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Enclosure(s)
Results particle analysis

Date 5 oktober 2021
Subject Onderzoek beademingsapparatuur

Dear [REDACTED],

On 20 July 2021 we received your request to research ventilators. The following request was received: "The IGJ asks the RIVM to perform measurements of the released volatile compounds and of the released particles in the used Philips devices of approximately 3-4 years old, types Dreamstation1 and the Trilogy100. The measurements are additional to the manufacturer's toxicity measurements and to be performed in a clinically representative setting. As a reference new devices are going to be measured and two copies of each device under investigation are going to be measured for scientific reproducibility."

With this letter we report our findings of the researched release of particles and volatile organic compounds (VOC) of the supplied devices.

Supplied products

On 15 and 22 July 2021 various ventilators were delivered to the RIVM, see Table 1 for the overview. These devices were registered in project MT2021/003, folders A1931 and A1938, with order numbers from A193101 to A193104 and from A193801 to A193804.

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Table 1. Supplied ventilators with available information about them.

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RIVM order number	Product	State	Number:
A193101	Dreamstation 1 Auto CPAP	New	SN J30630027AF04
A193102	Dreamstation 1 Auto BiPAP	New	SN J29408691C887
A193103	Dreamstation Pro CPAP	8941 hours used from 2017.03.21	SN J18295331DB5E
A193104	Dreamstation Auto CPAP	9025 hours used from 2016.05.09	SN J162574308EB5
A193801	Trilogy 100	Used	TV116111025
A193802	Trilogy 100	Used	TV117032260
A193803	Trilogy 100	New	TV120072845
A193804	Trilogy 100	New	TV12009221B

It was not possible to properly set up in the laboratory the used Trilogy with order number A193802 and the measurements were therefore not carried out.

General methodology for the analysis

Two different types of analysis were performed on the ventilators in parallel. During the first analysis, the volatile organic compounds (VOC) that may be released during the use of the device were evaluated. During the second analysis, the particles that may be released during the use of the device were evaluated. In Figure 1 the used setup is shown. The inlet of the ventilator is covered in such a way that the device takes in only (clean) nitrogen or compressed air. A T-piece was placed at the exhaust with a sample tube on one side and a connection to an external pump on the other. The sample tube is coupled to a Condensation Particle Counter (CPC), an Optical Particle Sizer (OPS) and a thermal desorption tube (TD-tube). The total flow through the ventilator was set at 15 l/min. The 15 l/min were divided as follows: 0,3 l/min CPC; 0,3 l/min TD-buis; 1 l/min OPS, 13,4 l/min external pump. The internal pump of the ventilator was switched on during the sampling and it holds the pressure in the exhaust at 4 mbar.

The measurements were performed at various time points in the lifespan of the ventilators. For the new devices the sampling was performed as described in NEN-ISO 18562-3:2017 at the first use, after 24 hours, and after 240 hours. The Dreamstation is normally used during the night thus 240 hours corresponds to 1 month of use. The used devices were measured at one time point as a model for longtime use.

The exposure when using the devices was determined on the basis of the 8 consecutive hours of usage with a breathing volume of 5L per minute in a fully calm state, or alternatively 0.3 m³/hour. The night-time is based on the breathing volume with corresponding exposure of 2.4 m³.

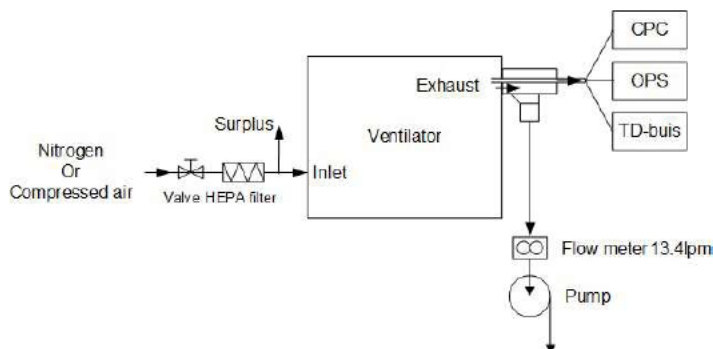


Figure 1. The set-up for the sampling from a ventilator.

Analysis of volatile organic compounds

A part of the air from the ventilator is directed to a TD-tube (TD-buis in Figure 1). Then the volatile compounds are semi-permanently bound to the adsorption material in the tube. After that, the trapped compounds are analyzed using gas chromatography coupled with mass spectrometry (GC-MS). To identify and quantify volatile compounds a standard VOC-mixture of circa 75 components of 100 ppb concentration was used.

Analysis particles count

To count the (possibly) released particles two detectors were used: CPC and OPS. Using the CPC detector the amount of particles from 6 nm to 2 μm per cm^3 air are measured. Using the OPS the distribution and the amount of the particles from 400 nm to 10 μm are measured.

Results and discussion

Volatile organic compounds, analysis and exposure

Table 2 provides an overview of the 10 VOC where minimally in one of the setups a concentration above the detection limit was measured. The general detection limit is set as 1.0 microgram/ m^3 , the measurement uncertainty of the analysis is estimated at 30 %. In general, the measured values are low and the measurement uncertainty is high. From the 10 detected compounds, 8 were measured from a Dreamstation and 4 from a Trilogy. From the Dreamstation no compounds were found after 24 hours and after 240 hours. There were more compounds measured in the used Dreamstation in comparison to a new Dreamstation. From the 4 compounds measured for the new Trilogy, there was only 1 compound measured for the used Trilogy in a lower amount.

The assessment of the possible health risks from exposure to VOC is based on the measured concentrations. It is assumed that these concentrations are the same as the concentration inhaled during the usage of a device. All measurements, except for the used Trilogy, were performed on 2 devices. The highest measured value from these 2 values is reported in Table 2. In case both of the values were above the detection limit, the reported value is underlined.

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Table 2. Overview of the 10 VOC where minimally in one of the setups a concentration above the detection limit was measured. The concentrations are underlined when the measurements were above the detection limit for both devices. The names of the compounds that are classified as possibly or probably carcinogenic to humans are given in bold.

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Compound name	Dream-station (new)	Dream-station (after 24 hours)	Dream-station (after 240 hours)	Dream-station (used)	Trilogy (new)	Trilogy (used)
2-butanone	1.1			1.5	2.3	
2-hexanone				<u>3.2</u>		
1,2,4-trimethylbenzene	<u>1.5</u>			1.0		
Acetone	<u>2.3</u>			<u>1.3</u>	<u>1.2</u>	
Naphthalene				<u>1.9</u>		
m,p-xylene	1.6					
Styrene	<u>2.8</u>			<u>2.6</u>		
Toluene				1.3		
Bromomethane					<u>5.7</u>	1.2
Chloromethane					<u>1.3</u>	

For the 10 compounds in Table 2 the limit values for air concentration for the general population were searched that are derived by the RIVM, the US EPA or the ATSDR. In the case of these sources, the limit value is the concentration of the compound that is not causing adverse health effects during lifelong exposure for 24 hours per day. Therefore, comparing measured values to the limit values is a conservative approach since the devices are not always used continuously nor lifelong. The Dreamstation is only used during sleep and/or a rest period where the inhalation minute-volume is low. No appropriate limit value was found for acetone. From the other 9 compounds, two compounds are classified by the IARC as probably or possibly carcinogenic (categories 2A and 2B), specifically naphthalene and styrene. These compounds were detected for the Dreamstation.

The limit value for naphthalene is based on a threshold approach. That means that for naphthalene a limit value can be derived for which there is no risk for cancer. Because the measured naphthalene concentration is lower than this limit value, no adverse health effects are expected. For styrene the limit values are of an older date and it is possible that carcinogenic effects are either not or insufficiently included. This means that the limit value may become lower if carcinogenic effects are accounted for. In this project no further judgement can be done in that regard. However, because the devices are not applied continuously nor

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lifelong and are only used during the sleeping period, where the inhalation volume is low, cancer risks at exposure are probably going to be low. To better evaluate those risks, a deeper research is required to evaluate the relation between the exposure to styrene and cancer appearance. That includes checking how representative the current analysis is for exposure in practice.

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Considering the none carcinogenic compounds, the measured values are mostly a lot lower than the limit value. Although, there was no limit value for the general population found for acetone, the conclusion can be based on the available data about acetone. Thus, the measured acetone concentration (only found at a new Dreamstation) leads to no health risks.

Styrene is the only compound that may need further attention. The first step could be to evaluate how representative are the results for the use of the Dreamstation in practice. Then, to perform a more accurate evaluation of the exposure concentration and duration. No definite conclusion about possible health risks can be drawn based on the current results.

Particles, analysis and exposure

Emitted particles from the used and new devices were analysed at the first use, after 24 hours and after 240 hours. The data from these measurements can be found in Appendix 1. At the first use of the Dreamstations measurable particles are released during the first hours. After the first hours of use at the Dreamstation and the Trilogy several peaks with particles were observed sporadically. The levels of the amounts of the measured particles however, including the ones measured during the first hours of use of the Dreamstation, are very low when compared to the amount of particles in a clean laboratory space or outdoor air. These background amounts are reported in Appendix 1 as well.

Conclusion

Various measurements were carried out on Dreamstation and Trilogy ventilators. The release of VOC and particles from order numbers A193101 to A193104 and A193801 to A193804 was found to be limited. Ten VOC were found above the detection limit. Only for styrene there is a reason for concern. To determine whether there are additional health risk as a result of exposure to styrene while using Dreamstation, as a first step a representative exposure assessment under practically relevant condition should be performed.

The amount of the released particles was very low when compared to the amount of particles in the outdoor air. Based on the measurements of particles no adverse health effects is expected while using these devices.

With this letter, I believe to have informed you sufficiently.

With kind regards,

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Appendix 1: Results particle analysis

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A193101

- After 0 hours (1 hour sampling)
 - OPS

	Average	Max
Count Median	0.40	0.48
Total Conc. (#/cm ³)	0.29	2.47
Mass Median	1.37	7.80
Total Conc. (µg/m ³)	0.14	3.26

After 6 min peak measurements
 - CPC
 - average concentration 0.53 p/cm³
 - Max concentration 54.7 p/cm³
 - During first 20 min elevated particle numbers, then <1 p/cm³
- After 24 hours (1 hour sampling)
 - OPS

	Average	Max
Count Median	0.44	0.48
Total Conc. (#/cm ³)	2.88	4.81
Mass Median	1.08	1.84
Total Conc. (µg/m ³)	0.64	1.03
 - CPC
 - average concentration 4.80 p/cm³
 - Max concentration 13.36 p/cm³
- After 10 days (1 hour sampling)
 - OPS

	Average	Max
Count Median	0.43	0.46
Total Conc. (#/cm ³)	2.81	5.76
Mass Median	0.95	1.12
Total Conc. (µg/m ³)	0.51	0.74
 - CPC
 - average concentration 5.24 p/cm³
 - Max concentration 14.78 p/cm³

A193102

- After 0 hours (1 hour sampling)
 - OPS

	Average	Max
Count Median	0.27	1.75
Total Conc. (#/cm ³)	0.20	1.40
Mass Median	0.78	8.16
Total Conc. (µg/m ³)	0.07	0.46

1 piekmeting na 6 min, wat deeltjes bij 9µm. Totale concentratie (deeltjes en massa) laag.
 - CPC
 - average concentration 0.37 p/cm³
 - Max concentration 99.85 p/cm³, peak during 5sec after ±50min

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- After 24 hours (1 hour sampling)

- OPS

	Average	Max
Count Median	0.38	0.49
Total Conc. (#/cm ³)	1.18	2.47
Mass Median	1.00	7.28
Total Conc. (µg/m ³)	0.17	0.95

Measurements from first 7 min a little bit higher. Low total concentration (particles and mass).

- CPC

average concentration 3.31 p/cm³
Max concentration 425.38 p/cm³, peak during 15 sec after turning on the dreamstation pump.

- After 10 days (1 hour sampling)

- OPS

	Average	Max
Count Median	0.42	0.48
Total Conc. (#/cm ³)	2.09	2.96
Mass Median	0.95	1.33
Total Conc. (µg/m ³)	0.45	0.86

- CPC

average concentration 4.05 p/cm³
Max concentration 8.1 p/cm³

A193103 (6 hour sampling)

- OPS

	Average	Max
Count Median	0.35	0.36
Total Conc. (#/cm ³)	0.46	0.64
Mass Median	0.50	0.69
Total Conc. (µg/m ³)	0.03	0.04

- CPC

Average concentration 0.77 p/cm³
Max concentration 9.92 p/cm³, peak during 5 sec after 22 min.

A193104 (used)

- OPS

	Average	Max
Count Median	0.67	4.21
Total Conc. (#/cm ³)	0.03	1.35
Mass Median	0.67	4.21
Total Conc. (µg/m ³)	0.03	1.35

Outliers between 2 and 4 hours. Low total concentration (particles and mass).

- CPC

average concentration 0.07 p/cm³
Max concentration 18.22 p/cm³, peak during 5 sec after 22 min.

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A193801

- OPS

	Average	Max
Count Median	0.32	0.47
Total Conc. (#/cm ³)	0.00	0.01
Mass Median	0.45	3.40
Total Conc. (µg/m ³)	0.00	0.03

Outliers at 8 and 33 min. Low total concentration (particles and mass).

- CPC

average concentration 0.52 p/cm³
Max concentration 0.84 p/cm³

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A193802

This device was not measured because it was not possible to set it up on the desired setting (constant flow of 4 mbar overpressure).

A193803

- OPS

	Average	Max
Count Median	0.34	0.39
Total Conc. (#/cm ³)	0.17	1.96
Mass Median	0.54	2.16
Total Conc. (µg/m ³)	0.02	0.10

Outliers at 56 min. Low total concentration (particles and mass).

- CPC

average concentration 7.20 p/cm³
Max concentration 140.79 p/cm³
First 2 min higher concentration, then slowly lowers to <10 p/cm³

A193804

- OPS

	Average	Max
Count Median	0.39	0.41
Total Conc. (#/cm ³)	0.75	0.96
Mass Median	0.76	0.99
Total Conc. (µg/m ³)	0.09	0.14

- CPC

average concentration 4.55 p/cm³
Max concentration 9.31 p/cm³

Background measurements

A193102 inlet on the laboratory air

- OPS

	Average	Max
Count Median	0.33	0.33
Total Conc. (#/cm ³)	28	29
Mass Median	0.37	0.39
Total Conc. (µg/m ³)	1.01	1.11

- CPC

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average concentration 2066 p/cm³
Max concentration 2176 p/cm³

Laboratory air

- OPS

	Average	Max
Count Median	0.33	0.33
Total Conc. (#/cm ³)	34	34
Mass Median	2.79	7.40
Total Conc. (µg/m ³)	2.17	2.90

- CPC

average concentration 3297 p/cm³
Max concentration 3459 p/cm³

Outside air

- OPS

	Average	Max
Count Median	0.33	0.33
Total Conc. (#/cm ³)	71	75
Mass Median	1.59	2.13
Total Conc. (µg/m ³)	5.08	5.94

- CPC

average concentration 6369 p/cm³
Max concentration 8993 p/cm³

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