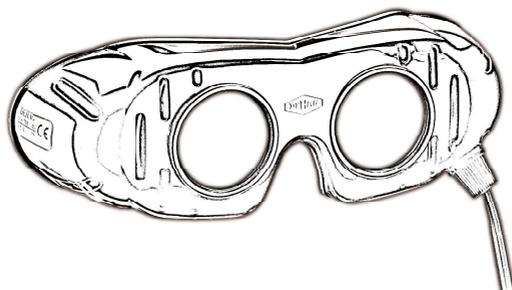




Nystagmus Spectacle

REF 501/521



User's instruction



v202307-AA

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.

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

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.

Note for the user

Any serious incident that has occurred in connection with the nystagmus spectacle should be reported to DEHAG Medizin-Technische Produktions GmbH & Co. KG and the competent authority of the Member State in which the user and/or patient is established.

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Safety instructions

General



- Please read this instruction carefully and retain them for reference.
 - Use this nystagmus spectacle solely in accordance with this instruction.
 - The lenses are very delicate, handle the nystagmus spectacle with great care.
 - Only the DEHAG battery container type 504 or the plug-in power supply type 506 are approved for powering the nystagmus spectacle.
 - Avoid placing the nystagmus spectacle on surfaces that could scratch the lenses.
 - The 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 nystagmus spectacle for functionality and integrity before each use.
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- A black circular icon containing a white wrench and screwdriver crossed, used to denote a repair or maintenance instruction.
- Have any repairs carried out solely by a qualified electrician.

- Never try to repair the nystagmus spectacle yourself.
- Repairs may only be carried out with original spare parts which are installed according to the intended use.
- Replace a defective lamp by carefully unscrewing the lamp from the socket. Only use an original DEHAG replacement lamp type 507 as a replacement.



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 nystagmus spectacle 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!

- Screen the 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 nystagmus spectacle or the accessoires!

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 DEHAG battery container type 504 or the plug-in power supply type 506 (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 nystagmus spectacle, the power cord and plug do not come in contact with water.
- Do not cut, pinch or separated the plug.
- Check the power cord regularly to make sure it is not damage.

- 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 the DEHAG battery container type 504 or plug-in power supply type 506 before putting them into operation.



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.

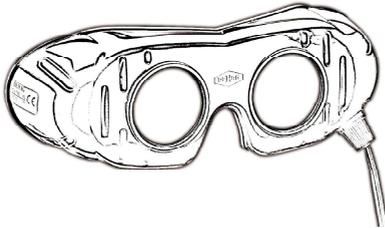
- Remove the plug from the power supply in the event of a malfunction during use, and before cleaning the nystagmus spectacle, fitting or removing an accessory, or storing the appliance after use.
- It is to use only the accessories specified by the manufacturer.
- Please note that you should only pull 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

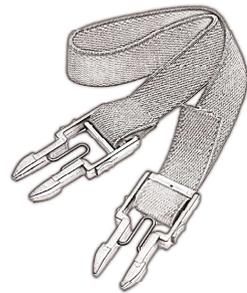
- Please check the packaging and complain any damage immediately to the carrier.
- After opening the packaging, please check the contents of the packaging for damage that may have occurred due to improper handling during transport.

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

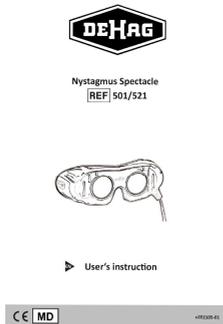
- 1x nystagmus spectacle type 501/521



- 1x clip-head strap



- 1x user's instruction



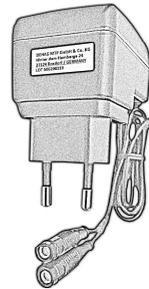
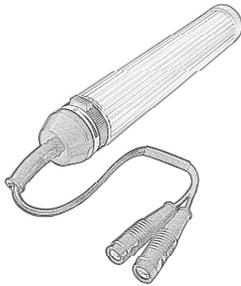
- 1x carton



Optional accessories

The power supply of the nystagmus spectacle is ensured by the following separately available accessories:

- DEHAG battery case type 504 or power supply type 506



Spare parts

You can reorder the following spare parts:

- replacement bulb type 507 cover black/white type 57.00.02/57.20.02



Operation

General

With the purchase of the nystagmus spectacle type 501/521 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 nystagmus 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 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 DEHAG battery container type 504 or into the power supply type 506 (both not included).
- Plug the power supply type 506 into a 220V power supply. The DEHAG 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 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.

Cleaning / disinfection: automatically



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

Cleaning / disinfection: manual

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 nystagmus spectacle after each use.

- Clean the 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 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.

Waste disposal



After the lifetime the instrument has to be littered in compliance with the local regulations and law or to be returned to the manufacturer! The following applies for the European Union: According to the EC Directive 2012/19/EC on Waste Electronic and Electrical Equipment (WEEE) do not dispose of this product as unsorted municipal waste. Prepare this product for reuse or separate collection as specified by the directive. If this product is contaminated, this directive does not apply. Low batteries have to be removed and littered according to the local regulations and law.

Technical data

- Type: 501 / 521
- Power supply: max. 4.5 Volt, 500mA
- Dimensions: 190 x 90 x 70 mm³
- Weight: approx. 180 g (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)
 - Spaulding: uncritical
- Storage and transport conditions:
 - Storage temperature: -30 to 60 °
 - Working temperature: 0 to 25 °C
 - Humidity: 30 to 75 %
 - Barometric pressure: 700 to 1,060 hPa

Guarantee terms

DEHAG Medizin-Technische Produktions GmbH & Co. KG guarantees the appliance for defects caused by manufacturing and/or material faults for 24 months from the date of purchase, subject to the following conditions.

- No charges will be made for labour, materials and shipping costs during the guarantee period. Any repairs carried out during the guarantee period do not extend the guarantee period.
- The importer automatically becomes the owner of any faulty parts or a faulty appliance (in the event of a complete replacement) replaced by the importer.
- All claims submitted under guarantee must be accompanied by the original bill of sale.
- Claims under guarantee must be submitted to the dealer where the appliance was purchased, or to the importer.
- The guarantee does not cover damage caused by:
 - Accidents, incorrect use, wear and/or neglect.
 - Faulty installation and/or use in a manner contravening the prevailing statutory, technical or safety regulations.

- For malfunction or damage caused by improper handling, especially handling contrary to the instructions or inadequate or improper care and maintenance.
- Malfunctions on electrical devices due to external influences, such as voltage changes, electromagnetic fields, radio interference, etc.
- Repairs carried out by the customer or third parties.
- Careless transport, i.e. without suitable or protection.
- The warranty does not cover batteries or other accessories that are attached to the nystagmus spectacle, if necessary.
- No claims can be submitted under this guarantee for damage other than repair or replacement of faulty parts. The manufacturer can never be held responsible for any consequential loss or damage, or any other consequences, resulting either directly or indirectly from the supply of the appliance by the manufacturer.
- All costs of transport, packing and transport insurance are borne by the purchaser.
- For defects that are asserted that occur after the warranty period or are not warranted.

Service

If a fault should occur please contact the DEHAG service department:



DEHAG Medizin-Technische
Produktions GmbH & Co. KG
Hinter dem Hamberge 24
37124 ROSDORF / GERMANY
Tel: 0551 / 3 25 19
Fax: 0551 / 37 61 06
E-mail: info@dehag.com
Internet: www.dehag.com

Declaration of Conformity

The  mark confirms that this product complies with the European Parliament Regulation 2017/745 (EU) of 05th April 2017 on medical devices.

Symbols

	Observe operating instructions!
	Service
	Dangerous voltage!
	Cleaning
	Manufacturer
	Disposal according to WEEE guidelines
	Order number
	Medical Device
	Medical Device complies with Directive 2017/745 (EU)