PHILIPS

Medical Device Field Safety Notice 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 field safety notice

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 field safety notice.

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 clinicians
- Information for patients

Communicating the field safety notice 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 regular website updates, we have created the following resources for you to communicate the field safety notice and guide your patients through the remediation process:

- Instructional videos available on My Philips for Professionals (My P4P)
- Step-by-step remediation process guide
- Video from Jan Kimpen, Chief Medical Officer, Royal Philips
- Study and test results summaries for patients
- Safety of the replacement device guide

Driving device registration

If your patients have not yet been registered, 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.

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

Keeping your patients updated

We understand that waiting for a replacement device may be frustrating for patients, which is why we are committed to enabling you to support your patients and prescribers throughout the process.

To deliver safe and effective therapy devices as quickly as possible, please consider the below key principles when delivering on the remediation plan:

1. Patient needs should be considered when prioritizing order delivery.
2. The patient/physician relationship is critical to managing therapy according to the patient's unique health needs.
3. The patient/durable medical equipment provider relationship is critical in managing continuity of care.

We also regularly share updates through the following:

- Emails to customers with patient and business updates
- 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, you can direct them to the resources we have created to help them become familiar with their new device.

If your patient has received a new DreamStation2 device, our e-learning course includes helpful materials for customers to familiarize themselves with this solution.

Sleep patients can find the following resources here

Resources for your patients include:

- Product details
- Proper cleaning and maintenance
- Information on new foam

Ventilation devices

We advise our customers to follow the latest updated guidance regarding remediation of ventilation devices.

Once you have received the replacement device, please set it up for your patient with their prescribed settings.

Need further assistance?

Please contact the Philips Respironics Customer Service team directly at 877-907-7508.

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