

PennTech Rotary Vial Washer RW-1150

The PennTech rotary vial washer, model RW-1150A, is specifically developed for parenteral applications.

It is obvious that parenterally administered drugs should be without microbial and particulate contamination. Therefore, the vial washer needs the ability to significantly reduce particulates from the containers.

In addition, a washer should have the intrinsic capability of obtaining a 3-log reduction in bacterial endotoxin.

The PennTech washer has been designed with the preceding in mind.



Rotary Washers versus In-Line Washers

PennTech has purposely chosen a rotary-type washer, as opposed to an in-line type washer.

Advantages of the rotary concept are:

1. Cleanliness

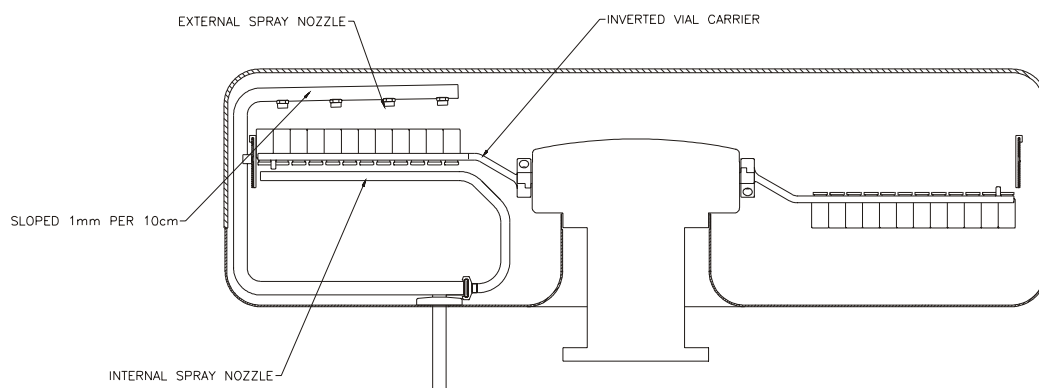
There are no moving parts in the washing chamber (except for the central turret).

In-line washers with a chain based drive mechanism inherently create more particulates than rotary washers.

2. Functionality

Each vial size has a dedicated set of change parts. Each set of change parts is designed to handle a specific size vial. In other words, each vial is optimally exposed to internal and external water spraying.

In-line washers, to the contrary, use vial holders (pockets) made for all vial sizes, from the smallest to the largest. This is a compromise to the effectiveness of the washing function.



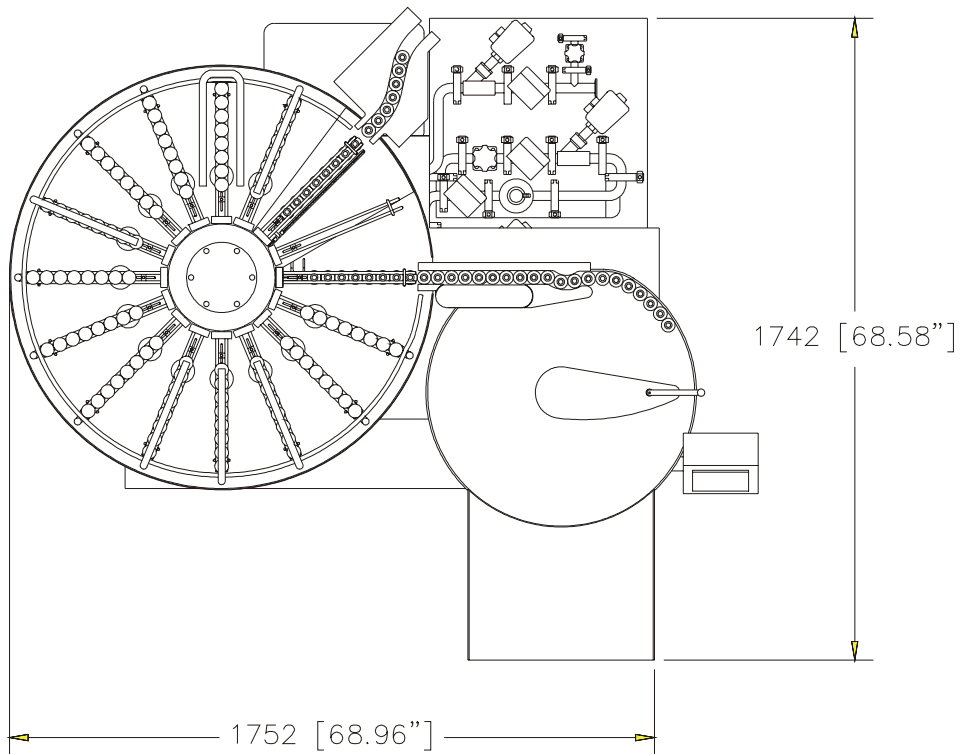
Advantages of the Rotary Concept (Continued)

3. Visibility

Due to the transparent polycarbonate cover over the washing chamber, the total washing function can be visually inspected. This is practically impossible with in-line washers.

4. Compact Size

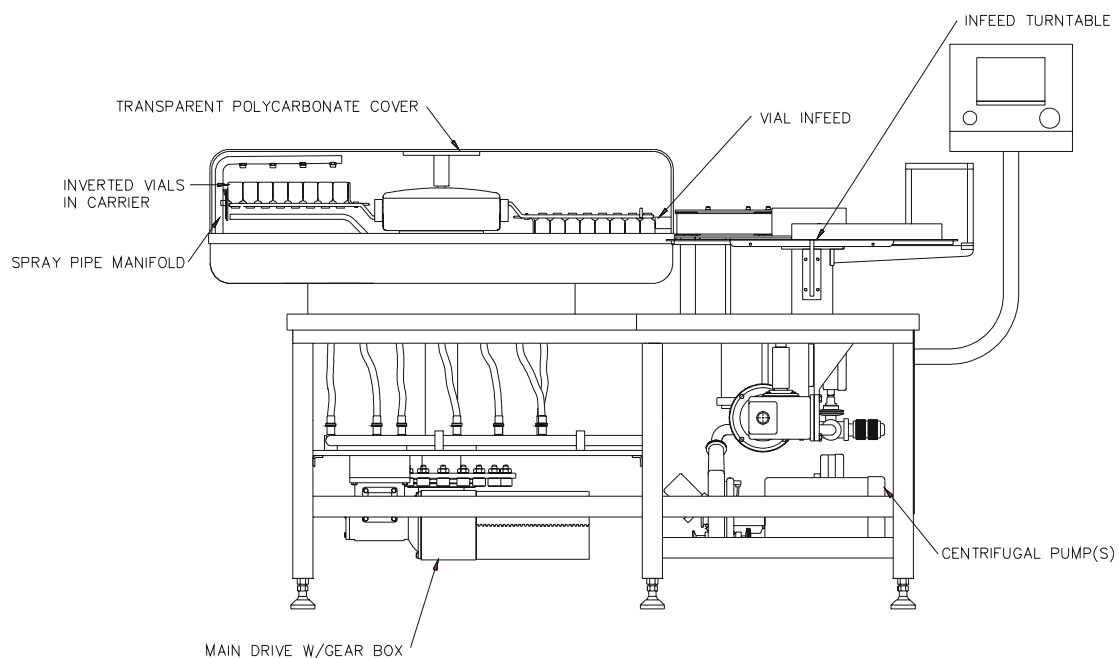
The rotary design allows for a small footprint. In fact, the PennTech machine occupies 2.7 meter² (1.9m x 1.4m) and is the most compact washing machine on the market today.



Advantages of the Rotary Concept (Continued)

5. Single File Container Outfeed

The cleaned vials leave the washer in a single file fashion. This means that the vials are immediately available for trayloading or for transporting to the filler in the clean room. In addition, when continuous sterilizing is required (using a sterilizing tunnel), the vials can be pushed onto the tunnel conveyor in a full loading pattern. This is a significant advantage over in-line washers whereby the loading pattern is less than optimum. This may result in "cold spots" in the sterilizing tunnel.



Stationary Nozzles versus Penetrating Nozzles

PennTech has chosen stationary nozzles, as opposed to penetrating nozzles.

There are several reasons for this choice:

1. Penetrating nozzles move in and out the vials. Everything that moves generates particulates. This is in violation with the function of the washer; i.e., to remove particulates.
2. Tests have shown that stationary nozzles are as effective as penetrating nozzles. The reason for this is due to the high velocity of the water exiting the spray pipe and entering the vial. Even small 2 ml vials with a 13 mm neck finish are effectively cleaned.
3. Penetrating nozzles may hit the neck finish of the vial and bend. Bent nozzles are not only ineffective; they may jeopardize the validation of the batch.

Standard Features of the PennTech Washer

- Thirteen effective washing or air blowing positions
- Separation between infeed and outfeed - position 16
- Intermittent washing and air blowing
(Reduces WFI consumption by approximately 25%.)
- Three washing zones:
 - Zone 1: Recirculated WFI using external tank with heating element, centrifugal pump and 10 inch (.2 μ) filter
 - Zone 2: Virgin WFI (water for injection)
 - Zone 3: Sterile air
- Water and air distribution through independent external manifold system allows for easy washing program changes
- All water and air contact parts are constructed of AISI-316 stainless steel
- All water and air pipes are pitched 3mm per 30cm (1/8" per foot), in order to obtain total system drainage
- Low air and water pressure protection with automatic system shutdown
- Pneumatically raising and lowering polycarbonate cover over wash chamber
- Standard Allen Bradley® PanelView 550 or optional PanelView 1000 Plus
- Allen Bradley SLC-5/04 or SLC-505 PLC
- Servo motor controlled main drive
- Stepper motor controlled outfeed actuator

Description of the PennTech Washer

The RW series of washing machines are designed to clean glass and plastic vials at an output rate between 2,000 and 24,000 vials per hour. Vial size range: 1-500cc.

The speed of the washer can be electronically adjusted between 10 and 30 indexes per minute.

The machine consists of the following major components:

- Infeed turntable with positive drive infeed mechanism
- Washing chamber with vial carriers
- Spray pipes
- Central indexing turret with drive mechanism
- Water/air distribution system
- Wash piping system
- Container outfeed mechanism
- Electrical panel with PLC
- Easy to use operator interface

Vial infeed is automatic and is governed by the supply of vials on the infeed table.

Vials are automatically loaded in dedicated carriers unique to each individual vial size.

During the washing treatment, the vials are indexed in an inverted position in such a way that the bottles line up exactly with the spray pipes across the neck openings.

Water and air spraying starts when the vials are lined up with the spray jets and stops during the indexing movement.

The washing program is selected by the customer. Selection is made using combinations of the following:

- Recirculated WFI (water for injection)
- Virgin WFI
- Sterile Air

There are sixteen indexing positions, thirteen of which can be used for the washing treatment.

The combined treatment time with WFI depends on the selected washing program and is independent of the output rate and may vary between ten and thirty seconds. In addition, sterile air blowing time may vary between seven and twenty seconds.

A programmable stepper motor with outfeed pusher controls the exiting of the vials from the washer.

The linear motion of the outfeed pusher as well as acceleration, deceleration and positioning is automatically selected (via PLC) for the vial size in use.

The operator controls the machine through an Allen Bradley PanelView 550 or optional PanelView 1000 operator interface with programmable input keys and error messages. The following error messages may be displayed:

1. Low container infeed
2. Discharge back-up
3. Low water pressure
4. Main column overload
5. Low WFI pressure
6. Low pump pressure
7. Low air pressure
8. Lid not closed
9. Discharge pusher jam
10. E-stop activated
11. Jog button unplugged
12. Jog button is inserted

The changeover to a different vial size requires only the use of a 5 mm Allen key and is accomplished in less than fifteen minutes by one operator.

Components Used in Washing Program

Sterile Air

- Sterile air pressure sensor with 4-20 mA transmitter and digital display
- Intermittent air jetting control
- Air filter housing with sample port

WFI

- Automatic drain valve
- Recirculation tank fill valve
- WFI pressure sensor with 4-20 mA transmitter
- Intermittent WFI spray control
- WFI sample port

Recirculated WFI

- Recirculating tank with level control and internal, immersion heating element
- Three horsepower centrifugal pump with drain
- Recirculated WFI temperature (RTD) sensor with digital display
- Recirculated WFI pressure sensor with 4-20 mA transmitter
- Ten inch filter housing with sample port
- Intermittent recirculated WFI spray control

Operator's Manual

- Operating instructions
- Preventive maintenance
- Trouble shooting
- 3D assembly drawings (AutoCAD)
- Recommended spare parts list
- Programming ladder diagrams
- Electrical schematics
- Original equipment manufacturer's manuals
- Certificates of compliance - Material
- Certificates of compliance - Component

Specifications RW-1150 Vial Washer

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|------------------------|---|
| DIMENSIONS: | <ul style="list-style-type: none">- Length: 1753mm (69 inches)- Width: 1753mm (69 inches)- Height to working surface: 889-940mm (35 - 37")- Height overall: 1168mm (46 inches) |
| OPERATOR INTERFACE: | <ul style="list-style-type: none">- Allen Bradley PanelView 550 (Optional PanelView 1000) |
| PLC: | <ul style="list-style-type: none">- Allen Bradley SLC 5/04 (Optional SLC 5/05) |
| VIAL RANGE: | <ul style="list-style-type: none">- 1ml – 500ml, glass or plastic |
| MAIN-DRIVE: | <ul style="list-style-type: none">- Servomotor |
| OUTFEED MECHANISM: | <ul style="list-style-type: none">- Fully programmable stepper motor /encoder |
| WASH CHAMBER COVER: | <ul style="list-style-type: none">- Clear polycarbonate |
| CONTACT PARTS: | <ul style="list-style-type: none">- AISI-316L stainless steel |
| SANITARY PIPING: | <ul style="list-style-type: none">- AISI-316L stainless steel |
| MACHINE FRAME: | <ul style="list-style-type: none">- AISI-304 stainless steel |
| PANELS AND COVER: | <ul style="list-style-type: none">- AISI-304 stainless steel |
| ELECTRICAL PANEL: | <ul style="list-style-type: none">- Nema 4X, AISI-304 stainless steel |
| INFEED TABLE MOTOR: | <ul style="list-style-type: none">- 1/3 HP DC adjustable speed |
| RTD: | <ul style="list-style-type: none">- Anderson |
| DIAPHRAGM VALVES: | <ul style="list-style-type: none">- Gemu or ITT |
| PRESSURE TRANSMITTERS: | <ul style="list-style-type: none">- Anderson or ReoTemp |
| FILTER HOUSINGS: | <ul style="list-style-type: none">- Pall |
| PUMP / MOTOR | <ul style="list-style-type: none">- Tri-Clover / Baldor (3hp) |
| IMMERSION HEATER: | <ul style="list-style-type: none">- Accutherm |
| WATER CONSUMPTION: | <ul style="list-style-type: none">- 1 – 4gpm, vial size & wash prog. dependent |
| UTILITY REQUIREMENT: | <ul style="list-style-type: none">- 220 Volt three phase (w/ recirculation pkg.) |
| WEIGHT: | <ul style="list-style-type: none">- Approximately 500 kg (1,110 lbs.) |