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

November 1, 2018

Dear Cardiologists, Cardiothoracic Surgeons, Anesthesiologists, Nurses, Critical Care Specialists and Biomedical Engineers:

We are writing to inform you that the FDA is evaluating recent reports of Getinge's Maquet/Datascope intra-aortic balloon pump (IABP) devices shutting down while running on battery power. These devices are used on critically-ill patients in health care facilities, including during transport. An interruption in treatment can result in serious patient injury or death.

BACKGROUND

The Maquet/Datascope IABP is a cardiac assist device placed in the descending aorta, just distal to the left subclavian artery. The device is an electromechanical system used to inflate and deflate intra-aortic balloons, which provides temporary support to the heart's left ventricle by increasing coronary perfusion and reducing left ventricular work. Getinge manufactures the following Maquet/Datascope IABP devices: Cardiosave (Hybrid and Rescue), CS300 and CS100/CS100i.

Since 2017, the FDA has received over 75 medical device reports of Maquet/Datascope IABP devices shutting down while running on battery, leading to pump stop and loss of hemodynamic support. Five of these reports described three patient deaths, although the deaths cannot be definitively attributed to the device shutting down. Other reports describe serious patient injury such as a sudden drop in blood pressure or the need for resuscitation. At least six reports indicated that there was no alarm warning before the device shutdown.

The onset of the shutdown as described in the reports ranges from immediately following disconnection of the IABP from AC power (electricity) to within the expected battery run time.

In addition to device shutdown, there are reports describing several battery issues that could lead to patient harm, such as the device not charging the battery, the battery charge indicator not working properly or not showing the correct status of the battery charge, or the battery depleting sooner than expected.

At this time, the root cause or incidence rate of these IABP devices shutting down while on batteries is not known. Although we are 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. The FDA wants to ensure you are aware of these device failures that have been observed in patients treated with Maquet/Datascope IABPs and reported to the FDA.

RECOMMENDATIONS

The FDA recommends that health care providers and facilities should follow each device's Operating Instructions Manual for recommendations on usage, charging, maintenance and storage of the system batteries, since battery run times and discharge cycles vary between IABP models.

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

- Ensure the IABP system is plugged into an AC outlet whenever possible *during patient use* to prevent the battery from depleting.
- Ensure the IABP system is plugged into an AC 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, please refer to the system's Operating Instructions Manual for recommendations for portable/battery operation. For example:
  - Prior to portable operation, the battery should be fully charged
  - Additional charged batteries should be on hand during transport, if applicable for the system

- Ensure the batteries are properly seated in the battery compartment/charger

- Periodically check battery run time and replace batteries as required, as recommended in each system's Operating Instructions Manual. 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 expected run time
  - When the labeled lifetime of the battery is reached
  - If the battery is broken, cracked, leaking or damaged

We encourage you to report to the FDA events of IABP devices shutting down while running on batteries, as well as any other battery issues that occur. Voluntary reports can be submitted through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (https://www.fda.gov/Safety/MedWatch/HowToReport/default.htm)**. Health care personnel employed by facilities subject to **FDA's user facility reporting requirements (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)** 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 medical 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 is working with the device manufacturer to better understand these device shutdown events while running on battery for Maquet/Datascope IABPs, and any contributing factors. The FDA will keep the public informed if significant new information becomes available.

CONTACT US

If you have questions about this communication, 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.

Sincerely,
/s/
William Maisel, MD, MPH
Chief Medical Officer
Center for Devices and Radiological Health
U.S. Food and Drug Administration

ADDITIONAL RESOURCES

- **Maquet Datascope Corp./Getinge Group Recalls the Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pumps (IABPs) Due to Possible Malfunction and Failure at High Altitudes (/MedicalDevices/Safety/ListofRecalls/ucm624816.htm)**
- **Getinge Issues Worldwide Voluntary Correction of Maquet/Getinge Cardiosave Intra-Aortic Balloon Pump (IABP) For Interruption and/or Inability to Start Therapy at Altitudes above 3,200 Feet/975 Meters (September 20, 2018) (https://www.fda.gov/Safety/Recalls/ucm621203.htm)**
- **Federal judge approves consent decree with Maquet Holding B.V. & Co.: FDA Press Release (February 4, 2015) (https://wayback.archive-it.org/7993/20170723002604/https:/www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm432925.htm)**

More in Letters to Health Care Providers (/MedicalDevices/Safety/LetterstoHealthCareProviders/default.htm)