BI-O.K.® EO Gas Biological Test Pack

Basic Principle:

The Joint Commission on Accreditation of Hospitals recommends that EO sterilizers be monitored for performance on a routine basis. Typically this consists of monitoring each load with biological indicators. Correct test performance requires a biological indicator and a chemical indicator (Type 5) be placed in the center of a standardized challenge pack. The recommended pack consists of a biological indicator placed in a plastic syringe, with the needle end open. The syringe, and a chemical indicator (Type 5) are placed in a cotton towel which is then placed in an instant sealing pouch. Correct test performance requires the BI-OK® EO Gas Biological Test Pack to be placed in a loaded chamber at the most challenging area for sterliant penetration, typically the middle of the top shelf. A sterilization cycle is performed based on sterilizer manufacturers' recommendations.

Following the cycle, the test pack is opened and the chemical indicator (Type 5) is examined for correct exposure. The biological indicator must be processed and evaluated after it was removed from the pack. The acid production associated with spore growth causes a change in color of the media. Growth of the biological indicator suggests inadequate sterilization conditions.

Instructions:

1. Place the pack in the most difficult area to sterilize, typically in the center of an EO gas sterilizer chamber.
2. Run a normal sterilization cycle.
3. Remove the pack form the sterilizer.
4. Check the process chemical indicator (Type 1) on the pack for exposure to the EO gas. The reactive ink should turn green when exposed to EO gas.
5. Open the pack, remove and examine Propper Short Gas-Chex integrating chemical indicator (Type 5)* for the correct exposure to sterilant. The reactive ink on Propper Short Gas-Chex sterilization indicator should turn green. If the reactive ink change is incorrect/incomplete, the test must be repeated with a new pack.
   **According to ISO 11140-1, Type 5 Integrating chemical indicators are the most accurate of the internal chemical indicators.*
6. Remove the BI-OK® EO Gas biological indicator from the pack. The process chemical indicator (Type 1) on the vial label should also turn green after the exposure to EO gas.
7. Identify the vial by load, sterilizer, and date.
8. If the ampoule in the vial looks damaged, or there is a media leakage, dispose of the damaged vial and repeat the test with a new pack.
9. Activate the BI-OK® EO Gas biological indicator by holding it in a vertical position. Compress the sides of the vial by using a manual crushing device to break the glass media ampule. The unit is properly activated when the media has been released from the ampule and the carrier inoculated with spores is in contact with the released media.
10. BI-OK® EO Gas biological indicator from the same lot should be used as a positive (unprocessed) control each time a sterilization test is performed.
11. Incubate the control (unprocessed) vial and the test (processed) vial(s) at 37 ± 2°C for 48 hours.

Interpretation:

1. Appearance of a color change from red to yellow is evidence of bacterial growth. All control (unprocessed) vials should show this color change within 48 hours. All test (processed) vials should remain red.
2. If test vials show a yellow color change, the ethylene oxide sterilization cycle was not successful. React to this sterilization failure immediately according to the policies of your institution.
3. File all information and results as a permanent record.

Limitations:

For use only in biological monitoring of ethylene sterilizers.

Storage:

Store BI-OK® EO Gas Biological Test Pack under normal room conditions (15-30°C; 59-86°F) 40-70% relative humidity. Store away from sterilants and other chemicals.

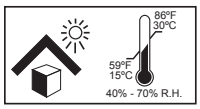
Disposal:

Dispose of positive, expired or unused BI-OK® EO Gas Biological Test Packs according to your institutional policy.

References:
• Accreditation Manual for Hospitals, JCAH, Chicago, IL, 1993
• AAMI/ANSI ST-41 "Good Hospital Practice: Performance Evaluation of Ethylene Oxide Sterilizers – Ethylene Oxide Test Packs"; AAMI, Arlington, VA, 1994

Explanation of symbols

= The date of manufacture
LOT = The lot number
= The expiration date



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