

Vapotherm 2000i Post Recall Frequently Asked Questions

Use Recommendation FAQs

Describe the proposed new use recommendations?

Vapotherm has released a revised Operating Instruction Manual which is available online at www.vtherm.com/customers. The revised manual is “Rev. D” and outlines all of the use recommendations for the Vapotherm 2000i. These modifications have been submitted to FDA as corrective actions for their review. Vapotherm firmly believes that these modifications have addressed the issues leading to the recall. Customers will be notified immediately if FDA or Vapotherm recommends any additional changes. The changes include:

- 1) Instructions for a new accessory, the Vapotherm Spike Set (VSS1), and a recommendation that the device be used with USP water for inhalation (sterile water) in a “closed system”
- 2) A modified disinfection procedure that uses cartridge by-pass tubes and allows for Control III® or Minncare® disinfectant solutions
- 3) Additional recommendations and warnings about using Standard Precautions and aseptic technique
- 4) A recommendation that the cartridge be used on a single patient basis until a reprocessing procedure can be validated and cleared for use.

How has the disinfection procedure changed?

The new disinfection procedure is similar to the two bag procedure released to the market in October 2005 with a few modifications. The new procedure allows the operator to use Control III® or Minncare® and disinfects the device alone without the cartridge in place using by-pass tubing. It also has a step to dry the unit before storage.

How did Vapotherm select the recommended disinfectant solutions?

Vapotherm selected two readily available hospital disinfectants and performed testing to ensure that the solutions, used in combination with Vapotherm’s recommended disinfection procedure, could produce a six log reduction of common hospital pathogens such as *Staphylococcus aureus*, *E. coli*, and *Pseudomonas aeruginosa*.

If the device is going directly back into service after it is disinfected do I still need to dry the device?

Yes, the proposed revised disinfection procedure requires the device to be dried as part of the disinfection process.

Why is the disinfection kit a single patient use item?

Although VapoTherm can provide recommended storage conditions, the company cannot control how the disinfection kit is actually stored in between uses. Improper storage conditions may affect the overall efficacy of the disinfection process. In an abundance of caution, VapoTherm's disinfection kit is now a single use disposable component of the system.

What should I do with old Vapor Transfer Cartridges (VTC)?

Used vapor transfer cartridges should be discarded. Unopened VTCs (VT01-A and VT01-B) can be returned to your distributor for an exchange. The product code for the High Flow Vapor Transfer Cartridge is now VT01-AS and the Low Flow Cartridge is now VT01-BS.

Can the VTC be reprocessed?

The Vapor Transfer Cartridge is currently a single patient use disposable item and can not be reprocessed. The proposed new Operating Instruction Manual has a warning against reprocessing and reusing the VTC. The Company is working to validate a reprocessing procedure but does not currently recommend reusing the cartridge.

Why is the VTC a single patient disposable?

VapoTherm is preparing validation studies to support a reprocessing procedure and multiple patient use for the VTC. However, until such procedures are cleared by FDA, the Company decided to seek clearance of the new version of the device with a single patient use disposable cartridge.

Technical & Regulatory FAQs

What kind of documentation will the hospital receive to verify that the unit has been processed through the recall?

The hospital will receive a letter documenting that the unit was processed through the recall with each VapoTherm 2000i device in a packing sleeve attached to the box.

Should our infection control department take culture samples of the device?

The Centers for Disease Control (CDC) does not recommend random microbiologic sampling in health-care facilities because there are not well defined standards for testing and it can be hard to interpret what is found. The following information is quoted from the CDC's MMWR (270, 343) "Do not conduct random, undirected, microbiologic sampling of air, water, and environmental surfaces in health-care facilities."

What was done to my device during the recall?

All devices were inspected and functionally checked. Any defective parts were replaced and the devices were disinfected using a validated 1000ppm chlorine dioxide procedure. The devices were then dried, packaged, and stored for shipment back to customers.

Why did the recall last so long?

VapoTherm conducted a comprehensive investigation into all reports of contamination. The Company also conducted verification and validation testing on all the proposed corrective actions. Those activities required clearance by FDA before they could be implemented and the devices could be shipped back to customers.

Has the CDC finished their investigation and will they release another MMWR summarizing all their findings?

Yes, the CDC has completed its investigation. They issued a document to VapoTherm summarizing the results of testing conducted in their lab as of September 1, 2006 which is available upon request. They have also indicated to VapoTherm that they will publish a final update in the MMWR.

Has a source of the reported contamination been identified?

No, VapoTherm, the CDC, and FDA never identified a source for the reported contamination. However, VapoTherm has taken actions to address all potential sources of intrinsic contamination. The Company's corrective actions have been the subject of numerous submissions to FDA and the CDC.

Business FAQs

Will Vapotherm extend my warranty?

Yes, Vapotherm will extend the warranty for any Vapotherm 2000i device that was still under warranty when the recall was initiated. The warranty will be extended by one year to account for the recall period.

Do I still need to have the annual preventative maintenance performed on the device?

Yes, you should still perform the regular preventative maintenance required for the devices on the same schedule. For instance, if your device is due for annual maintenance in April it should be sent in for preventative maintenance at that time. All devices were inspected and functionally checked and all problems were fixed but preventative maintenance was not performed if the device was functioning properly.

What should I do with my unopened Vapor Transfer Cartridges (VT01-A and VT01-B)?

Unopened cartridges should be returned to your distributor for an exchange.

What should I do with used cartridges from before the recall?

Used cartridges should be discarded.

What should I do with CK-101 and DK-201 kits?

Unopened CK-101 and DK-201 kits should be returned to your distributor for an exchange.

What should I do with Vapotherm WR1200 water bags?

Unopened cases of WR1200 water bags can be returned to the distributor for an exchange.