



VITALS

for Medical Transport Professionals

A Weekly Safety Newsletter

FDA RECALLS

Recalls happen when a medical device is defective, poses a risk to health, or both. When it is determined that a product violates FDA law, whoever made the device, distributes it or is otherwise responsible, voluntarily performs the recall. The FDA is notified when a recall is performed. The U.S. Food and Drug Administration has a very informative website dealing with Recalls. It is <http://www.fda.gov/cdrh/recalls/learn.html>.

A recall doesn't necessarily mean that a device can't be used. It may only need to be checked, adjusted or fixed. Actions that may result from a recall include: inspecting the device for problems, repairing or adjusting the device, re-labeling the device, destroying it, notifying patients of the problem, or monitoring patients for health issues.

The FDA can require a medical device recall, but that rarely happens. The FDA oversees the actions of the company recalling the device. The company must directly contact the customer who received the product and reach others who need to be informed. The company must help users identify the product, take steps to minimize consequences, and do what it takes to make sure that the problem doesn't happen again.



Classes of Recall

The FDA has three classes of recalls. Class I, high risk, is the most serious. In a Class I recall there is a reasonable chance that use of the product may result in serious health problems or death. A less serious sort or risk is seen in a Class II recall. A device named in a Class II recall has the possibility of causing temporary health problems or a remote chance of causing serious health problems. A Class III recall is used when there is little chance that use of or exposure to the device will cause health problems.

Defibtech of Guilford, Connecticut has recently voluntarily issued a Class I recall involving LifeLine Semi-Automatic External Defibrillators (AEDs) and ReviveR Semi-Automatic External Defibrillators with software versions 2.002 and earlier. The self-test software may clear a previously detected low battery, which may make the operator unaware of the low battery. The device may have inadequate energy for defibrillation, which could result in failure to resuscitate.

The 42,000 recalled units were distributed to schools, fire EMS, businesses, health clubs and hospitality companies. Customers can contact Defibtech at 877-453-4507, 203-453-4507 or at techsupport@defibtech.com.

