

## **Instructions for Use**

# USA – ENGLISH – INSTRUCTIONS FOR USE

## 3T Aerosol Collection Set Part no.: 050900100

This document supplements the current Heater-Cooler System 3T Operating Instructions and should be used in conjunction with them.

### Introduction

The 3T Aerosol Collection Set collects aerosol created by the Heater-Cooler 3T water tanks during use. The 3T Aerosol Collection Set replaces the use of the overflow bottle referenced in the Heater-Cooler System 3T Operating Instructions. **Please read all information carefully:** Failure to properly follow these instructions may allow for aerosol to be emitted from the Heater-Cooler 3T in its surrounding environment.

### Indications for use

The Stöckert Heater-Cooler System 3T is used with a Stöckert S3 heart-lung machine and/or any other heart-lung-machine featuring a separate temperature control for extracorporeal perfusion of durations of up to 6 hours.

### Device

The 3T Aerosol Collection Set consists of a suction canister, a suction canister lid and two pieces of tubing; the longer piece of tubing includes a connector (see Figure 1).

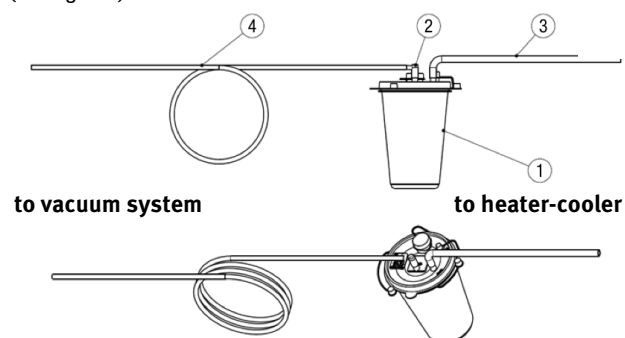


Fig. 1) Overview of the 3T Aerosol Collection Set: 1 = suction canister, 2 = pre-connected right angle connector, 3 = heater-cooler connection line, 4 = vacuum source line

### Warnings and precautions

- ▶ Prior to use, visually inspect the 3T Aerosol Collection Set to ensure that connections, seals and components were not damaged during shipment. Do not use the 3T Aerosol Collection Set if any defects are found.
- ▶ The use of a central hospital vacuum source is recommended for use with this disposable. The vacuum source must be capable of 20 l/min flow or greater.
- ▶ Use an overflow safety trap connected to the regulated vacuum source to avoid liquid introduction into the medical surgical vacuum system.
- ▶ Empty the overflow safety trap as needed to ensure that the vacuum source flow is not interrupted during use.
- ▶ If a central hospital vacuum source is not available, the use of a portable vacuum system capable of 20 l/min flow per ISO 10079-1 for Medical Suction Equipment is required. The portable vacuum source must be specified for medical applications and fulfill the requirements of IEC 60601-1 and IEC 60601-1-2.
- ▶ Do not place the portable vacuum system or any other object on top of the Heater-Cooler 3T.
- ▶ Follow the portable vacuum system supplier's mounting and operating instructions for the recommended use of the pump in an operating room environment.
- ▶ To avoid disturbances in the laminar flow area of the operating room, make sure that a portable vacuum system is placed in such a way that the exhaust flow is not directed towards the operating field, but towards the exhaust vent system.
- ▶ Power sources for the vacuum system selected must have connection to a back-up power generator to avoid loss of power during use.
- ▶ If the patient circuit 2 is used and water tank level adjustment is required, only add pre-mixed water/H<sub>2</sub>O<sub>2</sub> solution as per the separate Heater-Cooler System 3T Operating Instructions if the water level drops to the level where the red LED for the patient tank is activated. In such a case, add water until the first green LED is visible.
- ▶ The 3T Aerosol Collection Set is validated for 3 calendar days of use.
- ▶ Check the date of installation, which is written on the suction canister lid as per step 13 in this document, for the use-by-date of the 3T Aerosol Collection Set.
- ▶ The suction canister is not intended as a measuring device.
- ▶ The suction canister contents are potentially hazardous due to the possible collection of aerosolized bacteria. Use appropriate personal protection equipment (PPE) and handle accordingly.
- ▶ Store in dark place: long term exposure to light may compromise product performance and result in breakage during use.

## Instructions for use

**WARNING** indicates serious adverse reactions and potential safety hazards for the practitioner and/or the patient that may occur in the proper use or misuse of the device as well as the limitations of use and the measures to be adopted in such cases.

**CAUTION** indicates any special care to be exercised by a practitioner for the safe and effective use of the device.

1. Before starting a procedure, with the Heater-Cooler 3T and the vacuum source switched off, verify that the tank vacuum gauge indicator located on the heater-cooler is positioned at "0" (see Figure 2). If necessary, set the indicator needle to "0" using the adjustment screw near the bottom of the gauge.

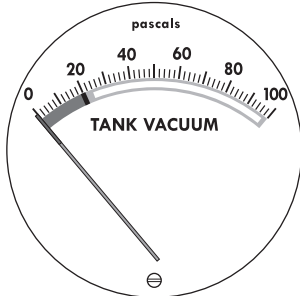


Fig. 2) Tank vacuum gauge (zero point and adjustment screw in bottom part of the gauge)

2. Ensure that a suction canister holder is attached to the right side or rear panel of the Heater-Cooler 3T (see Figures 3 through 5). The holder is attached by inserting the two top tabs into the vent slots on the heater-cooler and then allowing the holder to rest in a horizontal position. The holder should be positioned so that the base of the suction canister is above the base of the heater-cooler to avoid displacement of the canister from the holder during use.

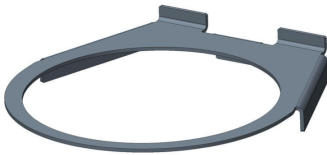


Fig. 3) Suction canister holder



Fig. 4) Holder installed on right side panel and on rear panel



Fig. 5) Tilt the holder up to insert or remove

3. Remove the components from the packaging.
4. Place the lid on the canister and press it down firmly around entire perimeter (see Figure 6).



Fig. 6) Canister lid assembled on the canister

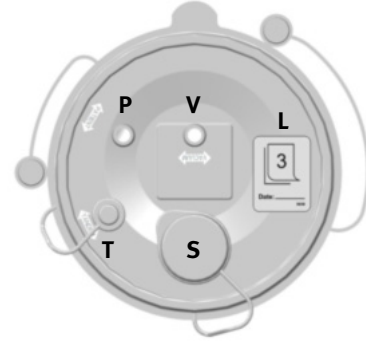


Fig. 7) Overview of the canister lid components: P = heater-cooler connection port, V = vacuum port, T = tandem port (shown here with tandem port cap applied), S = pour spout (shown here with pour spout cap applied), L = label for recording the installation date. The hydrophobic filter is located inside the device below the vacuum port.

5. Apply the cap firmly over the matching pour spout (S) (see Figures 6 and 7).
6. Apply the tandem port cap tightly over the tandem port (T) (see Figures 6 and 7).
7. Place the suction canister with the mounted lid into the suction canister holder (see Figures 8 and 9).

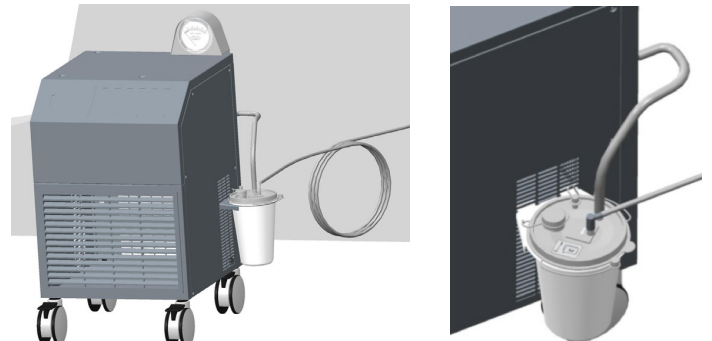


Fig. 8) Canister with lid inserted into the holder on side panel



Fig. 9) Canister with lid inserted into the holder on rear panel

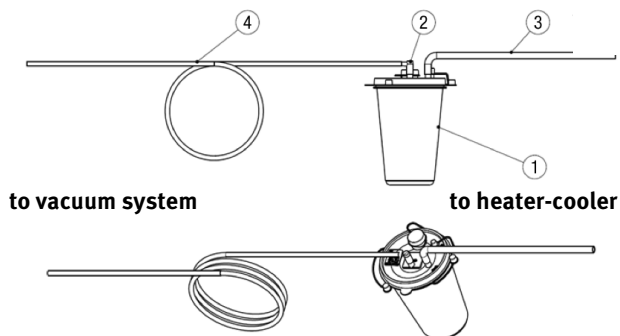


Fig. 10) Overview of the 3T Aerosol Collection Set: 1 = suction canister, 2 = pre-connected right angle connector, 3 = heater-cooler connection line, 4 = vacuum source line

8. Attach the short 46 cm (1.5 ft) heater-cooler connection line 3 (see Figure 10) to the heater-cooler overflow outlet and then connect it to the port (P) of the canister lid (see Figures 7, 8 and 9).
 

**Caution: Do not connect the short 46 cm (1.5 ft) heater-cooler connection line to the center vacuum source port (V) (see Figure 7) as this will potentially cause the hydrophobic filter to be exposed to water and will limit the vacuum flow to the canister.**
9. Attach the 366 cm (12 ft) ¼" ID vacuum source line 4 with pre-connected right angle connector 2 (see Figure 10) to vacuum port (V) (see Figures 7, 8 and 9), making sure that the tubing is fully connected and no tubing is kinked.
10. If additional length is required to access the vacuum source, attach the 366 cm (12 ft) ¼" ID vacuum extension line with connector to the 366 cm (12 ft) ¼" ID vacuum source line 4 (see Figure 10).
 

**Note: If required, the vacuum extension line must be ordered separately; part no. 050900111.**
11. Attach the other end of the 366 cm (12 ft) ¼" ID vacuum source line 4 (see Figure 10) to a regulated vacuum source (see Figure 11).
 

**Caution: The vacuum source line must be connected to a vacuum regulator to control and adjust flow to the 3T Aerosol Collection Set.**

**Note: It is recommended to use an overflow safety trap connected to the regulated vacuum source to avoid liquid introduction into the medical-surgical vacuum system.**

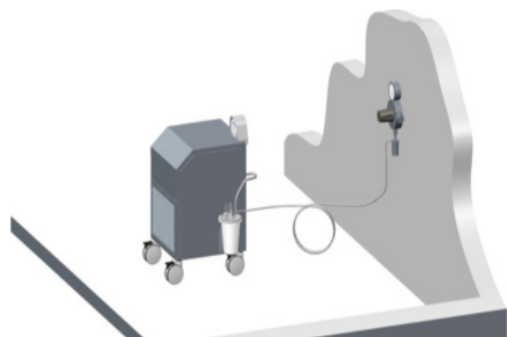


Fig. 11) 3T Aerosol Collection Set connected to the Heater-Cooler 3T and to the regulated vacuum source with the overflow safety trap

12. Check all caps and connections for proper sealing.
13. Write the date of installation on the label (L) located on the lid (see Figure 7).
 

**Caution: The 3T Aerosol Collection Set must be replaced within 3 calendar days of installation. It must also be replaced after a Heater-Cooler 3T water change or disinfection procedure.**

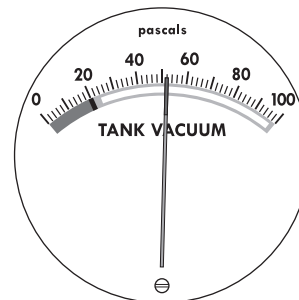


Fig. 12) Tank vacuum gauge with indicator in the acceptable area of operation (operate with full open vacuum flow applied to achieve > 50 Pa)

14. With the Heater-Cooler 3T switched off, adjust the vacuum source to full open vacuum flow so that the vacuum gauge on the Heater-Cooler 3T displays > 50 Pa (see Figure 12).
 

**Note: With full open vacuum flow the tank vacuum gauge may display > 100 Pa. The pressure gauge is rated to accept 100,000 Pa. The Heater-Cooler 3T with full open vacuum flow applied is not capable of reaching 100,000 Pa.**
15. Switch on the Heater-Cooler 3T and during use adjust the vacuum source to full open vacuum flow to ensure that the vacuum gauge on the Heater-Cooler 3T operates at > 50 Pa (see Figure 12).
 

**Warning: Operating the Heater-Cooler 3T with the vacuum level indicated on the tank vacuum gauge in the red solid zone limits the disposable's ability to collect aerosol from the Heater-Cooler 3T water tanks. Refer to section "Troubleshooting" for possible remedies.**

**Note: It is advised to add the check of vacuum level indicated on the tank vacuum gauge to your procedure set-up check list.**
16. Do not disconnect the vacuum source until the Heater-Cooler 3T is switched off. When the Heater-Cooler 3T is switched off, disconnect the vacuum source line from the vacuum regulator.
 

**Warning: Operation of the Heater-Cooler 3T without vacuum source applied will stop collection of aerosol from the water tanks.**
17. To prevent an excessive overflow of the tank volume capacity at the end of the procedure, empty the external circuits according to the following steps:
 

**Warning: Do not perform the external circuit emptying steps until the patient has been discharged from the operating room environment to reduce the potential of exposure to aerosol. Failure to close the external water circuit valves in the order specified below may result in increased levels of aerosol emission.**

  - Ensure that the vacuum source is applied and that the 3T Aerosol Collection Set is connected.
  - Always close one circuit valve at a time. Allow the external water circuit volume to enter the tank before closing the next valve.
  - Close the cardioplegia circuit valve and empty the cardioplegia circuit as per the separate Heater-Cooler System 3T Operating Instructions (water will move back to the cardioplegia tanks).
  - Close the patient circuit 1 valve and empty the patient circuit 1 as per the separate Heater-Cooler System 3T Operating Instructions (water will move back to the patient tank and potentially start overflowing from the tank to the canister).

– see the next page for further instructions if patient circuit 2 is used –

- If the patient circuit 2 is used and emptying the patient circuit 1 has already filled the suction canister with a volume greater than 0.5 liter, proceed as described in the following steps:
    - a) Empty the suction canister as per the following steps:
 

**Warning: As the canister contents are potentially hazardous due to the collection of aerosolized bacteria, use appropriate Personal Protection Equipment (PPE) and handle the contents accordingly. It is recommended to empty the suction canister outside the operating room, if possible.**

**Warning: Do not expose the suction canister hydrophobic lid filter to the water inside the canister as this condition will seal the filter stopping vacuum flow and limiting the disposable's ability to collect aerosol from the Heater-Cooler 3T water tanks.**

**Warning: Do not lift the canister by the lid as the weight of the contents may cause the lid to separate from the canister.**

      - ▶ Switch off the Heater-Cooler 3T.
      - ▶ Disconnect the short 46 cm (1.5 ft) heater-cooler connection line 3 (see Figure 10) from the port (P) of the suction canister lid (see Figures 7, 8 and 9).
      - ▶ Disconnect the 366 cm (12 ft) ¼" ID vacuum source line 4 with pre-connected right angle connector 2 (see Figure 10) from the vacuum port (V) of the suction canister lid (see Figures 7, 8 and 9).
      - ▶ Open the pour spout cap (S) (see Figures 6 and 7).
      - ▶ Empty the suction canister content according to hospital policy.
      - ▶ Reconnect the short 46 cm (1.5 ft) heater-cooler connection line 3 (see Figure 10) to the port (P) of the suction canister lid (see Figures 7, 8 and 9).
      - ▶ Reconnect the 366 cm (12 ft) ¼" ID vacuum source line 4 with pre-connected right angle connector 2 (see Figure 10) to the vacuum port (V) of the suction canister lid (see Figures 7, 8 and 9).
      - ▶ Apply the cap firmly over the matching pour spout (S) (see Figures 6 and 7).
      - ▶ Switch on the Heater-Cooler 3T to allow emptying the patient circuit 2.
    - b) Or drain water from the patient tank through the tank drain valve of the patient circuit until the orange LED blinks; once the orange LED is blinking, close the tank drain valve.
      - ▶ Close the circuit valve and empty the patient circuit 2 as per the separate Heater-Cooler System 3T Operating Instructions (water will move back to the patient tank).
18. If during external circuit emptying the suction canister is filled with water from the heater-cooler overflow outlet, empty the suction canister following the procedure described in step 17.
- Caution: If the suction canister is completely filled with water and has exposed the hydrophobic filter located below the vacuum source port to water, replace the 3T Aerosol Collection Set to avoid loss of vacuum performance caused by obstruction of the hydrophobic filter contacting the water. Exposure of the hydrophobic filter to water will cause the filter to block flow of air and will reduce and stop vacuum flow to the canister, reducing the disposable's ability to collect aerosol from the Heater-Cooler 3T water tanks.**

## Disposal

Dispose of the canister and tubing within 3 calendar days of installation. Check the installation date which is written on the label on the suction canister lid as discussed in step 13 in this document.

**Caution: When performing the Heater-Cooler 3T disinfection procedure leave the used 3T Aerosol Collection Set attached without vacuum source applied.**

**To prevent disinfectant vapor from getting to the vacuum source, disconnect the 366 cm (12 ft) ¼" ID vacuum source line from the suction canister prior to performing the disinfection procedure.**

**Replace the 3T Aerosol Collection Set after the disinfection procedure has been completed. It is recommended to carry out the replacement outside the operating room, if possible.**

1. Switch off the Heater-Cooler 3T.
2. Disconnect the short 46 cm (1.5 ft) heater-cooler connection line 3 (see Figure 10) from the heater-cooler overflow outlet (see Figures 8 and 9).
3. Disconnect the 366 cm (12 ft) ¼" ID vacuum source line 4 (see Figure 10) from the vacuum source (see Figure 11).
4. Remove the suction canister from the suction canister holder.
5. Transport the 3T Aerosol Collection Set to the disposal area.
 

**Warning: Do not lift canister by lid as the weight of the contents may cause the lid to separate from the canister.**
6. Dispose of the 3T Aerosol Collection Set according to hospital policy.

## Troubleshooting

- ▶ If the measured pressure inside the Heater-Cooler 3T tank is not greater than 50 Pa (see Figure 12), adjust the vacuum regulator of the vacuum source to full open vacuum flow until the tank vacuum gauge indicator reaches the acceptable area of operation (see Figure 12).
- ▶ If there is a loss of vacuum during the procedure, check that the vacuum source is operational, the canister is properly sealed, that all connections are tight and tubing is not kinked.
- ▶ If the suction canister is completely filled with water, exchange the 3T Aerosol Collection Set to avoid loss of vacuum performance caused by the obstruction of the hydrophobic filter contacting the water. Exposure of the hydrophobic filter to water will cause the filter to block flow of air and will reduce and stop vacuum flow to the canister, reducing the disposable's ability to collect aerosol from the Heater-Cooler 3T water tanks.
- ▶ If there is a loss of vacuum during the procedure, the air flow to the vacuum source may be obstructed. Check the vacuum source and the overflow safety trap for possible obstruction. If the overflow safety trap is completely filled and blocking the vacuum flow, empty it according to hospital policy.
- ▶ To manage excess condensation at the overflow safety trap, use a larger overflow safety trap of at least 200 ml capacity (e.g. Ohio Medical 275 ml Collection Bottle with ⅛" NPT Locking Gland).
- ▶ If no obstruction is found and a loss of vacuum is still observed, open the vacuum gauge service port located on the back of the machine (see Figure 13).
- ▶ Opening this service port by removing the Luer Lock cap will allow the vacuum source air flow to remove any potential obstruction within the pressure monitoring line internal to the Heater-Cooler 3T. Re-attach the Luer Lock cap and confirm the obstruction has been removed.

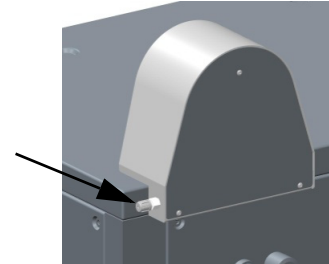


Fig. 13) Vacuum gauge service port










- ▶ If loss of vacuum is still observed, apply positive air pressure to the service port using a sterile syringe to deliver approximately 30 cc of air into the service port. Re-attach the Luer Lock cap and confirm the obstruction has been removed.

**Part numbers**

|  |           |
|--|-----------|
| 3T Aerosol Collection Set                                  | 050900100 |
| ¼" ID vacuum extension line with connector, 366 cm (12 ft) | 050900111 |

The 3T Aerosol Collection Set is supplied non-sterile for 3 calendar days of use. Discard in accordance with hospital procedures after use.

**Labeling**

|   |   |
|---|---|
|  | Attention, see Instructions for use   |
|  | Follow instructions for use<br>(white symbol on blue background)  |
|  | Batch code  |
|  | Purchase order number   |
| <b>Rx Only</b>  | Only applies in the U.S.A.:<br>Sale (and prescription) is restricted to physicians                              |
| <b>EA</b>   | Quantity  |
|  | Manufacturer  |
|  | Use by  |
|  | Dispose of the 3T Aerosol Collection Set within 3 calendar days from the installation date written on the label |
|  | Keep away from heat   |
|  | Keep dry  |

**Return of used product**

If for any reason this product must be returned to LivaNova USA, Inc., a returned goods authorization (RGA) number is required from LivaNova USA, Inc., prior to shipping.

If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton, or an equivalent carton, to prevent damage during shipment; and it should be properly labeled with an RGA number and an indication of the biohazardous nature of the contents of the shipment.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from the LivaNova USA, Inc. Returned Goods Coordinator, Quality Assurance Department (phone: 800-650-2623).

**Caution: It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment. Do not return products that have been exposed to blood-borne infectious diseases.**

The shipping address for returned goods is:

LivaNova USA, Inc.  
Returned CV Products  
14401 W. 65th Way  
Arvada, CO 80004

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