SECTION 11630 - STERILIZERS

PART 1 - GENERAL

1.1 SUMMARY

A. Section Includes:

1. Small Steam Sterilizer

1.2 REFERENCES

A. The following industry, association and government codes and standards are cited in this Section. They shall be followed as applicable to the design, fabrication, assembly and testing of the specified equipment.

1. American Society for Testing and Materials (ASTM)

2. Federal Occupational Safety and Health Act (OSHA)

3. Underwriters Laboratories (UL) Or Equivalent (ETL)

4. American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, Section IX

5. National Electric Manufacturers Association (NEMA)

6. National Electric Code (NEC)

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

8. American Welding Society (AWS)

9. American National Standards Institute (ANSI)

1.3 SUBMITTALS

A. 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.

B. Shop Drawings: Provide large scale plans and sections showing rough-in and anchor placements, clearances, and location of utilities for coordination with other trades.

C. Test Reports: Submit test reports verifying conformance to specified performance tests.

D. Manufacturer's operating and maintenance manuals.

1.4 QUALITY ASSURANCE

A. Manufacturer's Qualifications: Modern plant with proper tools, dies, fixtures and skilled workers to produce high quality equipment and meeting the following minimum requirements:

1. Ten years or more experience in manufacture of the type of equipment specified.

2. Ten installations of equal or larger size.

B. Installer's Qualifications: Authorized Beta Star equipment manufacturer.

PART 2 - PRODUCTS

2.1 STEAM STERILIZER

A. Manufacturer

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

B. Size and Characteristics

1. Chamber Size 20”w x 20”h x 38”d

2. Type Hi-Vacuum or Pulse Vacuum

3. Enclosure

a. Free Standing Cabinet

b. One wall recessed

c. Two wall recessed

4. Door Arrangement Double or Single Door

5. Door Type Vertical Sliding

6. Door Operation Pneumatically operated door

7. Steam Source House Steam or Integrated Electric Steam Generator

8. Mounting Free Standing, or Recessed

9. Basis of Design Beta Star Life Science Equipment of R-V Industries Model LS2020 SERIES

C. Description

1. Steam sterilizer, equipment with a fully programmable Beta Star 2008 PLC control system, to provide sterilization using saturated steam under pressure utilizing vacuum air removal principles.

2. Provide with process cycles suitable for the processing of hard goods, empty glassware, animal cages, lightly wrapped porous loads, or liquid loads in vented containers in the temperature range of 100°C to 140°C.

D. Sterilizer Construction

1. Design the chamber, weldments, doors, and jacket to meet the requirements of the ASME Boiler and Pressure Vessel. Code (Section VIII, Division 1 of the applicable document). The vessel shall be stamped, and a signed copy of the U-1 form shall be furnished by the manufacturer.

2. Vessel Identification: The autoclave vessel shall have one accessible information plate permanently fastened and shall provide the following information:

   a. Name and Address of the manufacturer.

   b. Serial Number or other unit identification.

   c. Chamber Pressure and Temperature rating.

   d. Jacket Pressure and Temperature Rating.

   e. Stamp of the inspection authority.

3. Vessel Construction: Design and construct the chamber, doors and jacket to maintain the specified operating pressures and temperatures. Design chamber to withstand operation from full vacuum to 45 psig.

4. Inner Chamber: Fabricate from SA240 type 316L stainless steel with min 25 Ra finish.

5. Jacket (Channeled): Construct of SA240 Type 304 stainless steel.

6. Chamber Floor: The lower part of the inner chamber shall form the chamber floor. The chamber floor shall be furnished with appropriate number of chamber drains, with strainers, to facilitate drainage.

7. Baffles: Provide chamber with baffled steam inlets. The internal chamber baffling of 316 stainless steel shall be designed to direct condensate to the chamber floor drain, to minimize load wetting by direct impingement on the load by condensate, and assure proper steam temperature distribution in the chamber.

8. Shell Insulation: Cover sterilizer jacket with minimum 1 inch thick bonded fiberglass insulation, encased in aluminum skin.

9. Safety Valve: Provide with ASME approved and stamped safety valve, set at the approved operating pressure of the vessel.

10. Validation Port: Typical unit is provided with a 1” NPT validation port located on the left and right side of the vessel. (Optional 1 ½” or 2” Tri-Clamp port also available). The port shall include a plug.

E. Door Construction

1. Provide pneumatic operated vertical sliding doors. The doors shall be operated using door push buttons located on the HMI. Door surfaces exposed to the chamber shall be constructed of welded SA-240, Type 316L stainless steel. Each door shall be continuously welded and reinforced to achieve rigidity. The exterior of the doors shall be insulated and covered with Type 304 stainless sheet steel, with a #4 brush finish to match fascia panels.

2. Door Sealing Mechanism: Design and construct to provide an airtight closure of the sterilizer for pressure, water, vacuum, and steam service. The doors shall be sealed using a one piece, easily replaceable silicone gasket, located in a channel groove on the chamber. The door seal shall engage when the door is closed. Compressed air shall be used to actuate the door gasket against the chamber providing a hermetic seal.

3. Door Safety Features:

   a. A cycle cannot be started until the doors are fully closed, locked, and sealed.

   b. The doors cannot be opened while a cycle is in progress.

   c. The doors shall not unseal while the chamber is under pressure or vacuum.

   d. In the event of a power failure, both doors shall remain sealed indefinitely until the power is restored.

   e. In the event of loss the air pressure to the door seal, a check valve shall prevent the door seal air from de-pressurizing.

   f. In the event of a power failure, a normally-open valve in the drain shall allow the chamber pressure to vent to allow the chamber to return to atmospheric conditions.

4. Pneumatic Door: Activated by using the touch screen.

5. Door Interlocks: Provide double door units with interlocks to prevent inadvertent opening during the process and to prevent both doors from being opened simultaneously.

F. Cycles:

1. Prevacuum Cycle: Provide for the sterilization of porous materials, hard goods, heat and moisture stabile porous materials and decontamination of supplies using vacuum assisted air removal.

2. Liquid Cycle (Vented Containers Only): The liquids cycle shall provide for the sterilization of liquids and media in vented borosilicated glass, water bottles or metal containers.

3. Prevacuum Leak Test Cycle: Provide an operator-selectable automatic leak test cycle. The cycle parameters shall be fixed and designed to verify the integrity of the door seal and piping system.

G. PLC Control System

1. General: The sterilizer process control system shall monitor, control and document all critical process parameters from both sides. The control system shall include an operator interface, printer, and PLC controller. Resistance Temperature Detectors (RTD's) shall be provided in chamber drain line and sterilizer jacket to sense and control variations in temperature. A pressure transmitter shall be provided to measure chamber pressure and vacuum. Process signals shall be converted into electrical impulses to provide accurate controller inputs and readouts throughout entire cycle.

2. Operating End User Interface: The user interface shall be a programmable 6” color touch screen operator interface. During in-cycle operation, the operator interface shall show sterilizer status, time of day, cycle times, temperature, pressure, and any abnormal process conditions. The operator interface shall contain screens with maintenance diagnostics and ability to view the status of the systems digital inputs and outputs, and analog inputs.

3. Printer: The printer shall be a 32 column, alphanumeric dot-matrix 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.

4. Main Controller Enclosure: The main controller enclosure contains the PLC, temperature transmitters and fuses for the system. All devices are wired back to this enclosure and is located in the equipment service area.

5. Audible Alert: The operator interface shall include an audible Alarm to annunciate end of cycle or an Alarm condition.

H. Process Configuration:

1. The operator control interface shall provide security access, service diagnostics, selection and configuration of cycles and cycle parameters.

2. Security Access: Five (5) levels of user/password security are provided within the operator interface: Guest (No Login), Operator, Supervisor, Technicians 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 can be disabled for the Operator level by the Administrator to allow operators to remain logged on.

3. 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, Automatic Leak Test (maintenance), and a Bowie Dick Test (maintenance). Default cycle recipe parameters are able to be modified with Supervisor access.

4. Print Format: The printout header contains: cycle name, cycle number, user ID, machine name, serial number, date and time cycle initiated, recipe process parameters, and cycle counter number. The printer shall also document time, temperature, pressure, change of phase, and alarms. A summary at the end of the cycle shall contain total time in sterilize phase, minimum and maximum temperatures/minimum and maximum pressure in the sterilize phase, total F0 accumulated, and number of alarms experienced during the cycle if a load probe (option) is selected for cycle run.

5. Duplicate Print (if required): The operator shall have the ability to re-print cycle data in the event the paper ran out or was jammed during the execution of the cycle.

6. Optional Multi-Flow Operation: Sterilizer shall have the capability to operate as a single door sterilizer from either side or as a pass-through sterilizer in either direction.

I. Alarms:

1. Each cycle alarm shall be logged onto the cycle printout. The log shall document the type, and time of alarm.

J. Service Diagnostics Mode:

1. The service diagnostic mode shall include, input/output testing, and change values. Access shall be via password security.

K. Cycle Safeguards:

1. Door/Cycle: Cycle shall not begin unless doors are closed, sealed, and locked

2. Interlocking Doors: Once a cycle has been started, unload door can not be opened until a successful cycle has completed. Load door may be opened after cycle is aborted.

3. Incorrect Process Parameter Entry: All parameters have a min and max value that prohibits the configuration of parameters outs side of acceptable ranges.

4. Optional Load Probe: A load probe is available for use with all cycles including F_0

5. Tamper-Proof Cycle Controls: Preprogrammed 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 level.

L. Sensors:

1. Pressure: The chamber pressure sensor shall be an absolute pressure type transducer mounted in the appropriate chamber piping. Pressure readouts on the HMI will be displayed to one decimal place (0.1 PSIA).

2. Temperature: Minimum two (2) separate temperature probes shall be provided for reliable process control. Each shall be a platinum, 100 ohm, resistance temperature detector (RTD), located in the chamber drain and jacket drain.

M. Utility Connections:

1. Plant steam to chamber and jacket: Pre-pipe unit so that only one steam supply to the sterilizer is required.

2. Optional 316L SS Chamber Piping for Clean Steam

3. High Vacuum System: Vacuum system shall allow operation of the system with as low as 40 psi water pressure. Vacuum system performance shall not be affected by normal fluctuations in the feed water temperature or pressure being fed to the system. Vacuum System shall require maximum 3 gallons per minute for vacuum system and condenser. Chilled water shall not be required to ensure the performance of the vacuum system.

4. Air Inlet Filter: The air inlet filter, used for vacuum break, shall be a hydrophobic type bacterial retentive absolute 1.3 micron air filter. The air filter shall be a replaceable cartridge mounted external to the chamber appropriately supported and connected.

5. Valves: Steam, water, and exhaust valves shall be solenoid-activated, pneumatically operated. . All valves shall be of brass and shall be provided with tags for identification. Optional stainless steel configurations are available.

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.

7. Pressure Gauges: Provide chamber and jacket analog pressure gauges. Each gauge shall be between 2-5 inch diameter, calibratable in-place, and visible to the operator. A second chamber and jacket gauge shall be provided on double door units.

N. Conditional Warranty

1. Unit shall carry a one (1) year warranty.

O. Available Options:

1. Rack with two (2) adjustable shelves. 316L stainless steel construction
2. Loading Cart. 316L stainless steel construction.
3. Transfer Carriage. 304 stainless steel construction. Glass bead finish
4. Bio-containment Seal to prevent cross-contamination between dirty side and mechanical space
5. BSL3 Effluent Decontamination

P. Utility Requirements:

1. Optional Vacuum System Power: 480V / 3 phase / 60 Hz / 3 amps or 208V / 3 phase / 60 Hz / 6.9 amps Customer to provide 30 amp disconnect with 5 amp /10 amp fuses for each leg.
2. Control Power: 120V / 1 phase / 60 Hz / 5 amps. Customer to provide 15 amp external wall mounted box and switch.
3. Cold Water High Vacuum: 3 GPM, 40 – 60 psig, ½" FNPT connection. Customer to provide shut-off valve.
4. Cold Water Pulse Vacuum: 8 GPM, 60-80 psig, ¾ " FNPT connection. Customer to provide shut-off valve.
5. Compressed Air: 2 SCFM, 80 – 100 psig, 1/2" FNPT connection. Customer to provide shut-off valve.
6. Optional Air Compressor: 120V / 1 phase / 60 Hz / 12 amps. Customer to provide dual outlet.
7. House Steam: 80 lb/hr, 60 – 80 psig, 1/2" FNPT connection (regulated to 40 PSI). Customer to provide shut-off valve
8. Drain: 3" floor drain.
9. Heat Rejection (doors closed): 2,000 btu/hr from each door, 3,400 btu/hr in mechanical space.