**FSCA identification:** Product recall RA2020 - 2246951

**Action type:** Follow-up Notification

**Product description:** LIFEPAK® 15 Monitor/Defibrillator

July 2020

Dear Customer,

Earlier this year Stryker notified you of a voluntary correction with our LIFEPAK 15 monitor/defibrillator where the device may not deliver a defibrillation shock after the "Shock" button on the keypad is pressed.

We would like to take this opportunity to clarify that this observed issue has happened on a very small percentage (0.2%) of distributed LIFEPAK 15 devices where most instances of the issue were identified outside of patient care by the operator's performance of the Daily Check recommended in the General Maintenance and Testing Section of the device Operating Instructions (pages 10-4 and the LIFEPAK 15 Monitor/Defibrillator Operator's Checklist, number 7).

Furthermore, we would like to reiterate that if the issue were to occur during patient care as indicated by a "disarming" message and the illumination of the service light after the defibrillation shock is attempted, immediately repeat your charge and shock cycle according to the Operating Instructions.

In the few observed instances of this issue during a patient event, a consecutive defibrillation shock was successfully delivered to the patient when the charge and shock cycle was repeated.

Since this issue is related to oxidation that has formed over time in some devices which have experienced infrequent use, the repeated defibrillation attempt by pressing the "Shock" button a second time demonstrated to remove the oxidation in the button allowing for a successful defibrillation attempt.

Stryker remains committed to delivering the highest standard of quality and is working to correct affected devices as soon as possible.

If you have any questions about this matter contact Stryker:


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Yours faithfully,

Sharun Thavarajan
Regulatory Affairs and Quality Assurance