

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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RESMED CORP.,  
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,  
Patent Owner.

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

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**PATENT OWNER'S PRELIMINARY RESPONSE  
UNDER 37 C.F.R. § 42.107**

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**PATENT OWNER'S EXHIBIT LIST**

<b>Exhibit</b>	<b>Description</b>
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

<b>Exhibit</b>	<b>Description</b>
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

<b>Exhibit</b>	<b>Description</b>
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 <a href="https://go.gale.com/ps/i.do?id=GALE%7CA12682650&amp;sid=googleScholar&amp;v=2.1&amp;it=r&amp;linkaccess=fulltext&amp;issn=00123692&amp;p=AONE&amp;sw=w&amp;userGr%E2%80%A6&amp;userGr&amp;userGroupName=anon%7E92eb47a3&amp;aty=open-web-entry">https://go.gale.com/ps/i.do?id=GALE%7CA12682650&amp;sid=googleScholar&amp;v=2.1&amp;it=r&amp;linkaccess=fulltext&amp;issn=00123692&amp;p=AONE&amp;sw=w&amp;userGr%E2%80%A6&amp;userGr&amp;userGroupName=anon%7E92eb47a3&amp;aty=open-web-entry</a>
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 <a href="https://bunny.net/academy/http/what-is-http-hypertext-transfer-protocol/#">https://bunny.net/academy/http/what-is-http-hypertext-transfer-protocol/#</a> , dated March 12, 2025
2021	Declaration of Jeffrey H. Price

## I. INTRODUCTION

In the event that the Director does not deny the Petition for the reasons given in the Discretionary Denial Brief, Patent Owner (“CleveMed”) respectfully requests that the Board deny the Petition on the merits because Petitioner has not established that Toge’s “tidal volume” is a “quantified level of severity data.” At best it represents a patient’s airflow data, which must still be analyzed to determine a “quantified level of severity.”<sup>1</sup>

The addition of Norman in Ground 2 does not resolve Toge’s deficiencies because although Norman discloses calculating the level of severity of the patient’s symptoms, it does not do so using a processor integrated into the PAP device, as claimed. Like Kumar, the analysis engine in Norman is on a separate machine. Furthermore, a POSITA would not have modified Toge with Norman because they work at cross purposes: Where Toge’s treatment system is premised on patient’s the physician receiving information in a timely fashion, Norman’s automated titration process relies on the machine to adjust the treatment.

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

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<sup>1</sup> The Petition challenges claims 15-29 (the “Challenged Claims”) of U.S. Patent No. 11,857,333 (the “333 Patent”). Pet. at 3.

## 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 determines the quantified level of severity of symptom data (for example, the number of apnea events) that is then used in the calculation of therapy efficacy data. *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, 48:65-49:61. An exemplary embodiment of the 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 (for example, respiratory airflow), and processor(s) for collecting and processing breathing metrics:

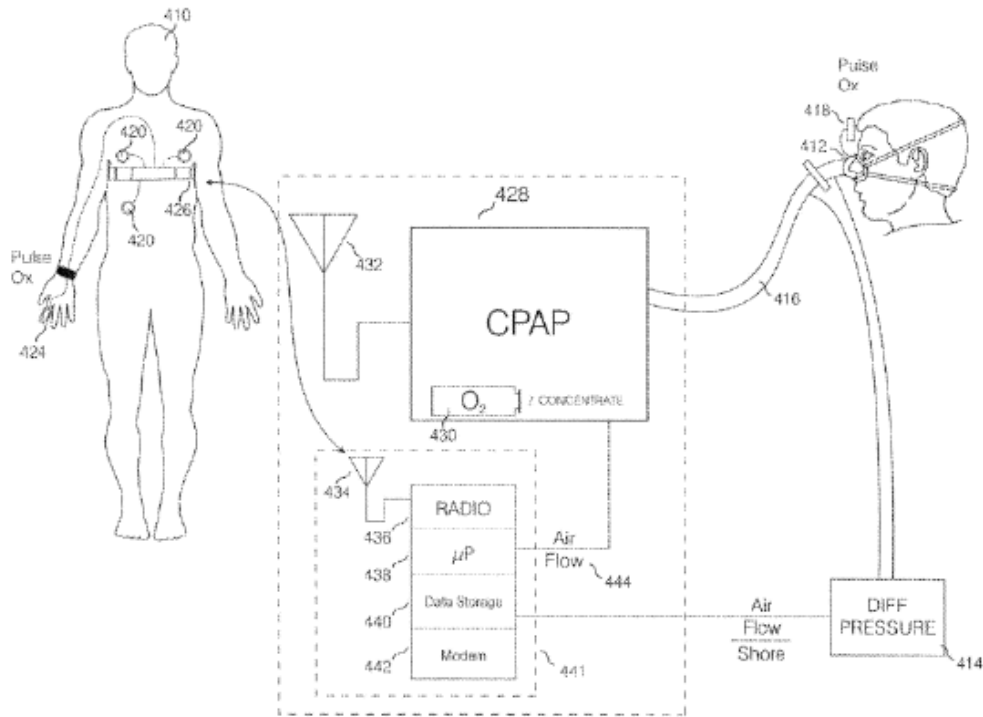


Fig. 8

*Id.* at FIG. 8. While treatment is ongoing, the PAP device also collects usage data and breathing metrics and passes that data to the processor for calculation of the severity of a patient's sleep disorder symptoms and further determination of therapy efficacy data based on such calculated data. *Id.* at 49:27-59.

After these calculations are performed, data (the collected data and/or the quantified level of severity data) is transmitted to a patient's or care provider's cellular phone as well as a remote internet site for 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**

For the purpose of this preliminary proceeding only, Patent Owner applies Petitioner's proposed definition of a POSITA in 2005, as one 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.

### **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, triggers the PAP device to push treatment data to the physician-side computer/mobile terminal (*i.e.* physician-side client devices) such that the physicians can take emergency measures. *See id.* at ¶¶ [0039], [0047], [0061]. For example, if a patient's oxygen saturation falls below 90%, the physician-side client devices are pushed this “crucial data” from the PAP device (*id.* at

¶¶ [0054], [0057]) where, in turn, the physicians can increase the prescription pressure, for instance. *See id.* at ¶ [0047].

**B. Kumar (Ex. 1008)**

Kumar operates in a fundamentally different way than Toge: It uses a web-based central server from which a physician can request patient data. As the figures reproduced below show, patient data is sent from a patient-side device 102 (blue, below) to its web-based central server 106 (red) where it is stored and transferred to a physician's device 104 once the device has requested the web page (e.g., TeleVital) and requested the patient data:

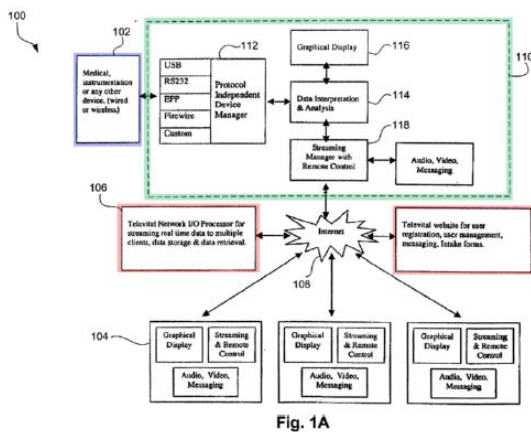


Fig. 1A

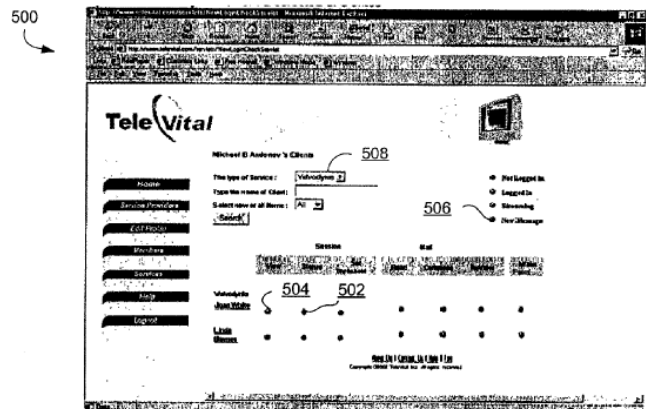
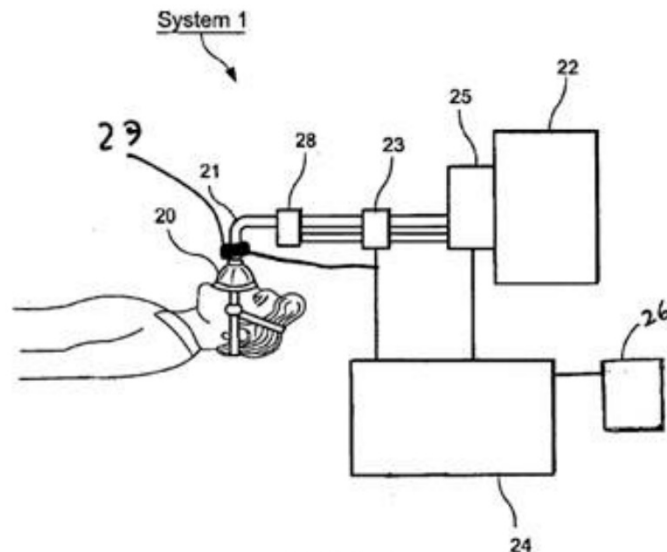


Fig. 5

Pet. at 24 (citing Ex. 1008, FIG. 1A (annotated)); Kumar at FIG. 5; *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].

**C. Norman (Ex. 1059)**

Norman describes a method and system for the automated titration of CPAP. Norman at Abstract. Norman's system 1 reproduced below includes a mask 20, tube 21, sensors 23, flow generator 22/flow control device 25 (*i.e.* the PAP/CPAP device), a processing arrangement 24, and a titration device 26.



Norman at FIG. 6; *see also id.* at ¶¶ [0019]-[0020], [0023]. The titration device may be attachable to the processing arrangement 24, or, alternatively, built into processing arrangement 24, where it receives data from the processing arrangement, analyzes the data, and adjusts the PAP pressure. *See id.* at ¶¶ [0024]-[0033], FIG. 7.

The titration device's adjustment of PAP pressure occurs periodically and without physician involvement. Norman explains that titration device 26 collects and stores data at **step 702**, analyzes the collected data at **step 704**, and then

determines an appropriate PAP pressure and adjusts that pressure periodically, e.g., “only at the beginning of a sleeping cycle,” at **step 706**. *Id.* at ¶¶ [0027]-[0033], FIG. 7. Norman explains that adjusting periodically the pressure improves over conventional automatic titration systems that “generate immediate feedback responses to the abnormal respiratory events from which they attempt to determine a single therapeutic pressure.” *Id.* at ¶ [0033].

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

Independent Claim 1 is patentable because Toge does not disclose calculating a “quantified level of severity data.” Contrary to Petitioner’s assertion, Toge’s tidal volume is not “quantified level of severity data.” It is, at best, breathing metric data that might be used to calculate “quantified level of severity data.” *See* Pet. at 15-17.

Toge explains that tidal volume is a patient’s respiratory airflow that is measured by a flow meter. *See* Toge at ¶ [0033] (“the measured value from this flow meter is used for the patient’s tidal volume Fp”), ¶ [0028] (“The flow meter 24 . . . detects and measures the airflow within the flow path 20 . . .”). Toge’s tidal volume data is equivalent to the ’333 Patent’s respiratory airflow that is measured using “devices such as a pneumotachometer.” *See* ’333 Patent at 12:51-63. The ’333 Patent explains that such breathing metrics, such as respiratory airflow, are *used “for*

*determining* a quantitative level of severity of a subject's sleeping disorder and/or symptoms." *Id.* at 45:34-42 (emphasis added).

In other words, Toge's respiratory airflow data, like the '333 Patent's respiratory airflow data, is not "quantified level of severity data." Rather, it is just used in its determination. For example, respiratory airflow data may be used to determine the number of apnea events during the therapy ("a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy."); Ex. 1002 at 229 ("The present invention . . . collects pressure or flow data from a PAP device which is used to determine the efficacy of the therapy by looking at the apnea event[s] that occur in the presence of the therapy.").

A POSITA understands that a patient's respiratory airflow data may be used to detect and distinguish between different types of apnea events, hypopnea events, and the like. *See* Ex. 2016 at 516 ("The criteria adopted to define respiratory events were a) apneas characterized by absence of, or drop in, airflow higher than 80% in relation to basal values, associated or not with alterations in chest and abdominal movements for more than 10 s; b) hypopneas, characterized by a drop in airflow between 50 and 80% of basal values, for more than 10 s, associated with an oxygen destruction of  $\geq 4\%$  or arousal . . ."); Ex. 2017 at 6. As Patent Owner's expert, Dr. D'Ambrosio explains, the number of apnea events as a "patient's calculated symptom data" and what "clinicians understand to represent" the "level of severity."

Ex. 1058, ¶ 32.<sup>2</sup> 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." Pet. at 16-17.

Based on the foregoing, Toge's tidal volume data is not "quantified level of severity data," as claimed. Accordingly, Petitioners have not raised a reasonable likelihood that Claim 15 of the '333 Patent is unpatentable over the combination of Toge and Kumar.

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

While Petitioner relies on Norman for limitations [15.c] and [15.e.1], Norman does not resolve the above deficiencies because it does not teach or suggest calculating "quantified level of severity data" on a PAP device's processor, and a POSITA would not have been modified Toge with Norman's "automated titration process." *See* Pet. at 49-61.

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<sup>2</sup> 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.

**A. Norman Does Not Disclose “Determin[ing] a Quantified Level of Severity Data” With the “Processor” That is “Integrated Into the PAP or CPAP Device”**

Norman does not resolve the deficiencies of Ground 1 because Norman does not determine “quantified level of severity data” with a “processor” that is “integrated into the PAP or CPAP device.” ’333 Patent at Claim 15. Instead, Norman’s titration device 26 analyzes the collected data, which is not part of the PAP/CPAP device.

As described in Section IV.C above, Norman’s system 1 includes a flow generator 22/flow control device 25 (the “PAP/CPAP device,” blue), a processing arrangement 24 (red), and a titration device 26 (green).

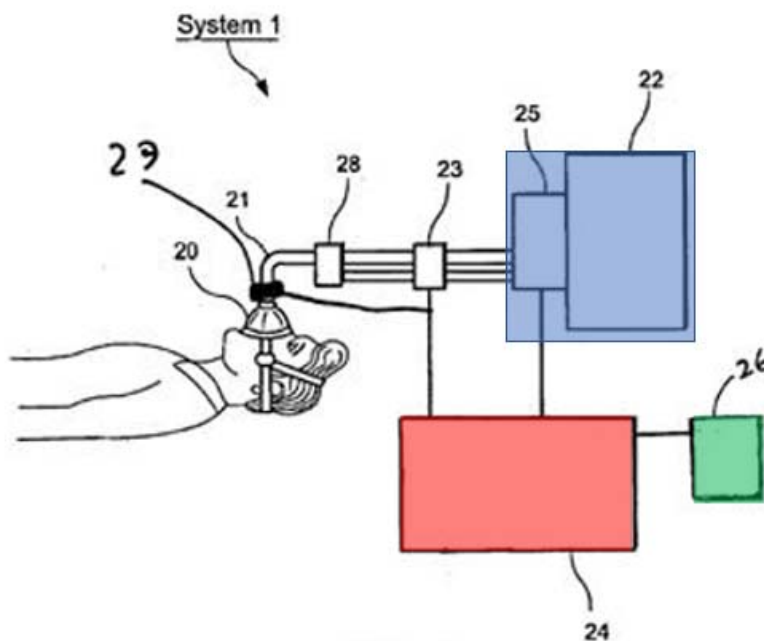


FIG. 6

Norman at FIG. 6 (annotated); *see also id.* at ¶¶ [0019]-[0020], [0023]. Both the processing arrangement of 24 and titration device 26 are separate from the PAP/CPAP device, which delivers continuous flow of pressurized air to the patient's airway. *See, e.g.*, Ex. 2018; Norman at ¶ [0020] (describes that the flow control device 25 “controls the pressure applied to the flow tube 21 by the flow generator 22”).

Accordingly, even if “that titration device 26 may be combined with processing arrangement 24,” (Pet. at 56), the processing arrangement is not the “processor” as claimed because it is not “integrated into” the PAP/CPAP device. Thus, Norman's titration device does not “determine a quantified level of severity data” because there is no “processor” that is “integrated into the PAP or CPAP device.”

**B. A POSITA Would Not Have Modified Toge With Norman**

A POSITA also would not have found it obvious to modify Toge's system with Norman's automated titration process where the PAP device would adjust the pressure *only periodically*, and where the data would be sent to a browser-based engine for *later access by a physician*. Such modification would have defeated Toge's primary purpose of sending data directly to physicians who can take immediate action (such as adjusting the pressure) at any time. *Medtronic, Inc. v. Teleflex Innovations S.à.r.l.*, 69 F.4th 1341, 1349-50 (Fed. Cir. 2023) (expressing

that the Board must consider whether “a proposed modification would interfere with a reference’s stated purpose” and where the purpose is destroyed, it counsels strongly against obviousness).

Toge’s purpose is directed to physician active monitoring and adjustment of patients’ PAP devices when and as needed. *See* Toge at ¶¶ [0047], [0057] (describing how physicians are pushed crucial data and make the necessary PAP pressure adjustments); *see also id.* at Abstract, ¶¶ [0001]-[0006]. With Toge’s system, the PAP device selectively pushes crucial data to the physician-side client devices when a threshold value is met:<sup>3</sup>

By setting thresholds in this manner, it becomes possible to selectively *transmit only the necessary or crucial data to the physician-side computer 4 or portable device 5.*

Toge at ¶ [0054] (emphasis added); *see also id.* at ¶¶ [0018]-[0019] (explaining that the computer/mobile terminal are client devices used by physicians, for example, at a hospital or clinic). For instance, Toge explains that by setting a threshold (for example, 90% oxygen saturation), the physician-side client devices are pushed

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<sup>3</sup> A push protocol is where a “sender can deliver traffic *at will* to a receiver” and the “receiver[] *passively accept* whatever the sender[] pushes to them.” Ex. 2019 at 25-26 (emphasis added)

“crucial data” when the threshold is met such that the physician can take emergency measures:

If the oxygen saturation, for example, falls below 90%, *physicians can take emergency measures such as adjusting* the prescription pressure to a higher level remotely from the physician-side computer 4 or mobile terminal 5 . . . .

*Id.* at ¶ [0047] (emphasis added); *see also id.* at ¶ [0039]. In this way, physicians adjust the pressure of the PAP device upon immediate review of data pushed to them.

Where Toge seeks physician involvement, Norman avoids through its automated titration process. As the automated titration process adjusts only periodically, e.g., “only at the beginning of a sleeping cycle,” without physician involvement. *See* Norman at ¶ [0033] (“*The system 1* may determine appropriate pressures by *adjusting pressure only at the beginning of a sleeping cycle* and by operating over the course of several sleeping cycles” (step 706)) (emphasis added), ¶ [0030] (the system may analyze the data during a predetermined time period (step 704) and adjusts the pressure at the subsequent time period (step 706)). The only time that a physician may be involved is when the titration device is activated (step 700) with the titration device automating the periodic PAP adjustment thereafter. *See id.* at ¶ [0024] (discussing step 700), ¶¶ [0028]-[0033] (discussing step 706). And in Petitioner’s envisioned combination, physicians are involved at a later time, for example, following the PAP adjustment.

In the envisioned combination, Norman's automated titration process is used alongside the wireless transmission of its alleged "quantified level of severity data" and "therapy efficacy data" to a browser-based engine/server where the data is stored for "*later* analysis/review by the physicians" (such as after the PAP device's adjustment). Pet. at 60 ("[Toge's] PAP device (as modified in view of Norman) [] wirelessly transmit[s] to the browser-based engine data associated [with] the [] treatment") (emphasis added); *id.* (explaining that "the remote engine provides a secured storage and access of the stored data . . . through web pages which serve as a graphical user interface"). Thus, in this envisioned combination, Norman's automated titration process would adjust Toge's PAP device *only periodically* with the data then sent to the browser-based engine/server *where it stored and later accessed by a physician for her review/analysis. Id.*<sup>4</sup>

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<sup>4</sup> Petitioner's assertion elsewhere that "the PAP device . . . may be adjusted in real-time by a physician" based on the "wireless transmitted data" is *only* if the physician is logged into the web page. Pet. at 62. In Petitioner's envisioned combination, the automated titration process makes the adjustments with the wirelessly transmitted data only available when the physician makes a requests to access the web page and data. Ex. 2020 at 2-3 ("[B]ecause information can only be pulled from a web server

Accordingly, if Toge's system were modified, the automated titration process would eliminate Toge's key functionality of physician active monitoring and PAP adjustments when and at all times necessary. Thus, contrary to Petitioner's allegations, Norman's automated titration process would not have improved Toge's system, but worsened it. Pet. at 50. The loss of functionality supports a finding that a POSITA would not have been motivated to make the proposed modification. *Cook Grp. Inc. v. Bos. Sci. Scimed, Inc.*, 809 F. App'x 990, 1000 (Fed. Cir. 2020) (“[T]he loss of key functions in the primary reference here supports a finding of no motivation to combine”).

A POSITA would also have found it unnecessary to use Norman's alleged “therapy efficacy data” and “quantified level of severity data” considering that Toge already includes data that PAP device adjustment is based on. Toge's tidal volume data is used for assessing efficacy and adjusting treatment, as Petitioner acknowledges. See Pet. at 35 (alleging that tidal volume “represent[s] the patient's

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after a client's request [] [t]he web server never pushes information to a client without a request”); Pet. at 60 (the physician upon a request accessing the data “through web pages”). Thus, all other times the data is stored for “later analysis/access by the physician[,]” which defeats Toge's purpose. Pet. at 60.

condition and efficacy of the treatment.”); *id.* (alleging that “if there is a decreasing trend in *tidal volume* . . . , emergency measures, such as *adjusting the prescription pressure* to a higher level, can be taken remotely.”) (emphasis added). Toge transmits tidal volume data to the physician-side devices where physicians themselves review the data and determine the appropriate PAP pressure immediately, whereas Norman collects data that is later analyzed by a titration device to determine the appropriate pressure. Norman at ¶ [0026] (“[C]ollected data may be stored together so that the data from several titration procedures may be accessed and analyzed by the titration device 26 to determine appropriate pressure controls.”). Thus, Norman’s data would only introduce redundancy in what physicians already do based on the transmitted tidal volume data. Toge at ¶ [0047] (adjusting the pressure of the PAP device).

For at least the foregoing reasons, a POSITA would not have found it obvious to implement Norman’s automated titrated process in Toge’s system.

**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 show by a reasonable likelihood that Toge in view of Kumar and/or Kumar and Norman renders obvious Independent Claim 15 and Grounds 3 and 4 do not resolve any of the above deficiencies, 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.

Respectfully submitted,

Date: May 12, 2025

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

The undersigned hereby certifies that the portions of the above-captioned **PATENT OWNER'S PRELIMINARY RESPONSE** specified in 37 C.F.R. § 42.24 has 3,185 words in compliance with the 14,000 word limit set forth in 37 C.F.R. § 42.24(b)(1). This word count was prepared using the Microsoft Word word-processing system used to prepare this paper.

Dated: May 12, 2025

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Cleveland Medical Devices, Inc.

**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>	May 12, 2025
<i>Manner of service</i>	Electronic Filing and Electronic Mail (PH-ResMed-CleveMed@paulhastings.com)
<i>Documents served</i>	PATENT OWNER'S PRELIMINARY RESPONSE
<i>Persons Served</i>	Paul Hastings LLP Lisa K. Nguyen David M. Tennant Grace Wang Kamilah Alexander Maksim Mints

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