

Otoscopio F.O. Sigma
Sigma F.O. Otoloscope
Otoloscope Sigma F.O.
Sigma F.O. Otoloskop
Sigma F.O. Otoloscópio
Sigma F.O. Otoloscópio
Σίγμα Φ.Ο. Ωτοσκόπιο
منظار الأذن .Sigma F.O

MANUALE D'USO E MANUTENZIONE
USE AND MAINTENANCE BOOK
INSTRUCTIONS DE FONCTIONNEMENT ET ENTRETIEN
BETRIEBS UND WARTUNGS ANWEISUNGEN
MANUAL DE USO Y MANTENIMIENTO
MANUAL DE USO E MANUTENÇÃO
ΕΓΧΕΙΡΙΔΙΟ ΧΡΗΣΗΣ ΚΑΙ ΣΥΝΤΗΡΗΣΗΣ
دليل الإستعمال والرعاية

ATTENZIONE: Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.

ATTENTION: The operators must carefully read and completely understand the present manual before using the product.

AVIS: Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.

ACHTUNG: Die Bediener müssen vorher dieses Handbuch gelesen und verstanden haben, bevor sie das Produkt benutzen.

ATENCIÓN: Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.

ATENÇÃO: Os operadores devem ler e entender completamente este manual antes de usar o produto.

ΠΡΟΣΟΧΗ: Οι χειριστές αυτού του προϊόντος πρέπει να διαβάσουν και να καταλάβουν πλήρως τις οδηγίες του εγχειριδίου πριν από την χρήση του.

الحذر: على العمال قراءة وفهم هذا الدليل بكامله قبل البدء باستعمال المنتج.



REF 31524 - 31523 - 31525
31526 - 31518



Teme l'umidità
Keep dry



Conservare al riparo della luce
solare diretta
Keep away from sunlight



Fabbricante
Manufacturer

Gima S.p.A.
Via Marconi, 1
20060 Gessate (MI) Italy
Made in U.A.E.



Apparecchio di Tipo B
Type B device



Fig-1

Dettagli prodotto

- 1 Testa dell'otoscopio
- 2 Finestra d'ingrandimento
- 3 Porta insufflazione aria
- 4 Interruttore on/off
- 5 Manico
- 6 Tappo
- 7 Speculum monouso
- 8 Speculum riutilizzabile
- 9 Adattatore insufflazione
- 10 Pompetta insufflazione

Product Detail

- 1 Otoscope head
- 2 Magnification window
- 3 Insufflation port
- 4 On / Off switch
- 5 Handle
- 6 End cap
- 7 Disposable ear tip
- 8 Reusable ear tip
- 9 Insufflation adaptor
- 10 Insufflation bulb

Détails de l'instrument

- 1 Tête otoscope
- 2 Fenêtre d'observation grossissante
- 3 Raccord de soufflerie
- 4 Interrupteur On / Off
- 5 Manche
- 6 Bouchon
- 7 Spécuments à usage unique
- 8 Spécuments réutilisables
- 9 Adaptateur insufflation
- 10 Poire d'insufflation

Produktdetails

- 1 Otoskop-Kopf
- 2 Vergrößerungsfenster
- 3 Gebläseanschluss
- 4 On-/ Off-Schalter
- 5 Handgriff
- 6 Verschlusskappe
- 7 Einweg-Ohrtrichter
- 8 Wiederverwendbarer Ohrtrichter
- 9 Gebläseadapter
- 10 Pumpball

Detalles del producto

- 1 Cabezal del otoscopio
- 2 Ventana de aumento
- 3 Puerto de insuflación
- 4 Interruptor de encendido/apagado
- 5 Mango
- 6 Tapa inferior
- 7 Espéculo auricular desechable
- 8 Espéculo auricular reutilizable
- 9 Adaptador de insuflación
- 10 Balón de insuflación

Detalhe do Produto

- 1 Cabeça do otoscópio
- 2 Janela de magnificação
- 3 Porta de sopro
- 4 Interruptor On / Off
- 5 Cabo
- 6 Tampa
- 7 Ponta para orelha descartável
- 8 Ponta para orelha reutilizável
- 9 Adaptador do soprador
- 10 Bomba de sopro

Λεπτομέρεια Προϊόντος

- 1 Κεφαλή ωτοσκοπίου
- 2 Παράθυρο μεγέθυνσης
- 3 Θύρα εμφύσησης
- 4 Διακόπτης ενεργοποίησης / απενεργοποίησης
- 5 Λαβή
- 6 Τελικό πώμα
- 7 Αναλώσιμος κώνος
- 8 Επαναχρησιμοποιημένος κώνος
- 9 Προσαρμογείς εμφύσησης
- 10 Λαμπτήρα εμφύσησης

تفاصيل المنتج

- 1 رأس المنظار
- 2 نافذة التكبير
- 3 فتحة النفخ
- 4 مفتاح التشغيل / الإيقاف
- 5 المقبض
- 6 نهاية الكأس
- 7 طرف للأذن للاستخدام مرة واحدة
- 8 طرف للأذن يعاد استخدامه
- 9 منظم النفخ
- 10 أنبوبة النفخ

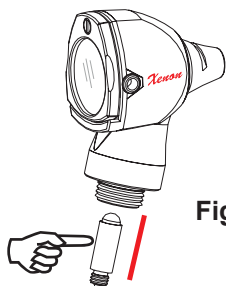


Fig-3

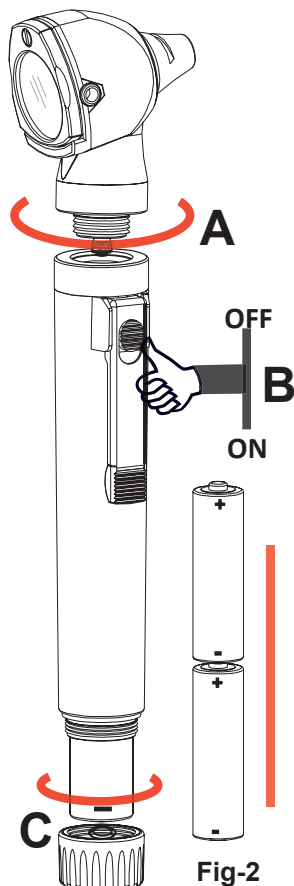


Fig-2

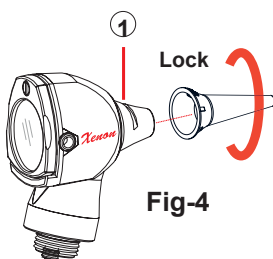


Fig-4

Peeloff
Protectivesheet

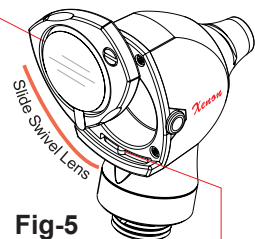


Fig-5

LensLockingPoint

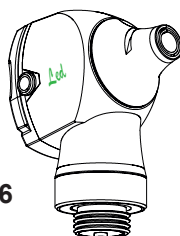


Fig-6

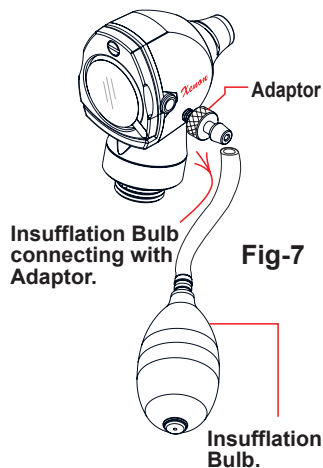


Fig-7

Insufflation
Bulb.

Instructions For Use

The operating and maintenance instructions found in this manual should be followed to ensure years of reliable service.

Please read these instructions carefully before using the Sigma and keep them in a safe place for future or use reference.

Intended Use

Sigma Otoscopes and associated accessories are intended for the examination of ear, the external auditory canal and the eardrum.

This instrument has an optical magnifying lens and battery-powered illumination handle, and recommended for use by medically qualified personnel to assess the health of ear through transmitting light into the ear canal.

This device is intended for transit treatment and examination.

Setting Up the Product

Head & Handle Attachment

To setup the Sigma Otoscope, align the otoscope thread with handle and rotate the head clockwise until head and handle firmly joined.(Fig-2, **A**)

Sigma Battery Handle

The Sigma battery handle should only be used as a power source for Sigma instruments. Grip the handle attached to Otoscope head. To turn ON the light, slide the switch with thumb towards the bottom of the handle.

To turn OFF the light, slide the switch with thumb towards the top of the handle. (Fig-2, **B**)

Insert Batteries

Arrange two AA/LR6 size good quality alkaline batteries for power. Rotate end cap counterclockwise to open the handle end cap. Insert two batteries into handle with positive (+) terminal towards the head and close the cap by rotating clockwise (Fig-2, **C**).



Note: Batteries are not included in sets.

The Otoscope is intended for transit treatment and the handle may gets warm by longer use. So let it be cool down before next application.

A harmless max temperature of 60° C will not be exceeded.

Sigma xenon otoscope model

Bulb Replacement

Rotate otoscope head counterclockwise to detach from handle.

Pull down the bulb and insert new bulb into socket and rotate the head clockwise until head and handle firmly joined (Fig-3).

Before replacing the bulb read below instruction carefully.



*Let the device cool down before changing the bulb.
Verify the bulb voltage / specification before changing.*

Operating

Sigma Otoscope should only be inserted into the auditory canal when a ear tip is fitted. Place the ear tip on the otoscope in such a way the projection inside the ear tip fits into the slit (Fig-4,1) and tighten the ear tip by twisting it slightly to the right.



Do not use otoscope without ear tip that may cause ear injury and / or cross contamination.

Do not reuse disposable ear tip that may result in contamination from one patient to another patient.

Do not point light in patient eyes that may cause eye injury.

Do not use excess force while locking the ear tip on head.

Magnifying Lens

Sigma Otoscope has 3x magnification that produces distortion-free images of the examined object. The magnification viewing window is permanently attached and can be swivelled aside for instrumentation. To facilitate the instrumentation rotate the viewing window clockwise as much as required (Fig-5).



Peel off the lens protective sheet before use (Fig-5)

Sigma LED otoscope model

The LED fixed and sealed into the otoscope head and cannot be changed because of its long life.

LED has 50,000 hours of extended lifetime.

Ensure no replacement of LED ever in the lifetime of the instrument.

Excellent light output of 85K LUX.

Extended battery life of 50 HOURS due to low current consumption of LED.

With a colour temperature of 5500K and CRI>80 colours are visible as they are.

Ear Tip

Ear tip is used in otoscope as viewing passage for direct examination of the external acoustic duct and tympanic membrane.

Choose the size of Ear tip suitable for the examination of the acoustic duct.

Insufflation Port (optional)

Sigma Otoscope have a connection port to facilitate the tympanic mobility test (Fig-7).

This can be carried out when the viewing window is closed by using optionally available insufflation bulb and adaptor.



Dose the pressure carefully with the insufflation bulb.

Cleaning / Sterilization and Maintenance

The Sigma F.O. Pocket otoscope is not suitable for treatment in the ultrasonic bath, for sterilization, spray disinfection or treatment by immersion in liquids.

Manual Cleaning Process

Use a damp cloth for cleaning the Sigma pocket otoscope.

For cleaning and disinfection, a disinfectant agent suitable for plastic medical products must be used.

Handle 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 of 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.

Precautions



Read the label before losing packing. Do not use if packaging has been open or damaged. Only qualified person should use it.

Handle the device with care and keep the instrument away from the range of insects and rodents.

Autoclaving is not permissible for this type of handle.

Ultrasonic cleaning is not recommended.

Store the device in clean environment at normal temperature.

Please ensure that the batteries, Handles and Ear Tips and other Sub-assemblies are discarded as clinical waste in accordance with local policies.

In accordance with local regulations this product should be disposed of as an electronic device separately.

Transport and Storage

Before transporting the appliance, make sure that it is correctly packaged ensuring also that there are no risks of shocks bumps or falls during the transport itself.

Damage to the appliance caused during transport and handling is not covered by the guarantee.

The device must be stored in a dry, Cool area away from direct sunlight.

It must not be placed in contact with any substances or chemical agents which could cause damage and reduce safety characteristics.

Operation

Temperature	10° C - 40° C
Humidity	30% - 75%
Air Pressure	700 hPa - 1060 hPa

Storage & Transport

Temperature	-20° C - 70° C
Humidity	10% - 90%
	(without condensation)
Air Pressure	500 hPa - 1060 hPa



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.*

For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product.

This product meets high qualitative standards both as regards the material and the production.

The warranty is valid for 12 months from the date of supply of GIMA.

During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons. Labor costs and personnel traveling expenses and packaging not included.

All components subject to wear are not included in the warranty.

The repair or replacement performed during the warranty period shall not extend the warranty.

The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use.

GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc.

The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed.

The defected products must be returned only to the dealer the product was purchased from.

Products sent to GIMA will be rejected.

