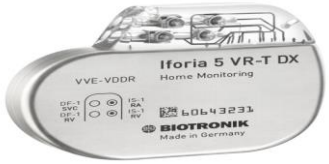
Medical Devices Safety Notice

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 Cardioverter Defibrillator
Device Model	390123-Iforia 5VR-T DX ProMRI DF-1 (4 Nos) / 390121- 5VR-T ProMRI DF4 (3 Nos)
Serial No.	60832476 / 60832428 / 60832440 / 60769912 / 60796180 / 60810913 / 60772253
Manufacturer	Biotronik SE & Co.KG
Country of Origin	Germany
Reference	https://www.biotronik.com/sites/default/files/2021-03/BIOTRONIK%20Field%20Safety%20Notice%20March%202021.pdf
Device picture	
Reason of Recall	NHRA initiates this FSN due to increased likelihood of premature battery depletion in a subset of devices of the following models of Implantable Cardioverter Defibrillators. There are no reports of serious injury or death associated with this issue but, this failure could result in an earlier than expected need for device exchange.
Action should be taken	If you have stock of the affected ICDs, please stop using them and contact the authorized representative **Gulf House Medical** at aniltitus@gulfhousemedical.com to take the necessary action for recall. And for patient who are already implanted with the affected ICDs need a follow up and in case of observing any unusual device behavior they need to contact their physician or authorized representative.

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

For more information please contact Medical_Devices@nhra.bh

Recall 2021 0018