

APPLICATION

The Reliance 680PG 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 680PG 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 11 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 33-3/4* x 50-1/2"
 (1263 x 857* x 1283 mm)
- Overall dimensions:
 79-1/2 x 87 x 62-3/8"
 (2019 x 2210 x 1584 mm)
- Loading height:
 30" (762 mm) from floor

* Height varies depending on loading accessories. See SD645 for details.

STANDARDS

The Reliance 680PG Pharmaceutical Grade Washer complies with the applicable requirements of the following standards:

- **Current Good Manufacturing Practices (cGMP)**, CFR Title 21, Part 211, Section D
- **Underwriters Laboratories (UL)**: Standard UL61010-1, Second Edition as certified by UL.
- **Canadian Standards Association (CSA)**: Standard CAN/CSA – C22.2 No.61010-1, Second Edition as certified by UL.
- **Uniform Building Code of California, Title 24** (Seismic anchoring requirements).

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

- Manifoldded Drying System
- Process Monitoring Package
- Chamber Spray Arms Monitoring
- Coverage Test

- Total Organic Carbon (TOC) Monitoring - Includes Process Monitoring Package
- Connection to External Uninterruptible Power Supply (UPS)
- Loop Drain Discharge Cool Down System
- Additional Chemical Injection Pump (Maximum Two)
- Cleaning and Passivation Treatment
- Inlet Valve for Wash Chamber (Maximum Two)
- Inlet Valve for Final Rinse Tank
- Heated Non-Recirculated Final Rinse
- Stainless-Steel Tags for Instrumentation With Customer Assigned Numbers
- Stainless-Steel Cabinet Enclosure Panel With Double Door
- Stainless-Steel Cabinet Enclosure Panel Single Door:
 - Right Service Side
 - Left Service Side
- Condensate Return to Drain
- Flanges on Steam Connections

- Validation Documentation - Additional Copies (Each Binder)
- Extended Manufacturing Documentation
- Extended Control System Validation Documentation
- Instrumentation Index/ISA Style Component Data Sheets and Loop Diagrams
- Electropolished Piping
- Single Point Wash/Rinse Water Inlet
- Rosemount Instrumentation (Pump Pressure and Temperature Transmitters)
- Detergent Injection Valves (Replaces Detergent Injection Pumps) - Maximum Three
- Steam and Water Utility Isolation Valves and Pressure Gauges
- Additional Day for Factory Acceptance Testing (FAT) - (Per Day)

Item _____

Location(s) _____

- **Governing Directive for Affixing of the CE Mark:**
Machinery Directive (2006/42/EC).
- **Conformity to Other Applicable Directives:**
Electromagnetic Compatibility Directive 2004/108/EC.
- Low Voltage Directive 2006/95/EC.
- **Standards applied to demonstrate conformity to the directives:**
EN/IEC61010-1, and EN/IEC61326-1.

FEATURES

Control is a programmable logic controller system provided with operating interfaces, optional impact printer, filter, breakers 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™ controller series with PanelView Plus™ 1000 operator interface.¹
- Siemens S7-300 series with MP-277 operator interface.

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 some 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 nonoperating end.

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 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 the spray nozzles. Filters 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 Pump (one peristaltic pump) is provided with low level sensor and pickup tube. Chemical containers are stored outside the unit, up to 50' (15 m) away.

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.

High Efficiency Particulate Air (HEPA) Filter (12 x 12" [305 x 305 mm]) is provided on the Chamber Air Intake, including DOP Validation Ports.

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 Instructions, including recommended spare parts.
 - » Manufacturer's Parts Cut Sheets*
- **Manufacturing and Qualification Documentation** including:
 - » Calibration Procedures
 - » Seismic Anchorage Report
 - » Factory Acceptance Test Procedure and Report (FAT)
 - » Cleaning and Passivation Procedure and Report (if option applies)
 - » Coverage Test Report (if option applies)
- **Control System Validation Documentation** including:
 - » Functional Specifications -Organization Chart
 - » Software Development Procedure
 - » Application Source Code Listings*

* Supplied on CD only.

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.

Power Disconnect Switch has a lockable, 3-phase nonfused disconnect switch located on the cover of the main electrical box.

Pressure Switch mounted on the air supply line shuts 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 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.

¹ CompactLogix™ and PanelView Plus™ are trademarks of Allen-Bradley, a Rockwell Automation Company.

CYCLE DESCRIPTION

Reliance 680PG 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.
- **NONRECIRCULATED FINAL RINSE** (if option applies): Pure water, or Water for Injection (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.
- **VAPOR REMOVAL:** Vapor is removed from the chamber for preset time.
- **CHAMBER COOLDOWN SEQUENCE:** After the final rinse, cycle can be programmed to circulate fresh air in the chamber until selected setpoint is reached (drying option required).

OPTIONAL FEATURES

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 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. Up to two peristaltic pumps can be provided with a low level sensor and a pick-up tube.

Heated, Nonrecirculated Final Rinse. Final rinse treatment can be programmed to spray the load with fresh, nonrecirculated, heated Pure Water or WFI. Final rinse water is pumped from the tank to the spray arms and injection accessories without going through filters or being recirculated.

The water is supplied from a built-in stainless-steel cylindrical storage tank mounted to the side of the unit. The 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 steam trap, a hydrophobic filter and a #316L stainless-steel vacuum switch. Up to nine pure water rinses may be selected. The tank is completely drained and dried at the end of each cycle.

Inlet Valve 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 for Wash Chamber (Maximum Two). 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.

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 With Customer Assigned Numbers. Identification numbers for instrumentation tags are provided by the Customer.

Additional Copy of Documentation. An additional hard copy of the complete documentation set is provided, including the User's manual, Factory Acceptance Test documentation, as well as the manufacturing and control system documentation (standard and optional). Manufacturer's booklets and CD's for installation, operation and maintenance for control systems, instrumentation and components are excluded.

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

- Recirculation Piping Schematic
- HEPA Filter Certificate (if applicable)
- Heat Number Certificates
- Material Certificates
- Surface Finish Report for Chamber
- Welding Documentation*

* *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 Design Specifications (Includes I/O List)
- Software Design Specifications
- Software Test Documentation (System Acceptance Testing)

Instrument Index/ISA Style Data Sheet and Loop Diagram.

Includes International Society of Automation (ISA) style component data sheets for main process instruments. The data sheet information consists of critical data such as STERIS item numbers, component type/usage, manufacturer, model number, pressure and temperature range, material of construction, functional connections, etc. This option also includes individual loop diagrams that are provided for each control loop or inter-connecting wiring between associated

equipment and apparatus in the system. The components tag number(s), terminal number(s) and wire color are indicated in each diagram.

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. National Pipe Thread (NPT) or British Standard Pipe Thread (BSPT) connections are replaced by bolted flanges.

Single Point Wash/Rinse Water Inlet. Provides a single point connection for the chamber's water port and final rinse tank's water port. Stainless-Steel piping and a multi-port diaphragm valve are included.

Detergent Injection Valves (Replaces Detergent Pumps; Maximum Three). The standard detergent injection pumps are replaced by stainless-steel diaphragm valves. To be used in conjunction with pressurized chemical loops.

Electropolished Piping. Interior surfaces of the piping in contact with the process water is both mechanically polished and electropolished to achieve a surface finish that does not exceed 20 $\mu\text{in.}$ (0.51 μm) Ra. This option does not apply to the instrumentation, valves, pump, spray arms, chamber and Final Rinse tank.

Rosemount Instrumentation Package (Pump Pressure and Temperature Transmitters). Anderson's instruments for the temperature and pressure (if applicable) measurements are replaced by instruments manufactured by Rosemount.

Steam and Water Utility Isolation Valves and Pressure Gauges. Provides manual shutoff ball valves and a gauge on the domestic water, steam, air and condensate return lines to isolate the washer from the utility lines.

Additional Day for FAT (per day). Factory Acceptance Test (FAT) is extended by one day to allow Customer to perform additional tests.

Process Monitoring Package. Includes several systems used to monitor critical cleaning process parameters. A conductivity system is used to monitor the concentration of chemicals during the wash phases. This system is also used to monitor the conductivity of the final rinse water, ensuring thorough rinsing is achieved prior to the drying process. The pressure at the outlet of the main circulation pump is constantly monitored to ensure optimal mechanical action. Finally, an impact printer (to keep records of the cycle data) and a sampling port (to allow for safely taking samples of wash and rinse water) are provided.

Manifolded Drying System. The washer is provided with a HEPA filtered system to dry both inner and outer surfaces of washed items. All heated surfaces downstream of HEPA filter are either #304 or #316 stainless steel. The drying system is supplied with validation ports located on each side of the HEPA filters, magnahelic gauges and pressure differential switches.

Spray Arm Monitoring. The rotation of all three chamber spray arms is monitored by proximity sensors. An alarm is generated if one of the spray arms stops rotating for more than a few seconds.

Total Organic Carbon (TOC) Monitoring (Includes Process

Monitoring Package). This system is used to monitor the Total Organic Carbon level in the last final rinse water, ensuring a high level of cleaning and rinsing is consistently achieved.

Connection to External Uninterruptible Power Supply (UPS). The main electrical system is modified to accommodate easy interfacing with an external UPS system and prevent loss of cycle data should electrical power be lost during a wash cycle.

Looped Drain Discharge Cool Down System. A heat exchanger using chilled water is used to cool down the effluent to a temperature lower than 60°C (140°F). The system eliminates the use of cold water for cooling purposes and reduces water consumption.

CONSTRUCTION

The washer is designed to meet the applicable requirements of Bio Processing Equipment (BPE) 2007. The wash chamber is constructed of #316L stainless steel; the frame and all fasteners are constructed of #304 stainless steel. Load weight capacity is 300 lb (136 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. Leveling legs are included to facilitate installation. Chamber is fitted with two sanitary water inlet ports.

All components of the wash/rinse system, including door interior, rotary spray arm(s), filters, 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 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 system. The sump is constructed of #316L stainless steel.

Piping is sloped at 2% (1.2°) ensuring complete and fast drying. Dead legs are limited to maximum 3D with the majority of the piping at 2D.

Diaphragm Valves (#316L stainless steel, 180 Grit) are used on the recirculation and drain piping. With an interior finish of 20 $\mu\text{in.}$ (0.5 μm) 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 optional 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. The accessories are designed for sanitary applications and are completely drainable.

ACCESSORIES

Refer to SD645, Accessories for Reliance® 580 and 680 Series Pharmaceutical Grade Washers.

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 programs.

UTILITY REQUIREMENTS

Important: Refer to equipment drawing 920-512-996 for details.

Cold Water

3/4" (19 mm) NPT or BSPT

Sump Water Inlet (Port 1)

1" (25 mm) tri-clamp

Sump Water Inlet (Port 2)

1" (25 mm) tri-clamp

Final Rinse Tank (Port 3) - if option applies

1" (25 mm) tri-clamp

Detergent Injection Valve(s) - if option applies

1/4" (6.4 mm) tri-clamp

Chilled Water - if Loop Drain Discharge Cool Down option applies

3/4" (19 mm) NPT or BSPT

Steam

1/2" (13 mm) NPT or BSPT

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

Condensate Return

1/2" (13 mm) NPT or BSPT

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

Air

3/8" (9.5 mm) NPT or BSPT

Vent

10" (254mm) ID vent connection

Drain

2" (51 mm) tri-clamp

Electricity

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).

Table 1. Engineering Data

| | |
|---|--|
| Shipping Weight | 2500 lb (1134 kg) |
| Operating Weight | 2929 lb (1328 kg) |
| A-weighted Equivalent: Surface Sound Pressure Level | 64.9 dB |
| Heat Loss (at 24°C [75°F]), 40% R.H. ambient: | 8000 Btu/h (8440 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.

NOTES

- Customer must ensure machine stands on a non-combustible floor.
- Total shipping dimensions (W x H x L): 72-3/4 x 104 x 86-1/2" (1847 x 2642 x 2197 mm)
- Isolation valves, vacuum breakers and fused disconnect switch (not provided by STERIS) should be installed on utility lines, as required on the equipment.
- Shut-off valves, vacuum breakers and fused disconnect switch (not provided by STERIS) should be installed on utility lines, as required on the equipment.
- Pipe sizes shown indicate terminal outlet only.
- Construction on the exhaust duct system from stainless steel is recommended. Seal the joints by welding to ensure a corrosion resistant and leakproof system for removal of condensed vapor. The duct should have drip leg(s) installed at any low point(s).
- 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.
- A 4" (102 mm) O.D. floor drain is recommended with floor sink.

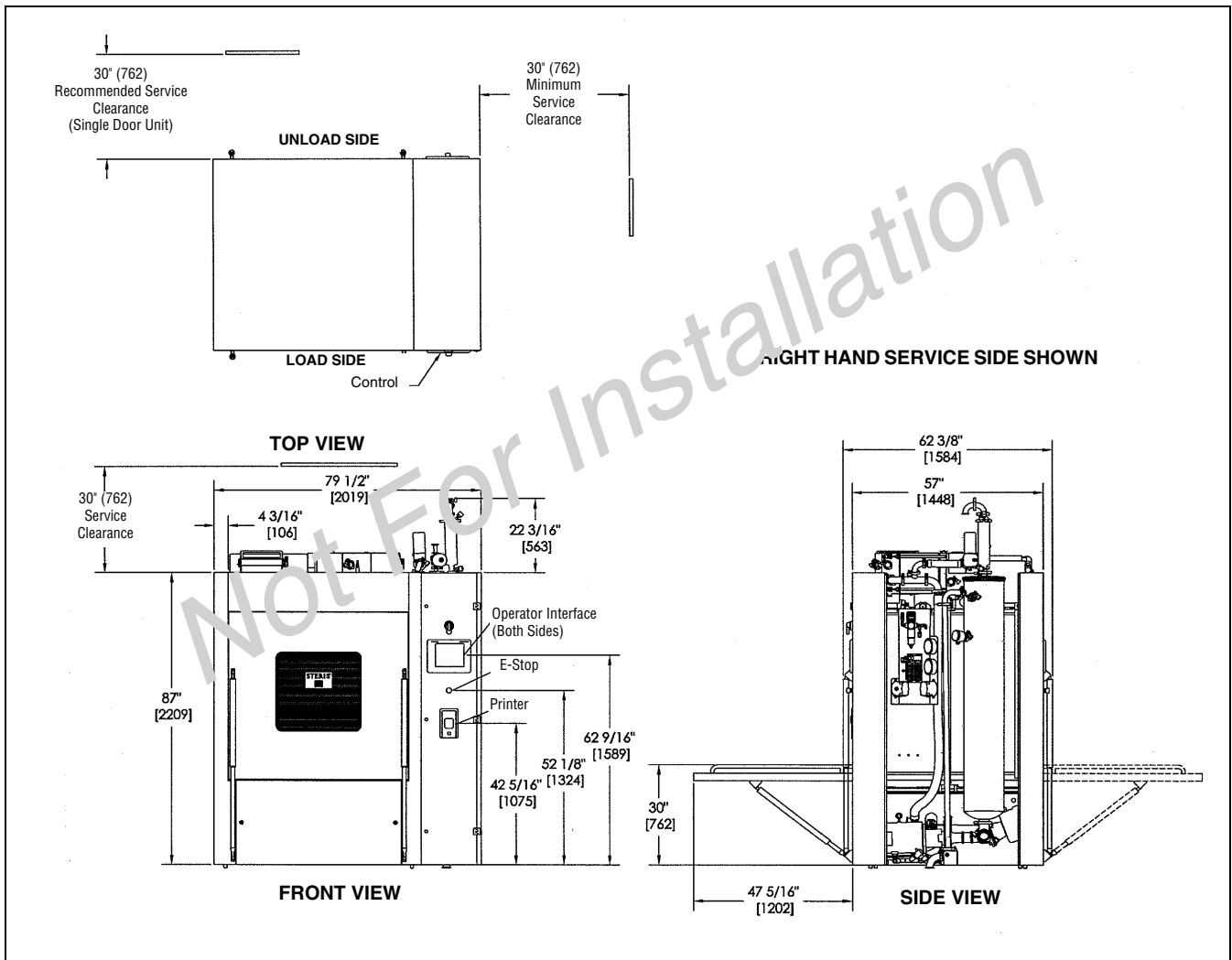
CUSTOMER IS RESPONSIBLE FOR COMPLIANCE WITH APPLICABLE LOCAL AND NATIONAL CODES AND REGULATIONS

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

Life Sciences

Refer to the Following Equipment Drawing for Installation Details

| Equipment Drawing Number | Equipment Drawing Title |
|--------------------------|--|
| 920-512-996 | Reliance 680PG Pharmaceutical Grade Washer |



For Further Information, contact:

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