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قطاع الأجهزة والمستلزمات الطبية
المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector
National Center for Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

رسالة سلامة
Safety Communication

To: Healthcare Providers	**إلى: مقدمي الرعاية الصحية**

Title	Risk of a cessation of ventilator therapy while in use on a patient	**العنوان**
Medical Device Description	Philips V680 Ventilator	**اسم ووصف الجهاز/المستلزم الطبي**
Medical Device Products Identifier	All V680 ventilators are potentially affected	**الأرقام للجهاز/المستلزم الطبي**
Manufacturer	Philips Healthcare	**اسم المصنع**
Authorized Representative	Philips Healthcare Saudi Arabia Ltd.	**الممثل المعتمد**

Medical Devices Marketing Authorization (MDMA)	GHTF-2019-1875, GHTF-2019-1889	**إذن التسويق**
Potential /Associated risks	If there is a "Vent Inoperative 1008: Machine and Proximal Pressure Sensors Failed" alarm, this will cause the V680 ventilator to cease therapy. A cessation of ventilator therapy while in use on a patient could potentially lead to severe hypoxemia and hypercarbia.	**المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي**
Recommendations	○ Continue to follow the below actions when utilizing the V680 Ventilator while you await receipt of Software Version 1.40: • **WARNING**: An alternative means of ventilation should be available whenever the ventilator is in use. • **WARNING**: If a fault is detected in the ventilator, disconnect the patient from it and immediately start ventilation with an alternative device. The ventilator must be removed from clinical use and serviced by authorized service personnel. • **WARNING**: Nebulization or humidification can increase the resistance of breathing system filters. When using a nebulizer or humidifier, monitor the breathing system filter frequently for increased resistance and blockage.	**التوصيات**
For Reporting	SFDA 19999 مركز الاتصال الموحد · NCMDR · يقظ Saudi Vigilance	**للإبلاغ**