Guidance notes 5 (GN5): The use of bench-top steam sterilisers

This authority's advice in relation to the use of bench-top steam sterilisers.

Bench top steam sterilisers (autoclaves)

- The most reliable method of sterilising equipment is moist heat using steam under pressure i.e. autoclave.
- Autoclaves operate at moist heat temperatures of between 121 Celsius and 134 Celsius.
- It is important that the correct type of autoclave is purchased for the type of sterilisation required.
- The type of equipment and quantity of equipment placed in it will also dictate the autoclave required.
- Effective sterilisation using a bench top steam steriliser relies on the correct use and maintenance of the unit.
- All persons operating bench top steam autoclaves should have received training on the safe use of portable autoclaves and follow manufacturers instructions.
- Training is often provided by manufacturers but needs to be requested by the operator.
- All training should be documented.

There are two main types of autoclave

- For both types of autoclaves, it is essential that the instruments are thoroughly cleaned by both manual and ultrasonic bath means to remove visible contamination before they are autoclaved. Any contamination remaining on the instruments will leave non-sterile areas underneath the contamination.
- Guidance should be sought from the Medical Devices Agency (MDA) on the type of autoclave most suitable for the work carried out.
- After purchase the autoclave must be correctly used, maintained and validated periodically according to the devices bulletin 'The Validation and Periodic Testing of Bench Top Steam Sterilisers' DB 9804.

Traditional bench top steam autoclaves (non vacuum)

These are considered suitable for solid or unwrapped instruments. Pouches or other wrappings must not be used in these autoclaves. It is important to leave as much air as possible around each object when placing in the autoclave. All equipment such as clamps must be sterilised in the open position to ensure all parts of the equipment get sterilised. Once sterilised items must be placed in a clean airtight container. They can be stored in this manner for up to three hours at which point they will then require resterilising prior to use.

Vacuum autoclaves

For the sterilisation of wrapped or pouched items e.g. instruments with lumens (i.e. tubes grips and tips) the ideal sterilisation practice is to use a vacuum steam autoclave. It is important that such a sterilizer has a drying cycle as well so that resultant loads are dry at the end of the cycle. Wet or damp pouches cannot be regarded as sterile as bacteria can penetrate into them. Intact dry pouches should be stored in a clean dry environment until use.

The owner of the autoclave is responsible for:

- ensuring the machine is certified as suitable by a competent person
- the machine is properly maintained and in a good state of repair
- installation and validation of the autoclave is done via an authorised person
- ensuring training of the operator occurs and is documented
- daily, weekly, quarterly and yearly testing is completed and documented in a logbook

Copies of the above MDA bulletins are available at a charge from MDA website.

The following sterilisation temperature bands, holding time and pressure for sterilisation, using high temperature steam must be checked daily before the start of the session and documented on the log sheet.

Please do not hesitate to contact our Regulatory Services should you wish for further advice, or to discuss this matter further.

Option	Sterilisation Temperature Range (˚C)			Approx pressure (bar)	Minimum hold (min)
	Normal	Minimum	Maximum		
A	136	134	137	2.25	3
B	127.5	126	129	1.5	10
C	122.5	121	124	1.15	15

Example of an autoclave record sheet

Autoclave record sheet							
Please keep these records in date order for inspection							
Autoclave type			Serial number				
Week commencing			Location				
Type of water used							
Pressure during holding period							
Cycle counter number							
Time to reach holding temperature							
Temperature during holding period							
Daily Test	Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
Total time at holding temp/ pressure							
Water drained at end of day							
Process check							
Printout attached							
Initials of authorised user							
Weekly safety test	**Yes/No**		**Comments**				
Door seals secure							
Door safety devices functioning correctly							
Safety valves operating correctly							
Name			Date		Signature		