



GIMA

PROFESSIONAL MEDICAL PRODUCTS

OCCHIALI NISTAGMO NYSTAGMUS SPECTACLES LUNETTES POUR NYSTAGMUS GAFAS NISTAGMO ÓCULOS NISTAGMO ΓΥΑΛΙΑ ΝΥΣΤΑΓΜΟΥ

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.

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.

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.

GIMA 31204



DEHAG

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



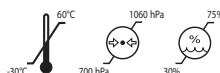
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Dear Customers,

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.
- 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.



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 loses 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!
- Screen the nystagmus spectacle and the accessories from the sun. Keep dry! The products have to shelter from humidity about 75%!
- Any signs or wear and tear due to regular use are excluded from the warranty!
- Make absolutely sure that no liquid enters the nystagmus spectacle or the accessories!

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 instruction, wrong or defective accessories.

Electricity

In order to provide the nystagmus spectacle with power, you can use the battery case code 31214 or the plug-in power supply code 31203 (not included in delivery). Other voltage sources are not permitted and will void the warranty and guarantee.

To increase safety, the connection of the nystagmus spectacle has been provided with a flat plug which does not fit into a mains socket. Therefore, never try to force the flat plug into a power outlet.

- Verify that the mains voltage is the same as that indicated on the type plate on the appliance before use.
- Only connect the power supply of the nystagmus spectacle to an earthed socket.
- Always remove the plug from the socket when the nystagmus spectacle is not in use.
- Always remove the plug from the wall socket by pulling on the plug, not the power cord.
- Make sure that the appliance, the power cord and plug do not come in contact with water.
- Do not cut, pinch or separate the plug.

- Check the power cord regularly to make sure it is not damaged.
- Do not use the nystagmus spectacle if the power cord is damaged. Have a damaged power cord replaced by a qualified service technician.

Use

- Before any use the product has to be cleaned or disinfected and the good function and the integrity has to be checked.
- Connect the nystagmus spectacle to a 4 volt power source before use.



Do not use other voltage sources, as higher voltages can burn out the lamps and thus increase the risk of accidents and injuries. In case of malfunction or damage caused by the use of other voltage sources, we cannot assume any liability or warranty.

- Please disconnect the nystagmus spectacle from the power source if you do not use them for a longer period of time.
- Make sure that your hands are dry before touching the nystagmus spectacle, power cord or plug.
- Remove the plug from the power supply in the event of a malfunction during use, and before cleaning the nystagmus spectacle, fitting or removing an accessory, or storing the appliance after use.
- It is to use only the accessories specified by the manufacturer.
- Please note that you should only pull on the pin plug/ socket and not directly on the cable when connecting or disconnecting the pin plug! The plugs of the nystagmus spectacle and the sockets of the power supply should only be pushed together/pulled apart.

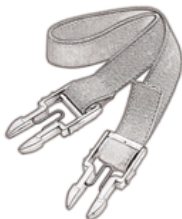
Package Contents

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

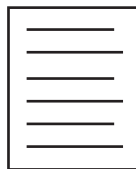
1x nystagmus spectacle



1x clip-head strap



1x user's instruction



1x carton



Optional accessories

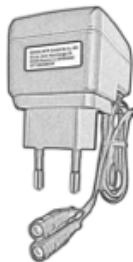
To power the nystagmus spectacle we recommend the following separately available accessories:

Battery case (31214)



or

Power supply (31203)



Operation

General

With the purchase of the nystagmus spectacle you have the opportunity to do an examination for which the nystagmus spectacle remain for a longer time on the patient's head. The associated clip-head strap provides a secure fixation of the spectacle in front of the patient's eyes and facilitates an easy search spontaneous and provoked nystagmus e.g. through shaking the head, storing or examinations on swivel-chaires.

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.
- Place the clip-head strap over the patient's ears and around the back of the head.
- Make sure that the nystagmus spectacle do not shift during the examination. If necessary, tighten the clip-head strap more tightly.
- Insert the flat plug of the nystagmus spectacle either into the battery container type 31214 or into the power supply code 31203 (both not included).
- Plug the power supply code 31203 into a 220V power supply. The battery case is powered by three 1.5 volt C LR14/AM-2 size batteries (baby cells).

Processing instructions

Store your nystagmus spectacle in a closed place where they are 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.

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.

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:	max. 4.5 Volt, 500mA
• Dimensions:	190 x 90 x 70 mm
• Weight:	approx. 180g (only spectacle)
• Protection class:	IP X0

Classification according to:

• MPG:	Class I, according to Annex VIII 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.