



### **“Getting More Information”**

Because the following document was developed a number of years ago, the contact information is no longer accurate. If you wish to contact the agency with questions, please use the following:

Mail: Office of Surveillance and Biometrics (HFZ 510)  
1350 Piccard Drive  
Rockville, MD 20850

FAX: 240-276-3356

Phone: 240-276-3357

Email: <mailto:phann@cdrh.fda.gov>

**FDA SAFETY ALERT:**  
Hazards of Heated-Wire Breathing Circuits

July 14, 1993

To: Hospital Administrators and Directors of Respiratory Therapy, Anesthesiology, ICU, Nursing Services, Home Healthcare Services, Biomedical/ Clinical Laboratory, and Risk Management:

This is to alert you that heated-wire breathing circuits used with humidifiers for ventilator patients may overheat, soften, and collapse if they are improperly used. FDA has learned of instances in which the breathing circuits melted, resulting in diminished gas delivery, fires, and patient and caregiver burns.

Two factors contribute to this problem:

**1. Electrical incompatibility between the heated-wire breathing circuit and the humidifier.**

Even when the electrical connectors for those heated-wire circuits are physically compatible, they may not be electrically compatible. Although the labeling for newly marketed breathing circuits must specify the humidifiers with which they are electrically compatible, older breathing circuits may not have this information. **If in doubt, users should consult their biomedical engineering support group or the breathing circuit manufacturer.**

**2. Operating the device outside the accepted range of specified flow or minute volumes.**

Recommended minimum and maximum minute volumes are generally listed in the labeling of the humidifier unit or the heated-wire breathing circuit. Operating either above or below these limits could result in melting. To avoid this problem, users should employ a heated-wire breathing circuit that is designed to operate at the desired minute volume.

In laboratory simulation tests conducted under low minute volume conditions, melting was observed primarily where the breathing circuit came into contact with another surface. In actual practice, this could occur if the device came into contact with a patient, bed rail, blanket, or piece of medical equipment. When operating within the range of recommended minute volumes, surface contact has not been found to cause melting. **As an extra precaution, users should not rest the circuit on other surfaces, or cover it with sheets, blankets, towels, clothing or other materials.** Instead, users are advised to use a boom arm or tube-tree to support the breathing circuit.

Please share this important information with staff members who are involved in respiratory care, and in the maintenance of these devices. To help disseminate the message, we are enclosing a notice that briefly summarizes the needed precautions. You may wish to post it in areas where heated-wire breathing circuits are used. Feel free to photocopy the notice as needed.

If you have any questions pertaining to this safety alert please contact:

Office of Training and Assistance

Center for Devices and Radiological Health, FDA

1901 Chapman Avenue, HFZ-240, Rockville, MD 20857,...FAX 301-227-8067.

FDA is interested in information concerning medical device problems. If you are aware of incidents involving heated-wire breathing circuits or any other medical device, you may report them through the FDA Medical Products Reporting Program, MedWatch, by phone at 1-800-FDA-1088 or by FAX at 1-800-FDA-0178. Also, the Safe Medical Devices Act of 1990 (SMDA 90) requires that device user facilities, including hospitals, ambulatory surgical facilities, nursing homes, and outpatient treatment facilities that are not physicians' offices, report device-related deaths, serious injuries, or serious illnesses to the FDA and/or the manufacturer depending upon the circumstances. Please use the procedures established by your facility for reporting such incidents.

Sincerely yours,

D. Bruce Burlington, MD

Director

Center for Devices and

Radiological Health

## **FDA SAFETY ALERT**

### **Hazards of Heated-Wire Breathing Circuits**

The U.S. Food and Drug Administration has learned of instances in which improperly used heated-wire breathing circuits have overheated, softened, or melted, causing diminished gas delivery, fires and burns to patients and caregivers.

To prevent such occurrences, it is important to follow these precautions:

1. Use only those heated-wire breathing circuits labeled for use with specific humidifier being used. When in doubt about whether the breathing circuit is electrically compatible with the humidifier, don't use it without first consulting your biomedical engineering support group or the breathing circuit manufacturer.
2. Make sure the heated-wire breathing circuit has a recommended minute volume compatible with the ventilator settings.
3. Don't cover heated-wire breathing circuits with sheets, blankets, towels, clothing, or other materials.
4. Don't rest the circuits on other surfaces, such as the patient's body, bed rails, blankets, or medical equipment. Instead, use a boom arm or tube-tree to support the breathing circuit.