Clinical Bulletin #19

We are committed to supporting clinicians through the complete remediation process and will provide a range of resources to help you better inform, instruct, and support your patients. The clinical bulletin will continue to offer news and updates on the PE-PUR foam voluntary recall/Field Safety Notice and will also be expanded to help address common topics and concerns on additional topics.

Please find below some recent information that we wanted to bring to your attention.

Sleep Updates

1. First-generation DreamStation CPAP devices

Philips Respironics has become aware of a potential issue with a limited number of first-generation DreamStation devices. A limited number of devices exhibited a device testing error prior to shipping. This issue may affect device settings and functionality. This issue is not anticipated to result in a patient safety concern.

No direct 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.

DMEs with affected devices currently in use, will be asked to review the settings and compare to the patient's prescribed settings and report any discrepancies.

Ventilation Updates

1. Trilogy Evo Instructions for Use

During an internal review of the Trilogy Evo and Trilogy Evo O2 Ventilators Instructions for Use (IFUs) manuals, Philips Respironics determined that the Contraindications Statement was incomplete.

The following contraindications apply to the Trilogy Evo and Trilogy Evo O2 Ventilators:

Instructions for Use Contraindications:
If the patient has any of the following conditions, consult the patient's health care professional before using noninvasive ventilation:

- An inability to maintain a patent airway or adequately clear secretions
- At risk to aspirate gastric contents
- Acute sinusitis or otitis media
- Epistaxis, causing pulmonary aspiration of blood
- Hypotension

The AVAPS-AE therapy mode is contraindicated for invasive use and patients less than 10 kg.
The AVAPS feature is contraindicated for patients less than 10 kg.

The contraindications listed above in bold, are either omitted or listed in other locations within the Instructions for Use and Clinical Manual.

(continued on next page)

Useful Links

PE-PUR Foam voluntary recall/Field Safety Notice - Information for Clinicians

Be sure to visit our clinicians information page regularly for the most current information for you and your patients

Masks and Magnets

Have additional questions about Philips Respironics masks and magnets? Learn more here.

Ventilation

For the latest ventilation news and updates, please visit this page.

For more information, visit Philips.com/src-update