In April 2016, Health Protection Scotland (HPS) and Health Facilities Scotland (HFS) released new ultrasound probe decontamination guidelines: *The NHSScotland Guidance for Decontamination of Semi-Critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes.*

This guide is designed to provide some background on the new guidelines and outlines one of the recommended solutions for automated high level disinfection of ultrasound probes. Implementing a trophon high level disinfection system will ensure your facility complies with the new requirements.
Why the guidelines have changed

The guidelines were developed in response to the release of a Medicines & Healthcare products Regulatory Agency (MHRA) Device Alert in June 2012 following the death of a patient from hepatitis B infection.1 The infection may have been associated with a failure to appropriately decontaminate a TOE probe between each patient use.

Additionally, Health Facilities Scotland (HFS) conducted a national survey of TOE, transvaginal (TV) and transrectal (TR) ultrasound probes to identify current decontamination practice for semi-invasive ultrasound probes across NHSScotland. The survey concluded that “there is an ongoing risk to patient safety with regard to decontamination of these semi-invasive ultrasound probes”.

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Why the guidelines recommend high level disinfection

What is high level disinfection?
High level disinfection (HLD) involves the complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. In comparison, low level disinfection, which is commonly carried out with wipes, does not kill mycobacteria, resistant viruses or bacterial spores.

Cross contamination risks
Under the Spaulding classification, probes that come into contact with mucous membranes or broken skin are considered to be semi-critical devices and should undergo high level disinfection (HLD) between patients. Semi-invasive ultrasound probes are used to scan internal organs and categorised as semi-critical devices, while non-invasive probes may contact broken skin. Consequently, both types of probe should undergo HLD between patients to mitigate the risk of transmitting infectious pathogens to patients.

Clinical evidence showing low level disinfection increases cross contamination risks
Currently the most common practice for decontaminating ultrasound probes is to use what are termed ‘low level’ wipes. A number of clinical studies have demonstrated the cross contamination risks associated with this type of disinfection method:

- A meta-analysis has shown that 12.9% of transducers are contaminated with pathogenic bacteria following disinfection with low level disinfectant wipes.\(^2\)
- Multiple studies have shown that HPV DNA persists on transducers after disinfection with low level disinfectant wipes.\(^3,5\)
- Studies show that sheaths (condoms) have a high rate of perforations before use and are “inefficient at preventing contamination when used on ultrasound transducers”.\(^6,7\)
- Ultrasound probe handles are not routinely disinfected and can harbour pathogens including MRSA.\(^8\)
- A fatal case of hepatitis B and non-fatal case of hepatitis C have been attributed to improper ultrasound transducer disinfection.\(^9,10\)

Multiple guidelines recommend HLD
In light of overwhelming evidence, multiple global guidelines now recommend high level disinfection of semi-invasive ultrasound probes:

- NHS Welsh Guidelines
- CDC: Centers for Disease Control and Prevention
- AIUM: American Institute of Ultrasound in Medicine
- AORN: Association of periOperative Registered Nurses
- ANSI: American National Standards Institute
- AAMI: Advanced Safety in Medical Technology
- RKI: Robert Koch Institute
- DGSV: Deutsche Gesellschaft für Sterilgutversorgung

low level disinfection DOES NOT KILL mycobacteria, resistant viruses or bacterial spores
Meeting the requirements of the HPS/HFS guidelines

The guidelines set out the operational procedures, together with roles and responsibilities of healthcare workers, involved with the decontamination of semi-invasive ultrasound probes. The decontamination policy details the recommended options for HLD, together with aspects to consider when selecting and purchasing a system.

In addition to the guidance, there are generic Standard Operating Procedures (SOPs) that cover the specific stages associated with the semi-critical ultrasound probe decontamination process:

**Appendix 1: Purchase of a decontamination system**

This section covers what you should be looking for to ensure compatibility of the disinfection system with specific brands and models of probes.

**Appendix 2: Validation, testing and maintenance of equipment**

This section covers the installation, commissioning, validation, periodic testing and repair of the two devices that are recommended for high level disinfection.

**Appendix 3: Training for staff**

This section outlines what is expected in terms of staff training and documentation of training records.

**Appendix 4: Product release**

This section summarises the available acceptance criteria for each system to ensure that all probes have been satisfactorily disinfected between patients. Each type of acceptance criteria gives reassurance to patients and operators that probes have been high level disinfected but not all criteria are available for each system.

**Appendix 5: Transport and storage of equipment**

This section covers the transport procedure that must be followed if the system cannot be used at the point of care. In this situation, ultrasound probes must be transported to a separate, dedicated decontamination area.

The section also outlines the procedure for storing probes in between use.

**Appendix 6: Decommissioning and disposal of equipment**

This section covers the procedure to be followed when the devices reach the end of their lifespan.

**Appendix 7: Semi critical ultrasound probe decontamination algorithm**

The algorithm in this section provides a poster representation that may be used as a quick reference guide to help you determine the appropriate process (HLD or other) to follow for decontaminating an ultrasound probe.

An SOP describing the recommended HLD methods for trophon is also included.
Selecting a disinfection system

The trophon EPR is the world’s leading automated HLD system for transvaginal and transrectal ultrasound probes and delivers a simple solution to ensure your facility complies with all the guideline requirements.

**Simple to use**
The trophon EPR is a simple to use, fully automated device for low temperature HLD.

**trophon is the global gold standard for HLD**
trophon EPR is the global standard of care for HLD of ultrasound probes. The system uses sonicated hydrogen peroxide sub-micron mist to ensure effective decontamination. trophon complies with leading healthcare recommendations and all EU conformity and regulatory requirements.

**Ultrasound probe compatibility**
Ensuring complete probe compatibility as mandated by the Medical Devices Directive is essential. trophon EPR is the only automated HLD system validated for use with over 1,000 probes.

**Only system proven to kill HPV**
The trophon EPR is the only high level disinfection system proven to kill high-risk, cancer-causing human papillomavirus (HPV). No other HLD systems have published evidence of effective testing against “real” natural, infectious HPV.

**Convenient Point Of Care use**
Fully enclosed, the trophon EPR can be conveniently located at the point of care. This dramatically improves workflow and disinfection turnaround times. It also eliminates the risk of probe damage that can occur when probes are transported to and from a separate decontamination room.

**Consistent disinfection process with a traceability solution**
The automated trophon EPR assures process consistency in every disinfection cycle. An optional documentation traceability solution helps ensure you meet HPS/HFS guidance requirements.

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**HPV: should I be concerned?**

HPV is a real risk in ultrasound exams. Published studies have shown that there is a risk of cross contamination between patients. Up to 7% of ultrasound probes remain contaminated with HPV despite the use of probe covers and routine disinfection. [1,3]

HPV can be transmitted non-sexually and, as a very stable virus, it can remain infectious on surfaces for days. [16,17]
What to consider before you purchase a system

The guidelines outline the following criteria to consider when selecting and purchasing a disinfection system.

Effective

Evidence to support effectiveness

The guidelines recommend considering evidence to support the decontamination system’s effectiveness. The trophon EPR meets all European requirements for HLD and has a wealth of independent, peer-reviewed and published clinical evidence to support its use for decontamination of semi invasive ultrasound probes. 8, 12, 13, 14

Importantly, peer reviewed, published research has demonstrated that the trophon is the only system proven effective against “real” natural, infectious human papillomavirus (HPV). Other high level disinfection systems cannot make this claim as they have not been tested against “real” natural, infectious HPV. 15

Safety of use

Fully closed to protect operators

The trophon EPR system is completely closed and disinfectant cartridges remain sealed until they are inserted into the device.

Compatibility with the range of probes to be used

trophon is validated by all major and many smaller probe manufacturers

The trophon EPR system has undergone extensive validation by all major and many smaller probe manufacturers who provide a written letter of validation. A list of more than 1,000 validated probes is available at www.nanosonics.co.uk/probes.

Ensuring probe compatibility

Ensuring that the disinfection system you select is compatible with the probes you use is very important. The Medical Devices Directive mandates that ultrasound probes must be validated by the probe manufacturer for compatibility and the new HPS/HFS guidelines recommend that you obtain this validation in writing as part of the process of selecting and purchasing your disinfection system.
Validation of effectiveness of disinfection process and practicality in clinical setting

Process validation is crucial to ensure decontamination is carried out to appropriate standards. The trophon EPR provides extra reassurance with comprehensive process validation:

- Sensors in the trophon device automatically measure the time, temperature and concentration of the disinfectant.
- An independent monitoring system (IMS) provides a secondary check of parameters before the device indicates a successful cycle via the control panel.
- A chemical indicator is used to provide independent confirmation and complete assurance that the decontamination cycle has been successful.

Costs

Improving safety and practice by implementing a HLD solution should not be cost prohibitive. Flexible purchase options to meet your budget needs should be available.

trophon is a cost effective high level disinfection solution

Many customers have reported that, when all relevant costs are taken into account, using the trophon system works out more economical over time.

Versatility

The trophon system is highly versatile and provides you with options to locate the system to maximise your facility’s workflow and further reduce costs.

The trophon device:

- Eliminates the issue of probe damage due to transport to and from a separate decontamination room.
- Eliminates the costs related to transport to and from a separate decontamination room, for example for additional labour time and transport containers.
- Dramatically improves workflow and disinfection turnaround times so potentially less probes are required per ultrasound suite.

For more information on trophon-related costs please contact Nanosonics on 01484 860581 or email ukinfo@nanosonics.eu.
• The trophon device has an energy saving feature to reduce energy consumption.
• Only waste products are environmentally friendly water and oxygen.
• The trophon disinfectant cartridges are 100% recyclable.
• More than 70% of the components in the device are recyclable.

Training

Appendix 3 of the HPS/HFS guidelines requires all staff to be adequately trained and for training records to be kept for each member of staff. The trophon EPR system makes training and record keeping simple:
• Nanosonics provides certified on site initial training.
• Online competency training with full certification is available.
• The online training module makes annual re-certification simple.
• A range of support materials is available for managers who prefer to develop an in-house training program.


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<tr>
<th>System</th>
<th>trophon® EPR system</th>
<th>UV light system</th>
<th>Wipe system</th>
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<tbody>
<tr>
<td>Global leading automated HLD system¹</td>
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<td>Proven to kill HPV²</td>
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<tr>
<td>Extensive range of probes validated and approved for use with system²</td>
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<tr>
<td>Cleared for use in major global markets⁴</td>
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<td>Compact size and versatile placement. No chemical waste disposal⁵</td>
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<tr>
<td>Automated with only one HLD cycle to select⁶</td>
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1. trophon adoption growing strongly worldwide.
3. trophon has undergone extensive validation by probe manufacturers who provide a written letter of validation. trophon is validated and approved for use with over 1,000 ultrasound probes.
4. Includes Europe, USA, Canada, Russia, Japan, Hong Kong, Singapore, Australia, New Zealand and South Korea.
5. trophon EPR measures just 49cm H x 34.5cm W x 34.5cm D and can be placed at the point of care on a bench, or mounted on the wall or a cart, providing versatility in location and placement. Other systems may expose staff to hazardous chemicals.
6. No confusion: fully automated trophon EPR has just one cycle to select to achieve complete HLD and sporicidal efficacy (including Aspergillus Niger).

1. Medical Device Alert Ref: MDA/2012/037 Issued: 28 June 2012
10. Medicines and Healthcare products Regulatory Agency (UK), Medical Device Alert Ref: MDA/2012/037
11. NHS Welsh Guidelines, CDC, AIUM, AAOR, ANSI, AAMI
17. Liu Z, et al. Penises not required: a systematic review of the potential for human papillomavirus horizontal transmission that is non-sexual or does not include penile penetration. Sexual Health, 2016, 13, 10-21