

Philips CPAP and BiPAP Machine Recall Frequently Asked Questions (FAQs) – Patient

What's the official site for the recall?

Go to: https://www.usa.philips.com/healthcare/e/sleep/communications/src-update

How often does the issue occur?

Philips has claimed that three (3) out of 10,000 machines, or 0.03%, have the issue. To date, Philips has not received reports of patient impact or serious harm as a result of this issue.

How do I know whether my device is on the list?

Download the <u>Philips Recalled Device Model Number List</u>. If the first few letters/numbers of your device model number (which is located at the bottom of the machine) can be found, your device is on the recall list.

If you cannot find the model number on your device, please email Respshopsales@respshop.com.

I have a machine on the recall list. Who should I contact?

Contact your physician first. They will be able to tell you whether your continued use the device will bring more harm or if you should keep using it while you are waiting for the recall service.

If my machine recall service is handled by Respshop, do I have to ship the unit to Respshop? Will the repaired/replaced unit be shipped from Philips directly? I do not want the package being rerouted and thus delay my therapy.

DreamStation CPAPs (all models) and BiPAP (pro and auto) units will be shipped to and from Philips directly, thus no delays. Philips will email you the call tag with the FedEx/UPS labels for return service. The service units will be shipped to you directly.

What if my machine was purchased elsewhere?

As long as the machine was purchased in the U.S., Respshop will help free of charge. Register your unit(s) at the <u>Respshop Recall Registration Page</u> and Philips will notify you when you can send back the unit to them.

Where do I ship the affected machine, and when?

Philips hasn't started repair or replacement yet. Once the process starts, if you have registered your machine, you will receive an email with the instructions. Customers living out of U.S. will need to ship the machine back to Respshop and they will coordinate the recall. (NOTE: Please do not ship any unit(s) back unless you are notified.)

Will the replacement/repair be free?

Yes.

Is the shipping free?

All U.S. shipping is free. If you currently live outside of the U.S., you will be responsible for the round-trip international shipping cost to/from the Respshop office in Redmond, Wash.

Where can I locate the machine serial numbers?

Check the samples here: <u>DreamStation</u>, <u>DreamStation Go</u>, <u>C Series</u>, <u>A Series BiPAP</u>, <u>60</u> <u>Series</u>, <u>50 Series</u>, and <u>Dorma SE</u>. Be mindful of a zero and the letter "O." Don't key in any spaces.

My machine is very old (e.g., 50 series and PR system one). Any suggestions?

We suggest you purchase a new machine as soon as possible. CPAP machines usually last for five (5) years. Even without the recall, the machine motor may be worn, may not be able to provide sufficient and accurate pressures, and it may be noisy. There may be dust accumulating inside the machine as well. Read Respshop's blog article: <u>3</u> Signs Your CPAP is About to Kick the Bucket. Respshop expects there will be a CPAP machine shortage in the U.S. market for a few months. If you decide to buy a new one, buy it soon.

Are any other products affected, like masks or oxygen concentrators?

No.

Are humidifiers recalled?

No. Only the blower (aka CPAP machine itself) is recalled.

Is an inline bacteria filter useful?

Philips has advised patients to discontinue using CPAP machines immediately unless 1) you are using a ventilator, or 2) your physician suggests you keep using it. Philips also has suggested using a bacteria filter under a physician's recommendation. Respshop suggests all patients consult their physician first, and encourages all patients to use bacteria filters as a temporary solution when they are waiting for Philips' recall repair or replacement. Also note, the inline bacteria filter may only block the debris but not the chemical emissions.

Are affected devices safe for use? Should affected devices be removed from service?

The recall notification advises customers using Bi-PAP and CPAP devices to discontinue use of affected units and consult with your physician to determine the benefits of continuing therapy and the potential risks. Philips is recommending that customers and patients halt the use of ozone-related cleaning products, and adhere to their device instructions for use and for approved cleaning methods.

When will the correction for this issue begin? How long will it take to address all affected devices?

As of August 3, 2021, Philips is redirecting all their production to the DreamStation with the new foam. They have stated that their production is 3x or 4x normal speed. However, Philips' new sound abatement foam is still under the Food and Drug Administration's (FDA) approval process. Once it is approved, Philips will start the



replacement/repair process. Considering over four million units are affected, we expect it will be a lengthy process.

Are affected devices being replaced or repaired?

Some devices will be replaced, while others will be repaired. Philips hasn't released any details yet. It is expected that the recently purchased CPAP machines will be replaced with either a DreamStation unit with updated foam or a DreamStation 2. Older CPAP machines and BiPAPs will be repaired (because no DreamStation 2 BiPAPs are in the U.S. market yet).

Will Philips provide a backup machine while my machine is being serviced?

No.

If my machine has to be replaced, will Philips ship the new machine to me first?

Philips has no policy yet (as of August 3, 2021).

Is using ozone cleaning still safe or recommended?

It is suggested to use ozone cleaning only for CPAP masks or parts. Do not use the ozone cleaner to clean any electrical components.

Are other manufacturer devices affected?

Only some Philips (Philips Respironics) models are affected. For more information, read the ResMed FAQs here >>