

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

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

JOINT CLAIM CONSTRUCTION BRIEF

Philip A. Rovner (#3215)
Jonathan A. Choa (#5319)
POTTER ANDERSON & CORROON LLP
P.O. Box 951
Wilmington, DE 19899
provner@potteranderson.com
jchoa@potteranderson.com
(302) 984-6000

*Attorneys for Plaintiff
Cleveland Medical Devices Inc.*

OF COUNSEL:

Paul J. Andre
Lisa Kobialka
James Hannah
Timothy Layden
Sabah Khokhar
KRAMER LEVIN NAFTALIS
& FRANKEL LLP
333 Twin Dolphin Drive
Suite 700
Redwood Shores, CA 94065
(650) 752-1700

Brian A. Biggs (#5591)
Angela C. Whitesell (#5547)
Matthew S. Middleton (#6877)
DLA PIPER LLP (US)
1201 North Market Street, Suite 2100
Wilmington, DE 19801-1147
brian.biggs@dlapiper.com
angela.whitesell@dlapiper.com
matthew.middleton@us.dlapiper.com
(302) 468-5700

*Attorneys for Defendant
ResMed Inc.*

OF COUNSEL:

Sean Cunningham
Tiffany Miller
David Knudson
DLA PIPER LLP (US)
401 B Street Suite 1700
San Diego, California 92101-4297
(619) 699-4787

Benu Wells
KRAMER LEVIN NAFTALIS
& FRANKEL LLP
1177 Avenue of the Americas
New York, NY 10036
(212) 715-9100

Nancy Braman
DLA PIPER LLP (US)
33 Arch Street 26th Floor
Boston, Massachusetts 02110-1447
(617) 406-6000

Date: June 21, 2023

TABLE OF CONTENTS

I.	AGREED-UPON CONSTRUCTIONS	1
II.	DISPUTED CONSTRUCTIONS	2
A.	CleveMed’s Introduction	2
B.	ResMed’s Introductions	2
1.	Answering Introduction	2
2.	Sur-Reply Introduction	3
C.	Term 1: “a base station” (’269 Patent, Claim 15).....	3
1.	Plaintiff’s Opening Position.....	3
2.	Defendant’s Answering Position	4
3.	Plaintiff’s Reply Position.....	9
4.	Defendant’s Sur-Reply Position	11
D.	Term 2: “calculating, based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject’s sleep disorder symptoms measured during use of the PAP device” (’269 Patent, Claim 1)	
	“calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject’s symptoms measured during the subject’s use of the PAP device” (’269 Patent, Claim 5)	
	“calculating both symptom data of a severity of the subject’s sleep disorder symptoms and/or an index of a subject’s symptoms measured during use of the PAP device” (’269 Patent, Claim 15)	13
1.	Plaintiff’s Opening Position.....	13
2.	Defendant’s Answering Position	14
a.	Terms 2-3	14
i.	The Claim Language Cannot Be Reconciled With Reasonable Certainty.	15

ii.	The Specification and Prosecution History Provide No Guidance About the Scope or Meaning of Terms 2 and 3.....	16
iii.	CleveMed’s Proposals Contradict the Intrinsic Record....	19
3.	Plaintiff’s Reply Position.....	20
a.	Defendant Takes Inconsistent Positions Regarding the Scope of the Asserted Claims	21
b.	Defendant Conflates Multiple Terms While Ignoring the Claim Language	22
4.	Defendant’s Sur-Reply Position	24
a.	Terms 2-3	24
E.	Term 3: “creating an output of the level of severity of a subject’s sleep disorder or symptoms” (’269 Patent, Claim 8)	26
1.	Plaintiff’s Opening Position.....	26
2.	Defendant’s Answering Position	27
3.	Plaintiff’s Reply Position.....	27
4.	Defendant’s Sur-Reply Position	27
F.	Term 8: “the data acquisition system consisting essentially of a data acquisition device having at least one first input adapted for receiving a first signal from a pulse oximeter sensor, an electronic component adapted for filtering and processing the first signal from the pulse oximeter sensor to remove artifacts, and a first output adapted for transmitting pulse oximeter sensor data based on the first signal from the pulse oximeter sensor to the PAP device” (’269 Patent, Claim 5)	27
1.	Plaintiff’s Opening Position.....	27
2.	Defendant’s Answering Position	28
3.	Plaintiff’s Reply Position.....	29
4.	Defendant’s Sur-Reply Position	30
G.	Term 13: “a database adapted to be remote from a home of the subject for receiving the collected data from the non-volatile memory through the transceiver on the portable patient interface box” (’535 Patent, Claim 8)	

“a database that is remote from the subject, the database adapted for receiving the collected data transferring from the transceiver.” (’937 Patent, Claim 1)

“a database remote from the home of the subject, the database adapted for receiving the collected data from the non-volatile memory transferred by the transceiver on the portable patient interface box” (’937 Patent, Claim 13)

Term 15: “transferring the collected data to a location remote from the subject’s home” (’399 Patent, Claim 1)

“transferring the collected data via cellular systems, internet, satellite, wired-network and/or land lines to a location remote from the subject’s home” (’399 Patent, Claim 8)

Term 16: “transmit with the transceiver or transmitter the obtained data including: snore and/or airflow data, respiratory effort data, blood oxygenation data, and body position data or related data to a remote database for analysis by a software stored on a processor” (’637 Patent, Claim 1)

Term 18: “transmitting the data from the memory of the patient interface box to the electronic interface via cellular systems, internet, satellite, wired-network and/or land lines to the sleep analysis unit or lab or to a database accessible to medical personnel” (’698 Patent, Claim 14)

Term 20: “the database accessible to individuals from the sleep analysis unit or lab adapted to receive the collected data and/or data based on the collected data from the non-volatile memory of the portable, wearable patient interface box uploaded to the database through the transceiver or the transmitter on the patient interface box” (’603 Patent, Claim 1)

Term 21: “transferring, at least in part, the collected data and/or data based on the collected data to a sleep analysis unit or lab or to the database adapted to operate at a first location other than the remote sleep location” (’603 Patent, Claim 8)... 30

1.	Plaintiff’s Opening Position.....	32
2.	Defendant’s Answering Position	33
3.	Plaintiff’s Reply Position.....	35
4.	Defendant’s Sur-Reply Position	37

- H. Term 14: “wherein the processor is further adapted for checking the adequacy of the collected data from the sensors prior to transmitting the collected data to the database” (’535 Patent, Claim 9)

“wherein the processor is further adapted for checking the adequacy of the collected data from the sensors prior to transferring the collected data to the database” (’937 Patent, Claim 9)

Term 19: “checking the adequacy of the data from the respiratory belt sensor and the air flow sensor with a processor prior to transmitting the data” (’698 Patent, Claim 15) 37

1. Plaintiff’s Opening Position..... 38

2. Defendant’s Answering Position 40

3. Plaintiff’s Reply Position..... 40

a. Terms 7, 14, and 19..... 40

4. Defendant’s Sur-Reply Position 41

I. Term 22: “pulse oximeter”..... 41

1. Plaintiff’s Opening Position..... 41

2. Defendant’s Answering Position 42

3. Plaintiff’s Reply Position..... 44

4. Defendant’s Sur-Reply Position 45

J. Term 24: “oxygenation” 46

1. Plaintiff’s Opening Position..... 46

2. Defendant’s Answering Position 46

3. Plaintiff’s Reply Position..... 47

4. Defendant’s Sur-Reply Position 47

K. Term 4: “a processor adapted for receiving the airflow sensor data and calculating both symptom data of a severity of the subject’s sleep disorder symptoms and/or an index of a subject’s symptoms measured during use of the PAP device and data of usage of the PAP device” (’269 Patent, Claim 15)

Term 5: “a processor adapted for receiving the pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor and calculating, based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject’s sleep disorder symptoms measured during use of the PAP device” (’269 Patent, Claim 1)

Term 6: “the processor further adapted for calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject’s symptoms measured during the subject’s use of the PAP device” (’269 Patent, Claim 5)

Term 7: “wherein the PAP device further comprises an electronic component adapted to allow the PAP device to be adjusted remotely based on the symptom data of the severity of the subject’s sleep disorder and/or the index of the subject’s symptoms transmitted to the remote internet site” (’269 Patent, Claim 18)

Term 10: “a processor adapted for collecting, measuring, digitizing and storing collected data to the nonvolatile digital memory from the airflow, respiratory effort, blood oxygenation and body position of the subject during sleep at home” (’535 Patent, Claim 8)

Term 11: “a processor adapted for collecting, measuring, and digitizing data corresponding to the airflow, respiratory effort, and blood oxygenation of the subject” (’937 Patent, Claim 1)

Term 12: “a processor adapted for collecting, measuring, digitizing and storing collected data to the nonvolatile digital memory from the airflow, the respiratory effort, the blood oxygenation and body position of the subject during sleep at home” (’937 Patent, Claim 13)

Term 17: “analyzing the transmitted data with a computer or processor programmed to identify and draw attention to physiological and technological events in the data” (’698 Patent, Claim 14)..... 48

1.	Plaintiff’s Opening Position.....	52
2.	Defendant’s Answering Position	57
a.	Terms 4-6, 10-12, 17.....	57
i.	The “Processor” Terms Should Be Construed Under § 112, ¶ 6.....	57
ii.	The “Processor” Terms Are Indefinite.	61
3.	Plaintiff’s Reply Position.....	63
a.	Terms 4-7, 10-12, 17.....	63
i.	Defendant’s Inconsistent Claim Construction Positions...	64
ii.	Section 112(6) Does Not Apply to the Processor Terms..	64

- iii. The Processor Terms are Definite..... 67
- 4. Defendant’s Sur-Reply Position 68
 - a. Terms 4-6, 10-12, 17..... 68
 - i. “Processor” Is A Means-Plus-Function Term..... 68
 - ii. The “Processor” Terms Are Indefinite. 70

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Aristocrat Techs. v. Int’l Game Tech.</i> , 521 F.3d 1328 (Fed. Cir. 2008).....	61, 70
<i>Artic Cat Inc. v. GEP Prods., Inc.</i> , 919 F.3d 1320 (Fed. Cir. 2019).....	36
<i>BASF Corp. v. Johnson Matthey Inc.</i> , 875 F.3d 1360 (Fed. Cir. 2017).....	21, 57, 67
<i>Bd. Of Regents of the Univ. of Tex. Sys. V. BENQ Am. Corp.</i> , 533 F.3d 1362 (Fed. Cir. 2008).....	15
<i>Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Sols., P.C.</i> , 482 F.3d 1347 (Fed. Cir. 2007).....	40, 41
<i>CFL Techs. LLC v. Osram Sylvania, Inc.</i> , No. 1:18-cv-01445-RGA, 2022 WL 606329 (D. Del. Jan. 21, 2022)	44
<i>Dayco Prods., Inc. v. Total Containment, Inc.</i> , 258 F.3d 1317 (Fed. Cir. 2001).....	9
<i>In re Donaldson Co.</i> , 16 F.3d 1189 (Fed. Cir. 1994) (en banc).....	64
<i>Dyfan, LLC v. Target Corp.</i> , 28 F.4th 1360 (Fed. Cir. 2022)	52
<i>Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.</i> , 279 F.3d 1022 (Fed. Cir. 2002).....	56
<i>Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.</i> , No. 2:15-CV-1202-WCB, 2016 WL 6138124 (E.D. Tex. Oct. 21, 2016).....	56
<i>Finjan, Inc. v. Proofpoint, Inc.</i> , No. 13-cv-05808-HSG, 2015 WL 7770208 (N.D. Cal. Dec. 3, 2015)	54, 55
<i>Fraunhofer-Gesellschaft Zur Forderung der Angewandten Forschung E.V. v.</i> <i>Sirius XM Radio Inc.</i> , No. 17-184-JFB-SRF, 2020 WL 549801 (D. Del. Feb. 4, 2020).....	56
<i>GE Lighting Sols., LLC v. AgiLight, Inc.</i> , 750 F.3d 1304 (Fed. Cir. 2014).....	9

<i>Groove Digital, Inc. v. United Bank</i> , 825 F. App'x 852 (Fed. Cir. 2020)	7, 10
<i>Home Diagnostics, Inc. v. LifeScan, Inc.</i> , 381 F.3d 1352 (Fed. Cir. 2004).....	10, 23
<i>Honeywell Int'l, Inc. v. Int'l Trade Comm'n</i> , 341 F.3d 1332 (Fed. Cir. 2003).....	20
<i>Intel Corp. v. Alacritech, Inc.</i> , IPR2017-01391, Paper 8 (PTAB Nov. 28, 2017)	70
<i>Interactive Gift Express, Inc. v. CompuServe Inc.</i> , 256 F.3d 1323 (Fed. Cir. 2001).....	10
<i>Interval Licensing LLC v. AOL, Inc.</i> , 766 F.3d 1364 (Fed. Cir. 2014).....	15
<i>Inventio AG v. ThyssenKrupp Elevator Americas Corp</i> , 649 F.3d 1350 (Fed. Cir. 2011).....	54, 55
<i>Koninklijke Philips N.V. v. ZOLL Lifecor Corp.</i> , No. 12-1369, 2015 WL 12781198 (W.D. Pa. July 15, 2015)	41
<i>Linear Tech. Corp. v. Impala Linear Corp.</i> , 379 F.3d 1311 (Fed. Cir. 2004).....	53, 54
<i>Mayne Pharma Int'l Pty Ltd. v. Merck & Co.</i> , No. 15-438-LPS, 2016 WL 7441069 (D. Del. Dec. 27, 2016)	28
<i>Merck & Co. v. Teva Pharm. USA, Inc.</i> , 395 F.3d 1364 (Fed. Cir. 2005).....	34
<i>Mobile Hi-Tech Wheels v. CIA Wheel Group</i> , 514 F. Supp. 2d 1172 (C.D. Cal. 2007)	45
<i>Nautilus, Inc. v. Biosig Instruments, Inc.</i> , 134 S. Ct. 2120 (2014).....	15
<i>Network Commerce, Inc. v. Microsoft Corp.</i> , 3d 1353, 1361 (Fed. Cir. 2005).....	11
<i>Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.</i> , 30 F.4th 1339 (Fed. Cir. 2022)	39
<i>Parity Networks, LLC v. Edgecore USA Corp.</i> , 2020 WL 8569299 (C.D. Cal. Dec. 22, 2020)	57

<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005).....	3, 32, 41, 42
<i>PPG Indus. v. Guardian Indus. Corp.</i> , 156 F.3d 1351 (Fed. Cir. 1998).....	28
<i>Realtime Adaptive Streaming LLC v. Adobe Sys. Inc.</i> , No. 18-9344-GW(JCx), 2019 WL 13039644 (C.D. Cal. July 25, 2019).....	52
<i>Samsung Elecs. Am. v. Prisua Eng’g Corp.</i> , 948 F.3d 1342 (Fed. Cir. 2020).....	52
<i>Seal-Flex, Inc. v. Athletic Track & Court Constr.</i> , 172 F.3d 836 (Fed. Cir. 1999).....	59
<i>In re Sinex</i> , 309 F.2d 488 (CCPA, 1962)	8
<i>Smartflash LLC v. Apple Inc.</i> , 77 F. Supp. 3d 535 (E.D. Tex. Dec. 4, 2014)	52
<i>Sonix Tech. Co. v. Publ’ns Int’l, Ltd.</i> , 844 F.3d 1370 (Fed. Cir. 2017).....	38
<i>Spherix Inc. v. Matal</i> , 703 F. App’x 982 (Fed. Cir. 2017)	70
<i>St. Isidore Research LLC v. Comerica Inc.</i> , No. 2:15-1390-JRG-RSP, 2016 WL 4988246 (E.D. Tex. Sept. 19, 2016).....	57, 58, 69
<i>Starhome GmbH v. AT&T Mobility LLC</i> , 743 F.3d 849 (Fed. Cir. 2014).....	42
<i>Symantec Corp. v. Computer Assoc. Intern Inc.</i> , 522 F.3d 1279 (Fed. Cir. 2008).....	12
<i>Syncpoint Imaging, LLC v. Nintendo of Am. Inc.</i> , No. 2:15-cv-00247-JRG-RSP, 2016 WL 55118 (E.D. Tex. Jan. 5, 2016)	52, 53, 54
<i>Syneron Med. Ltd. v. Invasix, Inc.</i> , 2018 WL 4696971 (C.D. Cal. Sept. 5, 2018)	57, 68, 69
<i>Takadu Ltd. v. Innovyze LLC</i> , C.A. No. 21-291-RGA, 2023 WL 2563157 (D. Del. Mar. 17, 2023).....	57, 69
<i>UltimatePointer, L.L.C. v. Nintendo Co.</i> , 816 F.3d 816 (Fed. Cir. 2016).....	67

<i>Unique Concepts, Inc. v. Brown</i> , 939 F.2d 1558 (Fed. Cir. 1991).....	8, 10
<i>VDPP LLC v. Vizio, Inc.</i> , No. 2021-2040, 2022 WL 885771 (Fed. Cir. Mar. 25, 2022).....	52
<i>Verizon Servs. Corp. v. Vonage Holdings Corp.</i> , 503 F.3d 1295 (Fed. Cir. 2007).....	11, 36, 44
<i>Vitronics Corp. v. Conceptronic, Inc.</i> , 90 F.3d 1576 (Fed. Cir. 1996).....	5, 9, 45
<i>Williamson v. Citrix Online, LLC</i> , 792 F.3d 1339 (Fed. Cir. 2015).....	<i>passim</i>
<i>Zeroclick, LLC v. Apple Inc.</i> , 891 F.3d 1003 (Fed. Cir. 2018).....	52, 64
<i>Zircon Corp. v. Stanley Black & Decker, Inc.</i> , 452 F. App'x 966 (Fed. Cir. 2011)	7, 10

Statutes

35 U.S.C. § 112(6)	<i>passim</i>
--------------------------	---------------

Other Authorities

Del. L.R. 7.1.3(c)(2).....	70
M.P.E.P. § 2111.03(III) (Rev. 07.2022, Feb. 2023)	28

I. AGREED-UPON CONSTRUCTIONS

Asserted Patent and Claim(s)	Term for Construction	Agreed Construction
'269 Patent ¹ : Claim 4	"ARMAX system identification model"	"Auto-Regressive Moving Average exogenous system identification model"
'269 Patent: Claim 4	"Fourier transform technique"	No construction necessary. Plain and ordinary meaning.
'399 Patent: Claims 1, 8 '535 Patent: Claim 8 '937 Patent: Claims 1, 2, 13 '603 Patent: Claim 13 '698 Patent: Claim 14 '637 Patent: Claim 1 '269 Patent: Claims 1, 5, 15	"Nasal cannula"	Plain and ordinary meaning, which is "a flexible tube having two prongs that extend into a user's nostrils and leave the nostrils open for free exhalation through the nose"
'399 Patent: Claims 1, 8 '535 Patent: Claim 8 '937 Patent: Claims 1, 13 '603 Patent: Claims 1, 8 '698 Patent: Claim 14	Pressure transducer	"device that converts physical pressure into an electrical signal"

¹ U.S. Patent No. 10,076,269 is referred to herein as the "'269 Patent."

'637 Patent: Claim 1		
-------------------------	--	--

II. DISPUTED CONSTRUCTIONS

A. CleveMed's Introduction

Plaintiff CleveMed's patent claims are readily understood by a person of ordinary skill ("POSITA"), and a lay person. Thus, despite Defendant's contentions to the contrary, few terms require construction. The intrinsic evidence undermines Defendant's assertions of indefiniteness and Defendant has no support, much less the requisite clear and convincing evidence, to claim that large swaths of claim language are means-plus-function elements under 35 U.S.C. § 112(6) ("§112(6)").

B. ResMed's Introductions

1. Answering Introduction

Defendant ResMed Inc.'s claim constructions track the plain meaning and the intrinsic record of the asserted patents and stay true to the actual meaning of the claim language, where that meaning can be discerned. However, the asserted claims of the '269 patent recite unintelligible language that fails to provide the public with the statutorily required notice of the metes and bounds of CleveMed's alleged inventions. Furthermore, the '269 patent's claims that recite a "processor adapted for"—and similar "processor" claim terms in the other asserted patents—recite only functional language, but the specification fails to disclose an algorithm for the claimed functions. The claims that recite these terms are therefore indefinite. Given the dispositive problems with its patents, CleveMed's proposals unsurprisingly seek to broaden the scope of the claims beyond the plain meaning of the words that the applicants chose to use. The Court should reject CleveMed's effort to transform the asserted claims into malleable objects with far broader scope than was ever intended.

2. Sur-Reply Introduction

The claims define the scope of the alleged invention. Ignoring this, CleveMed seeks to abandon the original claims and rewrite them under the guise of claim construction, resorting to general language in the specifications to argue that every embodiment or example is within the scope of the claims. CleveMed also argues the claimed systems are well understood because they are directed to “diagnosis,” but no claim recites this. Nor do CleveMed’s infringement contentions acknowledge this phantom “diagnosis” limitation that CleveMed invents to try to save its claims from indefiniteness. Indeed, if CleveMed were successful in importing a “diagnosis” limitation into the claims, noninfringement would be the result.

C. Term 1: “a base station” (’269 Patent, Claim 15)

Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
Plain and ordinary meaning, which is “a computer which connects other computers or wireless devices to a central hub and allows connection to a network.” This claim term is definite.	No construction necessary. Patentee dedicated “computer” / “personal computer” to the public. Alternatively: Indefinite.

1. Plaintiff’s Opening Position

The plain and ordinary meaning of “base station” is a computer which connects other computers or wireless devices to a central hub and allows connection to a network. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (claim terms “‘generally given their ordinary and customary meaning.’”) (citation omitted). This plain and ordinary meaning is consistent with the intrinsic evidence.

An embodiment in the ’269 Patent’s specification is the base station **40** - a computer with a base receiver, base microcontroller, base transmitter, memory (EEPROM), and a power supply.

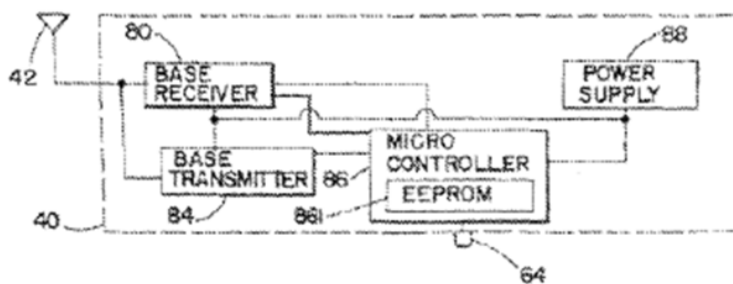


Fig. 3

'269 Patent at Fig. 3 and 12:4-8. This embodiment describes how the base station uses these components to connect other computers or wireless devices to a central hub and facilitates a connection to a network. For example, for one '269 Patent embodiment, the base station, which can be hardwired or receive wireless communications, obtains the physiological data, as it is connected with other computers or wireless devices. *Id.* at 8:36-56 ("Once processed, the physiological signals are transmitted wirelessly to the base station."), 8:48-56 (communication with base station can be hardwired or wireless), 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. A lay person or POSITA would understand from the '269 Patent that the base station can transmit data to another network device, including sending data to the PAP device so it can be remotely adjusted. *Id.* at 19:15-26, Claim 18. These disclosures describe how a base station is 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.

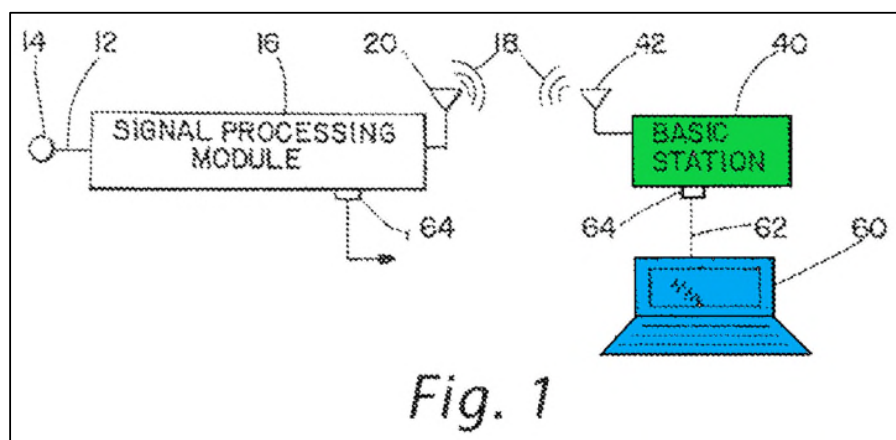
2. Defendant's Answering Position

The primary dispute for the term "a base station" is whether it can encompass a general-purpose personal computer. It cannot. Both the plain meaning of "base station" in the relevant field of art and the '269 patent specification—which "is the single best guide to the meaning of a

disputed term” (*Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996))— 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. Rather, the specification uses “base station” according to its plain meaning; namely, “a specialized transmission and reception station in a fixed location.” ResMed Ex. 1 (Sharony Decl.), ¶ 29.

Claim 15 recites three devices, “a base station, cellular phone, or PDA,” but not a “computer,” so the claim language does not include a computer within its scope. The ’269 patent specification also consistently discloses that a “base station” is different from a personal computer, which can be used to program the base station. For instance, the patent discloses “[a]n external programming means 60, shown in FIG. 1 as a personal computer, contains software which is used to program ... the base station 40 through data interface cable 62.” ’269 patent, 9:12-15 (emphasis added); *see also id.* 9:34-37. Later, the patent discloses that “base station 40” receives data, which is then “downloaded through connector 64 to the external programming means 60 or other personal computer (PC)” *Id.* 12:4-14 (emphasis added); *see also id.* 19:4-6 (“one or more sensors used in the system of the present invention can also be tethered to a computer, base station, cell phone, a PDA or some other form of processor or microprocessor.”).

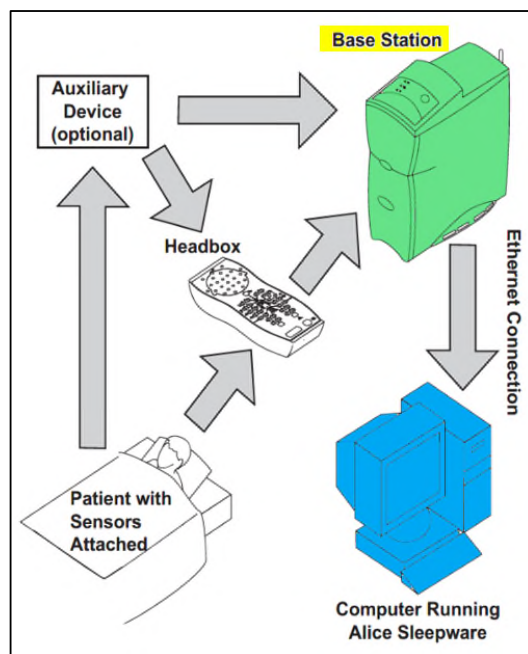
Consistent with the text, Figure 1 depicts “bas[ic] station 40” (shaded in green below) as a separate device from personal computer 60 (shaded in blue) that is used to program the base station:



See also '269 patent, 9:12-15 (personal computer 60 “contains software which is used to program ... the base station 40 through data interface cable 62.”). The specification discloses the “base station” as a specialized communication device, programmed in a specialized way, to receive and transmit the PAP device data. See '269 patent, 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 specially programmed (as in Figure 1) to serve as a base station for the claimed sleep disorder treatment system.

The extrinsic evidence confirms that the “base station” recited in the asserted claims has its plain meaning of “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.” ResMed Ex. 2, (Comprehensive Dictionary of Electrical Engineering); *see also* ResMed Ex. 1, ¶ 32. Other dictionaries in the relevant field of art are in accord with this plain meaning. ResMed Ex. 3 (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 relevant

time that included, for example, the “Alice 5 base station,” which is a “completely self-contained data collection device that is capable of gathering and storing information without the use of an outside computer”:



ResMed Ex. 4 (Alice 5 Setup and User’s Guide) at 1-8, 1-9 (emphasis and color annotations added).

Thus, the plain meaning of “base station”: (1) is a “specialized transmission and reception station” (thus giving meaning to the word “station”); (2) that is designed to be in “a fixed location” (thus giving meaning to the word “base”); and (3) is different from and therefore excludes a general-purpose personal computer—especially because CleveMed chose not to claim a “computer” in the asserted claims. *See Zircon Corp. v. Stanley Black & Decker, Inc.*, 452 F. App’x 966, 977-78 (Fed. Cir. 2011) (construing “ratio” to mean the embodiment “consistently” disclosed in specification as a ratio and excluding other embodiments); *Groove Digital, Inc. v. United Bank*, 825 F. App’x 852, 856-57 (Fed. Cir. 2020) (affirming construction limiting “applets” to require geotargeting where specification “repeatedly, consistently, and exclusively”

depicted applets as being geotargeted). In other words, 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 separate but unclaimed “personal computer” disclosed in the specification. Despite this, CleveMed’s infringement contentions do exactly that by trying to equate a general-purpose personal computer with the claimed “base station.” See ResMed Ex. 5 (AirSense 11 Chart) at 32-36.

Besides not tracking with the plain meaning of “base station,” CleveMed’s proposed construction makes no sense and finds no support in the intrinsic or extrinsic evidence. First, CleveMed’s proposed additions of “connects other computers” and “allows connection to a network” are statements of intended use, not limitations on the scope of the claim term. See, e.g., *In re Sinex*, 309 F.2d 488, 492 (CCPA, 1962) (merely a statement of intended use in an apparatus claim does not distinguish the structural apparatus). Second, CleveMed’s proposed addition of “to a central hub” is unsupported by anything in the surrounding claim language, the specification, or the extrinsic evidence—CleveMed appears to have made it up. Third, CleveMed’s proposal omits anything that describes the plain meaning of “base station,” including that it is a specialized device for transmitting and receiving data and is designed to be in a fixed location—all features of the “base station” disclosed and depicted in the ’269 patent. See ’269 patent, Figures 1, 3 (depicting base station with base receiver and base transmitter); 8:31-46, 9:4-32, 12:4-14. On the contrary, CleveMed’s proposal attempts to encompass any node in a network that can relay or forward information, but this, again fails to reflect the plain meaning of “base station.” CleveMed’s proposal therefore cannot be correct.

3. Plaintiff's Reply Position

Defendant's proposal of "base station" as (1) a "specialized transmission and reception station;" (2) that is designated to be in a "fixed location;" and (3) is different from a "computer" is a mixed bag of extrinsic evidence that is contrary to the intrinsic evidence, which describes a base station as being a computer. Answer at 7; *Dayco Prods., Inc. v. Total Containment, Inc.*, 258 F.3d 1317, 1324 (Fed. Cir. 2001) ("convoluted and artificial" constructions that are unapparent to a POSITA reading the intrinsic record are "simply unhelpful to the performance of our task."). Thus, Defendant's proposed construction excluding embodiments that include a computer is improper as a matter of law. *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1311 (Fed. Cir. 2014) ("[W]here claims can reasonably [be] interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment . . .") (citation omitted).

It is undisputed that the '269 Patent specification describes a base station as a computer, which is not limited in any manner and can be a personal computer. '269 Patent at 19:35-45 (disclosing a base station as a "computer" and a "computer or processor, which receives the data transmission and displays the data . . . [and] transfer[s] it for analysis."). It also describes embodiments of that computer, stating, for example, that a base station can include "a communications device for relaying the transmission, a communications device for re-processing the transmission, a communications device for re-processing the transmission then relaying it to another remote communication station, **a computer with wireless capabilities**, a PDA with wireless capabilities, a processor, a processor with display capabilities, and combinations of these devices." *Id.* at 19:8-24 (emphasis added). Claim 15 also recites elements of a computer for a "base station," "the base station . . . comprising a second radio frequency wireless module transceiver, a processor, a software, and a display." *Id.* at Claim 15; *Vitronics Corp. v.*

Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (when construing claims, courts “look to the words of the claims themselves.”) (citation omitted).

Defendant has no support for excluding computers from the definition of “base station.” *Interactive Gift Express, Inc. v. CompuServe Inc.*, 256 F.3d 1323, 1331-32, 1334 (Fed. Cir. 2001) (refusing to consider extrinsic evidence when the intrinsic evidence lacks ambiguity). It further has no grounds to claim there was a disavowal, which is necessary for seeking a negative limitation of excluding computers. *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004) (“Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language.”). Further, Defendant’s shift from its original construction of “computer/personal computer” to its current construction highlights how its proposal is not based on the intrinsic evidence. D.I. 62-2, JCC Ex. 2 at 1.

Defendant relies on questionable extrinsic evidence to compare base stations to the way cell towers are used in mobile networks, as opposed to base stations used in the sleep treatment and diagnostic field. Jafari Reply Decl., ¶¶ 4-8. POSITAs would look to terminology used in the relevant field, and not generally to the mobile cellular network field. ’269 Patent at 8:31-9:45; Jafari Reply Decl., ¶¶ 7-8.

Defendant also relies upon inapplicable case law, where there were express exclusions in the specification of certain embodiments, unlike here. *See Groove Digital, Inc. v. United Bank*, 825 F. App’x 852, 856-57 (Fed. Cir. 2020); *Zircon Corp. v. Stanley Black & Decker, Inc.*, 452 F. App’x 966, 977-78 (Fed. Cir. 2011). Further, unlike the situation in *Unique Concepts, Inc. v. Brown*, Claim 15 describes the “base station” as having computer components, and the specification discloses examples of the base station being a computer. 939 F.2d 1558, 1562 (Fed.

Cir. 1991) (mitered linear border pieces at issue were not claimed in the patent); '269 Patent at 19:8-24.

Unlike Defendant's exclusionary proposed construction, CleveMed's construction covers all the embodiments and examples in the specification. *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1305 (Fed. Cir. 2007) ("We normally do not interpret claim terms in a way that excludes disclosed examples in the specification.") (citation omitted). Reading Claim 15 as a whole, CleveMed's construction aligns with how the base station is recited in the claim and interacts with other elements, such as how the base station is a computer that connects with the PAP device through the "first radio frequency wireless module transceiver" to receive the symptom data and transmits the symptom data to a remote internet site. '269 Patent at Claim 15.

4. Defendant's Sur-Reply Position

The claim recites that "the base station, cellular phone, or PDA compris[e] ... a processor, a software, and a display," but CleveMed's and its expert's backwards analysis is wrong that shared components with a computer are enough to conclude a base station is a "computer." Reply, 8-9. CleveMed would read "base station" out of the claim. A PDA and a phone also share those basic components (as do ATMs, cash registers, and calculators), but like "base station," a device must have the characteristics of each of those specific devices to be one.² Answer, 4-7.

Without any support, CleveMed and its expert dismiss ResMed's plain meaning. But Dr. Jafari (and also Dr. D'Ambrosio) cites no evidence to support his opinions as a purported POSITA, so his opinion is entitled to no weight. *Network Commerce, Inc. v. Microsoft Corp.*, 3d

² CleveMed is wrong that "base station" is described as a "PDA, computer or cell phone." '269 patent, 19:35-45; Reply, 8-9.

1353, 1361 (Fed. Cir. 2005) (expert testimony unsupported by industry publications or other independent sources is not useful); *Symantec Corp. v. Computer Assoc. Intern Inc.*, 522 F.3d 1279, 1290-91 (Fed. Cir. 2008) (giving no weight to expert testimony that merely recited how the expert would construe the disputed term “based on his own reading of the specification”). The only contemporaneous dictionary definitions of “base station” in the record support ResMed’s plain meaning and are from the communications field. CleveMed fails to justify why these are not instructive where (a) the claimed component contains an RF transceiver, and (b) the patent describes “communications” as the central feature of the “base station.” ’269 patent, 9:3-12, 9:26-45, 19:10-23. CleveMed’s expert’s conclusory dismissal of the Respironics manual (not even mentioned in CleveMed’s reply) is also wrong—the manual shows the same configuration illustrated in the ’269 patent, namely, receiving sensor information and downloading it to a separate personal computer. ’269 patent, 12:4-14; ResMed Ex. 4, 1-7. CleveMed’s proposal to use the “sleep treatment and diagnostic field” as the only relevant context belies its infringement contentions, which point to a generic laptop for this limitation. Reply, 9; ResMed Ex. 5, 32-36.

CleveMed’s rebuttal plucks a single example from the specification’s run-on description of “base station” and “remote communication station” (a different component). Reply, 1 (quoting ’269 patent, 19:15-24). But the language CleveMed quotes confirms ResMed’s position that the essential characteristics of a “base station” are its specialized communication capabilities. ’269 patent, 19:15-24 (“communications device”); Answer, 4-7. In fact, CleveMed agrees the essential characteristics of the “base station” are its specialized communications capabilities (“connects other computers ... to a central hub and allows connection to a network”), but CleveMed’s vague construction fails to capture these capabilities and departs from the plain meaning of “base station” without any basis for doing so. ResMed’s plain meaning reflects what

the applicants disclosed in the patent and is depicted in CleveMed's opening brief (Opening, 3-4), so it is the correct construction.

D. Term 2: “calculating, based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject's sleep disorder symptoms measured during use of the PAP device” ('269 Patent, Claim 1)

“calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject's symptoms measured during the subject's use of the PAP device” ('269 Patent, Claim 5)

“calculating both symptom data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device” ('269 Patent, Claim 15)

Plaintiff's Proposed Construction	Defendant's Proposed Construction
These claim terms are definite.	Indefinite.

1. Plaintiff's Opening Position

Based on the intrinsic record, a POSITA would understand the “calculating” elements of the '269 Patent are 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. *See, e.g.*, '269 Patent at 19:46-57 (collection of sensor data), 20:1-8 (preparation of data for analysis), 20:9-31 (identifying exemplary “sleeping disorder data or signal analysis techniques”), 22:1-8 (describing output), Claims 1, 5, 15. 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 20:32-40), Auto-Regressive Moving Average (“ARMA”) model (*id.* at 20:41-21:15), Short-Time Fourier Transform model (*id.* at 21:16-40), and time-frequency signal analysis (*id.* at 21:41-67), among other “other on-line signal processing algorithms known” to a POSITA (*id.* at 20:26-31). The specification also

shows a POSITA how to assemble such a system. *See, e.g., id.* at Fig. 8 (described in part at 23:18-39).

Based on the detailed descriptions of the inputs, processing techniques, and outputs for these “calculating” elements, a POSITA would understand the scope of Claims 1, 5, and 15, including the meaning of “symptom data of a level of severity” and indices of symptom severity. Declaration of Dr. Roozbeh Jafari (“Jafari Decl.”), ¶¶23-26. For example, a POSITA would understand that the processor could be programmed to calculate a patient’s Apnea Hypopnea Index (“AHI”), which is an example of a medical measurement of the severity of a patient’s sleep disorder and is used to diagnose the severity of sleep apnea. *Id.*, ¶25. A POSITA would understand that 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 60-minutes, and match that result to an AHI severity level (e.g., mild, moderate, etc.). *Id.*; *see also* ’269 Patent, Claims 1, 5, 15. Moreover, a POSITA would understand from the intrinsic record the types of infringing symptom data, such as identified apneic events in the foregoing example. Jafari Decl., ¶25.

Notably, Defendant admitted that two techniques for “calculating” are definite. It agreed with CleveMed’s construction of “ARMAX system identification model” in Claim 4 and using the plain and ordinary meaning for “Fourier transform technique.” D.I. 62-1 at 1; D.I. 62-2 at 21. Indeed, as with all the other terms Defendant contends are indefinite, Defendant had no issue understanding the claims for its IPR petition and invalidity contentions. *See generally*, Declaration of Lisa Kobialka, Ex. 1 (IPR2023-00565, Paper 1).

2. Defendant’s Answering Position

a. Terms 2-3

Terms 2 and 3 are indefinite because, when read in light of the ’269 specification and the prosecution history, they “fail to inform, with reasonable certainty, those skilled in the art about

the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). “A patent does not satisfy the definiteness requirement of § 112 merely because ‘a court can ascribe *some* meaning to a patent’s claims.’” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014) (quoting *Nautilus*, 134 S. Ct. at 2130) (emphasis in original). Rather, the claims “must provide objective boundaries for those of skill in the art.” *Id.* The ’269 patent claims fail this definiteness requirement because the disputed claim language fails to inform those skilled in the art about the scope of the claimed invention.

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

The phrases “sleep disorder symptom data,” “sleep disorder symptom data of a level of severity,” “symptom data of a severity of the subject’s sleep disorder symptoms,” and “symptom data” are not terms of art and do not appear in the ’269 specification. ResMed Ex. 1, (Sharony Decl.) ¶ 35. The claims do not provide reasonable certainty as to what the calculated “symptom data” is supposed to be or what “severity” is being “calculated.” For example, a person of skill in the art would have no reasonable certainty whether the different language in claim 15 has the same meaning as the language in claims 1 and 5, including whether “symptom data of a severity” is different from “symptom data of a level of severity.” *Id.*, ¶ 36. Adding more confusion, claim 8 recites “creating an output of the level of severity of a subject’s sleep disorder or symptoms.” And claims 1 and 5 also recite “an index of a level of severity of the subject’s sleep disorder symptoms,” whereas claim 15 recites “an index of a subject’s symptoms.” All of these terms use different words and therefore are presumed to have different meanings. *Bd. Of Regents of the Univ. of Tex. Sys. V. BENQ Am. Corp.*, 533 F.3d 1362, 1371 (Fed. Cir. 2008) (“Different claim terms are presumed to have different meanings.”). A “level of severity,” for example, implies a categorization based on thresholds, such as high, medium, or low. But the claim language fails to

provide reasonable certainty to a skilled artisan as to what calculated “symptom data of a severity” or “of a level of severity” might be, and whether and how an index of a level severity is the same or different from an index of symptoms. The claims thus fail to provide reasonable certainty as to the scope of the different terms recited in the claims. ResMed Ex. 1, ¶¶ 36-38.

Furthermore, the disputed phrases in claims 1, 5 and 15 recite “... measured during use of the PAP device.” But nothing in the claim provides reasonable certainty as to how this phrase modifies the preceding language. For example, it is unclear whether it is the “symptoms,” “index,” “level,” or “symptom data” that is measured, and if one of those parameters is “measured” then what is the parameter that is “calculat[ed].” ResMed Ex. 1, ¶ 39. The claim language leaves these questions unanswered, so the claims are indefinite.

ii. The Specification and Prosecution History Provide No Guidance About the Scope or Meaning of Terms 2 and 3.

The '269 patent is silent about the disputed terms in claims 1, 5, and 15. For instance, the specification does not disclose an “index” calculated as the claims require. The only mention of an index is a “respiratory disturbance index” obtained using the prior art method of polysymnography ('269 patent, 1:51-54), which is not tied to the “calculating” or “creating” limitations of the asserted claims. The specification also does not refer to “symptom data” or describe what it might be. Instead, the specification suggests that symptoms may “increase or decrease,” have a “level” or “severity level,” and be “critical,” “predicted,” “impending,” “diagnosed,” and “treated.” '269 patent, 2:31-51, 20:1-21, 20:64-21:7, 22:30-34 (“severity or level of the subject’s symptoms increase or decrease”). These references do not provide any guidance about what “symptom data” is or how it is “calculate[ed].” ResMed Ex. 1, ¶¶ 40-41.

The specification describes analyzing signals from sensors “to determine the level of severity of the symptoms” (*id.*, 3:29-30, 23:27-29), creating “an output of a level of severity” (*id.*, 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.*, 4:39-40, 18:51-54, 18:60-64, 19:46-49). But the disputed terms in claims 1, 5, and 15 do not recite calculating a “level of severity,” and instead recite calculating “symptom data.” Notably, the claims of the parent application to which the ’269 patent claims priority recite the language used in the specification; namely, “a quantitative output of the level of severity of a subject's sleeping disorder or symptoms.” ResMed Ex. 6 (U.S. Patent No. 8,172,766), 23:16-19 (emphasis added). But CleveMed chose to use different claim language in the ’269 patent that has no corresponding disclosure in the specification for the claimed “symptom data” and “index.” ResMed Ex. 1, ¶ 42. A person of skill in the art reading the claims, therefore, would have no way of reconciling the claim language with the specification. *Id.*

The prosecution history is no help either. During prosecution of the ’269 patent’s parent application, CleveMed argued that “an apnea hypopnea index, or AHI, ... is an indicator of the level of severity of a patient’s sleep disordered breathing.” D.I. 62-5, Ex. B-31 (10/28/2011 Amendment, 6-7).³ CleveMed’s admission during prosecution may be an example of an index of a level of severity of a patient’s sleep disorder, but it says nothing about what “symptom data of a level of severity” or “index of a subject’s symptoms” might be.

³ CleveMed’s argument that ResMed’s IPR against the ’269 patent demonstrates that the claims are not indefinite fails to recognize that the PTAB cannot consider indefiniteness challenges in an IPR. ResMed’s IPR relied on the file history as evidence of an exemplary calculation within the scope of the claims but did not concede that the claims are definite. Opening, 13-14 (see Kobialka Ex. 1 at 38).

CleveMed argues that the specification's disclosure of using signal processing techniques (such as standard deviation or an ARMA model ('269 patent, 20:22-26)) on sensor data to predict or identify the onset of "symptoms" somehow supports the "calculating" and "creating" limitations of the asserted claims. Opening, 12-13. For at least four reasons, CleveMed is wrong.

First, the patent's discussion of signal processing techniques is not linked to calculating either the claimed "symptom data" or the claimed "index."

Second, the patent discloses that "[v]arious algorithms known to those skilled in the art are used to filter out noise from the [sensor] signal or data, and to then quantify the level of severity of the subject's sleeping disorder or symptoms," and that it is this "filtered data" that "is preferably analyzed using the techniques described in the following paragraph." '269 patent, 20:1-6. Thus, even if the "level of severity" could be an example of the claimed "symptom data" or "index," the signal processing techniques at columns 20-21 are not examples of calculating the level of severity (or symptom data)—rather, these techniques use the filtered sensor data, which is the same filtered data used to "quantify the level of severity of the subject's sleeping disorder or symptoms," to "predict the onset of ... symptoms." *Id.*, 20:18-21, 20:66-67 ("model shift foretells the onset of the symptom"), 21:5-8. The specification distinguishes this "prediction" analysis from the "analysis of a subject's sleeping disorder or symptoms." '269 patent, 2:31-48.

Third, dependent claim 4 recites that the signal processing techniques disclosed in the specification (such as standard deviation, recursively fit ARMAX, etc.) are used by the signal processing module that outputs pulse oximetry sensor data to the processor (through the PAP's second input), not that the claimed processor uses those methods to calculate "sleep disorder symptom data ... and/or an index of a level of severity." '269 patent, 24:24-30.

Fourth, even if the signal processing techniques could be referring to the claimed calculation of “symptom data” or “index” as CleveMed suggests (Opening, 12-13), the specification fails to identify a single example of what might be the calculated data or output, and never suggests if this output is “symptom data” or an “index.” Instead, the specification generically discloses “provid[ing] an output.” ’269 patent, at 22:1-8 (*see* Opening, 12-13). The specification therefore fails to provide any objective boundaries around what is the calculated “symptom data of a level of severity,” “symptom data of a severity of the subject’s sleep disorder symptoms,” or the claimed “index.”

iii. CleveMed’s Proposals Contradict the Intrinsic Record.

CleveMed’s proposal that the calculated “symptom data” can include “calculat[ing] when a subject has an apnea or hypopnea event” is wrong. CleveMed incorrectly suggests that a person of skill in the art would “understand the types of infringing symptom data,” identifying only a single example: “apneic events.” Opening, 13 (citing Jafari Decl., ¶ 25). Notably, neither CleveMed nor its expert point to anything in the intrinsic record, or any extrinsic evidence, linking these events to “symptom data.” Nor does the specification ever link such events to “symptom data.” Moreover, CleveMed’s proposal is contrary to the prosecution history and would violate the written description requirement. *Id.* During prosecution, original claims 1 and 5 recited that the “processor” is “adapted ... for identifying central apneas and hypopneas from the [sensor] data.” D.I. 62-4, Ex. B-6 (4/3/2017 Amendment), 2 (claim 21), 4 (claim 28). The examiner rejected the claims because the specification failed to provide written description support for the “apneas” limitation. D.I. 62-4, Ex. B-5 (7/12/2017 Rejection, 2-4). CleveMed amended the claim language to its present form, thereby informing a person of ordinary skill that

the disputed term does not and cannot encompass calculating/identifying an apnea event. D.I. 62-4, Ex. B-4 (10/12/2017 Amendment), 2, 4; *see also* ResMed Ex. 1 (Sharony Decl.), ¶ 46.

In summary, the disputed phrases, even when read in light of the '269 specification and the prosecution history, fail to “adequately perform their function of notifying the public of the patentee’s right to exclude,” and therefore are indefinite. *Honeywell Int’l, Inc. v. Int’l Trade Comm’n*, 341 F.3d 1332, 1339 (Fed. Cir. 2003).

3. Plaintiff’s Reply Position

The “calculating” elements of the '269 Patent are definite because a POSITA would understand the scope of Claims 1, 5, and 15 based upon the inputs, processing techniques, and outputs disclosed. Jafari Reply Decl., ¶¶ 9-10. For example, the processor can be programed to process the data received from the airflow sensor using a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time frequency signal analysis, or a wavelet analysis to calculate various symptom data, such as apneic events. Opening at 13-14.

Additionally, the terms “symptom data,” “symptom data of a level of severity,” “symptom data of a severity of the subject’s sleep disorder symptoms,” “index of a level of severity,” and “index of a subject’s symptoms” are commonly used terms of art in the sleep medicine field. D’Ambrosio Decl., ¶¶ 22-24; Jafari Reply Decl., ¶¶ 10-11. When read in the context of the claim as a whole, they inform clinical and technical persons of ordinary skill in the art of the boundaries of the inventions’ calculations and the inputs and algorithms used in generating these calculations. *Id.* For example, the claims and disclosures in the specification inform a POSITA of the types of symptom data that are calculable, *i.e.*, airflow and apneic events, and indexes, such as AHI. Jafari Reply Decl., ¶¶ 10-16 ; D’Ambrosio Decl., ¶¶ 25-26. 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 patient's sleeping disorder. Jafari Reply Decl., ¶¶ 10-16; D'Ambrosio Decl., ¶¶ 25-27.

a. Defendant Takes Inconsistent Positions Regarding the Scope of the Asserted Claims

Defendant has no clear and convincing evidence of indefiniteness. *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017) (citation omitted). For example, as Defendant admits in footnote 1, the file history has “an exemplary calculation within the scope of the claims.” Consequently, a POSITA is informed of at least one calculation as an indicator of a level of severity, such that the claim is definite.

Before the Patent Trial and Appeal Board (“PTAB”) in its IPR petition, Defendant's expert, Dr. Sharony, stated no construction was necessary for any claim element in the '269 Patent and he understood the scope of the '269 Patent for alleging invalidity based on prior art. *Compare* Kobialka Opening Decl., Ex. 1, IPR2023-00565, Paper 1 at 24 (P.T.A.B. March 22, 2023) *with* ResMed Ex. 1 (Sharony Decl.), ¶ 35. Despite admitting that the same standard for claim construction should be used here and in the IPR, Defendant nonetheless improperly applies different constructions. Kobialka Opening Decl., Ex. 1, IPR2023-00565, Paper 1 at 24 (P.T.A.B. March 22, 2023).

While it is questionable whether Dr. Sharony is a POSITA under Defendant's definition (ResMed Ex. 1, ¶ 27), what is not questionable is the fact that he has no experience in the sleep medicine field, such that his opinion should be given little, if any, weight. ResMed Ex. 1, ¶¶ 7-15. In contrast, CleveMed's experts have significant experience in the sleep medicine field, and explain that “symptom data,” “sleep disorder symptom data of a level of severity,” “symptom

data of a severity of the subject's sleep disorder symptoms," and "symptom data" are terms of art. Jafari Reply Decl., ¶¶ 10-12, 15; D'Ambrosio Decl., ¶¶ 3-10, 22-23.

b. Defendant Conflates Multiple Terms While Ignoring the Claim Language

Defendant's indefiniteness argument boils down to disputing the terms "symptom data" and "level of severity" by conflating the terms "measuring", "calculating" and "index" while ignoring the fact that the purpose of an "integrated sleep diagnosis and treatment device, and more particularly to an integrated apnea diagnosis and treatment device" is for diagnosing and treating sleep disorders and their symptoms. '269 Patent at 1:19-22, 2:55-3:8. These terms, as used in the claims, describe how this diagnosis and treatment is done. Claims 1, 5, and 15 recite that "a level of severity and/or an index of a level of severity of the subject's sleep disorder symptoms" is calculated based on certain data, such as the airflow data and/or pulse oximetry data, which is "measured during use of the PAP device." '269 at Claims 1, 5, 15; Jafari Reply Decl., ¶ 10. A POSITA, therefore, would understand the meaning of these terms, as they are used in the sleep medicine field, including how to calculate a level of severity or index of the level of severity based on the recited data. Jafari Reply Decl., ¶¶ 11-15; D'Ambrosio Decl., ¶¶ 22-27. Thus, a POSITA understands the bounds of the '269 Patent claims.

Defendant makes the nonsensical argument that apnea events were somehow written out of the '269 Patent. In addition to the '269 Patent's description of diagnosing and treating sleep apnea, as noted above, Defendant admits that the intrinsic record discloses "apnea hypopnea index (AHI)" as "an indicator of the level of severity." Thus, Defendant recognizes that the prosecution history supports the calculation of at least apneic events to determine the level of

severity of a subject's sleep disorder symptoms.⁴ This disclosure also shows that apneic events are symptom data, as a POSITA would know that to calculate AHI as an indicated level of severity, there must be apneic events upon which to base such a calculation. Thus, there is no "clear and unmistakable" disavowal of apnea events. *Home Diagnostics*, 381 F.3d at 1358.

There are substantial disclosures that inform a POSITA how to calculate symptom data. For example, the specification states that a "quantitative method for estimating or determining the severity of the subject's sleeping disorder or symptoms is preferably accomplished by using signals or data from the one or more sensors described herein." '269 Patent at 19:46-49. It further states that "[v]arious algorithms known to those skilled in the art . . . quantify the level of severity of the subject's sleeping disorder or symptoms," which informs a POSITA of the bounds of the calculations. *Id.* at 20:1-4. One algorithmic example in the specification is a standard deviation technique related to monitoring the increase in the pressure data. *Id.* at 20:32-40. Another is an Auto-Regressive Moving Average (ARMA) model that identifies order shifts in pressure sensor signal data to adapt treatment based upon the patient's symptoms. *Id.* at 20:41-21:15.

Finally, Defendant conflates "calculating" and "filtering" to broadly mean the same thing, ignoring that they are separate terms found in different limitations of only some claims. See Answer at 17-19; see also '269 Patent at Claims 1, 5 (claiming "filtering" and "calculating"), Claim 15 (no "filtering" limitation). The specification discloses that filtering is accomplished by a "digital filter" that passes the signal inputs through it to focus on good data of interest while excluding what is "commonly referred to as noise." '269 Patent at 16:22-24. This filtering is

⁴ AHI includes the sum of all the apneas (cease breathing) and hypopneas (shallow breathing), divided by total sleep time. D'Ambrosio Decl., ¶¶ 26-27.

done prior to the calculation of the symptom data severity level and allows the calculation's inputs to be as accurate as possible. Jafari Reply Decl., ¶ 13; '269 Patent at Claims 1, 5. Thus, "filtering" and "calculating" are distinct terms each with their own meaning and do not appear in all the claims.

4. Defendant's Sur-Reply Position

a. Terms 2-3

CleveMed cannot overcome its indefiniteness problem by rewriting these different claim terms to all mean the same thing. CleveMed focuses on simply "level of severity" (the only relevant phrase in the specification) and "index of a level severity," cleaving off "symptom data" and the rest of the disputed terms. *See* Reply, 19-20 (misquoting claims 1, 5, and 15). But the disputed terms of claims 1, 5, and 15 recite "symptom data of a [severity]/[level of severity]," and claim 15 recites "index of a subject's symptoms" (emphasis added). Even if "symptom data" and "level of severity" could individually be ascribed some meaning, that does not provide reasonable certainty about all of the claim language. CleveMed also fails to reconcile other issues created by the claims' plain language, including failing to explain why the "measured" part of the term refers back to the airflow data. Reply, 19-20.

CleveMed, not ResMed, conflates "measuring," "calculating," and "index" (*id.*, 5)—claims 1, 5, and 15 string these words together in a manner that cannot be understood with reasonable certainty. CleveMed's solution is to improperly read them out of the claim. CleveMed and its medical expert suggest for the first time, without any supporting evidence, that the calculated "symptom data" includes "airflow," "pulse and SpO2." Reply, 19-20; D'Ambrosio Decl., ¶25. But the claim language and CleveMed's own arguments against conflating "calculating" with "measuring" confirm this is incorrect. Reply, 19-20; Jafari Reply Decl., ¶12. Claims 1, 5, and 15 recite that the "airflow sensor ... measur[es] the respiratory airflow data"

(’269 patent, 23:65-66, 24:48-49, 26:7-9 (emphasis added)), so it cannot be true that the processor also calculates airflow. Further, the “pulse oximeter” measures pulse, oxygenation and ventilation—the processor does not “calculate[e]” these. ’269 patent, 7:40-41, 8:15.

CleveMed’s wordplay continues with (1) identifying apnea-hypopnea-index (AHI) as both a “level of severity” and the various “index[es]” of the claims (Reply, 19-20), and (2) describing AHI as both “a medical measurement” and calculation (Opening, 13). CleveMed’s shell game does not supply the reasonable certainty required by the law.

CleveMed’s experts also do not opine that the full claim terms are terms of art or explain what they are. D’Ambrosio suggests that “symptom data” alone is a term of art but fails to identify a single supporting document. D’Ambrosio Decl., ¶¶24-25. She also opines that “level of severity” and “index” are separately each terms of art, but confusingly uses apnea hypopnea index (AHI) as an example for both, never addressing an “index of a subject’s symptoms.” *Id.*, ¶¶26-27.

CleveMed’s suggestion that the signal processing techniques of the specification (’269 patent 20:22-21:67) could be used to calculate apneic events or “symptom data” is hindsight. Reply, 22-23. These techniques are not linked to the “symptom data” terms or past events such as apneas, but instead predict the onset of “symptoms.” Answer, 17-18.

Furthermore, ResMed’s IPR positions are not inconsistent with those here because ResMed “did not concede the claims are definite.” Reply, 20. The IPR identified apneahypopnea- index as one example within the scope of the claim based on CleveMed’s prosecution statements, but this example only speaks to the “index” part of the claims and does not inform a POSITA what the “symptom data of a level of severity” part of the claim means.

- E. Term 3:** “creating an output of the level of severity of a subject’s sleep disorder or symptoms” (’269 Patent, Claim 8)

Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
This claim term is definite.	Indefinite.

1. Plaintiff’s Opening Position

Like Term 2, based on the intrinsic record, a POSITA would understand the “creating” element is satisfied when a data acquisition system is designed to output information indicative of whether and to what extent a patient is suffering from sleep disorder symptoms. Claim 8 describes the specific inputs (*e.g.*, “signals from . . . one physiological sensor” on the patient), and the specification details processing and analysis methods known to a POSITA, as explained above. *See supra*, Part B (showing how specification explains “calculating” outputs, similar to what is “creat[ed]” in Claim 8). For example, the specification identifies the input types that would create useful output indicative of symptom severity, *i.e.*, “electro-physiological signals such as EEG, EKG, EMG, EOG . . . a subject’s blood gases such as CO₂ and O₂, and a subject’s respiratory patterns” *See, e.g.*, ’269 Patent, 5:31-41. A POSITA would also understand the bounds of the “level of severity,” which indicates, *e.g.*, the degree of deviation from the baseline characteristics of a patient without sleep disorder symptoms. Jafari Decl., ¶26.

For example, during an apneic event when a patient’s blood oxygen level drops below the normal range for a patient without a sleep disorder, the claimed system quantifies the degree of deviation and creates output information indicating the severity of the loss of blood oxygen and the severity of the patient’s apnea. *Id.* The specification explains that output information enables proper adjustment of the patient’s treatment. *See, e.g.*, ’269 Patent at 22:9-12, 22:29-40. A POSITA would understand how to design the data acquisition system to identify when the output information satisfies certain criteria, such as blood oxygenation loss over a predetermined

threshold, and trigger an increase in, *e.g.*, the amount of oxygen in the airflow that the PAP device delivers to the patient. *See, e.g., id.* At Fig. 8 (described at 23:18-39: microprocessor analyzes data from sensors to determine the severity of symptoms, then signals PAP device to change, *e.g.*, the flow of oxygen based on that analysis); Jafari Decl., ¶26. Thus, this claim term is definite, including “output of the level of severity.”

2. Defendant’s Answering Position

See Section II.D.2 (discussing ResMed’s Answering Position for terms 2-3).

3. Plaintiff’s Reply Position

Defendant mentions the “creating” element in Claim 8 in passing, as its arguments focus on the “level of severity” limitation. For the same reasons discussed above, the “level of severity” is definite. Jafari Reply Decl., ¶¶ 18-19.

4. Defendant’s Sur-Reply Position

See Section II.D.4 (discussing ResMed’s Reply Position for terms 2-3).

- F. Term 8:** “the data acquisition system consisting essentially of a data acquisition device having at least one first input adapted for receiving a first signal from a pulse oximeter sensor, an electronic component adapted for filtering and processing the first signal from the pulse oximeter sensor to remove artifacts, and a first output adapted for transmitting pulse oximeter sensor data based on the first signal from the pulse oximeter sensor to the PAP device” (’269 Patent, Claim 5)

Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
This claim term is definite.	Indefinite.

1. Plaintiff’s Opening Position

The claimed data acquisition system that “consist[s] essentially of” at least three recited elements—“at least one first input adapted for receiving a first signal. . . ,” “an electronic component . . . ,” and “a first output. . .”—is definite. ’269 Patent, Claim 5. “[C]onsisting

essentially of” is a transitional phrase “limit[ing] the scope of a claim to the specified materials or steps ‘and those that do not materially affect the basic and novel characteristic(s)’ of the claimed invention.” M.P.E.P. § 2111.03(III) (Rev. 07.2022, Feb. 2023) (emphasis and citation omitted). Claim 5’s characteristics include leveraging a distributed system architecture for sleep disorder diagnosis and treatment, receiving data from at least one physiological sensor and using it to calculate the severity of sleep disorder symptoms, and removing artifacts that impede diagnosis from that data. *See, e.g.*, ’269 Patent at Claim 5, 1:19-23, 1:40-2:51, 2:60-3:8, 3:29-32, 3:42-47, Figs. 1, 2 (described at 8:57-9:45, 10:22-40, 11:21-30), 22:29-40; *see also* D.I. 62-4, Ex. B-9 (5/27/2016 Office Action Response) at 11-12 (distinguishing Claim 34 (which became Claim 5) from the art). The ’269 Patent describes how components may be omitted “without changing the basic spirit of the invention,” including by changing the number or type of inputs as contemplated in Claim 5. ’269 Patent at Fig. 4, 12:61-13:6, 18:51-59. A POSITA thus understands that this element covers the recited data acquisition system and additional elements, such as additional inputs, that do not materially affect the claim’s novel characteristics. *See, e.g., Mayne Pharma Int’l Pty Ltd. v. Merck & Co.*, No. 15-438-LPS, 2016 WL 7441069, at *3 (D. Del. Dec. 27, 2016) (“consisting essentially of” claim is definite when specification outlined problems with past practices and beneficial characteristics of invention and exemplary embodiments).

2. Defendant’s Answering Position

CleveMed concedes that the disputed “data acquisition system” term uses the transitional phrase “consisting essentially of” in a way that “limits the scope of a claim to the specified materials or steps” and those “that do not materially affect the basic and novel properties of the invention.” Opening, 27; *see also* MPEP § 2111.03 (Rev. 07.2022); *PPG Indus. v. Guardian*

Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998). However, claim 5 also recites that the data acquisition system includes “at least one first input adapted for receiving a first signal from a pulse oximeter sensor,” but the specification fails to provide any guidance as to what, if any, additional inputs may or may not “materially affect the basic and novel properties” of the claimed system. The two sections of the ’269 patent specification identified by CleveMed fall well short of the required guidance. Opening, 27. The first, at columns 12-13, merely suggests that components may be combined, reordered, or omitted, but fails to reference the claimed “input” or provide any guidance as to when addition of a component does or does not materially affect the allegedly novel properties of the claimed system. ’269 patent, 12:61-13:6. CleveMed also points to a disclosure at column 18:51-59, but neither CleveMed nor the specification articulate whether the described inputs (EEG, ECG, blood gas monitors) would materially affect the system’s allegedly novel properties or not. CleveMed’s reliance on prosecution statements in reference to examined claim 34 are also misplaced because that claim did not recite the disputed term and did not issue as claim 5. Opening, 27; D.I. 62-4, Ex. B-9 (5/27/2016 Amendment), 4, 11-12.

3. Plaintiff’s Reply Position

Defendant’s argument regarding Term 8 is a red herring, as it focuses on the element of the claim relating to “at least one first input.” The claimed system’s novel properties, however, are “leveraging a distributed system architecture . . . , receiving data from at least one physiological sensor . . . to calculate the severity of sleep disorder symptoms, and removing artifacts that impede diagnosis from that data.” Opening at 27-28. Defendant does not present any rebuttal argument involving the distributed system architecture or the removal of artifacts from the pulse oximeter data that would previously impede or delay diagnoses. Thus, Term 8 is

definite because when the entire element is considered a POSITA is able to ascertain its boundaries with reasonable certainty.

4. Defendant's Sur-Reply Position

CleveMed's reply nonsensically quotes its own attorney argument from its opening brief that finds no support in the claims. The claim never recites a "distributed system" or "diagnosis." Reply, 28-29. Nor does CleveMed explain the relevance of artifact removal to the scope imposed by the "consisting of" language. Thus, "reading the entire element" does not, as CleveMed concludes, provide reasonable certainty as to what inputs in addition to the "at least one" are excluded by the claim language.

G. Term 13: "a database adapted to be remote from a home of the subject for receiving the collected data from the non-volatile memory through the transceiver on the portable patient interface box" ('535 Patent, Claim 8)⁵

"a database that is remote from the subject, the database adapted for receiving the collected data transferring from the transceiver." ('937 Patent, Claim 1)

"a database remote from the home of the subject, the database adapted for receiving the collected data from the non-volatile memory transferred by the transceiver on the portable patient interface box" ('937 Patent, Claim 13)

Term 15: "transferring the collected data to a location remote from the subject's home" ('399 Patent, Claim 1)

"transferring the collected data via cellular systems, internet, satellite, wired-network and/or land lines to a location remote from the subject's home" ('399 Patent, Claim 8)

Term 16: "transmit with the transceiver or transmitter the obtained data including: snore and/or airflow data, respiratory effort data, blood oxygenation data, and body position data or related data to a remote database for analysis by

⁵ U.S. Patent Nos. 10,925,535 (the "'535 Patent"), 11,064,937 (the "'937 Patent"), 10,426,399 (the "'399 Patent"), and 11,234,637 (the "'637 Patent") are all related. U.S. Patent Nos. 10,028,698 (the "'698 Patent") and 11,202,603 (the "'603 Patent") are related to each other. The foregoing six patents are collectively referred to herein as the "Home Sleep Test" or "HST" Patents.

a software stored on a processor” (’637 Patent, Claim 1)

Term 18: “transmitting the data from the memory of the patient interface box to the electronic interface via cellular systems, internet, satellite, wired-network and/or land lines to the sleep analysis unit or lab or to a database accessible to medical personnel” (’698 Patent, Claim 14)

Term 20: “the database accessible to individuals from the sleep analysis unit or lab adapted to receive the collected data and/or data based on the collected data from the non-volatile memory of the portable, wearable patient interface box uploaded to the database through the transceiver or the transmitter on the patient interface box” (’603 Patent, Claim 1)

Term 21: “transferring, at least in part, the collected data and/or data based on the collected data to a sleep analysis unit or lab or to the database adapted to operate at a first location other than the remote sleep location” (’603 Patent, Claim 8)

Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
Plain and ordinary meaning. No construction necessary.	“a database adapted to be remote from a home of the subject for receiving the collected data from the non-volatile memory through the transceiver on the portable patient interface box located at the subject’s home” (’535 Patent, Claim 8; ’937 Patent, Claim 1; and ’937 Patent, Claim 13) “transferring the collected data from the patient interface box located at the subject’s home to a location remote from the subject’s home” (’399 Patent, Claim 1) “transferring the collected data via cellular systems, internet, satellite, wired-network and/or land lines from the patient interface box located at the subject’s home to a location remote from the subject’s home” (’399 Patent, Claim 8) “transmit, with the transceiver or transmitter, on the portable patient interface box located at the subject’s home, the obtained data including: snore and/or airflow data, respiratory effort data, blood oxygenation data, and body position data or related data to a database located remotely to the patient interface box” (’637 Patent, Claim 1) “transmitting the data from the memory of the patient interface box located at the subject’s home to the electronic interface via cellular

	systems, internet, satellite, wired-network and/or land lines to the sleep analysis unit or lab remote from the patient interface box, or to a database remote from the patient interface box and accessible to medical personnel” (’698 Patent, Claim 14) “the database accessible to individuals from the sleep analysis unit or lab adapted to receive the collected data and/or data based on the collected data from the nonvolatile memory of the portable, wearable patient interface box uploaded to the database through the transceiver or the transmitter on the patient interface box located in the patient’s home” (’603 Patent, Claim 1) “transferring, from the patient interface box located in the remote sleep location, at least in part, the collected data and/or data based on the collected data to a sleep analysis unit or lab or to the database adapted to operate at a first location other than the remote sleep location” (’603 Patent, Claim 8)
--	--

1. Plaintiff’s Opening Position⁶

The plain language of these terms in the claims from the HST Patents have a well-understood plain and ordinary meaning. *Phillips*, 415 F.3d at 1312-13. At issue is whether the transmission of data must occur from a patient’s home. For the ’603 Patent, the claims involve a “remote sleep analysis and diagnosis” and the specification describes how a third party can transmit the data from outside the patient’s home. ’603 Patent at 16:15-18 (healthcare provider or another 3rd party from its facility can upload from the patient interface box); *see also* ’535 Patent at 8:4-6 (same). The related ’698 and ’603 Patents describe how the remote sleep analysis can be

⁶ The related ’535, ’399, ’937, and ’637 Patents share the same specification. Thus, CleveMed provides representative citations throughout its briefing to disclosures that are found in each patent in the family. Similarly, the related ’603 and ’698 Patents share a specification, such that citations to either specification are representative of both patents.

conducted “in a non-traditional location such as a hospital room, nursing home, a satellite hospital, hotel and the like.” ’698 Patent at 3:6-10, ’603 Patent at 3:13-17. The remaining related HST Patents have similar language. ’637 Patent at 8:47-52; ’535 Patent at 8:31-36; ’399 Patent at 8:39-44; ’937 Patent at 8:39-44.

The specifications describe how the data acquisition system was designed to be easily transported. *See, e.g.*, ’603 Patent at 12:9-11; ’399 Patent at 13:16-17, 13:43-46. They also describe the ability to store the data on removable memory for later transmission, such as on memory sticks, hard drives, floppy disks, including in the event of a transmission failure for a direct reading. *See, e.g.*, ’603 Patent at 13:24-14:7; ’399 Patent at 15:3-33 (storage of data onto removable media for later transmission). Thus, the HST Patents do not limit the location of the data transmission to the subject’s home.

2. Defendant’s Answering Position

As CleveMed concedes, the issue common to each disputed term in this group is “whether the transmission of data must occur from a patient’s home.” Opening, 31. According to the plain language of the claims, the answer to that question is “yes,” which is reflected in each of ResMed’s constructions. CleveMed, on the other hand, tries to run from the plain claim language by citing portions of the specification that do not support its position.

The HST patents try to distinguish the alleged invention from prior art in-home testing systems by claiming that the prior art systems were “not capable of transmitting data” from a patient’s home such that the data “can be periodically or continuously checked for adequacy” or to allow a “remote monitor” to attend a patient’s testing. *See* ’399 patent, 2:4-41, 7:61-8:3; ’603 patent, 2:37-3:9 (“None of the current methods for conducting a sleep study outside a sleep lab allow transmission of the collected data during the test,” *i.e.*, from the patient’s home). The HST

patents' specification also discloses that "portable" means the device is "capable of being transported relatively easily," where "[r]elative ease in transport means that the device is easily worn and carried ... to the point of use or application and then worn by the subject" '399 patent, 13:14-23 (emphasis added). Thus, CleveMed's new interpretation that the device be portable back to a clinician's office for subsequent transmission of the data to yet another location contradicts the very purpose of the alleged invention.

For terms 13, 15, and 16, the claim language requires that the data transmission occurs from the patient's home. Claim 8 of the '535 patent claims a "system for conducting an at-home sleep analysis comprising ... a portable patient interface box adapted to be worn by the subject on their torso while the subject sleeps or attempts to sleep at home." (emphasis added). Claims 1 and 13 of the '937 patent, claims 1 and 8 of the '399 patent, and claim 1 of the '637 patent all have similar preambles and claim language requiring "at home" sleep analysis with a portable patient interface box configured to be worn while the subject sleeps at home. Thus, ResMed's constructions are consistent with the express claim language. For the "at home" claim terms to have any meaning, transmission must occur from the patient's home. *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.").

Similarly, for terms 13 and 15, the disputed claim terms require "a database adapted to be remote from a home" or "transferring ... to a location remote from the subject's home." To give these terms meaning, the portable patient interface box must transfer the data from the subject's home. *Id.* For term 13, for example, if transmission from the portable patient interface box does not occur from the patient's home, then the term requiring a database that is "adapted to be remote from a home" would be meaningless. The same is true for term 15.

Last, for terms 18 and 20-21, CleveMed cites sweeping disclosure from the specification (Opening, 31-32), but ignores that the embodiments of those patents are restricted to an “at-home” data acquisition system. See ’603 patent, 23:57-24:15 (“The wireless in-home data acquisition system 50 transmits a signal based, at least in part, on one or more of the signals from the sensors on the subject. The wireless data acquisition system 50 transmits a signal 55 preferably in real time from the subject’s home 52 to a server 70 for analysis.”), 28:6-19 (“in-home data acquisition system”), Fig. 5. Thus, because the data acquisition system is only disclosed as an at-home system, a person of ordinary skill in the art would recognize that the claimed systems and methods must transmit data from the home of a subject.

3. Plaintiff’s Reply Position

The intrinsic evidence, which Defendant has completely ignored and failed to effectively rebut, demonstrates that these terms do not require that the data transmission must occur from the patient’s home. The specifications of the ’698 and ’603 Patents describe how the remote sleep analysis can be conducted “in a non-traditional location such as a hospital room, nursing home, a satellite hospital, hotel, and the like.” ’698 Patent at 3:6-10, ’603 Patent at 3:13-17. The remaining related HST Patents have similar language. ’637 Patent at 8:47-52 (providing various locations that would be similar to a subject’s home for purposes of an at-home sleep analysis); ’535 Patent at 8:31-36; ’399 Patent at 8:39-44; ’937 Patent at 8:39-44.

For terms 13, 15, and 16, Defendant ignores that the HST specifications explicitly extend the subject’s sleeping location beyond just their home by stating “the subject’s sleeping location includes but is not limited to the subject’s home, apartment, and the like, as well as a hotel” ’637 Patent at 8:47-52; ’535 Patent at 8:31-36; ’399 Patent at 8:39-44; ’937 Patent at 8:39-44. The specification further provides clarification that the data transmission can “be provided by a

3rd party service provider or by the healthcare facility’s information technology department,” which requires that the transmission occurs from a location other than the patient’s home or sleeping location. ’535 Patent at 8:3-6. Thus, Defendant’s proposal improperly excludes embodiments described throughout the specifications. *Verizon Servs.*, 503 F.3d at 1305. Additionally, Defendant’s emphasis on the “at home” language in the preamble does not relate to the location from where the data transmission must occur and is not part of the structure of the invention. *Artic Cat Inc. v. GEP Prods., Inc.*, 919 F.3d 1320, 1328 (Fed. Cir. 2019) (preamble of “a power distribution module for a personal recreational vehicle” is not limiting because the claims describe structurally complete inventions). Here, the deletion of the at home language in the preamble does not affect the operation of the invention. *Id.* at 1329.

Defendant’s argument regarding the database’s location or location receiving the data is also misdirection. The specification only requires that the database receiving the information not be located in the subject’s home. Thus, it does not support Defendant’s attempt to improperly add a limitation that requires the data transmission to originate from the subject’s home.

For terms 18, 20-21, a POSITA would recognize that the claimed systems and methods would have the ability to transmit data from locations beyond the patient’s home. The specifications describe at least one embodiment where patients send the HST device with the stored sleep data to the location where there is “a specialized security appliance” or where a secure transmission in compliance with HIPAA and HCFA guidelines can occur, *i.e.*, at a medical provider’s location. *See* ’399 Patent at 8:4-16, 14:47-15:33; ’698 Patent at 13:11-14:13, 16:3-15; ’535 Patent at 7:63-8:8, 14:40-15:26; ’937 Patent at 8:4-16, 14:47-15:33; ’603 Patent at 13:16-14:18, 16:8-20; ’637 Patent at 8:11-24, 14:54-15:40. Thus, a POSITA would recognize

that the data acquisition system would not be limited to transmitting only from the subject's home.

4. Defendant's Sur-Reply Position

CleveMed's rebuttal ignores that it is the claims that define the scope of the alleged invention, and ResMed does not merely rely on the claims' preambles. Reply, 34-36. The body of the '535 patent's claim 8 clearly requires the interface box be worn at home: "a portable patient interface box adapted to be worn by the subject ... while the subject sleeps or attempts to sleep at home." *See also* '937 patent claim 13, '399 patent claims 1, 8, '637 patent claim 1 (reciting similar language). Disputed terms 13 and 15 also require "a database adapted to be remote from a home" or "transferring ... to a location remote from the subject's home." Because the patient interface box must be in the home, the claims require transmission of data from the home, and CleveMed cannot change this plain language by citing broad specification language.

For terms 18 and 20-21, CleveMed cannot overcome the specific embodiments found in the specification by pointing to unrelated disclosures. Reply, 35-36; Answer, 32-33. Ultimately, CleveMed cannot ignore that the HST patents purport to distinguish themselves by pointing to remote monitoring while a patient is at home. Answer, 32-33.

H. Term 14: "wherein the processor is further adapted for checking the adequacy of the collected data from the sensors prior to transmitting the collected data to the database" ('535 Patent, Claim 9)

"wherein the processor is further adapted for checking the adequacy of the collected data from the sensors prior to transferring the collected data to the database" ('937 Patent, Claim 9)

Term 19: "checking the adequacy of the data from the respiratory belt sensor and the air flow sensor with a processor prior to transmitting the data" ('698 Patent, Claim 15)

Plaintiff's Proposed Construction	Defendant's Proposed Construction
These claim terms are definite.	Indefinite.

1. Plaintiff's Opening Position

Given the intrinsic record, a POSITA would understand with reasonable certainty that “checking the adequacy of the collected data” means programming a processor to evaluate sensor data input and determine whether it is possible for the second processor to make its determination of “whether the subject suffers from a sleeping disorder” based on that input. ’535 Patent at Claim 9, 5:2-4, 9:7-36, 10:49-12:38; ’698 Patent at Claim 15; Jafari Decl., ¶¶27-29. These terms thus satisfy §112. *See, e.g., Sonix Tech. Co. v. Publ’ns Int’l, Ltd.*, 844 F.3d 1370, 1377, 1381 (Fed. Cir. 2017) (finding POSITA could understand claim with reasonable certainty based on specification). The claimed adequacy check in the ’535 and ’937 Patents is based on objective criteria because a POSITA would understand from the specification the minimum requirements for the amount and availability of data and quality of signal to constitute a sufficient sample for diagnostic analysis. Jafari Decl., ¶27; *see also, e.g.*, ’535 Patent at 4:21-25 (collecting signals from sensors as input), 4:25-36 (describing using pre-processing to improve signal, such as removing motion artifacts), 5:36-41 (describing giving instructions to patient to make sensor adjustments to improve signal), 5:59-60 (describing applying a filter to improve signal), Fig. 1 (showing signal check loop, described at 22:54-23:7).

The specifications offer numerous examples of the actual sensors and how they can collect and transmit data, thereby defining the claims’ objective boundaries. *See, e.g.*, ’535 Patent, 9:7-36, 10:49-12:38. For example, they describe that the “simplest form” of an embodiment uses only two sensors “to measure a single channel of physiologic or kinetic data.” *Id.* at 9:9-11. A POSITA would understand that collected data is inadequate if either of these

basic sensors or the connected channel failed to transmit data, only intermittently transmitted data, or transmitted garbled data due to poor connectivity. Jafari Decl., ¶28.

The specifications also provide specific examples of issues that may exist in the collected data and how to fix them, which further informs the level of adequacy required to proceed to diagnosis and confirms that the “checking” terms are definite. *See Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 30 F.4th 1339, 1349 (Fed. Cir. 2022) (broad descriptive terms like “pliable” are definite when specification and claims describe exemplary materials or methods for satisfying the term, *e.g.*, exemplary characteristics of a sufficiently “pliable” catheter). For example, a POSITA can program the first processor to “remove motion artifacts” from the received signals, which “improves the quality of the data” because “the presence of motion artifact[s] can result in misdiagnosis, prolong procedure duration, and lead to delayed or inappropriate treatment decisions.” *See, e.g.*, ’535 Patent at 4:25-36, 18:64-19:11.

The specifications present detailed solutions to eliminate motion artifacts and correct other errors that render data inadequate. *See, e.g., id.* at 19:48-20:15, 21:21-30. They also define timing for determining data adequacy, such as evaluating signal quality prior to beginning the sleep study and periodically throughout to determine if corrective action is needed to address diminished quality. *Id.* at 22:10-24. Given the intrinsic record’s details, a POSITA would understand the boundaries of when collected data is adequate. *See, e.g., Niazi*, 30 F.4th at 1349.

The “checking adequacy” term in the ’698 Patent is similarly defined by objective criteria in the specification, including minimum requirements for sufficient data. *See* ’698 Patent at Claim 15, Fig. 1 (showing signal check loop, described at 22:25-45); Jafari Decl., ¶29. As described above, a POSITA would understand that data is inadequate if the transmission from a sensor failed, was interrupted, or was garbled. *See, e.g.*, ’698 Patent at 7:51-8:6 (describing

minimum sensors needed for adequate data collection), 14:20-52 (describing methods of improving poor transmission quality); Jafari Decl. ¶29. Further, the specification details specific issues arising from sensor data collection and how to fix them. *See, e.g.*, '698 Patent at 21:16-31 (appropriate timing for signal evaluation to reveal any reduction in quality), Fig. 1, 22:25-45 (describing adjustment of signals to improve quality). It also describes techniques for motion artifact removal that improve data quality, which are exemplary and reasonably certain methods to ensure adequate sensor data for diagnostic analysis. *See, e.g., id.* at 18:3-17 (describing how motion artifacts cause problems), 18:54-19:51 (describing use of an accelerometer to better remove artifacts), 19:52-20:26 (use of video for same), 20:27-36; Jafari Decl. ¶29. Thus, the term is definite because a POSITA would understand the objective boundaries as to what would be sufficiently adequate data to determine whether a patient has a sleeping disorder, as well as how to obtain such data.

2. Defendant's Answering Position

ResMed reserves these terms, all of which appear only in dependent claims, for summary judgment. Prior to briefing, CleveMed requested that ResMed reduce the number of disputed terms. *See* D.I. 64. ResMed agreed to reserve terms 7, 14, and 19, among others. ResMed Ex. 13. Despite this agreement, CleveMed briefed these terms. Because ResMed reserved these terms at CleveMed's request, there is no current dispute for the Court to resolve.

3. Plaintiff's Reply Position

a. Terms 7, 14, and 19

Defendant's decision to unilaterally seek to brief these terms at a later stage of the proceeding is a waiver of any disputes it has with CleveMed's construction. *See* Reply Declaration of Lisa Kobialka, Ex. 1 at 1 (4/11/23 Wells email) (Identifying Terms 14, 17, and 19 as being briefed by CleveMed); *Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Sols., P.C.*,

482 F.3d 1347, 1356 (Fed. Cir. 2007) (finding defendant waived claim construction argument by failing to raise it during the claim construction phrase).

4. Defendant's Sur-Reply Position

ResMed's decision to reserve these terms at CleveMed's request does not create waiver. Unlike the *Cent. Admixture* case, ResMed raised these disputes during claim construction and thus there are no issues of timeliness or notice to CleveMed. See *Koninklijke Philips N.V. v. ZOLL Lifecor Corp.*, No. 12-1369, 2015 WL 12781198, at *8 (W.D. Pa. July 15, 2015).

I. Term 22: "pulse oximeter"

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

1. Plaintiff's Opening Position

The plain and ordinary meaning applies to "pulse oximeter." *Phillips*, 415 F.3d at 1312-13 (a term that has a clear, plain and ordinary meaning, needs no further construction). Based on how the term appears throughout the HST Patents, a lay person as well as a POSITA, understand that "pulse oximeter" means an instrument used to measure the blood oxygenation, discussed below.

For example, the '937 Patent claims recite “the fingertip pulse oximeter adapted to be applied to a subject, [is used] for measuring blood oxygenation of the subject.” '937 Patent at Claims 1, 13; *see also* '399 Patent at Claims 1, 8, 14; '535 Patent at Claim 8 (“fingertip pulse oximeter . . . for measuring oxygenation of the subject”); '637 Patent at Claim 1 (“pulse oximeter . . . to measure blood oxygenation”); '603 Patent at Claim 1 (pulse oximeter used “to measure or derive . . . blood oxygenation during testing.”).

The specifications of the HST Patents and the '269 Patent lend further support, as they state that “[t]he pulse oximeter can measure the oxygenation of the subject’s blood.” '603 Patent at 10:26-28; '399 Patent at 11:56-58; '535 Patent at 11:48-50; '269 Patent at 7:40-41, 8:15-16. Thus, the intrinsic evidence supports the plain and ordinary meaning of an instrument used to measure the blood oxygenation.

2. Defendant’s Answering Position

The patents recite “pulse oximeter” according to its plain meaning to one of skill in the relevant art, which is “a noninvasive sensor which provides a continuous estimation of arterial hemoglobin oxygen saturation as well as the pulse rate” of a subject. *See* ResMed Ex. 7 at 81 (*Moron* reference, describing a monitoring network of pulse-oximetry sensors, including well-known pulse oximeters from vendors such as Nonin, Numed, and Cardguard); *see also* ResMed Ex. 8 (American Heritage Medical Dictionary (2nd ed. 2007)) (defining “pulse oximeter” as measuring “the oxygen saturation of arterial blood”); ResMed Ex. 1 (Sharony Decl.), ¶ 69. The Federal Circuit holds that “judges are free to rely on dictionaries” at the outset of the *Phillips* analysis to “help the court to better understand . . . the way in which one of skill in the art might use the claim terms.” *Starhome GmbH v. AT&T Mobility LLC*, 743 F.3d 849, 856 (Fed. Cir. 2014).

Under its plain and ordinary meaning, a “pulse oximeter” is a noninvasive sensor, meaning it does not penetrate the skin (it typically is attached to a subject’s fingertip). It also permits “continuous estimation of arterial hemoglobin saturation,” which is a critical feature of the asserted claims of the HST patents. The asserted claims of the HST patents recite methods of conducting home sleep testing where the pulse oximeter is used to measure and collect data of the “oxygenation of the subject while the subject attempts to sleep at home” (*see, e.g.*, ’399 patent, claim 1 (emphasis added)), which requires continuous estimation of the subject’s blood oxygenation. The patents’ specification also describe embodiments, like fingertip pulse oximeters, for providing “[r]eal-time analysis” and “continuous data transmission” for remote monitoring of the sleep test, which only makes sense if the pulse oximeter is continuously estimating oxygen saturation. *Id.* at 3:28-31; 6:30-36; 11:54-12:2. And of course, a pulse oximeter also measures the subject’s “pulse rate,” which is why it is called a pulse oximeter.

CleveMed’s proposal contradicts the plain meaning of “pulse oximeter” without any good reason for doing so. First, CleveMed’s proposal omits any reference to measuring “pulse rate,” which would read “pulse” out of “pulse oximeter.” Second, CleveMed’s proposal omits any reference to “continuous” measurement, which is required by the claims and specification. Third, CleveMed’s proposal does not even refer to measuring “hemoglobin saturation,” contrary to the HST patents’ specification (’399 patent, 11:54-12:2). Fourth, CleveMed tries to broaden this plain-meaning term to cover any device used to measure blood oxygenation, even though the patent specification discloses other devices that can measure blood oxygenation that are not pulse oximeters, including “transcutaneous oxygen monitoring, transcutaneous carbon dioxide monitoring, expired end carbon dioxide monitoring,” or “O2 or CO2 blood gas monitor[s].” ’269

patent, 7:40-43, 18:57-59. CleveMed's distorted proposal for this common, plain-meaning term cannot be correct.

3. Plaintiff's Reply Position

Defendant's wordy proposal unnecessarily adds language, such as "noninvasive," "continuous," and "arterial hemoglobin oxygen saturation," which will only serve to confuse the fact finder. *CFL Techs. LLC v. Osram Sylvania, Inc.*, No. 1:18-cv-01445-RGA, 2022 WL 606329, at *14 (D. Del. Jan. 21, 2022) (finding "no reason to deviate from the language of the claims as it will unnecessarily confuse the jury."). Specifically, Defendant's inclusion of the term "continuous" has no intrinsic support and will only confuse the jury. Defendant resorts to extrinsic evidence and the nonsensical assertion that the pulse oximeter provides a continuous estimation solely because of the location of the subject and how data is transmitted from the HST device. Neither the location or how data is transmitted necessitates that the pulse oximeter is "continuous" and Defendant has no support for such an assertion.

Further, Defendant ignores other embodiments showing that the data is stored in memory for transmission at a later time and thus is not "continuous" in the manner that Defendant suggests. '399 Patent at 14:50-57. Thus, Defendant's proposal improperly excludes embodiments disclosed in the specification. *Verizon Servs.*, 503 F.3d at 1305.

Pulse oximeters emit wavelengths of light and measure the absorption of this light to estimate the proportion of oxygenated blood which gives rise to many known issues. Jafari Reply Decl., ¶¶ 21-22. This estimation is typically calculated in intervals, for example, every three to five seconds. *Id.* Because pulse oximeters measure the perceived absorption of light, any connection issue with the subject will alter this measurement and produce gaps in its data. *Id.* The same is true for patients that have darker skin tones, dirt at the connection site, or nail polish

because they affect how light is absorbed. *Id.* Thus, inclusion of “continuous” in the manner that Defendant suggests is contrary to how a POSITA would know pulse oximeters to operate because there is always a gap between the measurements it takes which does not provide a truly continuous measurement. *Id.*

Defendant’s inclusion of “hemoglobin saturation” is unnecessary and seeks to include a term that appears nowhere in the specification. Answer at 43(citing ’399 Patent at 11:54-12:2). CleveMed’s definition does not broaden the plain and ordinary meaning of the term used in the claims, as the claims expressly state the pulse oximeter is “for measuring oxygenation.” ’399 Patent at Claim 1; *Vitronics Corp.*, 90 F.3d at 1582. Thus, CleveMed’s construction should be accepted as it tracks the intrinsic evidence, the language of the claims, and a POSITA’s understanding.

4. Defendant’s Sur-Reply Position

CleveMed proposes a “plain meaning” construction but nonsensically rejects any words not appearing in the specification, thereby improperly excluding a POSITA’s understanding of the term. CleveMed does not dispute that (1) pulse oximeters measure blood oxygen saturation “noninvasively” (’269 patent, 8:15-58; Reply, 43-44), or (2) a POSITA understands a pulse oximeter measures “hemoglobin saturation” (Reply, 43-44; Answer, 41-42). Rather than citing evidence, CleveMed resorts to an unfounded refrain about juror confusion. *See Mobile Hi-Tech Wheels v. CIA Wheel Group*, 514 F. Supp. 2d 1172, 1193 (C.D. Cal. 2007) (no juror confusion where the experts testified consistently with construction). CleveMed’s focus on “continuous” as somehow not including the “intervals” described by its expert further ignores a POSITA’s knowledge. Jafari Reply Decl., ¶ 21.

J. Term 24: “oxygenation”

Asserted Patent and Claim(s)	Plaintiff’s Proposed Constructions	Defendant’s Proposed Constructions
’399 Patent: Claims 1, 8 ’535 Patent: Claim 8 ’937 Patent: Claims 1, 13 ’603 Patent: Claims 1, 8 ’637 Patent: Claim 1	“level of oxygen”	Plain and ordinary meaning, which is “level of oxygen saturation of the blood”

1. Plaintiff’s Opening Position

“Oxygenation” has a straightforward meaning which is simply the level of oxygen. The claimed inventions describe capturing an estimation of the level of oxygen found in the subject’s blood using a pulse oximeter. ’603 Patent at 10:26-28; ’399 Patent at 11:56-58; ’535 Patent at 11:48-50; ’637 Patent at 11:64-66. Additionally, the HST Patents instruct that “[m]easurement of oxygenation and ventilation is preferably measured by pulse oximetry.” *See, e.g.*, ’937 Patent at 11:1-3. Thus, the intrinsic evidence supports CleveMed’s construction.

2. Defendant’s Answering Position

The claims and specification confirm that “oxygenation” refers to “the level of oxygen saturation in the blood.” The claims disclose a “fingertip pulse oximeter for measuring oxygenation of the subject.” *See, e.g.*, ’399 patent, claim 1. A skilled artisan would understand the fingertip pulse oximeter to measure “the oxygenation of the subject’s blood” and “changes in blood oxygen saturation,” because it measures the amount of light absorbed by hemoglobin, a protein in blood that carries oxygen. *See, e.g., id.*, 11:45-12:2; 22:6-8. Relevant medical

dictionaries also support ResMed’s construction. ResMed Ex. 10 (Taber’s Medical Dictionary (20th ed. 2005)) (defining “oxygenation” as “[s]aturation or combination with oxygen, as the aeration of the blood in the lungs”). CleveMed’s proposal is too broad because it omits that “oxygenation” refers to oxygen saturation of the blood.

3. Plaintiff’s Reply Position

“Oxygenation” does not require any construction because its plain and ordinary meaning is a “level of oxygen.” This definition is supported by the intrinsic record which describes oxygenation as an estimation of the level of oxygen found in the subject’s blood using a pulse oximeter. Opening at 46.

Defendant agrees that oxygenation refers to “the level of oxygen,” however, they seek to add the phrase “saturation in the blood,” which will only serve to confuse the jury. Defendant is left with only extrinsic evidence to support its proposition because its citations to the specification are a mixed bag referring to the reading of the pulse oximeter (’399 at 11:45-12:2) and the later analysis of the data by the processor to identify physiological events (*id.* at 22:6-8). Because the reading of the sensor and the analysis of the processor are conducted at separate steps of the claim (*id.*, Claim 1), combining descriptions of these steps into the construction of oxygenation imports unnecessary limitations into an otherwise straightforward term.

4. Defendant’s Sur-Reply Position

The intrinsic record confirms that a pulse oximeter measures “the oxygenation of the subject’s blood.” ’399 patent, 11:56-58 (“oxygenation of the subject’s blood”); ’269 patent, 5:53-54 (“blood oxygen saturation”); Answer, 47. CleveMed’s only dispute—speculating that “saturation of the blood” would confuse a jury—is not a valid reason to give a term a meaning

that does not reflect a POSITA's understanding. ResMed's construction is readily understandable by a lay jury with the benefit of expert testimony.

K. Term 4: “a processor adapted for receiving the airflow sensor data and calculating both symptom data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and data of usage of the PAP device” ('269 Patent, Claim 15)

Term 5: “a processor adapted for receiving the pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor and calculating, based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject's sleep disorder symptoms measured during use of the PAP device” ('269 Patent, Claim 1)

Term 6: “the processor further adapted for calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject's symptoms measured during the subject's use of the PAP device” ('269 Patent, Claim 5)

Plaintiff's Proposed Construction	Defendant's Proposed Construction
This claim term is definite and not subject to 35 U.S.C. § 112(6). In the alternative, to the extent 35 U.S.C. § 112(6) applies, the structure for these terms is evident from the claims themselves and from the specification: Functions: “receiving the airflow sensor data and calculating both symptom data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and data of usage of the PAP device” (Claim 15) / “calculating, based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject's sleep disorder symptoms measured during use of the PAP device” (Claim 1) / “calculating, based in part on both data from the respiratory airflow and pulse oximetry	Indefinite. Subject to 35 U.S.C. § 112(6). Functions: “calculating symptom data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and data of usage of the PAP device” (Claim 15) / “calculating, based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject's sleep disorder symptoms measured during use of the PAP device” (Claim 1) / “calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject's symptoms measured during the subject's use of the PAP device” (Claim 5)

sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject's symptoms measured during the subject's use of the PAP device" (Claim 5) Structure: a processor programmed to perform the identified functions as described in 3:9-47, 3:58-64, 3:65-4:4, 4:5-10, 4:11-19, 4:20-28, 4:29-36, 4:37-45, 7:27-43, 7:61-8:12, 8:13-30, 10:65-11:16, 13:29-54, 14:14-19, 15:34-63, 16:4-10, 18:51-19:7, 19:46-57, 20:1-31, 20:32-40, 20:41-21:14, 21:15-39, or 21:40-67	Structure: none disclosed
---	---

Term 7: "wherein the PAP device further comprises an electronic component adapted to allow the PAP device to be adjusted remotely based on the symptom data of the severity of the subject's sleep disorder and/or the index of the subject's symptoms transmitted to the remote internet site" ('269 Patent, Claim 18)

Plaintiff's Proposed Construction	Defendant's Proposed Construction
This claim term is definite and not subject to 35 U.S.C. § 112(6). In the alternative, to the extent 35 U.S.C. § 112(6) applies, the structure for this term is evident from the claims themselves and from the specification: Function: "allow the PAP device to be adjusted remotely based on the symptom data of the severity of the subject's sleep disorder and/or the index of the subject's symptoms transmitted to the remote internet site" Structure: a PAP device containing an electronic component as described in at least Fig. 7-8, 2:27-51, 3:29-44, 3:58-64, 3:65-4:4, 4:5-10, 4:11-19, 4:20-28, 4:29-36, 4:37-45, 9:62-10:8, 15:6-46, 15:47-63, 16:4-10, 22:1-8, 22:9-12, 22:29-40, 22:41-44, 23:7-17, or 23:24-33	Indefinite. Subject to 35 U.S.C. § 112(6). Function: "allowing the PAP device to be adjusted remotely based on the symptom data of the severity of the subject's sleep disorder and/or the index of the subject's symptoms transmitted to the remote internet site" Structure: none disclosed

Term 10: "a processor adapted for collecting, measuring, digitizing and

storing collected data to the nonvolatile digital memory from the airflow, respiratory effort, blood oxygenation and body position of the subject during sleep at home” (’535 Patent, Claim 8)

Term 11: “a processor adapted for collecting, measuring, and digitizing data corresponding to the airflow, respiratory effort, and blood oxygenation of the subject” (’937 Patent, Claim 1)

Term 12: “a processor adapted for collecting, measuring, digitizing and storing collected data to the nonvolatile digital memory from the airflow, the respiratory effort, the blood oxygenation and body position of the subject during sleep at home” (’937 Patent, Claim 13)

Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
These claim terms are definite and not subject to 35 U.S.C. § 112(6). In the alternative, to the extent 35 U.S.C. § 112(6) applies, the structures for these terms are evident from the claims themselves and from the specification: ’535 Patent, Claim 8: Function: “collecting, measuring, digitizing and storing collected data to the nonvolatile digital memory from the airflow, respiratory effort, blood oxygenation and body position of the subject during sleep at home” Structure: an in-home data acquisition device with a processor programmed as described in at least 2:42-3:6; 3:67-4:3; 4:8-17; 4:21-30; 4:37-44; 4:52-5:4; 5:29-5:46; 5:65-6:9; 6:10-20; 6:31-38; 8:55-8:66; 9:7-9:14; 9:23-9:26; 9:62-10:11; 10:24-34; 10:49-10:64; 10:65-11:1; 11:15-34; 11:40-45; 11:46-54; 11:65-67; 12:7-12:11; 12:27-12:38; 13:22-26; 14:36-56; 17:51-17:59; 18:16-18:31; 19:12-19:13; 19:48-19:54; 22:10-22:24; or 22:63-22:65 ’937 Patent, Claims 1 and 13: Function: “collecting, measuring, and digitizing data corresponding to the airflow, respiratory effort, and blood oxygenation of the subject” (Claim 1) /	Indefinite. Subject to 35 U.S.C. § 112(6). Functions: collecting, measuring, digitizing and storing collected data to the nonvolatile digital memory from the airflow, respiratory effort, blood oxygenation and body position of the subject during sleep at home. Structure: none

“collecting, measuring, digitizing and storing collected data to the nonvolatile digital memory from the airflow, the respiratory effort, the blood oxygenation and body position of the subject during sleep at home” (Claim 13) Structure: an in-home data acquisition device with a processor programmed as described in at least 2:52-3:16; 4:10-13; 4:18-27; 4:31-39; 4:47-54; 4:62-5:14; 5:39-56; 6:8-18; 6:19-28; 6:38-45; 8:63-9:7; 9:15-22; 9:31-34; 10:3-19; 10:32-42; 10:57-11:5; 11:6-9; 11:23-38; 11:48-53; 11:54-62; 12:6-8; 12:15-19; 12:34-45; 13:31-34; 14:43-63; 17:59-67; 18:24-39; 19:20-21; 19:56-62; 22:19-33; or 23:5-7	
---	--

Term 17: “analyzing the transmitted data with a computer or processor programmed to identify and draw attention to physiological and technological events in the data” (’698 Patent, Claim 14)

Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
This claim term is definite and not subject to 35 U.S.C. § 112(6). In the alternative, to the extent 35 U.S.C. § 112(6) applies, the structure for this term is evident from the claims themselves and from the specification: Function: “analyzing the transmitted data with a computer or processor programmed to identify and draw attention to physiological and technological events in the data” Structure: a computer or processor programmed as described in at least 5:47-50; 12:24-34; 12:49-13:9; 15:6-13; 15:44-67, 16:1-2; 16:38-18:2; 20:27-22:14; 22:25-51; 23:25-41; 23:57-24:9; 24:35-64; 26:45-27:30; or 27:34-67	Indefinite. Subject to 35 U.S.C. § 112(6). Function: identify and draw attention to physiological and technological events in the data Structure: None disclosed

1. Plaintiff's Opening Position

Terms 4-7, 10-12, 17 are not means-plus-function under §112(6). None of these elements uses the word “means,” and thus they are presumptively not subject to §112(6). *See Dyfan, LLC v. Target Corp.*, 28 F.4th 1360, 1365-66 (Fed. Cir. 2022) (claims are presumptively not in means-plus-function format if they do not recite “means”). Seven terms use “processor” (one of which uses “computer or processor”), and another uses “electronic component.” *See* Terms 4-6, 10-12, 17 (processor); Term 7 (electronic component). These terms are not merely “nonce” words “connoting a generic ‘black box’ for performing the recited computer-implemented functions.” *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1350 (Fed. Cir. 2015); *Zeroclick, LLC v. Apple Inc.*, 891 F.3d 1003, 1007-08 (Fed. Cir. 2018) (using generally functional language does not indicate a means-plus-function format; claim must use a functional word as a substitute for “means”). Rather, the terms at issue are well-understood by a POSITA to have a “sufficiently definite meaning as the name for structure.” Thus, §112(6) presumptively does not apply. Jafari Decl. ¶¶30-31; *Williamson*, 792 F.3d at 1348; *VDPP LLC v. Vizio, Inc.*, No. 2021-2040, 2022 WL 885771, at *2-4 (Fed. Cir. Mar. 25, 2022).

Courts routinely find that “processor” and similar terms are not subject to §112(6). *VDPP*, 2022 WL 885771, at *3-4 (presumption against means-plus-function not overcome for element reciting “a processor adapted to” perform certain functions); *Samsung Elecs. Am. v. Prisia Eng'g Corp.*, 948 F.3d 1342, 1353-54 (Fed. Cir. 2020) (“digital processing unit” does not invoke §112(6)); *Realtime Adaptive Streaming LLC v. Adobe Sys. Inc.*, No. 18-9344-GW(JC), 2019 WL 13039644, at *24 (C.D. Cal. July 25, 2019) (element reciting “processors configured to” perform actions did not invoke §112(6)); *Syncpoint Imaging, LLC v. Nintendo of Am. Inc.*, No. 2:15-cv-00247-JRG-RSP, 2016 WL 55118, at *23-24 (E.D. Tex. Jan. 5, 2016) (“processor”

did not invoke §112(6)); *Smartflash LLC v. Apple Inc.*, 77 F. Supp. 3d 535, 541 (E.D. Tex. Dec. 4, 2014) (“processor” “describes a class of structures” and not a nonce word invoking §112(6)); *Linear Tech. Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1320-21 (Fed. Cir. 2004) (reversing holding that “circuit for” performing a function terms were governed by § 112(6)).

Defendant cannot overcome this presumption by showing, as it must, that the elements fail to “recite sufficiently definite structure.” *Williamson*, 792 F.3d at 1349. In particular, words like “processor” do not invoke §112(6) where the claim “recites the objectives and operations of the processor,” and a POSITA would thus “understand the structural arrangements of the processor” *Syncpoint Imaging*, 2016 WL 55118, at *20, 23-24; *see also Linear Tech.*, 379 F.3d at 1320. Here, the claims state the disputed terms’ objectives and operations. Specifically:

- Term 4: Claim 15 (’269 Patent) explains that, as part of the PAP sleep disorder treatment system, the processor receives airflow sensor data and calculates both symptom data of a severity of the subject’s sleep disorder symptoms and/or an index of a subject’s symptoms measured during use of the PAP device and data of usage of the PAP device, to be transmitted to the base station, cellular phone or PDA, and retransmitted to a remote internet site.
- Term 5: Claim 1 (’269 Patent) explains that, as part of the PAP sleep disorder treatment system, the processor receives the pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor, and it calculates, based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject’s sleep disorder symptoms measured during use of the PAP device, to be transmitted to a remote location.
- Term 6: Claim 5 (’269 Patent) explains that, as part of a sleep disorder treatment system, the processor receives pulse oximetry sensor data from the second input and respiratory airflow data from the airflow sensor, and calculates based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject’s symptoms measured during the subject’s use of the PAP device, to be stored and later transmitted to a remote location.
- Term 7: Claim 18 (’269 Patent) (which depends on Claim 15) further explains that the electronic component allows the PAP device to be adjusted remotely based on the data the processor calculates, as part of the PAP sleep disorder treatment system.

- Term 10: Claim 8 ('535 Patent) explains that as part of a system for conducting at-home sleep analysis, the processor collects, measures, digitizes, and stores collected data to nonvolatile digital memory from the airflow, respiratory effort, blood oxygenation, and body position of the subject during sleep at home, to be uploaded and transferred to a remote database and analyzed remotely to determine whether the subject suffers from a sleeping disorder.
- Term 11: Claim 1 ('937 Patent) explains that, as part of system for conducting remote sleep analysis, the claimed processor collects, measures and digitizes data corresponding to the airflow, respiratory effort, and blood oxygenation of the subject, to be stored on nonvolatile digital memory and transferred to a remote database and analyzed to determine whether the subject suffers from a sleeping disorder.
- Term 12: Claim 13 ('937 Patent) explains that, as part of a system for conducting at-home sleep analysis, the processor collects, measures, digitizes and stores collected data to the nonvolatile digital memory from the airflow, the respiratory effort, the blood oxygenation and body position of the subject during sleep at home, to be transferred to a remote database and analyzed to determine whether the subject suffers from a sleeping disorder. To meet these objectives and operations, the claimed processor, which is part of a portable patient interface box, collects, measures, digitizes and stores collected data to the nonvolatile digital memory, which the transceiver transfers to a remote database.
- Term 17: Claim 14 ('698 Patent) explains that as part of a method of remote sleep analysis and diagnosis, the computer or processor analyzes data that has been collected from sensors on a patient in a remote facility and transmitted to the sleep analysis unit or lab (or a database accessible to medical personnel) to identify and draw attention to physiological and technological events in the data.

A POSITA would understand the structure from these descriptions of the terms'

objectives and operations. Jafari Decl., ¶32. Thus, they are not subject to § 112(6). *See Syncpoint Imaging*, 2016 WL 55118, at *23-24; *Linear Tech.*, 379 F.3d at 1320.

In addition, sufficient structure is disclosed where a claim describes how the processor “interacts with . . . other components,” or its “location and its relationship to other components.” *Finjan, Inc. v. Proofpoint, Inc.*, No. 13-cv-05808-HSG, 2015 WL 7770208, at *9-11 (N.D. Cal. Dec. 3, 2015) (“content processor” “has a sufficiently specific structure” such that §112(6) does not apply); *see also Inventio AG v. ThyssenKrupp Elevator Americas Corp*, 649 F.3d 1350,

1359-60 (Fed. Cir. 2011) (terms not subject to §112(6) where intrinsic record described how they connected to other elements), *overruled on other grounds*, *Williamson*, 792 F.3d at 1348-49.

Here, the claims specifically describe the interaction and relationship between the terms at issue and other components. For instance:

- Term 4: Claim 15 ('269 Patent) describes interaction/relationship between the processor, airflow sensor in the PAP device, radio frequency wireless module transceiver, base station (or cellular phone or PDA) and remote internet site.
- Term 5: Claim 1 ('269 Patent) explains that the processor is part of the PAP device and describes its interaction/relationship with an input, airflow sensor, module transceiver and remote location.
- Term 6: Claim 5 ('269 Patent) describes the processor's interaction/relationship with an input and airflow sensor and explains that the processor is "adapted to be either part of or external to the PAP device" and has "a second output" that interacts with a non-volatile memory.
- Term 7: Claim 18 ('269 Patent), which depends on Claim 15, further describes the interaction/relationship between the electronic component, PAP device and remote internet site.
- Terms 10-12: Claim 8 ('535 Patent), Claim 1 ('937 Patent) and Claim 13 ('937 Patent), respectively, describe the processor as part of a portable patient interface box and its interaction/relationship with the non-volatile digital memory, transceiver and remote database.
- Term 17: Claim 14 ('698 Patent) describes interaction/relationship between the computer or processor and memory of the patient interface box, electronic interface and sleep analysis unit or lab or database accessible to medical personnel.

These descriptions impart specific structure to a POSITA such that § 112(6) does not apply.

Jafari Decl., ¶133; *Finjan*, 2015 WL 7770208, at *9-11; *Inventio*, 649 F.3d at 1359-60.

The specifications further support the structure recited in the claims. For instance:

- Terms 4-6: '269 Patent at 8:13-30 (processor interaction with sensors), 18:51-19:7 (same), 19:8-45 (location and interaction of processor), 19:46-21:67 (processor objectives and exemplary techniques for calculating by processor based on sensor data), Fig. 8 (processor interaction with other components).

- Term 7: '269 Patent at 2:27-51, 3:29-44, 9:62-10:8, 15:6-16:10, 22:29-40, 23:24-33, Fig. 8 (all describing the adjustments to the PAP device allowed by electronic component, its objectives and its interactions with the processor and PAP device).
- Terms 10-12: '535 Patent at 14:36-56, 17:51-59, 18:16-31, 19:12-13, 19:48-54; '937 Patent at 14:43-63, 17:59-67, 18:24-39, 19:20-21, 19:56-62 (all describing operations and objectives of processor and interaction with components including sensors and memory).
- Term 17: '698 Patent at 12:24-25 (characteristics of computer/processor), 12:49-13:9 (computer/processor relationship with other components), Fig. 8 and 27:34-67 (same), 15:44-16:2 (computer/processor operations/objectives and interaction with other components), 20:27-24:64 (same).

For Term 17, §112(6) does not apply for the additional reason that method steps are presumed not to be subject to §112(6), unless they include “step for” type language. *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1028 (Fed. Cir. 2002) (finding error in applying §112(6) because reciting a series of acts in a process claim is not the same as reciting a “step for” a function). In the absence of such language, they should only be deemed subject to §112(6) if they fail to recite relevant “acts” to be performed. *Fraunhofer-Gesellschaft Zur Forderung der Angewandten Forschung E.V. v. Sirius XM Radio Inc.*, No. 17-184-JFB-SRF, 2020 WL 549801, at*6-8 (D. Del. Feb. 4, 2020), *R. & R. adopted* 2020 WL 1969508 (D. Del. Apr. 24, 2020) (finding “step for” language signals inventor’s intent to employ §112(6)); *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, No. 2:15-CV-1202-WCB, 2016 WL 6138124, at *4-5 & n.5 (E.D. Tex. Oct. 21, 2016) (a “method of administering [a] substance to a patient” is not step-plus-function language). Here, Claim 14 expressly recites the required action—“analyzing the transmitted data...to identify and draw attention to physiological and technological events in the data.” Thus, Term 17 is outside of the ambit of §112(6) for this additional reason.

Because the terms at issue connote structure to a POSITA, and the claims describe the objectives and operations of the terms and how they interact with other components, § 112(6)

does not apply. Thus, Defendant has not established by clear and convincing evidence that these terms render any claim indefinite. *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017) (defendant has “burden of proving indefiniteness by clear and convincing evidence”). Rather, these terms have their plain and ordinary meaning and require no further construction.

2. Defendant’s Answering Position

a. Terms 4-6, 10-12, 17

Several asserted claims recite a “processor” as a nonce word for the means for performing certain functions, thus invoking means-plus-function claiming under § 112, ¶ 6. Given that these terms do not use “means for” claiming, there is a rebuttable presumption that § 112, ¶ 6 does not apply. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015). This presumption is overcome if ResMed “demonstrates that the claim term fails to ‘recite sufficiently definite structure’ or else recites ‘function without reciting sufficient structure for performing that function.’” *Id.*

i. The “Processor” Terms Should Be Construed Under § 112, ¶ 6.

Courts have found the term “processor” to invoke § 112, ¶ 6 when the processor is “defined only by the function that it performs.” *St. Isidore Research LLC v. Comerica Inc.*, No. 2:15-1390-JRG-RSP, 2016 WL 4988246, at *14 (E.D. Tex. Sept. 19, 2016) (construing “processor configured to” under § 112, ¶ 6); *Syneron Med. Ltd. v. Invasix, Inc.*, 2018 WL 4696971, at *14 (C.D. Cal. Sept. 5, 2018) (“the disputed ‘processor ...’ terms are defined only by the function they perform”), *R&R adopted*, 2018 WL 11351325 (C.D. Cal. Sept. 28, 2018); *Parity Networks, LLC v. Edgecore USA Corp.*, 2020 WL 8569299, at *11 (C.D. Cal. Dec. 22, 2020). *Cf. Takadu Ltd. v. Innovyze LLC*, C.A. No. 21-291-RGA, 2023 WL 2563157, at *8 (D.

Del. Mar. 17, 2023) (finding that “analysis engine” is subject to § 112, ¶ 6 because the claim failed to recite sufficiently definite structure). Where the claims do not detail the objectives and operations of the processor in a way that connotes sufficient detail, then § 112, ¶ 6 applies. *St. Isidore Research*, 2016 WL 4988246, at *14.

Here, the disputed “processor” claims fall into two categories. First, the “processor” recited in claims 5 and 15 of the ’269 patent and claim 14 of the ’698 patent is not structurally part of or connected to any other element in the claim, and thus lack sufficient structure. Claim 15 of the ’269 patent recites a PAP sleep disorder system comprising several components, including (1) a PAP device, (2) a processor adapted to perform certain functions, (3) a mask or a nasal cannula, (4) a transceiver, and (5) a base station, cellular phone, or PDA. But the processor is not linked to any other element through any sort of structure or connection. The processor is described only in functional terms; namely, that it be “adapted for” receiving the airflow sensor data and calculating certain data. ResMed Ex. 1 (Sharony Decl.), ¶¶ 53-54. The claim does not recite how the processor receives this data, whether through wires, wirelessly, or some other way. *Id.*, ¶ 54. Indeed, the processor does not need to be connected to or part of the PAP device at all. *Id.* The processor is simply “adapted to” perform the recited functions, and thus it can constitute any means for processing, including someone using pencil and paper. *Id.* The processor in claim 15 is described only by its function, and the claim does not detail the objectives and operations of the processor in a way that connotes sufficient detail. *Id.*

Similarly, claim 5 of the ’269 recites a “processor” “adapted for” performing the following functions: (1) receiving pulse oximetry sensor data and airflow sensor data; (2) calculating certain data; and (3) providing, through a “second output” to some sort of “nonvolatile memory.” While claim 5 adds a third function to the processor, it provides no

further information regarding the structure of the claimed processor. *Id.*, ¶ 55. Like claim 15, the processor in claim 5 is simply “adapted for” performing these functions, and the claim does not describe how the processor receives the sensor data or whether the processor is connected to the PAP device at all. *Id.*

Claim 14 of the ’698 patent is directed to a method of remote sleep analysis, which includes (1) applying sensors to a patient for collecting data; (2) connecting the sensors to a patient interface box for collecting data; (3) storing the data; (4) transmitting the data to an electronic interface; (5) analyzing the data on some otherwise undescribed computer or processor; (5) medically analyzing the data and communicating the diagnosis to the patient. The claim describes the processor solely in functional terms, that it analyzes the transmitted data “to identify and draw attention to physiological and technological events in the data.” *Id.*, ¶ 56; *see also Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 172 F.3d 836, 843 (Fed. Cir. 1999) (differentiating between means-plus-function, which applies to “‘structure’ and ‘material,’” and step-plus-function, which applies to “acts”). The processor is not connected to any other structures in the claim; it simply needs access to the transmitted data. *ResMed Ex. 1*, ¶ 56. And while that data is transmitted in the claim to an “electronic interface for receiving the data for review by medical personnel,” the processor is not recited to be part of the electronic interface or even connected to it in any way. *Id.* Claim 14 of the ’698 patent recites that the function is performed by a computer or a processor, suggesting that the processor is unbounded because it is not simply a computer. *Id.*

The term “processor,” without more, does not indicate structure to person of skill in the art. *Id.*, ¶ 57. A processor can come in many forms—it can be a computer, a central processing unit, a microprocessor, or any other device with processing capability. *Id.* Given the breadth of

“processor” disclosed in the specification, a person of ordinary skill would have no information about what structure falls within or outside the scope of the term, whether that processor is internal or external or in any sort of device. ’269 patent, 8:26-36, 18:60-19:7. The recited processors are described only by their function, and the claims do not detail the operations of the processor or how the processor “interacts with other components in the [sleep disorder treatment system] in a way that might inform the structural character ... or otherwise impart structure” to the processor. *Williamson*, 792 F.3d at 1351. CleveMed contends these claims “describe the interaction/relationship between the processor” and other elements. Thus, the patentees took advantage of means-plus-function claiming and § 112, ¶ 6 applies.

Second, the claimed “processor” in claim 1 of the ’269 patent, claim 8 of the ’535 patent, and claims 1 and 13 of the ’937 patent is recited as an element of either a PAP device or a portable patient interface box. Claim 1 of the ’269 patent, for example, recites a signal processing module, a PAP device with several components, a mask or a nasal cannula, and a module transceiver. ResMed Ex. 1, ¶ 59. The PAP device is claimed to have a separate enclosure from the signal processing module, and comprises a blower, a second input, an airflow sensor, and a processor. *Id.* While the processor is part of the PAP device, it is still described in purely functional terms—it is “adapted for” receiving data from two sensors and calculating symptom data. *Id.* The claim does not recite any structure connecting the processor to the sensors; indeed, although the PAP device comprises several elements including a processor, the claim does not require that the processor be structurally integrated into the PAP device. *Id.* Although the claimed airflow sensor is described as “internal to the PAP device,” the processor is not recited as internal or even connected in any way to the PAP device.

Claim 8 of the '535 patent and claims 1 and 13 of the '937 patent are similar. While the claims recite that the portable interface box comprises several elements including the processor, the processor is described solely in functional terms. There is no requirement that the processor be structurally integrated into the portable interface box.

ii. The “Processor” Terms Are Indefinite.

If construed under § 112, ¶ 6, the parties agree that the function for each “processor” is recited in the claims themselves. The parties disagree about the corresponding structure. CleveMed’s portion of the joint claim construction chart describes that the structure is a “processor programmed to perform the identified functions” and provides a laundry list of specification citations. However, CleveMed devotes none of its opening brief to this argument, and should be precluded from presenting it for the first time in its reply brief.

General purpose computing hardware, however, is not adequate corresponding structure under *Williamson* and its progeny. When the disclosed structure is a computer or processor configured to carry out an algorithm, the Federal Circuit requires disclosure of a specific algorithm in the specification. *Aristocrat Techs. v. Int’l Game Tech.*, 521 F.3d 1328, 1331-32 (Fed. Cir. 2008); *see also Williamson*, 792 F.3d at 1352. Here, each of the claimed processors performs functions requiring an algorithm, such as receiving data, calculating data, digitizing and storing data. ResMed Ex. 1, ¶ 64. For instance, claim 15 of the '269 patent requires that the processor “calculate[e] both symptom data of a severity of the subject’s sleep disorder symptoms and/or an index of a subject’s symptoms measured during use of the PAP device and data of usage of the PAP device.” *See also* claims 1 and 5 (similar functions). This cannot be performed by a general-purpose computer; the processing device (whatever it is) must be specially programmed to perform these specific, specialized calculations. *Id.* The '269 patent does not

disclose any algorithms for performing this calculation. As discussed above with regard to Term 2, the specification fails to disclose the claimed “calculating ... symptom data” and the claimed “index” and therefore fails to link the claimed function to any structure disclosed in the specification. Also, the patent merely discloses a black box that takes the “signals or data from the one or more sensors” as inputs and determines “a quantitative level of severity of a subject’s sleeping disorder and/or symptoms.” ’269 patent, 18:60-64, 3:29-36, 5:31-41, 19:46-49, 20:1-4 (“Various algorithms known to those skilled in the art are used to filter out noise from the signal or data, and to then quantify the level of severity of the subject’s sleeping disorder or symptoms.”), 23:18-33; *see also* ResMed Ex. 1, ¶ 65. As discussed above for Term 2, even if the signal processing techniques at columns 20-21 could be considered linked to the claimed function, they do not provide a sufficient algorithm because they merely disclose generic, well-known tools to process data, and do not disclose an algorithm that results in calculation of the claimed “symptom data” or indices. *Id.* Moreover, the signal processing techniques do not disclose how to calculate the claimed symptom data and indices “based at least in part on both the respiratory airflow data and the pulse oximetry sensor data” as recited in claims 1 and 5. For example, the specification does not describe how to process the pulse oximeter data at all to perform the claimed “calculating” function, nor does the specification describe how to reconcile when the pulse oximetry data conflicts with the airflow data. *Id.*, ¶ 66.

Similarly, the “collecting, measuring, digitizing and storing” functions of the processors claimed in the ’535 and ’937 patents and the “analyzing” function of the processor in the ’698 patent require a specially programmed computer, and no such algorithm is disclosed in the specification. *Id.*, ¶ 67. For example, the ’535/’937 patent specification does not disclose an algorithm for “measuring ... airflow, respiratory effort, blood oxygenation and body position,”

and instead merely provides, for example, individual exemplary sensors that can be used. *See, e.g.,* '535 patent, 10:60-64 (“Measurement of oxygenation and ventilation is preferably measured by pulse oximetry,” etc.), 11:15-34 (measuring respirations with “a nasal cannula or a facemask” and “a pressure transducer”). With regard to the “analyzing” function of the '698 patent term, the specification merely provides a list of exemplary events, and fails to provide any guidance, let alone an algorithm, of how the processor allegedly identifies or “draw[s] attention to” those events. *See, e.g.,* '698 patent, 20:61-21:10. The specifications further notes that the system is “programmable” to perform the claimed functions. '698 patent, 11:12-15, 13:15-19, 14:3-6, 24:35-39; '535 patent at 12:36-38, 14:43-47, 15:17-30; '937 patent, 12:43-45, 14:47-54, 15:34-37.

Accordingly, the disputed terms are indefinite because the specification fails to disclose sufficient corresponding structure.

3. Plaintiff’s Reply Position

a. Terms 4-7, 10-12, 17⁷

Terms 4-6, 10-12, and 17 are not subject to §112(6) as they all recite the objectives and operations of the processor, such that a POSITA would “understand the structural arrangements of the processor” and its “location and its relationship to other components.” *See* Opening at 51-56. Defendant fails to demonstrate that these terms do not recite a definite structure and fails to overcome the presumption that they are not means-plus-function limitations. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348-49 (Fed. Cir. 2015). Defendant’s arguments simply ignore CleveMed’s showing of the processors’ significant structural details and interactions with other components, which undermines Defendant’s position. Opening at 52-56; Answer at 57-62;

⁷ Defendant concedes Term 7, as it failed to address this term.

Zeroclick, LLC v. Apple Inc., 891 F.3d 1003, 1008 (Fed. Cir. 2018) (“[T]he mere fact that the disputed limitations incorporate functional language does not automatically convert the words into means for performing such functions.”) (citation omitted).

i. Defendant’s Inconsistent Claim Construction Positions

Similar to Term 2, Defendant did not assert before the PTAB that the “processor” terms in the ‘269 Patent are means-plus-function. Rather, Defendant used the plain and ordinary meaning of “processor” and compared that ordinary meaning to the alleged prior art. *See* Kobialka Opening Decl., Ex. 1, IPR2023-00565, Paper 1 at 36-39, 44-46, 65-68 (P.T.A.B. Mar. 22, 2023); *see also In re Donaldson Co.*, 16 F.3d 1189, 1193-94 (Fed. Cir. 1994) (en banc) (district courts and PTAB apply same claim interpretation standard to means-plus-function limitations).

ii. Section 112(6) Does Not Apply to the Processor Terms

Defendant attempts to divide the processor claims into two categories, but in each instance, ignores critical claim language showing how the processor is integrated into the system and how it interacts with the other components. Jafari Reply Decl., ¶¶ 22-26. In its first category, Defendant claims that the processor in Claim 15 of the ‘269 Patent is not structurally a part of or connected to other elements. Answer at 59-63. This ignores the processor’s connection to the PAP device’s internal airflow sensor from which it receives the airflow data and its connection to the first radio frequency wireless module which receives the calculated symptom data and level of severity for transmission to the base station, cellular phone, or PDA. ‘269 Patent at Claim 15; Jafari Reply Decl., ¶¶ 23-24. In Claim 5 of the ‘269 Patent, the processor connects with and receives inputs from the pulse oximetry sensor and airflow sensor prior to calculating symptom data and a level of severity, and outputting its calculations to nonvolatile memory where it can be

used for transmission to a remote location. '269 Patent at Claim 5; Jafari Reply Decl., ¶¶ 23-25.

Thus, the claimed processor elements inform a POSITA of its structure based on the interactions with the other components as recited in the claims. Jafari Reply Decl., ¶¶ 23-25.

Similarly, Defendant reads the “computer or processor” limitation of Claim 14 of the '698 Patent in isolation to draw the same incorrect conclusion. Jafari Reply Decl., ¶ 25. When read as a whole, the claimed computer or processor receives the sensor data from the memory of the patient interface box so it can analyze the data to identify physiological and technological events indicative of a sleeping disorder. '698 Patent at Claim 14. Thus, the claim as a whole informs a POSITA not only of the structure, but also how the computer or processor interacts with other components of the claimed invention. Jafari Reply Decl., ¶ 25.

In its second category, Defendant admits that processor is structurally part of the PAP device in Claim 1 of the '269 Patent and the portable patient interface box in the claims for the '535 and '937 Patents. Thus, the processor is in the PAP device and the portable patient interface box. Defendant makes the nonsensical argument that even though the PAP device of Claim 1 of the '269 Patent includes the processor, the PAP device's processor is not connected to the PAP device because the word “internal” is not recited and there is no description regarding how the PAP's processor is connected to the PAP device. There is no need for such language because the processor is a claimed part of the PAP device. Thus, the structure and interaction of the processor with other components of these claimed inventions are disclosed. Jafari Reply Decl., ¶¶ 26-27. For the claims of the '535 and '937 Patents, Defendant offers no argument for why a POSITA would not understand the claimed processors' structure and its interaction with other components. Answer at 62-63; Jafari Reply Decl., ¶¶ 28-29. Thus, Section 112(6) does not apply.

Even if the Court did apply Section 112(6), the specifications of the Asserted Patents provide further structure showing how the processors receive inputs from the sensors, calculates symptom data, and facilitates the storing and transferring of the calculated data. For example, the '269 Patent disclosed that the processor receives sensor inputs through wired or wireless connections and tells a POSITA various means for how to calculate the data. '269 Patent at 8:26-30 (showing that the processor receives inputs from the data either wirelessly or through a wired connection); *id.* at 20:1- 21:67 (disclosing methods for calculating); *id.* at 15:64-16:21 (describing how to adjust parameters for better resolution of the A/D converter). In addition to the receipt and calculation of the above, the processor is responsible for facilitating the transfer and display of its calculated data. '269 Patent at 19:35-45 ("computer or processor, which receives the data transmission and displays the data . . . [and] transfer[s] it] for analysis.").

The specifications of the '937 and '535 Patents disclose further support for the structure of the processor and describe how it collects, measures, digitizes and stores patient data to the memory. *See, e.g.*, '937 Patent at 2:65-3:16, 3:66-6:45, 8:60-9:22 ('535 Patent at 2:55-3:6, 3:56-6:38, 8:52-9:14) (describing collection of data, e.g., "collecting multiple channels of data to evaluate a number of . . . features . . ."); '937 Patent at 10:57-12:14 ('535 Patent at 10:49-12:6) (detailing the techniques used to measure various physiological signals such as airflow, respirations, oxygenation and body position based on sensors); '937 Patent at 14:43-63 ('535 Patent at 14:36-56) (describing programming of system to, *inter alia*, "send all signal data to the removable memory . . ."); '937 Patent at 17:59-67 ('535 Patent at 17:51-59) (describing modules of system including "patient interface module that can collect, digitize, store, and transmit data. . ."); '937 Patent at 18:24-39 ('535 Patent at 18:16-31) (describing encoding techniques); '937 Patent, Figs. 2, 5 (showing processor and interaction with other elements).

Similarly, the specification of the '698 Patent discloses further support for the structure of the “computer or processor” and explains how it analyzes transmitted data to identify and draw attention to physiological and technological events in the data. *See, e.g.*, '698 Patent at 15:40-16:2, 27:34-67, Figs. 8-9 (describing computer/processor and relationship with other components); *id.* at 20:37-21:15 (describing analysis by computer/processor of the received signals to draw attention to physiological and technological events).

iii. The Processor Terms are Definite

Defendant fails to establish by clear and convincing evidence that the processor terms are indefinite. *BASF Corp.*, 875 F.3d at 1365. Here, Defendant simply parrots their arguments for Terms 2 and 3, which fail to acknowledge that a POSITA within the sleep medicine field would readily understand how to achieve and program the processor to perform these types of calculations and how to reconcile any conflicts that may arise in the inputs. Jafari Reply Decl., ¶ 27. Further, in its Section 112(6) argument, Defendant identifies the processor as part of the system and for performing the recited functions rendering the claims definite. Answer at 59-63; *UltimatePointer, L.L.C. v. Nintendo Co.*, 816 F.3d 816, 826 (Fed. Cir. 2016) (if an apparatus claim “is clearly limited to an apparatus possessing the recited structure and capable of performing the recited functions, then the claim is not invalid as indefinite.”) (internal quotations and citation omitted).

A POSITA knows how to program a processor to perform the “collecting, measuring, digitizing, and storing” functions and the “analyzing” function when reading the claims of the '698, '535, and '937 Patents in light of the specification. Jafari Reply Decl., ¶¶28-30. For example, in the '535 and '937 Patents, the measuring of airflow, respiratory effort, blood oxygenation and body position is accomplished using the different sensors disclosed and a

POSITA understands how to incorporate each sensor's measuring capability into the claimed invention. Jafari Reply Decl., ¶¶ 28-29; '535 Patent at 10:49-12:6 (disclosing techniques to measure airflow, respirations, oxygenation, and body positions with different sensors). A POSITA would understand that "analyzing the transmitted data with a computer or processor to identify and draw attention to physiological and technological events in the data" is a common analysis in the sleep medicine field and thus, know how to appropriately program the processors of the Asserted Patents. Jafari Reply Decl., ¶ 30; '698 Patent at 20:37-21:15 (disclosing embodiments to accomplish identify notable physiological and technological events).

Therefore, these terms are definite and require no further construction.

4. Defendant's Sur-Reply Position

a. Terms 4-6, 10-12, 17

i. "Processor" Is A Means-Plus-Function Term.

Neither Dr. Jafari nor CleveMed dispute the breadth of "processor" and neither tries to explain what structure a "processor" has. ResMed Ex. 1, ¶57 ("processor" could be "any ... device with processing capability"). Thus, CleveMed is wrong that the claims "as a whole" recite "the objectives and operations of the processor."

CleveMed and its expert confirm that "processor" is claimed in purely functional terms. For claims 5 and 15 of the '269 patent and claim 14 of the '698 patent, Jafari identifies the functional "objectives:" "receive" sensor data; "calculate" or "analyze" data; and "output" calculations. Reply, 64-66. But CleveMed fails to identify any structure in the claims that (a) connects the processor to the sensor, (b) performs the claimed calculations, or (c) transmits the output. See *Syneron*, 2018 WL 4696971, at *13 (distinguishing cases that did not apply 112, ¶6 when no "operation" disclosed). Instead, CleveMed improperly reads the specification into the claim. But the specification is even more ambiguous, disclosing "some form of device" that

transmits data “through either a wireless system, a tethered system or some combination thereof.” ’269 patent, 8:26-30; *see Williamson*, 792 F.3d at 1351 (rejecting written description that fails to describe the structural interaction between components). Patentees cannot broadly claim function and avoid means-plus-function by disclosing in the specification that the functions can be performed by any structure.

These “processor adapted for” terms are most similar to the “processor configured to” means-plus-function claims in *St. Isidore* and *Syneron*, which CleveMed never addresses. Answer, 57-58.

The claims in the second category recite some structure, but the processor is still claimed in purely functional terms. CleveMed takes the extreme position that the nonce word “processor” is not means-plus-function simply because the PAP device or patient interface box comprises several aspects, including a processor. Reply, 64-65. But this would elevate form over substance and allow drafters to claim functionality simply by tying it to (but not structurally integrating it into) some device. *See Takadu*, 2023 WL 2563157, at *2, *8 (construing “analysis engine” of a “computerized system” as means-plus-function). Again, the claims do not disclose the “operation” for performing the claimed functions (*i.e.*, the structure for receiving data from the sensors and calculating symptom data), and CleveMed does not identify any.

CleveMed’s argument that the specifications disclose “how to calculate the data” or “how it collects, measures, digitizes and stores patient data” is a red herring. First, the claims do not recite structure for performing these functions; just the structure-less “processor.” Second, the specification does not disclose how to perform the function. CleveMed identifies no structure or algorithm, and simply states that “POSITA is informed as to the various algorithms needed to perform these functions.” Jafari Reply Decl. ¶29. This is insufficient.

ii. The “Processor” Terms Are Indefinite.

By failing to raise it in its opening position, CleveMed waived any argument that if the “processor” terms are construed as means-plus-function, the specification discloses sufficient structure. *See* L.R. 7.1.3(c)(2). Even if the Court considers CleveMed’s reply, CleveMed has not identified a special purpose computer or sufficient disclosure to inform POSITA how to program a general purpose computer. Answer, 61-62. For instance, CleveMed does not identify any disclosure for calculating “both symptom data of a severity of the subject’s sleep disorder symptoms and/or an index of a subject’s symptoms.” *Id.* CleveMed relies solely on Jafari’s summary statement that “POSITAs are aware of the various algorithms” or “know how to program a processor to perform these calculations.” Jafari does not support his claims or identify the algorithms a POSITA would know to perform that function. Even if he had, his conclusory extrinsic testimony is not enough; the specification must disclose the algorithm. *Aristocrat*, 521 F.3d at 1331-32.

For the ’535, ’937, and ’698 processor claims, while collecting, measuring, digitizing, storing, and analyzing are described at a high level, no algorithm is disclosed, and CleveMed does not point to any. Instead, Jafari again tries to fill the gaps by saying a “POSITA is informed how to structure the processor to perform the claimed function,” but this is “simply a description of the outcome of the claimed functions, not a description of the structure, i.e., the computer programmed to execute a particular algorithm.” *Id.* at 1334-35.⁸

⁸ CleveMed’s criticism of ResMed’s proposal here that “processor” is means-plus-function while asking the PTAB in the IPR to adopt CleveMed’s position (plain meaning) for purposes of the IPR only ignores accepted PTAB practice. *See Spherix Inc. v. Matal*, 703 F. App’x 982, 983 (Fed. Cir. 2017); *Intel Corp. v. Alacritech, Inc.*, IPR2017-01391, Paper 8 at 7 (PTAB Nov. 28, 2017).

Respectfully submitted,

By: /s/ Philip A. Rovner

Philip A. Rovner (#3215)
Jonathan A. Choa (#5319)
**POTTER ANDERSON &
CORROON LLP**
Hercules Plaza
1313 N. Market Street, 6th Floor
P.O. Box 951
Wilmington, DE 19899
Telephone: (302) 984-6000
provner@potteranderson.com
jchoa@potteranderson.com

OF COUNSEL:

Paul J. Andre
Lisa Kobialka
James Hannah
Timothy Layden
Sabah Khokar
**KRAMER LEVIN NAFTALIS
& FRANKEL LLP**
333 Twin Dolphin Drive, Suite 700
Redwood Shores, CA 94065
Telephone: (650) 752-1700
pandre@kramerlevin.com
lkobialka@kramerlevin.com
jhannah@kramerlevin.com
tlayden@kramerlevin.com
skhokar@kramerlevin.com

*Attorneys for Plaintiff
Cleveland Medical Devices Inc.*

DATED: June 21, 2023

Respectfully submitted,

By: /s/ Brian A. Biggs

Brian A. Biggs (Bar No. 5591)
Angela C. Whitesell (Bar No. 5547)
Matthew S. Middleton (Bar No. 6877)
DLA PIPER LLP (US)
1201 North Market Street, Suite 2100
Wilmington, DE 19801-1147
Telephone: 302.468.5700
Facsimile: 302.394.2341
brian.biggs@us.dlapiper.com
angela.whitesell@us.dlapiper.com
matthew.middleton@us.dlapiper.com

Sean Cunningham
Tiffany Miller
David Knudson
DLA PIPER LLP (US)
401 B Street Suite 1700
San Diego, California 92101-4297
Telephone: 619-699-4787
Facsimile: 619-764-6787
sean.cunningham@dlapiper.com
tiffany.miller@dlapiper.com
david.knudson@dlapiper.com

Nancy Braman
DLA PIPER LLP (US)
33 Arch Street 26th Floor
Boston, Massachusetts 02110-1447
Telephone: 617-406-6000
Facsimile: 617-406-6100
nancy.braman@dlapiper.com

*Attorneys for Defendant
ResMed, Inc.*