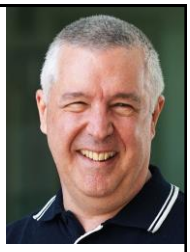
Contemporary Infection Control

2022



Emeritus Professor Laurence J. Walsh AO

BDSc(Hons), PhD, DDSc, GCEd, FRACDS, FFOP(RCPA), FFDT RCS Edin

Sterilizer chamber loading

Should be paper side down or sideways, like toast. Plastic at bottom creates issues for condensate pooling on plastic inside pouch at end of cycle.

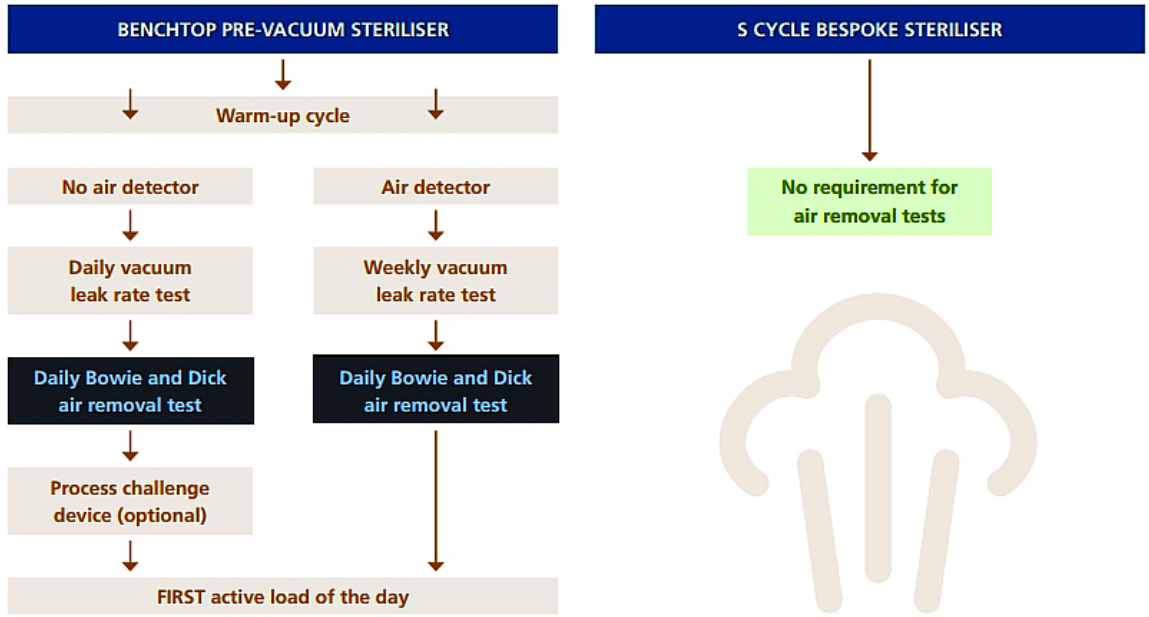
Sci-Can Statim, Nitram/Sirona DAC for handpieces, other types of S cycle units.

MUST follow MFR loading configuration precisely

MELAG S-Class
Euroklav 29 VS+

Vacuklav 44 B+
Evolution

B cycle units: Multiple programs and load types are possible.



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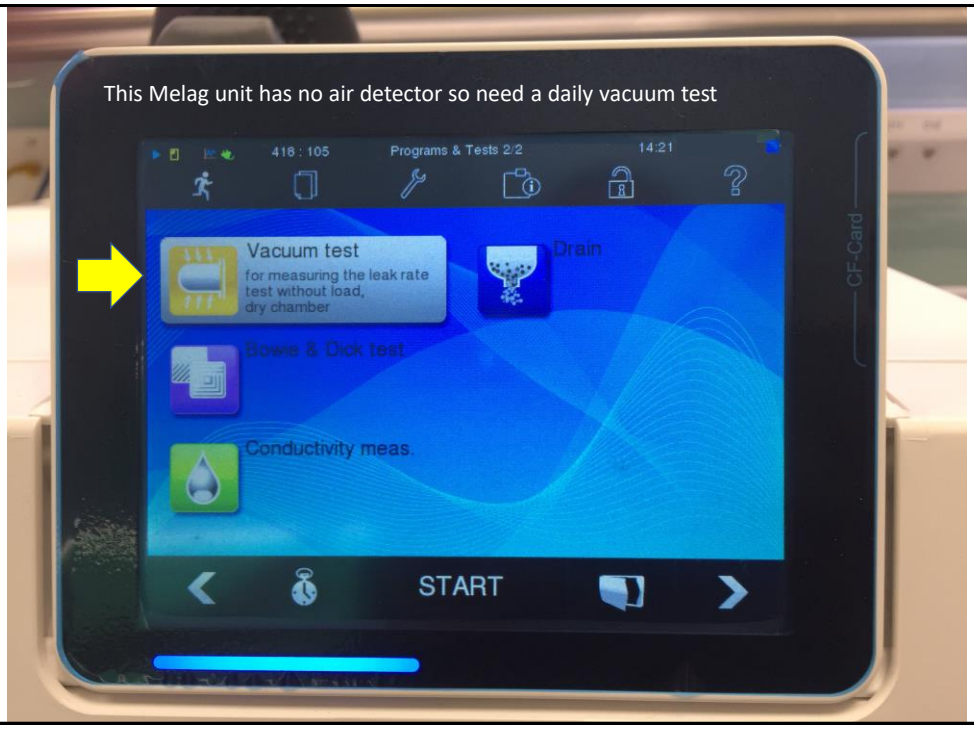
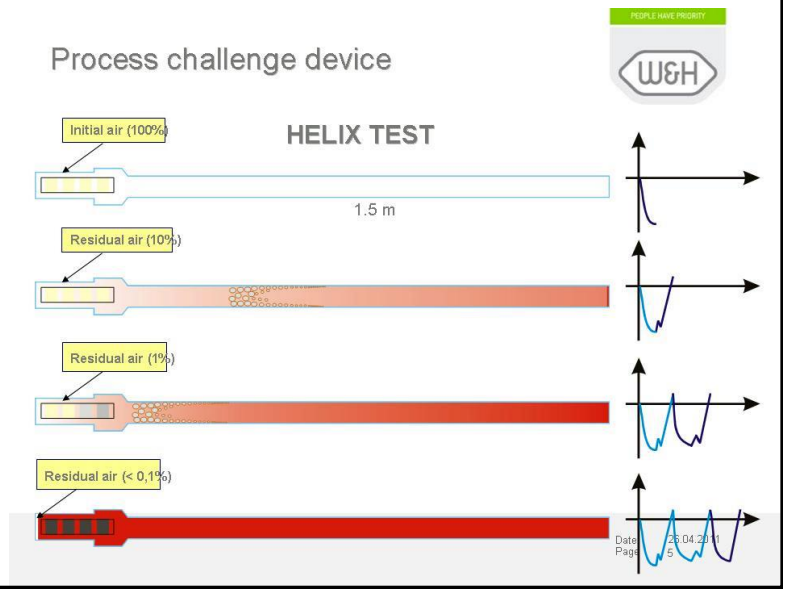


For pre-vacuum steam sterilizers, Bowie-Dick test daily after vacuum test (AS/NZS 4187:2014 and DR AS 5369:2021)

Later use of a PCD is optional.



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 microorganism 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.

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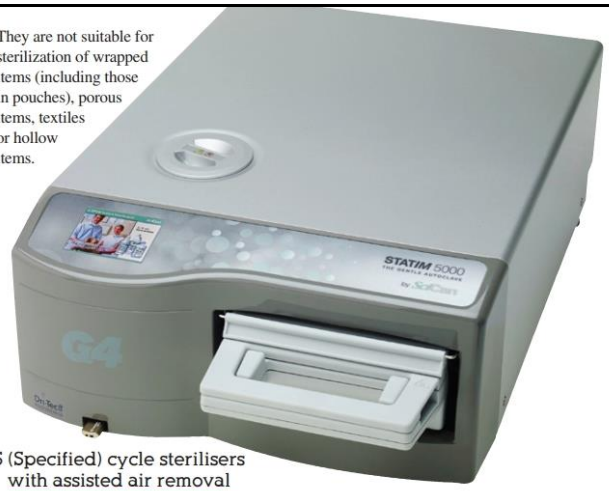
The three types of cycle and the technology behind them are described in the European Standard EN13060. Not all types of sterilizer or cycle are appropriate for all types of load items. EN13060 specifies the general requirements for small steam sterilizers, such as those used in small office dental practice, 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 handpieces) 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 positive 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.

Figures 1-2 (Above and below). The STATIM S cycle sterilizer and several examples of specified load configurations for this unit.

Statim Cassette Autoclaves
User Guidelines

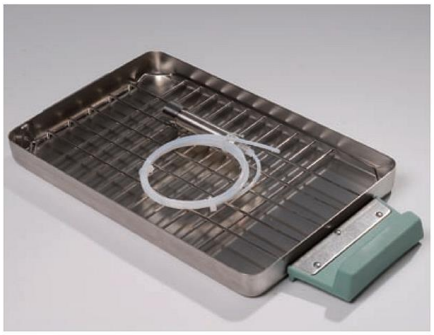
Following the recent Dental Hygiene Guidelines (2006) from the RKI in Berlin, SciCan recommends the following procedure for the daily validation of the Statim Cassette Autoclave.

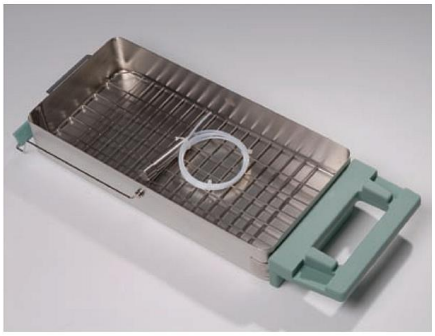
At the beginning of each day it is recommended to include the test Helix (only a Statim Helix, 01-108341, should be used) in an empty cycle without drying. The most challenging cycle should be selected: hollow, wrapped cycle of 3.30 minutes at 134°C. This will provide peace of mind that hollow instruments, such as handpieces, are being sterilised internally and externally. If the result shows that sterilisation has been achieved it is then only necessary to include an emulator with each successive cycle during that day. This process is repeated daily.

Should the result of this initial daily Helix test be negative, it should be repeated. If it is still negative, the instruments should be quarantined and a service call out should be made.

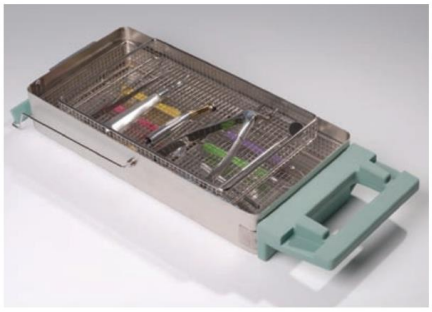
Similarly, should an emulator in any successive cycle show a negative result, the instruments should not be used and a service call should be made.

Statim Cassette Autoclaves and loads have been microbiologically tested according to EN14937. These tests show that semi-critical and critical instruments such as dental handpieces, ophthalmic phaco handpieces and rigid endoscopes can be sterilised wrapped or unwrapped.





Statim 5000S – Correct



Unwrapped

Max. 1.5 Kg

Wrapped

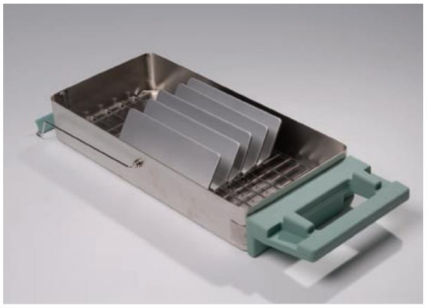


Plate positions for half load (5 bags)

Wrapped

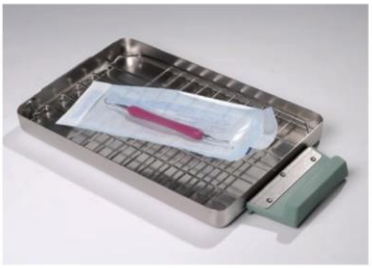
Do not over fill the cassette. Instruments should not be touching.

Statim 2000S – Correct

Unwrapped

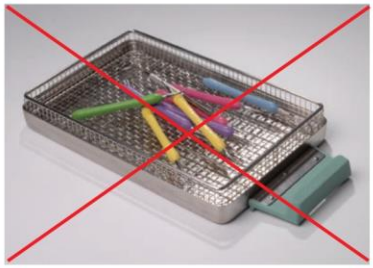
Max. 1000 gr

Unwrapped



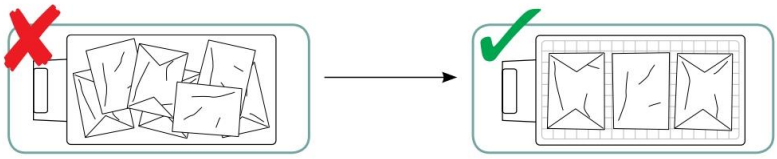
Wrapped*

Incorrect

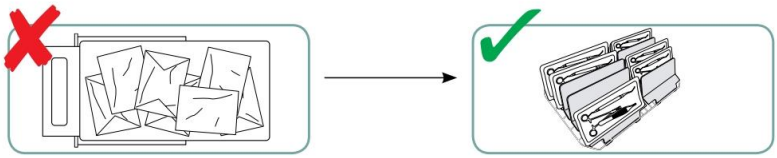


Loosely pack instruments in the bags to allow steam penetration to all instrument surfaces.

For STAT*IM* 2000 G4:



For STAT*IM* 5000 G4:

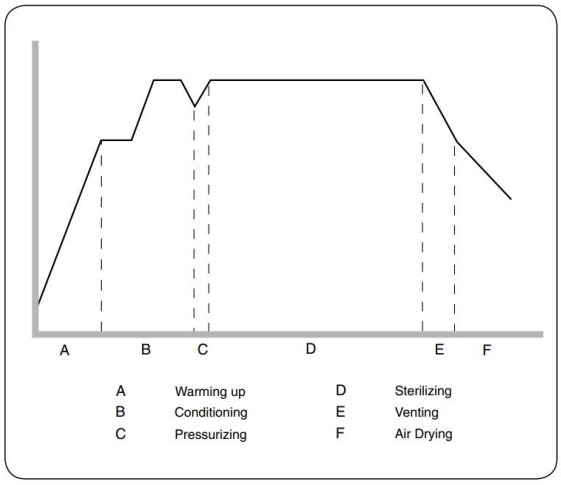


The rack with drying plates will hold 10 autoclave bags. Care must be taken to ensure that the combined weight of the loaded bags does not exceed 1.5 kg (3.3 lbs).

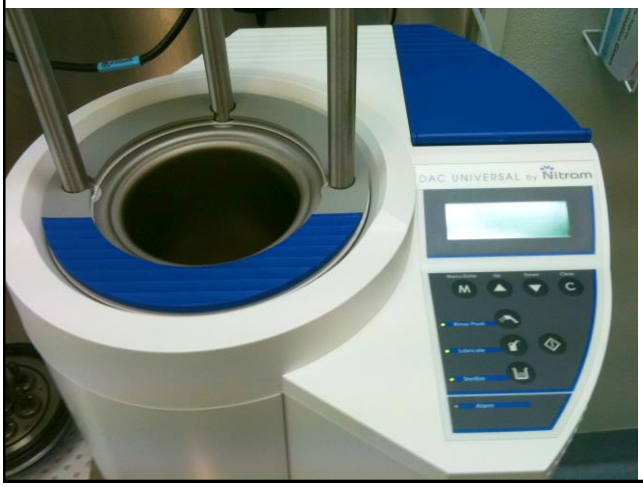
5.2.2. Wrapped Cycle
(STATIM 2000 G4)

The Wrapped Cycle is used to sterilize up to 1.0 kg (2.2 lbs) of solid and hollow metal instruments which have been sealed in paper / paper, or paper / plastic autoclave bags. Dental handpieces may be sterilized in this cycle.

To select the Wrapped Cycle, press the Wrapped Cycle button, then press the START button.



S cycle dedicated unit for handpieces (DAC)



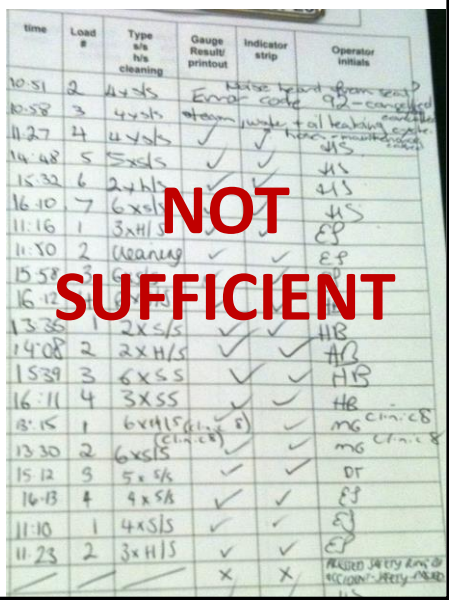
Cycle records: Need to cover all aspects stated in ADA 4th edition IPC guidelines

From the inside

So many elements, so much incredible technology and so many parts, completely integrated, in the right place and ready to serve and fulfil the daily requirements of a high end B type sterilizer!

- **EliSense**: Thanks to LED indicators and display the outstanding technology offers cycle status information, temperature information and much more to optimize both workflow and output at a glance.
- **EliTrace**: For the first time, the sterilization process can be traced and documented down to the individual instrument or instrument kit. Without additional software or computer.
- **Eco Dry+**: Eco Dry technology adapts the drying time to the mass of the load. This reduces the cycle time, increases the life span of your instruments and optimizes the energy consumption.
- **Intuitive interface**

More than just printout or data capture



NOT SUFFICIENT

The following items need a person to check them at the end of a cycle!

Visual inspection of sterilised wrapped items

When unloading the chamber, the unloading operator must visually check each package of wrapped items, as follows:

- Check the package for damage. There cannot be any items penetrating through the packaging.
- Check that the seals are intact along their length, with no interruptions.
- Check that the package is dry.
- Check that the external (Class 1) chemical indicator has made the required colour change.

BCI (tracking) information recorded in notes