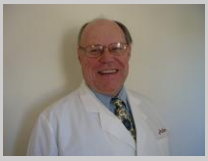
SGM BIOTECH®
BIOLOGICAL INDICATOR SPECIALISTS

Spore News™

Volume 7, Number 3
May 2010



John R. Gillis, Ph.D.
Technical Director

Introducing Process Challenge Device (PCD)

SGM Biotech is pleased to announce the introduction of its newest product line, the Process Challenge Device (PCD) for use externally on pallets processed in Ethylene Oxide sterilization. PCD is defined in AAMI/ANSI 11139 as an "item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process".

ISO 14161:2000 states "Process challenge devices and their placement in the product load should represent a challenge to the process that **is equivalent to or greater than** the challenge represented by the product load." This standard also includes the following statement: "The commercially available process challenge device shall **represent** a similar or greater challenge to the user's sterilization process than would be represented by the load."

This unique product is appropriate for both validation and routine monitoring of Ethylene Oxide sterilization cycles. For use in validation, SGM offers a set of four (4) PCDs with varying resistances. For the external PCD used in routine monitoring, select the PCD that is "equivalent to or greater than" the product challenge during the validation cycles. The PCDs contain the EZTest Gas self-contained biological indicator[1] to represent a challenge to the process that is equivalent to or greater than the challenge represented by the imbedded product PCD in the load.

A series of four PCDs resistances are assembled in a validation set (Figure 1). Each PCD type has been calibrated to impede the penetration of ethylene oxide gas and moisture at a defined rate, ranging from a lower challenge on one end, up through and ending with a significant challenge on the other end (see Figure 2). Using this range of available PCDs externally attached to the pallet during validation, the user selects the PCD that represents the configuration that is equal to or greater than the resistance of the product challenge imbedded in the load. This PCD would then be used externally as a routine monitor.

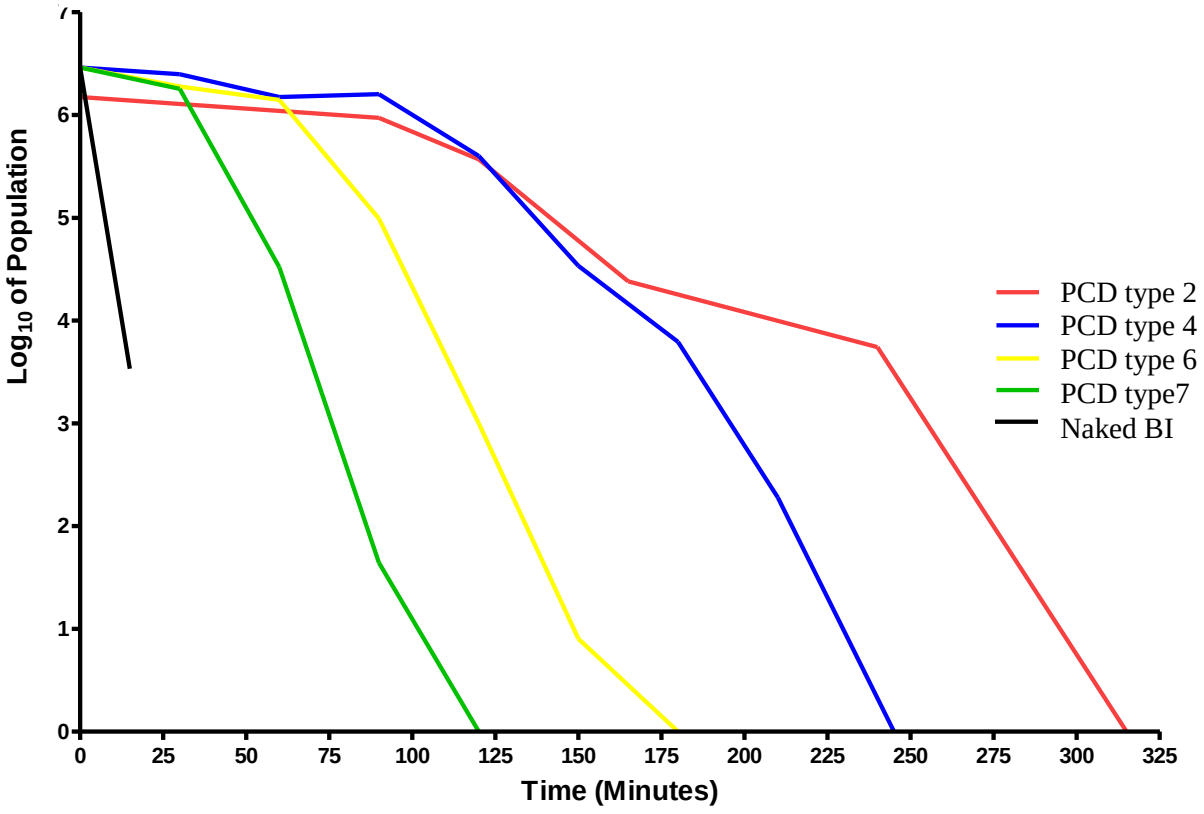
[1]Spore Strip PCD available upon request.

Figure 1

Figure 2 below illustrates a typical survivor curve of BIs in the PCDs exposed in an ethylene oxide resistometer. The black curve on the far left represents a "naked" BI, while the remaining four curves represent the same BI packaged in each of the four different PCD resistance types. The actual biological indicator lethality values appear in Tables I and II.

Figure 2

Survivor Curve of BIs, Naked and in Four PCD types Exposed in an Ethylene Oxide Resistometer



10 Evergreen Drive, Bozeman, MT 59715 • Phone: 406/585-9535 • FAX: 406/585-9219

www.sgmbiotech.com • e-mail: sporenews@sgmbiotech.com

Biological Indicator Lethality Characteristics

Table I

Sample Identification	Plateau Length (Minutes)	D-value 600mg/l, 54°C, 60± 10% RH	Coefficient of Determination (r^2)
Type 7 (1)	30	13.0	0.9801
Type 6 (2)	60	16.9	0.9844
Type 4 (3)	90	30.3	0.9866
Type 2 (4)	90	40.5	0.8971

Table II

Sample Identification	Kill Time Exposure	#Negative Units/Total Units
Type 7 (1)	125.0 minutes	20/20
Type 6 (2)	180.0 minutes	20/20
Type 4 (3)	275.0 minutes	20/20
Type 2 (4)	315.0 minutes (Estimated)	NA

The PCD complies with the global industry standard ISO 14161:2000 "Sterilization of health care products – Biological Indicators – Guidance for the selection, use, and interpretation of results". It takes the hassle and human error out of biological ethylene oxide sterilization monitoring, saving organizations both time and money.

Individual PCDs packaged 100 units per box. Validation sets packaged 31 per box (30 test units and one control set).

Process	Ethylene Oxide
Spores	*B. atrophaeus* (#9372)
Population	10^6
Incubation Time	48 hours
Incubation Temperature	36-38°C
Shelf Life	24 months

Reorder # EZTest Self-contained	Reorder # SGMStrip
PC7EZG/6 (Type 1)	PC7SGM/6 (Type 1)
PC6EZG/6 (Type 2)	PC6SGM/6 (Type 2)
PC4EZG/6 (Type 3)	PC4SGM/6 (Type 3)
PC2EZG/6 (Type 4)	PC2SGM/6 (Type 4)

SPORES DON'T LIE®

Please email us with topics you would like to see addressed in "Spore News".

10 Evergreen Drive, Bozeman, MT 59715 • Phone: 406/585-9535 • FAX: 406/585-9219

www.sgmbiotech.com • e-mail: sporenews@sgmbiotech.com