

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 3AV, 26AV, or 26BV autoclave with HC controls manufactured by Consolidated Sterilizer Systems.
- B. Other substitutions are not permitted.

#### 2.2 CONSTRUCTION

- A. General Product Description: Provide a new single door steam-based autoclave designed for rapid sterilization of moist heat compatible goods. The chamber shall seal using an air-actuated non-stick silicone polymer gasket against a vertically sliding 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):**

- **20" x 20" x 38"**
- **26" x 26" x 39"**
- **26" x 26" x 49"**

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

- **Gravity**
- **Liquid**
- **Pre-Vacuum**
- **Bowie Dick Test**
- **Vacuum Leak Test**

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 & 61010-2-040: Where applicable, each equipment skid shall be assembled per applicable standards and bear the markings of the approval agency.
6. OSHA: Equipment manufactured by the supplier shall be produced per all guidelines set forth by the Occupational Safety and Health at Work Act.
7. ANSI/AAMI ST-8 – Hospital Steam Sterilizers
8. IEC 61326-1 Edition 3.0 2020-10 – Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
9. **AAMI ANSI ST108:2023**

C. Sterilizer Construction

1. Chamber Construction: The sterilizer chamber shall be rectangular in shape and shall be constructed from 316L stainless 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 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 **316L 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 45 PSI.

3. Door Mechanism: The autoclave shall be provided with a vertically sliding door at one end. The door shall be constructed from 316L stainless steel and supported by stainless steel wire ropes and a counterbalance weight. The door seal shall be achieved using an air-actuated crush gasket constructed from an FDA-approved non-stick silicone polymer. The door gasket shall not require steam to maintain a seal. The door gasket design shall eliminate gasket tear and door jamming problems while maintaining a secure seal while there is pressure in the chamber, even in the event of complete loss of all utilities. No tools shall be required for gasket replacement.
4. Human Factors: All feedwater pumps and air compressors shall operate below 45 decibels. The door shall slide smoothly and freely and be easily operated with one hand. The door shall have a wide grip ergonomic handle for ease of operation. The sterilizer shall incorporate a fully opening hinged front panel for ease of maintenance.
5. 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.**
6. Waste Cooling: All waste shall be cooled to a preset adjustable temperature. The temperature shall be adjusted through a 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.
7. Steam Baffle: The sterilizer chamber shall be equipped with a 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.

8. 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.
9. 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.
10. 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”.
11. Air Inlet Filter: All air into the chamber used to break a vacuum shall pass through a 0.3 micron HEPA air filter.
12. 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.]**
  - ii. Mounting Arrangement: Sterilizer shall be **CHOOSE ONE fully enclosed on the sides by a 304L stainless steel paneled cabinet OR recessed behind the front wall**. 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. Rollers **(DELETE IF NOT SELECTED, ONLY AVAILABLE ON 3AV WITHOUT SEISMIC ANCHORING)** Sterilizer mounted on rollers for ease of installation, placement, and service. When service clearance is limited, the sterilizer may be moved for greater accessibility
- vi. Water Eco-System: 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.
- vii. Flood Alarm: 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.
- viii. Seismic Tie-Down: **(DELETE THIS SECTION IF NOT DESIRED)** Anchor points on equipment skid and appropriate documentation shall be provided to meet or exceed the local requirements of equipment anchorage for seismic activity.
- ix. Electropolish: **(DELETE THIS SECTION IF NOT DESIRED)** All wetted surfaces within the chamber shall be electro-polished
- x. Automatic Door: **(DELETE THIS SECTION IF NOT DESIRED)** Door shall be automated by a low force actuator and a counterweight. If the door encounters an obstacle, it shall automatically stop. For safety, the door shall not require greater than one pound of force to stop. Additionally, to prevent accidental actuation and hazard, door close motion shall require the door close button to be pressed and held throughout the entire closing motion.

- 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 vacuum pressure and pulses. The controller, touch screen, and thermal printer shall be mounted on the side of the chamber 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 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 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. 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.
11. 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.**
12. 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.



13. 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)**

- i. 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 250°F (121°C) and 275°F (135°C) as well as the sterilization time and dry time. Upon exhaust of a gravity cycle, the autoclave shall have the ability to draw a vacuum to dry the load.
- ii. 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.
- iii. Pre-Vacuum: 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. 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.**
- iv. Bowie Dick: 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.
- v. Vacuum Leak Test: 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.

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 contents. The door gasket shall not require pressurized steam 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 steam pressure to function properly.
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 is 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

- 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, min 1 1/2" drain piping, external to sterilizer footprint
  - iv. Compressed Air: 1/2" NPT, 50-80 psig, 99% dry & oil-free, 2 CFM **(IF HOUSE AIR IS NOT AVAILABLE, STERILIZER WILL BE SUPPLIED WITH A QUIET (<45dB) INTEGRAL AIR COMPRESSOR)**
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 a steam generator.
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)**