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Philips Respironics
Summary of PE-PUR Testing Results and Conclusions Available to Date

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Table of Contents

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I. Introduction

On June 14, 2021, Philips Respironics, initiated a voluntary recall notification[1] for certain sleep and respiratory care products to address potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foams in these devices. This Philips Respironics update is intended to provide healthcare providers, patients, and other stakeholders with updated information on testing results and third party confirmed conclusions to date on results and findings from testing PE-PUR foam used in recalled devices for volatile organic compounds (VOCs), particulate matter (PM), and other testing such that healthcare providers have additional information to make informed decisions regarding the risk of continued use of recalled products. ***The overall guidance for healthcare providers and patients in the most recent version of the recall notification remains unchanged at this time.*** For more information on the recall notification, as well as instructions for customers, patients and physicians, affected parties may contact their local Philips representative or visit philips.com/SRC-update.

Testing results and conclusions to date are organized by device in **Tables 1-5**. Within each device type, testing was performed on one of three categories of devices/PE-PUR foam.

- **New:** devices/foam tested after manufacturing, prior to use by patients
- **Used:** devices/foam tested after patient use (years of use, environmental factors, and conditions of devices vary)
- **Lab Aged:** devices/foam tested after exposure to elevated temperature and humidity to intentionally induce degradation of PE-PUR foam

Testing remains ongoing. The purpose and rationale of the ongoing testing is to identify and characterize health risks of (1) potential degradation of PE-PUR foam into particles, and (2) potential PE-PUR off-gassing of VOCs. The results of this testing will be evaluated to assess potential acute and chronic toxicological risks related to patient health. As new finalized testing results/analyses become available, Philips Respironics will update this summary, including **Tables 1-5**.

II. Overview of Testing Categories

Three categories of testing can generally be described in assessing potential patient risk: (A) VOC testing to identify and quantify organic compounds that may be inhaled during device use, (B) PM testing to determine concentrations of airborne particles as it relates to inhalation risks and established health thresholds, and (C) additional physical, chemical and biological testing related to patient risks if patients were in contact with PE-PUR foam material. These categories are described in more detail below.

A. VOC Testing at Device Level

VOC testing according to ISO 18562-3:2017 (Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds) was performed on the devices containing PE-PUR foam to (1) quantify VOC emissions from devices, and (2) assess the toxicological risk associated with exposure to the quantified concentrations of those VOCs. This testing

[1] Voluntary recall notification in the U.S. / field safety notice outside the U.S.

is performed on the entire device, not just the PE-PUR foam component. The purpose of this test is to determine if a detected and quantified VOC is likely to be associated with a toxicological risk based upon exposure during use of the device. For each detected and quantified compound, a worst-case estimate of daily exposure is determined and compared to a tolerable intake, which is the total amount of a compound that is considered to be without appreciable harm to health. This comparison is presented as a Margin of Safety (MOS) factor with an MOS value greater than 1.0, indicating the compound's worst-case estimate is below the compound's tolerable intake, and therefore suggests no appreciable harm to health.

B. Particulate Matter (PM) Testing at Device Level

PM testing according to ISO 18562-2:2017 (Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter) was performed on the devices containing PE-PUR foam to (1) quantify the particulate matter emitted from devices, and (2) assess whether the concentration detected is less than thresholds provided in the standard. This testing is performed on the entire device, not just the PE-PUR foam component. Specifically, ISO 18562-2 defines limits for airborne particles of sizes less than or equal to 2.5 µm in diameter (referred to as $PM_{2.5}$ with a limit of 12 µg/m^3) and those less than or equal to 10 µm in diameter (referred to as PM_{10} with a limit of 150 µg/m^3). As described in ISO 18562-2, these limits are taken from the US EPA National Ambient Air Quality Standards (40 § CFR Part 50). Particles greater than 10 µm in diameter are not evaluated in ISO 18562-2 testing (please see (C) Additional testing below and **General Testing Limitations** for more details).

C. Foam Level and Additional Device Level Testing

Additional testing is being performed in accordance with ISO 10993 (Biological evaluation of medical devices) to facilitate a toxicological risk assessment. This testing includes: chemical characterization (i.e. what chemicals may potentially extract or leach from the foam and have direct contact with body tissues and/or fluids), *in vitro* assessment (i.e. tests performed in a test tube, dish, etc. outside the body), and *in vivo* assessment (i.e. animal testing) of new, lab aged and/or used PE-PUR foam. In these tests, PE-PUR foam material is directly tested according to the ISO 10993 standards, unlike testing according to the ISO 18562 standards, which is performed on the entire device. Some additional testing has been completed on new and lab-aged foam, and the available results are reported in the Tables below, but additional testing is still ongoing (see **Section IV, General Testing Limitations**).

A chemical evaluation of new, used, and lab-aged PE-PUR foam will be conducted by identifying and quantifying chemicals that may be extracted or leached from the PE-PUR foam. The worst-case estimate of daily exposure will be informed by experiments to assess the amount of PE-PUR foam that can potentially be emitted from the device and contact the patient. A toxicological risk assessment on the extracted or leached chemicals will then be conducted in general accordance with ISO 10993 Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances, and Part 18: Chemical characterization of medical device materials within a risk management process. For each quantified compound extracted or leached from the PE-PUR foam, the worst-case estimate of daily exposure is determined and compared to a tolerable intake, which is the total amount of a compound that is considered to be without appreciable harm to health. This comparison is presented as a Margin of Safety (MOS) factor with an MOS value greater than 1.0, indicating the compound's worst-case

estimate is below the compound's tolerable intake, and therefore suggests no appreciable harm to health.

In vitro and *in vivo* assessments are conducted according to ISO 10993 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity, Part 5: Tests for *in vitro* cytotoxicity, and Part 10: Tests for irritation and skin sensitization. These tests are evaluated against *a priori* acceptance criteria to determine if the PE-PUR foam has "Passed" the test.

III. PE-PUR Foam Degradation Products

Toluene diisocyanate (TDI), toluene diamine (TDA), and diethylene glycol (DEG) are potential degradation products of PE-PUR material, depending on the degradation mechanism (e.g., due to high temperature) and the extent of degradation.

- TDI is a known degradation product at high temperatures, well above the anticipated use conditions of the recalled devices. Based on this, TDI is not expected to be a degradation product under normal use (consistent with the instructions for use) for the recalled devices. Further, TDI has not been detected in testing related to the recalled devices/PE-PUR sound abatement foam.
- TDA has not been detected as a VOC but was detected in one test as an extractable/leachable chemical in a lab degraded foam (Foam Type A, see **Table 6**, used in DreamStation 1, DreamStation Go, BiPAP A-Series/ and OmniLab, and System One). The associated third party toxicological risk assessment determined that the amount of TDA detected as an extractable/leachable chemical had a MOS value greater than 1.0, indicating no appreciable harm to health (see **Table 1 Row 12**, **Table 2 Row 6**, **Table 4 Row 7** and **Table 5 Row 6**, all based on the same testing result).
- DEG was detected as a VOC in multiple tests and as an extractable/leachable chemical, but all associated third party toxicological risk assessments indicated that the amount of DEG detected had a MOS value greater than 1.0, indicating no appreciable harm to health.

Key hazards related to inhalation or ingestion of TDI, TDA, or DEG include: TDI – respiratory sensitization and irritation, asthma, and carcinogenicity; TDA – skin sensitization, liver toxicity, reproductive toxicity, genotoxicity, and carcinogenicity; DEG – kidney toxicity and liver toxicity. As testing is ongoing to assess to what extent PE-PUR particulates may contact patients based upon the level of degradation, Philips Respironics cannot confirm that health risks for patients do not exist for potential degradation products, and as such, ***the overall guidance for healthcare providers and patients in the most recent version of the recall notification remains unchanged at this time***.

IV. General Testing Limitations

Healthcare providers and patients are advised that certain limitations exist regarding the current results presented herein and that these limitations are still being addressed with ongoing testing and evaluations.

ISO 18562-2 testing of devices quantifies the concentration of particles based only on their size range (2.5 µm to 10 µm in diameter), but does not include chemical characterization of these particles, or the detection of larger particles that may be emitted from the device (i.e., >10 µm PE-PUR foam particles).

As such, passing an ISO 18562-2 test does not indicate 'no health risk' of PE-PUR foam particulates being emitted from the device. Additional testing is ongoing for chemical characterization and to identify the health risk of larger PE-PUR foam particles that are potentially emitted. Toxicological risk assessments require an understanding of patient PE-PUR foam exposure (i.e., how much PE-PUR foam can contact a patient), and therefore, this assessment cannot yet be fully completed until sufficient data has been collected.

Another limitation in the presented results is the number of used devices that have finished VOC testing. For example, 5 used DreamStation 1 devices were selected for testing (refer to **Table 1**) based on the devices exhibiting varying degrees of visibly degraded PE-PUR foam. However, this sampling fraction may not necessarily reflect "worst-case" degradation among all potentially degraded devices.

With regard to testing on lab-aged foam, it is not clear to what extent lab-aging correlates to how the foam ages in used devices. Testing is ongoing to determine which lab-aging parameters correlate most closely with the foam condition in used devices.

As presented below in **Section V.A**, lab-aged foam (Foam type A) failed genotoxicity testing under the laboratory conditions of the Ames assay, but the implications of this result on overall patient health risk are still being assessed through additional testing (including the amount of foam that may contact a patient based upon the level of degradation). Per ISO 10993, a positive Ames result triggers a required follow-up evaluation including identification of potential confounding factors, and a weight of evidence assessment to determine a confirmed conclusion on potential risks for patients under expected usage of the device. To support this assessment, chemical characterization of PE-PUR foam as well as experiments to assess the amount of PE-PUR foam that can potentially contact the patient are being conducted.

Considering these collective limitations, Philips Respironics advises caution in interpretation of any one test result (pass or fail) as reflective of the overall patient risk.

The overall guidance for healthcare providers and patients in the most recent version of the recall notification remains unchanged at this time.

V. Summary Overview of Testing Status and Results by Platform

Specific conclusions regarding available testing results and third party confirmed conclusions reported to date for the three described categories listed above are contained in **Tables 1-5**, which are organized by device family. **Table 6** lists the type of PE-PUR foam used in each device (type A or type B). **Table 7** lists all acronyms and abbreviations.

- Current Status of VOC testing: Philips provided an update on December 23, 2021[2] that exposure to the level of VOCs identified to date for the first-generation DreamStation devices based on preliminary testing (see **Table 1**) is not typically anticipated to result in long-term health consequences for patients; however, additional VOC testing for DreamStation is ongoing and definitive conclusions will be provided after that testing is complete. Further, additional VOC

[2] Available at, https://www.usa.philips.com/healthcare/e/sleep/communications/src-update/news/update-on-the-test-and-research-program

testing for other devices affected by the recall is ongoing, and conclusions regarding exposure risks related to VOCs for those other devices will be provided when complete.

- Current Status of PM testing and additional testing (ISO 10993): **Tables 1-5** provide available testing results and third party confirmed conclusions reported to date for all affected devices. Comprehensive risk assessments of testing in all categories are ongoing for each device affected by the recall, and Philips Respironics will continue to provide updates on findings from these assessments.

It is important to note that, to date, only preliminary testing has been conducted on devices/foam that were exposed to ozone cleaning, which is not an approved cleaning agent. Therefore, a comprehensive risk assessment on the impact of ozone cleaning has not been performed. Further, devices may be made with one or more types of PE-PUR foam and certain foam types are used in multiple device platforms as indicated in **Table 6**. Therefore, foam testing may be applicable to multiple device platforms and is indicated as such in the tables below. Unless otherwise noted in the tables, all testing and conclusions were performed at one or more certified third-party laboratories and/or confirmed by third-party qualified experts.

A. DreamStation 1

Testing includes VOC and PM testing on the entire device containing PE-PUR sound abatement foam, and testing on PE-PUR foam extracts from the associated foam type. See **Table 1** for a listing of testing results available to date.

- **Device:** Philips provided an update on December 23, 2021 that exposure to the level of VOCs identified to date for the first-generation DreamStation devices (DreamStation 1) is not anticipated to result in long-term health consequences for patients based on ISO 18562-3 testing and evaluation of new, lab aged, and used devices. Additional testing, such as on used devices or devices with lab aged foam, is ongoing.

- **Foam:**
  - New foam (type A – refer to **Table 6**) passed ISO 10993 cytotoxicity, irritation and sensitization testing as well as ISO 10993 genotoxicity testing.
  - Lab-aged foam failed ISO 10993 genotoxicity testing, and therefore a weight of evidence assessment is ongoing to provide a confirmed conclusion on potential risks for patient under the expected usage. A preliminary non-exhaustive chemical characterization and toxicological risk assessment on lab-aged foam indicated all detected compounds had MOSs > 1.0. To support the full toxicological assessment, additional chemical characterization as well as experiments to assess the amount of PE-PUR foam that can potentially contact the patient are being conducted.

B. DreamStation Go

Testing includes VOC and PM testing on the entire device containing PE-PUR sound abatement foam, and the foam type is the same as DreamStation 1. See **Table 2** for a listing of testing results available to date.

- **Device:** One new device passed VOC and PM testing. Further testing of DreamStation Go is ongoing.

- **Foam:** Same foam type (type A – refer to **Table 6**) as **DreamStation 1.** Please refer to the foam testing described above in **Section V.A** for DreamStation 1.

C. Trilogy

Testing includes VOC and PM testing on the entire device containing PE-PUR sound abatement foam, and investigational materials characterization of the foam. See **Table 3** for a listing of testing results available to date.

- **Device:** Three new devices passed VOC and PM testing. Further testing of Trilogy is ongoing.

- **Foam:** New foam (type B – refer to **Table 6**) passed ISO 10993 cytotoxicity, irritation and sensitization testing, and genotoxicity testing is ongoing. Testing on lab-aged and used foam is ongoing. Preliminary foam material testing suggested that PE-PUR shows measurable degradation with exposure to high temperature and high humidity.

D. BiPAP A-Series and OmniLab

Testing includes VOC and PM testing on the entire device containing PE-PUR sound abatement foams. Each device contains 3 foams (types A and B – refer to **Table 6**), one is the same as the PE-PUR foam in DreamStation 1 (type A) and another one is the same as PE-PUR foam in Trilogy (type B). See **Table 4** for a listing of testing results available to date.

- **Device:** One new device passed VOC and PM testing. Further testing is ongoing for lab-aged and used devices.

- **Foam:** Each device contains 3 foams (types A and B – refer to **Table 6**). Foam type A is the same as DreamStation 1 and foam type B is the same as Trilogy. Please refer to the foam testing described above for DreamStation 1 (**Section V.A**) and Trilogy (**Section V.C**). Further testing on lab-aged and used foam is still ongoing.

E. System One

Testing includes VOC and PM testing on the entire device containing PE-PUR sound abatement foam, and on PE-PUR extracts. See **Table 5** for a listing of testing results available to date.

- **Device:** One new device passed VOC and PM testing. Further testing is ongoing for lab-aged and used devices.

- **Foam:** Same foam type (type A – refer to **Table 6**) as DreamStation 1, please see testing described above in **Section V.A**.

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Table 1. List of Testing Results for DreamStation 1

Device	Row	Device Category	# of Tests/Devices Tested	Testing Description	Result	Conclusion(s) and Additional Information[a]
DreamStation 1 (Foam Type A)	1	New [Entire Device]	4	Indoor Air Quality Evaluation for VOC and PM	Pass	All VOC emissions and particulates were below established limits. Testing conducted on standards available prior to ISO 18562.
	2	New [Entire Device]	6	PM (ISO 18562-2)	Pass	$PM_{2.5}$ and PM_{10} below ISO 18562-2 thresholds.
	3	New [Entire Device]	12	VOCs (ISO 18562-3)	Pass	All detected VOCs had MOSs > 1.0.
	4	New [Entire Device]	1	VOCs (ISO 18562-3)	AI	DD and phenol stabilizer identified initially as compounds of potential concern; Follow up toxicological risk assessment on phenol stabilizer suggests no risk concern for adverse health effects in patients. Additional analysis on DD indicates DD was likely misidentified during initial characterization (i.e. DD was likely not present in the tested device).
	5	Lab Aged [Entire Device]	3	VOCs (ISO 18562-3)[b]	Pass	All detected VOCs had MOSs > 1.0. Testing included devices with foam previously aged for 1 week, 2 weeks, or 3 weeks at 90°C and 95% relative humidity.
	6	New [Entire Device]	1	PM (ISO 18562-2) and VOCs (ISO 18562-3)	Pass	$PM_{2.5}$ and PM_{10} below ISO 18562-2 thresholds. All detected VOCs had MOSs > 1.0. Used devices were selected based on varying levels of degradation with four devices having visible degradation.
	7	Used [Entire Device]	5			
	8	New [Foam A]	3 tests	ISO 10993-5: Agar diffusion ISO 10993-10: GPMT, skin irritation	Pass	Negative for cytotoxicity, sensitization, and skin irritation under laboratory conditions

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Device	Row	Device Category	# of Tests/Devices Tested	Testing Description	Result	Conclusion(s) and Additional Information[a]
	9	New [Foam A]	6 tests (3 pre-treatment conditions[c], 2 labs)	Genotoxicity test ISO 10993-3: Ames	Pass	Negative for genotoxicity under laboratory conditions
	10	Lab Aged [Foam A]	24 tests (4 aging timepoints, 3 pre-treatment conditions[c], 2 labs)	Genotoxicity test ISO 10993-3: Ames	Fail/AI	Positive for genotoxicity under laboratory conditions for all foam aged at 90°C 95% RH for ≥2 weeks, and 1/6 foam samples aged at 90°C and 95% RH for 1 week. Associated toxicological risk assessment **ongoing**[d].
	11	New [Foam A]	1	Preliminary chemical characterization by ISO 18562-4/ISO 10993-18 (non-exhaustive)[b]	Pass	All detected compounds had MOSs > 1.0
	12	Lab Aged [Foam A]	3 aging timepoints	Preliminary chemical characterization by ISO 18562-4/ISO 10993-18 (non-exhaustive)[b]	Pass	All detected compounds had MOSs > 1.0 Testing included devices with blower box containing foam previously aged for 1 week, 2 weeks, or 3 weeks at 90°C and 95% RH.

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Table 2. List of Testing Results for DreamStation Go

Device	Row	Device Category	# of Tests/Devices Tested	Testing Description	Result	Conclusion(s) and Additional Information[a]
DreamStation Go (Foam Type A)	1	New [Entire Device]	1	Indoor Air Quality Evaluation for VOC and PM	Pass	All VOC emissions and particulates were below established limits. Testing conducted on standards available prior to ISO 18562.
	2	New [Foam A][e]	3 tests	ISO 10993-5: Agar diffusion ISO 10993-10: GPMT, skin irritation	Pass	Negative for cytotoxicity, sensitization, and skin irritation under laboratory conditions
	3	New [Foam A] [e]	6 tests (3 pre-treatment conditions[b], 2 labs)	Genotoxicity test ISO 10993-3: Ames	Pass	Negative for genotoxicity under laboratory conditions
	4	Lab Aged [Foam A] [e]	24 tests (4 aging timepoints, 3 pre-treatment conditions[b], 2 labs)	Genotoxicity test ISO 10993-3: Ames	Fail/AI	Positive for genotoxicity under laboratory conditions for all foam aged at 90°C and 95% RH for ≥2 weeks, and 1/6 foam samples aged at 90°C and 95% RH for 1 week. Associated toxicological risk assessment **ongoing**[c]
	5	New [Foam A] [e]	1	Preliminary chemical characterization by ISO 18562-4/ISO 10993-18[d]	Pass	All detected compounds had MOSs > 1.0
	6	Lab Aged [Foam A] [e]	3 aging timepoints	Preliminary chemical characterization by ISO 18562-4/ISO 10993-18[d]	Pass	All detected compounds had MOSs > 1.0 Testing included devices with blower box containing foam previously aged for 1 week, 2 weeks, or 3 weeks at 90°C and 95% RH.

[a] For reports that did not directly calculate a MOS, if the detected concentration or calculated dose was acknowledged as below the associated tolerable limit that is considered equivalent to MOS > 1.0.

[b] Each aging condition tested one of three samples that were treated prior to aging as follows: (1) production equivalent foam untreated, or (2) exposed to ozone, or (3) place in ventilated oven set at 60°C for a period of 24 hours prior to aging.

[c] Per the ISO 10993-3 standard, a positive result triggers a follow-up evaluation including identification of potential confounding factors, and a weight of evidence assessment to provide a confirmed conclusion on potential risks for patient under the expected usage. This is currently ongoing.

[d] Analytical data collection, chemical characterization, and/or VOC identification performed internally; toxicological risk assessment provided by a qualified third party.

[e] Foam Type A testing reported in this table is also reported in Table 1.

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Table 3. List of Testing Results for Trilogy

Device	Row	Device Category	# of Tests/Devices Tested	Testing Description	Result	Conclusion(s) and Additional Information
Trilogy 100/200 (Foam Type B)	1	New [Entire Device]	3	Indoor Air Quality Evaluation for VOC and PM	Pass	All VOC emissions and particulates were below established limits. Testing conducted on standards available prior to ISO 18562.
	2	New [Foam B]	3 tests	ISO 10993-5: Elution test ISO 10993-10: GPMT, skin irritation	Pass	Negative for cytotoxicity, sensitization, and skin irritation under laboratory conditions
	3	New [Foam B]	4 tests/various conditions	pH, conductivity, FTIR, DSC[a]	N/A	PE-PUR foam shows measurable degradation with exposure to high temperature and high humidity. Testing included foam previously aged for 1, 4, 7, 11 or 14 days at 90°C and 100% RH, as well as 2 field return customer complaint foams
	4	Lab-Aged [Foam B]	4 tests/various conditions			
	5	Field-Use [Foam B]	4 tests/various conditions			

[a] Analytical data collection performed internally.

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Table 4. List of Testing Results for BiPAP A30/A40/V30 and OmniLab

Device	Row	Device Category	# of Tests/Devices Tested	Testing Description	Result	Conclusion(s) and Additional Information[a]
BiPAP A30/A40/V30; OmniLab (Foam Types A and B)	1	New [Entire Device]	1	Indoor Air Quality Evaluation for VOC and PM	Pass	All VOC emissions and particulates were below established limits. Testing conducted on standards available prior to ISO 18562.
	2	New [Foam A][f]	3 tests	ISO 10993-5: Agar diffusion ISO 10993-10: GPMT, skin irritation	Pass	Negative for cytotoxicity, sensitization, and skin irritation under laboratory conditions
	3	New [Foam B][f]	3 tests	ISO 10993-5: Elution test ISO 10993-10: GPMT, skin irritation	Pass	Negative for cytotoxicity, sensitization, and skin irritation under laboratory conditions
	4	New [Foam A][f]	6 tests (3 pre-treatment conditions[b], 2 labs)	Genotoxicity test ISO 10993-3: Ames	Pass	Negative for genotoxicity under laboratory conditions
	5	Lab Aged [Foam A][f]	24 tests (4 aging timepoints, 3 pre-treatment conditions[b], 2 labs)	Genotoxicity test ISO 10993-3: Ames	Fail/AI	Positive for genotoxicity under laboratory conditions for all foam aged at 90°C and 95% RH for ≥2 weeks, and 1/6 foam samples aged at 90°C and 95% RH for 1 week. Associated toxicological risk assessment **ongoing**[c]
	6	New [Foam A][f]	1	Preliminary chemical characterization by ISO 18562-4/ISO 10993-18[d]	Pass	All detected compounds had MOSs > 1.0
	7	Lab Aged [Foam A][f]	3 aging timepoints	Preliminary chemical characterization by ISO 18562-4/ISO 10993-18[d]	Pass	All detected compounds had MOSs > 1.0 Testing included devices with blower box containing foam previously aged for 1 week, 2 weeks, or 3 weeks at 90°C and 95% RH.

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Device	Row	Device Category	# of Tests/Devices Tested	Testing Description	Result	Conclusion(s) and Additional Information[a]
	8	New [Foam B][f]	4 tests/various conditions	pH, conductivity, FTIR, DSC[e]	N/A	PE-PUR foam shows measurable degradation with exposure to high temperature and high humidity. Testing included foam previously aged for 1, 4, 7, 11 or 14 days at 90°C and 100% RH, as well as 2 field return customer complaint foams
	9	Lab-Aged [Foam B][f]	4 tests/various conditions			
	10	Field-Use [Foam B][f]	4 tests/various conditions			

[a] For reports that did not directly calculate a MOS, if the detected concentration or calculated dose was acknowledged as below the associated tolerable limit that is considered equivalent to MOS > 1.0

[b] Each aging condition tested one of three samples that were treated prior to aging as follows: (1) production equivalent foam untreated, or (2) exposed to ozone, or (3) place in ventilated oven set at 60°C for a period of 24 hours prior to aging.

[c] Per the ISO 10993-3 standard, a positive result triggers a follow-up evaluation including identification of potential confounding factors, and a weight of evidence assessment to provide a confirmed conclusion on potential risks for patient under the expected usage. This is currently ongoing.

[d] Analytical data collection, chemical characterization, and/or VOC identification performed internally; toxicological risk assessment provided by a qualified third party.

[e] Analytical data collection performed internally.

[f] Foam Type A and B testing reported in this table is also reported in Tables 1 and 3 respectively.

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Table 5. List of Testing Results for SystemOne, Dorma, REMstar, C-series BiPAP

Device	Row	Device Category	# of Tests/Devices Tested	Testing Description	Result	Conclusion(s) and Additional Information[a]
SystemOne; Dorma; REMstar; C-series BiPAP (Foam Type A)	1	New [Entire Device]	1	Indoor Air Quality Evaluation for VOC and PM	Pass	All VOC emissions and particulates were below established limits. Testing conducted on standards available prior to ISO 18562
	2	New [Foam A] [e]	3 tests	ISO 10993-5: Agar diffusion ISO 10993-10: GPMT, skin irritation	Pass	Negative for cytotoxicity, sensitization, and skin irritation under laboratory conditions
	3	New [Foam A] [e]	6 tests (3 pre-treatment conditions[b], 2 labs)	Genotoxicity test ISO 10993-3: Ames	Pass	Negative for genotoxicity under laboratory conditions
	4	Lab Aged [Foam A] [e]	24 tests (4 aging timepoints, 3 pre-treatment conditions[b], 2 labs)	Genotoxicity test ISO 10993-3: Ames	Fail/AI	Positive for genotoxicity under laboratory conditions for all foam aged at 90°C and 95% RH for ≥2 weeks, and 1/6 foam samples aged at 90°C and 95% RH for 1 week. Associated toxicological risk assessment **ongoing**[c]
	5	New [Foam A] [e]	1	Preliminary chemical characterization by ISO 18562-4/ISO 10993-18[d]	Pass	All detected compounds had MOSs > 1.0
	6	Lab Aged [Foam A] [e]	3 aging timepoints	Preliminary chemical characterization by ISO 18562-4/ISO 10993-18[d]	Pass	All detected compounds had MOSs > 1.0 Testing included devices with blower box containing foam previously aged for 1 week, 2 weeks, or 3 weeks at 90°C and 95% RH.

[a] For reports that did not directly calculate a MOS, if the detected concentration or calculated dose was acknowledged as below the associated tolerable limit that is considered equivalent to MOS > 1.0

[b] Each aging condition tested one of three samples that were treated prior to aging as follows: (1) production equivalent foam untreated, or (2) exposed to ozone, or (3) place in ventilated oven set at 60°C for a period of 24 hours prior to aging.

[c] Per the ISO 10993-3 standard, a positive result triggers a follow-up evaluation including identification of potential confounding factors, and a weight of evidence assessment to provide a confirmed conclusion on potential risks for patient under the expected usage. This is currently ongoing.

[d] Analytical data collection, chemical characterization, and/or VOC identification performed internally; toxicological risk assessment provided by a qualified third party.

[e] Foam Type A testing reported in this table is also reported in Table 1.

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Table 6. Sound abatement foam type per device

Devices	Foam Type	Foam Material
DreamStation 1	**A**	PE-PUR
DreamStation Go	**A**	PE-PUR
SystemOne; Dorma; REMstar; C-series BiPAP	**A**	PE-PUR
Trilogy 100/200	**B**	PE-PUR
BiPAP A30/A40/V30; OmniLab	**A and B**	PE-PUR for both

Table 7. Acronyms and Abbreviations

AI	Additional Information
°C	Celsius
CFR	Code of Federal Regulations
DD	Dimethyl diazene
DSC	Differential Scanning Calorimetry
EPA	U.S. Environmental Protection Agency
FDA	U.S. Food and Drug Administration
FTIR	Fourier Transform Infrared Spectroscopy
GC-MS	Gas Chromatography-Mass Spectrometry
GPMT	Guinea Pig Maximization Test
HHE	Health Hazard Evaluation
In vitro	Experimental studies conducted in biological material, e.g. cells in a test tube, outside the body
In vivo	Experimental studies conducted in animal model
ISO	International Organization for Standardization
MOS	Margin of Safety
PE-PUR	Polyester-Polyurethane
Phenol Stabilizer	Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl)

PM	Particulate Matter
$PM_{2.5}$	Particulate Matter with a diameter of 2.5 micrometers or less
PM_{10}	Particulate Matter with a diameter of 10 micrometers or less
RH	Relative Humidity
VOC	Volatile Organic Compounds
Wks	Weeks
$\mu g/m^3$	Micrograms per cubic meter