Decontamination Procedure for high level disinfection (HLD) of Semi-Critical Ultrasound Probes (Semi-invasive and Non-invasive): using automated hydrogen peroxide systems

1. PURPOSE

These operating instructions describe the method for decontamination of ultrasound probes using equipment based on hydrogen peroxide. This is a semi-automated process to achieve high level disinfection (HLD) of probes in a sealed chamber by exposure to hydrogen peroxide mist.

2. RESPONSIBILITIES

The User (unit manager) has overall responsibility for the ultrasound probe decontamination procedures within the department.
The Operator (person undertaking decontamination of ultrasound probes) performs this procedure.

3. PROCEDURE

Decontamination procedures should be performed in a designated room/area preferably separate from the clinical area. However, HAI risk-assessed procedures in the patient area are currently an acceptable solution when manufacturer's' recommend the ultrasound probe cannot be disconnected or there is no designated room/area separate from the clinical area (see NHSScotland guidance document for further information).

3.1 PREPARATION OF ULTRASOUND PROBE DECONTAMINATION EQUIPMENT

Ensure the equipment is switched on, warmed up and the printer contains paper, if applicable. Follow the equipment manufacturer's instructions and the equipment display to identify when to load the probe.

3.2 PRE-CLEANING OF PROBES – essential requirement

Perform hand hygiene and put on clean PPE (apron and gloves).

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Immediately after patient use inspect the protective sheath for integrity. Remove all accessories and the sheath from the probe. Using a low-linting wipe, remove the ultrasound gel and dispose of the sheath and wipes in the clinical waste.

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Dispose of any single use accessories (e.g. biopsy needle guide) into the appropriate waste stream (SHTN 3).

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Any reusable accessories needing sterilization should be reprocessed following manufacturers' instructions in a Central Decontamination Unit. Contact the Infection Prevention and Control Team or CDU manager.

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*Disconnect the probe from the console if recommended by the manufacturer and transport to the designated decontamination room or area. (See Transport and Storage SOP).

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

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Clean the probe and cable with a compatible detergent wipe, recommended by the probe and probe disinfection equipment manufacturers, to remove all visible contamination.

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Remove detergent residues with a compatible rinsing wipe and dry with a clean, single use, low-linting cloth.

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

3.3 INSPECTION

After pre-cleaning, examine the probes for cleanliness, dryness, damage and functionality. Ensure there are no signs of discolouration or cracks, giving particular attention to the probe tip.

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Report any non-compliance to the User. When appropriate, segregate and label the probe to prevent use.

3.4 DISINFECTION

Place the probe in the equipment chamber. Operate the equipment with strict adherence to the disinfection equipment manufacturer's instructions.

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

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

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

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Open the cabinet door, remove the probe and wipe with a low-linting cloth ensuring the probe is completely dry. Close the equipment door in readiness for the subsequent cycle.

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

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Check the printer-generated traceability labels produced after each cycle to confirm a successful decontamination process. Attach the traceability labels to patient records and into the equipment log book.

3.5 INSPECTION – post disinfection

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

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Report any non-compliance to the User. When appropriate, segregate and label the probe to prevent use.

4. PRODUCT RELEASE

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

- Test and maintenance records are satisfactory and up to date;
- System display indicates 'pass';
- Labels generated/completed and indicate 'pass';
- Process indicator 'pass' (if applicable);
- Visual inspection 'pass';
- Traceability records complete.

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

4.3 If a non-conformance is found during inspection of the ultrasound probe, the management is informed in order to decide the appropriate corrective actions.

5. VALIDATION, TESTING AND MAINTENANCE

This is monitored by the User (e.g. unit manager).
When applicable the installation, validation, periodic testing and repair are only carried out by the manufacturer's engineer.

5.1 INSTALLATION, COMMISSIONING AND VALIDATION

The User is responsible for ensuring the installation, commissioning and validation of the equipment is performed 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.

5.2 ANNUAL AND PERIODIC TESTING

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

5.3 MAINTENANCE AND ROUTINE CLEANING

Planned preventative maintenance is carried out as recommended by the manufacturer. Routine cleaning and maintenance is performed by the Operator (the person who undertakes probe decontamination).

Routine cleaning is carried out when the equipment chamber is cool. Wipe all accessible surfaces including the inside of the chamber with compatible detergent wipes until all surfaces are visibly clean.

5.4 FAULTS AND REPAIR

The Operator records the fault, then notifies the User,

The User investigates the fault. If unresolved, contact the local estates department (if it does not conflict with the service contract) and the manufacturer/supplier for repair.

Repair is carried out by the manufacturer's engineer when applicable. When complete, the User checks the repair is satisfactory. The Operator retains a record of the repair work in the log book.

6. RECORDS

Equipment log book
Traceability records
Maintenance and test records
Validation report