PHILIPS

Sleep and Respiratory Care Bulletin #8-9

We are committed to supporting clinicians through the complete 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. Be sure to visit our Australian clinician's information page regularly for the most current information for you and your patients.

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

Information from Philips Respironics

Philips Electronics Australia notes that the device manufacturer, Philips RS North America LLC (**Philips Respironics**), has periodically released on its US website communications (**Clinical Bulletins**) for physicians on recent developments as well as provide a status update on remediation efforts. The full set of Clinical Bulletins is available on the Philips RS North America Website here.

The information below in relation to device testing has been adapted from Clinical Bulletins #8 and #9 released by Philips RS North America (available in full at the website above). This information has not been separately verified by Philips Electronics Australia.

1. Mask Notification

We know that you and your patients may have questions regarding the global voluntary notification regarding certain sleep apnoea masks. This mask correction notice is unrelated to the PE-PUR foam correction and is to alert users of strengthened warnings and added contraindications in updated instructions and labeling of specific sleep apnoea masks that contain magnetic headgear clips. If the magnets come too close to certain implanted devices, the magnetic field may cause active implantable devices to malfunction or result in movement of other implantable devices.

Therefore, use of a mask with magnetic clips is contraindicated for patients where they, their household members, caregivers or bed partners that may be in close vicinity have implanted metallic medical devices/metallic objects that may be affected by magnets. For the affected patient group, Philips will be remediating with clips to replace the magnets or a replacement mask.

These masks may continue to be used according to the updated instructions and labeling if patients, or people in close proximity to them, **do not** have implanted metallic medical devices or metallic objects in the body. You can learn more here.

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

A copy of the notice published on the Australian Therapeutic Goods Administration's website on 7 November 2022 in relation to this issue and is accessible here.

2. New leadership focused on improving remediation execution

On October 15th, Roy Jakobs was appointed the President and CEO of Royal Philips. His priority is to improve execution to ensure we're doing all we can to help our patients. Delivering on this requires us to urgently improve things where it has not met your expectations. This includes further strengthening our patient safety and quality initiatives, to ensure we're doing all we can to help you.

3. Obtaining therapy settings from patients

It is critical for Philips to make every effort to correct all registered devices. To assist in progressing the correction, we appreciate your support with the below when communicating with your patients.

Patients who are not registered

Please encourage your patients to check if their device has been registered via the Philips portal. The portal can be found on www.philips.com/src-update. Registration is the initial important step to enable us to provide a corrected device to your patient. If patients require assistance with the Philips portal, please encourage them to contact Philips on 1800 009 579 in Australia (toll-free) or 0800 578 297 in New Zealand (toll-free).

Patients who have registered their CPAP or BiPAP device and are waiting for a correction

In Australia, if your patient's device has been registered and your patient has provided their correct mobile number, they will receive a text message from Philips. The text message will contain a link which will enable them to click through to confirm their details and provide their current device settings. If the device settings are provided to Philips, they will be inputted into the patient's replacement device before it is shipped to the patient.

There are different ways patients can provide their device settings to Philips:

1. Send their Secure Digital (SD) card located in their device to Philips: Philips will use the patient's current SD card to set their replacement device with the same settings. A reply-paid envelope with instructions will be sent to support the patient in sending Philips their SD card; or
2. Provide a Data Download: Patients can reach out to their independent pharmacy or reseller (where they purchased their device) or, contact their prescriber (where they received the prescription of their device) to obtain a full data download (this will be in the form of a PDF or a printed document). Patients will need to take their device or SD card with them, so their provider/prescriber can perform a full data download.

If your patient's device has been registered but your patient has not received a text message or email, please ask them to contact Philips on 1800 009 579 in Australia (toll-free) where they can request a link to be sent.

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What can you do to assist in progressing the correction?

1. Ask your patient to check if their device has been registered for the correction. This is via the link on www.philips.com/src-update. If their device is not registered, request them to do so.
2. Encourage your patients to provide device settings promptly in response to Philips' request for this information. It is very helpful if patients can respond via the link in the text message.
3. We recommend that you check in with your patient after they receive their replacement device. Upon using their device, if patients feel the settings are different, we recommend they reach out to their prescriber for support or contact Philips on the number 1800 830 517 in Australia (toll-free) or +61 2 9151 0289 in New Zealand.

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