



GIMA

PROFESSIONAL MEDICAL PRODUCTS

OCCHIALI NISTAGMO NYSTAGMUS SPECTACLES NYSTAGMUSBRILLE

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.

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.

GIMA 31206



DEHAG

Medizin-Technische Produktions
GmbH & Co.KG
Hinter dem Hamberge 24, 37124 Rosdorf
Made in Germany

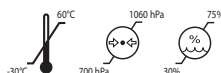


503

Distribuito da / Distributed by / Vertrieben von:

Gima S.p.A.

Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com



Dear Customers,

Thank you for purchasing this nystagmus spectacle. Please read this instruction carefully before using your new nystagmus spectacle carefully to ensure proper handling and long service life.

With the nystagmus spectacle it concerns an investigation instrument which serves to observe spontaneous quick ocular movements (nystagmus) with patients with disturbances of the balance sense.

Read the safety instructions carefully and still only use the nystagmus spectacle as described in this manual, so it does not accidentally come in injury or damage. Keep this instruction for use to the later checking up. With passing on of the nystagmus spectacle you also hand over this instruction for use.

Safety instructions

General



• Please read these instructions carefully and retain them for reference.

- Use this nystagmus spectacle solely in accordance with these instructions.
- The lenses are very delicate, handle the spectacle with great care.
- Avoid placing the nystagmus spectacle on surfaces that could scratch the lenses.
- Always place the nystagmus spectacle on the removable inlay in the outer carton.
- This nystagmus spectacle may only be used by medical staff. This instruction do not replace a good medical education.
- Misuse or any modification is not under the responsibility of the manufacturer.
- Please check every instrument before every use.
- Have any repairs carried out solely by a qualified electrician.
- Repairs may only be carried out with original spare parts which are installed according to the intended use.
- Never try to repair the nystagmus spectacle yourself.
- Replace a defective lamp by carefully unscrewing the lamp from the socket. Only use an original replacement lamp as a replacement.
- Please remove the batteries before sending the nystagmus spectacle.



Before removing the lamp, it is necessary to make sure that the instrument is off for some minutes to avoid the risk of burning.

- Any change leads to the exclusion of liability.
- The CE-sign looses its validity in case of the use of any non original spare parts.
- If you transfer the appliance to a third party, also hand over this instruction manual.



Warnings

- Do not use damaged instruments!
- Protect the nystagmus spectacle and its parts against all kind of mechanical damage or force!
- Avoid hitting the lenses, which could break and cause damages!
- Do not throw and use with care!
- Misuse, damage, and wear are not covered by the warranty!
- Any signs or wear and tear due to regular use are excluded from the warranty!
- Make absolutely sure that no liquid enters the battery handle or the nystagmus spectacle!
- Make sure to use dry batteries only and that the handle is clean and dry before inserting batteries!
- Screen the nystagmus spectacle and the accessoires from the sun. Keep dry! The products have to shelter from humidity about 75%!

Intended use

Device for short-term examinations or for mobile use in the field of vertigo diagnostics.

Indication/Contraindication

Whether the use of Frenzel spectacle is indicated depends on the type of nystagmus examined. For example, Frenzel spectacle are used to assess spontaneous nystagmus, but are not suitable for observing directional nystagmus.

Side effects and residual risks

Contamination due to non-compliance with the preparation instructions, wrong or defective accessories.

Electricity

- To ensure the power supply of the nystagmus spectacle, use three batteries of size C LR14 / AM-2 (baby cells) á 1.5 volts
- When inserting the batteries make sure the poles are connected correctly.

Insert the battery



Use



Before any use the product has to be cleaned or disinfected and the good function and the integrity has to be checked.

- It is to use only the accessories specified by the manufacturer.
- Unscrew the cover of the battery handle.
- Insert 3x 1.5 V C LR14 / AM-2 size batteries (batteries not inclusive) making sure the indicated battery polarity is observed.
- Then, turn the battery cover back onto the battery handle.
- Remove batteries from of the battery compartment as soon as they are empty or if the device will not be used for a longer period of time.

Package Contents

- Please check the packaging and complain any damage immediately to the carrier.
- After opening the packaging, please check the contents of the packaging for damage that may have occurred due to improper handling during transport.

Your LED nystagmus spectacle package includes all of the following items. If any of these items are missing, please contact the dealer for assistance.

1x nystagmus spectacle



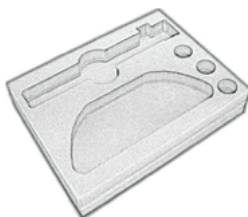
1x user's instruction



1x carton



1x inlay



Operation

General

With the purchase of the nystagmus spectacle you have the opportunity to do a short-term examination, in mobile use. The nystagmus spectacle is held directly in front of the patient's eyes, thus enabling a quick uncomplicated search for provocation nystagmus, e.g. by head shaking.

The nystagmus spectacle is equipped with strong refractive biconvex magnifying lenses with a power of +15 to +18 diopters. They prevent a sharp vision and the fixation of objects.

In this way, the patient's visual contact with objects in the environment is interrupted, which would hinder the fast eye movements. At the same time the highly illuminated eyes are easily observable under magnifying glasses.

Use

- Clean the nystagmus spectacle with a soft cloth moistened with water and a mild, alcohol-free detergent before each use. Then dry the glasses thoroughly with a soft dry cloth.
- Please make sure that the nystagmus spectacle is in an undamaged, technically perfect condition.
- Hold to the patient the nystagmus spectacle in front of the eyes over the nasal bridge.
- Hold the nystagmus spectacle firmly with one hand on the battery hold.
- Switch on the nystagmus spectacle by pressing the blue knob and turning the adjustment wheel clockwise.
- By turning the adjustment wheel clockwise, you can dim the brightness to the limit of the rotary switch (about. 3/4 turn).



If you turn the adjustment wheel without pushing the knob or turning the adjustment wheel further then the end stop can destroy the switch.

- Switching off the device is done in reverse order.
- When you will not be using the nystagmus spectacle for a prolonged period, take the batteries out of the batterie holder.

Processing instructions

Store your nystagmus spectacle in a closed place, on the inlay provided, where it is protected from dust and dirt to ensure their hygienic conditions.

All surfaces of the appliance are not sensitive to conventional, mild, alcohol-free cleaners. A soft cloth or absorbent paper should be used to apply cleaning liquids, in order to avoid scratching the surface and to dose and spread out the liquid better. Incorrect or incomplete cleaning may jeopardize the patient or medical staff !

Restriction regarding reprocessing

The end of the product service life is usually determined by wear and damage caused by use.

Place of use

Remove surface soiling with a soft disposable cloth.

Maintenance

Please sort damaged parts and have them repaired. If you send the nystagmus spectacle for repair, please remove the batteries before sending.

Cleaning / Disinfection: automatically

- An automatic cleaning and disinfection is not approved for the device.
- Do not disinfect by spray or soak!

Cleaning: manual

Clean the nystagmus spectacle after each use.

- Clean the nystagmus spectacle with a damp cloth and, perhaps, a little bit mild, alcohol-free cleaners or disinfectants.
- Never use corrosive or scouring cleaning agents or sharp objects to clean the appliance.
- Dry the nystagmus spectacle with a soft, dry cloth thoroughly.
- Do not immerse the nystagmus spectacle set in water, or in other liquids.

Drying

Allow the device to dry for at least one hour before reuse.

Otherwise there is a risk that an explosive mixture of air and cleaning agent may ignite when the device is switched on.

Control and testing

Check the parts after cleaning for visible dirt. You may need to repeat the cleaning.

Packaging

The nystagmus spectacle must not be packaged in sterile packaging. Other packages are also possible.

Sterilization

Do not sterilize the nystagmus spectacle, thus electronic components can be damaged by high temperatures.

Technical data

• Power supply:	3 x batteries baby cells type LR14/AM-2; á 1,5V
• Dimensions:	185 x 130 x 100 mm
• Weight:	approx. 270g (w/o batteries)
• Protection class:	IP X0

Classification according to:

• MPG:	Class I, according to Annex IV of Directive 2017/745 (EU)
• CE marking:	according to Directive 2017/745 (EU)
• RKI:	uncritical

Storage and transport conditions

• Storage temperature:	-30 to 60°C
• Working temperature:	0 to 25°C
• Humidity:	30 to 75%
• Barometric pressure:	700 to 1060 hPa

	Product code		Keep away from sunlight		Follow instructions for use
	Lot number		Keep in a cool, dry place		Date of manufacture
	Manufacturer		Medical Device compliant with Regulation (EU) 2017/745		Atmospheric pressure limit
	WEEE disposal		Temperature limit		Humidity limit
	Caution: read instructions (warnings) carefully		Medical Device		Unique Device Identifier



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.