LUXTEC

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ULTRALITE[®] PRO HEADLIGHT Operation and Service Manual ENGLISH

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INDICATION FOR USE

This fiber optic headlight system is designed to deliver illumination from a high intensity light source for surgical site illumination. While the cable light source end fittings are compatible with all light sources, brightness and spot quality vary with specific types of light sources. The UltraLite® Pro systems perform best with Luxtec Xenon light sources.

SYMBOLS

TABLE OF SYMBOLS

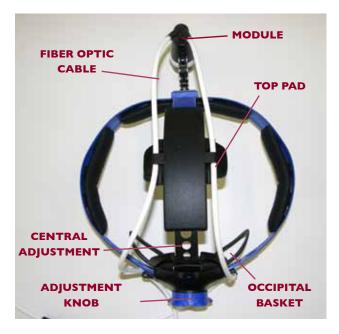
Found on a medical grade light source, other illumination related equipment, fiber optic cables and corresponding packaging.

\triangle	Attention; Consult Accompanying Documents	-	Fuse
Â	Caution: High Voltage	۲	Type CF Equipment
\checkmark	Equipotentiality	Ŕ	Type BF Equipment
÷	Protective Earth		High Temperature
1	On / Off	-Ò-	Brightness
ட	Stand-by	TOM	Motor
0	System Status Display	36	Fan
ō	System	C€	CE
- X	Do Not Dispose	⊕.	Listed by ETL
Ŧ	Push		Listed by CSA
$\overline{\mathbb{X}}$	Hours	REF	Part Number
<u>له</u>	Over Temperature	LOT	Batch Code
_∙ IIn	Intensity	SN	Serial Number
or)	Lamp	EC REP	Authorized Representative in the European Community
-Q- 			Manufacturer
Ţ	Keep dry	L	

GENERAL WARNINGS

- The user should carefully study this manual before making any attempt to use the product clinically.
- Instructions should be followed specifically, with special attention given to warnings and cleaning instructions. This manual should also be available to the surgical team during a procedure.
- Follow the instructions in the operating manuals of other manufacturer's equipment when they are used in conjunction with this product.
- Before every procedure, carefully inspect the fiber optic cable to ensure it has been properly maintained and cleaned and that it is fully functional.
- Use the light source at the lowest possible attenuation to prevent cable damage or excess heat.
- Light sources use high intensity lamps, which produce heat as well as brilliant light. The heat produced by the light source and the light output of the fiber optic cable can cause burns.
- Care should be taken to follow the maintenance and cleaning instructions.
- Excessive bending of the cable should be avoided.
- Use care not to point the headlight directly at the eye while in operation. The brilliant light output can cause severe eye discomfort.

FIRE HAZARD: DO NOT DRAPE OR COVER THE LIGHT SOURCE WHILE IT IS OPERATING. DO NOT PLACE THE FIBER OPTIC CABLE ON A DRAPE WHILE THE LIGHT SOURCE IS OPERATING.



PRECAUTIONS

- Take precautions to verify that the fiber optic cable is appropriately suited for the light source. Xenon and other high illumination light sources require premium fiber optic cables in order to achieve optimal performance and prevent damage to the fibers, thereby diminishing the quality of the light output or the useful life of fiber optic cable.
- Take precautions not to touch or disconnect the cable end fitting from the turret until the light source has been "shut down" for a period of time and allowed to cool. The cable end fitting will remain hot immediately following shut down, which can cause burns.
- Take precautions to not place and rest a hot cable end fitting and/or headlight on a patient or allow the system to come in contact with un-protected hands or tissue. The entire system should be allowed to cool following use. Failure to do so can cause burns and/or tissue damage.

ASSEMBLY

ASSEMBLY OF THE ULTRALITE[®] PRO HEADLIGHT SYSTEM

The UltraLite[®] Pro Headlight system consists of a headband, variable spot module, gown clips and a bifurcated fiber optic cable.

To assemble the headlight, attach the variable spot module (Fig 1)



to the headband by sliding the tapered bottom end of the module into the headband (Fig 2)



(Fig 2)

and push the top into the headband (Fig 3) until it makes an audible click.



(Fig 3)

To attach the fiber optic cable, insert the bifurcated metal fitting into the module (Fig 4a - b) until it clicks into place.



(Fig 4a)



(Fig 4b)

Thread the bifurcated cable on the left and right of the central headband unit (Fig 5) in an over-under pattern as shown.



Continue threading the bifurcated cables on the left and right of the headlight adjustment bracket in an over-under pattern as shown (Fig 6).



The cable can be slid forward or backward to allow more slack for comfort, as needed. To remove the cable from the module, grasp the strain relief in one hand and the module in the other hand and pull the strain relief straight up.

• **DO NOT** disassemble by grasping the bifurcated cables as damage to the glass fibers may occur.

WARNING

The cable is made of glass fibers. When adjusting the cable on the headband, do not bend the cable more than 60 degrees. When properly assembled the cable should curve gently around the contours of the head and the headband.

ASSEMBLY

ASSEMBLY OF THE ULTRALITE[®] PRO HEADLIGHT SYSTEM

Next open the headlight assembly fully by pulling the central unit (Fig 7) completely open and opening the



circumferential adjustment (Fig 8) fully.



The pad (Fig 9) should be at the front of the headlight.



(Fig 9)

Place the headlight on your head. The occipital basket should be aligned (Fig 10) as shown.



(Fig 10)

Grasp the headlight as shown (Fig 11) and push the headlight from front to back until it fits snugly. Adjust the pad front to back (Fig 12) for a more comfortable fit



(Fig II)



(Fig 12)

The headlight should then be adjusted circumferentially using the ratchet knob at the rear as shown (Fig 13). The UltraLite[®] Pro headlight is now ready for use. The headlight system comes with two gown clips to



(Fig 13)

relieve the weight of the fiber optic cable from the head. One clip should be attached to the surgical gown or scrubs at, or just below shoulder level (Fig 14). Be sure to leave enough slack in the cable to allow for



(Fig 14)

freedom of head movement. If the surgeon needs to detach the cable from the light source, the second gown clip is used to attach the cable to the gown or scrubs to eliminate the risk of dropping the cable.

The spot size of the light may be adjusted from 20 - 100mm (0.8 - 4 in), based on a 46cm (18 in) working distance, by adjusting the iris (Fig 15).



The module can be removed from the headband, if

ADJUSTMENTS

needed, by placing a small flathead screwdriver in the slot above the module in the headband (Fig 16) and pushing the module out. Be sure to remove the fiber optic cable from the module first.



CAUTION

To plug or unplug the fiber optic cable from the light source, it is recommended that the light source power be turned off. Be sure to hold the strain reliever near the end of the cable. This part of the cable is reinforced to prevent damage to the glass fibers inside and to prevent burns.

ADJUSTMENTS

Once the headlight module and fiber optic cable are attached to the headband, the headlight assembly is ready to use. The headlight module can be adjusted vertically while wearing the headlight system by grasping the module and aligning the light spot to a comfortable working position.

Luxtec manufactures its headlights to the highest quality standards. Each one is tested thoroughly before leaving the factory to ensure proper working conditions.

These instructions should help you get started with your new Luxtec equipment, quickly and easily. If you have any problems, please contact the Luxtec Service Department: 800-325-8966, or +1-508-835 -9700, Fax +1-508-835 -9976.

ALL HEADLIGHT SYSTEMS:

To ensure long life for the headband, cable, and modules, they should be stored in the duffel bag provided.

Fiber optic cables are fine, high quality optical instruments. You can prolong the useful life by following a few guidelines:

- Avoid stretching your cable, forming configurations involving sharp angles or kinks, or contact with sharp or pointed objects. The internal light fibers are made of glass, a material which breaks under stress. Fiber breakage will result in diminished light output.
- Utilize the gown clips (provided) to keep the headlight cable secured to the surgeon's gown for greater comfort and maneuverability.
- **DO NOT** use your fiber optic cable with any alterations to its original design or fabrication.
- Keep the optical faces from contacting the floor or other hard surfaces. The resulting scratches will diminish light output.

REPLACEMENT PARTS FOR ULTRALITE® PRO HEADLIGHT

Description		
2100BIF UltraLite® Pro headlight assembly with 9 ft (275 cm) premium bifurcated cable, Mark II module and gown clips		
UltraLite® Pro headlight assembly with 9 ft (275 cm) premium bifurcated cable, Mark II module and gown clips with		
UltraLite® Pro premium bifurcated fiber optic cable, 9 ft (275 cm)		
UltraLite® Pro premium bifurcated fiber optic cable, 11 ft (335 cm)		
UltraLite® Pro premium bifurcated fiber optic cable, 7.5 ft (230 cm)		
UltraLite® Pro replacement headband		
Mark II module, black		

CARE AND MAINTENANCE

WARRANTY

CLEANING MODULES

The headlight module may be wiped down with alcohol. The lens should be cleaned only with lens tissue available at any camera store. Follow the package directions. Follow all applicable bloodborne pathogen procedures as indicated by OSHA and/or your hospital requirements when cleaning and disinfecting.

WARNING

• DO NOT soak the UltraLite® Pro cable in any sterilization solution.

CLEANING HEADBAND

The headband may be cleaned by an alcohol wipedown or washed with lukewarm water and mild detergent.

CLEANING FIBER OPTIC CABLE

Luxtec suggests that the use of alcohol wipes to clean the headlight cables.

WARNING

• **DO NOT** soak the UltraLite® Pro cable in any sterilization solution.

There is a lens assembly at the light source end, which is not sealed and could allow moisture to penetrate behind the lens.

TROUBLESHOOTING

For additional technical assistance, please contact the Luxtec Service Department, 800-325-8966, or +1-508-835-9700, Fax +1-508-835-9976.

LUXTEC HEADLIGHT WARRANTY

Luxtec warrants that the equipment manufactured by Luxtec shall be free from defects in material and workmanship under normal use and service for a period of three (3) years, except the cable, from the date of shipment from Luxtec. Luxtec's sole and exclusive liability under warranty shall be, at Luxtec's option, either to repair or replace any component which fails during the warranty period due to any defect in workmanship or material F.O.B. factory if:

- I. Customer promptly reports such defect to Luxtec in writing,
- 2. If requested by Luxtec, customer returns equipment to Luxtec with shipping charges and,
- 3. Upon inspection, Luxtec finds the equipment to be defective.

This warranty is contingent upon normal and proper use of the equipment. It does not cover equipment modified without the written approval of Luxtec, subjected to unusual physical or electrical stress, or damaged during shipment. This warranty is nontransferable unless authorized in writing by Luxtec.

Luxtec reserves the right to make design changes on its products without liability to incorporate said change in Luxtec products previously designed or sold.

Upon receipt of the product, it should be carefully inspected. If any defect is discovered, notification must immediately be given to the manufacturer.

WARRANTY

LUXTEC CABLE WARRANTY

Luxtec warrants that the cables furnished shall be free from defects in material and workmanship under normal use and service for a period of 18 months. UltraLite® premium headlight cables feature a LIFETIME WARRANTY against browning.

RETURN POLICY

REPAIR AND RETURN

Any device must be clean when returned to Luxtec. Luxtec reserves the right to return unrepaired any equipment that is contaminated with blood or other organic material.

WARRANTY SERVICE AND REPAIR

To obtain service under warranty or return product for repair, the customer should contact the local Luxtec representative or call Luxtec Customer Service at 800-325-8966 or +1-508-835-9700.

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