Testing update for patients

On June 14, 2021, Philips initiated a field safety notification for certain continuous positive airway pressure (CPAP), bilevel positive airway pressure (BiPAP) and mechanical ventilator devices to address potential health risks related to the polyester-based polyurethane (PE-PUR) foam in these devices, specifically the possible foam degradation and release of volatile organic compounds (VOC) or particulate matter (PM) from the devices.

Since that time, Philips Respironics has been conducting extensive research, including testing by five certified testing laboratories in the U.S. and Europe, as well as other third-party experts, to assess the health risks related to the PE-PUR foam.

Philips understands and regrets the impact that this field safety notification is having on patients who use the affected devices. Patient safety and resolving the issue quickly are our top priorities. In line with this commitment, we are providing an update based on test results as of June 28, 2022.

Types of devices and foam tested

The five categories of devices tested, based on how the air flows through the device, are:

1. DreamStation 1 CPAP and BiPAP devices
2. DreamStation Go
3. System One CPAP and BiPAP devices
4. The Trilogy 100 and 200 mechanical ventilators
5. Omnilab and A-Series mechanical ventilators

Of the device groups tested, 95% are CPAP or BiPAP devices, and DreamStation 1 (first-generation) devices represent 68% of the registered affected devices globally.

Within each device type, testing was performed on three types of PE-PUR foam plus ozone testing, including:

1. New devices and foam that has not been used,
2. Used devices and foam that vary in the number of years of use, in the environment and conditions of use, in the degree of foam degradation, and
3. Laboratory-aged devices and foam that have been intentionally worn down by exposure to increased temperatures and humidity under controlled conditions in the laboratory.

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Testing protocols

Testing was performed on the entire device as well as on the PE-PUR foam alone following international standards.

Testing of volatile organic compounds included measuring emissions from the device to learn of any possible toxicologic risk associated with exposure to them.

Testing of particulate matter consisted of assessing the amount and size of particles in the device.

Additional testing was conducted to help detect any other toxicologic risk associated with exposure to the foam particles. These consisted of:

1. Analysis of any chemicals that might leave the foam and be in contact with body tissues and/or fluids,
2. Assessment of the foam in a test tube (in vitro testing), and
3. Assessment of the foam in living tissues (in vivo testing).

Results of particulate matter testing

To date, more than 60,000 DreamStation 1 devices that were returned have been inspected.

Of these, 99.5% of devices not cleaned by ozone methods showed no foam particulates. In contrast, 7% of ozone-cleaned devices had visible foam particles. This was 14 times higher than in non-ozone-cleaned devices.

Similarly, inspection of about 2,000 devices returned from Europe showed no significant degradation.

As the PE-PUR foam degrades, its foam shrinks, becomes sticky, but does not necessarily break down into particles. Additionally, the PE-PUR foam particles accumulate within the device and may not be emitted.

Results of volatile organic compounds (VOC) testing

Exposure to VOCs from new, used and laboratory-aged foam in the DreamStation 1 devices is not expected to result in long-term health consequences for patients. Both new and used devices with visible foam degradation met international standards for limits of emissions from the particulate matter.

Device	Volatile Organic Compound Testing	Particulate Matter Testing
DreamStation 1 (new foam)	Passed	Passed
DreamStation Go (new foam)	Passed	Passed
Trilogy (new foam)	Passed	Passed
Omnilab (new foam)	Passed	Passed
Omnilab (used foam)	Passed	On-going

Additional testing, including the effect of repeated ozone cleaning on foam degradation, is ongoing. Toxicologic testing of the foam particles is also continuing. Results from these tests will be reported as they become available.

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Conclusion

Philips Respironics is committed to further testing and reporting as we work through the repair and replacement program for affected CPAP, BiPAP and mechanical ventilator devices.

So far, testing shows that the VOC emissions are not expected to result in long-term health consequences, and that the level of particulate matter is within accepted international standards.

The overall guidance for healthcare providers and patients in the field safety notice remains unchanged at this time.

To learn more about the field safety notification, you can find information at philips.com/src-update