

May 13, 2011

FDA Safety Announcement: Defibtech Lifeline and ReviveR Automated External Defibrillators (AEDs): Recall - Software Defect May Cancel Shock



AUDIENCE: Emergency Medicine, Risk Manager

ISSUE: Devices subject to this recall include Model DDU-100 series with software version 2.004 or earlier, sold under the brand names Lifeline and ReviveR. AEDs using software version 2.004 or earlier may cause the device to cancel shock during the charging process. Failure to provide appropriate therapy may result in failure to resuscitate the patient.

BACKGROUND: AEDs are used on victims of sudden cardiac arrest when the patient is unconscious, unresponsive and not breathing.

RECOMMENDATION: Defibtech will provide customers with a free software upgrade. Because the conditions that may lead to a canceled shock occur rarely, it is recommended that customers keep their AEDs in service during the software upgrade process. Full instructions and recommendations are being mailed to affected customers. Defibtech is responsible for contacting all end users unless a distributor has agreed to contact their accounts directly regarding this field correction

Recalling Firm:

Defibtech, LLC
741 Boston Post Road, Suite 201
Guilford, CT 06437-2714

Public Contact: Questions regarding this recall may be directed to Al Raebuck, Customer Service Manager, Defibtech at techsupport@defibtech.com, 1-877-453-4507 or 1-203-453-4507.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of this product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the FDA recall notice, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm254929.htm>

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www.kcercoalition.com/alerts.htm