IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MONAGHAN MEDICAL CORP.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 17-712-LPS-CJB
	:	
SMITHS MEDICAL ASD, INC.,	:	
	:	
Defendant.	:	
	:	
SMITHS MEDICAL ASD, INC.,	:	
	:	
Counterclaim Plaintiff,	:	
	:	
v.	:	
	:	
MONAGHAN MEDICAL CORP.,	:	
	:	
Counterclaim Defendant.	:	
	:	

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MEMORANDUM OPINION

July 6, 2018
Wilmington, Delaware

STARK, U.S. District Judge:

Plaintiff Monaghan Medical Corp. ("Monaghan") has sought a declaratory judgment that it does not infringe any claim of U.S. Patent No. 7,059, 324 ("'324 patent"). Defendant Smiths Medical ASD, Inc. ("Smiths Medical") has counterclaimed that Monaghan infringes the '324 patent as well as U.S. Patent No. 6,581,598 ("'598 patent") (collectively, "patents-in-suit").

Presently before the Court are the parties' disputes over the meaning of certain claim terms in the asserted claims. The parties submitted technology tutorials (D.I. 64, 65), objections to technology tutorials (D.I. 68, 73), claim construction briefs (D.I. 54, 61, 69, 71), and expert declarations (D.I. 62, 71). The Court held a claim construction hearing on May 7, 2018. (*See* D.I. 97 ("Tr.")).

I. LEGAL STANDARDS

A. CLAIM CONSTRUCTION

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted).

"[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, the Court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim 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, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide. . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be

read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, "the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of

the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

B. INDEFINITENESS

A patent claim is indefinite if, "viewed in light of the specification and prosecution history, [it fails to] inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). A claim may be indefinite if the patent does not convey with reasonable certainty how to measure a

claimed feature. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). But "[i]f such an understanding of how to measure the claimed [feature] was within the scope of knowledge possessed by one of ordinary skill in the art, there is no requirement for the specification to identify a particular measurement technique." *Ethicon Endo–Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1319 (Fed. Cir. 2015).

II. CONSTRUCTION OF DISPUTED TERMS

The patents-in-suit[1] generally relate to positive expiratory pressure ("PEP") devices and methods using oscillatory positive expiratory pressure to treat patients. '324 patent, 1:12-18; '598 patent, 1:6-12. The methods and devices are designed to help remove excess mucus from patients suffering from certain lung problems. '324 patent, 1:21-26, 36-52; '598 patent, 1:15-20, 39-51. "In the use of PEP therapy, a patient breathes through an orifice restricter to generate a positive pressure in the lungs during exhalation, with the pressure falling to zero at the end of the exhalation." '598 patent, 1:39-42. "By selection of the proper-sized orifice, a given pressure is determined for the exhalation flow rate generated by an individual patient." *Id.* 1:42-44. "This extended, substantially constant, flow of elevated-pressure exhalation has been shown to be effective for moving secretions trapped in the lungs to the larger airways where the secretions can then be removed through coughing." *Id.* 1:44-48. "It has also been found that . . . treatment with PEP therapy is improved by combining positive expiratory pressure therapy with airway oscillation and intermittent air-flow acceleration." *Id.* 1:66-2:5.

[1]The patents-in-suit are related; the '324 patent is a continuation-in-part of the '598 patent. '324 patent, 1:4-6.

1. "discharge expiratory," "expiratory air," and "expiratory air pressure"

a. "discharge expiratory"[2]

Monaghan Indefinite
Smiths Medical "exhaled air"
Court "exhaled air"

b. "the discharge of expiratory air"[3]

Monaghan "the exhaled air from the lungs into the patient input opening"
Smiths Medical "exhaled air"
Court "exhaled air"

c. "the pressure of expiratory air"[4]

Monaghan "the pressure of exhaled air from the lungs"
Smiths Medical "the pressure of exhaled air"
Court "the pressure of exhaled air"

[2]This term appears in the '598 patent, claim 1.

[3]This term appears in the '598 patent, claim 1.

[4]This term appears in the '324 patent, claim 14.

d. "the expiratory air pressure"[5]

Monaghan "the exhaled air pressure from the lungs" (claim 2); "the exhaled air pressure from the lungs into the air flow tube" (claim 6)
Smiths Medical "exhaled air pressure"
Court "exhaled air pressure"

e. "the pressure of expiratory air discharged therethrough"[6]

Monaghan Indefinite
Smiths Medical "the pressure of the exhaled air passed through"
Court "the pressure of the exhaled air passed through"

f. "the pressure of expiratory air passed thereto"[7]

Monaghan "the pressure of exhaled air from the lungs passed into the inlet opening to the expiratory air responsive closure means"
Smiths Medical "the pressure of the exhaled air passed thereto"
Court "the pressure of the exhaled air passed thereto"

The parties agree that "expiratory air" refers to "exhaled air." Their dispute centers on

[5]This term appears in the '598 patent, claims 2 and 6.

[6]This term appears in the '598 patent, claim 6.

[7]This term appears in the '324 patent, claim 14.

whether additional limitations are included. To Smiths Medical, Monaghan's proposed constructions improperly add limitations as to the location where the expiratory air enters the claimed device and requiring the expiratory air to come directly from the lungs. (D.I. 69 at 3; *see also* Tr. at 7) While Smiths Medical acknowledges that in the claimed invention exhaled air is "exhaled from the lungs . . . at some point in time," it also contends that the claims do not include a "timing requirement that [exhaled air] be immediately preceded as coming from the lungs." (Tr. at 32) Monaghan argues that Smiths Medical's constructions "improperly ignore the location where exhalation occurs." (D.I. 61 at 4)

The Court agrees with Smiths Medical. According to the language of claim 1, for example, a patient exhales to discharge expiratory air into an air flow tube, and the expiratory air then passes into a non-linear discharge orifice, which is opened in response to the discharge of expiratory air. *See* '598 patent, 7:59-8-11 (claim 1). While there is no dispute that the expiratory air originates in the lungs, the claim language makes clear that the expiratory air discharged into the non-linear discharge orifice comes from the air flow tube. Moreover, the specification's focus on lungs is in the context of describing where the secretions or mucus are produced or where the positive pressure is generated, not how the expiratory air flows from the lungs into the claimed device. *See e.g.*, *id.* 1:15-48. Monaghan's constructions incorporating additional limitations are either unnecessary, redundant, or inconsistent with claim language.

The Court also disagrees with Monaghan's contention that the term "discharge expiratory" is indefinite. (D.I. 61 at 2-3) The record does not contain clear and convincing evidence of indefiniteness. A person of ordinary skill in the art ("POSA") would understand with reasonable certainty the meaning of the term in the patent's context. In explaining how PEP

therapy works, the specification notes that "a patient exhales against a resistance to generate expiratory pressure." '598 patent, 1:22-25; *see also id.* 1:38-41 ("In the use of PEP therapy, a patient breathes through an orifice restricter to generate a positive pressure in the lungs during exhalation . . . ."). The patent also makes numerous references to the discharge of expiratory air. *See e.g.*, '598 patent, 2:10-15 ("patient's expiratory air"); *id.* 3:38-41 ("discharges expiratory air"); *id.* 4:20-24 ("patient's or user's expiratory air"); *id.* 5:6-9 ("expiratory air discharge of a patient"); *id.* 5:66-6:8-24 ("patient's or user's expiratory air"); *id.* 7:1-31 ("patient's expiratory air is then discharged"). A POSA would understand the term to mean exhaled air. This conclusion is supported by Smiths Medical's expert's opinion. (*See* D.I. 70-1 ¶¶ 16-20) (explaining that POSA would understand meaning of term in patent's context to mean exhaled air).

Monaghan has also failed to prove by clear and convincing evidence that "the pressure of the expiratory air discharged therethrough" is indefinite due to lack of antecedent basis. (D.I. 61 at 4-5) In reciting various steps of the method, the claim language provides that the discharge of expiratory air through a non-linear discharge orifice is interrupted until the expiratory air pressure reaches a predetermined level. *See* '598 patent, 8:64-67 (Claim 6). Next, the discharge orifice is opened to allow for "the discharge of expiratory air therethrough until the pressure of the expiratory air discharged therethrough falls below said predetermined level." *Id.* 9:1-4. In this way, the claim language makes clear that the term refers to the pressure of the exhaled air as it passes through the discharge orifice. Again, this conclusion is supported by Smiths Medical's expert's opinion. (*See* D.I. 70-1 ¶¶ 21-24) (explaining that POSA would understand "term 'therethrough' refers to . . . 'discharge orifice' and the disputed term refers to the expiratory air

pressure as it is passing through the discharge orifice").

2. "non-linear discharge orifice"[8]

Monaghan "an orifice formed between an inner surface of an outwardly tapered conical discharge outlet and a closure member positioned within the discharge outlet, where the orifice is variable, not linear, as determined by the position of the closure member moving relative to the interior surface of the outwardly tapered conical discharge outlet, such that the air discharge rate through the discharge outlet is variable, not linear"
Smiths Medical "a discharge orifice whose change in opening shape and/or size does not follow a straight line"
Court "a discharge orifice whose change in opening shape and/or size does not follow a straight line"

Monaghan's proposed construction of this term is based on a purported definition Monaghan finds in the prosecution history.[9] (D.I. 61 at 6-7) But the "exacting" standards for lexicography are not met here. *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012). The prosecution history does not include "clear and unmistakable statements" defining or narrowing the scope of this term. *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014). Instead, it shows the applicant clarified that "the air discharge rate through the discharge outlet is variable, not linear or constant and therefore, 'non-linear.'" (D.I. 52 Ex. D JA0035-36) "The patentee is free to choose a broad term and expect to obtain the full scope of its plain and ordinary meaning unless the patentee explicitly redefines the term or

[8]This term appears in the '324 patent, claims 17 and 18, and in the '598 patent, claims 1, 2, and 6.

[9]Monaghan points out that the examiner rejected the term as being indefinite, *see* D.I. 52 Ex. D JA0035-36, and relying in part on this evidence, Monaghan's expert also suggests that the term is indefinite, *see* D.I. 62 ¶¶ 65, 69. Yet, Monaghan has not argued that the term is indefinite but, instead, has proposed a construction for the term.

disavows its full scope." *Thorner*, 669 F.3d at 1367.

Monaghan's construction also improperly reads limitations from the specification into the claims. *See Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014) ("While we read claims in view of the specification, of which they are a part, we do not read limitations from the embodiments in the specification into the claims."); *Prima Tek II, L.L.C. v. Polypap, S.A.R.L.*, 318 F.3d 1143, 1148 (Fed. Cir. 2003) ("Notwithstanding the fact that the claim language must be examined in light of the written description, limitations may not be read into the claims from the written description."). The specification explains where the orifice is located in the preferred and other embodiments. *See e.g.*, '324 patent, 2:14-28; 2:64-3:8. But these are not claim limitations.

The Court's conclusions are supported by the fact that Monaghan's construction would make certain dependent claims redundant. *See Ruckus Wireless, Inc. v. Innovative Wireless Sols., LLC*, 824 F.3d 999, 1004 (Fed. Cir. 2016) ("The doctrine of claim differentiation . . . encourages us to construe independent claims more broadly than their dependent claims."); *see also* Tr. at 47 (Monaghan acknowledging implication of redundancy)) Finally, Smiths Medical's expert's opinion also supports the Court's decision. (*See* D.I. 70-1 ¶¶ 12-15) (explaining that plain meaning of "orifice" is "'hole' or 'void'" and POSA would understand term is not limited by its surrounding structure and could take various shapes and structures)

3. "expiratory air responsive closure means"[10]

Monaghan	
Structure:	the '324 patent describes the structures identified in Figures 2, 7, 8, 10, and 13-[14]. These structures are further defined in the '324 patent as well. '324 patent, 4:18-49 (describing the closure means as a rocker portion for pivotal movement about pivot pins, the rocker portion having cone shaped air-flow closure member, and magnetically attractable material, the cone shaped air-flow closure members is sized and positioned for insertion into a tapered bell-shaped or trumpet-shaped air discharge outlet); 7:1-24 (describing a rocker assembly with two cone-shaped airflow closure member pivotally mounted at each end of the rocker arm, positioned to open or close a pair of complementary tapered bell-shaped or trumpet-shaped air-discharge outlets); 7:25-32 (describing an embodiment with a rocker and pivotally mounted with a weight at one end and a cone at the other)[11]
Function:	"actua[te] between an open position and a closed position in response to the pressure of expiratory air passed thereto"; "open[] in response to the presence of a predetermined pressure of expiratory air being passed in said path of air flow movement, and [] close[] in response to a predetermined rate of air pressure decrease through said discharge opening"; "pivotally mov[e] in response to expiratory air pressure between a closed position blocking the flow of expiratory air in said path of air flow movement and an open position permitting the flow of expiratory air in said path of air flow movement"
Smiths Medical	
Structure:	"a pivotally moveable rocker arm, spring assembly, or the equivalent"
Function:	"for closing or restricting the path of exhaled air"

[10]This term appears in the '324 patent, claim 14.

[11]Quoted from Smiths Medical's Initial Infringement Contentions Pursuant to November 13, 2017 Scheduling Order, dated November 30, 2017, at pp. 23-24.

Court	
Structure:	"a pivotally moveable rocker arm, spring assembly, or the equivalent, including structural components that make the rocker arm or spring assembly pivotally moveable"
Function:	"actua[te] between an open position and a closed position in response to the pressure of expiratory air passed thereto"; "open[] in response to the presence of a predetermined pressure of expiratory air being passed in said path of air flow movement, and [] close[] in response to a predetermined rate of air pressure decrease through said discharge opening"; "pivotally mov[e] in response to expiratory air pressure between a closed position blocking the flow of expiratory air in said path of air flow movement and an open position permitting the flow of expiratory air in said path of air flow movement"

The parties agree that the term is a means-plus-function term, *see* 35 U.S.C. § 112 ¶ 6, and also agree on its function.[12] The dispute is over the structure. Monaghan contends that the structures proposed by Smiths Medical – rocker arm, spring assembly – do not perform all of the recited functions and "fail[] to identify what structure makes the rocker arm 'pivotally moveable.'" (D.I. 61 at 10-11) Smiths Medical contends that Monaghan's structure is erroneous because it includes elements that are not necessary to perform the claimed function; also, "its inclusion of the cone shaped member violates the doctrine of claim differentiation." (D.I. 54 at 12)

The Court agrees with Smiths Medical. The specification describes multiple embodiments of the invention, each having a different type of closure means with different structural features. One type of structure for the closure means is a rocker arm. *See* '324 patent, Figs. 2, 7, 8, 10, and 13; *id.* 4:18-49, 7:1-33. Another type of structure is a spring assembly. *See id.* Fig. 15; *id.* 7:34-46. Both of these structures are described as pivotally moveable. *See id.*

[12]During the hearing, Smiths Medical indicated that it does not object to Monaghan's construction regarding function. *See* Tr. at 58.

4:18-21 ("As best illustrated in FIGS. 2, 7, 8 and 10, the rocker portion 440 is balanced for pivotal movement about pivot pins 441 on spaced pivot supports 481 formed on a platform 485 of the rocker support portion 480."); D.I. 70-1 ¶ 41) (Smiths Medical's expert explaining that spring assembly embodiment described in specification is also pivotally moveable) (citing '324 patent, 7:34-46).

Monaghan's construction is also wrong because it has the effect of importing a limitation – "a cone-shaped member" – from a dependent claim (claim 16) into an independent claim (claim 14). *See Versa Corp. v. Ag-Bag Int'l Ltd.*, 392 F.3d 1325, 1329–30 (Fed. Cir. 2004) (stating doctrine of claim differentiation creates "a presumption that each claim in a patent has a different scope"); *Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1233 (Fed. Cir. 2001) ("Although the judicially created doctrine of claim differentiation cannot override the statutory requirements of § 112, ¶ 6 . . . [it] is clearly applicable when there is a dispute over whether a limitation found in a dependent claim should be read into an independent claim, and that limitation is the only meaningful difference between the two claims.").

Smiths Medical's construction includes the phrase "pivotally moveable." But Smiths Medical argues that the structure that makes the rocker arm or spring assembly pivotally moveable "need not be identified because it is not necessary to perform the claim function." (D.I. 69 at 9) However, the agreed-upon function has the closure means alternate between an open position and a closed position in response to the pressure of expiratory air. This function cannot occur in the manner described without the structure that imparts pivotal movement. Hence, the structure for a "pivotally moveable" rocker arm or spring assembly necessarily includes the structure that imparts pivotal movement.

4. "control means"[13]

Monaghan	
Structure:	"the '598 patent describes the structures identified in Figures 2-3, 7-9, and 13. These structures are further defined in the 598 patent as well. 598 patent, 2:61-65 (describing the closure means as a rocker portion); 7:6-31 (describing the closure means as a rocker portion for pivotal movement about pivot pins, the rocker portion having cone shaped air-flow closure member, and magnetically attractable material, the cone shaped air-flow closure members is sized and positioned for insertion into a tapered conical interior); 5:29-37 (describing a rocker assembly balanced for pivotal movement about pivot pins, including a balancing pad and balancing cylinder on each end of the rocker assembly, and a flow cone carried at the end of the rocker platform positioned to be inserted into the tapered conical interior for closing the circular opening into the air tube)"[14]
Function:	"controlling the opening and closing of said non-linear discharge orifice in response to the pressure of the expiratory air discharged into said patient input opening"
Smiths Medical	
Structure:	"a pivotally moveable rocker arm or the equivalent"
Function:	"for closing or restricting the path of exhaled air"
Court	
Structure:	"a pivotally moveable rocker arm or the equivalent, including structural components that make the rocker arm or spring assembly pivotally moveable"
Function:	"controlling the opening and closing of said non-linear discharge orifice in response to the pressure of the expiratory air discharged into said patient input opening"

The parties again agree that the term is a means-plus-function term. They disagree, however, as to both the structure and function.

[13]This term appears in the '598 patent, claims 1and 2.

[14]Quoted from Smiths Medical's Initial Infringement Contentions Pursuant to November 13, 2017 Scheduling Order, dated November 30, 2017, at p 21.

With respect to function, the Court agrees with Monaghan, which proposes the literal claim language. *See generally Lockheed Martin Corp. v. Space Sys./Loral, Inc.*, 324 F.3d 1308, 1319 (Fed. Cir. 2003) (noting that "function is properly identified as the language after the 'means for' clause").

Turning to structure, Monaghan identifies a "rocker portion" while Smiths Medical proposes a "rocker arm." The Court discerns no material difference between the two. The Court agrees with Smiths Medical that a magnet and a cone-shaped member are not necessary to perform the claimed function. (*See* D.I. 69 at 12-13) For the same reasons given above with respect to the "closure means" term, the Court adopts Smiths Medical's proposed structure along with a modification to include structural components that impart pivotal movement.

5. "predetermined level, predetermined pressure, predetermined rate"

a. "a predetermined level"[15]

Monaghan "a level selected in advance of use"
Smiths Medical "a level selectable by a patient and healthcare provider that is chosen in advance of use"
Court "a level selected in advance of use"

b. "a predetermined pressure of expiratory air"[16]

Monaghan "a pressure of exhaled air from the lungs selected in advance of use"

[15]This term appears in the '598 patent, claim 6.

[16]This term appears in the '324 patent, claim 14.

Smiths Medical "a pressure of exhaled air selectable by a patient and healthcare provider that is chosen in advance of use"
Court "a pressure of exhaled air selected in advance of use"

c. "a predetermined rate of air pressure decrease"[17]

Monaghan "a negative change in pressure per unit of time selected in advance of use"
Smiths Medical "a decreasing rate of air pressure over time selectable by a patient and healthcare provider that is chosen in advance of use"
Court "a negative change in pressure per unit of time selected in advance of use"

The parties agree that the "predetermined" parameters are selected in advance of use, but primarily dispute[18] who makes the selection. Smiths Medical contends that these parameters are chosen by a patient and healthcare provider before using the claimed device. (D.I. 54 at 15) Monaghan argues that the claims do not require a patient or healthcare provider to make the selections. (D.I. 61 at 13-14)

The Court agrees with Monaghan. The claim language itself does not require the predetermined parameters to be chosen by a patient and healthcare provider. While the specifications describe embodiments containing magnetic material that allow a physician or a

[17]This term appears in the '324 patent, claim 14.

[18]With respect to Monaghan's argument that "expiratory air" must be "exhaled air from the lungs" (D.I. 61 at 14), the Court has already construed "expiratory air" to mean "exhaled air." With respect to the parties' dispute of the meaning of "rate," the Court does not see a meaningful difference, particularly as Monaghan does not dispute that "rate" is measured over time. (*See* D.I. 61 at 15)

user to adjust the pressure to a desirable level, *see e.g.*, '524 patent, 7:32-43; '398 patent, 5:54-64, they also describe embodiments lacking magnetic material and not allowing such adjustments, *see* '524 patent, 5:66-6:8;'398 patent, 6:13-31, 7:25-33.

Smiths Medical's citation to *Tech. Patents LLC v. T-Mobile (UK) Ltd.*, 700 F.3d 482, 493 (Fed. Cir. 2012), does not alter the Court's conclusion. While in that case the claims required a "receiving user" to "designate" a particular parameter "in order for anything to happen," *id.* at 495, here the specification discloses embodiments in which neither a patient nor healthcare provider can adjust a particular parameter.

6. "applying a biasing force for closing said discharge orifice"[19]/ "applying a biasing force for closing said discharge opening"[20]

Monaghan "applying a force to a structural element that forms the non-linear discharge orifice to cause the non-linear discharge orifice to close"
Smiths Medical plain and ordinary meaning, or alternatively "applying an opposing biasing force for closing the opening through which exhaled air passes through"
Court "applying an opposing biasing force for closing the opening through which exhaled air passes through"

The parties' dispute concerns whether the biasing force must be applied to a structural element that forms the orifice or opening (Monaghan's position) or whether the biasing force is only required to close the orifice or opening regardless of where it is applied (Smiths Medical's

[19]This term appears in the '598 patent, claim 6.

[20]This term appears in the '324 patent, claim 19.

position). The Court agrees with Smiths Medical. The scope of the term is broader than Monaghan's construction, which impermissibly reads a limitation into the claim. *See Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009) ("The asserted claims . . . do not contain a limitation to a key embedded in the preestablished data, and we decline to read such a limitation into them."). Specifically, the claim language is silent as to the structure on which the force is applied to close the discharge orifice; it simply states that a biasing force is applied for closing the discharge orifice or opening. *See* '598 patent, claim 6 ("applying a biasing force for closing said discharge orifice"); '324 patent, claim 19 ("applying a biasing force for closing said discharge opening").

7. "discharge opening"[21]

Monaghan Indefinite
Smiths Medical "opening through which exhaled air passes through"
Court "opening through which exhaled air passes through"

Monaghan contends that the claim is indefinite because it lacks antecedent basis and recites multiple openings for discharge, leaving a POSA unclear as to where the claimed "predetermined rate of pressure decrease" must occur to close the discharging outlet. (D.I. 61 at 16-17) Monaghan's indefiniteness arguments fail for lack of clear and convincing evidence. Although there is a lack of antecedent basis in the claims, the patent provides ample guidance on what the term means. *See Energizer Holdings, Inc. v. Int'l Trade Comm'n*, 435 F.3d 1366, 1370-

[21]This term appears in the '324 patent, claim 14.

71 (Fed. Cir. 2006) ("[D]espite the absence of explicit antecedent basis, [i]f the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite[;] . . . antecedent basis can be present by implication.") Here, when viewed in context, a POSA would know that the term refers back to the "discharge outlet which is opened." (*See* D.I. 69 at 16).

8. "a sufficient oscillatory positive expiratory pressure therapy has been effectuated"[22]

Monaghan Indefinite
Smiths Medical "therapy sufficient to induce movement of secretions trapped in the lungs to the larger airways"
Court "therapy sufficient to induce movement of secretions trapped in the lungs to the larger airways"

Monaghan contends the term is indefinite because the patent fails to "provide any objective criteria as to when the oscillatory positive expiratory pressure [PEP] is 'sufficient.'" (D.I. 61 at 17-18) Smith counters with expert opinion that a POSA would understand the scope of the term with reasonable certainty. (D.I. 54 at 19)

The Court does not find clear and convincing evidence of indefiniteness. A POSA would understand the meaning of the term in the context of the patent with reasonable certainty. *See Exmark Mfg. Co. Inc. v. Briggs & Stratton Power Prod. Grp., LLC*, 879 F.3d 1332, 1346 (Fed. Cir. 2018) ("All that is required is some standard for measuring the term of degree."). The specification explains that the claimed invention is designed to remove excess mucus secretions from patients suffering from certain lung problems. *See generally* '324 patent, 1:12-57 ("If these

[22]This term appears in the '324 patent, claim 18.

secretions are allowed to remain in the lungs, airway obstruction occurs resulting in poor oxygenation and possible pneumonia and/or death."). According to the patent, PEP therapy has been "[o]ne of the clinically recognized treatments for this condition." *Id.* 1:26-29. It "has been shown to be effective for moving secretions trapped in the lungs to the larger airways where the secretions can then be removed through coughing." *Id.* 1:42-45. The positive pressure can be tailored to meet the needs of an individual patient. *See id.* 1:39-41 ("By selection of the proper-sized orifice, a given pressure is determined for the exhalation flow rate generated by an individual patient.").

A POSA would understand with reasonable certainty that a patient would continue to use the device until it effectively removes excess mucus secretions in the lungs to clear the airways and provide the patient relief. Smiths Medical's expert supports this conclusion. (*See* D.I. 70-1 ¶¶ 29-36) The use of a subjective term does not necessarily make a term indefinite. *See Exmark*, 879 F.3d at 1346 ("No numerical precision is required when using . . . terms of degree."); *Sonix Tech. Co. v. Publ'ns Int'l, Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017) ("[W]e have rejected the proposition that claims involving terms of degree are inherently indefinite. Thus, 'a patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement.'").

9. "reducing the expiratory air pressure at a variable rate"[23]

Monaghan "reducing the pressure of air exhaled from the lungs by a quantity that varies per unit of time"
Smiths Medical "reducing the pressure on exhaled air at a pressure that changes over time"
Court "reducing the pressure on exhaled air at a pressure that changes over time"

The parties dispute the source of the expiratory air's pressure and the meaning of rate. The Court has already adopted Smiths Medical's position on the first issue and has already found there is no material difference between the parties' definitions of "rate."

10. "pivotally moveable"[24]

Monaghan "movable about a point"
Smiths Medical "movable about a pivot"
Court "movable about a pivot"

Smiths Medical contends that the patent shows "the closure member (rocker portion) is pivotal about pivot pins, not just movable about a hypothetical point." (D.I. 54 at 20) Monaghan argues that the prosecution history reveals that "pivotal movement only requires movement about a point, not a 'pivot.'" (D.I. 61 at 20) The Court agrees with Smiths Medical.

The specification explains that the rocker portion is moveable about a pivot, not a point. *See* '324 patent, Figs. 2, 7, 8, 10, 13, 14; *id.* 4:18-26 ("rocker portion 440 is balanced for pivotal

[23]This term appears in the '324 patent, claims 17, 18.

[24]This term appears in the '324 patent, claim 14.

movement about pivot pins 441 . . . pivot pins 441 are limited in their axial and vertical movement by a pair of locking guides 482"); *id.* 7:57-59 ("The pressure of the patient's expiratory air will raise the cone-shaped closure 447, causing the rocker portion 440 to pivot about the pivot pins 441 . . . ."). The prosecution history does not support a different conclusion. While the applicant amended the claim at issue "in accordance with the Examiner's suggestion" (D.I. 52 Ex. D JA0138), the applicant had previously disagreed with the Examiner that the prior art disclosed a "pivotally moveable" structure (*id.* JA0120). The prosecution history does not meet the "exacting" standard for disavowal of claim scope. *Thorner*, 669 F.3d at 1366; *see also Move, Inc. v. Real Estate All. Ltd.*, 413 F. App'x 280, 285 (Fed. Cir. 2011) (noting that applicant's "characterization . . . does not amount to a clear disavowal" of claim scope, in part because applicant did not "acquiesce in the examiner's characterization").

III. CONCLUSION

The Court construes the disputed terms as explained above. An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MONAGHAN MEDICAL CORP.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 17-712-LPS-CJB
	:	
SMITHS MEDICAL ASD, INC.,	:	
	:	
Defendant.	:	
	:	
SMITHS MEDICAL ASD, INC.,	:	
	:	
Counterclaim Plaintiff,	:	
	:	
v.	:	
	:	
MONAGHAN MEDICAL CORP.,	:	
	:	
Counterclaim Defendant.	:	
	:	

ORDER

At Wilmington, this **6th** day of **July 2018**:

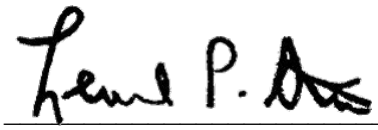
For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that the disputed claim terms are construed as follows:

Claim Term	**Court's Construction**
discharge expiratory	exhaled air
the discharge of expiratory air	exhaled air
the pressure of expiratory air	the pressure of exhaled air
the expiratory air pressure	exhaled air pressure
the pressure of expiratory air discharged therethrough	the pressure of the exhaled air passed through

the pressure of expiratory air passed thereto	the pressure of the exhaled air passed thereto
non-linear discharge orifice	a discharge orifice whose change in opening shape and/or size does not follow a straight line
expiratory air responsive closure means	Structure: a pivotally moveable rocker arm, spring assembly, or the equivalent, including structural components that make the rocker arm or spring assembly pivotally moveable Function: "actua[te] between an open position and a closed position in response to the pressure of expiratory air passed thereto"; "open[] in response to the presence of a predetermined pressure of expiratory air being passed in said path of air flow movement, and [] close[] in response to a predetermined rate of air pressure decrease through said discharge opening"; "pivotally mov[e] in response to expiratory air pressure between a closed position blocking the flow of expiratory air in said path of air flow movement and an open position permitting the flow of expiratory air in said path of air flow movement"
control means	Structure: a pivotally moveable rocker arm, spring assembly, or the equivalent, including structural components that make the rocker arm or spring assembly pivotally moveable Function: controlling the opening and closing of said non-linear discharge orifice in response to the pressure of the expiratory air discharged into said patient input opening
a predetermined level	a level selected in advance of use
a predetermined pressure of expiratory air	a pressure of exhaled air selected in advance of use
a predetermined rate of air pressure decrease	a negative change in pressure per unit of time selected in advance of use
applying a biasing force for closing said discharge orifice/applying a biasing force for closing said discharge opening	applying an opposing biasing force for closing the opening through which exhaled air passes through
discharge opening	opening through which exhaled air passes through

a sufficient oscillatory positive expiratory pressure therapy has been effectuated	therapy sufficient to induce movement of secretions trapped in lungs to the larger airways
reducing the expiratory air pressure at a variable rate	reducing the pressure on exhaled air at a pressure that changes over time
pivotally moveable	moveable about a pivot



HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE