ICARE® IC200 TONOMETER

POSITION FREEDOM

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® IC200 TECHNICAL INFORMATION

Device type and serial number information
Type: TA031.
The serial number is on the inside of the battery compartment cover and can also be shown on the display.
Dimensions: 43 mm (W) x 104 mm (H) x 214 mm (L).
Weight: 165 g (without batteries), 255 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. The device has BF-type electric shock protection. The single use probe and the forehead support of the device are considered as applied parts.

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.

ICARE® IC200 MEASUREMENT INFORMATION

Range: 7 mmHg – 50 mmHg (outside the measuring range IOP is estimated)
.**Accuracy:** ± 1.2 mmHg (≤ 20 mmHg) and ± 2.2 mmHg (> 20 mmHg).
Repeatability (coefficient of variation): < 8 %.
Measurement display: 0.1 mmHg interval for displayed IOP.

Comparative performance: The performance of the device is obtained from a clinical study, performed according to the American National Standard ANSI Z80.10-2014 and the International Standard ISO 8612:2009 for tonometers. The study was performed at the East West Eye Institute, LA, USA. In the study, 152 patients were measured in the sitting and supine positions. The mean paired difference and standard deviation were 0.50 mmHg and 1.72 mmHg in the sitting position (Icare-Goldmann) and 0.52 mmHg and 1.96 mmHg in the supine position (Icare-Perkins).

Mode of operation: Continuous.

Consumables: Single-use disposable probes, manufactured from medically approved materials, and tested for biocompatibility according to ISO 10993. Probe base, requires changing at periodical intervals (see manual).

Icare® ic200 Certifications & Approvals
Device has CE-mark (NB 0598). Device manufacturer is ISO 13485 certified The Icare® ic200 tonometer complies with: Medical Device Directive 93/42/EEC, Canadian Medical Device Regulations, RoHS Directive 2011/65/EU, China RoHS 2, Radio equipment directive 2014/53/EU, Part 15 of the FCC rules and RSS-210 of Industry Canada.

Study References:
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QUICK SAFETY
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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.