AASM

ADAPTING TO THE
Philips Respironics Sleep & Respiratory
Product Portfolio Changes

Webinar: Adapting to the Philips Respironics Sleep & Respiratory Product Portfolio Changes

MARCH 18 @ 2:00 PM - 3:00 PM CDT

Welcome

Multi-Society Discussion Group

American Academy of Sleep Medicine
American Academy of Neurology
American College of Chest Physicians
American Thoracic Society
American Association for Respiratory Care
American Association of Sleep Technologists

The panelists

M. Adeel Rishi, MD
AASM

Amanda Leightner, PhD
AARC

Aneesa Das, MD
CHEST

Karin Johnson, MD
AAN

Vaishnavi Kundel, MD, MS
ATS

Andrew Namen, MD
AASM

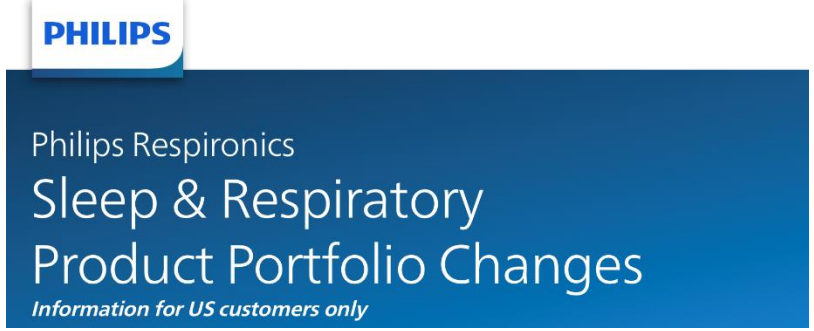
Jessica Schweller, APRN-CPN
AARC

Shannon Sullivan, MD
Moderator, AASM

Margaret Kay-Stacey, MD
AAN

Sarah Brennecka, MBA, RPSGT
AAST

Background



- 1/25/24: Philips announces it will stop selling 19 sleep and respiratory products
  - Sales of devices impacted by the 2021 recall have been on hold since then

- “In the US, and US territories, Philips Respironics will focus on the sale of consumables and accessories, including masks, and will not return to the sale of hospital ventilation products, certain home ventilation products, portable and stationary oxygen concentrators and sleep diagnostic products.”

- "Customers will be contacted directly regarding any order cancellations resulting from our portfolio changes."

https://www.usa.philips.com/healthcare/e/sleep-and-respiratory-care/src-portfolio-update
https://www.homecaremag.com/news/philips-respironics-discontinues-19-sleep-respiratory-devices

Impacted Devices

Product	Product type	Sales discontinuation	Shipments discontinuation	End of service
Alice 6	Sleep Diagnostic Machine	January 25, 2024	January 25, 2024	January 25, 2029
Alice NightOne	Sleep Diagnostic Machine	January 25, 2024	January 25, 2024	January 25, 2029
Alice PDx	Sleep Diagnostic Machine	September 2023	October 2023	October 1, 2028
CoughAssist	Airway Clearance Device	September 2023	October 2023	October 1, 2028
DreamStation Go	Portable PAP Therapy System	January 25, 2024	January 25, 2024	January 25, 2029
E30*	Ventilation Solution	November 2021	November 2021	November 1, 2026
EverFlo	Home Oxygen System	January 25, 2024	January 25, 2024	January 25, 2029
I-neb AAD Nebulizer	Respiratory Drug Delivery	September 2023	September 2023	October 1, 2028
Millennium M10	Home Oxygen System	January 25, 2024	January 25, 2024	January 25, 2029
NightBalance	Positional Sleep Therapy Device	September 2023	October 2023	October 1, 2026
OmniLab Advanced +	Titration System	January 25, 2024	January 25, 2024	January 25, 2029
Other nebulizers	Respiratory Drug Delivery	September 2023	October 2023	October 1, 2028
Other RDD products	Respiratory Drug Delivery	September 2023	October 2023	October 1, 2028
SimplyGo	Portable Oxygen Concentrator	January 25, 2024	January 25, 2024	January 25, 2029
SimplyGo Mini	Portable Oxygen Concentrator	January 25, 2024	January 25, 2024	January 25, 2029
Trilogy 100/200/202	Portable Ventilator	December 2020	December 2020	December 2025
Trilogy EVO and EV300	Home Ventilator	January 25, 2024	January 25, 2024	January 25, 2029
V30	Ventilator	October 2023	October 2023	October 1, 2028
V60 / V60 Plus	Ventilator	August 2022	August 2022	December 2029

https://www.usa.philips.com/healthcare/e/sleep-and-respiratory-care/src-portfolio-update

Evolving situation: Philips Respironics Sleep & Respiratory Devices

- Reported that Philips has agreed to halt US sales until it meets terms of a consent decree from FDA
  - Consent Decree: is an agreement between FDA and company, typically issued after serious violations of regulatory requirements
  - Can be thought of as a legally binding performance improvement plan. It is a court-enforced settlement, agreed to by all parties and approved by a court.
- Has been reported that the consent decree is in process of finalization and will be submitted to a U.S. court for approval
- When that happens, the consent decree will outline a roadmap of what actions and milestones Philips Respironics must meet to demonstrate regulatory compliance and restore the business.
- U.S. Department of Justice is negotiating the order as a representative of the FDA.

https://www.medtechdive.com/news/philips-consent-decree-fda-years-resolve/706686/

Additional Information from Philips

- **What is the definition of “end of service”?**
  Once a product is discontinued for sale, the manufacturer provides a specified number of years of service support wherein all relevant repair parts, accessories etc. necessary to use or service the device (during PMs and repairs) will be supplied pending parts availability.

- **My product that is discontinued failed within its warranty period and is unable to be repaired. How will you rectify this situation?**
  Philips will provide refunds as articulated in the warranty terms and conditions but will be unable to provide a replacement product.

https://www.usa.philips.com/healthcare/e/sleep-and-respiratory-care/src-portfolio-update

What does Philips' announcement mean for…

- …sleep laboratories and practices, and what issues are being encountered?
  - Adeel Rishi, MD, and Andrew Namen, MD, (AASM)

- …DME, sleep and respiratory care providers, coordination of care, and what issues are being encountered?
  - Aneesa Das, MD (CHEST), and Sarah Brennecka, MBA ,RPSGT (AAST)

What does Philips' announcement mean for…

- …patients who are dependent upon Philips Respironics devices at home, such as PAP and RAD devices; also cough assist, nebulizers, vents, etc?
  - Vaishnavi Kundel, MD (ATS), Amanda Leightner, PhD (AARC), and Jessica Schweller, APRN-CPN (AARC)

- …interfacing with payors who may not account for this disruption in health care? What are implications for vulnerable patient populations, as well as providers helping patients transition to different devices?
  - Karin Johnson, MD (AAN) and Meg Kay-Stacey, MD (AAN)

What does Philips' announcement mean for…

- …the practice of sleep medicine in general? respiratory medicine?

- …the remaining device marketplace; is it adequate to serve patients? What are the risks of having too few manufacturers of time-tested equipment? Too little availability?

Discussion

- How has the recall and withdrawal of Philips impacted workloads, potential for burnout, and retention/ recruitment of sleep workers (techs, RTs, DMEs, etc) in your work environment?

- What are some solutions you would propose?

Webinar Audience Q&A

Thank you to our panel and all participants!