

Health Service Executive

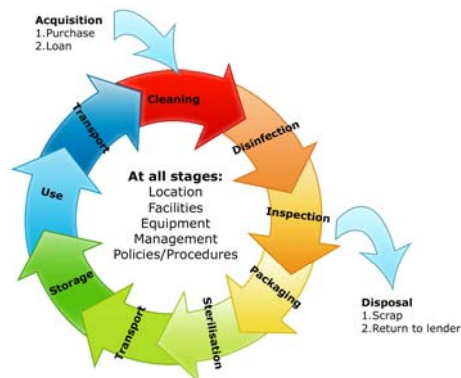
Guidance for

Decontamination of Semi-critical

Ultrasound Probes;

Semi-invasive and Non-invasive

Ultrasound Probes



Tús Áite do
Shábháilteacht 1 Othar
Patient Safety 1 First



Feidhmeannas Seirbhíse Sláinte
Health Service Executive

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Terminology and Acronyms used within the Guidance Document

“Semi-critical” the device is a reusable medical device which comes into contact with a mucous membrane or broken skin under the Spaulding Classification.³ The Spaulding Classification system is used to determine the infection risk associated with used medical devices and the associated decontamination method required. For the purposes of this guidance document Semi-invasive Ultrasound Probes and Non-invasive Probes in contact with broken skin are categorised as Semi-critical devices.

“Semi-invasive Ultrasound Probe” is an Ultrasound Probe which is used to ultrasound scan internal organs via non-sterile natural orifices i.e. the oesophagus, the vagina and the rectum. These are not sterile areas however the probes must undergo high level disinfection to ensure the probes are sufficiently decontaminated prior to use on the next patient.

“Non-invasive probe” is an Ultrasound Probe which is manufactured with the intention of scanning the patients skin to determine any underlying structures/anomalies. However the advancement of ultrasound scanning means they are increasingly used for scanning the skin which can be broken through the insertion of vascular devices or for the assessment of complex wounds. This increases the risk of contamination of the probe with blood which requires a high level disinfection process.

The terms **“Responsible Person”** and **“Operator”** are distinct and defined terms used throughout this guidance and associated procedures.

The **“Responsible Person”** is the Manager responsible for ensuring the probes are decontaminated, fit-for-purpose and safe for re use on the patient (e.g. Unit Manager, Lead Sonographer or Senior Charge Nurse).

The **“Operator”** is the person physically performing the decontamination processes (e.g. Sonographer, Nurse or Healthcare Worker). Equally it is the responsibility of the Operator to ensure decontamination procedures are performed according to HSE Guidelines and manufacturer instructions. An **“Operator”** is not a **“Responsible Person”**. However, in small units or in exceptional circumstances a **“Responsible Person”** can be an **“Operator”** if sufficiently trained.

AE(D) Authorising Engineer for Decontamination

CDU Central Decontamination Unit

EDU Endoscope Decontamination Unit

EWD Endoscope Washer Disinfector

HCAI Healthcare Associated Infections

HCW.	Healthcare Worker
HIQA	Health Information and Quality Authority
HLD	High Level Disinfection
IPCT	Infection Prevention and Control Team
PPE	Personal Protective Equipment
RIMD	Reusable Invasive Medical Devices
SIUP	Semi-invasive Ultrasound Probe
TOE	Transoesophageal Echocardiography
TR	Transrectal
TV	Transvaginal

1. Purpose

The Health Information and Quality Authority (HIQA)¹³ is an independent authority established to drive high quality safe care for people using our health services in Ireland. HIQA's role is to develop standards, inspect and review health services, and support informed decisions on how services are delivered. HIQA's ultimate aim is to safeguard people using services and improve the quality and safety of services across its full range of functions.

This guidance document sets out the operational procedures to support safe decontamination of Semi-critical Probes using High Level Disinfection (HLD) ensuring decontamination and infection prevention and control practice reflects national and international evidence of what is known to achieve best outcomes for patients. This guidance document covers specifically; Semi-invasive Ultrasound Probes (SIUPs) and Non-invasive Ultrasound Probes used in semi-critical procedures.

- SIUPs;
 - Transoesophageal Echocardiography (TOE);
 - Transvaginal (TV) and
 - Transrectal (TR) Ultrasound Probes.
- Non-invasive probes used on broken skin, for example;
 - for vascular access;
 - cannulation or
 - wound assessment.

The Guidance and Recommended Practices for decontamination of Semi-invasive Ultrasound Probes (SIUPs) and Non-invasive Ultrasound Probes used in semi-critical procedures were developed as follows:

- Extensive literature search.
- Consideration of the opinion of experts knowledgeable in the subject.
- Consideration of the available current best practice, both in Ireland and internationally, that may impact on decontamination of Semi-critical Ultrasound Probes
- Development of a draft Guidance document for distribution to key stakeholders for consultation.
- Feedback considered and where appropriate, incorporated into the current version of the Guidance document.

Throughout the guidance document and associated appendices and procedures the term “Probes” will be used when referring to general Probe Guidance. Where specific Probes are required to be discussed they will be mentioned specifically.

- The generic Appendices I—VI inclusive are intended to provide healthcare workers with the procedures required for the full decontamination process.
- An algorithm has been included as Appendix VII for healthcare workers involved in using and/or decontaminating Semi-critical Probes.
- The algorithm provides a poster representation to be used in the clinical and decontamination area for healthcare workers to use as a quick reference guide.
- A further three decontamination procedures detailing three different methods of HLD (Hydrogen Peroxide mist, ultraviolet-C light and manual multi-wipes) have been produced.

Appendices

- Appendix I Purchasing Ultrasound Probe decontamination systems
- Appendix II Validation, testing and maintenance of Ultrasound Probe decontamination systems
- Appendix III Training of healthcare workers involved in decontamination of Ultrasound Probes
- Appendix IV Procedures for release of disinfected Ultrasound Probes
- Appendix V Transport and storage of Ultrasound Probes
- Appendix VI Decommissioning and disposal of Ultrasound Probe decontamination equipment
- Appendix VI Decontamination algorithm for Ultrasound Probes

Decontamination Procedures

Decontamination Procedure for HLD using Hydrogen Peroxide system

Decontamination Procedure for HLD using Ultraviolet-C light system

Decontamination Procedure for HLD using Manual Multi-wipe system

2. Background

Ultrasound Probes are increasingly becoming a cornerstone in the diagnosis and treatment of patients in healthcare settings. Despite the beneficial impact on patient care, infection control concerns exist over the use of Probes and their role as a vector for pathogen transmission.¹ Under the Spaulding Classification Ultrasound Probes that come into contact with broken skin or intact mucous membrane are considered semi-critical devices and should undergo manual cleaning followed by High Level Disinfection (HLD) between patient use.^{2;3} This decontamination process significantly reduces microbial contamination (i.e. mycobacteria, fungi, viruses and bacteria) and renders it safe for reuse, although small numbers of bacteria spores may still be present.^{2;3}

The Health Information Quality Authority's 'Report on Unannounced Inspections' in 39 hospitals (2015), highlighted the need to focus on areas in hospitals where high risk invasive procedures are carried out. The report identified that in areas, such as interventional radiology, where Semi-critical Probes were in use, that infrastructure did not always support the implementation of best infection prevention and control practices.

In one interventional radiology department inspected, HIQA was not assured that practices — for disinfecting intracavity transducer Probes, such as Transrectal and Transvaginal probes, used during ultrasound diagnostic examinations — were in line with best practice. "The minimum acceptable standard for reprocessing these Transducer Probes is manual cleaning followed by high-level disinfection. Probes must be fully cleanable and be cleaned appropriately prior to disinfection in appropriate facilities" (HIQA, 2016).

In addition, a national survey of TOE, TV and TR Ultrasound Probes across NHS, conducted by Health Facilities Scotland (HFS) in 2012, concluded that there is an on going risk to patient safety with regard to decontamination of these SIUPs.

(Note: HLD using the manual multi-wipe system is the least preferred option for disinfecting SIUPs. Internationally it is recognised that the use of an automated validated process for decontaminating RIMD will provide enhanced risk reduction of infection transmission. It is recommended that a local risk assessment is performed if this option is to be used as an interim measure prior to implementation of an automated process)

3. HIQA Standards for Safer Better Healthcare

The Health Information and Quality Authority (HIQA) has developed the National Standards for Safer Better Care to describe what a high quality, safe service looks like. Improving the quality of care and providing a safe working environment are thus fundamental activities for the Health Service Executive (HSE). Prevention and control of Healthcare Associated Infection (HCAI) is central to these activities. Senior Managers must ensure that they have effective systems in place in their healthcare facilities to minimise the risks of infection to service users and staff.

Themes= The Health Information Quality Authority identify 8 themes for quality which are intended to work together. Collectively, these themes describe how a service provides high quality, reliable safe care for the service user. The four themes on the upper half of Figure 1 relate to dimensions of quality and safety and the four themes on the lower half of the figure relate to key areas of capacity and capability.

Decontamination practices in healthcare settings are aligned to all 8 themes, however, Theme 2 Effective Care and Support and Theme 3 Safe Care and Support are the key dimensions of quality and safety needed to support the delivery of safe decontamination services in healthcare settings.

Figure 1: Themes for Quality and Safety



Standards = term used by the Health Information Quality Authority and the Health Service Executive to describe the high-level outcomes required to contribute to the quality and safety of decontamination services.

Features = term used by the Health Information Quality Authority to describe elements of a standard that when taken together, will enable progress toward achieving the standard.

Recommended Practices = recommendations concern best practice in relation to the decontamination process. The Recommended Practices are intended to define correct decontamination practice and to promote service user and staff safety. They are also intended to serve as the basis for policy and procedure development in decontamination services within healthcare facilities.

How do HIQA Standards relate to decontamination of Semi-critical Ultrasound Probes?

Theme 1: Patient Centred Care and Support

Standard 1.1

Healthcare professionals effectively communicate with their patients about prevention, control and management of HCAI

Theme 2: Effective Care and Support

Standard 2.1

Decontamination and infection prevention and control practice reflects national and international evidence of what is known to achieve best outcomes for patients.

Theme 3: Safe Care and Support

Standard 3.1.1

An effective risk management strategy is in place to protect and minimise potential Healthcare Associated Infection risks from the service to patients.

Standard 3.1.4

Systematic identification of aspects of the delivery of care associated with possible increased risk of harm to service users and structured arrangements to minimise these risks including management and use of Semi-critical Ultrasound Probes and decontamination equipment.

Standard 3.1.6

Safe and effective management of medical devices in accordance with legislative requirements, national policy/guidelines and best national/international evidence.

Theme 6: Workforce Planning

Standard 6.3

Service Providers ensure their workforce have the competencies to deliver high quality safe effective care.

What does this mean to the patient?

The service is always looking for ways to make your healthcare safer.

The service is not just reacting when things go wrong-it is actively looking for ways to make the way it provides care safer.

The service learns from international and national evidence about the best ways of keeping you safe.

The service uses information relevant to the provision of safe services to inform continuous improvement of the safety of the service.

Theme 1: Patient Centred Care and Support

Standard 1.1

Healthcare professionals effectively communicate with their patients about prevention, control and management of HCAI

Features of a service meeting this Standard include:

Clear communication with every patient and their relative/carer throughout the care pathway about the importance of the prevention, control and management of infection, including HCAs.

Support and encouragement for patients and or relatives/carers to provide feedback, raise concerns or make complaints.

Theme 2: Effective Care and Support

Standard 2.1

Decontamination and infection prevention and control practice reflects national and international evidence of what is known to achieve best outcomes for patients.

Features of a service meeting this Standard include:

All Semi-critical Ultrasound Probes are safely and effectively decontaminated in keeping with legislation, national recommendations, standards and quality improvement initiatives that are based on best available evidence.

Development of local policies, procedures and protocols is consistent with current national guidelines and adheres to an evidence-based process. These are updated at least every 2 years and upon publication of new guidance.

Theme 3: Safe Care and Support

Standard 3.1.1

An effective risk management strategy is in place to protect and minimise potential HCAI risks from the service to patients.

Features of a service meeting this Standard include:

Implementation of evidence based clinical practice guidance and relevant legislation by the service to identify and manage occupational risks for exposure to HCAs and injuries.

The Health and Safety Authority Guide to the European Union Regulations (2014) “Prevention of Sharps Injury in the Health Sector” recognises that personnel working in decontamination practice are at risk of sharps or percutaneous injury.

Staff are facilitated to comply with standard precautions in all healthcare settings, for all patients, whether infection is known to be present or not. Staff are aware of the correct indications for application of personal protective equipment, including requirements for exposure prone procedures.

Access to an occupational health service is available for all staff.

Staff are informed of the benefits and drawbacks of vaccination and failure to vaccinate. It is recommended that as a minimum that all staff who are at risk through contact with blood and/or body fluids should be immunised against HBV, unless immunity has been previously established or vaccination contraindicated. An annual record is maintained of all staff uptake of influenza vaccination, in line with data protection legislation.

Systemic identification of potential risk factors associated with staff acquiring a HCAI. These include but are not limited to:

- Skin conditions such as dermatitis or other skin conditions that causes a break in skin integrity;
- allergies to products such as latex and hand hygiene products;
- exposure prone procedures;
- high risk settings such as decontamination and
- current infection, vaccination refusal/non-responder.

Theme 3: Safe Care and Support

Standard 3.1.4

Systematic identification of aspects of the delivery of care associated with possible increased risk of harm to service users and structured arrangements to minimise these risks. Including management and use of Semi-critical Ultrasound Probes and decontamination equipment.

Features of a service meeting this Standard include:

Facility: Best practice identifies that decontamination should be performed in a suitable location external to the clinical treatment area. This area facilitates the separation of clean and dirty activities. When designing a new local decontamination unit there must be dedicated non-clinical space provided for decontamination of Semi-critical Ultrasound Probes, to minimise opportunities for cross-infection of service users, clinical staff and cross-contamination of the working environment.

Appropriate arrangements are in place to support safe effective use of decontamination equipment associated with the reprocessing of Semi-critical Ultrasound Probes.

Use of a sheath/condom does not negate the need for Probes to undergo manual cleaning prior to HLD as there is limited evidence on their effectiveness as a barrier to reducing the risk of HCAI. A sheath should be used for diagnostic purposes in accordance with manufacturers' instructions and should be the correct size for the Probe to be used. The sheath should be visually inspected for damage after use. Where damage is identified it should be recorded in the decontamination records/patient notes.

All Semi-critical Ultrasound Probes are CE approved.

Single use devices are never reused.

All equipment used to decontaminate medical devices is CE approved and conforms to relevant European Standards.

Installation, commissioning servicing and annual revalidation of decontamination equipment is in compliance with European Standards, National Guidance and the Medical Device Directive 93/42/EEC.

Decontamination of Semi-critical Ultrasound Probes complies with manufacturer's instructions.

Theme 3: Safe Care and Support

Standard 3.1.6

Safe and effective management of medical devices in accordance with legislative requirements, national policy/guidelines and best national/international evidence.

Features of a service meeting this Standard include:

Cleaning and Disinfection: HLD using the manual multi-wipe system is the least preferred option for disinfecting Semi-critical Ultrasound Probes. Internationally it is recognised that the use of an automated validated process for decontaminating RIMD will provide enhanced risk reduction of infection transmission. It is recommended that a local risk assessment is performed if this option is to be used as an interim measure prior to implementation of an automated process.

Semi-critical Ultrasound Probes must be compatible with the detergents and decontamination methods that are used.

Commissioning and Validation: At a minimum decontamination equipment must be installed and commissioned by a Competent Person who provides documented evidence that they have been trained to commission and validate this equipment. Thereafter the Responsible Person will ensure that at a minimum an annual validation and service of all decontamination equipment is performed by a Competent Person. All commissioning, servicing and re-validation and documents must be retained by the Responsible Person for 11 years plus the lifetime of the equipment. Review documentation to ensure it is compliant to all relevant national and international standards.

Records are established and maintained to demonstrate the efficacy of the decontamination process and to identify the remedial action undertaken following failure of any part of the decontamination process. The Operator is responsible for recording any non-conformances with the decontamination process.

Tracking and Traceability: 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 the National Electronic Track and Trace system for RIMD's.

Theme 6: Workforce Planning

Standard 6.3

Service Providers ensure their workforce have the competencies to deliver high quality safe effective care.

Features of a service meeting this Standard include:

Training and Education: A formal mandatory induction programme for the workforce which includes a focus on communication and safety of users. Facilitation of each member of the workforce involved in decontamination of SIUP's in maintaining and developing their competencies to fulfil their roles and responsibilities in delivering high quality and safe care. Regular reviews of the development needs of the workforce to deliver high quality safe care and taking action to address and identified gaps in decontamination training.

Personnel who are involved in the decontamination of SIUP's and non-invasive Ultrasound Probes (Responsible Person/Operator) must receive documented training on the methods of decontamination and use of equipment. In addition, the Responsible Person/Operator must be trained by the supplier of this equipment, regarding the evidence that is needed to demonstrate that the load has been through an effective cleaning and HLD process.

4. Literature review on the decontamination of Semi-invasive Ultrasound Probes

A survey of Ultrasound Probe decontamination practices in Europe, by Nyhsen and Humphreys *et al.* (2016),¹⁴ identifies that there is a need to have a standardised approach to Ultrasound Probe decontamination to minimise the risk of infection transmission. A scientific literature review was undertaken by Health Protection Scotland (2012) and the HSE National Decontamination Advisory Group on the decontamination of Semi-invasive Ultrasound Probes which found that SIUPs present a number of challenges in terms of decontamination. Many cannot be sterilised as they are delicate, expensive, heat sensitive devices with electrical components that cannot withstand standard heat and steam decontamination techniques.^{4;5} However, unlike most Flexible Endoscopes, SIUPs have parts (e.g. handle, electrical components) that cannot be immersed in any liquid for cleaning or disinfection as this could result in corrosion or damage to electrical connections.^{5;6} Some Endoscope Washer Disinfectors (EWDs) can accommodate TOE probes by allowing immersion of the probe shaft in fluids, while protecting the handle and socket from exposure to fluids, however the handles still require manual decontamination.^{5;6} More recent developments in TOE Probe decontamination systems have seen the introduction of Washer-Disinfectors specifically designed to reprocess TOE Probes however, non-immersible parts (e.g. Probe cable, electrical image box) must be manually decontaminated as per manufacturers instructions; in addition, electrical safety tests must be carried out as per manufacturers instructions.

Studies have shown residual contamination on SIUPs when HLD is not performed and cases of cross infection have been reported where transmission was thought to have been caused by improper reprocessing of ultrasound transducers.^{5;7}

The standard of SIUP decontamination across the HSE and NHS Scotland is inconsistent, difficult to validate and does not give assurance of the recommended high level disinfection of SIUPs, meaning SIUPs remain a possible cross infection risk. In addition, the Medicines and Healthcare Products Regulatory Agency (MHRA) released a Medical Device Alert Ref: MDA/2012/037 on the 28th June 2012 in relation to the decontamination of reusable TOE, TV and TR Ultrasound Probes (transducers) in response to the death of a patient from hepatitis B which may have been associated with a failure to appropriately decontaminate a TOE probe.⁸

Use of sheaths

The CDC guidelines for the disinfection and sterilisation in healthcare facilities states “when probe covers are available, use a probe cover or condom to reduce the level of microbial contamination. Do not use a lower category of disinfection or cease to follow the appropriate disinfectant recommendations when using probe covers because sheaths and condoms can fail”.³

Summary

This Guidance Document provides HSE healthcare organisation with an evidence based approach to the decontamination of Semi-critical Probes. The guidance has incorporated the findings of the 2012 Health Facilities Scotland study, the recommendations from the MHRA Medical Device Alert (2012), the evidence from a full systematic literature review on the decontamination of SIUPs, conducted by HSE and NHS Scotland and the expert opinion of the National Decontamination Advisory Group including findings from the HIQA Report on Unannounced Inspections in 2015 (published March, 2016).

5. Roles and responsibilities for healthcare workers involved in the management and decontamination of Semi- critical Ultrasound Probes (Semi-invasive and Non- invasive).

5.1 Decontamination Lead/Nominated Person is responsible for:

- Supporting the overall decontamination of RIMD for the healthcare facility (for example, Decontamination Manager or Infection Control Manager).
- Guiding and supporting the delivery of effective and technically compliant decontamination services for Probes in accordance with best practice guidance.
- Supporting the Responsible Person in the implementation of an operational policy for decontamination of probes in accordance with local policies.
- Supporting the Responsible Person together with the Infection Prevention and Control Team (IPCT) in monitoring the implementation of the policy.

5.2 Responsible Persons role includes:

- The safe decontamination of Probes rests with the person designated as the “Responsible Person” (e.g. Unit Manager, Lead Sonographer or Senior Charge Nurse (SCN)).
- The Responsible Person ensures that the management of Probe decontamination is in accordance with equipment manufacturer’s instructions, the Probe manufacturer’s instructions and this HSE Guidance Document which covers the entire decontamination equipment life cycle from acquisition to disposal.
- Responsible Person must seek support/link with the Decontamination Lead and the IPCT to ensure safe decontamination processes are in place.

- The Responsible Person must ensure that planned preventative maintenance, repair and validation of decontamination equipment, including routine maintenance and testing of Probes is performed in accordance with manufacturer instructions and best practice guidance.
- Maintenance of validation records and traceability records for the lifetime of the equipment plus 11 years.

5.3 Operator is responsible for:

- Performing Probe decontamination procedures; decontamination equipment cleaning; ensuring Probes are fit for reuse on the patient and maintaining records for traceability purposes (i.e. Sonographer, Nurse or HCW).
- The Operator should be trained in Probe decontamination and deemed competent by the Responsible Person (Unit Manager), (Appendix III; training for healthcare workers undertaking Semi-critical Ultrasound Probe (Semi-invasive and Non-invasive) decontamination).

6.0 Decontamination Policy for Semi-critical Ultrasound Probes (Semi-invasive and Non-invasive)

6.1 Semi-critical Probes must be manually cleaned prior to using a HLD method.

There are four HLD methods available (in no particular order of preference):

Using Ultraviolet Light:

- Semi-critical Ultrasound Probe (Semi-invasive and Non-invasive) High Level Decontamination Procedure.

Using Hydrogen Peroxide:

- Semi-critical Ultrasound Probe (Semi-invasive and Non-invasive) High Level Decontamination Procedure

Endoscope Washer Disinfectors:

- (EWD) can be modified to accommodate TOE Probes. This method of decontamination must be undertaken following approval of the TOE Probe manufacturers and the EWD manufacturers to ensure compatibility and that probe warranties are not compromised. Areas using EWD for reprocessing TOE probes must ensure validated processes are in place to provide assurance that HLD has been achieved. Responsible Person must note that, despite using an EWD for decontamination of TOE Probes, a manual cleaning and disinfection of Probe handles must be in place.

Using Manual Multi-wipes:

- Semi-critical Ultrasound Probe (Semi-invasive and Non-invasive) High Level Decontamination Procedure. This is the least preferred option for decontaminating SIUP's.

6.2 Purchase of a Probe decontamination system should be based on the following criteria:

- Evidence to support effectiveness of the decontamination system.
- Training supports, to ensure effectiveness of the decontamination process
- Safety of use (for healthcare workers and patients) of the decontamination system including any possible process residue.
- Compatibility with the range of Ultrasound Probes.
- Validation of disinfection process and suitability within the clinical setting.

- Compatibility of wipes used for cleaning/disinfecting all surfaces of the decontamination equipment.
- Costs (purchase and maintenance).
- Environmental and energy impacts.

(Note: Ensure the number of Probes purchased for a particular machine meets the decontamination turnaround times. The purchased Probes must be compatible with the decontamination processes available in the hospital with emphasis on automated validated processing)

6.3 Purchase of a Probe decontamination system (Appendix I)

The Procedure for purchase of a Semi-critical Ultrasound Probe (Semi-invasive and Non-invasive) decontamination system is the responsibility of the Responsible Person (Unit Manager) and undertaken with advice from the Decontamination Lead, Procurement Lead/Manager, Authorising Engineer Decontamination (AE(D)), medical physics and infection control microbiologist/nurse with regard to the criteria stated in **6.1** and **6.2**.

6.4 Probe decontamination is carried out in accordance with the manufacturers

operational instructions for their decontamination systems, the re-processing instructions provided by the probe manufacturers and this guidance document. Should conflicting advice occur the Responsible Person should discuss the issue with the Decontamination Lead and the Infection Prevention and Control team (IPCT) and a solution agreed. This should be done in collaboration with Probe and decontamination system manufacturers.

6.5 Probes that can be disconnected (where recommended by the manufacturer) from the ultrasound machine should be purchased as a matter of preference where possible. This is to allow used probes to be transported to a designated decontamination area for reprocessing, reducing cross infection risks to patients and health and safety risks to healthcare workers (Appendix I).

6.6 Compatible probe sheaths/condoms

Use of a sheath/condom does not negate the need for probes to undergo manual cleaning and HLD as there is limited evidence on their effectiveness as a barrier to reducing the risk of HCAI. A sheath should be used for diagnostic purposes in accordance with manufacturers' instructions and should be the correct size for the Probe to be used. The sheath should be visually inspected for damage after use. Where damage is identified it should be recorded in the decontamination records/patient notes.

- 6.7 Decontamination equipment is validated, tested, maintained and operated** in keeping with the latest relevant standards and guidance and manufacturer's instructions. Validation, testing and maintenance of probe decontamination systems is the responsibility of the Responsible Person (Unit Manager) with guidance and support provided by the Decontamination Lead and the Infection Prevention and Control Team. The process for validation should be followed in line with chosen decontamination procedures (Appendix II and Decontamination Procedures for HLD).
- 6.8 Records are established and maintained** to demonstrate the efficacy of the decontamination process and to identify the remedial action undertaken following failure of any part of the decontamination process. The Operator is responsible for recording any non-conformances with the decontamination process. The Responsible Person (Unit Manager) is responsible for establishing and ensuring records are maintained and up to date. Records are securely stored either in electronic or paper format and readily accessible to permit traceability (for probes, decontamination equipment and patients). Guidance on record keeping can be found within the appendices and procedures where applicable. SIUP's must be tracked through the decontamination life cycle and linked to the patient on whom the device has been used.
- 6.9 All healthcare workers undertaking probe decontamination are trained** and their competence assessed by the Responsible Person in the relevant procedures and training is recorded (Appendix III).
- 6.10 Probes, their accessories, leads and connectors should be decontaminated prior to the first use of the day**, between patients and following the last patient of the day regardless of being stored on the ultrasound machine or in storage containers recommended by the manufacturers (this should not be the manufacturers carry case).
- 6.11 Probe decontamination should be conducted away from the clinical area** in a dedicated decontamination room where possible. However, it is recognised that due to limitations in some healthcare facilities and possible operational constraints, probe decontamination is carried out in the clinical area. If unable to relocate decontamination away from the clinical area then the Responsible Person, Decontamination Lead and the local IPCT should be involved in the risk assessment and development of local protocol and processes to minimise risk .

Where this is the case the HCAI risk assessment should be placed on the local Risk Register by the Responsible Person in the ongoing pursuit of the preference for a dedicated decontamination room.

The design of the decontamination facility used, be it in a separate room or incorporated in a clinical procedures room, must have a clearly designated flow from used (dirty) through to clean.

(Note: Mechanisms should be put in place to facilitate the decontamination of SIUP's in an Endoscope Decontamination Unit or a Central Decontamination Unit or at minimum external to the clinical treatment area. Adequate numbers of Probes should be purchased to allow effective turn around times)

6.12 Probe decontamination should be undertaken following the procedure for either;

- an ultra-violet light decontamination system;
- a Hydrogen Peroxide decontamination system or
- a manual multi-wipe system (the least preferred method).
- Use of an EWD within the Endoscope Decontamination Unit (EDU).

For departments using an EWD for the decontamination of TOE Probes local procedures should be in place for the pre cleaning of Probes and accessories. This should be agreed with the Decontamination Lead and the IPCT in accordance with Appendix V, Transport and Storage of Ultrasound Probes.

This will ensure the appropriate steps are taken for transport to and from the Endoscope Decontamination Unit (EDU) where the TOE probe will be reprocessed by trained decontamination healthcare workers. The procedure also describes the procedure for storage of TOE Probes on return to the unit.

An algorithm is available (Appendix VII) for the decontamination of Semi-critical: Semi-invasive and Non-invasive Probes using HLD. This can be printed as a poster for display within the clinical area and supports the three decontamination system procedures described.

6.13 The product (probe) release procedure defines the acceptance criteria to be met before the Probes are fit for reuse on the next patient. The product release procedure is performed by the Operator and monitored by the Responsible Person in line with Appendix IV.

For TOE Probes decontaminated within an EWD the product release will be performed by the healthcare workers within the decontamination facility and all local procedures must be followed before the TOE Probe is returned to the department for use.

- 6.14 Probes are returned to the ultrasound machine for storage following cleaning of the probe holder on the ultrasound machine** (Appendix V). Any additional probes should be transported clean and dry in a designated container (i.e. an Endoscope transport tray) to a designated storage area. The area for storage of clean Probes should be either provided by or recommended by the manufacturer. Manufacturer's instructions should be consulted regarding storage of Probes. If this guidance and manufacturer's instructions are contradictory the Responsible Person should discuss the issue with the Decontamination Lead, the manufacturer and the IPCT.
- 6.15 Tracking and Traceability**
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 the National Electronic Track and Trace system for RIMD's.
- 6.16 Decontamination equipment sent away for repair** should be cleaned/disinfected in accordance with manufacturer's instruction and be accompanied by a decontamination certificate.
- 6.17 Transport and Storage** of Semi-critical Probes should be followed in line with Appendix V.
- 6.18 Decommissioning and disposal of Probe decontamination systems** should be carried out by the organisation in line with local governance arrangements and monitored by the Responsible Person. Decommissioning and disposal of Probe decontamination systems should be followed in line with procedures recommended in Appendix VI.
- 6.19 Patient and healthcare workers exposure to hazardous materials** must be minimised and the Control of Substances Hazardous to Health (COSHH) regulations must be complied with.

APPENDIX I:

Purchase of probe decontamination system for Semi-critical (Semi-invasive and Non-invasive) Ultrasound Probes

1. Purpose

To define the process for purchasing decontamination equipment for Probes.

2. Responsibility

Purchase of a Probe decontamination system is the responsibility of the Responsible Person (Unit Manager).

3. Procedure

3.1 Purchase of probes with regard to decontamination

Consideration must be given to compatibility with the decontamination process proposed or already in place, with emphasis placed on the need for automated HLD processes. Probes which can be disconnected from the ultrasound machine should be purchased where possible. Where not possible to disconnect the Probe the Decontamination Lead and IPCT should be contacted to develop local processes to minimise cross infection risks and Health and Safety issues.

3.2 Purchase of Probe decontamination equipment

Prior to the purchase of new equipment, the following practitioners and staff experienced in decontamination (Decontamination Lead, AE(D), Procurement Manager, Medical Physics and a member of the Infection Prevention & Control Team, Responsible Person) are consulted to ensure compatibility of the Probe decontamination system with the probes to be used and the processes involved, with preference placed on the need for automated HLD processes.

The purchase specification contains the following:

- Compatibility with the Probes reprocessing instructions including written agreement with the equipment manufacturer regarding compatibility with specific brands and models of Probes.
- Service Level Agreements (SLAs) as applicable with for example Probe manufacturers, Probe decontamination system manufacturers, suppliers or agents.
- Indemnity offered against damage caused by the decontamination process.

- Expected throughput and time.
- Installation, validation, testing, revalidation requirements and ongoing maintenance.

On receipt of the equipment, the Manager and/or Operator carry out an inspection to verify that:

- The equipment received matches the purchase order;
- installation and commissioning have been carried out according to contract and meet safe operational requirements; and
- management pursue any non-conformance with the manufacturer.

Manufacturer's instructions for installation, operation, validation, testing and maintenance are added to the validation report.

APPENDIX II

Validation, testing and maintenance of Semi-critical (Semi-invasive and Non-invasive) Probe decontamination equipment

1. Purpose

To define the arrangements for the validation, testing and maintenance of Probe decontamination equipment.

2. Responsibility

The procedure is monitored by the Responsible Person (e.g. Unit Manager) with the support of the Decontamination Lead and IPC Team .

Routine cleaning and maintenance is performed by the Operator (the person performing the Probe decontamination).

The installation, validation, periodic testing and repair are only carried out by the manufacturer's engineer and monitored by the Responsible Person. Monitoring by the Responsible Person is to ensure the initial validation is complete before the equipment is used and to ensure annual validation tests are carried out by the manufacturer engineers and is recorded locally.

3. Procedure

Installation, commissioning and validation

The Responsible Person is responsible for ensuring that the installation, commissioning and validation of the equipment is performed by the manufacturer's authorised personnel in accordance with the manufacturer's instructions.

Maintenance and service contracts covering validation, testing and maintenance of the equipment are put in place during the purchasing stage and compliance monitored by the Responsible Person.

Annual and periodic testing

Follow the manufacturer's Service Schedule for periodic testing and revalidation timescales.

Responsible Person maintenance and routine cleaning

Planned preventative maintenance is carried out as recommended by the manufacturer.
Routine cleaning is carried out as recommended by the manufacturer.

Faults and repair

The Operator records the fault, and then notifies the Responsible Person and the manufacturer/supplier when a fault occurs.

The Responsible Person investigates the fault. If unresolved, contact the manufacturer for repair. The repair is carried out by the manufacturer's authorised service personnel. When complete, the Responsible Person checks the repair is satisfactory. The Operator retains a record of the repair work in the log book.

Records

Operators must be aware of the decontamination records to be completed for the SIUP decontamination system in use. The Responsible Person is responsible for ensuring records are kept up to date. Examples of decontamination records are:

- Equipment log book;
- Traceability records;
- Maintenance and test records and
- Validation Report.

APPENDIX III

Training for healthcare workers undertaking Semi-critical (Semi-invasive and Non-invasive) Probe decontamination

1. Purpose

To identify the training needs and provide training for all healthcare decontamination healthcare workers performing activities in the use and management of Probes and associated decontamination processes.

2. Responsibility

This process is the responsibility of the Responsible Person and the Operator.

3. Procedure

Job Description

Decontamination responsibilities should be reflected within the job description of each member of healthcare workers who is involved in the management and decontamination of Semi-invasive Ultrasound Probes.

Induction of new Healthcare workers

The Responsible Person is responsible for familiarising the new personnel with the working methods surrounding Semi-invasive Ultrasound Probes, equipment used to decontaminate Probes, and the decontamination processes.

All new members of healthcare workers work under the direction of staff trained in the decontamination of Probes until such time that they are assessed as competent to work independently.

Training needs assessment is carried out for a new healthcare worker and periodically thereafter. A training programme is generated and documented within their Training Plan/Record.

Examples of training include, PPE training, chemical training, percutaneous injury training, hand hygiene, manual handling, Probe decontamination.

Training Record

The Responsible Person and healthcare workers maintain and update the Training Record covering all healthcare workers working within the unit/department. The record identifies the training received and competencies of each member of healthcare workers.

Training Review

Prior to changes or introduction of new methods/equipment, healthcare workers are trained by a relevant qualified person e.g. training provider or manufacturer.

The Responsible Person reviews the competence of all healthcare workers, as local policy dictates, to evaluate the effectiveness of training and identify any further training needs.

The training programme is planned, documented and monitored to ensure delivery as scheduled in the Training Plan/Record. The Responsible Person is responsible for ensuring any agreed training programme is implemented. The content of the programme is reviewed as required by local policy. Upon completion of the training, the healthcare worker and Responsible Person completes the Training Plan/Record. For external training, copies of Attendance/Competence Certificates are obtained (if applicable) and filed in the Training Plan/Record. Details of all training requirements are recorded on their Training Plan/Record for future development.

APPENDIX IV

Release of disinfected Semi-critical (Semi-invasive and Non-invasive) Ultrasound Probes

1. Purpose

To define the procedure which ensures all Probes have been satisfactorily decontaminated to the required standard before release for use.

2. Responsibility

The product release procedure is performed by the Operator. The product release procedure is monitored by the Responsible Person.

3. Procedure

After completion of the Probe decontamination process, review the process to ensure acceptance criteria are met (e.g. a system check to confirm the equipment has functioned as per validation criteria).

If a non-conformance with the decontamination system process (i.e. system failure or visual residue on Probe) is found during inspection of the Ultrasound Probe, the management is informed in order to decide the appropriate corrective actions.

The product (Probe) is released after meeting the acceptance criteria set by the decontamination system manufacturer and the completion of the traceability record. Traceability labels are either manual or electronic and attached/tracked to the patient records and system log books.

APPENDIX V

Transport and storage of Semi-critical (Semi-invasive and Non-invasive) Ultrasound Probes.

1. Purpose

To define the procedures for transporting Probes after clinical use to a dedicated on-site decontamination area (either an adjacent room next to the patient treatment area or a nearby facility). All RIMD are considered to be soiled and contaminated after each use and can be a potential source of infection. Contaminated RIMD should be handled, collected and transported in a manner that avoids dissemination of contamination. Transport of soiled RIMD to the decontamination area should be accomplished **as soon as possible after use**. If delay is unavoidable, the Responsible Person must make sure that the item is safely contained and secured to await collection. RIMD returned for reuse after processing should be transported in a manner that will not compromise their status.

Storage of decontaminated Probes: RIMD must be stored in such a way that their integrity and microbial state is maintained (e.g. high-level disinfected).

2. Responsibility

The Responsible Person monitors the procedure .

The Operator performs the transport and storage elements of this procedure.

3. Transport Procedure of Contaminated Probes

Immediately after use, remove gross contamination and accessories as detailed in the decontamination procedure currently in use.

The Probe must be placed into a solid-walled container (example, Endoscope tray) for transfer to the decontamination area. The transport container should be clearly identified to denote if the contents are contaminated or disinfected. Probes and their cabling are fragile and should be handled with care. If transporting offsite ensure equipment is packed and secured by using UN type approved boxes to prevent damage or injury during transport and accompanied by a Decontamination Certificate.

4. Storage Procedure

Where manufacturer's instructions prevent disconnection from the ultrasound unit, decontaminated Probes are stored in the holder on the Sonography console and away from extremes of temperature and direct sunlight. Before receiving the decontaminated Probe, the holder is cleaned between patients with a detergent wipe and dried with a single use lint-free cloth/wipe followed by a single use disinfectant wipe. This process should be carried out whether the Probe can be disconnected or not. Probes are returned to the ultrasound machine for storage following cleaning of the holder. Any additional Probes should be stored clean and dry in a designated container in a designated area (to minimise the risk of reuse of contaminated Probes).

Manufacturer's instructions should be consulted regarding storage of Probes. If the guidance and manufacturer's instructions contradict the Responsible Person should discuss the issue with the Decontamination Lead, the manufacturer and the IPCT. Probes should be decontaminated prior to the first use of the day, between patients and following the last patient of the day regardless of being stored on the ultrasound machine or in containers.

(Note: Only store Probes in the manufacturer's carrying case after a decontamination cycle when transporting Probes out with the unit/department (e.g. when transporting for repair))

APPENDIX VI

Decommissioning and disposal of Semi-critical (Semi-invasive and Non-invasive) Ultrasound Probe decontamination equipment.

1. Purpose

To define the procedure for decommissioning and disposal of Probe decontamination equipment.

2. Roles and Responsibilities

This procedure is performed by the Operator. This procedure is monitored by the Responsible Person.

3. Procedure

Lifespan planning

Planning for end of equipment lifespan is an essential part of equipment management. Contact medical physics, the local Waste Management Officer and manufacturer for guidance.

The expected lifespan is adjusted in accordance with level of usage, maintenance record and repairs. A replacement criterion includes the following:

- Beyond economic repair;
- clinically or technically outdated;
- contaminated;
- unsuitable after changes to local/national policy, guidance or standards or
- absence of support or parts (e.g. manufacturer ceased trading).

Decommissioning

Prior to removing equipment from service, or if the manufacturer has ceased trading, contact medical physics and the local Waste Management Officer for guidance in line with local governance arrangements.

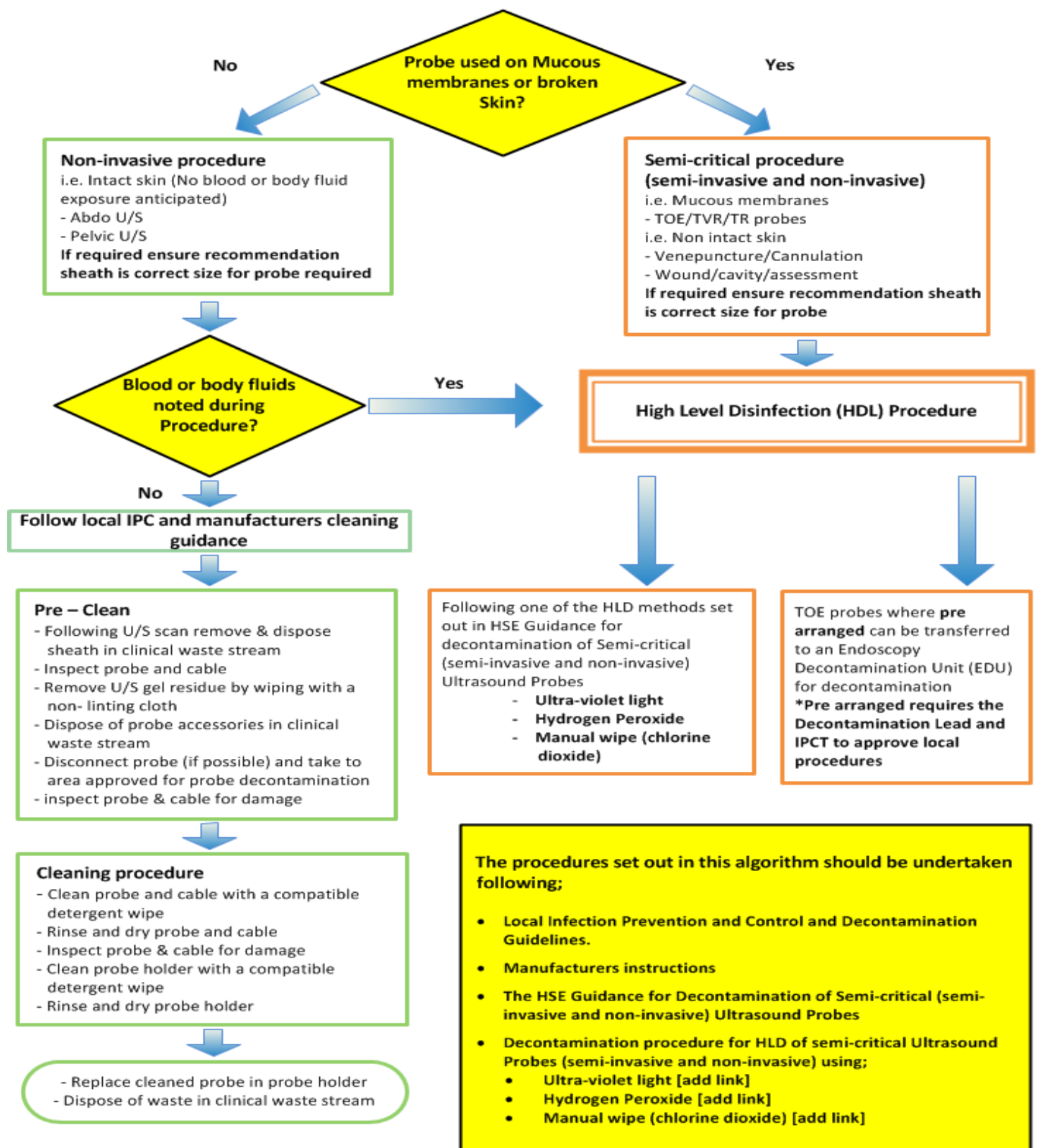
Erase any patient identifiable data from electronic storage media within the equipment .

Disposal

Manufacturers' instructions for use provide any specific information for environmental, disposal and/or recycling requirements for all equipment. Where practicable, equipment should be decontaminated prior to disposal.

APPENDIX VII: Health Service Executive Semi-critical Ultrasound Probe (Semi-invasive and Non-invasive)

Decontamination Algorithm (Adopted from NHS Scotland Guidance Document, 2016).



1. Decontamination Procedure for High Level Disinfection (HLD) of Semi-critical Ultrasound Probes (Semi-invasive and Non-invasive): using Automated Hydrogen Peroxide Systems.

1.1 Purpose

This procedure describes the method for decontamination of Ultrasound Probes using equipment based on Hydrogen Peroxide. This is a semi-automated process used to achieve High Level Disinfection (HLD) of Probes in a sealed chamber by exposure to Hydrogen Peroxide mist.

1.2. Responsibility

The Responsible Person (e.g. Unit Manager, Lead Sonographer or Senior Staff Nurse) has overall responsibility for the Ultrasound Probe decontamination procedures within the department.

The Operator (person undertaking decontamination of Ultrasound Probes) is responsible for carrying out the decontamination procedure according to this procedural document.

1.3. Procedure

Decontamination procedures should be performed in a designated room/area preferably separate from the clinical area. However, HCAI risk-assessed procedures in the patient area are currently an acceptable solution when manufacturer's recommend the Ultrasound Probe cannot be disconnected or there is no designated room/area separate from the clinical area.

1.3.1 Preparation of Ultrasound Probe decontamination equipment

At the start of each day wipe down all decontamination equipment using approved cleaning and disinfectant wipes. Ensure the equipment is switched on, warmed up, daily testing is performed and the printer contains paper, if applicable. Follow the equipment manufacturer's instructions for daily testing and the equipment display to identify when to load the probe.

1.3.2 Pre-cleaning of Probes essential requirements

- Perform hand hygiene and put on clean Personal Protective Equipment (PPE) e.g. apron and gloves.
- Immediately after patient use inspect the protective sheath for integrity.
- Remove all accessories and the sheath from the Probe. Using a single use lint-free cloth/wipe, remove the ultrasound gel and dispose of the sheath and wipes in the appropriate waste stream. Dispose of any single use accessories (e.g. biopsy needle guide) into the appropriate waste stream.
- Any reusable accessories needing sterilisation should be reprocessed following manufacturers instructions in a CDU. Contact the IPCT and Decontamination Lead.
- Disconnect the Probe from the console if recommended by the manufacturer and transport the Probe to the designated decontamination room or area. (Appendix V Transport and storage).

(Note: A service level agreement should be in place if Probes or their accessories are to be decontaminated by the CDU or EDU and include turn around times)

(*If decontamination requires to be in the patient area, ensure that there is clear segregation between dirty and clean processes)

1.3.3 Cleaning and inspection of Probes

Clean the Probe and cable with a compatible detergent wipe, recommended by the Probe and Probe disinfection equipment manufacturers, to remove all visible contamination. Carry out leak testing if recommended by Probe manufacturers

- Remove detergent residues with a compatible rinsing wipe and dry with a clean single use lint-free cloth/wipe.
- Remove PPE, perform hand hygiene and put on a clean apron and gloves.
- After cleaning, examine the probes for cleanliness, dryness, damage and functionality. Ensure there are no signs of discolouration or cracks, giving particular attention to the probe tip.
- Report any non-compliance to the Responsible Person. When appropriate, segregate and label the Probe to prevent further use. Follow manufactures instructions on reprocessing of non-compliant products/Probes.

1.3.4 Disinfection

Place the Probe in the equipment chamber. Operate the equipment with strict adherence to disinfection equipment manufacturer instructions.

Close the equipment door and follow the instructions on the display screen.

During the cycle clean the Probe holder on the ultrasound console, the equipment door and control panel with detergent wipes recommended by the manufacturer. Observe the display to ascertain when the cycle is complete.

Remove PPE perform hand hygiene and put on clean apron and gloves.

Open the cabinet door, remove the Probe and wipe with a single use lint-free cloth/wipe ensuring the Probe is completely dry. Close the equipment door in readiness for the subsequent cycle.

Place the Probe in the cleaned console holder on the ultrasound machine for next use and cover/or place in an appropriate container for storage.

Check the printer-generated traceability labels produced after each cycle to confirm a successful decontamination process. Attach the traceability labels to the patient records either manually into the equipment log book or electronically onto the IT system.

1.3.5 Inspection - post disinfection

After disinfection, inspect the Probe to ensure there are no signs of discolouration or cracks, giving particular attention to the Probe tip.

Report any non-compliance to the RP. When appropriate, segregate and label the Probe to prevent reuse. Follow manufacturer's instructions in the event of Probe failure.

1.3.6 Product release

After completion of the decontamination process, review the process to ensure acceptance criteria are being met:

- Daily test and maintenance records are satisfactory and up to date.
- System display and labels generated indicate a pass.
- Process indicator "pass" (if applicable).
- Visual inspection "pass".
- Traceability records complete.

The product is released after meeting the acceptance criteria and the completion of the traceability record. Traceability labels are attached to the patients record and system log book or electronically recorded to the patients chart.

If a non-conformance is found during inspection of the Ultrasound Probe the management is informed in order to decide the appropriate corrective actions.

1.3.7 Validation testing and maintenance

This is monitored by the Responsible Person. When applicable the installation, validation, periodic testing and repair are only carried out by the manufacturer's engineer.

The RP/Clinical Engineering is responsible for ensuring the installation, commissioning and validation of the equipment is performed in accordance with manufacturer's instructions.

Maintenance and service contracts covering validation, testing and maintenance of the equipment are put in place by the RP/Clinical Engineer. The Authorised Engineer for decontamination will review and sign off validation reports.

Follow the manufacturer's service schedule for periodic testing and revalidation time scales.

Planned preventative maintenance is carried out as recommended by the manufacturer.

1.3.8 Routine cleaning

Routine cleaning is performed by the Operator and carried out when the equipment chamber is cool. Wipe all accessible surfaces including the inside of the chamber with compatible detergent wipes until all surfaces are visibly clean. A disinfectant wipe should be used also.

1.3.9 Faults and repairs

The Operator records the fault then notifies the Responsible Person who will investigate the fault. If unresolved the Clinical Engineer should be contacted and they will contact the supplier/manufacturer for repair. When repair is completed by the manufacture's engineer the records are retained of the repair in a log book. Ensure equipment is revalidated after repair where appropriate.

1.3.10 Records

Equipment log book

Traceability records

Maintenance and test records

Validation reports.

2. Decontamination Procedure for High Level Disinfection (HLD) of Semi-critical Ultrasound Probes (Semi-invasive and Non-invasive): using Ultraviolet C Light

2.1 Purpose

This procedure describes the method for decontamination of Ultrasound Probes using equipment based on Ultraviolet C Light. This is a semi-automated process used to achieve High Level Disinfection (HLD) of Probes in a sealed chamber by exposure to Ultraviolet C Light.

2.2 Responsibility

The Responsible Person (e.g. Unit Manager, Lead Sonographer or Senior Staff Nurse) has overall responsibility for the Ultrasound Probe decontamination procedures within the department.

The Operator (person undertaking decontamination of Ultrasound Probes) is responsible for carrying out the decontamination procedure according to this procedural document.

2.3 Procedure

Decontamination procedures should be performed in a designated room/area preferably separate from the clinical area. However, HCAI risk-assessed procedures in the patient area are currently an acceptable solution when manufacturer's' recommend the Ultrasound Probe cannot be disconnected or there is no designated room/area separate from the clinical area.

2.3.1 Preparation of Ultrasound Probe decontamination equipment

At the start of each day wipe down all decontamination equipment using approved cleaning and disinfectant wipes. Ensure the equipment is switched on, warmed up, daily testing is performed and the printer contains paper, if applicable. Follow the equipment manufacturer's instructions for daily testing and the equipment display to identify when to load the probe.

2.3.2 Pre-cleaning of Probes essential requirements

- Perform hand hygiene and put on clean Personal Protective Equipment (PPE) e.g. apron and gloves.
- Immediately after patient use inspect the protective sheath for integrity.
- Remove all accessories and the sheath from the Probe. Using a single use lint-free cloth/wipe, remove the ultrasound gel and dispose of the sheath and wipes in the appropriate waste stream. Dispose of any single use accessories (e.g. biopsy needle guide) into the appropriate waste stream.
- Any reusable accessories needing sterilisation should be reprocessed following manufacturers instructions in a Central Decontamination Unit. Contact the IPCT and Decontamination Lead.
- Disconnect the Probe from the console if recommended by the manufacturer and transport the Probe to the designated decontamination room or area. (Appendix V Transport and storage).

(Note: A service level agreement should be in place if Probes or their accessories are to be decontaminated by the CDU or EDU and include turn around times)

(*If decontamination requires to be in the patient area, ensure that there is clear segregation between dirty and clean processes)

2.3.3 Cleaning and inspection of Probes

Clean the Probe and cable with a compatible detergent wipe, recommended by the Probe and Probe disinfection equipment manufacturers, to remove all visible contamination. Carry out leak testing if recommended by Probe manufacturers

- Remove detergent residues with a compatible rinsing wipe and dry with a clean, single use lint-free cloth/wipe.
- Remove PPE, perform hand hygiene and put on a clean apron and gloves.
- After cleaning, examine the probes for cleanliness, dryness, damage and functionality. Ensure there are no signs of discolouration or cracks, giving particular attention to the probe tip.
- Report any non-compliance to the Responsible Person/Responsible Person. When appropriate, segregate and label the Probe to prevent further use. Follow manufacture's instructions on reprocessing of non-compliant products/Probes.

2.3.4 Disinfection

Place the Probe in the equipment chamber. Operate the equipment with strict adherence to disinfection equipment manufacturer instructions.

Close the equipment door and follow the instructions on the display screen.

During the cycle clean the Probe holder on the ultrasound console, the equipment door and control panel with detergent wipes recommended by the manufacturer. Observe the display to ascertain when the cycle is complete.

Remove PPE perform hand hygiene and put on clean apron and gloves.

Open the cabinet door, remove the Probe and wipe with a single use lint-free cloth/wipe ensuring the Probe is completely dry. Close the equipment door in readiness for the subsequent cycle.

Place the Probe in the cleaned console holder on the ultrasound machine for next use and cover/or place in an appropriate container for storage.

Check the printer-generated traceability labels produced after each cycle to confirm a successful decontamination process. Attach the traceability labels to the patient records either manually into the equipment log book or electronically onto the IT system.

2.3.5 Inspection - post disinfection

After disinfection, inspect the Probe to ensure there are no signs of discolouration or cracks, giving particular attention to the Probe tip.

Report any non-compliance to the RP. When appropriate, segregate and label the Probe to prevent reuse. Follow manufacturer's instructions in the event of Probe failure.

2.3.6 Product release

After completion of the decontamination process, review the process to ensure acceptance criteria are being met:

- Daily test and maintenance records are satisfactory and up to date.
- System display and labels generated indicate a pass.
- Process indicator "pass" (if applicable).
- Visual inspection "pass".
- Traceability records complete.

The product is released after meeting the acceptance criteria and the completion of the traceability record. Traceability labels are attached to the patients record and system log book or electronically recorded to the patients chart.

If a non-conformance is found during inspection of the Ultrasound Probe the management is informed in order to decide the appropriate corrective actions.

2.3.7 Validation testing and maintenance

This is monitored by the Responsible Person. When applicable the installation, validation, periodic testing and repair are only carried out by the manufacturer's engineer.

The RP/Clinical Engineering is responsible for ensuring the installation, commissioning and validation of the equipment is performed in accordance with manufacturer's instructions.

Maintenance and service contracts covering validation, testing and maintenance of the equipment are put in place by the RP/Clinical Engineer. The Authorised Engineer for decontamination will review and sign off validation reports.

Follow the manufacturer's service schedule for periodic testing and revalidation time scales.

Planned preventative maintenance is carried out as recommended by the manufacturer.

2.3.8 Routine cleaning

Routine cleaning is performed by the Operator and carried out when the equipment chamber is cool. Wipe all accessible surfaces including the inside of the chamber with compatible detergent wipes until all surfaces are visibly clean. A disinfectant wipe should be used also.

2.3.9 Faults and repairs

The Operator records the fault then notifies the Responsible Person who will investigate the fault. If unresolved the Clinical Engineer should be contacted and they will contact the supplier/manufacturer for repair. When repair is completed by the manufacture's engineer the records are retained of the repair in a log book. Ensure equipment is revalidated after repair where appropriate.

2.3.10 Records

Equipment log book

Traceability records

Maintenance and test records

Validation reports.

3. Decontamination Procedure for High Level Disinfection (HLD) of Semi-critical Ultrasound Probes (Semi-invasive and Non-invasive): using a manual (Chlorine Dioxide) multi-wipe system

3.1 Purpose

These operating instructions describe the method for decontamination of Ultrasound Probes using a manual (**Chlorine Dioxide**) multi-wipe system. This is a manual process to achieve high level disinfection with a series of impregnated wipes that separately clean, disinfect and then rinse the Probes.

*(**Note:** This is the least preferred option and should only to be used as an interim measure prior to implementation of an automated Decontamination process)*

3.2 Responsibility

The Responsible Person (e.g. Unit Manager, Lead Sonographer or Senior Staff Nurse) has overall responsibility for the Ultrasound Probe decontamination procedures within the department. The Operator (person undertaking decontamination of Ultrasound Probes) performs this procedure.

3.3 Procedure

Decontamination procedures should be performed in a designated room/area preferably separate from the clinical area. However, HCAI risk-assessed procedures in the patient area are currently an acceptable solution where the Ultrasound Probe cannot be disconnected or there is no designated room/area separate from the clinical area (see HSE guidance document for further information). **These are manual decontamination procedures and to be fully effective, manufacturer's instructions must be strictly adhered to.** This option is only to be used as an interim measure prior to implementation of an automated decontamination process

3.3.1 Preparation

- Check the expiry/use by date on the multi wipe system product, if applicable.
- **Do not use if past the use by date.**
- Take one of each type of wipe (pre-clean, disinfect and rinse) from the box and have ready for use and place on a dedicated, clean work surface.

3.3.2 Pre-cleaning of Probes – essential requirement

- Perform hand hygiene and put on clean PPE (apron and gloves).
- Immediately after patient use inspect the protective sheath for integrity. Remove all accessories and the sheath from the Probe. Using a single use lint-free cloth/wipe remove the ultrasound gel and dispose of the sheath and wipes in the clinical waste.
- Dispose of any single use accessories (e.g. biopsy needle guide) into the appropriate recommended waste stream .
- Any reusable accessories needing sterilisation should be reprocessed following manufacturer's instructions in a Central Decontamination Unit. Contact the Infection Prevention and Control Team or CDU manager.
- Disconnect the Probe from the console if recommended by the manufacturer and transport in a covered solid walled container e.g. Endoscope tray, clearly indicating contaminated on the cover, to the designated decontamination area. (Appendix V) If the Probe can be disconnected it should be reprocessed external to the clinical treatment area e.g. in the CDU/EDU

(Note: If decontamination requires to be in the patient area, ensure that there is clear segregation between dirty and clean processes)

- Remove the pre-clean wipe from the sachet and unfold into palm of the hand. Retain the sachet for the bar code to enter into the audit trail book provided by the wipe manufacturer.
- Wipe the full length of the cable and Probe from cable end to Probe tip to remove all visible soiling. More than one wipe may be required if heavily soiled.
- Discard wipe and PPE to clinical waste, perform hand hygiene and put on clean PPE.

3.3.3 Inspection

- After cleaning, the Probes are examined by the Operator for cleanliness, damage and functionality. A leak test should be carried out if recommended by the manufacturers. Ensure there are no signs of discolouration or cracks, giving particular attention to the Probe tip.
- Report any non-compliance to the Responsible Person. When appropriate, label and segregate the Probe to prevent further use. Follow manufacturer's instructions for reprocessing of non-compliant Probes.

3.3.4 Disinfection

- Remove the disinfectant wipe from the sachet and unfold into palm of the hand. Retain the sachet for the bar code to enter into the audit trail book.
- Activate the wipe as indicated in the manufacturer's instructions ensuring the wipe is completely covered in foam.
- Carefully wipe the entire surface of the Probe and cable ensuring contact with the disinfectant for the time recommended in the manufacturer's instructions.

3.3.5 Rinse

- After the indicated contact time with disinfectant, remove the rinse wipe from the sachet and unfold in palm of hand. Retain the sachet for identification purposes e.g. enter the bar code into the audit trail book.
- Wipe the full length of Probe and cable thoroughly to remove excess disinfectant. Dry with a single use lint-free cloth/wipe.
- Discard used wipe and PPE to clinical waste.
- Record all three sachet bar codes in the audit trail book and affix labels to patient notes as indicated.
- Clean the Probe holder on the ultrasound console, with detergent wipes recommended by the console manufacturer.
- Replace the Probe in the clean console holder ready for next use.
- Remove PPE carry out hand hygiene and put on fresh PPE.

3.3.6 Inspection – post disinfection

- After rinsing and drying, inspect the Probe to ensure there are no signs of discolouration or cracks, giving particular attention to the Probe tip.
- Report any non-compliance to the Responsible Person. When appropriate, segregate and label the Probe to prevent further use.

3.4 Product Release

3.4.1 After completion of the decontamination process, review the process to ensure acceptance criteria are being met:

- Visual inspection 'pass';
- Traceability records complete.

3.4.2 The product is released after meeting the acceptance criteria and the completion of the traceability record. Traceability labels are attached to the patient records and electronic system/ system log books.

3.4.3 If a non-conformance is found during inspection of the Ultrasound Probe, the Responsible Person is informed in order to decide the appropriate corrective actions. Manufactures instructions should be followed for all non -conformances

3.5 Validation, Testing and Maintenance

This is monitored by the Responsible Person (e.g. Unit Manager, Lead Sonographer or Senior Staff Nurse).

3.5.1 Installation, commissioning and validation

Not applicable.

3.5.2 Annual and periodic testing

Not applicable

3.5.3 Maintenance and routine cleaning

Not applicable

3.5.4 Faults-Probe

The Operator records the fault, then notifies the Responsible Person.

The Responsible Person investigates the fault. If unresolved, contact the clinical engineering department (if it does not conflict with the service contract) and the manufacturer/ supplier for repair.

When complete, the Responsible Person/clinical engineering checks the replacement is satisfactory. The Responsible Person retains a record of the replacement in the Decontamination Manual.

3.6. RECORDS

Manual/electronic system log book and Traceability Records

Resources

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- 7) Ngu A, McNally G, Patel D, Gorgis V, Leroy S, Burdach J. Reducing Transmission Risk Through High-Level Disinfection of Transvaginal Ultrasound Transducer Handles. Infection Control & Hospital Epidemiology 2015;36(05):581-4.
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- 9) Health Facilities Scotland 2010. Scottish Health Planning Note 13 Part 3- Decontamination Facilities; Endoscope Decontamination Units, HFS.
- 10) Scottish Government 2012. Duty of Care – A Code of Practice. Crown. Edinburgh. <http://www.gov.scot/Resource/Doc/366562/0124804.pdf>
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- 14) Nyhsen C, Humphreys H, Nicolau C, Mostbeck G, Claudon M. Infection prevention and ultrasound probe decontamination practices in Europe: A survey of the European Society of Radiology. Insights Imaging (2016) 7;841-847