

Getinge Cardiosave IABP Safety Disk Update to Health Care Providers

Dear Valued Customer,

As you are aware, our ongoing supply chain shortages have significantly impacted our ability to build Safety Disks, which has affected the manufacturing of new Cardiosave intra-aortic balloon pumps (IABPs) as well as the availability of the spare parts required to maintain existing installed pumps.

Effective immediately, we will prioritize the production of Safety Disks for spare parts through at least April 2023. This will allow us to make significant progress toward resolving our back order to better meet your needs to maintain your existing pumps. Getinge will continue to partially produce new pumps up until the point the Safety Disk component is needed in the new pump production. These partially built pumps will allow us to quickly transition to final assembly (anticipated Q2 2023) at which point we will rebalance the allocation of Safety Disks to be used in new pumps and as spare parts. We do understand that this will add a further delay to new pump orders. However, our goal is to have as little impact as possible to the delivery timeline for new pumps.

As a reminder, we have provided guidance for the extended maintenance schedule of the Cardiosave Safety Disk in the attached appendix. If you need a temporary replacement pump while your IABP is undergoing service or while you are awaiting a spare part, please contact your local sales representative, who may be able to assist with a temporary replacement IABP via Getinge's loaner pool. We also encourage you to inform Getinge and 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 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

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.