Reliance® 380PG

Pharmaceutical Grade Washer

STERIS®

APPLICATION

Reliance 380PG Pharmaceutical Grade Washer is intended for thorough, efficient cleaning of various materials and components utilized in 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).

Specifications

Size (W x H x L)	**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.
	Chamber load capacity: 43-1/2 x 32-1/2 x 25" (1105 x 826 x 635 mm)
	Loading height: 32" (813 mm) from floor
Weight	**Shipping:** 1836 lb (833 kg) **Operating:** 1884 lb (855 kg)
Utility Requirements:	**Chilled Water (Looped Drain Discharge Cool Down Option) - Inlet and Outlet:** 3/4" NPT or BSPT
	Cold Water 3/4" NPT or BSPT
	Sump Water Inlet (Port 1): 1" TRI-CLAMP® fitting[1]
	Final Rinse Tank (Port 3) (If Option Applies) 1" TRI-CLAMP fitting
	Steam: 1/2" NPT or BSPT. [2]
	Condensate Return (Steam Heated Unit Only): 1/2" NPT or BSPT . [2]
	Air: 3/8" (10 mm) OD
	Vent: 6" (152 mm) inside diameter vent connection (not required if Non-Vented System option is selected).
	Electricity[3]: 480 V, 60 Hz, 3-Phase; or 380/400/415 V, 50 Hz, 3-Phase
	Drain: 2" TRI-CLAMP fitting (See Note 8)

1. *TRI-CLAMP® is a registered trademark of ALFA LAVAL INC.*
2. *NPT connection replaced by flange connection if option applies.*
3. *Siemens control requires 380/400/415 V, 50 Hz, 3-Phase.*

Connection to External UPS (If Option Applies): 120 V, 60 Hz; or 230 V, 50 Hz

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

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

STANDARDS

The Reliance 380PG Pharmaceutical Grade Washer complies with the applicable requirements of the following standards, as certified by ETL:

- **Underwriters Laboratory (UL):** UL 61010-1 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements, 3rd Edition
- **Canadian Standards Association (CSA):** CAN/CSA C22.2 No. 61010-1-12 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 1: General Requirements, 3rd Edition
- **International Electrotechnical Commission (IEC):** IEC 61010-1: 2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements; AMD1:2016 Consolidated version, 3rd Edition
- **Current Good Manufacturing Practices for Finished Pharmaceuticals (cGMP):** CFR Title 21, Part 211, Subpart D - Equipment
- **Quality System Regulation (QSR):** CFR Title 21, Part 820
- **Federal Communications Commission (FCC):** CFR 47, Part 15, Subpart B, Class A Unintentional Radiators.
- **California Building Standards Code (California Code of Regulations, Title 24):** for Seismic Anchoring Requirements.
- **Bioprocessing Equipment for sanitary design:** ASME BPE 2016 standard.
- **Good Automated Manufacturing Practices (GAMP®5)**
- **Software architecture and programming languages of the control program within PLC:** IEC 61131-3

The Reliance 380PG Pharmaceutical Grade Washer complies with the applicable requirements of Machinery (Directive 2006/42/EC).

The Reliance 380PG Pharmaceutical Grade Washer complies with the applicable requirements of Conformity to Other Applicable Directives:

- Electrical equipment designed for use within certain voltage limits (Directive 2014/35/EU)
- Electromagnetic Compatibility Directive (2014/30/EC)

The Reliance 380PG Pharmaceutical Grade Washer complies with the applicable requirements of standards applied to demonstrate conformity to the directives:

- EN 61010-1: 2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements, 3rd Edition.
- EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
- EN 55011:2009/A1:2010 Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement

FEATURES

Control (single or double door) is a programmable logic controller (PLC) system provided with operating interfaces, optional thermal printer, and all required hardware. Note the double-door configuration includes the PLC on the load-side and the following indicators and buttons on the non-operating/ unload end: alarm light, cycle status light, silence alarm button and emergency stop button. 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 cycle is started, programmed cycle values are locked and cannot be changed until cycle is complete.

Two standard programmable logic controllers are available:

- Allen-Bradley® CompactLogix™ controller series with PanelView Plus™ 7 1000 operator interface.[4]
- Siemens S7-1500 Controller with TP1200 Comfort 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 cylinders using control panel. Door(s) is (are) automatically pressed against silicone gasket to ensure complete air and water tightness. Door interlock system permits only one door to be opened at a time without aborting the cycle. During a cycle, neither door can be opened without first pressing STOP on touch screen. Each door is insulated, provided with a safety switch and an obstruction sensor.

Dual spray system includes two automatic manifold connectors at chamber bottom that automatically connect to a combination of accessory spindle headers that can be used with a single load. One sanitary rotary spray arm is positioned on top of wash chamber to ensure total coverage and even spray pressure on all surfaces of items being washed.

Service panels (two on front and on one side of 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 unit up to 50' away (15 m).

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

Process observation window in chamber door and an interior light allow operator to ensure spray arm is rotating and accessory spindles are not blocked.

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

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

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) is also included, if applicable.

Validation documentation (provided on USB Stick as Standard) includes the following documents. Hard copies are available as an option.

- **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

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 cover of high-voltage electrical box.

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

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

Electronic Data Security (Siemens or Allen-Bradley)

- Upgraded Siemens or Allen-Bradley control package provides 21 CFR Part 11 and EU Annex 11 capability. System includes Electronic Batch Report Data, Audit trail and batch cycle data that is viewable from the HMI screen via appropriate password setting, E-signature for final batch verification/acceptance, local removable memory for temporary data storage of audit trail and batch cycle data, and data export capability.

Electronic Data Security with Data Archiving and Enhanced Batch Reporting (Siemens or Allen-Bradley) Upgraded Siemens or Allen-Bradley control package provides 21 CFR Part 11 and EU Annex 11 capability. System includes Electronic Batch Report Data, Audit trail and batch cycle data (formatted into a PDF file) that is viewable from PC screen via appropriate password setting, E-signature for final batch verification/acceptance, local hard drive for data storage of audit trail and batch cycle data, and Data export capabilities.

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 inlet port on unit top.

Single point wash/rinse water inlet. Standard unit has no inlet valve. Pilot valve is supplied as standard. Optional, sanitary multi-port diaphragm valve may be connected to chamber inlet port and to final rinse tank inlet port on top of unit to supply washer with only one connection point.

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 ferrous 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. Final rinse treatment can be programmed to spray load with fresh, non-recirculated, heated Pure Water or WFI. Features include:

- Final rinse water is pumped from tank to spray arms and injection accessories without going through filters or being recirculated.
- Water is supplied from built-in stainless-steel cylindrical storage tank mounted to unit side.
- Tank is equipped with level control sensor, automatic fill, overflow with sanitary check valve, temperature transmitter, hydrophobic filter and #316L stainless-steel vacuum switch.
- For steam heating: tank is equipped with stainless-steel coil, steam valve and steam trap.
- For electric heating: tank is equipped with electrical heating element and over temperature switch.
- Up to nine pure water rinses may be selected. Tank is completely drained at end of each cycle and can be dried by selecting appropriate cycle (if drying option is available).

Non-Vented system (Drying option required). 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). Main electrical system is modified to accommodate easy interfacing with 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. Heat exchanger using chilled water cools effluent to lower than 140°F (60°C). System eliminates use of cold water for cooling and so reduces water consumption. Note that this option is not available for systems using the non-vented system option.

Spray arm monitoring. Chamber top spray arm rotation is monitored by proximity sensor. An alarm is generated if spray arm 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.

Stainless-Steel Cabinet Enclosure Panels. Panels are constructed of #304 stainless steel with #4 stainless-steel finish and enclose sides of Unit.

Extended Manufacturing Documentation.

Folder on USB Stick includes the following:

- HEPA Filter Certificate (if applicable)
- Piping Assembly Drawing
- Heat Number Certificates
- Material Certificates

- Surface Finish Report for Chamber
- Welding Documentation*[5]

Hard Copy of Documentation. A hard copy of complete documentation set is provided. Manufacturer's booklets and USB Stick for installation, operation and maintenance for control systems, instrumentation and components are excluded.

Extended Control System Validation Documentation. Folder on USB Stick includes the following:

- 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.
- Thermal printer is provided to keep records of the cycle data.
- A sampling port enables safe collection of wash and rinse water samples.
- Non-Vented System and Loop Drain Discharge Cool Down System options cannot be ordered together.

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.

A-weighted Equivalent: Surface Sound Pressure Level	65.6 dB
Maximum Water Consumption: per Recirculated Treatment[6] per Non-recirculated Treatment[6]	 14.5 U.S. gal (55 L) 16.9 U.S. gal (64 L)
Heat Loss (at 75°F [24°C], 40% R.H. ambient	7000 Btu/h (2051 w)
Maximum Steam Consumption: per Heated Treatment[6]	23 lb (10.5 kg)

ACCESSORIES

Refer to SD645, *Accessories for Reliance 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.

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 48.5 x 101 x 72.5" (1232 x 2565 x 1842 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).

5. *Welding documentation is provided for the chamber, process piping and final rinse tank.*
6. *Total consumption per cycle is dependent on the number of treatments selected for each cycle and if drain discharge cooldown is activated.*

10. This unit is not designed for use in areas that require explosion proof rated equipment.

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

Selections Checked Below Apply To This Equipment

CONTROL

☐ Allen-Bradley (50 Hz or 60 Hz)

☐ Siemens (50 Hz 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

☐ Manifolded Drying System

☐ Cleaning and Passivation Treatment

☐ Second Chemical Injection Pump

☐ Inlet Valve for Final Rinse Tank[7]

☐ Inlet Valve for Wash Chamber

☐ Heated Non-Recirculated Final Rinse

☐ Chamber Cool Down System (Drying Option Required)

☐ Total Organic Carbon Monitoring (TOC) – Includes Process Monitoring Package[8]

☐ Process Monitoring Package (without TOC)

☐ Condensate Return to Drain

☐ Chamber Spray Arms Monitoring

OPTIONS (Continued)

☐ Flange Connection on Steam Inlet/ Outlet

☐ Stainless-Steel Tags for Instrumentation With Customer Assigned Numbers

☐ Electronic Data Security – Siemens

☐ Electronic Data Security – Allen-Bradley

☐ Electronic Data Security with Data Archiving and Enhanced Batch Reporting – Siemens

☐ Electronic Data Security with Data Archiving and Enhanced Batch Reporting – Allen-Bradley

☐ Hard Copy of Documentation (Complete Set)

☐ Loop Drain Discharge Cool Down System[9]

☐ Extended Manufacturing Documentation

☐ Extended Control System Validation

☐ Non-Vented System (Drying Option Required)[9]

☐ Connection to External Uninterruptible Power Supply (UPS)

☐ Air Differential Seal (Clean Side Only)

OPTIONS (Continued)

☐ Steam and Water Utility Isolation Valves and Pressure Gauges

☐ Additional Day for Factory Acceptance Testing (FAT) – (Per Day)

☐ Instrumentation Index/ISA Style Component Data Sheets and Loop Diagrams

☐ Coverage Test

☐ Stainless-Steel Cabinet Enclosure Panels (Single or Double Door)

Item:	
Locations:	

7. This valve cannot be ordered if Heated Non-Recirculated Final Rinse Option is not installed on your Unit.
8. Also available for units in the field.
9. Non-vented system and loop drain discharge cooldown system cannot be ordered together.

For Further Information, contact:

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

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

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