CERTAIN PHILIPS RESPIRONICS CPAP MACHINES RECALLED

Almost 28% of commercial motor vehicle (CMV) drivers have mild to severe sleep apnea.[1] While Federal Motor Carrier Safety Administration (FMCSA) regulations do not specifically address sleep apnea, they do prescribe that a person with a medical history or clinical diagnosis of any condition likely to interfere with their ability to drive safely cannot be medically qualified to operate a CMV in interstate commerce. However, most cases of sleep apnea can be successfully treated.The most common treatment is the continuous positive airway pressure (CPAP) machine. But, what if drivers can't use their CPAP machine?

Recently, some medical examiners have run into issues where drivers are reporting that they have been unable to use their CPAP or BiPAP machines as these devices have been recalled. While the problem does not appear to be widespread, certain CPAPs and BiPaPs manufactured by Philips Respironics, a medical supply company that specializes in products that improve respiratory functions, have been recalled due to risk of exposure to debris and chemicals.[2]

In April 2021, Philips Respironics advised of potential health risks related to sound abatement foam used in specific Philips CPAP, bilevel positive airway pressure (BiLevel PAP) devices, and mechanical ventilators. On June 14, 2021, Philips issued a recall for those devices which were affected.[3,4] In the announcement, patients using CPAP or BiPAP devices were advised to discontinue use and work with their health care provider or durable medical equipment (DME) provider to "determine the most appropriate options for continued treatment."

The American Academy of Sleep Medicine held a panel discussion on the issue,[5] and offered a *Patient Assessment Tool* to guide advice to those patients using the impacted machines.[6] It was noted that patients should first be advised to register for repair or replacement on the Philips website and avoid using unapproved cleaning methods for their devices. Those with certain medical conditions or who meet any of the following criteria — Department of Transportation license requiring treatment of obstructive sleep apnea; occupation with operational safety requirements; extreme sleepiness or drowsy driving prior to using CPAP or BiPAP treatment; recent hospitalization for breathing problems; or discontinuation of PAP therapy would lead to substantial deterioration of functional status or quality of life — are to continue to use the device until it is replaced or repaired and/or to make an appointment to discuss treatment options.

In response to the recall announcement, the American College of Chest Physicians, American Academy of Sleep Medicine (AASM), American Academy of Neurology (AAN), American Thoracic Society (ATS), Alliance of Sleep Apnea Partners (ASAP), and American Sleep Apnea Association (ASAA), jointly submitted a request to the Centers for Medicare and Medicaid Services (CMS) and private insurance payers to temporarily suspend the 90-day adherence rule to allow patients to have existing equipment repaired or receive new equipment from DME suppliers.[7]

Editor's note – In response to this issue, I reached out to a few of my sleep medicine colleagues to see what they had been encountering and advising their patients whose use of CPAP or BiPAP devices is related to occupational safety. While some examiners only use a small number of Respironics devices in their practice, others have been significantly impacted by the recall. In general, they are pointing out that the risk/benefit ratio of the newer devices is low (Philips reported the risk of issues was 1 in 3,500 machine users in 2020), especially if not exposed to non-traditional cleaning methods such as ozone cleaners.

My sleep medicine colleagues are recommending that for those patients with older machines (or those which have used some non-traditional cleaning methods) to try to obtain a new machine, if possible, without waiting for the recall/replacement as some believe the backlog may be up to a year. Those in safety-sensitive positions are advised to continue treatment. In addition, the employer medical director/officers and other providers to whom I also spoke are continuing to require adequate use of the devices, especially for those patients with moderate to severe obstructive sleep apnea. Between the time this article was written and this newsletter published, the National Registry of Certified Medical Examiners (NRCME) sent the following email to medical examiners on August 10, 2021:

"The Federal Motor Carrier Safety Administration (FMCSA) has received several inquiries related to the Philips' voluntary recall notification for specific Philips Bi-Level Positive Airway Pressure (Bi-Level PAP), and Continuous Positive

Airway Pressure (CPAP), used for the treatment of obstructive sleep apnea (OSA). FMCSA encourages Medical Examiners to visit the Philips' website at https://www.usa.philips.com/healthcare/e/sleep/communications/src-update for additional information and instructions regarding appropriate actions concerning the recall."

Again, for update information, visit the Philips website, or the U.S. Food and Drug Administration (FDA) at: https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks#actions. The FDA site also includes recommendations for providers and patients.

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[1]Pack AI, Dinges DF, Maislin G. *A Study of Prevalence of Sleep Apnea among Commercial Truck Drivers* (Report No. DOT-RT-02-030). Washington, DC: U.S. Department of Transportation, FMCSA; 2002.
[2]US Food and Drug Administration. *Philips Respironics Recalls Certain Continuous and Non-Continuous Ventilators, including CPAP and BiPAP, Due to Risk of Exposure to Debris and Chemicals*. FDA; Medical Device Recalls. Available at: https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-continuous-and-non-continuous-ventilators-including-cpap-and.
[3]Philips Respironics. Medical Device recall notification (U.S. and Canada)/field safety notice (International Markets). Available at: https://www.philips.ca/healthcare/e/sleep/communications/src-update.
[4]Philips Respironics. *Letter to Device Users – URGENT: Medical Device Recall Philips Respironics Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent, BiPAP V30, and BiPAP A30/A40 Series Device Models, Sound Abatement Foam Susceptibility to Degradation and Volatile Organic Compound Emission.*
Available at: https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-letter-2021-05-a-2021-06-a.pdf.
[5]American Academy of Sleep Medicine. *Impact of the Philips PAP Recall on Patient Care and Sleep Center Operations*. AASM Live Panel Discussion June 18, 2021. Available at: https://aasm.org/event/philips-pap-recall/.
[6]American Academy of Sleep Medicine. *Philips PAP Recall: Sample Patient Assessment for Sleep Medicine Professionals* (Draft 6/23/2021). Available at: https://j2vjt3dnbra3ps7ll1clb4q2-wpengine.netdna-ssl.com/wp-content/uploads/2021/06/Philips-PAP-recall-SAMPLE-assessment.pdf.
[7]American College of Chest Physicians®. CHEST Issues Joint Statement in Response to Philips Device Recall. June 23, 2021. https://www.chestnet.org/newsroom/chest-news/2021/06/chest-issues-joint-statement-in-response-to-philips-device-recall.

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https://www.acoem.org/Publications/CDME-Review