ICARE® IC100 TONOMETER

EASY-TO-USE, PATIENT-FRIENDLY IOP MEASUREMENT

CLEANING AND DISINFECTING CONSIDERATIONS

1. DISINFECTION AND EYE SAFETY

The Joint Commission has brought up concerns about disinfection of tonometer tips.[1] Reviews of scientific studies on the subject have been published.[2-4]

Do not clean the Icare tonometer tips (probes).

There is no risk of infection with use of the Icare tonometers to measure eye pressure. The probe is the only part of the tonometer that touches the eye and the probe is disposable. Furthermore, the disposable probe is sterile (gamma-irradiated).

2. TONOMETER OUTER SURFACES AND THE PROBE BASE

There have been questions about cleaning the surfaces of the Icare tonometers with PDI brand wipes. PDI's Sani-Cloth Plus, Sani-Cloth Bleach, Super Sani-Cloth and Sani-Cloth Prime wipes can be used to clean the outer surfaces like the handle of the Icare tonometers. Follow the PDI's product labels as to effective wipe time and drying.

Do not use Sani-Cloth AF3 wipes for any Icare tonometer surfaces.

Do not use any wipes for cleaning the probe base (the brass tube where the probe is loaded).

Otherwise follow the Icare tonometer manual.

ICARE® IC100 TECHNICAL INFORMATION

Device type and serial number information
Type: TA011
The serial number is marked on the side of the tonometer and can also be shown on the display.
Device dimensions: 29 mm (W) x 95 mm (H) x 215 mm (L).
Display dimensions: 25.7 mm x 25.7 mm.
Weight: 140 g (without batteries), 230 g (4 x AA batteries).

Power source and electric connections:
4 x AA non-rechargeable batteries, 1.5 V alkaline LR6.
There are no electrical connections from the tonometer to the patient.
BF-type electric shock protection.

Operating environment: Temperature: +10 °C to +35 °C, Relative humidity: 30 % to 90 %, Atmospheric pressure: 800 hPa to 1060 hPa.
Storage environment: Temperature: -10 °C to +55 °C, Relative humidity: 10 % to 95 %, Atmospheric pressure: 700 hPa to 1,060 hPa.
Transport environment: Temperature: -40 °C to +70 °C, Relative humidity: 10 % to 95 %, Atmospheric pressure: 500 hPa to 1,060 hPa.

Mode of operation: Continuous.

Probe: Single-use, weight 26.5 mg, length 40.5 mm, diameter of the plastic tip 1.8 mm, manufactured from medically-approved materials, and tested for biocompatibility according to ISO 10993, sterilized using gamma radiation to achieve the Sterility Assurance Level (SAL) of <10 -6.
Probe base: requires changing at periodical intervals (see manual).

Icare® ic100 Measurement Information

Range: 7 mm Hg – 50 mm Hg (outside the measuring range IOP is estimated).
Accuracy: ± 1.2 mm Hg (≤ 20 mm Hg) and ± 2.2 mm Hg (> 20 mm Hg).
Repeatability (coefficient of variation): < 8 %.
Measurement display: 1 mm Hg interval for displayed IOP.

Comparative performance: Intraocular pressure (IOP) measurements with Icare tonometry have been compared to measurements using Goldmann applanation tonometry. The mean paired difference and standard deviation (Goldman–Icare) were found to be -0.4 mm Hg and 3.4 mm Hg. The performance data are obtained from a clinical study, 158 patients, conducted according to American National Standard ANSI Z80.10-2003 and International Standard ISO 8612.

Icare® ic100 Certifications & Approvals
Device has CE-mark (NB 0598).
US FDA 510 (k) cleared device.
Device manufacturer is ISO 13485 certified.
The Icare® ic100 tonometer complies with: Medical Device Directive 93/42/EEC, Canadian Medical Device Regulations, RoHS Directive 2011/65/EU.

For these reasons the safety of the Icare tonometers exceeds what is required for infection control of tonometer use in the USA.

References:

1. The Joint Commission. Disinfection of tonometers and other ophthalmology devices. Quick Safety. 2019 May; Issue 49.
2. Junk AK, Chen PP, Lin SC, Nouri-Mahdavi K, Radhakrishnan S, Singh K, Chen TC. Disinfection of Tonometers: A Report by the American Academy of Ophthalmology. Ophthalmology. 2017 Dec;124(12):1867-1875.
3. Atkins N, Hodge W, Li B. A Systematic Review Regarding Tonometry and the Transmission of Infectious Diseases. J Clin Med Res. 2018 Mar;10(3):159-165.
4. Ragan A, Cote SL, Huang JT. Disinfection of the Goldman applanation tonometer: a systematic review. Can J Ophthalmol. 2018 Jun;53(3):252-259.

The Joint Commission

QUICK SAFETY
ISSUE 49 | MAY 2019

DISINFECTION OF TONOMETERS AND OTHER OPHTHALMOLOGY DEVICES

Editorial Note: Please direct this Quick Safety to your organization's infection control and ophthalmology leadership.

ISSUE:

Health care organizations and providers that use tonometers and other devices that touch eyes need to be aware of an infection risk to patients. The American Academy of Ophthalmology has reported that transmission of adenovirus and herpes simplex virus HIV, hepatitis C virus (HCV), enterovirus 70, Pseudomonas aeruginosa, methicillin-resistant Staphylococcus aureus, Acanthamoeba, and prions (transmissible spongiform encephalopathies, such as Creutzfeldt-Jakob disease) could occur from failure to adequately disinfect ophthalmology devices, such as tonometers.[1]

Despite this information, a review of Joint Commission survey data identified either a lack of awareness of the requirements or misinterpretation of manufacturer's instructions — combined with lack of staff training and leadership oversight — related to the disinfection of ophthalmology devices. This has resulted in multiple declarations of an immediate threat to health and safety of patients.

Lack of compliance with reprocessing has been observed with the following items:

- Tonometers
- YAG laser lens
- Eye specula

Tonometer tips are particularly problematic because disinfectants can dissolve the glue that holds the hollow tip together, causing the tip to swell and crack. It's important to note that tonometer tips have been identified as sources of ophthalmic nosocomial outbreaks commonly linked to adenovirus types 8 and 19. Desiccated virus remains viable and can be recovered after 49 days on dried plastic or metal surfaces.[1]

Areas where these items are used include:

- Emergency departments
- Urgent care centers
- Ophthalmology clinics, optometrist offices, and procedure rooms
- Neonatal intensive care units (NICUs)

Items that touch mucous membranes — such as the eye — must be, at minimum, high-level disinfected. Items that contact or enter sterile tissues — such as instruments that are used for surgical procedures — or touch an ulcerated cornea must be sterilized.

SAFETY ACTIONS TO CONSIDER:

Health care organizations can use the following safety actions to protect patients from the risk of infection associated with tonometers and other ophthalmology devices:

- Review cleaning and disinfection instructions for use of eye instruments to ensure that they are being reprocessed appropriately. Items that touch intact surfaces of the eye must be high-level disinfected. Those that touch non-intact surfaces of the eye or are used for eye surgery must be sterilized.
- Ensure that disinfectants listed as compatible, other than bleach, are U.S. Food and Drug Administration (FDA)-approved high-level disinfectants. Manufacturers often list products as compatible that may be used for pre-cleaning. Some of these products may be commonly available surface disinfectants but are not effective as high-level disinfectants.
- Have available and follow manufacturer instructions for use for both the devices used for ophthalmology examinations and procedures, as well as cleaning and disinfection products.
- Have an individual who is knowledgeable about the different types of disinfectants review the product label and instructions for use. If instructions are unclear, technical services for the manufacturer of the item and any products used in conjunction with reprocessing should be contacted.

Resources:

[1] Disinfection of Tonometers: A Report by the American Academy of Ophthalmology. *Ophthalmology.* 2017 Dec;124(12):1867-1875. doi: 10.1016/j.ophtha.2017.05.033. Epub 2017 Jul 11
Note: This is not an all-inclusive list.