Clifton Health Department
Food Recall Notification

Public Health
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Food/Drug/Pet Recall: Stryker

Stryker announced today that the company is launching a voluntary field action on specific units of the LIFEPAK 15 monitor/defibrillators.

The company is notifying a population of LIFEPAK 15 customers of an issue that may cause their devices to fail to deliver a defibrillation shock after the "Shock" button on the keypad is pressed. This is a result of oxidation that may have formed over time within the "Shock" button.

The company is contacting customers with impacted devices to schedule the correction of their device(s), which will include replacement of the affected keypad. Stryker anticipates that all devices subject to this field action will be serviced by June 2021.

Most complaints associated with this issue were detected prior to patient use. Routine testing of the device can detect this fault condition. If a customer experiences this issue, they should contact Stryker as soon as possible at 1-800-787-9537 and select option 2.

The company is instructing customers to continue to use their LIFEPAK 15 monitor/defibrillator according to the Operating Instructions until the correction can be completed. Customers should continue to perform the daily check as described in the Operator's Checklist, specifically, the QUIK- COMBO therapy cable check as described in the General Maintenance and Testing Section (pages 10-4 and the LIFEPAK 15 monitor/defibrillator Operator's Checklist, number 7).

Information about this notice is available at:
http://www.strykeremergencycare.com/productnotices.

Impacted customers will be notified by letter and will be requested to verify their device status.

Customers with questions regarding this notification, please contact Stryker by calling 1-800-787-9537, option 2, 8:00 A.M. to 7:00 P.M. (EST), Monday - Friday, or by email to MedTechSup@stryker.com or 1-800- 329-7879.

In addition to contacting Stryker, any potential quality problems or adverse reactions or events associated with the use of a product from Stryker may be reported online to the U. S. Food and Drug Administration's MedWatch Safety Information and Adverse Event Reporting Program at https://www.fda.gov/safety/medwatch/, by phone 1 800 332 1088 or fax 1 800 FDA 0178.