

## CASCHETTO LED GIMA 5W - NERO GIMA LED HEADLIGHT 5W - BLACK LAMPE FRONTALE LED GIMA 5W - NOIR LED STIRNLEUCHTE GIMA 5W - SCHWA RZ CASCO LED GIMA 5W - NEGRO CAPACÊTE LED GIMA 5W - PRÊTO ΦΩΤΙΣΜΟΣ ΚΕΦΑΛΗΣ LED GIMA 5W - MAYPO خوذة بصيمام ثنائي باعث للضيو ء(LED) من صناعة 5W - GIMA 5

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.

Jeder schwere Unfall im Zusammenhang mit dem von uns gelieferten medizinischen Gerät muss unbedingt dem Hersteller und der zuständigen Behörde des Mitgliedsstaats, in dem das Gerät verwendet wird, gemeldet werden.

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.

É necessário notificar ao fabricante e às autoridades competentes do Estado-membro onde ele está sediado qualquer acidente grave verificado em relação ao dispositivo médico fornecido por nós.

Σε περίπτωση που διαπιστώσετε οποιοδήποτε σοβαρό περιστατικό σε σχέση με την ιατρική συσκευή που σας παρέχουμε θα πρέπει να το αναφέρετε στον κατασκευαστή και στην αρμόδια αρχή του κράτους μέλους στο οποίο βρίσκεστε.

يجب الإبلاغ فورا عن اي حادث خطير وقع فيما يتعلق بالجهاز الطبي الذي زودنا به إلى الجهة الصانعة والسلطة المختصة في الدولة العضو التي يقع .فيها



Made in China





Thank you for purchasing this product. To prevent damage to your product or injury to yourself or to others, read the following safety precaution in their entirety before using this equipment. Keep these safety instructions where all those who use the product will read them.

# Warnings and Cautions

 $\frown$  This product must not be used in the presence of flammable gases.

This product should not be immersed in fluids.

Do not shine the light directly into the patient's eyes.

Ensure that the headband power cord is located in the clips provided. The headlight body

should not be left covered with a cloth or similar.

Federal law restricts this device to sale or order of a physician.

## 1. Purpose and Features of the product

#### 1.1 Purpose

The headlight is used for examination and surgical operation in multifarious microsurgery.

#### 1.2 Features

- Light Source: Our LED without the heat of traditional Halogen headlight. With a color temperature of 5000 Kelvin, this
  light supplies bright, white, shadow-free light allowing the doctor to see tissue characteristics without distortion.
- Enjoy the flexibility of operating the headlight using the rechargeable Lithium battery, can use without the direct power source. It is one of the most comfortable lightweight headlights and suitable for all kinds of surgery.
- · The headlight could be used when it is charging.
- · Has low-battery indicator light.
- Adapts to any Binocular Loupes of GIMA.
- · Smart design, convenient for mobile diagnosis.

### 2. Operating Instructions

Attach the power cord by means of the clip provided. Place the instrument on your head and adjust for width and height to that it fits comfortably.

Connect the Headlight to the power adapter. Switch it on and use the headband right or left brightness control knob to select the required brightness.

Loosen the fixing screw to adjust the light head up and down and backwards or forwards. After adjustment, re-tighten the screw. The illuminated field of view can be selected by means of the slide control.

### 3. Maintenance

### 3.1 Battery charging and replacing

During charging the LEDs operate sequentially, in use they remain switched on. If the LEDs remain switched off, the unit is non-operational or the battery is switched off. The number of illuminated or sequentially-switched LEDs indicates the state of charge of the Li-ion battery. The state of charge is shown whether an instrument is connected or not. All four LEDs illuminated indicated a fully-charged battery,

If only the yellow LED illuminated, the battery must be recharged. Switch off the battery and recharge it by means of the transformer.

Caution: Please use the appropriate battery. The battery should never be placed in municipal waste. Please check local regulations for disposal of batteries.

### 3.2 Battery use and care

The capacity of Lithium battery will be changed by it's using condition. For maximum battery capacity, use the battery in room temperature ( $10 \,^{\circ}C \sim 40 \,^{\circ}C$ ). Do not expose the battery to extreme temperatures, if the battery is used in high or low temperatures, the battery capacity will be reduced.



The old batteries should never be placed in municipal waste.

### 3.3 Cleaning and sterilization

- The outer surface of the instrument may be cleaned with wet cloth, the remaining stains can be cleaned off with the
  mixture of 50% alcohol and 50% distilled water. Do not wipe with any corrosive detergent lest that the surface should
  be damaged.
- Cleaning the lenses: Mirror-cleaning paper or a drop of liquid solvent (50% alcohol and 50% aether) may be used to clean the lens, blow it carefully. If there is dust stained on the lens, blow them with a blowball or brush them with a dust pen.

Caution: Be careful to prevent the solvent into the instrument.

## 4. Technical Specification

Optical specifications 420mm illumination light spot Illumination in 200mm working distance Adjustable range: Fluctuation distance Angle range Vertical Weight: Headlight (excluding head band)	20-80mm ≥ 60000 lx 12.5mm ±25° 69g
Electrical specifications	Extremely bright light, 5W LED, life 20000 hours continuous burn,
Illumination Source	do not need to change the LED lamp.
Battery	7.4 V (4400 mAh) Lithium battery
Battery Run-time	Not less than 7 hours continuous runtime on a fully charged battery.
Battery Charging-time	Not more than 5 hours

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Battery Charging-time	Not more than 5 hours
Rating Adapter Voltage	100VAC-240VAC 50Hz/60Hz
Maximum Adapter Input Power	≤ 24 VA
Power Adapter Output	12V DC 2A
Electrical Safety	EN60601-1,EN60601-1-2 / CLASS II / Internal electrical power source

#### **Environment requirements**

Operation: Environment Temperature Relative Humidity Atmospheric Pressure

#### Storage: Environment Temperature

Relative Humidity Atmospheric Pressure 30% - 75% 700 hPa - 1060 hPa

+10°C - +40°C

-40°C - +55°C 10% - 90% 500 hPa - 1060 hPa

$\triangle$	Caution: read instructions (warnings) carefully	<b>E</b>	Follow instructions for use
CE	Medical Device compliant with Regulation (EU) 2017/745	М	Date of manufacture
×	Keep away from sunlight	Ť	Keep in a cool, dry place
REF	Product code	LOT	Lot number
X	WEEE disposal		Class II applied
[₩/<	Internal electrical power source	MD	Medical Device
Ŕ	Type BF applied part		



**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.