# Vent Alarms and Product Safety

**Recent news reports of deaths in the USA related to ventilator alarms have led ventilator users to caution their caregivers about listening for and responding quickly to ventilator alarms. An analysis of the FDA's adverse events' reports showed that problems with ventilator alarms were more frequently related to human error rather than a malfunction of the ventilator.**

The vent alarms may be improperly set or set to sound too low for a caregiver in another room to hear, and caregivers may have silenced the alarms.

In hospitals, "alarm fatigue" can cause nurses to become desensitized to audible alarms, many of which turn out to be false alarms, and thus tune them out.

Last year, the FDA issued an alert to hospitals and nursing facilities, warning that ventilator alarms are going unheard or unattended. The commission that accredits hospitals is revisiting a requirement that alarm safety be a patient safety goal in order for a hospital to be accredited.

Vent user Sandy Stuban suggested to the agency providing two of her caregivers that emphasis on alarm safety be incorporated into their continuing education program for all staff that cares for home ventilator users.

To be proactive on ventilator safety, vent users and health professionals can use the FDA's website:

**MedWatch** – to voluntarily report a serious adverse event, product quality problem, product use error, or "therapeutic nequivalence/ failure" suspected of being associated with the use of an FDA-regulated medical device. www.fda.gov/Safety/MedWatch/HowToReport/default.htm

**MAUDE (Manufacturer and User Facility Device Experience)** – to check a database of adverse events caused by medical devices. It includes voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

**Medical Device Recalls** – to learn about specific vent recalls, go to www.fda.gov/MedicalDevices/Safety/default.htm.

## Be Proactive

Vent users can also be proactive by taking care of their vents and following the instructions in the vent user manual. This includes cleaning the outside of the vent and the tubing, changing the inlet filters, making sure the batteries are operating and fully charged, the humidifier water is clean and other appropriate preventive maintenance for their particular vent. ▲

## Home Mechanical Ventilator Users:

## *Tell Us What You Think About Flying!*

**IVUN is conducting a survey, available in English, Dutch, French and Spanish, that explores the experiences of flying as a ventilator user.**

We ask you to complete it even if you think you will never fly. There are questions for ventilator users as well as for parents, who are invited to share their experiences when traveling with their child.

Please go online at www.ventusers.org/adv/issues.html and complete the survey by **March 5, 2012**.

IVUN is surveying the manufacturers of portable/home use ventilators and numerous airlines, too. What will we do with this information?

IVUN will post a report and a summary of its findings from all three groups on www.ventusers.org and on a poster presented at the joint meeting of the 13th International Conference on Home Mechanical Ventilation and the 4th European Respiratory Care Association Congress March 15-17 in Barcelona, Spain.

*Help us include as many users of home mechanical ventilation as possible. Ask your colleagues and friends to provide their experiences and opinions at www.ventusers.org/adv/issues.html.*