

NUOVA LAMPADA FRONTALE LED GIMA
NEW GIMA LED HEAD LIGHT
NOUVELLE LAMPE FRONTALE À LED GIMA
DIE NEUE GIMA STIRNLAMPE
NUEVO FARO LED GIMA
NOVA LANTERNA DE CABEÇA LED GIMA
ΝΕΟΣ ΦΑΚΟΣ ΚΕΦΑΛΗΣ LED GIMA

المصباح HL8000

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.
- 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.
- 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.
- 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.

- المهيف عقديي تلا وضعلا لودلاي ففةصتخملا طلسلاو ةعناصلا ةهجللاي لإ هب اندوز بذلاي بطلا زاهجلاب قلعنئاميف ع قو ريطخ تدا- يأ نع اروف غلابلا ب جيد

GIMA 30939



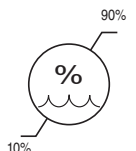
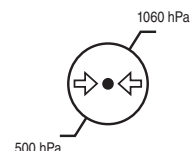
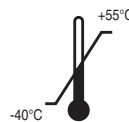
Zumax Medical Co., Ltd.
5 Zhiying Street, Suzhou New District,
Suzhou, Jiangsu, China
Made in China

REF HL8000

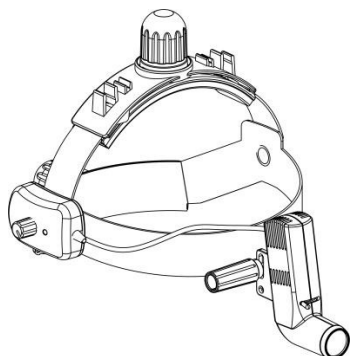
EC REP MedNet EC-REP GmbH Borkstrasse 10,
48163 Münster, Germany



Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com



ENGLISH



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.

Symbols:

	Illumination adjustment mark
	Caution: read instructions (warnings) carefully
	Class II applied
	Manufacturer
	Date of manufacture
	Product code
	Lot number
	Internal electrical power source
	Temperature limit
	Atmospheric pressure limit
	Humidity limit
	Authorized representative in the European community
	Medical Device compliant with Regulation (EU) 2017/745
	Keep in a cool, dry place
	Keep away from sunlight
	Follow instructions for use
	WEEE disposal
	Medical Device
	Unique device identifier

1. Read this article for Cautions and instructions for use.
2. Do not use this instrument in damp rooms. Do not expose the instrument to water splashes, dripping water or sprayed water.
3. This product must not be used in the presence of flammable gases.
4. Do not shine the light directly into the eyes.
5. 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.
6. Please use special certificated adapter.
7. Never scratch the glass cover with fingers or any other hard materials.
8. Federal law restricts this device to sale or order of a physician.
9. The battery life is 300 charges and discharges, exceeding the period creates a risk

1. PURPOSE AND FEATURES OF THE PRODUCT

1.1 Purpose

Headlight HL8000 is used for examination and surgical operation in multifarious microsurgery.

1.2 Features

- Light Source: LED source with color temperature of 5000K. 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.
- Battery indicator lights.
- Adapts to any Binocular Loupes.
- Smart design, convenient for mobile diagnosis.

2. OPERATING INSTRUCTIONS

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

Connect the Headlight to the power adapter. 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, retighten the screw. The illuminated field of view can be selected by means of the slide control.

3. MAINTENANCE

Caution: Qualified trained professional persons are needed to maintenance the product. Please contact with authorized dealer or manufacture.

3.1 Battery charging and replacing

3.1.1 Battery case BT552 is charged

Battery box BT552 (hereinafter referred to as the battery) yellow light, prompted to charge or replace as soon as possible to recharge the battery backup. If the power indicator only yellow light and continue to use, the battery will start self-protection, cut off the power to prevent the battery over-discharge.

When charging, connect one end of the power adapter output line to the round hole on the side of the battery, and the power adapter is plugged into the network power socket. At this point the charging indicator will flash from yellow to green followed by charging.

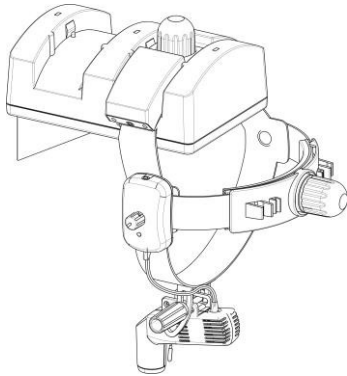
Charging lights are all off, indicating that the battery is full. When charging, the headset inspection lamp can continue to use.

3.1.2 Battery case BT556 is charged

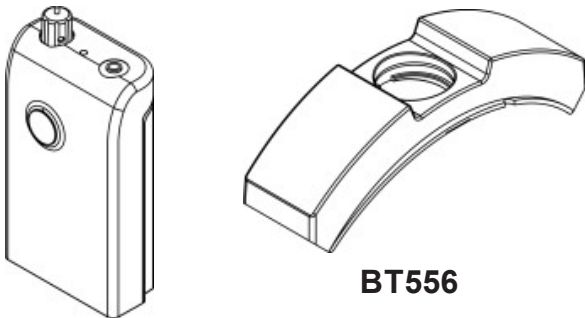
The headlamp can be plugged directly into the charger to charge when the battery power is depleted.

When charging, you should put the headlight in the charger and connect adapter one end connected to the charger and the other

end connected to power supply.



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



BT552

BT556

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°C ~40°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..

3.3 Cleaning and sterilization

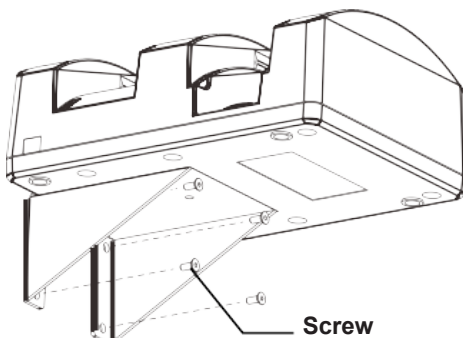
- The outer surface of the instrument may be cleaned with wet cloth, the remaining stains can be cleaned off with the mixture of 50% alcohol and 50% distilled water. Do not wipe with any corrosive detergent lest that the surface should be damaged.
- Cleaning the lenses: Mirror-cleaning paper or a drop 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 device..

4. INSTALLATION

4.1 Installing the cradle

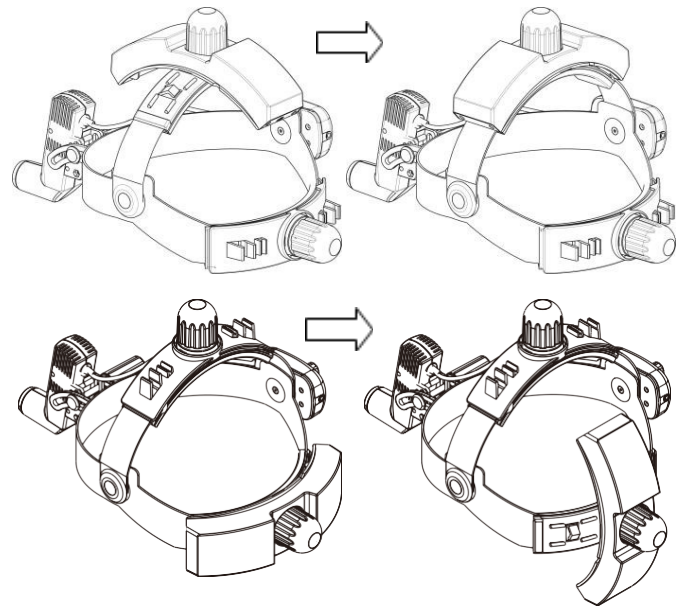
According to the battery box mounting hole in the wall, fighting two expansion screw holes and then typing the expansion screw sets and then installing the device as follow the picture.



4.2 Installing the battery into the headband

Installing as shown in below picture, the battery cartridge into the

adjusting knob cover, then rotate along time until the level stops. Removing, counter-clockwise rotation to 90 degree position and then pull it out. There are two types of battery installation, respectively, up or back.



5. TECHNICAL SPECIFICATION

Optical specifications		
illumination light spot at 420mm	20~80 mm	
Illumination in 200mm working distance	≥ 75000 lx	
Adjustable range		
Fluctuation distance	≥ 12,5 mm	
Angle range	Vertical ±25°	
Electrical specifications		
Headlight (excluding head band)	69 g	
Electrical specifications		
Illumination Source	5W LED, life 20000 hours continuous burn, do not need to change the LED lamp.	
Electrical Safety	EN60601-1, EN60601-1-2 Class II and internal electrical power source	
Accessories		
Battery BT552	7.4 V Recharged Lithium battery (4400mAh)	
Battery BT556	7.4 V Recharged Lithium battery (1800mAh)	
Power adapter input voltage	100VAC ~ 240VAC, 50Hz or 60Hz.	
Power adapter Output voltage and power	Output voltage 12 V, maximum input power ≤ 30 VA	
Battery Run-time	≥7 h (Maximum luminance) BT552 ≥3 h (Maximum luminance) BT556	
Battery Charging-time	≤ 5 ore BT552 ≤ 2,5 ore BT556	
Protection	Short circuit protection, power protection and over current protection.	
Environment requirements		
Operation	Temperature	+10°C ~ +40°C
	Rel. humidity	30% ~ 75%
	Air pressure	700 hPa ~ 1060 hPa



Storage	Temperature	-40°C – +55°C
	Rel. humidity	10% – 90%
	Air pressure	500 hPa – 1060 hPa



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.