

URGENT MEDICAL DEVICE SAFETY INFORMATION AND CORRECTION

Defibtech DDU-100 Series AEDs

March 11, 2011

Dear Customer:

Defibtech is notifying customers of a corrective action regarding DDU-100 series AEDs sold under the brand names Lifeline AED and ReviveR AED. **This recall affects only DDU-100 Series AEDs shipped with 2.004 software or earlier.** You can check whether your AED is affected by going to www.defibtech.com/fa11 and entering your serial number.

This corrective action for your AED addresses two possible conditions, which in rare cases may cause an affected AED to cancel shock during the charging process and not provide therapy. Your AED may be affected by one or both of these conditions.

If your AED is affected by this correction, keep your DDU-100 series AED in service until you have received your software upgrade card from Defibtech and have upgraded your AED.

Condition 1: In rare instances, the AED may cancel charge in preparation for a shock. This condition affects 65,885 AEDs distributed in the United States. Eleven occurrences of this condition were reported during patient use. In cases where a shockable rhythm was detected, all affected AEDs have delivered at least one shock, and in more than 70% of the cases the affected AED delivered two or more shocks. 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.

If this condition happens during a rescue, your AED may cancel shock, power off and report a service code 1005. If another AED is not available, turn off and then turn on your AED and continue the rescue. Outside radio interference may exacerbate this issue. If there is a radio transmitter near the AED (e.g. police radio) increase the distance between the radio and the AED and try using the AED again.

A subset of AEDs 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. This condition affects 6,973 AEDs distributed in the United States. Two occurrences of this condition were reported during patient use. Both 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 AED.

This condition only occurs in a very high humidity environment. In an event where this condition occurs, if another AED is not available, move the victim and AED to a lower humidity environment and continue the rescue.

To determine if your AED is affected by one or both of these conditions, go to www.defibtech.com/fa11 and enter your serial number as described below in the Immediate Recommendations section.

Immediate Recommendations.

Because both of these conditions occur very rarely, it is recommended that you keep your AED in service until you have performed the software upgrade. As always check the Active Status Indicator on the unit to make sure it is blinking green, and continue to maintain your AED in accordance with the instructions found in the User Manual. Defibtech is releasing a field software upgrade, which will address both these conditions. Your AED can be upgraded in the field at the location where it is stored with a simple one-minute upgrade process. Follow the instructions below to receive an upgrade card and instructions on how to perform the upgrade.

Our records indicate you own at least one of the DDU-100 series AEDs affected by this field correction. To confirm whether or not you own an affected AED, and if you do, to receive the field upgrade (which

can be used to upgrade multiple AEDs), it is important that you follow the instructions in the "Affected AED Determination" section below.

Note: This software upgrade will also upgrade your AED to the latest AHA 2010 AED protocol.

Affected AED Determination

- 1) Remove the pads from the storage pouch found on the back of your DDU-100 series AED and inspect the 9-digit serial number label. See illustration for location of the 9-digit serial number label.
- 2) Carefully note the 9-digit serial number on the back of the AED, then visit the Defibtech website at www.defibtech.com/fa11 and enter your serial number(s) to determine if your AED is affected by one or both of the conditions described above. Alternately, please email your serial number and contact information (name, address and email) to fa@defibtech.com, or call Defibtech directly at 1-877-453-4507 or 1-203-453-4507, and Defibtech will inform you if your unit is affected.
- 3) If your AED serial number is affected, confirm receipt of this notification with Defibtech as soon as possible:
 - Visit the Defibtech website at www.defibtech.com/fa11 and enter your serial number(s) and follow instructions, or,
 - You may fill out and mail the enclosed prepaid-postage 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 upgrading your AEDs.

- 4) Upon receipt of contact information from affected customers, Defibtech will send an upgrade kit to such customers consisting of a software data card, instructions on how to perform the upgrade, and a pre-paid upgrade confirmation postcard that must be returned to Defibtech upon completion of the software upgrade.
- 5) If your DDU-100 series AED serial number DOES NOT fall within the above range, your AED is not affected by this field correction. See step #6.
- 6) If you are receiving this letter, our records indicate that you are likely to have or have had an affected AED. If you believe that you have upgraded, retired or replaced your affected AED, please complete the information requested in the enclosed confirmation card, or go to www.defibtech.com/fa11 to update your information.

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,

A handwritten signature in blue ink, appearing to read 'Glenn W. Laub'.

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