# Safety Notice SN015/21

# Philips Sound Abatement Foam on selected sleep and respiratory devices – Product Defect Correction

**05 July 2021**

**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 and 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**

Tel: 02 9269 5500

Email: CEC-Recalls@health.nsw.gov.au

Internet Website: http://health.nsw.gov.au/sabs

Intranet Website: http://internal.health.nsw.gov.au/quality/sabs

**Review date**

July 2022

## Situation

The Therapeutic Goods Administration (TGA) has 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, there is no definitive evidence of long-term harm to patients caused by either issue. There have been no reports of death, due to exposure to the particulate matter or gas.

**Patients are advised not to cease use of these 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

To date, Philips Respironics has received a small number of complaints regarding the presence of black particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). A small subset of these complaints reported headache, upper airway irritation, cough, chest pressure, sinus infection and inflammatory responses. Some possible long-term effects, including carcinogenic effects and toxicity to liver, kidneys and nerves.

The affected devices are in use within the Australian hospital system and by direct customer purchase via retail pharmacy outlets. These devices include:

1. Trilogy 100 ventilator
2. BiPAP A40
3. BiPAP A30
4. Dreamstation BiPAP AVAPS
5. BiPAP AVAPS C Series (50 and 60 series)
6. Dreamstation BiPAP AutoSV
7. System One ASV4 (50 and 60 series)
8. Dreamstation CPAP Pro
9. REMstar Pro CPAP
10. Omnilab Advanced Plus



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## Assessment

- The current state-wide risk to patient safety is LOW.
- Approximately 7 800 affected devices are used in NSW Health services
- The affected devices are primarily used as home care devices. They may be also used in hospital settings where ventilated patients are preparing to transition to home, or the sleep laboratory setting
- The product defect correction is anticipated to take two to four months to complete in NSW public health services
- Risks of changing clinical therapy or transitioning to unfamiliar devices must be balanced against the *low risk* of continued use of these devices
- A limited number of alternate devices are available across NSW. Philips have developed a plan for repair or replacement to occur over the following months
- There is a risk that patients may cease therapy once they learn of this product defect. Therefore, *clear and consistent communication about the current low risk of harm and importance of continuing therapy is essential.*

## Clinical recommendations

- Advise patients to continue use of their sleep and respiratory devices
- Advise patients to contact their clinician or prescriber prior to changing or ceasing use of their device
- Consider whether the use of bacterial filters would be appropriate for some patient groups
- Advise patients to stop use of ozone-related (ultraviolet) cleaning products, and adhere to their device's Instructions for Use for approved cleaning methods
- Clinicians and prescribers can use the following factors to assess any concerns they have for specific patient prioritisation and management:
    - Clinical risk
    - Mental health risk
    - Occupational and driver safety risk
    - Device related risk.



## Required actions by Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant NSW Health stakeholders
2. LHD/SHNs to establish a list of affected devices and their location
3. Register NSW Health devices with Philips via www.philips.com/src-update for inclusion in the rectification plan

   Note: Devices provided by EnableNSW will be centrally registered with Philips
4. Ensure there is a process for risk assessment and documentation for vulnerable patients
5. Provide families/carers with information and education on continued safe management and use of affected Philips respiratory support devices as required
6. Enquires or escalation of concerns, please contact:
    - **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
7. Report any incidents associated with the affected devices into ims+ and TGA.

   For ims+ notifications, please ensure "Philips Respironics" is included in the Equipment tab "Manufacturer" field, to assist in collation of incidents related to this notice.