A National Outbreak of Ralstonia mannitolilytica Associated With Use of a Contaminated Oxygen-Delivery Device Among Pediatric Patients


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OBJECTIVES. In August 2005, the Centers for Disease Control and Prevention was notified of a *Ralstonia* species outbreak among pediatric patients receiving supplemental oxygen therapy with the Vapotherm 2000i (Vapotherm, Inc, Stevensville, MD). The Vapotherm 2000i is a reusable medical device that was used in >900 hospitals in the United States in 2005. *Ralstonia* are waterborne bacilli that have been implicated in hospital-acquired infections. We initiated an investigation to determine the source of the outbreak and implement infection control and prevention measures.

PATIENTS AND METHODS. We performed a case-control study at 1 hospital and conducted national case findings to obtain clinical and environmental samples for laboratory analysis. Case-patients had health care–acquired *Ralstonia* colonization or infection. Isolates were compared by using pulsed-field gel electrophoresis. We tested manufacturer-recommended disinfection protocols for the Vapotherm 2000i under simulated-use conditions.

RESULTS. Case-patients at the hospital (*n* = 5) were more likely to have received Vapotherm therapy than controls. Nationally, *Ralstonia mannitolilytica* was confirmed in 38 patients (aged 5 days to 7 years); 35 (92%) of the patients were exposed to the Vapotherm 2000i before recovery of the organism. Pulsed-field gel electrophoresis showed related *R. mannitolilytica* strains from isolates sent from 18 hospitals in 12 states. A Vapotherm machine reprocessed with a protocol proposed by the manufacturer grew *Ralstonia* spp after 7 days of simulated use. In December 2005, Vapotherm recalled the 2000i.

CONCLUSIONS. Our findings suggest intrinsic contamination of Vapotherm devices with *Ralstonia* spp. New medical devices may provide therapy equivalent to current devices yet pose novel reprocessing challenges.

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The views in this article are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

Key Words
*Ralstonia*, oxygen inhalation therapy, infant, equipment contamination, infection control, intrinsic contamination

Abbreviations
FDA—Food and Drug Administration
PMA—premarket approval
CDC—Centers for Disease Control and Prevention
OR—odds ratio
PFGE—pulsed-field gel electrophoresis
ClO₂—chlorine dioxide

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275) published in the public domain by the American Academy of Pediatrics
RALSTONIA SPECIES ARE Gram-negative bacilli that are commonly found in moist environments, such as water and soil, or on plants. They were implicated previously in health care-associated outbreaks, primarily because of contamination of patient care solutions.1–3 Ralstonia are opportunistic human pathogens, particularly among immunocompromised patients,4–6 and are an infrequent cause of infection. From January through April 2005, Ralstonia spp were recovered from respiratory cultures taken from 5 patients at hospital A, a pediatric hospital in Philadelphia, Pennsylvania. No Ralstonia spp had been recovered from patients at this hospital in the previous 2 years. Before culture, 4 of 5 patients were treated with the Vapotherm 2000i (Vapotherm, Inc, Stevensville, MD), a device that delivers humidified, warmed oxygen via nasal cannula. This portable oxygen-delivery device uses a 0.01-μm reusable filter cartridge to separate its air and water compartments and was used widely by neonatal clinicians, with ~5000 units used in >900 hospitals in the United States in 2005. A diagram of the Vapotherm device is shown in Fig 1.

The Vapotherm 2000i was originally cleared for marketing by the Food and Drug Administration (FDA) in August 2000 under a premarket-notification [510(k)] submission. The 510(k) process allows marketing of new medical devices on the basis of their comparability to legally marketed devices with the same intended use. This differs from the FDA’s premarket-approval (PMA) process for certain new or high-risk devices, which requires demonstration of a reasonable level of safety and effectiveness before approval.7 In 2000, almost 99% of new medical devices that were cleared for marketing were reviewed through the 510(k) process.8

In August 2005, hospital A and the Pennsylvania and Philadelphia Departments of Health invited the Centers for Disease Control and Prevention (CDC) to assist in an investigation.

PATIENTS AND METHODS

Hospital A Investigation

We conducted a matched case-control study at hospital A to delineate risk factors for health care-associated Ralstonia spp colonization or infection. A case-patient was defined as any patient from whom ≥1 Ralstonia culture was recovered from a clinical specimen between December 1, 2004, and August 31, 2005. Patients in whom Ralstonia was believed to be present before hospitalization were excluded.

Four controls were selected for each case. Cases and controls were individually matched on length of hospitalization. To ensure that patients with unrecognized Ralstonia colonization were not selected as controls, we limited control selection to patients who had chart documentation of a respiratory culture that did not grow Ralstonia. Information on potential risk factors for respiratory infection was abstracted from medical charts.

Assessment of the association between case status and categorical exposure variables was determined using the Cochran-Mantel-Haenszel statistic, with strata defined by match group. An adjusted odds ratio (OR) for each exposure was derived via the logit estimate9; 0.5 was added to each cell because of small stratum-specific sample size,10 and tables with a 0 sum row or column were not included in the computation. Statistical analyses were performed by using SAS 9.1 (Statistical Analysis System, Cary, NC).

On the basis of observations of infection control practices at hospital A, environmental samples of potential sources of Ralstonia spp were obtained and sent to the CDC. These included hospital potable water, ice from ice...
machines, sterile water, condensate from 2 mechanical ventilators, sterile respiratory solutions, used and unused Vapotherm filter cartridges, and surface swabs from 4 Vapotherm devices.

National Investigation
Because the Vapotherm 2000i is used in hospitals throughout the country, we conducted national case-finding via respiratory therapy, infectious disease, infection control, and public health communication networks to identify additional patients with *Ralstonia* spp colonization or infection. Institutions were asked to submit patient information and clinical and environmental isolates for identification and molecular testing. Probable cases were those in which *Ralstonia* was reported between January 1, 2005, and March 1, 2006, but no isolate was available for testing at the CDC. Confirmed cases had clinical isolates that were identified as *Ralstonia* spp in CDC laboratories. Differences between infected and colonized patients were measured by using the Mann-Whitney test statistic for continuous variables and the χ² test statistic for categorical variables.

Microbiology
Vapotherm filter cartridges were flushed with 45 mL of sterile water, phosphate-buffered saline, or Dey-Engley neutralizing broth (Becton Dickinson, Franklin Lakes, NJ). The resulting eluent was processed by membrane filtration through a 0.45-µm pore size, 47-mm mixed cellulose ester membrane filter (Millipore Corporation, Bellerica, MA) or by centrifugation at 3500 g for 15 minutes. Surface swabs of Vapotherm devices were obtained from air ports on the filter cartridge, air connections on the Vapotherm machine, and the machine port delivering humidified oxygen to the patient. Vapor samples were obtained from operating devices by connecting the oxygen-delivery tube to a sealed, sterile container and collecting the resulting condensate.

The CDC also cultured tap water used during the calibration step of new Vapotherm devices manufactured in Ireland. Environmental water and ice samples were collected with sodium thiosulfate to neutralize residual chlorine.

All samples were cultured on Trypticase soy agar with 5% sheep blood (Becton Dickinson), MacConkey II agar (Becton Dickinson), and R2A agar. Identification of isolate species was performed by using the Vitek 2 automated instrument (bioMérieux, Durham, NC) in combination with a series of standard biochemical tests.11

Molecular Typing
After digestion of chromosomal DNA with SpeI, molecular typing by pulsed-field gel electrophoresis (PFGE) was performed as described previously.12 PFGE patterns were compared by using Bionumerics 3.5 software (Applied Maths, Austin, TX), and isolates were considered related if Dice coefficients were >80% similar. For comparison, we obtained isolates of *Ralstonia mannitolylitica*, collected several years before the start of the current outbreak, from the *Burkholderia cepacia* Research Laboratory and Repository (University of Michigan, Ann Arbor, MI). PFGE analysis was also used to confirm species identification, demonstrating that *Ralstonia pickettii* isolates were genetically distinguishable from *R. mannitolylitica* isolates.

Testing of New Reprocessing Protocols
During the investigation, Vapotherm proposed 2 new disinfection protocols for its machines and cartridges. The CDC assessed the efficacy of each protocol on a machine that was known to be contaminated with *Ralstonia*. One protocol recommended circulating 200 ppm chlorine dioxide (ClO₂) in the device fluid path for 10 minutes with the filter cartridge in place. To test this protocol, vapor samples were obtained at 3 time points: before reprocessing, immediately after reprocessing, and after 7 days of continuous device operation outside of patient care areas.

The second protocol recommended circulating 1000 ppm ClO₂ in the device fluid path for 1 hour without a filter cartridge. This protocol was performed on a contaminated machine by Vapotherm personnel in Stevensville, MD; the machine was then shipped to the CDC. Vapor samples were obtained at 6 time points: before reprocessing, immediately after reprocessing, every 7 days for 21 days, and on day 30. During this period, the machine was run continuously in a CDC laboratory.

RESULTS
Hospital A Investigation
From January 1, 2004, to September 1, 2005, 5 case-patients were identified. Three patients had respiratory cultures that grew *R. mannitolylitica*; 2 patients had respiratory cultures that grew *R. pickettii*. Case-patient status was significantly associated with exposure to a Vapotherm device within 30 days before recovery of *Ralstonia* (OR: 18; 95% confidence interval: 2.2–140). No other exposures, including mechanical ventilation, were significantly associated with *Ralstonia* recovery (Table 1). Multiple *Ralstonia* spp were isolated from surface swabs taken from each of the Vapotherm devices that were tested (n = 4), whereas samples of hospital potable water, sterile water, ice, 2 mechanical ventilators, and sterile respiratory solutions did not grow *Ralstonia*. *Ralstonia* spp were also recovered from 10 (71%) of 14 used filter cartridges and 0 of 5 unused cartridges.

National Investigation
The CDC received reports of 45 patients from 20 hospitals. Three patients had respiratory cultures that grew *R. mannitolylitica*, collected several years before the start of the current outbreak, from the *Burkholderia cepacia* Research Laboratory and Repository (University of Michigan, Ann Arbor, MI). PFGE analysis was also used to confirm species identification, demonstrating that *Ralstonia pickettii* isolates were genetically distinguishable from *R. mannitolylitica* isolates.

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cases of *Ralstonia* (mean: 4 patients; range: 2–7 patients), whereas the remaining 11 (55%) each reported a single case. Isolates from 38 patients (84%) were confirmed by the CDC as *R. mannitolilytica*; isolates were not available for 7 cases. All 38 confirmed cases were pediatric patients (age range: 5 days to 7 years), and 35 (92%) were exposed to Vapotherm before recovery of *Ralstonia*.

For patients exposed to Vapotherm, median exposure time was 9 days (range: 1–121 days), and median duration between last Vapotherm exposure and first positive culture was 4 days (range: 0–38 days). In 8 cases (21%), the reporting clinician indicated that *Ralstonia* had caused an infection, whereas the remaining cases were believed to represent colonization. Infected patients were significantly younger (*P* = .002) than colonized patients and were more likely to have fever >38°C (*P* = .031), develop leukocytosis according to the treating clinician (*P* < .001), display evidence of pneumonia on chest radiography (*P* = .034), and receive antibiotic therapy to treat *Ralstonia* (Table 2). One infection (3%) was reported by the treating physician to have complicated the course of an infant’s underlying lung disease, possibly contributing to the patient’s death. Confirmed cases were identified from January 2005 to January 2006, and 24 (63%) of 38 were reported after the field investigation at hospital A (Fig 2).

### Microbiology

The CDC received 134 clinical and environmental isolates from 22 hospitals in 13 states: 111 (83%) were identified as *R. mannitolilytica* (38 clinical, 73 environmental). Two hospitals reported recovery of *R. mannitolilytica* from unused Vapotherm cartridges. One facility recovered *R. mannitolilytica* from 3 of 3 unused cartridges from a single lot; the other facility recovered *R. mannitolilytica* from 3 of 10 unused cartridges from 3 different lots. The CDC tested 26 new cartridges from 13 separate lots (including 2 lots from which contaminated new cartridges were reported) and failed to isolate any organisms.

Microbiologic analysis of samples taken from the Ireland facility where Vapotherm machines were calibrated yielded *Sphingomonas paucimobilis* from cultures of tap water and *B. cepacia* from swabs of the tap from which the water was drawn.

### Molecular Typing

Dice coefficients generated from analysis of the PFGE data for 111 isolates of *R. mannitolilytica* ranged from 100% to 59% relatedness. Clinical and environmental isolates from 18 (82%) of 22 hospitals in 12 noncontiguous states (Fig 3) were related, including isolates from 31 confirmed cases (82%). None of the 9 reference *R. mannitolilytica* isolates obtained before the outbreak began

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**Table 1**

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Cases <em>(N = 5), n (%)</em></th>
<th>Controls <em>(N = 20), n (%)</em></th>
<th>OR <em>(95% Confidence Interval)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Vapotherm use within 30 d</td>
<td>4 (80)</td>
<td>1 (5)</td>
<td>18 (2.2–140)</td>
</tr>
<tr>
<td>Ventilator use within 7 d</td>
<td>4 (80)</td>
<td>18 (90)</td>
<td>0.3 (0.01–8.2)</td>
</tr>
<tr>
<td>Nasogastric feeding</td>
<td>3 (60)</td>
<td>10 (50)</td>
<td>2.0 (0.1–31)</td>
</tr>
<tr>
<td>Inhaled medication</td>
<td>3 (60)</td>
<td>13 (65)</td>
<td>0.8 (0.1–3.9)</td>
</tr>
<tr>
<td>Cardiac ICU stay</td>
<td>3 (60)</td>
<td>3 (15)</td>
<td>5.1 (0.71–38)</td>
</tr>
<tr>
<td>Diagnosed cystic fibrosis</td>
<td>1 (20)</td>
<td>0 (0)</td>
<td>4.7 (0.75–29)</td>
</tr>
</tbody>
</table>

*a* Logit estimate for Cochran-Mantel-Haenszel test statistic.

**Table 2**

<table>
<thead>
<tr>
<th></th>
<th>Infected <em>(N = 8), n (%)</em></th>
<th>Colonized <em>(N = 30), n (%)</em></th>
<th><em>P</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age, d</td>
<td>14</td>
<td>56</td>
<td>.002</td>
</tr>
<tr>
<td>Male</td>
<td>3 (38)</td>
<td>17 (59)*</td>
<td>.289</td>
</tr>
<tr>
<td>Vapotherm exposure before culture</td>
<td>7 (88)</td>
<td>28 (93)</td>
<td>.587</td>
</tr>
<tr>
<td>Premature birth</td>
<td>6 (75)</td>
<td>23 (77)</td>
<td>.922</td>
</tr>
<tr>
<td>Fever &gt;38°C</td>
<td>4 (50)</td>
<td>3 (13)*</td>
<td>.031</td>
</tr>
<tr>
<td>Leukocytosis</td>
<td>6 (75)</td>
<td>2 (9)*</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Pneumonia by chest radiography</td>
<td>5 (63)</td>
<td>5 (22)*</td>
<td>.034</td>
</tr>
<tr>
<td>Antibiotic therapy for <em>Ralstonia</em></td>
<td>8 (100)</td>
<td>8 (35)*</td>
<td>.001</td>
</tr>
</tbody>
</table>

*a* Mann-Whitney test used for age variable; *χ*² test used for all other variables.

* One missing value.

* Seven missing values.
was related to these isolates. Hospitals from 10 additional states reported recovery of *Ralstonia* spp but either did not submit an isolate for confirmation or submitted isolates that were not related.

**Testing of New Reprocessing Protocols**

No organisms were recovered from the Vapotherm device tested immediately after disinfection with 200 ppm ClO₂. However, *R. mannitolytica* grew in the device 7 days after reprocessing. After disinfection with 1000 ppm ClO₂, fewer than 10 cfu/mL of *Methylobacterium* species were recovered from samples taken immediately after reprocessing and on day 3. No organisms were recovered from cultures performed 7, 14, 21, or 30 days postreprocessing.

**DISCUSSION**

Our investigation demonstrates that contamination of a respiratory gas humidification device resulted in the recovery of *R. mannitolytica* from patients in hospitals in 22 states. The organism could not be eradicated by using the manufacturer’s recommended disinfection protocol. Although generally of low virulence, *Ralstonia* spp can cause potentially serious health care-associated infections.³¹³¹⁴ This investigation, which epidemiologically and microbiologically linked transmission of *Ralstonia* to the Vapotherm 2000i humidification device, represents the largest reported outbreak associated with *R. mannitolytica* known to the authors. Genetically related strains in disparate geographic locations suggest intrinsic contamination of the Vapotherm 2000i as the cause of the outbreak (Fig 3), although the source of this contamination has not been identified. Because water is used to manufacture or calibrate both the Vapotherm device and its filter cartridge, contamination during the production of 1 these components represents the most likely explanation for this outbreak.

Intermittent cartridge contamination is 1 possibility. Although the CDC did not recover organisms from the unopened cartridges it tested, 2 hospitals reported recovery of *Ralstonia* spp from unopened filter cartridges. However, cartridges are manufactured by using deionized water subject to reverse osmosis and subsequently undergo high temperature drying and annealing (150°F for 4 hours, followed by 250°F for 40 minutes), which makes introduction and survival of organisms unlikely.

Another explanation for the outbreak is the introduction of *R. mannitolytica* into Vapotherm components during device calibration. Before the investigation, tap water was used to calibrate devices during manufacturing, and they were packaged for distribution before drying completely. Organisms in residual water in the machines could have formed biofilms in device tubing during shipping and storage,¹⁵ rendering them less susceptible to disinfection.¹⁶ *Ralstonia* spp are known to exhibit biofilm formation in plastic water piping.¹⁷ Once present in the devices, *Ralstonia* may have persisted because of a combination of factors, including warm and moist operating conditions that would promote bacterial growth, failure of end users to reprocess the devices on a consistent basis, and inability of the manufacturer’s original disinfection process to eradicate biofilms.

The results of this investigation are subject to several limitations. First, the source of Vapotherm device contamination was not identified. The CDC was unable to recover organisms from unopened cartridges, and *Ralstonia* spp were not recovered from water samples taken from the manufacturing plant. However, other waterborne microorganisms, including *S. paucimobilis* and *B. cepacia*, were found in the water source used for cali-
bration. Water samples sent to the CDC were collected several months after the proposed inoculation had occurred, long enough for the microbial flora of the water to have changed, obscuring evidence of *Ralstonia* contamination at an earlier time point.

A second limitation stems from the limited information describing the genetic diversity of *R. mannitolilytica* in the United States. If *R. mannitolilytica* has only marginal diversity, then the finding of genetically related strains in several states may not imply intrinsic contamination of the Vapotherm device. Because *Ralstonia* spp are ubiquitous environmental organisms, the outbreak could have resulted from concomitant but unconnected contamination with apparently related strains. However, our investigation helps show that such genetic uniformity is unlikely. Twenty-two percent of tested *R. mannitolilytica* isolates showed PFGE patterns that were <80% related to the predominant strain. Furthermore, comparison isolates of *R. mannitolilytica* obtained before the start of the outbreak were not related to isolates collected during the investigation.

The Vapotherm 2000i was cleared for marketing through the premarket-notification 510(k) process with the indication, “To add moisture to, and to warm breathing gases for administration to patients.” Unlike PMA submissions, which require data that demonstrate the safety and efficacy of devices, manufacturers of devices submitted for 510(k) review are generally not required to submit design and manufacturing test data to the FDA. Instead, a 510(k) submission relies on demonstration of “substantial equivalence” to a “predicate device” that has already been cleared for marketing. A new device is considered substantially equivalent if it has the same intended use and technologic characteristics as the predicate device and does not raise new questions of safety and effectiveness. Device manufacturers seeking to market through the 510(k) process can claim reprocessing efficacy if their products are “virtually identical from an infection control perspective to a predicate device for which disinfection has been validated.” The FDA granted the Vapotherm 2000i clearance on the basis of a comparison to other marketed respiratory gas
humidity. There are, however, unique aspects of the Vapotherm 2000i that distinguish it from other gas humidifiers from an infection control perspective. Respiratory therapy devices like the Vapotherm 2000i, are generally considered semi-critical medical devices, whose reusable components minimally require high-level disinfection between patients. However, reprocessing instructions for reusable components of the Vapotherm device recommended use of a low-level disinfectant between patients. Furthermore, because the Vapotherm 2000i used a reusable 0.01-µm filter cartridge as a "biological barrier" between air and water compartments, tap water was permitted in the device. In its 510(k) Indication for Use Statement, the company stated, "under normal working conditions, there was essentially no risk of bacterial contamination of nasal air flow."23

On the basis of the results of this investigation, the FDA issued a Preliminary Public Health Notification on December 20, 2005, advising health care providers to use alternate devices. On December 22, 2005, Vapotherm recalled the 2000i device. This action was classified by the FDA as a Class I recall, which is reserved for products that have a reasonable chance of causing serious health problems or death.

In response to the outbreak and investigation, Vapotherm introduced changes to their manufacturing process and disinfection and use parameters to address potential sources of device contamination (Table 3). In January 2007, the FDA determined that these modifications satisfied requirements for a 510(k) submission, and the Vapotherm device was reintroduced for use. The CDC and FDA recommend that clinicians intending to use the Vapotherm device follow the latest instructions for the device and its components, which can be obtained by contacting Vapotherm.

This investigation emphasizes the importance of careful attention to infection control principles during the development, regulatory review, and use of medical devices. New devices may perform equivalently to currently marketed devices, but may also present novel reprocessing challenges when used in clinical settings. In recognition of this, the FDA has identified device sterilization as 1 of 3 key areas for improvement for 510(k) submissions. All medical devices have the potential to become contaminated during use, and thereby carry the potential for transmission of infectious diseases. To protect patients from device-associated infections, manufacturers should ensure that reusable devices can be consistently and effectively reprocessed between users. Reusable medical device users should also be aware that review of validation data for reprocessing methods is generally not included as part of the current 510(k) premarket-notification process. Regardless of how devices are cleared for marketing, end users are encouraged to review infection control and reprocessing guidelines under actual-use conditions to help ensure patient safety when using medical devices.

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Our outbreak investigation group included Corey Robertson, MD (New Jersey Department of Health and Senior Services); Corinne Valentinik, MD, Morey Gardner, MD, Brenda Hinson, RN, Amie Keck, RT, and Fran Hixson, RN (St Mary’s Health Center, St Louis, MO); James Ripka, RRT, Claudia Castellon, RN, and Lawrence Ross, MD (Children’s Hospital Los Angeles, Keck School of Medicine, Los Angeles, CA); Daniel New, MD, Lori Patterson, MD, Sheila Ware, RRT-NPS, and Caroline Graber, RN (East Tennessee Children’s Hospital, Knoxville, TN); Susan A. Dolan, RN, John F. James, PhD, and Trent Lucas, RRT (Children’s Hospital, Denver, CO); Abbot Laptook, MD (Women and Infants’ Hospital of Rhode Island, Providence, RI); Barbara Stein, RN (Children’s Hospital of The King’s Daughters, Norfolk, VA); Jane Harper, MS, RN, and Kathleen Harriman, PhD (Minnesota Department of Health, St Paul, MN); Michelle Hulse, MD, and Jane Harper, MS (Children’s Hospitals and Clinics of Minnesota, Minneapolis, MN); Beth

<table>
<thead>
<tr>
<th>TABLE 3 Potential Sources of Intrinsic Contamination of Vapotherm System and Actions Taken by the Manufacturer in Response</th>
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</thead>
<tbody>
<tr>
<td>Potential Cause of Contamination</td>
</tr>
<tr>
<td>----------------------------------</td>
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<tr>
<td>Contamination of machine interior during initial calibration with unfiltered water</td>
</tr>
<tr>
<td>Contamination of vapor transfer cartridge, a component of the device, during manufacture</td>
</tr>
<tr>
<td>Contamination of either the Vapotherm device and/or vapor transfer cartridge during patient use</td>
</tr>
<tr>
<td>Failure to remove organisms during routine decontamination</td>
</tr>
</tbody>
</table>

* Previously, the device used a refillable reservoir bag that created an open water circuit and allowed the use of tap water for humidification.
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