

# Embattled Philips says respirators 'within safety limits'

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Under-fire Dutch medical device maker Philips said Wednesday extensive testing on its recalled respirator devices showed they were "within safety limits" for use, but that a final verdict rests with global regulatory authorities.

The Amsterdam-based company announced a global recall of its appliances to treat people suffering from sleep apnoea 18 months ago over concerns patients risked "possible toxic and carcinogenic effects" if they inhaled or swallowed pieces of degraded sound-dampening foam on the machines.

The recall has so far cost the company 2.2 billion euros (\$2.3 billion), pushed it to cut 4,000 jobs and seen one chief executive step down.

But the company announced on Wednesday that extensive testing showed the respirators were "compliant with... allowable limits for particle matter emissions."

Philips based its results on research done by five independent laboratories, third party experts as well as an external medical panel, it said.

The research found exposure to particle matter emissions from degraded foam "is unlikely to result in an appreciable harm to health in patients," Philips said.

"Today is important because it starts with reassuring that the product that we did put out actually was within the [safety limits](#)," Philips' chief executive Roy Jakobs told AFP.

## **'FDA is still considering'**

"This is a complex matter and we wanted to do a very scientific, thorough job," he added.

The latest test results have now been submitted to regulatory authorities including the US Food and Drug Administration, which still need to make an assessment.

"The FDA is still considering the data and analyses... provided and may reach different conclusions," Philips said.

Philips also noted that its advice to patients remains unchanged: consult with their doctor to consider whether to continue to use the affected models, or switch to a different model or [alternative treatments](#).

It said was continuing to test other models, including ones with a different type of foam.

It is also looking at the impact of non-regulatory approved cleaning methods on the machines, saying data available so far showed ozone cleaning to have exacerbated foam degradation.

Investors responded positively to Philips' announcement, with its [share price](#) jumping by over four percent in midday trade on the Amsterdam stock exchange's blue-chip AEX index.

Starting off as a lighting company more than 130 years ago, Philips has undergone major changes in recent years, selling off assets to focus on making high-end electronic healthcare products.

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