Minimate™ TFF Capsule and Minimate EVO TFF system

Operating Instructions

Original instructions

Table of Contents

1 Introduction

About this chapter

This chapter contains information about this manual and associated user documentation, important user information, and intended use of the product.

In this chapter

1.1 Important user information

Introduction

This section contains important user information about the product and this manual.

Read this before operating the product

All users must read the entire *Operating Instructions* before installing, operating, or maintaining the product.

Always keep the *Operating Instructions* at hand when operating the product.

Do not install, operate, or perform maintenance on the product in any other way than described in the user documentation. If you do, you can be exposed or expose others to hazards that can lead to personal injury and you can cause damage to the equipment.

Intended use

The Minimate™ TFF Capsule is intended for buffer exchange or concentration of samples up to 1 liter. For laboratory use only. Not for use in a manner other than indicated.

1.2 About this manual

Introduction

This section contains information about the purpose and scope of this manual, notes and tips, and typographical conventions.

Purpose of this manual

This manual provides information needed to install, operate, and perform maintenance in a safe way.

Scope of this manual

This manual is valid for the Minimate TFF Capsule and Minimate EVO TFF system.

Notes and tips

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

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

Typographical conventions

The text on a graphical user interface is identified in this manual by ***bold italic*** text.

The text on the label of a hardware item is identified in this manual by **bold** text.

Tip: *The text can include clickable hyperlinks to reference information.*

1.3 Associated documentation

Access user documentation online

Scan the QR code or visit *cytiva.com/instructions*. Enter the title or the document number to access the file.

Additional documentation

Refer to the following documentation:

- *Minimate TFF Capsule Quick Start Guide*
- Minimate TFF Capsule Data Sheet
- Introduction to TFF for Laboratory and Process Development Applications.
- Diafiltration: A Fast, Efficient Method for Desalting, or Buffer Exchange of Biological Samples.
- Desalting and buffer exchange by Dialysis, Gel Filtration or Diafiltration.

2 Safety instructions

About this chapter

This chapter describes safety precautions, labels, and symbols. In addition, emergency and recovery procedures are also described.

In this chapter

Important

WARNING

All users must read and understand the entire contents of this general safety chapter, and the specific safety precautions information in each subsequent chapter of this manual to become aware of the hazards involved.

2.1 Safety precautions

Introduction

This section describes the general hazards you must be aware of before performing installation, operation, or maintenance.

Definitions

This user documentation contains safety notices (WARNING, CAUTION, and NOTICE) concerning the safe use of the product. See definitions below.

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.

NOTICE

NOTICE indicates instructions that must be followed to avoid damage to the product or other equipment.

2.2 Labels and symbols

Nameplate

The nameplate provides information about the model, manufacturer, and technical data.

3 System description

About this chapter

This chapter gives an overview of Minimate TFF Capsule and Minimate EVO TFF system and a brief description of their functions.

In this chapter

3.1 System overview

Introduction

The Minimate TFF Capsule is the central part of a system for performing concentration or diafiltration on solutions of biomolecules. It is available with low protein binding Omega™ ultrafiltration membranes in several different molecular weight cutoffs. The membranes are encased in a polypropylene housing with luer connectors on the **Feed or Retentate** and **Vent or Filtrate** ports for easy connection to a pump and accessories.

- For laboratory and process development applications.
- Ideal for evaluation, process development, process optimization, and validation studies.
- Scalable to LV Centramate™ and Centramate systems.
- Easily connected up to Minimate EVO TFF or peristaltic pumps.
- Integrity tested and testable by user.
- All plastic construction.

Applications

Tangential flow filtration (TFF) is a rapid and efficient method for the concentration or diafiltration of biomolecules. It can be used in a wide range of applications.

- Concentrate and desalt proteins, peptides, or nucleic acids (DNA, RNA, oligonucleotides).
- Recover antibodies or recombinant proteins from clarified cell culture media.
- Process metal sensitive enzymes and molecules.
- Separate (fractionate) large from small biomolecules.
- Recover or remove viruses from solutions.
- Prepare samples prior to column chromatography.
- Concentrate samples after gel filtration.
- Replace dialysis applications.
- Depyrogenate water, buffers, and media solutions.

3.2 Minimate EVO TFF fittings kit

Introduction

The Minimate TFF Capsule comes with threaded luer plugs in each of the 4 ports. A fitting package with the following components is included.

Kit components

The Minimate EVO TFF fittings kit (part number 97014) includes:

- 3-way valve for reservoir (2)
- 1-way valve reservoir lid (2)
- Male luer coupler (1)
- Male luer lock - 1/8″ hose barb (3)
- Male luer lock - 1/8″ hose barb elbow (4)
- Female luer lock - 1/8″ hose barb (1)
- Tubing clamps (8)
- PharMed tubing (2 ft.)
- Screw clamp for tubing (1)
- Male luer plug (4)

3.3 Storage

The objective for proper storage is to make sure that the membranes remain wet and to prevent microbial growth during the time the membrane cassettes are not being used.

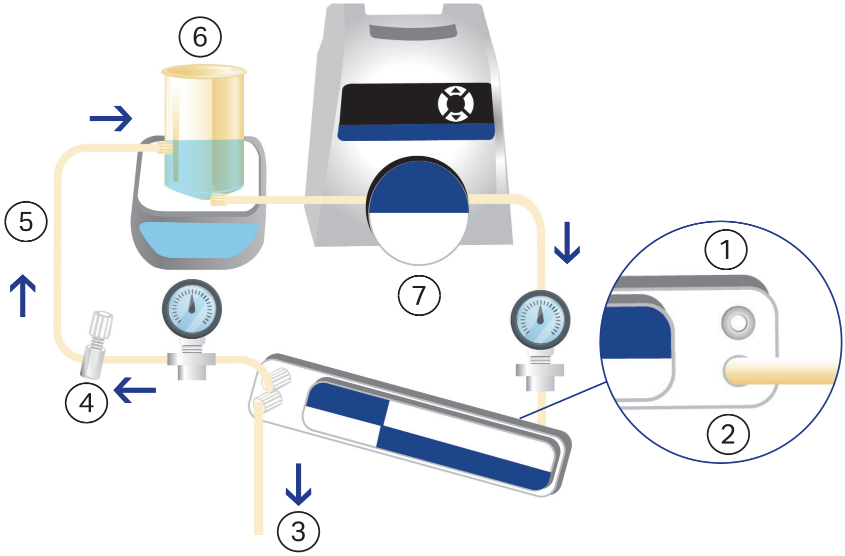
See below for recommended storage agents for Minimate TFF Capsule.

Table 3.1: Storage agents

Period	Solution
<3 days	Sterile water or saline solution
<6 months	0.05 to 0.1N NaOH
>6 months	15% glycerin + 0.05% sodium azide

Recommended storage temperatures: 4°C to 15°C (optimal), 25°C (maximum). Do not freeze.

3.4 Typical Minimate TFF Capsule setup



Part	Description
1	Vent or filtrate
2	Feed or retentate
3	Filtrate
4	Screw clamp valve
5	Retentate
6	Sample reservoir
7	Pump

The pump is connected with tubing between the process sample reservoir and the feed port on the Minimate TFF Capsule. Tubing connected to the retentate port is returned to the reservoir. This allows flow of product across (tangential to) the membrane surface to create a sweeping action that helps prevent membrane fouling by reducing buildup of particles and product on the surface. Pressure in this flow path, generated by the flow stream through the channel and by restricting the tubing connected to the retentate port with an adjustable clamp, is the driving force that creates liquid flow through the membrane (filtrate flow rate). The average pressure applied to the membrane is referred to as the transmembrane pressure (TMP). Increasing the TMP increases the filtrate flow rate, up to a point. Applying too much pressure will foul the membrane and reduce filtrate flow rate. Controlling the TMP helps regulate the filtrate flow rate.

Tubing connected to one of the filtrate ports serves to carry the filtrate (permeate) away from the device. The other filtrate port can be used as a vent for draining all liquid in the tubing after the process is finished.

4 Installation

In this chapter

4.1 Required equipment

Note: *Read about the capsules operating limits in* *Section 7.1 Specifications, on page 58**.*

- Minimate EVO TFF system: The Minimate EVO TFF system (Part no. OAPMPUNV) is optimized for use with Minimate TFF Capsule. The system includes a pump, pump head, 2 pressure gauges, 500 ml reservoir, stir plate and magnetic stir bar, valves, fittings, and a compact drip tray.

Alternatively the following equipment can be used:

- A peristaltic pump or equivalent with variable speed control capable of delivering a constant flow rate from 10 to 100 mL/min/capsule at pressures up to at least 2 bar (30 psi). The peristaltic pump head must be sized to accept 1.6 mm (1/16 in.) or 3.2 mm (1/8 in.) i.d. tubing. The Minimate EVO TFF fittings kit includes 3.2 mm (1/8 in.) i.d. tubing.
- Feed reservoir: Appropriately sized for the volume of sample or flushing solutions, e.g. 100 mL or 500 mL. Using a reservoir where liquid is drawn from the bottom allows the sample to be concentrated to a smaller volume due to the reduced hold-up volume.

4.2 Recommended equipment

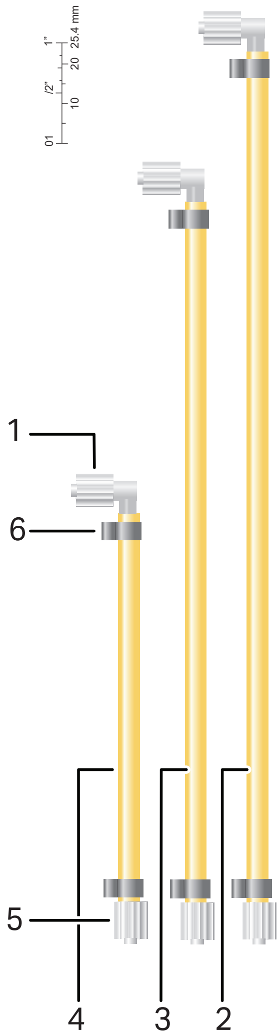
Table 4.1: Equipment

Parameter	Description
Pressure measuring device	Pressure gauge or transducer and display. At least one is recommended on the feed port. Additionally, one on both the retentate and filtrate ports may be added. The Minimate EVO TFF system provides both a feed and retentate pressure gauge.
Magnetic stir plate and stir bar	Provides adequate mixing in the reservoir.
Stop watch	Measures elapsed time when determining flow rates (crossflow and filtrate flux rate).
Pipettes and sample tubes	Collect samples for analysis.
Beakers and reservoirs	To hold and collect sample and waste.
Graduated cylinders	For accurately determining collected volumes.

4.3 Installing the Minimate EVO TFF system

Follow the steps below to install the Minimate EVO TFF system.

Step	Action
1	Cut PharMed tubing (yellow) to lengths as specified in the table below.



Step	Action

Part	Description
1	Male luer lock-1/8" hose barb elbow
2	Long tube 8-½" (216 mm) long
3	Mid length tube 7" (178 mm) long
4	Short tube 3-7/8" (99 mm) long
5	Male luer lock-1/8" hose barb
6	Tubing clamp

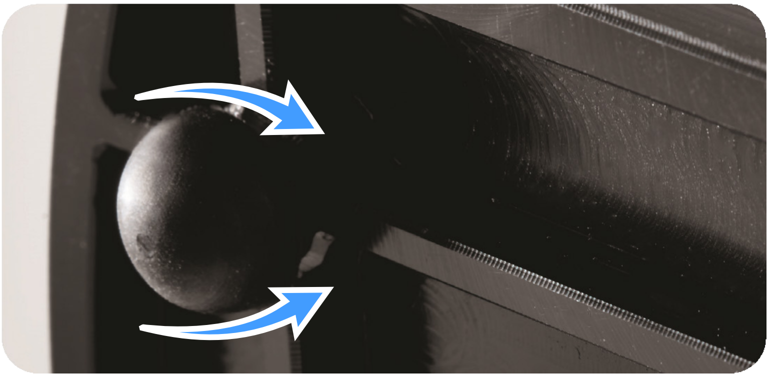
2 Slide tube clamps onto tubing and insert fittings into tubing as shown on back page.

3 Slide clamps over fitting ends and pinch together.

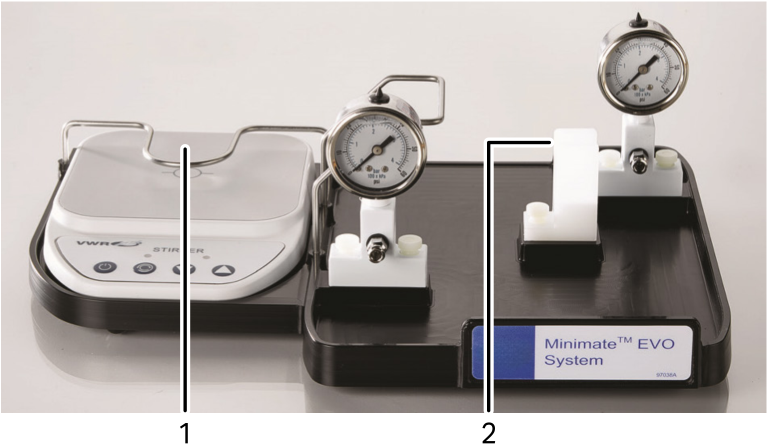
Tip:
Use pliers if necessary to assist.

4 Lay drip tray on work counter.

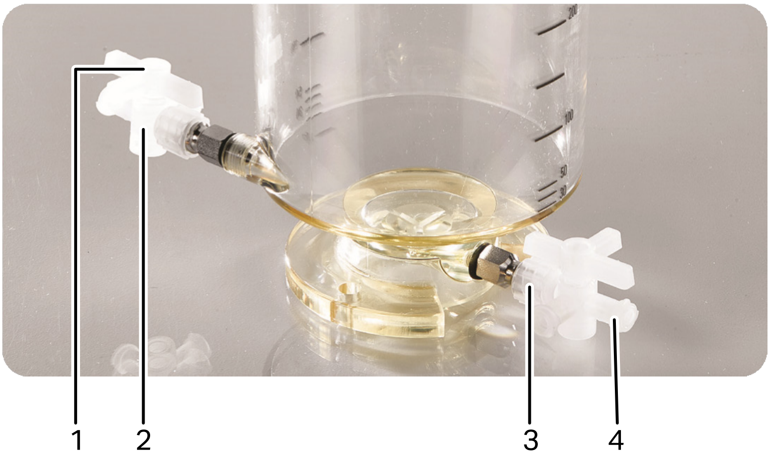
Note:
If there is any rocking of tray, the bottom feet can be adjusted by rotating as necessary as shown in te image below.



Step	Action
5	Slide the stir plate (1) into the left compartment of the drip tray underneath the reservoir bracket. Attach the capsule stand (2) on the raised boss in center of the drip tray with the screw in the threaded hole. Turn the screw until snug fit, but allows the stand to move.

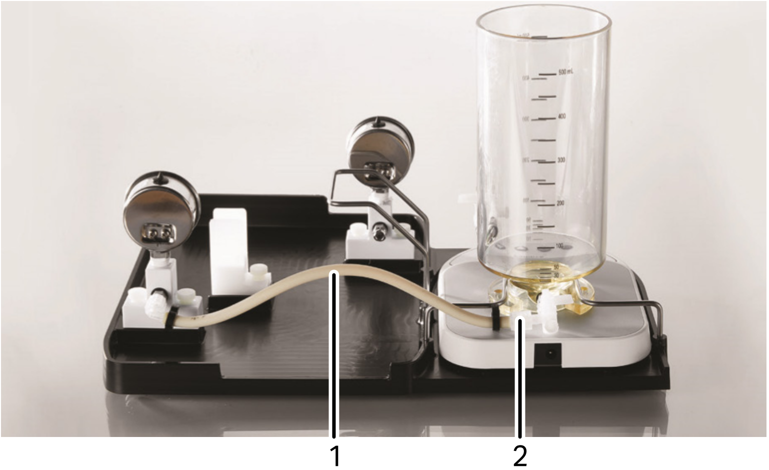


Step	Action
6	Connect 3-way valves to the fittings on the reservoir 3 way valve outlet (3)and 3 way valve inlet (2). Attach male luer plugs (1,4) onto female luer connectors on 3-way valves.



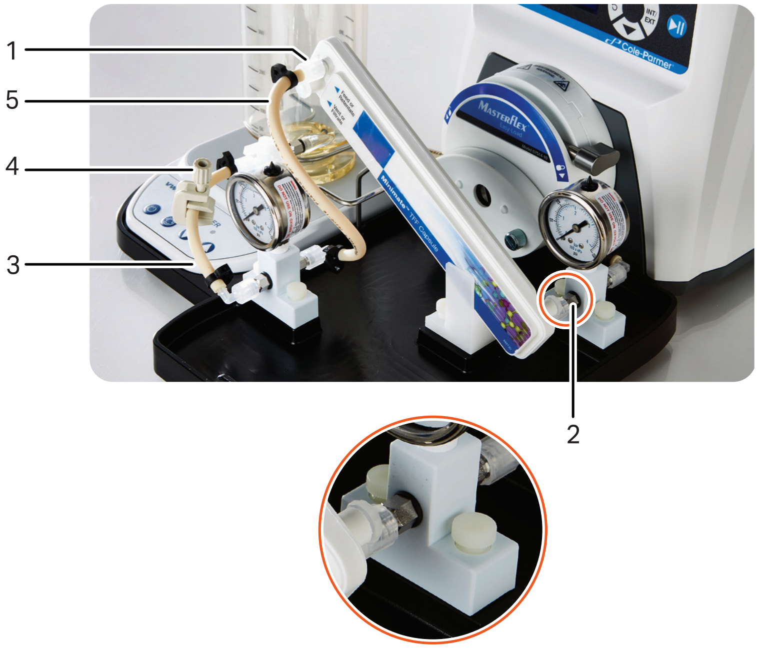
Step	Action
7	Place the reservoir onto a stir plate with outlet toward rear of the plate.

Step	Action
8	Connect the long tube (1) to the 3-way valve at the reservoir outlet (2) and to the fitting on the rear gauge mount.



Step	Action
9	Attach the pump head (1) onto the pump (3) with the supplied mounting screws (2).

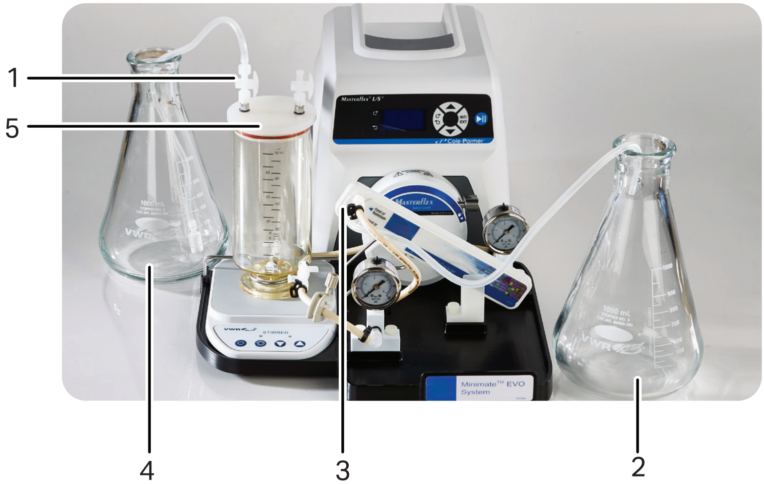
Step	Action
10	Place the tray in front of the pump and insert the tubing into the open pump head.
11	Close the pump head onto the tubing.
12	Attach the male luer coupler to the fitting on the front of the gauge mount. Attach the Minimate TFF Capsule feed port to the coupler, rotate capsule to the left into the capsule stand and onto the capsule bracket for support.



Part	Description
1	**Feed or Retentate** port
2	Male luer coupler (to feed port)
3	Short tube
4	Screw clamp
5	Mid length tube

Step	Action
13	Connect the mid-length tube to the fitting on the rear of forward gauge mount and to the retentate port on the capsule filter.

Step	Action
14	Connect the short tube to the fitting on the front of gauge mount and to the 3-way valve on the reservoir inlet. Attach an adjustable screw clamp to the tube. Remove the clamp when not in use, tubing can deform over time without fluid passing through the tubing.
15	Cut a length of tubing from the Minimate TFF Capsule packaging long enough to reach the filtrate collection vessel from the filtrate port on the filter capsule. Attach the tubing clamp and the female luer-1/8" hose barb to the tube. Connect the fitting to the filtrate port and place the open tube end into the filtrate receiver vessel.



Part	Description
1	One way valve
2	Filtrate collection vessel
3	Female luer-barb (to filtrate port)
4	Diafiltration vessel
5	Reservoir lid

Step	Action
16	If performing diafiltration, place the lid onto the reservoir. Connect the 1-way valves onto the fittings on top of the reservoir. From the Minimate TFF Capsule filter packaging, cut a length of tubing to reach from 1-way valve on reservoir lid top to the diafiltration vessel.
17	Attach a male luer-1/8" hose barb elbow and a tubing clamp. Attach the elbow to the 1-way valve on the lid and the other tube end into the diafiltra-tion vessel, sinker at the end of the tube optional.

4.4 Installing the Minimate TFF Capsule system

Follow the below steps to install the Minimate TFF Capsule system when not using the Minimate EVO TFF system.

Step	Action
1	Remove the caps from the feed and retentate ports of the Minimate TFF Capsule system. ***Note:*** *Do not discard the caps. They are required for storage.*
2	Screw a male luer-to-hose-barb connector (included) into each of the feed and retentate ports.
3	Cut a piece of tubing 3.2 mm (1/8") i.d., long enough to reach from the feed reservoir, through the pump head to the capsule. ***Note:*** *Keep tubing lengths as short as possible to reduce system hold-up volume.*
4	Connect the tubing to the hose-barb on one of the feed ports. Install the tubing in the pump head. Put the other end of the tubing into the reservoir. ***Note:*** *If a pressure gauge or transducer is used, connect the tubing to the pressure device. Then connect the pressure device as close as possible to the feed port using suitable connectors.* ***Note:*** **Feed or Retentate** *port are interchangeable. Depending on the orientation of the capsule, choose the port that is at the lowest elevation as the feed port. This allows for air to be easily expelled when liquid is pumped through the capsule.* ***Note:*** *The recommended crossflow for the Minimate TFF Capsule is 30 to 80 mL/min.*
5	Cut another piece of tubing, long enough to return from the retentate port to the sample reservoir.
6	Attach the tubing to the retentate hose-barb and put the other end in the reservoir. ***Note:*** *If a pressure gauge or transducer is used, connect the tubing to the pressure device. Then connect the pressure device as close as possible to the feed port using suitable connectors.*

Step	Action
7	Place the screw clamp on the retentate tubing close to the retentate port (after the pressure gauge if installed). Secure in place but do not tighten to restrict the tubing.
8	Remove one of the filtrate caps.
9	Attach a female luer-to-hose-barb fitting to one of the filtrate and vent ports. ***Note:*** *Depending on the orientation of the capsule, choose the filtrate port that is at the highest elevation. This allows air to be completely expelled from the filtrate side of the membrane. The filtrate channel can be drained easily by opening the other filtrate port as a vent.*
10	Attach a piece of tubing to the filtrate hose barb.
11	Install a tubing clamp over each piece of tubing where it connects to the hose barb. Pinch the clamp to tighten. ***Note:*** *Make sure the tubing is secure and does not easily pull off the hose barb.* ***Note:*** *Cytiva strongly recommends the use of pressure gauges or transducers connected on both the feed and retentate ports. If only one gauge is available, it must be used on the feed port. The use of pressure gauges allows accurate adjustment of feed pressures, which provide for better reproducibility between process runs. They can also help in the diagnosis of system problems.* 

4.5 Calibrate feed pump

Follow these steps to calibrate the feed pump.

Note: *If the pump does not have a digital read out of flow rate, it may be useful to calibrate the pump. This makes it easier to set flow rates.*

Step	Action
1	Connect tubing to the pump and put both ends in a reservoir with water.
2	Prepare a pump curve by measuring flow rate at different settings.
3	Take measurements at 5 or more settings.
4	Record setting and flow rate. This will allow you to easily adjust flow rates for the following procedures.

Table 4.2: Pump calibration

Pump setting	Flow rate

5 Operation

About this chapter

This chapter gives instructions on how to operate the Minimate TFF Capsule system in a safe way.

In this chapter

5.1 Procedures

Safety precautions

Warnings are given in the following procedures not to exceed a feed pressure of 2 bar (30 psi). This warning is related to the pressure rating of the tubing. If it is ascertained that the tubing being used can withstand higher pressures and the tubing clamps have been properly installed, higher pressures can be used. It is strongly recommended that the system be tested at the higher pressures with water before using any potentially dangerous solutions, i.e., caustic sanitizing agents. Do not exceed the pressure rating of any component in the system.

In this section

5.1.1 Flushing

Introduction

The Minimate TFF Capsule system contains traces of glycerin (humectant) and preservative (biocide). The humectant ensures that the membrane will easily accept water and allow high flux, and the preservative combats microbial growth during storage. These compounds must be flushed out before use. More rigorous flushing and sanitization may be required for more critical uses, while less flushing may be acceptable if the intended use is less critical. If the Minimate TFF Capsule has previously been used, cleaned and equilibrated in a storage solution, the same preconditioning procedure may be used.

Flushing the storage solution

Follow these steps to flush out the storage solution.

Step	Action
1	Place the tubing from the suction side of your pump (feed) into about 1 L of 0.2 µm filtered deionized water or water for injection (WFI).
2	Place the tubing from the retentate and filtrate ports into a drain or waste container.
3	Adjust pump to deliver a flow rate of about 40 mL/min. Slowly tighten retentate screw clamp to increase backpressure. This will increase flow through the filtrate lines.
4	Tighten clamp until filtrate flow rate is approximately equal to the retentate flow rate or until feed pressure reaches 2 bar (30 psi). **CAUTION** Do not exceed a feed pressure of 2 bar (30 psi).
5	Pump at least 250 mL of the water through the retentate tubing and 250 mL through the filtrate tubing to the drain (>500 mL total). ***Note:*** *If the Minimate TFF Capsule is not be sanitized prior to use, it is recommended that this step is repeated to further remove the glycerin and preservative.*
6	When flushing is almost complete, open the vent port and collect at least 10 mL of filtrate. A small beaker or test tube can be used to collect the liquid.
7	Replace the vent cap when finished.

Step	Action
8	A three-port valve with luer connectors may be attached to the drain port. A short piece of tubing attached to a luer-to-hose-barb fitting can be connected to one of the valve port. The valve can then be turned to drain the liquid into the beaker or close off the port.

5.1.2 Sanitization (recommended for critical applications)

Introduction

If required, the Minimate TFF Capsule can be sanitized prior to use.

The following solutions can be used to sanitize and depyrogenate the capsule.

- 0.1 to 0.5 N NaOH at 35°C to 45°C
- 0.1 to 0.5 N NaOH + 200 ppm NaOCl at 35°C to 45°C
- 200 to 400 ppm NaOCl (pH 6 to 8) at 25°C to 45°C

Note: *Must not be used if any metal parts come in contact with the solution.*

Sanitization is particularly important if the capsule has been previously used, cleaned and stored.

Sanitize the capsule

Follow these steps to sanitize the Minimate TFF Capsule.

Step	Action
1	Add about 200 mL of sanitizing solution into a reservoir. Place feed tubing into reservoir. Place the tubing from the retentate and filtrate ports into the reservoir.
2	Adjust pump to deliver about 50 mL/min. Slowly tighten clamp on retentate tubing until filtrate flow rate is approxmately 25% of the retentate flow rate. If filtrate flow rate is already >25% of retentate flow rate, proceed to next step. **CAUTION** Do not exceed a feed pressure of 2 bar (30 psi).
3	Circulate the sanitizing solution for about 45 minutes to 1 hour.
4	Flush out the sanitizing solution with water. Follow the procedure in *Flushing the storage solution, on page 31*.

5.1.3 Buffer-conditioning (optional)

Introduction

The buffer-conditioning step is used to precondition the Minimate TFF Capsule into the sample buffer (equilibrating solution) before the sample is added. This adjusts the pH and prevents the sample from being diluted with water, which may lower the ionic strength and possibly cause precipitation of product or other sample components. It is also used to remove air bubbles from the system and equilibrate the system components and fluid to operating temperature.

Buffer the storage solution

Follow the steps below to buffer the solution.

Step	Action
1	Add about 100 mL of buffer solution into the reservoir. Place feed tubing into reservoir. Place the tubing from the retentate and filtrate port(s) into the reservoir.
2	Adjust pump to deliver about 50 mL/min. Slowly tighten clamp on retentate tubing until filtrate flow rate is approximately 25% of the retentate flow rate. If filtrate flow rate is already >25% of retentate flow rate, proceed to next step. **CAUTION** Do not exceed a feed pressure of 2 bar (30 psi).
3	Circulate the buffer solution for 5 to 10 minutes.
4	Place the tubing from the retentate into a drain. Slowly start the pump and run until the liquid in the reservoir just reaches the bottom. ***Note:*** *Do not allow air to be drawn into the tubing.*

5.2 Concentration and diafiltration

Refer to the following documents:

Introduction to Tangential Flow Filtration for Laboratory and Process Development Applications.

Diafiltration: A Fast, Efficient Method for Desalting or Buffer Exchange of Biological Samples.

A TFF process datasheet is included for use in recording experimental conditions (see *Appendix C TFF process datasheet, on page 69*).

5.3 Normalized water permeability

Introduction

This procedure is strongly recommended if the Minimate TFF Capsule will be reused. The water permeability (filtrate flow rate per unit of applied pressure) is a measure of performance of the original clean membrane. The effectiveness of the cleaning protocol, that is, membrane recovery, can be evaluated by comparing the NWP of the membrane after cleaning to the original NWP.

$$Membrane\ recovery\ = \frac{NWP\ (after\ cleaning)}{NWP\ (original)} \times 100\%$$

Determining the normalized water permeability (NWP) for the Minimate TFF Capsule

Water permeability is a function of the hydraulic resistance of the membrane at a specified transmembrane pressure (TMP). It is related to the pore size, pore depth, and number of pores per unit area. It is significantly affected by temperature. Water permeability can be used as a standard upon which to measure the effectiveness of a cleaning regime after sample processing.

The original NWP of the Minimate TFF Capsule is essential to calculate as it is used as the basis to determine membrane recovery, i.e., how effectively the membrane was cleaned.

This procedure must be performed with all new Minimate TFF Capsule after the flushing and sanitization steps have been performed. The original NWP is determined by plotting the water filtrate flux rates at several trans-membrane pressures, typically 0.3 to 1 bar (5 to 15 psi) for UF membranes. From the graph, the original NWP is calculated at 0.7 bar (10 psi). This value is chosen for ease of calculation.

Water quality must be water for injection (WFI) or at minimum 0.2 µm filtered deionized water. Calculated water permeability rates are normalized to a temperature of 20°C by using a temperature correction factor (TCF 20°C) given in *Table 5.2, on page 39*.

For Minimate TFF Capsule that are reused from this point on, the NWP needs only to be measured and determined at a TMP of 0.7 bar (10 psi).

The NWP must be measured before processing and once again after cleaning. An example for determining NWP is shown below.

To determine the NWP, a pressure gauge is required on the feed and retentate ports. Filtrate pressure must be zero (0) provided there are no restrictions on the filtrate line and that the filtrate line is open to atmosphere.

Recirculate the filtrate and retentate streams back to the feed reservoir to minimize the volume of water needed.

Removing air from the retentate

All air must be removed from the retentate channel before determining the NWP as air bubbles will reduce the effective filtration area, resulting in low NWP values.

Step	Action
1	Turn on and increase the pump speed to generate a retentate flow rate of 80 to 100 mL/min.
2	Stop and restart the pump several times.
3	Observe whether any air is expelled from the retentate line when the pump is restarted.
4	If no air is observed, turn off the pump and proceed to the next step.

Determining the original NWP

Follow the steps below to determine the original NWP.

Step	Action
1	Tighten the retentate clamp to completely restrict retentate flow. The filtrate line must be open.
2	Adjust the feed flow rate to generate a TMP of approximately 0.33 bar (5 psi).
3	Measure the filtrate flow rate and calculate the flux rate in LMH (liters/m^2/h).
4	Adjust the feed flow rate to give a TMP of approximately 0.67 bar (10 psi).
5	Measure the filtrate flow rate and calculate the flux rate in LMH (liters/m^2/h).
6	Adjust the feed flow rate to give a TMP of approximately 1.0 bar (15 psi).
7	Measure the filtrate flow rate and calculate the flux rate in LMH (liters/m^2/h).
8	Plot filtrate flux rate vs. TMP. Draw a straight line from zero that best fits the data between 0.3 to 1 bar (5 to 15 psi).
9	From the curve determine the water flux rate at 0.7 bar (10 psi)

Recording data and calculations

The following tables may be used as an example for recording data and calculations.

Below table is for recording data and calculating NWP. This table is available to print at the rear of the document.

Table 5.1: Measurement temperature: _______ºC, TCF ______

Feed pressure psi/bar	Retentate pressure psi/bar	Filtrate pressure psi/bar	TMP psi/bar	Filtrate flow rate mL/min	Filtrate flux rate mL/min/cm^2	Filtrate flux rate LMH	Water permeability LMH/TMP	NWP LMH/TMP @ 20°C

$$TMP = \frac{(P_{feed} + P_{retentate})}{2} - P_{filtrate}$$

Note: *Assume $P_{filtrate}$ is O if no filtrate pressure gauge.*

Filtrate flux rate (mL/min/cm^2) = Filtrate flow rate (mL/min) / membrane area of 50 (cm^2)

To convert mL/min/cm^2 to LMH

LMH = mL/min/cm^2 × [1liter/1000 mL × 60 min/h × 10.000 cm^2/1m^2] = mL/min/cm^2 × 600

Filtrate flux rate (LMH) = Filtrate flux rate (mL/min/cm^2) × 600.

Water permeability (LMH/TMP) = Filtrate flux rate (LMH) / TMP

NWP (LMH/TMP @ 20°C) = Filtrate flux rate (mL/min/cm^2) × 600

Filtrate flux rate (LMH) = Filtrate flux rate (LMH) × Temperature correction factor (TCF) at operating temperature

The below table shows the temperature correction factors (TCF 20°C) for determining normalizing water permeability (NWP).

Table 5.2: TCF 20°C for determining NWP.

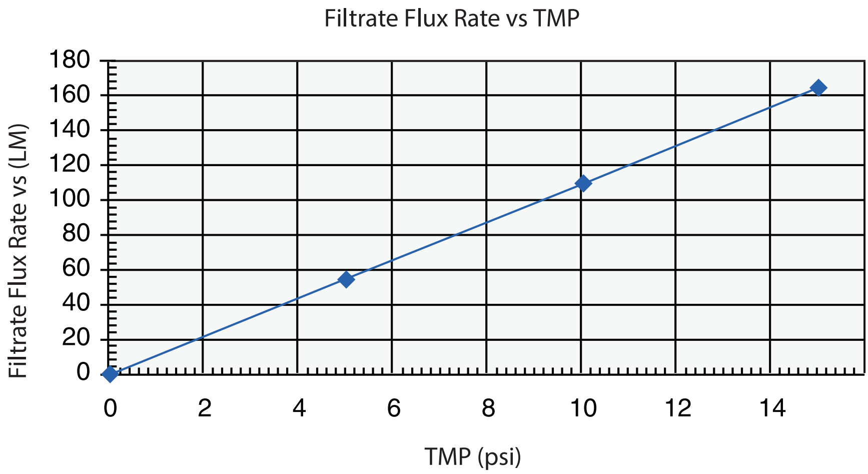
T °C	TCF 20°C	T °C	TCF 20°C	T °C	TCF 20°C	T °C	TCF 20°C
11	1.271	21	0.978	31	0.781	41	0.641
12	1.235	22	0.955	32	0.765	42	0.629
13	1.202	23	0.933	33	0.749	43	0.618
14	1.169	24	0.911	34	0.734	44	0.607
15	1.139	25	0.890	35	0.719	45	0.596
16	1.109	26	0.871	36	0.705	46	0.586
17	1.081	27	0.851	37	0.692	47	0.576
18	1.053	28	0.833	38	0.678	48	0.566
19	1.027	29	0.815	39	0.665	49	0.556
20	1.000	30	0.798	40	0.653	50	0.547

Example determination of NWP on a Minimate TFF Capsule

Water filtrate flux rates were measured for a Minimate TFF Capsule at TMP of 5, 10, and 15 psi. The temperature of the water was 16°C. Determine the original normalized water permeability (NWP).

Table 5.3: Data and calculations from example

Feed pres-sure psi/bar	Reten-tate pres-sure psi/bar	Filtrate pres-sure psi/bar	TMP psi/bar	Filtrate flow rate mL/min	Filtrate flux rate mL/min/cm^2	Filtrate flux rate LMH	Water permea-bility LMH/TMP	NWP LMH/TMP @ 20°C
5	5	0	5	4.6	0.092	55	-	-
10	10	0	10	9.2	0.184	110	11	12.2
15	15	0	15	13.8	0.276	165	-	-



The table below describes the text in the image above.

English text	Translation
Filtrate Flux Rate vs TMP	Filtrate Flux Rate vs TMP
Filtrate Flux Rate vs (LM)	Filtrate Flux Rate vs (LM)
TMP	TMP

Water Permeability = 110 LMH @ 10 psi = 11.0 LMH/psi

Normalized Water Permeability = 11.0 LMH/psi x TCF 20°C where TCF 20°C = 1.109 (correcting water permeability for temperature; from 16°C to 20°C)

Temperature correction factor from *Table 5.2, on page 39* for 16°C = 11.0°C LMH/psi x

Normalized Water Permeability = 11.0°C × 1.109 = 12.2 LMH/psi

5.4 System hold-up volume

Introduction

The system hold-up volume is the total volume contained within the feed and retentate flow path of the TFF system. Most of this volume is recoverable. The minimum working volume is the system hold-up volume plus a minimum volume of liquid that must remain in the bottom of the feed reservoir at the operating flow rate in order to prevent air from being drawn into the cassette system. Increasing the cross flow rate, increases the volume of product required in the bottom of the feed reservoir, in order to prevent air from getting drawn into the pump. The minimum working volume limits the maximum concentration factor achievable. Knowing the minimum working volume, you can calculate the minimum starting volume required to achieve a desired concentration factor.

Minimum starting volume = Minimum working volume × Concentration factor

If the actual starting volume is less than this value it will not be possible to reach the concentration factor.

Reservoir design significantly affects the minimum volume required to prevent air from getting into the system.

The Minimate EVO TFF system 500 mL reservoir was especially designed to minimize the working volume in the system.

Determining system hold-up volume

It is convenient to perform this procedure following the determination of water permeability and before performing air integrity measurements. The Minimate TFF Capsule and lines must already be filled with water and you will need to drain the feed and retentate flow path for the air integrity test anyway.

Step	Action
1	Clamp off the filtrate line.
2	Open the retentate screw clamp.
3	Pump down water into the reservoir until the volume is just above the bottom of the reservoir; then stop the pump. ***Note:*** *Do not allow air to be drawn into the tubing.*
4	Carefully transfer the retentate line into a 25 mL graduated cylinder.
5	Turn on the pump and allow remaining liquid to be pumped out.
6	Record the volume. This volume is the system hold-up volume.

Determining minimum working volume

Follow the below steps to determine minimum working volume.

Step	Action
1	Add water to the reservoir.
2	Direct retentate and filtrate lines into the feed reservoir. Open the retentate clamp and close the filtrate clamp.
3	Adjust the pump to deliver the operating retentate flow rate that will be used for the process.
4	Direct the retentate line to drain. Watch the water in the reservoir. When the water reaches a level where it appears that air is just about to get pulled up into the feed tubing, immediately return the retentate tubing back into the feed reservoir. Continue to circulate the water for a minute to confirm that no air is drawn into the tubing. If any air is drawn in, add water back into the reservoir until no more air is drawn into the tubing .
5	Direct the retentate tubing into a graduated cylinder and allow all the liquid to be pumped out into the cylinder.
6	Stop the pump. If any liquid remains in the reservoir, add it to the cylinder.
7	Record the volume in the cylinder. This is the minimum working volume for the system.

5.5 Minimate TFF Capsule integrity test

Introduction

Forward flow measurement is a quantitative test that measures the rate of air diffusing through the wetted membrane or passing through seal defects at a given pressure. Air diffusion rates can be performed on cassettes wetted with water or buffer solution.

Capsules are 100% integrity tested. Therefore it is not necessary to perform an integrity test on a new Minimate TFF Capsule. However, for critical applications or if the capsule will be reused, it is recommended that a forward flow air integrity test be performed to confirm integrity before and after use.

The forward flow integrity test detects system or membrane leaks. It does not provide a means to determine retention characteristics of the membrane.

A simple, quick and inexpensive test protocol is described below which can be performed without expensive measuring equipment. The protocol is performed after the capsule has been preconditioned and flushed with water in order to completely wet-out the membrane. A pressure gauge at the feed port is required. The pump must be self-priming, able to pump air at pressures to 30 psi. The Minimate EVO TFF system and most peristaltic pumps are suited for this procedure.

Water displacement method (quantitative)

Follow the below steps for water displacement method.

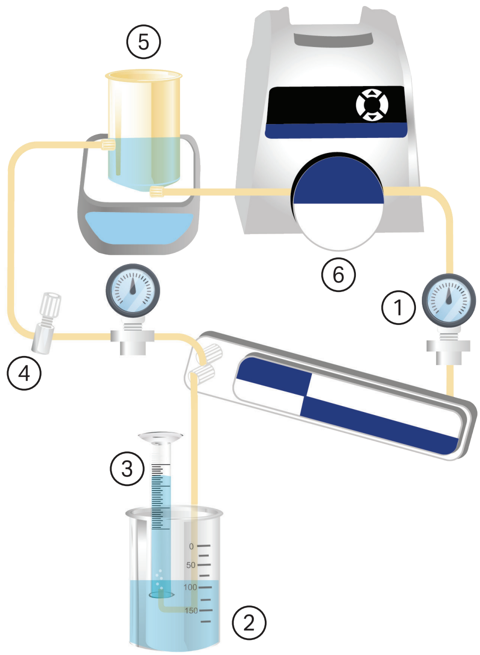
Step	Action
1	Thoroughly wet the membrane with water assuring that each pore is filled with liquid. Once the membrane is thoroughly wetted, the feed and retentate flow path is drained.
2	A graduated cylinder is filled with water and carefully turned upside down in a beaker full of water.
3	The end of the filtrate tube is placed inside the graduated cylinder.
4	The retentate port is then closed off. The system is pressurized to about 10 psi (0.7 bar) through the device feed port. *Result:* Air will diffuse through the membrane, exiting through the filtrate tubing and into the graduated cylinder.
5	The amount of air displaced over time is measured in mL/min. This is the air diffusion (forward flow) integrity test value.

Step	Action
6	Initially water in the filtrate line will be displaced. Wait until air starts to flow before taking any measurement, as any water left in the feed channel will first pass across the membrane. The membrane creates a barrier to air flow, not water flow.

Forward flow air integrity test procedure

This protocol describes performing the procedure using a peristaltic pump to generate airflow. For more accurate testing, a regulated, compressed air or nitrogen supply must be used.

The below image shows a setup for air integrity testing of the Minimate TFF Capsule.



Part	Description
1	Pressure gauge
2	Beaker
3	Inverted graduated cylinder
4	Screw clamp
5	Sample reservoir

Part	Description
6	Pump

Step	Action
1	Empty the feed reservoir.
2	Open retentate and filtrate screw clamps and pump out liquid from feed and retentate tubing.
3	Fill a 400 mL or larger beaker and a 25 mL graduated cylinder with water.
4	Invert the full graduated cylinder into the large beaker. Place a piece of paper or Parafilm over the mouth of the cylinder. Turn the cylinder over and remove the piece of paper after the mouth of the cylinder is below the water level in the beaker. The cylinder must remain filled with water.
5	Place the end of the filtrate tubing into the beaker. The filtrate tube must be open.
6	Slowly turn up the pump speed to give a retentate flow rate of 40 mL/min. Tighten the retentate screw clamp to apply a feed pressure of 10 psi.
7	Watch for bubbles emerging at the end of the filtrate tube. When the flow seems to be consistent, place the end of the filtrate tubing into the inverted cylinder. The cylinder can now rest on the bottom of the beaker. Make sure that the filtrate tubing is not crimped under the cylinder mouth.
8	Measure the amount of air entering the graduated cylinder for sixty seconds (mL/min). Compare to integrity specifications for the Minimate TFF Capsule.
9	If no air bubble reaches the cylinder within 3 to 5 minutes, the device is most likely within specifications. (Calculate the volume in the filtrate tubing and compare to the allowable airflow rate to see if sufficient waiting time has been allowed).

Pressure-hold test method (qualitative)

This procedure is a simple, quick method to test the integrity of a capsule and system. It involves pressurizing the capsule and then watching for a pressure decline. A drop in pressure indicates air leakage. The method can be used to check there are no leaks in connections and to confirm there are no gross defects in the capsule membrane.

Forward flow air integrity test procedure

Follow the below steps for a Forward flow air integrity test procedure.

Step	Action
1	Forward flow air integrity test.
2	Open retentate screw clamp and pump out liquid from feed reservoir.
3	Clamp both the retentate and filtrate lines.
4	Slowly increase the pump speed to build up the pressure to 1.6 bar (25 psi).
5	Stop the pump.
6	Clamp the feed tubing so air cannot flow backwards through the pump head.
7	Slowly open the filtrate screw clamp to relieve the pressure.
8	Observe the pressure on the feed pressure gauge. After an initial drop when the filtrate clamp is opened, the pressure must hold steady. If pressure drops below 0.7 bar (10 psi) when the filtrate valve is opened, remove the pump clamp and start the pump to bring the feed pressure to about 0.7 bar (10 psi). Stop pump and reapply clamp. If the pressure holds for 2 minutes, the cassette integrity must be good. On a defective cassette, the pressure would drop the 10 psi in a few minutes.
9	Observe the filtrate line. When the filtrate clamp is first opened, some liquid will be displaced. This is liquid which remained on the feed side and which is forced through the membrane (Liquid will pass freely through the membrane, but not the air). Liquid on the filtrate side will continue to be displaced if there is airflow through the membrane or seals until all the liquid in the tubing has been displaced. If you see a lot of air bubbling through the filtrate line, there could be an integrity failure. In this case a quantitative integrity test must be performed.

5.6 Product recovery

Following the concentration and diafiltration process, the product can be recovered from the system.

Product in concentrate

After processing, a significant portion of the product could be on the membrane in the form of a gel layer and needs to be recovered back into the solution before the system is drained. Recirculating fresh buffer can recover most of this gel layer, but may significantly dilute the product that has been concentrated. The following procedure can improve recovery without significant dilution. The actual procedure may have to be varied depending on TFF system configuration.

Step	Action
1	Following concentration/diafiltration, open the retentate valve and close off the filtrate line with a valve or screw clamp. Adjust the pump to give a retentate flow rate of 40 to 50 mL/min. Circulate the product for 5 to 10 minutes.
2	Stop the pump. Put the retentate tubing into a collection vessel. Start the pump and slowly pump out the product into the collection vessel. Stop the pump just before the volume in the reservoir reaches the bottom. Add to the reservoir a volume of buffer equal to the system hold-up volume. Pump out the product into the collection vessel stopping just as the liquid level reaches the bottom of reservoir. (This method displaces most remaining product left in the cassettes and hardware.) Record the volume collected.
3	Add just enough volume of buffer to the feed reservoir to allow circulation without pulling in air. Circulate for 10 minutes to try and recover additional product. The remaining liquid in the system can be pumped out into a separate container by allowing air to be pumped through capsule to displace it. A decision can then be made whether to combine this volume with the main product.

Product in filtrate

If the product is in the filtrate, raise the vent port so it is higher than the collection vessel. Make sure the end of the filtrate tubing is placed in the vessel. Open the vent port and allow any remaining filtrate in the capsule and tubing to be drained.

6 Maintenance

About this chapter

This chapter provides information about maintenance that must be performed by users of Minimate TFF Capsule.

In this chapter

6.1 Flushing and cleaning after use

If the Minimate TFF Capsule is to be reused, it must be cleaned after use and properly stored. Recommended cleaning solutions and protocols are given below.

The recommended cleaning agents for Omega membranes in the Minimate TFF Capsule are as follows.

Solution	Temperature
0.1 to 0.5 N NaOH	35°C to 45°C
0.1 to 0.5 N NaOH + 200 to 400 ppm NaOCl	35°C to 45°C
0.1 N nitric, acetic or phosphoric acid	-

6.2 Post treatment of Minimate TFF Capsule

Before introducing the cleaning solution into the membrane system, remaining product and contaminants must first be flushed free using either buffer or spent filtrate. The use of a buffered flush will eliminate possible solubility changes. Spent filtrate, assuming the product is in concentrate, eliminates the need for fresh buffer or water to be used to flush the system prior to introducing the cleaning agent, eliminating additional fouling concerns.

To flush the system, the retentate is directed to drain. For cleaning, the retentate and filtrate lines are returned back to the feed reservoir.

To assure proper flushing, it is essential to obtain high fluid velocities through the system to create sufficient turbulence at all wetted surfaces (membrane, tubing, components, etc.). It is also important to develop a positive pressure profile along the entire membrane path length (feed to retentate).

The procedure below will accomplish both requirements.

6.3 Flushing the retentate stream of excess matter

Follow the below steps to flush retentate stream of excess matter.

Note: *This procedure requires a screw clamp on both the retentate and filtrate lines.*

Step	Action
1	Direct the filtrate and retentate streams to waste.
2	Add buffer or spent filtrate to feed reservoir.
3	Open the retentate screw clamp and close the filtrate screw clamp.
4	Start the pump and increase speed until retentate flow rate is 50 to 80 mL/min.
5	Flush about 200 mL to drain to assure that a thorough flushing is accomplished.

6.4 Flushing the system with water

Follow the steps below to flush the system with water.

Step	Action
1	Drain the system.
2	Add at least 500 mL of 0.2 µm filtered deionized water or WFI. Place the tubing from the retentate and filtrate port into a drain or waste container.
3	Adjust pump to deliver a flow rate of about 40 mL/min. Slowly tighten the retentate screw clamp until the filtrate flow rate is approximately equal to the retentate flow rate. **CAUTION** Do not exceed a feed pressure of 2 bar (30 psi).
4	Pump at least 250 mL of the water through the retentate tubing and 250 mL through the filtrate tubing to the drain (>500 mL total).

6.5 Adding and circulating cleaning agent

Follow the below steps to add and circulate cleaning agent.

Step	Action
1	Drain system. Add the cleaning solution to the feed reservoir. ***Note:*** *Cleaning is more effective if solution is warmed to 35°C to 45°C before adding to reservoir.*
2	Return the retentate and filtrate line back to the feed reservoir.
3	Open the retentate and filtrate screw clamps.
4	Increase the pump speed to deliver 50 to 80 mL/min through retentate.
5	Adjust retentate clamp to generate a retentate pressure of about 2 bar (30 psi).
6	Run for about 2 to 3 minutes to flood the membrane with cleaning solution.
7	Open the retentate clamp and close the filtrate clamp.
8	Adjust pump speed give a retentate flow rate of 50 to 80 mL/min.
9	Run for 45 to 60 minutes for cleaning. ***Note:*** *If the cleaning solution gets dirty after only a few minutes, flush it out from the system using the following procedure and then immediately add fresh cleaning solution and repeat the cleaning cycle. Do not continue to circulate dirty cleaning solution as it will reduce the effectiveness of the cleaning process.*

6.6 Flushing the cleaning agent from capsule

Follow these steps to flush cleaning agent from the capsule.

Step	Action
1	Direct retentate and filtrate lines to drain.
2	Open retentate and filtrate clamps.
3	Remove feed tubing from cleaning solution.
4	Start pump and run until all solution has been purged from capsule.
5	Drain reservoir and add water for flushing, 0.2 µm filtered deionized water or WFI.
6	Close the filtrate clamp.
7	Turn on the pump and adjust to 50 to 80 mL/min. Run at least 250 mL through retentate to drain.
8	Stop the pump. Open filtrate clamp and then close retentate clamp. Refill reservoir with water if necessary.
9	Start pump and increase flow until the feed pressure is about 2 bar (30 psi). Run until a minimum of 250 mL is flushed through the filtrate to drain.

6.7 Determining the membrane recovery for the cleaned Minimate TFF Capsule

Membrane recovery is a calculation that defines the efficiency of the cleaning process performed on the membrane capsule.

It compares the normalized water permeability (NWP) after cleaning to the original NWP. The original NWP was measured when the membrane was first installed and preconditioned (see *Determining the original NWP, on page 37*) Water must be WFI or at a minimum, 0.2 µm filtered deionized water.

All water permeability rates are normalized to a temperature of 20°C by using a temperature correction factor (TCF 20°C) in *Table 5.2, on page 39*.

6.8 Determining the water permeability after cleaning

Follow these steps to determine NWP after cleaning.

Step	Action
1	Add water to the reservoir.
2	Return the retentate and filtrate line back to the feed reservoir.
3	Open the retentate and filtrate screw clamps.
4	Increase the pump speed to deliver 80 to 100 mL/min through retentate. Stop and restart the pump several times. Observe whether any air is expelled from the retentate line when the pump is restarted. If no air is observed, turn off pump and proceed to the next step.
5	Close the retentate clamp. Adjust the pump flow rate to develop an trans-membrane pressure of approximately 0.7 bar (10 psig). $$Membrane\ recovery\ = \frac{NWP\ (after\ cleaning)}{NWP\ (original)} \times 100\%$$
6	Measure the filtrate flow rate.
7	Calculate the filtrate flux rate in mL/min/cm^2 and LMH.
8	Calculate the water permeability at the recorded transmembrane pressure. Water Permeability = Filtrate Flux Rate (LMH)/TMP
9	Calculate the Normalized Water Permeability using the temperature correction factor (TCF 20°C) in *Table 5.2, on page 39*. NWP = Water Permeability x 20°C
10	Calculate the membrane recovery. Membrane recovery = (NWP after cleaning /original NWP) × 100%

If the membrane recovery is less than 75% to 80%, perform another cleaning cycle starting from *Section 6.5 Adding and circulating cleaning agent, on page 53*.

If after the second cleaning the NWP has increased but acceptable recovery has not been achieved, perform another cleaning cycle. If after the second cleaning the NWP has not increased, the cleaning agent or parameters (time, temperature, etc.) may have to be altered.

Note: *Between uses, the capsule is stored in a caustic solution (typically 0.05 N – 0.1 NaOH).*

Note: *During this time, remaining foulants on the membrane may be released and removed from the capsule when it is flushed prior to the next use. Therefore, it is not unusual to find membrane recoveries increase after storage versus values obtained immediately after cleaning.*

7 Reference information

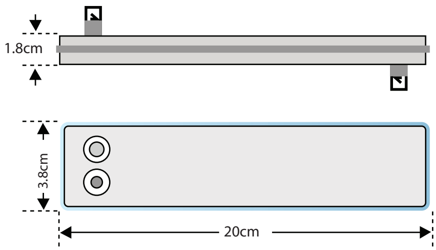
About this chapter

This chapter lists the technical specifications of the Minimate TFF Capsule. The chapter also includes recycling information, regulatory information and ordering information.

In this chapter

7.1 Specifications

Materials of construction

Parameter	Specification
Filter media	Omega membrane (modified polyethersulfone)
Housing	Polypropylene, glass reinforced
Screens, housing, housing sealing ring, fittings	Polypropylene
Membrane plate/filtrate channels	Polypropylene
Internal gasket	Ethylene propylene elastomer
Product dimensions	20 cm × 3.8 cm × 1.8 cm (L × W × H, nominal) 8" × 1.5" × 0.7" 
Effective filtration area	50 cm^2
Product hold up volume (**Feed or Retentate**)	~1.6 mL
Membrane/non-recoverable hold up volume	1.3 mL
Forward flow air integrity value	≤ 7 mL/min at 0.75 bar (10 psi)
Operating temperature range	5°C (41ºF) to 50°C (122ºF)
Maximum operating pressure at 20°C (68ºF)	4 bar (400 kPa, 60 psi)
Recommended crossflow	30 to 80 mL/min (0.6 to 1.6 L/min/ft^2)

Connections

Parameter	Specification
Feed	Female luer with external thread
Retentate	Female luer with external thread
Filtrate	Male luer with threaded lock ring

7.2 Recycling information

Introduction

This section contains information about the decommissioning of the product.

> **CAUTION**
>
> Always use appropriate personal protective equipment when decommissioning the equipment.

Decontamination

The product must be decontaminated before decommissioning. All local regulations must be followed with regard to scrapping of the equipment.

Disposal of Minimate TFF Capsule

It is recommended that after use, and prior to disposal, the Minimate TFF Capsule be flushed with clean water, sealed into an autoclave bag, and autoclaved at either 121°C for 30 minutes, or at 135°C for 15 minutes to sterilize. Dispose of the Minimate TFF Capsule in the bag, and do not open after autoclaving.

Do not seal the inlet and outlet connectors of the Minimate TFF Capsule prior to autoclaving as this will cause a build up of pressure, which may rupture the device.

Disposal and handling of the used filters must be in-line with national legislation and local regulatory requirements for the materials of construction. Due consideration must also be made to the nature of contaminants on the filters as the result of use.

Recycling of hazardous substances

The product contains hazardous substances. Detailed information is available from your Cytiva representative.

Disposal of electrical components

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

7.3 Regulatory information

Introduction

This section lists the regulations and standards that apply to the product. Your product is marked or listed according to the applicable regulatory requirements for your region. Local language translations are only provided according to regulatory requirements.

In this section

7.3.1 Contact information

Introduction

This section shows the contact information for support and manufacturing information.

Contact information for support

To find local contact information for support and sending troubleshooting reports, visit *cytiva.com/contact*.

Manufacturing information

The table below summarizes the required manufacturing information.

Requirement	Information
Name and address of manufacturer	Cytiva Puerto Rico Pall Boulevard Road 194 KM 0.4 Fajardo, PR 00738

7.3.2 European Union and European Economic Area

Introduction

This section describes the information that applies to the product in the European Union and European Economic Area.

Conformity with EU Directives

Refer to the EU Declaration of Conformity for the directives and regulations that apply for the CE marking.

If not included with the product, a copy of the EU Declaration of Conformity is available on request.

CE marking

The CE marking and the corresponding EU Declaration of Conformity is valid for the product when it is:

- used according to the *Operating Instructions* or user manuals, and
- used in the same state as it was delivered, except for alterations described in the *Operating Instructions* or user manuals.

7.3.3 South Korea

Introduction

This section describes the information that applies to the product in the Republic of Korea.

Compliance statement

NOTICE

Class A equipment (equipment for business use).

This equipment has been evaluated for its suitability for use in a business environment.

When used in a residential environment, there is a concern of radio interference.

유의사항

A급 기기(업무용 방송통신기자재)

이 기기는 업무용환경에서 사용할 목적으로 적합성평가를 받은 기기

로서 가정용 환경에서 사용하는 경우 전파간섭의 우려가 있습니다.

KC marking

	The KC symbol indicates RRA registration of compatibility in Korea. The registration number of the product will appear beside the symbol.
	이 기호는 한국에서 호환성에 대한 RRA 등록을 나타냅니다. 제품의 등록 번호는 기호 옆에 나타납니다.

7.3.4 General regulatory statements

Introduction

This section describes the information that is applicable to more than one geographical region.

EMC emission, CISPR 11: Group 1, Class A statement

NOTICE

This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

Intended use for supplied power cord

NOTICE

Power cord. Do not use the supplied power cords for any other equipment.

7.4 Ordering information

Parts

The table below lists Minimate TFF Capsule; self contained ultrafiltration tangential flow filtration capsule with luer connectors:

Part	Description	Pkg
OA001C12	Minimate TFF capsule 1 K Omega membrane	1/pkg
OA003C12	Minimate TFF capsule 3 K Omega membrane	1/pkg
OA005C12	Minimate TFF capsule 5 K Omega membrane	1/pkg
OA010C12	Minimate TFF capsule 10 K Omega membrane	1/pkg
OA030C12	Minimate TFF capsule 30 K Omega membrane	1/pkg
OA050C12	Minimate TFF capsule 50 K Omega membrane	1/pkg
OA070C12	Minimate TFF capsule 70 K Omega membrane	1/pkg
OA100C12	Minimate TFF capsule 100 K Omega membrane	1/pkg
OA300C12	Minimate TFF capsule 300 K Omega membrane	1/pkg
OA500C12	Minimate TFF capsule 500 K Omega membrane	1/pkg
OA990C12	Minimate TFF capsule 1000 K Omega membrane	1/pkg
OAPMPUNV	Minimate EVO TFF	1/pkg
97014	Minimate EVO TFF fittings kit includes: 3-way valve for reservoir (2), 1-way valve reservoir Lid (2), male luer coupler (1), male luer lock - 1/8" hose barb (3), male luer lock - 1/8" hose barb elbow (4), female luer lock - 1/8" hose barb (1), tubing clamps (8), PharMed tubing (2 ft.), screw clamp for tubing (1), male luer plug (4)	1/pkg

Appendix A

Pump calibration

Pump setting	Flow rate

Appendix B
Measurement temperature

Feed pres-sure psi/bar	Reten-tate pres-sure psi/bar	Filtera te pres-sure psi/bar	TMP psi/b ar	Filterat e flow rate mL/min	Filterat e flux rate mL/min /cm^2	Filter ate flux rate LMH	Water permea-bility LMH/TMP	NWP LMH/T MP @ 20°C

Appendix C
TFF process datasheet

- Sample identification:
- Application:
- TFF system:
- Membrane/cassettes
- Membrane area
- Date:
- Operator:

Readings

Process time (hr:mm)	Feed temp. (ºC)	Con. factor (x)	Diafiltrate volumes (DV)	Comments
Initial water data				
Filtrate flux rate				
Delta P				
Process data				
Final data water				
Filtrate flux rate				
Delta P				

Pressure readings

Feed (psi/bar)	Retentate (psi/bar)	Filtrate (psi/ bar)	TMP (psi/bar)	Delta P (psi/ bar)
Optimization yes or no				

Flow/Flux rate

Retent. (L/min)	CFF (L/min/ft^2)	Filtrate (mL/min)	Filtrate (LMH)

Volume

Feed (mL)	Filtrate (ML)

TFF process datasheet column description

Datasheet

Column	Units	Description
Process time	hr:min	Elapsed process time from beginning of concentration or diafiltration process. Either record actual clock time or elapsed time.
Feed Temperature	°C	Measured temperature of process solution.

Pressure readings

Column	Units	Description
Feed	psi/bar	Feed pressure (PF)
Retentate	psi/bar	Retentate pressure (PR)
Filtrate	psi/bar	Filtrate pressure (PP)
Transmembrane Pressure (TMP)	psi/bar	[(PF + PR) ÷ 2] - PP
Delta P	psi/bar	Pressure differential (PF – PR)

Flow rate/Flux rate

Column	Units	Description
Retentate flow rate	L/min	Measured retentate flow rate
Cross flow flux (CFF)	L/min/ft^2	Retentate flow rate ÷ membrane area (liters/ minute/ft^2)
Filtrate flow rate	mL/min	Measured filtrate flow rate
Filtrate flux rate	LMH	Filtrate flow rate ÷ membrane area (liters/meter^2)/ hour.

Volume

Column	Units	Description
Feed	mL	Remaining feed volume = (starting volume) – (total collected filtrate feed mL volume) (starting volume equals process volume added to reservoir plus hold-up volume if system was filled with liquid)
Filtrate	mL	Total collected filtrate volume
Concentration factor	x	Starting volume ÷ (starting volume – filtrate volume)
Diafiltration volumes	DV	The number of DV of diafiltration solution added. 1 DV = remaining feed volume at start of diafiltration
Comments		Indicate any observations or information considered important to fully describe process or events

To convert milliliters/minute to liters/hour, multiply by 0.06. To convert square feet to square meters, multiply by 0.093.

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