

Dear Customer,

Enclosed, please find the mandatory Battery Pack Update Kit for your Defibtech DBP-2800 battery pack(s). This update will address the issue described in our ***Urgent Medical Device Safety Information and Corrective Action*** letter dated May 20, 2010.

This kit includes the following:

- DSU-102 Update Data Card
- Update Certification Postcard
- Pre-paid Return Envelope

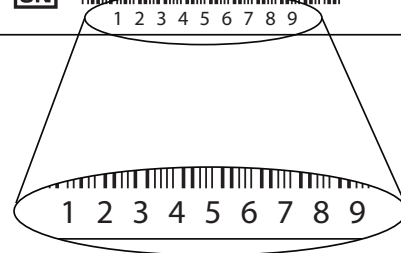
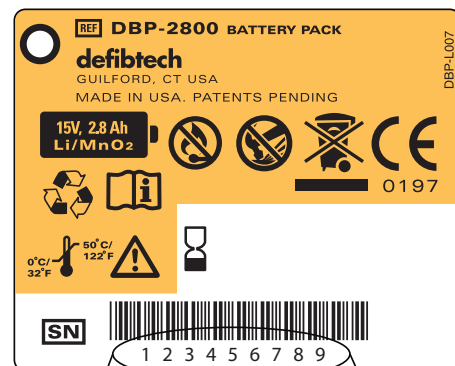
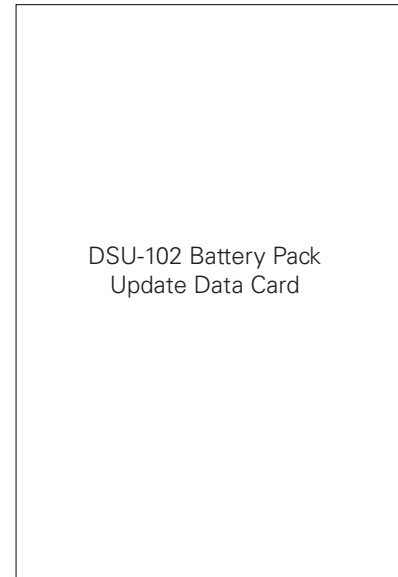
Please follow the instructions on the reverse side of this letter to update your affected DBP-2800 battery pack(s). Each Update Data Card can update approximately 100 batteries. Once the DBP-2800 battery pack(s) have been updated, return both the Update Data Card and Update Certification Postcard to Defibtech in the pre-paid envelope provided. Please remember to write down or verify the serial number for each updated battery on the Certification Postcard before returning the card to Defibtech. The 9-digit serial number can be found on the battery pack label under the barcode as shown below.

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

Sincerely,



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



SERIAL NUMBER

Defibtech DBP-2800 Battery Pack Update Procedure



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



Figure 2: Insert the DSU-102 Battery Pack Update Data Card label side up as shown.



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

1 **Insert Update 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-102 Battery Pack Update Data Card, label side up, 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. Re-insert the battery pack. The AED will perform a brief battery pack self-test and then turn off.

2 **Perform Update:**

WARNING: Therapy cannot be delivered while the update is in progress.

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 lights come on and the AED beeps. Release the ON/OFF button at this time and ***do not press any buttons or remove the battery pack until the update is complete.***
3. When the update is complete, the AED will announce ***“Upgrade Complete,”*** and ***“Powering Off.”***
4. If you hear ***“Upgrade Check OK,”*** the battery pack is either not affected by this correction or it has already been successfully updated.
5. If you do not hear ***“Upgrade Complete”*** or ***“Upgrade Check OK”*** then your battery pack was not successfully updated. Please contact customer service.

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

3 **Remove Update Card:**

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

4 **Re-insert 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 update 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 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 updated Battery Packs on the Update Certification Postcard, sign and date the Postcard, and then mail it with the Update Data Card to Defibtech in the postage-paid envelope.

7 **The AED and Battery Pack Are Now Ready for Use:**

The update is now complete.

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.