

TangenX™ PRO PD Low Holdup Volume (LHV) System

USER GUIDE



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Customer Support

txcustomerservice@repligen.com

508.845.6400

Repligen Corporation

111 Locke Drive

Marlborough, MA 01752, USA

www.repligen.com/tangenx

Contents

1. Product Contents	4
2. Required for operation	5
3. Important information before you begin	5
4. System Assembly Instructions	5
4.1 Unpacking the TangenX™ PRO PD LHV Frame.....	5
4.2 Pump Installation.....	6
4.3 Magnetic Stirrer Installation.....	8
4.4 Reservoir Installation.....	9
4.5 Tubing Installation – Reservoir to Pump Head to Holder Connection.....	9
4.6 Tubing Installation – Retentate Connection.....	10
4.7 Tubing Installation – Filtrate Connection.....	11
4.8 System Sanitization.....	12
4.9 Cassette Installation.....	13
5. Chemical Restrictions	13
5.1 Chemical Restrictions.....	13
5.2 CAUTION.....	13
6. Repligen TangenX™ Standard Warranty	14

List of Figures

Figure 1.1 Product contents.....	4
Figure 4.1 Unpacking the TangenX™ PRO PD LHV frame Step 3.....	5
Figure 4.2 Unpacking the TangenX™ PRO PD LHV frame Step 5.....	6
Figure 4.3 Pump installation Step 4.....	6
Figure 4.4 Pump installation Step 5.....	7
Figure 4.5 Pump installation Step 7.....	7
Figure 4.6 Magnetic Stirrer installation Step 2.....	8
Figure 4.7 Magnetic Stirrer installation Step 3.....	8
Figure 4.8 Reservoir installation Step 4.....	9
Figure 4.9 Reservoir to Pump Head to Holder Connection.....	10
Figure 4.10 Retentate Connection Step 3.....	10
Figure 4.11 Retentate Connection Step 6.....	11
Figure 4.12 Filtrate Connection Step 4.....	11
Figure 4.13 Torque Sequence.....	12

1. Product Contents

Before you begin set up of the TangenX™ PRO PD Low Holdup Volume (LHV) System, please check the shipping carton to ensure the following items have been included:

Figure 1.1 Product contents



- **TangenX™ PRO PD LHV Frame**
 - 304L stainless steel frame

- **TangenX™ PRO PD LHV Cassette Holder**
(Attached to Frame)
 - (1) 316L stainless steel manifold top plate
 - (1) 316L stainless steel manifold bottom plate
 - (2) 316L stainless steel tie rods
 - (2) 316L stainless steel washers
 - (2) bronze silicone nuts

- **TangenX™ PRO PD LHV Cassette System**
 - (2) 316L stainless steel tie rods
 - (2) 316L stainless steel washers
 - (2) Brass nuts
 - (1) TangenX™ PRO PD LHV 316L Stainless Steel Cassette Holder
(see contents listed above)
 - (1) 304L stainless steel frame to support system components
 - (4) 304L stainless leveling feet
 - (1) 100ml acrylic reservoir with lid
 - (1) MasterFlex® peristaltic pump with Easy Load III pump head
 - (1) Hanna® 12V magnetic stirrer w/ power supply
 - (3) 316L stainless steel gauges w/ mount
 - (2) Pinch clamps
 - (1) Digital Thermometer
 - (1) Magnetic stir bar
 - (6) Luer-Lock polypropylene fittings
 - (1) Luer-Loc 3-way polypropylene valve
 - (3) Tygon tubing sets:

- Retentate Tubing Pack
- Feed Tubing Pack
- Filtrate Tubing Pack

2. Required for operation

- 110V / 220V Power supply
- Filtrate Collection Vessel
- Retentate Collection Vessel
- Waste Collection Vessel
- Deionized (DI) water or water for injection (WFI)

3. Important information before you begin

Be sure to read the following instructions carefully:

- User Guide for the TangenX™ PRO PD LHV System (Sections 4 - 6)
- User Guide for TangenX™ PRO PD or TangenX™ SIUS™ PD TFF Cassettes

4. System Assembly Instructions

4.1 Unpacking the TangenX™ PRO PD LHV Frame

1. Open the 18" x 18" x 18" cardboard shipping container and remove the inner cardboard sleeve.
2. Carefully lift the TangenX™ PRO PD LHV frame and plywood packing base from the cardboard shipping container.
3. Place the TangenX™ PRO PD LHV frame on the bench-top and remove the four retaining bolts from the bottom of the plywood base. These bolts are no longer needed.

Figure 4.1 Unpacking the TangenX™ PRO PD LHV frame Step 3



4. Open the "accessory package" cardboard shipping container and remove the contents.

5. Locate the four leveling feet in the “accessory package” and thread them into the base of the LHV frame.

Figure 4.2 Unpacking the TangenX™ PRO PD LHV frame Step 5



6. The TangenX™ PRO PD LHV frame assembly is complete.

4.2 Pump Installation

1. Place the stainless steel frame on lab bench or other appropriate surface that will accommodate system (see specifications for system weight and dimensions).
2. Position frame so that angled cassette holder is to the left when facing the lab bench.
3. Place pump onto the lower right side of the frame when facing the lab bench. Slide pump carefully into the frame back end first so that the pump control panel faces forward.
4. Turn the frame so that the angled cassette holder is facing forward towards the operator.

Figure 4.3 Pump installation Step 4



5. Mount pump head onto the pump. See the Easy-Load® 3 pump head operating manual for instructions.

Figure 4.4 Pump installation Step 5



6. Pump head should be mounted so that the tubing will enter and exit vertically in the upwards position when loaded.
7. Plug the power cord into the back of the MasterFlex® L/S pump.

Figure 4.5 Pump installation Step 7



8. Ensure the plug is not tangled at the back of the pump and is within easy reach of an electrical outlet.
9. See MasterFlex® Operating Manual which includes pump operation guidelines, specifications and safety precautions.

CAUTION: FOLLOW ALL SAFETY PRECAUTIONS OUTLINED IN THE PRODUCT DOCUMENTATION.

4.3 Magnetic Stirrer Installation

1. Take the magnetic stirrer and locate the black rubber-padded “feet” underneath the plate.
2. The magnetic stir plate shelf is located on the upper right side of the frame when facing the lab bench. Position magnetic stirrer onto the shelf so that the “feet” align with the corresponding openings on the shelf. Slide magnetic stirrer back end first onto the frame so that the control panel faces forward. Set the magnetic stirrer “feet” completely into the openings on the shelf. Check to ensure magnetic stirrer is seated securely on the frame.

Figure 4.6 Magnetic Stirrer installation Step 2



3. Plug the power cord into the back of the magnetic stirrer.

Figure 4.7 Magnetic Stirrer installation Step 3



4. Ensure the plug is not tangled at the back of the magnetic stirrer and is within easy reach of an electrical outlet.

4.4 Reservoir Installation

1. The notched reservoir base that holds the reservoir is located on the frame right above the stir plate.
2. Obtain either the 100 ml or 500 ml reservoir, depending on which one will be used during processing.
3. Slide the reservoir into the reservoir base back end first so that the graduations and feed port face forward.
4. Place a magnetic stir bar into the reservoir.

Figure 4.8 Reservoir installation Step 4



4.5 Tubing Installation – Reservoir to Pump Head to Holder Connection

1. Remove the tubing from the “A” tubing pack.
2. Connect the tubing to the pump head following the Tubing Loading and Unloading procedure on page 6 and 7 of the Easy-Load®3 Pump Head Operating Manual.
3. Take the end of tubing that enters the pump head from the right (when facing the pump) and connect it to the barbed fitting on the feed port of the reservoir. Connection is made by gently pushing the tubing onto the barbed fitting and turning the tubing cap clockwise until the tubing is secure.
4. The feed port enters on the lower, right side of the holder closest to the pump head.
5. Take the end of the tubing that exits the pump head from the left (when facing the pump) and connect it to the barbed luer-lock fitting on the 3-way feed gauge block.

Figure 4.9 Reservoir to pump head to holder connection

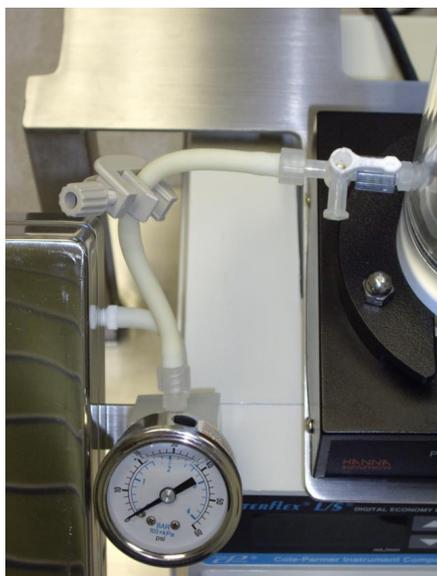


6. Connection is made by gently pushing the tubing onto the barbed fitting and turning the tubing cap clockwise until the tubing is secure.

4.6 Tubing Installation – Retentate Connection

1. Remove the two lengths of tubing from the “B” tubing pack.
2. Insert a 3-way valve into the retentate port of the acrylic reservoir.
3. Take the short length of tubing and connect one end to the 3-way valve on the retentate port of the holder (connect at the straight position end).

Figure 4.10 Retentate Connection Step 3



4. Place the pinch clamp onto the tubing as shown on the right and adjust to an open position (no back pressure).
5. Connect the other end of the tubing and to the 3-way gauge block attached to the retentate port. The retentate port exists on the top, right side of the holder closest to the reservoir.

- Attach the second, longer length of tubing to the 3-way valve on the acrylic reservoir (connect at the 90° angle end) as shown.

Figure 4.11 Retentate Connection Step 6



- Place the other end of the tubing into a collection vessel.

4.7 Tubing Installation – Filtrate Connection

- Remove the length of tubing from the “C” tubing pack.
- Attach one end of the tubing to the 3-way gauge block connected to the filtrate ports on the left side of the cassette holder using a barbed luer connector.
- Connection is made by gently pushing the tubing onto the barbed fitting and turning the tubing cap clockwise until the tubing is secure.
- Place the pinch clamp onto the filtrate tubing and adjust to an open position (no back pressure).

Figure 4.12 Filtrate Connection Step 4



- Place the other end of the tubing into a filtrate collection vessel.

4.8 System Sanitization

1. Open the stainless steel cassette holder by loosening the two bronze silicone nuts and remove them from the holder.
2. Remove the two stainless steel washers
3. Lift the end plate off the manifold.
4. Rinse a cut-out gasket with deionized water or WFI. Place the cut-out gasket flat against the bottom manifold; ensure that the holes in the gasket line up with the holes in the manifold.
5. Place the end plate on top of the cut-out gasket.
6. Install the tie-rod washers on each bolt leaving 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 140inlbs.
7. Using the calibrated torque wrench with an 11 mm (7/16") deep socket, tighten each hex nut ¼ turn following the torque sequence illustrated below. 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.

Figure 4.13 Torque Sequence



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. Direct both the retentate and permeate lines to the acrylic retentate reservoir.
9. Be sure all valves are open.
10. Fill the acrylic reservoir with 0.5M Sodium Hydroxide at ambient temperature.
11. Close the pump head and turn on the MasterFlex® pump. Adjust the flow to 120ml/min using the display panel and control pad on the face of the pump.
12. Allow the sanitizing solution to recirculate for approximately 20 to 30 minutes.
13. Turn off the pump and drain the reservoir to waste.
14. Refill the reservoir with DI water and direct the retentate and permeate lines to a waste vessel.
15. Turn on the MasterFlex® pump, adjust the flow to 120ml/min using the display panel and control pad on the face of the pump.
16. Flush the entire volume of DI water to the waste vessel.
17. Turn off the pump and remove the cut-out gasket reversing the installation procedure above.

4.9 Cassette Installation

1. Membrane cassettes (sold separately) must be installed with gaskets between the top and bottom manifold plates of the holder prior to operation.
2. Refer to the Membrane Cassette User Guide for TangenX™ PRO PD or TangenX™ SIUS™ PD Cassettes.

5. Chemical Restrictions

5.1 Chemical Restrictions

Do not use TangenX™ cassette systems with the following materials:

- DMF
- M-PYROL
- > 10% phosphoric acid
- Pure aromatic and chlorinated hydrocarbons
- Ketones
- DMSO
- Polar aromatics
- Aliphatic esters

5.2 CAUTION

In the event that the cassette system is subjected to any of the conditions listed below, it is recommended that you inspect for damage. Damage may occur as a result of the following:

- Dropping on hard surfaces, or other mechanical shock
- Excessive pressure (> 50 psi)
- Exposure to harsh chemicals
- Freezing
- Excessive heat (> 50°C)
- Over tightening fittings

6. 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.

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