Shropshire Community Health
NHS Trust

Document Details	
Title	Decontamination of Reusable Surgical and Dental Instruments Policy incorporating Decontamination of Flexible Nasendoscopes, Trans-vaginal Probes, Sigmoidoscopy Light Sources and Cryo-cautery Equipment
Trust Ref No	1114-89898
Local Ref (optional)	
Main points the document covers	This policy details actions required to decontaminate reusable surgical and dental instruments
Who is the document aimed at?	All staff who undertake decontamination procedures within Shropshire Community Health Trust
Author	Head of Infection Prevention and Control
Approval process	
Who has been consulted in the development of this policy?	This policy has been developed by the IPC team in consultation with appropriate senior Operations and Quality managers, Locality Clinical Managers, Specialist Nurses, Medicine Management and Public Health England
Approved by (Committee/Director)	Infection Prevention and Control Governance Meeting – notified to Quality and Safety Operational Group
Approval Date	21 June 2023
Initial Equality Impact Screening	Yes
Full Equality Impact Assessment	N/A
Lead Director	Director of Nursing and Workforce, DIPC
Category	Clinical
Sub Category	Infection Prevention and Control
Review date	30 June 2026
Distribution	
Who the policy will be distributed to	IPC Committee Members
Method	Electronically to IPC Committee Members and available to all staff via the Trust website
Document Links	
Required by CQC	Yes
Key Words	Decontamination. Reusable instruments. Surgical. Dental. CSSD. Ultrasonic. Cleaning. Single-use. Nasendoscope. Trans-vaginal. Sigmoidoscopy. Cryo-cautery

Amendments History		
No	Date	Amendment

Contents

1 Introduction

Decontamination plays a vital role in patient care by reducing the risk of exposure to patients and staff to infectious microbial agents. All reusable medical devices must be effectively decontaminated prior to reuse. The term 'device' is used throughout this policy to include medical devices, surgical instruments and medical equipment.

2 Purpose

The reprocessing of reusable surgical and dental instruments is preferably undertaken by an accredited Central Sterilisation Services Department (CSSD). These departments have the equipment and expertise to clean and sterilise reusable surgical instruments effectively and consistently, with economy of scale. However, where this is not possible the service areas must have appropriate facilities and equipment to undertake the reprocessing.

This policy is intended to support all staff involved in the decontamination of reusable surgical and dental instruments at a local level and services which send instruments for reprocessing at a CSSD within Shropshire Community Health NHS Trust (SCHT).

3 Definitions

Term / Abbreviation	Explanation / Definition
AE(D)	Authorising Engineer (Decontamination)
CCR	Clinical Case Review
CA	Conformity Assessment (compliant with UK device legislation)
CE	Conformité Européenne (compliant with EU legislation)
Cleaning	The process of physically removing a number of viable micro-organisms and organic matter.
CP	Competent Person
CSSD	Central Sterilisation Services Department
Decontamination	The elimination of micro-organisms and other material which could otherwise be transferred to a susceptible site and cause infection. It is a collective term describing the three processes of cleaning, disinfection and sterilisation
DIPC	Director of Infection Prevention and Control
Disinfection	The process of using heat or chemicals to reduce the number of viable organisms but is unable to inactivate all viruses or spores. Disinfection is not a substitute for sterilisation.
EN	European Norm
HCAI	Healthcare Associated Infection
HTM	Health Technical Memorandum
IPC	Infection Prevention and Control
MDA	Medical Devices Agency
PIR	Post Infection Review
RCA	Root Cause Analysis
SaTH	Shrewsbury and Telford Hospitals
SCHT	Shropshire Community Health NHS Trust

SIP	Service Improvement Plan
Sterilisation	The process to ensure an object is free from all viable micro-organisms, including spores. This is usually undertaken using steam.
UN	United Nations

4 Duties

4.1 Responsibility for Infection Prevention and Control (IPC) outside the immediate scope of this policy

For duties and responsibilities for IPC practices outside the specific scope of this policy, please refer to the IPC Arrangements and Responsibilities Policy on the Staff Zone SCHT Staff Zone (shropcom.nhs.uk).

4.2 IPC Duties specific to this policy

4.2.1 Infection Prevention and Control Team

The Infection Prevention and Control (IPC) team is responsible for providing specialist advice in accordance with this policy, for supporting staff in its implementation, and assisting with risk assessment where complex decisions are required.

The IPC team will ensure this policy remains consistent with the evidence-base for safe practice, and review in line with the review date or prior to this in light of new developments.

4.2.2 Roles and Responsibilities of Key Personnel Involved in Decontamination Procedures

The responsible personnel as noted in sections 4.6.1 to 4.6.3 below are identified via the Estates Service for the Trust.

4.2.2.1 Registered Authorising Engineer (Decontamination) (AE(D))

The authorising engineer is designated by management to provide independent auditing and advice on sterilisers and sterilisation and to review and witness validation and periodic test documentation. A list of suitably qualified AE(D) is maintained by the Institute of Healthcare Engineering and Estates Management (IHEEM).

4.2.2.2 Competent Person (Pressure Vessels) (CP)

The Competent Person (pressure Vessels) is the person or organisation undertaking certain legal responsibilities under the Pressure Systems Safety Regulations.

4.2.2.3 Competent Person (Decontamination) (Previously known as Test Person)

The Competent Person (Decontamination) undertakes the maintenance testing and validation work at quarterly and annual intervals; retains a maintenance “hotline” for urgent requests; together with manufacturers, undertakes commissioning tests.

4.2.2.4 User

The User is a person designated by management to be responsible for the management of the decontamination equipment including automated cleaning equipment and sterilisers.

4.2.2.5 Operator

The Operator is the person with the authority to operate decontamination equipment including automated cleaning equipment and sterilisers, including the noting of instrument readings and simple housekeeping duties and by agreement, daily/weekly testing.

Note: The person designated as the User or by delegation the Operator has the ultimate responsibility for certifying that decontamination equipment is fit for use. The User has the responsibility for ensuring the Operator has received adequate training.

Refer to Appendix 1 – Roles and responsibilities of key personnel involved in decontamination procedures.

5 Single-use Devices

A single-use device must only be used during a single treatment episode and then be disposed of. It is not intended to be reprocessed and used again even on the same patient at a later session.

The re-use of single-use devices has implications under the Medical Devices Regulations. Anyone who reprocesses or re-uses a device that is either CA or CE-marked for use on a single occasion bears the responsibilities normally carried by the manufacturer for the safety and effectiveness of the instrument.

Shown below is the symbol that identifies single-use items. This will appear on packaging but might not be present on individual items. If in doubt, further advice should be sought from the manufacturer.

6 Decontamination

Decontamination is the elimination of micro-organisms and other material which could otherwise be transferred to a susceptible site and cause infection. It is a collective term describing the three processes of cleaning, disinfection and sterilisation.

6.1 Decontamination Standards

Health Technical Memorandums (HTM) refer to Essential Quality Requirements compliance and Best Practice compliance:

HTM 01-01: Decontamination of Surgical Instruments

HTM 01-04: Decontamination of Linen for Health and Social Care

HTM 01-05: Decontamination in Primary Care Dental Practices.

HTM 01-06: Decontamination of Flexible Endoscopes

Essential Quality Requirements is a term that encompasses all existing statutory and regulatory requirements which incorporates the current Medical Device Regulations (MDR) and the approved Codes of Practice as well as relevant applicable standards. Local policy also includes the risk control and work plan to work towards Best Practice.

Best Practice is additional to the Essential Quality Requirements and refers to the full level of compliance that maybe achieved immediately or via documented improvement.

The main Essential Quality Requirements in HTM 01-05 are:

- Prior to the sterilisation process cleaned instruments are free of visible contaminants when inspected

- Instruments are reprocessed using a validated decontamination cycle: including cleaning/washing and storage to prevent microbiological re-colonisation
- Quarterly decontamination audits
- A detailed plan on how to progress decontamination processes towards Best Practice

The main Best Practice Requirements are:

- Use of a validated automated washer-disinfector for the cleaning process
- Decontamination processes are separate from clinical treatment areas
- Storage of instruments is separate from clinical treatment areas

The main Essential Quality Requirements in HTM 01-06 are:

- Endoscopes should be decontaminated in accordance with manufacturers' recommendations.
- Lumened instruments should be reprocessed using a validated automated process
- Policies and guidelines on the minimisation of recontamination or recolonisation should be in place.
- The production, maintenance and use of written procedures for each stage in the management, use and decontamination of endoscopes is required.

The main Best Practice Requirements are:

- Best Practice may require the use of separate rooms for the accommodation of clean (output) and dirty (input) work. In these facilities, the rooms should be used for this purpose only and access should be restricted to those staff performing decontamination duties
- A reliable computerised endoscope instrument tracking and traceability system interfaced to patient records should be in place and operational,
- Unless a decontaminated endoscope is being stored in a way validated to extend usable storage life or is in sterile packaging following sterilization, it should be used within three hours of decontamination.

6.2 Facilities Required for Decontamination

Wherever possible, the decontamination process should take place in a dedicated non-patient area. Any decontamination area will have specific design requirements e.g. floor / wall finishes, sanitary ware. Advice must be sought from the IPC team when designing such facilities.

Regardless of the location used for reprocessing contaminated instruments, a unidirectional dirty to clean workflow should be maintained so that used instruments are segregated at each stage of the process to reduce the risk of contact with contaminated instruments.

Contaminated and clean items must always be segregated and stored separately. Medical devices and equipment should be stored clean.

If storage of contaminated items is necessary, these items must be segregated and clearly labelled as contaminated.

7 Returning Used Instruments to the CSSD

Trust services that use a Central Sterilisation Services Department (CSSD) to process their instruments, must not manually clean instruments prior to return. Any excess secretions should be wiped once, using paper roll immediately after use and then placed in a plastic bag and into a UN approved rigid container and await collection from the dirty utility.

8 Transportation of Contaminated Devices or Equipment to the Decontamination Area

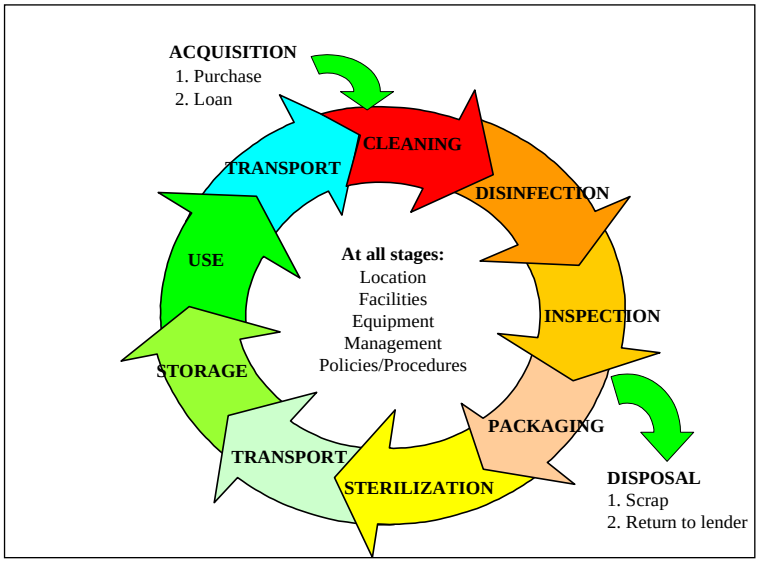
Transportation of contaminated re-usable instruments must always be transported in containers that are:

- Lidded and capable of being closed securely
- Leak-proof and easy to clean
- Rigid (in order to prevent the instruments becoming a sharps hazard and to protect them from damage)
- Lockable where appropriate (to prevent tampering)
- Clearly labelled where appropriate to identify the user and the contents

Separate transportation containers must be used for contaminated and clean instruments and the containers cleaned between each use.

If it is necessary for contaminated instruments to be transported via public transport, staff should refer to the requirements of the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2007, and the Health and Safety at Work etc. Act 1974.

9 Life-Cycle of Reusable Surgical Instruments



The diagram highlights each stage of the decontamination process through which surgical instruments pass before every use to ensure effective decontamination.

10 Cleaning

The principal methods of cleaning reusable instruments currently available are either:

- Manual
- Manual combined with automated process (as below)
- Automated:
  - Washer-disinfector
  - Ultrasonic cleaner

Wherever possible, cleaning should be undertaken using an automated and validated washer-disinfector in preference to manual cleaning. A washer-disinfector includes a disinfection stage that renders instruments safe for handling and inspection and reduces the risk of inoculation injuries.

Manual cleaning, governed by an appropriate protocol, is acceptable within the Essential Quality Requirement framework of HTM 01-05: Decontamination in Primary Care Dental Practices. Manual cleaning should be considered only where the manufacturer specifies that the device is not compatible with automated processes (including ultrasonic cleaning), when the washer disinfector is temporarily unavailable (for example for repair or validation) or when indicated by the manufacturer's instructions for use as a precursor to automated cleaning (such as the, for example, flexible endoscopes)

Exceptionally, where local experience indicates that pre-washing may be helpful (for example in the removal of tenacious dental materials such as cements) the instruments should be cleaned immediately. Such action may therefore be appropriate before automated cleaning. Instruments that cannot be cleaned should be discarded.

Effective cleaning of instruments is essential before sterilisation and will reduce the risk of transmission of infectious agents. The cleaning of instruments should be done as soon as possible after use because they may be more easily cleaned than those left for a time before reprocessing. Where this is not possible, water immersion or the use of a specialist foam spray intended to maintain a moist or humid environment are thought useful in aiding subsequent decontamination. Long periods of wet storage should, however, be avoided.

New instruments should be cleaned and sterilised before using for the first time, unless supplied as sterile.

Where recommended by the manufacturers, instruments and equipment that consist of more than one component e.g. amalgam carriers used in dentistry, should be dismantled to allow each part to be adequately cleaned. Staff should be appropriately trained to ensure competence in dismantling, cleaning, sterilising and reassembling of instruments.

10.1 General Requirements for Cleaning

Refer to manufacturers' instructions relating to cleaning of instruments and equipment, cleaning devices and cleaning solutions.

Ensure that instruments can be cleaned using a method available to the service.

All cleaning methods i.e. ultrasonic baths and washer-disinfectors must be verified, tested and documented to ensure validity of the entire cleaning process. Validation will demonstrate that all instruments and equipment are reliably and consistently cleaned within reproducible conditions.

Technical details for validation standards and procedures are provided in HTM 01-05 Part 3. The assistance of decontamination specialists will be necessary from time to time in order to ensure that equipment and procedures are validated in engineering terms.

10.2 Manual Cleaning of Instruments

Manual cleaning is not a consistently reproducible process, unable to be validated and therefore should be replaced with an automated cleaning method wherever possible.

Where manual cleaning is necessary e.g. as advised by the manufacturer and where the service is operating within the Essential Quality Requirements, or e.g. during mechanical failure of automated equipment, the process should be controlled as much as possible to reduce the variability in cleaning performance. All personnel involved in the decontamination of instruments should be trained in the content and application of this protocol and associated guidance. Refer to Appendix 2 – Manual Cleaning Methods.

The following advice aims to enable this control:

- Do not use any other solutions other than detergents specifically formulated for manual cleaning of instruments
- Chlorhexidine solutions are not recommended due to the increased risk of proteins adhering to steel

- Personnel undertaking manual cleaning should avoid splashing and the creation of aerosols at all times and must don appropriate personal protective equipment (PPE)
- Maintaining a dirty-to-clean workflow procedure will assist in the cleaning process

10.3 Ultrasonic Cleaning of Instruments

Ultrasonic cleaners work by exposing the items to be cleaned to high frequency sound waves in the liquid cleaning medium. High frequency sound waves are generated within the liquid by the vibration of one or more surfaces of the bath, caused by one or more transducers bonded to the outer surface(s). The transducers convert electrical power into vibrations of the required frequency and amplitude. The highly effective cleaning action occurs as a result of the penetrative agitation caused by cavitation i.e. the rapid formation and collapse of tiny bubbles within the liquid which are generated by the high frequency sound waves.

- Ultrasonic cleaning is suitable for instruments of high grade steel. Delicate instruments such as micro-surgery instruments and dental instruments can be effectively cleaned with little risk of damage
- Ultrasonic cleaning is effective for cleaning instruments with deep interstices that may be contaminated with body tissues e.g. dental burrs
- When combined with appropriate connection to an irrigation or flushing system, ultrasonic cleaners are also effective for cleaning internal and external surfaces of cannulated instruments
- Ultrasonic cleaners are less effective when used to clean plastic and similar readily compressible materials since they absorb much of the ultrasonic energy
- The manufacturer will normally recommend the chemical additives (detergents/enzymatic cleaners) which are compatible with the process. Low foaming surfactant or detergents should be used. Liquid general purpose detergent (GPD) as used for washing dishes is not suitable
- The manufacturer is obliged to specify how the ultrasonic cleaner may be disinfected for instance by high-temperature e.g. an 80°C cycle, or by a suitable disinfectant solution
- The manufacturer is obliged to specify the de-gassing time(s) to be used on start-up and when necessary, between each load of instruments processed
- The ultrasonic frequency used should be within the range 35 kHz ± 5 kHz and the energy input used may range from 5.0 W -1 to 20.0 W-1
- Ultrasonic cleaners can be designed to operate at a single frequency, across a frequency range, or with a feedback control system claimed to adjust the frequency in response to the loading conditions
- The ultrasonic cleaner should be fitted with a timer to control the duration of exposure, should be heated electrically and be thermostatically controlled
- The ultrasonic cleaner should be fitted with a means to drain the tank and the tank should be free draining so that no pools of water are left after draining
- The ultrasonic cleaner should have a secure, fitted, interlocking lid linked to the operating system to prevent normal operation if the lid is opened. This prevents the emission of aerosols during operation Aqueous solutions should be used. Ultrasonic cleaners using aqueous solutions can be effective at temperatures up to 90°C but it is normal practice to operate those for medical applications at temperatures between ambient and 40°C. This minimizes the rate of coagulation

of proteins and is compatible with the use of enzymatic cleaners, many of which are rapidly destroyed at higher temperatures.

10.3.1 Ultrasonic Cleaning Procedure

- Follow the manufacturer's recommendations for each stage of the ultrasonic operating procedure including use of solutions and correct time settings
- Ensure that joints or hinges are opened fully and instruments that need taking apart are fully disassembled before they are immersed in the solution
- Place instruments in a suspended basket and fully immerse in the cleaning solution, ensuring that all surfaces are in contact with the solution
- Do not overload the basket or overlap instruments which can result in poor cleaning and can cause wear to the instruments
- Do not place instruments on the floor of the ultrasonic cleaner which can result in poor cleaning and excessive instrument movement, causing damage To avoid damage to delicate instruments, a modified basket or tray system may be necessary depending on operational requirements
- Set the timer to the correct setting, close the lid and do not open until the cycle is complete
- Once the cycle is complete, drain the basket, rinse the instruments in clean, potable water to remove residual soil and detergents. A dedicated sink or bowl (separate from the one used for the original wash) should be used. Hand wash basins must not be used. This step may be omitted if the procedure involves the use of a washer-disinfector as the next stage in the decontamination process
- Dry the instruments using a disposable lint free cloth e.g. paper towel
- Visually inspect all items under an illuminated magnifier-ensuring they are clean, functional and in good condition
- Change the solution when it becomes obviously contaminated or at the end of every clinical session because the build-up of debris will reduce the effectiveness of cleaning. Ensure that staff are aware of the need to assess when a change of solution is necessary as advised in the operational requirements
- Instruments should be sterilised as soon as possible after cleaning to avoid air-drying, which can result in corrosion and/or microbial growth
- Instruments processed in a vacuum steriliser should be dried using a disposable lint free cloth before being wrapped
- At the end of each day the ultrasonic cleaner should be emptied, cleaned and left dry, following manufacturer's instructions. A record documenting these processes should be completed.

10.3.2 Ultrasonic Cleaner Validation, Maintenance and Testing

The ultrasonic cleaner should be maintained and serviced in accordance with manufacturer's instructions and be included in a planned preventative maintenance programme (PPM).

10.3.2.1 Daily Tests

The User or by delegation the Operator should:

- Remove and clean filters and strainers
- Visually examine all load items
- Ensure water/solution is changed when visibly soiled

- Drain ultrasonic at end of day/session

10.3.2.2 Weekly Tests

The User or by delegation the Operator should perform the Daily tests, as above plus:

- Check condition and cleanliness of lid seal
- Undertake a Protein Residue test

10.3.2.3 Quarterly Tests

The Competent Person should perform the Weekly checks plus:

- Safety checks
- Ultrasonic Activity test - Refer to Appendix 3
- Automated Control test
- Verification of calibration
- Cleaning Efficacy test (soil test)

10.3.2.4 Annual Tests

The Competent Person should undertake Quarterly tests plus:

- Annual re-validation tests
- Check the hardness of supply water
- Drainage test to ensure free-flowing drainage
- Lid operation if linked to cycle operation
- Check lid sealing properties

10.4 Wand Meters

Ultrasonic energy meters are available to monitor efficiency and operating frequency of ultrasonic cleaners. They are much quicker and more convenient than the classic foil ablation test but should be used with care. Precise positioning of the wand will need to be noted in order to make the test reproducible.

10.5 Monitoring and Documentation

The validation report provides auditable evidence of testing and must be retained in the vicinity of the machine and signed by the person performing the test. Tests performed by the Competent Person should be countersigned by the User or by delegation the Operator. Refer to Appendix 4 - Ultra Sonic Daily/Weekly Test Recording Sheets (or the manufacturer's log book can be used).

Records should be kept securely for the time specified in the SCHT Records Management Policy.

11 Disinfection

11.1 Washer Disinfectors

Using a washer disinfector is the preferred method for cleaning reusable surgical and dental instruments because it offers the best option for the control and reproducibility of cleaning; in addition the cleaning process can be validated under European Norms (ENs).

Washer-disinfectors are used to carry out the processes of cleaning and disinfection consecutively in an automated cycle. A typical washer disinfector cycle for instruments includes the following five stages:

- **Flush** – removes gross contamination, including blood, tissue debris, bone fragments and other fluid and solid debris. A water temperature of less than 45°C is used to prevent protein coagulation and fixing of soil to the instrument
- **Wash** – removes any remaining soil. Mechanical and chemical processes loosen and break up contamination adhering to the instrument surface. Detergents used in this process must be specified by the manufacturer as suitable for use in a washer-disinfector. They should also be compatible with the instruments being processed and supplied so as to perform correctly and avoid instrument degradation e.g. discolouration, staining, corrosion and pitting
- **Rinse** – removes detergent used during the cleaning process. This stage can contain several sub-stages. For the final stage of rinsing, water quality is of particular importance, since remaining contaminants, including salts, may be deposited on the surface of instruments, affecting both appearance and subsequent sterilisation. Therefore, most washer-disinfector manufacturers provide a separate water-supply inlet for the final rinse stage. It is recommended that reverse osmosis (RO) water or freshly distilled water be used for this stage (refer to manufacturer's instructions)
- **Thermal disinfection –** the temperature of the load is raised and held at the pre-set disinfection temperature for the required disinfection holding time e.g. 80°C for 10 minutes; or 90°C for 1 minute
- **Drying –** Purges the load and chamber with heated air to remove residual moisture

11.1.1 Using Washer Disinfectors

The manufacturer's instructions must be followed for all operational aspects on the use of washer disinfectors. This will include details of both the water quality/type to be used and directions on the detergents and/or disinfectants recommended for use with the device. These instructions form part of the EN requirements for either Conformity Assessment (CA) or Conformité Européenne (CE) marking.

- Staff must be trained in the correct operation of a washer disinfector, including how to perform daily tests and housekeeping tasks. Records of training and competencies should be maintained.
- The washer-disinfector must be loaded correctly, as incorrectly loaded instruments will not be cleaned effectively. Therefore, do not overload instrument carriers or overlap instruments
- Open instrument hinges and joints fully
- Attach instruments requiring irrigation to the irrigation system correctly, ensuring filters are in place if required e.g. for hand pieces, if specified by the manufacturer
- After cleaning, inspect instruments for cleanliness and check for any wear or damage before sterilisation using a simple magnifying device with task lighting.

11.1.2 Washer Disinfector Validation, Maintenance and Testing

The washer disinfector should be maintained and serviced in accordance with manufacturer's instructions:

11.1.2.1 Daily Tests

The User or by delegation the Operator should:

- Remove and clean filters and strainers
- Visually examine all load items

11.1.2.2 Weekly Tests

The User or by delegation the Operator should undertake Daily tests plus:

- Check condition of door seal
- Perform Protein Residue test

11.1.2.3 Quarterly Tests

The Competent Person should undertake Weekly checks plus:

- Check safe operation of door and door interlocks
- Perform Automated control test
- Verify calibration
- Cleaning Efficacy test (soil test)
- Chemical Dosing test – to confirm delivery of detergent
- Thermometric Disinfection test

11.1.2.4 Annual Tests

The Competent Person should undertake Quarterly tests plus:

- Annual re-validation tests
- Check the hardness of supply water

11.1.2.5 Monitoring and Documentation

The validation report provides auditable evidence of testing.

Cycle parameters should be recorded in a logbook dedicated to the individual washer disinfector together with details of routine testing and maintenance of the equipment. Refer to Appendix 5 – Washer Disinfector – Daily/Weekly Test Sheet. The use of automated data-loggers or interfaced small computer-based recording systems is acceptable, provided the records are kept securely and are replicated.

Standard log books are available and must be retained in the vicinity of the machine and signed by the person performing the test. Refer to Appendix 6 – Production Log Sheet – Washer Disinfector. Tests performed by the Competent Person should be countersigned by the User or by delegation, the Operator.

Records should be kept securely for the time specified in the SCHT Records Management Policy. Refer to Appendix 7 – Washer Disinfector History Record Sheet.

12 Inspection and Care of Instruments Prior to Sterilisation

All instruments that have been through any cleaning procedure, including processing by a washer-disinfector, should be inspected for functionality, cleanliness and condition using an illuminated magnifying light for any residual contamination, debris or damage. Instruments may become damaged during use or from general wear and tear. Any instruments found to be blunt, bent or damaged, or show signs of pitting or corrosion should be discarded, repaired or replaced.

Check joints, hinges and serrated surfaces, which are difficult to clean. If there is any residual contamination, the instrument should be rejected and should undergo another cycle of the cleaning process.

Instruments for repair should be decontaminated, labelled to identify they have been through the decontamination process, and then returned to either the manufacturer or a reputable repair company. For the decontamination of hand pieces, advice should be sought from the manufacturer as to which sterilisation cycle type is suitable.

12.1 The Use of Lubricants

Lubricants, usually in aerosol form, are often used during the decontamination and preparation process. This is often required by the manufacturer in order to lengthen the working life of some instruments. Any doubts about the relevance of instructions should be checked and confirmed in writing by the manufacturer.

It should be noted that using lubricants will inevitably introduce substances into a process designed to remove contamination. Where water is reused in the steriliser, this contamination may build up within the reservoir and the steriliser chamber. If lubrication is used in accordance with manufacturer's instructions and the water is changed at least once per day this build up will be reduced.

12.2 Lubricating Dental Hand Pieces

Dental hand pieces should be lubricated according to the manufacturer's instructions. The lubricant may be lost during the washer-disinfector process and may therefore require lubrication again before sterilisation. Separate, labelled canisters of lubricant should be used after each stage of the decontamination/sterilisation process.

13 Sterilisation

Within this Trust, sterilisation is achieved through pressurised steam for a period of time in an autoclave. The temperatures required to achieve sterilisation are 134 – 137°C for 3 minutes or 121 – 124°C for 15 minutes. Saturated steam under pressure, delivered at the highest temperature compatible with the product is the preferred method for the sterilisation of most instruments used in the clinical setting.

To facilitate sterilisation, load items must first be thoroughly cleaned and disinfected via a washer-disinfector. Validated sterilisation is effective in partially reducing prion infectivity.

In the case of newer autoclaves, the parameters monitored for each cycle of use will be stored and/or made available as a print-out to provide a record. These records should be photocopied, as the quality of the printout fades over time. The use of automated data-loggers or interfaced small computer-based recording systems is acceptable provided the records are kept securely and are replicated. Manual recording using a logbook is also acceptable and will be a necessity if a machine does not have an automatic print-out function. The record should, as a minimum, document the absence of a failure warning, or the temperature/pressure achieved. Records should be kept securely for the time specified in the SCHT Records Management Policy (refer to Appendix 1 of this policy – Roles and responsibilities of key personnel involved in decontamination procedures).

It is likely that steam sterilisers used in dental practices will have a chamber volume of less than 60L and thus be considered to be small sterilisers within the standards applied by national and international bodies.

13.1 Types of Small Sterilisers

Type N: Are non-vacuum sterilisers designed for non-wrapped solid instruments' air removal. In type N sterilisers, sterilisation is achieved by passive displacement with steam.

Type B: Are vacuum sterilisers incorporating a vacuum stage and are designed to reprocess load types such as hollow, air-retentive and packaged loads. A number of different cycles may be provided. Each cycle should be fully validated and used in accordance with instructions provided by both the steriliser manufacturer and the instrument manufacturer(s)

Type S: Are sterilisers specially designed to reprocess specific load types. The manufacturer of the steriliser will define exactly which load or instrument types are compatible. These sterilisers should be used in strict accordance with these instructions

Types B and N are most frequently used within community services.

In each case, staff should consult with the manufacturer/supplier of the steriliser(s) to ascertain the status of the machine in respect of validation/verification and the recording of parameters achieved during sterilisation cycle.

Types of Sterilisers

Cycle Type	Air Removal	Load Type	Advantages	Disadvantages
N	Passive (Gravity Displacement).	Non-wrapped solid items.	Simplest type. Least expensive to purchase, operate and maintain.	Not to be used for: • Hollow devices or those with lumens • Wrapped loads e.g. items in pouches.
B	Active (forced) air removal.	Wrapped or non-wrapped solid items e.g. forceps, dental probes. Wrapped or non-wrapped hollow items e.g. cannulas within dimensions specified by steriliser manufacturer. Porous loads e.g. fabrics, swabs, dressings.	Widest range of applications.	Expensive to purchase and maintain. Additional periodic testing required. Post-sterilisation drying stage, essential for wrapped items, increases total cycle times.
S	Active (forced) air removal.	Only suitable for types of loads specified by the steriliser manufacturer.	Wider range of applications than type N.	Expensive to purchase and maintain. Additional periodic testing required. Post-sterilisation drying stage, essential for wrapped items, increases total cycle times.

13.2 Sterilising Dental Hand Pieces

Dental hand pieces are constructed with a number of internal channels and pathways and are often difficult to clean, although the use of a validated automated washer-disinfector may be successful provided they are compatible. Sterilisation using a type B or type S steriliser is likely to be useful, although it is unlikely that total sterility will be achieved due to the presence of lubrication.

If no validated and compatible washer-disinfector is available, steam sterilisation will still be of value in generating a reduction in contamination levels and bioburden.

13.3 Maintenance of Reservoirs and Steriliser Chambers

It is essential that the sterilising process should not contaminate the load items. It is possible for benchtop steriliser loads to be contaminated by impurities in the water used to generate the steam. Contamination can be minimised by appropriate maintenance of the steriliser chamber and reservoir, and by the use of suitable quality water.

13.4 Sources of Contamination

13.4.1 Water Supply

Benchtop steam sterilisers generate their own steam either within the chamber or in an adjacent boiler within the casing. Water droplets are present in steam and will therefore contain the same contaminants as the water, including minerals, toxic metals, and micro-organisms. When steam condenses on the load during sterilisation, contaminants will be transferred to the surfaces of the load items where they will be concentrated when the load dries. The quality of the water in the steriliser reservoir, and chamber/boiler is therefore crucial.

13.4.2 Reservoir Water

Benchtop steam sterilisers usually have a reservoir for storing water to supply the chamber/boiler. Many discharge condensate and residual water back into the reservoir at the end of the cycle. Water left standing in the reservoir, and residual water or moisture in the chamber/boiler following a sterilisation cycle will quickly become colonised with micro-organisms.

13.4.3 Endotoxins

Although micro-organisms in the water will be destroyed during the sterilisation cycle, a heat-stable toxic substance (endotoxin) in bacterial cell walls may remain intact. Endotoxins are resistant to steam sterilisation and are only inactivated by heating for several hours at temperatures above 180ºc. Endotoxins will accumulate in the water and increasingly contaminate the steam until the water is changed. Some benchtop steam sterilisers discharge residual water and condensate into a separate container or direct to a drain. This minimises the accumulation of endotoxins in the water in the reservoir but does not remove the need for drainage and cleaning.

13.4.4 Debris

Microbial growth may be assisted by contamination of the water, for example with debris from poorly cleaned instruments and/or instrument trays, or oil from dental hand pieces. It is therefore essential all instruments and trays are thoroughly cleaned before entering the steriliser.

13.5 Water Quality

The Medicines and Healthcare Products Regulatory Agency (MHRA) recommends the use of sterile water for irrigation in benchtop steam sterilisers as it has specification limits for mineral, toxic metal, and endotoxin contaminants.

Any remaining sterile water in bottles for single use must be discarded immediately. Tap water is not recommended as it contains dissolved minerals which can cause scaling of the heating element or boiler and the chamber, leading to early failure.

Steriliser manufacturers often recommend the use of distilled, de-ionised, or reverse osmosis water. These generally have low (but unknown) levels of mineral contaminants; they do not have a specification for either endotoxins or micro-organisms and are likely to be contaminated with both.

Manufacturers' recommendations to use purified water safeguards the steriliser but may not prevent contamination of the load with organic substances that could be harmful to the patient. Sterile water for irrigation safeguards both the steriliser and the patient and is the preferred quality.

13.6 Cleaning

The water reservoir should be cleaned regularly, however few steriliser reservoirs are designed to be easily cleaned. Manufacturer's guidance on how to clean the reservoir

should be followed. There are anecdotal reports that some maintenance organisations have suggested the use of disinfectants to clean reservoirs, the internal surfaces of pipework and chambers/boilers. These disinfectants may cause corrosion of the chamber or other components of the pressure containment system and cause failure, with the associated high risk of injury to persons nearby. If using disinfectants for this purpose is considered, the advice of the steriliser manufacturer.

13.7 Maintenance

The following guidance should help to minimise contamination of the steriliser:

- Do not leave water standing in the reservoir for more than a few hours. If you are not sure how long the water has been there, change it
- At the end of the working day, or whenever the steriliser is to be left unused for several hours, drain the chamber and water reservoir, rinse all internal surfaces with sterile water for irrigation and leave to dry
- Do not top up the reservoir. Instead drain the contents and rinse carefully with sterile water for irrigation before refilling to the level recommended by the manufacturer
- Ensure all load items are scrupulously clean and dry before placing them in the steriliser

Further information on clean steam for sterilisation, and more detailed guidance, is available in HTM 01-01 Decontamination of Reusable Medical Devices.

13.8 Steriliser Validation, Maintenance and Testing

Testing is an integral part of ensuring that a steriliser consistently performs to operating parameters set during the machine's commissioning. Failure to carry out routine periodic tests and maintenance tasks could compromise safety. A schedule for periodic testing should be planned and undertaken in accordance with HTM 01-05.). The schedule should provide details of daily, weekly, quarterly and yearly testing or be in accordance with manufacturers' guidelines.

Each steriliser should have a logbook (file) in which details of the following are recorded:

- Routine tests
- Maintenance
- Validation
- Faults
- Modifications

The logbook should contain all information pertaining to the lifecycle of the equipment, from purchasing through to disposal.

If the steriliser has an automatic printer, the printout should be retained or copied to a permanent record. If the steriliser does not have a printer, the User or by delegation the Operator, will manually record the following information in the process log:

- Date
- Satisfactory completion of the cycle (absence of failure light)
- Temperature/pressure achieved
- Signature of the Operator

13.8.1 Daily Tests

The User or by delegation the Operator should:

- Clean the rubber door seal with a clean, damp, lint free, disposable cloth
- Check the chamber and shelves for cleanliness and debris
- Fill the reservoir with sterile water for irrigation
- Turn the power source on
- Some small sterilisers require a warm-up cycle before instruments can be processed. The manufacturer's instruction manual should be consulted. Perform the Automatic control test
- Perform a Steam penetration test e.g. Helix or Bowie-Dick tests (Type B and S only)

The steam penetration and automatic control tests may be carried out at the same time. The outcomes should be recorded in the logbook together with the date and signature of the person performing the test – Refer to Appendix 8 Daily Test Record – Non Vacuum Steriliser or Appendix 9 Daily Test Record - Vacuum Steriliser

Sterilisers should not be used until the daily tests have been carried out and the results found to be satisfactory.

If the steriliser fails to meet any of the test requirements, it should be withdrawn from service and advice should be sought from the manufacturer and/or maintenance contractor.

Summary of User Daily Tests

	Daily Test	Type N (Traditional)	Type B&S (Vacuum)
1	Steam Penetration		✓
2	Automatic Control	✓	✓

13.8.1.1 Steam Penetrations Test (for type B and S sterilisers only)

This test should be performed at the start of every day the steriliser is used, to ensure the air removal stage is effective and that any residual air and other non-condensable gases will not interfere with the sterilising process. It is essential to perform this test with only the test device in the chamber. Anything else in the chamber will disrupt the test and produce an erroneous result.

13.8.1.2 Automatic Control Test

Bench-top sterilisers without an automatic print out facility

- Run the steriliser empty of instruments on cycle 134ºC for 3 minutes
- Remain with steriliser and record elapsed time and indicated pressures and temperatures at all significant points in the operation cycle (see manufacturer's instructions)
- Compare the recordings with the record log obtained at quarterly testing and validation
- Sign the daily test log recording date and time

Tests can be carried out with a full load. However, it is recommended to pre-heat the steriliser when empty and record the readings as above. If started from cold with a full load the cycle is more likely to fail the tests therefore extra staff time is required to monitor a second test.

Bench-top sterilisers with an automatic print out facility

If there is an automatic print out facility available there is no need to carry out the daily and weekly automatic control test as described i.e. remaining with the steriliser during the cycle. The test can be performed by checking the cycle printout at the end of the cycle. Run the cycle then compare reading with quarterly reading.

For ease of use the print out generally prints pass or fail at the end of the cycle on the recorder print out.

The User or by delegation the Operator should sign the print out and file, recording the date and time.

13.8.1.3 Data Comparisons

All Users or by delegation the Operators must compare the indicated readings of pressure levels and temperature against the quarterly recordings.

During the plateau period of the cycles:

- Temperature must be within the sterilisation temperature band (see table below)
- The difference between the visually displayed temperatures and the recorded temperature must not exceed 2°C
- The difference between the visually displayed pressure and the recorded pressure must not exceed 0.1 bar

Note: This is not possible in all cases i.e. where the pressure is not printed on the recorder. In this incidence, validate the temperature readings only.

Sterilisation Temperatures Range (°C)			**Approx. Pressure (Bar)**	**Minimum Hold Time (Min)**
Normal	**Minimum**	**Maximum**		
136	134	137	2.25	3
122.5	121	124	1.15	15

If a cycle failure is detected i.e. indicated temperature, pressure or holding time, move outside the parameters as described above, a second automatic control test must be carried out.

In the event of a failure during the second test contact your contracted engineer and DO NOT USE THE STERILISER under any circumstances.

13.8.2 Weekly Tests

The User or by delegation the Operator should perform Daily tests plus:

- Check the door seal for sign of deterioration or leaks

The Competent Person or by agreement and training and resources the User or Operator should perform:

- Safety checks: door seal, security and performance of door safety devices; safety valves or other pressure-limiting devices are free to operate
- Residual air test – Type N and S only
- Air leakage test – Type B and S only

Outcomes should be recorded in the logbook together with the date and signature of the person performing the test and countersigned by the User, or by delegation the Operator.

Refer to Appendix 10 – Steriliser Weekly Test Sheet.

13.8.3 Quarterly Test

The Competent Person should perform Daily tests plus:

- Safety checks: door seal, security and performance of door safety devices; safety valves or other pressure-limiting devices are free to operate
- Thermometric test
- Verification of steriliser instruments
- Guidance on quarterly testing should be sought from the Competent Person Decontamination CP(D) Service Engineer.

13.8.4 Thermometric Test

These require specialised test equipment and only the Competent Person, who has the necessary training, experience, skills and equipment, should perform them. Guidance on quarterly testing should be sought from an Authorising Engineer.

If the steriliser controller indicates a failed operating cycle, the cycle must be regarded as unsatisfactory regardless of the results obtained from any chemical or biological indicators (chemical and biological indicators do not indicate that the load is sterile).

13.8.5 Chemical Indicators

If chemical indicators are used, they must meet the required international standards, e.g. BS EN ISO 11140 and should be used only for the process specified by the manufacturer. The correct indicator should be selected, following the indicator manufacturer's recommended instructions precisely for use and storage.

The use of an inappropriate indicator may give misleading results; indicator performance can be adversely affected by the storage conditions before use, the methods of use, and storage conditions after use. Indicators should not be used beyond the expiry date stated by the manufacturer.

Three types of chemical indicator are commonly used in steam sterilisers:

- **Process indicators** e.g. autoclave tape and indicators printed onto bags and pouches. These indicators serve only to distinguish processed items from unprocessed items and should not be used for any other purpose
- **Performance indicators** for specific tests e.g. indicators used to check the effectiveness of steam penetration into a test pack of a process challenge device
- **Integrating indicators** (emulating integrators) are available for monitoring steam sterilisers. They are designed to monitor the attainment of two of more critical variables in the sterilisation process, either by a graduated response or a defined end point reaction. Integrating indicators do not indicate sterility of the product.

Outcomes should be recorded in the logbook together with the date and signature of the Competent Person and countersigned by the User or by delegation, the Operator.

13.8.6 Annual Tests

The Competent Person should perform Quarterly tests plus:

- Chamber overheat cut-out test (where possible)
- Dryness test (Type B and S)
- Performance re-qualification: at the User's discretion (if performance qualification was performed at validation)
- Guidance on annual testing should be sought from an CP(D)Service Engineer

These outcomes should be recorded in the logbook together with the date and signature of the Competent Person and countersigned by the User or by delegation, the Operator.

13.9 Procedure on Failure of a Test

A test failure implies that the steriliser is not working to specification**.** The steriliser must be withdrawn from service immediately, the failure investigated, the cause rectified, and the steriliser re-tested successfully before being used.

Note: The User or by delegation the Operator, has the ultimate responsibility for certifying that the steriliser is fit for use.

13.10 Monitoring and Documentation

13.10.1 Routine Monitoring

For each production cycle the following procedures should be performed:

- Note whether the steriliser's controller indicated a passed or failed cycle
- Examine printouts from the steriliser's recorder to ensure that they are within the prescribed limits
- Document the actions taken if a failed cycle was indicated
- Document any fault or malfunction of the steriliser
- Keep records of every cycle

Routine monitoring of the process, in addition to periodic testing, is essential to provide assurance that sterilised loads are consistently produced.

13.10.2 Cycle Records

Every production cycle must be fully documented using standard log books or recording sheets – Refer to Appendices 8 and 9 – Non Vacuum and Vacuum Steriliser Daily Test Recording Sheets and Appendix 11 – Processed Log Sheet Benchtop Steriliser.

All records must be retained in the vicinity of the machine and signed by the person performing the test. Tests performed by the Competent Person should be countersigned by the User or by delegation, the Operator and kept securely for the time specified in the SCHT Records Management Policy.

The information recorded should include:

- The date and cycle number
- The type of load e.g. whether porous materials, solid instruments, hollow instruments or a mixture etc.
- The sterilisation cycle selected
- Whether the cycle was a pass or a fail
- The chart record for the cycle
- The identity of the Operator

14 Packaging

With a Type B vacuum steam steriliser, instruments will be pre-wrapped using purpose-designed materials compatible with the steriliser.

With a Type S steriliser, instruments may be placed in purpose-designed cassettes or other will be pre-wrapped using purpose- designed materials compatible with the steriliser. In both cases, instruments must be dry before they are placed in the packaging.

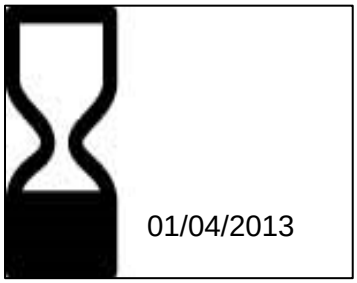
Wrapping should take place with a dry product shortly after washing and disinfection. Once wrapped instruments have been sterilised satisfactorily, the product may be stored for up to one year.

With a displacement steam steriliser (Type N), the instruments will not be wrapped prior to sterilisation. Immediately after removal from the steriliser, instruments may be wrapped using suitable sealed view-packs. Instruments must be dry before packing. In addition, the entire tray may be placed within a sealed pack for storage purposes; storage for up to one year is recommended. Products from a Type N steriliser may also be transferred for use within the current session. In this instance, whilst covering the instruments is essential to protect against dust and aerosols, wrapping is not required.

Regardless of the packaging used, the date of processing and the date by which they must be used by, or require further decontamination by, must be clearly indicated on the packaging.

14.1 Symbols Used on Medical Device Packaging

The following USE BY DATE symbol is the most commonly used on medical device packaging:



The symbol is intended to indicate that the device must not be used after the end of the month or day shown.

15 Storage of Decontaminated Instruments

Regardless of the approach described above, it is essential that stored instruments are protected against the possibility of recontamination. A barrier should therefore be maintained between the instruments and the clinical environment, being stored in a dry environment and protected against excessive heat. Clear identification of the contents of instrument packs and storage times must be maintained. For the majority of instruments, a first-in first-out principle will be helpful. The use of the Use by Date symbol (see section 14.1) will assist in this process. Unwrapped instruments in a clinical area which are in a lidded container can be kept for one day before reprocessing. Unwrapped instruments in a 'non-clinical' area which are kept covered in a lidded container can be used for up to one week before reprocessing.

16 Tracking and Traceability

A system should be in place to allow instruments to be tracked through decontamination processes Records of the tracking and traceability systems should be maintained, identifying the cleaning and sterilisation method used, the name of the person undertaking the decontamination and details of the items being processed.

Systems should also be implemented to enable the identification of patients on whom the instruments have been used. This will allow relevant patients to be identified in the event of exposure to potential risk and so instruments can be traced in the event of a failure in the decontamination cycle.

Sterile packs received from CSSD have an identity sticker which must be added to the individual patient's notes.

17 Manual Decontamination Method using Tristel Wipe System

Nasendoscopes (without lumens), trans-vaginal probes, sigmoidoscopy light sources and cryo-cautery handles and leads can be manually decontaminated using compatible wipes and procedures validated for that purpose, such as the Tristel Three Step Wipe System. Cleaning and disinfection are required even if single use sheaths are used.

The bellows and filters used in conjunction with the sigmoidoscopy light source are single-use and therefore are disposed of after each procedure. The cryo-cautery tips are decontaminated via CSSD.

All procedures for cleaning and disinfection of nasendoscopes, trans-vaginal probes, sigmoidoscopy light sources and cryo-cautery handles and leads should be carried out in accordance with the manufacturer's instructions. Appropriate personal protective equipment (PPE) must be worn e.g. gloves and apron, and eye/face protection if risk of splashing.

The Tristel wipe system involves a three-stage process. All staff using the Tristel wipe system must have received annual certificated training from the company's representatives prior to their use.

17.1.1 Step 1: Tristel Pre-Clean Wipe

The first step in the decontamination process of medical devices is the thorough cleaning of the surface to remove soil and organic matter prior to high-level disinfection/sterilisation. The Tristel Pre-Clean Wipe is impregnated with a low-foaming surfactant system combined with triple enzymes, producing ultra-low surface tension for rapid cleaning of any hard surface.

Procedure:

- Wash hands
- Put on disposable plastic apron and disposable nitrile gloves
- Take a sachet of pre-clean wipe, tear open and remove wipe.
- Unfold wipe and lay on the palm of your hand.
- Thoroughly wipe the surface of the nasendoscope, trans-vaginal probe or sigmoidoscopy light source until soil and organic matter have been visibly removed (in cases of heavy soiling more than one wipe should be used).
- Remove gloves
- Wash hands
- Put on new pair of gloves to perform leak test of nasendoscope (see section 17.1.2)

17.1.2 Leak Testing of Nasendoscopes

The leak test is carried out to determine if liquid can gain access to the inner cavity of an endoscope thereby causing extensive damage. This should be done every time, after pre-cleaning, to ensure the endoscope is intact. The leak test procedure should be followed according to the scope manufacturer's instructions and training for this is provided by the company. The leak tester must be cleaned with a detergent wipe after every use.

Where the leak testing is undertaken by the submersion method, clean water should be obtained from a source other than a clinical hand wash basin and be disposed of via a sluice or dirty utility room, not the clinical hand wash basin.

17.1.3 Step 2: Tristel Chlorine Dioxide Sporicidal Wipe

Tristel Sporicidal Wipes are the central part of the Tristel Wipes System and have been designed specifically for use with ENT scopes and ultrasound probes. The wipe, once activated with the foam pump, is sporicidal, mycobactericidal, bactericidal, virucidal and fungicidal within a 30 second contact time.

Procedure:

- Remove gloves after leak test.
- Wash hands.
- Put on new pair of gloves.
- Take sporicidal wipe sachet, tear open and remove.
- Unfold and lay in the palm of your hand.
- Take the lid off the foam bottle (note that the foam bottle is identified as Activator Foam). If the foam bottle is being used for the first time, depress the pump two to four times to prime the foamer.
- The first output from the foam bottle can be left on the wipe to be followed by two complete pumps. The foam bottle is then primed for subsequent wipes.
- For all subsequent wipes, pump two measures of Tristel Activator foam onto the wipe.
- Scrunch the wipe for 15 seconds. Ensure that it is evenly covered with foam. Presence of a 'chlorine like' odour confirms that the wipe is ready for use.
- Wipe the surface of the device until it has been covered with Tristel. All areas of the surface must come into contact with the wipe at least once.
- Once the entire surface has been wiped and covered with Tristel, wait 30 seconds; this must be timed precisely.
- Discard the wipe and gloves in the clinical waste.
- Wash hands.
- Put on new pair of gloves.

17.1.4 Step 3: Tristel Rinse Wipe

The final step in the decontamination process is the rinsing of the surface that has been treated by a chemical biocide. The Tristel Rinse Wipe is impregnated with de-ionised water and a low-level of antioxidant which will remove and neutralise chemical residues from a surface that has been decontaminated with a Tristel Sporicidal Wipe.

Procedure:

- Take a sachet of rinse wipe, tear open and remove wipe
- Unfold wipe and lay in palm of hand
- Thoroughly wipe surface of the device that has been decontaminated
- Discard wipe, apron and gloves in clinical waste
- Wash hands
- Document use of all wipes into the audit traceability book

17.1.5 Tristel Wipe Traceability System

The traceability system enables the user to:

- Identify the instrument being decontaminated
- Record the date and time of decontamination
- Record the patient's identification
- Confirm the use of each wipe used

In order to reduce the risk of environmental contamination, all devices used within a body cavity must be reprocessed if more than three hours has elapsed from the last decontamination process.

17.2 Storage

- Nasendoscopes must be decontaminated prior to storage and stored in a secure clean area, for example, a purpose-built cupboard or cabinet made of non-porous material that is easy to clean.
- As nasendoscopes are non-lumened, they do not need to be stored in a drying cabinet.
- The nasendoscope should be hung in a storage cabinet with the distal end hanging freely. Make sure that the insertion tube hangs vertically and as straight as possible and is not stored in the transport container.
- Trans-vaginal probes, sigmoidoscopy light sources and cryo-cautery equipment should be stored in a clean, wipeable container or cupboard to avoid environmental contamination.
- If it is necessary to store the trans-vaginal probe or the cryo-cautery equipment on the ultrasound machine it should be in such a way as to avoid environmental contamination and the 3 hour reprocessing rule observed.

17.3 Business Continuity

Services should have Business Continuity Plans in place in the event of a breakdown of any decontamination process in order to manage potential interruptions to the service.

17.4 Maintenance

All reusable medical devices must be adequately serviced and maintained via a service/maintenance contract with a reputable contractor and adequate documentation kept.

17.5 Transportation of Nasendoscopes, Trans-vaginal probes, Sigmoidoscopy Light Sources and cryo-cautery equipment between Departments

There may be occasions when both clean and dirty devices may be transported between departments. In each instance, a suitable leak proof container must be used for transport. The container must protect the device from damage and contamination during transport. Separate transport containers must be used for transport of clean and dirty devices to prevent cross-contamination. These containers must be decontaminated before and after each use. If devices are transferred between sites, arrangements must be made to ensure that the equipment is transported using appropriate transportation systems.

18 Consultation

This policy has been developed by the IPC team in consultation with appropriate clinical services managers, Senior Dental Nurse, Senior Radiographer, ENT Specialist Nurse and IPC Governance Meeting members.

A total of three weeks consultation period was allowed and comments incorporated as appropriate.

18.1 Approval Process

The IPC Governance Meeting members will approve this policy and its approval will be notified to the Quality and Safety Committee.

19 Dissemination and Implementation

This policy will be disseminated by the following methods:

- Managers informed via Datix who then confirm they have disseminated to staff as appropriate
- Staff - via Communications and IPC Newsletter
- Awareness raising by the IPC team
- Published to the Staff Zone of the Trust website

The web version of this policy is the only version that is maintained. Any printed copies should therefore be viewed as 'uncontrolled' and as such, may not necessarily contain the latest updates and amendments. When superseded by another version, it will be archived for evidence in the electronic document library.

19.1 Advice

Individual Services' IPC Link staff act as a resource, role model and are a link between the IPC team and their own clinical area and should be contacted in the first instance if appropriate.

Further advice is readily available from the IPC team or the Consultant Microbiologist.

19.2 Training

Managers and service leads must ensure that all staff are familiar with this policy through IPC induction and update undertaken in their area of practice.

In accordance with the Trust's mandatory training policy and procedure the IPC team will support/deliver training associated with this policy. IPC training detailed in the core mandatory training programme includes Standard Infection Control Precautions and details regarding key IPC policies. Other staff may require additional role specific essential IPC training, as identified between staff, their managers and / or the IPC team as appropriate. The systems for planning, advertising and ensuring staff undertake training are detailed in the Mandatory Training Policy and procedure. Staff who fail to undertake training will be followed up according to the policy.

Further training needs may be identified through other management routes, including Clinical Case Review (CCR), Root Cause Analysis (RCA) and Post Infection review (PIR), following an incident/infection outbreak or following audit findings. Additional ad hoc targeted training sessions may be provided by the IPC team.

Staff who undertake mechanical or manual decontamination of reusable surgical devices must undertake initial and subsequent annual training via the device manufacturer.

20 Monitoring Compliance

Compliance with this policy will be monitored as follows:

- Cleaning standards within Community Hospitals will be monitored in accordance with the Publicly Available Specification (PAS) 5748 framework
- Environmental and patient equipment cleaning will be monitored as part of local routine cleanliness audits
- An independent audit will be commissioned by the Authorised Engineer

- The IPC Governance Meeting will monitor compliance of the cleanliness audit scores and the IPC team audit programme
- Decontamination within Dental units will be audited using a national NHS dental audit tool which captures decontamination processes.

As appropriate the IPC team will support Services' Leads to undertake IPC CCRs/RCAs/PIRs. Managers and Services' Leads will monitor subsequent service improvement plans and report to the IPC Governance Meeting.

Knowledge gained from CCR/RCA/PIR and IPC audits will be shared with relevant staff groups using a variety of methods such as reports, posters, group sessions and individual feedback.

The IPC team will monitor IPC related incidents reported on the Trust incident reporting system and, liaising with the Risk Manager, advise on appropriate remedial actions to be taken.

21 References

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Part A - Management and Provision

Part B – Common Elements

Part C – Steam Sterilisers

Part D – Washer-disinfectors

Part E – Alternatives to Steam Sterilisation of Medical Devices

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Part A – Policy and Management

Part B – Design and Installation

Part C – Operational Management

Part D – Validation and Verification

Part E – Testing Methods

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Other related publications may be available from the Medicines and Healthcare products Regulatory Agency website at: http://www.mhra.gov.uk/

22 Associated Documents

This policy should be read in conjunction with SCHT's:

- Business Continuity Guidance
- Cleaning and Disinfection Policy
- Hand Hygiene Policy
- Prevention and Management of Needlestick Injuries: including Inoculation Incidents and Exposures to Blood Borne Viruses (BBV) Policy
- Records Management Policy and Strategy
- Standard Infection Control Precautions Policy
- Transmissible Spongiform Encephalopathies (TSEs) Policy
- Waste Management Policy
- Water Management Policy
- Water Safety Plan

23 Appendices

Appendix 1 – Roles and Responsibilities of Key Personnel involved in Decontamination Procedures

Appendix 2 – Manual Cleaning Methods

Appendix 3 – Ultrasonic Activity Test

Appendix 4 – Ultrasonic Daily / Weekly Test Recording Sheet

Appendix 5 – Washer Disinfector – Daily/Weekly Test Sheet

Appendix 6 – Production Log Sheet – Washer Disinfector
Appendix 7 – Washer Disinfector History Record Sheet
Appendix 8 – Daily Test Record - Non Vacuum Steriliser
Appendix 9 – Daily Test Record - Vacuum Steriliser
Appendix 10 – Steriliser Weekly Test Sheet
Appendix 11 – Processed Log Sheet – Benchtop Steriliser

Appendix 1 – Roles and Responsibilities of Key Personnel involved in Decontamination Procedures

	Daily checks	Weekly checks	Quarterly checks	Annual checks	Audit of process	Preparing instruments for sterilisation	Rinsing and cleaning internal surfaces	Draining reservoir and using correct water	Ensuring instruments are suitable for reprocessing	Ensuring safe storage of instruments	Ensuring traceability of instruments i.e. an audit trail of use
User (NB has ultimate responsibility, may or may not be involved in day to day use of the steriliser)	✓	✓ validation			Compares test results with record sheet left quarterly by Competent Person	✓	✓	✓	✓	✓	✓
Operative (by designation by User)	✓	✓ validation				✓	✓	✓	✓	✓	✓
Competent Person			✓ designated maintenance person	✓ validation report	✓						
Authorised Engineer				Independent audit ✓ External advisor	✓ External advisor						Advises on mechanisms for this

Appendix 2 – Manual Cleaning Methods

Immersion Method

- Wash hands
- Wear personal protective equipment (apron, gloves, face protection)
- Prepare sinks, equipment and setting-down areas
- Dismantle and open the instruments, as applicable, ready for immersion
- Fill the clean sink (NOT hand wash basin) with the appropriate amount of warm potable water and detergent (specified for the purpose and diluted correctly). Ensure correct temperature as recommended by the detergent manufacturer is maintained. Temperature of 45ºC or lower is required - a higher temperature will coagulate protein and inhibit its removal
- Fully immerse the instruments in the solution and keep under water during the cleaning process to prevent aerosols
- Whilst holding under the surface of the water, brush, wipe or agitate the item, using disposable cloths or long-handled brushes with soft plastic bristles
- Where high pressure jet guns are used for hollow instruments, they should only be connected to the cold water supply. The gun's distal end is connected to the instrument and held under water during the irrigation process
- Drain any excess cleaning solution prior to rinsing
- Rinse in a second sink with clean potable water, using the jet gun when necessary in the above manner
- After rinsing, drain and dry using a disposable lint free cloth
- Visually inspect all items under an illuminated magnifier-ensuring they are clean, functional and in good condition
- Cleaning cloths and some brushes are single-use and should be disposed of in accordance with SCHT Waste Management Policy. Reusable brushes should be washed in detergent and clean water and stored dry with head up
- Replace the cleaning solution and rinse-water after each use
- Complete relevant documentation, including the method and solutions used and details of the staff member who completed the procedure
- Treat any injury sustained as an inoculation injury and follow SCHT Prevention and Management of Needlestick Injuries: including Inoculation Incidents and Exposures to Blood Borne Viruses (BBV) Policy
- Ensure all staff are offered Hepatitis B immunisation

Non-immersion Method

Non-immersion manual cleaning methods are appropriate for certain equipment where items will become compromised by soaking in aqueous solutions e.g. electrical and electronic equipment.

- If the item is electrical, ensure that it is disconnected from the mains supply before commencing the cleaning procedure
- Wash hands
- Wear personal protective equipment (apron, gloves, face protection)
- Prepare sinks, equipment and setting-down areas
- Fill the clean sink (NOT hand wash basin) with the appropriate amount of water and detergent (specified for the purpose and diluted correctly). Ensure correct temperature as recommended by the detergent manufacturer is maintained
- Immerse the cleaning cloth in the detergent solution and wring thoroughly
- Commencing with the upper surface of the item, or clean to dirty direction, wipe thoroughly ensuring that detergent solutions does not enter electrical components
- Do not dip used cloth back into bowl of detergent, use new cloths as necessary
- Surfaces should be carefully dried using disposable, lint free cloth
- Dispose of cleaning materials safely in accordance with SCHT Waste Management policy
- Disposable detergent impregnated wipes may be used as an alternative to a water and detergent solution

Appendix 3 – Ultrasonic Activity Test

The ultrasonic activity should be validated quarterly by the User or by delegation, the Operator. This can be performed by an erosion pattern created on standard test aluminium foil exposed in the tank for a short period. This activity may not be uniform throughout the tank. Validation tests will determine the pattern variation at defined positions and the time required to produce this pattern.

The exposure time will depend upon the type of foil used (standard test foil is available to maximise repeatability).

The following equipment will be required:

- standard aluminium foil provided for ultrasonic cleaner testing
- adhesive tape (for example autoclave indicator tape or masking tape)
- a watch or clock with a second hand
- a rule or tape measure

Method

The following method should be used:

- Cut strips of aluminium foil in lengths 120 mm longer than the bath is deep. Roll up one end of the foil so that the foil is now as long as the bath is deep
- Ensure that:
    - The water in the tank is at the required level
    - The water in the tank is at the specified operating temperature
    - The required amount of any chemical additive specified by the manufacturer has been added
- Carry out the manufacturer's recommended start-up procedure. This will normally include a period of operation to eliminate dissolved gases from the solution in the bath (the degassing procedure)
- Using strips of adhesive tape across the top of the bath, suspend nine strips of the prepared foil in the bath in a 3 × 3 grid. Ensure that the rolled bottom end of each foil strip is no more than 10 mm above, but not touching, the bottom of the bath
- Operate the bath for the predetermined exposure time. This varies typically between 30 seconds and 10 minutes depending on the power rating of the ultrasonic transducers
- Remove the strips from the bath, blot-dry and examine. The strips can be filed conveniently by sticking them to a sheet of plain paper using a transparent adhesive tape
- Drain the bath and clean to remove debris of eroded aluminium foil

Results and Interpretation

When the foil strips are inspected, the areas that show maximum erosion should beat similar positions on all nine foils and each should be eroded to a similar extent.

On re-testing the extent of erosion, the erosion pattern should remain consistent. If the zones of erosion are markedly different on the nine foils, it indicates poor uniformity of cleaning which

may be due to failure of one or more of the transducers producing the ultrasonic vibration in the base of the bath.

A significant change between tests indicates a deterioration or failure in the transducers. If there is no erosion, this indicates complete failure. In the event of any of these findings, withdraw the ultrasonic cleaner from use and send it for repair or replace it.

Appendix 4 – Ultrasonic Daily / Weekly Test Recording Sheet

Daily Tests

	Remove and clean strainers and filters	Cleaning efficacy Visual examination of all load items	Drain machine at end of day Session Check	Certified fit for use by user
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				

Weekly Tests

Week Beginning	Remove and clean strainers and filters	Safety checks Check condition of door-seal including daily tests plus:	Protein residue test Pass/Fail	Certified fit for use by user

Faults identified and actions taken

Appendix 5 – Washer Disinfector – Daily/Weekly Test Sheet

Location of washer disinfector	
Make and Model	
Serial Number	
Date of test – (beginning)	

Detergent used and dilution										
Daily Test	**MONDAY**		**TUESDAY**		**WEDNESDAY**		**THURSDAY**		**FRIDAY**	
Cleaning efficacy (visual)	Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail
Remove and clean filters (if applicable)										
Initial of Competent Person										

Weekly Test		
Protein Residue Test	Pass	Fail
Safety Checks – condition of door seal	Pass	Fail
Signature of Competent Person		
Comments		

I have reviewed the records with the Competent Person and declare the Washer Disinfector **is / is not*** fit for use

User Signature ……

Name ……

(*delete as appropriate)

Appendix 6 – Production Log Sheet – Washer Disinfector

Practice Name	Start date for this sheet	
Location of washer disinfector	Make and Model of washer disinfector	Serial No.

Date	Cycle number	Cycle start time	Cycle selected	Description of load	Cycle pass	Printout check OK (if applicable	Comments and operator initials
					YES/NO	YES/NO	
					YES/NO	YES/NO	
					YES/NO	YES/NO	
					YES/NO	YES/NO	
					YES/NO	YES/NO	
					YES/NO	YES/NO	
					YES/NO	YES/NO	
					YES/NO	YES/NO	
					YES/NO	YES/NO	
					YES/NO	YES/NO	
					YES/NO	YES/NO	
					YES/NO	YES/NO	
					YES/NO	YES/NO	

Appendix 7 – Washer Disinfector History Record Sheet

Practice Name	Start date for this sheet	
Location of washer disinfector	Make and Model of washer disinfector	Serial No.

FAULTS RECORD						**MAINTENANCE RECORD**			
Fault number	Date	Cycle Number	Details of fault	Noted and reported by		Date	Fault Number	Maintenance Record – include servicing as well as fault finding details	Carried out by

Appendix 8 – Daily Test Record – Non Vacuum Steriliser

Week beginning	Steriliser Location
Department	Serial/Reference No.

		During sterilising hold period		Sterilising hold time		
	Cycle Number	Temp °C min/max	Pressure bar	Min : sec	Automatic control test result Pass/Fail	Certified fit for use by user
Monday				:		
Tuesday				:		
Wednesday				:		
Thursday				:		
Friday				:		
Saturday				:		
Sunday				:		

	Door seal clean	Chamber clean	Reservoir filled	Reservoir drained	Tasks completed by
Monday					
Tuesday					
Wednesday					
Thursday					
Friday					
Saturday					
Sunday					

Faults-new or existing (also enter in plant history record)

Appendix 9 – Daily Test Record – Vacuum Steriliser

Week beginning	Steriliser Location
Department	Serial/Reference No.

		During sterilizing hold period		Sterilizing hold time			
	Cycle Number	Temp °C min/max	Pressure bar	Min : sec	Automatic control test result Pass/Fail	Steam Penetration test Pass/fail	Certified fit for use by user
Monday				:			
Tuesday				:			
Wednesday				:			
Thursday				:			
Friday				:			
Saturday				:			
Sunday				:			

	Door seal clean	Chamber clean	Reservoir filled	Reservoir drained	Tasks completed by
Monday					
Tuesday					
Wednesday					
Thursday					
Friday					
Saturday					
Sunday					

Faults-new or existing (also enter in plant history record)

Appendix 10 – Steriliser Weekly Test Sheet

Steriliser Location	Serial/Reference No.
Department	

Week beginning	Cycle number	Automatic air leakage test result * Pass/fail	Residual air test Pass/fail	Automatic control test result Pass/Fail	Steam Penetration test Pass/fail/NA	Weekly safety checks	Certified fit for use by user

* Only where the steriliser has an in-built self –test programme. Otherwise the test should be carried out by a CP (D) and copies of the CP's (D) test sheets should be inserted.

Weekly safety checks (tick if satisfactory)						
Week beginning	Cycle number	Door seal	Door pressure interlock	Door closed interlock	Satisfactory/ Unsatisfactory	Tested by

Faults – new or existing

Appendix 11 – Processed Log Sheet – Benchtop Steriliser

Dental Practice				Start date for this sheet					
Department/location				Ref No.			Serial No.		
Date	Cycle Number	Cycle Start Time	Cycle Selected	Description of load			Cycle pass	Printout Checked OK (if applicable)	Comments and operator initials
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	

Date	Cycle Number	Cycle Start Time	Cycle Selected	Description of load			Cycle pass	Printout Checked OK (if applicable)	Comments and operator initials
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	
							Yes/No	Yes/No	