Is it sterile?

If you put a properly prepared load into your steriliser, how can you be sure that what comes out is sterile?

By Deborah Thame, B.Pharm

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As a professional responsible for sterilisation in your practice, the 'buck stops with you'; you are the one who will need an answer to this question. So how can you have complete confidence that your steriliser is working properly and that everything that comes out is properly sterilised? It is not quite as clear cut as you may think, however a simple system of monitoring and testing can be put in place that will give you documented evidence to support your claim that your loads are coming out sterile.

The Australian Standards requirements are based on the principle that there is no stand alone test to prove sterility of a load at the end of a cycle. In other words, no single practical testing method has been found that can 'stand-alone' to comprehensively prove a steriliser's effectiveness. Therefore, a *validation procedure* that involves a series of technical tests and operator tests and monitoring has been developed. Together, the results of these are considered acceptable evidence of effective and reliable sterilisation.

What can we test and why?

To answer this, a quick revision first about some key aspects of sterilisation will make it easy to understand the monitoring and testing. One of the most important things to remember is that the steam must come into direct contact with the micro-organism to kill it. The physics of it is rather technical but in essence, it is the heat transferred from the steam to the micro-organism when the steam condenses on the living surface of the micro-organism itself that actually kills it. In understanding this, other key issues fall into place.

Anything that insulates micro-organisms from the steam will prevent killing of the micro-organisms

Anything that 'insulates' surfaces of the device being sterilised will prevent the steam from contacting the micro-organisms. It is widely understood that physical debris such as blood, body fluids or body tissues remaining on any surface of any device will insulate that surface from the steam. The micro-organisms under the debris will not be contacted or killed by the steam. Put simply - if it is not clean, it cannot be made sterile, which is why the cleaning process is so important.

The other major insulator is air. Air acts to insulate the surface of the device in the same way that physical debris does, preventing the steam from contacting the surface and the micro-organisms on the surface. If any air is trapped within the chamber or within the load or device being sterilised, the surfaces associated with that air pocket will not be sterile. Complete air removal is a particular problem with cannulated items and porous items.

All surfaces of the load must be exposed to steam for an adequate period of time to ensure that all micro-organisms present will be killed

The amount of time required to ensure that all micro-organisms contacted will be killed depends on the temperature of the steam. Internationally accepted Temperature Pressure Time (TPT) relationships for steam under pressure sterilisation have been determined. The most commonly used in Australia are:

Temperature	Pressure	Time
134°C	204 kPa	3 minutes
121°C *	103 kPa	15 minutes

* Normally only for heat sensitive items that would be damaged at 134°C.

Whichever temperature setting is chosen, it is critically important that all surfaces of the load are exposed to steam at this temperature and pressure for the minimum time specified because any surfaces of the load not contacted for the full time will not be sterile. This 'time' is the *sterilising* or *holding* time only and does not include the parts of the cycle such as air removal, heating, cooling and drying that precede and follow the sterilising time.

Testing and monitoring of the steriliser are linked to these two principles. This can be divided into two areas: tests that should be routinely carried out by a trained steriliser technician and monitoring and tests that should be carried out by the operator.

STERILISER *WITH* VACUUM	Operator Schedule					Technician's Schedule	
	Every Cycle	Daily	Weekly	Optional	Performance Qualification/ Requalification	Commissioning	Performance Qualification/ Requalification
Calibration Testing							
Heat Distribution Testing							
Penetration Time Testing							
Temperature and Pressure Testing							
Leak / Vacuum Testing		If no air detector	If air detector				
Air Removal/Steam Penetration Testing		If B Class					
Monitoring of Physical Parameters							
Chemical Indicators-Class 1							
Chemical Indicators - Class 4, 5 or 6	If no printer						
Biological Indicators							If not done by operator
Enzyme Indicators							
Process Challenge Devices							
Data loggers and Thermocouples							

Key: Yellow shaded boxes indicate operator tasks and tests. Dark blue shaded boxes indicate tasks carried out by the technician.

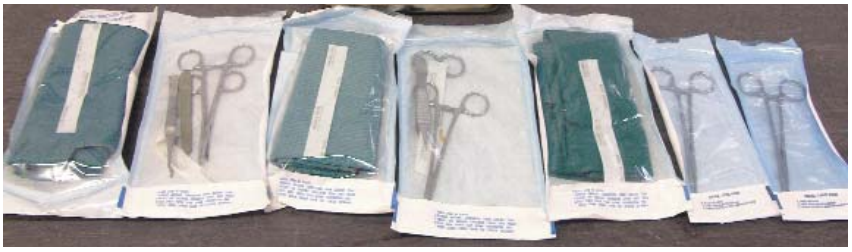
An example of a schedule of operator and technical tests for a steriliser with a vacuum function.

Testing that should be routinely carried out by the technician includes:

- Heat Distribution testing to establish the hot and cold spots within the steriliser chamber.
- Calibration testing to confirm the accuracy and performance of all temperature and pressure sensors, gauges, timers, displays, etc.
- Penetration Time testing that determines any delay between when the steriliser shows the temperature has been reached and when the most difficult to heat part of the load has reached this temperature.
- Time at Temperature testing to confirm the steriliser is reaching the correct temperature and pressure throughout the entire chamber for the entire cycle.

Testing and monitoring that should be routinely carried out by the operator includes:

- Leak/Vacuum testing (for sterilisers with a vacuum only) to check the integrity of the sterilisers vacuum system and confirm the steriliser has not developed any leaks that would allow air to leak into the chamber.
- Air removal/Steam Penetration testing (for B-class sterilisers only) to prove the steriliser is capable of removing all of the air from within the porous or Hollow A items in the load.
- Monitoring Physical Parameters using print-outs and chemical indicators to ensure that the temperature and time parameters are achieved.
- Biological Indicators to confirm the killing effectiveness of the steriliser.



An example of a photographic record of a "reference load" taken to assist operational staff.

This testing and monitoring can provide you with complete confidence in the effectiveness of the sterilisation process, providing peace of mind with respect to patient safety. Thorough documentation of all the testing and monitoring will provide you with the documentary support required to show that your steriliser is indeed functioning properly. Both are compelling reasons to undertake the task of learning and implementing a simple schedule of testing and monitoring of the steriliser in your practice.

Testing, monitoring and documenting will provide you with the 'proof' that what comes out of your steriliser is indeed sterile!

If you are interested in further information on the testing and monitoring of your small steam steriliser, or would like more information about how to set-up a system of testing and monitoring for your practice, STS Health have published an easy to read Practical Guide. Yor your complimentary copy, please email info@stshealth.com.au or call (08) 9244-4628.

About the author

Deborah Thame is the co-founder and Managing Director of STS Health, a wholly owned Australian company specialising in the distribution and maintenance of small steam sterilisation equipment.