GE Healthcare

Kvick Pilot and Process cassettes

Instructions for use

11-0026-31 AB

Table of contents

About this user guide

This user guide describes how to use Kvick™ Pilot and Kvick Process membrane cassettes. Topics include preparation for use, recommended operating conditions, cleaning and storing, and product specifications.

Audience

This user guide addresses the needs of scientists, process engineers, and technicians who operate pilot- and process-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 used with the Kvick Pilot and Kvick Process cassettes. If you need assistance with the instructions in this guide, contact GE Healthcare for more information.

Where to find more information

GE Healthcare publishes several user guides that may be helpful in using Kvick brand products (Figure 1).

You can download technical documents and learn more about GE Healthcare cassettes and cross-flow systems by visiting our website, www.gehealthcare.com.

Cross Flow System Safety: Multilingual Safety Instructions— Describes conditions and actions that can cause bodily injury or equipment damage when using cross flow systems. Describes how to avoid the risks. Supplied with GE Healthcare cassette holders and systems. Available for downloading from the GE Healthcare website.

MSDSs for glycerin, NaOH, and hydraulic fluid— Provides safe handling and disposal information. Available for printing and downloading from the GE Healthcare website.

Safety

Anyone who works with the Kvick Pilot and Kvick Process cassettes should read, understand, and follow the instructions in this user guide. If any operator does not understand an instruction, they should stop working with the Kvick Pilot and Kvick Process cassettes and contact GE Healthcare for guidance.

You should save these instructions and make them available to all users of the cassettes.

GE Healthcare designed the Kvick Pilot and Kvick Process cassettes for laboratory- and pilot-scale filtration of biological solutions using Kvick Pilot and Kvick Process cassette holders under the conditions stated in this user guide. If you use the cassettes in a manner not specified by GE Healthcare, you may impair the protection provided by the system and cassettes.

When using any pilot- or process-scale cross-flow equipment, the potential exists for personal injury unless you follow established safety procedures. When using GE Healthcare products, you should follow OSHA1, 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 Kvick Pilot and Kvick Process cassettes.

Warnings, cautions, and expert advice

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

➤ Safety

WARNING: A safety warning flag describes conditions or actions that can cause bodily harm and describes how to avoid the risk.

➤ Expert Advice

CAUTION: A caution flag describes conditions or actions that can damage equipment and describes how to avoid the risk.

➤ Expert Advice

TIP: An expert advice flag provides you with information equipment efficiently or achieve the best results.

Warning

If you overpressurize a cross-flow 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 weakest component in your cross-flow system. Wear the appropriate personal protection devices when testing the system.

If a cross-flow system leaks, it can release potentially hazardous process or cleaning fluids causing bodily harm. To prevent leaks and the release of potentially hazardous fluids, limit feed pressure on GE Healthcare cross-flow systems to 4 barg (60 psig), periodically check parts for wear, and ensure you assemble the components correctly. To monitor system pressure, GE Healthcare recommends that you install pressure gauges on the system as described 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

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.

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.

Caution

The following actions can damage cassettes: dropping on hard surfaces, other mechanical shock, excessive feed pressure, pressurizing the permeate ports, exposure to harsh chemical solutions, and freezing. If the cassette is subjected to any of these conditions, you should perform integrity testing and water flux on the cassette to check for internal damage.

Caution

Allowing ultrafiltration cassettes to dry out can permanently damage the membrane. To prevent damage from drying out during short periods of inactivity (1 to 3 days), wet out the membrane with buffer or saline solution. To prevent cracking of the membrane during long-term storage, follow the storage procedure on page 17. To prevent cracking during use, do not flow compressed air through the system for more than a few minutes.

1 In the United States, OSHA is the Occupational, Safety, and Health Administration

Chapter 1

Cassettes

Package contents

Cassette boxes include the following components:

- Cassette in sealed plastic bag
- Cassette gasket
- Certificate of compliance
- User Guide

Learning about cassettes

The two sizes of Kvick Pilot and Kvick Process cassettes share design components, including inlet and outlet ports, labeling, and alignment notches (Figure 2).

1. Inlet (feed) port
2. Outlet (retentate) port
3. Permeate port
4. Cassette information (see Figure 3)
5. Alignment notches
6. Incorporated gasket

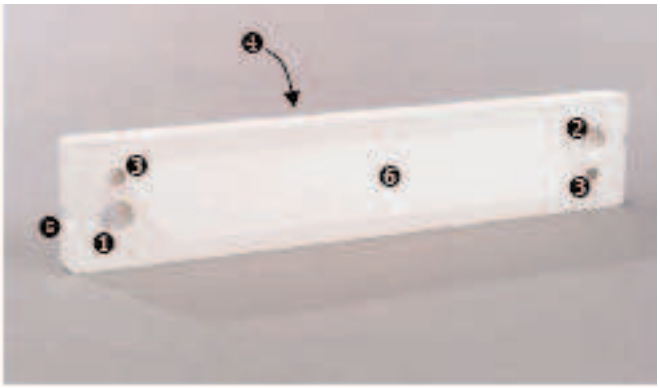

Figure 1. The main parts of a Kvick Pilot cassette

Product labeling

Cassette identifying information is laser engraved on the side of the cassette. The information describes the following: manufacturer, lot number, cassette type (Kvick Pilot or Kvick Process), part number, pore size (10K, 30K, 50K, etc.) and the membrane area in square feet and square meters (Figure 3).

Figure 2. Identifying information printed in the side of cassettes

Chapter 2

Using a cassette

Introduction

Preparing a cassette for use can be as simple as rinsing the cassette with deionized water. In critical applications, cassette preparation may include: (1) documenting the performance of the cassette, (2) ensuring the integrity of the cassette, and (3) sanitizing the cassette.

This user guide describes how to open and rinse the cassette with water—the most basic step of cassette preparation. The user guides for GE Healthcare cassette holders describe the other preparatory steps you may want to complete for critical applications.

➤ Safety

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.

➤ Expert Advice

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 GE Healthcare technical support team.

Preparing a cassette for use

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.

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.

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:

1. Following the safety instructions above, open the cassette bag, drain the cassette, and rinse the storage solution from the exterior of the cassette with high purity water.
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 (Figure 4). Close the feed, retentate, and permeate valves.
4. Fill the reservoir with an appropriate volume of DI water or WFI (5 liters per 0.09 mÇ [1.0 ftÇ] of membrane area).

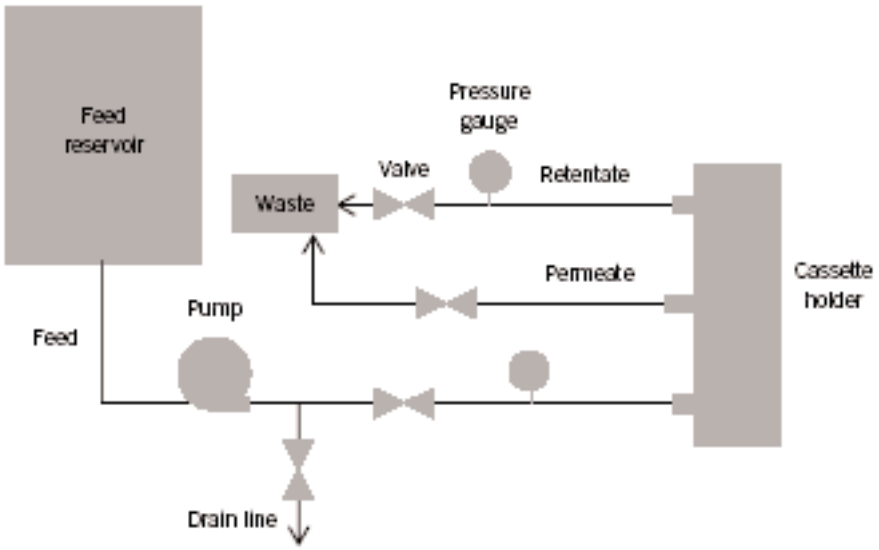

Figure 3. Typical setup for rinsing cassettes or the initial flow of cleaning solution at the start of cleaning

➤ **Expert Advice**

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 deionized water or water-for-injection when rinsing or flushing the cassette, or when making up cleaning solutions or adding dilution water to process fluids.

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 transmembrane pressure of 0.35 barg (5 psig).
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 the 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.2 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.

Recommended operating conditions

When using your cassette, fully open the permeate valve and adjust your pump speed and retentate valve to achieve the cross-flow rate required by your process.

If your feed is particularly viscous or has other unusual physical characteristics, contact the technical support team at GE Healthcare for assistance. Other recommended operating parameters include these:

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

Optimizing product recovery

You can optimize product recovery by reducing the cross-flow rate at the end of your process step. When you are done concentrating your product, reduce the cross-flow rate to 1/10 of the recommended processing cross-flow rate. Close the filtrate 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.

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 Preparing a cassette for use on page 13. Then clean the cassette following these steps:

1. Configure the system so that the retentate and permeate lines discharge to waste (Figure 4). Close the feed, retentate, and permeate valves.
2. Prepare the appropriate volume of a cleaning solution (1.5 to 2 liters per 0.09 mÇ [1.0 ftÇ] of membrane area). Table 1 describes recommended cleaning solutions.
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 (Figure 5). Open the feed, retentate, and permeate valves.
6. Start the pump. Adjust the retentate valve and pump speed to obtain the cross flow rate required for cleaning.

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

7. Circulate the cleaning solution for 30 to 60 minutes.

8. Drain the cleaning solution from the system using the drain line.

9. Flush it with buffer, WFI, or DI water as described in Preparing a cassette for use on page 00

Table 1. Recommended cleaning solutions

Cleaning agent	Cleaning conditions	Membrane type
1.5% Terg-A-Zyme®	Contact time ? 60 minutes Temperature ? 35°C (95°F)	Polyethersulfone and PolysulfoneA
1.5% Alconox® detergent	Contact time ? 60 minutes Temperature ? 40°C (95°F)	Polyethersulfone and Polysulfone
0.1 to 0.5N sodium hydroxide	Contact time ? 60 minutes Temperature ? 40°C (113°F)	Polyethersulfone and Polysulfone
200 to 300 ppm sodium hypochlorite in 0.1 to 0.5N sodium hydroxide	Contact time ? 60 minutes Temperature ? 20°C (68°F)	Polyethersulfone and Polysulfone

A Polysulfone membrane is used in GE Healthcare Hollow Fiber cartridges.

Storing a cassette

Before storing your cassette, clean it (see page 16) and flush it with a storage agent to keep the membrane wet and minimize biological growth:

- For storage less than 3 days, use clean water or 0.1 N NaOH
- For storage from 3 days to 6 months, use 0.1N 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 agent to the plastic bag and seal it. Place the sealed bag in a protected location at a temperature less than 25°C (77°F). Cold storage (but above freezing) provides the optimal storage conditions.

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. Reduce the clamping pressure as low a possible while avoiding leaks.

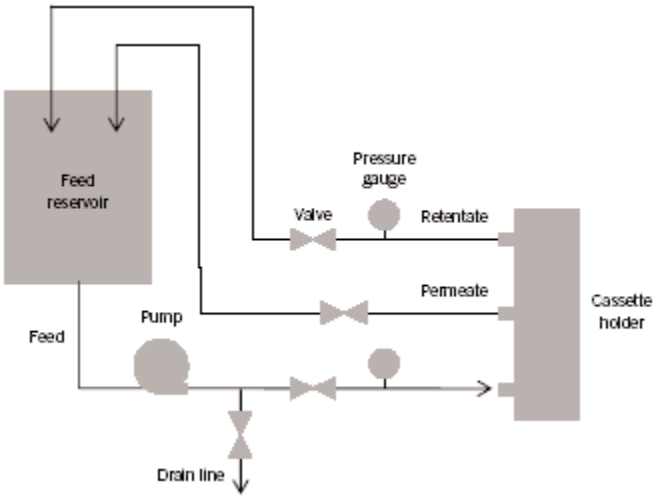

Figure 4. Typical setup for extended recirculation of cleaning solution during cleaning.

Chapter 3

Cassette specifications

Kvick Pilot specifications

Ordering information

Code number	Model number	Membrane area m^2	ft^2	Pore size NMWC*
56-4115-69	UFEPT 0005 025 ST	0.23	2.5	5,000
56-4115-70	UFEPT 0010 025 SE	0.23	2.5	10,000**
56-4115-71	UFEPT 0010 025 ST	0.23	2.5	10,000
56-4115-72	UFEPT 0030 025 ST	0.23	2.5	30,000
56-4115-73	UFEPT 0050 025 ST	0.23	2.5	50,000
56-4115-75	UFEPT 0100 025 ST	0.23	2.5	100,000

* Nominal molecular weight cutoff
** Tighter 10kD membrane than the regular 10kD

Materials of construction:

Membrane—polyethersulfone
Screen—polypropylene
Encapsulent and encapsulated gasket—silicone
Preservative solution—0.1 to 0.2 N NaOH and 20 to 22% glycerin

Recommended operating conditions:

pH range, long-term (storage)—2 to 13

pH range, short-term (cleaning)—1 to 14

Maximum operating temperature—50 °C

Maximum inlet pressure—4 barg (60 psig)

Kvick Process specifications

Ordering information

Code number	Model number	Membrane area m^2	ft^2	Pore size NMWC*
56-4115-55	UFEPR 0005 300 ST	2.79	30	5,000
56-4115-56	UFEPR 0010 300 SE	2.79	30	10,000**
56-4115-57	UFEPR 0010 300 ST	2.79	30	10,000
56-4115-58	UFEPR 0030 300 ST	2.79	30	30,000
56-4115-59	UFEPR 0050 300 ST	2.79	30	50,000
56-4115-63	UFEPR 0100 300 ST	2.79	30	100,000

* Nominal molecular weight cutoff
** Tighter 10kD membrane than the regular 10kD

Materials of construction:

Membrane—polyethersulfone
Screen—polypropylene
Encapsulent and encapusulent gasket—silicone
Preservative solution—0.1 to 0.2 N NaOH and 20 to 22% glycerin

Recommended operating conditions:

pH range, long-term (storage)—2 to 13

pH range, short-term (cleaning)—1 to 14

Maximum operating temperature—50°C

Maximum inlet pressure—4 barg (60 psig)

Chemical compatibility

GE Healthcare Kvick Pilot and Kvick Process cassettes are resistant to a wide range of chemicals. However, you can damage the cassettes by exposing them to chemicals incompatible with their materials of construction. The following table provides a general guide to the chemical compatibility of polyethersulfone, primary material of construction.

Solution	Polyethersulfone
Acetic acid (10 %)	Resistant
Acetic acid (1.7 M)	Resistant
Ammonium hydroxide (<5%)	Resistant
Benzyl benzoate	Limited resistance
Butanol	Resistant
Butyl acetate	Limited resistance
Carbon tetrachloride	Limited resistance
Chloroform	Limited resistance
Citric acid (10 %)	Resistant
Dichloroethylene	Not resistant
Diethyl ether	Resistant
Ethanol (10 %)	Resistant1
Ethanol (20 %)	Resistant1
Ethanol (40 %)	Resistant1
Ethyl ether	Resistant
Ethylene glycol (50%)	Resistant
Formaldehyde (1.7 M)	Resistant
Formic acid (10%)	Resistant
Fructose (saturated)	Resistant
Gelatine	Resistant
Glucose	Resistant
Glycerol	Resistant
Guanidine hydrochloride	Limited resistance
Hexane	Limited resistance

1 As the concentration of ethanol increases, cassette flux rate decreases.

Solution	Polyethersulfone
Hydrochloric acid (0.1%)	Limited resistance
Isopropyl alcohol	Resistant
Methanol (98 %)	Resistant
Mineral oil	Resistant
Nitric acid (0.1 M)	Resistant
Ozone Limited	Resistance
Peracetatic acid (0.2 %)	Resistant
Phosphoric acid (25%)	Limited resistance
Pyridine Limited	Resistance
Sodium chloride (0.5 M)	Resistant[1]
Sodium hydroxide (1M)	Resistant[2]
Sulfuric acid (25 %)	Limited resistance
Toluene	Limited resistant
Trichloroacetic acid (10 %)	Limited resistant
Triethanolamine	Resistant
Urea Limited	Resistance
Xylene Limited	Resistance

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

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