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URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Commercial name of the affected product: Defibtech DDU-100 series AEDs

FSCA-Identifier: 2011-03-11

Type of action: Device Modification

March 11, 2011

Dear Customer:

Defibtech is notifying customers of a field safety corrective action regarding DDU-100 series AEDs sold under the brand names Lifeline AED, ReviveR AED and Lifeforce 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 contacting your distributor or by going to www.defibtech.com/fa11 and entering your serial number.

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 or your distributor and have upgraded your AED.

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. One or both of these conditions may affect your AED.

Condition 1: In rare instances, the AED may cancel charging 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. In cases where a shockable rhythm was detected, all units have delivered at least one shock, and in more than 70% of the cases the affected unit delivered two or more shocks.

If this condition occurs 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 (less than 10%) 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. 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. The only reported cases of this condition during rescue have been in environments of greater than 95% relative humidity or condensing conditions.

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

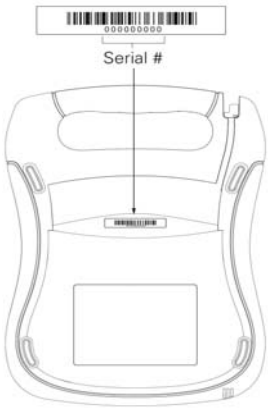
Immediate Recommendations.
Because both of these conditions occur very rarely, it is recommended that you keep your AED in service until you have performed the software upgrade. As always check the Active Status Indicator on the AED to make sure it is blinking green, and continue to maintain your AED 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 and quick upgrade process. Follow the instructions below to receive a software upgrade card and instructions on how to perform the upgrade.

Our records indicate you may 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/ERC 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 below 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 your distributor or contact them directly.

3) If your AED serial number is affected, confirm receipt of this notification with your distributor as soon as possible or visit the Defibtech website at www.defibtech.com/fa11 and enter your serial number(s) and follow instructions.

4) 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 go to www.defibtech.com/fa11 to update your information.

Transmission of this Field Safety Notice

This notice should to 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, 0830 to 1730 (GMT – 4:00), 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