

GIRTON VIAL EXTERIOR WASHER/DRYER MODEL GV150S

1. DESCRIPTION

The washer shall be a completely package tunnel washer type unit with all piping and electrical wiring for single service connections. The machine is designed to wash liquids and hygroscopic dust from the exteriors of filled and closed glass vials.

2. REGULATIONS, CODES AND STANDARDS

All engineering, design, manufacture and testing conforms to all applicable sections of the latest edition of the following codes, standards and specifications in effect at the time of order:

ASME-BPE - American Society of Mechanical Engineers

ANSI - American National Standard Institute

ASTM - American Society for Testing and Materials

OSHA - Occupation Safety and Health Administration

NEMA - National Electrical Manufacturers Associates

NEC - National Electrical Code

cGMP - Current Good Manufacturing Practices (CFR Title 21 parts 210 and 211)

NFPA - National Fire Protection Association

3. DIMENSIONS AND WEIGHT

- 3.1. Left Right Hand
- 3.2. Load Height: 36"
- 3.3. Overall Height: 48"
- 3.4. Overall Width: 36"
- 3.5. Overall Length: 130"
- 3.6. Operational Weight: 750 lbs.

4. CONSTRUCTION

4.1. Material Type and Finish:

- 4.1.1. **Washer Cabinet:** 14 gauge, T-304 T-316L stainless steel
Interior Finish: mill finish (2B) 35Ra or better 15Ra 8.5Ra
Exterior Finish: 35Ra or better
- 4.1.2. **Washer Tank:** 14 gauge, T-304 T-316L stainless steel
Interior Finish: mill finish (2B) 35Ra or better 15Ra 8.5Ra
Exterior Finish: 35Ra or better
- 4.1.3. **Compressed Air:**
Tubing Poly-flo T-304 stainless steel.
- 4.1.4. **Potable Water Supply Ball Valves:** T-304 stainless steel
- 4.1.5. **Water Jets and Piping:** T-316L stainless steel
Interior Finish: 35Ra or better Electro-polished to 15 Ra finish 20Ra
Exterior Finish: 35Ra or better
- 4.1.6. **Tri-Clamp Clamps:** T-304 stainless steel
- 4.1.7. **Fasteners:** T-304 stainless steel

4.2. Unit Design:

- The equipment is designed to be shipped and installed as a **single unit**. Some parts may be

removed prior to shipping (i.e., pumps) to decrease the possibility of damages during shipping. The maximum crate size will be approximately _____" x _____" x _____" with an estimated weight of _____ lbs.

4.3. **Size of Vials:**

2 ml through 200 ml.

Note: Other sizes can also be handled. Consult factory.

4.4. **Capacity:**

300 units pre minute, average 10 ml size.

150 units per minute, average 100 ml size.

Note: Proper adjustment of guides, jets, and pressure is important for different sizes to properly wash, dry, and maintain stability of the vials.

4.5. All **internal corners** have a minimum 5/16" radius.

4.6. See enclosed **Girton's Welding Specification** for information on current in-house welding procedures.

4.7. All visible **welds** on the exterior of the washing compartment are thoroughly cleaned. All welds on the interior of the washing compartment are ground and polished.

4.8. The **cabinet interior** is constructed to permit free draining and designed not to retain any of the process solutions.

4.9. **Upper portion of washer/dryer** will consist of removable covers, fabricated of clear acrylic plastic.

4.10. **Wash header** will be of a design to direct a soft flow of warm water from facility supply over the vials. The jets will be fully adjustable in all directions to accommodate the variety of vials, to allow the tops to stay dry, and to maintain the stability of the vials. The water supply to the washer/dryer is pressure regulated to control the water flow.

4.11. **Compressed air blow-off** will be of a design to direct a soft flow of clean oil free air from the facility supply over the vials for drying. The jets will be fully adjustable in all directions to accommodate the variety of vials, and to maintain the stability of the vials. The air supply to the washer/dryer will be regulated to control the airflow.

4.12. **Conveyor** - The washer/dryer will be provided with a stainless steel mesh type belt, running on UHMW plastic wear strips, to convey the vials through the unit. The conveyor will have individual belts in the wash and drying section. A single DC variable speed drive motor will power the conveyor system. Belt speed will be variable from 0 to 40 feet per minute. Infeed belt speed will be faster than discharge belt speed to maintain stability of vials. Adjustable drive rollers will be provided to assure proper tracking of conveyor belts.

4.13. **Vial guides** - Fully adjustable plastic guides are provided to control the full line of vial sizes through the wash and dry treatments.

4.14. **Legs** - The machine will be provided with stainless steel tubing legs with sanitary adjustable ball feet. Sufficient clearance will be maintained underneath the machine for proper sanitation.

4.15. A **removable door** is provided to provide the necessary access for maintenance to those items located under the washer.

4.16. **Potable water supply ball valves** are threaded connections.

4.17. All **ancillary valves and equipment are positioned** on the washing machine rear and the bottom of the washer.

4.18. **Tri-clamp connection** use **EPDM gaskets** and are connected by means of heavy-duty clamps with wing nuts.

4.19. **Seals, gaskets, and bearings** are compatible with the temperatures and concentrations of cleaning agents to be used. Customer will supply information on chemicals to be used.

4.20. A **compressed air system** is supplied with a filter regulator.

4.21. The washer is piped and wired for **single service connection** for each utility requirement.

5. CONTROLS AND OPERATION

- 5.1. The control system incorporates an **Allen Bradley Compact Logix @PLC**. This provides 512K of memory with Ethernet communication ability. The processor is aware of and controls all items on the washer. I/O cards are selected to match the control voltage. An isolated relay card is used to control high current draw items or items not operable at the control voltage. Analog cards are set to accept 4 - 20 mA inputs, unless otherwise noted.
- 5.2. The operator-machine consists of an **Allen Bradley Color Panelview Plus 600**, which incorporates a touch screen for operator control. This allows the user with proper password level to access all parameters of a wash recipe. All alarms are shown on the display, as well as announced audibly.
- 5.3. The washer is provided with the ability to use a printer to record operation reports. The customer should mount the printer close to the washer. Communication to the printer is RS232C so the maximum recommended distance from the washer is 50 ft. The report contains the following data: machine identification, operator, date and time, step name with time, temperature (min-max), etc.
- 5.4. Girton provides three levels of **password protection** to the control system:
 - Operator Level – access to selection of existing programs only
 - Maintenance Level – access to all maintenance screens
 - Engineering Level – access to all levels. Allows changes to be made to existing programs and new programs to be developed.
- 5.5. Girton's control system provides the ability to **alarm on abnormal conditions**. The washer has alarms based on each I/O point failure. This provides a comprehensive way of determining a device failure or process deviation. In general, all analog inputs to the system will have low and high alarm points settable by the customer. Also, all safety devices, such as door switches or emergency stop buttons, have alarms associated with them.
- 5.6. **Fused disconnect switch** is supplied and located in the main electrical enclosure to cut power to the entire unit. The system is designed so if the disconnect is in the "ON" position the electrical enclosure is not be able to be opened.
- 5.7. The washer is equipped with **Emergency Stop** switches located at critical points on the machine. All doors are equipped with limit switches wired directly to the output voltage. Opening any door will disconnect voltage from output cards thereby shutting down the system. These switches are also wired as inputs to the PLC so that an alarm may be generated. All services are equipped with fail-closed-valves.
- 5.8. See enclosed **Girton's Electrical Specification** for information on wiring, conduit, tagging, instrument installation and color-coding.
- 5.9. **Noise level** as measured from 3 ft. from the washer will be a **minimum of 85 dBa**.

6. DOCUMENTATION

- 6.1. **3 Hard copies and 1 electronic copy of Girton Documentation Package.** Validation requirements and considerations are playing an increasingly major role in the purchase of new equipment or systems. Validation requires documented evidence that the equipment or system will reliably perform in a manner consistent with the original design specifications. Generation of this documentation needs to be considered at the inception of the project and implemented throughout the design and manufacturing stages of the equipment. In most instances, the equipment vendor is the most qualified party to generate the majority of the required documentation.

The documentation provided by Girton Manufacturing Co., Inc. is designed to be a complete package including all data and checklists necessary to qualify the installation and operation of the equipment and/or system. All equipment built by Girton is completely factory assembled and tested. The documentation is used to perform Factory Acceptance Testing; witnessed and approved by the customer. All tests necessary for Installation and Operation Qualification of the equipment are performed on the equipment prior to its arrival on the job-site. Any modifications or additions required to qualify the equipment can be made at the factory prior to shipment.

This index lists all documentation supplied by Girton Manufacturing Co., Inc.

1 DRAWINGS

DRAWINGS

Installation/General Arrangement

P&ID – Piping and Instrumentation Drawing

ELECTRICAL SCHEMATICS & PANEL DRAWINGS

ELECTRICAL SCHEMATICS - 3 Phase Wiring Diagrams, Control Wiring Diagrams, I/O Wiring Diagrams

PANEL LAYOUTS - PLC Panel Layout, Motor Starter Panel Layout

AIR PIPING SCHEMATICS

2 EQUIPMENT DATA

INSTRUMENT LIST

Tag numbers, manufacturer, model number, serial number, and description for all instruments installed on the washer.

MECHANICAL EQUIPMENT LIST

Component description, manufacturer, model number, and materials of construction.

CONTROL SYSTEM COMPONENT LIST

Tag numbers, manufacturer, model number, serial number, and description for all control system components installed on the washer.

EQUIPMENT LUBRICATION LIST

List of lubricants used to maintain the washer.

USER MANUAL

Instructions for operating the equipment including loading, unloading, control system operation, and safety precautions. Maintenance schedules and repair procedures for all equipment and instruments.

CALIBRATION AND CERTIFICATION

Calibration sheets, certifications and procedures for calibrating all critical instruments provided by Girton.

(SHORT TERM) PRICED SPARE PARTS LIST

PRICED SPARE PARTS LIST

Listing of replacement parts and their corresponding order numbers. Instructions on information required when ordering replacement parts.

COMPONENT CATALOG BROCHURES

Manufacturer's catalog information concerning installation, operation, and maintenance procedures for all purchased mechanical equipment and instruments.

CUSTOMER SERVICE POLICY

Tells about the warranty, damages, replacement parts, returned merchandise, field service, cancellation, and special equipment.

3 SOFTWARE DATA

QUALITY AND PROJECT PLAN

Defines the quality and project objectives for the washer and its automated control system.

FUNCTIONAL SPECIFICATION

Outlines functional requirements for the equipment.

HMI & PLC DESIGN SPECIFICATIONS

This document defines the hardware and software specifications for the washer and its component parts. The purpose of this document is to describe the complete operation of the automated process control system for the washer.

PROGRAMS ON CD

RS VIEW

Reports generated by the display software, which define screen elements and tag numbers corresponding to PLC addresses.

PLC RS LOGIX 500 PROJECT REPORT

Annotated listing of all code used to implement the software design.

4 FACTORY ACCEPTANCE TEST

ABXXX FAT Instructions / Reference
ABXXX Section 02 FAT Approval Drawing Review Test
ABXXX Section 03 FAT Instrument Tests
ABXXX Section 04 FAT Mechanical Equipment Tests
ABXXX Section 05 FAT Electrical Tests
ABXXX Section 06 FAT Utility Tests
ABXXX Section 07 FAT Control System Hardware Tests
ABXXX Section 08 FAT Control System Software Tests
ABXXX Section 09 FAT Calibration Tests
ABXXX Section 10 FAT HMI Tests
ABXXX Section 11 FAT Operation Tests
ABXXX Section 12 FAT Alarm Tests
ABXXX Section 13 FAT Power Failure Tests
ABXXX Section 14 FAT Summary Report Tests
ABXXX Section 15 FAT Project Tests
ABXXX FAT Signature Log
ABXXX FAT Instrument Log
ABXXX FAT Exception Log
ABXXX FAT Test Progress Sheet
ABXXX FAT Exception Form

5 PASSIVATION & PUNCHLIST REPORTS

Passivation Procedure
Passivation Report
Completed Punchlist

VOLUME 3 OF 4

6 SITE ACCEPTANCE TEST

ABXXX SAT Instructions / Reference
ABXXX Section 02 SAT Approval Drawing Review Test
ABXXX Section 03 SAT Instrument Tests
ABXXX Section 04 SAT Mechanical Equipment Tests
ABXXX Section 05 SAT Electrical Tests
ABXXX Section 06 SAT Utility Tests
ABXXX Section 07 SAT Control System Hardware Tests
ABXXX Section 08 SAT Control System Software Tests
ABXXX Section 09 SAT Calibration Tests
ABXXX Section 10 SAT HMI Tests
ABXXX Section 11 SAT Operation Tests
ABXXX Section 12 SAT Alarm Tests
ABXXX Section 13 SAT Power Failure Tests
ABXXX Section 14 SAT Summary Report Tests
ABXXX Section 15 FAT Project Tests
ABXXX SAT Signature Log
ABXXX SAT Instrument Log
ABXXX SAT Exception Log
ABXXX SAT Test Progress Sheet
ABXXX SAT Exception Form

7 WELDING

Procedure Qualification Record (PQR)

Weld Procedure Specifications (WPS)
Welding Procedure Qualifications (WPQ)
Weld Inspector Qualifications
Weld Logs and Weld Maps.

8 CERTIFICATIONS

Material Certifications sent with raw materials and some instruments ordered specifically for this project

Work Order Trace Report
Material Test Reports
Certificates of Conformance/Compliance

7. SERVICE REQUIREMENTS

- 7.1. **Electrical:** 1 phase, 60 cycle, 120 volt, _____ amperes.
- 7.2. **Hot Water:** 180°F. Recommended minimum rate of flow of 7.5 gallons per minute. 1/2" T-C connection to the machine.
- 7.3. **Drain:** 2" NPT from the machine to the drain.
- 7.4. **Compressed Air:** 1/2" T-C connection, 25-PSI minimum, 25 CFM.

8. WARRANTY

- 8.1. Girton Manufacturing Co., Inc. warrants equipment of original manufacture against defect in workmanship and material for a period of one year from date of shipment. Provided; however, the equipment has been operated under normal working conditions for such said equipment, that it has been properly serviced and cared for, and that no adjustments have been made by unauthorized personnel that could adversely affect the operation or life of the equipment.

Girton Manufacturing Co., Inc. will replace or repair defective merchandise at its plant, FOB Millville, PA, if after inspection; the equipment or components that Girton manufactured are defective. Girton Manufacturing Co., Inc. extends to its customers on all purchased components parts, the warranty of the supplier of such said parts.

No expense, liability, or responsibility will be assumed by Girton for repairs outside Girton's factory, without written authority from Girton Manufacturing Co., Inc.

The foregoing warranty excludes all other warranties, guaranties, and/or representations; whether expressed, implies, or oral, INCLUDING, BUT NOT LIMITED TO, ALL CONDITIONS AND EXCLUSIONS OF IMPLIED WARRANTY OF MERCHANTABILITY AND OR FITNESS FOR THE PURPOSE, and the warrantor's liability for any direct damage arising from a legally proven breach of the warranty hereby extended is limited to the customer's invoice cost of the goods warranted.

- 8.2. DISCLAIMER OF CONSEQUENTIAL DAMAGES LIABILITY - Girton Manufacturing Co., Inc. shall not be liable for consequential damages of any kind, including incidental labor or other costs.

9. CANCELLATION

- 9.1. Any order on which work had been started may be cancelled only by consent of Girton Manufacturing Co., Inc. and by agreement on the part of the purchaser to cover whatever cost has been incurred, if any, to the date of the cancellation, including engineering, administrative, material purchases, labor, and overhead expended.

10. CUSTOMER TO WITNESS PRELIMINARY FACTORY ACCEPTANCE TEST (FAT)

- 10.1. Customer may witness preliminary testing performed at Girton Manufacturing Co., Inc. prior to shipment to customer's facility.

Customer will supply adequate samples of the items being washed. If customer specifies a particular chemical to be used, they shall supply it, complete with a MSDS Report. Customer shall be responsible for disposal or removal of excess chemical from premises.

- 10.2. **Factory Acceptance Test (FAT)** – Girton Manufacturing Co., Inc. will provide the necessary personnel for a maximum of 3 days to assist with the Factory Acceptance Test (FAT). The Girton Factory Technicians will work with the customer’s personnel in verifying the washer is built and operates according to the FAT documentation.

11. DOCUMENTS

- 11.1. ___ # sets of **Approval Documents** will be provided to the Customer in ___ days weeks after receipt of order. Production work will not be initiated until these drawings are returned to Girton Manufacturing Co., Inc. with the appropriate signatures of the customer.

12. INSTALLATION

- 12.1. Installation will be **done by others**.

Supervision of installation by Girtons - Girton Manufacturing Co., Inc. will provide a technician for _____ (*# of days*) who will work with the customer’s in-house personnel or with an outside contractor. The technician(s) will provide instructions for all phases of re-assembly including moving the equipment, leveling, re-assembly, and connection to utilities for an additional fee.

Set-in-place installation by Girtons -

Girton Manufacturing Co., Inc. will provide the necessary non-union labor to re-assemble the equipment and make it ready for utility connections at the customer’s site. The customer will be responsible for receiving the equipment, unloading and moving it to the area where it is to be installed prior to Girton’s arrival and for connecting the utilities.

Girton Manufacturing Co., Inc. will provide the necessary union labor to re-assemble the equipment and make it ready for utility connections at the customer’s site. The customer will be responsible for receiving the equipment, unloading and moving it to the area where it is to be installed prior to Girton’s arrival and for connecting the utilities.

Complete installation by Girtons

Girton Manufacturing Co., Inc. will provide the necessary non-union labor and material to perform a complete installation of the equipment. This includes receiving the equipment at the customer’s site, unloading, uncrating, move in place, re-assembly and connection to existing utilities. The utilities must be within 4 feet from the equipment.

Girton Manufacturing Co., Inc. will provide the necessary union labor and material to perform a complete installation of the equipment. This includes receiving the equipment at the customer’s site, unloading, uncrating, move in place, re-assembly and connection to existing utilities. The utilities must be within 4 feet from the equipment.

13. TERMS AND CONDITIONS

- 13.1. Payment Terms:
Please consult factory.
- 13.2. The 6% PA sales tax will be assessed on all sales. If you believe the products covered by this proposal are exempt from this tax, please send to Girton Manufacturing Co., Inc. your PA sales tax exemption certificate.

14. SHIPPING

- 14.1. Freight terms:
Collect
Prepaid by customer and add to Invoice
Third Party Billing
- 14.2. Shipment will be provided by transportation arranged by Girton Manufacturing Co., Inc.
customer.
- 14.3. Shipment from Millville, PA ___ to ___ weeks, after receipt of signed Documents by Girton Manufacturing Co., Inc.

15. TOTAL COST PER SPECIFICATION, CONSULT FACTORY

16. OPTIONS

- 16.1. The Human Machine Interface (HMI), mounted on the washer, consists of a Allen Bradley PLC based display Model RAC6181, which will be programmed using RSView SE software, which incorporates a touch screen for operator control and monitoring. This allows the user with proper password level to access all parameters of a wash recipe. All alarms are shown on the display, as well as announced audibly. Use of this system complies with CFR21 Part 11.
- 16.2. **Cabinet flush down piping** – A system of stainless steel piping and spray jets will be provided to spray down the interior of the washer to maintain a clear interior. System would be manually operated by a two-way valve.
- 16.3. **Heated air blow** – The unit will be provided with an _____ KW electric heating element to raise the compressed air temperature from 70°F to 120°F.
- 16.4. **Recirculation wash system**, which includes a 1/2 HP recirculating pump level controls and programming to allow a recirculated wash followed by a non-circulated final rinse.
- 16.5. **T-316 stainless steel construction** on wetted surfaces.
- 16.6. **Additional copies of our Documentation Package** (reference item # _____ of this specification) may be purchased.
- 16.7. **Optional Documentation:**
- 16.7.1. Surface Finish Map and Certificate of Compliance
 - 16.7.2. Slope Map of Process Contact Tubing and Certificate of Compliance
 - 16.7.3. Video Weld Logs
 - 16.7.4. Sound Level Certificate of Conformance
- 16.8. **Supervision of installation (YSOFI)** – Girton Manufacturing Co, Inc. will provide ONE Qualified Technician for ____ (# of days) contiguous* on-site days to Supervise and Direct Customer Personnel, Contractors or Subcontractors in all phases of Installation. This includes oversight of Uncrating and Moving the Equipment into a prepared⁽¹⁾ Wash Room, Leveling and Reassembly, Utility⁽²⁾ and Additional Support Systems⁽³⁾ Connections. Supervision of Unloading the Shipping Truck will be performed *only if* delivery occurs during the scheduled timeframe.
- Supervision of Installation (SofI) does **not** include Sub-Contracting, Equipment or Tools or Tool Rental, Dumpsters and/or Trash Disposal, Multiple Trips from our Factory (except at our discretion and as deemed necessary by our Technical Service Manager), Additional Site Preparation, Materials for Floor Protection, Integration Materials or Fabrication (other than Modular Walls, Fascia Panels, and items purchased from Girton Mfg. as an option), Equipment Start Up, Training of Personnel or Assisting with SAT or Validation Documentation.
- The Customer will be responsible for all facets of installation not specifically included above. Equipment Start Up, Training of Personnel, Assisting with SAT or Validation Documentation may be purchased from Girton separately.
- A Field Report will be submitted to the Customer within one week of completion of the installation.
- Supervision of Installation is a quoted option and valid as part of the original equipment order. Service ordered after the original equipment order date will require a re-quote. Travel expenses are included in the first day billing. Additional contiguous days may be purchased for a flat fee of \$____.00 per day, but should be purchased prior to the first on-site day, if possible. This information is based on non-union labor. Special provisions and prices apply when union labor and/or prevailing wages are required. Contact your Sales Rep for further details.
- 16.9. **Set-in-place Installation (YSIP)** - Girton Manufacturing Co, Inc. will provide Qualified Technicians for ____ (# of days) contiguous* on-site days to Unload and Uncrate, Move the equipment to a prepared⁽¹⁾ location, Reassemble and Level the Equipment. Girton Manufacturing Co, Inc. will provide all Personnel, Material, Tools and Equipment to perform the task, including Fork Trucks, Dumpsters, Welders, Hand Tools, Floor Protection and Trash Elimination.

Set-In-Place Installation (SIP) does **not** include Utility⁽²⁾ Connections, Connection of Additional Support Systems⁽³⁾, Multiple Trips from our Factory (except at our discretion and as deemed necessary by our Technical Service Manager), Additional Site Preparation, Integration Materials or Fabrication (other than Modular Walls, Fascia Panels, etc., purchased from Girton Mfg. as an option), Equipment Start Up, Training of Personnel or Assisting with SAT or Validation Documentation.

The Customer will be responsible for all facets of installation not specifically included above. Equipment Start Up, Training of Personnel, Assisting with SAT or Validation Documentation may be purchased from Girton separately.

A Field Report will be submitted to the Customer within one week of completion of the installation.

Set-In-Place Installation is a quoted option and valid as part of the original equipment order. Service ordered after the original equipment order date will require a re-quote. Travel expenses are included in the first day billing. Additional contiguous days may be purchased for a flat fee of \$____.00 per 8 Hr. man-day, but should be purchased prior to the first on-site day, if possible.

This information is based on non-union labor. Special provisions and prices apply when union labor and/or prevailing wages are required. Contact your Sales Rep for further details.

- 16.10. **Complete Installation (YINSTALL)** - Girton Manufacturing Co, Inc. will provide Qualified Technicians for ____ (# of days) contiguous* on-site days to Unload, Uncrate, Move the equipment to a prepared⁽¹⁾ location, Reassemble, Level the Equipment and Connect Utilities⁽²⁾ to **existing stubs** within 6' of the machine. Girton Manufacturing Co, Inc. will provide all Personnel, Material, Tools and Equipment to perform the task, including Fork Trucks, Dumpsters, Welders, Hand Tools, Floor Protection and Trash Elimination. Test and Demonstration (see below) is part of this option. If this cannot be completed contiguously (due to unavailable utilities, Customer personnel availability, etc.), a return trip must be scheduled and additional travel expenses will apply.

Complete Installation (CI) does **not** include Multiple Trips from our Factory (except at our discretion and as deemed necessary by our Manager), Additional Site Preparation, Connection of Additional Support Systems⁽³⁾, Integration Materials or Fabrication (other than Modular Walls, Fascia Panels, etc., purchased from Girton Mfg. as an option), Equipment Start Up, Training of Personnel or Assisting with SAT or Validation Documentation.

The Customer will be responsible for all facets of installation not specifically included above. Equipment Start Up, Training of Personnel, Assisting with SAT or Validation Documentation may be purchased from Girton separately.

A Field Report will be submitted to the Customer within one week of completion of the installation.

Complete Installation is a quoted option and valid as part of the original equipment order. Service ordered after the original equipment order date will require a re-quote. Travel expenses are included in the first day billing. Additional contiguous days may be purchased for a flat fee of \$____.00 per 8 Hr. man-day, but should be purchased prior to the first on-site day, if possible.

This information is based on non-union labor. Special provisions and prices apply when union labor and/or prevailing wages are required. Contact your Sales Rep for further details.

- 16.11. **Test and Demonstration (YTD)** - Girton Manufacturing Co, Inc. will provide ONE Qualified Technician for ____ (# of days) contiguous* on-site days to perform Start Up Testing, such as verifying utility connections and capacities, electrical supply voltage and amperage, motor rotations, completeness of assembly, missing components, etc., on fully installed⁽⁴⁾ equipment. The Technician will make normal *equipment* adjustments and test operation against factory standards. Upon completion of satisfactory testing, the Technician will demonstrate all phases of the use and operation of the equipment to any interested parties, provided sufficient time is allotted. We recommend that three to four hours be dedicated for effective demonstration. We highly recommend that at least one User of each level of access (Operator, Maintenance, Supervisor/Engineering, Administrative) be present for the demonstration. *Demonstration must not be confused with training; it is NOT a substitute for a complete and formal training session*, 'Demonstration' is informal, with the Technician covering the highlights of the equipment and operation and hazard awareness, and answering questions from interested parties. No handout sheets or post-training testing is given.

Test and Demonstration (T&D) does **not** include mechanical reassembly or completion of wiring or pneumatics (on-skid or otherwise), any function that is normally part of the three Installation options described above, Multiple Trips from our Factory (except at our discretion and as deemed necessary by our Technical Service Manager), Additional Site Preparation, or Assisting with SAT or Validation Documentation.

The Customer will be responsible for all facets of installation not specifically included above. Supervision of Installation, Set in Place Installation, Complete Installation, Training of Personnel, Assisting with SAT or Validation Documentation may be purchased from Girton separately.

A Field Report and a copy of an Attendance Record for the demonstration will be submitted to the Customer within one week from the end of the visit.

Test and Demonstration is a quoted option and valid as part of the original equipment order. Service ordered after the original equipment order date will require a re-quote. Travel expenses are included in the first day billing. Additional contiguous days may be purchased for a flat fee of \$____.00 per 8 Hr. man-day, but should be purchased prior to the first on-site day, if possible.

This information is based on non-union labor. Special provisions and prices apply when union labor and/or prevailing wages are required. Contact your Sales Rep for further details.

- 16.12. **Start Up (YSTART)** - Girton Manufacturing Co, Inc. will provide ONE Qualified Technician for ____ (# of days) contiguous* on-site days to perform Start Up Testing, such as verifying utility connections and capacities, electrical supply voltage and amperage, motor rotations, completeness of assembly, missing components, etc., on fully installed⁽⁴⁾ equipment. The Technician will make normal *equipment* adjustments and test operation against factory standards. Start Up does **not** include mechanical reassembly or completion of wiring or pneumatics (on-skid or otherwise), any function that is normally part of the three Installation options described above, Multiple Trips from our Factory (except at our discretion and as deemed necessary by our Technical Service Manager), Additional Site Preparation, or Assisting with SAT or Validation Documentation.

The Customer will be responsible for all facets of installation not specifically included above. Supervision of Installation, Set in Place Installation, Complete Installation, Training of Personnel, Assisting with SAT or Validation Documentation may be purchased from Girton separately.

A Field Report will be submitted to the Customer within one week from the end of the visit.

Start Up is a quoted option and valid as part of the original equipment order. Service ordered after the original equipment order date will require a re-quote. Travel expenses are included in the first day billing. Additional contiguous days may be purchased for a flat fee of \$____.00 per 8 Hr. man-day, but should be purchased prior to the first on-site day, if possible. This information is based on non-union labor. Special provisions and prices apply when union labor and/or prevailing wages are required. Contact your Sales Rep for further details.

- 16.13. **Training (YTR)** - Girton Manufacturing Co, Inc. will provide ONE Qualified Technician for ____ (# of days) contiguous* on-site days to formally and thoroughly provide in-depth training to Operators, Maintenance Technicians, Engineering and Administrative Level Personnel. Our Technician will provide a combination of classroom and hands-on field training. A 'Question and Answer' period is encouraged.

16.13.1. **Topics covered are:**

- Hazard Awareness,
- Alarms and the causes of and responses to them,
- Routine Operation,
- Routine Maintenance and Trouble Shooting,
- Set Up, Management and Modification of Recipes (Cycles),
- User Management (Administration).

16.13.2. **Training (TRN)** covers the full range of access and use:

16.13.2.1. **'Operator'** level training covers the daily operation and maintenance, and is the shortest and most basic training.

16.13.2.2. **'Maintenance'** level training includes full Operator training and adds the extensive maintenance diagnostic capabilities available through the HMI, and PM requirements.

16.13.2.3. **'Engineering'** level training will include condensed Operator and Maintenance coverage and adds in-depth Recipe (Cycle) Generation and Management and Recipe and Alarm Set Points. Engineering training is typically restricted to those individuals responsible for control of validated operation.

16.13.2.4. **'Administrator'** level training will have condensed coverage for all levels of use, but will focus primarily on User Administration and Security. At this level, Users Names and Passwords are assigned and Levels of Access Controlled.

Whenever possible, a computer presentation will be shown and pertinent hand out sheets will be distributed. An Attendance Roster and post-training Retention Test will be given and copies will be provided to the Customer.

Training is a quoted option and valid as part of the original equipment order. Service ordered after the original equipment order date will require a re-quote. Travel expenses are included in the first day billing. Additional contiguous days may be purchased for a flat fee of \$_____.00 per day, but should be purchased prior to the first on-site day, if possible. This information is based on non-union labor. Special provisions and prices apply when union labor and/or prevailing wages are required. Contact your Sales Rep for further details.

- 16.14. **Site Acceptance Testing Assistance (YSAT)** - Girton Manufacturing Co, Inc. will provide ONE Qualified Technician for ____ (# of days) contiguous* on-site days to assist the Customer's Validation Group(s) with IQ/OQ of fully installed⁽⁴⁾ and running equipment. Girton Mfg. will provide an SAT Template based on the factory test documents and appropriate programming software and test instruments necessary to duplicate the factory tests. Girton Technicians will assist the Customer by providing clarification of test procedures and test results, and through our experience with the PLC and HMI Programming. Sample SAT documents are typically submitted to the Customer for early review. Machine specific documents shall be submitted to the Customer a minimum of two weeks prior to SAT.

Girton Technicians will *not* be responsible for completing partial installations, test document revisions or test completion.

A Field Report will be submitted to the Customer within one week of completion of the SAT.

Site Acceptance Test is a quoted option and valid as part of the original equipment order. Service ordered after the original equipment order date will require a re-quote. Travel expenses are included in the first day billing. Additional contiguous days may be purchased for a flat fee of \$_____.00 per day, but should be purchased prior to the first on-site day, if possible. This information is based on non-union labor. Special provisions and prices apply when union labor and/or prevailing wages are required. Contact your Sales Rep for further details.

16.15. Notes:

- 16.15.1. ⁽¹⁾ "Prepared" site is defined as one at which the building is enclosed, the floor and floor coatings are complete and where Girton personnel can work reasonably unhindered. Electricity (for tools) *must* be available. It is preferred, but not mandatory, that utilities⁽²⁾ are complete and available.
- 16.15.2. ⁽²⁾ "Utilities" are defined as Potable Water (Hot and/or Cold), Steam, Condensate, Ventilation, Electrical, Compressed and/or Instrument Air, and Drains. "Utilities" does *not* include Purified (DI, WRO, WFI, etc.) water sources that require high-purity pipe welding, remote Detergent systems or controls, Chiller/Glycol system piping, Facility Control or Data Systems, networked or otherwise.
- 16.15.3. ⁽³⁾ "Additional Support Systems" are defined as Purified Water (DI, WRO, WFI, etc.), Chiller systems, Detergent Systems, Combustible Liquids or Gas, and Breathing Air. Connection of Additional Support Systems is *always* the responsibility of the Purchaser.
- 16.15.4. ⁽⁴⁾ "Fully Installed" is defined as the equipment being in-place and leveled, and connected to all utilities and additional support systems. Integration with building fabric is not required.

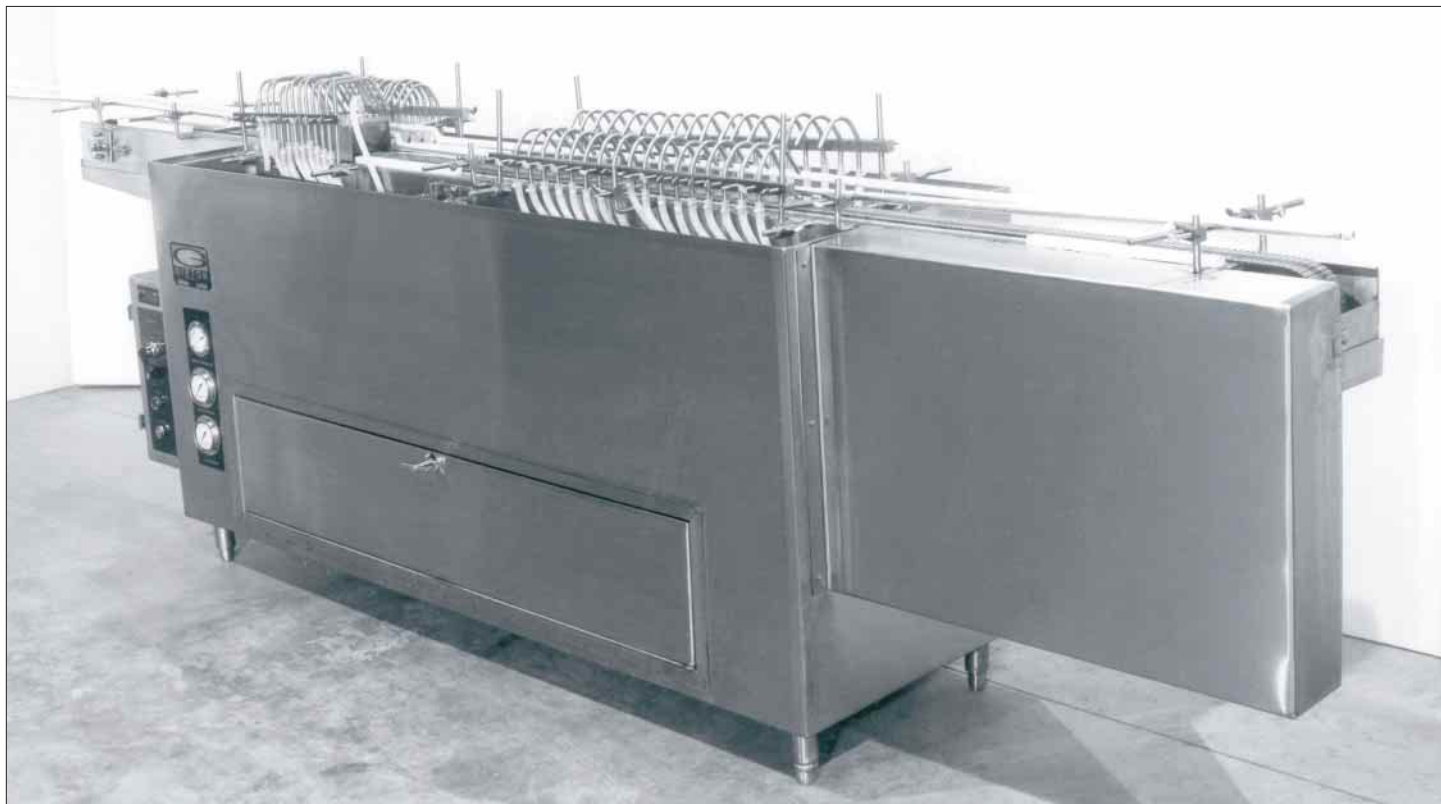
* Excluding Saturdays, Sundays and/or Holidays, unless prearranged.

GIRTON MODEL GV150S VENDOR LIST

COMPONENT	VENDOR
Controller	Allen Bradley
Limit Switches	Allen Bradley
Temperature Transmitter	Burns
Terminal Strip	Square D
Fuses and Fuse Holder	Ferraz Shawmutt
Header Hoses	Pure Fit
Compressed Air Filter Regulator	ASCO
Sanitary Diaphragm Valve	ITT
Emergency Stop Switch	Allen Bradley

Girton

GV150S Vial Exterior Washer



Features:

- Construction T-316L Stainless Steel Wetted Surfaces
- Manually Adjustable Water And Air Nozzles To Accommodate Various Sized Vials
- Manually Adjustable Guide Rails To Guide The Vials Through The Unit
- PLC Controlled
- Touch Screen Operator Interface
- Variable Speed Drive
- Stainless Steel Wire Mesh Belt

Available Options:

- Cabinet Flush Down
- Recirculated Wash Cycle
- Heated Air For Blow-Off
- Casters For Mobility



Girton

Girton Manufacturing Co., Inc.

P.O. Box 900 • Millville, PA 17846-0900

phone: 570.458.5521

fax: 570.458.5589

website: www.girton.com

e-mail: info@girton.com

Meeting the needs of the pharmaceutical industry since 1927.