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## Philips Respironics Recall of Positive Airway Pressure and Noninvasive Ventilation Devices

### A Brief Statement to Inform Response Efforts and Identify Key Steps Forward

On June 14, 2021, Philips Respironics issued a voluntary recall notification in the United States and a field safety notice internationally of the vast majority of models of continuous positive airway pressure (CPAP), bilevel PAP (BPAP), and mechanical ventilator devices produced over the last decade. The goal was to “ensure patient safety in consultation with regulatory agencies” (1) because of 1) risk of exposure to particulates released from polyester-based polyurethane sound abatement foam and 2) off-gassing of potentially toxic or carcinogenic concentrations of volatile organic compounds (VOCs). High environmental humidity and use of unauthorized ozone-based cleaning devices may accelerate degradation of foam. Potential symptoms listed by the manufacturer include rhinitis and sinusitis, upper airway irritation, cough, chest pressure, headache, or dizziness, which were reported by 11 (0.03%) patients in 2020 (2). The U.S. Food and Drug Administration (FDA) advised on July 22, 2021, that more than 1,200 complaints and 100 injuries were reported on this issue (3). The duration of exposure necessary to produce symptoms has not been reported or is unknown. For example, Philips has not clarified whether a one-time overnight exposure, such as a 2- to 8-hour period for a split-night or full-night titration sleep study, would impose unacceptably high risk. Exposure-related cancer and deaths have not been reported thus far.

The guidance from the manufacturer (current as of August 15, 2021) is that 1) patients using recalled life-sustaining mechanical ventilator devices should continue therapy as prescribed until discussion with the healthcare provider and 2) patients using recalled CPAP and BPAP devices should discontinue use and work with the healthcare or durable medical equipment provider to determine next steps. A timeline for replacement or repair by Philips remains unclear. Devices from other manufacturers are not reported to be affected by this recall.

### Logistical Impact of the Recall Is Vast and Unprecedented in Scope

The recall notice impacts 3–4 million devices worldwide, resulting in exceedingly high population attributable and public safety risk of untreated sleep-disordered breathing (SDB) and pulmonary disease if device usage is discontinued without replacement or alternative therapy (4). The majority have underlying SDB (i.e., obstructive sleep apnea, central sleep apnea, or hypoventilation disorders). Thus, the scale and logistical impact of this recall far exceed that of the field safety notice of adaptive servo-ventilators that followed the release of results from the SERVE-HF (Treatment of Sleep-disordered Breathing with Predominant Central Sleep Apnea by Adaptive Servo Ventilation in Patients with Heart Failure) trial with implications focused on central sleep apnea (5, 6). One challenge is that many PAP users may not be aware of the recall or whether their device is affected. In addition, ongoing supply chain shortages for replacement devices are posing a global threat to many patients in sleep, pulmonary, and critical care medicine. Even ongoing (e.g., ADVENT-HF [Effect of Adaptive Servo Ventilation on Survival and Hospital Admissions in Heart Failure] NCT01128816) and planned clinical trials have been affected. Finally, given the lack of guidance for sleep laboratories using these devices, patients who need but who are not yet using recalled devices are also affected by delays in care.

Three immediate conundrums emerged:

1. The need to qualify the recommendation by Philips Respironics to discontinue CPAP and BPAP therapy immediately;
2. The need to relay this voluntary recall notification in a timely manner to the millions of afflicted patients; and
3. The need to determine how sleep laboratories that use recalled equipment for titration studies should manage their clinical testing needs.

This editorial aims to summarize current knowledge and offer suggestions for clinical decision-making.

### Immediate Discontinuation of PAP Therapy May Harm Some Patients

For patients who use mechanical ventilators for immediate life-sustaining reasons, the decision to continue therapy is clear, as the

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benefit of avoiding imminent mortality outweighs longer-term risks. However, in non-life-sustaining situations, decision-making becomes less straightforward and calls for weighing the risks of continuing therapy against the risks of discontinuing the device for an unknown length of time. Although empiric data about risks are still limited, we believe PAP discontinuation to be unacceptably risky in certain groups.

## Patient-centered Shared Decision-Making Requires Consideration of Both Risks and Benefits of PAP Therapy

The American Thoracic Society partnered with sister societies to provide initial guidance that *patients with the following should not discontinue therapy until first discussing their needs with their clinician*:

1. Severe breathing difficulties;
2. Pulmonary, cardiovascular, or neurologic comorbidity; and
3. Safety-critical occupations or positions (e.g., professional drivers, pilots, and heavy equipment operators).

We expand the list of things that should prevent discontinuation of PAP until further discussed with their clinician:

1. Drowsy driving before using CPAP or BPAP;
2. Recurrent or recent admission for respiratory failure;
3. Severe SDB or sleep-related hypoxia; and
4. Other conditions that increase medical risk, such as pregnancy.

This guidance is similar to that from the FDA on June 30, 2021, and is consistent with the conclusion that continuing use of an affected CPAP or BPAP machine may be suitable if the clinician determines that the benefits outweigh the risks identified in the recall notification (7). Both differ from the Philips recommendation for immediate discontinuation.

Clinicians may reasonably have their patients with mild disease temporarily discontinue PAP therapy while awaiting repair or replacement of their device, with close follow-up for development of hypersomnia/drowsy driving. In the interim, alternative treatment approaches should be considered: behavioral strategies (e.g., weight loss, exercise, or limiting alcohol); positional therapy; oral appliances; and/or neurostimulation devices. Use of an older/alternate PAP device may be considered, and they must be checked carefully to ensure it is not subject to recall, that the pressure level is appropriate, and that the machine is still functioning effectively. These decisions should be individualized, carefully discussed, and documented. However, most of these alternate therapies are not effective immediately (e.g., weight loss) or available (e.g., nerve stimulation).

## What Patients Should Do

All patients using a recalled device should be advised to 1) access the Philips Respironics website to determine if their device has been recalled and enter the repair-or-replace queue at <https://www.philipssrcupdate.expertinquiry.com/> or by telephone (877-907-7508) and 2) stop use of ozone- or

ultraviolet light-based cleaners; the FDA issued a prior safety communication stating that such devices were not FDA approved, had never demonstrated effectiveness in reducing infections (their stated purpose), and may lead to airway irritation from potential inhalation of ozone (8).

Patients using a recalled mechanical ventilator device for life-sustaining reasons were advised initially by the manufacturer and others that an in-line bacterial filter should be used (2). Although these filters may reduce foam-related particulate exposure, they will not filter volatile gases and therefore not mitigate risk from VOCs. If filters are used with CPAP and BPAP, potential effects include 1) incompatibility of filters with heated tubing; 2) reduction in effective airway pressure; and 3) interference with autosensing algorithms. For these reasons, Philips no longer recommends the use of such filters (9).

## Clinicians and Societies Should Be Aware of Ethical Implications

This situation serves as a test of our core principles of medical ethics, which are as follows:

1. **Informed consent and autonomy:** The uncertainty of the risk due to foam degradation and VOC toxicity challenges informed consent, as decision-making about risks of continuing use first requires access to such information. Much remains unknown about the risk, and the role of modifying factors such as patterns of exposure, demographic characteristics, comorbidities, and local environmental factors (e.g., temperature and humidity);
2. **Harm reduction:** Similarly, uncertainty of risk and the variability in benefits of PAP/noninvasive ventilation therapy means that how best to minimize harm will also be uncertain for individuals. To minimize harm may compel some patients to continue using their device for immediate safety as suggested by experts from multiple medical societies, thereby placing their decision in conflict with the manufacturer's recommendations (10–12). The uncertainty surrounding availability of replacement devices, and thus the potential duration of time off therapy, also makes quantification of risk difficult; and
3. **Justice:** Engagement with vulnerable populations requires attention; these include older, underserved, low-income, or physically impaired individuals who may have difficulty accessing information regarding the recall and risk mitigation strategies, and pediatric patients who will require careful family-based discussions. If replacement devices are scarce, medical triaging of resources within the United States and internationally may be needed so that unaffected devices may be channeled to those with higher medical acuity. Monitoring of extremely young children who are ventilator dependent may be necessary, as few therapeutic options other than home ventilators are available, posing a serious issue in the face of likely impending supply shortages. Moreover, children may have greater long-term effects from both exposure to VOCs and/or withdrawal of treatment.

## Clinicians and Societies Should Respond Strategically

The device recall has imposed great burden on our patients, clinicians, and health systems because of its vast scale, limited availability of concrete data about risk and duration of risk, and in some cases, the lack of equally effective treatment alternatives. To address these challenges, healthcare practices must respond strategically by doing the following:

1. Consider creating dedicated response teams with trained members who will address the logistical challenge of disseminating accurate, timely, and clinically appropriate information to all appropriate stakeholders. This includes a wide range of members in the workforce, including specialties outside of pulmonary, critical care, and sleep medicine, to serve the needs of all patients, including the most vulnerable ones. Resources (e.g., telemedicine) and groups (e.g., communications teams, advanced practice provider teams, respiratory therapists) that were established during the coronavirus disease (COVID-19) pandemic may be integrated to enhance efficiency and provide potential solutions;
2. Clinical pathways to conduct assessment and testing for those with signs, symptoms, or health issues that may have resulted from device-related exposures also require development;
3. In the event of prolonged shortages, professional societies and other stakeholders will need to develop guidance to ensure equitable allocation of resources, particularly given high potential for these shortages to further exacerbate health inequities; and
4. Finally, cohort studies to quantify the device-attributable risk need to be conducted by comparing outcomes in patients using Philips devices against appropriately selected control groups.

## Corporate Responsibility to Device Consumers and Future Opportunities

Although Philips Respironics acknowledged potential financial risk on an April 26, 2021, quarterly report call, in hindsight, the company did not seize the opportunity to leverage key stakeholders who could have helped cushion the impact of the crisis. Foremost was the opportunity to partner with regulatory agencies, professional societies, other equipment manufacturers, or durable medical equipment companies in developing a coordinated plan to inform the public and remediate the situation. A well-assembled team is essential to disseminate communications to patients and physicians—not just to inform but to prepare, plan, and execute a mitigation strategy and to offer a suitable timeline for repair and replacement of devices (13).

Philips owns and controls a server with patient information; why the portal was not used to directly notify patients using affected devices remains unclear. Instead, the responsibility for notifying patients has fallen squarely on individual suppliers and practices, who continue to expend personnel and resources to address patients' questions, concerns, and complaints. Beyond gathering information on adherence or equipment performance, and beyond marketing, this database and communication portal has the capacity to serve an

important role in relaying patient safety information and remains an untapped resource.

To date, Philips has provided no information about repair and replacement costs or how those costs will be paid or when or how mitigation will occur; these questions continue to be posed by patients who are seeking answers from their healthcare providers, and some of whom are expending out-of-pocket costs to obtain alternate therapies. Moving forward, full partnership with industry and durable medical equipment providers can be helpful to identify which patients have or had affected devices, gather adherence and other data, and serve as a communication portal.

In summary, the current crisis underscores the need for partnership, timely communication, and transparency among industry, regulatory agencies, professional societies, and patients. In the months ahead, there is still time to create and build such partnerships, leveraging our skills and capacities to rise to this challenge with a common interest and purpose: optimally informed and equitable care of our patients. ■

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