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# Hydrogen Peroxide Gas Plasma

DISINFECTION AND STERILIZATION GUIDELINE  
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Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)

## AT A GLANCE

Hydrogen Peroxide Gas Plasma from the Guideline for Disinfection and Sterilization in Healthcare Facilities (2008).

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## Overview


New sterilization technology based on plasma was patented in 1987 and marketed in the United States in 1993. Gas plasmas have been referred to as the fourth state of matter (i.e., liquids, solids, gases, and gas plasmas). Gas plasmas are generated in an enclosed chamber under deep vacuum using radio frequency or microwave energy to excite the gas molecules and produce charged particles, many of which are in the form of free radicals. A free radical is an atom with an unpaired electron and is a highly reactive species. The proposed mechanism of action of this device is the production of free radicals within a plasma field that are capable of interacting with essential cell components (e.g., enzymes, nucleic acids) and thereby disrupt the metabolism of microorganisms. The type of seed gas used and the depth of the vacuum are two important variables that can determine the effectiveness of this process.

In the late 1980s the first hydrogen peroxide gas plasma system for sterilization of medical and surgical devices was field-tested. According to the manufacturer, the sterilization chamber is evacuated and hydrogen peroxide solution is injected from a cassette and is vaporized in the sterilization chamber to a concentration of 6 mg/l. The hydrogen peroxide vapor diffuses through the chamber (50 minutes), exposes all surfaces of the load to the sterilant, and initiates the inactivation of microorganisms. An electrical field created by a radio frequency is applied to the chamber to create a gas plasma. Microbicidal free radicals (e.g., hydroxyl and hydroperoxyl) are generated in the plasma. The excess gas is removed and in the final stage (i.e., vent) of the process the sterilization chamber is returned to atmospheric pressure by introduction of high-efficiency filtered air. The by-products of the cycle (e.g., water vapor, oxygen) are nontoxic and eliminate the need for aeration. Thus, the sterilized materials can be handled safely, either for immediate use or storage. The process operates in the range of 37-44°C and has a cycle time of 75 minutes. If any moisture is present on the objects the vacuum will not be achieved and the cycle aborts.<sup>856, 881-883</sup>

A newer version of the unit improves sterilizer efficacy by using two cycles with a hydrogen peroxide diffusion stage and a plasma stage per sterilization cycle. This revision, which is achieved by a software modification, reduces total processing time from 73 to 52 minutes. The manufacturer believes that the enhanced activity obtained with this system is due in part to the pressure changes that occur during the injection and diffusion phases of the process and to the fact that the process consists of two equal and consecutive half cycles, each with a separate injection of hydrogen peroxide.<sup>856, 884, 885</sup> This system and a smaller version<sup>400, 882</sup> have received FDA 510[k] clearance with limited application for sterilization of medical devices (Table 6). The biological indicator used with this system is *Bacillus atrophaeus* spores.<sup>851</sup> The newest version of the unit, which employs a new vaporization system that removes most of the water from the hydrogen peroxide, has a cycle time from 28-38 minutes (see manufacturer's literature for device dimension restrictions).

Penetration of hydrogen peroxide vapor into long or narrow lumens has been addressed outside the United States by the use of a diffusion enhancer. This is a small, breakable glass ampoule of concentrated hydrogen peroxide (50%) with an elastic connector that is inserted into the device lumen and crushed immediately before sterilization.<sup>470, 885</sup> The diffusion enhancer has been shown to sterilize bronchoscopes contaminated with *Mycobacteria tuberculosis*.<sup>886</sup> At the present time, the diffusion enhancer is not FDA cleared.

Another gas plasma system, which differs from the above in several important ways, including the use of peroxide vapor, was removed from the marketplace because of reports of corneal destruction to patients who had been processed in the sterilizer.<sup>887, 888</sup> In this investigation, exposure of potentially wet ophthalmologic bores and brass components to the plasma gas led to degradation of the brass to copper and zinc.<sup>888, 889</sup> The experimenters showed that when rabbit eyes were exposed to the rinsates of the gas plasma-sterilized instruments, corneal decompensation was documented. This toxicity is highly unlikely with the hydrogen peroxide gas plasma process since a toxic, soluble form of copper would not form (LA Feldman, written communication, April 1998).

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## Mode of Action

This process inactivates microorganisms primarily by the combined use of hydrogen peroxide gas and the generation of free radicals (hydroxyl and hydroproxyl free radicals) during the plasma phase of the cycle.

## Microbicidal Activity

This process has the ability to inactivate a broad range of microorganisms, including resistant bacterial spores. Studies have been conducted against vegetative bacteria (including mycobacteria), yeasts, fungi, viruses, and bacterial spores.<sup>469, 721, 856, 881-883, 890-893</sup> Like all sterilization processes, the effectiveness can be altered by lumen length, lumen diameter, inorganic salts, and organic materials.<sup>469, 721, 855, 856, 890, 891, 893</sup>

## Uses

Materials and devices that cannot tolerate high temperatures and humidity, such as some plastics, electrical devices, and corrosion-susceptible metal alloys, can be sterilized by hydrogen peroxide gas plasma. This method has been compatible with most (>95%) medical devices and materials tested.<sup>884, 894, 895</sup>

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