

Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication

رسالة سلامة

A number of bugs and technical issues

Device/ Product Description:	blood purification device		
Brand Name:	HF440		
Affected product:	Software Release Versions: 2.8 to 3.1.4		
Manufacturer:	Infomed SA		
Problem:	 A number of bugs and technical issues corrected through software updates include: Waste Flow Errors: Leads to interrupted treatment and erroneous error codes. Wi-Fi Connection: Wi-Fi being turned on can crash unit during treatment. Treatment Data: Treatment history, nursing staff record data to patient records not available. Date Format Conflicts: Date format inconsistent across different screens; sometimes DD/MM/YYYY, other times MM/DD/YYYY Intermittent screen freezing: Touchscreen becomes inoperable. 		
Recommendation /Actions:	 Make sure that this document is reached to the end-users. Contact the authorized representative for the required software updates. For more information, Please see 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:		

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	NCMDR Vigilance system (19999) unified call center	2 SFDA
Devices/Products photo:		FDA
Authorized Representative Details	AR name:	Advance Nfood Medical Company
	Assigned Contact Person:	Abdullah al dosary
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