

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 OBJECTIONS TO EVIDENCE
UNDER 37 C.F.R. § 42.64**

Patent Owner Cleveland Medical Devices, Inc. (“CleveMed” or “Patent Owner”) objects under the Federal Rules of Evidence and 37 C.F.R. § 42.64(b)(1) to the admissibility of the following documents submitted by Petitioner ResMed Corp. (“ResMed” or “Petitioner”) in its Petition for *Inter Partes* Review. *See* Paper No. 1. Trial was instituted on July 30, 2025. *See* Paper No. 12. Thus, Patent Owner’s objections are timely under 37 C.F.R. § 42.64(b)(1). Patent Owner serves Petitioner with these objections to provide notice that Patent Owner will move to exclude the above-identified exhibits as improper evidence.

I. PETITIONER’S EVIDENCE

A. Objections to the Declaration of Dr. Jason Kirkness (Ex. 1003, the “Kirkness Declaration”)

Patent Owner objects to the Kirkness Declaration under Federal Rules of Evidence (“FRE”) 802 as inadmissible hearsay if Petitioner does not make Dr. Kirkness available for deposition in this proceeding. Further, the Kirkness Declaration is inadmissible under *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) and FRE 702–703 at least because Dr. Kirkness’s opinions are conclusory, do not disclose the underlying facts or data in support of his opinions, and are unreliable.

B. Objections to the Declaration of Dr. Sandeep Chatterjee (Ex. 1005, the “Chatterjee Declaration”)

Patent Owner objects to the Chatterjee Declaration under FRE 802 as inadmissible hearsay if Petitioner does not make Dr. Chatterjee available for

deposition in this proceeding. Further, the Chatterjee Declaration is inadmissible under *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) and FRE 702–703 at least because Dr. Chatterjee's opinions are conclusory, do not disclose the underlying facts or data in support of his opinions, and are unreliable.

C. Various Exhibits and Publications

Patent Owner objects to the admissibility of the following exhibits for at least the following reasons:

Exhibit No.	Description
Ex. 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/tmobile-usa-and-hp-launch-the-first-truly-integrated-wireless
Ex. 1015	M. Berthon-Jones, “Feasibility of a Self-Setting CPAP Machine,” <i>Sleep</i> 16:S120-123 (1993) (“Berthon-Jones 1993”)
Ex. 1016	D. Rapoport, “Methods to Stabilize the Upper Airway Using Positive Pressure,” <i>Sleep</i> 19(9): S123-S130 (“Rapoport 1996”)
Ex. 1019	S. Thompson et al., “Sleep as a Teaching Tool for Integrating Physiology and Motor Control,” <i>Advances in Physiology Education</i> (2001)
Ex. 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”)
Ex. 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)

Exhibit No.	Description
Ex. 1026	ResMed, "AutoSet Portable II Plus Overview & Interpretation Guide, Rev. 1," (1999)
Ex. 1027	ResMed, "AutoSet T, Optimal Therapy for your OSA Patients," (2000)
Ex. 1028	Sunrise Medical, "DeVillibis® AutoAdjust™ LT Nasal CPAP System Instructions Guide Model 8054," (1999)
Ex. 1029	Respironics, "Introducing the REMstar Auto. A simply smarter Smart CPAP" (2002)
Ex. 1030	ResMed Origins, downloaded from https://document.resmed.com/enus/documents/articles/resmed-origins.pdf on May 3, 2022.
Ex. 1032	F. Roux, et al., "Continuous Positive Airway Pressure: New Generations," Clinics in Chest Medicine (2003)
Ex. 1033	Loube, D., "Technologic Advances in the Treatment of Obstructive Sleep Apnea Syndrome," CHEST 116:1426- 1433 (1999)
Ex. 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>
Ex. 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)
Ex. 1036	S. Wilber, et. al., "Patient Monitoring and Anesthetic Management: A Physiological Communications Network," JAMA 191:893-898) (1965)
Ex. 1037	M. Weil, et. al., "Experience With a Digital Computer for Study and Improved Management of the Critically Ill," JAMA 198:1011-1016 (1966)

Exhibit No.	Description
Ex. 1038	C. Lilly, et. al., "Critical Care Telemedicine: Evolution and State of the Art," <i>Critical Care Medicine</i> 42:2429-2436 (2014)
Ex. 1039	M. Breslow, et. al., "Effect of a multiple-site intensive care unit telemedicine program on clinical and economic outcomes: An alternative paradigm for intensivist staffing," <i>Critical Care Medicine</i> 32:31-38 (2004)
Ex. 1040	K. Zundel, "Telemedicine: history, applications, and impact on librarianship," <i>Bull Med Libr. Assoc.</i> 84:71-79 (1996)
Ex. 1042	A. Boudewyns, et. al., "Two months follow up of auto-CPAP treatment in patients with obstructive sleep apnoea," <i>Thorax</i> 54:147-149 (1999)
Ex. 1043	D. Lankford, "Wireless CPAP Patient Monitoring: Accuracy Study," <i>Telemedicine Journal and e-Health</i> 10:162-169 (2004)
Ex. 1046	D. Gourley, et. al., <i>HTTP The Definitive Guide</i> (2002)
Ex. 1047	D. Mauro, et. al., <i>Essential SNMP</i> (2001)
Ex. 1048	F. Adelstein, et. al., <i>Fundamentals of Mobile and Pervasive Computing</i> (2005)

Petitioner has failed to authenticate Exhibits 1011, 1015-1016, 1019, 1023, 1025-1030, 1032-1040, 1042-1043, and 1046-1048 under FRE 901 and FRE 602. Specifically, Petitioner has failed to establish that Exhibits 1011, 1015-1016, 1019, 1023, 1025-1030, 1032-1040, 1042-1043 and 1046-1048 are what Petitioner claims they are, and has failed to authenticate Exhibits 1011, 1015-1016, 1019, 1023, 1025-1030, 1032-1040, 1042-1043 and 1046-1048.

To the extent that Petitioner attempts to rely on any date that appears on Exhibits 1011, 1015-1016, 1019, 1023, 1025-1030, 1032-1040, 1042-1043 and 1046-1048 to establish public accessibility of Exhibits 1011, 1015-1016, 1019, 1023, 1025-1030, 1032-1040, 1042-1043 and 1046-1048 as a printed publication or prior art reference, the date is hearsay under FRE 801 and does not fall within a hearsay exception under FRE 802 and FRE 803. Further, the dates in Exhibits 1011, 1015-1016, 1019, 1023, 1025-1030, 1032-1040, 1042-1043 and 1046-1048 have not been authenticated and are inadmissible under FRE 901.

Exhibits 1019, 1023, 1025-1030, 1032-1040, 1042-1043 and 1046-1048 are not relevant under FRE 401 because Petitioner did not rely on Exhibits 1019, 1023, 1025-1030, 1032-1040, 1042-1043 and 1046-1048 in its Petition, and therefore are inadmissible under FRE 402. Additionally, exhibits 1039 and 1040 are not relevant under FRE 401 and inadmissible under FRE 402. Exhibits 1015-1016, 1023, 1025, 1033-1040 and 1042-4043 are incomplete and thus confusing, of minimal probative value, outweighed by prejudice, and/or a waste of time and therefore inadmissible under FRE 403.

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

Respectfully submitted,

Dated: August 13, 2025

/James Hannah/

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(Case No. IPR2025-00246)

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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), service was made on the Petitioner as detailed below.

<i>Date of service</i>	August 13, 2025
<i>Manner of service</i>	Electronic Filing and Electronic Mail (PH-ResMed-CleveMed@paulhastings.com)
<i>Documents served</i>	PATENT OWNER'S OBJECTIONS TO EVIDENCE UNDER 37 C.F.R. § 42.64
<i>Persons Served</i>	Paul Hastings LLP Lisa K. Nguyen David M. Tennant Grace Wang Kamilah Alexander Maksim Mints

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