Reliance® 980PG

Pharmaceutical Grade Washer

STERIS®

APPLICATION

Reliance 980PG Pharmaceutical Grade Washer is designed for thorough, efficient cleaning of various materials and components utilized in cosmetic, biotechnology and pharmaceutical manufacturing process industries, large vessels, containers, drums, Integrated Bulk Containers (IBCs), pallets, blenders, hoppers and other large items. Washer can also be used to process components from filling or packaging machines.

DESCRIPTION

The Reliance 980PG Pharmaceutical Grade Washer is a mechanical washer equipped with a Programmable Logic Controller (PLC) Modular System. The control includes a userfriendly operator interface screen.

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 (cGMPs).

The washer is equipped with three factory set, adjustable cycles: Light, Medium, and Heavy. Eight additional cycles are available for customized programming to meet specific operating requirements. One cycle is dedicated exclusively for drying.

Specifications

Size (W x H x L)	**Washer cabinet dimensions:** 2836 x 2908 x 2370 mm (111-5/8 x 114-1/2 x 93-5/16")
	Effective chamber load capacity: 1200 x 2032* x 2159 mm (47-1/4 x 80 x 85")
	Loading height: 30" (762 mm) from floor
Weight	**Shipping:** 3150 lb (1429 kg) **Operating:** 3750 lb (1134 kg)
Utility Requirements:	**Cold Water**[1] 1" BSPT
	Main Recirculation Tank (Port 1 and Port 2) 1" TRI-CLAMP fitting
	Final Rinse Tank (Port 3) - if option applies 1" TRI-CLAMP fitting
	Building Plant Steam 1-1/2" NPT, BSPT or Flange
	Condensate Return 1" NPT, BSPT or Flange
	Air[2] 1/2" NPT or BSPT
	Drain[3] 4" OD
	Vent – 6" ID Fan Outlet
	Electricity[4] 480 V, 60 Hz, 3-Phase, 21.5 Amps (18.2 kVa); or 380/400/415 V, 50 Hz, 3-Phase, 23.5 Amps (18.2 kVa)

1. *Only necessary where local regulations require drain cool down system.*
2. *Clean, dry, oil-free instrument air is required.*
3. *Floor drain is recommended with floor sink.*
4. *Variance not to exceed 10% of the supply voltage.*

STANDARDS

The Reliance 980PG Pharmaceutical Grade Washer complies with the applicable requirements of the following standards:

- Safety standards:
  - IEC 61010-1: 2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements; Corrigendum 1 2011, Corrigendum 2 2013, 3rd Edition.
  - UL 61010-1 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements, 3rd Edition.
  - 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
- Governing Directive for the affixing of the CE mark: Electrical equipment designed for use within certain voltage limits (Directive 2014/35/EU)
- Conformity to other applicable directives: Electromagnetic compatibility (Directive 2014/30/EU)
- Standards applied to demonstrate conformity to the directives:
  - CENELEC EN 61010-1: 2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements, 3rd Edition.
  - CENELEC EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
  - CENELEC EN 55011:2009/A1:2010 Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
- Guidelines and other regulations followed:
  - Current Good Manufacturing Practices for Finished Pharmaceuticals (cGMP) CFR Title 21, Part 211, Subpart D - Equipment » Good Automated Manufacturing Practices (GAMP®5) for Control Systems
  - IEC 61131-3 Software architecture and programming languages of the control program within PLC
  - Quality System Regulation (QSR) CFR Title 21, Part 820 » California Building Standards Code (California Code of Regulations, Title 24) for Seismic Anchoring Requirements
  - ASME BPE standard, Bioprocessing Equipment for sanitary design

FEATURES

Control is a Programmable Logic Controller (PLC) system provided with operating interfaces, thermal printer, filter, breakers and all required hardware. Memory can contain up to ten processing cycles programmable (three factory-set cycles: Light, Medium and Heavy; one drying cycle) according to Customer preferences. Once a cycle is started, programmed cycle values are locked in and cannot be changed until cycle is complete. System is designed in accordance to Good Automated Manufacturing Practices (GAMP 5) guidelines.

Two standard PLCs are available::

- Allen-Bradley® CompactLogix™ controller series with PanelView Plus™ 7 1000 operator interface.[5]
- Siemens S7-1500 Controller with TP1200 Comfort Operator Interface.

USB Port supplied and easily accessible from unit load-side Control panel. Port provides connectivity for user to export cycle data.

Sanitary Spray System includes three rotary spray arms, one on each side of the chamber and a third on top of chamber, to optimize load coverage.

Manifolded Coupling System includes coupling on washer side wall capable of diverting recirculated solution on a manifolded loading cart. Same connector can be used for connection of a spray device for internal coverage containers.

Sumpless Solution Delivery System washer cabinet base is minimized to 7-1/4" (184 mm) deep by using independent staging tanks located within mechanical core. An in-line booster is located in recirculation system to provide fast heating of solutions.

Process Observation Window and Interior Light allow operator to verify cycle performance.

Single or Double Swing-Out Doors are insulated and made airtight/watertight by a silicone inflatable seal gasket to ensure process integrity. Electromagnetic lock on chamber door(s) ensures proper locking of chamber by adding a significant force. Double door configuration includes a door interlock system that allows for only one door to be opened at a time, preventing risk of cross-contamination.

Mechanical Core contains all critical components of Solution Delivery System. Mechanical core is placed on casters to allow easy access to system components and efficient installation. It is designed to increase accessibility to all system components. All piping is sanitary. Threaded legs providing adjustment are supplied to facilitate leveling of mechanical core.

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. An additional self-cleaning filter is located in recirculation system to prevent clogging of spray nozzles.

Pressure Transmitter is installed in recirculating piping to monitor pump pressure during wash and rinse treatments. This feature assures appropriate and consistent mechanical action is delivered throughout entire cycle.

Electronic Temperature Control. Sanitary Resistance Temperature Detectors (RTD) with transmitters are used to provide accurate control inputs and readouts throughout cycles. In-line RTD sensors are located just prior to spray jets to verify load sanitizing temperatures.

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

Process Monitoring Package. Several systems are used to monitor critical cleaning parameters including:

- Conductivity system used to monitor chemical concentration during wash phases. 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 cycle data.
- Sampling port enables safe collection of wash and rinse water samples.

Sampling Valve (installed in recirculation piping) allows for safe collection of wash or rinse water samples.

Drying Systems. Washer is equipped with a High-Efficiency Particulate Air (HEPA) filtered drying system to dry inner and outer surfaces of washer items, and interior of final rinse tank (optional), if necessary. All downstream surfaces from HEPA filter are 316 stainless steel. Chamber drying system is supplied with validation ports located on each side of HEPA filter. In both systems, drying is non-recirculated. In addition, a standard cool-down phase is included at cycle end, but can be adjusted by supervisor. Drying fan is activated, but drying coils are not functional; thus, air circulating inside chamber is not heated. System runs for a minimum of one minute at end of washing cycle, whether drying is selected or not, and until set temperature is reached (limited to 60 minutes).

One Chemical Injection Pump is included as standard. Two additional pumps can be added (as an option) to accommodate various chemicals. Pumps are provided with low level sensors and pick-up tubes. Customer supplied chemical containers are stored outside the unit, up to 8' (2.5 m) off the ground, and at a distance of up to 50' (15 m) from the washer.

Drain Discharge Cool Down is provided on 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 60°C (140°F) while being discharged to building drain system. Drain discharge cool down system can be activated or deactivated in accordance with local, state, and federal regulations.

Factory Acceptance Testing (FAT) includes verification of unit configuration 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 unit can reproduce cycle parameters recommended by Process And Cleaner Evaluation study (PACE), if applicable.

Stainless-Steel Tag (for Instrumentation) is attached to each instrument with a chain. Identification numbers are assigned by the factory.

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

Door Interlock System prevents both doors from being opened simultaneously. For pass-through (double door) washers, clean side/unload door cannot be opened until cycle has been completed. Unload door remains sealed up to five hours in case of a power failure.

Door Lock-Out Sensors prevent cycle from starting if door is not fully closed, and also stops washer operation if a door is opened during a cycle.

Emergency Stop Cables, located on each side of interior wash chamber, instantly stop washer operation if pulled down.

Control ON/OFF Selector Switch, located inside load side control panel, can be used to turn off control power for servicing unit.

Key Service Switch (a key-operated selector switch) is used to lock washer operation. It prevents a cycle from being started while servicing unit. It also resets unit if Emergency Stop button is pressed or emergency cables inside chamber are pulled.

Power Disconnect Switch (lockable, 3-phase nonfused disconnect switch) is located on cover of main electrical box.

Emergency Stop Buttons are supplied at both load and unload ends to de-energize all outputs to safe position when pressed in case of emergency.

CYCLE DESCRIPTION

Reliance 980PG Pharmaceutical Grade Washer operation is simple and fully automatic with minimal operator intervention required.

Washer features three factory-set cycles (Light, Medium and Heavy) that can be modified by operator; seven fully programmable cycles; and one drying cycle. Up to 15 recirculated or non-recirculated treatments, and nine final rinses can be programmed in any selected order for wash cycles.

Basic units offer a typical treatment schedule (factory-set Medium cycle) consisting of following:

- **Pre-Wash** (non-recirculated). Fresh water is sprayed (by spray arms only) over load for 60 seconds, then sent directly to drain, flushing self-cleaning filter instead of being recirculated over load.
- **Wash**. Fresh water is sprayed into chamber. Chemical is injected for 54 seconds by a selected chemical pump. Chemical concentration can be set from 00 to 360 seconds, or from 100 to 100,500 □Scm2. Solution is heated to 150°F (65.5°C) maximum temperature and recirculated under pump pressure for six minutes. Suction pump, which is activated at cycle beginning, continues to drain for one minute after recirculation pump has stopped. System is then drained by gravity once treatment is completed.
- **Rinse 1 and 2** (unheated). Fresh water is sprayed into chamber. Water is recirculated under pump pressure for 90 seconds. Suction pump, activated at cycle beginning, continues to drain for one minute after recirculation pump has stopped. System is then drained by gravity once treatment is completed.
- **Final Rinse** (non-recirculated). Water is sprayed over load for 25 seconds. Suction pump, which is activated at end of cycle, drains water for one minute; after one minute, sump is drained by gravity once treatment is completed. Following this sequence, a second identical phase is performed.
- **Drying**. Drying phase removes hot humid air from chamber. Selected time for this non-recirculated phase is 10 minutes and temperature setpoint is 65.2°C (149°F).

OPTIONAL FEATURES

STERIS provides a wide variety of standard options to enable the Customer to configure a unit to meet their application requirements with maximum flexibility.

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.

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.

Stainless-Steel Tags for Instrumentation With Customer Assigned Numbers. Identification numbers for instrumentation tags are provided by the Customer.

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 Manufacturing Documentation. Folder on USB Stick includes the following:

- Recirculation Piping Schematic
- HEPA Filter Certificate (if applicable)
- Heat Number Certificates
- Material Certificates
- Surface Finish Report for Chamber
- Welding Documentation[6]

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)

Instrument Index/ISA Style Data Sheet and Loop Diagram. Includes International Society of Automation (ISA) style component data sheets for main process instruments. Data sheet information consists of critical data such as STERIS item numbers, component type/usage, manufacturer, model

6. *Welding documentation is provided for the chamber, process piping and final rinse tank*

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 system. Components tag number (s), terminal number(s) and wire color are indicated in each diagram.

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

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

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

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

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.

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

Water Consumption per Fill[7]	Noise Level[8](enclosed)	Heat Loss
Main Tank (Recirculated): 40 U.S. gal (151.4 L) Final Rinse Tank: 37 U.S. GAL (140 L)	83.5 dBa	12,000 BTU/h (3540 W)

ACCESSORIES

Compressor is complete with tank and pressure switch. Oilless compressor operates at 50 dB (A). Wiring at installation not provided by STERIS.

Manifolded Loading Cart (heavy duty stainless-steel cart) is designed to support vessels, containers and miscellaneous components during wash procedure.

Exterior stainless-steel jacket package is provided to cover insulation on service and non-service sides.

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. Unit is delivered in three crates, ready for installation.
   - First crate contains chamber. (L x W x H): 2553 x 2108 x 2642 mm (100-1/2 x 83 x 104") Weight: 3150 lb (1429 kg).
   - Second crate contains mechanical core. (L x W x H): 2438 x 1219 x 2604 mm (96 x 48 x 102-1/2") Weight: 3050 lb (1384 kg).
   - Third crate contains remaining components. (L x W x H): 2438 x 1219 x 1384 mm (96 x 48 x 54-1/2) Weight: 900 lb (408 kg).
     All open pipe connections or pipes are plugged with caps to prevent the possibility of contamination.
2. Customer must assure the machine stands on a noncombustible floor.
3. STERIS recommends that shut off valves and vacuum breakers (not provided by STERIS) be installed on service lines, and that disconnect switches (with lockout in OFF position [not provided by STERIS]) be installed in electric supply lines near the equipment.
4. Pipe sizes shown indicate terminal outlets only. Building service lines, not provided by STERIS, must supply the specified pressures and flow rates.
5. Construction of the exhaust duct system from stainless steel is recommended. Seal the joints by welding to assure a corrosion resistant and leak proof system for removal of condensed vapor. The duct should have drip leg(s) installed at any low point(s).
6. Condensate to be connected to a non-pressurized gravity return main or vented condensate receiver. Add 3.45 kPa (1/2 psi) for each 305 mm (12") of condensate head pressure to the minimum dynamic steam pressure. Maximum rise not to exceed a total of 4.57 m (15') head.
7. STERIS recommends illumination of the service area (If applicable), along with provision of a convenience outlet for maintenance.
8. A 102 mm (4") O.D. floor drain is recommended with the floor sink.
9. This unit is not designed for use in areas that require explosion proof rated equipment.

7. Total consumption per cycle is dependent on the number of treatments selected for each cycle.
8. Calculated as described in ISO-3746 standard.

Refer to the Following Equipment Drawing for Installation Details	
Equipment Drawing Number	**Equipment Drawing Title**
10269498	Reliance 980PG Pharmaceutical Grade Washer

Selections Checked Below Apply To This Equipment

CONTROL

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

CONTROL LOCATION(Facing Load Side)

- ☐ Right
- ☐ Left

SWING -OUT DOORS

- ☐ Single
- ☐ Double

ACCESSORIES

- ☐ Compressor
- ☐ Manifolded Loading Cart
- ☐ Exterior stainless-steel jacket package

OPTIONS

- ☐ Load draining System
- ☐ Chamber Spray Arms Monitoring
- ☐ Coverage Tests
- ☐ Instrumentation Tags, Customer Assigned Numbers
- ☐ Compressor
- ☐ Connection to External Uninterruptible Power Supply (UPS)
- ☐ Additional Chemical Injection Pump (Maximum Two)
- ☐ Cleaning and Passivation Treatment
- ☐ Inlet Valve for Wash Tank (Maximum Two)
- ☐ Inlet Valve for Final Rinse Tank
- ☐ Heated Non-Recirculated Final Rinse
- ☐ Flanges on Steam Connections
- ☐ Stainless-Steel Cabinet Enclosure Panels (Single or Double Door)

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

Item:	
Locations:	

For Further Information, contact:

STERIS®
STERIS Corporation
5960 Heisley Rd.
Mentor, OH 44060–1834 ▪ USA
440–354–2600 ▪ 800–548–4873
www.steris.com

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