PHILIPS

Dear Physician,

On April 26 2021, Philips provided an important update regarding proactive efforts to address identified issues with a component in certain products of our sleep and respiratory care portfolio. On July 2 2021, following consultation with the Therapeutic Goods Administration (TGA) and Medsafe, Philips announced it is conducting an Urgent Product Defect Correction in Australia and Recall for Product Correction in New Zealand for specific sleep and respiratory care devices due to two issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in certain Philips continuous and non-continuous ventilators:

1) the PE-PUR foam may degrade into particulates which may enter the device's air pathway and be ingested or inhaled by the user, and
2) the PE-PUR foam may emit certain chemicals.

We are treating this matter with the highest possible seriousness and have been working to address this issue as thoroughly as possible.

Patient Registration

Please ensure your patients have registered their device via the Philips portal which can be found on www.philips.com/src-update. Registration is the initial important step to enable us to provide a remediation to your patient.

Remediation

Philips will shortly commence remediation in Australia and New Zealand. All remediated devices will have a new material for the PE-PUR sound abatement foam.

A replacement plan is underway and manufacturing of DreamStation devices has commenced. Philips expects replacement to start in October and have started to contact registered patients and customers with instructions on the next steps to implement this.

Philips will be replacing the base unit of the following devices with a new base unit:

- DreamStation CPAP Pro, Auto CPAP, Auto BiPAP, BiPAP autoSV, BiPAP AVAPS

The base unit includes the device only without a humidifier or modem. The base unit replacement device will be set to the patient's prescription or current device settings.

Philips will be replacing the following devices with an equivalent substitute device from the DreamStation family:

- 50 Series CPAP, BiPAP autoSV
- 60 Series BiPAP autoSV, BiPAP AVAPS, BiPAP ST

The substitute device includes a device and humidifier. The substitute device will be set to the patient's prescription or current device settings.

Philips Sleep and Respiratory Care
Philips Electronics Australia Limited, 65 Epping Road, North Ryde NSW 2113, www.philips.com.au

Replacement devices will be delivered to the patient's nominated address and will include instructions on how to set up their replacement device and their return their affected device to Philips. If you have patients on devices other than the ones mentioned above, we will continue to keep you informed on the timings for remediation of those devices.

Patients who need to be prioritised

Philips recognise that there is a need for some devices to be replaced as a matter of priority and has, in partnership with NSW Health and the Australasian Sleep Association, developed a prioritisation pathway for clinicians to increase the priority of their patients for sooner remediation where required.

Factors to be considered for an increased priority are:

Prioritisation Level		Description
1	High	Severe mental illness/behavioural issues- potential for distress or disruption to therapy if remediation delayed
1	High	High risk infants/children
1	High	Likely disruption to therapy AND risk of harm to self/others due to clinical risks (e.g., severe hypoxaemia/hypercapnia, risk of hospitalisation), occupational risks (e.g., truck driver).
1	High	Respiratory disease consequent to previous occupational exposures to isocyanates e.g., spray painting, manufacture of plastics/synthetics/insulation, and timber floor varnishing
1	Med-High	Additional risk factors as highlighted by the person's clinician e.g., VC <50% pred, MIP <40, increased daytime usage of device- case-by-case
2	Medium	Device-related risks e.g., lack of suitable alternative devices in view of age/weight/necessity for Philips's ventilation modes
3	Med/Low	Geographical factors (unable to travel to try an alternative device)

Philips is unable to undertake clinical assessments of patients, whereby the responsibility ultimately lies with the physician. If you wish to increase the priority of any of your patients, please see below instructions for the "Physician Escalation Process".

Physician Escalation Process

To prioritise a patient, physicians need to send an email to Philips with the information below to srcescalation.anz@philips.com:

- Email Title: Philips Device Clinical Prioritisation
- Device Serial Number:
- Device Name:
- Postcode:
- Patient Full Name:
- Patient Phone:
- Patient Email:
- Priority Level (1, 2 or 3):
- Current prescription/ device settings:

PHILIPS

Please ensure you have the consent of the patient to share their personal information with Philips.

Upon receipt of your email, Philips will place the patient on the prioritization pathway for expedited remediation.

Philips deeply regrets the inconvenience caused by this issue. We are dedicating significant time and resources to give affected patients and customers the service they expect and deserve as we resolve this matter as our top priority.

Our commitment to patient care is at the heart of everything we do. We are dedicated to supporting you and your patients throughout this process. Should you have any further questions or require assistance please contact your Philips representative.

We will continue to share updates as we manage through this remediation process.

For more information, visit philips.com/SRC-update.

Sincerely,

Penny Stewart
General Manager
Philips Sleep and Respiratory Care
Australia and New Zealand