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	Implantable Infusion Pump (**SynchroMed® II**)
Device Model	8637-20 and 8637-40
Manufacturer	Medtronic
Country of Origin	USA
Reference	https://www.medtronic.com/us-en/healthcare-professionals/products/product-performance/targeted-drug-delivery-product-advisories.html#pa-october-2019 http://wwwp.medtronic.com/ProductLookup/lookup.html?faId=382&alId=382
Device picture	
Reason of Recall	NHRA initiates this FSN due to the presence of a foreign particle inside the pump motor assembly which could interfere with motor gear rotation and lead to a permanent motor stall and will result in cessation of drug infusion therapy.
Action should be taken	In case of having the above defected medical device, please stop using it and contact your local agent to take the necessary action for replacement. **In case of adverse event please contact NHRA at medical_devices@nhra.bh**

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

For more information please contact Medical_Devices@nhra.bh