August 2025
Wayne, NJ, USA

Cardiosave Intra-Aortic Balloon Pump (IABP) Field Safety Corrective Action (FSCA) Status

Dear Valued Customer:

On May 8, 2024, the U.S. FDA published a letter to Health Care Providers expressing concerns regarding safety and quality of Getinge's Cardiosave IABP. The safety and quality concerns cited pertained to previously communicated recalls and did not relate to any new unreported issues.

Getinge remains intensely focused on all remediation efforts to address open recalls, known as Field Safety Corrective Actions (FSCAs). This includes providing additional information to customers through Field Safety Notices (FSNs) and correcting Cardiosave IABP units in the field. Getinge continuously updates the FDA on software and hardware design changes, testing strategies, and results to ensure timely implementation of all FSCAs.

To date, the open Cardiosave IABP FSCAs are being resolved as follows:

- **Notification Only:** Getinge sent FSNs to customers with information on issues, updated guidance on best practices, and/or updates to preventative maintenance activities. A customer acknowledgement to the FSNs was requested. Getinge will continue to follow up with customers who have not yet responded.

- **Hardware and Software Corrections:** Solutions are available and field corrections are completed and/or being scheduled for customer units.
    - **Coiled Cable** (replace two-piece cable with one-piece cable) – 99% completed in the field.
    - **Safety Disk** (replace affected safety disks) – 100% completed in the field.
    - **Li-Ion Battery Packs** (replacement of specific batches of batteries) – 100% completed in the field, with release of software update pending.
    - **Altitude Autofill Failure** (update units in the field to software version B.17) – 99% installed in the field.

- **Future Software Update**: A software update addressing six of the FSCAs has been developed and is being implemented in markets outside the U.S. (OUS) that have received Health Authority approval including the European CE region. Usability testing has been completed with U.S. clinicians and the results have been shared with the U.S. FDA.

- **Future Hardware Updates:** Hardware updates addressing the below FSCAs have been developed and are being implemented in markets OUS that have received Health Authority approval including the European CE region. Submission to the U.S. FDA is planned for the end of 2025.
    - Power Management Board/ Solenoid Board
    - System Overtemperature

- Fluid Ingress
- Management of Balloon Perforations (Blood Back)

We are aware of the challenges these open FSCAs have caused for your healthcare system as you continue to deliver high quality care to patients. Our teams are relentlessly working to bring the necessary corrective actions to customers as soon as possible. For details on any Cardiosave FSCA impacting your health system, please reach out to your local Getinge Sales Representative.

Best Regards,

Patricia Fitch

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Getinge