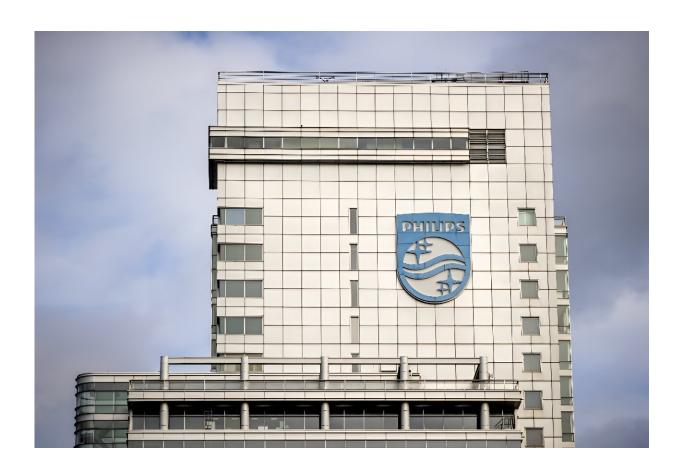


## Philips stock slumps after new FDA warning

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Philips has been badly affected by the recalls.

Shares in Dutch medical device manufacturer Philips plunged Wednesday after the US Food and Drug Administration warned that its new machine to help patients sleep risked overheating.

Philips stock spiked down five percent at the opening on the Amsterdam



market, then traded lower to a seven-percent fall, hugely underperforming the wider market, which was flat.

The FDA advised patients using the company's DreamStation 2 machine to "carefully monitor" the device "for signs of overheating".

The US body said it had received reports "such as fire, smoke, burns, and other signs of overheating" from people using the machine.

It recommended that customers carefully follow the users' manual and examine the machine for "unusual smells or changes in appearances before and after each use."

The machine is designed to help patients with <u>sleep apnea</u>, a condition where people develop breathing difficulties in their sleep.

The FDA's initial analysis suggests that an electrical and/or mechanical malfunction was to blame.

The issue appears to be unrelated to a 2021 recall of sleep machines that sent the company into turmoil, although some of the DreamStation 2 machines were sent as replacements.

In that recall, the FDA said foam in the machine could potentially be breathed in or swallowed, posing possible health risks to patients.

"Based on the currently available evidence, the agency does not believe the <u>safety issue</u> with the DreamStation 2 is related to the foam used in the machine," the FDA said.

The <u>company</u> announced in September it had reached a partial settlement to compensate US customers affected by the 2021 recall.



No total was given, but Philips Respironics, a US subsidiary, set aside 575 million euros (\$615 million) in the first quarter of 2023 "to cover for the estimated costs of the final settlement".

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