Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: May 4, 2011

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Defibtech, LLC Recall

SUGGESTED ACTION: **Class I Recall; DDU-100 Series AEDs shipped with 2.004 software or earlier because corrective action addresses two possible conditions, which in rare cases may cause an affected AED to cancel shock during the charging process and not provide therapy which may result in failure to resuscitate the patient ; Information is provided in case of consumer inquiry.**

From the information provided by FDA, the product being recalled may have been distributed in the State of Indiana. The AEDs affected by this recall have been distributed globally to fire departments, EMS, health clubs, schools, and other organizations. The Food and Drug Administration (FDA) has determined that this action is a Class I recall. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Defibtech Announces a Voluntary Recall of DDU-100 series AEDs

Contact:
Consumer:
877-453-4507
techsupport@defibtech.com

Media:
Ray Valek
708-352-8695
ray@defibtech.com

FOR IMMEDIATE RELEASE - April 29, 2011 - Defibtech, LLC is initiating a worldwide voluntary recall of certain DDU-100 series semi-automatic external defibrillators (AEDs) sold under the Lifeline AED and ReviveR AED brand names, including 65,885 AEDs distributed in the United States. This recall affects only DDU-100 Series AEDs shipped with 2.004 software or earlier. This corrective action addresses two possible conditions, which in rare cases may cause an affected AED to cancel shock during the charging process and not provide therapy which may result in failure to resuscitate the patient. Both conditions are not detectable by the periodic self test.

Condition 1: In rare instances, the AED may cancel charge in preparation for a shock. Based on field data, the odds of an affected AED having this happen are less than a 1 in 400,000 chance per month for any given AED.

A subset of AEDs (less than 11%) that are affected by Condition 1 are also affected by Condition 2: In rare instances, the AED may cancel charge in preparation for a shock in very high humidity conditions. The only reported cases were in environments of greater than 95% relative humidity or condensing conditions. Based on field data, the odds of an affected AED having this happen are less than a 1 in 250,000 chance per month for any given affected AED.

Defibtech will provide customers with a free software upgrade to address these issues. The correction to the AED will be able to be performed at the location where the AED is deployed.

Because both of these conditions occur very rarely, it is recommended that customers keep their AEDs in service until they have performed the software upgrade. Full instructions and recommendations are being mailed to affected customers. This customer notification, as well as instructions on determining whether an AED is affected, can also be found on the www.defibtech.com/fa11[1] web page. For additional information regarding this recall, please refer to the above referenced web page, contact your distributor, or contact Defibtech at techsupport@defibtech.com, 1-877-453-4507 or 1-203-453-4507.

The AEDs affected by this recall have been distributed globally to fire departments, EMS, health clubs, schools, and other organizations. The Food and Drug Administration (FDA) has determined that this action is a Class I recall. Any adverse reactions experienced with the use of this product and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800- FDA-1088, or on the MedWatch website at www.fda.gov/medwatch[2].

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RSS Feed for FDA Recalls Information[3] [what's this?[4]]