SurgiMag Maestro Cordless LED Headlight User Manual

Read this user manual thoroughly before use, and keep it handy so you can always find it w hen you need it.

SGM-IFU-001-OH-ENG (Rev.0)

Preface

The contents and specifications herein are subject to change without prior notice, and SurgiMag Co., Ltd. assumes no respo nsibility for consequences resulting from inaccuracies or typos , if any.

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About Symbols

The following terms or symbols are used on the device or herein to indicate especially important information.

	Check the manufacturer name	~ 1	Date of manufacture
REF	Catalog number	LOT	Lot Number
X	Limited operating temp	Ţ	Fragile - handle with care
\triangle	CAUTION! Notification of important operating		Serial number
	and maintenance instruction	Ť	Beware of rain/moisture
٨	Instructions for use		Instructions: Waste from Electrical and Electronic Equipment (WEEE)

About Authorization

This is a medical equipment. Authorized to manufacture by and reported to Ministry of Food and Drug Safety as follows:

Manufacturing Authorization Number	Je 7575	
Manufacturing Item Report Number	Jesin 21-1648	
Item Family	General medical equipment	
Rating	Class 1	
ltem	A03000 Medical Light and Lamps	
Item Name	A03030.01 Operating Headlamps	
Model Name	Maestro	
Manufacturer	SurgiMag Co., Ltd.	
Country of Manufacture	Republic of Korea	
Address	No 104, 34, Sangni 1-gil, Deokjin-gu, Jeonju-si, Jeollabuk-do, 54882, Rep. of KOREA	

Safety Precautions

Be sure to be aware of the following safety precautions before using the equipment. Failure to comply with them may lead to a ccidents such as fire, property damage, and physical injury, and the manufacturer is not responsible for injuries or damages cau sed by failure to follow the instructions.



WARNING

- Do not use the equipment for any purpose other than that described in the manual.
- Do not use or store the equipment near fire or flammable materials.
- Keep the equipment out of reach of children.
- Do not disassemble or modify the equipment.
- Do not insert foreign objects into the equipment.
- Do not drop or jolt the equipment.
- Do not heat the equipment using a microwave or oven.
- Do not touch the LED or the body during use.
- Do not short-circuit the equipment touch points.

Usage Precautions

- Do not remove the equipment serial number label.
- Do not touch the bottom of the battery pack or the electrical touch points of the LED headlight connections.

- Keep at least 200mm from the patient during use.
- Do not hang the equipment using the exposed cables of the LED headlight. The wires might break and cause an error.
- This device is not waterproof and should not be used with liquid or in a humid environment.

A Charging Precautions

- Do not use the device if the electrical touch points or plugs are damaged.
- Only use a direct current power supply and power cord supplie d. Otherwise, emissions may increase and/or immunity may d ecrease, and the system may not meet IEC 60601-1-2 requirements. The manufacturer is not responsible for any risk or damage caused by the use of direct current power su pplies not provided by the company.
- Do not touch the power cord or plug with wet hands. There is a risk of electric shock or product failure.
- Do not apply excessive pressure to or bend the power cord. There is a risk of fire or electric shock

A Battery Precautions

- The battery used in this product is a lithium ion polymer.
- Check the product for any external anomalies during your first use after opening.
- If the battery is inflated, leaky, emits an odor, or otherwise, s top using the equipment and contact the place of purchase or the manufacturer.

- The battery should be charged at 0 40 °C (32 104 °F).
 Charging outside the range may lengthen the charging time.
- Battery life is significantly shortened at -10 °C (14 °F) or bel ow. In this situation, hold the battery in your hand or put it i n your pocket to keep it warm before use. However, be care ful not to heat the battery directly, as this may cause an exp losion.
- Only charge the battery with a direct current power supply provided by the manufacturer.
- The battery is a consumable with about 500 times of charge/ discharge availability.
- To extend the life of the battery pack, do not store the battery pack fully charged or discharged.
- Using the battery for purposes other than the specified ones may cause the battery to overheat, ignite, explode and cause serious injury.
- Do not apply any powerful impact or pressure to the battery, such as drilling holes in it, hammering it, putting in a pocket and sitting on it, or stepping on it. There is a risk of fire or e xplosion.
- Do not disassemble or alter the battery. Safety and protection devices in the battery may be damaged leading to overheating followed by fire and explosion.
- If battery fluid leaks into your eyes, do not rub or press your eyes, but immediately wash them with running water and se ek medical advice. Do not use eye drops without your docto r's consent.

- Do not let the battery terminals contact metallic objects such as coins, keys, wires, necklaces, or clips. Do not put it with coi ns into a pocket or connect the positive and negative poles wi th wires.
- Do not directly solder onto the battery.
- Do not allow the battery to come into contact with liquid.
- Remove and discard expired batteries according to establish ed regulations. There is a risk of explosion if incinerated or heated and of environmental pollution unless adequately se parated for disposal.

LED Precautions

- Do not jolt the LED. This will lead to errors.
- Do not excessively bend the cable of the LED connected to the LED headlight.
- Clean the contaminated lens gently with a soft cloth dampened with alcohol.
- Do not shine the LED light directly to the eyes. This equipm ent complies with the blue light testing standards for safety established by the International Electrotechnical Commission (IEC), and as with any other product, should not be looked in to directly.
- Ensure that all screws and removable components are secured to the device before use.

⚠ Signals Indicating Device Failure

Stop using the equipment and disconnect the power source or battery immediately in the following situations:

- The device is hot.
- The device emits smoke or odor.
- The color or shape of the device has changed.

If you notice any other abnormal differences, stop using it immediately.

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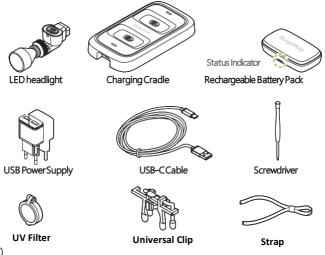
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Introduction

Surgimag[™] Maestro[™] Headlight is a wireless medical LED lighting dev ice. Maestro is designed to facilitate medical and surgical treatment b y shining LED lighting on the affected area. Without the need of a ca ble between the LED headlight and light lens, the wireless equipment offers freedom of movement for treatment/ surgery and less fatigue in use. It is also designed to be attached directly to TTL (Through The L ens) loupes, headbands, ophthalmic dress, safety glasses, and more.

Components

Check the following information to ensure that all components are present.



Product Specificatio

Batteries		DC 3.7V 500 mah Li-Polymer	
Runtime		 About 1.5 hours (on third step mode, at max luminance) About 2.5 hours (on second ster.) 	
		 About 2.5 hours (on second step) About 4 hours (on first step mode, at max luminance) 	
Buffering Time About 1 hour & 40 mins		nour & 40 mins	
Light Source Device		High Pow	er LED (White Light)
	Medical DC Supply Sou		Input: AC 100 - 240 V, 50 - 60 Hz. 0.3 A
Option			Output: DC 5 V 2 A
	Charger Power		Input: DC 5 V 2 A
			Output: DC4.2 V 1.0 A

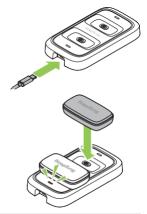
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Preparations Before Use

Charge the battery. The device is shipped without being charged and so should be charged before use.

1. Connect the provided DC power supply to the charging cradle.

2. Place the battery on the charging cradle. The LED of the charging cradle turns orange. When the battery is fully charged, the LED of the charging cradle turns off. It takes about 1.5 hours to fully charge.





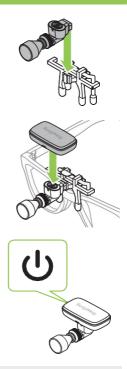
When placing the battery on the charging cradle, make sure that the battery is placed with the correct magnetic polarity. The manufacturer is not responsible for any failure caused by wrong positioning.

3. Connect the fully charged battery with the LED headlight.



How to Use

- Use either a universal clip or a T-shape clip to mount the LED headlight (without a battery) into the glass frame.
- Mount the battery into the headlight with the status indicator facing forward. At this time, be careful not to let hairs or foreign objects get caught between the touch points.
- 3. Touch the right side of the battery to turn the headlight on and off.





When the battery pack is running low, the battery wa rning indicator lights up in red and flashes periodically. In this case, do not start the procedure and replace th e battery. The battery warning indicator does not flas h when the battery is removed from the headlight. *RED LED light: Battery low waring indicator **4.** Touch the top of the battery to adjust brightness.



Steps	Brightness (Lux) / WD 350 mm	Runtime
1	4800	4 hours
2	10,000	2 hrs 20 mins
3	15,500	1 hrs 30 mins

5. Adjust angle of the LED headlight. At this point, you can tighten the screw to lock the headlight in the desired position.





Do not point the LED headlight toward the eyes. Do not loo k directly at the lamp when turned on, as this device may e mit hazardous optical radiation. Direct exposure to intens e LED light can cause permanent eye damage. (IEC 62471 Risk Group 1)

6. When finished, touch the side of the battery to switch it off.

Troubleshooting

- The LED headlight does not turn on.
 - The battery may be discharged. Charge the battery before us e.
 - The touch point may not have been properly in place. Wipe the touch point of the battery with a dry cloth and mount it again.
- The LED indicating battery attachment does not turn on.
 The battery may not have enough power left. Charge the batter y before use. If the problem persists after charging the battery, contact the seller or the manufacturer.
- The battery is overheated and is smoking.
 Stop using immediately and contact the seller or the m anufacturer.
- The battery has expanded in size.
 The battery has reached end of life and needs to be replaced. St op using immediately and contact the seller or the manufacture r.
- The touch button does not work.

The button may be broken by external shock. Please contact the seller or the manufacturer.

Management

Cleaning and Disinfection

The headlight is delicate and should be cleaned and disinfected ac cording to the instructions below. Otherwise, the device can be d amaged.

- Use isopropyl alcohol with a concentration of 70% or less
- Wet soft cotton or cloth with a disinfectant solution and wipe the equipment. Remove excess liquid from the cloth or cotton by squeezing it out before use.
- Wet a soft cloth with a neutral detergent, wipe the outside of the equipment and let it dry.
- Be careful not to pull exposed cables when cleaning the equipment.
- If the glasses need to be cleaned, remove the headlight, clean and dry the glasses and then mount the headlight again.
 - Do not use equipment or turn on the power in water.
 - Do not spray water or chemicals directly on the surface of the equipment.



- Do not place the equipment in any liquid or an ultrasonic cleaner.
- . Do not place it in a sterilizer or chemical sterilizer.
- Do not clean the equipment with water or volatile chemicals such as benzene, thinner, or acetone. T he liquid can penetrate and cause malfunction or other accident.

Storage

- If you are not going to use the equipment for an extended period of time, remove the battery from the headlight.
- Store in a dry place with temperature of 0 40 °C (32 104 °
 F) away from direct sunlight, and not affected by air pressure, temperature, or humidity. Note that cold temperatures below -10 °C (14 °F) cause battery degradation, making charging difficult and runtime shorter.

	Operates	Does Not Operate
Ambient	0 - 40 °C	-10 - 40 °C
Temperature	(32 - 104 °F)	(14 °F - 104 °F)
Relative Humidity	30 - 85%	30 - 85%
Barometric Pressure	860 –1060 hpa	860 –1060 hpa
85%	∬ <i>_</i> − 40°C	- 1060 hPa



- Store in a location not affected by air containing dirt, salt, and/or ions.
- Store in a location not affected by vibration, shock, heat, etc.
- Do not place the light in your pocket. The device might overheat.
- Do not pull, twist, or bend the power cord excessively.

Disposal

- According to the European Union's Waste from Electrical an d Electronic Equipment (WEEE) guideline, waste electrical/ ele ctronic products cannot be disposed of as household waste a nd must be collected, recycled, or disposed of separately.
- If you intend to discard the equipment, contact the seller or the manufacturer for recycling.
- Electrical/electronic equipment contains hazardous substan ces and may pose a risk to human health and the environm ent if disposed in a local government landfill that is not desi gned to prevent material from leaking into soil or groundwa -ter.
- The Maestro series include lithium-ion batteries. Recycle or dispose of them according to national, state, and/or local re gulations.

Transport

- Package the product in bubble-filled packaging, shipping box or similar packaging to prevent damage to the product during shipping.
- When loading the product into a hand cart, pick-up truck, or car trunk, load the product packaging box with the proper updown orientation.
- If you are transporting the equipment by hand, secure it with both hands and remove the power line and charger from the body.

Quality

If the product fails during use, you can receive complimentary service one year from the date of purchase. However, if the f ailure is caused by customer error or natural disaster, service will be charged for even within the warranty period.

Service is charged for when:

- 1 year has passed from the date of purchase
- The product has been disassembled, repaired, or modified by a person other than an authorized technician.
- The product has failed because the safety precautions herein were not followed
- The product has failed due to user negligence



