

DERMATOSCOPES

Attention:

Thank you for purchasing our product. The Dermatoscope meets the most stringent requirements regarding the selection of manufacturing material, performance, safety and final control. These operating instructions manual is related to "Gima Pocket" Dermatoscope brands. These instructions must be followed to ensure the performance and durability of Dermatoscope. The operator/user must read and understand this manual thoroughly to keep the product performance durable and reliable for defined period.

After opening the package, it is necessary to check all the components against standard configuration. Check that these are all present and in perfect condition.

Intended Use:

The Dermatoscope is used for pre-operative evaluation of cutaneous pigmented lesions with aim of differentiating early melanoma, which requires excision from non-melanomatous pigmented lesions that may safely be left untreated.

Patient Population:

Dermatoscope is designed and intended to be used for skin examination of all patient population.

Features:

The Dermatoscope has an optical magnifying lens which enhance the view of skin surface during examination. The Dermatoscope head is used along with battery-powered handles for outer skin examination.

The Dermatoscope is intended for transient use and examination.

Features of All Dermatoscopes						
Devices	Design	Locking	Magnification	Focal length	Configuration	Batteries
Gima Pocket	Pocket size	Standard Screw locking	10x	25mm	Replaceable 2.5V Xenon / Halogen Lamp	2 x 1.5V 'AA' type 2.5V Rechargeable

Product Overview:



Gima Pocket Dermatoscope			
1. Focusing Ring	2. Dermatoscope Head	3. Skin Contact plate	4. Screw locking
5. ON/OFF button	6. Pocket clip	7. Diagnostic Handle	8. End cap

Operating Instructions

Attach the Dermatoscope head with its handle against respective locking configuration. Hold the Dermatoscope head and handle in each hand, align both parts with each other and assemble them. See Fig# 1

1. In Gima Pocket Dermatoscope, rotate the Dermatoscope head or handle with respect to each for firm assembly.
2. Check that the connection between head and handle is perfect.
3. Check the working of ON/OFF button in Dermatoscope.
4. In Gima Pocket Dermatoscope, push the button to ON position. The light will turn ON and the Dermatoscope is in operating position.
5. 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 corneum, apply oil (Mineral oil, Petroleum Jelly, etc.).
6. With your index finger on the Focusing Ring, adjust for optimal focus while your eye is resting on the Eye Guard.
7. To measure pigmented skin lesions, the graduated contact plate must be used.
8. Switch OFF the device after use to preserve the batteries.

Gima Pocket Dermatoscope

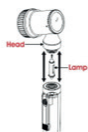


Fig. 1

⚠ Dermatoscope is intended for Transient examination. The handle may get hot but maximum temperature of 48oC will not be exceeded.

The contact plate is an Applied Part.

⚠ Dermatoscope can only be used by trained professional and qualified medical personnel in a healthcare facility. It cannot be used by a lay person.

✖ Do not use the equipment in case it is damaged. Avoid precarious repairs. Repairs shall be carried out with original spare parts only, which shall be installed according to the intended use. For any other repair/replacement apply to your retailer.

Magnification lens:

All the Dermatoscope have magnifying lens of 10x magnification. The magnifying lens are used to enlarge the object being examined. The user rotates the Focusing Ring to adjust the magnification of skin being examined.

Accessories: Skin contact plates:

Gima Pocket Dermatoscope



Fig. 2

Skin contact plate is an essential accessory of Dermatoscope. The skin examination can only be performed when the skin contact plate is attached with Dermatoscope head. There are two types of the skin contact plate given and these must be attached with Dermatoscope head as illustrated in fig# 2.

i. Contact Plate Plain - ii. Contact Plate with Scale

Gima Pocket Dermatoscope



Fig. 3

Replacement Procedures:

Lamp replacement procedure:

All these Dermatoscope models contain Xenon/Halogen Bulbs and LEDs. The replacement procedure for bulb and LED is given below. Turn OFF the device and disassemble the Dermatoscope head with handle. Pull the lamp downward/out from the Bulb/LED holder, as illustrated in fig# 3.

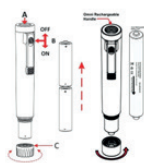
⚠ Always turn OFF the device before unlocking the Dermatoscope head from handle and let the lamp the cool down before touching it for replacement. Otherwise, there is risk severe burn in touching the hot lamp.

Batteries replacement:

Turn OFF the device and unscrew the cap of the handle and shake out old batteries as illustrated in Fig# 4. Insert new batteries as per the procedure illustrated in Fig# 4. However, Gima Pocket Dermatoscope is powered by two 'AA' type batteries or rechargeable alkaline batteries.

Take care that the poles point in the right direction as indicated i.e. positive point comes first during insertion of regular as well as rechargeable batteries.

- ⚠** Replacement of the batteries should always be carried out by qualified personnel. For inserting Li-ion Battery always follow marking given on the battery label.



Rechargeable system:

All these Dermatoscopes can be converted in to rechargeable system. Gima Pocket diagnostic handle can be converted into rechargeable handle by simply replacing the plastic end cap of the handle with all metal end cap. Insert the rechargeable batteries in the respective handle as described in battery replacement procedure.

The charging procedure for each handle is described below;

1. The Gima Pocket rechargeable handle, along with rechargeable battery, can be charged with Zi-mini charger.

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

Cleaning and Disinfection

Dermatoscope Head:

Clean and disinfect the outer surface of the Dermatoscope head with a soft cloth and inner surface with a cotton wool bud soaked into 70% isopropyl alcohol or water. Do not dip the head in any disinfection solution.

Lens:

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 Ultrasonic cleaner, alcohol or other chemicals to clean the lenses as this degrade lens quality, and they will scratch the coated surface of the lenses.

- ⚠** Do not use rough cloth for cleaning the lens to avoid scratches.

Skin Contact Plate:

The skin contact plate must be taken off after each examination. It can withstand the cleaning or disinfection by soaking in alcohol solution, Cidex etc. It can also be cleaned with 70% isopropyl alcohol solution. Skin contact plates can also be autoclaved. Autoclave the skin contact plate at 134oC for at least 5 minutes or autoclave it at 121oC for 30 minutes.

Note: Do not exceed the temperature of 135oC and pressure 28 psi.

Handle:

The handle can be cleaned with a cloth soaked with disinfectant. However, it cannot be dipped/soaked into liquids. Remove batteries prior to cleaning.

Operating Environment:

Temperature Limitation

Humidity Limitation

Atmospheric Pressure Limitation



Transport/Storage Environment:

Temperature Limitation

Humidity Limitation

Atmospheric Pressure Limitation



Maintenance:

The Dermatoscope does not require regular maintenance. However, the light source i.e. Bulb or LED can be replaced as per above-mentioned replacement procedure.

Service:

The device has no components serviceable by the end-user.



Disposal of the Device:

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.

Note:

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.

Cautions/General Warnings:

1. Read the label before unpacking.
2. Do not use the device in case it is damaged. Apply to your retailer/distributor.
3. Periodically check the battery conditions, making sure that no sign of corrosion or oxidation is present. If necessary, replace them with new ones.
4. Carefully handle the batteries as the liquids can irritate skin and eyes.
5. Before usage, thoroughly check the product. The same Operation shall be carried out after cleaning.
6. Check that the connection between the head and the handle is perfect and that the On/Off Button works correctly.
7. If the light is intermittent or, in case, it does not turn on, check the bulb/LED, the batteries and the electrical contacts.
8. This product is not allowed to enter or be used in areas with strong magnetic fields e.g. MRI scanners.
9. Any unauthorized modification/service is strictly prohibited at user end so, always contact the authorized person or send the unit back to the authorized agent.
10. Autoclaving and Flash sterilizing the Dermatoscope head and battery handle will result in severe electrical and mechanical damages so, these are strictly prohibited.
11. Ultrasonic cleaning is not recommended.
12. Store the device in clean and recommended environment.

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.

REF	EN Product code - IT Codice prodotto - FR Code produit - ES Código producto - PT Código produto - GR Κωδικός προϊόντος - DE Erzeugniscode - PL Numer katalogowy - BG Код на продукта - HR Šifra proizvoda - LT Prekės kodas - NL Productcode		EN Type B applied part - IT Parte applicata di tipo B - FR Appareil de type B - ES Aparato de tipo B - PT Aparelho de tipo B - GR Ζωστική σύνδεση B - DE Gerätetyp B - PL Z części typu B - BG Тип В приложена част - HR Tip B primijenjen dio - LT B tipo prietaikyti dalis - NL Toegepast onderdeel type B
EC REP	EN Authorized representative in the European community - IT Rappresentante autorizzato nella Comunità europea - FR Représentant autorisé dans la Communauté européenne - ES Representante autorizado en la Comunidad Europea - PT Representante autorizado na União Europeia - GR Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Ένωση - DE Autorisierter Vertreter in der EG - PL Uprawniony przedstawiciel we Wspólnocie Europejskiej - BG Упълномощен представител в Европейската общност - HR Ovlašten predstavnik u Europskoj zajednici - LT Įgaliojatis atstovas Europos bendrijoje - NL Bevoegde vertegenwoordiger in de Europese Gemeenschap		EN Keep away from sunlight - IT Conservare al riparo dalla luce solare - FR À conserver à l'abri de la lumière du soleil - ES Conservar al amparo de la luz solar - PT Guardar ao abrigo da luz solar - GR Αποφύγετε το φως από ηλιακή ακτινοβολία - DE Vor Sonneneinstrahlung geschützt lagern - PL Przechowywać z dala od światła słonecznego - BG Съхранявайте далеч от съпътства светлина - HR Držite zaštićeno od sunčevog svjetla - LT Saugoti nuo saulės spindulių - NL Afgeschermd van zonlicht opslaan
MD	EN Medical Device - IT Dispositivo medico - FR Dispositif médical - ES Producto sanitario - PT Dispositivo médico - GR Ιατροτεχνολογικό προϊόν - DE Medizinprodukt - PL Wyrob medyczny - BG Медицински продукт - HR Medicinski proizvod - LT Medicininis prietaisas - NL Medisch hulpmiddel		EN Follow instructions for use - IT Seguire le istruzioni per l'uso - FR Suivez les instructions d'utilisation - ES Siga las instrucciones de uso - PT Siga as instruções de uso - GR Ακολουθήστε τις οδηγίες χρήσης - DE Folgen Sie den Anweisungen - PL Patrz podrecznik użytkownika - BG Следвайте инструкциите за употреба - HR Slijedite upute za uporabu - LT Vadovaukites naudojimo instrukcijomis - NL Volg de gebruiksaanwijzing
CE	EN Medical Device compliant with Regulation (EU) 2017/745 - IT Dispositivo medico conforme al regolamento (UE) 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 o regulamento (UE) 2017/745 - GR Ιατρική συσκευή σύμφωνα με την ΚΑΝΟΝΙΣΜΟΣ (ΕΥ) 2017/745 - DE Medizinprodukt im Sinne der Verordnung (EU) 2017/745 - PL Wyrob medyczny zgodny z Rozporządzeniem (UE) 2017/745 - BG Медицински продукт, съответстващ на Регламента (ЕУ) 2017/745 - HR Medicinski proizvod skladan Uredbi (EU) 2017/745 - LT Medicinos prietaisas, atitinkantis reglamentą (ES) 2017/745 - NL Medisch hulpmiddel in overeenstemming met verordening (EU) 2017/745		EN WEEE disposal - IT Smaltimento RAEE - FR Disposition DEEE - ES Disposición WEEE - PT Disposição REEE - GR Άδωξη WEEE - DE Beseitigung WEEE - PL Oddzielną zbiórką dla tego urządzenia - BG Изхвърляне на OEO - HR Zbrinjavanje OEO - LT EEJ atlieki šalinimas - NL Verwijdering AEEA
	EN Manufacturer - IT Fabricante - FR Fabricant - ES Fabricante - GR Παράγωγος - DE Hersteller - PL Producent - BG Производител - HR Proizvođač - LT Gamintojas - NL Fabrikant		EN Imported by - IT Importato da - FR Importé de - ES Importado de - PT Importado de - GR Εισαχρησμένος από - DE Importiert von - PL Importowane z - BG внос от - HR Uvezen iz - LT Importavo - NL geïmporteerd uit
	EN Date of manufacture - IT Data di fabbricazione - FR Date de fabrication - ES Fecha de fabricación - PT Data de fabrico - GR Ημερομηνία παραγωγής - DE Herstellungsdatum - PL Data produkcji - BG Дата на производство - HR Datum proizvodnje - LT Pagaminimo data - NL Productiedatum		EN Temperature limit - IT Limite di temperatura - FR Limite de température - ES Limite de temperatura - PT Limite de temperatura - GR Όριο θερμοκρασίας - DE Temperaturgrenzwert - PL Granica temperatury - BG Температурна граница - HR Ograničenje temperature - LT Temperatūros riba - NL Drempelwaarde temperatuur
	EN Caution: read instructions (warnings) carefully - IT Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso - FR Attention: lisez attentivement les instructions (avertissements) - ES Precaución: lea las instrucciones (advertencias) cuidadosamente - PT Cuidado: leia as instruções (avisos) cuidadosamente - GR Προσοχή: διαβάστε προσεκτικά τις οδηγίες (εισαγωγές) - DE Achtung: Anweisungen (Warnungen) sorgfältig lesen - PL Ostrożnie - Zobacz instrukcję obsługi - BG Внимание: прочетете инструкциите (предупрежденията) внимателно - HR Opaz: pažljivo pročitajte upute (upozorenja) - LT Dėmesio: perskaitykite ir atidžiai laikykitės naudojimo instrukcijų (spėjimų) - NL Opgelet: Lees en volg aandachtig de gebruiksaanwijzing (waarschuwingen)		EN Humidity limit - IT Limite di umidità - FR Limite d'humidité - ES Limite de humedad - PT Limite de humidade - GR Όριο υγρασίας - DE Feuchtigkeitsgrenzwert - PL Granica wilgotności - BG Граница на влажност - HR Ograničenje vlažnosti - LT Drėgmės riba - NL Drempelwaarde vochtigheid
	EN Keep in a cool, dry place - IT Conservare in luogo fresco ed asciutto - FR À conserver dans un endroit frais et sec - ES Conservar en un lugar fresco y seco - PT Armazenar em local fresco e seco - GR Αποθηκεύστε σε δροσερό και στεγνό περιβάλλον - DE An einem kühlen und trockenen Ort lagern - PL Przechowywać w suchym miejscu - BG Пазете на хладно, сухо място - HR Držite na hladnom i suhom mjestu - LT Laikyti vėsioje ir sausio vietoje - NL Koel en droog opslaan		EN Atmospheric pressure limit - IT Limite di pressione atmosferica - FR Limite de pression atmosphérique - ES Limite de presión atmosférica - PT Limite de pressão atmosférica - GR Όριο ατμοσφαιρικής πίεσης - DE Luftdruck-Grenzwert - PL Granica ciśnienia atmosferycznego - BG Граница на атмосферно налягане - HR Ograničenje atmosferskog tlaka - LT Atmosferos slėgio riba - NL Drempelwaarde atmosferische druk
UDI	EN Unique device identifier - IT Identificatore univoco del dispositivo - FR Identifiant unique de l'appareil - ES Identificador de dispositivo único - PT Identificador exclusivo do dispositivo - GR Μοναδικό αναγνωριστικό συσκευής - DE Eindeutige Kennung des Geräts - PL Unikalny identyfikator urządzenia - BG Уникален идентификатор на устройството - HR Jedinstveni identifikator uređaja - LT Unikalus įrenginio identifikatorius - NL Unieke apparat-ID	LOT	EN Lot number - IT Numero di lotto - FR Numéro de lot - ES Número de lote - PT Número de lote - GR Αριθμός παρτίδας - DE Chargennummer - PL Kod partii - BG Номер на партида - HR Broj serije - LT Broj serije - NL Broj serije

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