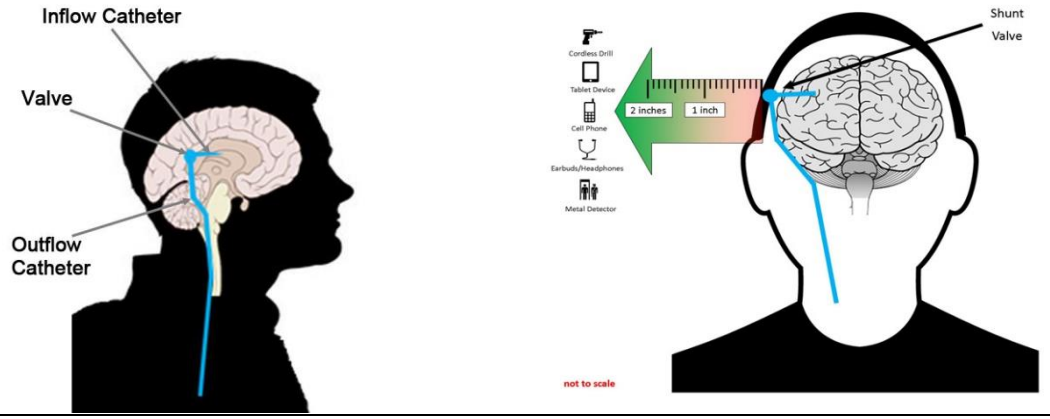
Medical Devices Safety Notice

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	Implanted Hearing Devices
Brand Name	Multiple Brands
Lot No.	N/A
Manufacturer	Multiple Manufacturers
Country of Origin	Multiple
Reference	https://www.sfda.gov.sa/ar/medicaldevices/Weekly%20Alerts/(SG-1907-76-H).pdf https://www.fda.gov/medical-devices/letters-health-care-providers/programmable-csf-shunts-and-magnetic-field-interference-implanted-hearing-devices-letter-health-care?utm_campaign=FDA%20MedWatch%20Programmable%20CSF%20Shunts%20and%20Magnetic%20Field%20Interference%20with%20Implanted%20Hearing%20Devices&utm_medium=email&utm_source=Eloqua
Device picture	

For more information please contact Medical_Devices@nhra.bh

Reason of Recall	NHRA Initiates this FSN to increase awareness about potential complications in patients implanted with both programmable cerebrospinal fluid (CSF) shunt systems and some hearing implants that contain magnets, such as cochlear implants, bone conduction hearing devices, or middle ear hearing devices. Patients implanted with programmable CSF shunt systems may have a potential risk of experiencing an unintended change in their valve setting if exposed to strong magnetic fields. If magnetic interactions inadvertently change the programmable CSF shunt valve settings, then over- or under-drainage of CSF may occur. Patients may experience symptoms such as altered mental status, headaches, lethargy, irritability, vomiting, changes in vision, and difficulty walking. If left untreated, symptoms could progress to include loss of consciousness, seizures, hemorrhage, or even death.
Action to be taken	• Educate patients and caregivers about this potential risk and be sure they know when to have their programmable CSF shunt valve checked, what symptoms are associated with potential over- or under-drainage of CSF, and when to contact health care provider. • Check the programmable CSF shunt valve setting after placement or adjustment of other devices that contain magnets to ensure that the setting has not changed. Only a trained clinician, such as a neurosurgeon, should check the shunt valve setting and adjust the setting, if necessary. • Consider the location of placement of the programmable CSF shunt valve if the patient has other implanted devices known to contain magnets in close proximity. • Contact the device manufacturer for further information.

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

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