IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

RESMED CORP.,	)	
	)	
Plaintiff and Counterclaim Defendant,	)	Case No. 1:23-cv-02221-BMB
	)	
v.	)	
	)	
CLEVELAND MEDICAL DEVICES, INC.,	)	
	)	
Defendant and Counterclaim Plaintiff.	)	
	)	

DEFENDANT AND COUNTERCLAIM PLAINTIFF
CLEVELAND MEDICAL DEVICES, INC.'S
OPENING CLAIM CONSTRUCTION BRIEF

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a) the PAP or CPAP device via a cellular system, or

b) the cellular phone

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I. INTRODUCTION

Cleveland Medical Devices, Inc.'s ("CleveMed") proposed constructions for the claim terms "base station" and "respiratory ventilation" are based upon the intrinsic record. A person of ordinary skill in the art ("POSITA") would understand the meaning of these terms based on the intrinsic record, namely, the patent claims and their specifications, and the prosecution history. Further, CleveMed's extrinsic evidence supports how a POSITA would understand these terms, as evidenced in the declarations of CleveMed's technical and clinical experts, Dr. Roozbeh Jafari ("Jafari Decl.") and Dr. Carolyn D'Ambrosio ("D'Ambrosio Decl.").

The remaining terms at issue from the Asserted Patents[1] are definite because they are readily understood by a POSITA and amply supported by the Asserted Patents' specifications. In addition to the expert declarations, several of these terms are similar to ones that the Patent Trademark Trial and Appeal Board ("PTAB") and the U.S. District Court for the District of Delaware have held to be definite in related patents.

II. BACKGROUND

A. CleveMed Is an Innovator in Sleep Disorder Technologies

CleveMed is a small innovative company who provides home sleep testing products and services that it developed. Founded in 1990 in Cleveland, Ohio with the mission of innovating technologies that would maximize the clinical quality and subject access to sleep disorder treatment and testing, CleveMed spent years researching and developing technologies to provide portable sleep testing and treatment solutions to the over 32 million U.S. subjects suspected of suffering from undiagnosed and untreated obstructive sleep apnea. Sleep apnea is a highly

[1] The "Asserted Patents" are U.S. Patent No. 11,602,284 ("the '284 Patent"), U.S. Patent No. 11,375,921 ("the '921 Patent"), U.S. Patent No. 11,690,512 ("the '512 Patent), U.S. Patent No. 11,786,680 ("the '680 Patent"), U.S. Patent No. 11,857,333 ("the '333 Patent"), and U.S. Patent No. 11,872,029 ("the '029 Patent"). Dkt. No. 1, Ex. 1; Dkt. No. 70, Exs. 1-2, 39. 42-43.

prevalent sleep disorder that is defined as the cessation of breathing during sleep and occurs in three forms: obstructive sleep apnea, central sleep apnea, and mixed sleep apnea. These apneas negatively affect the sufferer's sleep and often cause sleep deprivation. Prior diagnostic tests were either written questions to subjects that often yielded inaccurate results, or an all-night polysomnography, *i.e.*, sleep study, conducted in a lab and often followed by all-day in-clinic monitoring. *See, e.g.*, '921 Patent at 1:40-2:11. The most common treatment for apnea at the time that the Asserted Patents were filed in 2005 and 2006 was for subjects to use a positive airway pressure ("PAP") device that force subjects to breathe by delivering pressurized air while they sleep, and, in particular, a continuous positive airway pressure ("CPAP") device that could only deliver air at a single level of pressure.

CleveMed developed technologies that integrate diagnostic capabilities into therapeutic devices that subjects can use to monitor and treat their symptoms at home with PAP devices so that clinicians can monitor subjects' responses to the treatment and adjust therapies remotely based on data. *See, e.g.*, *id.* at 2:33-46. Prior to these inventions, no treatment device on the market could adjust the subject's treatment based upon their current physiological state or current symptoms. *See, e.g.*, *id.* at 2:23-32. Certain of CleveMed's claimed inventions use a PAP integrated with diagnostic sensors to detect the subject's physiological condition and respiration parameters such as airflow, respiratory effort, and oxygenation, to name a few. *See, e.g.*, *id.* at 6:10-7:30. The claimed inventions also provide a means for predicting the onset of sleeping disorders and providing a treatment in anticipation of these symptoms. *Id.* at 2:23-32.

In recognition of CleveMed's innovation, the Patent and Trademark Office ("USPTO") awarded CleveMed over 40 patents for its inventions. At issue are five patents that disclose technologies for PAP devices, and one patent that discloses technology for sleep testing.

1. The PAP Patents

One family of CleveMed's innovative patented technologies generally discloses systems and methods for sleep disorder diagnosis and treatment, including through PAP devices that subjects can use while sleeping to diagnose and treat various sleep disorders. *See, e.g.*, '921 Patent, Abstract. The '921 Patent, '284 Patent, '029 Patent, '680 Patent, and '333 Patent are all members of this family of patented technologies, and are referred to herein as the "PAP Patents."

The PAP Patents generally disclose systems and methods for combining the treatment of a PAP device with the diagnostic capability of home sleep tests for sleep disorders to obtain the best of both worlds. For example, the PAP Patents cover technologies for systems to record physiological signals detected by various sensors, calculate diagnostic values for the recorded signals via a specialized processor to automatically adjust a subject's treatment based on their physiological condition, and wirelessly transmit physiological signals, physiological data, and data reflecting a subject's usage of the system to both the subject and his or her clinician. *See, e.g.*, '921 Patent, Claim 1; *see also generally*, Jafari Decl., ¶ 17; D'Ambrosio Decl., ¶ 16. They also cover a radio frequency wireless transceiver to provide a clinician of the therapy's efficacy and the severity of the sleep disorder symptoms that the subject experienced while sleeping, using specialized software on the subject's cellular phone or on a remote internet site. *See, e.g.*, '921 Patent, Claim 1; *see also generally*, Jafari Decl., ¶ 17.

The PAP Patents are descendants of a shared priority application that was filed on November 4, 2005, and ultimately matured into U.S. Patent No. 8,172,766 (the "'766 Patent"). The '766 Patent has three branches of descendants. The first branch began with U.S. Patent No. 10,076,269 ("the '269 Patent"). Declaration of Sabah Khokhar ("Khokhar Decl.") filed herewith, Ex. 1. The '921 Patent, '284 Patent, and '029 Patent are successive continuations descending from the '269 Patent, which means that they share the same specification as the '269

Patent. Thus, claim construction and definiteness rulings applicable to the ’269 Patent can be relevant to its direct descendants which share the same written description.

The ’680 Patent and ’333 Patent are also members of this family, although each is a continuation-in-part. Thus, they include the same original specification as the rest of the family as well as some additional material, and claim priority back to the ‘766 Patent. As such, while the ’680 Patent and ’333 Patent include the written description that is common to all the PAP Patents, they each have their own additional written description that supports their respective sets of claims. Due to these family relationships, the relevant time of invention for purposes of claim construction is in 2005.

2. The ’512 Patent

The remaining patent, the ’512 Patent, generally relates to a data acquisition system for electroencephalogram (“EEG”) and other physiological conditions. ’512 Patent, Abstract; *see also generally* D’Ambrosio Decl., ¶ 17. It relates to a wireless sleep diagnostic system, such as systems that may be used for sleep studies. *Id.* The ’512 Patent claims a priority date of June 16, 2006, which is the filing date of the earliest-filed patent application in the ’512 Patent’s family. ‘512 Patent, Cover at 2. Due to this family relationship, the relevant time of the invention for claim construction for the ’512 Patent is in 2006.

B. Other Venues Have Rejected ResMed’s Allegations Against Related Patents

After CleveMed obtained its patents, ResMed Corp. (“ResMed”) and its parent company, ResMed Inc., began selling infringing sleep solutions, despite being aware of CleveMed’s patent portfolio. *See, generally*, Khokhar Decl., Ex. 2, *Cleveland Medical Devices, Inc. v. ResMed, Inc.*, No. 22-794-GBW, Dkt. No. 1, Complaint (D. Del. June 16, 2022). CleveMed filed a complaint in the District of Delaware in June 2022 against ResMed Inc. (the “Delaware Action”), asserting infringement of various patents, including the ’269 Patent related to the PAP

Patents here. *Id*. The Delaware Court issued a claim construction order addressing claim terms for the '269 Patent that overlap with those at issue here. *See, generally*, *id.*, Ex. 3, the Delaware Action, Dkt. No. 181. For example, the Delaware Court ruled that the term "base station" means "a computer that can communicate with other devices." *Id.* at 8-11. It also held that various claim terms similar to the ones at issue here in the '269 Patent are definite. *Id.* at 12-23.

ResMed filed various other actions, seeking to invalidate CleveMed's patents. For example, ResMed petitioned the PTAB for a post-grant review ("PGR") seeking to invalidate the '284 Patent (the "'284 PGR") on December 13, 2023, on several grounds, including an alleged lack of sufficient written description in the patent specification to support the claims. Khokhar Decl., Ex. 4, *ResMed Corp. v. Cleveland Medical Devices, Inc.*, PGR2024-00012, Paper 1 (P.T.A.B. Dec. 13, 2023) ("PGR2024-00012"). The PTAB found that the '284 Patent, one of the PAP Patents here, had an adequate written description and enablement, confirming that its claims are reasonably understood by a POSITA. *Id.*, Ex. 5, PGR2024-00012, Paper 7 (P.T.A.B. Jun. 24, 2024) at 10-24. The PTAB's holding confirmed the definiteness of terms similar to those at issue here, such as claim terms involving "treatment efficacy" or "the data of severity of sleep disorder symptoms . . . ." *See, e.g.*, *id.* at 12, 14. Thus, the '284 PGR is additional evidence of definiteness for the PAP Patents.

C. A Person of Ordinary Skill in the Art Would Understand CleveMed's Constructions and the Definiteness of the Claim Terms

The level of skill of a POSITA is evaluated as of the time of the inventions of the Asserted Patents. Due to their family relationships, the relevant dates for the Asserted Patents are in 2005 and 2006. In that timeframe, "a person with an undergraduate degree in biomedical engineering, electrical engineering, or a similar field, or who has 3 to 5 years of experience in the relevant medical devices industry." Jafari Decl., ¶ 16; D'Ambrosio Decl., ¶ 15.

III. ARGUMENT

A. The Intrinsic and Extrinsic Evidence Supports CleveMed's Constructions of the Two Terms to be Construed

The parties have identified two claim terms for construction in this case: "base station" and "respiratory ventilation." Claim construction is where the Court "determin[es] the meaning and scope of the patent claims asserted to be infringed" based upon the intrinsic and extrinsic evidence. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996); *Google LLC v. EcoFactor, Inc*., 92 F.4th 1049, 1055 (Fed. Cir. 2024) ("[C]laim construction serves to define . . . the patentee's right to exclude.") (citations omitted).

The intrinsic evidence, which includes the patent claims and their specifications, the prosecution history, and rulings from the PTAB, support CleveMed's proposed constructions for these terms. *Google*, 92 F.4th at 1058 (courts "primarily rely on . . . the claims themselves, the specification, and the prosecution history of the patent" for claim construction); *Ravin Crossbows, LLC v. Hunter's Mfg. Co.*, No. 5:23-cv-598, 2024 WL 895156, at *2 (N.D. Ohio Mar. 1, 2024) (noting "intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language.") (citation omitted). Extrinsic evidence, which includes the declarations of CleveMed's technical and clinical experts, and the U.S. District Court for the District of Delaware's determinations regarding the construction of the same or similar terms in directly related patents, provide additional support for CleveMed's constructions.

1. Term 1: "base station" ('921 Patent, Claims 1, 7, 8, and 12)

CleveMed's Proposed Construction	ResMed's Proposed Construction
A computer that can communicate with other devices	Specialized transmission and reception station designed to be in a fixed location

"Base station" is a computer that can communicate with other devices. This meaning is fully consistent with the intrinsic evidence because the '921 Patent's specification ***describes*** a

base station as a computer. *See, e.g.*, '921 Patent at 19:35-45 (disclosing a "computer" as a "computer or processor, which receives the data transmission and displays the data . . . [and] transfer[s] [it] for analysis."), 19:8-24 (describing various embodiments of that computer); *Ravin*, 2024 WL 895156, at *2 ("The specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive.'") (citation omitted).

The Court should also "look to the words of the claims themselves" to construe a claim term. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Here, the claims disclose the base station as having computer elements, such as a wireless transceiver, processor, and display, where the processor has "software stored on a non-transitory computer readable medium." *See, e.g.*, '921 Patent, Claims 1, 7, 12 (each claiming "a base station . . . comprising a second radio frequency wireless transceiver, the second processor and a display"). Thus, CleveMed's construction is consistent with the claim language itself. *Ravin*, 2024 WL 895156, at *2 ("The . . . starting point . . . is . . . with the language of the asserted claim itself.").

Other embodiments in the specification support CleveMed's construction. For example, the '921 Patent describes an embodiment in Figure 3 in which base station 40 is a computer with a base receiver, base microcontroller, base transmitter, memory (EEPROM), and a power supply. '921 Patent at Fig. 3, 12:4-8. In Figure 3, the base station uses these components to connect other computers or wireless devices to a central hub and facilitates a connection to a network. *Id.* Also, the base station receives wireless communications and obtains physiological data through its connections with other computers or wireless devices, such that it is functioning as a computer in communication with other devices. *Id.* at 8:31-41 ("Once processed, the physiological signals are transmitted wirelessly to the base station."), Fig. 1. The base station receives data through a connector and then transmits the data to an external programming means,

personal computer, or data storage device, where it can be viewed in real time, analyzed, and saved. *Id.* at 12:11-14. Thus, CleveMed's construction is based upon the intrinsic record that describes a base station as a functional computer system that connects the PAP devices with a network where the collected data can be stored and analyzed in a central hub, such as the cloud.

Based on these disclosures, a POSITA would understand from the '921 Patent that the base station is a computer, and that it can transmit data to another network device, including sending data to the positive airway pressure "PAP device" so it can be remotely adjusted. '921 Patent at 19:15-26; Jafari Decl., ¶¶ 20-27.

Notably, in the Delaware Action, that Court construed the "base station" claim term found in the related '269 Patent that has the same specification as the '921 Patent, as "a computer that can communicate with other devices." Khokhar Decl., Ex. 3 at 11; *see also E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1070 (Fed. Cir. 2019) (no error in considering a related patent in claim construction where there is some common subject matter). Thus, based on the same portions of this shared specification cited above, the Delaware Court adopted CleveMed's construction. In rejecting ResMed Inc.'s proposal, which is the same overly limited one that ResMed advances here, the Delaware Court found no intrinsic evidence supported limiting a base station to "'transmission and reception station' in a 'fixed' location with 'specialized' functionality." Khokhar Decl., Ex. 3 at 10. It further noted that ResMed Inc.'s proposed construction attempted to "improperly import[] limitations into the claim," which violates a central tenet of claim construction. *Id.* at 9; *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1320 (Fed. Cir. 2005) ("one of the cardinal sins of patent law [is] reading a limitation from the written description into the claims") (citation omitted). The Delaware Court further rejected ResMed Inc.'s proposal for base station, stating that it could not "rely on extrinsic evidence to

alter the meaning of 'base station' when that meaning is clear from the intrinsic evidence." Khokhar Decl., Ex. 3 at 10-11; *see also Interactive Gift Express, Inc. v. CompuServe, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (when "claim language is clear on its face, then our consideration of the rest of the intrinsic evidence is restricted to determining if a deviation from the clear language of the claims is specified.").

2. Term 2: "respiratory ventilation" ('512 Patent, Claim 1)

CleveMed's Proposed Construction	ResMed's Proposed Construction
The process of respiratory breathing wherein air flows into the lungs during inspiration and out of the lungs during expiration	The amount of air into the lungs during inspiration and out of the lungs during expiration

"Respiratory ventilation" is "the process of respiratory breathing wherein air flows into the lungs during inspiration and out of the lungs during expiration." Put simply, this term refers to moving air in and out of the lungs (*i.e.*, breathing) while a subject uses the sleep diagnostic data acquisition system, which is consistent with how the claims and specification of the '512 Patent use this term. For example, Claim 1 describes that respiratory ventilation may be measured directly or indirectly by a sensor, while Claim 2 gives specific examples of measuring respiratory ventilation according to respiratory effort (*i.e.*, breathing effort) or snore. '512 Patent, Claims 1, 2. A POSITA would understand ventilation in these claims to mean the process of respiratory breathing based on these uses in context. D'Ambrosio Decl., ¶ 19.

Further, a POSITA would understand the specification as describing examples of how the claimed sensors can measure various characteristics of a subject's respiratory ventilation because it explains that "[t]he subject's respirations can be measured by measurement of airflow, respiratory effort, oxygenation and ventilation, and the like." *See, e.g.*, '512 Patent at 8:61-63. Additionally, the specification discloses embodiments using an airflow sensor for measuring "a subject's nasal and/or oral breathing pattern" and measuring respirations by measuring

respiratory airflow, both of which a POSITA would understand as another measurable characteristic of a subject's respiratory ventilation. *Id.* at 9:6-9, 9:57-10:4; D'Ambrosio Decl., ¶ 19. Thus, in light of the intrinsic evidence that associates measuring a subject's respirations (*i.e.*, breathing) with measuring various fluctuations that occur during inspiration and expiration (*e.g.*, fluctuations in effort, breathing pattern, airflow), a POSITA would understand that "respiratory ventilation" is "the process of respiratory breathing wherein air flows into the lungs during inspiration and out of the lungs during expiration." Jafari Decl., ¶¶ 29-30; D'Ambrosio Decl., ¶ 19.

CleveMed's construction is based on the intrinsic evidence and does not add any extra limitations. In contrast, ResMed's proposal limits this claim term to the "amount of air into the lungs," which excludes the many other embodiments of the '512 Patent specification. Indeed, the specification discloses an embodiment of directly or indirectly measuring respirations of the subject via "the use of a pulse oximeter." *See, e.g.*, '512 Patent at 9:57-10:4; *see also* Jafari Decl., ¶ 29. Because the pulse oximeter collects respiration data by measuring the oxygenation of a subject's blood, it necessarily cannot measure the amount of air in and out of the lungs during inspiration and expiration. *See id.* at ¶ 31. Thus, ResMed has no support for importing the limitation of a measurable amount of air in and out of the lungs into its construction.

B. CleveMed's Definite Terms That Inform a POSITA With Reasonable Certainty About the Scope of the Invention

Each of the following terms is definite because their plain and ordinary meanings are readily understood by a POSITA in the context of the claims and in light of the specification, as detailed below. *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014) (claims are indefinite only if they fail to inform a POSITA of the scope of the invention with "reasonable certainty"); *id.* at 908 ("[D]efiniteness is to be evaluated from the perspective of someone skilled

in the relevant art.") (citations omitted); *Sonix Tech. Co. v. Publ'ns Int'l, Ltd.*, 844 F.3d 1370, 1381 (Fed. Cir. 2017) ("[W]hether a claim is indefinite must be judged 'in light of the specification' . . . of the patent in which it appears.") (citation omitted).

ResMed cannot satisfy its burden of proving by clear and convincing evidence that the terms are indefinite. *Monode Marking Prods., Inc. v. Columbia Marking Tools, Inc.*, No. 1:18 cv 16, 2019 WL 4727447, at *1 (N.D. Ohio Sept. 27, 2019) (as a patent's claims "carry a presumption of validity," a party challenging validity must prove an indefiniteness contention by clear and convincing evidence). In fact, for each of Terms 3 through 7 below, ResMed has not identified what it actually contends is indefinite within these long quotations from claims that it is baselessly challenging. When considered within the context of the claims, these claim terms are definite, as explained below. *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1367-68 (Fed. Cir. 2017) (holding claims not indefinite where defendant "has read too much into the specification" and gives the Court "no persuasive reason to conclude that a relevant skilled artisan, reading the claims in light of the specification," would come to the same conclusion).

1. Term 3: "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, and 12)

Term 4: "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, and 12)

These two terms together describe how the claimed first processor is adapted to process incoming sensor data in order to calculate the severity of a subject's symptoms and determine the effectiveness of treatment. Based on the plain language of the claims, a POSITA would readily

understand the meaning of these two terms from their description of the system collecting, calculating, and analyzing a subject's sleeping disorder symptom data. Specifically, a POSITA would understand the meaning of the "generating and outputting" element from the claims' disclosure of a processor programmed to (1) receive as an input and process airflow sensor data about a subject using a PAP device, and (2) output information on the efficacy of the subject's sleep disorder treatment, including whether and to what extent the subject exhibits sleep disorder symptoms while using the PAP. *See, e.g.*, '921 Patent, Claim 1. The "measuring and calculating" element is understood when that processor is programmed to work with an airflow sensor to (1) calculate the severity of sleeping disorder symptoms during treatment and (2) provide data relating to the treatment's efficacy. *See, e.g.*, *id.* The claimed system can calculate when a subject has an apnea or hypopnea event using sensor data from the subject and the average number of such events over the total period of time spent sleeping, and determine a subject's Apnea Hypopnea Index ("AHI") severity level, which is an example of a medical measurement of the severity of a subject's sleep disorder and is used to diagnose the severity of sleep apnea. Jafari Decl., ¶ 39. Thus, the claim language itself describes the scope of the invention with reasonable certainty to a POSITA. *See* Jafari Decl., ¶¶ 41-42.

The specification supports this reading because it describes systems for receiving and analyzing signals from sensors, and for diagnosing and creating an output reflecting the severity of a subject's sleeping disorders or symptoms. *See, e.g.*, '921 Patent at 3:54-4:44, 7:27-8:25. The specification provides specific examples of the "quantitative method for estimating or determining the severity" of the disorder or symptoms based on sensor signals. *Id.* at 19:46-57. The system can then prepare that data for analysis (*id.* at 20:1-8) and use different exemplary "sleeping disorder data or signal analysis techniques" (*id.* at 20:6-31) to create useful output

information (*id.* at 22:1-8). For example, in one embodiment a device can "physically treat" a sleep disorder by adjusting treatment "using the output of the level of severity" of the disorder. *Id.* at Fig. 7 (as described at 22:41-44). In a similar embodiment, a device uses a microprocessor to process data or signals from sensors to determine a level of severity of a sleep disorder or sleep disorder symptoms, in order to then transmit a signal based on the level of severity to the device to control the flow of air or gas to the subject. *Id.* at Fig. 8 (as described at 23:18-33).

Based on these detailed descriptions of the collecting, calculating, and analyzing of a subject's sleeping disorder symptom data in the claims and specification of the '921 Patent, a POSITA would understand the full scope of the claims, including the meaning of "symptom data of the severity of the sleeping disorder symptoms," "treatment's efficacy," a "quantitative output" of such data, and an index of a subject's symptoms. *See* Jafari Decl., ¶¶ 37-44; D'Ambrosio Decl., ¶¶ 28-35. In particular, with respect to a term of degree, such as "severity of the sleeping disorder symptoms," "prior cases establish that the written description is key to determining whether a term of degree is indefinite." *Sonix*, 844 F.3d at 1378. Further, as Dr. D'Ambrosio explains, each of these terms has an ordinary meaning to clinical professionals and would be readily understood—for example, a "level of severity" will correspond to "how dire a subject's calculated symptom data might be." D'Ambrosio Decl., ¶¶ 28-35. A POSITA would understand from the claims and specification what types of symptom data that are calculable, *i.e.*, airflow and apneic events, and indexes, such as AHI. Jafari Decl., ¶ 39; D'Ambrosio Decl., ¶¶ 32-33. Further, a POSITA would recognize that each value calculated for a specific type of symptom data or index is representative of the level of severity of a subject's sleeping disorder. Jafari Decl., ¶ 39. And finally, a POSITA would understand the processor could be programmed to calculate a subject's AHI. *Id.*; D'Ambrosio Decl., ¶¶ 32-33. Thus, the entirety of both these

claim terms is definite because they are understandable to a POSITA.

A POSITA would readily understand this "measuring and calculating" term, similar to the "generating and outputting" term discussed above (Term 3), from descriptions of an airflow sensor and processor adapted to measure and calculate the severity of a subject's sleeping disorder. *See* Jafari Decl., ¶¶ 39-44. The specification details how the system measures signal data collected from sensors, particularly from "the diagnostic part of the system or device." *See, e.g.*, '921 Patent at 3:4-24 (measuring "airflow, respiratory effort, oxygenation and ventilation, and the like"); *see also* 6:10-8:25 (disclosing sensors used to determine events of obstructive, central, and mixed apneas and hypopneas), 7:27-8:25 (describing sensors used to measure various parameters of a subject's respirations), 13:29-54 (measurement type means), 19:46-57 (collection of sensor data). It also describes how the system uses that data to calculate the level of severity of the subject's sleeping disorder system – particularly, "diagnosing and creating an output of a level of severity of a subject's sleeping disorder." *See, e.g.*, *id.* at 3:54-4:44, *see also id.* at 8:33-36 (describing system used to receive and analyze signals from sensors), 8:57-9:45 (describing Fig. 1 showing inputs from sensors, a signal processing module that accepts inputs from sensors and generates a signal encoded with data corresponding to the input), 20:1-8 (preparation of data for analysis), 20:6-31 (identifying exemplary "sleeping disorder data or signal analysis techniques"), 22:1-8 (describing output), Figs. 1-2, Claims 1, 7, 12.

For both the "generating and outputting" and "measuring and calculating" terms, the '921 Patent provides detailed descriptions of accomplishing such calculations, such that a POSITA would readily understand the scope of Claims 1, 7, and 12. Jafari Decl., ¶¶ 39-44. For example, the processor could be programmed to calculate a subject's AHI. *Id.*, ¶ 38. As mentioned above, the claimed system can calculate when a subject has an apnea or hypopnea event using sensor

data from the subject and the average number of such events over the total period of time spent sleeping, and determine an AHI severity level. *Id.*; *see also* '921 Patent, Claims 1, 7, 12. Moreover, a POSITA would understand from the intrinsic record the types of infringing symptom data that satisfy the claims, such as identified apneic events. Jafari Decl., ¶ 39.

The Delaware Court rejected ResMed Inc.'s indefiniteness allegations involving similar terms found in the related '269 Patent, which involved calculating sleep disorder symptom data, including a level of severity or index of a subject's symptoms, because the terms were definite and used terms of art.[2] *See* Khokhar Decl., Ex. 3 at 17. The Court held that symptom data, level of severity, and index were all terms of art "within the clinical sleep study field" that conveyed meaning to a POSITA. *Id.* at 18. These phrases appear in the similar "generating and outputting" claim element at issue here, and, as explained above, a POSITA would readily understand them in the context of the intrinsic record of the '921 Patent. The Court found 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." *Id.* at 17.

Finally, the PTAB rejected ResMed's written description allegations in its PGR petition it submitted for the '284 Patent, which is a continuation of the '921 Patent, that included similar terms such as "the data of severity of sleep disorder symptoms of the subject and the data of

[2] Specifically, the Court agreed with CleveMed's expert, Dr. D'Ambrosio indicating that "'symptom data' refers to the physiological and technological data indicative of the patient's condition while they sleep or attempt to sleep"; that clinicians use "level of severity" "to represent the [sic] how dire a patient's calculated symptom data may be"; and that 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." Khokhar Decl., Ex. 3 at 18.

usage of the PAP device by the subject both calculated by the PAP device" and "an index of treatment efficacy." Khokhar Decl., Ex. 5 at 11-16; *see also infra*, Term 6 (further discussing "an index of treatment efficacy"). In finding that this "calculated" term was adequately supported by the specification, the PTAB found that "the specification discloses that the gathered information is processed to monitor the condition of the subject (*i.e.*, the system quantitatively estimates or determines the 'severity of sleep disorder symptoms') and how much pressure / flow of gas is to be provided to the subject (*i.e.*, the system calculates the 'usage of the PAP device by the subject')" and that "the device monitors how often it has to supply support to the subject." *Id*. at 16. Thus, in view of the intrinsic and extrinsic evidence, these claims are definite. *GeigTech E. Bay LLC v. Lutron Elecs. Co.*, No. 18 Civ. 05290 (CM), 2024 WL 68418, at *1 (S.D.N.Y. Jan. 5, 2024) ("[I]nter partes review and post grant review . . . become part of the patent's prosecution history."); *Intertainer, Inc. v. Hulu, LLC*, 660 F. App'x 943, 948 (Fed. Cir. 2016) ("[T]he [PTO] should also consult the patent's prosecution history in proceedings in which the patent has been brought back to the agency for a second review."); *see also Sonix*, 844 F.3d at 1379 ("The prosecution history of the[] patent, which includes the reexamination history . . . .") (citation omitted).

2. Term 5: "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)

A POSITA would readily understand this "calculating" claim element from the detailed descriptions in the '029 Patent's specification regarding a system calculating an index based on the severity of the subject's sleep disorder or the subject's use of a PAP device. For this calculation, the system uses data regarding the severity of symptoms, data reflecting the subject's usage of the PAP device, and/or an index that is based on either or both of these categories of

data. *See, e.g.*, '029 Patent at 19:61-20:5 (collection of sensor data), 20:16-23 (preparation of data for analysis), 20:24-46 (identifying exemplary "sleeping disorder data or signal analysis techniques"), 22:14-21 (describing output). The specification details at least four exemplary techniques that a POSITA could use for such a calculation, such as a standard deviation technique (*id.* at 20:47-55), Auto-Regressive Moving Average ("ARMA") model (*id.* at 20:56-21:29), Short-Time Fourier Transform model (*id.* at 21:30-55), and time-frequency signal analysis (*id.* at 21:55-22:13), among "other on-line signal processing algorithms known" to a POSITA (*id.* at 20:41-46). The specification also shows a POSITA how to assemble such a system. *See, e.g.*, *id.* at Fig. 7 (described in part at 22:54-23:30), Fig. 8 (described in part at 23:31-54). A POSITA would understand from these disclosures the necessary signal processing techniques and algorithms needed to program the processor with in order to derive data concerning the severity of the patient's sleep disorder symptoms and the patient's usage of the PAP device. *Id.* at 20:16-22:21. Further, a POSITA would be able to use the severity and usage data to determine an index of the patient's sleep disorder symptoms and treatment efficacy.

As noted above, the claim terms for "generating and outputting," "measuring and calculating," and this "calculating" term for the '029 Patent use terms of art readily understood by a POSITA, such as data of a severity of sleep disorder symptoms. *See, e.g.*, Jafari Decl., ¶¶ 45-47. The signal processing techniques also constitute terms of art that are reasonably certain to a POSITA. *Id.*, ¶ 46. Dr. Jafari explains that a POSITA would understand to use an ARMA model "on the measured pressure sensor signal data to identify order shifts which are used to adapt treatment based upon the patient's symptoms," and that such an analysis can be used to provide predictive treatment based on identifying characteristic shifts in the sensor's signal data in order to trigger a change to the level of treatment provided by the subject's device.

Jafari Decl., ¶¶ 43, 46 (citing ’029 Patent at 20:24-46).

ResMed’s arguments are undercut by their admitted understanding of the signal processing techniques disclosed in the ’029 Patent. For instance, the parties agreed upon a construction for standard deviation, which is “a measure of how dispersed data is in relation to the mean.” *See* Khokhar Decl., Ex. 6, 11/4/24 ResMed’s Final Claim Constructions and Evidence at 14. Further, because the ’029 Patent is a continuation of the ’284 Patent, the Delaware Court’s claim construction order in regards to the ’269 calculating terms are again instructive. In the Delaware Action, ResMed Inc. admitted that two of the four techniques involved in the ’269 Patent’s “calculating” terms convey meaning to a POSITA, and it has no basis to reverse course now in the context of the ’029 Patent. Specifically, ResMed Inc. and CleveMed agreed that the proper construction of the claimed “ARMAX system identification model” in the ’269 Patent was “Auto-Regressive Moving Average exogenous system identification model.” Khokhar Decl., Ex. 3 at 7. Additionally, the parties agreed that the plain and ordinary meaning for the claimed “Fourier transform technique” was “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.” *Id.* Further, the Delaware Court found that all four of the signal processing techniques described in this shared specification of the ’269 Patent sufficiently disclosed support for the “calculating” terms at issue in that action. *Id.* at 16-17. While Claim 1 of the ’029 Patent does not specifically claim one or more of these techniques, ResMed cannot reasonably claim that inclusion of these techniques in the specification somehow fails to support the claims. There is no question that a POSITA would know and readily understand the ’029 Patent’s disclosures of these techniques for signal processing. Indeed, with respect to a patent’s definiteness requirements, a patent need

only provide clarity, as "absolute precision is unattainable." *Nautilus*, 572 U.S. at 899.

Moreover, the Delaware Court acknowledged that a POSITA would recognize that each value calculated for a specific type of symptom data is representative of the level of severity of a subject's sleeping disorder. Khokhar Decl., Ex. 3 at 18 (discussing '269 Patent "calculating" terms). Just as with the "generating and outputting" and "measuring and calculating" terms (Terms 3 and 4), the phrases "data of a severity of the sleep disorder symptoms" and indices of symptom severity are commonly used terms of art in the sleep medicine field that inform clinical and technical POSITAs of the boundaries of the inventions' calculations and the inputs and algorithms used in generating these calculations, when read in the context of the claim as a whole. Jafari Decl., ¶ 46; D'Ambrosio Decl., ¶ 32.

3. Term 6: "related to the subject's treatment and the treatment's efficacy" ('029 Patent, Claim 1)

A POSITA would readily understand the term "related to the subject's treatment and the treatment's efficacy" as closely related to the severity of a subject's sleep disorder symptoms, in the sense that calculating a higher level of severity from collected data indicates a lower treatment efficacy. Indeed, the '029 Patent specification amply describes collecting data related to, analyzing, and quantifying the severity of a subject's sleep disorder symptoms in order to diagnose sleeping disorders. *See, e.g.*, '029 Patent at 18:66-19:22 (describing sensors used to determine a quantitative level of severity of a subject's sleeping disorder and/or symptoms), 20:16-23:30 (quantifying the level of severity of a subject's sleeping disorder or symptoms).

In addition to the intrinsic record, a POSITA would further understand the meaning of the term based on the language of Claim 1, which requires that the index of treatment efficacy be calculated "based in whole or in part on a data of severity of sleep disorder symptoms of the subject and/or a data of usage of the PAP device by the subject." '029 Patent, Claim 1; Jafari

Decl., ¶ 48; D'Ambrosio Decl., ¶ 32 (stating that the "level of severity" represents sleep apnea indices such as AHI which indicate "how dire a patient's calculated symptom data may be."). That an index of treatment efficacy is based on a data of severity of sleep disorder symptoms further shapes the understanding that treatment efficacy is related to a level of severity of sleep disorder symptoms. Indeed, Dr. D'Ambrosio explained she has used terms of art like "treatment's efficacy" in her clinical practice, "when discussing the diagnosis and treatment of a patient's sleeping disorder with colleagues" who understand that "treatment's efficacy" is related to the level of severity of the subject's symptoms, in the sense that calculating a higher level of severity indicates a lower treatment efficacy. D'Ambrosio Decl., ¶ 34.

This understanding is consistent with the '029 Patent specification's description that one of the key benefits of the '029 Patent is that the level of severity of a subject's sleep disorder systems can be used to adjust, in real-time, the treatment being provided to the subject based on their current physiological symptoms. '029 Patent at 22:42-50, 2:38-40. In this context—where the level of severity is determined during treatment and used to adjust that treatment—a POSITA would understand that the level of severity relates to the subject's treatment and the treatment's efficacy. Further, the '029 Patent discloses collecting usage data and data representing breathing metrics, including a subject's airflow pressure, nasal pressure, respiratory effort, pulse oximetry, oxygenation and ventilation, and the like. *Id.* at 3:25-31, 5:46-56, 7:43-59, 23:25-30. These breathing metrics, collected during the subject's treatment, are used to determine a level of severity of the subject's symptoms to diagnose and treat the subject in real-time. *See id.* at 3:25-31, 5:46-56, 7:43-59, 23:25-30, 20:16-30. Accordingly, the '029 Patent discloses calculating an index of treatment efficacy based on the severity data and usage data because it calculates a level of severity of the subject's symptoms while the subject is using the treatment device. *See id*. at

3:23-31, 3:41-42, 5:46-56,7:43-59, 20:16-30, 23:6-40; Jafari Decl., ¶ 49.

As noted above, the ’029 Patent is a continuation of the ’284 Patent that was subject to ResMed’s written description allegations in the ’284 PGR. Two terms at issue in the ’284 PGR involved data related to a subject’s treatment and its efficacy: “an index of treatment efficacy” and a claim term covering retransmission of, *inter alia*, “the data of usage related to the subject’s treatment and the treatment efficacy, in whole or part, calculated by the PAP device.” Khokhar Decl., Ex. 5 at 12-14, 19-21. The PTAB found that the specification amply supported both terms because it disclosed that “the system uses data collected from the sensors to evaluate the severity of the subject’s sleeping disorder and efficacy of the current treatment, and can adjust the treatment without human intervention as needed,” such as by “regulat[ing] the physical or chemical treatment.” *Id.* at 14 (citing ’284 Patent at 3:37-55, 19:3-17); *id.* at 21 (applying same reasoning to the retransmitting “data . . . related to the subject’s treatment . . .” term). Thus, a POSITA would understand with reasonable certainty that the shared specification of the ’029 Patent and ’284 Patent discloses what types of data may be related to a subject’s treatment and how a system collects, analyzes, and uses such information. This Court should also confirm that the term “related to . . . efficacy” is definite.

4. Term 7: “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)

A POSITA would understand from the detailed description of the method for transmitting collected data or the level of severity to a cell phone or a remote station that this term is definite. Indeed, the '333 Patent's specification describes the method for transmitting data or the level of severity. For example, Figure 1 shows a module transmitter, and the description of Figure 1 states "[t]he signal processing module 16 generates a signal 18 encoded with data corresponding to the external input 12. The signal processing module 16 transmits the signal 18 by wireless means to a base station 40." *See, e.g.*, '333 Patent at Fig. 1, 35:45-48. Specifically, "the signal processing module generates a radio frequency signal 18 by frequency modulating a frequency carrier and transmits the radio frequency signal through module antenna 20." *See, e.g.*, *id.* at Fig. 1, 35:49-53, 36:2-27 (describing programming the signal processing module to transfer radio frequency signals both to and from the base station and signal processing module).

Other figures of the '333 Patent explicitly show features of the method for transmitting the data or level of severity. For instance, Figure 2 shows a base transmitter and a module transmitter, which "employs frequency synthesis to generate the carrier frequency." *Id.* at Fig. 2, 38:13-14, 38:53-56. Figure 3 also shows a base transmitter. *Id.* at Fig. 3, 50:28-32. Additionally, Figure 6 shows the process of transmitting messages. *Id.* at Fig. 6, 44:56-46:51.

Based on these disclosures, a POSITA would understand from the '333 Patent that data is transmitted from the PAP or CPAP device or a cellular phone to a remote station via a radio frequency wireless link or cellular system, for example, when a radio frequency signal is transmitted or when data is transmitted by wireless means. Jafari Decl., ¶¶ 50-54. The specification describes wireless transmission of signals to an intermediary device, such as a cell phone, a modem, a wireless router, a router, a PDA, a computer, a processor, or combinations thereof, at a remote location for remote review or processing of signals for diagnostic or

treatment purposes. *See, e.g.*, '333 Patent at 4:2-39, 20:20-43 (explaining transmitting the data wirelessly, including transmitting data wirelessly from the patient interface box to the base station, which then transmits the data via either a wireless method or a wired connection).

A POSITA would also understand from the specification that the data transferred is the collected data or the quantified level of severity. *See, e.g.*, *id.* at 5:3-31 (describing collecting physiological data), 5:3-8:61 (describing various embodiments in which the systems transmit or retransmit signals from sensors), 8:62-9:3 (describing diagnosing and creating a quantitative output of the severity of the sleeping disorder or symptoms), 14:61-18:21 (same). A POSITA would further understand from the specification that the data is transferred for further analysis with a second processor or a server and then there is a review of the collected data, the quantified level of severity, and/or this analysis by a clinician, technician or physician. *See, e.g.*, *id.* at 18:22-20:19 (describing wirelessly transmitting pre-processed signals to a processor's receiver for analysis), 20:44-21:38 (describing transmitting physiological signals used to determine a quantitative level of severity of a subject's sleeping disorder and/or symptoms), 49:27-45 (describing Fig. 8, which shows a microprocessor for processing the data or signals to determine a level of severity of the subject's sleeping disorder or symptoms). A POSITA would know that the main purpose of these integrated apnea diagnostic and treatment devices is to measure and calculate data of the severity of a subject's sleep disorder symptoms. "Level of severity" is a term of art of art in the sleep testing and treatment industry that is readily understood by POSITAs, and therefore a POSITA would understand that the data transferred would relate to or consist of the level of severity. D'Ambrosio Decl., ¶ 32; Jafari Decl., ¶¶ 55-56.

5. Term 8: "the therapy efficacy data" ('333 Patent, Claim 15)

A POSITA would understand the term "therapy efficacy data" to mean data calculated based on data collected while a subject is undergoing treatment to determine the severity of a

subject's sleep disorder symptoms and whether the PAP device that is part of the method needs to be adjusted. *See, e.g.*, '333 Patent at 5:28-31 (describing collecting physiological data that is used to adjust the PAP device to effectively treat the subject's sleep-related breathing disorder). The plain language of Claim 15 of the '333 Patent indicates exactly what data is collected, analyzed, and transmitted. *Id.* at Claim 15 (describing "collecting data with the PAP or CPAP device from the flow or pressure sensor during a time period of the therapy"). The data reflecting the effectiveness of treatment is based on this collected data and/or quantified level of severity of symptoms data, and the effectiveness can be determined by either the PAP device's processor, the second processor at the remote station, or a cellular phone with the requisite software. *Id.* Efficacy is determined after the quantified level of severity data is transmitted to a remote location for further analysis. *Id.* The '333 Patent specification describes that one of the key benefits of the '333 Patent is that the level of severity of a subject's sleep disorder systems can be used to adjust, in real-time, the treatment being provided to the subject based on their current physiological symptoms. *See, e.g.*, *id.* at 22:25-46, 46:30-51. The specification describes embodiments in which the treatment device gathers data for analysis in order to calibrate any necessary adjustment, such that evaluating data that indicates a treatment device's performance also constitutes a way of determining therapy efficacy and generating therapy efficacy data that can be reviewed and used. *See, e.g.*, *id.* at 5:14-31; *see also id.* at 23:20-60 (describing specific processing techniques useful in such an analysis). Jafari Decl., ¶¶ 57-59.

Thus, based on the intrinsic record, a POSITA would understand that "the therapy efficacy data" is data similar to and based on the severity of a subject's sleep disorder symptoms that determines the effectiveness of the therapy used in treating a sleep-related breathing disorder and whether a PAP device need adjustment. *Nevro Corp. v. Boston Sci. Corp.*, 955 F.3d 35, 43-

44 (Fed. Cir. 2020) (holding that the term "therapy signal," which related to pain-relief therapy, was "confirmed by the specifications of the asserted patents, as they consistently identify treating pain as the purpose of the claimed invention"); *see also* D'Ambrosio Decl., ¶¶ 34-35; Jafari Decl., ¶ 58. In fact, Dr. D'Ambrosio explained that she has used the term "therapy efficacy data" in her practice, that clinical professionals understand it to be based on the severity of a subject's sleep disorder symptoms, and that it is used to determine if adjustment to treatment is warranted. D'Ambrosio Decl., ¶¶ 34-35. Given this context—where the level of severity is determined during treatment (not to mention used to adjust that treatment)—a POSITA would understand that the level of severity is similar to and a basis for the therapy efficacy data.

During ResMed's PGR, the PTAB considered a similar term to the one at issue here and found it adequately disclosed in the patent specification. The '333 Patent is a family member of the '284 Patent that was subject to ResMed's PGR proceedings. The term "therapy efficacy data" in the '333 Patent is similar to the term "an index of treatment efficacy," discussed above, because both involve collecting data from sensors to evaluate the severity of the subject's sleeping disorder and thus the efficacy of the current treatment. *See* D'Ambrosio Decl., ¶¶ 34-35; *see also* Jafari Decl., ¶ 58. As noted above in connection with the term "an index of treatment efficacy," the PTAB found that this term was definite because the specification amply disclosed a system that could perform such collection, determination, and resulting therapy adjustment. Khokhar Decl., Ex. 5 at 13-14. The PTAB found this term definite. *Id.* And as discussed above for Term 6, ResMed has identified no reason, much less clear and convincing evidence, for why determining "the therapy efficacy data" in this context is not readily understood by a POSITA when determining "an index of treatment efficacy" in the '284 Patent ***is*** understood. Thus, the Court should find this term definite.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 25, 2024, a complete copy of the foregoing **DEFENDANT AND COUNTERCLAIM PLAINTIFF CLEVELAND MEDICAL DEVICES, INC.'S OPENING CLAIM CONSTRUCTION BRIEF** was served via electronic mail upon the following counsel of record for Plaintiff ResMed Corp.:

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