

Sterilization of Dental Instruments

Dental Clinical Guidance



Last reviewed January 2016

No substantive changes to the legislation, regulations or generic national guidance on which the current SDCEP Decontamination Into Practice guidance is based were found. This guidance remains unchanged and extant until the next review.

December 2011

The Scottish Dental Clinical Effectiveness Programme (SDCEP) is an initiative of the National Dental Advisory Committee (NDAC) and is supported by the Scottish Government and NHS Education for Scotland. The Programme aims to provide user-friendly, evidence-based guidance for the dental profession in Scotland.

SDCEP guidance is designed to help the dental team provide improved care for patients by bringing together, in a structured manner, the best available information that is relevant to priority areas in dentistry, and presenting this information in a form that can be interpreted easily and implemented.

'Supporting the dental team to provide quality patient care'



Sterilization of Dental Instruments

Dental Clinical Guidance

Decontamination Into Practice: Part 2

Last reviewed January 2016

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December 2011

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Sterilization of Dental Instruments

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1 Introduction

'*Decontamination Into Practice*' is part of a national initiative to promote and standardise good decontamination practice in dental primary care.

Part 1, '*Cleaning of Dental Instruments*' (published in 2007) deals with how to clean dental instruments thoroughly, including thermal disinfection using a washer-disinfector, and advice about rinsing, drying and inspection of the instruments after cleaning.

Part 2, '*Sterilization of Dental Instruments*' focuses on how to sterilize dental instruments after cleaning, using small steam sterilizers. It provides advice that is based on health and safety regulations and current technical guidance on sterilization within healthcare. It has been developed through consultation with various experts and end-users.

The advice in this document aims to be practical and achievable with the equipment most commonly used in the primary care dental practice environment. There are risks associated with the reuse of instruments. By adopting procedures consistent with this guidance in dental practices in Scotland, a very significant risk reduction and an improvement in decontamination and patient safety will be achieved. As new knowledge and technology develops it may be necessary to update this guidance.

Supplementary information is provided in the introduction and appendices of the '*Decontamination Into Practice*' series. Many of the weblinks included can be accessed via the Decontamination section of the Scottish Dental website: www.scottishdental.org. Notably, the following Scottish Health Technical Memoranda (SHTM) have detailed information on how to choose, use and validate equipment for decontamination processes:

- *SHTM 2010 Sterilization*
- *SHTM 2030 Washer-disinfectors* (includes ultrasonic cleaners)

As sterilization is a highly technical activity, on occasion it may be necessary to consult an Authorising Engineer (Decontamination) for specific advice concerning validation, periodic testing, maintenance and operational management as defined in SHTM 2010. The Authorising Engineer (Decontamination) service for NHSScotland is provided by Health Facilities Scotland (see Appendix 5). Note that at time of writing, there are relatively few of these specialists to advise both secondary and primary care services.

1 Introduction

1.1 Sterilization in the Dental Practice

The decontamination of reusable dental instruments includes:

- cleaning
- thermal disinfection, if a washer-disinfector is available
- rinsing
- drying
- inspection for dryness, functionality and cleanliness
- wrapping before sterilization when using a vacuum sterilizer
- sterilization
- wrapping after sterilization when using a non-vacuum sterilizer

Sterilization is an essential step in the reprocessing of reusable dental instruments that have become contaminated, or are potentially contaminated, with saliva, blood or other biological fluids. This includes dental handpieces. The aim of sterilization is to break the chain of potential cross-infection between patients by killing micro-organisms, including spores. However, prion proteins are not fully deactivated by the sterilization process. Therefore, effective instrument cleaning is particularly important to physically remove contamination, including prion proteins, prior to sterilization.

Sterilization using a steam sterilizer is recommended as the most efficient, cost effective and safe method of sterilizing dental instruments in primary care dental practices. The sterilization process must be validated to ensure that instruments are reliably and consistently sterilized using predetermined and reproducible conditions.

To kill microorganisms, the instruments need to be exposed to steam at a specified temperature for a specific holding time. Although other options exist, the preferred temperature-pressure-time relationship for all small steam sterilizers is 134–137°C, 2.1–2.25 bar gauge pressure for at least a 3 minute holding time.

It is preferable to use reusable instruments that can withstand both an automated cleaning/disinfection process and steam sterilization or to use single-use instruments. Reusable instruments that cannot withstand steam sterilization must be decontaminated as recommended by the instrument manufacturer.

1 Introduction

1.2 Sterilization Cycles in Small Steam Sterilizers

The sterilization cycle in a small steam sterilizer is a pre-programmed sequence of operating stages. There are three types of sterilization cycle, Type N, Type B and Type S. These cycles differ in the manner in which air is removed, the types of load they can sterilize, and whether or not items can be wrapped during sterilization. Table 1 summarizes the features associated with each type of cycle.

Table 1 Types of sterilization cycle in small steam sterilizers

| Cycle type | Method of air removal | Type of load | Comments | Alternative names for sterilizers that can perform these cycles |
|------------|---|--|--|---|
| N | Passive air removal from the sterilizer chamber (gravity displacement) by steam | Unwrapped, solid items | <p>Simplest type of cycle.</p> <p>Cannot assure sterilization of hollow instruments or those with lumens</p> <p>Not suitable for wrapped loads (e.g. items in pouches)</p> <p>Produces a 'sterilized' rather than a 'sterile' product, i.e. the product does not remain sterile beyond the end of the sterilization cycle.</p> <p>Sterilizers that perform only type N cycles are the least complex to operate and the least expensive to maintain.</p> | Non-vacuum, Type N, Bowl and Instrument, Gravity Displacement, or Unwrapped Instrument & Utensil (UIU) Sterilizer |
| B | Active (forced) air removal using a vacuum pump | <p>Wrapped or unwrapped solid items</p> <p>Wrapped or unwrapped hollow items</p> | <p>Has the widest range of applications.</p> <p>Can be used for the sterilization of lumened instruments as specified by the manufacturer.</p> <p>A post-sterilization drying stage is essential for wrapped items. This increases the total cycle time.</p> <p>Due to the method of air removal and the additional periodic testing required, sterilizers capable of Type B cycles are relatively expensive to purchase and maintain. However, they offer the advantage that they can be used to produce sterile wrapped instruments.</p> | Vacuum or Type B Sterilizer |
| S | Active (forced) air removal by, for example, steam pulsing | Only suitable for the types of loads specified by the sterilizer manufacturer | <p>Some but not all sterilizers designed to perform Type S cycles can sterilize wrapped and/or hollow items.</p> <p>A Type S cycle is only compatible with sterilization of unwrapped, wrapped or hollow items if the sterilizer manufacturer specifies that this is the case.</p> <p>Some have rapid cycle times but a post-sterilization drying stage is essential for wrapped items. This increases the total cycle time.</p> <p>Some sterilizers have instrument cassettes that allow transport of sterile instruments.</p> <p>Sterilizers capable of Type S cycles are relatively expensive to purchase and maintain.</p> | |

1 Introduction

As some sterilizers can perform more than one type of sterilization cycle, it is more correct to refer to the type of cycle performed rather than the type of machine. However, the following terms are often used for convenience:

- Non-vacuum sterilizer or Type N sterilizer
- Vacuum sterilizer or Type B sterilizer

This guidance describes the sterilization of unwrapped instruments in any type of sterilizer and wrapped instruments in a vacuum sterilizer, but not specifically a Type S sterilizer. This is because the various makes of Type S sterilizers differ in the type of load they can be used for and some may not be suitable for sterilizing wrapped instruments. Refer to the manufacturer's instructions for advice on the use of Type S sterilizers.

1.3 Sterilized versus Sterile

Instruments are regarded as **sterilized** when they

- have been cleaned, inspected and have undergone sterilization unwrapped (in any type of sterilizer) and are stored in a manner designed to limit environmental recontamination. By undergoing the sterilization process, the chain of potential microbial cross-infection between patients is broken.

Instruments are considered to be **sterile** when they

- have been cleaned, inspected and then wrapped before being sterilized in a sterilizer designed to process wrapped instruments (e.g. a vacuum sterilizer); to maintain sterility, these instruments must be stored with the wrapping intact until immediately before use;

or

- are bought as sterile single-use items and used in accordance with manufacturers' instructions. (i.e. used immediately on removal from the sterile pack and used only once).

1 Introduction

1.4 Sterilization of Dental Handpieces

There is currently no agreed method for the effective decontamination of dental handpieces. Research to assess the effectiveness of various methods of handpiece decontamination is ongoing. At present, it is best practice to follow manufacturer's instructions for handpiece cleaning. After cleaning it is then essential to sterilize handpieces in a steam sterilizer. Although the effectiveness of sterilization of the internal structures is unclear, processing in a sterilizer ensures that the external surfaces are sterilized and may also contribute to risk reduction through further thermal disinfection of the internal structures.

- ♥ When purchasing new handpieces, ensure that they can withstand thermal disinfection and steam sterilization.
- ♥ Always process dental handpieces in a steam sterilizer as part of their decontamination. Replace existing handpieces that cannot withstand steam sterilization.
- ♥ Follow the handpiece manufacturer's decontamination instructions.
- ♥ If necessary, contact the handpiece manufacturer to request clarification of their instructions.
- ♥ Lubricate handpieces before and/or after sterilization as recommended by the manufacturer. If lubrication is required both before and after sterilization, use separate designated 'cleaned only' and 'sterilized' canisters of lubricant, labelled accordingly.
 - Automated 'handpiece cleaning machines' can be used to lubricate handpieces. These machines are not validated for cleaning and do not disinfect. However, their use may prolong handpiece life and can be particularly useful if handpieces are cleaned in a washer disinfectant. See also '*Cleaning of Dental Instruments*' for advice on alternative methods for cleaning handpieces (Section 4.4.1) and care of handpieces after cleaning (Section 5.2.4).

2 Organising Sterilization Within the Decontamination Area

2.1 Purchasing a Small Steam Sterilizer

Before purchasing a small steam sterilizer, to ensure that it is suitable for your use:

- Specify clearly to the supplier the type of loads that you intend to reprocess including:
 - the quantities of instruments you are likely to reprocess per load and per day;
 - instrument cassette/tray dimensions (if used);
 - whether the loads include solid or hollow instruments;
 - whether instruments will be wrapped or unwrapped.
- Ensure the sterilizer carries the CE mark. This indicates that the manufacturer claims compliance with the Essential Requirements of the Medical Device Directive.
- Ensure that the sterilizer complies with British Standards (BS EN 13060) and SHTM 2010.
- Check with the supplier that:
 - they can install the sterilizer to be consistent with SHTM 2010 requirements and provide certification of this;
 - they will provide written operating instructions and training;
 - they can guarantee an efficient repair service and response time and can provide replacement equipment if necessary;
 - they can supply a contract for maintenance and testing in accordance with the manufacturer's instructions;
 - the sterilizer performs a cycle that can be validated (see Section 6).
- Ask the supplier to provide details in writing of:
 - how many instrument trays, cassettes or racks the sterilizer can process in one cycle;
 - how long a cycle takes;
 - the number of different cycles the sterilizer can perform;
 - dimensions and door orientation;
 - a local servicing agent;
 - the costs involved for installation, validation, periodic testing and maintenance;
 - periodic tests, including whether the machine can perform these tests automatically and whether the User can perform them;
 - how long the machine is out of action for maintenance (and how many times per year);
 - the electrical and/or plumbing requirements;
 - any other specific requirements (e.g. water quality and quantity required per cycle);
 - whether the machine has a printer installed or an electronic data logger and if so whether this records temperature, pressure and sterilization hold time;
 - whether other attachments or accessories are required and whether they have been included in the costs.

2 Organising Sterilization Within the Decontamination Area

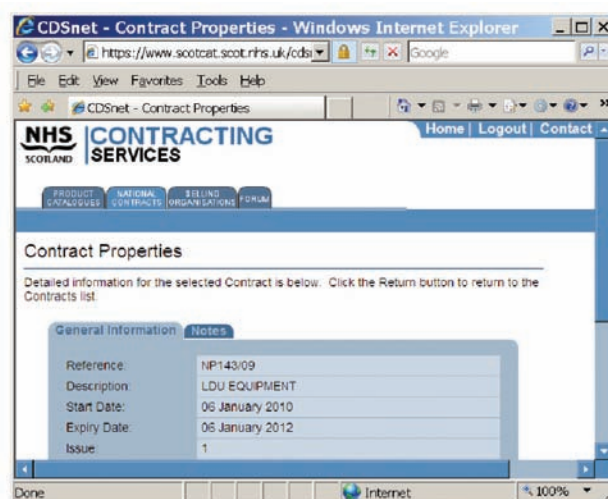
The resource requirements (e.g. costs and time for testing, level of staff training) will differ significantly depending on the type of sterilizer. In 2011, following an assessment of the current literature, the Scottish Health Technologies Group determined that there is lack of evidence to conclude that the provision of benchtop steam vacuum sterilisers in primary care dental practices in Scotland would increase patient safety and thereby justify the cost (Advice Statement 003/11, which will be subject to periodic review). While cost is a concern, it is essential to follow manufacturers' reprocessing instructions for both sterilizer and instruments to inform your decisions about purchase of a small steam sterilizer.

2.1.1 The NHSScotland National Contract for Decontamination Equipment

NHSScotland has a national contract for local decontamination unit (LDU) equipment that was created following a period of equipment testing. The contract includes the purchase price of several small steam sterilizers and gives details of the additional costs for installation, commissioning, testing and maintenance. A full support package which includes both the equipment and the additional costs is also listed.

Note that the current national contract does not include any Type S sterilizers (see Section 1.2). Further items are added periodically and, therefore, it is important to check the contract for the latest information.

All GDC registered dentists in Scotland can view the contract at the NHS National Procurement website, CDSnet: www.scotcat.scot.nhs.uk/cdsnet/cdsnet.asp (see Appendix 6 for further details).



Health Facilities Scotland and the Chief Dental Officer recommend that all decontamination equipment (ultrasonic cleaners, washer disinfectors and sterilizers) is purchased using the national contract as a guide. A sterilizer purchased via the contract will meet the specifications included in the points listed in Section 2.1 **provided that the additional installation, commissioning, testing and maintenance package is also purchased**. The suppliers are listed on CDSnet and need to be contacted directly to purchase equipment.

- Consult the LDU equipment contract at www.scotcat.scot.nhs.uk/cdsnet/cdsnet.asp to inform purchasing decisions and consider quoting it when purchasing new equipment.

2 Organising Sterilization Within the Decontamination Area

2.2 Purchasing Reusable Instruments

Failure to comply with manufacturer's instructions can adversely affect the safety of an instrument and affect product guarantees or warranties.

- ♥ Check the manufacturer's instructions **before** purchase to ensure that instruments are suitable, that is:
 - they are good quality and CE marked;
 - they can withstand the temperature and pressure applied during the steam sterilization cycle used in your sterilizer;
 - whether there is a limit to how many times an instrument can be sterilized (e.g. electrosurgery tips).
- ♥ If there are reusable instruments in use that cannot withstand sterilization, source alternatives which can be sterilized or which are single use.

2.3 Staff Roles

Appendix 4 details the personnel necessary for validation and quality assurance. This includes both staff in the practice and external personnel.

- ♥ Appoint a User as the named person responsible for appointing operators and ensuring their competence, and for the day-to-day management of each sterilizer, its use, maintenance and testing and relevant documentation. In a dental practice, this role could be delegated to a suitably trained member of staff, for example, a senior dental nurse or practice manager.
- ♥ Appoint Operators to operate each sterilizer, including performing basic housekeeping duties.

2.4 Staff Training

It is a requirement of the Provision and Use of Work Equipment Regulations 1998, Glennie Technical Requirements, HPS LDU Guidance and MDA DB 2002(06) that all staff that manage, supervise or operate sterilizers are trained in their use and maintenance. The practice owner (Management – refer to Appendix 4 for key personnel) is responsible for ensuring that systems are in place for ongoing staff training.

- ♥ Ensure all members of the dental team who undertake decontamination of dental instruments are competent, supervised and trained. For sterilization they should:
 - understand the procedures detailed in this guidance;
 - know what kind of sterilizer(s) are in the practice and what type of cycle is used in each sterilizer;

2 Organising Sterilization Within the Decontamination Area

- know how to prepare the range of instruments used in the practice correctly for sterilization, including new instruments, loading configuration, lubrication, inspection, wrapping, labelling;
- know how to store instruments after sterilization;
- understand record management.

💡 Refer to Section 2.1 of '*Cleaning of Dental Instruments*' for general information about staff training, Hepatitis B vaccination and use of Personal Protective Equipment (PPE).

2.5 Sterilization Workflow

The decontamination process is carried out as a dirty-to-clean workflow within the Local Decontamination Unit (LDU). SHPN 13 Part 2 provides guidance on LDU design, including workflow. Sections 2.2 and 2.3 of '*Cleaning of Dental Instruments*' provide advice on setting up an area dedicated for decontamination of dental instruments, including the preferred arrangement.


- 💡 After instrument cleaning, ensure the decontamination area has the following items for sterilization arranged in the order listed:
- an area for loading unwrapped instruments into trays or cassettes for sterilization or for pre-sterilization wrapping of instruments if using a vacuum sterilizer.
 - a steam sterilizer;
 - an area for set down and cooling following removal from the sterilizer and for wrapping or bagging instruments that have been sterilized unwrapped;
 - a dedicated, clean, rigid, labelled box with a lid to transport instruments to the clinical or storage area safely and securely.
- 💡 Ensure instrument storage is clean, orderly, enclosed (e.g. in trays, cassettes or pouches), and is not on open shelving.
- Ideally, instruments are stored in an area that is separate from the decontamination unit, well lit, secure, dry and away from direct sunlight.
- 💡 Ensure storage is arranged so that sterile and sterilized instruments cannot be confused.


3 Important Factors in Effective Sterilization


3.1 Health & Safety Requirements for Small Steam Sterilizers


The particular hazards associated with the use of steam sterilizers include burns from steam or hot metalwork (including instruments), explosive displacement of a door if not properly secured and infection resulting from inadequate instrument processing. The Pressure Systems Safety Regulations 2000 (PSSR) covers the installation and use of steam sterilizers. As a legal requirement, each sterilizer must have:

- a written scheme of examination;
- a periodic examination of the pressure system;
- third party liability insurance;
- a record of repairs and maintenance of the pressure system.

 Following installation and before use, obtain a written scheme of examination for each sterilizer from the manufacturer, supplier or insurer that has been prepared by a Competent Person (Pressure Vessels).

 Arrange for a Competent Person (Pressure Vessels) to conduct safety examinations in accordance with the written scheme of examination for the sterilizer, and retain a certificate as proof of each inspection. This examination is in addition to regular and routine maintenance.


 Obtain third-party liability insurance that specifically covers risks associated with the operation of pressure vessels. Such risks may not be covered by practice insurance.

 To comply with legislation, keep records of all examinations and repairs to the pressure system.

Your insurance company may provide details of Competent Persons (Pressure Vessels), or advice can be sought from an Authorising Engineer (Decontamination). The HSE leaflet '*Written schemes of examination*' provides further information. The Competent Person (Pressure Vessels) can also advise how frequently the safety examination is required for each sterilizer (typically at least once every 14 months).

3.2 Installation and Validation of Small Steam Sterilizers

To ensure that a small steam sterilizer reliably sterilizes each load, it is particularly important that the sterilizer is installed and commissioned correctly and that the sterilization process is validated for the specified load.

 Ensure that your supplier installs and commissions a new sterilizer and that a Test Person (Sterilizers) validates the sterilization process before use as specified in SHTM 2010 and MDA DB 2002(06). Keep all records in the sterilizer logbook (see Section 3.7).

Section 6 provides further information about validation.

3 Important Factors in Effective Sterilization

3.3 Testing and Maintenance of Small Steam Sterilizers

- Ensure that each sterilizer is subject to a documented, planned maintenance programme and periodic testing schedule (see Section 6), for example, through a service contract with your supplier or Test Person (Sterilizers) or Maintenance Person (Sterilizers).
- Record in the logbook details of all testing and maintenance carried out on each sterilizer.

3.4 Cleanliness of Instruments

Contamination of instruments with residual tissue, body fluids, oil or other deposits such as cements can prevent the direct contact between the steam and surfaces of the instruments that is necessary for effective sterilization. Also, any deposits left on instruments before sterilization might become fixed to the instruments making them more difficult to remove later. These deposits can also enter the water in the sterilizer reservoir and encourage growth of microorganisms or accumulation of endotoxins, which could contaminate instruments processed subsequently.

- Ensure all items to be sterilized are clean and dry before placing them in the sterilizer chamber (see '*Cleaning of Dental Instruments*').

3.5 Loading of Instruments

Air removal might be impeded if instruments are not loaded correctly and steam may not contact every surface of every instrument. This steam contact is essential for sterilization to occur.




- Load the sterilizer according to the manufacturer's instructions and as specified at validation.
- Ensure instruments do not overlap.
- Open hinged instruments to expose all of the surface area to the steam.
- Place instruments on perforated trays, cassettes or racks that have been validated for use with the selected sterilization cycle.
- Do not overload the sterilizer chamber or individual trays or containers with instruments.



3 Important Factors in Effective Sterilization

3.6 Water for Use in Steam Sterilizers

Water used for sterilization must be essentially free of chemicals and endotoxins. In MDA DB2002(06), the MHRA recommends Sterile Water for Irrigation BP though other forms of purified water of equivalent specification can be used, for example certain freshly drawn reverse osmosis (RO) or freshly prepared distilled waters. The use of tap water is not acceptable as this can lead to a build up of contaminants that can be harmful and/or might damage the sterilizer.

-  Fill the empty sterilizer reservoir with water of suitable quality. Do not use tap water.
-  Change the water at least once per day or sooner if the chamber water is visibly coloured or cloudy. Record when each water change is done.
-  If considering purchasing a water purification system to produce distilled or reverse osmosis water within the practice, first seek advice from an Authorising Engineer (Decontamination).

3.7 Sterilizer Logbook and Record Keeping

A logbook is required for each sterilizer as a permanent record of the complete history of the sterilizer and could provide useful evidence in the event of an adverse incident. Alternative examples of pages of a sterilizer logbook are given in Appendix 7 and in MDA DB2002(06). Logbooks can also be purchased from Health Facilities Scotland.

-  Keep the logbook near the sterilizer so that routine information can be recorded easily.

Include in the logbook:

- installation, commissioning and validation tests and checks;
- the written scheme of examination under the Pressure Systems Safety Regulations 2000 (PSSR) (see Section 3.1);
- a record of inspection under the scheme of examination;
- results of periodic testing;
- a record of reservoir water changes;
- a record of any cycle that fails and actions taken, including what was done with the unsterilized load;
- a record of all maintenance, repairs or modifications.

-  Retain the logbook for inspection.

4 Sterilization Procedure

The key consideration when determining sterilization operating procedures is the type of sterilizer and sterilization cycle that is being used because this dictates whether or not the instruments can be wrapped before sterilization. Instruments can only be wrapped before sterilization if using a vacuum (or compatible Type S) sterilizer designed for wrapped instruments.

Some procedures are common to all sterilizers and are described in Section 4.1. Specific procedures for sterilizing unwrapped and wrapped instruments are then described in Section 4.2 and 4.3 respectively.

4.1 General Operation of Steam Sterilizers

- ♥ Have in place a written sterilization procedure that is based on manufacturer's instructions and that includes loading, choice of sterilization cycle, procedure after sterilization and record keeping and ensure that all staff follow this written procedure.
- ♥ On each day that the sterilizer is used, carry out the daily housekeeping checks and daily tests (see Section 6).
- ♥ Ensure that maintenance and testing records for all sterilizers in use are up to date and satisfactory.

4.1.1 Before Sterilization

- ♥ Change your gloves and plastic apron before handling the cleaned instruments, remembering to wash your hands or use alcohol rub on visibly clean hands before putting on new gloves.
- ♥ If moving cleaned instruments to a sterilizer in another room, use a dedicated, clean, rigid, labelled container with a lid.
- ♥ Transfer instruments to the sterilizer as soon as possible after cleaning, thermal disinfection if a washer-disinfector is used, drying and inspection for cleanliness and functionality. Only wrap instruments before sterilization if using a vacuum sterilizer.
- ♥ Load instruments correctly (see Section 3.5). For specific advice about unwrapped and wrapped instruments refer to Sections 4.2 and 4.3.
- ♥ Check that there is sufficient water in the reservoir (see Section 3.6).
- ♥ Select and start the sterilization cycle.
- ♥ If instruments are not to be sterilized at the end of the day, clean and dry them, clearly label them as unsafe for handling or use and reprocess them through the full decontamination cycle the next working day.

4 Sterilization Procedure

4.1.2 After Sterilization

- ♥ Check that the sterilizer indicates that the cycle was satisfactory.
- ♥ Using the printout or data logger fitted to the sterilizer, confirm that the required temperature (usually 134–137°C) was held for at least 3 minutes and, if recorded, that the required pressure (usually 2.1–2.25 bar) was attained during the cycle.
 - In the absence of a printer or data logger that provides this information, manual monitoring and recording of each cycle is necessary. An Authorising Engineer (Decontamination) can advise on a suitable procedure. Upgrade to a machine with a suitable printer or data logger as soon as possible.
- ♥ Record that the cycle was satisfactory (e.g. sign the printout and retain it as a record).
 - Some practices choose to keep an electronic record by scanning signed printouts in batches, thus avoiding the need to store large quantities of printouts.
- ♥ Use special tray lifters or heatproof gloves to carefully unload the sterilizer.
- ♥ For instruments sterilized wrapped, check each package is satisfactory (as detailed in Section 4.3.1).
- ♥ If any of the above cycle conditions is not achieved or there is a problem with instruments unloaded from the sterilizer, ensure that the details are recorded, notify the User and reprocess the instruments from the start of the decontamination cycle (cleaning, thermal disinfection if available, and sterilization).



4.1.3 At the End of the Day

- ♥ Follow the manufacturer's instructions to drain and clean the chamber and reservoir at the end of each day and leave dry.

4.2 Unwrapped Instruments (All Sterilizers)

If using a non-vacuum sterilizer, the instruments must be processed unwrapped.

Instruments processed unwrapped are classified as 'sterilized' and are not sterile (see Section 1.3).

Solid instruments can be sterilized unwrapped in any type of sterilizer. The sterilization of hollow or lumened instruments can only be achieved if they are cleaned effectively and a vacuum (or a compatible Type S) sterilizer is used (see Table 1).

4 Sterilization Procedure

- ♥ When processing instruments using a non-vacuum sterilizer, ensure that the instruments are unwrapped.
 - Note that the sterilization of the internal surfaces of instruments with lumens processed in a non-vacuum sterilizer cannot be guaranteed.
 - Refer to Section 1.4 regarding the sterilization of dental handpieces.
- ♥ If possible, process instruments using a sterilization cycle with a drying stage.
- ♥ When using a vacuum sterilizer, if the load includes hollow or lumened instruments, ensure that a drying stage is included.

4.2.1 Handling and Storage of Unwrapped Instruments Immediately After Sterilization

Instruments that have been sterilized unwrapped are designated as 'sterilized only' (see Section 1.3). It is currently acceptable for instruments sterilized unwrapped to be kept for later use. However, they must be:

- dry – it is very important that instruments are completely dry when stored because dampness encourages growth of microorganisms and corrosion of instruments;
 - protected from contamination;
 - stored correctly - note that storage of loose unwrapped instruments is unacceptable.
-
- ♥ Clean hands and put on clean gloves and a clean apron before handling unwrapped instruments that have been removed from the sterilizer. Take additional precautions if the instruments are still hot.
 - ♥ Examine newly sterilized instruments visually for dryness. Ideally the instruments will be dry on removal from the sterilizer but, if a drying cycle has not been used, manual drying using disposable, non-linting wipes may be necessary.
 - ♥ Do not leave sterilized instruments exposed in the clinical environment.
 - ♥ Store instruments individually or in sets in clean, dry conditions and in a manner that prevents recontamination.
 - Options include, placing instruments in covered trays, cassettes or clip-in trays in enclosed boxes or cupboards in a rack system, or sealing within clean, single-use, sterilization grade wrapping material or self-seal sterilization bags/pouches.
-

4 Sterilization Procedure

- When labelling wrapped instruments, write on the labels before attaching them to the wrapping. Do not write on the wrapping directly with ballpoint or felt pen as this might damage it.
- Store instruments in clean enclosed cupboards, drawers or boxes in an orderly manner that avoids damaging the wrapping.
- Do not store any instruments on open shelving or on work surfaces in clinical areas.
- Use a first-in, first-out stock rotation to minimise the duration of storage.



4.3 Wrapped Instruments (Vacuum Sterilizers)

Instruments can only be processed wrapped in a vacuum (or a compatible Type S) sterilizer that is designed for wrapped instruments. If using a non-vacuum sterilizer, refer to Section 4.2.

As wrapping and labelling are part of the validation process, the sterilizer should be re-validated when introducing new wrapping and labelling.



- If wrapping instruments prior to sterilization in a vacuum sterilizer, ensure that:
 - the wrapping material manufacturer's instructions are followed;
 - the wrapping materials are compatible with the steam sterilization process (in dental practices, self-seal sterilization pouches are typically used);
 - only a single layer of wrapping material is used;
 - each instrument is wrapped separately or as a set of instruments for a single treatment held in a cassette that prevents them overlapping;
 - the correct size of pouch is used (i.e. only slightly larger than the contents);
 - the method of sealing preserves the microbial barrier properties of the wrapping and enables the pack to be opened aseptically (e.g. self-seal or fold three times and apply autoclave tape).
- Attach a pre-written or pre-printed adhesive label to each pack that includes the word 'Sterile', the process date, the sterilizer identification and cycle number. Do not write on the label after attaching it to the wrapping and do not write directly onto the wrapping with a ballpoint or felt pen as this might damage it.

4 Sterilization Procedure

- ♥ Use a chemical process indicator that is either printed on the pouch or available as a label or tape.
 - Note that this does not indicate sterility but simply distinguishes items that have been exposed to a sterilization process from those that have not.
- ♥ Ensure that the selected sterilization cycle includes a drying stage.
 - It is essential to dry the load before the sterilizer chamber is opened otherwise the wrapped instruments will not remain sterile.

4.3.1 Handling and Storage of Wrapped Instruments Immediately After Sterilization

Careful handling and storage of sterilized packs will ensure that the contents remain sterile until the pack is opened.

- ♥ Check the wrapping material for dampness, tears, broken seals or any other damage and that the label is intact and the details are legible.
 - It is very important that instruments are completely dry when stored because dampness encourages growth of microorganisms and corrosion of instruments.
- ♥ Handle packs carefully so that they are not dropped or damaged.
- ♥ Do not place newly sterilized wrapped instrument packs on cool or solid surfaces because these items are cooling fast and are in a vulnerable state because the warm vapour leaving the pack can condense to form 'dew' that wets the wrapping materials.
- ♥ If a wrapped item or pack is wet, is dropped on the floor, is torn or has broken seals, it is no longer sterile. Unwrap the instruments and return them to the start of decontamination process.
- ♥ If wrapped sterile instrument packs are to be stored for some time, confirm that the process date is marked clearly on the wrapping to enable stock rotation.
- ♥ Check that the chemical process indicator has changed colour correctly. If it has not, investigate the problem, assess the disruption to the decontamination process and reprocess the instruments from the start of the decontamination cycle.
- ♥ Store wrapped instruments in clean, enclosed cupboards, drawers or boxes in an orderly manner that avoids damaging the wrapping (i.e. dry with little variation in temperature and minimal handling).
- ♥ Do not store instruments on open shelving or on work surfaces in clinical areas.
- ♥ Use a first-in, first-out stock rotation to minimise the duration of storage of sterile instruments.

5 Inspection of Instrument Packs Before Use

• Ensure hands are clean and dry when handling instrument packs.

• Check each pack is satisfactory before use. Do not use the instrument(s) if either:

- the outer wrapping or seals are damaged;
- the pack is moist (see photograph);
- the pack has labelling that is damaged or incorrect;
- the pack has a process indicator that has not changed colour correctly; or
- the instruments are visibly soiled.

Instead, open the pack and return the instrument(s) to the start of the decontamination process.

• If an instrument appears damaged, remove it from use.



6 Validation, Periodic Testing and Maintenance of Small Steam Sterilizers



There is no practical way of determining that items processed in a steam sterilizer have been sterilized. Instead, tests need to be carried out regularly to confirm that during each sterilization cycle the sterilizer reproduces the operating conditions that were previously established as effective for sterilization. Essentially, testing is necessary to confirm that the machine reproducibly does what it was designed and set up to do.

Validation is a documented process used to show that sterilization will repeatedly and consistently take place to a satisfactory standard when defined operating conditions are used. These operating conditions include the choice of sterilization cycle, the nature of the load, the loading pattern, wrapping, trays or containers and labelling. Validation comprises a series of specified checks and tests carried out annually and as part of the commissioning process following installation of a new sterilizer. These checks and tests are performed by a Test Person (Sterilizers) as specified in SHTM 2010.

In addition, satisfactory **periodic testing** is necessary to provide ongoing reassurance that the sterilizer is performing consistently as specified at validation. The legal requirement is to carry out periodic tests as specified in the sterilizer manufacturer's instructions. Daily and weekly tests will normally be carried out by practice personnel and are described below. Quarterly (if specified by the manufacturer) and yearly (also known as annual revalidation) tests require specialist equipment and are performed by external personnel [a Test Person (Sterilizers)]. If the manufacturer's instructions are not available, periodic testing as recommended within SHTM 2010 is necessary.

Table 2 lists the periodic tests that SHTM 2010 Part 3 and MDA DB2002(06) describe in detail for the various types of steam sterilizers. For specific guidance on testing and maintenance of Type S sterilizers, refer to the manufacturer's instructions.

A planned programme of preventive **maintenance** is also required for each sterilizer. Maintenance work is carried out by a qualified maintenance person. In some cases when parts (e.g. temperature probes) are changed, it is necessary to have the sterilization cycle revalidated.

-  For advice on validation of new or existing sterilizers, contact an Authorising Engineer (Decontamination).
-  Obtain a written test schedule for each sterilizer from a Test Person (Sterilizers) or an Authorising Engineer (Decontamination).

6 Validation, Periodic Testing and Maintenance of Small Steam Sterilizers

6.1 Housekeeping and Safety Checks

6.1.1 Daily Housekeeping Checks for All Sterilizers

At the start of each day:

- ♥ Wipe the door seal with a clean, disposable, damp, non-linting cloth and carry out any other checks required by the manufacturer.
- ♥ Check that the chamber and shelves are clean.
- ♥ Refill the reservoir with suitable quality water (see Section 3.6).
- ♥ When switching the power on, check that the ventilation louvres are not covered to avoid overheating.
- ♥ If recommended by the sterilizer manufacturer, preheat the sterilizer chamber before performing daily tests.
- ♥ Record completion of the daily checks in the sterilizer logbook.

6.1.2 Weekly Safety Checks for All Sterilizers

Before carrying out any weekly tests, the following checks are carried out in addition to the daily housekeeping checks.

- ♥ Examine the door seal for signs of wear or damage.
- ♥ Examine the security and performance of the door safety features including the hinges and the locking mechanism as detailed in the manufacturer's instructions.
- ♥ If a fault is detected in the door seal or safety features, ensure this is corrected before carrying out weekly tests or using the sterilizer.
- ♥ Record satisfactory completion of the weekly safety checks in the sterilizer logbook.

6.2 Automatic Control Test for All Sterilizers

The automatic controller is the device within the sterilizer that controls the sterilization cycle. To be sure that it is working, an automatic control test is carried out every day either using the sterilization cycle parameter values recorded on the printout or electronic data logger, or by manually observing and recoding the cycle parameters if there is not a suitable recorder fitted. In addition, a manual automatic control test should also be carried out once per week for all sterilizers.

The Automatic Control Test can be done when sterilizing a standard load, unless also carrying out a steam penetration test for a vacuum sterilizer (see Section 6.3) at the same time. This is usually the first cycle of the day.

6 Validation, Periodic Testing and Maintenance of Small Steam Sterilizers

6.2.1 Automatic Control Test Using a Recorder

This test is carried out once per day if the sterilizer is fitted with a suitable recorder (i.e. a printer or electronic data logger). If a suitable recorder is not fitted, a manual automatic control must be carried out each day (see Section 6.2.2).



- ♥ Run a sterilization cycle with a standard load or an empty chamber (the chamber must be empty if also carrying out a steam penetration test in a vacuum sterilizer).
- ♥ At the end of the cycle, check the printout or data logger to ensure that the recorded cycle parameters (temperature, pressure, hold time) are within the specified range for the cycle and comparable to the values obtained at validation.
- ♥ Keep a record of the recorded values for temperature, pressure and hold time.
- ♥ If the automatic control test is unsatisfactory (i.e. the recorded temperature, pressure or hold time are not within the specified range for the cycle), record the test as a fail and do not use the sterilizer until the fault has been resolved.
 - In this case, return any instruments that were loaded in the sterilizer to the start of the decontamination process.
- ♥ Sign the logbook.

6.2.2 Manual Automatic Control Test

This test is carried out once per day if the sterilizer does not have a suitable recorder fitted, and once per week if there is a suitable recorder.

- ♥ Run a sterilization cycle with a standard load or an empty chamber (the chamber must be empty if also carrying out a steam penetration test in a vacuum sterilizer).
- ♥ Begin timing the sterilization hold period of the cycle when the sterilizer reaches the sterilizing temperature (the display might also indicate when this point is reached).
- ♥ Note the bar pressure reached during the hold period.
- ♥ Note the temperature reached during the hold period.



6 Validation, Periodic Testing and Maintenance of Small Steam Sterilizers

- Record the temperature, pressure and hold time in the sterilizer logbook. Record the test as a pass if these values are within the specified range for the cycle and comparable to the values obtained at validation.
- If the automatic control test is unsatisfactory (i.e. the temperature, pressure or hold time are not within the specified range for the cycle), record the test as a fail and do not use the sterilizer until the fault has been resolved.
- Sign the logbook.

6.3 Steam Penetration Test for Vacuum Sterilizers

This test is carried out in vacuum sterilizers designed to sterilize wrapped instruments. It is intended to show that steam will rapidly and evenly penetrate a test device that is similar to the intended load.

- Refer to the sterilizer manufacturer's instructions for the recommended test device and indicator (e.g. Bowie-Dick).
- At the start of the day, select the usual sterilization cycle and perform the test with the chamber empty apart from the test device, following the test device manufacturer's instructions.
- Record whether the test was a pass or a fail in the sterilizer logbook.
- If the steam penetration test result is unsatisfactory, repeat the test. A second unsatisfactory test result confirms that there is a fault. Arrange for a Maintenance Person (Sterilizers) to investigate and do not use the sterilizer to sterilize instruments until the fault has been resolved.

6.4 Air Leakage Test for Vacuum Sterilizers

If air leaks into the sterilizer chamber at a higher rate than specified by the manufacturer, it might interfere with the penetration of steam into the load and, as the air will not have passed through the bacteria retentive filter, there is a risk of recontaminating the load. An air leakage test involves removing air from the chamber, isolating the chamber and monitoring the pressure for a period of time. Air leakage will cause an increase in the chamber pressure.

- If an automatic test is available, carry out an air leakage test according to the manufacturer's instructions once per week.
 - It is preferable to have a sterilizer that is capable of performing an automatic test because otherwise a Test Person (Sterilizers) is required to perform a weekly manual test.
 - Note that some manufacturers specify that an air leakage test is carried out each day before the steam penetration test.
- Record the results in the sterilizer logbook.

6 Validation, Periodic Testing and Maintenance of Small Steam Sterilizers

6.5 Automatic Air Detection System Function Test for Vacuum Sterilizers

Sterilizers that actively remove air from the load before sterilization (e.g. using a vacuum pump) are fitted with a means of detecting whether any air present in the chamber is sufficient to impair sterilization during each cycle. A test is performed each week to check that the air detector is functioning correctly. The details of the test vary between different makes of sterilizer. If the User cannot perform this test, it will require a Test Person (Sterilizers) to visit weekly to perform the test. This will add significantly to your costs so check this before purchase.

- ♥ Carry out an automatic air detection system function test as specified in the manufacturer's instructions once per week.
- ♥ Record the results in the sterilizer logbook.

6.6 Other Periodic Tests

- ♥ Arrange for a Test Person (Sterilizers) to carry out quarterly (if specified by the manufacturer) and yearly (annual revalidation) tests (e.g. through purchase of a new sterilizer via the NHSScotland national contract with the full support package or by arrangement with a contractor). A suitably experienced and qualified maintenance person may perform some of these tests (see Appendix 4).
- ♥ Ensure details are recorded in the sterilizer logbook.

6.7 Maintenance of Small Steam Sterilizers

- ♥ Obtain a maintenance contract to carry out the programme of preventative maintenance tasks as specified in the manufacturer's instructions.
- ♥ If the manufacturer's programme of maintenance is not available, consult the Maintenance Person (Sterilizers) (who might be an employee of the supplier or manufacturer) to devise a suitable programme.
- ♥ Ensure details of all maintenance work are recorded in the sterilizer logbook, including problems, faults, preventative and corrective actions.
- ♥ If any maintenance or modification work is carried out to the pressure system, seek the advice of a Competent Person (Pressure Vessels) before using the sterilizer.

6 Validation, Periodic Testing and Maintenance of Small Steam Sterilizers

Table 2 Periodic tests for small steam sterilizers

| Tests | Performed by | Sterilizer Type | | |
|--|--------------|-----------------|-----------|---|
| | | Non-vacuum /N | Vacuum /B | S |
| Daily tests | | | | |
| Automatic control test | User | ✓ | ✓ | ✓ |
| Steam penetration test | User | | ✓ | ✓ |
| Weekly tests | | | | |
| Weekly safety checks (door seal and lock) | User | ✓ | ✓ | ✓ |
| Air leakage test (Automatic)§ | User* | | ✓ | ✓ |
| Air detection system function test (Automatic) | User* | | ✓ | ✓ |
| Automatic control test | User | ✓ | ✓ | ✓ |
| Steam penetration test | User | | ✓ | ✓ |
| Quarterly tests | | | | |
| Weekly safety checks | TP(S) | ✓ | ✓ | ✓ |
| Air leakage test (automatic) | TP(S) | | ✓ | ✓ |
| Air leakage test (sensors connected) | TP(S) | | ✓ | ✓ |
| Automatic control test | TP(S) | ✓ | ✓ | ✓ |
| Verification of calibration of sterilizer instruments | TP(S) | ✓ | ✓ | ✓ |
| Thermometric test for a small load | TP(S) | ✓ | ✓ | ✓ |
| Air leakage test (sensors removed) | TP(S) | | ✓ | ✓ |
| Air detection system function test (automatic) | TP(S) | | ✓ | ✓ |
| Steam penetration test | TP(S) | | ✓ | ✓ |
| Yearly and revalidation tests | | | | |
| Yearly safety checks | TP(S) | ✓ | ✓ | ✓ |
| Steam non-condensable gas test | TP(S) | | ✓ | ✓ |
| Steam superheat test | TP(S) | | ✓ | ✓ |
| Steam dryness test | TP(S) | | ✓ | ✓ |
| Air leakage test (automatic) | TP(S) | | ✓ | ✓ |
| Air leakage test (sensors connected) | TP(S) | | ✓ | ✓ |
| Automatic control test | TP(S) | ✓ | ✓ | ✓ |
| Verification of calibration of sterilizer instruments | TP(S) | ✓ | ✓ | ✓ |
| Chamber overheat cut-out test | TP(S) | ✓ | | |
| Air detector test for a small load | TP(S) | | ✓ | ✓ |
| Air detector test for a full load | TP(S) | | ✓ | ✓ |
| Thermostatic test for a small load | TP(S) | ✓ | ✓ | ✓ |
| Thermostatic test for a full load | TP(S) | ✓ | | |
| Test for performance requalification as required by the User | TP(S) | ✓ | ✓ | ✓ |
| Air leakage test (sensors removed) | TP(S) | | ✓ | ✓ |
| Air detection system function test (automatic) | TP(S) | | ✓ | ✓ |
| Steam penetration test | TP(S) | | ✓ | ✓ |

* The user may perform these tests only with the prior agreement by an Authorising Engineer (Decontamination), AE(D)

§ Some manufacturers recommend a daily (rather than a weekly) air leakage test.

TP(S) = Test Person (Sterilizers)

The information in this table is collated from Tables 4a and 4c of SHTM 2010 Part 3 and MDA DB 2002(06). Refer the manufacturer's instructions for guidance on Type S sterilizers.

The Scottish Dental Clinical Effectiveness Programme (SDCEP) is an initiative of the National Dental Advisory Committee and is supported by the Scottish Government and NHS Education for Scotland. The Programme aims to provide user-friendly, evidence-based guidance for the dental profession in Scotland.

SDCEP guidance is designed to help the dental team provide improved care for patients by bringing together, in a structured manner, the best available information that is relevant to priority areas in dentistry, and presenting this information in a form that can be interpreted easily and implemented.

'Sterilization of Dental Instruments' is the second of the SDCEP series *'Decontamination Into Practice'* which aims to help the evolution towards compliance with the relevant statutory and mandatory requirements and standards. *'Sterilization of Dental Instruments'* provides advice on all aspects of instrument sterilization, including equipment purchase, important considerations, procedures for sterilization and the testing of equipment.

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