DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FDA SAFETY ALERT:
Laerdal Defibrillators

To: Directors of Emergency Medical Services **January 26, 1994**
Emergency Health Care Provider Organizations
(You are encouraged to copy and distribute this alert.)

This is to alert you to serious problems with defibrillators manufactured by Laerdal Manufacturing Corporation, and to ask that you take certain precautions to prevent similar incidents in the future.

The products in question are Laerdal's HeartStart (HS) Automatic and Semi-Automatic External Defibrillators, models HS 1000, HS 1000S and HS 3000. **FDA has reports of malfunctions of these defibrillators that could result in patient deaths or serious injuries.**

Reported problems thus far are as follows:

Model HS 1000 (automatic)

Failure to treat ventricular fibrillation resulting in failure to shock. This rare but critical failure is believed to be a problem of the diagnostic software program. Additional investigation is underway and field data on the failure rates are actively being sought.

Model HS 1000S (semi-automatic)

A second, unnecessary shock delivered more than 20 seconds after a normal sinus rhythm had been restored by a first shock.

Model HS 3000 (semi-automatic)

1. Failure of devices to operate due to keypad malfunctions. A machine may fail to power up or may power up, complete a power-on self-test, and then automatically turn off.

2. Loss of power due to a faulty connection between the battery pack and the device.

3. Failure to operate due to defective optocoupler components, resulting in a "Check Electrode" message that cannot be cleared. This problem is associated with a recall by Laerdal of some HS 3000 models.

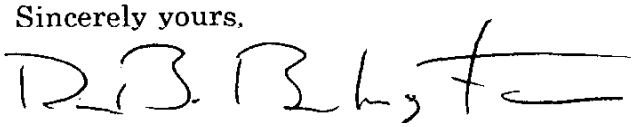
FDA has instructed the company to further investigate the cause of these problems and their magnitude. **In the meantime, users of Laerdal defibrillators should take the following precautions. Note that the first two steps are recommended for all defibrillators:**

- Test the defibrillator at the beginning of each shift. The enclosed Operator Shift Checklist can be used for this purpose.
- Perform all periodic maintenance recommended by the manufacturer.
- If using Model HS 1000S, be sure to check the patient for evidence of pulse and breathing before allowing the machine to deliver a second or repeated shock, which may be unnecessary.

FDA is interested in identifying and further defining problems related to medical devices. If you are aware of any deaths, serious injuries, or serious illnesses involving Laerdal defibrillators or other devices, please report them to your hospital Medical Device User Facility Reporting person (if appropriate) or directly to MedWatch, the FDA Medical Products Reporting Program at 1-800-FDA-1088.

Questions about this safety alert may be directed by mail to Lily Ng, Office of Surveillance and Biometrics, HFZ-510, CDRH, FDA, 1390 Piccard Drive, Rockville, MD 20850 or by FAX to 301-594-2968.

Sincerely yours,



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

AUTOMATED DEFIBRILLATORS: OPERATOR'S SHIFT CHECKLIST

Date: _____ **Shift:** _____ **Location:** _____

Mfr/Model No.: _____ **Serial No. or Facility ID No.:** _____

At the beginning of each shift, inspect the unit. Indicate whether all requirements have been met. Note any corrective action taken. Sign the form.

	Okay as found	Corrective Action/Remarks
1. Defibrillator Unit		
Clean, no spills, clear of objects on top, casing intact		
2. Cables/Connectors		
a. Inspect for cracks, broken wire, or damage		
* b. Connectors engage securely		
3. Supplies		
a. Two sets of pads in sealed packages, within expiration date		
b. Hand towel		
c. Scissors		
d. Razor		
* e. Alcohol wipes		
* f. Monitoring electrodes		
* g. Spare charged battery		
* h. Adequate ECG paper		
* i. Manual override module, key, or card		
* j. Cassette tape, memory module, and/or event card plus spares		
4. Power Supply		
a. Battery-powered units		
(1) Verify fully charged battery in place		
(2) Spare charged battery available		
(3) Follow appropriate battery rotation schedule per manufacturer's recommendations		
b. AC/Battery backup units		
(1) Plugged into live outlet to maintain battery charge		
(2) Test on battery power and reconnect to line power		
5. Indicators/*ECG Display		
* a. Remove cassette tape, memory module, and/or event card		
b. Power-on display		
c. Self-test ok		
* d. Monitor display functional		
* e. "Service" message display off		
* f. Battery charging; low battery light off		
g. Correct time displayed — set with dispatch center		
6. *ECG Recorder		
a. Adequate ECG paper		
b. Recorder prints		
7. Charge/Display Cycle		
* a. Disconnect AC plug — battery backup units		
b. Attach to simulator		
c. Detects, charges and delivers shock for "VF"		
d. Responds correctly to nonshockable rhythms		
* e. Manual override functional		
f. Detach from simulator		
* g. Replace cassette tape, module, and/or memory card		
8. *Pacemaker		
a. Pacer output cable intact		
b. Pacer pads present (set of two)		
c. Inspect per manufacturer's operational guidelines		
☐ **Major problem(s) identified (OUT OF SERVICE)**		

** Applicable only if the unit has this supply or capability*

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Signature: _____