

MEMBRANE OPERATING CHARACTERISTICS

Take care to use the membrane at the lowest pressure possible while still producing consistent permeate flow. Although higher operating pressures initially improve flow rate, they also promote increased concentration polarization and membrane compaction, which ultimately limits flow. With very low NMWL membranes, lower operating pressure may also reduce the retention of salts and very low molecular weight species.

Table 3 Recommended Crossflow Rates

	Crossflow	ΔP
LP Screen	4-8 L/min/m ²	10 psi (0.7 bar)*
EP Screen	6-12 L/min/m ²	5 psi (0.35 bar)*
J Channel	10-15 L/min/m ²	<1 psi (0.07 bar)

* Typical ΔP measured with water and permeate closed

Table 4 Maximum Recommended Operating Pressures

Maximum Operating Pressures at 30°C	
Forward	100 psi (7 bar)
Reverse	7 psi (0.48 bar)

Table 5 Air Integrity Test Specification

Air Diffusion Rates	
Ultrafiltration 0.65kD thru 5kD	≤ 323 sccm/m ² @ 15 psi (1 bar)
Ultrafiltration 10kD thru 300kD	≤ 323 sccm/m ² @ 7.3 psi (0.5 bar)
Microfiltration ≥ 0.1 um	≤ 323 sccm/m ² @ 3 psi (0.2 bar)

Maximum Operating Temperature 50°C

CHEMICAL COMPATIBILITY

TangenX™ membrane cassettes are compatible with the following:

- ACN (<15%)
- DMF, DMSO (<40%)
- DMAC (<15%)
- Phosphoric acid (<1M)
- Sodium Hypochlorite (<400ppm)
- Sodium Hydroxide (<0.5M)

TangenX™ membrane cassettes are NOT compatible with the following:

- Pure aromatic and chlorinated hydrocarbons
- Ketones
- Polar aromatics
- Aliphatic esters

A more comprehensive list is available in the cassette validation guide.

CAUTION

In the event that the cassette is subjected to any of the conditions listed below, it is recommended that you perform both cassette integrity and water flux tests to ensure your cassette is not damaged. Damage may occur as a result of the following:

- Dropping on hard surfaces, or other mechanical shock.
- Poking with sharp objects on screened surfaces
- Excessive feed pressure.
- Excessive permeate backpressure, or pressurizing the filtrate port.
- Exposure to harsh chemicals.
- Freezing.
- Excessive heat.
- Drying out – ultrafiltration or microfiltration membrane that is allowed to dry out can permanently damage the pore structure.



MEMBRANE CASSETTES MUST REMAIN WET AT ALL TIMES TO MAINTAIN PRODUCT INTEGRITY AND PERFORMANCE.

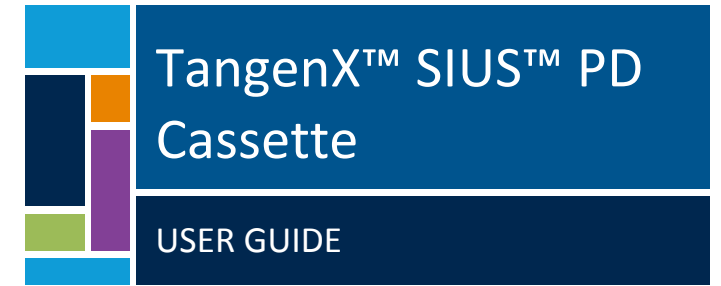


FOR TECHNICAL SUPPORT OR ORDER ASSISTANCE PLEASE CALL YOUR LOCAL SALES REPRESENTATIVE.

REPLIGEN TANGENX™ STANDARD WARRANTY

Repligen Corporation warrants its TangenX™ 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. **REPLIGEN 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 Repligen TangenX™ products appearing in published catalogues and product literature may not be altered except by express written agreement signed by an officer of Repligen. Representations, oral or written, which are inconsistent with this warranty or such publications are not authorized and if given, should not be relied upon.

In the event of a breach of the foregoing warranty, Repligen's sole obligation shall be to repair or replace, at its option, the applicable product or part thereof, provided the customer notifies Repligen promptly of any such breach. If after exercising reasonable efforts, Repligen is unable to repair or replace the product or part, then Repligen shall refund to the customer all monies paid for such applicable product or part. **REPLIGEN SHALL NOT BE LIABLE FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL OR ANY OTHER DAMAGES RESULTING FROM ECONOMIC LOSS OR PROPERTY DAMAGE SUSTAINED.**



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PRODUCT CONTENTS

Package includes the following:

1. TangenX™ SIUS™ PD - 0.01 m² (0.11 ft²), 0.02 m² (0.22 ft²), 0.1 m² (1.1 ft²) single-use filtration cassette
2. EPDM Gaskets
3. Stack Stabilizer Plate for L01J and M01J configurations

IMPORTANT INFORMATION BEFORE YOU BEGIN CASSETTES

- **Product is packaged wet and must remain hydrated for optimal performance. Keep bag sealed until cassette installation (step 3 below).**
- TangenX™ SIUS™ PD cassettes are compatible with the TangenX™ PRO PD cassette holder. A list of other cassette holders is shown in the cassette holder compatibility guide.
- Cassettes may be stacked to increase filtration surface area; however, use only one type of membrane molecular weight cutoff at one time. *Do not install a mixture of cassettes with different pore sizes in the hardware.*
- Cassettes must be equilibrated with an appropriate buffer (i.e., phosphate buffered saline) to ensure the neutralization of the 0.2M sodium hydroxide storage agent in the membrane filter. It is important to use pre-filtered buffer to avoid fouling the membrane or introducing contaminants into the system that could affect membrane performance and product recovery.

GASKETS

- Gaskets are intended to be single use; Repligen recommends that you replace gaskets with each cassette changeover. Repligen supplies two gaskets per cassette. Installation of the first cassette requires two gaskets; stacking additional cassettes requires only one gasket. Extra gaskets should be saved to replace worn or damaged gaskets.

PUMP

- When using TangenX™ cassettes, select a pump with adequate capacity; crossflow rate ranges (see Table 3) are feed channel type and process fluid dependent.

TANGENX™ SIUS™ PD CASSETTE INSTALLATION

1. Lift the end plate off the manifold of the TangenX™ PRO PD cassette holder.
2. Rinse the EPDM gaskets with deionized water or WFI. Place a rinsed gasket flat against the bottom manifold; ensure that the holes in the gasket line up with the holes in the manifold.
3. Using scissors carefully open the cassette bag to remove cassette.
 - WARNING: Each cassette is stored in 0.2M sodium hydroxide solution as a preservative. Follow standard safety procedures for handling 0.2M sodium hydroxide, including the use of gloves, safety goggles, and lab coat.**
4. Place the cassette into the holder flat against the gasket. Place another gasket on top of the cassette. Ensure that the holes in the manifold, gaskets, and cassette are completely aligned. If you are using multiple cassettes, continue the same gasket/cassette/gasket pattern, ending with a gasket between the last cassette and the end plate.
5. Place the end plate on top of the last gasket of the cassette or cassette stack.
6. Install the tie-rod spacers (if used) and washers on each bolt leaving a minimum of 18 mm (0.75 inch) of thread exposed on the rod. By hand, screw the nut on each bolt and hand tighten evenly by alternating from one nut to the other. Bolts must be further tightened to within the recommended torque values shown in Table 1 using a calibrated manual torque wrench.

Table 1 Recommended Torque Values

Holder Type	Torque Range (in-lbs)	Torque Range (nm)
TangenX™ PRO PD	120 – 180	14 – 20

7. Using the calibrated torque wrench with an 11/16" deep style socket, tighten each hex nut ¼ turn following the torque sequence illustrated in Figure 1. Tighten the first nut ¼ turn, and then tighten the second nut ¼ turn alternating back and forth until the torque wrench "clicks". Repeat this sequence until the wrench "clicks" without turning the nut. The "click" of the torque wrench indicates that the nut has reached the set point torque value.

CAUTION: Nuts must be tightened uniformly to avoid damaging the cassette. Leakage may result from non-parallel plate alignment or over compression of the cassettes at one end.

8. Wait 5-10 minutes and allow the gaskets to relax before re-torquing. Check each nut, per the Figure 1 sequence, using the torque wrench at its set point torque value (see step 7 above).

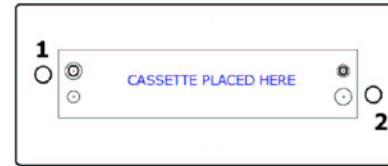


FIGURE 1
TORQUE SEQUENCE FOR
TANGENX™ SIUS™ PD CASSETTES

9. Re-torque to a maximum of 180 inch-pounds, as needed, to create a liquid-tight seal.

NOTE: Torque may change during processing as the cassettes may compress, or as the cassettes expand or contract with temperature changes. Periodically check the torque of the bolts and adjust torque as needed.

10. **For L01J and M01J Cassette Configurations:**

- Installation of J-Channel Stack Stabilizer Plate
- Open the cassette packaging and follow the installation instructions outlined in the product use guide.
- Place the first EPDM gasket in the cassette holder by laying it on the lower manifold plate with the notches aligned with the tie rod bolts.
- Next, install the first cassette in the cassette holder by laying it on the gasket with the notches aligned with the tie rod bolts.
- Place the second EPDM gasket on the cassette by laying it in place with the notches aligned with the tie rod bolts.
- Install the stack stabilizer plate on the top of the EPDM gasket with the holes aligned with the tie rod bolts.
- Repeat steps 2-5 when installing subsequent cassettes in the holder.
- Once the final cassette and the last EPDM gasket are installed, place the stainless steel top plate on top of the cassette stack with the holes aligned with the tie rod bolts.
- Install the tie rod spacers and bronze nuts as outlined in the product use guide.

EQUILIBRATION OF TANGENX™ SIUS™ PD CASSETTES

Cassettes must be equilibrated with an appropriate buffer (i.e., phosphate buffered saline) to ensure the neutralization of the 0.2M sodium hydroxide storage agent in the membrane filter. Verify the pH of the effluent from the cassette is neutralized to minimize any possible interaction with your particular application. For most applications, further sanitization is not required.

INTEGRITY TEST ⓘ

The integrity test provides a non-destructive method used to verify the integrity a TFF cassette. Each cassette manufactured by Repligen undergoes strict release testing, including an air integrity test. This release test verifies the integrity of the cassette prior to shipment; however it can't guarantee the integrity of the cassette's installation in the holder at the time of use. In the rare case there is an integrity issue, it can be a result of shipping damage or improper installation. Therefore, a pre-use integrity test should be conducted on site and can easily be performed following the cassette installation and flush. Integrity test specifications are shown in Table 5 of this guide. A detailed procedure (AN1002) for the measurement of air integrity can be obtained by contacting Repligen or your local sales representative.

CLEANING OF THE CASSETTE SYSTEM

TangenX™ SIUS™ PD Cassettes are intended for single use only, post-use cleaning and re-use is not recommended. To clean the TFF system following use, recirculate 0.5M sodium hydroxide through the system with all valves open. Cassettes are left in place during the system cleaning procedure to provide a flow path for the cleaning solution. Alternatively the cassettes may be removed and a spacer gasket⁽¹⁾ is put in place of the used cassettes. Upon completion of the cleaning cycle, flush the system with WFI, or DI water prior to draining and discarding the cassettes. Table 2 lists possible recommended cleaning solutions. ¹Spacer gaskets for flushing may be obtained by contacting Repligen.

Table 2 Recommended Cleaning Solutions

Cleaning Agent	Cleaning Conditions
0.5N Sodium Hydroxide	Contact Time = 30 – 60 minutes Temperature = 35°C (95°F)
1.5% Alconox® Detergent	Contact Time = 30 – 60 minutes Temperature = 40°C (104°F)

DISPOSAL OF USED TANGENX™ SIUS™ PD CASSETTES

TangenX™ SIUS™ PD cassettes are removed by reversing the cassette installation procedure. If the cassettes are difficult to separate from the holder, a thin plastic spatula² can be slid under the edge of the cassette to break the seal. Used cassettes can be disposed of in a similar fashion as other disposable equipment. ²One cassette extractor is included with each shipment of TangenX™ SIUS™ PD cassettes.

STORAGE OF UNUSED TANGENX™ SIUS™ PD CASSETTES

Membrane cassettes must remain sealed in their original packaging prior to use to maintain their characteristics, integrity, and prevent microbial growth. Below are critical factors to remember when storing unused TangenX™ SIUS™ PD cassettes: Recommended storage temperature:

- 4°C - 25°C long term (>7 Days)
- 50°C short term (<7 Days)
- Do not freeze cassettes

IDENTIFICATION: IF.PUG.005	DOCUMENT APPROVAL COVER SHEET TANGENX™ SIUS™ PD CASSETTE PRODUCT USE GUIDE	
REVISION: R11		

TWO-SIDED BROCHURE ONLY	COVER SHEET ONLY
<div style="display: inline-block; border: 1px solid black; padding: 5px; margin: 5px;">PRINT 1</div> <div style="display: inline-block; border: 1px solid black; padding: 5px; margin: 5px; margin-left: 20px;">PRINT 50</div>	<div style="display: inline-block; border: 1px solid black; padding: 5px; margin: 5px;">PRINT COVER SHEET</div>

TANGENX™ SIUS™ PD CASSETTE PRODUCT USE GUIDE

REVIEW AND APPROVAL

AUTHOR	REVIEWER	APPROVAL
Mark Perreault R&D Director	Altina Moura Manufacturing Supervisor	Joseph Voss Quality Assurance Manager

REVISION HISTORY

REV	DOCUMENT CHANGE #	DESCRIPTION OF CHANGE	AUTHOR	DATE
R0	N/A	Initial.	MPE	10-Nov-2008
R1	F.DMO-I08/042	Corrected air diffusion values to represent external specification of 323ccm/m ² .	MPE	18-Nov-2008
R2	N/A	Inserted statement instruction to keep bag sealed until cassette installation.	MPE	25-Feb-2009
R3	F.DMO-I09/003	Modified air integrity test specification pressure for 10 kD - 300 kD MWCO's (F.DMO-I09/003)	JCO	31-Mar-2009
R4	IF.DMO-1033 12/006	Added column to table 3 and corrected psi/bar figure	MPE	04-Apr-2012
R5	IF.DMO-1033 12/016	See IF.DMO-1033 12/016 for details.	MPE	22-Oct-2012
R6	IF.DMO-1033 12/022	See IF.DMO-1033 12/022 for details.	MPE	17-Dec-2012
R7	IF.DMO-1033 13-012	Added ACN compatibility, See DMO for details.	MPE	06-Aug-2013
R8	DMO-15034	Replaced novasep web address with order@tangenx.com, changed R7 to R8 on first page, replaced Laskarides with Santos, and author is now VRA.	VRA	29-Jul-2015
R9	DMO-15067	To add instructions for assembly of L01J and M01J configurations with stack stabilizer plate.	VRA	08-Dec-2015
R10	DMO-18007	Update company name to Repligen and the product name to the Repligen branded name	JVO	31-JAN-2018
R11	DMO-18011	Added "E" Screen and cross flow rate to table 3	MPE	06-MAR-2018

STATUS

APPROVED

EFFECTIVE DATE

06 MAR 2018