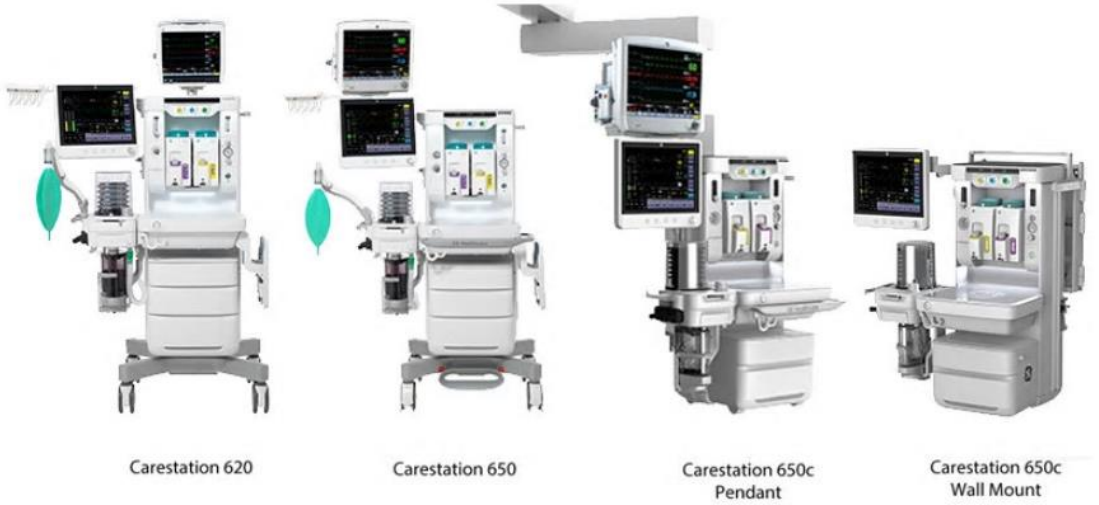
Safety Communication رسالة سلامة

Loose cable connection may result in loss of mechanical ventilation

Device/ Product Description:	Anesthesia Systems
Brand:	Carestation 620/650/650c (A1 & A2)
Affected product:	Use the table below to identify the affected device serial numbers: **Affected Devices - WU Manufactured** **Year (YY)** / **Fiscal Week (FW)** / **Manufacture Site (SA)** 2018 / 34 to 52 / WA 2019 / 01 to 24 / WA **Affected Devices - MA Manufactured** **Year (YY)** / **Fiscal Week (FW)** / **Manufacture Site (SA)** 2018 / 34 to 52 / MA 2019 / 01 to 30 / MA 
Manufacturer:	GE Healthcare
Problem:	The Manufacturer has become aware that there is a potential for a loose cable connection inside specific manufactured anesthesia devices. This would cause a loss of mechanical ventilation and the system will provide high priority audio and visual alarms. Loss of mechanical ventilation could lead to hypoxia if the clinician does not intervene.

Recommendation/ Actions:	1. Review this notice and ensure that affected personnel are aware of the contents. 2. Contact the authorized representative for required correction. 3. If you observe the message – "Ventilate Manually!" change from mechanical to manual ventilation. At any time, the clinician may use a self-inflating bag to ventilate the patient and/or switch to another anesthesia device. 4. Perform the planned maintenance (PM) every 12-months at a minimum per the User's Reference Manual, which includes inspection of the cable connection. For more information, Please click here. If you think you had a problem with your device or a device your patient uses, please do not hesitate to report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center
Devices/Products photo:	

Authorized Representative Details		
	AR name:	GE Healthcare
	Assigned Contact Person:	Samer Albawardi
	Mobile/Phone:	0555402028
	Email:	ksa.ra@ge.com