

OCCHIALI LED NISTAGMO LED NYSTAGMUS SPECTACLE

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.

GIMA 31207

**DEHAG**

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

REF**823**

Distribuito da/Distributed by:

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Dear Customer,
thank you for purchasing this LED nystagmus spectacle. Please read this instruction carefully before using your new LED nystagmus spectacle carefully to ensure proper handling and long service life.

Other languages of the instructions for use can be found on our homepage www.dehag.com.

With the LED 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 LED 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 LED nystagmus spectacle you also hand over this instruction for use.

Safety instructions

General



- Please read this instructions carefully and retain them for reference.
- Use this LED nystagmus spectacle solely in accordance with this instruction.
- The lenses are very delicate, handle the LED nystagmus spectacle with great care.
- Avoid placing the LED nystagmus spectacle on surfaces that could scratch the lenses.
- Always place the LED nystagmus spectacle on the removable inlay in the outer carton.
- The LED 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 the LED nystagmus spectacle for functionality and integrity before each use.
- Have any repairs carried out solely by a qualified electrician.
- Please remove the batteries before sending the LED nystagmus spectacle.
- Never try to repair the LED nystagmus spectacle yourself.
- Repairs may only be carried out with original spare parts which are installed according to the intended use.
- 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 LED nystagmus spectacle to a third party, also hand over this instruction manual.

Warnings

- Do not use damaged instruments!
- Protect the LED 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!
- Screen the LED nystagmus spectacle and the accessoires from the sun. Keep dry! The products have to shelter from humidity about 75%!
- 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 LED nystagmus spectacle.
- Make sure to use dry batteries only and that the handle is clean and dry before inserting batteries!

Intended use

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

Indication/Contraindication

Whether the use of LED nystagmus spectacle is indicated depends on the type of nystagmus examined. For example, LED nystagmus 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 LED 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 batteries



Use

- Before any use the LED nystagmus spectacle 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 LED nystagmus spectacle

1x user's instruction



1x carton

1x inlay



Operation

General

With the purchase of the LED nystagmus spectacle type 823 you have the opportunity to do a short-term examination, in mobile use. The LED 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 LED 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.

The LED nystagmus spectacle is equipped with a timer function that facilitates the observation of the deflections within a certain period of time. In addition, the glasses are equipped with an activated switch-off function. Here the illumination of the LED nystagmus spectacle switches off one minute after the timer has expired, a renewed wearing of the LED nystagmus spectacle automatically switches it on again. The LED nystagmus spectacle also has a „Low Battery“ indicator, which signals that the batteries have been changed when empty.

Use

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



Make sure that you do not over turn the rotary switch, otherwise the switch may become unusable!

- Switching off the device is done in reverse order.
- To start the timer function, press the timer button with the illustrated stopwatch on the battery handle. The flashing diode indicates the sequence of the respective times (30, 60 or 90 seconds).
- The brightness of the LED nystagmus spectacle is regulated by turning the rotary switch on the battery handle. Turning it towards 0 reduces the brightness, turning it in the opposite direction increases the brightness of the LEDs.
- With the automatic switch-off and switch-on function, the LED nystagmus spectacle switches off after approx. one minute after the timer has elapsed. The light will turn on again when the device are picked up.
- When you will not be using the LED nystagmus spectacle for a prolonged period, take the batteries out of the batterie holder.

Deactivation / activation of the switch-off function

- To deactivate the switch-off function, hold down the timer button on the battery hold while turning on the rotary switch at the same time.
- Release the timer after turning off the 30 sec LED (approx. 1 second) and turn off the LED nystagmus spectacle and then turn them on again. A short flash of the 30-sec-LED after switching on signals the deactivated automatic switch-off.
- Activating the switch-off function is the same as for deactivating the switch-off function.

Low Battery indicator

- The „Low Battery“ indicator shows you an empty battery by turning the LED nystagmus spectacle on by five flashes of all three diodes. Insert, according to the correct polarity, three new, similar 1.5 V batteries of size C LR14 / AM-2 (baby cells), preferably alkaline batteries.
- Please dispose of used batteries according to local regulations.

Processing instructions

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

All surfaces of the appliance are not sensitive to conventional, mild 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 LED nystagmus spectacle for repair, please remove the batteries before sending.

Cleaning / Disinfection: automatically

Validated procedure:



Pre-cleaning with a cloth soaked with 80% ethanol.

Wipe disinfection with a soft, lint-free non-woven cloth soaked with ECOLAB incidin Oxy Foam S. Reaction time according to the manufacturer of the disinfectant 1 minute.

Clean the LED nystagmus spectacle after each use.

- Clean the LED nystagmus spectacle with a damp cloth and possibly some mild detergent.

- Never use corrosive or scouring cleaning agents or sharp objects to clean the appliance.
- Dry the LED nystagmus spectacle with a soft, dry cloth thoroughly.
- Do not immerse the LED 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 LED nystagmus spectacle must not be packaged in sterile packaging. Other packages are also possible.

Sterilization

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

Technical data

• Power supply:	3x batteries baby cells type LR14/AM-2; á 1.5V
• Dimensions:	223 x 150 x 70 mm3
• Weight:	approx. 400 g (w/o batteries)
• Protection Class:	IP X0

Classification according to:

• Classification:	Class I, according to Annex VIII of Directive 2017/745 (EU)
• Classification:	Risk group I according to DIN EN 62471
• CE marking:	according to Directive 2017/745 (EU)
• Classification RKL:	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
	Medical Device		Caution: read instructions (warnings) carefully		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.

