



Ronin X Series Surgical Headlights & Ronin X Series Chargers

Instructions for Use (IFU)

Caution: Thoroughly read all instructions prior to operating the devices.
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Ronin X Series Diagram



1. DESCRIPTION

The Ronin X Series Surgical Headlight provides supplemental high intensity illumination to aid visualization in a surgical and clinical setting. The headlight consists of a head mounted luminaire, a hip mounted battery holster, and Ronin approved battery packs. Available battery packs vary in energy capacity and physical dimensions. The luminaire is connected to the battery holster via a cable, and the battery holster can be loaded with a desired battery variant. The diameter of the illuminated spot can be adjusted at the luminaire using the spot diameter adjustment knob. Power and LED intensity can be adjusted at the battery holster using the ON/OFF switch and dimming knob respectively. A Ronin approved power supply is provided. Use only Ronin approved batteries and power supplies.

Additional information and replacement parts can be found at www.RoninSurgical.com

2. INDICATION FOR USE

Ronin X Series Surgical Headlights are intended to supply supplemental high intensity illumination to aid visualization in a surgical or clinical setting.

3. CONTRAINDICATIONS

The Ronin X Series Surgical Headlight is contraindicated for use in neonatal transillumination, ophthalmic procedures, or with heat or photosensitive surfaces/patients, including but not limited to those who have received photosensitizing agents such as hematoporphyrin derivatives.

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

4. INSTALLATION (For Charger Only)

Installation should ONLY be done by persons with proper authorization, professional licensing, and liability protection.

The X Series Supercharger, or an array of X Series Superchargers, must not be installed in direct sunlight or on insulative or heat sensitive surfaces as excess heat may accumulate and cause a risk of burn or fire.

The charger may be positioned on a desk or flat surface. Some charger models are equipped with a mounting plate with pre-drilled holes, which permits fastening via screws to any suitable wall or flat surface. **FOR MOUNTING USING SCREWS OR OTHER WALL PIERCING FASTENERS installation MUST ONLY be done by a person with proper authorization, professional licensing, and liability protection.** The installation professional must ensure avoidance of, and damage to, potentially hidden components behind the wall or other surface including but not limited to: liquid or gas pipes, electrical tubing or wiring, HVAC piping or ducting, water and sewer piping, fire alarm or fire suppression components, electronics, and any equipment that may be in direct or indirect connection to any of the above. It is the responsibility of the professional to ensure the device is properly secured to avoid the device detaching during normal use, which may cause damage to the device or harm to any persons nearby.

RONIN IS NOT LIABLE for either anticipated or unanticipated effects on any surfaces, buildings, equipment, property or people resulting directly or indirectly from the installation of any Ronin product.

During installation:

Be sure the device is disconnected from wall power during installation.

For power supplies with housing bodies that plug directly into a wall outlet (not via an AC cable) ensure that the power supply is accessible. This is CRITICAL if the chosen array or installation limits access to the DC electrical plug connected to the device. In case of emergency, staff must be able to terminate power to the device by disconnecting the unit from wall power.

For power supplies with both an AC Cable side and DC Cable side ensure that at least one end of the AC power cable (the cable running from the power supply body to the wall outlet) is accessible. This is CRITICAL if the chosen array or installation limits access to the DC electrical plug connected to the device. In case of emergency, staff must be able to terminate power to the device by disconnecting the unit from wall power.

For installation using screws or other wall piercing fasteners, select an appropriate fastener and anchor for the given surface. Use as many of the predrilled fastener holes in the metal backing plate as is required to securely hold the device. Be sure to account for the weight of the batteries,

power supply, and maximum mechanical force applied by users during use or that the device may endure during unanticipated forces such as earthquakes.

DO NOT drill any additional holes in the charger mounting plate or device.

DO NOT drive any screws through any part of the charger other than the holes of the provided mounting plate.

5. NORMAL USE

The user should carefully study the Instructions for Use (IFU) before using the X Series Surgical Headlight. Instructions should be followed, with special attention given to warnings, precautions, controls, and user specifications.

The IFU should be made available to appropriate personnel. This IFU contains information about the proper procedures for preparing this product for its use and care.



WARNING: DO NOT use the Ronin X Series Headlight at a distance of less than 12 inches (30 cm) measured from the end of the luminaire to any illuminated surface. It is the responsibility of the user to ensure proper use of the headlight and monitor whether use of the emitted light is causing any desiccation, singe, burn, fire or other harmful effects at the surface.



WARNING: Before every use the X Series Surgical Headlight System **MUST** be carefully inspected to ensure it has been properly maintained, cleaned, and is fully functional. **DO NOT** use if inspection reveals any debris, or damaged or loose parts or pieces. Failure to do so could result in hazards including burn, fire, shock, or contamination. Contact Ronin at +1 (415) 226-9414 or email Ronin at Support@RoninSurgical.com for repair and replacement.



WARNING: Risk of burn or fire if device is not turned OFF at the end of use. The Operator **MUST** turn the holster switch to OFF, and/or remove the battery, and/or disconnect the Luminaire from the holster, even if it appears that the battery is fully depleted. A depleted Lithium Ion battery, like most chemical batteries, has the ability to partially recharge without the addition of external power. This may cause the device to illuminate without notice and remain illuminated until the battery is again depleted.

See IFU section WARNINGS AND PRECAUTIONS for further detail on the above points in addition to other important information.

Ronin X Series Surgical Headlights are intended to supply supplemental high intensity illumination to aid visualization in a surgical or clinical setting.

Suggested use is to first don the battery holster, then the luminaire with the links in a compressed upside down “U” configuration. Load a Ronin approved battery logo-side out. After the luminaire and battery holster are comfortably adjusted, bring the luminaire down between the eyes, positioning it as close to the bridge nose as possible to create light coaxial to the eyes.

The supplied links support compatibility with variable surgical needs including face shields and loupes. Do not operate with the links fully extended to avoid bumping heads with another surgeon, to reduce mechanical shaking, and to achieve the greatest safe working distance to the surface.

Turn the power switch from OFF to ON, then adjust the position of the luminaire, illumination angle, distance from desired surface, spot size, and LED intensity to produce the desired illumination. For more detailed instructions see the Instructions for Use (IFU) section OPERATING INSTRUCTIONS (NORMAL MODE OPERATION)

Headlight must be properly turned off and/or disconnected from power following use. **See IFU section WARNINGS AND PRECAUTIONS for further detail.**



WARNING: Once a battery has been fully charged remove it from the charger. Failure to do so could result in hazards including burn, fire, shock, or contamination.

To charge a battery, insert the battery with the logo side facing the front of the charger and make sure the battery connectors on both the charger and battery are aligned. It can take up to 30 seconds for the indicator lights on the charger to illuminate. Orange indicates charging. Green indicated fully charged. Remove the battery from the charger once it has been fully charged.

See IFU section WARNINGS AND PRECAUTIONS for further detail.

6. UNPACKING THE UNIT

Remove the unit from its container and properly dispose of any packaging material. Batteries may be shipped separate from the unit to comply with shipping regulations.

7. WARNINGS AND PRECAUTIONS

WARNINGS are used to signal potential hazards which could lead to death or serious injury.

PRECAUTIONS are used to warn of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or damage to the equipment or other property.

Warnings



- The user should carefully study the Instructions for Use (IFU) before using the X Series Surgical Headlight. Instructions should be followed, with special attention given to warnings, precautions, controls, and user specifications. The IFU should be made available to appropriate personnel.



- This IFU contains information about the proper procedures for preparing this product for its use and care.



- **WARNING:** Before every use the X Series Surgical Headlight System **MUST** be carefully inspected to ensure it has been properly maintained, cleaned, and is fully functional. **DO NOT** use if inspection reveals any debris, or damaged or loose parts or pieces. Failure to do so could result in hazards including burn, fire, shock, or contamination. Contact Ronin

at +1 (415) 226-9414 or email Ronin at Support@RoninSurgical.com for repair and replacement.



- **WARNING:** Risk of burn or fire if device is not turned OFF at the end of use. The Operator **MUST** turn the holster switch to OFF, and/or remove the battery, and/or disconnect the Luminaire from the holster, even if it appears that the battery is fully depleted. **A depleted Lithium Ion battery, like most chemical batteries, has the ability to partially recharge without the addition of external power. This may cause the device to illuminate without notice and remain illuminated until the battery is again depleted.**



- **WARNING:** DO NOT use the Ronin X Series Headlight at a distance of less than 12 inches (30 cm) measured from the end of the luminaire to any illuminated surface. It is the responsibility of the user to ensure proper use of the headlight and monitor whether use of the emitted light is causing any desiccation, singe, burn, fire or other harmful effects at the surface.



- **WARNING:** RISK OF BURN OR FIRE FROM EMITTED PHOTONIC ENERGY. The Operator, in their professional judgment, **MUST** determine and observe a safe brightness setting, distance to the illuminated surface, and duration of time illuminating the surface, for the given circumstances, variables, conditions and unique surface/patient sensitivities.



- **WARNING:** Operator **MUST** take into account variation in surface temperature rise from factors including but not limited to: additional sources of energy, starting surface temperature, surface light absorbance/reflectance, surface thermal conductivity/capacitance, and surface conditions/preparations such as chemicals or moisture.



- **WARNING:** Operator **MUST** take into account usage circumstances, conditions, variables, and unique surface/patient sensitivities that cannot be anticipated here, including but not limited to chemical, genetic, pharmacological, photosensitivity, thermal sensitivity, and preexisting conditions, **each of which may make even typical safe working distances unsuitable and potentially unsafe.**



- **WARNING:** Use only enough light for good visualization. Avoid prolonged close stationary illumination of tissue to reduce the risk of burn or thermal injury.



- **DO NOT** use previous experience with other headlight models or illumination technologies when determining the safe usage of the Ronin X Series Headlight with regard to working distance, light intensity, and surface illumination duration. Please read these instructions, as each light source has different operating and use instructions.



- **WARNING:** ULTIMATELY IT IS SOLELY THE OPERATOR'S RESPONSIBILITY TO ENSURE SAFE USAGE OF THE DEVICE.



- **WARNING:** During peak charging, the enclosure of the power supply may get very hot to the touch. If the outside of the power supply is uncomfortable to touch, (a) allow it to cool by waiting for the batteries to fully charge, or (b) disconnect the batteries and allow the charger to cool before touching or holding the power supply.



- **WARNING:** During normal use, the luminaire, holster, battery, and charger may be very warm to the touch, but never uncomfortable. Any level of significant discomfort is NOT normal. If unit is uncomfortably warm, immediately stop using the Ronin X Series Surgical Headlight System and report the issue to Ronin customer service at +1 (415) 226-9414 or email Support@RoninSurgical.com



- **WARNING: DO NOT** charge a lithium ion battery that has been in a fully depleted, uncharged, or "dead" state for a period of 6 months or more. Dispose of the battery safely



per local regulations and contact Ronin for replacement. Failure to do so could result in hazards including burn, fire, shock, or contamination.

- **WARNING:** Once a battery has been fully charged remove it from the charger. Failure to do so could result in hazards including burn, fire, shock, or contamination.
- **WARNING:** Safely dispose of all Ronin lithium ion batteries 5 (five) years from date of receipt. Failure to do so could result in hazards including burn, fire, shock, or contamination.
- In a single fault condition, the temperature of the luminaire, holster, charger and batteries can get hot, creating a possible risk of a burn if touched.
- The luminaire inlet and outlet air vents **MUST** be adequately ventilated in open air and free of obstructions to allow proper cooling of the device.
- While powered, the luminaire, holster, and charger **MUST NOT** be placed or installed on a thermally insulative surface and **MUST** be in a well ventilated open air environment away from external heat sources to allow for proper cooling. Otherwise, excessive heat may accumulate and could result in permanent damage to the equipment, excessive temperatures, or fire.
- No modification of this equipment is permitted, unless as specifically instructed by Ronin.
- **DO NOT** open the enclosure. The X Series Surgical Headlight System has no serviceable parts. Opening the device enclosure voids the warranty and creates a risk of shock, burn, or fire. Please contact Ronin at +1 (415) 226-9414 or email Ronin at Support@RoninSurgical.com for repair and replacement.
- **DO NOT** insert anything into, tamper with, or open any sealed or assembled components of the Ronin X Series Surgical Headlight. There are precisely installed safety components and electrically live circuits. Slight alterations or interference can result in permanent damage to the equipment, excessive temperatures, burn, fire or electrical shock. Maintenance should be limited to following cleaning instructions as indicated by Ronin. Please contact Ronin at +1 (415) 226-9414 or email Ronin at Support@RoninSurgical.com for repair and replacement.
- **DO NOT** use the X Series Surgical Headlight System in wet environments or expose it to water or liquids. It **IS NOT** sealed or designed for water resistance or fluid ingress.
- To reduce the risk of fire and electric shock, **DO NOT** expose electrical equipment to moisture. When cleaning, do not immerse any electrical device in liquid.
- **DO NOT** store or use liquids of any type on or above the X Series Surgical Headlight System.
- **DO NOT** press on the fan blades to avoid damaging or cracking them.
- In a fault condition the light may suddenly and without notice cease to produce light. The user is responsible for ensuring that interruption of light output does not create an unacceptable risk. If such a determination is made, alternate arrangements (such as a standby headlight) should be made by the user to reduce the risk.
- When moving while wearing the X Series Surgical Headlight System use precaution to avoid catching headlight components on anything that could suddenly pull the device away from the user's body resulting in either harm to the device or user.
- Care should be taken if the equipment is used simultaneously or adjacent to other equipment; if simultaneous or adjacent use is inevitable, the equipment should be observed to verify normal operation prior to use.
- Follow the instructions of other manufacturers' equipment when used in conjunction with this product.

- **Explosion: DO NOT** use the Ronin X Series Surgical Headlight in oxygen-enriched environments or environments with flammable anesthetics, liquids, vapors, gases or dusts.
- **DO NOT** allow the emitted high intensity light to shine directly into eyes as it may cause permanent damage.
- **DO NOT** use the X Series Surgical Headlight System in ocular surgery or in a surgical procedure requiring direct illumination of the eye.
- **Unattended use** of the X Series Surgical Headlight System by children or persons not familiar high intensity surgical headlights may be dangerous.
- **DO NOT** use this device in a magnetic resonance (MR) environment or in any environment where MRIs are used.
- **DO NOT** sterilize the X Series Surgical Headlight System by placing the device in an autoclave or other sterilizer. This device should only be cleaned as instructed in IFU section CLEANING.
- Safety precautions **MUST** always be exercised when using electrical equipment to prevent operator/patient shock, fire hazard or equipment damage.
- **DO NOT** allow persons, devices, or sensitive surfaces beneath the charger installation to avoid physical harm or contamination. When charger is installed on a wall or elevated surface, due to improper installation, improper use, or material failure, the charger or batteries may unexpectedly detach and/or fall. See IFU section INSTALLATION for further detail.
- **DO NOT** drill any additional holes in the charger mounting plate.
- **DO NOT** drive any screws through any part of the charger other than the holes of the provided mounting plate.
- During charger installation, ensure that the power supply body or at least one end of the AC power cord (if equipped) is accessible. This is CRITICAL if the chosen array or installation blocks access to the DC barrel jack. In the case of emergency, staff must be able to terminate power to the device by unplugging the unit from the wall.
- Use **ONLY** Ronin approved power supplies and batteries (U80507, U80510, RK0320-M, RK0321-M as of this IFU revision) with this device. Contact Ronin for the most up to date list of approved batteries and power supplies.
- **DO NOT** use defective, damaged, or unauthorized batteries or power supplies. They can pose a risk of electric shock, burn, fire, and explosion. If the battery or power supply shows any signs of damage, leakage, or cracking, it must be replaced immediately, and only with a Ronin approved battery or power supply.
- Battery **MUST** be inserted so that that the 5-pin connector in the holster or charger mates with the 5 slots on the battery. **DO NOT** force battery during mating as misaligned pins may damage the battery or the device and may result in risk of electrical shock, burn, or fire.
- Improper handling of the battery can lead to heat generation, smoke, bursting, or fire.
- **DO NOT** drop the device or any of its components as it may damage or break the device. This may cause unexpected behavior and potential for fire, burn, shock, or contamination.
- **DO NOT** remove the label from the battery.
- **DO NOT** immerse the battery in water or other liquids.
- **DO NOT** charge or use batteries with non approved Ronin devices.
- **DO NOT** disassemble or modify the battery.
- **DO NOT** directly connect or short-circuit the positive (+) and negative (-) battery terminals.

- To avoid short circuits, keep battery terminals away from metal objects.
- **DO NOT** expose the battery to temperatures higher than 49°C/120°F.
- While not in use, during storage, and during shipping, the battery **MUST** be removed from the battery holster to ensure that the LED is not accidentally powered on, which could result in permanent damage to the equipment, excessive temperatures, or fire.
- For Shipping and Transport of Lithium Ion batteries (most critically for Air Shipping and Air Transport), the most up to date regulations of the Common Carrier (UPS, FedEx, USPS, etc.) and local and federal authorities **MUST** be strictly adhered to. Violation of these regulations, either knowingly or unknowingly, may constitute a felony. See the IFU section BATTERY STORAGE, TRANSIT, AIR TRAVEL AND SHIPPING for more information on proper shipping and transport. **IF A CUSTOMER BREAKS TRANSPORT LAWS RONIN ASSUMES ZERO LIABILITY.** Improper disposal of batteries may create an explosion or contamination hazard. Never dispose of batteries in refuse containers. Do not dispose of the battery in fire. Always recycle batteries according to local regulations.
- For shipping and transport ensure the battery terminal is securely taped or access is otherwise blocked to prevent accidental short circuit of the positive (+) and negative (-) battery terminals.
- To ensure patient and operator safety and optimal product performance, use only recommended accessories and supplies with the system according to the IFU. Use of accessories 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.
- The X Series Surgical Headlight System complies with applicable domestic and international standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using the device in close proximity to other equipment.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the X Series Surgical Headlight System, including cables specified by Ronin. Otherwise, degradation of the performance of this equipment could result.

Precautions

- CAUTION: Use only cleaning agents and chemicals identified by Ronin as suitable for use on the Ronin X Series Headlight system and related accessories. Use of alternative cleaning agents may cause harm to the product. See IFU section CLEANING for appropriate cleaning agents.
- CAUTION: To prevent damage to the cable or connector components, **DO NOT** hold, carry, plug or unplug the unit by any of its cables.
- CAUTION Immediately stop using the Ronin X Series Surgical Headlight and report any significant user discomfort or issues with the unit to Ronin customer support at +1 (415) 226-9414 or email Ronin at Support@RoninSurgical.com
- CAUTION: Do not operate with the links fully extended to avoid bumping heads with another surgeon, reduce mechanical shaking, and to achieve the greatest safe working distance to the surface.
- CAUTION: When moving while wearing the X Series Surgical Headlight System use precaution to avoid inadvertently contaminating sterile or sensitive surfaces.

- CAUTION: Do not allow the user's hair to enter the luminaire vent housing or fan assembly to avoid harm to the user or device.
- If the LED does not turn off when the power switch is in the OFF position, remove all power sources and contact Ronin for service.
- Luminaire links may be tightened or loosened by hand or with an appropriate tool to produce a desired retention force. **DO NOT** overtighten as it may damage the device.
- If the fan is not spinning while the LED is illuminated, unplug the luminaire, remove all power sources and contact Ronin for service.
- If the fan is making unexpected noise or vibration contact Ronin for service.
- Although firmware based thermal safeguards are in place, the luminaire is also equipped with a thermal fuse as a fail-safe against excessive temperatures. If the unit is operated without proper ventilation or experiences a fault condition the fuse may trip (open-circuit) and the luminaire will need to be returned to Ronin for service. The thermal fuse is never intended to trip during normal use.

8. IMPORTANT SAFETY INFORMATION

ENVIRONMENT

Temperature:	Operating Environment:	50°F (10°C) to 85°F (30°C)
	Storage:	32°F (0°C) to 140°F (60°C)
Relative Humidity:	Operating Environment:	30 to 75% rH non-condensing
	Storage:	10 to 95% rH non-condensing
Atmospheric Pressure:	Operating Environment:	700 to 1060hPa
	Storage:	500 to 1060hPa

- For continued protection against risk of fire and shock, only use the unit with Ronin provided power supplies.
- Do not store the Ronin X Series device in direct sunlight.
- Do not use outdoors in the rain, snow, or underwater.
- Read all instructions thoroughly before using the Ronin X Series Surgical Headlight.
- **ONLY** Ronin approved batteries U80507, U80510, RK0320-M, RK0321-M (as of this IFU revision). Please contact Ronin for the most up to date list of approved batteries.
- Both the power supply connector and battery are the main power disconnect devices for the Ronin X Series surgical headlight. If the LED does not turn off when the ON/OFF rocker switch is OFF or a malfunction is suspected, both unplug the power supply from the wall and remove the battery from the battery holster. During installation, ensure that at least one end of the AC power cord (the cord running from the Power Supply brick to the wall outlet) is accessible.
- This device complies with Part 18 of the FCC Rules, as well as international electromagnetic compatibility requirements. Operation is subject to the following two conditions:
1) This device may not cause harmful interference. 2) This device must accept any interference received, including interference that may cause undesired operation.
These limits are designed to provide reasonable protection against harmful interference in a commercial installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment causes interference with radio or television reception,

which can be determined by turning the equipment off and on, you are encouraged to try to correct the interference by one or more of the following measures:






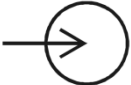

- Reorient the receiving antenna.
- Relocate the system with respect to the receiver.
- Move the system away from the receiver.
- Plug the system into a different outlet so that the system and the receiver are on different branch circuits.







CONTACT INFORMATION

Manufacturer:
RONIN SURGICAL CORP.

Phone: +1 (415) 226-9414
web: www.RoninSurgical.com
Email: Support@RoninSurgical.com

9. EXPLANATION OF SYMBOLS

Symbol	Description
	Power ON
	Power OFF
	Caution Hot Surface
	Caution: Refer to Instructions
	Stepped Variable LED Illumination Intensity
	"Aux 1" - Auxiliary Electrical Power Output
	"Remote" - Hand Operated Switch

	Read Instruction Manual
	Complies with 47 CFR Part 18 for Industrial, Scientific, and Medical Equipment
	Temperature Range (for Storage Conditions)
	Humidity Range (for Storage Conditions)
	MR Environment Unsafe
	Do Not Dispose in Trash

10.OPERATING INSTRUCTIONS (NORMAL MODE OPERATION)

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The IFU should be made available to appropriate personnel. This IFU contains information about the proper procedures for preparing this product for its use and care.



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WARNING: Risk of burn or fire if device is not turned OFF at the end of use. The Operator **MUST** turn the holster switch to OFF, and/or remove the battery, and/or disconnect the Luminaire from the holster, even if it appears that the battery is fully depleted. A depleted Lithium Ion battery, like most chemical batteries, has the ability to partially recharge without the addition of external power. This may cause the device to illuminate without notice and remain illuminated until the battery is again depleted.

See IFU section WARNINGS AND PRECAUTIONS for further detail on the above points in addition to other important information.

Don the battery holster: Connect the ends of the battery holster belt (if supplied) and adjust to desired tightness. For maximum comfort, the belt should rest loose and low across the hips, rather than higher on the waist.

The battery holster itself should be positioned over the user's right hip, over the tailbone, or any position between these two points. This range of positions allow ideal accessibility for cable connection, and unhindered battery swapping by support staff

Don the Luminaire: Position headband such that the luminaire is centered between the eyes. Adjust headband using the ratchets and straps as equipped. The headband should be snug on the head, but comfortable. Suggested use is to first don the battery holster, then the luminaire with the links in a compressed upside down "U" configuration.

Connect the Luminaire Cable: Position the keyed cable connector against the mating socket on the battery holster. Turn clockwise and counterclockwise while gently pressing downward to engage. DO NOT FORCE THE CONNECTOR. To disconnect the cable, grasp only the connector collar (not the cable) and pull upward.

Battery Selection: For use with only battery models authorized and supplied by Ronin. For a list of authorized batteries contact Ronin customer support at +1 (415) 226-9414 or email Ronin at Support@RoninSurgical.com

Battery Loading: Load battery into the battery holster with the connection terminal oriented both downward and toward the user's hip. DO NOT FORCE THE BATTERY INTO THE BATTERY HOLSTER INCORRECTLY OR IT MAY JAM OR DAMAGE THE DEVICE.

Powering the LED and Selecting Illumination Intensity: To turn LED power ON, turn the battery holster switch from OFF to ON. Then select the desired illumination intensity using the dimming knob. To turn LED power OFF, turn the battery holster switch from ON to OFF.

Luminaire Position Adjustment: Bring the luminaire down, positioning it as close to the bridge nose as possible to create light coaxial to the eyes. Do not operate with the links fully extended to avoid bumping heads with another surgeon, reduce mechanical shaking, and to achieve the greatest safe working distance to the surface.

While the LED is ON, adjust luminaire position and angle to project the desired illumination spot. Spot diameter may be increased or decreased by rotating the luminaire's lens adjustment knob within its groove.

Headlight must be properly turned off and/or disconnected from power following use. **See WARNINGS AND PRECAUTIONS section in the IFU for further detail.**

Luminaire links may be tightened or loosened by hand or with an appropriate tool to produce a desired retention force. Do not overtighten as it may damage the device.

Once the desired position and intensity settings are achieved, the user may turn the LED to OFF to conserve battery until illumination is again desired.

Battery Exhaustion During Use: If a procedure lasts longer than the battery charge allows, the unit will alert the user approximately 10 minutes and 5 minutes prior to battery exhaustion via auditory warnings and via haptic vibration. This is to allow the user to alert support staff to swap the battery prior to loss of light. There is no further warning after the 5-minute auditory warning and the LED will turn off abruptly when the battery is exhausted or begin to flicker. Once the 10 minute warning is given, the Blue Indicator Light on the side of the holster will begin to blink, visually indicating that the battery needs replacement.

End of Procedure: Turn LED to OFF at the battery holster using the ON/OFF switch. The blue indicator light will turn off if it is not already off from battery exhaustion. Remove the battery to charge in a Ronin supplied charger.

International Use: Care should be taken to ensure that you have the appropriate cord and plug configuration for the country in which the Ronin X Series Surgical Headlight is to be operated. The AC input of the Power supply is rated 100-240V, 50-60Hz.

Battery Charging: To charge a battery, insert the battery with with the logo side facing the front of the charger and make sure the battery connectors on both the charger and battery are aligned. It can take up to 30 seconds for the indicator lights on the charger to illuminate. Orange indicates charging. Green indicated fully charged. Remove the battery from the charger once it has been fully charged.



WARNING: Once a battery has been fully charged remove it from the charger. Failure to do so could result in hazards including burn, fire, shock, or contamination.

See IFU section **WARNINGS AND PRECAUTIONS** for further detail.

11. INDICATOR LEDS, BATTERY CHARGING, AND BATTERY FUEL GAUGE

Indicator LEDs:

ORANGE - SOLID	Battery charging
GREEN - SOLID	Battery fully charged / Ready for use
BLUE - SOLID	Switch to ON (Normal Operation)

BLUE – SLOW BLINKING	Battery is low and needs to be replaced immediately
BLUE – RAPID FLASH	Fault condition. Contact Ronin for Service

Battery Charging: Insert the desired battery module into the charger unit with the connection terminal oriented both downward and toward the battery connector. Charging will start within 30 seconds and is indicated by a solid orange indicator light. When the indicator light is solid green, the battery is fully charged.

A battery that is past its useful life is safe for use, however it will significantly reduce operating time. Contact Ronin immediately for battery replacement.

Battery Fuel Gauge: Each battery pack has an embedded charge indicator that visually depicts the battery's current charge level in 20% increments. Certain battery models have indicators that are always on. Others equipped with advanced fuel gauges require the press of a small button near the battery connector to activate.

12. BATTERY REPLACEMENT

Battery Replacement: Contact Ronin for battery replacement. Call Ronin at +1 (415) 226-9414 or email: Support@RoninSurgical.com

13. BATTERY DISPOSAL

For Battery disposal send back to Ronin or dispose of in accordance with local battery disposal regulations.

14. BATTERY STORAGE, TRANSIT, AIR TRAVEL AND SHIPPING

Storage: Always remove battery from the holster unit while not in use. The battery may stay in the charger without damaging it. It is suggested that the battery be removed if the charger is not plugged into the wall, as the charger will drain the battery over several days while in sleep mode.

Transit: ALWAYS remove battery prior to transit to eliminate the chance of the LED being powered accidentally.

Air Travel: At the time of this printing, FAA regulation [49 CFR 175.10\(a\)\(18\)](#) provides the following rules that pertain to all Ronin approved lithium ion batteries:

- **Carry-on only:**

"All uninstalled lithium ion batteries must be carried in carry-on baggage only. When a carry-on bag is checked at the gate or at planeside, all spare lithium batteries must be removed from the bag and kept with the passenger in the aircraft cabin." Please find the most up to date FAA regulations regarding transportation of lithium energy cells.

- **Size limits:** All Ronin approved batteries as of this printing meet the lithium ion battery energy capacity limit of 100 watt hours (Wh) or less per battery. If unsure, please see the watt hours printed on each battery label.

- **Quantity limits:** There are no quantity limits for all Ronin approved batteries.
- **Protection from damage:** All batteries must be physically protected from damage (especially puncture).
- **Battery terminals must be protected from short circuit** (i.e., the terminals must not contact conductive materials or metal). This can be accomplished by placing each battery in a tight fitting or sealed bag. Alternatively, the battery terminals can be covered by robust tape such as duct tape or masking tape.

Shipping:

- Specific carrier (UPS, FedEx, USPS) rules and federal laws must be strictly followed. Knowingly or unknowingly violating these rules can constitute a felony. Please see the specific instructions provided by Ronin for each shipment and contact Ronin customer support at +1 (415)226-9414 or email Ronin at Support@RoninSurgical.com with further questions.

15. TROUBLESHOOTING AND FAQ

If you are having problems with the operation of the Ronin X Series Surgical Headlight, review this section to see if a solution is described. If you are still having trouble, call Ronin at +1 (415) 226-9414 or email: Support@RoninSurgical.com.

LED is switching off before the battery is fully discharged.

Confirm that the battery charge is not exhausted, or nearly exhausted. If the battery is exhausted, headlight performance may be unreliable. Swap for a charged battery and confirm normal operation behavior resumes.

Alternatively, if the battery is fully charged and the light is turning off, it may relate to the unit's thermal protection circuit. The Ronin X Series Surgical Headlight has a thermal protection circuit to allow peak performance while protecting the life of the LED and the safety of the user. If the unit is operated in a warm environment the unit can automatically dim the LED by slightly to reduce heat generation. This is considered part of the unit's normal operation.

If the unit continues to trigger the protection circuit the unit will further dim the LED. This is not part of the normal operation of the unit and will trigger the blue LED to double flash. Usually this is caused by the fan not spinning resulting in the device overheating. If the unit has turned off it will not power the LED again until (1) the LED has cooled down and (2) the power ON/OFF switch has been toggled. Please ensure the unit is properly ventilated. If the light turns off again in a well-ventilated environment and, please call Ronin at +1 (415) 226-9414 or email: Support@RoninSurgical.com for service.

The battery holster is uncomfortably warm.

The Ronin X Series Surgical Headlight uses a substantial amount of energy to deliver high intensity illumination. A byproduct is the accumulation of heat in the battery holster. It is normal for the unit to be warm to the touch but should never be uncomfortable during use. Please contact Ronin for service if the battery holster is uncomfortably warm.

There is unusual noise coming from the luminaire while the LED is powered.

The unit is equipped with a high performance long-life fan, however with prolonged use the fan may begin to buzz or creak. Please return to Ronin for service if such a condition is experienced.

The battery depletes abnormally fast.

This is most often the result of a battery that is past its useful life. Please contact Ronin at +1(415)226-9414 or email: Support@RoninSurgical.com for replacement.

16. CLEANING

Cleaning of external surfaces

Regularity: As Needed

1. Remove all power sources by removing batteries and unplugging the power supply at either the wall outlet or the DC input to the unit.
2. All external surfaces can be wiped with a cloth dampened (not saturated) with a mild detergent and water, or 70% isopropyl alcohol. Excess solution entering the headlight assembly could damage internal components.

When cleaning the lens, point the luminaire downward so that solution does flow into the device.

DO NOT USE HYDROGEN PEROXIDE or any cleaning products other than those described in the immediately preceding paragraphs. Doing so may damage components of the headlight, will void the warranty, and may create hazards to the user or patient.

3. Do not operate the Ronin X Series Surgical Headlight until it is dry.

CAUTION: Avoid excess solution entering the luminaire cooling chamber as it may damage internal components.

CAUTION: Do not immerse any component of the X Series Surgical Headlight System as it is not rated for water ingress.

CAUTION: Do not sterilize the X Series Surgical Headlight system by placing the device in an autoclave or other sterilizer. This device should only be cleaned by wiping the product down with appropriate cleaning agents as instructed in IFU section CLEANING.

CAUTION: Do not press on the fan blades to avoid damaging or cracking them.

WARNING: No part of the device enclosure is to be opened for cleaning. Opening the device enclosure voids the warranty and creates a risk of shock, burn, or fire.

17. MAINTENANCE

The Ronin X Series Surgical Headlight requires no routine servicing. However, before every procedure, the X Series Surgical Headlight MUST be carefully inspected to ensure it has been properly maintained, cleaned, and is fully functional. DO NOT use if inspection reveals any debris, damaged components, or loose pieces.

18. DECLARATION OF CONFORMITY

We, RONIN SURGICAL CORP. declare under our sole responsibility that the model Ronin X Series Surgical Headlight and supplied accessories are in conformity with the following standards or other normative documents:

ANSI/AAMI ES60601-1:2005 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (*IEC 60601-1:2005, MOD.*)

AAMI ANSI IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 4)

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19. WARRANTY

Ronin warrants to the initial purchaser (“Purchaser”) that each new Ronin X Series Surgical Headlight (“Product”) purchased directly from Ronin or an authorized Ronin distributor will be free from defects in materials and workmanship under normal use for a period of twelve (12) months from the date of its initial shipment to the Purchaser, or such Extended Warranty period purchased by Purchaser, from the date of initial shipment (“Warranty”). Repair or replacement of products (or parts thereof) under this Warranty does not extend the Warranty period. Products that are not new are subject to separate warranties expressly provided in connection with the sale of such products.

The obligations of Ronin under this Warranty shall be limited to repair or replacement (at Ronin’s option) of any product (or part thereof) under Warranty that Ronin reasonably determines to be covered by this Warranty and to be defective in workmanship or materials. Ronin shall determine whether to repair or replace products and parts covered by this Warranty. All products or parts replaced shall become Ronin’s property. During Warranty service, Ronin may, but shall not be required to, make engineering improvements to the warranted products or parts.

Prior to shipping your Ronin X Series Surgical Headlight for repair under this Warranty you MUST call Ronin at +1 (415) 226-9414 and select “Customer Service” or email: Support@RoninSurgical.com to obtain a Return Authorization Number (RMA). RETURNS AND REPAIR RETURNS WILL NOT BE ACCEPTED WITHOUT AN RMA.

Products shipped to Ronin by the Purchaser under this Warranty shall be suitably packaged to protect the product. If the Purchaser ships a product to Ronin in unsuitable packaging, any physical damage in the product upon receipt by Ronin (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of the Purchaser. Risk of loss or damage to the Ronin X Series Surgical Headlight System during shipment under this Warranty shall be borne by the party shipping the product.

This Warranty shall be invalid if the warranted products (or parts thereof) have been subject to misuse, neglect, or accident; have been damaged by causes external to the warranted product; have been affixed to any nonstandard accessory attachment; have had the serial number removed or made illegible; or have been disassembled, modified, serviced, or reassembled by anyone other than Ronin, unless authorized by Ronin.

Ronin will not be responsible for the effect on safety, reliability, and performance of the product if:

a) assembly, extensions, readjustments, modifications, or repairs are carried out by anyone other than Ronin or persons authorized to perform repair service on Ronin’s behalf; or b) the electrical installation does not comply with the requirements of the applicable national and international standards, including requirements of the IEC; or c) the product is not used in accordance with Ronin’s instructions for use.

THIS WARRANTY, TOGETHER WITH ANY OTHER EXPRESS WRITTEN WARRANTY THAT MAY BE ISSUED BY RONIN, IS THE SOLE AND EXCLUSIVE WARRANTY AS TO RONIN PRODUCTS, AND EXTENDS ONLY TO THE PURCHASER AND IS EXPRESSLY IN LIEU OF ANY OTHER WRITTEN, ORAL OR IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. RONIN SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE (INCLUDING WITHOUT LIMITATION LOST PROFITS) DIRECTLY OR INDIRECTLY ARISING FROM THE SALE, INABILITY TO SELL, USE, OR LOSS OF USE OF ANY PRODUCT.

DISCLAIMER OF WARRANTIES

Ronin X Series Surgical Headlight devices are subjected to extremely variable: environments, proximity to ancillary equipment, unanticipated connections, and physical conditions. The devices may fail to function for a variety of causes. Despite the exercise of all due care in the design, component selection, manufacture and testing prior to sale, the devices can be damaged, before, during, or after use, by improper handling or other intervening acts. Consequently, no Warranty is made that failure or cessation of the function of the device will not occur.