PHILIPS

Medical Device Voluntary Recall Information

Philips Respironics Sleep and Respiratory Care devices

While we work to provide patients with a replacement device as quickly as possible, we want you to feel informed about each step of the remediation process and the tools and resources available to support your patients.

Learning more about the voluntary recall notification

In June 2021, after discovering a potential health risk related to a part in certain CPAP, BiPAP and Mechanical Ventilator devices, Philips Respironics issued a voluntary recall notification.

Please refer to the following resources to make sure you are up-to-date with the latest information:

Full list of affected devices

Read the FSN recall notification

We continue to work with independent partners to conduct extensive testing and analysis of results on affected devices, including biocompatibility evaluations. You can find the most up-to-date testing results here.

Our information hub is continuously updated with the latest resources and information:

- Information for customers
- Information for patients
- Information for clinicians

Communicating the recall to patients

Since we made the decision to recall affected CPAP, BiPAP and Mechanical Ventilator devices, we have developed several resources for patients.

As well as notifying patients directly ourselves through regular emails, website updates and social media content, we have also created the following resources for you to communicate the recall to your patients and guide them through the remediation process:

The following resources can be found on My Philips for Professionals:

- Phone calls and recorded voice messages
- Instructional videos
- Social media communications (LinkedIn, Twitter, Facebook and Instagram)
- Physical letter to physicians
- In-office materials for physicians
- Print and online communications

Additional helpful information can also be found on our information hub:

- A step-by-step remediation process guide
- A guide of who's who in the remediation process
- Information on the safety of replacement devices

Driving patient registration

If you or one of your patients have not yet registered an affected device, this should be done as soon as possible to begin the remediation process.

Registering an affected device is the first step in the remediation process.

Patients and customers can use the link below to register affected devices.

Register an affected device

Need support on how to register a device?

Watch our video guide

Once you have successfully registered a patient's device, we recommend that you share the following communication:

> *We have partnered with Philips Respironics to get your replacement device with your prescribed settings to you as quickly as possible. Visit the Patient Portal with your confirmation number, for the most up-to-date information on the status of your replacement device.*

Keeping your patients updated

We understand that waiting for a replacement device may be frustrating for patients, which is why we are working to become clearer. For Philips managed patients, you may instruct them to go to the Philips Respironics Portal where they can find estimated shipment dates.

To help ensure your patient receives their device as quickly as possible, please make sure that:

- Your patients have responded to the patient prioritization questions in the Patient Portal. This will be reflected on your weekly auto-report from Philips Respironics.
- For Philips managed patients, all prescribed patient settings are up-to-date in Care Orchestrator.
  - Please note that if the data in Care Orchestrator is not correct, the patient will be marked as inactive and their prescription will not be up-to-date.
  - In cases where we have not received the relevant information from the DME, we will reach out to the patient to get their therapy settings and manage them directly. This is essential to ensure that patients with affected devices receive them as soon as possible.

We also regularly share updates through the following:

- Monthly emails to registered patients with relevant updates
- Monthly emails to customers with patient and business updates
- Monthly clinical communications
- FAQs on our website
- Research and testing results on our website

Supporting replacement devices

Sleep devices

Once your patient has received their replacement device for sleep apnea therapy, please direct them to the resources we have created to help them become familiar with their new device.

If your patient has received a new DreamStation 2 device, our e-learning course includes helpful materials, for DMEs to familiarize themselves with this solution.

Patients can also find information on returning their affected device here.

Resources for your sleep patients are available here.

Resources for your patients:

- Product details
- Proper cleaning and maintenance
- Information on new foam
- Setup and return instructions

Ventilation devices

We are advising our customers to send devices back to Philips Respironics for remediation, then replace affected devices for patients. Once you have received the new devices, please set up the new device for your patients directly with their prescribed settings.

If your patient is in need of a loaner device during this transition please contact your Philips Respironics Account Manager.

Need further assistance?

Please contact the Philips Customer service team at 877-907-7508 or use recall.support@philips.com for dedicated DME support.

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