

APPLICATION

The Reliance 380PG 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 380PG 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).

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:

43-1/2 x 32-1/2 x 25" (1105 x 826 x 635 mm)

Overall dimensions:

66-3/8 x 91 x 32" (1686 x 2311 x 813 mm)

[Add 12" (305 mm) to W with TOC Monitoring option.]

Loading height:

32" (813 mm) from floor

STANDARDS

Washer meets the applicable requirements of the following standards:

- **Current Good Manufacturing Practices (cGMP), CFR** Title 21, Part 820.



Typical only - some details may vary.

- **Good Automated Manufacturing Practices (GAMP 5)**
- **Underwriters Laboratory (UL):** Standard 61010-1:2005 Second Edition.
- **Canadian Standards Association (CSA):** Standard CAN/CSA-C22.2 No. 61010-1, Second Edition.
- **Uniform Building Code of California, Title 24** (Seismic anchoring requirements).
- **Governing Directive for Affixing of the CE Mark:** Machinery Directive (206/42/EC).
- **Conformity to Other Applicable Directives:** Electromagnetic Compatibility Directive 2004/108/EC.
- Low Voltage Directive 2006/95/EC.

The Selections Checked Below Apply To This Equipment

CONTROL

- Allen-Bradley®
- Siemens (50 Hz Units Only)

HEAT

- Steam
- Electric*

VOLTAGE

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

DOOR TYPE

- Single
- Double

ACCESSORIES

See SD645

OPTIONS

- Manifoldd Drying System
- Cleaning and Passivation Treatment

- Second Chemical Injection Pump
- Inlet Valve for Final Rinse Tank
- Inlet Valve for Wash Chamber
- Heated Non-Recirculated Final Rinse (Steam)
- Non-Heated Non-Recirculated Final Rinse
- Chamber Cool Down System (Drying Option Required)
- Process Monitoring Package
- Condensate Return to Drain
- Chamber Spray Arms Monitoring
- Flange Connection on Steam Inlet/Outlet
- Stainless-Steel Tags for Instrumentation With Customer Assigned Numbers
- Validation Documentation – Additional Copies
- Loop Drain Discharge Cool Down System
- Extended Manufacturing Documentation
- Extended Control System Validation Documentation

- Non-Vented System
- Total Organic Carbon Monitoring (TOC) - Includes Process Monitoring Package
- Connection to External Uninterruptible Power Supply (UPS)
- Air Differential Seal (Clean Side Only)
- Steam and Water Utility Isolation Valves and Pressure Gauges
- Additional Day for FAT (per Day)
- Instrumentation Index/ISA Style Component Data Sheets and Loop Diagrams
- Coverage Test

* Units without Heated Non-Recirculated Final Rinse only

Item _____

Location(s) _____

- **Standards applied to demonstrate conformity to the directives:** EN/IEC-61010-1 and EN-IEC-61326-1.
- The washer is designed to meet the applicable requirements of BPE 2007 (Bio Processing Equipment).

FEATURES

Control (single or double door) is a programmable logic controller system provided with operating interfaces, impact printer 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™ controller series with PanelView Plus™ 1000 operator interface.¹
- Siemens S-300 series with TP-270 operator interface.

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

One sump inlet port is provided on standard units.

Automatic vertical sliding door(s) operated by pneumatic cylinder(s) using the control panel. Door(s) is (are) automatically pressed against a silicone gasket to ensure complete air and water tightness. 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 screen. Each door is insulated, provided with a safety switch and an obstruction sensor.

Dual spray system includes three automatic manifold connectors at chamber bottom that automatically connect to a combination of accessory spindle headers that can be used with a single load. Two 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 pump (one peristaltic pump) is provided with foot valve, low level sensor and pickup tube. Chemical containers are stored outside the unit up to 50' away (15 m).

Process observation window in the chamber door and an interior light allow operator to ensure 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 spray nozzles. The filter is easily removed for cleaning.

High Efficiency Air (HEPA) Filter (8 x 8" [203 x 203 mm]) is provided on the Chamber Air Intake, including DOP Validation Ports.

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.

Stainless-Steel tag (for instrumentation) is attached to each instrument. Identification numbers are assigned by the factory.

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. Demonstration that the unit can reproduce the cycle parameters recommended by the Process And Cleaner Evaluation study (PACE), if it applies, is also included.

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

- **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 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 non-fused disconnect switch located on the cover of the main electrical box.

Safety edge sensor located at door bottom prevents door from closing should an obstruction be detected.

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

Additional sanitary water level sensor is provided to abort cycle and automatically drain sump should an overflow situation occur.

Pressure switch mounted on the air supply line shuts 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 380PG 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 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 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.
- **DRYING** (if option applies): HEPA filtered, heated air is circulated under pressure for preset time through final rinse tank (if applicable), piping, spray nozzles and chamber to ensure all load items surfaces, chamber and final rinse tank are thoroughly dried.
- **VAPOR REMOVAL:** Vapor is removed from the chamber for preset time.
- **CHAMBER COOL DOWN SEQUENCE:** After the last treatment, fresh air is recirculated in the chamber until selected setpoint is reached (dryer option required).

OPTIONAL FEATURES

Air differential seal. An air differential seal is installed on the clean side of the unit (double-door configurations only) to minimize air flow between dirty and clean sides of barrier wall.

Second detergent injection pump. Another peristaltic pump can be provided with a low level sensor and a pick-up tube.

Inlet valve for final rinse tank. Standard unit has no inlet valve. Pilot valve is supplied as standard. Optional sanitary diaphragm valve may be connected to the final rinse tank inlet port on top of the unit.

Inlet valve for wash chamber. Standard unit has no inlet valve. Pilot valve is supplied as standard. Optional sanitary diaphragm valve may be connected to the inlet port on top of the unit.

Stainless-Steel tags for instrumentation (with Customer assigned numbers). Stainless-steel tag identification numbers for instrumentation are provided by the Customer.

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.

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

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 surfaces, providing a better corrosion-resistant surface. Solution also passivates entire recirculation, chamber, sump and final rinse system.

Heated, non-recirculated final rinse (steam-heated units only). Final rinse treatment can be programmed to spray the load with fresh, non-recirculated, 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 at the end of each cycle and can be dried by selecting appropriate cycle (if drying option is available).

Non-Heated, non-recirculated final rinse. Final rinse treatment can be programmed to spray the load with fresh, non-recirculated, 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 and overflow with sanitary check valve. Tank is also equipped with a #316L stainless-steel vacuum switch. Up to nine pure water rinses may be selected. The tank is completely drained at the end of each cycle and can be dried by selecting appropriate cycle (if drying option is available).

Non-Vented system. Vapor can be exhausted through a condenser to the room, eliminating the need to vent the unit. Includes vapor removal fan.

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.

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

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

Chamber cool down (drying option must also be selected). The chamber air temperature is lowered by circulating fresh air into the chamber. Once the set temperature is reached, the air circulation stops and unload door can be opened.

Looped drain discharge cool down system. A heat exchanger using chilled water cools the effluent to lower than 140°F (60°C). The system eliminates the use of cold water for cooling and so reduces water consumption.

Spray arm monitoring. Chamber top spray arms rotation is monitored by proximity sensors. An alarm is generated if one of the spray arms stops rotating for more than a few seconds.

Manifolded drying system. 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 made of #316L stainless steel. Drying system is supplied with validation ports located on each side of the HEPA filters.

Additional copy of documentation. An additional hard copy of the complete documentation set is provided. Manufacturer's booklets and CDs for installation, operation and maintenance for control systems, instrumentation and components are excluded.

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

- HEPA Filter Certificate (if applicable)
- Piping Assembly Drawing
- 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) includes 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)

Process monitoring package. Several systems are used to monitor critical cleaning process parameters including:

- Conductivity system used to monitor chemical concentration during wash phases. This conductivity system is also used

to monitor final rinse water conductivity, ensuring thorough rinsing is achieved prior to drying process.

- Main circulation pump outlet pressure is constantly monitored to ensure optimal mechanical action.
- Impact printer is provided to keep records of the cycle data.
- A sampling port enables safe collection of wash and rinse water samples.

Total Organic Carbon (TOC) monitoring (includes Process monitoring package). This system is used to ensure a high level of cleaning and rinsing is consistently achieved by monitoring the TOC level in the last final rinse water.

Instrument Index/ISA Style Data Sheet and Loop Diagram. Includes 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 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.

CONSTRUCTION

The wash chamber is constructed of #316L stainless steel. Water inlet is designed to 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. Welds are polished and grounded to 1/2" (12.7 mm) radius minimum.

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

The sump capacity for the washer is 14.5 gal (55 L). A sanitary designed heating coil (steam or electric) in the bottom of the sump can raise and maintain water temperature up to 180°F (82°C) during pre-wash, wash and rinse phases. The sump is constructed with an automatic solution level control, automatic water fill and safety overflow system.

All sump components constructed of #316L stainless steel. All treatments are under pressure of 5 HP (3.7 Kw) stainless-steel sanitary recirculating pump with 135 U.S. gal/min (511 L/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. Piping is sloped at 2% (1.2°) ensuring complete and fast draining. Dead legs are limited to maximum 3D with the majority of the piping at 2D.

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 enables control to back-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 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 programs.

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.

Table 1-1. Engineering Data

Shipping Weight	1460 lb (662 kg)
Operating Weight	1250 lb (568 kg)
A-weighted Equivalent: Surface Sound Pressure Level	74.5 dB
Maximum Water Consumption: per Recirculated Treatment* per Non-recirculated Treatment*	14.5 U.S. gal (55 L) 16.90 U.S. gal (64 L)
Heat Loss (at 75°F [24°C], 40% R.H. ambient)	7000 Btu/h (7385 kJ/h), sensible
Maximum Steam Consumption: 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.

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) 43 x 102 x 70" (1092 x 2591 x 1778 mm).
6. 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).
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 87°F (30.5°C).

UTILITY REQUIREMENTS

IMPORTANT: Refer to equipment drawing 920-515-291 for installation details and specifications.

Cold Water

3/4" (19 mm) NPT or BSPT

Sump Water Inlet (Port 1)

1" (25 mm) Tri-Clamp

Final Rinse Tank (Port 3) (If Option Applies)

1" (25 mm) Tri-Clamp

Steam

1/2" (13 mm) NPT or BSPT.

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

Condensate Return (Steam Heated Unit Only)

1/2" (13 mm) NPT or BSPT

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

Air

3/8" (10 mm) OD

Chilled Water - Inlet and Outlet (Looped Drain Discharge Cool Down Option)

3/4" (19 mm) NPT or BSPT

Vent

6" (152 mm) inside diameter vent connection (not required if Non-Vented System option is selected).

Drain

2" (51 mm) Tri-Clamp

(See **NOTE #8** on Page 5)

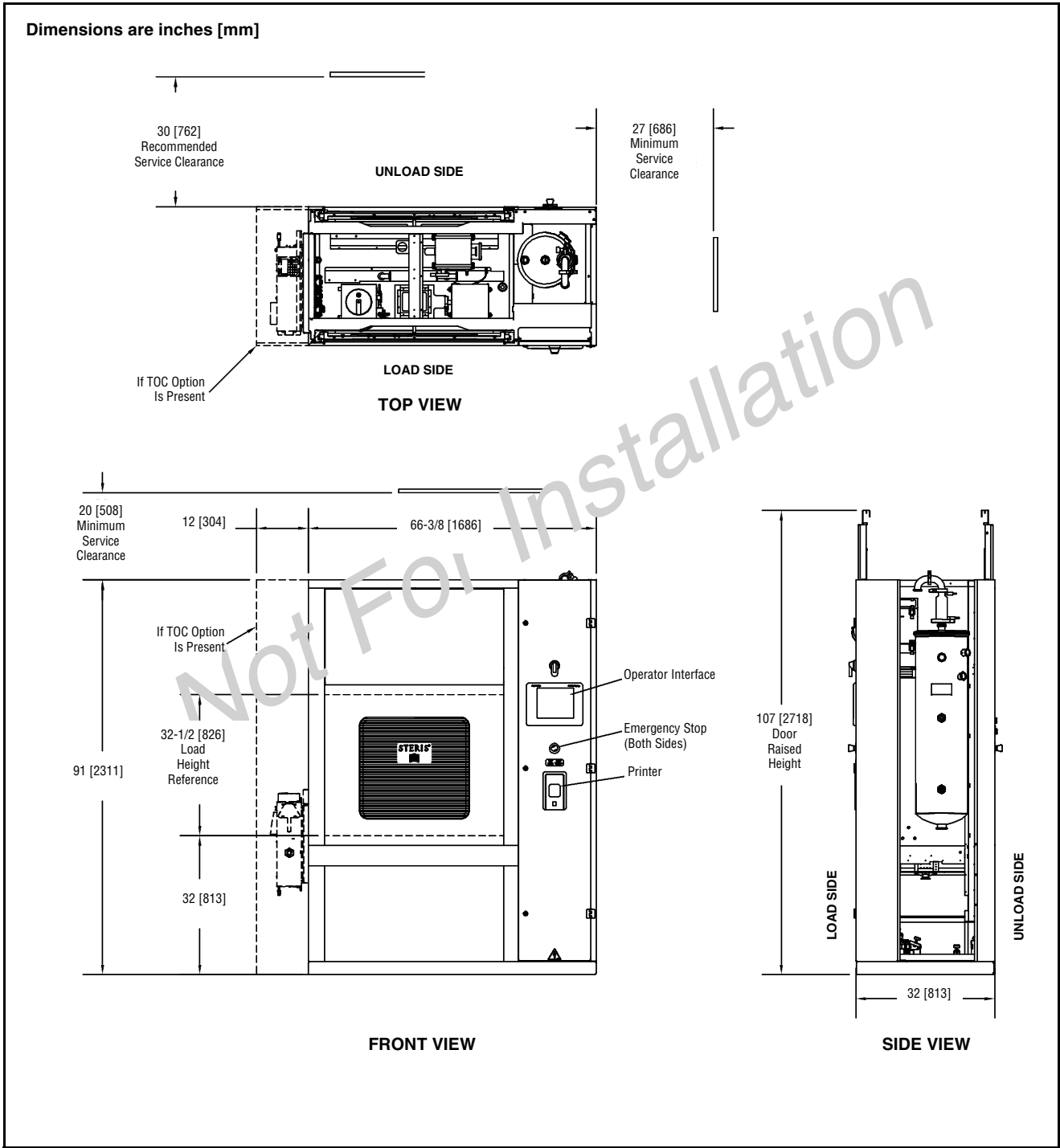
Electricity

480 V, 60 Hz, 3-Phase

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

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

Refer to the Following Equipment Drawing for Installation Details	
Equipment Drawing Number	Equipment Drawing Title
920-515-291	Reliance 380PG Pharmaceutical Grade Washer (Typical)



For Further Information, contact:

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