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

July 12, 2024

URGENT MEDICAL DEVICE SAFETY REMOVAL – USER
Voluntary Product Field Action Notice of Defibtech RMU-2000 ARM XR Chest Compression Device

Commercial name of affected product:
Defibtech RMU-2000 ARM XR Chest Compression Device

FSCA Identifier (date): FA2024-01
Type of Action: Removal

Dear Valued User of Defibtech **RMU-2000 ARM XR Chest Compression Device**

Defibtech is notifying Users of a recall regarding RMU-2000 sold under the brand name ARM XR. We have identified an issue requiring that units be returned to Defibtech. See attachment to this letter, which details the affected serial number(s) of RMU-2000 Chest Compression Device(s) shipped to you. We are also communicating this information to the U.S. Food and Drug Administration (FDA).

As Defibtech cannot confirm at this point that the issue described below will not occur in the field, it is required that the Chest Compression Devices identified be returned to Defibtech. We will work with customers on options for replacement of the returned devices.

Details on affected devices:
Records indicate you have one or more of the serial numbers that require action. Below is an image of the RMU-2000 Compression Module. Please see Attachment for information about affected units.

RMU-2000
Compression Module

Description of the problem:
This recall is being conducted due to a problem identified in the motor used in the affected Chest Compression Devices. This component may cause the device to stop compressions, and if a malfunction occurs, the device could delay therapy.
Defibtech has received two complaints related to Chest Compression Devices stopping compressions. One complaint was associated to a patient death but we have no evidence that it was attributed to the device malfunction. The second complaint did not lead to a serious injury or death.
As indicated in the Defibtech RMU-2000 Automated Chest Compression System User Manual, if the RMU-2000 stops during compressions, the user should remove the RMU-2000 from the patient and start manual chest compressions as soon as possible.

Risk to health:
There is a possibility that this issue may cause an affected Chest Compression Device to fail to operate. Devices are unlikely to cause injury or harm, delay of therapy can be mitigated as users may perform manual compressions in place of using automated compressions. 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:
Inventory:

1. Confirm receipt of this notice by checking the "Read" receipt option in the email notification containing this communication, or email FA2024@defibtech.com directly to confirm receipt, so that our records may be updated.
2. Check the compression module label's 9-digit serial number of any units in your inventory against the serial numbers listed in the attachment.
3. It is requested you quarantine the listed Chest Compression Devices and Defibtech will contact you to arrange their return to Defibtech.
4. If you have further transferred the device to another entity or department, you must provide this notice to affected parties or provide us with the contact information for that entity in the attached sheet of serial numbers shipped to you.

Please return any affected units as identified in the Attachment for replacement. Your device will be refunded, repaired or replaced at no cost to you.

Dedicated support for handling all aspects of the return of identified units 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 FA2024@defibtech.com.

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

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, 7:30 A.M. to 6:00 P.M. (Eastern), Monday - Friday.

Thank you for your attention and cooperation.

Sincerely,

Kei Yoshizawa
President
Defibtech LLC

Attachments:

- List of Chest Compression Device(s) by serial number shipped to you