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Shared Services Partnership
Specialist Estates Services

# WHTM 01-06
## Part F

Welsh Health Technical Memorandum

# Decontamination of flexible endoscopes

## *Part F: Decontamination of Semi-Critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes*

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# Overview

## Scope of Welsh Health Technical Memorandum 01-06 Parts A, B, C, D ,E and F

Welsh Health Technical Memorandum (WHTM) 01-06 is part of a suite of evidence-based policy and guidance documents on the management and decontamination of reusable medical devices designed to reflect the need to continuously improve outcomes in terms of:

- patient safety;
- clinical effectiveness;
- patient experience.

It is also designed to reflect the need to ensure the environment in which decontamination procedures are carried out is fit for purpose.

The documents allow local decisions to be made in the formulation of an appropriately developed, risk controlled, operational environment within the healthcare facilities that decontaminate flexible endoscopes. They also set out how the decontamination of reusable medical devices can be carried out in a cost effective way using risk assessment controls and procedures whilst placing patient safety as its top priority.

Guidance is also offered on the management and decontamination of flexible endoscopes, principally gastrointestinal scopes and bronchoscopes. They also aim to support healthcare establishments in implementing appropriate and effective decontamination measures to reduce the risks of person-to-person transmission of human prion diseases.

### WHTM 01-06 is divided into six parts:

**Part A:** Policy and management sets out the Welsh Government's policy for an endoscope decontamination service. The document covers flexible endoscope management and decontamination only. Clinical issues relating to endoscopy or the manufacture of endoscope washer-disinfectors (EWD) are not discussed.

Furthermore, this document does not cover the processing of flexible endoscopes used to examine sterile body sites. These endoscopes should be sterile, possibly using low temperature gas sterilization, and may be the subject of future guidance.

The document discusses transmissible spongiform encephalopathy (TSE) infectious agents and sets out guidance on the management and handling of endoscopes after they have been used on patients at increased risk of vCJD.

**Part B:** Design and installation sets out guidance on the design and installation of endoscope reprocessing units.

**Part C:** Operational management sets out guidance on operational responsibilities together with advice on the procurement and operation of EWDs.

**Part D** Validation and verification highlights the types of tests and maintenance procedures that are needed to provide evidence that decontamination has been achieved.

**Part E:** Testing methods discusses the principles and methods that are used in the tests described in this WHTM and detailed in BS EN ISO 15883-4:2009.

**Part F:** Decontamination of Semi-Critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes this document sets out the operational procedures to support safe decontamination Probes using decontamination methods and infection prevention and control practice.

**Note**
The WHTM 01-06 suite of documents is based on continued improvement of standards of delivery at the point of use and constantly striving to reduce the risk element to both users and the patient. The technology involved is constantly improving to meet the demands of the service, and evidence based results and research should always be investigated.

## Who should use WHTM 01-06 Part F

Part F is intended as a guide for management, for technical personnel with appropriate training and experience and also for users responsible for decontamination of ultrasound probes. It will also be of interest to decontamination leads, microbiologists, infection control officers, arch architects, planners, estates managers, supplies officers, and others in both the public and private sectors.





# 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 suciently decontaminated prior to use on the next patient.

**"Non-invasive probe**" is an Ultrasound Probe which is manufactured with the intention of scanning the patient's 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 **"User"** and **"Operator"** are distinct and defined terms used throughout this guidance and associated procedures.

The **"User"** 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 national guidelines and manufacturer instructions.

### AE(D) Authorising Engineer for Decontamination

The AE(D) is defined as a person designated by management to provide independent auditing, advice and guidance on decontamination systems and to review and witness documentation on validation. NWSSP/SES undertake this role on behalf of Health Boards and Trusts and present technical advice/ guidance to Welsh government. (Ref WHTM 01/01-part A paragraph 7.26 to 7.29).

### CDU Central Decontamination Unit

The CDU is a purposed built facility, managed by dedicated personnel that undertakes all decontamination activities within the healthcare premises.

### EDU Endoscope Decontamination Unit

The EDU is a purposed built facility, managed by dedicated personnel that undertakes all endoscope decontamination activities within the healthcare premises.

**EWD Endoscope Washer Disinfector**
A washer/disinfector designed to reprocess flexible endoscopes.

**HCAI Healthcare Associated Infections**
Healthcare associated infections can develop either as a direct result of healthcare interventions (such as medical or surgical treatment) or from being in contact with the healthcare setting. These can be hospital or community based HCAIs.

**ODL Operational Decontamination Lead**
The Decontamination Lead is organisationally responsible for the effective and technically compliant provision of decontamination services. The Decontamination Lead is responsible for the implementation of an operational policy for decontamination (Ref WHTM 01/01-part paragraphs 7.13 to 7.18).

**HCW Healthcare Worker**

**HIQA Health Information and Quality Authority**

**HLD High Level Disinfection**

**LLD Low 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 Ultrasound probe**

**TR Transrectal Ultrasound Probe**

**TV Transvaginal Ultrasound Probe**

**Standards =** term used to describe the high-level outcomes required to contribute to the quality and safety of decontamination services.

**Features =** term used 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.





# Contents

1

Chapter 1

# 1. Purpose

## General

**1.1** This guidance document sets out the operational procedures to support safe decontamination of Semi-critical Probes using decontamination methods and infection prevention and control practice. This guidance reflects national and international evidence of what is known to achieve best outcomes for patients.

**1.2** The guidance has been developed to supplement existing guidance presented within WHTM 01/06 parts A to E and 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.

Vascular Access, for example:

- venipuncture/cannulation
- fine needle aspirations/guided biopsy
- drainage procedures
- wound cavity assessments

**1.3** 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 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.

**1.4** 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, ultravioletC light and manual multi-wipes) have been produced:
  i. Decontamination Procedure for HLD using Hydrogen Peroxide system
  ii. Decontamination Procedure for HLD using Ultraviolet-C light system
  iii. Decontamination Procedure for HLD using Manual Multi-wipe system





2

Chapter 2

# 2. Background

## General

**2.1** 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 each 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]

**2.2** National surveys of TOE, TV and TR Ultrasound Probes across NHS Wales, conducted by Welsh Government representatives in 2014,16,18, concluded that there is an ongoing need to continually develop practices to reduce risks to patients' safety with regard to decontamination of these SIUPs.

**2.3** The conclusion of the national surveys identified several requirements for departments undertaking such activities. These findings were reported in summary reports at the conclusion of the survey, both to each organisation and as part of a generic survey closure report.

**2.4** HLD using the manual multi-wipe system is the least preferred option for disinfecting SIUPs. As a result of inconsistencies due to operator intervention, HLD using the manual wipe system is the least preferred, that the use of an automated validated process for decontaminating RIMD will provide enhanced risk reduction of infection transmission.

**2.5** It is acknowledged that certain premises or clinical circumstances dictate that organisations do not use automated systems (e.g., low use clinics and/use of portable scanning equipment). It is recommended there is continual progression towards the use of automated validated processes. However, as an interim, where manual multi-wipe systems are used, it is recommended that a local risk assessment is performed when this option is to be used and/or because of resilience in event of machine breakdowns. Purchase of additional probes to enable return transport to department centres for validated HLD remains a safer option and is in keeping with the principle of decontamination and sterilisation being undertaken by trained experts in dedicated departments..

**2.6** Cleaning is an essential pre-requisite for decontamination processes, but also systems must be in place to ensure devices are free from chemical residues prior to any high-level disinfection procedure. Following cleaning, there should be no process residues on devices at the conclusion of the decontamination process.

**2.7** When determining the decontamination methodology to be used, a formal risk assessment should be carried out to determine the types of risks present:

**2.8** There are three types of risks to consider:

- Patient Risks receiving procedures using the medical devices.
- Operator Safety cleaning/disinfecting the medical devices used for treatment.
- Environmental Risk associated with bi-products or waste when undertaking such decontamination procedures.

**2.9** The risk assessment must be completed using the appropriate stakeholder group within the organisation and assess the likelihood and consequence of infection to both patient and staff.

## Evidence:

**2.10** A scientific literature review was undertaken by Health Protection Scotland on the decontamination of Semi-invasive Ultrasound Probes. The conclusion found that SIUPs present several challenges in terms of decontamination. Many cannot be sterilized as they are delicate, expensive, heat sensitive devices with electrical components that cannot withstand standard heat and steam decontamination techniques.

**2.11** However, unlike most flexible endoscopes, certain probes have parts (e.g., handle, electrical components) that cannot be immersed in any liquid for cleaning or disinfection as this could result in corrosion.

**2.12** 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.

**2.13** NHS Scotland conclude that studies have shown residual contamination on SIUPs when HLD is not performed. Cases of cross infection have been reported where transmission was thought to have been caused by improper reprocessing of ultrasound transducers.

## Summary

**2.14** This Guidance Document provides NHS Wales with an evidence-based approach to the decontamination of Semi-critical Probes. The guidance has incorporated the findings of the various national surveys carried out within NHS Wales (2014/2016/2018), the 2018 Health Facilities Scotland study, the recommendations from the MHRA Medical Device Alert (2012/037), the evidence from a full systematic literature review on the decontamination of SIUPs, conducted by HSE and NHS Scotland.





3

Chapter 3

# 3 The Decontamination Process

## General

**3.1** The Diagram on page 14 highlights each stage of the decontamination process through which medical devices pass before every use.

**3.2** Effective decontamination requires the attainment of acceptable standards at all stages of the life cycle. Failure to address issues in any of these stages will result in inadequate decontamination.

**3.3** At all stages of reprocessing, the following issues need to be considered:

i. the existence of effective management arrangements.
ii. the existence of policies and procedures for all aspects of decontamination work.
iii the location and activities where decontamination takes place.
iv. facilities and equipment at each location.
v. ensuring the equipment used is validated, maintained, and tested in accordance with manufacturer's guidelines and legislation.

## Cleaning and Disinfection:

**3.4** Cleaning is essential and the most important step in the reprocessing life cycle. UK guidelines mandate the manual cleaning of visible soil from the device, to include probe and cable.

**3.5** The preferred method of cleaning is using an immersion method within dedicated wash/rinse sinks, using cleaning agents designed for purpose and concentrated to validated levels. However, this guidance acknowledges that immersion methods are not always possible with Ultrasound probes, so secondary systems must be confirmed.

**3.6** The removal of visible soil from probe and cable as per the Instructions For Use (IFU) is an essential pre-requisite prior to further decontamination stage and the activity must be, followed by a robust visual inspection of cleanliness prior to disinfection or sterilisation.[1]

**3.7** Removal of chemical residues from the probes is essential after the cleaning phase, prior to HLD , remaining chemical residues may interact with the probe material causing damage and also may interact with any subsequent high level disinfection process. Historical evidence is able to confirm such residues can be the source of device damage when interacting with HLD procedures. Rinsing maybe necessary where pre-clean wipe compatibility is not confirmed with device or HLD process.

**3.8** 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.

**3.9** Where manual cleaning systems are used in isolation and are not followed by an automated/ validated procedure, it is essential that all activities are documented, can be traced and operators who complete tasks are trained and competency assessed routinely by appropriate personnel. Systems should also be audited routinely by the organisations Decontamination Lead or IPC representative.

**3.10** Medical devices must always be compatible with all detergents and decontamination methods that are used. Compatibility statements from suppliers of probe manufacturer and wipe manufacturer must be confirmed in writing prior to use for decontamination activities.

**3.11** When choosing a wipe for pre-cleaning/disinfection of a probe following removal of the probe cover, User's must consider the following:

- Choose an appropriate wipe or a pH neutral detergent wipe for pre-cleaning the probe
- The chosen wipe should be recommended & approved by the probe manufacturer as being compatible with their ultrasound probe; review Instructions For Use (IFU)

The (IFU/label) of the chosen wipe should be consulted to determine:

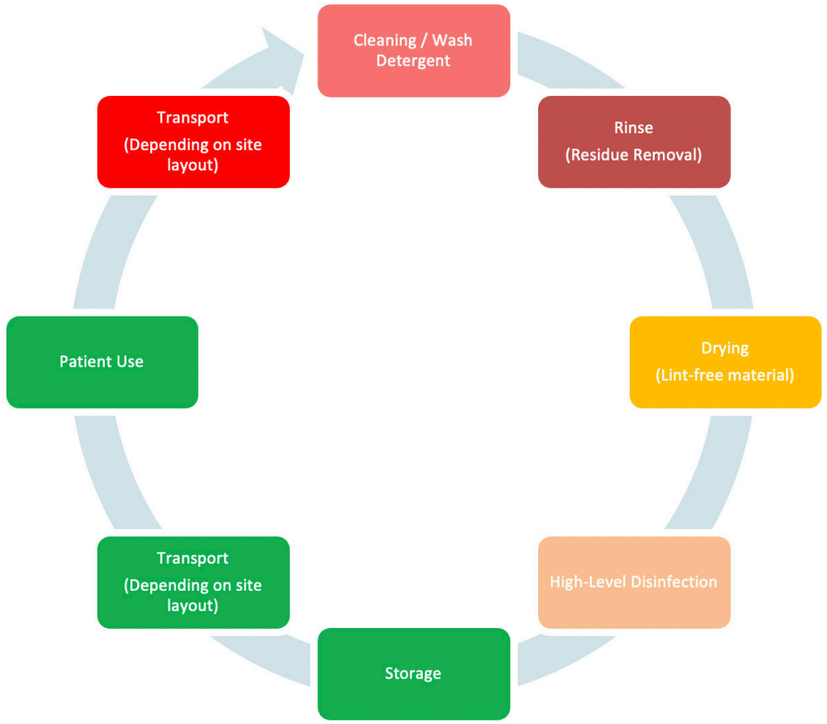
- Chosen wipe should be classified under UKCA as a medical device (with a CE mark & accompanying number)
- Chosen wipe should not contain any type of alcohol
- Do not use wipes where the IFU/label states 'do not mix with other chemicals'; this indicates the chemistry may not compatible with other HLD chemistries



**3.12** The recommended steps for probe reprocessing are:

- Patient Use
- Bedside Clean (If delays are presented prior to return transport)
- Transport
- Cleaning
- Rinsing (Where compatibility uncertainties remain)
- Drying (Essential where moisture would interact with subsequent processes)
- High Level Disinfection
- Transport/Storage
- Preparation for Use (Gel selection/cover)
- Patient Use

**Decontamination Life Cycle Diagram – Semi Critical Probes (No Sterilization)**



**3.13** The information in each of these steps need to be linked through formal traceability systems and responsibilities at each stage must be confirmed.

**3.14** Device inspection 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, combined cleaning and disinfection wipes or appropriate liquid detergents diluted as per instructions. The chemical composition is vitally important to ensure the efficacy of the solution is optimised.

## Types of HLD methods available (in no order of preference):

### Using Compatible Ultraviolet Light Systems:

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

**3.16** Confirmation of compatibility from ultrasound device manufacturers must always be sought prior to utilization of such UV light HLD systems. Where such systems are used there must be a robust validation procedure to determine optimal values of equipment performance and performance qualification tests to determine whether the efficacy of the installed equipment achieves HLD, with no shadowing present.

### Using Hydrogen Peroxide Systems:

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

**3.18** Confirmation of compatibility from ultrasound device manufacturers must always be sought prior to utilization of such HLD systems.

### Endoscope Washer Disinfectors:

**3.19** (EWD) can accommodate TOE Probes with use of appropriately designed systems to protect the integrity of electronic components. 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.

**3.20** Confirmation of compatibility from ultrasound device manufacturers must always be sought prior to utilization of EWD systems.



### Using Manual Multi-wipes:

**3.21** Semi-critical Ultrasound Probe (Semi-invasive and Non-invasive) High Level Decontamination Procedure. This is the least preferred option for decontaminating SIUP's as the process cannot be validated and is subject to operator variation and process drift over time, not least when there are clinical pressures within a department.

**3.22** Confirmation of compatibility from ultrasound device manufacturers must always be sought prior to utilization of individual manual multistage wiping systems.

**3.23** Additionally, there must be consideration for alternative systems that have advanced with technology. Evidence of process effectiveness must be determined and agreed prior to acceptance.

**3.24** For any method of decontamination, it is essential that the manufacturers of the HLD equipment and the SUIP instructions for use must be reviewed and assessed as compatible before purchase and development of processing instructions.

4

Chapter 4

# Service Best Practice

## Features of a service meeting Best Practice Standard include:

**4.1** 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. Any area where the manual multiple wipe method is used can never be considered Best Practice and health boards and trusts should always be looking to move to methods that can be validated.

**4.2** Decontamination methods must always be compatible with the devices and must not present any degradation to the device or ancillary cable, handles etc. Where uncertainties are present the User must contact the device manufacturer and other advisors within the organisation such as the ODL, IPC team and AED for guidance.

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

**4.4** Policies should be escalated to strategic decontamination group and Ultrasound governance groups for review and acceptance.

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

**4.6** 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.

**4.7** Use of Personal Protective Equipment (PPE) during decontamination activities must be in accordance with local strategies and standard operating procedures.

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

**4.9** Internal audits are carried out to ensure compliance to best practice.

**4.10** Staff are trained and competency assessed at regular intervals .

**4.11** Decontamination activities should be undertaken in a dedicated area external



5

Chapter 5

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

to clinical activities.

## Operational Decontamination Lead

**Nominated person is responsible for:**

**5.1** Supporting the overall decontamination of reusable ‘invasive’ medical devices for the healthcare facility (for example, Decontamination Manager or Infection Control Manager).

**5.2** Guiding and supporting the delivery of effective and technically compliant decontamination services for Probes in accordance with best practice guidance.

**5.3** Supporting the Responsible Person in the implementation of an operational policy for decontamination of probes in accordance with local policies.

**5.4** Supporting the Responsible Person together with the Infection Prevention and Control Team (IPCT) in monitoring the implementation of the policy.

**5.5** Be the link between all key stakeholders to determine the best solution for the organisation for decontamination of all medical devices within the organisation. This will require communication with other relevant stakeholders to include the User, RP, IPC, AE(D) and others.

## Responsible Persons (User)

**Responsible Persons (User) role includes:**

**5.6** The adherence to an agreed policy for decontamination of Probes rests with the person designated as the “Responsible Person” (e.g., Unit Manager, Lead Sonographer or Senior Charge Nurse (SCN)).

**5.7** The Responsible Person ensures that the management of Probe decontamination is in accordance with manufacturer's instructions and relevant WHTM Guidance Document which covers the entire decontamination equipment life cycle from acquisition to disposal.

**5.8** Responsible Person must seek support/link with the Decontamination Lead and the IPCT to ensure safe decontamination processes are in place.

**5.9** 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.

**5.10** The Responsible Person must ensure there is an appropriate program of operator training in place and co-ordinate with training providers. Such training should be reviewed annually for every operator though competency assessment and refresher/new training as required.

**5.11** Maintenance of validation records and traceability records for the lifetime of the equipment (as a guide a minimum 11 years' timeframe).

## Operator

**Operator is responsible for:**

**5.12** 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).

**5.13** Escalating any concerns with process, equipment failures etc.

**5.14** Product release is in accordance with required information.

**5.15** Responsible for attending training at the frequency determined in the Organisational Decontamination policy.





**5.16** The Operator should be trained in Probe decontamination and deemed competent by the Responsible Person (Unit Manager) by undertaking a documented competency assessment.

**5.17** Training programs for operators should include the following where appropriate to duties:

- Probe Decontamination Techniques, to include inspection/cleaning/drying
- Anatomy of devices
- COSHH training
- Use of automated/validated HLD systems
- Documentation and trace-ability requirements, to include SOP's
- Record keeping
- Escalation strategies
- Occupational Health requirements
- PPE
- Transportation and Storage

**5.18** Descriptions for other key stakeholders can be found in WHTM 01/01 part A Chapter 7.0, Functional Responsibilities

6

Chapter 6

# Facilities for Decontamination Activities

## General

**6.1** Best practice identifies that decontamination activities should be performed in a suitable location external to the clinical treatment area. This area should facilitate 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 minimize opportunities for cross-infection of service users, clinical staff and cross-contamination of the working environment.

**6.2** Adequate space should be dedicated for decontamination and there must be consideration to ancillary services serving the locality, to include ventilation and other critical services.

**6.3** Decontamination and storage facilities are workplaces, and it is a legal requirement under the Building Regulation that they be ventilated.

i. To help to meet this legal requirement

ii. To maintain a comfortable working environment for the staff

ii. To remove airborne hazards (biological and chemical) arising from the decontamination process

iv. To preserve the quality of devices that have been decontaminated.

**6.4** To fulfil these purposes, air will need to be supplied and extracted with the correct pressure cascade to ensure that air flows from the clean to the less clean areas of the facility. The ventilation system should be designed, installed, validated, maintained, and operated to ensure that contaminants arising from the decontamination process are contained and removed.

**6.5** All ventilation systems serving both clinical and decontamination facilities must meet relevant requirements of WHTM 03/01. This will include periodic plant system maintenance and cleaning regimes to maintain the integrity of the built environment.

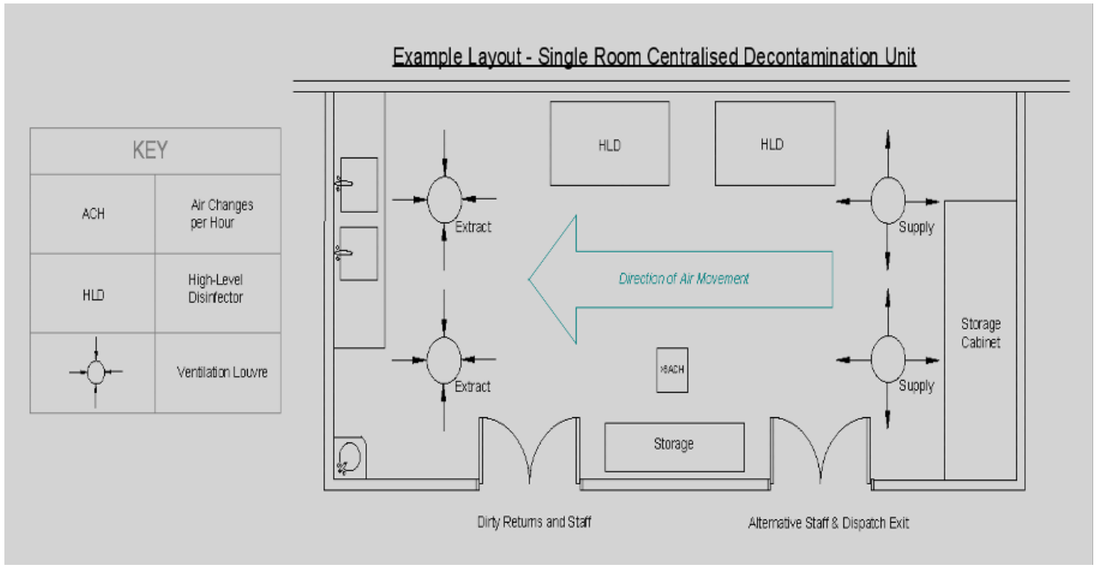


**6.6** Where decontamination is undertaken in the clinical area, consideration must be given to distance the activity from the patient area. Other considerations include:

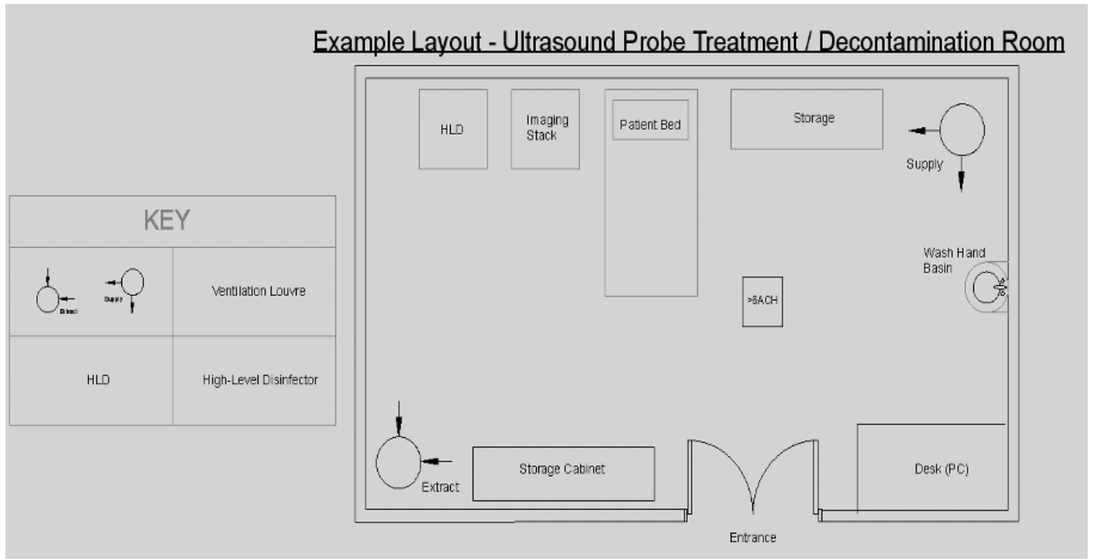
- Designated work surface space
- Provision of hand wash facilities
- Segregation of dirty/clean processes
- Disposal of any items used during the decontamination process
- Storage of items used for decontamination and device usage.
- Routine domestic cleaning arrangements.
- Assessment of COSHH implications within the room environment.
- Provision of Traceability (Electronic and/or manual systems).

**6.7** The IPCT, Estates representatives and OPDL must be consulted to undertake necessary risk assessments to reduce the potential for any cross infection or inadvertent errors when completing decontamination.

**Example of Single Room Decontamination Area**



**Example of Clinical Room with decontamination activities taking place within.**




**6.8** Guidance on development of such facilities dedicated for decontamination can be sourced from WHTM 01/06-part B. Advice must be sought from local Estates and Facilities, the AE(D), IPC and ODL at early stages of any project development plan to create appropriate decontamination facilities.

**6.9** Consideration must be given and decontamination solutions presented where User's are using equipment between wards/clinics. The Decontamination Lead, Infection Prevention and Control teams must assess risks and determine the most appropriate practice in alignment with recommendations illustrated in this guidance.





7

Chapter 7

# Operational Management Considerations

## Use of a Probe Barrier

**7.1** The purpose of probe barriers (sheaths) is to provide an additional layer of protection to prevent gross soiling of the reusable device. Where used, there should be consideration given to periodic bioburden testing as part of quality control, they are usually supplied as unsterile.

**7.2** Literature evidence and studies are available to demonstrate the high frequency of probe sheath perforation. Use of such barriers does not negate the need for Probes to undergo full decontamination, to include manual cleaning prior and HLD between each patient use

**7.3** A sheath, designated for purpose and appropriately certificated in accordance with national standards (UKCA/CE marked) 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.

**7.4** Any devices and ancillary items manufactured for single use application, that are used during clinical activities, must never be re-used and should always be disposed after each use of in accordance with the organisations policies. In no instance should the devices be re-used.

## Transport and storage

**7.5** If the reprocessing workflow requires probe transportation, the following requirements should be met:

- The probe cover and any gel should be removed immediately after the examination and prior to transportation.
- Point of use bedside clean should be completed where such delays are known, with appropriate solutions manufactured for purpose.
- Dirty (i.e., contaminated/used) probes should be transported in (lockable/sealed) solid-walled containers with a biohazard label or other means of identifying contaminated status (such as colour coded covers).
- Transport routes should facilitate easy manoeuvring and avoid high areas of traffic.
- Disinfected/sterile probes should always remain separate from contaminated probes and be transported in clean (lockable/sealed) containers with a label or other means of identifying decontaminated status (such as colour coded covers).

**7.6** According to WHTM 01/06 guidelines, medical devices after reprocessing should be either immediately used (within three hours as specified as best practice for decontamination of flexible endoscopes (WHTM01-06)) or stored in a manner that maintains HLD status before next patient use. However, guidance issued through a working party for the Journal of Hospital Infection stated that such storage is not critical with non-lumened devices such as ultrasound probes.

**7.7** Organisations must develop guidance based upon robust risk mitigation where the recommended timescales are not adhered.

**7.8** 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/ODL) to determine the maximum storage time for probes (see note).
- If the probe is to be used after the agreed window, it should be fully reprocessed before the next patient use.

**7.9** Consideration must be in place for transport where portable scanning equipment is used. Provision of decontamination prior to movement between clinics and protection from environmental contamination are factors that must be assessed as part of this process.

## Console Storage Procedure

**7.10** 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.



**7.11** Before receiving the decontaminated Probe, the holder is cleaned between patients with a compatible detergent wipe and dried with a single use lint-free cloth/wipe followed by a single use disinfectant wipe. Any such wipes used must be compatible with the device manufacturers material specification and used in accordance wipe manufacturer's instructions for use. Where chemical residues remain, they must be removed after decontamination of the console, using agreed rinse solutions/systems.

**7.12** 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).

**7.13** Manufacturer's instructions should be consulted regarding storage of Probes.

## Standard Operating Procedures

**7.14** Standard Operating Procedures must be developed for each system/procedure used within the organisation. This must clearly identify the agreed stages of each part of the reprocessing life cycle of Ultrasound probes. As a guide the SOP must include systems used for:

- Device integrity checks
- Pre-cleaning, methodologies
- Use of chemicals, to include any immersion concentrations and optimum exposure times/ temperatures for process, recommended exposure times and cleaning action are controlled and recorded on each occasion where wipes are used. Cleaning and wipes will indicate on their packaging if suitable for use on medical devices as many are wipes intended for environmental surface cleaning/disinfection rather than medical devices.
- A rinse stage must be completed, using appropriate rinse solutions, where chemical residues are present post cleaning and prior to HLD. This will be necessary where non-compatible wipes are used for decontamination activities (check compatibility statements).
- Drying of probes post cleaning – use of appropriate dry, lint free, cloths designated for purpose.
- Use of HLD/Sterilization – to include product release requirements
- Compatibility requirements when using HLD systems to include all automated and manual systems used.
- Storage/Transport – to include timescales for storage post HLD and agreed protocols for any covers used (such protocols need agreement with the ODL and IPCT within the organisation)
- Cleaning of the ultrasound unit, to include surfaces and where the probe sits
- Ultrasound Probe use requirements – to include selection/use of gel/cover and pre-examination checks.

**7.15** The SOP must also consider ancillary factors that may include storage of consumables used during the HLD process, storage/use of chemical indicators used during the HLD process, and any other equipment specific checks determined by the probe/decontamination equipment manufacturer.

**7.16** Training procedures must ensure all personnel undertaking Decontamination and device usage are familiar and are competent to work within the developed SOP's.

**7.17** SOP's must be reviewed and revised through the Strategic Decontamination and Ultrasound Governance Groups.

## Record Keeping

**7.18** Records are established and maintained to demonstrate the effcacy 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, escalate such issues to the manager or RP in a timely manner. There needs to be a formal escalation policy in place to ensure all non-conformities are registered in the agreed manner.

**7.19** The Operator is responsible for recording any non-conformances with the immediate decontamination process.

**7.20** The Responsible Person (Unit Manager) is responsible for establishing and ensuring records are maintained and up to date. This responsibility includes reviewing all raised non conformances, ensuring appropriate corrective action is completed within an appropriate timescale.

**7.21** Records must be 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.

## Tracking and Traceability

**7.22** A system must be in place to ensure Probes are tracked through the whole decontamination process and linked to the patient on whom the devices have been used. The organisation should work toward implementing an electronic tracking system for RIMD's.

**7.23** This guidance acknowledges the preference for using compatible electronic systems for traceability purposes. All traceability systems used must be consistent with the organisations record keeping systems and must include records of any manual pre- cleaning as well as automated part of process.

**7.24** Traceability systems must be audited routinely, and this audit must be kept for record purposes.



**7.25** Requirements of a Trace-ability System:

- Retain records of all patient/patient activity associated to the device.
- Confirm the operator/user undertaken Decontamination activities.
- Record all parts of the decontamination activities to render a re-usable device/probe safe for further patient usage.
- Record all consumable items used during the decontamination process.
- Record any storage activities between each patient use.
- Be compatible with any internal Information Technology policies.
- Will present the organisation with the required information to protect itself in the event of a patient related query.

## Transportation

**7.26** Procedures defining the transportation of Probes, after clinical use, to a dedicated onsite decontamination area (either an adjacent room next to the patient treatment area or a nearby facility) must be developed.

**7.27** All RIMD are soiled and contaminated after each use and can be a potential source of infection. Contaminated RIMDs 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 device 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.

**7.28** Remove gross contamination and accessories as detailed in the decontamination procedure currently in use. The Probe must be placed into a clean 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 (lockable) to prevent damage or injury during transport and accompanied by a Decontamination Certificate.

**7.29** Any container used must be appropriately cleaned prior to re-use the next occasion.

## Storage of decontaminated Probes

**7.30** RIMD must always be stored in such a way that their integrity and microbial state is maintained (e.g., high-level disinfected).

8

Chapter 8

# Commissioning and Validation of HLD Equipment

## General

**8.1** 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. Such validation must include installation, operational and performance qualification.

**8.2** Thereafter the Responsible Person will ensure that at a minimum period, an annual validation and service of all decontamination equipment is performed by a Competent Person. Such validation will include operational and performance requalification.

**8.3** All commissioning, servicing and re-validation and documents must be retained in a secure location by the Responsible Person for 11 years plus the lifetime of the equipment (this maybe electronic or through archived retention). Review documentation to ensure it is compliant to all relevant national and international standards.

**8.4** Validation reports must be submitted for formal authorization by representatives who understand the validation process, such representatives will include the ODL, the AP(D) and the AE(D).

**8.5** Advice on validation is available from the AE(D) representing the organisation.

**8.6** Manual systems of decontamination cannot be validated or verified as there are too many variables to determine.

## Installation Qualification (IQ):

**8.7** Process of obtaining, and documenting, evidence that equipment has been delivered, manufactured, and installed, in accordance with its specification.



## Operational Qualification (OQ):

**8.8** Process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

## Performance Qualification (PQ):

**8.9** Process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with pre-determined criteria and there-bye yields product meeting its specification.

## Periodic Validation:

**8.10** Routine monitoring and control systems must be in place where using automated technology. This is to ensure the validated processes and periodic validation in accordance with national and international guidance. WHTM 01/06 specifies such guidance within Wales, and this specifies that weekly/quarterly and annual validations are carried out.

**8.11** The nature of the work, volume of clinical activity, clinical risks, equipment manufacturers recommendations and available resource may dictate that periods of validation are not at the frequency identified within the guidance (Ref WHTM 01/06-part D).

**8.12** The level of testing is based upon the complexities of equipment used monitoring systems incorporated.

**8.13** Derogation away from recommended practice must be fully agreed with key stakeholders within the organisation to include the Decontamination Lead, Authorised Engineer (Decontamination), User, Infection Prevention Control and Ultrasound Governance Lead.

## Equipment Maintenance:

**8.14** Automated systems used for decontamination activity must be maintained in accordance with principles of manufacturer's recommendations. A maintenance schedule must be in place and implemented to check/replace critical components at recommended intervals. Such maintenance must be documented, and records of activities retained with the equipment documentation.

**8.15** It is recommended that all service/validation activity is carried out under the relevant permit to work protocols in place within the organisation.

9

Chapter 9

# Training and Education

**9.1** A formal mandatory induction programme for the workforce must be in place, 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 any and identified gaps in decontamination training. Such training must be included prior to any changes or introduction of new methods/equipment or techniques.

**9.2** 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.

**9.3** Training of staff undertaking activities must be undertaken to appropriate levels and carried out at routine intervals (annual update programme as a minimum) by providers who are competent for the training activities. Accredited training on decontamination principles should be considered for the User and the ODL.



**9.4** 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. Such training must include:

- Decontamination Principles
- Identification of the item to be used and ancillary components, to include awareness of need to repair.
- Correct use of PPE before use
- COSHH training relevant to products used, to include use/storage and disposal of chemicals. actual decontamination methodologies, documentation used and trace-ability requirements.
- Use of automated technology used for HLD.
- Use of compatible cleaning wipes used during the decontamination process.
- Trace-ability systems used
- Record Keeping in accordance with organisations policy
- Storage of devices

**9.5** Upon completion of the training, the healthcare worker and Responsible Person completes the Training Plan/Record and competency assessment. All training (internal and external must be documented and certificates and filed within the Training Plan/Record. Details of all training requirements are recorded on their Training Plan/Record for future development.

10

Chapter 10

# Summary of Essential Requirements to be considered for Decontamination

**10.1 Probe decontamination is carried out in accordance with the manufacturer**s 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.

**Compatible probe sheaths/condoms**

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.

**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.

**All healthcare workers undertaking probe decontamination are trained** and their competence assessed by the Responsible Person in the relevant procedures and training is recorded.

**10.2 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).



**10.3 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 generally 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 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.

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

**10.4 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.

**10.5 Probes are returned to the ultrasound machine for storage following cleaning of the probe holder on the ultrasound machine**. 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.

**10.6 Decontamination equipment sent away for repair** should be cleaned/disinfected in accordance with manufacturer's instruction and be accompanied by a decontamination certificate.

**10.7 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 within local policies.

**10.8 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.

**10.9 Audit** - A robust audit system must be in place to ensure all stages of the process, training, records management, validation and other systems are all being managed in accordance with the agreed SOP and national requirements. Such an audit should be completed by the individual departments, the organisations Decontamination Lead and IPC representative.

A1

Appendix 1:

# 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 regarding 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. There are significant advantages keeping the same probe with the same ultrasound machine, both from a traceability perspective and in respect lowering risk of device damage.

### 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.
- Indemnity offered by manufacturer/third party providers maintaining the probe

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.

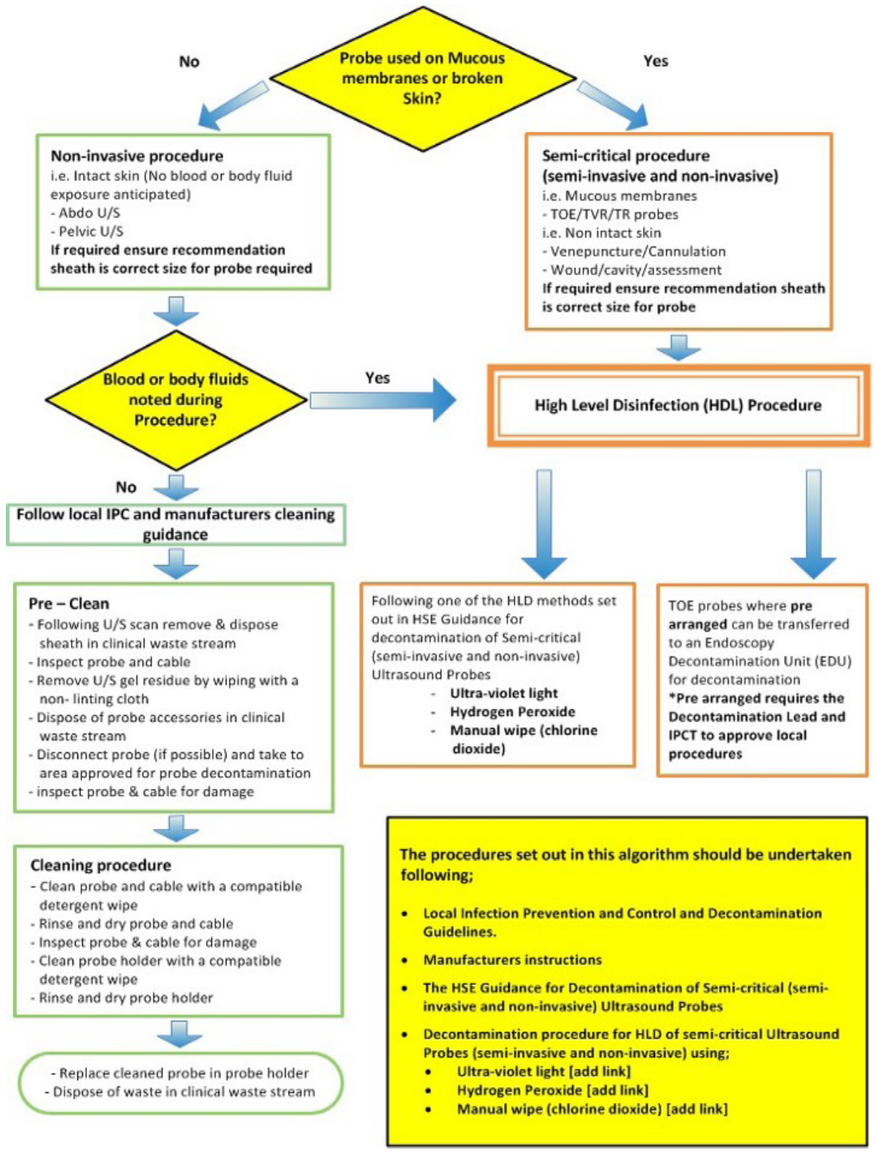
Anticipated lifespan of probe and ultrasound machine.

A2

Appendix 2:

# Semi-critical Ultrasound Probe (Semi-invasive and Non-invasive) Decontamination Algorithm (A guide developed from NHS Scotland Guidance Document, 2016).

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








A3

Appendix 3:

# Use of Ultrasound Gel

## General

Contaminated ultrasound gel has been associated with outbreaks of infection in various settings and or identified as a potential vector for infection. [1-9] Standard ultrasound gel is not produced as a sterile product. Ultrasound and ultrasound guided procedures are conducted routinely both in radiology and clinical areas, including use in high dependency care and among patients with immunosuppression. Available guidance on good practice in use of ultrasound gel for the UK setting is available as shown below: –

**Good infection prevention practice: using ultrasound gel – GOV.UK (www.gov.uk)**
**PSN065 Ultrasound Gel – Issued January 2023**

Burkholderia aenigmatic is a newly described species within the Burkholderia cepaciacomplex (Bcc). Outbreaks of Bcc due to contamination of aqueous pharmaceutical, medical and hygiene products including mouthwash, ultrasound gel, nebulization solution and liquid soap have been described in various settings. It is hypothesized that this outbreak may be caused by contamination of such a product which is widely distributed. Initial investigations are suggestive of a potential link with ultrasound gel.

**1. Purpose**
To reduce the incidence of potential infection using ultrasound gel.

**2. Objectives**
To ensure the use of sterile gel is adopted for use in investigations outlined below (procedure)

**3. Scope**
To ensure sterile ultrasound gel is used for the investigations outlined below in all relevant areas where ultrasound is undertaken.

**4. Materials**
Sterile Gel, pre-sterile gel filled condoms.

**5. Training Implications**
All staff implicated will be informed to adopt the new practice.

**6. Procedure**

Sterile ultrasound gel **must** be used in the following circumstances:

- for invasive procedures, i.e., any ultrasound guided procedure which involves passing a device through tissue such as intravenous line insertion or fine needle aspirate where there is contact with non-intact skin. This also includes 'viewing or initial assessment' of a site by ultrasound prior to undertaking an aseptic invasive procedure.
- Where there is contact with mucous membrane (e.g., for trans-rectal or transvaginal procedures)
- Where the ultrasound examination is near to an indwelling invasive device, such as an intravenous line or suprapubic catheter
- for examinations on immunocompromised, neonatal intensive care or critically ill hospitalised patients (such as in in high dependency settings)
- Where there is contact with or near to non-intact skin (any alteration in skin integrity such as a rash or surgical wound, including umbilicus in neonates).

The condoms used for transvaginal and trans-rectal examinations need to be preloaded with gel, latex free and are non – sterile. They are individually wrapped.

The probe covers and gel used for invasive procedures (examples above) would be sterile as they are purchased in a pack which includes both the sterile gel and probe cover. Sterile gloves must be worn.

The probe covers for the larger curve linear / linear probes used on non-intact skin would be sterile as again they are purchased in a pack which includes both the sterile gel and probe cover although this is not performed as a sterile technique. Nonsterile gloves worn.

## General principle – Use of Ultrasound Gel (Ref example presented by Swansea Bay UHB)

- Ensure healthcare workers carry out hand hygiene before and after use of ultrasound gel.
- Gel should be stored according to manufacturers' instructions in an area that is dry and away from potential sources of contamination.
- Dispose of container if it appears soiled, is damaged or is out of date.
- Ensure to check and only use products within their expiry date and discard any product that has exceeded expiry or has exceeded the manufacturer's recommended time after opening.



## Which type of ultrasound gel to use

An example of a decision-making tree has been produced by the UK Health Security Agency.
Sterile ultrasound gel must be used:

- for invasive procedures, which is any ultrasound-guided procedure that involves passing a device through skin into sterile tissue, such as intravenous line insertion or fine needle aspirate
- if an invasive procedure is likely to be undertaken in the following 24 hours – this includes 'viewing or initial assessment' of a site by ultrasound prior to undertaking an (aseptic) invasive procedure. If an unplanned invasive procedure is indicated and undertaken within 24 hours of non-sterile gel use, then clean and prepare the site as indicated in the general principles of non-sterile ultrasound gel use section
- in labour where there is high likelihood of C-section or invasive instrumentation during delivery
- where there is contact with or near to non-intact skin (any alteration in skin integrity such as a rash or surgical wound, including umbilicus in neonates)
- where the ultrasound examination is near to an indwelling invasive device, such as an intravenous line or suprapubic catheter
- where there is contact with a mucous membrane (for example for transrectal, transvaginal or ophthalmic procedures) – note: sterile gel to be used inside and outside of probe covers
- for examinations on severely immunocompromised individuals. This must be guided by a clinical risk assessment
- in an intensive-care setting, high-dependency, or equivalent unit/s, including neonatal intensive care units
- NB - For procedures involving potential contact with blood, mucous membranes, body fluids or non- intact skin, sheaths/ transducer covers must be used. Please follow the Health Board's protocol for decontamination of probe/ transducers following sheath removal.

Non-sterile ultrasound gel may be used:

- during low risk, general examinations on intact skin, not relating to an invasive procedure or within 24 hours prior to an invasive procedure.

For sterile ultrasound/ lubricating gel:

- Ensure that only unopened sachets and containers that are labelled as 'sterile' are used.
- Sterile gels are single-use only and MUST NOT be re-used under any circumstances. Discard any remaining gel immediately following use.

For non-sterile ultrasound gel:

- Ultrasound gel bottles must be marked with the date of first use. An indelible marker should be used in preference to sticky labels.
- Once opened, bottles must be used within one month of opening. Any bottles with gel remaining after this time should be disposed of.
- Ensure to check and only use products within their expiry date.
- Use single- use sachets or pre-filled, multi- patient disposable bottle.
- No re-filling of gel bottles should take place.
- Gel bottles should be kept upright to avoid inadvertent contact with holder.
- It is recommended that the outside of the gel bottle is wiped with an appropriate disinfectant between patients.
- Tip/nozzle of bottle should not come into contact with anything – if it does, clean immediately with a disinfectant wipe
- Remove ultrasound gel from the patient's skin following procedure and advise patients to wash area when feasible
- If an invasive procedure is subsequently undertaken within 24 hours of the use of non-sterile gel at or near to the site, then ensure all residual gel is removed, and the skin is thoroughly cleaned using antiseptic skin preparation in line with local policy for the procedure (note: sterile ultrasound gel should normally be used in advance of invasive procedures as detailed in the Which type of gel to use section.

**Warming of gel**

The warming of non-sterile gel bottles is not advised unless there is clinical benefit that outweighs applying gel at room temperature. Where the warming of gel is deemed necessary, the use of dry heat is preferable to water. Gel bottles should be kept upright in warmers and not inverted. Bottles should be marked with the date of first use and disposed of after one week. Warmers should be cleaned regularly according to the manufacturer's instructions, where these exist, or clean according to local guidance.





Appendix IV:

# Resources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9) Health Facilities Scotland 2010. Scottish Health Planning Note13 Part 3 - Decontamination Facilities; Endoscope Decontamination Units, HFS.

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12) Health and Safety Executive 2002. Control of substances Hazardous to Health (COSHH).

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15) Infection Prevention Toolkit: **www.ultrasoundinfectionprevention.or.uk**

16) Health Service Executive (HSE) Quality Improvement Division (2017). HSE Guidance for Decontamination of Semi-critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes. Document: QPSD-GL[1]028-1.