



LSII-202038  
STERILIZER MACHINE SPECIFICATION  
A-83-37629

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## 1.0 PART I – GENERAL

### 1.1 Vessel Volume

1.1.1 Steam sterilizer, internal volume of 20" x 20" x 38".

### 1.2 References

1.2.1 Following industry association and government codes and standards shall be followed as applicable to the design, fabrication, assembly and testing of the specified equipment.

1.2.1.1 American Society for Testing and Materials (ASTM)

1.2.1.2 American Society of Mechanical Engineers  
Bioprocessing Equipment (ASME BPE)

1.2.1.3 Code of Federal Regulations (CFR)

1.2.1.4 Current Good Manufacturing Practices of the US Food  
and Drug Administration (cGMP)

1.2.1.5 International Society of Automation (ISA)

1.2.1.6 Federal Occupational Safety and Health Act (OSHA)

1.2.1.7 Underwriters Laboratories (UL), Canadian Standards  
Association (CSA) and Canadian Underwriters  
Laboratories (cUL).

1.2.1.8 American Society of Mechanical Engineers Boiler and  
Pressure Vessel Code (ASME BPVC)

1.2.1.9 National Electric Manufacturers Association (NEMA)

1.2.1.10 National Fire Protection Association/National Electric  
Code (NFPA/NEC)

1.2.1.11 United States Pharmacopoeia (USP)

1.2.1.12 American Society of Mechanical Engineers (ASME),  
Unified Pressure Vessel Code, Section VIII

1.2.1.13 American Welding Society (AWS)

1.2.1.14 American National Standards Institute (ANSI)

1.2.1.15 National Institute of Standards and Technology (NIST)

1.2.1.16 California Building Code (CBC)



### **1.3 Submittals**

- 1.3.1 **Product Data:** Submit manufacturer's data for each item of equipment specified. Include dimensions, configurations, construction details, and attachments. Indicate location, size, and service requirements for each utility connection.
- 1.3.2 **Shop Drawings:** Provide large scale plans and sections showing rough-in, anchor placements, clearances, and location of utilities for coordination with other trades.
- 1.3.3 **Test Documentation:** As required by end-user specification; machine test documents may be submitted for approval prior to execution.
- 1.3.4 **Manufacturer's Installation/Operation/Service Manual.**

### **1.4 Quality Assurance**

- 1.4.1 **Manufacturer's Qualifications:** Modern plant with proper tools, dies, fixtures and skilled workers to produce high quality equipment meeting the following minimum requirements:
  - 1.4.1.1 Ten years or more experience in manufacture of the type of equipment specified.
  - 1.4.1.2 Ten installations of equal or larger size.
- 1.4.2 **Installer's Qualifications** by; or as authorized by Beta Star Life Science Equipment.

## **2.0 PART II - PRODUCTS**

### **2.1 Steam Sterilizer**

- 2.1.1 **Manufacturer:**

Beta Star Life Science Equipment  
R-V Industries, Inc.  
584 Poplar Road  
Honey Brook, PA 19344

2.1.2 Size and Characteristics:

2.1.2.1 Chamber Size: 20"w x 20"h x 38"d

2.1.2.2 Vacuum Type: Water ejector based vacuum system, or Envirovac Water-conservation vacuum system

2.1.2.3 Installation Type: Free standing or recessed

2.1.2.3.1 Cabinet

2.1.2.3.2 One wall recessed

2.1.2.3.3 Two wall recessed

2.1.2.4 Door Arrangement: Single or double door

2.1.2.5 Door type: Vertical sliding

2.1.2.6 Door Operation: Manual or optional electric motor driven

2.1.2.7 Steam Source: House steam, electric steam generator, or clean steam generator.

2.1.2.8 Basis of Design: Beta Star Life Science Equipment of R-V Industries Model LSII-202038

**2.2 Sterilizer Description**

2.2.1 Steam sterilizer with a fully programmable Allen Bradley PLC control system that provides sterilization using saturated steam under pressure which utilizes vacuum air removal principles.

2.2.2 Provide with process cycles suitable for the processing of hard goods, biological waste (bio-bags), animal cages, wrapped porous loads, or liquid loads in vented containers in the temperature range of 100°C to 138°C.

2.2.3 Provide optional Isothermal Temperature Control Range of 78°C to 100°C for all cycle options.

**2.3 Pressure Vessel Details**

2.3.1 Engineered chamber weldment, door, and vessel jacket in accordance with the standards as defined by the American Society of Mechanical Engineers (ASME), Unified Pressure Vessel Code, Section VIII, Division 1. Fabricated pressure vessel to bear the ASME inspection authority stamp.

- 2.3.2 Vessel Identification: The autoclave vessel shall have one accessible data plate permanently fastened. data plate will display the following information:
  - 2.3.2.1 Name of the manufacturer.
  - 2.3.2.2 Manufacturer's serial number.
  - 2.3.2.3 Manufacturers work order number.
  - 2.3.2.4 Manufacturers item number.
  - 2.3.2.5 Year of manufacture.
  - 2.3.2.6 Canadian Registration Number (CRN) (if applicable.)
  - 2.3.2.7 Chamber pressure and temperature rating.
  - 2.3.2.8 Jacket pressure and temperature rating.
  - 2.3.2.9 Stamp of the inspection authority.
  - 2.3.2.10 National Board Number
- 2.3.3 Vessel Construction: Engineered and fabricated chamber, door(s) and jacket to maintain the specified operating pressures and temperatures from full vacuum to 45 psig at 300°F.
- 2.3.4 Inner Chamber: Fabricated from SA-240 type 316L stainless steel. Optionally, material that contains higher levels of corrosion resistance may be selected.
- 2.3.5 Wetted vessel component finish to be glass bead blast. Optional mechanical finish surface up to 20 Ra is available.
- 2.3.6 Jacket Construct of SA-240-304 or optionally specified SA-240-316 type stainless steel.
- 2.3.7 Chamber Floor: The lower part of the inner chamber shall form the chamber floor. Chamber floor geometry shall facilitate free flow gravity drain. Chamber floor will be furnished with appropriate number of chamber drains, each with their own drain strainer to prevent clogging.
- 2.3.8 Baffled Steam Injection: Directed steam injection utilizing the flanged and dished ASME head to control flow, distribute temperature, deflect condensate to the chamber drain and minimize load wetting by eliminating direct steam impingement on the load.

- 2.3.9 Shell Insulation is removable for vessel inspection. The vessel insulation is comprised of double sided silicone cloth coated fiberglass mat, 1.5" minimum thickness with complete pressure vessel coverage.
- 2.3.10 Safety Valve: Provide with ASME approved and stamped safety valve(s). Safety valve set point to be the Maximum Allowable Work Pressure (MAWP) of the vessel. Safety valve capacity to sufficiently relieve the peak flow of the complete piping system.
- 2.3.11 Typical unit is provided with (2) 1" NPT chamber validation ports with (1) accessible from the service space of the machine. Optional 1-1/2" or 2" Tri-Clamp port also available. The port shall include a plug.

## **2.4 Sterilizer Door Description**

- 2.4.1 Manual (or optional) automatic electrically operated vertical sliding door(s). Door(s) surface exposed to the chamber shall be constructed of welded SA-240, Type 316L stainless steel or optionally specified SA-240-2205 duplex stainless steel. Door(s) shall be fabricated to maintain rigidity throughout the design operating temperature and pressure range. The exterior of the door(s) are covered with Type 304 stainless steel with a #4 brush finish to match fascia panels.
- 2.4.2 Door(s) sealing Mechanism: Engineered and fabricated to provide an airtight closure of the sterilizer for pressure, water, vacuum, and steam service. The door(s) shall be sealed using a one piece, easily replaceable silicone gasket. The door retention shall automatically engage when the door is closed. Compressed air or optional steam shall be used to actuate the door gasket against the door plate providing a hermetic seal.
- 2.4.3 Door Safety Features
  - 2.4.3.1 A cycle may not be started until the door(s) are fully closed and sealed.
  - 2.4.3.2 The door(s) cannot be opened while a cycle is in progress.
  - 2.4.3.3 The door(s) shall not unseal unless the chamber is +/-2 PSIA of ambient pressure.
  - 2.4.3.4 Door(s) gasket supply circuit includes check valve(s) to maximize door seal integrity in the event of a power failure.

- 2.4.3.5 In the event of a power failure, a normally-open valve in the drain shall allow the chamber pressure to vent, thereby returning the chamber to atmospheric pressure.
  - 2.4.3.6 Integral door seal/lock control system monitors vessel and door seal pressure.
  - 2.4.4 Optional Electrically Operated Door Description
    - 2.4.4.1 Operated by HMI provided push-button(s).
    - 2.4.4.2 Operator to close door with HMI provided momentary push-button(s).
  - 2.4.5 Door Interlocks: Provide double door unit with interlocks to prevent inadvertent opening during process and to prevent both doors from being opened simultaneously. Door control mode is configurable to accommodate Bio-Safety Level (BSL) door interlock or pass-through operation.
- 2.5 Sterilizer Cycle Descriptions**
- 2.5.1 Pre-Vacuum Cycle: Pre-conditioning of load during air removal using programmable positive and negative ramped pressure pulsing to remove entrapped air. Includes programmable, ramped vacuum drying.
  - 2.5.2 Micro Isolator Cycle: Pre-vacuum cycle using programmable positive and negative ramped pressure pulsing to reduce internal and external crazing of animal housing. Micro Isolator Cycle designed to minimize stress of items being sterilized
  - 2.5.3 Liquid Cycles
    - 2.5.3.1 Used for liquids in vented borosilicate glass or metal containers. The liquid cycle controls positive steam pressure and vacuum assisted air removal along with programmable, ramped heating and exhaust to ambient pressures at end of cycle.
    - 2.5.3.2 Liquid with optional air cooling cycle introduces filtered ambient temperature air during exhaust to speed cooling.



- 2.5.3.3 Liquid Cycle with optional pre-vacuum: Pre-conditioning of load using programmable positive and negative ramped pressure pulsing to assist in removal of entrapped air. Chamber temperatures and pressures are controlled to prevent boil over of product. Liquid Cycle includes controlled ramped exhaust to ambient with optional vapor removal phase.
- 2.5.4 Gravity Cycle
  - 2.5.4.1 Designed for non-air retentive products. Gravity Cycle utilizes positive steam pressure with vacuum assist air removal for conditioning of the load. The end of cycle exhaust is programmable to provide dry and non-dry phases.
- 2.5.5 Bio-Waste Cycle
  - 2.5.5.1 Designed for vacuum pre-sterilization conditioning through positive and negative pressurization to ensure air removal from mixed products in containers. Programmable ramped steam pressurization is used to maximize heat penetration of mixed laboratory biohazard waste. Bio-Waste cycle utilizes slow exhaust to prevent boil over.
- 2.5.6 F<sub>0</sub> Temperature Control Cycle (Optional)
  - 2.5.6.1 Designed for the sterilization of heat sensitive materials using time-at-temperature calculations beginning at a predetermined point of the conditioning phase. This reduces the product exposure to higher temperatures normally found in standard sterilization cycles.
- 2.5.7 Isothermal Cycle (Optional)
  - 2.5.7.1 Designed for conditioning of heat sensitive materials at a temperature range of 78<sup>o</sup>C – 100<sup>o</sup>C.
- 2.5.8 Test Cycles
  - 2.5.8.1 Pre-programmed automatic Leak test cycle to verify and record vessel and supply piping pressure integrity.
  - 2.5.8.2 Pre-programmed Daily Air Removal (Bowie-Dick) test. Air removal test verifies removal of residual air from chamber and load. Air Removal Test also indicates steam penetration into the load.

## 2.6 Sterilizer PLC Control System

- 2.6.1 The sterilizer process control system shall monitor, control and document all critical process parameters from the Door 1 and/or optional Door 2 side of the sterilizer. The control system shall include a Human/Machine Interface, (HMI) Controller, printer, Program Logic Controller (PLC) processor and emergency stop switch. Resistance Temperature Detectors (RTD's) shall be provided in sterilizer chamber and jacket drains to sense and control variations in temperature. A pressure transmitter shall be provided to measure chamber pressure and vacuum.
- 2.6.2 Operating (Door 1) Human Machine Interface (HMI): The HMI shall be a programmable 5.7" color touch screen operator interface. During in-cycle operation, the HMI shall show sterilizer status, time of day, cycle times, temperature, pressure, and any abnormal process conditions. The operator interface shall contain screens with the ability to view the status of the systems digital inputs and outputs, and analog inputs.
- 2.6.3 Printer: The printer shall be a 32 column, alphanumeric dot-matrix (or optional thermal) printer using 2-1/4 inch wide, single-ply paper. An automatic paper take-up mechanism is provided. Paper is accessible from the front of the control. Cycle Data printed by the sterilizer includes time in cycle, chamber pressure and chamber temperature. In addition to this real time based logging, the printer will also print alarm messages, cycle data and phases. Systems with the optional load probe installed and enabled will provide printed load probe temperature and accumulated  $F_0$ .
- 2.6.4 PLC Controller Enclosure: The main controller enclosure contains the low (24VDC) voltage PLC and system fuses. All 24 VDC monitor and control devices are wired back to this enclosure. The PLC Controller Enclosure is accessible from the machine service space.
- 2.6.5 Power Distribution Enclosure: The line voltage (120VAC) control components are segregated from low voltage components. 120VAC components are installed and accessible according to safe minimum workspace requirements of NEC section 110.26.
- 2.6.6 Audible Alarm: The operator interface shall include an audible alarm to annunciate end of cycle or an alarm condition.

## **2.7 Operator Interface Description**

2.7.1 The Human/Machine Interface, (HMI) shall provide security access, service diagnostics, cycle selection and configuration of cycles and cycle parameters. Security Access: Five (5) levels of user/password security are provided within the operator interface: Guest (No Login), Operator, Supervisor, Technician and Administrator. The password security shall prevent sterilizer operation and/or cycles and their cycle values from being changed by unauthorized personnel. An automatic logoff feature has an inactivity timer to ensure unauthorized personnel do not gain access under another user's session. The auto logoff feature may be disabled for the Operator by the Administrator to permit operators to remain logged on.

2.7.2 Cycles: The following cycles shall be operator-selectable from the operator interface: Thirty (30) programmable cycle processes are available to be configured for Pre-Vacuum, Liquid, Biowaste, Hard Goods. Default cycle recipe parameters are able to be modified with Supervisor access. In addition to the programmable cycles there are four maintenance cycles: Leak Test, Air Removal, Insitu Filter SIP (optional), and EN285 Air Detect (optional).

2.7.3 Printer shall document all cycle information including: Owner Name, Machine Name, Machine Serial Number, Cycle Number, Cycle Type, Cycle Count, Current Date, Start Time, User Name and Cycle Parameters.

2.7.3.1 Duplicate Print: The operator shall have the ability to re-print cycle data for the last completed cycle.

## **2.8 Alarms**

2.8.1 Continuous system monitoring, alert and alarm functionality identifies any abnormal or unsafe operating condition. The alarm history is retained for review. Each cycle alarm shall be logged onto the cycle printout. The log shall document the type, and real time occurrence.

## **2.9 Service Diagnostics Mode**

2.9.1 The service diagnostic mode maintenance screen shall include: input/output testing, analog calibration and Process and Instrumentation (P&ID) controller tuning parameters. Access shall be via password security.



## **2.10 Beta Connect Control System (Optional)**

2.10.1 Includes remote factory service connection with 256-bit encryption security. Beta Connect has four different service options:

### **2.10.2 Remote Service Support**

2.10.2.1 Provides immediate service, troubleshooting and control updates initiated through the secure connection by Beta Star certified technicians.

### **2.10.3 Mobile Observation and Control**

2.10.3.1 Observe and control a sterilizer HMI from any location utilizing a smart phone or tablet. Cycle alarms, errors and alerts may be viewed by multiple users and devices.

### **2.10.4 Sterilization Network Management**

2.10.4.1 Monitor and control multiple sterilizers in a network or facility from one command center computer.

### **2.10.5 Predictive Maintenance and Analysis**

2.10.5.1 Provide predictive service analytics by monitoring sterilizer usage data.

## **2.11 Cycle Safeguards**

2.11.1 Door/Cycle: Door locating safety switch prevents cycle start unless doors are closed and fully retained.

2.11.2 Door Operation: Door control mode is configurable to provide Multi-Flow, Pass-Through or Bio-Safety Level (BSL) door operation. All operations prevent two doors from being unsealed at any time.

2.11.2.1 Multi-Flow: Permits operator to select unload door at the beginning or end of cycle.

2.11.2.2 Pass-Through: Provides door interlock function to ensure material cannot be unloaded outside of the contained space prior to sterilization.

2.11.2.3 Bio-Safety Level (BSL): Provides door interlock function to ensure BSL material cannot be unloaded outside of the contained space prior to sterilization. BSL operation may be configured to permit same door load/unload.

- 2.11.3 Incorrect Process Parameter Entry: All parameters have a min/max value that prohibits selection of parameters outside of acceptable ranges.
- 2.11.4 Tamper-Proof Cycle Controls: Pre-programmed cycle configurations shall be provided to limit the operator responsibility. Once cycle is started all cycle parameters are locked. The operator can only start the cycle, monitor and acknowledge alarms. Cycle parameters are only configurable by the Supervisor or higher level.

## **2.12 Sensors**

- 2.12.1 Pressure: The chamber pressure sensor shall be an absolute pressure type transducer mounted in the appropriate chamber piping. Pressure on the HMI will be displayed to two decimal places (0.10 PSIA).
- 2.12.2 Temperature: Minimum two (2) separate temperature probes shall be provided for process control. Each shall be a platinum, 100 ohm Resistance Temperature Detector (RTD). RTD's to be located in the chamber drain and jacket drain. RTD indicated temperature will be displayed to one decimal place (0.1°C) on the HMI.

## **2.13 Utility Connections**

- 2.13.1 Plant steam to chamber and jacket: Machine will be pre-piped to suit installation facility utility specifications. Optional integral control steam generator may be provided.
- 2.13.2 Standard piping material to include copper/brass/bronze components. Optional 316L stainless steel components provided as required to accommodate clean steam supply systems.
- 2.13.3 Vacuum generation to be provided by single pass or optional turbine pump, (Enviro-Vac®) recirculated water ejector system. Enviro-Vac® system performance shall not be affected by normal fluctuations in the feed water temperature, pressure or flow rates. Chilled water supply is not required but may be utilized to enhance vacuum system water conservation.
- 2.13.4 Air Inlet Filter: The air inlet filter, used for vacuum break, shall be a hydrophobic type bacterial retentive absolute 0.2 micron air filter. The air filter shall be a replaceable cartridge mounted external to the chamber appropriately supported and connected.
- 2.13.5 Valves: Process valves shall be electrically actuated solenoid or pneumatically actuated angle seat type.



2.13.6 Automatic Condenser Exhaust: The piping system shall provide automatic condensing of chamber steam and disposal of effluent discharge at a maximum temperature of 140°F (60°C) at the floor drain inlet.

2.13.7 Pressure Gauges: Directly connected analog gauges provided on pressure vessel and piping system permit operator and service personnel to monitor system pressure at all times.

## **2.14 Warranty**

2.14.1 Standard warranty duration is one year parts and labor. Extended warranty terms available as optioned by Beta Star or required by End-User Specification.

## **2.15 Loading Equipment Options**

### **2.15.1 Single Bottom Shelf**

2.15.1.1 Fixed position 316 stainless steel flat loading surface. Tool-less installation and removal permits chamber drain access.

### **2.15.2 Rack Support System**

2.15.2.1 Includes 316 stainless steel fixed position bottom shelf, side mounted shelf support system and one standard sliding shelf. Up to (2) additional sliding shelves, (3 maximum) may be provided as required to accommodate end-user load configuration.

### **2.15.3 Loading Cart and Transfer Carriage**

2.15.3.1 Includes 316 stainless steel chamber tracks, adjustable shelf supporting cart and 304 stainless steel cart support carriage. Cart provided with (2) standard 316 stainless steel shelves. Optional shelves may be provided as required to accommodate end-user load configuration.



## 2.16 Plumbing Utility Requirements

Plumbing Utility Requirements <sup>1</sup>					
Plumbing Utility	Connection Size	Standard Material <sup>2</sup>	Flow Rate		Pressure
			Peak	Average	
Drain Size	3"	By Others, Suitable for 140°F/60°C	N/A	N/A	Atmosphere (Gravity drain)
House Steam	1/2"	Black Iron/Brass or Stainless	90 LB/HR	60 LB/HR	50 - 80 PSIG
Water, Ejector Vacuum Equipped Machine (Standard)	3/4"	Copper	8 GPM	4 GPM	60 - 80 PSIG
Water, EnviroVac® Equipped Machine (Optional)	1/2"	Copper	2 GPM	1 GPM	40 - 60 PSIG
Hot Water, Electric Steam Generator Equipped Machine (Optional)	1/2"	Copper	1/2 GPM	1/4 GPM	40 - 60 PSIG
Instrument Air, Pneumatic Valve Equipped Machine (Optional)	1/2"	Copper	2 SCFM	1 SCFM	80 - 100 PSIG

Key	
1	Recommended utility values indicate design standard for efficient machine operation. Consult with the Beta Star Sales Staff for site specific utility values which may fall outside of indicated ranges.
2	Material(s) may vary to suit installation.



## 2.17 Electrical Utility Requirements

Electrical Utility Requirements					
Electrical Utility	Voltage	Phase	Frequency	Amp Draw	Type
Sterilizer Controls	120V	1	60 Hz	2	Dedicated Circuit
EnviroVac® (Standard Single Phase) <sup>3</sup>	120V	1	60 Hz	9.4	Dedicated Circuit
EnviroVac® (Optional Three Phase Assembly) <sup>3</sup>	208V	3	60 Hz	6.9	Disconnect
EnviroVac® (Optional Three Phase Assembly) <sup>3</sup>	480V	3	60 Hz	3.0	Disconnect
Electric Steam Generator Heating Elements (Optional)	208 / 480V	3	60 Hz	83 / 36	Disconnect
Electric Steam Generator Controls (Optional)	120V	1	60 Hz	5	Dedicated Circuit
Air Compressor (Optional) <sup>4</sup>	120V	1	60 Hz	12	Duplex Outlet
Ethernet Connection Required for Optional Beta Connect Remote Connectivity System					

Key	
3	Operating voltage must be specified.
4	Air compressor only required for pneumatic valve machine installations which have no house instrument air available.

## 2.18 Heat Loss

### 2.18.1 Single Door Cabinet

2.18.1.1 (4,730) Btu/hr heat loss to room

### 2.18.2 Single Door Recessed

2.18.2.1 (2,136) Btu/hr heat loss to operator side

2.18.2.2 (2,594) Btu/hr heat loss to service space

### 2.18.3 Double Door Recessed

2.18.3.1 (1,782) Btu/hr heat loss to each operator side

2.18.3.2 (2,365) Btu/hr heat loss to service space

## 2.19 Installation Options

2.19.1 California Building Code (CBC) Approved Seismic restraint system.