SOP
Use of Steam Autoclaves

Ministry of Health and Wellness
MAURITIUS

March 2025

Approval Form

Version: 1.0 **Effective date:** 20/3/25

STANDARD OPERATING PROCEDURE FOR THE USE OF STEAM AUTOCLAVES			
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PEER REVIEW

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Date of next review: 31/12/2028

Standard Operating Procedure for Steam Autoclaves

Challenges faced

During recent visits to the five regional hospitals in Mauritius, it was observed that the majority of surgical instruments that are used in the wards and outpatient departments are re-processed at the point of use. Several wards have dry heat sterilisers and medical devices are cleaned after use and placed mostly uncovered in the dry heat sterilisers. They are sometimes placed in a stainless-steel container with a lid which does not fit tightly or at other times they are placed in a bigger drum with a closed lid. When the drum is however opened to take out instruments, the remaining instruments can no longer be regarded as sterile. The cycle temperatures and duration are not standardised and vary between wards and hospitals. Processed instruments often stay in the steriliser until they are used. Sterilisers are frequently opened to take out instruments to use. Storing sterilised surgical instruments uncovered poses a risk of contamination and these instruments cannot be regarded as sterile.

It is the recommendation by both the World Health Organisation (WHO)[1] and the Centre for Diseases Control and Prevention (CDC)[2] that clean surgical instruments should be wrapped in the appropriate material prior to sterilization. It is further recommended that saturated steam under pressure is the preferred method for sterilisation of re-usable medical devices. Steam sterilisation is non-toxic, inexpensive, has rapid microbicidal and sporicidal activity and rapidly heats and penetrates fabrics. The process can also be validated.[1,2]

Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide guidance on the use of steam sterilisation to ensure sterile re-usable medical devices.

Key points

1. Moist heat in the form of saturated steam under pressure is the most widely used and dependable method of sterilisation of re-usable medical devices. Steam sterilisation is nontoxic, inexpensive, rapidly microbicidal, sporicidal, and rapidly heats and penetrates fabric.[3]
2. According to Spaulding's classification, sterilisation is required for critical medical devices and, whenever possible, semi-critical medical devices to ensure that it is safe to use on the next patient. The preferred method for sterilisation of heat-resistant critical devices is steam/moist heat sterilisation.[1]
3. Choosing the correct sterilisation process is important to prevent damage to the item or compromise sterility.[1]
4. Sterilisation and the provision of a sterile device for a patient procedure is dependent on the whole cycle of decontamination, including cleaning, packaging, sterilisation, storage/transport, and even to the point of preparing and using the device on a patient.[1]
5. Always first consult the manufacturer's instruction to ensure that a medical device can be re-processed in an autoclave, as well as the time and temperature required for sterilisation.
6. **All medical devices that are sterilised, must first be cleaned properly with an enzymatic cleaner to ensure that all dirt, blood and body fluids are removed. Steam cannot penetrate optimally if devices are not clean.**[1,2]

7. Inspect and assemble all clean items and pack/wrap in the appropriate packaging.
8. Packaging material and techniques are designed to hold and protect the devices in order to facilitate sterilisation and to maintain sterility and permit aseptic removal of contents at the point of use.
9. The material selected depends on the recommended method of sterilisation and must comply with international standards.
10. Steam sterilisation is achieved via direct contact of the steam with all surfaces of the medical devices.
11. Non-porous items, such as stainless-steel forceps, needle holders, scissors, and retractors, do not trap air and therefore allow surface contact to be readily achieved.
12. Porous items, such as textiles, wrappers, rubber or plastic items, items with lumens or with sliding parts that can trap air/liquid and/or present a challenge to surface contact by the sterilant, require longer exposure times to ensure adequate steam penetration.[1,2,4]

Steps to be followed

Daily Preparation:

1. Ensure the chamber of the autoclave is clean and free of debris. Clean the chamber daily before it is used.
2. Ensure that there is adequate recording paper to monitor cycles and that the monitor is in working order.
3. The first cycle of the day is a ''warm-up'' cycle if the autoclave has been turned off or was idle for a few hours. The purpose of the warm-up cycle is to ensure that all the autoclave components reach their operating temperature and will reduce the failure of validation tests caused by cold components that contribute to air leaks.
4. On the second cycle place a class 2 indicator (Bowie & Dick test pack), in the warm empty chamber above the drain, on a pre-vacuum cycle (first or second of the day depending on whether the sterilizer was shut down). Run the test according to manufacturers' instructions. This is done to ensure adequate air removal from the chamber.[5]
5. Record the result and keep the used Bowie Dick test in a folder/secure place. All records should be kept for 5 years.
6. If the Bowie Dick test failed, repeat the test with a new Bowie Dick test pack.
7. If the Bowie Dick test fail again, shut down the autoclave for repair and recall all sterile packs after the last positive Bowie Dick test result.
8. Do a biological indicator test at least once a week according to manufacturers' instructions, with the first full load of the day as well as any load containing implants to ensure that the autoclave reaches the correct temperature for the correct duration to destroy all micro-organisms and spores. *Geobacillus stearothermophilus* spores are used for the monitoring of steam sterilization processes because they demonstrate a high resistance towards steam and high temperatures.[1,5,6]
9. Test the biological indicator in the associated incubator and record the results once it is available. [1,2,4] All records have to be kept for 5 years.

Operational Guidelines

1. Ensure that items that are sterilized are compatible with high temperatures.

2. Ensure that all packed instruments are labelled with the contents, date of sterilisation, name of person who packed the instruments.
3. Ensure that all packed items have a chemical indicator on the outside (autoclave tape) and at least a class 4 indicator inside the pack. Chemical indicators are used to confirm that the sterilant (steam) achieved good penetration in the items being sterilized and that all the parameters of the sterilization process have been met.[1,5,7]
4. Load the autoclave according to manufacturers' instructions.
5. Do not overfill the chamber. Ensure that there is adequate space to allow steam penetration of all surfaces and facilitate air removal.
6. Packages must not be in contact with the walls or ceiling of the chamber. The packages might be damaged from the heat or moisture may occur.
7. Place concave devices e.g. bowls at an angle to avoid pooling of condensate.
8. Textile packs should be placed perpendicular to the steriliser cart shelf.
9. Steri-peel packs should be placed on their edges with multiple packages being placed paper to plastic.
10. Rigid containers should not be stacked unless validated by the manufacturer for that configuration.
11. Non-porous items, such as stainless-steel forceps, needle holders, scissors, and retractors, do not trap air and thus allow surface contact to be readily achieved.
12. Porous items, such as textiles, wrappers, rubber or plastic items, items with lumens or with sliding parts that can trap air/liquid and/or present a challenge to surface contact by the sterilant, require longer exposure times to ensure adequate steam penetration. Porous loads can be a challenge to sterilize by steam.
13. Load baskets and carts in such a manner that hands of CSSD staff will not touch the packs when removing the hot trolley.
14. Make sure the door to the chamber is locked, and the appropriate cycle is selected based on the type of devices being processed.
15. On completion of the cycle, the "cycle complete indicator" will appear. Visually check the graph / printer to determine that all parameters have been met. Record the result and keep the printout.
16. In the event of a cycle failure, the entire load will need to go through the full decontamination cycle.
17. The person responsible for checking the load should sign their name on the printout before opening the autoclave door for tracking purposes.
18. Don the appropriate personal protective equipment (PPE) such as heat-resistant gloves and open the door while standing to the side to prevent burns.
19. Remove the sterile packs on a trolley. Do not touch hot packs.
20. Allow packs to cool down in a secure area. The amount of time for cooling depends on the devices that have been sterilised.[8]
21. Inspect sterilised packs to ensure integrity, external chemical indicators have changed as well as water damage or dampness.
22. Damp packs are not regarded sterile and should be re-processed.
23. Record results in a logbook and file for each autoclave.

24. Transport to sterile store.[1,4]

Monitoring of sterilisation cycles

All sterilization cycles have to be monitored to ensure sterility of the reprocessed medical devices. The following are methods of monitoring:

1. Physical: Monitor and record displays and printouts.
2. Chemical: Internal and external indicators.
3. Biological: Spore test.[1]

If the autoclave does not have a built-in printer, the operator should record the physical parameters of the autoclave. Table 1 refers:[1]

Table 1: Examples of parameters that must be recorded

Date	Autoclave number	Load number	Start cycle	Start sterilisation time	End of sterilisation time	End cycle time	Signature

Biological and Chemical Monitoring:

1. Biological indicator (BI):
    - Daily spore test e.g. *Geobacillus stearothermophilus*, which are highly resistant to steam sterilisation.
    - Place the BI in the most challenging location within the load, such as the centre of dense packs or the bottom of containers.
    - Run the cycle as usual.
    - After the cycle, incubate the BI according to the manufacturer's instructions (usually at 55-60°C for 24-48 hours) in the commercially available incubator for the specific BI. (Rapid tests are available which give a reading within 1 hour).
    - Check for any growth in the BI. No growth indicates successful sterilisation, while growth indicates a failure in the process.
    - Record the results.[1,2]
    - Positive spore test results are relatively rare and can be attributed to operator error, inadequate steam delivery, or equipment malfunction.[2]

2. Chemical indicators:

- Class 1 indicator (process indicator): Autoclave tape on the outside which changes colour when exposed to heat.
- Class 2 indicator (used in specific tests): Bowie Dick that should be done daily to test for air removal.
- Class 4 indicator (multivariable indicator): Inside the pack. Check for two or more autoclave parameters; time and temperature and indicate exposure to a predetermined

sterilisation process e.g. 134°C x 3 mimutes.[1]

3. Keep a record of the results and a copy of the Bowie Dick test results.
4. It is the responsibility of the Theatre Staff to check the internal indicator for colour change prior to surgery. The indicator should be placed in the patient's folder as part of the intra-operative notes or kept in an appropriate register for 5 years.
5. Any malfunctioning should be reported and the pack sent back to CSSD for re-processing.
6. The complete load has to be re-called when there is a sterilisation failure.[1]

Autoclave temperatures and cycle times

The preferred temperatures and durations for steam sterilisation depend on the type of load and the specific requirements of the items being sterilized. Here are the commonly recommended settings:

1. **121°C (250°F) for 15-30 minutes**:
    - This is the standard setting for most general sterilisation needs.
    - Typically used for items like glassware, metal instruments and certain plastics.

2. **132°C (270°F) for 4-5 minutes**:
    - This higher temperature is used for faster sterilisation cycles.
    - Often used for surgical instruments and other heat-resistant items.

3. **134°C (273°F) for 3 minutes**:
    - Used for rapid sterilisation of standard loads.
    - Suitable for items that can withstand higher temperatures for shorter periods.[1,2]

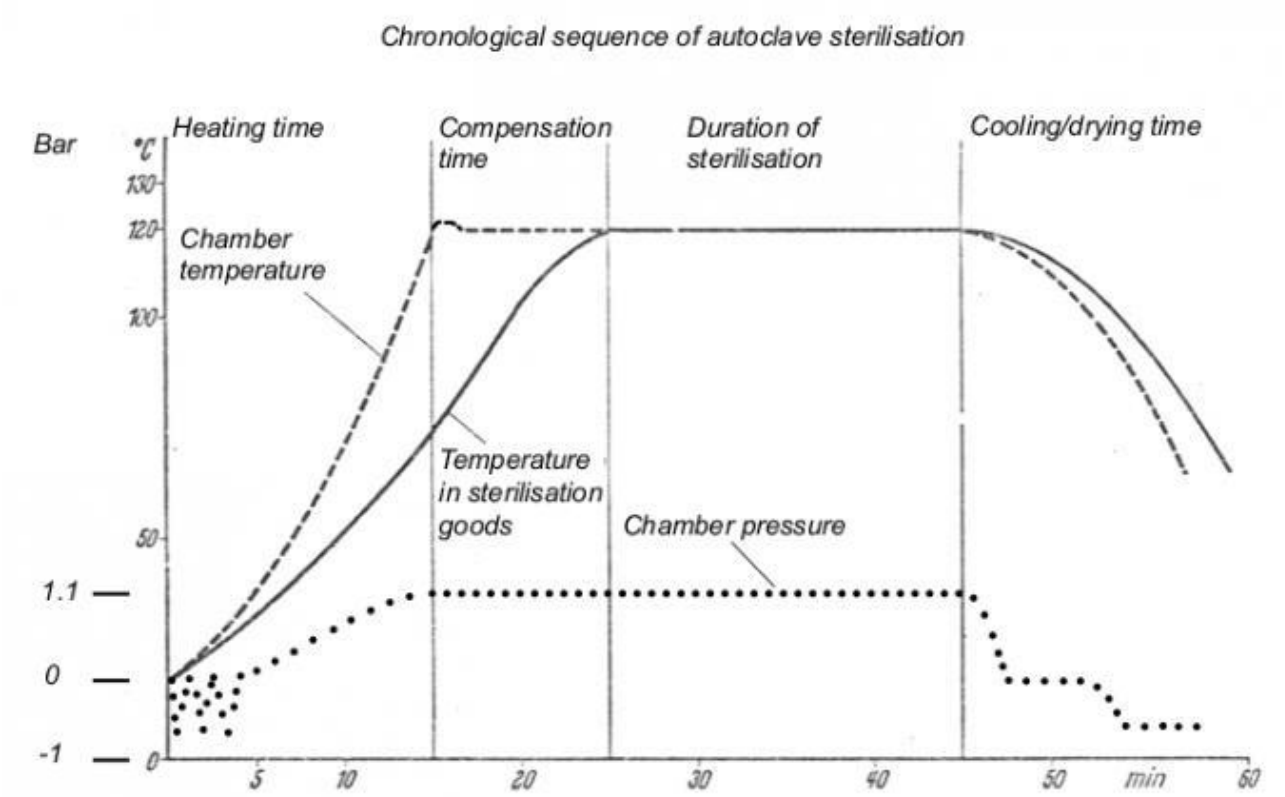

Figure 1: Example of an autoclave cycle trends chart (pressure and temperature vs time). The entire cycle can last for one hour or more. Taken from https://www.steamsterilizerautoclave.com/sale-8242464-liquid-cycle-with-pressure-ballasting-steam-autoclave-sterilization-using-autoclave.html.

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