

المملكة الصربية السحودية Saudi Food & Drug Authority

Medical Devices Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication

رسالة سلامة

Update of the Instructions For Use for the FreeGo Enteral Feeding Pump

Device/ Product Description:	FreeGo Enteral Feeding Pump
Affected product:	Ref No. S400-054 GTIN Number: 5391503600473 Serial Number: All serial numbers
Manufacturer:	Zevex Inc
Problem:	A repeated user error of not clearing alarms per the instructions for use, led to the occlusion alarm sensor on the pump being temporarily disabled. This allowed the pump to continue operation without the occlusion alarm activating while no feed was being delivered to the patient.
Recommendation /Actions:	 Take note of the amended and reinforced instructions for use. Ensure the information is available at point of pump use. Ensure the pump operator manual is available to the user. 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

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Abbott Freeco **Ⅲ** ← ◄) **Devices/Products** photo: AR name: Abbott Saudi Arabia for Trading Authorized Assigned Contact Person: Sulaiman M Alayed Representative **Details** Mobile/Phone: 0505186744 Email: Sulaiman.alayed@abbott.com

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