IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CLEVELAND MEDICAL DEVICES INC., an Ohio Corporation, Plaintiff, v. RESMED INC., a Delaware Corporation, Defendant.	C.A. No. 22-794-GBW

MEMORANDUM OPINION

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Wilmington, Delaware

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

In this action filed by Plaintiff Cleveland Medical Devices Inc. ("CleveMed") against Defendant ResMed, Inc. ("ResMed"), CleveMed alleges infringement of U.S. Patent Nos. 10,076,269 (the "'269 Patent"), 10,426,399 (the "'399 Patent"), 10,925,535 (the "'535 Patent"), 11,064,937 (the "'937 Patent"), 10,028,698 (the "'698 Patent"), 11,202,603 (the "'603 Patent"), and 11,234,637 (the "'637 Patent"). Before the Court is the issue of claim construction of multiple terms in these patents. The Court held a claim construction hearing (the "Hearing") and has considered the parties' related submissions. *See* D.I. 96, 97, 98, 116, 128.

I. LEGAL STANDARDS

A. Claim Construction

"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) (en banc) (internal quotation marks omitted); *see also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) ("A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention"). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. The Court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.* The ultimate question of the proper construction of a patent is a question of law, although subsidiary fact-finding is sometimes necessary. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (quoting *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996)).

"The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing *Phillips*, 415 F.3d at 1312–13). A person of ordinary skill in the art "is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at at 1313.

"When construing claim terms, the court first looks to, and primarily rely on, the intrinsic evidence, including the claims themselves, the specification, and the prosecution history of the patent, which is usually dispositive." *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1276 (Fed. Cir. 2013). "Other claims of the patent in question, both asserted and unasserted, can . . . be valuable" in discerning the meaning of a disputed claim term because "claim terms are normally used consistently throughout the patent," and so, "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Phillips*, 415 F.3d at 1314. In addition, "[d]ifferences among claims can also be a useful guide[.]" *Id.* 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.

In addition to the claim, the Court should analyze the specification, which "is always highly relevant to the claim construction analysis ... [as] 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). 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. "Even when the specification describes only

a single embodiment, [however,] 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) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)). And, the specification "is not a substitute for, nor can it be used to rewrite, the chosen claim language." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

The Court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980. The 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[.]" *Phillips*, 415 F.3d at 1317.

In some cases, the 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. Overall, while extrinsic evidence may be useful, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1317 (internal quotation marks and citations omitted).

B. Indefiniteness

Section 112 of Title 35 imposes a definiteness requirement on patent claims. 35 U.S.C. § 112(b) (requiring that the claims "particularly point[] out and distinctly claim[] the subject matter which the inventor .. . regards as the invention"). "The primary purpose of the definiteness

requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, e.g., competitors of the patent owner, can determine whether or not they infringe." *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002). "A patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). To determine indefiniteness, courts examine "the patent record-the claims, specification, and prosecution history-to ascertain if they convey to one of skill in the art with reasonable certainty the scope of the invention claimed." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). Like claim construction, definiteness is a question of law, but the Court must sometimes render factual findings based on extrinsic evidence to resolve the ultimate issue of definiteness. *See, e.g., Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1376 (Fed. Cir. 2017); *see also Teva*, 135 S. Ct. at 842-43. "Any fact critical to a holding on indefiniteness ... must be proven by the challenger by clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003); *see also Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).

C. Means-Plus-Function

The Patent Act provides:

> [a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. § 112(f); 35 U.S.C. § 112 ¶ 6 (2006) (same). Such "[a] means-plus-function limitation recites a function to be performed rather than definite structure or materials for performing that function." *Lockheed Martin Corp. v. Space Sys./Loral, Inc.*, 324 F.3d 1308, 1318 (Fed. Cir. 2003) (citation omitted). "The duty of a patentee to clearly link or associate structure with the claimed function is the quid pro quo for allowing the patentee to express the claim in terms of function under section 112 . . ." *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1211 (Fed. Cir. 2003) (citation omitted*); see Twin Peaks Software Inc. v. IBM Corp.*, 690 F. App'x 656, 660 (Fed. Cir. 2017) (citing *Med. Instrumentation & Diagnostics*, 344 F.3d at 1211).

"To determine whether § 112, para. 6 applies to a claim limitation, our precedent has long recognized the importance of the presence or absence of the word 'means.'" *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1346 (Fed. Cir. 2015) (en banc). "The failure to use the word 'means' creates a rebuttable presumption that § 112, ¶ 6 does not apply." *Zeroclick, LLC v. Apple Inc.*, 891 F.3d 1003, 1006 (Fed. Cir. 2018) (quoting *Williamson*, 792 F.3d at 1346). The presumption can be overcome, and § 112, ¶ 6 will apply, "if the challenger demonstrates that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function." *Id.* (emphasis added) (internal quotation marks, brackets, and citation omitted); *see also Advanced Ground Info. Sys., Inc. v. Life360, Inc.*, 830 F.3d 1341, 1347 (Fed. Cir. 2016) ("In determining whether this presumption has been rebutted, the challenger must establish by a preponderance of the evidence that the claims are to be governed by § 112, ¶ 6."); *Greenberg v. Ethicon Endo–Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed. Cir. 1996) (noting that the district court relied on evidence extrinsic to the patent in reaching its conclusion that a term invoked means-plus-function treatment). "[T]he essential inquiry is not merely the presence or absence of the word 'means,' but whether the words of the claim are understood by persons of

ordinary skill in the art to have a sufficiently definite meaning as the name for structure." *Dyfan, LLC v. Target Corp.*, 28 F.4th 1360, 1365 (Fed. Cir. 2022) (citations omitted). "What is important is ... that the term, as the name for structure, has a reasonably well understood meaning in the art." *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed. Cir. 1996).

II. AGREED-UPON TERMS

The parties agreed upon the following constructions, which the Court will adopt. D.I. 116 at 1; D.I. 128.

Claim Term	Agreed-Upon Construction
"ARMAX system identification model" ('269 Patent, Claim 4)	"Auto-Regressive Moving Average exogenous system identification model"
"short-time Fourier transform" ('269 Patent, Claim 4)	Plain and ordinary meaning, which is "a sequence of Fourier transforms of a windowed signal. A Fourier transform is a technique that uses a mathematical operation to convert a signal or data from the time domain to the frequency domain"
"nasal cannula" ('399 Patent, Claims 1, 8; '535 Patent, Claim 8; '937 Patent, Claims 1, 2, 13; '603 Patent, Claim 13; '698 Patent, Claim 14; '637 Patent, Claim 1; '269 Patent, Claims 1, 5, 15)	Plain and ordinary meaning, which is "a flexible tube having two prongs that extend into a user's nostrils and leave the nostrils open for free exhalation through the nose"
"pressure transducer" ('399 Patent, Claims 1, 8; '535 Patent, Claim 8; '937 Patent, Claims 1, 13; '603 Patent, Claims 1, 8; '698 Patent, Claim 14; '637 Patent, Claim 1)	"device that converts physical pressure into an electrical signal"

III. DISPUTED TERMS

a) Term 1:[1] "a base station"

Disputed Term	Plaintiff's Proposed Construction	Defendant's Proposed Construction	The Court's Construction
"a base station" ('269 Patent, Claim 15)	Plain and ordinary meaning, which is "a computer which connects other computers or wireless devices to a central hub and allows connection to a network." This claim term is definite.	"a specialized transmission and reception station in a fixed location"[2] Alternatively: Indefinite.	"a computer that can communicate with other devices"

The parties dispute whether the term "a base station" can encompass a general-purpose computer. D.I. 116 at 4-5; Claim Construction Hearing Transcript ("Tr.") 9:6-11; 14:17-19; 15:19-21.

Claim 15 of the '269 Patent recites:

> **15.** A positive airway pressure (PAP) sleep disorder treatment system comprising:
> a PAP device with an enclosure further comprising:
> a blower having an air output,
> an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject while using the PAP and outputting airflow sensor data;
> a processor adapted for receiving the airflow sensor data and calculating both symptom data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and data of usage of the PAP device;
> a mask or a nasal cannula;
> a first radio frequency wireless module transceiver and
> a base station, cellular phone, or PDA;
> the first radio frequency wireless module transceiver adapted for receiving and transmitting the symptom data of the severity of

[1] Term numbers correspond with the parties' labels in the Amended Joint Claim Construction Brief. D.I. 116.

[2] Tr. 14:15-16.

> the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and the data of usage to the base station, cellular phone or PDA;
> the base station, cellular phone, or PDA comprising a second radio frequency wireless module transceiver, a processor, a software, and a display, the base station, cellular phone, or PDA adapted to display the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms, and to retransmit the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms and the data of usage received from the PAP device to a remote internet site.

'269 Patent cl. 15. Starting with the claim language, Claim 15 recites a system "comprising", among other features, "a base station, cellular phone, or PDA." ResMed argues that the claim language is "dispositive" because the word "computer" is not recited. Tr. 13:18-14:10. However, "[i]n the patent claim context[,] the term 'comprising' is well understood to mean 'including but not limited to.'" *CIAS, Inc. v. All. Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007) (citation omitted). "The disjunctive 'or' plainly designates that a series describes alternatives." *SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1199 (Fed. Cir. 2013). Thus, while ResMed argues that the claim language dispositively forecloses any construction of base station as a "computer" because "computer" was not recited in the claim, use of the term "comprising," combined with the use of the disjunctive conjunction "or" supports the notion that a "base station" or "cellular phone" or "PDA" constitute non-exclusive alternatives. Therefore, the Court cannot agree with ResMed that the claim language forecloses any construction of "base station" as a computer.

The specification, which is, "the single best guide to the meaning of a disputed term,"[3] further suggests that ResMed improperly imports limitations into the claim. As disclosed by the

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[3] *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

specification, "[p]referably, the remote communication station or base station can be *any device* known to receive RF transmissions such as those transmitted by the wireless data acquisition system described herein." '269 Patent, col. 19:12-15 (emphasis added). "The remote communication station or base station by way of example but not limitation can include a communications device for relaying the transmission, a communications device for re-processing the transmission, a communications device for re-processing the transmission then relaying it to another remote communication station, *a computer with wireless capabilities*, a PDA with wireless capabilities, a processor, a processor with display capabilities, and combinations of these devices." *Id.*, col. 19:15-24 (emphasis added). Thus, the specification confirms that a base station could include "any device" including a "computer."

ResMed argues that a base station cannot be a computer because the specification distinguishes between "a base station on the one hand and a personal computer on the other." Tr. 17:12-18:3; D.I. 116 at 6-7. But the specification language ResMed cites in support thereof states that a computer can program a base station: "An external programming means 60, shown in FIG. 1 as a personal computer, contains software which is used to program the signal processing module 16 and the base station 40 through data interface cable 62." '269 Patent, col. 9:12-15; *see also* D.I. 116 at 6-7 (citing '269 Patent, col. 9:34-37, col. 12:4-14). ResMed's citations do not support the conclusion that, because a computer can program a base station, then a base station cannot be a computer.

Aside from noting that a base station can be programmed by a computer, ResMed points to no other intrinsic evidence compelling a construction of "base station" as limited to a "transmission and reception station" in a "fixed" location with "specialized" functionality. While ResMed points to various technical dictionaries and an expert declaration, D.I. 116 at 5-7, the

Court cannot rely on extrinsic evidence to alter the meaning of "base station" when that meaning is clear from the intrinsic evidence. *Seabed Geosolutions (US) Inc. v. Magseis FF LLC*, 8 F.4th 1285, 1290 (Fed. Cir. 2021).

Finally, ResMed seemingly argues that CleveMed has disavowed claim scope, faulting CleveMed's proposed construction for "tr[ying] to reinsert the computer aspect that was omitted from the claim." Tr. 15:3-5. Yet ResMed points to nothing in the prosecution history or the specification to indicate disavowal. *See Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004) ("Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language."); *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) ("Disavowal requires that the specification [ ] make[ ] clear that the invention does not include a particular feature, ... or is clearly limited to a particular form of the invention[.]").

Accordingly, because CleveMed is entitled to the full scope of the claim language and there is no evidence of disavowal, the Court declines to import ResMed's proposed limitations into the claim language. The Court also declines to adopt CleveMed's construction, particularly as the phrase "central hub" appears nowhere in the '269 Patent.

Thus, viewing the disputed term in the context of the '269 Patent, the Court construes "base station" to mean "a computer that can communicate with other devices."[4] *See Trs. of Columbia Univ. v. Symantec Corp.*, 811 F.3d 1359, 1363 (Fed. Cir. 2016) ("The only meaning that matters in claim construction is the meaning in the context of the patent.").

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[4] ResMed acknowledged that the specification describes "a communication device that relays signals, data to another device. And that's what a base station does." Tr. 22:1-3.

b) Term 2: "calculating . . ."
Term 3: "creating . . ."

Disputed Terms	Plaintiff's Construction	Defendant's Construction	The Court's Construction
Term 2 "calculating, based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject's sleep disorder symptoms measured during use of the PAP device" ('269 Patent, Claim 1) "calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject's symptoms measured during the subject's use of the PAP device" ('269 Patent, Claim 5) "calculating both symptom data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device" ('269 Patent, Claim 15)	These claim terms are definite.	Indefinite.	Not indefinite.
Term 3 "creating an output of the level of severity of a subject's sleep disorder or symptoms" ('269 Patent, Claim 8)	These claim terms are definite.	Indefinite.	Not indefinite.

The parties dispute whether these terms as they appear in Claims 1, 5, 8, and 15 of the '269 Patent are indefinite. D.I. 116 at 16-17; 21.

Claim 1 of the '269 Patent recites:

1. A positive airway pressure (PAP) sleep disorder treatment system comprising:

a signal processing module comprising a first input adapted for connecting to a pulse oximeter sensor with a signal, electronics adapted for filtering and processing the signal, and an output adapted for outputting pulse oximetry sensor data;

a PAP device adapted for treating a subject's sleep disorder, the PAP device with a separate enclosure from the signal processing module further comprising:

a blower having an air output,

a second input adapted for receiving the pulse oximetry sensor data from the output of the signal processing module,

an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow data of a subject using the PAP device, and

a processor adapted for receiving the pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor and calculating, based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject's sleep disorder symptoms measured during use of the PAP device;

a mask or a nasal cannula; and

a module transceiver adapted for receiving and transmitting the sleep disorder symptom data of the level of severity and/or the index of the level of severity of the subject's sleep disorder symptoms to a remote location.

'269 Patent, cl. 1. Claim 5 of the '269 Patent recites:

5. A sleep disorder treatment system comprising:

a data acquisition system;

a positive airway pressure (PAP) device; and

a processor;

the data acquisition system consisting essentially of a data acquisition device having at least one first input adapted for receiving a first signal from a pulse oximeter sensor, an electronic component adapted for filtering and processing the first signal from the pulse oximeter sensor to remove artifacts, and a first output adapted for transmitting pulse oximeter sensor data based on the first signal from the pulse oximeter sensor to the PAP device;

the PAP device comprising:

a hose,

a blower,

an airflow sensor with a second signal adapted for measuring respiratory airflow of a subject,

a second input for receiving pulse oximetry sensor data from the data acquisition device; and

a mask or nasal cannula for treating a subject's sleep disorder symptoms; and

the processor adapted for receiving pulse oximetery [sic] sensor data from the second input and the respiratory airflow data from the airflow sensor, the processor further adapted for calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject's symptoms measured during the subject's use of the PAP device, the processor adapted to be either part of or external to the PAP device and having a second output, the second output adapted for providing sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a nonvolatile memory to be used for later transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a remote location.

'269 Patent, cl. 5. Claim 8 of the '269 Patent recites:

8. A sleep disorder treatment system comprising:

a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the at least one physiological sensor; and

a positive airway pressure apparatus for providing pressurized air and dosing and chemically treating a subject's sleep disorder or symptoms with a pharmaceutical agent, the positive airway pressure apparatus comprising a controller adapted to adjust the pharmaceutical agent, at least in part, using the output of the level of severity of the subject's sleep disorder from the data acquisition system.

'269 Patent, cl. 8. ResMed argues that a skilled artisan would not be able to discern how to calculate "sleep disorder symptom data," "sleep disorder symptom data of a level of severity," "symptom data of a severity of the subject's sleep disorder symptoms," "symptom data", or "index level of severity" because the disputed claim terms "string[s] together somewhat similar words in

five different ways." Tr. 34:20-35:1. ResMed faults CleveMed for "argu[ing] that all five of these somehow mean the same thing" because, according to ResMed, "different claim terms are presumed to have different meanings" and "[t]his leaves a skilled person no guidance as to the scope of the claims." Tr. 34:21-25; D.I. 116 at 15-17; *see also* Tr. 41:18-20 ("We see CleveMed and its expert conflating all the terms to essentially mean the same thing, but we know this cannot be correct."). ResMed further contends that while "the disputed phrases in claims 1, 5 and 15 recite '... measured during use of the PAP device'[,] . . . nothing in the claim provides reasonable certainty as to how this phrase modifies the preceding language." D.I. 116 at 16-17 ("For example, it is unclear whether it is the 'symptoms,' 'index,' 'level,' or 'symptom data' that is measured, and if one of those parameters is 'measured' then what is the parameter that is 'calculat[ed].'"). Thus, says ResMed, "[t]he claim language leaves these questions unanswered, so the claims are indefinite." D.I. 116 at 17.

The Court disagrees. As an initial matter, ResMed advances the wrong standard for analyzing indefiniteness. Whether a patent leaves "questions unanswered" is not the standard. *See Nature Simulation Sys. Inc. v. Autodesk, Inc.*, 50 F.4th 1358, 1366 (Fed. Cir. 2022) ("Although the district court adopted the argument of Autodesk's expert that there are 'unanswered questions' about the claims, this was not the correct standard for evaluating whether the claims met the standard for definiteness."). Further, to the extent ResMed argues that indefiniteness necessarily arises from the '269 Patent's inconsistent "flavors" of claim terms because such "flavors" are presumed to have different meanings, Tr. 34:20-35:1, that too is not the proper standard. "'Claim language, standing alone' is not the correct standard of law and is contrary to uniform precedent" to determine indefiniteness. *Nature Simulation*, 50 F.4th at 1364 (quoting *Sonix Tech.*, 844 F.3d

at 1376).[5] Rather, "[p]atent claims are viewed and understood in light of the specification, the prosecution history, and other relevant evidence, as 'would have allowed a skilled artisan to know the scope of the claimed invention with reasonable certainty.'" *Id.*

Applying the proper standard, ResMed has not met its burden to prove by clear and convincing evidence that a skilled artisan would be unable to discern the scope of the claimed invention with reasonable certainty. *Nautilus*, 572 U.S. at 901. The specification discloses that, "[t]he quantitative method for estimating or determining the severity of the subject's sleeping disorder or symptoms is preferably accomplished by using signals or data from the one or more sensors described herein." '269 Patent, col. 19:46-49. "Various algorithms known to those skilled in the art are used to filter out noise from the signal or data, and to then quantify the level of severity of the subject's sleeping disorder or symptoms. This filtered data is then is [sic] preferably analyzed" using "signal-processing techniques that are utilized to predict the onset of these symptoms. These are: (i) the standard deviation technique, (ii) a recursively it ARMAX system identification model, (iii) the Short-Time Fourier Transform (SFFT) technique, and (iv) time-frequency signal analysis with a variety of different kernels." *Id.*, col. 20:1-5; 18-26. "The diagnostic device of the present invention is used to provide an output which is then used either

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[5] *Cf. Giesecke & Devrient GmbH v. United States*, 163 Fed. Cl. 430, 461 (2023) (noting that *Nautilus* requires the Court to "read the claims in light of the specification" and rejecting argument that claim terms "clearly" and "clearly modified" were indefinite: "As discussed above, the specification uses 'allocated' and 'unequivocally allocated' to describe the same association between two data records. A PHOSITA would understand only one relationship-type is described by the terms 'allocated,' 'clearly allocated,' and 'unequivocally allocated.' The modifying adverbs are 'inartful surplusage' but do not modify the underlying meaning. Defendants could not articulate how 'clearly' could modify 'allocated' and give it a different meaning. ('THE COURT: ... [H]ow is 'clearly allocated' and 'allocated to' different? [DEFENDANTS]: ... I would just point to the word 'clearly' and the fact that defendants are arguing that 'clearly' limits the claim term and that it can't just be disregarded. ... [T]he crux of our view is just that we don't know what 'clearly' means and that's precisely the reason ... we're alleging indefiniteness here.')") (internal citations and quotation marks omitted).

automatically to adjust the treatment device or by a clinician or the subject to adjust the device which provides the physical or chemical treatment device which is another part of the system of the present invention." *Id.*, col. 22:1-7. "The present invention is envisioned to be particularly valuable in the treatment of sleep apneas. With the present invention it is envisioned that modifications can be made to a subject's treatment regiment as the severity or level or the subject's symptoms increase or decrease better regulating the therapeutic treatment of the subject's sleeping disorder. For example, with a subject who has sleep apnea, delivery of a physical treatment such as CPAP can be adjusted during the treatment based on the sleep diagnosis results. The CPAP machine would preferably be set up to receive some type of signal, which would cause an adjustment in the flow rate or pressure of the breathing gas being delivered to the subject." *Id.*, col. 22:29-40. Thus, based on the specification's detailed descriptions, the Court agrees with CleveMed that a skilled artisan would understand the "calculating" elements to be satisfied "when a processor is programmed to (1) receive as an input and process physiological sensor data about a patient using a PAP device; and (2) output information on whether and what extent a patient exhibits sleep disorder symptoms while using the PAP." D.I. 116 at 14-15. Although ResMed repeatedly notes that "sleep disorder symptom data," "sleep disorder symptom data of a level of severity," "symptom data of a severity of the subject's sleep disorder symptoms," and "symptom data" are "not terms of art and do not appear in the '269 specification," D.I. 116 at 16, 17, 24, 25, the Court does not understand indefiniteness to be determined by whether a disputed claim term appears verbatim in the specification.

Finally, testimony from ResMed's expert, Dr. Sharony, does not amount to clear and convincing evidence that the "calculating" terms are indefinite. *See generally* D.I. 97-1 at 144-188 ("Sharony Declaration"). As the Court understands Dr. Sharony's declaration, he does not opine

that a skilled artisan cannot calculate "sleep disorder symptom data," "sleep disorder symptom data of a level of severity," "symptom data of a severity of the subject's sleep disorder symptoms," or "symptom data." Rather, he concludes that those terms are "not terms of art" (¶ 35) and opines that they are indefinite because they "confuse a POSITA as to whether these terms have the same meaning" (¶ 37) and the '269 Patent is "silent" as to their meaning (¶¶ 40-42).[6] CleveMed responded with a declaration from its expert, Dr. D'Ambrosio, who opines that, within the clinical sleep study field, "'symptom data' refers to the physiological and technological data indicative of the patient's condition while they sleep or attempt to sleep"; "level of severity" is used by clinicians "to represent the [sic] how dire a patient's calculated symptom data may be"; and an "index", which "takes individual and combined symptom data points and averages them over a one-hour period of sleep", is "[a]nother calculation a sleep clinician would commonly expect . . . symptom data to be compiled and presented." *See* D.I. 97-1 at 446-453 ("D'Ambrosio Declaration") ¶¶ 24, 26, 27. Dr. D'Ambrosio concludes that "[b]ased upon the disclosures in the '269 Patent, a POSITA understands how to calculate the symptom data in order to derive the severity of the patient's symptoms." *Id.* ¶ 26.[7] Having reviewed both declarations coupled with the intrinsic record, they support CleveMed's position that a skilled artisan would be able to discern the scope of the "calculating" terms with reasonable certainty.

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[6] *3Shape A/S v. Align Tech., Inc.*, C.A. No. 18-886-LPS, 2020 WL 2188857, at *4 (D. Del. May 6, 2020), *report and recommendation adopted*, C.A. No. 18-886-LPS, 2020 WL 7695898 (D. Del. Dec. 28, 2020) ("At this time, the Court finds that Align has not met its burden to show indefiniteness. While Align's expert opines that the first and second excluded volumes are the same, he does not appear to dispute that a person of skill in the art can in fact calculate them. Because of that, I decline to find at this time that the patent terms are indefinite.").

[7] Dr. D'Ambrosio is a medical doctor practicing in the field of sleep medicine. D'Ambrosio Declaration ¶¶ 3-10. Dr. Sharony does not have a medical degree. Tr. 54:10-11. Nor does he appear to have any experience in the sleep disorder field. *See generally* D'Ambrosio Declaration.

Accordingly, ResMed has not met its burden to show that these terms are indefinite by clear and convincing evidence. *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017) (citation omitted). The parties did not brief any alternate constructions, so there is no remaining dispute the resolution of which requires the Court to construe these terms.

c) Terms 4 and 6: "processor . . . "

Disputed Term	Plaintiff's Construction	Defendant's Construction	The Court's Construction
Term 4 "a processor adapted for receiving the airflow sensor data and calculating both symptom data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and data of usage of the PAP device" ('269 Patent, Claim 15)	Terms 4 and 6 are definite and not subject to 35 U.S.C. § 112(6). In the alternative, to the extent 35 U.S.C. § 112(6) applies, the structure for these terms is evident from the claims themselves and from the specification: **Functions**: "receiving the airflow sensor data and calculating both symptom data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and data of usage of the PAP device" (Claim 15) / "calculating, based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject's sleep disorder symptoms measured during use of the PAP device" (Claim 1) / "calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject's symptoms measured during the subject's use of the PAP device" (Claim 5) **Structure**: a processor programmed to perform the identified functions as described in 3:9-47, 3:58-64, 3:65-4:4, 4:5-10, 4:11-19, 4:20-28, 4:29-36, 4:37-45, 7:27-43, 7:61-8:12, 8:13-30, 10:65-11:16, 13:29-54, 14:14-19, 15:34-63, 16:4-10, 18:51-19:7, 19:46-57, 20:1-31, 2	Indefinite. Subject to 35 U.S.C. § 112(6). **Functions**: "calculating symptom data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and data of usage of the PAP device" (Claim 15) / "calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject's symptoms measured during the subject's use of the PAP device" (Claim 5) **Structure**: none disclosed	Not subject to 35 U.S.C. § 112(6).
Term 6 "the processor further adapted for calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject's symptoms measured during the subject's use of the PAP device" ('269 Patent, Claim 5)			

The parties dispute whether "processor" should be construed as a means-plus-function term governed by 35 U.S.C. § 112 and found indefinite for lack of structure (as ResMed suggests, D.I. 116 at 51-56), or found not subject to 35 U.S.C. § 112 (as CleveMed suggests, *id.* at 47-51).

As an initial matter, the parties agree that, because the terms do not use "means for" claiming, there is a rebuttable presumption that § 112, ¶ 6 does not apply. D.I. 116 at 51-52 (citing *Williamson*, 792 F.3d at 1348). Thus, to overcome the presumption, ResMed must "*demonstrate*[] that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function." *Zeroclick*, 891 F.3d at 1007 (quoting *Williamson*, 792 F.3d at 1348). The Court concludes that ResMed has not met its burden.

ResMed argues that "processor" as used in Claim 15 is not "structurally part of or connected to any other element in the claim" and is described "in purely functional terms." D.I. 116 at 52. Claim 15 of the '269 Patent recites in part: "a PAP device with an enclosure further comprising . . . an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject while using the PAP and outputting airflow sensor data", "a processor adapted for receiving the airflow sensor data and calculating both symptom data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and data of usage of the PAP device", and a "first radio frequency wireless module transceiver adapted for receiving and transmitting the symptom data of the severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device." '269 Patent, cl. 15. Although ResMed argues that the processor is "simply 'adapted to' perform the recited functions," D.I. 116 at 52-53, that "the disputed limitations incorporate functional language does not automatically convert the words into means for performing such functions." *Zeroclick*, 891 F.3d at 1008. Here, the processor is connected to both

the PAP device's internal airflow sensor from which it receives the airflow data, and to the first radio frequency wireless module which receives the calculated symptom data of the severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms. Indeed, the claims themselves state the objections and operations of the processor and provide an input-output structure. *Align Tech., Inc. v. 3Shape*, C.A. No. 17-1648-LPS, 2021 WL 2320139, at *7 (D. Del. June 7, 2021); *Techno View IP, Inc. v. Facebook Techs., LLC*, C.A. No. 17-386-CFC-CJB, 2018 WL 6427874, at *7–8 (D. Del. Dec. 7, 2018); *see also Syncpoint Imaging, LLC v. Nintendo of Am. Inc.*, C.A. No. 15-00247-JRG-RSP, 2016 WL 55118, at *20-21 (E.D. Tex. Jan. 5, 2016). This is not a situation where the "claims do not describe how this processor interacts with the other claimed components in a way that might inform the structural character of the limitation." *Cf. WSOU Invs. LLC v. Google LLC*, No. 2022-1064, 2023 WL 6531525, at *4 (Fed. Cir. Oct. 6, 2023). Accordingly, § 112, ¶ 6 does not apply to the "processor" term as used in Claim 15.

ResMed similarly argues that "processor" as used in Claim 5 "does not describe how the processor receives the sensor data or whether the processor is connected to the PAP device at all." D.I. 116 at 53. Claim 5 of the '269 Patent recites in part: "the PAP device comprising . . . an airflow sensor with a second signal adapted for measuring respiratory airflow of a subject . . .a second input for receiving pulse oximetry sensor data from the data acquisition device . . .the processor adapted for receiving pulse oximetery [sic] sensor data from the second input and the respiratory airflow data from the airflow sensor, the processor further adapted for calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject's symptoms measured during the subject's use of the PAP device, the processor adapted to be either part of or external to the PAP device and having a second output, the second output adapted for providing

sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a nonvolatile memory to be used for later transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a remote location." '269 Patent, cl. 5. Thus, the processor connects with and receives inputs from the pulse oximetry sensor and airflow sensor prior to calculating symptom data and a level of severity, and outputs its calculations to nonvolatile memory where it can be used for transmission to a remote location. Again, as with Claim 15, the claim language of Claim 5 state the objections and operations of the processor and provide input-output structure. *Syncpoint*, 2016 WL 55118, at *20-21; *Techno View*, 2018 WL 6427874, at *7–8. Indeed, Claim 5 recites additional structure that "the processor [is] adapted to be either part of or external to the PAP device." '269 Patent, cl. 5. Accordingly, § 112, ¶ 6 does not apply to the "processor" term as used in Claim 5.

In sum, ResMed has not met its burden to compel the Court to conclude that the "processor" terms used in Claims 15 and 5 of the '269 Patent are subject to means-plus-function claiming. *VDPP LLC v. Vizio, Inc.*, No. 2021-2040, 2022 WL 885771, at *2 (Fed. Cir. Mar. 25, 2022). Concluding otherwise would erroneously "not giv[e] effect to the unrebutted presumption against the application of § 112, ¶ 6." *Zeroclick*, 891 F.3d at 1008. The parties did not brief any alternate constructions, so there is no remaining dispute the resolution of which requires the Court to construe this term.

d) Term 15: "transferring..."

Disputed Term	Plaintiff's Construction	Defendant's Construction	The Court's Construction
"transferring the collected data to a location remote from the subject's home" ('399 Patent, Claim 1) "transferring the collected data via cellular systems, internet, satellite, wired-network and/or land lines to a location remote from the subject's home" ('399 Patent, Claim 8)	Plain and ordinary meaning. No construction necessary.	"transferring the collected data from the patient interface box located at the subject's home to a location remote from the subject's home" ('399 Patent, Claim 1) transferring the collected data via cellular systems, internet, satellite, wired-network and/or land lines from the patient interface box located at the subject's home to a location remote from the subject's home ('399 Patent, Claim 8)	Plain and ordinary meaning. No construction necessary.

The parties dispute whether the "transferring" of data must occur from a subject's home. D.I. 116 at 31-32. CleveMed argues it does not, *id.* at 31-32, while ResMed says it does., *id.* at 33-35.

Claim 1 of the '399 Patent recites:

> **1.** A method of conducting home sleep testing comprising the steps of:
>
> providing a subject with a portable patient interface box worn by the subject on its torso and a nasal cannula or a facemask, a respiratory effort belt and a fingertip pulse oximeter, the patient interface box comprising a battery, at least one kinetic sensor, a nonvolatile digital memory, a pressure transducer, an air port for connecting a nasal cannula or a facemask to the pressure transducer within the patient interface box, and releasable connector sensor inputs to electrically connect and disconnect the respiratory effort belt and the fingertip pulse oximeter, the nasal cannula or facemask for measuring airflow of the subject, the respiratory effort belt for measuring respiratory effort of the subject, the kinetic sensor for measuring body position or

orientation and the fingertip pulse oximeter for measuring oxygenation of the subject;

applying and connecting the nasal cannula or facemask, the respiratory effort belt and the fingertip pulse oximeter to the subject, and further the patient interface box to the subject's torso;

measuring and collecting data through the patient interface box of the airflow, respiratory effort, body position or orientation and oxygenation of the subject while the subject attempts to sleep at home;

digitizing and storing the collected data from the subject in the nonvolatile digital memory of the patient interface box;

transferring the collected data to a location remote from the subject's home;

providing a computer or a processor at the remote location for analyzing the transferred collected data to identify and draw attention to physiological or technological events in the data indicative of a sleeping disorder; and

further analyzing at a minimum the transferred collected data and/or the identified physiological and technological events in the data at the remote location or another remote location to determine whether the subject suffers from a sleeping disorder.

'399 Patent, cl. 1. Claim 8 of the '399 Patent recites:

8. A method of conducting home sleep testing comprising the steps of:

providing a subject with a portable patient interface box worn by the subject on its torso and a nasal cannula or a facemask, a respiratory effort belt and a fingertip pulse oximeter, the patient interface box comprising a battery, at least one kinetic sensor for measuring body position, a nonvolatile digital memory, a pressure transducer, an air port for connecting a nasal cannula or a facemask to the pressure transducer within the patient interface box, and releasable connector sensor inputs to electrically connect and disconnect the respiratory effort belt and the fingertip pulse oximeter, the nasal cannula or facemask for measuring airflow of the subject, the respiratory effort belt for measuring respiratory effort of the subject, the kinetic sensor for measuring body position or orientation and the fingertip pulse oximeter for measuring oxygenation of the subject;

applying and connecting the nasal cannula or facemask, the respiratory effort belt and the fingertip pulse oximeter to the subject and to the patient interface box, and further the patient interface box to the subject's torso;

> measuring and collecting data of the airflow, respiratory effort, body position or orientation and oxygenation of the subject while the subject attempts to sleep at home;
> digitizing and storing the collected data from the subject in the nonvolatile digital memory of the patient interface box;
> transferring the collected data via cellular systems, internet, satellite, wired-network and/or land lines to a location remote from the subject's home;
> providing a computer or a processor at the remote location for analyzing the transferred collected data to identify and draw attention to physiological or technological events in the data indicative of a sleeping disorder; and
> further analyzing at a minimum the transferred collected data and/or the identified physiological and technological events in the data at the remote location or another remote location to determine whether the subject suffers from a sleeping disorder.

'399 Patent, cl. 8. Starting with the claims, Claims 1 and 8 of the '399 Patent claim a "method of conducting home sleep testing comprising . . . measuring and collecting data . . . while the subject attempts to sleep at home." The claims further require "transferring the collected data . . . to a location remote from subject's home." ResMed argues that for the "at home" limitation to have any meaning in these claims, "transmission must occur from the patient's home." D.I. 116 at 33. But Claims 1 and 8 on their face do not limit the location of the transmission; they merely provide that the transmission must occur from somewhere "to a location remote from the subject's home." '399 Patent, cl. 1, 8.

Turning to the specification, it too supports a construction that the transfer of data need not be limited to the subject's home in at least two ways. First, it discloses that, "[v]arious embodiments of the present invention include the step of applying at least two sensors to the subject. The sensors can be applied at any location, such as a physician's office or place of business, or the subject's home or other sleeping location. The subject's sleeping location includes but is not limited to the subject's home, apartment, or the like, as well as a hotel, nursing home, or other location where an individual could sleep and where this analysis could be done more

controllably and/or less expensively than in an attended sleep lab or hospital setting." '399 Patent, col. 8:30-44. Therefore, consistent with the claims, the specification suggests that the claimed method can be performed while the subject "attempts to sleep at home," and that "home" could include a variety of locations beyond simply the subject's "home." ResMed seems to argue that "home" means a subject's domicile or residence, explaining that, "[t]he fact that there is disclosure of that transferring occurring in locations other than the patient's home is of no moment . . . because they intentionally limited the claim to the collection and transfer of data that occurs while the patient is sleeping in his or her home." Tr. 63:23-64:5; *see also* D.I. 116 at 33. But ResMed's argument is not persuasive in view of Claims 1 and 8 which on their face do not limit the location of the transmission.

Second, the specification permits, but does not render necessary, the contemporaneous transfer of data that ResMed's construction seems to require. For example, one exemplary embodiment discusses the real-time transfer of data that could occur consistent with ResMed's construction—i.e. "transferring the collected data from the patient interface box located at the subject's home." *See* '399 Patent, col. 6:17-26 ("In still a further embodiment, the present invention includes the steps of applying two or more sensors to a subject; connecting the sensors to an in-home data acquisition system; collecting signals from the sensors while the subject attempts to sleep at home; transmitting to another location the signals or another signal based at least in part on at least one of the signals from the sensors applied to the subject at a substantially same time as the signals are received or created; and analyzing the data to determine whether the subject has a sleep disorder. The step of transmitting or retransmitting the signals at a substantially same time allows real-time analysis of the data, rather than waiting for the conclusion of the test in order to begin data analysis."). However, another exemplary embodiment does not require such

real-time transmission and further contemplates that the transfer or "retrieval" of data could occur at a location that is different from the subject's home. *See* '399 Patent, col. 4:13:25 ("Another embodiment of the present invention includes the steps of applying two or more sensors to a subject; connecting the sensors to an in-home data acquisition system; collecting signals from the sensors while the subject attempts to sleep at home; storing the signals on removable memory; retrieving the signals; and analyzing the signals to determine whether the subject has a sleeping disorder. The steps of storing and retrieving the signals allow the analysis to be completed at a convenient time, rather than requiring analysis as the data is collected. These steps also allow the in-home data acquisition system to be reused after the data is removed with the removable memory, even if the data has not been viewed or analyzed.").

Indeed, the specification further teaches that sleep data may be stored for later transmission and may be "provided by a 3rd party service provider or by the healthcare facility's information technology department." '399 Patent, col. 8:11-14; *see also id.*, col. 14:47-63 ("The in-home data acquisition system can be programmed to send all signal data to the removable memory, to transmit all data, or to both transmit all data and send a copy of the data to the removable memory. When the in-home data acquisition system is programmed to store a signal or pre-processed signal, the signals from the sensors can be saved on a medium in order to be retrieved and analyzed at a later date. Media on which data can be saved include, but are not limited to chart recorders, hard drive, floppy disks, computer networks, optical storage, solid-stale memory, magnetic tape, punch cards, etc. Preferably, data are stored on removable memory. For both storing and transmitting or retransmitting data, flexible use of removable memory can either buffer signal data or store the data for later transmission. Preferably, nonvolatile removable memory can be used to customize the system's buffering capacity and completely store the data."); *Id.*, col. 15:3:9 ("If however the

in-home data acquisition system is configured to send all data to the removable memory for storage, then the system does not transmit any information at that time. In this situation, the data stored on the removable memory can be retrieved by either transmission from the in-home data acquisition, or by removing the memory for direct reading.").

Thus, neither the claims nor specification support ResMed's limitation requiring the transfer of data to originate from the subject's home. ResMed does not argue that CleveMed has disavowed claim scope. Therefore, because plain and ordinary meaning is the default in claim construction, *Phillips*, 415 F.3d at 1316, and the claims are clear on their face, "transferring the collected data to a location remote from the subject's home" and "transferring the collected data via cellular systems, internet, satellite, wired-network and/or land lines to a location remote from the subject's home" will be afforded their plain and ordinary meaning without further construction.

e) Term 22: "pulse oximeter"

Disputed Term	Plaintiff's Construction	Defendant's Construction	The Court's Construction
"pulse oximeter" ('399 Patent, Claims 1, 8; '535 Patent, Claim 8; '937 Patent, Claims 1, 2, 13; '603 Patent, Claims 1, 8; '637 Patent, Claim 1; '269 Patent, Claims 1, 5, 9)	"instrument used to measure the blood oxygenation"	Plain and ordinary meaning, which is a "noninvasive sensor that provides a continuous estimation of arterial hemoglobin oxygen saturation and pulse rate"[8]	"instrument used to measure the blood oxygenation"

Although the parties agree that "pulse oximeter" should be construed according to its plain meaning, they dispute what that plain meaning is. D.I. 116 at 40-42.

The claims of the '399, '535, '937, '603 and '637 Patents[9] recite that a "fingertip pulse oximeter" is used for "measuring oxygenation of the subject." '399 Patent, cl. 1, 8 ("the fingertip pulse oximeter for measuring oxygenation of the subject"); '535 Patent, cl. 8 ("a fingertip pulse oximeter . . . the pulse oximeter for measuring oxygenation of the subject"); '937 Patent, cl. 1 ("a fingertip pulse oximeter adapted to be applied to a subject, for measuring blood oxygenation of the subject"); *id.*, cl. 2 ("the fingertip pulse oximeter"); *id.*, cl. 13 ("a fingertip pulse oximeter . . . the pulse oximeter for measuring oxygenation of the subject"); '603 Patent, cl. 1 ("fingertip pulse oximeter . . . to measure or derive . . . blood oxygenation during testing"); *id.*, cl. 8 ("at least three sensors selected from a group consisting accelerometer(s), fingertip pulse oximeter (s), rip belt(s), respiratory effort belt(s), pressure sensor(s), microphone(s), strain gauge(s), pressure transducer(s) and transducer(s), the [sic] at least three sensors are adapted to measure and/or derive at least the

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[8] At the Hearing, ResMed represented that it had revised its construction to remove the word "continuous." Tr. 74:2-4.

[9] The '535 Patent, '937 Patent, '399 Patent, and '637 Patent are related. The '698 Patent and '603 Patent are related. D.I. 116 at 31 n.6. CleveMed explains, and ResMed does not dispute, that the '535, '399, '937, and '637 Patents share the same specification. *Id.* at 31 n.8.

subject's air flow or snore, respiratory effort, and blood oxygenation"); '637 Patent, cl. 1 ("the fingertip pulse oximeter being configured to be applied to a fingertip of the subject to measure blood oxygenation of the subject"). The specifications of these patents disclose that "[t]he pulse oximeter can measure the oxygenation of the subject's blood." '603 Patent, col. 10:26-28; '399 Patent, col. 11:56-58; '535 Patent, col. 11:48-50; '937 Patent, col. 11:56-57. "Preferably, pulse oximeters are placed on a subject's earlobe or fingertip. More preferably, the pulse oximeter is placed on the subject's index finger." '637 Patent, col. 12:4-6; *see also, e.g.*, '603 Patent, col. 10:33-35. Thus, the intrinsic record of the '399, '535, '937, '603 and '637 Patents confirms that a "pulse oximeter" is simply an "instrument used to measure the blood oxygenation."

Turning to the '269 Patent, Claim 1 recites "a pulse oximeter sensor with a signal, electronics adapted for filtering and processing the signal, and an output adapted for outputting pulse oximetry sensor data[.]" '269 Patent, cl. 1. Claim 5 recites: "the data acquisition system consisting essentially of a data acquisition device having at least one first input adapted for receiving a first signal from a pulse oximeter sensor, an electronic component adapted for filtering and processing the first signal from the pulse oximeter sensor to remove artifacts, and a first output adapted for transmitting pulse oximeter sensor data based on the first signal from the pulse oximeter sensor to the PAP device[.]" Claim 9 recites: "[t]he sleep disorder treatment system of claim 8 wherein at least one physiological sensor comprises a pulse oximeter sensor." *Id.*, cl. 9. The '269 Patent's specification states that, "[t]he pulse oximeter can measure the oxygenation of the subject's blood" and "[p]referably, pulse oximeters are placed on a subject's earlobe or fingertip. More preferably, the pulse oximeter is placed on the subject's index finger." *Id.*, col. 8:15-16, 23-25. Thus, the intrinsic record of the '269 Patent confirms that a "pulse oximeter" is simply an "instrument used to measure the blood oxygenation."

Although ResMed seeks to further define "pulse oximeter" as "a noninvasive sensor" that can also measure "pulse rate", D.I. 116 at 40-42, such additions are unnecessary in view of the patents' written descriptions. CleveMed agreed that "arterial hemoglobin oxygen saturation and oxygenation are synonymous." Tr. 80:7-11. ResMed agreed to drop "continuous" from its proposed construction. Tr. 74:2-4.

Thus, because plain and ordinary meaning is the default in claim construction, *Phillips*, 415 F.3d at 1316, the Court construes "pulse oximeter" according to its plain meaning—"instrument used to measure the blood oxygenation."

f) Term 24: "oxygenation"

Disputed Term	Plaintiff's Construction	Defendant's Construction	The Court's Construction
"oxygenation" ('399 Patent, Claims 1, 8; '535 Patent, Claim 8; '937 Patent, Claims 1, 13; '603 Patent, Claims 1, 8; '637 Patent, Claim 1)	"level of oxygen"	Plain and ordinary meaning, which is "level of oxygen saturation of the blood"	Plain and ordinary meaning, which is "level of oxygen saturation of the blood"

Although the parties agree that "oxygenation" means "level of oxygen," they dispute whether "oxygenation" should be construed to include ResMed's addition of "saturation in the blood." D.I. 116 at 44-46.

Starting with the claims of the '535, '937, '603 and '637 Patents, they recite that the "oxygenation" of the subject is "blood oxygenation." '535 Patent, cl. 8 ("a fingertip pulse oximeter . . . the pulse oximeter for measuring oxygenation of the subject"); '937 Patent, cl. 1 ("a fingertip pulse oximeter adapted to be applied to a subject, for measuring blood oxygenation of the subject"); '603 Patent, cl. 1 ("fingertip pulse oximeter . . . to measure or derive . . . blood

oxygenation during testing"); *id.*, cl. 8 (sensors used to measure "blood oxygenation"); '637 Patent, cl. 1 ("the fingertip pulse oximeter being configured to be applied to a fingertip of the subject to measure blood oxygenation of the subject"). Blood oxygenation is also taught by the relevant specifications. '603 Patent, col. 10:26-28 ("[t]he pulse oximeter can measure the oxygenation of the subject's blood"); '637 Patent, col. 11:62-67 (same). *See also* '535 Patent, col. 21:66 (describing "blood oxygen saturation); '937 Patent, col. 22:7-8 (same). Thus, the intrinsic record of the '535, '937, '603 and '637 Patents confirms that a "oxygenation" is the "level of oxygen saturation of the blood."

The '399 Patent is in accord. Claims 1 and 8 of the '399 Patent do not define "oxygenation" as "blood oxygenation." *See* '399 Patent, cl. 1 ("fingertip pulse oximeter for measuring oxygenation of the subject"); *id.*, cl. 8 ("the fingertip pulse oximeter for measuring oxygenation of the subject"); *id.* ("measuring and collecting data of the airflow, respiratory effort, body position or orientation and oxygenation of the subject while the subject attempts to sleep at home"). Nevertheless, the '399 Patent specification teaches that a "pulse oximeter can measure the oxygenation of the subject's blood by producing a source of light at two wavelengths" because "[h]emoglobin partially absorbs the light by amounts that differ depending on whether it is saturated or desaturated with oxygen." '399 Patent, col. 11:56-60. The '399 Patent specification also teaches that data analysis is used "to draw attention to a physiological or technological event" and "[p]hysiological events include, but are not limited to, changes in blood oxygen saturation." *Id.* at col. 22:3:8. Therefore, the intrinsic record of the '399 Patent confirms that a "oxygenation" is the "level of oxygen saturation of the blood."

Although CleveMed agrees that "arterial hemoglobin oxygen saturation and oxygenation are synonymous . . . That's what oxygenation is; it's the oxygen saturation of the blood," Tr. 80:7-

11, CleveMed argues that ResMed's addition of "saturation in the blood" will "only serve to confuse the jury," D.I. 116 at 45, or create ambiguity with the term "saturation," Tr. 81:20-83:10. This Court concludes that omitting "saturation of the blood" could lead to greater ambiguity and confusion for this term as used in the relevant patents, particularly in concert with the "pulse oximeter."

Accordingly, because plain and ordinary meaning is the default in claim construction, *Phillips*, 415 F.3d at 1316, the Court construes "oxygenation" according to its plain meaning—"level of oxygen saturation of the blood."

IV. CONCLUSION

The Court will adopt the parties' agreed-upon constructions and construe the disputed claim terms as described above. The Court will issue an Order consistent with this Memorandum Opinion.