

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	Ingenia Ambition S Marlin 1.5T Ingenia 1.5T S	Achieva 1.5T Achieva 3.0T
Device Model	782108 781474 781347	781296 781278
Manufacturer	Philips Medical Systems	
Country of Origin	Netherlands	
Reference	Link	
Reason of Alert	NHRA initiates this FSN due to identifying a loose g-MDU terminal connection in certain MR systems, which may cause smoke or fire. This could lead to patient and user risks such as asphyxia and delays in diagnosis.	
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 Mohammed fakhroo & Bros WLL at sandeep@fakhroo.com	

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

For more information please contact Medical_Devices@nhra.bh