

## **Planning a Double-Door Autoclave for Clean Rooms or Containment Suites.**

In the majority of cases Double-Door autoclaves can generally be considered to be a bespoke design, albeit one that is created by adding a second door to a standard model.

Unless the room is specifically designed around the autoclave (not common, even with New Build Laboratories) then a certain amount of 'tailoring' of the autoclave design will be necessary.

Each site is different, with the requirement for doors to be hinged to swing in different directions and with the location of electrical, water and drain services.

Final manufacture therefore requires full details of the proposed location and operation routines. Such details are essential for a smooth installation and commissioning process. 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.

The detailed planning process should take into consideration the following factors:

### **Direction of Workflow**

In general terms, double-door autoclaves are 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 the case of 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. The autoclave will be sealed at the point of passing through a wall by means of a bulkhead.

Close sealing of the bulkhead and wires, pipes etc passing through it is observed as closely as possible in the design of the autoclave but it is not normal for this sealing to be considered absolute at the manufacturing stage - extra sealing may be required during installation. In addition, the integrity of the containment may be improved by an air pressure differential between the rooms in which the equipment is located.

### **Door operation**

It is an essential requirement of the BS2646 standard that double ended 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, under the same BS 2646 directive, 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.

### **Maintenance & Servicing**

In the case of a containment suite autoclave it is usual for most of the autoclave to be located within the unloading room with just the door section of the autoclave protruding into the containment area. This enables the majority of maintenance tasks to be completed without the need for an engineer to enter the containment area. Since nearly all of the autoclave plant is located in the unloading end it follows that the drain and other services will also be at this end, minimising the number of pipes and wires etc that need to pass through the wall or bulkhead. It is desirable for the main electrical isolator to be located at the unloading end, again to minimise on penetration of the wall but consideration should be given to the ability to shut down the autoclave from the loading end in an emergency.

In the case of a clean room installation it is usual for most of the autoclave to be located within the loading room. Again this permits most maintenance tasks to be performed without the need for the engineer to enter the clean area. In this case however this is more important as certain maintenance tasks can present a serious threat to the clean area. Again, the services should be located at the same end as the majority of the autoclave plant.

### **Recording device**

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. There are arguments to support locating the recording device at either end of the autoclave. Consider the following:

- It is desirable for the operator unloading the autoclave to be able to examine the record before opening the autoclave.
- Which end of the autoclave is the autoclave log to be kept? The recording device should be at the same end.
- It is often not permissible to take a paper record from a containment area.
- A paper record will shed fibres in a clean room.

### **Thermocouple entry ports**

As with recording devices there are arguments to support location of these at either end. However, the author strongly recommends that entry ports are located on the unloading end side of the wall for a

containment suite and the loading end for a clean room with the ports being as close as possible to the wall for the following reasons:

- During commissioning tests and periodic re-validation it will be necessary to place thermocouples in the load as the autoclave is being loaded. This requires that the entry port is located close to the loading end, but does not necessarily mean that it has to be located on the loading end side of the wall.
- It may not be desirable to take test and recording equipment into a clean room or containment area.
- And again, it is often not permissible to take a paper record from a containment area.
- It is often necessary to operate the test equipment whilst operating the autoclave loading end controls (provisions can be made to overcome this).
- If the test and recording equipment are inside the containment area / clean room the requirement to don / remove protective clothing each time the area is entered / exited is time consuming.

### **Steam heated units**

In the case of direct steam heated autoclaves it is desirable for the steam plant to be located at the main plant end of the autoclave. However, as it is necessary for the steam pressures to be monitored from the loading end, in the case of containment suite sites this will necessitate passing the pressure gauge pipes through the wall and possibly the provision of a duplicate pair of pressure gauges.

### **Clean room applications**

Electrically heated autoclaves have a water charge inside the chamber, which will be exposed to the clean room when the door is opened and presents a potential source of contamination if non-sterile water is being fed into the autoclave. It may be desirable to use a purified and / or sterilised water supply. Whilst the steam produced from the water within the autoclave leaves most of its contaminants behind in the water reservoir, if there is a risk associated with contamination of the load, this presents another case for the use of purified and / or sterilised water. It is common for autoclave water level controls to work by means of conductivity. If purified water is to be used this will require special consideration. Highly purified water is corrosive to some metals and this will also require consideration.

Due to similar contamination considerations to the above it may be desirable to provide a clean steam supply for direct steam heated units.

### **Pipes entering and exiting the autoclave**

In the case of a single ended autoclave it is common for pipe work and electrical connections to be made at the rear of the autoclave. In this way, unsightly pipes with potential heat hazards are secreted behind the autoclave. However, in the case of a double-door autoclave it is necessary for services to connect via the sides of the autoclave, and further consideration for the covering or guarding of pipes may also be necessary. This is a particular concern if larger items such as drain condensers or exhaust filters are fitted.

In some cases it may be worth considering enclosing the whole of the autoclave excluding the doors with partitions to effectively form a plant room.

By taking these factors into consideration and working closely with the autoclave manufacturer you can help to ensure an effective and functional autoclave installation.

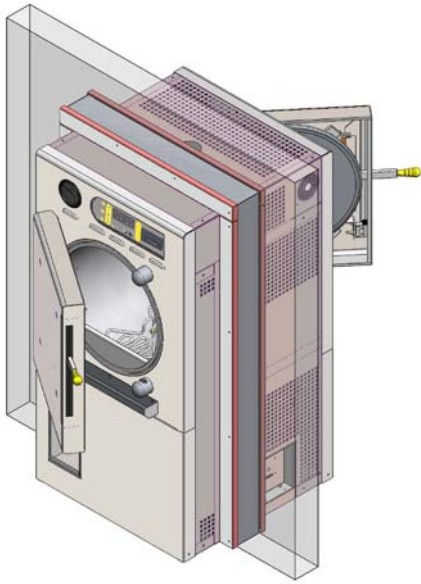
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*A typical double-door installation within a containment suite in the Royal London Hospital. This view is from the unloading end.*



*The unloading end of a clean room application.*



*Elevation of a “through-the-wall” double- door autoclave for loading from a containment suite or unloading to a clean room.*

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Issued by DJB Publicity Ltd.

Tel: 01634 263 273 Fax: 01634 263 293 E-mail: [david@djpublicity.co.uk](mailto:david@djpublicity.co.uk) Release Date: March 09