FDA Public Health Notification: Safety Tips for Preventing Hospital Bed Fires (You are encouraged to copy and distribute this information)

Updated: March 30, 2004 Originally Posted: December 18, 2003

Dear Colleague:

The Food and Drug Administration has received 95 reports of fires involving electrically powered hospital beds since 1993. To help prevent incidents of this kind, we have developed the enclosed lists of safety tips. They apply to all electrically powered healthcare beds. They may be particularly useful for older model beds. One list is intended for the clinical staff and the other for staff responsible for bed maintenance. Please feel free to detach the lists and reproduce them in your institution.

Reporting Bed Fires to FDA

The Safe Medical Devices Act of 1990 (SMDA) requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. FDA is interested in additional data on adverse events of fires involving hospital beds. Healthcare providers employed by facilities that are subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facilities. All other providers may submit their reports to MedWatch, FDA's voluntary reporting program. The reports can be submitted by phone at 1-800-FDA-1088; by fax at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, Maryland 20857, or online at http://www.accessdata.fda.gov/scripts/medwatch/.

Getting More Information

If you have questions regarding this notification, please contact Lily Ng, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland 20850, by fax at 301-594-2968, or by email at <u>phann@cdrh.fda.gov</u>. Additionally, a voice mail message may be left at 301-594-0650, and your call will be returned as soon as possible.

All of the FDA medical device postmarket safety notifications can be found on the World Wide Web at <u>http://www.fda.gov/cdrh/safety.html</u>. Postmarket safety notifications also can be obtained through e-mail on the day they are released by subscribing to our list server. You may subscribe at <u>http://list.nih.gov/archives/dev-alert.html</u>.

Sincerely yours,

David W. Feigal, Jr., MD, MPH Director Center for Devices and Radiological Health Food and Drug Administration

Enclosure

FDA Safety Tips to Prevent Fires Caused by Hospital Beds: Clinical Staff

The following safety tips should be routinely used by the clinical staff to reduce the risk of fires caused by hospital beds.

It is assumed that normal behavioral policies such as prohibitions against smoking, lighting candles, etc., are already in place. The fire risks posed by oxygen administration to a patient in bed are not addressed in this list of safety tips.

- 1. <u>Connect the bed's power cord directly into a wall-mounted outlet</u>. Use only a power cord meeting the bed manufacturer's requirements. Make sure that the wall-mounted outlet will accommodate a heavy duty or hospital-grade plug and that the outlet is in good working order. The plug of the power cord should fit tightly into the wall outlet. The plug body, the wall outlet, and the wallplate should not be cracked or chipped. The plug blades should be securely retained in the plug body. When the bed has a power cord with a three-prong plug, the ground pin of the plug should be intact and secure. When in doubt about any of these concerns, check with your facility maintenance staff or biomedical engineering department.
- 2. Do not connect the bed's power cord to an extension cord or to a multiple outlet strip. Whenever possible, avoid the use of extension cords or multiple outlet strips in patient rooms for any medical electrical equipment since they are highly vulnerable to physical damage that can cause fires. If the use of extension cords or multiple outlet strips cannot be avoided, use only heavy duty or hospital-grade connectors that are approved by the facility's engineering department. Extension cords and multiple outlet strips should only be installed by properly-trained electrical maintenance personnel. Multiple outlet strips should be mounted on a fixed object (e.g., equipment cart or night stand) to reduce the risk of liquid spills and physical damage. In addition, if multiple-receptacle outlet boxes are used, they also should be protected from the risk of liquids spills and physical damage. All extension cords and multiple outlet strips should be tagged and inspected routinely.
- 3. <u>Visually inspect the bed's power cord for damage</u>. The bed's power cord, as well as power cords from other medical electrical equipment, can sustain damage from crushing, pinching, shearing, cutting, or from being worn through from cleaning solutions. They also can be damaged by bed movement, deterioration from use or aging, or human or equipment traffic. Furniture placement (e.g., a rocking chair positioned too close to a power cord) also can be hazardous. The cord's insulation should be intact and there should be no evidence of bulging, stretching, crimping, cracking, or discoloration, especially at the ends, where the cord is attached to the plug body and to the bed itself.

- 4. <u>Do not cover the bed's power cord or any power cord with a rug or carpet</u>. Rugs or carpets can prevent normal air flow, which can lead to greater heat build-up. Covered power cords also are more prone to being walked on or having furniture placed directly on them. The bed maintenance staff should place the cord in a low or no traffic area.
- 5. Ensure that appropriate staffs inspect all parts of the bed frame, motor and hardware, mattress, and the floor beneath and near the bed for build-up of dust and lint.
- 6. <u>Test the bed to assure that it moves freely to its full limit in both directions</u>. In many facilities, wall mounted outlets are located directly behind the hospital bed. Check to be sure that the vertical motion of the bed does not interfere with the bed's power cord or plug. In addition, the bed's hand control cable and all other power cords should not be threaded through mechanical parts of the bed or bed rails where normal bed movement may damage or cut the cable.
- 7. <u>Test the bed's hand and panel control, including the patient lockout features, to assure that the bed is working properly</u>.
- 8. <u>Inspect the covering of the bed's control panel and the patient control panel to</u> <u>assure that the covering is not cracked or damaged</u>. Cracked or damaged covers can allow liquids or other conductive material to penetrate to the switches.
- 9. <u>Check patient bed occupancy monitors and all other equipment in the patient's</u> room with plug-in power supplies for indications of overheating or physical <u>damage</u>. Make sure that the power supplies are plugged into a wall socket where they cannot be contacted by bed clothes, bedding, etc.
- 10. <u>Report to the bed maintenance personnel, any unusual sounds, burning odors, or</u> <u>movement deviations observed in the controls, motors, or the limits switch</u> <u>functions</u>.
- 11. <u>Assure that all manufacturers' recalls, urgent safety notices, etc., have been followed</u>.

FDA Safety Tips to Prevent Fires Caused by Hospital Beds: Staff Responsible for Bed Maintenance

The following safety tips should be routinely used by the staff responsible for bed maintenance to reduce the risk of fires caused by hospital beds.

It is assumed that normal behavioral policies such as prohibitions against smoking, lighting candles, etc., are already in place. The fire risks posed by oxygen administration to a patient in bed are not addressed in this list of safety tips.

In addition to the safety tips listed for clinical staff, bed maintenance personnel should regularly:

 Perform routine electrical safety testing per the manufacturer's recommendation or based on your facility's established protocols. When the bed has a power cord with a three-prong plug, assure that the electrical resistance of the safety ground conductor and the level of leakage current (line conductor-to-safety ground and neutral conductor-to-safety ground) meet applicable standards. One such standard, IEC 60601-1, specifies 0.2 ohms and 500 µA leakage current for these two values. IEC 60601-1 is formally recognized by the Food and Drug Administration. UL 2601-1 is a widely used American version of IEC 60601-1. Your facility may use other comparable standards.

Note 1: FDA is concerned with the safety of medical devices but electrical wiring of buildings is not within the Agency's scope of responsibility. However, we wish to emphasize that any protection afforded by the bed's ground pin is negated if the receptacle is not properly grounded. If you have questions about the adequacy of your facility's building wiring, we recommend that you contact a qualified electrician or consult the code authority in your jurisdiction.

Note 2: Beds with two-prong power cord plugs are considered safe if they are approved as a Class II (double-insulated) device by a nationally recognized testing laboratory such as UL. Major medical device standards (IEC 60601-1, UL 544/UL1097, and UL 2601-1 and the healthcare facilities standard NFPA-99) require that devices with double-insulated construction are to be marked with either "Double-Insulated," "Double Insulation," or the international symbol for such These markings are to appear on the body (frame or controls enclosure) of the device.

2. <u>Check all electrical outlets, including accessory outlets that may be mounted on patient beds, for cleanliness, physical integrity, and functionality</u>. The IEEE standard 602-1996, section 4.2.2 advises that hospital-grade outlets be used and that they should be mounted with the ground pin or neutral blade up to assure that any metal that may drop between the plug and the wall will most likely contact an unenergized blade. (Specifications for "hospital-grade" connectors appear in UL498-2001, Supplement SD.)

- 3. <u>Check the bed's power cord and other power cords connected to medical electrical equipment in the patient's room to assure that heavy duty or hospital-grade plugs are used, contact pins are straight and secure, and that strain reliefs are adequate.</u>
- 4. <u>Check battery-powered beds for hot spots in their power cords, batteries, voltage inverters, and battery chargers.</u>
- 5. <u>Check, maintain and service the bed's motors and mechanism in accordance with the manufacturer's recommended service plan to assure that the motors are not stalling and overheating.</u>
- 6. <u>Check that all gas and liquid fittings (such as on specialty care beds) are in good</u> <u>condition, without leaks or other signs of visible damage</u>.
- 7. <u>Check that all switch-type circuit breakers move freely</u>.
- 8. <u>Check that the ratings of external fuses match the requirements of the device and that the appropriate spare fuses are present</u>. Fuses have a number of critical ratings in addition to their current rating. Be very careful when making substitutions. Using the incorrect fuse can negate its protective function, leading to equipment damage and/or fire.
- 9. <u>Check the bed's and all other electrical power cable connectors in the patient's room</u> to assure that they are in good condition. Keep all power cords free of moving bed parts. Keep power cords off the floor if possible. If running power cords on the floor cannot be avoided, they should be located in low or no traffic areas and then taped down only as minimally necessary to avoid a tripping hazard.
- 10. <u>Check your equipment inventory for beds that have 120volt AC powered patient and clinician controls</u>. These controls are vulnerable to liquid spills that have led to bed fires. Contact the bed manufacturer regarding options to convert the patient control to a low voltage AC powered control. When replacement or conversion of such beds is not a reasonable option, regularly perform maintenance to prevent possible electrical arcing or overheating.
- 11. Assure that all manufacturers' recalls, urgent safety notices, etc., have been followed.