

CATS[™] TONOMETER - INSTRUCTIONS FOR USE

1. SAFETY

1.1 Important general notes

WARNING!

The measuring prisms listed in this instruction are not sterilized when shipped. They must be cleaned and disinfected prior to their first use.

NOTE!

- All the warnings and notes in this instructions-for-use must be followed without exception.
- Examinations should only be performed with undamaged, cleaned and disinfected measuring prisms.
- The measuring prisms used must not be damaged as they might otherwise damage the patient's cornea.
- Improper preparation can result in the transmission of diseases to the patient and user as well as damage to the measuring prisms.
- Residue from cleaning agents and disinfectants can irritate and burn the patient's eye.
- As a rule, the measuring prisms may be prepared together but should not be prepared with any other products.

1.2 Operation, environment

NOTE!

- The operation and preparation must only be performed by qualified, trained personnel, whose training corresponds to the task of the operator.
- The operator of the CATSTM Tonometer Prism measures IOP utilizing the same method as with all Goldmann applanation prisms. For detailed instructions for measuring IOP, please refer to your Goldmann applanation tonometer's user manual. Regarding achieving centration, gently adjust the CATS Tonometer Prism on the center of the patient's cornea, turn the calibrated dial on the tonometer clockwise until two undistorted fluorescein semi-circles are seen to meet and form a horizontal 'S' shape. The correct end point is when the inner edges of the two fluorescein semi-circle images just touch.

Appropriate professional assessment and caution are necessary.

1.3 Warranty and product liability

- The measuring prisms must be handled as described in the "Safety" section.
- Improper handling can damage the product. This voids all guarantee claims.
- Continuing to use a product damaged by incorrect handling can lead to personal injury. In this case, the manufacturer accepts no liability.
- Soaking or wiping the CATS™ Tonometer Prism with alcohol will VOID the warranty.

2. CLEANING AND DISINFECTION OF MEASURING PRISMS

2.1 Manual cleaning steps

NOTE!

- Only manual non-immersion cleaning as described below should be used for this prism.
- For personal and safety reasons, personnel should wear disposable gloves during both the cleaning and disinfection procedures.
 - Prepare Enzol enzymatic detergent per manufacturer's recommendation at 1 oz. per gallon of tap water.
 - 2. Dampen lint-free cloth(s) with the prepared detergent solution and use to wipe the CATS Tonometer Prism to remove all visible soil. Use caution to ensure the cloth is not saturated with the solution.
 - 3. Carefully hand-dry the surfaces using a clean lint-free cloth.
 - 4. Dampen lint-free cloth with IPA (isopropanol) and use to wipe the Tonometer prism to remove any remaining soil. Use caution to ensure the cloth is not saturated with the solution.

NOTE!

- The operator accepts all liability for the use of detergents.
- Safely dispose of used cleaning materials.

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2.2 Disinfection steps

NOTE!

- Prior to disinfection, always clean the tonometers first.
- Always disinfect the CATSTM Tonometer Prism before use. Hand hygiene must be considered to prevent any contamination.
- Do not disinfect using Alcohol, Acetone or UV radiation.
- Do not immerse the CATS Tonometer Prism in liquid for more than 1 hour.
- Do not allow the CATS Tonometer Prism to be in an environment in which the temperature is greater than 60°C.
 - 1. Equilibrate a water bath of Cidex OPA to 20°C.
 - 2. Ensure minimum effective concentration (MEC) of the Cidex OPA using Cidex OPA test strips
 - Fully immerse CATS Tonometer Prism in the Cidex OPA bath for 12 minutes. Ensure all air bubbles are removed from the surface of the Tonometer prism by agitating.
 - Remove CATS Tonometer Prism from the Cidex OPA bath and rinse it under running water for a minimum of 3 minutes to remove the disinfectant.
 - Dry the disinfected CATS Tonometer Prism with a clean, sterile lint-free cloth.
 - 6. Store the disinfected CATS Tonometer Prism in a suitable container.
 - Safely dispose of the disinfectant fluid, following the procedure listed on the disinfectant bottle.

WARNING!

Only use clean, residue-free and undamaged measuring prisms. Prior to every use, the contact surface of the measuring prism must be inspected for contaminants and damage (scratches, cracks and sharp edges). This must be performed with a slit lamp microscope at 10X to 16X magnification.

3. Period of use

WARNING!

How long may measuring prisms be used?

Due to the large number of variables to be taken into account (type and concentration of disinfectants used, number of patients, handling, etc.), it is practically impossible to make a statement as to how often and/or how long a measuring prism can be safely used. Check the CATS Tonometer Prism under the Slit lamp and ensure there are no cracks / chips. The chemical used in the diagnosis process (for example: Fluorescein) will get into the cracks and will show up if observed under the slit lamp. Do not use it if there is any sign of cracks / chips.

Rx Only

The CATS™ Tonometer Prism is intended to be used with Goldmann type tonometers for the measurement of intraocular pressure.



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