

APPLICATION

For testing biological and chemical indicators for steam sterilization.

DESCRIPTION

The Steam BIER-XLS (Biological Indicator Evaluator Resistometer) system is designed in accordance with ISO18472:2006 to provide reproducible reference environmental conditions for evaluating the resistance of microbial populations to steam sterilization.

The BIER-XLS test system incorporates a dynamic air removal system with a leak detection system to verify that air is removed from the test system. The evacuation is followed by a rapid pressurization with steam to the pre-selected sterilization temperature. Following exposure, the chamber is rapidly depressurized to atmospheric pressure to minimize exposure to steam.

Steam BIER-XLS systems are factory programmed with **Prevacuum** or **Gravity** cycles.

Chamber Interior Dimensions

5" diameter (cylindrical) x 10" deep (127 x 254 mm)

STANDARDS

Each Steam BIER-XLS system meets applicable requirements of the following listings and standards, and carries the appropriate symbols:

- **UL 61010-1**
- **EN 61010-1** (upon request)
- **CSA C22.2, No. 61010-1 and 61010-2-040**
- **Pressure Equipment Directive (PED) 97/23/EC** (upon request)
- **ASME Code, Section VIII, Division 1 for unfired pressure vessels.** The pressure vessel is so stamped; ASME Form U-1 is furnished.
- **EMC Directive:** 2004/108/EC, 93/68/EEC, 92/31/EEC, 89/336/EEC (upon request)
- **Low Voltage Directive:** 2006/95/EC, 93/68/EEC, 72/23/EEC (upon request)
- **Machinery Directive (MD):** 2006/42/EC, 98/37/EEC, 93/68/EEC, 91/368/EEC, 89/392EEC (upon request)



(Typical - details may vary.)

FEATURES

Control Options allow the operator to choose either temperature control or pressure control during steam charge and exposure:

- **Jacket RTD Control** – when the BIER-XLS system achieves steam charge temperature, the jacket-chamber isolation valve opens, and the chamber and the jacket essentially become one vessel. The chamber RTD controls both the chamber and jacket temperature.

The Selections Checked Below Apply To This Equipment

MODEL

- Steam BIER-XLS System

OPTIONS

- Steam Generator (Carbon Steel) 6kW

Item _____

Location(s) _____

- **Chamber Probe** – a thermocouple is supplied with the BIER-XLS system for sensing chamber temperature.
- **Pressure Control** – assumes that the chamber is a perfect steam atmosphere and that the steam tables are accurate in describing the temperature inside the chamber. The system calculates the pressure needed to reach the set temperature using a fourth-order polynomial equation. The temperature control is based entirely on pressure.
- **Maximum Obtainable Vacuum** – 3 kpa.
- **STERIS Datalink System** – provides a secure approach to capturing and archiving local print report data. The Datalink system is comprised of two parts: (1) a Customer-supplied IBM compatible PC to run Datalink System applications, referred to as the Host; and (2) a remote data interfacing unit, built upon Microsoft Access, to store the data. The print report data collection interface passively T's off of the existing printer data communication cable and requires no programming changes to the Steam BIER-XLS controller (21 CFR Part 11 Compliant).
- **Ink-on-paper impact printer**, located near the screen, provides an easy-to-read printed record of all pertinent cycle data on 2-1/4" (5.7 mm) wide paper. Data is automatically printed at the beginning and end of each cycle, and at transition points during the cycle.
Printer take-up spool stores an entire roll of paper, providing cycle records which can be saved for future reference. Three paper tape rolls are furnished with each system.

Cycle configuration is performed by accessing the Cycle Values menu through the touch screen. Up to 19 cycles may be configured; one additional cycle (20) is available for remote programming/operation by a host PLC. In addition to adjustment of cycle values, the following operating parameters can also be changed through the Cycle Values menu:

- **User name and access code.** A 10-character alpha-numeric user name and four-digit numerical password are required when entering the operator, supervisor or service mode. Operating the BIER-XLS system, starting a cycle or accessing the Cycle Values menu causes the display to request the entry of an access code. If the access code is not properly entered, the display returns to the standby or main menu screen, denying the user access to the BIER-XLS system or programming.
- **Temperature display and printout units** are Celsius (°C) or Fahrenheit (°F). Temperature is set, displayed, controlled and printed to the nearest 0.1°. Recalibration is not required when changing temperature units from °F to °C, and vice versa.
- **Pressure/vacuum display and printout units** are PSI or KPascals. Recalibration is not required when changing pressure units.

CYCLE DESCRIPTION

The Steam BIER-XLS system can be programmed with Prevacuum or Gravity cycle. Range of temperature can be set from 221-286° F (105-141° C).

CONTROL SYSTEM

Design Features

The process control system monitors, controls and documents all critical process parameters. The control system includes an operator interface, printer and main controller.

The control system is factory-programmed with standard cycles. Each cycle is adjustable to meet specific processing requirements. All control configuring is performed through the touch screen display.

All critical control system components have been designed and selected to tolerate the working internal environment of the Steam BIER-XLS system.

A fan with filter is installed within cabinet to keep components cool and dust-free.

Operator interface control panel, consisting of a color touch-screen and impact printer, is located on the front of the system.

- **Siemens color touch-screen** enables the user to easily program the desired cycle. Program information and operating characteristics are shown on a LCD display. The Siemens screen is 320 x 240 pixel resolution, 5.7" type.
The display indicates the appropriate control buttons, operator prompts and status messages necessary to assist in the system operation. All displayed messages are complete phrases with no codes to be cross-referenced. The display also indicates any abnormal conditions that may exist either in or out of a cycle.

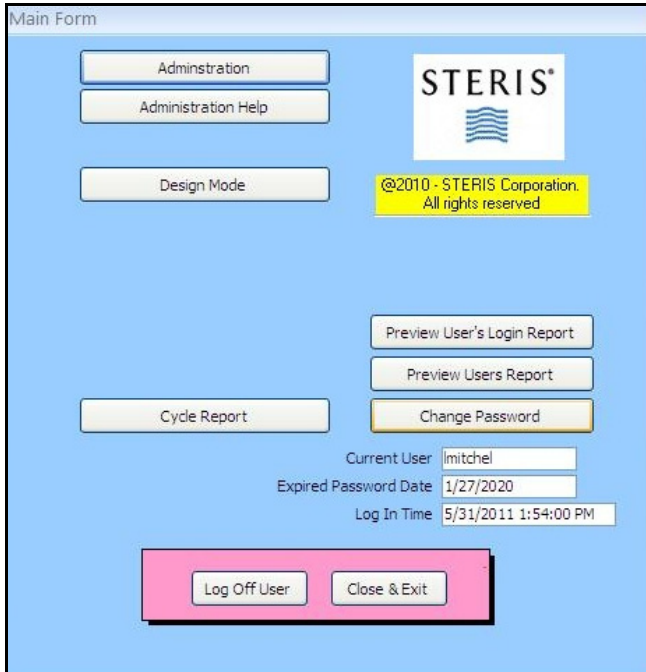
STERIS DATALINK

How STERIS Datalink Works

The Datalink System stores the BIER-XLS print cycle data in an MS Access database which is 21 CFR Part 11 compliant. Print cycle data is collected and stored in real time. After logging into the database and starting a BIER-XLS cycle, the data collection system automatically starts logging print cycle information and continues to do so until the cycle completes. Stored data (in XLS, XML, or parsed XLS file format) can then be viewed, printed or exported to Excel. Data viewed or printed can be for the current cycle or any previous stored cycle. To be supplied by the Customer is a standard desktop PC or laptop PC with Office 2003 (or 2007) and MS Access installed. An Ethernet cable, also provided by the Customer, is required to transfer data from BIER-XLS to the PC.

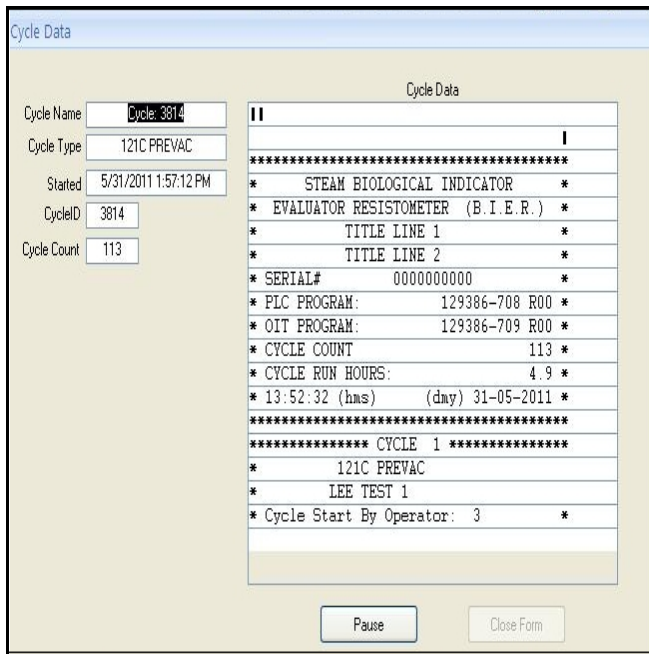
Typical Screen Shots and Reports

After logging in to the Datalink system, the Main form opens. The following image depicts the Main form from the Designer mode.



Main Form (Designer Mode)

After a cycle is started, data collection begins.



Cycle Data Collection Screen

A report of the data can be viewed. Page 4 depicts a View Cycle Report. The View Cycle Data can also be parsed to XLS format as depicted on page 5.

SAFETY FEATURES

Safety Valve limits the amount of pressure buildup so the vessel pressure rating of 55 psig is not exceeded.

Cycle Safeguards against incorrect process parameter entry cause the control system to reject any cycle parameters that exceed pressure vessel system design temperatures and pressures.

CONSTRUCTION

Shell Assembly

The chamber, weldments, door and jacket are engineered to meet the requirements in design, materials and construction of the ASME Boiler and Pressure Vessel Code (Section VIII, Division 1). The vessel is so stamped and a signed copy of the U-1 form is furnished.

Two fabricated, stainless-steel shells, one within the other, form the BIER-XLS vessel. Type 316L stainless-steel end frame is welded to chamber. Back of chamber is fitted with welded, 316L stainless-steel formed head.

Steam-supply opening in chamber is shielded by a stainless-steel shelf/diffuser.

Chamber Door

Manual door is constructed of single piece of Type 316L stainless steel. Door is sealed by a compression gasket, and hinged with a Quick-Action Cam Lock door closure mechanism. Machined end frame ensures accurate door alignment. Locking mechanism prevents door from opening if chamber pressure is greater than 0.5 psig. **Door with 1" (25.4 mm) Viewport** allows observation of chamber contents during testing.

Steam Source

Steam BIER-XLS systems are operated on Customer supplied house steam. An optional 6 kW steam generator is available.

Pressurized Booster Pump

Provides adequate water pressure to water ejector in order to draw vacuum.

Piping

All piping connections terminate within the confines of the Steam BIER-XLS system, and are accessible from the back of the system. **Two Thermocouples** allow additional monitoring of chamber. Load temperature data is measured and sent to the printer.

OPTIONS

6 kW Electric Carbon Steel Steam Generator is offered if house steam is not available.

Cycle_3814_Parsed.xls [Compatibility Mode] - Microsoft Excel

Home Insert Page Layout Formulas Data Review View Acrobat

MS Sans Serif 10 A A

Font Alignment Number Styles

Clipboard Paste

Wrap Text Merge & Center

General

Conditional Formatting as Table Cell Styles

A1 InfoName

| | A | B | C | D | E | F | G | H | I | J | K | L | M |
|----|--|-----------|----------|---------|---------|----------|----------|----------|---------|---------|---------|-------|------------------|
| 1 | InfoName | InfoValue | PhPres | PhTemp | PhTime1 | PhTime2 | ChmbPres | ChmbTerr | RefTemp | TC1Temp | TC2Temp | Phase | Duration |
| 2 | CYCLEID: | 3814 | | | | | | | | | | | |
| 3 | | | | | | | | | | | | | |
| 4 | ***** | | | | | | | | | | | | |
| 5 | STERILIZ STEAM BIOLOGICAL INDICATOR | | | | | | | | | | | | |
| 6 | STERILIZ EVALUATOR RESISTOMETER (B.I.E.R.) | | | | | | | | | | | | |
| 7 | STERILIZ TITLE LINE 1 | | | | | | | | | | | | |
| 8 | STERILIZ TITLE LINE 2 | | | | | | | | | | | | |
| 9 | SERIAL#: 0000000000 | | | | | | | | | | | | |
| 10 | PLC PROC 129386-708 R00 | | | | | | | | | | | | |
| 11 | OIT PROC 129386-709 R00 | | | | | | | | | | | | |
| 12 | CYCLE CC 113 | | | | | | | | | | | | |
| 13 | CYCLE RU 4.9 | | | | | | | | | | | | |
| 14 | TIME / DA 13:52:32 (hms) (dmy) 31-05-2011 | | | | | | | | | | | | |
| 15 | ***** | | | | | | | | | | | | |
| 16 | CYCLE: 1 | | | | | | | | | | | | |
| 17 | CYCLE: 121C PREVAC | | | | | | | | | | | | |
| 18 | CYCLE: LEE TEST 1 | | | | | | | | | | | | |
| 19 | OPERAT 3 | | | | | | | | | | | | |
| 20 | ***** | | | | | | | | | | | | |
| 21 | | | | | | | | | | | | | |
| 22 | PHASE: | PRE-CON | 4.5kPa | | | 0sec | | | | | | | PRE-CONDITION |
| 23 | | | | | | 13:52:32 | 95.1 | 121.1 | 157.7 | 34.0 | 35.6 | | PRE-CONDITION |
| 24 | | | | | | 13:52:37 | 41.9 | 121.0 | 157.7 | 34.0 | 35.5 | | PRE-CONDITION |
| 25 | | | | | | 13:52:41 | 4.1 | 121.0 | 157.7 | 34.0 | 35.5 | | PRE-CONDITION |
| 26 | PHASE DI | 00:09m:s | | | | | | | | | | | PRE-CON 00:09m:s |
| 27 | PHASE: | COME-UP | 204.9kPa | 121.0°C | | | | | | | | | COME-UP |
| 28 | | | | | | 13:52:41 | 4.1 | 121.0 | 157.7 | 34.0 | 35.5 | | COME-UP |
| 29 | | | | | | 13:52:46 | 27.4 | 121.0 | 157.7 | 34.0 | 35.6 | | COME-UP |
| 30 | | | | | | 13:52:51 | 153.7 | 121.0 | 157.7 | 34.1 | 35.6 | | COME-UP |
| 31 | | | | | | 13:52:51 | 155.2 | 121.0 | 157.7 | 34.1 | 35.6 | | COME-UP |
| 32 | PHASE DI | 00:10m:s | | | | | | | | | | | COME-UP 00:10m:s |
| 33 | PHASE: | EXPOSUF | 204.9kPa | 121.0°C | 01:00 | | | | | | | | EXPOSURE |
| 34 | | | | | | 13:52:51 | 155.2 | 121.0 | 157.7 | 34.1 | 35.6 | | EXPOSURE |
| 35 | | | | | | 13:52:52 | 159.5 | 121.0 | 157.7 | 34.1 | 35.7 | | EXPOSURE |
| 36 | | | | | | 13:52:53 | 170.7 | 121.0 | 157.7 | 34.2 | 35.6 | | EXPOSURE |
| 37 | | | | | | 13:52:54 | 187.0 | 121.0 | 157.7 | 34.1 | 35.5 | | EXPOSURE |
| 38 | | | | | | 13:52:55 | 204.4 | 121.0 | 157.7 | 34.0 | 35.5 | | EXPOSURE |
| 39 | | | | | | 13:52:56 | 208.4 | 121.0 | 157.7 | 34.0 | 35.5 | | EXPOSURE |
| 40 | | | | | | 13:52:57 | 205.9 | 121.0 | 157.7 | 34.0 | 35.4 | | EXPOSURE |
| 41 | | | | | | 13:52:58 | 205.9 | 121.0 | 157.7 | 34.0 | 35.4 | | EXPOSURE |
| 42 | | | | | | 13:52:59 | 205.9 | 121.1 | 157.7 | 34.0 | 35.3 | | EXPOSURE |

View Cycle Data Parsed to XLS Format

MOUNTING ARRANGEMENT

The Steam BIER-XLS system is supported by a welded, painted steel stand. Steam BIER-XLS systems are shipped with side and back panels for freestanding installation. Steam BIER-XLS systems can be recessed into a wall as required. Each Steam BIER-XLS system is equipped with four casters for ease of movement.

PREVENTIVE MAINTENANCE

A global network of skilled service specialists can provide periodic inspections and adjustments to help assure low-cost peak performance. STERIS representatives can provide information regarding Annual Maintenance Agreements.

NOTES

1. Pipe sizes shown indicate terminal outlets only. Building service lines, provided by third parties, must supply the specified pressures and flow rates.
2. Disconnect switches with OFF position lockout only should be installed in electric supply lines (by Customer) near the equipment.
3. Accessible emergency shutoff valves are required for steam and water (by Customer).
4. House steam option requires a thermo-dynamic trap in steam supply line (by Customer).
5. Flexible hose connections are recommended for water line (5/8" ID) and drain line (3/4" ID) (by Customer).
6. Clearances shown are minimal for installing and servicing the equipment. Recommended service area is 18" (457 mm) on each side and at back of the Steam BIER-XLS system.

UTILITY REQUIREMENTS

Water

30 to 50 psig dynamic, 5/8" (16 mm) FPT pipe, 5.0 to 8.0 gpm capacity.

Drain

0 psig, 3/4" (19 mm) FPT pipe size, 10 gpm gravity feed.

Electric

- Controls – 230 Volt, 60 Hz, 15 A.
- Boiler – 240 Volt, 60 Hz, 1-phase, 30 A.

ENGINEERING DATA

Shipping Weight:

200 lbs (90.6 kg)

Shipping Dimensions (H x W x D):

69 x 22 x 36" (1752 x 559 x 914 mm), on casters.

CUSTOMER IS RESPONSIBLE FOR COMPLIANCE WITH APPLICABLE LOCAL AND NATIONAL CODES AND REGULATIONS.

The base language of this document is ENGLISH. Any translations must be made from the base language document.

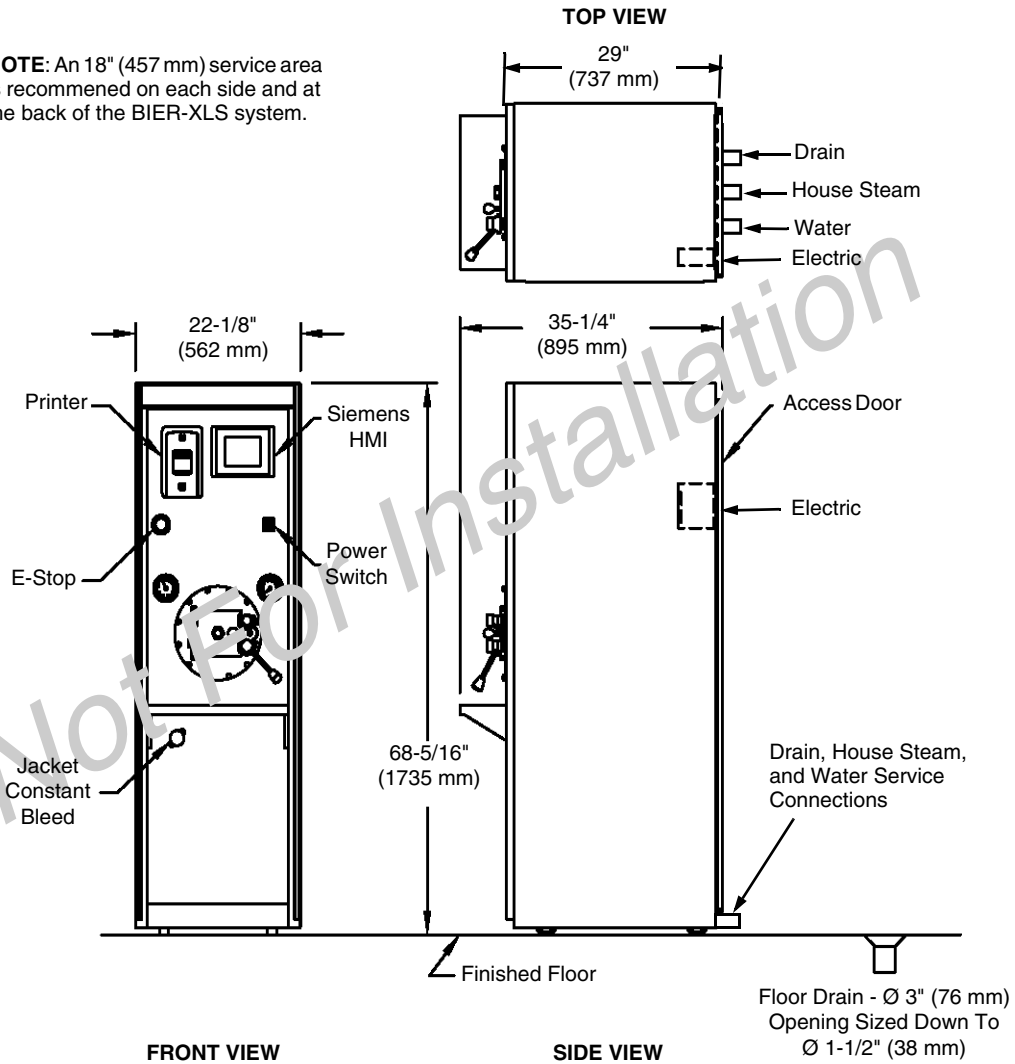
Refer to the Following Equipment Drawing for Installation Details

| Equipment Drawing Number | Equipment Drawing Title |
|--------------------------|--|
| 200020-847 | Amsco® Steam BIER-XLS Biological Indicator Evaluation Resistometer System with Siemens Control |

Dimensions are inches (mm)

Dimensions are typical - drawing is not to scale.

NOTE: An 18" (457 mm) service area is recommended on each side and at the back of the BIER-XLS system.



For further information, contact:



STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834 • USA
440-354-2600 • 800-548-4873
www.STERISLifeSciences.com