

trophon® EPR

An effective high level disinfection solution for ultrasound probes that can reduce risks and increase compliance

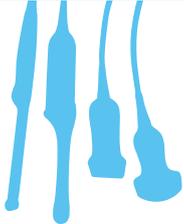
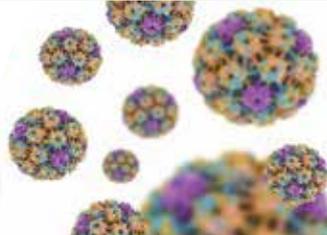
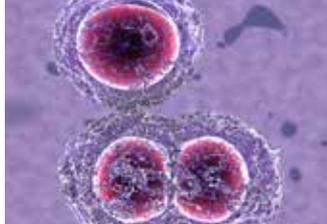
Why you need trophon



trophon EPR is safe, versatile and simple



Reduce the risk of ultrasound infection

 <p>12.9% of probes are contaminated with pathogenic bacteria following routine disinfection²</p>	<p>Up to 7% of ultrasound probes were found to be contaminated with human papilloma virus after disinfection with low level wipes³</p> 	
<p>More than 80% of probe handles that were not disinfected had residual pathogens including MRSA⁴</p>		 <p>Up to 81% of barrier sheaths and condoms leak⁵⁻¹³</p>

Compliance to high level disinfection guidelines

To reduce the risk of ultrasound probe cross-infection, it is important to know when to perform the high level disinfection (HLD) process.

HLD should be performed on ultrasound probes that are used in semi-critical procedures, as defined by the Spaulding Classification. Applying the correct level of disinfection is based on the procedure the probe is going to be used for on the next patient. In order to determine when to apply HLD to your semi-critical probes, refer to the diagram below.



*Critical probes should be sterilised, or can also be high level disinfected and used with a sterile sheath.¹⁴

Standards and guidelines recommend high level disinfection

Semi-critical and critical ultrasound transducers must minimally undergo HLD even if used with a sheath:



ASUM/ACIPC

The Australasian Society for Ultrasound in Medicine (ASUM)/Australasian College for Infection Prevention and Control (ACIPC) Guidelines state that “If the transducer comes in direct contact with non-intact skin, blood or mucous membranes transducers should be cleaned with [and undergo] HLD (e.g. open wounds, intact infected skin, ultrasound guided interventional and surgical procedures, needle guided procedures and intra-operative uses).”¹⁴

Semi-critical reusable medical devices must minimally undergo HLD:



TGA

“These devices (semi-critical medical devices), when disinfected, must be subjected to at least a high level disinfection process with an ‘instrument grade high level disinfectant’.
Therapeutic Goods Administration (TGA) Order No. 54, 2009.”¹⁵



ASNZS 4187-2014

“HLD as the minimum reprocessing standard for ultrasound probes used in semi-critical procedures is also advised by Standards Australia/Standards New Zealand (ASNZS) 4187-2014 guidelines.”¹⁶



NHMRC

“Semi-critical Reusable medical devices (RMDs) require cleaning followed by high-level disinfection at a minimum.”¹⁷ National Health and Medical Research Council (NHMRC)

Human papilloma virus – a major driver for new guidelines and the adoption of trophon

Ultrasound probes are a potential source of human papilloma virus (HPV) infection, posing a new challenge for infection prevention.



American Journal of Obstetrics and Gynecology

*A proposal to reduce the transmission risk of HPV via transvaginal ultrasound*¹⁸

- References the findings of Professor Craig Meyer’s first and second HPV papers
- Recommends use of trophon as a system proven to kill HPV
- Suggests that the FDA consider adding the neutralisation of HPV to its standards for high level disinfectants



Journal of Obstetrics and Gynaecology Research

*Possible non-sexual modes of transmission of human papilloma virus*¹

- Draws attention to semi-critical ultrasound probes as a source of non-sexual HPV transmission and discusses the evidence
- Highlights the CDC recommendation to high level disinfect semi-critical ultrasound probes and also states ‘sonicated hydrogen peroxide’ is highly effective against HPV16 and HPV18

The challenges of using traditional disinfection methods

Traditional Method	Risks	Examples
Manual wiping (exposes the operator and patient to chemicals)	<ul style="list-style-type: none"> Wiping with chemicals can be a health and safety risk Probes may still be contaminated after disinfection Probe handle may remain contaminated 	<ul style="list-style-type: none"> Chemical exposure can occur during manual wiping with skin and eye contact or inhalation of fumes Patients could be exposed to chemicals if probe rinsing does not occur/is not adequate Residual bacteria (including MRSA) remain on > 80% of probe handles when not wiped during the disinfection process⁴ Manual wiping is unable to consistently reduce bacterial contamination on probes to background levels¹⁰ Manual processes cannot assure reproducible reprocessing every time
Manual wiping (can increase the risk of operator error)	<ul style="list-style-type: none"> The manual wipes method may not be as effective as an automated system Increased risk of contamination with a manual disinfection method Low disinfectant wipes or sprays are less effective than a high level disinfection method 	<ul style="list-style-type: none"> A study showed that an automated method was significantly more efficacious than manual wipes in the high level disinfection of ultrasound probes¹⁰ Research has shown a 2.9-fold increased risk of contamination with manual disinfection methods versus an automated reprocessing solution¹⁰ A meta-analysis has shown that 12.9% of probes are contaminated with pathogenic bacteria following disinfection with low level disinfectant wipes or sprays¹¹
Ultraviolet C (UVC) exposure	<ul style="list-style-type: none"> Light travels in a straight line resulting in shadow areas forming where the light path is blocked and can't reach the surface UVC light may require two cycles to be effective against fungi 	<ul style="list-style-type: none"> Ultrasound probe shadowing due to cracks, crevasses, or parts of probes that have unusual contours for biopsy needle placement, could result in the UVC light not being completely effective Some fungi are significantly resistant to UVC light and require double cycles to achieve true high level disinfection¹⁹⁻²⁰
Protective sheaths	<ul style="list-style-type: none"> Probe sheaths can often have microscopic tears 	<ul style="list-style-type: none"> Protective sheaths (or condoms) do not negate the need for high level disinfection¹⁴ Sheaths can have microscopic perforations before use – up to 81%⁵⁻¹³

trophon is a simple to use automated high level disinfection solution that delivers consistent results



Why choose trophon?

trophon is the safe, versatile and simple way to prevent ultrasound probe cross-infection.

- Guidelines recommend the use of an automated high level disinfection system
- trophon is the world's leading automated high level disinfection system for ultrasound probes
- trophon delivers an effective solution to ensure your facility complies with all guideline requirements

trophon benefits

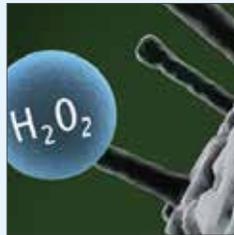


How trophon technology works

trophon's high-frequency ultrasonic vibrations generate a sonically activated, supercharged hydrogen peroxide (H_2O_2) mist that kills bacteria, fungi and viruses.



Sonicated. Ultrasonic vibrations generate sound-wave energy to create an ultrafine mist



Supercharged. Free radicals disperse, disrupt and kill bacteria, fungi and viruses



Success. Message confirms completion of high level disinfection, chemical indicator colour change validates disinfection

trophon EPR efficacy

- ✓ trophon EPR inactivates drug resistant pathogens, spores and pathogens that cause sexually transmitted infections (STIs).
- ✓ trophon EPR inactivates the mandated subset of microorganisms, as required by Australian regulations and is proven to also eliminate an extended range of infectious pathogens.



Bactericidal



Virucidal

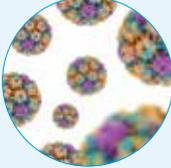
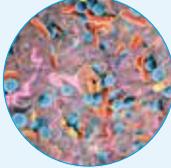
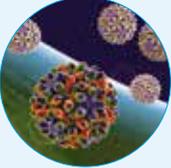
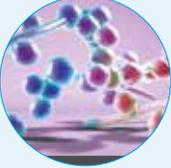
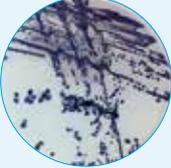


Fungicidal



Mycobactericidal

trophon helps to reduce cross-contamination risks

Sexually transmitted infections (STIs)	Drug resistant bacteria	Spores
<ul style="list-style-type: none"> • Relevant to women's health where transvaginal probes are used • Can cause infertility and significant morbidity and mortality 	<ul style="list-style-type: none"> • Rise of drug resistant bacteria is a serious healthcare problem • Can cause serious infections following invasive procedures e.g. central line placement 	<ul style="list-style-type: none"> • High level disinfectants are expected to be sterilants with an <u>extended</u> contact time • Laboratory testing with trophon shows inactivation of <i>Clostridium difficile</i> spores within cycle time
<div style="display: flex; flex-wrap: wrap; justify-content: space-around;"> <div style="text-align: center;"> Gonorrhea</div> <div style="text-align: center;"> HPV</div> <div style="text-align: center;"> MRSA</div> <div style="text-align: center;"> VRE</div> <div style="text-align: center;"> Hepatitis B/C</div> <div style="text-align: center;"> Chlamydia</div> <div style="text-align: center;"> CRE</div> <div style="text-align: center;"> Candida</div> <div style="text-align: center;"> HIV</div> </div>	<div style="text-align: center;"> <i>Clostridium difficile</i></div>	

Have you trophoned today?

Join the thousands of healthcare facilities worldwide that use trophon to high level disinfect their ultrasound probes

References: 1. Ryndock E, Robison R, Meyers C. Susceptibility of HPV16 and 18 to high level disinfectants indicated for semi-critical ultrasound probes. *J Med Virol.* 2016;88(6):1076-80. 2. Leroy, S.J., Infectious Risk of endovaginal and transrectal ultrasonography, *Journal of Hospital Infection*, 83(2):99-106, 2012. 3. Ma STC et al, Transvaginal ultrasound probe contamination by the human papillomavirus in the emergency department, *Emergency Medicine Journal*, 1-4, 2012. 4. Ngu A. et al. Reducing Transmission Risk Through High-Level Disinfection of Transvaginal Ultrasound Transducer Handles, *Journal for Infection Control & Hospital Epidemiology*, volume 36, May 2015. 5. Highett M, Claman P. High rates of perforation are found in endovaginal ultrasound probe covers before and after oocyte retrieval for in vitro fertilization-embryo transfer. *J Assist Reprod Genet.* 1995;12(9):606-9. 6. Amis S et al. Assessment of condoms as probe covers for transvaginal sonography. *J Clin Ultrasound* 2000;28(6):295-8. 7. Milki AA and Fisch JD. Vaginal ultrasound probe cover leakage: implications for patient care. *Fertil Steril* 1998;69(3):409-11. 8. Storment JM et al. Ineffectiveness of latexcondoms in preventing contamination of the transvaginal ultrasound transducer head. *South Med J* 1997;90(2):206-8. 9. Masood J et al. Condom perforation duringtransrectal ultrasound guided (TRUS) prostate biopsies: a potential infection risk. *Int Urol Nephrol* 2007;39(4):1121-4. 10. 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 Obstet Gynecol.* 2016;47(5):646-51. 11. Leroy S. Infectious risk of endovaginal and transrectal ultrasonography: systematic review and meta-analysis. *The Journal of hospital infection.* 2013;83(2):99-106. NAN0046. 12. Rooks VJ, Yancey MK, Elg SA, Brueske L. Comparison of probe sheaths for endovaginal sonography. *Obstet. Gynecol.* 1996;87:27-9. 13. Odwin CS, Fleischer AC, Kepple DM, Chiang DT. Probe covers and disinfectants for transvaginal transducers. *J Diagnostic Med. Sonography* 1990;6:130-5. 14. ACIPC-ASUM. Guidelines for Reprocessing Ultrasound Transducers. *Australasian Journal of Ultrasound in Medicine.* 2017;20(1):30-40. 15. 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>). 16. 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. 17. 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/guidelines-publications/cd33>). 18. Meyers J, Ryndock E, Conway MJ, Meyers C, Robison R. Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants. *J Antimicrob Chemother.* 2014;69(6):1546-50. 19. W. Kowalski, *Ultraviolet Germicidal Irradiation Handbook*, Springer-Verlag Berlin Heidelberg 2009. 20. J. G. Anderson, N. J. Rowan, S. J. MacGregor, R. A. Fouracre and O. Farish, Inactivation of food-borne enteropathogenic bacteria and spoilage fungi using pulsed-light. *IEEE Transactions on Plasma Science*, vol. 28, no. 1, pp. 83-88, Feb 2000.



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