

Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	Access 2 Immunoassay Analyzer
Device Model	81600N
Lot No.	574538
Manufacturer	Beckman Coulter
Country of Origin	USA
Reference	Link
Reason of Alert	NHRA initiates this FSN due to improper alignment of the sample motor to the sample wheel in certain Access 2 Immunoassay Analyzers, leading to irregular carousel motion that may damage the motor or sensor, potentially causing 'Sample Carousel Motion Error' events and delaying patient test result reporting.
Action should be taken	Please refer to "Actions to be taken by Customer/ User" in the attached FSN And for more information please contact the authorized representative Yousuf Mahmood Husain Co W.L.L at Wessam.mamdouh@ymh.com .

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh