

SECTION 11 53 00 – LAB STERILIZERS  
SECTION 11 71 00 – MEDICAL STERILIZERS

PART 1 - GENERAL

1.1 RELATED SECTIONS

- A. Division 22 Plumbing
- B. Division 26 Electrical

1.2 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: Show complete construction details, fittings, plumbing connections, electrical connections, filters, and other information necessary to fully describe each unit and its installation. Include plans and elevations. Include service requirements and clearances to walls and ceilings.
- C. Operation & Service Manuals: Provide a detailed description of equipment operation, controls, and safety features. Include wiring and plumbing schematics as well as maintenance schedule and procedure.

1.3 QUALITY ASSURANCE & QUALIFICATIONS

- A. Manufacturer Qualifications: The manufacturer shall be an expert in the related field and shall specialize in the product provided. The manufacturing facility shall produce high-quality equipment and meet OSHA requirements.
  - 1. The manufacturer shall have a minimum of twenty-five years of documented experience providing similar products in the US market.
  - 2. The manufacturer shall have a minimum of one hundred installations of similar products within the US market.
  - 3. The manufacturer is Buy America Act compliant.
- B. Installer Qualifications: The manufacturer shall make available a factory-trained and certified installation technician to provide product installation, startup, and training.
- C. Service Qualifications: The manufacturer shall make available a factory-trained and certified service technician whose office is local to the installation site.

- D. Warranty: The product shall carry a minimum of one year warranty on all parts supplied as well as a fifteen-year warranty on all pressure vessels provided.

#### 1.4 DELIVERY, STORAGE, AND HANDLING

- A. Protect finished surfaces during handling and installation with a protective covering of polyethylene film or another suitable material. Supply each unit with a Tip-And-Tell drop indicator on the outside of the packaging to notify receiving personnel of any possible damage during transit.

### PART 2 – PRODUCTS

#### 2.1 MANUFACTURERS

- A. Basis-of-Design: Subject to compliance with requirements, provide model SSR or SR autoclave with X1 controls manufactured by Consolidated Sterilizer Systems.
- B. Other substitutions are not permitted.

#### 2.2 CONSTRUCTION

- A. General Product Description: Provide a new double door pass-thru steam-based autoclave designed for rapid sterilization of moist heat compatible goods. The chamber shall seal using a solid silicone static gasket mounted on a hinged door. The autoclave shall be controlled by a PLC and shall come equipped with a color touch screen. The control system HMI shall be user-friendly and have a highly intuitive menu-driven system.

The sterilization chamber shall have an interior height, width, and depth measuring: **(CHOOSE ONE):**

- **16" x 16" x 26"**
- **20" x 20" x 38"**
- **24" x 24" x 36"**
- **24" x 24" x 48"**
- **26" x 26" x 39"**
- **26" x 26" x 49"**
- **24" x 36" x 36"**
- **24" x 36" x 48"**
- **24" x 36" x 60"**
- **24" x 36" x 72"**

The autoclave and controller shall be preconfigured to run: **(CHOOSE ALL THAT APPLY)**

- **Gravity**
- **Liquid**

- **Pre-Vacuum**
- **Liquid Cycle with Load Probe**
- **Bowie Dick**
- **Vacuum Leak Test**
- **Low Temperature/Isothermal (NOT AVAILABLE ON BSL-3 STERILIZERS EQUIPPED WITH EFFLUENT DECONTAMINATION)**
- **Air Over Pressure**
- **F<sub>0</sub>**
- **Rapid Cool (NOT AVAILABLE ON BSL-3 STERILIZERS EQUIPPED WITH EFFLUENT DECONTAMINATION)**
- **Continuous/Life Cycle Testing**
- **ATF Bioreactor**
- **Steam-Air Mix (NOT AVAILABLE ON BSL-3 STERILIZERS EQUIPPED WITH EFFLUENT DECONTAMINATION)**

B. Standards: All products supplied shall meet the appropriate standards where applicable.

1. ASME Code Section I – Rules for Construction of Power Boilers: Any fired pressure vessel supplied shall meet the requirements of the latest edition of the referenced code and bear the markings of the approval agency.
2. ASME Code Section VIII Division 1 – Rules for Construction of Pressure Vessels: Any unfired pressure vessel supplied shall meet the requirements of the latest edition of the referenced code and bear the markings of the approval agency.
3. ASME CSD-1 – Controls and Safety Devices for Automatically Fired Boilers: Any steam boiler supplied shall meet the requirements of the latest edition of the referenced code.
4. CRN (Canadian Registration Number) – Any pressure vessel shipped to Canada shall bear the markings of the approval agency.
5. UL, cUL 61010-1 & 61010-2: Where applicable, each equipment skid shall be assembled per applicable standards and bear the markings of the approval agency.
6. IEC EN 61010-1:96 – Safety requirements for electrical equipment for measurement, control, and laboratory use.
7. IEC EN 61010-2-041:96 – Specific requirements for steam autoclaves.
8. OSHA: Equipment manufactured by the supplier shall be produced per all guidelines set forth by the Occupational Safety and Health at Work Act.
9. ANSI/AAMI ST-8 – Hospital Steam Sterilizers

### C. Sterilizer Construction

1. Chamber Construction: The sterilizer chamber shall be rectangular in shape and shall be constructed from **CHOOSE ONE 316L stainless steel OR nickel-clad steel** with interior dimensions of height, width, and depth as listed in section 2.2.A. The chamber design, construction, and material shall conform to ASME code Section VIII Division 1 and display a U1 stamp. Chamber fabrication, welding, and assembly shall occur in the USA and be certifiable as Made in the USA. The chamber shall have an internal polish of 150 grit or better, and all chambers constructed of stainless steel shall be passivated. The chamber shall be fully jacketed by steam, partial jackets are not acceptable.
2. Jacket Construction: The jacket shall be constructed from **CHOOSE ONE steel OR 316L stainless steel OR 304L stainless steel** and shall completely envelop the entire width and length of the chamber. The jacket design, construction, and material shall conform to the ASME Code Section VIII Division 1 and be stamped to withstand a working pressure of 60 PSI.
3. Door Mechanism: The autoclave shall be provided with a door at each end. Each door shall be constructed from 316L stainless steel supported by a stainless steel hinge. Additionally, each door shall use a minimum of twelve solid stainless steel locking elements. In the event of the failure of any one locking element, the door shall continue to support the load within performance specifications. The door seal shall be achieved using a static crush gasket constructed of solid silicone. The door gasket shall not require pressurized steam, pressurized air, or electricity to maintain a positive seal. The static gasket design shall eliminate gasket tear and door jamming problems while maintaining a secure seal even in the event of complete loss of all utilities. No tools shall be required for gasket replacement.
4. Piping: All valves, re-build kits, plumbing components, fittings, and headers shall be non-proprietary. No custom manifolds or distribution systems shall be installed on the sterilizer. The piping system shall be designed such that all valves used are the same make and model thereby decreasing maintenance costs. All pressure piping shall be rated for the appropriate loads. All pipe, valve, and internal component locations shall be customized to suit the service requirements of the installation site. Materials of construction shall be as follows **CHOOSE ONE:**
  - **All wetted piping on the product side shall be constructed from 316L stainless steel.**
  - **All wetted piping on the product side shall be constructed from brass, bronze, and copper.**
5. Waste Cooling: All waste shall be cooled to a preset adjustable temperature. The temperature shall be adjusted through the sterilizer control system touch screen to assist

with water savings. If the waste temperature exceeds the set-point or if there is a sensor failure, the system shall alarm and an alarm shall be displayed on the screen, on the printout, and stored in an alarm history report. Visible indications are required to inform the user and prevent potential damage to the facility's drain plumbing.

6. Steam Baffle: The sterilizer chamber shall be equipped with baffled steam inlet. The internal chamber steam baffle shall be designed to direct condensate towards the chamber floor drain to minimize load wetting by direct impingement on the load by condensate and help assure proper steam temperature distribution in the chamber.
7. Insulation: The jacket of the autoclave and all steam service piping shall be insulated with a fiberglass-based material of at least 1" thick. The insulation shall not contain chlorides.
8. Protective Coatings: All exposed non-stainless steel surfaces shall have a protective enamel coating. The coating shall prevent damage to the autoclave and provide an aesthetically pleasing appearance. The enamel shall be adhered to the base metal and shall not wash or scrub off. Additionally, the enamel shall be specially formulated to protect against corrosive elements.
9. Chamber Penetrations: The chamber shall have at least one externally accessible penetration available to the user. This penetration shall be easily accessible and re-sealable. The chamber floor shall be furnished with an appropriate number of drain ports each with a removable strainer. The strainer shall insert into the drain port and retain all particles greater than 0.05". **(DELETE THIS SECTION IF NOT DESIRED)** An additional externally accessible penetration shall be supplied with a 2" connection for a sanitary fitting compatible with all manufacturers of 3 segment clamp-type seals. The wall thickness tolerances for this fitting will adhere to ASTM A269/70 standards to ensure compatibility with all standard sanitary tubing and butt-weld fittings in the USA.
10. Air Inlet Filter: All air into the chamber used to break a vacuum shall pass through a 0.3 micron HEPA air filter.
11. Options: **(DELETE ALL OPTIONS NOT DESIRED)**
  - i. Steam Source: **(CHOOSE ONE)**
    - Building Supplied Steam Source: The steam shall be provided via a building steam supply. **[OPTIONAL: A 5-micron steam filter shall be supplied to remove particulates and suspended moisture entrained in the building steam line. The steam filter housing shall be constructed from 316L stainless steel, shall be insulated, and shall be equipped with a steam trap.**

**The filter element shall be cleanable and indefinitely reusable to minimize ongoing maintenance costs.]**

- Electric Steam Generator: The steam generator shall be constructed from **CHOOSE ONE high strength steel OR 316L stainless steel**. The generator shall be equipped with a 6" diameter or larger port for cleanout and inspection. Port shall be located such that all welds may be inspected and all areas are accessible for cleaning. The generator shall be equipped with an easily accessible manual blow-down valve, a feed-water pump, **[OPTIONAL FOR STEEL BOILERS ONLY: and an automatically controlled blow-down valve.]**
  - Electric-Steam Combination: The sterilizer shall be equipped with both an electric steam generator as well as the ability to function off of a building-supplied steam source. The steam generator shall be constructed from **CHOOSE ONE high strength steel OR 316L stainless steel**. The generator shall be equipped with a 6" diameter or larger port for cleanout and inspection. Port shall be located such that all welds may be inspected and all areas are accessible for cleaning. The generator shall be equipped with an easily accessible manual blow-down valve, a feed-water pump, **[OPTIONAL FOR STEEL BOILERS ONLY: and an automatically controlled blow-down valve.]**
  - Stream-to-steam Clean Steam Generator: The steam generator shall utilize facility-provided steam to generate clean steam from a de-ionized water source. A stainless steel feedwater pump and all required heat exchangers shall be included. All wetted parts on the clean steam side shall be constructed from 316L stainless steel and passivated.
- ii. Mounting Arrangement: Sterilizer shall be **CHOOSE ONE cabinet paneled on one end and recessed behind a wall on the other OR recessed between two walls**. All appropriate stainless steel paneling, fascia, and trim to provide an aesthetic finished appearance shall be provided.
- iii. Shelving: **(DELETE THIS SECTION IF NOT DESIRED)** Items shall be loaded into the sterilizer on two removable stainless steel wire shelves. The shelving shall be constructed from high luster 316L with an electro-polished finish. The shelving shall be constructed to support a uniform load of 100 pounds per shelf.
- iv. Loading Cart & Transfer Carriage: **(DELETE THIS SECTION IF NOT DESIRED)** A loading cart and transfer carriage constructed from 316L shall be provided. All stainless-steel surfaces shall be polished to 150 grit or better. The loading cart shall be designed to support a uniform load of up to 500 pounds evenly distributed. Additionally, the loading cart shall have one height-adjustable upper shelf and one stationary lower shelf with the capability to add up to two

optional additional shelves. The wheeled carriage shall be capable of locking securely to the autoclave and the cart. The carriage shall be equipped with a self-aligning guidance mechanism to ensure proper mating with the autoclave.

- v. **Water Eco-System: (standard build, DELETE THIS SECTION IF WaterEco Plus or WaterEco Plus is selected)** The sterilizer shall incorporate a water-saving system that reduces wastewater consumption by 90%. This system shall be integral to the autoclave and fit within the autoclave's footprint. The system shall cool effluent using a combination of air, previously cooled effluent, and a minimal amount of cold water. It shall also monitor, measure and report quenching water consumption through the touch screen. The system shall be constructed of a non-welded design made from non-proprietary parts to reduce the cost of service and maintenance.
- vi. **WaterEco Plus System: (DELETE THIS SECTION IF NOT DESIRED)** All waste condensate shall be cooled to below 140F before discharge to the facility drain. The cooling system shall not consume fresh cold water during normal operation; all cooling shall be accomplished through the use of a closed-loop facility-provided chilled water system. The cooling system shall include all heat exchangers and pumps necessary to provide adequate cooling of discharged effluent. In the event of a chilled water utility loss, the system shall incorporate a safety backup to continue to cool effluent to below 140F before discharge to the facility drain. The system shall monitor, measure and report quenching water consumption through the touch screen. The system shall be integral to the autoclave and fit within the autoclave's footprint.
- vii. **WaterEco Vacuum Plus System: (DELETE THIS SECTION IF NOT DESIRED) (ONLY FOR PRE-VACUUM UNITS)** The vacuum system shall incorporate a recirculation loop and a liquid ring vacuum pump such that all water provided to the vacuum system is recycled discharge. The recirculation system shall include all heat exchangers and pumps necessary to provide adequate cooling of recirculated vacuum water. The system shall receive and quench all hot waste from the sterilizer and cool it down to below 140F before discharge to the facility drain. Neither the vacuum system nor the quenching system shall consume fresh cold water during normal operation; all cooling shall be accomplished through the use of a closed-loop facility-provided chilled water system. The system shall monitor, measure and report quenching water consumption through the touch screen.
- viii. **Biological Cross-Contamination Barrier Flange: (required with BSL3 configuration, DELETE THIS SECTION IF NOT DESIRED)** The sterilizer shall be equipped with a stainless steel biological cross-contamination barrier flange seal (bio-seal). This feature shall seal the wall opening around the autoclave to prevent the escape of biological agents from the isolated area or intrusion of contamination into the clean area. The bio-seal shall be fully welded to the

autoclave chamber and all penetrations through the barrier flange for either wiring or plumbing shall be fully welded and/or fully potted to prevent leaks. The bio-seal shall mate to a solid silicone gasket that in turn mates to an airtight framework in the wall cutout. The silicone gasket shall be of a single-piece construction; multi-piece gaskets with overlapped and compressed edges are not permitted. Welded studs with nuts instead of through-holes with bolts shall be provided for all gasket fastening attachment points to ensure a secure and airtight seal. The bio-seal, wall framework, ancillary metal components, and fasteners shall all be constructed from stainless steel to withstand decontamination chemicals. The bio-seal shall be designed such that it meets requirements for BSL-3 and shall provide an airtight barrier that is capable of passing industry-standard leak tests.

- ix. Air Differential Seal: **(DELETE THIS SECTION IF NOT DESIRED)** The sterilizer shall be equipped with a combination of a stainless steel flange and silicone rubber gasket designed to allow the laboratory it serves to maintain an air pressure differential within the lab space. This feature shall seal the wall opening around the autoclave to prevent the large wall opening around the sterilizer from allowing air to pass into or out of the lab, removing the pressure differential. The seal shall consist of a flange continuously welded around the sterilizer chamber, with all penetrations through the barrier fully welded and/or fully potted to prevent leaks. The flange shall mate to a solid silicone gasket that in turn mates to the wall cutout surrounding the autoclave. The silicone gasket shall be of a single-piece construction; multi-piece gaskets with overlapped and compressed edges are not permitted. Welded studs with nuts instead of through-holes with bolts shall be provided for all gasket fastening attachment points to ensure a secure and airtight seal. The flange and all ancillary metal components and fasteners shall all be constructed from stainless steel to withstand decontamination chemicals. The air differential seal shall be designed such that it is capable of passing industry-standard leak tests.
- x. Electric Door-Interlock: **(required with BSL3 configuration, DELETE THIS SECTION IF NOT DESIRED)** The sterilizer shall incorporate an electro-mechanical lock on each door. This system shall prevent both doors from being opened simultaneously thereby preventing cross-contamination between the contained and uncontained area. The lock shall be configured to prevent a selected door from opening if the autoclave contains non-sterile contents. The door unseal mechanism shall operate independently of the controller so that a controller malfunction cannot cause cross-contamination. For fail-safe operation, the door seal shall not require any utilities to maintain a positive seal. Additionally, in the event of a power loss, the doors shall remain locked and sealed indefinitely to prevent the release of unsterile goods.
- xi. Flood Alarm: **(DELETE THIS SECTION IF NOT DESIRED)** In the event of excessive liquid in the chamber, an alarm shall sound and a message shall be displayed warning the user about the flood condition.



- xii. Seismic Tie-Down: **(DELETE THIS SECTION IF NOT DESIRED)** Brackets, mounting hardware, and appropriate documentation shall be provided to meet or exceed the local requirements for seismic activity-resistant equipment.
  - xiii. Electropolish: **(DELETE THIS SECTION IF NOT DESIRED)** All wetted surfaces within the chamber shall be electro-polished.
- D. Controls – The sterilizer shall be equipped with an industrial programmable logic controller (PLC) capable of monitoring and controlling the sterilizer. The PLC shall allow the user to easily view and modify all applicable sterilization cycle parameters such as sterilization temperature and time, dry time, and **(ONLY AVAILABLE ON PRE/PULSE VACUUM UNITS)** vacuum pressure and pulses. The controller, touch screen, and thermal printer shall be mounted on the side of the chamber at eye level to isolate the components from steam, moisture, and heat while providing the user with a comfortably positioned interface. For ease of service, all wires shall be clearly labeled and match labels in all provided electrical drawings. All electrical components shall be available as off-the-shelf components and shall be non-proprietary. No custom circuit boards, communication boards, breakout boards, or chips shall be installed on the sterilizer.
- 1. Color Touch Screen (HMI): The screen shall feature a 7” widescreen color touch-sensitive display with a bright LED backlight and a wide-angle viewing range. All buttons or selectable areas shall be immediately obvious and displayed as “3D” objects whereas all information and general text shall be displayed as “2D”. The intuitive user interface shall employ a modern GUI to guide the operator through the screens to the successful completion of a sterilization cycle. All control screens shall contain a home button to return to the main screen. Any messages, alarms, or prompts displayed shall be in plain English.
  - 2. Electronic Data Storage via SD/USB: Cycle data is stored on a non-volatile flash memory device and saved in CSV format.
  - 3. Manager Menu: The controller shall have a separate password-protected manager menu. From this menu, the autoclave manager shall be able to create cycles and set sterilization parameters. Additionally, the manager shall have the ability to modify the time and date settings, change the measurement units, and edit print record settings to match lab SOPs.
  - 4. Service Menu: The controller shall have a separate password-protected service menu. This menu system shall allow service personnel to easily diagnose and calibrate the equipment as well as adjust settings vital for proper sterilizer operation. All temperature and pressure sensors shall be able to be calibrated in the field using a three-point calibration. The menu shall allow authorized personnel to manually control all valves and pumps. Additionally, the state of all inputs and outputs shall be displayed.

5. Service and Preventative Maintenance Reminder Alerts: The controller displays alerts on the touch screen and prints at adjustable use-based or time-based user-programmed intervals.
6. Alarms: The controller shall produce an audible signal upon all alarms, aborted cycles, or ends of completed cycles. An alarm message shall be displayed on the screen and an audible signal sounded if:
  - i. The jacket temperature exceeds the set point.
  - ii. The chamber pressure exceeds the set point.
  - iii. The chamber temperature exceeds the set point.
  - iv. The jacket temperature probe fails.
  - v. The chamber temperature probe fails.
  - vi. The chamber temperature has not reached the setpoint within the expected time.
  - vii. The jacket temperature has not reached the setpoint within the expected time.
  - viii. The chamber temperature falls below the set point during sterilization.
  - ix. The cycle is completed.
7. Energy Saver Calendar: To save energy and water the controller shall have the ability to automatically turn on and off the steam supplied to the jacket steam based on certain times of day and days of the week.
8. Auto-Idle Shutoff: To save energy and water the controller shall have the ability to automatically enter a low-power standby mode when no cycle has been run for a manager the configurable amount of time. Upon entering standby mode, steam consumption shall be stopped to reduce heating and cooling utility demands.
9. Internal Battery Backup: In the event of a power loss, all passwords, cycle parameters, custom cycles, and user data shall be retained by a battery backup for up to 6 months.
10. Secondary Controls: On pass-thru units, both ends of the sterilizer shall be equipped with a 7" color touch screen capable of all service, supervisor, and user functionality. Additionally, both sides shall be equipped with an E-Stop.
11. Printer: A thermal printer with easy-to-use drop-in paper loading shall be mounted below the touch screen. The printer shall output all pertinent information regarding the sterilization cycle at user-defined intervals. Information shall include operator identification code, sterilizer identification code, cycle number, cycle type, cycle stage, time, chamber and jacket pressure and/or temperature, alarms or messages, and cycle completion status. Printer paper shall be easy to change and shall not require the use of tools.
12. Dry Contacts: **(DELETE THIS SECTION IF NOT DESIRED)** The sterilizer shall communicate to the building automation system through 2-wire Form-C dry contacts.

The sterilizer shall signal when **(CHOOSE SIGNALS DESIRED)** a door is open, the sterilizer is on, there is an alarm condition, a cycle is in progress.

13. Remote Troubleshoot: **(DELETE THIS SECTION IF NOT DESIRED)** The controller shall communicate through Ethernet and allow factory service personnel to view cycle configurations, display contents, sterilizer status, and program information thereby reducing the need for service personnel to perform site visits. Additionally, software updates and extra features may be remotely installed.
14. Security and Traceability: Cycle name and sterilization parameter configuration settings shall be password protected to prevent accidental or unauthorized modification by anyone except the manager. The manager shall have the option to allow or prevent users from editing cycle parameters for individual cycles. The ability to run a cycle shall be password protected to identify the operator on the cycle report print-out; user passwords shall never be printed. At least 50 password-protected users shall be available. The autoclave shall support multi-level password-protected access for users, service, manager, and factory access.
15. Effluent Decontamination: **(required with BSL3 configuration, DELETE THIS SECTION IF NOT DESIRED)** The autoclave shall not release viable spores or bacteria to the plumbing discharge line. Any liquid effluent, if present, shall be held in the chamber for the duration of any sterilization cycle. All aerosol effluent shall pass through a 0.2 micron hydrophobic HEPA filter with 99.9998% or greater efficiency. The filter shall be located in the chamber utilizing the chamber as a sterilization jacket. The filter shall be sterilized in place and shall not require special disposal. Additionally, special tools or service personnel shall not be required for filter replacement.
16. Cycles: Controller shall be programmable for up to 50 cycles. Cycles available shall be presented in an intuitive display for selection by the user. The manager shall be able to be set up shortcuts for commonly used cycles. Commonly used cycles shall appear on a Favorites screen to allow quick and easy user access. The autoclave shall be preconfigured to run all the cycles in this section. Each cycle shall have key parameters that are user-customizable. Additionally, these key cycle parameters shall be easily viewed before and during a cycle run. **(DELETE ANY CYCLE BELOW NOT DESIRED & DELETE ALL BOLD TEXT)**
  - a. Gravity: A gravity cycle shall displace the air in the chamber with pressurized steam. This cycle shall be used mainly for unwrapped goods. The operator may select a sterilization temperature anywhere between 212°F (100°C) and 270°F (133°C) as well as the sterilization time and dry time. **(DELETE THE BOLD TEXT IF NOT DESIRED)** There shall be at least 12 gravity cycles available for use. Upon exhaust of a gravity cycle, the autoclave shall have the ability to draw a vacuum to dry the load.

- b. Liquids: A liquids cycle allows vented liquid goods to be sterilized while preventing boil-over. The rate of exhaust shall be adjustable through the controller. The autoclave shall also be equipped with an automatic jacket blow-down. The controller shall have the ability to automatically release jacket steam pressure. The exhaust rate shall be adjustable through the controller. **(DELETE THE BOLD TEXT IF NOT DESIRED)** There shall be at least 12 liquid cycles available for use.
- c. Pre-Vacuum: **(DELETE THIS SECTION IF NOT DESIRED)** After the conditioning phase, a series of steam pulses and vacuum draws shall ensure that the air has been removed from the load. Includes the ability to vacuum dry through post-vacuum. There shall be at least 12 pre-vacuum cycles available for use. The number of pulses, pulse steam pressure, vacuum pulse pressure, sterilization temperature, sterilization time, and dry time shall be customizable for each cycle. Vacuum shall be created using a **CHOOSE ONE a venturi-based water ejector OR a liquid ring vacuum pump with a bronze impellor and bronze pump head.**
- d. Liquid Cycle with Load Probe: **(DELETE THIS SECTION IF NOT DESIRED)** Controller shall use an RTD that the user inserts into the load. The RTD and controller shall detect, display and print the temperature of a liquid load. The sterilization phase shall not begin until the load has reached the cycle specified temperature.
- e. Bowie Dick: **(DELETE THIS SECTION IF NOT DESIRED)** **(ONLY AVAILABLE ON PRE-VACUUM UNITS)** The controller shall be preconfigured to allow the user to run a daily air removal test per the standards outlined in the latest edition of ANSI/AAMI ST-8.
- f. Vacuum Leak Test: **(DELETE THIS SECTION IF NOT DESIRED)** **(ONLY AVAILABLE ON PRE-VACUUM UNITS)** The controller shall provide easy verification of vacuum depth capability as well as vacuum seal integrity of the chamber and the piping. The test shall detect leaks greater than one mmHG (one Torr) per one minute.
- g. Air-Over Pressure: **(DELETE THIS SECTION IF NOT DESIRED)** Throughout the exhaust phase, chamber pressure shall be maintained at or above the sterilization pressure until the load has cooled down to a user-configurable temperature. The load temperature shall be measured through the use of a load probe. The rate of exhaust shall be adjustable.
- h. Low Temperature: **(DELETE THIS SECTION IF NOT DESIRED)** **(NOT AVAILABLE ON BSL-3 STERILIZERS EQUIPPED WITH EFFLUENT DECONTAMINATION)** For the sterilization of temperature-sensitive goods, the controller shall permit a zero pressure sterilization cycle between

temperatures of 190°F and 212°F. Sterilization temperature and time shall be adjustable.

- i. **F<sub>0</sub>: (DELETE THIS SECTION IF NOT DESIRED)** A user-selectable cycle for the sterilization of loads sensitive to total heat input shall be provided. The F<sub>0</sub> cycle shall allow the user to enter the desired F<sub>0</sub> value. The sterilization phase shall terminate once this value has been reached. The actual F<sub>0</sub> achieved shall be reported by the autoclave.
  - j. **Continuous/Life-Cycle Testing: (DELETE THIS SECTION IF NOT DESIRED)** A specified sterilization cycle shall be programmed with a user-selected option to allow the cycle to be automatically repeated without further user interaction. The number of repetitions shall be user-adjustable.
  - k. **Rapid Cool: (DELETE THIS SECTION IF NOT DESIRED) (NOT AVAILABLE ON BSL-3 STERILIZERS EQUIPPED WITH EFFLUENT DECONTAMINATION)** The chamber shall be equipped with spray nozzles to cool down all sterilized products. The nozzles and spray mechanism shall be designed to substantially reduce the cycle cool-down time when sterilizing high heat capacity loads such as liquids or metal goods.
  - l. **ATF Bioreactor: (DELETE THIS SECTION IF NOT DESIRED)** Sterilizer shall feature a cycle with a series of temperature ramps and holds. The cycle shall be designed specifically to safely sterilize ATF (Alternating Tangential Flow) Bioreactors without damage to any hollow fiber filters.
  - m. **Steam-Air Mix: (DELETE THIS SECTION IF NOT DESIRED) (NOT AVAILABLE ON BSL-3 STERILIZERS EQUIPPED WITH EFFLUENT DECONTAMINATION)** The sterilizer shall employ air counter-pressure throughout the entire cycle to permit the sterilization of sealed loads without rupturing the load.
- E. **Safety Features:** The sterilizer provided shall incorporate the features described herein to maximize the safety of users and the surrounding building.
- 1. **Fail-Safe Door:** The autoclave's door shall be designed such that in the event of complete utility loss the sterilizer retains all pressure. The door gasket shall not require pressurized steam, pressurized air, or electricity to maintain a positive seal. Additionally, the door locking mechanism shall be designed to tolerate the failure of multiple locking elements without compromising seal integrity or safety.
  - 2. **Pressure Lockout:** The sterilizer shall prevent the user from opening the door while there is a positive pressure greater than 2 PSI within the chamber. To provide

maximum safety, the lockout shall be purely mechanical in function and shall not rely on any utility connections including steam, air, or electricity for proper operation.

3. **Pressure Relief Valve:** All pressure vessels shall come equipped with ASME-approved pressure relief valves that are marked by the approval agency. The valve shall be rated no higher than the maximum working pressure of the vessel it's connected to. The outlet of the relief valve shall be piped to direct discharge down to the open atmosphere within 6" of the floor.
4. **Door Switch:** A door switch shall be present to prevent the addition of steam to the chamber unless the door is closed and the locking mechanism is engaged.
5. **Cycle Abort:** The operator shall have the ability to abort the current cycle and safely release the chamber pressure.
6. **Emergency Stop:** The operator shall have the ability to instantly shut down the sterilizer in the event of an emergency by actuation of a clearly labeled button accessible from any door on the sterilizer. The e-stop shall be a red mushroom-style button that is push activated and twisted to release to deactivate. When activated, the e-stop shall illuminate and display a message on the touch screen and printout to indicate that the e-stop has been activated.
7. **Manual Exhaust Valve:** A manually-operated chamber exhaust valve shall be easily accessible by the operator for use in the event of utility loss.
8. **Boiler Pressure Control: (ONLY ON UNITS WITH ELECTRIC BOILER)** Any steam boiler supplied shall conform to the latest edition of CSD-1. The boiler shall have a primary operating pressure control and a secondary safety pressure control with a manual reset.
9. **Touch Safe:** All trim, paneling, and fascia shall be properly isolated from heat sources to prevent accidental burns.

#### F. Utility Connections

1. Utilities required for a Standard Unit
  - i. **Controller Power: 120VAC/60Hz 1-Phase, 10 Amps, non-GFCI outlet. Or 220VAC/50Hz 1-Phase, 10 Amps, Hard Wired. (CHOOSE ONE)**
  - ii. **Cold Water:** 1" NPT, 45 psig Dynamic minimum, 80 psig static maximum, 12 gpm capacity minimum, with shut off valve and union. Water to meet quality requirements as per autoclave manufacturer for general use.

- iii. Drain: 3" diameter funnel drain or 6" floor sink with 2-1/2" air gap, 15 gpm capacity minimum, min 1 1/2" drain piping, external to sterilizer footprint
  - iv. Ethernet: RJ-45 connection with Internet access. **(ONLY ON UNITS WITH STERINET CONNEX, DELETE IF NO CONNEX)**
2. Steam Source Utilities Required **(CHOOSE ONE BELOW)**
- i. House Steam Supply: 3/4" NPT, 50-80 psig dynamic, 180 lbs/hr, insulated line with drip leg and trap, 300-325F, 97% to 100% saturated, condensate and particulate-free, with shut off valve and union.
  - ii. Electric Generator:
    - a. Electric: **208/240/380/480VAC (CHOOSE ONE)**, 3-Phase, **XX** Amps, fused disconnect or breaker
    - b. Treated Water: 1/2" NPT, 45 psig Dynamic minimum, 80 psig static maximum, 1 gpm, with shut off valve and union. Water to meet quality requirements as per autoclave manufacturer for the steam generator.
  - iii. Electric-Steam Combo:
    - a. Steam Supply: 3/4" NPT, 50-80 psig dynamic, 180 lbs/hr, insulated line with drip leg and trap, 300-325F, 97% to 100% saturated, condensate and particulate-free, with shut off valve and union
    - b. Electric: **208V/240V/380V/480V (CHOOSE ONE)**, 3-Phase, **XX** Amps, fused disconnect or breaker
    - c. Treated Water: 1/2" NPT, 45 psig Dynamic minimum, 80 psig static maximum, 1 GPM capacity minimum, with shut-off valve and union. Water to meet quality requirements as per autoclave manufacturer
  - iv. Steam-to-Steam Clean Steam Generator:
    - a. Steam Supply: 1-1/4" NPT, 75-90 psig dynamic, 350 lbs/hr, insulated line, 300F-325F, with shut off valve and union.
    - b. Condensate Return: 1-1/4" NPT, insulated line
    - c. De-ionized Water: 1/2" NPT, 45 psig Dynamic minimum, 80 psig static maximum, 1 gpm, with shut off valve and union.
3. Additional utilities required for a unit with Special Options
- i. Vacuum Pump Electrical: **208/240/380/480VAC (CHOOSE ONE)**, 3-Phase, 20 Amps **(ONLY REQUIRED ON UNITS WITH LIQUID RING VACUUM PUMP)**
  - ii. Dry Contacts: 2 Form-C dry contact compatible signal wires per dry contact output. **(ONLY REQUIRED FOR UNITS WITH DRY CONTACTS)**

- iii. Compressed Air: 1/2" NPT, 50-75 psig, 99% dry & oil-free, 10-35 CFM (**ONLY REQUIRED ON UNITS WITH AIR-OVER-PRESSURE OR STEAM-AIR MIX CYCLE**)
- iv. Chilled Water Supply & Return: 1" NPT, 20 psig dynamic min supply, 35-55F, 10 gpm capacity, -5 psig max drop and +15F max temp rise on the return line, insulated line with ball valve and union (**ONLY REQUIRED ON UNITS WITH WATER ECO PLUS OR WATER ECO VAC PLUS**)