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EVALUATION OF THE **BI-O.K.™ EO GAS BIOLOGICAL TEST-PAK**
Compared to the Standard Test Pack

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Propper BI-O.K. ™ EO Gas Biological Test-Pak

Product Description and Purpose: Propper's BI-O.K.™ EO gas biological test-pak is a biological test pack which comes complete with a biological indicator. It was designed to be a challenge equivalent to the currently recommended pack in monitoring ethylene oxide sterilization cycles. The purpose of this study was to compare the results of the BI-O.K.™ EO gas biological test-pak to those obtained with the standard pack.[1]

Materials and Methods: BI-O.K.™ EO gas biological test-paks and standard packs were prepared using 3 different lots of BI-O.K.™ EO gas biological vials. Five test packs were tested per sterilizer run in an ethylene oxide BIER vessel (Joslyn Sterilizer Corporation, Farmington, NY). After cycles were completed, the test packs were opened and the vials were aerated in a safety cabinet for 30 minutes. The indicators were then activated, incubated at 37°C for 48 hours, and examined for evidence of growth.

Results: Data from the sterilization runs are listed in the following table.

Biological Indicator Results (Number Positive/ Total)

Propper BI-O.K.™ EO Gas Biological Test Pack

Time	Lot G 43	Lot G 46	Lot G 47	Total
15 min	10/10	10/10	10/10	30/30
20 min	10/10	10/10	10/10	30/30
25 min	3/10	5/10	3/10	11/30
30 min	0/10	0/10	1/10	1/30
35 min	0/10	0/10	0/10	0/30
AAMI Recommended Test Pack				
15 min	3/3	3/3	4/4	10/10
25 min	2/3	1/3	3/4	6/10
35 min	0/3	0/3	0/4	0/10

These performance characteristics are also in agreement with the published values for a similarly approved product designed to monitor ethylene oxide sterilizers (ATI Disposable Biological EO Test Packs).

Discussion and Conclusions: The data indicate that under the test conditions and vessel parameters used,[2] the BI-O.K.™ EO gas biological test-pak and the standard test pack show virtual equivalence in resistance to ethylene oxide sterilization. The Propper test-pak can be used as a convenient replacement for the standard pack.

References:

[1] AAMI/ANSI ST-41 "Good Hospital Practice: Performance Evaluation of Ethylene Oxide Sterilizers - Ethylene Oxide Packs"; AAMI, Arlington, VA, 1994.

[2] Data on file, Propper Manufacturing Co., Inc.