Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عمان
وزارة الصحة
مركز سلامة الدواء
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 43 **dated** 24/3/2024 **Regarding NCMDR Field Safety Notice of Trilogy Evo, Trilogy Evo O2, Trilogy EV300 from (mfr: 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**

DSC مركز سلامة الدواء Drug Safety Center

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

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Circular No. 43 **/ 2024**

13 -09-1445 H
24 -03-2024

Field Safety Notice of Trilogy Evo, Trilogy Evo O2, Trilogy EV300 from Philips Healthcare.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20952
Product	Trilogy Evo, Trilogy Evo O2, Trilogy EV300.
Description	Portable ventilator, electric.
Manufacturer	Philips Healthcare.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	All Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 devices.
Reason	A software algorithm that calculates remaining battery life can malfunction and cause the device to either: A. Issue a Loss of Power alarm that stops CPAP or PSV therapy while operating on battery power alone. B. Issue a Battery Depleted alarm while continuing therapy if plugged into a permanent power source, such as AC or DC power.
Action	1. The devices may be used following the Philips instructions found in the attachment under "Actions that should be taken by the customer / user in order to prevent risks for patients or users". 2. Philips Respironics is developing a software correction that will remedy this issue. It will be released for download by all device users in the second quarter of 2024. When available, you will receive an additional notification advising how to access and install the software on your devices. 3. Contact the local agent for remedial action.
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 through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

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

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URGENT Field Safety Notice

Trilogy Evo, Trilogy Evo O2, Trilogy EV300
Loss of Power Alarm

26-FEB-2024

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 this letter for your records.

<Dear Customer>,

Philips Respironics has become aware of a potential safety issue with Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 devices where the ventilator can issue a Battery Depleted or Loss of Power alarm while sufficient power is still available. This can result in a sudden loss of ventilation while the device alarms. Philips Respironics has received twenty (20) reports of this malfunction and has observed no incidents of patient injury or harm. This URGENT Field Safety Notice is intended to inform you about:

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

All Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 devices are susceptible to this problem.

A software algorithm that calculates remaining battery life can malfunction and cause the device to either:

A. Issue a Loss of Power alarm that stops CPAP or PSV therapy while operating on battery power alone.
B. Issue a Battery Depleted alarm while continuing therapy if plugged into a permanent power source, such as AC or DC power.

This can only happen if all of the following conditions are met:

1. The device is operating in CPAP or PSV mode
2. The device is not able to detect the respiratory effort of the patient for at least ten minutes and fifty-five seconds

Patients most vulnerable to this issue include neonatal and pediatric patients, patients recently removed from anesthesia, or other patients with low inspiratory effort due to their potential for minimally detectable respiratory effort.

This malfunction is due to a software algorithm calculation error and is not a malfunction of the internal or detachable batteries. An alarm, which can stop therapy, may occur even if there is sufficient battery life remaining.

This malfunction will not happen in ventilation modes other than CPAP and PSV.

2. Hazard/harm associated with the issue

A Loss of Power event can cause irreversible harm to the most vulnerable patient populations, including death, if the associated alarm is not observed with the appropriate response. This is because the Loss of Power alarm will cause CPAP or PSV therapy to stop while the high priority alarm alerts the care provider to the issue.

3. Affected products and how to identify them

All Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 devices are susceptible to this problem.

4. Actions that should be taken by the customer / user in order to prevent risks for patients or users

Your device(s) may continue to be used safely in CPAP or PSV mode for all users if all safety measures are followed:

- Ensure the Backup Ventilation is set to ON and the apnea interval setting is correct and appropriate based on the clinical assessment of the patient. This will minimize the chances for a CPAP or PSV supported patient to encounter a loss of power malfunction.
- Keep the device plugged into AC or DC power to the greatest extent possible.
- Keep an alternative form of ventilation on standby. If the device must be unplugged for patient transport, plug the device back in as soon as you reach your destination.
- Do not leave a patient unsupervised while operating on battery power alone.
- Follow typical monitoring protocols for ventilated patients such as use of backup monitors, including pulse oximetry or heart rate.

Immediately plug the device into a power source if a Loss of Power alarm occurs. This includes AC power, DC power, or installing a fully charged detachable battery. If none of these power sources are available, then remove the detachable battery and put it back in. Each of these will clear the alarm and restart the ventilator.

<u>This notice must be distributed to all members of your organization responsible for setting up and supervising patients that use these devices. This notice must also be distributed to any organizations to which you have further distributed Trilogy Evo, Trilogy Evo O2, or Trilogy EV300 devices.</u>

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5. Actions planned by Philips Respironics to correct the problem

Philips Respironics is developing a software correction that will remedy this issue. It will be released for download by all device users in the second quarter of 2024. When available, you will receive an additional notification advising how to access and install the software on your devices.

If you need any further information or support concerning this issue, please contact your local Philips Respironics sales representative.

This notice has been reported to the appropriate Regulatory Agencies.

Philips Respironics regrets any inconvenience caused by this problem.

Sincerely,

Thomas J. Fallon
Head of Quality for Sleep and Respiratory Care

PHILIPS

URGENT Field Safety Notice

Reference: Trilogy Evo Battery Failure Alarm
Trilogy Evo, Trilogy Evo O2, and Trilogy EV300
2024-CC-SRC-001

Instructions: Please complete and return this form to Philips Respironics promptly and no later than 30 days after receipt. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the issue, and management of the necessary steps to avoid the issue. This form can be completed by filling out the required fields, scanning, and emailing to met.quality@philips.com

Philips Respironics will follow up with the person who submitted this form with a full list of devices that were sold to the customer and for periodic progress on device software updates.

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 the Trilogy Evo, Trilogy Evo O2, or Trilogy EV300 device.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please send this completed form to met.quality@philips.com