Ultrasound Infection Prevention Toolkit

UK and Ireland

Ver. 1.0

Prevention of infection during ultrasound probe use and reprocessing

www.ultrasoundinfectionprevention.org.uk/

Introduction

The decontamination of ultrasound probes is essential to reduce the risk of contracting a healthcare-acquired infection.

This toolkit has been assembled in consultation with clinical experts with backgrounds in infection prevention and instrument reprocessing.

The objective in developing this toolkit has been to provide a resource regarding infection prevention during the use and reprocessing of ultrasound probes.

This toolkit will support you to locate the ultrasound probes within your organisation, as well as guide you on how to measure the risks associated with the procedure for which the probe has been used.

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Tool 1: Part A - Locate

This list of strategies can help locate ultrasound machines in your facility. Locating ultrasound machines can be challenging, as they may move around, be uncatalogued, or be unknown to personnel responsible for probe use and reprocessing.

Tool 1: Part B - Profile

After locating ultrasound machines with the Locate tool, this audit tool containing ready to use forms and observation checklists can be used to observe and assess procedure-specific ultrasound SOP and practice. First, list of ultrasound systems present in the deparment, record the probes used and related prcedures, then assess the documentation in place before auditing the actual practice.

Tool 2: Algorithm

This tool is organised by department and provides a range of typical procedures that may be encountered in that department. Probe use and reprocessing requirements based on national guidelines (NHS Scotland, HSE Ireland, SCoR/BMUS) and international standards (ESR, ECMUS and WFUMB) are presented as a decision making algorithm. The flow chart can be printed out and displayed throughout office and procedure rooms and used as a quick reference chart for healthcare workers to determine whether a practice is compliant with available guidelines. An editable chart allows further adjustment following approved local processes.

Tool 3: Example Risk Assessment

This tool contains four editable templates designed to guide the assessment of potential hazards that may be encountered during the use and reprocessing (cleaning, disinfection, storage) of ultrasound probes. A sample risk matrix is provided with further instructions for completion. A facility should aim to mitigate all significant harm to the lowest risk rating. If that is not possible, the existing workflow and/or products should be reconsidered.

Tool 4: Policy Development Framework

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

Foreword

This UK and Ireland toolkit has been adapted from the original U.S. toolkit, which was assembled in consultation with North American clinical experts with backgrounds in infection prevention and instrument reprocessing. The objective in developing this adapted toolkit has been to provide a relevant resource regarding infection prevention during the use and reprocessing of ultrasound probes in the United Kingdom and Ireland.

UK-specific adaptions have been made by:

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Approach and Principles

These tools have been assembled based on best practice national and regional guidelines [1-10] with the goal of reducing infection risks associated with ultrasound use in the interest of patient safety. They are intended to guide the development of institutional policies and procedures, with an understanding that each institution can vary in the patient groups cared for, settings, types of care provided.

Funding

The development of this toolkit has been supported by Nanosonics Ltd. Nanosonics Ltd strives to improve the safety of patients, clinics, their staff and the environment by transforming the way infection prevention practices are understood and conducted and introducing innovative technologies that deliver improved standards of care.

Important Note

The information, materials and opinions contained in this toolkit have been prepared for general information purposes only, are not intended to constitute clinical or other professional advice and should not be relied on or treated as a substitute for such advice on the subject matter.

Please consider this guidance in light of the reader's own professional training and judgement and specific regulations, guidelines, policies and procedures of each region, institution and department. This toolkit does not replace directions contained in a manufacturer instructions for use (IFUs) documents, nor does it replace institutional policies/workflows, but is intended to be used in conjunction with them. This Important Note applies to all parts of this toolkit.

Disclaimer

Nanosonics manufactures and supplies automated high-level disinfection systems for ultrasound probes. Whilst all commercially reasonable efforts have been taken to prepare this toolkit, Nanosonics will not accept any liability or responsibility of any kind for reliance on the information, materials and opinions contained in this toolkit, including for any death or injury to persons. Nanosonics makes no warranties, representations or undertakings about the content (including, without limitation, the quality, accuracy, completeness or fitness for any particular purpose of such content). To the fullest extent permitted by law, Nanosonics will not be liable for any loss or damage (including any consequential, incidental, special or indirect damages) whatsoever or for any loss of data, loss arising from interruption to business, loss of profits or other damage or losses of any third party arising out of or in any way relating to errors, omissions, or inaccurate or out-of-date information in this document. Any and all use or reliance on this toolkit is at your own risk.

Healthcare professionals should undertake their own enquiries as necessary and exercise professional judgement when assessing the needs of the particular patient. Copies of the journal articles and references referred to in the toolkit can be provided upon request.

Acronyms

AEd: Authorised Engineer (Decontamination)
BMUS: The British Medical Ultrasound Society
ECMUS: European Committee for Medical Ultrasound Safety
ESR: European Society of Radiology
HCO: Health Care Organisation
HLD: High-Level Disinfection
HSE Ireland: Health Service Executive Ireland
HTM: Health Technical Memorandum
IFU: Instructions of Use
ILD: Intermediate-Level Disinfection
IPC: Infection Prevention and Control
IQ: Installation Qualification
LLD: Low-Level Disinfection
MHRA: Medicines & Healthcare products Regulatory Agency
NHS Scotland: National Health Services Scotland
OQ: Operation Qualification
PPE: Personal Protective Equipment
PPM: Planned Preventive Maintenance
P.Q.: Performance Qualification
RIMDS: Reusable Invasive Medical Devices
SCoR: Society and College of Radiographers
SOP: Standard Operating Procedure
SSD: Sterile Services Department
WFUMB: European Federation of Societies for Ultrasound in Medicine and Biology

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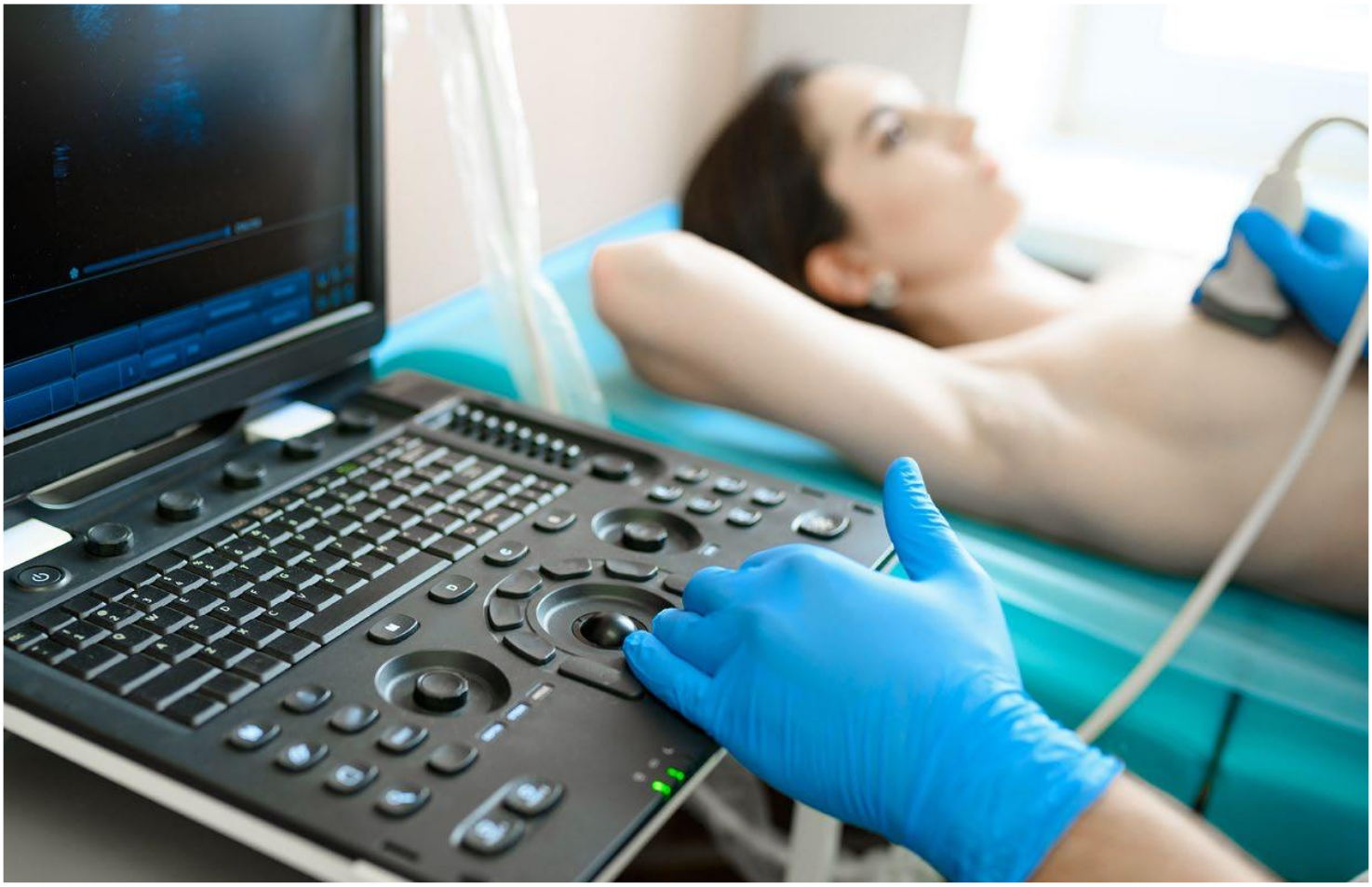

Prevention of infection during ultrasound probe use and reprocessing

Tool 1 Locate and profile

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Tool 1: Part A – Locate

Objective: Locate the departments/clinics using ultrasound at your facility.

This list of strategies can help locate ultrasound machines in your facility. Locating ultrasound machines can be a challenging task, as they may move around, be uncatalogued, or may be unknown to personnel with responsibility for probe use and reprocessing.

The options listed can be used to determine where ultrasound is used in order to facilitate follow up on any issues related to infection prevention. The different options below may be relevant based on the type and size of your facility. More than one strategy may be used in attempting to locate ultrasound machines. Strategies are ranked in order of assumed effectiveness.

Tool 1: Part A – Locate

Department name: double click to type here

Locate the departments/clinics using ultrasound at your facility.

Strategy	Rationale	How	Limitations
1. **Locate where ultrasound machines are by searching the organisation's asset register.**	The HCO's assets registry department maintains an asset register of equipment used throughout the facility. The asset register links the ultrasound machine to department locations.	Ask HCO's assets registry department to provide a complete list of ultrasound probes and consoles from their asset register. Identify the service they belong to and the department in which they are located.	· Not all ultrasound machines may be listed on the register. · Asset registers may be incomplete (e.g. due to mergers/acquisitions, purchases being made by local departments, trial equipment being used, replacement of old equipment, equipment shared between several departments or other reasons).
2. **Locate where ultrasound consumables are being used (e.g. gel, probe sheaths/ covers).**	All ultrasound probes are used with ultrasound gel which is essential for imaging quality. Some ultrasound probes are used with sheaths/covers. Locating ultrasound gel and probe covers will lead to the departments using ultrasound probes.	Approach the procurement and/ or logistics team to request they search purchase orders and inventory lists for each service department/facility, and provide a report of material.	· It may be difficult to obtain purchase orders and inventory, particularly if a central system is not in place. · Some consumables may be ordered centrally and distributed, or may be ordered and purchased locally (e.g. by individual departments or units). · It may be difficult to identify consumables due to multiple brands/ suppliers.
3. **Survey departments to identify where ultrasound is used.**	End users are the best placed to know where ultrasound is being used.	Approach departments and ask about their ultrasound use. Methods include but are not limited to: departmental/facility wide email, physically visiting or phoning each department and/or patient care unit leadership. Also, the assumption is that most Emergency departments, Critical Care Units and Operating departments will use USS (ultrasound scan) during procedures. It might be worthwhile to make contact with a clinical specialist i.e. critical care scientist who could advise of locations that routinely use USS for cannulations etc.	· It may be time consuming to reach all departments. · It may be difficult to identify staff with full knowledge of ultrasound use in their department.
4. **Identify ultrasound procedures in HCO coding systems records.**	Ultrasound procedures should be coded. If ultrasound procedure item codes are obtained, they can then be used to identify which departments or providers are performing those procedures.	Identify ultrasonography procedure codes; coding and information department for a list of ultrasound procedure item codes and determine which departments are performing those procedures.	· Coding may not provide department specific information. · The coding system may not be set up to readily perform these searches. · Not all services using ultrasound probes for diagnosis or treatment will record these as ultrasound procedures .

Tool 1: Part B – Profile

Objective: Profile policy and practice for each ultrasound procedure at your facility.

After locating ultrasound machines with the Locate tool, this audit tool can be used to observe and assess procedure-specific ultrasound policy and practice. The page can be printed, and ultrasound procedures for each facility area can be used for individual observation sessions. First, record the procedure and department, then work through the profile form. The questions guide the user through their policy, and an observation checklist is provided to record actual practice. The tool leads the user to an action plan (part C) if there is no policy or if there are discrepancies between policy, practice and guidelines.

Tool 1: Part B – Profile

Profile policy and practice for each ultrasound procedure at your facility.

a) Department and ultrasound systems

Department	Date	Assessor / Auditor	Operator(s) present

	Ultrasound machines identification	Manufacturer(s)
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

b) Probes and procedures

Probe name	Probe type (surface / endo-cavitary)	Probe ID*	Probe Serial Number	Probe Manufacturer	Procedure(s)	Spaulding Classification (non critical / semi-critical / critical)

**** ID number given by the HCO***

c) Documentation

Questions	Answers			Comments
Does the facility/department have SOP(s) for reprocessing ultrasound probes?	□ Yes	□ No	□ Not specified	
Do the operators have access to the US probe(s) IFU?	□ Yes	□ No	□ Not specified	
Is the reprocessing system manual?	□ Yes	□ No	□ Not specified	
Is the reprocessing system automated?	□ Yes	□ No	□ Not specified	
If yes to the automated question above: Has the automated reprocessor been validated, serviced and tested in line with national and international standards and following the manufacturer's recommendation?	□ Yes	□ No	□ Not specified	
Where are the validation and service reports stored?	□ Yes	□ No	□ Not specified	

d) Probe Reprocessing Procedure Audit:

Procedure name/type: _____

Spaulding classification: □ Non-critical □ Semi-critical □ Critical

SOP name	SOP number	SOP revision date

Questions	Answers			Comments
Is the SOP compliant with the relevant guidelines standards and manufacturer's IFU (compatibility)?	□ Yes	□ No	□ Not specified	

Observe Practice: How is the probe reprocessed and used for this procedure?

Step	Observations				Comments
Post-procedure cleaning (bed-side)	□ No	□ Yes	Method used:	□ Not specified	
Containment of contaminated probe	□ No	□ Yes	Method used:	□ Not specified	
Cleaning	□ No	□ Yes	Method used:	□ Not specified	
Disinfection type	□ LLD	□ HLD	Method used:	□ Not specified	
Disinfection method	□ Manual	□ Automated	Method used:	□ Not specified	
Terminal process step	□ LLD	□ HLD	□ sterilisation	□ Not specified	
Cover use	□ None	□ Single-use non-sterile	□ Sterile	□ Not specified	
Gel use	□ Multi-use bottle	□ Single-use non-sterile	□ Single-use sterile	□ Not specified	
Multi-use Gel max usage	□ 1 day	□ > 1 day	Please specify:	□ Not specified	
Reprocessing Traceability	□ No traceability	□ Manual	□ Electronic	□ Not specified	
Post processing storage	□ No	□ Yes	Method used:	□ Not specified	
Time limit defined?	□ No	□ Yes	Time limit:	□ Not specified	
Other steps(s) (please specify)					

Assess Practice

Questions	Answers			Comments
Is the observed practice fully compliant with the SOP?	□ Yes	□ No	□ Not specified	
Where are the training records stored?	Please specify:		□ Not specified	
Are the operators trained for this procedure?	□ Yes	□ No	□ Not specified	
Type of training	□ Internal	□ External	□ Not specified	

Audit Conclusion

Comments

If your SOP and practice are compliant: File this form, ensure ongoing training for all users.

If your SOP needs updating and/or users are not trained according to your SOP: **Go to Part C.**

Tool 1: Part C – Action Plan

Objective: Address any deviations identified in Part B – Profile.

Create an itemised action plan. The action plan should have a review date to assess its effectiveness and re-audit if necessary.

To ensure compliance, continuous improvement and effectiveness, the action plan should be reviewed at least annually.

Audit location: _____

Action Plan				Progress Update	Re-audit	
Auditor/assessor: Date:				Auditor/assessor: Date:	Auditor/assessor: Date:	
Deviations identified	Actions required	Person responsible	Priority High Medium Low	Status	Outcome	Action effectiveness *(How do you prove that the actions have been effective?)*

Action Plan Example

Action Plan				Progress Update	Re-audit	
Auditor/assessor: Date:				Auditor/assessor: Date:	Auditor/assessor: Date:	
Deviations identified	Actions required	Person responsible	Priority High Medium Low	Status	Outcome	Action effectiveness *(How do you prove that the actions have been effective?)*
SOP to be created	*1.Review IFU*	*XX*	*High*	*1.IFU reviewed*	*SOP conform with IFU*	
	2.Create a standardised procedure	*XX*	*High*	*2. SOP created*	*SOP is available in folder for all staff*	*Perform process audits once a year*
	3.Communicate SOP to all relevant staff	*Y.Y.*	*Medium*	*3. Awareness training rolled out*	*All relevant staff have been asked to describe the SOP*	
	4. Update training folders	*Y.Y.*	*Medium*	*Staff training folders to be updated*		

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