

**PHILIPS**

# Progress update

## Philips Respironics field action

April 29, 2024

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# Philips Respironics Field Action

## Progress to date

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Remediation of sleep therapy devices almost complete; ventilation ongoing

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

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Reached agreement to resolve economic loss, personal injury, and medical monitoring litigation in the US

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Reached agreement with US government on a consent decree

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Back to market outside the US; servicing US market under agreed conditions part of the consent decree

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## Priorities ahead

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Finalize recall and testing

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DoJ investigation, other legal proceedings

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Demonstrate compliance with the regulatory requirements and restore Respironics business

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Gradually restore position

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



# Resolution of personal injury and medical monitoring litigation in the US



# Summary of settlement (1/3)

- Philips and plaintiffs' leadership, through a Court-appointed mediator, have reached an agreement to resolve the personal injury litigation and the medical monitoring class action in the US
- Addresses ~58K individuals who filed a claim or who entered the census registry
- Philips and Philips Respironics do not admit fault, liability, or that any injuries were caused by the devices
- Plaintiffs' leadership and the Settlement Administrator are responsible for allocation of the amount to claimants they deem eligible. Philips is not endorsing any particular injury or injury value
- Philips Respironics has agreed to pay capped total amount of USD 1.1 billion (covering all costs); the related payments are expected in 2025 and to be funded from company's cash flow generation
- Plaintiffs' leadership will discontinue remaining claims in the Multidistrict Litigation (MDL), and Census registry will be terminated

## Summary of settlement (2/3)

- Regardless of whether eligible individuals have filed a case, joined the census registry, or done nothing at all, they will have six months from the date of the settlement to sign up for the settlement
  - No incentive for law firms to advertise for new cases after settlement, as those firms will be excluded from compensation for those new cases
- Amount is capped regardless of number of participants
- Plaintiffs' leadership commits to achieving at least a 95% participation rate among eligible claimants
- As part of settlement, Plaintiffs' leadership and Respironics will seek a case management order (so-called Lone Pine Order) to require any individuals who still wish to pursue a claim, whether they qualify or not, to come forward with prima facie injury, exposure, and causation evidence, or else face dismissal
- Philips and Plaintiffs' leadership are confident that the vast majority of potential claimants have already submitted a claim or entered the census registry, as:
  - Recall was initiated almost three years ago, followed by extensive advertising
  - Multidistrict Litigation formed almost three years ago
  - Census registry active since September 2022, with volumes stable in recent months

## Summary of settlement (3/3)

- New claims that surface after six months:
  - Will also be subject to Lone Pine order
  - Will have to prepare their own experts reports as those have not been filed and will not be exchanged, submitted to the Court, finalized or made public
  - May be time barred as statute of limitation is which on average is 2-3 years after recall was initiated (in Jun-21) or from the date an injury allegedly connected to the devices manifests itself (while PE-PUR foam has been used since 2008)



# Regulatory and other legal proceedings

# 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 139,400 MDRs filed by Philips Respironics to the FDA from April 2021 through March 31, 2024. In the three months from January through March 2024, Philips Respironics filed approximately 12,700 MDRs.
- The vast majority (90%) of the MDRs filed since April 2021 up to and including March 2024 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



# Civil litigation

- 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
- 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
- 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
- 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



# Consent Decree



## Summary of the main terms (1/3)

- Primarily focuses on Philips Respironics' business operations in the US, including its facilities in Murrysville, New Kensington, Mount Pleasant and Pittsburgh in Pennsylvania ("Covered Respironics Facilities").
- Intended to resolve a complaint for an injunction based on alleged failures to comply with the FDA's Current Good Manufacturing Practice requirements and requirements for reporting corrections and removals.
- Philips Respironics' business operations must demonstrate continued compliance with the FDA's Current Good Manufacturing Practice requirements for medical devices as incorporated in the FDA's Quality System Regulation.

## Summary of the main terms (2/3)

- Retain independent quality system experts to supervise the compliance improvement program in the Covered Respironics Facilities and Other Sleep and Respiratory Care facilities<sup>1</sup>.
- Report to the FDA all actions taken to address all observations made by the experts and ensure the Covered Respironics Facilities and Other Sleep and Respiratory Care facilities are in compliance with the relevant requirements<sup>2</sup>.
- Complete the rework, replacement, and refund activities in accordance with the Recall Remediation Plan as approved by the FDA.
- Retain testing and design experts to review and evaluate the testing of the new silicone sound abatement foam<sup>3</sup> and review the design of devices reworked as part of the recall.

1. Facilities (other than the Covered Respironics Facilities) at which Philips' Sleep and Respiratory Care business manufactures or services Sleep and Respiratory Care devices: Shenzhen (China) and Alajuela (Costa Rica) | 2. Detailed requirements are listed in the Consent Decree that can be found in the court docket: <https://www.pawd.uscourts.gov> | 3. Devices with the new silicone sound abatement foam have been subject to extensive testing in accordance with the applicable industry testing standards and may continue to be used in accordance with the instructions for use. Their use is not impacted by Consent Decree.

# Summary of the main terms (3/3)

## In the US:

- Will continue to service sleep and respiratory care devices already with healthcare providers and patients, and to provide accessories (including patient interfaces), consumables and replacement parts.
- Will resume sales of new CPAP or BiPAP sleep therapy devices or other respiratory care devices only when the relevant requirements are met.
- Agreed to disgorgement payments from sales of Medically Necessary Devices<sup>1</sup>. Sales of Patient Interfaces (masks) and other consumables and accessories in the US are allowed under a separate exemption, which does not have a disgorgement requirement.
- Sales injunction and disgorgement payments to occur until Covered Respironics Facilities are in compliance with the relevant requirements and the rework, replacement, and refund activities are completed in accordance with the Recall Remediation Plan.

## Outside the US:

- Will continue to provide new sleep and respiratory care devices, accessories (including patient interfaces), consumables, replacement parts and services, subject to certain requirements.
- It is common for Consent Decrees (including this one) to include requirements (e.g. controls and documentation) for exports to prevent reimportation of the medical devices into the US.



# Testing

# 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 low prevalence of significant visible foam degradation/volume reduction</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>

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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)

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## 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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