

Hydrogen peroxide is preferred when selecting high level disinfection for oocyte retrieval and other applications



Are high level disinfection methods suitable for transvaginal ultrasound probes used in oocyte retrieval and other IVF applications?

Selecting a high level disinfection method for IVF applications

When selecting a high level disinfection method for IVF applications, special attention should be given to toxicity risks. While it is clear that hydrogen peroxide has many favourable disinfection characteristics, alternative manual disinfection methods with soaks and impregnated wipes could cause irritation in staff and patients, and may not guarantee the same reprocessing endpoints for each cycle.

The points below summarise the case for automated hydrogen peroxide as a preferred disinfectant for IVF applications.

- In the United States, the Center for Disease Control (CDC) guidelines recommend H₂O₂ disinfection for retrieved cells based on its lesser toxicity compared to other disinfectants: *“High-level disinfection with a product (e.g., hydrogen peroxide) that is not toxic to staff, patients, probes, and retrieved cells should be used until the effectiveness of alternative procedures against microbes of importance at the cavitory site is demonstrated by well-designed experimental scientific studies.”*¹
- Disinfectant studies conducted at the Food and Drug Administration (FDA) Office of Science and Technology in the United States showed that there is a several-hundred fold difference in the relative toxicity of various disinfecting substances. Hydrogen peroxide was classified in the lowest risk group with the 50% toxic concentration (TC50) being greater than 1 mM (34 µg/mL).²
- Most human cells are naturally exposed to some level of hydrogen peroxide and in contact with mammalian tissues, hydrogen peroxide is immediately broken down to oxygen and water by the action of catalases.³⁻⁴ The highest catalase activities are observed in highly vascularised tissues including mucous membranes. Hydrogen peroxide is produced naturally by commensal lactobacilli in the vagina and even plays an antibacterial role by preventing growth of bacterial species associated with bacterial vaginosis.⁵
- Wipe systems usually do not have a rinsing step, required to remove disinfectant residues from the ultrasound probe. Always ask the wipe manufacturer for evidence that there are no residuals left on the probe after disinfection to prevent allergic or toxic reactions in patients.

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- Manual soaking and wipe systems can expose reprocessing staff to harmful chemicals, through eye and skin exposure or through vapour inhalation. Automated systems minimise chemical exposure and physical discomfort, and ensure reprocessing endpoints are met at every cycle by removing human error.⁶
- Manual soaking and wipe systems often cannot disinfect the ultrasound

probe handle. For soak systems this is because many probes cannot be fully immersed; for wipe systems often disinfection is omitted from the protocol. In these cases, >80% of probe handles remain contaminated with potentially pathogenic organisms, including methicillin resistant *Staphylococcus aureus* (MRSA).⁷⁻⁸

Why choose trophon® EPR as your preferred high level disinfection system?

trophon EPR is an automated high level disinfection device specifically designed for disinfecting ultrasound probes. It uses a sonicated hydrogen peroxide mist to achieve high level disinfection in an automated seven-minute cycle. trophon is ideal for applications where toxicity is a major concern, particularly for procedures such as oocyte retrieval.

In comparison to manual disinfection methods such as soaking and wiping, trophon dramatically reduces the risk of exposure to toxic disinfectant chemistries for retrieved cells, patients and staff. At the end of each cycle, the hydrogen peroxide disinfectant is broken down into water and oxygen. Levels of residual hydrogen peroxide on disinfected ultrasound probes are well below the minimum doses required to cause toxic effects and can be considered non-toxic. trophon is also fully automated, reducing the risk of operator error compared to manual methods.

trophon is safe to use

Nanosonics has conducted a safety assessment of peroxide residues on ultrasound probes disinfected by trophon in accordance with ISO 10993-1 and the FDA Blue Book Memo G95-1. The assessment considers the worst-case scenario including use of 50% H₂O₂ (rather than the standard 35%), the use

of maximum dosage, the use of old and worn ultrasound probes with surface imperfections, the use of five serial disinfection cycles without any wiping (contravening 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, ultrasound probes are used with both gel and a probe cover meaning that normal clinical exposures would be exceedingly low.

hydrogen peroxide is a preferred high level disinfection method

Hydrogen peroxide based high level disinfection is preferred for ultrasound probes where toxicity, sensitisation and irritation are of significant concern, particularly in sensitive IVF procedures such as oocyte retrieval. What's more,



trophon's hydrogen peroxide residual levels are below toxicity thresholds.

trophon is an enclosed, automated disinfectant that minimises chemical exposure to staff and ensures reproducible high level disinfection with every cycle by eliminating human error. The fact that hydrogen peroxide is a naturally occurring substance in the body and is rapidly degraded in tissues and mucous, makes it a favourable choice for high level disinfection ultrasound probes used in IVF applications.

Standards and guidelines recommend semi-critical and critical ultrasound transducers must minimally undergo high level disinfection even if used with a sheath (Australasian Society for Ultrasound in Medicine (ASUM)/Australasian College for Infection Prevention and Control (ACIPC) Guidelines; Therapeutic Goods Administration (TGA) Order No. 54, 2009; Standards Australia/Standards New Zealand (AS/NZS) 4187-2014; National Health and Medical Research Council (NHMRC))⁹⁻¹²

Contact us for further information.

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References: **1.** Rutala WA, Weber DJ, Healthcare Infection Control Practices Advisory Committee (HICPAC), Centers for Disease Control and Prevention (CDC). USA. Guideline for Disinfection and Sterilization in Healthcare Facilities. 2008 (Updated 15 February 2017). Available at: <https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines.pdf>. **2.** Sagripanti JL, Bonifacino A. 2000. Cytotoxicity of liquid disinfectants. *Surgical infections* 1:3-14. **3.** Halliwell B, Clement MV, Long LH. 2000. Hydrogen peroxide in the human body. *FEBS letters* 486:10-13. **4.** (ECETOC) ECfEaToC. 1996. Special Report No 10: Hydrogen Peroxide OEL Criteria Document. **5.** Sgibnev AV and Kremleva EA. Vaginal Protection by H₂O₂-Producing Lactobacilli. *Jundishapur J Microbiol.* 2015; 8(10): e22913. **6.** Ofstead CL, Wetzler HP, Snyder AK, Horton RA. Endoscope reprocessing methods: a prospective study on the impact of human factors and automation. *Gastroenterology nursing : the official journal of the Society of Gastroenterology Nurses and Associates.* 2010;33(4):304-11. **7.** Ngu A, McNally G, Patel D, Gorgis V, Leroy S, Burdach J. Reducing Transmission Risk Through High-Level Disinfection of Transvaginal Ultrasound Transducer Handles. *Infection control and hospital epidemiology.* 2015 May;36(5):581-4. **8.** Buescher DL, Mollers M, Falkenberg MK, Amler S, Kipp F, Burdach J, et al. Disinfection of transvaginal ultrasound probes in a clinical setting: comparative performance of automated and manual reprocessing methods. *Ultrasound in obstetrics & gynecology : the official journal of the International Society of Ultrasound in Obstetrics and Gynecology.* 2016;47(5):646-51. **9.** ACIPC-ASUM. Guidelines for Reprocessing Ultrasound Transducers. *Australasian Journal of Ultrasound in Medicine.* 2017;20(1):30-40. **10.** Therapeutic Goods Order No. 54B. Standard for Disinfectants and Sterilants (Amendment to Therapeutic Goods Order No. 54). *Therapeutic Goods Act 1989; 2009* (<https://www.legislation.gov.au/Details/F2009C00327>). **11.** Standards Australia/Standards New Zealand. AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations (superseding AS/NZS 4187:2003). Standards Australia; 2014. **12.** Australian Government/ National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010). NHMRC; 2010 (<https://www.nhmrc.gov.au/guidelinespublications/cd33>).