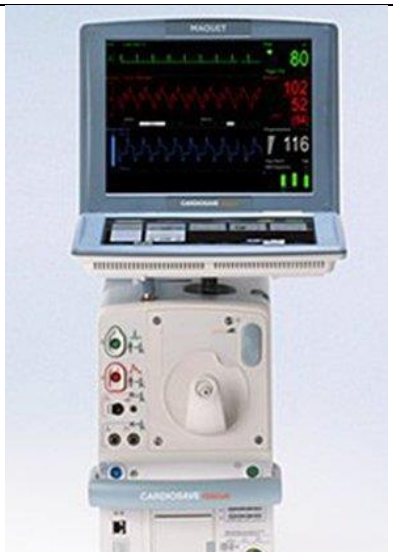
المركز الوطني للبلاغات الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Urgent Safety Communication

Intra-Aortic Balloon Pumps-Battery Power May Deplete Earlier than Expected

Device/ Product Name:	Intra-Aortic Balloon Pumps (IABPs): CARDIOSAVE(Hybrid, Rescue), CS300 and CS100/CS100i.
Lot numbers/Serials:	Not specified
Manufacturer:	Maquet Datascope Corp. / Getinge Group
Problem:	SFDA would like to bring your attention to the hazard associated with the battery power of the **Intra-Aortic Balloon Pumps** model: **CARDIOSAVE Hybrid, CARDIOSAVE Rescue**. • The battery operating time may not last the expected time. Either because they are not fully charged or at the end of life. • If the CARDIOSAVE runs out of battery power and line power or a replacement battery is not readily available, the patient may be seriously injured. This Safety Communication is being issued to ensure that all hospitals are aware of the issue and that adequate action is taken to mitigate potential risk to the patients.
Recommendation/Actions:	• Health care providers shall follow each device's Operating Instructions Manual for recommendations on usage, charging, maintenance and storage of the system batteries, since battery run times and discharge cycles vary between IABP models. • Ensure the IABP system is plugged into an AC outlet whenever possible during patient use to prevent the battery from depleting. • Ensure the IABP system is plugged into an AC outlet when the system is not in use. The batteries should be kept at a full charge even when the IABP is not in use. • When transporting patients within or between facilities, please refer to the system's Operating Instructions Manual for recommendations for portable/battery operation. For example: - Prior to portable operation, the battery should be fully charged - Additional charged batteries should be on hand during transport, if applicable for the system

	- Ensure the batteries are properly seated in the battery compartment/charger • Periodically check battery run time and replace batteries as required, as recommended in each system's Operating Instructions Manual. A reduction in run time can occur over a battery's life for reasons such as age, storage temperature and discharge depth. Batteries should be replaced: - After reaching the maximum number of charge-discharge cycles - When the battery provides less than the minimum expected run time - When the labeled lifetime of the battery is reached - If the battery is broken, cracked, leaking or damaged • Report to SFDA any adverse events suspected to be associated with affected **Intra-Aortic Balloon Pumps** model: **CARDIOSAVE Hybrid, CARDIOSAVE Rescue** through National Center for Medical Devices Reporting (NCMDR) Or Saudi Vigilance Prompt reporting of adverse events can help the SFDA identify and better understand the risks associated with medical devices.
Devices/Products photo:	 CARDIOSAVE® IABP Rescue  CARDIOSAVE® IABP Hybrid

Authorized Representative Details	**Company name:**	**Al-Jeel Medical & Trading Co. LTD**
	Contact Person:	**Meshal Aleshaiwy**
	Phone:	**+966112168222 Ext:253, 234**
	Email:	**aljeel.sfda@aljeel.com**

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative for corrective action.

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2412
Fax: +966 (11) 2757245

SFDA committed to keep the identities of the reporter and the patient confidential.

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Sincerely,
NCMDR Team