PHILIPS

Sleep and Respiratory Care Bulletin #6

July 2022

Field Safety Notice: 2021-05-A & 2021-06-A.

We know how important it is for you and your patients to be informed on all aspects of their sleep therapy and treatment. This bulletin was created to help address common questions and concerns as well as provide a status update on remediation efforts as they become available. Please find below some recent information that we wanted to bring to your attention. We invite you to consult our website regularly to keep informed of updates and for additional information on this field safety notice: Visit our clinician information page.

1. Summary of Philips Respironics Testing Results available to date

We are committed to providing additional data as it becomes available from the on-going third-party testing such that healthcare providers have updated information to make informed decisions regarding the risk of continued use of affected products. An updated summary can be viewed/downloaded at Testing Results. The overall guidance for healthcare providers and patients in the most recent version of the Field Safety Notice remains unchanged at this time.

2. Device remediation update

To date, Philips Respironics has produced 535,000 new devices and repair kits for Western Europe out of which around 69% replacement devices have already reached our customers in the region[1]. We expect to complete over 90% of the production and shipments to customers in 2022. To help facilitate this, we encourage customers and their patients to finalise registrations as quickly as possible. You can find the latest information on our progress here.

3. Our approach to remediation

When we issued the field safety notice, we immediately focused our efforts to respond to this issue as quickly as possible. We expanded our production shifts, service and rework capacity in applicable manufacturing sites and intend to maintain this expansion until the remediation program is completed. We are not currently selling these products and all remediated devices should be allocated to patients affected by the field safety notice.

1. Based on data available as of 23/06/2022

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

4. Useful information for your patients

We continue to provide regular updates for patients. This month, along with an update on our progress to-date, we are reiterating our commitment to patient safety and providing them with further clarification on the steps involved in the remediation process and further patient-facing content on test results.

5. DME and clinician replacement device training is now available

Some of your patients have received new DreamStation 2 CPAP devices as part of the remediation process. To help support, we have created product trainings within the Philips Learning Connection designed to assist with the setup and use of replacement devices. The trainings can be found at the **Learning Connection**.

We thank you for your continued patience and trust and will continue to provide regular updates to you through this process.

Note: the data and information in this document are valid as of the date indicated on the document. If you read this document at a later date, the details and information may no longer be up-to-date due to new developments.

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