U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

"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

March 28, 1985

FDA SAFETY ALERT:
DEFIBRILLATOR BATTERIES

Dear Administrator:

This is to alert you and all operators of cardiac defibrillators with rechargeable batteries that a potentially serious malfunction can occur because of premature battery failures. Please share this safety alert with all departments or individuals having responsibility for cardiac defibrillating equipment.

Although you may have heard from certain manufacturing about the problem, other makes and models could present a similar hazard.

We have received several recent reports of premature failure of some battery packs causing an ability to charge defibrillators to selected energy levels. The battery packs contain certain models of nickel-cadmium batteries manufactured by General Electric and distributed through defibrillator manufacturers and battery pack assemblers. These batteries may lose a substantial amount of their charge within a few days after being removed from the charger, and may fail suddenly and without warning. Testing will not reliably identify batteries subject to the potential failure.

GE has noticed defibrillator manufacturers of the problem associated with some batteries produced from June through December of 1984. Three manufactures of defibrillators- Physio Control (Feb. 15,1985), Datascope (March 13, 1985), and Hewlett-Packard (March 21, 1985) – have recalled suspect battery packs from purchasers of their equipment. The affected battery packs are used in the following defibrillator models:

Manufacturer	Models
Physio Control	LIFEPACK 5
	LIFEPACK 6
	LIFEPACK 6S
	LIFEPACK 7
Datascope	M/D3
	M/D3A
Hewlett-Packard	78619A
	78620A

FDA and GE are investigating the possibility that other manufacturers of defibrillators may have used these batteries. We are not providing battery model numbers or specific date codes at this time because such information may not be readily accessible

on the battery packs, and because GE is still conducting testing for other possibly defective lots. Users of all defibrillator with rechargeable batteries should contact manufacturers of their equipment for further information as it becomes known.

Until further specific information or replacement batteries are received, inform all operators and label all equipment with the following precautions immediately:

For defibrillator that use either line power (A/C) or batteries, select line power whenever possible.

When batteries must be used:

1. Insure that they are fully charged either by leaving them constantly charging or by frequently exchanging them in the charger, depending upon the charging procedure recommended by the defibrillator manufacturer.

2. Have spare batteries and/or defibrillators available as a backup in the event a battery problem should arise during emergency field operations.

You may obtain further information about this notice from Mr. Michael Audet of our Office of Training and Assistance at (301) 443-4600.

Reports of incidents relating to defibrillator batteries or other problems should be reported to the manufacturer.

We appreciate your cooperation and hope this information will help prevent further problems.

Sincerely yours,
John C. Villforth
Director
Center for Devices and Radiological Health