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URGENT MEDICAL DEVICE SAFETY INFORMATION AND CORRECTION

Defibtech DBP-2800 Battery Packs

May 20, 2010

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, 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 during charging for a shock, then cancel charge and not provide therapy. If this situation occurs, the AED will speak "shock cancelled" followed by "service code 1003" while powering off.

This situation can occur only with 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 battery packs. This issue affects a total of 5,418 DBP-2800 battery packs distributed worldwide, of which 1,524 of these battery packs were distributed in the United States. Four occurrences of this issue have been reported worldwide during patient use, with one confirmed patient death. It is projected that this error condition may occur during patient use with an average probability of approximately 0.04% per unit per year (i.e. 1 out of 2,500 affected battery packs).

Defibtech is releasing a field software application to change a charging parameter that is stored in the battery pack. 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 and a Defibtech supplied battery pack update data card. The battery pack update will be performed by inserting the update data card into the DDU-100 series AED containing an affected battery pack. The easy-to-follow update instructions included with the update data card will guide you through the necessary steps to perform and confirm the correction.

Our records indicate you own at least one of the identified DBP-2800 battery packs affected by this recall. 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 "Affected Battery Pack Determination" section below.

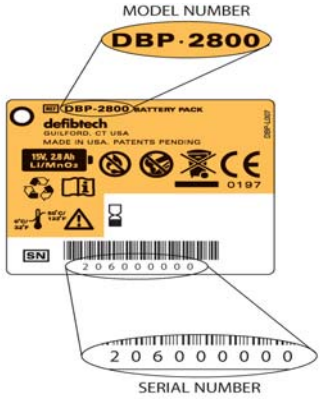
Immediate Recommendations

- Determine if your battery pack is affected by this correction by following the steps on page 2.
- If your battery pack is affected by this correction, keep your DDU-100 series AED and battery in service until you have received your battery pack update card from Defibtech and have updated your battery pack. Make sure that you have a replacement battery pack available, and arrange for a backup AED if you do not have a replacement battery pack available.
- If during a rescue, your AED cancels shock and shuts down with a service code 1003, replace the battery pack and proceed with the rescue. If this condition occurs, the AED containing an affected DBP-2800 battery pack will announce "Shock Cancelled", "Service Code 1003", "Powering Off".

- If your battery pack is not affected by this correction, keep your DDU-100 series AED and battery in service and maintain it in accordance with the User Manual.

Affected Battery Pack Determination

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 (e.g. 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/batteryFA. 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 Defibtech as soon as possible:
    - Visit the Defibtech website at *www.defibtech.com/batteryFA*. Enter your serial number(s) and follow instructions, or,
    - You may fill out and mail the enclosed postage-prepaid confirmation card, or,
    - You may also fax the completed confirmation card to 1-203-738-1072.

    Note: It is very important for you contact us either through the Defibtech website or return this card to confirm that you have received this notice. This information will expedite the process of updating your battery pack.

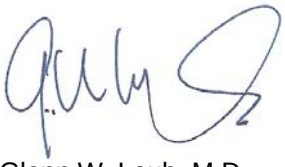
4) If your DBP-2800 serial number DOES NOT fall within the above range, your battery pack is not affected by this recall. See step #5.

5) If you are receiving this letter, our 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 complete the information requested in the enclosed confirmation card, or go to *www.defibtech.com/batteryFA.*

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 1-877-453-4507 or 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,



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