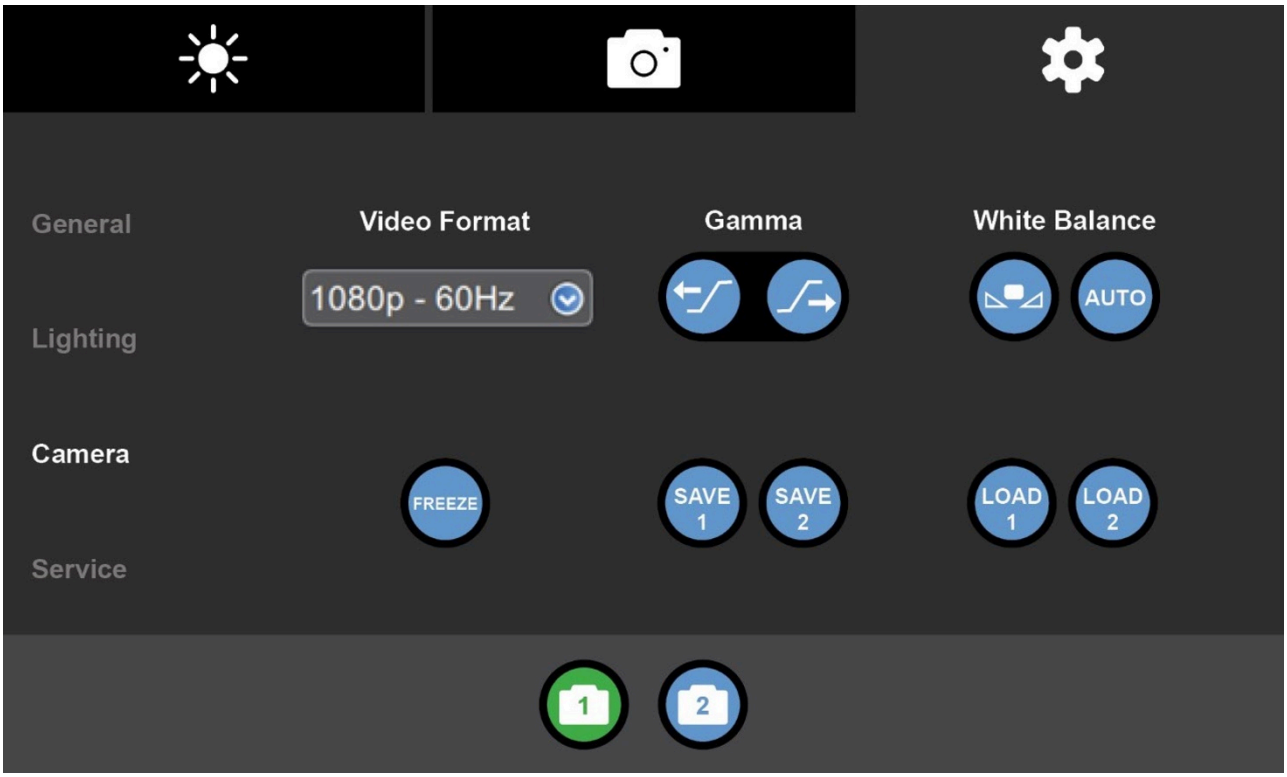


Figure 6-65. Freeze

Save

1. Press Settings button on wall control.
2. Press Camera.
3. Press Save button to save current camera setting.

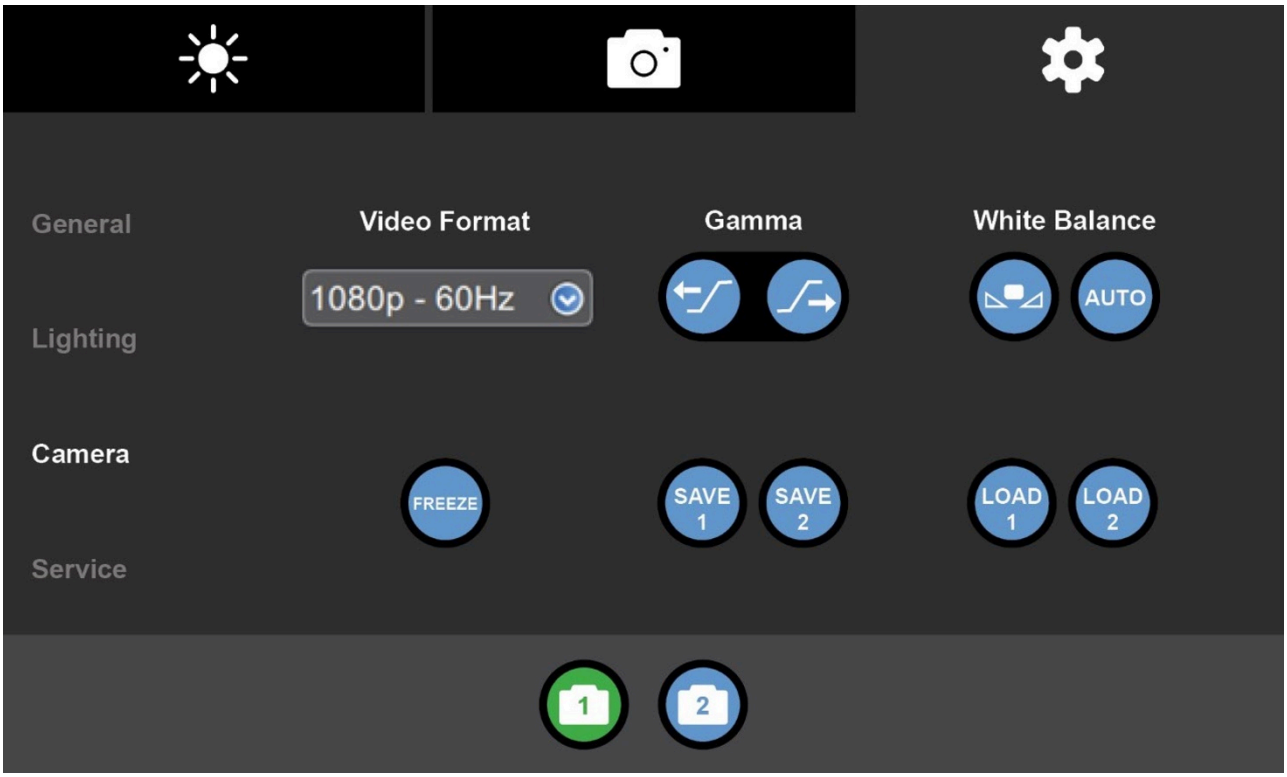


Figure 6-66. Save

Load

1. Press Settings button on wall control.
2. Press Camera.
3. Press Load button to retrieve previously saved camera setting.

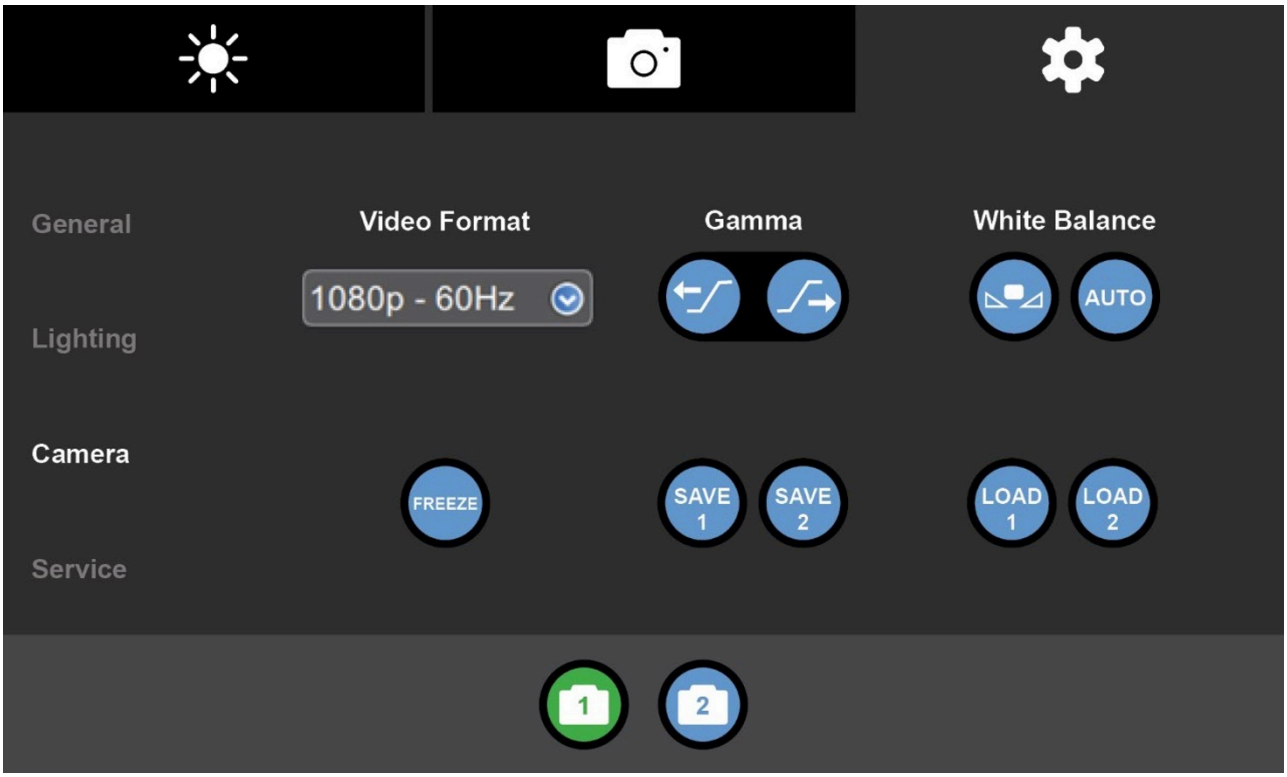


Figure 6-67. Load

Camera Selection

1. Press Settings button on wall control.
2. Press Camera.
3. Press Camera 1&2 buttons to switch which camera is being controlled. The button that is green shows the camera you're actively controlling.

   NOTE: The green button shows the camera being actively controlled.

6.21 Ambient Light Fixture

Ambient Light Operation Overview

The ambient light provides low-level, general illumination in the surgical suite. Illumination from the ambient light fixture can be configured to operate manually (turned on or off at the wall control), or the ambient light can be configured to operate automatically (turns off when any system lighthead is turned on and turns on when all system lightheads are turned off). When configured for automatic operation, the ambient light can still be manually turned on or off at the wall control.

Turning Ambient Light On Using Wall Control

1. Press LIGHTS on wall control.
2. Press ambient light button to turn green ambient light on.

   NOTE: When ambient light is on, ambient light button on wall control turns green.

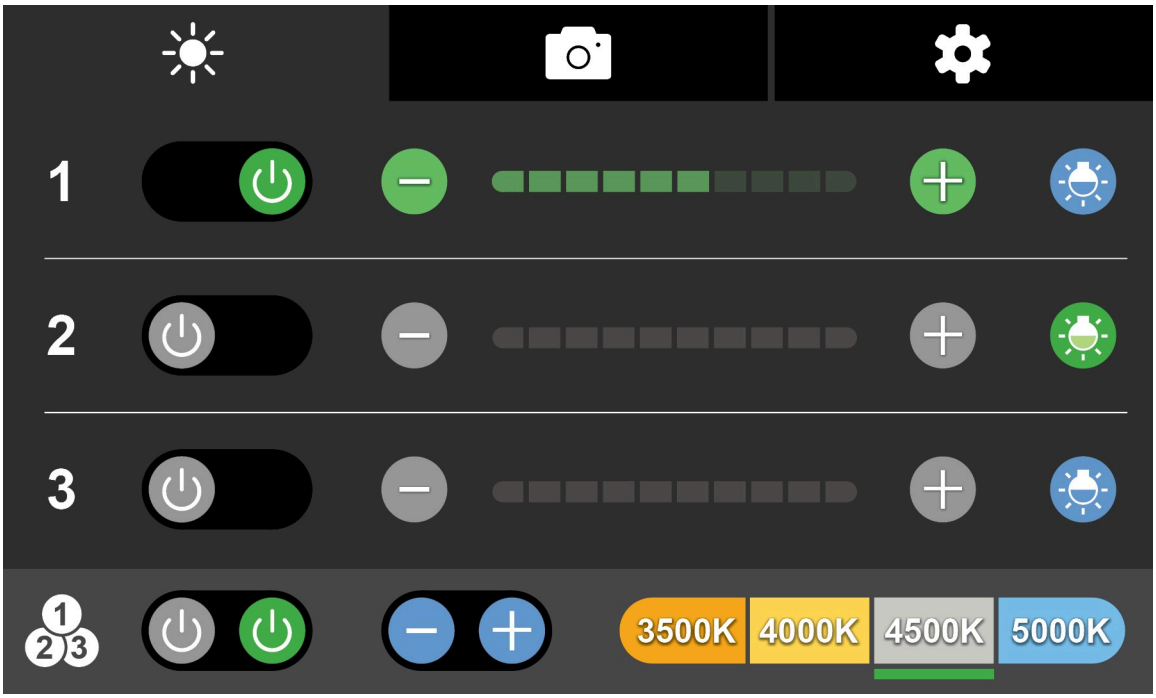


Figure 6-68. Turn Ambient Light On

Turning Ambient Light Off Using Wall Control

1. Press LIGHTS on wall control.
2. Press ambient light button to turn green ambient light off.

   NOTE: When ambient light is off, ambient light button on wall control turns blue.

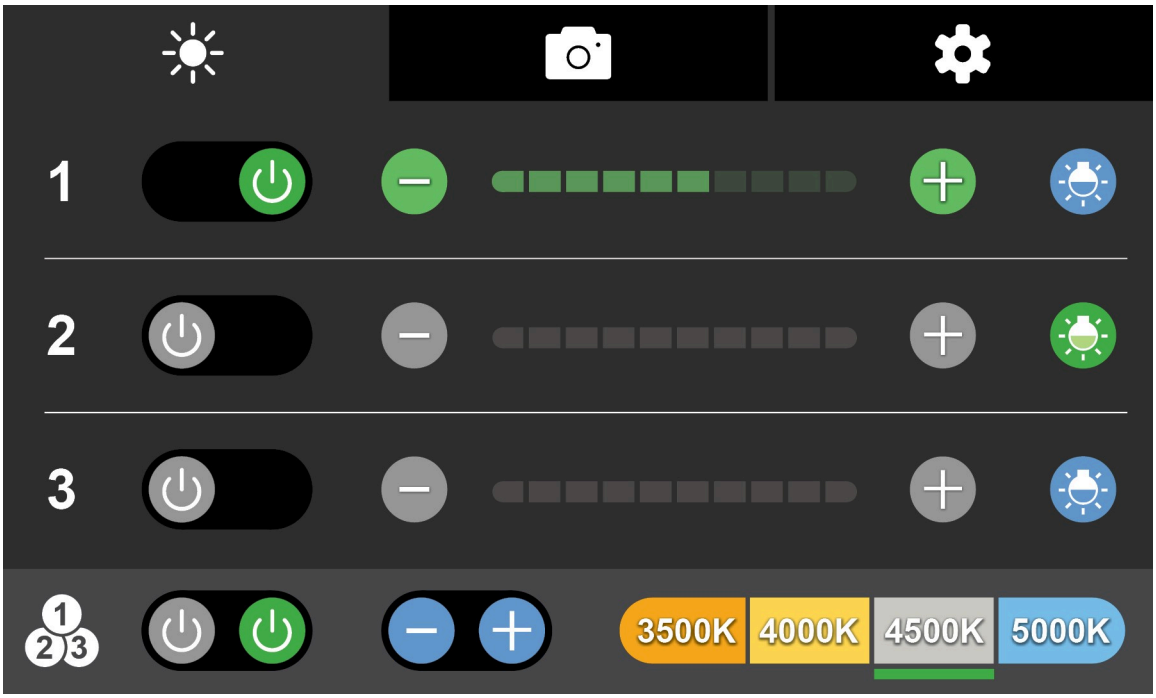


Figure 6-69. Turn Ambient Light Off

Setting Ambient Light to Auto Mode

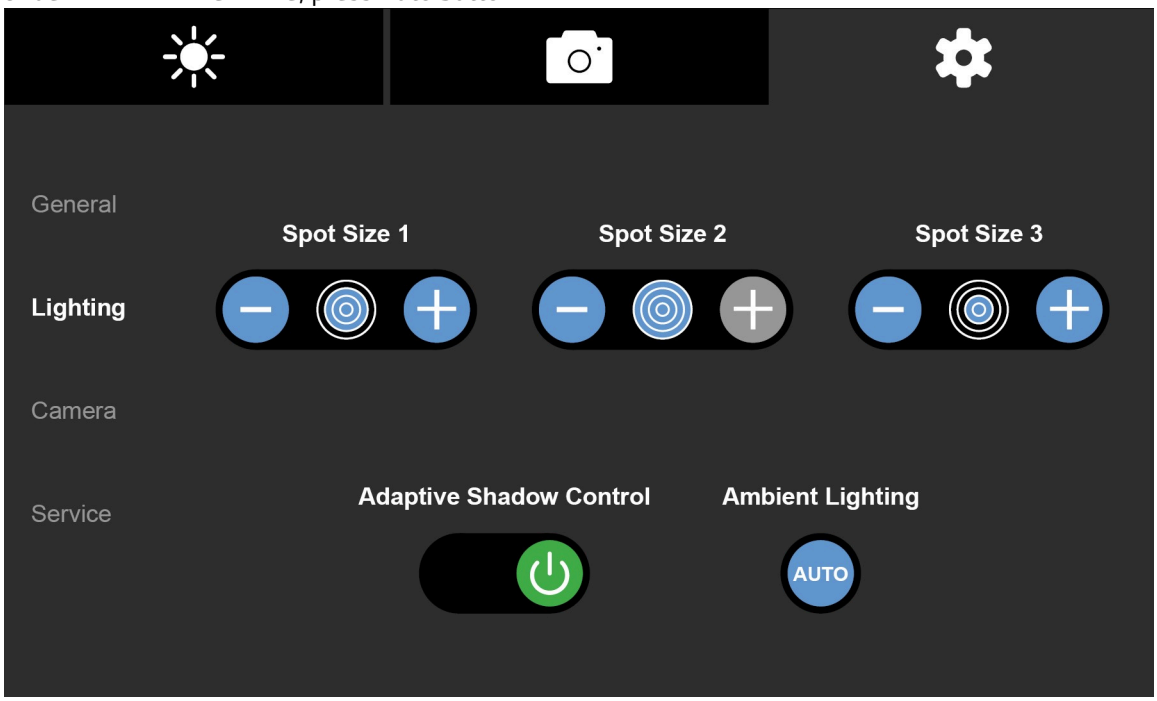
WARNING

ELECTRIC SHOCK HAZARD

⚠ Avoid possibility of electric shock, and refer any servicing of the ambient light fixture to qualified service personnel.

1. Press SETTINGS on wall control.

2. Under AMBIENT LIGHTING, press Auto button.



Routine Maintenance and Inspection

7.1 Cleaning The Equipment

Cleaning Equipment

WARNING

PERSONAL INJURY AND/OR POSSIBLE EQUIPMENT DAMAGE HAZARD

⚠ Do not attempt to clean lighthead/monitor unless power is turned off and the lighthead/monitor has cooled sufficiently.

WARNING

ELECTRIC SHOCK HAZARD

Avoid electric shock hazard. The monitor mount may be live and must be treated carefully during cleaning and disinfection:

⚠

- If a mains plug is present, please disconnect it.
- Do not use spray cleaning and/or disinfecting agents sprays.
- Do not spray fluid into sockets or monitor mount openings. Do not allow fluid to penetrate them.

WARNING

RISK OF CONTAMINATION AND INFECTION OF PATIENTS

Certain parts of the product are made of plastic. Solvents may dissolve plastic. Concentrated acids, caustic solutions and media with more than 60% alcohol may cause material embrittlement. Damaged parts may fall into open wounds. If cleaning fluid is allowed to penetrate the device, surplus cleaning agent may drip into open wounds.

⚠

- Make sure that no fluid penetrates into the device during cleaning.
- To avoid damage to plastic parts, do not use scouring agents, alkaline, acidic or corrosive cleaning agents.
- Do not use bleaching agents on stainless-steel parts.

CAUTION

POSSIBLE EQUIPMENT DAMAGE

Use of any disinfectant solution OTHER than those listed here may cause discoloration or deformation on the system components:

- Coverage® Plus Germicidal Surface Wipes Disinfecting/Deodorizing/Cleaning Wipes
- Quaternary Ammonium Compound (Quats) with Ethanol solvent
- Quaternary Ammonium Compound (Quats) with Isopropyl Alcohol (IPA) solvent
- Quaternary Ammonium Compound (Quats) with IPA + 2-Butoxyethanol solvent
- Quaternary Ammonium Compound (Quats) + Biguanide
- H2O2 (Hydrogen Peroxide)
- Neutral Cleaners

The use of H2O2 + PAA (Hydrogen Peroxide + Peracetic Acid) is strongly discouraged for use on all STERIS products.

Always follow manufacturer instructions for concentrations and use of cleaning products.

Avoid discoloration of the wall control. Do not clean wall control with povidoneiodine solutions or allow such solutions to contact bezel, bezel label and display surfaces.

Prevent leakage of fluids into interior of lighthead or wall control. Ensure no excess fluids remain on lighthead or panel during and after cleaning.

Cleaning and disinfecting agents used on this lighting system must be certified by their manufacturer to be compatible with the following materials: polycarbonate, polyetherimide, santoprene.

DO NOT SPRAY any cleaning product directly onto the lighthead, monitor, wall control, or any system components. Clean wall control with a clean, lint-free cloth dampened with 90% isopropyl alcohol. For other system components, dampen a clean, soft cloth with the cleaning solution and wring out the excess moisture.

STERIS recommends the following equipment for use when cleaning the surgical lighting system:

- Pail
- Sponge
- Lint-Free Cloth Wipes
- Rubber Gloves
- Mild Household Detergent (e.g., Dishwashing Liquid)

General Cleaning/Disinfecting Procedure

WARNING

PERSONAL INJURY HAZARD AND/OR EQUIPMENT DAMAGE HAZARD

⚠ Do not attempt to clean lighthead unless power is turned off and the lighthead has cooled sufficiently.

CAUTION

POSSIBLE EQUIPMENT DAMAGE

Use of any disinfectant solution OTHER than those listed here may cause discoloration or deformation on the lens surface:

- Coverage® Plus Germicidal Surface Wipes Disinfecting/Deodorizing/Cleaning Wipes
- Quaternary Ammonium Compound (Quats) with Ethanol solvent

⚠
- Quaternary Ammonium Compound (Quats) with Isopropyl Alcohol (IPA) solvent
- Quaternary Ammonium Compound (Quats) with IPA + 2-Butoxyethanol solvent
- Quaternary Ammonium Compound (Quats) + Biguanide
- H2O2 (Hydrogen Peroxide)
- Neutral Cleaners

⚠ The use of H2O2 + PAA (Hydrogen Peroxide + Peracetic Acid) is strongly discouraged for use on all STERIS products.

⚠ Always follow manufacturer instructions for concentrations and use of cleaning products.

⚠ Avoid discoloration of the wall control. Do not clean wall control with povidoneiodine solutions or allow such solutions to contact bezel, bezel label and display surfaces.

⚠ Prevent leakage of fluids into interior of lighthead, monitor, or wall control. Ensure no excess fluids remain on lighthead, monitor or panel during and after cleaning.

⚠ Cleaning and disinfecting agents used on this lighting system must be certified by their manufacturer to be compatible with the following materials: polycarbonate, polyetherimide, santoprene.

⚠ DO NOT SPRAY any cleaning product directly onto the lighthead, monitor, wall control, or any system components. Clean wall control with a clean, lint-free cloth dampened with 90% isopropyl alcohol. For other system components, dampen a clean, soft cloth with the cleaning solution and wring out the excess moisture.

STERIS recommends the following procedures when cleaning the surgical lighting system:

1. Ensure lighthead is turned off and has cooled sufficiently.
2. Wear rubber gloves.
3. Prepare an approved cleaning or disinfecting solution in accordance with the directions on the container's label.
4. **DO NOT SPRAY** any cleaning product directly onto the lighthead, monitor, wall control, or any system components. Clean wall control with a clean, lint-free cloth dampened with 90% isopropyl alcohol. For other system components, dampen a clean, soft cloth with the cleaning solution and wring out the excess moisture.
5. Thoroughly wipe the areas to be cleaned.
6. Rinse all surfaces with a clean soft cloth wipe and clear water.
7. Wipe all surfaces dry with a clean dry soft cloth.
8. Verify sterilizable handle cover (when used) is sterilized using a standard hospital cycle.

   NOTE: Always sterilize sterilizable handle cover between procedures. Sterilize light handle using conventional hospital sterilization procedures and a standard sterilization prevacuum or gravity cycle.

Areas To Be Cleaned Before Each Use

WARNING

PERSONAL INJURY AND/OR POSSIBLE EQUIPMENT DAMAGE HAZARD

⚠ Do not attempt to clean lighthead/monitor unless power is turned off and the lighthead/monitor has cooled sufficiently.

CAUTION

POSSIBLE EQUIPMENT DAMAGE

Use of any disinfectant solution OTHER than those listed here may cause discoloration or deformation on the lens surface:

- Coverage® Plus Germicidal Surface Wipes Disinfecting/Deodorizing/Cleaning Wipes
- Quaternary Ammonium Compound (Quats) with Ethanol solvent

⚠
- Quaternary Ammonium Compound (Quats) with Isopropyl Alcohol (IPA) solvent
- Quaternary Ammonium Compound (Quats) with IPA + 2-Butoxyethanol solvent
- Quaternary Ammonium Compound (Quats) + Biguanide
- H2O2 (Hydrogen Peroxide)
- Neutral Cleaners

⚠ The use of H2O2 + PAA (Hydrogen Peroxide + Peracetic Acid) is strongly discouraged for use on all STERIS products.

⚠ Always follow manufacturer instructions for concentrations and use of cleaning products.

⚠ Avoid discoloration of the wall control. Do not clean wall control with povidoneiodine solutions or allow such solutions to contact bezel, bezel label and display surfaces.

⚠ Prevent leakage of fluids into interior of lighthead, monitor, or wall control. Ensure no excess fluids remain on lighthead or panel during and after cleaning.

⚠ Cleaning and disinfecting agents used on this lighting system must be certified by their manufacturer to be compatible with the following materials: polycarbonate, polyetherimide, santoprene.

⚠ DO NOT SPRAY any cleaning product directly onto the lighthead, monitor, wall control, or any system components. Clean wall control with a clean, lint-free cloth dampened with 90% isopropyl alcohol. For other system components, dampen a clean, soft cloth with the cleaning solution and wring out the excess moisture.

The following areas of the system must be cleaned and disinfected before each use of the lighthead.

- **Suspension Arm** – Wipe the entire suspension arm, including the suspension fork and yoke.
- **Lighthead** – Wipe both top and side surfaces.
- **Non-Sterile Handle** – Wipe all areas of the handle, including those covered when the handle cover is installed.
- **Lens** —

  IMPORTANT: *Clean only the exterior surface of the lens.*

  1. *Clean/disinfect the outer surface of the lens as outlined in General Cleaning/Disinfecting Procedure.*
  2. *Wipe the outer surface of the lens with an anti-static cleaner and soft cloth.*
  3. *When using a sterilizable light handle cover, verify it is sterilized according to facility sterile protocols between each surgical procedure.*
     - *When using disposable sterile light handle covers, verify a new one is used for each procedure.*
- **Wall Control** – Wipe panel with an anti-static cleaner and soft cloth. See *General Cleaning/Disinfecting Procedure* for cleaning instructions.

7.2 Disinfection

The product is not intended for sterilization.

CAUTION

HEALTH HAZARD

⚠

Disinfecting agents may contain substances which are detrimental to your health and may cause injuries to the skin or eyes on contact or damage the respiratory organs if inhaled. Observe safety measures:

- Follow the hygiene guidelines.
- Observe the information supplied by the disinfecting agents manufacturer.
- Disinfect surfaces every work day and in the event of contamination

.

The standard disinfection procedure for the product is wipe disinfection. The operator is to determine hygiene guidelines and the corresponding safety measures for the disinfection procedure to be used.

- Immediately disinfect the affected areas after contamination by potentially infectious material (e.g. blood, secretions or excrement).
- Observe application concentration.
- Do not spray for surface disinfection; wipe instead.
- Only use wiped areas after the time required for the disinfecting agents to take effect has passed and the surfaces have fully dried.

7.3 Preventive Maintenance

WARNING

SHOCK AND BURN HAZARD

⚠

Disconnect all utilities to lighting fixture before servicing. Do not install the lighting fixture unless all utilities have been properly locked out. Always follow OSHA Lockout-Tagout and electrical safety-related work practice standards.

WARNING

ELECTRIC SHOCK HAZARD

⚠

- Do not remove covers or perform service other than as described in this operator manual. Refer servicing to qualified service personnel.
- The OFF position on the system ON/OFF touch pad of the wall control turns off control to camera and lightheads, but system is still energized. This mode is referred to as STANDBY, and the ON/OFF LED flashes once per second while system is in this mode.

WARNING

PERSONAL INJURY HAZARD AND/OR EQUIPMENT DAMAGE HAZARD

⚠

- Do not attempt to clean lighthead unless lighthead is turned off and has cooled sufficiently.
- Do not attempt to adjust suspension system. Refer servicing to qualified service personnel.
- No part of this system shall be serviced while in use with a patient.

---

1. Regular service and maintenance MUST be performed only by STERIS or a STERIS-trained technician. Any work performed by inexperienced or unqualified persons or the installation of unauthorized parts could cause personal injury, invalidate the warranty or result in costly damage.
2. Under no circumstances should this equipment be serviced without the Maintenance Manual. The Maintenance Manual can be purchased by contacting STERIS Customer Service.
3. A detailed Preventive Maintenance schedule and replacement parts list can be found in the Maintenance Manual. The Maintenance Manual can be purchased by contacting STERIS Customer Service.
4. Preventive Maintenance is essential in keeping this equipment in optimal working condition. STERIS recommends establishing an annual maintenance agreement with STERIS service.
5. Preventive Maintenance and regular service must be performed according to the Maintenance Manual in order to comply with the requirements for essential performance and compliance with electromagnetic compatibility.

   IMPORTANT: *Use only authorized STERIS replacement parts when conducting any maintenance on the equipment.*

NOTE: Refer to the HarmonyAIR ALYON Surgical Lighting System Installation Instructions (11041489) and HarmonyAIR ALYON Surgical Lighting System Maintenance Manual (764340522) to safely replace components.

7.4 Inspect Suspension

Start at the highest point on the suspension, and work out toward the lightheads on each suspension arm. Verify proper operation of each braking point. If necessary, adjust each of the brakes in turn, with the goal of eliminating both binding and drift in the system. Refer to Maintenance Manual, if necessary.

7.5 Inspect Wall Control

1. Cycle through intensity cycle for each lighthead controlled by the system.
   - Verify the number of lightheads on system matches number of lighthead identified by wall control.
   - Verify function of lightheads with wall control commands.
   - Verify function of all video camera commands if system is equipped with a camera.

Troubleshooting

8.1 Troubleshooting

Introduction

WARNING

PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD

⚠ Repairs and adjustments to this equipment should be made only by fully qualified service personnel. Maintenance performed by inexperienced, unqualified personnel or installation of unauthorized parts could cause personal injury, invalidate the warranty or result in costly equipment damage. Contact STERIS Service regarding service options.

⚠ Do not attempt to clean lighthead/monitor unless power is turned off and the lighthead/monitor has cooled sufficiently.

⚠ Do not attempt to adjust suspension system. Refer servicing to qualified service personnel.

Use the following Troubleshooting Chart to identify problems with the surgical lighting system. The chart also offers probable causes and corrections to problems that may occur.

If you are unable to correct the problem with this Troubleshooting Chart, or if a problem occurs that is not described on the chart, please contact STERIS. A representative will arrange to have your equipment promptly put into working order by a STERIS-trained service representative. **Never permit unqualified persons to service the lightheads, suspension arms, or electronic system components.**

IMPORTANT: *Refer to separate operating and troubleshooting instructions supplied with monitor(s).*

Fault Display

System faults may be indicated in two locations.

1. Back lit (+) and (-) control buttons pulse/flash to indicate a fault condition that results in loss of essential performance.
2. Wall Control screen displays a fault icon in the top right of the screen to indicate a fault condition. See *Figure 8-1*. The fault may indicate communication problems, software incompatibility, disabled non-essential functions because of a fault condition, or loss of essential performance.



Figure 8-1. Wall Control Fault Icon

Wall Control Fault Log Indications

The wall control is capable of displaying fault messages. Fault messages, for the most part, are intended for use by trained STERIS service technicians. An operator not trained in servicing this equipment can provide fault message information to STERIS when communicating a service issue. A summary of faults that can appear in the fault log is given in *Table 8-1*.

IMPORTANT: *Refer any problems with 'yes' listed under the Service Required column to STERIS. Also, '#' indicates a numeric value on the display.*

Table 8-1. Wall Control Fault Indications

Fault Message	Description	Service Required
System configuration change detected	When system is powered up, detected configuration is different than configuration that was previously accepted as being correct.	Yes
Invalid Lighthead Configuration. Contact Service	One or more lightheads are plugged into an incorrect connector on hub breakout board(s)	Yes
Invalid Lighthead # assembly	Control boards in a lighthead are not all compatible (# is a lighthead number between 1 and 4).	Yes
System firmware incompatibility, update system firmware	Firmware on a control board does not support detected revision of control board hardware.	Yes
System primary DC power output # failure	Power combiner output voltage is below power failure threshold. (# is Power combiner primary output A or B)	Yes
Power supply # failure	Voltage of one of the system power supplies is below power failure threshold (# is a power supply number between 1 and 4).	Yes
System date/time not set	Real-time clock time and date are not set. Time and date are used when logging events and faults.	No
Master Control - Lighthead # communication failure	Master control has lost communication with a lighthead (# is a lighthead number between 1 and 4).	Yes
Lighthead # handle button stuck	One of the buttons on handle or camera module is stuck in pressed position (# is a lighthead number between 1 and 4).	No

Table 8-1. Wall Control Fault Indications (continued)

Fault Message	Description	Service Required
Lighthead # yoke button stuck	One of the buttons on lighthead yoke is stuck in pressed position (# is a lighthead number between 1 and 4).	No
Lighthead # distance sensor # failure	An LED module in a lighthead has lost communication with its distance sensor (first # is a lighthead number between 1 and 4, second # is an LED module number between 1 and 6).	Yes
System firmware not current, update system firmware	Deployment file on master control has different versions of firmware than firmware loaded on control boards.	Yes
Camera module firmware download failure on Lighthead #	An attempt to update firmware on camera module on a lighthead has failed (# is a lighthead number between 1 and 4).	Yes
Lighthead # firmware download failure	An attempt to update the firmware on a lighthead has failed (# is a lighthead number between 1 and 4).	Yes
Master Controller firmware download failure	An attempt to update firmware on a master controller has failed	Yes
User Interface file update failure	Updating user interface files on master control has failed.	Yes
Invalid calibration on Lighthead #	Calibration information on a lighthead is not valid (# is a lighthead number between 1 and 4).	Yes
Lighthead # - camera module failure	A lighthead has lost communication with camera module that is installed in the lighthead or camera module cannot communicate with internal camera (# is a lighthead number between 1 and 4).	No
UI to MC Communication Failure	UI has lost communication with master control	Yes
Hardware mismatch, system contains fixed and adjustable color lightheads	System has detected both ALYON and ALYON ACT Lightheads connected to the same wall control.	Yes

8.2 Auto Intensity Is Not Working

Condition

Light intensity does not update after pattern change is made.

General Troubleshooting	Additional Information
Intensity issue or sensor issue.	1. Contact STERIS.

8.3 Camera Communication Failure

Condition

Previously installed camera has stopped communicating with lighthead board.

General Troubleshooting	Additional Information
Previously installed camera issue.	1. If available, try camera in another OR room, or another camera. 2. Contact STERIS.

8.4 Camera Module/Lighthead/Master Controller Firmware Download Failure

Condition

Firmware cannot be downloaded from micro SD card.

General Troubleshooting	Additional Information
Firmware cannot be downloaded.	1. Contact STERIS.

8.5 CANBUS Error

Condition

Bad communication scenario between lighthead and master control (reported by lighthead).

General Troubleshooting	Additional Information
Communication scenario between lighthead and master control issue.	1. Contact STERIS.

8.6 Distance Sensor Failure

Condition

Distance sensor shows no connection or shorted internally.

General Troubleshooting	Additional Information
Distance sensor issue.	1. Contact STERIS.

8.7 Invalid Calibration

Condition

Calibration values are corrupt from factory values.

General Troubleshooting	Additional Information
Calibration issue.	1. Contact STERIS.

8.8 Light Does Not Turn On

Condition

No response from wall control or lightheads.

General Troubleshooting	Additional Information
Possible malfunctions at wall control.	1. Contact STERIS.
If lighthead cannot be turned on using surgeon controls, lighthead power has been compromised.	1. Contact STERIS.

8.9 Light Handle Button Stuck

Condition

Surgeon controls on lighthead are not working properly.

General Troubleshooting	Additional Information
Light handle issue.	1. Contact STERIS.

8.10 Light Pattern Does Not Change with Handle Rotation

Condition

Light pattern does not change diameter when light handle rotated.

General Troubleshooting	Additional Information
Hardware issue.	1. Contact STERIS.

8.11 Lighthead/Monitor/Accessory Drifts Once Set in Position and Released

Condition

The position changes from where it was set.

General Troubleshooting	Additional Information
Incorrect brake adjustment.	1. Contact STERIS.
Central hub not level.	1. Contact STERIS.

8.12 Low Light Output

Condition

Various electrical and mechanical conditions may contribute to low light output.

General Troubleshooting	Additional Information
Light intensity setting.	1. Verify wall control fault icon is not present on wall control touchscreen. 2. Verify light intensity is set at intended setting. 3. Verify auto intensity is set at intended setting at wall control light setting. 4. If the problem persists, contact STERIS.

8.13 Master Controller - Lighthead Communication Failure

Condition

Master control board issue.

General Troubleshooting	Additional Information
The master control board has lost communication with at least one lighthead.	1. Turn ON lighthead from surgeon controls. 2. Verify lighthead is getting power. 3. Contact STERIS.

8.14 Monitor Does Not Operate As Expected

Condition

Monitor image may be blank or distorted.

General Troubleshooting	Additional Information
Monitor parameters may be incorrect.	1. Read operator manual for applicable monitor. Verify proper settings. 2. If the problem persists, contact STERIS.

8.15 Poor Light Pattern

Condition

Mechanical problem with pattern change mechanism.

General Troubleshooting	Additional Information
Lighthead issue.	1. Contact STERIS.
LED misalignment on lighthead cover.	1. Contact STERIS.

8.16 Poor Video Image Quality

Condition

Loss of all or partial video signal due to cable degradation.

General Troubleshooting	Additional Information
Settings or signal issue.	1. Contact STERIS.

8.17 Power Supply Failure

Condition

One of the dc power supplies has stopped working.

General Troubleshooting	Additional Information
DC power supply stopped working.	1. Contact STERIS.

8.18 Pulse-Width Modulation (PWM) Security Is Active

Condition

Calibration values are corrupted or a lighthead board hardware failure.

General Troubleshooting	Additional Information
Calibration issue or lighthead board hardware issue.	1. Contact STERIS.

8.19 Rotary Handle Failure

Condition

Position sensor(s) inside lighthead failed.

General Troubleshooting	Additional Information
Position sensor(s) inside lighthead issue.	1. Contact STERIS.

8.20 SD Card Not Detected

Condition

Master controller detects no SD card present.

General Troubleshooting	Additional Information
SD card issue.	1. Contact STERIS.

8.21 System Battery Power Failure

Condition

Battery power being supplied by hospital has failed.

General Troubleshooting	Additional Information
Battery power being supplied by hospital issue.	1. Contact STERIS.

8.22 System Date/Time Not Set

Condition

System time and date not set.

General Troubleshooting	Additional Information
System time and date issue.	1. Set system time and date per operators manual. 2. Contact STERIS.

8.23 System Firmware Mismatch/Incompatible

Condition

System firmware mismatch/incompatible

General Troubleshooting	Additional Information
Firmware issue.	1. Contact STERIS.

8.24 Temporary Loss of Light Function or Camera Operation

Condition

Light or monitor may temporarily drop out when other equipment is used in operating room.

General Troubleshooting	Additional Information
Other equipment in OR causing interference.	1. Isolate which exterior equipment causes loss of light or camera signal. 2. Remove or relocate exterior equipment to minimize interference. 3. If the problem persists, contact STERIS.

Replacement Parts

The parts listed in this section are necessary to repair this unit in most instances.

Table 9-1. Recommended Spare Parts

Description	Part Number
Brake Screw, Lighthead/Yoke Connection	10095937
Brake Screw, Lighthead Yoke	580002037
Single Use LOCTITE®[2] 242	P129377-290
Non-Sterilizable Handle, Surgeon Control	LAS0042
Sterilizable Surgeon Control Handle	LB23
A-Series Light Handle (Sterilizable)	LAS0027 (Requires Item 10098927)
Handle Core Assembly	10098927 (Requires Item LAS0027)
A-Series Adapter for LB22 Sterilizable Handle	LAS0039 (Requires Item LB22)
Sterilizable Handle, Aluminum, Non-Surgeon Control	LB22 (Requires Item LAS0039)
Disposable Sterile Cover for Light Handle	LB53
ALYON HD Camera	LYH1007
Sterilizable Silicone Handle Cover	LAS0036
Sterile Light Handle Covers (Case)	LB83
Sterile Universal Handle Covers (Case)	LB82
Sterile HD Camera Handle Covers (Case)	LB84
Disposable Sterile Cover for Camera	LB54

2. LOCTITE® is a registered trademark of Henkel Corporation.

Appendix

10.1 EMC Compliance Technical Data

The HarmonyAIR ALYON Surgical Lighting System requires special precautions regarding EMC and need to be installed and put into service according to the EMC information provided in these accompanying documents.

WARNING

PERSONAL INJURY AND/OR POSSIBLE EQUIPMENT DAMAGE HAZARD

⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12”) to any part of the HarmonyAIR ALYON Surgical Lighting System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ A risk of increased emissions or decreased immunity may result if any additional cables are attached.

⚠ This device has not been tested for compatibility with all other potential RF Emitters such as X-ray, Metal Detectors, Electrosurgical Equipment, Diathermy Equipment, 5G Cellular, NFC, WPT, or Electronic Article Surveillance (EAS) devices. Caution should be used if such emitters are present within the use environment.

⚠ 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.

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

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

<table>
<tr><td colspan="3">The HarmonyAIR ALYON Surgical Lighting System is intended for use in the electromagnetic environment specified below. The Customer or the user of the HarmonyAIR ALYON Surgical Lighting System should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions Test</td><td>Compliance</td><td>Electromagnetic environment – Guidance</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The HarmonyAIR ALYON Surgical Lighting System 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.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class A</td><td rowspan="3">The HarmonyAIR ALYON Surgical Lighting System 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

PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD

⚠ 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 HarmonyAIR ALYON Surgical Lighting System or shielding the location.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The HarmonyAIR ALYON Surgical Lighting System is intended for use in the electro-magnetic environment specified below. The Customer or the user of the HarmonyAIR ALYON Surgical Lighting System should assure that it is used in such an environment.			
Immunity Test	IEC 60601 4th Edition Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±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%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	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	±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 in-put lines IEC 61000-4-11	0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% UT, 25/30 cucles Single phase: at 0° 0% U_T; 250/300 cycle	0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% UT, 25/30 cucles Single phase: at 0° 0% U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HarmonyAIR ALYON Surgical Lighting System requires continued operation during power mains interruptions, it is recommended that the HarmonyAIR ALYON Surgical Lighting System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 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.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The HarmonyAIR ALYON Surgical Lighting System is intended for use in the electro-magnetic environment specified below. The Customer or the user of the HarmonyAIR ALYON Surgical Lighting System should assure that it is used in such an environment.			
Immunity Test	IEC 60601 4th Edition Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 0.15 MHz-80MHz 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz 3 V/m 80 MHz to 2.7 GHz	3 Vrms 0.15 MHz-80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the HarmonyAIR ALYON Surgical Lighting System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. D= (3.5/10) √P 80 MHz to 800 MHz D= (7/10) √P 800 MHz to 2.7 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: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
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 HarmonyAIR ALYON Surgical Lighting System is used exceeds the applicable RF compliance level above, the HarmonyAIR ALYON Surgical Lighting System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HarmonyAIR ALYON Surgical Lighting System.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The HarmonyAIR ALYON Surgical Lighting System is intended for use in the electromagnetic environment specified below. The Customer or the user of the HarmonyAIR ALYON Surgical Lighting System should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level			Compliance Level			Electromagnetic Environment – Guidance
IMMUNITY to proximity fields from RF wireless communi-cations equipment	MHz	Modulation	Field Strength	MHz	Modulation	Field Strength	Portable and mobile RF communications equipment should be used no closer to any part of the HarmonyAIR ALYON Surgical Lighting System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $E = [6/d] \sqrt{P}$ $d = [6/E] \sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
	385	18 Hz	27 V/m	385	18 Hz	27 V/m	
	450	18 Hz	28 V/m	450	18 Hz	28 V/m	
	710	217 Hz	9 V/m	710	217 Hz	9 V/m	
	745	217 Hz	9 V/m	745	217 Hz	9 V/m	
	780	217 Hz	9 V/m	780	217 Hz	9 V/m	
	810	18 Hz	28 V/m	810	18 Hz	28 V/m	
	870	18 Hz	28 V/m	870	18 Hz	28 V/m	
	930	18 Hz	28 V/m	930	18 Hz	28 V/m	
	1720	217 Hz	28 V/m	1720	217 Hz	28 V/m	
	1845	217 Hz	28 V/m	1845	217 Hz	28 V/m	
	1970	217 Hz	28 V/m	1970	217 Hz	28 V/m	
	2450	217 Hz	28 V/m	2450	217 Hz	28 V/m	
	5240	217 Hz	9 V/m	5240	217 Hz	9 V/m	
	5500	217 Hz	9 V/m	5500	217 Hz	9 V/m	
	5785	217 Hz	9 V/m	5785	217 Hz	9 V/m	
	0.1342	2.1 kHz	65 A/m	0.1342	2.1 kHz	65 A/m	
	13.56	50 kHz	7.5 A/m	13.56	50 kHz	7.5 A/m	
	0.030	CW	8 A/m	0.030	CW	8 A/m	
Proximity magnetic fields IEC 61000-4-39	65 A/m at 134.2 kHz, 2.1 kHz Pulse Modulation 7.5 A/m at 13.56 MHz, 50 kHz Pulse Modulation			65 A/m at 134.2 kHz, 2.1 kHz Pulse Modulation 7.5 A/m at 13.56 MHz, 50 kHz Pulse Modulation			Proximity magnetic fields should be that of a typical commercial or hospital environment.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment and the HarmonyAIR ALYON Surgical Lighting System.

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	80 to 800 MHz d = [3.5/3] √P	800 to 2.7 GHz d = [7/3] √P	710, 745, 780, 5240, 5500, 5785 MHz d = [6/9] √P	385, 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz d = [6/28] √P
0.01	0.117	0.233	0.067	0.021
0.1	0.369	0.738	0.211	0.070
1	1.170	2.333	0.667	0.214
10	3.689	7.379	2.108	0.700
100	11.667	23.333	6.670	2.143

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: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.