GIG CYMRU NHS WALES Bwrdd Iechyd Prifysgol Caerdydd a'r Fro Cardiff and Vale University Health Board	**Reference Number:** UHB 259 **Version Number:** 3 **Date of Next Review:** October 2021 **Previous Trust/LHB Reference Number:** N/A

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 across the Cardiff and Vale University Health Board (the UHB).

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 Ultrasound Governance group.
Accountable Executive or Clinical Board Director	Director Of Therapies and Health Science.
Author(s)	Sally Lynch, Senior Sonographer Nerys Thomas, Superintendent Sonographer

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		07/05/2019	

Contents Page

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 below[1].

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.

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 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.

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 skin 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

Disinfection Process Skin to Skin Exposure (Low Risk)

All transducers used for skin to 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. (Clay free white roll- 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 cleanisept wipe and allowed to dry.

Disinfection Wipe System (Low Risk)

Clean off excess gel from transducer with paper

↓

Remove gloves (if worn)

↓

Wash hands thoroughly

↓

Clean gloves to be worn

↓

Use <u>CLEANISEPT</u> wipe to clean transducer and allow to dry

↓

Use a further <u>CLEANISEPT</u> to clean the transducer holder and allow to dry

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

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 ultrasound procedures should be sterile and a new sachet should be used for each patient.

EFSUMB Guidelines on Interventional Ultrasound

(INVUS), Part I

General Aspects (long Version)

Trophon EPR Decontamination System

After patient contact all transducers must have scanning gel removed with soft paper (Clay free white roll - 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 shutting down 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 Cleanisept

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 arms length)

Wipe No 3 – Clean the transducer holder.

The TROPHON training video does not include wipe no 2 which is recommended by the decontamination lead for the UHB and must be adhered to.

Check that the transducer is dry prior to insertion into Trophon cabinet. If not wipe with a soft lint free cloth (Clay free white roll) 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 that the pre-clean has been done, please see example in appendix.

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 soft cloth (paper roll), gloves must be worn for this process.

If no residue present the transducer should still be wiped with clay free paper before re-use.

The chemical indicator disc should be colour checked to confirm a successful decontamination cycle.

Trophon EPR Decontamination System

Place pre-cleaned dry transducer into disinfection chamber.

↓

Insert chemical indicator disc and close door.

↓

Confirm transducer clean and dry by selecting “yes” on control panel.

↓

Press start button.

↓

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

↓

Wipe transducer with clay free roll before re-use

Chemical indicator disc colour change:
(refer to chemical indicator on packaging)

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.

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 Cleanisept wipes has been opened you are required to put a label on the cleanisept tub 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 tub is closed after use to ensure that the wipes do not dry out.

(See appendix for label example)

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 patient request form.

Document scan request 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.

(Does not apply if the transducer has been used for skin to skin 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

Trophon Log Book

HLD Traceability log (part 1) - Affix Trophon printer label / manually enter fields

HLD Traceability log (part 2) - Complete Traceability log

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 messages. 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 EPR.

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

Empty Nanonebulant cartridges can be safely disposed of in black bag waste.

TRISTEL TRIO DECONTAMINATION SYSTEM

PRE-CLEAN

Put on clean gloves.

↓

Open Pre- Clean Wipe (**Orange Sachet**).

↓

Wipe whole transducer from machine end of cable to tip of transducer.

↓

Wipe the transducer holder.

↓

Discard wipe & change gloves.

↓

Put on clean gloves.

↓

Open sporicidal wipe (**Purple Sachet**).

↓

Add 2 pumps of foam to wipe and ‘scrunch’ together for 15 seconds.

↓

Wipe whole transducer from tip to cable.

↓

Wipe the transducer holder

↓

Leave for 30 seconds.

↓

Open rinse wipe (**Green Sachet**) wipe whole transducer from tip to cable

↓

Wipe the transducer holder

All waste **MUST** be disposed of in orange bagged bins.

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 scan request 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.

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 request form if within the 3 hour time frame.
(Does not apply if the transducer has been used for skin 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.

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

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 2019

Appendix

Decontamination methods / COSHH

Tristel

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

Tristel COSHH – Radiology

Tristel wipe system coshh assessments.p

Trophon

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

Nanonebulant COSHH - Radiology

Trophon nanonebulant 218859

Trophon clean covers

http://www.trophon.com/probes

Consumables

<u>Cleanisept Wipes.</u> Non Catalogue via Oracle

The Scientific Instrument Centre

ICDRSCLEANISEPT/2 – Cleanisept Wipes 12 tubs of 100
ICDRSCLEANISEPT/3 – Cleanisept Wipes 12 refill packs of 100

<u>Trophon – Accessories</u>. Order point Toshiba via Oracle

Nanonebulant

Chemical Indicator Discs

Printer Roll

Trophon clean covers (N00102)

Kimberley Clarke

Clay free white roll Code - 7277
Code – 7286

References

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

http://www.wales.nhs.uk/sites3/documents/254/WHTM%2001-06%20Part%20C.pdf

Standards for the NPSA and RCR Safety checklist for radiological interventions

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/

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

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

Example of cleanisept sticker. Stickers to be sourced locally within each department.

CLEANISEPT WIPES.

DATE OPENED -

DISPOSE OF WITHIN ONE MONTH OF OPENING.

Example of Trophon sticker. Pre-clean needs to be written on to the existing label and then ticked to confirm it has been done.

TROPHON

28/02/2019 10:39 SN:36545-027

Disinfection: PASS Cycle-1375 PC-

Indicator :Pass Fail:

Operator:

Probe:

Notes