

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	CARESCAPE Central Station (CSCS) V2.0
Affected Devices	SKN17400026SA / SNF18150007SA / SNF18150012SA / SNF18150014SA / SNF18150015SA / SNF18150017SA / SNF18150018SA / SNF18150019SA / SNF18150020SA / SNF18150021SA / SNF18150022SA / SNF18150028SA / SNF18150029SA / SNF18150030SA / SNF18150031SA / SNF18150032SA / SNF18150037SA / SNF18150038SA / SNF18150039SA / SNF18150040SA / SNF18150041SA / SNF18150042SA / SNF18150043SA / SNF18150044SA / SNF18150045SA / SNF18150051SA / SNF18150052SA / SNF18150053SA / SNF18150054SA / SNF18150055SA
Manufacturer	GE Healthcare
Country of Origin	USA, Mexico, Taiwan
Reference	https://ncmdr.sfda.gov.sa/FileDownload.ashx?f=ca&fid=9540
Reason of Alert	NHRA initiates this FSN because if the CARESCAPE Central Station (CSCS) V2.0 is used with an unapproved keyboard that contains a mute key, and if the mute key is pressed, the audio will be muted resulting in loss of audible alarms. This issue can result in a delay in noticing a change in patient condition. Visual alarms are not impacted.
Action should be taken	<ul style="list-style-type: none"> It is important to ensure that your staff continues to be aware of the serious risks if an unapproved keyboard is used with the CSCS V2.0. Ensure all users who interact with CSCS V2.0 are fully aware of, understand, and always follow these instructions. You can continue to use the CARESCAPE Central Station V2.0 with the GE-approved keyboard that is shipped with every CARESCAPE Central Station. The approved GE keyboard can be identified by the following characteristics. These characteristics can be placed in slightly different locations depending on the keyboard model:

For more information please contact Medical_Devices@nhra.bh

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| | <ol style="list-style-type: none">1) Marked with Seal Shield logo2) Marked with GE logo3) Alarm Audio Pause key |
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And for more information please contact the authorized representative **Gulf Pharmacy** at quality@gctbahrain.com

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

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