

# Clinical Bulletin #12

This month, you'll notice that along with news and updates on the Philips Respironics PE-PUR foam voluntary recall/field safety notice (FSN), we will also explore topics related to ventilation devices and masks with magnets. Please find recent updates below.

## PE-PUR Foam voluntary recall/FSN News and Updates

### 1. Connectivity issues with a limited number of remediated DreamStation units

Philips Respironics has identified and traced a limited number (~1,000 worldwide) of remediated DreamStation units that may experience connectivity issues when syncing to Care Orchestrator. This is due to an incorrect serial number being issued in Care Orchestrator during the remediation process. This may affect the ability to download prescription settings to the device or the device may have incorrect prescription settings for the patient. **This does not present a safety concern for your patients.**

**No action is required from the clinician.** We will be providing DMEs who remediate patients directly with details of the affected serial numbers and, where relevant, asking them to notify their patients. Patients who are managed by Philips Respironics will be contacted directly to inform them of the issue and to set up replacement and return of affected devices.

### 2. Useful information for your patients

In January 2023, Philips Respironics introduced an Auto-adjusting CPAP remediation program dedicated to a set of exception patients for whom we had not been able to obtain prescription information and thus could not send a replacement device until now.

As of February 27, 2023, approximately **113,000** patients provided consent\* to receive a replacement device with Auto-adjusting CPAP settings with approximately **55,000** orders.

Additional information on the Auto-adjusting CPAP program can be found [here](#).

*\*Patients have been advised to contact their physician to discuss whether the Auto-adjusting CPAP mode is appropriate for their therapy needs.*

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### 3. Patient Portal

Given the progress we have made to date in the remediation, if your Philips Respironics-managed patients are still awaiting their DreamStation or SystemOne replacement device or financial payment, it may be because Philips Respironics is waiting for them to make an important selection or provide us with further information\*. Without this information or consent, we cannot ship their replacement device. Please encourage your Philips Respironics-managed patients to log into the Patient Portal using their confirmation code or the serial number of their affected device to see if there is a request for additional options to be selected, or information to be completed.

Your patients can find the portal [here](#).

*\*Registered DreamStation Go patients will receive communication as they become available. No action needed at this time.*

### 4. Patient Contact and Support Page

Patients may still have questions about the remediation process, their status, or may need additional support once they have received their replacement device. We have recently updated our [Contact and Support](#) page to help patients quickly and easily find the support they need.

## Ventilation news and updates

### 1. Field Safety Notice

In February 2023, Philips Respironics released an FSN to communicate a corrective action for the Trilogy Evo platform of ventilators identifying an issue that could impact patient safety if not mitigated. The Trilogy Evo O2, Trilogy Evo Universal and Trilogy EV300 devices that are used in the hospital environment are affected by this FSN.

Philips Respironics has discovered, through internal testing, that accuracy of delivered oxygen may deviate below the required tolerance of 5% from setpoint when providing high concentration oxygen therapy. Additionally, if equipped, the internal FiO2 sensor may indicate a value higher than the device is actually delivering. This may vary based on the patient's lung capacity, lung resistance, use of a particulate filter, or circuit configuration. In the worst case, this may lead to under delivery of oxygen.

Additional information on the Trilogy Evo Platform of Ventilators Field Safety Notice can be found [here](#).

## Masks with Magnets news and updates

Following our communications in September announcing updated instructions and labeling of specific sleep therapy masks that contain magnetic headgear clips, a study on masks with magnets has been released in the Journal of Clinical Sleep Medicine and can be found on the JCSM website [here](#).

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## Useful Links

### **PE-PUR Foam voluntary recall/FSN News and Updates for Clinicians**

Be sure to visit [our clinicians information page](#) regularly for the most current information for you and your patients

### **Masks and Magnets Updates**

Have additional questions about Philips Respironics masks and magnets? Learn more, [here](#).

### **Ventilation Updates**

For the latest ventilation news and updates, please visit [this page](#).



For more information, visit [Philips.com/src-update](https://philips.com/src-update)

