

**PHILIPS**

# Progress update

## Philips Respironics field action

January 29, 2024

innovation  you



# Philips Respironics Recall

## Progress to date

---

Remediation of >99% of sleep therapy devices complete<sup>1</sup>; ventilators ongoing

FDA feedback received on testing and analysis for sleep therapy devices<sup>2</sup>

---

Reached agreement to resolve economic loss class action in the US

---

Philips agrees with FDA on terms of consent decree

483 remediation in progress

Started serving new patients with sleep therapy devices outside the US

## Priorities ahead

---

Finalize recall and testing

---

Manage litigation, DoJ investigation

---

Comply with terms of consent decree

Gradually restore position

---

1. Over 99% of the sleep therapy device registrations that are complete and actionable have been remediated | 2. 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. 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	Devices exposed to Ozone	<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	Bioassay evaluation, chemical characterization and toxicological risk assessment (ISO 10993)	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
	Particulate Matter testing (ISO 18562-2)	<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	Visual inspection	<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</li></ul>
DEC '21	VOC testing (ISO 18562-3)	<ul style="list-style-type: none"><li>• Emissions within safety limits based on ISO 18562-3 (devices not exposed to ozone)</li></ul>

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

# 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)

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

## Next steps

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

---

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>

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. The known differences between the DreamStation foam and the foam for the Trilogy 100/200, are that the latter can be used with an acrylic pressure sensitive adhesive, has a lower density, has a different thickness, and also contains an additive to reduce potential flammability

# 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)

---

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

---

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



# Regulatory and legal



# Philips agrees with FDA on main terms of consent decree

- The consent decree is now being finalized and will be submitted to the relevant US court for approval
- Mainly focused on Philips Respironics business operations in the US
- Will provide a roadmap of defined actions, milestones, and deliverables for us to demonstrate compliance with regulatory requirements and to restore the business
- In the US:
  - will continue to service sleep and respiratory care devices already with healthcare providers and supply accessories, consumables, patient interface and replacement parts
  - Until relevant consent decree requirements are met, will not sell new CPAP or BiPAP sleep therapy devices or other respiratory care devices
- Outside of the US: will continue to provide new sleep and respiratory care devices, accessories, consumables, patient interface and replacement parts and services
- Financial impact: recorded provisions of EUR 363 million in Q4 2023; expect ~100 bps of costs related to remediation activities and disgorgement payments in 2024

## 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, with final approval pending; provision of EUR 575 million has been recorded in Q1 2023
- As of January 11, 2024, around 675 personal injury claims have been filed and are currently pending and approximately 56,000 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 personal injury claims and medical monitoring class action 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 has sought 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”
  - In January 2024, Philips countersued the company and its private equity owner, DW Health Partners, for marketing SoClean’s ozone cleaners as compatible with Philips PAP devices despite knowing that ozone can degrade PE-PUR foam. Allegations include false advertising, trademark dilution and deceptive trade practices
- 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
- 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 126,700 MDRs filed by Philips Respironics to the FDA from April 2021 through December 31, 2023, of which 10,270 in the three months September 2023 – December 2023
- The vast majority (93%) of the MDRs filed since April 2021 up to and including December 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

