DEVICE

BULLETIN

MEDICAL DEVICES AGENCY

# *Benchtop Steam Sterilizers – Guidance on Purchase, Operation and Maintenance*

*MDA DB2002(06)*
*October 2002*


The Medical Devices Agency helps safeguard public health by working with users, manufacturers and lawmakers to ensure that medical devices meet appropriate standards of safety, quality and performance and that they comply with the relevant Directives of the European Union.

Our primary responsibility is to ensure that medical devices achieve their fullest potential to help healthcare professionals give patients and other users the high standard of care they have a right to expect.

*The Medical Devices Agency is an Executive Agency of the Department of Health*

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# 1. EXECUTIVE SUMMARY

This Bulletin provides guidance on the purchase, operation and maintenance of all types of benchtop steam sterilizers. It is a revised compilation of the guidance previously issued in DB9605 and DB2000(05).

**Who this document is for**

This guidance is intended for potential purchasers, and all current owners and users of benchtop steam sterilizers and should be of particular interest to:

- chiropodists and podiatrists;
- community healthcare workers;
- consultants in communicable disease control;
- consultant microbiologists;
- day surgery unit staff;
- dental nurses;
- dental practice managers;
- dental practitioners;
- environmental health officers;
- general practice managers;
- general practice nurses;
- general practitioners;
- infection control teams;
- operating theatre staff;
- outpatients departments;
- primary care trusts (PCTs);
- risk managers.

## 2. INTRODUCTION

Minor surgical procedures are increasingly being performed in primary healthcare facilities. There are a number of choices for obtaining the sterilized devices for these procedures:

- use single-use equipment;
- have your reusable devices reprocessed by a SSD; or
- reprocess them yourself.

**Never reuse medical devices designated for single-use**

**Note**: The term 'devices' is used throughout this bulletin to encompass devices, instruments and medical equipment.

If you choose to use reusable devices, whenever practicable you should obtain them from a Sterile Services Department (SSD). These have the equipment and expertise to clean and sterilize reusable medical devices effectively and consistently, combined with economy of scale.

In the absence of a central sterilizing service, a benchtop steam sterilizer may be used. However, it must be suitable for the intended loads, and it must be validated, maintained and operated properly. Benchtop steam sterilizers contribute to the prevention of cross infection, especially in primary healthcare, but also in non-medical practices such as tattooing, body piercing and beauty treatments. Benchtop steam sterilizers do not require permanent connections to mains services.

Steam sterilization is the most practicable method for sterilizing reusable medical devices in healthcare premises because it has high lethality, it is rapid and it is non-toxic. The standard temperature/pressure/time relationships for steam sterilization are shown in Table 1. We recommend that you use the highest temperature compatible with the load items.

**Table 1 Sterilization temperature bands, holding times and pressures for steam sterilization.**

| Sterilizing temperature range (°C) | | Approximate pressure (bar) | Minimum hold time (minutes) |
|---|---|---|---|
| Minimum | Maximum | | |
| 134 | 137 | 2.25 | 3 |
| 126 | 129 | 1.50 | 10 |
| 121 | 124 | 1.15 | 15 |

The effectiveness of the process depends upon direct contact between the steam and all surfaces of the load. Therefore all items that you intend to sterilize must be clean and dry before you place them in the sterilizer chamber. Contamination with residual tissue, body fluids, oil or other deposits:

- will prevent contact between the steam and the surfaces of the load;
- might become fixed to the load items and be difficult to subsequently remove;
- might also contaminate the water and encourage bacterial growth.

Cleaning may be done manually or mechanically but we recommend mechanical cleaning wherever possible, as it is more consistent than manual cleaning and can be validated. Manual cleaning can also carry a risk of generating infectious aerosols unless the process is carried out carefully.

The MDA's publication 'Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Advisory Committee to Department of Health Medical Devices Agency' provides details of decontamination methods and procedures.

Air retained within the chamber and load can also prevent steam contact. Consequently it is important that the operator should load the sterilizer according to the manufacturer's instructions and take care not to overload it, otherwise air removal might be impaired and sterilizing conditions might not be attained.

'…all parts of the load to be sterilized must be free of air, so that it may be permeated by the steam.'
Sterilisation by steam under increased pressure.
The Lancet 28 February 1959.

## 2.1 Classification of benchtop steam sterilizers

A European standard for benchtop steam sterilizers is currently being prepared*. It classifies benchtop steam sterilizer cycles according to the types of load they are intended to process, which are summarised in Table 2:

**Table 2 Types of sterilization cycle**

| 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:<br>• hollow devices or those with lumens;<br>• wrapped loads (e.g. items in pouches). |
| **B** | Active (forced) air removal. | Wrapped or non-wrapped solid items (e.g. forceps, dental probes).<br><br>Wrapped or non-wrapped hollow items (e.g. cannulae within dimensions specified by sterilizer manufacturer).<br><br>Porous loads (e.g. fabrics, swabs, dressings). | Widest range of applications. | Expensive to purchase and maintain.<br><br>Additional periodic testing required.<br><br>Post-sterilization drying stage essential for wrapped items increases total cycle times. |
| **S** | Active (forced) air removal. | Only suitable for types of loads specified by the sterilizer manufacturer. | Wider range of applications than Type N. | Expensive to purchase and maintain.<br><br>Additional periodic testing required.<br><br>Post-sterilization drying stage essential for wrapped items increases total cycle times. |

**Note:** Ideally, only the highest specification cycle should be available to the operator. Other cycles should be disabled, until specifically needed.

* 'Small steam sterilizers' prEN13060 : 2002 (E)

**Traditional (gravity displacement) benchtop steam sterilizers** displace air passively from the chamber and load by steam generated within the sterilizer chamber or in a separate boiler within the sterilizer's casing. This is known as a 'Type N' cycle.

**Vacuum benchtop sterilizers** have a pump or some other active method to remove air from the chamber and load. This type of air removal is found in 'Type B' cycles and some 'Type S' cycles.
They are described variously as vacuum benchtop sterilizers, benchtop porous load sterilizers, Type B sterilizers, or sometimes Type S sterilizers.

**Note:** Type S sterilizers should be used to process only the types of loads specified by the sterilizer manufacturer.

Vacuum benchtop steam sterilizers have:

- a forced air removal stage prior to the sterilizing stage;
- a post-sterilization drying stage.

**Alternative air removal systems.** Some sterilizers remove air by using a succession of steam pulses, in which the chamber is alternately pressurised and then depressurised to near atmospheric pressure (or to below atmospheric pressure where this process is augmented by a vacuum pump). Air can also be removed from tubular devices by injecting steam through the lumens.

**Type N cycles** are intended to be used to sterilize solid devices that are not wrapped. Devices that are wrapped (the term 'wrapped' includes sterilization pouches) and devices that are hollow or have lumens cannot be sterilized in this type of sterilizer. These types of loads should ideally be sterilized in a SSD but alternatively may be sterilized in a properly functioning vacuum steam sterilizer that has been validated for the intended load (see section 4.1).

**Type B** cycles are intended for wrapped solid items (e.g. forceps, dental probes), hollow items (e.g. cannulae, tubing), whether or not they are wrapped, and for porous loads e.g. fabrics, swabs and dressings. They are necessary for items that cannot be processed using a Type N cycle (or a Type S cycle, unless it is intended specifically for these load types). Type B cycles **must** have a drying stage to ensure that the load is dry before the door is opened, which can increase the total cycle time considerably.

**Type S cycles** are intended for types of loads specified by the manufacturer of the sterilizer. They have a forced air removal system. (Forced air removal can be achieved using a vacuum pump, or superatmospheric pulsing or steam injection through the lumens of devices).

The effectiveness of the air removal stage determines the types of load they are designed to process. Some models have a drying stage, which will prolong the cycle time.

## 3. PURCHASING

Before purchasing a benchtop steam sterilizer, you should consider the numerous factors involved in obtaining sterilized medical devices. These are summarised in Appendix 1.

Benchtop sterilizers are regulated as medical devices and must comply with the Medical Devices Regulations 2002, which require all medical devices to carry the CE marking. Therefore, the CE marking does not help in choosing between makes and models.

**Buyer beware**

- The manufacturer should state clearly the types of load for which the sterilizer is suitable.
- You should only use the type of sterilizer that is suitable for the types of loads that you intend to process.
- Some sterilizers have more than one type of cycle. Ensure you use the correct cycle for the load.
- The presence of a vacuum stage does not guarantee that the sterilizer is capable of processing every type of load.

When seeking quotations from prospective suppliers you should specify clearly the type of load that you intend to reprocess. Important factors will be:

- quantities of instruments you are likely to reprocess per load and per day;
- whether the loads are solid (e.g. forceps, dental probes);
- if you want to process hollow items (e.g. cannulated devices, dental handpieces), what the limitations are for their length and diameter;
- whether you intend to process porous loads;
- the types and numbers of layers of wrapping that you expect to use;
- whether you wish to store sterile devices in packs or wrapping for future use.

This will form part of the purchasing contract and places the onus on the supplier to provide equipment that is fit for the purpose that you have specified. The supplier will also be under an obligation to draw your attention to any limitations to the use of the sterilizer. The contract should also specify who has the responsibility for installing the sterilizer and performing installation checks and tests to ensure that the sterilizer will perform to its design specification. These tests are likely to require specialist knowledge and equipment.

Many sterilizers are bought on verbal assurances of their suitability but are later found to be unsuitable for the intended purpose. You should ask for the assurances in writing to reduce the possibility of misunderstandings.

The purchasing decision should be made in conjunction with a person with the necessary purchasing authority (e.g. the purchasing manager). The decision will also benefit from inputs from:

- your local infection control advisor;
- the estates and medical engineering departments (or anyone else who is likely to maintain, service and test the equipment);
- an Authorised Person (sterilizers) (AP);
- any other users who can provide personal experience of the equipment.

It is also important to try to involve everyone who might use the sterilizer. If possible obtain one for a trial period before committing yourself to purchase as this will help you to assess other important aspects e.g.:

- whether the instructions for use are intelligible to the operator;
- the routine maintenance;
- the running costs;
- ease of use;
- cycle time.

Later difficulties will be minimised if you consult fully at the purchasing stage.

You might be offered the option of a printer, installed on the machine. It is not a requirement to have a recorder fitted, or attached, to the sterilizer but it is desirable because it makes testing easier and provides permanent records (see sections 4.4 and 5.6).

## 3.1 Service and maintenance

Efficient and effective service support is vital and should be an important factor in your purchasing decision.

Ask the supplier if:

- they can provide a service contract;
- they provide periodic testing;
- they can provide evidence that the test person is qualified;
- they have the necessary calibrated test equipment;
- spares are readily available;
- they place restrictions on the provision of spares;
- they give a guaranteed response time in the event of the sterilizer malfunctioning and what the costs are;
- they will provide a loan machine if repairs cannot be made on site.

If the supplier is unable to provide any of the above, ask if they have a servicing agent, or if there is an organisation they can recommend.

Vacuum benchtop steam sterilizers are much more complicated than their traditional counterparts and, in general, complicated devices tend to break down more frequently, and cost more to repair.

Ideally all repairs and servicing activities should be covered by a recognised quality system. Section 5 provides more information on maintenance and testing of benchtop steam sterilizers, and general information is provided in MDA's Device Bulletin DB9801. Guidance on the use of third party repair and maintenance organisations has been published in another MDA Device Bulletin, DB2000(02).

If considering purchasing a used steam sterilizer, please refer to MDA DB9801 (Supplement 2) Guidance on the Sale, Transfer of Ownership and Disposal of Used Medical Devices.

# 4. OPERATION

## 4.1 Installation, validation and periodic testing

After you have bought your sterilizer it has to be:

**(i) Installed and then validated.**
A new sterilizer has to be installed, commissioned and validated before you use it. You should retain all records of these activities in the sterilizer logbook for future reference (see section 4.4). An AP will be able to provide advice about the validation of a new sterilizer and a qualified Test Person (sterilizers) (TP) should carry out the validation tests.

**(ii) Used according to the manufacturer's instructions.**
You should use your sterilizer only to process the types of loads that the manufacturer specifies and you should keep the weight of the load within the limit specified by the sterilizer manufacturer. If you process other types of loads, or exceed the weight limit, the devices might not be sterilized (see section 2.1 for further information about the types of sterilizer and their correct application).

**(iii) Maintained and tested periodically.**
See section 5.

Because sterilizers perform a crucial role in prevention of cross infection, a new machine should never be used 'straight from the box'. Although the manufacturer should have tested it to ensure that it was working before it left the factory, that does not guarantee that it will function correctly when it is delivered. It must be tested before you use it to ensure that it **is** working correctly.

## 4.2 Use of sterilizers

Before any loads are processed you should ensure that all the relevant checks and tests are performed to provide assurance that the sterilizer is safe to use, that it is functioning correctly and that it will sterilize loads consistently. **Check that there is water in the reservoir before you attempt to operate the sterilizer.** (You will find information about the appropriate water quality in section 6).

## 4.3 Training

It is a requirement of the Provision and Use of Work Equipment Regulations 1998 that everyone who operates, supervises or manages work equipment must be trained adequately.

Effective cleaning of devices prior to disinfection or sterilization is of the utmost importance in reducing the risk of transmission of infectious agents (NHS Executive HSC 1999/179). If they are not clean they cannot be sterilized. It is therefore essential to train operators in the correct techniques.

Well-trained staff using well-maintained equipment minimises risks both to themselves and to the patient; failure to sterilize a device has implications for both. Litigation involving cross infection is particularly difficult to defend and in the event of an adverse incident, discovery of failures in training or maintenance may lead to a finding of liability by the courts, and charges of professional misconduct.

Vacuum benchtop sterilizers are complicated pieces of equipment and operators who are familiar with other types of steam sterilizer are not necessarily trained to operate vacuum benchtop steam sterilizers unless they have received specific training in the use of this equipment.

## 4.4 Records

You should keep a permanent record for each sterilizer, to provide evidence that it was/is functioning correctly and achieving sterilizing conditions consistently.

This permanent record can take any convenient form e.g. a book, a loose-leaf folder, or an electronic device (provided that it will give a printout on demand). Appendix 2 gives examples of logbooks.

It should be kept close to the sterilizer so that records can easily be kept up to date. It should provide a complete history of the sterilizer and should include:

- records of commissioning and validation tests and checks;
- routine monitoring of every sterilization cycle (see section 5.6);
- if the cycle failed, the actions taken to correct the problem – and what you did with the unsatisfactory load;
- results of all periodic testing (daily and weekly tests performed by the operator, and the quarterly and annual tests performed by the TP);
- records for every item of maintenance, repair, or any modifications;
- the written scheme of examination under the Pressure Systems Safety Regulations 2000 (PSSR) (see section 4.6.3);
- records of the inspection under the scheme of examination;
- certificate of insurance for the pressure system;
- records of training of the operator.

The NHS Executive publication HSC 1999/053 provides guidance on the time for which records should be retained.

The logbook is an important document that provides the maintenance and performance history of the sterilizer and could provide useful evidence in the event of an adverse incident.

## 4.5 Storage of devices after sterilization

After the end of the sterilizing stage, the steam condenses in the sterilizer chamber, so the load will be wet unless there is a subsequent effective drying stage whilst in the sterilizer.

**Non-wrapped wet devices**
Devices that have been sterilized, non-wrapped, in either a traditional or a vacuum sterilizer, may be used wet, directly from the sterilizer (the water will be sterilized). **These devices will not be sterile at the point of use unless they are removed from the sterilizer, kept, and used, in a controlled atmosphere such as in a hospital operating theatre.**

Controlled atmospheres are seldom found in primary care. The sterilized load items will be contaminated immediately the sterilizer door is opened. The devices cannot therefore be regarded as being sterile but will be in the same condition as the atmosphere in the treatment area.

Devices processed in a traditional benchtop steam sterilizer should be processed non-wrapped and ideally used directly from the sterilizer.

**Non-wrapped dried devices**
If you wish to store sterilized devices for later non-sterile use:

- they must be dried thoroughly in the sterilizer, before opening the door;
- they can then be stored in a clean, disinfected, dry, airtight container.

The microbiological condition of these devices should differ little from those of non-wrapped devices that are used direct from the sterilizer.

**Micro-organisms are carried on dust particles and thrive in wet or damp conditions. They cannot propagate in dry conditions.**

**Sterile use**
If you wish to store sterilized devices for future use in sterile conditions you must:

- process them in suitable wrapping material, in a **suitable** sterilizer that has an effective post-sterilization drying cycle;
- ensure that the packaging material is thoroughly dried **before** the sterilizer door is opened.

**Micro-organisms can penetrate through packaging that is wet or has any damp patches and may re-contaminate the load from the moment the sterilizer door is opened. Subsequently drying the packages (e.g. on a radiator) is inappropriate.**

Items within packaging can only be regarded as sterile if they have been subjected to a validated sterilization process and they are dry when they are removed from the sterilizer. Loads packaged after sterilization, for later use, cannot be considered sterile.

Some users of traditional benchtop sterilizers process non-wrapped devices, then wrap them (e.g. in a pouch) and repeat the process, presuming that the wrapped devices will then be sterile. This procedure is time-consuming and is unlikely to offer any improvement over sterilization of non-wrapped devices, drying them in the sterilizer and then keeping them clean (as described above).

**Storage time**
There is no specified shelf life for sterilized items. Products will remain sterile indefinitely provided the packaging remains intact, clean and dry. However, you should be aware that some devices and/or packaging might deteriorate over time. You should therefore:

- set a shelf life by consultation with the manufacturers of the device and wrapping;
- have an effective stock management system to ensure sterile items are either used within that shelf life, or are re-sterilized.

Packages must be inspected for damage before they are opened. If there is any sign of damage to the packaging, the contents must be re-sterilized before they are used.

## 4.6 Health and safety

Users will go some way towards meeting their obligations under the Consumer Protection Act and Health and Safety at Work etc Act by ensuring that equipment:

- complies with safety requirements;
- is installed and maintained appropriately;
- is validated and routinely tested;
- is operated by properly trained operators.
- is operated in accordance with the manufacturer's instructions.

Users should also ensure that there is a written scheme of examination for the pressure system under the PSSR. The pressure system must be examined periodically in accordance with this scheme.

### 4.6.1 Hazards

Some common hazards associated with benchtop steam sterilizers are:

- Burns from steam or hot instruments.
- Hot pressurised steam in the chamber.
- Contamination of the sterilizer load with endotoxin (see section 6).
- Infection resulting from inadequate processing.

### 4.6.2 The circumvention of sterilizer safety features

**On no account should any safety feature be interfered with, circumvented or overridden.**

Benchtop steam sterilizers are equipped with a number of safety features designed to protect the operator and anyone else in their vicinity from hazards, should any part of the sterilizer fail. You should have these safety devices inspected and tested in accordance with the manufacturer's instructions, which should be incorporated into the sterilizer's planned programme of maintenance to satisfy the PSSR.

To prevent serious injury to the operator and others, the sterilizer door must prevent access to the chamber while it is under pressure.

- You should not be able to open the door until the 'cycle complete' signal is indicated and there is no residual pressure in the chamber**.**
- If the chamber pressure is indicated electronically, there should also be a mechanical indication in case the electronics or power fails.
- Opening the sterilizer door when a fault message has been cancelled may result in hot water being spilt and possible injury to the operator.

Anyone who becomes aware of any malfunction or faulty equipment should report it immediately and all necessary remedial action should be taken before the sterilizer is operated.

Sterilizers that are not maintained correctly and are not tested periodically can be dangerous. The force on a benchtop sterilizer door can be about ¾ tonne.

### 4.6.3 Legal and insurance considerations

Everyone who uses the sterilizer, or the equipment processed in it, should be aware of the legal implications if infection occurs due to failure of the sterilizing process (Gifford 1998, Leigh 1998). Users should have third party liability insurance to cover the particular risks associated with pressurised equipment and steam. General insurance almost certainly will not cover these risks and medical practice insurance might not cover sterilizers unless they are mentioned specifically.

Pressurised steam is hazardous. Sterilizers should be insured to cover the particular risks associated with steam sterilizers. Some insurers specialise in this type of risk and might be the most economical choice.

The PSSR covers the installation and use of this type of equipment and amongst other things require:

- a 'written scheme of examination' for the pressure system to be drawn up by a Competent Person (pressure vessels) (CP) and
- periodic examination of the pressure system by a CP in accordance with the written scheme.

The insurer, the sterilizer manufacturer or an independent inspection organisation should be able to provide a suitable written scheme of examination. They might also have a CP who can carry out the inspection. Before the insurer will accept the insurance risk, they might insist that their own CP inspect the pressure system. This inspection might also satisfy the requirement for periodic examination under the PSSR.

An operator or owner acting negligently in circumventing safety features might:

- put themselves and others at risk of injury (or even death);
- incur legal liability for injury or damage to people and property;
- be committing a criminal offence.

Their actions might also invalidate insurance cover taken out to indemnify users and their employers against legal liability.

Relevant safety legislation imposes obligations for the safe operation of pressure systems. Sterilizer door locks and their operating mechanism, hinges and door seals all form part of the pressure containment system. Failure to ensure the safety of a pressure system can be a criminal offence.

# 5. MAINTENANCE, PERIODIC TESTING, ROUTINE MONITORING AND DOCUMENTATION

## 5.1 Introduction

Maintenance, periodic testing, routine monitoring and documentation are an essential combination to ensure that a sterilizer is functioning correctly and that it will produce sterilized loads consistently. This is because the effectiveness of the sterilization process cannot be verified retrospectively by inspection or testing of the product, and can only be guaranteed if sterilizing conditions are created throughout the sterilizer chamber and the load during every cycle. Guidance on these activities is provided in HTM2010 (NHS Estates) and DB9804 (MDA 1998).

## 5.2 Maintenance

A Test Person (TP) should draw up a schedule for periodic testing. It is the responsibility of the TP and the owner or user to ensure that these tests are performed.

You should carry out the manufacturer's recommended routine maintenance tasks at the intervals specified in the user instructions or manual. Appropriate maintenance and safety checks are necessary to ensure that the sterilizer will sterilize consistently and safely. The integrity of the pressure system must be checked periodically to ensure it conforms to the PSSR.

Poor maintenance has been a major factor in incidents in which sterilizer doors have opened while the chamber is under pressure, or where failure of the door seal has caused rapid discharge of steam. You should pay particular attention, therefore, to door locking mechanisms, which should be tested and inspected for wear as part of the weekly testing procedure. Door seals should be inspected weekly and replaced if they leak or show signs of deterioration.

The recommended safety features are described in HSE Guidance Note PM 73 'Safety at Autoclaves' (Health and Safety Executive 1998).

## 5.3 Periodic testing

Periodic testing consists of a programme of tests that are intended to demonstrate that the sterilizer's performance is satisfactory. The tests are carried out at daily, weekly, quarterly and yearly intervals, with the user and the TP sharing the responsibility for performing them. These tests are preceded by safety checks which are intended to ensure the sterilizer is both safe to use and to test.

**If the sterilizer fails any safety check you should not attempt to test it until the faults have been corrected and the sterilizer passes all safety checks.**

- The user does the daily tests. After suitable training and with the agreement of the Authorised Person (AP) the user may also do the weekly tests.
- Some of the weekly tests for vacuum benchtop steam sterilizers normally require the services of a TP and use of specialised equipment, and therefore cannot be performed by the user. However, some manufacturers have designed an automated test facility into the sterilizer so that the sterilizer can perform some of the specialised tests itself.

- The quarterly and annual tests require specialised equipment and skills, and should be carried out only by a properly qualified TP. Each cycle available to the user should be tested.

**If the sterilizer is not tested periodically you will not know if it is working correctly.**

### 5.3.1 User daily tests

**Table 3 Summary of user daily tests**

| | Daily test | Type N (Traditional) | Type B & S (Vacuum) | Appendix 4 reference | DB 9804 reference |
|---|---|---|---|---|---|
| (i) | Steam penetration | | ✓ | 1.2 | A.1 |
| (ii) | Automatic control | ✓ | ✓ | 1.1 | A.2 |

(i) The steam penetration test is intended to show that steam will penetrate rapidly and evenly into a test device that is at least as difficult to sterilize as the intended load. The test device contains an indicator that responds (usually it changes colour – and should do so completely) only when steam penetration is adequate. It is essential to use both the steam penetration test device and the indicator specified by the sterilizer manufacturer, otherwise the test results may be dangerously misleading (see section 5.4). The test piece and the indicator should be as specified in BS EN867, or an alternative provided that it is equivalent.

**If a cycle is provided specifically to test the effectiveness of steam penetration, it must have the same air removal stage as used during routine sterilization cycles.**

If you do not use the test device and indicator combination specified by the sterilizer manufacturer, the results might be dangerously misleading.

(ii) The automatic control test may be done at the same time as the steam penetration test, but is not required if the sterilizer is equipped with a recorder that provides a permanent record of the temperature, pressure and elapsed time during all sterilizing cycles. However, it is essential to compare the printed record of every cycle with one obtained when the sterilizer was known to be functioning correctly (e.g. during the periodic testing performed by the TP).

**You should check with the manufacturer whether you have to pre-heat the sterilizer chamber before performing these tests, as this can extend the test time.**

### 5.3.2 Weekly safety checks

The user should perform the following safety checks before starting the sequence of weekly tests:

- examine the door seal for signs of deterioration or leaks;
- check the security and performance of door safety devices.

**WARNING do not attempt to open the door while the chamber is pressurised.**

**Any defects must be corrected before attempting to perform the weekly tests or before using the sterilizer.**

### 5.3.3 Weekly tests

These tests should be performed after successful completion of the weekly safety checks. They should be performed by the TP but the user may perform them with the agreement of the AP.

**Table 4 Summary of weekly tests**

| | Weekly test | Type N (Traditional) | Type B & S (Vacuum) | Appendix 4 reference | DB9804 reference |
|---|---|---|---|---|---|
| a) | Air leakage test (automatic) | | ✓ | 2.2.1 | A.3.1 |
| b) | Automatic air detection system function test | | ✓ | 2.3 | ♦ |
| c)* | Automatic control test | ✓ | ✓ | 1.1 | A.2 |
| d)* | Steam penetration test | | ✓ | 1.2 | A.1 |

♦ Test method specified by the manufacturer.
* These tests may be done at the same time.

The air leakage test is intended to check that air will not leak into the sterilizer during periods of vacuum, at a rate that is greater than that specified by the sterilizer manufacturer. Air leaking into the chamber can:

- impair steam penetration into the load and prevent sterilization;
- recontaminate the damp load during the drying phase.

### 5.3.4 Quarterly and annual checks and tests

These require specialised test equipment and only a person (e.g. a TP) who has the necessary training, experience, skills and equipment should perform them. Guidance on quarterly and annual testing should be sought from an AP.

## 5.4 Use of chemical and biological indicators

If the sterilizer's 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.**

### 5.4.1 Chemical indicators

If you use chemical indicators, they should meet the requirements of relevant standards (e.g. BS EN 867, ISO 11140) and they should be used only for the process specified by the manufacturer. If you wish to use an indicator you should select the correct one and follow the indicator manufacturer's recommended instructions precisely – both for use and storage. **The use of an inappropriate indicator may give dangerously 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 sterilizers:

- 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. the indicators used to check the effectiveness of steam penetration into a test pack or a process challenge device;
- integrating indicators (emulating integrators) are available for monitoring steam sterilizers. They are designed to monitor the attainment of two or more critical variables in the sterilization process, either by a graduated response or a defined end point reaction.

**Integrating indicators do not indicate sterility of the product.**

### 5.4.2 Biological indicators

Biological indicators must meet the requirements of the standard BS EN 866 (BSI 1997). They are of limited value in steam sterilization and are restricted to a few special applications in process validation. In those applications they should always be regarded as additional to the measurement of temperature, pressure and time.

Biological indicators should not be used for periodic testing of steam sterilizers or for the routine monitoring of the process.

## 5.5 Procedure on failure of a test

A failure of a test implies that the sterilizer is not working to specification. The user should have a written procedure for handling test failures but, in all cases, the sterilizer must be withdrawn from service, the failure investigated, the cause rectified, and the sterilizer re-tested successfully before being used.

**Note: The user has the ultimate responsibility for certifying that the sterilizer is fit for use.**

## 5.6 Monitoring and documentation

Records of maintenance, testing and operating cycles provide evidence that the process will deliver sterile product consistently. HTM2010: Part 4 (NHS Estates 1997) provides guidance on the testing documentation that should be kept. Records of checks, tests and maintenance performed on the sterilizer's chamber must be documented and kept securely as specified in the PSSR (see section 4.6.3 and Appendix 5).

**Routine monitoring**
For each production cycle you should:

- note whether the sterilizer's controller indicated a passed or failed cycle;
- examine printouts from the sterilizer's recorder to ensure that they are within the prescribed limits;
- note the actions you took if a failed cycle was indicated;
- note any fault or malfunction of the sterilizer;
- keep records of every cycle.

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

**Cycle records**
Every production cycle must be fully documented and the records kept securely for the time specified by management. 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 sterilization cycle selected;
- whether the cycle was a pass or a fail;
- the chart record for the cycle;
- the identity of the operator.

**Recorders**
It is not a requirement to have a recorder fitted, or attached, to the sterilizer but it is desirable because it:

- provides a permanent record of daily tests;
- reduces time spent in performing daily tests;
- provides a permanent record of all production cycles;
- provides a unique cycle number that can be entered in the patients' notes to assist traceability;
- eliminates the possibility of typographical errors.

Records must be kept; the MDA recommends that benchtop steam sterilizers should always be equipped with a printer.

The printout should be kept securely in the sterilizer logbook (see section 4.4). Electronic data storage can replace printed records.

**Note:** Some types of printouts fade quickly (e.g. from thermal printers) and you might therefore need to take special action to preserve these records (e.g. photocopying).

**Master process record**
A record of the values and permitted tolerances of the cycle variables for each correctly functioning operating cycle, and for each load type that is to be processed, should be provided by the AP, the TP or the manufacturer. This is the master process record against which:

- the user should compare production cycle records to verify that sterilizing conditions have been achieved for each load;
- the results of the weekly tests should be compared to establish whether the sterilizer is functioning correctly and achieving sterilizing conditions;
- the results of periodic tests and performance re-qualification tests can be compared.

**Daily test records**
The results of the daily tests should be recorded in the sterilizer logbook, dated and signed by the user. Steam penetration indicator test sheets, marked with the result of the test, dated and signed by the operator, should be retained for at least six months and stored under the conditions recommended by the manufacturer of the test sheet.

The NHS Executive's Health Service Circular HSC 1999/053 provides guidance on the time for which records should be retained.

# 6. MAINTENANCE OF RESERVOIRS AND STERILIZER CHAMBERS

## 6.1 Introduction

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

## 6.2 Sources of contamination

**Water supply**
Benchtop steam sterilizers generate their own steam either within the chamber or in an adjacent boiler within the casing. Water droplets are present in steam, therefore it will contain the same contaminants as the water. These include minerals, toxic metals, and micro-organisms and their toxic products. When the steam condenses on the load during sterilization, 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 sterilizer reservoir, and chamber/boiler, is therefore crucial.

**Reservoir water**
Benchtop sterilizers usually have a reservoir for storing water to supply the chamber/boiler. Many benchtop steam sterilizers discharge condensate and residual water back into the reservoir at the end of each cycle Water left standing in the reservoir, and residual water or moisture in the chamber/boiler following a sterilization cycle, will quickly become colonised with micro-organisms which can be harmful to the patient.

**Endotoxins**
Although the micro-organisms in the water will be killed during the sterilization cycle, a heat-stable toxic substance (endotoxin) in the cell wall of many of them will remain intact. Endotoxins are resistant to steam sterilization and are only inactivated by heating for several hours at temperatures above 180$^{o}$C. Endotoxins will continually accumulate in the water and increasingly contaminate the steam until the water is changed. There are also benchtop steam sterilizers that 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 it does not remove the need to drain and clean it frequently.

**Debris**
Microbial growth may be assisted by contamination of the water, for example with debris from poorly cleaned instruments, or oil from dental handpieces.

## 6.3 Cleaning

The water reservoir should be cleaned regularly, however few sterilizer reservoirs are designed to be easily cleaned. The MDA recommends that you follow the manufacturer's guidance on how to clean the reservoir. 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 might 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 (see section 4.6.1). If you are considering using disinfectants for this purpose, you should follow the advice of the sterilizer manufacturer.

## 6.4 Water quality

The MDA recommends the use of sterile water for irrigation BP in benchtop steam sterilizers as it has specification limits for mineral, toxic metal, and endotoxin contaminants.

Tap water is not recommended as it contains dissolved minerals which can cause scaling (furring) of the heating element (or boiler) and the chamber, and lead to their early failure.

Sterilizer manufacturers usually recommend the use of distilled, de-ionised, or reverse osmosis water. These generally have low (but unknown) levels of mineral contaminants but they do not have a specification for either endotoxins or micro-organisms and they are likely to be contaminated with both. Although there is no official specification for reverse osmosis water, when the process is carefully controlled it can produce water that has both low mineral and low endotoxin contents.

Manufacturers' recommendations to use purified water safeguards the sterilizer 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 sterilizer and the patient and is the preferred quality if you perform surgically invasive procedures, in which endotoxin might be introduced parenterally into the patient. Endotoxin contamination of the sterilizer water might be of less concern if all the procedures carried out in a practice present low risk of endotoxin contamination to the patient (e.g. the instruments only make contact with intact skin or mucous membrane).

## 6.5 Suggested maintenance

The following guidance should help you to minimise contamination of your sterilizer.

- Don't 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 sterilizer 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 them dry.

- Don’t top up the reservoir. First drain the contents and then rinse it 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 sterilizer.

**To minimise contamination of the sterilizer and its load, contents of part used containers of sterile water for irrigation should be discarded, as its microbiological purity will be compromised from the moment the container is opened.**

Further information on clean steam for sterilization, and more detailed guidance, is available in HTM 2031 ‘Clean steam for sterilization’ (NHS Estates 1997); paragraphs 4.50 to 4.66 provide information that is particularly relevant to users of benchtop steam sterilizers.

# 7. GLOSSARY

**AP –** see Registered Authorised Person

**BP** – British Pharmacopoeia

**Competent Person (pressure vessels) (CP)** is a competent person or organisation undertaking certain legal responsibilities under the Pressure Systems Safety Regulations.

**Controlled atmosphere** – is one which has adequate controls to maintain a comfortable working temperature (e.g. 18 to 26°C), the relative humidity between 40% and 60%, and airborne microbiological contaminants below 35 colony forming units per cubic metre.

**Forced air removal (active air removal)** is the removal of air from the chamber using mechanical means. (A vacuum pump, steam pulsing or steam injection through the lumen of a device may be considered to be forced air removal).

**Hollow devices e.g. devices with lumens**
If a device is open at **one** end, it is hollow if:
– the ratio of cavity length to diameter is greater than one,
If a device is open at **both** ends, it is hollow if:
– the ratio of cavity length to diameter is greater than two.

**Lumen** – a cavity or channel within a tube.

**Manager** – the person who is ultimately accountable for the operation of the premises. Depending on the nature of the organisation, this may be the owner, occupier, employer, general manager, chief executive, or other person of similar authority. In small, autonomous installations the manager might also be the user.

**Manufacturer** – a person or organisation responsible for the manufacture of a sterilizer or other equipment.

**Operator** – any person with the authority to operate a sterilizer, including the noting of sterilizer instrument readings and simple housekeeping duties and by agreement daily/weekly testing.

**Performance qualification (PQ)** is the process of obtaining and documenting evidence that the equipment as commissioned will produce acceptable product when operated in accordance with the process specification.

**Porous material** – material, or load configuration, that can hold or trap air that will interfere with steam penetration.

**Registered Authorised Person (sterilizers) [AP(s), abbreviated to AP]** is a person designated by management to provide independent auditing and advice on sterilizers and sterilization and to review and witness validation and periodic test documentation. A list of suitably qualified APs is maintained by the Institute of Healthcare Engineering and Estates Management (IHEEM) (see Appendix 6).

**Sterile** – an object or area is sterile if it is free from viable micro-organisms, including bacterial spores and viruses.

**Sterilizing conditions** – the ranges of the cycle variables that must prevail throughout the chamber and load during the holding time.

**Test Person (sterilizers) [TP(s), abbreviated to TP]** is a person designated by management to carry out validation and periodic testing of sterilizers.

**Type B** sterilization cycles are intended for the sterilization of wrapped and non-wrapped solid, hollow and porous loads. They have a forced air removal system.

**Type N** sterilization cycles are intended for the sterilization of non-wrapped solid products. Air removal is achieved by passive displacement with steam.

**Type S** sterilization cycles are intended only for the sterilization of products specified by the manufacturer of the sterilizer. They have a forced air removal system.

**User** – the person designated by management to be responsible for the management of the sterilizer. In a hospital the user could be a sterile services manager or theatre manager or, in primary care, a general practitioner, dentist, or other healthcare professional.

**Validation** – a documented procedure for gathering and interpreting data to show that the sterilizer complies with the manufacturer's specifications and that it is capable of sterilizing product consistently, when used according to the manufacturer's instructions. It consists of commissioning checks and tests to show that it is working correctly, and other (performance qualification) checks and tests to make sure the load (as defined by the manufacturer) will be sterilized.

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DB 9801 Supplement 2 Guidance on the sale, transfer of ownership and disposal of used medical devices. October 2001

DB 2000(04) Single-use medical devices: implications and consequences of reuse. August 2000.

DB 9804. The validation and periodic testing of benchtop vacuum steam sterilizers. June 1998.

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SN 2002(24) Steam penetration tests in vacuum benchtop sterilizers.

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SN 2000(18) Handling of surgical instruments on loan from another organisation. October 2000.

SN 1999(32) Storage of sterile medical devices. September 1999.
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SN 9619 Compatibility of medical devices and their accessories and reprocessing units with cleaning, disinfecting and sterilizing agents. July 1996

# Appendix 1 Factors to consider in choosing between benchtop sterilizers, single-use devices or SSD

By using single-use devices or by having your devices reprocessed by a SSD, you reduce your legal liability that might arise from reprocessing devices yourself.

The practicability of using a SSD will be determined by a number of factors, particularly the timely availability of sterilized devices, which will depend on:

- the turn-round time* of using the SSD service;
- the number of instruments or instrument sets that you have. (You will need more instruments when the turn-round time is long or if you use the instruments frequently.)

Safety (e.g. the assurance that the load has been sterilized) should be the prime consideration. The most cost-effective solution should emerge from careful consideration of the respective costs of each option.

If you use a SSD these will include:
- cost of additional instruments to accommodate long turn-round times;
- logistics;
- cost of the SSD service.

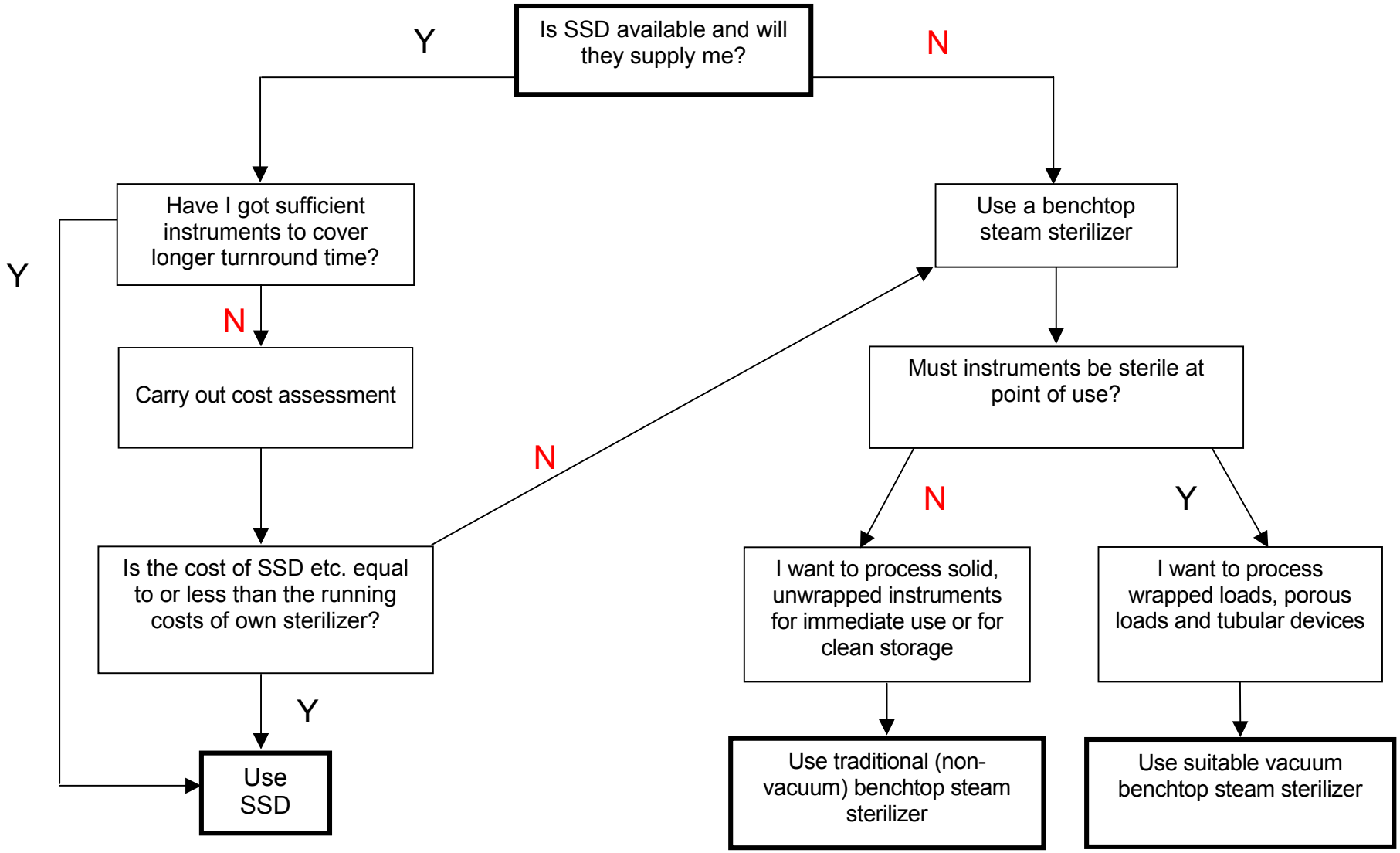
These should be weighed against the costs for the benchtop sterilizer option, including:
- the purchase price of the sterilizer;
- time required for daily testing;
- cost of maintenance and periodic testing;
- operational costs (electricity, sterile water, insurance etc.);
- cost of additional instruments to accommodate prolonged cycle times;
- cost of training operators;
- reliability factor (where assessable);
- cost of meeting legal requirements (see section 4.7.2);
- cost and operation of automated instrument cleaning equipment.

The costs of using a SSD will be counterbalanced by benefits, including:
- increase in time available to treat patients;
- reduction in maintenance costs;
- effective cleaning of instruments using validated process;
- sterilization in wrapping, providing assurance that the instrument is sterile up to the point of use;
- sterilization of hollow devices and devices that have lumens;
- transfer of risk and liability associated with the decontamination process to SSD;
- improved traceability of the devices.

**MDA's advice is to use a SSD to reprocess all reusable devices, wherever possible**. This has been shown to be cost effective (Wilson et al 1999).

* Turn-round time is the time between the used instruments being despatched and their return from the SSD.

## Flow chart for decision making



# Appendix 2 Ten good-practice points for the use of benchtop steam sterilizers

- Where possible, use a sterile service facility rather than processing locally.
- Do not process wrapped, tubular or textile products in a conventional benchtop steam sterilizer – process them only in a suitable vacuum benchtop steam sterilizer.
- All items must be clean and dry before loading into the sterilizer. Do not overload the sterilizer – the load items might not be sterilized.
- Sterilization performance must be checked frequently (daily [this includes the steam penetration test on vacuum benchtop sterilizers] and weekly by the user; quarterly and annually by a competent test person). Keep written records. This is in addition to routine maintenance and cleaning.
- Drain and clean chamber and reservoir at the end of each day and leave dry. Replenish with sterile water for irrigation from an unopened container.
- Have the sterilizer's pressure system checked for safety. Keep records of all checks and repairs to the pressure system. This is a legal requirement. Do not circumvent safety features.
- Keep permanent records of every sterilization cycle.
- Keep written records all testing and maintenance carried out on every sterilizer. The records should be kept in a logbook.
- Technical advice is available from Registered Authorised Persons (sterilizers) (AP(s)). Infection Control Nurses can advise on prevention of cross infection. Consult them if you are not sure how to sterilize a piece of equipment.
- Never re-process single-use devices.

# Appendix 3 Examples of logbook pages

Appendix 3(iv) and Appendix 3(v) are reproduced with the kind permission of Scottish Healthcare Supplies. See Appendix 6 for contact details.

## Appendix 3(i) Summary details

| **Autoclave details** | | |
|---|---|---|
| Hospital/location | Department | Serial No. |
| Ref. No. | | |

| **Contents** - the following forms: | | | | | |
|---|---|---|---|---|---|
| **Name of form** | **Code** | **No.** | **Copy** | **Purpose** | **Appendix** |
| Daily test sheet | | 1 | No | A record of all daily testing | 3(ii) |
| Weekly test sheet plant history record | | 10 | No | A record of faults/maintenance | 3(iii) |
| Quarterly and yearly test sheets | | 54 | Yes | Test person's quarterly and yearly test sheets | |
| Test history record | | | Yes | History of the weekly, quarterly and yearly tests | 3(iv) |
| Autoclave history record sheet | | | Yes | Record of all faults, maintenance and repairs to the autoclave | 3(v) |
| Production log sheet | | | No | Provides a record of every sterilizer load processed | |

| **Personnel** | **Name/organisation** | **Tel. No.** |
|---|---|---|
| Management | | |
| User | | |
| Operator(s) | | |
| Infection control nurse | | |
| Competent Person(pressure vessels)* | | |
| Authorised Person (sterilizers)* | | |
| Test person(s)* | | |
| Maintenance person(s)* | | |
| Microbiologist (sterilizers)* | | |

*These personnel should have qualifications/ training/ registration defined in HTM2010 Part 1.

| **Pressure systems safety regulations 2000**<br>This section to be filled in by the Competent Person (pressure vessels) | | |
|---|---|---|
| Written scheme of inspection exists/is suitable | | |
| Inspection carried out on | Date: | Inspected by: |
| Result of examination / comments | | |
| | | |
| | | |

| **Review of records by Authorised Person (sterilizers)** | | |
|---|---|---|
| Date | Comments on review | Signature |
| | | |
| | | |
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| | | |

# Appendix 3(ii) Daily test sheet

Tests to be carried out in accordance with HTM2010.

| Sterilizer location | Serial No. | Week beginning |
|---|---|---|
| Department | | Ref. No. |

| | | During sterilizing hold period | | Sterilizing hold time | Automatic control test result Pass/Fail | Steam penetration test Pass/Fail | Certified fit for use by user |
|---|---|---|---|---|---|---|---|
| | Cycle number | Temp °C min/max | Pressure bar | Min : sec | | | |
| Mon | | / | | : | P/F | P/F | |
| Tue | | / | | : | P/F | P/F | |
| Wed | | / | | : | P/F | P/F | |
| Thur | | / | | : | P/F | P/F | |
| Frid | | / | | : | P/F | P/F | |
| Sat | | / | | : | P/F | P/F | |
| Sun | | / | | : | P/F | P/F | |

| **Reservoir water changes (where applicable).** Drain, rinse and refill with sterilized water for irrigation. See HTM 2031 | | | |
|---|---|---|---|
| | Cycle number when water changed | Comments | Water changed by |
| Monday | | | |
| Tuesday | | | |
| Wednesday | | | |
| Thursday | | | |
| Friday | | | |
| Saturday | | | |
| Sunday | | | |

| **Faults-new or existing (also enter in plant history record)** |
|---|
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# Appendix 3(iii) Weekly test sheet

Tests to be carried out in accordance with DB9804.

| Sterilizer location | Serial No. | Department |
|---|---|---|
| Ref. No. | | |

| Week beginning | Cycle number | *Automatic air leakage test result Pass/Fail | *Automatic air detector system function test Pass/Fail | Automatic control test result Pass/Fail | Steam penetration test Pass/Fail | Weekly safety checks Satisfactory/ Unsatisfactory | Certified fit for use by user |
|---|---|---|---|---|---|---|---|
| | | P/F | P/F | P/F | P/F | S/U | |
| | | P/F | P/F | P/F | P/F | S/U | |
| | | P/F | P/F | P/F | P/F | S/U | |
| | | P/F | P/F | P/F | P/F | S/U | |
| | | P/F | P/F | P/F | P/F | S/U | |
| | | P/F | P/F | P/F | P/F | S/U | |
| | | P/F | P/F | P/F | P/F | S/U | |
| | | P/F | P/F | P/F | P/F | S/U | |

* Only where the sterilizer has an in-built self-test programme. Otherwise the test should be carried out by a TP and copies of the TP's 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 |
| | | | | | S/U | |
| | | | | | S/U | |
| | | | | | S/U | |
| | | | | | S/U | |
| | | | | | S/U | |
| | | | | | S/U | |

| **Faults- new or existing (also enter in plant history record)** |
|---|
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## Appendix 3(iv) Autoclave history record sheet

| | | |
|---|---|---|
| Type of autoclave | | |
| Hospital/Location | Start date for this sheet | |
| Department | Ref. No | Ser. No |

| **FAULTS RECORD** | | | | | | **MAINTENANCE RECORD** | | | |
|---|---|---|---|---|---|---|---|---|---|
| Fault number | Date | Cycle number | Details of fault | Noted and reported by | | Date | Fault number | Maintenance Record-include PPM as well as fault finding details | Carried out by |
| | | | | | | | | | |
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## Appendix 3(v) Production log sheet- benchtop autoclave

| Hospital/ Location | Start date for this sheet | |
|---|---|---|
| Department | Ref. No | Ser. 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 | |
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# Appendix 4 User tests for benchtop steam sterilizers

## 1 Daily tests

You should perform the daily tests every day that the sterilizer is used, as they are your check that the sterilizer is achieving sterilizing conditions. (The daily tests also form part of the quarterly and annual tests carried out by the TP(s).)

### 1.1 Automatic control test

The test requires the temperature and pressure profiles, and the elapsed time of the cycle to be compared with the values obtained when the sterilizer was known to be working correctly e.g. immediately after the TP(s) tested it using calibrated instruments. You should perform the test using the sterilizing cycle with the highest temperature compatible with the load. If your sterilizer does not have a printer fitted, observe and note the following during the sterilizing (holding) stage of the cycle:

- the chamber temperatures and pressures indicated on the gauges;
- their maximum values;
- its duration in minutes and seconds.

A printer fitted to the sterilizers will perform this task for you, providing an accurate, permanent, record and saving your time. **Note it is the MDA's opinion that benchtop sterilizers should be equipped with a printer.** You should compare the values that you noted, or the values on the print out, with those on the master process record (see section 5.7).

The test can be considered satisfactory if at the end of the cycle:

- the chamber temperature and pressure is within the limits of the appropriate band, for the duration of the holding time, as specified in Table 1(see section 2);
- a visual display of 'cycle complete' is indicated;
- no mechanical or other anomaly is observed.

For traditional, gravity displacement sterilizers (Little Sister® types), the test should be performed with the chamber empty (see HTM 2010 Part 3,) but to save time, it is often performed while sterilizing a load. If you perform the test with a load, ideally the load composition should be the same each day). For sterilizers with a type B or type S cycle, you can do this test at the same time as the steam penetration test (T1.2) but the steam penetration test must be performed with the chamber empty except for the test device.

### 1.2 Steam penetration test (for type B and S sterilizers only)

You should perform this test at the start of every day the sterilizer is used, as it is important to be sure that the air removal stage is effective, and that any residual air and other non-condensable gases (NCG) will not interfere with the sterilization 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.**

#### 1.2.1 Sterilizers with Type B cycles

This test is analogous to the Bowie and Dick test performed on large porous load sterilizers in hospitals' SSD departments. A specified test pack of material, containing a special chemical indicator, is processed through a sterilization cycle. When the level of NCG is below predetermined limits, steam will penetrate rapidly and completely into the pack and the indicator will show a uniform colour change. When NCG is present, it will collect towards the centre of the pack as a bubble and will impair contact between the steam and the indicator. The temperature or moisture level (or both) will be lower in the region of the bubble and will result in a non-uniform colour change of the indicator. When the indicator is examined

after processing, a uniform colour change of the indicator over its entire surface shows that sufficient air and other NCG had been removed to allow the steam to penetrate rapidly and evenly into the test pack.

The result of the test should be recorded in the sterilizer log book, and the indicator paper should be marked with the result and kept for reference for six months. (The relevant standard, BSEN867: 2001 requires the colour of the processed indicator to remain stable for six months after processing, when stored according to the manufacturer's instructions.)

**If the test result is unsatisfactory, repeat the test. If it is still unsatisfactory, the sterilizer is faulty. Call an engineer to investigate and repair the fault. The sterilizer must not be used until the fault has been rectified.**

There are two types of test pack, a standard test pack that you make up yourself, and a proprietary single-use test pack that you purchase. The specification for the standard pack is provided in BS EN 867: 2001 Part 5. You have to incorporate into the pack an indicator sheet made to a stringent specification. Proprietary packs normally incorporate an appropriate indicator sheet during manufacture.

**Note: You must use the test pack specified by the sterilizer manufacturer because if you do not, the results could be dangerously misleading.**

If you use the standard test pack, you should use it according to the instructions of the sterilizer manufacturer but if you use a proprietary test pack, follow the instructions of the manufacturer of the test pack.

### 1.2.2 Sterilizers with Type S cycles

This type of cycle is for processing the loads specified by the sterilizer manufacturer. The sterilizer manufacturer will therefore have to specify the test to demonstrate the effectiveness of the air removal stage. You should use only that test unless there is an alternative available that has equivalent performance. (NB Validation data must be available to demonstrate equivalence.)

### 1.2.3 Test procedure

**Use only the test pack specified by the sterilizer manufacturer.**

Place the test pack in the position specified by the manufacturer - which should be the position from which it is most difficult to remove air from the load. Select a standard cycle or the cycle specified by the sterilizer manufacturer.
**Note: if there is a special cycle for the air removal test, it must have exactly the same air-removal process as the standard processing cycles.**

At the end of the test, examine the indicator sheet. The test is satisfactory if the indicator has changed colour uniformly over its entire surface, as specified by the indicator manufacturer.

## 2 Weekly tests

### 2.1 Safety checks

You should perform these before starting the sequence of weekly tests.

Examine the door seal and replace it if necessary. You might need to call an engineer to do this.

Check the security and performance of door safety features

**Note: It would not be prudent to attempt to open the door while the chamber is pressurised. The door securing mechanism (which includes hinges as well as the door lock and interlocks) should be checked before the chamber is pressurised, or at the start of a cycle. You should consult the sterilizer manufacturer for details of the appropriate procedure.**

## 2.2 Air leakage test

This test should be performed weekly. It is an important test because if air leaks into the chamber at a rate greater than that specified by the sterilizer manufacturer:

- it might interfere with the penetration of steam into the load and prevent sterilization;
- during the drying stages, it will not have passed through the bacterial retentive filter and there is a risk of recontaminating the load.

Air is first removed from the chamber until the pressure is the lowest achieved in all of the cycles available on the sterilizer and then the vacuum source is isolated and all valves connected to the chamber are closed. The absolute pressure is measured at the end of the vacuum stage. Any subsequent rise in the chamber pressure will be caused by air leaking into it - and the rate of pressure rise in the chamber is measured.

Ideally the sterilizer should be equipped with an automated test cycle so the user can do the test. If there is not an automatic test facility, a TP(s) has to do the test using special, calibrated instruments.

The pass/fail criteria are:

- the absolute pressure at the end of the air removal stage is within the limits specified by the manufacture and
- the rate of pressure rise must not be greater than 1.3 mbar per minute.

**A machine that fails to meet the requirements of this test should not be used until the fault has been rectified and the test satisfactorily completed.**

### 2.2.1 Automatic test - user.

You should carry out this test weekly, following the instructions of the sterilizer manufacturer

The sterilizer must indicate clearly whether the test result is a pass or fail.

### 2.2.2 Manual test - Test Person.

This test method is described in HTM2010: Part 3 paragraphs 11.1 to 11.18.

The test should be considered satisfactory if the absolute pressure at the start of the 10 minute period is within the limits specified by the manufacturer, and the rate of pressure rise during the test is not greater than 1.3 mbar per minute.

The detailed method and pass / fail criteria are in DB 9804 Annex A.

## 2.3 Air detectors

Because effective removal of NCG is so important to the achievement of sterilizing conditions, porous load sterilizers must be fitted with a means to detect, during every cycle, residual NCG that would prevent the attainment of sterilizing conditions. These devices are commonly called air detectors. Vacuum benchtop steam sterilizers must be equipped with either an air detector, or another system that is capable of being validated, for detecting the presence of NCG.

### 2.3.1 Air detector testing

The air detection system must be tested weekly, quarterly and annually to demonstrate that it is functioning correctly. This test is performed weekly.
There is such a wide variety of vacuum benchtop steam sterilizers that there is not a standard air detection system, and each sterilizer manufacturer must therefore specify the test method to demonstrate that the automatic air detection system is functioning correctly. Although the test methods may differ, in all cases the test result shall meet the criteria specified in 5.1 of DB9804 when using a test pack representing the maximum density of porous load material that the sterilizer is capable of processing.

Air detector system performance tests and function tests must also be performed quarterly and annually by the TP(s) using independent, calibrated instruments. The results of these tests shall demonstrate the correct functioning of any automatic air detection system fitted to the sterilizer.

# Appendix 5 Regulation of transportable steam sterilizers

### The medical devices directive and the medical devices regulations

Medical devices are regulated throughout Europe by the Medical Devices Directive, Council Directive 93/42 EEC – which has been transposed into UK law as the Medical Devices Regulations 2002 SI 2002 No 618. These pieces of legislation regard sterilizers as medical devices if their manufacturer intends them to be used for re-processing reusable medical devices.

Since the Directive and the Regulations came into force in June 1998, medical devices may be placed on the market (i.e. supplied) only if the manufacturer claims the equipment meets the relevant 'essential requirements' of the Directive. This means that the equipment is considered to be as safe as possible and is fit for its intended purpose. Such devices must bear the CE marking to signify the claim of conformity and this enables the product to be freely sold throughout the EC without further control.

To help manufacturers to meet the essential requirements, the European Commission has mandated harmonised European standards to cover specific essential requirements. Products manufactured to comply with such standards are automatically presumed to satisfy the relevant essential requirements. A European standard for transportable steam sterilizers is in preparation (BS prEN 13060:2002) but it will be some time before it is finished. Until then only the following standards are considered to be relevant to vacuum benchtop steam sterilizers:

**European Standard BS EN 554**: **1994:** Sterilization of medical devices - validation and routine control of sterilization by moist heat.

**British Standard 3970: Part 1: 1990:** Sterilizing and disinfecting equipment for medical products; specification for general requirements.

Further information on the Medical Devices Regulations is available from the MDA.

### Pressure systems safety regulations

Steam is particularly hazardous, and steam sterilizers are a source of contained energy. To protect Users and others from risk of injury if any part of the pressure system fails, there are regulations for the design and construction (including safety features) of these sterilizers, and also for their use. Design and constructional aspects are covered by the Pressure Equipment Regulations while use and maintenance are covered by the Pressure Systems Safety Regulations 2000 (PSSR). The owner of the sterilizer is primarily responsible for compliance with the PSSR.

**Operation.**

There is a duty on the employer to ensure that anyone using, managing or supervising work equipment has received adequate training (PSSR). The employer must also provide:

- all procedures and information needed for the equipment to be operated safely;
- any special procedures to be followed in the event of an emergency (e.g. failure of the door gasket);
- information on the dangers of forcing doors (either open or closed);
- instructions for checking door locking mechanisms in both the open and closed positions;
- instructions for checking that the chamber is not pressurised before attempting to open the door.

**Maintenance**

The equipment must be properly maintained and kept in good repair to prevent danger. The type and frequency of maintenance will depend upon a number of factors including:

- the age of the equipment;
- how much it is used;
- reports of previous maintenance or inspection;
- any repairs or modifications that have been made;
- manufacturers instructions;
- reports of examinations made under the written scheme of examination.

**The written scheme of examination.**
The PSSR require pressure equipment to be inspected periodically and the owner's responsibilities (summarised) are:

- to define the scope of the written scheme of examination. A Competent Person (pressure vessels) (CP) must provide the written scheme, CPs may be found via the manufacturer or insurer);
- to ensure that the parts of the sterilizer defined in the written scheme are examined by a CP;
- not to allow the sterilizer to be operated unless a written scheme has been drawn up and certified as suitable by a CP;
- to ensure that the system is properly maintained in good repair, so as to prevent danger.

The Competent Person (Pressure Vessels) has two principal duties under the Regulations:

- drawing-up the written scheme of examination, or certifying that it is suitable;
- carrying out examinations in accordance with the written scheme, assessing the results and reviewing the written scheme for its suitability.

Information on Competent Persons (Pressure Vessels) can be obtained from United Kingdom Accreditation Service (see Appendix 6).

**An Authorised Person (sterilizers) will be able to advise on the application of these Regulations to any particular system.**

# Appendix 6 Sources of further information

**Association of British Health-Care Industries (ABHI)**
St Georges House
195-203 Waterloo Road
London
SE1 8WD

http://www.abhi.org.uk
Email: enquiries@abhi.org.uk
Tel: 020 7787 3060 Fax: 020 7787 3061

**NHS Estates**
The Information Centre
1 Trevelyan Square
Boar Lane
Leeds LS1 6AE

Website: http://www.nhsestates.gov.uk/
Email: nhs.estates@doh.gsi.gov.uk,
Tel: 0113 254 7070 Fax: 0113 254 7167

**NHS Purchasing and Supply Agency (PASA)**
Premier House
60 Caversham Road
Reading
RG1 7EB

Website: http://nww.pasa.nhs.uk/
Email: pasa@doh.gsi.gov.uk
Tel: 0118 980 8600 Fax: 0118 980 8650

**Scottish Healthcare Supplies**
Trinity Park House
South Trinity Rd
Edinburgh
EH5 3SH

Website: http://www.show.scot.nhs.uk/shs/
Email: supplies@shs.csa.scot.nhs.uk
Tel: 0131 552 6255 Fax: 0131 552 6535

**The Health and Safety Executive**
Website: http://www.hse.gov.uk/
Tel: 08701 545500
E-mail: hseinformationservices@natbrit.com

**The Institute of Healthcare Engineering and Estate Management (IHEEM),**
2 Abingdon House
Cumberland Business Park
Northumberland Road
Portsmouth
P05 1DS

Website: http://www.iheem.org.uk/
Email: iheem@btconnect.com
Tel: 023 9282 3186 Fax: 023 9281 5927

**United Kingdom Accreditation Service (UKAS)**
21-47 High Street
Feltham
Middlesex
TW13 4UN

Website: http://www.ukas.com/
E-mail: info@ukas.com
Tel: 020 8917 8400

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SE1 6XH Fax: 01623 724 524 Email: doh@prologistics.co.uk

Quoting reference MDA DB2002(06)

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Medical Devices Agency
An Executive Agency of the Department of Health
ISBN 1 84182 615 4
OCT 02 20K