



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
DERMATOSCOPI 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, privor 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 az székhely szerinti tagállam illetékes hatóságának jelezni kell bármilyen olyan súlyos balesetet, amely az általunk szállított orvostechnikai eszközzel kapcsolatban történt.

Gima 31187



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Made in Pakistan



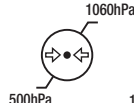
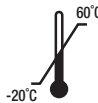
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Attention:

Thank you for purchasing our product. The dermatoscope meets the most stringent requirements concerning material selection, performance, safety and final inspection. This user manual applies to "GIMA 2000" brand dermatoscopes. These instructions must be followed to ensure the performance and durability of the dermatoscope. The operator/user must thoroughly read and understand this manual in order for the product to operate in a long-lasting and reliable manner for a defined period of time.

After opening the package, we recommend you check all the components, referring to the standard configuration. Check that none are missing and that they are in perfect condition.

Intended use:

The dermatoscope is used for a preoperative assessment of pigmented skin lesions with the purpose of differentiating primary melanoma, which requires excision, from nonmelanoma pigmented lesions that may safely be left untreated.

Patient population:

The dermatoscope is designed and intended for the examination of skin across the entire patient population.

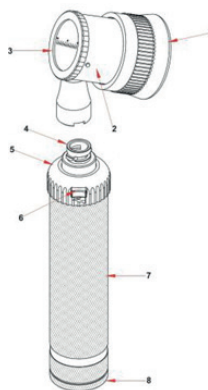
Features:

The dermatoscope is equipped with optical magnifying lenses that enhance the view of the skin surface during the examination. The dermatoscope head is used together with the battery-powered grips for external skin examination. The dermatoscope is intended for transient use and examination.

Features of all dermatoscopes	
Devices	GIMA 2000
Models	Standard
Lock	Bayonet lock
Magnification	10x
Focal length	25 mm
Configuration	Replaceable 2.5 V Xenon / Halogen lamp
Batteries	2 x "AA" 1.5 V batteries 2.5 V rechargeable batteries

Note: All accessories for the various dermatoscope models are listed separately in the section dedicated to accessories.

Product overview:



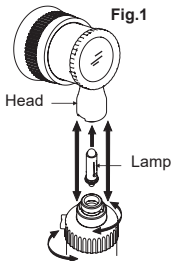
GIMA 2000 Dermatoscope


1. Focus ring
2. Dermatoscope head
3. Skin contact plate
4. Bayonet lock
5. Dimmer
6. ON/OFF button
7. Diagnostic grip
8. Closing cap


Instructions for Use


Attach the dermatoscope head and grip relative to the respective lock configuration. Support the dermatoscope head and grip by each handle, align both parts with each other, and assemble them. See Fig. no. 1

1. In the GIMA dermatoscope, align the bayonet grooves on the head of the dermatoscope with those on the grip. Rotate the head or grip in the opposite direction to the other to ensure a secure connection
2. Check that the connection between the head and the grip is perfect.
3. Check the proper working order of the dimmer on the GIMA dermatoscope.
4. On the GIMA dermatoscope, press the button on the grip and rotate the knob clockwise. The light will turn on and the dermatoscope will be in the operating position. The "ON" position of the grip is indicated by the red indicator. The light intensity can be adjusted by turning the knob clockwise or counter-clockwise as required.
5. Gently place the contact plate on the lesion, so that this is in the centre of the contact plate, then examine its surface structure. To reduce reflection from the stratum corneum, apply oil (mineral oil, petroleum jelly etc.).
6. With your index finger on the focus ring, adjust for optimal focus while your eye is on the eye rest.
7. To measure pigmented skin lesions, you must use the graduated contact plate.
8. Switch off the device after use to preserve the batteries. On the GIMA dermatoscope, rotate the knob counter-clockwise. A click will be heard when the button reaches the OFF position.



 The dermatoscope is intended to be used for transient examination. The grip may warm up, but the maximum temperature will not exceed 48°C. The contact plate is an applied part.

 The dermatoscope may only be used by trained personnel and by duly qualified medical personnel in a healthcare facility. It cannot be used by ordinary people.

 Do not use the equipment if it is damaged. Avoid precarious repairs. Repairs must be carried out only with original spare parts, which must be installed according to their intended use. For any other repairs/replacements, contact the dealer.

Magnifying glasses:

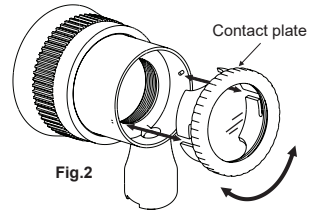
All the dermatoscopes are equipped with 10x magnifying glasses. Magnifying glasses are used to magnify the object under examination. The user rotates the focus ring to adjust the magnification of the skin being examined.

Accessories:

Skin contact plates:
The skin contact plate is an essential accessory of the der-

matoscope. Skin examination can only be carried out when the skin contact plate is attached to the dermatoscope head. There are two types of skin contact plates supplied and they must be attached to the dermatoscope head as shown in fig. no. 2.

- 1 Flat contact plate
- 2 Graduated contact plate

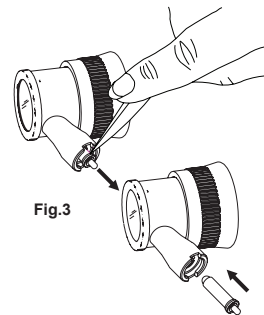



1. Do not use the dermatoscope without the skin contact plate as it may contaminate the device and cause cross-infection.
2. Inspect the skin contact plate before each use for rough edges or surfaces.
3. Do not reuse the skin contact plate without cleaning/sterilising it, as it may cause cross-infection.

Replacement procedures:

Lamp replacement procedure:


All these dermatoscope models contain LED and halogen/xenon lamps. The replacement procedure for the lamp and LED is given below. Switch off the device and disassemble the dermatoscope head with the grip. Pull the lamp downwards/outwards from the lamp/LED holder as shown in fig. no. 3.

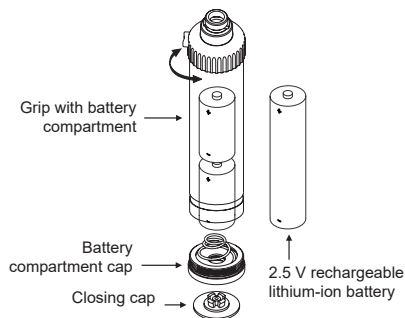


 Always switch off the device before unlocking the dermatoscope head from the grip and allow the lamp to cool before touching it for replacement. Otherwise, there is a risk of serious burns from touching the hot lamp.

Replacing the batteries:

Switch off the device and unscrew the grip cap, then remove the old batteries as shown in Fig. no. 4. Insert the new batteries as per the procedure detailed in Fig. no. 4. The GIMA dermatoscope is powered by two "C" type batteries; the rechargeable version is powered by two 1.5 V rechargeable alkaline or "C" type batteries. Take care that the poles point in the correct direction as shown, i.e. the positive pole takes precedence when inserting both normal and rechargeable batteries.

 Battery replacement must always be carried out by qualified personnel. When inserting the lithium-ion battery, always follow the marking on the battery label.



Storage/Transportation Conditions:



Maintenance:

The dermatoscope does not require routine maintenance. However, the light source, i.e. the lamp or LED, can be replaced according to the replacement procedure detailed above.

Support:

The device has no components that can be repaired by the end user.

General Precautions/Warnings:

1. Read the label before unpacking the product.
2. Do not use the device if it is damaged. Contact your dealer/distributor.
3. Periodically check the condition of the batteries, verifying that there are no signs of corrosion or oxidation. If necessary, replace them with new ones.
4. Handle batteries with care, as the liquids can irritate skin and eyes.
5. Check the product carefully before use. The same checks must be carried out after cleaning.
6. Check that the connection between the head and the grip is perfect and that the on/off button works correctly.
7. If the light works intermittently or if it does not turn on at all, check the lamp/LED, batteries and electrical contacts.
8. This product must not be introduced or used in areas with strong magnetic fields, e.g. near MRI scanners.
9. Any unauthorised modification/repair by the user is strictly prohibited, therefore we advise always contacting the person in charge or returning the unit to the authorised agent.
10. Autoclaving or flash sterilisation of the dermatoscope head and grip with battery compartment will cause serious electrical and mechanical damage; it is therefore strictly prohibited.
11. Ultrasonic cleaning is not recommended.
12. Store the device in a clean environment and as recommended.

Rechargeable system:

All these dermatoscopes can be converted into a rechargeable system. Insert the rechargeable batteries into the respective grip, as described in the battery replacement procedure. The charging procedure for each grip is described below: The GIMA 2000 dermatoscope diagnostic grip, together with the rechargeable battery, can be charged using the Zoom charger.

Note: For further details, please read the Zoom and Zi-mini charger IFUs.

Cleaning and Disinfecting

Dermatoscope head:

Clean and disinfect the external surface of the dermatoscope head with a soft cloth and the internal surface with a cotton swab dipped in 70% isopropyl alcohol or water. Do not immerse the head in any disinfectant solutions.

Lenses:

Lenses can be cleaned using a cotton-tipped applicator moistened with alcohol or a solution of water and mild detergent.



Do not use an abrasive ultrasonic cleaner, alcohol or other chemicals to clean the lenses as they will degrade the quality and scratch the coated surface of the lenses.



Do not use a rough cloth to clean the lens to avoid scratches.

Skin contact plate:

The skin contact plate must be removed after each examination. It can bear cleaning or disinfection by soaking in alcohol solution, Cidex etc. It can also be cleaned with a 70% isopropyl alcohol solution. Skin contact plates can also be autoclaved. Autoclave the skin contact plate at 134°C for at least 5 minutes, or at 121°C for 30 minutes.

Note: Do not exceed a temperature of 135°C and pressure of 28 psi.

Grip:

The grip can be cleaned with a cloth soaked in disinfectant. However, it cannot be immersed/soaked in liquids. Remove batteries before cleaning.

Operating Environment:

Temperature limits Humidity limits Atmospheric pressure limits



Shelf life:

The useful shelf life of the dermatoscope is 5 years.



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 - Indice dei simboli GB - Symbol index FR - Index des symboles
ES - Índice de símbolos PT - índice de símbolo SE - Symbol index
RO - Index de simboluri HU - Szimbólum index**

	<p>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)</p>
	<p>IT Conservare in luogo fresco ed asciutto GB Keep in a cool, dry place FR À 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</p>
	<p>IT Fabbricatore GB Manufacturer FR Fabricant ES Fabricante PT Fabricante RO Producător SE Tillverkare HU Gyártó</p>
	<p>IT Codice prodotto GB Product code FR Code produit ES Código producto PT Código produto RO Cod produs SE Produktkod HU Termékkód</p>
	<p>IT Seguire le istruzioni per l'uso GB Follow instructions for use FR Suivre les instructions d'utilisation ES Sigla las instrucciones de uso PT Siga as instruções de uso RO Respectați instrucțiunile de utilizare SE Följ bruksanvisningen HU Kövesse a használati utasításokat</p>

	<p>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</p>
	<p>IT Importato da GB Imported by FR Importé par ES Importado por PT Importado por RO Importat de SE Importerad av HU Importálta</p>
	<p>IT - Identificatore univoco del dispositivo GB - Unique device identifier FR - Identifiant unique de l'appareil ES - Identificador de dispositivo único PT - Identificador exclusivo do dispositivo RO - Identificatorul unic al dispozitivului DE - Unique Device Identifier (Eindeutige Kennung des Geräts) SE - Unik identifierare för enheten uredaja HU - Az eszköz egyedi azonosítója</p>
	<p>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 regulamental (UE) 2017/745 SE Den medicintekniska produkten överensstämmer med förordning (EU) 2017/745 HU A 2017/745/EU rendelethez megfelelõ orvostechnikai eszköz</p>

	<p>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</p>		<p>IT - Non sterile GB - Non-sterile FR - Pas stérile ES - No estéril PT - Não estéril SE - Ej steril RO - Nestérl HU - Nem steril</p>
	<p>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</p>		<p>IT - Limite di temperatura GB - Temperature limit FR - Limite de température ES - Límite de temperatur PT - Limite de temperatura SE - Lagras mellan och ° C RO - A se păstra la temperaturi cuprinse între și ° C HU - és °C között tárolandó</p>
	<p>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</p>		<p>IT - Limite di umidità GB - Humidity limit FR - Limite d'humidité ES - Límite de humedad PT - Limite de humidade SE - Fuktighetsgräns RO - Limită de umiditate HU - Páratartalom határérték</p>
	<p>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</p>		<p>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</p>
	<p>IT Dispositivo medico GB Medical Device FR Dispositif médical ES Producto sanitario PT Dispositivo médico RO Dispozitiv medical SE Medicinteknisk produkt HU Orvosteknikai eszköz</p>		<p>IT - Limite di pressione atmosferica GB - Atmospheric pressure limit FR - Limite de pression atmosphérique ES - Límite de presión atmosférica PT - Limite de pressão atmosférica PL - Granica ciśnienia atmosferycznego SE - Atmosfäriskt tryck RO - Limită de presiune atmosferică HU - Légköri nyomás határértéke</p>