Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No.....59..... dated 27/3/22 Regarding NCMDR FSCA of V60/V60 Plus/V680 Ventilator from (mrf: Philips Healthcare).

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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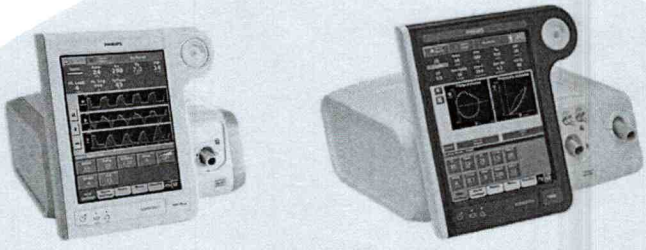
Circular No. 59 **/ 2022**

24 -08-1443 H

27 -03-2022

Field Safety Corrective Action of V60/V60 Plus/V680 Ventilator From Philips Healthcare.

Source	NCMDR- Nationa Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16073
Product	V60/V60 Plus/V680 Ventilator.
Description	Ventilator.
Manufacturer	Philips Healthcare.
Local Agent	Mustafa Sultan Science & Industry Co.L.L.C.
The affected products	All V60/V60 Plus and V680 ventilators.
Reason	Potential issue that 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: 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".
Action	1. Philips is not advising customers to remove affected Philips V60/V60 Plus or V680 ventilators from service. 2. They may continue to be used in accordance with their instructions for use and the guidance in the attached FSN. 3. Contact the local agent for remedial action.
Product Picture	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om

1448

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

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PHILIPS

Field Safety Notice
Philips Respironics - Hospital Respiratory Care

V60/V60 Plus/V680 Ventilator
35V Rail

14 March 2022

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

Dear Customer,

All V60/V60 Plus and V680 units have been identified to have potential issue that 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:

1. What the problem is and under what circumstances it can occur

All V60/V60 Plus and V680 units have been identified to have potential issue that 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:

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".

To date, Philips Respironics has been made aware of two (2) serious injuries and one (1) death associated with this issue.

2. Describe the hazard/harm associated with the issue

These issues can result in a serious injury which can be life-threatening or result in death. Specifically:

1. Should the ventilator cease to operate, activates both visual and audible alarms, and the clinician does not respond to the alarms in a timely manner, the patient may experience hypoxemia and/or hypercarbia.
2. Should the ventilator cease to operate with no visual and/or audible alarms alerting the clinician, the patient may experience hypoxemia and/or hypercarbia. In addition, while less likely it is possible that the patient may experience severe hypoxemia.

PHILIPS

3. Affected products and how to identify them

All V60/V60 Plus and V680 ventilators are impacted by this issue.

4. Describe the actions that should be taken by the customer / user in order to prevent risks for patients

Philips is not advising customers to remove affected Philips V60/V60 Plus or V680 ventilators from service. They may continue to be used in accordance with their instructions for use and the guidance in this Field Safety Notice.

- **Connect the Philips Respironics V60/V60 Plus/V680 to a nurse call/remote alarm system.** Philips Respironics V60/V60 Plus and V680 ventilators have the capability to be connected to a nurse call/remote alarm system. We strongly recommend using a nurse call/remote alarm system. The nurse call/ remote alarm will provide a backup signal to the clinician even if the ventilator's primary alarm system does not activate. To prevent possible patient injury due to non-annunciating alarms, verify the operation of any nurse call/ remote alarm device before use.
    - To connect the Philips Respironics V60/V60 Plus to a remote alarm system, follow the directions provided on Section B-5: Remote Alarm Port of the V60/V60 Plus Operator's Manual.
    - To connect the Philips Respironics V680 to a remote alarm system, follow the directions provided on Page 208: Remote Alarm Port of the V680 Operator's Manual.

- **Respond to Alarms.** Promptly respond to all low priority alarms and immediately respond to all high-priority alarms presented by the ventilator.

- **Oxygen Analyzer.** Install oxygen analyzer/monitor, and follow the manufacturer's instructions for setup, alarms, and calibration.

- **Provide Pulse Oximetry,** to inform the clinician of a change in the patient's condition.

- **Access to Alternative Ventilation Device.** Always have immediate access to an alternative means of ventilation. If a Philips Respironics V60/V60 Plus or V680 ventilator experiences a shutdown, disconnect the patient, and immediately start ventilation with an alternate device.

- **Acknowledge Receipt of this Recall Letter.** Acknowledge receipt of this notification by fax or e-mail, via the attached "FIELD SAFETY NOTICE RESPONSE FORM".

Should you experience your device shutting down (with or without alarms), contact your local customer service representative to report the issue.

This notice needs to be provided to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

5. Describe the actions planned by Philips to correct the problem

Upon request Philips can provide technical assistance to implementing the nurse call/ remote alarm capability.

PHILIPS

If you need any further information or support concerning this issue, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>

This notice has been reported to the appropriate Regulatory Authorities.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Thomas Fallon
Head of Quality Assurance
Philips Hospital Respiratory Care

PHILIPS

FIELD SAFETY NOTICE RESPONSE FORM

Field Correction Regarding the V60/V60 Plus and V680 35V Rail

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Field Safety Notice Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name:_____

Street Address:_____

City/State/ZIP/Country:_____

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle Philips Respironics V60/V60 Plus and V680 Ventilators.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Upon completion and Acknowledgment return it to Philips by either of the following methods:

1. <Reply form return details to be completed by the KM / country>.