Health Protection Scotland

NHS National Services Scotland

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

March 2016

Health Facilities Scotland
Decontamination Services

Contents

Terminology used within the guidance document

"**Semi-critical**" 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 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 the blood which requires a high level disinfection process.

The terms "**User**" and "**Operator**" are distinct and defined terms used throughout this guidance and associated SOPs.

The "**User**" is the manager responsible for decontamination and production of fit-for-purpose probes (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).

An "**Operator**" is **not** a "**User**". However, in small units or in exceptional circumstances a "**User**" can be an "**Operator**" if sufficiently trained.

1.1 PURPOSE

This guidance sets out the operational procedures covering decontamination of Semi-critical probes using High Level Disinfection (HLD). This 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 vascular access,
  - cannulation or
  - wound assessment)

Throughout the guidance document and associated Appendices/SOPs 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.

In addition to the guidance, generic Standard Operating Procedures (SOPs) are provided as appendices and are referenced throughout the guidance document. The generic SOPs are intended to provide healthcare staff with the procedures required for the full decontamination process. An algorithm has been included as Appendix 7 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 staff to use as a quick reference guide. A further three SOPs detailing three different methods of HLD (hydrogen peroxide mist, ultraviolet-C light and manual multi-wipes) have been produced and links to the SOPs are provided throughout this document.

2.0 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 high level disinfection (HLD) between patients[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]

2.1 Literature review on the decontamination of Semi-Invasive Ultrasound Probes

A scientific literature review was undertaken by HPS on the decontamination of Semi-Invasive Ultrasound Probes which found 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, 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 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] 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 evidence from the literature review shows:

- There is high level (1+ and level 2) published evidence to support the use of Ultra Violet light systems for decontamination of SIUPs
- There is low level published evidence (level 3) to support the use of automated chemical systems (hydrogen peroxide) for decontamination of SIUPs
- There is low level published evidence (level 3) to support the use of a manual detergent/disinfection/rinse (multi-wipe) system for decontamination of SIUPs
- There is no published scientific evidence available to review to support the use of an EWD for decontamination of TOE Probes
- Non-invasive ultrasound probes were not included within the remit of the literature review. However the Spaulding classification system (referenced within the literature review) describes any device which comes into contact with broken skin as semi-critical.[3] This is the same for semi-invasive probes and the rationale for inclusion within the guidance document.

Levels of evidence

The following grades were given to the available evidence within the literature review using SIGN methodology.

1+ Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

2 Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal

3 Non-analytic studies, e.g. case reports, case series

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]

2.2 Health Facilities Scotland (HFS) national survey.

Health Facilities Scotland (HFS) conducted a national survey of TOE, TV and TR ultrasound probes to identify current decontamination practice for SIUPs across NHS

Scotland which concluded that there is an ongoing risk to patient safety with regard to decontamination of these SIUPs.

2.3 Health Protection Scotland (HPS) SBAR on sheaths

Health Protection Scotland (HPS) undertook a rapid review of the literature in 2014 regarding sheaths and produced a Situation Background Assessment and Recommendations (SBAR) regarding their use. The literature was related to lumened and non lumened scopes however it is agreed by the expert steering group it is relevant to probes. HPS concluded there was no comprehensive assessment of the evidence for sheaths in relation to infection control and healthcare associated infection (HAI). Therefore if HLD is being undertaken between patients then a sheath is not required to reduce cross transmission risks. A sheath only requires to be used if clinically indicated to aid the diagnostic procedure. The CDC guidelines for the disinfection and sterilisation in healthcare facilities support this advice which 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]

The standard of SIUPs decontamination across NHSScotland 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. This guidance document provides NHS Scotland Health Boards with an evidence based approach to the decontamination of semi-critical probes. The guidance has incorporated the findings of the 2012 HFS study, the recommendations from the MHRA Medical Device Alert, the evidence from a full systematic literature review on the decontamination of SIUPs and the expert opinion of the Endoscopy and Primary Care Working Group and the HAI Reusable Medical Devices Expert Advisory Steering Group. Where evidence was lacking the guidance was developed using the expert opinion of national experts from the HAI Reusable Medical Devices Expert Advisory Steering Group and associated subgroups.

3.0 ROLES AND RESPONSIBILITIES FOR HEALTHCARE WORKES INVOLVED WITH DECONTAMINATION OF SEMI-CRITICAL ULTRASOUND PROBES (semi-invasive and non-invasive)

3.1 Decontamination Lead/Nominated Person is responsible for:

- The overall decontamination of reusable medical devices for the health board (i.e. Decontamination manager or Infection Control Manager)
- Providing effective and technically compliant decontamination services for probes in accordance with best practice guidance
- Implementing an operational policy for decontamination for probes in accordance with the policies outlined in **Section 4.0 (Decontamination Policy)**
- Monitoring the implementation of the policy. This can be done using the policies outlined in **section 4.0**

3.2 User is responsible for:

- The responsibility for decontamination of probes rests with the person designated as the "User" (e.g. Unit manager, Lead Sonographer or Senior Charge Nurse (SCN)).
- The User's responsibilities include ensuring that the management of probe decontamination is in accordance with equipment manufacturer's instructions, the probe manufacturer's instructions and this National Services Scotland (NSS) guidance document. These cover the entire decontamination equipment life cycle from acquisition to disposal.
- The User should identify the Decontamination Lead for the health board to ensure the user has the appropriate contact regarding decontamination expertise.

3.3 Operator is responsible for:

- Performing probe decontamination procedures; decontamination equipment cleaning; routine maintenance and testing; ensuring probes are fit for purpose 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 User (unit manager). See Appendix 3; SOP: training for staff undertaking semi-critical ultrasound probe (semi-invasive and non-invasive) decontamination).

4.0 SEMI-CRITICAL ULTRASOUND PROBE (semi-invasive and non-invasive) DECONTAMINATION POLICY

4.1 **Semi-critical probes should be decontaminated using a HDL method**.

There are four methods available;

- **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
- **using manual multi-wipes**;
  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. Users must note that despite using an EWD for decontamination of TOE probes a manual cleaning and disinfection of the handles must take place.

The evidence to support the 4 methods of decontamination can be found within the **Background section 2.1 (evidence from the literature review).**

4.2 **Purchase of a probe decontamination system should be based on the following criteria;**

- Evidence to support effectiveness of the decontamination system from this guidance document and decontamination system manufacturers. This can be found in **section 2.1**
- Safety of use (for staff and patients) of the decontamination system including any possible process residue
- Compatibility with the range of ultrasound probes
- Validation of disinfection process and practicality within the clinical setting
- Compatibility of wipes used for cleaning/disinfecting the internal surfaces of the decontamination equipment
- Costs (purchase and maintenance)
- Environmental and energy impacts

4.3 **Purchase of a probe decontamination system (see appendix 1)** Standard Operating Procedure (SOP) for purchase of a Semi-critical ultrasound probe (semi-invasive and non-invasive) decontamination system) is the responsibility of the User (unit manager) and undertaken with advice from the decontamination lead, procurement lead/manager, Authorising Engineer Decontamination (AE(D)), medical physics and Infection Control Doctor or nurse with regard to the criteria stated in **4.1**.

4.4 **Probe decontamination is carried out in accordance the manufacturers** of the decontamination systems instructions, the re-processing instructions provided by the probe manufacturers and with this guidance document. Should conflicting advice occur the User 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.

4.5 **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 staff.

4.6 **Compatible probe sheaths/condoms** - Use of a sheath/condom does not negate the need for probes to undergo HLD as there is limited evidence on their effectiveness as a barrier to reducing the risk of HAI. A sheath should be used if clinically indicated 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.

4.7 **Decontamination equipment is validated, tested, maintained and operated** in keeping with latest relevant standards and guidance and manufacturer's instructions. Validation, testing and maintenance of probe decontamination systems is the responsibility of the User (unit manager). The SOP for validation should be followed in line with chosen decontamination procedure. See Appendix 2 (for generic SOP) for Validation, testing and maintenance of semi-critical ultrasound probe (semi-invasive and non-invasive) probe decontamination equipment, and decontamination systems SOPs for ultra violet light, hydrogen peroxide and manual multi-wipes.

4.8 **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 User (unit manager) is responsible for establishing and ensuring records are maintained and up to date. Records are securely stored either in electronic or paper form and readily accessible to permit traceability (for probes, decontamination equipment and patients). Guidance on record keeping can be found within the appendices and SOPs where applicable.

4.9 **All staff undertaking probe decontamination are trained** and their competence assessed by the User in the relevant procedures. This training is recorded. See Appendix 3 - SOP: Training for staff undertaking decontamination of semi-critical ultrasound probes (semi-invasive and non-invasive).

4.10 **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 storage containers recommended by the manufacturers (this should not be the manufacturers carry case).

4.11 **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 User, Decontamination Lead and the local IPCT should be involved in the risk assessment and development of local protocol and processes using manufacturers instructions. Where this is the case the HAI risk assessment should be placed on the local Risk Register by the User in the ongoing pursuit of the preference for a dedicated decontamination room.

4.12 **Probe decontamination should be undertaken following the SOP** for either;

- An Ultra-violet light decontamination system
- A hydrogen peroxide decontamination system
- A manual multi-wipe system

An algorithm is available (see Appendix 7) 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 system SOPs described.

- EWD within the endoscopy 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. This should be agreed with the Decontamination Lead and the IPCT. The SOP for transport and storage should be followed (see Appendix 5: SOP for transportation and storage of semi-critical ultrasound probe (semi-invasive and non-invasive)). This will ensure the appropriate steps are taken for transport to and from the Endoscopy Decontamination Unit (EDU) where the TOE probe will be reprocessed by trained decontamination staff. The SOP also describes the procedure for storage of TOE probes on return to the unit.

4.13 **The Product (probe) Release procedure defines the acceptance criteria to be met** before the probes are fit for use on the next patient. The product release procedure is performed by the Operator and monitored by the User in line with Appendix 4- SOP: semi-critical ultrasound probe (semi-invasive and non-invasive) decontamination; product (probe) release. Product release processes can also be found in the SOP for decontamination using UVC, chemical disinfection (hydrogen peroxide) and multi wipe (chlorine dioxide) systems. For TOE probes decontaminated within an EWD the product release will be performed by the staff within the decontamination facility and all local procedures must be followed before the TOE probe is returned to the department for use.

4.14 **Probes are returned to the ultrasound machine for storage following cleaning of the holder** (see Appendix 5: SOP for transportation and storage of semi-critical ultrasound probes (semi-invasive and non-invasive)). 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. Manufacturers instructions should be consulted regarding storage of probes. If this guidance and manufacturers instructions are contradictory the User should discuss the issue with the Decontamination Lead, the manufacturer and the IPCT.

4.15 **The design of the decontamination facility used,** be it in a separate room or incorporated in a clinical procedures room, should have a clearly designated flow from used (dirty) through the cleaning and disinfection process to clean and available for storage and use.

The area designated for the decontamination of probes should be designed following discussion with the Decontamination Lead and the IPCT. The User is responsible for ensuring the decontamination facility is “fit for purpose” and should refer to the principles set out in SHPN13 Part 3 – Decontamination Facilities -Endoscope Decontamination Units. [9] This provides design guidance on sizing decontamination facilities, room layouts and a room data sheet specifying furniture/fittings and surface finishes.

4.16 **Tracking and Traceability-** A system allowing the tracking and tracing of probes through the decontamination process to the patient should be in place.

4.17 **Decontamination equipment sent away for repair** should be cleaned and be accompanied by a Decontamination certificate.

4.18 **Transport and Storage** Semi-critical probes SOP should be followed in line with the SOP: Transport and Storage of semi-critical ultrasound probes (semi- invasive and non-invasive) (see Appendix 5).

4.19 **Decommissioning and disposal of probe decontamination systems** should be carried out by the Operator and monitored by the User who has overall responsibility. Decommissioning and disposal of probe decontamination systems SOP should be followed in line with procedure (see Appendix 6). Large waste electrical goods are classed as hazardous waste and there is a duty of care under the 'Duty of Care – A Code of Practice (Oct 2012') (http://www.scotland.gov.uk/Publications/2012/ and Environmental Waste (Scotland) Regulations 2012 to dispose of them responsibly. Contact the Waste officer and refer to Scottish Health Technical Note 3 NHSScotland waste management guidance Part C: Compendium of regulatory requirements (February 2015) for further information.

4.20 **Patient and staff exposure to materials** must be minimised and the Control of Substances Hazardous to Health (COSHH) regulations must be complied with.

APPENDIX 1: STANDARD OPERATING PROCEDURE FOR PURCHASE OF A SEMI-CRITICAL (semi-invasive and non-invasive) PROBE DECONTAMINATION SYSTEM

1.0 PURPOSE

To define the process for purchasing decontamination equipment for probes.

2.0 RESPONSIBILITY

Purchase of a probe decontamination system is the responsibility of the User (unit manager).

3.1 PROCEDURE

3.2 Purchase of probes with regard to decontamination

3.1.1 Probes are purchased through the National Procurement Framework (NP167/14 Multi-modality imaging) or an approved supplier list. Consideration must be given to compatibility with the decontamination process proposed or already in place. 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.

3.3 Purchase of probe decontamination equipment

3.3.1. 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) are consulted to ensure compatibility of the probe decontamination system with the probes to be used and the processes involved.

3.2.2 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.

3.2.3 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;

- Management pursue any non-conformance with the manufacturer.

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

APPENDIX 2 - STANDARD OPERATING PROCEDURE: VALIDATION, TESTING AND MAINTENANCE OF SEMI CRITICAL (semi-invasive and non-invasive) PROBE DECONTAMINATION EQUIPMENT

1.0 PURPOSE

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

2.0 RESPONSIBILITY

The procedure is monitored by the User (e.g. unit manager).
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 User. Monitoring by the User 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.

3.1 PROCEDURE

3.2 INSTALLATION, COMMISSIONING AND VALIDATION

The User is responsible for ensuring 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 by the User.

3.3 ANNUAL AND PERIODIC TESTING

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

3.4 USER 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.

3.5 FAULTS AND REPAIR

The Operator records the fault, then notifies the User, local estates (if it does not conflict with the service contract) and the manufacturer/supplier when a fault occurs.

The User 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 User checks the repair is satisfactory. The Operator retains a record of the repair work in the log book.

4.0 RECORDS

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

Equipment log book
Traceability records
Maintenance and test records
Validation report

APPENDIX 3 – STANDARD OPERATING PROCEDURE: TRAINING FOR STAFF UNDERTAKING SEMI CRITICAL (semi-invasive and non-invasive) PROBE DECONTAMINATION

1.0 PURPOSE

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

2.0 RESPONSIBILITY

This process is the responsibility of the User and the Operator.

3.1 PROCEDURE

3.2 Job Description

3.2.1 Decontamination responsibilities should be reflected within the job description of each member of staff who is involved in the management and decontamination of semi-invasive ultrasound probes.

3.3 Induction of New Staff

3.3.1 The User 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.

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

3.3.3 Training needs assessment is carried out for a new staff member and periodically thereafter. A training programme is generated and documented in within their Training Plan/Record.

3.4 Training Record

The User and staff maintain and update the Training Record covering all staff working within the unit/department. The record identifies the training received and competencies of each member of staff.

3.5 Training Review

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

3.5.1 The User reviews the competence of all staff, as local policy dictates, to evaluate the effectiveness of training and identify any further training needs.

3.5.2 The training programme is planned, documented and monitored to ensure delivery as scheduled in the Training Plan/Record.

3.5.3 The User is responsible for ensuring any agreed training programme is implemented.

3.5.4 The content of the programme is reviewed as required by local policy.

3.5.5 Upon completion of the training, the member of staff and User completes the Training Plan/Record. For external training, copies of Attendance/Competence Certificates are obtained (if applicable) and filed in the Training Plan/Record.

3.5.6 Details of all training requirements are recorded on their Training Plan/Record for future development.

APPENDIX 4 – STANDARD OPERATING PROCEDURE: SEMI CRITICAL (semi-invasive and non-invasive) PROBE DECONTAMINATION - PRODUCT (probe) RELEASE

1.0 PURPOSE

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

2.0 RESPONSIBILITIES

The product release procedure is performed by the Operator
The product release procedure is monitored by the User

3.0 PROCEDURE

3.1 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)

3.2 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.

3.3 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 attached to the patient records and system log books.

APPENDIX 5 – STANDARD OPERATING PROCEDURE: TRANSPORT AND STORAGE OF SEMI CRITICAL (semi-invasive and non-invasive) ULTRASOUND PROBES

1.0 PURPOSE

To define the procedures for:

1.1 Transporting probes (if required) after clinical use to a dedicated on-site decontamination area (either an adjacent room next to the patient treatment area or a nearby facility).

1.2 Storage of decontaminated probes.

2.0 RESPONSIBILITY

The User monitors the procedure (i.e. ensures the appropriate processes are in place to follow the SOP).
The Operator performs the transport and storage elements of this procedure.

3.0 TRANSPORT PROCEDURE OF CONTAMINATED PROBES (if disconnected)

3.1 Immediately after use, remove gross contamination and accessories as detailed in the decontamination procedure in use. See SOP in Appendix 4: Semi critical (semi-invasive and non-invasive) probe high level decontamination procedure and SOPs for ultra violet light, hydrogen peroxide and manual multi-wipes.

3.2 If probe decontamination is being performed in a local (same hospital), place the contaminated probe into a solid-walled container (i.e. endoscope tray) for transfer to the decontamination area immediately after use. Porters may assist Operators for transportation. Probes and their cabling are fragile and should be handled with care.

3.3 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. Further information is included in the NHSScotland, Guide to the Carriage of Dangerous Goods Regulations with respect to Used Medical Devices 2013 available from the HFS website. http://www.hfs.scot.nhs.uk/services/decontamination-services/guidance/

4.0 STORAGE PROCEDURE

4.1 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.

4.2 Before receiving the decontaminated probe the holder is cleaned between patients with a detergent wipe and dried with a lint-free cloth. This process should be carried out whether the probe can be disconnected or not.

4.3 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. Manufacturers instructions should be consulted regarding storage of probes. If the guidance and manufacturers instructions

contradict the User should discuss the issue with the Decontamination Lead, the manufacturer and the IPCT.

4.4 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.

4.5 **Only store probes in the manufacturer's carrying case after a decontamination cycle and when transporting probes out with the unit/department** (e.g. when transporting for repair).

APPENDIX 6 – STANDARD OPERATING PROCEDURE: DECOMMISSIONING AND DISPOSAL OF SEMI CRITICAL (semi-invasive and non-invasive) ULTRASOUND PROBE DECONTAMINATION EQUIPMENT

1.0 PURPOSE

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

2.0 ROLES AND RESPONSIBILITIES

This procedure is performed by the Operator.
This procedure is monitored by the User.

3.1 PROCEDURE

3.2 LIFESPAN PLANNING

Planning for end of equipment lifespan is an essential part of equipment management. Contact National Procurement (NP), 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;
- Absence of support or parts (e.g. manufacturer ceased trading).

3.3 DECOMMISSIONING

3.2.1 Prior to removing equipment from service, or if the manufacturer has ceased trading, contact NP, medical physics and the local Waste Management Officer for guidance;

3.2.2 Erase any patient identifiable data from electronic storage media within the equipment to the appropriate standard.

3.3 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.

Large waste electrical goods are classed as hazardous waste and there is a duty of care under the 'Duty of Care – A Code of Practice (Oct 2012') (http://www.scotland.gov.uk/Publications/2012/ and Environmental Waste (Scotland) Regulations 2012 to dispose of them responsibly. Contact the Waste officer and refer to Scottish Health Technical Note 3 NHSScotland

waste management guidance Part C: Compendium of regulatory requirements (February 2015) for further information.

APPENDIX 7: NHSScotland Semi-critical Ultrasound Probe (semi-invasive and non-invasive) Decontamination Algorithm

Probe used on Mucous membranes or broken skin?

No

Non- invasive procedure
i.e. Intact skin (No blood or body fluid exposure anticipated)
- Abdo U/S
- Pelvic U/S

If required ensure recommended sheath is correct size for probe required

Blood or body fluids noted during procedure?

No

Follow cleaning guidance in the NIPCM

Pre – clean
- Following U/S scan remove & dispose sheath in clinical waste stream.
- Inspect probe and cable
- Remove U/S gel residue by wiping with a non-linting cloth
- Dispose of probe accessories in clinical waste stream
- Disconnect probe (if possible) and take to area approved for probe decontamination
- Inspect probe & cable for damage

Cleaning procedure
- Clean probe & cable with a compatible detergent wipe
- Rinse and dry probe and cable
- Inspect probe & cable for damage
- Clean probe holder with a compatible detergent wipe
- Rinse and dry probe holder

- Replace cleaned probe in probe holder
- Dispose of waste in clinical waste stream

Yes

Yes

Semi-critical procedure (semi –invasive and non-invasive)
i.e. Mucous membranes
- TOE/TV/TR probes

i.e. Non intact skin
- Venepuncture/Cannulation
- Wound/cavity assessment

If required ensure recommended sheath is correct size for probe

High Level Disinfection (HDL) Procedure

Following one of the HLD methods set out in NHSScotland Guidance for decontamination of Semi-critical (semi-invasive and non-invasive) Ultrasound Probes
- **Ultra-violet light**
- **Hydrogen Peroxide**
- **Manual wipe (chlorine dioxide)**

TOE probes where **pre arranged** can be transferred to an endoscopy decontamination unit (EDU) for decontamination
***Pre arranged requires the Decontamination Lead and the IPCT to approve local procedures.**

The procedures set out in this algorithm should be undertaken following;

- **Standard Infection Control Precautions (SICP) within the National Infection Prevention and Control Manual (NIPCM)** http://www.nipcm.hps.scot.nhs.uk/
- **The NHSScotland Guidance for decontamination of Semi-critical (semi-invasive and non-invasive) Ultrasound Probes**
- **SOPS: Decontamination procedure for HLD of semi-critical Ultrasound Probes (semi-invasive and non-invasive) using;**
  - **Ultra-violet light [add link]**
  - **Hydrogen Peroxide [add link]**
  - **Manual wipe (chlorine dioxide) [add link]**

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