GETINGE

January 2026

URGENT MEDICAL DEVICE CORRECTION
Battery Charging Station
Battery is unable to charge in the left bay of Battery Charging Station
Reference Number: OT 1428023

Product Code/Part Number:	0998-00-0802
Distributed Affected Serial Number:	200019347EAI 200019447EAI 200019847EAI 210017525EAI 210017925EAI 210018025EAI 210018425EAI 210018625EAI 210019025EAI 210020044EAI 210020144EAI 210020244EAI 210020544EAI 210020944EAI 210021044EAI 210021144EAI 210021344EAI 210022144EAI 210022544EAI 210023244EAI
UDI Code:	10607567111964
Manufacturing Dates:	11/2020 to 11/2021
Distribution Dates:	12/30/2020 to 12/17/2024

Dear Risk Manager,

Datascope Corp., a subsidiary of Getinge, is initiating a voluntary Medical Device Correction on Battery Charging Stations, an accessory to the Cardiosave Intra-Aortic Balloon Pump (IABP).

Identification of the issue:

The Battery Charging Station is an optional dual-bay charger used to charge the rechargeable Cardiosave IABP Lithium-Ion batteries when they are not being used to operate the IABP. Getinge has identified that a protruding

screw in the left battery bay limits full insertion of certain batteries and prevents proper charging. The right bay of the Battery Charging Station is not affected by this issue.

The batteries that are not compatible with the left bay of the Battery Charging Station can be identified visually by snapped-in plastic cap inserts (see Figure 1 image below). Distribution of these batteries began in September 2025.

Note: The batteries that do not have the snapped-in inserts can be charged in either bay.

Figure 1: Cardiosave Lithium-Ion Batteries (A) incompatible with the Battery Charging Station Left Bay and Cardiosave Lithium-Ion Batteries (B) compatible with the Battery Charging Station Left Bay.

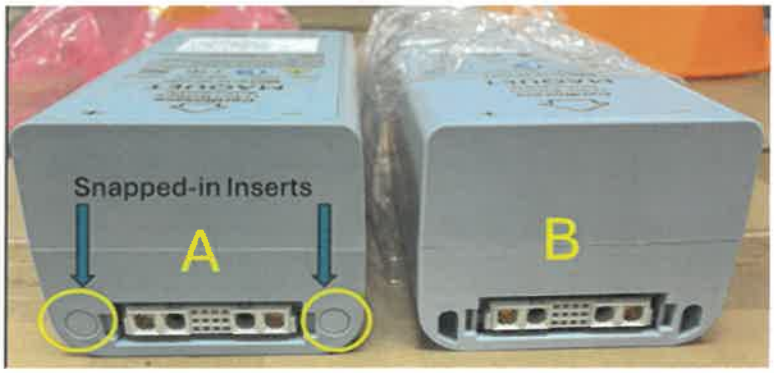


Figure 1

The Battery Charging Station can still be used to charge Cardiosave batteries. Batteries that are **not compatible** with the Battery Charging Station must be charged in the right bay only as described below.

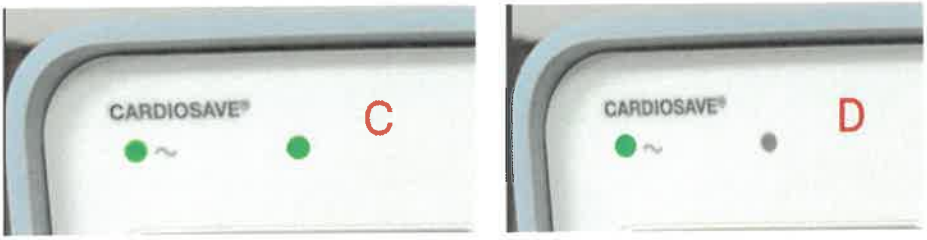
Battery Charging Instructions when using the Battery Charging Station:

1. Inspect battery(ies) to determine if they are compatible with the left bay of the Battery Charging Station. These batteries can be identified by: snapped-in cap inserts as shown in Figure 1.

2. If the batteries are not compatible with the left battery bay, use only the right charging bay as follows:
   - Insert the battery into the right charging bay
   - Allow the battery to charge completely
   - Remove the battery
   - Insert the next battery requiring charging into the right battery bay

3. Identify if the battery is charging:
   - The Battery Charging Station status LED above the battery slot will flash green while the battery is recognized and charging. If this LED is not illuminated, then the battery has not been recognized and will not charge.
   - During battery charging, the five (5) battery status LEDs on the battery pack will flash sequentially, as displayed below:

- When charging is complete, the Battery Charging Station status LED will illuminate in solid green, as shown in image "C" below. If it is not charged, it will remain unlit, as shown in image "D" below.



Risk to Health:

The issue with the left bay of the Battery Charging Station does not result in risk to patient health. The Battery Charging Station is not intended for use in transport. As of December 18, 2025, Datascope has not received complaints related to this issue.

Note: Batteries are able to be inserted in Cardiosave Battery Bays (left and right). When used in Hybrid configuration and plugged to a power source, the Cardiosave will be able to charge the batteries. There is no impact on Cardiosave performance due to this issue and therefore no patient impact.

Actions to be taken by the customer:

Our records indicate that you may have one or more Battery Charging Station(s) in your facility. Please forward this information to all current Battery Charging Station users within your facility.

- If you are currently using one of the affected Battery Charging Stations, please follow the instructions in the Battery Charging Instructions section of this letter.
- Complete and sign the attached Response Form to acknowledge that you have received and understand this notification. Return the completed form to recallresponses.grc@getinge.com.

Actions to be taken by Getinge:

- A Getinge representative will contact your facility to schedule a service visit. The protruding screw in the Battery Charging Station will be replaced. The hardware correction will be performed at no cost to your facility.

If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax using the following:

- **Online**: www.accessdata.fda.gov/scripts/medwatch/
- **Regular Mail**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form
- **Fax**: 1-800-FDA-0178

We apologize for any inconvenience this correction may cause. If you have any questions, please call Datascope/Getinge Customer Support at 1-888-943-8872, options 4, 2, 1, Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone).

This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

Ojas Zatakia
Senior Director Quality Assurance & Regulatory Compliance