MedLED® Headlights

INSTRUCTIONS FOR USE



TRULY CORDLESS™ MADE IN THE USA

WELCOME TO MEDLED®

Thank you for purchasing a MedLED® headlamp system - the most advanced surgical headlamp available. Please read these instructions and keep them for your reference.

IMPORTANT INSTRUCTIONS: Failure to observe these very important instructions for use can result in injury, unforeseen consequences resulting from inappropriate use, product failure and warranty lapse. Do not tamper or change the labeling and/or this instructions for use.

Please read instructions carefully before using the product. Store in a safe place for future reference.

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APPLIES TO MEDLED HEADLIGHT, BATTERY, UNIT & 4-BAY DESKTOP CHARGER. Read/understand these safety requirements.

IMPORTANT NOTES: Batteries should be replaced every year. If the batteries swell, crack or get hot, DO NOT charge or use them.

Discard them appropriately and replace accordingly. The battery used in this device may present a fire or chemical burn hazard if mistreated. In order to avoid damage to persons or properly e.g., by electric shock, fire, ignificin, explosion, leakage, or rupturing.

- ONLY USE the provided batteries and chargers for the headlight system purchased. VARTA Microbattery Inc., manufactures the batteries and therefore holds all claims, representations, and warranties. Riverpoint Medical assumes no liability whatsoever and disclaims any express, implied or statutory warranty relating to its batteries and reserves the right to make changes to specifications and product descriptions at any time without notice.
- NOTE that it is recommended to leave the headlamp charging when not in use. When disconnecting the power cord pull from the plug not the cord itself. When storing, remove batteries from unit and store in box they were supplied in.
- ONLY CHARGE/USE in environmental temperatures between 0 to +30 °C
- ONLY USE in environmental humidity between 65 +/- 20%RH
- ONLY STORE in environmental temperatures between: 0 to +25 °C
- . ONLY USE charger in dry locations in an isolated area. Keep away from rain, snow, flammables, excessive heat and/or moisture.
- DO NOT open battery, dispose of in fire, put in backwards, mix with used or other battery types, short circuit, disassemble, heat above 60°C (140°F), or incinerate.
- DO NOT handle damaged/leaking batteries. Dispose promptly and properly by following LiPO handling and safety precautions.
- . DO NOT plug battery chargers into an extension cable.
- . DO NOT forcibly bend power cord / place heavy objects on it; DO NOT pull, yank, or put stress on any of the wires.
- DO NOT operate if cord is severed or if batteries and/or 4-bay charger have been dropped or damaged.
- . DO NOT use a damaged charger, disassemble or modify any part of the charger.
- . DO NOT use an unauthorized power supply or charge a damaged battery.
- . DO NOT allow metallic objects to contact the metal parts of the DC connectors in the charger ports or contacts of the battery.
- NOTE the headlight battery packs or 4-bay charger console may warm up during charge mode. The aluminum bezel / light engine also may get warm during use. This is normal and not a malfunction. Avoid skin contact to these areas during these times.
- NOTE that any changes, attempted self-repairs, or modifications not approved by Riverpoint will void any warranty on the unit and may inadvertently result in safety hazards and/or injuries.
- . NOTE that these products are intended to increase visibility only and are not intended to come in contact with the patient.
- . NOTE do not charge the batteries in the surgical field of use.

MISCELLANEOUS INSTRUCTIONS

INSTRUCTIONS FOR USE: Please refer to the manufacturer or the authorized dealer if you have any queries regarding correct usage of a partial far headlamp.

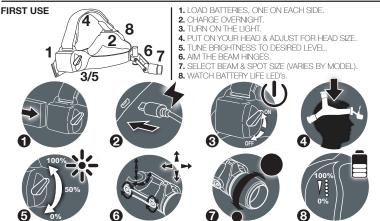
CLEANING: Before cleaning, disconnect the charger from the device and power off completely. Avoid excessive moisture as this may cause serious damage to the circuitry and present safety risks and void the warranty. The instrument housing may be cleaned with a soft cloth moistened with alcohol or a non-aggressive disinfectant solution. Do not soak or spray with disinfectant. The black padding strips may be removed for cleaning by pulling apart the snaps. The pads may be cleaned the same way; do not soak or spray with disinfectant. New pads are available as accessories and should be no timely replaced.

DISPOSAL: This product must be disposed of separately as an electronic device in accordance with the local regulations. Dispose of used batteries promptly and properly. In some regions, the disposal of lithium batteries in household or business waste may be prohibited. Kindly dispose of used batteries in a responsible manner.

DENTISTRY APPLICATION: A yellow filter may be used to prevent premature hardening of the composite material. Contact your sales rep for more information.

GENERAL SAFETY PRECAUTIONS & WARNINGS: Do not shine the headlight directly into anybody's eyes. Never hold microscopes or other optical lenses in front of the headlight. The LED light source is intense and has a high secondary exposure potential due to its blinding effect. Temporary reduction in visual aculty and afterimages on occur, leading to initiation, annoyance, visual impairment, and even accidents, depending on the situation. Use the rheostat for dimming to the appropriate setting. Do not use the bezel's aperture adjustment pin for adjusting beam angle. Pin intended for side-to-side motion only, not pivoting the bezel.

FOR SAFE USAGE: Switch off the device using the rheastat dimmer when not in use, When in use, the aperture of the headlight must not be covered with a towel or any similar material, as it could otherwise become very warm. The bezel should not come into contact with any skin during use. When not in use, it is always best to keep the headlight unit plugged into the charger.



ROUTINE USE

WATCH THE BATTERY LIFE by referencing the five LED indicators located on the face of the left battery pack.

- Each chamber represents a ~20% portion of the accumulated battery life remaining. Note, the gauge may need up to a
 full discharge cycle to read the correct battery level. The MedLED Hyperfite™ does not indicate battery level status.
- Change when there is only one indicator illuminated. Once all five of the indicators are depleted, there is a short period of time before the batteries are fully exhausted and the light turns off.

CHARGE THE HEADLIGHT. The USB charger takes <u>6.5 hours</u> when charging the batteries in the headlamp. Plug the micro-B USB jack into the light and the standard USB end into either the 5V wall adapter or a computer USB port.

NOTE: The batteries should be used in pairs and should not be mixed and matched, particularly when using a charged battery with a dead battery or a new battery with an old battery. When two batteries are correctly installed, they will charge/discharge simultaneously. When only one battery is connected/active, the battery indicator LED's will blink indicating to connect the second battery. It is recommended to leave the headlight on the charger while not in use with the rheostat powered off. When in storage, remove the batteries from the unit and store in safe location. Batteries should be replaced every 12 months. If battery becomes hard to insert or remove, this means the batteries have swelled and use should be ceased immediately. Contact your representative to purchase additional batteries and dispose of used batteries responsibly.

4-BAY DESKTOP CHARGER, KEEP SPARE BATTERIES CHARGED using this console,

A full charge is reached in 10 hours. This charger is an accessory and may need to be purchased separately. TO USE THE 4-BAY DESKTOP CHARGER:

- 1. Place the console in a safe location on a tabletop near a wall socket away from any spill or fire hazards.
- 2. Plug the charging cable in. Red/amber LED's will illuminate.
- Insert the batteries into the slots. Ensure the batteries are keyed correctly and placed fully into each slot.
 Indicator I ED reference:

Blinking Green = Charging. Solid Green = Fully charged.

Solid Red / Amber = Not installed or connected. Insert again fully. Blinking Red = Battery fault - try a different battery.

GENERAL HEADLIGHT SPECIFICATIONS

THE LIGHT

BRIGHTNESS: See "ORDERING" page.

LIGHT SOURCE: Powerful white LEDs, class 1M/EN 60825-1:1997

LED LIFETIME: 100,000+ hours. It is not necessary to change the LED light source.

THE BATTERY

BATTERY CHARGE TIME IN LAMP: 6.5 Hours

BATTERY CHARGE TIME IN 4-BAY DESKTOP CHARGER: 10 Hours

TOTAL BATTERY LIFETIME: Replace at least every 12 months

OTHER

 $\operatorname{BATTERY}$ LIFE, WEIGHTS, AND OTHER INFORMATION: Refer to brochures.

LED COLOR TEMPERATURE: Reference between 5,000-6,500° Kelvin.

RELEVANT STANDARDS

CE Certified.

USB Wall Charger: IEC 61000.

Battery: UL 2054, EN 55014-2:1997+A1:2001, meets the requirements of Battery Directives.

LED: IEC 62471:2006 - "Exempt" Group.

General: RoHS Compliant.

SYMBOLS KEY



"MANUFACTURED BY"



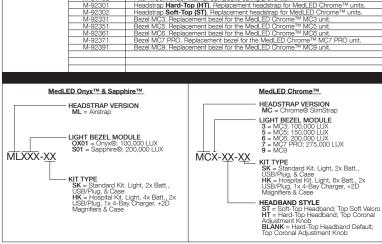
"EUROPEAN CONFORMITY"



"REFER TO INSTRUCTIONS FOR USE"

ORDERING PAGE 4

HEADLAMP	ORDER CODE	DESCRIPTION
MedLED Classic™	ML001-XX	25,000 LUX mounted on MedLED SOFTSTRAP™ headband.
MedLED Hyperlite™	MLH01-XX	50,000 LUX mounted on MedLED CLIPLIGHT™ with battery belt pack.
MedLED Onvx™	MLOX01-XX	100.000 LUX mounted on MedLED AIRSTRAP™ headband.
MedLED Sapphire™	MLS01-XX	200,000 LUX mounted on MedLED AIRSTRAP™ headband.
MedLED Chrome™	See below KEY	Modular Light Bezels mounted on MedLED SLIMSTRAP™ headband.
MedLED Accessories	M-90002	Battery Set, For MedLED Onyx™ and Sapphire™ AIRSTRAP™.
MedLED Accessories	M-90002	Battery Set. For MedLED Chrome™ SLIMSTRAP™.
	M-92051	Battery Pack, For MedLED Chrome. Battery Pack, For MedLED Hyperlite™.
	M-90102	Charger Wall Unit (US). 5V@1A UPS Charger & USB Cable.
	M-90102	Charger Wall Unit Int'l (US/EU/UK/AU). 5V@1A UPS Charger & USB Cable.
	M-90151	Charger USB Cable (Only).
	M-90202	Charger 4-Bay Desktop (US). 4-Bay Dock, Wall Plug, & USB Cable.
	M-90202	Charger 4-Bay Desktop (03), 4-Bay Dock, Wall Plug w/ Int'l Plug Clips, & USB Cable.
	M-9030X	Magnifier +2D (X=1); +2.5D (X=2); +3D (X=3); +3.5D (X=4); +4.0D (X=5); +4.5D (X=6).
	IVI-9030A	For MedLED Onyx TM , Sapphire TM and MC3.
	M-9032X	Magnifier +2D (X=1); +2.5D (X=2); +3D (X=3); +3.5D (X=4); +4.0D (X=5); +4.5D (X=6).
	IVI-9032A	For MedLED MC5, MC6, MC7 PRO, MC9.
	M-90901	Padding Set. Neoprene Snap (3pc.). MedLED Onyx™ and Sapphire™.
	M-91302	Padding Set. Neoprene Snap (Spc.), MedLED Chrome TM Hard-Top (HT).
	M-91303	Padding Set. Neoprene Velcro (3pc.). MedLED Chrome™ Hard-Top (HT).
	M-91304	Padding Set. Neople in Velcro (Spc.), MedLED Chrome ** Hard-Top (HT).
	M-91305	Padding Set. Soft Pillow Velcro (Spc.). MedLED Chrome Marting (TT).
	M-91306	Padding Set. Soft Wipeable Velcro (3pc.). MedLED Chrome™ Hard-Top (HT).
	M-91312	Padding Set. Soft Wipeable Velcio (Spc.): Wedleb Chrome™ Hard-Top (HT).
	M-91313	Padding Set. Neoprene Velcro (3pc.) 10-Pack. MedLED Chrome TM Hard-Top (HT).
	M-91314	Padding Set. Neopherie Velcro (Spc.) 10-Pack. MedLED Chrome Mard-Top (HT).
	M-91315	Padding Set, Soft Pillow Velcro (2pc.) 10-Pack, MedLED Chrome™ Soft-Top (ST).
	M-91316	Padding Set. Soft Wipeable Velcro (3pc.) 10-Pack. MedLED Chrome™ Hard-Top (HT).
	M-90902	Case. For MedLED Onyx™ and Sapphire™.
	M-90912	Case, For MedLED Chrome TM .
	M-91002	Hyperlite Mounting, Loupe and glasses clip adapting set.
	M-91007	Filter Hyperlite. Amber filter for composite curing prevention.
	M-91101	Filter Onyx / MC3, Amber filter for composite curing prevention.
	M-91103	Filter MC6. Amber filter for composite curing prevention.
	M-92301	Headstrap Hard-Top (HT). Replacement headstrap for MedLED Chrome™ units.
	M-92302	Headstrap Soft-Top (ST) . Replacement headstrap for MedLED Chrome™ units.
	M-92331	Bezel MC3, Replacement bezel for the MedLED Chrome™ MC3 unit.
	M-92351	Bezel MC5. Replacement bezel for the MedLED Chrome™ MC5 unit.
	M-92361	Bezel MC6. Replacement bezel for the MedLED Chrome™ MC6 unit.
	M-92371	Bezel MC7 PRO, Replacement bezel for the MedLED Chrome™ MC7 PRO unit.
	M-92391	Bezel MC9. Replacement bezel for the MedLED Chrome TM MC9 unit.
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For product questions or to place an order, please contact:

Your Distributor.

If your distributor is unknown please contact the manufacturer:

The Manufacturer.

MedLED® Products

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LIMITED MANUFACTURERS' WARRANTY

WARRANTY: 1 YEAR MANUFACTURERS WARRANTY. CHECK WITH YOUR DISTRIBUTOR FOR EXTENDED WARRANTIES.

Piverpoint Medical (herein referred to as the "Manufacturer") warrants this unit (herein referred to as "Product") as free from defects in materials and workmanship that result in Product failure during normal usage according to the following terms and conditions:

- 1. The Product labels and/or these instructions for use are not to be removed or modified as it comes from the Manufacturer.
- The limited warranty extends only to the original end-user purchaser and holder of the warranty and is not transferable or assignable to any other third party.
- This limited warranty is ONLY applicable in the country or territory where the product was purchased from the Manufacturer's authorized headlamp retailer and is valid ONLY if used and returned with original headlamp contents/accessories.
- 4. During the Warranty Period, the Manufacturer will repair or replace, at its sole option, any defective parts that will not operate for their intended purpose with new or refurbished parts if such repair or replacement is needed.
- 5. This limited warranty does NOT apply to:
- a. The carrying case and accessories (batteries, charger, and other items included in a kit other than the headlight unit).
- b. Damage caused by abnormal wear and tear, abnormal use or conditions, misuse, neglect, abuse, accident, improper handling or storage, unauthorized modifications, alterations, or repairs not performed by a certified technician, improper use of any electrical source or third-party battery, operator error, non-compliance with instructions or other acts which are not the fault of Manufacturer, including damage or loss during shippina. Further claims are excluded.
- c. Any product that has its labels or serial number altered, defaced or removed.
- d. Any defect that occurred after the expiration of the Warranty Period.
- 6. The Manufacturer's limit of liability under the Limited Warranty is limited to the actual cash value of the Product at the time you return the Product for repair.
- 7. THE FOREGOING LIMITED WARRANTY IS YOUR SOLE AND EXCLUSIVE REMEDY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE MANUFACTURER HEREBY DISCLAIMS THE APPLICABILITY OF ANY IMPLIED WARRANTY OF ENTIRESS OF LISE FOR THE PRODUCT.
- 8. THE MANUFACTURER WILL NOT BE RESPONSIBLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL PUNITIVE OR CONSEQUENTIAL
- DAMAGES ARISING FROM OR RELATING TO THE USE OF THIS PRODUCT.
- 9. It is required to disinfect the headlamp before returning for repair.

