trophon®: closed, automated disinfection designed for chemical safety

Critical Summary

- The trophon device maximises safety for staff and patients by minimising chemical exposure.
- The trophon disinfectant is enclosed in a cartridge and punctured only when correctly inserted and sealed inside the trophon device.
- Hydrogen peroxide is preferred for environments where toxicity and sensitisation are of significant concern, such as in IVF settings.
- The trophon device additionally offers automated high level disinfection (HLD), ensuring reproducible reprocessing for every single patient.

trophon® is the global standard of care for ultrasound probe reprocessing at point of care. 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. 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 trophon NanoNebulant® containing 35% hydrogen peroxide is ready for use and enclosed in a cartridge until loaded inside the trophon device. 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 and after the disinfection cycle. Extensive leak testing has been performed as well as risk assessments to demonstrate the operator and patient are at minimal risk of unsafe hydrogen peroxide vapour exposures defined by EH40/2005 introduced by the European Commission Directive (EU) 2017/2398.[1,2]

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 a validated test methodology.[3] 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.

Nanosonics has conducted safety assessments of hydrogen peroxide residues on transducers disinfected by the trophon device in accordance with International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1. The safety assessment considers the worst case scenario including use of 50% hydrogen peroxide (rather than the standard 35%), the use of maximum dosage, the use of old and worn transducers with surface imperfections, the use of 5 serial disinfection cycles without any wiping (contravening the instructions for use) and assumes that a probe cover and coupling gel are not used. Under these worst case conditions, the residuals of hydrogen peroxide were found to present negligible biocompatibility risk based on an extensive literature search, even with chronic exposure. In real-world use, transducers are used with both gel and a probe cover meaning that clinical exposures would be exceedingly low.

Environmentally friendly 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 there is no risk of injury or chemical exposure commonly associated with disposal of bulk liquid disinfectants.

The trophon system has been designed with the patient environment in mind to provide a workflow solution for ultrasound users operating in a range of clinical specialties. The ability of the trophon device to minimise the risk of chemical exposure forms an integral part of its design to maximise staff and patient safety.

SPOTLIGHT: HLD in IVF Settings

IVF settings are complex, requiring specific processes to ensure patient safety and safe handling of sensitive embryos and oocytes.

Hydrogen peroxide is a preferred disinfectant for IVF applications

- When selecting a HLD method for IVF applications, special attention needs to be given to toxicity risks.
- Hydrogen peroxide has negligible reproductive and developmental toxicity risk according to the European Chemicals Agency (ECHA):

> "A toxicologically meaningful systemic availability of hydrogen peroxide and transportation of the substance via blood circulation therefore is unlikely. This view is supported by the available repeated dose toxicity studies, which did not result in primary systemic effects. It can be concluded that a data gap with regard to studies of reproductive and developmental toxicity does not exist."[4]

- Hydrogen peroxide is a naturally occurring substance in the body. Commensal lactobacilli in the vagina produce hydrogen peroxide that plays an antibacterial role by preventing growth of bacterial species associated with bacterial vaginosis.[5] Hydrogen peroxide is also rapidly degraded into oxygen and water in tissues and mucous.[6,7]

Automation ensures reproducible reprocessing for every patient

- Automated disinfection of ultrasound probes is strongly recommended across Europe.[8-16] Automated reprocessing eliminates variables inherent in manual methods such as wiping and establishes traceable, reproducible processes. Automated processes are also validated to achieve their expected performance outcomes consistently every time helping keep patients safe from infection transmission risk.

The trophon device enhances safety

- The trophon device mitigates chemical exposure risk and has been shown to leave residual levels of hydrogen peroxide which are below thresholds for toxicity.[1,3] The fact that hydrogen peroxide is also a naturally occurring substance in the body that is rapidly degraded in tissues and mucous makes it a favourable choice for HLD of ultrasound probes in IVF applications.
- The trophon device is also automated and validated, meaning that the critical parameters (e.g., time, temperature, dosage) are controlled and all surfaces of the probe head and handle are disinfected every time.
- In standard healthcare settings, the trophon system can be used in the patient environment with a dirty to clean workflow. IVF settings are complex, requiring specific processes to ensure safe handling of sensitive embryos and oocytes. It is therefore recommended reprocessing areas are separated from areas where embryos and oocytes are handled.

Conclusion

The ability of the trophon system to minimise the risk of chemical exposure forms an integral part of its design to ensure compatibility with and safety in the patient environment. Additionally, hydrogen peroxide has negligible reproductive and developmental toxicity risk when evaluated according to Regulation (EU) No 528/2012. Hydrogen peroxide is ideal for applications where toxicity is a major concern, such as IVF settings. In these sensitive settings, the trophon system additionally offers validated, automated HLD, ensuring reproducible disinfection for every single patient.

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. Health and Safety Executive. (2020). EH40/2005 Workplace exposure limits (Fourth edition). **2.** Nanosonics internal leak test reports. **3.** Nanosonics internal hydrogen peroxide residual reports. **4.** European Chemicals Agency. 2015. Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products: Assessment Report Hydrogen Peroxide (March 2015). **5.** Hillier SL, et al. Clin Infect Dis. 1993;16 Suppl 4:S273-81. **6.** Halliwell B, et al. FEBS letters. 2000;486(1):10-3. **7.** European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC). Special Report No 10: Hydrogen Peroxide OEL Criteria Document. 1996. **8.** European Society of Radiology (ESR). (2017). Insights Imaging 8(6): 523-535. **9.** Society and College of Radiographers and British Medical Ultrasound Society (2017). **10.** Health Service Executive Quality Improvement Division (2017). Document: QPSD-GL-028-1. **11.** Health Protection Scotland (2016). NHSScotland Guidance for Decontamination of Semi-Critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes. **12.** KRINKO and BfArM (2012). Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz: 66. **13.** Ministère des Solidarités et de la Santé (2019). Proposition technique du groupe de travail national:28. **14.** Ministere des solidarites et de la sante (2019). NOTE D'INFORMATION N° 79 du 19 juillet 2019 relative a la desinfection des sondes endocavitaires: 4. **15.** Werkgroep Infectie Preventie (2017). Reiniging, desinfectie en sterilisatie van medische hulpmiddelen voor hergebruik niet-kritisch, semi-kritisch of kritisch gebruik: 56. **16.** World Federation for Hospital Sterilisation Sciences (2019). Guideline for Reusable Medical Devices. https://wfhss-guidelines.com/.

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