

MANUFACTURER VOLUNTARY RECALL UPDATE

On June 23, 2021 Health Canada issued a Class 2 recall of Philips Respironics ("Philips") products. Information is available on the Health Canada website at:

https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75889r-eng.php#reason-motif

Philips also issued their own Field Safety Notification to announce the voluntary recall. The Field Safety Notification and other information can be found here: https://www.philips.ca/healthcare/e/sleep/communications/src-update

Pulse Air Heart and Lung Centre previously mailed you information on the recall and the actions that you were to take. This is a follow up notification to ensure the necessary steps have been taken so that, as your CPAP provider, we can ensure that you have access the resolution to the recall. Please review the following steps and take the required action:

- 1) Do you have a Phillips Respironics CPAP machine?
 - **NO -** I do not have a Phillips Respironics CPAP machine no further action is required you may destroy this letter **YES -** I have a Phillips Respironics machine **Proceed to Step 2**
- 2) Have you registered your Philips Respironics serial number on the patient recall portal?
 - **YES** I have registered You must now email **clientsupport@pulseair.ca** your confirmation number, date of registration and contact information
 - NO- I have not registered Proceed to Step 3
- 3) Registration of your machine, whether you are still using it or not, is required by entering the serial number of each Philips Respironics machine and your relevant personal information on the following website:

https://www.philipssrcupdate.expertinguiry.com/?ulang=en

- ✓ Scroll to the bottom of the page
- ✓ Select that you are a Θ Patient/Device User/Caregiver and that your country choice is Canada.
- ✓ Enter your serial number (do not use the number that starts with an "H")
- ✓ You will be advised if you own an affected device
- ✓ If you have a recalled device, you will be prompted to proceed with registration
- ✓ Follow prompts to enter your contact information
- email clientsupport@pulseair.ca with your contact information, recall confirmation number and date of registration

Philips Respironics has begun distribution of new Dreamstation 2 CPAP machines. Unfortunately, every CPAP provider is given only a small number of units every month which will extremely hamper our ability to distribute new units in a timely manner. Respironics has advised us that their goal is to have provided Pulse Air with enough CPAP machines to complete the recall in the next 12 months. We have a <u>dedicated CPAP recall team</u> who will reach out to you as the replacement units become available. We again apologize for the slow progress; however, this is a global recall, and all CPAP providers are experiencing the same restrictions.

Pulse Air considers our patients' health our top priority. Due to the high volume of calls, we request all inquiries be directed to our client support service department at: **clientsupport@pulseair.ca**.

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