Electrol Specialties Company
441 Clark Street
P.O. Box 7
South Beloit, Illinois 61080 USA
Tel 815-389-2291 – Fax 815-389-2294
www.esc4cip.com

ELECTROL SPECIALTIES COMPANY

Validatable Cleaning of Filter Housings in Line

The increased use of larger multi-element filter housings in pharmaceutical and biotech processes has focused increased attention on the amount of time and effort often associated with the removal of filter housings from a line and relocating them to an off line CIP station. Leading edge companies are rapidly accepting Electrol Specialties' developed process for CIP of filter housings, as part of the process CIP circuit (in-line), thereby reducing the handling of the housing components, and the possibility of handling damage, while providing improved cleaning and operator safety. To make this approach work properly, effective CIP design must provide for incorporating the associated piping and valves required for flushing, steaming, blow-down, integrity testing, filtration, as well as CIP operations.

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Applications and Spray Devices

Figure 1

Left – The Disc Distributor applies a sheet of water at low pressure at the very top of the filter housing dome. The holes in the disc are to allow CIP flush, wash and rinse solutions to fully cover all surfaces of the CIP device.

Right – The Tube Spray device emulates a fixed drilled spray ball and can be installed to any depth required to assure coverage of auxilliary nozzles present in some filter housing domes.

In order to facilitate effective cleaning of filter housings in line, those filter housings must be part of a closed circuit. Traditionally this approach would result in the filter housing just being a wide spot in the line and during the CIP process; it would have some diminishing portion of trapped air in the dome and a somewhat stagnant pool of solution in the lower part of the housing. The ESC approach supplements all the CIP supply steps with air injection. Using air injection in the CIP supply allows the air to separate when the solution enters the filter housing being cleaned, and also maintains a pressure in the circuit while substantially evacuating the housing of solution. Now, coupled with one of ESC high volume low pressure spray devices, the cleaning solutions and rinses can be actively moving down the sidewalls and head of the filter housing, thereby exposing these surfaces to turbulent flow and constantly replenished solutions, the key to effective CIP. The high volume low pressure spray devices easily allow for flow rates necessary to reach 5 fps in the various lines in that circuit being cleaned e.g. 45 gpm for 2" lines. By using these ESC high flow, low pressure, spray devices, shown in Figure 1, it allows filter housings to be cleaned in series or even in series followed in line by a tank or vessel. The flow rate for the circuit in the example is dictated by the line or vessel flow requirement.

Two different spray distribution devices have been developed by ESC. A simple disc distributor that assures full coverage of filter housings of commonly used diameters at high flow rates and minimal pressure, and a spray tube that provides a controllable pattern more analogous to a fixed ball spray for use in filter housings fitted with auxiliary nozzles in the domes. Both sprays are fabricated of 316L Stainless Steel, electro-polished, and designed and intended for permanent installation during all phases of the cleaning, steaming and filtration processes. These devices, depending on the application and product, may be left in place even during processing of the product.

The schematic of a filter housing and valves shown in **Figure 2** is representative of the typical design and engineering practices now in use. Transfer line piping of 1-1/2" diameter requires a flow of 23-25 gpm and 43-45 gpm is required for 2" size. All top piping connections for Venting, CA, CS and water (if required) would be located on the inlet manifold with minimum dead leg valves and thus be subjected to full CIP/SIP treatment with the housing. Valve 2 must be automated, as must the downstream valve to any vessel spray and fill pipe, a normal practice. The operation requires full flow through the filter housing spray at all times, with air injected to the CIPS stream as required to keep the housing essentially empty. Valve 2 would be opened for a couple of seconds of each minute to clean the inlet connection, as would Valve 4 to the downstream vessel fill connection.

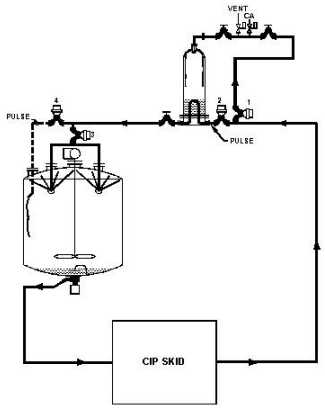

Figure 2 – Example of Commercial Practice to Clean FH, Transfer Line, and Vessel from CIP Skid

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Figure 3 – Multiple filter housing series flow

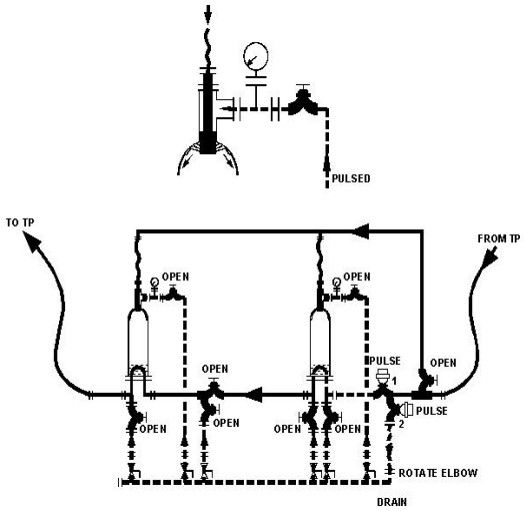

Figure 2 illustrates how a process vessel, filter housing and top piping, process piping, CIP Skid and CIPS/R piping is typically arranged in a CIP circuit.

Even though this in-line filter housing cleaning approach works best in new facilities and major upgrades it is possible to retrofit to existing filter housings and filter carts. The following **Figure 3** and photos illustrate Filter Carts fitted with housings which had 1" vent ports on the inlet nozzles and were already piped with manual valves and 1/2" COND piping. The substitution of air actuators on two hand valves and the provision of a swing elbow to drain and relocatable to the outlet port of one valve made it possible to apply automated CIP to several filter carts essentially similar to those shown in the included photos. The Tube Spray was selected to permit the inlet nozzle tee branch to be cleaned by reverse flow through the VENT/COND lines. The CIP Procedure included the following steps.

- Remove cartridges and wipe housing joints.
- Install CIPS Hose to DRAIN Elbow rotated up.
- Open all Hand Valves Fully.
- Filter Housings will be sprayed with solution and entrained air.
- Outlet Valve will be closed and ‘pulsed” open 5 seconds of each minute to clean inlet connection to first housing.
- CIPS valve to Vent Drain piping will be “pulsed” open 5 seconds of each minute to clean COND/VENT piping.
- For SIP, drain connection will be moved to COND (trapped) header provided.

Two different applications of the above are shown in the photographs below.

Two Filter Housings of like size cleaned in parallel (left) and of unlike size cleaned in parallel (right)

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Validatable Cleaning of Filter Housings in Line (cont.)

Air Injection Requires Air Disengagement - Whereas the introduction of air to the CIP Flush, wash and rinse solutions substantially reduces water, chemical and time requirements, it imposes some design and operating constraints. The CIP return flow from any line circuits containing Filter Housings must be to a CIP Skid which allows air disengagement before the return flow enters the CIP Supply pump. The ESC SUEA (Single-Use Educator-Assisted) CIP skid has handled return flow from such circuits in a highly effective manner. Conventional low speed (1750 rpm) return pumps may be used if a vented process vessel is downstream of the Filter Housing. A means of disengaging all air from the return stream is essential, either prior to or as part of the CIP Skid and the by-pass type CIP System requires air disengagement capability upstream of the CIP skid.

These ESC spray devices have proven very effective in CIP of filter housings using the above approach. The ESC spray devices are provided with material certifications, weld logs, weld maps and surface finish reports to be used as part of the overall system validation. ESC is available to provide consultation for specific applications upon request.

Validation

The typical validation process after proper circuit hydraulic design and evaluation would include all the usual parameters for any cleaning validation, and include some data to be specifically aware of relative to this approach:

- Method to verify solution flow rate for the circuit, typically included within the CIP package.
- Method to control and verify clean air injection rate recommended to be 2.5 times the total filter volume in slpm (typical Brooks mass air flow controller at the CIP skid)
- Method to establish time to reach equilibrium in the housing during start-up (typical sight glass in line down stream from last housing to see air water mixture).
- Verify effective and repeatable return flow as one now has a solution heavily entrained with air
- Riboflavin testing to assure coverage in the filter housing(s)
- Swab test to verify cleaning efficacy