NOTES

Surface Decontamination in an Autoclave Chamber with Formaldehyde Gas

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Received for publication 2 April 1971

A simple device for the conversion of a standard steam autoclave into a formaldehyde gas sterilization chamber is described.

The use of formaldehyde gas for surface sterilization of heat-labile items has been shown to be extremely effective (1, 2). Ethylene oxide gas is more frequently used even though it requires a complex system, is dangerous, may damage plastics, and is not very reliable if all surfaces are not exposed to the gas. A formaldehyde decontamination system eliminates these disadvantages by requiring only a gastight area containing a heater to volatalize the paraformaldehyde powder and a way to remove the fumes after a contact period. This paper describes a newly developed door which permits temporary conversion of a steam autoclave into a gaseous formaldehyde decontamination chamber.

The door (Fig. 1) is constructed of 1-inch (2.54 cm) transparent Plexiglas, slightly smaller than the locking lip of an autoclave. A standard bicycle tire inner tube, attached to the periphery of the inner door surface with Silicon Seal (General Electric), serves as an inflatable gasket. To hold the door in place during inflation, six aluminum tabs pivot and lock under the autoclave lip. Two handles are provided to facilitate placement of the unit. Penetrating the door is a nylon glove port (Snyder Co.) with an attached neoprene glove held by a hose clamp. This provides access to move items so that all surfaces may be exposed during decontamination.

Two ball valves (Hoake) equipped with three filters (Mine Safety Appliance) penetrate the door to allow removal of formaldehyde gas and replacement with aseptic air. The incoming air is passed through a valve and into the autoclave chamber by first passing through a filter which is 99.98% effective for 0.3-μm particles. The chamber gas is exhausted through a similar filter, placed in the back of the autoclave chamber, through Tygon tubing which connects to the valve penetrating the door and then into a pump which forces the gases through a filter designed to remove organic vapors.

Electricity for the hot plate is provided through a sealed, 12-pin penetration (Deutsch Co.) mounted in the Plexiglas with a bayonet adaptor attached on each side. The adaptors are wired to an outside male electrical plug and an inside female plug. A second electrical penetration increases experimental capability. All penetrations are sealed with plexiglas cement (PS 18, Cadillac Plastics) or Silicone Seal.

To decontaminate with formaldehyde gas, the following procedures are followed. Seal the chamber drain of the autoclave with plastic tape. Load the chamber with a hot plate, paraformaldehyde powder in a Pyrex dish (0.3 per ft³ of
autoclave space), a can of Freon gas, and the item(s) to be sterilized. Swing attached autoclave door out of the way. Set the Plexiglas door in position, insert the tabs under the autoclave lip, and inflate the gasket with air to 35 psi.

Using the rubber glove, release Freon gas inside the autoclave until the glove extrudes. If it remains pressurized, the unit is well-sealed and it is safe to proceed. Return the unit to ambient pressure, activate the hot plate, and maintain it at 200°C until all of the paraformaldehyde powder has volatilized. All objects in the autoclave should be moved at least once to expose all surfaces to the gas. After a 16-hr gas contact period, formaldehyde gas is evacuated through the organic vapor filter and fresh air is allowed to enter through the inlet filter. After 4 hr (minimum) of air-washing, the door, the tape, and the sterilized items are removed; remaining gaseous residue in the autoclave is quickly removed by one steam cycle.

This door was found to be completely leak-free when tested on an Amsco autoclave pressurized with 4 inches (water gauge) of Freon-12 and checked with a General Electric halogen detector calibrated to detect a leak rate of less than 0.04 oz of gas per year. Thirty-five pounds of gasket pressure was found to afford repeatable gastight seals around the edges of the door.

$Bacillus\ subtilis$-impregnated spore strips (Amsco, $10^6$ spores) were used to test the sterilizing ability of the system. The strips, enclosed in petri dishes, were placed at 12 locations in the autoclave. After a 16-hr contact period and a 4-hr air-wash, the spore strips were incubated in tryptic soy broth at 37°C for 7 days. None of the spore strips showed any evidence of visible organisms.

I express sincere appreciation to W. Ellis, Paul Phillips, E. J. Haynes, and Sylvia A. Rose of Brown & Root-Northrop for their invaluable assistance in this project. This research was carried out in part at Brown & Root-Northrop under the auspices of the National Aeronautics and Space Administration.

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