



GIMA

PROFESSIONAL MEDICAL PRODUCTS

OTOSCOPIO F.O. SIGMA SIGMA F.O. OTOSCOPE OTOSCOPE F.O. SIGMA FASEROPTIK-OTOSKOP SIGMA OTOSCOPIO F.O. SIGMA OTOSCÓPIO F.O. SIGMA OTOSKOP SIGMA F.O. SIGMA F.O. OTOSCOPI ΩΤΟΣΚΟΠΙΟ ΟΠΤΙΚΗΣ ΙΝΑΣ SIGMA

منظار فحص الأذن كامل الخيارات من طراز SIGMA سيجم

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.

È 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.

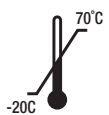
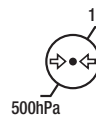
يجب الإبلاغ فوراً عن أي حادث خطير وقع فيما يتعلق بالجهاز الطبي الذي زدنا به إلى الجهة الصناعية والسلطة المختصة في الدولة العضو التي يقع فيها

REF

31511 - 31513 - 31518 - 31523 - 31524 - 31525
31526 - 31580 - 31591 - 31592 - 31593



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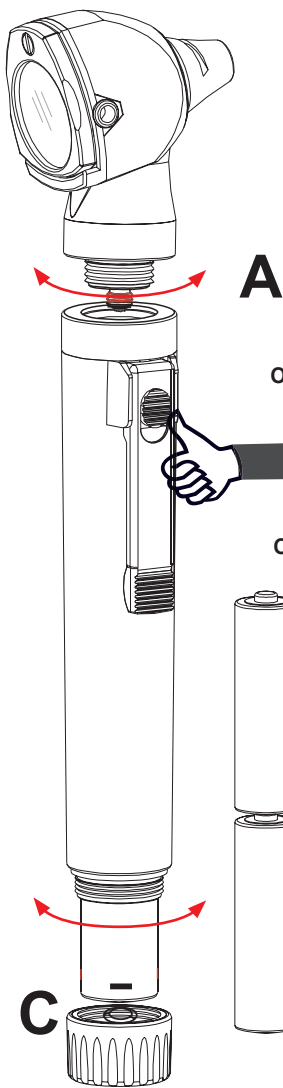


Fig-2

for rechargeable handle

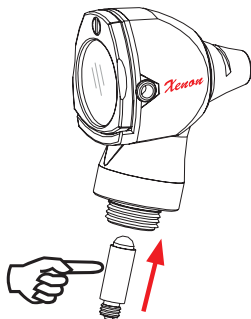


Fig-3

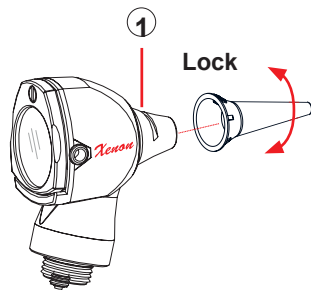


Fig-4

Peel off Protective sheet

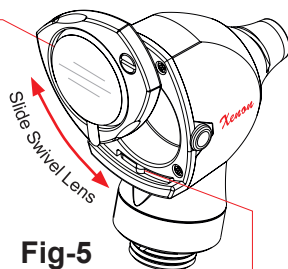


Fig-5

Lens Locking Point

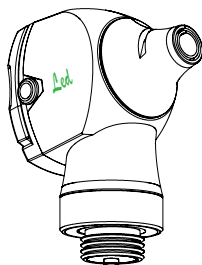


Fig-6

Insufflation Bulb connecting with Adaptor.

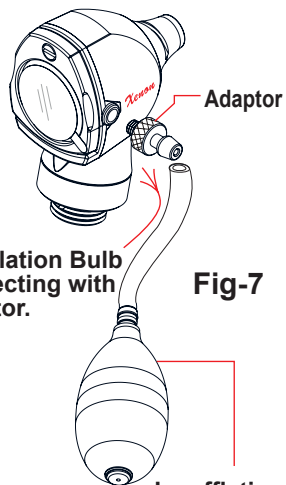


Fig-7

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 Oscopes 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 Oscope, 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 Oscope 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.

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.

The Oscope 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 Oscope 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 Oscope 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 50K LUX.

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

With a colour temperature of 4000K and CRI>80 colours are visible as they are.

Sigma-C led otoscopes

- Light weight alternative to the standard Desk top direct light Oscope for easy examination of ear and nose, and small procedures.
- Made from impact resistant re-enforced plastic and highly corrosion resistant stainless steel material for exterior finish.
- Swivel type window with 3X magnification lens for sharp image and minimal reflection.
- Insufflation port for pneumatic testing of tympanic mobility.
- 50,000 hours of extended lifetime ensures no replacement of LED ever in the lifetime of the instrument.
- Brighter than Xenon model. 7500 LUX as compared to 4000 on the Standard model Oscopes.
- Extended battery life of 50 hours due to low current consumption of the LED.
- With a color temperature of 4300K, CRI > 95 and R9 = 88 ensures that colors 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 Oscope 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 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.

**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.*

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.

	<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) DE Achtung: Anweisungen (Warnungen) sorgfältig lesen ES Precaución: lea las instrucciones (advertencias) cuidadosamente PT Cuidado: leia as instruções (avisos) cuidadosamente PL Ostrzeżenie – Zobacz instrukcję obsługi RO Atenție: Citiți și respectați cu atenție instrucțiunile (avertismentele) de utilizare GR Προσοχή: διαβάστε προσεκτικά τις οδηγίες (ενστάσεις)</p> <p>AR الحذر: قراءة التعليمات (التحذيرات) بعناية</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 DE Medizinprodukt im Sinne der Verordnung (EU) 2017/745 ES Producto sanitario conforme con el reglamento (UE) 2017/745 PT Dispositivo médico em conformidade com a regulamento (UE) 2017/745 PL Wyrób medyczny zgodny z Rozporządzenie (UE) 2017/745 RO Dispozitiv medical realizat în conformitate cu prevederile regulamentul (UE) 2017/745 GR Ιατρική συσκευή σύμφωνα με την ΚΑΝΟΝΙΣΜΟΣ (ΕΕ) 2017/745</p> <p>AR جهاز طبي يتوافق مع التوجيه (UE) 2017/745</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 DE An einem kühlen und trockenen Ort lagern ES Conservar en un lugar fresco y seco PT Armazenar em local fresco e seco PL Przechowywać w suchym miejscu RO A se păstra într-un loc răcoros și uscat GR Διατηρείται σε δροσερό και στεγνό περιβάλλον</p> <p>AR يحفظ في مكان بارد وجاف</p>		<p>IT Conservare al riparo dalla luce solare GB Keep away from sunlight FR À conserver à l'abri de la lumière du soleil DE Vor Sonneneinstrahlung geschützt lagern ES Conservar al amparo de la luz solar PT Guardar ao abrigo da luz solar PL Przechowywać z dala od światła słonecznego RO A se păstra ferit de razele soarelui GR Κρατήστε το μακριά από ηλιακή ακτινοβολία</p> <p>AR يحفظ بعيدا عن أشعة الشمس</p>
	<p>IT Fabbricante GB Manufacturer FR Fabricant DE Hersteller ES Fabricante PT Fabricante PL Producent RO Producător GR Παραγωγός</p> <p>AR الشركة المصنعة</p>		<p>IT Data di fabbricazione GB Date of manufacture FR Date de fabrication DE Herstellungsdatum ES Fecha de fabricación PT Data de fabrico PL Data produkcji RO Data fabricației GR Ημερομηνία παραγωγής</p> <p>AR تاريخ التصنيع</p>
	<p>IT Codice prodotto GB Product code FR Code produit DE Erzeugniscode ES Código producto PT Código produto PL Numer katalogowy RO Cod produs GR Κωδικός προϊόντος</p> <p>AR كود المنتج</p>		<p>IT Numero di lotto GB Lot number FR Numéro de lot DE Chargennummer ES Número de lote PT Número de lote PL Kod partii RO Număr de lot GR Αριθμός παρτίδας</p> <p>AR رقم الدفعة</p>

	<p>IT Seguire le istruzioni per l'uso GB Follow instructions for use FR Suivez les instructions d'utilisation DE Folgen Sie den Anweisungen ES Siga las instrucciones de uso PT Siga as instruções de uso PL Patrz po-drecznik użytkownika RO Respectați instrucțiunile de utilizare GR Ακολουθήστε τις οδηγίες χρήσης AR اتبع التعليمات للاستخدام</p>		<p>IT Parte applicata di tipo B GB Type B applied part FR Appareil de type B DE Gerätetyp B ES Aparato de tipo B PT Aparelho de tipo B PL Z częścią typu B RO Componentă aplicată de tip B GR Συσκευή τύπου Β AR جهاز من النوع B</p>
	<p>IT Smaltimento RAEE GB WEEE disposal FR Disposition DEEE DE Beseitigung WEEE ES Disposición WEEE PT Disposição REEE PL Oddzielna zbiórka dla tego urządzenia RO Eliminare DEEE GR Διάθεση WEEE AR التخلص WEEE</p>		<p>IT Dispositivo medico GB Medical Device FR Dispositif médical DE Medizinprodukt ES Producto sanitario PT Dispositivo médico PL Wyrób medyczny RO Dispozitiv medical GR Ιατροτεχνολογικό προϊόν AR جهاز طبي</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 DE Unique Device Identifier (Eindeutige Kennung des Geräts) GR Μοναδικό αναγνωριστικό συσκευής PL Unikalny identyfikator urządzenia RO Identificatorul unic al dispozitivului AR معرف فريد للجهاز</p>		<p>IT Limite di temperatura GB Temperature limit FR Limite de température DE Temperaturgrenzwert ES Limite de temperatur PT Limite de temperatura PL Przechowij pomiędzy i ° C RO A se păstra la temperaturi cuprinse între și ° C GR Διατηρείται μεταξύ -10 και 49°C AR يحفظ بين و درجة مئوية</p>
	<p>IT Limite di umidità GB Humidity limit FR Limite d'humidité DE Feuchtigkeitsgrenzwert ES Limite de humedad PT Limite de humidade PL Granica wilgotności RO Limită de umiditate GR Όριο υγρασίας AR حد نسبة الرطوبة</p>		<p>IT Limite di pressione atmosferica GB Atmospheric pressure limit FR Limite de pression atmosphérique ES Limite de presión atmosférica PT Limite de pressão atmosférica DE Luftdruck-Grenzwert PL Granica ciśnienia atmosferycznego RO Limită de presiune atmosferică GR Όριο ατμοσφαιρικής πίεσης AR حد الضغط الجوي</p>
	<p>IT Rappresentante autorizzato nel Regno Unito GB Authorized Representative in the UK FR Représentant autorisé au Royaume-Uni ES Representante autorizado en el Reino Unido PT Representante autorizado no Reino Unido DE Autorisierter Vertreter im Vereinigten Königreich GR Εξουσιοδοτημένος Αντιπρόσωπος στο Η.Β PL Autoryzowany Przedstawiciel w Wielkiej Brytanii RO Reprezentant autorizat în Marea Britanie AR الممثل المعتمد في المملكة المتحدة</p>		<p>IT - Rappresentante autorizzato in Svizzera GB - Authorized Representative in Swiss FR - Représentant autorisé au Suisse ES - Representante autorizado en Suizo PT - Representante autorizado no Suíço DE - Autorisierter Vertreter im Schweizer GR - Εξουσιοδοτημένος Αντιπρόσωπος στο Ελβετός PL - Autoryzowany Przedstawiciel w Szwajcarski RO - Reprezentant autorizat în Marea Britanie AR الممثل المعتمد في المملكة المتحدة</p>