trophon®: closed, automated disinfection designed for chemical safety

Critical Summary

- The trophon device maximizes safety for staff and patients by minimizing chemical exposure.
- The trophon disinfectant is enclosed in a cartridge until loaded inside the trophon device. No additional OHS measures are required at point of care (POC).
- Risk of chemical exposure from bulk liquids is reduced as no harmful residual chemicals are left on the transducer after completion of disinfection process.

trophon® is the global standard of care for ultrasound probe reprocessing at POC. The trophon family includes the trophon EPR and trophon2 devices, which share the same core technology of sonically activated hydrogen peroxide. trophon's high-frequency ultrasonic vibrations generate a hydrogen peroxide (H_2O_2) mist that kills bacteria, fungi, viruses and mycobacteria. Ultrasound probes are often high level disinfected in a centralized location in the hospital setting outside of the patient examination room. This is partly attributed to the chemical exposure risks associated with disinfection using bulk liquid disinfectants, such as glutaraldehyde (GTA) and ortho-phthalaldehyde (OPA).

Risk of chemical exposure from bulk liquid disinfection

Disinfection with bulk liquid chemicals such as aldehydes are toxic and reprocessing rooms require installation of ventilation, eye wash stations and sinks limiting their POC use.

Toxicity is possible from both direct contact with the chemical and vapour inhalation. There have been several reports of anaphylaxis in patients following cystoscopy where the medical device was reprocessed using OPA.[1,2]

Bronchial asthma and dermatitis can also be triggered by occupational OPA exposure.[3] OPA exposure has been shown to have detrimental effects on embryo development during toxicity testing for in vitro fertilization programs.[4]

One study found a 39% increased risk of spontaneous abortion with occupational exposure to sterilizing agents like GTA and formaldehyde.[5] The CDC guidelines recognize and discuss the risks of anaphylaxis from OPA exposure.[6]

The risk of chemical exposure during bulk liquid disinfection is high from preparation of the chemical, to reprocessing of the probe through to waste disposal once the chemistry expires. The manual nature of this workflow increases the likelihood of direct contact and vapour inhalation by reprocessing staff.

Given the risks, a review concluded there was a need to move toward a glutaraldhyde free sonography environment.[7]

The trophon system: maximizing safety by minimizing chemical exposure

The trophon system is a POC alternative to centralized ultrasound probe disinfection with bulk liquid disinfectants. The trophon device has been tested and validated with safety and design features to ensure patients and staff are at minimal risk of chemical exposure.

Chemistry supplied sealed and ready to use

The trophon system does not require mixing or dilution of disinfectant chemicals. The 35% hydrogen peroxide is ready for use and enclosed in a cartridge until loaded inside the trophon device (trophon Sonex-HL®). The cartridge is punctured only when correctly inserted and sealed inside the trophon device. There is no user interaction with the cartridge until the bottle is empty and needs to be replaced.

Extensively vapour tested

The trophon device is a closed disinfection system and there is minimal risk of hazardous exposure to hydrogen peroxide vapour during or after the disinfection cycle. Extensive leak testing has been performed in various conditions as well as risk assessments to demonstrate the operator and patient are at minimal risk of unsafe hydrogen peroxide vapour exposures defined by the Occupational Safety and Health Administration (OSHA) in the US.[8,9]

Extensively residuals tested

A large range of both surface and endocavitary probes have been tested for hydrogen peroxide residuals after the trophon disinfection cycle using an internally validated test methodology.[10] This testing is conducted to ensure the probe is safe for use on patients without putting them at risk of chemical exposure during an examination. Additionally, the trophon User Manual specifies wiping the probe with a low lint cloth after each cycle.

No requirement for eye wash stations

Eye wash stations are not required for the trophon system at POC. Institutional policy may however require that eye wash stations be installed. The trophon system is designed to ensure the patient and sonographer are not at risk of chemical exposure. The sealed cartridge and overall closed disinfection design ensures there is minimal risk of chemical splashing. System checkpoints ensure the disinfection cycle does not commence until the cartridge is inserted correctly and the chamber is sealed. In the US, the letter of interpretation by OSHA states "*If hazardous materials are present at a worksite in such a way that exposure could not occur (for example, in sealed containers that will not be opened, or caustic materials in building piping), then an eyewash or emergency shower would not be necessary.*"[11]

Environmentally neutral waste products

The trophon device produces water and oxygen gas as by-products and the liquid waste is collected in the waste drawer located inside the device. The operator is notified when the waste drawer needs to be emptied. This is easily done by donning gloves, removing the drawer and disposing of its contents according to your local guidelines. The waste drawer has minimal volume and the operator is not at risk of injury or chemical exposure commonly associated with disposal of large volumes of bulk liquid disinfectants.

The trophon system: the POC solution for ultrasound

The trophon system has been engineered with POC use in mind to provide a workflow solution for sonographers managing the time and resource constraints of centralized reprocessing with bulk liquid disinfectants. The ability of the trophon device to minimize the risk of chemical exposure forms an integral part of its engineering to ensure compatibility with and safety at POC.

Contact us today for your specific needs on point of care reprocessing, understanding when to HLD or for an educational session at your facility.

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References 1. Sokol WN. J Allergy Clin Immunol. 2004;114(2):392-7. **2.** Cooper DE, et al. J Endourol. 2008;22(9):2181-4. **3.** Fujita H, et al. J Occup Health. 2006;48(6):413-6. **4.** Ackerman SB, et al. J In Vitro Fert Embryo Transf. 1985;2(3):132-7. **5.** Lawson CC, et al. Am J Obstet Gynecol. 2012;206(327):e1-8. **6.** Centre for Disease Control and Prevention (CDC). Guideline for Disinfection and Sterilization in Healthcare Facilities. 2008. **7.** Pearlman O. J Diagn Med Sonogr. 2019;35(1):49-57. **8.** United States Department of Labour Occupational Safety and Health Administration (OSHA). Hydrogen Peroxide. Date accessed: Dec 2019. Available at: https://www.osha.gov/chemicaldata/chemResult.html?recNo=630. 2018. **9.** Nanosonics internal leak test reports. **10.** Nanosonics internal hydrogen peroxide residual reports. **11.** United States Department of Labour Occupational Safety and Health Administration (OSHA). Response to letter June 1, 2009 regarding standard numbers 1910.151 and 1910.151(c). Date Accessed: Dec 2019. Available at: https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=27089. 2010.

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