

Date: 07 April 2022
Reference Number: SG-2204-387-H

Medical Device Sector
National Center for Medical Devices Reporting

Safety Communication
رسالة سلامة

To: Healthcare providers	إلى: مقدمي الرعاية الصحية
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Title:	Risk of unexpected shutdown	العنوان:
Medical Device Description	V60/V60 Plus/V680 Ventilator	اسم ووصف الجهاز/المستلزم الطبي:
Manufacturer:	Philips Healthcare	اسم المصنع:

Registration Status:	Marketing authorization : GHTF-2019-1875 / GHTF-2019-1889/ MDMA-1-2019-5861	إذن التسويق:								
Associated Risks:	<p>Based on manufacturer filed safety notices, a Potential issue could affect the main electrical circuit ("35V Rail") powering the ventilator and alarm. In some cases, this issue may result in either one of the following scenarios:</p> <ol style="list-style-type: none"> 1. The ventilator ceases to operate, activating both visual and audible alarms. 2. The ventilator ceases to operate and does not activate either a visual or audible alarm causing a "silent shutdown". <p>These issues can result in a serious injury which can be life-threatening or result in death.</p>	المخاطر المرتبطة:								
Recommendations:	<ul style="list-style-type: none"> • Connect the Philips Respironics V60/V60 Plus/V680 to a nurse call/remote alarm system. • Respond to Alarms. • Oxygen Analyzer. • Provide Pulse Oximetry. • Access to Alternative Ventilation Device. • Train all relevant staff on alternative ventilators 	التوصيات:								
Authorized Representative Details:	<table border="1"> <tr> <td>AR name:</td> <td>Philips Healthcare Saudi Arabia Ltd.</td> </tr> <tr> <td>Assigned Contact Person:</td> <td>Mohammed Alsamhan</td> </tr> <tr> <td>Mobile/Phone:</td> <td>0503879145</td> </tr> <tr> <td>Email:</td> <td>sfda.sa.met@philips.com</td> </tr> </table>	AR name:	Philips Healthcare Saudi Arabia Ltd.	Assigned Contact Person:	Mohammed Alsamhan	Mobile/Phone:	0503879145	Email:	sfda.sa.met@philips.com	معلومات الممثل المعتمد:
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Related Links	NCMDR	Here	المركز الوطني لبلاغات الأجهزة والمنتجات الطبية	روابط ذات صلة
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For Reporting:				للإبلاغ:
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