

Patient Safety Alert

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- Item:** Hospital-grade power cords, manufactured by Electri-Cord and sold to medical equipment manufacturers
- Specific Incident:** On October 19, 2009, the FDA issued a report “Safety Investigation of Certain Medical Device Power Cords: Initial Communication” regarding Electri-Cord power cords supplied to medical device manufacturers and the potential for incidents of sparking, charring, and fires. FDA indicates “the potential risks from this power cord failure include electrical shock, delay in setup and therapy, interruption of therapy, device failure, and fires. Depending on the device and therapy, these failures may potentially lead to serious adverse health consequences, including death.”
- The FDA estimates there are 2 million affected cords on the market. Thus far, Abbott Nutrition, Arizant Healthcare, ConMed Linvatec, Edwards Lifesciences, Fresenius Medical Care, Hospira, KCI, Medtronic, Philips Healthcare, and Smiths Medical have identified use of Electri-Cord power cords on some of their equipment. Other medical equipment companies are likely affected, but have not yet been identified.
- General Information:** Replacement of all affected cords or plugs will eventually be necessary, but because there may not be enough replacement cords available on the market, VAMCs will need to prioritize replacement. Of utmost concern are cords that are attached to devices in oxygen-enriched environments or those attached to life support devices. Therefore, it is only necessary to immediately replace a cord or plug if a) it is used in an oxygen-enriched environment, b) it is used on a life support device, or c) it fails. Cords that don't fit into these three categories can be addressed on a less immediate basis (e.g., during scheduled device preventive maintenance).
- The affected cords can be identified as follows:
- a. The cords have a black plastic piece (described as a plug bridge) that connects the terminal prongs,
 - b. The ground pin is round (unaffected cords have a 'U' shaped ground pin), and
 - c. The cords have the name Electri-Cord on the face of the plug.
- Please refer to the attached FDA notice for pictures of the cord plug. Note: While the pictures show a clear plug, the plug may also be opaque. Also, approximately 80% of the cords are detachable, the rest are permanently mounted to the equipment.

Actions:

1. By close of business (COB) June 2, 2010, **Biomedical Engineering** shall inspect, without jeopardizing patient care, the power cords of the following devices:

- a) those used in oxygen-enriched environments (e.g., ORs, ICUs),
- b) those used with life support devices, and
- c) those that have failed (i.e., those that have sparked, charred, or showed evidence of a fire).

If the power cord is affected as described by this notice, replace it with an unaffected cord or replace the plug. Also, note the manufacturer and model of the device, inform the manufacturer of the discovery, and provide a list of identified devices to Paul Sherman at the VA Center for Engineering & Occupational Safety and Health (CEOSH). His email is listed below. Mr. Sherman will consolidate and pass the information on to the FDA.

2. By close of business (COB) June 2, 2010, **Biomedical Engineering** shall have a plan in place to inspect devices that have not been captured by Action 1 (e.g., inspecting the devices during scheduled device preventive maintenance). This will ensure that the remaining corded devices in the facility (those not attached to life supporting devices or devices used in oxygen-enriched environments) will be assessed. If affected cords are found during inspection, they should be replaced as they become available. Also, note the manufacturer and model of the device, inform the manufacturer of the discovery, and provide a list of identified devices to Paul Sherman at CEOSH.

3. By COB June 2, 2010, the **Facility Director (or designee)** will ensure there is a plan in place for inspection of medical equipment present in patient's homes and a plan to address any affected power cords. This plan should also include noting the manufacturer and model of the device, informing the manufacturer of the discovery, and providing a list of identified devices to Paul Sherman at CEOSH. .

4. By COB June 16, 2010, the **Patient Safety Manager** shall document the status of this Patient Safety Alert on the VHA Hazardous Recalls/Alerts website. <http://vawww.nbc.med.va.gov/visn/recalls/index.cfm>.

Addl. Information:

CEOSH will maintain a list of affected vendors on its website. Additionally, VAMCs should monitor FDA Enforcement Reports and other sources to identify additional affected vendors.

Sources:

Food and Drug Administration (FDA), VA CEOSH, and ECRI Institute

Attachment:

FDA Report: "Safety Investigation of Certain Medical Device Power Cords: Initial Communication" dated October 19, 2009

Contact:

Paul Sherman at CEOSH: paul.sherman@va.gov or (314) 894 - 6100, or Lori King at the National Center for Patient Safety: lori.king2@va.gov or (734) 930 – 5890.

ATTACHMENT

Medical Devices

Safety Investigation of Certain Medical Device Power Cords: Initial Communication

Date Issued: October 19, 2009

Audiences: Health Care Professionals, Patients/Caregivers Using Medical Devices in the Home, Medical Device Manufacturers

AFFECTED PRODUCTS

Certain medical device AC power cords equipped with a plug that has a prong and ground-pin insert design and a black plastic bridge connecting the terminal prongs on the plug (see Figure 1). Medical device power cords that do not have a black bridge connecting the terminal prongs on the plug are not affected (see Figure 2)

Figure 1: Affected Plug

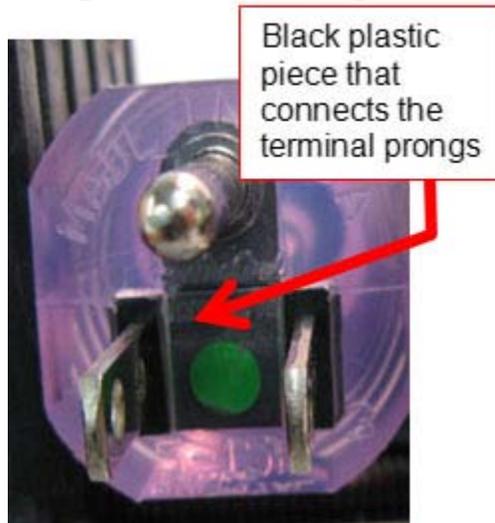


Figure 2: Not Affected Plug



SUMMARY OF PROBLEM AND SCOPE

FDA is investigating whether certain types of power cords used with medical devices may be defective.

Two medical device manufacturers (Hospira, Inc. and Abbott Nutrition) have sent FDA 122 reports of sparking, charring, and fires from the power cords used with their devices. The companies' investigations of these reports determined that the power cord's prongs may crack and fail at/or inside the plug.

ATTACHMENT (continued)

The potential risks from this power cord failure include electrical shock, delay in setup and therapy, interruption of therapy, device failure, and fires. Depending on the device and therapy, these failures may potentially lead to serious adverse health consequences, including death.

All the reports received so far from Hospira and Abbott have involved AC power cords with the black plastic bridge (see Fig. 1 above) manufactured by the Electri-cord Manufacturing Company. Hospira have voluntarily recalled devices with the affected power cords and are making appropriate replacements for existing customers.

FDA is aware that Electri-cord has supplied the affected power cords to other medical device manufacturers. The agency is now attempting to determine which devices may be equipped with these cords, because they could pose the same potential risk of electrical shock, delay in setup and therapy, interruption of therapy, device failure, and fires.

RECOMMENDATIONS/ACTIONS

For Device Users

While further investigation into this matter continues, FDA recommends that all users of medical devices, either in healthcare facilities or in the home, closely monitor the wear and tear on the electric cords used to power these devices. This vigilance is especially important in oxygen rich environments, in which electrical sparking and arcing may trigger a fire.

If you have a medical device that uses a power cord with a black plastic bridge (see Fig. 1) and notice that it has bent or cracked prongs, an outer sheath that is visibly burnt, a black residue, or signs of excessive wear and tear, take the following actions:

- Have a contingency plan to prevent any disruption of patient care.
- Stop using the device with the affected power cord as soon as possible, without jeopardizing patient care.
- Contact the medical device manufacturer or sales representative to report the power cord failure and to request the appropriate replacement/repair.
- Submit a report to the Food and Drug Administration as stated in the “Reporting Problems” section below.

Personnel in healthcare facilities should follow protocols for handling equipment malfunctions as required by their facilities.

For Medical Device Manufacturers

ATTACHMENT (continued)

If you manufacture a device with a power cord manufactured by Electri-Cord, or if you have received complaints of device malfunction associated with sparking, charring, or fires from the power cords please:

- Evaluate your medical device to determine whether the power cord is the source of any problems associated with sparking, charring or fires.
- Report events to FDA on FDA Form 3500A, for any complaints that meet the requirements stated in 21 CFR, Part 803 “Medical Device Reporting.”
- Perform the appropriate voluntary correction and/or removal action as stated in the requirements under 21 CFR, Part 806, “Reports of Corrections and Removals.”

FDA ACTIVITIES

FDA is continuing to investigate this problem and will provide additional information as it becomes available.

For more information from Hospira, Inc. and Abbott Nutrition regarding cord replacement please call the numbers below.

Manufacturer	Recall Information	Contact Information
Hospira, Inc.	August 14, 2009 Urgent Device Recall for AC Power Cords	1-800-615-0187 (available between 6:00 a.m. and 4:00 p.m. PST)
Abbott Nutrition	September 4, 2009 Urgent Device Recall for Flexiflo® Quantum Enteral Pump	1-877-457-0249 (available between 8:30 a.m. and 5:00 p.m. EST)

HOW TO REPORT PROBLEMS TO THE FDA

For Health Care Professionals and Home Users of Medical Devices

If the AC power cord on your medical device shows signs of sparking, charring or fires, we urge you to file a voluntary report electronically with MedWatch, the FDA Safety Information and Adverse Event Reporting program (OMB Approval No. 0910-0291), or you can report directly to MedWatch by phone at 1-800-FDA-1088, or obtain the fillable form online at <https://www.accessdata.fda.gov/scripts/medwatch/>, print it out and fax to 1-800-FDA-0178 or mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787. Include the brand name, manufacturer, and model number of the device that has the defective power cord as part of the report. **Healthcare professionals employed by a facility that is subject to FDA's user facility reporting requirements should follow the reporting procedures established by the**

ATTACHMENT (continued)

facility.

For User Facilities

FDA requires hospitals and other facilities to report deaths and serious injuries associated with the use of medical devices. If a user facility suspects that a reportable adverse event was related to the use of a defective power cord, they should follow the reporting procedure established by their facility. Mandatory reporting requirements for user facilities are found in 21 CFR, Part 803 “Medical Device Reporting.”

For Medical Device Manufacturers

In accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50, FDA requires manufacturers to submit to us, within thirty calendar days of becoming aware, all reportable events involving a device that:

- has or may have caused or contributed to a death, serious injury, or
- has malfunctioned, and the malfunction of the device or a similar device would be likely to cause or contribute to a death or serious injury if it were to recur.

All reports will help us gather additional information related to this problem and assess its public health impact.

CONTACT INFORMATION

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@CDRH.FDA.GOV or 800-638-2041.

This document reflects FDA's current analysis of available information, in keeping with our commitment to inform the public about ongoing safety reviews of medical devices. The nature, magnitude and possible public health impact of this situation are not yet clear.