

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

RESMED CORP.,

*Plaintiff / Counterclaim
Defendant,*

V.

CLEVELAND MEDICAL DEVICES, INC.,

*Defendant / Counterclaim
Plaintiff.*

Case No. 1:23-cv-02221-BMB

**PLAINTIFF RESMED CORP.'S
OPENING CLAIM CONSTRUCTION BRIEF**

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I. INTRODUCTION

Cleveland Medical Devices, Inc.’s six asserted patents are the product of more than 15 years of patent prosecution, numerous continuation and continuation-in-part applications, and overzealous lawyering. The resulting claims are lengthy and inscrutable jumbles of words that would leave a person of skill in the art—to say nothing of a jury—to wonder what the metes and bounds of certain terms are. But the Patent Act requires patentees to “particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention” so the public has notice of what is inside and outside the scope of the claims. 35 U.S.C. § 112. The disputed terms addressed below do not distinctly claim the scope of the invention, and CleveMed relies on this ambiguity to try stretch its claims to prop up its infringement theories in this case.

Terms 1-4 are indefinite for two independent reasons. First, the claims are irreconcilably convoluted and impossible to parse what elements are performing which functions and what data results. Second, the claims lack necessary antecedent basis, injecting further ambiguity into the terms such that a person of skill in the art cannot understand the metes and bounds of the terms. Terms 5 and 6 also fail for lack of antecedent basis. For Term 5, a person of ordinary skill in the art cannot determine with reasonable certainty whether the claim requires one remote station performing certain functions or two remote stations that split those functions between them. Each is an equally plausible interpretation, but each covers a distinct configuration such that a person of skill in the art cannot determine whether a system with one remote station is inside or outside the scope of the claims. For Term 6, it is not reasonably certain whether “the therapy efficacy data” is or includes the data recited earlier in the claim, including “the collected data,” “the quantified level of severity data,” and/or “this analysis.”

Last, although CleveMed does not contend that any of the accused products has the claimed “base station” (recited in the claims as an alternative to “a cell phone or a PDA”),

CleveMed nonetheless asks the Court to construe the term. ResMed’s construction gives full meaning to the word “base” in “base station,” while CleveMed’s proposal broadly encompasses any computer with communication capabilities. To the extent the Court believes this term requires construction, it should adopt ResMed’s construction.

II. BACKGROUND OF THE ASSERTED PATENTS

A. The ’921, ’284, And ’029 Patents

The ’921 patent family traces its roots to U.S. Patent No. 8,172,766 (“the ’766 patent”), which was filed on November 4, 2005 and issued on May 8, 2012. On April 5, 2012, CleveMed filed a continuation application to the ’766 patent, which issued on August 8, 2018 as U.S. Patent No. 10,076,269 (“the ’269 patent”) and is asserted in the now-stayed litigation in the District of Delaware, *Cleveland Medical Devices Inc. v. ResMed Inc.*, C.A. No. 22-794-JLH (the “Delaware Action”). From there, CleveMed filed three more continuation applications in succession, each sharing the same inventors, figures, and specification. On August 8, 2018, CleveMed filed application No. 16/057,963, which issued as the ’921 patent (Doc. No. 70-1) on July 5, 2022. CleveMed filed a continuation application to the ’921 patent on May 26, 2022, application No. 17/825,266, which issued as the ’284 patent (Doc. No. 1-1) on March 14, 2023. CleveMed filed a continuation application to the ’284 patent on February 3, 2023, application No. 18/105,277, which issued as the ’029 patent (Doc. No. 70-43) on January 16, 2024.

The ’921, ’284, and ’029 patents are directed to “an integrated sleep diagnosis and treatment device” and “method of sleep diagnosis and treatment.” ’921 patent, Abstract. However, the claims of these patents do not recite a “diagnosis” component and are only directed to a sleep disorder treatment system. The relevant components of the claimed system are (1) a positive airway pressure (PAP) device comprising a sensor, a processor, and a radio frequency wireless transceiver, (2) software for use with a cell phone, and (3) a remote internet site.

B. The '680 And '333 Patents

The '680 and '333 patents also trace their roots to the '766 patent, but they extend from different branches of the family tree. On July 19, 2007, CleveMed filed application No. 11/880,046, which is a continuation-in-part of the application that issued as the '766 patent in which the applicant added new figures and new matter to the specification. From the '046 application, CleveMed filed three more continuation applications, the third of which was filed on October 11, 2019 and issued on October 17, 2023 as the '680 patent (Doc. No. 70-39).

On July 19, 2007, CleveMed filed application No. 11/879,934, which is another continuation-in-part of the '766 patent that added the same figures and much of the same new matter to the specification as the '046 application. From the '934 application, CleveMed filed two more continuation applications, the second of which was filed on July 5, 2017 and issued on January 2, 2024 as the '333 patent (Doc. No. 70-42). The asserted claims of the '680 and '333 patents recite similar components and features as the '921, '284, and '029 patents.

C. The '512 Patent

The '512 patent (Doc. No. 70-2) is in a different patent family from the other five asserted patents and is directed to “a data acquisition system for EEG and other physiological conditions, preferably wireless, and method of using such system.” '512 patent, Abstract. The '512 patent traces its priority to an application filed on June 16, 2006.

III. LEGAL STANDARDS

“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. AWS Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quote omitted). Claim construction is a matter of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325 (2015). “The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim

interpretation.” *Phillips*, 415 F. 3d at 1313. Where the meaning of a term is not readily apparent, courts may look to “those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.” *Id.* at 1314.

Usually, a court first considers the claim language, then the remaining intrinsic evidence, then in some circumstances extrinsic evidence. *See Interactive Gift Exp., Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331-32 (Fed. Cir. 2001). While “the claims themselves provide substantial guidance as to the meaning of particular claim terms[,]” a court also must consider the context of the surrounding words. *Phillips*, 415 F. 3d at 1314. The specification “is always highly relevant to the claim construction analysis and indeed is often the single best guide to the meaning of a disputed term.” *AstraZeneca AB v. Mylan Pharms. Inc.*, 19 F.4th 1325, 1330 (Fed. Cir. 2021) (quotation omitted). A court may refer to extrinsic evidence if the disputed term’s ordinary meaning cannot be discerned from the intrinsic evidence. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996). Although a court may not use extrinsic evidence to vary or contradict the claim language, extrinsic materials “may be helpful to explain scientific principles, the meaning of technical terms, and terms of art that appear in the patent and prosecution history.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995).

Furthermore, “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). “Indefiniteness is a matter of claim construction, and the same principles that govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction.” *Monode Marking Prod., Inc. v. Columbia Marking Tools, Inc.*, 1:18-cv-16, 2019 WL 4727447, at *1 (N.D. Ohio Sept. 27, 2019).

IV. AGREED CONSTRUCTIONS

The parties have agreed to the following constructions for the following terms:

Asserted Patent(s) and Claim(s)	Term for Construction	Agreed Construction
'512 patent, Claim 1	"pressure transducer"	"device that converts physical pressure into an electrical signal"
'921 patent, Claims 5, 9, 14	"a respiratory disturbance index"	Plain and ordinary meaning, which is "is the number of apneas, hypopneas, and respiratory effort-related arousals (RERAs) per hour of sleep"
'921 patent, Claims 1, 7, 12; '284 patent, Claims 9, 12; '029 patent, Claims 8, 11; '680 patent, Claims 10, 15, 20; '333 patent, Claim 26	"standard deviation technique"	Plain and ordinary meaning, which is "a measure of how dispersed data is in relation to the mean"

V. DISPUTED CONSTRUCTIONS

- A. **Term 1: "generating and outputting the data related to the subject's treatment and the treatment's efficacy by receiving sensor data from the airflow sensor, and calculating both the quantified symptom data of the severity of the sleeping 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" ('921 patent, claims 1, 7, 12)**

Term 2: "measuring and calculating a data of a quantitative output of the severity of a subject's sleeping disorder symptoms during a treatment and further providing for a data related the subject's treatment and the treatment's efficacy" ('921 patent, claims 1, 7, 12)

ResMed's Proposed Construction	CleveMed's Proposed Construction
Indefinite.	No construction necessary. Plain and Ordinary Meaning. These claims are definite.

Claims 1, 7, and 12 of the '921 patent are indefinite. Each claim covers nearly a column of text and generally recites a "sleep disorder treatment system" that comprises, among other things, "a PAP device" with "a blower," "an airflow sensor," and "a first processor." '921 patent, claims 1, 7, 12. But when the claims try to recite what data is measured, generated,

outputted, and calculated by the processor and/or the airflow sensor, the claims devolve into a morass of words that fail to inform those skilled in the art about the scope of the claimed invention. See Ex. 1, Declaration Of Alan R. Schwartz, M.D. On Claim Construction (“Schwartz Decl.”) at ¶¶ 40-44. Because the limitations fail to “provide objective boundaries” with respect to these claims, a person of skill in the art cannot know what these ambiguous categories of data are or where and how these data are measured, generated, outputted and calculated. *Nautilus*, 572 U.S. at 901. Thus, claims 1, 7, and 12 of the ’921 patent fail to “particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention” and are, thus, indefinite under § 112, ¶ 2.

1. The Claim Language Cannot Be Reconciled With Reasonable Certainty.

The claim language fails to distinctly point out what elements perform which functions. For instance, claims 1, 7, and 12 recite “data related to the subject’s treatment and the treatment’s efficacy,” and the claims specify that this data is “generat[ed] and output[ed]” by a “first processor” (Term 1). The claims recite that the “generating and outputting” of the “data related to the subject’s treatment and the treatment’s efficacy” is “by receiving sensor data from the airflow sensor, and calculating both the quantified symptom data of the severity of the sleeping 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.” The poor grammar and syntax of the claims is alone enough to render it indefinite. But the words the applicant chose create an inherent ambiguity about whether the “generating and outputting” of the “data related to the subject’s treatment and the treatment’s efficacy” is based on (a) the claimed “calculating” or (b) only based on “receiving sensor data from the airflow sensor.” Ex. 1, Schwartz Decl. at ¶ 45 (“a POSITA understands that ‘symptoms’ are far removed from ‘sensor data’ and any calculations

based thereon.”). There also is no way to tell whether the “calculating” is in any way based on the “receiving sensor data from the airflow sensor.” *Id.*

Further, although Term 1 recites that “the data related to the subject’s treatment and the treatment’s efficacy” is generated and output by a first processor “by receiving sensor data from the airflow sensor” and possibly also by “calculating both the quantified symptom data of the severity of the sleeping 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,” Term 2 recites that “the airflow sensor and the first processor are adapted for ... further providing for a data related to the subject’s treatment and the treatment’s efficacy.” This begs the question of whether “the data related to the subject’s treatment and the treatment’s efficacy” of Term 1 is or is not based on “the quantified symptom data of the severity of the sleeping 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.” The claims do not answer that question. Ex. 1, Schwartz Decl. at ¶ 48. A person of ordinary skill therefore cannot determine whether Term 2 is superfluous, or whether Term 2 recites an additional limitation on the claimed airflow sensor and first processor are “adapted for,” and, if so, what that additional limitation might be. *Id.*

2. Claims 1, 7, And 12 Lack Necessary Antecedent Basis.

The requirement of antecedent basis is a rule of patent drafting administered during patent examination. *Energizer Holdings, Inc. v. Int’l Trade Comm’n*, 435 F.3d 1366, 1370 (Fed. Cir. 2006). The rule typically requires that claim elements are first introduced with an indefinite article, as “a” or “an,” and thereafter the same element used later in a claim may be referred to using “the” or “said.” See Ex. 2, Manual of Patent Examining Procedure (“MPEP”) 2173.05(e). Failure to provide an antecedent basis renders a claim indefinite when the claim language introduces a lack of clarity that “fail[s] to inform, with reasonable certainty, those skilled in the

art about the scope of the invention.” *Collabo Innovations, Inc. v. OmniVision Techs., Inc.*, No. 16-197-JFB-SRF, 2017 WL 3670661, at *9 (D. Del. Aug. 25, 2017). As the MPEP explains, “[t]he lack of clarity could arise where a claim refers to ‘said lever’ or ‘the lever,’ where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference.” Ex. 2, MPEP 2173.05(e).

Term 1 recites “the data related to the subject’s treatment” and “the quantified symptom data of the severity of the sleeping disorder symptoms,” but the claims do not previously recite these phrases using “a” or “an.” This lack of antecedent basis creates a lack of clarity because “a data” is recited elsewhere in the claim (twice in Term 2) and it is not clear whether the claim is referring to the same or different data. *See Bushnell Hawthorne, LLC v. Cisco Sys., Inc.*, 813 F. App’x 522, 526 (Fed. Cir. May 14, 2020) (“With three different IP addresses to choose from, a POSA faced with the ‘said different IP Address’ limitation is left to wonder which of the different IP addresses is ‘said’ different one.”). Thus, it is unclear whether Terms 1 and 2 are referring to the same data parameters, or whether Term 2 introduces additional data parameters that the claimed airflow sensor and first processor are “adapted for measuring and calculating” and “further providing.” Ex. 1, Schwartz Decl. at ¶ 46.

Term 1 also recites that the “first processor” performs “calculating” of “the quantified symptom data of the severity of the sleeping disorder symptoms,” but here again that phrase is not recited anywhere else in the claims. Later in the claims, Term 2 recites a slightly different phrase, “measuring and calculating a data of a quantitative output of the severity of a subject’s sleeping disorder symptoms during a treatment.” Ex. 1, Schwartz Decl. at ¶ 47. Thus, it is unclear what dependence, if any, there is between Term 1’s “the quantified symptom data of the severity of the sleeping disorder symptoms” and Term 2’s “a data of a quantitative output of the

severity of a subject's sleeping disorder symptoms during a treatment.” *Id.*; see also *Bushnell*, 813 F. App'x at 526.

3. The Specification And Prosecution History Provide No Guidance About The Scope Or Meaning Of Terms 1 And 2.

The patent specification does not resolve these uncertainties in the claims. Ex. 1, Schwartz Decl. at ¶ 49. The specification does not use the terms “efficacy,” “treatment efficacy,” “symptom data,” “quantitative symptom data,” “an index of a subject's symptoms,” or “a data of a quantitative output of the severity of a subject's sleeping disorder symptoms.” The specification recognizes that a “sleeping disorder” is different from “symptoms of a subject's sleep disorder.” See '921 Patent, 2:60-3:3 (*e.g.*, discussing treating a subject's symptoms or the sleep disorder itself).

According to the specification, “flow information” from a “flow sensor” and/or pressure sensor (not an airflow sensor adapted for measuring the respiratory airflow of a subject) could be used “to control the pressure or flow of gas provided to the subject, monitor the condition of the subject, monitor the usage of the pressure support device, any combination thereof, or the like.” '921 patent, 23:8-17. But the specification does not provide any examples, or any clarity, as to what parameters are purportedly generated as part of this control or monitoring that would provide reasonable certainty as to whether the claimed “generating and outputting” is in any way based on the “calculating” of “quantified symptom data of the severity of the sleeping 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.” Ex. 1, Schwartz Decl. at ¶ 50. The only guidance from the specification is that the control and monitoring could be based on data from the flow sensor and/or pressure sensor. *Id.* But symptoms are far removed from sensor signal information and the data parameters calculated therefrom. The specification also does not explain how “data

related to the subject's treatment and the treatment efficacy" are derived from "quantified symptom data" or "an index of a subject's symptoms," or how "quantified symptom data" or "an index of a subject's symptoms" are derived from flow information. This does not provide reasonable certainty what "data related to the subject's treatment and the treatment's efficacy" would be based on or whether it would be based on calculation of "the quantified symptom data of the severity of the sleeping 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." *Id.* at ¶ 51.

The specification also fails to clarify the dependence, if any, between "the quantified symptom data of the severity of the sleeping disorder symptoms" of Term 1 and "a data of a quantitative output of the severity of a subject's sleeping disorder symptoms during a treatment" of Term 2. Ex. 1, Schwartz Decl. at ¶ 52. The claim recites that the processor adjusts the blower using "the data of the quantitative output of the level of severity of the subject's sleeping disorder symptoms during treatment." Looking to the specification, it describes, *e.g.*, "a device for physically or chemically treating a subject's sleeping disorder, which can be adjusted using the output of the level of severity of the subject's sleeping disorder." '921 patent at 3:56-60.

Thus, the specification's teachings that (a) "information from the flow sensor 320 and/or pressure sensor 322 is used, for example, to control the pressure or flow of gas provided to the subject" ('921 patent at 23:12-15) and (b) an "output of a level of severity" is used to adjust a treatment device together could provide some guidance as to what the claimed system uses as "a data of a quantitative output of the severity of a subject's sleeping disorder symptoms during a treatment." Ex. 1, Schwartz Decl. at ¶ 52. But this does not provide reasonable certainty as to what dependence, if any, there is between "the quantified symptom data" of Term 1 and "a data of a quantitative output of the severity of a subject's sleeping disorder symptoms" of Term 2. *Id.*

Moreover, with regard to an index, the patent never refers to the claimed index, does not define it, and does not define any interrelationship between the claimed index and the other terms in the claim. Neither the term “index of a subject’s symptoms measured during use of the PAP device,” nor any similar “index” term, are used in the patent. Ex. 1, Schwartz Decl. at ¶ 53. The patent only refers to a “respiratory disturbance index” obtained using the prior art method of polysomnography, which the patent distinguishes from the purported invention. ’921 patent at 1:51-54. A respiratory disturbance index is a well-known term of art that refers to the number of apneas, plus hypopneas, plus respiratory-effort related arousals per hour of sleep, but the ’921 patent does not reference apneas or hypopneas or any other respiratory event, or any index based on those events. Ex. 1, Schwartz Decl. at ¶ 54. Nor does the patent discuss any other indexed parameter, for example, such as an index of a physiological parameter. The specification also does not use the term or provide an example of “symptom data” or even a “symptom.” The specification merely suggests that symptoms, for example, may “increase or decrease,” have a “level” or “severity level,” and be “critical” or “predicted.” ’921 patent at 2:31-51, 20:1-21, 20:64-21:7, 22:30-34. But these attributes do not guide a skilled person to any resolution as to the relationships (if any) between the claimed “data” parameters. Ex. 1, Schwartz Decl. at ¶ 54.

The specification also describes analyzing signals from sensors “to determine the level of severity of the symptoms” (’921 patent at 3:29-30, 23:27-29), creating “an output of a level of severity” (*id.* at 3:60-67, 4:5-31, 5:34-35, 22:11-12, 22:43-44), and creating “a quantitative output” or “quantitative level of severity of a subject’s sleep disorder and/or symptoms” (*id.* at 4:39-40, 18:51-54, 18:60-64, 19:46-49). The disputed terms, however, do not use this language. The specification therefore does not provide objective guidance as to the relationship, if any, among “the quantified symptom data of the severity of the sleeping disorder symptoms and/or an

index of a subject's symptoms measured during use of the PAP device,” “the data related to the subject’s treatment and the treatment's efficacy,” and “data related to the subject’s treatment and the treatment’s efficacy.” Ex. 1, Schwartz Decl. at ¶ 54.

The prosecution history is no help either. During prosecution of the '921 patent's parent, the applicant noted that “an apnea hypopnea index, or AHI ... is an indicator of the level of severity of a patient’s sleep disordered breathing.” Ex. 3, '766 FH 10/28/2011 Amendment at 6-7. However, this language relates to a possible example of an index of a level of severity of a patient’s sleep disorder. AHI is not itself a “symptom,” “index of a subject’s symptoms,” or “quantified symptom data.” Thus, whether AHI is an indicator of a level of severity of a subject’s sleep disordered breathing does not provide any guidance as to the relationship, if any, between “data related to the subject’s treatment and the treatment's efficacy” and “quantified symptom data” or an “index of a subject’s symptoms.” The prosecution history of the '921 patent itself also does not provide reasonable certainty as to the meaning of Terms 1 or 2. See Ex. 4, '921 FH 4/20/2022 Amendment at 2-3; Ex. 5, '921 FH 5/23/2022 Notice of Allowability at 2-3; Ex. 1, Schwartz Decl. at ¶ 55. Moreover, the file history suggests that “data related to the subject’s treatment and the treatment’s efficacy” and “quantified symptom data of the severity of the sleeping disorder symptoms and/or an index of a subject’s symptoms measured during use of the PAP device” mean the same thing. Ex. 6, '921 FH 5/17/2021 Amendment at 11 (in comparison to the “claim allowed in the parent case” (the '269 patent), “[t]he same data is being transferred as in the parent case but refer to it as ‘data related to the subject’s treatment and its efficacy’”); Ex. 1, Schwartz Decl. at ¶¶ 55-56. Thus, the scope and meaning of Terms 1 and 2 cannot be resolved with reasonable certainty.

4. The Plain and Ordinary Meaning Of Certain Words Provides No Guidance As To The Scope Of The Claim.

To the extent certain words in the claim such as “symptom” and “efficacy” have understood meanings to a person of ordinary skill, these understandings do not provide reasonable certainty as to the scope of Terms 1 and 2. Ex. 1, Schwartz Decl. at ¶ 57. “Efficacy” is typically based on a marker for the disease progress, whereas “effectiveness” typically includes efficacy plus clinical manifestation or outcomes of the disease process. *Id.* ¶¶ 57-58. In this context, symptoms (a term used in the claims) could support therapeutic effectiveness rather than efficacy, but the patent does not disclose how a patient’s symptoms, a quantification of symptoms, a quantification of “symptom data,” or an “index of a subject’s symptoms” allegedly figure into assessment of treatment efficacy. *Id.* Terms 1 and 2 also recite “sleeping disorder symptoms,” but the patent specification never mentions what a “symptom,” “symptom data,” or “quantified symptom data” might be. Furthermore, the meaning of “symptom” is different depending on the context, such as what is being treated. *Id.* at ¶¶ 58-60.

These understandings of the ordinary meaning of the terms “efficacy” and “symptoms” do not assist in providing reasonable certainty as to the scope of Terms 1 and 2. *Id.* at ¶ 61. As discussed, symptoms support effectiveness rather than efficacy; that is, therapeutic effectiveness includes efficacy along with other elements such as reported symptoms. But the claims do not recite “effectiveness.” An apnea-hypopnea index (AHI), while an “index,” is not itself linked to or informative of a subject’s symptoms. Therefore, the ordinary use of those terms would suggest that the claimed “data related to the subject’s treatment and the treatment’s efficacy” is not based on “calculating both the quantified symptom data of the severity of the sleeping disorder symptoms and/or an index of a subject’s symptoms measured during use of the PAP device.” *Id.* at ¶ 62. In that case, the “data related to the subject’s treatment and the treatment’s

efficacy” might only be based on “receiving sensor data from the airflow sensor.” *Id.* But the specification and ordinary meaning of the relevant terms fail to provide reasonable certainty that this is the correct meaning of the claim. *Id.*; *see also id.* at ¶¶ 63-64. Moreover, as discussed above, the file history suggests that “data related to the subject's treatment and the treatment's efficacy” and “quantified symptom data of the severity of the sleeping disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device” mean the same thing. Ex. 6, '921 FH 5/17/2021 Amendment at 11. Thus, the scope and meaning of Terms 1 and 2 cannot be resolved with reasonable certainty.

- B. Term 3: “calculating: i) the data of a severity of the sleep disorder symptoms of the subject, ii) the data of usage of the PAP device by the subject, and/or iii) the index based in whole or in part on either i) or ii) or both i) and ii)” ('029 patent, claim 1)**

Term 4: “related to the subject's treatment and the treatment's efficacy” ('029 patent, claim 1)

ResMed's Proposed Construction	CleveMed's Proposed Construction
Indefinite.	No construction necessary. Plain and Ordinary Meaning. This claim is definite.

Terms 3 and 4 are indefinite because, when read in light of the '029 specification and file history, they “fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus*, 572 U.S. at 901; Ex. 1, Schwartz Decl. at ¶ 65 Terms 3 and 4 are not terms of art. Terms 3 and 4 also do not appear in the specification, so the patentee did not act as its own lexicographer. Like Terms 1 and 2, Terms 3 and 4 suffer from grammatical and syntax chaos that fails to provide the requisite notice as to the scope of the claim.

Term 3 recites “calculating: i) the data of a severity of the sleep disorder symptoms of the subject, ii) the data of usage of the PAP device by the subject, and/or iii) the index based in whole or in part on either i) or ii) or both i) and ii).” Term 4 and its surrounding language further

recites: “i) and ii), or i), ii), and iii), related to the subject’s treatment and the treatment’s efficacy in whole or part.” Thus, the claim language appears to suggest that at least “i) the data of a severity of the sleep disorder symptoms of the subject, ii) the data of usage of the PAP device by the subject” are “related to the subject’s treatment and the treatment’s efficacy in whole or part.” Ex. 1, Schwartz Decl. at ¶ 66. But the certainty as to the scope of the claim stops there.

For example, the ordinary understanding of “data of usage of the PAP device by the subject” might mean the duration of usage of the PAP device or a measurement of the patient’s compliance with or adherence to therapy, but there is no reasonable certainty what it means for this parameter to also be “related to the subject’s treatment and the treatment’s efficacy” as required by the claim. Ex. 1, Schwartz Decl. at ¶ 66. Again, “efficacy” is typically based on a marker for the disease progress, such as AHI that is not discussed in the patent. *Id.* But neither the claim nor the patent specification link the concepts of “data of usage” to “a subject’s treatment and the treatment’s efficacy.” *Id.* In other words, if a device calculates data of usage of a PAP device by the subject, what additional aspects of that data must be present to practice the claim? If it means the data of usage must be used to determine efficacy, that does not comport with the claim that does not otherwise require that efficacy be determined. *Id.*

There is also no reasonable certainty what it means for “the data of a severity of the sleep disorder symptoms of the subject” to be “related to the subject’s treatment and the treatment’s efficacy in whole or part.” Ex. 1, Schwartz Decl. at ¶ 67. As discussed above for Terms 1 and 2, although the patent specification (which is the same for the ’921 and ’029 patents) describes generating “an output of a level of severity” and the applicant conceded that AHI is an “indicator of the level of severity,” the intrinsic record does not otherwise address or explain what a “data of severity of the sleep disorder symptoms of the subject” might be. *Id.*; *see also id.* ¶¶ 59-60.

For example, “data of severity of sleep disorder symptoms” is not a term of art, and the patent specification does not address what such “data” might be. *Id.* at ¶ 67. Also, symptoms are indicative of effectiveness rather than efficacy; therefore, it is unclear how a “data of severity of sleep disorder symptoms” might be “related to ... the treatment’s efficacy.” *Id.* Because the specification does not address efficacy or the terms used in the claim, it fails to provide objective guidance to inform a skilled person with reasonable certainty how a “data of severity of sleep disorder symptoms” is “related to ... the treatment’s efficacy.” *Id.* at ¶ 68.

Last, with regard to “iii) the index,” a person of ordinary skill would understand this phrase to refer to the previously recited “index of treatment efficacy of the subject” in the claim. *Id.* at ¶ 69. But neither the claims nor the specification provide reasonable certainty what additional limitation, if any, the phrase “related to the subject’s treatment and the treatment’s efficacy in whole or part” imposes on the “index of treatment efficacy of the subject.” *Id.* As discussed above, “efficacy” is not addressed in the patent, and the ordinary meaning of the words in the claim do not inform a person of ordinary skill as to the scope of the claim. *Id.*

- C. Term 5: “transmitting, in either order, both 1) the collected data and/or the quantified level of severity data to a cellular phone via a radio frequency wireless link; and 2) the collected data and/or the quantified level of severity data to the remote station from either a) the PAP or CPAP device via a cellular system, or b) the cellular phone to a remote station via the cellular system or the Internet for further analysis with a second processor or a server at the remote station and review of the collected data, the quantified level of severity and/or this analysis by a clinician, technician or physician” (’333 patent, claim 15)**

ResMed’s Proposed Construction	CleveMed’s Proposed Construction
Indefinite.	No construction necessary. Plain and Ordinary Meaning. This claim is definite

Term 5 is not reasonably certain to a person of skill in the art because it is unclear whether the claim requires one remote station or at least two remote stations in the transmission

pathway. *See Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008). Claim 15 recites a method of treating a subject's sleep apnea by (a) providing a therapy using a PAP or CPAP device, (b) collecting certain data with that device, (c) analyzing "the collected data to determine a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy," (d) transmitting certain data via certain pathways, and (e) "further determining the therapy efficacy data." The transmitting step (d) requires two transmissions to be made. In one transmission, the "collected data and/or the quantified level of severity data" is transmitted "to a cellular phone via a radio frequency wireless link." In the other, the same data is transmitted "to the remote station from either a) the PAP or CPAP device via a cellular system, or b) the cellular phone to a remote station via the cellular system or the Internet for further analysis with a second processor or a server at the remote station"

The latter transmission pathway cannot be clearly parsed. The claim recites transmitting data "to the remote station," but there is no antecedent basis earlier in the claim for "remote station." The transmission "to the remote station" can occur via one of two paths. Focusing on the second, the transmission occurs "to the remote station from ... b) the cellular phone to a remote station via the cellular system or the Internet." There are two equally plausible but very different ways to parse this limitation. On one hand, "the remote station" and "a remote station" could refer to the same remote station to which the cellular phone transmits the data. However, the indefinite article "a" typically is used to introduce a claim element, while "the" refers back to that element later in a claim. Claim 15 reverses that order. Further, reading "the remote station" and "a remote station" to be the same station would be identical to reading the phrase as "the remote station from ... b) the cellular phone via the cellular system of the Internet," which effectively reads "a remote station" out of the claim. *See Merck & Co. v. Teva Pharm. USA*,

Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005) (“A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.”).

On the other hand, the “the remote station” and “a remote station” could be two different remote stations. This meaning makes some sense in view of how claim terms are typically construed, such that indefinite articles like “a” typically precede the first time an element appears in a claim. Further, the specification supports that the data may be transmitted to more than one remote station. See ’333 patent at 15:59-62 (data can be transmitted to “a remote monitoring station, remote analysis station, remote data storage station, and the like”), 20:66-21:11 (discussing a first “receiver” which can be in a “remote communication station” that can reprocess a transmission and “relay[] it to another remote communication station”); 22:6-8 (“optionally, two different remote communication stations can be used”). Indeed, the specification discloses that “[t]he preferred embodiment realizes the remote system as two separate components with a patient interface module that can collect, digitize, store, and transmit data to a base station module that can store, process, compress, encrypt, and transmit data to a remote monitoring location.” *Id.* at 34:21-29. But if the patentee intended to claim more than one remote station, the patentee could have used different names for each or recited them as a “first” remote station and a “second” remote station.

The remainder of the claim only confuses the issue further. The claim recites that the transmission allows “for further analysis with a second processor or a server at the remote station” Once again, the claim could recite a singular remote station that receives the transmission from the cellular phone via a cellular system or Internet that is also capable of performing the claimed analysis. Or “the remote station” might refer back only to the preceding “the remote station” or only to the preceding “a remote station,” such that only one of the remote stations

includes a second processor or a server, and a person of skill in the art cannot determine which is which. *See Bushnell*, 813 F. App'x at 526.

D. Term 6: “the therapy efficacy data” ('333 patent, claim 15)

ResMed's Proposed Construction	CleveMed's Proposed Construction
Indefinite.	No construction necessary. Plain and Ordinary Meaning. This claim is definite.

Claim 15 of the '333 patent recites “the therapy efficacy data” without first introducing the term with “a” or “an.” This lack of antecedent basis creates an irreconcilable ambiguity about whether the categories of data or information recited earlier in the claim—“collected data,” “a quantified level of severity data,” and “this analysis”—are included or excluded, in whole or in part, within the scope of “the therapy efficacy data.” Thus, claim 15 is indefinite. *Nautilus*, 572 U.S. at 901.

Claim 15 does not explain what “the therapy efficacy data” refers to or whether it is different from or inclusive of the “collected data,” “a quantified level of severity data,” or “this analysis.” The claim recites “collecting data with the PAP or CPAP device from the flow or pressure sensor during a time period of the therapy,” and refers to that data as “the collected data.” The “collected data is analyzed “with the processor ... to determine a quantified level of severity data based on the subject’s sleep apnea symptoms during the therapy.” Then, “the collected data and/or the quantified level of severity data” is transmitted “for further analysis with a second processor or a server at the remote station and review” of what are now three nebulous categories of data or information: “[1] the collected data, [2] the quantified level of severity and/or [3] this analysis.”

Then the claim recites “the therapy efficacy data”—which does not appear earlier in the claim—with the definite article “the,” which indicates the claim is supported by antecedent basis.

The specification does not use that term. Relying solely on the plain meaning of the words in that phrase, a person of skill in the art cannot determine whether this data refers to: (i) “the collected data” from the flow or pressure sensors; (ii) “the quantified level of severity data” analyzed at the processor”; (iii) “this analysis” performed at the second processor or a server at the remote station; or (iv) some combination (i)-(iii). Indeed, the last limitation recites “determining the therapy efficacy data” (whatever “determining” means) in the precise locations that (i)-(iii) are analyzed or transmitted; namely, the processor of the PAP or CPAP device (which analyzes (i) and determines (ii)), the second processor or server (which conducts “further analysis” (iii)), or the cellular phone (which transmits (i) and (ii)).

But interpreting “the therapy efficacy data” as a nebulous combination of or subset of (i)-(iii) is contradicted by the last limitation: “to receive and display the quantified level of severity data and/or therapy efficacy data to the subject or a care provider.” This clause confirms “the quantified level of severity data” and “the therapy efficacy data” are not coextensive, but it does not explain whether they are wholly different data sets or whether the former is a subset of the latter. Nor can “the therapy efficacy data” reasonably be considered coextensive with (iii) “this analysis,” because the claim only recites “that analysis” occurring at the remote station and not at the PAP or CPAP device or cellular phone. The specification and file history of the ’333 patent do not resolve this lack of clarity, leaving a person of ordinary skill to wonder which data is “the therapy efficacy data.” Because the intrinsic record fails to provide reasonably certainty of “the therapy efficacy data,” claim 15 is indefinite. *See Bushnell*, 813 F. App’x at 526.

E. Term 7: “respiratory ventilation” (’512 patent)

ResMed’s Proposed Construction	CleveMed’s Proposed Construction
Plain and ordinary meaning, which is “the amount of air into the lungs during	Plain and ordinary meaning, which is “the process respiratory breathing wherein air

inspiration and out of the lungs during expiration”	flows into the lungs during inspiration and out of the lungs during expiration”
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As ResMed proposes, “respiratory ventilation” means “the amount” of air into and out of the lungs, while CleveMed incorrectly tries to claim the entire process of respiratory breathing. Claim 1 of the ’512 patent recites “at least two sensors ... adapted ... to measure or derive respiratory ventilation directly or indirectly.” The surrounding claim language confirms that it is measured or derived directly or indirectly using sensors. Thus, ResMed’s construction that specifies that “respiratory ventilation” is “the amount of air” is consistent with the claim language. But CleveMed’s proposal that “respiratory ventilation” is “the *process* [of] respiratory breathing” does not comport with the claim language that informs a person of skill that it is something measured or derived using sensors. Measuring or deriving an amount of air (ResMed’s proposal) is more consistent with the claim language than measuring or deriving a process (CleveMed’s proposal). Ex. 1, Schwartz Decl. at ¶¶ 70, 72.

Dependent claim 2 provides two examples of ventilation—respiratory effort and snore—both of which are exemplary parameters that indirectly measure the “amount” of air. Ex. 1, Schwartz Decl. at ¶¶ 71, 73. For example, respiration belts measure respiratory effort by measuring abdominal and/or thoracic expansion—indirectly measuring the amount of air that causes that expansion. ’512 patent at 9:11-13 (“[r]espiration belts can be used to measure a subject’s abdominal and/or thoracic expansion.”). And the ’512 patent discloses estimating “snore” by using pressure transducers that indirectly measure the amount of airflow. ’512 patent at 3:25-30 (“pressure transducers, are used to measure ... snore parameters.”).

Last, the extrinsic evidence supports ResMed’s construction. See Ex. 7, Steadman’s Medical Dictionary (2006) (“In physiology, the tidal exchange of air between the lungs and the atmosphere.”); Ex. 8, Taber’s Cyclopedic Medical Dictionary (2005) (“In physiology, the

amount of air inhaled.”); Ex. 9, West Textbook at 17 (“the total volume leaving the lung each minute.”)¹; Ex. 1, Schwartz Decl. at ¶¶ 74-76.

F. Term 8: “base station” (’921 patent)

ResMed’s Proposed Construction	CleveMed’s Proposed Construction
Plain and ordinary meaning, which is “specialized transmission and reception station designed to be in a fixed location.”	“a computer that can communicate with other devices”

The claims recite three options: “a base station, a cell phone or a PDA.” CleveMed’s contentions accuse the “cell phone” option but do not point to “a base station.” Ex. 10. As such, this construction is not relevant to the parties’ contentions, and CleveMed has not explained why it proposes this term for construction. Nevertheless, both the plain meaning of “base station” in the relevant field of art and the ’921 patent specification—which “is the single best guide to the meaning of a disputed term” (*Vitronics*, 90 F.3d at 1582)—confirms that the patentee used the term “base station” in its ordinary sense, which a skilled artisan would understand does not encompass a general-purpose computer without reflecting the plain language of the term “base station.” Rather, the specification uses “base station” according to its plain meaning; namely, “a specialized transmission and reception station in a fixed location.”

ResMed’s construction gives full meaning to “base” both as to its function (“specialized transmission and reception”) and its relationship to the claimed PAP device (“designed to be in a fixed location”). In contrast, CleveMed now abandons the construction of “base station” it proposed in the Delaware Action, and asks this Court to adopt the Delaware court’s construction. *See* Ex. 11 at 8. But the Delaware court misconstrued the intrinsic record and, as a result, construed the term too broadly. There, the parties disputed the meaning of “base station” in

¹ The definition for “respiratory ventilation” could also include “the amount ... per unit of time.”

claim 15 of a parent to the '921 patent, the '269 patent. ResMed proposed the same construction it proposes here, while CleveMed proposed “a computer which connects other computers or wireless devices to a central hub and allows connection to a network.” *Id.*

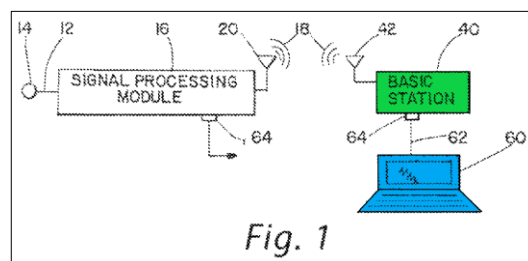
The Delaware court rejected both parties' proposals and construed “base station” based on a single passage from the specification. The shared specification discloses that “[t]he remote communication station or base station” can comprise three different “communications devices,” including one “for relaying the transmission,” one for “re-processing the transmission,” or one for both “re-processing the transmission then relaying it” to a number of communications devices, including “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.” '921 patent at 19:15-24. The Delaware court apparently misread that passage, which describes a specialized base station communicating with a computer, to mean the base station can simply be any computer. Ex. 11 at 10. Even CleveMed did not propose such an expansive construction in the Delaware Action. *Id.* at 8.

CleveMed's new proposal to adopt the Delaware court's construction fails for three reasons. First, CleveMed's new construction would read “base station” out of the claim and swallow other devices identified in the claims, *i.e.*, the cellular phone or PDA, that a person of skill in the art would understand to have distinct meanings. *See Merck*, 395 F.3d at 1372 (“A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.”). Second, the construction swallows other computing devices identified in the specification as being distinct from a “base station,” such as the personal computer and the remote transmission station. Because “subject matter disclosed but not claimed in a patent application is dedicated to the public” (*Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562-

1563 (Fed. Cir. 1991)), the claimed “base station” cannot encompass the separately disclosed but unclaimed “personal computer.” Third, the new CleveMed construction ignores and is at odds with the extrinsic evidence that shows “base station” has an established meaning in the field. This Court should consider the extrinsic evidence together with the intrinsic record “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a [POSA], or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Phillips*, 415 F.3d at 1318.

The plain language of the claims and specification also supports ResMed’s construction. Claims 1, 7, and 12 of the ’921 patent recite three devices, “a base station, cellular phone, or PDA,” but not a general purpose “computer.” The claimed base station, like the cell phone and PDA, must have a second radio frequency wireless transceiver, a second processor, and a display for displaying certain treatment data “to the subject or a care provider.” Although a personal computer can typically perform these functions, the ’921 specification consistently discloses that a “base station” is more specialized than a personal computer. For instance, the specification recites as distinct devices “a computer, base station, cell phone, a PDA or some other form of processor or microprocessor” that can be “tethered to” one or more sensors. ’921 patent, 19:4-7 (emphases added). The specification recites as devices that can “regulate the physical or chemical treatment of the subject,” “a separate computer, base station or processor, a PDA, a processor on a device for treating the subject’s sleeping disorder or a combination of these processors.” *Id.* at 18:64-9:4 (emphases added).

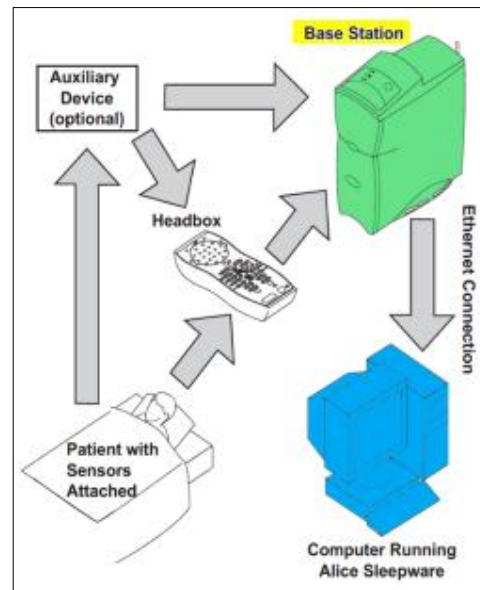
Consistent with the text, Figure 1 depicts “basic station 40” (shaded in green) as a separate device from personal computer 60 (shaded in



blue) used to program the base station. *See also* '921 patent at 9:12-15, 9:34-37, 12:4-14.

Although the specification discloses that the “base station” can be “any device known to receive RF transmissions” (*id.* at 8:24), it still must be the “base” for the claimed sleep disorder treatment system (as in Figure 1).

Extrinsic evidence confirms that the plain meaning of “base station” in the art is “a specialized transmission and reception station in a fixed location” that is different from a general-purpose personal computer. Technical dictionaries in the relevant art define “base station” as “a fixed transceiver in a mobile communications system.” Ex. 12, Comprehensive Dictionary of Electrical Engineering. Other dictionaries in the relevant field are in accord with this plain meaning. Ex. 13, McGraw-Hill Dictionary of Electrical and Computer Engineering (“A station in a land mobile system which



remains in a fixed location and communicates with the mobile stations”). And other PAP device manufacturers, including Philips Respironics, offered systems at the time of the alleged invention with a “base station” that functions as a “specialized transmission and reception station designed to be in a fixed location.” As shown on the right, the “Alice 5 base station” is a “completely self-contained data collection device that is capable of gathering and storing information without the use of an outside computer.” Ex. 14 at 1-8, 1-9 (emphasis and color added). CleveMed’s other patents use “base station” the same way. *E.g.*, '680 patent at 57:4-7, Fig. 9. Thus, the Court should adopt ResMed’s construction of “base station” because it gives full meaning to the term and is consistent with the intrinsic and extrinsic evidence.

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CERTIFICATE OF SERVICE

I, Michael R. Reed, hereby certify that on this 25th day of November, 2024, a copy of PLAINTIFF RESMED CORP.'S OPENING CLAIM CONSTRUCTION BRIEF was served upon the following counsel of record via electronic mail:

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