PHILIPS

December 4, 2023

To our valued customers:

On November 28, the U.S. Food and Drug Administration (FDA) released a safety communication regarding possible thermal issues with the DreamStation 2 sleep therapy device while in use.

There was not a sharp increase of reportable complaints. As part of our ongoing commitment to patient safety and quality, we conducted a retrospective review of possible DreamStation 2 thermal complaints initiated over the course of an almost three-year period since its launch in 2021. We filed approximately 270 reports with the FDA over the last three months as part of this post market surveillance. These reports were submitted in batches starting in August 2023, which we believe may have been interpreted incorrectly as a sharp increase in customer complaints.

DreamStation 2 can continue to be used. As with any medical device, the instructions for use should be followed.

Our number one priority continues to be patient safety and quality and we treat all feedback from our patients and our regulators with the highest levels of urgency. It is important to note:

- Outside of continued adherence to the instructions for use, no additional action is needed by patients or DME/homecare providers as a result of the FDA's publication.
- There is no product recall at this time.

If you have any questions on this matter, please reach out to your Philips Respironics Account Manager.

Thank you for your continued trust.

Sincerely,

Sam Talya

Business Category Leader
Sleep & Respiratory Care
Philips Respironics