

TEAM INTEGRITY + A GREAT PRODUCT = SUCCESS

THE STORY OF THE VAPOTHERM COMEBACK

by Bob Miglino RRT, MPS

Things are looking up these days at Vapotherm, a respiratory manufacturer located by the Chesapeake Bay in Maryland. In 2008, the Company plans to launch its new acute care device, Precision Flow™ as well as a new line of home care products. The Company is also expanding its reach in the US and abroad as High Flow Therapy is adopted in more and more hospitals. In fact, Vapotherm recently, earned an Export Achievement Certificate from the U.S. Department of Commerce, an award given to companies who have successfully entered the international marketplace. It wasn't too long ago, however, that the Company had to navigate uncharted waters.

As most respiratory therapists, nurses and pulmonary physicians know all too well, the Vapotherm 2000i Respiratory Gas Humidifier System was recalled by Vapotherm in 2005 due to possible contamination with *Ralstonia* spp. cultures.

The FDA noted that premature neonates, immuno-compromised patients and those with underlying respiratory illnesses (such as cystic fibrosis) might be at particularly high risk for infection if exposed to breathing gases from a contaminated Vapotherm device. Though the specific cause for *Ralstonia* spp. had not been identified, Vapotherm, Inc. immediately interacted with its hospital customers, the CDC and the FDA; updating its operating instruction manual (pertaining to disinfection processes) and implementing additional corrective actions to minimize risk to patients. Toward the end of 2005, the Company made the decision to voluntarily recall all devices to investigate root cause and implement any additional needed corrective actions. While clearly a difficult decision for Vapotherm and its customers, this caution and cooperation with regulatory and health agencies is exactly what device manufacturer's should do in these situations since a medical manufacturer's first responsibility is always patient and care-giver safety.

In reality, recalls are fairly common across the device industry, but they are particularly challenging for smaller, private companies to manage from a financial and customer relations standpoint. It must also be remembered that at the time of the recall, the 2000i represented the majority of

Vapotherm's business. End-users also need to appreciate that often, recalls start a vicious cycle that many companies fail to survive. The cycle begins, of course, with a sudden and total loss of income for the company. This often leads to staff layoffs and cut backs in research and development. Then there are the substantial costs associated with recalling product, investigating reports and making any required device or labeling modifications. A recalled product and its modifications or corrective actions then has to be presented and cleared by the FDA. If all goes well there, the company then has the final expense of reintroducing the product to the market. For Vapotherm, a year of lost business and all these costs could have been a fatal blow. But failure was not an option. The therapy was too important and the 2000i was a revolutionary product considered by

just about everyone who's ever used it, to be a true clinical breakthrough. In fact, Vapotherm established the modality of High Flow Oxygen Therapy used in hundreds of hospitals today as a result of their success in finding a way to deliver high flows of breathing

How do patients benefit from Vapotherm's technology?

Humidity - The Vapotherm output is close to 100% relative humidity at body temperature or above and below. Respiratory water loss can be greatly reduced or eliminated, and the high humidity has been found to help mobilize thickened airway secretions.

Warmth - Vapor-saturated respiratory gases are delivered at or above body temperature, so there is no cooling of the airway. Most sensation of nasal flow comes from airway cooling, so even at high flows there is very little sensation with the Vapotherm.

Comfort - The warmth and high humidity contribute to patient comfort. Most patients report that they prefer Vapotherm therapy with a nasal cannula to the use of face masks. Vapotherm use relieves airway irritation, soreness and dryness.

High Flow - Because the Vapotherm is so comfortable to use, high flows are possible. Patients needing high flows of oxygen benefit particularly because they can use a cannula instead of a face mask, and high nasal flow may also reduce shortness of breath and improve gas exchange.

Convenience - A face mask makes it difficult to eat and talk, and may cause distress in claustrophobic patients. The nasal cannula is comparatively unobtrusive and causes much less interference with daily activities.

gases via a nasal cannula. Their patented membrane cartridge was the answer to the question of how to deliver a gas stream that was ideally conditioned (i.e. molecular water vapor, saturated, but without condensation) at high flows at or above body temperature. It had long been known that if a way could be found to foster this concurrence of attributes - flow, humidity and warmth, the result could be used to treat a broad range of indications. Vapotherm developed that answer.

The device itself, and High Flow Therapy as a modality, was proven and being used worldwide but it was going to take more than a good device to survive the recall and make a successful comeback. It was going to take leadership and perseverance. The Vapotherm management team, pictured here, credits a combination of dedicated employees, patient investors and a clear need for the therapy for carrying them through. "For anyone who has seen the great benefits of high flow first hand, there was no question the therapy and the technology was going to survive", said Kevin Thibodeau, VP of Sales and Marketing. "We were fortunate to have the backing of our investors to carry us through a very challenging period. This meant we were able to avoid any staff reductions and continue forward with several new products that were in development including the Precision Flow™. More importantly, we were fortunate to have a very loyal customer

base, one that encouraged us to persevere for the sake of the therapy. We never anticipated the process taking as long as it did, however, and we realize this placed a great strain on our users as well. Probably the most frustrating thing for us was that we were not able to communicate much during the latter stages of the process as we awaited our release. We knew we had a lot of work to do restoring the confidence of many customers, and that job began as soon as we had our release to go back to market".

There was a tremendous amount of hard work, uncertainty and stress for Vapotherm as they worked their way thru



the recall, but they successfully emerged at the end of 2006 and began the task of getting hundreds of customers back up and running. In fact, Vapotherm management said that 2007 had turned out to be a great come back year and that they now looked forward to an even brighter 2008 when they plan to launch several new products.

Doing all this while simultaneously launching a new device is nothing short of amazing, yet that is exactly what was done when Vapotherm introduced their new Precision Flow™ device in December 2007. Precision Flow™ is not a replacement for the 2000i, but decision-makers should take a good look at it since it is the first high flow therapy device to integrate (and that's the important word here) humidification, gas blending, flow control and full alarm functionality into a single device for the delivery of nasal cannula inspired gases. (The company has submitted and is awaiting 501(k) clearance.) Meanwhile, Vapotherm has received their patent license relating to their technology.)

"With Precision Flow™, the respiratory community will have a new option in high flow that includes broader functionality, additional safety features and ease of use. We developed the Precision Flow™ with extensive input from our respiratory therapist customers and we believe the device will meet their stated requirements for performance, safety and cost-effectiveness." said Kevin Thibodeau, Vice President of Sales and Marketing. The triple lumen design is the vital component for Vapotherm products and is used with both the 2000i and the new Precision Flow™. "Our patient delivery circuit design is

Neonatal - Vapotherm's products are used in NICU's and PICU's because they have created a system for delivery of ideally conditioned flows of gases from 1-8 lpm, perfect for these patients. Neonatal and Low Flow Applications utilize a specially designed Vapor Transfer Cartridge developed by Vapotherm. The system allows for the delivery of heated and humidified gases - molecular high humidity - through HFNC™ brand nasal cannula and other neonatal or pediatric patient interfaces such as trach masks and oxyhoods.

unique in the field and provides Vapotherm a competitive advantage through the delivery of optimally conditioned breathing gases all the way to the patient, whereas conventional approaches can result in significant temperature and



Principal Officers - L to R: Kevin Thibodeau, VP Sales and Marketing, Robert Storey, President and CEO, William Niland, Chairman of the Board and Larry Grant, Chief Financial Officer.

humidity loss" said William Niland, Chairman and Chief Business Development Officer at Vapotherm.

The fundamental additions to Vapotherm's new Precision Flow™ product revolve around the control of flow rates and FiO2 management. The 2000i handles these two high flow variables externally. For instance, the Precision Flow™ has an integrated electronic air/O2 blender and flow controllers. The 2000i does not and the user must use standard mechanical blenders and flow meters external to the device. The precision flow also has an oxygen sensor to check set/delivered O2 concentration as well as a back-up battery for transport and safety. Lastly, Precision Flow™ has a completely disposable water path; in fact, the only disinfection process required is simple wipe down. The additional safety features and the integrated flow and blending control make Precision Flow™ ideal for ICU and emergency room environments where ease of use is critical to the practitioner.

Vapotherm is indeed a great example of a small company that has been able to succeed despite some significant challenges. They have two great products, excellent corporate leadership and literally a world of patients who benefit daily from the clinical benefits of their products. The way they handled their recall also sends a message of sound responsibility clinicians around the world can depend on.

For more information, visit www.vtherm.com on-line and see their products up close at the 8th annual FOCUS conference. Vapotherm will be exhibiting in Booth 518.

