

## Sleep and Respiratory Care Bulletin #9

April 2023

Field Safety Notice: 2021-05-A & 2021-06-A.

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

### 1. PE-PUR foam voluntary FSN news and updates

#### Dr. Jan Kimpen, Senior Medical Advisor, answers key questions from patients

As we continue to make progress on shipping replacement devices, we have caught up with Dr. Jan Kimpen, to explore some of the most common questions we're hearing from your patients, from device safety to the latest testing and research results.

Questions and answers can be found [here](#).

### 2. 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](#).

Be informed that, as of the beginning of 2023, we have made significant progress in updating the existing contraindications and warnings of each affected masks and can confirm that the **Amara View Full Face mask**, **DreamWear Full Face mask** and **DreamWisp Nasal mask** have now been re-released for sale. Our Wisp Nasal Mask, and Wisp Youth Nasal Mask remain impacted by our biocompatibility evaluation requirement (ISO18562).

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### 3. Useful Links

#### PE-PUR foam voluntary field safety notice News and Updates for clinicians

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

Patients may still have questions about their replacement device: the page [Learn more about your replacement device](#) can help them to quickly and easily find the support they need.

#### Masks and magnets updates

You 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](#).

*Note: the data and information in this document are valid as of the date indicated on the document. If you read this document at a later date, the details and information may no longer be up-to-date due to new developments.*



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