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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	Potential of Environmental Contamination of Device Sensor	العنوان
Medical Device Description	Trilogy Evo, Trilogy Evo O2, Trilogy Evo Universal, Trilogy EV300 ventilators	اسم ووصف الجهاز/المستلزم الطبي
Manufacturer	Philips	اسم المصنع
Medical Devices Marketing Authorization (MDMA)	MDMA-1-2019-5958	إذن التسويق
Potential /Associated risks:	Environmental debris may accumulate on the internal machine flow sensor causing partial occlusion which may impact accurate delivery of pressure, volume, or flow. A malfunction caused by this issue can result in patient harm up to hypoxemia if not addressed by the care provider.	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	<ul style="list-style-type: none"> - These devices can continue to be safely used in line with the mitigations below as well as in accordance with the instructions for use. <p>To help prevent accumulation of debris on the machine flow sensor:</p> <ul style="list-style-type: none"> o Use the Philips approved particulate filter which prevents a significant majority of airborne aerosols and particulate from entering the device. This filter must be replaced between patients and monthly as indicated in the Instructions for Use. Using this filter was previously optional. <u>This is now required.</u> o Use the air-inlet filter as indicated in the Instructions for Use. o Installation of the particulate filter will not require a change to therapy settings. <ul style="list-style-type: none"> - For more information of affected products, review the Safety Alert Link 	التوصيات
For Reporting	  	للإبلاغ: