Pellicon® 2 Filters

User Guide

P35430 Rev D, 09/2011

Contents

Introduction

This guide provides installation and maintenance procedures for Pellicon® 2 cassettes. It is not intended to provide validation protocols or supporting data for validation purposes. Please refer to the device validation guide for this information.

Membrane Type

Install only filters containing one type of membrane in the filter holder at one time. Do not mix filters with different pore sizes or nominal molecular weight cutoffs. The amount of membrane used depends on the filter surface area required for your particular application. Avoid touching the filter membrane surface.

Intercassette Gaskets

All Pellicon® 2 cassettes (0.5m^2) and maxi filters (2.5 m^2) are shipped with two silicone gaskets for use between cassettes during filter installation.

Pump Capacity

When operating Pellicon® 2 filters, be sure to select a pump with adequate capacity. Recommended feed crossflow rates are:

A and C Screen devices: 4 - 6 liter/min/m^2

V Screen devices: 5 - 35 liter/min/m^2

Optimal cross flow will depend on the actual solution being filtered.

Water Quality

High quality water, as defined in this table, must be used for cassette preporatory steps.

Constituent	Acceptable Concentration
Fe	<0.05 ppm
Ca, Mg	<25 ppm
Mn	<0.05 ppm
Turbidity	<1.0 JTU
Al	<0.5 ppm
SDI 15 (fouling index)	preferably <3.0
Reactive Silica	<2 ppm
Particulate Matter	None
Colloidal Silica	Nil
Oil, Grease, etc.	None

Reverse osmosis permeate or water for injection is recommended whenever possible.

Nominal Molecular Weight Limit (NMWL)

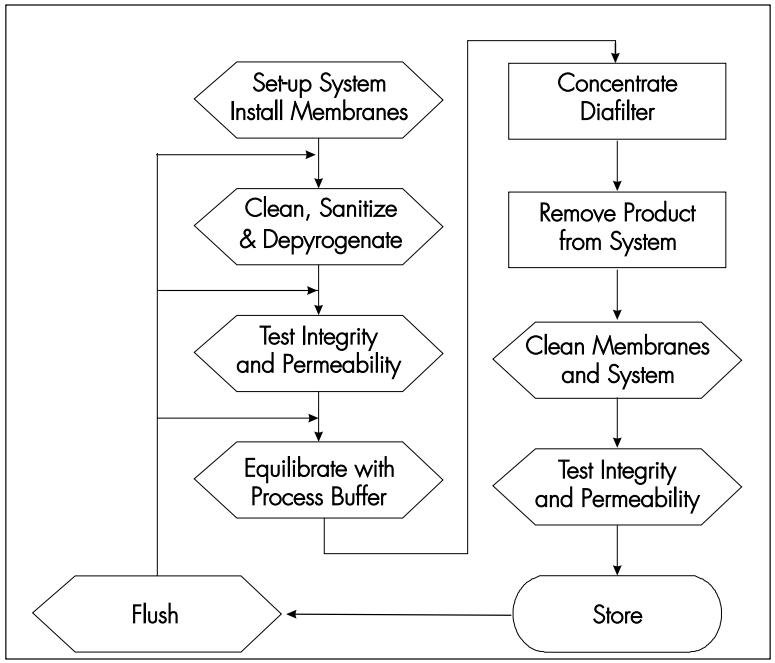
Membrane	NMWL (Daltons)
Biomax® Membrane Polyethersulphone	
Biomax® 5	5,000
Biomax® 8	8,000
Biomax® 10	10,000
Biomax® 30	30,000
Biomax® 50	50,000
Biomax® 100	100,000
Biomax® 300	300,000
Biomax® 500	500,000
Biomax® 1,000	1,000,000
Ultracel® Membrane (PLC Series) Composite Regenerated Cellulose	
PLCCC (PC005)	5,000
PLCGC (PC010)	10,000
PLCTK (PC030)	30,000
PLCHK (PC100)	100,000
PLCMK (PC300)	300,000
PLCXK (PC01M)	1,000,000
Ultracel® Membrane (PL Series) Composite Regenerated Cellulose	
PLAC	1,000
PLBC	3,000
PLCC	5,000

Membrane	NMWL (Daltons)
PLGC	10,000
PLTK	30,000
PLHK	100,000
PLMK	300,000
Ultracel® Membrane (PT Series) Composite Regenerated Cellulose	
PTGC	10,000
PHSA-G	10,000
PHSA-T	HI-FLUX 10,000
PTTK	30,000
PTHK	100,000
PTMK	300,000
Membrane	Pore Size
Durapore® Membrane PVDF	
VVPP	0.10 µm
GVPP	0.22 µm
HVMP	0.45 µm
DVPP	0.65 µm

Installation

Pellicon® 2 cassettes should be installed in a Pellicon® 2 Cassette Holder as described in the holder installation manual.

This flow chart shows the recommended prep, cleaning and testing steps, which are detailed in this guide, for Pellicon® 2 devices.



Flushing Operation

Pellicon® 2 cassette filters should be flushed prior to and after filtering process solutions and suspensions, prior to and after each cleaning, depyrogenation or sanitization step.

Feed Channel Flush

The feed side flush is required to remove preservative fluid from the upstream side of the membrane.

1. Fill the Pellicon® 2 system with high quality water (see page 6).
2. Fully open the retentate valve and direct the retentate to drain.
3. Turn on the feed pump and pump water into the feed port of the Pellicon® holder. The feed flow rate for Pellicon® A or C screens is 4 to 6 lpm/m^2 and the flow rate for Pellicon® V screens is 5 to 35 Lpm/m^2.
4. Flush the filter(s) until approximately 2-5 liters of water per m^2 of installed filter area has been removed from the retentate port. Some volume will flow out of the permeate port as well. The permeate volume removed during this step is unimportant and will vary according to membrane type installed.

Permeate Channel Flush

The permeate side flush is required to remove preservative fluid from the membrane and permeate channels.

1. Partially close the retentate valve to achieve the retentate pressure listed here. More open membranes may not reach this pressure. Feed pressure may be increased to 5.0 bar (80 psi) for tighter membranes. Target is 100 L/hr/m^2 (LMH) permeate flow or approximately 30% conversion of the feed flow into permeate flow.

Membrane Cutoff	Permeate Pressure
1,3 ,5 kD	1.1-1.4 bar (16 - 20 psi)
10 kD	0.6-1.0 bar (8.7 - 14.5 psi)
30 kD	0.3-0.6 bar (4.4 - 8.7 psi)
>50kD	Control filtrate to 100 LMH with permeate valve or pump on the filtrate site

2. Flush the filter(s) until a total of 10-20 liters of water per m^2 of installed filter area has been pumped through the system to drain. Depending on individual removal criteria, the total flush volume can be adjusted.

3. Drain the retentate and filtrate piping.

Cleaning Operation

This cleaning operation applies to all situations where solution should be exposed for a period of time to all parts of the system. Membrane regeneration, system sanitization, depyrogenation and system storage require a cleaning step.

Some applications require a two-step cleaning procedure. In these cases it is imperative that the primary cleaning agent be flushed completely from the system to avoid potentially harmful chemical reactions between cleaning agents. A full cleaning recipe encompasses a sequence of flushes and recirculations to achieve regeneration of the membrane performance, sanitization, dyprogeneation and residual flush out from the system.

To select a cleaning method, identify your application or suspected foulant from the Cleaning Agent Selection Chart on page 11. Select the cleaning agent or agents compatible with your membrane type and application requirements.

Sanitization, depyrogenation and storage agents are chosen similarly. In many instances, sanitization and depyrogenation may be accomplished in the same step.

Feed Channel Cleaning

1. Direct permeate and retentate lines back to the cleaning tank. Close the tank drain valve and open the retentate line or valve (and permeate valve, if present).

2. Fill tank with clean warm water (40-50 °C). From the Cleaning Conditions Table choose a cleaning agent which will remove the probable foulants from the system. Add the selected cleaning solution to the tank at the recommended concentration.

3. Fully open the retentate valve.

4. Turn on the feed pump and pump water into the feed port of the Pellicon® holder. The feed flow rate for Pellicon® A or

C screens is 4 to 6 lpm/m² and the flow rate for Pellicon® V screens is 5 to 35 Lpm/m².

Permeate Channel Cleaning

1. Partially close the retentate valve to achieve the retentate pressure listed here. More open membranes may not reach this pressure. Feed pressure may be increased to 5.0 bar (80 psi) for tighter membranes. Target is 100 LMH permeate flow or approximately 30% conversion of the feed flow into permeate flow.

Membrane Cutoff	Permeate Pressure
1,3 ,5 kD	1.1-1.4 bar (16 - 20 psi)
10 kD	0.6-1.0 bar (8.7 - 14.5 psi)
30 kD	0.3-0.6 bar (4.4 - 8.7 psi)
>50kD	Control filtrate to 100 LMH with permeate valve or pump on the filtrate site

Recirculate the cleaning solution for the prescribed time period. With consumable agents such as chlorine, monitor the concentration of the agent over the course of the cleaning cycle and add additional cleaning agent as needed to maintain the recommended concentration.

2. If the system is complex and has other associated manifolding, ensure that all wetted surfaces in the manifolds are exposed to the solution. Likewise, all valves that have been exposed to process fluids should also be exposed. It is good practice to cycle (partially open and the partially close) valves at least twice over the course of the cycle to ensure that all wetted internal surfaces of the valve body are exposed to the solution.

Flush

After the cleaning cycle is complete direct the retentate and permeate to drain and continue to run until the tank is empty, then shut down and drain retentate and permeate piping.

Cleaning Conditions

Primary cleaning agents for these foulants: Organics, Biofilms, Bioploymer, Proteins and Polyphenolic are listed here.

Membrane	Series	Cleaning Agents	Concentration	Temperature °C	pH	Time (min.)
Biomax®	PT	NaOH	0.1 – 1.0N	40-50	13-13.7	30-60
		NaOCL	250 - 500 ppm active chlorine	40-50	1.0-1.1	30-60
		NaOH/NaOCL	0.1N/250 ppm	40-50	13	30-60
Durapore®		NaOCL	250 ppm active chlorine	40-50	10-11	30-60
Ultracel®	PLAC, PLBC, PLCC, PLCCC	NaOH	0.1N	20-25	13	30-60
	PLGC, PLCGC, PLTK, PLCTK, PLCHK, PLCMK, PLCXK	NaOH	0.1N	25-40	13	30-60

Cleaning Conditions

Secondary

Membrane	Foulants	Cleaning Agents	Concentration	Temperature °C	pH	Time (min.)
All	Biopolymers, Proteins, Colloidal Deposits, Poly-phenolic Fats, Oils, Grease, Antifoams, Scale	Tergazyme®	0.2%	40–50	9–10	30–60
All	Proteins, Lipids,	Triton®-X 100	0.1%	40–50	5–8	30–60
All	Lipopolysaccarides,	SDS	0.1%	40–50	5–8	30–60
All	Oils, Antifoams	Tween® 80	0.1%	40–50	5–8	30–60
All	Proteins, Protein precipi-tates	Urea	7M	40–50	8	60
All	Mineral Scale					
All	Nucleic Acids	HNO3 H3PO4	0.1N 0.1N	40–50 40–50	1.0 1.0	30 30
All	Iron, Manganese	Citric Acid	Scale	(Adjust to pH 3 with	1%	40–50

Sanitization Procedure

Sanitization should always be performed after the membrane system has been thoroughly cleaned and flushed to reduce bioburden.

Sanitization pressures, flow rates and volumes are identical to those used for cleaning. See Cleaning Procedure.

Based on membrane compatibility, select a sanitizing agent from the table below:

Sanitization Conditions and Agents

Membrane Type	Sanitizing Agent	Concen-tration	Temp. °C	pH	Time (min.)
All	Chlorine (NaOCl)	20–50 ppm (Active Chlorine)	20–50	7–8	15–30
All	Peracetic-Acid	100-200 ppm (0.25-0.40%)	10–40	3.5	15
PT Series	NaOH	0.1–0.5N	30–50	13-13.7	30
PL Series	NaOH	0.1N	40–50*	13	30
Biomax	NaOH	0.1–1.0N	30–50	13-13.7	30
All	Formalde-hyde (forma-line solution)	1–2%	20–30	5–8	30

* Use milder conditions if effectiveness of agent is still observed. Better membrane life has been observed at 20–25 °C for PLAC, PLBC, PLCC and PLCCC membranes and 25–40 °C for PLGC.

Depyrogenation Procedure

Depyrogenation should only be performed after the system has been cleaned, sanitized, and flushed.

Depyrogenation flow rate, pressure and volumes are identical to those used for cleaning. See Cleaning Procedure.

Water for injection should be used during depyrogenation.

Based on membrane compatibility, select a depyrogenation agent from the table below.

Depyrogenation Conditions and Agents

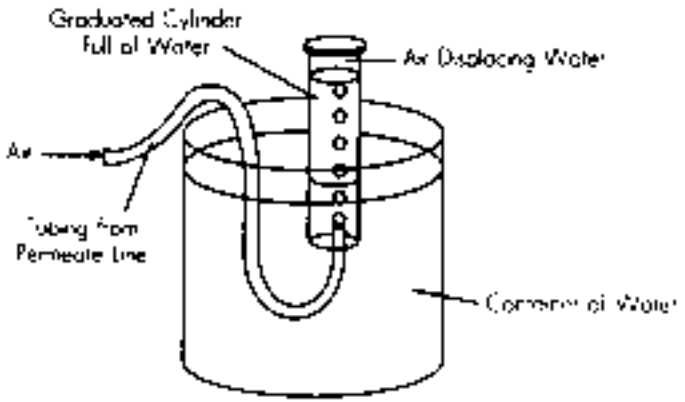
Membrane Type	Sanitizing Agent	Concen-tration	Temp. °C	pH	Time (min.)
PT Series Biomax®	NaOH	0.1-1.0N	30-50	13-13.7	30
PL Series	NaOH	0.1N	30-50*	13	30
PT Series Biomax® Durapore	NaOCl	300 ppm Active Chlorine (600 ppm NaOCl)	30-50	10-11	30
All	H3PO4	0.1N	30-50	1.0	30

* Use milder conditions if effectiveness of agent is still observed. Better membrane life has been observed at 20-25 °C for PLAC, PLBC, PLCC and PLCCC membranes and 25-40 °C for PLGC etc.

Integrity Test Procedure

The module integrity should be tested on a cleaned and thoroughly flushed system. The presence of residual cleaning agents can significantly alter integrity test results.

1. Ensure that the system is thoroughly cleaned and that the membrane is thoroughly wetted. Thorough wetting can be ensured by recirculating water at 2.1 bar (30 psi) TMP for 5 minutes.
2. Drain the system of water. **It is important to drain the retentate side of the system as thoroughly as possible.**
3. Attach a regulated and filtered air supply to the feed or retentate side of the holder, preferably to the more elevated end.
4. Isolate either the feed or the retentate manifold by closing a valve or capping the manifold if there is no valve on it.
5. The permeate line should be open at all times
6. Slowly raise the air pressure to the recommended value and wait 5 minutes to purge residual water in the permeate line. Do not exceed the recommended air pressure, which will displace water from the membrane pores and result in excessively high air flow. Rewet the membrane if this occurs.
7. Measure and record the air pressure, temperature and the air flow rate exiting the permeate line. The air flow rate may be measured with an air flow meter or by measuring the air displaced into a submerged and inverted volumetric cylinder as shown in the figure below.
8. Compare the measured air flow rate to the specified flow value in the following table. If the measured flow rate exceeds the specified flow value, refer to the Troubleshooting section of this guide.



Recommended Air Flow Rates to Confirm Integrity of Pellicon® Cassette Filters

Membrane	Air flow through a fully wetted membrane (cc/min)				
	0.1 m^2 (1.1 ft^2)	0.5 m^2 (5.4 ft^2)	2.0 m^2 (21.5 ft^2)	2.5 m^2 (26.7 ft^2)	Test Pressure bar (psi)
	Mini	Cassette	Maxi	Maxi	
Biomax® Membrane					
Biomax® 5	<4	<18	<72	<90	0.68 (10)
Biomax® 8	<4	<18	<72	<90	0.68 (10)
Biomax® 10	<4	<18	<72	<90	2.4 (30)
Biomax® 30	<4	<18	<72	<90	0.68 (10)
Biomax® 50	<4	<18	<72	<90	0.68 (10)
Biomax® 100	<4	<18	<72	<90	0.68 (10)
Biomax® 300	<12	<60	<240	<300	0.68 (10)
Biomax® 500	<12	<60	<240	<300	0.68 (10)
Biomax® 1,000	<12	<60	<240	<300	0.68 (10)
Ultracel® Membrane (PLC Series)					
PLCCC	<7	<35	<145	<175	2.4 (30)
PLCGC	<7	<35	<145	<175	2.4 (30)
PLCTK	<4	<18	<72	<90	0.68 (10)
PLCHK	<3	<12	<48	<60	0.68 (10)
PLCMK	<4	<18	<72	<90	0.68 (10)
PLCXK	<4	<18	<72	<90	0.68 (10)
Ultracel® Membrane (PL Series)					
PLAC	<3	N/A	<192	N/A	0.34 (5)
PLBC	<3	N/A	<192	N/A	0.34 (5)
PLCC	<3	<12	<192	N/A	0.34 (5)
PLGC	<10	<46	<125	N/A	0.34 (5)
PLTK	<12	<60	<240	N/A	0.34 (5)
PLHK	<12	<60	<240	N/A	0.34 (5)
Durapore® Membrane					
VVPP	<3	<12	<48	N/A	0.68 (10)
GVPP	<3	<12	<48	N/A	0.68 (10)
HVMP	<3	<12	<48	<60	0.68 (10)
DVPP	<3	N/A	<48	N/A	0.68 (10)

Measurement of Normalized Water Permeability (NWP)

The normalized water permeability (NWP) for Pellicon® 2 Cassette Filter membranes should be established prior to the first use of each filter. New membranes should be cleaned, flushed, sanitized and depyrogenated before measuring NWP. The NWP measured at this point is used as a benchmark against which subsequent water permeability measurements are compared. These subsequent NWP measurement are used to determine cleaning efficacy.

1. Direct the permeate and retentate lines back to the cleaning tank. Close the tank drain valve and open the retentate line or valve. Open the permeate valve if present.

2. Fill the Pellicon® 2 system with filtered deionized water, water for injection, or reverse osmosis permeate. The flush water must be extremely pure to avoid fouling the membranes or introducing other contaminants into the system.

3. Turn on the feed pump and pump water into the feed port of the Pellicon® holder. The feed flow rate for Pellicon® A or C screens is 4 to 6 lpm/m^2 and the flow rate for Pellicon® V screens is 5 to 35 Lpm/m^2. The same conditions MUST be used each time NWP is measured in order to ensure accuracy.

4. Recirculate the water for 5-10 minutes. Ensure that the pressure and the temperature conditions are stable.

5. Record the feed and permeate flow rate, feed, retentate, and permeate pressures, and the temperature of the water.

6. After the recirculation is complete, shut down the feed pump and drain the system.

7. Calculate the NWP:

$$NWP = \frac{R\,F}{A\left\{\left[\frac{P_{in} + P_{out}}{2}\right] - P_p\right\}}$$

These units yield LMH/bar [liters/m^2 x hours x bar]

$$\frac{FJ_f}{TMP}$$

J_f = permeate flux

TMP = Transmembrane Pressure

Calculate:
R = Permeate Flow Rate in L/hour
P_{in} = Feed Pressure in bar
P_{out} = Retentate Pressure in bar
T = Water Temperatures in °C
Pp = Permeate Pressure (if non-zero) in bar
A = Total Filter area in m^2
F = Temperature correction factor from table below.

8. The first NWP after processing may be 10-20% lower than the initial NWP. This decrease is normal and is a result of the membrane being conditioned. No additional decline in NWP should occur for several process runs.

After cleaning, if the membrane NWP is ±20% of the pre-run NWP value, process stream reproducibility will result. The acceptance criterion for cleaning efficacy is membrane and application specific, and may vary between plants. Key importance is stable process flux and no carryover. See TB1502EN00, *Techniques for Demonstrating Cleaning Effectiveness of Ultrafiltration Membranes* for further information.

If the NWP decreases significantly from run-to-run, cleaning procedures may be inadequate. Alternative cleaning agents and procedures should be investigated. Contact a Technical Service Representative for assistance.

NWP Temperature Correction Factor (F)*

Temperature		F	Temperature		F	Temperature		F
(°F)	(°C)		(°F)	(°C)		(°F)	(°C)	
125.6	52	0.595	96.8	36	0.793	68.0	20	1.125
123.8	51	0.605	95.0	35	0.808	66.2	19	1.152
122.0	50	0.615	93.2	34	0.825	64.4	18	1.181
120.2	49	0.625	91.4	33	0.842	62.6	17	1.212
118.4	48	0.636	89.6	32	0.859	60.8	16	1.243
116.6	47	0.647	87.8	31	0.877	59.0	15	1.276
114.8	46	0.658	86.0	30	0.896	57.2	14	1.310
113.0	45	0.670	84.2	29	0.915	55.4	13	1.346
111.2	44	0.682	82.4	28	0.935	53.6	12	1.383
109.4	43	0.694	80.6	27	0.956	51.8	11	1.422
107.6	42	0.707	78.8	26	0.978	50.0	10	1.463
105.8	41	0.720	77.0	25	1.000	48.2	9	1.506
104.0	40	0.734	75.2	24	1.023	46.4	8	1.551
102.2	39	0.748	73.4	23	1.047	44.6	7	1.598
100.4	38	0.762	71.6	22	1.072	42.8	6	1.648
98.6	37	0.777	69.8	21	1.098	41.0	5	1.699

*Based on Water Fluidity Relative to 25 °C (77 °F) Fluidity Value
F= $(\mu_{T\,^{\circ}C}/\mu_{25\,^{\circ}C})$ or $(\mu_{T\,^{\circ}F}/\mu_{77\,^{\circ}F})$

Storage Procedure

Direct permeate and retentate lines back to the cleaning tank.

Feed Channel Flush

1. Close the tank drain valve and open the retentate line or valve (and permeate valve, if present) .
2. Fill tank with clean warm water (40-50 °C). From the Cleaning Conditions Table choose a storage solution which is compatible with the membrane installed in the system, and choose the recommended concentration for that agent. Add the selected storage solution to the tank at the recommended concentration.
3. Fully open the retentate valve.
4. Turn on the feed pump and pump water into the feed port of the Pellicon® holder. The feed flow rate for Pellicon® A or C screens is 4 to 6 lpm/m² and the flow rate for Pellicon® V screens is 5 to 10 lpm/m².

Permeate Channel Flush

1. Partially close the retentate valve to achieve a retentate pressure as per the table below. More open membranes may not reach this pressure. Feed pressure may be increased to 5.0 bar (80 psi) for tighter membranes. Target is 100 LMH permeate flow or approximately 30% conversion of the feed flow into permeate flow.

Membrane Cutoff	Permeate Pressure
1,3 ,5 kD	1.1-1.4 bar (16 - 20 psi)
10 kD	0.6-1.0 bar (8.7 - 14.5 psi)
30 kD	0.3-0.6 bar (4.4 - 8.7 psi)
>50kD	Control filtrate to 100 LMH with permeate valve or pump on the filtrate site

2. Recirculate the storage solution for 5-10 minutes

3. After the storage cycle is complete direct the retentate and permeate to drain and continue to run until the tank is empty, then shut down and drain retentate and permeate piping

Suitable storage containers include plastic freezer bags with zipper-type seals, molded polyethylene or polypropylene freezer containers, or plastic pails with locking and sealing lids. Submerge in solution in appropriate container. Filters can be kept at 2-8 °C if desired.

Storage Solutions for Pellicon® 2 Cassette Filters

Storage Solution	Membrane Type	Concentration	pH	Recommended Time Period (months)
NaOH	PT Series Biomax	0.1N @ 20 °C max	13	6
	PLAC, PLBC, PLCC, PLCCC	DO NOT USE NaOH Use Alternative		
	PLGC	0.1N @ 20 °C max	13	4
		0.05N @ 20 °C max	12.7	8
	All other PL membranes	0.1N @ 20 °C max	13	6
		0.05N @ 20 °C max	12.7	12
Roccal®-II (Benzalkoniumchloride)	All	0.1%	7	12
Acetic/Phosphoric	All	1%/ 0.12 M	2-3	6
H3PO4	All	0.1N	2	6
NaHSO3	All	1.0%	4-8	2
Sodium Azide	All	0.05%	4-8	3

These recommended storage agents will ensure membranes remain wet and will prevent microbiological growth without damage to the filter.

Upon reinstallation, the filters should be flushed, cleaned and sanitized prior to use.

Filters should be stored in liquid-tight bags or in containers at 4 - 25 °C. Filters should not be frozen.

Most membranes can be stored indefinitely in these solutions without membrane damage. Fresh solutions should be prepared after the recommended time period to prevent microbial growth.

Ultracel® PL and PLC series membranes can be stored in NaOH only for the recommended time period. Longer exposure may result in membrane damage.

Troubleshooting

Problem	Possible Causes	Suggestions
Integrity test failure or low retention	Areas of membrane incompletely wetted; flush with water, retest	Circulate 10-20% ethanol solution 5-10 minutes
	Inadequate pump capacity (need 0.4	Use larger pump gpm/ft^2 or 17 liter/min/m^2) when wetting filters
	Compression of filter stack inadequate	Torque unit again; retest. increase torque if necessary Check intercassette gaskets Inspect threads, nuts and tie rods as described in Holder User Guide.
	Temperature change since last time holder was torqued	Torque unit again; retest
	Chemical compatibility problem	Review compatibility of filter with chemicals used; replace filter
	Damage to membrane	Visually inspect filter and replace as needed
	Improper membrane selection	
	Worn device	Replace device
Low NWP Value	System not vented properly	Ensure system is vented so that air is removed
	Sysem and device not completely flushed	Flush system and device
	Sysem and device not completely cleaned	Clean system and device
	Worn device	Replace device

Problem	Possible Causes	Suggestions
High NWP Value	Sysem and device not properly cleaned	Clean system and device as outlined on page 11
	System and device over pressurized	Reduce system pressure
	Worn device	Replace device

Standard Warranty

Millipore Corporation ("Millipore") warrants its products will meet their applicable published specifications when used in accordance with their applicable instructions for a period of one year from shipment of the products. **MILLIPORE MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** The warranty provided herein and the data, specifications and descriptions of Millipore products appearing in Millipore's published catalogues and product literature may not be altered except by express written agreement signed by an officer of Millipore. Representations, oral or written, which are inconsistent with this warranty or such publications are not authorized and if given, should not be relied upon.

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Technical Assistance

For more information, contact the office nearest you. In the U.S. and Canada, call toll-free 1-800-645-5476

In Europe, call +33 (3) 90 46 89 50 or visit www.millipore.com/offices. Visit the tech service page on our web site at http://www.millipore.com/techservice.