Update On Device Failure Associated with Getinge's Maquet/Datascope Intra-Aortic Balloon Pumps – Letter to Health Care Providers

November 19, 2019

The U.S. Food and Drug Administration (FDA) is providing an update on our evaluation of device failures associated with Getinge's Maquet/Datascope intra-aortic balloon pump (IABP) devices: Cardiosave (Hybrid and Rescue), CS300 and CS100/CS100i. In our previous letter to health care providers (/medical-devices/letters-health-care-providers/device-failure-associated-getinges-maquetdatascope-intra-aortic-balloon-pumps-letter-health-care), the FDA informed providers about reports of Maquet/Datascope IABP devices shutting down while running on battery power, leading to pump stop and loss of hemodynamic support. Since the previous communication on November 1, 2018, the FDA has received over 60 additional medical device reports related to this issue, including two patient deaths and one serious patient injury. Although the deaths cannot be definitively attributed to the device shutting down, these devices are used on critically-ill patients in health care facilities, including during transport, and any interruption in treatment can result in serious patient harm or death. The FDA wants to ensure health care providers are aware of these device failures reported to the FDA that continue to be observed in patients treated with Maquet/Datascope IABPs.

In July 2019, the FDA issued a notification about a Class I recall for all Maquet/Datascope Intra-Aortic Balloon Pumps (IABPs) (/medical-devices/medical-device-recalls/datascopegetinge-recalls-cardiosave-hybrid-cardiosave-rescue-cs300-and-cs100100i-intra-aortic) due to the potential risk of battery failure. As part of the recall, Maquet/Datascope is contacting each customer to schedule a training visit to review updated battery instructions, use, care and maintenance. Additionally, a reference guide specific to each IABP based on the Operating Instructions Manual(s) is now provided with each device. Customers with questions about the training can contact Maquet/Datascope Technical Support Department at 1-888-627-8383 (select option "3") from 8:00 AM - 6:00 PM (Eastern Time), Monday through Friday.

The FDA continues to work with the manufacturer to examine and address the root cause of these IABP devices shutting down while running on battery power. Maquet/Datascope is currently developing a Cardiosave battery maintenance software upgrade. A similar software upgrade was released for the CS300 and CS100/CS100i in 2017. Although the FDA remains concerned about the device shutdown events associated with Maquet/Datascope IABPs, we recognize that these systems may be the best option for circulatory support for some patients.

RECOMMENDATIONS

The FDA recommends that facilities who use Maquet/Datascope IABPs review the firm's notice (https://info.getinge.com/iabpbatterycarecustomerletter) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) regarding the recall, review the newly developed quick reference guides (https://info.getinge.com/ca-batteryguides) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), and schedule a training visit as soon as possible.

In addition, the FDA recommends that users and servicers of Maquet/Datascope IABP devices:

- Follow each device's Operating Instructions Manual for recommendations on usage, charging, maintenance and storage of the system batteries. Battery run times and discharge cycles vary between IABP models.
- Ensure that during patient use, whenever possible, the IABP is plugged into an AC power outlet, to reduce the potential observed problems while operating on battery.
- Ensure the IABP is plugged into an AC power outlet when the system is not in use. The batteries should be kept at a full charge even when the IABP is not in use.
- When transporting patients within or between facilities, refer to the IABP Operating Instructions Manual for recommendations on portable/battery operation. For example:
    - Prior to portable operation, the battery should be fully charged.
    - For Cardiosave Rescue and Cardiosave Hybrid only:
        - Additional charged batteries should be on hand during transport.

        - Ensure the batteries are properly seated in the battery compartment/charger and the IABP Console is completely seated/secured into the IABP Cart.
- Check battery run time and replace batteries as required, as recommended in the Operating Instructions Manual for each IABP. A reduction in run time can occur over a battery's life for reasons such as age, storage temperature and discharge depth. Batteries should be replaced:
    - After reaching the maximum number of charge-discharge cycles.
    - When the battery provides less than the minimum specified run time.
    - If the battery is broken, cracked, leaking or damaged.
    - When the labeled lifetime of the battery is reached.
- Immediately replace batteries for the Cardiosave Hybrid and Cardiosave Rescue IABPs that are older than 4 years, as the labeled lifetime for these batteries is 4 years. For all replacement batteries, ensure only Datascope approved/sourced batteries are installed/used.
- Follow informational messages on the display screen for CS100/CS300 IABPs regarding the batteries. For example, the “Battery Maintenance Required” message indicates that the IABP internal battery requires maintenance. For all replacement batteries, ensure only Datascope approved/sourced batteries are installed/used.
- Report to the FDA events of IABP devices shutting down while running on batteries, as well as any other battery issues or other device failures or patient injuries as a result of the device that occur. Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda). Health care personnel employed by facilities subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facilities. Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with these devices.
    - When possible, return devices associated with, or suspected to be associated with, any adverse events or device malfunction to the manufacturer for evaluation to help them and the FDA better understand the issue.

FDA Actions

The FDA continues to work with the manufacturer and will keep the public

informed if any significant new information or recommendations become available.

Contact Us

If you have questions about this letter, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV), 1-800-638-2041 or 301-796-7100.

Previous Letter On This Topic

https://www.fda.gov/medical-devices/letters-health-care-providers/device-failure-associated-getinges-maquetdatascope-intra-aortic-balloon-pumps-letter-health-care (/medical-devices/letters-health-care-providers/device-failure-associated-getinges-maquetdatascope-intra-aortic-balloon-pumps-letter-health-care)