

Dear Customer,

Enclosed, please find the mandatory Software Upgrade Kit for your Defibtech DDU-100 AED(s). This upgrade will address the issue described in our ***Urgent Medical Device Safety Information and Corrective Action*** letter dated February 16th, 2007. The software will also upgrade your Defibtech AEDs to the latest 2005 American Heart Association (AHA) Guidelines.

This kit includes the following:

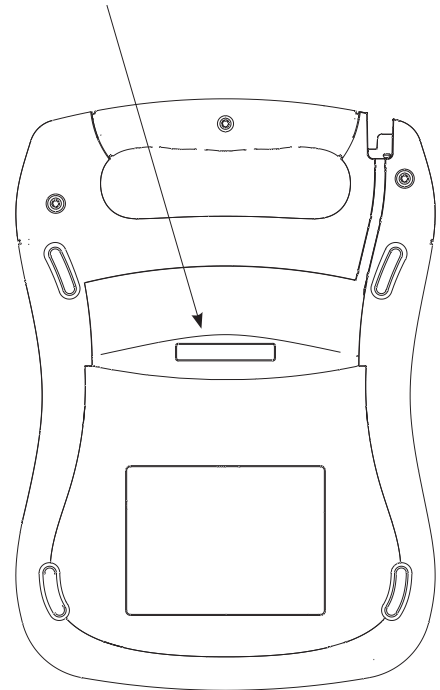
- DSU-100 Software Upgrade Data Card
- Upgrade Certification Postcard
- Pre-paid Return Envelope
- User Manual Addendum for AHA 2005 Guidelines

Please follow the instructions on the reverse side of this letter to upgrade your AED(s). Each Software Upgrade Data Card can upgrade more than 30 AEDs. Once all AEDs have been upgraded, return both the Software Upgrade Data Card and Upgrade Certification Postcard to Defibtech in the pre-paid envelope provided. Please remember to write down or verify the serial number for each upgraded AED on the Certification Postcard before returning the card to Defibtech. The 9-digit serial number can be found on the back of the AED behind the pad pouch as shown at right.

For the latest information and technical guidance, please visit [www.defibtech.com/upgrade](http://www.defibtech.com/upgrade). If you have any questions or need further assistance, please contact Defibtech at [techsupport@defibtech.com](mailto:techsupport@defibtech.com) or by calling 1-877-453-4507 or 1-203-453-4507.

Sincerely,

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



# Defibtech DDU-100 AED Software v2.003 Upgrade Procedure



Figure 1: Press orange release button to eject the battery pack.



Figure 2: Insert the DSU-100 Software Upgrade Data Card as shown.



Figure 3: Push the card in until it clicks into place flush with surface as shown.

## 1 Insert Upgrade Card:

1. Press the orange release button to eject the battery pack as shown in *Figure 1*.
2. Remove the battery pack and insert the DSU-100 Software Upgrade Data Card into the small slot as shown in *Figure 2*. Push the card in until it clicks into place flush with the surface as shown in *Figure 3*.
3. Replace the battery pack. The AED may perform a brief battery pack self-test and then turn off.

## 2 Perform Upgrade:

1. Turn the AED on by pressing and releasing the green ON/OFF button.
2. After the AED begins speaking, **press and continue to hold down** the green ON/OFF button for approximately 5 seconds until you hear *“Performing Unit Upgrade.”* Release the ON/OFF button at this time and **do not press any buttons or remove the battery pack until the upgrade completes.**
3. The AED will beep and the status lights will blink as the upgrade progresses. When the upgrade is complete, the AED will announce *“Unit Upgrade Complete, Version 2,0,0,3”* and then *“Powering Off”*.

**Note:** If you hear *“Upgrade Error,” “Data Card Error,” “Data Card Full,” “Data Card Missing,”* or *“Replace Data Card,”* at any point during this process, the upgrade may not have been successful. Contact your distributor or Defibtech Customer Service at [techsupport@defibtech.com](mailto:techsupport@defibtech.com) or 1-(877) 453-4507 or 1-(203) 453-4507.

## 3 Remove Upgrade Card:

Wait for the AED to power off, then eject the battery pack and remove the upgrade card by pushing the card in and releasing. The card will partially eject and can then be removed.

## 4 Replace Battery Pack:

Ensure that a good 9-volt battery is installed in the battery pack, then re-insert the battery pack. The AED will perform a brief battery pack self-test and then turn off.

## 5 Perform Unit Self-Test:

Perform a manually-initiated self-test as follows:

1. With the AED off, **press and continue to hold down** the green ON/OFF button for approximately 5 seconds until the unit speaks *“Performing Unit Self-Test.”*
2. Release the ON/OFF button and wait for the self-test to complete (approximately ten seconds). The unit's lights will cycle on and off and you will hear a series of internal clicks.
3. Upon completion of the test, the unit will report the test results and then automatically shut off. Verify that the unit reports “Unit OK” before it shuts down.
4. If you hear any other message at the conclusion of the self-test, the upgrade may not have been successful. Refer to Section 5 of the User Manual (*“Maintaining and Troubleshooting the DDU-100 AED”*) or contact your distributor or Defibtech Customer Service at [techsupport@defibtech.com](mailto:techsupport@defibtech.com) or 1-877-453-4507 or 1-203-453-4507.

## 6 Mail Data Card and Certification Card to Defibtech:

Please write down or verify the serial number(s) from your upgraded AED(s) on the Upgrade Certification Postcard, sign and date the Postcard, and then mail it with the Upgrade Data Card to Defibtech in the postage-paid envelope.

## 7 The AED is Now Ready for Use:

The upgrade is now complete.

**Note:** After a successful upgrade to the AED, please stop the monthly manual self-tests recommended in our previous Urgent Medical Device Safety Information and Corrective Action notification letter.

Please review the User Manual Addendum for AHA 2005 Guideline changes and store it with your DDU-100 User Manual.

As part of the normal routine maintenance recommended in the DDU-100 User Manual, continue to verify the status of the AED on a daily basis by visually 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.