

GN 4 - Guidance Notes on the use of bench top steam sterilizers

This Authority's advice in relation to the use of bench top steam sterilizers is given as follows:

Bench Top Steam Sterilizer – (autoclave)

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°C and 134°C.

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 sterilizer 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 :

- 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 3 hours at which point they will then require re-sterilising 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. 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. Consult devices bulletin 'Bench Top Steam Sterilizers – Guidance on Purchase, Operation and Maintenance' (DB 2002(06))

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 Sterilizers' DB 9804.

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:

MHRA
Business services
Hannibal House
Elephant and castle
London SE1 6TQ

Email: info@mhra.gov.uk
Tel: 020 7084 2000

Further information on use of bench top steam sterilizers is available on the 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

Example of an Autoclave record sheet

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

We hope that this information has been of assistance. However, please do not hesitate to contact us on the number given above, should you wish for further advice, or to discuss this matter further