Press release

November 1, 2018
Gothenburg, Sweden

Getinge clarifies FDA communication to health care providers

Following the media coverage relating to the FDA communication to health care providers Getinge would like to make the following clarification.

On November 1, 2018, the American Food and Drug Administration (FDA) posted a Health Care Provider letter on the FDA Website regarding post market safety concerns with Maquet/Getinge ballonpump products.

Getinge would like to clarify that FDA is evaluating recent medical device reports (MDR) of ballonpumps shutting down while running on battery power. The communication from FDA today is part of a normal process to inform health care facilities and providers when needed to ensure proper use of devices and the health and safety of patients. 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.

Getinge does not expect the cost to be material and are working closely with the FDA to understand and resolve this issue.

The letter can be found on FDAs website or via this link.

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About Getinge

Getinge is a global provider of innovative solutions for operating rooms, intensive-care units, sterilization departments and for life science companies and institutions. Based on our first-hand experience and close partnerships with clinical experts, healthcare professionals and medtech specialists, we are improving the everyday life for people, today and tomorrow.