

URGENT MEDICAL DEVICE SAFETY INFORMATION AND CORRECTIVE ACTION

Defibtech DDU-100 Series AEDs

February 16, 2007

Dear Customer:

Defibtech is notifying customers that version 2.002 and earlier versions of the software in DDU-100 Series AEDs (“Lifeline” and “ReviveR”) may, under certain circumstances, clear a “Low Battery” or “Replace Battery” warning that was previously detected by an automatic self-test. If this condition occurs, the operator may be unaware of the low battery, and the device may be unable to deliver a shock.

This situation can occur only in units with low batteries. After a period of a low battery warning, the software may stop reporting the warning and the operator may be unaware of the low battery condition. A low battery may have insufficient power to deliver a shock. During a rescue, replacing the low battery pack will allow the unit to function normally.

The probability of this occurring is higher when a battery is near end-of-life. Field data indicate that battery life is typically greater than three years.

Devices with operating software version 2.002 and earlier versions are subject to this correction. Our records indicate you own at least one of the identified DDU-100 Series AEDs that was initially sold with the affected software.

Defibtech is releasing a new version of software to correct this issue. You will be able to install the new version of software in the field, where the unit is deployed. Defibtech will follow up this notification with a communication detailing our plan to provide this software upgrade. Distribution of this new software may take 12 to 16 weeks.

Follow the detailed instructions in the “Immediate Recommendations” section below and Defibtech recommends that you keep your DDU-100 Series AED in service until your unit’s software is upgraded.

Immediate Recommendations

These recommendations apply only to units running version 2.002 software or earlier versions. To determine the software version of a unit, turn the unit on, wait until the unit begins speaking, and then press and hold the on/off button for approximately five seconds until the unit begins speaking again. Prior to automatically turning itself off, the unit will speak the version number; if the unit does not speak a version number, the software version is 1.201.

We advise that you **perform the following procedure immediately and then once per month** until the unit’s software has been upgraded:

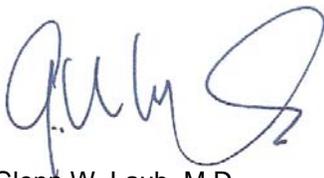
- Perform a manually initiated self-test:
 - Press and hold the on/off button for approximately five seconds until the unit speaks, “Performing Unit Self-test.” Once the unit begins to speak, release the on/off button.
 - The unit will run a comprehensive self-test for approximately ten seconds, report its status, and then automatically shut off. The unit will speak:
 - “Unit OK” – the unit and battery are rescue-ready.
 - “Replace Battery Pack Now” or “Battery Pack Low” – battery pack is low and may not have sufficient energy to perform a rescue. Replace battery pack immediately.
 - “Replace Nine Volt Battery” – the nine volt battery in the battery pack needs to be replaced. Replace nine volt battery with a lithium battery as described in the User Manual and perform a second manually initiated self-test as described above.
 - If any other message is spoken, refer to Section 5 of the User Manual (“Maintaining and Troubleshooting the DDU-100 AED”). If you have any questions, remove the unit from service and contact your distributor or Defibtech Customer Service at 1-877-453-4507 or e-mail us at techsupport@defibtech.com.
 - NOTE: This procedure should only be run once a month as described above. Each manually initiated self-test consumes battery capacity.
- After the above test has been performed, continue to verify the status of the AED on a daily basis as recommended in the DDU-100 User Manual (Routine Maintenance, Section 5.2) by checking the Active Status Indicator (ASI) on the upper right corner of the AED:
 - Flashing green ASI indicates that the unit and battery are operational.
 - Flashing red ASI or no flashing ASI indicates the unit needs service. Remove unit from service and follow the troubleshooting instructions in the User Manual.

We are communicating this information to the U.S. Food and Drug Administration (FDA) and to international regulatory agencies.

Please fill out the enclosed postage-prepaid confirmation card to verify that you have received this notification and mail the card as soon as possible. Please note that it is very important for you to return this card to Defibtech to confirm that you have received this notice. For your convenience, you may also fax the completed card to 1-203-738-1072.

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, 8:30 A.M. to 5:30 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