SPOTLIGHT *feature*

# Safety, Hazard Containment & Sterilising Equipment

## Ins and Outs of Autoclaves in a Sterile Lab

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The decision to put items in an autoclave is borne out of a necessity to decontaminate. This could be making waste safe ready for ultimate disposal or, the routine sterilisation, before and after use, of instruments, petri dishes and glassware used in lab processes such as culture grow. Whatever the application the requirement is clearly defined, that of making items 'safe and pure'.

Laboratory autoclaves are a familiar sight in most research, university labs and clean rooms and often taken for granted despite the importance of their role in protecting the environment and preventing spread of disease and infection. They are generally available in a number of shapes, sizes and configurations, all with the same operating principle of using saturated pressurised steam to kill potential harmful bacteria, particularly in bio-hazardous waste.

The ability to combine pressurised steam at a given temperature in a totally enclosed chamber has established the autoclave as one of the most successful machines for eradication of micro-organisms. Not to be confused with cleaning, autoclaves achieve total sterilisation of material placed in the chamber. To achieve a sufficient kill rate it is necessary to raise the temperature such that even the most thermo-tolerant organisms are inactivated, hence the classic 121°C for 15 minutes.

Typical autoclave designs include:

1. small benchtop
2. compact top loading
3. cylindrical front loading
4. rectangular front loading
5. pass through (also known as double dc
6. power doors


The decision as to what to buy will depend on a number of parameters such as the physical size of items to be sterilised, what requires sterilising, the frequency and the available space within the laboratory. The location of the actual laboratory within a building is also paramount. While bench top autoclaves and those with a small footprint usually present fewer problems on installation, larger autoclaves can present problems. It is not unknown for some manufacturers to leave their equipment at the bottom of the stairs if there is not an easy way in.

Also, the increased sophistication of laboratory autoclaves with venting and vacuum systems, coupled with increased awareness of possible bio-hazards means that in most cases it is no longer sensible to plan the position of an autoclave without considering drainage and water supplies.

Before making a final choice it is wise to speak with a reputable autoclave manufacturer who will provide advice and guidance. Often you will be able to arrange a site survey to make sure that everything is going to fit.

| Process | Sterilising Temperatrue (see 1.3.24 of BS2646.1:1993) | | Holding time (see 1.3.23 of BS2646.1.1:1993) | |
|---|---|---|---|---|
| | minimum °C | maximum °C | minimum mins °C | maximum mins |
| Liquid | 121 | 124 | - | 15 |
| | 115 | 118 | - | 30 |
| Equipment and glassware | 121 | 124 | 15 | - |
| | 126 | 129 | 10 | - |
| | 134 | 138 | 3[a] | - |
| Make-safe[b] | 121 | 125[b] | 15 | - |
| | 126 | 130[b] | 10 | - |
| | 134 | 138 | 3[a] | - |
| [a] loads which comprise a variety of items and containers do not heat uniformly. Short holding times are therefore subject to large proportionate variations and should be avoided if possible. | | | | |
| [b] the maximum temperature is greater for some make-safe processes than for correspomding equipment and glassware processes, to permit easier attainment of sterilising conditions throughout the load. | | | | |

*Figure 1. Typical Recommended Sterilizing Process Temperatures*

### Correct Programming

Some manufactures use simple push-button technology to control the setting of the sterilising process parameters of temperature and time. It is by far the easiest system to use – the actual setting defined by the HSE (Health and Safety Executive) following extensive research *(See Figure 1)*, to ensure total eradication of harmful bacteria.

During sterilisation it is important that the saturated steam comes into direct contact with the media – for wrapped goods in plastic bags consideration should be given to choosing an autoclave with a vacuum phase. In this design the pre-vacuum mode efficiently removes ambient air from the chamber and load, allowing steam to completely penetrate the product whilst the post-vacuum cycle pulls steam and condensate out of the autoclave during this drying phase, the longer the vacuum runs the cooler and dryer the load. The overall benefit is a faster cycle time.

### Sterilisation Check

On the market there is an array of autoclave accessories, such as tapes for quick visual indication that your materials were exposed to the steam process, not that the process was successful. A better sterility check should be frequently carried out using Biological Indicators (Geobacillus stearothermophilus), typically these indicators consist of a plastic container with a cap and a crushable glass ampoule with recovery media and a disc inoculated with spores.

There is also the well-known Bowie & Dick test where the colour of the indicator sheet changes from blue to pink confirming that steam penetration has been effective up to the centre of the sterilisation pack.

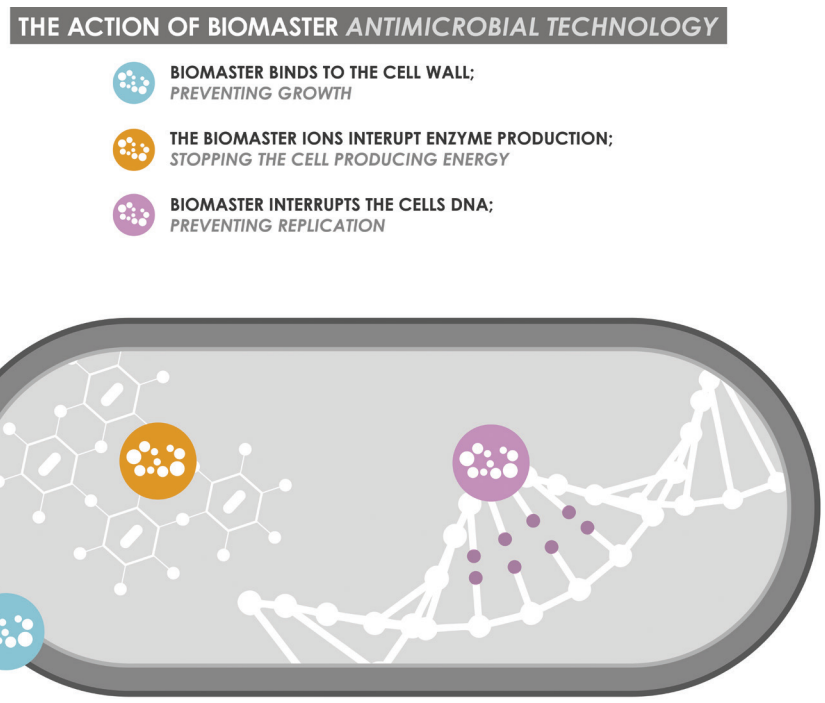
### External Protection

Inhibiting the growth of harmful bacteria and minimising the threat of cross-contamination is vital in hygiene critical areas within agricultural, pharmaceutical, food processing, educational and health care laboratories. Bacteria commonly encountered in these areas are capable of prolonged survival on most surfaces, in optimal conditions they can reproduce every twenty minutes, spreading rapidly where they dwell.

In busy, multi-user laboratories there is always the risk of cross-contamination on lab surfaces including that of the autoclave cabinet. There is the possibility that the exterior of the autoclave may come into contact with bacteria – whilst opening the autoclave door staff may place the load on the top of the cabinet, people may inadvertently lean on the autoclave - bacteria transfer is easy.

Responsible autoclave manufacturers will take precaution to prevent such transfer by coating frames and panels during production with an anti-microbial coating. One global autoclave manufacturer applies a branded agent from Biomaster, this ensures effective antibacterial protection for the effective lifetime of the product, helping to keep surfaces clean and hygienic, and reducing the threat of cross-contamination. The tough epoxy finish is proven to reduce bacterial growth by up to 99.99% and is highly effective against MRSA, E.coli, Listeria, Legionella, Campylobacter, Salmonella, Pseudomonas and over 50 other species.

Silver is the active ingredient in Biomaster Protection, an additive range created by Addmaster (UK) Ltd. The company developed the means and method to safely and effectively incorporate the silver into durable epoxy paint finishes. It disperses throughout the entire paint, will not wash off and lasts for the coatings lifetime.




The advantage of using a silver based technology is that it is inorganic and non-leaching, which means unlike organic antimicrobial technologies it stays within the item it is added to, providing antimicrobial protection without allowing bacteria to develop resistance. This particular epoxy finish has been tested to ISO 22196:2011 standards to prove its antimicrobial efficacy.

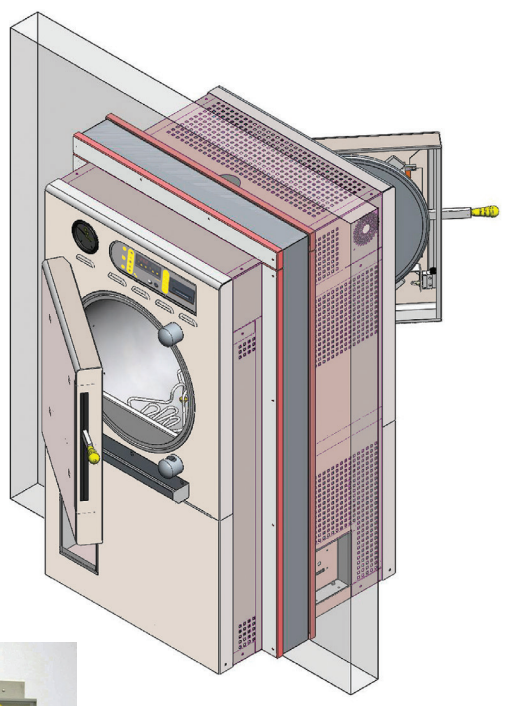
## Maintaining Lab Sterility

Every lab is unique in what processes and procedures take place – some requiring a more sterile working environment than others, there may even be air locks for staff to pass through, extracting, cleansing and renewing the air, a system in operation where high risk conditions are the norm.

In a similar manner, some laboratories need to have a secure, clean exit path for its waste media so that it can be safely discarded.

To satisfy this requirement a number of prominent laboratory autoclave manufacturers are able to build pass-through (also referred to as double-door) steam sterilisers. Every pass-through autoclave provides a sterile path in and out of sealed laboratories.

In general terms, this type of autoclave is employed within clean rooms and containment suites. In the case of a clean room application the autoclave is used for the sterilisation of equipment entering a clean or aseptic area such as a pharmaceutical production environment.



In a containment application the autoclave is used for the de-contamination of material prior to its release from the containment suite which would typically be a laboratory handling high-risk hazardous material. In both cases isolation of both ends of the autoclave is required.

These autoclaves tend to be a heavily modified standard product design, placing two units back-to-back and inclusion of a unique chamber which is open both ends to allow for doors at either end. The build also requires inclusion of a bulk head enabling the autoclave to be built into a dividing wall separating the lab from the outside world.

Each site will have different requirements doors to be hinged to swing left or right, location of electrical, water and drain services - final manufacture therefore requires full details of the proposed location and operation routines.

By far the best way to achieve this is to involve the manufacturer in the planning process from a very early stage, including site surveys and/or the supply of detailed drawings.

It is an essential requirement of the BS2646 standard that double door autoclaves have interlocks to prevent both doors being open at the same time as this would obviously breach the integrity of the site. Further, an interlock must be present to prevent the door at the unloading end from being opened until the sterilisation cycle has been successfully completed and the load is safe to pass into the unloading end. It is also necessary to prevent the release of the loading door until the unloading door has been opened, subsequently closed and locked. An override is usually fitted to permit opening of the loading door should this be required and only by means of a key, to prevent unauthorised operation.

In terms of control, a typical set-up could be that only one side of the double door steriliser has access to the full control system, the other side equipped with just a screen to show process status so that staff are aware when a job is complete and it is safe to remove the media or waste.

In the case of a containment suite it is usual for most of the autoclave to be located in the unloading room with just the door section of the autoclave protruding into the containment area. This enables most maintenance tasks to be completed without the need for an engineer to enter the containment area. For a clean room installation it is usual for most of the autoclave to be located within the loading room as this enables maintenance tasks to be performed without the need for the engineer to enter the clean area.

For all applications requiring a double-door autoclave it is essential to have a recording device fitted to produce a permanent record of each autoclave cycle, whether by a printer integral to the autoclave control system or an independent chart recorder.

## Conclusion

To ensure the sterility of a busy laboratory a number of factors must be considered to maintain a safe working environment. There is no perfect off-the-shelf answer since every laboratory, every application and every location will have unique requirements and goals, it is always best to seek expert help from autoclave manufacturers before making a major investment for you lab.