


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	FORE-SIGHT ELITE Tissue Oximeter Module and FORE-SIGHT ELITE Absolute Tissue Oximeter Monitor
Device Model	HEMFSM10 and 01-06-3000
Lot No.	15701131, 15701132
Manufacturer	Edwards Lifesciences
Country of Origin	USA
Reference	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16049
Device picture	
Reason of Alert	NHRA initiates this FSN due to The StO2 values may be inaccurately low when using either the FORE-SIGHT ELITE Tissue Oximeter Module (Model HEMFSM10) or the FORE-SIGHT ELITE Absolute Tissue Oximeter Monitor (Model 01-06-3000) with the Fore-Sight Elite large sensor (FSESL) in certain somatic locations (arms and legs). While the StO2 absolute values are impacted, the directional trend remains accurate, but may have a larger magnitude change.
Action should be taken	Customers are to refrain from using the large sensors on certain somatic locations (arms and legs). Cerebral and flank/abdomen locations for the large sensors are not impacted. 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.

For more information please contact Medical_Devices@nhra.bh