

STAZIONE DI RICARICA per oto-oftalmoscopi SIGMA CHARGING STATION for SIGMA oto-ophthalmoscope STATION DE CHARGE pour oto-ophtalmoscopes SIGMA ESTACIÓN DE CARGA para oto-oftalmoscopios SIGMA

Manuale d'uso - User manual Manuel de l'utilisateur - Guía de uso

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.



General Instructions

a) The charging station along with power transformer is intended for installation in hospitals outside the Patient Environment at least 1.5m from the patient pursuant to IEC 60601-1.

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- b) There is no restriction for installation in case the Charger is to be powered up using laptop or PC. Do not touch the handle (under charging) and patient at the same time.
- c) After connecting the USB cable with the charging station and Power transformer to AC mains, the charging station is ready to use (the red indicator light shows "Stand By" position). After insertion of the battery handle, the color of the indicator light changes to any of the four colors as per charge status or voltage level of the battery under charging.

Features

- 1) Smooth and Aesthetic design.
- 2) Equipped with USB type $\sim C$ "connector for power input.
- Smart circuitry for constant, automatic and safe charging for optimum performance and increased life of the battery.
- 4) Indicator light with multiple colors for Charge Status of the battery from 0% -100% as below:

Power On	0-30%	30%-60%	60%-90%	90%-100%	

- 5) Full Battery Charge in 2.5 hours.
- Can be connected to PC or laptop via standard USB cable type C eliminating the need of Power transformer.
- 7) Power Transformer with multi plug options and USB cable can be supplied on demand.
- 8) The Charger follows CC \ CV charging mode.
- 9) It is independent from AC mains voltage and connected to Gima standard 5.0V power transformer equipped with USB type C connector. Another most advanced feature is that it can easily be connected to either laptop or PC using USB type C cable.
- 10) Max. Charging Current up to 0.5A.
- 11) Max. Charging Voltage up to 4.2V.
- 12) Device should be turned off when not in use and to safely terminate the device, user should unplug the device from the AC mains/Wall Socket or Board.
- 13) Specifications of Charging Unit: Input Voltage: 5.0V DC Output Voltage: 4.2V DC Charging Current: 0.5A max Protection Class: II
- 14) Specifications of Power Transformer: Input Voltage: 100-240VAc, 50/60 Hz Output Voltage: 5.0V DC Output Current: 1A Protection Class: II Cable with connector: USB Type C
- 15) Dimensions: Dimensions: 60mm (2.3") x 62mm (2.4"), Weight: 108 grams

Assembling

Attach the Power input Plug with the Power Transformer. Connect the USB Type C cable, coming out from Power transformer, with the charger and connect the power transformer to AC mains/Wall Socket. The red indicator light shows that the power is connect and the Charger is ready to use now.



Intended use

The charging station is intended to charge Gima Rechargeable Handles having rechargeable 2.5V Li-po battery.

Use of Rechargeable Handle:

- The charger is intended to supply power to handle for charging the battery.
- Before putting the battery handle into charging station please check the battery, do not put the battery for charging if leakage occurs.
- Remove the batteries from the handle if not in use for long time.

Cleaning

Before cleaning disconnect the device from AC mains. The outside of the charging station can be cleaned with a damp, soft and lint-free cloth to disinfect the unit. Dipping the unit into solutions or cleaning agents is not allowed. Periodically check the charging station, making sure that no sign of corrosion or oxidation and dust is present, in case they are present, it is highly recommended to clean the charger.

Do not use abrasive ultrasonic cleaners, alcohol or other chemicals to clean the unit as this may degrade the outside surface of the charger, as they will scratch the surface. Autoclaving and Flash sterilization of the charger result in severe electrical damages.

Storage

Since the product is made of corrosion-proof materials suitable for the environmental conditions foreseen for its normal use, it does not require special care, however it is necessary to store it in such a way as to make sure that it is protected from dust, and water to assure its hygienic conditions and protection against short circuit. Moreover, it is recommended to store the charger without battery in place.

Recommended Operating Environment

Operation

Temperature	0°C to 40°C	
Humidity	5% to 70%	
Air Pressure	700hPa to 1000hPa	

Storage and Transport

Temperature	-20°C to 80°C	
Humidity	5% to 90% (Without Condensation)	
Air Pressure	700hPa to 1000hPa	

Use and Maintenance

- Handle the charger carefully as it contains circuit for charging battery.
- Any unauthorized modification/service is not allowed because it may cause short circuit that may damage the equipment, so always contact an authorized person or send the unit back to the manufacturer for repair.
- Disconnect the charger from main supply prior to any maintenance.
- Charger is not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide. An explosion may result.
- Examine the charging station for wear or damage monthly. Clean the charger once in a week according to the Cleaning Section of this manual.
- Do not charge dry cells. When used and stored properly, charging station will serve you many years.

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General Warnings

Check the correct operation of the device before use. Do not use the device if there are visible signs of damage. Do not use the device in fire or explosion risk area (e.g. oxygen saturated or an anesthetic saturated environment). Do not modify the device. Use only original Gima parts, spare parts, accessories and power sources. The device must not be placed near strong magnetic fields, e.g. MRI Units. Check the device for contamination before use. If necessary, clean the device or dispose of it in the event of non-removable contamination

Precautions

- The unit should be handled carefully.
- The product shall be used by qualified personnel only. Do not use the equipment in case it is damaged. Apply to your retailer. Avoid precarious repairs. Repairs shall be carried out with original spare parts only, which shall be installed according to the intended use.
- When placing or replacing the handle in the charging compartments, ensure that the internal contacts in the compartments are clean and that the instrument is switched off.
- Use only with 'Gima' standard Power transformer and 'Gima' rechargeable handle. Using non-standard power transformer can damage the charger.
- Do not short the charging pins, it can burn the charging circuit or cause fire. Carefully handle the charger and immediately replace in case of any damage. Avoid precarious repairs. Repairs shall be carried out with original spare parts only, which shall be installed according to the intended use. Protect charging pins against short circuiting.

Ť	Keep in a cool, dry place		Manufacturer
*	Keep away from sunlight	CE	Medical Device compliant with Regulation (EU) 2017/745
(Follow instructions for use	Â	Caution: read instructions (warnings) carefully
REF	Product code	MD	Medical Device
LOT	Lot number	~~	Date of manufacture
X	WEEE disposal	UDI	Unique device identifier
9%	Humidity limit	\$•\$	Atmospheric pressure limit
	Temperature limit		



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.