GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales	**Reference Number:** PHW 28-TP01 **Version Number: 1** **Date of Next review:**

Decontamination Procedure for Reusable Medical Devices and Care Equipment in PHW

Introduction and Aim

This document supports the Public Health Wales (PHW) Decontamination Policy by describing actions undertaken by Public Health Wales staff, and those contracted to deliver services within the organisation on behalf of PHW, regarding implementation of current Decontamination guidance and standards for reusable medical devices and care equipment.
The aim is to ensure consistent application of best practice and adherence to recommended guidance and statutory requirements.

Linked Policies, Procedures, National Guidance, and Written Control Documents

Policies and procedures available on the Clinical Governance and Infection Control Policies - Public Health Wales (nhs.wales) intranet page:

- Policy for the Decontamination of Reusable Medical Devices and Equipment used for Service User/Patient Care (PHW policy 28 TP01)
- Medical Devices and Equipment Management Policy (PHW 69)
- Medical Devices and Equipment Procedure PHW 69/TP01
- Infection Prevention and Control Policy (PHW 27)

Available from the Risk Management, Health and Safety and Estates Policies - Public Health Wales (nhs.wales) intranet pages:

- Health and Safety policy (PHW 10)
- Waste management procedure (PHW 63-TP01)
- Procedure for the disposal of obsolete and surplus equipment, vehicles, furniture and consumables (PHW63-TP02)

Other documents:

- British Safety (BS)/European Union (EU) testing and HSE biocide regulations
- Healthcare Associated Infection (HCAI) Code of Practice code-of-practice-for-the-prevention-and-control-of-healthcare-associated-infections.pdf (gov.wales)

- Decontamination of Medical Devices: a Development Plan for Healthcare Organisations (Development Plan)
- National Infection Prevention and Control Manual for Wales, in particular section 1.5.
- UK 5-year Action Plan for Antimicrobial Resistance 2024 to 2029
- PHW decontamination of medical devices development plan
- The Duty of Quality Statutory Guidance 2023 and Quality Standards 2023
- Waste electrical and electronic equipment (WEEE) regulations (2013)
- Welsh Health Technical Memoranda (WHTM):
- 01-01 Decontamination of surgical instruments (medical devices) used in acute care (for laboratory autoclave management & validation):
    - Part A: Management and Provision
    - Part C: Steam sterilization and steam for sterilization
- 01-06 Decontamination of flexible endoscopes:
    - Part F: Decontamination of Semi-Critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes
- 07-01 Safe Management of Healthcare waste

Scope

This Procedure is applicable to all staff working within PHW who are responsible for and/ or are involved in the use of devices and any elements of the decontamination process for reusable medical devices and care equipment on PHW or other NHS premises. It is also applicable to any staff (including those contracted to work within PHW services on behalf of the organisation) who are involved with the use and decontamination of PHW devices and healthcare equipment prior to inspection, service, maintenance or repair. Staff must adhere to PHW policies and procedures for medical device decontamination and their management. All staff using reusable medical devices and care equipment need to be able to risk assess and/or competently carry out the correct methods of decontamination required. Decontamination is a science in its own right and best undertaken by staff specifically trained and competent for this task

Equality and Health Impact Assessment	An Equality and Health Impact Assessment has been undertaken. No groups are identified as being negatively impacted by this policy.
Approved by	Infection Prevention and Control Group
Approval Date	
Review Date	
Date of Publication:	

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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 Corporate Governance Team.

Summary of reviews/amendments				
Version number	**Date of Review**	**Date of Approval**	**Date published**	
V1				This Decontamination Procedure document has been developed to comply with High Level Disinfection Guidance and with the Public Health Wales requirements to create two distinct Policy and Procedure documents.

Contents

1. Introduction

Decontamination is a term used to describe a combination and hierarchy of processes i.e. cleaning, disinfection, sterilization. Inadequately decontaminated medical devices and healthcare equipment can be a source for the transmission for microorganisms and may subsequently cause a Healthcare associated infection (HCAI). Healthcare Associated Infections (HCAIs) occurring from the failure to effectively decontaminate medical devices (especially invasive devices) are costly and can result in patient/service user distress, increased morbidity and even death. Such incidents may indicate poor quality of care and lead to reputational loss. Public Health Wales is committed to safety of the service user by preventing any avoidable HCAIs including those associated with the use and management of reusable medical devices and care equipment. In order for Public Health Wales to assure itself that robust and consistent decontamination procedures are applied, the documents above provide specific guidance and resources for staff to ensure they have the correct information to act competently:

Effective decontamination processes for medical devices and care equipment are essential to ensure such items do not pose an infection risk for service users/patients and /or healthcare staff and/or contractors who are employed to use, service maintain and repair medical equipment. Public Health Wales needs to consider not only the compatibility, quality and safety of equipment used but also the requirements for the effective decontamination of it.

It is essential that medical devices and care equipment are managed safely to ensure they are used as designed, maintained in a good state of repair and decontaminated in accordance with manufacturer Instructions for Use (IFU), Welsh Health Technical Memoranda (WHTM) and PHW policy so they do not harbour pathogenic microorganisms.

This decontamination procedure along with the PHW decontamination policy are specific to devices and equipment used and decontaminated by PHW employees. Public Health Wales procures services that are provided by Health Boards/Trusts e.g. bowel screening. Decontamination of equipment in this case will be managed according to the individual Health Board/Trust decontamination and medical device management policies and procedures. As such PHW must have a robust assurance framework to include scrutiny and audit that provider organisations are operating in accordance with best practice and national guidance for decontamination as detailed in relevant WHTM & WHBN e.g. WHTM 01-01 parts A-E, 01-06 parts A-F, WHTM 03-01, WHBM 04-01 and expert advisory groups guidance like Joint Advisory Group on GI endoscopy (JAG). JAG accreditation standards are used to define a high-quality, safe and appropriate

endoscopy service, delivered by a highly trained, highly supported and highly-motivated workforce.

NB. **Single use devices must not be reprocessed or re-used under any circumstances.**

2. Roles and Responsibilities

This section outlines the roles and responsibility for:

- Public Health Wales
- Chief Executive
- Executive Director of Quality, Nursing & Allied Health Professionals
- Infection Prevention & Control Group
- Managers
- Staff
- Lead Nurse for Infection Prevention and Control
- Operational Health and Safety Manager
- Operational Decontamination Lead

2.1 Public Health Wales

Public Health Wales has a responsibility to ensure:

- Facilities, services and equipment used by the organisation for decontamination must comply with relevant Welsh Health Technical Memoranda (WHTMs) and Welsh Health Building Notes (WHBN) provided by NHS Wales Shared Services Partnership (NWSSP) technical guidance and best practice as well as Medicines and Healthcare products Regulatory Agency (MHRA) directives (https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety)

- Medical device decontamination must be managed in accordance with PHW Health and Safety policy and Health and Safety Executive (HSE) regulations (including COSSH (2002), Personal Protective Equipment (PPE) (2022)) related guidance to ensure staff safety.

- Compliance with decontamination processes are measured using audits that include observations of practice, questions/feedback from staff and environmental audits. The results of data collected will be reported to and monitored by the Infection Prevention and Control Group. Datix will also be used to identify incidents related to the processes, policy and any resulting harms. As a minimum, yearly audits of the decontamination of clinical medical devices and care equipment is expected unless otherwise specified by the manufacturer and/or there is an incident or concern raised about the decontamination process re methodology or competency.

- Clinical staff undergo mandatory level 1 and level 2 Infection Prevention & Control (IPC) training as per national requirement. Training will include SICPs and use of appropriate PPE for the task assessed against the hierarchy of control. They must also be competently trained for decontamination of devices and equipment they are using or decontaminating. Training in decontamination of specific devices or equipment should be completed by suitably qualified staff and/or accredited providers and/or, representatives or suppliers/companies. This training will be updated as required for the device and/or if the decontamination process or products used are changed. Training will include any specific methodology in accordance to manufacturer Instructions for Use (IFU). Training frequency and % compliance will be monitored by the department manager and be reported to the Infection Prevention and Control Group.

- Adequate resources are provided to ensure devices/equipment are decontaminated using the correct products and equipment according to manufacturer IFU and PHW policy, decontaminated using correct methodology and at the right frequency. It is a preference of PHW, and in accordance with appropriate WHTM's, decontamination is carried out using automated/validated technologies, Resources may include e.g. time to complete the task, competent staff, cleaning materials and products, compatible disinfectants and associated specialist decontamination equipment.

- There are Trust incident reporting systems e.g. Datix available for staff to use to report decontamination failures, exposure injuries, medical device failures or inappropriate use and importantly any suspected or confirmed HCAI following use.

Failure to comply with statutory and legislative requirements leaves a healthcare provider liable to prosecution. The organisation could be the subject of litigation if it could not prove that there were management systems in place. This could lead to financial and reputational loss for the organisation as well as the potential harm to the patient or staff.

2.2 Chief Executive

The Chief Executive has a strategic responsibility to ensure the Decontamination policy is adhered to while the operational authority for decontamination of equipment lies with the individual user and clinical /departmental managers.

2.3 Executive Director of Quality, Nursing & Allied Health Professionals

The Executive Director of Nursing is the designated executive decontamination lead for PHW who reports to the Board with responsibility for ensuring that this procedure and the decontamination policy is implemented and adhered to across the organisation.

2.4 Infection Prevention and Control (IPC) Group

The IPC group has responsibilities to:

- Contribute to the review and approval of this and other IPC policies and procedures.

- To receive and scrutinise and analyse data related to the application of this procedure e.g., audit, surveillance, training compliance in monitoring performance of the services

- Review any incidents, complaints and harm related to use of medical devices and care equipment including HCAI, device failure, exposures to products.

- Review the actions identified through incident investigations and lessons that need to be learnt for the organisation.

- Escalate any serious concerns from the IPC group to the Executive Board via the Executive lead for decontamination.

2.5 Managers

Managers are responsible for ensuring that staff are aware of their responsibilities and comply with this Procedure. They are also responsible for ensuring that staff have the appropriate resources available to facilitate decontamination as detailed in this procedure.

Managers have responsibility to ensure that:

- Staff carrying decontamination tasks have easy access to the PHW decontamination policy and procedure as well as related local or organisation protocols for operational use.

- Staff receive the appropriate training in Decontamination, this should include how to decontaminate reusable devices/equipment, adherence to manufacturer's guidance, waste management policy for disposal of medical devices or equipment;

- Staff are compliant with mandatory training in Health & Safety (H&S), IPC and are competent in use of the appropriate PPE for the decontamination task being undertaken. Training records are available for inspection and assurance.

- Managers undertake local audits of the decontamination processes and of individual staff competency and compliance with policy/procedures (as a minimum annually) to provide assurance to the IP&C group.

- Staff are trained to recognise packaging symbols on sterile and non-sterile goods/packs used to supplement procedures (see **Appendix 1**) so that they recognise:
    1. Single use or re-usable,
    2. Single patient use or limited use
    3. Sterile or non-sterile
    4. It's within expiry date - manufacturing date /processing date
    5. How to store the items correctly re temperature and humidity
    6. Any safe disposal information.

- Traceability systems in use are robust and audited on a regular basis e.g., in the decontamination of semi critical ultrasound probes and endoscope in commissioned services.

- Single use devices are used in accordance with the Medicines and Healthcare Products Regulatory Agency (MHRA) guidance and are chosen, according to risk.

- Staff are trained to access and report via incident reporting systems e.g., Datix any incident or near miss occurring as a result decontamination processes and/or device management.

- An accurate medical devices and equipment asset register is maintained for their screening centre and informs the Trust's overall the Medical Devices register. Working closely with the Medical Device Safety Officer this will ensure there is a managed approach that allows PHW to ensure that medical devices are suitable for their intended purpose; are in a safe and serviceable condition and meet the necessary safety and legislative standards.

- The Asset register is reviewed regularly (as a minimum annually) or as items are added and removed in collaboration with the Medical Devices Safety Officer. It should accurately reflect all equipment currently in use for date of purchase and manufacturer recommended end of product life, compliance with service maintenance and repair requirements as well as the method of decontamination.

- Adequate storage space is available so that medical devices and equipment are stored safely and securely to prevent damage or misuse and in accordance with manufacturer guidance re temperature/humidity/packaging etc. Such storage areas must not be accessible to unauthorised persons.

- Decontamination issues identified with reusable medical devices will be discussed and reported to Medical Devices and the IPC groups.

- COSHH risk assessments and Materials Safety data sheets must be available for all chemicals/decontamination products used by staff at the point of use, with clear instructions what to do in the event of person harm and/or chemical spillage

- Cascade any additional decontamination requirements or information to staff in a timely manner.

- Relevant health surveillance is undertaken where appropriate for those undertaking decontamination duties e.g., hand health, respiratory health.

- Staff are reminded of their duty of care in respect of their own vaccination status and protection against blood and body fluid exposure e.g., HBV vaccine.

- Managers discuss IPC responsibilities with the member of staff as part of their annual appraisal processes of clinically facing staff (my contribution).

- Any known or suspected infection transmission related to medical devices or decontamination processes must be urgently escalated to the operational decontamination and IPC leads who will report to the Executive lead. In line with Public Health Wales' Incident Management Policy and Procedure, any incident must be reported on Datix in the usual way within 24 hours of the incident being noted. Any incidents that fall within the definition of a 'National Reportable Incident' (NRI) must be nationally reported in line with the principles set down in the National Policy on Patient Safety Incident Reporting and Management.

- Details of how to submit such reports are included in the Incident Management Policy and Procedure. Incident reporting and management procedure For further information, the Risk and Putting Things Right (PTR) Manager or PTR team should be consulted.

- A rapid basic investigation will initially be undertaken by the local manger to determine source and any immediate actions taken before undertaking a thorough investigation. A summary report of the incident will be submitted to the IPC group e.g. SBAR and added to

datix. This will describe the actual causes, further actions needed, and any lessons learnt that need to be disseminated to other PHW services or wider e.g. Surgical Materials Testing Laboratory (SMTL), the Medicines and Healthcare products Regulatory Agency (MHRA) etc.

2.6 Staff

Staff using devices and/or undertaking any decontamination tasks have an individual responsibility to:

- attend appropriate training and maintain competency in Infection Prevention and Control, decontamination processes and device management.
- Utilise available resources, both written and online for information on issues relating to decontamination.
- recognise packaging marks for single use and reusable devices including checking and recording of record expiry dates on all products prior to use where applicable.
- Use single use devices in accordance with MHRA guidance and are chosen, according to documented risk, over reusable devices.
- Adhere to the manufacturer's guidance and IFU in the use of device, use of any chemical or decontamination equipment used on the device and utilise waste management policy for safe disposal.
- Report any incidents in a timely manner via the incident reporting system e.g., when there is a near miss or known decontamination failure, a medical device failure or inappropriate use, injury or harm occurring as a result of either including HCAI or exposure injury to blood/body fluids or chemicals.
- To manage medical devices and decontamination products/equipment in a manner that prevents damage and adheres with manufacture instructions for use, storage and disposal.
- Must not modify devices or processes.
- Accurately and legibly complete traceability records for appropriate decontaminated devices.
- adhere to PHW policy and procedures for medical devices, decontamination and H&S.

2.7 Lead Nurse for Infection Prevention and Control

The Lead Nurse for Infection Prevention and Control has the responsibility to:

- Ensure all IPC related policies and procedure documents are reviewed and updated promptly as a minimum every 3 years and reflect current and new evidence.

- Ensure the decontamination policy and procedure are reviewed and updated promptly as a minimum every 3 years and reflect current any new evidence for the decontamination tasks being undertaken or the device and equipment in use.

- Provide guidance on the required level of infection prevention and control training required for clinical facing staff and for those who undertake basic decontamination duties commensurate with their role.

- To provide, guide and advise managers on accessing resources about decontamination to support mandatory IPC and specific decontamination training requirements of their staff.

- Work with service leads to assure that they can access any specific training on decontamination and use of devices, equipment or products. This may be provided from within PHW or by external expert providers/manufacturers. The frequency of update training and how competency will be achieved should be described in training plans.

- Work with NWSSP/SES to maintain decontamination knowledge for the service as part of the 'All Wales' decontamination group and to participate in any all-Wales decontamination audits of PHW facilities. Results of audits will be reported to the IPC group for assurance.

- Support managers in completing audits of decontamination in their service and providing the necessary tools to do so.

- Will actively engage in any investigation process e.g., RCA or post infection review of any known or suspected infection transmission in relation to medical device of care equipment use and decontamination processes.

- Engage in pre-procurement purchasing scrutiny of any medical devices and decontamination products to ensure effective

decontamination can be performed within NHS Trust policy and that agreed products are used within appropriate facilities.

- Any identified risks with regard to inadequate decontamination reported from the screening assurance processes will be escalated to the Infection Prevention and Control Group initially and subsequently to the Quality, Safety and Improvement Committee. The lead IPC nurse should participate in the investigation of the root causes.

- Ensure decontamination requirements for specific situations or organisms such as incidents and/or outbreaks of infection will be communicated, and guidance given to all relevant staff in a timely manner. The IPC lead will monitor and seek assurance from managers that implementation has been achieved.

- Will actively work with PHW Sustainability Lead to ensure decontamination processes are working toward carbon neutral without compromising the effectiveness of the decontamination process and subsequent patient safety.

2.8 Operational Health and Safety Manager

The Health and Safety Manager has responsibility to:

- Advise on the suitability (from a Health and Safety perspective) of all policies, procedures, systems of working and use of chemicals associated with the Decontamination process.

- Advise (from a Health and Safety perspective) on the environmental suitability of activity areas used or intended to be used for decontamination activities.

- Ensure that Health and Safety risk assessments relating to all activities related to decontamination, including the movement of equipment and devices are undertaken as required and that the results of these are communicated to the appropriate Manager and to the Decontamination Lead who will in turn present to the IPC group.

- Report concerns or incidents to the Corporate Health and Safety Manager.

2.9 Operational Responsible Lead for Decontamination

2.9.1 The operational decontamination lead is organisationally responsible for:

- the effective, and technically compliant, provision of decontamination services supported by the authorising engineer commissioned through Shared Services Partnership.

- the implementation of operational policies for decontamination.

- ensuring specific operational policies and procedures are in place for the decontamination of all medical devices, and that these policies clearly define the roles and responsibilities of all personnel who may be involved in the use, installation and maintenance of decontamination equipment.
- monitoring the implementation of the policies and should have a competent understanding of the decontamination of medical devices, guidance, legislation and standards.

- The post undertaking the role of responsible person /operational decontamination Lead needs to have undertaken suitable training in all aspects of the decontamination systems used in the organisation to support Public Health Wales services.

2.9.2 External Authorising Engineer

- Public Health Wales commissions from NHS Wales Shared Services Partnership a senior decontamination engineer to acts as its external authorizing engineer and provide advice and guidance for decontamination related matters.

2.9.3 Medical Devices Safety Officer

- The Medical Devices Safety Officer is the Specialist Lead for Trust-wide management of medical devices.

3. Definitions

A list of abbreviations and their meanings can be found in **Appendix 2.**

Decontamination is a combination of processes which removes or destroys contamination, so that infectious agents or other contaminants cannot reach a susceptible site in sufficient quantities to initiate infection or other harmful response. Different levels of decontamination can be used dependent on the device and the procedure involved. Some devices need to be sterile at the point of use e.g., needles, syringes, surgical instruments and may be single use. It is used to render any re-usable item safe for further use. The decontamination process is intended to:

- Make the item safe for staff to handle or manipulate without presenting an infection transmission hazard.

- Make the item safe from an infection transmission hazard prior to, and after use on a service user/patient. Correct decontamination also ensures freedom from contamination from previous use that could lead to incorrect diagnosis e.g. tissue sampling. Correct decontamination prevents unnecessary exposure of the service user/patient to chemicals used in the decontamination process.

The levels of decontamination are:

- **Cleaning**: the process that physically removes soiling including large numbers of micro-organisms and the organic material on which they thrive.
- **Disinfection**: the reduction of the number of viable micro-organisms on a product to a level previously specified as appropriate for its intended further handling or use. Cleaning always precedes disinfection unless a combined product is used.
- **High Level Disinfection:** significantly reduces microbial contamination (i.e., mycobacteria, fungi, viruses and bacteria) and renders it safe for reuse, although small numbers of bacterial spores may still be present.
- **Sterilization**: the process used to render an object free from viable micro-organisms including viruses and bacterial spores. (BS EN 556-1:2001). Cleaning and disinfection always precede sterilisation.

NB. PHW does not undertake the sterilisation of any medical device or reprocess surgical instruments. Sterile items are bought in as required.

Microbiology operates an autoclave specifically for decontamination of laboratory waste and not medical devices. This autoclave is covered by a suite of specific Standard Operating Procedures (SOPs) available from the Health & Safety Manager, Microbiology Division:

- MDHS 008 Disinfection and spillage policy
- MDHSE 004 Autoclave standard operating procedure
- MDRA 004 Risk assessment for autoclaves
- MDHS 021 Procedure for the segregation and decontamination of clinical waste
- CDHS 022 Procedure for the sterilisation of genetically modified waste by autoclaving

It must be validated in accordance with appropriate guidelines, currently that is WHTM 01/01 part A, C and HTM 2010 (Search Results - NHS Wales Shared Services Partnership.

PHW procures Health Boards/Trusts to provide bowel screening services but does not have any decontamination units, does not reprocess endoscopes

or sterilise instruments itself. Staff working in decontamination units must be trained in accordance with the Welsh HTM documents 01 01 Parts A to E: Decontamination of reusable medical devices (2018) and 01 06 Parts A to F: Decontamination of Flexible Endoscopes. PHW will need to seek through their assurance framework that decontamination units providing services to PHW are validated and operating according to the appropriate guidance.

4. Medical Device Management

A medical device refers to an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

i. Diagnosis, prevention, monitoring, treatment or alleviation of disease
ii. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
iii. Investigation, replacement physiological process, or
iv. Control of conception.

Public Health Wales must ensure that systems and processes are in place for the use, maintenance and service of reusable devices. Public Health Wales policy *Medical Devices and Equipment Management Policy (PHW 69)* should be referred for guidance on:

- The wider definition of a medical device and their uses
- The legislation - mandatory, statutory and best practice guidance governing medical devices
- Assessing Safety and Quality performance
- Procurement/acquisition processes
- Decommissioning and disposal
- Device acceptance procedures for planned and routine maintenance, device storage, repairs
- Use of loan equipment
- Training
- Compliance
- Adverse Incidents
- Use for non- designated purposes

4.1 Key controls for effective decontamination of devices

The essential requirements for good decontamination practice for medical devices and care equipment are:

a. Having robust management controls in place.
b. Ensuring medical devices are used appropriately i.e.
   - Fit for purpose

- In accordance with manufacturer IFU
- Properly maintained, monitored and validated
- Used by staff who are fully trained and competent
- Conforming to standards and requirements
- Track and trace systems link device usage to individual service users/patients
- Robust records are maintained throughout the decontamination process
- Appropriate facilities are provided for decontamination; A suitable built environment, segregated for dirty/clean activities, as a minimum the workflow should reduce any inadvertent errors with clean/dirty devices
- Single use instruments are not decontaminated for subsequent use
- Use of appropriate decontamination methods and products and equipment to effect the required outcome e.g. cleaning, disinfection, sterilisation
- Robust incident reporting and investigation processes to manage failures and near misses
- Surveillance systems to detect service user/ patient/staff harm.

(See **Appendix 3** – Decontamination Life cycle)

4.2 Purchasing medical devices and equipment that require decontamination.

The purchase of medical devices and care equipment should be in collaboration with managers, users, health and safety leads, engineering (if appropriate) and the Lead Nurse for Infection Prevention and Control. To ensure effective decontamination can be undertaken and IPC risks are identified, the lead nurse IPC along with the Medical devices safety officer must be consulted and contribute to the pre procurement processes of new medical devices and equipment used in a clinical care. Prior to purchase the following should be assessed

- Whether a single-use or a reusable product is more appropriate based on infection risk?
- How easy it is to decontaminate e.g., does the device need dismantling before processing that could increase exposure to pathogens?
- Is specific precautions and PPE required and if so what?
- Is the facility suitable to safely carry out the decontamination process e.g., ventilation, light, decontamination sink/surfaces, storage of decontamination products and equipment
- Has the organisation the capability to decontaminate devices with electrical components, as described by the manufacturer?
- Is the in-use life of the device specified by the manufacturer?

- Can the method of cleaning/disinfection specified by the manufacturer IFU be safely achieved in accordance to PHW polices for IPC, H&S, COSHH, medical device management and decontamination?
- What is the cost associated with specific cleaning products or equipment and alternatives re sustainability e.g. can the item withstand the use of current Chlorine-containing products, or other recommended disinfectant products, is HLD required and if so what type (hydrogen peroxide versus UVC)?
- Has sustainability and environmental impact been considered in use of the product or equipment across its lifespan and to disposal?
- Do staff require specific training to undertake the decontamination process and who will provide that training?
- If the product is heat or pressure sensitive, what alternative means of decontamination are recommended, and can they be achieved?
- Are there specific risks highlighted for vulnerable staff and/or service users? E.g. allergies to chemical components of products
- Can the Trust comply with the disposal requirements stated by the manufacturer and National guidance.

4.3 Risk Assessment:

The decontamination method chosen must be assessed according to:

- The risk associated with the use of a particular device or piece of equipment.
- What it is exposed during use and likelihood of contamination
- The infection transmission risk posed to patients and staff if decontamination is inadequate.
- The Manufacturer instructions for use (IFU).

Before undertaking any reprocessing staff should use the risk assessment tool to determine the required, cleaning, disinfection and sterilising process needed. Manufacturer's guidance should always be followed when decontaminating any equipment/instruments.

The Spaulding Classification is used to stratify the risk of infection transmission based on the patient tissue that the device will contact during use. The device classification determines the level of decontamination required.

Classification of infection risk associated with the decontamination of medical devices according to Spaulding:

Spaulding Classification	Application of Device Or Procedures	Risk of Infection Transmission	Recommendation/level of Decontamination
Critical	**Introduced into sterile tissue or bloodstream** e.g. surgical instruments; IV needles, biopsy needles. **In close contact with broken skin or broken mucous membrane**.	High	Cleaning and disinfection followed by **Sterilization**
Semi-critical	In contact with mucous membranes not penetrating sterile tissue e.g. flexible endoscopes, vaginal specula, trans vaginal scopes. In contact with intact skin prior to penetrating a sterile tissue e.g. breast biopsy, CVC insertion. Contaminated with particularly virulent or readily transmissible organisms. Before use on immunocompromised patients.	Medium	Cleaning followed by **High Level Disinfection (HLD)** or sterilization NB: Where sterilization will damage equipment, cleaning followed by HLD may be used as an alternative
Non-critical	In contact with healthy non infected/colonised skin. Care equipment e.g. stethoscope, BP cuffs, examination couch, procedure trolley.	Low	Cleaning & low-level disinfection if required.

Under the Spaulding Classification Ultrasound Probes that come into contact with broken skin or intact mucous membrane are considered semi-critical devices and should undergo manual cleaning followed by High Level Disinfection (HLD) between each patient use. In addition, it is strongly recommended that HLD is used on probes used on intact skin when used prior to an invasive procedure e.g., breast biopsy, insertion of a central venous line, prior to aspiration of a body cavity. There have been case reports of infection transmission as a result of ultrasound probes only being cleaned and/or low level disinfected prior to an invasive procedure. Therefore PHW breast screening services will adhere to WHTM 01-01 (part F)*Decontamination of flexible endoscopes Part F: Decontamination of Semi-Critical Ultrasound Probes; Semi-invasive and Non-invasive Ultrasound Probes* in the decontamination of ultrasound probes when used prior/during breast biopsy procedures (see **Appendix 4**).

4.4 Care Equipment

Care equipment can be classified as either:

Single-use – equipment which is used once on a single patient and then discarded. It must never be reused, even on the same patient. The packaging carries the symbol here:

Examples include:

- Needles and syringes - they should never be used on more than one patient or reused to draw up additional medication.
- Disposable specula for cervical screening
- IV devices
- Breast biopsy needles
- Tonometer prisms, ophthalmoscope/otoscope specula

1. **Single patient use** – equipment which can be reused on the same patient. It must be labelled with patient name and disposed of at end of use on that patient. Will often require decontamination between use on same patient e.g. hoist slings, nebuliser sets and oxygen masks,

Reusable invasive equipment - used once on a patient then decontaminated before use on next patient e.g., endoscopes and surgical instruments which usually require HLD or sterilisation

Reusable non-invasive equipment (often referred to as communal equipment) - Re –usable care equipment can become contaminated with blood, other body fluids, secretions and excretions and transfer infectious agents during the delivery of care. This type of equipment (often referred to as communal equipment) are reused on more than one patient and require decontamination between each use or between different tasks on the same patient. It is not intended for single-use or single-patient use. Examples of items which come into this category include: couches, manual handling devices, stethoscopes, wheelchairs, ultrasound probes, mammography x-ray machines, diabetic eye screening camera frames.

NB. Not all care equipment is validated or described by the manufacture as medical devices but manufacturers are obliged to provide decontamination advice for all CE marked products.

NB. Single use devices must not be reprocessed or re-used under any circumstances.

5. Decontamination Methods

Following the risk assessment, the device or equipment will be classified (critical, semi critical or non-critical), which will indicate the level of decontamination required. The chosen decontamination method will be determined from information supplied by the manufacturer of the device or equipment and their IFU and will depend on:

- the heat, pressure, moisture and chemical tolerance of the object.

The use of automated/validated systems are recommended.

As an example, ultrasound probes will not withstand high temperature or steam pressure sterilisation, they cannot be fully immersed due to the electrical components and specific non-linting cloths must be used to clean the heads to prevent scratches to the surface.

Manufacturer guidance must be adhered to, and systems must be compatible, to ensure that the properties of the device are not altered by incorrect handling, reprocessing or decontamination.

Decontamination of reusable non-invasive devices and care equipment (**Appendix 4**) must be undertaken:

- Between each use
- After exposure to blood or body fluid or where there is other visible contamination

- At regular predefined intervals as part of an equipment cleaning protocol and
- Before inspection, service, maintenance or repair.

All clinical areas need a clear protocol for all devices and care equipment being used that details:

- Methodology of cleaning/disinfection.
- The frequency of cleaning/disinfection.
- The decontamination product (s) to be used.
- The H&S and IPC controls including appropriate PPE.
- Evidence the cleaning/disinfection has been undertaken, date, time and person. This can be recorded as part of a cleaning schedule or post use protocol and/or use of commercially available 'I am clean' labels/roll. Additional data is required for HLD (see section 7. Traceability).

Advice should be sought from the lead IPC nurse on specific infections. Additional guidance may be provided should an incident or outbreak of infection occur, or another pandemic situation arises which will take precedence over this routine procedure.

5.1 Cleaning

Cleaning is an essential pre-requisite of any decontamination process prior to disinfection or disinfection and sterilisation. Cleaning must be undertaken before disinfection (unless a combined cleaning disinfection product is used). Using manual or mechanical cleaning will depend on what the device will withstand and in accordance with the manufacture IFU.

Mechanical cleaning e.g., using a validated washer-disinfector or ultrasonic machine provides a validated process of cleaning and is used for e.g. endoscopes, surgical instruments etc. and should be used for critical and semi-critical devices if compatible. However, not all devices can withstand mechanical cleaning and so manual cleaning will be the method used for PHW clinical services e.g., ultrasound probes and medical devices.

Manual cleaning must be carried out in a methodical and logical way to ensure all parts of the device or equipment have been cleaned in the correct order:

- top to bottom,
- inside to out,
- clean to dirty parts,
- then correctly reassembled to ensure recontamination does not take place during the process.

Appendix 5 shows the correct method for cleaning surfaces using the 's' method of wiping, to ensure that all surfaces are included.

A general-purpose neutral detergent in a solution of warm water of 0.1% or detergent impregnated disposable wipe is usually sufficient to effectively clean non-critical medical devices and communal equipment (examination couches, breast plates etc) not contaminated by blood or body fluids unless advised otherwise by the manufacturer. If there is evidence the service user has an existing or suspected infection and/or the item is contaminated by blood or body fluids then cleaning will be followed by disinfection, or the use of an approved combined detergent/disinfection product.

Certain devices or equipment may require specific products to clean and/or decontaminate as per manufacturer IFU.

5.2 Disinfection

Disinfection should only be used where sterilisation is not required and where cleaning with detergent is inadequate. Manual disinfection using approved disinfectants is adequate for non-critical items, High Level disinfectants will be required for semi critical devices. However, consistency cannot be guaranteed as a result of human factors where manual disinfection is used.

All disinfectants must be approved and compatible for use in accordance to Manufacturer IFU and PHW policy for IPC and medical device management. Using products not stated or outside of manufacture instructions may increase risk of HCAI and render any warranty of the device void. If non-approved products are used it should be following a robust risk assessment with IPC and medical device lead for PHW and potentially the manufacturer. Alternative products should be included on the risk register for that directorate and approved via the IPC committee so that PHW accepts liability in event of a decontamination failure or damage to a device.

Disinfectants are provided by manufacturers in a number of delivery systems i.e. wipes, pouring liquids, sprays, for immersion, vapour. If used, room ventilation must be appropriate and specified within the MSDS. Those used in PHW must have been approved for use to ensure they are validated products that meet the British Safety (BS)/European Union (EU) testing and HSE biocide regulations so that their antimicrobial properties cover the spectrum of activity required for the device against e.g. viruses, bacteria, spores, fungi.

Key testing regulations include:

- **BS EN 14485** defines the trials and testing process required, with liquid formulations required to pass.

- **BS EN 13727** and **EN1276** assesses bacterial activity.
- **BS EN 14476** disinfectants can have full virucidal activity; limited virucidal activity & enveloped virus only.

Products may already be diluted or require reconstitution but whatever the product or delivery system, staff handling them must be adequately trained in their safe use within COSHH regulations.
The Lead Nurse for Infection Prevention and Control should be consulted for approval of any new disinfectants purchased.

When using disinfectants:

- staff must be adequately trained and assessed as competent in handling and decontamination product including disinfectants.
- never mix with other products.
- use in the correct dilution: higher or lower concentrations are wasteful and potentially harmful.
- Check expiry dates - they must not be used beyond that date. Date product when first opened and dispose of in accordance to manufacturer recommendations for after opening use by date.
- Where chemicals need to be diluted or mixed, always use freshly prepared solutions that must be dated and labelled accordingly with strength e.g., hypochlorite 1000ppm.
- Do not store reconstituted/diluted products longer than advised, (usually 24 hours but refer to manufacturer guidance).
- Never decant solutions to non-designated containers or containers that have previously contained a different product.
- Use appropriate PPE and protective clothing supplied by the employer.
- Ensure adequate ventilation of the area when the product is being used.
- Immediately report any untoward incidents or exposures related to the disinfectant.
- Ensure spillage kits are available if volumes of liquid disinfectants are being used or stored for use.

- Adhere to COSHH regulations for safety data and storage.

- Dispose of waste products, including waste containers, according to waste management policy.

(See **Appendix 6**) for the management of blood and body fluid spillages.

5.3 Automated washer-disinfectors

There are currently no automated washer-disinfectors within Public Health Wales used for decontamination of medical devices used on service users/patients.

5.4 Decontamination of Equipment and Devices following use on a known/suspected infectious service user/patient.

The principles of Standard Infection Control Precautions (SICP) must be applied at all times for all service users as it is not known who is or is not infectious especially if they have no symptoms.

Service users will be encouraged to rearrange their appointment if they feel unwell and/or develop symptoms of an acute infection, including respiratory symptoms, gastrointestinal symptoms or skin rashes etc. until they have recovered. Otherwise, screening should be undertaken, and IPC precautions applied.

Staff should take appropriate measures to decontaminate the environment (see environmental cleanliness policy) and equipment/devices used before and after all appointments.

Where the patient is known or suspected of being infectious, this may require the additional use of a disinfectant for communal equipment and devices in addition to cleaning and/or additional use of single use devices (see **Appendix 7**).

The same applies for those who are known, suspected or declare they are colonised or infected with organisms that are implicated in HCAI such e.g., Meticillin-resistant *Staphylococcus aureus* (MRSA), Clinically Significant Antimicrobial Resistant Organisms (CSARO) or blood borne viruses. If they are known to be infectious and can be seen at the end of the day, then arrange if possible but it is not essential requirement in dealing with these cases and the service user care should always be first priority. The Lead Nurse for IPC can be contacted for further advice.

See the Waste Management Policy on how to dispose of waste generated from patients with infections or colonised with drug resistant organisms.

6.Traceability and Record Keeping

Track and trace systems for critical and semi critical devices that require and/or sterilisation must include accurate records of all decontamination processes undertaken and how/who has undertaken them. Digital track and trace software systems are preferred to ensure a robust and valid system that can be audited and interrogated and utilised to ensure the full details of the processes are recorded. They also support a rapid look back exercise to trace potential cross infection or HCAI from use of the device. PHW should be working toward a digital traceability system for the HLD of semi critical devices. Track and trace systems for HLD of ultrasound probes must include:

- Identifying data of the service user/patient the device is used on as per NHS protocol.
- Place/setting of decontamination (include address, room, clinic).
- The product (s) used – serial numbers and expiry dates of all of them.
- Data and time of decontamination – length of processes (if applicable).
- Name of the person who has undertaken the decontamination process - Printed and signature name date for manual systems.
- Specific record books for manual systems that are retained for 11 years.
- The record must be complete and legible for inspection and audit.

The Consumer Protection Act (1987) (6), and in particular Product Liability has implications for the processing of devices used for service user/ patient care. It is essential to maintain adequate records that demonstrate how a particular device was processed. SOPs, Working Instructions and traceability records, to include product release by user. This includes a description of the method/s employed together with details of available trained personnel with copies of training records. The organisation should have the ability to demonstrate how instruments/equipment have been processed through the decontamination cycle.

7. Storage of Sterile Products and Decontaminated Medical Devices/Care Equipment

7.1 Sterile goods

Storage should be appropriately designed and provided to:

- prevent damage and protect the packaging – a breach in packaging will introduce contamination.
- Prevent exposure to contamination from service users or the clinical area.
- Ensure the correct storage temperature as advised by the manufacturer – if the temperature is too high or too low this will affect shelf life and possible function of the product e.g. plastics or gloves may become brittle. Products must be stored from direct sunlight and water in a secure, dry and cool environment.
- Ensure the correct humidity level as advised by the manufacture.
- Space is sufficient to allow for the strict rotation of stock – dates should be checked monthly.
- Shelving, draws, racking, cupboards should have impervious surfaces for ease of cleaning. Ideally allowing dust or particles to fall through to the floor and allow the free movement of air around the stored product. A routine monthly cleaning schedule is required as a minimum to maintain cleanliness of all storage.
- Products must be stored above floor level.

Before use, sterile products should be checked to ensure that:

- The packaging is intact and has not been exposed to dirt/dust/moisture/damage etc and the product is still within the expiry date.
- The sterilisation indicator confirms the pack has been subjected to an appropriate sterilisation process.

7.2 Medical Devices/Care Equipment

Storage should be appropriately allocated and designed to:

- prevent damage and protect the device or equipment.

- adhere to that described by the manufacture – specialist devices may require specific storage boxes/containers to prevent damage to delicate parts.
- allow ease of access and comply with manual handling requirements.
- Shelving, flooring, cupboards should have impervious surfaces for ease of cleaning. Ideally allowing dust or particles to fall through to the floor and allow the free movement of air around the stored product. A routine monthly cleaning schedule is required to maintain cleanliness of all storage areas.
- If required, allow for charging of the device.
- Devices must be stored from direct sunlight and water in a secure, dry and cool environment so that the correct temperature and humidity is maintained.
- When not in used, prevents exposure to contamination from service users or the clinical area. Consider covering the equipment to prevent collection of dust and potential contamination.
- Thorough drying of equipment is essential before storage or use on the next patient.
- Consider covering the equipment to prevent collection of dust and potential contamination.

8. Transportation

Equipment, medical devices and clean/sterile goods including instruments must be transported so as to prevent microbial contamination or damage and protect the individual transporting them so that:

- Any containers used for transportation must be dedicated and suitable for purpose, lockable and easily decontaminated for re-use.
- Any inserts for supporting the device during transportation must also be easily cleaned.
- Records of which items of devices and equipment are transported, on what date, by whom, and between which locations must, be made and retained for audit.
- Containers, trolleys, boxes etc. used for transporting soiled items should be labelled with the word BIOHAZARD. This could be a device

or equipment which could not be decontaminated by the department and will also have a decontamination certificate attached (See **Appendix 8**.)

- Containers, trolleys, boxes etc. used for transporting decontaminated items after decontamination should be labelled DECONTAMINATED MEDICAL DEVICES.

- Contaminated and decontaminated devices or sterile/clean goods and must be kept separate and ideally in different vehicles.

9. Decontamination of equipment prior to inspection, service or repair

All equipment must be appropriately decontaminated before inspection, service or repair in accordance with Department of Health (1993) HSG (93) 26. A certificate of decontamination must be completed which indicates if and how it was decontaminated or if it couldn't be decontaminated and the reason why.

Staff and/or contractors carrying out service, maintenance inspection or repair duties (onsite or despatched to another site or the manufacturer) must not be placed at risk by being exposed to contaminated items. Manufacturers' instructions must be followed to ensure effective decontamination of all devices and equipment.

Decontamination certificates (see **Appendix 8**) must also be completed where equipment/devices are being sent for waste disposal and/or recycling. Prior to the transfer of ownership and disposal of used medical devices they must be adequately decontaminated, and a decontamination certificate provided.

In addition, there must be safe systems of work established for those who inspect, service or repair medical or laboratory equipment on either healthcare premises or elsewhere. This will ensure that the items have certified as properly decontaminated prior to works to prevent exposure to infection and decontaminated post service, repair to ensure contamination from the work is not transferred to clinical settings or samples etc.

10. Monitoring and auditing

Clinical areas within Public Health Wales will participate in an agreed audit programme (as a minimum annually) agreed via the IPC group and with the service manager, to include IPC management and cleanliness of medical devices and care equipment utilising standardised audit tools

agreed by the IPC Group. Results to be reported to the Infection Control group, in addition to the operational/responsible lead and Medical Devices officer and validation of audits will be performed by the Lead Nurse for Infection Prevention and Control.

In line with Public Health Wales' Incident Management Policy and Procedure, incidents must be reported on Datix in the usual way within 24 hours of the incident being noted. Any incidents that fall within the definition of a 'National Reportable Incident' (NRI) must be nationally reported in line with the principles set down in the National Policy on Patient Safety Incident Reporting and Management.

Details of how to submit such reports are included in the Incident Management Policy and Procedure. Incident reporting via Datix will be used to inform the IPC group of any incidents, complaints, exposures etc including near misses Investigations of serious incidents should include a summary report submitted to the IPC group and added to datix. This will describe the actual causes, further actions needed, and any lessons learnt that need to be disseminated to other PHW services or wider e.g. SMTL, MHRA etc.

Contact details:

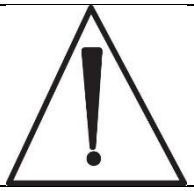
Lead Nurse for Infection Prevention and Control (Corporate)
HARP@wales.nhs.uk

Appendix 1 - Packaging Symbols for goods/packs

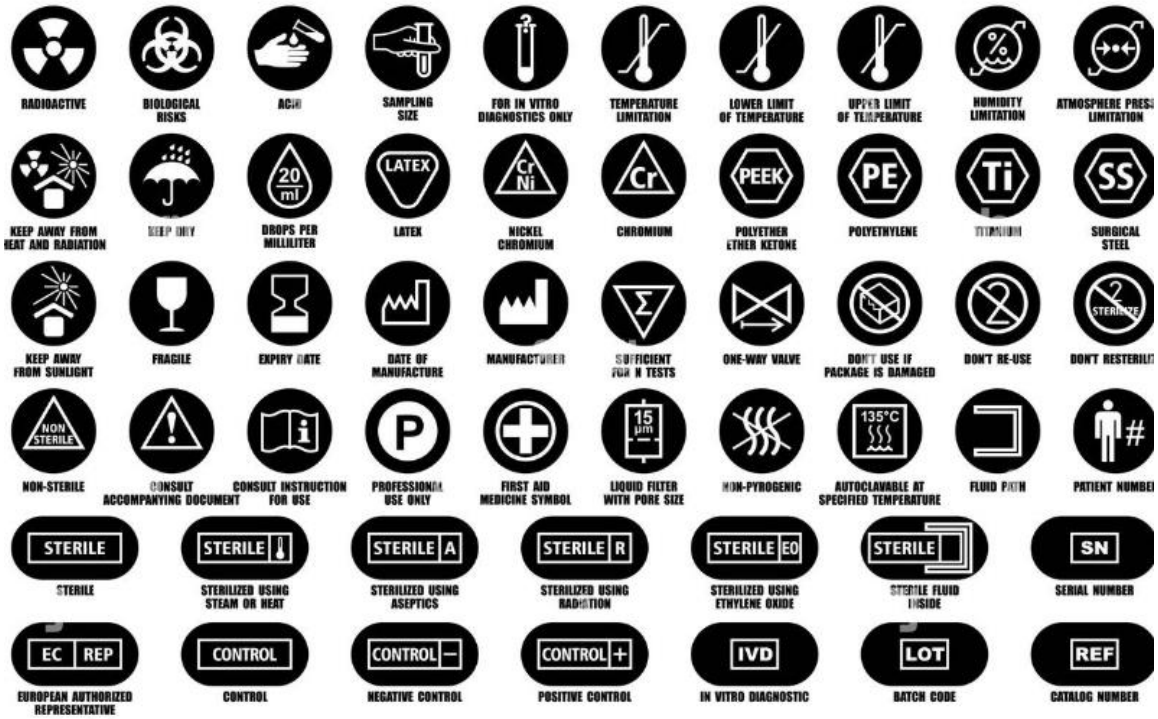
There is an international standard for medical device labelling which employs symbols to provide a visual and a universal means by which device information can be imparted to users. Translation of some technical terms can sometimes be open to misinterpretation.

The following symbol is used to indicate that a medical device should not be re-used ie. Single use

A number of the most commonly used symbols are reproduced below, together with an explanation as to their meaning:

	Batch Code
	Serial Number
	Attention: see instructions for use
	Date of Manufacture
	Use by date

STERILE	Sterile
STERILE R	Sterilized by irradiation
STERILE	Sterilized by heat
STERILE EO	Sterilized by ethylene oxide

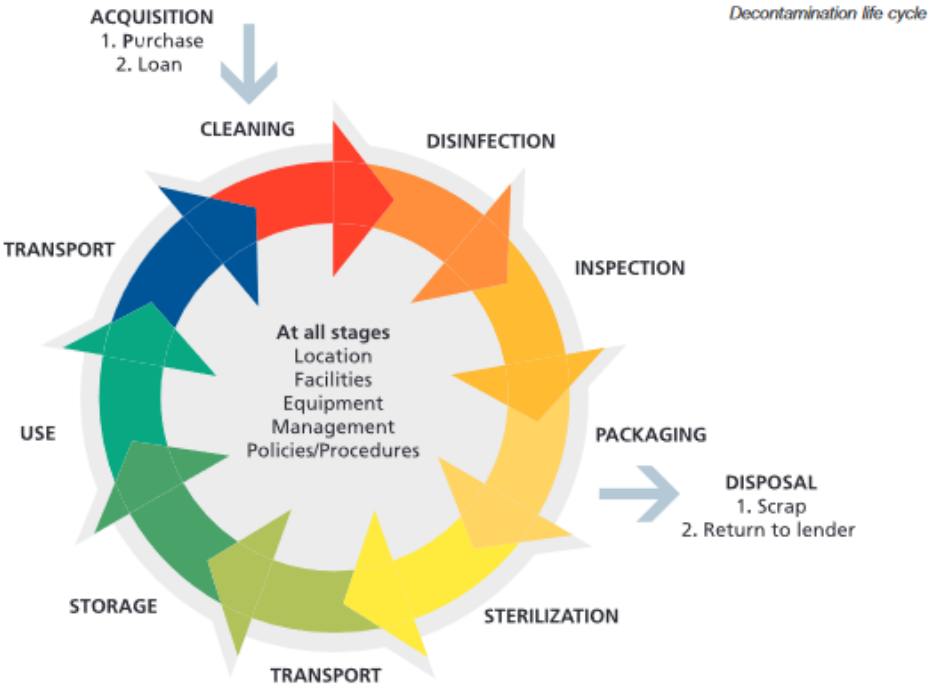


Appendix 2 – Abbreviations & Meanings

Abbreviation	Meaning
IFU	Instructions for Use - information provided by the manufacturer to inform the user of the device of its safe and proper use, of its intended performances and of any precautions to be taken under the Medical Devices Regulations 2002.
IPC	Infection Prevention & Control - a practical, evidence-based approach preventing patients and health workers from being harmed by avoidable infections.
H&S	Health & Safety – the aim to create and maintain safe, healthy environments for people to work and live in by identifying, assessing, and controlling potential hazards and risks.
HCAI	Healthcare-associated infection
MHRA	The Medicines and Healthcare products Regulatory Agency - regulates medicines, medical devices and blood components for transfusion in the UK.
PHW	Public Health Wales – the organisation.
PPE	Personal Protective Equipment - all equipment which is intended to be worn or held by a person at work and which protects the person against one or more risks to that person's health or safety, and any addition or accessory designed to meet that objective'.
SMTL	Surgical Materials Testing Laboratory - provide testing and technical services regarding medical devices to the Welsh NHS.
SOP	Standard Operating Procedure - a set of written instructions that describes the step-by-step process that must be taken to properly perform a routine activity.
SBAR	'Situation, Background, Actions/Assessment, Recommendations' – a report template that provides a standardised way of communicating issues.

Appendix 3 - Decontamination Life Cycle

Decontamination Life Cycle of Reusable Sterile Devices



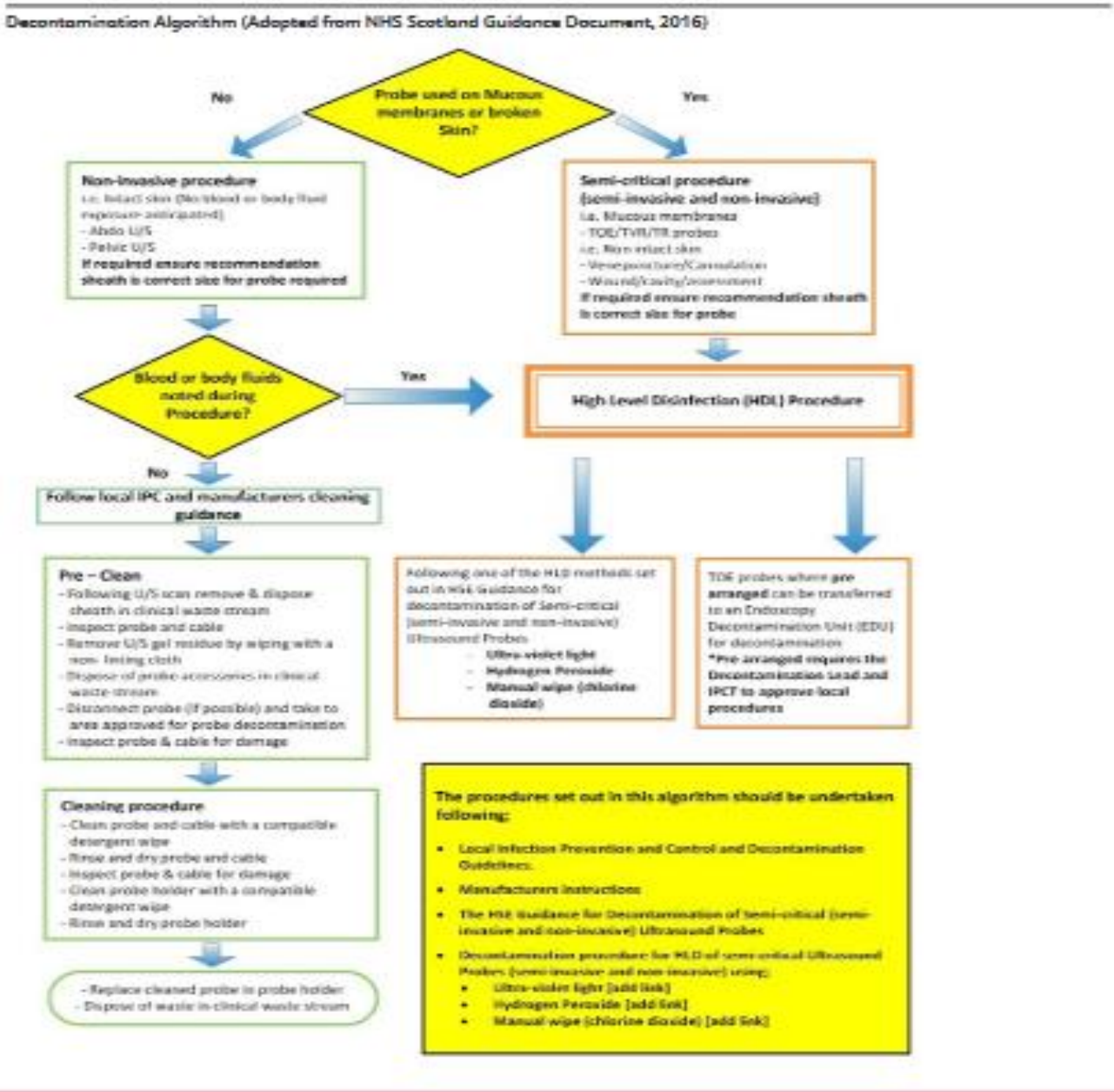
Decontamination life cycle diagram – semi critical probes (no sterilization)

To undertake decontamination effectively requires all the processes illustrated in the life cycle to be implemented correctly, with appropriate controls and monitoring in place. The speed at which medical devices pass through the cycle can impact on the efficacy of decontamination. A key factor influencing this is the size of the stock of devices requiring processing. Achieving minimum standards at each stage of the life cycle depends on location; facilities available; equipment used; how the process is managed, and the policies and procedures employed.

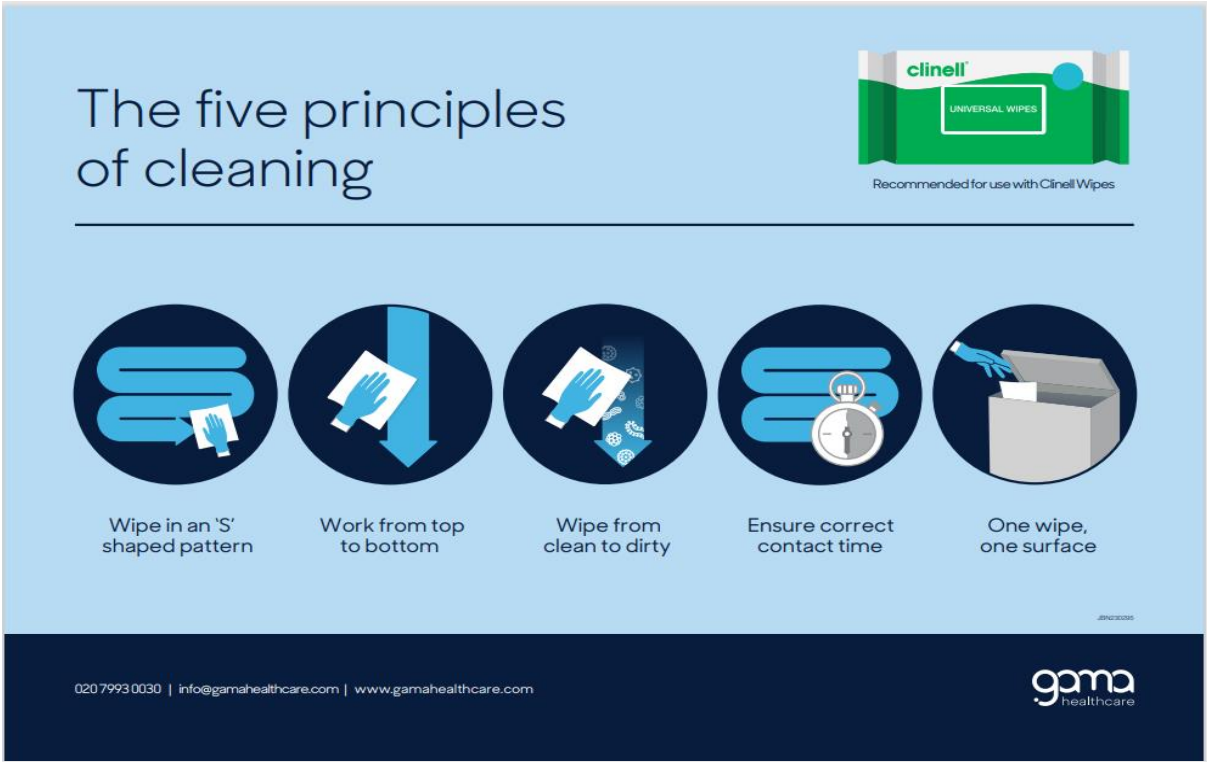
Appendix 4 – Decontamination Algorithm WHTM 01-06 part F

Appendix 2:

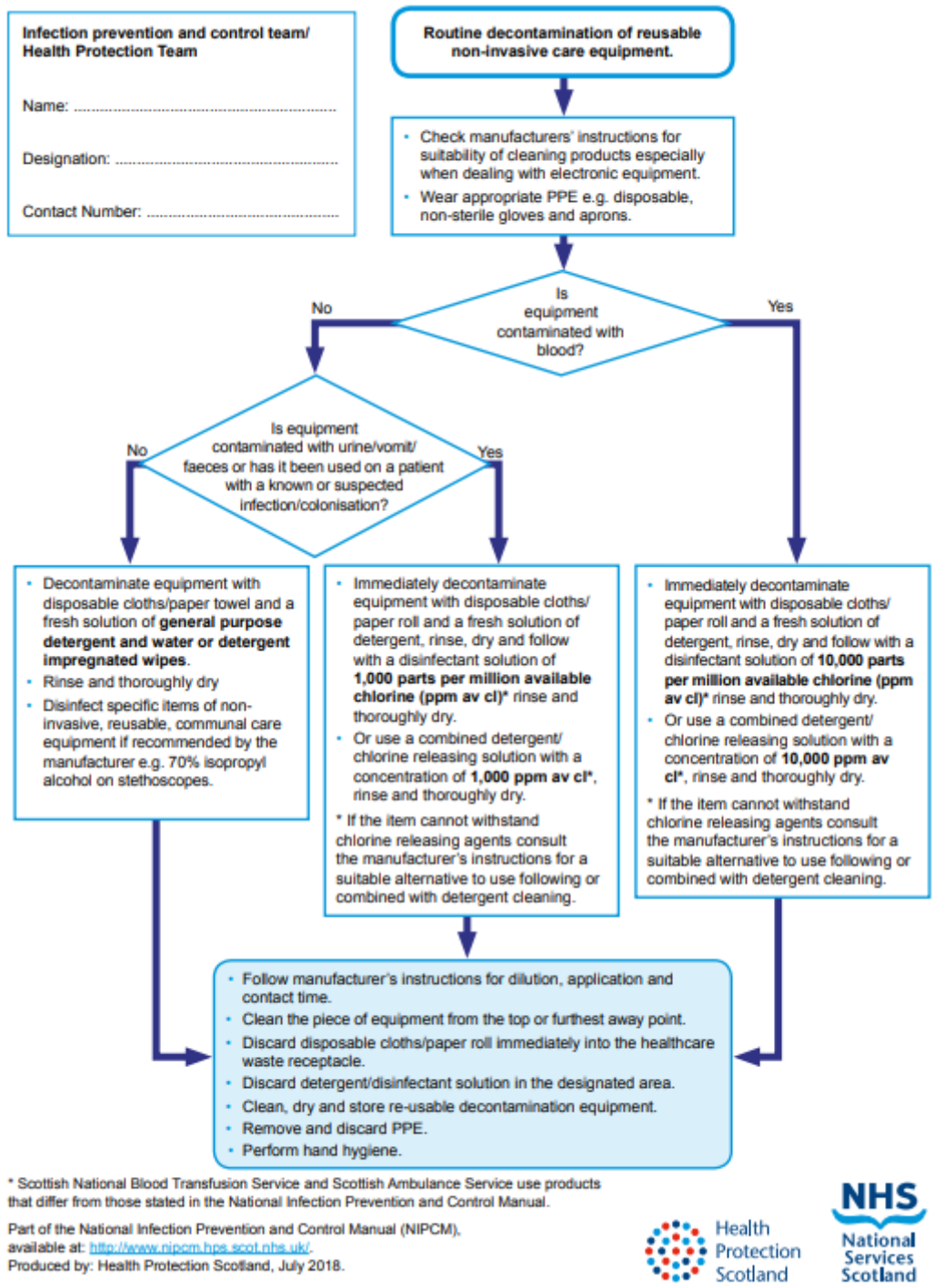
Semi-critical Ultrasound Probe (Semi-invasive and Non-invasive) Decontamination Algorithm (A guide developed from NHS Scotland Guidance Document, 2016).



Appendix 5 - The five principles of Cleaning Using Surface Wipes



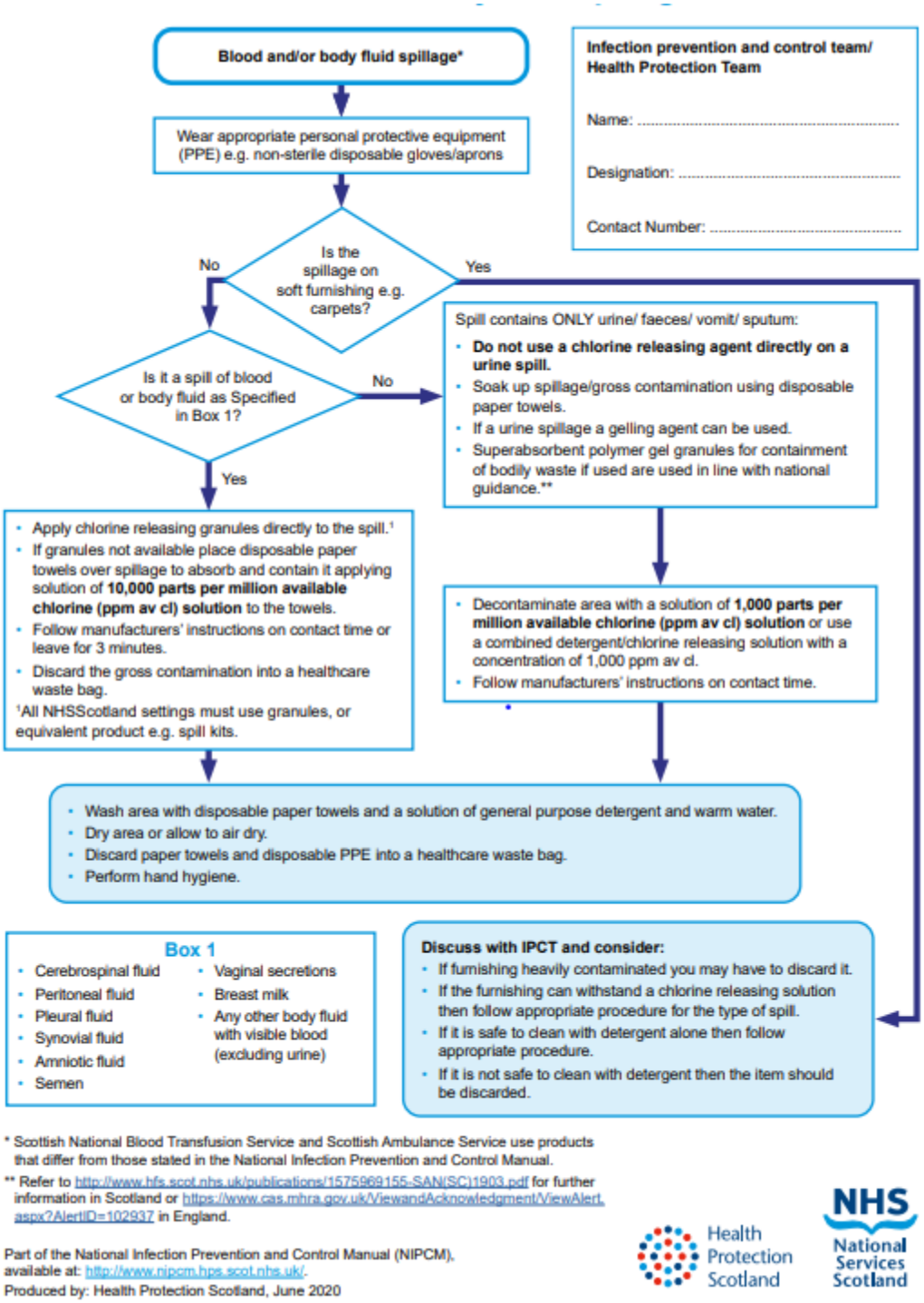
Appendix 6 - Decontamination of reusable non-invasive care equipment



https://phw.nhs.wales/services-and-teams/harp/infection-prevention-and-control/nipcm/,

Add a line about produced by and permission to use.

Appendix 7 - Management of blood and body fluid spillages



https://phw.nhs.wales/services-and-teams/harp/infection-prevention-and-control/nipcm/, Appendix 9

Appendix 8 – Sample certificate of decontamination

GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales

SERVICING AND DECONTAMINATION FORM FOR MEDICAL DEVICES

FROM:	TO:

Make and description of equipment/item .....

Model/Serial/Batch No. .....

Other distinguishing marks .....

This equipment/item has been cleaned in preparation for inspection, servicing repair or transportation **Yes** ☐ **No** ☐

1. Has this equipment/item been used in any invasive procedure or been in contact with blood, other body fluids, respired gases, or pathological samples? **Yes** ☐ **No** ☐
2. Has this equipment/item been exposed internally or externally to hazardous materials as indicated below? **Yes** ☐ **No** ☐

Provide further details here

Yes ☐ **No** ☐	Blood, tissue, body fluids, respired gases, pathological samples	
Yes ☐ **No** ☐	Chemicals or substances hazardous to health	
Yes ☐ **No** ☐	Other hazards/biohazards	

3. Has the item/equipment been suitably decontaminated? If YES, indicate method and materials used.

Yes ☐ **No** ☐	External	
Yes ☐ **No** ☐	Internal	

4. If the equipment/item could not be decontaminated, please indicate why:

5. If the equipment/item could not be decontaminated, state the nature of the risk and the precautions to be adopted:

6. Has the equipment/item been suitably prepared to ensure safe handling/transportation? **Yes** ☐ **No** ☐
7. Has the item/equipment been involved in a reportable incident or occurrence?

Yes ☐ **No** ☐	If yes, briefly describe

I declare that I have taken all reasonable steps to ensure the accuracy of the above information.

Signature _____ Division _____

Name (print) _____ Position _____ Date _____