



Validation

Validation is a documented procedure for obtaining, recording and interpreting results. The process is required to establish that the sterilisation protocols/procedures followed by a practice will consistently yield sterile instruments and equipment, as exactly the same procedure is followed for every part of each sterilisation process. Validation is 'proving' the entire process from start to finish.

Validation is the process of repeated checks made by the staff of the practice to ensure the process is continually achieving the desired end result. Appropriate procedures must be followed from start to finish to achieve and maintain sterility. The sterilisation cycle should be validated for all routine loads and protocols followed for cleaning and packaging. Sufficient storage for sterile, packaged items must be available.

Each step of the sterilisation process must be routinely monitored and checked, including checking all staff members perform all of the tasks in the same repeated manner, and that the process used for the worst case scenario positively kills organisms. It is then assumed that each cycle will achieve the same result. Validation is about documentation of procedures, staff training and recording. It is about performing all associated tasks in a standard, documented way, which has been tested so that when you repeat it, you can be confident of the end result each time.

Prerequisites for Validation

Before validation can be implemented the following processes must be in place:

1. A comprehensive written procedure for the precleaning of instruments prior to sterilisation that can be easily read and interpreted by all staff
2. Staff education of all procedures in the sterilisation process, which include infection control procedures and safe, efficient processing
3. Prevalidation measurements to be done by a service technician:
 - a. Chamber studies – identify 'cold' spot
 - b. Penetration time – you *must* have a *prepared, unsealed challenge pack* to present when conducting routine annual servicing and calibration of your steriliser



Validation Methodology

1. Document results of the empty chamber heat distribution studies (obtained from service company), which identify the "cold" spot.
2. Document cycles to be used (temperatures and time).
3. Prepare the hardest-to-sterilise pack in terms of density or product (challenge pack). Place one biological indicator inside the challenge pack and seal.
4. Prepare a full load using the normal cleaning and packing process (validation load).
5. Document items to be validated (challenge pack and validation load).
6. Place one biological indicator in the "cold" spot.
7. Document the exact location of the biological indicators and packs by use of a diagram or map of the chamber.
8. Load the steriliser to ensure reproducibility and operate the sterilization cycle.
9. Do three consecutive, identical loads including biological indicators. The instruments should be re-packaged before re-loading each cycle. An additional indicator is used as a control (see notes).
10. Document all findings, interpret and assess results (pass = 100%).

(3 cycles using 2 indicators per cycle: pass, 1 control indicator: fail. Total of seven indicators)

Notes

Any load run subsequently and which does not exceed the parameters of the validated load can be treated as a load not requiring biological indicators provided routine mechanical/physical monitoring occurs with each cycle and a Class 1 chemical indicator is used.

Any subsequent variation of the load exceeding the parameters of the validated load requires re-validation before use.

All loads must be monitored by either a printer readout or a class 4, 5 or 6 indicator.

Revalidation must be performed annually along with routine twelve monthly servicing and calibration.

The additional control indicator does not go in the steriliser at all. It is placed outside the autoclave and is used to illustrate the results of growth whereas the six indicators that do go in the steriliser should present no growth.

Once all cycles are examined, checked and documented, send off indicators to pathology or if you can access an incubator place in vials sideways and click in so the inside glass breaks to feed the germs. Once these are incubated, six vials should be purple (no growth) and the control should be yellow (growth).



Validation Record (2 pages)

Name of Practice: _____

Date of validation: _____

Batch number and **test** indicator description: _____

Servicing/testing records from service provider attached (tick):

Temperature and time at which validation is being done:	°C	min
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Challenge Pack

Type	Contents	
eg Suture Set	eg. - kidney dish, galley pot, 10 gauze swabs, scissors, stitch holder	

Validation Load

Contents (eg. Suture set, scissors, forceps)		

Position of test indicators and challenge pack



Note: Control test not to be sterilised.



Test indicator results

	Position 1	Position 2
Load 1		
Load 2		
Load 3		
Control		

Validation Methodology completed:

Validation process successful (if not, attach details):

Signature of person who performed validation: _____