

Filed on behalf of: ResMed Corp.

Filed: January 14, 2026

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,

Petitioner,

v.

CLEVELAND MEDICAL DEVICES INC.,

Patent Owner.

Case No. IPR2025-00246
U.S. Patent No. 11,857,333

**PETITIONER'S REPLY TO
PATENT OWNER'S RESPONSE**

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1004	Curriculum Vitae of Jason Kirkness, Ph.D.
1005	Declaration of Sandeep Chatterjee, Ph.D. (“Chatterjee”)
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1007	RESERVED
1008	U.S. Patent Pub. No. 2002/0198473 to Kumar et al. (“Kumar”)
1009	U.S. Patent No. 7,575,005 to Mumford et al. (“Mumford”)
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1011	“ <i>T-Mobile USA and HP Launch the First Truly Integrated Wireless iPAQ Handheld - T-Mobile Newsroom</i> ” (July 2004) available at https://www.t-mobile.com/news/press/t-mobile-usa-and-hp-launch-the-first-truly-integrated-wireless
1012	WIPO Publication No. WO2005096737A2 to Farrell et al. (“Farrell”)
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1015	M. Berthon-Jones, "Feasibility of a Self-Setting CPAP Machine," <i>Sleep</i> 16:S120-123 (1993) ("Berthon-Jones 1993")
1016	D. Rapoport, "Methods to Stabilize the Upper Airway Using Positive Pressure," <i>Sleep</i> 19(9):S123-S130 ("Rapoport 1996")
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1019	S. Thompson et al., "Sleep as a Teaching Tool for Integrating Physiology and Motor Control," <i>Advances in Physiology Education</i> (2001)
1020	U.S. Patent No. 5,704,345 to Berthon-Jones ("Berthon-Jones345")
1021	U.S. Patent No. 7,168,429 to Matthews et al. ("Matthews")
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1023	C. Sullivan, "Reversal of Obstructive Sleep Apnoea by Continuous Positive Airway Pressure Applied through the Nares," <i>Lancet</i> 1981:1862-5 ("Sullivan 1981")
1024	U.S. Patent No. 6,484,719 to Berthon-Jones ("Berthon-Jones719")
1025	Teschler, H., et al., "Automated Continuous Positive Airway Pressure Titration for Obstructive Sleep Apnea Syndrome," <i>Am. J. Respir. Crit. Care Med.</i> 54:734-740 (1996)
1026	ResMed, "AutoSet Portable II Plus Overview & Interpretation Guide, Rev. 1," (1999)

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1027	ResMed, "AutoSet T, Optimal Therapy for your OSA Patients," (2000)
1028	Sunrise Medical, "DeVillibis® AutoAdjust™ LT Nasal CPAP System Instructions Guide Model 8054," (1999)
1029	Respironics, "Introducing the REMstar Auto. A simply smarter Smart CPAP" (2002)
1030	ResMed Origins, downloaded from https://document.resmed.com/en-us/documents/articles/resmed-origins.pdf on May 3, 2022.
1031	RESERVED
1032	F. Roux, et al., "Continuous Positive Airway Pressure: New Generations," Clinics in Chest Medicine (2003)
1033	Loube, D., "Technologic Advances in the Treatment of Obstructive Sleep Apnea Syndrome," CHEST 116:1426-1433 (1999)
1034	American Academy of Sleep Medicine Task Force. (1999). <i>Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. Sleep, 22(5), 667-689</i>
1035	J. Meurice, et al., "Efficacy of Auto-CPAP in the Treatment of Obstructive Sleep Apnea/Hypopnea Syndrome," Am. J. Respir. Crit. Care Med. 153:794-8 (1996)
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1038	C. Lilly, et. al., "Critical Care Telemedicine: Evolution and State of the Art," Critical Care Medicine 42:2429-2436 (2014)
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1040	K. Zundel, "Telemedicine: history, applications, and impact on librarianship," Bull Med Libr. Assoc. 84:71-79 (1996)
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1043	D. Lankford, "Wireless CPAP Patient Monitoring: Accuracy Study," Telemedicine Journal and e-Health 10:162-169 (2004)
1044	Japan Patent Office Patent Application Pub. No. P2002-291889A to Toge ("Toge")
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1058	Declaration of Dr. Carolyn D'Ambrosio, submitted by Patent Owner in the District Court litigation
1059	U.S. Patent Pub. No. 2005/0268912 to Norman et al. ("Norman")
1060	U.S. Patent No. 6,675,797 to Berthon-Jones
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I. INTRODUCTION

The Petition established that the challenged claims of the '333 Patent (directed to a networked PAP device) would have been obvious over Toge in view of the knowledge of a POSITA or in view of Kumar and Norman. PO primarily argues that Toge does not calculate “a quantified level of severity data” and does not include a processor “integrated into” the PAP. But PO's arguments are unsupported, ignore disclosures in Toge and Norman, and conflict with the law.

II. GROUND I: THE CHALLENGED CLAIMS ARE OBVIOUS OVER TOGE IN VIEW OF KUMAR

A. Toge and Kumar render obvious “analyzing with the processor the collected data to determine a ‘quantified level of severity data’ based on the subject’s sleep apnea symptoms during therapy.”

The Petition establishes that Toge's tidal volume is a “quantified level of severity data.” Pet., 15; *see also* DI 20-21. Specifically, the Petition describes Toge's disclosure of a “control unit 250 (‘processor’) to calculate/determine certain parameters” and, in particular, that “calculates the tidal volume [] based on the air pressure and/or flow rate.” *Id.* The Petition explains that the “tidal volume” as determined by the control unit is “a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy” because a POSITA would have understood that it represents the “level [or “severity”] of airway obstruction the patient experiences during the sleep apnea treatment using the PAP device.” *Id.*; Kirkness ¶157-159. The tidal volume is “quantified” because it is a calculated

volume, that once it reaches a particular threshold level, can trigger data transmission to alert a physician if, for instance, the volume is “zero milliliters per breath,” a complete absence of airflow. Pet., 15-16; Kirkness ¶¶157-159. The PAP therapy can be adjusted based on the “quantified level of severity” symptom data to, for example, “counter/treat the more severe level of airway obstruction observed from the decreasing tidal volume.” Kirkness ¶158.

1. “Quantified level of severity data” should be given its plain and ordinary meaning

In order to evade the prior art, PO offers a narrow claim construction for a “quantified level of severity data,” stating it should mean “a [calculated] value that indicates how dire a patient’s symptoms are.” POR, 8. But PO’s construction lacks both intrinsic and extrinsic support.

“quantified level of severity data”	
Petitioner’s Construction	PO’s Construction
plain and ordinary meaning	a [calculated] value that indicates how dire a patient’s symptoms are ¹

¹ Although the Petition quotes the related language from Dr. Ambrosio’s declaration (Pet., 4, 17), it was only to demonstrate how the prior art meets the claim limitation even under PO’s interpretation. Petitioner did not and does not adopt Dr. Ambrosio’s “definition” of “quantified level of severity” in its claim construction

PO suggests its construction “is consistent with the plain language of the term and with the position CleveMed’s expert, Dr. D’Ambrosio, advanced in a parallel litigation between the parties²” Pet, 8; EX1058. It is neither.

To begin with, PO points to no intrinsic evidence to support its construction, and that is because there is none. Neither the ’333 patent nor the claims define a “quantified level of severity data,” let alone as “a calculated value that indicates how dire a patient’s symptoms are.” And there is no other description in the patent to justify defining it as such. In fact, the patent specification’s disclosures regarding determining a level of symptom severity are broad, establishing that it can generally be derived from any sensor data and/or breathing events. *See* EX1001, 3:44-46 (“Signals from the[] sensors are then analyzed to determine the level of severity of the symptoms of the subject’s sleep disorder...”); *id.*, 22:25-28 (“The 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

section and, as further discussed below, PO has altered Dr. D’Ambrosio’s testimony for its construction of the term here.

² *Resmed Corp. v. Cleveland Medical Devices, Inc.*, Case No. 1:23-cv-02221-BMB (N.D. Ohio Nov. 16, 2023).

more sensors described herein”); *id.*, 49:5-8 (“[T]he pressure can be increased by differing amounts depending on ... the severity of the breathing events”); *see also* Kirkness ¶106.

Second, PO's construction is not consistent with Dr. D'Ambrosio's referenced statements³ or their purpose and, thus, is not supported by them. Dr. D'Ambrosio was not addressing the meaning of any terms. Her opinions were on whether certain terms in the '512, '029, and '333 patents had written description support (“I also understand the parties disagree whether certain claims are definite. ...I have been asked for my opinion as to whether the claim terms described below are definite under [the above] standards.”). EX1058 (D'Ambrosio Decl) ¶¶26-27. To conflate determining written description support for a claim term with the term's meaning is legally improper. *See, e.g., Trading Techs. Int'l, Inc. v. Open E Cry, LLC*, 728 F.3d

³ Petitioners note that PO does not cite Dr. Ambrosio's written description statements accurately, instead, opting to broaden them. Dr. D'Ambrosio stated that clinicians understood “level of severity” “to **represent** the [sic] how dire a patient's **calculated symptom data may be**”). EX1058 ¶32 (emphases added). Thus, Dr. D'Ambrosio's description was conditional (“may be”) as opposed to absolute (“are”), as PO contends. Additionally, Dr. D'Ambrosio described “calculated symptom data” as opposed to PO's altered construction of “a patient's symptoms,” generally. *Id.*

1309, 1319 (Fed. Cir. 2013) (“[C]laim construction and the written description requirement are separate issues that serve distinct purposes”).

Third, PO also alleges that Dr. D'Ambrosio and Dr. Schwartz equated specific sleep apnea indices (respiratory disturbance index (RDI) and apnea-hypopnea index (AHI)) with “level of severity.” POR, 8-9. (“Dr. Schwartz’s understanding” was “that sleep apnea indices represent the level of severity of sleep disordered breathing with sleep apnea indices”). But that is not what either expert said. Dr. Schwartz opined on whether the term “index of treatment efficacy” had written description support in the specification of another patent, U.S. Patent No. 11,602,284 (“the ’284 patent”)⁴ (EX2026), a patent not even related to the ’333 patent. Thus, Dr. Schwartz performed a written description analysis of different claim terms for a different patent. Relying on his testimony is improper. *Trading Techs. Int’l*, 728 F.3d at 1319. Moreover, Dr. Schwartz did not mention AHI or RDI at all in his discussion.⁵

⁴ ’284 claim 1 language: “index of treatment efficacy of the subject using a PAP device” where “the index [is] based in part on data of severity of sleep disorder symptoms of the subject.” EX2026 ¶42.

⁵ Dr. Schwartz discussed how PO’s statements during the prosecution of a patent related to the ’284 patent (U.S. Patent No. 10,076,269) were inconsistent with PO’s

And Dr. D'Ambrosio indicated that sleep apnea indices were but an example of a way to determine a "level of severity," not that the indices were required or the only means to do so, which is what PO appears to suggest here (*see* POR, 8-9). *See* EX1058 ¶32. Finally, nothing in the '333 patent specification limits determining "a quantified level of severity" to the calculation of AHI and/or RDI (in fact, RDI is nowhere mentioned in the specification), and PO identified no support in the specification for such a narrow interpretation.

For the foregoing reasons, a "quantified level of severity data" should be given its plain and ordinary meaning instead of being cabined by PO's definition, which is unsupported by both the intrinsic and extrinsic evidence.

2. Toge's tidal volume is a "quantified level of severity data based on the subject's sleep apnea symptoms during therapy" under either construction

Toge discloses calculating a "quantified level of severity data" under both its plain and ordinary meaning and PO's erroneous construction. The Petition establishes that tidal volume is "a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy" as, under both constructions, it "represents the level of severity based on the patient's sleep apnea symptoms during

position regarding written description support for "level of severity" in the PGR proceeding. *See* EX2026 ¶46.

the treatment, because it represents, for example, the level of airway obstruction the patient experiences during the sleep apnea treatment using the PAP device.” Pet., 15; Kirkness ¶157. The “level of airway obstruction” is a “level of severity” of a patient’s apnea symptoms. *Id.* Dr. Kirkness also describes that in Toge, a physician can monitor a patient’s condition (i.e., apnea symptoms) through assessing “tidal volume information.” *See* Kirkness ¶157. Further, the ’333 patent clearly states that “[s]ignals from the[] sensors are [] analyzed to determine the level of severity of the symptoms of the subject's sleep disorder.” EX1001, 3:44-47. Toge’s PAP system does just that, the reference extensively detailing how the PAP/CPAP processor could calculate tidal volume based on data obtained from system sensors. *See* EX1044 [0034]-[0037]; *id.* [0038] (“The control unit 250 substitutes the determined values of Ft, Fa, and Fb into the above formula (1) to calculate the tidal volume Fp.” ... “Furthermore, there are tidal volumes per breath and minute ventilation volumes calculated per minute. The control unit 250 calculates either or both of these based on the settings.”. *Id.* As such, tidal volume is “*a quantified level of severity*” and “*a calculated value* that indicates how dire a patient’s symptoms are.” Pet., 15-17; Kirkness ¶¶156-60; Chatterjee ¶¶120-25.

PO, however, argues that “[t]idal volume data is not a calculated AHI, RDI, or other ‘quantified level of severity data,’” it is a breathing metric that may be used to identify obstructive breathing events, such as apneas and hypopneas.” POR, 8

First, PO's statement is incorrect. As discussed above, the Petition and Dr. Kirkness describe why tidal volume is a "quantified level of severity data." *See supra*. Second, PO's statement is irrelevant. Neither the patent nor the claims require calculation of AHI, RDI, or any other index to determine a "quantified level of severity data." *See* discussion II.A.1 *supra*. PO's attempt to limit the claims to those indices is unwarranted. Petitioner also notes that in the paragraph PO cites to in Dr. Schwartz's declaration, he indicates that breathing metrics are a level of severity data. *See* EX2026 ¶46 ("standard sleep disordered breathing *metrics*" [] were well validated *indicators of the type and severity* of sleep disordered breathing") (emphasis added).

Accordingly, because Toge's tidal volume is a "quantified level of severity data based on the subject's sleep apnea symptoms during therapy," Toge in view of Kumar, render obvious the challenged claims. Kirkness ¶157.

III. GROUND II: THE CHALLENGED CLAIMS ARE OBVIOUS IN VIEW OF TOGE AND KUMAR IN FURTHER VIEW OF NORMAN

A. Toge in view of Kumar and Norman render obvious a PAP system that determines a "quantified level of severity data based on the subject's sleep apnea symptoms during the therapy"

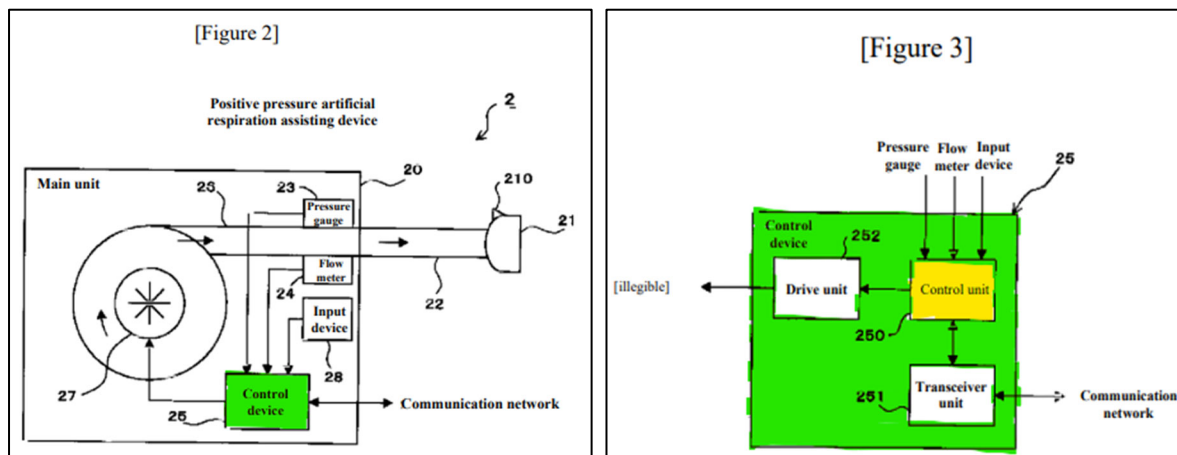
The Petition describes Norman's disclosure of "a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy" in combination with Toge and Kumar. Pet., 57-58; *see also* Kirkness ¶235; Chatterjee

¶227.

But PO argues that “Norman does not determine ‘a quantified level of severity data’ (identified as counts/indexes) using a processor “integrated” into the PAP device” because “[n]either Toge nor Norman discloses the claimed “processor . . . integrated into the PAP or CPAP device.” POR, 12. To make out its argument that the processor disclosed in Toge and Norman is not “integrated into” the PAP/CPAP, PO proposes a specific construction for “integrated into” stating, “[i]n the context of the claim, ‘integrated into’ means that the processor is inside the PAP/CPAP device.” POR, 13. PO’s construction is improper. PO again provides no intrinsic evidence to support its construction of “integrated into,” and nothing from the specification or the claims indicates that the processor must be “inside the PAP/CPAP”; that is, the patent contains no definition of “integrated” and no description of the processor being “inside” the PAP. But even under PO’s construction, both Toge and Norman disclose a processor “integrated into” and “inside” of the PAP/CPAP. *See* DI, 23-24.

For instance, Toge discloses a control unit 250 that functions as the PAP’s processor. *See* EX1044 [0048] (“[T]he control unit 250 can be constructed using a program describing the processing of the control unit 250 as explained so far, along with a CPU or microcontroller (and peripheral circuits). Alternatively, it can be constructed using hardware circuits capable of executing the aforementioned

processing.”). Toge explicitly states that control device 25 containing control unit 250 is inside of the PAP. *See id.* [0021], [0023] (“The positive pressure artificial respiration assisting device 2 comprises a main unit 20” ... “equipped with ... *a control device 25*” ... that “*further comprises a control unit 250*...”. *See also* Pet., 12-13; Kirkness ¶¶150-51; Chatterjee ¶¶113-15 (emphases added). This configuration is depicted in the figures- Figure 2 shows a PAP with internal control device 25, and Figure 3 shows control device 25 having internal control unit 250 (the processor).



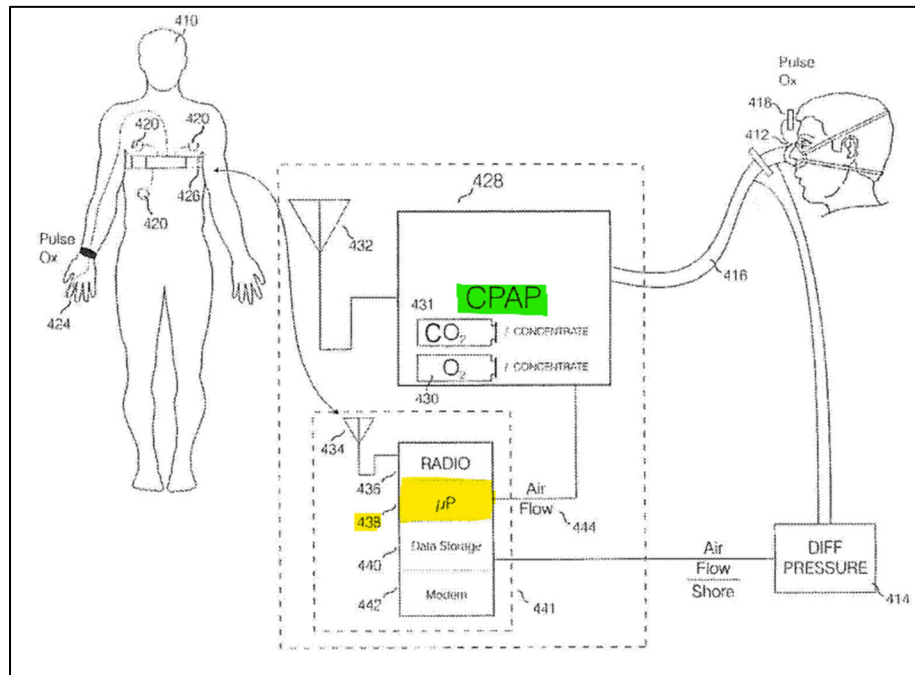
EX1044, Figures 2 and 3

PO ignores these figures in favor of solely discussing Figure 1, which does not depict control unit 250 or its configuration details. *See* POR, 13-14. In fact, even relay device 3 can be integrated into the PAP through the processor (control unit 250). *See* EX1044 [0060] (“[R]elay device 3 can be *incorporated into* the positive pressure artificial respiration assisting device 2 (*the control unit 250 of the control device 25*), allowing it to be configured as an *integrated unit with the*

positive pressure artificial respiration assisting device 2.") (emphases added); *see also* Pet., 12-13. As such, Toge's processor is integrated into the PAP. *See also* DI, 24. PO's statement to the contrary is incorrect.

Norman also discloses a processor "integrated into" the PAP/CPAP and, further, "inside" of the PAP/CPAP. *See* EX1059 [0023] ("Those skilled in the art will understand that the titration device 26 may be attached to any conventional PAP therapy system. *Alternatively, the titration device 26 may be built into the system 1* (e.g., the titration device 26 *may be combined with the processing arrangement 24*") (emphases added); *see also* Pet., 56 ("Norman discloses that titration device 26 may be combined with processing arrangement 24 (collectively the claimed "processor"). Thus, Norman explicitly states that the titration device/processing unit is "built into" (i.e., "integrated into") the CPAP system ("System 1"). *See* EX1059 [0023].

In contrast, the '333 patent does not describe (*see supra*) or even illustrate a processor "inside" of a CPAP. For instance, Figure 8, the only figure that depicts a microprocessor (microprocessor 438), does not show microprocessor 438 "inside" of the CPAP. *See* EX1001, Fig. 8. Instead, Figure 8 illustrates microprocessor 438 as being "integrated into" a cohesive, functional CPAP system (*see* dashed lines).



EX1001, Figure 8.

Thus, PO's "inside" construction appears to exclude Figure 8, a preferred embodiment.⁶ See *SynQor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1378-79 (Fed. Cir. 2013) ("A claim construction that excludes the preferred embodiment is rarely, if ever, correct") (internal quotation marks omitted).

B. A POSITA would have been motivated to combine Toge and Kumar with Norman

The Petition describes generally why a POSITA would have been motivated to further combine Norman's automated titration CPAP device with the Toge and

⁶ Figure 8 appears to be a preferred embodiment as it is depicted on the patent coverpage.

Kumar system. *See* Pet., 49-50 (Norman's "CPAP device that allows [for] 'automated titration'" that improves "the accuracy and efficacy of the CPAP treatment process" and, consequently, "patient's compliance and satisfaction"); *see also* Kirkness ¶¶222-23; Chatterjee ¶¶218-21.

Despite these disclosures, PO argues "Toge's control unit 250 does not analyze collected sensor data, it collects that sensor data and sends it to the physician's computer for analysis." POR, 15. This is nonsensical. Toge's processor is not so limited that the PAP is dependent on the physician computer to analyze data. As discussed above, the processor in Toge PAP "calculates the tidal volume" based on air pressure and flow rate' and that calculated tidal volume is "a quantified level of severity data" because it represents the "level of airway obstruction the patient experiences during the sleep apnea treatment using the PAP device." Pet., 15; Kirkness ¶¶156-157; Chatterjee ¶¶120-125. PO ignores these disclosures. PO's erroneous conclusion is also based on its belief that Norman (and Toge) do not disclose a processor located inside the PAP (POR, 15, 16) ("Norman does not cure Toge's deficiency because it also discloses analyzing sensor data at an external titration device rather than with a processor inside a PAP/CPAP device."). Petitioner has already disproved PO's incorrect interpretation above (*see* III.A *supra*).

Accordingly, a POSITA would have been motivated to further combine Norman with Toge and Kumar.

**IV. GROUNDS III AND IV: THE CHALLENGED CLAIMS ARE
OBVIOUS IN VIEW OF TOGE IN VIEW OF KUMAR AND
FURTHER IN VIEW OF BURTON AND/OR NORMAN (CLAIM 19)**

PO does not make any arguments regarding Grounds 3 and 4 beyond those for claim 15 above. POR, 16. Accordingly, for the reasons discussed above, Toge in view of Kumar and Burton and/or Norman render obvious the challenged claims.

V. CONCLUSION

The Board should find all challenged claims unpatentable.

Dated: January 14, 2026

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CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24

I hereby certify that Petitioner's Reply to Patent Owner's Response complies with the word count limitation of 37 C.F.R. § § 42.24(a)(1)(i) because the Reply contains a total of 2,840 words, calculated by Microsoft Word's word-count feature. This total excludes the cover page, signature block, and the parts of the Reply exempted by Rule 37 C.F.R. § 42.24(a)(1).

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CERTIFICATE OF SERVICE

I hereby certify that on January 14, 2026, a true and correct copy of the foregoing **PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE** is being served by electronic mail on Patent Owner's counsel of record listed below, pursuant to its Mandatory Notices:

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