

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

-----X
SOCLEAN, INC.

Plaintiff,

- against -

Case No.

SUNSET HEALTHCARE SOLUTIONS, INC.

Defendant.

-----X

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S
EMERGENCY MOTION FOR AN EX PARTE
TEMPORARY RESTRAINING ORDER AND/OR A PRELIMINARY INJUNCTION**

Table of Contents

	Page(s)
PRELIMINARY STATEMENT	1
STATEMENT OF FACTS	3
I. The SoClean Patents	3
II. SoClean Created the Market for Automated CPAP Cleaning Devices.	4
III. SoClean Has Policed its Intellectual Property Rights.....	5
IV. Sunset Introduced its Infringing Products at a Lower Price	6
V. Sunset’s Infringement is Willful.....	7
VI. A Preliminary Injunction Is Needed To Protect SoClean from Irreparable Harm Caused by Sunset’s Sales of Its Infringing Accused Product.....	7
ARGUMENT	8
I. SoClean Is Likely To Succeed On Its Patent Infringement Claims.....	10
II. SoClean Will Suffer Irreparable Harm Without An Injunction.....	14
III. The Balance of Hardships Weighs Decidedly in SoClean’s Favor	17
IV. Enjoining Sunset’s Patent Infringement Advances the Public Interest	19
CONCLUSION.....	20

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Abbott Labs. v. Sandoz, Inc.</i> , 544 F.3d 1341 (Fed. Cir. 2008).....	8, 9, 17, 18
<i>Acumed LLC v. Stryker Corp.</i> , 551 F.3d 1323 (Fed. Cir. 2008).....	15, 16
<i>Apple Inc. v. Samsung Elecs. Co.</i> , 809 F.3d 633 (Fed. Cir. 2015).....	15
<i>Arborjet v. Rainbow Treecare Sci. Advancements</i> , 794 F.3d 168 (1st Cir. 2015).....	8
<i>Broadcom Corp. v. Emulex Corp.</i> , 732 F.3d 1325 (Fed. Cir. 2013).....	15, 16
<i>Cal. Med. Prods. v. Emergency Med. Prods.</i> , 796 F. Supp. 640 (D.R.I. 1992).....	20
<i>Celsis in Vitro, Inc. v. CellzDirect, Inc.</i> , 664 F.3d 922 (Fed. Cir. 2012).....	16, 18
<i>Contour Design, Inc. v. Chance Mold Steel Co., Ltd.</i> , 2010 U.S. Dist. LEXIS 121761 (D.N.H. 2010)	16, 19
<i>Cytoc Corp. v. TriPath Imaging, Inc.</i> , 505 F. Supp. 2d 199 (D. Mass. 2007)	12
<i>Douglas Dynamics, LLC v. Buyers Prods. Co.</i> , 717 F.3d 1336 (Fed. Cir. 2013).....	15, 19
<i>Dunkin’ Donuts Franchised Rests. LLC v. ABM Donuts, Inc.</i> , 2011 U.S. Dist. LEXIS 139074 (D.R.I. 2011).....	17
<i>Indivior Inc. v. Dr. Reddy’s Labs., S.A.</i> , 752 Fed. Appx. 1024 (Fed. Cir. 2018).....	18
<i>M-I LLC v. FPUSA, LLC</i> , 626 Fed. Appx. 995 (Fed. Cir. 2015).....	17
<i>Mallinckrodt. v. Masimo</i> , 147 Fed. Appx. 158 (Fed. Cir. 2005).....	19

Metalcraft of Mayville v. Toro
 848 F.3d 1358 (Fed. Cir. 2017).....8, 9

Outside the Box Innovations, LLC v. Travel Caddy, Inc.,
 695 F.3d 1285 (Fed. Cir. 2012).....10

Pfizer, Inc. v. Teva Pharms. USA, Inc.,
 429 F.3d 1364 (Fed. Cir. 2005).....10

Phillips v. AWH Corp.,
 415 F.3d 1303 (Fed. Cir. 2005).....10

Presidio Components, Inc. v. Am. Tech. Ceramics Corp.,
 702 F.3d 1351 (Fed. Cir. 2012).....15

Sanofi-Synthelabo v. Apotex, Inc.,
 470 F.3d 1368 (Fed. Cir. 2006).....18

Smith & Nephew, Inc. v. Interlace Med., Inc,
 955 F. Supp. 2d 69 (D. Mass. 2013)19

Toro Co. v. Deere,
 355 F.3d 1313 (Fed. Cir. 2004).....11

Trebro Mfg., Inc. v. Firefly Equip., LLC,
 748 F.3d 1159 (Fed. Cir. 2014).....17

Vaqueria Tres Monijitas, Inc. v. Irizarry,
 587 F.3d 464 (1st Cir. 2009).....18

Veracode, Inc. v. Appthority, Inc.,
 137 F. Supp. 3d 17 (D. Mass. 2015)19

Winter v. Nat’l Res. Def. Council,
 555 U.S. 7 (2008).....8

Statutes

35 U.S.C. § 154.....8

35 U.S.C. § 283.....1, 14

Plaintiff SoClean, Inc. (“SoClean”) respectfully submits this memorandum of law, together with the Declaration of Dean Marcarelli, executed February 20, 2020 (“Marcarelli Decl.”), the Declaration of Kurt Maw, executed February 18, 2020 (“Maw Decl.”) and the Declaration of Clancy Galgay, executed February 20, 2020 (“Galgay Decl.”), in support of SoClean’s motion pursuant to Rule 65 of the Federal Rules of Civil Procedure and 35 U.S.C. § 283 seeking an ex parte temporary restraining order and/or a preliminary injunction against Defendant Sunset Healthcare Solutions, Inc. (“Sunset”).

PRELIMINARY STATEMENT

Sunset used its position as a distributor for SoClean to obtain confidential information regarding SoClean’s products, distribution channels, pricing models, and business and product development strategies to develop its own copycat products and business so that it could compete directly and unfairly with SoClean. Sunset is now illicitly riding the coattails of SoClean’s success by manufacturing and selling an infringing knock-off version of SoClean’s patented technology at a cheaper price through the same channels as it had marketed the SoClean device. Sunset’s infringement should be enjoined.

SoClean is the leader in the design, development, and sales of automated CPAP disinfecting devices, including the SoClean 2 automated CPAP disinfecting device, which uses SoClean’s patented technology to enable a user to disinfect their CPAP device through the use of an ozone operating system that connects to the user’s CPAP device and allows for ozone to flow through the CPAP device thereby disinfecting the device. Prior to SoClean marketing its first product in 2012, the market for automated CPAP disinfecting devices did not exist. Importantly, SoClean built the market through its development of the patented technology and extensive

advertising about the importance of cleaning CPAP devices and the opportunity to do so with an automated disinfecting device as a supplement to handwashing.

Due to SoClean's great success in creating the market for automated CPAP disinfecting devices, many cheap knock-off products (such as counterfeit filter cartridge replacements) have entered the market, and SoClean has had to actively police the market to remove these counterfeits. Defendant Sunset is another such company looking to capitalize on the popularity of SoClean's technology and market recognition. Until recently, Sunset had been a distributor of SoClean's product to numerous Durable Medical Equipment resellers ("DMEs"). As a result, Sunset learned SoClean's marketing and pricing strategy—including the confidential prices that SoClean sold its product to DMEs—and development concepts and, in many ways, had become associated with SoClean in the eyes of these DMEs.

Sunset's product is a knock-off of SoClean's product with the same look and feel which is certain to confuse customers. SoClean's Complaint asserts infringement of SoClean's patents covering the systems, methods, and devices for ozone sanitization of CPAP devices (collectively the "SoClean Patents"), as well as breach of the Distribution Agreement and other related state law claims. This motion for a temporary restraining order and/or preliminary injunction focuses on infringement of United States Patent Number 10,434,205 ("the '205 Patent"), entitled "Systems, Methods, and Devices for Ozone Sanitization of Continuous Positive Airway Pressure Devices."

In January 2020, SoClean discovered Sunset's infringing sales of a product that Sunset has branded "the Zoey" (the "Accused Product"). As of today, Sunset continues to infringe the SoClean patents and is ramping up its marketing efforts for the Zoey. In particular, SoClean recently learned that Sunset intends to market and present its product at the second largest tradeshow in the United States focused exclusively on the home medical equipment ("HME")

market,^{1/} the Medtrade Spring convention, which is scheduled to begin on March 3, 2020. *See* Marcarelli Decl. ¶ 28; Galgay Decl. Ex. J. Sunset's recent entry into the DME sales channel has already detrimentally impacted SoClean's sales. If Sunset is allowed to continue to market its product generally—and specifically at the major convention and trade show in early March—SoClean will be irreparably harmed. Sunset's infringement is harming SoClean by causing lost current sales, lost future sales, lost market share, price erosion, brand erosion, and lost goodwill. SoClean is also being forced to consider lowering its price—and the price of any future products—in order to compete with Sunset's infringing product.

Due to the high likelihood of success on SoClean's claims for patent infringement, a temporary restraining order should be issued to restrain Sunset from selling its infringing product generally, and restrain Sunset from presenting, promoting, marketing, or selling the Zoey at the upcoming major convention and trade show in Las Vegas on March 3-5, 2020, where Sunset is expected to heavily promote its new product. In addition, following a hearing, Sunset should be preliminarily enjoined from importing, making, using, selling, and offering for sale the Accused Product, and from inducing others to use the product in the United States pending the final determination of this action.

STATEMENT OF FACTS

I. The SoClean Patents

Prior to SoClean, the market for automated CPAP disinfecting devices did not exist. Marcarelli Decl. ¶ 6. Instead, CPAP users would either clean their devices by hand, which is a messy and time consuming process, or forego cleaning their CPAP machines at all, to the detriment

^{1/} While there are slight differences between HMEs and DMEs, they are generally used interchangeably and there is no difference between the two for purposes of this Motion. Marcarelli Decl. ¶ 32.

of their health. In addition, some CPAP users would forgo even using the CPAP machine due to the hassle of cleaning the devices, again to the detriment of their health.

Having identified this market opportunity, SoClean designed an automated CPAP disinfecting device that would supplement handwashing of CPAP machines. After significant engineering effort, SoClean successfully found a solution and since then has sought to capitalize on its extensive research, marketing, and development efforts by filing for its first patents in 2011, which were granted in 2015. Marcarelli Decl. ¶¶ 3, 6. As of today, SoClean holds numerous patents on its technology, including the patents at issue here (the '205 and '492 Patents), and has multiple pending patents. *See* Galgay Decl. Exs. A and B.

II. SoClean Created the Market for Automated CPAP Cleaning Devices.

SoClean has marketed and sold its automated CPAP disinfecting devices since 2012. In 2019, SoClean sold more than 650,000 SoClean 2 devices worldwide, which includes over 600,000 sold in the United States. Marcarelli Decl. ¶ 7.

SoClean spent years in research and development efforts to refine the technology and components to make its products safe, effective, and useful to consumers. *Id.* at ¶ 8. Moreover, SoClean has spent more than \$43 million on advertising (online and television) and promoting its products since 2018. *Id.*

Over the years, SoClean's products have been repeatedly recognized in the industry and press for their innovation and appeal. Marcarelli Decl. ¶ 10. For example SoClean was recognized as one of the Deloitte 500 fastest growing companies in 2019. *Id.* In addition, SoClean was the second-place winner of the 2016 Innovative HME Retail Product Award at Medtrade. The Innovative HME Retail Product Award is a biannual award that recognizes value-add products that contribute to retailers' bottom line. *Id.* In 2017, SoClean won the Small

Business Association of New England (SBANE) Innovation Award that is given annually to companies and organizations that transformed innovative idea(s) into a product or service that delivers proven value to customers. *Id.*

Capitalizing on its long history of promoting its novel technology, in 2019, SoClean launched a new marketing campaign featuring William Shatner (“the Shatner promotion”). Marcarelli Decl. ¶ 9. The Shatner promotion cost almost \$2.5 million just to create the content and in royalty payments to date paid to the talent for airing the commercials, which does not include the extensive cost to air the commercials. *Id.* In the last quarter of 2019, SoClean spent over \$12 million in other marketing costs to advertise its products, including on television, and to promote and maximize sales of its patent-protected products. *Id.* *The market has responded and sales have increased dramatically. Id..*

III. SoClean Has Policed its Intellectual Property Rights

In order to (a) protect the value of the SoClean name and reputation, (b) protect the value of SoClean’s products, such as the SoClean 2 device, and (c) maximize the impact of SoClean’s advertising dollars, SoClean has aggressively policed the market to eliminate knock-off products (particularly knock-off replacement filters) that infringe, in particular, SoClean’s trademarks. Marcerelli Decl. ¶ 11. SoClean has filed dozens of online complaints against knock-off and counterfeit products being sold via Amazon.com and other marketplaces. *Id.* SoClean also has sent numerous cease and desist letters to infringers. *Id.*

SoClean has also protected the value of its intellectual property rights through its contracts with its distributors which include provisions protecting its IP rights. For example, on April 20, 2019, SoClean and Sunset entered into their Distributor Agreement (“the Agreement”) in which Sunset agreed to serve as a distributor to advertise, market, and sell SoClean’s products

to subdistributors, resellers, and end-users in the United States. *See* Marcarelli Decl. ¶ 13; Galgay Decl. Ex. E. Sunset agreed that SoClean retained all rights, title, and interest in and to all intellectual property rights embodied in the SoClean products, including the manufacture and/or production of the products, and all patent rights, trade secret rights, and other proprietary rights in or relating to the Products. Sunset further acknowledged and agreed that the Agreement did not grant to Sunset any intellectual property rights in the SoClean products. *See* Marcarelli Decl. ¶ 17; Galgay Decl. Ex. E ¶ 26. However, while acting as a distributor for SoClean, Sunset copied SoClean’s patented designs, and developed and then began marketing Sunset’s automated CPAP disinfecting machine, the Zoey. *See* Marcarelli Decl. ¶ 19.

IV. Sunset Introduced its Infringing Products at a Lower Price

In January 2020, SoClean learned that Sunset had begun selling the Accused Product, which infringes the SoClean Patents and directly competes with the SoClean products. Marcarelli Decl. ¶¶ 26-27. The Accused Product is currently sold exclusively through many of the same home medical equipment distributors (“HMEs” or “DMEs”)—which are also used by SoClean—and are marketed via Sunset’s own web page, www.cleanwithzoey.com. Marcarelli Decl. ¶ 28; Galgay Decl. Exs. F, H, and I. Sunset sells the Zoey at a price point of \$299 or less, compared to SoClean’s price point of \$348 for its SoClean 2 device. Marcarelli Decl. ¶ 30.

Because Sunset has copied SoClean’s device, Sunset is also benefitting substantially from SoClean’s advertising and marketing efforts to create the market for automated CPAP disinfecting devices. Marcarelli Decl. ¶¶ 31-34. If the competition from Sunset’s infringing products is allowed to persist, SoClean will have no option but to reduce the price of its SoClean 2 device and also lower the prices of any new products it releases. Marcarelli Decl. ¶¶ 30, 40-42.

V. Sunset's Infringement is Willful

Sunset has admitted to DMEs that Sunset made the Zoey “the most comparable to SoClean than other units on the market.” Marcarelli Decl. ¶ 29. In other words, throughout the time that Sunset was marketing SoClean’s products and learning SoClean’s marketing strategies, Sunset was attempting to design a directly competing, infringing product that would be “most comparable” to a SoClean 2 device but would sell at a lower price and through the same channels. As described here, Sunset plainly failed to engineer a non-infringing product *vis-a-vis* SoClean’s patents. Maw Decl. ¶ 6; Galgay Decl. Exs. C and D.

VI. A Preliminary Injunction Is Needed To Protect SoClean from Irreparable Harm Caused by Sunset's Sales of Its Infringing Accused Product

SoClean is being significantly and irreparably harmed by Sunset’s sales of the Zoey, which is currently being sold nationally through the same channels that carry SoClean’s products—specifically through DMEs—and Sunset is expected to broaden its marketing as it launches its infringing product at the upcoming Las Vegas convention and trade show, and through eventual online sales at websites like Amazon.com and/or through Target and Walmart. Marcarelli Decl. ¶¶ 30, 36, 39. Such actions would cause further significant and immediate harm to SoClean. As the Accused Product begins to be sold and marketed more broadly—and currently there is a promotional special of “buy 10 get one free” for DMEs—it is substantially undercutting the market for SoClean’s patented devices, which will only escalate with time. Marcarelli Decl. ¶¶ 36-37, 39. Further, the value of the advertising dollars that SoClean spends in creating and broadening the market is being diluted by the presence of this cheaper knock-off, infringing product. Marcarelli Decl. ¶ 33. Sunset did not have to pay the development costs, the costs to create the market, or the costs to bring the product to market. Sunset simply stole SoClean’s patented invention and seeks to ride SoClean’s advertising and engineering coattails.

Unfair competition from Sunset and its undercutting of prices is jeopardizing SoClean's right and opportunity to profit from the exclusivity to which it is entitled under the Patent Laws. Moreover, if Sunset is allowed to continue to sell its infringing product, SoClean will suffer price erosion, will be forced to lower its prices, will see sales decline below projections, and will lose market share among other damages. It will also lose conveyed sales from sales of replacement components, such as filter cartridges. Marcarelli Decl. ¶ 40.

ARGUMENT

A patent grants the patent owner the right to exclude others from making, using, or selling the claimed invention for the term of the patent. 35 U.S.C. § 154. A preliminary injunction may be granted to protect that exclusive right, and “the standard for granting or denying a motion for preliminary injunction is not unique to patent law.” *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1367 (Fed. Cir. 2008). Instead, “the standard of the regional circuit should apply.” *Id.*

“A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest.” *Winter v. Nat'l Res. Def. Council*, 555 U.S. 7, 20 (2008); *Arborjet v. Rainbow Treecare Sci. Advancements*, 794 F.3d 168, 171 (1st Cir. 2015). A defendant cannot defeat a preliminary injunction merely by raising “substantial questions.” *See Abbott Labs.*, 544 F.3d at 1368–1369.

Using these four factors, courts have repeatedly employed preliminary injunctions to protect patent-holders. For example, in *Metalcraft of Mayville v. Toro*, the Federal Circuit affirmed a preliminary injunction against the sale of infringing lawnmower accessories. *See* 848 F.3d 1358 (Fed. Cir. 2017). After determining that the patent-holder was likely to succeed on

the merits, the Court determined that “the damage to [the patent-holder] is irreparable because it is impossible to quantify the damages caused by the loss of a potentially lifelong customer,” including lost future sales and fewer recommendations by customers. *See id.* at 1368.

Considering the balance of equities and public interests, the Court noted the patent-holder’s “substantial hardship in being forced to compete against its own patented invention,” and the fact that, after the injunction, the public could continue to obtain the patented product from the patent-holder, or obtain substitute non-infringing products. *See id.* at 1369.

Similarly, the Federal Circuit has also upheld preliminary injunctions on medical products, as in *Abbott Laboratories v. Sandoz*, where the court considered an infringing, soon-to-be-released generic drug. *See* 544 F.3d 1341 (Fed. Cir. 2008). After deciding that the patent was likely infringed, the Court found that the patent-holder would be irreparably harmed absent an injunction, even though there were already other, (properly) licensed generic alternatives already on the market. *See id.* at 1361–62 (finding irreparable harm by way of lost market share and revenue). Moving on to the balance of hardships, the Federal Circuit approved the lower court’s finding that “preserving the status quo preserves the current market structure,” and thus that the patent-holder would “lose much more if this Court did not enjoin [the] infringing conduct,” because allowing the infringer to enter the market would lead to the often irreversible “erosion of markets, customers, and prices.” *See id.* at 1362. Finally, the court determined that there was a significant public interest in encouraging medical development by way of protecting their related patents. *See id.*

Like these cases, and as demonstrated below, SoClean has clearly established each of the required elements and is entitled to preliminary injunctive relief to prevent the irreparable harm Sunset is causing.

I. SoClean Is Likely To Succeed On Its Patent Infringement Claims

The Accused Product infringes at least Claims 1, 2, 6, 7, and 11 of the '205 Patent because it contains every element of each of those claims. Maw Decl. ¶ 6; Galgay Decl. Ex. C. “Determining the likelihood of infringement requires two steps, first claim construction and second a comparison of the properly construed claims to the accused product.” *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1372 (Fed. Cir. 2005).

In construing a claim, courts begin with the language of the claim, which “define[s] the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Claim terms “are generally given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips*, 415 F.3d at 1312-1313 (quoting *Vitrionics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Beyond that, to ascertain meaning the court may look first to the intrinsic evidence (the context of the claims, the patent specification, and the prosecution history). *Id.* at 1313–16. Most often, this will resolve any ambiguity. *Id.* at 1315. The court may not, however, import limitations from the specification into the claim, such as by limiting the claims to the embodiments described in the specification. *See id.* at 1323–24. While the court may rely on dictionaries, dictionary definitions must not be allowed to undermine the intrinsic evidence of a claim’s meaning. *Id.* at 1319.

If there is a reasonable dispute as to the elements of asserted claims of a patent, those disputes should be resolved through claim construction. *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1302-1303 (Fed. Cir. 2012). Claim construction at the preliminary injunction stage need not be comprehensive or final, *see id.*, and no explicit claim construction is necessary if, as here, the construction is straightforward with respect to claims

whose meaning cannot be reasonably disputed, *Toro Co. v. Deere*, 355 F.3d 1313, 1322 (Fed. Cir. 2004). Here, the construction of the claim terms is straightforward and the terms in the claims of the '205 Patent should be given their ordinary meaning. *See Toro*, 355 F.3d at 1322.

In particular, for purposes of this Motion, SoClean has attached a Claim Chart detailing on an element by element basis the Accused Product's infringement of Claims 1, 2, 6, 7, and 11 of the '205 patent.^{2/} *See Galgay Decl. Ex. C*. The Claim Chart plainly establishes that the Accused Product practices each element of the Asserted Claims 1, 2, 6, 7, and 11. In addition, SoClean has attached the Declaration of Kurt Maw, a mechanical engineer who was involved in the development of SoClean's CPAP disinfecting device, and who reviewed the Claim Chart, the '205 patent, and the Accused Product, among other materials, and provides his opinion as to why each and every asserted claim of the '205 patent is infringed by the Accused Product. SoClean has also submitted the Declaration of its Chief Marketing Officer, Dean Marcarelli, who explains the significant harms being caused by Sunset.

The Accused Product plainly practices each element of Claim 1. Claim 1 of the '205 Patent reads as follows:

A system comprising:

- a. An ozone device comprising an ozone operating system and an ozone distribution line;
- b. A connector unit configured to fluidly couple the ozone device to a continuous positive airway pressure (CPAP) device, the connector unit comprising:
 - i. A first end comprising a first opening configured to couple to a reservoir of said CPAP device;
 - ii. A second end comprising a second opening configured to couple to a hose of said CPAP device.

^{2/} To simplify the issues for this motion for a temporary restraining order and preliminary injunction, SoClean is only relying on infringement with respect to Claims 1, 2, 6, 7, and 11 of the '205 patent. As outlined in SoClean's complaint against Sunset, however, SoClean has alleged additional claims for infringement of its intellectual property rights by Sunset.

- iii. A first passageway extending between the first opening and the second opening, the first passageway defined at least in part by a wall of said connector unit, wherein said wall extends between the first end and the second end; and
- iv. A port comprising a third opening that is configured to couple to the ozone distribution line and a second passageway, wherein the second passageway extends through the wall and is at least partially disposed within the first passageway.

Maw Decl. ¶ 7; Galgay Decl. Exs. A and C.

The Zoey is plainly an ozone (O₃) device comprising an ozone operating system and an ozone distribution line (“an ozone device”). Sunset’s own advertising and its User Manual demonstrates that it is an “ozone device.” *See, e.g.*, Galgay Decl. Exs. G and H. For example, the video on Sunset’s website demonstrates that the Zoey is an ozone operating system with an ozone distribution line. *See, e.g.*, Maw Decl. ¶¶ 19-21. This is further demonstrated in the Maw Declaration, and the Maw images and figures are attached as an Appendix to this Motion.

Claim 1 also has five elements regarding a “connector unit,” each of which are met by the Accused Product. First, Claim 1 sets out a “connector unit configured to fluidly couple the ozone device” to a CPAP device. The Zoey includes a connector unit (referred to as a “tube connector” by Sunset) configured to fluidly couple the ozone device to a continuous positive airway pressure (CPAP) device. *See* Maw Decl. ¶ 20; Galgay Decl. Ex. C.

Next, Claim 1 requires “the connector unit comprising^{3/} a first end comprising a first opening configured to couple to a reservoir of said CPAP device,” and a “second end comprising a second opening configured to couple to a hose of said CPAP device.” As shown in another image taken from Sunset’s website, and as clearly labeled by SoClean, Zoey’s “tube connector”

^{3/} The term “comprising” means “including, but not limited to.” Thus, the accused device may contain elements in addition to those explicitly mentioned in the claim. *See Cytoc Corp. v. TriPath Imaging, Inc.*, 505 F. Supp. 2d 199, 216 n.15 (D. Mass. 2007) (citing *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1235 (Fed. Cir. 2005)).

comprises a first opening that is configured to couple to a reservoir of a CPAP device, and a second opening that couples to a hose of a CPAP device. *See* Maw Decl. ¶ 21; Galgay Decl. Ex. C.

Next, Claim 1 requires that the connector unit comprise “a first passageway extending between the first opening and the second opening, the first passageway defined at least in part by a wall of said connector unit, wherein said wall extends between the first end and the second end.” *See*, Maw Decl. ¶¶ 7, 22; Galgay Decl. Ex. C. The Zoey includes a “tube connector” that clearly extends between the end of a CPAP hose and the CPAP device, and connects the ozone generator to the reservoir of the CPAP. There is a passageway between the opening that couples to the CPAP device and the opening that couples to the CPAP hose. *See*, Maw Decl. ¶ 22; Galgay Decl. Ex. C. Thus, that element of Claim 1 is plainly met by the Accused Product.

The final element of Claim 1 requires “a port comprising a third opening that is configured to couple to the ozone distribution line and a second passageway, wherein the second passageway extends through the wall and is at least partially disposed within the first passageway.” Maw Decl. ¶¶ 7, 23. The Zoey includes a tube connector that includes a spout (port) that is configured to couple to the injection hose (ozone distribution line). Maw Decl. ¶ 23. The opening of the spout is configured to couple to the injection hose and a second passageway that extends through the wall of the tube connector. The second passageway includes a sidewall, wherein part of that sidewall extends into the first passageway. Thus, the Zoey includes a second passageway that extends through the wall of the tube connector and “is at least partially disposed within the first passageway.” Maw Decl. ¶ 23; Galgay Decl. Ex. C. Again, this element of Claim 1 is met by the Accused Product.

Because every claimed element of Claim 1 of the ‘205 Patent is met by the Accused Product, the Accused Product infringes at least Claim 1 of the ‘205 Patent. In addition and as

explained in the Claim Chart and in the Maw Declaration, the Zoey also infringes at least dependent Claims 2, 6, 7, and 11 of the '205 Patent. *See* Maw Decl. ¶ 6; Galgay Decl. ¶ Ex. C. Therefore, SoClean is likely to succeed on the merits of its infringement claims.

II. SoClean Will Suffer Irreparable Harm Without An Injunction

SoClean's automated disinfecting device, the SoClean 2, is its sole product (not including components of the device). If not enjoined, Sunset's marketing and sales of the Accused Product will cause irreparable harm to SoClean. Through SoClean's significant advertising and marketing efforts—including the recent expensive Shatner promotions—and by reason of the quality and great practical success of its products, SoClean has created a market for automated CPAP disinfecting devices and deserves to have its exclusive right to prevent others from practicing its invention be protected.

Sunset is now piggy-backing on the success and efforts of SoClean. Sunset is manufacturing and selling its infringing product in the United States in the same channel where SoClean sells its products and where Sunset had sold SoClean's product previously. In addition, Sunset is selling its product at a lower price point, causing a significant risk of lost sales, lost future sales, and price erosion. Because Sunset's cheaper product also looks remarkably like the SoClean (presumably, intentionally so) and is being marketed by SoClean's prior distributor, Sunset's Accused Product will create even greater confusion in the market. Irreparable harm is inevitable as a result of Sunset's marketing and sales of its infringing and directly competing product. SoClean's losses on these sales and sales of replacement components will also be difficult to precisely and fully quantify. Marcarelli Decl. ¶ 39.

U.S. patent law expressly provides for the grant of injunctions to prevent infringement by a competitor, "in accordance with the principles of equity." 35 U.S.C. § 283. With regards to

equity in patent cases, “the right to maintain exclusivity [is] a hallmark and crucial guarantee of patent rights,” and “[e]xclusivity is closely related to the fundamental nature of patents as property rights.” *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 642 (Fed. Cir. 2015). What’s more, “the need to protect this exclusivity would certainly be at its highest when the infringer is one’s fiercest competitor.” *Id.* Thus, “[i]n view of that right [to exclude], infringement may cause a patentee irreparable harm not remediable by a reasonable royalty.” *Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1328 (Fed. Cir. 2008). That is why “[t]he courts have a long history of remedying trespass on property rights—including patent rights—by removing the trespasser.” *Broadcom Corp. v. Emulex Corp.*, 732 F.3d 1325, 1338 (Fed. Cir. 2013). The court’s equity analysis “proceeds with an eye to the ‘long tradition of equity practice’ granting ‘injunctive relief upon a finding of infringement in the vast majority of patent cases.’” *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1362 (Fed. Cir. 2012) (citation omitted); *Apple*, 809 F.3d at 638–39 (“[G]iven the difficulty of protecting a right to *exclude* through monetary remedies’ . . . historically courts have granted injunctions upon a finding of infringement”) (emphasis in original) (quoting *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 395 (2006) (Roberts, J., concurring)).

“Patent property rights are especially difficult to protect with solely monetary relief” *Broadcom*, 732 F.3d at 1338 (citing *Presidio*, 702 F.3d at 1362–63). Specifically, “[w]here two companies are in competition against one another, the patentee suffers the harm—often irreparable—of being forced to compete against products that incorporate and infringe its own patented inventions.” *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1345 (Fed. Cir. 2013). Moreover, “[i]rreparable injury encompasses different types of losses that are often difficult to quantify, including lost sales and erosion in reputation and brand distinction,” *id.* at

1344, as well as manufacturing delays, damage to distribution channels, and loss of customers, *see Contour Design, Inc. v. Chance Mold Steel Co., Ltd.*, 2010 U.S. Dist. LEXIS 121761, at *33–34 (D.N.H. 2010). *See also Acumed*, 551 F.3d at 1328 (“[I]nfringement may cause a patentee irreparable harm not remediable by a reasonable royalty”); *Celsis in Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) (“Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm.”).

There is no legitimate dispute that the Accused Product competes directly with SoClean’s patented automated CPAP cleaning device. Indeed, SoClean has already begun to feel the effects of Sunset’s infringement—losing sales in just one month and feeling pressure to lower its prices. Marcarelli Decl. ¶¶ 35-38. Of course, Sunset can afford to sell its knock-off vehicles at a lower price point because Sunset has not incurred the substantial research and development costs borne by SoClean to advance the technology, nor has Sunset spent millions of dollars in advertising to build the market for automated cleaning devices.

Without an injunction, Sunset will continue selling its less expensive, knock-off devices, incorporating SoClean’s patented technology, in a market that SoClean created and where it should be entitled to enjoy its exclusive patent rights. Protection against such unlawful direct competition is precisely what patent law grants. *See, e.g., Broadcom*, 732 F.3d at 1337 (affirming grant of permanent injunction and upholding finding of irreparable harm where parties were “direct competitors in a limited market” for a product where “the patented feature . . . drive[s] the demand for the product”).

Such irreparable harm, visited upon SoClean by a direct competitor, weighs heavily in favor of the issuance of the requested preliminary injunction.

III. The Balance of Hardships Weighs Decidedly in SoClean's Favor

The balance of hardships weighs decidedly in favor of SoClean. If an injunction is denied, Sunset will continue capitalizing on the market that SoClean built, infringing SoClean's Patents, and denying SoClean its exclusive rights. Further, other infringers will be encouraged to ignore SoClean's efforts to exclude them, or to enter into the market with new infringing products. SoClean will lose its exclusivity to establish and maintain a market for its automated CPAP disinfecting device. *See Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1172 (Fed. Cir. 2014) (where defendant was "the only non-licensed competitor in the market," balance of hardships favored patentee because this "suggest[ed] that this patent will have significantly less value if Trebro cannot use it to exclude an infringing product from the market."); *Abbott Labs.*, 544 F.3d at 1362 (upholding lower court's ruling that the balance of hardships weighed in favor of an injunction, because allowing the infringer to enter the market would lead to the often irreversible "erosion of markets, customers, and prices"). *See also Dunkin' Donuts Franchised Rests. LLC v. ABM Donuts, Inc.*, 2011 U.S. Dist. LEXIS 139074, at *20–21 (D.R.I. 2011) (finding that the balance of equities favored the plaintiff, because "in contrast to the harm [the plaintiff] is suffering, any harm to Defendants is completely self-inflicted and thus cannot be deemed irreparable as a matter of law."). Competition from infringing products will further erode prices and SoClean's market share. Allowing Sunset to continue its sales pending trial would let it build market share and benefit from SoClean's creation of a market for automated CPAP disinfecting devices.

By contrast, Sunset's hardship if the preliminary injunction is granted is no greater than any other patent infringer's. Sunset's recent entry into the market weighs in favor of granting an injunction. *See, e.g., M-I LLC v. FPUSA, LLC*, 626 Fed. Appx. 995, 999 (Fed. Cir. 2015) (upholding preliminary injunction where the patent-holder had been marketing its product for

five years before the infringer began marketing their own); *Abbott Labs.*, 544 F.3d at 1362 (affirming lower court’s finding that “preserving the status quo preserves the current market structure,” and thus the patent-holder would “lose much more if this Court did not enjoin [the] infringing conduct,” because allowing the infringer to enter the market would lead to the often irreversible “erosion of markets, customers, and prices”)

Moreover, Sunset is knowingly infringing the SoClean Patents, and has explained to DMEs that it has taken a calculated risk of infringing SoClean’s patents and purportedly “worked around” them to create the “most comparable” product to the SoClean 2 device. *See* Marcarelli Decl. ¶ 29. Such knowing infringement weighs in favor of granting an injunction: “while we are sympathetic to defendants’ claims of hardship, this is a situation of their own doing.” *Vaqueria Tres Monijitas, Inc. v. Irizarry*, 587 F.3d 464, 486 (1st Cir. 2009) (finding balance of hardships weighed in favor of injunction, and thus confirming the district court’s decision to grant an injunction). *See, e.g., Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (affirming preliminary injunction, because “[the defendant’s] harms were ‘almost entirely preventable’ and were the result of its own calculated risk to launch its product pre-judgment.”); *Indivior Inc. v. Dr. Reddy’s Labs., S.A.*, 752 Fed. Appx. 1024, 1041 (Fed. Cir. 2018) (finding that “the court did not clearly err in finding that [the infringer’s] harms were ‘almost entirely preventable’ and were the result of its own calculated risk to launch its product pre-judgment.”) (internal quotations omitted).

Sunset’s decision to forge ahead with its infringing product means that any potential harm resulting from an injunction is caused by Sunset itself, and is insufficient to tip the balance of equities in its favor. Accordingly, this element strongly favors granting a preliminary injunction. *See, e.g., Celsis*, 664 F.3d at 931 (affirming grant of preliminary injunction and finding equities

favored injunction where “the preliminary record suggest[ed] that [defendant’s] losses were the result of its own calculated risk in selling a product with knowledge of [plaintiff’s] patent”).

IV. Enjoining Sunset’s Patent Infringement Advances the Public Interest

“In general, the public interest favors protecting the rights of patentees and enforcing the patent system.” *Veracode, Inc. v. Appthority, Inc.*, 137 F. Supp. 3d 17, 94–95 (D. Mass. 2015) (quoting *Smith & Nephew, Inc. v. Interlace Med., Inc.*, 955 F. Supp. 2d 69, 79 (D. Mass. 2013)). *See also Contour Design*, 2010 U.S. Dist. LEXIS at *34 (“[I]njunctive relief against violations of intellectual property rights promote commercial morality.”) (citation omitted). In general, the public interest “favors protecting the rights of patentees and enforcing the patent system.” *Smith & Nephew*, 955 F. Supp. 2d at 79 (citing *ActiveVideo Networks v. Verizon Commc’ns*, 694 F.3d 1312, 1341 (Fed. Cir. 2012); *Douglas Dynamics*, 717 F.3d at 1345–46). At times, “competition serves the public interest . . . [and] ensures competitive pricing and fosters innovation,” however, “cheap copies of patented inventions have the effect of inhibiting innovation and incentive.” *Douglas Dynamics*, 717 F.3d at 1346. As a result, “protection of patent rights takes precedence over public interest in competition.” *Id.*; *Veracode*, 137 F. Supp. 3d at 94–95.

In addition, Sunset occupies a small share of the market, while SoClean is the market leader for automated CPAP disinfecting devices. While there is a public interest in product availability, it is unlikely that the public would suffer from a shortage of the products if the injunction were granted as SoClean can fill any gap in sales of these products left by Sunset’s exclusion. *See* Marcarelli Decl. ¶ 43; *see Mallinckrodt v. Masimo*, 147 Fed. Appx. 158, 177–78 (Fed. Cir. 2005) (the public interest does not prevent an injunction against the defendant’s medical device sales because, “[i]f an injunction were to issue, doctors and hospitals would have

the option of switching to any of [the other] brands instead of [the defendant's] products.”); *Cal. Med. Prods. v. Emergency Med. Prods.*, 796 F. Supp. 640, 648 (D.R.I. 1992)

The public would not be affected by an injunction against Sunset. This factor weighs in favor of granting a preliminary injunction.

CONCLUSION

SoClean has shown a likelihood of success of proving that Sunset infringes at least Claims 1, 2, 6, 7, and 11 of the ‘205 Patent, and the balance of any hardship clearly favors SoClean. Further, the public interest favors granting a temporary restraining order and/or a preliminary injunction. SoClean faces immediate and irreparable harm with Sunset recently launching its product and escalating its marketing efforts significantly at the major convention and trade show in Las Vegas that begins on March 3, 2020. Accordingly, the Court should grant a temporary restraining order and/or a preliminary injunction against Sunset’s presenting, promoting, marketing, or selling the Accused Product at the MedTrade Spring convention and Sunset’s importation, manufacture, use, and sale in the U.S. of the Accused Product pending the final determination of this action.

DATED: February 20, 2020

Respectfully submitted,

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
AND POPEO, P.C.

/s/ H. Joseph Hameline

H. Joseph Hameline (BBO No. 218710)

Thomas H. Wintner (BBO No. 667329)

Clancy Galgay (BBO No. 673116)

One Financial Center

Boston, MA 02111

Tel: (617) 348-3000

Fax: (617) 542-2241

HJGalgay@mintz.com

TWintner@mintz.com

CGalgay@mintz.com

Attorneys for Plaintiff

APPENDIX IMAGES

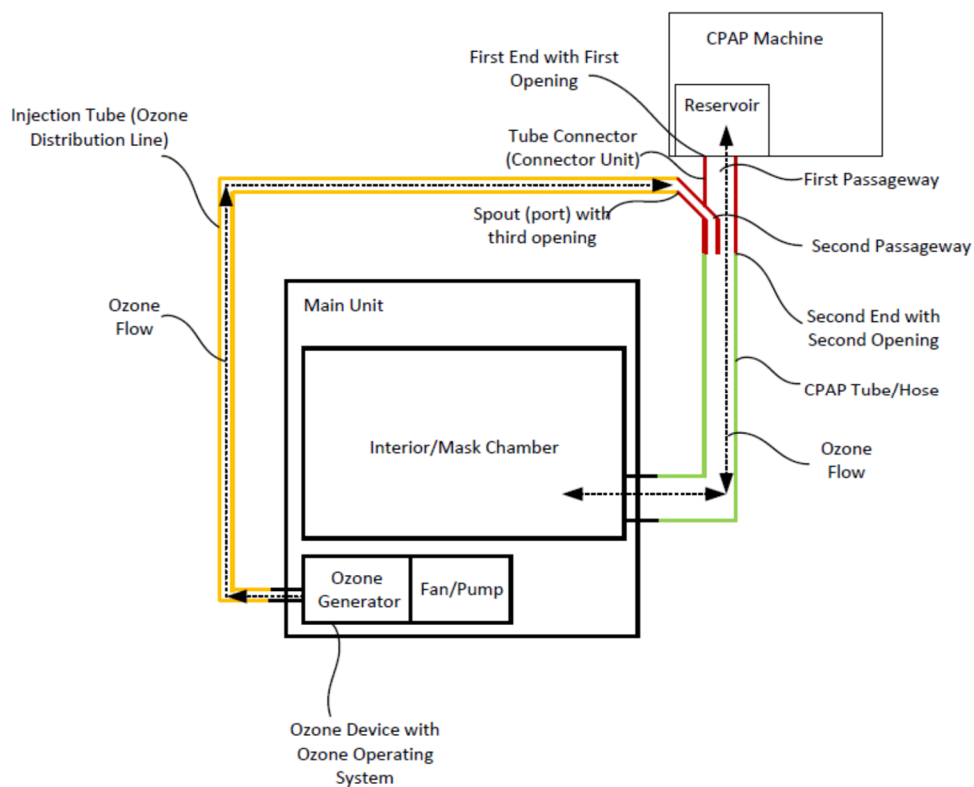


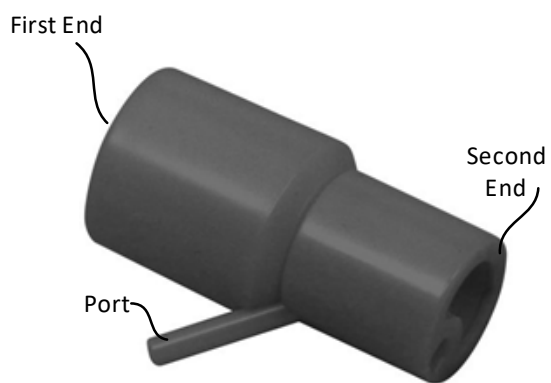
Figure 1: High Level Diagram of the Zoey Cleaning System



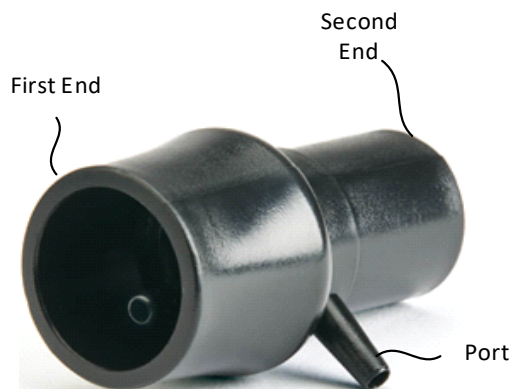
Zoey "Injection Tube"



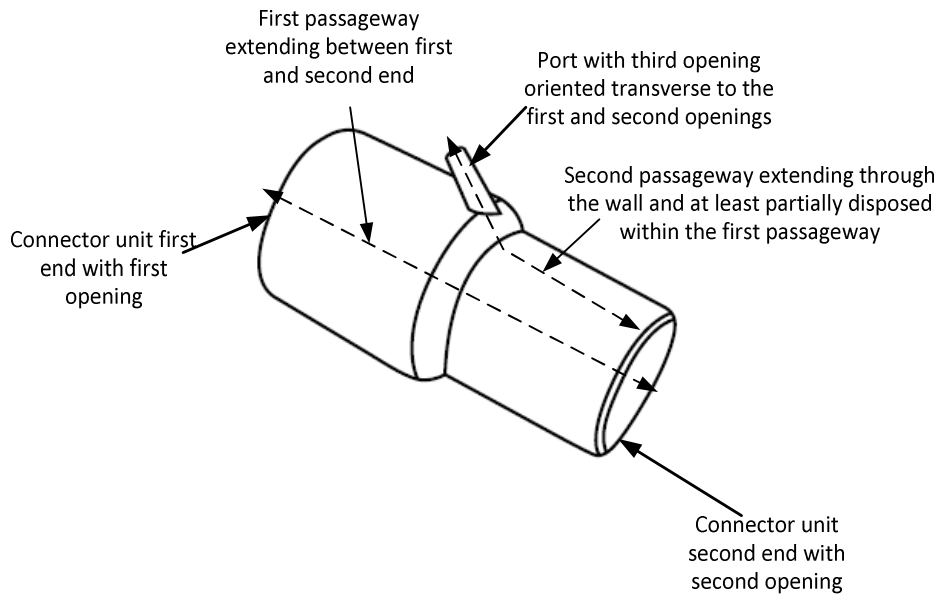
SoClean "Ozone Distribution Line"



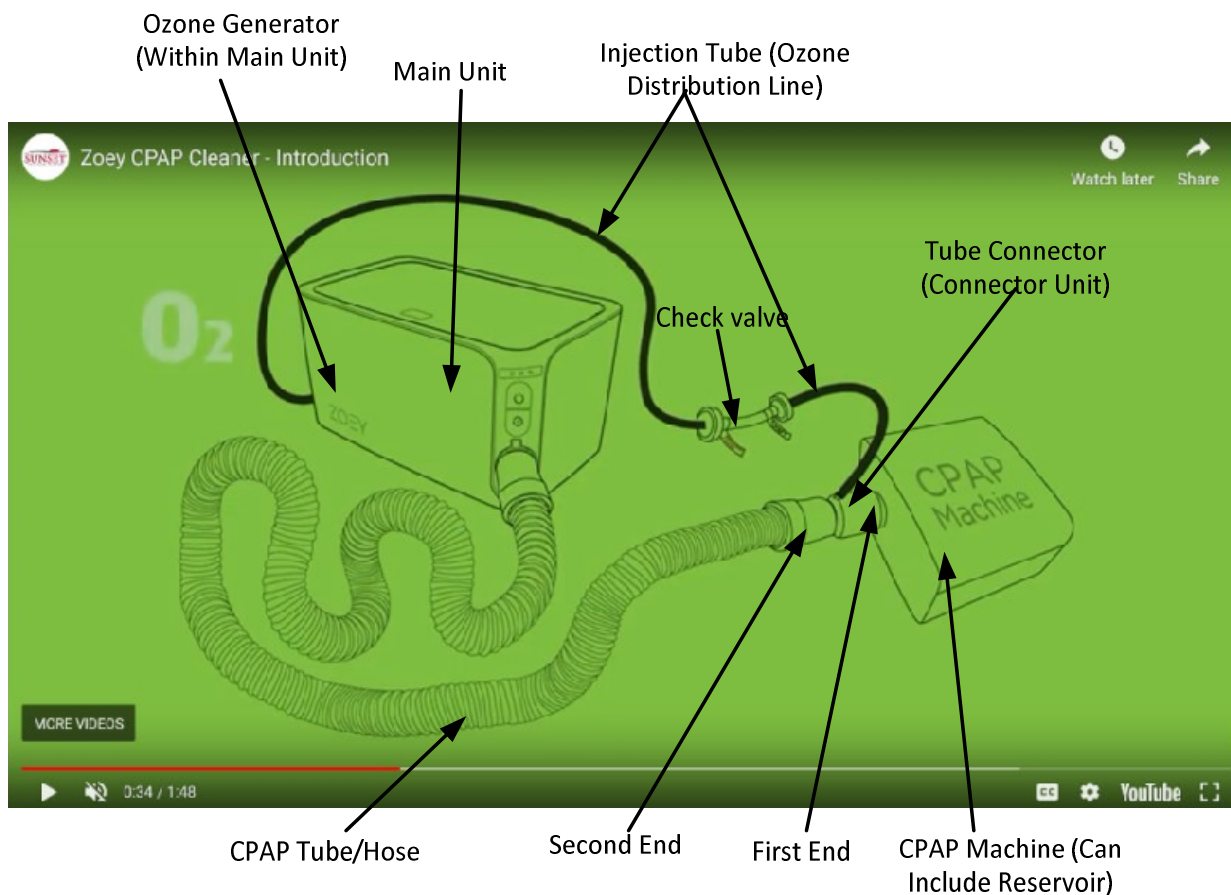
Zoey "Tube Connector"



SoClean Connector Unit



Zoey Tube Connector



The Zoey – Assembled