


Safety Communication

Potential risks associated with using of ARCUS treatment table manufactured before 2009 by FREI AG

Device/ Product Name:	ARCUS treatment tables
Lot numbers/Serials:	All tables manufactured before 2009
Manufacturer:	Getinge (known as FREI AG)
Problem:	<p>SFDA would like to bring your attention that Getinge (known as FREI AG) issued a Field Safety Notice about the medical device mentioned above that in rare cases, the adjustment motor may fail on treatment tables with power adjustment that are older than 10 years, leading to a possible collapse of the treatment table.</p> <p>This Safety Communication is being issued to ensure that all hospitals are aware of the issue and that adequate action is taken to mitigate potential risk to the patient and therapist.</p>
Recommendation/Actions:	<p>SFDA recommends to check the production year of all adjustment motors on your treatment tables. Motors manufactured older than 10 years (before 2009) should be replaced as a precaution.</p> <p>SFDA becomes aware that some customers/ users bought the mentioned tables from showrooms and the Authorized Representative unable to complete the corrective action.</p>
Devices/Products photo:	

Authorized Representative Details	Company name:	Gulf Medical Co.
	Phone:	(012) 6512828
	Email:	regulatory@gulfmedical.com

For further information, please **see the FSN below** or [Click Here](#).

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative for an appropriate action.

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.

Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2479
Fax: +966 (11) 2757245

Or

Saudi Vigilance
<https://ade.sfda.gov.sa/>

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Sincerely,
NCMDR Team