NOTICE OF FILING

Details of Filing

Document Lodged:	Concise Statement
Court of Filing	FEDERAL COURT OF AUSTRALIA (FCA)
Date of Lodgment:	2/06/2025 2:17:45 PM AEST
Date Accepted for Filing:	3/06/2025 9:49:14 AM AEST
File Number:	NSD867/2025
File Title:	SECRETARY OF THE DEPARTMENT OF HEALTH, DISABILITY AND AGEING v PHILIPS ELECTRONICS AUSTRALIA LIMITED ACN 008 445 743
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA

Registrar

Important Information

This Notice has been inserted as the first page of the document which has been accepted for electronic filing. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties.

The date of the filing of the document is determined pursuant to the Court's Rules.

Form NCF1

Concise Statement

No. of

Federal Court of Australia

District Registry: New South Wales

Division: General

Secretary of the Department of Health, Disability and Ageing

Applicant

Philips Electronics Australia Limited ACN 008 445 743

Respondent

A. Overview

1. The respondent, Philips Electronics Australia Ltd (**PEAL**) is, and was during the period 2 June 2019 to 2 June 2021 (**Relevant Period A**) and 7 July 2021 to 13 October 2022 (**Relevant Period B**) (collectively **Relevant Period**), the person in relation to whom the kinds of medical devices in **Appendix A** (**Devices**) were included in the Australian Therapeutic Goods Register (**ARTG**). Philips RS North America LLC (formerly, Respironics Inc) (**Respironics**), a related entity of PEAL based in the United States, manufactured the Devices. PEAL supplied the Devices for use in Australia. Appendix A identifies the minimum number of instances of supply of the Devices in the Relevant Period, set out by ARTG entry and the models (or kinds of medical devices) under each of those entries.

2. The Devices are ventilator devices, continuous positive airway pressure (**CPAP**) devices (which deliver air at a single pressure to keep the airway open), and bi-level positive airway pressure (**BiPAP**) devices (which provide two levels of pressure, being one for inhalation and one for exhalation). The Devices contained a polyester-based polyurethane foam (**PE-PUR foam**) for sound abatement purposes. There was a real risk of the PE-PUR foam degrading (**PE-PUR Defect**). The PE-PUR Defect had the potential to harm the health of users, including from inhalation and ingestion of small particulates, and could result in lower air flow or affect the Device's ability to provide therapy to published specifications.

3. Due to the PE-PUR Defect, the Devices supplied during the Relevant Period A did not comply with essential principles 1, 2, 3, 4, 7.1(a), 7.6 and/or 9.2 in Schedule 1 of the

Filed on behalf of (name & role of party) Secretary of the Department of Health, Disability and Ageing, Applicant
Prepared by (name of person/lawyer) Rebecca Jaffe
Law firm (if applicable) HWL Ebsworth Lawyers
Tel (03) 8644 3500 Fax 1300 365 323
Email rjaffe@hwle.com.au
Address for service (include state and postcode) Level 8, 447 Collins Street, MELBOURNE 3000

Therapeutic Goods (Medical Devices) Regulations 2002 (Cth) (**Regulations**). Each instance of such supply contravened s 41MAA(2) of the *Therapeutic Goods Act 1989* (Cth) (**TG Act**).

4. In addition, during the Relevant Period B, PEAL supplied a model under ARTG entry 159490 with a silicone sound abatement foam (**Trilogy 100 Device**). There was a real risk of the silicone foam becoming separated from its housing and causing low inspiratory pressure in Trilogy 100 Devices (**Silicone Delamination Defect**). By reason of the Silicone Delamination Defect, each instance of supply of the Trilogy 100 Devices during the Relevant Period B did not comply with essential principles 1, 2, 3, 4 and/or 6. Each instance of such supply contravened s 41MAA(2) of the TG Act.

B. Important facts giving rise to the claim

5. The Devices were intended to mechanically control or assist a user's breathing. The ventilator devices were intended to provide continuous or intermittent ventilatory support for the care of individuals requiring mechanical ventilation. The CPAP and BiPAP Devices were intended to provide positive airway pressure therapy for the treatment of obstructive sleep apnoea and/or respiratory insufficiency. The Devices had an expected service life up to 5 years.

6. The Devices typically contained an inlet filter from which air travelled into a blower box, after which it ultimately travelled to the user's airway. During the Relevant Period A, Respironics manufactured the Devices using PE-PUR foam, which was usually placed in the blower box of the Devices. The purpose of the PE-PUR foam was to reduce noise emitted from the Device motors when they were used.

C. Non-Compliance with the essential principles by reason of the PE-PUR Defect

Risk of degradation of the PE-PUR foam

7. When used under normal conditions, there was a real risk that the PE-PUR foam in the Devices could degrade when it reacted with moisture (hydrolysis). This risk increased when the Devices were operated in conditions of high heat and/or high humidity.

Potential for harm from PE-PUR Defect

8. The degradation of the PE-PUR foam within the air inlet path of the Devices could pose a biological risk to patients. If the PE-PUR foam degraded, there was a risk that potentially hazardous and unacceptable levels of particulates could exit the Devices and enter the patient's respiratory tract and/or gastrointestinal tract. Potential harm from short and intermediate term exposure to those byproducts of degraded PE-PUR foam included: skin, eye and respiratory tract irritation, inflammatory response, headache, asthma, effects on the user's reproductive system and neoplasia. Potential harm from long term exposure

included cytotoxic, genotoxic, and carcinogenic effects. The degradation of the PE-PUR foam could also result in lower air flow or affect the Device's ability to provide therapy to published specifications. The probability of degradation, and consequential harm to the patient, was unacceptable, given the potentially serious consequences to patients.

Failure to conduct adequate risk analysis

9. By at least November 2015, Respironics became aware of the risk that the PE-PUR foam in the Devices, or devices similar to the Devices, could degrade. In addition, there were multiple assessments and/or test reports between 2016 and 2021 where Respironics was notified of the PE-PUR Defect and the potential harm to patients that could be caused by that defect. Examples of documents showing Respironics' knowledge are set out in **Appendix B**.

10. Accordingly, by at least the start of the Relevant Period (2 June 2019), Respironics knew or should have known that the PE-PUR foam used in the Devices could degrade and result in short, intermediate and/or long-term harm for patients. However, until around early 2021, Respironics did not: (a) perform any, or any adequate, risk analysis in relation to PE-PUR foam degradation; (b) implement any design change to replace the PE-PUR foam; or (c) take any other corrective action, such as recalling the Devices.

11. On or around 14 June 2021, the parent company of PEAL and Respironics, Koninklijke Philips N.V (**Royal Philips**), announced a global recall of certain ventilators, CPAP and BiPAP devices, including the Devices, due to the risks posed by the degradation of the PE-PUR foam. The stated risks included the emission of particulates that could be inhaled or ingested by the patients, potentially leading to patient harm. On 1 July 2021, the TGA issued two Recall Action Notifications in relation to the devices that were the subject of Royal Philips' recall announcement, including the Devices.

Non-compliance with the essential principles by reason of the PE-PUR Defect

12. In light of paragraphs 7 to 11 above:

    a. the intended use of the Devices included to assist patient breathing;

    b. when the Devices were used under the conditions and for the purposes for which they were intended, the PE-PUR foam used in them was susceptible to degradation when it reacted with moisture (hydrolysis);

    c. if the PE-PUR foam degraded, small particulates could be inhaled or ingested by patients. In addition, it could result in lower air flow or affect the Device's ability to provide therapy to published specifications;

d. the degraded PE-PUR foam potentially posed a biological risk to patients, including because inhalation or ingestion of particulates could result in the harm summarised at paragraph 8 above;

e. the probability of degradation, and consequential harm to the patients, was unacceptable, given the potentially serious consequences to patients;

f. by at least the start of the Relevant Period (2 June 2019), Respironics was on notice that the PE-PUR foam had a risk of degradation and a potential to cause harm to users, but failed to perform any, or any adequate, risk analysis; and

g. until at least June 2021, PEAL continued to supply the Devices with PE-PUR foam.

13. By reason of the matters set out at paragraphs 7 to 12 above, the Devices with the PE-PUR Defect did not comply with essential principles 1, 2, 3, 4, 7.1(a), 7.6 and/or 9.2.

D. Non-compliance with the essential principles by reason of the Silicone Delamination Defect

14. During the Relevant Period B, Respironics carried out a design change on Trilogy 100 Devices, which involved replacing the PE-PUR foam with silicone sound abatement foam. The silicone foam was secured in its housing using an adhesive tape. Respironics provided repair kits containing the silicone foam and adhesive tape to PEAL, which installed silicone foam in the devices (**Remediated Devices**). PEAL supplied the Remediated Devices on 417 occasions in Australia.

Risk of separation of the foam

15. By around 7 October 2022, PEAL identified that the silicone sound abatement foam being used in the Trilogy 100 Devices could separate from its housing, becoming detached directly under the blower (being the Silicone Delamination Defect). Once the foam became detached from the housing, it could move loosely in the inlet airpath housing, potentially obstructing that path. This defect could manifest within 30-90 days of use.

Potential harm to patients

16. If the silicone sound abatement foam was detached and able to move freely within the airpath, it could obstruct the airpath (thus decreasing the amount of air flowing into the device) or completely block it (preventing air from flowing into the device). This could lead to a low inspiratory pressure resulting in ventilation failure or underventilation. Ventilation failure or underventilation could in turn result in hypoventilation, hypoxemia, hypercapnia and asphyxia. There was a reasonable probability that the patient could experience such adverse health events.

Failure to conduct adequate risk analysis

17. Respironics and/or PEAL did not conduct adequate risk analysis of the use of the silicone foam with the adhesive and did not eliminate or reduce the risks posed by the Silicone Delamination Defect to the extent possible by adopting a policy of inherently safe design. The processes adopted to identify potential failures (including Device Failure Mode Effect Analysis procedures) were insufficient to ensure that risks were effectively mitigated once identified. In particular, the foam and adhesive tape specifications were not defined, which resulted in inadequate qualification and validation of the bond, leading to the separation of the adhesive from the foam.

Non-compliance with the essential principles by reason of the Silicone Delamination Defect

18. In light of paragraphs 15 to 17 above, the Remediated Devices with the Silicone Delamination Defect did not comply with essential principles 1, 2, 3, 4 and/or 6.

E. No consent or exemption

19. The Applicant did not consent to the supply of the Devices or the Remediated Devices for the purposes of s 41MAA(2)(c) of the TG Act.

20. In addition, for the purposes of s 41MAA(2)(d), the Devices and the Remediated Devices were not of a kind covered by an exemption in force under s 41GS of the TG Act.

F. The relief sought from the Court

21. The Applicant seeks the relief set out in the Originating Application.

G. The primary legal grounds for the relief sought

22. On each occasion that PEAL supplied a Device with the PE-PUR Defect during the Relevant Period A, it contravened s 41MAA(2) of the TG Act. For the reasons set out at paragraphs 7 to 12 above, the Devices did not comply with essential principles 1, 2, 3, 4, 7.1(a), 7.6 and/or 9.2. In addition, the Applicant did not consent to the supply of the Devices and the Devices were not covered by an exemption in force under s 41GS of the TG Act.

23. Further, on each occasion that PEAL supplied a Remediated Device with the Silicone Delamination Defect during the Relevant Period B, it contravened s 41MAA(2). For the reasons set out at paragraphs 15 to 17 above, the Remediated Devices did not comply with essential principles 1, 2, 3, 4 and/or 6. In addition, the Applicant did not consent to the supply of the Remediated Devices and those devices were not covered by an exemption in force under s 41GS of the TG Act.

H. The alleged harm

24. An objective of the essential principles is to ensure that medical devices perform as intended and that they are safe and effective. This is effected through a general requirement that medical devices supplied in Australia comply with the essential principles.

25. The supply of the Devices posed potential risk of harm to patients, as set out at paragraph 8 above. In addition, the supply of the Remediated Devices posed a risk of harm to patients as set out at paragraph 16 above.

Certificate of lawyer

I Rebecca Jaffe certify to the Court that, in relation to the concise statement filed on behalf of the Applicant, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 2 June 2025

Signed by Rebecca Jaffe

Lawyer for the Applicant

Appendix A – Number of instances of supply of Devices

ARTG ID	Model	Product Code	No. of Supply Contraventions		TOTAL
			PE-PUR	Silicone	
159490	Trilogy 100	AU1054096B	150	417	567
200289	BiPAP A40 (A-Series)	1111171	99	n/a	99
209934	DreamStation BiPAP ASV	AUX900T15	80	n/a	80
		AUX900T15C	263	n/a	263
285420	DreamStation AVAPS/ST Ventilator	AUX1131T15	323	n/a	323
327227	OmniLab Advanced +	1111127	43	n/a	43
295664	DreamStation CPAP	AUX400S15	180	n/a	180
		AUX400T15	2,363	n/a	2,363
		AUX400T15C	10,726	n/a	10,726
	DreamStation Auto CPAP	AUX500S15	110	n/a	110
		AUX500T15	2,658	n/a	2,658
		AUX500T15C	23,747	n/a	23,747
	REMstar Pro System One 60 Series	AU461TS	98	n/a	98
	REMstar Auto System One 60 Series	AU561S	1	n/a	1
		AU561TS	36	n/a	36
257012	DreamStation Auto BiPAP	AUX700T15	74	n/a	74
		AUX700T15C	203	n/a	203
257013	DreamStation Go	AUG400S15	359	n/a	359
		AUG500S15	764	n/a	764
		AUG400H15	353	n/a	353
		AUG500H15	1,217	n/a	1,217
		TOTAL	**43,847**	**417**	**44,264**

Appendix B – Particulars of Respironics' knowledge

The table below sets out examples of documents which show Respironics' knowledge of the PE-PUR Defect and/or its consequences. The documents below do not represent an exhaustive list.

Item	Date	Document	Connection with Respironics	Relevant information[1]
1	24 October 2013	Product Analysis Report with Notification Number: 305149147 (PAU.001.022.0022)	The report bears the "Philips" logo and identifies "Philips Respironics" as the manufacturer of the product being considered in the report.	This report refers to an incident in October 2013 in which a patient, who used a Trilogy 100 device, died (at 0025-0026). The report contains an email from [redacted], [redacted](a division of "Philips Electronics" (ie PEAL)), which notes that the cause of death was the patient going apneic (at 0023). The report also contains a questionnaire completed in October 2013, which identifies that the available information suggests that the device may have caused or contributed to the death (at 0026). The report states "*the device was disassembled and there was evidence of contamination and debris in the inlet air flow path, the impeller of the motor blower and the flow sensor assembly. Inside of the flow sensor assembly the flow straightener was occluded with contamination which would cause the lower flows on the output of the device*" (at 0036). This report further identifies that the device in question failed on the Trilogy Multi-Function Test Station because the test station did not attempt to test the positive flow verification steps, and negative flow verification steps failed, due to insufficient airflow caused by contamination from the degraded PE-PUR foam (at 0037).
2	30 August 2016	Report entitled 'Degradation of damping foam muffler respironics Trilogy Appliance' Report:	The report states that it is "Property of Koninklijke Philips N.V." and concerns "Respironics" devices.	The report states that "*polyester urethanes show bad resistance against high humidity in combination with high temperature*" (at 0493).

[1] The Applicant relies on the entirety of each document. The information in this column provides reference to some relevant information contained in each document.

		AST282T-161438 (PEA.002.001.0492)		
3	4 December 2017	Product Analysis Report with Notification Number: 307114335 (PAU.001.022.0060)	The report bears the “Philips” logo and identifies “Philips Respironics” as the manufacturer of the product being considered in the report.	This report refers to an instance from 2017 where a service technician “*replaced a worn out air path assembly*” on a Trilogy 100 device (at 0061). The technician identified that a build-up of degraded PE-PUR foam inside the blower box caused a device to malfunction, as it became stuck (at 0061). The report states: “*Performance testing of Blower motor troubleshooting procedure ER: 2217864 finds blower has an internal failure and is not producing therapy due to ingesting of the enclosure foam. Blower motor impeller completely consumed the enclosure foam rendering it locked*” (at 0071). The report also states that “*Vent Engineering confirmed foam appears environmentally degraded*” (at 0072). In addition, this report states: “*This issue could affect the devices ability to perform at published specifications*” (at 0062).
4	8 March 2018	Product Analysis Report with Notification Number: 307245191 (PAU.001.022.0090)	The report bears the “Philips” logo and identifies “Philips Respironics” as the manufacturer of the product being considered in the report.	This refers to a complaint from March 2018 involving a Trilogy 100 device in which the air path foam had disintegrated and was replaced by a technician to address the issue (at 0091). The report states: “*this type of failure could affect the ability of the device to provide therapy to published specifications*” (at 0091).
5	22 May 2018	'Exposure to Polyester-Polyurethane Foam Particulates from Trilogy 100 Inlet Air Path Foam Degradation: Biological Risk Assessment' (PEA.013.001.1787)	The report bears the “Respironics” logo. Authored by [redacted], who is addressed in Appendix D of the report as: [redacted].	The report observes that the inlet airpath foam of Trilogy devices was found to undergo degradation in 17 documented cases (at 1802-1803). The report states: “*This foam is an open-cell PE-PUR material that likely underwent hydrolysis leading to deposition of particulate matter throughout several Trilogy airpath components*” (at 1803).

6	15 June 2018	Health Hazard Evaluation in relation to the Trilogy 100 and 200 devices (PEA.013.001.1779)	The report bears the "Philips Respironics" logo. The report also identifies a number of contributors and persons who provided approvals, who held roles (among other things) in engineering and regulatory affairs.	The report refers to 17 instances of alleged degradation of the foam in the air inlet path foam of Trilogy devices (at 1780). The report identifies the cause of the hazard as continuous, long-term exposure to environmental conditions of high temperature combined with high humidity (at 1781). The report further states that this degradation could cause airborne particulates from the foam pad to enter Ventilator Breathing System (VBS) that could be introduced to the patient airway (see 1780, 1781).
7	19 June 2019[2]	Parent Child CAPA[3] Detail Report PR ID: 7211 (PEA.013.001.1705)	The report bears the "Philips" logo and refers to complaints being received by "Philips Respironics" (at 1708).	The report refers to two complaints received by Philips Respironics in April 2019 regarding degradation of the PE-PUR foam in a System One PAP device. The report states that: 1. Investigation determined the cause of the degradation was due to chemical breakdown of the foam from exposure to water, caused by long-term exposure to environmental conditions (at 1708). 2. The scope of the report was expanded beyond the Respironics System One device in the original complaint to include all Respironics devices which have the same material used for sound abatement foam (at 1708). The expanded scope "*would include certain Respironics Sleep Therapy, Ventilator, and Non- Ventilator devices"* (at 1708). Between April 2019 to April 2021, there had been ten reported cases of alleged harm for all impacted devices, which generally included complaints of headache, upper airway irritation, cough, chest pressure, and sinus infection (at 1708).
8	2 July 2020	Report entitled 'Exposure to Polyester-Polyurethane Foam Particulates From System One Foam	The report bears the "Respironics" logo.	This report addresses issues that arose in relation to four Positive Airway Pressure (**PAP**) devices: three DreamStation devices and a System One device (at 4864, 4865). The report identifies that the devices contained a PE-PUR foam and states:

[2] This is the date the report was "opened". It appears to have been open until 3 June 2022.
[3] Being a reference to corrective and/or preventative actions.

		Degradation: Biological Risk Assessment ER 2241475 v00' (PEA.001.002.4862)		1. The PE-PUR foam from those devices underwent analysis which confirmed degradation of the material via hydrolysis (at 4864). 2. The biological and toxicological risks from exposure to degraded PE-PUR foam were of concern and the severity of harm was crucial with respect to both the 30 kg and 70 kg patient populations of the System One medical device (at 4864). "*Based upon the high-level toxicological analysis, and the exposure calculations after adjustment for route of exposure and different foam degradation scenarios, there is evidence of toxicological risk from exposure to degraded PE-PUR foam and particulates*" (at 4886).
9	10 December 2020	Report entitled 'Degraded Polyester-Polyurethane Foam-Biological Risk Assessment' (PEA.001.002.4915)	The report bears the "Respironics" logo. Authored by [redacted], who is addressed in report as [redacted].	The report evaluates potential biological risks posed by the degradation of the PE-PUR foam. It states (at 4918): "*Philips Respironics Inc. (PRI) has received field reports of CPAP and ventilator units returned to service centers with degraded sound abatement foam. The sound abatement foam is a polyester based polyurethane (PE-PUR) foam located in the gas pathway of the device. The PE-PUR foam from these field returns previously underwent FTIR analysis which confirmed degradation of the material via hydrolysis*." The results summarised in the report do not appear to relate to PE-PUR foam used in a specific device but concern the PE-PUR foam used within "*the PRI* [Philips Respironics] *portfolio of CPAP and ventilator devices*" (at 4921). The report concludes the following (at 4918, 4932): *"Overall, based on an understanding of the toxicological significance of the foam degradants and the results of the ISO 10993 testing to include mutagenic responses in both a bacterial and mammalian system, the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam*."

10	26 April 2021	Health Hazard Evaluation entitled 'ER 2241623 – Foam Degradation in Trilogy Devices, Version 00' with REF QSP 7.3-286 (PEA.001.002.4817)	The report bears the "Philips Respironics" logo. The report also identifies a number of contributors and persons who provided approvals, who held roles (among other things) in engineering and regulatory affairs.	The report states that Philips Respironics initiated the Health Hazard Evaluation to evaluate potential foam degradation in the context of Trilogy devices (at 4819). The evaluation assesses the risks associated with physical exposure to foam particulates (at 4819). The report notes that "[a]*ll devices in the field and released in inventory currently using the polyester-based polyurethane foam (PE-PUR) could be subject to this potential failure mode*" (at 4817). The report notes that 66 complaints had been received in relation to foam degradation in the Trilogy devices (at 4825). While no harm was reported for Trilogy devices, 10 cases of harm were reported for PAP devices (at 4825, 4827). The report identifies the hazard as "*Biocompatibility / Toxicity of chemical constituents*" and describes the cause of the hazard as follows (at 4820): 1. "*Polyester-based polyurethane foam (PE-PUR) is used as a sound abatement foam in the Trilogy device airpath. Based on all available data generated to date, Philips Respironics determined that the PE-PUR foam's reaction with moisture (hydrolysis) was a source of the foam degradation potentially caused and/or exacerbated by the following factors:* 2. *Device operation in higher heat and humidity environmental conditions; and/or* 3. *Use of unapproved cleaning and disinfection methods with the Trilogy device (e.g. ozone)*." The report further states: 4. If the PE-PUR foam degrades, small particulates may be expelled from the device blower box, through the motor and patient circuit, and could enter the patient's respiratory tract and/or gastrointestinal tract (at 4820). 5. Harm resulting from short-term and intermediate exposure is "*exacerbation or worsening of the underlying patient condition*". Potential harms from short term and intermediate exposure include: irritation (skin, eye, and respiratory tract); inflammatory response;

				headache; asthma; effects on the reproductive system; and neoplasia. Harm resulting from long term exposure is cytotoxic, genotoxic, and potential carcinogenic effects (at 4821). 6. The estimated level for severity of harm was "*3 (crucial)*" for both short/intermediate and long-term exposure. The report states that both could result in "*serious injury*" being injury that is "*life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment*" (at 4821). 7. As for probability of harm, the likelihood of exposure was "*2 (occasional)*", meaning there is a "*remote probability*" that use would cause harm (at 4827, 4829). The report concludes that the hazards described in the report represent an unacceptable risk to patients (at 4830, 4832).
11	26 April 2021	Hazard Health Evaluation entitled 'ER 2241621 – Foam Degradation in PAP Devices, Version 00' with REF QSP 7.3-286 (PEA.020.001.0001)	The report bears the "Philips Respironics" logo. The report also identifies a number of contributors and persons who provided approvals, who held roles (among other things) in engineering and regulatory affairs.	The report concerns, among others, the following devices: SystemOne (Q-Series); DreamStation CPAP, Auto CPAP, BiPAP; and DreamStation Go CPAP, Auto CPAP (at 0001). The report states that Philips Respironics initiated the Health Hazard Evaluation to evaluate potential foam degradation in the context of PAP devices based on available data generated to date (at 0004). The evaluation assesses the risks associated with physical exposure to foam particulates (at 0004). In addition, the report notes that "[a]*ll devices in the field and released in inventory currently using the polyester-based polyurethane foam (PE-PUR) could be subject to this potential failure mode*" (at 0001). The findings set out in the report include: 1. Based on available data, "*Philips Respironics determined that the PE-PUR foam's reaction with water (hydrolysis) was a source of the foam degradation potentially caused and/or exacerbated by*" device operation in higher heat and humidity environmental conditions and/or use of unapproved cleaning and disinfection methods (for example, ozone) (at 0006).

				2. If the PE-PUR foam degrades, small particulates of the foam may be expelled from the device blower box, through the motor and patient circuit, and could enter the patient's respiratory tract and/or gastrointestinal tract (at 0006). 3. Harm resulting from short-term and intermediate exposure is "*exacerbation or worsening of the underlying patient condition*". Potential harms from short term and intermediate exposure include: irritation (skin, eye, and respiratory tract); inflammatory response; headache; asthma; effects on the reproductive system; and neoplasia. Harm resulting from long term exposure is cytotoxic, genotoxic, and potential carcinogenic effects (at 0007). 4. The estimated level for severity of harm was "*3 (crucial)*" for both short/intermediate and long-term exposure. The report states that both could result in "*serious injury*" being injury that is "*life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment*" (at 0007). 5. As for probability of harm, the likelihood of exposure was "*2 (occasional)*", meaning there is a "*remote probability*" that use would cause harm (at 0013, 0015). The report concludes that the hazards described in the report represent an unacceptable risk to patients (at 0016, 0018).
12	26 April 2021	Health Hazard Evaluation entitled 'ER 2241622 – Foam Degradation in NIV Devices, Version 00' with REF QSP 7.3-286 (PEA.020.001.0021)	The report bears the "Philips Respironics" logo. The report also identifies a number of contributors and persons who provided approvals, who held roles (among other things) in engineering and regulatory affairs.	This report concerns, among others, DreamStation ASV; DreamStation ST, AVAPS; A-Series BiPAP A40; and OmniLab Advanced+ (at 0021). The report states that Philips Respironics initiated the Health Hazard Evaluation to evaluate potential foam degradation in the context of non-invasive ventilator devices based on available data generated to date (at 0029). The evaluation assesses the risks associated with physical exposure to foam particulates (at 0029). In addition, the report notes that "[a]*ll devices in the field and released in inventory currently using the*

				polyester-based polyurethane foam (PE-PUR) could be subject to this potential failure mode" (at 0021). The findings set out in the report include: 1. Based on available data, "*Philips Respironics determined that the PE-PUR foam's reaction with water (hydrolysis) was a source of the foam degradation potentially caused and/or exacerbated by*" device operation in higher heat and humidity environmental conditions and/or use of unapproved cleaning and disinfection methods (for example, ozone) (at 0030). 2. If the PE-PUR foam degrades, small particulates of the foam may be expelled from the device blower box, through the motor and patient circuit, and could enter the patient's respiratory tract and/or gastrointestinal tract (at 0030). 3. Harm resulting from short-term and intermediate exposure is "*exacerbation or worsening of the underlying patient condition*". Potential harms from short term and intermediate exposure include: irritation (skin, eye, and respiratory tract); inflammatory response; headache; asthma; effects on the reproductive system; and neoplasia. Harm resulting from long term exposure is cytotoxic, genotoxic, and potential carcinogenic effects (at 0031). 4. The estimated level for severity of harm was "*3 (crucial)*" for both short/intermediate and long-term exposure. The report stated that both could result in "*serious injury*" being injury that is "*life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment*" (at 0031, 0034). 5. As for probability of harm, the likelihood of exposure was "*2 (occasional)*", meaning there is a "*remote probability*" that use would cause harm (at 0037).

				The report concludes that hazards described in the report represent an unacceptable risk to patients (at 0040, 0042).
13	November 2021 reporting on events from 2015 onwards	Observations of the US Food and Drug Administration (**FDA**) following an inspection of the Respironics facility between August and November 2021 (PEA.004.001.0051)	Authored by [redacted] FDA. Issued to [redacted]	This report identifies that: 1. In around November 2015, Philips Respironics became aware of a preventative maintenance servicing procedure implemented on Trilogy ventilator devices, in response to foam degradation issues and complaints (at 0052, 0071). The procedure was implemented by Philips Japan Ltd only in Japan (at 0052). 2. There were at least 14 instances, assessments and/or test reports between April 2016 and January 2021 where Respironics was aware of issues and concerns related to potential foam degradation and/or particulate emissions with various devices (at 0053), including: 3. A report dated August 2016, which focused on polyester polyurethane analysis and degradation stated, among other things, "*Polyester urethanes show bad resistance against high humidity in combination with high temperature*" (at 0054). o A report dated December 2018, which referred to the above analysis and noted that the problem was found to be hydrolysis of the polyester polyurethane foam, and the team was considering change to silicone foam (at 0055). o A report dated May 2019, which also referred to evidence of hydrolysis and stated, "*This chemical reaction can occur if the foam is constantly wet, i.e. expose[d] to high heat and humidity*" (at 0055). o A biological risk assessment dated July 2020, which stated, among other things, "*the biological and toxicological risks from exposure to degraded PE-PUR foam are of concern and the severity of harm is crucial with respect to both the 30 kg and 70*

				kg patient populations of the System One medical device" (at 0057). o A further report dated December 2020, which evaluated the potential biological risks posed by degraded PE-PUR foam and concluded that degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam (at 0057-0058). A report dated January 2021 referred to these findings and concurred with them (at 0058). o Toxicology reports dated 2021 considered that the foam was mutagenic (at 0059) and had cytotoxic potential (at -0060). A biological risk assessment dated 2021 stated, "*Overall, based on an understanding of the toxicological significance of the foam degradants and the results of the ISO 10993 testing to include mutagenic responses in both a bacterial and mammalian system, the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam*" (at 0060).