

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner.

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

PATENT OWNER'S RESPONSE

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PATENT OWNER'S EXHIBIT LIST

Exhibit	Description
2001	Intentionally Omitted
2002	Intentionally Omitted
2003	Intentionally Omitted
2004	Excerpts of Plaintiff and Counterclaim Defendant ResMed Corp.'s Initial Invalidity and Unenforceability Contentions cover pleading, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 23-cv-02221-BMB (N.D. Ohio), served on July 15, 2024
2005	Excerpts of Defendant ResMed Inc.'s Initial Invalidity Contentions cover pleading from <i>Cleveland Med. Devices, Inc. v. ResMed, Inc.</i> , No. 22-cv-00794-JLH (D. Del.) (the "Delaware Case"), served on February 21, 2023
2006	Excerpts of Plaintiff ResMed Corp.'s Response and Affirmative Defenses to Defendant's Second Amended Counterclaims for Patent Infringement, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB, Dkt. No. 75 (N.D. Ohio), filed on April 25, 2024
2007	Excerpts of Declaration of James Hannah in Support of Defendant CleveMed's Opposition to Plaintiff ResMed's Motion for Temporary Stay Pending Mediation, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 23-cv-02221-BMB, Dkt. No. 87-1 (N.D. Ohio), filed on August 21, 2024
2008	Excerpts of Declaration of Lisa Kobialka in Support of Defendant CleveMed's Opposition to Plaintiff ResMed's Motion to Stay, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 23-cv-02221-BMB, Dkt. No. 100-1 (N.D. Ohio), filed on January 24, 2025
2009	Excerpts of ResMed Corp.'s Reply in Support of its Motion to Stay, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 23-cv-02221-BMB, Dkt. No. 101 (N.D. Ohio), filed on January 31, 2025

Exhibit	Description
2010	Excerpts of Defendant Cleveland Medical Devices, Inc.'s Memorandum in Support of its Motion to Dismiss Plaintiff's Complaint for Declaratory Judgment of Noninfringement, or to the Extent Not Granted, to Transfer, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 23-cv-00500-TWR-JLB, Dkt. No. 10-1 (S.D. Cal.), filed on June 5, 2023
2011	<i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB, Dkt. No. 87-5, Declaration of Hani Kayyali in Support of Patent Owner's Opposition to Motion to Stay Pending Mediation (N.D. Ohio), filed on August 21, 2024
2012	Excerpts of Petitioner's parent company's (ResMed) Q4 FY2024 Earnings call, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB, Dkt. No. 87-6 (N.D. Ohio), filed on August 21, 2024
2013	Excerpts of Defendants' Initial Validity and Enforceability Contentions Pursuant to L.P.R. 3.7, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB (N.D. Ohio), served on August 5, 2024
2014	Case Management Order, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB, Dkt. No. 54 (N.D. Ohio), filed on January 10, 2024
2015	Excerpts of Exhibit H01 – List of Obviousness Combinations from Defendant's Supplemental Invalidity Contentions, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB (N.D. Ohio), served on January 9, 2025
2016	M.C. Bagnato, et al., "Comparison of AutoSet and polysomnography for the detection of apnea-hypopnea events," <i>Braz. J. Med. Biol Res.</i> , vol. 33(5), May 2000

Exhibit	Description
2017	Salmi, T., et al., "Evaluation of automatic analysis of SCSB, airflow and oxygen saturation signals in patients with sleep related apneas," Chest, vol. 96, no. 2, Aug. 1989, available at https://go.gale.com/ps/i.do?id=GALE%7CA12682650&sid=googleScholar&v=2.1&it=r&linkaccess=fulltext&issn=00123692&p=AONE&sw=w&userGr%E2%80%A6&userGr&userGroupName=anon%7E92eb47a3&aty=open-web-entry
2018	Kelly Pneumatics webpage - How Does a CPAP Machine Work? – printed on May 9, 2025
2019	Duan, Zhenhai, et al., "Push vs. Pull: Implications of Protocol Design on Controlling Unwanted Traffic" (USENIX July 7, 2005)
2020	Bunny webpage, "What is the Hypertext Transfer Protocol (HTTP)?" available at https://bunny.net/academy/http/what-is-http-hypertext-transfer-protocol/# , dated March 12, 2025
2021	Declaration of Jeffrey H. Price
2022	Declaration of Dr. David A. Borkholder in Support of Patent Owner's Response
2023	Transportation.gov webpage, "Continuous Positive Airway Pressure (CPAP) Machines," available at https://www.transportation.gov/resources/individuals/aviation-consumer-protection/assistive-device-guides/continuous-positive#:~:text=Basic , dated August 12, 2025
2024	Cleveland Clinic webpage, "CPAP Machine: What It Is, How It Works & Side Effects," available at https://my.clevelandclinic.org/health/treatments/22043-cpap-machine , dated October 24, 2025
2025	Apnea Hypopnea Index (AHI), dated December 23, 2023, available at https://www.resmed.co.in/blogs/apnea-hypopnea-index

Exhibit	Description
2026	Declaration of Alan R. Schwartz, M.D., <i>ResMed Corp. v. Cleveland Medical Devices, Inc.</i> , No. PGR2024-00012, Ex. 1020 (P.T.A.B. Dec. 13, 2023)
2027	K. Sutherland, et al., "Efficacy versus Effectiveness in the Treatment of Obstructive Sleep Apnea: CPAP and Oral Appliances," <i>Journal of Dental Sleep Medicine</i> , Vol. 2, No. 4, 2015
2028	K. Abu, et al., "Obstructive sleep apnea diagnosis and beyond using portable monitors," <i>Sleep Medicine</i> , Vol. 113, 260-274, Jan. 2024
2029	N. Ghahjaverestan, et al., "Sleep apnea severity based on estimate tidal volume and snoring features from tracheal signals," <i>J. Sleep Res.</i> , Vol. 32, No. 2, Sept. 2021
2030	Cambridge Dictionary, Definition of "into" available at https://dictionary.cambridge.org/us/dictionary/english/into , dated October 24, 2025
2031	Merriam-Webster Dictionary, Definition of "into" available at https://www.merriam-webster.com/dictionary/into , dated October 24, 2025
2032	Declaration of Dr. Michael Goodrich in Support of Patent Owner's Contingent Motion to Amend and Request for Preliminary Guidance
2033	U.S Patent Application No. 11/266,899
2034	Online Learning Platform webpage, "What is single-tier, Two-tier and Three-tier Architecture of Software?" available at https://statlearner.org/what-is-single-tier-two-tier-and-three-tier-architecture-of-software , dated July 17, 2025
2035	AlgoMaster webpage, "Client-Server Architecture," by Ashish Singh, available at https://algomaster.io/learn/system-design/client-server-architecture , dated September 8, 2025

I. INTRODUCTION

The Challenged Claims are patentable over Toge in view of Kumar (Ground 1) because Toge's "tidal volume" is not "a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy." The tidal volume measured during treatment represents the amount of air moving through the patient's lungs with each breath.¹ In Toge and Kumar, breathing metrics like the patient's tidal volume are sent to dedicated processors, which analyze the metrics to identify individual symptoms. Further analysis of this symptom data is then required to determine the severity of those symptoms. Accordingly, Ground 1 fails because it depends on the untenable position that the subject's tidal volume is or represents "a quantified level of severity" of the subject's symptoms during treatment.

The addition of Norman in Ground 2 does not resolve Toge's deficiencies because although Norman discloses determining the level of severity (identified as counts/indexes), it does not do so using a processor integrated into the PAP device, as claimed. Like in Toge and Kumar, Norman discloses analyzing data collected by a medical device, like a CPAP machine, on a dedicated processing arrangement external to the CPAP machine. Petitioner's contention that a POSITA would have

¹ The Petition challenges claims 15-29 (the "Challenged Claims") of U.S. Patent No. 11,857,333 (the "333 Patent"). Pet. at 3.

implemented Norman's algorithm at the CPAP machine, instead of at its external processing arrangement, is the product of hindsight. This aspect of the claims is missing from Toge, Kumar, and Norman, and Petitioner has not established any other motivation for making this modification of the references' teachings when explaining how a POSITA allegedly would have combined them.

Grounds 3 and 4 only challenge Dependent Claim 19 and therefore fall with Grounds 1 and 2.

II. OVERVIEW OF THE '333 PATENT

The '333 Patent discloses an integrated diagnosis and treatment device for patients suffering from sleep apnea and other sleep disorders. '333 Patent at Abstract.

The device monitors a patient's breathing metrics and the device's usage data while simultaneously providing a sleep-disorder treatment, such as applying continuous positive airway pressure or a pharmaceutical intervention. *See id.* at Abstract, 10:58-12:67, 45:34-42. The monitored breathing metrics include respiratory airflow and effort, blood oxygenation levels, and the like. *Id.* at 3:27-43, 12:51-67. From these breathing metrics, a PAP device identifies events corresponding to the patient's symptoms (e.g., individual apnea events) and calculates a quantified level of severity the patient's symptoms (e.g., the number of apnea events per hour). The system also calculates therapy efficacy data, which may

be, for example, a quantified level of severity of the patient's symptoms while treatment is underway. *Id.* at 21:33-38, 45:34-37, 49:27-38.

In a preferred embodiment, the '333 Patent discloses a positive airway pressure ("PAP") device with internal airflow sensors that monitor the patient's airflow. *Id.* at 45:34-42, 48:65-49:59. An exemplary PAP device, shown below, includes an air pressure device, a blower, a hose, a mask or nasal cannula, an airflow sensor, and a pressure sensor for measuring breathing metrics (*e.g.*, respiratory airflow), and processor(s) for collecting and processing breathing metrics:

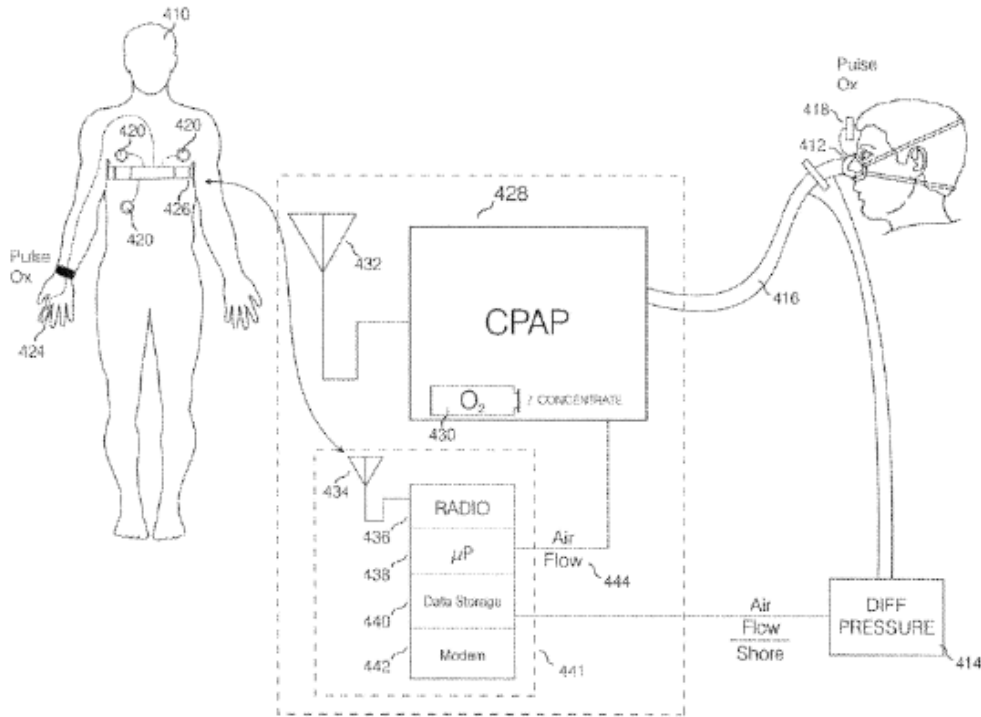


Fig. 8

Id. at FIG. 8. While treatment is ongoing, the PAP device collects usage data and breathing metrics and passes that data to the processor, which calculates the severity

of a patient's sleep disorder symptoms and data representing the efficacy of the PAP therapy. *Id.* at 49:27-59.

After these calculations are performed, the PAP device transmits the collected data and/or the quantified level of severity data to a patient's or care provider's cellular phone and to a remote site for further analysis. *Id.* at 22:8-14 (“For example, with the sleep diagnosis and treatment system of the present invention, the remote communication system of the present invention can be a wireless router, which establishes a broadband internet connection and transmits the physiological signal to a remote internet site for analysis . . .”).

III. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art in 2005 is someone having “a bachelor's degree in mechanical engineering, electrical engineering, computer science, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience working with diagnostic sensor systems and network data systems, such as networked PAP machines. Additional experience could substitute for less education, and additional education could likewise substitute for less experience.” Pet. at 3-4; Ex. 2022 (“Borkholder Decl.”) at ¶ 28.

IV. THE RELEVANT ASSERTED ART

A. Toge (Ex. 1044)

Toge's system enables a physician to remotely monitor a patient who is being treated with a PAP device. Toge at Abstract. The physician can set one or more

threshold values that, when met, trigger the PAP device to push alerts to the physician's computer or mobile device. *See id.* at ¶¶ [0050]-[0058], [0061]. For example, if a patient's oxygen saturation falls below 90%, the PAP device pushes this "crucial data" to the physician's devices. *Id.* at ¶¶ [0054], [0057]. In response to these alerts, the physician can, for example, increase the prescribed pressure that the PAP machine provides to the patient. *See id.* at ¶ [0047]; Borkholder Decl. at ¶ 29.

B. Kumar (Ex. 1008)

Kumar operates a web-based central server that hosts patient data and sends data to physicians upon request. In Kumar's system, patient data is sent from **patient-side device 102** to **web-based central server 106** where it is stored for later retrieval. When physicians wish to view a particular patient's data, they use physician's devices 104 to request and view data using a webpage interface:

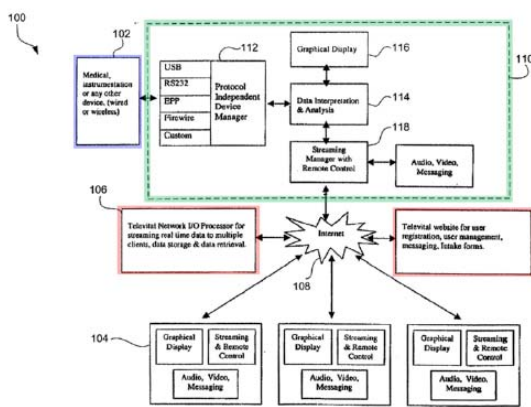


Fig. 1A

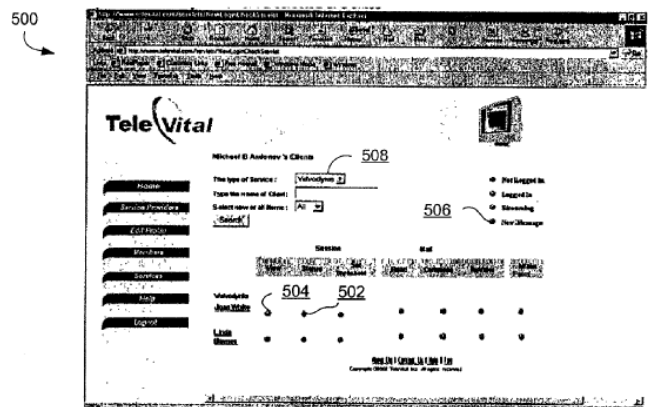


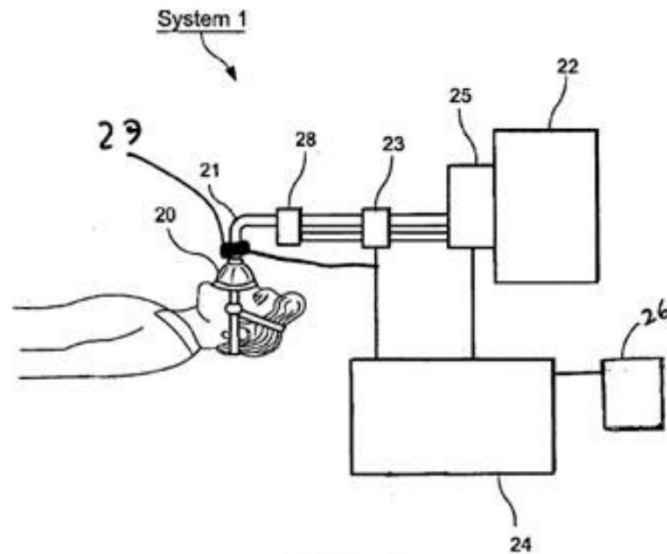
Fig. 5

Pet. at 24 (citing Ex. 1008, FIG. 1A (annotated)); Kumar at FIG. 5 (showing the webpage interface to central server 106); *see also id.* at ¶ [0067] (“[T]he system includes one or more patient-side devices 102 for collecting data from a patient/client, one or more provider-side devices 104, and an engine implemented on a central server 106.”), ¶¶ [0078]-[0083], [0091]-[0092]; Borkholder Decl. at ¶ 30.

C. Norman (Ex. 1059)

Norman describes a method and system for the automated titration of a PAP device with a processing arrangement 24 set apart from the PAP device. Norman at Abstract, FIG. 6. Norman's system 1 reproduced below includes a mask 20, tube 21, flow generator 22/flow control device 25 (*i.e.* the PAP/CPAP device),² a processing arrangement 24, and a titration device 26. Norman at FIG. 6; *see also id.* at ¶¶ [0019]-[0020], [0023]. Unlike the invention disclosed and claimed in the '333 Patent, Norman discloses determining counts/indexes based on collected data with a titration device 26 that is separate from the PAP/CPAP device:

² The components of a PAP/CPAP machine are the “Flow Generator, Air Pressure Hose, and [mask] interface.” Ex. 2023 at 2-3; *see also* Ex. 2024 at 2.



Norman, FIG. 6; *id.*, Claim 28 (reciting the “coupling to a positive airway pressure supply system a removable diagnostics unit . . . including a processor”). Titration device 26 processes and analyzes “data collected by the processing arrangement.” *See id.* at ¶ [0025], FIG. 7; Borkholder Decl. at ¶ 31.

V. GROUND 1: TOGE IN VIEW OF KUMAR DOES NOT DISCLOSE A PAP DEVICE THAT CALCULATES “QUANTIFIED LEVEL OF SEVERITY DATA”

Independent Claim 15 is patentable because Toge does not disclose a PAP machine that determines “a quantified level of severity data based on the subject’s sleep apnea symptoms during the therapy,” as properly construed. The term “quantified level of severity data” may be, for example, index that represents how dire a patient’s calculated symptom data may be. Toge’s tidal volume is a breathing metric that might be analyzed to identify the patient’s symptoms and determine their

severity, but without further analysis, the tidal volume does not represent the patient's symptoms or the severity of those symptoms.

A. Claim Construction: “Quantified Level of Severity Data”

A POSITA would understand that the claimed “quantified level of severity data” is a value that indicates how dire a patient's symptoms are. Borkholder Decl. at ¶ 32 (citing Ex. 2025 at 2). This construction is consistent with the plain language of the term and with the position CleveMed's expert, Dr. D'Ambrosio, advanced in the parallel litigation between the parties:

Since the time of the invention, a commonly used term within the clinical sleep setting has been “*level of severity*” which clinicians understand to represent the *how dire a patient's calculated symptom data may be*. For example, a clinician would recognize a patient's symptom's [sic] as severe if their data shows a *respiratory disturbance index (RDI) or apnea-hypopnea index (AHI)* of greater than or equal to 30 events per hour of sleep. The RDI is the sum of all the apneas, hypopneas, and Respiratory Effort Related Arousals (RERAs) divided by total sleep time. The AHI is the sum of all the apneas and hypopneas divided by the total sleep time.

Ex. 1058 at ¶ 32 (emphasis added).³ This is also consistent with Petitioner's expert, Dr. Schwartz's, understanding in a related PGR proceeding. Ex. 2026 at ¶ 46 (asserting that sleep apnea indices represent the level of severity of sleep disordered breathing with sleep apnea indices).

An index such as AHI or RDI is calculated based on breathing events that are collected over time and calculated to assess the severity of symptoms. *See* Borkholder Decl. at ¶ 33 (citing Ex. 2027 at 175). For instance, the patient's respiratory airflow data may be analyzed to identify sleep disordered breathing events, including apneas, hypopneas. Further analysis may count the number of the events that occur over a period of time. *See* Borkholder Decl. at ¶ 33 (Ex. 2016 at 516).

Thus, a POSITA would recognize "quantified level of severity" as a calculated value that represents how dire a patient's symptoms are. Borkholder Decl. at ¶ 34.

³ Dr. D'Ambrosio submitted her declaration in support of Patent Owner's claim construction briefing at District Court (N.D. Ohio). Dr. D'Ambrosio is a physician at Brigham and Women's Hospital in the Section of Sleep and Circadian Disorders with over 25 years of experience in the field of sleep medicine. Ex. 1058, ¶¶ 4-5.

B. Toge's Tidal Volume Data is Not a "Quantified Level of Severity Data"

Toge's tidal volume data is not a "quantified level of severity data," as properly construed. Tidal 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. Borkholder Decl. at ¶ 35.

To the extent that tidal volume is relevant to the claims, it refers to the "data" collected "with the PAP or CPAP device from the flow or pressure sensor," not "the subject's sleep apnea symptoms" or "a quantified level of severity" of those symptoms. *Id.* at ¶ 36. Tidal volume refers "the volume of air that is inspired or expired during a respiratory cycle." Ex. 2028 at 13-14. Toge discloses measuring this value directly with a flow meter located in the patient's mask or, if a dedicated flow meter is not provided, with several different flow meters and pressure gauges located throughout the system. Toge at ¶ [0033] ("Among the transmission data, if a flow meter (not illustrated) is provided near the patient's nose within the nasal mask 21, the measured value from this flow meter is used for the patient's tidal volume Fp."); *see also id.* at ¶¶ [0034]-[0038] (measuring the patient's tidal volume with internal flow sensors and mask-based pressure gauges).

Consistent with the record evidence, tidal volume does not represent the subject's symptoms or their severity, although it can be analyzed to identify

individual apnea and hypopnea events. Ex. 2028 at 13-14 (“[H]ypopnea events are defined as a reduction of $\geq 50\%$ or 74% in tidal volume from baseline and apnea events as absence of tidal volume for at least 10s.”); *see also* Ex. 2029 at 1 (“Sleep apnea can be characterized by reductions in the respiratory tidal volume This study investigates the feasibility of estimating the severity of sleep apnea, as quantified by the apnea/hypopnea index (AHI) using the estimated tidal volume The reductions in tidal volume were detected as potential respiratory events.”); Borkholder Decl. at ¶ 37.

Accordingly, while tidal volume may be analyzed to identify “the subject’s sleep apnea symptoms,” it does not represent those symptoms, let alone “a quantified level of severity data based on the subject’s sleep apnea symptoms during the therapy,” absent further analysis. *See* Borkholder Decl. at ¶ 38; Ex. 1058, ¶ 32. In this regard, Petitioner’s reference to tidal volume amounting to “zero milliliters per breath” represents the breathing metric data used to determine the apnea event, not the calculated “quantified level of severity data,” which indicates how dire a patient’s calculated symptoms are. Pet. at 16-17; *supra* § V.A.

Considering the foregoing reasons, Toge’s tidal volume data is not “quantified level of severity data,” as claimed. The Challenged Claims are, therefore, patentable over the combination of Toge and Kumar because the references alone, and in

combination, do not disclose a “quantified level of severity data.” Borkholder Decl. at ¶ 39.

VI. GROUND 2: THE CHALLENGED CLAIMS ARE PATENTABLE OVER TOGE IN VIEW OF KUMAR AND NORMAN

Norman does not cure Toge's deficiencies with respect to claim limitation [15.c] because Norman does not determine “a quantified level of severity data” (identified as counts/indexes) using a processor “integrated” into the PAP device, and Petitioner has not established that a POSITA would not have been motivated to determine such calculations at Toge's control unit 250, which Petitioner maps to the claimed “processor . . . integrated into the PAP or CPAP device.” Toge, Kumar, and Norman all disclose analyzing data collected from a PAP machine at a dedicated external processor, and Petitioner's conclusory assertion that a POSITA would have modified these references to reach the claims is the product of hindsight. Borkholder Decl. at ¶ 40.

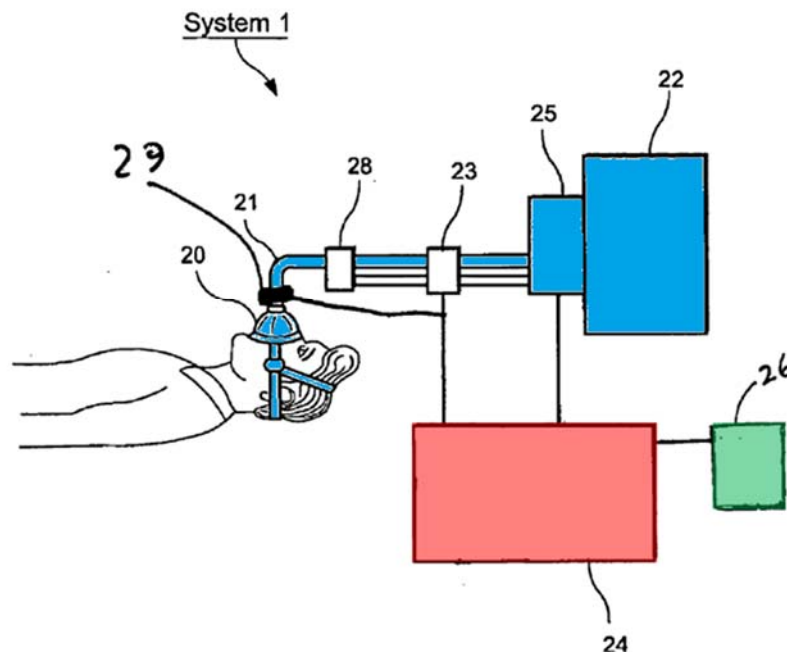
A. Neither Toge nor Norman Discloses a PAP Device that Quantifies the Level of Severity of the Patient's Symptoms

Neither Toge nor Norman discloses the claimed “processor . . . integrated into the PAP or CPAP device” that “analyze[s] . . . the collected data to determine a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy.” '333 Patent at Claim 15; Borkholder Decl. at ¶¶ 41-42.

In the context of the claim, “integrated into” means that the processor is inside the PAP/CPAP device. The term “integrated into” describes not just an integration but an *integration “into.”* *Innova/Pure Water v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004) (“[A]ll claim terms are presumed to having meaning in a claim.”). The “into” language gives effect to “integrate” to mean that the processor is inside the PAP/CPAP device. *See* Ex. 2030 at 1 (defining “into” as “the inside . . . of a place”); Ex. 2031 at 1 (defining “into” as “insertion”).

As discussed above, Toge discloses collecting sensor data, including the patient’s tidal volume, and analyzing that data on an external device, like the physician’s computer. *See* § V.B, *supra*. 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. *See* Norman at ¶¶ [0025]-[0026]; Borkholder Decl. at ¶ 42.

Norman’s system does not include a processor that inside a PAP/CPAP device determines counts/indexes. Borkholder Decl. at ¶¶ 43-44. Instead, Norman’s **processing arrangement 24** and **titration device 26** (identified as the claimed “processor”) are external to the **PAP/CPAP Device** componentry, as the illustration below shows. *See* Ex. 2023 at 1 (PAP/CPAP device’s basic components are “the Flow Generator, Air Pressure Hose, and Interface”).



Norman at FIG. 6 (annotated); *see also id.* at ¶¶ [0019]-[0020], [0023], Claim 28 (“coupling to a positive airway pressure supply system a removable diagnostics unit . . . including a processor”), Claim 33. Based on this configuration, the identified processor’s determination of “counts/indexes” (Pet. at 57) is performed external to the PAP/CPAP device. *See* Norman at ¶ [0028].

Therefore, Norman does not disclose this limitation, or cure Toge’s deficiencies, at least because the identified processor is not inside the PAP/CPAP device. Pet. at 56-57, 61. And for the reasons discussed below, a POSITA would not have been motivated to determine Norman’s counts/indexes teachings at Toge’s PAP device. Borkholder Decl. at ¶ 44.

B. Petitioner Fails to Establish Motivation to Further Modify the Teachings of Toge and Norman to Reach the Claimed Invention

Petitioner's argument that a POSITA would have implemented Norman's calculations at Toge's PAP processor fails because neither reference suggests analyzing sensor data at the PAP machine, and Petitioner does not explain why a POSITA would modify the teachings of the references to arrive at the claimed invention. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (“[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.”); Borkholder Decl. at ¶¶ 45-48.

Petitioner's argument that a POSITA would have performed Norman's data analysis at Toge's PAP processor relies on the untenable premise that “Toge already discloses a CPAP device that collects sensor data and analyzes the sensor data using a processor.” Pet. at 60-61. As detailed above, 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. *See* § V.B, *supra*,. Thus, the patient's tidal volume is measured directly or indirectly from sensor data and sent to the physician's device at regular intervals so that the physician can remotely evaluate the trend in the patient's condition over time. Toge at ¶ [0039] (describing a physician evaluating “decreasing trend in the tidal volume” that could require “adjusting the prescription pressure to a higher level”); *see also id.* at ¶ [0051] (sending tidal

volume data to the physician-side device). Accordingly, to the extent symptom identification and severity analysis occurs in Toge's system, that activity is performed at the physician's device, not the PAP machine's processor.

Norman also does not calculate counts/indexes using a processor integrated into a PAP device, so it cannot be "simply assum[ed] that 'an ordinary artisan would be awakened to modify prior art in such a way as to lead to an obviousness rejection.'" *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1354 (Fed. Cir. 2013). Petitioner does not identify any *other* motivation or reasoning that would explain why its proposed combination of Toge and Norman results in a method that neither discloses nor contemplates. Therefore, the Board should reject Petitioner's contention that a POSITA would have performed Norman's index determinations at Toge's PAP device as the product of impermissible hindsight.

VII. GROUNDS 3 AND 4: DEPENDENT CLAIM 19 IS PATENTABLE OVER TOGE IN VIEW OF KUMAR AND BURTON AND/OR KUMAR, NORMAN AND BURTON

Because Petitioner fails to demonstrate that Toge in view of Kumar or additionally in view of Norman renders obvious Independent Claim 15, Petitioner also fails to establish that Dependent Claim 19 is unpatentable.

VIII. CONCLUSION

For at least the foregoing reasons, Patent Owner respectfully requests that the Board deny institution.

Patent Owner's Response
IPR2025-00246 (U.S. Patent No. 11,857,333)

Dated: October 29, 2025

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Cleveland Medical Devices, Inc.

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

The undersigned hereby certifies that the portions of the above-captioned **PATENT OWNER'S RESPONSE** specified in 37 C.F.R. § 42.24 has 3,192 words in compliance with the 14,000 word limit set forth in 37 C.F.R. § 42.24(b)(2). This word count was prepared using the Microsoft Word word-processing system used to prepare this paper.

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CERTIFICATE OF SERVICE

The undersigned certifies, in accordance with 37 C.F.R. § 42.6(e), and pursuant to agreement by the parties that filing with the Board through the P-TACTS constitutes electronic service if Patent Owner provides the foregoing document (excluding exhibits), that service was made on the Petitioner as detailed below.

<i>Date of service</i>	October 29, 2025
<i>Manner of service</i>	Electronic Filing and Electronic Mail (PH-ResMed-CleveMed@paulhastings.com)
<i>Documents served</i>	PATENT OWNER'S RESPONSE
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