Learning to Use the **Kvick Lab** Cassette Holder

User Manual

cytiva.com

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1 Important user information

All users must read this entire manual to fully understand the safe use of Kvick Lab™ Cassette Holder.

⚠	**WARNING** **WARNING** indicates a hazardous situation which, if not avoided, could result in death or serious injury. It is important not to proceed until all stated conditions are met and clearly understood.

⚠	**CAUTION** **CAUTION** indicates a hazardous situation which, if not avoided, could result in minor or moderate injury. It is important not to proceed until all stated conditions are met and clearly understood.

Note: *A note is used to indicate information that is important for trouble-free and optimal use of the product.*

Recycling

Waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of the equipment.

2 About this user guide

This user guide describes how to use the Cytiva Kvick Lab cassette holder. Topics include how to integrate and connect the holder to your cross-flow system, how to install cassettes, and how to use and clean the holder and cassettes.

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2.1 Audience

This user guide addresses the needs of scientists, process engineers, and technicians who operate laboratory and pilot-scale cross-flow systems. The level of information presented in this guide assumes the user possesses basic laboratory and technical skills, and has the knowledge and documentation to safely operate any user supplied equipment connected to the Kvick Lab cross-flow system. If you need assistance with the instructions in this guide, contact Cytiva for more information.

2.2 Where to find more information

You can consider this user guide as part of a set. When you purchase Kvick Lab cassettes or a Kvick Lab crossflow system, you receive the other documents in the set (see the list below).

You can download technical documents and learn more about Kvick Lab cassette holders and cross-flow systems by visiting our website, *cytiva.com*.

You can also receive customer and technical support by visiting *cytiva.com*.

Key documents for Kvick Lab products

- **Kvick Lab Cross-Flow System: Instructions for Use –** Describes how to install, use, and maintain theKvick Lab cross-flow system, reservoir, feed pump, and accessories. Supplied with Kvick Lab cross-flow systems.
- **Learning to Use the Kvick Lab Cassette Holder —** Describes how to use the Kvick Lab cassette holder. Topics include: installation in a cross-flow system, operation, and cleaning. Supplied with Kvick Lab cassette holder.
- **Cytiva Cassettes: Instructions for Use —** Describes basic operational procedures such as flushing, cleaning, and specifications. Supplied with cassettes.
- **MSDSs for glycerin and NaOH —** Provides safe handling and disposal information. Available for printing and downloading from the Cytiva website.

2.3 Safety

Everyone who works with the Kvick Lab cassette holder should read, understand, and follow the instructions in this user guide and the safety guide entitled: *Cross-Flow System Safety: Multilingual Safety Instructions* (provided with your system).

If you do not understand an instruction, you should stop working with the Kvick Lab holder and contact Cytiva for guidance. You should save the user and safety guides and make them available to all users of the Kvick Lab holder.

Cytiva designed the Kvick Lab cassette holder for laboratory scale filtration of biological solutions using membrane cassettes under the conditions stated in this user guide. If you use the holder and cassettes in a manner not specified by Cytiva, you may impair the protection provided by the holder and cassettes.

When using any laboratory, pilot-scale, or production cross-flow equipment, the potential exists for personal injury unless you follow established safety procedures. When using Cytiva products, you should follow OSHA, federal, state, and local safety regulations for equipment installation and operation. You should follow your company's safety regulations. You should follow the specific safety instructions provided in this user guide and any original equipment manufacturer user guides provided with your system.

Only qualified personnel who are adequately trained and who understand the operating instructions should install, operate, maintain, and inspect the Kvick Lab cassette holder.

2.4 Warnings, cautions, and tips

This user guide uses symbols and blocks of text to provide you with safety warnings and other important information:

WARNING

WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury. It is important not to proceed until all stated conditions are met and clearly understood.

CAUTION

CAUTION indicates a hazardous situation which, if not avoided, could result in minor or moderate injury. It is important not to proceed until all stated conditions are met and clearly understood.

Tip: *A tip contains useful information that can improve or optimize your procedures.*

WARNING

If you overpressurize the cassette holder and cross-flow filtration system with compressed air during integrity testing, system components can rupture causing bodily harm. To avoid the rupture of a system component due to over pressurization with compressed air, use a pressure regulator to limit the pressure of your compressed air supply to the maximum operating pressure of your system components. For the Kvick Lab cassette holder and Kvick Lab system, the maximum operating pressure is 4 barg (60 psig). Wear the appropriate personal protection devices when testing the system.

If a cross flow system leaks, it can release potentially hazardous process fluids or cleaning fluids, causing bodily harm. To prevent leaks and the release of potentially hazardous process or cleaning fluids, limit feed pressure to 4 barg (60 psig) for Kvick Lab holders and systems. Periodically check parts for wear and ensure you assemble the components correctly. To monitor system pressure, Cytiva recommends that you install pressure gauges on cross-flow systems as illustrated in this user guide. Isolate and depressurize your system before disassembling it. Periodically inspect the system’s gaskets, seals, and connections for wear. Ensure you assemble the holder correctly following the instructions in this guide. Wear the appropriate personal protection devices and clothing when operating and cleaning the system.

WARNING

The cassette and cassette bag contain an aqueous solution containing 0.1 to 0.2 N NaOH and 20 to 22% glycerin by weight. When opening the cassette bag, follow the standard safety procedures for handling aqueous NaOH, including the use of safety glasses, safety gloves, and protective lab coat.

To avoid unexpected spilling, hold the cassette package upright over a sink and trim the top of the cassette bag with scissors. Drain and dispose of the excess storage solution in accordance with environmental regulations.

To avoid inadvertent contact with the storage solution after the cassette is removed from the bag, rinse the outside surface of the cassette with high purity water.

WARNING

Cassette holders are heavy. Dropping a cassette holder on your feet or hands can cause bodily injury. To prevent injury from dropping a cassette holder on your feet or hands, ensure you have a secure, controlled grip and a sufficient number of people — or the proper equipment — to move the cassette holder. Wear safety shoes. The weight of cassette holders requires that you support them well, especially when integrated into a cross-flow system. Ensure the holder and piping is properly supported and that piping supports meet local safety codes.

Mishandling potentially hazardous process and cleaning solutions can cause bodily harm. To safely handle potentially hazardous process, cleaning, and storage solutions, read the material safety data sheets for the solutions you use. Follow the material safety data sheet instructions for safe handling and use the personal protection equipment required by your company, and local, state, and federal laws.

CAUTION

If the Kvick Lab system pump runs dry (without any process fluid in it), you can damage the pump. To prevent damage to the pump, ensure that fluid is present in the reservoir and feed line whenever you run the pump.

CAUTION

Using tap water to flush or rinse your cassette can plug the pores of membrane with the relatively large particulates (rust, dirt, minerals, bacteria, etc.) found in tap water. To prevent plugging the pores of the cassette, always use 0.2-μm filtered or water-for-injection (WFI) when rinsing or flushing the cassette, or when making up cleaning solutions or adding dilution water to process fluids. In this user guide, the term clean water means 0.2-μm filtered water or WFI.

3 Kvick Lab Cassette Holder

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3.1 Unpacking and lifting the cassette holder

Your Kvick Lab cassette holder arrives packed in a cardboard box that includes the torque wrench and documentation. To unpack the system, place the box on the ground. Open the top of the box and remove foam insert. Remove the cassette holder, documentation, and torque wrench. When you transport the cassette holder, hold it firmly with two hands by the stand.

3.2 Package contents

Each shipment of a Kvick Lab cassette holder includes the following components:

- Kvick Lab holder
- Torque wrench, socket, and torque wrench instructions
- User guide
- Certificate of analysis

3.3 Learning about the holder

The Kvick Lab cassette holder is designed to hold 1 to 5 cassettes. Together, the holder and the cassettes enable you to separate, concentrate, and diafiltrate biological solutions with precision. For example, you can complete ultrafiltration at laboratory volumes (starting volumes of less than 1 liter).

3.4 Features

The Kvick Lab holder simplifies operation with fewer parts and connections than other types of cross-flow cassette holders. Cytiva cassette holders share the following features: (1) three forward facing ports for convenience, (2) vertically orientated hardware for best drainage and product recovery, (3) uses state-of-the-art Cytiva cassettes that include several patented and new-to-market features that increase safety, facilitate use, and improve process control and product quality, and (4) highly competitive economics of use.

The main components include a flow distribution manifold, back plate, and tie rods (see the Figure below). These components hold the cassettes in place and manage the flow of process fluids into and out of the cassettes. To ensure ease of use, the holder is mounted on a stand and uses industry-standard sanitary fittings.

The Kvick Lab holder can hold multiple Kvick Lab cassettes providing a maximum membrane area of 0.55 m^2 (6.0 ft^2). Cytiva manufactures Kvick Lab cassettes with a wide range of molecular weight cutoffs to meet a variety of applications.

1. Flow distribution manifold
2. Back plate
3. Spacers
4. Washer
5. Nut
6. Guide rods
7. Stand
8. Retentate port
9. Filtrate port
10. Feed port
11. Tie rod

Figure 3.1: Parts of a Kvick Lab cassette holder

3.5 Learning about cassettes

The two sizes of Kvick Lab cassettes share design components, including inlet and outlet ports, labeling, and alignment notches (see the Figure below).

1. Inlet (feed) port or outlet (retentate) port
2. Permeate port
3. Cassette information
4. Alignment notches
5. Incorporated gasket

Figure 3.2: The main parts of a Cytiva cassette

4 Connecting the Holder to Your System

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4.1 Where to install the holder

The integration of the cassette holder into your cross-flow system depends upon your application and filtration goals. You can complete many cross-flow objectives using a basic cross-flow configuration (see the Figure below). To learn about alternate system configurations for special applications, contact Cytiva.

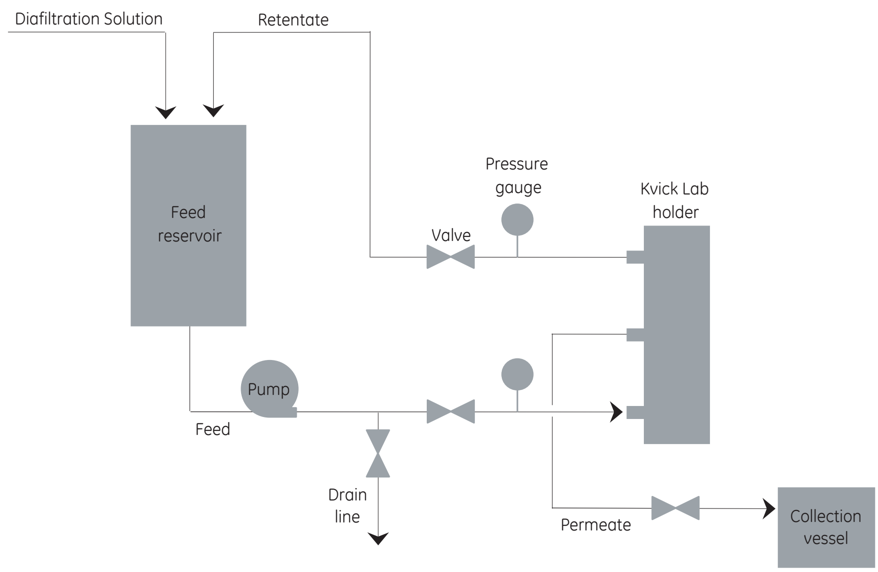

Figure 4.1: Basic cross-flow system configuration

4.2 How to install the holder

Gathering materials

Gather the following materials to install your Cytiva cassette holder into your cross-flow system:

- A cross-flow system including a feed reservoir, feed pump, a minimum of two glycerin-filled pressure gauges, and three flow control valves
- System piping and fittings to connect the feed pump, permeate collection vessel, and feed reservoir to the holder. The system piping must end in ½-inch sanitary clamps to connect to the Kvick Lab holder.
- Three, fractional sanitary clamps and ½-inch gaskets

Making the connections

Place the Kvick Lab holder on a sturdy lab bench near your cross-flow system. Stabilize and level the holder using the adjustable feet. Keep piping runs short to minimize holdup volume. Connect the holder's feed, retentate, and permeate ports to your system's piping using the three gaskets and sanitary clamps.

5 Installing Cassettes in the Holder

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5.1 Introduction

To install a cassette in your holder, place the cassette and a gasket in the holder and clamp them in place using the tie rod spacers and nuts. You must tighten the nuts to a specific torque value to ensure the proper clamping force is applied to seal the cassette in place.

5.2 Determining how many cassettes you can install

The Kvick Lab holder can hold multiple cassettes depending upon the cassette type and the membrane area your application requires (see the Table below).

Table 5.1: Cassette installation guide for the Kvick Lab cassette holder

Cassette type	Cassette size	Number of cassettes	Nut torque
Kvick Lab Packet	100 cm^2 (0.11 ft^2)	1 to 10	13.5 Nm (120 in-lb)
Kvick Lab	0.11 m^2 (1.2 ft^2)	1 to 5	20.3 Nm (180 in-lb)

5.3 Installing the cassettes

Follow these steps to install cassettes in Kvick Lab cassette holders:

Step	Action
1	Remove the tie rod nuts, washers, and spacers. Slide the back plate away from the flow distribution manifold (*Fig. 5.1, on page 25*).
2	***To install one cassette***, clean and wet a silicone gasket by rinsing it with DI water or water-for-injection (WFI). Place the gasket against the flow distribution manifold, aligning the holes in the gasket with the holes in the manifold. The gasket will stick to the manifold. Place the cassette into the holder with the gasket-side of the cassette facing the backing plate, and slide the cassette against the gasket. ***To install two or more cassettes***, complete the step above for installing one cassette. Place the second cassette into the holder between the first cassette and the backing plate. Ensure the gasketed side of the second cassette faces the backing plate. Place subsequent cassettes in the holder in similar fashion.
3	Slide the backing plate forward to hold the cassettes in the hardware, ensuring the holes in the manifold, gasket, and cassettes line up.
4	Add spacers to the tie rods until about 0.75-inches (16 mm) of thread is exposed on each tie rod. Reinstall the washers and nuts. Fingertighten the nuts evenly.
5	Tighten each nut alternately 1/4 turn at a time with the supplied torque wrench and socket until each nut is tightened to the values listed in *Table 5.1, on page 23* above. If a seal is not achieved, there may be a cassette, gasket, or surface finish irregularity. Discontinue torque tightening and inspect the sealing surfaces.

To learn how to use the torque wrench, consult the torque wrench user's guide.

Tip: *The nut torque values are based on the tie rod threads being dry. You should not oil the tie rod threads. Oiled tie rod threads will result in too much clamping pressure being applied to the cassette.*

Tip: *The nut torque values in the above procedure are based on the holder and cassette being at 18 to 23 °C (64 to 74 °F). Lower or higher temperatures experienced during processing and cleaning can change the clamping force applied to the cassette (due to expansion and contraction of the holder and cassette). Increases in temperature, in particular, can damage cassettes. Therefore, you should periodically check the nut torque. If the nut torque is too high, excessive clamping force can damage the cassette. If the nut torque is too low, insufficient clamping force can cause leaks or give false integrity test results.*

1. Flow distribution manifold
2. Back plate
3. Gasket
4. Cassette with integral gasket facing the backing plate
5. Tie rod
6. Spacer
7. Washer
8. Nut
9. Guide rod

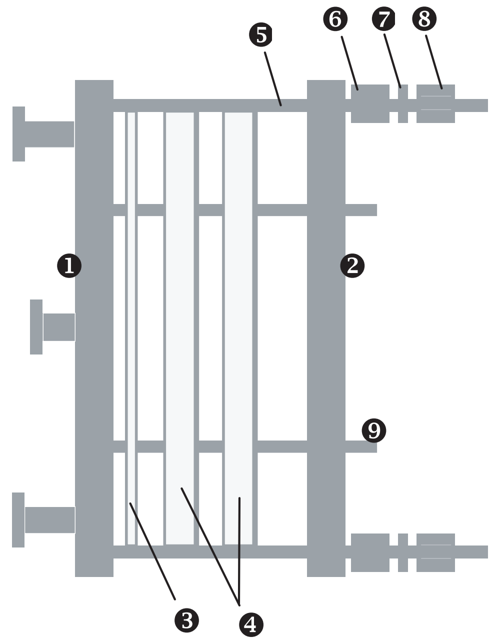

Figure 5.1: Top view of Kvick Lab holder showing assembly

6 Preparing a Cassette for Use

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6.1 Introduction

Before using a new Kvick Lab cassette, you must flush it with DI water or WFI to remove the storage solution. Many applications require that you complete several of the other preparatory stages listed below to ensure the cassette and the holder perform properly and consistently:

Rinse Storage Solution from the Cassette — before using a new cassette—or a used one that you cleaned and stored—you must flush the storage solution from the cassette.

Determine the Water Flux — you determine the water flux by measuring water flow through the cassette's membrane under controlled process conditions. By measuring the water flow before and after use, you can determine cleaning effectiveness and monitor the cassette's performance.

Test the Integrity of the Cassette — in this two-part process, you check the system and cassette for leaks or damage to the membrane.

Sanitize the Cassette — when you require sanitary processing conditions, you can sanitize the cassette with sanitizing agents.

Condition the System with Buffer — conditioning exposes your cross-flow system's wetted parts to an appropriate buffer before you introduce your product to the system. The conditioning minimizes unwanted chemical reactions between your product and the wetted parts. The buffer can also bring the system to the proper operating temperature before processing begins.

WARNING

The cassette and cassette bag contain an aqueous solution containing 0.1 to 0.2 N NaOH and 20 to 22% glycerin by weight. When opening the cassette bag, follow the standard safety procedures for handling aqueous NaOH, including the use of safety glasses, safety gloves, and protective lab coat.

To avoid unexpected spilling, hold the cassette package upright over a sink and trim the top of the cassette bag with scissors. Drain and dispose of the excess storage solution in accordance with environmental regulations.

To avoid inadvertent contact with the storage solution after the cassette is removed from the bag, rinse the outside surface of the cassette with high purity water.

Tip: *Expert users normally establish pump curves for the system configuration they plan to use. By establishing a pump curve, they can quickly and accurately set the pump speed to achieve the recommended flow rate during processing. To determine the flow rate without a pump curve, you would have to disconnect the retentate line and measure the flow rate using a graduated cylinder and stop watch. If you need help in developing a pump curve, contact Cytiva technical support team.*

6.2 Stage 1 – Rinse storage solution from the cassette

Opening the cassette bag safely

The cassette and cassette bag contain an aqueous solution containing 0.1 to 0.2 N NaOH and 20 to 22% glycerin by weight. When opening the cassette bag, follow the standard safety procedures for handling aqueous NaOH, including the use of safety glasses, safety gloves, and protective lab coat.

Step	Action
1	To avoid unexpected spilling, hold the cassette package upright over a sink and trim the top of the cassette bag with scissors. Drain and dispose of the excess storage solution in accordance with environmental regulations.
2	To avoid inadvertent contact with the storage solution after the cassette is removed from the bag, rinse the outside surface of the cassette with high purity water.
3	If you allow an ultrafiltration cassette to dry out, the membrane will be damaged. Therefore, do not store the cassette without rewetting it with an approved storage solution.

Rinsing the storage solution from the cassette

At a minimum, before using a new or used-and-stored cassette, rinse the storage solution from the cassette following these steps:

Step	Action
1	Open the cassette bag and remove the cassette following the safety instructions above.
2	Install the cassette in the cassette holder. (See your cassette holder's user guide for specific installation instructions.)
3	Configure the system so that the retentate and permeate lines discharge to waste (see *Fig. 6.1, on page 29*). Close the feed, retentate, and permeate valves.
4	Fill the reservoir with an appropriate volume of clean water (6 liters per 0.11 m^2 [1.2 ft^2] cassette).

Step	Action
5	Open the feed and retentate valves and close the permeate valve. Pump about 10 percent of the water through the retentate line to waste, maintaining a feed pressure of 0.35 barg (5 psig).

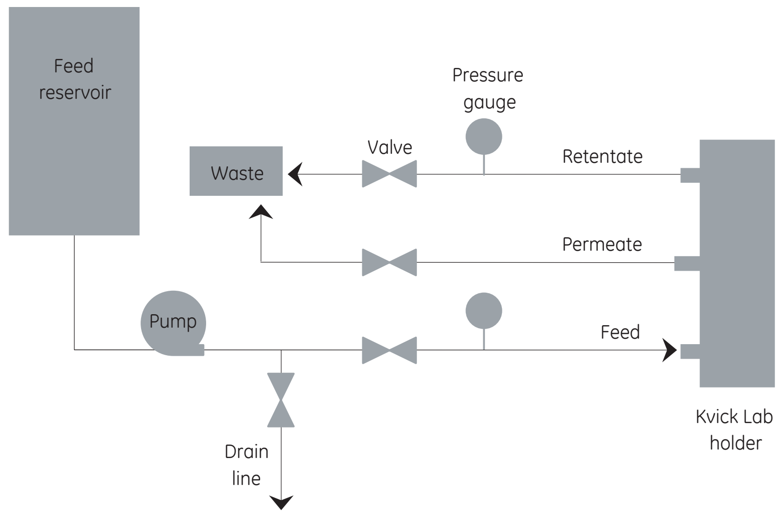

Figure 6.1: Typical setup for rinsing cassettes

CAUTION
Using tap water to flush or rinse cassettes can plug the pores of the membrane with the relatively large particulates (rust, dirt, minerals, bacteria, etc.) found in tap water. To prevent plugging the pores of the cassette, always use 0.2 µm filtered water or water-for-injection when rinsing or flushing the cassette, or when making up cleaning solutions or adding dilution water to process fluids.

Step	Action
6	Open the permeate valve and close the retentate valve and pump the remaining water through the permeate line to waste, maintaining a feed pressure of 0.35 barg (5 psig).
7	If needed for your application, sample and analyze the last volume of drain water pumped from the system for traces of storage or cleaning solution[1]. Repeat steps 4 through 7 until you achieve the needed level of storage solution removal.
8	If needed, circulate buffer to prepare the cassette and system for processing.

[1] You can analyze the rinse water using analytical techniques or with residual indicator kits readily available from scientific equipment supply houses.

6.3 Stage 2 – Measuring water flux

Measuring water flux involves measuring the flow of water through the cassette's membrane under controlled conditions. You convert the measurement into units that represent water flux. The water flux value you obtain provides an indicator of the performance of the cassette.

Cytiva recommends that you measure water flux when the cassette is new and before each use. By tracking the water flux measurements, you can; (1) determine the effectiveness of cleaning cycles, and (2) determine when a cassette reaches the end of its service life.

Measuring water flux manually requires about 30 minutes and this equipment: graduated cylinder, stopwatch, thermometer, calculator, pen and paper. If you have a flow meter installed on the permeate line, you can use the flow meter for measuring flux.

Summary of water flux measurement procedure

The following steps summarize how to measure water flux:

Step	Action
1	Measure the water flow from the permeate port at two transmembrane pressures.
2	Calculate water flux in $l/m^2/hr$ (LMH) for the two water flow measurements.
3	Plot the two flux values. Then interpolate Kvick Lab cassette water flux at 0.7 barg (10 psig) transmembrane pressure.
4	Normalize the water flux value to 20 °C and 1 psig to arrive at flux in LMH/psig @ 20 °C.
5	Record the flux value as a benchmark for future comparison. Compare the flux with previously obtained values.

The following text describes how to complete each step.

Measure flow from the permeate port

Follow these steps to measure the water flow rate from the permeate port:

Step	Action
1	Rinse the cassette following the instructions in *Section 6.2 Stage 1 – Rinse storage solution from the cassette, on page 28*.
2	Setup your cross-flow system to circulate the retentate and permeate back to the feed reservoir (*Fig. 5.1, on page 25*).
3	Fill the feed reservoir with a volume of deionized water or WFI. Fully open the feed, retentate, and permeate valves.

Step	Action
4	Start the feed pump and adjust it and the retentate valve to obtain a transmembrane pressure of 0.3 barg (5 psig). Using a graduated cylinder and stop watch, measure and record the permeate flow rate in ml/min. Record the temperature of the water in the feed reservoir.
5	Adjust the feed pump and retentate valve to produce a transmembrane pressure of 1 barg (15 psig). Using a graduated cylinder and stop watch, measure and record the permeate flow rate in ml/min. Record the temperature of the water in the feed reservoir.
6	Drain the system.

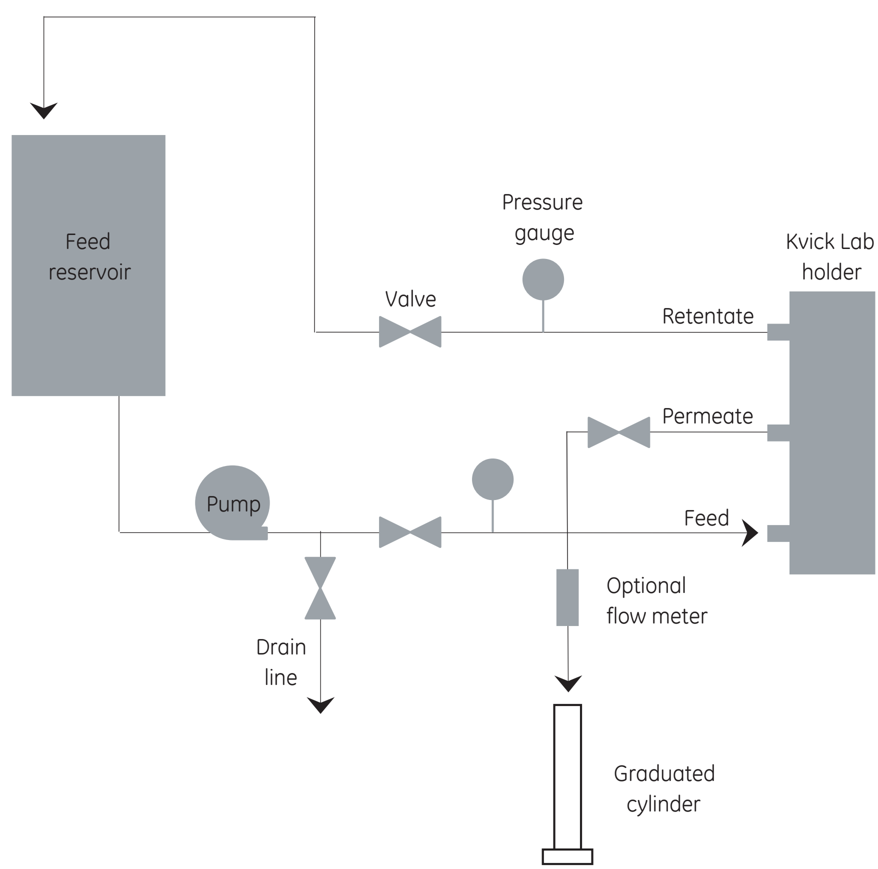

Figure 6.2: Typical configuration for measuring water flux

Calculate flux in l/m^2/hr

Convert the permeate flow rate measurements to flux using this equation:

Flux in LMH (l/m^2/hr) = {permeate flow in ml/min ÷ cassette surface area in square meters} × 0.06

Plot flux and determine flux at 0.7 barg

Plot the calculated flux values against the transmembrane pressure (see the Figure below). Determine the water flux in LMH at 0.7 barg (10 psig). In Figure 10, the flux at 0.7 barg (10 psig) is 115 LMH.

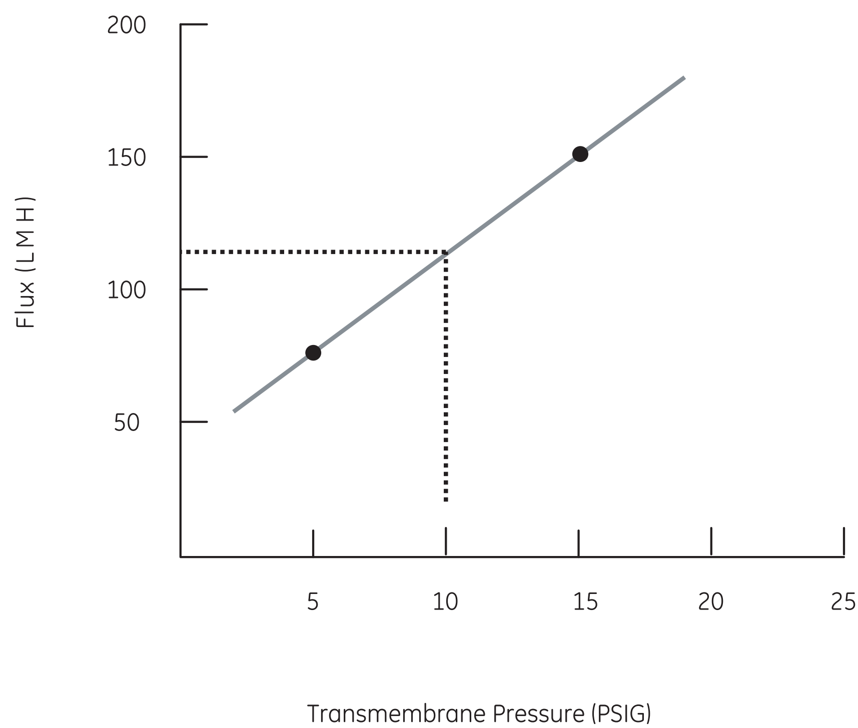

Figure 6.3: Plot of water flux versus transmembrane pressure

Normalize water flux to 20 °C and 1 psig

Follow these steps to normalize the water flux value to 20 °C and standardize to 1 psig to arrive at flux in LMH/psig at 20 °C:

Step	Action
1	Multiply the calculated flux value by the appropriate viscosity correction factor in Table 1. For example, if the flux at 0.7 barg (10 psig) is 115 LMH, and the temperature of the water during permeate flow measurement was 18 °C, then the flux normalized to 20 °C is: 115 LMH x 1.053 = 121 LMH/10 psig
2	To standardize the flux value to 1 psig, divide the normalized water flux value by 10 psig. For example, 121 LMH ÷ 10 = 12.1 LMH/psig

Record the Flux Value

Record the normalized flux value in your laboratory notebook or production records as a benchmark for future comparison. If the cassette is used, compare the flux with previously obtained values to determine the performance of the cassette over time. Many users replace cassettes when, after cleaning, the normalized water flux falls below 60 to 80 percent of the normalized flux value when the cassette was new.

If after cleaning, the flux is low, you can try alternative, aggressive cleaning processes. Contact Cytiva for more information.

Table 6.1: Viscosity correction factors

Temperature in °C when permeate flow was measured	Viscosity correction factor	Temperature in °C when permeate flow was measured	Viscosity correction factor
4	1.567	25	0.890
5	1.519	26	0.871
6	1.472	27	0.851
7	1.428	28	0.833
8	1.386	29	0.815
9	1.346	30	0.798
10	1.307	31	0.781
11	1.271	32	0.765
12	1.235	33	0.749
13	1.202	34	0.734
14	1.169	35	0.719
15	1.139	36	0.705
16	1.109	37	0.692
17	1.081	38	0.678
18	1.053	39	0.665
19	1.027	40	0.653
20	1.000	41	0.641
21	0.978	42	0.629
22	0.955	43	0.618
23	0.933	44	0.607
24	0.911	45	0.596

6.4 Stage 3 – Test the integrity of the cassette

Before using your cross-flow system and cassette to process product, test the cross-flow system to ensure it does not leak. Then test the integrity of the cassette.

To test your cross-flow system for leaks, pressurize it with water and check the tubing or piping connections for leaks. To test the integrity of the cassette, pressurize the system with compressed air and measure the diffusional flow of air through the cassette membrane. A high flow rate (above the cassette's specification) indicates there might be a hole or tear in the membrane.

Follow the instructions below to test the system for leaks, and to test the integrity of the cassette.

Test your system for leaks

To test your cross-flow system for leaks, fill the system with clean water. Open the feed valve. Open the retentate valve. Close the permeate valve. Start the feed pump on slow speed and throttle the retentate valve until the feed pressure reads 3 barg (45 psig). Check all connections for leaks.

Test the integrity of the cassette

To measure diffusional air flow through the membrane via the permeate port, you will need to add a compressed air line, pressure regulator, and shutoff valve to your cross-flow system. You also need the following equipment: a 500-ml beaker, 50-ml graduated cylinder, stopwatch, and a piece of flexible tubing (*Fig. 6.2, on page 31*).

Test the integrity of the system and cassette manually by following the procedure described below.

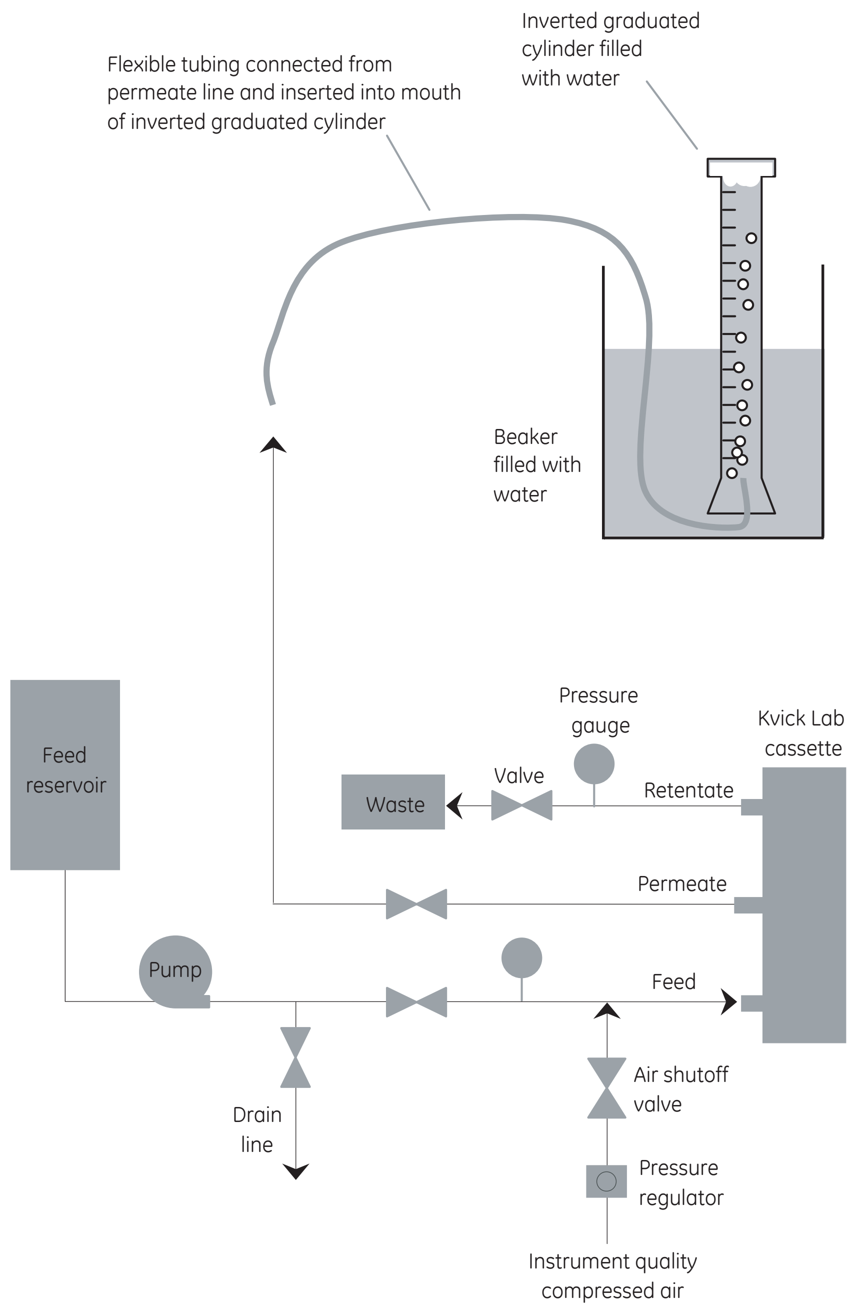

Figure 6.4: Flow diagram for testing a cross-flow system and cassette before use

Check the integrity of the Cassette

When you establish that the system is leak-free, test the integrity of the Kvick Lab cassette by following these steps.

Step	Action
1	Ensure the compressed air valve is closed and the pressure regulator is set to 0 barg (0 psig). Close the feed and drain valves, and open the retentate and permeate valves.
2	Remove water from the cassette feed-retentate path by opening the compressed air valve, and slowly adjusting the pressure regulator to 0.3 barg (5 psig). Flow air through the system until water stops draining from the retentate line. Close the retentate valve to allow the air pressure to drive the water from the permeate port and permeate line.
3	Slowly adjust the pressure regulator to 1 barg (15 psig).
4	Fill a 50-ml graduated cylinder with water and place it inverted in a 500-ml beaker half filled with water. Connect flexible tubing to the permeate outlet (*Fig. 6.4, on page 35*).
5	When the air bubble rate is stable, note the time and the standing air volume in the graduated cylinder. When 5 to 10 ml of air has collected in the graduate cylinder, record the time and air volume again.
6	Using the time and air volume data, calculate the air diffusion rate in ml/min/ft^2 @ 1 barg (15 psig).
7	Compare your results with the specifications below. If your measured flow rate is less than the specification, the Kvick Lab cassette is acceptable for use. The specifications are: 60 ml/min/Kvick Lab cassette at 1 barg for 10K and 10KS cassettes 60 ml/min/Kvick Lab cassette at 1 barg for 30K cassettes 60 ml/min/Kvick Lab cassette at 1 barg for 50K cassettes 60 ml/min/Kvick Lab cassette at 1 barg for 100K cassettes
8	When the Kvick Lab cassette passes integrity testing, you can sanitize it (Stage 4), condition it with buffer (Stage 5), or process product as required.
9	If the Kvick Lab cassette fails the integrity test, contact your Cytiva representative for help.

6.5 Stage 4 – Sanitizing the Kvick Lab cassette

Clean and rinse the Kvick Lab cassette, then follow these steps to sanitize the cassette:

Step	Action
1	Configure the system so that the retentate and permeate lines discharge into the feed reservoir (*Fig. 6.5, on page 37*). Close the drain valve.
2	Fill the feed reservoir with 1.5 to 2 liters of 0.1 N sodium hydroxide for each cassette in your system. The temperature of the solution should be 35 to 45 °C.
3	Open the feed, retentate, and permeate valves. Start the pump. Adjust the retentate valve and pump speed to obtain a retentate pressure of 0.7 barg (10 psig) and the following retentate flow rate: **875 ml/min for each 0.11 m^2 (1.2 ft^2) Kvick Lab cassette installed**
4	Circulate the sanitizing solution for minimum of 60 minutes at a temperature of 35 to 45 °C. Stop the pump. If you are going to store the Kvick Lab cassette, rinse and add storage solution as described in *Chapter 11 Specifications, on page 59*.
5	If you are sanitizing the Kvick Lab cassette before use, drain the sanitizing solution from the system and then rinse the Kvick Lab cassette following the rinsing procedure in *Section 5.1 Introduction, on page 22*.

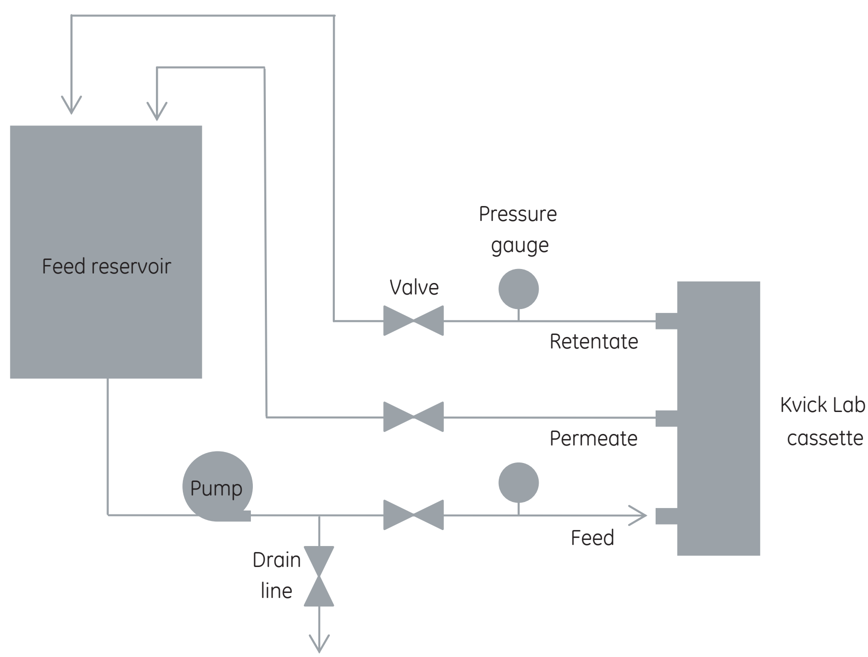

Figure 6.5: Typical setup for sanitizing a Kvick Lab cassette and system

6.6 Stage 5 – Conditioning the system with buffer

Before processing your sample, precondition the cross-flow system with a buffer similar in pH and ionic strength to that of your sample. Conditioning the system removes trapped air and minimizes unwanted chemical reactions between your sample and the wetted parts of the cross-flow system. You can also use buffer conditioning to stabilize the temperature of the cross-flow system. Follow these steps to condition the system with buffer:

Step	Action
1	Setup your cross-flow system to circulate the retentate and permeate back to the feed reservoir (*Fig. 6.6, on page 39*).
2	Prepare the buffer solution, and if necessary, condition it to the proper temperature. The recommended volume of buffer solution is 1 liter per cassette.
3	Put the buffer in the feed reservoir. Open the feed, retentate, and permeate valves. Start the feed pump and increase the feed rate until solution flows from the retentate and permeate lines.
4	Close the retentate valve to produce about 0.3 to 1 barg (5 to 15 psig) of retentate pressure. Run until no bubbles appear in the permeate stream.
5	Open the retentate valve and close the permeate valve. Increase the retentate flow rate to the recommended operating cross-flow rate: **600 to 800 ml/min per 0.11-m^2 (1.2-ft^2) Kvick Lab cassette** Run until no bubbles appear in the retentate stream.
6	Open the permeate valve. Adjust the retentate valve until the retentate flow is about 10 percent of the feed flow. Adjust the feed pump to maintain a feed pressure of 1.6 to 2.8 barg (25 to 40 psig) for ultrafiltration cassettes.
7	Circulate the buffer for four minutes to condition the system for pH and ionic stability. If conditioning for temperature control, continue circulating until the temperature of the system stabilizes.
8	Remove the buffer from the feed reservoir. Keep buffer in other parts of the system to prevent air from entering the system.

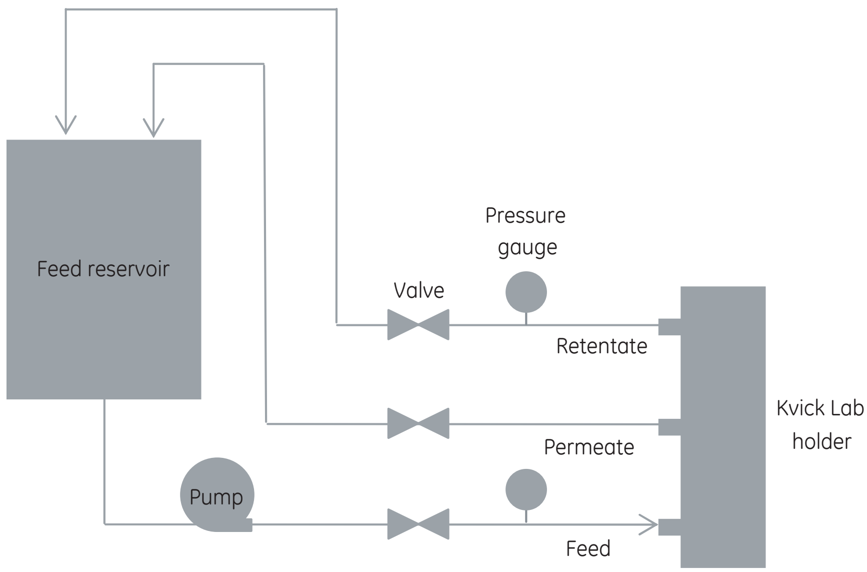

Figure 6.6: Typical configuration for conditioning the system with buffer

7 Using the Holder

In this chapter

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7.1	Introduction	41
7.2	Stage 1 – Starting the cross-flow process	43
7.3	Stage 2 – Operating the system in a steady state	44
7.4	Stage 3 – Shutting the system down and recovering product	45

7.1 Introduction

Equipment configuration and process conditions for cross-flow processes vary widely depending upon the application, system design, process objectives, and product objectives. However, many cross-flow processes share three main stages:

- Startup
- Steady state operation
- Shutdown and product recovery

This chapter describes a general procedure for using your Kvick Lab. You must adjust the procedures based on your specific goals and application. If you need assistance, contact your Cytiva representative.

Process flow in a cross-flow system

A typical system for many cross-flow applications includes three pressure gauges (for precise process control and safety), feed tank, permeate collection vessel, and a drain line (*Fig. 7.1, on page 42*). The operating procedures described in this chapter are based on *Fig. 7.1, on page 42*.

Recommended operating conditions

When using your Kvick Lab cassette, fully open the permeate valve and adjust your pump speed and retentate valve to achieve the recommended cross-flow rate. The recommended operating conditions for many applications are:

Transmembrane pressure—1.7 to 2.4 barg (25 to 35 psig)

Cross-flow rate—600 to 800 ml/min per 0.11 m^2 (1.2 ft^2) cassette

If your feed is particularly viscous or has other unusual physical characteristics, contact the technical support team at Cytiva. The team can show you how to optimize your cross-flow process.

Other recommended operating parameters include these:

- pH range, long-term (operating or storage) – 2 to 13
- pH range, short-term (cleaning) – 1 to 14
- Maximum operating temperature – 50 °C
- Maximum inlet pressure – 4 barg (60 psig)

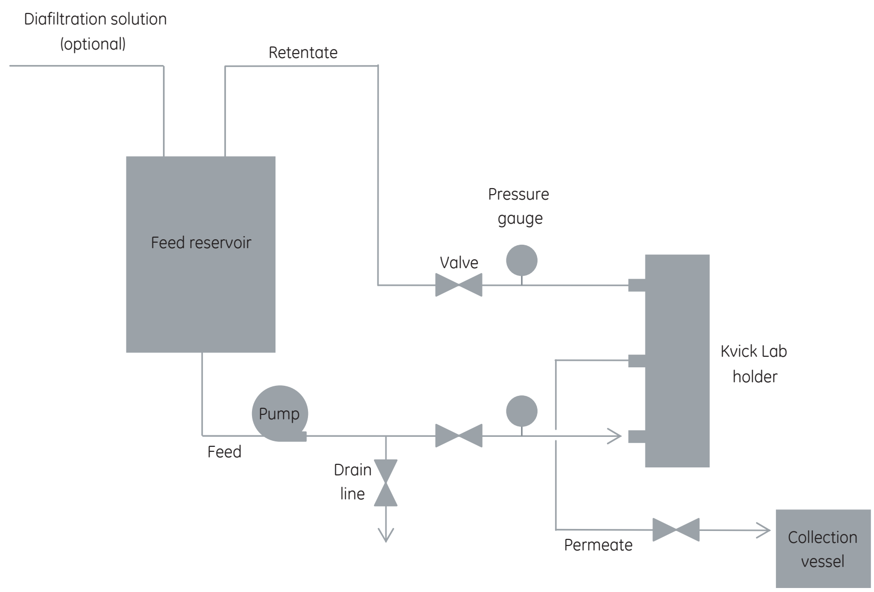

Figure 7.1: Typical process flow path for cross-flow processes

7.2 Stage 1 – Starting the cross-flow process

Follow these steps to start a typical cross-flow process:

Step	Action
1	Drain residual water from the system and equilibrate the system with water or buffer.
2	Close the permeate valve; open the feed and retentate valves; and close the drain valve (if equipped).
3	Direct the permeate line to an appropriate container or drain; for example, a permeate container, waste container, or process drain.
4	Fill the feed tank with product. Start the feed pump and slowly circulate the product through the system for about three to four minutes. Recirculation helps purge trapped air from the flow channels, maximizing membrane performance.
5	Open the permeate valve. Slowly increase the pump speed until the optimal cross-flow rate is achieved. Using the retentate valve, adjust the retentate backpressure until the system reaches the optimum transmembrane pressure. ***Tip:*** *If you do not know the relationship between your pump speed setting and the feed flow rate, it may be difficult to consistently achieve the process conditions you desire. Therefore, to ensure consistent performance and ease of use, prepare a pump curve on your feed pump before processing so that you know the relationship between pump speed and flow rate.*
6	Monitor the product level in the feed tank to ensure the pump does not run dry. As the level drops, you can add additional product to the feed tank.
7	If needed, transfer diafiltration solution into the feed tank at a controlled rate to maintain a working volume in the feed tank. (The required number of diafiltration volume exchanges varies greatly with respect to the particular characteristics of a product.) Typically, in biopharmaceutical processes, six volume exchanges of buffer are commonly processed through the feed tank.
8	Continue processing following the steps in *Section 7.3 Stage 2 – Operating the system in a steady state, on page 44*.

7.3 Stage 2 – Operating the system in a steady state

During steady state operation, you monitor the process and record the process information that you need for product development, process development, process validation, or quality control. Key operational data includes these:

- Transmembrane pressure
- Feed pressure
- Retentate pressure
- Product temperature
- Feed volume (initial and final)
- Diafiltrate volume
- Permeate flow rate
- Permeate volume
- Retentate cross-flow rate
- Various product quality analyses

7.4 Stage 3 – Shutting the system down and recovering product

Before shutting your cross-flow filtration system down, you can complete two recovery methods to maximize the recovery of product. One recovery method helps remove the buildup of product on the surface of the membrane inside the cassette. The other method helps you recover the most product volume from the system piping and cassette.

Capturing product from the membrane surface

The first product recovery method involves reducing the cross-flow rate at the end of your processing step. For example, when you finish processing your product, reduce the cross-flow rate to 1/10 of the recommended processing cross-flow rate. Close the permeate valve or reduce the feed pressure to 0.3 barg (5 psig). Retentate pressure should be 0 barg (0 psig). Circulate the remaining product for 15 minutes. This procedure will help recover product buildup from the surface of the membrane.

Maximizing the volume of product recovered

The second product recovery method maximizes the volume of product you can recover from the system piping and cassette. The method involves slightly over concentrating the product, then adding a small volume of permeate back into the system to flush concentrated product from the feed-retentate loop. This method is described below in the following steps:

Step	Action
1	As the process nears completion, decrease the pump speed to minimize flow rate, vortexing in the feed tank, and the possibility for product foaming.
2	When you reach the slightly over concentrated volume, collect about 200 to 500 ml of permeate in a container. Stop the pump and close the permeate valve.
3	Attach a line to the drain valve and connect the other end aseptically to your collection vessel (*Fig. 7.2, on page 46*). ***Tip:*** *Many types of pumps will be damaged if you run them dry. Therefore, monitor the liquid level in the tank and shut off the pump when the tank is empty.* **WARNING** If maximum recovery is required, you can remove product from the system by applying a lowpressure nitrogen flow to the retentate side of the system. Contact your Cytiva representative for additional details.

Step	Action
4	Open the drain valve, and with the retentate valve open, start-up the pump at a slow speed. Apply backpressure by slightly closing the retentate valve if needed to assist in removal of product from the drain line. Stop the pump as the tank fully drains.
5	Close the drain valve. Add a portion of saved permeate to the feed tank and circulate for two to three minutes. Open the drain valve and circulate (and apply backpressure by slightly closing the retentate valve if needed) to drain the product from the feed-retentate loop. Stop the pump. Repeat step 5 as needed to recover the maximum volume of product.

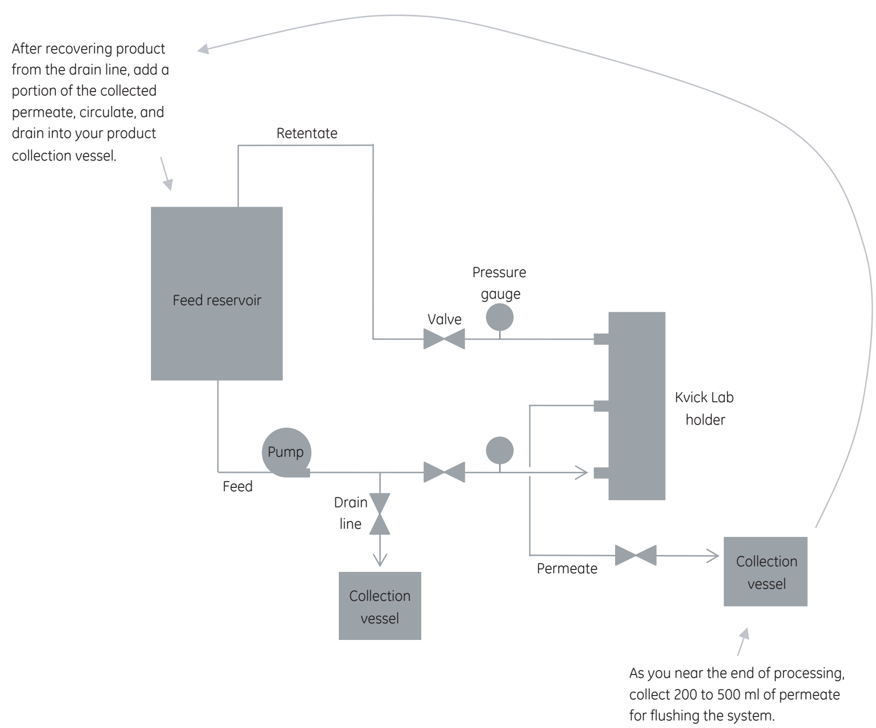

Figure 7.2: Typical process flow path for shutting the system down and recovering product

8 Cleaning and Storing

In this chapter

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8.1	Introduction	48
8.2	Stage 1 – Cleaning a cassette after use	49
8.3	Stage 2 – Measuring water flux	50
8.4	Stage 3 – Storing the cassette and holder	51

8.1 Introduction

You can reuse cassettes if you clean and store them properly. The cleaning and storage stages include these:

Cleaning the Cassette – Rinsing the cassettes with water prior to cleaning ensures the most effective use of the cleaning solution and prevents solubility changes that can prevent effective cleaning. Circulating a cleaning solution dissolves and physically removes contaminates from the cassette. Flushing with water removes the cleaning solution from the cassette.

Measure the Water Flux – you measure the water flux and compare it to the water flux when the cassette was new. You can then determine cleaning effectiveness.

Store the Cassette and Holder – Storing the cassette and holder involves adding a storage solution and preparing the system for short-term or long-term storage. The goal is to keep the membrane wet and to prevent microbial growth during storage.

8.2 Stage 1 – Cleaning a cassette after use

You can reuse a cassette if you clean and store it properly. To clean a used cassette, flush it with buffer, WFI, or DI water as described in *Section 6.2 Stage 1 – Rinse storage solution from the cassette, on page 28*. Then clean the cassette following these steps:

Step	Action
1	Configure the system so that the retentate and permeate lines discharge to waste (*Fig. 6.1, on page 29*). Close the feed, retentate, and permeate valves.
2	Prepare the appropriate volume of a cleaning solution (1.5 to 2 liters per 0.11 m^2 (1.2 ft^2) Kvick Lab cassette. The Table below describes recommended cleaning solutions. ***Tip:*** *Heating the rinse water or buffer to 40 to 50 °C can increase the effectiveness of the rising process.*
3	Fill the feed reservoir with the cleaning solution.
4	Open the feed and retentate valves and pump about 10 percent of the cleaning solution through the retentate line to waste. Open the permeate valve and close the retentate valve and pump about 10 percent of the cleaning solution through permeate line to waste.
5	Stop the pump and configure the system so that the retentate and permeate lines discharge into the feed reservoir. Fully open the feed and retentate valves. Crack open the permeate valve.
6	Start the pump. Adjust the retentate valve and pump speed to obtain 1 to 1.5 times your processing crossflow rate.
7	Circulate the cleaning solution for 30 to 60 minutes.
8	Drain the cleaning solution from the system using the drain line.
9	Rinse the cassette and system with clean water as described in *Section 6.2 Stage 1 – Rinse storage solution from the cassette, on page 28*.

Table 8.1: Recommended cleaning solutions

Cleaning Agent	Cleaning Conditions
0.5 M NaOH	30 minutes at room temperature
1 M NaOH	2 hours at 50 °C
0.5 M NaOH with 300 ppm NaOCl	30 minutes at room temperature
0.5 M NaOH with 500 ppm NaOCl	30 minutes at room temperature
0.5 M NaOH, then 0.5 M H_2SO_4	30 minutes at room temperature for each solution
Double cleaning with 0.5 M NaOH with 300 ppm NaOCl	30 minutes at room temperature for each cycle

8.3 Stage 2 – Measuring water flux

To determine the effectiveness of cleaning and the end of the service life of the cassette, you should measure the water flux after cleaning. Compare the water flux measurement with the as new and historical flux measurements.

To determine the cassette's water flux, follow the procedure described in this user guide. However, instead of measuring the flux at the two recommended pressures, measure the flux flow at the target pressure for your type of cassette – 0.7 barg (10 psig) for ultrafiltration cassettes – and determine the cassette's water flux normalized to a water temperature of 20 °C.

Interpreting water flux values

Compare the post-cleaning flux value with the as new flux values. If the post-cleaning flux values are less than 60 to 80 percent of the new flux values, you may have to repeat or change the cleaning procedure. If, after all cleaning attempts, the post-cleaning flux values are still less than 60 to 80 percent of the new flux values, you may want to replace the cassette.

8.4 Stage 3 – Storing the cassette and holder

Short-term storage

After completing stages 1 and 2, flush the cassette with a storage agent as described below to keep the membrane wet and minimize biological growth:

- For storage less than 3 days, use 0.2 M filtered water
- For storage less than 6 months, use 0.1 N NaOH
- For storage longer than 6 months, use a storage solution of 0.1 N NaOH and store the cassette at 4 °C.

For long-term storage (more than ten days), remove the cassette from the holder and place it into an air-tight plastic tub or heavy-duty, zip-lock-type plastic bag. Add about 50 to 100 ml of the storage solution to the plastic bag and seal it. Ensure the storage solution fully covers the cassette. Place the sealed bag in a protected location at a temperature of 4 °C.

For short-term storage (five to ten days), keep the cassette in the holder and circulate the storage solution for 10 to 15 minutes, close the system valves, disconnect the electrical power to the feed pump, and ensure the feed reservoir is properly sealed. On manually-clamped holders, loosen the tie rod nuts alternately ½ turn at a time until you can just turn the nuts by hand. Tighten the nuts to a torque of 10 to 15 Nm (88 to 133 in-lbs). On hydraulic systems, keep the cassettes and gasket in the holder and pressurize the hydraulic system to 35 to 69 barg (500 to 1000 psig) to prevent fluid from leaking from the cassette holder.

9 Troubleshooting

In this chapter

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9.1 Troubleshooting guide

If the Kvick Lab holder does not seem to work properly, consult the troubleshooting guide (see the Table below).

Table 9.1: Kvick Lab holder troubleshooting guide

Symptom	Possible Cause	Solution
Holder leaks from between flow manifold and backing plate	Insufficient clamping force	Check tie rod nut torque
	System is being run at excessive operating pressures	Run system at proper operating pressures
	Cassette gasket damaged or not seated properly	Remove and inspect gasket. Reinstall gasket.
	Cassette sealing surfaces damaged	Remove and inspect sealing surfaces on the cassette. Replace cassette if necessary.
	Sealing surface of the flow manifold or backing plate scratched	Inspect sealing surface of flow manifold and backing plate for scratches. Replace or have Cytiva polish the scratched surface.
Process solution leaks from sanitary connections	Sanitary connection gasket missing, worn, damaged, improperly mounted, or wrong size	Inspect gasket for wear, damage, and proper sizing. Reinstall gasket.
	Sanitary clamp loose	Tighten sanitary clamp
Feed pressure is too high	Cassette fouled	Clean cassette
	Obstruction in feed line or retentate line	Inspect lines for obstruction
	Feed inlet in cassette plugged	Switch feed and retentate lines to reverse flow, and flush with DI water or WFI Retorque tie rod nuts
System leaks during integrity testing	Insufficient clamping force Improperly seated cassette or gasket	Locate leaking area by feeling air leak with hand, or by applying soapy water and looking for bubbles. Remove, inspect, and reinstall cassette and gasket

Symptom	Possible Cause	Solution
	Sealing surface of holder or cassette damaged	Locate leaking area by feeling air leak with hand, or by applying soapy water and looking for bubbles. Remove cassette and gasket and inspect sealing surface of flow manifold, backing plate, and cassette
	Faulty valve	Check integrity of valves and replace as needed.

10 Maintenance

WARNING
Inspecting the cassette holder without shutting down the cross-flow system to which it is attached (disconnecting the power cable, disconnecting the compressed air supply, and decompressing the system) can result in bodily injury from the accidental starting of the pump or unexpected release of pressure. To prevent bodily injury, disconnect the power cable, disconnect the compressed air line, and depressurize the system before performing inspections and maintenance on the system.

In this chapter

Section		See page
10.1	Inspection	56
10.2	Maintenance	57
10.3	Storing the holder	58

10.1 Inspection

Periodically – based on usage – you should make these inspections:

- Inspect the tie rods and nuts for excessive wear and replace as needed.
- Inspect the mating surfaces of the flow manifold and backing plate for scratches.
- Inspect the sanitary connection gaskets for damage or wear and replace the gaskets as needed.
- Check the rigidity of the stand. If the stand wobbles, tighten the screws that hold the legs and cross braces together.

If the mating surfaces of the flow manifold and backing plate become excessively scratched, contact your Cytivarepresentative for assistance.

10.2 Maintenance

After using the holder, you should wash down the exterior components with clean water to remove dirt and residual process/cleaning solutions. Blow the wash water out of the flow manifold channels with compressed air. Wipe the holder dry with a clean, lint-free cloth.

Tip: *The nut torque values are based on the tie rod threads being dry. You should not oil the tie rod threads. Oiled tie rod threads will result in too much clamping pressure being applied to the cassette.*

10.3 Storing the holder

To store the holder, clean it as noted above and place several layers of a clean cloth between the flow manifold and the backing plate. Install the spacers, washers, and nuts, and lightly hand tighten to hold the cloth and backing plate in place. Place the holder in a dry, protected area such as a cabinet to prevent contamination or accidental dropping.

11 Specifications

In this chapter

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11.2	Materials of construction	61
11.3	Operating parameters	62

11.1 Size and dimensions

Feed and retentate port fittings – 1/2 in. TC

Permeate port fittings – 1/2 in. TC

Dimensions (approximate W x D x H) – 23 x 25 x 19 cm (9 x 10 x 7.5 in.)

Shipping weight (approximate) – 7.7 kg (17 lb)

11.2 Materials of construction

Wetted parts:

- Flow distribution manifold – Polished 316L stainless steel, Ra <0.8 um
- Back plate – Polished 316L stainless steel

Nonwetted parts:

- Tie rods, washers, stand – Stainless steel
- Tie rod nuts – Bronze

11.3 Operating parameters

When using your Kvick Lab cassette, fully open the permeate valve and adjust your pump speed and retentate valve to achieve the recommended cross-flow rate. The recommended operating conditions for many applications are:

Transmembrane pressure – 1.7 to 2.4 barg (25 to 35 psig)

Cross-flow rate – 600 to 800 ml/min/ per 0.11 m^2 (1.2 ft^2) cassette

Recommended operating temperature – 5 to 50 °C

Maximum operating temperature – 121 °C (250 °F)

Maximum operating pressure – 4 barg (60 psig)

Operating pH – 1 to 14

Cassette holdup volume – 20 m

Hardware holdup volume (feed/retentate) – less than 2 ml

Maximum membrane area – 0.55 m^2 (6.0 ft^2)

Type and number of cassettes:

Kvick Lab – 0.11 m^2 (1.2 ft^2), maximum of 5 cassettes installed

Kvick Lab – 100 cm^2 (0.11 ft^2), maximum of 10 cassettes installed

12 Appendix

In this chapter

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12.2	Cassette sanitizing Agents	65
12.3	Parts and accessories	66

12.1 Chemical compatibility

You can damage a Kvick Lab cassette holder by exposing it to chemicals incompatible with stainless steel. The gaskets used to connect piping to the sanitary fittings of the holder are made of EPDM, and are resistant to many types of chemicals (see the Table below). Consult the *Cytiva Cassettes: Instructions for Use* manual for guidelines on the chemical compatibility of cassettes.

Table 12.1: Chemical resistance of Kvick Lab cassette holder wetted parts

Chemical	SS 316L Resistance	EPDM Resistance
Acetic acid 1.7 M	Resistant	Resistant
EtOH 20%	Resistant	Resistant
EtOH 40%	Resistant	Resistant
Ethylene glycol 50%	Resistant	Resistant
Formaldehyde 1.7 M	Resistant	Resistant
Formic acid 10%	Resistant	Resistant
Glycerol 100%	Resistant	Resistant
Hydrochloric acid 0.1 M	Not recommended	Resistant
Isopropyl alcohol 30%	Resistant	Resistant
Nitric acid 0.1 M	Resistant	Resistant
Phosphoric acid 25%	Limited resistance	Resistant
Sodium chloride 0.5 M	Resistant[1]	Resistant
Sodium hydroxide 2 M	Resistant[2]	Resistant
Triflouroacetic acid 0.1%	Resistant	Resistant
Triton™ X-100 100%	Resistant	Resistant
Urea 8 M	Resistant	Resistant

1 Do not use sodium chloride in storage solutions. Sodium chloride can cause corrosion on stainless steel at pH less than 5.
2 Maximum recommended exposure is 4 hours.

12.2 Cassette sanitizing Agents

Sanitizing Agent	Sanitizing Conditions
0.5 to 1 N sodium hydroxide	Minimum contact time for sanitization = 60 minutes

12.3 Parts and accessories

Description	Model Number	Code Number
Kvick Lab cassette holder	KLHR0105000SS	56-4112-79
Retentate or permeate valve (ITT Biotek valve, 25 Ra, EP ½-inch sanitary clamp)	KFSY01071DV05	56-4112-95
In-line pressure gauge, 0 to 4 barg (0 to 60 psig)	KLS0105APGA60	56-4113-91
½-inch sanitary clamp	KFSY0107TCL05	56-4112-85
½-inch EPDM gasket	KFSY0107TCG05	56-4112-86
Kvick Lab holder torque wrench	KLTW0001	56-4112-84
1 Kvick Lab cassette gasket	KYLAGS001011	56-4113-66
3 Kvick Lab cassette gaskets	KYLAGS001033	56-4113-65
½-inch TC-CPM style fitting	KLSY0105PCM05	56-4113-92
CPM fitting o-ring, 6 per package	KFSY0107PCM0RI	56-4112-89
½-inch SS blanking cap	KLSY0105SSC01	56-4112-98
½-inch TC by 3/8-inch HB adaptor	KLSY0105HBF01	56-4112-37
½-inch TC by ¼-inch HB adaptor	KLSY0105HB4F01	56-4113-26
Kvick Lab valve and pressure gauge kit	KLSY0105PRKIT	56-4113-69

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