



# GIMA

PROFESSIONAL MEDICAL PRODUCTS

**OFTALMOSCOPIO F.O. SIGMA**  
**SIGMA F.O. OPHTALMOSCOPE**  
**OPHTALMOSCOPE F.O. SIGMA**  
**FASEROPTIK-OPHTHALMOSKOP SIGMA**  
**OFTALMOSCOPIO F.O. SIGMA**  
**OFTALMOSCÓPIO F.O. SIGMA**  
**OFTALMOSKOP SIGMA F.O**  
**SIGMA F.O. OFTALMOSCOP**  
**ΟΦΘΑΛΜΟΣΚΟΠΙΟ ΟΠΤΙΚΗΣ ΙΝΑΣ SIGMA**

منظار فحص العين كامل الخيارات من طراز **SIGMA** سيجما

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.

Jeder schwere Unfall im Zusammenhang mit dem von uns gelieferten medizinischen Gerät muss unbedingt dem Hersteller und der zuständigen Behörde des Mitgliedsstaats, in dem das Gerät verwendet wird, gemeldet werden.

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.

Należy poinformować producenta i kompetentne władze danego Kraju członkowskiego o każdym poważnym wypadku związanym z wyrobem medycznym naszej produkcji.

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.

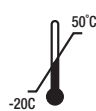
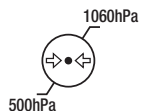
Σε περίπτωση που διαπιστώσετε οποιοδήποτε σοβαρό περιστατικό σε σχέση με την ιατρική συσκευή που σας παρέχουμε θα πρέπει να το αναφέρετε στον κατασκευαστή και στην αρμόδια αρχή του κράτους μέλους στο οποίο βρίσκεστε.

يجب الإبلاغ فوراً عن أي حادث خطير وقع فيما يتعلق بالجهاز الطبي الذي زودنا به إلى الجهة الصانعة والسلطة المختصة في الدولة العضو التي يقع فيها

**REF** 31527 - 31529 - 31530 - 31582



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Made in Pakistan



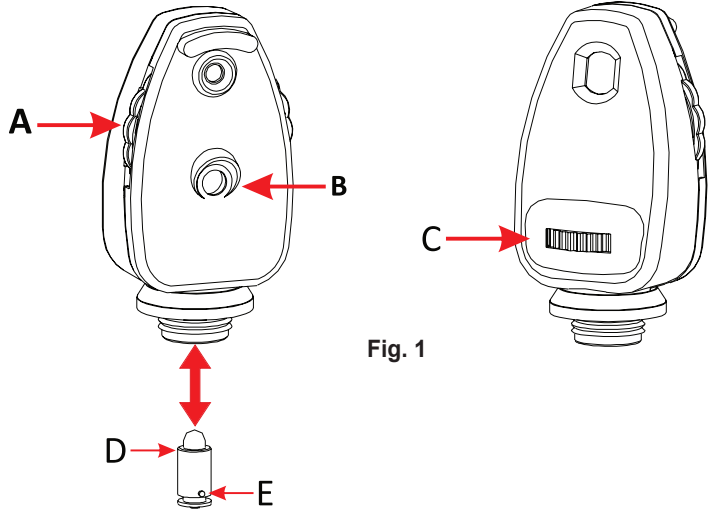


Fig. 1

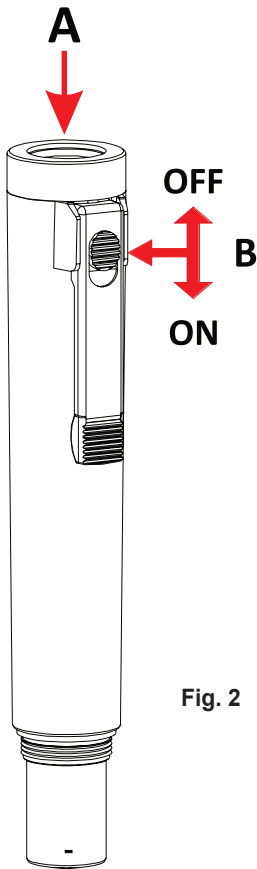
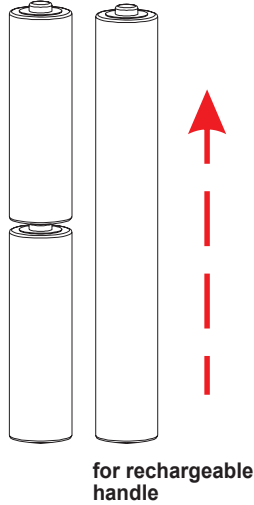
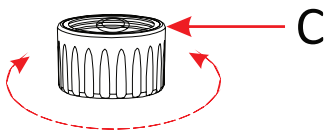


Fig. 2



for rechargeable handle



## Range of applications

- The Sigma ophthalmoscope is designed for examination of the eye.
- During examination, hold the instrument with your index finger on the lens wheel (a). you can also operate the aperture wheel (c) in this way.
- Window (b) shows the selected lens value. Minus lenses are shown red, plus lenses black.



Do not use the equipment in case it is damaged. Apply to your retailer.

## Operating Instruction

Attach the ophthalmoscope head to the handle and turn on the device for examination, turn the wheel (a) clockwise or counterclockwise to select the desired lens. The power of the selected lens is visible through window (b). Sigma ophthalmoscope is equipped with a set of 5 different aperture, which can be selected by turning the wheel (c).

## Changing the lamp

Unscrew the instrument from the handle and pull the lamp (d) downwards. Wipe the new lamp glass clean and insert it so that the locating pin (e) fits the slit.

Allow lamp to cool down for some time before replacing it.

## Cleaning

The housing can be wiped clean with a cloth moistened with alcohol. Glass surfaces can be cleaned with a cotton wool bud in the same way.

## Applicable Standards

ISO 15004-1 (Ophthalmic instruments - Fundamental requirements and test methods).



The performance of this instrument can only be guaranteed if genuine Medical Devices lamps and alkaline batteries are used.

## Warnings and Cautions

The light emitted from the ophthalmoscope is potentially hazardous.

The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument, when operated at maximum intensity, will exceed the safety guideline after 13 minutes when lit with a LED lamp (blue base). Exposure times are cumulative for a 24-hour period.

- 333 seconds (5 min 33 sec) in case of a free eye
- 227 seconds (3 min 47sec) in case of a fixed eye



When using Halogen illumination, no acute optical radiation hazards are identified. However, Medical Devices recommends limiting the intensity of the light directed into the patient's eye to the minimum level that is necessary for diagnosis. Infants, persons with aphasia, and persons with diseased eyes are at a greater risk. The risk is also increased if the examined person has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source within the previous 24 hours. This will apply particularly if the eye has had exposure to retinal photography. The intended use of this device is for routine ophthalmic exams on the order of typically less than 60 seconds per eye. Although there is a benefit versus risk factor in any medical procedure, these more complicated exams should not exceed a three minute exam time in 24 hours. Significant use of this device beyond its intended use is not recommended; it may cause harm to the eyes.

## Feature

- Made from impact resistant re-enforced plastic.
- Enhanced Xenon/Halogen super bright light.
- Easy replacement of lamp.
- 5 different apertures.



- Large Spot: For normal funduscopy.
- Small spot: For reduced reflection with small pupils.
- Semi Circle: For reduced reflection with small pupils.
- Fixation Star: For determination of central or eccentric fixation, very suitable for examining children.
- Red-free filter: For contrast-enhancement when assessing fine vascular disorders.
- Color Coded 18 lenses for excellent resolution (Black for +, Red for -).

+1	2	3	4	6	8	10	15	20
-1	2	3	4	6	8	10	15	20

## **Sigma Battery Handle**

### **Range of applications**

The sigma battery handle should only be used as a power source for Sigma instruments.

### **Instrument connector**

Internal thread in handle head (a).

### **Operating the Handle**

Push switch (b) down which will turn the power on and the lamp will light up. This position is indicated by a RED indicator comes into view.

To switch off the instrument, push switch up.

### **Batteries**

2 alkaline cells (AA/LR6).

### **Handle with rechargeable system**

- The handle with rechargeable system has all the characteristics of a standard Sigma.
  - A metal cap (cod. 31588) converts standard handles into rechargeable ones.
  - The metal cap can be used both with "AA" batteries and the rechargeable battery.
- For grips with rechargeable system, a 2.5 V lithium-ion battery is used (code 31587), which is included in the set.

### **Note**

The metal cap can be purchased separately, thereby converting a standard handle into a rechargeable one.

### **Changing the batteries**

Unscrew the end-cap (c) and shake out the old batteries. Insert new batteries as shown in Fig. 2. Take care that the poles point in the right direction as indicated.

### **Cleaning**

The handle can be cleaned with a cloth soaked with disinfectant; however it cannot be dipped into liquids.



- Do not use the equipment in case it is damaged. Apply to your retailer.
- Periodically check the battery conditions, making sure that no sign of corrosion or oxidation is present. In case of necessity replace them with new alkaline ones.
- Carefully handle the batteries as the liquids they contain can irritate skin and eyes.
- Before being used, thoroughly check the product. The same operation shall be carried out after cleaning.
- Check that the connection between the head and the handle is perfect and that the On/Off Button works correctly.
- If the light is intermittent or in case it does not turn on, check the bulb, the batteries and the electrical contacts.



















### **Operation**

Temperature	10°C - 35°C
Humidity	30% - 75%

Air pressure	700 hPa - 1060 hPa
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**Storage & Transport**

Temperature	-20°C - 50°C
Humidity	10% - 90% (without condensation)
Air pressure	500 hPa - 1060 hPa

	Caution: read instructions (warnings) carefully		Follow instructions for use
	Keep in a cool, dry place		Keep away from sunlight
	Manufacturer		Date of manufacture
	Product code		Lot number
	Medical Device compliant with Regulation (EU) 2017/745		Type B applied part
	WEEE disposal		Medical Device
	Unique device identifier		Temperature limit
	Humidity limit		Atmospheric pressure limit
	Authorized Representative in the UK		Authorized Representative in Switzerland



**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.