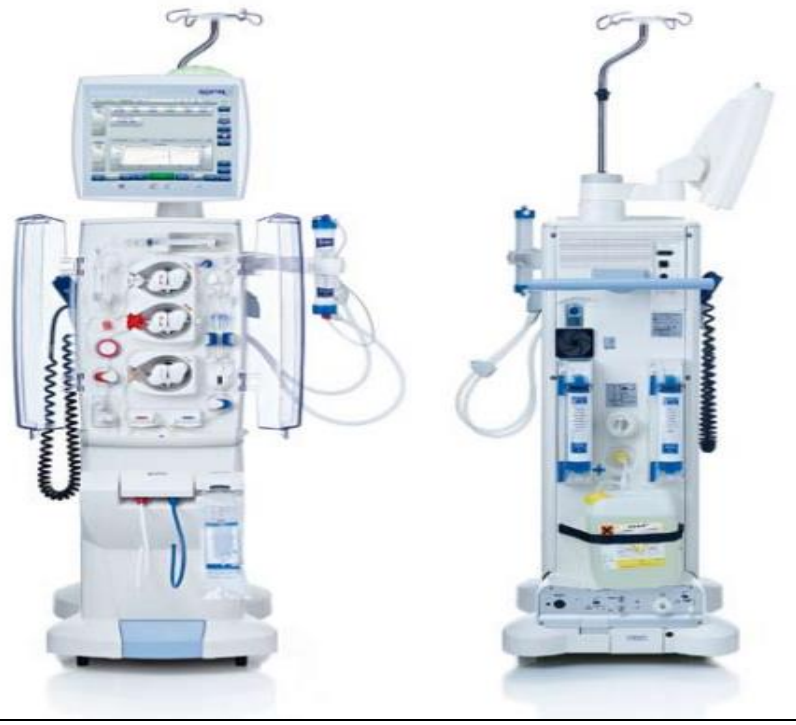
المركز الوطني للبلاغات الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Safety Communication

Fresenius 5008 & 5008S Hemodialysis machines may fail

Device/ Product Description:	Hemodialysis machines
Brand Name:	Fresenius
Lot numbers/Serials:	Fresenius 5008 & 5008S
Manufacturer:	Fresenius Medical Care
Problem:	The ultrafiltration pump in the above systems may fail, potentially leading to inadequate fluid removal during treatment. This failure cannot be identified during the manufacturer's technical safety checks. It can happen suddenly, without the machine alarming, and can be identified only by observing incomplete fluid removal from patients after dialysis treatments.
Recommendation/ Actions:	• **Staff responsible for patient care:** - Ensure that operators of these machines have read the information in this safety communication and are alerted to the potential risk of inadequate fluid removal without the machine's alarm sounding. Consider updating associated user guidance documents for these machines. - Consider checks after each dialysis treatment to ensure that enough fluid has been removed. - If you observe frequent episodes of inadequate fluid removal by these machines, notify your local technical/EMBE staff or the manufacturer. This will be noticeable if patient weight is frequently heavier than expected after treatment. • **Staff responsible for maintenance of these machines:** - Quarantine the machine if you observe frequent unexplained episodes of inadequate fluid removal. - Contact the manufacturer to arrange for replacement of the UF pump. - Consider including an additional periodic UF accuracy check as part of the machine's planned maintenance checks. You can find more information and recommendations from (HERE).

Devices/Products photo:	

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative of your product 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
4904 northern ring branch rd - Hitteen Dist.
RIYADH 13513 - 7148
Tel: +966 (11) 2038222 Ext: 2995, 2952
Fax: +966 (11) 2757245
Or
Saudi Vigilance

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Sincerely,
NCMDR Team