



VAPOTHERM

# Vapotherm® 2000i DK-301 Process Phases

## Phase 1

### Predisinfection

- Remove unit from patient care area
- Cut delivery tube to drain unit
- Discard all disposables
- Disinfect wipe unit



## Phase 2

### Disinfection

- Disinfect wipe **all** connections
- Attach Bypass tubing & Y-Spike assembly
- Circulate solution in Cleaning Mode (CL)
- Hold time: **10 minutes**

## Phase 3

### Rinse

- Remove Bag B
- Lower Bag A
- Attach sterile water bag
- Run in Cleaning Mode (CL) until empty



## Phase 4

### Dry and store

- Remove sterile water bag
- Attach O<sub>2</sub> tubing
- Run 15 liters of air
- Lay unit on side for **2 mins**
- Dry unit in upright position for **25 mins**

Use Standard Precautions and aseptic techniques during this procedure.

## Routine Disinfecting Protocol

### 1.1 Disinfection Supplies

- DK-301 (a-e included in kit)
  - Disinfection Bag A
  - Disinfection Bag B
  - Disinfection Tube
  - Cartridge Bypass Tubes
  - Y-Spike Assembly
- Gloves
- Safety Glasses
- Disinfectant wipes, 70-90% isopropyl alcohol
- Approved Disinfectant
- 1000 ml Sterile Water Bag
- Medical Grade Air Source
- Standard adult flow meter with oxygen 7ft tubing attached

#### WARNINGS:

Vapotherm should be disinfected after each patient or every 30 days on a single patient.

Do not disinfect in an open patient care area.

The DK-301 disinfection kit is a single use item. Operators should open a new disinfection kit for each disinfection procedure and discard the components at the end of the procedure.

Disinfection Procedure should be performed in a well ventilated area. Use Standard Precautions and aseptic techniques during this procedure.

The Vapor Transfer Cartridge **SHOULD NOT** be in place when disinfecting the unit.

The Vapor Transfer Cartridge is a single use disposable and must be discarded after each patient use.

DK-301 IS NOT designed to disinfect Vapor Transfer Cartridges.

### 1.2 Pre-Cleaning Process

- After patient use, it is recommended that the Vapotherm 2000i System remain attached to the IV pole with all the component parts intact.
- Move the Vapotherm 2000i System to a hospital approved reprocessing area outside the patient care area.

**WARNING:** The water circuit of the Vapotherm 2000i System is not sterile and can potentially have bacterial contamination. The water circuit of the device should never be opened in a patient care area. Transport the Vapotherm 2000i System to an appropriate area for draining, cleaning and disinfection.

- Wash hands and put on gloves.
- Drain the Vapotherm 2000i System in a receptacle by cutting the delivery tube. (Fig. 1)
- Remove and dispose of the delivery tube, cannula, VSS-1 spike set, and sterile water source.
- Remove and dispose of the vapor transfer cartridge.

**WARNING:** The water circuit of the Vapotherm 2000i system has the potential for bacterial growth so standard precautions should be used to open the water circuit. Disposable components should be disposed of in accordance with hospital guidelines and operators should wash their hands after breaking down the device.

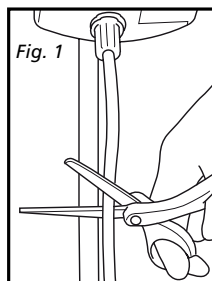


Fig. 1

### 1.3 Pre-Disinfection Cleaning and Decontamination

- Wash hands and put on new gloves.

**WARNING:** Always use standard precautions when cleaning and disinfecting the Vapotherm 2000i system. Always use individually wrapped 70-90% isopropyl alcohol disinfectant wipes when wiping down the Vapotherm 2000i and disinfection kit components.

Always use a new disinfectant wipe taken directly from the package or container and ensure that the disinfectant wipe has not dried out before using it on the Vapotherm 2000i device.

- Wipe exterior casing including inside hinged cover with an approved disinfectant wipe. (Fig. 2)
- Wipe inside and outside of the following connections with an approved disinfectant wipe:
  - Four cartridge connection ports inside hinged cover (Upper and lower cartridge air tubes and the water connection ports)
  - Water inlet and air inlet connectors on rear of unit
  - Delivery tube port on the bottom of unit.

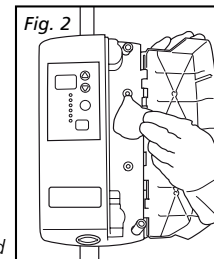


Fig. 2

### 1.4 Set-up

- Take the 4 inch bypass tube with 90° barb fittings (Bypass Tube A) and wipe the ends with an approved disinfectant wipe. Press firmly into the inner cartridge connection ports (water circuit). (Fig. 3)
- Take the 6 inch bypass tube with straight barb fittings (Bypass Tube B) and wipe the ends with an approved disinfectant wipe. Insert firmly into outer upper and lower cartridge ports (air circuit). (Fig. 4)

**WARNING:** The Bypass Tubing has been designed to optimize the flow of solutions through the Vapotherm 2000i system. Failure to use the Bypass Tubing supplied by Vapotherm™, Inc. could lead to improper disinfection and/or drying.

- Close hinged cover.
- Prepare 200ml of approved disinfectant solution and add it to Bag A with slide clamp closed (see Appendix A – “Disinfection Solutions” for approved disinfection solutions, appropriate concentrations, and required hold times).

#### WARNINGS:

Disinfection solutions, concentrations and hold times in Appendix A have been verified by independent laboratory testing to adequately disinfect the Vapotherm™ 2000i machine when following these instructions. Modifying this procedure or using an alternative disinfection solution, concentration, or hold time could result in inadequate disinfection thereby increasing the risk of contamination. Always wear gloves when handling disinfectant solutions, work in a well ventilated area, and use an accurate measuring device to ensure the proper concentration of disinfection solution and water.

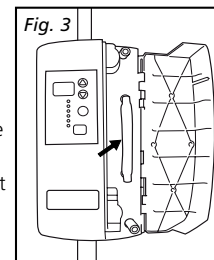


Fig. 3

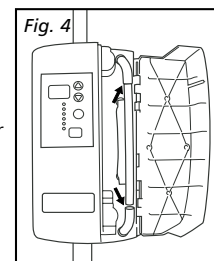


Fig. 4

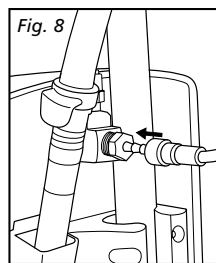
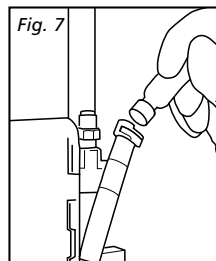
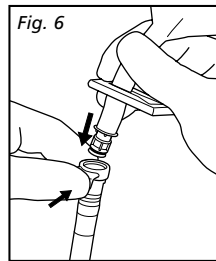
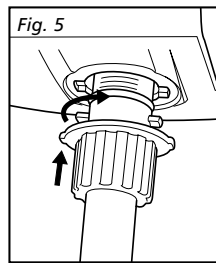
## Routine Disinfecting Protocol

### 1.4 Set-up (cont.)

6. Hang Bag A with 200 ml of approved disinfecting solution from IV pole hook.
7. Wipe blue end of disinfection tube with an approved disinfectant wipe. Insert into bottom port of Vapotherm™ 2000i system. Press firmly into place, rotate 1/4 turn clockwise, and pull down slightly to lock in position. (Fig. 5)
8. Wipe the other end of the disinfection tube with an approved disinfection wipe and attach it to the bottom outlet of Bag A. Lock into place. (Fig. 6)
9. Suspend Bag B on a separate hook on IV pole. Cap should be firmly closed to minimize potential spilling.
10. Attach Y-Spike Assembly by:
  - a. Disinfect wipe male colder fitting end of Y-Spike Assembly and insert into water inlet port on the back of the Vapotherm 2000i system. Lock into place. (Fig. 7)
  - b. Disinfect wipe the O<sub>2</sub> bushing connector end of the Y-Spike Assembly. Attach connector to the air inlet connector port on the back of the Vapotherm 2000i system. (Fig. 8)
  - c. Disinfect wipe the spike end of the Y-Spike Assembly and insert into bottom outlet of Bag B until it comes to a stop.

**WARNING:** If spike is not properly inserted, it may cause disinfectant to leak creating a potential safety risk. The spike should be inserted into Bag B up to the ridge at the bottom of the spike. Do not insert the spike past the ridge at the bottom of the spike.

**NOTE:** If the spike is inserted too far into Bag B it will be difficult to remove, do not insert the spike past the ridge at the bottom of the spike. If the spike is hard to remove from Bag B rotate the spike while removing it to make it easier.



### 1.5 Disinfect Gas and Water Circuits

1. Open clamp on Bag A. Disinfectant will start to drain from Bag A through the unit and into Bag B. (Fig. 9)
2. When disinfectant has stopped draining into Bag B, clamp Bag A.

**NOTE:** Not all contents from Bag A will drain into Bag B.

3. Start the Vapotherm 2000i system in cleaning mode by pressing the Mute and Power buttons at the same time (Fig. 10). Disinfectant will circulate through gas and water circuits.

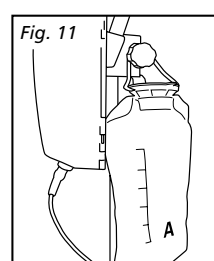
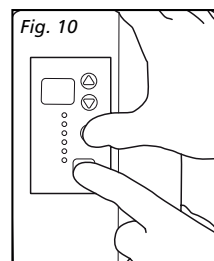
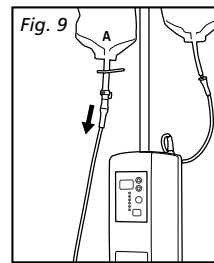
**WARNING:** Operating the Vapotherm 2000i system in cleaning mode for less than the required hold time may not adequately disinfect the machine and could lead to contamination of the air and water circuits thereby increasing the risk of infection.

4. After circulating disinfection solution through the machine for the appropriate hold time, turn the Vapotherm 2000i off by pressing the power button.
5. Unclamp and lower Bag A and hang onto Vapotherm IV pole clamp knob. (Fig. 11)
6. The disinfectant that was contained in reservoir Bag B, has circulated through the unit, and the circulated disinfectant solution drains into Bag A for collection and disposal.
7. Hang 1000 ml of pre-packaged sterile water on IV pole.
8. Loosen cap on Bag A to allow air to vent out of the bag as sterile water fills the bag.

**WARNING:** The disinfection procedure has been specifically designed to use 200 ml of disinfection solution and 1000 ml of sterile water. Bag A is designed to hold 1200 ml of solution. Using larger than the recommended volumes during disinfection or rinsing could cause a spill of diluted disinfection solution.

9. Close the clamp on Bag B, remove the spike, and discard the Bag B in accordance with all applicable regulations and institutional guidelines.
10. Wipe spike with an approved disinfectant wipe and firmly insert into the spike port of a prepackaged sterile water bag. Confirm that water is flowing.
11. Immediately start the Vapotherm 2000i in cleaning mode by pressing the Mute and Power buttons at the same time. (Fig. 10)
12. Run the cleaning mode to circulate the sterile water through the Vapotherm 2000i system until all the water has drained from the sterile water bag. Immediately turn off the system.
13. Clamp tubing and close cap on Bag A and disconnect the bag from the disinfectant tube.

**CAUTION:** Running the system dry can damage the water pump.



**WARNING:** Failure to clamp off or close the cap of Bag A firmly before disconnecting it from the disinfection tube could cause diluted disinfection solution to spill.

14. Leave all DK-301 tubing connected to the Vapotherm system.
15. Dispose contents of Bag A in accordance with all applicable regulations and institutional guidelines.

### 1.6 Drying

1. Ensure that the Disinfectant Tube, Cartridge Bypass Tubes and the Y-Spike Assembly are all in place.

**CAUTION:** In order to dry the Vapotherm 2000i system, the Disinfectant Tube, Bypass Tubes and the Y-Spike Assembly must all be connected to the Vapotherm 2000i system.

2. Remove the spike from the empty sterile water bag and wipe with an approved disinfectant wipe.
3. Insert spike from Y-Spike Assembly into standard oxygen tubing.
4. Set flowmeter to 15 lpm.
5. Take the Vapotherm 2000i system and position the system flat on its side opposite the cartridge door for 2 minutes. (Fig. 12)
6. After 2 minutes attach the Vapotherm 2000i device back on the IV Pole and continue to dry at 15 lpm for 25 minutes.
7. After a minimum of 25 minutes, disconnect the disinfection tube, the cartridge By-Pass tubing and Y-Spike assembly and close the door to the cartridge area for storage. Discard all components of the DK-301 kit in accordance with all applicable regulations and institutional guidelines.
8. Wipe down exterior casing with disinfectant wipe.
9. Place a sticker over the cartridge access door to certify that the device has been disinfected.
10. Log the disinfection procedure on a Vapotherm 2000i Disinfection Log Sheet or in a similar log approved by your institution. Appendix B has a Sample Disinfection Log. The Disinfection Log can be accessed and printed out at [www.vtherm.com](http://www.vtherm.com).
11. Place the system in a clean plastic cover and seal the end by tying a knot or a clip.
12. The system is now ready for use or storage.

**CAUTION:** Do not set the flowmeter above 35 lpm or start the drying process without the disinfecting tube in place. This can cause damage to the pressure transducers in the Vapotherm 2000i system.

### WARNING:

Gram (-) bacteria can grow in moist environments. The Vapotherm 2000i system should not be stored with visible water remaining in the device.

Vapotherm should be disinfected after each patient or every 30 days on a single patient. Do not disinfect in an open patient care area.

The DK-301 disinfection kit is a single use item and must be discarded after the disinfection procedure.