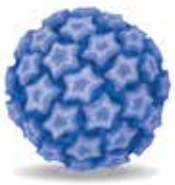
GE Healthcare

Human Papilloma Virus and Ultrasound Transducers:
Why take risk if you have options?

A new study shows that trophon® EPR is the only high level disinfection system for ultrasound probes proven to be effective against high-risk, cancer causing strains of Human Papilloma Virus (HPV).[1]

Commonly used disinfectants do not kill high-risk HPV



Due to the difficulties of producing natural, infectious HPV for research, disinfectant efficacy testing against HPV has not previously been possible. This changed recently when the world's first method to produce sufficient infectious HPV for research was developed, and the first HPV disinfectant efficacy study was published in 2014.[9] The results showed that two disinfectants commonly used for high level disinfection in healthcare facilities, glutaraldehyde and ortho-phthaladehyde (OPA) do not kill natural, infectious, high-risk HPV 16 – even after 24 hours of contact time.[9]

trophon EPR
Simply smarter probe disinfection.

trophon EPR is a high level disinfection system that is fast and simple. Disinfection takes place in an automated, closed system and uses a vaporized hydrogen peroxide solution.

The compact design means it can be located at the point of care, helping to improve patient workflow, while the fully enclosed system helps protect both patients and staff by limiting exposure to harmful disinfectant chemicals.

Did you know?

Up to **7.5%** of transvaginal ultrasound transducers were found to have HPV DNA after low level disinfection with wipes[2]

Human Papilloma Virus (HPV) is associated with **99.7%** of cervical cancers as well as a number of other cancers including anal, vaginal, vulvar and penile[3]

Clinical studies have shown that **3-7%** of endocavitary probes remain contaminated with high-risk HPV DNA after ultrasound exams and routine disinfection[4, 5, 6]

One of the **TOP 5** non-compliance findings by The Joint Commission is reducing the risk of infections associated with medical devices or equipment[7]

Up to **9%** of barrier sheaths and condoms leak[8]

Endocavity ultrasound probes are classified as semi-critical as they come in contact with mucous membranes or non-intact skin.

HLD

Multiple guidelines recommend ***high level disinfection (HLD)*** *of probes between patients.*

HLD is defined as *complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores, within the manufacturer's recommended contact time.*

FDA guidance requires disinfectants to achieve a > 4 $\log_{10}$ reduction for a virucidal claim.

Summary of Clinical Studies

SUSCEPTIBILITY OF NATIVE HPV16 TO DISINFECTANTS

DISINFECTANT	45 MINUTES	RESULT	24 HOURS	COMPLETE INACTIVATION	VIRUCIDAL
2.4% GTA*	✗	<1 $\log_{10}$	Not tested	✗	✗
3.4% GTA	✗	<1 $\log_{10}$	✗	✗	✗
0.55% OPA#	✗	<1 $\log_{10}$	✗	✗	✗
0.525% hypochlorite	✓	4.862 $\log_{10}$	Not tested	✗	✓

* Glutaraldehyde # ortho-phthalaldehyde

In a further clinical study, surface carrier tests against HPV16 and HPV18 were carried out using OPA, hypochlorite and trophon EPR. The testing was conducted according to manufacturers' instructions to simulate normal clinical use conditions (concentration, time, temperature) and met FDA requirements for virucidal testing.

OPA was shown to be ineffective against both HPV16 and HPV18. While hypochlorite was effective against both viruses, it is not a high level disinfectant and is not suitable for use with ultrasound probes. **The trophon EPR achieved > 4 $\log_{10}$ reduction and complete inactivation of both HPV16 and HPV18, meeting FDA requirements.**[1]

SUSCEPTIBILITY OF HPV16 AND HPV18 TO CLINICAL DISINFECTIONS USED ON ULTRASOUND PROBES

DISINFECTANT	HPV16	HPV18	COMPLETE INACTIVATION	VIRUCIDAL
0.55% OPA#	<1 $\log_{10}$	<1 $\log_{10}$	✗	✗
Hypochlorite (0.87%)	4.95 $\log_{10}$	4.62 $\log_{10}$	✗	✓
trophon EPR (35% H_2O_2)	>7.39 $\log_{10}$	>5.87 log10	✓	✓

ortho-phthalaldehyde

Imagination at work

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1 Meyers, C., et al., Efficacy of a high-level disinfectant system against high-risk human papilloma virus. Presented at SHEA 2015.

2 Ma STC et al, Transvaginal ultrasound probe contamination by the human papillomavirus in the emergency department, *Emergency Medicine Journal*, 1-4,, 2012.

3 Walboomers JMM,Jacobs MV,Manos MM, et al. Human papillomavirus is a necessary cause of invasive cervical cancer worldwide. J Pathol. 1999; 189: 12–19.

4 Casalegno et. Al.: High Risk HPV Contamination of Endocavity Vaginal Ultrasound Probes: An Underestimated Route of Nosocomial Infection?, PLOS ONE, Oct 2012, Volume 7, Issue 10.

5 Ma et al.: Transvaginal ultrasound probe contamination by the human papillomavirus in the emergency department, Emerg Med J, 2012.

6 M'Zali et al. Persistence of microbial contamination on transvaginal ultrasound probes despite low-level disinfection procedure. PLoS One 2014;9:e93368.

7 Electronically accessed www.jointcommission.org/issues/.

8 Vickery K, et al. Evaluation of an automated high-level disinfection technology for ultrasound transducers, *Journal of Infection and Public Health*, 2013.

9 Meyers, J., et al., Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants. J Antimicrob Chemother, 2014.

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