

# **propper**

# PROFESSIONAL INFORMATION REPORT **99-2**

## **Comparison of the Propper PASS/FAIL™ Challenge Pack to Biological Test Pack Results**

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## PROPPER'S PASS/FAIL™ CHALLENGE PACK

### Product Description and Purpose:

Propper's PASS/FAIL™ Challenge Pack is a specially constructed steam sterilization test pack which comes complete with a Vapor Line® steam integrator. It was designed to be equivalent in performance to a biological indicator in an approved pack for monitoring typical hospital steam sterilization cycles.<sup>1,2</sup> The purpose of this study was to compare the results of the PASS/FAIL™ pack to those obtained with biological challenge pack systems.

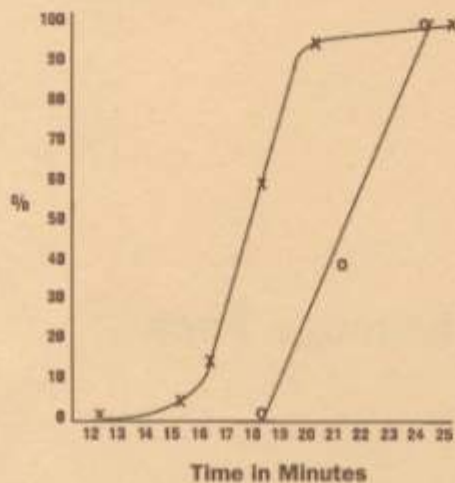
### Materials and Methods:

PASS/FAIL™ Challenge Packs were prepared using three different lots of Vapor Line integrators. A maximum of four packs were tested per sterilizer run. A total of 10 packs were tested per lot of Vapor Line, sterilizer time, and temperature. Three lots of Propper BI-O.K.® Steam Test Pack and three lots of Attest® packs from 3M were employed as the biological test packs. A 24x36x54 inch manually operated, custom built sterilizer was used for all cycles.

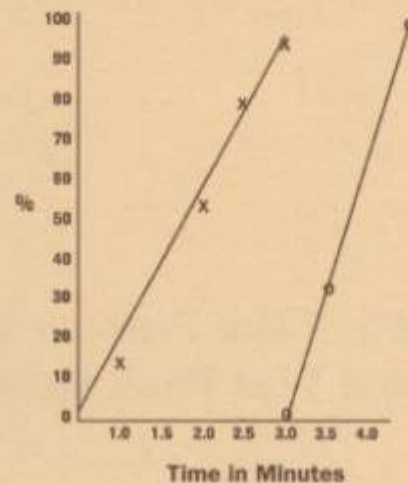
### Results

Data from the 121°C gravity cycles are presented in the graph below (left). The biological results began to show evidence of acceptable cycles at 15-16 minutes of exposure. At 17 minutes most of the cycles produced acceptable biological results. The Vapor Line® integrator in the PASS/FAIL™ packs demonstrated no pass results at 18 minutes, and 100% pass after 24 minutes of exposure. The results of the 134°C prevacuum cycles are shown in the graph below (right). Biologicals began to show a low level of acceptable results after only one minute of exposure, and were 100% acceptable at three minutes. The Vapor Line® integrator demonstrated no pass results at three minutes, and was 100% pass at the end of the standard 4 minute cycle.

Percent Pass/Acceptable — 121° Gravity Cycles



Percent Pass/Acceptable — 134° Prevacuum Cycles



X — X Biologicals    O — O Pass/Fail Pack

### Discussion and Conclusions

The results indicate that under the test conditions and vessel parameters used, the Propper PASS/FAIL™ Challenge Pack yields results similar to those obtained by biological test packs. The new pack with Vapor Line® demonstrated a more narrow time range for variable results than the biological test packs. This is an indication of the improved reproducibility of this technology as opposed to biologicals. In addition, the results of the Vapor Line® integrator in the PASS/FAIL™ pack can be read immediately without any specialized equipment. Results of biological testing are not available for 24 hours or longer.

Recently the JCAHO has clarified its position on performance testing of sterilizers.<sup>3</sup> It neither specifies the frequency of the testing nor the method used to perform these tests. The selection of test method is left up to the decision of individual hospitals. If a product demonstrates, either by published scientific study or by testing by the hospital, that it is comparable to an approved method, it may be substituted for the approved method. The data in this report support the equivalence in performance of the PASS/FAIL™ Challenge Pack to that of packs using biological indicators.

### References:

1. AAMI/ANSI ST-46 "Good Hospital Practice: Steam Sterilization and Sterility Assurance." 1994
2. Propper Professional Information Report 97-3, Evaluation of the BI-O.K.® Steam Test-Pak Compared to the Standard 16 Towel Biological Test Pack, Propper Mfg. Co., Inc. 1997
3. "Sterilization: What does the Joint Commission look for?" in Infection Control & Sterilization Technology, June 1996.

(If you require additional information regarding the PASS/FAIL™ Challenge Pack or any aspect of sterilization, telephone the Propper Sterilization Hotline 800/221-2280 — 9 A.M. to 5 P.M. Eastern Time.)

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