PHILIPS

Test and research program
Respironics' PE-PUR sound abatement foam

21 December 2022

innovation you

Important information

Forward-looking statements and other important information
This document and the related oral presentation, including responses to questions following the presentation, contain certain forward-looking statements with respect to the financial condition, results of operations and business of Philips and certain of the plans and objectives of Philips with respect to these items. Examples of forward-looking statements include statements made about our strategy, estimates of sales growth, future Adjusted EBITA*), future restructuring and acquisition-related charges and other costs, future developments in Philips' organic business and the completion of acquisitions and divestments. Forward-looking statements can be identified generally as those containing words such as "anticipates", "assumes", "believes", "estimates", "expects", "should", "will", "will likely result", "forecast", "outlook", "projects", "may" or similar expressions. By their nature, these statements involve risk and uncertainty because they relate to future events and circumstances and there are many factors that could cause actual results and developments to differ materially from those expressed or implied by these statements.

These factors include but are not limited to: Philips' ability to gain leadership in health informatics in response to developments in the health technology industry; Philips' ability to transform its business model to health technology solutions and services; macroeconomic and geopolitical changes; integration of acquisitions and their delivery on business plans and value creation expectations; securing and maintaining Philips' intellectual property rights, and unauthorized use of third-party intellectual property rights; Philips' ability to meet expectations with respect to ESG-related matters; failure of products and services to meet quality or security standards, adversely affecting patient safety and customer operations; breaches of cybersecurity; Philips' ability to execute and deliver on programs on business transformation and IT system changes and continuity; the effectiveness of our supply chain; attracting and retaining personnel; COVID-19 and other pandemics; challenges to drive operational excellence and speed in bringing innovations to market; compliance with regulations and standards including quality, product safety and (cyber) security; compliance with business conduct rules and regulations; treasury and financing risks; tax risks; reliability of internal controls, financial reporting and management process. For a discussion of factors that could cause future results to differ from such forward-looking statements, see also the Risk management chapter included in the Annual Report 2021.
Philips has recognized a provision related to the voluntary recall notification in the US/field safety notice outside the US for certain sleep and respiratory care products, based on Philips' best estimate for the expected field actions. Future developments are subject to significant uncertainties, which require management to make estimates and assumptions about items such as quantities and the portion to be replaced or repaired. Actual outcomes in future periods may differ from these estimates and affect the company's results of operations, financial position and cash flows.

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All amounts are in millions of euros unless otherwise stated. Due to rounding, amounts may not add up precisely to totals provided. All reported data is unaudited. Financial reporting is in accordance with the accounting policies as stated in the Annual Report 2021 except for the adoption of new standards and amendments to standards which are also expected to be reflected in the company's consolidated IFRS financial statements as at and for the year ending December 31, 2022. Prior-period amounts have been reclassified to conform to the current-period presentation; this includes immaterial organizational changes

* Non-IFRS financial measure. Refer to reconciliation of non-IFRS information

Overview of testing process (1/2)

Affected CPAP, BiPAP and mechanical ventilator devices

- ~95% of registered devices are CPAP and BiPAP
- DreamStation1 represents ~68% and System One ~26% of the devices
- Trilogy 100/200 represent ~3% and OmniLab Advanced Plus ~2% of the devices

Comprehensive and thorough process, to ensure patients and physicians have accurate information

- Working with 5 independent, certified testing laboratories in the US and Europe
- Leveraged external experts with extensive scientific and regulatory experience and independent external medical panel
- Time taken to test and analyse the data per device category[1] and condition[2] is substantial
- Hundreds of tests, multiple repeat tests
- Test plan and approach presented to and discussed with the FDA; relevant competent authorities still reviewing the extensive data and insights

1. Five device categories based on air path design; 2. Three device conditions: devices with new, used and lab-aged PE-PUR foam.

Overview of testing process (2/2)

VOC testing (ISO 18562-3)	To identify and quantify volatile organic compounds that may be inhaled	**Dec-2021**
Visual inspection and assessment of the foam in used devices	To assess the prevalence of visible foam degradation	**Jun-2022**
Particulate Matter testing (ISO 18562-2)	To determine presence and concentrations of respirable particulates	**Jun-2022**
Bioassay evaluation, chemical characterization and toxicological risk assessment (ISO 10993)	To fully assess potential patient risk under use conditions, as we had previously reported that lab-degraded foam failed genotoxicity, cytotoxicity and irritation tests under laboratory conditions	**Today**

Evaluated pristine foam in unused new devices, lab-aged foam, and foam in devices used by patients

Extensive test and research program completed for DreamStation1 devices

Low prevalence of significant visible foam degradation in devices inspected

Ozone cleaning 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

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 – NEW

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

Thorough consideration and mitigation of testing limitations that are inherent to any test standard and/or scientific research

Testing per ISO 18562 only captures a "snapshot" of device performance during degradation

- To address this, testing was performed on multiple used devices with differing usage and observed visual foam degradation, and on lab-aged foam that has been intentionally degraded to different degrees

Differences may exist in how the lab-aged PE-PUR foam degrades compared to the used foam over the lifetime use of the device

- The differences were considered in the completed risk assessments. Lab-aging conditions are not intended to be predictive of foam degradation progression observed in used devices

Testing per ISO 18562-2 quantifies concentration of respirable particulate based only on their size range, but does not measure non-respirable particles nor characterize the chemicals present in particles

- To address this, additional testing in accordance with ISO 10993 and very conservative assumptions were taken

Visual inspections qualitative in nature and do not quantify VOCs or particulates within or emitted from device

- The visual inspection results did not contribute to the risk assessment calculation

Additional chemical characterization and toxicological risk assessment (biocompatibility test for DreamStation1 devices)

Background

- Performed to further understand the level of toxicity of such particles if these were to reach the patient
- Relevant as we had previously reported that lab-degraded foam failed genotoxicity, cytotoxicity, and irritation test under laboratory conditions

Rigorous testing

- Chemical characterization of lab-aged foam as well as foam from used devices
- Repeat tests and very conservative toxicological risk assessments conducted to assure confidence in results
- Included identification of potential confounding factors, and a weight of evidence assessment to determine a confirmed conclusion

Completion of biocompatibility test for DreamStation1 devices shows encouraging results

Exposure to particulate matter, including potential respirable and non-respirable particulates, is unlikely to result in an appreciable harm to health in patients

Based on PM tests (ISO 18562-2) and complete biocompatibility tests (ISO 10993)

Exposure to volatile organic compound emissions (VOCs) is not anticipated to result in long-term health consequences for patients

Based on ISO 18562-3 testing and consistent with the results presented in December 2021

Visual inspection shows that the prevalence of visible foam degradation is low

Self-reported as not using ozone-cleaning and consistent with the results presented in June 2022

- These devices have not been exposed to ozone-cleaning in line with the instructions for use
- Philips Respironics' guidance for healthcare providers and patients remains unchanged

Results to date on the impact of ozone cleaning on PE-PUR foam degradation – DreamStation1 devices

Ozone cleaning exacerbates foam degradation

Devices from the US and Canada with user-reported ozone cleaning 14x more likely to have significant visible foam degradation compared to devices with no user-reported ozone exposure

Exposure to particulate from degraded foam with self-reported ozone use in DreamStation1 devices is unlikely to result in an appreciable harm to health in patients

Based on testing and analyses regarding risks associated with respirable and non-respirable particulates; Reviewed and validated by third-party experts

The VOC toxicological risk of this ozone-induced foam degradation is still being assessed

Trilogy 100/200 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

Silicone foam testing

- Previous testing for DreamStation2 and repaired DreamStation1 had demonstrated acceptable results, including to the FDA
- In November 2021, the FDA requested additional testing to determine what, if any, potential safety risks may be posed to patients by silicone-based foam
- Independent testing laboratories engaged to further confirm safety of silicone foam in response to FDA request; additional VOC testing on a wider sample of devices
- **Based on the final reports subject to FDA review, Philips Respironics has not identified any safety issues**

Next steps

- Finalize toxicological risk assessment of the VOC emissions resulting from ozone-induced foam degradation in DreamStation1 devices

- Complete testing for SystemOne (~26% of registered devices) and DreamStation Go (~1%), which contain the exact same foam as the DreamStation1 devices

- Completion of remaining VOC and PM testing, as well as chemical evaluation and toxicological assessments for Trilogy 100/200 (~3%) and OmniLab Advanced Plus (~2%), where a different PE-PUR foam is used

- Ongoing engagement with FDA and other competent authorities

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.

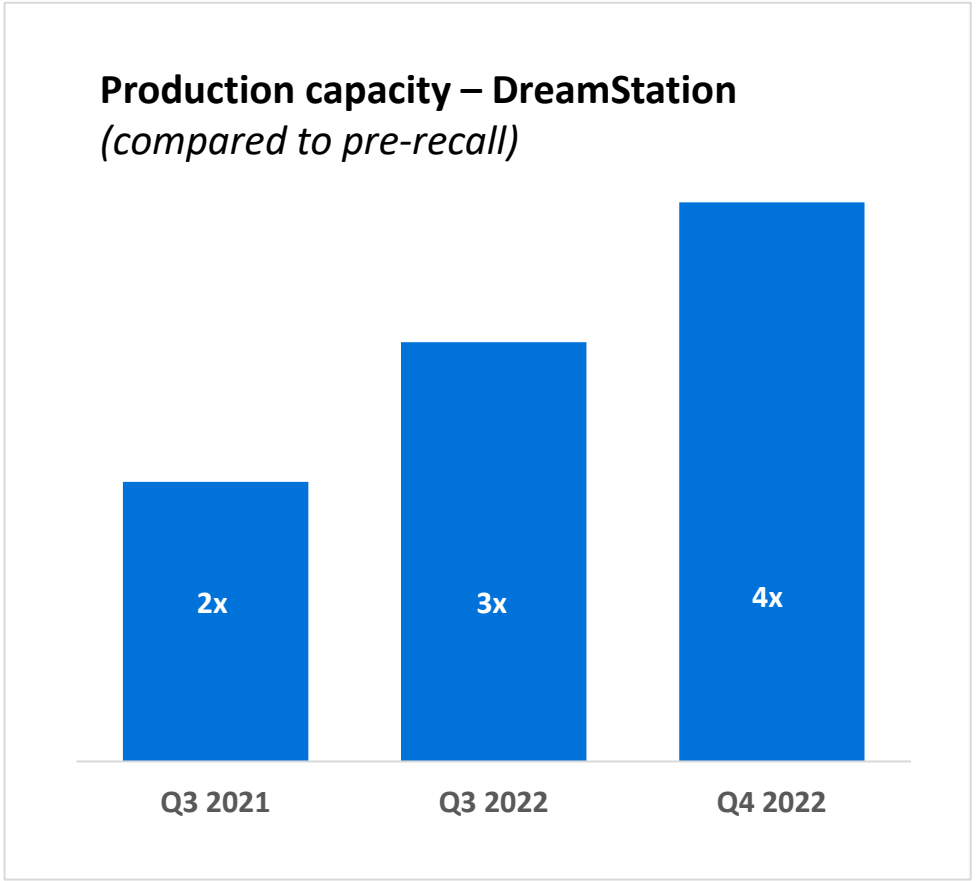
Completing around 90% of the required production in 2022

The task at hand

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

Progress to date

- Quadrupled production capacity compared to pre-recall
- >1 thousand people cross functional team engaged
- Dependency on supply of materials and global logistics capacity
- On-track to complete ~90% of required production in 2022
- For shipment and delivery to patients early 2023

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