

Philips Respironics Masks with Magnets Correction Mask Replacement and Patient Notification Compensation Programs

February 14, 2023

Dear Customer,

On Sept 6, 2022, Philips Respironics announced a worldwide voluntary notification to users of specific CPAP or Bi-Level PAP therapy masks containing magnets. We refer you to the Urgent Medical Device Correction letter you should have received for additional information on the voluntary action being taken by Philips Respironics.

There is a subset of the patient population who currently uses masks with magnets that can no longer use the masks because the masks do not comply with the new contraindication / enhanced warning. With that in mind, Philips Respironics will be offering non-magnetic mask and mask components to customers to help effectuate the replacement of masks and mask components for patients who are impacted by this labeling update. In addition, Philips Respironics is offering one-time compensation, via a credit to your account, for the time and resources needed to contact patients with affected masks about the urgent Medical Device Correction and mask replacement program for impacted patients.

The Mask Replacement Program (MRP) will be as follows:

For mask purchasers, non-magnetic clips and alternative non-magnetic masks will be offered to those purchasers, free of charge at a rate of up to 5% of their unit orders for the Products based on unit sales from Jan 1, 2021, through Sept 6, 2022. Order forms will be provided to each customer along with their total allowable mask and component units equaling the first order 5% allotment.

Impacted Mask or Component to be replaced	Replacement Mask or Component
Amara View mask with magnetic headgear clips	Amara View non-magnetic talon clips RP
Wisp/Wisp Youth mask w/ magnetic headgear clips	Wisp/Wisp Youth non-magnetic headgear clips RP
DreamWear Full Face Mask	Amara View mask with magnetic headgear clips AND Amara View non-magnetic talon Clips RP
DreamWisp	DreamWear nasal mask, Wisp, or Pico
Therapy Mask 3100 NC	DreamWear nasal mask
Therapy Mask 3100 SP	DreamWear silicone pillows mask

Philips Respironics will provide an additional supply of non-magnetic masks and/or components in defined increments where an additional supply beyond the 5% allotment is demonstrated to be needed to satisfy patient needs related to this device labeling correction.

Customers will be able to place orders for alternative masks and mask components once they complete the Mask Replacement and Patient Notification Compensation Agreement (Agreement). Please also note, that inventory return requests of unopened and undamaged recall masks will have the 10% restocking fee waived and Philips will pay the transportation costs.

The Patient Notification Compensation Program is as follows:

Customers will be offered reimbursement for the necessary expenses and associated costs at \$2.50 per patient. To receive compensation, customers must agree to:

- Complete the Agreement and then sign and return the Patient Notification Attestation (Attestation) regarding their patient outreach efforts. Required information includes number of patients contacted, type of communication, dates communication was made/completed.
- 2. Maintain an internal record of patient notifications.



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Prior to receiving masks or mask components as part of the Replacement Program or reimbursement as part of the Compensation Program, the Agreement and Attestation must be completed and returned. Importantly, Products should NOT be returned but should be disposed of by patients according to their local regulations.

Your Action: Email mask.support@philips.com for a copy of the agreement. The agreement will only be available upon request. When you email mask.support@philips.com for the agreement, please include your sold-to information and address.

Once the Agreement is implemented, the order form and Attestation form will be emailed to you. You will then submit the completed order form and/or Attestation to mask.support@philips.com

Sincerely, Philips Respironics