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A Clinical User's Perspective.

Dr Peter Cantin.

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Pre 2012……

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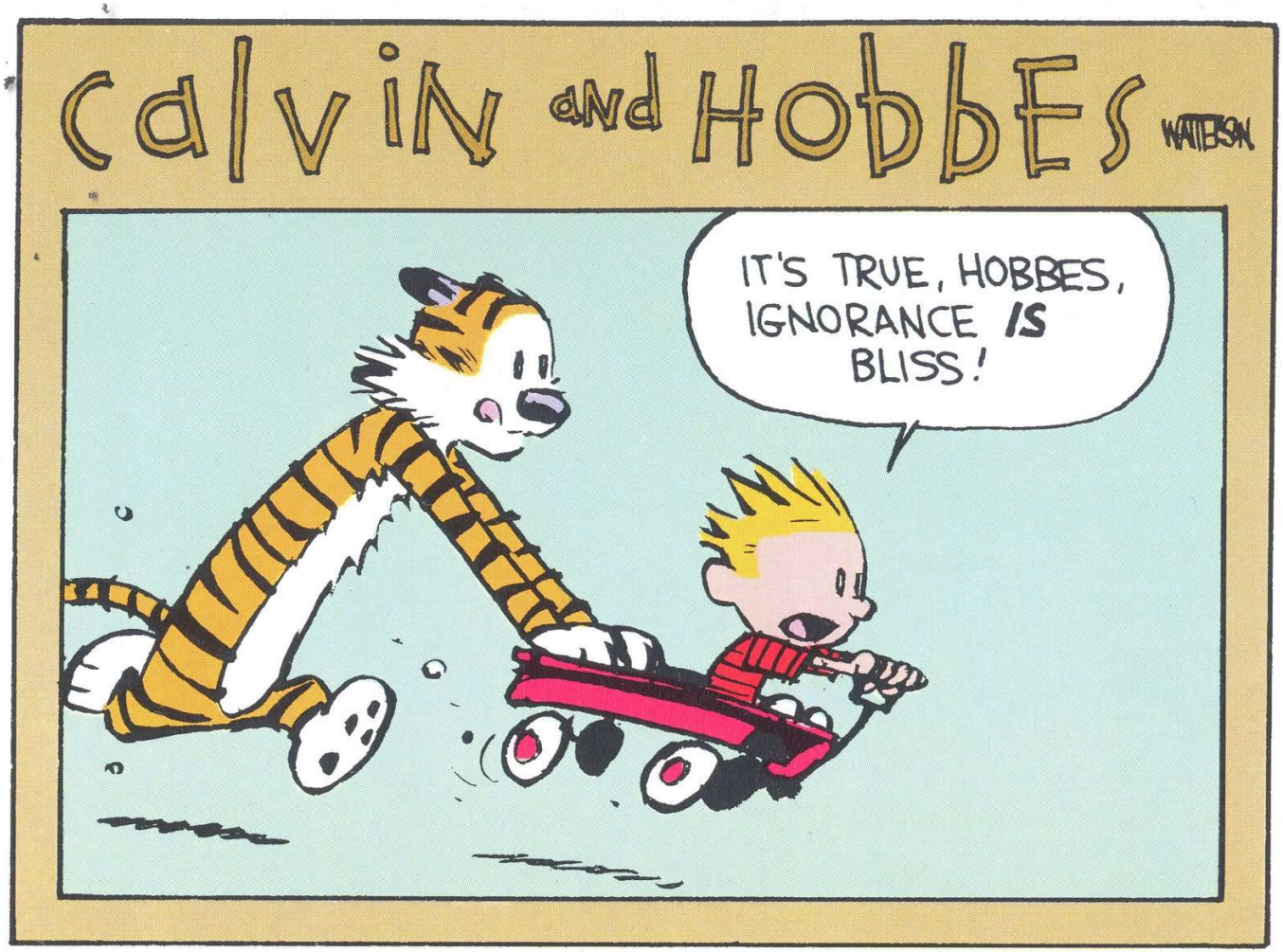

And then……

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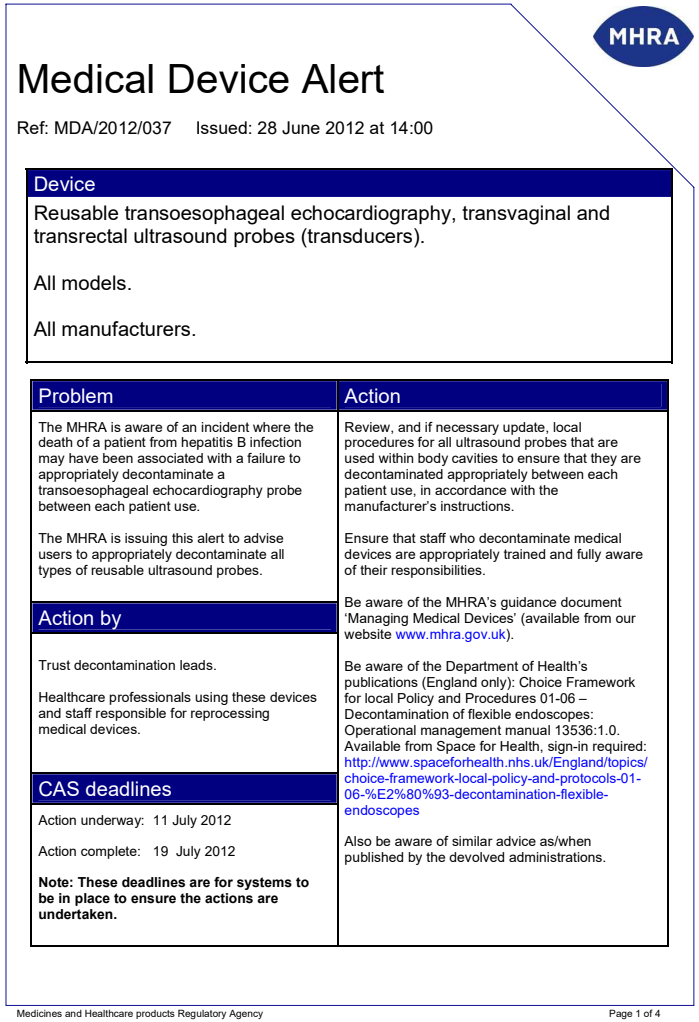

MHRA

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 by

Trust decontamination leads.

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

CAS deadlines

Action underway: 11 July 2012

Action complete: 19 July 2012

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

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).

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%93-decontamination-flexible-endoscopes

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

Medicines and Healthcare products Regulatory Agency Page 1 of 4

- '**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**.'

U/S Workload.

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	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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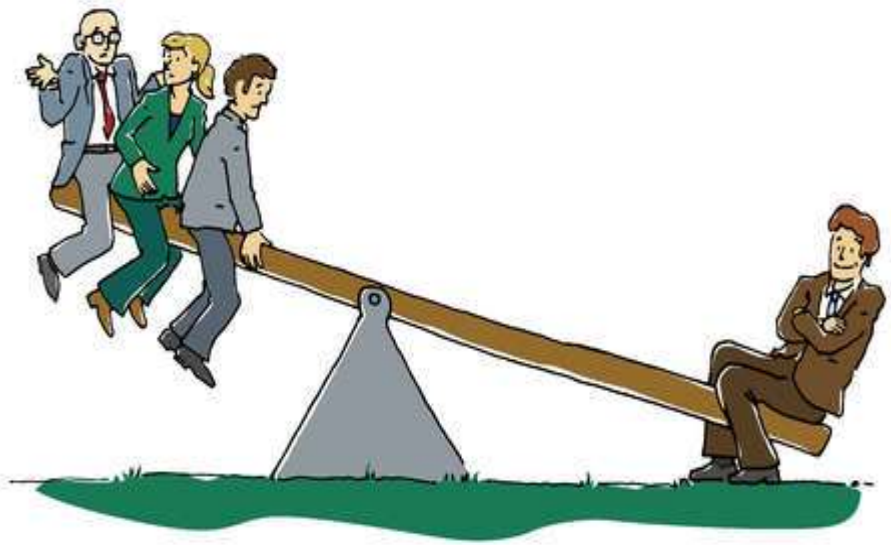
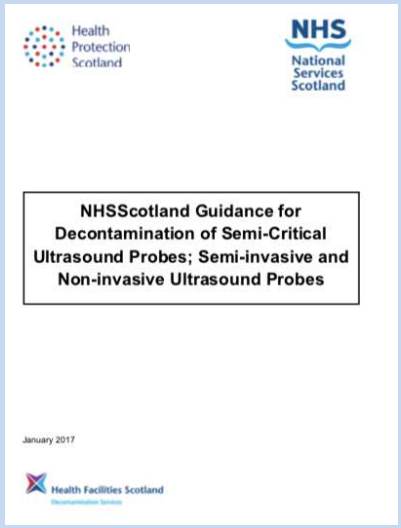


- **National Tariff vs Cost of Decontamination**
- **Decontamination vs Service delivery.**

Current Guidance.

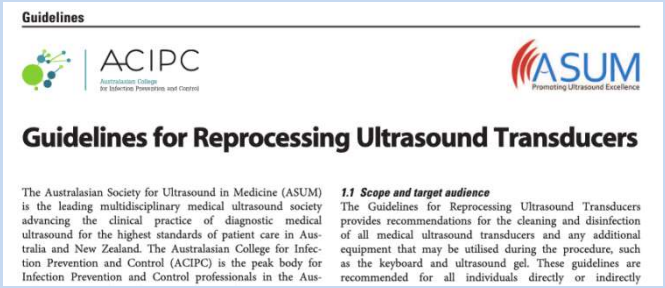

Health Protection Scotland

NHS National Services Scotland

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

January 2017

Health Facilities Scotland


Guidelines

ACIPC

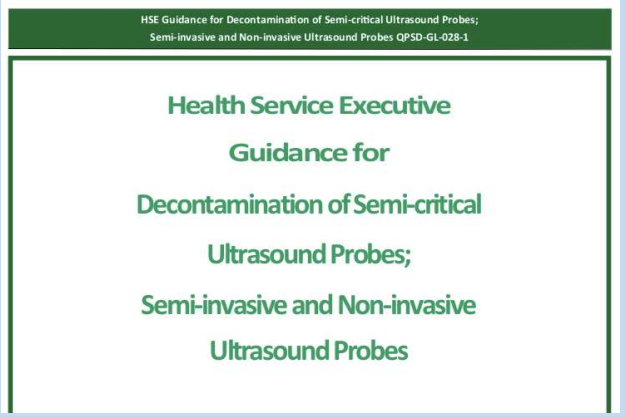
ASUM

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


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

Health Service Executive

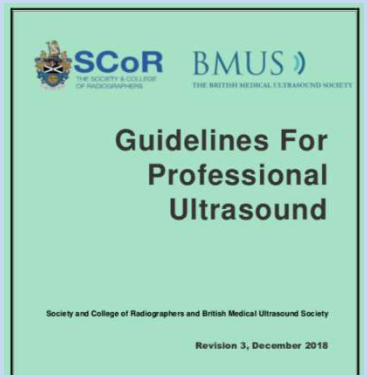
Guidance for

Decontamination of Semi-critical

Ultrasound Probes;

Semi-invasive and Non-invasive

Ultrasound Probes


SCoR

BMUS

Guidelines For Professional Ultrasound

Society and College of Radiographers and British Medical Ultrasound Society

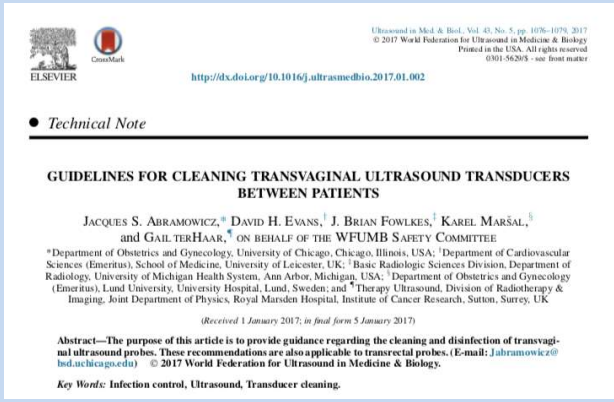
Revision 3, December 2018


aium Official Statements

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


ELSEVIER

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

Technical Note

GUIDELINES FOR CLEANING TRANSVAGINAL ULTRASOUND TRANSDUCERS BETWEEN PATIENTS

JACQUES S. ABRAMOWICZ,* DAVID H. EVANS,† J. BRIAN FOWLKES,‡ KAREL MARŠAL,§ and GAIL TERHAAR,¶ ON BEHALF OF THE WFUMB SAFETY COMMITTEE

*Department of Obstetrics and Gynecology, University of Chicago, Chicago, Illinois, USA; †Department of Cardiovascular Sciences (Emeritus), School of Medicine, University of Leicester, UK; ‡Basic Radiologic Sciences Division, Department of Radiology, University of Michigan Health System, Ann Arbor, Michigan, USA; §Department of Obstetrics and Gynecology (Emeritus), Lund University, University Hospital, Lund, Sweden; and ¶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: Jabramowicz@bsd.uchicago.edu) © 2017 World Federation for Ultrasound in Medicine & Biology.

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


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

CrossMark

GUIDELINE

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

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

Received: 25 July 2017 /Revised: 3 October 2017 /Accepted: 5 October 2017 /Published online: 27 November 2017

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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

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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	**Minimum** of high-level disinfection	Respiratory therapy equipment, flexible endoscopes
Intact skin	Noncritical items	Intermediate-level, disinfection, low-le3vel disaffection or cleaning	Tourniquets, blood pressure cuffs, linens, furniture

Terminology.

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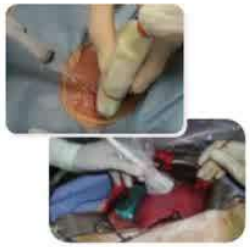
Review: The Spaulding classification[1,2]

CDC guidelines for ultrasound probes



Device Classification

Device contacts sterile tissue or body sites, vascular system or the bloodstream

CRITICAL

Device contacts mucous membranes or non-intact / broken skin

SEMI-CRITICAL

Device contacts intact skin only

NON-CRITICAL

Minimum Disinfection Level Requirement

if sterilization is not possible, CDC guidelines permit HLD if used with a sterile sheath.[1]

#

Sterilization — *All viable microorganisms must be destroyed.*

High Level Disinfection — *All viable microorganisms must be destroyed, except bacterial spores.*

Low Level Disinfection — *Most vegetative bacteria and viruses destroyed, except bacterial spores, mycobacteria, fungi, or small non-lipid viruses.*

28

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

Nanosonics 2018

Roles and Responsibilities

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- ***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.

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- ‘***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.

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Operator.

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

U/S Manufacturers.

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- 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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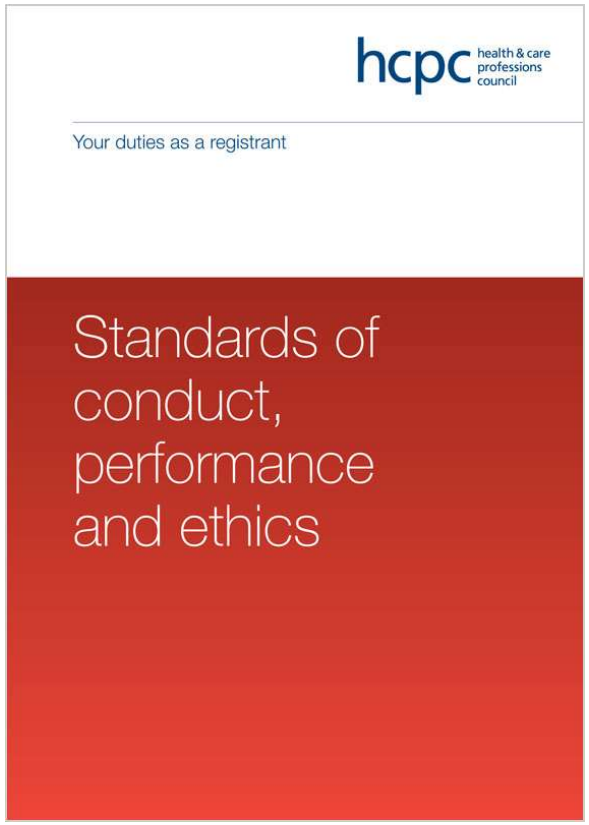

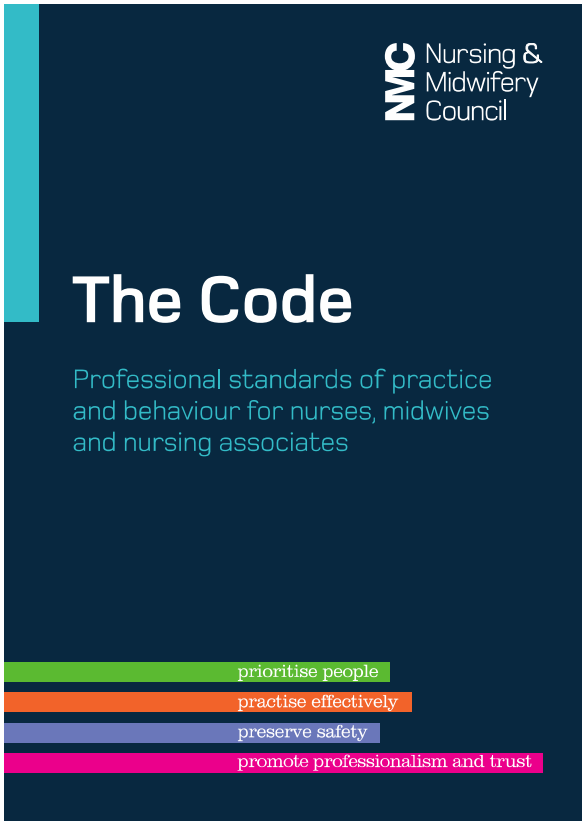

Regulatory Position.

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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

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

Clear SOPs

Types of Decontamination (Spaulding Classification)[2]

Type of decontamination	Cleaning	Cleaning and disinfection	Cleaning and sterilisation
When to use	• **Intact skin** e.g. transabdominal examinations, superficial structures, vascular	• **Broken skin (inc post interventional procedures)** • **Infected skin** • **Contact with known pathogenic microbes** • **Intracavity examinations with mucous membrane contact** e.g. transvaginal or transrectal examinations	• **Use in a sterile area of the body** e.g. intraoperative or intracranial examination
What to use	Manufacturer approved wipes	An automated decontamination system is best practice. Where this is not possible manufacturer approved wipes and cleaning system	Manufacturer approved sterilisation device or process
Warnings	Check approved options for each type of transducer Gentle use Training needed	Training, monitoring and review of any cleaning system used is required. Audit trail required of decontamination for every endo-cavity examination. Handle with care and where relevant use personal protective equipment (PPE) Training is needed	Training, monitoring and review of any cleaning system used is required. Audit trail required of decontamination for every patient Handle with care and where relevant use personal protective equipment (PPE) Training is needed

Low-Level Disinfection

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- 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.

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- Approved Multi-stage wipe system.
- Approved Automated system.
  - UV-C Decontamination systems
  - H2O2 mist Decontamination systems
- Approved Chemical Bath system.

Multi-stage Wipe System.

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- 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.*

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Multi-stage wipe system

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

Pelvic US Workflow. Manual System.

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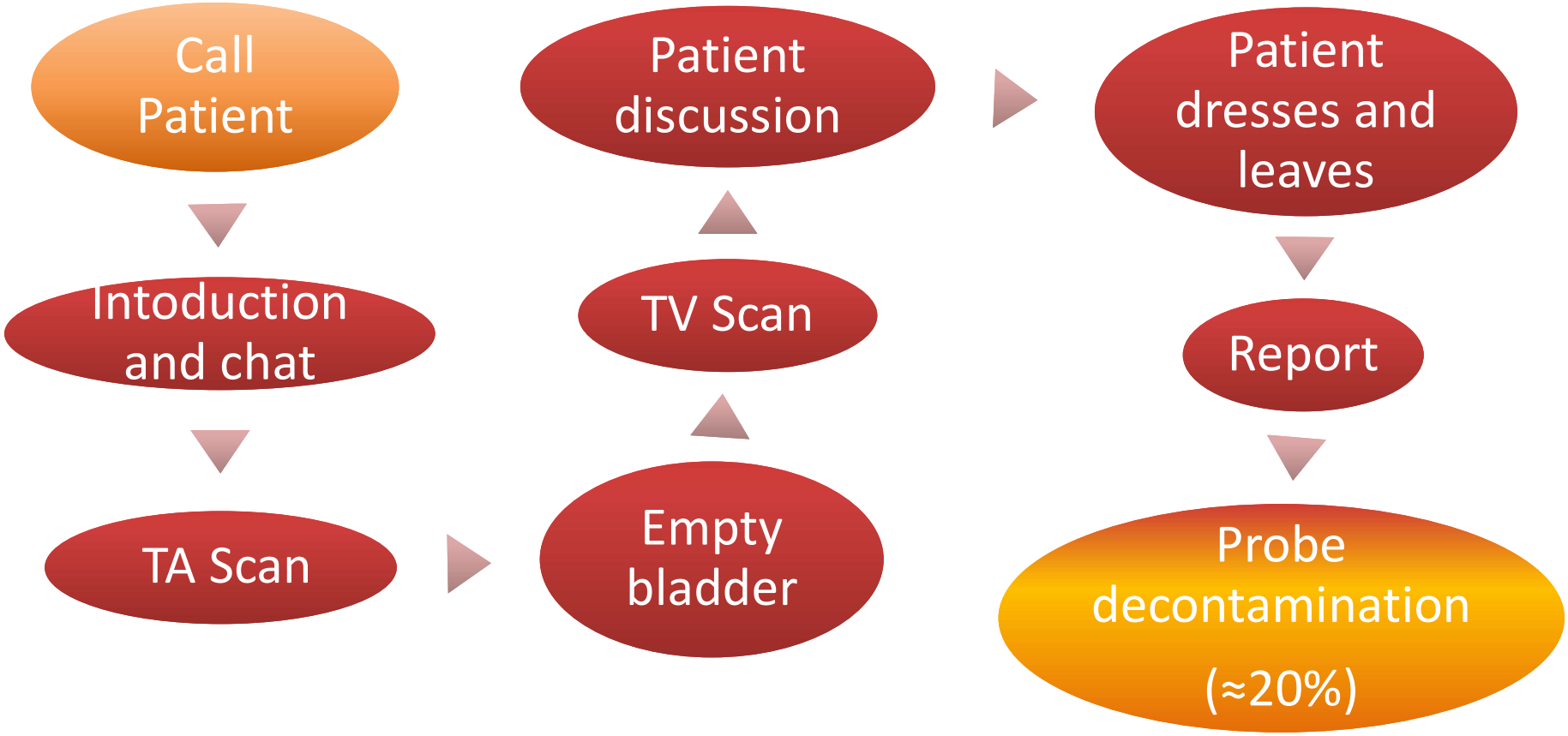

Automated systems.

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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.
- Compatibility to be checked with equipment manufacturer
- Capital costs.
  - Leasing vs purchase outright.

Pelvic US Workflow. Automated System.

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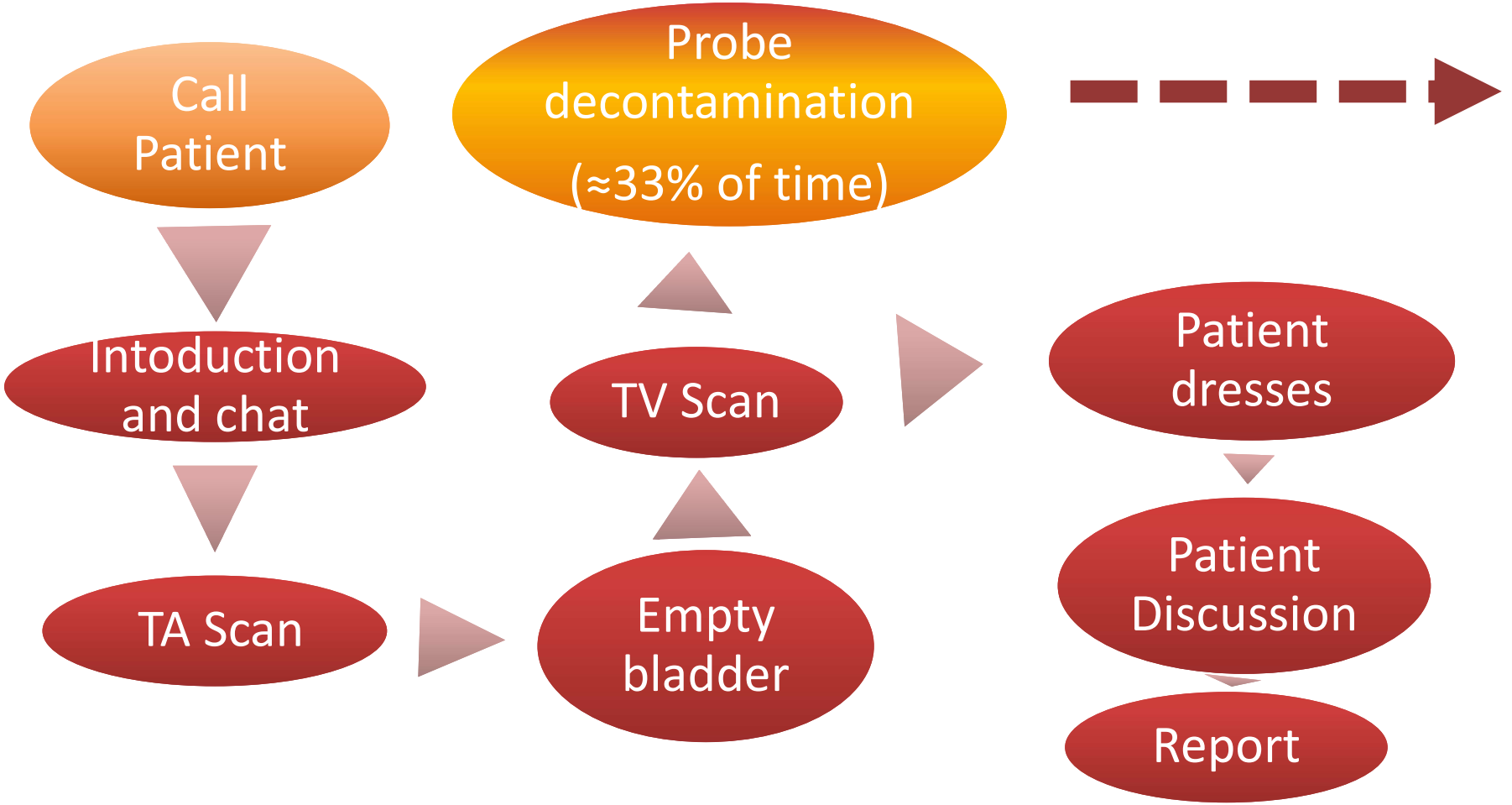

Manual vs Automated vs manual systems

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< go to previous page

ULTRASOUND in Obstetrics & Gynecology

isuog

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. '

Key messages
The sonographer perspective.

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- 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, time effective and simple to use.