

VIEW  
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BULLETIN

*Guidance on the  
Purchase,  
Operation and  
Maintenance of  
Vacuum Benchtop  
Steam Sterilizers*



HEALTH ESTATES

ESTATE POLICY

*An Executive Agency of the Department of  
Health, Social Services and Public Safety*

*Áisíneacht Feidhmeannach don Roinn Sláinte,  
Serbhísí Sóisialta agus Sábháilteacht Phoiblí*

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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*



The key aim of the Northern Ireland Adverse Incident Centre (NIAIC), part of Health Estates, is to record and investigate reported adverse incidents involving Medical Devices and equipment used in Health and Personal Social Services in Northern Ireland and to issue warning notices and guidance to help prevent recurrence and avert patient or user injury. NIAIC has direct links with MDA who co-ordinate across the adverse incident centres in England, Scotland, Wales and Northern Ireland. NIAIC also disseminates safety information in Northern Ireland, including information provided by MDA.

*Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety.*

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# 1. SUMMARY

This Bulletin provides guidance on the purchase, operation and maintenance of benchtop steam sterilizers that have a forced air removal system to provide Type B or Type S sterilization cycles. These sterilizers are marketed as vacuum benchtop steam sterilizers or porous load benchtop steam sterilizers. Sterilizers with Type N cycles (the traditional benchtop steam sterilizer) are covered in Device Bulletin DB9605 (NI)<sup>1</sup> and are not referred to in detail in this publication.

Who this document  
is for

It is intended for potential purchasers, and all current owners and users of benchtop steam sterilizers that are intended to process:

- ◆ hollow medical devices, either wrapped or unwrapped;
- ◆ wrapped solid devices;
- ◆ porous loads.

**This bulletin should be of particular interest to:**

- ◆ **podiatrists;**
- ◆ **community healthcare workers;**
- ◆ **dental nurses;**
- ◆ **general dental practitioners;**
- ◆ **environmental health officers;**
- ◆ **general medical practitioners;**
- ◆ **infection control teams;**
- ◆ **operating theatre staff;**
- ◆ **practice nurses;**
- ◆ **risk managers;**
- ◆ **health and safety officers/advisors.**

## 2. INTRODUCTION

Steam is the preferred method for sterilizing medical devices because of its high lethality, which ensures that the process is both rapid and effective when the sterilizer is used and maintained properly. Benchtop steam sterilizers are readily available from a number of manufacturers; they are compact and therefore find widespread application in the prevention of cross infection, especially in primary healthcare.

Minor surgical procedures are increasingly being performed in primary healthcare facilities. Whenever practicable the sterilized items required for these procedures should be obtained from a central Sterile Services Department (SSD). These have the equipment and expertise to decontaminate and sterilize reusable medical devices effectively and consistently, combined with economy of scale. In the absence of central sterilizing services a benchtop steam sterilizer may be used but it must be suitable for the intended loads, and it must be validated, maintained and operated properly.

Steam sterilization requires direct contact between dry saturated steam and all surfaces of the load at one of the temperature/pressure/time relationships shown in Table 1. You should use the highest temperature compatible with the product.

**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

Direct contact with steam is prevented by blood, mucus and tissue deposits on the load items, and by air present in the chamber and load. Sterilizing conditions will not be achieved unless load items have been cleaned thoroughly and air removed effectively from the chamber and load. Cleaning may be done manually or mechanically; guidance is available in MDA's publication 'Guidance on Decontamination'<sup>3</sup>.

## Classification of benchtop steam sterilizers

A European standard for benchtop steam sterilizers is presently being prepared\*. It classifies benchtop steam sterilizer cycles according to the types of load they are intended to process.

There are two distinct types of benchtop steam sterilizer cycles, which use different methods to remove air from the chamber and load.

- (a) 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.
- (b) 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.

## Vacuum benchtop steam sterilizers

Vacuum benchtop steam sterilizers have the following features:

- a forced air removal stage prior to the sterilizing stage;
- a post-sterilization drying stage;
- no connections to mains services (except for electricity) are necessary.

They are intended to sterilize:

- hollow devices, either wrapped or unwrapped;
- wrapped solid devices;
- porous loads.

They go under several descriptions including vacuum benchtop sterilizers, or benchtop porous load sterilizers. They might also be described as Type B (or sometimes Type S) sterilizers. Type B sterilizers, should have only Type B cycles; Type S sterilizers should have only Type S cycles.

**Type B** cycles are intended for wrapped solid, hollow or porous loads and are necessary for items that cannot be processed in a Type N cycle (or a Type S cycle that is not intended specifically for these load types). They **must** have a drying stage to ensure that the load is dry before the door is opened, which lengthens the cycle time considerably.

**Type S** cycles are intended for loads specified by the manufacturer of the sterilizer. They have a forced air removal system whose effectiveness determines the types of load they are designed to process. Some models have a drying stage, which will prolong the cycle time.

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.

For the purpose of this Bulletin, all benchtop steam sterilizers with a forced air removal system are described as vacuum benchtop steam sterilizers.

\* 'Small steam sterilizers' prEN 13060

## 3. PURCHASING

### 3.1 Introduction

Before deciding to purchase a sterilizer first consider the alternatives which are mainly:

- to have your reusable devices reprocessed by a SSD or
- to reprocess them yourself.

Alternatively you could use single-use equipment. The term ‘devices’ is used throughout this bulletin to encompass devices, instruments and medical equipment. **Never reuse medical devices designated for single-use.**

**MDA’s and NIAIC’s advice is to use a SSD to reprocess all reusable devices, wherever possible.** This has been shown to be cost effective<sup>23</sup>.

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

- the turnround time\* of the SSD service;
- the number of instruments or instrument sets that you have. (You will need more instruments when the turnround time is long or if you use the instruments frequently<sup>22</sup>.)

### 3.2 Cost considerations

Cost is likely to be one of the determinants in your choice but 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 (if necessary to accommodate long turnround times);
- cost of the SSD service.

These should be weighed against the costs for the benchtop sterilizer option, including:

- the purchase price of the sterilizer;
- prolonged cycle time compared with traditional benchtop sterilizers;
- time required for daily testing;
- cost of maintenance and periodic testing;

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\* Turnround time is the time between the used instruments being dispatched and their return from the SSD.

- operational costs (electricity consumption, cost of consumables e.g. sterile water and insurance etc.);
- cost of additional instruments (if required) to accommodate prolonged cycle times;
- cost of training operators;
- reliability factor (where assessable);
- cost of meeting legal requirements (see Annex 4).

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 instrument is sterile up to the point of use;
- sterilization of hollow instruments and instruments with lumens;
- transfer of risk and liability for decontamination standards to SSD;
- improved traceability of decontamination process.

If the benchtop sterilizer option is selected, it should be a vacuum type equipped with a Type B or a suitable S cycle if you wish to sterilize:

- instruments that have lumens or are hollow;
- instruments in any form of wrapping.

Porous loads should be processed only in a Type B cycle, validated for your intended loads.

Vacuum benchtop steam sterilizers are much more complicated than traditional benchtop steam sterilizers (Type N cycle), which makes them relatively expensive to purchase. Also they require much more care in their use and maintenance, and much more rigorous periodic testing, which makes them expensive to use and to maintain in proper working order (further information is given in Section 5 and in DB9901(NI)<sup>4</sup>). Their cycle times are generally considerably longer than for their traditional counterparts (especially when there is a drying stage), which will add to their running costs. If you are contemplating purchasing a sterilizer, consider carefully whether you need this type.

### 3.3 Selection between makes and models

All medical devices being placed on the market have to conform to the Medical Devices Regulations<sup>7</sup> and bear the CE marking. Benchtop sterilizers are regulated as medical devices and have to comply with these Regulations, so the CE marking is therefore of no help in choosing between makes and models.

When seeking quotations from prospective suppliers you should specify clearly the type of load that you intend to reprocess. Important factors will be the nature and quantities of the instruments, particularly the lengths and internal diameters of lumens, the types and numbers of layers of wrapping that you expect to use, and whether you intend to process porous loads. This will form part of the purchasing contract and places the onus on the supplier to supply 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 oral 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.**

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

The purchasing decision should be made in conjunction with a person with the necessary purchasing authority (e.g. the

Purchasing Manager if there is one). The decision will also benefit from inputs from other knowledgeable people such as an Authorised Person (sterilizers) (AP) and your local infection control advisor. Later difficulties will be minimized if you consult fully at the purchasing stage.

Contributions should include those from the Estates and Medical Engineering departments (or anyone else who is likely to maintain, service and test the equipment) and any other users who can provide personal experience of the equipment. It is also important 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 feasibility of routine maintenance that the operator needs to perform, and the running costs.

**It is MDA's and NIAIC's opinion that benchtop steam sterilizers should always be equipped with a pressure and temperature recorder.**

### 3.4 Service and maintenance

Efficient and effective service support is important 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.

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.

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

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 Device Bulletins DB9904(NI)<sup>5</sup> and DB2000/02(NI)<sup>23</sup>.

### 3.5 Traditional versus vacuum benchtop steam sterilizers

Steam sterilization can only be effective when all air has been removed from the sterilizer chamber and the load. The composition of the load and the nature and characteristics of the load items are important factors that can impede air removal – and therefore determine the appropriate type of sterilizer to use.

Most instruments must be sterilized before being reused in order to prevent cross infection but some do not necessarily need to be used in a sterile

You should be aware that sterilizers that have a vacuum system (or other method of forced air removal) does not guarantee that they are suitable for processing every type of load. It is essential that the sterilizer has been validated for the types of loads that you intend to process. It is also essential that the tests should be performed on the relevant production cycles.

state. This applies to many of the instruments used in primary healthcare e.g. vaginal speculae and dental instruments, which must be sterilized between patients but the sterilized instruments need only to be kept clean and dry after sterilization and before reuse.

Instruments that are not hollow (i.e. without crevices, or lumens) may be processed in a traditional benchtop sterilizer (Type N cycle) – but the instruments must not be wrapped. If the instruments are hollow, or tubular, or have crevices, they must be processed in a sterilizer with forced air removal (i.e. using a Type B or suitable Type S cycle) that has been validated for the intended load.

- Unwrapped solid devices may be processed in a traditional benchtop (Type N cycle).
- Hollow devices may be processed unwrapped in a benchtop sterilizer that is intended for this type of load. They require a Type B or suitable Type S cycle that has been validated for the devices to be processed.
- All devices that are processed in any form of wrapping must be processed using a Type B or S cycle, in a sterilizer that is intended for this type of load. It must have an effective post-sterilization drying

“...all parts of the load to be sterilized must be free of air, so that it may permeated by the steam.”  
(Sterilization by steam under increased pressure –  
The Lancet 28 February 1959)

stage to ensure that the product is dry before the sterilizer door is opened. The load items must then be stored in a clean and dry environment<sup>6</sup>.

Some sterilizers offer a variety of cycles but MDA considers that operators should have access to only one cycle in order to minimise the possibility of selecting an incorrect cycle and failing to sterilize the load.

A sterilizer designated ‘Type B’ should have only a Type B cycle; a sterilizer designated ‘Type S’ should have only a Type S cycle. They should not also have a Type N cycle. It may be necessary to request the supplier to disable type N cycles on a multicycle sterilizer.

## 4. OPERATION

### 4.1 Introduction

After you have bought your sterilizer it has to be installed and then validated to make sure that it works correctly before you use it. It should be used according to the manufacturer's instructions and you should have it maintained and tested periodically to ensure that it is working correctly - and that it will continue to do so in future. Sterilizer manufacturers design and test their equipment to process specific types of load. **You should use your sterilizer only to process the types of loads that the manufacturer specifies. If you process other types of loads, they might not be sterilized (see Section 3 for further information about the types of sterilizer and their correct application).**

### 4.2 Installation and validation

A new sterilizer has to be installed and then validated before you use it. You should retain all records of the validation in a sterilizer logbook for future reference (see Section 4.5.1).

An AP will be able to provide advice about the validation of a new sterilizer and a Test Person (sterilizers) (TP) should carry out the validation tests. A TP should draw up a schedule for periodic testing - and it is the responsibility of the TP and the owner or user to ensure that these tests are performed. You can find guidance on validation and periodic testing, and the test methods, in Device Bulletin DB9901(NI)<sup>4</sup>.

### 4.3 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).

All items that you intend to sterilize must be clean and dry before you place them in the sterilizer chamber because contamination with residual tissue, body fluids, oil or other deposits:

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

MDA's publication 'Guidance on Decontamination'<sup>3</sup> provides details of decontamination methods and procedures.

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

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

#### 4.4 Training

It is a requirement of the Provision and Use of Work Equipment Regulations (Northern Ireland) 1999 that everyone who operates, supervises or manages work equipment must be trained properly<sup>8</sup>.

Cleaning and sterilization (i.e. decontamination) are essential to prevent

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

cross infection. Effective cleaning of devices prior to disinfection or sterilization is of the utmost importance in reducing the risk of transmission of infectious agents<sup>21</sup>. If they are not clean they cannot be sterilized. It is essential therefore to train

operators in the correct techniques and use of these processes to ensure successful and consistent sterilization of devices. 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<sup>9</sup>. Cases of cross infection are particularly difficult to defend<sup>10</sup> 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, charges of professional misconduct and potential award of damages.

#### 4.5 Records

##### 4.5.1 Sterilizer logbook

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

This record is usually described as a logbook but it can take any convenient form that provides a permanent record e.g. a book, a loose-leaf folder, or an electronic device (provided that it will give a printout on demand).

Whatever its format, 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;
- a record of every sterilization cycle, including the type of load and the cycle that was selected, and whether the cycle was satisfactory;
- 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 test person);
- records for every item of maintenance, repair, or any modifications;
- the written scheme of examination under the Pressure Systems and Transportable Gas Containers (Northern Ireland) Regulations 1991;
- records of the examination under the written scheme;
- certificate of insurance for the pressure system;
- records of training of the operator.

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 occurrence.

There are examples of a range of typical sterilizer log book pages in Annex 3.

After the end of the sterilization cycle, the steam condenses within the sterilizer

chamber and the load will be wet unless there is a subsequent effective drying stage. Instruments that are to be used immediately may be processed unwrapped and used wet (the water will be sterile) or after partial drying by natural evaporation. If you wish to store sterilized devices for future use, they must be dry and be stored in a clean dry container but they cannot be regarded as sterile. If you wish to store sterilized instruments in a sterile state for future use, you must process them in suitable wrapping material, in a validated vacuum benchtop sterilizer that has an effective post-sterilization drying cycle. The packaging material must be thoroughly dried before the sterilizer door is opened. Bacteria can penetrate through packaging that is wet or has any damp patches, and the load is liable to recontamination as soon as the sterilizer door is opened. **Subsequently drying the packages e.g. on a radiator is inappropriate** and the contents can only be considered to be clean; they must not be regarded as sterile.

Note that the unwrapped instruments only remain sterile if they are used direct from the sterilizer in a controlled atmosphere.

There is no specified shelf life for sterilized items. Products will remain sterile indefinitely provided the integrity of the packaging remains intact, clean and dry, but you should be aware that some

items might deteriorate over time<sup>6</sup>. You should therefore set a shelf life and 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 Storage of devices after sterilization

## 4.7 Health and safety

Users of benchtop steam sterilizers must ensure that the equipment:

- complies with safety requirements;
- is installed and maintained appropriately;
- is operated in accordance with the manufacturer's instructions and that
- there is a written scheme of examination of the pressure system under the regulations and
- the pressure system is examined in accordance with the written scheme of examination.

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.

There are also risks arising from contamination of the sterilizer with endotoxin that can accumulate if the sterilizer chamber and reservoir are not maintained. Section 6 provides more information.

As well as the hazards of infection resulting from inadequate processing, the sterilizer itself is a source of stored energy and is thus potentially dangerous if it is not correctly used and maintained. Also bear in mind that steam is particularly hazardous and that the instruments might be hot when they are removed from the sterilizer.

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. There should be a mechanical indicator to show if there is residual pressure. If a fault occurs, the assistance of a trained engineer may be required before the door can be safely opened and the fault diagnosed. Opening the sterilizer door when the fault message has been cancelled may result in hot water being spilt with the possibility of personal injury.

Because of the hazards associated with steam sterilizers, their use and maintenance is strictly regulated under the Pressure Systems and Transportable Gas Containers (NI) Regulations 1991 (PSTGCR) and their design and manufacture are regulated under the Pressure Equipment Regulations, 1999<sup>12</sup> (PER).

#### 4.7.1 The circumvention of sterilizer safety features

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

Sterilizers that are not maintained correctly and are not tested periodically can be dangerous. The thrust on a benchtop sterilizer door can be about  $\frac{3}{4}$  tonne.

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 PSTGCR.

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

#### 4.7.2 Legal and insurance considerations

Pressurized steam is hazardous. Sterilizers should be insured to cover the particular risks associated with steam sterilizers. Some insurers specialise in this type of risk.

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<sup>9,10</sup>. They should also be aware of

the particular hazards associated with pressure vessels and steam. Users should have third party liability insurance to cover the particular risks associated with pressurised equipment and steam. Household insurance almost certainly will not cover these risks and the practice insurance might not cover sterilizers unless they are mentioned specifically.

The PSTGCR cover 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 in conjunction with 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 their own CP carries out an inspection of the pressure system, which might also satisfy the requirement for periodic examination under the PSTGCR.

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. Sterilization therefore depends on quality assurance principles which require the process to be validated, the sterilizer to be maintained, tested periodically, and its performance monitored routinely. Guidance on these activities is provided in Device Bulletin DB9901(NI)<sup>4</sup> and Health Technical Memorandum (HTM) 2010<sup>14</sup>.

### 5.2 Maintenance

You should carry out the manufacturer's recommended routine maintenance tasks at the intervals specified in the user instructions or manual. Safety checks form part of the periodic tests that you or a TP perform on the sterilizer. Appropriate maintenance and safety checking are necessary to ensure that the sterilizer will sterilize consistently and safely, and the integrity of the pressure system must be checked periodically to ensure it conforms to the PSTGCSR<sup>2</sup>.

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' (Plant and Machinery Series) (1998).<sup>13</sup>

### 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, and the user and the TP<sup>4,14</sup> share 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 AP the user may also do the weekly tests; this should be simplified if the

sterilizer is able to perform these tests automatically. 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.

### 5.3.1 Daily tests

The user may perform these tests.

Table 2.

	Test	DB 9901(NI) <sup>4</sup> reference
1	Steam penetration test	A.1
2	Automatic control test*	A.2

\*This test can be done at the same time as the previous test.

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 5.6).

Unless you use the test device and indicator combination recommended by the sterilizer manufacturer, the results might be dangerously misleading.

**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.**

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. It is essential to compare the printed record with one obtained when the sterilizer was known to be functioning correctly (e.g. during the periodic testing performed by the TP).

**NOTE : You should check with the manufacturer whether you have to pre-heat the sterilizer chamber before performing these tests.**

### 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;
- check the security and performance of door safety devices.

**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 3.**

	Test	DB 9901(NI) <sup>4</sup> reference
1	Air leakage test (automatic)	A.3.1
2	Automatic air detection system function test	◆
3	Automatic control test	A.2
4	Steam penetration test*	A.1

◆ Test method specified by the manufacturer.

\* May be done at the same time as the previous test.

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, because air leaking into the chamber will not be sterile as it will not have passed through the bacteria-retentive filter.

### 5.3.4 Quarterly and annual checks and tests

These require specialised test equipment and only a person who has the necessary training, experience, skills and equipment should perform them.

#### 5.4 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**

#### 5.5 Routine monitoring

For each production cycle you should:

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

##### 5.5.1 Recorders

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

- reduces time spent in performing daily tests;
- provides a permanent record of 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.

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

The printout should be kept securely in the sterilizer logbook. 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.**

#### 5.6 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<sup>15, 16, 17</sup>. **Chemical and biological indicators do not indicate that the load is sterile.**

### 5.6.1 Chemical indicators

If you use chemical indicators, they should meet the requirements of EN 867<sup>16</sup> 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 manufacturer's recommended instructions precisely both for use and storage. **The use of an inappropriate indicator may give dangerously misleading results<sup>15, 16</sup>; 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<sup>17</sup>.

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

- process indicators e.g. autoclave tape and indicators printed onto bags and pouches, serve only to distinguish processed items from unprocessed items. These indicators 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 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**

### 5.6.2 Biological indicators

Biological indicators should meet the requirements of EN 866<sup>15</sup>. They are of limited value in steam sterilization<sup>17</sup> 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.

## 5.7 Documentation

Records of maintenance, testing and operating cycles provide evidence that the process will deliver sterile product consistently. HTM 2010<sup>14</sup>: Part 4 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 PSTGCR.

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 (MPR) 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 user 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.

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.

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.

## 6. MAINTENANCE OF RESERVOIRS AND STERILIZER CHAMBERS

### 6.1 Introduction

It is important that the sterilizing process should not contaminate the load items<sup>17</sup>. Many sources of potential contamination will be obvious, but it may not be obvious that 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 using water of suitable quality.

Benchtop steam sterilizers generate their own steam either within the chamber or in an adjacent boiler. Turbulence at the surface of boiling water disperses water droplets into the steam, which will therefore 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 is therefore crucial.

Benchtop sterilizers usually have a reservoir for storing water to supply the chamber or boiler. Water left standing in the reservoir, and residual water or moisture in the chamber following a sterilization cycle, will quickly become colonised with micro-organisms which can be harmful to the patient. Microbial growth may be assisted by contamination of the water with debris from imperfectly cleaned instruments and oil, for example from dental handpieces.

Although the micro-organisms 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°C.

Endotoxins, even in minute quantities can cause an inflammatory response when introduced into blood and tissues. Their levels in sterilizer water therefore need to be controlled, which is most readily accomplished by emptying and cleaning the chamber and reservoir frequently, and replenishing with water of appropriate quality.

## 6.2 Water quality

Sterile water for irrigation BP has specifications for mineral, toxic metal, and endotoxin levels, and this is the quality of water that we recommend to be used in benchtop steam sterilizers.

Because tap water contains dissolved minerals which can cause scaling of the heating element 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 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.

Sterilizer manufacturers seldom consider the microbiological quality of the water, or its other organic contaminants and they rarely provide guidance on the need to empty and clean the reservoir and chamber, and to replace the water frequently. Their recommendation to use purified water therefore safeguards the sterilizer but does not prevent contamination of the load with organic substances that can be very 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).

## 6.3 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.
- Drain the chamber and water reservoir, rinse all internal surfaces with sterile water for irrigation and leave them dry, at the end of the working day, or whenever the sterilizer is to be left unused for several hours.
- 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 Health Technical Memorandum 2031<sup>18</sup> ‘Clean steam for sterilization’; 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.

**Competent Person (Pressure Vessels) (CP)** – a competent person or organisation undertaking certain legal responsibilities under the Pressure Systems and Transportable Gas Containers Regulations (NI) 1991.

**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)** – 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.

**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)** – 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.

**PPM**– planned preventative maintenance.

**PSSR** – Pressure Systems Safety Regulations<sup>2</sup>.

**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 Annex 5).

**Sterile** – 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]** – 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 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 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.

## 8. REFERENCES

1. The purchase, operation and maintenance of benchtop steam sterilizers. DB9605(NI), Health Estates, 1997.
2. The Pressure Systems & Transportable Gas Containers (Northern Ireland) Regulations 1991. Northern Ireland equivalent legislation to the GB legislation, The Pressure Systems and Safety Regulations 2000, is currently in preparation.
3. Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Advisory Committee to Department of Health Medical Devices Agency. MDA 1996, 1999, ISBN 1 85839 518 6.
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5. Medical Device and Equipment Management for Hospital and Community-based Organisations. DB 9904(NI), Health Estates 1999
6. Storage of Sterile Medical Devices. Safety Action Notice SAN 99(45), Health Estates 1999.
7. The Medical Devices Regulations 1994, SI 1994 No. 3017. The Stationery Office.
8. The Provision and Use of Work Equipment Regulations (Northern Ireland) 1999, SR No 304
9. Gifford P. HSE's Strategy for the Health Care Sector. ISSM Journal Vol. 3 No. 1 July – September 1998.
10. The Law and Hospital Infection, Mr B Leigh, Hempsons Solicitors, London Journal of Hospital Infection, vol 40, Supplement A, September 1998, ISSN 0195-6701.
11. The Reuse of Medical Devices Supplied for Single use only. DB9501, Health Estates 1996 and DB (NI) 2000(04), Single use Medical Devices: Implications and Consequences of Reuse.
12. The Pressure Equipment Regulations 1999 SI 1999 No.2001. The Stationery Office.
13. Guidance Note PM 73 from the Health and Safety Executive – Safety at Autoclaves.
14. Health Technical Memorandum HTM 2010 Part 3: Validation and verification. Part 4: Operational Management. The Stationery Office.
15. BS EN 866: 1997 Biological systems for testing sterilizers and sterilization processes. BSI.
16. BS EN 867: 1997 Non-biological systems for use in sterilizers – Part 3 Specification for Class B indicators for use in the Bowie and Dick test. Draft BS EN 867 Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers type B and type S. BSI.
17. BS EN 554: 1994. Sterilization of Medical Devices – Validation and Routine Control of Sterilization by Moist Heat. BSI 1994.

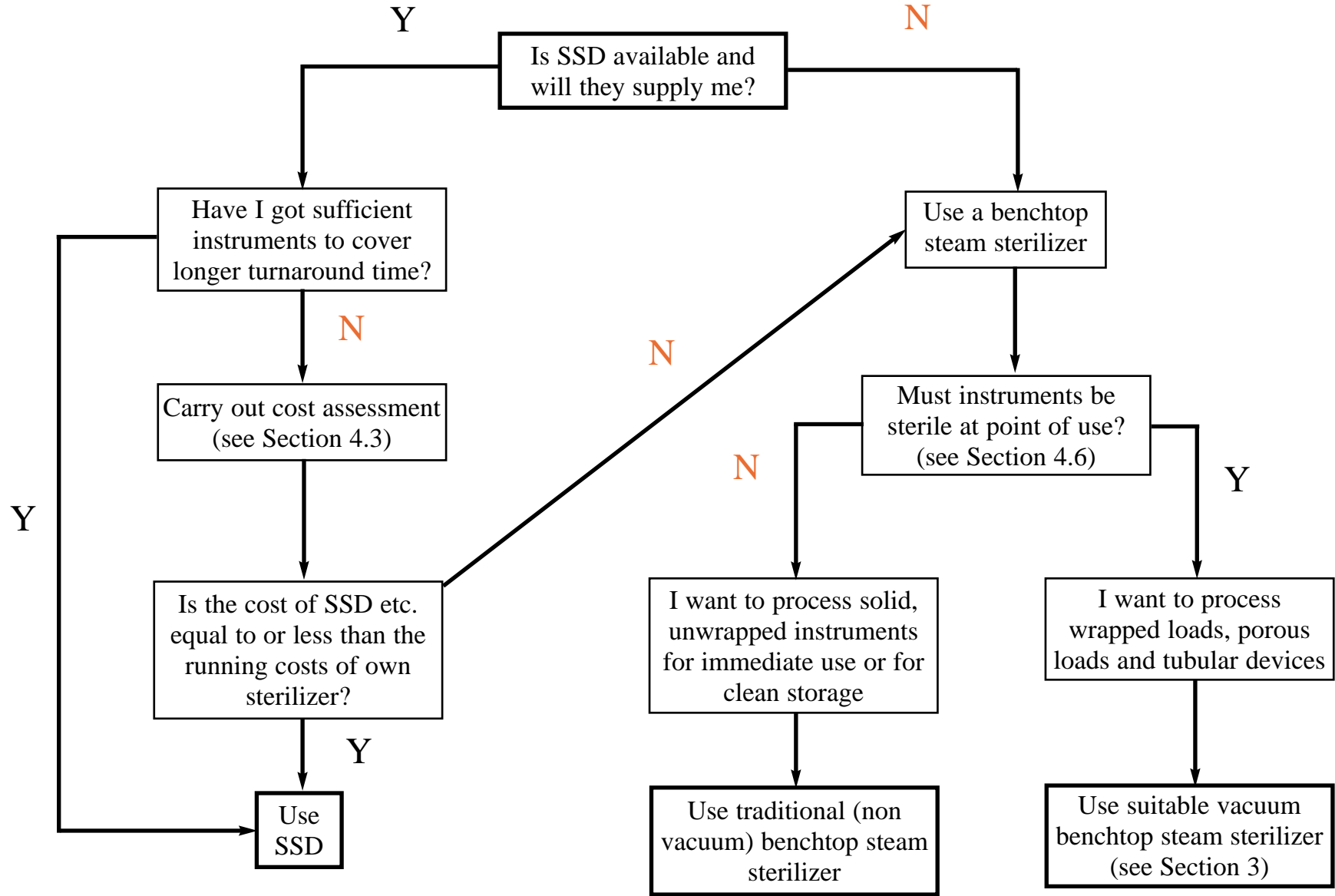
18. Health Technical Memorandum HTM 2031 Clean steam for sterilization. The Stationery Office 1997.
19. Council Directive 93/42/EEC 14 June 1993 concerning medical devices. Official Journal of the European Communities, L169, vol. 36, 12.7.93.
20. BS 3970: Part 1: Sterilizing and disinfecting equipment for medical products. Part 1. Specification for general requirements. BSI.
21. HSS (MD) 16/99, November 1999, Controls Assurance in Infection Control: Decontamination of medical devices. Department of Health, Social Services and Public Safety.
22. Wilson A P R, Brent D, Beckett G. Benchtop sterilizers and CSSD. Journal of Hospital Infection 1999; 43: 246-247.
23. Medical Devices and Equipment Management: Repair and Maintenance Provision. DB 2000/02(NI), Health Estates, 2000.

## **ANNEX 1 TEN GOOD-PRACTICE POINTS FOR THE USE OF BENCHTOP STEAM STERILIZERS**

- Use a sterile service facility instead if possible.
- 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 and weekly by the user; quarterly and annually by a competent test person). 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. Do not circumvent safety features. These are legal requirements.
- Keep permanent records of every sterilization cycle.
- Keep written records of 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. 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.

# ANNEX 2 FLOW CHART FOR DECISION MAKING

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## **ANNEX 3 EXAMPLES OF LOGBOOK PAGES**

Annex 3(iv) and Annex 3(v) are reproduced with the kind permission of Scottish Healthcare Supplies. See Annex 5 for contact details.

## ANNEX 3(i)

<b>AUTOCLAVE DETAILS</b>		
Hospital/location	Department	Serial No.
Ref. No.		

<b>CONTENTS</b> — the following forms :				
Name of form	Code	No.	Copy	Purpose
Daily test sheet			No	A record of all daily testing
Weekly test sheet plant history record			No	A record of faults/maintenance
Quarterly and yearly test sheets			Yes	Test person's quarterly and yearly test sheets
Test history record			Yes	History of the weekly, quarterly and yearly tests
Autoclave history record sheet			Yes	Record of all faults, maintenance and repairs to the autoclave
Production log sheet			No	Provides a record of every sterilizer load processed

<b>PERSONNEL</b>	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 HTM 2010 Part 1.		

<b>PRESSURE SYSTEMS SAFETY REGULATIONS 2000</b>		
This section to be filled in by the Competent Person (pressure vessels)		
Written scheme of examination is suitable		
Examination carried out on	Date	Examined by
Result of examination/comments		

<b>REVIEW OF RECORDS BY AUTHORISED PERSON (STERILIZERS)</b>		
Date	Comments on review	Signature

## ANNEX 3(ii) DAILY TEST SHEET

Tests to be carried out in accordance with HTM 2010.

Sterilizer Location	Ser. No.	Week beginning
Department		Ref. No.

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

<b>RESERVOIR WATER CHANGES (where applicable).</b> 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			

<b>FAULTS — NEW OR EXISTING (ALSO ENTER IN PLANT HISTORY RECORD)</b>

## ANNEX 3(iii) WEEKLY TEST SHEET

Tests to be carried out in accordance with DB9804.

Sterilizer location	Ser. 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	S/U	
			:	P/F	P/F	S/U	
			:	P/F	P/F	S/U	
			:	P/F	P/F	S/U	
			:	P/F	P/F	S/U	
			:	P/F	P/F	S/U	
			:	P/F	P/F	S/U	
			:	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.

<b>WEEKLY SAFETY CHECKS (Tick if satisfactory)</b>						
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	

<b>FAULTS — NEW OR EXISTING (ALSO ENTER IN PLANT HISTORY RECORD)</b>





## ANNEX 4 REGULATION OF TRANSPORTABLE STEAM STERILIZERS

### A4.1 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<sup>19</sup> – which has been transposed into UK law as the Medical Devices Regulations SI 1994 No 3017. 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 fully 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, 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<sup>17</sup>.

**British Standard 3970: Part 1: 1990:** Sterilizing and disinfecting equipment for medical products; specification for general requirements<sup>20</sup>.

Further information on the Medical Devices Regulations is available from Health Estates – including a series of Bulletins to explain various aspects of the Directive (ANNEX 6).

## A4.2 Pressure Systems & Transportable Gas Containers 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<sup>13</sup> while use and maintenance are covered by the Pressure Systems and Transportable Gas Containers (NI) Regulations 1991 (PSTGCR). The owner of the sterilizer is primarily responsible for compliance with the PSTGCR. A Northern Ireland equivalent of the GB legislation, The Pressure Systems and Safety Regulations, 2000, is currently in preparation.

### **Operation**

There is a duty on the employer to ensure that anyone using, managing or supervising work equipment has received adequate training<sup>9</sup>. 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;
- manufacturer's instructions;
- reports of examinations made under the written scheme of examination.

### **The written scheme of examination**

The PSTGCR 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 must provide the written scheme, they 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 Competent Person (Pressure Vessels);
- not to allow the sterilizer to be operated unless a written scheme has been drawn up and certified as suitable by a Competent Person (Pressure Vessels);
- 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 the National Accreditation of Inspection Bodies (see Annex 5).

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

## ANNEX 5 SOURCES OF FURTHER INFORMATION

Health Estates  
Stoney Road  
Dundonald  
Belfast BT16 1US  
Tel: 02890 523714

Regional Supplies Service  
77 Boucher Crescent  
Boucher Road  
Belfast BT  
Tel: 02890 667799

The Institute of Healthcare Engineering and Estate Management (IHEEM),  
2 Abingdon House,  
Cumberland Business Park,  
Northumberland Road,  
Portsmouth PO5 1DS  
Tel: 01705 823 186

The Health and Safety Executive for Northern Ireland (HSENI)  
83 Ladas Drive  
Belfast BT6 9FR  
Tel: 02890 542122

National Accreditation of Inspection Bodies  
United Kingdom Accreditation Service  
Queens Road  
Teddington  
Middlesex TW11 0NA  
Tel: 020 8943 6657

The Association of Sterilizer and Disinfector Manufacturers  
St George's House  
195-203 Waterloo Road  
London SE1 8WD  
Tel: 020 7787 3060  
Fax: 020 7787 3061



## **ANNEX 6 HEALTH ESTATES/MDA PUBLICATIONS RELEVANT TO STERILIZATION**

DB9501 January 1995. The Reuse of Medical Devices Supplied for Single use only.

DB9605 (NI) June 1996. The purchase, operation and maintenance of benchtop steam sterilizers.

DB9607 (NI) November 1996. Decontamination of Endoscopes.

DB9901 (NI) February 1999. The validation and periodic testing of benchtop vacuum steam sterilizers.

SAN (NI) 99(53) Storage of Sterile Medical Devices.

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## **DISTRIBUTION**

This Device Bulletin should be brought to the attention of general medical practitioners, community healthcare workers, general dental practitioners, podiatrists, practice nurses, dental nurses, operating theatre staff, infection control teams, risk managers and environmental health officers.

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