

Test and research program

Respironics' PE-PUR sound abatement foam

May 16, 2023



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; challenges in connection with Philips' strategy to improve execution and other business performance initiatives; the resilience 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 including privacy and upcoming ESG disclosure and due diligence requirements; treasury and financing risks; tax risks; reliability of internal controls, financial reporting and management process; global inflation. 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 2022.

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. Furthermore, Philips is a defendant in several class-action lawsuits and individual personal injury claims, and is in ongoing discussions with the FDA regarding a proposed consent decree. Given the uncertain nature of the relevant events, and of their potential financial and operational impact and associated obligations, if any, the company has not made any provisions in the accounts for these matters, except for the following. In the first quarter of 2023, Philips Respicronics recorded a provision in connection with an anticipated resolution of the economic loss class action pending in the US. The provision is subject to final resolution and court approval of the negotiated settlement agreement and is based on Philips' best estimate for the expected settlement amounts, which is, in part, based on the expected number of claims ultimately filed pursuant to the settlement once it is approved. Actual outcomes in future periods of the above matters may differ from these estimates and affect the company's results of operations, financial positions and cash flows.

Third-party market share data

Statements regarding market share, contained in this document, including those regarding Philips' competitive position, are based on outside sources such as specialized research institutes, industry and dealer panels in combination with management estimates. Where information is not yet available to Philips, market share statements may also be based on estimates and projections prepared by management and/or based on outside sources of information. Management's estimates of rankings are based on order intake or sales, depending on the business.

Use of non-IFRS information

In presenting and discussing the Philips Group's financial position, operating results and cash flows, management uses certain non-IFRS financial measures. These non-IFRS financial measures should not be viewed in isolation as alternatives to the equivalent IFRS measure and should be used in conjunction with the most directly comparable IFRS measures. Non-IFRS financial measures do not have standardized meaning under IFRS and therefore may not be comparable to similar measures presented by other issuers. A reconciliation of these non-IFRS measures to the most directly comparable IFRS measures is contained in this document. Further information on non-IFRS measures can be found in the Annual Report 2022.

Fair value information

In presenting the Philips Group's financial position, fair values are used for the measurement of various items in accordance with the applicable accounting standards. These fair values are based on market prices, where available, and are obtained from sources that are deemed to be reliable. Readers are cautioned that these values are subject to changes over time and are only valid at the balance sheet date. When quoted prices or observable market data are not readily available, fair values are estimated using appropriate valuation models and unobservable inputs. Such fair value estimates require management to make significant assumptions with respect to future developments, which are inherently uncertain and may therefore deviate from actual developments. Critical assumptions used are disclosed in the Annual Report 2022. In certain cases, independent valuations are obtained to support management's determination of fair values.

Presentation

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 2022 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, 2023.

Today's update

Complete testing on the impact of ozone cleaning on PE-PUR foam degradation for DreamStation1 devices

Represent **~68%** of registered devices

Unlikely to result in appreciable harm to health in patients

Extensive test and research program completed for SystemOne and DreamStation Go¹

Represent **~27%** of registered devices

Unlikely to result in appreciable harm to health in patients

Philips Respironics has provided the completed set of test results and analyses for the sleep therapy devices to the FDA and other competent authorities. The FDA is still considering the data and analyses that Philips Respironics has provided and may reach different conclusions.

Encouraging complete test results for DreamStation1 devices

NEW

MAY '23	Devices exposed to Ozone	<ul style="list-style-type: none">• 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)	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Foam degradation does not contribute to appreciable elevated levels of respirable particles• Low prevalence of significant visible foam degradation• Ozone cleaning exacerbates foam degradation
DEC '21	VOC testing (ISO 18562-3)	Emissions within safety limits based on ISO 18562-3 (devices not exposed to ozone)

Encouraging test results for SystemOne and DreamStation Go¹

NEW

Exposure to foam particulates and VOCs is unlikely to result in an appreciable harm to health in patients

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)



Comprehensive and rigorous 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, independent external medical panel

Repeat tests and very conservative toxicological risk assessments conducted to assure confidence

Very conservative assumptions and conditions were considered

- Sample focused on devices with various degrees of degradation
 - VOC and PM tests done under various clinically relevant flow rate conditions. Conditions published based on worst-case scenario of a clinically relevant rate of 17 L/minute for VOC emissions and clinically relevant rate of 90 L/minute for PM emissions
 - Ozone-induced degradation from up to 500 cleaning cycles
-

Included identification of potential confounding factors, and a weight of evidence assessment to determine a confirmed conclusion

Test plan and approach presented to and discussed with the FDA; relevant competent authorities still reviewing the extensive data and insights

Next steps

Expected in Q3 2023

Complete 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 devices¹

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.



Appendix

Overview of testing process

VOC testing (ISO 18562-3)	To identify and quantify volatile organic compounds that may be inhaled
Visual inspection and assessment of the foam in used devices	To assess the prevalence of visible foam degradation (not used for risk assessment)
Particulate Matter testing (ISO 18562-2)	To determine presence and concentrations of particulates
Bioassay evaluation, chemical characterization and toxicological risk assessment (ISO 10993)	To fully assess the potential toxicological risk of particulates

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

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 studies¹ 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.

