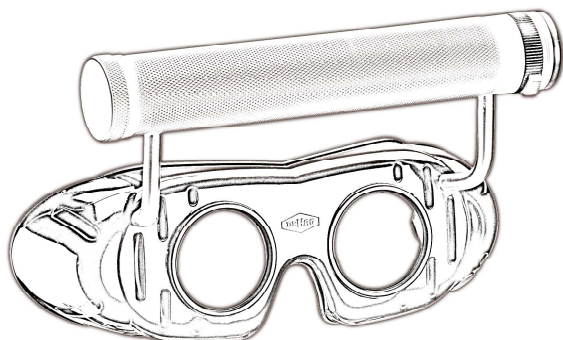




## Nystagmus Spectacle

REF 503/523



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](http://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.


## Contents

- Safety instructions
- Package Contents
- Operation
- Preparation instruction
- Waste disposal
- Technical data
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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 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.
  - 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.
- 
- A black circular icon containing a white wrench and screwdriver crossed, used to denote repair or maintenance instructions.
- Have any repairs carried out solely by a qualified electrician.

- Please remove the batteries before sending the nystagmus spectacle.
- 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 battery handle or the 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 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

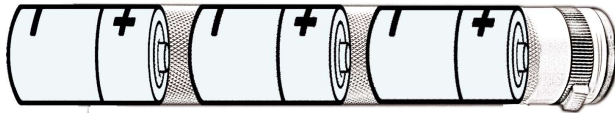
Contamination due to non-compliance with the preparation instructions, wrong or defective accessories.

## 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 batteries



## 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.

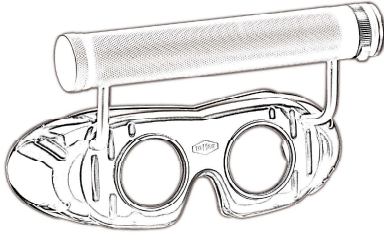
## Package Contents

- 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 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 503/523



- 1x user's instruction



Nystagmus Spectacle  
REF 503/523

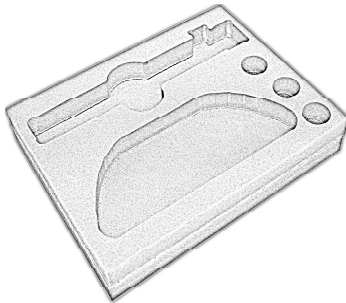


► User's instruction



v02307-01

- 1x inlay



- 1x carton



## Operation

### General

With the purchase of the nystagmus spectacle type 503/523 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 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 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 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.

## 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.

## 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 EU 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: 503 / 523
- Power supply: 3 x batteries baby cells type LR14/AM-2; á 1.5V
- Dimensions: 185 x 130 x 100 mm<sup>3</sup>
- Weight: approx. 270 g (w/o batteries)
- 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:












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Internet: [www.dehag.com](http://www.dehag.com)

## CE-Declaration of Conformity

The CE mark confirms that this product complies with the European Parliament Regulation 2017/745 (EU) of 05<sup>th</sup> 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)