

Ultrasound Infection Prevention Toolkit

Ver. 1.0



Prevention of infection during
ultrasound probe use and reprocessing

Tool 4 Policy Development Framework

www.ultrasoundinfectionprevention.org.uk/

This tool is a SOP development framework designed to help develop infection prevention policies and is to be applied to all settings where ultrasound is used and reprocessed. It can be used to develop a universal hospital SOP or a department specific SOP and has been developed based on major guidelines, standards and evidence based scientific literature.

Purpose and scope

This tool has been developed for healthcare personnel developing infection prevention policies for ultrasound probe use and reprocessing. It is designed as a SOP framework for application in all settings where ultrasound is used. This framework can be used to develop a universal hospital SOP or a department specific SOP. See *Instructions*.

This tool is based on UK/Irish Standards, local, regional and global guidelines, and evidence based scientific literature.¹⁻²² It is a general document that may need to be modified in line with the specific regulations, guidelines, policies and procedures of each institution and department. All manufacturer instructions for use (IFU) must be consulted prior to use. This tool covers the following aspects related to ultrasound probe use and reprocessing: cleaning, disinfection/sterilisation, storage, ultrasound use (gel, probe covers), responsibilities, education and training.

Instructions

Read through each section and modify it so the SOP applies to your clinical setting.

When customising a SOP for your facility/department/processes, consider the probe models used, ultrasound procedures performed, whether the SOP is department specific or hospital wide, and the existing reprocessing workflows currently in use.

Blue boxed text specifies further instructions for each section.

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1. Revision history

Date	Revision number	Change(s)	Reference section

2. Scope

This SOP defines the requirements for ultrasound probe use and reprocessing at [specify facility/department]. All healthcare workers that use ultrasound in procedures, perform the reprocessing of ultrasound probes, and/or oversee the reprocessing and use of ultrasound should be trained and competent in this SOP.

'Ultrasound probe' refers to external ultrasound probes (e.g. surface, Doppler, linear probes) and non-lumened endocavity probes (e.g. transvaginal, transrectal and transoesophageal probes).

Update this Scope to specify facility/department.

3. Overview of ultrasound probe reprocessing and use

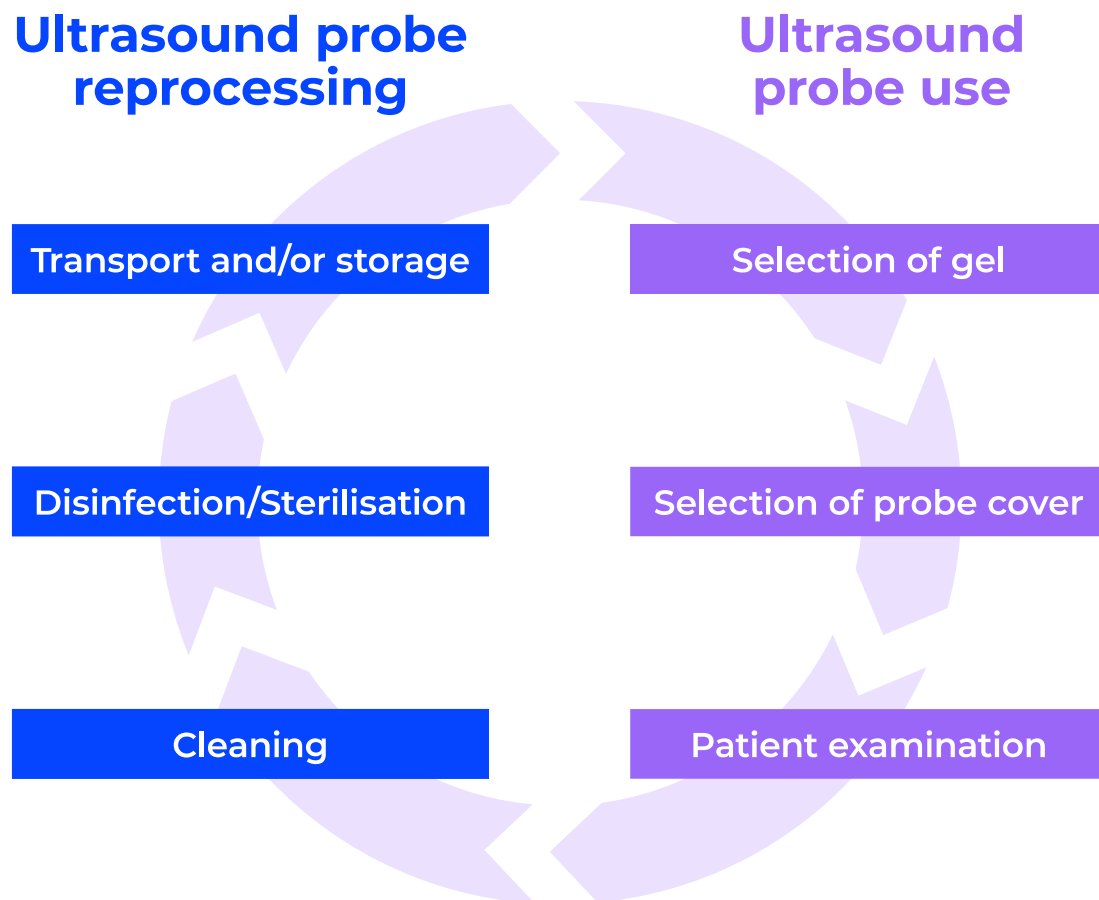


Figure 1. Stages of ultrasound probe reprocessing and use covered in this SOP. Traceability needs to be incorporated throughout this process (see *Traceability*).

The steps in ultrasound probe reprocessing and use are summarised in *Figure 1*. The steps are probe cleaning, HLD/LLD disinfection/sterilisation, transport/storage, gel selection, cover selection and patient use. The information in these steps need to be linked (traceability) and responsibilities throughout this process must be clearly defined.

The requirements in this SOP relating to ultrasound reprocessing and use have been developed based on local (Society and College of Radiographers/British Medical Ultrasound Society - SCoR/BMUS, Health Service Executive (HSE) Ireland and National Health Service (NHS) Scotland), regional (European Society of Radiology - ESR and European Committee for Medical Ultrasound Safety - ECMUS) and global (World Federation for Ultrasound in Medicine and Biology - WFUMB) guidance.^{1-3,5-7}

As ultrasound probes and endoscopes are similar heat-sensitive medical devices, NHS England and NHS Wales health technical memorandums relating to decontamination of flexible endoscopes will also be referenced.^{4,10-11}

This SOP also follows recommendations from the manufacturer instructions for use (IFUs) of chemical sterilants, high-level disinfectants, reprocessing equipment and ultrasound probes used at this facility to ensure compatibility with probe materials.

This SOP complies with the following local and state regulation/policies [list relevant regulations].

Update this overview to specify relevant regulations.

4. Ultrasound probe reprocessing

4.1 Cleaning

Cleaning is essential and the most important step in reprocessing. Improper cleaning “will” render subsequent disinfection/sterilisation ineffective. UK and Ireland guidelines mandate the manual removal of visible soil from probe and cable as per the IFU, followed by a visual inspection of cleanliness prior to disinfection or sterilisation.¹⁻⁹

Extra care should be taken when cleaning probes, paying extra attention to indentations or complex surfaces. The probe IFU should always be consulted for cleaning instructions and lists of compatible products. Typical cleaning solutions indicated for use with ultrasound probes include detergent-based cleaning wipes, or appropriate liquid detergents diluted as per instructions. Caution should be taken to prevent aerosol creation. The cleaning method should be indicated for use on ultrasound probes, be effective, be compatible with the probe and be safe for the user. Ensure appropriate PPE is available for staff to undertake the cleaning process. Perform rinsing if required by the IFU of the cleaning product. At the conclusion of the cleaning process, the probe should be dried using lint-free cloths to prevent interference in subsequent steps.

Note the cleaning process used in your department/facility and reference or specify the standard operating procedure (SOP) here.

4.2 Disinfection and Sterilisation

4.2.1 Assigning the Spaulding Classification of the Probe

Each ultrasound probe should be classified according to the Spaulding criteria based on its intended use. Medical devices can be classified into three categories based on the patient tissues they contact and associated infection transmission risk. The Spaulding Classification system dictates the level of disinfection/sterilisation required for the ultrasound probe.¹¹

Non-Critical ultrasound probes

- Will only contact **healthy intact skin**, will not contact mucous membranes, the bloodstream or sterile tissues.
- Require a minimum of **low-level disinfection (LLD)**.
- Example procedures where the ultrasound probe is non-critical include abdominal scans on healthy skin.

Semi-Critical ultrasound probes

- Contact **mucous membranes** or **non-intact skin (e.g. skin with abrasions, dermatitis, chapped skin, rash, psoriasis)**. Semi-critical probes do not contact sterile tissues or the bloodstream.
- Require a minimum of **high-level disinfection (HLD)** so that the device is free from all microorganisms except for a small number of bacterial spores.
- Example procedures where the ultrasound probe is semi-critical include:
 - Endocavity ultrasound of healthy mucosa (e.g., transvaginal, transrectal, transoesophageal echocardiography scans)
 - Abdominal or other diagnostic scans on non-intact skin
 - Surface wound assessment (e.g. partly healed wound).
- **Unless specified by the manufacturer or risk assessed otherwise, semi-critical ultrasound probes must be used in conjunction with a sheath.**^{1-6,10}

Critical ultrasound probes

- Contact or enter **sterile body cavities, sterile tissue or the vascular system**.
- Confer high risk for infection transmission if they are contaminated with any microorganism.
- Require **sterilisation** to be free from viable microorganisms, but if this is not possible use HLD in conjunction with a sterile sheath.
- In general, critical ultrasound probes include those used in surgical procedures and some ultrasound guided interventions (e.g. percutaneous procedures where the probe can contact the puncture site). These invasive procedures require a sterile field and sterile instrumentation as they access sterile body sites.
- **The SCoR/BMUS and ESR guidelines recommend critical ultrasound probes undergo HLD and be used with a sterile sheath.**^{1,8} Alternatively, probes may undergo sterilisation if possible.

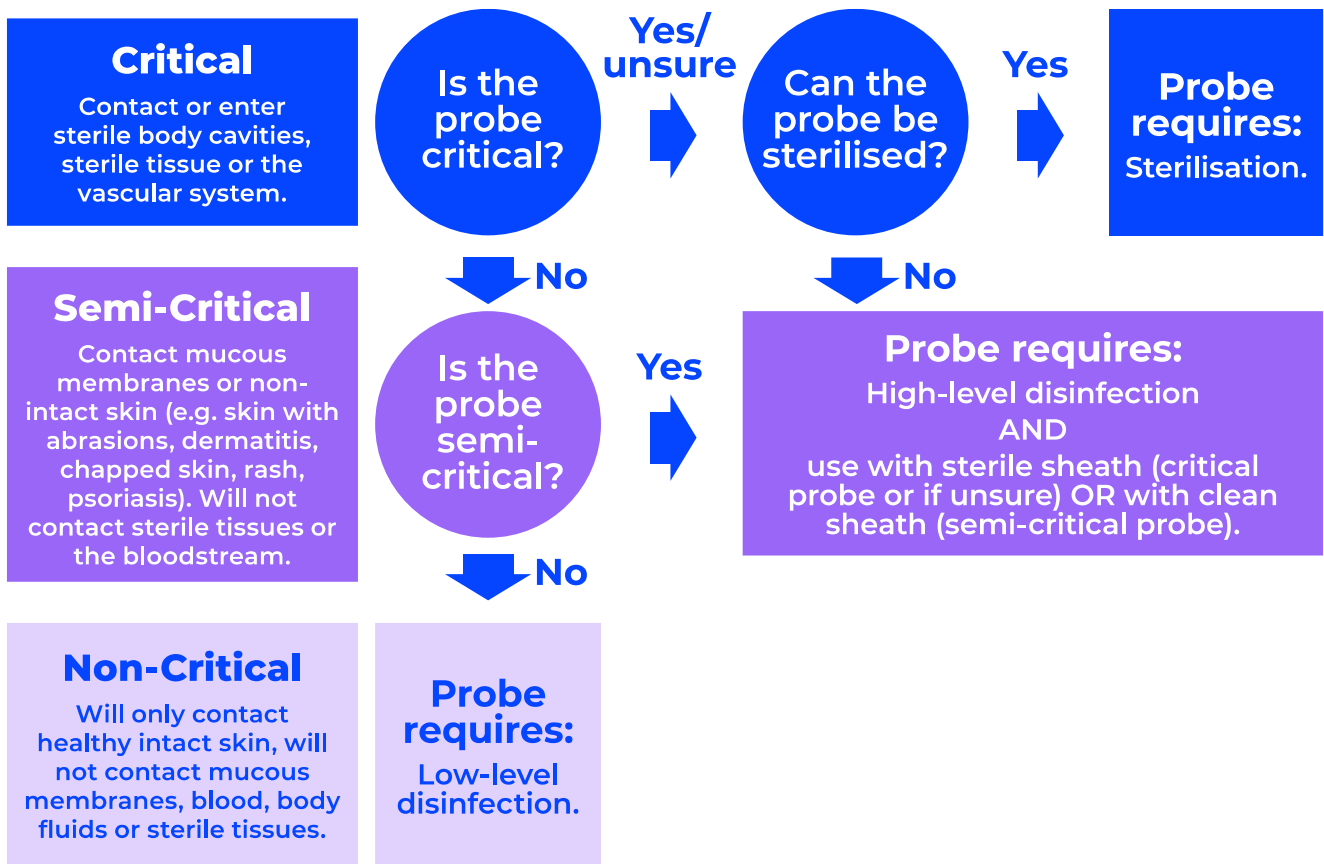


Figure 2. A flowchart decision tree to determine the level of reprocessing and sheath type is required before use of an ultrasound probe on a patient.

Apply the above rationale to the procedures used in your department/facility. List the procedures performed and assign the Spaulding Classification of the probe and sheath and reference or specify the SOP here.

4.2.2 Methods of disinfection and sterilisation

Cleaning is a critical requirement prior to any disinfection/sterilisation process.¹⁻¹⁰ It is important to ensure that disinfection/sterilisation is compatible with the ultrasound probe such that probe integrity is not compromised.

Note the disinfection/sterilisation process used in your department/facility and reference or specify the SOP here.

4.2.3 Validation

All reprocessing steps (cleaning, disinfecting, packing or sterilising processes) should be validated according to national and international standards. Automated reprocessing steps require an installation qualification (IQ), operational qualification (OQ), performance qualification (PQ) and routine monitoring, testing and control.^{4,9,10}

Installation qualification (IQ)

The purpose of IQ is to demonstrate that the equipment supplied to perform HLD/sterilisation and the environment in which the equipment is installed (services qualification, e.g. water quality), comply with the manufacturer's installation specifications. IQ is undertaken by the supplier of the equipment.

Operational qualification (OQ)

The purpose of OQ is to demonstrate the capability of the equipment to deliver the HLD/sterilisation endpoints defined by the IFU, and is also undertaken by the manufacturer or service provider. This is performed without a load, or with a defined test material. OQ is performed immediately after installation, relocation, modification, service change or repair.

Performance qualification (PQ)

The purpose of PQ is to demonstrate that HLD/sterilisation endpoints are met with device loads intended to be reprocessed by the health service organisation. Physical performance qualification (PPQ) and microbiological performance qualification (MPQ) are required to be performed by the organisation. PPQ requires validation that critical physical parameters are achieved, and MPQ requires validation of the microbiological lethality of the process. PQ is performed immediately after IQ and OQ, relocation, modification, service change or repair. The results of PQ are to be monitored and authorised by the User and the AEd.

Routine monitoring and control

The purpose of routine monitoring and control is to ensure the validated processes for the device are delivered to the actual device at every HLD/sterilisation cycle. Types of monitors are shown in *Figure 3*. The IFU should be followed to determine monitor type, frequency, placement and interpretation of results.

Periodic validation in accordance with national and international guidance. HSE/HTM 01/06 requires weekly/quarterly and annual validations. The nature of the work, volume of clinical activity, clinical risks and available resource may dictate that periods of validation are not at the frequency identified within the guidance. Derogation away from recommended practice must be fully agreed with key stakeholders within the organisation to include the Decontamination Lead, Authorised Engineer (Decontamination), User and Ultrasound Governance Lead.

Equipment service:

Systems used to provide HLD/sterilisation must be maintained in accordance with basic principles of manufacturer's recommendations. A PPM regime should be developed and implemented to check and replace when needed all critical components.

Types of validation monitors

Biological indicators

Standardised, viable populations of bacterial endospores are used to determine if sterilisation of the load was successful.

Chemical indicators

A chemical colour change verifies that process parameters were reached in the disinfection cycle to achieve endpoints (automated reprocessing), or verifies the disinfectant had the appropriate concentration before starting the cycle (manual reprocessing).

Physical monitors

These include thermometers, timers or solution test strips to check concentration of active ingredient is at effective levels.

Sterilisation

High-level disinfection

Figure 3. A summary of different types of monitors which can be employed for process validation.

As part of cycle validation, ensure monitor results are documented and stored to facilitate traceability and ensure all staff are trained regularly in their use and interpretation.¹⁻¹⁰

Note the validation processes required in the IFU for your disinfection/sterilisation process and reference or specify the SOP here.

Where biological indicators are used, they must be an inoculated carrier with defined number of definitive viable micro-organism within primary pack to present a stern challenge for the particular medium used for HLD/sterilisation.

Manual reprocessing step

Manual reprocessing requires routine monitoring and control in accordance with local SOPs to include cleaning efficacy testing. In addition, it should be validated if technically possible.

4.2.4 Reprocessing failure

If a reprocessing cycle fails, ensure the probe is not used on the patient and follow the procedure for non-conformance outlined in Appendix IV of HSE Ireland or NHS Scotland Guidance for Decontamination of Semi-critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes.²⁻³

In the event of multiple reprocessing cycle failures, the following may provide a pragmatic approach to resolving the issue and ensuring patient safety is not compromised.

1. Refer to the disinfectant/sterilisation IFU to troubleshoot. If troubleshooting is unsuccessful, document and report the process/device and nature of failure (to the appropriate body i.e. NIAIC, MHRA, MDRA etc.) and remove from service.
2. Head of department, risk management, or infection control department and others per local protocol should be immediately notified. An investigation should be conducted to seek the root cause and assess any patient harm, and a decision made regarding patient notification. Departments'/hospitals' vigilance procedure should be followed.
3. After the problem is corrected, the process/device should be thoroughly validated (via a range of monitors and/or diagnostic cycles) and in accordance with Appendix II of HSE Ireland or NHS Scotland Guidance for Decontamination of Semi-critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes and/or in consultation with the NHS UK/Northern Ireland health technical memorandums before being returned to service.^{2,3,7-9}

Note disinfection/sterilisation process specific steps required in the event of a reprocessing failure at your facility here or reference the SOP.

4.2.5 Rinsing and drying

Sterilisation in terminal barriers (wrapped/boxed) does not require any rinsing or drying. For HLD, refer to the IFU to determine rinsing and drying requirements. Determine the number of rinses (if required), the quality of rinse water that should be used (e.g. sterile or reverse osmosis water) and a drying method that does not compromise the HLD condition.^{2,3,7-9}

List requirements here or reference SOP.

4.2.6 Transport and storage

If the reprocessing workflow requires probe transportation, the following requirements should be met (references HSE Ireland, NHS Scotland):

- The probe cover and any gel should be removed immediately after the examination and prior to transportation.
- Dirty (i.e. contaminated/used) probes should be kept moist using appropriate systems and transported in (lockable/sealed) solid-walled containers with a biohazard label or other means of identifying contaminated status.
- Transport routes should facilitate easy maneuvering and avoid high areas of traffic.

- Disinfected/sterile probes should remain separate from contaminated probes at all times and be transported in clean (lockable/sealed) containers with a label or other means of identifying decontaminated status.
- If transporting on a public road the Carriage of Dangerous Good (CDG) act²⁹ (UK) or Carriage of Uncleaned Reusable Invasive Medical Devices by Road²³ (Ireland) should be complied with.

According to Appendix V of the HSE Ireland and UK guidelines and standards, medical devices after reprocessing should be either immediately used (within three hours as specified as best practice for decontamination of flexible endoscopes⁹ (HTM01-06)) or stored in a manner that maintains HLD status before next patient use.²⁻⁹ Applying this to ultrasound probes, terminally sterilised probes can be stored in their terminal barrier or container they were sterilised in. For probes that have undergone HLD, ensure that:

- The storage location supports the clinical workflow and patient throughput (e.g. on the console, in a cabinet in the treatment room, in a separate room).
- A storage method is selected to prevent contamination from the environment. For example, use a clean single use storage cover when storing on the console or cabinet.
- Probes are dry before being stored.
- Probes are labelled to distinguish whether probe has undergone LLD, HLD or sterilisation and dated (e.g. on the probe storage cover).
- Probes are stored in a manner which will prevent cables and plug (which do not typically undergo HLD or liquid chemical sterilisation) from contacting the probe handle or body.
- A risk assessment should be conducted (in conjunction with infection control team) to determine the maximum storage time for probes.
- If the probe is to be used after the three hour window, it should be fully reprocessed before the next patient use.

High-level disinfected and sterilised items should be protected from recontamination while being transported to their point of use.

Update this section with facility/department specific transportation (if required for the disinfection process used) and storage requirements. Ensure requirements above are addressed and considered. Reference any relevant SOPs.

4.2.7 Traceability

Documentation is essential for retrospective investigations associated with gaps or failures in reprocessing and outbreaks of infection. Documentation, record keeping and monitoring of chemical sterilisation processes and high-level disinfection processes is required for traceability and quality control.¹⁻¹⁰

Traceability processes should be compliant with evidence based standards and guidelines for ultrasound use. According to UK and Irish guidelines, a system must be in place to ensure probes are tracked through the decontamination process and linked to the patient on whom the devices have been used.²⁻³ UK Health Technical Memorandums also require that records pertaining to

cleaning, disinfection, patient use, operator, as well as records relating to qualification and validation are maintained, preferably via an automated system.^{7,8} The following data should be recorded in a readable and retrievable format and linked to the patient the device is used upon in accordance with local records retention policy SOP.

4.2.8 Equipment process

According to UK Health Technical Memorandums for the decontamination of flexible endoscopes, the following data should be recorded and linked to the patient the device is used upon:

Operator

- Operator identity.
- The person responsible for the release of the product and who is giving assurance that the medical device is fit for purpose is recorded.
- Visual inspection (separate operator preferred).

Patient

A record such that the patient identity retrospectively be clearly established against the equipment used and the validated decontamination procedure applied;

- The probe's unique identifier (GS1 where available).
- The reprocessing machine and cycle is recorded.
- Batch number or product code such as to permit the materials or chemistry used in decontamination to be identified.
- Date and time (may be produced by electronic system).
- Evidence that the probe is operating satisfactorily (there is a duty of care on the clinical operator to ensure this is the case).

All reprocessing failures or inconclusive results also need to be recorded and the procedures outlined in '*Inadequate Reprocessing*' followed.

Traceability systems must be routinely audited to ensure details are recorded, readable, retrievable and provide the organisation the required governance and accountability.

Best practice states that traceability systems should be electronic but can be manual. ²⁻¹⁰

The HSE Ireland² states that:

"A system must be in place to ensure Probes are tracked through the decontamination process and linked to the patient on whom the devices have been used. The organisation should work toward implementing an electronic tracking system that will integrate with a national track and trace system for RIMDs." ²

The benefits of completing the above are:

- Should a patient recall be required because of a systems error, having traceability records allows for the appropriate recall to be carried out.
- If a systems error is because of human error, it is possible to identify an employee that may require further training.

- If a systems error occurs, it is possible to identify the machine that requires investigation, servicing or validation.
- If a patient develops an infection post procedure, it is possible to identify which device was used for their procedure.

Update this section with your disinfection/sterilisation process and workflow specific traceability process. Ensure above requirements are met and specify methods and information that needs to be collected, linked, stored and maintained.

5. During an ultrasound procedure

This section expands on probe barrier use and specifies use requirements based on the Spaulding Classification of the ultrasound probe. This rationale should be applied to each procedure in your facility/department and specified.

5.1 General

It is important to ensure all equipment necessary for the procedure is fit for purpose. Additionally, robust protocols should be used to prevent cross-contamination between surfaces, probes, operators and the patient.

It is also important to remember that unexpected changes in patient procedures may occur and will require considering whether the selected probe is still appropriately decontaminated for the upcoming procedure. For example, the patient may present with non-intact skin (e.g. dermatitis, rash or wound) when intact skin was expected. This would make the probe semi-critical instead of non-critical and will consequently require HLD versus LLD.

See *Disinfection and Sterilisation* for assigning the Spaulding Classification to the probe.

5.2 Probe barriers

Probe sheaths (e.g. dedicated covers, condoms) are an additional layer of protection to prevent excessive soiling on the medical device and to minimise the chance of cross-contamination between patients. Sheaths are available sterile and non-sterile (usually clean-room manufactured). Condoms are typically non-sterile.

UK Guidelines require endocavity probes to undergo high-level disinfection and be used with a single use sheath.¹⁻⁴ SCoR/BMUS and ESR guidelines require critical probes undergo sterilisation, and if this is not possible, the probe should minimally undergo HLD and be used with a sterile sheath.^{1,4}

Studies have demonstrated the high frequency of probe sheath perforation rates, occurrences of probe sheath contamination post procedure and difficulties involved with visually determining probe sheath breaches and perforations.¹²⁻¹⁵ HSE Ireland and NHS Scotland reference CDC Guidelines state that use of a probe cover does not negate the need for high level disinfection or sterilisation of the probe:^{2,3,10}

“Do not use a lower category of disinfection or cease to follow the appropriate disinfectant recommendations when using probe covers because these sheaths and condoms can fail.”

See *Disinfection and Sterilisation* for assigning the Spaulding Classification to the probe and the associated cover use.

5.3 Gel use

Ultrasound coupling gel is necessary to allow passage of the ultrasound energy into patient tissues and is required for a good quality image. It is used in almost all ultrasound procedures. As such, SOP describing safe handling and use is paramount to reducing and preventing cross-contamination. Numerous outbreaks from contaminated ultrasound gel have been reported in the literature. In some cases these infections have been associated with invasive procedures such as ultrasound guided central venous catheter placement, pericardiocentesis, amniocentesis and surgeries.¹⁶⁻²¹ Gel is typically available in single-use sachets (sterile and non-sterile) as well as in non-sterile multi-use gel bottles. Careful selection of the correct type of gel is important for preventing infections. A rationale for sterility requirements for gel use can be derived from the Spaulding Classification. For critical items sterile gel should be used for semi-critical, a minimum of single-use clean room manufactured gel should be used, and for non-critical, a minimum of multi-use gel can be used (*Table 2*).

After completion of the procedure, the probe should be immediately cleaned and all visible gel and bioburden removed before subjecting the probe to subsequent reprocessing steps. Relevant staff should have regularly updated competency based training in the use of probe covers and ultrasound coupling gel.

Table 2. Ultrasound gel use during ultrasound guided procedures check vs latest guideline from Public Health England²⁴

Non-Critical probes	Semi-Critical probes	Critical probes
<ul style="list-style-type: none"> Multiuse, non-refillable gel acceptable. 	<ul style="list-style-type: none"> Single-use gel at a minimum Sterile single-use gel mandatory according to Public Health England²⁴ 	<ul style="list-style-type: none"> Sterile single-use gel.
Considerations	Considerations	Considerations
<ul style="list-style-type: none"> Avoid multi-use gel where possible, single-use gels preferred. If used, care should be taken not to touch the patient or probe with the tip of the multi-use gel bottle. Discard multiuse bottles based on facility SOP and IFU. Refillable bottles should be avoided due to established risk of bacterial growth. Generally gel warmers should not be used due to the risk of pathogen growth. If warming of gel is performed, the use of dry heat is preferable to use of water.²³ 	<ul style="list-style-type: none"> Use aseptic technique when handling. 	<ul style="list-style-type: none"> Use aseptic technique when handling Sterile single-use gel is the minimum requirement for invasive procedures where there is risk of the probe and gel contacting sterile tissue and blood.
General considerations (all gel)		
<ul style="list-style-type: none"> Ensure gel is only used within its shelf life Store gel protected from sources of contamination (e.g. dust, moisture) Check before use for evidence of contamination. 		

6. Staff and responsibilities

The levels of staff and corresponding reprocessing responsibilities may vary depending on the size and structure of healthcare facilities. However, staff at all levels should have sound general knowledge of decontamination principles, including basic elements of infection control, microbiology and process chemicals in order to ensure their health and safety obligations.^{7,9} Assigning responsibility for the decontamination processes is important for quality assurance, accountability and effective patient safety.^{2-4,7,9}

6.1 Management

Management have oversight responsibility for all elements of the decontamination process and to ensure adherence and compliance with this SOP.

HTM 01-01²⁵ Definition:

“6.48 The Senior Operational Manager is technically, professionally and managerially responsible (and accountable to the Decontamination Lead) for the engineering aspects of decontamination (for example, decontamination equipment and the environment).”

6.2 User

The user is responsible for ensuring that all periodic testing and maintenance of both the probes and any decontamination equipment is carried out as per agreed schedule and that records/ reports are retained safely. They are also responsible for ensuring probes are appropriately decontaminated, fit-for-purpose and safe for reuse.²⁻³.

HTM 01-01²⁵ Definition:

“6.49 The User is defined as the person designated by Management to be responsible for the management of the process. The User is also responsible for the Operators.

6.50 In the acute sector, the User could be a sterile services manager.

6.51 The principal responsibilities of the User are as follows:

- *to certify that the decontamination equipment is fit for use;*
- *to hold all documentation relating to the decontamination equipment, including the names of other key personnel;*
- *to ensure that decontamination equipment is subject to periodic testing and maintenance;*
- *to appoint operators where required and ensure that they are adequately trained;*
- *to maintain production records;*
- *to establish procedures for product release in line with the quality management system;*
- *to ensure that procedures for production, quality control and safe working are documented and adhered to in the light of statutory requirements and accepted best practice.*

6.52 The User may seek the advice of infection control teams, which may consist of a DIPC, Infection Control Doctor or Microbiologist (Decontamination).”

Specify supervisory personnel (profession level) at your facility/department here.

6.3 Reprocessing personnel (operators)

Processing personnel should have documented competence in relevant cleaning methods and microbiocidal processes and must be trained by the supplier of equipment related to the specific HLD/sterilisation process used in the department. Furthermore, they should have knowledge of general disinfection/sterilisation and infectious disease transmission principles and aspects of safe use of liquid/chemical HLD/sterilisation (if relevant), such as:^{2,3}

- Probe decontamination.
- Safe Chemical use and disposal.
- Inspection of cleaning, drying and rinsing processes.
- Manual handling.
- Monitoring of HLD/sterilisation processes.
- Maintaining documentation for traceability purposes.
- Recording and reporting adverse incidents.
- Occupational injury management (for example, percutaneous injury, eye splash, aerosols).
- Safety with regard to using the equipment and personal hygiene.
- Use of PPE to protect skin, eyes, mucus membranes, clothing, and maintain HLD/sterilisation integrity.
- Transportation and storage.

HTM 01-01²⁵ Definition:

“6.65 The Operator is defined as any person with the authority to operate decontamination equipment, including the noting of instrument readings and simple housekeeping duties.

6.66 Operators should have their tasks defined in their job description. Operators should also have documented training records to demonstrate that they are competent at undertaking their assigned tasks.”

For training recommendations see the paragraph below.

Specify reprocessing personnel (profession level) at your facility/department here.

6.4 Training

As stated in HTM01-01, *“all staff, including managers, directly or indirectly involved in decontamination of surgical instruments to be competent on the basis of appropriate education, training, skills and experience.”*

Staff involved in reprocessing and ultrasound equipment usage should receive documented competency-based orientation and induction training prior to commencing decontamination responsibilities. Additionally, annual update training should be performed for the duration of their employment.

Training should be provided by authorised suppliers of cleaning solutions, decontamination equipment and any organisation accredited for education within the decontamination field.

Training should establish the knowledge base required to safely perform reprocessing and use ultrasound in procedures with the goal of removing operator error, promoting staff and patient safety and ultimately mitigating infection transmission risks.^{2-3,7,9}

This training should be documented

For training requirements and schedule refer to 6.3.

7. Evaluating changes to products and processes

All aspects of this SOP should be reviewed with infection prevention and other relevant subject matter experts when setting up the use of ultrasound for the first time, purchasing new ultrasound equipment or making changes to existing processes. Additional considerations are:

Safety – The Irish and Scottish guidelines require staff and patient safety must not be compromised by the chosen reprocessing workflows and processes.²⁻³ Consider chemical exposure risks from bulk liquids and vapours. Work area design considerations must be assessed (e.g. ventilation, designated dirty/clean sinks, hazardous waste disposal units, emergency showers) if required.

Evidence – Effectiveness of the chosen decontamination system must be demonstrated with validation of the process.²³

Compatibility - Healthcare organisations should ensure compatibility in regards to the probe reprocessing instructions, including written statement from the chemical/equipment manufacturer regarding compatibility with specific brands and models of probes.

Cost – Financial factors related to chemical/equipment (e.g. purchase, validation, running costs and maintenance) should be evaluated with respect to financial risk, patient benefit, and value for money.²⁻³

Reprocessing time – Consider time required to examine patients versus time for reprocessing. If there is high patient turnover it may be necessary to adapt the reprocessing schedule or purchase additional probes for efficient turnaround time.

Reprocessing location – If probes are reprocessed at point of use, then the disinfection method must be safe for patients and staff. The UK, Irish and European Standards and Guidelines require a dirty to clean workflow during reprocessing.²⁻³ This should be observed regardless of reprocessing location with designated dirty and clean areas to prevent cross-contamination. If transport of dirty or clean devices is required to a central reprocessing area, then a probe transportation protocol must be observed to prevent mixing of dirty and clean instruments (See *Transport and Storage*).

Automated or manual reprocessing – Consideration should be given to automated versus manual processes. There is a strong preference for automated processes in Ireland^{2,24} and the UK¹⁻³ and it is well accepted that validated automated decontamination processes minimise the influence of human factors on reprocessing outcomes and should be adopted where possible.²²

References

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