This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FDA SAFETY ALERT:
UNSAFE PATIENT LEAD WIRES AND CABLES

To: All Hospital Administrators,
Risk Managers, and
Pediatric Department Directors

September 3, 1993

I am writing to alert you to the potential for electrocution of infants on apnea monitors when inappropriate, and therefore unsafe lead wires and cables are used with this device, and to urge that you take certain precautions to avoid such incidents in the future. Recently, a baby on a hospital apnea monitor was electrocuted when inappropriate lead wires were substituted and apparently were accidently connected into an electrical power source. In the May-June 1993 issue of Health Devices, ECRI reported on similar accidents with apnea monitors and other devices.

Be advised that a hospital's use of an unsafe lead with an apnea monitor may be dangerous to the patient, and may also be a violation of the Federal Food, Drug, and Cosmetic Act.

In 1985, we alerted hospitals and users of home apnea monitors about the potential for electrocution or burns. In those cases, older children plugged the connector pins of the electrode leads from an infant's apnea monitor system into either AC power cords or a wall outlet, resulting in electrocution or burns.

Since 1985, the Food and Drug Administration (FDA) has cleared for marketing only those home use apnea monitors with cables and leads designed to prevent unsafe connections. This protective design has also been required on hospital apnea monitors cleared for marketing since 1989.

Nonetheless, some hospitals are still using older units, or wires and cables from other devices, which do not have the protective design. Even with the new models, it may be possible for staff to switch cables and/or lead wires, creating a hazard.

Although the probability of infant electrocution under similar conditions is small, the risk is not acceptable, particularly since safe lead wires and cables are available. FDA's immediate concern is to safeguard infants on apnea monitors. We are also concerned with patient safety when unprotected lead wires and cables are used with other devices. The agency is investigating the appropriate regulatory actions that may be taken with manufacturers of apnea monitors, cabling systems, and other medical devices that use patient electrodes.

(over)

FDA recommends that hospitals take the following measures to help prevent accidents caused by unsafe lead wires and cables:

- Purchase and use only safety protected lead wires and cables with apnea monitors to prevent lead wire connection to a power source. If possible, remove unprotected lead wire/cable combinations from hospital areas that use apnea monitors.

- Alert staff to the potential for this type of accident, so they are aware not to use these unsafe connection systems.

- Consider replacement of all unprotected lead wire/cable systems for all medical devices that use patient electrodes.

Until your facility replaces all unprotected lead wire/cable systems, you should take the following precautions:

- Flag or mark all power cords with "120 volts" at the female end to aid in preventing staff from accidentally inserting an electrode lead wire.

- Disconnect patients from monitors only at the monitor or at the patient electrode. Do not disconnect at the junction between the lead wire and the patient cable. Place tape over this connection to make it inconvenient to disconnect the patient at this point.

- Hard-wire or clamp the power cable to the monitor so that the power cable is unavailable for any inappropriate connection.

Please share this information with the purchasers and biomedical engineers in your institution. The attached illustration may be helpful in understanding the correct device connections.

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, including apnea monitors, 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.

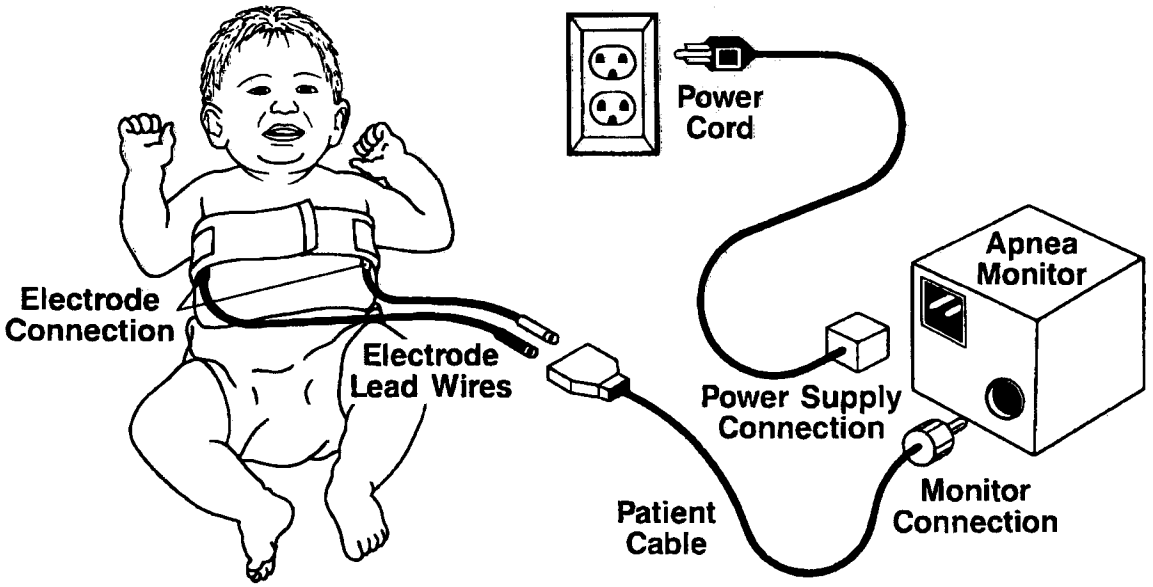
Questions may be directed by mail to Susan E. Bounds, FDA, HFZ-306, 1390 Piccard Drive, Rockville, MD 20850, or by FAX at 301- 594-1967. Thank you for your help in this important effort.

Sincerely yours,

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

Safety Alert for Apnea Monitors

Correct Connections



This picture shows the correct way to connect the infant to the Monitor. The ELECTRODE LEADS are plugged into the PATIENT CABLE which in turn connects to the MONITOR. The MONITOR is connected to the WALL SOCKET by the POWER CORD.

These pictures show situations in which accidents can occur. The ELECTRODE LEADS can be incorrectly plugged into:

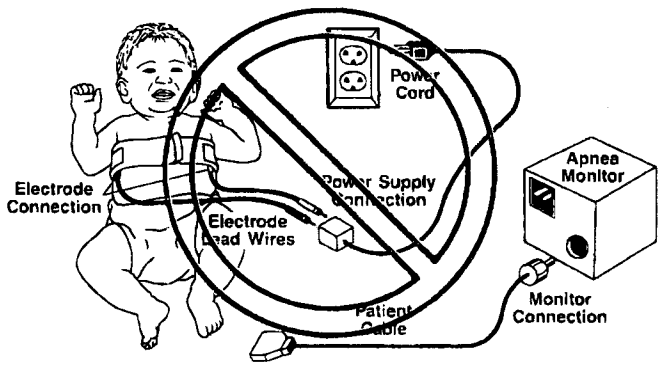
A. the POWER CORD

B. a WALL SOCKET

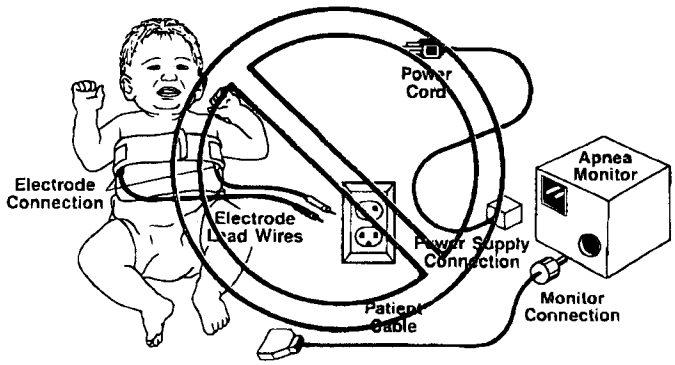
C. an EXTENSION CORD, or other appliance cord

instead of being plugged into the PATIENT CABLE.

A. DANGEROUS/INCORRECT POWER CORD CONNECTION



B. DANGEROUS/INCORRECT WALL SOCKET CONNECTION



C. DANGEROUS/INCORRECT EXTENSION CORD CONNECTION