trophon®2

Simply Smarter

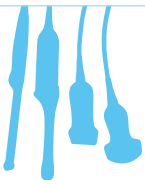
High Level Disinfection for Ultrasound Probes

Why you need trophon

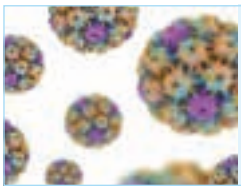
trophon2 is the latest **innovation in ultrasound probe high level disinfection**. It features an enhanced design, simple and fast workflows, plus AcuTrace™ for digital record keeping and seamless integration with your hospital IT system.

nanosonics
Infection Prevention. For Life.

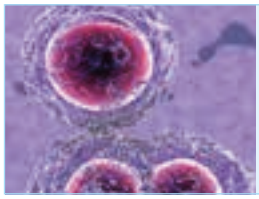
Reduce ultrasound probe cross-infection risk by knowing when to perform high level disinfection to meet guideline requirements



Patients are **41%** more likely to receive positive bacterial cultures after a transvaginal scan where probes were low level disinfected.[1]



MHRA alert released due to patient death from hepatitis B infection attributed to improperly reprocessed endocavitary probe.[2]



More than **80%** of probe handles that are not disinfected had residual pathogens.[3]

Up to **9%** of barrier sheaths and condoms leak and thus their use does not replace need for cleaning and disinfection.[4-7]

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.

What procedure will your probe be used for?

Patient Contact Site	Probe will only contact healthy, intact skin	Probe may contact mucous membranes or non-intact skin	Probe may contact or enter sterile tissue or the bloodstream
Spaulding Classification	**Non-Critical** **Surface ultrasound (intact skin)**	**Semi-Critical** **Endocavitary** • transvaginal scans • transrectal scans **Surface ultrasound (broken skin)** • scan across partially healed wound • scan across rash	**Critical** **Intraoperative procedures** **Biopsies** **Ultrasound guided procedures where the probe may contact sterile tissue†** • drainages • injections • tissue sampling
			
Disinfection / Sterilization Requirements	**Minimum LLD**   **Further protection with HLD**	**Minimum of HLD** 	**HLD or Sterilization‡** 

Probe is ready for procedure

†Ultrasound devices that contact or enter sterile tissue are classed as critical even if a cover is used.[8,9] Ultrasound guided procedures are diverse and many carry a risk of contact with sterile tissue.
‡Critical probes must be sterilized, however if sterilization is not possible the CDC permits high level disinfection with use of a sterile sheath.[8]
The above table has been developed based on the Spaulding classification which sets medical device reprocessing requirements.[10] The FDA and CDC both offer specific guidance for ultrasound probe reprocessing as indicated here.[8,9]

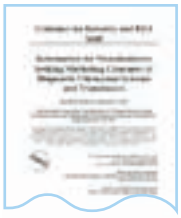
Standards and guidelines recommend high level disinfection

Semi-critical and critical ultrasound probes must minimally undergo HLD even if used with a sheath.

CDC (USA)

'A vaginal probe and all endocavitary probes without a probe cover are semi-critical devices because they have direct contact with mucous membranes (e.g., vagina, rectum, pharynx). While use of the probe cover could be considered as changing the category, this guideline proposes use of a new condom/probe cover for the probe for each patient, and because condoms/probe covers can fail, the probe also should be high-level disinfected.' (pg. 19)

'Do not use a lower category of disinfection or cease to follow the appropriate disinfectant recommendations when using probe covers because these sheaths and condoms can fail.' (pg. 89).[11]



FDA

'The probe used in a semi-critical application should be cleaned and sterilized or at least receive high level disinfection after use even if a sheath was used. Probes used for critical applications should be cleaned and sterilized after use even if a sterile sheath was used. Sheaths can fail during use and the level of resulting contamination may not be easily visible.' (pg. 57) [9]

AAMI

'Semi-critical devices are those that contact intact mucous membranes or non-intact skin during use, but do not usually penetrate the blood barrier or other normally sterile areas. If a semi-critical device cannot be sterilized, it must be subjected to a high-level disinfection process...' (pg. 109) [12]

AORN

'Endocavity ultrasound probes should be processed by high-level disinfection or sterilization. Endocavity ultrasound probes are introduced into a variety of body orifices (eg, vagina, rectum, trachea). These probes contact mucosal tissue and are therefore classified as semi-critical devices that required cleaning and minimum of high level disinfection.

The collective evidence shows that endocavity ultrasound probes present a high risk of contamination with pathogenic microorganisms after ultrasound procedures and that disinfection by methods other than high-level disinfection or sterilization may not be sufficient to eliminate the organisms even when a sheath or cover is used.' (pg.I.HLD4) [13]

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

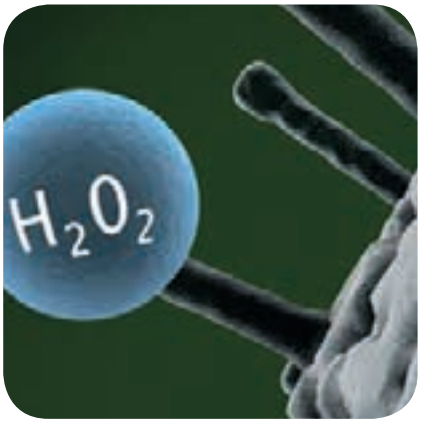
The challenges of using traditional disinfection methods

Method	Risks	Challenges
Liquid disinfectant-manual soaking wipes	• Disinfectant method may not allow the transducer handle to be immersed in the solution • Probe handles may remain contaminated	• Residual bacteria (including MRSA) remain on > 80% of probe handles which are not immersed during liquid soak disinfection[14]
Liquid disinfectant-chemicals used in soaking	• Soaking with chemicals can be a health and safety risk • Manual soaking can be ineffective	• 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 HPV16[15]
Protective sheaths	• Probe sheaths often have microscopic tears or break	• Protective sheaths (or condoms) do not negate the need for HLD[5] • Sheaths can have microscopic perforations before use up to 81%[4-7]

How trophon2 technology works

The trophon 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.

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High Level Disinfection for Ultrasound Probes

Why choose trophon2?

The trophon system is recognized as the world's leading automated high level disinfection solution for transvaginal, transrectal probes and surface probes. It delivers a smarter option for ultrasound probe reprocessing offering options such as track and trace with the benefit of audit-ready high level disinfection record keeping.

Introducing the latest innovation in ultrasound probe high level disinfection

Smart Protection

Reducing risk

trophon2 delivers superior protection for patients, staff and the environment

Smart Flexibility

Improving efficiency

trophon2 streamlines set-up, can be customized to your workflow and has extensive probe compatibility

Smart Functionality

Increasing compliance

trophon2 enhances user experience so you can perform high level disinfection simply, automatically, and with confidence

Smart Traceability

Increasing audit readiness

AcuTrace™ simplifies the creation of accurate digital records, all stored on your trophon2

Smart Integration

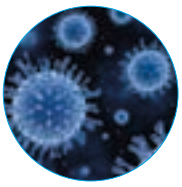
Simplifying data access

trophon2's AcuTrace™ PLUS delivers an upgradeable option to seamlessly connect all trophon devices to your hospital information system

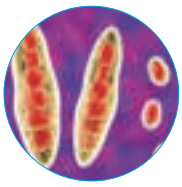
trophon* efficacy

- ✓ trophon inactivates drug resistant pathogens, spores and pathogens that cause sexually transmitted infections (STIs)
- ✓ trophon 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

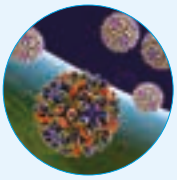
Mycobactericidal

trophon helps to reduce cross-contamination risks#

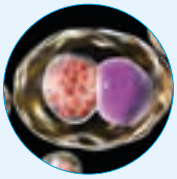
Sexually transmitted infections (STIs)	Drug resistant bacteria	Spores
• Relevant to women's health where transvaginal probes are used • Can cause infertility and significant morbidity and mortality	• Rise of drug resistant bacteria is a serious healthcare problem • Can cause serious infections following 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



Hepatitis B/C



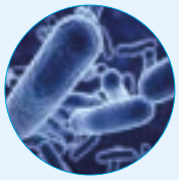
Chlamydia

Candida

HIV

MRSA

VRE



CRE

Clostridium difficile

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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, Inc. (Distributor) 7205 E 87th Street, Indianapolis, IN 46256, USA
T 1-844-TROPHON 1-844-876-7466 E info@trophon.com www.trophon.us

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