PHILIPS

16 February 2023

Dear valued customers,

With this letter, we would like to take the opportunity to share updates on different on-going topics:

1. Update on the completed testing for first-generation DreamStation devices
2. Patient Interface Field Safety Notice2
3. Update on the biocompatibility evaluation requirement (ISO 18562)

1. Update on the completed testing for first-generation DreamStation devices

Based on the comprehensive testing and analysis that we have done over the past 18 months – working with five independent certified laboratories, as well as third party experts and physicians- we now have a complete set of results for the first-generation DreamStation devices (approximately 68% of the registered devices globally). We had already communicated earlier that our visual inspection results to date indicate that the prevalence of visible foam degradation is low, and that test results for volatile organic compound and particulate emissions for both new and used first-generation DreamStation devices are below the safety limits of the applicable standards. This latest third-party chemical evaluation and toxicological risk assessment of degraded foam concluded that for the first-generation DreamStation devices, exposure to foam particulates is unlikely to result in an appreciable harm to health in patients.

- **Philips Respironics has provided the data and analyses to the FDA and other competent authorities. The FDA is still considering the data and analyses that Philips Respironics has provided and may reach different conclusions.**
- **Healthcare providers, patients, and other stakeholders should use the complete update, including information on the limitations of the testing, for any informed decision making and should not solely rely on the overview presented here.**
- **Philips Respironics' guidance for healthcare providers and patients remains unchanged.**
- **Philips Respironics will continue with the remediation program.**

Please visit patient information page to find more information and resources for use with your patients, including the complete update on the PE-PUR testing results and conclusions available to date, a video message from Jan Kimpen, our Chief Medical Officer and from Jan Bennik, Head of Test and Research Program, with additional details on the result.

Be sure to visit our dedicated customer information page regularly for the most current information relative to the Field Safety Notice[1], including Remediation progress Updates and Ventilation updates.

[1] FSN 2021-05-A e FSN 2021-06-A
[2] FSN 2022-CC-SRC-001

PHILIPS

2. Patient Interface Field Safety Notice

In September 2022, Philips Respironics released a Field Safety Notice[2] alerting customers worldwide about the updated instructions and labeling for specific sleep therapy masks containing magnetic clips. The already present warnings in the user guide have been strengthened, and contraindications have been added.

Further information regarding the Voluntary Notification for Labelling Changes for Masks with Magnets can be found on our dedicated website which includes full details of the new contraindications and warnings as well as details of the impacted masks and FAQ's for support.

As of the beginning of 2023 we are pleased to inform you that 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, DreamWisp Nasal Mask and Therapy Mask 3100 NC/SP have now been re-released for sale. Our Wisp Nasal Mask, and Wisp Youth Nasal Mask remain impacted by our biocompatibility evaluation requirement (ISO18562)

Your sales representative will be able to provide with more detail on the above and support with questions around availability of our sleep therapy mask portfolio.

3. Update on the biocompatibility evaluation requirement (ISO 18562)

As of December 2022, ISO 18562 validation of approximately 66% of the relevant product SKUs has been completed. And the pace of progress continues to accelerate beyond this point.

While we have been able to complete validations and restart shipment on some critical products, such as the AF541 mask, our most critical hospital mask, others remain delayed. Evaluations resulting from the Philip Respironics field safety notification (14 June 2021) continue to place a substantial demand on our laboratory evaluation capacity.

We still have significant stock of a number of impacted SKUs that have been stored within the European Union, for which we are able to continue taking orders and executing shipments.

We are not able to produce new inventory of any impacted product until ISO validation/certification for that product is completed. Since the duration of some evaluations can take up to 30 weeks, we may not have sufficient inventory already within the European Union to cover the entire evaluation period. Once the inventory currently in the European Union is depleted, we will not be able to accept any more orders.

At this time, we remain unable to give a firm date as to when order intake and shipment will resume for depleted SKUs. We anticipate that the majority of evaluations will be completed by the end of Q1 2023. We will also continue to release SKUs as they are validated, which will allow some products to become available earlier.

Your sales representative will continue to keep you informed about the progress we are making and notify you about SKUs that have received ISO certification and are released for sale.

[1] FSN 2021-05-A e FSN 2021-06-A
[2] FSN 2022-CC-SRC-001