

# Reliance® 680PG

Pharmaceutical Grade Washer



## APPLICATION

Reliance 680PG Pharmaceutical Grade Washer is designed 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 680PG Pharmaceutical Grade Washer is a cabinet-type washer equipped with a programmable logic controller (PLC) 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).



## Specifications

<b>Size (W x H x L)</b>	<b>Overall dimensions:</b> 79-1/2 x 87 x 62-3/8" (2019 x 2210 x 1584 mm) <b>Chamber load capacity:</b> 49-3/4 x 33-3/4 <sup>1</sup> x 50-1/2" (1263 x 857 <sup>1</sup> x 1283 mm) <b>Loading height:</b> 30" (762 mm) from floor
<b>Weight</b>	<b>Shipping:</b> 2500 lb (1134 kg) <b>Operating:</b> 2929 lb (1328 kg)
<b>Utility Requirements:</b>	<b>Chilled Water (Looped Drain Discharge Cool Down Option) - Inlet and Outlet:</b> 3/4" NPT or BSPT <b>Cold Water</b> 3/4" NPT or BSPT <b>Sump Water Inlet (Port 1):</b> 1" TRI-CLAMP® fitting <sup>2</sup> (Port 2) 1" TRI-CLAMP fitting Final Rinse Tank (Port 3) - if option applies 1" TRI-CLAMP fitting <b>Detergent Injection Valve(s)</b> - if option applies 1/4" TRI-CLAMP fitting <b>Steam:</b> 1/2" NPT or BSPT. <sup>3</sup> <b>Condensate Return (Steam Heated Unit Only):</b> 1/2" NPT or BSPT. <sup>3</sup> <b>Air:</b> 3/8" (10 mm) OD <b>Vent:</b> 10" ID vent connection <b>Electricity</b> <sup>4</sup> : 480 V, 60 Hz, 3-Phase, 30 Amps (24.2 kW); or 380/400/415 V, 50 Hz, 3-Phase, 36 Amps (24 kW) <b>Drain:</b> 2" TRI-CLAMP fitting (See ) <b>Connection to External UPS (If Option Applies):</b> 120 V, 60 Hz; or 230 V, 50 Hz

1. Height varies depending on loading accessories. See SD645 for details.  
2. TRI-CLAMP® is a registered trademark of ALFA LAVAL INC.  
3. NPT connection replaced by flange connection if option applies.  
4. Siemens control requires 380/400/415 V, 50 Hz, 3-Phase.

**IMPORTANT:** Refer to equipment drawing 920-512-996 for installation details and specifications.

## STANDARDS

The Reliance 680PG 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 2019 standard.
- **Good Automated Manufacturing Practices (GAMP®5)**
- **Software architecture and programming languages of the control program within PLC:** IEC 61131-3

The Reliance 680PG Pharmaceutical Grade Washer complies with the applicable requirements of Machinery (Directive 2006/42/EC).

The Reliance 680PG 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 680PG 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.<sup>5</sup>
- Siemens S7-1500 Controller with TP1200 Comfort Operator Interface.

**Spray System** includes an automatic manifold connector at bottom of chamber that automatically couples to accessory header, allowing connection of accessories.

Sanitary rotary spray arms are positioned on top and sides of wash chamber and under some accessory headers 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.

**Drop Down Door** (single or double) is insulated, airtight and watertight, to ensure process integrity. Double door configuration includes a door interlock feature and a second emergency stop on the unload side of the unit.

**NOTE:** Hinged door(s) available upon request.

**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).

**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** (12 x 12" [305 x 305 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.

**Chamber cool down.** 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.

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

**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.

**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.

**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 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 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

**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.** Phosphoric acid solution removes ferris contamination from surfaces, providing better corrosion-resistant surface. The solution also passivates entire recirculation, chamber, sump and final rinse system.

**Additional Detergent Injection Pump.** Up to two peristaltic pumps can be provided with low level sensor and pick-up tube.

### **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.

**SLT Smart Assistant** is an iPad®-based application allowing Operators, through locally enabled Wi-Fi connection, to attach pictures of load items to the wash cycle batch report. Pictures must be taken using the iPad Pro® (included) and can be selected and transferred to the washer HMI. Customer-provided Standard Operating Procedures (SOP's) in PDF format can be downloaded and viewed on the tablet. Note that this option is only available with washers equipped with the **Electronic Data Security System with Data Archiving and Enhanced Batch Reporting option (Siemens)**.<sup>6</sup>

**Smart AR Loading Technology** is an iPad®-based application using augmented reality to guide Operators while loading items on Reliance GMP racks. Custom-made augmented reality experiences are created to mimic the User's Standard Operating Procedures, reducing the risk of bad wash cycles due to poor item placement. **Smart AR Loading Technology** is a completely offline solution and is compatible with any new or existing Reliance PG washer.<sup>7</sup>

**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 tank to spray arms and injection accessories without going through filters or being recirculated. Water is supplied from a built-in stainless-steel cylindrical storage tank mounted to unit side. 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. Tank is completely drained and dried at 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 valve for wash chamber. (Maximum Two).** Standard unit has no inlet valves. Pilot valves are supplied as standard. Optional sanitary diaphragm valves are connected to inlet ports on top of unit.

**Single point wash/rinse water inlet.** Standard unit has no inlet valve. Pilot valve is supplied as standard. Optional, sanitary multipoint 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).

**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.

**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.

6. iPad® and iPad Pro® are trademarks of Apple Inc., registered in the U.S. and other countries.

7. iPad® is a trademark of Apple Inc., registered in the U.S. and other countries.

**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\*<sup>8</sup>

**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.

**cGMP Qualification Factory Acceptance Test.** This option provides two days of specific software testing, in addition to the regular Factory Acceptance Test (FAT). The following extra items are covered and documented in the STERIS-supplied FAT protocol (when applicable); user management and user levels, cycle configuration, power failure, backup and recovery, audit trail and electronic data security.

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

A-weighted Equivalent: Surface Sound Pressure Level	64.9 dB
Heat Loss (at 24 °C [75 °F]), 40% R.H. ambient:	8000 BTU/hr (2344 w)
Max. Water Consumption: per Recirculated Treatment <sup>9</sup> per Non-recirculated Treatment <sup>9</sup>	26.80 U.S. gal (101.4 L) 31.34 U.S. gal (118.6 L)

**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

- 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.

**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.

peak performance. STERIS representatives can provide information regarding annual maintenance programs.

**NOTES**

1. Customer must ensure machine stands on a non-combustible floor.
2. Total shipping dimensions (W x H x L): 72-3/4 x 104 x 86-1/2" (1847 x 2642 x 2197 mm)

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

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 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).
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. 4" (102 mm) O.D. floor drain is recommended with floor sink. Drain is 1-1/2" TC when washer is equipped with loop drain discharge cool down option.
9. This unit is not designed for use in areas that require explosion proof rated equipment.

**Refer to the Following Equipment Drawing for Installation Details**

<b>Equipment Drawing Number</b>	<b>Equipment Drawing Title</b>
920-512-996	Reliance 680PG Pharmaceutical Grade Washer

## Selections Checked Below Apply To This Equipment

### CONTROL

Allen-Bradley (50 Hz or 60 Hz)  
Siemens (50 Hz Only)

### SERVICE SIDE

Right  
Left

### 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  
Chamber Spray Arms Monitoring  
Coverage Test  
Total Organic Carbon (TOC) Monitoring - Includes Process Monitoring Package<sup>10</sup>  
Process Monitoring Package (without TOC)

### OPTIONS (Continued)

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<sup>11</sup>  
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

### OPTIONS (Continued)

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  
SLT Smart Assistant  
Smart AR Loading Technology  
Hard Copy of Documentation (Complete Set)  
Extended Manufacturing Documentation  
Extended Control System Validation Documentation  
Instrumentation Index/ISA Style Component Data Sheets and Loop Diagrams  
Single Point Wash/Rinse Water Inlet  
Steam and Water Utility Isolation Valves and Pressure Gauges  
Additional Day for Factory Acceptance Testing (FAT) - (Per Day)  
Single Point Wash/Rinse Water Inlet Valve  
cGMP Qualification Factory Acceptance Test

Item:	
Locations:	

10. Also available for units in the field.

11. This valve cannot be ordered if Heated Non-Recirculated Final Rinse Option is not installed on your Unit.

**For Further Information, contact:**



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