PHILIPS

Progress update

Philips Respironics field action

July 24, 2023

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Resolving the recall for patients remains our highest priority

2023	H1 2023	2023-2025
Finalize recall and testing	~99% of recall units produced; >4.5M units[1] w/ patients and care providers Completed all testing and analysis for DS1, DS Go and System One devices	Manage impact of proposed Consent Decree
Manage litigation, DoJ investigation	Provision related to anticipated resolution of the economic loss class action in the US	Manage litigation, DoJ investigation
483 remediation and clarity on proposed Consent Decree	483 remediation in progress	Gradually restore position

Taking the learnings of Respironics recall
to raise Patient Safety and Quality to the highest standards across Philips

1. New replacement devices and repair kits required for the remediation of the total currently registered affected devices. Note: More information on the Respironics recall can be found here

Testing and literature review

Positive and reassuring complete test results for DreamStation1 devices

MAY '23	**Devices exposed to Ozone**	• Exposure to VOC emissions unlikely to result in appreciable harm to health • Based on assessment of ozone-induced degradation from up to 500 cleaning cycles
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)	• Foam degradation does not contribute to appreciable elevated levels of respirable particles • Exposure to particulates from degraded foam with self-reported ozone use is unlikely to result in an appreciable harm to health in patients
JUNE '22	**Visual inspection**	• Foam degradation does not contribute to appreciable elevated levels of respirable particles • Low prevalence of significant visible foam degradation • Ozone cleaning exacerbates foam degradation • July 23: Additional visual inspection confirms low prevalence of significant visible foam degradation/volume reduction **(NEW)**
DEC '21	**VOC testing** (ISO 18562-3)	Emissions within safety limits based on ISO 18562-3 (devices not exposed to ozone)

Positive and reassuring complete test results for SystemOne and DS Go

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 (NEW)

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

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[1]

1. 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[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.

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. Philips booked EUR 575 million provision in Q1 2023 in connection with the anticipated resolution of the economic loss class action on behalf of users, hospitals and private insurers in the US
  - expect to submit a negotiated settlement agreement to the court for preliminary approval in due course
  - being negotiated, with the assistance of a court-appointed mediator, as a potential class action settlement that will resolve the claims of all similarly situated class members in the US, whether they have filed a lawsuit or not
  - subject to final court approval, payments are not expected to begin until Q1 2024 at the earliest
- As of July 15, 2023, around 600 personal injury claims have been filed and are currently pending and approximately 50,000 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 the medical monitoring class action and personal injury claims is not expected before 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 anticipated settlement of the economic loss claims in the US

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 108,000 MDRs filed by Philips Respironics to the FDA from April 2021 through June 2023, of which 4,200 in the three months April 2023 – June 2023
- The vast majority (94%) of the MDRs filed since April 2021 up to and including June 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


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