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Steris Amsco BIER System

(Biological Indicator Evaluator Resistometer)

Testing Biological Indicators for Steam and EO Sterilization Effectiveness

The Amsco® BIER (Biological Indicator Evaluator Resistometer) Systems are designed to provide environmental conditions for evaluating the resistance of microbial populations to sterilization. These systems may also be used for evaluation of chemical indicators, vacuum and pressure damage to packaging, and cycle development.

There are two models available:

- The Amsco steam BIER Vessel for testing steam biological indicators.
- The Amsco EO BIER Vessel for testing ethylene oxide biological indicators.

The Benefits of Amsco BIER Systems

Reliability and Durability

The BIER Systems are comprised of an inner and outer shell, a back head, and a door. All components are 316L grade stainless steel with a glass bead finish – the highest quality surfaces finished for optimal performance and maintenance.

All critical control system components have been designed and selected to tolerate the working internal environment of the BIER vessels. The systems generate reproducible results through reliable process control and monitoring.

Operator Safety

- **Safety Valve:** Limits the amount of pressure buildup so that the vessel pressure rating of (15 psig [1 barg]) for the EO BIER vessel and (55 psig [3.8 barg]) for the steam BIER vessel is not exceeded. The valve creates a safe environment throughout the cycle.
- **Door Switch:** Acts as a signal to the control system that the door is fully closed. If the signal is lost during a cycle, the cycle aborts, and the chamber is vented with a controlled exhaust. This function ensures effectiveness, efficiency, and safety throughout the cycle.

Validatable Operation

The process control system includes an operator interface, touch screen, printer, and main controller. It monitors, controls, and documents all critical process factors. A "hard copy" is provided for each cycle, allowing customers to keep accurate records.

- **Ink-jet Printer:** Provides an easy-to-read record of all pertinent cycle data that is automatically printed at the beginning and end of each cycle as well as transition points during the cycle.
- **Data Collection Drive:** All data is collected on a 3/4" floppy disk. The information can be easily transferred to common computer programs for further analysis using an Excel spreadsheet format.

Ease of Use

The control system is factory-programmed with standard cycles for simplified operation by all users. Each cycle is adjustable to meet specific processing requirements and to provide process flexibility.

The easy-to-use operator interface control panel consists of a touch screen, printer, and data collection disk drive. The screen features a color graphic display which can be operated by pressing the touch-sensitive "buttons" shown on the screen. All displayed messages are complete phrases with no codes to be cross-referenced.

Optimal Cycle and Function Configuration

A "supervisor access" to the System Program Access menu on the touch screen limits changes in cycle parameters to authorized personnel, assuring secure cycle programming. Adjustments and changes can be performed through the

System Program Access menu for:

- Operator/Supervisor's Identification Numbers: An access code can be set and required in order to operate the unit and/or change the cycle values. Operator codes are used to operate the unit only; Program Access Area, supervisor's code is required to enter the System. Access can be limited to 15 operators and three supervisors, each with a different access code.
- **Selectable Cycle Name:** This function allows the user to name each cycle with any combination of letters, numbers, and blank spaces up to 40-characters in length. Allows a distinctively clear and customized naming process.
- Time, Data, Cycle Number, and BIER Unit Identification Number: These functions can be accessed and modified by an authorized supervisor.
- **Print Interval:** Allows adjustment of the cycle status data collection printouts generated during the cycle.
- Data Collection Drive Interval: Permits adjustment of the time period between cycle status data collection (faster or slower than printed data).

- Calibration: Permits temperature and pressure calibration. The control system provides a printed record of all calibration data for verification to current settings.
- EO units automatically calculates achieved EO concentration and relative humidity.
- EO BIER units are factory programmed with 100% EO Oxyfume 2000, and Oxyfume 2002 cycles. Steam BIER units are factory programmed with prevacuum, flush, and gravity cycles.

Quality Construction

A cooling fan with filter is installed to maintain positive pressure within the cabinet, keeping components cool and dust-free.

The Amsco BIER System for testing steam (Siemens controlled) meets the electrical equipment for measurement, control, and laboratory use standard (EN61326-1).

- Manually Operated Chamber Door: The machined end frame construction results in accurate door alignment. When the door is closed it is sealed to the pressure vessel end frame with evenly distributed pressure, which assures safe operation. A 3" diameter viewpoint is standard on the steam BIER door.
- **Piping:** All piping connections terminate within the confines of the Amsco BIER systems and are easily accessible from the back and sides of the unit.

Options

EO Disposer System: A catalytic reaction converts ethylene oxide gas in the EO BIER vessel's exhaust to carbon dioxide and water vapor.

STERIS Biological Indicators

Spordex® Biological Indicator Strips are designed for determining the effectiveness of steam and ethylene oxide sterilization procedures. Inoculated with Bacillus Subtilis for EO, and Bacillus Stearothermophilus for steam, these strips ensure consistent sterility monitoring. STERIS also offers Spordex Spore Suspensions and Verify® Self Contained Biological Indicators.



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