

Guidelines for Transoesophageal Echocardiography Probe Cleaning and Disinfection from the British Society of Echocardiography

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Abstract

The clinical utility of Transoesophageal Echocardiography (TOE) is well established. Being a semi-invasive procedure however, the potential for transmission of infection between sequential patients exists. This has implications for the protection of both patients and medical staff. Guidelines for disinfection during gastrointestinal endoscopy (GIE) have been in place for many years^{1,2}.

Unfortunately, similar guidance is lacking with respect to TOE. Although traversing the same body cavities and sharing many similarities with upper GIE, there are fundamental structural and procedural differences with TOE which merit special consideration in establishing a decontamination protocol. This document provides recommendations for TOE probe decontamination based on the available evidence, expert opinion and modification of current British Society of Gastroenterology guidelines.

Glossary of Terms

Automated Endoscope Reprocessor Washer-Disinfector machine capable of disinfection and rinsing to a reproducible standard and where the performance can be validated and verified.

Cleaning The physical removal of infectious agents (but not necessarily their destruction) and the organic material which can shield them from disinfectants.

Detergent Chemical that suspends organic material making subsequent removal easier.

Disinfection The process of reduction in viable infectious agents to a safe level.

Decontamination The process of cleaning combined with disinfection or sterilisation that makes medical devices safe for reuse.

Decontamination Lead Person responsible for implementing the operational policy for decontamination within a healthcare establishment.

Decontamination User : Person designated by management to take overall responsibility for the management of the decontamination equipment.

Decontamination Operator Person with the authority to operate decontamination equipment.

Sterilisation The process of rendering objects free from all viable micro-organisms.

Areas of exclusivity:

Clean Area – The area post-decontamination

Dirty Area – The area pre-decontamination

Components of the Transoesophageal Probe

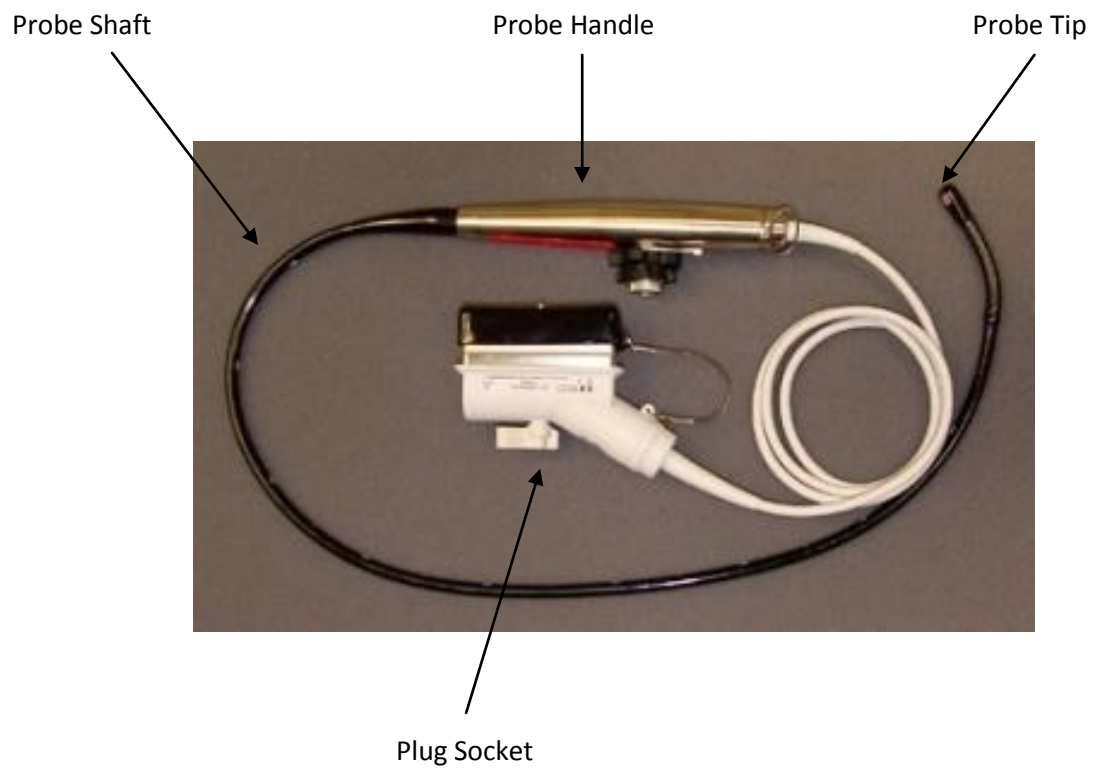
Probe Shaft: flexible with identifiable markers to assess depth of insertion

Probe Handle: contains both wheel and lock devices with steering buttons

Probe Tip: the flexible scan head housing the transducer, usually 7.5mm width x 5.5mm height x 18.5mm length, although new probe tips may be smaller

Plug Socket: end of the cable to attach the probe to its associated equipment

Figure 1. Components of a standard TOE probe



Introduction

The basic principles underpinning successful decontamination of reusable equipment are cleaning and either manual or automated disinfection. TOE probes do not warrant sterilisation, as they are endoscopes not penetrating sterile areas of the body (unlike laparoscopes or other surgical instruments), nor is sterilisation a feasible option.

Structural design of a TOE probe

All TOE probes, irrespective of the manufacturer, share the same components (see Glossary and Figure 1): a flexible tip, a shaft, a probe handle with steering controls and a cable which attaches to the plug socket in its associated equipment (**Figure 1**). Handling of any part of this apparatus results in a potential source of infection (**Figure 2** – these were probes considered to have been decontaminated by a manual wipe system and were ready for re-use with a subsequent patient). During passage into a patient, there is contact with intact mucous membranes and the potential for contact with non-intact mucous membranes. This means that TOE probes require disinfection to a similar level as upper GIE³.

Figure 2. Any part of the TOE probe can be a source of contamination.



(Photograph: Peter Hoffman)

A TOE probe is flexible, reusable, delicate, expensive and heat sensitive. A TOE probe cannot withstand the standard techniques of sterilisation utilising heat and steam. Whilst gas sterilisation is possible, the high costs and long cycle times involved at present render this technique impractical for routine use.

Advantages over GIE. Unlike standard upper GIE, TOE probes do not have internal channels for air, water or biopsy, which reduces exposure to those risks that prompted greater awareness of UK decontamination practices in 2004 (MHRA Medical Device Alert 2004/028)³ and makes contamination far more accessible for removal and disinfection.

Disadvantages over GIE. The probe handle, including the steering mechanism and the plug socket, is not sealed and cannot be immersed in any liquid for cleaning or disinfection. Entry of fluid or contamination in this region may result in corrosion and damage to electrical connections as well as serving as a vector for infection⁴.

Transmission of infection during TOE

Evidence that there is a risk of cross infection is minimal but absence of evidence is not evidence of absence of risk. Estimating the infection risk is difficult for several reasons. Firstly, there are no well-performed, comprehensive studies relating to infection control in TOE practice. Secondly, the onset of infections relating to procedures may be delayed until after discharge from hospital making diagnosis and reporting unlikely. As a marker for comparison, the reported frequency of infection following upper GIE is 1 in 1.8 million studies⁵. Based on this wider reporting in relation to upper GIE and bronchoscopy, it seems sensible to implicate the same causative agents during TOE^{5,6,7} (See Table 1). Thirdly, the possibility remains of transmission of infectious micro-organisms from one individual to another via the TOE probe with very long incubation periods. The issue of prion infection will be discussed in a later section.

Table 1 Examples of agents potentially transmissible by TOE

<i>Cross-infection from patient to patient and patient to staff</i>
a. Bacteria – <i>Helicobacter pylori</i> , <i>Pseudomonas aeruginosa</i> , <i>Salmonella species</i> , <i>Mycobacterium species</i>
b. Viruses – Hepatitis B & C, HIV
c. Prions – vCJD
<i>Contamination of patients from the decontamination procedure</i>
a. Bacteria – <i>Pseudomonas aeruginosa</i> , <i>Legionella pneumophila</i> , <i>Mycobacterium species</i>

There are no data relating to patient-patient risk of infection during TOE. The aim of decontamination is the prevention of cross infection from one individual to another, which is the focus of these guidelines.

Recommendations for TOE Decontamination

Effective decontamination strategies should promote health and safety of staff & patients alike. Care should be taken to safeguard TOE probe integrity and prevent damage that renders manufacturer warranty inoperable. Therefore, an ideal decontamination policy should consider the following:

Health and safety at work

Manufacturer warranties

Appropriate use of disinfectants

Clear delineation of 'clean' and 'dirty' areas in TOE probe decontamination and storage

A robust technique of decontamination

Training and provision of staff to engage in quality assurance audit and ensure traceability

General Considerations

Health and safety. The Health and Safety at Work etc. Act 1974⁸(HSAWA) requires employers to ensure the safety and welfare of all employees as far as is reasonably practicable. In turn, employees should comply with the established precautions to safeguard their working environment. A risk assessment should be performed before selection and purchase of an appropriate disinfectant for use with TOE. There are numerous disinfectants currently available on the market which may have potential hazardous effects. Further guidance is available from The Control of Substances Hazardous to Health Regulations 1994⁹ (COSHH)

Manufacture warranty. Prior to purchase of a TOE probe, an Echo department should review the manufacturer's recommendations regarding decontamination to ensure that these can be carried out within the resources available. This is important for a number of reasons. Firstly, adherence to such instructions is mandatory to safeguard equipment warranty by the manufacturer. Use of incompatible disinfectants or those not recommended renders the manufacturer warranty (and potentially the service contract) invalid, irrespective of any perceived damage, or lack thereof, to probes⁴. Secondly, use of a specific disinfectant may be recommended by a manufacturer even though that disinfectant may not be available within the UK. For example, glutaraldehyde is commonly used in the USA and may be recommended for a probe but it is not available in the UK and use exposes a department to legal action through the HSAWA and COSHH. Guidance listing the information to be supplied by manufacturers of probes and disinfectants can be sought by referencing the Medical Devices Agency¹⁰.

This document cannot be exhaustive in giving trade names of detergents or disinfectants. It is suggested that you consult with your Infection Prevention team and/or endoscopy unit for advice on

what is available for use in your establishment, for example, type of non-linting wipe with neutral detergent for probe pre-cleaning.

Choice of disinfectant. A wide range of products exist (see Table 2), but the choice of disinfectant should be governed by microbicidal range, safety and compatibility with the TOE probe^{1,11}. Agents used to date include aldehydes, hydrogen peroxide, peracetic acid, chlorine dioxide, superoxidised water and alcohols. The use of alcohols and aldehydes as a disinfectant is discouraged owing to their fixative properties, resulting in protein (including prion protein) retention on the probe¹.

Table 2. Comparison of disinfectants and their characteristics

Agent	Microbicidal efficacy				Compatibility*	Inactivation by organic matter
	Spores	Mycobacteria	Bacteria	Viruses		
Peracetic acid	5 – 10 mins	5 – 10 mins	<5 mins	<5 mins	Varies	No
Chlorine dioxide	5 – 10 mins	5 – 10 mins	<5 mins	<5 mins	Varies	Yes
Superoxidised water	10 mins	<5 mins	<5 mins	<5 mins	Varies	Yes

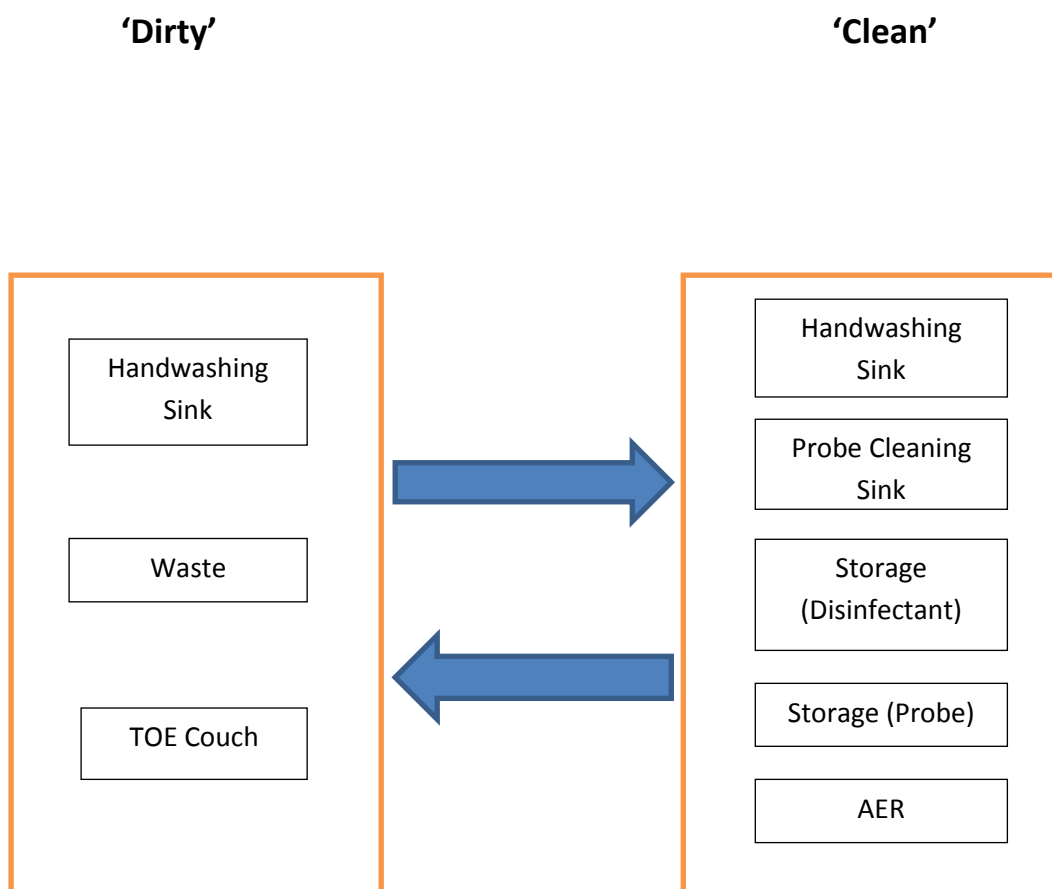
TOE Facility. Ideally, a suitable location (see Figure 3) for performance of TOE should comprise a two room facility: one in which the procedure is performed and a separate room for decontamination.

The procedure room should include space for hand washing, disposal of health care waste (including sharps & non-sharps), and safe and secure TOE probe storage.

The decontamination room should include space for a sink for cleaning the probe, a separate sink for hand washing, disinfectant storage and for the automated endoscope reprocessor (AER) if already in place, or facilities for manual disinfection instead. There should be a clear flow of work within this room with distinct and separate dirty and clean areas.

In facilities where the TOE procedure and disinfection are to take place in the same room, there should be pre-designated 'dirty' (pre-decontamination) and 'clean' (post-decontamination) areas to ensure that fully decontaminated probes cannot be confused with non- or partially decontaminated probes. Separating dirty and clean areas is a major step in eliminating probe recontamination or mistakenly using a probe that has not been fully decontaminated.

Figure 3. Schematic of two room layout for decontamination



There should be a clearly identified location for storage of decontaminated probes. This must be situated within the 'clean' area of the room so that there is no risk of recontamination of disinfected probes.

If two rooms are to be used, it is recommended that a rigid case should be available for transport of probes to minimise risk of damage.

Storage of TOE Probes. TOE probes should not be stored in their delivery cases. This is a high risk strategy – if one incompletely decontaminated probe is ever put in the case, the case will recontaminate all subsequent probes.

Ideal storage would be to hang the probe in a locked cupboard. An alternative would be to store the probe in a rigid tray (1-2 days) – longer storage may result in distortion of the probe shaft. Trays do not need to be sterile but should be visibly clean. The use of a tray liner and cover system may be beneficial particularly in transporting the probes, for example, using a green = clean and red = contaminated cover. This is widely used for flexible endoscopes and would be useful.

There is no time-limit to storage of a clean probe in a clean area, as recommended above. Minimal environmental (i.e. non-patient derived) contamination should not pose any risk to patients in this context. There are no lumens within which microorganisms can grow. There is no need to reprocess if stored in closed cupboard or covered tray before patient use.

Protective sheaths. Sheaths are additional physical barriers to infection and probe damage. They do not however, cover the whole of a TOE and so do not remove the possibility of cross infection from material deposited on the probe handle, cable or plug socket (see Figure 2). Sheaths are subject to perforation which may be undetectable to the naked eye. Perforation rates as high as 4.4% have been reported and may require a post-use air tightness test to confirm maintenance of structural integrity^{12,13}. Therefore, TOE probes should undergo the same decontamination whether or not a sheath is used.

Technique and facilities for decontamination

The following is a step-through guide to the guidelines for decontamination.

Pre-assessment. Standard infection control precautions should be adopted for each patient irrespective of status. However, placing of patients deemed to be of higher risk of carriage of infectious micro-organisms towards the end of a list may allow more time for disinfection of relevant surfaces within the room.

If a sheath is to be used during TOE, prior latex allergy or intolerance should be established. Alternative sheaths¹⁴ (e.g. polyurethane) should be trialled in positive cases since potentially life-threatening reactions have previously been reported^{15,16} or the procedure could be done without a sheath.

TOE Facility. Before and after each patient, all probe and hand contact surfaces should be thoroughly wiped with a disinfectant.

Personnel. Before and after each patient, thorough hand washing should be carried out by all those present. The hands are the most common source of spreading infection¹⁷. The majority of micro-organisms may be removed by a short and thorough washing of the hands¹⁸.

Personnel involved in the TOE procedure should wear single use gloves and an apron. If splashing of bodily fluid is likely, then face and eye protection should be considered.

Probe Cleaning. Decontamination should commence immediately following probe removal from the patient. If a sheath is used, this should be removed directly.

The probe shaft and probe tip should then be wiped with a single use non-linting wipe moistened with detergent solution to remove gross contamination. It is suggested that you consult with your Infection Prevention team and/or endoscopy unit for advice on what is available for use in your establishment, for example, type of non-linting wipe with neutral detergent.

A separate, similar second wipe (the first wipe will now be too contaminated to clean effectively) should then be used to wipe other parts of the probe to include non-immersible parts higher up, including the handle and plug socket. This second wipe reduces the potential for contamination on the housing unit etc. from the operator's hand.

The TOE probe should then be carefully inspected to ensure there has been no structural damage to cause loss of structural integrity of the coating that could allow ingress of contaminated material. Leak testing to demonstrate holes in the probe (different from electrical leak testing), as performed with gastroscopes, cannot be carried out with TOE probes as there is no port to permit insufflation of air.

The TOE plug socket should then be disconnected from the machine and the probe transported to the pre-designated decontamination area in a covered rigid container.

If the initial wipe has not thoroughly removed all visible contamination, the TOE probe should without delay then be immersed (whilst sparing the housing unit) in a sink or wash basin utilising a detergent made up to the dilution and contact times stipulated by the manufacturer. It is essential for effective disinfection that any organic matter that may inhibit disinfectant action and shield microbes is removed. Immersion of the probe in a detergent solution at a specified concentration for a specified time as a standard procedure would represent best practice. If necessary, the probe should be wiped with a cloth under the water level to remove all remaining visible contamination.

Following detergent use, the probe should be thoroughly rinsed with potable quality water to remove any residual detergent - if the detergent is not compatible with the disinfectant used in the next step.

Probe Disinfection. Probe cleaning must be followed by probe disinfection between every patient. Probe disinfection may be automated or manual. Automated disinfection has the highest quality assurance for TOE probe decontamination and should be considered best practice. Manual disinfection is an alternative whilst working towards best practice.

Manual Disinfection. Methods include the use of disinfectant wipes and baths. If manual disinfection is to be performed, particular care must be taken to ensure that disinfection is carried out not only

to the probe tip and shaft but also to the handle, cable and sections of the socket. It is important to ensure strict adherence to the manufacturer's instructions. Steps to be taken:

- Remove a wipe from closed sachet;
- Unfold the wipe and lay out on the palm the operator's hand;
- Cover the wipe with disinfectant solution to the volume recommended by the manufacturer, ensuring there is no delay between dispensing and use
- Wipe the whole TOE surface until it has been covered with disinfectant;
- All areas of the surface must come into contact with the wipe at least once for the recommended contact time;
- Discard the wipe to clinical waste.

Rinse thoroughly after disinfection to remove disinfectant residues after processing.

Automated Cleaning. Some AERs will accommodate TOE probes by allowing immersion of the probe shaft in fluids and protecting the probe handle and socket from fluid exposure. This will provide a standardised decontamination procedure. However, the non-exposed parts of the probe will require manual decontamination as described above.

Detergents to be used within AERs should again be in accordance with manufacturer guidelines. Following AER use and as part of the complete AER cycle, further rinsing with sterile water and drying in air is recommended.

The use of dedicated AERs for automated decontamination of endoscopes is validated and recommended for use if available^{2,19}. The advantages of this method are efficacy, reproducibility and diminished staff and patient exposure to potentially toxic disinfectants. The disadvantages are the high capital and running costs. The AER unit itself may become a source of contamination⁷ and therefore needs to be subjected to a self disinfection procedure at the start of each working day.

Successful modification (development of sealant around the housing apparatus) of AERs to enable total TOE probe immersion has been reported recently. The study numbers are too small at this stage to recommend routine longer term use²⁰.

All AERs should be validated and tested in accordance with up to date NHS Estates Health Technical Memorandum (HTM) 2030 guidance¹⁹ (to be replaced by HTM 01-06 in the near future).

Rinse water should be potable quality if manual cleaning/disinfection/rinsing is used or, if an AER is used, it should be within the limits specified by HTM 2030 (or Choice Framework for local Policy and Procedure [CFPP] 01-06 when published).

Staff Training, Education and Quality Assurance

Although different to GI endoscopy, the echocardiographer and allied health care professionals should be aware of the responsibilities outlined in the *Health Act 2006*²¹. This act emphasises the need for staff involved with decontamination to:

- Be trained and hold appropriate competences for their role
- Have monitoring systems to ensure that processes are fit for purpose
- Have tracking systems in place to ensure quality
- Identify and track patients after device usage in the event of future complication/infection

Following an incident that resulted in inadequate decontamination, *MHRA guidance (2004/28)*³ review of practice highlighted the following as particular problems to avoid, including: incompatibilities between endoscope and AERs; staff being unfamiliar with decontamination processes; poor communication between manufacturers of endoscopes and AERs. In order to specifically take these above points into account, it is recommended that:

1. When purchasing a TOE, AER or disinfectants, the manufacturer/supplier should be contacted to ensure compatibility and provide training tools
2. Regular audit of TOE decontamination practices is undertaken which may form the basis of a Care Quality Commission external examination
3. Each Trust should have a Decontamination Network in place to include a nominated Lead, Operational Manager and Operator/User
4. The User's responsibilities should include: certification of decontamination equipment as being fit to use, overseeing maintenance work to include quality assurance and training other operators to perform similar tasks
5. In the event of adverse incidents or concerns related to equipment failure / disinfectant malfunction, the MHRA should be contacted
6. A blame free culture of incident reporting should be encouraged

Record keeping. Each probe should have a unique identifier and a record of the probe used on each patient and the decontamination procedure should be retained in the patient records and/or the unit records.

Special Considerations

Prion Infection

Providing decontamination of the TOE is to approved standards, the use of the instrument is deemed to be of low risk in relation to transmission of prion infection. Advice relating to prion infection is up-dated regularly and attention should be drawn to the following sites^{22,23} for guidance:

<http://www.dh.gov.uk/ab/ACDP/TSEguidance/index.htm#jumpTo3>

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_117682.pdf

Conclusions

This document proposes a working solution to disinfection that can be implemented in Cardiology Departments for safe practice in transoesophageal echocardiography. There is little evidence relating to infection control within transoesophageal echocardiography, so the information provided represents a consensus of opinion. There are effectively two procedures possible within this document, a wipe-based disinfection system and a process based on automated processor disinfection. The former can be achieved with little additional modification of current departments but the latter will require additional investment in many. Correct application of either of these processes is important not only for patient care but also to ensure that it is possible to prove that proper decontamination has taken place and that a given TOE procedure is not at fault should a patient be subsequently found to have blood-borne viral infection.

Summary of Key Recommendations for Decontamination

1. Health and safety at work

Ensure compliance with Health and Safety at Work etc. Act 1974

Follow guidance from the Control of Substances Hazardous to Health Regulations 1994

Departmental policies should be in place in the event of disinfectant spillage or staff sensitivity to a disinfectant

Wear single use gloves, goggles and aprons when handling disinfectants

2. Safeguarding manufacturer warranty

Check cross-compatibility of disinfectants and AERs

Reference MDA Device Bulletin

3. Disinfectants

Check disinfectant compatibility with TOE probes and AERs

Check disinfectant concentrations and contact times are per manufacturer recommendations

Glutaraldehyde based disinfectants should not be used in the UK

Alcohol based products should not be used for disinfecting TOE probes

4. Protective sheaths

Sheaths may reduce the level of probe contamination but their contribution to infection prevention does not reduce the need for further probe decontamination.

Consider polyurethane types in the event of latex intolerance/allergy

Only an air tightness test confirms non-perforation

Decontamination technique should remain the same as for sheathless procedures and if used, decontamination must continue to be performed to cover transmission of infection from the probe handle, cable and socket.

5. Workplace

Ensure a nearby sink or washbasin for cleaning and rinsing

Predesignated 'dirty' and 'clean' areas should be in place

Restrict entry to staff familiar with decontamination practices

Probes should not be stored in their delivery cases

Probes should be stored in a locked cupboard or in a rigid tray

Consider transportation of probes using a tray liner and cover system

6. Decontamination technique

a i) Manual

Commence cleaning immediately following probe withdrawal

Initial wiping, followed by rinsing and near maximal immersion in disinfectant (sparing the probe housing unit)

Disinfectant to be made up to manufacturer recommended concentrates and contact times

And / Or

ii) Automated

Only use AERs if compatible and recommended by manufacturers. If the AER use does not comply with manufacturers' recommendations, it is possible that warranty and service contracts will be invalidated.

Disinfectant to be made up to the disinfectant manufacturers recommended concentrates and contact times

Rinsing with sterile water and air drying following AER use should be considered part of the AER cycle

b) Manual disinfection of those parts of the probe not immersible in the AER

c) Wipe all work surfaces clean

d) Handwashing

7. AERs

Routine AER self-disinfection

Culture rinse water weekly

Change water filters as per manufacturer guidance

8. Staff training

Register with the Care Quality Commission

Facilitate equipment training or training opportunities with manufacturers

9. Quality assurance

Designated Network to include Lead, Operational Manager and Operators/Users

Departmental Auditing

10. Incident Reporting and traceability

Blame free incident reporting culture is encouraged

Contact MHRA in event of suspected equipment/disinfectant malfunction

A log of procedures and identifiable probe label should be cross referenced for recording and traceability

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