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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

ERIC WHINSTON and ROBIN WHINSTON **Plaintiffs** **v.** **KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; PHILIPS RS NORTH AMERICA, LLC (f/k/a RESPIRONICS, INC.); PHILIPS HOLDING USA, INC., AND PHILIPS RS NORTH AMERICA HOLDING CORP.** **Defendants**	:	**Case No.** '22CV1339 MMA MDD **PLAINTIFFS' COMPLAINT AND JURY DEMAND**

Plaintiffs Eric Whinston and Robin Whinston, by and through his undersigned counsel hereby submit the following Complaint and jury demand against Defendants Koninklijke Philips N.V., Philips North America LLC, Philips RS North America, LLC (f/k/a Respironics, Inc.), Philips Holding USA, Inc., and Philips RS North America Holding Corporation.

This litigation involves Plaintiff Eric Whinston's significant personal injuries

suffered as a result of his use of a defective continuous positive airway pressure (CPAP) Dreamstation medical device, which was recalled by Defendants on June 14, 2021. In support of their Complaint, Plaintiffs allege as follows:

PARTIES AND JURISDICTION

1. Plaintiff Eric Whinston is a resident and citizen of San Diego, California, in San Diego County.

2. Plaintiff Robin Whinston is a resident and citizen of San Diego, California, in San Diego County. Plaintiff Robin Whinston is the wife of Plaintiff Eric Whinston.

3. Plaintiffs allege an amount in controversy in excess of Seventy-Five Thousand dollars ($75,000), exclusive of interest and costs.

4. Defendant Koninklijke Philips N.V. ("Royal Phillips") is a public limited liability company established under the laws of The Netherlands, with is principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of the Philips Group of healthcare technology businesses, including its Connected Care business segment, which includes sleep and respiratory care.[1]

5. Royal Philips holds directly or indirectly 100% of its subsidiaries Philips North America, LLC and Philips RS North America, LLC.

6. Upon information and belief, Royal Philips controls Philips North America, LLC and Philips RS North America, LLC in the manufacturing, selling, distributing, and supplying of various medical devices, including mechanical ventilators, continuous positive airway pressure (CPAP) machines, and Bi-Level Positive Airway Pressure (Bi-PAP) machines.

7. Defendant Philips North America, LLC is a limited liability company organized under the laws of Delaware with is principal place of business in Cambridge, Massachusetts. Upon information and belief, the sole member of the

[1] Philips Annual Report, 2021.

LLC is Philips Holding USA, Inc., a corporation organized under the laws of Delaware with its principal place of business in Cambridge, Massachusetts. Defendant Philips North America, LLC is a resident of both Delaware and Massachusetts.

8. Defendant Philips RS North America, LLC is a limited liability company organized under the laws of Delaware with is principal place of business in Pittsburgh, Pennsylvania. Upon information and belief, the sole member of the LLC is Philips RS North America Holdings, a corporation organized under the laws of Delaware with its principal place of business in Cambridge, Massachusetts. Defendant Philips RS North America, LLC is a resident of Delaware, Pennsylvania, and Massachusetts.

9. Defendant Philips RS North America was formerly known as and operated under the business name Respironics, Inc. Royal Philips acquired Respironics in 2008 for approximately $5 billion. In October 2020, Respironics, Inc. changed its name to Philips RS North America. Defendant Philips RS North America Holding corporation was also formed in October 2020.

10. Defendant Philips Holding USA, Inc. is a corporation organized under the laws of Delaware with its principal place of business in Cambridge, Massachusetts. Defendant Philips Holding USA, Inc. is 100% directly or indirectly owned by Royal Philips. Defendant Philips Holding USA, Inc. is a resident of both Delaware and Massachusetts.

11. Defendant Philips RS North America Holding corporation is organized under the laws of the state of Delaware with its principal place of business in Cambridge, Massachusetts. Defendant Philips RS North America Holding corporation is 100% directly or indirectly owned by Royal Philips. Defendant Philips RS North America Holding corporation is a resident and citizen of both Delaware and Massachusetts.

12. Defendants Royal Philips, Philips North America, LLC, Philips RS

North America LLC, Philips Holding USA, Inc., and Philips RS North America Holding (hereinafter collectively "Defendants" or "Philips") develop, design, manufacture, market, distribute and sell various medical devices, including mechanical ventilators, CPAP machines, and Bi-PAP machines.

13. Defendants market, distribute, and sell their medical devices, including CPAP machines, in various states, including California, to consumers including Plaintiff Eric Whinston.

14. This Court has personal jurisdiction over Defendants, as Defendants purposefully availed themselves of conducting business and activities within this State regarding their marketing, distribution and sale of mechanical ventilators, CPAP machines, and Bi-PAP machines.

15. As a result of such actions by Defendants in this State regarding their marketing, distribution and sale of CPAP machines, Plaintiff Whinston used Defendants' defective CPAP machines and suffered personal injuries as a result.

16. Plaintiffs allege damages in excess of $75,000 exclusive of interest and costs.

17. This Court has jurisdiction pursuant to 28 U.S.C. § 1332, as complete diversity exists between Plaintiffs and Defendants and the amount in controversy exceeds $75,000.

18. Venue is proper within this district pursuant to 28 U.S.C. § 1391, because a substantial part of the events giving rise to this action occurred in this district.

FACTUAL BACKGROUND

19. Sleep apnea is a disorder in which breathing is disturbed temporarily during sleep. For patients with sleep apnea, breathing may stop or become very shallow when sleeping. Sleep apnea may be associated with fatigue, daytime sleepiness, interrupted sleep, or snoring, among other symptoms. Serious cases of sleep apnea may lead to hypertension, heart attack, or stroke, among other ailments.

20. Sleep apnea may be treated by continuous positive airway pressure (CPAP) therapy. In CPAP therapy, a machine delivers a continuous flow of air through a mask over the patient's nose and/or mouth, which assists breathing by increasing air pressure in the throat so that the airway does not collapse during inhalation.

21. Similar to CPAP machines, Bilateral Positive Airway Pressure (BiPAP) machines can also be used to treat sleep apnea. The main difference between the CPAP and BiPAP devices is that BiPAP machines have two pressure settings – one pressure for inhalation and a lower pressure for exhalation.

22. Patients who use CPAP or BiPAP machines typically use them every day/night. Sleep apnea symptoms may return quicky if therapy is discontinued. These devices are intended and designed to provide medical benefits to those who use them.

Defendants' Dreamstation CPAP and BiPAP medical devices

23. Defendants design, manufacture, distribute, and sell several CPAP and BiPAP machines used to assist people with sleep apnea, including their Dreamstation line of products.[2]

24. Defendants sought and obtained clearance from the Food and Drug Administration (FDA) in October 2013 to market its Dreamstation CPAP and BiPAP devices under Section 510(k) of the Medical Device Amendment to the Federal Food, Drug and Cosmetic Act. *See* 21 U.S.C. § 360 et seq.

25. The 510(k) approval process by the FDA is regarded as a simplified application process, which does not require extensive review and approval by the FDA. The 510(k) approval is basically a "grandfathering" process, in which the manufacturer is only required to demonstrate that the device to be marketed is

[2] In order to help protect its business and line of products, in June 2015, Defendant Royal Philips applied for a US Trademark for "DREAMSTATION" in connection with its line of CPAP medical devices sold and distributed in the United States. The "DREAMSTATION" trademark was granted in July 2016.

substantially equivalent to a device marketed prior to May 28, 1976, or substantially equivalent to a device which has already been found to be substantially equivalent through the 510(k) premarket notification process. If substantial equivalence is demonstrated, the FDA allows the product to be marketed but does not actually approve the design. The 510(k) approval process is rooted in a determination of "substantial equivalence" rather than safety and effectiveness. 21 CFR § 807.100.

26. While CPAP devices have been around since the mid-1980s, the original devices were generally large and noisy. Consequently, manufacturers worked to develop devices that were smaller and quieter.

27. In order to make their CPAP and BiPAP devices quieter, Defendants began using sound abating foam to help reduce the sound and vibration emitted from the motor and airflow of the machines. For the medical devices at issue in this litigation, Defendants designed and manufactured these machines with a polyester-based polyurethane (PE-PUR) sound abating foam.

28. In fact, Defendants advertised their Dreamstation device as "one of the quietest devices on the market" and "63% quieter" than the AirSense 10 machine from ResMed, a competitor of Defendants.[3]

29. While Defendants chose a polyester-based polyurethane for its sound abating foam in its Dreamstation CPAP medical devices, competitor ResMed manufacturers most of its CPAP medical devices with "a polyether polyurethane foam material that our team selected based on studies that show it's more resistant to water than alternative materials, and therefore is more durable in moist environments."[4]

30. The problem with polyester-based foams, as opposed to polyether-based foams, is it is highly susceptible to hydrolysis. Hydrolysis is a chemical reaction in

[3] Available at 62e4f43a1349489ba3cca77c0169c6ef.pdf (philips.com) (last accessed August 23, 2022.)

[4] Available at Other Manufacturer Recall 2021 - ResMed (last accessed August 29, 2022.)

which a molecule of water breaks one or more chemical bonds, thus resulting in a breakdown of the PE-PUR foam material. It is thought that if a humidifier is attached and used with the CPAP or BiPAP machine, the foam is at greater risk of breakdown.

31. Upon information and belief, the mixture of chemicals in Defendants' PE-PUR sound abatement foam also results in an acidic byproduct. The acidic byproduct can also speed up the process of hydrolysis and thus, faster degradation of the PE-PUR foam.

32. Upon information and belief, the natural air pressure across Defendants' PE-PUR sound abatement foam also chips away at the foam, resulting in degradation of the PE-PUR foam over time.

33. As a result of the foam degradation, tiny foam particles may enter the device's airy pathway and be ingested or inhaled by the user of the CPAP or BiPAP machine.

34. Defendants' PE-PUR sound abatement foam also releases (aka "off-gases") a number of harmful chemicals, also known as Violate Organic Compounds (VOCs), which may be inhaled or ingested by the CPAP or BiPAP user.

35. As a result of the PE-PUR foam off-gases and/or degradation, a number of toxic and harmful compounds including formaldehyde, adipic acid (AA), toluene diisocyanate (TDI), Toluene Diamine (TDA), Dimethyl Diazene (DD) and Diethylene Glycol (DEG), are released and potentially inhaled and/or ingested by the user of the CPAP and BiPAP machines.

36. Ingestion and/or inhalation of these chemicals are known to be hazardous to human health and can lead to a number of injuries, such as respiratory sensitization, respiratory irritation, skin sensitization, asthma, carcinogenicity, liver toxicity, kidney toxicity, reproductive toxicity, and genotoxicity.[5]

[5] Available at philips-respironics-update-on-pe-pur-testing-results-and-conclusions-available-to-date.pdf. (Last accessed August 26, 2022.)

Defendants' Recall And Prior Knowledge Of Risks Associated With PE-PUR Foam

37. In April 2021, Defendants issued their Quarterly report out of Amsterdam, which stated:

> Regulatory Update: Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use. The risks include that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone, and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation Dreamstation product family. Philips' recently launched next-generation CPAP platform, Dreamstation 2, is not affected. Philips is in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these possible risks.

38. Despite such statements being made by Defendants in April 2021, Defendants did not recall their Dreamstation CPAP and BiPAP machines at that time.

39. On June 14, 2021, Defendants issued a recall of their CPAP, BiPAP, and mechanical ventilator devices to "address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component of these devices."

40. Defendants issued the recall due to the risks posed to users from the PE-PUR foam, specifically the risk that "the PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone, and high heat and high humidity environments may also contribute to foam degradation."

41. The recall included CPAP, BiPAP, and mechanical ventilator devices manufactured between 2009 and April 26, 2021. The majority of CPAP and BiPAP

machines recalled were the Dreamstation line of products.[6]

42. Defendants' recall described the possible health risks to users: "The potential risks of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects. The potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects."

43. On July 8, 2021, Defendants provided supplemental clinical information for physicians and providers of CPAP, BiPAP and mechanical ventilator devices.[7] The supplemental information stated that "the degradative by-products of a PE-PUR foam after a humid ageing experiment were found to include diethylene glycol (DEG), toluene diamine isomers (TDA) and toluene diisocyanate isomers (TDI)." The clinical information also identified concerning chemicals from the off-gassing as dimethyl diazene and phenol 2.6-bis (1,1-dimethylethyl)-4-(1-methylpropyl).

44. On July 13, 2021, the FDA classified Defendants' recall as a Class 1 recall, the most serious type of recall, which indicates that use of the recalled devices may cause serious injury or death resulting from the inhalation or ingestion of PE-PUR foam particles or off-gassed chemicals.

45. Defendants knew or should have known about the potential health risks from the PE-PUR sound abatement foam used in their CPAP, BiPAP, and mechanical ventilator devices long before notifying the public on June 14, 2021.

46. Following the recall, FDA conducted an inspection of Defendants' manufacturing facilities in Pennsylvania. On November 9, 2021, FDA issued a 483

[6] Defendants' Dreamstation 2 line of CPAP medical devices, approved by the FDA for marketing in July 2020, were not included in the June 14, 2021 recall, as Defendants elected to use a silicon based sound abatement foam in the these CPAP devices, rather than the PE-PUR foam.

[7] Available at global-supplemental-clinical-information-document-070821-r6.pdf (philips.com) (last accessed August 23, 2022.)

Report detailing the observations during the inspection of Defendants' facilities.[8]

47. The FDA 483 Report details several observations related to Defendants' recalled ventilators, CPAP, and BiPAP devices, including: Defendants' risk analysis was inadequate; Defendants' procedures for corrective and preventative action (CAPA) have not been adequately established; Defendants' design validation did not ensure that their devices conformed to the defined user needs and intended uses; Defendants' procedures for design change have not been adequately established; and Defendants' management with executive responsibility had not ensured that the quality policy was understood, implemented and maintained at all levels of the organization.

48. In terms of Defendants' knowledge of problems associated with the degradation and off-gassing of its PE-PUR sound abatement foam, the 483 Report[9] notes several observations:

a. "Specifically, there were at least fourteen instances, assessments, and/or test reports, dated from 04/01/2016 to 01/22/2021, where your firm was aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions, with various Sleep and Respiratory care devices . . . ."

b. ". . . a Dreamstation 1 device failed emissions testing for VOCs and Aldehydes, which was analyzed/tested from 01/18/2019 to 01/25/2019. Specifically, Table 3 documents that the tolerable limits of the Formaldehyde compound were exceeded during initial operation, ..."

c. "Alternatively, your firm manufacturers various CPAP and BiPAP devices, which also include similar air path assemblies and/or the affected polyester polyurethane foam. Furthermore, per a complaint analysis conducted by your firm on April 9, 2021, your firm received

[8] An FDA Form 483 report is issued after an inspection by FDA personnel when an investigator has observed any condition(s) that may constitute violations of the Food Drug and Cosmetic Act. Available at FDA Form 483 Frequently Asked Questions | FDA.

[9] Form 483 Report available at Philips Respironics, Inc., Murrysville, PA. 483 dated 11/09/2021 (fda.gov) (last accessed August 25, 2022).

approximately eighty complaints related to foam degradation, on non-Triology ventilator devices, from 2014 to 2017."

d. "No formal investigation, risk analysis, or CAPA were initiated, performed, or documented, in response to the at least 222,000 complaints that could potentially be related to foam degradation and received from 2008 to 2017, prior to the initiation of CAPA INV 0988 in 2018."

e. "A query of your firm's consumer complaints from 01/01/2008 to current, for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, resulted in over 222,000 complaints, and over 175,000 of which occurred between 2008 to 2017."

f. "Furthermore, your firm performed a foam degradation-related complaint analysis, dated 04/09/2021, as part of CAPA 7211, and identified 1,254 complaints confirmed to be related to foam degradation from 2014 to April 2021."

g. "No formal CAPA was initiated or implemented, when appropriate. Specifically, email correspondence between your firm and your raw foam supplier beginning 10/30/2015 and forward, document that your firm was made aware of polyester polyurethane foam degradation issues in/around October 2015, which was later confirmed by your foam supplier on 08/05/2016, via email. Alternatively, no CAPA was initiated or implemented."

h. "Specifically, firm management, including management with executive responsibility, were aware of potential foam degradation issues concerning CPAPs, BiPAPs, and Trilogy ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021."

49. Despite Defendants' prior knowledge of potential problems with its PE-PUR sound abatement foam, Defendants took no action until June 13, 2021, to warn consumers, users, physicians, and/or suppliers of the potential health hazards associated with the use of its CPAP and BiPAP medical devices.

Federal Requirements

50. At all relevant times hereto, federal law required Defendants to comply with Current Good Manufacturing Practices ("CGMP") which are set forth in 21 CFR § 820 *et seq*.

51. Pursuant to 21 CFR § 820.5, Defendants are required to establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. *See* 21 CFR § 820.3(v).

52. Pursuant to 21 CFR § 820.22, Defendants are required to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

53. Pursuant to 21 CFR § 820.30(a), Defendants are required to establish and maintain procedures to control the design of their devices in order to ensure that specified design requirements are met.

54. Pursuant to 21 CFR § 820.30(c), Defendants are required to establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient.

55. Pursuant to 21 CFR § 820.30(d), Defendants are required to establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

56. Pursuant to 21 CFR § 820.30(e), Defendants are required to establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

57. Pursuant to 21 CFR § 820.30(f), Defendants are required to establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

58. Pursuant to 21 CFR § 820.30(g), Defendants are required to establish and maintain procedures for validating the device design. The design validation procedure must be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validations must ensure that devices conform to defined user needs and intended uses and must include testing of production units under actual or simulated use conditions.

59. Pursuant to 21 CFR § 820.30(h), Defendants are required to establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

60. Pursuant to 21 CFR § 820.30(i), Defendants are required to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

61. Pursuant to 21 CFR § 820.70(a), Defendants are required to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, Defendants are required to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls must include:

a. Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;

b. Monitoring and control of process parameters and component and device characteristics during production;

c. Compliance with specified reference standards or codes;

d. Approval of processes and process equipment; and

e. Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

62. Pursuant to 21 CFR § 820.70(b), Defendants are required to establish and maintain procedures for changes to a specification, method, process, or procedure.

63. Pursuant to 21 CFR § 820.70(g), Defendants are required to ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

64. Pursuant to 21 CFR § 820.72, Defendants are required to ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Defendants are required to establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained.

65. Pursuant to 21 CFR § 820.75(b), Defendants are required to establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Defendants are required to ensure that validated processes are performed by qualified individuals.

66. Pursuant to 21 CFR § 820.90, Defendants are required to establish and maintain procedures to control product that does not conform to specified requirements.

67. Pursuant to 21 CFR § 820.100, Defendants are required to establish and maintain procedures for implementing corrective and preventive action. The procedures must include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems;

b. Investigating the cause of nonconformities relating to product, processes, and the quality system;

c. Identifying the action(s) needed to correct and prevent recurrence of non-conforming product and other quality problems;

d. Verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished device;

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

g. Submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

68. At all relevant times hereto, Defendants failed to comply with the Current Good Manufacturing Practices ("CGMP") set forth above and in 21 CFR § 820 when designing, testing, manufacturing, inspecting, labeling, and distributing the Dreamstation CPAP medical devices. Accordingly, pursuant to 21 CFR § 820.1(c) Defendants' Dreamstation CPAP medical devices are adulterated under 21 U.S.C. § 351.

69. Likewise, Defendants' Dreamstation CPAP medical devices are adulterated because, among other things, they fail to meet established performance standards, and/or the methods, facilities or controls used for their manufacture,

packing, storage or installation and are therefore not in conformity with federal requirements. *See* 21 U.S.C. § 351.

70. Pursuant to federal law, Defendants' Dreamstation CPAP medical devices are misbranded because, among other things, the labeling is false and misleading and the devices are dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

Plaintiff Eric Whinston

71. In June 2016, Plaintiff Eric Whinston underwent a sleep study ordered by his physician. The sleep study demonstrated moderate obstructive sleep apnea and his physician recommended CPAP therapy.

72. Plaintiff Eric Whinston started using a Philips Dreamstation Auto CPAP with humidifier and heated tube in July 2016. (Exhibit A) (Ref # DSX500T11, Serial # J1655609675F8).

73. Plaintiff Eric Whinston used his Dreamstation CPAP medical device continuously from July 2016 until mid-June 2021, when he received notice of the recall.

74. In July 2021, Plaintiff Eric Whinston saw his primary care physician for a referral to a neurosurgeon to address his chronic back issues. As part of the work-up for the referral, Plaintiff's physician ordered an MRI and chest x-ray.

75. Plaintiff's physician noted the chest x-ray demonstrated interstitial pulmonary disease and referred Plaintiff Eric Whinston to a pulmonologist.

76. In October 2021, Plaintiff Eric Whinston was evaluated by a pulmonologist who noted Mr. Whinston had no past pulmonary issues but complained of shortness of breath for the last year and chronic cough, worsening over the past 5-6 months.

77. Plaintiff Eric Whinston's pulmonologist ordered a chest CT scan, which revealed combined emphysema with mild pulmonary fibrosis and a nonspecific 10 mm right upper lobe nodule.

78. Throughout late 2021 and early 2022, Plaintiff Eric Whinston continued treatment with his pulmonologist, who was monitoring his pulmonary fibrosis and providing recommended treatments and respiratory therapy.

79. In April 2022, Plaintiff Eric Whinston underwent another chest CT scan, which showed an increase in size of the right upper lobe nodule, worrisome for malignancy.

80. In May 2022, Plaintiff Eric Whinston underwent a PET scan, with showed increased FDG uptake, concerning for malignancy.

81. Subsequently, Plaintiff Eric Whinston consulted with an oncologist and on July 5, 2022, underwent a right upper lobe lobectomy to remove the concerning nodule. Pathology confirmed squamous cell carcinoma.

82. Plaintiff Eric Whinston continues to treat with his oncologist and pulmonologist.

83. Upon information and belief, Plaintiff Eric Whinston's Dreamstation CPAP device with PE-PUR sound abatement foam was defective resulting in the off-gassing of chemicals and foam degradation and was a proximate cause of his personal injuries, including but not limited to pulmonary fibrosis and squamous cell lung cancer.

84. Plaintiff Eric Whinston did not know and could not have reasonably known prior to the Defendants' recall on June 14, 2021, that Defendants' Dreamstation CPAP medical devices were not safe for use as the PE-PUR sound abatement foam was releasing dangerous chemicals and particles susceptible to inhalation or ingestion by users.

FIRST CAUSE OF ACTION

Strict Products Liability Failure to Warn

85. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

86. Defendants are the manufacturers, designers, marketers, distributors, and sellers of Dreamstation CPAP medical devices.

87. The Dreamstation CPAP medical devices manufactured, designed, marketed, distributed, and sold by Defendants were defective due to inadequate warning or instruction because at the time the medical devices left Defendants' control and was supplied to Plaintiff Eric Whinston, Defendants knew or should have known the medical devices were unreasonably dangerous and not reasonably suited for their intended use, as the PE-PUR sound abatement foam in these devices released dangerous chemicals and particles which could be inhaled or ingested by users.

88. Despite the fact that Defendants knew or should have known about the increased risk of serious adverse effects with their Dreamstation CPAP medical devices, Defendants failed to adequately warn users, including Plaintiff Eric Whinston, and/or their health care providers that the PE-PUR sound abatement foam released dangerous chemicals and particles which could be inhaled or ingested by users.

89. The Dreamstation CPAP medical devices manufactured, designed, marketed, distributed, and sold by Defendants were defective due to Defendants' failure to instruct Plaintiff Eric Whinston and/or his physicians on how to mitigate the risks associated with the releasing of chemicals and particles by the PE-PUR sound abating foam, such as instructing the user not to use the CPAP with the humidifier, which may speed up the process of hydrolysis.

90. The Dreamstation CPAP medical devices manufactured, designed, marketed, distributed, supplied, and sold by Defendants were also defective due to inadequate post-marketing warning or instruction, because after Defendants knew of the problems with the degradation and off-gassing of the PE-PUR sound abatement foam which increased the risk of serious health problems to users, Defendants failed to provide adequate and/or timely post-market warnings to such users and/or their health care providers.

91. The significantly increased risk of harm from the degradation and off-gassing of the PE-PUR sound abatement foam was not a known or obvious danger such that ordinary consumers like Plaintiff Eric Whinston would have been aware of such risks.

92. Based on Plaintiff Eric Whinston's diagnosis of sleep apnea by his physician and prescription for the use of a CPAP machine, Plaintiff was supplied Defendants' Dreamstation CPAP medical device, which he used for several years based upon Defendants' representations that it was safe and effective for the treatment of sleep apnea.

93. Had Plaintiff Eric Whinston and/or his physicians been aware of the serious safety risks associated with the use Defendants' Dreamstation CPAP medical device, he would not have been prescribed and would not have used the medical device and would have obtained a CPAP medical device from a different manufacturer.

94. Defendants' failure to give adequate warnings and instructions was a proximate cause of Plaintiff's injuries, including but not limited to: personal injury, bodily harm, emotional distress, pain and suffering, permanent physical injury, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

95. Defendants' conduct as alleged in this Complaint shows that Defendants acted with malice, oppression, fraud, and/or with a conscious disregard of the rights and safety of others, so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION

Strict Liability Manufacturing Defect

96. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

97. Defendants are the manufacturers, designers, marketers, distributors, and sellers of Dreamstation CPAP medical devices.

98. Defendants' CPAP medical devices, including the one used by Plaintiff Whinston, were defective in manufacture and construction when they left Defendants' hands in that they failed to comply with Defendants' own design specifications.

99. As a result of these manufacturing defects, Defendants' Dreamstation CPAP medical devices, including the one used by Plaintiff Eric Whinston, were unreasonably dangerous.

100. The manufacturing defects of Defendants' Dreamstation CPAP medical device were a proximate cause of Plaintiff's injuries, including but not limited to: personal injury, bodily harm, emotional distress, pain and suffering, permanent physical injury, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

101. Defendants' conduct as alleged in this Complaint shows that Defendants acted with malice, oppression, fraud, and/or with a conscious disregard of the rights and safety of others, so as to warrant the imposition of punitive damages.

THIRD CAUSE OF ACTION

Negligence

102. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

103. Defendants are the manufacturers, designers, marketers, distributors, and sellers of Dreamstation CPAP medical devices.

104. Defendants had a duty to exercise reasonable care in the design, manufacture, testing, sale and/or distribution of their Dreamstation CPAP medical

devices, including a duty to ensure that such devices did not pose a significantly increased risk of bodily harm and adverse events.

105. Defendants failed to exercise reasonable care in the design of their Dreamstation CPAP medical devices in that Defendants knew, or should have known, that polyester-based foam, as opposed to polyether-based foam, was highly susceptible to hydrolysis and, thus, degradation.

106. Defendants failed to exercise reasonable care in the design of their Dreamstation CPAP medical devices in that Defendants knew, or should have known, that the PE-PUR sound abatement foam used in their devices released dangerous chemicals and particles which could be inhaled or ingested by users.

107. Despite such knowledge, Defendants breached their duty to exercise reasonable care and continued to design their Dreamstation CPAP medical devices with PE-PUR sound abatement foam.

108. Defendants breached their duty to exercise reasonable care in the manufacturing of their Dreamstation CPAP medical devices as Defendants' medical devices failed to comply with Defendants' own design specifications.

109. Defendants breached their duty to exercise reasonable care in the sale and distribution of their Dreamstation CPAP medical devices in that Defendants knew or should have known the devices were not safe for their intended use, and Defendants failed to warn users and/or their health care providers that the PE-PUR sound abatement foam released dangerous chemicals and particles which could be inhaled or ingested by users.

110. Defendants breached their duty to exercise reasonable care in the sale and distribution of their Dreamstation CPAP medical devices in that Defendant knew or should have known the devices were not safe for their intended use, and Defendants failed to instruct Plaintiff Eric Whinston and/or his physicians on how to mitigate the risks associated with the releasing of chemicals and particles by the PE-

PUR sound abating foam, such as instructing the user not to use the CPAP with the humidifier, which may speed up the process of hydrolysis.

111. Defendants had a duty to inspect and/or test their medical devices to ensure they were safe for their intended use.

112. Defendants breached their duty to exercise reasonable care in the inspection and/or testing of their Dreamstation CPAP medical devices as Defendants knew or should have known that the PE-PUR sound abatement foam released dangerous chemicals and particles which could be inhaled or ingested by users.

113. Defendants knew or should have known that consumers such as Plaintiff Eric Whinston would foreseeably suffer injuries as a result of Defendants' failure to exercise reasonable care, as described above.

114. Defendants' negligence was a proximate cause of Plaintiff's injuries, including but not limited to: personal injury, bodily harm, emotional distress, pain and suffering, permanent physical injury, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

115. Defendants' conduct as alleged in this Complaint shows that Defendant acted with malice, oppression, fraud, and/or with a conscious disregard of the rights and safety of others, so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION

Breach of Express Warranty

116. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

117. Defendants are the manufacturers, designers, marketers, distributors, and sellers of Dreamstation CPAP medical devices.

118. At the time Defendants manufactured, designed, marketed, distributed, sold and/or supplied their Dreamstation CPAP medical devices, Defendants expressly warranted that their devices were safe and fit for use, they were of

merchantable quality, the risks associated with using their devices were minimal and comparable to other substantially similar CPAP devices, and they were adequately tested and fit for their intended use.

119. Defendants, in their user manual, expressly warranted that the Dreamstation CPAP medical device "shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale."

120. In reliance upon Defendants' express warranties, Plaintiff Eric Whinston used Defendants' Dreamstation CPAP medical device in a manner prescribed and directed and, therefore, in the foreseeable manner normally intended, recommended, promoted, and marked by Defendants.

121. Defendants' Dreamstation CPAP medical devices did not conform to Defendants' express warranties as the medical devices were not safe for their intended use, were not of merchantable quality, were not free from defects, and the risks of harm from use was unreasonable.

122. As a proximate result of Defendants' breach of express warranty, Plaintiff suffered damages, including but not limited to: personal injury, bodily harm, emotional distress, pain and suffering, permanent physical injury, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

FIFTH CAUSE OF ACTION

Breach of Implied Warranty

123. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

124. Defendants are the manufacturers, designers, marketers, distributors, and sellers of Dreamstation CPAP medical devices.

125. At the time Defendants manufactured, designed, marketed, distributed, sold and/or supplied their Dreamstation CPAP medical devices, Defendants

impliedly warranted that their devices were of merchantable quality and fit for their ordinary and intended use.

126. The Dreamstation CPAP medical devices manufactured, designed, marketed, distributed, sold and/or supplied by Defendants to Plaintiff Eric Whinston did not conform to their implied warranties and representations as such medical devices were not safe for use by consumers and posed an increased risk of physical injury.

127. As proximate result of Defendants' breach of express warranty, Plaintiff suffered damages, including but not limited to: personal injury, bodily harm, emotional distress, pain and suffering, permanent physical injury, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

SIXTH CAUSE OF ACTION

Loss of Consortium

1. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

2. Plaintiff Robin Whinston was married to Plaintiff Eric Whinston at all relevant times herein, including when Plaintiff Eric Whinston suffered his injuries.

3. As set forth above, Plaintiff Eric Whinston suffered injuries as a direct and proximate result of Defendants' actions.

4. As a direct and proximate result of the injuries suffered by Plaintiff Eric Whinston because of Defendants' actions, Plaintiff Robin Whinston has suffered loss of consortium injuries, including but not limited to, loss of love, companionship, comfort, care, assistance, protection, affection, society, and moral support.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against each of the Defendants individually, and jointly on each of the above-referenced claims and Causes of Action and further demands as follows:

1. Compensatory damages in excess of the $75,000 jurisdictional amount, including but not limited to compensation for injury, pain, suffering, mental anguish, emotional distress, loss of enjoyment of life, permanent physical injury, and other non-economic damages in an amount to be determined at trial of this action;

2. Economic damages in the form of reimbursement for costs associated with the use of Defendants' medical device, past and future medical expenses, out-of-pocket expenses, and other economic damages in an amount to be determined at trial of this action;

3. Punitive Damages;

4. Attorneys' fees, expenses, and costs of this action;

5. Pre-judgment and post-judgment interest; and

6. Such further relief as this Honorable Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury as to all issues which can be so tried.

RESPECTFULLY SUBMITTED,

/s/ *M. Elizabeth Graham*
M. Elizabeth Graham (SBN 143085)
GRANT & EISENHOFER P.A.
201 Mission Street, Suite 1200
San Francisco, CA 94105
Phone 415-229-9720
egraham@gelaw.com

Melanie. S. Bailey (OH 0075821)
BURG SIMPSON ELDREDGE HERSH & JARDINE, P.C.
201 East Fifth Street, Suite 1340
Cincinnati, OH 45202
Phone: (513) 852-5600
mbailey@burgsimpson.com

Luke T. Pepper (PA 87100)
BURG SIMPSON ELDREDGE HERSH & JARDINE, P.C.
40 Inverness Drive East
Englewood, CO 80112
Phone: (303) 792-5595
lpepper@burgsimpson.com

Exhibit A

DELIVERY RECEIPT

9524 Kearny Villa Road STE 107
STE 107
San Diego, CA 92126
800-758-7571

Branch: Advanced Homecare
Inv Location: Advanced Homecare
Date: 07/18/2016
CSR: Wayne, Chelsey
Order #: 96914
Patient ID: 39096
Customer #: 29205
Account #:
DOB: 11/21/1947
Gender: Male **Ht (in):** **Wt (lb):**

Bill To: Whinston, Eric K
12245 Candy Rose Ct
San Diego, CA 92131-
(858) 578-9684

Ship To: Whinston, Eric K
12245 Candy Rose Ct
San Diego, CA 92131-
(858) 578-9684

HIPAA Signature on file: Yes

Insurance: NORIDIAN HEALTHCARE SOLUTIONS (E) / AARP / United Healthcare (P)

Ord Qty	Del Qty	Type	Item	Ext. Allow	Ext. Amt.	Tax	Co-Pay
1	1	Rental	DSX500T11/RESP. DREAMSTATION AUTO APAP W/ A-FLEX, HH & SC Serial Number: J1655609675F8				
1	1	Purchase	DSXHCP/RESP. DREAM STATION HEATED HUMIDIFIER				
6	6	Purchase	1122519/RESP. DREAMSTATION FILTER				
1	1	Purchase	DREAMSTATION POLLEN/RESP. DREAMSTATION POLLEN FILTER				
1	1	Purchase	SYS1HT15/RESP. HEATED TUBING				
1	1	Purchase	100600C/DREAMSTATION CELLULAR MODEM Serial Number: WD2359869E02E				
1	1	Purchase	1105179/RESP. NUANCE PRO GEL FRAME				
1	1	Purchase	1105178/RESP. NUANCE PRO HEADGEAR				
6	6	Purchase	1105174/RESP. NUANCE MEDIUM NASAL PILLOW				
			Total				

Thank You For Your Business!!!

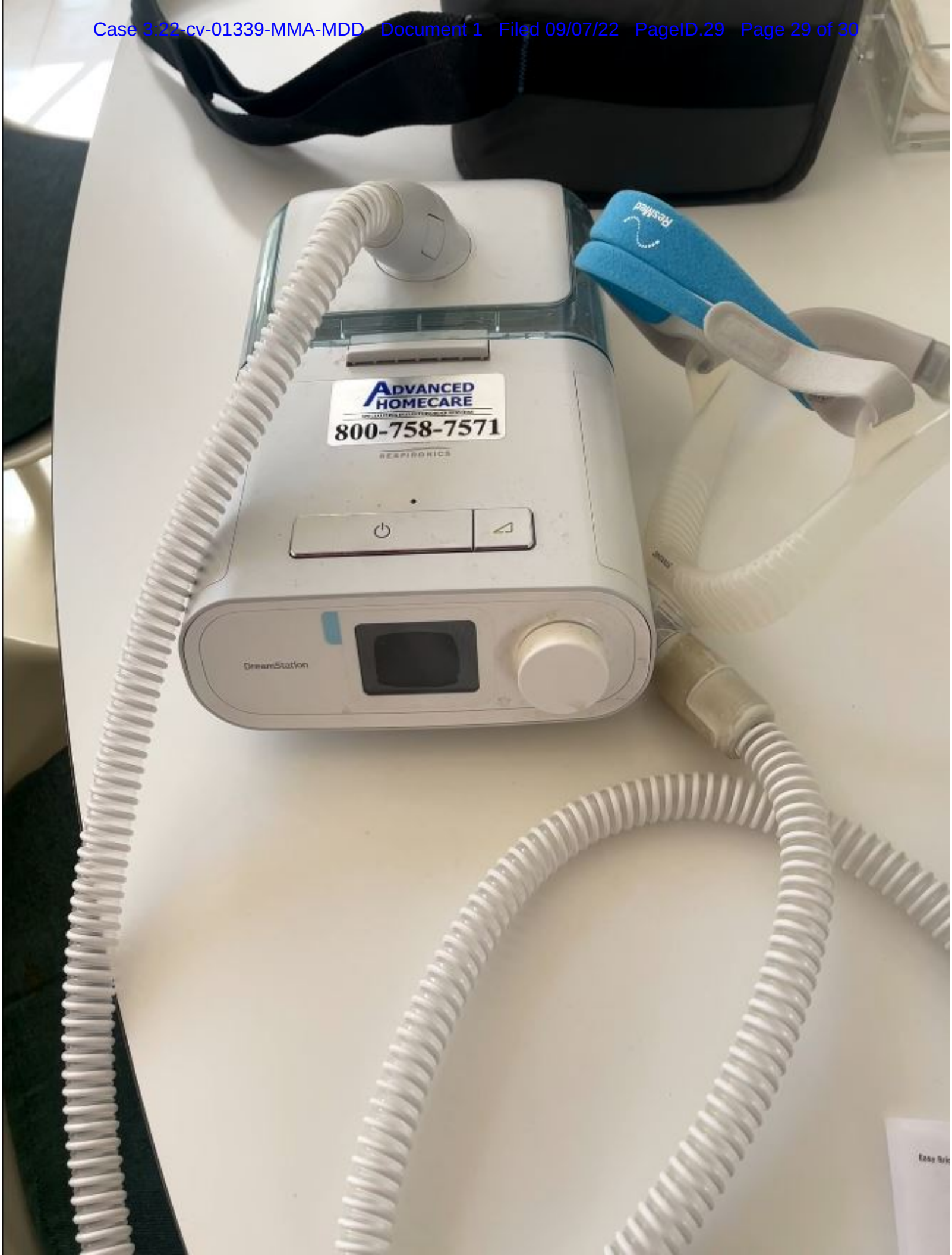
Signature
Whinston, Eric K

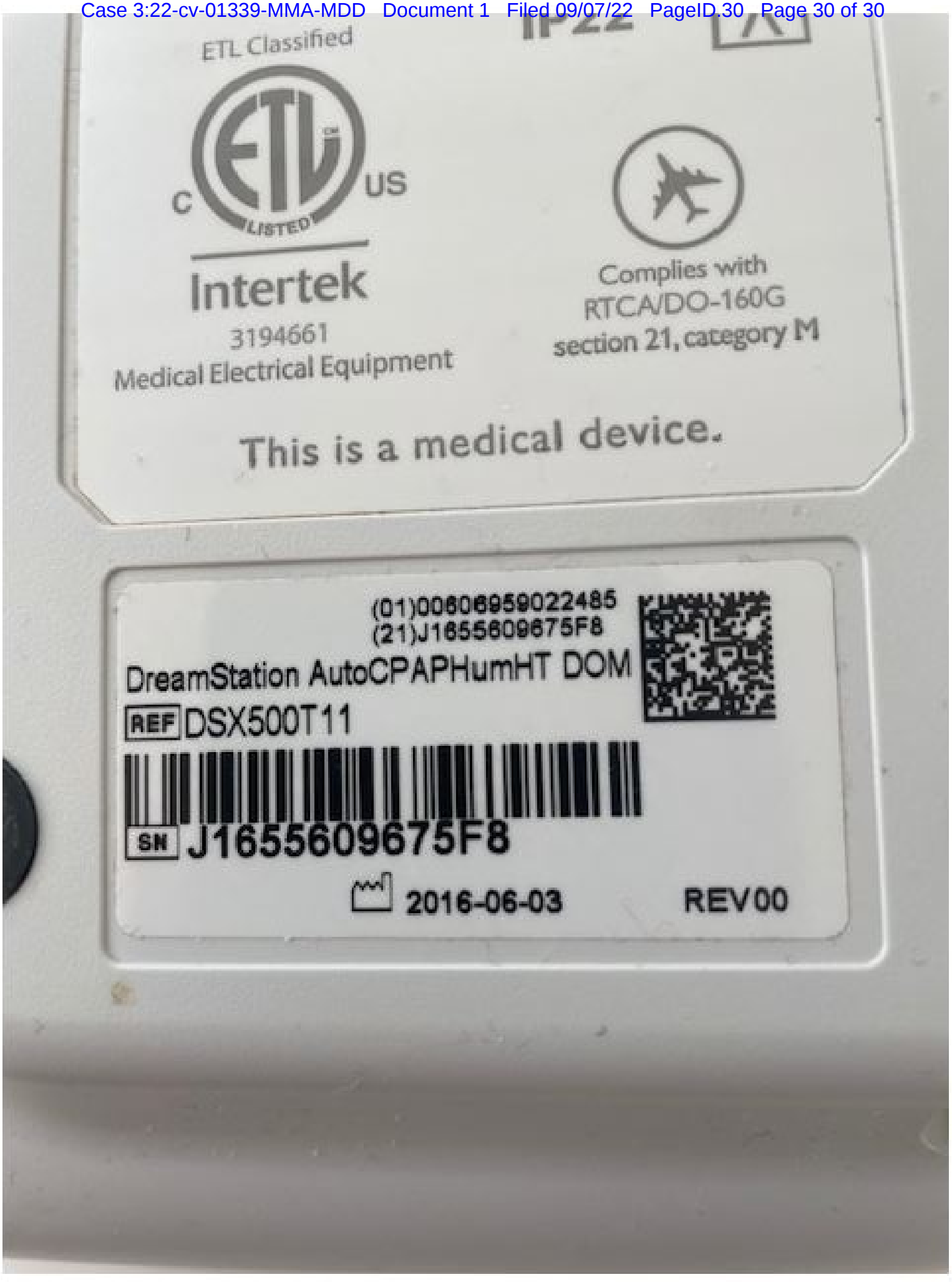
Date
07/18/2016 09:39

Tech Signature
San Diego Office Clinician

Relationship to Patient: Self

Reason patient could not sign:


ADVANCED HOMECARE
800-758-7571
RESPIRONICS
DreamStation


IP22
ETL Classified
C ETL US
LISTED
Intertek
3194661
Medical Electrical Equipment
Complies with
RTCA/DO-160G
section 21, category M
This is a medical device.
(01)00606959022485
(21)J1655609675F8
DreamStation AutoCPAPHumHT DOM
REF DSX500T11
SN J1655609675F8
2016-06-03
REV00