

Safety Communication

رسالة سلامة

Intra-Aortic Balloon Pumps May Exhibit Various Problems

Device/ Product Description:	Intra-Aortic Balloon Pumps (IABPs)
Brand:	Cardiosave Hybrid, Cardiosave Rescue, CS100, CS100i, CS300
Lot/Serial Number:	ALL
Manufacturer:	Getinge's Maquet/Datascope
Problem:	<ol style="list-style-type: none"> 1. Cardiosave Hybrid and Cardiosave Rescue IABP devices may not recognize AC/wall power when devices are plugged in, which may lead to devices unexpectedly shutting down. 2. Cardiosave IABP devices may unexpectedly shut down during a specific set of conditions. 3. Certain Cardiosave Li-Ion Battery Packs may experience unexpected short battery runtime and should not be used. 4. Fluid entering the Cardiosave IABP device may cause unexpected pump shutdown or the inability to initiate therapy.
Recommendation/Actions:	<ul style="list-style-type: none"> • Be aware that device failures (while running on battery power or AC power) continue to be observed in patients treated with Maquet/Datascope Cardiosave IABP devices. • Consider having alternative charged IABP devices available and ready in the event of device failure. • Ensure that Cardiosave IABP devices are not susceptible to shutting down during the removal of a battery. • Do not eject a battery in the following circumstances: <ul style="list-style-type: none"> - If there is a singular battery in either battery charging bay and the unused battery bay is empty

- The battery is charging on AC power (indicated by a flashing LED on the battery pack)

- Examine your inventory to determine whether you have any affected Cardiosave lithium-ion battery packs.
- Replace any affected battery with an unaffected battery, and remove affected product from areas of use.
- Affected products are eligible for credit or replacement at no cost.
- Never place fluids on top of the unit. In case of accidental spillage, wipe clean immediately and have the unit serviced to ensure no hazard exists.
- Use the plastic weather display and rescue cover any time the Cardiosave Rescue IABP is used outdoors, especially when there is the possibility of wet weather.

For more information, Please click [here](#)

If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through:
[NCMDR](#)
[Vigilance system](#)
 (19999) unified call center

Devices/Products photo:



Authorized Representative Details	AR name:	Al-Jeel Medical
	Assigned Contact Person:	Meshal Aleshaiwy
	Mobile/Phone:	0508827808
	Email:	aljeel.sfda@aljeel.com