



# Getinge provides more information on FDA communication to health care providers

**Following the release of the FDA communication to health care providers Getinge would like to provide the following information.**

On December 16, 2021, the American Food and Drug Administration (FDA) posted a Health Care Provider letter on the FDA Website regarding a Class 1 Recall for Getinge/Datascope/Maquet Recalls Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) due to reports of fluid leaks. Getinge performed a correction to these devices in May 2018. The current voluntary field correction is a further action to eliminate fluid ingress.

Fluid entering the Cardiosave IABP may short-circuit various electronic components thus leading to system shutdown. Getinge/Datascope/Maquet plans to correct all IABP devices in the field to include various internal and external component upgrades that will be made available in an Ingress Prevention Upgrade Kit and will be installed by a Getinge service representative starting first half of 2022. Customers will also receive redesigned Display and Rescue Covers for the Cardiosave transport console.

The communication from FDA today is part of a regular process to inform health care facilities and providers to ensure proper use of devices and the health and safety of patients.

Customers have been informed by Getinge. The cost for the field correction is not material for Getinge and a provision was made in previous quarters. The letter is available on FDAs website or [via this link](#).

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## **About Getinge**

With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions that aim to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs over 10,000 people worldwide and the products are sold in more than 135 countries.