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URGENT NATIONWIDE RECALL of Vapotherm® 2000i Respiratory Gas Humidification Devices

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FOR IMMEDIATE RELEASE -- January 24, 2006 --- Vapotherm, Inc., Stevensville, Maryland, is initiating a nationwide recall of all Vapotherm 2000i Respiratory Gas Humidification devices. Some of these devices have been found to contain the *Ralstonia* species of bacteria. *Ralstonia*, as with any gram-negative organism, may cause infection, sepsis and in most severe cases be life threatening.

Health care practitioners should seek alternative respiratory gas humidification devices. Any health care facilities that have the Vapotherm 2000i device **must** return all devices to Vapotherm, Inc. Instructions for return are listed on our recall information website at http://www.vtherm.com/recall or by calling Vapotherm, Inc. at 1-866-827-6843. The "Vapotherm 2000i" label is located on the front of the device on the lower right hand corner. If there is a question in identification of the product please contact Vapotherm for assistance.

This device is used in both the home and in health care institutions for warming and humidifying breathing gases, such as oxygen, delivered by nasal cannula.

The firm first learned that patients were colonized by the bacteria from a Pennsylvania hospital on August 17, 2005, and subsequently issued a voluntary recall of the Vapotherm 2000i on October 13, 2005. FDA has since been apprised of this action.

At this time, the following information is known:

- There are numerous reports of *Ralstonia* colonization, including three reports of infection.
- One hospital, reported a death, but this has not been confirmed by Vapotherm
- 26 hospitals in 16 states have reported positive cultures of *Ralstonia* species from the Vapotherm 2000i device.

Vapotherm's investigation is currently ongoing to identify the source of the *Ralstonia* contamination. In the meantime, Vapotherm's plans include recalling and performing a disinfection process on the units.

The Vapotherm 2000i devices were distributed through specialty distributors in the U.S. and internationally. Consumers with questions regarding this recall may contact the company at 1-866-827-6843, or Kevin Thibodeau at 410-604-3977.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.