Issue date
27 July 2022

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:
- Medicine
- Nursing and Midwifery
- Sleep Laboratories
- Respiratory Departments
- Paediatrics

Biomedical Engineers
Staff caring for home care patients on continuous and non-continuous ventilation

Expert Reference Group
Content reviewed by:
HealthShare NSW
EnableNSW
Agency Clinical Innovation
Respiratory, Sleep Medicine, Paediatric, Spinal Clinicians
Ministry of Health

Clinical Excellence Commission
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Internet Website:
http://health.nsw.gov.au/sabs
Intranet Website:
http://internal.health.nsw.gov.au/quality/sabs

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July 2023

UPDATE: Philips Sound Abatement Foam on selected sleep and respiratory devices

Situation

What is new in this safety notice?

- A staged remediation/replacement program has been underway since November 2021[1]
- In NSW, some affected devices remain unregistered with Philips
- Philips is contacting prescribers to obtain up-to-date settings for their registered patients' devices[2]
- Philips is contacting all registered patients to confirm device usage (active/inactive), contact and shipping details
- Philips is contacting some registered patients to obtain the current settings for their device via phone, mail, email and SMS
- Some patients have received replacement devices with incorrect settings[1].

Patients continue to be advised *not to cease* use of affected devices without speaking to their clinician or prescriber who can advise on the benefits of continuing therapy with these devices against the risks related to the sound abatement foam.

Background

In July 2021, the Therapeutic Goods Administration (TGA) issued two product defect correction notices (RC-2021-RN-01372-1 and RC-2021-RN-01373-1) for selected continuous and non-continuous ventilators (certain CPAP, Bi-Level PAP and Ventilator Devices). Issues relating to the foam used to lower the sound and vibration emitted by these devices include:

- The foam may degrade into particles which may enter the devices' air pathway and be ingested or inhaled by the user. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone
- The foam may off-gas certain chemicals. Product testing has demonstrated that off-gassing mostly occurs during initial operation and may possibly continue throughout the device's useful life.

To date, the following incidents have been reported:

- The presence of black particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)
- General symptoms such as headache, upper airway, skin and eye irritation, cough, chest pressure, sinus infection and inflammatory responses.

If a patient identifies black particles within the airpath circuit or has general symptoms that are related to their device, they should contact their clinician/prescriber and Philips for further advice/assistance to remediate/replace their device.

Assessment

Affected devices are in use within the Australian hospital system and by direct customer purchase via retail pharmacy outlets. These devices include[1,3]:

No.	Model	Also known as	Remediation/replacement commenced
1	DreamStation CPAP Pro DreamStation Auto CPAP System One (50 Series) CPAP System One (50 Series) Auto CPAP	*DreamStation CPAP*	November 2021
2	DreamStation BiPAP autoSV DreamStation BiPAP AVAPS DreamStation BiPAP S/T System One BiPAP AVAPS (C-Series) System One BiPAP S/T (C-Series) System One BiPAP autoSV, System One BiPAP autoSV Advanced	*DreamStation ASV* *DreamStation AVAPS* *DreamStation S/T* *C Series AVAPS (50 Series)* *C Series AVAPS (60 Series)* *C Series S/T (60 Series)* *SystemOne ASV4 (50 Series)* *SystemOne ASV4 (60 Series)*	December 2021
3	System One (60 Series) CPAP System One (60 Series) Auto CPAP	*REMstar Pro CPAP*	March 2022
4	Trilogy 100 Ventilator		April 2022
5	BiPAP A40 Ventilator (A-Series) BiPAP A30 Ventilator (A-Series) OmniLab Advanced Plus DreamStation GO	*A-Series BiPAP A40* *A-Series BiPAP A30*	To be advised

To identify a device that has been remediated check if the UDI is included in the device label (sticker). See the below before and after labels and compare with that on the device.

Before

UDI included in remediated device label [1]

After

Recommendations

In the course of providing healthcare in NSW, you may be in contact with patients who use an affected Philips Respironics device.

For patients with devices not yet remediated:

- Check if the device has been registered and a patient script has been provided to Philips
- Inspect the airpath circuit for black particles
- Assess the patient for any symptoms related to their device
- Escalate any concerns regarding the patient's need for prioritisation for early rectification to Philips, EnableNSW and/or the treating physician/clinician, as required.

Recommendations cont:

Patients with remediated devices:

- Check that the correct patient settings have been applied to their remediated device
- Escalate any concerns regarding incorrect settings to the treating physician/clinician, EnableNSW and/or Philips, as required.

Contact details:

To register a device, provide script details, enquires or for escalation of concerns:

- **EnableNSW customers**: 1800 362 253, select option 3, or via email enable@health.nsw.gov.au
- **Physician/clinician only enquiries**: Philips 1800 830 517, select option 2 (Physicians), or via email srcanz.support@Philips.com
- **Direct purchase customers**: Philips 1800 009 579 or visit the website at www.philips.com/src-update.

Reporting incidents:

Please include in your ims+ notification:

- Equipment tab "Manufacturer" field: Philips Respironics
- Device Model: As recorded on the device label
- Device Serial Number: SN Alpha/numeric from the device label
- If the device has been remediated, include date of the remediation of the device, if known.

Required actions for the Local Health Districts/Networks

- Distribute this Safety Notice to all relevant NSW Health stakeholders
- Ensure there is a process for risk assessment and escalation for patients who are using these devices
- Provide families/carers with information and education on safe management and use of affected Philips respiratory support devices, as required
- Report any incidents associated with these devices into ims+ and TGA.

References

1. Therapeutic Goods Administration. 2022. *Philips recall action for CPAP, Bi-Level PAP devices and mechanical ventilators* [Online]. Available at: https://www.tga.gov.au/alert/philips-recall-action-cpap-bi-level-pap-devices-and-mechanical-ventilators#t1 [Accessed 14 July 2022].
2. EnableNSW. 2022. *Philips Respiratory Devices – information for prescribers, TGA Product Defect Correction on some Philips respiratory devices* [Online]. Available at: https://www.enable.health.nsw.gov.au/services/hrp/philips-respiratory-devices-information-for-prescribers [Accessed 14 July 2022]
3. Philips. 2022. *Philips Sleep and Respiratory Care Devices – Australia and New Zealand* [Online]. Available at: https://www.philips.com.au/healthcare/e/sleep/communications/src-update#affected_devices [Accessed 14 July 2022]
4. Philips. 2022. URGENT: Medical Device Recall, Philips Respironics CPAP and Bi-Level PAP Devices [Online]. Available at: https://www.usa.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/en_US/philips-recall-letter-2021-11-16-a-cpap-a-ventilator-recall-letter-us-revised.pdf [Accessed 14 July 2022].