741 Boston Post Road Suite 201 Guilford, CT 06437 v: 203.453.6654

April 20, 2020

URGENT FIELD SAFETY NOTICE

Voluntary Product Field Action Notice of Defibtech DDU-2000 Series AEDs – International Markets

Commercial name of affected product: DDU-2000 Series Automated External Defibrillator (AED)
FSCA Identifier (date): FA2020-01
Type of Action: Return of device to manufacturer

Dear Valued User of Defibtech Lifeline AEDs:

Defibtech has notified your distributor of a Field Action Notice regarding DDU-2000 Series AEDs sold under the brand names Lifeline VIEW, Lifeline ECG, and Lifeline PRO. We have identified an issue requiring select units be returned to Defibtech for replacement. This Field Action affects only DDU-2000 Series AEDs shipped within the last several months. As Defibtech cannot confirm at this point that the issue described below will not occur in the field, it is required that the AEDs in question be returned to your distributor who is responsible for returning them to Defibtech for replacement. Your distributor will be replacing your returned unit with a new one. Please do not include the pads and battery packs when you return your unit to your distributor.

Details on affected devices:
Records indicate you have one or more of the serial numbers that requires action. Please see Attachment for information about affected units.

Description of the problem:
This corrective action addresses a hardware issue with a particular electrical component used in the identified AEDs. This component may, under certain circumstances, cause the AED to abort a shock delivery, or reset unexpectedly. This problem was identified within the manufacturing process. To date, there have been **no** field complaints reported. Due to the potential for the issue to occur in the field, and out of an abundance of caution, all affected serial numbers should be returned to your distributor for replacement.

Risk to health:
There is a possibility that this issue may cause an affected AED to cancel a shock during the charging process, to fail to deliver shock, and/or fail to deliver shock in range. Based on the risk of failure, if alternate units are available for use, please return affected units to the distributor and they will be replaced. If no alternate units are available, please inform your distributor and continue using the device with caution until replacement is provided.

Dedicated support for handling all aspects of the return of identified units for replacement will be provided by Defibtech. We will be contacting your distributor shortly to help them with the process, and answer any questions. If you have any questions now, please feel free to contact us.

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Defibtech is committed to ensuring our products meet the highest quality standards and that our customers are fully supported. We are working together with Competent Authorities and global regulatory authorities to ensure this matter is fully addressed and handled in an expeditious manner. I sincerely apologize for any inconvenience this may cause you. As always, Defibtech Customer Support is available by calling 1-877-453-4507, 8:30 A.M. to 5:30 P.M. (Eastern), Monday - Friday.

Thank you for your attention and cooperation.

Sincerely,

Bob Reinhardt

Bob Reinhardt
President / CEO
Defibtech LLC