

Operations Manual for the Filtrate Drain System (FDS)



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1.0 Description

- 1.1 As part of routine membrane filtration sterility testing, the filtrate (*solution that flows through the membrane filtration units*) passes from the isolator's internal environment and into a Collection Vessel stationed in the room.
- 1.2 To facilitate this process, a Filtrate Drain System or **FDS** has been uniquely designed and developed by Ardien Consulting Services.
- 1.3 The **FDS** comprises the following items:

Item 1: Manual Sanitary Diaphragm Valve, Clamps and Gaskets



Item 2: Sanitary Check Valve with Proprietary Spring Tension



Item 3: Sanitary to Quick-Disconnect Adapter, Clamp and Gasket



Female Valved Quick-Disconnect

Item 4: Filtrate Tubing and Dissimilar Quick-Disconnects



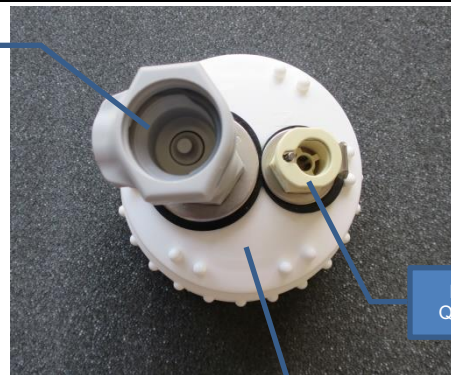
Male Open Quick-Disconnect

Male Elbowed Valved Quick-Disconnect

Item 5: Collection Vessel Cap Assembly with Dissimilar Quick-Disconnects and Attached Tubing

Top View

Side View



Female Valved Quick-Disconnect

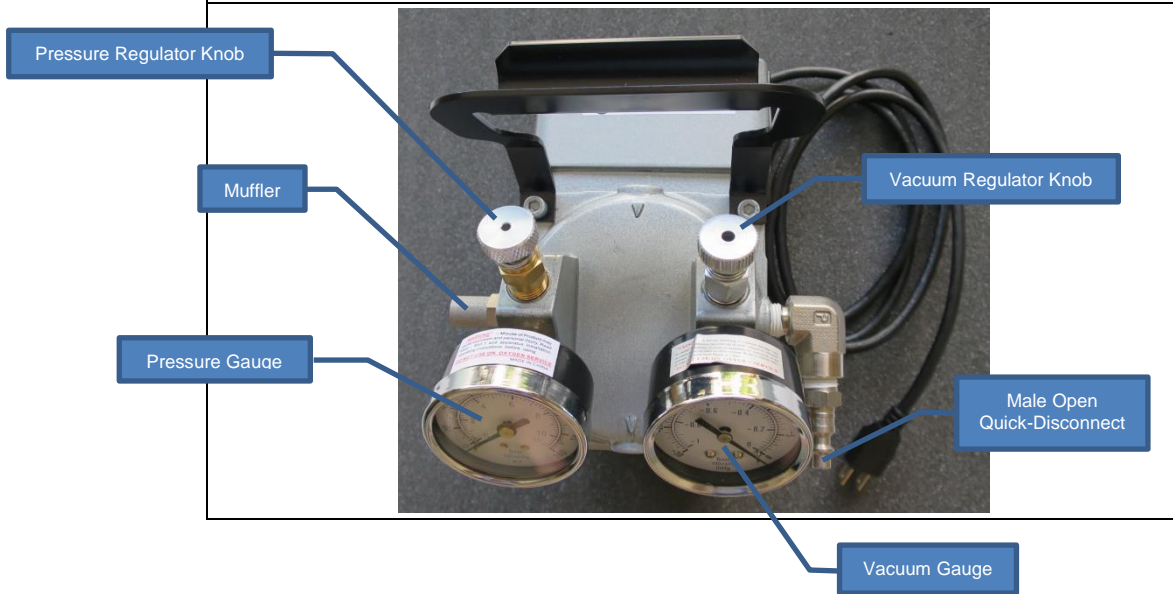
Female Valved Quick-Disconnect

Modified Collection Vessel Cap

Item 6: Vacuum Tubing with Dissimilar Quick-Disconnects

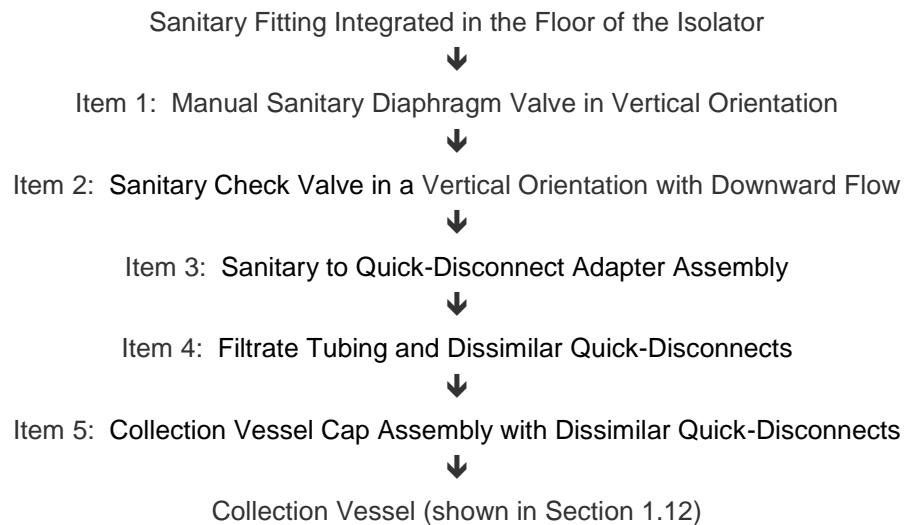


Item 7: Vacuum Pump with Regulators, Quick-Disconnect and Muffler






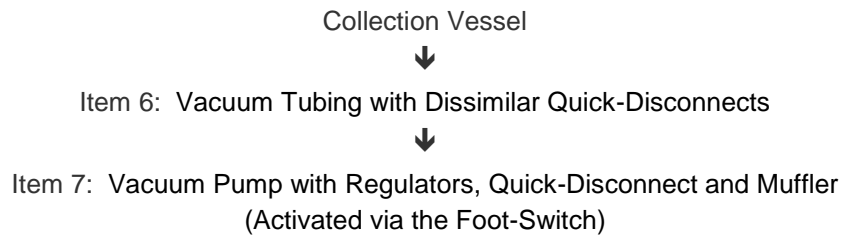
1.4 The flow of filtrate is in the following order;



- 1.5 There are 3 inline valves prior to the connection at the Collection Vessel: (1) Manual Sanitary Diaphragm Valve, (2) Sanitary Check Valve, and (3) Quick-Disconnects. The order is such that the most aseptic valve (Manual Sanitary Diaphragm Valve) is in the closest proximity to the isolator, followed by the Sanitary Check Valve and finally the valved Quick-Disconnects.
- 1.6 Flow through the membrane filtration units and into the **FDS** is enhanced via the vacuum pump which is activated via a footswitch; thus filtration through the membrane filtration units is accelerated. The operator working in the isolator can easily activate the vacuum pump while working in the gloves of the isolator.

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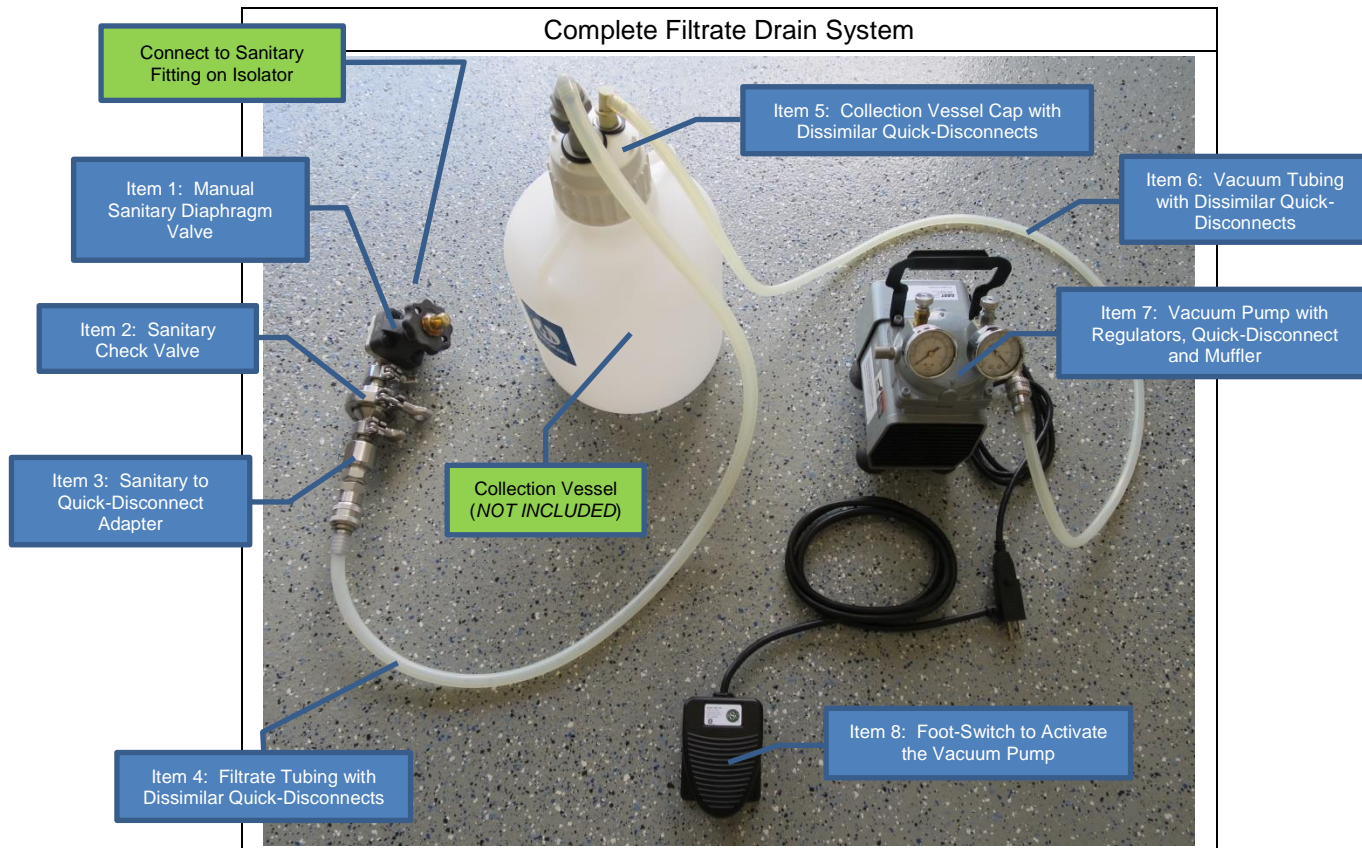
- 1.7 The Sanitary Check Valve (Item 2) is normally in a closed position and is designed to prevent potential back-flow into the isolator. It is only until a slight/moderate negative pressure in the Collection Vessel is created that the piston in the Sanitary Check Valve automatically opens allowing flow of filtrate through the Manual Sanitary Diaphragm Valve. This slight/moderate negative pressure in the Collection Vessel is created by the operation of the vacuum pump. This negative pressure is accomplished via flow in the following order:




- 1.8 Dissimilar quick-disconnect fittings are used throughout the **FDS** making it impossible to inadvertently make an improper connection.
- 1.9 The Collection Vessel is capable of being sealed to prevent airborne contamination from entering into the Collection Vessel. The internal surfaces of the Collection Vessel can be disinfected prior to connecting to the **FDS**. For further information, see Section 5.0.
- 1.10 The Collection Vessel provides complete operator protection/separation from the filtrate.
- 1.11 The Collection Vessel is not part of the **FDS** and must be purchased separately. Listed below is a link to the recommended Collection Vessels that are compatible with the **FDS**. Two sizes are recommended: 10L or 20L. In most cases, the 10L is the best choice, but this depends on the volume and sterility testing method performed in the session.

Link: <https://www.thermofisher.com/order/catalog/product/2319-0020?ICID=search-product>

1.12 When all the quick-disconnect fittings are connected, the complete **FDS** is configured as shown below:



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2.0 Safety

- 2.1 Discard the filtrate waste in the Collection Vessel as per local procedures.
- 2.2 The electrical connection (Vacuum Pump and Foot-Switch) should be made such that it is no less than 10 inches above the floor of the room. If an extension cord is to be used, make sure the connection point of the extension cord is no less than 10 inches above the floor.

3.0 Material Specifics

NOTE: *Materials in the FDS are selected for long term compatibility with all liquids that comprise the filtrate.*

- 3.1 **Item 1:** Manual Sanitary Diaphragm Valve, Clamps and Gaskets
 - 3.1.1 Manual Sanitary Diaphragm Valve.
 - Size: ¾" (DN20) Sanitary Tri-Clamp Tube.
 - Body: Forged 316L Stainless Steel.
 - Diaphragm: PTFE (FDA).
 - Bonnet: Plastic (PAS).
 - 3.1.2 Clamps.
 - Size: ¾" (DN20) Sanitary Tri-Clamp Tube.
 - Material: 304 Stainless Steel.
 - 3.1.3 Gaskets.
 - Size: ¾" (DN20) and ½" (DN15) Sanitary Tri-Clamp Tube.
 - Material: Silicone.
- 3.2 **Item 2:** Sanitary Check Valve
 - 3.2.1 Size: ¾" (DN20) Sanitary Tri-Clamp Tube.
 - 3.2.2 Body: 316L Stainless Steel.
 - 3.2.3 Gasket: Viton.
 - 3.2.4 Spring: Stainless Steel, Proprietary Spring Tension to Suit Installation.
- 3.3 **Item 3:** Sanitary to Quick-Disconnect Adapter Assembly, Clamp and Gasket
 - 3.3.1 Sanitary to Quick-Disconnect Adapter Assembly.
 - Size: ¾" (DN20) Sanitary Tri-Clamp Tube.
 - Sanitary Adapter Material: 316L Stainless Steel.
 - Quick-Disconnect Body Material: 303 Stainless Steel.
 - Quick-Disconnect Seal Material: Buna-N Rubber.

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3.3.2 Clamps.

- Size: ¾" (DN20) Sanitary Tri-Clamp Tube.
- Material: 304 Stainless Steel.

3.3.3 Gaskets.

- Size: ¾" (DN20) and ½" (DN15) Sanitary Tri-Clamp Tube.
- Material: Silicone.

3.4 **Item 4:** Filtrate Tubing with Dissimilar Quick-Disconnect Fittings

3.4.1 Quick-Disconnect.

- Coupling Size: ½".
- Body Material: 303 Stainless Steel.

3.4.2 Tubing.

- Size: 3/8" ID, 5/8" OD.
- Material: Silicone.
- Approximate Length: 4 feet.

3.4.3 Quick-Disconnect.

- Coupling Size: 3/8".
- Body Material: Polypropylene.
- Seal Material: EPDM Rubber.

3.5 **Item 5:** Collection Vessel Cap with Dissimilar Quick-Disconnect Fittings and Attached Tubing

3.5.1 Collection Vessel Cap.

- Body Material: Polypropylene.
- Seal Material: Silicone.
- Sealing Washers: Fluorosilicone and Silicone.
- Washers: PTFE and PVC.
- Internal Fittings: Polypropylene.
- Sealant: Dow Corning 700.

3.5.2 Quick-Disconnect.


- Coupling Size: 3/8".
- Body Material: Polypropylene.
- Seal Material: Buna-N Rubber.

3.5.3 Quick-Disconnect.

- Coupling Size: ¼".
- Body Material: Polypropylene.
- Seal Material: EPDM Rubber.

3.5.4 Tubing.

- Size: 3/8" ID, 5/8" OD.
- Material: Silicone.
- Approximate Length: 1.5 feet.

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3.6 Item 6: Vacuum Tubing with Dissimilar Quick-Disconnect Fittings

3.6.1 Quick-Disconnect.

- Coupling Size: ¼”.
- Body Material: Polypropylene.
- O-Ring Material: EPDM Rubber.

3.6.2 Tubing.

- Size: ¼” ID, ½” OD.
- Material: Silicone.
- Approximate Length: 5 feet.

3.6.3 Quick-Disconnect.

- Coupling Size: ¼”.
- Body Material: 303 Stainless Steel.
- Seal Material: Buna-N Rubber.

3.7 Item 7: Vacuum Pump with Regulators, Quick-Disconnect Fitting and Muffler

3.7.1 Vacuum Pump with Regulators.


- Oil Free
- Housing Material: Aluminum.
- Power Source: Electrical.
- Horsepower Rating: 1/8 HP.
- Duty Cycle: Continuous.
- Plug Type: 3 Prong.
- Phase: Single.
- Frequency: 60 Hz.
- Voltage: 120V AC.
- Current: 4.2 A.
- Cord Length: 6 feet.
- Noise in Operation: 65 dB (without Muffler).
- Approximate Weight: 16 lbs (7.3 kg).

3.7.2 Quick-Disconnect.

- Coupling Size: ¼”.
- Body Material: 303 Stainless Steel.
- Elbow Adapter Material: 316 Stainless Steel.

3.7.3 Muffler and Adapter.

- Adapter: 316 Stainless Steel.
- Adapter Thread Size: ¼” NPTM x ½” NPTF.
- Muffler Body and Fitting: 316 Stainless Steel.
- Muffler Thread Size: ½” NPTM.
- Muffler Maximum Flow Rate: 200 CFM @ 100 PSI.
- Muffler Removes Particles Down To: 100 microns.
- Muffler Noise Reduction Rating: 10 – 20 dB.

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3.8 **Item 8:** Foot-Switch to Activate the Vacuum Pump.


- 3.8.1 Housing: Die-Cast, Powder-Painted Finish.
- 3.8.2 Action: Maintained (Push ON / Push OFF).
- 3.8.3 Cord Length: 8 feet.
- 3.8.4 Power Source: Electrical.
- 3.8.5 Voltage Rating: 125 V AC.
- 3.8.6 Current Rating: 15 A.
- 3.8.7 Plug Type: 3 Prong, "Piggyback" Type.

4.0 Required Utilities

- 4.1 Electrical: 120 VAC, 15 A.

5.0 Filtrate Drain System Procedure


- 5.1 Connect the Collection Vessel to the Filtrate Drain System as shown in Section 1.12, if not already done so.
- 5.2 Assemble the Membrane Filtration Unit Drain Tray within the isolator and connect the Waste Discharge Tubing to the drain in the isolator chamber floor.
- 5.3 Pour approximately 100 mL of 6% hydrogen peroxide liquid (sterile) into the Drain Tray.
- 5.4 Turn on the Vacuum Pump of the Filtrate Drain System via the Foot-Switch.
- 5.5 Open the Manual Sanitary Drain Valve (Item 1) and allow the 6% hydrogen peroxide liquid within the Drain Tray to flow through the Waste Discharge Tubing, through the Filtrate Drain System and into the connected Collection Vessel stationed outside the isolator. For further information, see Section 1.4.
- 5.6 When testing for the session is complete, pour approximately 100 mL of 6% hydrogen peroxide liquid (sterile) into the Drain Tray and allow the liquid to flow through the Waste Discharge Tubing, through the Filtrate Drain System and into the connected Collection Vessel stationed outside the isolator.
 - NOTE:** *This step also removes any remaining residual membrane filtration rinsing fluid (e.g. Fluid A or Fluid D) from the FDS.*
- 5.7 Close the Manual Sanitary Drain Valve (Item 1).
- 5.8 Disconnect the tubing from the Collection Vessel Cap with Dissimilar Quick-Disconnects (Item 5).
- 5.9 Discard the liquid contents of the Collection Vessel as per appropriate waste procedures.

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- 5.10 Remove the Collection Vessel Cap with Dissimilar Quick-Disconnects (Item 5) and pour approximately 200 mL of distilled (or better quality) water into the Collection Vessel. Thread the Collection Vessel Cap with Dissimilar Quick-Disconnects (Item 5) tightly on the Collection Vessel and rotate the Collection Vessel to allow the liquid to contact the sides of the Collection Vessel and the internal surfaces of the Collection Vessel Cap with Dissimilar Quick-Disconnects (Item 5). Unthread the Collection Vessel Cap with Dissimilar Quick-Disconnects (Item 5) and discard the liquid contents per appropriate waste procedures.
- 5.11 Repeat Step 5.10 one additional time.
- 5.12 Pour approximately 200 mL of 6% hydrogen peroxide liquid (sterile) into the Collection Vessel. Thread the Collection Vessel Cap with Dissimilar Quick-Disconnects (Item 5) tightly on the Collection Vessel and rotate the Collection Vessel to allow the liquid to contact the sides of the Collection Vessel and the internal surfaces of the Collection Vessel Cap with Dissimilar Quick-Disconnects (Item 5).
- 5.13 Connect the Collection Vessel to the Filtrate Drain System as shown in Section 1.12.

6.0 General Cleaning

- 6.1 This method includes the general external cleaning procedure for the various items that make up the Filtrate Drain System.
- 6.1.1 Clean items/components using low-particulate wipe(s) saturated with 70% isopropyl alcohol. Allow to dry.

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7.0 General Troubleshooting

- 7.1 Refer to this Operations Manual.
- 7.2 Please feel free to contact Ardien Consulting Services if there are any technical questions related to the content of this document or the Filtrate Drain System.
- 7.3 Contact Ardien Consulting Services.
 - 7.3.1 Name: Rick Nieskes
 - 7.3.2 Email: rick@ardienconsulting.com
 - 7.3.3 Telephone: 262-548-9748
 - 7.3.4 Cell: 262-853-9748

7.4 Vacuum Performance Decrease

NOTE: See Item 7 on page 5 of 14 for the parts referenced in this section.

- 7.4.1 Make sure the Pressure Regulator Knob on the left side of the Vacuum Pump (adjacent to where the Muffler is attached) is slightly open. You should detect air flowing out of the hole in the top of the Pressure Regulator Knob when the Vacuum Pump is activated. If not, slightly open the Pressure Regulator Knob. If dust-like particulates flow out of the hole in the top of the Pressure Regulation Knob, it is likely the Muffler is loaded with particulates. In such case, proceed to Step 7.4.2 to clean the Muffler.
- 7.4.2 Remove the Muffler from the Vacuum Pump using a suitable wrench. Gently tap the Muffler to remove any particulates trapped inside the Muffler. Clean the Muffler with soap and water then rinse with 70% isopropyl alcohol.