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PROFESSIONAL
INFORMATION
REPORT **2004-01**

**Comparison Testing of the Propper WATS
System vs. Biologicals for Steam Sterilizers
in The Professional Office**

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August 2004

Product Description and Purpose:

The Propper WATS system is a product designed for the weekly testing of steam sterilizers in professional offices.

It consists of one Biological Test Pack with mailing envelope and a culture service included. Propper has been producing this product and supplying the culture service for fifteen years to assist professional offices in complying with the regulations that such testing be performed on a routine basis. It also includes three peel pouches and Propper's Vapor Line[®] chemical integrators. Vapor Line has been shown to be equivalent to the performance of biological indicators in past studies.^{1,2} The purpose of this study was to compare the results of the two systems to ensure that the Vapor Line in a peel pouch would provide results equivalent to the biological indicator results.

Materials and Methods:

Tests were conducted in a 16-inch diameter by 24-inch sterilizer with an external steam source. The come-up time in this unit ranged from 40 to 65 seconds. Three lots of Duo-Spore[®], and three lots of Vapor Line were tested. In each sterilizer cycle, ten pouches were run - five with the biological indicator, and five with the chemical integrator. For each exposure time and temperature, 20 indicators per lot were used.

Following the sterilization cycles, the packs were opened, and the results of the Vapor Line integrators recorded. The biological indicator spore strips were aseptically transferred to a modified tryptic soy broth which is used in the culture service, and incubated at $56 \pm 2^\circ\text{C}$ for 48 hours. Growth of the biological indicator was determined by a color change of the pH indicator in the medium from red to yellow.

Results:

The results of this study are summarized in Table 1. In all cases, which employed three lots of each indicator, three temperatures, and various times, the Vapor Line integrator did not show a PASS result until after all biological indicators showed a satisfactory cycle by lack of survival.

Discussion and Conclusion:

All sterilizers are designed by their manufacturers to have a built-in time safety factor in the cycle. This is usually called the "overkill" period. It is designed to deliver the amount of exposure needed to give a one-in-a-million chance that an organism will survive. Although biological indicators have been the Gold Standard by which sterilization cycles are usually validated, they cannot measure into this overkill time. The newer chemical integrators can be designed to do so. They can therefore serve as an assurance that the sterilizer is delivering not only the conditions needed to kill biologicals, but also an additional margin of safety.

Propper's Vapor Line has been shown previously to be equivalent in performance to biological indicators when tested without packaging¹, or in a pack (PASS/FAIL[®]) designed for testing large hospital steam sterilizers². The present study corroborates the results of the previous two. The results of the Vapor Line indicator are a convenient, instant readout that can be used to verify the correct operating parameters of steam autoclaves when used with packaging designed for testing both large hospital sterilizers and the small bench top sterilizers commonly found in professional offices.

Table 1

Percent of Tests Showing No Growth or PASS

		250°F								
Minutes		2	4	6	7	10	13	16	19	22
Duo-Spore		0	66.7	95	100	ND	ND	ND	ND	ND
Vapor-Line		ND	ND	ND	ND	0	5	61.7	93	100

		260°F								
Minutes		1	2	3	4	5	7	9	11	
Duo-Spore		0	55	80	100	ND	ND	ND	ND	
Vapor Line		ND	ND	ND	ND	0	23.3	80	100	

		270°F				
Minutes		1	2	3	4	5
Duo-Spore		61.7	100	ND	ND	ND
Vapor Line		ND	0	23.3	46.7	100

ND = Not Done

References:

1. Propper Professional Information Report 95-1, Performance of Propper's Vapor Line® Integrator versus Biological Indicators. Propper Mfg. Co., Inc. 1998.
2. Propper Professional Information Report 99-2, Comparison of the Propper PASS/FAIL® Challenge Pack to Biological Test Pack Results. Propper Mfg. Co., Inc. 1999.

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If you require additional information regarding Vapor Line sterilization integrators or any other aspect of sterilization, telephone the Propper Sterilization Hotline 800-221-2280 - 9am-5pm Eastern Time

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