



[FDA](#) > [CDRH](#) > [Medical Device Recalls](#) > LifeLine® Semi-Automatic External Defibrillators (AEDs) and ReviveR® Semi-Automatic External Defibrillators (AEDs)

## Class 1 Medical Device Recalls - LifeLine® Semi-Automatic External Defibrillators (AEDs) and ReviveR® Semi-Automatic External Defibrillators (AEDs)

**Date Recall** February 17, 2007

**Initiated:**

**Product:** Lifeline® Semi-Automatic External Defibrillators (AEDs) and ReviveR® Semi-Automatic External Defibrillators (AEDs)

**Use:** Automatic external defibrillators are intended to be used for the treatment of cardiac arrest. The defibrillators deliver a shock to the heart to restore normal heart rhythm. Prior to delivering the shock, the device analyzes the patient's heart rhythm to determine if a shock is appropriate.

**Recalling Firm:** Defibtech®, LLC  
741 Boston Post Road, Suite 201  
Guilford, CT 06437

**Reason for Recall:** Defibtech®, LLC, is initiating a voluntary worldwide recall of Lifeline® Semi-automatic External Defibrillators (AEDs) and ReviveR® Semi-automatic External Defibrillators (AEDs). This recall affects all Lifeline® and ReviveR® AEDs with software versions 2.002 and earlier. The self-test software for these devices may allow a self-test to clear a previously detected low battery condition. If this situation occurs, the operator may be unaware of the low battery, and the device may be unable to deliver a defibrillation shock, which could result in failure to resuscitate a patient.

**Public Contact:** Consumers with questions may contact the Customer Service Manager at 1-203-436-6654

**FDA District:** New England

**FDA Comments:** Defibtech®, LLC, initiated notification of its distributors and customers by letter on February 22, 2007. Defibtech®, LLC, determined the need for this recall after learning of three reports of malfunctions from end users. The company has provided a maintenance procedure that can be used to verify functionality of the device until the software upgrade has been installed,

allowing the device to remain in service. A copy of this maintenance procedure is being mailed to customers. This procedure, as well as instructions on determining the software version of a unit, can be found on the [www.defibtech.com/fa2007](http://www.defibtech.com/fa2007) web page. For questions regarding this recall, please refer to the above referenced web page, contact your distributor or contact Defibtech®, LLC, at [techsupport@defibtech.com](mailto:techsupport@defibtech.com), 1-877-453-4507 or 1-203-453-4507.

Defibtech®, LLC, will provide customers with a free software upgrade to address this issue for all affected AEDs. This software upgrade will be able to be installed in the field where the unit is located. The software upgrade is expected to be available within the next ten weeks.

Defibtech®, LLC, has distributed approximately 42,000 units worldwide through distributors to end users including: schools, Fire & EMS, businesses, health clubs and hospitality companies. The products can be identified by the words “Lifeline AED®” and “ReviveR AED TM” on the front of the device.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that, should this particular malfunction occur, use of the affected product may cause serious injury or death if the problem is not corrected.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by FAX.

- **Online:** [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- **Regular Mail:** use postage-paid FDA form 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm).  
Mail to MedWatch 5600 Fishers Lane, Rockville, MD  
20852-9787
- **FAX:** 1-800-FDA-0178

For more information about this recall, please see the company's press release at [http://www.defibtech.com/news/2007\\_0307\\_recall.html](http://www.defibtech.com/news/2007_0307_recall.html).

Updated March 7, 2007

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