STERIS®

RELIANCE® 680 PHARMACEUTICAL GRADE WASHER

APPLICATION

The Reliance 680 Pharmaceutical Grade Washer is designed 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 680 Pharmaceutical Grade Washer is a cabinet-type washer equipped with a programmable logic controller system.

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).



Typical only - some details may vary.

Size (W x H x L)

- Chamber load capacity:
  49-3/4 x 37-3/4 x 50-1/2"
  (1263 x 958 x 1283 mm)
- Overall dimensions:
  79-1/2 x 87 x 57"
  (2019 x 2210 x 1448 mm)
- Loading height:
  25-1/2" (647 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 Laboratories (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

SERVICE SIDE
(facing load side)
- ☐ Right
- ☐ Left

DOOR TYPE
- ☐ Single
- ☐ Double

ACCESSORIES†
See SD645

OPTIONS
- ☐ Additional Factory Acceptance Tests:
  - ☐ Coverage Test
  - ☐ Cleaning and Rinsing Tests
- ☐ Cleaning and Passivation
- ☐ 3rd Chemical Injection Pump (std.2)
- ☐ HEPA Filter on Chamber Intake
- ☐ Inlet Diaphragm Valve for Final Rinse Tank
- ☐ Inlet Diaphragm Valve (max.2) 1", #316 L Stainless Steel
- ☐ Non-Recirculated Final Rinse (Steam Heated)
- ☐ Stainless-Steel Cabinet Enclosure Panels
  - ☐ Single Door, Right Service Side
  - ☐ Single Door, Left Service Side
  - ☐ Double Doors
- ☐ Condensate Return to Drain System
- ☐ Flange Connection on Steam Inlet/Outlet
- ☐ Stainless-Steel Tags for Instrumentation with Customer Assigned Numbers
- ☐ Validation Documentation – Additional Copies
- ☐ Extended Manufacturing Documentation
- ☐ Extended Control System Validation Documentation

Item _____

Location(s)_____

_____

- **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 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 in 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.

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

Spray System includes an automatic manifold connector at the bottom of the chamber that automatically couples to the accessory header, allowing connection of accessories. Sanitary rotary spray arms are positioned on the top and sides of the wash chamber and under accessory headers to ensure total coverage and even spray pressure on all surfaces of items being washed.

Drop Down Door (single or double) is insulated, airtight, and watertight, to ensure process integrity. Double door configuration includes door interlock feature and remote control panel on non-operating end.

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

Process Observation Window in the chamber door and an interior light allows the operator to verify the spray arms are rotating and the accessory spindles are not blocked.

Removable Stainless-Steel Debris Filter, located in bottom of wash chamber (sump), prevents large debris from entering the piping system and pump. Perforated stainless-steel filter prevents clogging of the spray nozzles. Filter can easily be removed for cleaning.

Drain Discharge Cool Down is provided on the unit, with cold water connection for effluent cool down. 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 building drain system. This feature can be disabled in the control system.

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

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 (0.5µm) as Ra.

Sampling Valve body is made of #316 stainless steel and is installed on the sump. The O-Ring/Seal is made of EPDM.

HEPA-Filtered Drying System (two units) is supplied: non-recirculated, and recirculated. The drying phase is programmable from 0 to 99 minutes at a temperature adjustable between 32°F (0°C), and 204°F (96°C). Typical drying time is 15 minutes.

Automatic Damper is pneumatically operated to control vapor exhaust from the unit for enhanced temperature control and vapor removal. The damper is designed to prevent backflow from the exhaust system and contamination of the chamber. Air-intake system features a non-reversing louver and connection for customer-supplied intake filter. The damper controls pressure during exhaust removal.

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 set point 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 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

SAFETY FEATURES

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

Control ON/OFF Selector Switch on the side of the main electrical control box can be used to turn off the 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.

Automatic Door-Latching System (pneumatically operated) seals wash chamber door(s) during cycle and provides the interlock feature for double door units, for improved heating efficiency and operator safety.

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 680 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 a cycle is selected, the 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 recirculated 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 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.
- **CHAMBER COOLDOWN 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]).

OPTIONAL FEATURES

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

- **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 recirculation, chamber, sump, and final rinse system.

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

HEPA Filter on Chamber Intake. Supplied with a pre-filter, a 12 x 12" (305 x 305 mm) HEPA filter can be provided on the chamber air intake.

Non-Recirculated Final Rinse (Steam Heated). 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 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, pneumatic 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 at the end of the day to prevent microbial contamination (range of time: 00:00-99:59 min.).

Inlet for Final Rinse Tank. A 1" (25 mm) sanitary 316L stainless-steel diaphragm valve, spring-to-close, PTFE diaphragm, 20 microinch (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.

Back Panel for Single Door Unit. The back of single door units can be fitted with a 304 panel stainless-steel.

Top Mounted Utility Connections. Connection points for cold water, steam, and condensate return are relocated on the top of the washer.

Stainless-Steel Cabinet Enclosure Panels. The panels are of #304 stainless steel with #4 stainless steel finish and enclose the sides of the unit.

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.

Extended Manufacturing Documentation. Binder (and CD) include the following additional manufacturing information:

- Recirculation Piping Schematic
- Instrumentation and Heat Number Map
- 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) 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)

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.

Flange Connection on Steam. NPT or BSPT connections are replaced by bolted flanges.

CONSTRUCTION

The wash chamber is constructed of #316L stainless steel; the frame and all fasteners are constructed of #304 stainless steel. Load weight capacity is 220 lbs (100 kg), excluding the weight of the accessory. Wash chamber is insulated with 1" (25.4 mm) thick fiberglass insulation with a vapor barrier covering top, door, and bottom of chamber to minimize noise and heat loss. Levelling legs are included to facilitate installation. Chamber is fitted with two sanitary inlet ports.

All components of the wash/rinse system, including door interior, rotary spray arm(s), filter, heating coil, piping, and valves, are constructed of #316L stainless steel (including steam piping).

The sump capacity for the washer is 26.8 U.S. gal (101 L). A sanitarydesigned 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. The sump is constructed of 316L stainless steel.

Diaphragm Valves (#316L stainless steel, 180 Grit) are used on the recirculation and drain piping. With an interior finish of 20 microinch (0.5µm) as Ra, the diaphragm is in PTFE. Valves are installed at an angle to allow complete drainability.

All treatments are under pressure of a 7.5 HP (5.6 Kw) stainless-steel sanitary-pump with 200 U.S. gal/min (757 L/min) capacity. 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.

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, in the drying system, and optional final rinse tank.

Washer is interpiped 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.

UTILITY REQUIREMENTS

Cold Water (15)
3/4" (19 mm) NPT or BSPT; 10-25 psig (69-172 kPa) dynamic; 75°F (24°C) max. Max. flow rate: 20 U.S. gal/min (76 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) dynamic. 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/min).

Vent (86)

10" (254 mm) dia. vent connection; 175 scfm (5 m^3/min), 3/4" (19 mm) W.C. of negative static pressure.

Drain (60)

2" (51 mm) tri-clamp.

Electricity (90)

480 V, 60 Hz, 3-Phase, 3-Wire, 30 Amps (24.2 kW).

380/400/415 V, 3-Phase, 4-Wire, (neutral required) 50 Hz, 36 Amps (24 kW).

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

NOTES

1. Customer must assure machine stands on a non-combustible floor.
2. Total shipping height is 99" (2514 mm). Unit crate is (W x H x L) 72-34 x 102 x 86-1/2" (1847 x 2590 x 2197 mm)
3. Isolation valves, vacuum breakers, and fused disconnect switch (not provided by STERIS) should be installed on utility lines, as required on the equipment.
4. Shut-off valves, vacuum breakers, and fused disconnect switch (not provided by STERIS) should be installed on utility lines, as required on the equipment.
5. Pipe sizes shown indicate terminal outlet only.
6. Construction on 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.

Table 1-1. Engineering Data

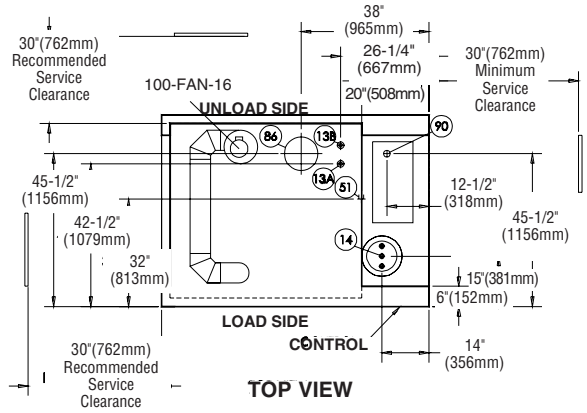
Shipping Weight	2500 lb (1134 kg)
Operating Weight	2929 lb (1328 kg)
A-weighted Equivalent: Surface Sound Pressure Level	67.1 dB
Heat Loss (at 75°F [24°C]), 40% R.H. ambient:	7000 Btu/h (7385 kJ/h), sensible
Max. Water Consumption: per Recirculated Treatment* per Non-recirculated Treatment*	26.80 U.S. gal (101.4 L) 31.34 U.S. gal (118.6 L)

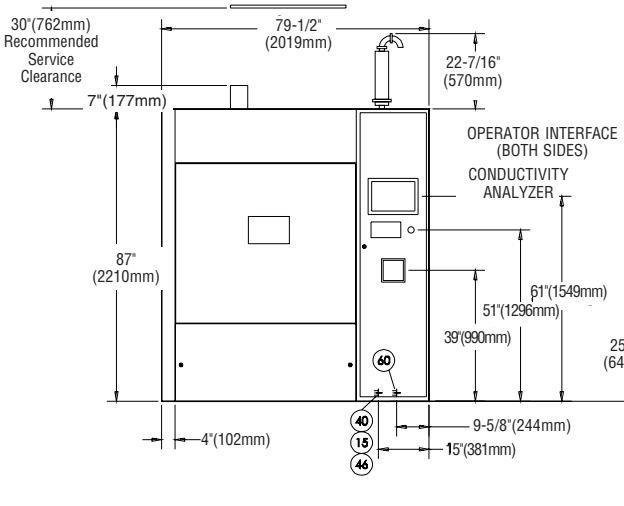
* *Total consumption per cycle is dependent on the number of treatments selected for each cycle and if drain discharge cooldown is activated.*

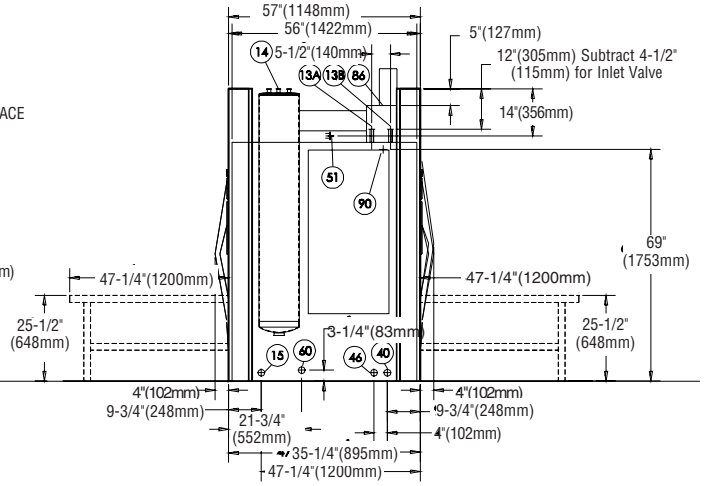
STERIS Corporation, Quebec, Canada, is an ISO 9001 and ISO 13485 certified facility.

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

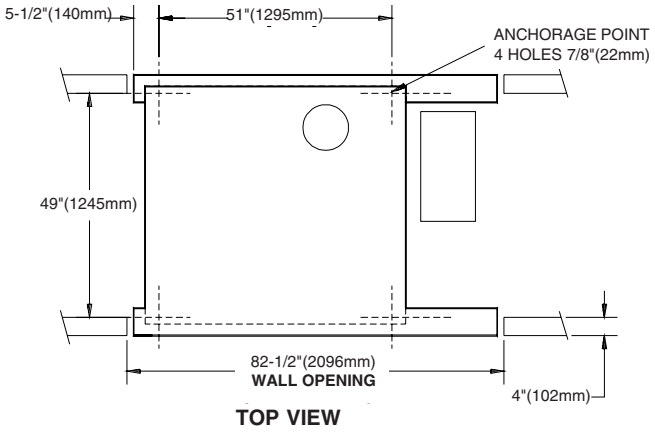
Dimensions shown here are typical, and subject to change without notice.
REFER TO STERIS EQUIPMENT DRAWINGS FOR COMPLETE AND DETAILED INSTALLATION SPECIFICATIONS.



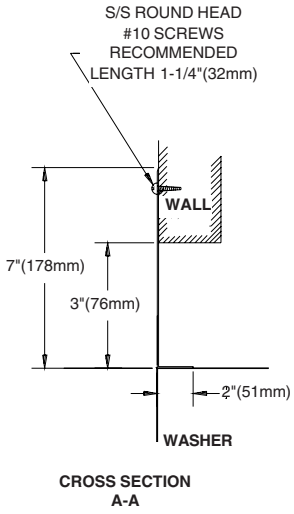




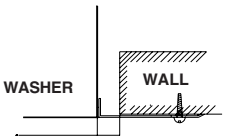
Dimensions shown here are typical, and subject to change without notice.
REFER TO STERIS EQUIPMENT DRAWINGS FOR COMPLETE AND DETAILED INSTALLATION SPECIFICATIONS.



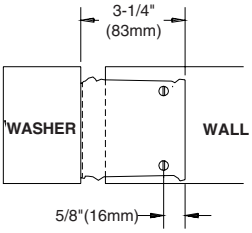
TOP VIEW



CROSS SECTION
A-A

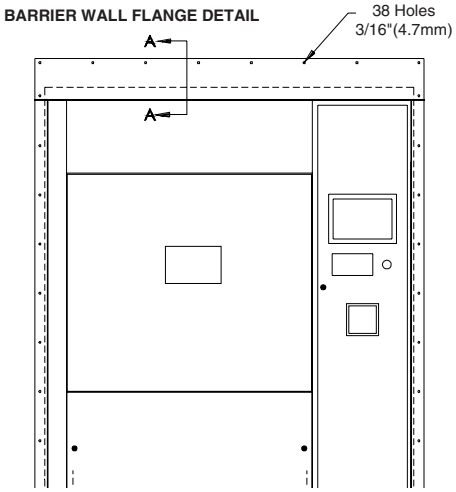


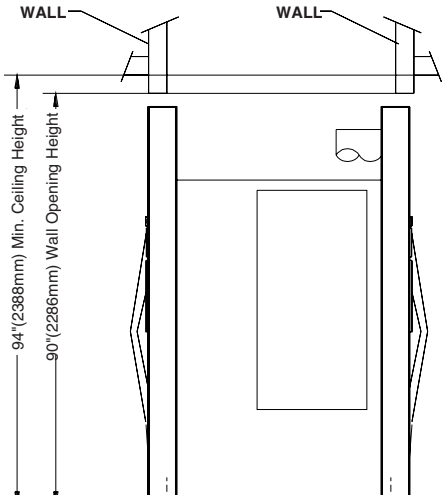
TOP VIEW



FRONT VIEW

BARRIER WALL FLANGE DETAIL





For Further Information, contact:

STERIS®

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

SD599 ©2006, STERIS Corporation. All rights reserved. (03/01/06)

This document is intended for the exclusive use of STERIS customers, including architects or designers. Reproduction in whole or in part by any party other than a customer is prohibited.