741 Boston Post Road Suite 201 Guilford, CT 06437 v: 203.453.6654

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Commercial name of the affected product: Defibtech DBP-2800 Battery Packs

FSCA-Identifier: 2010-04-28

Type of action: Device Modification

Dear Customer:

Defibtech is notifying customers of a correction regarding DBP-2800 Battery Packs, an accessory used by the DDU-100 series AEDs sold under the brand names, Lifeline AED and ReviveR AED. **This recall affects only DBP-2800 battery packs shipped prior to June 4, 2007 (as identified by the serial numbers specified below).**

In rare instances, when the AED is used with an affected battery pack, the AED may falsely detect an error condition, cancel charge and not provide therapy. This situation can occur only in DBP-2800 battery packs shipped prior to June 4, 2007. Although the probability of this condition occurring is very low, as a precaution, Defibtech is correcting all potentially affected batteries.

Records indicate you own at least one of the identified DBP-2800 battery packs affected by this recall.

Defibtech is releasing a field software application to change a parameter in the battery. You will be able to perform this correction to your affected battery pack at the location where it is deployed using any DDU-100 series AED. To confirm whether or not you own an affected battery pack, and if you do, to receive the field update, it is important that you follow the instructions in the "Immediate Recommendations" section below. Your distributor will follow up this notification with a communication detailing the plan to provide this field software application. Distribution of the new field software application may take 2 to 4 weeks.

If your battery pack is on the affected list, you are advised to keep your DDU-100 series AED and battery in service and maintain them in accordance with the User Manual. If during a rescue, your AED cancels shock and shuts down with a service code, we recommend replacing the battery pack and proceeding with the rescue.

Immediate Recommendations

1) Remove the battery pack from the DDU-100 AED and inspect the battery pack label. As illustrated below, your battery pack label identifies the model or type of battery pack.
    - If your battery pack model number is DBP-2800, please go to step #2.
    - If your battery pack model number is NOT DBP-2800 (i.e. DBP-1400, DBP-RC2), your battery pack is not affected by this recall. Please go to step #5.

2) **Only DBP-2800 battery packs shipped prior to June 4, 2007 are affected.** To determine if your DBP-2800 battery pack is affected:
    - Find the 9-digit serial number on the battery pack label as illustrated below.
    - Affected battery pack serial numbers range:

      a) Between 202001005 and 202005916, or,

      b) Between 206001001 and 206009871.

Note: Visit the Defibtech website at www.defibtech.com. Enter your serial number(s) for confirmation.

3) If your DBP-2800 serial number falls within the above range, confirm receipt of this notification with your distributor to coordinate and expedite the update to your battery pack.

4) If your DBP-2800 serial number DOES NOT fall within the above range, your battery pack is not affected by this recall. See step #5.

5) *If you are receiving this letter, records indicate that you are likely to have or have had an affected DBP-2800 battery. If you believe that you have retired or replaced your affected DBP-2800, please confirm this information with your distributor.*

Transmission of this Field Safety Notice

This notice should be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact.

I sincerely apologize for any inconvenience this may cause you. If you have any questions regarding this notification, please contact your distributor or Defibtech Technical Support at techsupport@defibtech.com or call +1-203-453-4507, 8:30 A.M. to 5:00 P.M. (Eastern), Monday - Friday. Defibtech is committed to ensuring our products meet the highest quality standards and that our customers are fully supported.

Sincerely,

Glenn W. Laub, M.D.
CEO
Defibtech, LLC