Understanding the different types of steam sterilizers and their cycles

by Professor Laurence J. Walsh AO

Despite its long history, steam sterilisation continues to be an area where some dental practices struggle to understand the process, the equipment, and how to use it to ensure consistent performance. While virtually all dental practices have steam sterilizers (also known as autoclaves), many staff do not know the differences between the major types.

Sterilisation using saturated steam kills microorganisms by transferring heat onto the items which are being sterilized, as the steam condenses. When steam changes to liquid water, this also moistens the organisms, which increases the kill rate. Statistically, a sterilizing cycle is designed so that the opportunity for a micro-organism to survive is less than one in 1 million (This is known as the sterility assurance level, or SAL). At a temperature of 134 degrees Celsius, this time interval is 3.5 minutes.

The three types of cycle and the technology behind them are described in the European Standard EN13060. Not all types of sterilizer or cycle are appropriate for all types of load items. EN13060 specifies the general requirements for small steam sterilizers, such as those used in small office dental practice, and the methods used to test their performance, by applying standard test loads.

Displacement autoclaves (also called gravity autoclaves)

These utilize superheated steam to displace air downwards and out of the sterilizing chamber. The process that removes air is **very gentle,** i.e. by the action of steam rising coupled with cold air falling vertically by gravity in the chamber. This makes these sterilizers unsuitable for hollow items (including dental handpiec-

es) and also for wrapped items. Their cycles are known as "N" cycles, where the N means *None hollow* and *None wrapped (Naked solid items).*

- These can be used only for sterilization of unwrapped solid instruments that are NOT required to be stored in a sterile state.
- Sterilized items from N cycles are unwrapped so cannot be kept in a sterile state.
- They are not suitable for sterilization of wrapped items (including those in pouches), porous items, textiles or hollow items.

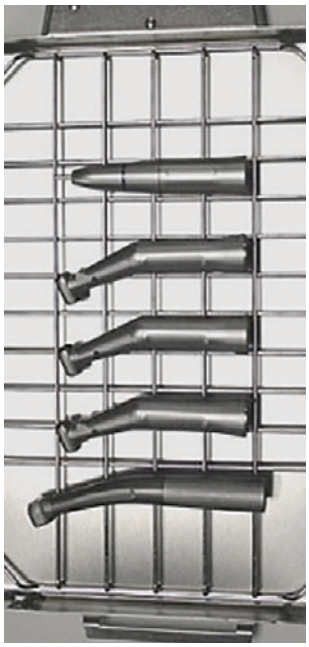
S (Specified) cycle sterilisers with assisted air removal

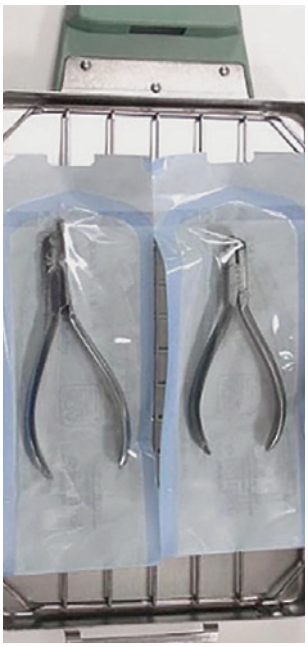
Steam sterilizers with S cycles are for *Specific* products. The manufacturer of the sterilizer has determined what a particular cycle of the sterilizer can be used for, and has specified that information for the user. In other words, the sterilizer manufacturer provide details of their performance capabilities, which they have established by conducting specific tests with those load types.

A range of bespoke (dedicated) S cycle units have been developed, including units for sterilizing dental handpieces and cassette-type compact sterilizers that use on-demand steam generation and posi- tive pressure pulsing for rapid processing (e.g. SciCan STATIM™). It is essential that staff read the instructions for these sterilisers carefully so that loads match those specified as being suitable.

S cycles use various processes for active air removal, overcoming the limitations experienced in N cycles that employ gravity displacement. This is why bespoke sterilizers with S cycles can sterilize restorative dental handpieces.

- These sterilizers may use pulsing of steam from a steam generator to facilitate air removal from the load by an active process, or may use a pre-vacuum process.
- These sterilizers can process any load type that the manufacturer has specified the load configuration for, including handpieces and wrapped items. See the examples below. Items need to be separated, not piled on top of one another. This applies for loose instruments and dental handpieces, as well as for paper/plastic pouches.
- Unwrapped dental handpieces can be sterilized in an S cycle unit, according to the manufacturer's instructions. Likewise, wrapped dental handpieces could also be sterilized in an S





cycle unit, if that is what the manufacturer stipulates. As an example of the latter, the STATIM has been tested for hollow wrapped items. In each case, refer to the manufacturer's instructions for what load types are permitted, and follow that advice exactly.

- They should not be used with items that are wrapped in multiple layers.
- They achieve rapid drying by a combination of forced filtered air or pre-vacuum and heat.
- Bespoke (dedicated) S cycle sterilizers that do not use pre-vacuum do NOT require air leak tests or air removal tests.

Pre-Vacuum autoclaves (sometimes called Class B cycles, "Big" sterilizers)

These use a vacuum pump to pump air from the chamber prior to entry of steam. The removal of air is designed to facilitate the entry and penetration of steam into the load. The air can be pumped out in one continuous phase, or in several separate phases (referred to as multi-pulsed). The latter gives better and faster air removal than a single suction phase, particularly from items with internal pipes.

Monitoring of steam sterilizers

Regular monitoring of performance for ALL types of autoclaves is necessary to prove that sterilization process param- eters are adequate. The use of chemical monitors is dictated by the type of auto- clave and the relevant standards, such as Table 7.1 of AS/NZS 4815. Such routine testing ensures that sterilization process parameters are being met on a regular basis and when the results are recorded in a permanent logbook. It verifies that certain staff members have operated the cycle and have checked the contents of the completed load to ensure that they meet expectations. There is little point in recording data from sterilizer cycles on memory cards or on hard copy printouts if these records are never scrutinised carefully immediately after the cycle has completed.

Methods for monitoring

Monitoring of autoclaves uses several methods:

- **Physical monitors** (gauges, displays, print-outs) - from every load.
- **Chemical indicators** - which change colour when proper sterilizing conditions have been achieved (e.g. adhesive inks, tapes, strips) - used on and within packs and pouches. These provide a visual assurance that conditions for sterilisation were met (heat, steam).
- **Biological indicators** (**BI's,** spore tests) - which are used at calibration and validation. Spore tests should be used after installation of a new autoclave, a major redesign or reloca- tion, servicing or major repair, after suspected malfunction, whenever the type of load or packaging system is changed, and during and after training of new staff in autoclave operation.

Pre-vacuum autoclaves are unique in that they require leakage testing for the chamber (to check the door seals and other internal leaks) as well as daily tests for proper air removal (i.e. Bowie-Dick test or helix process challenge device). The Bowie-Dick test assesses penetration of steam into a porous load, while the helix test assesses hollow items.

Sterilizer cycle records

The log of autoclave cycle data provides the necessary written documentation of sterilisation and includes parameter informa- tion on the batches of items that have been sterilised. An entry into this log should be made for all autoclave cycles, regardless of whether or not they include any packs of critical instruments.

The log book ruled columns would have the following headings:

- Date;
- Time at the commencement of the autoclave cycle;
- Cycle number in that day;
- Cycle temperature and time parameters (which will differ according whether the load contains wrapped items or unwrapped items);
- Nature of the load (numbers of packs, instrument cassettes, etc);
- Batch number(s) of packs included in that load (if any);
- Identification of the loading operator who placed items in the sterilizer chamber;
- Result of the autoclave physical read- outs (displays) or printout for that cycle;
- Result of the particular chemical indica- tors (Class 1, 4, 5 or 6) used in the cycle. This checking should include all external and all internal chemical indicators;
- Result for checking packages for conformity (e.g. seals are intact, and packages are not damp or wet); and
- Identification (signature or initials) of the unloading operator as the person who has checked the autoclave readouts and chemical indicator result, and who authoriz- es release of the load for use.

A separate book should be kept for each autoclave, if several autoclaves used in the practice. It is also prudent to compile a list of names, initials and abbreviations of operators of the autoclave, for reference purposes.

About the author

Professor Laurence J. Walsh is based at The University of Queensland School of Dentistry. He serves as the technology editor and infection control of Australasian Dental Practice magazine and is the editor of the ADA Infection Control Guidelines. Prof. Walsh is a noted commentator on and user of new technologies.

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