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# A sonographer's perspective of decontamination

Peter Cantin.

University Hospitals Plymouth NHS  
Trust.



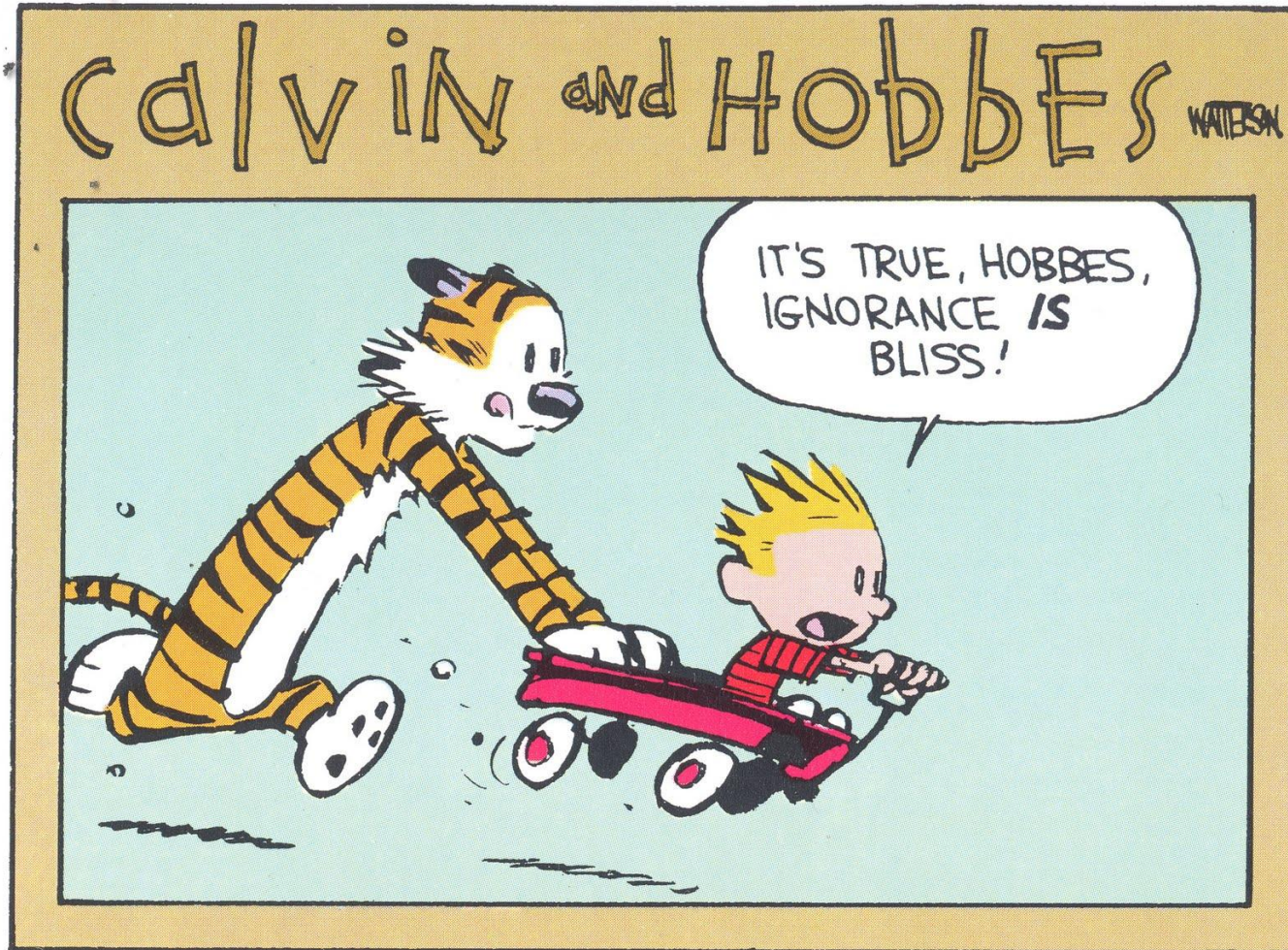
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# Pre 2012.....

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# And then.....

## Medical Device Alert

Ref: MDA/2012/037 Issued: 28 June 2012 at 14:00

### Device

Reusable transoesophageal echocardiography, transvaginal and transrectal ultrasound probes (transducers).

All models.

All manufacturers.

### Problem

The MHRA is aware of an incident where the death of a patient from hepatitis B infection may have been associated with a failure to appropriately decontaminate a transoesophageal echocardiography probe between each patient use.

The MHRA is issuing this alert to advise users to appropriately decontaminate all types of reusable ultrasound probes.

### Action

Review, and if necessary update, local procedures for all ultrasound probes that are used within body cavities to ensure that they are decontaminated appropriately between each patient use, in accordance with the manufacturer's instructions.

Ensure that staff who decontaminate medical devices are appropriately trained and fully aware of their responsibilities.

Be aware of the MHRA's guidance document 'Managing Medical Devices' (available from our website [www.mhra.gov.uk](http://www.mhra.gov.uk)).

### Action by

Trust decontamination leads.

Healthcare professionals using these devices and staff responsible for reprocessing medical devices.

Be aware of the Department of Health's publications (England only): Choice Framework for local Policy and Procedures 01-06 – Decontamination of flexible endoscopes: Operational management manual 13536:1.0. Available from Space for Health, sign-in required: <http://www.spaceforhealth.nhs.uk/England/topics/choice-framework-local-policy-and-protocols-01-06-%E2%80%933-decontamination-flexible-endoscopes>

### CAS deadlines

Action underway: 11 July 2012

Action complete: 19 July 2012

Also be aware of similar advice as/when published by the devolved administrations.

**Note: These deadlines are for systems to be in place to ensure the actions are undertaken.**

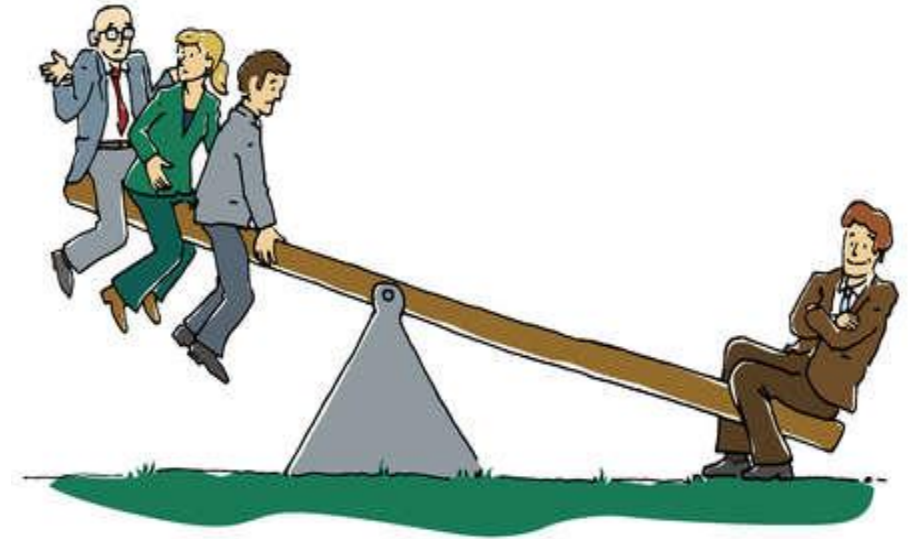
- **‘Review and if necessary update** local procedures for all ultrasound probes that are used within **body cavities** to ensure that they are **decontaminated appropriately between each patient use** in accordance with **manufacturer instruction.**’

# The Imaging Challenge.

	2014/15	2018/19	Average growth p.a.	Average additional activity
Plain X-ray (DID)	22.6m	23.5m	0.9%	208k
Non-obstetric ultrasound (DMOI)	6.6m	7.6m	3.8%	261k
CT (DMOI)	4.7m	6.1m	6.8%	352k
MRI (DMOI)	2.9m	3.6m	5.6%	176k
DEXA (DMOI)	389k	455k	4.0%	16k
PET-CT (DID)	89k	177k	18.7%	22k
Mammography*	2.7m	2.8m	1.2%	32k

<https://www.england.nhs.uk/wp-content/uploads/2020/11/diagnostics-recovery-and-renewal-independent-review-of-diagnostic-services-for-nhs-england-2.pdf>

# Department perspective?



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- **National Tariff vs Cost of Decontamination**
- **Decontamination vs Service delivery.**

# Current Guidance.



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**NHSScotland Guidance for Decontamination of Semi-Critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes**

## Guidelines



ACIPC  
Australian College  
for Infection Prevention and Control



## Guidelines for Reprocessing Ultrasound Transducers

The Australasian Society for Ultrasound in Medicine (ASUM) is the leading multidisciplinary medical ultrasound society advancing the clinical practice of diagnostic medical ultrasound for the highest standards of patient care in Australia and New Zealand. The Australasian College for Infection Prevention and Control (ACIPC) is the peak body for Infection Prevention and Control professionals in the Aus-

### 1.1 Scope and target audience

The Guidelines for Reprocessing Ultrasound Transducers provides recommendations for the cleaning and disinfection of all medical ultrasound transducers and any additional equipment that may be utilised during the procedure, such as the keyboard and ultrasound gel. These guidelines are recommended for all individuals directly or indirectly



## Guidelines for Cleaning and Preparing External- and Internal-Use Ultrasound Transducers Between Patients, Safe Handling, and Use of Ultrasound Coupling Gel

### Summary

Adequate transducer preparation is mandatory. The level of preparation depends on the type of examination performed. Routine high-level disinfection (HLD) of internal transducers between patients is mandatory, due to the use of a high-quality sterile cou-

HSE Guidance for Decontamination of Semi-critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes QPSD-GL-028-1

Health Service Executive  
Guidance for  
Decontamination of Semi-critical  
Ultrasound Probes;  
Semi-invasive and Non-invasive  
Ultrasound Probes

January 2017



Guidelines For  
Professional  
Ultrasound

Society and College of Radiographers and British Medical Ultrasound Society

Revision 3, December 2018

Insights Imaging (2017) 8:523–535  
<https://doi.org/10.1007/s13244-017-0580-3>

## GUIDELINE

## Infection prevention and control in ultrasound - best practice recommendations from the European Society of Radiology Ultrasound Working Group

Christiane M. Nyhsen<sup>1</sup> · Hilary Humphreys<sup>2,3</sup> · Roland J. Koerner<sup>4</sup> · Nicolas Grenier<sup>5</sup> · Adrian Brady<sup>6</sup> · Paul Sidhu<sup>7</sup> · Carlos Nicolau<sup>8</sup> · Gerhard Mostbeck<sup>9</sup> · Mirko D'Onofrio<sup>10</sup> · Afshin Gangi<sup>11</sup> · Michel Claudon<sup>12</sup>

Received: 25 July 2017 / Revised: 3 October 2017 / Accepted: 5 October 2017 / Published online: 27 November 2017  
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Ultrasound in Med & Biol., Vol. 45, No. 5, pp. 1076–1078, 2017  
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0301-5626/5 - see front matter

<http://dx.doi.org/10.1016/j.ultrasmedbio.2017.01.002>

### • Technical Note

## GUIDELINES FOR CLEANING TRANSVAGINAL ULTRASOUND TRANSDUCERS BETWEEN PATIENTS

JACQUES S. ABRAMOWICZ,<sup>6</sup> DAVID H. EVANS,<sup>1</sup> J. BRIAN FOWLKE,<sup>1</sup> KAREL MARŠAL,<sup>5</sup> and GAIL TERHAAR,<sup>4</sup> ON BEHALF OF THE WFUMB SAFETY COMMITTEE

<sup>6</sup>Department of Obstetrics and Gynecology, University of Chicago, Chicago, Illinois, USA; <sup>1</sup>Department of Cardiovascular Sciences (Emeritus), School of Medicine, University of Leicester, UK; <sup>2</sup>Basic Radiologic Sciences Division, Department of Radiology, University of Michigan Health System, Ann Arbor, Michigan, USA; <sup>3</sup>Department of Obstetrics and Gynecology (Emeritus), Lund University, University Hospital, Lund, Sweden; and <sup>4</sup>Therapy Ultrasound, Division of Radiotherapy & Imaging, Joint Department of Physics, Royal Marsden Hospital, Institute of Cancer Research, Sutton, Surrey, UK

(Received 1 January 2017; in final form 5 January 2017)

**Abstract**—The purpose of this article is to provide guidance regarding the cleaning and disinfection of transvaginal ultrasound probes. These recommendations are also applicable to transrectal probes. (E-mail: [j.abramowicz@bsd.uchicago.edu](mailto:j.abramowicz@bsd.uchicago.edu)) © 2017 World Federation for Ultrasound in Medicine & Biology.

**Key Words:** Infection control, Ultrasound, Transducer cleaning.



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# What do sonographers need to know?



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- Working knowledge of infection control and decontamination
- Current recommendations
- Their own roles and responsibilities
- Professional regulatory obligations
- Methods of decontamination and work flow.
- Manufacturer recommendations.

# Knowledge

**Spaulding's Classification System**  
1968 Earl Spaulding

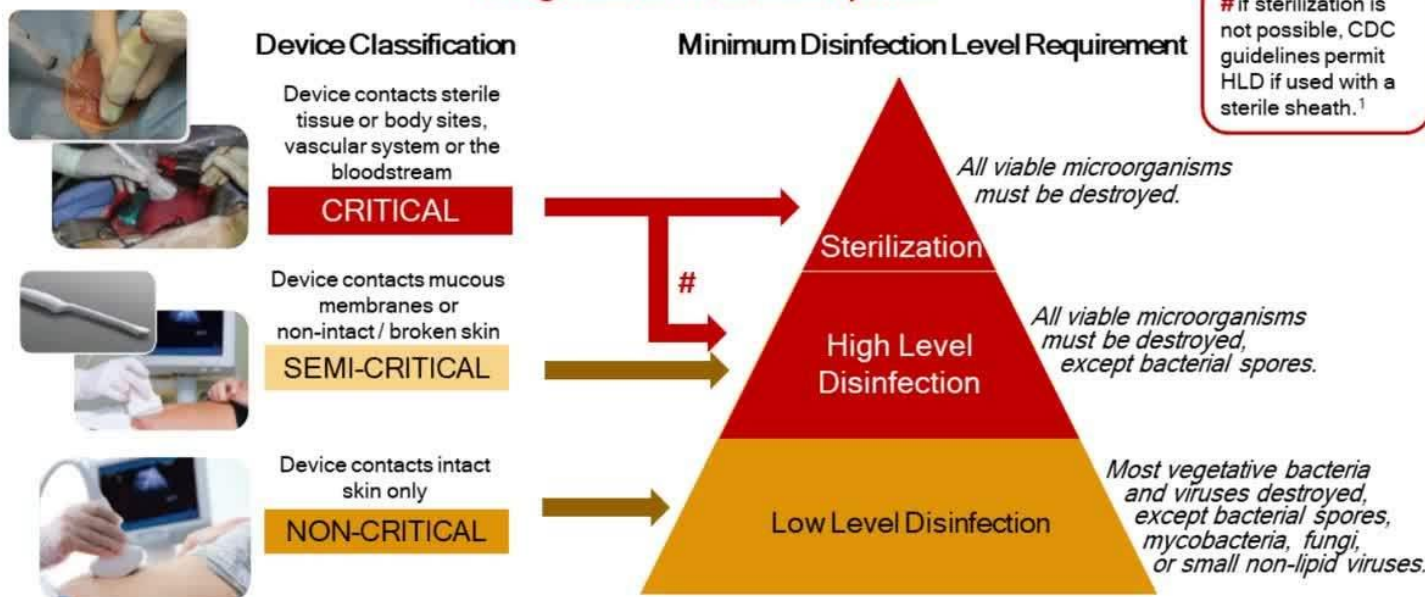
Items that come in contact with	Classification	Processing required	Examples
Sterile tissue or vascular system	Critical	Sterilization	Surgical instruments, cutting endoscopic accessories, catheters, needles
Nonintact skin or mucus membranes	Semi-critical	<b>Minimum</b> of high-level disinfection	Respiratory therapy equipment, flexible endoscopes
Intact skin	Noncritical items	Intermediate-level, disinfection, low-level disinfection or cleaning	Tourniquets, blood pressure cuffs, linens, furniture



# Terminology.

## Review: The Spaulding classification<sup>1,2</sup>

*CDC guidelines for ultrasound probes*



<sup>1</sup> Rutala WA, Weber DJ. HICPAC, CDC. Guideline for Disinfection and Sterilization in Healthcare Facilities. 2008.

# Roles and Responsibilities

- ***Decontamination Lead.***
  - Supporting organisational strategy in decontamination
  - Guidance in implementing best practice in decontamination
  - Supporting responsible person in implementing acceptable decontamination practices
  - Supporting responsible person in monitoring decontamination policy.

- ***‘Responsible Person.’***
  - Responsible for the safe decontamination of ultrasound probes.
  - Following manufacturers and HSE guidance from acquisition to disposal.
  - Links with decontamination lead.
  - Maintenance, repair and validation according to manufacturer instructions.
  - Record keeping. Validation and traceability for lifecycle +11 years.

# *Operator.*

- Undertakes decontamination.
- Cleaning and traceability.
- Adequate training
- Reports to Responsible User.

# *U/S Manufacturers.*

- Ensure that ultrasound probes can undergo high level decontamination procedures & underwrite these.
- Make explicit what is and is not acceptable decontamination practice
- Ensure ultrasound probes are sufficiently robust to withstand reasonable handling.
- Provide choice where possible.
- *Agreed standard between manufacturers?*

# Regulatory Position.



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Your duties as a registrant

Standards of  
conduct,  
performance  
and ethics



## The Code

Professional standards of practice  
and behaviour for nurses, midwives  
and nursing associates

prioritise people

practise effectively

preserve safety

promote professionalism and trust



Good medical  
practice

Working with doctors Working for patients

General  
Medical  
Council

# Regulatory Position.



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- ‘6.1 You must take all reasonable steps to reduce the risk of harm to service users, carers and colleagues as far as possible.’
- ‘6.2 You must not do anything, or allow someone else to do anything, which could put the health or safety of a service user, carer or colleague at unacceptable risk.’
- ‘7.1 You must report any concerns about the safety or well-being of service users promptly and appropriately.’
- ‘7.2 You must support and encourage others to report concerns and not prevent anyone from raising concerns.’
- ‘7.4 You must make sure that the safety and well-being of service users always comes before any professional or other loyalties.’

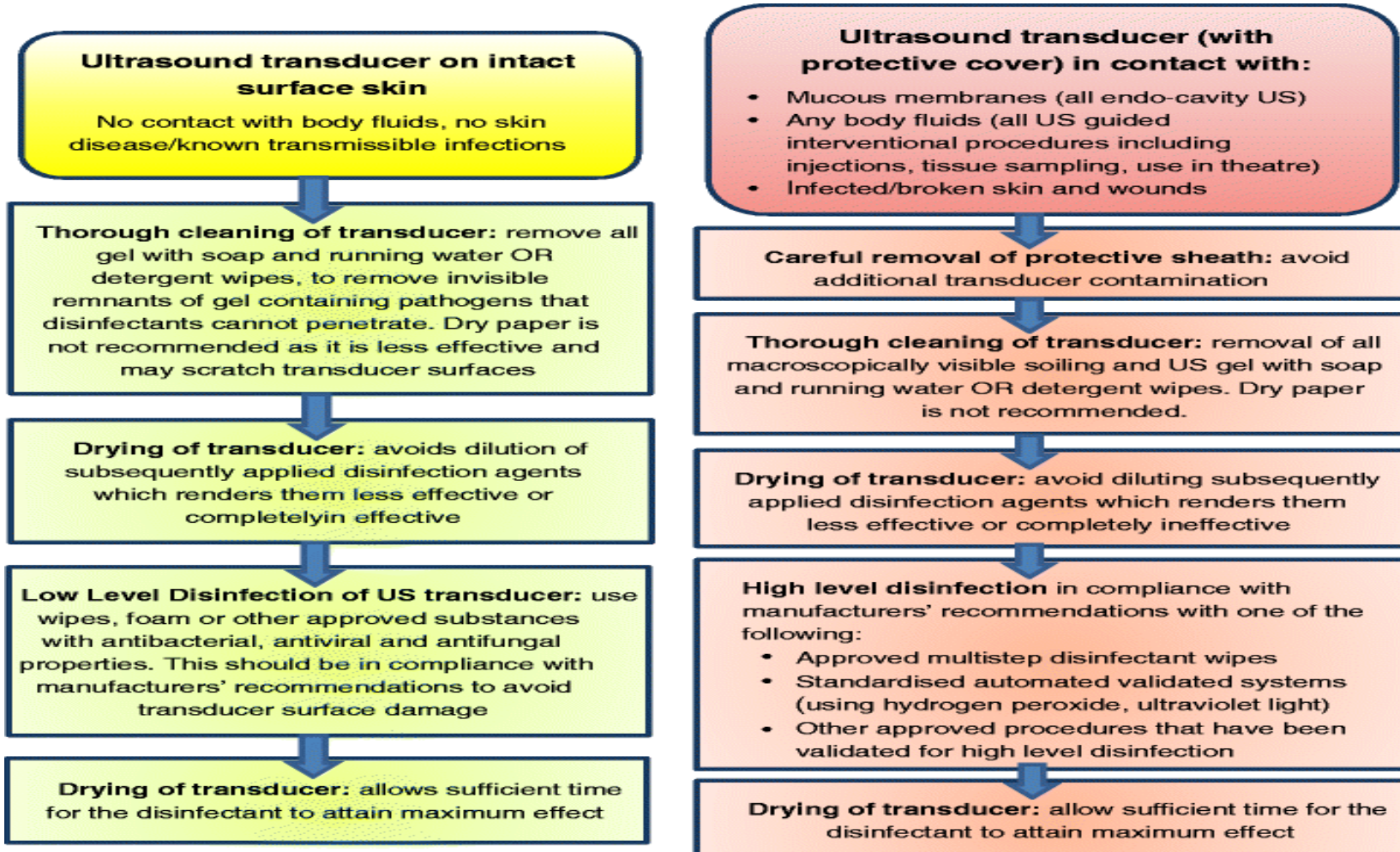
**HCPC. Standards of conduct, performance and ethics.  
2018.**

# Department perspective

- Quick.
- Easy.
- Safe.
- Minimise impact on ultrasound list.
- Safe for operator.
- Minimise risk of damage to probes/ultrasound equipment.



# Clear SOPs



# Low-Level Disinfection

- Non-Critical Transducers.
- Manually remove all ultrasound gel prior to cleaning.
- (a) Clean transducer using a TGA-approved disposable cleaning wipe or system intended for use on medical devices.

Or

- b) Clean transducer using freshly made up solution of cleaning agent at the correct concentration. Rinse thoroughly under running water to remove cleaning agent residues. Dry using a single-use low linting cloth.

# High-Level Disinfection.

- Approved Multi-stage wipe system.
- Approved Automated system.
  - Trophon
  - Germitec
- Approved Chemical Bath system.

# Multi-stage Wipe System.

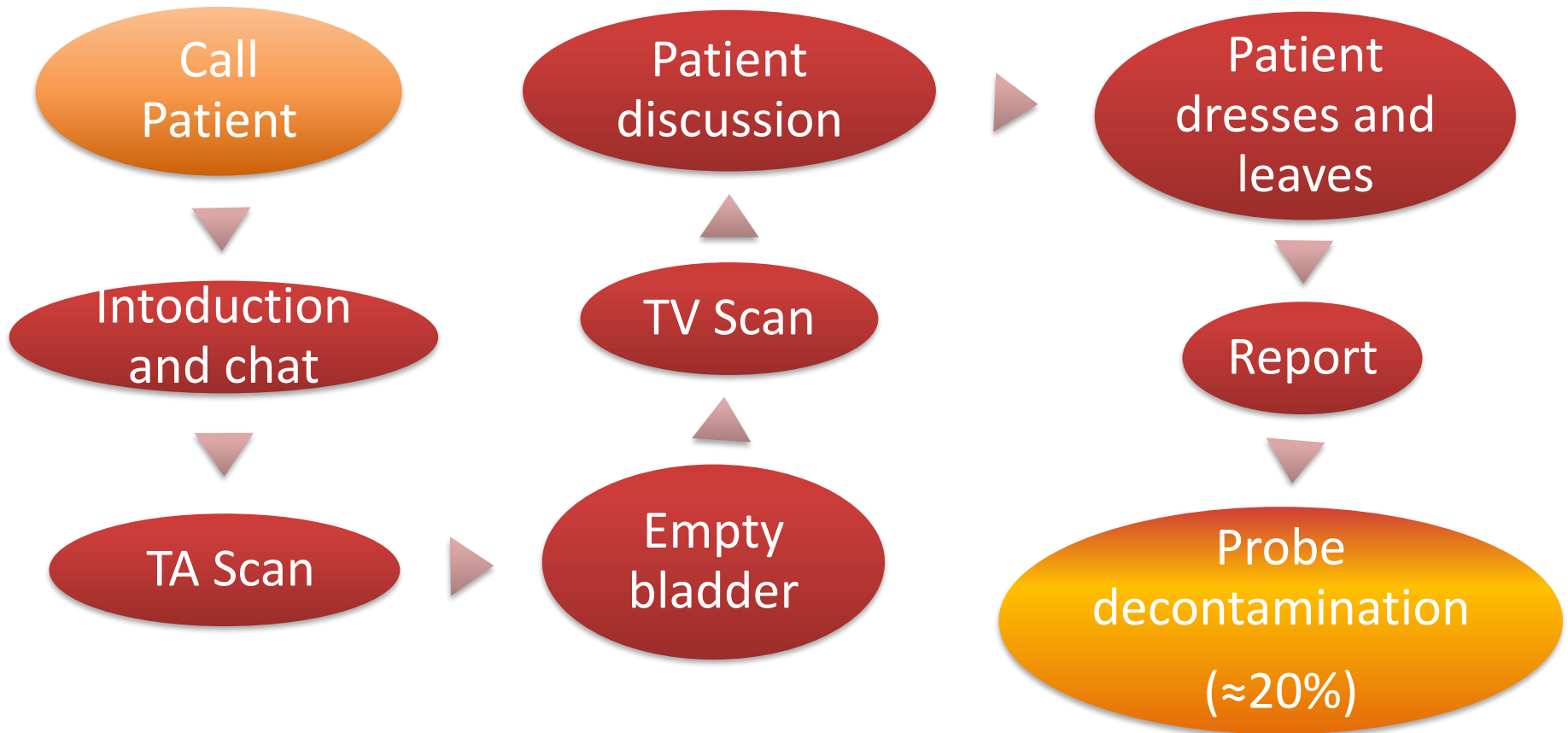
- Portable
- Can be undertaken quickly during a busy ultrasound list.
- Relatively easy to implement across numerous sites
- Easy to Undertake.
- Assures high level disinfection *if done correctly.*

# Multi-stage wipe system

- **Non-automated.**
- Difficult to assure consistency of procedure between multiple operators.
- Traceability?
- Validation of process?



# Pelvic US Workflow. Manual System.



# Automated systems.



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# Automated Systems.

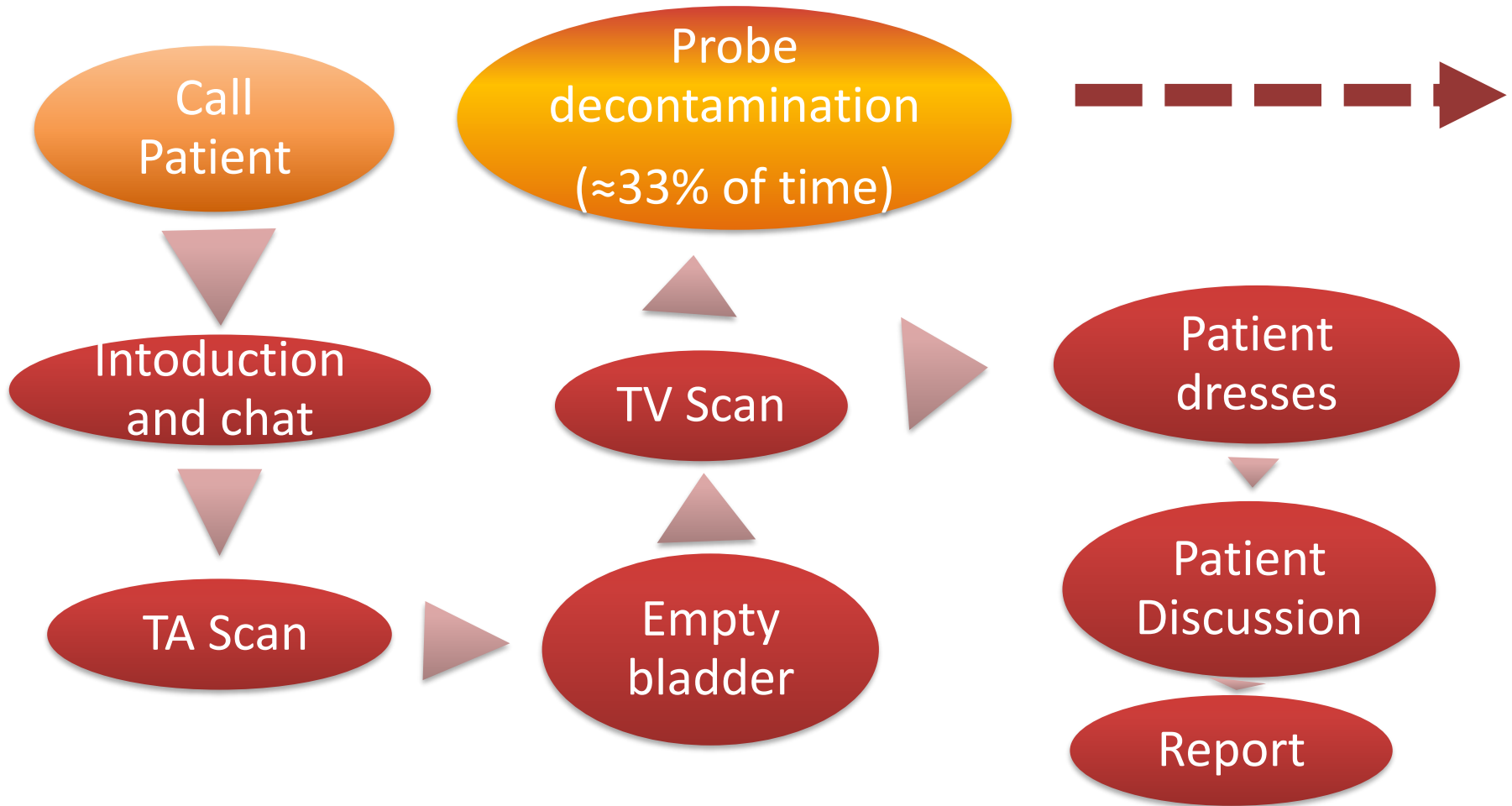
- **Automation of process**
- Reduced variation in practice between operators.
- Electronic record keeping.
- Assurance of process easier.



# Automated systems.

- Lower levels of portability.
- Validation of reliability of equipment complex.
- Consumables.
- Probe damage?
- Capital costs.
  - Leasing vs purchase outright.

# Pelvic US Workflow. Automated System.



# Automated vs manual systems



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[< go to previous page](#)

**ULTRASOUND**  
in Obstetrics & Gynecology



Original Paper | [Free Access](#)

**Disinfection of transvaginal ultrasound probes in a clinical setting: comparative performance of automated and manual reprocessing methods**

D. L. Buescher , M. Möllers, M. K. Falkenberg, S. Amler, F. Kipp, J. Burdach ... [See all authors](#) 

First published: 01 October 2015 | <https://doi.org/10.1002/uog.15771> | Cited by: 5

 SECTIONS

 PDF  TOOLS  SHARE

ABSTRACT

- “This study favored automated disinfection owing to its significantly higher efficacy compared with a manual method.’

# Record Keeping.

- Short code on RIS system.
  - Type of decontamination.
  - Ultrasound Probe Number
  - Decontamination Unit
  - Cycle Number
  - Name of person undertaking decontamination

# Key messages

## The sonographer perspective.

- Ultrasound service delivery is under enormous pressure nationwide.
- High-level decontamination is **not** optional.
- State registered ultrasound practitioners are obliged to ensure safe practices for patients.
- Departments need support from decontamination leads to ensure best practice.
- Solutions need to be safe, assured, cost effective and time effective.