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| **Medical Device Sector** |  |  | **قطاع الأجهزة والمنتجات الطبية** |
| **Surveillance & Biometrics Executive Department** | |  | **الإدارة التنفيذية للرقابة والقياسات الحيوية** |
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| **Safety Communicationرسالة سلامة**  **Shut Down Unexpectedly Due to a Premature Component Failure** | |
| **Device/ Product Description:** | Ventilators |
| **Brand:** | V60 |
| **Affected product:** |  |
| **Manufacturer:** | PHILIPS Theraputic Care |
| **Problem:** | A solder connection on the Power Management printed circuit board assembly (PCBA) of affected V60 ventilators is subject to solder connection failure. This solder joint connects a component (designated as R31) to the PCBA.  In the most common failure mode of the solder joint (estimated to be less than 1 in 650 of affected devices), the failure will cause the blower to lose power, spool down, and trigger a visual and audible High Priority “Check Vent” alarm (See Figure 1) to alert clinicians to switch the patient to alternative ventilation. This failure mode is referred to as an “open failure.”  A significantly less common failure mode was identified in which the solder experiences an intermittent connection. The intermittent connection disrupts expected operation and triggers the unit to shutdown unexpectedly. Should this intermittent failure occur, the ventilator will shut down without issuing an alarm.  In the event that the open failure mode occurs, the ventilator will cease to ventilate the patient, but will appropriately alarm to notify clinicians of the need for alternative ventilation. This may lead to moderate patient hypoxemia (reduced blood oxygen level).  In rare cases of an intermittent solder joint failure, an unexpected shutdown will occur ceasing ventilation without appropriate alarming and indication. Clinicians will not be alerted to the shut down by the V60 ventilator alarm, which could lead to hypercarbia (excess blood carbon-dioxide level) and severe hypoxemia if the loss of ventilation is not otherwise promptly recognized. |
| **Recommendation/Actions:** | * Review this notice and ensure that affected personnel are aware of the contents. * Follow directions in the operator’s manual and in the Field Safety Notice to further reduce any risk associated with this potential failure. From the Operator’s Manual:  1. Use an external O2 monitor/analyzer and set the ventilator alarm thresholds appropriately. 2. Promptly attend to all alarms presented by the ventilator. 3. Ensure that an alternative means of ventilation is available whenever the ventilator is in use.  * Additional directions:  1. Determine whether the V60 ventilator is affected by this correction without interrupting therapy. 2. If a V60 ventilator experiences a shutdown, disconnect the patient and immediately start ventilation with an alternate device. Contact a local customer service contact to report the failure and to schedule corrective maintenance to replace the Power Management PCBA at a time when the ventilator will not be in use.   For more information, Please click [here.](https://ncmdr.sfda.gov.sa/FileDownLoad.ashx?f=ca&fid=8764)  If you think you had a problem with your device or a device your patient uses, please do not hesitate to report the problem to SFDA through:  [NCMDR](https://ncmdr.sfda.gov.sa/Default.aspx)  [Vigilance system](https://ade.sfda.gov.sa/Home/Report)  19999 unified call center |
| **Devices/Products photo:** |  |
| **Authorized Representative Details** | |  |  | | --- | --- | | AR name: | Philips Healthcare Saudi Arabia Ltd. | | Assigned Contact Person: | Alawi AlKhadhrawi | | Mobile/Phone: | 0503879145 | | Email: | sfda.sa.met@philips.com | |