



VAPOTHERM

The accepted standard in
high flow therapy

Vapotherm 2000i Recall Release Information

December 1, 2006 Stevensville, MD

Presentation Overview

- Vapotherm Investigative Testing
- Vapotherm Validation Testing
- Vapotherm Corrective Actions

Investigative Testing

FDA Microbiological Testing

- The FDA obtained un-opened disposables from VapoTherm, its distributors, and hospital customers including unopened cartridges from a hospital that reported *Ralstonia* contamination
- The FDA found NO CONTAMINATION in any of the disposables they tested (water bags, delivery tubes, cannulas, or cartridges) including 4 cartridges collected from a hospital that reported intrinsic contamination of unopened cartridges¹

1) FDA Laboratory Testing obtained by VapoTherm through the Freedom of Information Act (FOIA)



CDC Microbiological Testing

- The CDC tested 26 unopened cartridges from 13 different lots and found NO intrinsic contamination²
- A VapoTherm 2000i device heavily contaminated with the “outbreak” strain of *Ralstonia* was disinfected with 1000ppm ClO₂ by the Company and the water circuit was monitored by the CDC for 30 days – there was NO *Ralstonia* re-growth²
- The same VapoTherm device was disinfected by CDC representatives using Control III and condensate was collected from the devices for 30 days – there were NO organisms recovered in any of the samples²

2) Testing Report provided to VapoTherm by the CDC and available upon request



CDC National Investigation

- Up to 32 hospitals reported potential *Ralstonia* contamination over a ten month period in 2005
- Ten states showed a similar genetic strain of *Ralstonia*
- Up to eight potential patient infections reported to CDC using a physician reporting tool
- Vapotherm investigated a potential death reported to CDC and found no evidence of correlation
- During the investigation timeframe Vapotherm sold over 100,000 delivery tubes



Vapotherm Validation Testing



Validation Studies

- Microbial efficacy validation testing was conducted by Nelson Laboratories, a well respected FDA registered lab in Utah
- Validation testing was designed in accordance with applicable ANSI, AAMI, ASTM, and FDA guidance documents

Minnicare® Validation Studies

- VapoTherm 2000i devices were challenged with $>10^6$ cfu/ml of *Staph*, *Pseudomonas*, and *E.coli* and disinfected with 1% Minnicare® using VapoTherm's recommending procedure.
- The average log reduction was 8.5 log reduction/device and every replicate was greater than a 6 log reduction



Control III® Validation Studies

- Vapotherm 2000i devices were challenged with $>10^6$ cfu/ml of *Staph*, *Pseudomonas*, and *E.coli* and disinfected with 0.8% Control III® using Vapotherm's recommended procedure
- The average log reduction was 7.9 log reduction/device and every replicate was greater than a 6 log reduction

1000ppm ClO₂ Disinfection Procedure Validation Studies

- Disinfection Procedure performed as a corrective action during the Recall Process
- Vapotherm 2000i devices were challenged with $>10^6$ cfu/ml of *M.terrae*
- The average log reduction was 8.5 log reduction/device and every replicate was greater than a 6 log reduction

1000ppm ClO₂ Disinfection Procedure Quality Control (QC) Testing

- Vapotherm performed random QC testing of devices processed through the recall to monitor the efficacy of the procedure
- QC testing established that there is a 95% Confidence Interval that Vapotherm 2000i devices processed through the recall were acceptable for release

Corrective Actions

Vapotherm Spike Set (VSS1)

- Vapotherm developed an accessory, the VSS1, which allows users to connect the Vapotherm 2000i device directly to a standard sterile water bag
- Revised use recommendations require the use of USP water for inhalation (sterile water) with the Vapotherm 2000i in a “closed system”
- The VSS1 and revised use instructions are designed to mitigate the risk associated with the uncontrolled nature of tap water and an “open system”

DK-301 Disinfection Procedure

- The DK-301 disinfection procedure is very similar to the “two bag” procedure released in October 2005 except that the new procedure disinfects the 2000i without the cartridge in place using bypass tubing.
- The DK-301 procedure allows operators to choose between Minncare® and Control III® disinfectant solutions
- The procedure has been validated to produce a 6 log reduction in vegetative organisms with both disinfectants

Single Use Disposables

- Vapotherm recommends that all disposable components of the Vapotherm 2000i System be used on a single patient use basis:
 - Vapor Transfer Cartridge
 - Delivery Tube
 - Cannulas
 - Vapotherm Spike Set
 - Disinfection Kit – 301

Revised Instructions For Use (IFU)

- Revised IFU increase emphasis on:
 - Aseptic technique
 - Routine disinfection in between every patient or every 30 days, whichever comes first
 - A requirement that the device be disinfected outside the patient care environment
 - A recommendation to maintain a “closed” water circuit with sterile water using the VSS1

New Job Aids & Instructional Material

- Vapotherm has developed new job aids and instructional material for the Vapotherm 2000i:
 - In-service video (available online and in DVD)
 - E-learning courses

The Vapotherm Innovation Program

Vapotherm is committed to being the thought leader in High Flow Therapy (HFT™) and is striving to continually improve all aspects of humidified high flow therapy via a nasal cannula. The Vapotherm product development team has a number of exciting innovations on the horizon and we would like to thank you for all of your support and encouragement over the last year.

