DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

August 3, 1998

IMPORTANT PUBLIC HEALTH MESSAGE

Dear Administrator or Risk Manager:

I am writing to let you know about an important requirement that will help to safeguard patients from electrical hazards associated with the lead wires and cables used on many medical devices. Beginning January 1, 1999, only electrode lead wires and patient cables that are protected may be used with the following devices:

- breathing frequency monitors;
- ventilatory effort monitors (apnea detectors);
- electrocardiographs (ECGs);
- radiofrequency physiological signal transmitters and receivers;
- cardiac monitors;
- electrocardiograph electrodes (including pre-wired ECG electrodes);
- patient transducer and electrode cables (including connectors);
- medical magnetic tape recorders (e.g., Holter monitors);
- arrythmia detectors and alarms; and
- telephone electrocardiograph transmitters and receivers.

Protected cables and leads are those that cannot be inadvertently inserted into electrical outlets and thus pose an electrocution hazard to patients. We are taking this action because patients in the past have been seriously harmed or killed when unprotected electrode lead wires and patient cables have been accidentally inserted into live electrical outlets—in some cases by young children, and in others by health care personnel.

You can fulfill this requirement through the use of inexpensive adapters to protect cables and leads, which are available from many sources for most medical devices. In some cases, retrofitting may work. Contact your suppliers to see what kind of correction will work best for you. If the correction means you are facing an unreasonably expensive fix, you may request a variance or exemption from FDA. The request needs to document that conversion adapters are not feasible and retrofitting is far too expensive. Your request must also propose an alternate method of dealing with the problem and clearly show that it is effective in protecting patients.

The requirement I am describing in this letter applies to devices already in use. We have already addressed the problem as it applies to newly manufactured devices by means of a performance standard which went into effect in May, 1998. Under the standard, device manufacturers must use protected electrode lead wires and patient cables.

For the present, we have applied both the manufacturer performance standard and the user facility requirement to the ten devices in the above list because they pose the greatest risk. But beginning on May 9, 2000, these requirements will apply to electrode lead wires and patient cables that are used with all types of medical devices. In the interim, we strongly suggest that you avoid mistakes by labeling all of your devices that use electrode lead wires and patient cables with a cautionary statement, such as "USE ONLY PROTECTED CABLES AND LEADS WITH THIS DEVICE" and by segregating protected and unprotected electrode lead wires and patient cables.

I am urging you to share the above information with your risk managers, biomedical engineers, nursing staff, and various departments that use electrode lead wires and patient cables, so they can make sure your facility is making the required changes.

You can find more information about this matter on our Web Page at http://www.fda.gov/cdrh (search in the Topic Index under L for Lead Wires). Or you may contact Mr. Stewart Crumpler in our Office of Compliance at 301-594-4659 or by facsimile at 301-594-4672.

We appreciate your cooperation on this very important public health issue.

Sincerely yours,

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

Enclosures