Sleep apnea patients struggle as common CPAP machine is recalled

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Millions of U.S. sleep apnea patients are scrambling to find ways to

protect their nightly slumber, following a voluntary recall from one of the nation's leading manufacturers of CPAP breathing machines.

Philips Respironics agreed to a voluntary recall of continuous positive airway pressure (CPAP) machines in late June, over concerns that noise-dampening foam inside the devices might degrade and produce toxic particles and gases.

Patients with severe sleep apnea now face a difficult choice if they own one of the Philips machines—go without good sleep for months on end, shell out $1,000 for a new device, or keep using a breathing aid that could harm their health.

Philips said in September it could take up to a year to repair or replace all machines affected by the recall.

Many patients simply won't be able to wait that long, said Dr. Steven Feinsilver, director of the Lenox Hill Hospital Center for Sleep Medicine, in New York City.

"I have lots of patients—I was just talking to an airline pilot—who are in positions where being sleepy is not trivial," Feinsilver said.

Sleep doctors across the country have been flooded with calls from patients worried that the machine that helps them get a good night's sleep might harm their health, said American Academy of Sleep Medicine president Dr. Raman Malhotra.

"Just me individually, I have hundreds of patients on these machines, and our sleep center alone has several thousand," said Malhotra, an assistant professor of neurology in the sleep medicine section at Washington University School of Medicine in St. Louis. "Personally, I get somewhere in the 10 to 20 range calls a day. Our center gets over 100 a

day."

In a statement, Philips said it's churning out repair kits and replacement devices as fast as it can. The company has been producing 55,000 per week and hopes to increase that to 80,000 per week in coming months.

"We are working to address this issue as expeditiously as possible," Philips said in the statement. "Given the number of devices currently in use (estimated at 3 to 4 million units globally based on production and shipment data—about half are in the U.S.), we expect to complete the repair and replacement programs in each country within approximately 12 months from obtaining the relevant regulatory clearances."

As many as 25 million U.S. adults suffer from sleep apnea, according to the American Sleep Association.

The condition occurs when muscles in the back of the throat relax and block the airway, stopping a person's breathing and causing them to wake. This can happen more than 30 times an hour throughout the night, destroying a person's ability to get good rest, the association says.

"There were times where I would literally fall asleep mid-sentence talking to someone because I was so exhausted from not going to sleep the night before," sleep apnea patient James Colbert told CBS News in a report about the Philips recall.

CPAP machines improve sleep by pushing a steady stream of air into the patient's nose and mouth, through a mask strapped onto the face. The constant air pressure keeps the airways open.

"As soon as you see a CPAP machine, you know it must really work, because no one would sleep with this stupid-looking thing if it didn't work," Feinsilver said. "When I first broach the idea, everybody

immediately says there's no way I could sleep with this thing. Then they come back and say they can't sleep without it."

Philips issued the recall after learning that the polyurethane foam used to muffle the noise produced by some of its CPAP machines could break down over time. The foam might produce particles that would be inhaled by the user, or release potentially toxic gases.

"The potential risks of exposure to chemicals released into the device's air pathway from the PE-PUR foam include headache; dizziness; irritation in the eyes, nose, respiratory tract, and skin; hypersensitivity; nausea/vomiting; and toxic and carcinogenic effects," the U.S. Food and Drug Administration said in its recall notice.

The recall caught sleep doctors by surprise.

"Unfortunately, Respironics said stop using your machine immediately and call your doctor, which is a big problem because as your doctor, I have no idea what to tell you, and not a whole lot of options," Feinsilver said. "This was done very badly. I think anybody in the field would tell you that."

The CPAP machine market is dominated by Philips Respironics and a San Diego-based medical device firm called ResMed, Feinsilver and Malhotra said.

"I have perhaps 1,000 patients on CPAP, probably a third to a half of whom are on Respironics machines," Feinsilver said.

Plenty of CPAP machines are available from ResMed and other smaller companies, but patients will have to fork over as much as $1,000 if their insurance won't cover the cost of a replacement device, the doctors said.

"You can buy one, with a prescription. But insurance isn't going to pay for a second one unless the first one is at least five years old," Feinsilver said.

Patients with mild to moderate sleep apnea might be able to try other strategies to improve their sleep, Malhotra said. They could raise the head of their bed, sleep on their side, or lose weight.

They also might consider being fitted with an oral device designed to maintain good breath during sleep, Malhotra said.

"It moves the lower jaw forward during sleep," Malhotra said. "By doing that, that does bring the tongue and the soft tissue forward and opens up the airways during sleep."

For his part, Feinsilver tells patients who can't afford a new device to keep using their Philips machine until it is repaired or replaced.

He said the devices filter air upon intake, so he personally can't figure out how particles or gases produced from foam located outside the blower would be inhaled by the patient.

"Everything in medicine is balancing risk and benefit. That's always true," Feinsilver said. "And as far as I can tell, the risk of whatever the problem is with this machine is smaller than the risk of sleep apnea if you have significant sleep apnea."

Malhotra agreed.

"If we feel the benefits of the machine outweigh the potential risk, then we recommend continuing the machine, which is the case in many cases if not most that we come across," he said. "These patients are on a machine for a reason, and it's really helped their quality of life and their

health. It's just not safe to come off of it, even with the risk that Philips is stating."

More information: The U.S. Food and Drug Administration has more about the Philips recall. The American Sleep Association has more about sleep apnea.