PHILIPS

Sleep and Respiratory Care Clinical Bulletin #17–19

We are committed to supporting clinicians through the correction* process and will provide resources to help you better inform, instruct, and support your patients. This bulletin was created to help address common questions and concerns as well as provide a status update on correction efforts as they become available. Please find updates below.

Sleep Updates

1. First-generation DreamStation Device Testing Error

You may have read about an issue where a limited number of first-generation DreamStation devices exhibited a device testing error prior to shipping. This issue does not affect DreamStation devices in Australia or New Zealand and no action is required here.

Ventilation Updates

1. Trilogy Evo Instructions for Use

During an internal review of the Trilogy Evo and Trilogy Evo O2 Ventilators Instructions for Use (IFU) 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 IFU manuals.

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*Urgent Product Defect Correction in Australia and Recall for Product Correction in New Zealand.

The updated Contraindications in the Clinical and Caregiver Manual Addendum are as follows:

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.

Note: *The AVAPS-AE therapy mode and the AVAPS feature are not available for Trilogy Evo Universal devices.*

The Clinical and Caregiver Manual Addendum (Ref. 1147302) will be sent to customers to provide to all current users. All new devices will be supplied with the Instructions for Use (Ref. 1146290 & Ref. 1146291) and the Clinical and Caregiver Manual Addendum (Ref. 1147302).

Useful Links

PE-PUR Foam Product Correction* News and Updates for Clinicians

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

Patients may still have questions about the correction process or may need additional support once they have received their replacement device. We have recently created our Contact and Support page to help patients quickly and easily find the support they need.

Masks and Magnets Updates

Do 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.

For more information, visit philips.com/SRC-update.

*Urgent Product Defect Correction in Australia and Recall for Product Correction in New Zealand.