GIMA

PROFESSIONAL MEDICAL PRODUCTS

DERMATOSCOPIO GIMA XENON ALOGENO - 10x
GIMA XENON HALOGEN DERMATOSCOPE - 10x
DERMATOSCOPE GIMA XÉNON HALOGÈNE - 10x
DERMATOSCOPIO GIMA XENON HALÓGENO - 10x
DERMATOSCÓPIO GIMA XENON HALOGÊNIO - 10X
DERMATOSCOP GIMA XENON HALOGEN - 10x
DERMATOSKOP GIMA XENON HALOGEN - 10x
GIMA XENON HALOGÉN DERMATOSZKÓP - 10x

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.

Orice accident grav produs, privitor la dispozitivul medical fabricat de firma noastră, trebuie semnalat producătorului și autorității competente în statul membru pe teritoriul căruia își are sediul utilizatorul.

Det är nödvändigt att meddela tillverkaren och de behöriga myndigheterna i den berörda medlemsstaten, om alla allvarliga olyckor som inträffat i samband med den medicintekniska utrustning som levererats av oss.

A gyártónak, illetve a székhely szerinti tagállam illetékes hatóságának jelezni kell bármilyen olyan súlyos balesetet, amely az általunk szállított orvostechnikai eszközzel kapcsolatban történt.

REF **808-550-25 (Gima 31187)**

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

EC REP Obelis s.a. Bd Général Wahis 53
B-1030 Brussels, Belgium

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

MD

M31187-M-Rev.7-09.23

Attention

Thank you for purchasing our Dermatoscope. The operator/user must carefully read and understand this manual thoroughly to keep the product performance durable and reliable for longer period.
After opening the packaging, first of all it is necessary to check all the components against the standard configuration. Check that they are all present and in perfect conditions.

About Our Product

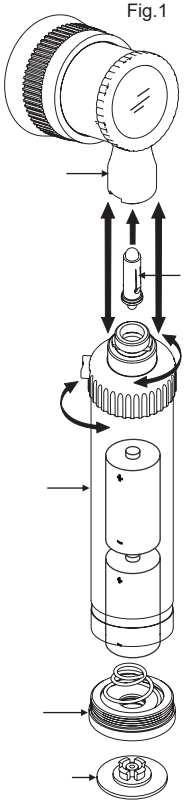
The Dermatoscope is used for pre-operative evaluation of cutaneous pigmented lesions with the aim of differentiating early melanoma, which requires excision from nonmelanomatous pigmented lesions that may safely be left untreated. The use of the Dermatoscope three-color test could reduce excision of benign melanocytic naevi, and thus prevent both unnecessary minor surgical workload and patient morbidity.

Feature

1) Halogen Light for true tissue color.
2) Graduated skin contact plate to measure pigmented skin lesions.
3) Significant 10X magnifications.
4) This product has focal range +/- 5D (correction).
5) Focal length is 25mm.
6) Autoclavable contact plates.

This Dermatoscope is available in the reliable bayonet locking system and is equipped with a 2.5 V Xenon/halogen lamp to be powered by two 1.5 V “C” type batteries.
This Dermatoscope is packed in zipper case with vacuum formed inner fitting.

Fig.1



Operating Instructions

Before using, it is necessary to install the battery components into the handle proceed as illustrated in battery replacement procedure.
The Dermatoscope handle can be powered by two 1.5V “C” type batteries. Alkaline batteries are highly recommended for optimum performance.
Place the Dermatoscope on top of the handle by aligning the slots to the ones on the handle. Push down and twist clockwise until it locks on the handle.
Push the white button on the handle and twist the black knob towards the left hand side. The unit is now in operation.
The intensity of the light can be adjusted by turning the knob clockwise or counter clockwise.
Gently rest the contact plate on the lesion such that the lesion is in the center of the contact plate and examine for its surface structure. To reduce glare from stratum conneum, apply oil (Mineral oil, Petroleum Jelly, etc).
With your index finger on the Rubber Focusing Ring, adjust for optimal focus while your eye is resting on the Rubber Eye Guard.
Observe the illuminated and magnified lesions, making notes for treatment.
To measure pigmented skin lesions, the graduated contact plate must be used.
Switch of the unit after use to preserve batteries. Twist the black knob towards right until an audible click sound is heard once the button comes to its off position.

Care and Maintenance

Periodically check the battery conditions, making sure that no sign of corrosion or oxidation is present.

Cleaning and Sterilization

Contact Plate

The contact plate must be taken off after each examination.
The contact plate can withstand cleaning or disinfection by soaking in alcohol solution, cidex, etc.
The contact plate can also be autoclaved up to 135º C and Pressure of 28 p.s.i.

Lens

The lens can be cleaned by using a moistened cotton-tipped applicator with alcohol or a solution of water with mild detergent.
Do not use abrasive materials to clean the lenses as they will scratch the coated surface of the lenses.

Handle

The handle can be cleaned with a moist cloth.
Battery handle shall not be dipped into water. Remove battery components while cleaning

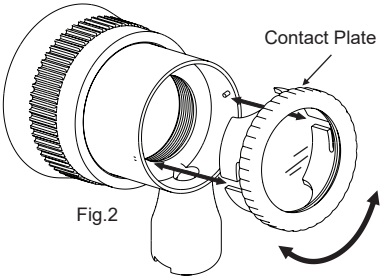


Fig.2

Lamp Replacement Procedure

Before removing the lamp, make sure that the device has been turned off for some minutes other wise you run the risk of being burnt. Lamps may be hot. So it's necessary to let it cool.

Remove Dermatoscope head from the power source as advised in operating instructions (See fig.1).
Pull out lamp with nail file or similar tool (if necessary) by getting it under the base of lamp (See fig.3).
Use recommended lamp for replacement by carefully aligning pin on lamp shaft with slot in Dermatoscope head. Push the lamp until seated well.

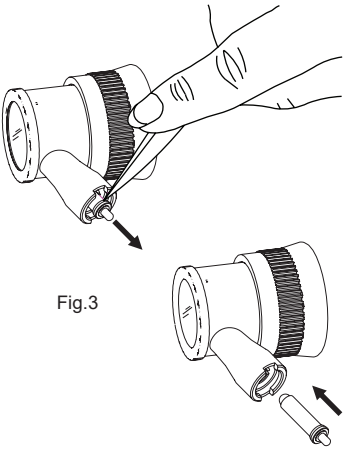


Fig.3

Clean the contact plate with cleaning solution prior to autoclaving.

Battery Replacement Procedure

In case of necessity replacement of new batteries then carefully handle the batteries as the liquid in a leaking battery can irritate skin and eyes.

While replacing batteries it is necessary to use exclusive alkaline type batteries.

a) Open the battery compartment, to do this, turn the end cap counter clock wise.
b) Once opened, insert the batteries paying attention to the direction of poles (See fig 1).
c) To close the battery compartment, screw down the cap clock wise and check that the batteries are in contact with poles.

Storage

Since the product is made of corrosion-proof materials suitable for environmental conditions foreseen for its normal use, it does not require special care. However it is necessary to store it in a closed place making sure that is protected from dust and dirt to assure it's hygienic properties. Store in clean environment and preserve in normal temperature.

Precautions

Dermatoscope is equipped with halogen lamp and shall be used exclusively with alkaline batteries type "C" correctly installed.
This shall be used by qualified medical personnel only.
Don't use the equipment in case it is damaged. Apply to your retailer.
If the instrument has rusted then don't use it.
Avoid precarious repairs.
Repairs shall be carried out with original spare parts only, which shall be installed according to the intended use.
Protect lamp surface against abrasions and scratches.

***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.

	**IT** Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso **GB** Caution: read instructions (warnings) carefully **FR** Attention: lisez attentivement les instructions (avertissements) **ES** Precaución: lea las instrucciones (advertencias) cuidadosamente **PT** Cuidado: leia as instruções (avisos) cuidadosamente **RO** Atenție: Citiți și respectați cu atenție instrucțiunile (avertismentele) de utilizare **SE** Varsamhet: läs anvisningarna (varningar) noga **HU** Figyelem: Figyelmesen olvassa el és kövesse a használati utasításokat (figyelmeztetéseket)		**IT** Dispositivo medico conforme al regolamento (UE) 2017/745 **GB** Medical Device compliant with Regulation (EU) 2017/745 **FR** Dispositif médical conforme au règlement (UE) 2017/745 **ES** Producto sanitario conforme con el reglamento (UE) 2017/745 **PT** Dispositivo médico em conformidade com a regulamento (UE) 2017/745 **RO** Dispozitiv medical realizat în conformitate cu prevederile regulamentul (UE) 2017/745 **SE** Den medicintekniska produkten överensstämmer med förordning (EU) 2017/745 **HU** A 2017/745/EU rendeletnek megfelelő orvostechnikai eszköz
	**IT** Conservare in luogo fresco ed asciutto **GB** Keep in a cool, dry place **FR** Á conserver dans un endroit frais et sec **ES** Conservar en un lugar fresco y seco **PT** Armazenar em local fresco e seco **RO** A se păstra într-un loc răcoros și uscat **SE** Förvara på svalt och torrt ställe **HU** Száraz, hűvös helyen tárolandó		**IT** Conservare al riparo dalla luce solare **GB** Keep away from sunlight **FR** Á conserver à l'abri de la lumière du soleil **ES** Conservar al amparo de la luz solar **PT** Guardar ao abrigo da luz solar **RO** A se păstra ferit de razele soarelui **SE** Skyddas från solljus **HU** Napfénytől védve tárolandó
	**IT** Fabbricante **GB** Manufacturer **FR** Fabricant **ES** Fabricante **PT** Fabricante **RO** Producător **SE** Tillverkare **HU** Gyártó		**IT** Data di fabbricazione **GB** Date of manufacture **FR** Date de fabrication **ES** Fecha de fabricación **PT** Data de fabrico **RO** Data fabricației **SE** Tillverkningsdatum **HU** Gyártás dátuma
	**IT** Codice prodotto **GB** Product code **FR** Code produit **ES** Código producto **PT** Código produto **RO** Cod produs **SE** Produktkod **HU** Termékkód		**IT** Numero di lotto **GB** Lot number **FR** Numéro de lot **ES** Número de lote **PT** Número de lote **RO** Număr de lot **SE** Satsnummer **HU** Tételszám
	**IT** Seguire le istruzioni per l'uso **GB** Follow instructions for use **FR** Suivez les instructions d'utilisation **ES** Siga las instrucciones de uso **PT** Siga as instruções de uso **RO** Respectați instrucțiunile de utilizare **SE** Följ bruksanvisningen **HU** Kövesse a használati utasításokat		**IT** Parte applicata di tipo B **GB** Type B applied part **FR** Appareil de type B **ES** Aparato de tipo B **PT** Aparelho de tipo B **RO** Componentă aplicată de tip B **SE** Typ B tillämpad del **HU** B típusú alkalmazott rész

	**IT** Smaltimento RAEE **GB** WEEE disposal **FR** Disposition DEEE **ES** Disposición WEEE **PT** Disposição REEE **RO** Eliminare DEEE **SE** Avfallshantering av elektrisk och elektronisk utrustning (WEEE) **HU** RAEE szerinti ártalmatlanítás		**IT** Dispositivo medico **GB** Medical Device **FR** Dispositif médical **ES** Producto sanitario **PT** Dispositivo médico **RO** Dispozitiv medical **SE** Medicinteknisk produkt **HU** Orvostechnikai eszköz
	**IT** Importato da **GB** Imported by **FR** Importé par **ES** Importado por **PT** Importado por **RO** Importat de **SE** Importerad av **HU** Importálta		**IT -** Rappresentante autorizzato nella Comunità europea **GB -** Authorized representative in the European community **FR -** Représentant autorisé dans la Communauté européenne **ES -** Representante autorizado en la Comunidad Europea **PT -** Representante autorizado na União Europeia **RO -** Reprezentant autorizat pe teritoriul Comunității Europene **SE -** Auktoriserad representant i Europeiska gemenskapen **HU -** Meghatalmazott képviselő az Európai Közösségben