



Fresenius Medical Care

***** URGENT Device RECALL for AC Power Cords
Manufactured by ELECTRI-CORD, Mfg. Co. *****

To: Device Users: 2008K, 2008K2, 2008K@home, 2008H and Granuflo I Mixer

Date: November 13, 2009

Re: Fresenius Medical Care NA Urgent Device Recall for AC Power Cords

Contact:

Fresenius Medical Care North America Customer Service
1-800-227-2572

Fresenius Medical Care North America ("Fresenius") is initiating this recall for certain Fresenius devices that may have a defective plug, which is part of an AC power cord manufactured by Electri-Cord Manufacturing Company ("Electri-Cord"). This alert is being issued in response to a Food and Drug Administration (FDA) alert regarding customer reports of sparking, charring and fires of similarly designed AC power cords in **non-dialysis** products manufactured by other companies. Fresenius is advising all customers to assess whether their devices have the affected Electri-Cord AC power cords and inspect the cord plugs for evidence of damage (charring, discoloration of the plastic, broken or loose prongs).

The potential risks from power cord failure include electrical shock, delay in setup and therapy, interruption of therapy, device failure, and fires, which may be exacerbated in an oxygen-rich environment. Depending on the device, therapy, and environment, these failures may lead to potential serious injury or death.

Affected Products:

2008 K Hemodialysis Machines	
2008K2 Hemodialysis Machines	
2008K@home Hemodialysis Machines	
2008H Hemodialysis Machines	
Granuflo I Mixers	
Main power supply assembly	P/N 190011 (60Hz)
	P/N 190092 (50Hz)
AC power cord assembly	P/N 150425 (hemodialysis machines)
	P/N 160089 (Mixers)



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Reason for Correction:

Certain power cords used on the above listed Fresenius hemodialysis machines and the Granuflo mixer may crack and fail at/or inside the plug resulting in sparking, charring, melting, or fire from the power cord plug. Replacement AC power cords purchased for repairs also may be affected. The affected power cords are manufactured by Electri-Cord Manufacturing Company and have a prong and ground-pin insert design. These cords can be identified by a black plastic bridge connecting the terminal prongs on the plug (see Figure 1 below).

This recall is limited to device power cords with a prong and ground-pin insert design, which can be identified by a black plastic bridge connecting the terminal prongs on the plug (see Figure 1 below) manufactured by Electri-Cord Manufacturing Company.

Figure 1: Affected Plug





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Devices with Electri-Cord power cords that do not have a black bridge connecting the terminal prongs on the plug are not affected (see Figure 2). Power cords from manufacturers other than Electri-Cord, which may or may not have a black bridge connector, are not affected.

Figure 2: Not Affected Plug



Recommended Actions:

Inspect the power cords on all Fresenius Medical Care NA hemodialysis machines and Granuflo I Mixers to determine if any of these devices have an affected Electri-Cord power cord. Please also inspect your inventory of power supply assemblies and replacement AC power cords.

Preventive maintenance requirements for inspection of the AC wiring including the power plug and cords may be found in the Preventive Maintenance Manual for each hemodialysis device, and in the Operator's Manual for the Granuflo I Mixer. Operator's manuals, Preventive Maintenance Manuals and other technical documents may be down-loaded at no cost from the Fresenius Medical Care NA website at www.fmc-na.com. Click on "Dialysis Products" tab, then "Product Support Documentation" tab.



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If you determine that your facility has any of the affected Electri-Cord power cords, inspect the plugs for each affected Electri-Cord power cord for the following:

- Bent or cracked prongs
- Charring or burnt plastic
- Discolored plastic
- Other signs of excessive wear and tear

If you identify defective power cords with any of the above defects, stop using the device with the affected power cord as soon as possible, without jeopardizing patient care, and contact Fresenius Medical Care NA Customer Service at 1-800-227-2572 (available from 7 a.m. to 5 p.m., Pacific time) for instructions on receiving replacement plugs.

If you have affected power cords that are not exhibiting any of these characteristics, monitor the power cords regularly for excessive wear and tear, and be mindful not to subject the power cords to misuse or abuse. Please pay particular attention to machines used in the home or acute setting or that are moved and frequently plugged and unplugged from wall outlets. To prevent damage, instruct personnel not to use the cord to unplug the device from the wall outlet (“yank the plug from the wall”) and to refrain from rolling over the cord or plug.

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Fresenius Medical Care NA has not received any reports of serious patient harm related to the situation. Any adverse events experienced with the use of these products and/or quality problems may also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.