Beyond servicing: Disclosing agent in the sterilising room

By Deborah Thame, B.Pharm

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Have you ever had a patient come into your dental practice who insists that they are cleaning their teeth properly and one look in their mouth tells you that they're fooling themselves? They insist that they have a great new toothbrush and a veritable smorgasbord of dental floss but you can clearly see considerable plaque build up on their teeth. Utilising your disclosing agent and your best chairside manner, you explain how to best use the toothbrush and the dental floss to obtain the good oral hygiene outcome that you both desire.

What has this got to do with sterilising? Same concept, different application! When was the last time you applied "disclosing agent" to your steriliser? There is more to obtaining a good sterilising outcome than simply putting the instruments into the steriliser, just as there is more to cleaning teeth than putting a toothbrush into your mouth. You may be confident that you are doing everything correctly but will it pass a "disclosing agent" test? Performance testing your steriliser as detailed in AS/NZS 4815[1] effectively serves as a "disclosing agent" for your steriliser procedures. You can have the best steriliser in the world and excellent staff but variables such as pack size, wrapping materials used, instrument complexity, variety of materials within an individual load, total load size, load configuration within the chamber, etc, all impact on the effectiveness of the steriliser to sterilise your load. The underlying principle of performance testing is to provide a documented basis for the assertion that the entire contents of every load processed through your steriliser can be confidently expected to be sterilised every time you use your steriliser. When you track critical instruments, it is this documentation that provides the primary evidence - evidence of performance testing is what you are tracking to.

Performance testing and monitoring is carried out at two levels and both are essential. The first level, Performance Qualification (PQ), is carried out by suitably qualified technical personnel. This acts as the basis for the second level of testing and monitoring, which is carried out by your practice staff on a daily/weekly basis. This second level of testing has been discussed in previous articles (see "Bowie Dick and other Air Removal Testing" *Australasian Dental Practice Mar/Apr 2007* and "Is It Sterile" *Auxiliary May/ June 2007)* and is detailed at length in "A Practical Guide to testing and monitoring small steam sterilisers", available free of charge from STS Health, so I will refrain from repeating myself here. What I would like to discuss in more detail is the PQ testing carried out by your steriliser service company.

We must start by clearing up one misconception, PQ is not servicing. Servicing of your steriliser involves checking the mechanics, hydraulics, electronics and electrical systems in

your steriliser and replacing parts subject to regular wear, so as to ensure that the steriliser continues to function safely and to the specifications set down by the manufacturer. This normally also includes calibration, which independently verifies the temperature and time of the sterilising cycle with no load in the chamber.

PQ is about testing your steriliser with your load, therefore testing is carried out using your "challenge pack" (representative of the most difficult to sterilise pack) within your "reference load" (largest load). If your steriliser is successful in sterilising this "worst case" load, then it is accepted that any of your smaller, easier to sterilise loads will be fine. PQ requires verification of both 1) physical parameters and 2) microbiological lethality. PQ testing is unique to each steriliser and results from one steriliser cannot be extrapolated to other sterilisers processing the same load.

Performance Qualification is carried out by suitably qualified technical personnel.

1. Physical parameter verification independently confirms that the physical parameters of time, temperature and pressure required for sterilisation (e.g. 3 minutes at 134ºC and 204kPa) were maintained throughout all parts of *your* challenge pack and reference load during the selected cycle in *this* particular steriliser. In other words, every surface of every item in this load was subject to steam at the required temperature and pressure for the minimum time necessary to effect sterilisation. This is very important as the time taken for all parts of the load to reach sterilising temperature can vary significantly depending on the age, model and technology of the steriliser and the size, layout and complexity of the load. Testing is carried out, with your challenge pack and reference load in the chamber, using certified independent measuring equipment that produces a printout of the cycle parameters throughout the cycle. The thermocouples are positioned in specific locations within the load and measurements are recorded at specified intervals throughout the cycle. Both the steriliser's printout and the technician's independent printout form part of the testing documentation and must be retained with the technician's written report.

2. Microbiological lethality verification is to confirm the killing effectiveness of the steriliser cycle for your load. For this testing, biological indicators containing bacterial spores are used, since spores are the most difficult of living micro organisms to kill using steam sterilisation. If the spores are inactivated, it is reasonable to expect that all other living micro organisms will also have been killed. This test is carried out using commercially available biological indicators, commonly either impregnated strips or small vials. They are processed through the steriliser in a specified manner with the challenge pack and reference load and then cultured to see if any of the bacteria survived.

Since PQ testing must show the consistency of the performance of your steriliser, both types of tests are required to be repeated a number of times on the one occasion, thereby providing evidence of the consistent performance of your steriliser. This testing should be carried out with installation (in addition to IQ and OQ) and then, at a minimum, every 12 months (see AS/NZS 4815:2006 Table 7.1).

Performance testing of your steriliser is a fundamental part of good sterilisation practice. It lays the foundation for how the sterilisation is carried out on a daily basis, defining maximum load sizes and appropriate loading configurations to ensure correct sterilisation. Performance testing provides the evidence basis that allows the operator to confidently monitor every cycle using the steriliser's own print-out, allowing for parametric release of the load. Performance testing is the foundation on which the risk management documentation of sterilising re-usable instruments is built. If performance testing has not been a part of your practice, I strongly urge you to discuss it with your service provider today.

Reference

1 AS/NZS 4815:2006 Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment. Available at www.saiglobal.com/shop/Script/search.asp

About the author

Deborah Thame is the co-founder and Managing Director of STS Health, an Australian company specialising in the sale and maintenance of steam sterilisation equipment. STS Health imports the Mocom range of Millennium sterilisers available through Henry Schein Halas nationwide. For more information, call (08) 9244-4628 or visit www.stshealth.com.au