



PROFESSIONAL INFORMATION REPORT **97-3**

EVALUATION OF THE **BI-O.K.™ STEAM TEST-PAK**
Compared to the Standard 16 Towel Biological Test Pack

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Propper's BI-O.K.™ Steam Test-Pak

Product Description and Purpose:

Propper's BI-O.K.™ steam test-pak is a biological steam sterilization test pack which comes complete with biological indicator. It was designed to be a challenge equivalent to the currently recommended 16 towel pack in monitoring 250°F gravity and 270°F pre-vacuum steam cycles.¹ The purpose of this study was to compare the results of the BI-O.K.™ steam test-pak to those obtained with the 16 towel pack.

Materials and Methods:

BI-O.K.™ steam test-paks and 16 towel packs were prepared using 3 different lots of BI-O.K.™ steam test vials. Either 4 BI-O.K.™ paks or one 16 towel pack were tested per sterilization cycle. Both a 24x36x54 inch manually operated and a 20x20x40 inch programmed sterilizer were used in this study. After the cycles were completed, the test packs were allowed to cool, and the biological indicators were removed and activated. The BI-O.K.™ indicators were incubated at 56±2°C and examined after 48 hours of incubation.

Results:

Data from the 270°F pre-vacuum cycles are listed in Table 1. During the 3 times tested using a total of 180 biological indicators, the results from the BI-O.K.™ steam test-pak closely matched the results for the 16 towel pack. Data from the 250°F gravity displacement exposures are shown in Table 2. Both packs had virtually identical performance.

Table 1- 270 °F Pre-Vacuum Cycles

	BI O.K.™ Test-Pak	16 Towel Pack
Exposure Time	Biological Indicator Results ^a	Biological Indicator Results
1 Min.	25/30	23/30
2 Min.	9/30	6/30
3 Min.	2/30	2/30

Table 2- 250 °F Pre-Vacuum Cycles

	BI O.K.™ Test-Pak	16 Towel Pack
Exposure Time	Biological Indicator Results ^a	Biological Indicator Results
15 Min.	29/30	27/30
20 Min.	2/30	0/30
25 Min.	0/30	Not Done

^aNumber Survivors/ Number exposed

Discussion and Conclusions:

The data indicates that under the test conditions and vessel parameters used, the BI-O.K.™ test-pak and the standard 16 towel pack show virtual equivalence in relative resistance to penetration to saturated steam.

The 16 towel pack is subject to variation in preparation, and possibly resultant resistance to steam penetration. The folding, compression and taping of the towel pack are variables which are eliminated by the use of Propper's BI-O.K.™ steam test-pak.

References:

¹ AAMI/ANSI ST-46 "Good Hospital Practice: Steam Sterility Assurance," 1994, Association for the Advancement of Medical Instrumentation, Arlington, VA.

