



GIMA

PROFESSIONAL MEDICAL PRODUCTS

NUOVA LAMPADA FRONTALE WIDA A FIBRE OTTICHE **NEW WIDA: F.O. HEAD LIGHT** **NOUVELLE LAMPE FRONTALE À F.O. WIDA** **NUEVA LÁMPARA FRONTAL DE FIBRA ÓPTICA WIDA**

- È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.
- All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.
- Il est nécessaire de signaler tout accident grave survenu et lié au dispositif médical que nous avons livré au fabricant et à l'autorité compétente de l'état membre où on a le siège social.
- Es necesario informar al fabricante y a la autoridad competente del Estado miembro en el que se encuentra la sede sobre cualquier incidente grave que haya ocurrido en relación con el producto sanitario que le hemos suministrado.

REF

808-750-01 (GIMA 30853) 808-746-01 (GIMA 30854)



Medical Devices (Pvt) Ltd
Wazirabad Road, Ugoki Sialkot.
Pakistan - Made in Pakistan

EC REP

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ATTENTION:

Thank you for purchasing our product. The F.O Headlights meet the most stringent requirements regarding the selection of manufacturing material, performance, safety and final control. These operating instructions manual is related to Fiber Optic Headlights (GIMA codes 30853 and 30854). These instructions must be followed to ensure the performance and durability of the both devices. The operator/user must read and understand this manual thoroughly to keep the Product performance durable and reliable for defined period.

After opening the package, it is necessary to check all the components against standard configuration. Check that these are all present and in perfect condition.

INTENDED USE:

The F.O headlights are the medical devices used for illumination during examination. These medical devices are used by surgeons / health care professionals for Surgery, ENT examination, Laparoscopy, Neuro-endoscopy and other examinations.

PATIENT POPULATION:

The F.O headlights are not designed to be used directly on patients. However, these devices are used by doctors, surgeons and/or health care professionals for examination of complete patient population.

FEATURES:

The featured of both devices are given below;

Fiber Optic Headlights

- The Fiber Optic headlight is supplied with ergonomic head band, which is padded and fully adjustable in circumstances and height
- Superior comfort, durability and adjustability
- Head band cleaning made easier by removeable and washable padding
- Double lens precision optical with adjustable holder to focus the light point
- Illumination axis adjustable over wide range
- 3.5mm fiber optic bundle cable length 2.3 meter
- Connector for use with other manufacturer's projectors are available Supplied standard with Storz connector
- GIMA code 30853 has double lens precision optical with adjustable holder to focus the light point

OPERATING INSTRUCTIONS

Before using the product, it is necessary to adjust the helmet to the head size. To do this, use opposite adjusting screw located at the side, allowing to tight or loose the headbands.

- i. Adjust the head band according to heads size and wear the device on head for operation
- ii. Install the device according to the installation procedure and adjust the device for intended examination
- iii. Place the patient at right position and switch ON the device for examination

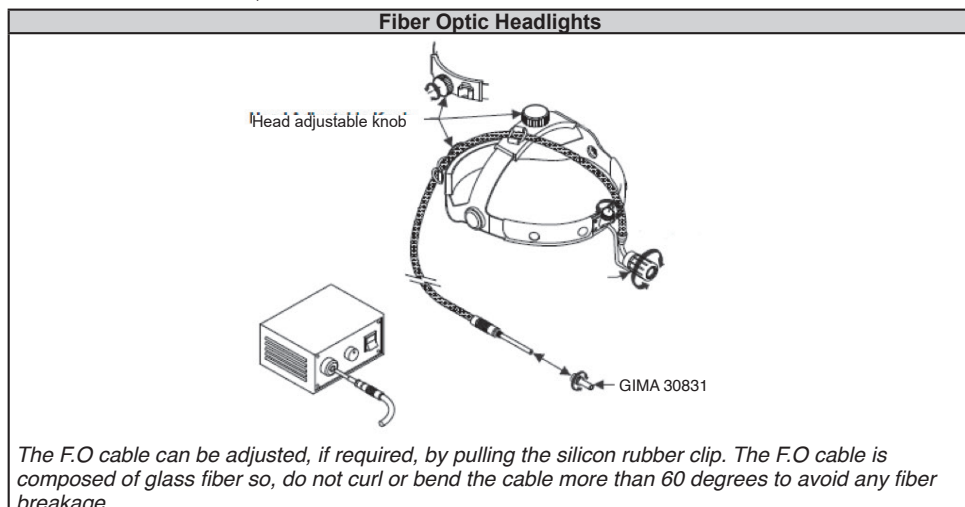
AVVERTENZE



- The F.O Headlight is not compatible to use in MRI environment.
- Do not use the product in direct contact with skin. Use suitable protection.
- The F.O headlights can only be used by trained professional and qualified medical personnel in a healthcare facility.
- The Fiber light cable is delicate. Handle it with care. Do not curl it or bend it more than 60° to avoid breakage in glass fibers.
- Always switch off the device after the use.
- Does not use the devices at distance closer than 25 cm for longer periods, it may result in Erythema.
- Do not look directly into the light source of headlight when illuminated. It can compromise the eyesight.
- Do not remove the fiber optic cable from the light source when light source is ON. The light guide distal end may transfer extreme heat. Proximal end of fiber optic cable may also be hot after use.
- Disassemble the devices only when these are turned OFF and heat is dissipated.
- Do not use the equipment in case it is damaged. Avoid precarious repairs. Repairs shall be carried out with original spare parts only, which shall be installed according to the intended use. For any other repair/replacement apply to your retailer.

INSTALLATION

These medical devices have a simple set-up and installation procedure. The installation of medical devices is illustrated below;



Note: Always turn OFF the device and keep the it for few minutes for cooling before disassembly and/or replacement of any component.

CLEANING OF F.O HEADLIGHT

The F.O Headlights don't require general cleaning. These devices are manufactured to last longer and resistant to most of chemicals except methyl ethyl ketones. However, these can be cleaned by using following steps;

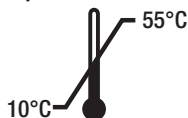
- Cold clean the helmet with some disinfectant and a sponge
- Always keep the fiber light guide light source end clean by using a damp cloth for optimal light output. Allow to dry before use.



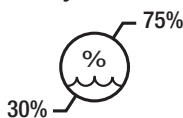
- Always turn OFF the device before cleaning. Don't immerse the F.O headlight into sterilizer or disinfectant liquids. It could cause damage to device.
- Avoid scratching or striking ends of fibers cable. Reduction in light transmission may occur.

OPERATING ENVIRONMENT:

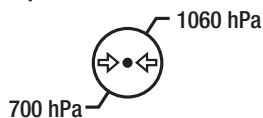
Temperature Limitation



Humidity Limitation

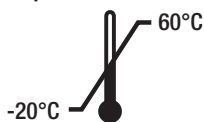


Atmospheric Pressure Limitation

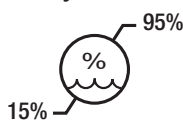


STORAGE ENVIRONMENT:

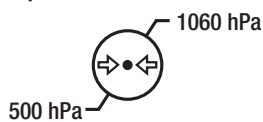
Temperature Limitation



Humidity Limitation



Atmospheric Pressure Limitation



MAINTENANCE:

These devices are maintenance free.

SERVICE:

The device has no components serviceable by the end-user.

CAUTIONS/GENERAL WARNINGS:

- Read the label before unpacking. Do not use the device in case of damaged packing.
- Do not use the equipment in case it is damaged. Apply to your Retailer / Distributor.
- Always remember that packing elements (paper, cellophane, stitches, adhesive tape, etc.) can cut and/or hurt if they are not carefully handled. They shall be removed with adequate means and shall not be left at the mercy of irresponsible persons.
- If the light is intermittent or in case it does not turn on, check the batteries and the electrical contacts.
- This product is not allowed to enter or be used in areas with strong magnetic fields e.g. MRI scanners.
- Any unauthorized modification/service is strictly prohibited at user end so, always contact the authorized person or send the unit back to the authorized agent.
- Autoclaving and Flash sterilizing of devices will result in severe electrical and mechanical damages so, these are strictly prohibited.
- Ultrasonic cleaning is not recommended
- Store the device in clean and recommended environment
- Conservare il dispositivo in un ambiente pulito e secondo quanto raccomandato

SHELF-LIFE:

The product has been conceived to last longer. However, the minimum shelf-life of these devices is 5 years.

SYMBOL INFORMATION:

	Keep away from sunlight		Medical Device compliant with Regulation (EU) 2017/745		Keep in a cool, dry place
	Product code		Consult instructions for use		Manufacturer
	Caution: read instructions (warnings) carefully		Lot number		Medical Device
	WEEE disposal		Data di fabbricazione		Temperature Limitation
	Humidity Limitation		Atmospheric Pressure Limitation		Imported by
	Authorized representative in the European community				Unique device identifier



Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.