

Center for Devices and Radiological Health**IMPORTANT PUBLIC HEALTH MESSAGE**

8/3/98

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);
- arrhythmia 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.

