

Important Safety Information

Field Safety Notice No. 2010-01/01

Reissued Notice on the Correct Monitoring, Handling and Use of Tonometer Measuring Prisms

Affected medical devices: Tonometer Measuring Prism

Koeniz, June 30, 2010

Dear Sir or Madam,

In August 2008 and June 2009, we informed you about reports of faulty and leaky tonometer measuring prisms. These incidents were mainly attributable to the following causes:

- Insufficient monitoring of the condition of measuring prisms before use and consequent use of damaged measuring prisms
- Insufficient disinfectant or inadequate disinfection procedure
- Insufficient rinsing after disinfection
- Use of inappropriate disinfectants

After consulting the Swiss Agency for Therapeutic Products, Swissmedic, we are contacting you once again as users of Tonometer Measuring Prisms with this Field Safety Notice. We have revised our Instructions for Use and made it more explicit. Furthermore, each new Tonometer Measuring Prism will be supplied with an extra Instructions for Use, which is an excerpt of the Tonometer Instruction for Use and describes the correct way to handle the measuring prism in detail.

Nothing has changed in terms of the actual principle of monitoring, cleaning and disinfection.

You are responsible for ensuring that you only perform examinations on your patients with properly cleaned, disinfected and intact measuring prisms.

We would like to remind you once again of the most important rules and precautions:

- Measuring prisms are dispatched in a non-disinfected condition.
- Examinations may only be carried out with measuring prisms that are cleaned and disinfected correctly.
- Diseases can be transferred to patients and measuring prisms can be damaged by incorrect disinfection.
- Disinfectant residues in the patient's eyes can lead to irritation or chemical burns. Therefore prisms must be thoroughly rinsed after disinfection.
- The measuring prisms must be removed from their mountings and placed in the disinfectant solution.
- The measuring prisms may not be disinfected together with other instruments and devices (danger of mechanical damage!)
- For an optimal cleaning and disinfection the measuring prisms must be submerged and move freely in the fluid. Prior to disinfection the measuring prisms must be rinsed under cold running water for 30 to 60 seconds. Extremely dirty measuring prisms can additionally be cleaned using a mild soap and a cotton-wool ball.
- After disinfection the measuring prisms must be rinsed thoroughly under running cold potable water for 10 to a maximum of 60 minutes. The measuring prisms should then be dried with a clean, soft single-use cloth, and stored in a clean dry, closable container.
- Only clean and undamaged measuring prisms may be used. Residues can lead to irritation of the patient's eye or chemical burns.

**NOTE!**

Disinfection may only be carried out using disinfectants that have been checked for material compatibility by HAAG-STREIT. The current compatibility list is enclosed with every tonometer and every measuring prism. It can also be found on the HAAG-STREIT AG homepage (www.haag-streit.com). The exact effectiveness, concentration and stand times can be taken from the manufacturer's recommendations and references.

**FORBIDDEN!**

The measuring prism is made from PMMA material. The following restrictions are valid:

- disinfection with alcohol
- cleaning with acetone
- disinfection with UV irradiation
- sterilisation with steam or ethylene oxide
- immersion in fluid for longer than one hour
- temperatures over 60 °C

**NOTE!**

We recommend our DESINSET for efficient disinfection and storage.

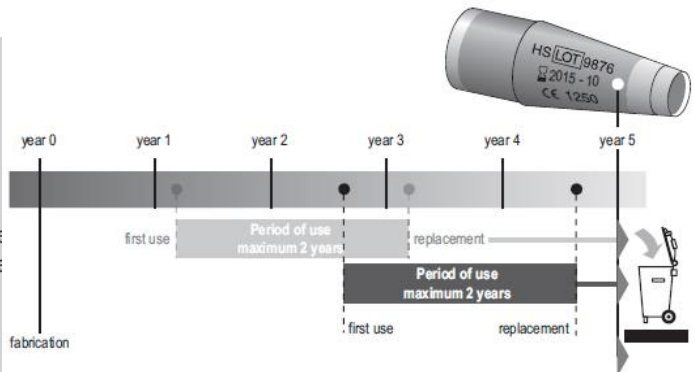
**WARNING!**

Do not use damaged measuring prisms.

Prior to each use, the contact surface of the measuring prism must be checked for contamination or damage (scratches, cracks or sharp edges.) This must be carried out using the slit-lamp microscope at a 10 to 16-fold magnification. When found to be damaged, the measuring prism may no longer be used to avoid damage to the patient's cornea. Disinfectant can penetrate into cracks in the measuring prism and lead to chemical burns on the patient's eye during tonometry.

We would like to draw your attention again to the permissible service life of tonometer measuring prisms:

WARNING!
How long may measuring prisms be used?
 Due to the large number of variables to be taken into account (type and concentration of the 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. The measuring prisms are stamped with an expiry date (YYMM). They must not be used beyond this date. HAAG-STREIT recommends a maximum service life of two years before the expiry date. This service life applies subject to normal conditions of use, i.e., in compliance with the instructions contained in these instructions for use. The period of use begins with the first application. The given time periods are not valid for damaged measuring prisms, they must be immediately replaced.



Please follow the Instructions for Use precisely with regard to all these matters. You can download it from the following website:

<http://www.haag-streit.com/products/tonometry/at-900r.html>

If you are unable to access this link, you can request the Instructions for Use free of charge from your local HAAG-STREIT distributor.

Please ensure that within your organization, all users of tonometer measuring prisms and other persons who need to be informed are made aware of this **Important Safety Information**. If you have handed over tonometer measuring prisms to third parties, please forward them a copy of this information.

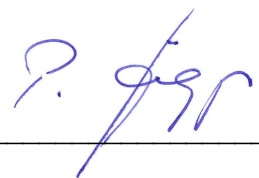
The Swiss Agency for Therapeutic Products, Swissmedic, has received a copy of this **Important Safety Information**.

If you have further questions on the correct way to handle tonometer measuring prisms, please contact your local HAAG-STREIT distributor.

HAAG-STREIT AG



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