




Date: 2 June 2024

Reference Number: SG-2406-420-H

قطاع الأجهزة والمستلزمات الطبية
المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector
National Center for Medical Devices Reporting

رسالة سلامة
Safety Communication

To: Healthcare Provider		إلى: مقدمي الرعاية الصحية
Title	UHI-4 stopping CO2 gas supply with the front panel LED turning off	العنوان
Medical Device Description	High Flow Insufflation Unit	اسم ووصف الجهاز/المستلزم الطبي
Manufacturer	Olympus Medical Systems	اسم المصنع
Authorized Representative	Gulf Medical Co.	الممثل المعتمد
Medical Devices Marketing Authorization (MDMA)	MDMA-1-2028-1043	إذن التسويق
Potential /Associated risks	If the UHI-4 detects a pressure sensor failure, the UHI-4 will raise an error. This error causes activation of the alarm, the front-panel LEDs turn off, and stops the CO2 supply. If this occurs before the procedure during set up, it may delay initiating treatment. In the event the UHI-4 CO2 supply stops during a procedure, the device becomes unusable. This could potentially result in a prolonged procedure and/or require additional medical intervention(s).	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	You should continue to quarantine the product until: <u>For units 5 years and older:</u> Your unit receives both the software update and a CR Board replacement. <u>For units under 5 years of age:</u> Your unit receives the software update.	التوصيات
For Reporting	  	لإبلاغ