STERIS®

RELIANCE® 9800 PHARMACEUTICAL GRADE WASHER

APPLICATION

The Reliance 9800 Pharmaceutical Grade Washer is intended for thorough cleaning of various materials and components used in the cosmetic and pharmaceutical manufacturing process industries, such as large vessels, containers, drums, Integrated Bulk Containers (IBCs), pallets, blenders, hoppers, and other large items. The washer can also be used to process components from filling or packaging machines.

DESCRIPTION

The Reliance 9800 Pharmaceutical Washer is a mechanical washer equipped with a PLC Modular Control System. The control includes a user-friendly operator interface screen.

The washer is designed with three factory set, adjustable cycles: Light, Medium, and Heavy. Seven additional cycles are available for customized programming to meet specific operating requirements. One cycle is exclusively for drying needs.

Reliance Pharmaceutical Grade Washers are designed, manufactured, validated, and documented according to the latest global practices and standards to facilitate customer compliance with current Good Manufacturing Practices (cGMPs).

Size (W x H x L)

Overall dimensions:



(Typical only - some details may vary.)

- Washer cabinet – 109-11/16 x 114-1/2 x 93-5/16" (2785 x 2908 x 370 mm)
- Effective chamber load capacity – 44-1/2 x 80 x 85" (1130 x 2032 x 2159 mm)

STANDARDS

The Reliance 9800 Pharmaceutical Grade Washer complies with the following standards:

- **Current Good Manufacturing Practices (cGMP)** CFR Title 21, Part 211, Section D.
- **Underwriters Laboratories (UL),** Standard 61010A-1.
- **Uniform Building Code of California,** Title 24 (Seismic Anchoring Requirements).
- **Machinery Directive** 98/37/EC.

The Selections Checked Below Apply To This Equipment

SWING-OUT DOORS
- ☐ Single
- ☐ Double

CONTROL
- ☐ Allen-Bradley
- ☐ Siemens

CONTROL LOCATION (Facing Load End)
- ☐ Right Side
- ☐ Left Side

OPTIONS
- ☐ Heated, Non-Recirculated Final Rinse Water Rinse
- ☐ Load Draining System
- ☐ Diaphragm Inlet Valves (Max. 3) Qty.__
- ☐ Instrumentation Tags, Customer Assigned Numbers
- ☐ Extended Manufacturing Documentation
- ☐ Extended Control System Documentation
- ☐ Additional Copies of Validation Binders Qty. __
- ☐ Coverage Tests
- ☐ Cleaning and Passivation Treatment

ACCESSORIES
- ☐ Service Side Enclosure Panels
- ☐ Barrier Wall Flanges Qty. __
- ☐ Compressor
- ☐ Manifolded Loading Cart
  - ☐ Spray Ball for Manifolded Loading Cart
  - ☐ Support for Lids
- ☐ Exterior Stainless-Steel Jacket Package
- ☐ Spray Ball Accessory

Item _____

Location(s)_____

_____

- **Low Voltage Directive** 73/23/EEC amended by 93/68/EEC.
- **Electromagnetic Compatibility Directive** 89/336/EEC amended by 93/31/EEC and 93/68/EEC.
- **Standards applied to demonstrate conformity to the directives:** EN/IEC-61010-1, EN/IEC-61326.

FEATURES

The PLC monitors and controls all washer operations and functions. Memory is available for ten process cycles (included three factory-set cycles: Light, Medium, and Heavy), and one drying cycle. The control system includes hardware, an operator interface, and impact printer. The system is designed in accordance to Good Automated Manufacturing Practice (GAMP) guideline.

Two standard PLCs are available:

- **Allen-Bradley CompactLogix™ controller**[1] series with PanelView Plus 1000 operator interface.
- **Siemens S-300** series with TP-270 operator interface.

Sanitary spray system includes two horizontally mounted spray headers, one on each side of chamber, to optimize load coverage and cycle time. Horizontal spray headers alternate movement in a vertical direction to eliminate competing spray action within the chamber.

Manifolded coupling system includes an automatic coupling on the side wall of the washer capable of diverting recirculated solution on a manifolded loading cart. The same connector can be used for manual connection of a spray device for internal coverage containers.

Sumpless solution delivery system washer cabinet base is minimized to 7-1/4" (184 mm) deep by using independent staging tanks located within the mechanical core. An in-line booster is located in the recirculation system to provide fast heating of solutions.

Process observation window and interior light allow the operator to verify cycle performance.

[1] *CompactLogix and PanelView Plus are trademarks of Allen-Bradley*

Single or double swing-out doors are insulated and made airtight and watertight by a silicone inflatable seal gasket to verify process integrity. A sealed, tempered glass observation window is provided on each chamber door to allow the operator to verify the washing process. An electromagnetic lock on the chamber door(s) verify proper locking of the chamber by adding 600 pounds to the force needed to open the door when it is activated. Double door configuration includes a door interlock system that allows for only one door to be opened at a time, preventing the risk of cross-contamination.

Mechanical core contains all critical components of the Solution Delivery System. The mechanical core is placed on casters to allow easy access to system components and efficient installation. It is designed to increase accessibility to all system components. All piping is sanitary. Threaded legs providing adjustment are supplied to facilitate leveling of the mechanical core.

Filters (a removable stainless-steel debris screen) are located in the bottom of the wash chamber (sump), to prevent large debris from entering the piping system and pump.

An additional self-cleaning filter is also located in the recirculation system to prevent clogging of spray nozzles.

Pressure transmitter is installed in the recirculating piping to monitor the pump pressure during wash and rinse treatments. This feature assures appropriate and consistent mechanical action is delivered throughout the entire cycle.

Electronic temperature control. Sanitary Resistive Temperature Device sensors (RTD) with transmitters are used to provide accurate control inputs and readouts throughout the cycles. RTD sensors are located in-line, just prior to spray jets, to verify load sanitization temperatures.

Automatic floor tilt system slopes the processed load at the beginning of the cycle to allow flat surfaces to drain properly. Floor is automatically returned to level position at cycle completion for smooth loading and unloading. It can be enabled or disabled by the supervisor, as desired (an option in the configuration mode).

Recirculation pump motor variable frequency drive allows the motor to start slowly, reducing the risk of thermal shock inside the washer. Flow of water into the chamber increases steadily during the first seconds of operation, preventing positive or negative pressure peaks from appearing instantly in the chamber, considerably reducing constraints in the structure.

Conductivity validation system controls and measures conductivity of the wash solution and final rinse water during the cycle. This control monitors the conductivity level, and injects detergent to achieve the wash solution set point, and controls the number of rinses to achieve the final rinse water conductivity setpoint.

A sampling valve (installed in the recirculation piping) allows for the safe collection of samples of wash or rinse water.

Drying systems. The washer is equipped with a High-Efficiency Particulate Air (HEPA) filtered drying system to dry inner and outer surfaces of washer items, and the interior of the final rinse tank (optional), if necessary. All of the surfaces downstream of the HEPA filter are 316 stainless steel. The chamber drying system is supplied with validation ports located on each side of the HEPA filter. In both systems, drying is non-recirculated. In addition, there is a cool-down phase at the end of the cycle that is standard, but can be adjusted by the supervisor. The drying fan is activated, but drying coils are not functional; thus, air circulating inside the chamber is not heated. The system runs for a minimum of one minute at the end of the washing cycle, whether drying is selected or not, and until the set temperature is reached (limited to 60 minutes).

Chemical injection pumps. Three peristaltic pumps are included to accommodate various chemicals. Pumps are provided with low level sensors and pick-up tubes. Customer supplied chemical containers are stored outside the unit, up to 8' (2.5 m) off the ground, and at a distance of up to 50' (15 m) from the washer.

Drain discharge cooldown system. The washer is provided with cold water connection for effluent cooldown. If sump water temperature is higher than 140°F (60°C), cold water is automatically mixed

with effluents. Effluents are cooled down to at least 140°F (60°C) while being discharged to the building drain system. The drain discharge cool down system can be activated or deactivated in accordance with local, state, and federal regulations.

Stainless-Steel Tags for Instrumentation. A stainless-steel tag is attached to each instrument with a chain. Identification numbers are assigned by the factory.

Factory Acceptance Test (FAT). The basic FAT includes the verification of the configuration of the unit and accessories, verification of instrumentation calibration, verification of alarms and cycle operation, testing of all inputs and outputs, review of engineering, manufacturing, and software validation documentation, as well as the demonstration that the unit can reproduce the cycle parameters recommended by the Process And Cleaner Evaluation (PACE) study, if it applies.

- **Manufacturing and Qualification Documentation, including:**
  - » Calibration Procedures
  - » Seismic Anchorage Report
  - » Factory Acceptance Test Procedure (FAT) and Report
  - » HEPA Filter Certificate (If option applies)
  - » Cleaning and Passivation Procedure and Report (if option applies)

- **Control System Validation Documentation, including:**
  - » Functional Specifications
  - » Organizational Chart
  - » Software Development Procedure
  - » Application Source Code Listings
  - » Operator Interface Program Listings

Additional copies of each validation binder can be supplied.

SAFETY FEATURES

- **Emergency Stop Pushbuttons.** Washer is equipped with external emergency stop pushbuttons (on both ends) that automatically stop operation of the washer.
- **Door Interlock System.** The interlock mechanism prevents both doors from being opened simultaneously. For pass-through (double door) washers, the clean side/unload door cannot be opened until the cycle has been completed. The unload door remains sealed up to five hours in case of a power failure.
- **Door Lock-Out Sensors** prevent the cycle from starting if the door is not fully closed, and also stops washer operation if a door is opened during a cycle.
- **Emergency Stop Cables,** located on each side of the interior wash chamber, instantly stop washer operation if pulled down.
- **Power Disconnect Switch** (a lockable, 3-phase, non-fused disconnect switch) is located on the cover of the main electrical box.
- **Control ON/OFF Selector Switch,** located inside the load side control panel, can be used to turn off the control power for servicing the unit.
- **Key Service Switch** (a key-operated selector switch) is used to lock washer operation. It prevents a cycle from being started while servicing the unit. It also resets unit if the Emergency Stop button is pressed or emergency cables inside the chamber are pulled.

CYCLE DESCRIPTION

The Reliance 9800 Pharmaceutical Grade Washer operation is simple and fully automatic with minimal operator intervention required.

Washer features three factory-set cycles (Light, Medium, and Heavy) that can be modified by the operator; seven fully programmable cycles; and one drying cycle. Up to 15 recirculated or non-recirculated treatments, and nine final rinses can be programmed in any selected order for the wash cycles.

The basic units offer a typical treatment schedule (factory-set Medium cycle) consisting of the following:

- **Pre-Wash (non-recirculated).** Fresh water is sprayed over the load for 42 seconds, then sent directly to the drain, flushing the self-cleaning filter instead of being recirculated over the load. Time for this non-recirculated treatment is 42 seconds.
- **Wash.** Fresh water is sprayed into the chamber. The chemical is injected for 54 seconds by one of the selected chemical pumps. Chemical concentration can be set from 00 to 360 seconds, or from 100 to 37,500 μScm^2. The solution is heated up to 150°F (65.5°C) maximum temperature and recirculated under pump pressure for four minutes. The drain pump, which is activated at the beginning of the cycle, continues to drain for one minute after the recirculation pump has stopped. The system is then drained by gravity once the treatment is completed.
- **Rinse 1 (unheated).** Fresh water is sprayed into the chamber. Water is recirculated under pump pressure for 90 seconds. The drain pump, which is activated at the beginning of the cycle, continues to drain for one minute after the recirculation pump has stopped. The system is then drained by gravity once the treatment is completed.
- **Final Rinse (non-recirculated).** Water is sprayed over the load for 42 seconds. The drain pump, which is activated at the end of the cycle, drains water for one minute; after one minute, the sump is drained by gravity once the treatment is completed.
- **Drying.** The drying phase removes hot humid air from the chamber. Selected time for this non-recirculated phase is 10 minutes.

OPTIONAL FEATURES

STERIS provides a wide variety of standard options to enable the customer to configure a unit to meet their application requirements with maximum flexibility.

- **Heated, Non-Recirculated Final Rinse.** Pure water or WFI rinse treatment can be programmed to spray the load with non-recirculated, heated water. The water is supplied from a stainless-steel cylindrical storage tank mounted to the side of the unit. The tank is equipped with a level control sensor, automatic fill, sanitary check valve, stainless-steel coil for steam heating, temperature transmitter, steam valve, and steam trap. Unit is

equipped with a hydrophobic filter and a #316L stainless-steel vacuum switch on the non-recirculated final rinse tank option. During a final rinse treatment, the air entering into the tank that replaces the water sprayed on the load is filtered through a **hydrophobic filter.** A **vacuum switch** installed on the tank stops the treatment if the vacuum becomes too high, and an alarm message is displayed on the operating control. The cartridge/filter housing connection and the vacuum switch have 1-1/2" (38 mm) tri-clamp fittings.

- **Load Draining System** includes a 316 stainless-steel sanitary pump that can be connected to the drain outlet of a vessel (load) to accelerate its draining, verifies efficient coverage, and reduces cycle time.
- **Diaphragm Water Inlet Valves** (maximum of three) for connection to the inlet ports provided on the top of the washer.
- **Instrumentation Tags, Customer Assigned Numbers** (stainless-steel tag identification numbers for instrumentation) are provided by the customer.
- **Extended Manufacturing Documentation.** A binder and CD include the following additional manufacturing information:
  - Recirculation and Steam Supply Piping Schematic
  - Heat Number Certificates
  - Material Certificates
  - Surface Finish Report for Chamber
  - Instrument Index and ISA Data Sheets
  - Welding Procedure Specifications (WPS)*
  - Procedures Qualification Report (PQR)*
  - Welding Map Drawings*
  - Welding Logs*

* *Welding documentation is provided for the chamber, process piping, and final rinse tank.*

- **Extended Control System Validation Documentation.** A binder and CD include the following additional information on the control system and software:
  - Software History
  - Hardware Configuration
  - Software Specifications
  - Software Validation
  - Testing of Software Parameters (includes I/O Testing, Cycle Description, Security System Features, and Specifications)
- **Cleaning and Passivation Treatment.** A phosphoric acid solution removes any ferris contamination from the surfaces, providing a better corrosion resistant surface. The solution also passivates the entire recirculation, chamber, sump, and final rinse system.
- **Coverage Test** is performed on customer provided or representative components, using Riboflavin soil and ultraviolet light as an inspection method.

CONSTRUCTION

Mechanical Construction

Mechanical construction consists of the pneumatic, instrumentation, pump, piping, spraying, and frame systems. Washer is designed and built as a free standing, pit mounted unit with the pump and piping systems separate from the cabinet assembly, with single point utility connections. All components of the wash/rinse system, including debris screens, moving spray arms, piping, and valves are constructed of 316L stainless steel.

- **Wash Chamber** construction is sanitary. All interior surfaces are manufactured from 316L stainless steel with a continuous argon weld. The interior surface is polished to a 25-35 micro-inch (0.6-0.9 micrometer) Ra. Welding process meets GTAW standards. All wetted parts welds are 100% penetration welded, using argon shielding gas. Chamber is insulated with 1.0" (25.4) thick fiberglass insulation with a vapor barrier covering top, sides, and bottom to minimize noise and heat loss. The bottom is equipped with a 316L stainless-steel debris screen to prevent large debris from entering the piping system and pump. Screen is easily removable for cleaning. A 32-watt fluorescent light enclosed in the ceiling of the wash chamber is provided to illuminate the interior for visual coverage verification.
- **Pneumatic System** is designed to distribute compressed air to the various pneumatic devices. The air piping system is equipped with a pressure regulator, pressure indicator, and pressure switch, pneumatic ON/OFF solenoid control valves, and polyethylene tubing for air distribution to the solenoids.
- **Piping.** The washer is interpiped and interwired to require only one connection for each service utility. Piping and tubing are designed and constructed of 316L stainless steel, sanitary, interior 25 micro-inch (0.6 micrometer) Ra, exterior 35 micro-inch (0.9 micrometer) Ra; tri-clamp with silicon gaskets, ASTM A269 or A270, GTAW. Steam piping is constructed of brass, NPT or BSPT fittings. A sanitary sensor is fitted in the lowest point of the piping system to verify all that piping is fully drained.
- **Circulation System.** All components of the wash/rinse system, including debris screens, moving spray arms, piping, and valves are constructed of 316L stainless steel.
- **Pumps** include magnetic starter, overload protection, and double sealed bearings (not requiring lubrication). All pump motors are the high efficiency washdown type with TEFC enclosure. Each pump is installed for complete drainability.
  - 15 HP (11.2 kW) recirculation pump, sanitary wetted parts (impeller, shaft, and casing) are built with 316L stainless steel with interior surface 25 micro-inch (0.6 micro-meter) Ra; rated at 42 gal/min. at 238'-7" of head pressure (159 L/min. at 73 m).
  - 10 HP (7.5 kW) suction pump, sanitary wetted parts (impeller, shaft, and casing) are built with 316L stainless steel with interior surface 25 micro-inch (0.6 micrometer) Ra; rated at 100 gal/min, at 75' of head pressure (379 L/min at 23 m).
  - 7.5 HP (5.6 kW) load draining pump (optional), sanitary wetted parts (impeller, shaft, and casing) are built with 316L stainless steel

with interior surface 25 micro-inch (0.6 micro-meter) Ra; rated at 90 gal/min, at 35' of head pressure (341 L/min at 11 m).

- **Spray System.** Sanitary horizontal spray headers (built with 316L stainless steel and Teflon) alternate movement in a vertical direction to eliminate competing spray action within the chamber. A tubular, non-threaded design with removable end piece allows for complete and easy cleaing. Sensors monitoring the movement of the rodless pneumatic cylinder assure that if the spray headers stop functioning, an alarm is triggered, and the cycle is interrupted.

ACCESSORIES

Service side enclosure panels. Stainless-steel side panels and supports are supplied to enclose the mechanical core. The enclosure is designed to be easily cleaned, and to give access to the mechanical core components.

Barrier wall flanges include two stainless-steel flanges, and one top flange. Once installed, these assure proper seal between the unit, wall, and ceiling.

Compressor is complete with tank and pressure switch. Oil-less compressor operates at 50 dB (A). Wiring at installation not provided by STERIS.

Manifolded loading cart (heavy duty stainless-steel cart) is designed to support vessels, containers, and miscellaneous components during the wash procedure.

- Support for lids (316L stainless-steel support) is provided to hold tank covers and lids in place.
- Spray ball for manifolded loading cart can be installed on the loading cart to accommodate vessels with large openings, and verify complete coverage.

Spray ball accessory (stainless-steel) can be used to clean the interior of containers and vessels when connected to the interior manifold coupling system.

Exterior stainless-steel jacket package (304L stainless-steel panels) are provided to cover insulation on service and non service sides.

PREVENTIVE MAINTENANCE

A global network of skilled service specialists can provide periodic inspections and adjustments to help ensure low-cost peak performance. STERIS representatives can provide information regarding annual maintenance agreements.

NOTES

1. Unit is delivered in three crates, ready for installation.

   The first crate contains the chamber. Dimensions (L x W x H): 100-1/2" x 83" x 104" (2553 x 2108 x 2642 mm); 3150 lbs (1429 kg).

   The second crate contains the mechanical core. Dimensions (L x W x H): 96" x 48" x 102-1/2" (2438 x 1219 x 2604 mm); 3050 lbs (1384 kg).

   The third crate contains the rest of the components. Dimensions (L x W x H): 96" x 48" x 54-1/2" (2438 x 1219 x 1384 mm); 900 lbs (408 kg).

   All open pipe connections or pipes are plugged with caps to prevent the possibility of contamination.
2. Customer must assure the machine stands on a non-combustible floor.
3. STERIS recommends that shut off valves and vacuum breakers (not provided by STERIS) be installed on service lines, and that disconnect switches (with lockout in OFF position [not provided by STERIS]) be installed in electric supply lines near the equipment.
4. Pipe sizes shown indicate terminal outlets only. Building service lines, not provided by STERIS, must supply the specified pressures and flow rates.
5. Construction of the exhaust duct system from stainless steel is recommended. Seal the joints by welding to assure a corrosion resistant and leakproof system for removal of condensed vapor. The duct should have drip leg(s) installed at any low point(s).
6. Condensate to be connected to a non-pressurized gravity return main or vented condensate receiver. Add 1/2 psi (3.45 kPa) for each 12" (305 mm) of condensate head pressure to the minimum dynamic steam pressure. Maximum rise not to exceed a total of 15' (4.57 m) head.
7. STERIS recommends illumination of the service area (If applicable), along with provision of a convenience outlet for maintenance.
8. A 4" (102 mm) O.D. floor drain is recommended with the floor sink.

STERIS Corporation, Quebec, Canada is an ISO 9001 and ISO 13485 certified facility.

The base language of this document is ENGLISH. Any translations must be made from the base language document.

Table 1-1. Engineering Data

Shipping Weight (maximum)		Operating Weight		Water Consumption per Fill*	Noise Level** (enclosed)	Heat Loss
Chamber	Mechanical Core	Washer	Mechanical Core	Main Tank (Recirculated): 40 U.S. gal (151.4 L)	78.1 dBa	12,000 BTU/h (3540 W)
3150 lb (1429 kg)	3050 lb (1384 kg)	3750 lb (1134 kg)	2500 lb (1134 kg)	Final Rinse Tank: 37 U.S. GAL (140 L)		

** Total consumption per cycle is dependent on the number of treatments selected for each cycle.*
*** Calculated as described in ISO-3746 standard.*

UTILITY REQUIREMENTS

Cold Water[1] (15)

1" NPT or 1" BSPT. Flow rate: max. 70°F - 39 U.S. GPM (21°C - 148 L/min); min. 40°F - 27.4 U.S. GPM (4°C - 104 L/min.).

Main Recirculation Tank - Port 1 (13A) and Port 2 (13 B)

Tri-clamp 1". Dynamic pressure: 5-20 psig (0.3 - 1.4 bar). Max. static pressure: 80 psig (5.5 bar). Flow rate: 10-30 GPM (37.8 - 113.5 L/min).

Final Rinse Tank - Port 3 (14) (Option)

Tri-clamp 1". Dynamic pressure: 5-20 psig (0.3 - 1.4 bar). Max. static pressure: 80 psig (5.5 bar). Flow rate: 10-25 GPM (37.8 - 94.6 L/min.).

Building Plant Steam (40)

1-1/2" NPT or 1-1/2" BSPT; 15-50 psig (3.5 - 5.5 bar) dynamic; Max. static pressure 120 psig

(8.3 bar). Average flow rate:300 lbs/hr at 50 psig (135 kg/hr at

3.4 bar). Peak flow rate: 1250 lbs/hr(570 kg/hr). Steam quality: clean and dry.

Condensate Return (46)

1" NPT or 1" BSPT. Peak Flow rate: 10 U.S. GPM (37.85 L/min).

Air[2] (51)

1/2" NPT or 1/2" BSPT. 90-125 psig (6.2 - 8.6 bar). Max. particle size: 5.0 micron; max. particle density: 4.15 ppm (5 mg/cubic meters);Max. dew point for water content: 37 to 45°F (3-7°C), as per ISO-8573-1.

Drain[3] (60)

4" OD (102 mm). Flow rate: 90 U.S. GPM (409 L/min).

Vent (86)

Fan outlet, 6" O.D. Flow rate; 750 scfm (21.2 cubic meters/min).

Electricity[4] (90)

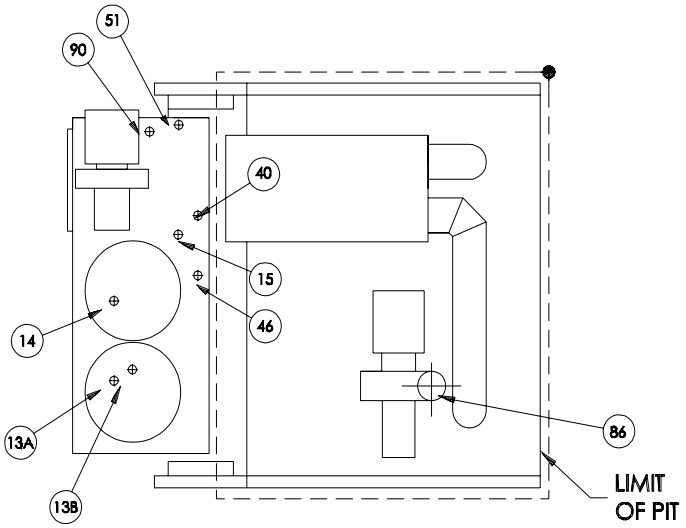
460/480 V, 60 Hz, 3-Phase, 3-wire, 29.5 Ampsor 380/400/415 V 50 Hz, 3-Phase, 3-wire (neutral not required), 28 Amps.

1. Only necessary where local regulations requires drain cool down system.
2. Clean, dry, oil-free instrument air is required.
3. Floor drain is recommended with floor sink.
4. Variance not to exceed 10% of the suppy voltage.

CUSTOMER IS RESPONSIBLE FOR COMPLIANCE WITH APPLICABLE LOCAL AND NATIONAL CODES AND REGULATIONS.

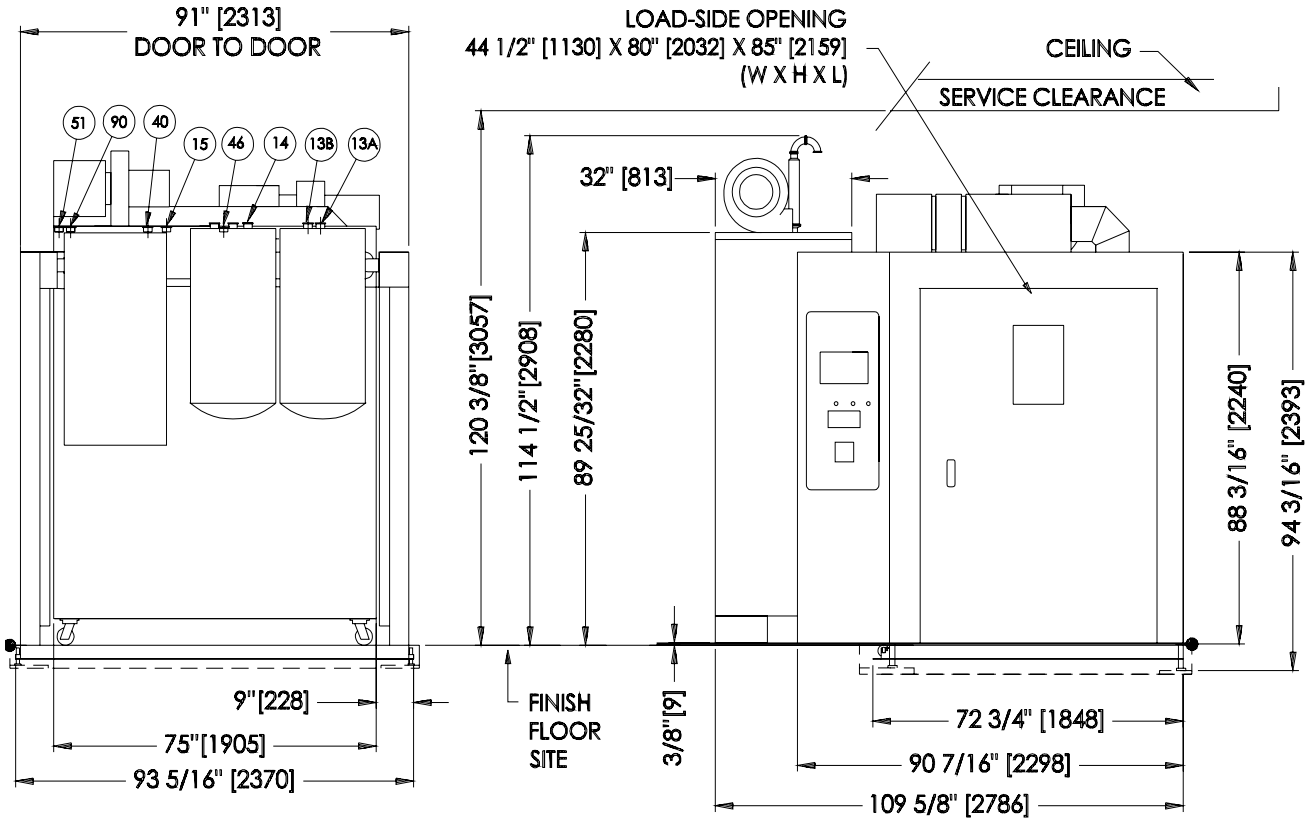
Dimensions shown here are typical, and subject to change without notice.
REFER TO STERIS EQUIPMENT DRAWINGS FOR COMPLETE AND DETAILED INSTALLATION SPECIFICATIONS.

Left Hand Control



TOP VIEW

Dimensions are inches (mm)

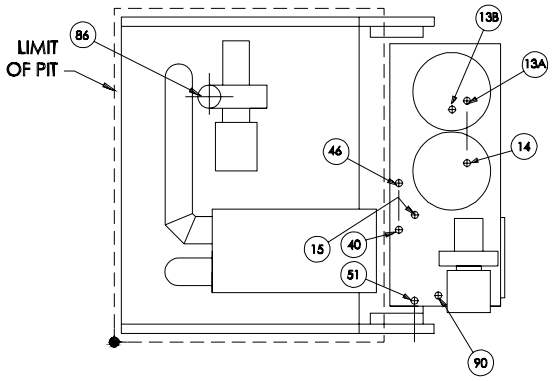


SIDE VIEW

FRONT VIEW

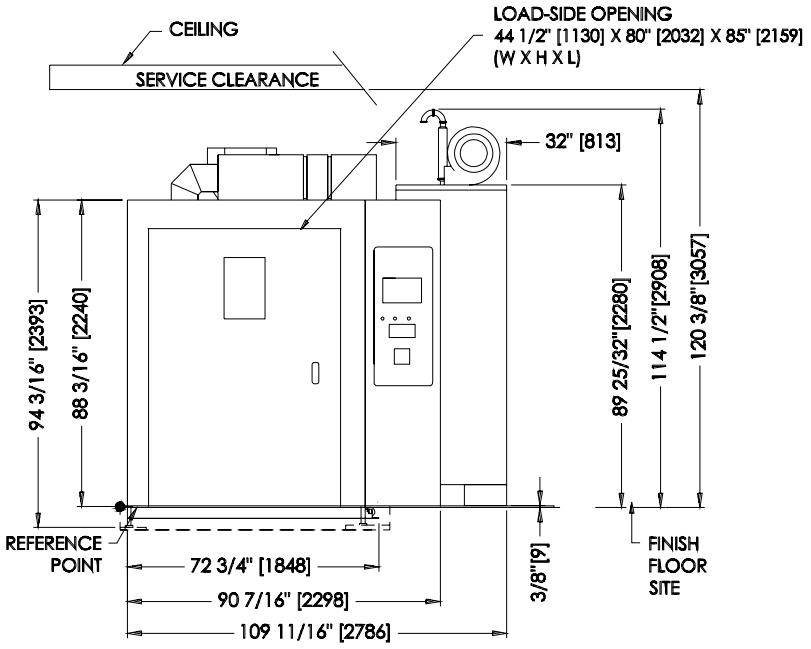
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REFER TO STERIS EQUIPMENT DRAWINGS FOR COMPLETE AND DETAILED INSTALLATION SPECIFICATIONS.

Right Hand Control

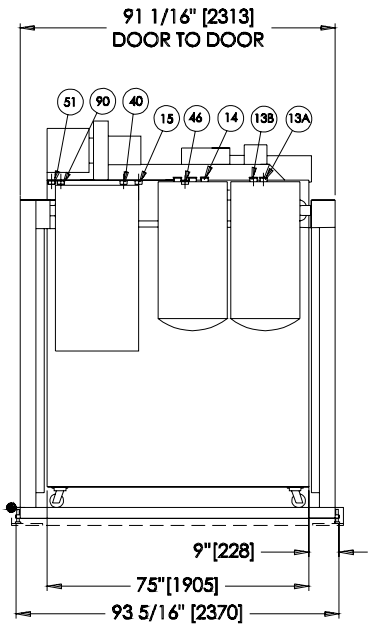


TOP VIEW

Dimensions are inches (mm)



FRONT VIEW



SIDE VIEW

For Further Information, contact:

STERIS®

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834 • USA
440-354-2600 • 800-548-4873
www.steris.com

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