PHILIPS

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

June 28, 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.

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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.

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 2021.

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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

Extensive test and research program launched in June 2021

Patient safety is number one priority - doing everything we can to deliver a solution to patients and care givers

- Test and research results to date for DreamStation1 devices are encouraging and insightful
  - Very low prevalence of significant visible foam degradation in the over 63,000 devices inspected
  - Ozone cleaning vastly exacerbates foam degradation
  - Volatile organic compounds (VOC) emissions within established ISO limits
  - 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
- Biocompatibility testing and assessment of degraded foam still on-going to fully assess potential patient risk
- Independent analysis in the American Journal of Respiratory and Critical Care Medicine[1] and in the European Respiratory Journal[2] do not show any correlation between the occurrence of cancer and Respironics PAP devices

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; 2. Cancer risk in adherent users of polyurethane foam-containing CPAP devices for sleep apnea, European Respiratory Journal 2022.

Overview of testing process (1/2)

Visual inspection and assessment of the foam in used devices	To assess the prevalence of foam degradation
VOC testing (ISO 18562-3)	To identify and quantify organic compounds that may be inhaled during device use
Particulate Matter testing (ISO 18562-2)	To determine concentrations of respirable particulates
Additional physical, chemical and biological testing (ISO 10993)	To fully assess potential patient risk, as we had previously reported that lab-degraded foam failed genotoxicity, cytotoxicity and irritation test thresholds

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

Overview of testing process (2/2)

Affected CPAP, BiPAP and mechanical ventilator devices

- 95% of registered devices are CPAP and BiPAP
- Devices divided into 5 product categories*: DreamStation 1 and SystemOne represent 68% and 26% of the devices, respectively
- Test plan and approach presented to and discussed with the FDA; agency's feedback was considered

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

- Working with 5 certified testing laboratories in the US and Europe
- Leveraged outside experts with extensive regulatory experience
- Time taken to test and analyse the data per product category and situation is substantial
  - Hundreds of tests, throughput time of many months
  - Multiple repeat tests to provide confidence
  - Testing in parallel where possible, sequentially where required or capacity constrained

** DreamStation1, DreamStation Go, System One CPAP and BiPAP devices, Trilogy 100 and Trilogy 200 mechanical ventilators, OmniLab ventilator and the A-Series mechanical ventilator*

PE-PUR foam - Visual inspection (1/2)

0.5% of DreamsStation1 devices with (self-reported) no Ozone use had significant visible foam degradation;
Important as only degraded foam would emit particulates

- 60,847 devices inspected from US and Canada
  - 36,341 reported no Ozone use, of which 0.5% showed degradation
- 1,360 from various countries in Europe, where ozone cleaning products have very low penetration
  - None showed significant foam degradation
- 931 from Japan, mostly not exposed to ozone cleaning
  - None showed any signs of foam degradation

* *Results apply to new and lab aged DreamStation1 devices*

PE-PUR foam - Visual inspection (2/2)

7% of devices with (self-reported) Ozone use had significant visible foam degradation

- 14x higher degradation rate compared to devices with (self-reported) not Ozone use
- Ozone is an unapproved cleaning method

Visual inspection of DreamStation1 devices from the US and Canada			
	# of inspected devices	# of devices with visual foam degradation/volume reduction	% of devices with visual foam degradation/volume reduction
No use of ozone cleaning*	36,341	164	0.5%
Use of ozone cleaning*	11,309	777	7%
Unknown*	13,197	164	1%
Total	60,847	1,105	2%

Of the devices inspected, 422 were linked to a reported visible particle complaint, of which only 4% actually showed foam degradation

** Self-reported by user;*
Results apply to new and lab aged DreamStation1 devices

PE-PUR foam - VOC testing

Performed to:

1) Quantify VOC emissions from devices that may be inhaled during use
2) Assess toxicological risk associated with exposure to quantified concentrations of those VOCs

VOC emissions are within established limits*

- Exposure to level of VOC identified to date for the DreamStation1 tested in compliance with ISO 18562-3 is not anticipated to result in long-term health consequences for patients
- This information was previously provided in an update on December 23, 2021

New DreamStation Go, SystemOne, Trilogy 100/200 devices, and new and used OmniLab devices passed VOC testing

- Testing to assess impact of repeated ozone cleaning on VOC emissions is ongoing

**Results apply to new and lab aged DreamStation1 devices not exposed to Ozone cleaning in accordance with the instructions for use.*

PE-PUR foam - Particulate Matter testing

Performed to:

1) Quantify particulate matter emissions from devices
2) Assess whether concentration detected is less than thresholds provided in the standard

New and used devices all compliant with ISO 18562-2 allowable limits*

- Results suggest degradation did not contribute to appreciable elevated levels of respirable particles; even in devices with significant visible foam degradation
- Used devices were evaluated for cleanliness based on a visual inspection. Average particulate matter counts in devices classified as ‘dirty’ were significantly greater than those classified as ‘clean’

New DreamStation Go, SystemOne, Trilogy 100/200 and OmniLab devices passed Particulate Matter testing

- Particulates matter testing is ongoing for used OmniLab devices
- Testing to assess impact of repeated ozone cleaning on Particulate Matter emissions is ongoing

**Result applies to new and lab aged DreamStation1 devices not exposed to Ozone cleaning in accordance with the instructions for use.*

PE-PUR foam - Additional testing

- Biocompatibility test of (degraded) PE-PUR foam still on-going, to fully assess potential patient risk

- Further chemical characterization and risk assessment needed to further understand if:
  - the foam in used devices reach the same level of degradation as lab-aged foam
  - degraded foam particles actually reach the patient and, if so, in which quantity
  - the level of toxicity of such particles if these were to reach the patient

- This test is relevant as we had previously reported that lab-degraded foam failed genotoxicity, cytotoxicity, and irritation test

- Will provide regular updates

Silicone foam testing - in response to FDA request in November 2021

- Previous testing for DreamStation2 and repaired DreamStation1 had demonstrated acceptable results, including to the FDA

- Independent testing laboratories engaged to further confirm safety of silicone foam in response to FDA request
  - Additional VOC testing performed based on a wider sample of over 50 devices
  - No safety issues identified to date
  - Assessment is being completed
  - Final reports subject to FDA review, which are expected in coming months

Independent literature and epidemiological studies

- Team of external scientists review existing literature and independent epidemiological studies
- Philips Respironics was not involved in the studies or the analysis
- Two of these studies have robust methodology and high statistical quality according to experts and show no correlation between the occurrence of cancer and use of Respironics PAPs

Analysis published in the American Journal of Respiratory and Critical Care Medicine[1] (December 2021)	Analysis published in the European Respiratory Journal[2] (May 2022)
• Based on data from a large multicenter cohort study • 6,903 patients between 2012 and 2020 • Including 1,220 Philips Respironics PAP users	• Based on data from a large multicenter cohort study • 4,447 between 2007 and 2018 • Including 1,648 Philips Respironics PAP users

- Other studies to date do not lead to different conclusions; but have major methodological and reporting limitations, including the recent Swedish study

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; 2. Cancer risk in adherent users of polyurethane foam-containing CPAP devices for sleep apnea, European Respiratory Journal 2022.

Repair and Replace program

The task at hand

- 5.5 million devices expected to be repaired or replaced, from over 100 countries
- Represents over 5x previous annual production volume of ~1 million devices

Progress to date

- Tripled production capacity compared to pre-recall
- >1000 people working on recall
- Extensive communication program
- Majority of devices approved for release by regulators, started shipments in Q4 2021
- ~2.7 million repair and replace units produced to date

Challenges faced

- Dependency on supply of materials, including from China, and global logistics capacity

Target to execute 90% of the repair and replacement program by the end of 2022


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