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

April 21, 2020

URGENT MEDICAL DEVICE REMOVAL

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

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 ReviveR VIEW. We have identified an issue requiring select units be returned to Defibtech for screening. 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 Defibtech for screening. They will then be returned to you, or replaced, if needed.

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, out of an abundance of caution, all affected serial numbers should be returned for screening.

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.
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Actions to be taken by the Customer/User:

1. If you have additional AEDs on hand , please quarantine and return any affected units as identified in the Attachment for screening or replacement. Do not include the pads and battery packs when you return your unit.

2. If no other AEDs are available, please continue using the device with caution until a loaner or replacement is provided.

3. Ensure that all users of the AED are informed of the product issue.

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

Dedicated support for handling all aspects of the return of identified units for screening will be provided by Defibtech. We will be contacting you shortly to help you with the process and answer any questions. If you have questions now, please feel free to contact us using the email address FA2020@defibtech.com.

Defibtech is committed to ensuring our products meet the highest quality standards and that our customers are fully supported. 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.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Thank you for your attention and cooperation.

Sincerely,

Bob Reinhardt

Bob Reinhardt
President / CEO
Defibtech LLC