Urgent Safety Communication

Urgent FSN's of Cardiosave Hybrid IABP Manufactured by Maquet Datascope Corp.

Device/ Product Name:	Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pumps (IABPs)
Lot numbers/Serials:	**SERIAL NUMBERS:** All Serial Numbers manufactured from December 12, 2011 and ongoing are affected **MODEL/PRODUCT Part No.:** ○ Cardiosave Hybrid: 0998-00-0800-XX ○ Cardiosave Rescue: 0998-UC-0800-XX **MANUFACTURING DATES:** All units manufactured since December 12, 2011 and ongoing **DISTRIBUTION DATE:** 2012 Mar 6 to 2018 August 31
Manufacturer:	Maquet Datascope Corp. / Getinge Group (**Known as GETINGE**)
Problem:	Saudi FDA would like to bring your attention that **Maquet Datascope Corp.** is issuing an **Urgent FSN's** to inform you that Maquet/Getinge has received complaints involving the Cardiosave Intra-Aortic Balloon Pumps (IABPs) regarding the use of certain IABs at altitudes above 975 Meters. The Cardiosave may not successfully complete the autofill process required to initiate pumping. This failure may result in either interruption of therapy upon the first maintenance autofill or the inability to start therapy.
Recommendation/Actions:	On September 24, 2018, Maquet Datascope Corp. issued an Urgent Device Correction letter to all device consignees along with an Instructions for Use Addendum. The letter instructed users to follow the operating altitudes permissible for certain

intra-aortic balloons, as specified below for the Cardiosave Hybrid and Cardiosave Rescue IABPs:

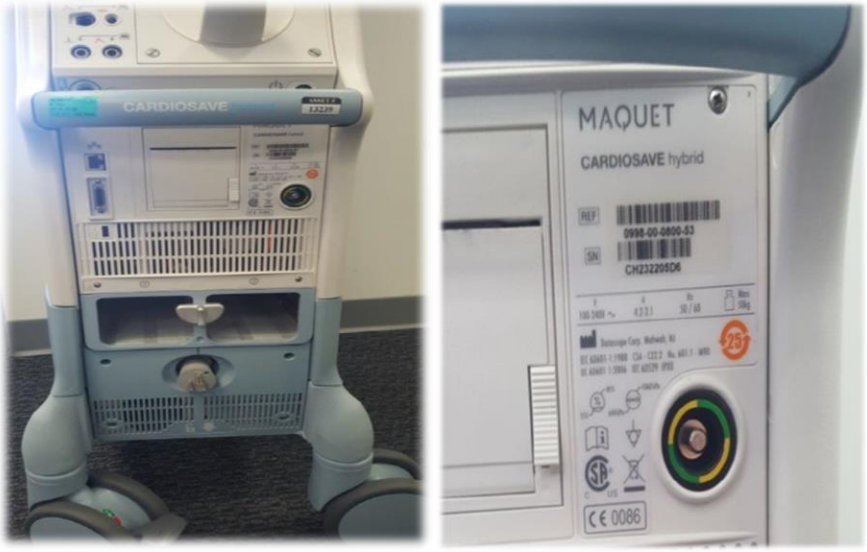
Balloon Name and Size	Operating Altitude
• Sensation 34 cc / 40cc • Sensation Plus 40cc / 50cc	• -1250 feet to 3200 feet (795 mmHg) (1060 hPa to 901 hPa)
• Mega 50cc	• -1250 feet to 5000 feet (795 mmHg to 632 mmHg) (1060 hPa to 843 hPa)
• Mega 30cc / 40cc • Linear 25cc / 34cc / 40cc	• -1250 feet to 12,000 feet (795 mmHg to 483 mmHg) (1060 hPa to 644 hPa)

Alternatively, use a Cardiosave CS100 or CS300 IABP, since they are not affected by this issue.

Maquet/Getinge is also currently developing a software correction to address this issue. Maquet/Getinge anticipates installing the updated software beginning in February 2019. A

Maquet/Getinge Service representative will contact customers to schedule software installation at no cost.

Devices/Products photo:



CARDIOSAVE IABP – Location of Part Number (REF) and Serial Number (SN)

Authorized Representative Details		
	Company name:	**Al-Jeel Medical & Trading Co.**
	Contact Person:	**Alaa Mohamed Mahmoud**
	Phone:	**+966597715854**
	Email:	amohamed@elajougroup.com

For further information, please **see the FSN below or Click Here.**

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

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Sincerely,
NCMDR Team