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Cardiff and Vale
University Health Board

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Decontamination of Ultrasound Transducers - Standard Operating Procedure

Introduction and Aim

Decontamination of non-sterile reusable equipment is fundamental to maintain a high standard of infection prevention and protection for patients within CVHB Healthcare setting.

The following Operating Procedure standardizes the process of decontamination of the Ultrasound Transducers within Radiology

Objectives

Ensure all staff follow the correct and standardized decontamination procedures for Ultrasound Transducers.

Scope

This procedure applies to all of our staff in all locations including those with honorary contracts who undertake Medical Ultrasound Examinations and Procedures

Equality Impact Assessment

An Equality Impact Assessment has not been completed. This is because the SOP has been written to support the implementation of the overarching Decontamination Procedure. An Equality Impact Assessment for this Procedure will be completed when the Decontamination Procedure is reviewed.

Documents to read alongside this Procedure

www.nanosonics.com.au
www.tristel.com
<http://www.wales.nhs.uk/sites3/documents/254/WHTM%2001-06%20Part%20C.pdf>

Approved by

Decontamination Group
IP&C
Ultrasound Governance group.

Accountable Executive or Clinical Board Director

Director Of Therapies and Health Science.

Author(s)

Sally Lynch, Senior Sonographer
Nerys Thomas, Consultant Sonographer

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the [**Governance Directorate.**](#)

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Summary of reviews/amendments			
Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	02/04/2015	22/04/2015	This is a new Standard Operating Procedure.
2	06/05/2016	09/05/2016	Use of Trophon clean covers adopted.
3	08/12/2021	01/10/2021	Solely using Cleanisept wipes. Sterile gel used for interventional procedures.
4	11/01/2024	18/04/2024	Trophon 2 Trophon dry wipes (lint free) Incidin oxy wipe replacing Cleanisept wipes Radiology/Canon specific SOP

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DECONTAMINATION OF ULTRASOUND TRANSDUCERS

Standard Operating Procedure (SOP)

Introduction

The following Operating Procedure standardizes the process of decontamination of the Ultrasound Transducers across the Cardiff and Vale UHB (CVHB).

Decontamination of non -sterile reusable equipment is fundamental to maintain a high standard of infection prevention and protection for patients within CVHB Healthcare setting.

Definitions

Since ambiguity with terms can be a particular problem with decontamination the definitions used in this document are given below¹.

Contamination – the soiling or pollution of inanimate objects or living material with potentially infectious substances. In the clinical situation this is most likely to be organic matter (e.g. blood, faeces etc.) but may also include inorganic substances such as dust. Such contamination may be transferred to a susceptible host (person).

Decontamination – a process, which removes or nullifies contamination by biomass reduction and thereby prevents microorganisms reaching a susceptible (body) site in sufficient quantities to cause infection.

Cleaning – a process that physically removes contamination but does not necessarily destroy microorganisms. Cleaning is a necessary pre-requisite to ensure effective disinfection or sterilization.

Disinfection – a process used to reduce the number of viable organisms but which may not inactivate some viruses and bacterial spores.

Sterilization – a process used to render the object completely free from viable microorganisms, including viruses.

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Decontamination of transducers (Intermediate and high risk) (Intracavity/Contaminated with bodily fluids)

Trophon or Tristel must be used for the decontamination of all Intracavity transducers and any transducer that is contaminated by bodily fluids

As a Health board we have adopted the Trophon decontamination system. Tristel Trio wipe system to be used for decontamination only when Trophon is unavailable.

Key User / Trainer

All Departments / Directorates are required to name a Key User / Trainer.

Role and Responsibilities

Compliance.

Equipment Validation and Maintenance.

Record Keeping and Archive.

Training to include a register of users.

Audit. – Annual.

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Choice of decontamination method for medical/surgical devices.

The choice of decontamination method for medical/surgical devices and instruments is related to the risk of infection associated with usage in a given process. For example, for medical equipment the following apply:

Transducers used for intra-cavity examinations interventional procedures or any examination where the transducer comes into contact with bodily fluids/wounds/broken skin (intermediate and high risk) must be covered with an appropriate cover (sterile bag/condom) prior to the examination.

Transducers must be decontaminated before and after each examination/s.

A repeat of the decontamination process **must** be undertaken pre intracavity / interventional examination if the transducer has been used for a skin to skin examination. The 3 hour window for decontamination does not apply if the transducer has been used for a transducer to skin examination and will require the decontamination process to be repeated.

Table 1 - Risk of Infection Level of Risk	Definition	Suitable Processes	Examples
Low	Items/surfaces used in contact with intact skin or no contact is involved.	Cleaning.	Wash bowls, mattresses, baths, toilets, commodes, walls, floors.
Intermediate	Items that have contact with mucous membranes or Items/surfaces that would normally be low risk but are contaminated by microbes that are easily transmitted/likely to cause infection.	High level disinfection or sterilization Low level disinfection	Flexible endoscopes, vaginal specula, Bed pans, source isolation room fixtures and fittings
High	Items that penetrate skin/mucous membranes or enter the vascular system or other sterile body areas.	Sterilization	Surgical instruments

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PLEASE NOTE- THIS SOP PERTAINS TO THE DECONTAMINATION OF CANON ULTRASOUND EQUIPMENT. IF USING OTHER MANUFACTURES PLEASE REFER TO THEIR GUIDANCE.

Disinfection Process for Tranducers with skin Exposure (Low level Decontamination)

- All transducers used for skin contact **must** be cleaned after each examination.
- The operator must first remove any gloves worn during the examination and then disinfect their hands with thorough hand washing.
- The transducer must be wiped clean to remove any transmission gel. (Trophon dry wipes- Canon recommendation)
(Please check with manufacturer if not using Canon)
- Clean gloves to be worn.
- The transducer and the probe holder should then be cleaned with a Incidin OXY-WIPE wipe and dried with a Trophon dry wipe.

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Disinfection Wipe System (Low Risk)

Clean off excess gel from transducer with Trophon

dry wipe



Remove gloves (if worn)



Wash hands thoroughly



Clean gloves to be worn



Use OXY-WIPE to clean transducer and dry with a Trophon dry wipe



Use a further OXY-WIPE to clean the transducer holder and allow to dry

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PRE-INTERVENTIONAL INFECTION PREVENTION AND CONTROL

TECHNIQUE FOR GENERAL HAND DECONTAMINATION

Technique

- If a ring is worn, either remove it or ensure that the area underneath is washed.
- Turn on taps. Adjust water temperature and flow to desired settings
- Wet hands under running water.
- Apply soap to hands Utilise the technique illustrated on the hand washing posters and shown on page 10.
- Ensure all areas of the hands are covered, including the wrists and forearms if applicable.
- Pay particular attention to fingertips, nails, thumbs and the area between the fingers.
- All areas of the hands and wrists should be vigorously rubbed. Rinse hands under running water.
- Dry hands with disposable paper towels. Use a used or new paper towel to turn off the running water then discard.
- Dispose of the paper towels using the foot pedal on the bin, ensuring that hands are not re-contaminated in the process.

Then

-If indicated apply alcohol gel (for example on certain units additional hand decontamination with alcohol is required at all times).

-Ensure it is rubbed into all area of the hands.

-Pay particular attention to fingertips, nails, thumbs and the area between the fingers.
Allow alcohol to evaporate fully so that hands are completely dry

http://nww.cardiffandvale.wales.nhs.uk/pls/portal/docs/PAGE/POLICY_PAGEGROUP/LIBRARY/HAND%20DECONTAMINATION%20PROCEDURE.PDF

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IPC prior to Interventional Ultrasound Procedures

An appropriate transducer condom/sheath should be used prior to any interventional procedure. However, the use of a sheath/condom does not negate the need for the transducer to undergo High Level Disinfection (HLD). This is due to the limiting factors of a condom/sheath in the prevention of Healthcare associated infections.

It is paramount that the appropriate sheath/condom is used in accordance with local and manufacturers guidelines. The sheath/condom should always be inspected post procedure to ensure that there is no damage evident.

Ultrasound gel

The ultrasound gel used in interventional and intra-cavity ultrasound procedures must be **sterile** and a new sachet should be used for each patient. Within Radiology please refer to the Sterile gel SOP.

EFSUMB Guidelines on Interventional Ultrasound

(INVUS), Part 1

General Aspects (long Version)

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Trophon EPR Decontamination System

After patient contact all transducers must have scanning gel removed with Trophon dry wipe- Canon recommendation. (Check with manufacturer if not using Canon equipment)

Please note that the transducer must be unplugged from the ultrasound machine before Trophon decontamination commences. Failure to unplug the probe could result in the machine malfunction as it believes the probe is overheating. The probe should feel cool to touch before it is plugged back into the machine.

The decontamination of the transducers is a 3 stage process.

STAGE 1

Clean gloves to be worn

Pre-clean the transducer, transducer holder and cable using x 3 Incidin Oxy-Wipe disinfectant wipes;

Wipe No 1- Clean from tip of transducer down to cable end of handle

Wipe No 2 – Clean cable from end of handle, ensuring approximately one meter is cleaned (one arm's length)

Wipe No 3 – Clean the transducer holder.

Check that the transducer is dry prior to insertion into Trophon cabinet. A Trophon dry wipe or lint free wipe must be used) Canon recommendation. Check with manufacturer if not using Canon equipment

If the Transducer is not thoroughly dry it will compromise the decontamination process.

Before inserting the probe into the Trophon chamber you will be required to select yes on the Trophon control panel to confirm that you have pre-cleaned the probe. You also need to manually indicate on the Trophon sticker that the pre-clean has been done, please see example in appendix.

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STAGE 2

Decontaminate transducer (including handle but not cable) in the Trophon EPR disinfection chamber (see flow chart on page).

STAGE 3

On completion of stage two, check transducer for any residue. If present this should be removed using a Trophon Dry wipe, gloves must be worn for this process.

If no residue present the transducer should still be wiped with a dry wipe before re-use.

Trophon indicator discs/Logging the trophon Chemical Indicators

No other chemical indicators are approved for use in the trophon2 device. Check expiry date of the trophon Chemical Indicators. Expired Chemical Indicators cannot be used to run disinfection cycles.

If AcuTrace is enabled, log the new batch of trophon Chemical Indicators:

1. Select Menu ◇ AcuTrace ◇ Log Chemical Indicators.
2. Follow the onscreen instructions.

Note: Chemical Indicators must be scanned at the start of every new carton. As this is a manual process it is important for users of trophon2 to complete this step each time a new Chemical Indicator carton is opened. Trophon Chemical Indicators must be stored in their original packaging and not be shared across trophon devices outside of it's original packaging. Note: If you are running trophon2 Software Version 1.4 and later, trophon2 will notify the user during the first cycle of the day if the trophon Chemical Indicators logged in the system are 30 days from expiry. Users will be reminded again 5 days before expiry and everyday thereafter. These reminders will not occur on earlier software releases. Do not use Chemical Indicators after expiration date. Confirm Chemical Indicators are within expiry before use. If you are running trophon2 Software Version 1.4 and later, disinfection cycles will not run after the Chemical Indicators have

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expired. Log trophon Chemical Indicators with valid expiry date to continue use of the trophon2 device.

The chemical indicator is a mandatory second verification of the HLD cycle and must indicate a pass result. The Trophon 2 device will automatically verify if all parameters were met.

The Trophon Chemical Indicator responds to a combination of specified time, disinfectant dosage and disinfectant concentration. These critical parameters need to be met for the chemical indicator to change to a pass colour. This qualitative colour change provides independent confirmation of success of each disinfection cycle. Indicator packaging incorporates AcuTrace technology to record and store batch and expiry details directly into trophon2.

Check the chemical Indicator (CI) pass status using the colour assessment chart on the chemical indicator box. Please note that BOTH the Trophon 2 touch screen must indicate a successful cycle for the probe to be ready for use. If either the CI or Trophon 2 touch screen indicates a fail, repeat the cycle.

Please refer to paragraph 1.15 of the Trophon 2 training guide in the appendix.

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Trophon EPR Decontamination System

Scan the Acu-trace medical instrument tag until you hear a beep

Place pre-cleaned dry transducer into disinfection chamber. (Only Incidin oxywipe to be used as pre-clean with Canon systems)



Scan the Acu-trace medical instrument tag until you hear a beep

Place pre-cleaned dry transducer into disinfection chamber. (Only Incidin oxywipe to be used as pre-clean with Canon systems)



Insert chemical indicator disc and close chamber door.



Scan your programmed operator card to start the disinfection cycle



End of cycle, when indicated by light panel.
Open door & check transducer for any residue



Wipe transducer with Trophon Dry wipe before re-use

Confirm chemical indicator disc colour change:
(Refer to chemical indicator on packaging to confirm successful decontamination)

Trophon clean cover.

At the end of the session or examination where there is the likelihood that the device may be used by another operator or left unattended a **Trophon clean cover** needs to be placed over the Transducer and the post clean Trophon label needs to be affixed to the bag.

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If Trophon isn't available in an area or there is a system failure then the Tristel three wipe system should be adopted.

Once a new packet of OXY-wipe wipes has been opened you are required to put a label on the packet to indicate what date the wipes were opened. After one month of the opening date any wipes that are unused need to be disposed of and replaced with a new packet.

Please ensure that the packet is closed after use to ensure that the wipes do not dry out.

Please place a sticker with the date on the packet so ensure this is complied with- example in Appendix.

RECORD KEEPING

A. Electronic

Radiology Radis 2

Pre and Post Clean

Post Decontamination cycle – Print and complete x 2 Trophon labels

Label 1 - Affix Trophon printer label to Trophon traceability form.

Scan traceability form to include Completed Trophon Printer label against patient visit.

Label 2 – Affix to Trophon clean cover to indicate decontamination. Retain the second label for next patients pre- clean if decontamination falls within a 3 hour window or is not used in the interim.

(Does not apply if the transducer has been used for a skin examination within this window)

Pre -clean If decontamination falls outside the 3 hour window dispose of the **Trophon clean cover** and the post clean tag (Label 2)

Electronic systems - Non Radiology

Other departments – local process to be agreed with UHB Decontamination group

B. Manual

Other departments – local process to be agreed with UHB Decontamination group

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STORAGE AND REPLACEMENT OF NANONEBULANT

The Nanonebulant cartridges contain hydrogen peroxide and are provided completely sealed. The seal is only broken by the Trophon EPR unit when inserted.

The Trophon EPR will display a message asking to “replace cartridge” when a new cartridge is required. Please follow the on screen instructions. A single cartridge will perform circa 37/40 cycles.

Gloves Must be worn when replacing Nanonebulant Cartridges

The cartridge cannot be removed from the unit until all the chemical has been utilised or a system purge completed. This is a safety feature of the Trophon 2.

The unused Nanonebulant cartridges must be stored away from a direct source of heat, on a shelf or cupboard that is only accessible to staff.

Nanonebulant stored in a patient area must be stored in a lockable cupboard. COSHH the empty Nanonebulant cartridges can be safely disposed of in black bag waste.

Fault Management

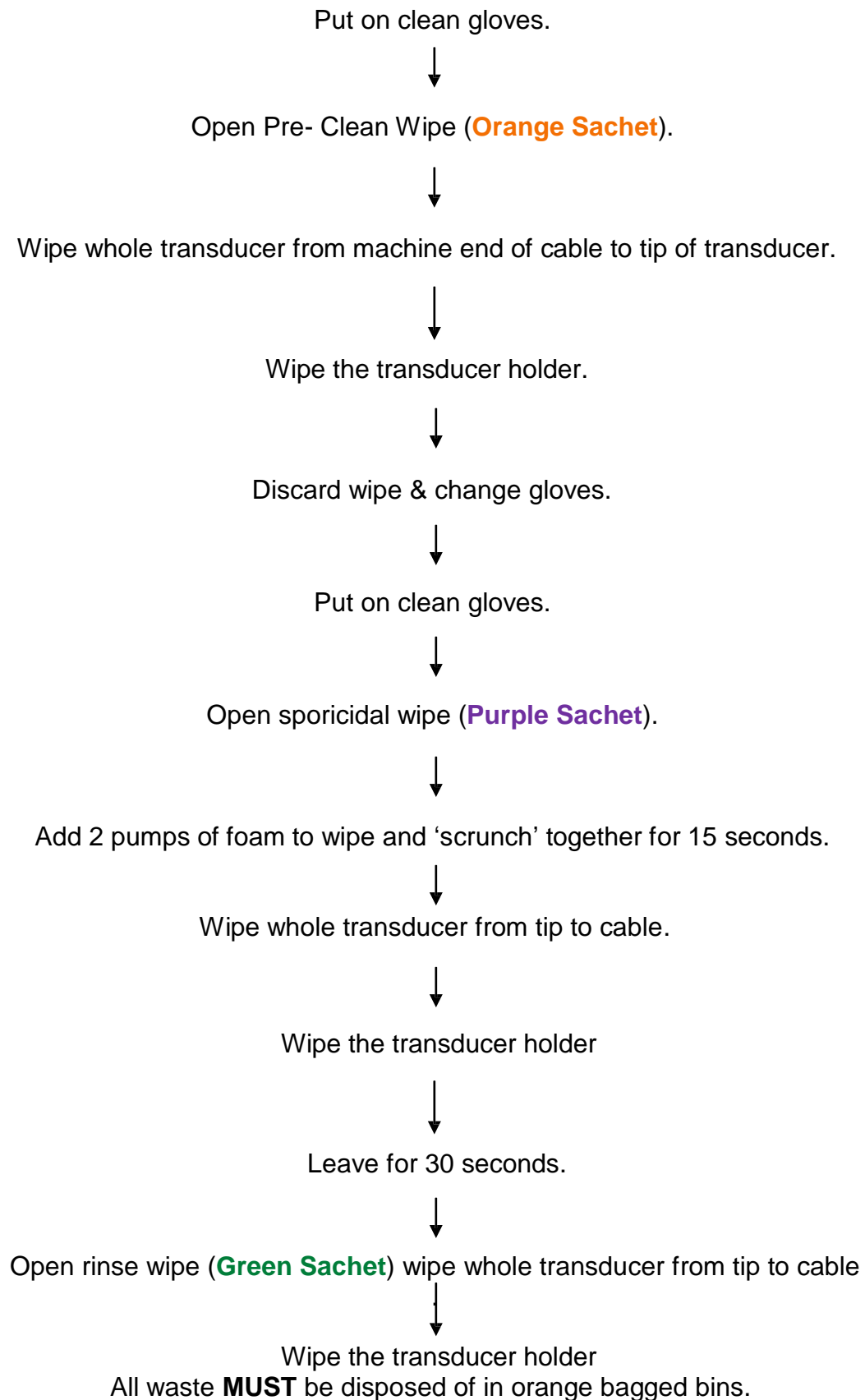
The trophon units are support by our MES support team. In the event of a system fault or issue you should stop using the equipment immediately. Please notify Canon Medical Systems via the details below together with the serial number of the trophon unit, location and any error codes:

- Canon Medical Systems UK – 01293 653710
- Email: cvuhb.uk@eu.medical.canon In the event of a trophon system breakdown please report to your Manager/Lead and the CVUH MES team.

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TRISTEL TRIO DECONTAMINATION SYSTEM

PRE-CLEAN



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RECORD KEEPING.

Tristel Record Book

PRE-CLEAN

Pre Clean of transducer prior to examination

Enter device item details i.e. transducer type and serial number along with date and time.

Place Patient Identity label in Tristel record book.

Enter pre-clean wipe lot number and expiry date in the relevant section and tick to confirm

Sporicidal wipe - place one traceability label from packet in record book along with the foam pump/activator lot number and tick to confirm

Apply second traceability label onto scan request form / patient record.

Radiology – Document traceability form to include traceability label against visit.

All other departments – local process to be agreed.

Enter Rinse wipe record lot number and expiry date in the relevant section and tick to confirm

Enter Name and Signature of person responsible for decontamination in the Confirmation box.

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POST-CLEAN

As soon as the procedure has finished the transducer MUST undergo a post-clean decontamination as above. If the transducer isn't to be re-used immediately a **Trophon clean cover** needs to be placed over the transducer. **Please refer to the TRISTEL record book to ensure the time falls within the 3 hour window before next use.**

RECORD KEEPING

Place one of the sporicidal wipe stickers into record book. The second sporicidal wipe sticker is kept for next patients tracebil if within the 3 hour time frame.

(Does not apply if the transducer has been used for probe to skin within this window)

If decontamination falls outside 3 hour window the second sticker from the sporicidal wipe needs to be stored in the destination of device box and Indicate "post decontamination" in patient details section of record book.

Enter device item details i.e. transducer type and serial number along with date and time.

Place Patient Identity label in Tristel record book.

Enter pre-clean wipe lot number and expiry date in the relevant section and tick to confirm.

Sporicidal wipe - place one traceability label from packet in record book along with the foam pump/activator lot number and tick to confirm.

Apply second traceability label.

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Audit

The auditor should be from the clinical area / clinical board and will report to the decontamination group.

Record keeping will be monitored by the record keeper as part of the audit.

The decontamination group will instruct suitable remedial actions if audit data is unsatisfactory or record keeping is incomplete.

Local process to be agreed.

E.g Tristel

Quality Audit Trail Record Book e.g One Record book per Ultrasound Unit / Device. (Locally agreed by department)

Date	Patient no	Dept / Room	Device	Record Keeping Complete	Record Keeping Incomplete

Trophon

Electronic

Review of Intracavity and Interventional cases.

Date	Patient no	Dept / Room	Device	Record Keeping Complete	Record Keeping Incomplete

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Manual

Review of Intra-cavity and Interventional cases. Review of Record Keeping.

Date	Dept / Room	Device	Record Keeping Complete	Record Keeping Incomplete

Sally Lynch / Nerys Thomas 2024

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Appendix

Decontamination methods / COSHH

Tristel

<http://www.tristel.com/products/healthcare/ultrasound/trio-wipes-system/>

Tristel COSHH – Radiology



blob:https://outlook.office.com/32c306c4-73aa-48be-9f65-c4c137d8c276
ONE DRIVE

Trophon

<http://www.Trophon.com.au/Trophon-EPR/Trophon-EPR>

Nanonebulant COSHH - Radiology



Trophon
nanonebulant 218859

Trophon clean covers

<http://www.trophon.com/probes>

Ecolab Incidin oxywipe- Safety data sheet-

blob:https://outlook.office.com/d3fbb2a5-5b95-4a51-81bd-ff0f85bdf36b

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Consumables

Trophon – Accessories. Order point via Oracle

Nanonebulant

Chemical Indicator Discs

Printer Roll

Dry wipes

Incidin Oxy-Wipe

Trophon clean covers (N00102)

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References

Welsh Health Technical Memorandum 01-06. Decontamination of flexible Endoscopes. Part F Operational Management

[WHTM 01-06 Part F Decontamination of flexible endoscopes.pdf](#)



WHTM 01-06 Part
F_Decontamination

Standards for the NPSA and RCR Safety checklist for radiological interventions

[http://www.rcr.ac.uk/docs/radiology/pdf/bfcr\(10\)17_npsa.pdf](http://www.rcr.ac.uk/docs/radiology/pdf/bfcr(10)17_npsa.pdf)

Ultrasound transducer cleaning, decontamination, disinfection and sterilization September 2014

https://www.sor.org/system/files/article/201410/ultrasound_probe_cleaning_decontamination_disinfection_and_sterilisation.pdf

BMUS- Guidelines for professional ultrasound practice.

<https://www.bmus.org/policies-statements-guidelines/professional-guidance/guidelines-for-professional-ultrasound-practice/>

Trophon2 training guide-

https://issuu.com/nanosonics/docs/trophon_2_operation_training_guide#

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Trophon 2 User manual

<https://www.bing.com/ck/a?!&&p=2011ad691caa5b1cJmltdHM9MTcwNjU3MjgwMCZpZ3VpZD0yMDRkMDIyOC0yODMzLTY2Y2QtMTJmNi0xNjI2MjkxNDY3OTAmaw5zaWQ9NTlxMg&ptn=3&ver=2&hsh=3&fclid=204d0228-2833-66cd-12f6-162629146790&psq=ventilation+of+room+trophon&u=a1aHR0cHM6Ly93d3cubmFub3Nvbmljcy5jb20vbWVkaWEvbnZtbWw0aXAvaDAzMDgyLXRyb3Bob24yLXVzZXItbWFudWFsLXJvdy5wZGY&ntb=1>

Hand washing

http://nww.cardiffandvale.wales.nhs.uk/pls/portal/docs/PAGE/POLICY_PAGEGROUP/LIBRARY/HAND%20DECONTAMINATION%20PROCEDURE.PDF

Example of Oxy-wipe sticker. Stickers to be sourced locally within each department.

INCIDIN OXY-WIPE.

DATE OPENED -

DISPOSE OF WITHIN ONE MONTH OF OPENING.

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Example of Trophon sticker.

<p>TROPHON 2</p> <p>08/01/2024 10:39</p> <p>SN:36545-027</p> <p>Disinfectant-hospital number</p> <p>Chemical indicator- 22PI213</p> <p>Clean and dry –yes</p> <p>Operator- Sally Lynch</p> <p>Cycle- pass</p> <p>Disinfection: PASS</p> <p>Chemical Indicator :Pass</p> <p>Operator: sally lynch</p> <p>Probe name: pvt-781vte</p> <p>Probe serial number- fsd2385879</p>
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Decontamination Q&A provided my Canon medical systems LTD

It is highly recommended that the cleaning guidance and decontaminating for transducers are followed at all times.

Where can I find products that can be used for cleaning Ultrasound transducers?

Details of approved products that can be used for cleaning Canon Medical Systems Ultrasound transducers can be found in the IFU (information for use) that are supplied with every new transducer. Alternatively, details of approved products are published on the Canon Medical Systems Corporation website and can be found here:

<https://ultreatment.app.medical.canon/en/>

What should I do if I am unclear about a cleaning agent?

We recommend consulting the IFU (information for use) which are supplied with every new transducer or contact a Canon Medical Systems Sales Specialist, Service Engineer or Application Specialist. Can I use a non-approved cleaning agent? Using a non-approved product may place your sensitive diagnostic equipment at risk of irreparable damage. The use of non-approved products will invalidate your warranty and/or negate any Canon Medical Systems service provision on your transducer. Canon Medical Systems will not be responsible for any damage caused by the use of non-approved agents, nor for the cost of replacement of the transducer.

What happens if I use non-approved disinfecting/cleaning agent? Only approved products should be used because some chemicals and processes are harmful to the materials used in the manufacture of your devices. In 2013 the MHRA issued an alert which advised that the use of the wrong disinfection or detergent wipe can damage the plastic surfaces of medical devices. Details of the MHRA alert can be found here: Detergent and disinfectant wipes used on reusable medical devices with plastic surfaces – risk of degrading plastic surfaces - GOV.UK (www.gov.uk)

Is disinfection the same as sterilization? No. Disinfection is the process of reducing the load of pathogens. This normally uses a chemical that destroys the pathogens. Sterilization methods often use a high temperature (134°C) which is above the

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manufacturer's product temperature limits and will damage your Ultrasound transducer.

Can residue from cleaning agents be harmful?

All agents must be compatible with our devices, and should be used in accordance with the guidelines supplied by the manufacturer of the agent. It is however, recommended that residual product is removed prior to use in accordance with the Guidelines for cleaning, disinfection and sterilization of transducers.

Can I use multiple or a combination of products?

This has not been tested or validated and therefore the mixing of products cannot be recommended. The combining of products/methods, even residues, may lead to unexpected or accelerated chemical reactions, which may damage transducers and should be avoided. The use of a combination of products may lead to the damage of transducers and is undertaken at the owner's risk.

Can I use paper towels for cleaning the Ultrasound Transducer?

This is not recommended because paper towels can be abrasive and over time can damage the sensitive lens of the transducer. Our recommendation is to use a soft cloth or gauze.

Can I use the same product for all my Ultrasound Transducers?

No, not all Ultrasound Transducers can be decontaminated by using the same method or product. It is recommended to consult the IFU (information for use) before cleaning. Do all recommended products decontaminate to the same level? No, we recommend consulting your Infection control lead or the supplier of your chosen decontamination product for advice.