

trophon® EPR

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

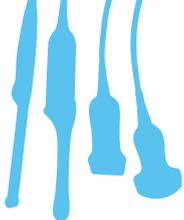
Why you need trophon



trophon EPR is safe, versatile and simple

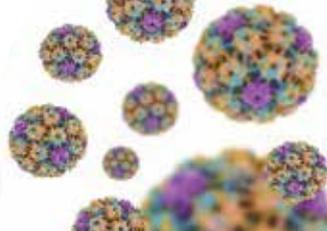


Reduce the risk of ultrasound infection

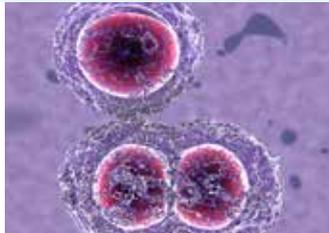


12.9% of probes are contaminated with pathogenic bacteria following routine disinfection²

Up to **7%** of ultrasound probes were found to be contaminated with human papilloma virus after disinfection with low level wipes³



More than **80%** of probe handles that were not disinfected had residual pathogens including MRSA⁴




Up to **81%** of barrier sheaths and condoms leak⁵⁻¹³

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:



CDC

“...because condoms/probe covers can fail, the [semi-critical ultrasound] probe also should be high-level disinfected.”¹⁴



AIUM

“All internal transducers (eg, vaginal, rectal, and transesophageal transducers) as well as intraoperative transducers require high-level disinfection before they can be used on another patient.” “Because of the potential disruption of the barrier sheath, high-level disinfection with chemical agents is necessary.”¹⁵

Semi-critical reusable medical devices must minimally undergo HLD:



FDA

“Semicritical devices...sterilize these devices between uses whenever feasible, but high level disinfection is minimally acceptable.”¹⁶



AAMI

“Semicritical devices should be sterilized, if possible. However, if sterilization is not feasible, the device, at a minimum, must be subjected to a high-level disinfection process...”¹⁷



TJC

Semi-critical devices that contact mucous membranes or non-intact skin should minimally undergo High Level Disinfection.¹⁸

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*¹⁹

- 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

Method	Risks	Challenges
Liquid disinfectant-manual soaking technique	<ul style="list-style-type: none">• Disinfectant method may not allow the transducer handle to be immersed in the solution• Probe handles may remain contaminated	<ul style="list-style-type: none">• Residual bacteria (including MRSA) remain on > 80% of probe handles which are not immersed during liquid soak disinfection⁴
Liquid disinfectant-chemicals used in soaking	<ul style="list-style-type: none">• Soaking with chemicals can be a health and safety risk• Manual soaking can be ineffective	<ul style="list-style-type: none">• Exposure to GTA and OPA can pose severe health and safety risks for all• Requires a ventilated room and plumbed to a micro-filtered water line• GTA and OPA are ineffective against HPV16¹⁹
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 HLD⁵• 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

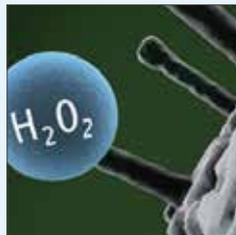


How trophon technology works

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 FDA standards and is proven to also eliminate an extended range of infectious pathogens.



Bactericidal



Virucidal

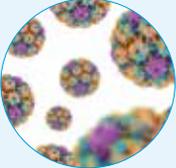
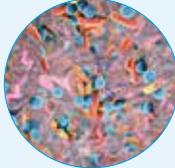
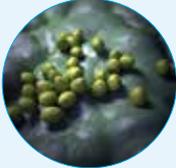
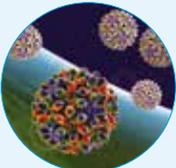
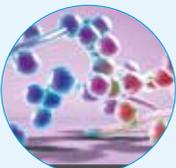
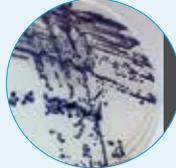


Fungicidal



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;"> <div style="text-align: center; margin: 5px;"> Gonorrhea</div> <div style="text-align: center; margin: 5px;"> HPV</div> <div style="text-align: center; margin: 5px;"> MRSA</div> <div style="text-align: center; margin: 5px;"> VRE</div> <div style="text-align: center; margin: 5px;"> Hepatitis B/C</div> <div style="text-align: center; margin: 5px;"> Chlamydia</div> <div style="text-align: center; margin: 5px;"> CRE</div> <div style="text-align: center; margin: 5px;"> Candida</div> <div style="text-align: center; margin: 5px;"> HIV</div> </div>		 <i>Clostridium difficile</i>

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 endovaginatl 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. Rutala WA, Weber DJ, HICPAC. *Guideline for Disinfection and Sterilization in Healthcare Facilities.* USA: Centers for Disease Control; CDC 2008. (<https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines.pdf>) 15. American Institute of Ultrasound in Medicine. *Guidelines for cleaning and preparing external and internal-use ultrasound probes between patients.* AIUM Official Statement. Online at: <http://www.aium.org/officialStatements/57>. Accessed March 8, 2016. 16. Federal Drug Administration. *Guidance for Industry and FDA Reviewers: Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants.* 200 <http://www.aami.org/standards/index.aspx?navItemNumber=504> 0. 17. AMMI <http://www.aami.org/standards/index.aspx?navItemNumber=504> 18. Electronically accessed: Joint Commission Alert is Another Wake-Up Call for Awareness of Improper HLD or Sterilization. <http://www.infectioncontroltoday.com/articles/2014/08/joint-commission-alert-is-a-another-wakeup-call-for-awareness-of-improper-hld-or-sterilization.aspx> 19. 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.



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