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FEDERAL SPECIFICATION

WASHER-STERILIZER SURGICAL INSTRUMENT

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. The washer-sterilizer covered under this specification shall be the horizontal, vacuum-pressure, gravity air removal type for processing surgical instruments and utensils, using saturated steam as the sterilizing agent.

1.2 Classification. The washer-sterilizer shall be of one size and the following style as specified (see 6.2).

1.2.1 Size. The minimum clearance inside dimensions of the washing and sterilizing chamber shall be 16 inches wide by 16 inches high by 26 inches long.

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-thru); for recessing through one wall partition

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:

PPP-T-60 - Tape Pressure Sensitive Adhesive, Waterproof for Packaging.
PPP-B-601 - Boxes, Wood, Cleated Plywood.
PPP-B-621 - Boxes, Wood Nailed and Lock-Corner.
PPP-B-640 - Boxes, Fiberboard, Heavy Duty.
CC-M-636 - Motors, Fractional Horsepower, (Alternating Current).
PPP-C-843 - Cushioning Material, Cellulosic.
QQ-N-281 - Nickel-Copper Alloy Bars, Plates, Rods, Sheets, Strips, Wire, Forgings, and Structural and Special Shaped Sections.
QQ-S-766 - Steel Plate, Sheets, and Strip-Corrosion-Resisting.

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 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 - Crates. Wood; Lumber and Plywood Sheathed, Nailed and Bolted.
MIL-C-132 - Crates, Open Wood; Maximum Capacity 2,500 pounds.
MIL-C-3744 - Crates, Wood, Open, 12,000 and 16,000 pound capacity.
MIL-L-10547 - Sheet, Overwrap: Water Vapor Proof or Water Proof, Flexible.
MIL-P-116 - Preservation, Methods of.
MIL-I-45208 - Inspection Requirements.
MIL-S-36585 - Sterilization Test Strip Set, Bacterial Spore.

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.

The American Society of Mechanical Engineers (ASME):

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

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

American National Standards Institute, Inc. (ANSI) Standard:

A 40.8 - National Plumbing Code

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

American Society for Testing and Materials (ASTM) Publications:

B 88 - Seamless Copper Water Tube.
B 135 - Seamless Brass Tube.
B 43 - Seamless Red Brass Pipe.
B 456 - Specification for electrodeposited coating of nickel plus chromium.

(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 Electric Code.
No. 56 - Code for the Use of Flammable Anesthetics.

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

United States Pharmacopoeial Convention, Incorporated (USP):

Pharmacopoeia of the United States.

(Application for copies should be addressed to the Mack Publish1ng Company, Easton, PA 18042.)

3. REQUIREMENTS

3.1 Compliance with Standards.

3.1.1 Pressure vessel. The design, material, and test of each washer-sterilizer shall conform to applicable requirements of the ASME Boiler and Pressure Vessel Code, Section VIII, Pressure Vessels, Division I.

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

3.1.2 Electrical components. The electrical components of each washer-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.

3.1.2.1.1 Fractional horsepower. Shall be continuous duty, class A or B insulation, CC-M-636.

3.2 Materials.

3.2.1 Corrosion resisting metal. 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 plated metals. Chrome plate on die castings shall meet the requirements for service condition SCL in ASTM B 456 except equivalent nickel thickness shall be 0.3 mil. Chromium plate on copper alloys shall also meet SCL except the equivalent nickel thickness shall be 0.1 mil.

3.2.6 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, unless otherwise specified herein, 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.

3.2.7 Piping. Steam, water and waste lines 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 washer-sterilizer to conform to the requirements of ANSI A 40.8.

3.2.8 Manual valves. Handvalves on steam and water supply lines shall be bronze with synthetic discs or equivalent parts. Handvalve shutoffs requiring routine operation shall have renewable nickel-copper-alloy seats. Such valves shall be easily accessible to the operator from the control end of the washer-sterilizer. Each valve shall withstand a 350-psig, hydrostatic test and be leakproof when tested at 100 psig air pressure with valve body submerged in water. Each valve shall have a renewable, low-heat-conducting and nonloosening handle. Durable letters on the handle shall show the purpose of the valve.

3.3 Design. Each washer-sterilizer shall operate on the gravity-air-removal principle and consist of a chamber assembly, single- or double-door assembly, operating controls, exhaust system, chamber-drain system, power system, mounting devices, and material-handling accessories. The washer-sterilizer shall be furnished complete, ready for connection to building utility service lines.

3.4 Performance characteristics. The washer-sterilizer shall wash and sterilize surgical instruments and utensils in one operation or, at the option of the operator, only sterilize the instruments or utensils for either three or ten minutes as selected. Performance of the unit shall conform to the requirements specified in 4.2.3.4 and 4.2.3.5.

3.5 Maintainability.

3.5.1 Service access. Panels shall be easily removable for servicing the components behind them.

3.5.2 Wiring diagrams. Wiring diagrams shall be securely attached to the washer-sterilizer in accessible locations such as inside of 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 washer-sterilizer, and secured in a protected location.

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

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.

3.5.3.2 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.

3.5.3.3 additional data. When specified (see 6.2), fifteen 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 chamber assembly for a style A or style B washer-sterilizer shall consist of a single shell, backhead and door frame. If a style C unit is specified the washer-sterilizer shall have a single shell with a door frame on each end.

3.6.1.1 Shell. The shell shall be hot-rolled carbon steel designed to withstand internal pressures of not less than 33 psig. The inside surfaces shall be clad with nickel or nickel-copper alloy as specified in 3.2.4. The exterior of the shell (including backhead if a style A or style B washer-sterilizer) shall be insulated with a glass-fiber blanket commercially rated one inch thick; both sides of the blanket shall be covered with an aluminum foil. The insulation shall be secured to the washer-sterilizer with thermosetting tape or aluminum straps.

3.6.1.2 Backhead. The backhead for a style A or style B washer-sterilizer shall be constructed of hot-rolled, carbon steel. Surfaces exposed to the sterilizing chamber shall be clad steel as specified in 3.2.4.

3.6.1.3 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 assembly. Each door assembly shall consist of a door,an opening and closing mechanism and safety locks. The door swing shall allow unobstructed access to the chamber. Door shall be attached to the door 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), and reversible in the field without parts, welding or drilling.

3.6.2.1 Door materials. The material used for the door shall be cast bronze, corrosion-resisting steel or hot-rolled carbon steel clad on the chamber side with nickel or nickel-copper alloy as specified in 3.2.4. The hinges 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 six months after initial operation. Gaskets shall be held in brass, bronze or corrosion-resisting metal grooves. Grooves on clad doors shall be so installed as not to expose the ferrous metal (beneath the cladding) to steam vapor. Outside surfaces of the door plate and door-securing members shall be concealed (to the maximum permitted by the ASME Code) by a cover. The cover shall be of corrosion-resisting steel.

3.6.2.2 Door operation. All functions of opening and closing the door (or doors) and positioning, tightening and loosening the door-holding members shall be by a low-heat-conducting handwheel or a quick-throw arm. The opening and closing mechanism shall be so arranged that the holding members will be fully engaged before gasket seal can be established. 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 overtightening of door.

3.6.2.3 Safety lock. Each door shall lock automatically when pressure in the chamber rises to between 0 and 4 psig; the lock shall not release until pressure is reduced to approximately atmospheric. In addition, a second mechanical lock shall prevent the door (or doors) from being opened while the unit is in the wash cycle.

3.6.3 Operating controls.

3.6.3.1 Automatic control. Shall be a motor-driven mechanism that controls all functions of the washer-sterilizer. The control shall also be manually operable without electric power by a single programming wheel, dial or handle with cycle-phase indictor. Depressing the appropriate button on the main control panel shall program the washer-sterilizers to either (1) wash and sterilize goods in the chamber or (2) sterilize the goods for three or ten minutes as selected. The cycle sequences shall be as follows:

Wash and sterilize

(a) Fill chamber with cold water (to loosen gross soil on the load).
(b) Inject steam into chamber to agitate and heat the water to approximately 150 deg. F.
(c) Drain chamber.
(d) Charge the chamber with steam to 270 deg. - 274 deg. F.
(e) Hold the chamber and load at 270 deg. F for 3 minutes.
(f) Return chamber to approximately atmospheric pressure.

Sterilize

(a) Charge the chamber with steam to 270 deg. F.
(b) Hold the chamber and load at 270 deg. F for either three or ten minutes as selected.
(c) Return chamber to approximately atmospheric pressure.

After the cycle has started, no further operator attention shall be necessary until an audible signal and pilot light indicate completion of the cycle. The end-of-cycle alarm shall cease automatically when the door of the washer-sterilizer is opened or within approximately two minutes after completion of the cycle, whichever occurs first. Sequential signal lights shall indicate each phase of each cycle sequence. The sterilizing exposure timer shall not actuate until the chamber has reached 270 deg. F. The control shall be so designed that a cycle cannot be started unless the washer-sterilizer door or doors is (are) closed and the holding members engaged. The control shall be fused for operation on 120-volt, 60-cycle electric power and driven by a intermittent-duty motor.

3.6.3.2 Temperature-indicator-recorder. This instrument shall be provided to indicate and record chamber temperature throughout the washing and sterilizing cycles. The sensor shall be in the chamber-drain line. Temperature shall be recorded on a chart driven by a synchronous (24-hour) timing motor. The chart pen shall be the capillary or cartridge type; one capillary of ink shall be sufficient for at least three months' usage and the ink supply shall be visible. One hundred charts and a one-year ink supply shall be furnished.
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3.6.3.3 Associated instrumentation. Shall include a chamber-pressure gauge (two if a style C washer-sterilizer) and automatic timers. The sterilizer exposure timers shall automatically reset itself upon completion of the selected cycle and in the event of electric power failure, in addition they shall automatically reset itself if the chamber temperature should fall 2 deg. F below the sterilizing value. A style C washer-sterilizer shall be provided with indicators that show when a cycle is in process, when the chamber may accept a load of goods for processing and when an in-process load is sterile.

3.6.3.4 Location of automatic control components. Electrical components shall be located on the washer-sterilizer to conform to the requirements of NFPA No. 56. Instruments and other components of the automatic control which require operator attention shall be in a panel above the door frame on the control end of the sterilizer. The additional chamber pressure gauge and other cycle-status indicators for a style C washer-sterilizer shall be above the door frame opposite the control end.

3.6.4 Exhaust system. An automatic condenser shall be provided. It shall function through the automatic control and shall also be manually operable from the control end of the sterilizer. The condenser shall include a corrosion-resisting-metal, copper or brass heat exchanger, waste line, and building waste-line funnel. Steam and condensate from the chamber shall enter the heat exchanger where the steam shall be condensed. Condensate shall then flow from the heat exchanger, through the waste line and into the funnel. The funnel shall be sized or designed to prevent spillage from the top. The waste line shall terminate at one side or rear of the washer-sterilizer. The condenser shall be designed to prevent backflow of steam and condensate into the washer-sterilizer or building water-supply system.

3.6.5 Power system. The washer-sterilizer shall operate on steam from an independent source delivered at 50 to 80 psig; cold water, at 30 to 50 psig. No heating coils or heating elements shall be employed. Steam and water lines shall terminate in fittings at the side or rear of the washer-sterilizer for ready connection to building service lines. The steam supply line shall include a strainer, a shut-off valve and a pressure regulator that automatically maintains the selected chamber pressures.

3.6.5.1 Safety-valve setting. The washer-sterilizer safety valve shall be set to relieve pressure in excess of the rated maximum operating pressure of the vessel and be sealed to prevent change of adjustment.

3.6.6 Chamber-drain system. The chamber of each washer-sterilizer shall be provided with an opening in the floor to pass air, steam and condensate during the sterilizing cycle. The opening shall be fitted with a brass, bronze, or corrosion-resisting-metal strainer to catch lint and dirt. The drain line shall include a thermostatic steam trap, drain pan and shut-off valve. The chamber floor shall be pitched to the drain fitting, which shall be flush with the chamber floor.

3.6.7 Mounting devices. The washer-sterilizer chamber shall be supported by a steel stand equipped with adjustable, corrosion-inhibiting floor flanges and fitted with panels. The front, side, remote and top panels shall be constructed of corrosion-resisting steel.

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

3.6.7.1 Front and remote panels. Each front and remote panel shall comprise a lower section that covers 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 remote panels shall not be less than 0.050 inch thick and shall be fitted with adjustable kick plates. No fasteners shall be exposed on the exterior of the washer-sterilizer. Front and remote panels shall include gaskets or other suitable means that will ensure a tight fit, along their entire top and side borders, where they abut wall partitions or companion side and top panels.

3.6.7.2 Side and top panels. These panels shall be formed from single sheets not less than 0.050 inch thick and they shall be removable without tools. No fasteners shall be visible from the exterior of the washer-sterilizer.

3.6.7.3 Canopy. When specified (see 6.2 and 6.3), a ventilating canopy shall be provided, for a style A or B sterilizer. The canopy shall replace the washer-sterilizer top panel and shall be attached to the washer-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 washer-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 washer-sterilizer cabinet panel approximately eight inches. Air-intake openings shall be provided in the canopy overhang and, if required, in the washer-sterilizer side cabinet panels to meet the airflow requirements of 6.3. 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 washer-sterilizer cabinet panels. Weldments on surfaces of the canopy exposed to view from the front or sides of the washer-sterilizer shall be ground and polished so that the canopy will appear as a seamless unit. If canopy is for a style A washer-sterilizer, a corrosion-resisting-steel panel shall also be included to fully enclosed the rear of the washer-sterilizer cabinet.

3.6.8 Materials handling accessories.

3.6.8.1 Instrument trays. A rack and two instrument trays shall be furnished with each washer-sterilizer. Each instrument tray shall be made entirely of welded, nickel-copper alloy. It shall have a wire-mesh or perforated-metal bottom and a carrying handle at each end, which shall fold or retract approximately flush with the top or end of the tray. The tray shall be not less than 20-1/2inches long by 10-1/2 inches wide by 2-1/2 inches deep.

3.6.8.2. Rack. The rack shall be a framework of welded (polished) nickel-copper alloy easily removable from the washer-sterilizer chamber. The rack shall have angle guides or shelves to support the trays. Stops shall allow the shelves or angle guides to be withdrawn approximately one-half of their length for easy loading and unloading. Shelves shall be made of welded, nickel-copper-alloy-wire rods, suitably reinforced.

3.6.9 Finish. The finish of the washer-sterilizer and materials-handling accessories shall be free of burrs or roughness which could cause personal injury, impede cleaning or damage goods. Unless otherwise specified herein, the finish of the various components of the washer-sterilizer shall conform to the manufacturer's regularly employed commercial standards.

3.6.9.1 Corrosion protection. Exposed surfaces of the outer shell, including backhead of a style A or style B washer-sterilizer and mounting stand, shall be suitably coated to protect the parts from corrosion.

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

3.6.10 Nameplate. Each washer-sterilizer shall have one or more nameplates, permanently fastened (welded, bonded,or with drive screws) and reasonably accessible, containing at least the name of the manufacturer, manufacturer's type and model designation, serial number, and electrical characteristics, contracts or purchase order numbers.

3.6.11 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.

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 inspection 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 washer-sterilizer shall be visually examined and operated to determine conformance to the design and construction

requirements of this specification. Nonconforming washer-sterilizers and parts shall be rejected and replaced with conforming washer-sterilizers or parts.

4.2.2 Materials and instruments. Physical and chemical tests of materials shall be conducted to determine conformance with these specifications. Nonconforming materials shall be replaced with conforming materials. Certificates of quality from the supplier of materials and the instruments listed in table I shall be acceptable in lieu of the washer-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 each washer-sterilizer covered by this specification, using the test methods specified herein. A washer-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 a washer-sterilizer accepted by the Government under this specification shall be certified by the manufacturer and kept on file for two 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 tests specified in 4.2.3.4 and 4.2.3.5 may, at the procurement contracting officer's discretion, be waived for contracts which specify washer-sterilizers conforming to those 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 the washer-sterilizer shall be so installed as not to hinder accurate operation. The test instruments shall be calibrated at least annually to assure laboratory accuracy.

4.2.3.2.2 Accuracy of instruments. When tested against certified laboratory standards, controls and instruments shall be accurate within the limits shown in table I.

TABLE I. Accuracy of instruments

Instrument	Range	Accuracy (plus or minus)
Chamber Pressure Gauge	0-60 psig	2 percent
Temperature-Indicator-Recorder	80-300 deg. F	2 deg. F
Timer (sterilizing phase)	0-10 minutes	plus 4 minutes minus 0 (on repeated operation)

4.2.3.2.3 Environment. The tests shall be conducted in an area with ambient temperature maintained between 65 deg. and 95 deg. F (18 deg. and 35 deg. C) and at the local atmospheric pressure. The tests required by 4.2.3.4 and 4.2.3.5 shall be started with the washer-sterilizer and test load (if required) at the ambient test-area temperature.

4.2.3.2.4 Installation and operation of washer-sterilizer. Operation of the washer-sterilizer during the tests shall be in accordance with the manufacturer's instructions specified in 3.5.3. Water required for operation of the washer-sterilizer shall be delivered at 30 to 50 psig; steam, shall be delivered at 50 to 80 psig. The test requiring only a sterilizing cycle shall be started with the chamber at ambient pressure and steam port to the wash-sterilizer closed.

4.2.3.3 Test load. The test specified in 4.2.3.5 shall be conducted with two trays of surgical instruments (in the chamber). Each tray shall conform to the requirements of 3.6.8.1 and shall contain 100 metal surgical instruments including retractors, forceps and hemostats. A spore strip conforming to MIL-S-36586, inoculated with a mixture of Bacillus stearothermophilus and Bacillus subtilus dried spore population adjusted to survive 270 deg. F for 20 seconds and to be killed when exposed to 270 deg. F for two minutes, shall be placed amid the instruments in each tray.

4.2.3.4 Washing and sterilizing test. Install a thermocouple in the washer-sterilizer chamber-drain-line fitting; connect the lead wire to a potentiometer. Then proceed as follows:

(a) Program the automatic control for a complete wash and sterilize cycle.
(b) Actuate the cycle and record the time.
(c) Actuate the potentiometer.
(d) When the cycle-phase light indicates that the sterilizing phase of the cycle has begun, record the time.
(e) Record the time when the end-of-cycle alarm first sounds.

4.2.3.4.1 Test results. No more than 26 minutes shall have elapsed between the time the control was initially actuated for the cycle and the time the end-of-cycle alarm first sounded. In addition, the potentiometric reading from the thermocouple in the chamber shall have been 270 deg. - 274 deg. F for not less than three minutes following the start of the sterilizing phase of the total cycle.

4.2.3.5 Sterilizing efficiency test. Place the instrument trays (4.2.3.3) in the chamber of the washer-sterilizer and program the automatic control for a 10-minute sterilizing cycle. Then actuate the cycle and record the time; record the time again when the end-of-cycle alarm first sounds. Finally, remove the spore strips from the instrument trays and test them for sterility as recommended in the U. S. Pharmacopoeia.

4.2.3.5.1 Test results. No more than 15 minutes shall have elapsed between the time the cycle was initially actuated and the time the end-of-cycle alarm first sounded. In addition, all spores on each of the spore strips shall have been killed.

4.2.3.6 Dielectric strength. All current-carrying parts of each unit shall withstand, without arcing or other evidence of insulation or design failure, a dielectric test of 900 volts, 60-Hz AC, single phase, supplied for one minute between the exposed, noncurrent-carrying parts and the current-carrying parts, with the unit at maximum operating temperature attained in normal use.

4.2.3.7 Temperature control. When measured by a thermocouple in the chamber drain line, sterilizing temperature shall not fall below, nor exceed by 4 deg. F, that set on the temperature indicator-recorder.

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 II. 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 II. Examination of preparation for delivery

Examine	Defect
Contents	Not as specified.
Containers	Not as specified.
Markings	Omitted; incorrect; illegible; improper size, location, sequence 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 PPP-B-640, the examination for defects in closure and reinforcement shall be in accordance with the appendix of that specification.

4.2.5. A certificate of compliance shall be furnished with each washer-sterilizer by the manufacturer, that the washer-sterilizer supplied under this specification meets all the requirements as called for herein. (see 6.2).

5. PREPARATION FOR DELIVERY

5.1 Packaging. Packaging shall be level A, B, or C, as specified (see 6.2).

5.1.1 Level A.

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

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

5.1.1.4 Instruction books and parts list. 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 washer-sterilizer shall be packaged as specified in 5.1.1.

5.1.3 Level C. The washer-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 Washer-sterilizer. Each washer-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 washer-sterilizer exceeds 1000 pounds net weight, it shall be packed in a crate conforming to MIL-C-3774, nailed assembled skid-type base. The contents of the crate shall be blocked, braced and anchored in accordance with MIL-C-104, and waterproof 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 is 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 Washer-sterilizer. Each washer-sterilizer shall be packed as specified in 5.2.1.1 except that the container shall be class I, domestic type; waterproofing shall not be required.

5.2.5 Level C. Each complete washer-sterilizer shall be packed to ensure 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 markings required by the contract or order, shipping container(s) 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, shipping container(s) shall be marked in accordance with MIL-STD-129.

6. NOTES

6.1 Intended use. The washer-sterilizer covered by this specification are intended and designed to remove only gross soil and to sterilize articles known to be, or suspected of being, contaminated with infectious agents. Processing must be followed by normal cleaning, wrapping and sterilizing techniques.

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 1.2.1 and 1.2.2).
(c) Number of copies and distribution of instruction books and parts lists, if different from requirements of 3.5.3, 3.5.3.1 and additional information if required.
(d) Where instruction booklets and parts list are to be forwarded for review and approval (see 3.5.3.2).
(e) When the fifteen additional copies of data are required (see 3.5.3.3).
(f) State whether right or left hand door swing is required(see 3.6.2).
(g) State if canopy is required (see 3.6.7.3).
(h) Responsibility for inspection, if different from the requirements of 4.1.
(i) Selection of applicable levels of packaging and packing (see 5.1).
(j) If for installation in the continental United States, supervision of installation, test and demonstration by a thoroughly qualified technician employed by the manufacturer and trained in his plant.
(k) The contracting officer must require a certificate of compliance that each washer-sterilizer furnished under this specification complies with all requirements as specified in the specification. (see 4.2.5).

6.3 Canopy. When this accessory can be conveniently connected to the room air-exhaust system, sensible heat loss from the washer-sterilizer to the room can be substantially reduced. This is because the room air can be allowed to flow through the louvered openings in the washer-sterilizer cabinet panels and canopy overhang to entrain heat from the washer-sterilizer body and moisture-laden air from the chamber (produced upon opening the door following a process cycle) and conduct them directly into the room air-exhaust system. Before specifying a canopy, the need for it should be certified by the hospital engineer.

Military Coordinating Activity:

DSA - DM

Preparing Activity:

VA - MED

Civil Agency Coordinating Activity:

VA - MED
GSA - FSS

Orders for this publication are to be placed with General Services Administration, acting as an agent for the Superintendent of Documents. See Section 2 of this specification to obtain extra copies and other documents referenced herein. Price 35 cents each.