

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION**

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EDDIE BAILEY, on behalf of himself  
and all others similarly situated,

*Plaintiff,*

v.

SOCLEAN, INC.

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*Defendants.*

**Case No.**

**CLASS ACTION COMPLAINT**

**DEMAND FOR JURY TRIAL**

Plaintiff Eddie Bailey ("Plaintiff" or "Plaintiff Bailey"), on behalf of himself and the class of all others similarly situated as defined below, for his complaint against Defendant SoClean, Inc. ("SoClean"), alleges as follows:

**INTRODUCTION**

1. SoClean manufactures and markets devices used to clean continuous positive airway pressure ("CPAP") machines, which treat sleep apnea since approximately 2012. SoClean has used false and misleading representations about its devices to market the SoClean 2 CPAP Sanitizing Machine, the SoClean 2 Go CPAP Sanitizing machine, and their predecessor devices (collectively "the SoClean devices"). The SoClean devices work by generating ozone to sterilize and deodorize CPAP machines. Ozone (O<sub>3</sub>) is an unstable toxic gas with a pungent characteristic odor—sometimes described as "clean" smelling—that can kill bacteria and viruses. To be effective as a germicide, ozone must be present in a concentration far greater than can be safely tolerated by people or animals.

2. SoClean's marketing materials fail to disclose that its devices emit ozone, which is a longstanding requirement of federal law. Instead, SoClean falsely represents that its devices use

"activated oxygen" to clean CPAP machines. SoClean markets the devices as "safe" and "healthy," which is false give that they generate toxic ozone gas at levels that substantially exceed federal regulations. SoClean falsely represents that its devices use "no water or chemicals" or "no harsh chemicals" to clean CPAP machines, despite using ozone gas - a harsh chemical that causes respiratory problems in humans. SoClean represents that its devices use the same sanitizing process found in "hospital sanitizing," however, hospitals cannot and do not use ozone sanitizers in spaces occupied by patients. SoClean also claims that separately sold filters convert "activated oxygen" into "regular oxygen," which is false because SoClean's filters have no measurable effect on the device's ozone output. Finally, SoClean falsely claims that its devices are "sealed" such that "activated oxygen" (*i.e.*, ozone) does not escape the devices. SoClean devices are so dangerous and destructive that several of the largest manufacturers of CPAP machines in the United States require purchasers to acknowledge that they have been informed that if the purchaser uses a SoClean device to clean their CPAP machine, the warranty of their CPAP machine will be voided.

3. SoClean's misrepresentations have allowed it to command ninety-percent of the relevant market. Due to the nature of SoClean's business, its customers all have breathing problems for which they are receiving medical treatment in the form of CPAP therapy. If CPAP users knew that the SoClean devices generate unsafe levels of toxic gas, which is then pumped into their CPAP machines and into their bedrooms, they would find this risk material to their purchasing decisions.

4. SoClean's representations are designed to mislead consumers into believing that the machine uses a benign form of oxygen to clean CPAP machines rather than a harsh gas that is generally only suitable for commercial sanitization under highly controlled conditions. These

misrepresentations are made more egregious because the SoClean devices are designed and marketed for use on the consumer's bedside table and because CPAP users suffer from many symptoms that ozone exposure exacerbates - making the falsehoods especially reprehensible and dangerous.

### **PARTIES**

5. Plaintiff, Eddie. Bailey is an adult resident citizen of Flat Rock, Michigan.

6. Defendant SoClean, Inc., is a Delaware corporation with its principal place of business at 12 Vose Farm Road, Peterborough, New Hampshire 03458.

### **JURISDICTION & VENUE**

7. Subject Matter Jurisdiction. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d), because **(1)** the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs, (2) the action is a class action, (3) there are members of the Class who are diverse from Defendant, and (4) there are more than 100 class members.

8. Personal Jurisdiction. the Court has personal jurisdiction over SoClean because SoClean regularly conducts business in Michigan and because SoClean has falsely advertised the product to consumers who reside in Michigan, including consumers who reside in the Eastern District of Michigan. SoClean has also sold its products in the state of Michigan, including in the Eastern District of Michigan. In addition, SoClean committed tortious acts in Michigan, including in the Eastern District of Michigan, and Plaintiff's claims arise out of such acts, and/or because SoClean has otherwise made or established contacts in Michigan, including the Eastern District of Michigan, sufficient to permit the exercise of personal jurisdiction.

9. Venue. Venue is proper in this judicial district pursuant to 28. U.S.C. § 1391(d) and (c) and 18 U.S.C. § 1965, because SoClean is subject to personal jurisdiction in this judicial district and because a substantial part of the events giving rise to the claims in this action occurred in this judicial district. Specifically, SoClean has run television, online, radio, and print advertising campaigns to promote its products, which reach the millions of consumers who reside in the United States, including in the Eastern District of Michigan.

### **FACTUAL ALLEGATIONS**

10. SoClean manufactures and sells medical devices that clean continuous positive airway pressure ("CPAP") machines. Plaintiff is the owner of a SoClean CPAP cleaning device and has used that device on a regular basis since he purchased the device.

#### **I. Continuous Positive Airway Pressure Therapy**

11. Continuous Positive Airway Pressure ("CPAP") therapy is a common nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a hose and a nasal or facemask device that delivers constant and steady air pressure to an individual's throat to help individuals breathe.

12. Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual's airway can reopen. Often these interruptions are so brief that the individual will not remember. Despite the brevity of the interruptions, the sleep cycle disruption caused by sleep apnea can dramatically impact a person's lifestyle, including negatively impacting

energy, mental performance, and long-term health. CPAP therapy helps treat sleep apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

## **II. Bi-Level Positive Airway Pressure Therapy**

13. Bi-Level Positive Airway Pressure ("BiPAP") therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or face mask device to maintain air pressure in an individual's airway. BiPAP therapy is distinguishable from CPAP therapy, however, because Bi-Level PAP devices deliver two alternating levels - inspiratory and expiratory - of pressurized air into a person's airway, rather than the single continuous level of pressurized air delivered by a CPAP device. The inspiratory positive airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. Bi-Level PAP devices deliver one level of pressurized air (the inspiratory positive level) to assist as the person inhales, and another level (the expiratory level) as a person exhales.

## **III. Mechanical Ventilation**

14. Mechanical ventilation is a treatment to help a person breathe when they find it difficult or are unable to breathe on their own. A mechanical ventilator pushes airflow into the patient's lungs to help them breathe. Mechanical ventilation may be invasive ventilation with a tube inserted into the patient's airway, performed in the intensive care unit in the hospital or a long-term institutional setting. Non-invasive ventilation can be used at home by people with respiratory difficulties.

## **IV. The Market for CPAP Sanitizing Devices**

15. The SoClean devices are compatible with many brands of CPAP machines.

16. An estimated 8 million people in the United States use a CPAP machine.

17. CPAP machines are most commonly prescribed for sleep apnea, a potentially serious disorder in which an individual's breathing repeatedly stops and starts while sleeping. the most common form of sleep apnea is caused by airway obstruction.

18. CPAP machines are also used to treat diseases such as pulmonary fibrosis and Chronic Obstructive Pulmonary Disease ("COPD"), an umbrella term used to describe progressive lung diseases characterized by increasing breathlessness.

19. While sleeping, a CPAP user wears a face mask, which is attached by a hose to a machine that pressurizes air.

20. Room air is drawn into the CPAP machine through an air intake and, once inside, the machine pressurizes the air. *See* Ex. A (Airflow Diagrams), Figure 1.

21. The pressurized air is then pumped from the CPAP's air outtake, through a hose, and into the facemask, delivering just enough air pressure to keep the user's upper airway passages open while sleeping. *See* Ex. A (Airflow diagrams), Figure 1.

22. Some CPAP machines also include a heated humidifier that is either fully integrated into the machine or easily attached. Use of the humidifier is optional; generally, it can either be turned off or detached.

23. Many CPAP users concerned with health and cleanliness are interested in regularly sanitizing or disinfecting their CPAP equipment.

24. The SoClean devices use ozone gas in an attempt to clean CPAP equipment.

25. The SoClean 2 and the SoClean 2 Go work similarly, but the SoClean 2 Go is a smaller, more portable version. *Compare* Ex. B (SoClean 2 Photos), *with* Ex. C (SoClean 2 Go Photos).

26. The SoClean devices are Class 1 medical devices subject to the Medical Device Amendments to the Food, Drug and Cosmetic Act ("FDCA") and the implementing regulations promulgated by the Food and Drug Administration ("FDA").

27. As Class I medical devices, the SoClean devices are not subject to premarket review by the FDA.

**V. FDA Regulation of Ozone**

28. All medical devices must comply with the FDA's Maximum Acceptable level of Ozone Rule, 21 C.F.R. § 801.415 (2019).

29. The FDA's Maximum Acceptable Level of Ozone requirements took effect in 1974. *See* FDA Final Rulemaking: Ozone Generators and Other Devices Generating Ozone, 39 Fed. Reg. 13773-74 (Apr. 17, 1974).

30. The FDA has determined that "[o]zone is a toxic gas." 21 C.F.R. § 801.415(a).

31. The FDA initially regulated ozone in medical devices because "[i]n order for it to be effective as a germicide, ozone must be present in a concentration far greater than that which can be safely tolerated by man and animals." FDA Notice of Proposed Rulemaking, 37 Fed. Reg. 12644 (June 27, 1972); *accord* 21 C.F.R. § 801.415(a) (same).

32. The FDA found that "in tests conducted to study the bactericidal properties of ozone, test animals have died before the bacteria were completely destroyed." FDA Notice of Proposed Rulemaking, 37 Fed. Reg. 12644 (June 27, 1972).

33. The FDA has determined that ozone exposure causes "undesirable physiological effects on the central nervous system, heart, and vision" and "the predominant physiological effect of ozone is primary irritation of the mucous membranes. Inhalation of ozone can cause sufficient irritation to the lungs to result in pulmonary edema." 21 C.F.R. § 801.415(b).

34. FDA regulations make it illegal for a medical device to "generate[] ozone at a level in excess of .05 part per million by volume of air circulating through the device...." 21 C.F.R. § 801.415(c)(1).

35. FDA regulations make it illegal for a medical device to "cause[] an accumulation of ozone in excess of .05 part per million by volume of air ... in the atmosphere of enclosed space intended to be occupied by people for extended periods of time, e.g., houses, apartments, hospitals, and offices." 21 C.F.R. § 801.415(c)(1).

36. FDA regulations make it illegal for a medical device to "generate ozone and release it into the atmosphere in hospitals or other establishments occupied by the ill or infirm." 21 C.F.R. § 801.415 (c)(2).

37. FDA regulations make it illegal for a medical device "[t]o generate ozone and release it into the atmosphere and does not indicate in its labeling the maximum acceptable concentration of ozone which may be generated (not to exceed .05 part per million by volume of air circulating through the device) as established herein and the smallest area in which such device can be used so as not to produce an ozone accumulation in excess of .05 part per million." 21 C.F.R. § 801.415(c)(3).

## VI. Ozone Gas

38. Ozone (O<sub>3</sub>) is an unstable blue gas with a pungent characteristic odor.

39. Ozone gas forms when oxygen molecules (O<sub>2</sub>) interact with electricity and recombine with oxygen atoms (O) to form ozone (O<sub>3</sub>).<sup>1</sup>

40. Because ozone is an unstable gas, over time it gradually breaks down by recombining with other molecules to re-form oxygen (O<sub>2</sub>).

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<sup>1</sup> Oxygen atoms (the "O" on the periodic table of elements) and oxygen molecules (the O<sub>2</sub> that we breathe are both commonly called oxygen.



41. In still air at room temperature, studies show it can take up to twenty-five hours for ozone levels to reduce by half,<sup>2</sup> and ozone continues to break down at this rate until it dissipates.

42. When ozone encounters organic material, its third oxygen atom can detach from the ozone molecule and re-attach to molecules of the other substance, thereby altering the chemical composition of the other substance.

43. This reaction, called oxidation, can kill bacteria, viruses, and odors.

44. In sufficiently large quantities, ozone is also toxic to human beings.

45. In smaller quantities, breathing ozone for even a short time can cause adverse health consequence in human beings.

46. Ozone inhalation predominantly affects the respiratory system, and can cause irritation, pulmonary edema, and reduced lung function.

47. Breathing ozone can cause cough and shortness of breath.

48. Breathing ozone can compromise the body's ability to fight respiratory infections.

49. Breathing ozone can worsen asthma symptoms.

50. Breathing ozone can worsen symptoms in people with heart disease.

51. Ozone can react with other chemicals in the air to produce additional chemicals and fine particles that can also be irritating to the eyes, nose, throat, and lungs.

## **VII. SoClean's CPAP Sanitizing Process**

52. The SoClean devices sanitize CPAP machines by generating ozone and circulating it throughout the user's CPAP equipment.

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<sup>2</sup> J.D. McClurkin & D.E. Maier, Half-Life time of Ozone as a Function of Air Conditions and Movement, Presentation at the 10<sup>th</sup> Int'l Working Conf. on Stored Product Protection (2010), <http://works.bepress.com/dirk-maier/44/> (finding that ozone's half-life varies based on atmospheric conditions with a maximum half-life of 1,524 minutes (25 hours) in dry still cool air).

53. The SoClean devices work on a variety of different CPAP models and can be used on CPAPs with or without humidifiers.

54. Each SoClean device features an ozone generator, a black hose with a connector, and a chamber. *See* Ex. B (SoClean 2 Photos), Figure 1; Ex. C (SoClean 2 Go Photos), Figures 1-2.

55. The SoClean 2 has a hard-plastic box as the chamber. *See* Ex. B (SoClean 2 Photos), Figures 1-2.

56. Inside the SoClean 2's chamber, there is a spot for a filter cartridge. *See* Ex. B (Photos of SoClean 2 Device), Figure 1.

57. The SoClean 2 Go uses a cloth bag with a draw string as the chamber. *See* Ex. C (SoClean 2 Go Photos), Figures 1,4.

58. On the SoClean 2 Go's cloth chamber, there is an outside pocket for a filter cartridge. *See* Ex. C (Photos of SoClean 2 Go Device), Figure 4.

59. The approximately 3.5" long and 1" square filter cartridges consist of a plastic shell filled with granulated charcoal.

60. SoClean makes and markets replacement filter cartridges to SoClean owners and represents that the filter must be replaced every six months for the life of the machine.

61. To set up a SoClean device initially, a user connects the black hose to his CPAP tank's air output opening, where the face-mask hose also attaches. *See* Ex. B (SoClean 2 Photos), Figure 3; *See* Ex. C (SoClean 2 Go Photos), Figure 2.

62. Connecting the black hose sometimes requires an adapter specific to the user's CPAP model.

63. Once connected, the black hose remains attached to the user's CPAP even while the SoClean device is not in use.

64. SoClean recommends that its customers run at least one cleaning cycle every day.

65. During a cleaning cycle, the SoClean device actively generates ozone for approximately 7 to 14 minutes.

66. To run a cleaning cycle, the user places his face mask into the SoClean device's chamber and closes the lid or draw string. *See* Ex. B (SoClean 2 Photos), Figure 2; Ex. C (SoClean 2 Go Photos), Figure 1.

67. The user can then manually initiate a cleaning cycle by pressing a button or series of buttons.

68. Alternatively, the SoClean 2 automatically runs a cleaning cycle every day when its digital clock reads 10:00 AM.

69. When a cleaning cycle starts, the SoClean device begins generating a large quantity of ozone gas that travels through the black hose into the CPAP's tank.

70. From the CPAP's tank, some of the ozone travels to the face mask and accumulates inside the SoClean device's chamber.

71. By design, this process inundates the CPAP mask, hose, and tank with ozone, killing bacteria, viruses, and odors found within.

72. During a cleaning cycle, the SoClean 2 consistently generates 30 ppm of ozone by volume of air circulating through the device. *See* Ex. D (SoClean 2 Lab Reports) at 1.

73. And within a SoClean device's chamber, 140 ppm of ozone accumulates during a cleaning cycle.

74. During and after a cleaning cycle, ozone escapes a SoClean device in two ways.

75. First, ozone is pumped into the user's CPAP machine and, because CPAP machines are not airtight, that ozone vents into the user's bedroom.

76. This occurs because a CPAP machine has an open air path between its air intake (where room air enters the machine to be pressurized) and its air outlet (where the face mask and the SoClean device connect to the machine). *See* Ex. A (Airflow Diagrams), Figure 1.

77. Accordingly, ozone that enters the CPAP's air outlet (where the SoClean and face mask attach) can freely escape through the CPAP's air-intake opening. *See* Ex. A (Airflow Diagrams), Figure 2.

78. Anyone in proximity to the device can then inhale the escaped ozone.

79. SoClean users generally keep their SoClean devices attached to their CPAP machines in the bedroom on a bedside table, as consistently depicted by SoClean in marketing materials. *See, e.g.,* Ex. F (SoClean Marketing Materials), Figures 1-2.

80. When a SoClean 2 is run for 12 minutes, 28 ppm of ozone escapes the device and accumulates in a 50-liter Teflon chamber-with or without a filter cartridge installed. *See*, Ex. D (SoClean 2 Lab Reports) at 2-3.

81. This is 560 times the FDA's limit on ozone generation and accumulation by medical devices. *See* 21 C.F.R. § 801.415(c)(1).

82. When a SoClean 2 Go is run for 10 minutes, 5.6 ppm of ozone escapes the device and accumulates in a 27-liter glass chamber- with or without a filter cartridge installed. *See*, Ex. E (SoClean 2 Go Lab Report).

83. This is 112 times the FDA's limit on ozone generation and accumulation by medical devices. *See* 21 C.F.R. § 801.415 (c)(1).

84. Second, ozone remains in the CPAP mask, hose, and tank after a cleaning cycle.

85. During normal CPAP use, the user inhales this leftover ozone through the face mask as air from the CPAP machine flows into the mask.

86. SoClean does not advise users of the risk posed by remaining ozone.

87. Buried in the user guides, SoClean advises users to leave the mask in the SoClean device for two hours "to achieve maximum sanitizing," SoClean 2 Go User Guide at 12, or so that "all disinfecting is complete," SoClean 2 User guide at 16.

88. The SoClean 2 Go User Guide never warns that the two-hour post-cycle waiting period is intended to avoid exposure to unsafe levels of toxic gas. The SoClean 2 User Guide, in an unrelated FAQ on page 18, states: "The activated oxygen disinfects your equipment and naturally breaks down to regular oxygen within two hours." However, the SoClean 2 User Guide never links the waiting period is intended or required to allow toxic gas to dissipate.

89. But the ozone within the CPAP mask, hose, and tank does not breakdown within two hours.

90. During testing, ozone levels remain at 3 ppm two hours after a SoClean's cleaning cycle was complete. *See* Ex. D (SoClean 2 Lab Reports) at 4.

91. When using their CPAP after a cleaning cycle, users often complain of a strong odor.

92. The odor is attributable to ozone gas that remains in the CPAP mask, hose, and tank.

93. The FDA's Maude database, where consumers can report adverse experiences with medical devices, contains the following consumer complaints about SoClean, which are attributable to the adverse effects of unwitting ozone exposure:

- a. "I purchased a soclean c-pap-cleaner. I followed all of the directions i.e., preashed the unit, hoses etc. I then cleaned the cpap machine using

soclean at the recommended settings. That evening i slept with the cleaned machine. The smell of ozone was strong. The mfr calls ozone activated oxygen. After about 6 hours, i experienced a severe asthma attack which i have never had before. Treatment with rescue inhaler, steroids, bronchodilators. I have cough predominant asthma. The coughing was so severe that i injured my back."<sup>3</sup>

- b. "Purchased a soclean 2 cpap sanitizer from apria direct health care. Upon using machine a strong odor was noted on mask, but was told this was normal and that it was like the ocean smell. After the first week i began having trouble with my breathing. It continued to get worse. Started breathing treatments and prednisone did not help. I then found out that they used ozone to sanitize the cpap machine. Checked the (b)(6) clinic web site only to find ozone is an irritant and can cause asthma attacks. Called apira direct and they told me to return the machine. They do not advise you of this danger. I ended up in an urgent care center today for the asthma attack."<sup>4</sup>
- c. "After approximately 3 months of using soclean 2 cpap cleaner i noticed i was getting sick, started having chest pains for short periods of time each day and felt tired all the time. After research of the product, found it uses ozone to disinfect and found i had most of the symptoms of excess ozone in my system. After 3 days of not using it i am feeling much better with no instances of chest pain and my cold is going away along with my lungs clearing up. I will be seeing my doctor in 2 weeks to be referred to a cardiologist for assessment."<sup>5</sup>
- d. "I used the soclean cpap cleaning machine, after i purchased it for (b)(6). It used ozone to cleanse cpap machine. There was ozone residue left in my cpap after using the soclean, and that ozone residue burned my sinuses and lungs. This product is hazardous to people's respiratory systems and it causes pain. It caused me severe pain. This product is unregulated and it should be regulated. I went to the doctor and was told to discontinue use of the soclean machine."<sup>6</sup>

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<sup>3</sup> MAUDE Adverse Event Report: Inceptus SoClean 2, FDA (Sept. 10, 2016), [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mcldrfoi\\_id=5969746&pc=LRI](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mcldrfoi_id=5969746&pc=LRI).

<sup>4</sup> MAUDE Adverse Event Report: SoClean2 CPAP Sanitizer, FDA (Mar. 12, 2018), [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi\\_id=7472673&pc=LRI](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7472673&pc=LRI).

<sup>5</sup> MAUDE Adverse Event Report: SoClean Inc. SoClean Disinfectant, Medical Devices, FDA (Mar. 12, 2018), [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi\\_id=7352173&pc=LRI](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7352173&pc=LRI).

<sup>6</sup> MAUDE Adverse Event Report: SoClean Inc. SoClean CPAP Cleaning Machine Disinfectant, Medical Devices, FDA (May 1, 2017), [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi\\_id=7805317&pc=LRI](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=7805317&pc=LRI).

- e. "I purchased a soclean2 pap disinfecting device on (b)(6) 2018, from (b)(6) center in (b)(6), to clean my cpap unit. Since using the product from that time, i have noticed my sense of taste and smell have diminished dramatically as well as a very dry and an unusual taste in my mouth. Everything i eat tastes bland. Can you tell me if this product has side effects that are causing me these issues? i have not changed anything else in my diet. Including no new medications. Is there residue left from the cleaning that are irritating my mucous membranes? i have appointments to see a pulmonary and nose/throat specialist as well as my dentist to rule out any other medical issues. As i mentioned before, there have been no changes to my diet or lifestyle and current blood tests show no issues."<sup>7</sup>
- f. "Since using soclean to disinfect my cpap i suffer difficulty and pain breathing. My lungs hurt. Shortly after waking in the morning i have nausea. Fda safety report id# (b)(4)."<sup>8</sup>
- g. "I have been using the soclean cpap sanitizer for a little over 7 months and have been getting headaches and sinus issues lately. I thought it was related to spring allergies but after researching it seems that the ozone remaining in the sanitizing unit could be the culprit. Fda safety report id # (b)(4)."<sup>9</sup>
- h. "Used a soclean 2 last night. It disinfected at 10:00am on (b)(6) 2021 and i went to bed at 10:00pm and when i put the mask on it had a strong odor. I put the mask on and eventually the smell went away. Used my cpap machine through the night. The next day, i was having trouble breathing and my lungs don't feel right. I used one time and my breathing is terrible. I am needing an inhaler. I am returning the product to apriadirect where i purchased it from. I called them and told them what happened and i need to return it. They just wanted to sell me a different machine. I will clean it myself going forward."<sup>10</sup>
1. "Used the soclean 2 cpap cleaning machine. The first night i immediately felt a headache (i suffer from migraine). The headache

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<sup>7</sup> MAUDE Adverse Event Report: SoClean, Inc SoClean2 CPAP Sanitizing Machine Disinfectant Medical Devices, FDA (Feb. 20, 2019), [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi\\_id=8377760&pc=LRI](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8377760&pc=LRI).

<sup>8</sup> MAUDE Adverse Event Report: SoClean, Inc. SoClean2 Disinfectant, Medical Devices, FDA (Apr. 1, 2021), [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi\\_id=12075158&pc=LRI](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=12075158&pc=LRI).

<sup>9</sup> MAUDE Adverse Event Report: SoClean, Inc. SoClean CPAP Sanitizer Disinfectant, Medical Devices, FDA (May 3, 2021),

[https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi\\_id=11938365&pc=LRI](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=11938365&pc=LRI).

<sup>10</sup> MAUDE Adverse Event Report: SoClean, Inc. SoClean 2 Disinfectant, Medical Devices, FDA (May 27, 2021), [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi\\_id=11912835&pc=LRI](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=11912835&pc=LRI).

would last the majority of the next day and return each night. Night five, i had no headache when putting on my cpap mask which was taken right out of the soclean 2 machine (cleaned it 14 hours prior and let it sit in the closed machine to allow the ozone to dissipate) and immediately got a headache once i started breathing the air. Fda safety report id# (b)(4)."<sup>11</sup>

94. These experiences are representative of consumers' experiences with ozone exposure through the SoClean devices.

95. Similar consumer complaints can be found across the internet.

### **VIII. SoClean's False and Misleading Representations**

96. SoClean has made material misrepresentations about the SoClean devices' ozone output across many forums, which are not only false but dangerous for consumers.

#### **A. SoClean's Failure to Disclose Its Ozone Generation and Use of the Term "Activated Oxygen"**

97. The SoClean devices' packaging does not disclose that the SoClean devices generate ozone or the levels of ozone generated.

98. Marketing materials for the SoClean devices do not disclose that they generate ozone or the levels of ozone generated.

99. Instead, SoClean represents to consumers that it uses "activated oxygen" to sanitize CPAP machines.

100. These omissions and representations are false and misleading.

101. The SoClean devices use ozone to sanitize CPAP machines.

102. As the EPA explains: "Manufacturers[, like SoClean,] and vendors of ozone devices often use misleading terms to describe ozone," similar to activated oxygen, that "suggest that ozone is a healthy kind of oxygen." *Ozone Generators that are Sold as Air Cleaners*, EPA

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<sup>11</sup> MAUDE Adverse Event Report: SoClean, Inc. SoClean 2 Disinfectant, Medical Devices, FDA (June 6, 2021), [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftv1/AUDE/detail.cfm?mdrfoi\\_id=12008122&pc=LRJ](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftv1/AUDE/detail.cfm?mdrfoi_id=12008122&pc=LRJ).



(Nov. 27, 2018), <https://www.epa.gov/indoor-air-quality-iaq/ozone-generators-are-sold-air-cleaners>.

103. However, "[o]zone is a toxic gas with vastly different chemical and toxicological properties from oxygen." *Id.*

104. SoClean has represented across many forums that the SoClean devices use "activated oxygen." For example:

- a. The product packaging for the SoClean 2 never mentions ozone and the box states: "Activated Oxygen powers through your CPAP reservoir, hose, and mask." *See* Ex. G (SoClean 2 Packaging), Figure 6.
- b. • SoClean's website homepage does not mention ozone but states: "SoClean's activated oxygen cleaning completely sanitizes your CPAP mask, hose, and reservoir without any water or chemicals."<sup>12</sup>
- c. Since at least 2015, SoClean has used a promotional brochure advertising the SoClean devices that does not mention ozone and states: "SoClean's activated oxygen completely sanitizes your mask, hose, and reservoir without any water or chemicals."
- d. SoClean's Amazon Store page for the SoClean devices states: "The SoClean CPAP Cleaner and Sanitizer uses activated oxygen to eliminate any germs and bacteria that may be lingering in your CPAP equipment. SHOP NOW."<sup>13</sup>

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<sup>12</sup> SOCLEAN, [www.SoClean.com](http://www.SoClean.com) (last visited Apr. 10, 2019).

<sup>13</sup> *SoClean: SoClean Devices*, AMAZON, [https://www.amazon.com/stores/page/AA9FC37A-8D02-46CA-937C-CB1DF57940B7?ingress=2&visitid=2a75c335-30b8-4b76-a046-481679118819&ref=bl\\_dp\\_s\\_web\\_9315360011](https://www.amazon.com/stores/page/AA9FC37A-8D02-46CA-937C-CB1DF57940B7?ingress=2&visitid=2a75c335-30b8-4b76-a046-481679118819&ref=bl_dp_s_web_9315360011) (last visited Apr. 20, 2019).

- e. The SoClean 2 Amazon product page maintained by the company fails to disclose that the SoClean 2 generates ozone and states: "The SoClean CPAP sanitizing machine uses safe, natural, activated oxygen to thoroughly sanitize and disinfect your entire CPAP system."<sup>14</sup>
- f. Previously, on the SoClean Website, in answer to the FAQ "Why do I smell ozone in my mask at night when the unit ran in the morning?" SoClean falsely states: "What you smell is not ozone; the equipment is being oxidized with activated oxygen, and that is what you smell - it is completely safe. Some suggestions to lessen the smell: 1) Make sure you use the neutralizing pre-wash. 2) Increase the cleaning time to 12 minutes for a few weeks, then decrease to 7 minutes. 3) Blow air from your CPAP through your mask for 5 minutes before using it. 4) Do not use fragrance wipes or any fragrance products to clean your CPAP equipment, as this will intensify the smell."<sup>15</sup>
- g. The 2014 and 2017 online versions of the SoClean 2 User Guide never mentions ozone and state that SoClean disinfects with "activated oxygen."<sup>16</sup>

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<sup>14</sup> *SoClean 2 + Respiration DreamStation and System One Adapter (SoClean 2 CPAP Cleaner and Sanitizer Bundle with Free Adapter)* by SoClean, AMAZON, [https://www.amazon.com/dp/BOOJWVV4VW/ref=cm\\_sw\\_r\\_sms\\_awdb\\_tl\\_6D0UCbTKP73ZT](https://www.amazon.com/dp/BOOJWVV4VW/ref=cm_sw_r_sms_awdb_tl_6D0UCbTKP73ZT) (last visited Apr. 20, 2019).

<sup>15</sup> *SoClean and Activated Oxygen FAQs*, SOCLEAN, <https://www.soclean.com/sleeptalk/documentation/soclean-activated-oxygen-faqs/> (last visited Apr. 16, 2019).

<sup>16</sup> 2017 SoClean 2 User Guide, SOCLEAN, [https://www.soclean.com/wpcontent/uploads/2017/03/soclean2\\_manual\\_RevH.pdf](https://www.soclean.com/wpcontent/uploads/2017/03/soclean2_manual_RevH.pdf).

h. The online version of the SoClean 2 Go User Guide never mentions ozone and states: "The SoClean 2 Go users no fluids in its operation. It sanitizes with activated oxygen. No fluids or water are used in this process."<sup>17</sup>

105. Buried deep within SoClean's website are a user-support FAQ page and a "white paper" that disclose that "activated oxygen" is, in actuality, ozone.

106. The Brochure states: "The SoClean uses ozone - also known as O<sub>3</sub> or activated oxygen - to sanitize CPAP equipment. Ozone is a 100% safe, naturally occurring gas that has been used to purify water since the 1800s. In today's world, it's a trusted sanitizing process used by hospitals, food handlers and the hotel industry."

107. The FAQ titled "What is Activated Oxygen" states:

Activated oxygen also known as ozone, or O<sub>3</sub> is defined by Merriam-Webster dictionary as: 1. a form of oxygen that is found in a layer high in the earth's atmosphere. 2. fresh healthy air especially near the sea. Activated oxygen is a three atom oxygen molecule.

This three atom molecule is a colorless gas with powerful oxidizing properties, formed from oxygen by electrical discharges or ultraviolet light. it differs from normal oxygen (O<sub>2</sub>) but over time or with forced filtration, will break back down to normal oxygen (O<sub>2</sub>) that we breathe.

Many become confused over the term ozone. There is good ozone and there is bad ozone. Most commonly used is bad ozone which is linked to high ozone alerts or smog alerts in certain areas of the world. This kind of ozone is mixed with toxic gases that can be breathed in. Good ozone is found in our upper atmosphere or you may smell the essence of ozone after a thunderstorm. Activated oxygen (ozone) is known as one of the best and most effective means to natural disinfection. This process is commonly used in array of applications such as public water filtration, fruit and vegetable handling, hotel housekeeping, and hospital disinfection. Please see common FAQs to learn more about activated oxygen (ozone) or see activated oxygen in SoClean to learn how the SoClean safely disinfects your CPAP equipment."<sup>18</sup>

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<sup>17</sup> SoClean 2 Go User Guide, SOCLEAN, [https://www.soclean.com/wpcontent/uploads/2014/10/soclean2Go\\_manual\\_revA.pdf](https://www.soclean.com/wpcontent/uploads/2014/10/soclean2Go_manual_revA.pdf).

<sup>18</sup> *What is activated oxygen?*, SOCLEAN, <https://www.soclean.com/sleep-talk/documentation/activatedoxygen/>.

108. Not only are the foregoing disclosures obscure and difficult to locate, but they are themselves affirmatively false and misleading.

109. The disclosures do nothing to cure SoClean's falsehoods.

**B. Representations that the SoClean Devices use "No Chemicals" and/or "No Harsh Chemicals"**

110. SoClean falsely represents that its devices use "no water or chemicals" or "no harsh chemicals" to clean CPAP machines.

111. These representations are false and misleading.

112. The SoClean devices use ozone gas to clean CPAP machines.

113. Ozone is a chemical.

114. Ozone is a harsh chemical.

115. So Clean has repeatedly represented that its devices use "[n]o water or chemicals" or "no harsh chemicals" to clean CPAP machines across many forums. For example:

- a. The box for the SoClean 2 states: "No water or chemicals." Ex. G (SoClean 2 Packaging), Figure 3.
- b. Since at least March 28, 2016, SoClean's website homepage has read: "SoClean kills 99.9% of CPAP germs and bacteria in your mask, hose and reservoir with no disassembly, no water, and no chemicals in order to enhance your home CPAP experience."<sup>19</sup>
- c. SoClean has aired the television commercial "Getting Sick from a Dirty CPAP" at least 10,929 times nationwide since 2018, representing that the SoClean devices use "no harsh chemicals" to clean CPAP machines.

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<sup>19</sup> SOCLEAN, [www.SoClean.com](http://www.SoClean.com) (last visited Apr. 10, 2019).

- d. SoClean has aired the television commercial "CPAP Cleaner and Sanitizer" at least 22, 058 times nationwide since 2016, representing that the SoClean devices use "no chemicals" to clean CPAP machines.
- e. SoClean has aired the television commercial "Safely Sanitize and Disinfect" at least 6,325 times nationwide between 2017 and July 2018, representing that the SoClean devices use "no harsh chemicals" to clean CPAP machines.
- f. SoClean has aired the television commercial "Automated CPAP Sanitizer" at least 512 times nationwide in 2018, representing that the SoClean devices use "no harsh chemicals" to clean CPAP machines.

**C. Representations that the SoClean Devices Are "Safe" and "Healthy" for Use**

- 116. SoClean often markets its device as "safe" and "healthy."
- 117. These representations are false and misleading.
- 118. A device that releases toxic gas into a user's bedroom at levels exceeding federal regulations is not "safe" or "healthy."

119. SoClean has repeatedly represented that its devices are safe and healthy across many forums. For example:

- a. The packaging for the SoClean 2 states: "Breathe Healthy, Breathe SoClean." *See* Ex. G (SoClean 2 Packaging), Figure 4.
- b. Since at least March 28, 2016, SoClean's website homepage has represented that the SoClean devices offer "Safe, healthier CPAP cleaning."<sup>20</sup>

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<sup>20</sup> SOCLEAN, [www.SoClean.com](http://www.SoClean.com) (last visited Apr. 17, 2019).

- c. A brochure advertising the SoClean and SoClean 2 Go used since at least 2015 reads: "The SoClean makes it easy for any CPAP user to safely and naturally clean and sanitize their equipment on a daily basis."
- d. A brochure advertising the SoClean and SoClean 2 Go used since at least 2015 reads: "Featuring the same safe, effective sanitizing process as the SoClean, the SoClean 2 Go is the perfect travel companion for any CPAP user - so small it can fit easily anywhere."
- e. SoClean has aired the television commercial "Getting Sick from a Dirty CPAP" at least 10,929 times nationwide since 2018, representing that the SoClean devices help users stay healthy.
- f. SoClean has aired the television commercial "CPAP Cleaner and Sanitizer" at least 22,058 times nationwide since 2016, representing that the SoClean devices improve users' health.
- g. SoClean has aired the television commercial "Safely Sanitize and Disinfect" at least 6,325 times nationwide between 2017 and July 2018, representing that the SoClean devices safely sanitize CPAP masks and hoses.
- h. In a brochure that consumers can obtain from SoClean only if they provide a name and valid email address, SoClean states that: "The SoClean uses ozone - also known as O<sub>3</sub> or activated oxygen - to sanitize CPAP equipment. Ozone is a 100% safe, naturally occurring gas that has been used to purify water since the 1800s. In today's world, it's a trusted sanitizing process used by hospitals, food handlers and the hotel industry."

1. An Amazon product page maintained by the company reads: "The SoClean CPAP sanitizing machine uses safe, natural, activated oxygen to thoroughly sanitize and disinfect your entire CPAP system."<sup>21</sup>

J. A SoClean FAQ page represents that: "What is the concentration of ozone inside the SoClean CPAP cleaner and sanitizer? SoClean uses enough ozone to thoroughly sanitize your CPAP equipment and by the time you open the chamber it will have decreased to 0 ppm."<sup>22</sup>

k. SoClean's representations, advertisements, and written materials have been false in the past and continue to be false and misleading to the present.

**D. Representations that the SoClean Devices Use the Same Sanitizing Process Used in Hospitals**

120. SoClean represents that its devices use the same sanitizing process found in hospital sanitizing.

121. This representation is false and misleading.

122. Hospital ozone decontamination systems can only be used in vacant, sealed rooms.

123. Hospitals cannot and do not use ozone sanitizers in spaces occupied by patients.

124. SoClean devices, however, are marketed for use in the home, specifically bedrooms, and marketing materials often depict the SoClean device on the user's nightstand.

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<sup>21</sup> *SoClean 2 + Respiration DreamStation and System One Adapter (SoClean 2 CPAP Cleaner and Sanitizer Bundle with Free Adapter)* by SoClean, AMAZON, [https://www.amazon.com/dp/BOOFKBUOX6/ref=sspa\\_elk\\_detail\\_1?psc=1&pd\\_rd\\_i=B00FKBU0X6&pd\\_rd\\_w=9S2ks&pf\\_rd\\_p=80559:f3c-f83b-49cl-8a72-40f936e9df7a&pd\\_rd\\_wg=4ucG4&pf\\_rd\\_r=BAAXN03P5HSPQ64V7BWZ&pd\\_rd\\_r=238c6796-5fee-11e9-97cc-7fd3667cd97a&smid=AC3UW2IWHXI2H](https://www.amazon.com/dp/BOOFKBUOX6/ref=sspa_elk_detail_1?psc=1&pd_rd_i=B00FKBU0X6&pd_rd_w=9S2ks&pf_rd_p=80559:f3c-f83b-49cl-8a72-40f936e9df7a&pd_rd_wg=4ucG4&pf_rd_r=BAAXN03P5HSPQ64V7BWZ&pd_rd_r=238c6796-5fee-11e9-97cc-7fd3667cd97a&smid=AC3UW2IWHXI2H) (last visited Apr. 15, 2019).

<sup>22</sup> *SoClean and Activated Oxygen FAQs*, SoCLEAN, <https://www.soclean.com/sleeptalk/documentation/soclean-activated-oxygen-faqs/> (last visited Apr. 16, 2019).

125. SoClean has repeatedly represented that its devices are used in hospital sanitizing across many forums. For example:

- a. Since at least 2015, SoClean has used a promotional brochure advertising the SoClean devices that includes:



- b. Since at least 2015, SoClean has used a "rack card" advertising the SoClean devices that includes:



[www.SoClean.com](http://www.SoClean.com)

- c. The box for the SoClean 2 features a similar image that states: "SoClean uses the same sanitizing process found in:" "water," "produce," "hotels," and "hospitals." See Ex. G (SoClean 2 Packaging), Figure 5.
- d. The SoClean 2 Amazon product page maintained by the company reads "Activated oxygen[.] SoClean uses the same safe and proven sanitizing and disinfecting



process found in water purification, produce handling, hotel housekeeping and hospital sanitizing.',<sup>23</sup>

- e. In a brochure that SoClean requires consumers to provide a name and valid email address to obtain, SoClean states that: "The SoClean uses ozone - also known as O<sub>3</sub> or activated oxygen - to sanitize CPAP equipment. Ozone is a 100% safe, naturally occurring gas that has been used to purify water since the 1800s. In today's world, it's a trusted sanitizing process used by hospitals, food handlers and the hotel industry."

**E. The Charcoal Filter Cartridges**

126. SoClean represents that the filter cartridges convert "activated oxygen" back into "normal oxygen."

127. This representation is false and misleading.

128. The FDA has determined that there is no reliable way to guarantee the rapid breakdown of ozone to prevent its accumulation in enclosed spaces. *See* FDA Final Ozone Rulemaking, 39 Fed. Reg. 13773, ¶ 6 (Apr. 17, 1974).

129. The filter does not prevent the SoClean devices from emitting ozone into the environment.

130. The SoClean filter does not prevent ozone from escaping into the atmosphere.

131. The SoClean filter has no measurable effect on ozone accumulation.

132. SoClean has repeatedly represented across many forums that its filters convert "activated oxygen" into "regular oxygen." For example:

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<sup>23</sup> SoClean 2 + Respirationics DreamStation and System One Adapter (SoClean 2 CPAP Cleaner and Sanitizer Bundle with Free Adapter) by SoClean, AMAZON, [https://www.amazon.com/dp/BOOFKBUOX6/ref=cm\\_sw\\_r\\_sms\\_c\\_api\\_i\\_PCIVCb62EDG8E](https://www.amazon.com/dp/BOOFKBUOX6/ref=cm_sw_r_sms_c_api_i_PCIVCb62EDG8E) (last visited Apr. 21, 2019).

- a. The SoClean webpage selling replacement filters states that "[t]he Cartridge Filter converts activated oxygen back to regular oxygen as it leaves the SoClean 2 chamber."<sup>24</sup>
- b. The 2017 online version of the SoClean 2 User Guide states: "Additionally, any excess activated oxygen passes through a filter which converts it back to regular oxygen before release."<sup>25</sup>
- c. The online version of the SoClean 2 Go User Guide states: "This filter converts activated oxygen back into normal oxygen. Replace every 6 months."<sup>26</sup>

**F. Representations that SoClean Is a Sealed or "Closed-Loop" System**

133. SoClean represents that the SoClean is a "closed system" and that no "activated oxygen" escapes the device.

134. this representation is false and misleading.

135. A closed-loop system is one in which ozone circulates within but does not leave the device.

136. the SoClean devices circulate ozone through the CPAP machine which is then released into the ambient air or breathed by the CPAP user.

137. SoClean has repeatedly represented across many forums that its devices are a "closed system" and/or that no "activated oxygen" escapes. For example:

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<sup>24</sup> Cartridge Filter Kit- SoClean 2, SOCLEAN, <https://www.soclean.com/product/cartridge-filter-kit-soclean-2/> (last visited Apr. 15, 2019).

<sup>25</sup> 2017 SoClean 2 User Guide, SOCLEAN, [https://www.soclean.com/wpcontent/uploads/2017/03/soclean2\\_manual\\_RevH.pdf](https://www.soclean.com/wpcontent/uploads/2017/03/soclean2_manual_RevH.pdf).

<sup>26</sup> 2014 SoClean 2 User Guide, SOCLEAN, [https://www.soclean.com/wpcontent/uploads/2014/04/soclean2\\_manual\\_RevE.pdf](https://www.soclean.com/wpcontent/uploads/2014/04/soclean2_manual_RevE.pdf).

- a. A "CPAP cleaning demo video" hosted on the SoClean homepage shows "activated oxygen" circulating through the CPAP machine and SoClean device, but no "activated oxygen" escaping the CPAP machine during the cleaning process.<sup>27</sup> See Ex. F (Marketing Materials), Figure 3. Online, the video appears next to the "Buy Now" button.
- b. A SoClean FAQ webpage represents the following: "What is the concentration of ozone inside the SoClean CPAP cleaner and sanitizer? SoClean uses enough ozone to thoroughly sanitize your CPAP equipment and by the time you open the chamber it will have decreased to 0 ppm."<sup>28</sup>
- c. The 2017 online version of the SoClean 2 User Guide states: "The SoClean produces activated oxygen in a closed system."<sup>29</sup>
- d. The 2014 online version of the SoClean 2 User Guide states: "Is the SoClean harmful to me or the environment? No. The activated oxygen generator is always kept at a safe level and never reaches the outside environment."<sup>30</sup>

138. SoClean has made additional false and misleading representations about the SoClean devices similar to those alleged in paragraphs 96 to 137.

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<sup>27</sup> SOCLEAN, <https://www.soclean.com> (last visited Apr. 21, 2019).

<sup>28</sup> SoClean and Activated Oxygen FAQs, SOCLEAN, <https://www.soclean.com/sleeptalk/documentation/soclean-activated-oxygen-faqs/> (last visited Apr. 16, 2019).

<sup>29</sup> 2017 SoClean 2 User Guide, SOCLEAN, [https://www.soclean.com/wpcontent/uploads/2017/03/soclean2\\_manual\\_RevH.pdf](https://www.soclean.com/wpcontent/uploads/2017/03/soclean2_manual_RevH.pdf).

<sup>30</sup> 2014 SoClean 2 User Guide, SOCLEAN, [https://www.soclean.com/wpcontent/uploads/2014/04/soclean2\\_manual\\_RevE.pdf](https://www.soclean.com/wpcontent/uploads/2014/04/soclean2_manual_RevE.pdf).

139. Upon information and belief, SoClean perpetuates the falsehoods alleged in paragraphs 96 to 137 by paying or otherwise incentivizing individuals to create blog posts and online reviews repeating the falsehoods.

140. Upon information and belief, SoClean perpetuates the falsehoods alleged in paragraphs 96 to 137 by using search engine optimization services.

**G. The Effect of SoClean's False Advertising**

141. The foregoing false claims deceive consumers into believing that the SoClean devices do not generate ozone, do not release ozone into the atmosphere, and are safe, healthy, and suitable for use in consumer's bedrooms.

142. SoClean's falsehoods have allowed it to command a ninety-percent share of the market for CPAP sanitizing/sterilization devices.

143. SoClean's false advertising leads consumers to purchase SoClean's products when they would not otherwise do so.

144. Due to the nature of SoClean's business, its customers all have breathing problems for which they are receiving medical treatment in the form of CPAP therapy. In fact, CPAP users are so concerned about their health that they experience the considerable inconvenience of using a CPAP machine and wearing a CPAP face mask to sleep every night.

145. CPAP users would find the risk posed by the SoClean devices generating unsafe levels of toxic gas, which is then pumped into their CPAP machines and their bedrooms, material to their purchasing decisions.

146. SoClean's false advertising poses a threat to public health.

147. Ozone exposure at levels exceeding .05 ppm negatively affects respiratory health.

148. Epidemiologic studies suggest that those with existing breathing problems may experience adverse symptoms of ozone exposure at concentrations even lower than .05 ppm.

149. SoClean's false representations have deceived and harmed consumers.

### **TOLLING AND ESTOPPEL**

#### **H. DISCOVERY RULE TOLLING**

150. Plaintiff and the Class had no way of knowing about SoClean's conduct with respect to the health risks associated with the use of the SoClean's devices.

151. Neither Plaintiff nor any other members of the Class, through the exercise of reasonable care, could have discovered the conduct by SoClean alleged herein. Further, Plaintiff and members of the Class did not discover and did not know of facts that would have caused a reasonable person to suspect that SoClean was engaged in the conduct alleged herein.

152. For these reasons, all applicable statutes of limitations have been tolled by the discovery rule with respect to claims asserted by Plaintiff and the Class.

#### **I. FRAUDULENT CONCEALMENT TOLLING**

153. By failing to provide immediate notice of the adverse health effects associated with continued use of the SoClean devices, SoClean concealed its conduct and the existence of the claims asserted herein from Plaintiff and the members of the Class.

154. Upon information and belief, SoClean intended its acts to conceal the facts and claims from Plaintiff and members of the Class. Plaintiff and the members of the Class were unaware of the facts alleged herein without any fault or lack of diligence on their part and could not have reasonably discovered Defendant's conduct. For this reason, any statutes of limitations that otherwise may apply to the claims of the Plaintiff or members of the Class should be tolled.

### **CLASS ACTION ALLEGATIONS**

155. Plaintiff seeks certification on behalf of a class defined as follows (the "Class"):

All persons who were or are citizens of the State of Michigan who purchased or used a SoClean device to clean and sanitize their CPAP, BiPAP or Mechanical Ventilation machine.

156. Plaintiff reserves the right to modify or refine the definitions of the Class based upon discovery of new information and in order to accommodate any of the Court's manageability concerns.

157. Excluded from the Class are: (a) any Judge or Magistrate Judge presiding over this action and members of their staff, as well as members of their families; (b) Defendant's and Defendant's predecessors, parents, successors, heirs, assigns, subsidiaries, and any entity in which Defendant or its parents have a controlling interest, as well as Defendant's current or former employees, agents, officers, and directors; (c) persons who properly execute and file a timely request for exclusion from the Class; (d) persons whose claims in this matter have been finally adjudicated on the merits or otherwise released; (e) counsel for Plaintiff and Defendant; and (f) the legal representatives, successors, and assigns of any such excluded persons.

158. **Numerosity (Rule 23(a)(1)).** The Class is so numerous that joinder of individual members herein is impracticable. The exact number of members of the Class, as herein identified and described, is not known, but upon information and belief, the Defendant sold its products to millions of individuals.

159. **Commonality (Rule 23 (a)(2)).** Common questions of fact and law exist for each cause of action and predominate over questions affecting only individual Class members, including the following:

- whether Defendant owed a duty of care to Plaintiff and the Class;

- whether Defendant knew or should have known that its products posed health risks;
- whether Defendant wrongfully represented that its products were safe;
- whether Defendant wrongfully represented that its products were safe to use;
- whether Defendant wrongfully failed to disclose that ozone that was produced by, used in, and escaped from, its products posed health risks users;
- whether Defendant's representations and omissions in advertising, warranties, packaging, and/or labeling were false, deceptive, and/or misleading;
- whether those representations and omissions were likely to deceive a reasonable consumer;
- whether a reasonable consumer would consider the presence, or risk of, health risks as a material fact in purchasing one Defendant's products;
- whether Defendant had knowledge that those representations and omissions were false, deceptive, and misleading;
- whether Defendant breached its express warranties;
- whether Defendant breached its implied warranties;
- whether Defendant engaged in false advertising;
- whether Defendant's conduct was negligent per se;
- whether Defendant made negligent and/or fraudulent misrepresentations and/or omissions; and
- whether Plaintiff and the members of the Class are entitled to actual, statutory, and punitive damages.

160. **Typicality (Rule 23(a)(3)).** Plaintiffs claims are typical of the claims of the other members of the proposed Class. Plaintiff and members of the Class (as applicable) suffered injuries as a result of Defendant's wrongful conduct that is uniform across the Class.

161. **Adequacy (Rule 23(a)(4)).** Plaintiff's interests are aligned with the Class he seeks to represent. Plaintiff has and will continue to fairly and adequately represent and protect the interest of the Class. Plaintiff has retained competent counsel highly experienced in complex litigation and class actions and the types of claims at issue in this litigation, with the necessary resources committed to protecting the interest of the Class. Plaintiff has no interest that is antagonistic to those of the Class, and Defendant has no defenses unique to Plaintiff. Plaintiff and his counsel are committed to vigorously prosecuting this action on behalf of the members of the Class. Neither Plaintiff nor Plaintiff's counsel have any interest adverse to those of the other members of the Class.

162. **Superiority.** This class action is appropriate for certification because class proceedings are superior to other available methods for the fair and efficient adjudication of this controversy, and joinder of all members of the Class is impracticable. The prosecution of separate actions by individual members of the Class would impose heavy burdens upon the Courts and Defendant, would create a risk of inconsistent or varying adjudications of the questions of law and fact common to members of the Class, and would be dispositive of the interest of the other members not parties to the individual adjudications or would substantially impair or impede their ability to protect their interests. Class treatment will create economies of time, effort, and expense and promote uniform decision-making.



163. **Manageability.** This proposed class action presents fewer management difficulties than individual litigation, and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single court.

164. Class certification, therefore, is appropriate under Fed. R. Civ. P. 23(b)(3) because the above common questions of law or fact predominate over any questions affecting individual members of the Class, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

### **CLAIMS FOR RELIEF**

#### **FIRST CLAIM FOR RELIEF**

##### **BREACH OF EXPRESS WARRANTY (on behalf of the class)**

165. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

166. SoClean marketed and sold its products into the stream of commerce with the intent that its products would be purchased by Plaintiff and the Class.

167. SoClean expressly warranted, advertised, and represented to Plaintiff and the Class that its products were safe and appropriate for human use.

168. SoClean made these express warranties regarding its products' quality and fitness for use in writing through its website, advertisements, and marketing materials, and on its products' packaging and labels. These express warranties became part of the basis of the bargain that Plaintiff and the Class entered in to upon purchasing Defendant's products.

169. SoClean's advertisements, warranties, representations, and omissions regarding health risks associated with its products, were made in connection with the sale of its products to Plaintiff and the Class. Plaintiff and the Class relied on SoClean's advertisements, warranties,

representations, and omissions regarding its products in deciding whether to purchase and use SoClean's products.

170. SoClean's products do not conform to SoClean's advertisements, warranties, representations, and omissions in that they are not safe, healthy, and appropriate for human use, and pose risks of serious injury and disease.

171. SoClean therefore breached its express warranties by placing its products into the stream of commerce and selling them to consumers, when their use posed health risks, had dangerous effects and were unsafe, rendering these products unfit for their intended use and purpose, and unsafe and unsuitable for consumer use as marketed by SoClean. These associated health effects substantially impair the use, value, safety of the products, and render them worthless.

172. SoClean was aware, or should have been aware, of the toxic or dangerous health effects of the use of its products, but nowhere on the package labeling or package inserts or on SoClean's websites or other marketing materials did SoClean warn Plaintiff and members of the Class that they were at risk of developing adverse health effects as a result of the dangerous ozone generated by, and used in, SoClean's products.

173. Instead, SoClean concealed the dangerous health effects of the ozone generated by, and used in, SoClean's products and deceptively represented that these products were safe, healthy, and appropriate for use. SoClean thus utterly failed to ensure that the material representations they were making to consumers were true.

174. The adverse health effects associated with use of SoClean's products existed when they left SoClean's possession or control and were sold to Plaintiff and members of the Class. The dangers associated with use of SoClean's products were undiscoverable by Plaintiff and members of the Class at the time of purchase of SoClean's products.

175. As manufacturers, marketers, advertisers, distributors and sellers of the products used by the Plaintiff and members of the Class, SoClean had exclusive knowledge and notice of the fact that its products did not conform to the affirmations of fact and promises.

176. In addition, or in the alternative, to the formation of an express contract, SoClean made each of the above-described representations and omissions to induce Plaintiff and members of the Class to rely on such representations and omissions.

177. SoClean's affirmations of fact and promises and its omissions were material, and Plaintiff and members of the Class reasonably relied upon such representations and omissions in purchasing and using SoClean's products.

178. All conditions precedent to SoClean's liability for its breach of express warranty have been performed by Plaintiff or members of the Class.

179. Affording SoClean an opportunity to cure its breaches of written warranties would be unnecessary and futile here. SoClean, in addition to having actual knowledge based on reasonable notice from user reports and its lab testing that the use of the SoClean and SoClean 2 by its customers, in the manner set forth in SoClean's own printed materials, such as advertisements and instructions, presented an unsafe medical situation to SoClean customers. SoClean had ample opportunity to stop using the ozone method in cleaning its customers' CPAP machines.

180. As a direct and proximate result of SoClean's breaches of express warranty, Plaintiff and members of the Class have been damaged because they did not receive the products as specifically warranted by SoClean. Plaintiff and members of the Class did not receive the benefit of the bargain and suffered damages at the point of sale stemming from their overpayment for SoClean's products.

181. Plaintiff and the Class seek actual damages, attorneys' fees, costs, and any other just and proper relief available thereunder for SoClean's failure to deliver goods conforming to their express warranties and resulting breach.

**SECOND CLAIM FOR RELIEF**

**BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY  
(on behalf of the Class)**

182. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

183. SoClean is a merchant engaging in the sale of goods to Plaintiff and the Class.

184. There was a sale of goods from SoClean to Plaintiff and the Class, either directly or indirectly, by and through the Plaintiffs, or Class members', medical providers and/or medical suppliers.

185. At all times mentioned herein, SoClean manufactured or supplied its products, and prior to being purchased by Plaintiff and the Class, SoClean impliedly warranted to them that SoClean's products were of merchantable quality, fit for their ordinary use, and conformed to the promises and affirmations of fact and omissions made on SoClean's products' labels and packaging, including that SoClean's products were safe and appropriate for human use. Plaintiff and the Class relied on SoClean's promises and affirmations of fact and omissions when they purchased and used SoClean's products.

186. Contrary to these representations and warranties, SoClean's products were not fit for their ordinary use and did not conform to SoClean's affirmations of fact and promises and omissions because use of SoClean's products is accompanied by the risk of adverse health effects, which does not conform to the labels and packaging of these products.

187. SoClean breached its implied warranties by selling its products that failed to conform to the promises or affirmations of fact made on the packaging or label, as use of each

product was accompanied by the risk of developing adverse health effects that do not conform to the packaging or label.

188. SoClean was on notice of this breach, as it was made aware of the adverse health effects accompanying use of the devices through user reports submitted to SoClean and through lab testing.

189. Privity exists because SoClean impliedly warranted to Plaintiff and the Class through the warranting, packaging, advertising, marketing, and labeling that SoClean's products were natural, and suitable for use to clean CPAP, BiPAP, and Mechanical Ventilator, and made no mention of the attendant health risks associated with use of SoClean's products.

190. As a direct and proximate result of SoClean's conduct, Plaintiff and the Class have suffered actual damages in that each product they purchased is worth less than the price they paid and which they would not have purchased at all had they known of the attendant health risks associated with the use of each of SoClean's products.

191. Plaintiff and the Class seek actual damages, attorneys' fees, costs, and any other just and proper relief available thereunder for SoClean's failure to deliver goods conforming to their implied warranties and resulting breach.

### **THIRD CLAIM FOR RELIEF**

#### **FRAUDULENT MISREPRESENTATION (on behalf of the Class)**

192. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

193. SoClean failed to advise Plaintiff and the Class that SoClean's products posed serious health risks to their users and SoClean falsely represented to Plaintiff and the Class that SoClean's products were safe for human use.

194. SoClean intentionally, knowingly, and recklessly made these misrepresentations and omissions to induce Plaintiff and the Class to purchase SoClean's products.

195. SoClean knew that its representations and omissions about its products were false in that its products generated and used ozone and thus were at risk of causing adverse health effects to users of its products, which does not conform to the products' labels, packaging, advertising, and statements. SoClean knowingly allowed its packaging, labels, advertisements, promotional materials, and websites to intentionally mislead consumers, such as Plaintiff and the Class.

196. Plaintiff and the Class did in fact rely on these omissions and misrepresentations and purchased and used SoClean's products to their detriment. Given the deceptive manner in which SoClean advertised, represented, and otherwise promoted its products, Plaintiffs and the Class members' reliance on SoClean's omissions and misrepresentations was justifiable.

197. As a direct and proximate result of SoClean's conduct, Plaintiff and the Class have suffered actual damages in that they purchased SoClean's products (a) that were worth less than the price they paid, (b) which they would not have purchased at all had they known of the health risks associated with the use of SoClean's products, and (c) which did not conform to the products' labels, packaging, advertising, and statements.

198. Plaintiff and the Class seek actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws.

#### **FOURTH CLAIM FOR RELIEF**

##### **FRAUD BY OMISSION (on behalf of the Class)**

199. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

200. SoClean concealed from, and failed to disclose to, Plaintiff and the Class that use of SoClean's products is accompanied by a risk of adverse health effects, which does not conform to the products' labels, packaging, advertising, and statements.

201. SoClean was under a duty to disclose to Plaintiff and the Class the true quality, characteristics, ingredients and suitability of SoClean's products because: (a) SoClean was in a superior position to know the true state of facts about its products; (b) SoClean was in a superior position to know the risks associated with the use of, characteristics of, and suitability of its products for use by individuals; and (c) SoClean knew that Plaintiff and the Class could not reasonably have been expected to learn or discover prior to purchasing SoClean's products that there were misrepresentations and omissions by SoClean in the packaging, labels, advertising, and websites regarding the health risks associated with use of these devices.

202. The facts concealed or not disclosed by SoClean to Plaintiff and the Class were material in that a reasonable consumer would have considered them important when deciding whether to purchase SoClean's products.

203. Plaintiff and the Class justifiably relied on SoClean's omissions to their detriment. The detriment is evident from the true quality, characteristics, and risk associated with the use of SoClean's products, which is inferior when compared to how SoClean's products are advertised and represented by SoClean.

204. As a direct and proximate result of SoClean's conduct, Plaintiff and the Class have suffered actual damages in that they purchased SoClean's products (a) that were worth less than the price they paid, (b) which they would not have purchased at all had they had known of the health risks associated with the use of SoClean's products, and (c) which do not conform to the products' labels, packaging, advertising, and statements.

205. Plaintiff and the Class seek actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws.

**FIFTH CLAIM FOR RELIEF**

**NEGLIGENT MISREPRESENTATION  
(on behalf of the Class)**

206. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

207. SoClean had a duty to Plaintiff and the Class to exercise reasonable and ordinary care in the developing, testing, manufacture, marketing, distribution, and sale of SoClean's products.

208. SoClean breached its duty to Plaintiff and the Class by developing, testing, manufacturing, advertising, marketing, distributing, and selling products to Plaintiff and the Class that did not have the qualities, characteristics, and suitability for use as advertised by SoClean and by failing to promptly remove its products from the marketplace or to take other appropriate remedial action upon becoming aware of the health risks of its products.

209. SoClean knew or should have known that the qualities and characteristics of its products were not as advertised or suitable for their intended use and were otherwise not as warranted and represented by SoClean. Specifically, SoClean knew or should have known that: (a) the use of its products was accompanied by risk of adverse health effects that do not conform to the packaging and labeling; (b) its products were adulterated, or at risk of being adulterated, by the ozone the products generated, and used; and (c) the products were otherwise not as warranted and represented by SoClean.

210. As a direct and proximate result of SoClean's conduct, Plaintiff and the Class have suffered actual damages in that they purchased SoClean's products (a) that were worth less than the price they paid, (b) which they would not have purchased at all had they known they generated,



and used, ozone that could cause users of the products to suffer adverse health effects, and (c) which do not conform to the products' labels, packaging, advertising, and statements.

211. Plaintiff and the Class seek actual damages, attorneys' fees, costs, and any other just and proper relief available.

#### **SIXTH CLAIM FOR RELIEF**

##### **UNJUST ENRICHMENT (on behalf of the Class)**

212. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

213. Plaintiff and the Class conferred substantial benefits on SoClean through their purchase of its products. SoClean knowingly and willingly accepted and enjoyed these benefits.

214. SoClean either knew or should have known that the payments rendered by Plaintiff and the Class were given with the expectation that SoClean's products would have the qualities, characteristics, and suitability for use represented and warranted by SoClean. As such, it would be inequitable for SoClean to retain the benefit of the payments under these circumstances.

215. SoClean's acceptance and retention of these benefits under the circumstances alleged herein make it inequitable for SoClean to retain the benefits without payment of the value to Plaintiff and the Class.

216. Plaintiff and the Class are entitled to recover from SoClean all amounts wrongfully collected and improperly retained by Defendant, plus interest thereon.

217. Plaintiff and the Class seek actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws.

**SEVENTH CLAIM FOR RELIEF**

**FAILURE TO WARN  
(on behalf of the Class)**

218. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

219. SoClean either knew, or should have known, of the substantial dangers involved in the reasonably foreseeable use of the SoClean products, *inter alia*, the exposure to ozone in the cleansing by the SoClean products.

220. SoClean failed to provide necessary and adequate safety and instructional materials and warnings of the risks and means available to reduce and/or minimize the risk of breathing a toxic gas and/or particulate matter while using a SoClean product.

221. SoClean failed to provide necessary and adequate information, warnings, and/or instructional material regarding the fact that there are other products on the market that do not contain the toxic gas in the SoClean products.

222. SoClean failed to warn users of the SoClean product from repeated use, so that users could make an informed decision on continued use of the SoClean product. As a result, Plaintiff and the Class members have suffered physical harm, worry and anxiety, pain and suffering, and medical expenses.

223. SoClean knew, or should have known, given its expertise that these substantial dangers were not readily recognizable to an ordinary consumer, or user, and that such persons would use these products in the belief that the user was protected from injury.

224. The Plaintiffs damages were a legal and proximate result of the actions of SoClean, which owed a duty to warn Plaintiff and Class members of the risk of substantial harm associated with the foreseeable use of the SoClean product.

SoClean's failure to warn caused the Plaintiffs and Class member's personal injuries and losses.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for judgment as follows:

- A. An order certifying this action on all counts, and the Class requested herein as a Class Action, designating Plaintiff as the representative of the Class and appointing Plaintiffs counsel as Class counsel for the Class;
- B. An order declaring that SoClean's actions constitute:
  - l. A breach of express warranty;
  - ii. A breach of implied warrant of merchantability;
  - m. Failure to warn;
  - lv. Fraudulent misrepresentation;
  - v. Fraud by omission;
  - vl. Negligent Misrepresentation; and
  - vll. Unjust Enrichment.
- C. A judgment that SoClean is liable to Plaintiff and the Class as described herein for damages, including but not limited to, physical injury, pain and suffering, worry,

anxiety, medical expenses, psychological damages, medical monitoring ansng therefrom, and that SoClean be ordered to establish medical monitoring protocols as the Court deems necessary in regards to the proof herein;

- D. A judgment awarding Plaintiff and members of the Class all appropriate damages as is appropriate to be determined at trial;
- E. A judgment awarding Plaintiff and the Class pre-judgment and post-judgment interest in an amount prescribed by law;
- F. A judgment awarding Plaintiff and the Class costs and fees, including attorneys' fees, as prescribed by law; and
- G. Grant such other legal, equitable, or further relief as the Court may deem just and proper.
- H. Plaintiff requests a trial by jury for all issues so triable.

Respectfully Submitted,

[REDACTED]

Date: March 10, 2022

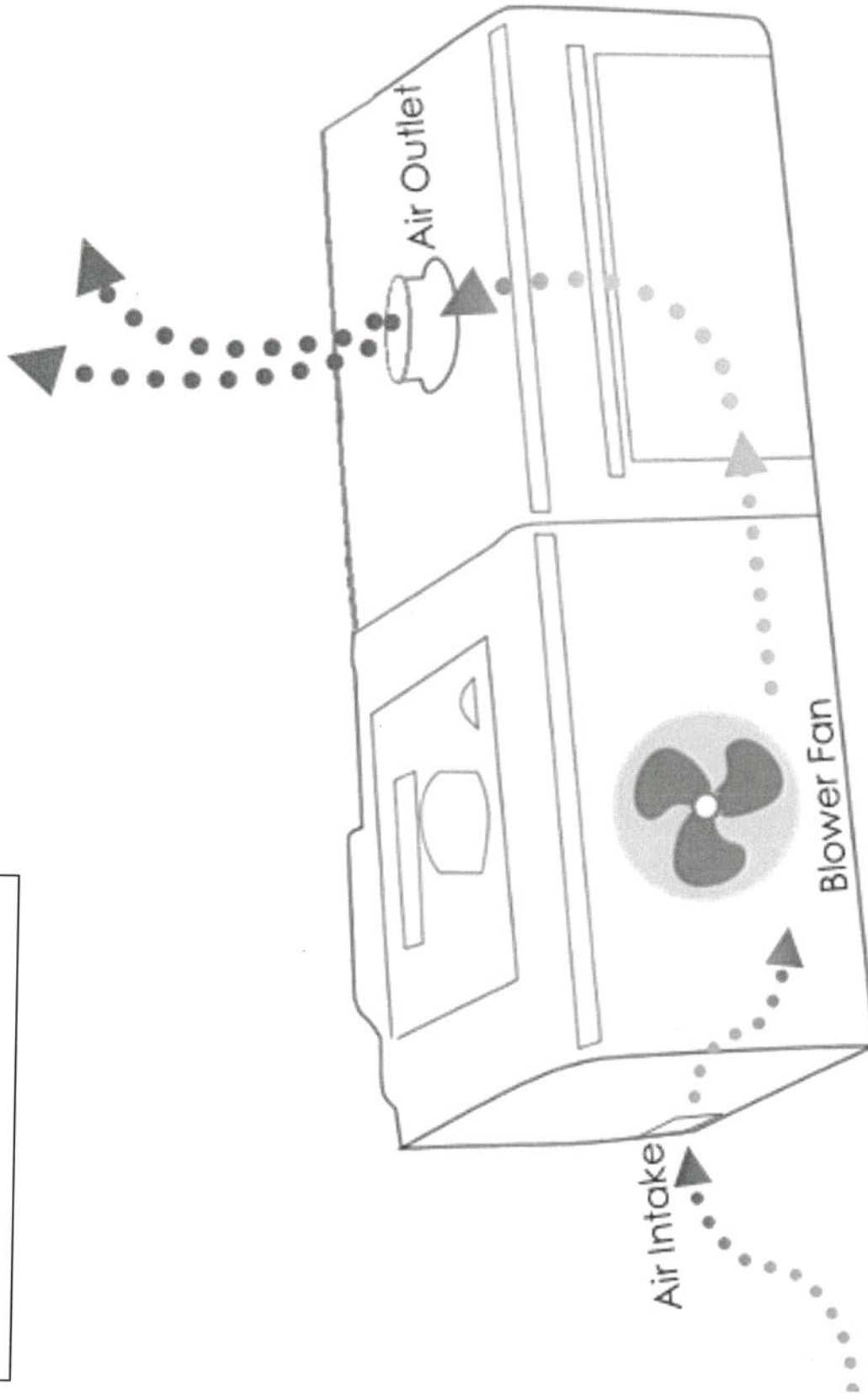
[REDACTED]

## EXHIBIT A

AIRFLOW DIAGRAMS

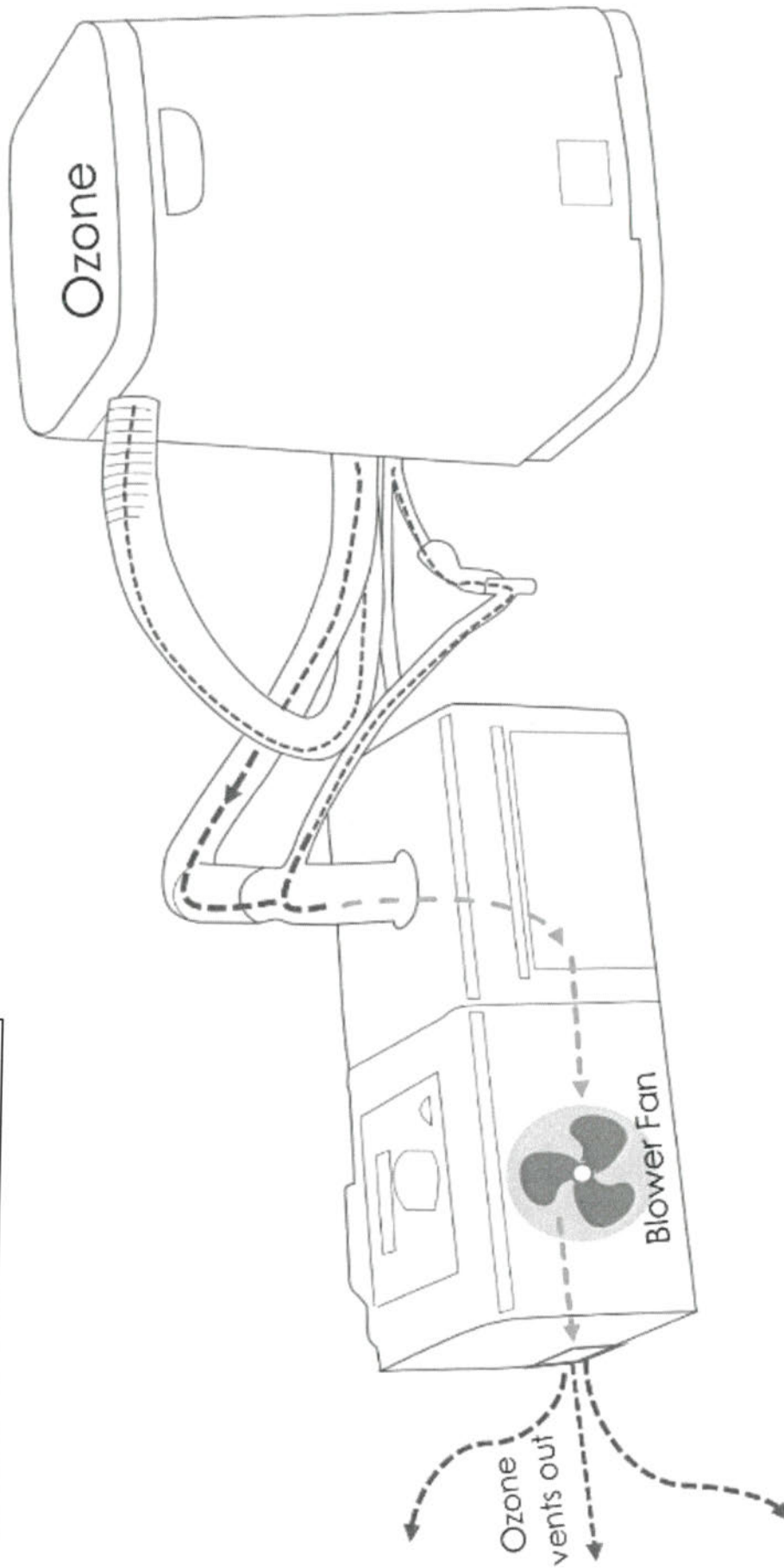
**Figure 1**

Airflow through a



**Figure 2**

Flow of Ozone from the SoClean 2 and  
into a



## EXHIBIT B



SoClean 2

Figure 1



**Figure 2**  
SoClean 2 with CPAP Mask



**Figure 3**



## EXHIBIT C

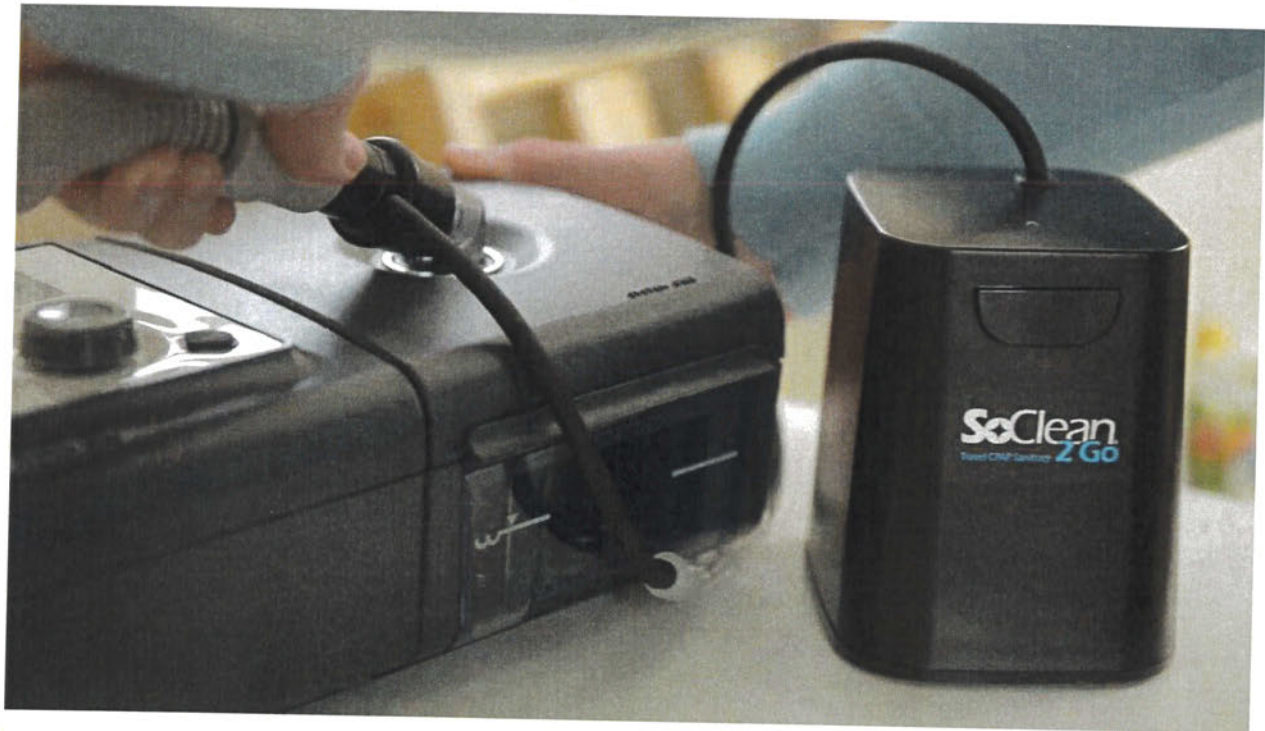


SoClean 2 Go

**Figure 1**  
SoClean 2 Go System



**Figure 2**  
SoClean 2 Go Attached to CPAP



**Figure 3**  
SoClean 2 Go – Scale



**Figure 4**  
SoClean 2 Go Filter



## EXHIBIT D

Research Triangle Park Laboratories, Inc.  
7201 ACC Blvd., Suite 104  
Raleigh, NC 27617



ISO 17025 Compliant  
PA Registration #68-1664  
DEA Registered

919 510-0228 Telephone

919 510-0141 Fax

Web Site: [www.rtp-labs.com](http://www.rtp-labs.com)

April 19, 2019

3B Medical  
799 Overlook Drive  
Winter Haven, FL 33884

Attn: Alex Lucio, CEO

**PROJECT: Ozone Testing**

**RTP Labs ID: 19-025-1 Device Ozone Output Test**

The testing was conducted on the CPAP cleaning device received on March 23, 2019. We received a "SoClean2 Model SC1200 S/N SC120018100700580" device with a RESMED CPAP SN 23141234692. The SoClean2 and CPAP devices were tested for ozone emissions to determine if it exceeded the Federal Regulation for medical devices 21 CFR 801.415 of 0.05 parts per million (ppm).

*For this particular test the SoClean2 ozone generator output line was directly measured without going through the CPAP device or into the chamber.* The SoClean2 was turned on and an ozone sample was collected and analyzed after 1 min.

SoClean2 Direct Output		
Control	<0.05 ppm	
1 min	30.0 ppm	Exceeded Ozone Limit

If you have any questions, please give me a call at (919) 510-0228.

Sincerely,

Alston Sykes, Principal Chemist



Research Triangle Park Laboratories, Inc.  
7201 ACC Blvd., Suite 104  
Raleigh, NC 27617



ISO 17025 Compliant  
PA Registration #68-1664  
DEA Registered

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Web Site: [www.rtp-labs.com](http://www.rtp-labs.com)

April 19, 2019

3B Medical  
799 Overlook Drive  
Winter Haven, FL 33884

Attn: Alex Lucio, CEO

**PROJECT: Ozone Testing**  
**RTP Labs ID: 19-025-3 With Filter Test**

The testing was conducted on the CPAP cleaning device received on March 23, 2019. We received a "SoClean 2 Model SC1200 S/N SC120018100700580" device with a RESMED CPAP SN 23141234692. The SoClean2 and CPAP devices were tested for ozone emissions to determine if it exceeded the Federal Regulation for medical devices 21 CFR 801.415 of 0.05 parts per million (ppm).

The testing was conducted using ASTM D5116 "Small Scale Chamber Determination of Volatile Organic Emissions from Indoor Materials/Products" using a 50-liter Teflon chamber. At the beginning of the test, an ozone Control sample was collected in the chamber to demonstrate that no ozone was in the chamber prior to turning on the device. *The SoClean2 filter was installed per instructions and the device was turned on and an ozone sample was collected and analyzed at the end of the 12 min cycle for the SoClean2 device.* The SoClean 2 device automatically turned off after 12 min. At the end of each test the device was removed and the chamber was purged with clean air to remove any residual ozone from any previous test.

	SoClean 2 With filter	
Control	<0.05 ppm	
12 min Cycle	28.0 ppm	Exceeded Ozone Limit

If you have any questions, please give me a call at (919) 510-0228.

Sincerely,

Alston Sykes, Principal Chemist

Research Triangle Park Laboratories, Inc.  
7201 ACC Blvd., Suite 104  
Raleigh, NC 27617



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April 19, 2019

3B Medical  
799 Overlook Drive  
Winter Haven, FL 33884

Attn: Alex Lucio, CEO

**PROJECT: Ozone Testing**  
**RTP Labs ID: 19-025-2 Without Filter Test**

The testing was conducted on the CPAP cleaning device received on March 23, 2019. We received a "SoClean2 Model SC1200 S/N SC120018100700580" device with a RESMED CPAP SN 23141234692. The SoClean2 and CPAP devices were tested for ozone emissions to determine if it exceeded the Federal Regulation for medical devices 21 CFR 801.415 of 0.05 parts per million (ppm).

The testing was conducted using ASTM D5116 "Small Scale Chamber Determination of Volatile Organic Emissions from Indoor Materials/Products" using a 50-liter Teflon chamber. At the beginning of the test, an ozone Control sample was collected in the chamber to demonstrate that no ozone was in the chamber prior to turning on the device. *The SoClean2 filter was removed from the device and the device was turned on and an ozone sample was collected and analyzed at the end of the 12 min cycle for the SoClean2 device.* The SoClean2 device automatically turned off after 12 min. At the end of each test the device was removed and the chamber was purged with clean air to remove any residual ozone from any previous test.

SoClean 2 Without filter		
Control	<0.05 ppm	
12 min Cycle	28.0 ppm	Exceeded Ozone Limit

If you have any questions, please give me a call at (919) 510-0228.

Sincerely,

Alston Sykes, Principal Chemist

Research Triangle Park Laboratories, Inc.  
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April 19, 2019



ISO 17025 Compliant  
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3B Medical  
799 Overlook Drive  
Winter Haven, FL 33884

Attn: Alex Lucio, CEO

**PROJECT: Ozone Testing**

**RTP Labs ID: 19-025-4 With Filter Test, 2 hour Wait.**

The testing was conducted on the CPAP cleaning device received on March 23, 2019. We received a "SoClean2 Model SC1200 S/N SC120018100700580" device with a RESMED CPAP SN 23141234692. The SoClean2 and CPAP devices were tested for ozone emissions to determine if it exceeded the Federal Regulation for medical devices 21 CFR 801.415 of 0.05 parts per million (ppm).

The testing was conducted using ASTM D5116 "Small Scale Chamber Determination of Volatile Organic Emissions from Indoor Materials/Products" using a 50-liter Teflon chamber. At the beginning of the test, an ozone Control sample was collected in the chamber to demonstrate that no ozone was in the chamber prior to turning on the device. *The device was turned on and an ozone sample was collected and analyzed after waiting 2 hours after the end of the 12 min cycle for the "SoClean2" device.* The SoClean2 device automatically turned off after 12 min. At the end of each test the device was removed and the chamber was purged with clean air to remove any residual ozone from any previous test.

SoClean2 With filter 2 Hr Wait		
Control	<0.05 ppm	
12 min Cycle	3.0 ppm	Exceeded Ozone Limit

If you have any questions, please give me a call at (919) 510-0228.

Sincerely,

Alston Sykes, Principal Chemist

## EXHIBIT E



Research Triangle Park Laboratories, Inc.  
7201 ACC Blvd., Suite 104  
Raleigh, NC 27617

919 510-0228 Telephone  
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Web Site: [www.rtp-labs.com](http://www.rtp-labs.com)

September 26, 2018



ISO 17025 Compliant  
PA Registration #68-1664  
DEA Registered

3B Medical  
799 Overlook Drive  
Winter Haven, FL 33884

Attn: Alex Lucio, CEO

**PROJECT: Ozone Testing**  
**RTP Labs ID: 18-079-2**

The testing was conducted on the CPAP cleaning device received on September 7, 2018. We received a "SoClean 2 Go Model SC1300 S/N 1300SC052418128" device. The device was tested for ozone emissions to determine if it exceeded the Federal Regulation for medical devices 21 CFR 801.415 of 0.05 parts per million (ppm).

The testing was conducted using ASTM D5116 "Small Scale Chamber Determination of Volatile Organic Emissions from Indoor Materials/Products" using a 27-liter glass chamber. At the beginning of each test, an ozone Control sample was collected in the chamber to demonstrate that no ozone was in the chamber prior to turning on the device. The device was turned on and an ozone sample was collected and analyzed at 20 min time points for the "SoClean 2 Go" device. The "SoClean 2 Go" device automatically turned off after 14 min, and we modified our test procedure to test the ozone at 10 min. At the end of each test the device was removed and the chamber was purged with clean air to remove any residual ozone from the previous test.

	SoClean 2 Go Mask in bag w/filter	SoClean 2 Go Mask out of bag w/filter	SoClean 2 Go Mask out of bag Filter out of chamber	
Control	<0.05 ppm	<0.05 ppm	<0.05 ppm	
10 min	5.60 ppm	5.60 ppm	5.60 ppm	Exceeded Ozone Limit

If you have any questions, please give me a call at (919) 510-0228.

Sincerely,

Alston Sykes, Principal Chemist

## EXHIBIT F

SOCLEAN MARKETING MATERIALS

**Figure 1**  
SoClean 2 Go Bedside Table Marketing<sup>1</sup>



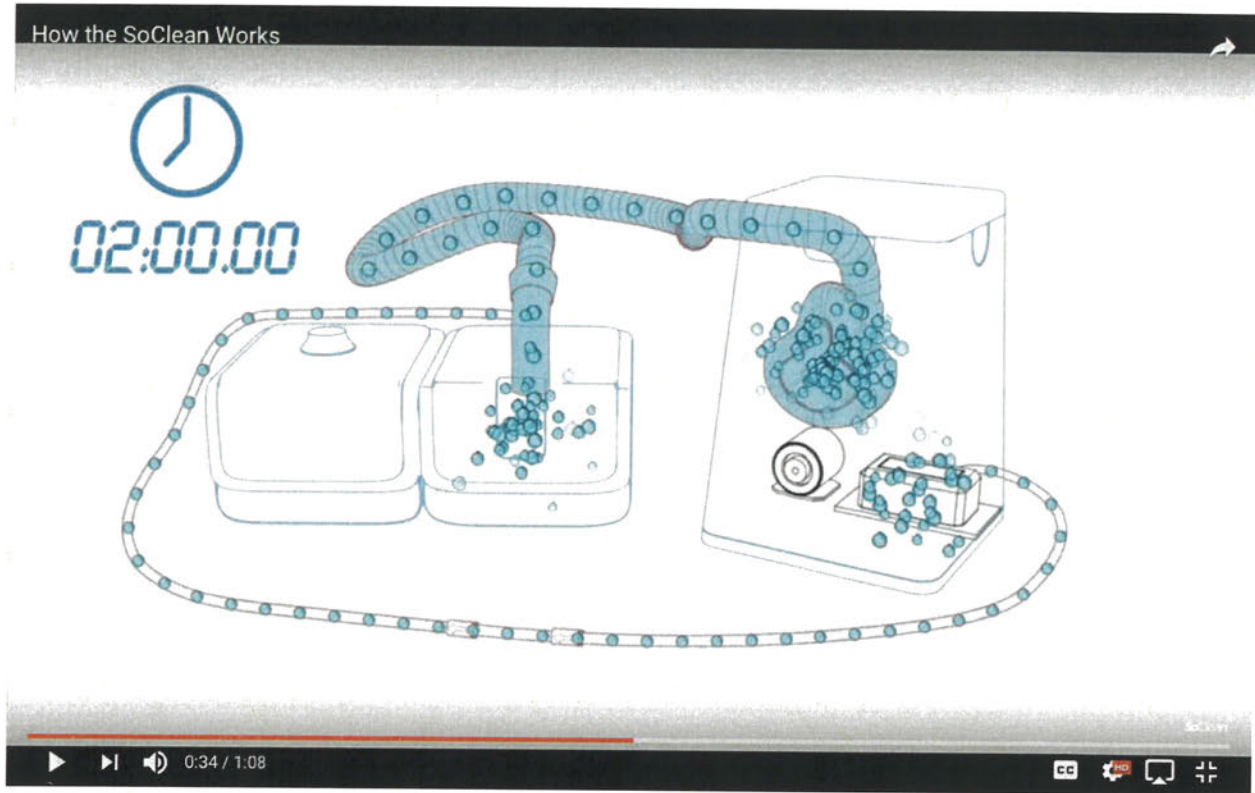
**Figure 2**  
SoClean 2 Bedside Table Marketing<sup>2</sup>



<sup>1</sup> Source: SoClean, *4 Tips for Traveling with a CPAP Machine*, SOCLEAN (Aug. 31, 2017), <https://www.soclean.com/sleep-talk/2017/08/31/4-tips-traveling-cpap-machine/>.

<sup>2</sup> Source: SOCLEAN, [www.SoClean.com](http://www.SoClean.com) (last visited Apr. 21, 2019).

**Figure 3**  
Video Still Depicting Ozone Circulation<sup>3</sup>



<sup>3</sup> Sources: SOCLEAN, [www.SoClean.com](http://www.SoClean.com) (last visited Apr. 21, 2019); SoClean (SoCleanUSA), *How the SoClean Works*, YOUTUBE (May 15, 2017), <https://youtu.be/DHY24IccaAM>.



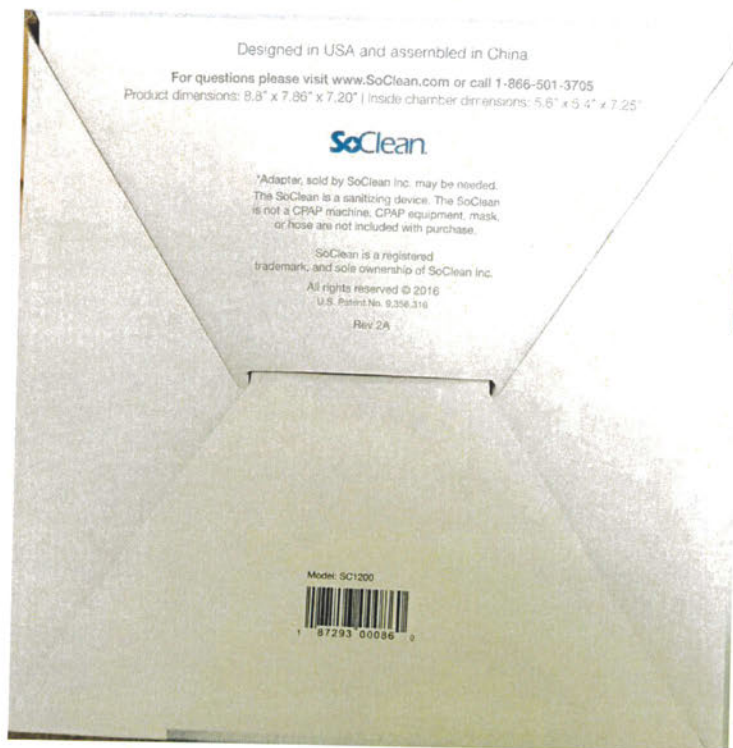
## EXHIBIT G

**SoClean 2 PACKAGING**

**Figure 1**  
Top of Box



**Figure 2**  
Bottom of Box



**Figure 3**  
Side of Box

**SoClean.2**

# Automated CPAP Sanitizer

Cleans and sanitizes CPAP mask, hose,  
and heated humidifier reservoir.

Close the lid and go!

Completely automated sanitizing

No equipment disassembly

No water or chemicals

Kills 99.9% of CPAP germs

**#1**  
As rated by  
CPAP Users

**SoClean**

**FDA**  
Registered  
3009534409



Independently Lab  
Tested and Approved





**Figure 4**  
Side of Box





**Figure 5**  
Side of Box

SoClean uses the  
same sanitizing  
process also found in:



Water



Produce

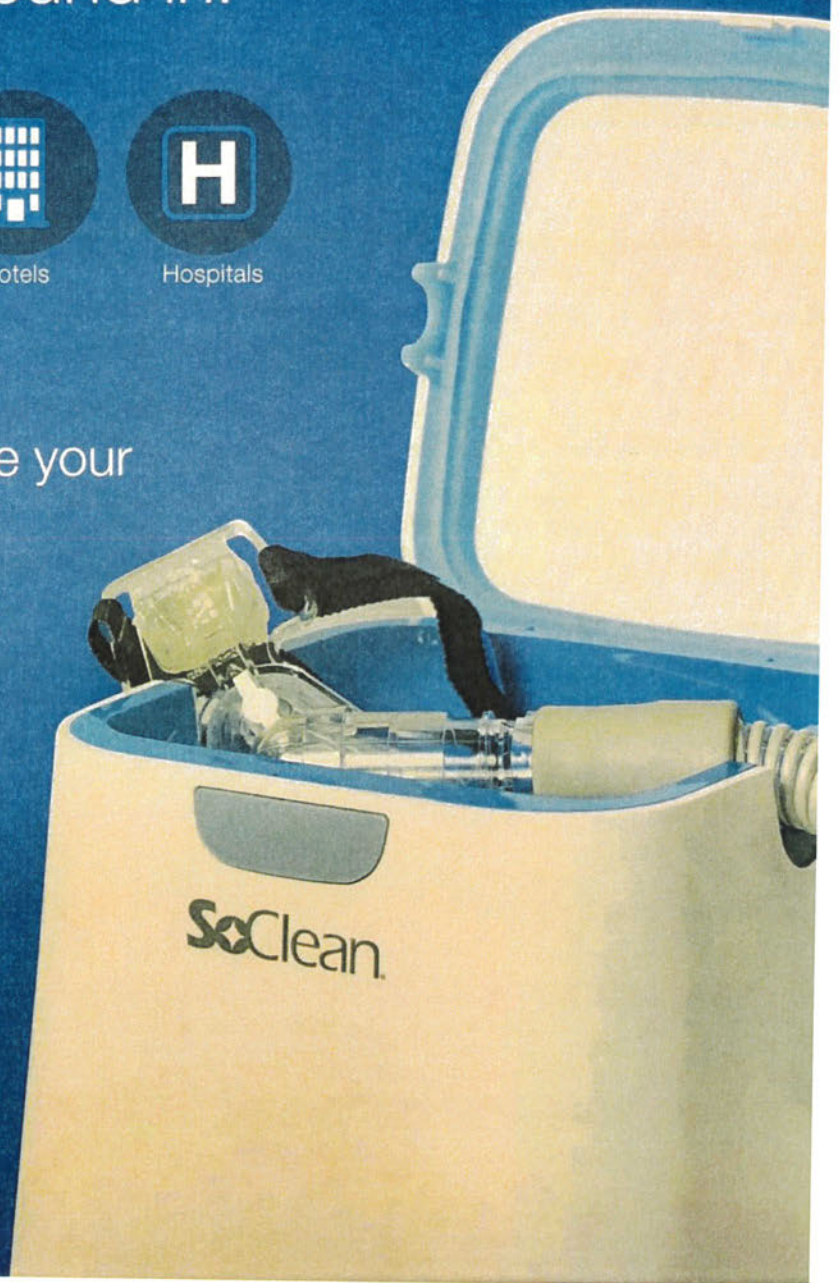


Hotels



Hospitals

This is how we make your  
CPAP SoClean!



[www.SoClean.com](http://www.SoClean.com)

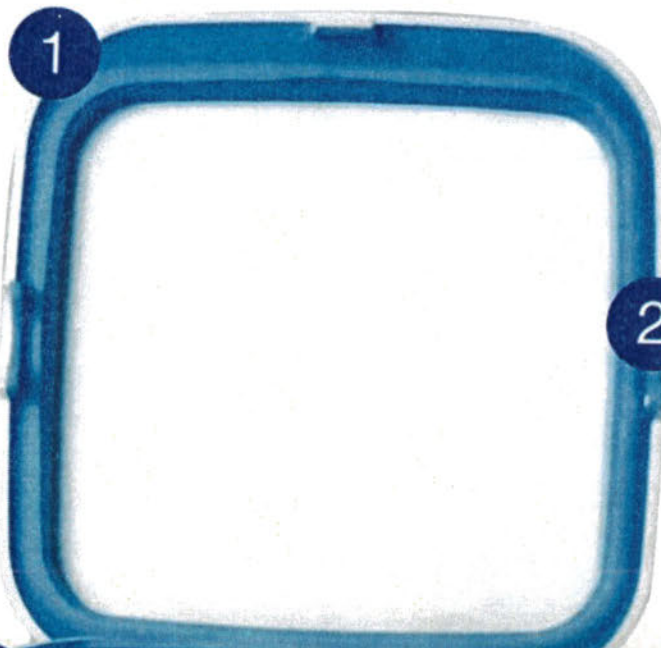


**Figure 6**  
Side of Box

Who knew sanitizing  
your CPAP equipment  
could be this easy

**Simple  
one-time setup**

SoClean connects with all  
types of PAP equipment  
including CPAP, Bi-PAP,  
BPAP, and VPAP



**Close the lid  
and go!**

SoClean starts  
automatically when  
you place your mask  
in the chamber and  
shut the lid.

**Kills CPAP germs  
within minutes**

Activated Oxygen  
powers through your  
CPAP reservoir, hose,  
and mask.

Don't use a heated  
humidifier? No problem  
you can still use SoClean.



Fits all popular  
mask types and  
CPAP machines



**SoClean.**

[www.SoClean.com](http://www.SoClean.com)