When Decontamination Goes Wrong

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Authorising Engineer (Decontamination)

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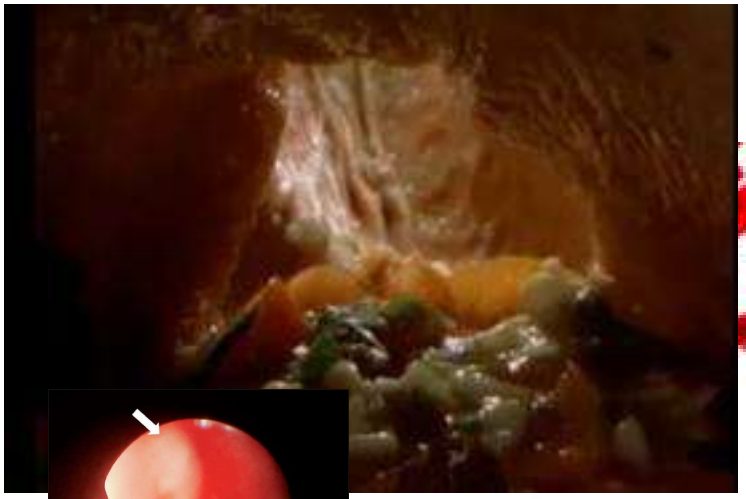
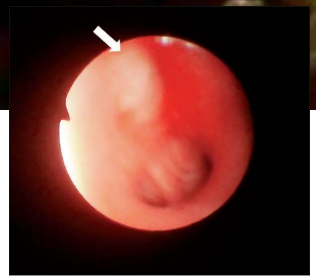
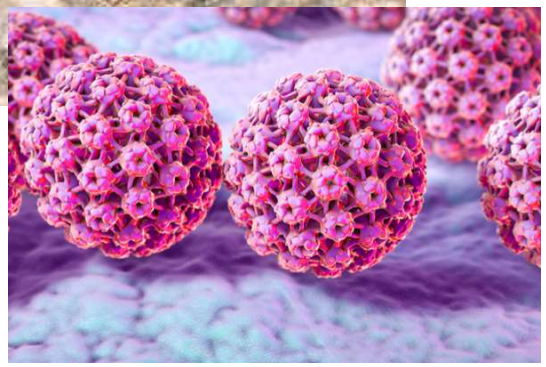
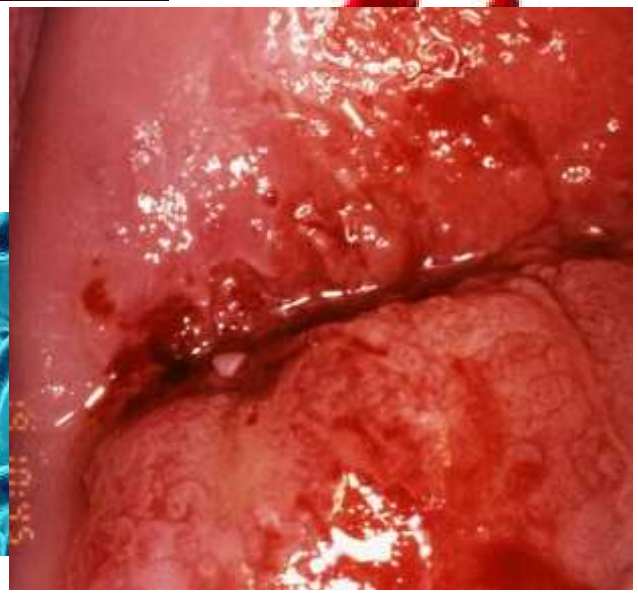
Devices are exposed to..









The Purpose of Decontamination

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Reasons:

- To protect the patient from disease/death
- To protect staff from disease
- To protect staff from litigation/dismissal
- To protect the organisations reputation/ prevent financial liquidation
- To protect the organisation from litigation

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Risk Comes From The Unlikeliest Places!

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Nosocomial Outbreak of *Klebsiella pneumoniae* Producing SHV-5 Extended-Spectrum β-Lactamase, Originating from a Contaminated Ultrasonography Coupling Gel

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Received 2 December 1997/Returned for modification 8 February 1998/Accepted 18 February 1998

***Klebsiella pneumoniae* resistant to ceftazidime was isolated from six adult women and two neonates hospitalized between July and November 1993 in the Department of Obstetrics and Gynecology of Boucicaut Hospital (Paris, France). The epidemiological investigation revealed a notably short delay (less than 48 h) between admission and contamination of the six adults and peripartum transmission to the neonates. The only environmental source of ceftazidime-resistant *K. pneumoniae* was the ultrasonography coupling gel used in the emergency room. Phenotypic (biotyping and antibiotyping) and genotypic (plasmid profile and pulsed-field gel electrophoresis) analysis of all the clinical isolates indicated the spread of a single strain. It produced SHV-5 and TEM-1 β-lactamases, as demonstrated by isoelectric focusing and gene sequencing. The risk of cross-contamination in ultrasonography procedures is usually low and had not been associated so far with bacteria producing an extended-spectrum β-lactamase (ESBL). Furthermore, this is the first time an epidemic of an SHV-5 ESBL-producing member of the family *Enterobacteriaceae* has been reported from a French hospital.**

PLoS One. 2012;7(10):e48137. doi: 10.1371/journal.pone.0048137. Epub 2012 Oct 24.

High risk HPV contamination of endocavity vaginal ultrasound probes: an underestimated route of nosocomial infection?

Casalegno JS[1], Le Bail Carval K, Eibach D, Valdeyron ML, Lamblin G, Jacquemoud H, Mellier G, Lina B, Gaucherand P, Mathevet P, Mekki Y.

Author information

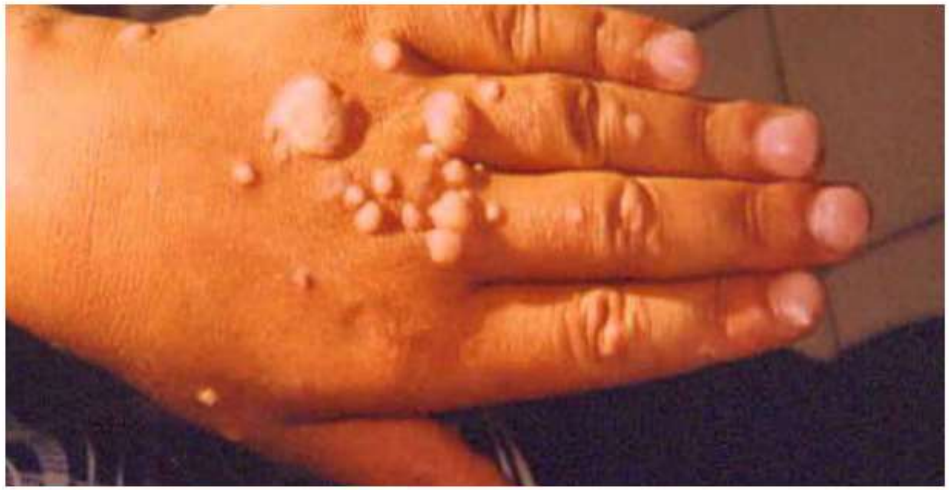
Abstract

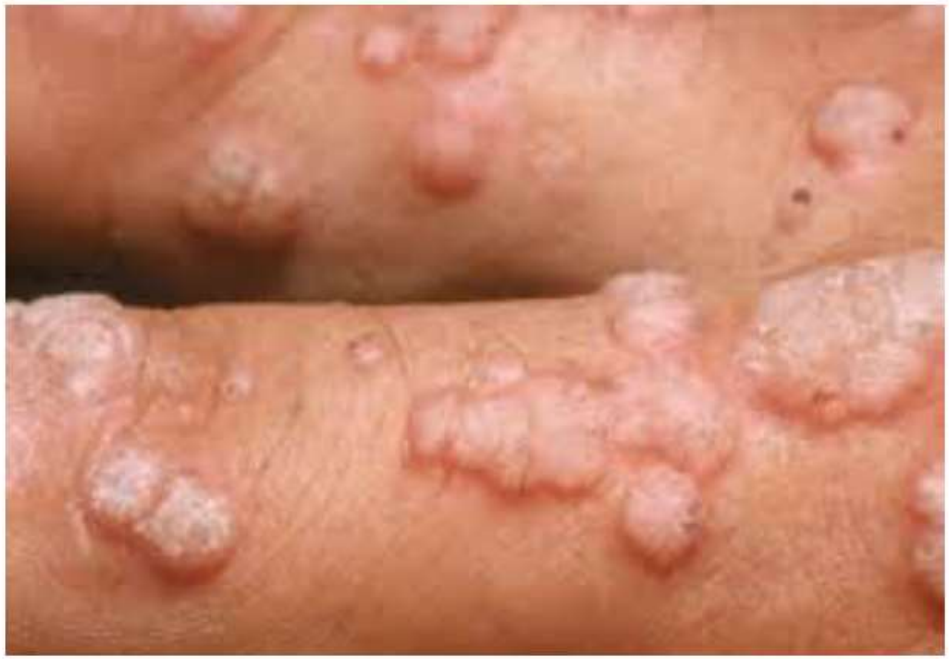
BACKGROUND: Endocavity ultrasound is seen as a harmless procedure and has become a common gynaecological procedure. However without correct disinfection, it may result in nosocomial transmission of genito-urinary pathogens, such as high-risk Human Papillomavirus (HR-HPV). We aimed to evaluate the currently recommended disinfection procedure for covered endocavity ultrasound probes, which consists of "Low Level Disinfection" (LLD) with "quaternary ammonium compounds" containing wipes.

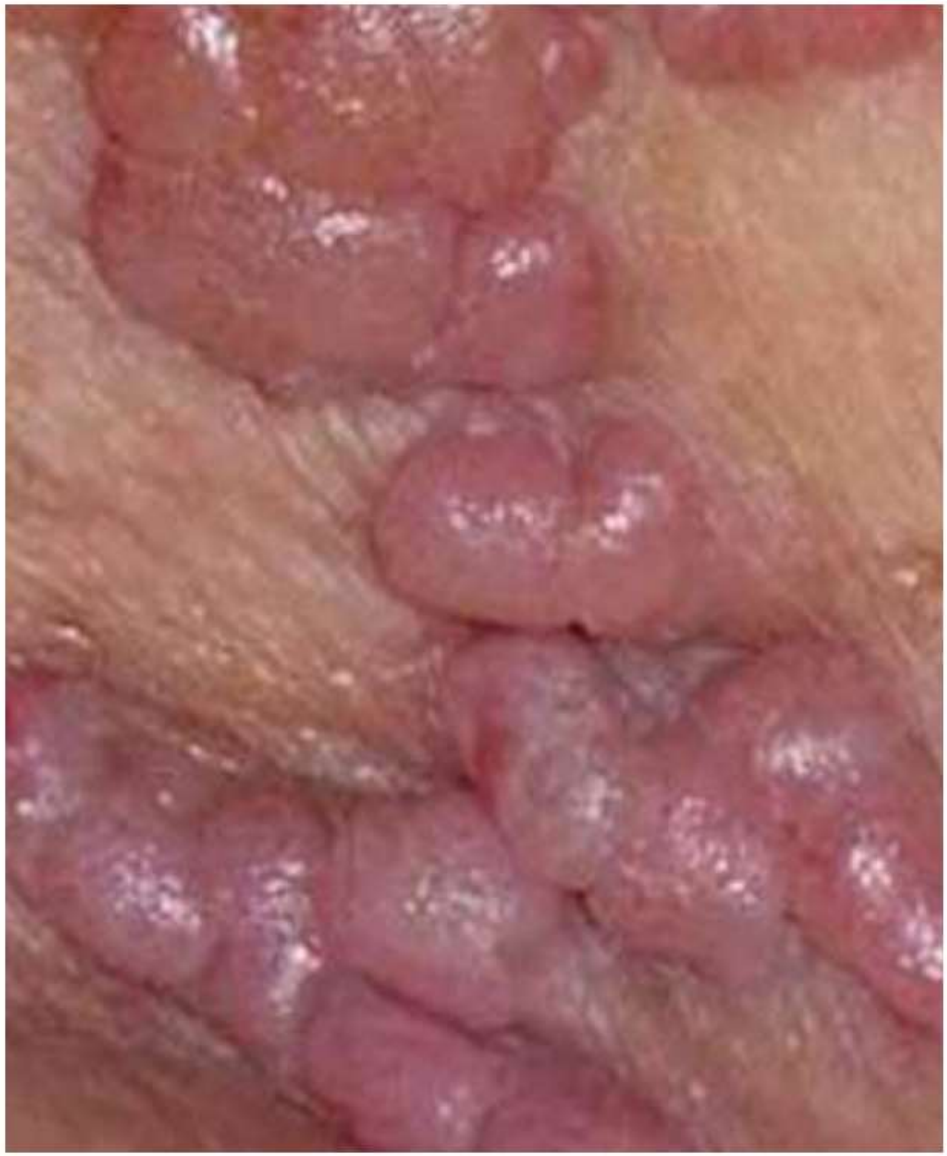
METHODS: From May to October 2011 swabs were taken from endovaginal ultrasound probes at the Gynecology Department of the Lyon University Hospital. During the first phase (May-June 2011) samples were taken after the ultrasound examination and after the LLD procedure. In a second phase (July-October 2011) swab samples were collected just before the probe was used. All samples were tested for the presence of human DNA (as a marker for a possible transmission of infectious pathogens from the genital tract) and HPV DNA with the Genomica DNA microarray (35 different HPV genotypes).

RESULTS: We collected 217 samples before and 200 samples after the ultrasound examination. The PCR was inhibited in two cases. Human DNA was detected in 36 (18%) post-examination samples and 61 (28%) pre-examination samples. After the ultrasound LLD procedure, 6 (3.0%) samples contained HR-HPV types (16, 31, 2×53 and 58). Similarly, HPV was detected in 6 pre-examination samples (2.7%). Amongst these 4 (1.9%) contained HR-HPV (types 53 and 70).

CONCLUSION: Our study reveals that a considerable number of ultrasound probes are contaminated with human and HR-HPV DNA, despite LLD disinfection and probe cover. In all hospitals, where LLD is performed, the endovaginal ultrasound procedure must therefore be considered a source for nosocomial HR-HPV infections. We recommend the stringent use of high-level disinfectants, such as glutaraldehyde or hydrogen peroxide solutions.







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But we have a vaccine?

- Blood-borne viruses in the workplace by HSE
  - Specific legislation on hazards that arise from working with biological agents such as BBVs is contained in the Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH). Under COSHH you have a legal duty to assess the risk of infection for employees and others affected by your work. When the risk is known, you need to take suitable precautions to protect their health
  - Immunisation (vaccination) is available against HBV but not all other BBVs. The need to be immunised should be determined by the risk assessment. It should only be seen as a supplement to reinforce other control measures.

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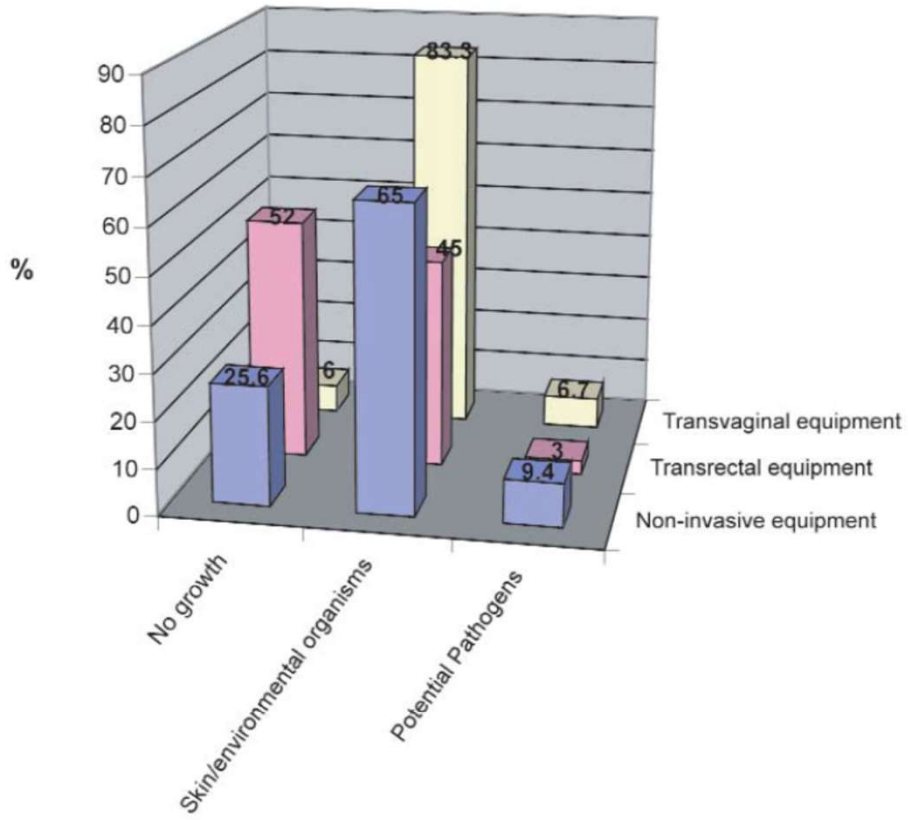
Table 1. Potential pathogens isolated

Scanner	Site	Pathogen
Non-invasive	Probe	*Haemolytic streptococci* *Enterococcus faecalis* *Acinetobacter sp* (0001073)
	Probe holder	*Enterococcus faecium* (x2) *Enterococcus faecalis* *Acinetobacter lwoffii* *S. aureus* (fully sensitive)
	Keyboard	*Acinetobacter sp* *Acinetobacter lwoffii* *Acinetobacter sp* (0001073) *Enterococcus faecium* *Enterococcus faecalis* (x4)
	Gel	*S. aureus* (fully sensitive)
Transrectal	Probe	*E. coli* (5144532)
	Keyboard	*Acinetobacter sp* (0000051)
Transvaginal	Probe	*S. aureus* (fully sensitive)
	Keyboard	*Pseudomonas putida* (44443455) *S. aureus* (fully sensitive) (x2)



	No growth	Skin/environmental organisms	Potential Pathogens
Non-invasive equipment	25.6	65	9.4
Transrectal equipment	52	45	3
Transvaginal equipment	6	83.3	6.7

An investigation of the microbiological contamination of ultrasound equipment
Sykes A, Appleby M, Perry J, Gould K, British Journal of Infection Control AUGUST 2006 VOL. 7 NO. 4

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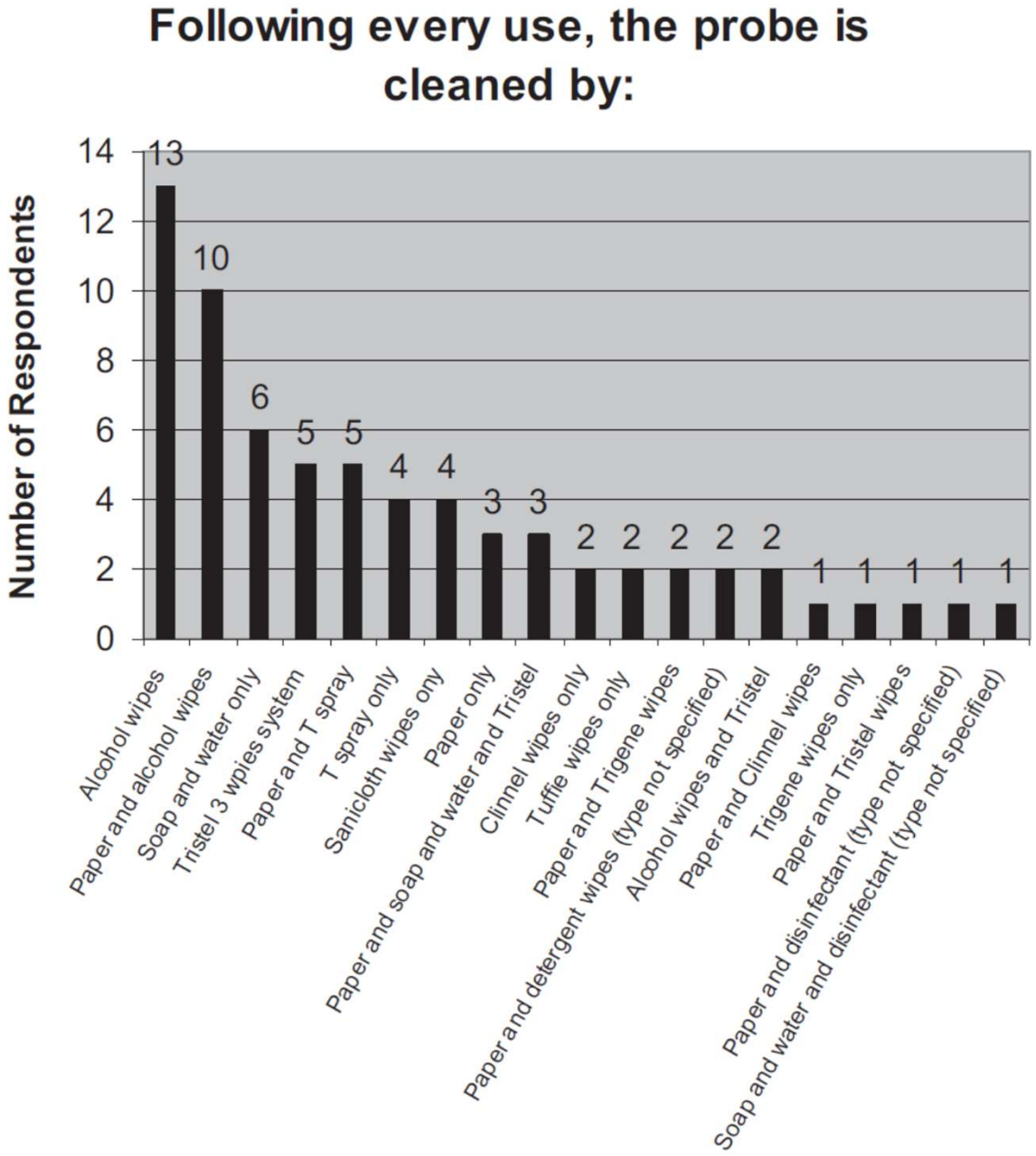

Gray RA, et al., Decontamination of transvaginal ultrasound probes: Review of national practice and need for national guidelines, Clinical Radiology (2012), doi:10.1016/j.crad.2012.02.015

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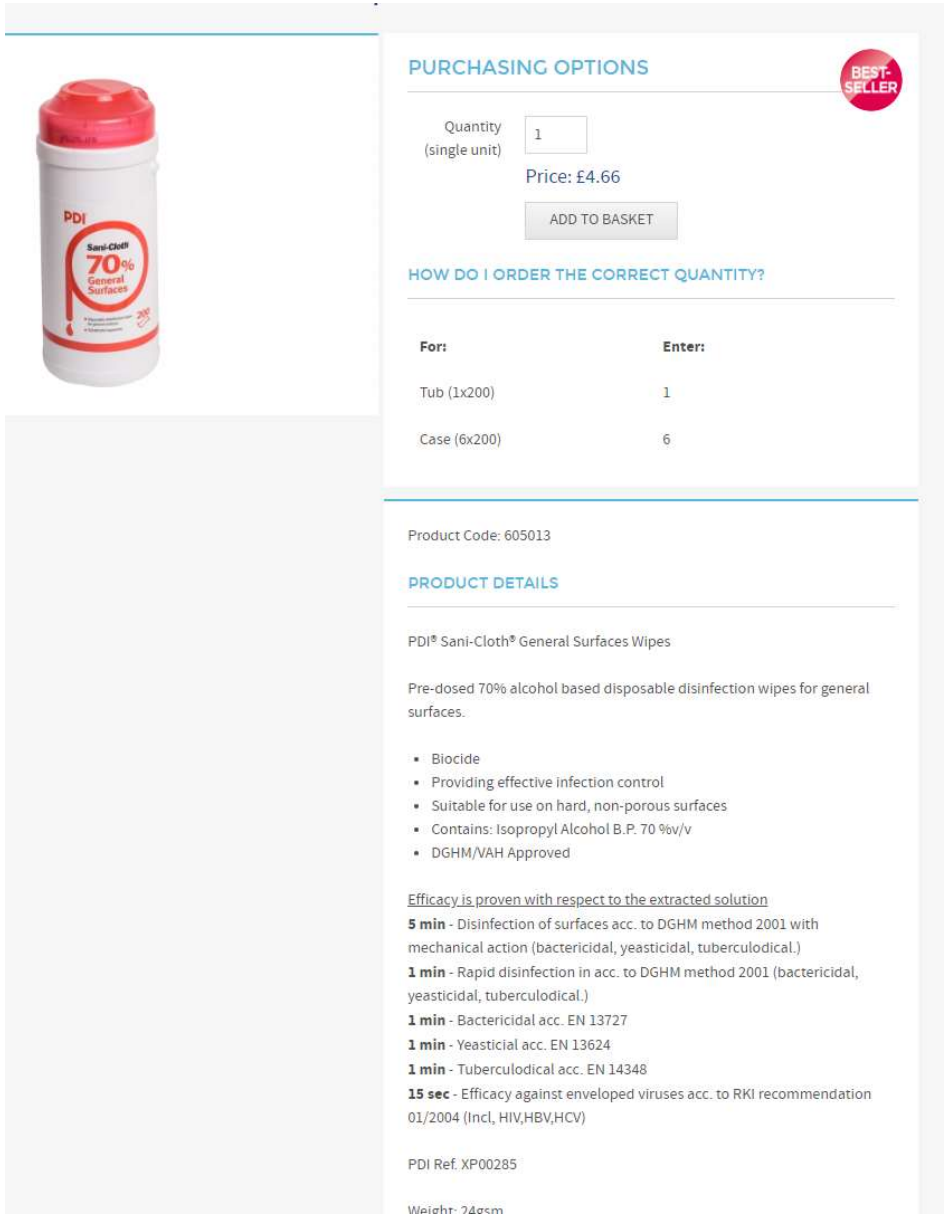

Wipes – an example!

Sani-Cloth® 70% general surface wipes are pre-dosed, alcohol, non-linting disposable disinfection wipes for non-invasive medical devices and non-porous hard surfaces.

<u>Efficacy is proven with respect to the extracted solution</u>

5 min - Disinfection of surfaces acc. to DGHM method 2001 with mechanical action (bactericidal, yeasticidal, tuberculodical.)

1 min - Rapid disinfection in acc. to DGHM method 2001 (bactericidal, yeasticidal, tuberculodical.)

1 min - Bactericidal acc. EN 13727

1 min - Yeasticial acc. EN 13624

1 min - Tuberculodical acc. EN 14348

15 sec - Efficacy against enveloped viruses acc. to RKI recommendation 01/2004 (Incl, HIV,HBV,HCV)

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BS ISO 17664

- Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
  - Wider scope – 2004 edition only sterilization
  - Part 1:2021 Critical and semi-critical medical devices
  - Part 2:2021 Non-critical medical devices

BS ISO 17664

- This document specifies requirements for the information to be provided by the medical device manufacturer for the processing of non-critical medical devices not intended to be sterilized.
- This includes information for processing prior to use or reuse of the medical device.
- The document specifies requirements to assist manufacturers of medical devices in providing detailed processing instructions that consist of the following activities where applicable:
  a) preparation before processing;
  b) cleaning;
  c) disinfection;
  d) inspection and maintenance;
  e) packaging;
  f) Sterilization (Part 1 only)
  g) storage;
  h) transportation.

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ISO 17664:2021

6.2.1 At least one validated method shall be specified for each applicable stage of processing of the medical device. The method shall be relevant (appropriate) to the market in which the medical device is to be supplied.

6.3.3 Where an incompatibility of the medical device with a substance(s) or processing condition(s) (that can impact upon patient safety) is known, this information shall be provided.

6.7.1.1 (Part1) or 6.6.1 (Part 2) If the medical device is intended to be disinfected, at least one validated (automated) disinfection method shall be specified unless the medical device cannot withstand any such process, in which case a statement shall be provided which alerts the user to this issue.

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COMPATIBLE by design

Check your Equipment Compatibility.
Verified compatibility on over 1,000 medical devices.

Manufacturer	Equipment Type	PDI Product	
Toshiba	Toshiba Transducers	All Tested Products	CHECK COMPATIBILITY

Toshiba Transducers **is not compatible or not yet tested** for compatibility with PDI products.

PDI is constantly working with medical equipment manufacturers for testing and IFU inclusion.
Help us partner with the medical device manufacturer for compatibility testing.

We're here to help. Check our resource library for additional compatibility information. ›

COMPATIBLE by design

Check your Equipment Compatibility.
Verified compatibility on over 1,000 medical devices.

Manufacturer	Equipment Type	PDI Product	
GE Healthcare	Logiq Probe Model C31	All Tested Products	CHECK COMPATIBILITY

Logiq Probe Model C31 **is compatible** with the following PDI products:
Results by GE Healthcare

Compatible PDI products:
Sani-Cloth® AF3 Germicidal Disposable Wipe
Sani-Cloth® Plus Germicidal Disposable Cloth
Sani-Cloth® Bleach Germicidal Disposable Wipe
Discontinued Sani-Cloth® HB Germicidal Disposable Wipe

We're here to help. Check our resource library for additional compatibility information. ›

Can Safety for Re-use be Confirmed?

- Decontamination is a “special process”
- Cannot directly measure success
- Need to measure indirectly
- This requires pre-determined process requirements and …
- … an ability to validate these and monitor on every occasion!

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Validation

- Validation is the documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with a pre-determined specification.

- Validation, testing and maintenance of probe decontamination systems is the responsibility of the User (unit manager).

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What to expect from a validation process:

- Visual inspection of the system and components
- Test of alarm systems (door lock, power failure, dosing failure, over/under temperature, data connections, lamp failure)
- Automatic control type test (operational cycle test)
- Dosing system check/calibration (disinfectant or UV dose)
- Temperature calibration (if temperature control used or temperature limits are applicable
- Performance Qualification:
  - Microbiological efficacy
  - Residual disinfectant (for some processes)

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Checking The Validation Report

- Do you know who undertook the testing?
  - Is it stated in the report?
  - Was he qualified to do so?
    - Is there a certificate of competency or training in the report?
- What instrumentation was used?
  - Is it stated in the report?
  - Is it calibrated?
  - Are all the calibration certificates included in the report
- Were all the necessary/requested tests undertaken?
  - The best reports have a list of the tests carried out either in the beginning or back of the report
  - Make a checklist of expected tests if you are unsure which tests should be included

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Checking The Validation Report

- Did all the tests pass?
- If there are test failures:
  - Were retests undertaken during the testing period?
  - Are further retests needed?
  - Were repairs needed during the testing period and if so did those repairs invalidate previous tests?
- Are the required machine cycle printouts included within the report?

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Legislation

- Consumer Protection Act 1987:
  - Part 1 implements EU Council Directive 85/374/EEC (product liability) providing compensation to be paid to persons injured by a defective product. There may also be civil liability violations with payment for damages.
- Health and Safety at Work Act 1974
  - Section 3 makes it a criminal offence if a Trust fails to conduct its undertaking in such a way as to ensure that patients are not exposed to health or safety risks. This is a very high standard of care with a reverse burden of proof (i.e. it is for the Trust to prove that it did take all reasonably practicable steps). (Sanction: Unlimited maximum fine).
  - Section 7 also makes it a criminal offence for any employee to fail to take reasonable care for the health and safety of patients who may be affected by his acts or omissions at work. This could apply from front line staff right up to chief executive level. (Sanction: £5,000 maximum fine).
- Criminal Offence of Manslaughter:
  - If a patient dies as a result of an infection passed on through inadequately decontaminated surgical instruments, then the criminal offences of manslaughter (for individuals) and corporate manslaughter (for Trusts) can also apply.

The Future?

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