

**APPLICATION**

The Reliance 580 Pharmaceutical Grade Washer is intended for thorough, efficient cleaning of various materials and components utilized in the biotechnology and pharmaceutical manufacturing process industries, such as glassware, vessels, filling line components, and exchange parts.

**DESCRIPTION**

The Reliance 580 Pharmaceutical Grade Washer is a cabinet-type washer, equipped with a programmable logic controller system. It simultaneously accepts up to three mixed loads of various sizes and shapes, increasing productivity.

The washer is designed, manufactured, validated, and documented according to the latest global practices and standards to facilitate customer compliance with current Good Manufacturing Practices (cGMP's).

The washer is equipped with eleven adjustable cycles, three of which are preprogrammed (light, medium, and heavy).

**Size (W x H x L)**

**Chamber load capacity:**

36 x 30 x 24"  
 (914 x 762 x 610 mm)



Typical only - some details may vary.

**Overall dimensions:**

- 63-3/8 x 91 x 30"  
 (1610 x 2311 x 762 mm)

**Loading height:**

- 36-3/8" (923 mm) from floor

**STANDARDS**

Washer meets the applicable requirements of the following standards:

**Current Good Manufacturing Practices (cGMP), CFR Title 21, Part 211, Section D.**

- **Underwriters Laboratory (UL):** Standard 61010A-1 as certified by UL.
- **Uniform Building Code of California, Title 24** (Seismic anchoring requirements).
- **Governing Directive for Affixing of the CE Mark:** Machinery Directive (98/37/EC).

**The Selections Checked Below Apply To This Equipment**

**CONTROL**

- Allen-Bradley®
- Siemens

**VOLTAGE**

- 480 V, 3-Phase, 60 Hz
- 380/400/415 V, 3-Phase, 50 Hz

**DOOR TYPE**

- Single
- Double

**ACCESSORIES**

See SD645.

**OPTIONS**

- Additional Factory Acceptance Test
  - Coverage Test
  - Cleaning and Rinsing Tests
- Cleaning and Passivation Treatment
- Third Chemical Injection Pump (std. 2)
- Inlet Valve for Final Rinse Tank
- Inlet Valve 1" (maximum 2), #316 L Stainless-Steel Diaphragm
- Non-Recirculated Final Rinse (Steam Heated)
- Chamber Cool Down System
- Top Mounted Utility System
- Condensate Return to Drain
- Back Panel for Single Door Unit
- Flange Connection on Steam Inlet/Outlet
- Stainless-Steel Tags for Instrumentation with Customer Assigned Numbers

- Validation Documentation – Additional Copies
- Vapor Removal Fan
- Extended Manufacturing Documentation
- Extended Control System Validation Documentation

Item \_\_\_\_\_

Location(s) \_\_\_\_\_

- **Governing Directive for affixing of the CE Mark:** Machinery Directive (98/37/EC).
- **Conformity to Other Applicable Directives:** Electromagnetic Compatibility Directive 89/336/EEC amended by Directive 91/263/EEC, Directive 92/31/EEC, and Directive 93/68/EEC.
- Low Voltage Directive 73/23/EEC amended by Directive 93/68/EEC.
- **Standards applied to demonstrate conformity to the directives:**  
EN/IEC-61010-1, and  
EN-IEC-61326.

## FEATURES

**Control** (single or double door) is a programmable logic controller system provided with operating interfaces, impact printer, filter, fuses, and all required hardware. Memory can contain up to 11 processing cycles (programmable according to customer preferences). Cycle phase times, temperatures, and other key process parameters are also programmable. Once a cycle is started, the programmed cycle values are locked and cannot be changed until the cycle is complete.

Two standard programmable logic controllers are available:

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

**Automatic damper** is pneumatically operated to control vapor exhaust from the unit, for enhanced temperature control and vapor removal. The damper controls pressure during exhaust removal.

**Two sump inlet ports** are provided on standard units.

**Automatic single door/automatic double doors** operate(s) by pneumatic cylinder(s) using touch pads on the control panel. The door interlock system permits only one door to be opened at a time. During a cycle, neither door can be opened without first pressing STOP on the touch pad. Each door is insulated, provided with a safety switch, and an obstruction sensor.

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

**Pump outlet pressure transmitter** at the recirculation pump outlet monitors pressure and eases validation of the cleaning process. The product surface is #316L stainless steel with a surface finish of 20 microinch as (0.5 µm) Ra.

**Sampling valve** body is made of #316 stainless steel and is installed on the sump. The O-ring/seal is made of ethylene-propylene-diene rubber (EPDM). The outlet port is a hose barb type.

**Dual spray system** includes three automatic manifold connectors at the bottom of the chamber that automatically connect to a combination of accessory spindle headers that can be used with a single load. Sanitary rotary spray arms are positioned on top of the wash chamber to ensure total coverage and even spray pressure on all surfaces of items being washed.

**Service panels** on the front and on one side of the washer provide access to all components, including piping, valves, electrical components, and wiring.

**Detergent injection pumps** (two peristaltic pumps) can accommodate various chemicals. Pumps are provided with foot valves, low level sensors, and pickup tubes. Chemical containers are stored outside the unit up to 50' away (15 m).

**Process observation window** in the chamber door and an interior light allows operator to ensure the spray arms are rotating and the accessory spindles are not blocked.

**Removable stainless-steel debris filters**, located in bottom of wash chamber (sump), prevent large debris from entering the piping system and pump. Perforated stainless-steel filters prevent clogging of spray nozzles. All filters are easily removed for cleaning.

**Spare parts kit** containing spare parts that may be required for start-up are included as standard.

**Drain Discharge Cool Down** is provided on the unit with cold water connection for effluent cool down. Cold water is automatically mixed with effluent to cool down from 180°F (82°C) to at least 140°F (60°C) while being discharged to building drain system. This feature can be disabled in the control system.

**HEPA-filtered drying system** is provided to dry both inner and outer sur-

faces of washed items. The system includes a 2.5 HP (1.8 Kw) blower and electric heaters. The drying phase is programmable from 0 to 99 minutes, at a temperature adjustable from 32°F (0°C) to 204°F (96°C). Typical drying time: 15 minutes.

**Conductivity validation system** is provided with conductivity probes and control to measure conductivity of wash solution and final rinse water during a cycle. This control monitors the conductivity level and injects detergent to achieve the wash solution setpoint and controls the number of rinses to achieve the final rinse water setpoint.

**Factory Acceptance Testing (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 study (PACE), if it applies.

**Stainless-steel tag** (for instrumentation) is attached to each instrument with a chain. Identification numbers are assigned by the factory.

**Validation documentation** (also on CD) is provided with one copy of the following documentation binders:

- **User's Manual** including:
  - » Uncrating/Installation Instructions
  - » Operator and Maintenance Manual, including equipment drawings, piping and instrumentation drawings (PI&D), and recommended spare parts, electrical schematics, layout drawings, and cut sheets for PI&D items.
- **Manufacturing and Qualification Documentation** including:
  - » Calibration Procedures -Seismic Anchorage Report
  - » Factory Acceptance Test Procedure and Report (FAT)
  - » HEPA Filter Certificate (if option applies)
  - » All steam piping made with 316 stainless steel
  - » Cleaning and Passivation Procedure and Report (if option applies)

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

\* Also supplied on disk.

## SAFETY FEATURES

**Safety door switch** prevents a cycle from starting if door is not fully closed, and also stops washer operation if a door is opened during a cycle.

**Control ON/OFF selector switch** inside the control box can be used to turn off the 110 V power for servicing the unit.

**Power disconnect switch** has a lockable, 3-phase non-fused disconnect switch located on the cover of the main electrical box.

**Pressure switch** mounted on the air supply line will shut off the unit if air pressure drops below operating level.

**Emergency stop button(s)** is (are) supplied at the load end (and unload end if it applies) to de-energize all outputs to safe position when pressed in case of emergency.

## CYCLE DESCRIPTION

Reliance 580 Pharmaceutical Grade Washer features 11 programmable cycles. Possible standard treatments include: one to five pre-wash, one to five wash, one to five rinse, and one to nine final rinse treatments. Once cycle is selected, washer automatically processes load through the programmed treatments.

Washer is programmed with three factory-set processing cycles: LIGHT, MEDIUM, and HEAVY. All three factory-set cycles can be modified by the operator to include the following treatments:

- **PRE-WASH:** Sump is filled with selected water. Solution is recirculated under pump pressure for preset time. On completion of treatment, water is sent to drain.
- **WASH:** Sump is filled with selected water and chemical (if selected) is injected. Solution is heated and recir-

culated under pump pressure for preset time. On completion of treatment, water is sent to drain.

- **RINSE:** Sump is filled with selected water. Solution is heated and recirculated under pump pressure for preset time. On completion of treatment, water is sent to drain.
- **RECIRCULATED FINAL RINSE:** Sump is filled with selected water. Pure water or WFI is heated and recirculated under pump pressure for preset time. On completion of treatment, water is sent to drain.
- **NON-RECIRCULATED FINAL RINSE** (if option applies): Pure heated water or WFI from optional feed tank is sprayed under pump pressure, on a once-through basis, for preset time. On completion of treatment, water is sent to drain.

## OPTIONAL FEATURES

### Additional Factory Acceptance Tests.

In addition to the Basic Factory Acceptance Testing, the following tests can be performed:

- **Chamber Cool Down Sequence:** After the final rinse, cycle can be programmed to circulate fresh filtered air in the chamber until selected set point is reached (range: ambient-100°C [ambient-212°F]).
- **Coverage Test:** A coverage test is performed on customer provided or representative components, using Riboflavin soil and ultraviolet light as an inspection method.
- **Cleaning and Rinsing Tests:** These tests can be performed with customer provided soil and components, using the cycle parameters recommended by the Process And Cleaner Evaluation study (PACE), if it applies. Cleaning efficacy will be evaluated using gravimetric, visual, or water break free methods (ASTM F22-65). Rinsing efficacy will be evaluated using the conductivity method.
- **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 recircula-

tion, chamber, sump, and final rinse system.

### Additional detergent injection pumps.

A third peristaltic pump is provided with a low level sensor and a pick-up tube.

**Inlet valve for final rinse tank.** A 1" (25 mm) sanitary #316L SS diaphragm valve, spring-to-close, polytetrafluoroethylene (PTFE) diaphragm, 20 micro-inch (0.5 µm) as Ra.

**Inlet valves.** Standard unit has no inlet valves. Pilot valves are supplied as standard. Optional sanitary diaphragm valves may be connected to the inlet ports on top of the unit.

**Top mounted utility connections.** Connection points for cold water, steam, and condensate return are relocated on the top of the washer.

**Non-recirculated final rinse (steam heated).** Pure water or WFI rinse treatment can be programmed to spray load with non-recirculated, heated water. The water is supplied from a sanitary stainless-steel storage tank mounted on the side of unit, concealed by the cabinet panels. Tank is equipped with a level control sensor, automatic fill, overflow with sanitary check valve, stainless-steel coil for steam heating, temperature transmitter, steam valve, and trap. During a final rinse treatment, the air entering the tank replacing the water sprayed on the load and 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. The final rinse tank can be dried at the end of the cycle or the end of the day to prevent microbial contamination (range of time: 00:00 - 99:59 min.).

**Non-vented system.** Vapor can be exhausted through a condenser to the room, eliminating the need to vent the unit.

**Back panel for single door unit.** The back of single door units can be fitted with a stainless-steel 304 panel.

**Condensate return to drain.** The condensate return outlet is internally connected to the drain outlet of the washer.

Condensate is mixed with cold water prior to being discharged.

**Stainless-steel tags for instrumentation.** Stainless-steel tag identification numbers for instrumentation are provided by the customer.

**Validation documentation.** Additional copies of each validation binder can be supplied.

**Vapor removal fan.** A vapor removal fan can be included to remove vapor from the chamber during the cycle.

**Extended manufacturing documentation.** Binder (and CD) includes the following additional manufacturing information:

- Instrumentation and Heat Number Map
- Piping Assembly
- Heat Number Certificates
- Material Certificates
- Surface Finish Report for Chamber
- ISA Data Sheets
- Instrument List
- Loop Diagrams
- 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.** Binder (and CD) includes 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)

**Flange connection on steam.** NPT or BSPT connections are replaced by bolted flanges.

## CONSTRUCTION

The wash chamber is constructed of #316L stainless steel. Both water inlets

on the top prevent water backflow at interconnection points.

The chamber is insulated with 1" (25 mm) thick fiberglass insulation with a vapor barrier covering top, sides and bottom of chamber to minimize noise and heat loss. Surface finish is 20 microinch (0.5 µm) Ra.

All components of the wash/rinse system, including debris screens, rotary spray arms, piping and valves, are constructed of #316L stainless steel (including steam piping).

The sump capacity for the washer is 16.55 gal (62.7 liters). A sanitary designed heating coil in the bottom of the sump raises and maintains water temperature up to 180°F (82°C) during wash and rinse phases. The sump is constructed with an automatic solution level control, automatic water fill and safety overflow piping.

All sump components are constructed of #316L stainless steel. All treatments are under pressure of a 5 HP (3.7 Kw) stainless steel sanitary recirculating pump with 108 U.S. gal/min.

Diaphragm valves are used on the recirculation and drain piping. With an interior finish of 20 microinch (0.5 µm) as Ra, the diaphragm is in PTFE. Valves are installed at an angle to allow complete drainability.

Pump impeller, shaft, and casing are fitted with a mechanical seal. Pump motor is equipped with totally enclosed frame, magnetic starter, overload protection, fuse protection, and double sealed bearings, requiring no periodic lubrication.

The washer frame, cabinet, and all fasteners are constructed of #304 stainless steel. Levelling legs are included to facilitate installation.

An internal battery backs up all cycle memory for a minimum of two years. Electrical dry contacts are provided to transmit alarm conditions to external monitoring system.

Temperature transmitters sense temperature inside the wash chamber and optional final rinse tank and provide accurate control inputs and readouts throughout all cycles.

Washer is interpipied and interwired, requiring only one connection for each

service and utility hook-up. All equipment information is engraved on a #304 stainless-steel nameplate.

All accessories are constructed of #316L stainless steel. They are designed for sanitary applications and are completely drainable.

## ACCESSORIES

Refer to SD645.

## 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. Customer must ensure machine stands on non-combustible floor.
2. Shut-off valves, vacuum breakers, and fused disconnect switch (not provided by STERIS) should be installed on utility lines as required on the equipment.
3. Pipe sizes shown indicate terminal outlet only.
4. Connections should be in accordance with local codes.
5. Unit crate size is (W x H x L) 40 x 97 x 70" (1010 x 2460 x 1770 mm).
6. Construction of the exhaust duct system from stainless steel is recommended. Seal the joints by welding to assure a corrosion resistant and leak-proof system for removal of condensed vapor. The duct should have drip leg(s) installed at any low point(s).
7. 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.
8. A 4" (102 mm) O.D. floor drain is recommended with floor sink.
9. All values are based on LIGHT cycle, with an incoming water temperature of 70°F (21°C).

## UTILITY REQUIREMENTS

### Cold Water (15)

1/2" NPT or BSPT, 40-50 psig (276-345 kPa); 70°F (21°C) max.; 8.0-9.0 U.S. gal/min (30-34 L/min).

#### If non-vented option is selected (11-13):

U.S. gal/min (42-49 L/min).

### Sump Water Inlet (Port 1) (13a)

1" (25 mm) Tri-Clamp; 35-50 psig (241-345 kPa); 15-25 U.S. gal/min (57-95 L/min).

### Sump Water Inlet (Port 2) (13b)

1" (25 mm) Tri-Clamp; 35-50 psig (241-345 kPa); 15-25 U.S. gal/min (57-95 L/min).

### Final Rinse Tank (Port 3) (14)

#### (if option applies) –

1" (25 mm) Tri-Clamp; 35-50 psig (241-345 kPa); 15-25 U.S. gal/min (57-95 L/min).

### Steam (40)

1/2" (13 mm) NPT or BSPT; 30-50 psig (206-345 kPa). Peak flow rate: 250 lbs/hr (113 kg/h).

*NOTE: NPT connection replaced by flange connection if option applies.*

### Condensate Return (46)

1/2" (13 mm) NPT or BSPT

*NOTE: NPT connection replaced by flange connection if option applies.*

### Air (51)

1/2" (13 mm) NPT or BSPT; 80-125 psig (552-860 kPa). Peak flow rate: 15 scfm (0.4 m<sup>3</sup>/min).

### Vent (86)

6" (152 mm) diameter vent connection; 75 scfm, 3/4" (19 mm) W.C. of negative static pressure (not required if non-vented system option is selected).

3" (76 mm) diameter vent connection (if vapor removal fan option is selected; not required if non-vented system option is selected).

### Drain (60)

2" (51 mm) Tri-Clamp; 4" (102 mm) O.D. floor drain is recommended with-floor sink.

### Electricity (90)

480 V, 60 Hz, 3-Phase, 9.2 Amps (7.1 kW).

380/400/415 V, 3-Phase, 50 Hz, 4 wires (neutral required) 9.5 Amps (5.6 Kw)

**Table 1-1. Engineering Data**

|   |  |
|---|--|
| Shipping Weight   | 1460 lb (662 kg)                                 |
| Operating Weight  | 1692 lb (767 kg)                                 |
| A-weighted Equivalent:<br>Surface Sound<br>Pressure Level                                 | 74.5 dB  |
| Max. Water Consumption:<br>per Recirculated Treatment*<br>per Non-recirculated Treatment* | 16.55 U.S. gal (62.7 L)<br>16.90 U.S. gal (64 L) |
| Heat Loss (at 75°F [24°C],<br>40% R.H. ambient)   | 7000 Btu/h (7385 kJ/h), sensible                 |
| Max. Steam Consumption:<br>per Heated Treatment*  | 23 lb (10.5 kg)                                  |

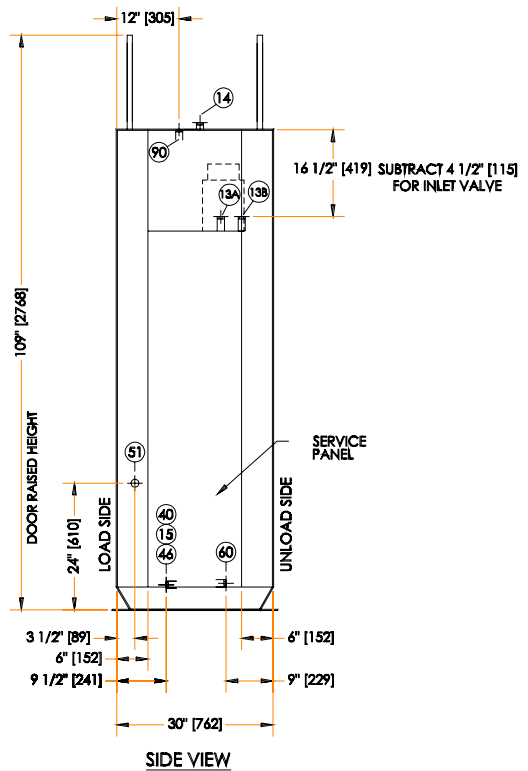
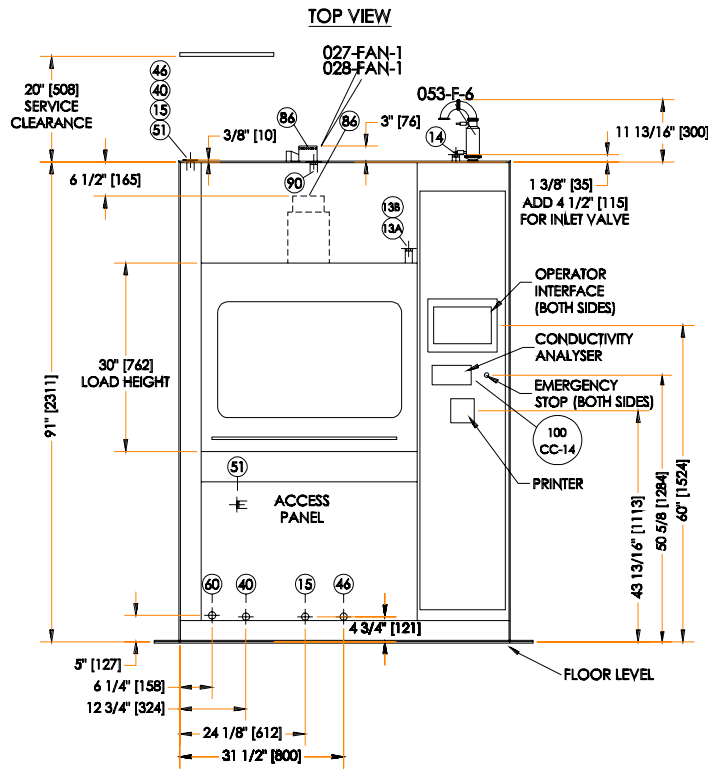
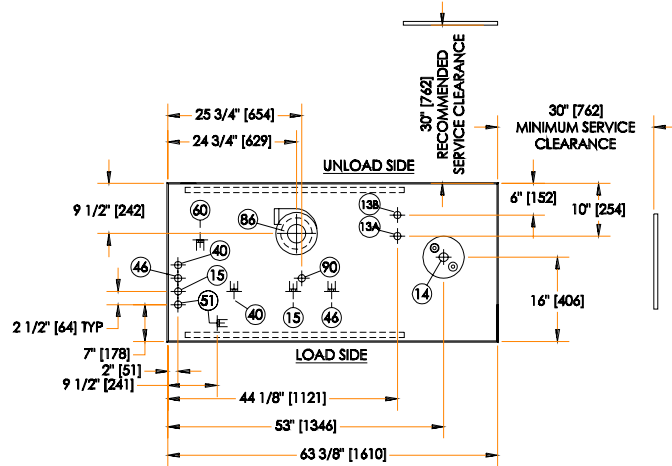
\* Total consumption per cycle is dependent on the number of treatments selected for each cycle and if drain discharge cooldown is activated.

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base language document.**

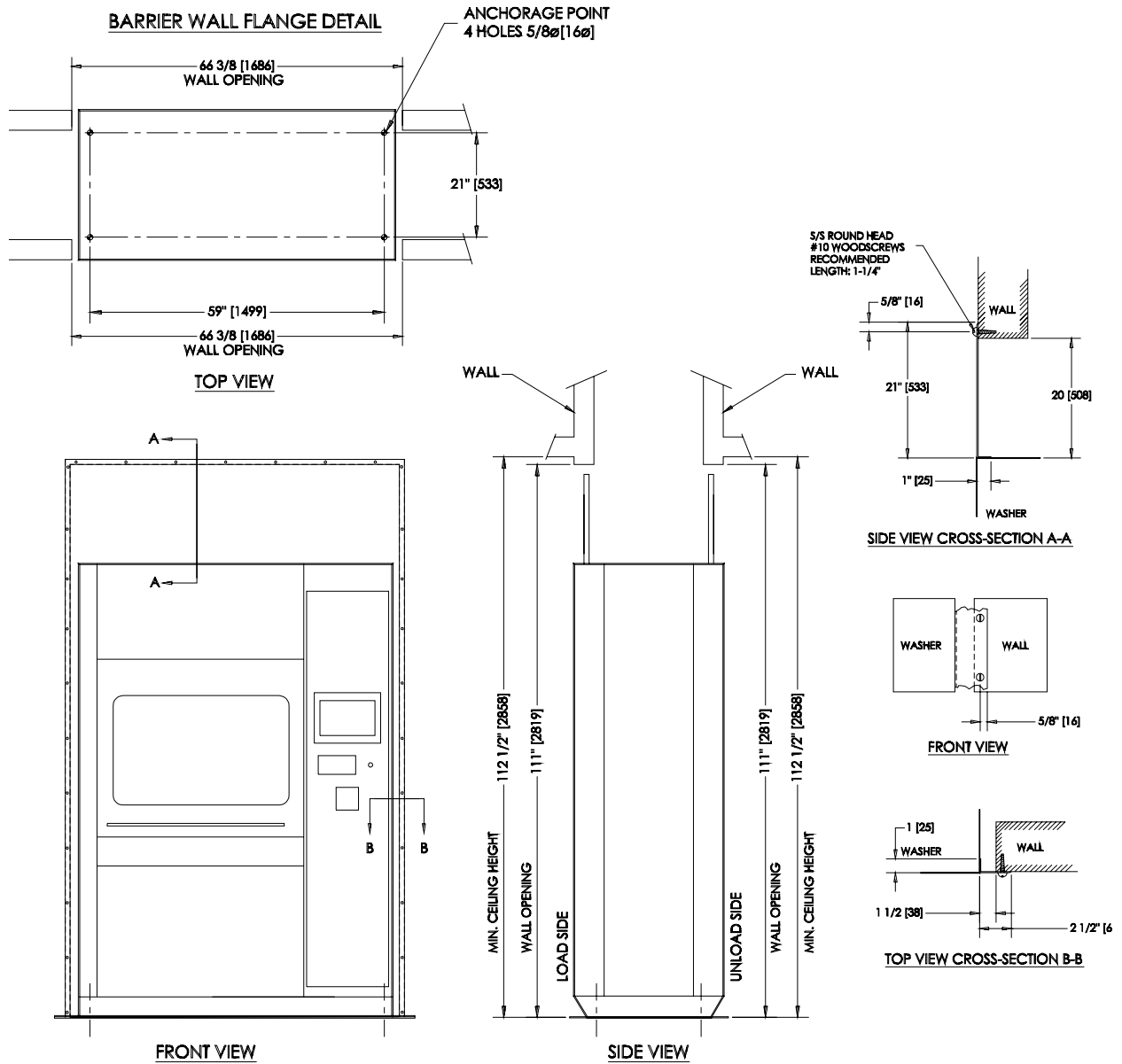
**Dimensions shown here are typical, and subject to change without notice.  
REFER TO STERIS EQUIPMENT DRAWINGS FOR  
COMPLETE AND DETAILED INSTALLATION SPECIFICATIONS.**

Dimensions are inches (mm)



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