

**PHILIPS**

# Progress update

## Philips Respironics field action

October 23, 2023

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# Resolving the recall for patients remains our highest priority

## 2023

Finalize recall of sleep therapy devices

Agree details of further testing with FDA<sup>1</sup>

Manage litigation, DoJ investigation

483 remediation and clarity on proposed Consent Decree

## YTD 2023

Remediation of >99% of sleep therapy devices complete<sup>2</sup>; ventilators ongoing

FDA feedback received on testing and analysis for sleep therapy devices<sup>1</sup>

Reached agreement to resolve economic loss class action in the US

483 remediation in progress

Started serving new patients with sleep therapy devices outside the US

## 2023-2025

Finalize recall and testing

Manage litigation, DoJ investigation

Manage impact of proposed Consent Decree

Gradually restore position

1. Following ongoing communications with the FDA, Philips Respironics has agreed to implement additional testing to supplement current test data on PE-PUR foam. The FDA stated that current testing is extensive and conducted with independent parties and expressed no concerns with its validity or objectivity. Philips Respironics is in discussions with the FDA on the details of further testing | 2. Over 99% of the sleep therapy device registrations that are complete and actionable have been remediated

Note: More information on the Respironics recall can be found [here](#);



# Testing and literature review

# Positive and reassuring complete test results for DreamStation1 devices <sup>1</sup>



MAY '23	<b>Devices exposed to Ozone</b>	<ul style="list-style-type: none"> <li>• Exposure to VOC emissions unlikely to result in appreciable harm to health</li> <li>• Based on assessment of ozone-induced degradation from up to 500 cleaning cycles</li> </ul>
DEC '22	<b>Bioassay evaluation, chemical characterization and toxicological risk assessment (ISO 10993)</b>	Exposure to particulates is unlikely to result in an appreciable harm to health in patients, even based on a worst-case assumption that the patient is exposed to 100% of the foam volume
DEC '22	<b>Particulate Matter testing (ISO 18562-2)</b>	<ul style="list-style-type: none"> <li>• Foam degradation does not contribute to appreciable elevated levels of respirable particles</li> <li>• Exposure to particulates from degraded foam with self-reported ozone use is unlikely to result in an appreciable harm to health in patients</li> </ul>
JUNE '22	<b>Visual inspection</b>	<ul style="list-style-type: none"> <li>• Foam degradation does not contribute to appreciable elevated levels of respirable particles</li> <li>• Low prevalence of significant visible foam degradation</li> <li>• Ozone cleaning exacerbates foam degradation</li> <li>• July '23: Additional visual inspection confirms low prevalence of significant visible foam degradation/volume reduction</li> </ul>
DEC '21	<b>VOC testing (ISO 18562-3)</b>	Emissions within safety limits based on ISO 18562-3 (devices not exposed to ozone)

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## Positive and reassuring complete test results for SystemOne and DS Go<sup>1</sup>

Exposure to foam particulates and VOCs is unlikely to result in an appreciable harm to health in patients, including in devices exposed to Ozone cleaning

### Based on complete, third party:

- Risk assessment of foam particulates - Particulate Matter testing (ISO 18562-2),
- VOC testing (ISO 18562-3),
- Bioassay evaluation, chemical characterization, toxicological risk assessment (ISO 10993)

## Next steps

Additional testing for sleep therapy devices to supplement current test data as agreed with the FDA<sup>1</sup>

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VOC and Particulate Matter testing, as well as chemical evaluation and toxicological assessments for Trilogy 100/200 (~3% of registered devices), and OmniLab (~2% of registered devices)

New Trilogy 100/200 devices passed VOC and PM testing to date, as well as several biocompatibility tests including ISO 10993 cytotoxicity, irritation and sensitization testing

New and lab-aged Trilogy 100/200 foam failed ISO 10993 genotoxicity testing under laboratory conditions, and therefore a weight of evidence assessment is ongoing to confirm or exclude potential risks for patients

These devices contain a different type of PE-PUR foam than the DreamStation1 devices<sup>2</sup>

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## Summary of third-party epidemiological studies

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)

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Two of the studies<sup>1</sup> showed no statistical difference in cancer risk between users of Philips Respironics PAP devices and users of other brands of PAP devices

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Eleven studies provided limited additional insights, but their results also suggested no excess risk of cancer associated with use of PAP devices

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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.



# Regulatory and legal



# Regulatory and legal update - Civil litigation (1/2)

- Collective and individual civil complaints have been filed in various jurisdictions globally, including but not limited to the US, Australia, Canada, Israel and Chile. The complaints variously allege economic loss, personal injury and, in some cases, the need for medical monitoring
- In the US, putative economic loss and medical monitoring class actions and personal injury lawsuits have been consolidated into a multidistrict litigation (MDL) in Pennsylvania
  - reached an agreement to resolve all economic loss claims in the class action, which received preliminary Court approval on October 10, 2023; provision of EUR 575 million has been recorded in Q1 2023
- As of October 16, 2023, around 670 personal injury claims have been filed and are currently pending and approximately 54,000 individuals had joined the voluntary, court-approved census registry for potential personal injury claimants who have not filed claims but may do so in the future
- Visibility on potential outcomes on medical monitoring class action and personal injury claims is not expected before late 2024

## Regulatory and legal update - Civil litigation (2/2)

- SoClean, a manufacturer of ozone-based CPAP cleaning devices, filed an amended complaint against Philips and certain of its US affiliates, including Philips Respironics, 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 is seeking dismissal of the case in its entirety, including on the basis that the FDA has stated that CPAP ozone cleaners, like SoClean’s products, “are not legally marketed for this use”
- Securities class action suit was filed against the company in August 2021 in the US, alleging Philips’ statements in connection with the recall triggered a fall in stock price. Plaintiffs filed a Second Amended Complaint in November 2022, which Philips has since moved to dismiss
- Given the uncertain nature of the relevant events, and of their potential impact and associated obligations, if any, the company has not provided for these matters other than the settlement of the economic loss claims in the US MDL

# Regulatory and legal update - FDA/DOJ

- Philips Respironics continues to engage with the US Food and Drug Administration (FDA) on the steps it has taken 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 address the identified issues on a forward-going basis
- On April 8, 2022, Philips Respironics and certain of Philips' subsidiaries in the US received a subpoena from the DOJ to provide information related to events leading to the Philips Respironics recall

# Medical Device Reporting

- 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.”
- 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 approximately 116,400 MDRs filed by Philips Respironics to the FDA from April 2021 through September 30, 2023, of which 7,200 in the three months July 2023 – September 2023
- The vast majority 93% of the MDRs filed since April 2021 up to and including September 2023 are alleged technical malfunctions that do not involve serious injury or death. Based on the investigations to date, Philips Respironics has found no conclusive data linking these devices and the deaths reported in the MDRs

