GE Healthcare

Chromaflow Packing stations

Instructions for Use

Chromaflow

Important user information

All users must read this entire Instruction for Use, to fully understand the safe use of the Chromaflow Packing station.

Safety notices

This Instruction for Use contains safety notices concerning the correct use of the column. This information is provided to allow users to avoid personal injury and/or damage of the equipment, and to present information that can optimize the use of the columns. The various types of safety notices include:.

WARNING! The WARNING! sign and box highlights instructions that must be followed to avoid personal injury. It is important not to proceed until all stated conditions are met and clearly understood.

CAUTION! The CAUTION! box highlights instructions that must be followed to avoid damage to the product or other equipment. It is important not to proceed until all stated conditions are met and clearly understood.

IMPORTANT! The IMPORTANT! box highlights instructions or details relating to instructions that will help to ensure optimal use of the equipment.

Note: The Note is used to indicate information important for trouble-free and optimal use of the product.

Declaration of conformity

This product meets the requirements of applicable CE-directives. A copy of the corresponding Declaration of Conformity is available on request.

The **CE** symbol and corresponding declaration of conformity, is valid for the instrument when it is:

- used as a stand-alone unit, or
- connected to other CE-marked GE Healthcare instruments, or
- connected to other products recommended or described in this manual, and
- used in the same state as it was delivered from GE Healthcare, except for alterations described in this manual.

Note: The Declaration of conformity is valid only for systems that are marked with the CE logo.

Contents

1 Chromaflow Packing station

The Chromaflow™ Packing station is a semi-automatic packing station designed for use with Chromaflow columns. Using a Chromaflow Packing station with Chromaflow columns makes column preparation and packing a simple and clean operation, as well as helping to reduce operator time.

The Chromaflow Packing station consists of a control panel mounted on a frame, with two pumps and four valves housed underneath. The valves and pumps are controlled pneumatically and are operated from the control panel. As valves and pumps are brought into operation, indicators on the control panel display the relevant flow paths.

Two models of Chromaflow Packing station are available: Pack 50, which utilizes two pumps each with a maximum 50 l/min capacity, and Pack 100, which utilizes two pumps each with 100 l/min capacity. For drawings and other relevant documentation, please refer to the appropriate section in the Documentation Binder.

1.1 Application

The Chromaflow Packing station is a semi-automatic packing station designed for use with Chromaflow columns. GE Healthcare is not liable if the Chromaflow Packing station is used with equipment other than that specified in this manual.

1.2 Approved operators

To use the Chromaflow Packing station, the operator must have read, understood, and be aquainted with this Instructions for Use.

1.3 Product markings

The Chromaflow Packing station is marked with:

- GE Healthcare Code No: 18-1163-74 (Pack 50)
18-1162-08 (Pack 100)
- Serial number
- Year of manufacture
- Operating temperature: +4 to +30 °C
- Supply air pressure: 6 to 7 bar g
- Air consumption: 500 Nl/min* (Pack 50)
1000 Nl/min* (Pack 100)
- Maximum outlet pressure: 7 bar g

- Pump capacity: 50 l/min (Pack 50)
  100 l/min (Pack 100)
- EX category: II 3G
- These rating marks can be found on the rating plate:

Fig 1-1. The Chromaflow Packing station rating plate.

Note: A label in the local language is only available in countries within the EU. If not delivered with Chromaflow Packing station, it can be ordered from your local GE Healthcare office or GE Healthcare Bio-sciences AB in Sweden.

1.4 Safety compliance

The CE-marked Chromaflow Packing station complies with the EU directive described in the Declaration of Conformity in this Instructions for Use. The compliance with the directive is valid only under the condition that the Chromaflow Packing station is installed, operated, and maintained according to the Documentation Binder and Instructions for Use. To maintain compliance, use only spare parts approved or supplied by GE Healthcare.

1.4.1 Use in potentially explosive atmospheres

EX marking

The EX code on the identification label defines the level of explosion protection of the equipment. The EX category of the equipment must be in conformity with the protection level of the room where it is to be used.

Ex II 3 G

Equipment in this category is designed to be capable of functioning in conformity with the operating parameters established by the manufacturer and ensuring a normal level of protection. Equipment in this category is intended for use in areas in which explosive atmospheres caused by gases, vapors, or mists are likely to occur or, if they do occur, are likely to do so only infrequently and for a short period only.

When used in potentially explosive atmospheres, the following precautions should always be observed:

- Avoid discharge from static electricity by grounding/earthing the column. Use a grounding wire connected from the plant grounding network to the Packing station grounding plate (see Figure below). A grounding kit is included with the delivery of the Chromaflow Packing station.

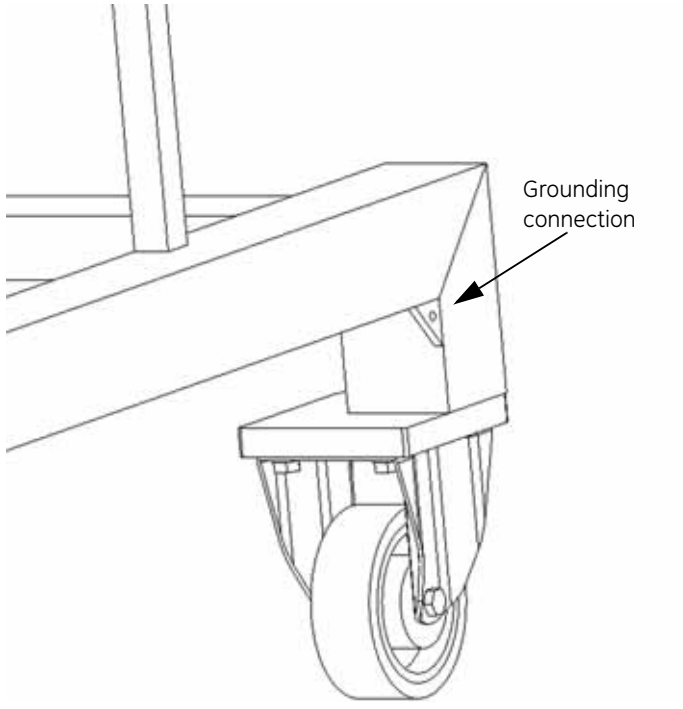

Fig 1-2. The grounding connection on the Chromaflow Packing station.

1.5 Safety precautions

IMPORTANT! Whenever the column is used, always keep the Instructions for Use for the column on hand.

IMPORTANT! The end user must ensure that all installation, maintenance, operation and inspection is carried out by qualified personnel who are adequately trained and understand the operating instructions.

WARNING! Always use protective clothing appropriate with the current application to ensure personal safety during operation.

WARNING! Pay extra attention when working close to the packing station.

WARNING! Do not exceed the rated pressure of the incoming air supply, otherwise there is a risk of personal injury and damage to the column. A suitable safety device must be fitted.

1.6 Technical specifications

1.6.1 General

The primary technical specifications for Chromaflow Packing stations are listed in the tables below.

Table 1-1: Dimensions and design specifications for Chromaflow Packing stations.

Description	
Footprint	810 x 715 mm
Height	1175 mm
Weight Pack 50 Pack 100	 115 kg 130 kg
Operating temperature	4 to 30 °C
Supply air pressure	6 to 7 bar g
Noise level (maximum)	85 dB (A)
Air consumption Pack 50 Pack 100	 500 Nl/minute 1000 Nl/minute
Max. outlet pressure	7 bar g
Pump capacity Pack 50 Pack 100	 50 l/min 100 l/min

Table 1-2: Materials of construction and media contact information for Chromaflow Packing stations.

Part	Material	In contact with pumped media?
Valve bodies	1.4435 (316L) forged	Yes
Valve diaphragms	EPDM	Yes
Pump housings	HDPE	Yes
Pump diaphragms	PTFE coated	Yes
Pump balls	PTFE	Yes
Pump inlet/outlet	1.4435 (316L)	Yes
Pump seals	EPDM	Yes
Piping	1.4435 (316L)	Yes
Frame	1.4401 (316)	No
Wheels	Polyurethane coated	No

Table 1-3: Interface connection dimensions and sizes for the Chromaflow Packing station.

Interface	Dimension, internal diameter	Flange type and size
Packing station inlet B	Pack 50: 1" (22.1 mm) Pack 100: 1.5" (34.8 mm)	Pack 50: TC 1" Pack 100: TC 1.5"
Packing station inlet C	Pack 50: 1" (22.1 mm) Pack 100: 1.5" (34.8 mm)	Pack 50: TC 1" Pack 100: TC 1.5"
Packing station inlet SOB	1" (22.1 mm)	TC 1"
Packing station outlet D	1" (22.1 mm)	TC 1"
Packing station outlet SIT	1" (22.1 mm)	TC 1"
Packing station outlet SIB	1" (22.1 mm)	TC 1"

1.6.2 Noise level

The noise level from Chromaflow Packing station has been measured during packing/unpacking. The test was performed at maximum pump capacity at a point 1 m from the surface of the packing station and 1.6 m from the floor.

Max. measured noise level: 85 dB (A)

1.6.3 Chemical resistance

Table 1-4 is a guide to the resistance of Chromaflow Packing station to chemicals and solvents commonly used in process chromatography. The information has been compiled from published material from several sources, not from individual tests on the components of Chromaflow Packing station.

It should be noted that the effects of a chemical will be more severe at higher temperatures and pressures and that combined effects have not been taken into consideration.

In general, the use of the following chemicals should be avoided:

- Powerful oxidizers (such as peroxides)
- Fluorine and halenogenated compounds
- Chlorinated solvents (such as methylene chloride)
- Esters
- Aromatic hydrocarbons (such as toluene)
- High concentrations of strong acids

Table 1-4: Chemical resistance of materials in Chromaflow Packing stations.

Substance	**Concentration by volume**	**Resistance 60–90 days**
Acetic acid	1.7 M	OK
Ethanol	40%	OK
Ethylene glycol	50%	OK
Formaldehyde	1.7 M	OK
Formic acid	10%	OK
Glycerol	100%	OK
Hydrochloric acid	0.1 M	See note 1
Isopropyl alcohol	30%	OK
Nitric acid	0.1 M	OK
n-Propanol	100%	OK
Phosphoric acid	25%	See note 2
Sodium chloride	0.5 M	See note 1
Sodium hydroxide	2 M	OK
Trifluoroacetic acid	0.1%	OK
Triton™ X-100	100%	OK
Tween™/Tri-n-butyl phosphate	1% / 0.3%	OK
Urea	8 M	OK

Note 1: Not recommended. The stainless steel will be affected.

Note 2: Limited resistance.

1.7 Storage

Prior to storage, Chromaflow Packing station must be cleaned properly to ensure that all slurry is removed from the tubing. The Chromaflow Packing station must be stored at room temperature and must not be exposed to extreme temperatures. A common storage technique is to seal off all inlets and outlets, and use 20% ethanol as storage solution. However, long-term and other special storage conditions may require other solutions. For additional advice on storage, contact your GE Healthcare service representative.

1.8 Operating panels

The Chromaflow Packing station is controlled via upper and lower operating panels. The upper panel provides a view of the flow scheme, a gauge showing the packing pump air pressure, and the ability to toggle the flow path between inlets B and C, and between column SIT and SIB (see Figure 1-3).

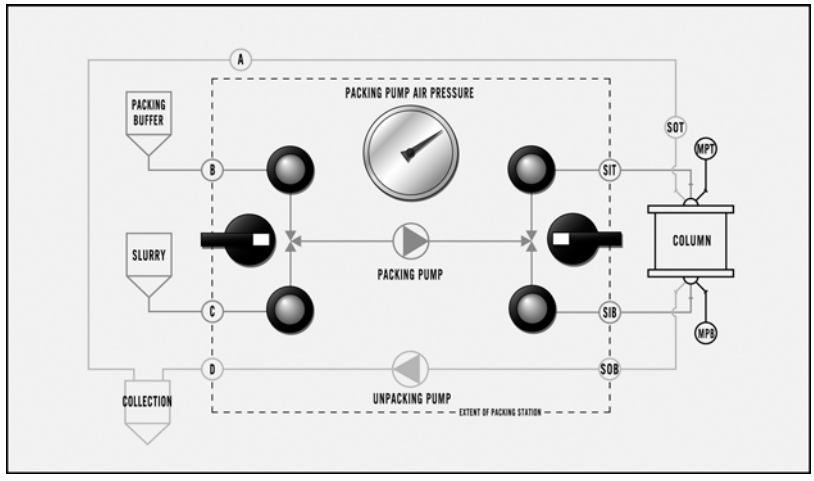

Fig 1-3. Diagram of the upper operating panel.

The lower operating panel is the primary point for operating the packing station. The following functions are available:

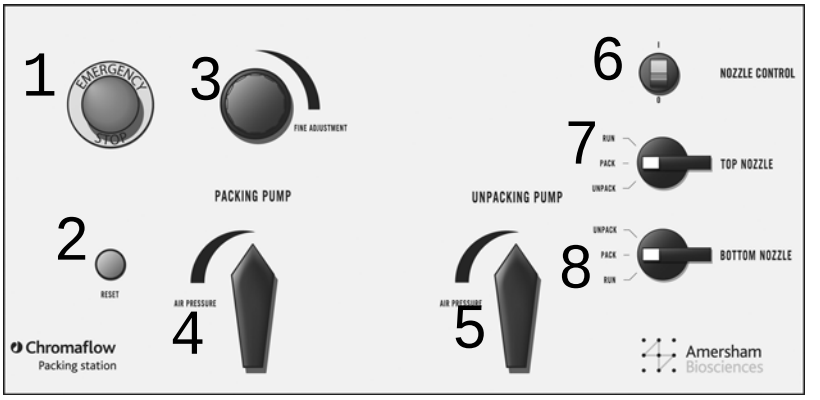

Fig 1-4. Diagram of the lower operating panel.

1. Emergency STOP button – Stops the system when pushed. All pneumatic air is purged, inlet and outlet valves are closed, and both pumps stop. To reactivate it, twist the button out.
2. RESET – After reactivating the STOP button, push this button and hold down for a few seconds to return the system to the same status as before the emergency STOP.

WARNING! When the system is reactivated using the RESET button the pumps will start at the same setting prior to pressing the emergency STOP button. If the pump setting was on maximum then reactivating the system will start the pumps at the maximum level delivering a sudden high level of noise, and also an immediate high pressure increase in the system. You are advised to reduce the pump setting prior to using the RESET button.

3. FINE ADJUSTMENT – Use this knob to make fine-scale adjustments to the PACKING PUMP air pressure.
4. PACKING PUMP (AIR PRESSURE) – Controls the amount of air delivered to the PACKING PUMP.

Note: This bypasses the FINE ADJUSTMENT knob.

5. UNPACKING PUMP (AIR PRESSURE) – Controls the amount of air delivered to the UNPACKING PUMP.
6. NOZZLE CONTROL – Activates (I) or deactivates (0) the TOP and BOTTOM NOZZLE toggle switches.

Note: The nozzle control should always be set to (0) when the nozzle control function is not used.

7. TOP NOZZLE – Sets the TOP NOZZLE to RUN, PACK, or UNPACK.
8. BOTTOM NOZZLE – Sets the BOTTOM NOZZLE to RUN, PACK, or UNPACK.

2 Before operation

2.1 Unpacking on delivery

When removing the Chromaflow Packing station from the shipping crate, use a fork lift positioned under the base frame. Be sure to place the packing station on a level surface.

CAUTION! During lifting operations to help prevent damage to the surfaces of the Chromaflow Packing station and thus minimize the risk of rusting, you are advised to place a soft material between the forks of the fork lift truck and the station frame.

2.2 Preparing the column and Packing station

2.2.1 Physical installation

Refer to the Documentation Binder for pneumatic connections. Check to verify that the column has been properly leveled.

2.2.2 Air supply

During operation, the Chromaflow Packing station requires a supply of compressed air, 6–7 bar g.

2.3 Connecting the Chromaflow Packing station to the column

IMPORTANT! The suggested connection schemes are of a general nature. Users may wish to alter the configuration, depending on specific needs. If there is any question about the safety of the intended setup, please contact your GE Healthcare representative for clarification.

Follow the instructions below for proper connection of the Chromaflow Packing station to the column and vessels. Refer to Figure 2-1 below to clarify this operation.

Note: Check the inner diameter of the tubing connected to the Chromaflow Packing station and the column. If the inner diameter is too small, it can lead to high back-pressure and reduced flow capacity. To avoid creating steps in the flow pathways, always use the same diameter connector seals. In addition, to ensure a smooth transition from one diameter to another, always use conical reducers.

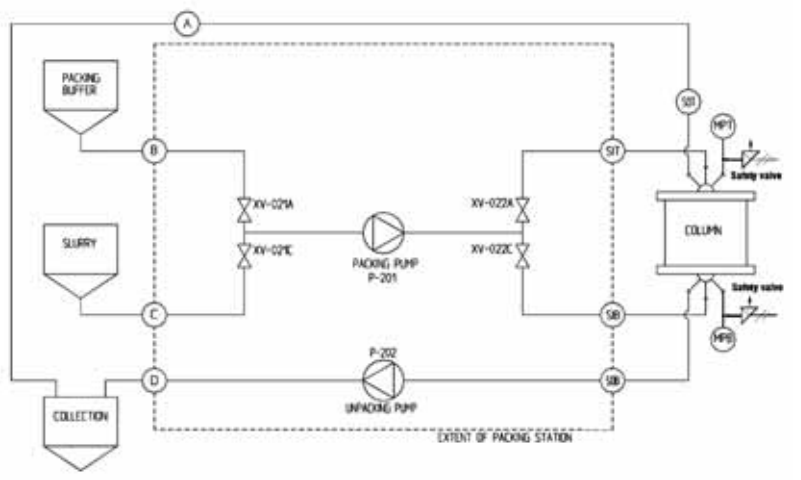

Fig 2-1. Connecting the Chromaflow Packing station prior to operation.

1. Connect Outlet (SIT) to column (SIT).
2. Connect Outlet (SIB) to column (SIB).
3. Connect Inlet (SOB) to column (SOB).

Make the following connections to join the tanks to the Chromaflow Packing station:

1. Connect Inlet (C) to Slurry tank.
2. Connect Inlet (B) to Water/Buffer tank.
3. Connect Outlet (D) to Waste/Collection tank.

Note: Use closed vessels to prohibit evaporation.

On the column, mount a 3-way valve on both MPT and MPB. The valves should have the same inner diameter as the column inlet/outlet. To be able to determine when the packing is completed, connect a pressure gauge (maximum range 0 to 6 bar) to the mobile phase top (MPT) when using downward packing, and to the mobile phase bottom (MPB) when packing with upward flow. Connect a tube from the MPB valve to a drain.

WARNING! Ensure that any tubing on the floor is placed so that the risk for tripping accidents is minimized.

Consult your column Instructions for Use or User manual for further instructions on connecting the column to a packing station.

2.4 Preoperational checks

Prior to operation check that:

- the indicators on the control panel are functioning correctly, otherwise there is a risk that the Chromaflow Packing station will try to operate a column with its outlet valves closed.
- tubing from the Chromaflow Packing station to the inlet and outlet tanks, and from the Chromaflow Packing station to the column, is properly connected in accordance with the respective Instructions.
- all tubing is in good condition and verify that there is no risk for leakage at any connection.
- the outlet tubing or piping from the Chromaflow Packing station is connected to the equipment that is part of the closed system, for example a tank with lid.
- the pneumatic air supply, that furnishes the valves and pumps with compressed air, is assembled correctly.
- at least one outlet valve on the column is open before starting the pump, otherwise pressure may exceed the design limit.

2.5 Priming the column and packing station

Before proceeding with packing, the Chromaflow Packing station and column must be primed.

IMPORTANT! Various methods are available for priming the Chromaflow Packing station and associated column. The instructions provided below are a general method that is suitable for many situations. However, modifications to this method may be necessary, depending on the set up of the system and operating procedures. If further instructions on priming or packing are needed, please contact your local GE Healthcare representative.

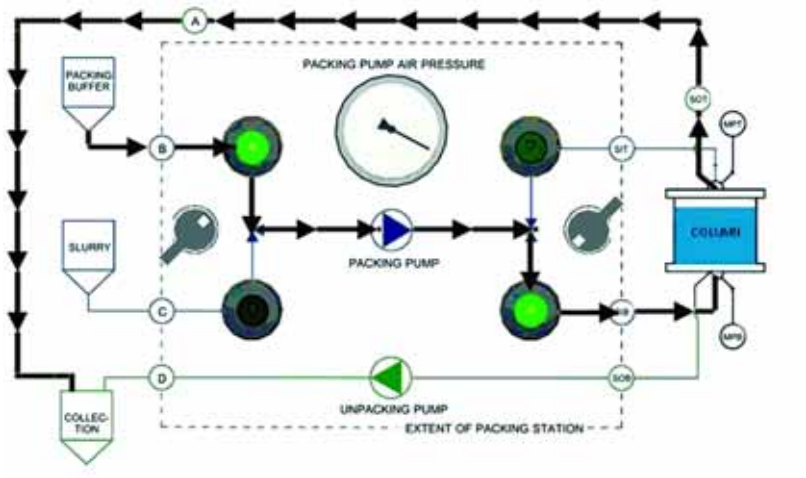

Fig 2-2. Schematic flow chart when priming.

To prime the Chromaflow Packing station and column, refer to the schematic above and follow these steps:

1. Set the top nozzle to the UNPACK position and the bottom nozzle to the RUN position (see left).
2. Connect a fluid source to MPB and slowly run liquid into MPB. This will remove air from the MPB and from beneath the bed support. Allow sufficient time to ensure that the bottom distributor is flooded.
3. Set the bottom nozzle to the PACK position.
4. Open B and SIB and start the packing pump to fill the vessel (via the bottom nozzle) until liquid exits through SOT to the collection tank, then stop the packing pump.
5. Retract the top nozzle to the RUN position.
6. Continue the flow of liquid out through MPB in order to remove air bubbles from the bottom distributor.
7. Open the valve on the MPT and continue flowing liquid through SIT until all air has been driven through the top bed support and out through MPT.
8. Close MPT and allow pressure to build up without exceeding the maximum pressure. Open MPT to purge the last air bubbles, then stop the flow and close MPT. Repeat the same procedure for MPB.
9. Retract the bottom nozzle to RUN position.

The Chromaflow Packing station and column are now primed and ready to pack.

3 Operation

Prior to operating the Packing station, be sure to follow the instructions laid out in Chapter 2 of this Instructions for Use.

IMPORTANT! As stated elsewhere in this manual, the packing and unpacking instructions are a general method that may not be useful for all situations. Modifications to these instructions (and to the connections between the packing station, the column, and the vessels) may be necessary under other operating scenarios. Contact your GE Healthcare representative for further information.

IMPORTANT! Several of the steps in the following sections refer to the use of a pressure gauge. These particular steps are part of a general method suggested by GE Healthcare, although modifications can be made to these instructions that do not need a pressure gauge. To order a pressure gauge, please contact your GE Healthcare representative.

3.1 Column packing with the Chromaflow Packing station

Chromaflow columns can be packed via the bottom or top nozzle. The instructions below are for packing from the top. To pack from the bottom, carry out the same procedure for the connections and flow path via the bottom nozzle.

3.1.1 Packing from the top

Note: Make sure that the column has been prepared for packing as described in Chapter 3 of the Chromaflow columns Instructions for Use.

1. Connect a flexible pipe/hose to MPB and secure a loop that is above the top of the maximum bed height. This will prevent siphoning.
2. With the top nozzle in the RUN position, open C and SIT and start the packing pump. Slurry will flow through the pump into the top nozzle and back to the slurry tank via SOT and the flexible hose, thus priming the packing lines.

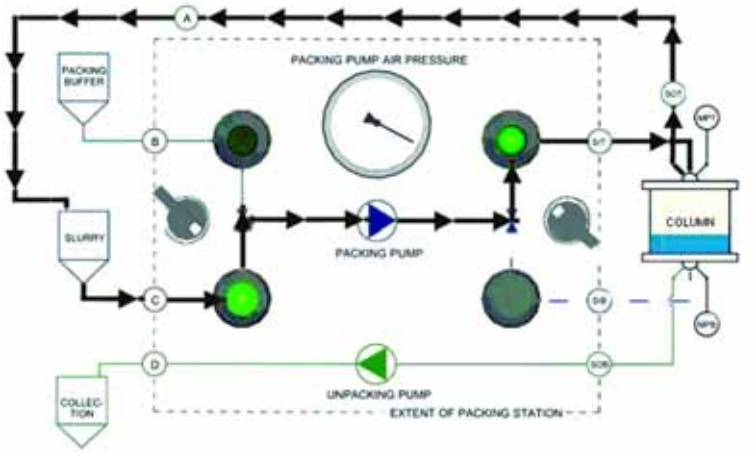

Fig 3-1. Schematic flow diagram of the packing set up.

3. At this time, it is possible to adjust the flow to suit the optimized flow rate for the media in use. Adjust the pump speed by using the FINE ADJUSTMENT knob on the operating panel and reading the resulting flow from a flow meter (alternatively, read the flow by using a stop watch and bucket). Adjusting the flow can also be achieved by using the pressure gauge and measuring the column pressure drop. Refer to media instructions for approximate flow rates.
4. Open MPB and insert the top nozzle to the PACK position.
5. Once the column is packed, retract the top nozzle and change the suction to inlet B to flush out the packing lines with packing buffer.
6. Close MPB.

Note: Remember to stir the media slurry during packing to prevent it from settling.

7. Stop the pump and disconnect suction B.
8. Run the pump dry to remove most of the residual liquid.

The column is now ready to equilibrate and test.

3.2 Unpacking the column with the Chromaflow Packing station

Unpacking the column takes about 20–25 minutes. Before starting with this procedure make sure that:

The set up is the same as for packing, with the addition of:

- Outlets A and D are connected to the slurry vessel.

Phase 1

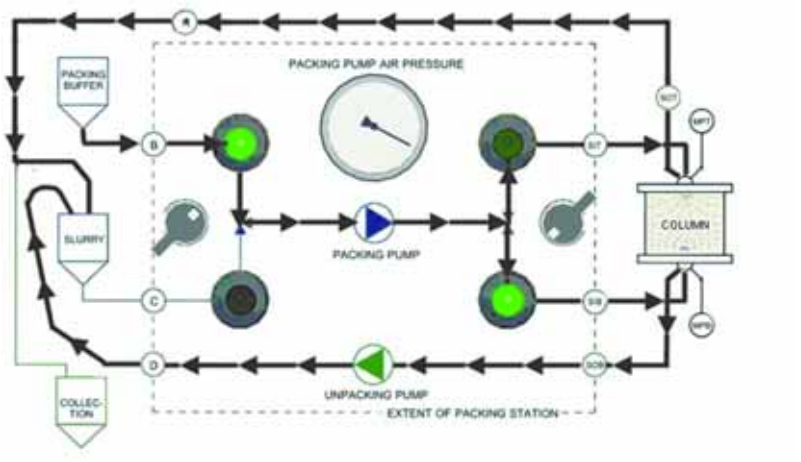

Fig 3-2. Schematic flow diagram, step 1, for unpacking set up.

1. Fill the packing buffer tank with about four times the column bed volume of unpacking liquid.
2. Set the suction of the packing pump to B.
3. Set both top and bottom nozzles to the UNPACK position (fully extended).
4. Set the discharge of the packing pump to the bottom nozzle.
5. When the slurry is recirculating easily, increase the flow to maximum.
6. Start the packing pump on a slow setting. Monitor the column pressure to assure that it does not exceed limits.
7. When the media in the column begins to form a slurry, switch the suction from B to C. Slurry will now be recycled into the column and back to the slurry tank.
8. Toggle between top and bottom nozzles until all of the recycling media is slurry. On acrylic tubes, breakthrough can be observed through the column wall.
9. Stop the packing pump and direct outlets A and D to the collection vessel to remove slurred media.

Phase 2

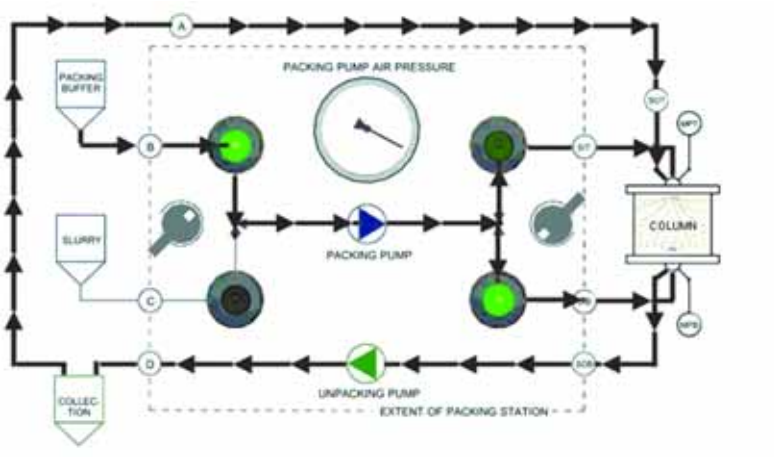

Fig 3-3. Schematic flow diagram, step 2, for unpacking set up.

1. Start the unpacking pump. Slurry is removed from the column via outlet D, and air is entered into the column via inlet A.

Note: Ensure that the orifice leading from Collection to the column via outlet A is above the surface of the slurry to allow air to be pumped.

2. Change to B and use the packing pump, toggling between the top and bottom nozzles to flush out the remaining media.
3. When empty, stop the pumps. Set the top nozzle to Pack position. Pump packing buffer through SIT and simultaneously run the unpacking pump for a final rinse of the bed supports and the complete column.

Note: You can monitor the column pressure so that it is not subjected to over-pressure.

4. Retract both nozzles and flush the lines and the unpacking pump with packing buffer.

The unpacking procedure is now completed.

3.3 Cleaning the column

Connect the column as shown in the figure below.

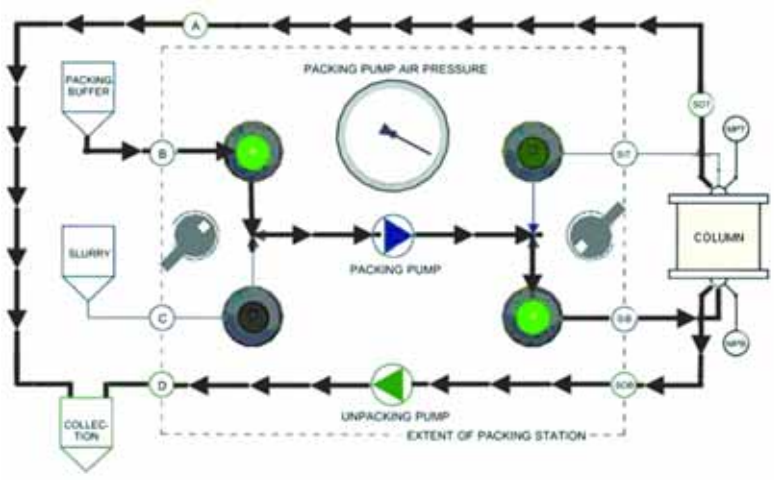

Fig 3-4. Schematic flow diagram for cleaning the column and Packing station.

Fill the Packing Buffer tank with cleaning solution. Then select the following process positions:

1. With both top and bottom nozzles in the UNPACK position (fully inserted into the column), configure the packing station in the following manner:

   Inlet (B) – cleaning solution
   Outlet (A) – to collection vessel / waste
   Outlet (D) – to collection vessel / waste

2. Turn the packing pump on and toggle between the column (SIT) and (SIB). Cleaning solution will spray out from the top and bottom nozzles, respectively. Continue this procedure for some minutes.
3. Stop the packing pump and run the unpacking pump until all cleaning solution is removed from the column.
4. Retract the top nozzles to its RUN position (level with the bed support). Run both pumps simultaneously. Stop the pumps when the top bed support appears to be free of beads.
5. If there still are cleaning liquid in the column, remove it by inserting the top nozzle to its unpack position and use the unpacking pump to empty the column.
6. To clean the mobile phases, select the PACK position on the bottom nozzle (mid-position).
7. Select the UNPACK position on the top nozzle (fully inserted).
8. Pump liquid via the bottom nozzle. Once the column is full, liquid starts to exit via SOT. Check the column pressure on the packing pressure gauge. It should not rise above the column pressure rating; lower pressure by reducing the pump speed.

9. Open MPB and close SOT by retracting the top nozzle, when column interior appears to be free of air. Liquid will now leave via MPB and clean the bottom mobile phase.
10. To clean the top mobile phase, close MPB and open MPT.
11. Stop the pump and close MPB and MPT when both mobile phases are cleaned. Insert top and bottom nozzle to unpack position and use the unpacking pump to empty the column.
12. Finally, repeat steps 1 to 9 using 20% ethanol, then allow the column to drain. The column is now clean and ready to pack or store.

3.4 After use

Rinse the Chromaflow Packing station carefully after it has been used and make sure there is no adsorbent remaining. Residual adsorbent can restrict or block the flow passages, resulting in an increase in pressure.

3.5 Disconnecting the Chromaflow Packing station from column

CAUTION! Always **TURN OFF** the compressed air supply before disconnecting the Chromaflow Packing station from the column.

Clean the Chromaflow Packing station carefully, making sure that there is no hazardous liquid remaining in the tubing. Remove the tubing between the Chromaflow Packing station and the column.

4 Maintenance and troubleshooting

4.1 General

WARNING! Do not perform any type of maintenance work while the packing station is connected to an air supply.

IMPORTANT! Only approved operators are allowed to do maintenance work on Chromaflow Packing station.

The Chromaflow Packing station is designed to require a minimum of service and maintenance. The only maintenance that can be safely carried out by an operator is replacement of the gaskets between the tubing and outlets of Chromaflow Packing station. For ordering information, refer to the Spare Parts List.

For maintenance work other than that specified above, please contact your local GE Healthcare representative.

4.2 Cleaning before maintenance/service

IMPORTANT! Make sure that the packing station has been thoroughly cleaned to remove any infectious or aggressive fluids.

A Health And Safety Declaration /Liability form must always be completed prior to maintenance/service by GE Healthcare personnel, or if the equipment is to be returned.

A decontamination report is enclosed in the Documentation Binder supplied with the Chromaflow Packing station.

4.3 Troubleshooting

- If the packing station does not function at start up (i.e. the valves are not working), check that the compressed air supply is sufficient.
- If the flow is not working as planned check the status of the inlet and outlet valves and that the flowpath is open.

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www.gehealthcare.com/protein-purification-bioprocess

GE Healthcare Bio-Sciences AB
Björkgatan 30
751 84 Uppsala
Sweden

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Chromaflow is covered by the following patents: US 5,213,683; US 5,282,973; GB 2 307 028B; EP 776243.

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GE Healthcare Bio-Sciences AB
Björkgatan 30, 751 84 Uppsala, Sweden

GE Healthcare Europe GmbH
Munzinger Strasse 5, D-79111 Freiburg, Germany

GE Healthcare UK Ltd
Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, UK

GE Healthcare Bio-Sciences Corp
800 Centennial Avenue, P.O. Box 1327, Piscataway, NJ 08855-1327, USA

GE Healthcare Bio-Sciences KK
Sanken Bldg. 3-25-1, Hyakunincho, Shinjuku-ku, Tokyo 169-0073, Japan

Asia Pacific Tel +85 65 62751830 Fax +85 65 62751829 • Australasia Tel +61 2 8820 8299 Fax +61 2 8820 8200 • Austria Tel 01 /57606 1613 Fax 01 /57606 1614 • Belgium Tel 0800 73 890 Fax 02 416 8206 • Canada Tel 1 800 463 5800 Fax 1 800 567 1008 • Central & East Europe Tel +43 1 972 720 Fax +43 1 972 722 750 • Denmark Tel +45 70 25 24 50 Fax +45 45 16 2424 • Eire Tel 1 800 709992 Fax +44 1494 542010 • Finland & Baltics Tel +358 9 512 3940 Fax +358 9 512 39439 • France Tel 01 69 35 67 00 Fax 01 69 41 98 77 • Germany Tel 0800 9080 711 Fax 0800 9080 712 • Greater China Tel +852 2100 6300 Fax +852 2100 6338 • Italy Tel 02 26001 320 Fax 02 26001 399 • Japan Tel 81 3 5331 9336 Fax 81 3 5331 9370 • Korea Tel 82 2 6201 3700 Fax 82 2 6201 3803 • Latin America Tel +55 11 3933 7300 Fax +55 11 3933 7304 • Middle East & Africa Tel +30 210 96 00 687 Fax +30 210 96 00 693 • Netherlands Tel 0800-82 82 82 1 Fax 0800-82 82 82 4 • Norway Tel +47 815 65 777 Fax +47 815 65 666 • Portugal Tel 21 417 7035 Fax 21 417 3184 • Russia, CIS & NIS Tel +7 495 956 5177 Fax +7 495 956 5176 • Spain Tel 902 11 72 65 Fax 935 94 49 65 • Sweden Tel 018 612 1900 Fax 018 612 1910 • Switzerland Tel 0848 8028 10 Fax 0848 8028 11 • UK Tel 0800 515 313 Fax 0800 616 927 • USA Tel +1 800 526 3593 Fax +1 877 295 8102

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