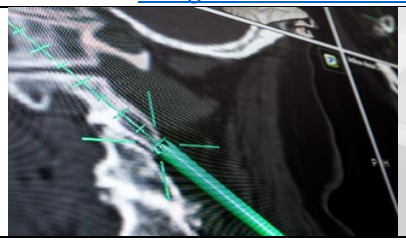
Medical Devices Safety Notice

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	Spine & Trauma 3D Navigation Software
Device Code	HAW
Manufacturer	BrainLab
Country of Origin	Germany
Reference	https://www.fda.gov/medical-devices/medical-device-recalls/brainlab-ag-recalls-spine-trauma-3d-navigation-due-inaccurate-display-may-result-user
Device picture	 
Reason of Recall	NHRA initiates this FSN due to the potential for incorrect information to display during surgery that may prevent the surgeon from accurately navigating surgical tools inside the patient. this may cause: • Damage to the patient's body. • Another un-necessary surgical procedure. • Serious life-threating patient injuries or death.
Action required	In case of having the affected device, please stop using it and contact the manufacturer at us.support@brainlab.com to take the necessary action

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

For more information please contact Medical_Devices@nhra.bh