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SUPERSEDING
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April 30, 1970, and
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November 9, 1940

FEDERAL SPECIFICATION

STERILIZER, ETHYLENE OXIDE GAS, FOR HEAT- AND MOISTURE-LABILE SURGICAL INSTRUMENTS AND SUPPLIES (NONPORTABLE)

This specification was approved by the Commissioner, Federal Supply Service, General Services Administration, for the use of all Federal agencies.

1. SCOPE AND CLASSIFICATION

1.1 Scope. This specification covers a sterilizer for processing heat and moisture-labile materials, using an ethylene oxide gas mixture as the sterilizing agent (see 6.1).

1.2 Classification. The sterilizer shall be of one type and of the following sizes and styles, as specified (see 6.2):

1.2.1 Size. The minimum clearance dimensions of the sterilizing chamber interior, excluding space required for the baffle, shall be as shown in table I.

TABLE 1. Sterilizing chamber dimensions

Size	Width	Height	Length
1	20	20	38
2	24	36	36
3	24	36	48
4	24	36	60

1.2.2 Style.

Style A - Single door, cabinet enclosed (free standing).
Style B - Single door; for recessing through one-wall partition.
Style C - Double door (for goods pass-through); for recessing through one-wall partition.
Style D - Double door (for goods pass-through); for recessing through two-wall partitions (only sizes 3 and 4).

2. APPLICABLE DOCUMENTS

2.1 The following documents, of the issues in effect on date of invitation for bids or request for proposal, form a part of this specification to the extent specified herein:

Federal Specifications:

CC-M-636 - Motors, Fractional Horsepower (Alternating Current).

CC-M-641 - Motors, Integral Horsepower (Alternating Current).
FF-C-77 - Casters, Industrial Duty.
PPP-B-621 - Boxes, Wood, Nailed and Lock-Corner.
PPP-T-60 - Tape, Pressure Sensitive Adhesive, Waterproof, for Packaging.
PPP-B-601 - Box, Wood, Nailed and Lock-Corner.
PPP-B-640 - Box, Fiberboard, Corrugated, Triple-Wall.
PPP-C-843 - Cushioning Material, Cellulose.

FSC 6530

QQ-N-281 - Nickel-Copper, Alloy (Monel and R-Monel) Bars, Plates, Rods, Sheets, Strips, Wire, Forgings, and Structural and Special-Shaped Sections.
QQ-S-766 - Steel Plates, Sheets, and Strip-Corrosion-Resisting.
WW-P-541 - Plumbing Fixtures, Land Use.

Federal Standard:

Fed. Std. No. 123 - Marking for Shipment (Civil Agencies).

(Activities outside the Federal Government may obtain copies of Federal Specifications, Standards, and Handbooks as outlined under General Information in the Index of Federal Specifications and Standards and at the prices indicated in the Index. The Index, which includes cumulative monthly supplements as issued, is for sale on a subscription basis by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.)

(Single copies of this specification and other Federal Specifications required by activities outside the Federal Government for bidding purposes are available without charge from Business Service Centers at the General Services Administration Regional Offices in Boston, New York, Washington, DC, Atlanta, Chicago, Kansas City, MO, Fort Worth, Denver, San Francisco, Los Angeles, and Seattle, WA.)

(Federal Government activities may obtain copies of Federal Specifications, Standards, and Handbooks, and the Index of Federal Specifications and Standards, from established distribution points in their agencies.)

Military Specifications:

MIL-C-104 - Crate, Wood, Lumber, and Plywood Sheathed; Nailed and Bolted.
MIL-C-132 - Crates, Open Wood; Maximum Capacity 2,500 Pounds.
MIL-C-3774 - Crates, Wood, Open, 12,000 to 16,000 Pound Capacity.
MIL-L-10547 - Liners, Case and Sheet, Overwrap, Water-Vaporproof or Waterproof, Flexible.
MIL-P-116 - Preservation Methods of
MIL-S-36586 - Sterilization Test Strip Set, Bacterial Spore.
MIL-T-45208 - Inspection Requirements.

Military Standards:

MIL-STD-105 - Sampling Procedures and Tables for Inspection by Attributes.
MIL-STD-129 - Marking for Shipment and Storage.

(Copies of Military Specifications and Standards required by suppliers in connection with specific procurement functions should be obtained from the procuring activity or as directed by the contracting officer.)

2.2 Other publications. The following documents form a part of this specification to the extent specified herein. Unless a specific issue is identified, the issue in effect on date of invitation for bids or request for proposal shall apply.

American Society of Mechanical Engineers (ASME) Publication:

Boiler and Pressure Vessel Code, Section VIII - Pressure Vessels,

Division 1.

(Application for copies should be addressed to the American Society of Mechanical Engineers, United Engineering Center, 345 East 47th Street, New York, NY 10017.)

American National Standards Institute (ANSI) Standard:

A 40.8 - National Plumbing Code.

(Application for copies should be addressed to American National Standards Institute, 1430 Broadway, New York, NY 10018.)

American Society for Testing and Materials (ASTM) Standards:

B 88 - Seamless Copper Water Tube.
B 135 - Seamless Brass Tube.
B 43 - Seamless Red Brass Pipe.

(Application for copies should be addressed to the American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.)

National Fire Protection Association (NFPA) Publications:

No. 70 - National Electrical Code.
No. 56 - Code for the Use of Flammable Anesthetics.

(Application for copies should be addressed to the National Fire Protection Association, 60 Batterymarch Street, Boston, MA 02110.)

United States Pharmacopoeial Convention, Inc.:

Pharmacopoeia of the United States (USP).

(Application for copies should be addressed to the Mack Publishing Company, Easton, PA 18042.)

3. REQUIREMENTS

3.1 Compliance with standards.

3.1.1 Pressure vessel. The design, construction, materials, and testing of each pressure vessel (including the door(s)) shall conform to applicable requirements of the ASME Boiler and Pressure Vessel Code, Section VIII - Pressure Vessels Division 1.

3.1.1.1 Certification. The manufacturer shall furnish with each sterilizer certification as required by the referenced ASME Boiler and Pressure Vessel Code.

3.1.2 Electrical components. The electrical components of each sterilizer shall conform to applicable requirements of NFPA No. 70.

3.1.2.1 Motors. Motors shall be of sufficient size for the duty to be performed, and shall not exceed their nameplate ratings when the driven equipment is operating at specified capacity under the most severe conditions likely to be encountered. The motors shall have over-current protection.

3.1.2.1.1 Fractional horsepower. Shall conform to style A3 or B3, continuous duty, class A or B insulation, CC-M-636.

3.1.2.1.2 Integral horsepower. Motors of one horsepower and larger shall conform to type II, style A3 or B3, class B insulation, CC-M-641, and have magnetic starters.

3.2 Materials.

3.2.1 Corrosion-resisting metal. Whenever corrosion-resisting metal is required, it shall Be either nickel-copper alloy or corrosion-resisting steel.

3.2.2 Corrosion-resisting steel. Corrosion-resisting steel shall conform

to QQ-S-766, class 304, where welding is required; class 302, 304, 201, or 202, if formed without welding.

3.2.3 Nickel-copper alloy. Nickel-copper alloy shall conform to QQ-N-281.

3.2.4 Clad steel. Clad steel shall consist of nickel or nickel-copper alloy and steel, mill rolled under heat and pressure until they are integrally bonded over their entire interface.

3.2.5 Chromium plating. Chromium plating shall conform to WW-P-541, section 9.

3.2.6 Piping. Steam, water, and waste lines on the sterilizer shall be seamless copper tubing, conforming to the requirements of ASTM B 88, or seamless red brass conforming to ASTM, B 135, Alloy 1, or ASTM B 43. Fittings shall be brass. Piping shall be installed on the sterilizer to conform to the requirements of ANSI A 40.8.

3.2.7 Fasteners. Where brass, bronze, copper, or corrosion-resisting metal parts are welded or otherwise joined to each other, the welding rods or other fasteners shall be of the same material as that so joined. Where necessary to join these parts to dissimilar metals, the welding rods or other fasteners shall be of the same material as the part welded or fastened to the dissimilar metal. Tetrafluoroethylene tape or other suitable inert compound shall be applied to threaded connections involving dissimilar metals.

3.2.8 Manual valves. Handvalves on steam and water supply lines shall be bronze with renewable, synthetic discs or equivalent parts. Each valve shall withstand a 350-psig hydrostatic test or be leakproof when tested at 100-psig air pressure with valve body submerged in water. Each valve shall have a renewable, lot-heat-conducting and nonloosening handle. Durable letters on the handle shall show the purpose of the valve. All handvalves shall be easily accessible from the control end of the sterilizer.

3.2.9 Gas-carrying valves. Parts of valves in contact with the sterilant shall be of materials certified by the sterilizer manufacturer to be suitable for the purpose.

3.3 Design. The sterilizer shall be designed to use a gaseous sterilant consisting of approximately 12 percent ethylene oxide and 88 percent halogenated hydrocarbons (by weight), automatically dispensed from a storage cylinder or cylinders (see 6.1). Each sterilizer shall include a horizontal sterilizing chamber with pressure-tight door(s), automatic operating controls, sterilant and load-conditioning systems, vacuum and exhaust system, heating system, mounting devices, and material handling accessories (see 3.6.9).

3.4 Performance characteristics. Operation of the sterilizer shall include the following to conform to the requirements of 4.2.3.3.3:

(a) Mechanically evacuate air from the sterilizing chamber and load prior to the sterilizing process.
(b) Control humidification of chamber while under vacuum.
(c) Charge the chamber with the sterilant.
(d) Expose the load to the sterilant, in the presence of the chamber conditions (temperature, humidity, ethylene oxide concentration, and exposure time) required for sterilization.
(e) Provide at least one post-exposure-period evacuation of the chamber and load within the range of 20 to 30 inches Hg. (gauge) followed by relieving the chamber to approximately atmospheric pressure by ambient air (passed to the chamber through a bacteria-retentive filter).

3.5 Maintainability.

3.5.1 Service access. Panels (see 3.6.8) on a style A or C sterilizer shall be easily removable for servicing the components behind them.

3.5.2 Wiring diagrams. Wiring diagrams shall be securely attached to

sterilizer in an accessible location, such as inside a control panel, terminal board cover, or control housing door, or furnished separately in protective covers.

3.5.3 Instruction books and parts lists. Unless otherwise specified (see 6.2), two copies of booklets containing the following information shall be furnished with each sterilizer:

(a) Instructions for installing, operating, and performing preventative maintenance on the equipment.

(b) List of service parts (identified by manufacturer's part number) and quantity required for preventive maintenance.
(c) If specified in the invitation for bid, additional information such as roughing-in drawings, power requirements, structural modifications, and special support devices shall be furnished (see 6.2).

3.5.3.1 Distribution. Unless otherwise specified (see 6.2), the instruction books and parts lists shall be shipped with the sterilizer to which they pertain.

3.6.3.2 Approval of data. Unless otherwise specified (see 6.2), two copies of instruction books and parts list shall be forwarded to the Procuring Agency for review and approval prior to delivery of the sterilizer. The data is to be furnished sufficiently early to allow time for revision of data as required by the Procuring Agency as a condition of approval.

3.6.3.3 Additional data. When specified (see 6.2), 15 copies of instruction books and parts lists shall be forwarded to the Procuring-. Agency upon completion of the contract or purchase order.

3.6 Components.

3.6.1 Chamber assembly. The assembly for sizes 2, 3, or 4 shall consist of inner and outer shells placed one within the other to provide a jacket over the lengthwise exterior surfaces of the inner shell. The shell or shells for a single-door sterilizer shall be joined by a door frame or end frame on one end and a backhead on the opposite end. The shells for a double-door sterilizer shall be joined at each end by a door frame or end frame. The chamber assembly for a size 1 may be a single shell. The material for both single and double shells shall be welded, hot-rolled carbon steel. The inside surfaces of the inner or single shell shall be clad with nickel or nickel-copper alloy as specified in 3.2.4. The chamber shall include nickel-copper-alloy loading car tracks. Tracks for a size 2, 3, or 4 shall be secured to the chamber floor without exposing the metal beneath the floor cladding to the sterilant.

3.6.1.1 Insulation. The exterior of the chamber (including backhead for a single-door sterilizer) shall be insulated with a glass-fiber blanket commercially rated 1 inch thick; both sides of the blanket shall be covered with aluminum foil. The insulation shall be secured to the sterilizer with thermosetting tape or aluminum straps.

3.6.1.2 Backhead. The backhead for a single-door sterilizer shall be hot-rolled carbo steel or nickel-copper alloy. Surfaces exposed to the sterilizing chamber shall be as specified in 3.2.4.

3.6.1.3 Baffle. A baffle of nickel-copper alloy shall shield the opening where the sterilant and sterilant-conditioning agents enter the chamber.

3.6.1.4 Door frame. Each door frame, frame closure, or end ring shall have a smoothly ground, nickel-copper-alloy surface for door gasket contact.

3.6.2 Door. Size 1 shall have a manually operated door or doors. Doors for other sizes shall be manually or power operated as specified (see 6-2). Each door assembly shall consist of a door, an opening and closing mechanism, and safety look. The door swing shall allow unobstructed access to the chamber. The door shall be attached to its respective frame by a bearing-mounted hinge. The hinge shall be adjustable for accurate

door-gasket alignment and easy door opening and closing. Door swing shall be right or left-hand as specified (see 6.2). Door swing for size 1 shall be reversible in the field without parts, welding, or drilling. The opening and closing mechanism shall be so designed that the holding numbers will be fully engaged before gasket seal can be established.

3.6.2.1 Door materials. The material for the door shall be cast bronze, or, hot-rolled carbon steel clad on the chamber side with nickel or nickel-copper alloy as specified in 3.2.4, or corrosion-resisting steel as specified in 3.2.2. The hinge shall be bronze, brass, corrosion-resisting steel, or chromium-plated steel. The chamber side of each door shall be provided with a gasket which shall be warranted by the manufacturer to be suitable for at least 6 months after initial operation. The gasket shall be held by a groove in the door, or by corrosion-resisting retainers on the door. The grooves in a clad door shall be fabricated to prevent exposure of the ferrous metal under the cladding to the sterilant. Outside surfaces of the door and door-securing members shall be concealed (to the maximum permitted by the ASME Boiler and Pressure Vessel Code) by a cover. The. cover shall:be of the same material specified for the sterilizer panels (see 3.6.3).

3.6.2.2 Safety lock. Each door shall look automatically when pressure in the chamber rises to between zero and 4 psig; the lock shall not release until the pressure is reduced to approximately atmospheric. The electrical control system for a power-operated door shall be so designed that Power to the door-drive mechanism shall terminate when the sterilizer chamber is pressurized. Components of the safety lock.exposed to the sterilant or sterilant-conditioning agents shall be brass, bronze, or corrosion-resisting metal.

3.6.2.3 Manually-operated door. All functions of opening and closing a manually-operate door and positioning, tightening, and loosening the door-holding members shall be by a low-heat-conducting handwheel, or quick-throw arm and low-heat-conducting handwheel. It shall be possible to tighten, but not loosen, the door while the chamber is under pressure greater than 4 psig. In lieu of the ability to tighten the door with chamber pressurized, the door may be equipped with an audible indication when seal is effected and a device to prevent over-tightening of door.

3.6.2.4 Power-operated door. Shall be equipped with a mechanism to close and lock the door pressure tight, close it without compressing the gasket, and unlock and open it fully. The door shall also be manually operable in the event of power failure. The power-drive controls shall include door-positioning selectors and automatic overload protection. The door shall be so designed that it will stop automatically if it encounters an obstruction while being opened or closed. Controls requiring operator attention shall be conveniently accessible. Conduit, gears, wiring, and other components of the power system on the front of the sterilizer shall be concealed by the door cover or front panel (see 3.6.8.1). Maintenance of the door and its removal from the sterilizer shall not require disconnecting any soldered wire joints. The door operating system shall he fused for operation on 120 volt, 60 Hz electric power.

3.6.3 Operating controls. All functions of the sterilizer (see 3.4) shall be automatically controlled. After programing the control, closing the door(a), and depressing a start button, no further operator attention shall be necessary until completion of the sterilizing process is indicated by an alarm or signal light. The control unit shall be.fused for operation on 120 volt, 60 Hz electric power and shall include associated instrumentation and a combination indicator-recorder. The automatic control shall not operate unless the sterilizer door (doors) is (are) closed with the holding members engaged.

3.6.3.1 Associated instrumentation. Shall include cycle-phase-indicating lights, a switch to start and top the processing cycle, main power switch,

sterilizer-exposure timer, manual cycle-phase selector and indicator, and over-temperature warning light-with reset (see 3.6-6). In addition, size 1, without an automatic cylinder-changeover control (see 3.6-4.1), shall be provided with a low-gas (sterilant) pressure indicating light. A style C or style D sterilizer shall have the following supplemental instruments, a chamber-vacuum-pressure gauge (accurate within the limits-specified in 4.2.3.5), and an indicator to show when the sterilizer is ready to operate when a cycle is on and when a cycle has been completed.

3.6.3.1.1 Timer. The sterilizing exposure timer shall be adjustable to provide the capability of sterilizing those items to be processed within the range of 0 and at least 6 hours. It shall be accurate within the limits specified in 4.2.3.6 and automatically return to its original setting upon completion of the interval set and if electric power fails.

3.6.3.1.2 Interlock for style C and D. When specified (see 6.2 and 6 3), the sterilizer shall so equipped that under routine operating conditions, only one of the doors can be opened at a time and then only if the opposite door is closed pressure-tight. In addition, after starting a-sterilizing-process cycle, the interlock shall prevent the door on the sterilized-goods unloading and of the sterilizer from being opened until the cycle has been completed. The interlock shall include a bypass, operable by a removable key, to allow simultaneous opening of the doors for maintenance of the sterilizer. Signal lights shall also be provided as follows: at each and of the sterilizer, to indicate when the door at the opposite end is open or closed pressure-tight; and, on the end opposite the main operating controls to indicate process-cycle completion.

3.6.3.2 Indicator-recorder. This instrument shall indicate vacuum and pressure and record temperature, vacuum and pressure in the sterilizing chamber throughout the processing cycle. The recording mechanism shall be driven by a synchronous (24-hour) timing motor. The ink supply for the recorder shall be by a cartridge on the pen arm or by a capillary device. The cartridge or capillary supply shall be sufficient for at least 3 months use, and the ink supply shall be visible. One hundred recording charts and an approximate 1-year ink supply shall be furnished. The indicator-recorder shall be accurate within the limits specified in 4.2.3.5.

3.6.3.3 Location of automatic control components. All components of the automatic control which require operator attention shall be in a panel(s) above the door frame on the control end of the sterilizer. The supplemental instruments for a double-door sterilizer (see 3.6.3.1) shall be above the door frame opposite the control end.

3.6.3.4 Load conditioning system. Prior to the sterilant entering the chamber, the load and chamber shall be humidified by steam from an independent source 50 to 80 psig dynamic and thermostatically controlled to maintain the load between 125 and 135 deg. F. The relative humidity shall not be less than 30 percent, unless unit is provided with a complete range of humidity selection. Components of the system shall include a strainer, hand-valve shutoff, solenoid valves, and thermostatic steam trap having a replaceable element and seat.

3.6.4 Sterilant conditioning system. Unless otherwise specified (see 6.2), size 1 shall be designed to operate from a single cylinder of sterilant. Sterilizers of the other sizes shall be equipped to operate from two cylinders. The sterilant-charging components shall include a sterilant filter, supply hand-valve shutoff, supply pressure gauge (accurate within the limits specified in 4.2.3.5), and flexible hose or hoses to connect the sterilant-charging system to the supply cylinders). This system shall receive the sterilant in liquid form, vaporize and heat it to approximately 160 deg. F, and automatically supply it to the chamber. If the supply of sterilant is depleted during a cycle prior to satisfying the chamber and load demand, timing will not begin and the cycle will not be completed. Each hose shall be at least 32 inches long, tetrafluoroethylene lined, and covered with bronze or corrosion-resisting steel wire braid; burst pressure rating shall be 1,000 psig.

3.6.4.1 Automatic cylinder-changeover control. This control shall accommodate two sterilant cylinders and, when properly connected to the sterilizer and sterilant cylinders, automatically perform the following functions without interrupting a processing cycle in the sterilizer:

(a) Switch out the in-use cylinder when the pressure in it drops to approximately 20 psig; and
(b) Switch in sterilant supply from a second (serviceable) cylinder, regardless of its alternate position in relation to the control.

Located in a control box arranged for attachment to the sterilizer shall be such controls as a handvalve shutoff for each cylinders pressure gauge (accurate within the limits specified in 4.,2.3.6) for each cylinder, and lights to warn of low cylinder pressure(s). The controls shall operate on 120,volt, 60 Hz electric power. Check valves shall also be provided to prevent backflow of sterilant and condensate from the sterilizing chamber.

3.6.5 Vacuum and exhaust systems.

3.6.5.1 Vacuum system. Shall consist of a water-ring vacuum pump with drive motor, associated valves, fittings, and accessories. The motor shall be provided with automatic overload protection and operate on 208 to 240/480 volt 60 Hz three-phase electric power as specified (see 6.2). The pump and motor shall be beneath the sterilizing chamber, within the confines of the sterilizer framework. The system shall operate on water supply pressure of 30 to 60 psig.

3.6.5.2 Exhaust system. Condensate, steam, and sterilant shall be evacuated from the sterilizing chamber through a line that extends from an opening in the chamber floor to the vacuum pump. The pump exhaust shall be fitted for connection to the building waste line. The opening in the bottom of the sterilizing chamber shall be fitted with a removable, corrosion-resisting metal screen to trap lint and similar solids. The chamber floor shall be pitched to the drain fitting, which shall be flush.

3.6.5.2.1 Bacteria-retentive filter. The bacteria-retentive filter, through which air shall be passed to the sterilizing chamber following exhaust of the sterilant, shall conform to the requirements of 4.2.3.4.

3.6.6 Heating system. Heat for size 1 shall be by renewable electric heaters provided with the sterilizer, or by building steam supply, as specified (see 6.2). A size 2, 3, or 4 shall be designed for heating by steam from an independent source delivered at 50 to 80 psig. Electrical characteristics of the heaters shall be a provided for the vacuum pump motor. The sterilizer chamber shall be provided with over-temperature protection so that if the selected temperature is exceeded by 15 deg. F, a warning light will glow, sterilant supply will cease, and the chamber will be evacuated and flushed with filtered air.

3.6.7 Safety valve setting. Safety valve for the sterilizing chamber shall be set to relieve-pressure in excess of the rated working pressure of the vessel and be sealed to prevent change of adjustment.

3.6.8 Mounting devices. Each sterilizing chamber shall be supported by a steel stand equipped wit adjustable, corrosion-inhibiting floor flanges and fitted with panel(s) as shown below. The front, side, back, and top, panels shall be corrosion-resisting steel.

Style A - A front panel, two side panels, and a top panel shall enclose the sterilizer body, pipes, and fittings.
Style B - A front panel.
Style C - Front and back panels, two side panels, and a top panel shall enclose the sterilizer body, pipes, and fittings that project beyond the wall partition.
Style D - Front and back panels.

3.6.8.1 Front and back panels. Each front and back panel shall comprise a lower section that will cover the area to each side of and below the door frame, and any area above the door frame not covered by an instrument panel.

Front and back panels shall not be less than 0.050 inch thick, and fitted with adjustable kickplates. No fasteners shall be exposed from the exterior of the sterilizer, and the panels shall include gaskets or other suitable means which will assure a tight fit along the entire top and side edges where they abut wall partitions or companion top and side panels.

3.6.8.2 Side and top panels. Shall be formed from shoots not lose than 0.050 inch thick. No fasteners shall be visible from the exterior of the sterilizer.

3.6.6.3 Canopy. When specified (see 6.2), a ventilating canopy shall be provided, for a style A or C sterilizer. The canopy shall replace the sterilizer top panel and shall be attached to the sterilizer frame in such manner that the canopy will snugly fit to the sterilizer cabinet panels and not interfere with their ready removal. The canopy shall form a plenum which shall terminate at the top center (of the end nearest the wall into or against which the sterilizer is to be installed) in a flanged duct for ready connection to the building vent system. The plenum shall be at least 19 inches deep at its vent connection point, and shall slope to overhang the sterilizer cabinet end panel approximately 8 inches. Air-intake openings shall be provided in the canopy overhang and, if required, in the sterilizer side cabinet panels to meet the airflow requirements of 6.4. Such air-intake openings shall be the stamped-louver type and shall include adjustable, knob-and-spring actuated dampers. The canopy shall be of welded construction and of the same material as the sterilizer cabinet panels. Weldments on surfaces of the canopy exposed to view from the front or sides of the sterilizer shall be ground and polished so that the canopy will appear as a seamless unit. If canopy is for a style A sterilizer, a corrosion-resisting steel panel shall also be included to fully enclose the rear of the sterilizer cabinet.

3.6.9 Materials handling accessories. The sterilizer shall be provided with the materials handling accessories listed in table II (see 6.1.1 and 6.2).

TABLE II. Accessories

Accessories	Sizes			
	1	2	3	4
Bottom shelf	X			
Two shelves	X			
Three shelves	X			
Loading car	X	X	X	X
Carriage	X	X	X	X

"X" indicates the accessories which should be considered for Ethylene Oxide Gas Sterilizers.

3.8.9.1 Bottom shelf. The bottom shelf shall be made of nickel-copper-alloy wire rod and extend the full usable length and width of the interior of the sterilizer chamber. The shelf shall be of welded construction and provided with nickel-copper-alloy supports to prevent goods on the shelf from contacting the chamber floor.

3.6.9.2 Shelves. Each shelf shall be made of nickel-copper-alloy wire rods and extend the full usable length and width of the sterilizing chamber. When fully loaded, the shelf shall slide freely on nickel-copper-alloy angle guides. The angle guides shall, if affixed to the sterilizing chamber walls, be installed without exposing the ferrous metal beneath the chamber cladding to the sterilant. Stops shall be provided to allow each shelf to be withdrawn approximately 1/2 its length.

3.6.9.3 Loading cars.

3.6.9.3.1 Size 1. The loading car for size 1 shall consist of a framework, two shelves, axles, and wheels. Minimum outside dimensions of the framework shall be 33 inches by 18 inches wide by 14 inches high. The upper shelf shall be adjustable to three heights. The loading car, while containing an evenly distributed, 100-pound load shall rotate freely on a corrosion-resisting metal track assembly which shall be provided. The wheels shall be bearing mounted and made of nickel-copper alloy, bronze, or brass; the axles shall be nickel-copper alloy, bronze, or corrosion-resisting steel. Other parts of the car shall be welded nickel-copper alloy.

3.6.9.3.2 Sizes 2, 3, and 4. The loading car for a size 2, 3, or 4 shall be a welded, nickel--copper-alloy framework (with open sides) supported on corrosion-resisting steel, bronze or brass, bearing-mounted wheels. The axles shall be constructed of nickel-copper-alloy, bronze, or corrosion-resisting steel. The framework shall contain a full-length, full-width, bottom shelf; a removable load-retaining gate (to form one side closure) and not less than two adjustable full-width, full-length shelves, or four adjustable, half-width, full-length shelves. Eight half-width, half-length shelves may be furnished in lieu of the four half-width, full-length shelves if for size 4. The adjustable shelves shall be removable and provide at least seven loading heights. The shelves and load-retaining gate shall be made of welded, nickel-copper-alloy wire rod. While containing an evenly distributed, 600-pound load, the car shall roll freely on the tracks inside the sterilizing chamber (see 3.6.1). Dimensions of the car shall be as shown in table III.

TABLE III. Loading car dimensions

Size	Minimum outside dimensions (inches) of car framework Length	Width	Height
2	35	21	28
3	47	21	28
4	59	21	28

3.6.9.4 Carriages.

3.6.9.4.1 Size 1. The carriage for size 1 shall be a table-like structure of corrosion-resisting metal, supported by four casters (two swivel and two fixed) conforming to class C, style A, FF-C-77, except that they shall be fitted with nonmarking polyurethane or synthetic tires. The carriage shall include a top surface with height-adjustable tracks or wheels to receive the loading car from the sterilizer, a shelf beneath the track assembly for storing and transporting supplies, and a handle to facilitate maneuverability. Latches shall be provided to secure the carriage to the sterilizer while the loading car is wheeled onto the carriage tracks, and to secure the loading car while it is transported on the carriage. These latches shall be operable from the handle end of the carriage.

3.6.9.4.2 Sizes 2, 3, and 4. The loading car carriage for a size 2, 3, or 4 shall be a caster-mounted structure containing height-adjustable tracks or wheels to receive the loading car from the sterilizer. The casters shall conform to class c, style A, FF-C-77, except that they shall be fitted with nonmarking polyurethane or synthetic tires. The carriage shall,be maneuvered by a handle at one end. Spring-loaded latches shall be provided to secure the carriage to the sterilizer while the loading car is wheeled onto the carriage tracks, and to secure the loading car while it is transported on the carriage. These latches shall be operable from the handle and of the carriage. The carriage shall also be equipped with nonmarking, resilient bumpers or similar devices to protect walls or furniture from damage. The carriage structure shall be made of welded or bolted, corrosion-resisting steel or coated metal.

3.6.10 Finish. The sterilizer and materials handling accessories shall be free of burr an roughness which could cause personal injury, impede cleaning, or damage goods processed in the sterilizer. Unless otherwise specified, the

finish of the various components of the sterilizer shall conform to the manufacturer's regularly employed commercial standards.

3.6.10.1 Corrosion protection. Exposed surfaces of the outer shell, including backbeat of a single-door sterilizer and sterilizer mounting stand, shall be suitably coated to protect the parts from corrosion.

3.6.10.2 Door Parts. Corrosion-resisting metal, exterior door, and door-frame parts (except handwheel) not concealed by door cover, shall have a,satin finish. Parts of other than corrosion-resisting metal shall be chromium plated and polished to a satin or brighter finish.

3.6.10.3 Carriage. A carriage not of corrosion-resisting steel construction shall have the manufacturer's commercial, baked-on epoxy finish.

3.6.11 Nameplate. Each sterilizer shall have one or more nameplates, permanently fastened (welded, bonded, or with screws) and reasonably accessible, containing at least the following data:

Name of manufacturer
Manufacturer's type and model designation
Serial number
Electrical characteristics
Contracts or purchase order number

3.6.12 Workmanship. The products supplied under this specification shall be new and free from defects and imperfections that might affect their safety, serviceability, maintainability, and appearance.

3.6.13 Dielectric strength. Each sterilizer shall withstand the test specified in 4.2.3.6.

4. QUALITY ASSURANCE PROVISIONS

4.1 Responsibility for inspection. Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure that supplies and services conform to prescribed requirements.

4.2 Quality conformance inspections.

4.2.1 Design and construction. Prior to shipment, each sterilizer shall be visually examined and operated to determine conformance to the design and construction requirements of this specification. Nonconforming sterilizers and parts shall be rejected and replaced with conforming sterilizers or parts.

4.2.2 Materials and instruments. Physical and chemical tests of materials shall be conducted to determine performance with these specifications. Nonconforming materials shall be replaced with conforming materials. Certificates of quality from the supplier of materials and the instruments (listed in 4.2.3.5 - table IV) used in manufacturing the sterilizer shall be acceptable in lieu of the sterilizer manufacturer performing such physical and chemical tests to determine conformance to these specifications.

4.2.3 Performance. The supplier shall conduct performance inspections on the sterilizer covered by this specification, using the test methods specified herein. A sterilizer failing to pass the tests shall be replaced or reworked, and retested until it satisfactorily passes the tests.

4.2.3.1 Test records. Records of tests satisfactorily performed on sterilizers accepted by the Government under this specification shall be certified by the manufacturer and kept on file for 2 years, available for examination by the Government upon request. Such test records may be recertified once every 12 months, following their initial certification, for subsequent use as provided in 4.2.3.1.1.

4.2.3.1.1 Waiver of testing. The performance inspection tests specified in 4.2.3.3 through 4.2.3.4.2 may, at the procurement contracting officer's discretion, be waived for subsequent contracts which specify sterilizers of the same size (other characteristics excluded) as those previously tested, and for which the manufacturer has certified or recertified test records on file.

4.2.3.2 Test conditions.

4.2.3.2.1 Apparatus and instruments. Apparatus and instruments used for testing shall be so installed as not to hinder accurate operation. The test instruments shall be calibrated at least annually to assure accuracy.

4.2.3.2.2 Environment. The tests shall be started with the sterilizer and test load at the ambient, test area temperature and pressure.

4.2.3.2.3 Installation and operation of sterilizer. Operation of the sterilizer during the tests shall be in accordance with the manufacturer's instructions, specified in 3.5.3. Water for operation of the sterilizers shall be delivered at 20 to 50 psig. Except for a size I sterilizer with electric chamber-heating system, steam shall be delivered to the test unit at 50 to 80 psig.

4.2.3.3 Sterilizing efficiency test.

4.2.3.3.1 Test load. The test load shall consist of.four packs containing the articles listed below. Each of the packs shall be wrapped with a double layer of 40-pound kraft paper or with a double layer of muslin. Each pack shall contain three paper strips, each inoculated with Bacillus subtilis (globigii) dried spore population of $10^{\lfloor 6 \rfloor}$ average per strip as specified in MIL-S-36506. The test strips shall be placed in remote locations, such as inside of rubber gloves or tubing, and at the centermost positions of the test packs.

Contents of test packs:

(a) One pack containing 25 miscellaneous surgical instruments;
(b) One pack containing one pair of rubber gloves;
(c) One pack containing one each of the following anesthesia accessories: breathing bag, face piece, "Y"-type connecting hose, rubber and plastic airways, and endotracheal catheter;
(d) One pack containing a polyethylene, cardiovascular catheter, a broncho-scope, and a nylon-wover ureteral catheter.

4.2.3.3.2 Test procedure. The test shall be conducted as follows:

Step 1 - Place the test packs on one or more shelves in the sterilizing chamber.
Step 2 - Operate the sterilizer for a complete automatic sterilizing cycle, recording the time the control is actuated to start the cycle.
Step 3 - Record the time the end-of-cycle alarm or light actuates and then immediately remove the packs from the chamber.
Step 4 - Remove the spore strips from the test packs and test them for sterility as recommended in the latest edition of the Pharmacopoeia of the United States.

4.2.3.3.3 Test results. The entire test sterilizing cycle shall be conducted in nor more than 3-1/2 hours, and there shall be no visible moisture on or damage (cracking, crazing, discoloration, deformation) to any of the articles processed. Sterility of the test load shall be evidenced by the killing of all spores on the 12 spore-inoculated strips which were processed in the test packs.

4.2.3.4 Test of bacteria-retentive filter.

4.2.3.4.1 Test procedure. The test shall be conducted as follows:

Step 1 - Sterilize the entire filter system.
Step 2 - Attach a tank to the intake side of the filter, (The tank shall contain an atomizing device and a water suspension of bacteria of a strain foreign to those used for other procedures in the laboratory where this test is performed.) Introduce sufficient bacteria into the filter intake system, through the atomizing device, to produce a minimum count of 10 organisms per cubic foot of air entering the filter system. Allow air containing the bacteria to be drawn through the filter system, at maximum flow rate, into a liquid trap.

Step 3 - Pass the liquid from the trap through a 0.45-micron membrane filter. Place this filter in a suitable culture medium, such as plate count agar or trypticase broth, for 48 hours. Then examine the culture for the presence of bacteria.

4.2.3.4.2 Test results. The culture examination for bacteria (Step 3) shall demonstrate zero count of the test organism.

4.2.3 Accuracy of instruments. When tested against certified laboratory standard, controls and instruments shall be accurate within the limits shown in table IV.

TABLE IV. Accuracy of instruments

Instrument	Test Range	Accuracy (plus or minus)
Indicator-recorder		
Vacuum	0-30 in Hg	2 percent
Pressure	0-35 psig	2 percent
Temperature	80-280 deg. F	2 deg. F
Sterilizing exposure timer	0-6 hours	+4.0 min.-0 (on repeated operation)
Chamber-vacuum pressure gauge for double-door sterilizer	30 in. Hg - 60 psig	2 percent
Sterilant cylinder pressure gauge	0-300 psig	2.0 percent

4.2.3.6 Dielectric strength. With the sterilizer chamber at the maximum temperature it is key to encounter during normal operation, apply gradually increasing 60 Hz potential between the current-carrying parts and the metal enclosure. Voltage, s follows, shall be maintained for 1 minute:

Rated Nominal Voltage of Component and Circuitry	Test Voltage to be Applied
120	900
over 120	1,000 volts plus twice the nominal rated Voltage

There shall be no arcing or other evidence of insulation of design failure.

4.2.4 Examination of preparation for delivery. An examination shall be made to determine whether the packaging, packing, and marking comply with the requirements of section 5. Defects shall be scored as specified in table V. Sampling shall be in accordance with MIL-STD-105. The sample unit shall be one container fully prepared for delivery. The lot shall be the number of containers offered for inspection at one time. The inspection level shall be S-2 with an AQL of 4.0 expressed in terms of percent defective.

TABLE V. Examination of preparation for delivery

Examine	Defect
Contents	Not as specified.
Containers	Not as specified.
Markings	Omitted; incorrect; illegible; improper size, location, sequences or method of application.
Materials	Component missing or damaged.
Workmanship	Bulging or distortion of container, cushioning inadequate, improper, or missing.

4.2.4.1 Examination of closure and reinforcement of containers. When shipping containers are required to comply with PPP-B-601, PPP-B-621, or P-B-640, the examination for defects in closure and reinforcement shall be in accordance with the appendix of that specification.

5. PREPARATION FOR DELIVERY

5.1 Packaging. Packaging shall be level A, B, or C, as specified.

5.1.1 Level A.

5.1.1.1 Motors. Openings in electric motors shall be sealed with tape conforming to PPP-T-60, type II, class 1.

5.1.1.2 Indicators, gauges, and dials. All indicators, gauges, and dials shall be covered with cushioning material conforming to PPP-C-843 and the cushioning material secured in place with tape specified herein.

5.1.1.3 Switch boxes, outlets, connections, and drain-line openings. Switch boxes, outlets, connections, and drain-line openings shall be sealed with tape specified herein.

5.1.1.4 Instruction books and parts lists. Instruction books and parts lists shall be packaged together in accordance with MIL-P-116, method IC-1, and secured to the sterilizer in a protected location.

5.1.1.5 Trays and racks. Trays and racks shall be secured by tying, blocking, or bracing to prevent movement during transit.

5.1.2 Level B. The sterilizer shall be packaged as specified in 5.1.1.

5.1.3 Level C. The sterilizer shall be packaged in accordance with the supplier’s commercial practice.

5.2 Packing. Packing shall be level A, B, or C, as specified (see section 6).

5.2.1 Level A.

5.2.1.1 Sterilizer. Each sterilizer shall be packed in container conforming to PPP-B-621, class 2, style optional; or to PPP-B-601, overseas type; or to PPP-B-640, class 2, grade A, style optional. When a sterilizer exceeds 1,000 pounds net weight, it shall be packed in a crate conforming to MIL-C-3774, nailed assembly, skid-type base, or MIL-C-104, bolted assembly, plywood sheath, skid-type base. The contents of the crate shall be blocked, braced, and anchored in accordance with MIL-C-104, and waterproofed with a shroud extending to the base of the crate in accordance with the appendix to MIL-C-132. The contents of a nailed wood or fiberboard container shall be waterproofed within a sealed case liner conforming to MIL-L-10547, except that a sealed case liner may be omitted from a fiberboard container when it is sealed with water-resistant tape in accordance with the appendix to the fiberboard container specification.

5.2.1.2 Loading cars. Each loading car shall be packed in a container conforming to PPP-B-621, class 2, style optional; or to PPP-B-601, overseas type; or to PPP-B-640, class 2, grade A, style optional. The contents of a nailed wood or fiberboard container shall be waterproofed within a sealed case liner conforming to MIL-L-10547, except that a sealed case liner may be omitted from a fiberboard container when it is sealed with water-resistant

tape in accordance with the appendix to the fiberboard container specification. Strapping shall be in accordance with the appendix to the applicable container specification.

5.2.2 Level B.

5.2.2.1 Sterilizer. Each sterilizer shall be packed as specified in 5.2.1.1, except that the container shall be class 1 domestic type, waterproofing shall not be required.

5.2.2.2 Loading car. Each loading car shall be packed as pacified in 5.2.1.2, except that the container shall be class 1, domestic type; waterproofing shall not be required.

5.2.3 Level C. Each complete sterilizer shall be packed to assure carrier acceptance and safe delivery to destination in container(s) complying with the rules and regulations applicable to the mode of transportation.

5.3 Marking.

5.3.1 Civil agencies. In addition to marking required by the contract or order, the shipping containers shall be marked in accordance with Fed. Std. No. 123.

5.3.2 Military activities. In addition to markings required by the contract or order, the shipping container(s) shall be marked in accordance with MIL-STD-129.

6. NOTES

6.1 Intended use. It is intended that the sterilizers covered by this specification be for ordinary hospital applications and for operation only with nonflammable (in any proportion of air at temperatures up to 130 deg. F (54,55 deg. C)) ethylene oxide sterilants having low vapor pressure. Such sterilants would comprise a mixture of not more than 12.75 percent ethylene oxide (by weight) and dichlorodifluoromethane or trichloromonofluoromethane, or both. Consequently, when sterilizers designed to use other ethylene oxide sterilant mixtures are required, appropriate equipment specifications should be prepared locally in consultation with the concerned medical, safety, architectural, and equipment planning staffs and equipment manufacturers' representatives.

6.1.1 Materials handling accessories. Special consideration should be accorded the options offered in 3.5.9 for materials handling accessories. It is important that the sterilizers be ordered with the desired quantity of shelves or loading cars and carriages. The following should be considered when specifying loading cars and carriages:

(a) Style A or style B sterilizer - Three sets, to provide one loading car in the sterilizer (with carriage standing by), one car and carriage at a work station, and one car and carriage in the post-sterilizing aeration area.
(b) Style C or style D sterilizer - Three sets for use as indicated in (a) above, plus one additional carriage for each loading car on the "unloading" end of the sterilizer.

6.1.2 Sterilant supply. This specification does not cover the sterilant for operation of the sterilizers. Cylinders of the appropriate sterilant are available from local distributors of medicinal gases.

6.1.3 Aeration. Residual ethylene oxide sterilant that remains in most goods following sterilization can be harmful to body tissue. It is important that this residual be removed prior to use of such goods. Appropriate medical authorities should be consulted as to the need for any special equipment which might be required to expedite the aeration of goods sterilized by ethylene oxide.

6.2 Ordering data. Purchasers should select the preferred options permitted herein, and include the following information in procurement

documents:

(a) Title, number, and date of this specification.
(b) Size and style required (see 1.2).
(c) Number of copies and distribution of instruction books and parts lists, if different from the requirements of 3.5.3, 3.5.3.1, and 5.1.1.4; and additional information, if required.
(d) Where instruction booklets and parts list are to be forwarded for review and approval.
(e) When the 15 additional copies of data are required (see 3.5.3.3).

(f) State if door(s) shall be manual or power operated (see 3.6.2). Note: A power door shall be acceptable in lieu of a manual door when offered.
(g) State whether a right- or left-hand door swing is desired (see 3.6.2).
(h) Whether automatic sterilant cylinder-changeover device is required for size 1 sterilizer (see 3.6.4.1).
(i) Electrical characteristics for the vacuum pump motor (see 3.6.5.1).
(j) Whether electric or steam heat is required for a size 1 sterilizer (see 3.6.6).
(k) Selection of materials handling accessories (see 3.6.9).
(l) Responsibility for inspection, if different from the requirements of 4.1.
(m) Selection of applicable levels of packaging and packing (see 5.1).
(n) If for installation in the continental United States, supervision of installation, test, and demonstration by a thoroughly qualified technician employed by and trained in the equipment manufacturer's plant.
(o) When interlock is required for a style C or D sterilizer (see 3.6.3.1.2 and 6.3).
(p) State if canopy is required (see 3.6.8.3). Before specifying a canopy, the need for it should be verified by the hospital engineer.

6.3 Interlock. This device should be specified when highly infectious materials are to be loaded into a double-door sterilizer in one room, be processed in the sterilizer, and then be removed in an adjacent room. Interlocks are normally specified only for sterilizers used in biomedical research laboratories and other special locations; therefore, before specifying this device, the need should be verified with the cognizant professional medical staff.

Military Coordinating Activity:

DSA-DM

Civil Agency Coordinating Activities:

GSA-FSS
VA-MED

Preparing Activity:
VA-MED

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