

Getinge IABP Product Shortage Notification to Health Care Providers

Dear Valued Customer,

At Getinge, we strive to be forward-thinking, evaluating our business, and continually searching for ways to improve our products and processes. You should know that ongoing supply chain issues have significantly impacted our ability to build intra-aortic balloon pumps (IABPs), intra-aortic balloon catheters (IABs) and spare parts due to raw material shortages.

In response to these shortages, we are providing guidance for the maintenance of the Cardiosave Safety Disk and Lithium-Ion Battery in the attached appendix. In the event that you need a replacement pump, while your IABP is undergoing service, please contact your local sales representative who may be able to assist with a temporary IABP. We also encourage you to inform Getinge or to work directly with hospitals in your area if you have any underutilized Getinge IABs or IABPs and are willing to share them with Hospitals in need.

We are manufacturing IABs, IABPs, as well as spare parts, albeit that production is at a lower volume than is needed to quickly fulfill open orders. The production team is continuously improving output in addition to improving our processes to avoid future disruptions. However, due to the persistently high volatility in our global supply chain, we are not in a position to provide dates for when these items will return to normal production. Please note that any adverse reactions or quality problems experienced with the use of these products may be reported to Getinge and the FDA: www.accessdata.fda.gov/scripts/medwatch/.

We remain committed to supporting patients and clinicians and deeply regret this supply disruption. Thank you for your patience and understanding.

Sincerely,

Jennifer Paradise

VP Product Area – Cardiac Assist

APPENDIX – Cardiosave IABP Temporary Maintenance Updates – November 29, 2022

Safety Disk Maintenance Notification

- Based on our current supply limitations of the Cardiosave Hybrid and Rescue Intra-aortic Balloon Pump (IABP), we are temporarily modifying the recommended maintenance schedule of the Cardiosave Safety Disk from every 4-years or 6-million cycles to every 4-years or 9-million cycles.
- This extension is contingent on the Safety Disk continuing to pass the Pneumatic Module Leak Test, which should be performed before or after each use as per the Operating Instructions.
- Additionally, if blood is suspected of having entered the Safety Disk, the pump should be evaluated by Biomed/Technical Service to determine if blood entered the Safety Disk and to replace contaminated components if necessary.

Cardiosave Lithium-Ion Battery Maintenance Notification

- Based on our current supply limitations, we are temporarily modifying the recommended maintenance schedule of the Cardiosave Lithium-Ion batteries. Battery replacement may not be necessary at 200 full discharge cycles or after 4-years of operation. This modification is contingent on the individual battery run time being ≥ 45 -minutes at a heart rate that is less than or equal to 120 beats per minutes. This temporary extension to the maintenance schedule should only be followed when your total battery runtime is ≥ 90 -minutes. If your hospital routinely requires total battery time in excess of 90-minutes, we continue to recommend following the original maintenance schedule. Please note that this modification to the maintenance schedule will not impact the performance of the system or alarms in any way. However, it's important that you continue to monitor the performance of these batteries routinely.

To obtain optimum battery performance and expected battery life, the following guidelines should be observed:

- The batteries should be maintained at full charge when the IABP is not in use. It is required that the IABP be plugged into an AC outlet when the system is not in use.
- If the unit must be stored for an extended time period (2 months or longer) and AC power is not available to maintain the batteries, or if the unit is stored in an ambient exceeding the maximum operating temperature, remove the batteries from the Pump Console. Due to battery self-discharge the batteries must be fully recharged at least every six (6) months.
- Excessive heat and cold may be detrimental to battery life. Do not operate the system outside of the recommended operating temperature of: 10 °C to 40 °C (50 °F to 104 °F). Also, do not store batteries outside of our recommended storage temperature of: -20 °C to 60 °C (-4 °F to 140 °F).
- For storage exposure below -20 °C, we recommend allowing the Cardiosave pump to be exposed to room temperature for at least 90-minutes before operating on battery power.

- When a Low Battery message is displayed after any system operation, the battery should be recharged as soon as possible to prevent battery damage.
- Do not short circuit the battery or battery terminals.
- Batteries should be stored and transported in their protective case when not in use. Avoid storing the batteries with any conductive materials, such as copper, steel, iron, brass, etc...