Safety Notice 002/24

Issue date
18 March 2024

Distributed to:
Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Chief Executives
Directors of Clinical Governance

We recommend you also inform:
Directors, Managers and Staff of:
- Respiratory
- Sleep Medicine
- Emergency Department

Expert Reference Group

Content reviewed by:
Adult Respiratory and Sleep Physicians
Paediatric Respiratory and Sleep Physicians
ACI Respiratory Network
HealthShare NSW
State Preparedness and Response Unit

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Review date
July 2024

Use of Trilogy Evo, Trilogy Evo 02 and Trilogy EV300 devices while in CPAP and PSV mode

Situation

The Therapeutic Goods Administration (TGA) issued a Class II Urgent Product Defect Correction notice (RC-2024-RN-00170-1) for Trilogy Evo, Trilogy Evo 02 and Trilogy EV300. The ventilator may 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.

A software update is required to address the issue however this will not be available until Quarter 2 (April – June 2024).

Background

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.

Philips have received 20 reports of this malfunction but there have been no incidents of patient injury or harm. No incidents related to this recall notice have been reported in NSW Health.

Assessment

These issues impact public and private health services.

Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 devices are used in adult and paediatric settings.

These ventilators are used by patients in the community, but not always set to **CPAP or PSV** mode.

Clinical Recommendations

1. Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 devices can continue to be used safely if all of the following measures are followed:

    - Ensure the Backup Ventilation is set to ON and the apnoea interval setting is correct and appropriate for clinical assessment of patient.
    - Keep the device plugged into AC or DC power where possible.

- Keep an alternative form of ventilation on standby. If the device is unplugged for patient transport, plug the device back immediately upon return.
- Do not leave a patient unsupervised while operating on battery power alone. · Follow typical monitoring protocols for ventilated patients.
- Immediately plug the device into a power source if a Loss of Power alarm occurs. If no 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.

2. Clinicians should review their patient lists to identify people who use Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 in **CPAP or PSV** mode.
3. Clinicians are required to contact these patients to discuss the potential risks and provide advice about their ongoing safe use.

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians and clinical departments where patients with ventilators may access services.
2. Include this Safety Notice in relevant handovers and safety huddles
3. Undertake a local risk assessment to identify patients who use the devices in CPAP or PSV mode
4. Contact patients who use devices in CPAP or PSV mode to discuss safety measures
5. Escalate any concerns to cec-recalls@health.nsw.gov.au
6. Report any incidents associated with these [devices] into ims+ and TGA.