Addendum to the Position Statement from the Canadian Thoracic Society, Canadian Sleep Society and the Canadian Society of Respiratory Therapists

Philips Respironics Device Recall

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The purpose of this document is to provide an update of the *Position Statement from the Canadian Thoracic Society, Canadian Sleep Society and the Canadian Society of Respiratory Therapists Philips Respironics Device Recall* from July 2021. This recall continues to be a challenge for patients, practitioners, and medical device distributors across Canada.

- In November 2021, Philips updated the guidance of its recall notifications to align them with Health Canada recommendations: "*For patients using BiLevel PAP and CPAP devices, consult with your physician on a suitable treatment plan*". This guidance was updated from the previous recommendation from Philips to stop therapy before consulting with a physician. If a patient has already consulted with a physician, no further action is required. Philips advised that they talk to a health care provider to decide on a suitable treatment for their medical condition, which may include: stopping use of an affected device, using another similar device that is not part of the recall, using alternative treatments for sleep apnea, or continuing to use an affected device. (https://www.philips.ca/healthcare/e/sleep/communications/src-update).

- As per our previous statement, there should be shared decision-making between the patient, their family or other supports, and physicians to carefully balance risks of continuing versus interrupting the use of affected devices, and consideration of alternative treatments/devices

available. The decision to continue prolonged use of a recalled device needs to be individualized and documented in the medical record.

- In December 2021, Philips provided an update on the test and research program in connection with the first generation DreamStation devices:

    - In terms of particulate matter, the majority were >8 µm, and unlikely to penetrate the deep lung tissue; smaller particulates (<1-3 µm) are capable of diffusing into deep lung tissue and deposit into the alveoli. During testing performed by an outside laboratory on lab degraded foam, smallest particulate size was 2.69 µm.

    - In terms of volatile organic compounds (VOC), "Review by Philips and an outside medical panel determined that exposure to the level of VOCs identified for the first-generation DreamStation devices is not typically anticipated to result in long-term health consequences. The update on these findings is intended to inform health care providers of the most recent data, but the overall guidance for physicians and patients in the recall notification remains unchanged at this time."

    - These results may not be applicable to other devices affected by the recall, nor to devices that were also exposed to ozone or other non-authorized cleaning methods.

    - More toxicological information may be available later this year.

- Based upon discussions with Philips, as of February 2022, approximately 670,000 registered devices have been affected in Canada (approximately 440,000 are CPAP/auto machines). Approximately 200,000 are active patients, as indicated by the patient registering their machine on the website.

- **Of note, both the medical device distributor and the patient need to register for the recall; patients should be advised to register their machines on the website or by phone with Philips (1-877-907-7508) to ensure that the company knows the devices are active**. Individual patients who register their devices with Philips also need to make sure their device is registered with a medical device distributor. All replacement devices will be distributed by Philips to medical device distributors, who will be responsible for making the exchange. Individuals who purchased recalled devices second hand or from an online store are also entitled to a replacement provided they register it with Philips personally AND have it registered by a distributor.

- Philips is tracking adverse events associated with recalled devices. Patients who have had an adverse event should be advised to report them via the Philips toll-free recall support line: 1-877-907-7508.

- Philips is forecasting that the majority of active devices should be replaced by October-December of this year (see https://www.philips.com/a-

w/about/news/archive/corpcomms/news/press/2022/philips-fourth-quarter-results-2021.html). As of February 2022, approximately 20,000 have been replaced.

- There is currently only Health Canada approval for the DreamStation 2; there is no approval yet for the other devices (e.g. Trilogy) and we will share information as more becomes available. Philips is prioritizing patient devices, and timelines for laboratory devices are not clear.

- Medical device distributors are receiving devices based on their purchase history, being delivered in installments. All manufactured devices from Philips are currently allocated to replace affected recalled devices.

- Given the recall and supply chain issues affecting other CPAP manufacturers, patients requiring *new devices* have been affected by device shortages. The impact appears to vary by province and region. Medical device distributors should work with sleep physicians and other health care professionals to ensure optimal resource allocation. If devices need to be triaged due to inadequate supply, the following factors should be considered:

    - Severity of sleep apnea in terms of AHI, desaturation
    - Severity of symptoms attributable to sleep disordered breathing (e.g. sleepiness)
    - Comorbid conditions or pregnancy that might be exacerbated by untreated sleep disordered breathing
    - If the patient is in a safety critical occupation.