FDA Device Defect Announcement: Stryker LIFEPAK 15 Defibrillator

On February 9, 2019 hospitals with LIFEPAK 15 monitor/defibrillators were notified by the FDA and the manufacturer that some devices may lock up after delivering a shock. Device Automatic Self-Tests do not identify this fault, as it occurs during defibrillation.

Customers/hospitals are advised to continue to perform the daily check as described in the Operator's Checklist. Stryker has released a corrective action plan to address the problem, but the device fix must be executed during use, e.g. while delivering life-saving defibrillation to individuals in cardiopulmonary arrest.

To ensure hospital staffs are prepared to trouble shoot this defect during defibrillation, we recommend the hospital train staff now on how to respond when the problem occurs and the hospital have a plan in place to obtain alternative devices nearby should the corrective action fail.

For additional information or questions, please review the FDA and manufacture's announcement concerning the Stryker LIFEPAK 15 monitor/defibrillator defect, or contact your IRMS risk manager.

https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/stryker-launches-voluntary-field-action-specific-units-lifepakr-15-monitordefibrillator

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