This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FDA SAFETY ALERT:
HAZARDS OF VOLUME VENTILATORS AND HEATED HUMIDIFIERS

September 15, 1993

To: Hospital Administrators and Risk Managers:

This is to alert you that FDA has several reports of patient deaths and injuries resulting from malfunctioning volume ventilators and/or heated humidifiers, and to urge that you take certain precautions to prevent such incidents in the future.

One incident of fire, in which three patients died, is believed to have originated in either a Puritan-Bennett Cascade IA humidifier or in the Puritan-Bennett 7200 series ventilator to which the humidifier was attached. This incident is still being investigated. We have received reports that units from all series of Puritan-Bennett Cascade humidifiers and Puritan-Bennett ventilators have been associated with fires and/or overheating. We also have reports that humidifiers and volume ventilators from other firms have overheated.

In another incident, an employee sustained electrical injury requiring hospitalization when a Puritan-Bennett 7200 series ventilator chassis became electrically live as a result of a damaged power cord inside the unit.

To prevent further deaths and injuries, we recommend that you take the following precautions for all volume ventilators and heated humidifiers used in both health care facilities and homes:

- Immediately remove from service any heated humidifier and/or volume ventilator which has shown signs of overheating, smoking or electrical malfunction (e.g., sparking or causing shocks). Do not return these units to service until they have been evaluated for safety by an authorized factory representative or other authorized personnel and repaired if necessary.

- Use an audible temperature alarm that senses gas temperature in the line delivering gas to the patient on any humidifier used in conjunction with a volume ventilator. Be sure to test the alarm periodically for proper functioning.

- Review the service and maintenance records for volume ventilators and heated humidifiers to assure that they currently meet all service recommendations of the manufacturer. (For example, Puritan-Bennett recommends replacing the thermoswitch in the Cascade I series humidifiers every five years.) Reviewing service records is especially important for used or remanufactured equipment.

- Check power cords regularly for damage both inside and outside the unit.

- Assure that power cords are properly fitted with strain relief devices inside the chassis.

(over)

HFZ-306
U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

FDA SAFETY ALERT:
HAZARDS OF VOLUME VENTILATORS
AND HEATED HUMIDIFIERS

If you have any questions pertaining to this safety alert, please contact Sue Ellen Bounds in the Office of Surveillance and Biometrics, Center for Devices and Radiological Health, FDA, 1390 Piccard Drive, Rockville, MD 20850, FAX 301-594-1967.

Please remember that the Safe Medical Devices Act of 1990 requires hospitals and other user facilities to report deaths, serious illnesses and injuries associated with the use of medical devices, including humidifiers and ventilators, to FDA or to the manufacturer. You may report such incidents by phoning 301-427-7500, by FAXing 301-881-6670, or by writing FDA, CDRH, MDR User Reporting, P.O. Box 3002, Rockville, MD 20857.

Sincerely yours,

D. Bruce Burlington, M.D.
Director
Center for Devices and
Radiological Health