

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	Oxygen (O2) Sensors
Device Model	K54019-2-1
Lot No.	531672, 531671, 531670
Manufacturer	CooperSurgical
Country of Origin	USA
Reference	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=188271
Reason of Recall	<p>NHRA initiates this FSN for Oxygen Sensors supplied for use in the following incubator and work chamber products; G185 Standard 110V, G185 SensorTech 110V, G185 Standard 230V, G185 SensorTech 230V, G210 InviCell Standard, G210 InviCell Standard US, G210 Invicell Plus Optional pH and External Monitoring, G603 Work Chamber 115V, & G603 Work Chamber 230V. [CooperSurgical part numbers K22400-110, K22200-110, K22400-230, K22200-230, K59500, K59700, K60000, 3.641.831.153, & 3.641.832.153].</p> <p>This FSN issued because these Units are displaying output readings that differ from the measurements taken using a Gas Analyzer. When the display is reading a target setting of 5%, an external meter is reading between 3% and 12% and the Incubator does not alarm. May result in loss of embryo during storage.</p>
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative Gulf Pharmacy at qualit@gctbahrain.com to take the necessary action for replacement.

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

For more information please contact Medical_Devices@nhra.bh