PHILIPS

Progress update
Philips Respironics field action

October 24, 2022

innovation you

Extensive patient, clinician and regulator engagement

- **Driving patient engagement** and registrations with new dedicated registration system and infrastructure
  - Patient outreach through mailing, call center, websites and direct contact with interest groups
  - Comprehensive DME outreach
  - Met the requirements in FDA's 518(a) order and continue to report progress
- **Engagement with regulators** to optimize the recall efforts, and agree priority replacement
- **Sharing progress on testing program** to ensure patients and physicians fully informed

© Koninklijke Philips N.V.

Around 90% of the recall program units produced and shipped by end 2022

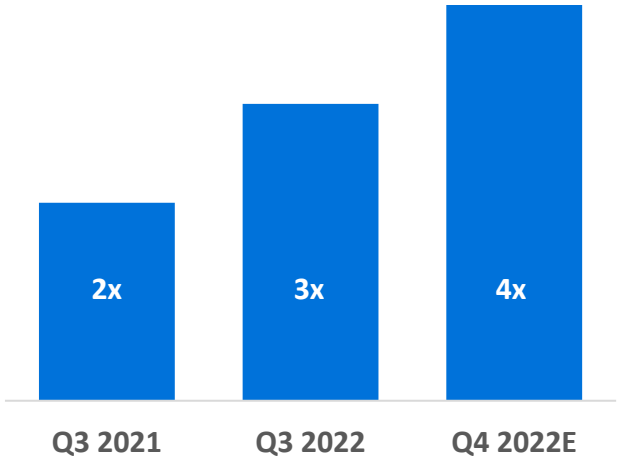
The task at hand

- Around 5.5M devices expected to be repaired or replaced
- Equivalent to over 5x previous annual production volume
- >1 thousand new product configurations released globally
- Partnering with DME's for patient delivery

Progress to date

- Quadrupled production capacity compared to pre-recall
- >1,000 people cross functional team engaged
- ~4M repair and replace units produced to date
- Dependency on supply of materials and global logistics capacity

Production capacity – DreamStation
(compared to pre-recall)



© Koninklijke Philips N.V.

Testing and literature review

© Koninklijke Philips N.V.

Extensive test and research program continues and shows insightful results to date

- **Hundreds of tests** with long throughput time, working with certified testing labs and numerous external experts
- **Results to date for DreamStation1 devices**
  - Very low prevalence of significant visible foam degradation in the over 63k devices inspected
  - Ozone cleaning materially exacerbates foam degradation
  - Volatile organic compounds (VOC) emissions within ISO limits (devices not exposed to Ozone)
  - Foam degradation does not contribute to appreciable elevated levels of respirable particles; within ISO limits
  - Even when significant visible particulates are formed, likely to accumulate and stick inside the device
- **Biocompatibility testing and assessment** of PE-PUR foam is still on-going to fully assess potential patient risk
- More information on the latest testing results can be found here: https://www.philips.com/a-w/about/investor-relations/recall-sleep-and-respiratory/testing

© Koninklijke Philips N.V.

Philips Respironics engaged external scientific experts to conduct a systematic review

- There were thirteen identified epidemiological studies, all of which found no consistent statistical association between use of PAP devices - including Philips Respironics'- and the risk of cancer in patients with obstructive sleep apnea (OSA)
- Two of the studies[1] showed no statistical difference in cancer risk between users of Philips Respironics PAP devices and users of other brands of PAP devices
- Eleven studies provided limited additional insights, but their results also suggested no excess risk of cancer associated with use of PAP devices
- The 2022 study by Palm and others reported more frequent prescription of respiratory relief medication among patients with both OSA and obstructive lung disease, but no statistical difference in hospitalization, i.e. health outcomes, was observed for OLD among OSA patients between the users or polyurethane PAP and non-foam PAP

1. An Association between Positive Airway Pressure Device Manufacturer and Incident Cancer? A Secondary Data Analysis; American Journal of Respiratory and Critical Care Medicine, 2021, Volume 204, Issue 12 pp. 1484–1488; Cancer risk in adherent users of polyurethane foam-containing CPAP devices for sleep apnea, European Respiratory Journal 2022.

© Koninklijke Philips N.V.

Regulatory and legal

© Koninklijke Philips N.V.

Regulatory and legal update - FDA/DOJ

- Philips Respironics continues to engage with the US Food and Drug Administration (FDA) on the progress it has made on the actions in response to the FDA's Form 483 observations

- Since July 2022, Philips Respironics has been in discussions with the US Department of Justice (DOJ), acting on behalf of the FDA, regarding the terms of a proposed consent decree to resolve the identified issues

- In addition, on April 8, 2022, Philips Respironics and certain of Philips' US subsidiaries received subpoenas from the DOJ to provide information related to the events leading to the Philips Respironics recall. The relevant subsidiaries are cooperating with the agency in the ongoing investigation

© Koninklijke Philips N.V.

Regulatory and legal update- Civil litigation

- Collective and individual civil complaints have been filed in various jurisdictions globally, including in the United States, Australia, Canada, Israel, Chile, France and the Netherlands. The complaints allege economic loss, personal injury and, in some cases, the need for medical monitoring related to devices subject to the Philips Respironics recall

  - In the United States, as of September 30, 2022, approximately 225 personal injury lawsuits and approximately 100 putative class actions have been consolidated into a multidistrict litigation (MDL) in Pennsylvania. In September 2022, the Court requested that plaintiffs resubmit consolidated or master complaints for their economic loss, medical monitoring and personal injury claims, and a new briefing process is under way. In all cases formal discovery has started, which is expected to continue well into 2023

- SoClean, an ozone cleaner manufacturer, filed an amended complaint against Philips in October 2022 for alleged unfair competition, tortious interference with business relationships, defamation and commercial disparagement. Philips believes SoClean's claims have no basis in fact or law and will be seeking dismissal of the case in its entirety, including on the basis that the FDA has stated SoClean's products were illegally marketed

- In the Eastern District of New York, a securities class action suit was filed against the company in August 2021, alleging Philips' statements in connection with the recall triggered a fall in stock price. Philips moved to dismiss the class action in early March 2022 and awaits the Court's decision

- Given the uncertain nature and timing of the relevant events, and of their potential impact and associated obligations, if any, the company has not provided for these matters

© Koninklijke Philips N.V.

Medical Device Reporting

Process

- Medical device manufacturers are required to submit medical device reports (MDRs) to the FDA when they receive complaints for certain types of device malfunctions and safety issues
- These complaints may be submitted to the manufacturer by health care professionals, patients, caregivers and consumers
- The FDA acknowledges that “the submission of an MDR itself is not evidence that the device caused or contributed to the adverse outcome or event” and that the “cause of an event cannot typically be determined from this reporting system alone”

Background

- Following Philips’ public statements on possible risks to users in April 2021 and the June 2021 recall notification/field safety notice, Philips Respironics received a steep increase in complaints allegedly associated with possible foam degradation
- This led to 69,000 MDRs filed by Philips Respironics to the FDA from April 2021 through July 31, 2022
- Since June 2021, Philips Respironics has worked with certified testing laboratories and third-party experts to develop and execute a comprehensive test and research program

© Koninklijke Philips N.V.


PHILIPS