trophon® EPR

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

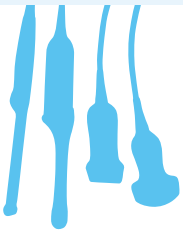
Why you need trophon

trophon EPR is safe, versatile and simple

trophon®
PROVEN TO KILL HIGH-RISK HPV[1]

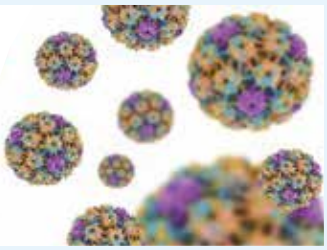
nanosonics
Infection Prevention. For Life.

Reduce the risk of ultrasound infection

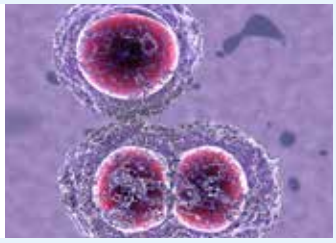


12.9% of probes are contaminated with pathogenic bacteria following routine disinfection[2]

Up to **7%** of ultrasound probes were found to be contaminated with human papilloma virus after disinfection with low level wipes[3]



More than **80%** of probe handles that were not disinfected had residual pathogens including MRSA[4]



Up to **81%** of barrier sheaths and condoms leak[5-13]

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 process.

High level disinfection 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 high level disinfection to your semi-critical probes, refer to the diagram below.

WHAT PROCEDURE WILL YOUR PROBE BE USED FOR?

Procedure

Probe used on mucous membranes or broken skin

Probe used on healthy intact skin

Spaulding Classification

Semi-Critical
(Semi-invasive and non-invasive)

Intracavity
- Transvaginal scans
- Transrectal scans

Surface ultrasound (broken skin)
- Wound/cavity/burn/assessment
- Venepuncture/Cannulation
- Breast biopsies
- Interventional
- Piccline insertion

Non-Invasive
- Abdominal surface ultrasound
- Pelvic surface ultrasound

If blood or bodily fluids noted during procedure - need to high level disinfect

Disinfection / Requirements

High level disinfection is assured by using trophon, a compact and automated point of care solution that is safe, versatile and simple to use.

Standardise with high level disinfection

Or low level disinfection
Follow local IPC and manufacturer's cleaning guidance

PROBE HAS BEEN TROPHONED AND IS READY FOR PROCEDURE

trophon complies with all UK guidelines and audit requirements

Standards and guidelines recommend high level disinfection

High level disinfection is advised in European, Irish, Scottish and Welsh guidelines as the minimum standard in ultrasound probe reprocessing for intracavity ultrasound probes that contact mucous membranes. Additionally, the guidelines advise high level disinfection for non-invasive surface probes used on broken skin.[15-20]

SCoR and BMUS

The Society & College of Radiographers and the British Medical Ultrasound Society advises that all ultrasound transducer probes undergo cleaning followed by disinfection or sterilisation. Critical probes should minimally undergo high level disinfection and be used with a sterile sheath. All semi-critical probes should undergo high level disinfection regardless of sheath use. The guidelines also reference the Welsh and Scottish, and more recently the Irish and Australian ultrasound probe reprocessing guidelines.[10-15]

HPS/HFS (Scotland)

In 2016, Health Protection Scotland (HPS) and Health Facilities Scotland (HFS) released new guidelines. Previously Health Facilities Scotland (HFS) had conducted a national survey of transoesophageal echocardiography probes, transvaginal and transrectal ultrasound probes to identify current decontamination practice for semi-invasive ultrasound probes across NHS Scotland. It concluded that "there is an ongoing risk to patient safety with regard to decontamination of these semi-invasive ultrasound probes."[16]

HSE (Ireland)

The Health Services Executive (HSE) guidelines state: "High level disinfection using the manual multi-wipe system is the least preferred option for disinfecting semi-invasive ultrasound probes. Internationally it is recognised that the use of an automated validated process … will provide enhanced risk reduction of infection transmission."[17]

NHS (Wales)

The National Health Service Wales guidelines recommend ultrasound probes preferably be disinfected with automated decontamination processes. Manufacturers of automated decontamination devices and manual procedures must provide evidence for reaching the claimed disinfection endpoints and this should be investigated during the procurement process. Traceability should be incorporated in all reprocessing workflows.[18]

European Society of Radiology (ESR)

The guidelines stated that in Germany, "Merz et al., like others, favours automated systems for high level disinfection, in particular devices using hydrogen peroxide (Trophon® EPR), now approved by the US Food and Drug Administration. Another important aspect of automated systems is the standardised and reproducible decontamination process thus avoiding operator-associated errors or variations. Ultraviolet (UV) light is less effective in eradicating microbes in comparison to hydrogen peroxide."[19]

EFSUMB (ECMUS)

The European Committee for Medical Ultrasound Safety (ECMUS) is a committee of the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB). The ECMUS guidelines recommend all internal transducers (vaginal, rectal, transesophageal probes) and intra-operative probes undergo cleaning followed by high level disinfection before use in a new patient. Automated, manufacturer validated processes are preferred as long as full documentation of the process (i.e. traceability) is available.[20]

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

Ultrasound probes are a potential source of HPV infection, posing a new infection prevention challenge.

American Journal of Obstetrics and Gynecology

A proposal to reduce the transmission risk of HPV via transvaginal ultrasound[21]

- Recommends the 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

The challenges of using traditional disinfection methods

Traditional Method	Risks	Challenges
Manual wiping (exposes the operator and patient to chemicals)	• Wiping with chemicals can be a health and safety risk • Probes may still be contaminated after disinfection • Probe handle may remain contaminated	• 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 process[4] • Manual wiping is unable to consistently reduce bacterial contamination on probes to background levels[10] • Manual processes cannot assure reproducible reprocessing every time
Manual wiping (can increase the risk of operator error)	• 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	• A study showed that an automated method was significantly more efficacious then manual wipes in the high level disinfection of ultrasound probes[10] • Research has shown a 2.9-fold increased risk of contamination with manual disinfection methods versus an automated reprocessing solution[10] • A meta-analysis has shown that 12.9% of probes are contaminated with pathogenic bacteria following disinfection with low level disinfectant wipes or sprays[11]
Ultraviolet C (UVC) exposure	• 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	• 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 disinfection[22-23]
Protective sheaths	• Probe sheaths can often have microscopic tears	• Protective sheaths (or condoms) do not negate the need for high level disinfection[15] • 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

Safe

trophon delivers safety for patients, staff and the environment.

REDUCE RISK

Versatile

trophon streamlines set-up and workflow. It also has extensive probe compatibility.

REDUCE COST

Simple

trophon makes ultrasound probe disinfection automated, consistent and fast. Plus training and record keeping is simple.

INCREASE COMPLIANCE

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 European Standards and is proven to also eliminate an extended range of infectious pathogens.

Bactericidal

Virucidal

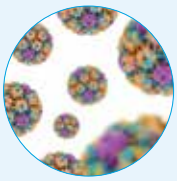
Fungicidal

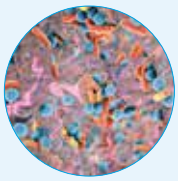
Mycobactericidal

trophon helps to reduce cross-contamination risks

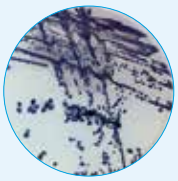
Sexually transmitted infections (STIs)	Drug resistant bacteria	Spores
• Relevant to women's health where transvaginal probes are used • Can cause infertility and significant morbidity and mortality	• Rise of drug resistant bacteria is a serious healthcare problem • Can cause serious infections following invasive procedures e.g. central line placement	• High level disinfectants are expected to be sterilants with an extended contact time • Laboratory testing with trophon shows inactivation of *Clostridium difficile* spores within cycle time

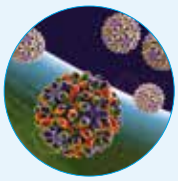

Gonorrhea


HPV


MRSA

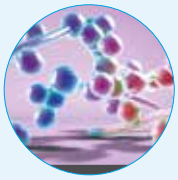

VRE


Clostridium difficile


Hepatitis B/C


Chlamydia


CRE


Candida


HIV

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, SJ., Infectious Risk of endovaginal and transrectal ultrasonagraphy, 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 A A and Fisch JD. Vaginal ultrasound probe cover leakage: implications for patient care. Fertil Steril 1998;69(3):409–11. **8.** S torment J M e t a l. Ineffectiveness of latex condoms in preventing contamination of the transvaginal ultrasound transducer head. South Med J 1 997;90(2):206–8. **9.** Masood J et al. Condom perforation during transrectal 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/disinfectionguidelines.pdf). **15.** Reference: Society and College of Radiographers (SCoR) and British Medical Ultrasound Society (BMUS). Guidelines For Professional Ultrasound Practice. Section 1.7: Transducer Cleaning and Disinfection. Revision 2, December 2017. Available at: https://www.bmus.org/static/uploads/resources/SCoR__BMUS_Guidelines_for_Professional_Ultrasound_Practice_Revised_Dec_2017_cG4AOnF.pdf. **16.** Health Facilities Scotland, NHS National Services Scotland, Health Protection Scotland. Scotland, March 2016. NHS Scotland Guidance for Decontamination of Semi-Critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes. Document: HPS/HFS Version 1.0. **17.** Health Service Executive (HSE) Quality Improvement Division – Decontamination Safety Programme. Ireland, January 2017. HSE Guidance for Decontamination of Semi-critical Ultrasound Probes; Semi-invasive and Noninvasive Ultrasound Probes. Document: QPSD-GL-028-1. **18.** Welsh Health Technical Memorandum WHTM 01-06. Wales, 2014. Decontamination of flexible endoscopes Part C: Operational management (Including guidance on non channelled endoscopes and ultrasound probes). **19.** Nyhsen CM, Humphreys H, Koerner RJ, Grenier N, Brady A, Sidhu P, et al. Infection prevention and control in ultrasound - best practice recommendations from the European Society of Radiology Ultrasound Working Group. Insights into imaging. 2017. 8:523–535. Available at: https://link.springer.com/content/pdf/10.1007%2Fs13244-017 0580-3.pdf. **20.** European Committee for Medical Ultrasound Safety (ECMUS). Best Practice recommendations for cleaning and disinfection of ultrasound transducers whilst maintaining transducer integrity. 2017. **21.** 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. **22.** W. Kowalski, Ultraviolet Germicidal Irradiation Handbook, Springer-Verlag Berlin Heidelberg 2009. **23.** 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," in IEEE Transactions on Plasma Science, vol. 28, no. 1, pp. 83-88, Feb 2000.

nanosonics
Infection Prevention. For Life.

Nanosonics Limited (Headquarters)
(Manufacturer)
14 Mars Road
Lane Cove NSW 2066
Australia
T +61 2 8063 1600
E info@nanosonics.com.au
www.nanosonics.com.au

Nanosonics UK
(Distributor)
Unit 2, Linfit Court, Colliers Way
Clayton West, Huddersfield HD8 9WL
United Kingdom
T +44 1484 860581
E ukinfo@nanosonics.co.uk
www.nanosonics.co.uk

Nanosonics France
(Commercial and Technical Support)
16, allée des Longs Réages
91190 Gif sur Yvette
France
T +33(0)6.40.96.81.79
E info@nanosonics.eu
www.nanosonics.fr

Nanosonics Europe GmbH
(EU Representative)
Poppenbuetteler Bogen 66
22399 Hamburg
Germany
T +49 40 46856885
E info@nanosonics.eu
www.nanosonics.eu

MM0578-UK-BR V01