STERIS®

HAMO® T-420 PHARMACEUTICAL GRADE WASHER SIEMENS PC CONTROL

APPLICATION

For thorough efficient cleaning of various materials and components such as glassware, vessels, filling line components, and exchange parts utilized in the biotechnology and pharmaceutical manufacturing process industries.

DESCRIPTION

The Hamo T-420 Pharmaceutical Grade Washer is a cabinet-type washer equipped with a programmable PC control system. It simultaneously accepts up to two mixed loads of various sizes and shapes, increasing productivity.

Hamo pharmaceutical grade washers are 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 provides up to 99 fully programmable cycles, each cycle capable of performing up to 99 different phases.

Size (W x H x L)

- **Chamber load clearance:** 50-3/4 x 27-1/2 x 31-1/2" (1290 x 700 x 800 mm)
- **Overall dimensions:** 102-3/8 x 70-7/8 x 41-3/4" (2600 x 1800 x 1060 mm)
- **Loading height:** 31-5/8" (804 mm) from floor



(Typical only - some details may vary.)

STANDARDS

The washer meets the applicable requirements of the following standards:

- **Current Good Manufacturing Practices (cGMP)**
- **Governing Directive for affixing of the CE Mark:** Machinery Directive (98/37/EC).
- **Conformity to other applicable directives:** Electromagnetic Compatibility Directive 89/336/EEC amended by Directive 91/263/EEC, Directive 92/31/EEC, and Directive 93/68/EEC.
- Low Voltage Directive 73/23/EEC amended by Directive 93/68/EEC.

The Selections Checked Below Apply To This Equipment

CHAMBER HEIGHT
- ☐ 27-1/2" (700 mm)
- ☐ 39-3/8" (1000 mm)

DOOR TYPE
- ☐ Single
- ☐ Double

HEATING
- ☐ Steam
- ☐ Electric*

OPTIONS
- ☐ 480 V, 3-Phase, 60 Hz
- ☐ 230 V, 3-Phase, 50 Hz
- ☐ 200 V, 3-Phase, 50 Hz
- ☐ 200 V (208 V), 3-Phase, 60 Hz
- ☐ 400 V, 3-Phase, 50 Hz
- ☐ 400 V, 3-Phase, 60 Hz
- ☐ In-line Sanitary Steam Heat Exchanger Water (Steam Heated Units Only)
- ☐ Independent Rinse System, Including Coupler and Air Blow Out†
- ☐ Monitoring Wash Arm Rotation
- ☐ Monitoring Direct Rinse Arm Rotation (Unit with Independent Rinse Option Only)
- ☐ Flow Meter on Dosing Pump 1
- ☐ Flow Meter on Dosing Pump 2
- ☐ Flow Meter on Dosing Pump 3
- ☐ Sanitary Water Inlet Valve Maximum 3
- ☐ Ventilation Connection/Condensation Collector System
- ☐ Air Heat Recovery System
- ☐ Isometric Piping Drawings with Weld Log
- ☐ Bar Code Reader
- ☐ Software Documentation Package FS/SDS/HDS
- ☐ Pre-filter F8
- ☐ PDVS Sensor Package: Water Temperature, Water Pressure, and Air Temperature

** Not recommended if water is heated above 180°F (82°C) on units with 39-3/8" (1000 mm) chamber height.*

† Requires special accessories and process air.

Item _____

Location(s)_____

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- **Standards applied to demonstrate conformity to the directives:**
  - **EN 60204-1,** Safety of machinery – electrical equipment of machines, – Part 1: General requirements
  - **EN 12100-1:2003,** Safety of machinery – basic concepts, general principles for design – Part 1: Basic terminology, methodology
  - **EN 12100-2:2003,** Safety of machinery – basic concepts, general principles for design – Part 2: Technical principles and specifications

FEATURES

Control (single or double door) – An Industrial Panel PC (IPC) controller system (Siemens Simatic Panel 670) is provided with an operating interface (Color TFT touch-screen resistive) and all required hardware. The memory accommodates up to 99 processing cycles, programmable according to customer preferences. The cycle phase times, temperatures, and other key process parameters are also programmable. Once a cycle is started, the programmed cycle values are locked in and cannot be changed until the cycle is complete.

Three Sump Inlet Ports. Standard unit is equipped with three chamber inlet ports for process water.

Automatic Single Door/Automatic Double Door. Vertical rising door(s) is automatically opened by an electric motor and belt. The door(s) on units with 27-1/2" (700 mm) chamber is equipped with full glass windows allowing the operator to see the cleaning process and spray arms rotation. 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 and equipped with a safety switch and obstruction sensor.

Pump Outlet Pressure Transmitter. A pressure transmitter at the recirculation pump outlet monitors pressure and eases validation of the cleaning process. The product surface is 316L stainless steel.

Sampling Valve. A manual membrane valve is provided to facilitate sampling of wash solution or rinse water. The valve is made of 316L stainless steel and is fitted with tri-clamp connections.

Dual Spray System. The washer includes two connectors located on each side of the chamber that automatically connect to the removable baskets. The washer includes two top-mounted and two bottom-mounted rotary spray headers (316L stainless steel) in the wash chamber to optimize load coverage and cycle time.

Service Panels on the front and back of the washer provide access to all components including piping, valves, electrical components, and wiring.

Detergent Pumps. Three peristaltic dosing pumps are included in order to accommodate various chemicals. The pumps are provided with 6'.0" (2 m) long hoses, filter screens, and check valves. The customer-supplied chemical containers are stored outside the unit.

Removable Stainless-Steel Debris Filters, located in the bottom of the wash chamber (sump), prevent large debris from entering the piping system and pump and prevent clogging of the spray nozzles. All filters are easily removed for cleaning.

HEPA-Filtered Drying System. The unit is provided with a HEPA-filtered drying system to dry both inner and outer surfaces of washed items. The system includes a (3 HP) 2.2 kW blower and a 12 kW electric heater.

Conductivity Validation System. The unit is provided with conductivity probes and controls to measure the conductivity of final rinse water during a cycle. This system monitors the conductivity level and controls the number of rinses to achieve the final rinse water setpoint.

Factory Acceptance Testing. The basic Factory Acceptance Testing (FAT) includes the verification of the configuration of the unit and accessories, verification of instrumentation calibration, verification of cycle operation, testing of all inputs and outputs, review of engineering, manufacturing, and qualification documentation, as well as demonstration that the unit can reproduce the cycle parameters recommended by the Process And Cleaner Evaluation (PACE®) study (if applicable).

Tags for Instrumentation.* The identification numbers are assigned by the factory.

* *Each instrument is labeled with an instrumentation tag.*

Validation Documentation. As standard, all units are provided with two copies of the following documentation binders:

- **Operation and Technical Documentation** including:
  - » Set-up
  - » Instructions
  - » Operating Instructions
  - » Technical Data
  - » System Functions
  - » Safety Information
  - » Maintenance, Replacement of Parts
  - » Spare Parts List
  - » Software for PC
  - » Editing Washing Cycles
  - » Process Data Visualization System (PDVS on Machine Probes)
  - » Definitions
  - » Description of Special Modules (if applicable)
  - » Folder with Recovery Boot Floppy Disk, and Hard Disk Image on CD
  - » Schematic
- **Qualification Documentation** including:
  - » Introduction
  - » Project Information, Content, Guide to Use the Document, Order Confirmation
  - » Project Description
  - » Washer Specifications
  - » Project Certificates
  - » Hamo Certificates and Project Drawings
  - » Calibration Certificates
  - » System Test Report (FAT documentation)
  - » Parts List (listed numerically and alphabetically)
  - » Parts Data Sheets and Certificates
  - » Description of Special Modules and Accessories (if applicable)
  - » Special Processes

SAFETY FEATURES

Safety Door Switch prevents a cycle from starting if the door is not fully closed, and also stops washer operation if a door is opened during a cycle.

Safety Door Strip at the bottom of the door prevents the door from closing in the event of an obstruction.

Power Disconnect Switch. A 3-Phase, non-fused disconnect switch is located on the facia panel on the load end of the washer.

Pressure Switch mounted on the air supply line shuts off the unit if air pressure drops below operating level.

Emergency Stop Button(s) is supplied at the load end (and unload end, if applicable) to de-energize all outputs to safe position when pressed in case of emergency.

Pressure Safety Switch on Dryer System. A pressure switch in the drying air circulation system monitors air pressure in the system. If the pressure drops below the set level, the unit stops and shows an alarm. The switch is provided on electric heated units only.

CYCLE DESCRIPTION

Hamo T-420 Pharmaceutical Grade Washer features 99 programmable cycles. Each cycle can include up to 99 different phases or treatments. The treatment time can be adjustable from 0-99 hours, 59 minutes, and 59 seconds. Temperature can be set from 86-199°F (30-93°C) for pre-wash, wash, neutralize, rinse, final rinse, and cool down cycles. Once the cycle is selected, the washer automatically processes the load through the programmed treatments.

All cycles can be modified by the operator to include the following typical treatments:

- **PRE-WASH.** The sump is filled by selected water. The solution is then sprayed over the load and inside items under pump pressure. The timer starts according to the timing selection. The solution is drained by gravity after the cycle is complete.
- **WASH.** The sump is filled with selected water and the chemical is injected in the sump according to the setpoint. The solution is then sprayed under pump pressure over the load and inside the items while being heated up to the setpoint. The timer starts according to the timing selection. The system is drained by gravity once the treatment is complete.
- **NEUTRALIZE.** The sump is filled with selected water. The chemical is injected in the sump according to the setpoint. The solution is then sprayed under sump pressure over the load and inside the items while being heated up to the setpoint. The timer starts according to the timing selection. The system is drained by gravity once the treatment is complete.
- **RINSE.** The sump is filled with selected water. The solution is then sprayed under pump pressure over the load and inside the items while being heated up to the setpoint. The timer starts according to the timing selection. The system is drained by gravity once the treatment is complete.
- **FINAL RINSE.** The sump is filled with selected water. The solution is then sprayed under pressure over the load and inside the items while being heated to the setpoint. The timer starts according to the timing selection. Upon completion of the cycle, conductivity of the rinse water is verified. The phase is repeated until the setpoint is reached or until the allowable maximum number of rinses is reached. The alarm sounds and the system is drained by gravity once the treatment is complete.
- **DRYING.** Heated filtered air is injected into the chamber and in the baskets according to the time and temperature selection. The humid air is evacuated through the exhaust system. The drying phase is programmable from 0-99 hours, 59 minutes, and 59 seconds with a temperature range of 86-248°F (30-120°C).
- **COOL DOWN.** The filtered air is injected into the chamber and in the baskets according to time and temperature selection. Humid air is evacuated through the exhaust system.

OPTIONAL FEATURES

A wide variety of regular options are available, allowing the customer to configure a unit to meet specific application requirements with maximum flexibility.

In-line Sanitary Heat Exchanger. The heat coil located by the sump is replaced with two double-shell sanitary heat exchangers located in the recirculation piping system.

NOTE: This option is available for steam heated units only.

Independent Rinse System. The machine can be equipped with a completely independent, non-recirculated final rinse sanitary piping system. The pure water is directly fed from the supply line to a separate set of spray arms. The pure water is also directed to separate spindles on the baskets through an automatic coupling system. After the rinse is complete, the piping and spray systems can be dried using compressed process air. Rinsing and drying sequences can be programmed to alternate between internal and external surfaces for the right or left basket.

NOTE: Special baskets and process air are required for this option.

Monitoring of Wash Arms Rotation. The wash spray arms rotation can be monitored using proximity sensors that are located on the sides of the wash chamber. This system verifies that constant coverage is provided.

Monitoring of Independent Rinse Wash Arms Rotation. Independent rinse-wash-spray-arms rotation can be monitored using proximity sensors located on the sides of the wash chamber. This system verifies that constant coverage is provided during the non-recirculated final rinse.

NOTE: Only available when the independent rinse option is selected.

Flow Meter on Dosing Pumps (Up to Three). Flow meters can be added in the detergent injection lines to measure the quality of detergent that is injected during the wash cycles. The following options can be selected:

- Flow meter for dosing pump 1
- Flow meter for dosing pump 2
- Flow meter for dosing pump 3

Sanitary Water Inlet Valves (Up to Three). The standard washer is supplied without water filling valves. Electrical contact and pneumatic pilot valves are supplied to activate customer provided valves. Optional diaphragm valves can be provided by STERIS and installed on the machine at the factory using a tri-clamp connection.

Ventilation Connection/Condensation Collector System. The system reduces the amount of vapor that is discharged in the ventilation system. It includes a 316L stainless-steel hopper to collect condensed vapor and direct the water to the main drain connection.

Air Heat Recovery System. The air heat recovery system is installed on the top of the machine. The incoming drying air is preheated from the hot outlet drying air. The hot outlet drying air is cooled down; the collected condensed vapor is drained directly to the machine drain. This option includes all internal connections and is made of 316L stainless steel.

Bar Code Reader. A wireless, handheld bar code reader is provided to read bar code tags or labels that are attached to the baskets or the load itself. The code is transmitted to the control system, which can then automatically select the appropriate cycle from a local or remote data base.

Pre-filter F8. An additional filter can be installed at the inlet of the drying blower.

PDVS Sensor Package. Process Data Validation System (PDVS) is an on-line, real time system used to monitor and record critical process parameters during the cycles. The data is compared to validated cycles that are stored in the master data file. The option includes the software, additional pump pressure transmitter, water, and air temperature probes. The PDVS stops the program and displays a clear text error message should the monitored parameters not correspond to the set parameters.

Isometric Piping Drawings and Weld Logs. The following documents are provided:

- Welder Certificates
- Weld Logs for Sanitary Piping
- Description of Passivation and Electrolythical Polishing
- Isometric Drawings for Piping System
- Print-outs from Orbital Welding Machines

Software Documentation Package. The binder includes the following additional information on the control system and software:

- Software History
- Functional Specifications
- Hardware Specifications
- Software Design Specifications

Voltage Options. The washer operates on 400 V, 3-Phase, 50 Hz but can be modified to operate with the following voltages:

- 230 V, 3-Phase, 50 Hz
- 200 V, 3-Phase, 50Hz
- 200 V, (208 V), 3-Phase, 60 Hz
- 400 V, 3-Phase, 60 Hz
- 480 V, 3-Phase, 60 Hz

CONSTRUCTION

All components of the wash/rinse system, including rotary spray arms, piping, and valves are constructed of 316L stainless steel.

The wash chamber and sump are constructed of 14 gauge (0.078) 316L stainless steel. The chamber does not contain spot welds or overlap surfaces. It is designed to inhibit corrosive action and allow for easy cleaning. The wash chamber and sump do not present any exposed threads. The welds are polished and grounded to 3/4" (20 mm) radius minimum. The flat surfaces are reduced to minimum and sloped to verify complete drainage. The chamber is available with two different loading heights; 27-1/2" (700 mm) and 39-3/8" (1000 mm). The interior surface is polished to a 0.4 μm (0.8 for welds) Ra (15-32 μinch).

The welding process meets GMP standards. All wetted parts welds are 100% penetration welded, using argon shielding gas.

The chamber is insulated with 1/2" (13 mm) thick chloride free melamine resin based foam, fiberglass insulation with a vapor barrier covering top, sides, and bottom to minimize noise and heat loss.

The wash chamber is illuminated by two sanitary mounted lighting fixtures located outside of the wash compartment. The lighting fixtures facilitate visual verification of the wash process.

ENGINEERING DATA

Shipping Weight:	2000 lb (900 kg)
Operating Weight:	1543 lb (700 kg)
A-weighted Equivalent: Surface Sound Pressure Level	67 dBa
Max. Water Consumption/Fill:	20 U.S. gal (75 L)
Max. Steam Consumption: » per Heated Treatment*	29 lb (13 kg)

* *Total consumption per cycle is dependent on the number of treatments selected for each cycle.*

The bottom of the wash chamber is equipped with two 316L stainless-steel debris screens to prevent large debris from entering the piping system and pump. The filter is manufactured with smaller openings than jet orifices, to prevent the jets from clogging. The filter is easily removed for cleaning.

The water inlets are located on top of the chamber to prevent backflow of water at point of interconnection.

The sump is equipped with a pressure transmitter for water level control, and optional filling valves.

The sump capacity is approximately 20 gal (75 L). The sump is equipped with a removable, sanitary, 316L stainless-steel heating coil, valve, and trap to raise and maintain the water temperature. The steam piping is also made of 316L stainless steel.

NOTE: The steam coil is not applicable if the sanitary heat exchanger option is selected.

The electric heated units are fitted with electrical heating elements 24 kW.

The wash chamber loading capacity is 130-175 lb (60-80 kg), excluding the weight of the accessory, depending on the baskets configuration.

All water connections to the chamber/sump are made with tri-clamps. The chamber and doors form a positive seal for air and water, maintaining the barrier wall integrity.

The unit is fitted with sanitary connection ports to be used with optional probes for the Process Data Validation System (PDVS). Water temperature, air temperature, and pump pressure ports are provided.

All treatments are under pressure of a 10 HP (7.5 kW) 316L stainless-steel sanitary pump rated at 264 gal/min (1000 L/min) at 50' (15 m) head pressure.

Diaphragm valves are used on the drying and drain piping. Butterfly valves are used for the recirculation system. The valves are made of 316L stainless steel with an interior finish of 25 micro-inch as Ra (0.6 micron).

The washer frame, cabinet, and fasteners are made of 304L stainless steel.

Leveling legs are included to facilitate the installation.

PREVENTIVE MAINTENANCE

A global network of skilled service specialists can help provide periodic inspections and adjustments to verify low-cost peak performance. STERIS representatives can provide information regarding annual maintenance agreements.

STERIS AG, a subsidiary of
STERIS Corporation
Pieterlen, Switzerland is an
ISO 9001:2000 and ISO 13485:2003
certified facility.

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

NOTES

1. The customer must verify the machine stands on a non-combustible floor.
2. The shut-off valves, vacuum breakers, and fused disconnect switch (not by STERIS) should be installed on the utility lines as required on the equipment.
3. The pipe sizes shown indicate terminal outlet only.
4. The connections should be in accordance with local codes.
5. The unit crate size is (W x H x L) 110-1/4 x 98-1/2 x 47-1/4" (2800 x 2500 x 1200 mm).
6. It is recommended the duct system (not by STERIS) be constructed of stainless steel. Seal the joints by welding to verify a corrosion resistant and leakproof system for removal of condensed vapor.
7. Steam condensate is 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 is not to exceed a total of 15' (4.57 m) head.
8. A 4" (102 mm) OD floor drain is recommended with floor sink.

UTILITY REQUIREMENTS

Cold Water Inlet (1)
Tri-clamp 1" (25 mm);
35-72 psig (2.5-5.0 bar);
75°F (24°C) max;
6.6 U.S. gal/min (25 L/min);
20 U.S. gal/Phase (75 L/Phase)

Hot Water Inlet (2)
Tri-clamp 1" (25 mm);
35-72 psig (2.5-5.0 bar);
100°F (40-85°C) max;
6.6 U.S. gal/min (25 L/min);
20 U.S. gal/Phase (75 L/Phase)

Pure Water Inlet (3)
Tri-clamp 1" (25 mm);
35-72 psig (2.5-5.0 bar);
68-185°F (20-85°C);
6.6 U.S. gal/min (25 L/min);
20 U.S. gal/Phase (75 L/Phase)

Drain Outlet (4)
Tri-clamp 3" (76 mm);
26 U.S. gal/min (100 L/min),
Max. 200°F (93°C)

Electricity (5)
Electric Heated Units
400 V, 3-Phase, 50 Hz, 54 Amp
480 V, 3-Phase, 60 Hz, 45 Amp
400 V, 3-Phase, 60 Hz, 54 Amp
230 V, 3-Phase, 50 Hz, 93 Amp
200 V, 3-Phase, 50 Hz, 107 Amp
200 V, 3-Phase, 60 Hz, 107 Amp

Steam Heated Units
400 V, 3-Phase, 50 Hz, 26 Amp
480 V, 3-Phase, 60 Hz, 22 Amp
400 V, 3-Phase, 60 Hz, 26 Amp
230 V, 3-Phase, 50 Hz, 46 Amp
200 V, 3-Phase, 50 Hz, 52 Amp
200 V, 3-Phase, 60 Hz, 52 Amp

Steam (If Applicable) (6)
DN15; Flange;
30-72 psig (2.1-5.0 bar);
250 lb/hr (113 kg/h);
29 lbs (13 kg)/Heated Phase

Condensate Return (If Applicable) (7)
DN15; Flange;
0.5 U.S. gal/min (1.88 L/min)

Exhaust (8)
6-5/8" (168 mm); OD; 50 Pascal
Negative Static Pressure;
353 scfm (10 m^3/min)

Plant Compressed Air (9)
3/8" (8 mm); Quick Connection;
70-85 psig (5-6.0 bar) Dynamic;
1 scfm (.025 m^3/min)

WFI (Independent Rinse Option) (10)
Tri-clamp 1" (25 mm);
35-72 psig (2.5-5.0 bar);
68-185°F (20-85°C);
16 U.S. gal/min (60 L/min);
According to cycle time

Process Air (Independent Rinse Option) (11)
Tri-clamp 1" (25 mm)
35-72 psig (2.5-5.0 bar);
10 scfm (0.25 m^3/min)

Air Inlet for Drying System (12)
4-1/2" (114 mm) OD;
353 scfm (10 m^3/min)

Modem (13)

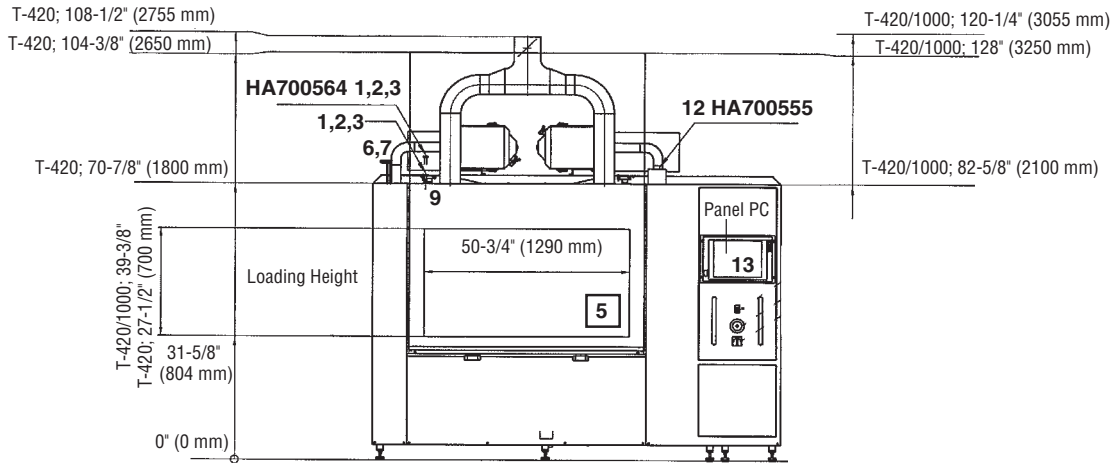
CUSTOMER IS RESPONSIBLE FOR COMPLIANCE WITH APPLICABLE LOCAL AND NATIONAL CODES AND REGULATIONS.

Dimensions shown here are typical, and subject to change without notice.
REFER TO STERIS EQUIPMENT DRAWINGS FOR COMPLETE AND DETAILED INSTALLATION SPECIFICATIONS.

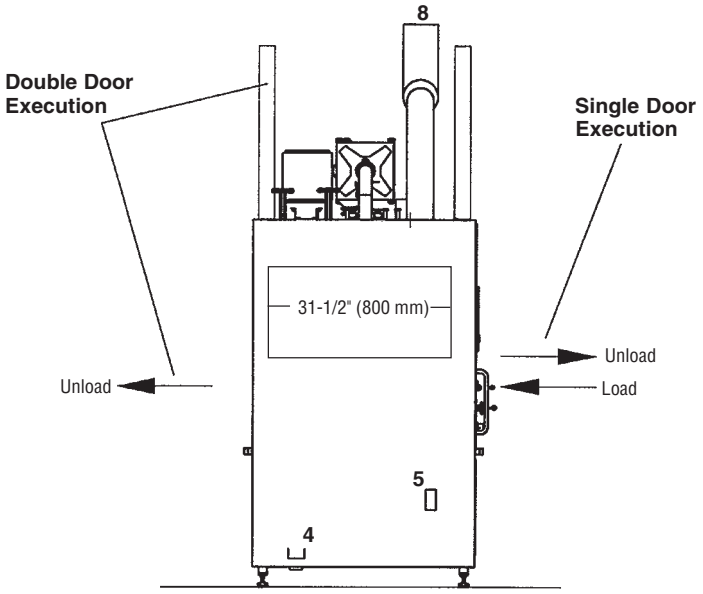
Dimensions are inches (millimeters)

NOTE: Drawing is not to scale.

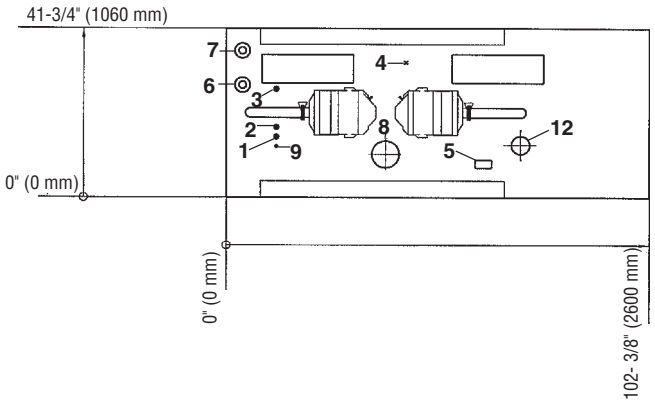
Front View



Left Side View



Top View



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