Corporate Office
99 Seaview Blvd., Port Washington, NY 11050
Toll Free: 877.224.0946 • 516.998.4600
www.drivemedical.com

JUNE 29, 2021 STATEMENT ON DRIVE DEVILBISS HEALTHCARE'S RESPONSE TO PHILIPS CPAP RECALL

On June 14, 2021, Philips issued a formal recall notification and field safety notice for various models of its CPAP, BiLevel and Mechanical Ventilation devices, due to potential health risks related to sound abatement foam used in the products. Philips reported that the polyester/polyurethane foam used in its devices may degrade into particles that may enter the device's air pathway and be ingested or inhaled by the user, and that the degradation of the foam may cause an off-gassing of certain chemicals. Philips also reported that the foam degradation and potential off-gassing may be caused or exacerbated by the use of unapproved cleaning methods, such as ozone devices, and from prolonged use in high heat and humidity environments.

Drive DeVilbiss Healthcare has not identified any issues similar to the ones identified by Philips. Our DV6 series CPAP devices use a silicone foam for sound abatement. This foam is not related in material or design to polyester/polyurethane foams. In addition, although our DV5 series CPAP devices do use a polyester/polyurethane foam for sound abatement, there is a wide variance in the mechanical and chemical properties of these foams based on their specific formulations, the processes used to manufacture them, and the unique design and performance characteristics of the devices in which they are used. Drive DeVilbiss performs constant, continuous post-market surveillance and analysis of sales, service and repair data, which has not detected any problems similar to the ones identified by Philips since the DV5 series was introduced in 2007.

Drive DeVilbiss Healthcare notes that ozone cleaning devices are not approved or regulated by the FDA (see the below links to FDA statements on these devices). We have not performed any clinical, safety or validation testing of these devices, and we advise against using ozone or UV cleaning with any of our CPAP devices. We recommend following only the cleaning and disinfection instructions outlined in the device-specific user manuals.

FDA Public Notice: Ozone & UV CPAP Cleaning https://www.fda.gov/consumers/consumer-updates/cpap-machine-cleaning-ozone-uv-light-products-are-not-fda-approved

FDA Public Notice: Risks of using Ozone & UV CPAP Cleaning Devices https://www.fda.gov/medical-devices/safety-communications/potential-risks-associated-use-ozone-and-ultraviolet-uv-light-products-cleaning-cpap-machines-and

Drive DeVilbiss Healthcare takes this situation very seriously, and will continue to analyze and monitor the issues very closely.