

## **Ultrasound Transducer Decontamination – Best Practice Summary**



If a patient asks whether the ultrasound transducer is cleaned effectively prior to their scan, can you reassure them that it is?

If not, this best practice summary is for you.

This best practice summary has been developed from the national and international guidelines and articles published over the last 5 years<sup>1–10</sup>. It is intended to provide users of ultrasound with the information and general principles required to promote, ensure and evidence effective and safe decontamination of ultrasound machines and transducers. This summary is primarily related to transducer and ultrasound machine decontamination. Whilst this is important, it is not the only consideration in the overall protection of patients from infection. Consideration should also be given to all equipment and consumables, but this sits outside the remit of this summary.

This best practice summary should be implemented across the whole organisation, with consideration of all ultrasound machines and transducers, including loan and demonstration equipment, and in liaison with the local infection control team.

The potential for infection transmission from intracavity ultrasound transducers in particular is considerable<sup>2</sup>. There have been two previous Medicines and Healthcare Products Regulatory Agency (MHRA) alerts relating to transducer cleaning and disinfection, these are:

- Reusable transoesophageal echocardiography, transvaginal and transrectal ultrasound probes (transducers) – failure to appropriately decontaminate (2014)<sup>5</sup>
- <u>Ultrasound transducer probes with an internal lumen used for taking transrectal prostate</u>
   biopsies (2009)<sup>7</sup>

#### **Terminology:**

A number of different terms and phrases are used when considering the level of decontamination.

- The term **transducer** is used through this summary. It is noted that this is interchangeable with the term probe.
- Decontamination is a general term used for all aspects of transducer cleaning. It is defined
  by Bradley et al<sup>2</sup> in the 2018 published paper 'Guidance for the decontamination of
  intracavity medical devices: the report of a working group of the Healthcare Infection
  Society' as:

"the sequence of processes including cleaning and microbiocidal actions that make a reusable medical instrument safe for reuse. It is important to realise that this is a far wider process than merely, for example, which chemical agent is chosen"

- **Disinfection** is the term used to describe cleaning something, usually with a chemical, in order to destroy or prevent the growth of organisms, usually bacteria.
- **Cleaning** includes the removal of gel, transducer covers, and other matter from the transducer. Cleaning should take place before disinfection or sterilisation.
- Cleaning and disinfection is "a lower level than elimination of microbes but with quality assurance that ensures that an item is safe without necessarily being sterile"<sup>2</sup>
- Cleaning and sterilisation eliminates microbes from the transducer.

It must be noted that although the terms are commonly used there are no concepts of 'low level' or 'high level' disinfection in the United Kingdom (UK) or Europe. These terms are used in regulatory matters in the United States of America where their Food and Drug Administration has a list of disinfectants that have passed specific regulatory tests and can be called "high level". In the UK, any manufacturer can call anything a high level disinfectant – it has no regulatory meaning. These terms are not used in this advice and summary and are actively discouraged.

Disinfection must have an element of microbial killing/inactivation.

Cleaning and sterilisation will eliminate all microbes from a transducer. The transducer and cable need to be wrapped before sterilisation in a way that will preserve its sterility until use.

### How can manufacturers help?

Every manufacturer has specific approved products that are recommended for each transducer and ultrasound machine decontamination. This information can be obtained via their individual websites.



When considering a purchase ask the Applications Specialists for a list of recommended decontamination products for each transducer and ultrasound machine.

Not all the transducers for a particular ultrasound machine can be decontaminated by the same product or method without causing damage.

## What is the history of your transducers?

It is important to understand the provenance of your transducers.

 If the transducer has been repaired or deviates from the Original Equipment Manufacturer's (OEM) specification, certain products or devices may be unsuitable for safe decontamination<sup>3</sup>.

#### **General Principles:**

Careful use of any product or device is needed. Follow advice and guidance from product or device suppliers. Misuse can cause damage to transducers and machines.



Vigorous cleaning with paper can damage the lens on a transducer

The ultrasound machines may need to be cleaned using a different product to that used to clean transducers and cables. An incorrect product or misuse can cause cracking of the plastic machine casing and de-plasticising of the transducer housing and cables. De-plasticising can cause the cables to become discoloured and sticky.

Care is needed when cleaning transducers and cables. Avoid bending or trapping cables or knocking transducer heads, if being placed in disinfection devices. Care is required when removing and reconnecting transducers from connectors to avoid bending connecting pins.

Accidental damage can happen. Be open and transparent about this. If a transducer is dropped or damage is noted whilst cleaning, remove from service and report to a manager.

Covers must be used on intracavity transducers, but it is important to be aware that using a cover on the transducer is not in itself an effective method of preventing contamination, as covers may have holes or contamination can occur when removing the covers or via a contaminated glove<sup>2</sup>.

Training for all staff members who will be using products and devices is essential. Staff members must be aware that whatever product is used, poor understanding and deviating from the correct disinfection process could compromise the desired level of disinfection and can damage transducers.

Training should be provided for all new members of staff during induction and for all staff when new products or devices are introduced. Annual training and assessment is essential to maintain safe and effective practice. The date of the initial and subsequent training should be recorded. Consider including this in the staff member's annual appraisal.

A clear and concise departmental and organisational guideline of practice / standard operating procedure is required and should be regularly reviewed and updated at a recommended interval of 12 months and maximum interval of 3 years. Manufacturer guidance on transducer decontamination should be reviewed each time a product or device is changed or when a new machine or transducer is purchased<sup>2</sup>.

Disinfectant-impregnated wipes that contain an effective disinfectant are widely used but the assurance that all surfaces are in contact with liquid disinfectant for the required time is not as easy to achieve as a high-quality assurance standardised and automated process. Therefore, best practice is the use of an automated system. If an automated system is used in preference to a wipe system, as recommended by Bradley at al<sup>2</sup>, an effective process which follows manufacturer's guidance should be in place to ensure that the automated system in its own right is clean and a log of such cleaning is kept.

A record of cleaning and disinfection and / or sterilisation must be kept for any transducer that has been in contact with anything other than intact skin i.e. for transducers that need disinfection or sterilisation. This may take the form of a log-book or electronic database. The log should be able to identify that the transducer was cleaned after each examination. Minimum dataset includes:

- Patient identifier;
- transducer serial number;
- cleaning product serial number;
- date and time;
- staff member undertaking cleaning.

Each clinical and / or storage area should be risk assessed and a clear process of being able to easily identify and differentiate dirty and clean transducers must be in place. Consider the use of disposable storage bags, clips or labels and clearly labelled clean and dirty 'zones'.

Liaison with the local infection control team is strongly advised to ensure department practice is approved and agreed by the employing institution.

## Five steps to decontamination:

- 1 Remove transducer cover, gel / visible soiled material from transducer.
- 2 Visually inspect the transducer, cable and machine. Report any signs of damage and remove affected piece of equipment;
- 3 Determine the level of decontamination required and refer to the manufacturer's guidance on cleaning products or devices which can be used;
- 4 Follow decontamination process
- 5 Record actions where required.





# Types of Decontamination (Spaulding Classification)<sup>2</sup>

Type of	Cleaning	Cleaning and disinfection	Cleaning and sterilisation
decontamination			
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

This summary links to Quality Standards for Imaging (QSI) standards LM2, FR3, FR4, FR5, SA2 and SA5<sup>11</sup>.

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