



“Getting More Information”

Because the following document was developed a number of years ago, the contact information is no longer accurate. If you wish to contact the agency with questions, please use the following:

Mail: Office of Surveillance and Biometrics (HFZ 510)
1350 Piccard Drive
Rockville, MD 20850

FAX: 240-276-3356

Phone: 240-276-3357

Email: <mailto:phann@cdrh.fda.gov>



**FDA Public Health Advisory:
Unsafe Electrode Lead Wires and Patient Cables Used With Medical Devices**

December 28, 1993

To: Directors of Nursing, Risk Managers, Biomedical/Clinical Engineering Departments

On September 3, 1993, FDA issued a Safety Alert warning health care professionals of the potential hazards of using unsafe electrode lead wires and patient cables with apnea monitors. **I am now extending that warning to include all other devices that may use electrode lead wires with unprotected pins.** Examples of some of these devices include, but are not limited to:

cardiac monitors,
electrocardiographs (ECGs),
electroencephalographs (EEGs),
electromyographs (EMGs),
electrophysiology equipment,
multi-parameter patient monitors,
muscle stimulators,
nerve stimulators,
neurostimulators, and
respiratory monitors.

The use of electrode lead wires with unprotected pins is hazardous to patients. FDA has received sporadic reports of shocks, burns and electrocutions when electrode lead wires with unprotected pins were plugged directly into a power source.

The attached illustration may be helpful in understanding both safe and unsafe electrode lead wire and patient cable connections; we recommend that you post copies in all appropriate areas of your facility.

Although manufacturers have been changing the design of their electrode lead wires and patient cables to minimize the hazard, some health care facilities still use older models of electrode lead wires and patient cables, creating a potential hazard. If you still have these older models, we recommend that you immediately:

- Alert all staff to the hazard of using electrode lead wires with unprotected pins by distributing copies of this advisory to all units in your facility that use medical devices with patient electrode lead wires, including: Critical Care, Emergency Room, Operating Room, Medical-Surgical, Pediatric, Neonatal, and Purchasing Departments. Also distribute copies to home health care providers and suppliers affiliated with your facility.
- Replace electrode lead wires that have unprotected pins with lead wires that have **protected** pins if they are commercially available. Replace patient cables with those that accept only protected pins. *Note: Adapters for patient cables are available from some manufacturers.* Discard or destroy all unsafe lead wires and patient cables so they cannot be accidentally used.

Until all electrode lead wires with unprotected pins and all patient cables that accept unprotected pins are replaced or fitted with adapters, we recommend you take the following precautions:

- For devices that use patient cables, disconnect patients only at the device or at the patient electrode. **DO NOT** disconnect patients from devices at the junction between the lead wire and the patient cable. Place tape over the connection between the electrode lead wire and the patient cable to make it inconvenient to disconnect the patient at this junction.
- Flag or label all detachable 120-volt power cords at the female end with a warning. This warning should alert users to the presence of hazardous voltage and/or the danger of connecting lead wires with unprotected pins into a power cord.
- Hard-wire or clamp all detachable 120-volt power cords to their respective devices so they cannot be removed by the user.

For further information on this issue, see: ECRI. Risk of electric shock from patient monitoring cables and electrode lead wires. *Health Devices* 1993; 22(5-8):301-303.

Please remember that the Safe Medical Devices Act of 1990 requires hospitals and other user facilities to report deaths, serious illnesses and injuries associated with the use of medical devices to FDA or to the manufacturer. You may report such incidents by phoning 301-427-7500, by FAXing 301-881-6670, or by writing FDA, CDRH, MDR User Reporting, P.O. Box 3002, Rockville, MD, 20847-3002.

Questions regarding this advisory may be directed by mail to the Office of Surveillance and Biometrics, FDA, HFZ-510, 1390 Piccard Drive, Rockville, MD 20850, or by FAX at 301-594-2968. Thank you for your help in this important effort.

Sincerely yours,

A handwritten signature in black ink, appearing to read "D. B. Burlington". The signature is written in a cursive, somewhat stylized font.

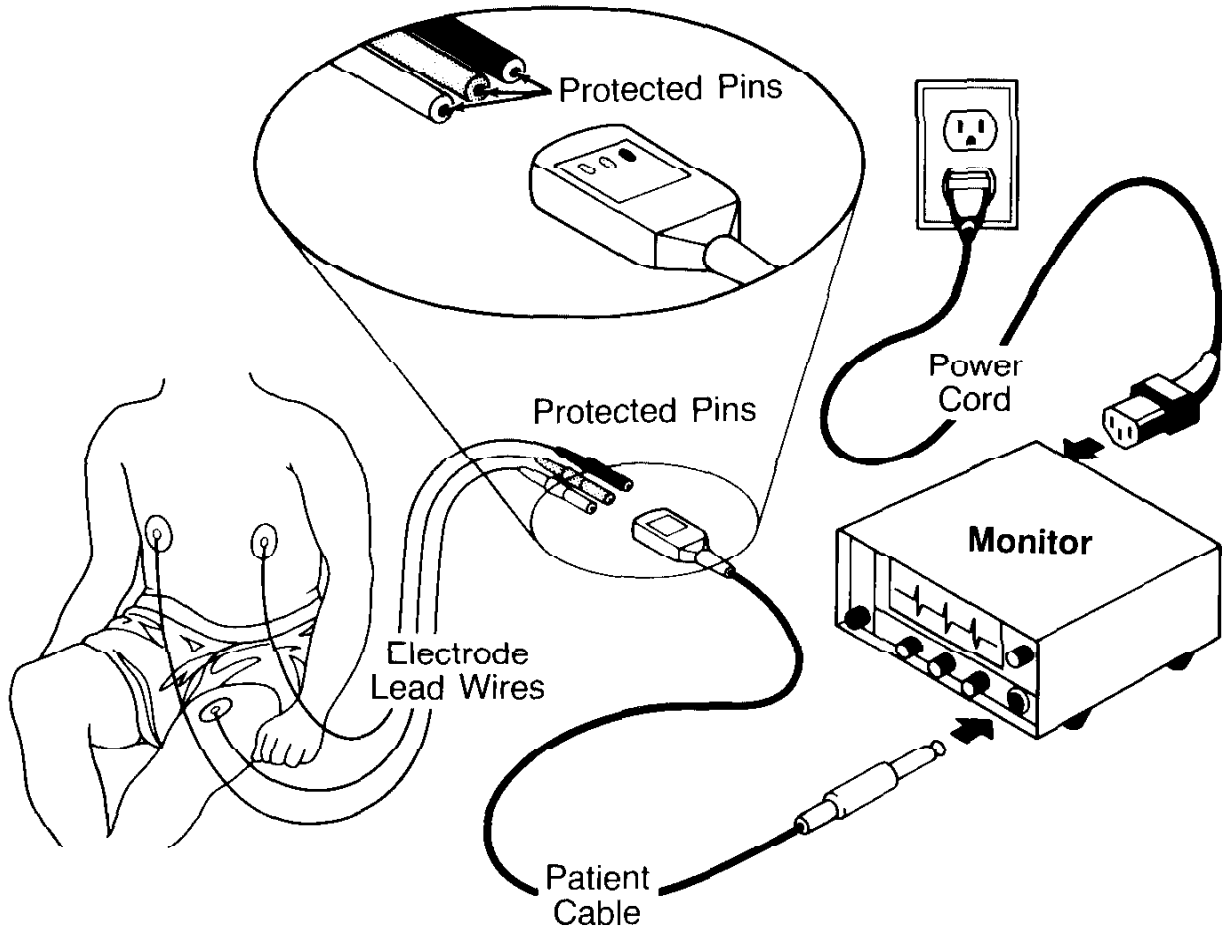
D. Bruce Burlington, M.D.

Director

Center for Devices and Radiological Health

SAFE

Lead Wires with Protected Pins and Correct Connections



Use only lead wires that have protected pins. Protected pins can not accidentally be plugged into power cords or electrical outlets.

UNSAFE

Lead Wires with Unprotected Pins and Incorrect Connections

