PHILIPS

Sleep and Respiratory Care update

Clinical information for physicians

- On April 26, 2021, Philips provided an important update regarding proactive efforts to address identified issues in a number of Sleep and Respiratory Care products, due to possible risks related to a sound abatement foam component.
- At that time, out of an abundance of caution and based on available information, Philips advised of potential health risks related to sound abatement foam used in specific Philips Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) devices, and Mechanical Ventilators. Philips has utilized polyester-based polyurethane (PE-PUR) sound abatement foam, to dampen device vibration and sound during routine operation.
- The company also indicated that analysis of potential health risks was ongoing, and that further information would be provided when available. As a result of extensive ongoing review following this announcement, on June 14, 2021, the company issued a recall notification (U.S. only) / field safety notice (Outside of U.S.) for specific affected devices.
- Philips is taking this opportunity to provide clinicians and patients with information on potential risks related to affected units. Examples of potential risks include exposure to degraded sound abatement foam particles or exposure to chemical emissions from the sound abatement foam material. One reason for the degradation may be the use of unapproved cleaning methods such as ozone, or in some regions, high environmental heat and humidity factors (not from device use).
- Philips' quality management system processes and analysis of user reports have indicated that this material may lead to patient harm and impact clinical care.
- While there have been limited reports of headache, upper airway irritation, cough, chest

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pressure and sinus infection that may have been associated with the foam, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.

- To date, Philips has not received reports of life-threatening injury or death due to this issue.
- By means of the recall notification (U.S. only) / field safety notice (Outside of U.S.), Philips is informing customers and users of potential impacts on patient health and clinical use related to this issue, as well as instructions on actions to be taken.
- Philips is also notifying customers and users of affected devices that the company will replace the current sound abatement foam with a new material that is not affected by this issue.

The recall notification (U.S. only) / field safety notice (Outside of U.S.) also advises patients and users to:

- FOR BILEVEL PAP AND CPAP DEVICES: Discontinue use of affected BiLevel PAP and CPAP devices, and consult with physicians to determine the most appropriate options for continued treatment, based on the benefits of continuing therapy and potential identified risks.
- FOR LIFE-SUSTAINING VENTILATOR DEVICES: Do not stop or alter prescribed therapy on affected life-sustaining mechanical ventilator devices, without consulting with physicians.
    - Philips recognizes that in certain care settings, alternate options for therapy may not exist or may be severely limited for patients who require the Trilogy 100 and 200 for emergency, life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of the Trilogy 100 and 200 may outweigh the risks.

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    - If physicians determine that a patient must continue using this device, use of an inline bacterial filter is recommended per Instructions for Use; it may reduce exposure to degraded sound abatement foam particles, though bacterial filters will not reduce exposure to potential Volatile Organic Compounds (VOCs). Consult your Instructions for Use for guidance on installation.

  - FOR ALL DEVICES:

    - Register affected devices on the recall website, philips.com/src-update.

      1. The website provides current information on the status of the recall notification (U.S. only) / field safety notice (Outside of U.S.) and how to receive permanent corrective action to address the two issues.

      2. The website also provides instructions on how to locate an affected device Serial Number and will guide users through the registration process.

- Philips is recommending that customers and patients do not use ozone-related cleaning products.

- Additionally, Philips is reminding customers and patients to review the age of their BiLevel PAP and CPAP devices, as they are recommended to be replaced after five years of use.

The two potential hazards outlined in the safety notification for affected devices are described below:

Foam Degradation Exposure

- **Potential Hazard:** Philips has determined from user reports and lab testing that under certain circumstances the foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user of its Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) and Mechanical Ventilator devices. The foam degradation may be exacerbated by environmental conditions of higher temperatures and humidity in certain regions. Unauthorized cleaning methods such as ozone may accelerate potential degradation.

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- The absence of visible particles does not mean that foam breakdown has not already begun. Lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:
  - Toluene Diamine
  - Toluene Diisocyanate
  - Diethylene glycol

- **Potential Harm:** A patient may be exposed to foam particles by inhalation or ingestion that could result in harm. There has been no patient death reported to date.
- With limited reports, the following risks are considered:
  - Foam particles may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve.
  - The potential risks of degraded foam exposure include: Irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic effects.
  - To date, Philips Respironics has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). Philips also has received reports of headache, upper airway irritation, cough, chest pressure and sinus infection.

Volatile Organic Compounds (VOCs) - e.g. Chemical Emissions from Foam

- **Potential Hazard:** Lab testing performed for and by Philips has also identified the presence of VOCs which may be emitted from the sound abatement foam component of affected device(s). VOCs are emitted as gases from the foam included in the CPAP, BiLevel PAP and MV devices and may have short- and long-term adverse health effects.

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Standard testing identified two compounds of concern (COC) may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:

- Dimethyl Diazine
- Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)-

- **Potential Harm:** During initial or subsequent operation of the device, a patient may be exposed to VOCs. To date, Philips has received no reports of these types of safety issues alleged to be related to chemical emissions, but toxicological risk assessment indicates that VOCs levels exceed a safe exposure threshold. We have considered the following risks:
  - VOCs may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve.
  - The potential risks of chemical exposure due to off-gassing include: headache/ dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/ vomiting, toxic and carcinogenic effects. There have been no reports of death as a result of this type of exposure.
  - **To date, Philips has received no reports of patient harm resulting from these types of safety issues alleged to be related to chemical emissions.**

If I am a physician or a care provider, what steps can I take:

- We understand that every patient's care is unique and requires individual consideration. Therefore, we respect the alignment that needs to happen between patient and physician for a personalized recommendation on the best course of action. We are committed to providing clinical information on the recall notification (U.S. only) / field safety notice (Outside of U.S.) to support patient care. Please visit philips.com/src-clinician-update for up to date information and resources.

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- Please refer to the following resources as needed:
    a. Visit philips.com/src-update to view Philips responses to the situation, and instructions provided to patients and home care providers on replacing or repairing the devices.
    b. Description of the risks of using the impacted devices as outlined above.
- Explore alternative treatment options for your patients and their according timelines of availability.
- Regarding guidance for clinical use of affected devices:
    a. For patients on life-sustaining therapy (Trilogy 100 and 200), if alternate option for therapy does not exist, the benefit of continued usage of these devices may outweigh the risk.
        i. In this circumstance, providers are strongly urged to use an approved bacterial filter per Instructions for Use; it may reduce exposure to degraded sound abatement foam particles, though bacterial filters will not reduce exposure to potential VOCs.
        ii. Follow preventive maintenance (PM) schedules as specified in the device labeling.
    b. For patients on CPAP or BiLevel PAP devices, physicians should evaluate the benefits of treatment vs the risk of exposure, with the context of patient conditions, to determine the most appropriate care plan. If you make a clinical recommendation to continue device use, please instruct the patient to follow the cleaning procedure per the Instructions for Use. Note: while proper cleaning may help to identify presence of particles within the device, patients are still at risk of exposure to degraded sound abatement foam particles and VOCs.

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