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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

DEFENDANT RESMED INC.'S FINAL INVALIDITY CONTENTIONS

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I. INTRODUCTION

Pursuant to Section 3(d) and (g) of the Court's Scheduling Order dated November 3, 2022 (D.I. 40) and the modifications thereto (D.I. 119, D.I. 159, D.I. 168, D.I. 187), and the Court's Order dated October 20, 2023 (D.I. 177), Defendant ResMed Inc. ("ResMed") hereby provides its Final Invalidity Contentions, including the charts at Appendices A - G (collectively, the "Final Contentions") to Plaintiff Cleveland Medical Devices, Inc. ("CleveMed"). The Final Contentions address the invalidity of the asserted claims of U.S. Patent Nos. 10,426,399 ("the '399 patent"); 10,925,535 ("the '535 patent"); 11,064,937 ("the '937 patent"); 11,202,603 ("the '603 patent"); 10,028,698 ("the '698 patent");11,234,637 ("the '637 patent"); and 10,076,269 ("the '269 patent") (collectively, the "Asserted Patents").

II. RESERVATION OF RIGHTS

ResMed's Final Contentions address the asserted claims identified by CleveMed in its Final Infringement Contentions dated November 13, 2023. Should the Court allow CleveMed to later assert infringement of additional claims not identified in CleveMed's Final Infringement Contentions, or to supplement its infringement contentions with additional infringement theories with respect to the asserted claims, ResMed reserves the right to supplement its Final Contentions to assert invalidity of those additional claims and/or to assert invalidity based on the additional infringement theories.

ResMed's discovery and investigation in connection with this lawsuit are ongoing, including discovery from CleveMed. Thus, these Final Contentions are based on information obtained to date. ResMed reserves the right to supplement its Final Contentions in response to information learned in fact or expert discovery, including identification of additional prior art. Accordingly, ResMed's Final Contentions are subject to modification, amendment, or supplementation in accordance with the Scheduling Order, the Local Rules of the Delaware

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District Court, and/or the Federal Rules of Civil Procedure as this action progresses and additional information is obtained.

ResMed's Final Contentions are also based in whole or in part on its present understanding of the asserted claims and CleveMed's Final Infringement Contentions, including the priority dates and conception/reduction to practice dates of the Asserted Patents identified by CleveMed in its Objections and Responses to ResMed's First Set of Interrogatories, Interrogatory No. 2. ResMed, however, does not admit or concede that the asserted claims of the Asserted Patents are entitled to a particular priority date or conception date, whether earlier or later than the priority dates claimed in the specifications of the Asserted Patents or in CleveMed's Interrogatory Responses and/or Final Infringement Contentions. ResMed reserves the right to contest these priority and conception/reduction to practice dates, and to the extent ResMed's Final Invalidity Contentions suggest or assert inconsistent priority or conception dates, such suggestions and/or assertions are made in the alternative in accordance with the spirit and scope of the Federal Rule of Civil Procedure 8(e).

For purposes of these Final Contentions only, ResMed has, in certain circumstances, applied the claims to the prior art in view of CleveMed's allegations or positions. As such, ResMed's Final Contentions are not adoptions or admissions by ResMed as to the accuracy or correctness of CleveMed's allegations or positions. By providing these Final Contentions, ResMed does not accept CleveMed's apparent interpretation of the claims as reflecting the proper scope of the claims.

These Final Contentions apply the Court's claim constructions as set forth in its October 30, 2023 memorandum opinion and order (D.I. 181, 182), but they should not be construed in any way as admissions or adoptions as to any particular claim scope or construction, including

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any admission or adoption that the Court's claim constructions are correct. Nor are they admissions that any particular claim element is met in any particular way. ResMed does not agree with CleveMed's application of the claims in CleveMed's Final Infringement Contentions and denies infringement. To the extent the parties raise or the Court resolves any claim construction disputes that have not heretofore been raised, ResMed reserves the right to amend its Final Contentions accordingly.

In these Final Contentions, ResMed has applied the prior art to the asserted claims in part based on the assumption that CleveMed contends those claims are definite, that CleveMed finds written description support for those claims, and CleveMed contends that they are enabled under 35 U.S.C. § 112.[1] However, these Final Contentions do not represent agreement or a view by ResMed as to the meaning, definiteness, written description support for, or enablement of any claim contained therein. As disclosed below, ResMed challenges the validity of at least some of the asserted claims of the Asserted Patents for failure to comply with § 112.

ResMed's Final Contentions are responsive at least to the same level of specificity of CleveMed's Final Infringement Contentions. ResMed does not concede that CleveMed's Final Infringement Contentions provide sufficient specificity, and ResMed provides these Final Contentions without waiving any right to receive from CleveMed full, complete, and specific infringement contentions. Moreover, nothing herein should in any way be construed as an admission that any of the accused products, or any of ResMed's other products, infringe any of the asserted claims.

ResMed reserves the right to rely on contentions, charts, prior art references, and other statements relating to any ground of invalidity identified by any potential or actual licensees for

[1] All references herein to 35 U.S.C. sections refer to the pre-AIA version of the statute.

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the Asserted Patents and by any party in any other past, present, or future litigation involving the Asserted Patents.

ResMed also incorporates by reference all grounds of invalidity identified in any present or future reexamination, *inter partes* review, covered business method (CBM) patent review, or other post-issuance review by the Patent and Trademark Office of the Asserted Patents. ResMed further incorporates by reference the production of documents associated with any grounds for invalidity for the Asserted Patents. ResMed further incorporates any grounds of invalidity known to CleveMed or any affiliated party, whether or not disclosed. ResMed also requests that all such contentions from every case involving the Asserted Patents be produced to ResMed as soon as possible after they are served on, or become known to, CleveMed.

III. ANTICIPATION AND OBVIOUSNESS (35 U.S.C. §§ 102 AND 103)

A. Legal Standard

Under 35 U.S.C. § 102, "[a] patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention." *Schering Corp. v. Geneva Pharm., Inc*., 339 F.3d 1373, 1377 (Fed. Cir. 2003). A prior art reference may anticipate a claim limitation even though the limitation is "not expressly found in that reference." *MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365 (Fed. Cir. 1999); *Standard Havens Prod., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1369 (Fed. Cir. 1991) ("An anticipatory reference … need not duplicate word for word what is in the claims."). Instead, "[a]nticipation can occur when a claimed limitation is 'inherent' or otherwise implicit in the relevant reference." *Standard Havens,* 953 F.2d at 1369; *see also Schering Corp. v. Geneva Pharm.,* 339 F.3d 1373, 1377 (Fed. Cir. 2003) ("[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference."). In addition, the prior art document "may incorporate subject matter by

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reference to another document such that the incorporated material becomes part of the host document for the purposes of anticipation." *Apple Inc. v. Int'l Trade Comm'n*, 725 F.3d 1356, 1362 (Fed. Cir. 2013).

Under 35 U.S.C. § 103, a patent may not issue "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." Pre-AIA 35 U.S.C. § 103(a). Thus, "[a]n invention which has been made, and which is new in the sense that the same thing has not been made before, may still not be patentable if the difference between the new thing and what was known before is not considered sufficiently great to warrant a patent." *Graham v. John Deere Co.*, 383 U.S. 1, 13–14 (1966). Obviousness is a question of law based on underlying factual findings concerning: "(1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness," otherwise known as "secondary considerations." *Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 877 (Fed. Cir. 1993); *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1339 (Fed. Cir. 2008).

To prove that a patent is obvious, a party must demonstrate "that a skilled artisan would have had reason to combine the teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so." *Eurand, Inc. v. Mylan Pharmaceuticals Inc.*, 676 F.3d 1063, 1069 (Fed. Cir. 2012); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."). Although an analysis of any teaching, suggestion, or motivation to

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combine known elements might provide "helpful insight[s]," the overall obviousness inquiry must be "expansive and flexible." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007) (rejecting "rigid and mandatory formulas" that "that deny factfinders recourse to common sense").

A reason to combine may be found explicitly or implicitly, in one or more of the following:

1. A person of ordinary skill in the art's knowledge or common sense;
2. The prior art references themselves;
3. The subject matter acknowledged as prior art in the asserted patent;
4. The interrelated teachings of multiple prior art references identified herein;
5. The nature of the problem to be purportedly solved by the asserted patent and the existence of similar improvements in similar applications;
6. Design incentives and other market forces, including the advantages of creating a superior and more desirable product and the effects of demands known to the design community or present in the marketplace;
7. The ability to implement the alleged invention as a predictable variation of the prior art;
8. Combining prior art elements according to known methods to yield predictable results;
9. Improvements in similar devices;
10. Applying a known technique to a known device (method or product) ready for improvement to yield predictable results;
11. Any needs or problems known in the field and purportedly addressed by the asserted patent – *i.e.*, "obvious to try";
12. The number of identified, predictable solutions to the problem(s) purportedly addressed by the asserted patent;
13. The simple substitution of one known elements for another to obtain predictable results; and
14. Some teaching, suggestion, or motivation in the prior art that would have led one

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> of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

See KSR Int'l Co., 550 U.S. at 416-418, 421. ResMed discusses certain of these reasons more specifically below and in the attached charts. The fact that other reasons are not discussed more specifically should not be interpreted as an admission or concession that it does not apply. To the contrary, the discussion below simply provides more explanation of certain reasons.

Finally, the use of hindsight is not permitted when determining whether a claim would have been obvious to one having ordinary skill in the art. *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 421, (2007) (cautioning against "the distortion caused by hindsight bias" and obviousness "arguments reliant upon *ex post* reasoning"). To protect against the improper use of hindsight when assessing obviousness, a court is required to consider secondary considerations or objective indicia of non-obviousness. *Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1310 (Fed. Cir. 2010). Secondary considerations of nonobviousness may include "commercial success, industry praise, unexpected results, copying, industry skepticism, licensing, and long-felt but unsolved need." *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc*., 699 F.3d 1340, 1349 (Fed. Cir. 2012). To the extent CleveMed has offered in written discovery responses evidence they contend establishes non-obviousness, at a minimum, CleveMed has not identified nor established a nexus to the claimed systems or methods, and in particular, to the alleged inventive aspect of the asserted claims over the prior art. Discovery has just begun and CleveMed has not substantiated any of the alleged "evidence" identified thus far, and ResMed has not yet had the opportunity to obtain discovery on such alleged "evidence." ResMed reserves the right to challenge the alleged "evidence" CleveMed has offered in its written discovery responses, and any additional "evidence" identified in the future.

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B. Reservation of Rights

Exhibits A01-F04, and G05 are claim charts that specifically identify prior art that anticipates and/or renders obvious each of the asserted claims of the Asserted Patents. In addition to the references identified in the Exhibits, ResMed reserves the right to rely on any of the patents or publications in the respective claimed priority chains of the Asserted Patents, the references cited on the face of the Asserted Patents and related patents, any admitted prior art references in the specification of the Asserted Patents and related patents, the prosecution histories of the Asserted Patents and related patents, the references cited in any USPTO proceedings, including PTAB proceedings, related to the Asserted Patents or related patents, any references known to CleveMed or any affiliated party, and the references cited in any invalidity contentions that have been or will be submitted in any action or proceedings involving the Asserted Patents or related patents. ResMed may also rely on expert testimony and any additional prior art located or developed during the course of discovery, including prior art exhibiting the state of the art or knowledge of a POSITA. ResMed may further rely on any of the prior art references in these Final Contentions to demonstrate a motivation to combine. ResMed may further rely on expert testimony to demonstrate a motivation to combine. ResMed may further rely on (i) foreign counterparts of U.S. patents identified in these Final Contentions; (ii) U.S. counterparts of foreign patents and foreign patent applications identified in these Final Contentions; and (iii) U.S. and foreign patents and patent applications corresponding to articles and publications identified in these Final Contentions. Moreover, ResMed reserves the right to rely on other references (irrespective of whether such references themselves qualify as prior art) to show the state of the art, and/or rely on expert testimony to provide context to, or aid in, understanding the cited portions of the identified prior art.

In the charts submitted herewith, the cited excerpts of each reference are only examples

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of how the reference anticipates the asserted claims, discloses the identified claim limitation, or renders the claim obvious. ResMed reserves the right to rely on un-cited portions of the prior art references (including any information incorporated by reference) and on other publications, expert testimony, and other evidence for any of the following reasons: (i) as aids in understanding and interpreting the cited portions, (ii) as providing context to the cited portions, (iii) as additional evidence that the prior art discloses a claim limitation or an asserted claim as a whole; (iv) to establish that an item of prior art discloses a claim limitation or an asserted claim as a whole, and (v) to establish bases for combinations of certain items of the reference that render the asserted claims obvious under 35 U.S.C. § 103 in view of the knowledge of a person of ordinary skill in the art. Where ResMed cites to a particular figure in a reference, the citation should be understood to encompass the caption and description of the figure and any text relating to the figure. Conversely, where ResMed cites to particular text referring to a figure, the citation should be understood to include the figure as well.

To the extent that CleveMed argues that any of the references listed as anticipatory does not disclose one or more elements of the claim, ResMed reserve the right to use one or more of these references as rendering the claims obvious in view of knowledge in the art under 35 U.S.C. § 103. In addition, any suggested obviousness combinations set forth herein are in the alternative to ResMed's anticipation contentions and are not to be construed to suggest that any reference included in any combination is not anticipatory in its own right. In particular, ResMed is currently unaware of the extent to which CleveMed will contend that certain limitations of the asserted claims are not disclosed in the art identified by ResMed as anticipatory. To the extent that an issue arises with respect to any such claim limitation, ResMed reserves the right to identify other references and combinations, which may make obvious the addition of the

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allegedly missing limitation to the disclosed system or method. In addition, ResMed may rely on some references under both 35 U.S.C. § 102 and 35 U.S.C. § 103. It is established law that "a rejection for obviousness under § 103 can be based on a reference which happens to anticipate the claimed subject matter." *In re Meyer*, 599 F.2d 1026, 1031 (C.C.P.A. 1979).

C. The HST Patents (The '399 Patent, '535 Patent, '937 Patent, '603 Patent, '698 Patent, and '637 Patent)

1. Identification of Prior Art

The following prior art patents and published patent applications relate to the invalidity of the asserted claims of the '399 Patent, '535 Patent, '937 Patent, '603 Patent, '698 Patent, and '637 Patent (collectively, the "HST Patents"). Each of the following may qualify as prior art as of an earlier date than the listed date, e.g., an earlier publication or filing date. ResMed reserves the right to supplement the priority dates for the below listed references as discovery continues.

Prior Art Patents and Published Applications	Filed Date	Issue/Publication Date	Invalidity Basis
United States Patent No. 9,801,589 to Schwaibold	04/04/2007	10/31/2017	Anticipation and/or obviousness
United States Patent Application Publication No. 2003/0199945 to Ciulla	02/10/2003	10/23/2003	Anticipation and/or obviousness
United States Patent No. 7,967,760 to Lang	04/29/2005	11/09/2006	Obviousness

The following prior art non-patent publications relate to the invalidity of the asserted claims of the HST Patents.

Prior Art Publications	Date of Publication	Invalidity Basis
Puzzuoli, et al., *Remote Transmission and Analysis of Signals from Wearable Devices in Sleep Disorders*	2005	Obviousness

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Prior Art Publications	Date of Publication	Invalidity Basis
Evaluation, Computers in Cardiology, 2005, 32:53-56 ("Puzzuoli")		

The following prior art products and systems relate to the invalidity of the asserted claims of the HST Patents.

Prior Art Products/Systems	Date of Availability	Invalidity Basis
ResMed's Embletta PDS product and related software	November 2000	Anticipation and/or obviousness
Crystal Monitor 20-S and related software, including Crystal PSG	No later than 2004	Anticipation and/or obviousness

The Embletta PDS and Crystal Monitor 20-S were known or used by others in this country and/or in public use or on sale in this country more than one year prior to the June 8, 2007 priority date of the HST patents. For the Embletta PDS this is evidenced by, for example, the Embletta PDS Launch Bulletin, which states that ResMed launched and distributed the Embletta PDS "World-Wide" in December 2000. RMD-063081 (listing the date of implementation is listed as "immediate"). *Id.* The Embletta PDS Launch Bulletin further notes that the "Embletta PDS includes Somnologica for Embletta software." *Id.* at 3. Yet another example is the Embletta PDS product made available for inspection. The inspected and photographed Embletta PDS was used by, tested, and certified by the Royal Adelaide Hospital with a certification expiration of December 30, 2002. For the Crystal Monitor 20-S this is evidenced by, for example, CleveMed's 2006 website listing the Crystal Monitor for sale and [redacted] for the Crystal Monitor 20-S. RMD-076827;

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RMD-076402. Additional evidence for the Embletta PDS and Crystal Monitor 20-S is identified in the respective claim charts A03-F03 and A04-F04.

Regarding the Crystal Monitor 20-S, ResMed reserves the right to rely on the Crystal Monitor 20-B to the extent that the Crystal Monitor 20-S and 20-B are identical. The only difference between the Crystal Monitor 20-S and 20-B is that they operate on different frequencies. Since the claims of the HST patents do not require specific frequencies, the Crystal Monitor 20-S and 20-B are identical for all relevant invalidity purposes.

In addition to the products in the chart above, ResMed continues to investigate the identities of the individuals or entities involved in the first sale, offer for sale, or public use of prior art products that were made using the system recited by the asserted claims of the HST Patents. ResMed will produce additional documents relating to the invalidity of the asserted claims by those products as they become available.

2. Final Contentions

The asserted claims of the HST Patents are anticipated by at least the prior art identified and detailed in Exhibits A01-F04. ResMed contends that each item of prior art identified above and/or in the accompanying claim charts anticipates one or more of the asserted claims of the HST Patents, either expressly, implicitly, or inherently, as understood by a person having ordinary skill in the art. In some instances, ResMed may treat certain prior art as anticipatory where certain elements are inherently present.

If the finder of fact determines that some limitation of a given claim was not disclosed by an asserted reference, ResMed contends that the prior art references identified in Exhibits A01-F04, in combination with the knowledge and skill of a person of ordinary skill in the art at the time of the alleged invention and/or in combination with the disclosures of other prior art, including but not limited to the prior art references identified in Exhibits A01-F04 and/or the

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additional prior art references disclosed herein, would have rendered all of the asserted claims of the HST Patents obvious. To the extent that any asserted claim of the HST Patents is found not to be anticipated by a corresponding reference, such claim would have been obvious over that reference.

ResMed has provided exemplary combinations in Exhibits A01-F04 for specific claim limitations which identify exemplary secondary references and exemplary disclosures therefrom. Each prior art reference evidences teachings, suggestions, motivations, and/or other reasons to combine it with the other identified references in ways that render obvious all of the asserted claims of the HST Patents. In addition to any specific combinations of prior art disclosed using claim charts, ResMed reserves the right to rely on any combination of prior art references disclosed in these contentions.

Attached hereto are the following charts setting forth where in the prior art references each element of the asserted claims are found. ResMed reserves the right to supplement these Final Contentions. For example, ResMed reserves the right to rely on the CleveMed Crystal Monitor 16 and/or 20-S, which are products allegedly marketed and sold by CleveMed.

Exhibit	**Description of Charts for ’399 Patent**
A01	United States Patent No. 9,801,589 to Schwaibold
A02	United States Patent Application Publication No. 2003/0199945 to Ciulla
A03	ResMed’s Embletta PDS product and related software, including Somnologica
A04	CleveMed Crystal Monitor 20-S, and related software, including Crystal PSG

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Exhibit	Description of Charts for ’535 Patent
B01	United States Patent No. 9,801,589 to Schwaibold
B02	United States Patent Application Publication No. 2003/0199945 to Ciulla
B03	ResMed’s Embletta PDS product and related software, including Somnologica
B04	CleveMed Crystal Monitor 20-S, and related software, including Crystal PSG

Exhibit	Description of Charts for ’937 Patent
C01	United States Patent No. 9,801,589 to Schwaibold
C02	United States Patent Application Publication No. 2003/0199945 to Ciulla
C03	ResMed’s Embletta PDS product and related software, including Somnologica
C04	CleveMed Crystal Monitor 20-S, and related software, including Crystal PSG

Exhibit	Description of Charts for ’603 Patent
D01	United States Patent No. 9,801,589 to Schwaibold
D02	United States Patent Application Publication No. 2003/0199945 to Ciulla
D03	ResMed’s Embletta PDS product and related software, including Somnologica
D04	CleveMed Crystal Monitor 20-S, and related software, including Crystal PSG

Exhibit	Description of Charts for ’698 Patent
E01	United States Patent No. 9,801,589 to Schwaibold

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Exhibit	Description of Charts for ’698 Patent
E02	United States Patent Application Publication No. 2003/0199945 to Ciulla
E03	ResMed’s Embletta PDS product and related software, including Somnologica
E04	CleveMed Crystal Monitor 20-S, and related software, including Crystal PSG

Exhibit	Description of Charts for ’637 Patent
F01	United States Patent No. 9,801,589 to Schwaibold
F02	United States Patent Application Publication No. 2003/0199945 to Ciulla
F03	ResMed’s Embletta PDS product and related software, including Somnologica
F04	CleveMed Crystal Monitor 20-S, and related software, including Crystal PSG

One of ordinary skill in the art would have understood how to combine the teachings of the prior art references referred to in these Final Contentions and would have been motivated to pursue such combinations for numerous reasons. For example, all references identified in Exhibits A01-F04 are analogous art because each of them is from the same field of endeavor as the claimed inventions of the ’399, ’535, ’937, ’603, ’698, and ’637 Patents, collection of physiologic and kinetic data from a subject using an in-home data acquisition system for conducting a sleep analysis. *See, e.g.*, ’399 Patent, Abstract. One of ordinary skill in the art would have combined particular features of systems, apparatuses, and methods disclosed in certain of the prior art references with other prior art references that do not expressly disclose such particular features because, *e.g.*, (i) the teachings of the references are interrelated and cite each other, (ii) it would have been a simple substitution of particular features in one reference

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into the systems, methods, and/or processes of another reference, (iii) the nature of the problem alleged by the Asserted Patents made such combinations apparent and a matter of common sense, (iv) design incentives and other market forces would have made the advantages of such combinations clear, (v) such combinations would have been predictable variations of the prior art, (vi) such combinations would have yielded predictable results, (vii) it would have been obvious to try such combinations, and (viii) such combinations would be within a finite number of identified, predictable solutions to the problem alleged by the Asserted Patents.

Many of the identified references disclose known systems, components, protocols, and methods for in-home collection of data for conducting a sleep analysis, and, more specifically, methods and systems for in-home collection of physiologic and kinetic data from a subject, and transmission or transference of that data to a remote location. *See, e.g.,* Su, et al., *A Comparison of Polysomnography and a Portable Home Sleep Study in the Diagnosis of Obstructive Sleep Apnea Syndrome, Otolarynology-Head and Neck Surgery*, 131:9, 844-50, 2004; Oliver, et al., *HealthGear: A Real-time Wearable System for Monitoring and Analyzing Physiological Signals*, IEEE, Proceedings of the International Workshop on Wearable and Implantable Body Sensory Networks, 2006 ("Oliver"); Dingli, *Evaluation of a Portable Device for Diagnosing the Sleep Apnoea/Hypopnoea Syndrome*, 21 Eur Respir. J. 253-59 (2003) ("Dingli") Ento Key, *Home Sleep Testing in the Diagnosis and Treatment of Sleep Disordered Breathing* ("Ento Key"); Bridevaux, Inter-Observer Agreement on Apnoea Hypopnoea Index Using Portable Monitoring of Respiratory Parameters, 137 Swiss Med Wkly 602-07 (2007) ("Bridevaux"); Davidson, *Home Sleep Testing*, Division of Otolaryngology-Head and Neck Surgery, University of California at Sand Diego and VA San Diego Health Care System ("Davidson"); Patel, Home Sleep Testing, Operative Techniques in Otolaryngology (2007) 18, 33-51 ("Patel"); Poels, Evaluation of a New

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Device for Home Cardiorespiratory Recording in Children ("Poels"); *see also* US 2002/0165462 to Westbrook et al. ("Westbrook"), discussed in more detail in section III.D.2, below.

For example, Davidson in March 2007, in an article entitled "Home Sleep Testing," compares the Embletta PDS home sleep testing device with several other home sleep testing devices, including the Stardust Sleep Diagnostic Device by Respironics, Inc.; the NovaSom QSG by Sleep Solutions, Inc.; the SNAP Model 6 by SNAP Laboratories LLC; the Watch-PAT100 by Itamar Medical Ltd.; the Remmers Sleep Recorder (formerly SnoreSat) by SagaTech Electronics Inc.; and the Edentrace by Puritan Bennett. Davidson at 21, 25, 29, 34, 37, 38. Another article by Patel et al states that "[a] multitude of portable home sleep testing machines are available. The units known to the authors, along with the manufacturer and references, are listed in Table 3." Patel at 3. Other products include Home Monitoring Systems by DigiTrace Care Services Inc.; the NightWatch by HealthDyne Technologies; the Medilog MPA-S by Oxford Instruments; the P-Series Sleep System by Compumedics; and the microsleep Sleep Analysis System by Medtronic Inc. Still other systems include Braebon PSG Diagnostic Systems, Sleep Sensors, and Outcome Software, such as the MediByte Screener; Puritan Bennett PSGs, such as the Sandman Pocket Portable Recorder; and Grass Technologies PSGs, such as the Comet PSG, SleepTrek Portable Sleep Screener, and Aura PSG. As such, a POSITA in June 2007 would have been aware of a wide variety of home sleep monitoring devices and would have known that home sleep monitoring had been performed for "many years," at least since the mid to late 1990s. A POSITA would therefore have found it obvious to modify a device to sleep monitoring device to add a home sleep monitoring and testing capability. The motivation for a POSITA to modify was well know. For example, Dingli states: "Home-based sleep studies have potential advantages in terms of decreased costs [7], including no charges for hospital accommodation, convenience, as well as possibly

improved sleep quality for the patients. A recent study, comparing the sleep quality of in-laboratory sleep studies to home-based studies, showed better sleep efficiency, more time spent in rapid eye movement and slow wave sleep, and significantly fewer arousals during the home-based studies." Dingli at 1. The Dingli study estimated that the Embletta's home sleep monitoring cut costs by 42%. Dingli at 6. Similarly, Patel estimates that home sleep tests are 25 to 30% of the cost of PSG. Patel at 11. Additionally, Davidson concludes that "[b]ased on accuracy, sensitivity, specificity, ease of application, physician acceptance, expense, and patient acceptance, multichannel home sleep testing is the preferred sleep test for patients with snoring and a presumptive diagnosis of SDB." Davidson at 46. Also in March 2007, Patel states that "Testing at home is reported to be more comfortable by patients, and common sense suggests that this is a better paradigm. It is the authors' opinion that home sleep testing is a valid, cost-effective, objective measure of SDB, and should be used for routine diagnosis and monitoring of SDB." Patel at 2. Additionally, Poels in 2003 stated that "[i]nterest in home-based PSG is growing because hospital-based PSG is costly and time-consuming." Poels at 3. Thus, a POSITA in June 2007 would have been motivated to modify a sleep monitoring device to add home sleep monitoring and testing capability and, considering the large number of marketed home sleep testing devices in March 2007 and earlier, a POSITA would have a reasonable expectation of success in such a modification.

For the avoidance of doubt, the products listed above are used to show background, state of the art, motivation to combine, and knowledge of a POSITA. The only products used as anticipation or obviousness references in the analysis herein are the Embletta PDS and Crystal Monitor 20-S.

Furthermore, a POSITA viewing one prior art home sleep test diagnostic system would look to other similar systems to meet the elements of the patented claims at least because such

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combinations would have yielded predictable results and it would have been obvious to try such combinations. For example, references discussing the Embletta system have recognized the various advantages of home-based sleep studies:

> Home-based sleep studies have potential advantages in terms of decreased costs [7], including no charges for hospital accommodation, convenience, as well as possibly improved sleep quality for the patients. A recent study, comparing the sleep quality of in-laboratory sleep studies to home-based studies, showed better sleep efficiency, more time spent in rapid eye movement and slow wave sleep, and significantly fewer arousals during the home-based studies.

Dingli, *Evaluation of a Portable Device for Diagnosing the Sleep Apnoea/Hypopnoea Syndrome*, 21 Eur. Respir. J. 253-59 (2003) ("Dingli"). A POSITA would have thus been motivated to combine Embletta PDS, or any other identified prior art system, with features that benefit and improve upon home-based sleep systems, such as the ability for a system to, *e.g.*, utilize a transceiver "adapted to transfer the collected data from the nonvolatile digital memory via cellular systems, Internet satellite, wired-network and/or land lines" to a "a database adapted to be remote from the home of the subject for receiving the collected data." *See, e.g.*, '535 patent, claim 1.

For the same reasons, a POSITA viewing the CleveMed PSG system identified above would look to other known systems to solve problems common among the various systems.

Moreover, a POSITA would have found it obvious to combine different versions of a product that similarly accomplish home sleep test diagnostics, *e.g.*, Crystal Monitor 16, Crystal Monitor 20-S and 20-B, and/or SleepScout. For example, a POSITA in 2007 viewing the Embletta PDS product as it was produced in 2002 would also look to the Embletta PDS product as it was produced in 2006.

All of the reasons discussed above for combining references are incorporated by reference into the claim charts whether or not specifically stated.

[redacted]

D. The ’269 Patent

1. Identification of Prior Art

The following prior art patents and published patent applications relate to the invalidity of the asserted claims of the ’269 patent. Each of the following may qualify as prior art as of an earlier date than the listed date, *e.g.*, an earlier publication or filing date. ResMed reserves the right to supplement the priority dates for the below listed references as discovery continues.

Prior Art Patents and Published Applications	Filed Date	Issue/Publication Date	Invalidity Basis
United States Patent No. 6,167,258 (“Schmidt”)	10/09/1998	12/26/2000	Obviousness
United States Patent Application Publication No. 2002/0165462 (“Westbrook”)	12/28/2002	11/07/2002	Obviousness
US Patent No. 6,287,264 (“Hoffman”)	04/23/1999	09/11/2001	Obviousness

The following prior art non-patent publications relate to the invalidity of the asserted claims of the ’269 patent.

[redacted]

Prior Art Publications	Date of Publication	Invalidity Basis
Mohd Fadlee A. Rasid and Bryan Woodward, *Bluetooth Telemedicine Processor for Multichannel Biomedical Signal Transmission via Mobile Cellular Networks*," IEEE Transactions on Information Technology in Biomedicine, Vol. 9, No. 1, March 2005, at 35 ("Rasid")[2]	03/2005	Obviousness

The following prior art products that are components of the ResMed Prior Art systems identified below, in addition to their documentation (incorporated herein), relate to the invalidity of the asserted claims of the '269 patent.

Prior Art Products	Date of Availability
ResMed AutoSet Spirit device	Prior to Nov. 4, 2004
ResMed AutoScan/ResScan software and related hardware	Prior to Nov. 4, 2004, and at least prior to Nov. 4, 2005
ResMed ResLink (a.k.a. "[redacted]")	Prior to Nov. 4, 2004

[2] B. Woodward and M.F.A. Rasid, Wireless Telemedicine: The Next Step, 4th Int'l IEEE EMBS Special Topic Conference on Information Technology Applications in Biomedicine, 2003, at 43 ("Woodward") is a 2003 disclosure by the same authors of similar work disclosed in the later 2005 Rasid publication. Because, in response to ResMed's Interrogatory No. 2, CleveMed has continually changed its contention regarding the alleged conception date for the '269 patent asserted claims and has failed to provide sufficient support for its alleged conception, diligence, and reduction to practice, CleveMed has prejudiced ResMed's ability to prepare its invalidity contentions. Specifically, CleveMed's contentions regarding conception and diligence in reduction to practice as of the date of service of these invalidity contentions do not establish either (1) conception before the publication date of Rasid, or (2) diligence between March 2005 and the filing date of the application to which the '269 patent claims priority. Based on the information made available to ResMed, ResMed relies on Rasid, and not Woodward, as invalidating prior art to the '269 patent asserted claims. To the extent it is determined that Rasid is not prior art, or if CleveMed supplements its contentions with regard to conception and diligence in reduction to practice with additional facts or information, ResMed reserves the right to rely on Woodward in place of Rasid. ResMed also reserves the right to rely on similar disclosures as those provided in Farrell in an earlier publication for at least the same reasons.

[redacted]

Prior Art Products	Date of Availability
ResMed ResTraxx device (module) and related backend software and components, including the ResMed ResTraxx Data Center (RDC) (a.k.a. [redacted])	Prior to March 2005, and at least prior to Nov. 4, 2005

The above table identifies the primary individual components of the following two prior art ResMed systems that anticipate or render obvious the asserted claims of the '269 patent, which are addressed in more detail at Exhibit G05:

Prior Art System	**Invalidity Basis**
System 1: ResMed AutoSet Spirit + ResLink + AutoScan 5.4[3]	Anticipation and/or obviousness
System 2: ResMed AutoSet Spirit + ResTraxx (including RDC)	Anticipation and/or obviousness

In addition to the products in the chart above, ResMed continues to investigate the identities of the individuals or entities involved in the first sale, offer for sale, or public use of prior art products that were made using the systems recited by the asserted claims of the '269 patent. ResMed will produce additional documents relating to the invalidity of the asserted claims by those products as they become available. Evidence of first sale, offer for sale, or public use in the United States is identified in Exhibit G05.

[3] As explained in the documentation produced by ResMed for AutoScan 5.x, the 5.x versions are "version[s] of AutoScan that supports the ResLink developed for the S7 Elite and AutoSet Spirit flow generators. This includes the initial English version of AutoScan 5.0, the USA version (5.1) and the ROW [rest of world] version of AutoScan (5.2). AutoScan 5.3 (RoW) adds support for the VPAP III ST-A flow generator. AutoScan 5.4 (US) adds support for the VPAP III and AutoSet Respond flow generators." [redacted] ResMed is not relying on any of the changes (or "delta") from AutoScan 5.1 to 5.4 that merely support additional flow generators that ResMed is also not relying on for its contentions. ResMed is instead relying on the same functionality in AutoScan 5.4 as disclosed in AutoScan 5.1 and identified in ResMed's previously amended contentions for RPA System 1.

[redacted]

2. Final Contentions

The asserted claims of the ’269 patent are anticipated by at least the prior art identified and detailed in Exhibit G05.[4] ResMed contends that each item of prior art identified above and/or in the accompanying claim charts anticipates one or more of the asserted claims of the Asserted Patents, either expressly, implicitly, or inherently, as understood by a person having ordinary skill in the art. In some instances, ResMed may treat certain prior art as anticipatory where certain elements are inherently present.

If the finder of fact determines that some limitation of a given claim was not disclosed by an asserted reference, ResMed contends that the prior art references identified in Exhibit G05, in combination with the knowledge and skill of a person of ordinary skill in the art at the time of the alleged invention and/or in combination with the disclosures of other prior art, including but not limited to the prior art references identified in Exhibit G05 and/or the additional prior art references disclosed herein, would have rendered all of the asserted claims of the ’269 patent obvious. For example, the ’269 patent appears to rely extensively on the knowledge of a person of skill in the art to satisfy the statutory requirements of 35 U.S.C. § 112, and ResMed reserves the right to rely on that same knowledge as prior art in combination with one or more of the disclosed references. To the extent that any asserted claim of the ’269 patent is found not to be anticipated by a corresponding reference, such claim would have been obvious over that reference.

ResMed has provided exemplary combinations in Exhibit G05 for specific claim

[4] ResMed’s initial contentions included Exhibits G01-G06. In accordance with DI 56 denying the parties’ stipulation to remove the limits on the number of prior art references, ResMed has amended its contentions to rely on Exhibit G05 and withdraws Exhibits G01-G04 and G06, but these contentions retain the original numbering to avoid confusion.

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[redacted]

limitations which identify exemplary secondary references and exemplary disclosures therefrom. Each prior art reference evidences teachings, suggestions, motivations, and/or other reasons to combine it with the other identified references in ways that render obvious all of the Asserted Claims of the ’269 patent. In addition to any specific combinations of prior art disclosed using claim charts, ResMed reserves the right to rely on any combination of prior art references disclosed in these contentions.

Attached hereto are the following charts setting forth where in the prior art references each element of the asserted claims are found. ResMed reserves the right to supplement these Final Contentions.

Exhibit	Description
G05	ResMed Prior Art (“RPA”) – HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY

The following analysis applies to the attached Exhibit G05 in addition to the motivations identified above and expressly in the exhibits.

(a) State of the Art and Obviousness of the Alleged Inventions

The asserted claims of the ’269 patent are directed to positive airway pressure (PAP) sleep disorder treatment systems. PAP systems for sleep disorder treatment were well-known in the art by the time of the application for the ’269 patent, and also before the alleged conception date of the ’269 patent. The ’269 patent provides very little, if any description, of how to apply the disclosed system to sleep disorder treatment systems, and instead relies heavily on the knowledge of a POSITA for numerous features recited in the asserted claims. Accordingly, the ’269 patent appears to admit that such features were well known to a POSITA.

The specification of the ’269 patent admits that “the most common method of treating the

[redacted]

sleeping disorder of sleep apnea is by apply a continuous positive gas pressure to the patient's airway, which has the effect of forcing the patient to breath through application of the pressure." '269 patent, 2:17-21. The '269 patent notes that "[m]ore advanced, but still very basic devices have been developed that adjust this continuous positive gas pressure through sensors built into the device for creating the positive gas pressure, which measure gas flow through the device." '269 patent, 2:21-25. However, the '269 patent incorrectly concludes that "[n]one of the devices on the market can be used to adjust a patient's treatment, whether physical or chemical, based on the patient's current physiological state. Further none of the current devices can be used to adjust a patient's treatment, based on the patient's current symptoms. Still further, none of the current devices can be used to predict the onset of symptoms of various sleeping disorders and provide treatment in anticipation of such symptoms. Still even further, none of the current devices can be used to adjust a treatment device based on the subject's physiological signals." '269 patent, 2:27-37. On the contrary, as established in the chart at exhibit G05, such devices were not only known in the art, but disclosed, for example, by ResMed. *See, e.g.*, ResMed Prior Art (Exhibit G05).

The '269 patent admits, for example, that a "conventional pressure support system 310 shown in FIG. 7 includes a pressure generator 312, a blower, piston or bellows, that receives a supply of gas from a gas source, such as ambient atmosphere, … or pressured gas tanks … and creates a flow of breathing gas … having a pressure greater than the ambient atmospheric pressure." '269 patent, 22:45-54. Figure 7, depicting a "conventional pressure support system," also depicts a flow sensor 320 and a pressure sensor 322 internal to the PAP device housing.

Indeed, these conventional PAP systems were well-known in the art. As one example, WO 2005/096737 to Farrell ("Farrell") discloses:

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[redacted]

> The most common treatment of [sleep disordered breathing] SDB is to administer continuous positive airway pressure (CPAP). The use of nasal CPAP to treat OSA was invented by Sullivan and taught in U.S. Patent 4,944,310. Briefly stated, CPAP treatment acts as a pneumatic splint of the airway by the provision of a positive pressure, usually in the range 4-20 cm H20. The air is supplied to the airway by a motor driven blower that is coupled via an air delivery hose to a nose (or nose and/or mouth) mask sealed with the patient's face. More sophisticated forms of CPAP treatment may be provided by bi-level ventilators, proportional assist ventilators and servo-controlled ventilators. Such devices are typically used by the patient on a daily basis before and during sleep.
>
> For example, nasal CPAP treatment of OSA may involve the use of an automated blower, such as the AUTOSET T™ device or AUTOSET SPIRIT™ available from ResMed Ltd. Examples of suitable nasal CPAP masks are the MIRAGE™ nasal mask and the MIRAGE™ full face mask also available from ResMed Ltd. The AUTOSET T™ device continuously monitors the state of the patient's airway and determines an appropriate pressure to treat the patient, increasing it or decreasing it as necessary. Alternatively, bi-level pressures are delivered to the patient as in the VPAP II™ devices also available from ResMed Ltd. Some of the principles behind the operation of the AUTOSET T™ and VPAP II™ devices are described in U.S. Patent 5,704,345.

Farrell, 1:22-2:5.

As recognized by Farrell, ResMed's own PAP systems were well known in the art, including the ResMed AutoSet T and AutoSet Spirit devices. *See, e.g.,* ResMed Prior Art Claim Chart, Exhibit G05; D. Alan Lankford, *Wireless CPAP Patient Monitoring: Accuracy Study, Telemedicine Journal and e-Health*, Vol. 10, No. 2, 2004, at 162 ("Lankford"). As demonstrated in the attached claim chart, these ResMed Prior Art anticipates, or at least renders obvious, the asserted claims.

As another example, US 2005/0211249 to Wagner ("Wagner") discloses in its Background section, consistent with the knowledge of a POSITA:

> Additionally known are apparatus for performing the CPAP therapy (continuous positive airway pressure) which, in this application, are also designated as ventilator. The CPAP therapy is described in

[redacted]

> Chest. Volume No. 110, pages 1077-1088, October 1996 and in Sleep, Volume No. 19, pages 184-188. A CPAP-apparatus applies, by means of a compressor, preferably via a humidifier, via a hose and a nose mask, a positive overpressure up to approximately 30 mbar to the respiratory tract of the patient. This positive pressure is to ensure that the upper respiratory tract remains fully opened during the whole night, so that no obstructive apneas will occur (DE 198 49 571 A1).
>
> "FIG. 1 shows a CPAP-apparatus 1 and a patient 19. The CPAP-apparatus comprises a compressor 4, a respiratory hose 9, a respiratory mask 18, a pressure sensor 11 and a flow sensor 16. For the generation of an positive pressure the compressor 4 includes a turbine 8. The turbine is also designated as blower, blower unit, compressor, ventilator or fan. In this patent these terms are used synonymously. In the CPAP-apparatus as shown the pressure sensor 11 is accommodated in the compressor housing. In the mask, or in the proximity of the mask, one or several small holes 2 are provided which allow the formation of an air flow from the compressor to the holes 2 on the time average. This prevents the accumulation of CO2 in the respiratory hose 9 and allows the supply of the patient with oxygen.

Wagner, ¶¶ 4-5.

To the extent a well-known component of a PAP system is not expressly disclosed in a prior art reference, a POSITA would have recognized it to be present, or at least found it obvious based on the '269 patent's admission of the common components of PAP systems known in the art. For example, a POSITA, given the prior art disclosures, would have known to look to disclosures like the ResMed Prior Art, Farrell and its incorporated Berthon-Jones references (e.g., US 5,704,345), Lankford (which specifically identifies ResMed flow generators), Wagner, and also US 2002/0022973 to Sun et al. ("Sun"), and US 2002/0165462 to Westbrook et al. ("Westbrook") (discussed in more detail below) for details on how to implement the well-known features of PAP systems. By the time of the application for the '269 patent there were already multiple PAP systems providers in the market, and implementation of the claimed systems would have required no more than the ordinary level of skill in the art. *See, e.g.*, Francoise J. Roux and

[redacted]

Janet Hilbert, *Continuous positive airway pressure: new generations*, Clin. Chest Med. 24, 2003, at 315-342 ("Roux"), Table 3.

[redacted]

[redacted]

(b) Air Flow Sensors and Pulse Oximetry Sensors

The asserted claims recite an air flow sensor and, in some instances, a pulse oximeter sensor. These were common, well-known sensors used in biomedical telemetry systems, and also in sleep disorder breathing diagnostic and treatment systems. The ’269 patent admits that “[s]ensors which can be used are known to those skilled in the art.” ’269 patent, 6:10-11. The ’269 patent also notes “[t]hese sensors include electrodes for measuring electro-physiological signals such as EEG, ECG, EMG, EOG and the like. These electro-physiological signals can be obtained by any method known in the art, or subsequently developed by those skilled in the art to detect these types of signals.” ’269 patent, 6:10-16. The ’269 patent also admits that “[o]ther sensors can be used to measure various parameters of a subject's respirations. The subject's respirations can be measured by measurement of airflow, respiratory effort, oxygenation and ventilation, and the like. Measurement of airflow is preferably measuring using sensors or devices such as a pneumotachometer, strain gauges, thermal sensors, transducers, piezo sensors, magnetometers, pressure sensors, static charge-sensitive beds, and the like. These sensors or devices, also preferably measure nasal pressure, respiratory inductance plethysmography, thoracic impedance, expired carbon dioxide, tracheal sound and the like. Measurement of respiratory effort is preferably measured by esophageal pressure, surface diaphragmatic EMG, and the like. Measurement of oxygenation and ventilation is preferably measured by pulse oximetry, transcutaneous oxygen monitoring, transcutaneous carbon dioxide monitoring, expired end carbon dioxide monitoring, and the like.” ’269 patent, 7:27-43. Furthermore, the “Technical Background” section of the ’269 patent admits that known devices had been developed before the alleged invention “that adjust [] continuous positive gas pressure through sensors built into the device for creating the positive gas pressure, which measure gas flow through the device.” ’269 patent, 2:17-25.

[redacted]

However, the ’269 patent does not identify any preference for a type of air flow sensor (nor do the asserted claims), and fails to suggest any specific reason or advantage for selecting a pulse oximeter to use in combination with an air flow sensor. These sensors, alone and in combination, were common, well known features of PAP sleep disorder treatments systems known in the art. As the ’269 patent appears to admit, there were a handful of relevant physiological parameters and biometric system data a POSITA would have known to try and measure for a PAP sleep disorder treatment system, including airflow, respiratory effort, and oxygenation. As the ’269 patent also appears to admit, there were a handful of common, well-known sensor types to measure these parameters, and selection of which particular sensors to use would have been a design choice.

As known in the art, and disclosed, for example, by Wagner and Farrell (above), PAP devices typically included a number of sensors to detect air flow and pressure so as to adjust the pressure of treatment provided to the patient, and also oximeters, such as pulse oximeter, to detect oxygenation. *See, e.g.*, Farrell, 5:31-6:5 (pulse oximeter). As another example, Mechlenburg describes that the “variable pressure therapy systems include a sensor (not shown) that detects the conditions of the patient so that the pressure provided to the patient can be controlled based on the detected condition. For example, if the pressure provided to the patient varies with the patient's breathing cycle, a sensor, such as a flow or pressure sensor associated with breathing circuit 40, is provided to detect changes in the breathing cycle, such as changes from inspiration to expiration and vise versa. The pressure/flow delivered to the patient is controlled by the pressure control unit to vary depending on whether the patient is inhaling or exhaling.” US 2003/0213489 (“Mechlenburg”), [0020].

As yet another example, Sun discloses: “To achieve these more complicated forms of

[redacted]

pressure/flow control, the present invention contemplates providing a flow sensor 63 and/or pressure sensor 65, for monitoring the flow and/or pressure of breathing gas delivered to the patient. This is necessary, for example, in a bi-level or ventilator system operating on a spontaneously breathing patient, to determine when the appropriate cycle and trigger points occur. To achieve that auto-titration pressure support, where the pressure level varies with the condition of the patient, for example by increasing the pressure levels if the patient experiences snoring, apneas, or obstructed breathing, the present invention contemplates providing other sensors, such as a microphone, respiratory belt, and oximeter, either alone or in combination with flow and/or pressure sensors 63 and 65, for monitoring the condition of the patient and controlling the pressure support based thereon." Sun, [0060]; *see also* US 2001/0018557 ("Lynn"), ¶¶24-25, 33, 54-56; US 8,069,852 ("Burton"), 5:53-6:4.

The '269 patent asserted claims recite that the airflow sensor is "internal to the PAP device." To the extent a prior art reference does not discloses this specific configuration it would have been an obvious modification to the system. First, it was well known in the art to incorporate the well-known flow sensor within the PAP device. For example, Farrell, Sun, and the ResMed Prior art disclose this. *See* Farrell, 5:1-13, FIG. 1; Sun, ¶¶52, 58-60, FIG. 4 (showing housing 45), ResMed Prior Art Claim Chart, Exhibit G05; *see also* Wagner, ¶¶ 4-5, '269 patent at 2:17-25 (admitting that known devices "measure gas flow through the device," which a POSITA would have understood to disclose measuring gas flow internal to the PAP device). A POSITA would have known that there were only a handful of locations within the system to place the airflow sensor, including internal to the PAP device as claimed. For example, Berthon-Jones recognized, as was known in the art, that "it may not be convenient to mount the flow transducer 44 at or near the mask 30, nor to measure the mask pressure at or near

[redacted]

the mask. An alternative arrangement, where the flow and pressure transducers are mounted at or near the air pressure generator (in the embodiment being the turbine 34) is shown in FIG. 3." US 5,704,345 ("Berthon-Jones"), 8:31-36.

The asserted claims also recite that the "airflow sensor internal to the PAP device" is "adapted for measuring the respiratory airflow of a subject … ." '269 patent, claim 15 (*see also* claims 1, 5). CleveMed has argued in the IPR proceeding against the '269 patent that this requires detection of "physiological information" and that a "sensor that measures the output of the CPAP machine's blower rather than the respiratory airflow of the subject" does not satisfy this claim limitation. IPR2023-00565, Paper No. 6 (6/29/2023), 23, 31. However, the '269 specification does not disclose an "airflow sensor internal to the PAP device" that measures respiratory airflow as CleveMed has argued in the specification. For example, CleveMed points to the disclosure at column 7, lines 27-42, quoted above as disclosure of an embodiment of a "CPAP machine [that] measures a patient's respiratory airflow using a pressure sensor located within the device," and argues that "[t]his measurement is from the flow sensor 320 and pressure sensor 322, which monitors the condition of the subject, monitors the usage of the pressure support device, and controls the blower." IPR2023-00565, Paper No. 6 (6/29/2023), 5-6 (citing '269 patent, 23:7-17). However, the '269 patent specification does not disclose that an *airflow* sensor located *internal* to the PAP device measures "the respiratory airflow of a subject" as claimed, but instead that a sensor for such a measurement is located within the air hose, mask, or cannula in order to measure this information. The specification recites that a device "optionally … has a sensor *in the air hose* 416, which can measure the differential pressure 414 and thereby accurately *measure air flow provided to the patient*." '269 patent, 23:36-39 (emphasis added). Similarly, the specification recites that "nasal cannula or facemask can be used to measure the

[redacted]

subject's respiratory airflow" using a "pneumotachograph consisting of a standard oxygen nasal cannula or facemask respectively connected to a pressure transducer and placed in the nares … ." '269 patent, 7:63-8:2. An example of this configuration appears to be presented in Figure 7 showing the "pressure sensor 322" as part of the hose (subject circuit 314). To the extent CleveMed is arguing that a flow sensor that measures the airflow within the PAP device (whether from the output of the blower or other location before entering the breathing circuit to the patient) cannot satisfy the "airflow sensor" limitation, this belies CleveMed's admission that such a configuration, as shown in Figure 7, is an embodiment of the claimed "airflow sensor." ResMed's invalidity contentions demonstrate that this configuration was not only disclosed in the prior art, but was a well-known configuration, as discussed above. IPR2023-00565, Paper No. 6 (6/29/2023), 5-6 (citing '269 patent, 23:7-17). Indeed, CleveMed has accused of infringement the same configuration of sensors in the ResMed products that were well known and disclosed by, for example, the ResMed prior art. *See, e.g.*, Exhibit G05. To the extent CleveMed is arguing that a *calculation* of the mask flow based on data from a flow sensor and/or pressure sensor "internal to the PAP device" satisfies the "airflow sensor" claim limitation, this was also well-known in the prior art and disclosed, for example, in Berthon-Jones at column 8, lines 31-62 (also discussed above in regard to disclosing the obvious locations for an airflow sensor as known to a POSITA).

Moreover, a POSITA would have been aware that polysymnography (PSG) was the "gold standard" for the diagnosis of sleep disordered breathing. For example, as taught by Westbrook:

> A conventional full overnight PSG includes recording of the following signals: electroencephalogram (EEG), submental electromyogram (EMG), electrooculogram (EOG), *respiratory airflow* (oronasal flow monitors), respiratory effort

[redacted]

> (plethysmography), *oxygen saturation (oximetry)*, electrocardiography (ECG), snoring sounds, and body position. *These signals are considered the "gold standard"* for the diagnosis of sleep disorders in that they offer a relatively complete collection of parameters from which respiratory events may be identified and SA may be reliably diagnosed.

US 2002/0165462 ("Westbrook"), ¶10 (emphasis added). Westbrook further teaches, as was known in the art:

> A *finger pulse oximeter sensor is typically utilized with commercially available* equipment used for sleep studies to acquire pulse ate and oximetry readings of blood oxygen saturation. In accordance with the present invention, however, the system 10 utilizes a physiological monitor 12 having a pulse oximeter (SpO2) sensor affixed to the patient's forehead to acquire pulse and oximetry readings. Forehead oximetry is sometimes applied in surgical, critical care, emergency room, and other clinical care applications, but its use has not been reported in sleep studies."

Westbrook, ¶65, *see also* 58, 33, 22-23, 161 (addition of airflow signal), 164-167 (integration with CPAP device).

Indeed, commercially available finger pulse oximeter sensors were well-known in the art. Notably, CleveMed's infringement contentions allege the NONIN Xpod oximeter, used in combination with an adapter to connect the oximeter to the accused ResMed PAP devices, practices the claimed signal processing module / data acquisition system and associated pulse oximeter sensor. However, such oximeters and adapters were well-known in the prior art to the '269 patent. ResMed had incorporated a NONIN oximeter with its PAP devices by 2003. *See* ResMed Prior Art claim chart, Exhibit G05. As was also known in the art, NONIN and other manufacturers had developed Bluetooth enabled pulse oximeters, such as the NONIN wrist-worn module. M. J. Moron, E. Casilari, R. Luque and J. A. Gazquez, *A wireless monitoring system for pulse-oximetry sensors, 2005 Systems Communications* (ICW'05, ICHSN'05, ICMCS'05, SENET'05), 2005, 79-84, at 81-82, Figure 1 ("Moron"). Thus, to the extent a prior art reference

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is found to not disclose a pulse oximetry sensor, it would have been obvious, at least based on the desire of an implementer to strive for the "gold standard" in input signals for identifying sleep events, but also the ubiquity of pulse oximeters commercially available, which would have made incorporation of such a sensor and its corresponding signal processing module (such as the Xpod) no more than a conventional, implementation detail within the level of ordinary skill in the art.

In addition, a POSITA would have recognized the benefit of having an additional source of physiological data about the patient during treatment. It was well-known that each sensor signal is subject to variability. Air flow, for example, is subject to leak that impacts the data from an air flow sensor, thereby potentially skewing any data relied on, *e.g.*, for calculating apnea events, and ultimately AHI, for example, and also adjusting the pressure provided to the patient, or other settings of the system. A POSITA would have been motivated to include a pulse oximeter that provides information regarding oxygen desaturation in order to provide an additional independent means for supplementing the data and analysis related to the air flow sensor. Moreover, the AASM Task Force recognized, in 1999 that "where there was uncertainty about a[] [sleep related breathing] event, other information like oxygen desaturation or an arousal could be a useful arbiter." *Sleep-Related Breathing Disorders in Adults: Recommendations for Syndrome Definition and Measurement Techniques in Clinical Research*, SLEEP, Vol. 22, No. 5, 1999, pp. 667-689, ("1999 Chicago Criteria") at 674. As one example in the art, the ResMed AutoSet Portable II Plus collects and reports "Oximetry, respiratory effort, heart rate and body position … to further confirm diagnosis and treatment." AutoSet Clinical III Software, page 2; *see also* AutoSet II Portable II Plus Clinician's Manual, page 15, 50, 55 (showing "Oximetry Analysis dialog group"); Lankford, 168 (disclosing incorporating pulse oximetry into the remote

[redacted]

wireless CPAP device monitoring system); Lynn, ¶¶24, 25, 33, 54-56 (recognizing the usefulness of oxygen saturation information for sleep apnea diagnosis and treatment and incorporating a "conventional pulse oximeter" with a CPAP therapy system). The addition of such a sensor, as discussed herein, would have been merely a matter of incorporating off the shelf commercial components.

Moreover, a POSITA would have further been motivated to incorporate pulse oximetry sensors into a PAP device sleep disorder treatment system with the knowledge of the various diagnostic parameters for sleep disordered breathing, including apneas, hypopneas, and indices including "apnea index," "apnea-hypopnea index," and "respiratory disturbance index." A POSITA would have been familiar with the use of a commonly known handful of types of sensor data to identify, determine, or calculate such parameters, and the types of well-known sensors to obtain such data. For example, Guilleminault was considered a leading clinician and researcher on sleep apnea, and published numerous well-known papers and studies that a POSITA would have been familiar with. Guilleminault explained that "[a]n apnea has been defined as a cessation of airflow at the level of the nostrils and mouth lasting at least ten seconds," and that a "sleep apnea syndrome is diagnosed if, during seven hours of nocturnal sleep, at least 30 apneic episodes are observed in both [REM] and [NREM] sleep … ." Guilleminault C, van den Hoed J, and Mitler MM, Clinical overview of the sleep apnea syndromes, In: C Guilleminault and WC Dement (Eds), SLEEP APNEA SYNDROMES, Alan R Liss, New York, 1978, pp. 1-12 ("Guilleminault 1978"), at 2; *see also* Christian Guilleminault and Vivien C. Abad, *Obstructive sleep apnea syndromes*, Med. Clin. N. Am. 88, 2004, pp. 611-630 ("Guilleminault 2004"). Guilleminault also taught that "the use of an 'Apnea Index,' *i.e.*, the number of sleep apneas per sleep-hour, frequently gives a better indication of the seriousness of the disorder," and that

[redacted]

"Patients diagnosed with 'sleep apnea syndrome' always presented an abnormally elevated apnea index and a similar predominant type of apnea (central, mixed, or obstructive)." *Id.*

In 2004, Guilleminault observed that "[v]arious criteria have been utilized to define hypopnea, including (1) greater than 50% reduction in the amplitude of breathing from baseline during sleep, or (2) less than 50% reduction in the amplitude of breathing during sleep *associated with either greater than 3% oxygen desaturation* or an arousal, or (3) greater than 30% reduction in the amplitude of breathing during sleep or 30% reduction in the nasal cannula-pressure transducer curve *associated with oxygen desaturation greater than or equal to 4%*, and (4) event duration greater than or equal to 10 seconds." Guilleminault 2004, at 615. A POSITA would have known that oxygen desaturation and arousals could be determined (and typically were determined) using pulse oximetry sensor data. According to Guilleminault, "OSA can be classified based on the apneas plus hypopneas per hour of sleep index (AHI) or respiratory disturbance index ([RDI] apneas plus hypopneas plus respiratory event-related arousals per hour of sleep) into mild (5<AHI or RDI<15); moderate (15<AHI or RDI<30); or severe (AHI or RDI>30)." *Id.* at 615-616; *see also* Westbrook, ¶19.

As was also known in the art, and recognized for example, in Westbrook, discussed above, polysymnography was known as the standard and routine methodology for diagnosing obstructive sleep apnea. Guilleminault 2004, at 616. Guilleminault also describes the approach of "split-night full-night polysymnography" in which "the first half of the night is spent in diagnostic recording, with the second half of the night used for CPAP titration." *Id.* This "split-night study requires the recording and analysis of the same parameters as a standard diagnostic full-night polysymnography" (Guilleminault 2004, at 616) which a POSITA would have recognized includes both pulse oximetry sensor data to track oxygen desaturation, and air flow

[redacted]

sensor data, as shown in the below graph:

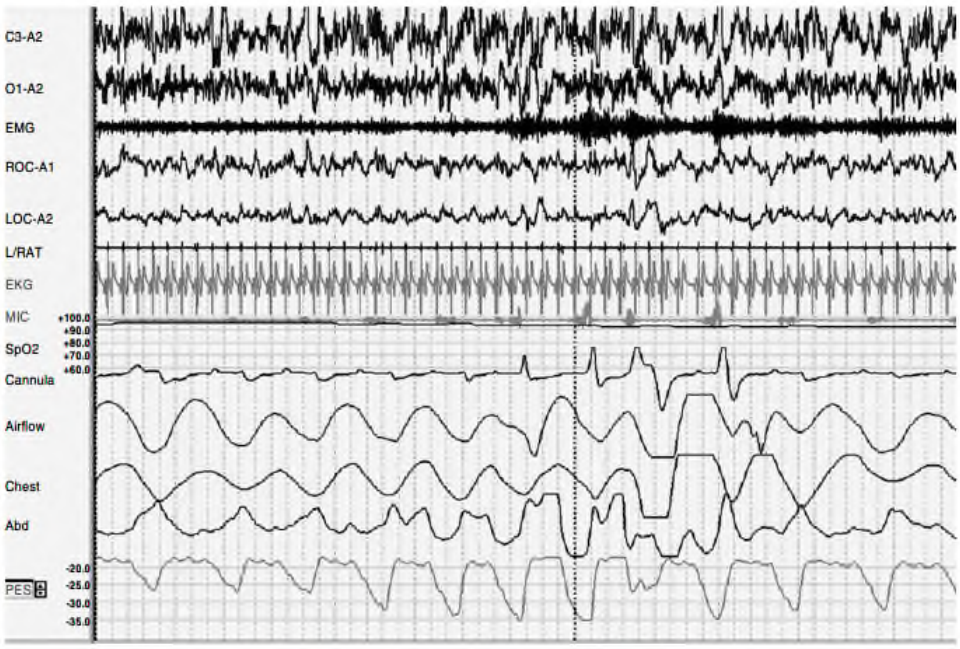

Fig. 1. Polysomnogram of a patient with OSA. The cannula and airflow channels demonstrate reduction in oronasal airflow consistent with a hypopnea. Paradoxical respiration is noted on the chest and abdominal effort channels. Esophageal pressure crescendo with Pes reversal associated with an arousal is seen.

Guilleminault 2004, at 617 (showing SpO2 and Airflow sensor data).

Guilleminault also recognized, as was known in the art, that "Autotitrating positive airway pressure devices detect snoring, apneas, hypopneas, flow limitation, and changes in airway resistance or impedance, which are then interpreted by a central processing unit based on specific diagnostic algorithms to determine the resultant voltage for the autotitrating positive airway pressure blower in response to these signals." Guilleminault 2004, at 622. It was well-known to a POSITA that the handful of known sensors and their corresponding data used to detect apneas and hypopneas, for example, included flow sensors and blood oxygen level sensors, such as pulse oximeters. In particular, a POSITA would have recognized or at least found it obvious to include sensors and processing features for the detection of hypopneas, which (as discussed above) relied on oxygen desaturation information that a POSITA would have found

[redacted]

it obvious to obtain from a pulse oximeter, as was well-known in the art. *See, e.g.*, The AASM Manual for the Scoring of Sleep and Associated Events, 2007 ("AASM Manual"), Section 4.

Similar to Guilleminault, Roux describes the use of PAP devices known in the art, and discloses, for example:

> In general, the number of respiratory disturbances per hour of sleep (RDI) or the sum of apneas and hypopneas per hour of sleep (AHI) is used as the summary statistic to diagnose OSA and determine the severity of sleep disordered breathing. It has become increasingly clear that the RDI can vary as much as tenfold [74] depending on the technique used to measure airflow [75] and the definitions used to define specific respiratory events (eg, percent flow change, degree of oxygen desaturation, presence/absence of arousal on encephalogram). The best metric to define OSA and the cutoff between normal and abnormal is controversial [76,77]. The RDI can have internight and intranight variability, and it is possible for OSA to be missed on one night of monitoring [78,79]. Despite these limitations, in the United States, level I PSG is the gold standard for diagnosing OSA and guiding treatment options, and it is against this standard that other options must be compared.

Francoise J. Roux and Janet Hilbert, Continuous positive airway pressure: new generations, Clin. Chest Med. 24, 2003, at 315-342 ("Roux"), page 321, *see also* 324 ("RDIs determined by APAP"). Roux further presented a collection of multiple studies evaluating automatic PAP ("APAP") devices on the market, some of which measured and recorded oxygenation. *See, e.g.*, Roux, at 326-330. A POSITA would have recognized, or at least found it obvious, that oxygenation was measured using a pulse oximeter.

It would have been obvious to modify the PAP devices of the prior art, to the extent not expressly disclosed, to calculate RDI in addition to the other commonly known metrics for diagnosing and monitoring sleep disordered breathing, as was known in the art. Such a modification would have been a mere design choice, known to a POSITA.

(c) "Sleep disorder symptom data … and/or an index," etc.

Claim 1 of the '269 patent recites "calculating, based in part on both the respiratory

[redacted]

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," claim 5 recites "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," claim 8 recites "creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the at least one physiological sensor," and claim 15 recites "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."

However, the '269 patent does not disclose how to calculate or create these claimed parameters. For example, the '269 patent disclosure merely provides: "One or more sensors are used to develop the data or signals used in the present invention for determining a quantitative level of severity of a subject's sleeping disorder and/or symptoms." '269 patent, 18:51-54. "The signals from the one or more sensors used in various embodiments of the present invention are preferably analyzed using a processor and software that can quantitatively estimate or determine the severity of the subject's sleeping disorder or symptoms." '269 patent, 18:60-64; *see also* 19:46-49 ("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 more sensors described herein.")

The '269 patent does not mention calculating an "index of a subject's symptoms," or an "index of a level of severity of the subject's sleep disorder symptoms," and only makes a passing reference to "obtaining respiratory disturbance index to diagnose sleep apnea" in the Background section of the specification. '269 patent, 1:51-54.

[redacted]

In addition, neither "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" are terms of art, nor would a POSITA recognize these terms to have well-defined boundaries. As noted above, the '269 patent fails to provide even a single example of a parameter within the scope of these terms, or how to calculate one.

Regardless, the prior art discloses or at least renders obvious PAP sleep disorder treatment systems that calculate indices, such as apnea index, apnea-hypopnea index, and respiratory disturbance index, and various parameters, including apneas, and hypopneas, as discussed above. *See, e.g.*, Burton, 6:42-62, 7:18-41, 8:6-31, *see also* 13:28-33, 14:54-15:55 (teaching automatic adjustment based on at least one index, use of more than one sensor signal to detect an event), FIGs. 1-2; Lankford, 164. As one example, Berthon-Jones discloses one example of how to identify the occurrence of an apnea using airflow sensor data. Berthon-Jones, 6:66-7:29, FIG. 1. The ResMed Prior Art also discloses calculation of AHI based at least on air flow sensor data. *See* Exhibit G05. In addition, the 1999 Chicago Criteria teach that information such as oxygen desaturation (measured, for example, using a pulse oximeter) is a useful arbiter when there is uncertainty about a sleep-related breathing event.

Furthermore, CleveMed's infringement contentions allege that the relevant limitations of claims 1, 5, and 8 are practiced by recording "95th percentile, max and median of the 1-minute average value of SpO2." Final Infr. Cont., Chart I, 22. CleveMed's contentions fail to allege a single parameter calculated "based in part on *both* the respiratory airflow data and the pulse oximetry sensor data" is practiced by the accused products, and instead appear to allege that the claims are satisfied by a single calculation based on respiratory airflow data and a separate, single calculation based on pulse oximetry sensor data practice the claims. If it is determined

[redacted]

that merely determining mathematical statistics from the pulse oximetry data alone satisfies this claim limitation, the prior art discloses or at least renders obvious such a feature. It would have been a mere implementation detail to determine statistics from collected pulse oximetry data, and would have been an obvious process to apply to the collected pulse oximeter data. For example, a POSITA would have recognized that the collected pulse oximeter data alone would be most useful in the form of statistics such as max, median, and 95th percentile to the monitoring health care provider, as opposed to viewing only the raw sensor data points. This is also disclosed, for example, by the ResMed Prior Art. *See* Exhibit G05.

In addition, to the extent CleveMed is alleging mere identification of apneas or hypopneas, the number of apneas or hypopneas per sleep session, number of apneas or hypopneas over a particular time period, or determination of statistics from the flow sensor data alone satisfy this limitation, such features were disclosed by or at least rendered obvious by the prior art. *See, e.g.*, Exhibit G05 (ResMed Prior Art); Lankford at 162-164; Burton, 6:42-62, 13:28-33, 14:54-15:55 (identifying values or occurrences such as AHI and apnea occurrences determined from measured physiological parameters that are used to adjust treatment levels; use of more than one sensor signal to detect an event). For example, for a PAP device that is auto-adjusting, a POSITA would have recognized that the device determines statistics in the collected flow sensor data, and identifies one or more apneas or hypopneas in order to adjust the settings of the PAP device. This would have been conspicuously obvious, to the extent not expressly disclosed, for disclosures in which the flow sensor is the only sensor employed by the PAP device. A POSITA would have alternatively at least found this obvious given the general purpose of the PAP device to collect data directed to the user's sleep disordered breathing, which a POSITA would have recognized should include identification of apneas and/or hypopneas.

[redacted]

Furthermore, CleveMed's Reply Claim Construction brief relied on a declaration from Dr. D'Ambrosio. *See, e.g.,* Amended Joint Claim Construction Brief (D.I. 116), at 21-23. CleveMed's claim construction briefing did not present any alleged "plain meaning" for the data and index terms recited in the claims, but Dr. D'Ambrosio's declaration purportedly did. *See, e.g.,* Memorandum Opinion (D.I. 181), at 18. For example, Dr. D'Ambrosio opined that "[c]linical professional understand [sic] that 'symptom data' refers to the physiological and technological data indicative of the patient's condition while they sleep or attempt to sleep." D'Ambrosio Decl. at 24. Dr. D'Ambrosio further opined:

> The different sensors used to monitor and diagnose a patient result in different types of symptom data that is calculable. '269 Patent at 3:9-28; 6:10-8:30. For example, based on Claim 15's use of an internal airflow sensor, one would use the term "symptom data" to refer to at least the ***patient's: airflow, inhalation pressure, exhalation pressure, apnea events, hypopnea events, I:E ratio***. See '269 Patent at Claim 15; '269 Patent at 7:61-8:12. When looking at Claims 1 and 5, "symptom data" would refer to those data points identified above and ***also include pulse and SpO_2*** due to the inclusion of the pulse oximeter into the system. '269 Patent at Claims 1, 5; '269 Patent at 8:13-25.

D'Ambrosio Decl. at ¶ 25 (emphasis added).

Dr. D'Ambrosio provided additional interpretations of the relationship of "symptom data" and "severity" or "level of severity" that find no support in the '269 patent specification:

> Based upon the disclosures in the '269 Patent, a POSITA understands how to ***calculate the symptom data in order to derive the severity of the patient's symptoms***. '269 Patent at 18:51-21:67. A commonly used term within the clinical sleep setting is "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 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. RERAs include arousals from sleep in the definition.

[redacted]

> Hypopneas include oxygen desaturation of equal to or greater than 4% from the baseline oxygen saturation associated with a reduction in airflow limitation. Clinically, ***both the RDI and AHI can be used to determine severity*** but Medicare only recognizes AHI. The denominator in these indices is total sleep time. ***Any of the measures*** themselves can be of concern and ***indicate severity of illness***. Severe reduction in ***airflow***, very high ***numbers of obstructive apneas, oxygen saturations below 88% sustained for 5 minutes*** or greater are all concerns for severe symptoms. However, they are most often considered together to evaluate severity of illness.

D'Ambrosio Decl. at ¶ 26 (emphasis added). It is unclear from Dr. D'Ambrosio's declaration what she alleges are "level of severity," e.g., is AHI a level of severity? Regardless, it appears that Dr. D'Ambrosio's opinion is that the "symptom data" of the claim include: respiratory disturbance index (RDI), apnea-hypopnea index (AHI), reduction in airflow, numbers of obstructive sleep apneas, and oxygen saturation. These parameters were all well-known to a POSITA and disclosed in the prior art.

Regarding the "index" recited in the '269 patent Asserted Claims, CleveMed's expert further opined:

> Another calculation a sleep clinician would commonly expect the symptom data to be compiled and presented is in the form of an "index." '269 Patent at Claims 1, 5, 15. An ***index takes individual and combined symptom data points and averages them over a one-hour period of sleep***. For example, if a patient sleeps seven hours and has 70 total instances where they cease breathing (apnea events) or present shallow breathing (hypopnea), they would have ***an apnea-hypopnea index (AHI)*** of 10, which a sleep clinician interpret as being mildly elevated but some clinicians would consider this still in the normal range. If instead that patient had 175 total apnea and hypopnea events in seven hours of sleep, a sleep clinician would understand the patient's AHI to be 25 and in a moderate severity range.

D'Ambrosio Decl. at ¶ 26 (emphasis added). Again, it is unclear from Dr. D'Ambrosio's declaration whether she considers AHI to be an index of a level severity, a level of severity, or and/or also an index of a subject's symptoms as recited in the asserted independent claims of the

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’269 patent. Regardless, calculation of AHI was a well-known feature of commercial PAP devices known to a POSITA, and disclosed in the prior art.

Dr. D’Ambrosio’s opinions as to the scope of the claimed “symptom data,” “severity,” and “index” terms is in conflict with the statements made by CleveMed during prosecution of the ’269 patent. CleveMed amended the claims on March 27, 2018 to add that “calculating symptom data” was “based in part on both the respiratory airflow data and pulse oximetry sensor data.” ’116 FH, 3/27/2018 Amendment at 2, 4. CleveMed argued that the Wright reference does not teach a “*processor adapted for receiving sensor data from both the signal processing module and the airflow sensor and calculating symptom data based in part on both the respiratory airflow data and pulse oximetry sensor data of level of severity and/or an index of a level of severity* of the subject's sleep disorder symptoms,” but “Wright uses the data collected with its system to *calculate and analyze stroke indicators* **not to calculate a level of severity or an index of a level of severity of the subject’s sleep disorder breathing symptoms** as claimed.” ’116 FH, 3/27/2018 Remarks at 10 (italics and underline in original, bold added). CleveMed also argued in numerous places that the Wright reference does not disclose the claimed “calculating” features, but “rather calculates and stores stroke recovery information,” citing paragraphs 30-45 of Wright. ’116 FH, 3/27/2018 Remarks at 10-11, see also page 12 (emphasis added). But a review of Wright’s paragraphs 30-45 shows that Wright described monitoring “patient health characteristics including, for example, oral and/or nasal airflow, snore, … oximetry, pulse rate, … and flattening index via the diagnosis unit and sensors in the blower” (¶ 34), generating “several indices” including “[o]ne such index [] based upon a functional relationship between the number of central or obstructive apneas over a particular time period” (¶¶ 35-36), and identifying an apnea (¶ 37). The claims were then allowed by the examiner in response to these arguments (and amendments

[redacted]

"for grammatical/typographical errors").

A POSITA having considered the above amendments and statements by CleveMed to the PTO to obtain allowance of its claims would understand that the calculated "symptom data of a level of severity," "level of severity," and "index of a level of severity" and similarly worded claim terms are not merely statistics of the physiological or system conditions alone that are measured by the sensors, such as pressure, leak, airflow, pulse rate, oxygen saturation (*e.g.*, SaO2 or SpO2), snore, or flattening index because such measurements or statistics could also be used to determine stroke related parameters as disclosed by the Wright reference. Instead, CleveMed argued the calculated parameters are different from those disclosed by Wright. A POSITA would understand this mean that the claims require calculation of a parameter from the sensor data that is specifically a "level of severity or an index of a level of severity of the subject's sleep disorder breathing symptoms as claimed." '116 FH, 3/27/2018 Remarks at 10.

Thus, the statements of CleveMed's expert Dr. D'Ambrosio that the claimed "symptom data" could merely be "patient's: airflow, inhalation pressure, exhalation pressure, apnea events, hypopnea events" and "also include pulse and SpO_2" are contrary to the statements made by CleveMed to the patent office in its efforts to obtain allowance of the claims. Indeed, the very parameters Dr. D'Ambrosio recites are disclosed in Wright. However, the prior art identified herein discloses the claimed parameters consistent with Dr. D'Ambrosio's declaration. ResMed's reliance on such parameters for its invalidity contentions should not be considered an admission that the same or similar parameters in the accused products infringe the asserted claims.

(d) Signal Processing and Data acquisition

The asserted claims of the '269 patent include four independent claims: 1, 5, 8, and 15. The bulk of the disclosure of the '269 patent is directed to signal processing of data from physiological or biometric sensors, such as EEG, ECG. However, neither claims 8 nor 15 recite

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any signal processing components, and claims 1 and 5 merely recite a generic "signal processing module" and "data acquisition system" that were well known in the art. Moreover, the '269 patent's disclosure at column 8, line 57 through column 18, line 50, and Figures 1-6, are near identical to the disclosure in US 6,167,258 to Schmidt et al. ("Schmidt"), which issued December 26, 2000 and is therefore prior art under 35 U.S.C. § 102(b). The '269 patent's asserted claims recite numerous limitations disclosed in Schmidt, which were also basic signal processing components and features known to a POSITA for implementing a system collecting biometric or physiological sensor data. Schmidt discloses, for example, "[r]eferring now to FIG. 4, there is shown a block diagram of the input means 22 and A/D means 24 of the *signal processing module* 16, which provides for the *data acquisition function* of the present invention." Schmidt, 8:20-23.

A POSITA would have recognized that the signal processing module's main function is to condition the signal from a sensor(s) before it is ready to be transmitted. For example, a temperature sensor or a pulse oximeter outputs an analog signal that would typically need to be digitized (using A/D converter) and encoded, particularly before being inputted to a communication module to be transmitted or a processor for analysis and further processing of the sensed data. For example, Figure 2 of Elena shows a typical signal processing module that conditions and processes signals before output.

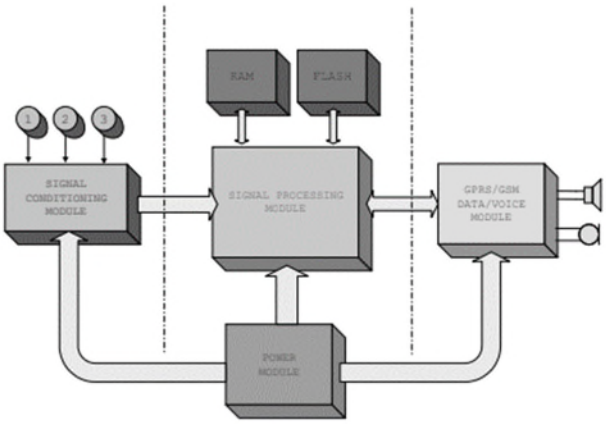

Figure 2. A block diagram of PAC

Elena, et al., Design of a Mobile Telecardiology System Using GPRS/GSM Technology, Engineering in Medicine and Biology, 2002, Departamento Ingeniería Electrónica, Escuela Superior Ingenieros, FIG. 2.

As was also known in the art, Kirianaki teaches, for example: "According to [7] 'Data Acquisition (DAQ) is collecting and measuring electrical signals from sensors and transducers and inputting them to a computer for processing.' Further processing can include the sensors' characteristic transformation, joint processing for many parameters as well as statistical calculation of results and presenting them in a user-friendly manner." Kirianaki, et al., DATA ACQUISITION AND SIGNAL PROCESSING FOR SMART SENSORS, 2002, John Wiley & Sons Ltd, at 22.

As acknowledged in Schmidt, "all data acquisition systems generally operate in a similar fashion. They receive an external input from some type of sensing device, condition and/or convert the input to a format suitable for transmission, as necessary, and transmit it to another piece of equipment usually a monitor or controller, which may be a computer, and more specifically, a personal computer." Schmidt, 1:22-28. A POSITA would have known to apply such knowledge to the PAP systems disclosed at prior art at exhibit G05 to arrive at the asserted claims of the '269 patent. Such features would have been minor implementation details that a POSITA would have known to incorporate, as acknowledged by the disclosure of Schmidt. As

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an additional example in the art, Burton discloses that "[t]he sensors input their physiological data to the controller (incorporates pre-processing required for treatment control), which receives the data and determines arousal or onset of arousal. In one embodiment, the controller includes an analog processing circuit which converts analog signals from the sensors into a digital signal. The analog processing circuit utilizes known preamplifying, amplifying, conditioning, and filtering configurations to enable the analog sensor signal to be converted into a digital signal. In some instances, the sensor may directly input a digital signal." US 8,069,852 ("Burton"), 7:18-27.

Moreover, CleveMed's infringement contentions allege that this claim limitation is practiced as follows: "ResMed provides a signal processing module through its Air 10 Oximetry Module. The Air 10 Oximetry Module has an oximeter port (first input) adapted for connecting to a Xpod Oximeter which is a pulse oximeter sensor. … The Air10 Oximetry Module receives the signal from the XPOD and converts it to a suitable format for transfer to the AirSense 10." Final Infr. Cont., Chart I, 9-10. As explained and identified above, pulse oximeters, including those developed and sold by NONIN, along with their corresponding signal processing module in the Xpod that is used with accused Oximetry Module, were well known to a POSITA and disclosed, for example by the ResMed Prior Art. *See* Exhibit G05. It would have been at least obvious to include such an "adapter" connected to a pulse oximeter sensor and adapted to output pulse oximetry sensor data to the disclosed PAP device, at least for the basic reason that the data communicated would need to be in a format for receipt and processing by the PAP device. Such a feature would have been an obvious implementation detail well known to those skilled in the art.

(e) System Configuration, Wireless Transmission, and Remote Monitoring

Claims 1, 5, and 15 of the '269 patent recite various system configurations for

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transmission of the calculated "sleep" parameter "to a remote location" or a "remote internet site." However, transmission of compliance or usage data of a PAP sleep disorder treatment system, along with parameters calculated by the PAP device (such as apneas and AHI), to a remote location or "remote internet site" was well-known in the prior art. *See, e.g.*, United States Patent Application Publication No. 2003/0236450 ("Kocinski"), ¶9, 12, 28, 45, 49, FIGs. 1, 10. For example, the ResMed Prior Art included ResMed's AutoScan and ResScan software for remote monitoring and analysis of data collected and calculated at ResMed PAP devices. *See* ResMed Prior Art Claim Chart, Exhibit G05. ResMed's ResTraxx and RDC ([redacted]) system also disclosed transmission of usage and calculated data from the ResMed PAP devices, such as the S7 Elite and AutoSet Spirit, to a remote database, accessible by a health care provider to review the usage and calculated data. *Id.*; *see also* Lankford, 164-165. Kocinski also discloses transmission of compliance and calculated data to a remote location for review by a health care professional. *See* Kocinski, ¶¶ 8-10, 28, 35, 46, Fig. 11.

Notably, asserted claim 15 does not specify the location of the claimed processor in the system, *e.g.*, whether it is within the PAP device or somewhere else, and claim 5 recites that "the processor adapted to be either part of or external to the PAP device." However, the '269 patent fails to recognize any specific unexpected result or challenge in performing the claimed "calculating" at a processor either at the PAP device, external to the PAP device, and/or remote to the PAP device, receiving the calculated parameters at a first radio frequency wireless module transceiver, transmitting the calculated parameters to a base station, cellular phone or PDA adapted to display the calculated parameters, and the base station/cellular phone/PDA further retransmitting the calculated parameters to a remote internet site. Instead, the '269 patent merely provides a laundry list of a variety of different configurations of a system employing RF

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communication, noting that "[p]referably, the remote communication station or base station can be any device known to receive RF transmissions." '269 patent, 19:8-45. Thus, the '269 patent appears to recognize there was no inventive or non-obvious aspect to the claimed configuration (to the extent even disclosed by the '269 patent), thereby confirming a POSITA would have found the claimed configuration at least obvious as amongst those known in the art and obvious to try. The specific configuration, *e.g.*, whether wired or wireless communication links were used, was merely an implementation detail a POSITA would have known to try amongst those known in the art. Indeed, the prior art discloses numerous configurations in a similar fashion, teaching that they were all interchangeable and no one less desirable or less effective over the other as to teach away from the claimed configuration.

Moreover, telemedicine was an established field of endeavor by the time of the application for the '269 patent, and numerous publications had documented various already implemented communication system configurations for collecting information from biomedical systems at the location of a patient, and transmitted data to remote locations.

As one example in the prior art, Jasemian discloses a telemedicine "system based on the Bluetooth protocol … and the general packet radio service (GPRS) for GSM mobile phones. The patient unit contained a telemetry device (T3300, Danica Biomedical), a Bluetooth module (ROK 101 800, Ericsson) and a mobile phone (T610, Ericsson). Yousef Jasemian and Arendt Nielsen, *Evaluation of realtime, remote monitoring telemedicine system using the Bluetooth protocol and a mobile phone network*, Journal of Telemedicine and Telecare 2005, Vol. 11, Issue 5, at 256 (accepted January 13, 2005)("Jasemian"); *see also* Y Jasemian, E Toft, and L Arendt-Nielsen, *Real-time remote monitoring cardiac patients at a distance*, Proceedings of the 2nd Open ECG Workshop, Berlin, Germany, 2004. The Bluetooth module is a short-range (10m)

device that enables the telemetry unit to communicate with the mobile phone wirelessly. The mobile phone used the GSM/GPRS Network (Sonofon, Denmark) to communicate with a modem server and a central monitoring station." Jasemian, 256.

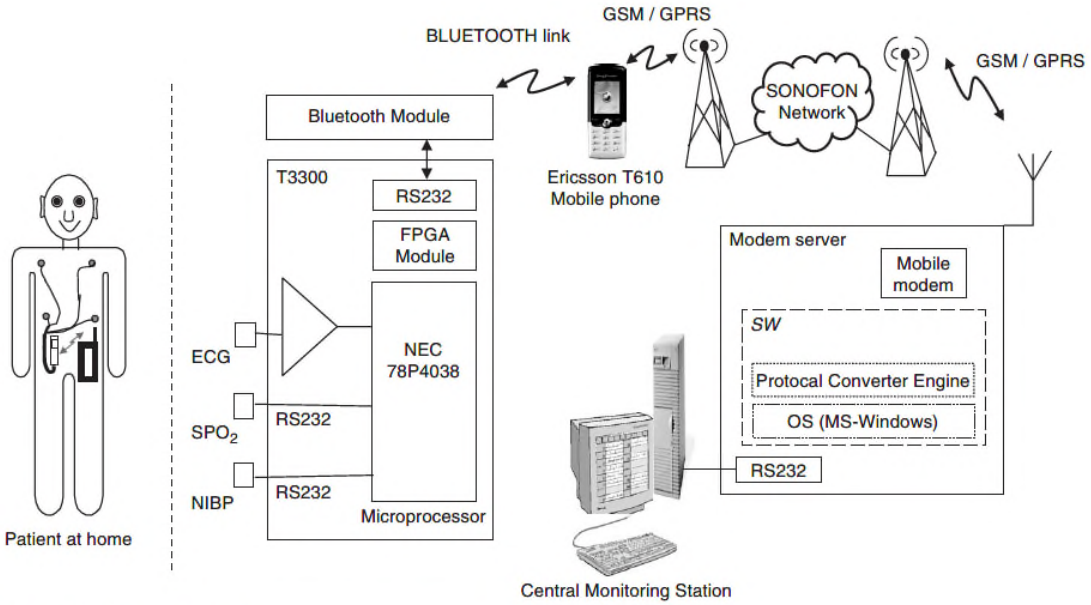

Figure 1 System architecture

Jasemian, Figure 1.

Woodward discloses a similar telemedicine system:

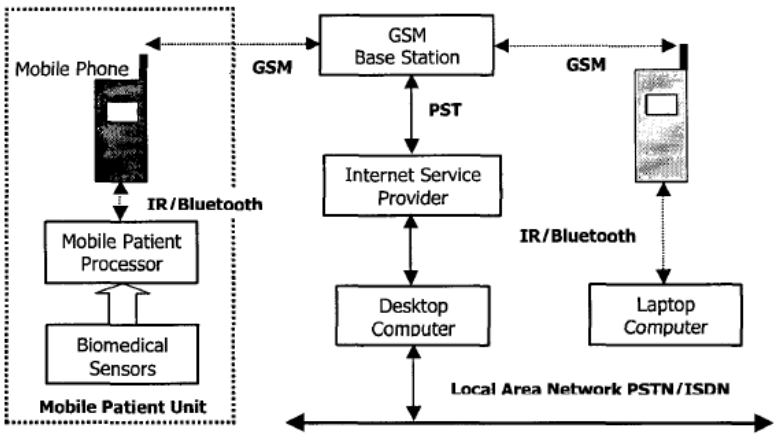

Fig. 1 Telemedicine system with mobile telephone and PSTN communications links

This paper reviews a number of recent wireless telemedicine

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> projects that have been carried out around the world, then focuses on the design and development of a wireless telemedicine system using a conventional mobile telephone. The system is capable of transmitting up to four sets of biomedical data from a patient via the Global System for Mobile communications (GSM) cellular network to a hospital or surgery. It is designed to be generic, so it may also be used for non-medical applications, and to be "future-proofed" in view of constantly evolving telecommunications technology, including the introduction of the Third Generation (3G) protocol as a replacement for the present GSM protocol.

B. Woodward and M.F.A. Rasid, *Wireless Telemedicine: The Next Step*, 4th Int'l IEEE EMBS Special Topic Conference on Information Technology Applications in Biomedicine, 2003, at 43 ("Woodward"), 43.

> While the transmission of biomedical data by satellite is demonstrably feasible for long-range wireless links, it is more likely that mobile telephones using cellular networks will be adopted for transmission over shorter ranges. Among the technical problems is the issue of how to link the data from the patient (via a mini-processor) to the phone. This may possibly be done by a direct connection, or by a wireless connection such as an acoustic, infra-red or Bluetooth radio link [l8]. It is only recently that the potential advantages of Bluetooth and other wireless technologies have been recognized, including the Wireless Application Protocol (WAP) for cell phones [19], and Personal Digital Assistants (PDA) [20,21].

Woodward, 44.

> The main contribution of this paper has been to describe the present scope and future potential of mobile communications in telemedicine. A modular-structured system has been used to illustrate the concept. The mobile patient unit comprises a processing unit, which accepts signals from one or more sets of sensors, linked by a wireless channel to a mobile telephone. The prototype version is designed to transmit digitised electrocardiogram signals to a hospital via the GSM mobile telephone cellular network. New compression and signal processing algorithms, such as wavelet techniques, can be integrated to optimise the performance of the system under different mobile conditions. The modular design of the system should enable telemedicine providers to adapt to future technology advances.

Woodward, 45; *see also* Mohd Fadlee A. Rasid and Bryan Woodward, *Bluetooth Telemedicine Processor for Multichannel Biomedical Signal Transmission via Mobile Cellular Networks*,"

[redacted]

IEEE Transactions on Information Technology in Biomedicine, Vol. 9, No. 1, March 2005, at 35 ("Rasid"), Abstract ("a system to transmit a patient's biomedical signals directly to a hospital for monitoring or diagnosis, using an unmodified mobile telephone"), §§ I.B, III.A, IV, Figs. 2, 4.

As another example, Rasid discloses:

> One of the emerging issues in m-Health is how best to exploit the mobile communications technologies that are now almost globally available. The challenge is to produce a system to transmit a patient's biomedical signals directly to a hospital for monitoring or diagnosis, using an unmodified mobile telephone. The paper focuses on the design of a processor, which samples signals from sensors on the patient. It then transmits digital data over a Bluetooth link to a mobile telephone that uses the General Packet Radio Service. The modular design adopted is intended to provide a "future-proofed" system, whose functionality may be upgraded by modifying the software.

Rasid, Abstract; *see also* Mohd Fadlee A Rasid, *Multi-Channel GPRS-Based Mobile Telemedicine System With Bluetooth and J2ME Interfaces*, Doctoral Thesis, Department of Electronic and Electrical Engineering, Loughborough University (October 2005) ("Rasid Thesis"), Abstract. Rasid's system included the following communication links, shown in Figure 2: "1) short-range Bluetooth link between patient and telephone; 2) GPRS to a base station and to other mobile telephones; 3) land lines (PSTN) and an Internet service provider (ISP) to a hospital server and database; 4) LAN to clinicians." Rasid, § I.C.

[redacted]

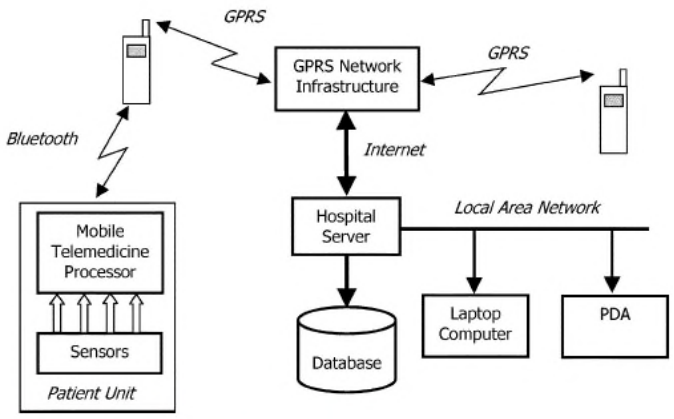


Fig. 2. Mobile telemedicine system.

Rasid, Fig. 2; *see also* Rasid Thesis at Figures 6.1, 6.20.

In Rasid's system the "[s]ignal inputs from the patient are those normally used for monitoring purposes, such as the ECG (and heart rate), blood pressure, body temperature, and SpO," and these "signals are fed to the Bluetooth-enabled processor unit, where they are digitized and stored in memory. Next, the digitized data are transmitted to a Bluetooth mobile telephone and subsequently via the GPRS cellular network to a base station, then to a hospital via conventional PSTN lines or a cellular network. The data received at the hospital server are available to a clinician via the hospital's LAN, either through the personal computer (PC), laptop, or personal digital assistant (PDA). Alternatively, the clinician away from the vicinity of the hospital may receive a patient's data via a mobile telephone and a PDA." Rasid, § III.A.

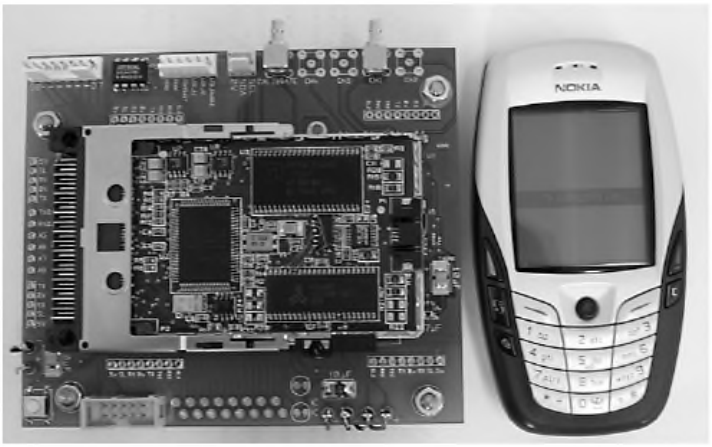
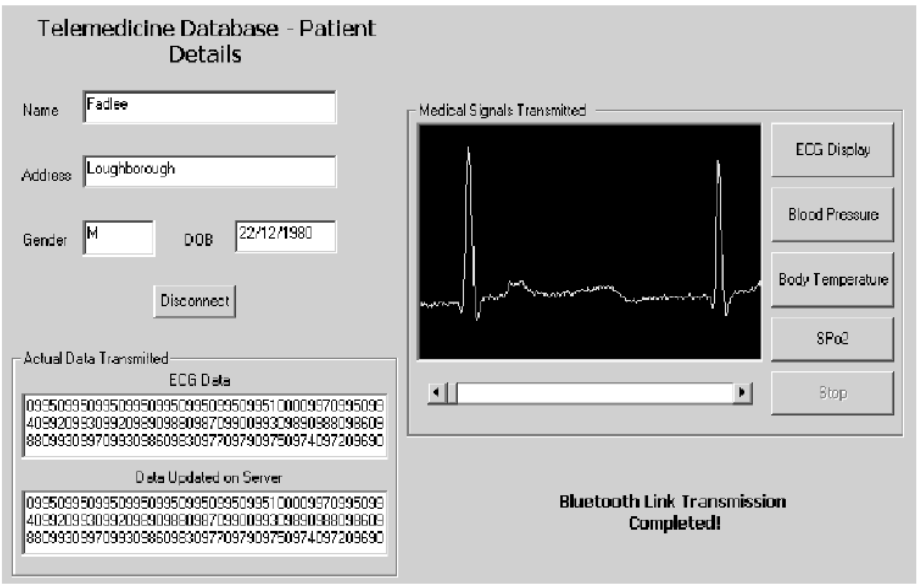


Fig. 4. Layout of mobile telemedicine processor.

Rasid, Fig. 4.



Rasid, FIG. 9, *see* § IV (simulated patient interface to the mobile telephone); *see also, e.g.*, Rasid Thesis, 98, 133 showing UI on Nokia mobile phone displaying collected signal data.

As demonstrated by Woodward, Rasid, and Jasemian, it was known in the art and within the level of ordinary skill to select a configuration including that recited in the ’269 patent claims for receiving collected and calculated biometric data, transmitting it, *e.g.*, over a Bluetooth connection to a cellular phone capable of displaying the data, and the cellular phone retransmitting the data to a remote location, such as an “internet site.” It would have been obvious to implement such a configuration for devices like PAP devices that were typically

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placed in a patient's bedroom, connected to a power outlet, and with hose and mask connected as well. A POSITA would have recognized the benefits of a health care professional to review usage or compliance data and also data calculated at the PAP device for treatment purposes, in addition to adjustment of device settings, as was known in the art. A POSITA would have recognized it to be inconvenient not only for the patient to remove the device from their bedroom, but also that it was typically cumbersome to transport the PAP device to the location of the health care provider. A POSITA therefore would have been motivated to implement a configuration like telemedicine systems disclosed and known in the art, like those described and implemented by Woodward, Rasid, Jasemian, and also Lankford (*see* ResMed Prior Art, Exhibit G05). In one example, it would have been obvious to implement the claimed "radio frequency wireless module transceiver" for short range communication between a medical device and a patient's cellular phone or PDA. For example, Bluetooth was a well-known communication protocol that could be implemented by incorporating a Bluetooth wireless module transceiver into devices such as the PAP apparatus's known in the art in order to transmit the data collected and calculated at the PAP device for remote review. A POSITA would have recognized, for example, that it was known for PAP devices to have an incorporated or external modem, could be implemented with an RF transceiver module as claimed, using for example, a Bluetooth, PAN, WLAN, or cellular modem that includes an RF wireless transceiver as known in the art. In particular, a POSITA would have been motivated to use Bluetooth because, as was known to a POSITA, "Bluetooth is a universal short-range low-power radio protocol operating in the unlicensed industrial, scientific, and medical frequency band." Rasid, § II.A. It also would have been obvious to make the combination with a cellular phone. A POSITA would have been motivated to do so, for example, because it would avoid the need to connect a separate

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communications link, or to use a different cellular subscription for the user's PAP device to transmit the PAP device data to the remote location. It also would have been more power efficient and avoid unwanted interference by using a Bluetooth connection to a cellular phone, rather than the PAP device using its own wireless transmission. As also recognized by Rasid, incorporating the complex communications protocol, like cellular or other LAN, into a cellular phone rather than the PAP device provides for easy updates to the quickly evolving and changing communications technology, updates that would be difficult to incorporate into a medical device like a PAP apparatus.

With regard to dependent claim 16 that specifically recites the use of Bluetooth, the '269 patent fails to identify any specific advancement by using the "Bluetooth wireless protocol," mentioning Bluetooth only once and only generally stating that "IR or Bluetooth wireless technology can be used for data transmission." '269 patent, 8:39-48. Thus, the '269 patent appears to rely on the knowledge of a POSITA to apply Bluetooth wireless technology generally to the disclosed system. As established above and in the attached exhibits, a POSITA would have found it at least obvious to similarly use their knowledge of Bluetooth wireless technology to arrive at the claimed system. A POSITA would have been motivated to do so, for example, because of Bluetooth's ubiquity in the art, low operating power, and design to avoid interference.

All of the reasons discussed above for combining references are incorporated by reference into the claim charts whether or not specifically stated.

IV. INVALIDITY UNDER 35 U.S.C. § 112

A. Lack of Written Description and Enablement Under 35 U.S.C. § 112 ¶ 1

Section 112 requires that a patent "contain a written description of … the manner and process of making and using [the invention] in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and use the same." 35 U.S.C. § 112 ¶ 1. A patent is invalid if the written description does not "describe the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application, *i.e.*, that the patentee invented what is claimed." *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005); *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008) (same). "[T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). "Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Id*. The specification provides inadequate support where it "fail[s] to demonstrate that the patentee possessed the *full scope* of the invention recited in [the claim] … ." *LizardTech*, 424 F.3d at 1345 (emphasis added). "The level of detail required to satisfy the written description requirement depends, in large part, on the nature of the claims and the complexity of the technology. *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285 (Fed. Cir. 2012). But a "mere wish or plan" for obtaining the alleged invention does not satisfy the written description requirement. *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1344 (Fed. Cir. 2013). Put another way, "a description that merely renders the invention obvious does not satisfy the requirement." *Ariad*, 598 F.3d at 1351. Instead, "all the limitations must appear in the specification." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). ResMed contends that, at least under CleveMed's actual and/or apparent application of the claims, the specifications of at least one or more of the Asserted Patents do not include a sufficient written description supporting the claims.

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Section 112 likewise requires that the specification "enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the" alleged invention. 35 U.S.C. § 112 ¶ 1. A claim is not enabled if, "at the effective filing date of the patent, one of ordinary skill in the art could not practice their full scope without undue experimentation." *Wyeth and Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013). "This important doctrine prevents both inadequate disclosure of an invention and overbroad claiming that might otherwise attempt to cover more than was actually invented." *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012).

"Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors may include: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id*. Although "a specification need not disclose what is well known in the art," "[t]ossing out the mere germ of an idea does not constitute enabling disclosure." *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). A patent "cannot simply rely on the knowledge of a person of ordinary skill to serve as a substitute for the missing information in the specification." *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 941 (Fed. Cir. 2010).

1. The '399 Patent

The asserted claims of the '399 Patent, at least under CleveMed's actual and/or apparent application of the claims, are invalid under 35 U.S.C. § 112 ¶ 1 because the specification lacks an adequate written description of the alleged invention and fails to enable the full scope of the alleged invention.

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- "digitizing and storing the collected data from the subject in the nonvolatile digital memory of the patient interface box" (claims 1, 8);

- "releasable connector sensor inputs to electrically connect and disconnect the respiratory effort belt and the fingertip pulse oximeter" (claims 1, 8); and

- "providing a computer or processor at the subject's location for checking the adequacy of the collected data from the sensors prior to a transmitter transferring the collected data to the remote location" (claim 2).

2. The '535 Patent

The asserted claims of the '535 patent, at least under CleveMed's actual and/or apparent application of the claims, are invalid under 35 U.S.C. § 112 ¶ 1 because the specification lacks an adequate written description of the alleged invention and fails to enable the full scope of the alleged invention.

- "a transceiver adapted for uploading the collected data from the non-volatile memory of the portable patient interface box" (claim 8);

- "releasable connector sensor inputs adapted to electrically connect and disconnect the respiratory effort belt and the fingertip pulse oximeter to the patient interface box" (claim 8);

- "a software provided for a computer and/or second processor adapted to be located at a location remote from the subject for analyzing the transferred collected data from the database to identify and draw attention to physiological or technological events in the data indicative of a sleeping disorder" (claim 8);

- "the software or a second software provided for the computer and/or second processor adapted for further analyzing and displaying and/or printing at a minimum the transferred collected data and/or the identified physiological and technological events in the data at the remote location or another remote location to determine whether the subject suffers from a sleeping disorder." (claim 8);

- "a second air port adapted for connecting the respiratory effort belt to the second pressure transducer" (claim 8); and

- "the processor is further adapted for checking the accuracy of the collected data from the sensors prior to transmitting the collected data" (claim 9).

[redacted]

3. The ’937 Patent

The asserted claims of the ’937 patent, at least under CleveMed’s actual and/or apparent application of the claims, are invalid under 35 U.S.C. § 112 ¶ 1 because the specification lacks an adequate written description of the alleged invention and fails to enable the full scope of the alleged invention.

- “a transceiver adapted for transferring the collected data from the non-volatile memory” (claims 1, 13);
- “a second air port adapted for connecting the respiratory effort belt to the second pressure transducer” (claim 1);
- “at least one software stored on computer readable storage media and executed by a computing device, the software when executed is adapted for analyzing at least part of the data from the database to identify and draw attention to physiological or technological events indicative of a sleeping disorder” (claims 1, 13);
- “the at least one software when executed is further adapted for outputting at least: i. the transferred collected data, ii. the identified physiological and technological events, or iii. both (i) and (ii)” (claims 1, 13); and
- “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” (claim 9).

4. The ’603 Patent

The asserted claims of the ’603 patent, at least under CleveMed’s actual and/or apparent application of the claims, are invalid under 35 U.S.C. § 112 ¶ 1 because the specification lacks an adequate written description of the alleged invention and fails to enable the full scope of the alleged invention.

- “electronics including at least three input channels which are programmed to receive collected data in real-time from at least three sensors” (claims 1, 8);
- “a transceiver or a transmitter then further to upload the collected data, and/or data based on the collected data to the database” (claims 1, 8);
- “at least two sensor connectors adapted to electrically connect the at least three sensors directly to the at least three input channels” (claims 1, 8);

[redacted]

- "to be electrically hardwired and/or releasably connected to the three input channels" (claim 1);

- "a two-way communication link adapted to output the i) respiratory effort, snore and blood oxygenation data from the database, ii) the identified and quantified physiological events in the data, or iii) both i) and ii) in a form adapted for a professional medical diagnosis of whether the patient suffers from a sleep disorder." (claim 1); and

- "wherein the snore is measured and/or derived using a pressure sensor or microphone" (claim 7).

5. The '698 Patent

The asserted claims of the '698 patent, at least under CleveMed's actual and/or apparent application of the claims, are invalid under 35 U.S.C. § 112 ¶ 1 because the specification lacks an adequate written description of the alleged invention and fails to enable the full scope of the alleged invention.

- "the respiratory belt sensor being electrically hardwired and releasably connected to a portable patient interface box" (claim 14);

- "electronics, which are programmed to collect and transmit data to an electronic interface" (claim 14);

- "collecting data with the electronics of the patient interface box" (claim 14);

- "analyzing the data with a computer or processor programmed to identify and draw attention to physiological and technological events in the data" (claim 14); and

- "checking the adequacy of the data from the respiratory belt sensor and the air flow sensor with a processor prior to transmitting the data" (claim 15).

6. The '637 Patent

The asserted claims of the '637 patent, at least under CleveMed's actual and/or apparent application of the claims, are invalid under 35 U.S.C. § 112 ¶ 1 because the specification lacks an adequate written description of the alleged invention and fails to enable the full scope of the alleged invention.

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- "a processor" (claim 1);
- "a transceiver or transmitter" (claim 1);
- "a second air port adapted for connecting the respiratory effort belt to the second pressure transducer" (claim 1); and
- "wherein the data is encrypted prior to transmission to the remote database." (claim 15).

7. The '269 Patent

The asserted claims of the '269 patent, at least under CleveMed's actual and/or apparent application of the claims, are invalid under 35 U.S.C. § 112 ¶ 1 because the specification lacks an adequate written description of the alleged invention and fails to enable the full scope of the alleged invention.

- "an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow data of a subject using the PAP device" (claim 1);
- "an airflow sensor with a second signal adapted for measuring respiratory airflow of a subject" (claim 5);
- "an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject while using the PAP and outputting airflow sensor data" (claim 15);
- "a processor adapted for receiving … the respiratory airflow data from the airflow sensor" (claim 1);
- "the processor adapted for receiving … the respiratory airflow data from the airflow sensor" (claim 5);
- "an electronic component adapted for filtering and processing the first signal from the pulse oximeter sensor to remove artifacts" (claim 5);
- "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

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of the PAP device" (claim 5);

- "a module transceiver adapted for receiving and transmitting the sleep disorder symptom data of the level of severity and/or the index of the level of severity of the subject's sleep disorder symptoms to a remote location" (claim 1);

- "a second input adapted for receiving the pulse oximetry sensor data from the output of the signal processing module" (claim 1);

- "a second input adapted for receiving the pulse oximetry sensor data from the output of the data acquisition device" (claim 5);

- "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 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" (claims 1, 5);

- "a first output adapted for transmitting pulse oximeter sensor data based on the first signal from the pulse oximeter sensor to the PAP device" (claim 5);

- "a positive airway pressure apparatus for providing pressurized air and dosing and chemically treating a subject's sleep disorder or symptoms with a pharmaceutical agent, the positive airway pressure apparatus comprising a controller adapted to adjust the pharmaceutical agent, at least in part, using the output of the level of severity of the subject's sleep disorder from the data acquisition system" (claim 8);

- "the data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the at least one physiological sensor" (claim 8);

- "a processor adapted for … 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);

- "a first radio frequency wireless module transceiver … adapted for receiving and transmitting the symptom data of the 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 the data of usage to the base station, cellular phone, or PDA" (claim 15);

- "a base station" (claim 15);

- "the base station, cellular phone, or PDA comprising a second radio frequency wireless module transceiver, a processor, a software, and a display, the base

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station, cellular phone, or PDA adapted to display the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms" (claim 15);

- "the first radio frequency wireless module transceiver of the PAP device and the second radio frequency wireless module transceiver of the base station, cellular phone, or PDA communicate using Bluetooth wireless protocol" (claim 16);

- "The system of claim 15, wherein the airflow sensor data is processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis." (claim 20)

As one non-limiting example of lack of enablement of the terms identified above, the specification fails to disclose how a "nasal cannula" could be used with a positive airway pressure sleep disorder treatment system as claimed by the '269 patent. For example, there is no disclosure in the '269 patent of how to use a "nasal cannula" to *treat* sleep disordered breathing by delivering pressurized air to a patient; it was known in the art that use of a nasal cannula, without a specialized approach, should not be used for PAP treatment for numerous reasons. Neither the '269 patent specification nor the claims recite any special method of PAP treatment that would be effective if a nasal cannula, rather than a mask, is used with the system.

As another example, there is no description of the claimed "an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow data of a subject using the PAP device" or similar limitation. CleveMed has argued in IPR2023-00565, Paper No. 6 (6/29/2023), that merely measuring blower flow within the PAP device enclosure does not practice the claimed airflow sensor. However, the '269 does not disclose or enable an airflow sensor that is "adapted for measuring the respiratory airflow data of a subject using the PAP device." Instead, the '269 patent suggests that to "accurately measure air flow provided to the patient" a "sensor *in the air hose* 416 is used to measure the differential pressure," and does not disclose how an airflow sensor within the enclosure of the PAP device could be configured to measure the

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respiratory airflow of the patient. ’269 patent, 23:36-39. If CleveMed alleges the disclosure in the ’269 patent at Figure 7, and column 22:7-17 provides written description support for this limitation, this material was copied from a competitor’s patent at a section describing the prior art, and is therefore not a feature of the alleged invention but instead a feature of conventional PAP systems known in the art. *See* US 6,644,311 (“Truitt”).

B. Indefiniteness Under 35 U.S.C. § 112 ¶ 2 and/or ¶ 6

Under 35 U.S.C. § 112, a “patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, 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). “The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, *e.g.*, competitors of the patent owner, can determine whether or not they infringe.” *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28-29 (1997)). Put another way, “[a] patent holder should know what he owns, and the public should know what he does not.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002).

ResMed contends that, at least under CleveMed’s actual and/or apparent application of the claims, the Asserted Claims of the Asserted Patents fail to inform a person of ordinary skill in the art about the scope of the invention with reasonable certainty.

1. The ’399 Patent

At least under CleveMed’s actual and/or apparent application of the claims, the asserted claims of the ’399 patent are invalid under 35 U.S.C. § 112 ¶ 2 for indefiniteness because the specification and prosecution history of the ’399 patent would not inform those skilled in the art

about the scope of the alleged invention with reasonable certainty.

- "releasable connector sensor inputs to electrically connect and disconnect the respiratory effort belt and the fingertip pulse oximeter" (claims 1, 8);
- "applying and connecting the nasal cannula or facemask, the respiratory effort belt, and the fingertip pulse oximeter to the subject" (claims 1, 8); and
- "transferring the collected data to the remote location" (claim 2).

2. The '535 Patent

At least under CleveMed's actual and/or apparent application of the claims, the asserted claims of the '399 patent are invalid under 35 U.S.C. § 112 ¶ 2 for indefiniteness because the specification and prosecution history of the '399 patent would not inform those skilled in the art about the scope of the alleged invention with reasonable certainty. Further, the asserted claims of the '399 patent are invalid for indefiniteness because the specification does not disclose adequate corresponding structure, material, or acts for several claim terms reciting functional language subject to 35 U.S.C. § 112 ¶ 6.

- "a transceiver adapted for uploading the collected data from the non-volatile memory of the portable patient interface box" (claim 8);
- "releasable connector sensor inputs adapted to electrically connect and disconnect the respiratory effort belt and the fingertip pulse oximeter to the patient interface box" (claim 8); and
- "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." (claim 9).

3. The '937 Patent

At least under CleveMed's actual and/or apparent application of the claims, the asserted claims of the '937 patent are invalid under 35 U.S.C. § 112 ¶ 2 for indefiniteness because the specification and prosecution history of the '937 patent would not inform those skilled in the art about the scope of the alleged invention with reasonable certainty. Further, the asserted claims

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of the ’937 patent are invalid for indefiniteness because the specification does not disclose adequate corresponding structure, material, or acts for several claim terms reciting functional language subject to 35 U.S.C. § 112 ¶ 6.

- “so as to make a determination of whether the subject suffers from a sleeping disorder” (claims 1, 13);
- “wherein the transceiver is further adapted to transfer the collected data from the nonvolatile digital memory via cellular systems, Internet, satellite, wired-network and/or land lines to the database.” (claim 10).

4. The ’603 Patent

At least under CleveMed’s actual and/or apparent application of the claims, the asserted claims of the ’603 patent are invalid under 35 U.S.C. § 112 ¶ 2 for indefiniteness because the specification and prosecution history of the ’603 patent would not inform those skilled in the art about the scope of the alleged invention with reasonable certainty.

- “electronics including at least three input channels which are programmed to receive collected data in real-time from at least three sensors” (claims 1, 8);
- “a transceiver or a transmitter then further to upload the collected data, and/or data based on the collected data to the database” (claims 1, 8);
- “at least two sensor connectors adapted to electrically connect the at least three sensors directly to the at least three input channels” (claims 1, 8);
- “the at least three sensors are selected from a group consisting of: accelerometer(s), fingertip pulse oximeter, pressure sensor, microphone, strain gauge and transducers” (claims 1, 8);
- “the at least three sensors adapted 1) to be applied to a finger and torso of the subject” (claim 1);
- “to be electrically hardwired and/or releasably connected to the three input channels” (claim 1); and
- “wherein one or more of the at least three sensors are further adapted to measure or derive the subject's body position while sleeping” (claims 2, 9).

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5. The ’698 Patent

At least under CleveMed’s actual and/or apparent application of the claims, the asserted claims of the ’698 patent are invalid under 35 U.S.C. § 112 ¶ 2 for indefiniteness because the specification and prosecution history of the ’698 patent would not inform those skilled in the art about the scope of the alleged invention with reasonable certainty.

- “analyzing the data with a computer or processor programmed to identify and draw attention to physiological and technological events in the data” (claim 14);
- “the respiratory belt sensor being electrically hardwired and releasably connected to a patient interface box” (claim 14); and
- “checking the adequacy of the data with a processor” (claim 15).

6. The ’269 Patent

At least under CleveMed’s actual and/or apparent application of the claims, the asserted claims of the ’269 patent are invalid under 35 U.S.C. § 112 ¶ 2 for indefiniteness because the specification and prosecution history of the ’269 patent would not inform those skilled in the art about the scope of the alleged invention with reasonable certainty. Further, the asserted claims of the ’269 patent are invalid for indefiniteness because the specification does not disclose adequate corresponding structure, material, or acts for several claim terms reciting functional language subject to 35 U.S.C. § 112 ¶ 6.

- “calculating … 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);
- “the processor adapted for receiving pulse oximetery [sic] sensor data from the second input and the respiratory airflow data from the airflow sensor, … the processor adapted to be either part of or external to the PAP device” (claim 5);

[redacted]

- "the second output adapted for providing sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a nonvolatile memory to be used for later transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a remote location" (claim 5);

- "creating an output of the level of severity of a subject's sleep disorder or symptoms" (claim 8);

- "the data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the at least one physiological sensor" (claim 8);

- "adjust the pharmaceutical agent" (claim 8);

- "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" (claim 15);

- "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" (claim 5);

- "to be used for later transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a remote location" (claim 5);

- "a remote internet site" (claim 15);

- "a base station" (claim 15);

- "retransmit" (claim 15); and

- "The system of claim 15, wherein the airflow sensor data is processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis" (claim 20) – invalid as indefinite as a mixed method/apparatus claim.

V. OBVIOUSNESS TYPE DOUBLE PATENTING

The Federal Circuit has emphasized that the doctrine of obvious-type double patenting

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("OTDP") "limit[s] a patentee to one patent term per invention or improvement," thereby protecting the "bedrock principle of our patent system that when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention." *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1212, 1214 (Fed. Cir. 2014). As the Federal Circuit explained in *Gilead*, that "principle is violated when a patent expires and the public is nevertheless barred from practicing obvious modifications of the invention claimed in that patent because the inventor holds another later-expiring patent with claims for obvious modifications of the invention." *Id.*, 1214; *see also Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1373 (Fed. Cir. 2014) (the doctrine is "designed to prevent an inventor from securing a second, later expiring patent for the same invention," and "ensures that a particular invention (and obvious variants thereof) does not receive an undue patent term extension").

A challenged claim is invalid under OTDP if the differences between the challenged claim and an expired claim render the claims not "patentably distinct," *i.e.*, the challenged claim is obvious over or anticipated by the expired claim. *Abbvie*, 764 F.3d at 1374. "Patentably distinct" differences do not exist when challenged claims represent, for example, "minor linguistic difference[s]" or "obvious variations" of the expired claims, or are "slightly broader" or "merely a subset" of the expired claims. *Georgia Pacific Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1327-28 (Fed. Cir. 1999). In this respect, "the law of obviousness-type double patenting looks to the law of obviousness generally." *Abbvie*, 764 F.3d at 1378. Thus, if the challenged claim is an obvious variation of an invention claimed in the expired patent, the challenged claim will be invalid. *Id.*

Further, "case law firmly establishes that a later genus claim limitation is anticipated by,

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and therefore not patentably distinct from, an earlier species claim." *Eli Lilly & Co. v. Barr Labs. Inc.*, 251 F.3d 955, 971 (Fed. Cir. 2001). For example, a claim term reciting a sunburn anticipates a claim term reciting skin damage because a sunburn is a species of skin damage. *Perricone v. Medicis Pharma. Corp*., 432 F.3d 1368, 1374 (Fed. Cir. 2005). In the other direction, "[i]t is well-settled that a narrow species can be non-obvious and patent eligible despite a patent on its genus." *Abbvie*, 764 F.3d at 1379 (emphasis added). But, "not every species of a patented genus is separately patentable." *Id*. When a "genus is so limited that a person of ordinary skill in the art can at once envisage each member of this limited class, a reference describing the genus anticipates every species within the genus." *Id*. A species contained in a previously patented genus, however, may nonetheless be patentable if the species manifests unexpected properties or produces unexpected results. *Id*. at 1380.

"Obviousness-type double patenting is a judicially created doctrine that 'prevents the extension of the term of the original patent via the patenting of an obvious variation.'" *In re Hitachi Metals, Ltd*., 603 F. App'x 976, 978–79 (Fed. Cir. 2015) (quoting *Georgia–Pac. Corp. v. U.S. Gypsum Co*., 195 F.3d 1322, 1326 (Fed. Cir. 1999)). "Under obviousness-type double patenting, a patent is invalid when it is merely an obvious variation of an invention disclosed and claimed in an earlier patent by the same inventor." *Georgia–Pac. Corp*., 195 F.3d at 1326. The determination of whether there is obviousness-type double patenting is a two-step process. "First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences." *Eli Lilly & Co. v. Barr Lab'ys, Inc*., 251 F.3d 955, 968 (Fed. Cir. 2001). "Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct." *Id*. "A later patent claim is not

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patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim." *Id*.

One or more of the asserted claims of the '269 patent are obvious under OTDP in view of the issued claims of at least US 11,375,921 ("the '921 patent) and/or US 11,602,284 ("the '284 patent). The '269 patent claims priority to U.S. patent application no. 11/266,899, filed November 4, 2005, and the cover page of the '269 patent identifies a patent term extension under 35 U.S.C. § 154(b) of 1304 days. The '921 patent also claims priority to U.S. patent application no. 11/266,899, filed November 4, 2005, and the cover page of the '921 patent identifies a patent term extension under 35 U.S.C. 154(b) of 677 days. The '284 patent issued March 14, 2023 and claims priority to U.S. patent application no. 11/266,899, filed November 4, 2005. The cover page of the '284 patent recites a patent term extension of "0 days." Thus, the '269 patent, '921 patent, and '284 patent all claim priority to the same application, but the '269 patent, if given the term extension identified on its cover page, would expire after both the '921 and '284 patents. The subject matter of the asserted claims of the '269 patent are not patentably distinct from the claims of the '921 patent and/or the '284 patent, and any differences are mere obvious modifications of the '921 and/or '284 patent claims.

VI. DERIVATION / LACK OF INVENTORSHIP

Upon information and belief, the Asserted Patents are invalid due to derivation and lack of inventorship pursuant to pre-AIA 35 U.S.C. § 102(f). *See Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303, 1313 (Fed. Cir. 2011) (patents are rendered invalid if the claimed invention was derived from someone other than the named inventor(s)). [redacted]

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[redacted]

[redacted]

[redacted] Upon information and belief, CleveMed, and/or one or more of the named inventors used knowledge obtained from ResMed and incorporated ResMed's technology and know-how into certain aspects of the claimed inventions. Thus, the claimed invention(s) of the Asserted Patents were derived from someone other than the named inventors and are rendered invalid and unenforceable. [redacted].

As another example, the majority of the specification of the '269 patent was copied from others that CleveMed did not identify as inventors. For example, Figure 7 of the '269 patent and its description at column 22, line 45 through column 23, line 17 were copied from Figure 1 and its corresponding description in US Patent No. 6,644,311 ("Truitt") that issued November 11, 2003, naming Patrick W. Truitt and Winslow K. Duff as inventors, and Respironics, Inc. as the assignee. *See, e.g.*, [redacted] RMD-306019 at Fig. 1, 1:45-2:10. All asserted claims of the '269 patent appear to rely solely on these copied disclosures from Truitt for the requirements of 35 U.S.C. § 112, first paragraph. For example, CleveMed has argued that the claimed "respiratory airflow data of a subject" is measured "from the flow sensor 320 and pressure sensor 322, which monitors the condition of the subject, monitors the usage of the pressure support device, and controls the blower," citing the text of the '269 patent at column 23, lines 7-17 copied from Truitt. *See* IPR2023-00565, Paper No. 6 (6/29/2023), 5-6 (citing '269 patent, 23:7-17). CleveMed also argued that Figure 7, which is copied Figure 1 from Truitt, shows "[a]n exemplary embodiment of the CPAP device" of the claimed invention. *Id.* at 5.

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There is no other disclosure in the ’269 patent specification of an airflow sensor “internal to the PAP device” as claimed other than that disclosed in the material copied from Truitt. Similarly, the only disclosure in the ’269 patent specification of a “blower having an air output” as claimed is in the material copied from Truitt. However, neither Mr. Truitt nor Mr. Duff are identified as inventors on the ’269 patent.

As another example, the text of the ’269 patent at column 20, line 11 through column 21, line 67 was copied from the text that appears in US Patent Application Publication No. 2004/0129838 (“Lisy”), published July 8, 2004. *See, e.g.*, RMD-306007 at ¶¶40-45. CleveMed relied on the text of column 20 through 21 as disclosing “exemplary techniques that a POSITA could use for [the claimed] calculation” of claims 1, 5, and 15 (D.I. 116 at 14, 23, 26-27). Asserted claim 20 also appears to rely solely on the copied text at columns 20-21 for the requirements of 35 U.S.C. § 112, first paragraph. However, the identified inventors Frederick J. Lisy, Mehul P. Patel, Jack M. DiCocco, Reed Carver, and Troy Prince on the Lisy patent are not named as inventors for the ’269 patent.

As a third example, the text of the ’269 patent at column 19, at least lines 12 through 45 were copied from U.S. Patent No. 8,187,209 (or at least application no. 11/082,668) (“Giuffrida”) that issued May 29, 2012 from an application filed March 17, 2005, naming Joseph Giuffrida as the sole inventor. *See, e.g.*, RMD-305981 at 13:5-36. Independent claims 1, 5, and 15 of the ’269 patent appear to rely solely on the copied text from Giuffrida for the requirements of 35 U.S.C. § 112, first paragraph. For example, the only disclosure of the claimed “remote location” or “remote internet site,” or cellular phone or PDA is at the material copied from Guiffrida. However, Mr. Giuffrida is not identified as an inventor for the ’269 patent.

As a fourth example, the text of the ’269 patent at column 4:65-5:18, and 8:57-18:50, and

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Figures 1-6, appear to have been copied from US 10,076,269 to Schmidt at 4:46-59, 4:63-14:54 and Figures 1-6. Schmidt issued December 26, 2000 and is prior art to the ’269 patent under 35 U.S.C. § 102(b). Independent claims 1, 5, and 8 of the ’269 patent appear to rely solely on the copied text from Schmidt for the requirements of 35 U.S.C. § 112, first paragraph, particularly for the “signal processing module” and “data acquisition” elements of the claims. However, the additional named inventors on the Schmidt patent, Donald C. Ferencz and Steven P. Hendrix, are not named as inventors for the ’269 patent.

Thus, the claimed invention(s) of the Asserted Patents were derived from someone other than the named inventors and are rendered invalid and unenforceable.

VII. PATENT ELIGIBILITY (35 U.S.C. § 101)

Claims directed to an abstract idea that do not add an inventive concept are ineligible for patent protection. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc*., 566 U.S. 66, 69–70 (2012); *Bilski v. Kappos*, 561 U.S. 593, 601–02 (2010). Determining whether the subject matter of a claim is patent-ineligible is a two-step process. *Alice*, 134 S. Ct at 2355; *Mayo*, 566 U.S. at 69–70. First, the Court must “determine whether the claims at issue are directed to a patent-ineligible concept” such as an abstract idea. *Alice*, 134 S. Ct. at 2355. Second, if the claims are directed to a patent-ineligible concept, the Court must “consider the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent eligible application.” *Id.* (internal quotations omitted). “The ‘abstract idea’ step of the inquiry calls upon us to look at the ‘focus of the claimed advance over the prior art’ to determine if the claim’s ‘character as a whole’ is directed to excluded subject matter.” *Affinity Labs of Texas, LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1257 (Fed. Cir. 2016). “The ‘inventive concept’ step requires us to look with more specificity at what the claim elements add, in order to

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determine 'whether they identify an inventive concept in the application of the ineligible subject matter" to which the claim is directed." *Id*. at 1258. Several principles help guide the analysis of whether the claims are directed to an abstract idea. First, "the abstract idea exception does not turn solely on whether the claimed invention comprises physical versus mental steps." *In re Marco Guldenaar Holding B.V.*, 911 F.3d 1157, 1161 (Fed. Cir. 2018). "It is well-settled that mere recitation of concrete, tangible components is insufficient to confer patent eligibility to an otherwise abstract idea." *In re TLI Commc'ns LLC Pat. Litig.*, 823 F.3d 607, 613 (Fed. Cir. 2016). Second, implementation of an abstract concept using conventional generic computer components is insufficient to transform an abstract idea into a patent-eligible invention. *Prism Technologies LLC v. T-Mobile USA, Inc.*, 696 F. App'x 1014, 1016 (Fed. Cir. 2017).

ResMed's contention that the asserted claims are invalid under 35 U.S.C. § 101 ("§ 101") are made in the alternative, and do not constitute, and should not be interpreted as, admissions that any of the asserted claims are not anticipated or rendered obvious by any prior art.

1. The HST Patents

The asserted claims of the HST Patents are directed to the abstract idea of automating a medical process that doctors and technicians have long performed manually. In particular, the claims describe collecting, transferring, and analyzing the data of an at-home (or remote) patient for the diagnosis and/or treatment of sleeping disorders. The claims rely on generic computer hardware (*e.g.*, "patient interface box," "non-volatile digital memory," "battery," "nasal cannula or a facemask," "processor," "software," "sensors") performing their usual, conventional, and routine functions (*e.g.*, "collecting," "digitizing, "storing," "transferring," and "receiving"). The claims do not, for example, describe an improvement to a computer system itself, and do not describe any particular processing step. Claims that "provide no useful guidance as to how [the] purported function is achieved cannot be directed to a technological solution." *cxLoyalty, Inc. v.*

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Maritz Holdings Inc., 986 F.3d 1367, 1378 (Fed. Cir. 2021).

Further, the claims recite automating a medical diagnosis (*i.e.*, "to determine whether the subject suffer from a sleeping disorder"), and the Federal Circuit has "consistently held diagnostic claims unpatentable as directed to ineligible subject matter." *See, e.g., Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 967 F.3d 1319, 1325 (Fed. Cir. 2020). The claims of the HST patents claim nothing more than (1) measuring and collecting certain attributes of the patient (*e.g.*, "airflow"; "respiratory effort"; "body position or orientation"; "oxygenation") using generic sensor hardware; (2) transferring the collected data through generic means, such as a USB transceiver or removable SD card; and (3) analyzing that data using generic software to determine whether the subject suffers from a sleeping disorder. Thus, the claims recite nothing more than applying known methods to detect certain attributes of the patient and reaching a conclusion: that the patient has a sleeping disorder. *See Cleveland Clinic Foundation v. True Health Diagnostics LLC*, 760 F. App'x 1013, 1018 (Fed. Cir. 2019) ("They only recite applying known methods to detect MPO levels in plasma, comparing them to standard MPO levels, and reaching a conclusion: that the patient's blood MPO levels are elevated in comparison to a control group. This conclusion is simply another articulation of the natural law that blood MPO levels correlate with atherosclerotic CVD."). The routine, conventional, and generic nature of these steps and the associated software is demonstrated, for example, by the HST patents' specifications and CleveMed's infringement contentions. *See, e.g.*, CleveMed's '399 Patent Final Infringement Contentions at 20 (alleging data claims may be met by USB transceiver connection); '399 patent at 4:22-25, 14:43-15:33, 16:65-17:28, 24:22-25:9.

Further, long before the purported invention, the processes for diagnosing and treating sleep disorders—that is using sensors, oximeters, respiratory effort belts, and masks or nasal

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cannulas to collect and analyze data and deliver treatment—was carried out manually or with the human mind. Accordingly, the claims are directed to an abstract idea. *See, e.g.*, *D & M Holdings Inc. v. Sonos, Inc.*, 309 F. Supp. 3d 207, 216 (D. Del. 2018) (stating that claims directed to the "automation of a previously manual step" are directed to an abstract idea); *Enco Sys., Inc. v. DaVincia, LLC*, 845 F. App'x 953, 957 (Fed. Cir. 2021) ("[T]he focus of the claimed advance is simply the abstract idea of automating the AV-captioning process."); *CardioNet, LLC v. InfoBionic, Inc*., 816 F. App'x 471 (Fed. Cir. 2020) (claims reciting the monitoring, analyzing, and displaying of cardiac information relating to arrhythmia events are "directed to collecting, analyzing, and displaying data, which we have repeatedly held to be abstract concepts").

Moreover, the claims of the HST Patents do not claim any inventive concept that would transform the abstract idea into patent-eligible subject matter. The steps recited are generic and well known, and there is nothing inventive in their ordered combination. "If a claim's only 'inventive concept' is the application of an abstract idea using conventional and well-understood techniques, the claim has not been transformed into a patent-eligible application of an abstract idea." *BSG Tech LLC v. Buyseasons, Inc*., 899 F.3d 1281, 1290-91 (Fed. Cir. 2018). In addition, simply automating a fundamental human activity and applying this concept to a general purpose computer environment is not enough as a matter of law to remove these claims from being directed to an abstract idea. *OIP Techs., Inc. v. Amazon.com, Inc*., 788 F.3d 1359, 1363 (Fed. Cir. 2015) ("Relying on a computer to perform routine tasks more quickly or more accurately is insufficient to render a claim patent eligible."). The Federal Circuit has "consistently rejected" claims "using a known technique in a standard way to observe a natural law" such as medical diagnostics. *Cleveland Clinic*, 760 F. App'x at 1019. Further, there are not "additional features" (as the *Alice* Court cited) that make this claim more than a recitation of the abstract idea. For

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example, the claims recite no non-routine components or unique steps. Lastly, the dependent claims add nothing inventive and fail to offer any meaningful limitation over the abstract idea claimed in the independent claims.

The lack of an inventive concept is underscored by the fact that substantial portions of HST patents' specifications are copied verbatim from prior art. In particular, the HST patents copied U.S. Patent No. 8,437,843 to Kayyali ("Kayyali 1"), filed on June 16, 2006, and issued on May 7, 2013; U.S. Patent No. 6,993,380 to Modarres ("Modarres"), filed on June 4, 2003, and issued on January 31, 2006; U.S. Patent No. 11,690,512 to Kayyali ("Kayyali 2"), filed on January 9, 2023, and issued on July 4, 2023 (collectively, the "HST Copied Prior Art"). The chart below summarizes CleveMed's extensive copying and demonstrates that significant portions of the HST patents' specifications were copied from the prior art, including:

'698 Claim	**Exemplary Limitation**	**Copied From**
1	A method of remote sleep analysis and diagnosis comprising the steps of: a) applying, at least two sensors to a patient located in a facility remote to a sleep analysis unit or lab, the at least two sensors including a respiratory belt sensor and a patient airflow sensor, the respiratory belt sensor being electrically hardwired and releasably connected to a portable patient interface box worn or carried by the patient, and the airflow sensor internal to the same patient interface box and adapted to be applied to the patient through a nasal cannula or breathing mask, which is connected to the patient interface box by an airport; b) connecting both the respiratory belt sensor, and the nasal cannula or breathing mask directly to the patient interface box, which is part of a portable wireless data acquisition system comprising the patient interface box and a cellular phone, the patient interface box further comprising electronics, which are programmed to collect and transmit data to the cellular phone, the cellular phone having a first electronic interface for receiving the data, the cellular phone which is programmed to transmit data to an second electronic interface for receiving the data for review by medical personnel; c) collecting data with the electronics of the patient	*See*, *e.g.*, FIG. 1, Kayyaali 1; 16:3-61.

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'698 Claim	**Exemplary Limitation**	**Copied From**
	interface box in real-time from the at least two sensors on the patient located in the remote facility while the patient is attempting to sleep; d) transmitting, at least in part, the data from the patient interface box to the cellular phone; e) transmitting wirelessly the data, at least in part, from the cellular phone to the sleep analysis unit or lab, or to a database accessible to medical personnel located remote from the patient through the electronic interface; f) analyzing the data with a computer or processor programmed to identify and draw attention to physiological and technological events in the data; g) further medical analysis of the transmitted data and the physiological and technological events in the data to medically diagnose whether the patient suffers from a sleep disorder; and	

'399 Claim	**Exemplary Limitation**	**Copied From**
1	1. A method of conducting home sleep testing comprising the steps of: providing a subject with a portable patient interface box worn by the subject on its torso and a nasal cannula or a facemask, a respiratory effort belt and a fingertip pulse oximeter, the patient interface box comprising a battery, at least one kinetic sensor, a nonvolatile digital memory, a pressure transducer, an airport for connecting a nasal cannula or a facemask to the pressure transducer within the patient interface box, and releasable connector sensor inputs to electrically connect and disconnect the respiratory effort belt and the fingertip pulse oximeter, the nasal cannula or facemask for measuring airflow of the subject, the respiratory effort belt for measuring respiratory effort of the subject, the kinetic sensor for measuring body position or orientation and the fingertip pulse oximeter for measuring oxygenation of the subject; applying and connecting the nasal cannula or facemask, the respiratory effort belt and the fingertip pulse oximeter to the subject, and further the patient interface box to the subject's torso; measuring and collecting data through the patient interface box of the airflow, respiratory effort, body position or orientation and oxygenation of the subject while the subject attempts to sleep at home; digitizing and storing the collected data from the	*See, e.g.*, FIG. 1, Kayyaali 1; 15:27-16:17.

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	subject in the nonvolatile digital memory of the patient interface box; transferring the collected data to a location remote from the subject's home; providing a computer or a processor at the remote location for analyzing the transferred collected data to identify and draw attention to physiological or technological events in the data indicative of a sleeping disorder; and further analyzing at a minimum the transferred collected data and/or the identified physiological and technological events in the data at the remote location or another remote location to determine whether the subject suffers from a sleeping disorder.	

"While the fact that a particular limitation is found in a prior art reference does not by itself establish that the limitation is 'well understood, routine, and conventional' for purposes of step two of the section 101 analysis, the presence of multiple prior art references going back years before the priority date of the invention at issue can provide important evidence that the limitation relied on by the patentee does not constitute an 'inventive concept' for section 101 purposes." *F45 Training Pty Ltd. v. Body Fit Training USA Inc.*, No. CV 20-1194-WCB, 2022 WL 17177621, at *11 (D. Del. Nov. 17, 2022); *GREE Inc. v. Supercell OY*, No. 2:19-cv-70, 2020 WL 887733, at *2 (E.D. Tex. Feb. 24, 2020) (The court "must compare th[e] inventive concept to the universe of prior art to determine whether the claims merely involve activity that was 'well-understood, routine and conventional.'"); *see also Mayo Collaborative Servs. v. Prometheus Lab'ys*, 566 U.S. 66, 90 (2012) ("We recognize that, in evaluating the significance of additional steps, the § 101 patent-eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap."). Indeed, home sleep monitoring systems with identical capabilities to the claims of the HST patents were well known in the field. *See* Section II.C.2.

When stripped of what was well understood, routine, and conventional, the claims of the HST patents are directed to an abstract idea, as identified above, and the claims do not add an inventive concept.

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2. The ’269 Patent

The asserted claims of the ’269 patent are directed to the abstract idea of “collecting information, analyzing it, and displaying certain results of the collection and analysis.” *See Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016). In particular, the claims of the ’269 patent are directed to collecting, analyzing, and transmitting a patient’s data related to the diagnosis and/or treatment of sleeping disorders. To accomplish this abstract task, the claims rely on generic hardware (*e.g.*, “pulse oximeter,” “PAP device,” “airflow sensor,” “mask or nasal cannula,” “processor,” “data acquisition system”; “module transceiver”; “base station”). The claims do not, for example, describe an improvement to a system itself, and do not describe any particular processing step. Rather, the claims merely recite this generic hardware as performing abstract operations (*e.g.*, “connecting”; “outputting”; “receiving”; “transmitting”; “calculating”). *See* § II.D.2.(c), discussing Declaration of D’Ambrosio In Support of CleveMed Reply Claim Construction Brief, e.g., at ¶¶24-27 (describing that the claimed “calculating” and “creating” could include, e.g., merely calculating “airflow,” pulse, or SpO_2, which are simply outputs of the sensors or conventional statistics based thereon). The processes for diagnosing and treating sleep disorders disclosed in the claims is no more than a “process of gathering and analyzing information of a specified content, then displaying the results, and not any particular assertedly inventive technology for performing those functions. They are therefore directed to an abstract idea.” *Elec. Power*, 830 F.3d at 1354.

Moreover, the claims of the ’269 patent do not claim any inventive concept that would transform the abstract idea into patent-eligible subject matter. The steps recited are generic and well known, and there is nothing inventive in their ordered combination. In addition, the ’269 patent merely implements the above-mentioned abstract idea through the use of conventional, general-purpose hardware with associated computer and transceiver equipment such as a pulse

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oximeter, PAP device, airflow sensor, mask or nasal cannula, processor, and base station. The use of a computer in a "computer-implemented invention … must involve more than performance of 'well-understood, routine, [and] conventional activities previously known to the industry'" to supply the necessary "inventive concept" under *Alice*'s second step. *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat. Ass'n*, 776 F.3d 1343, 1348 (Fed. Cir. 2014) (quoting *Mayo*, 132 S. Ct. at 1294). "[L]imiting the claims to the particular technological environment of [PAP devices] is, without more, insufficient to transform them into patent-eligible applications of the abstract idea at their core." *Elec. Power*, 830 F.3d at 1354. Further, there are not "additional features" (as the *Alice* Court cited) that make this claim more than a recitation of the abstract idea. For example, the claims recite no non-routine components or unique steps. Lastly, the dependent claims add nothing inventive and fail to offer any meaningful limitation over the abstract idea claimed in the independent claims.

The lack of an inventive concept is underscored by the fact that substantial portions of '269 patent specification are copied verbatim from prior art. In particular, the '269 patent copied U.S. Patent No. 6,167,258 to Schmidt ("Schmidt"), filed on October 9, 1998, and issued on December 26, 2000; U.S. Patent No. 6,644,311 to Truitt ("Truitt"), filed on December 19, 2001, and issued on November 11, 2003; U.S. Patent Pub. No. 2004/0129838 to Lisy ("Lisy"), filed on January 3, 2003, published on July 8, 2004; U.S. Patent No. 8,187,209 to Giuffrida ("Giuffrida"), filed on March 17, 2005, and issued on May 29, 2012; U.S. Patent No. 6,993,380 to Modarres ("Modarres"), filed on January 4, 2003, and issued on January 31, 2006 (collectively, the "Copied Prior Art"). The chart below summarizes CleveMed's extensive copying and demonstrates that significant portions of the '269 patent's specification was copied from the prior art, including:

[redacted]

’269 Patent Specification	Copied From
Figs. 1-6	Schmidt Figs. 1-6
Fig. 7	Truitt Fig. 1
1:25-2:10	Modarres 1:21-2:27
4:65-5:18	Schmidt 4:46-59
6:16-59	Modarres 6:40-7:14
8:57-18:50	Schmidt 4:63-14:54
19:12-45	Giuffrida 13:5-36
20:11-21:67	Lisy para. 40-45
22:45-23:17	Truitt 1:45-2:10

Significant portions of the Copied Prior Art were also incorporated into the application that issued as the ’269 patent.

’269 Claim	**Limitation**	**Copied From**
1	A positive airway pressure (PAP) sleep disorder treatment system comprising:	*See, e.g.*, Truitt, FIG. 1; 1:24-55.
	a signal processing module comprising a first input adapted for connecting to a pulse oximeter sensor with a signal, electronics adapted for filtering and processing the signal, and an output adapted for outputting pulse oximetry sensor data;	*See, e.g.*, Schmidt, FIG. 1; 4:63-5:51.
	a PAP device adapted for treating a subject's sleep disorder, the PAP device with a separate enclosure from the signal processing module further comprising:	*See, e.g.*, Truitt, FIG. 1; 1:24-55.
	a blower having an air output,	*See, e.g.*, Truitt, FIG. 1; 1:24-55.
	a second input adapted for receiving the pulse oximetry sensor data from the output of the signal processing module,	*See, e.g.*, Schmidt, FIG. 2; 5:52-6:35.
	an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow data of a subject using the PAP device, and	*See, e.g.*, Truitt, FIG. 1; 1:44-2:11.
	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	*See, e.g.*, Schmidt, FIG. 2; 5:52-6:35; Modarres, 1:21-2:27.

[redacted]

	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;	
	a mask or a nasal cannula; and	*See, e.g.*, Truitt, FIG. 1; 1:44-2:11.
	a module transceiver adapted for receiving and transmitting the sleep disorder symptom data of the level of severity and/or the index of the level of severity of the subject's sleep disorder symptoms to a remote location.	*See, e.g.*, Schmidt, FIG. 2; 5:52-6:35; Modarres, 1:21-2:27; Giuffrida, 13:5-36.
4[5]	The system of claim 1 wherein the signal is processed by the signal processing module using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.	*See, e.g.*, Lisy, ¶40.
5	A sleep disorder treatment system comprising:	*See, e.g.*, Truitt, FIG. 1; 1:24-55.
	a data acquisition system;	*See, e.g.*, Schmidt, FIG. 4; 8:20-65.
	a positive airway pressure (PAP) device; and	*See, e.g.*, Truitt, FIG. 1; 4:61-5:13.
	a processor;	*See, e.g.*, Schmidt, FIG. 2; 5:52-67.
	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;	*See, e.g.*, Schmidt, FIG. 4; 8:20-65.
	the PAP device comprising: a hose, a blower, an airflow sensor with a second signal adapted for measuring respiratory airflow of a subject, a second input for receiving pulse oximetry sensor data from the data acquisition device; and a mask or nasal cannula for treating a subject's sleep disorder symptoms; and	*See, e.g.*, Truitt, FIG. 1; 1:44-2:11.

[5] The listed claims are exemplary and similar or identical limitations from other claims are omitted. For example, claim 4 is representative of claims 6, 14, and 20.

[redacted]

	the processor adapted for receiving pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor, 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, the processor adapted to be either part of or external to the PAP device and having a second output, the second output adapted for providing sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a nonvolatile memory to be used for later transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a remote location.	*See, e.g.*, Schmidt, FIG. 2; 5:52-6:35; Modarres 1:21-2:27; Giuffrida, 13:5-36.
8	8. A sleep disorder treatment system comprising:	*See, e.g.*, Truitt, FIG. 1; 1:24-55.
	a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the at least one physiological sensor; and	*See, e.g.*, Schmidt, FIG. 4; 8:20-65.
	a positive airway pressure apparatus for providing pressurized air and dosing and chemically treating a subject's sleep disorder or symptoms with a pharmaceutical agent, the positive airway pressure apparatus comprising a controller adapted to adjust the pharmaceutical agent, at least in part, using the output of the level of severity of the subject's sleep disorder from the data acquisition system.	*See, e.g.*, Truitt, FIG. 1; 1:24-55.
15	A positive airway pressure (PAP) sleep disorder treatment system comprising:	*See, e.g.*, Truitt, FIG. 1; 1:24-55.
	a PAP device with an enclosure further comprising: a blower having an air input an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject while using the PAP and outputting airflow sensor data;	*See, e.g.*, Truitt, FIG. 1; 1:24-55.
	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;	*See, e.g.*, Schmidt, FIG. 2; 5:52-6:35; Modarres, 1:21-2:27.

[redacted]

	a mask or a nasal cannula	*See, e.g.*, Truitt, FIG. 1:44-2:11.
	a first radio frequency wireless module transceiver; and	*See, e.g.*, Schmidt, FIG. 2; 5:52-6:35.
	a base station, cellular phone, or PDA;	*See, e.g.*, Schmidt, FIG. 1; 4:63-5:51; Giuffrida, 13:5-36.
	the first radio frequency wireless module transceiver adapted for receiving and transmitting the symptom data of the 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 the data of usage to the base station, cellular phone or PDA;	*See, e.g.*, Schmidt, FIG. 2; 5:52-6:35; Giuffrida, 13:5-36.
	the base station, cellular phone, or PDA comprising a second radio frequency wireless module transceiver, a processor, a software, and a display, the base station, cellular phone, or PDA adapted to display the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms, and to retransmit the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms and the data of usage received from the PAP device to a remote internet site.	*See, e.g.*, Schmidt, FIG. 1; 4:63-5:51; Giuffrida, 13:5-36.

"While the fact that a particular limitation is found in a prior art reference does not by itself establish that the limitation is 'well understood, routine, and conventional' for purposes of step two of the section 101 analysis, the presence of multiple prior art references going back years before the priority date of the invention at issue can provide important evidence that the limitation relied on by the patentee does not constitute an 'inventive concept' for section 101 purposes." *F45 Training Pty Ltd. v. Body Fit Training USA Inc.*, No. CV 20-1194-WCB, 2022 WL 17177621, at *11 (D. Del. Nov. 17, 2022); *GREE Inc. v. Supercell OY*, No. 2:19-cv-70, 2020 WL 887733, at *2 (E.D. Tex. Feb. 24, 2020) (The court "must compare th[e] inventive concept to the universe of prior art to determine whether the claims merely involve activity that was 'well-understood, routine and conventional.'"); *see also Mayo Collaborative Servs. v. Prometheus Lab'ys*, 566 U.S. 66, 90 (2012) ("We recognize that, in evaluating the significance

[redacted]

of additional steps, the § 101 patent-eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap.").

However, the Copied Prior Art confirms that the material copied into the '269 patent was conventional and well-understood. For instance, the portions of Truitt that were copied were disclosed as "conventional" and described in the "Background of the Invention" section of the Truitt patent. *See, e.g.,* Truitt, FIG. 1; 1:24-55. [redacted] When stripped of what was well understood, routine, and conventional, the claims of the '269 patent are directed to an abstract idea, as identified above, and the claims do not add an inventive concept.

VIII. PRIOR ART DOCUMENT PRODUCTION

Pursuant to Paragraph 3(d) of the Scheduling Order, ResMed produced prior art references throughout the fact discovery phase of this case. Some of the produced prior art documents are highly confidential and are being produced on an outside attorneys' eyes only

[redacted]

basis (HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY) pursuant to the Stipulated Protective Order entered in this matter. (*See* D.I. 46).

Dated: November 20, 2023

Respectfully submitted,

/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@dlapiper.com
angela.whitesell@dlapiper.com
matthew.middleton@us.dlapiper.com

Sean Cunningham
Tiffany Miller
David Knudson
DLA PIPER LLP (US)
4365 Executive Drive, Suite 1100
San Diego, California 92121-2133
Telephone: 858-677-1400
Facsimile: 858-677-1401
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.

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CERTIFICATE OF SERVICE

I, Brian A. Biggs, do hereby certify that on this 20th day of November, 2023, the attached **DEFENDANTS' FINAL INVALIDITY CONTENTIONS** was served upon the following counsel of record via electronic mail:

Philip A. Rovner
Jonathan A. Choa
POTTER ANDERSON & CORROON LLP
Hercules Plaza
1313 North Market Street, 6th Floor
P.O. Box 951
Wilmington, Delaware 19801
(302) 984-6000
provner@potteranderson.com
jchoa@potteranderson.com

Benu Wells
KRAMER LEVIN NAFTALIS & FRANKEL LLP
1177 Avenue of the America
New York, NY 10036
(212) 715-7590
bwells@kramerlevin.com

Paul J. Andre
Lisa Kobialka
James Hannah
Timothy Layden
Sabah Khokhar
Jennifer L. Gilbert
Melissa T.H. Brenner
Michael H. Lee
Charles Keller
KRAMER LEVIN NAFTALIS & FRANKEL LLP
333 Twin Dolphin Drive, Suite 700
Redwood Shores, CA 94065
(650) 752-1700
pandre@kramerlevin.com
lkobialka@kramerlevin.com
jhannah@kramerlevin.com
tlayden@kramerlevin.com
skhokhar@kramerlevin.com
jgilbert@kramerlevin.com
mbrenner@kramerlevin.com
mhlee@kramerlevin.com
ckeller@kramerlevin.com

/s/ Brian A. Biggs
Brian A. Biggs (DE Bar No. 5591)

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FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

ResMed's invalidity contentions, including this chart, are based in part on Cleveland Medical's ("CleveMed") infringement contentions and apparent claim interpretations. In some instances, certain claim limitations are expressly or inherently present in the prior art in light of CleveMed's apparent claim interpretations in its infringement contentions. ResMed offers these contentions in response to CleveMed's infringement contentions and without prejudice to any position ResMed may later take as to any claim construction issues. To the extent these contentions reflect claim constructions that are consistent with CleveMed's infringement contentions, no implication is intended, nor should any inference be drawn, that ResMed agrees with any construction implied by CleveMed's infringement contentions.

ResMed offered for sale, sold, or otherwise made publicly available in the United States no later than November 4, 2005, and, at least some instances before March 2005 and before November 4, 2004, the herein identified "ResMed Prior Art." This chart refers to the following devices, software, components, accessories, and publications (including those identified in the chart below or known components of the systems, such as masks, tubing, connectors, cables, adapters, data cards, card readers, pulse oximeters and their corresponding components/cables, and other accessories) collectively and in the alternative as the "ResMed Prior Art" or "RPA," which are prior art to the '269 patent under pre-AIA 35 U.S.C. § 102(a), (b), (f) and/or (g):

- ResMed AutoSet Spirit flow generator device (*see, e.g.,* AutoSet Spirit Clinician's Manual (RMD-063968), [redacted], [redacted] RMD-0318396 Specimen Photographs);[i]
- ResMed AutoScan software and related hardware (*see, e.g.,* AutoScan 5.4 Clinician's Manual (RMD-311263)(RMD-311340), RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures);[ii]
- ResMed ResLink device and accessories, including the NONIN Xpod and pulse oximeter sensor (*see, e.g.,* ResLink Launch Brochure, ResLink Clinician's Guide, ResLink User's Manual, [redacted] RMD-0318396 Specimen Photographs);[iii]
- ResMed ResTraxx device and related software, including the ResMed ResTraxx Data Center (RDC) (a.k.a. [redacted] a.k.a. [redacted]). *See, e.g.*: [redacted] ResTraxx Patient Management Brochure (1010126), ResTraxx Quick Reference Guide (30859), ResTraxx Wireless Patient Monitoring Atlas (1010562) ("ResTraxx Atlas") (RMD-063341)(RMD-129625), [redacted] RDC User's Manual (RMD-306688); [redacted] RMD-0318396 Specimen Photographs);[iv]

- ResMed mask systems (*see, e.g.*, Mirage Full Face Mask Series 2 User Instructions, Mirage Mask User's Guide USA, Ultra Mirage Full Face Mask User's Guide, Mirage Vista Mask User Guide; RMD-0318396 Specimen Photographs).

CleveMed's final infringement contentions, served November 13, 2023, assert claims 1, 5, 8, 15, 16, and 20 (collectively "the asserted claims") of U.S. Patent No. 10,076,269 ("the '269 patent"). The below chart refers in some instances to CleveMed's corrected infringement contentions exhibits served in January 2022 for claims 1, 5, 8, 9, 13, 15-18, and CleveMed's contentions served September 25, 2023 for claim 20. Based on CleveMed's infringement contentions, the asserted claims of the '269 patent are invalid in view of the ResMed Prior Art as either anticipated, under pre-AIA 35 U.S.C. § 102, and/or as obvious, under 35 U.S.C. § 103. In particular, for at least the same reasons CleveMed alleges the accused ResMed products practice the asserted claims, the ResMed Prior Art anticipates and/or renders the asserted claims obvious. The chart below discloses, in view of CleveMed's infringement contentions against the accused ResMed products, how the ResMed Prior Art discloses, either expressly or inherently, and/or renders obvious the asserted claims. Nothing in the chart below should be interpreted as an admission that the accused features and functionality identified in CleveMed's infringement contentions practice the asserted claims. ResMed also incorporates the discussion of the state of the art, admitted prior art, and knowledge of a POSITA from the cover pleading served herewith.

CleveMed's infringement contentions remain deficient for many reasons, including those identified in ResMed's correspondence to CleveMed regarding its September 25, 2023 amended contentions, and those identified below, that CleveMed is yet to cure. These deficiencies have prejudiced ResMed's ability to develop its invalidity defenses. If CleveMed clarifies or otherwise revises its infringement allegations, ResMed reserves the right to modify its invalidity contentions accordingly. Furthermore, CleveMed first identified claim 20 as an asserted claim in its September 25, 2023 amended contentions, and withdrew claim 4. Claim 20 is vastly different from claim 4, for example because claim 20 is directed to processing of airflow sensor data, which is processed and used differently than a pulse oximeter sensor signal that is the subject of newly withdrawn claim 4. Furthermore, claim 20 does not specify that the processing is in any way related to the processor term recited in the independent claim 15 from which claim 20 depends, and therefore has a different structure overall from claim 4 that links the processing to the signal processing module of claim 1. Claim 20 is also invalid as indefinite as a mixed method/apparatus claim. ResMed reserves the right to supplement its contentions for claim 20 given the late identification of claim 20.

The following exemplary systems (including disclosed accessories such as the NONIN pulse oximeter, Xpod, and associated cables, masks, hoses, adapters, etc. identified in the chart below) anticipate one or more asserted claims of the '269 patent based at least on CleveMed's infringement contentions, and at least render obvious the asserted claims either alone or in combination with the prior art identified in the below chart.

System 1: ResMed AutoSet Spirit + ResLink + AutoScan 5.4

System 2: ResMed AutoSet Spirit + ResTraxx (including RDC)

The citations provided are exemplary and do not necessarily include each and every disclosure of a limitation in the reference. ResMed has endeavored to cite to the most relevant portions of the identified prior art, but other portions of the identified prior art may additionally disclose, either expressly or inherently, and/or render obvious, one or more limitations of the asserted claims. ResMed reserves the right to rely on: (1) uncited portions of the identified prior art; (2) other prior art not identified herein; (3) references that show the state of the art and the knowledge of a person of skill in the art, irrespective of whether such references themselves qualify as prior art to the asserted patents; (4) factual testimony from the inventors or authors of the prior art references, or purveyors of prior art devices; and/or (5) expert testimony, to provide context to or aid in understanding the prior art, the state of the art, and/or the knowledge of a person of ordinary skill in the art. ResMed reserves the right to rely on any materials incorporated by reference into any cited prior art reference. To the extent ResMed asserts that a claim limitation is indefinite, ResMed has used its best efforts to interpret the claims to fulfill its duties in charting the prior art references.

Where ResMed cites to a particular drawing or figure in the accompanying charts, the citation encompasses the description of the drawing or figure, as well as any text associated with the drawing or figure. Similarly, where ResMed cites to text concerning a figure, the citation encompasses that figure. This prior art at least discloses certain claim limitations, and ResMed reserves the right to rely on inherency to demonstrate the invalidity of the asserted claims. ResMed may rely on cited or uncited portions of the prior art, other documents, factual testimony, and expert testimony to invalidate the asserted claims.

This chart also references the following disclosures:

- US Patent No. 6,167,258 to Schmidt, et al., issued December 26, 2000 ("Schmidt");
- US Patent Application Publication No. 2002/0165462 to Westbrook et al., filed December 28, 2001 and published November 7, 2002 ("Westbrook");
- D. Alan Lankford, *Wireless CPAP Patient Monitoring: Accuracy Study*, Telemedicine Journal and e-Health, Vol. 10, No. 2, 2004, at 162 ("Lankford");
- B. Woodward and M.F.A. Rasid, *Wireless Telemedicine: The Next Step*, 4th Int'l IEEE EMBS Special Topic Conference on Information Technology Applications in Biomedicine, 2003, at 43 ("Woodward");

- Mohd Fadlee A. Rasid and Bryan Woodward, *Bluetooth Telemedicine Processor for Multichannel Biomedical Signal Transmission via Mobile Cellular Networks,"* IEEE Transactions on Information Technology in Biomedicine, Vol. 9, No. 1, March 2005, at 35 ("Rasid");[1]
- Mohd Fadlee A Rasid, Multi-Channel GPRS-Based Mobile Telemedicine System With Bluetooth and J2ME Interfaces, Doctoral Thesis, Department of Electronic and Electrical Engineering, Loughborough University (October 2005) ("Rasid Thesis");
- US Patent No. 6,287,264 to Hoffman, filed April 23, 1999 and published September 11, 2001 ("Hoffman");
- R. Paradiso, et al., *Wearable Health Care System for Vital Signs Monitoring*, 4th Annual IEEE Conf. on Information Technology Applications in Biomedicine, 2003, at 283 ("Paradiso");
- Guilleminault C, van den Hoed J, and Mitler MM, *Clinical overview of the sleep apnea syndromes*. In: C Guilleminault and WC Dement (Eds), SLEEP APNEA SYNDROMES, Alan R Liss, New York, 1978, pp. 1-12 ("Guilleminault 1978");
- Christian Guilleminault and Vivien C. Abad, *Obstructive sleep apnea syndromes*, Med. Clin. N. Am. 88, 2004, pp. 611-630 ("Guilleminault 2004");
- Francoise J. Roux and Janet Hilbert, *Continuous positive airway pressure: new generations*, Clin. Chest Med. 24, 2003, at 315-342 ("Roux");
- The AASM Manual for the Scoring of Sleep and Associated Events, 2007 ("AASM Manual");
- US Patent No. 5,704,345 to Berthon-Jones, filed November 4, 1994, issued January 6, 1998 ("Berthon-Jones");
- Kirianaki, et al., DATA ACQUISITION AND SIGNAL PROCESSING FOR SMART SENSORS, 2002, John Wiley & Sons Ltd ("Kirianaki").

Evidence of use, sale, or offer to sell in the United States for RPA Systems 1-2 is found in the documents cited herein, in addition to the following: [redacted]

[1] Woodward is a 2003 disclosure by the same authors of similar work disclosed in the later 2005 Rasid publication. Because, in response to ResMed's Interrogatory No. 2, CleveMed has continually changed its contention regarding the alleged conception date for the '269 patent asserted claims and has failed to provide sufficient support for its alleged conception, diligence, and reduction to practice, CleveMed has prejudiced ResMed's ability to prepare its invalidity contentions. Specifically, CleveMed's contentions regarding conception and diligence in reduction to practice as of the date of service of these invalidity contentions do not establish either (1) conception before the publication date of Rasid, or (2) diligence between March 2005 and the filing date of the application to which the '269 patent claims priority. Based on the information made available to ResMed, ResMed relies on Rasid, and not Woodward, as invalidating prior art to the '269 patent asserted claims. To the extent it is determined that Rasid is not prior art, or if CleveMed supplements its contentions with regard to conception and diligence in reduction to practice with additional facts or information, ResMed reserves the right to rely on Woodward in place of Rasid.

[redacted]

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ResMed Prior Art ("RPA") v. '269 Patent

[redacted] RMD-311631 ResMed Annual Report 2002; RMD-311667 ResMed Annual Report 2003; RMD-311707 ResMed Form 10-K 2004; RMD-209549 ResMed Annual Report 2004; RMD-308753 ResMed Form 10-K 2005.

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Claim Language [1pre]	ResMed Prior Art ("RPA")
[1pre] A positive airway pressure (PAP) sleep disorder treatment system comprising:	To the extent the preamble is limiting, RPA discloses this preamble. For example, the RPA devices of Systems 1-2 are PAP sleep disorder treatment devices. Alone or in combination with components (such as masks, tubing, and other accessories) and software discussed below, these devices provide a "system" with the claimed features. *See*, *e.g.*, RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures; RMD-0318396 Specimen Photographs; [redacted] **ResMed AutoSet Spirit (System 1, 2)** The ResMed AUTOSET® SPIRIT™ system is designed to provide continuous positive airway pressure (CPAP) therapy to patients with obstructive sleep apnea (OSA). Patients with OSA experience recurrent obstruction of their upper airway (apneas) due to relaxation of the tongue and soft palate while they sleep. Common symptoms are associated with poor sleep quality and may include excessive daytime sleepiness and tiredness, as well as diminished concentration and memory loss. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3974. The AUTOSET SPIRIT system is intended for the treatment of obstructive sleep apnea (OSA) in adult patients. Data collection capabilities also assist in the management of continuous positive airway pressure (CPAP) treatment. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3976. [redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]
	[redacted]
	The AUTOSET SPIRIT system is designed for clinical use and home treatment of adult patients with obstructive sleep apnea (OSA). The system has two therapy modes for treating OSA: **CPAP** mode and **AutoSet** mode.

Claim Language [1pre]	ResMed Prior Art ("RPA")
	RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980. CPAP MODE In CPAP mode, the AUTOSET SPIRIT unit provides fixed-pressure room air via tubing to the mask worn by your patient. The continuous air stream "splints" open the upper airway, preventing airway collapse. AUTOSET SPIRIT delivers pressure within the range 4 to 20 cm H_2O. To make the beginning of treatment more comfortable, you may set a ramp so the pressure starts low and gradually increases to full treatment pressure over the ramp time. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980. AUTOSET® MODE The treatment pressure required by your patient may vary through the night, and from night to night, due to changes in sleep state, body position, and airway resistance. In AutoSet mode AUTOSET SPIRIT provides only sufficient pressure to maintain upper airway patency. You can set the minimum and maximum allowable treatment pressures. The unit analyzes the state of the patient's upper airway on a breath-by-breath basis and delivers pressure within the allowed range according to the degree of obstruction. The AutoSet algorithm adjusts treatment pressure as a function of three parameters: inspiratory flow limitation, snore, and apnea. The flow sensor, located in the AUTOSET SPIRIT unit, enables detection of inspiratory flow limitation and apneas. The pressure sensor, also located in the unit, enables measurement of pressure and snore. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.

Claim Language [1pre]	ResMed Prior Art ("RPA")

COMPONENTS OF THE AUTOSET® SPIRIT™ SYSTEM

The following are supplied as part of an AUTOSET SPIRIT system.

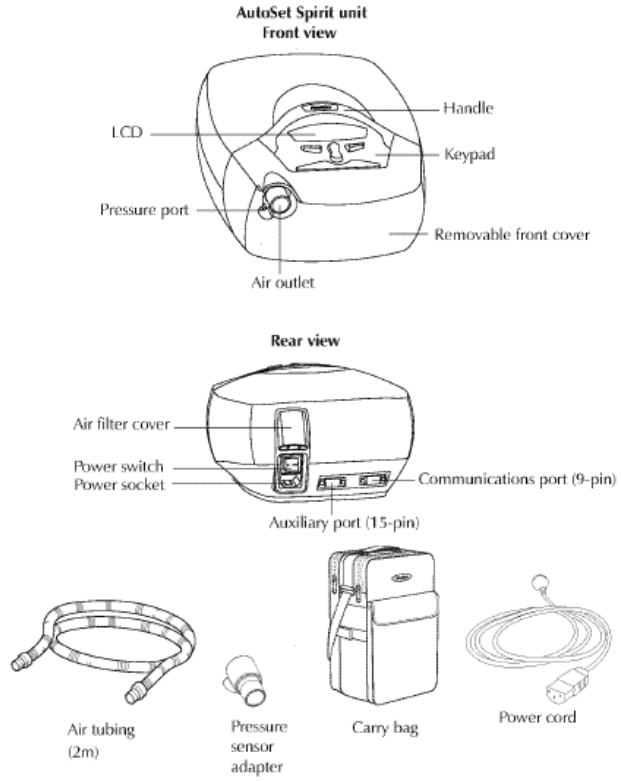
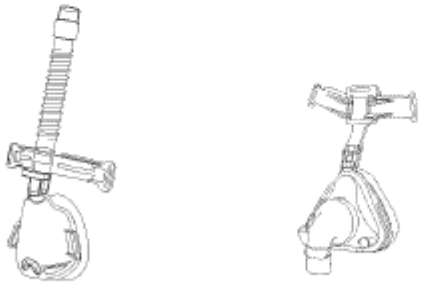


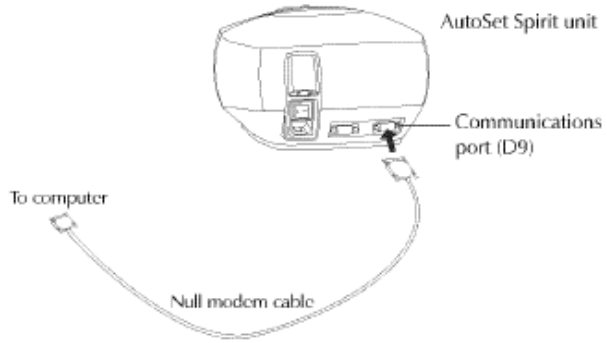
Figure 4: AutoSet Spirit system components

RMD-063968 (AutoSet Spirit Clinician's Manual) at -3983.

Claim Language [1pre]	ResMed Prior Art ("RPA")
	ACCESSORIES The following accessories may be purchased separately. AUTOSET SPIRIT ACCESSORIES Air tubing 9ft10in (3m) HUMIDIFIER ACCESSORIES (HUMIDAIRE and ResMed PASSOVER only) Pressure sensor line Short air tubing 7.5in (19cm) for HumidAire connection Medium air tubing 21in (52cm) for humidifier connection RMD-063968 (AutoSet Spirit Clinician's Manual) at -3984.

Claim Language [1pre]	ResMed Prior Art ("RPA")
	HUMIDIFIERS A humidifier may be required if your patient experiences dryness of the nose, mouth, or throat. The following humidifiers (supplied separately) are compatible for use with AUTOSET SPIRIT units. HUMIDAIRE 2i heated humidifier HUMIDAIRE™ heated humidifier ResMed PASSOVER humidifier RMD-063968 (AutoSet Spirit Clinician's Manual) at -3984.

Claim Language [1pre]	ResMed Prior Art ("RPA")
	MASK SYSTEMS The following ResMed mask systems (supplied separately) are recommended for use with the AUTOSET SPIRIT system. *ULTRA* MIRAGE™ MASK — MIRAGE® FULL FACE MASK — FULL FACE MASK SERIES 2  MIRAGE® MASK — MODULAR MASK WARNING For therapy in **AutoSet** mode, use one of the recommended ResMed masks. The AutoSet algorithm has appropriate parameters for these masks. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3985.

Claim Language [1pre]	ResMed Prior Art ("RPA")
	AUTOSCAN™ SOFTWARE AUTOSCAN is designed to enable review of the data stored in an AUTOSET SPIRIT unit. Data from up to 365 sessions may be stored and downloaded. Refer to the *AutoScan Clinician's Manual* or *Help* for details.  RMD-063968 (AutoSet Spirit Clinician's Manual) at -3986. REMOTE DATA ACCESS You can download data from an AUTOSET SPIRIT unit in your patient's home to AUTOSCAN software on your computer using modems. Both you and your patient require a modem set up for this purpose. The patient attaches the modem to the right communications port on the AUTOSET SPIRIT unit and to a phone line. You attach your modem to the serial port on your computer and a phone line. Refer to complete instructions for modem use in the *AutoScan Clinician's Manual*. RMD-063968 (AutoSet Spirit Clinician's Manual) at -4015.

[redacted]

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ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

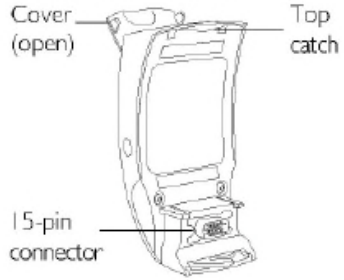
Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted] **ResLink (System 1)** The RESLINK is intended to be used with the ResMed AUTOSET® SPIRIT™ and S7™ ELITE systems. The RESLINK has two distinct functions: • enhanced collection, storage and transfer of data (including pulse oximetry data), and • upgrade of the AUTOSET SPIRIT and S7 ELITE software. RMD-063198 (ResLink Clinician's Guide) at -3199.

Claim Language [1pre]	ResMed Prior Art ("RPA")

THE RESLINK SYSTEM

The following are supplied as part of the RESLINK system:

- RESLINK device



ResLink (front view)

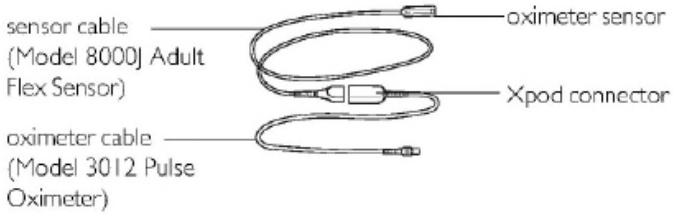
ResLink (back view)

- SmartMedia card

The RESLINK pouch also contains the *ResLink User's Manual* and the SmartMedia card Mailback card.

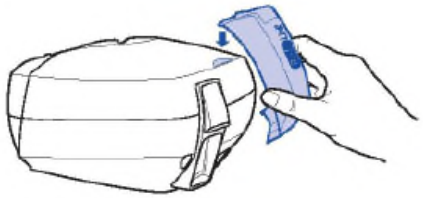
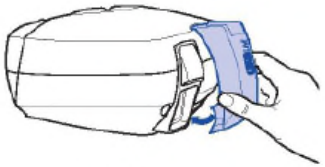
ACCESSORIES

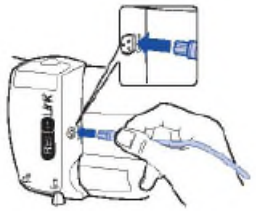
The NONIN ® Model 3012 Pulse Oximeter and Model 8000J Adult Flex Sensor (available from ResMed) are compatible for use with the RESLINK.

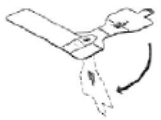
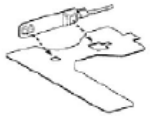


RESMED

RMD-063198 (ResLink Clinician's Guide) at -3199.

Claim Language [1pre]	ResMed Prior Art ("RPA")
	Connecting the ResLink to the flow generator The flow generator should be set up according to the instructions in the user's manual. **WARNING** **Before connecting the RESLINK, make sure that the flow generator is switched off.** 1. Place the top catch of the RESLINK onto the notch at the back of the flow generator.  2. Push the bottom of the RESLINK onto the auxiliary port at the back of the flow generator.  3. Slide the lever at the back of the RESLINK to the right, to lock the RESLINK in place. RMD-063198 (ResLink User's Manual) at -3211-12.

Claim Language [1pre]	ResMed Prior Art ("RPA")
	USING THE RESLINK Connecting an Oximeter (optional) Your clinician may have supplied an oximeter for use with the RESLINK. Connecting an oximeter to the RESLINK allows collection and storage of oximetry data (oxygen saturation and pulse rate). 1. Ensure that the sensor cable is properly connected to the Xpod connector. 2. Insert the oximeter plug into the RESLINK oximeter port. The 'Oximeter Connected' message will be displayed on the LCD indicating successful connection of the oximeter to the RESLINK.  RMD-063198 (ResLink User's Manual) at -3213-14.

Claim Language [1pre]	ResMed Prior Art ("RPA")
	Attaching the Oximeter Sensor (optional) **CAUTION** **The oximeter sensor will not function properly if there is nail polish on your fingernails.** 1. Peel the paper backing away from the FlexiWrap.  2. Firmly press the oximeter sensor onto the adhesive side of the FlexiWrap.  3. Carefully position any one of your fingers (not the thumb) on the adhesive side of the FlexiWrap. Ensure that the dotted line is at the tip of your finger. Wrap the flaps around your finger. 4. Carefully fold the FlexiWrap over the tip of your finger so that the two diodes are vertically aligned. Wrap the short flap around your finger. 5. Wrap the long flap around your finger to secure the sensor. 6. Secure the sensor wire to the base of the finger or wrist using medical tape. RMD-063198 (ResLink User's Manual) at -3214-15.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 115

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

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Exhibit 1024 - Page 116

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 117

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 118

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

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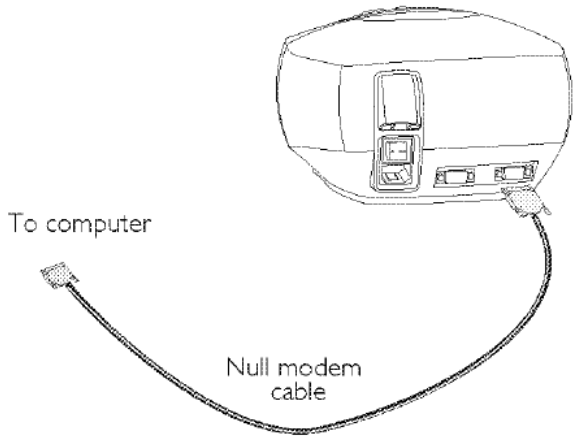
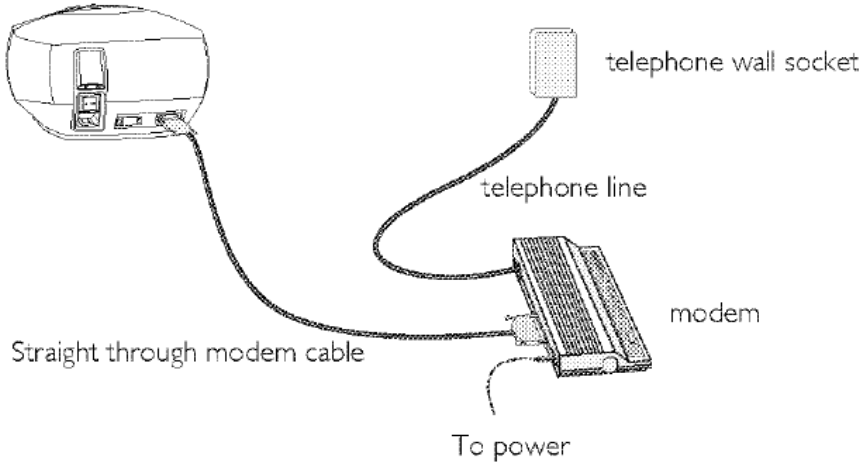
Exhibit 1024 - Page 119

Claim Language [1pre]	ResMed Prior Art ("RPA")
	 RMD-289749 (ResLink Launch Brochure) at -9749 and -9756. ResMed introduces ResLink™–the first truly modular sleep-disordered breathing (SDB) therapy management tool with significant benefits for the patient, sleep laboratory, prescribing physician, and equipment provider. The portable ResLink module simply clips onto ResMed's AutoSet Spirit™ system. ResLink captures and stores high-resolution patient compliance and efficacy data, including oximetry. This information is easily accessed and transferred via a 32MB SmartMedia™ card and then downloaded to a PC using ResMed's AutoScan™ software. RMD-289749 (ResLink Launch Brochure) at -9750. **Comprehensive efficacy data with oximetry** ResLink reports on significant parameters such as minute ventilation, snore, flattening, SpO_2, pulse rate, pressure response, leak, events, and AHI, providing visible insights into treatment efficacy. ResLink presents this efficacy information along with integrated oximetry data for simultaneous onscreen viewing and analysis. RMD-289749 (ResLink Launch Brochure) at -9751.

Claim Language [1pre]	ResMed Prior Art ("RPA")
	 RMD-289749 (ResLink Launch Brochure) at -9755. **AutoScan 5.4 (System 1)** AUTOSCAN™ 5.4 has been developed to view summary data and detailed data obtained from the RESLINK™ via the SmartMedia™ card. Summary data and Night profile data obtained from the flow generator can also be viewed as in previous versions of AUTOSCAN. AUTOSCAN 5.4 has data collection and management capabilities that provide an adjunct for patient management. The flow generator systems intended to be used with AUTOSCAN 5.4 are the ResMed AUTOSET® SPIRIT™, S7™ ELITE, VPAP® III, VPAP III ST, VPAP III ST-A, and AUTOSET RESPOND™. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1269.

Claim Language [1pre]	ResMed Prior Art ("RPA")
	FLOW GENERATOR COMPATIBILITY The following flow generators are compatible with AUTOSCAN 5.4: • AUTOSET SPIRIT • AUTOSET RESPOND • VPAP III, VPAP III ST, VPAP III ST-A, • S7 ELITE. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277. RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures, at -0318349.

Claim Language [1pre]	ResMed Prior Art ("RPA")
	CONNECTING THE FLOW GENERATOR TO THE COMPUTER In order to download data into AUTOSCAN 5.4, your computer must be connected by cable to the flow generator. NOTES *If your flow generator is connected to a ResControl, you must disconnect the ResControl before connecting the flow generator to your computer for interfacing to AutoScan 5.4.* Plug the null modem cable into the PC connection port on the flow generator and into an available serial port at the back of your computer (**COM1, COM2, COM3** or COM4).  Figure 2: Connecting the flow generator to the computer RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277 – 78. USING MODEMS You can download summary and Night Profile data on your flow generator remotely via modem. We recommend *Windows NT 4.0 SP6* and 3Com U.S. Robotics 56k Voice Faxmodems for this purpose. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1279.

Claim Language [1pre]	ResMed Prior Art ("RPA")
	USING MODEMS TO DOWNLOAD DATA You may download summary and Night Profile data remotely via modem. These operations require that both you and the patient have modems. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1290.  RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1290. MANAGING PATIENT INFORMATION AUTOSCAN 5.4 allows you to record patient information, clinical details and notes in the patient file. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1297. Detailed and summary data from a patient's flow generator are stored on a SmartMedia card by the RESLINK. The SmartMedia card is removed and sent to the clinician at the end of the study period. The SmartMedia card is inserted into a SmartMedia card reader attached to the clinician's computer, and the data can then be downloaded and viewed in AUTOSCAN 5.4. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1301.

Claim Language [1pre]	ResMed Prior Art ("RPA")
	The Detailed Data screen displays nine traces of data downloaded via the RESLINK from the flow generator. You can view data in the Detailed Data screen in increased detail or as a compact overview. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1303. The Detailed Data screen for that session will be displayed. The graph display area shows the downloaded data in the trace panels: • Events (s) • Minute Ventilation (L/min) • Leak (L/s) • Pulse Rate (bpm) • SpO_2 (%) • AHI (Events/hr) • Pressure (cm H_2O)[a] • Snore (Quiet to Loud)[a] • Flattening (Round to Flat)[a] • Respiratory rate (BPM).[b] [a] AUTOSET SPIRIT and S7 ELITE only [b] VPAP III series only NOTE *Pulse rate and SpO_2 are derived from the oximeter reading.* RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1304.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 126

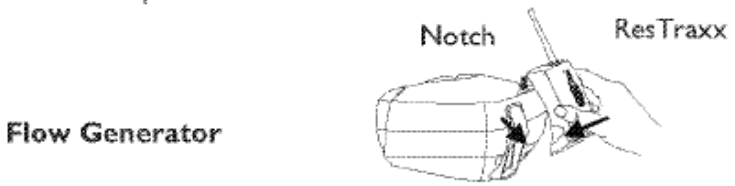
[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 127

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted] *See also* RMD-0318346 ResMed Virtual Machine and AutoScan screen captures, e.g., at -0318352, 0318367-369. **ResTraxx (including RDC) (System 2)** ResTraxx™ allows the wireless transfer of information from a continuous positive airway pressure (CPAP) unit to a clinician at a remote location via a two-way pager network. ResTraxx is intended to be used with ResMed S7™ Elite, AutoSet® Spirit™, AutoSet® Respond™, and VPAP® III flow generator systems on adults with obstructive sleep apnea. RMD-062642 (ResTraxx Quick Reference Guide) at -2642.

Claim Language [1pre]	ResMed Prior Art ("RPA")
	Attaching the ResTraxx 1. Turn the flow generator to OFF. 2. Slide lever on back of ResTraxx to the left. 3. Place top catch on ResTraxx onto notch at back of unit.  4. Push 15-pin connector on ResTraxx onto connection port on back of unit. 5. Slide lever on back of ResTraxx to the right to lock it into place. 6. Turn the main power switch at the back of flow generator to the ON position. 7. A green LED on top of ResTraxx will light up 15 - 20 seconds after unit is turned on, then begin to flash. 8. After about 15 seconds, a series of messages will appear on the flow generator display, indicating the unit's initialization and registration status of unit. 9. After initialization, the standby screen appears on the flow generator display and the unit begins transmitting information. RMD-062642 (ResTraxx Quick Reference Guide) at -2642. [redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

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Exhibit 1024 - Page 130

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

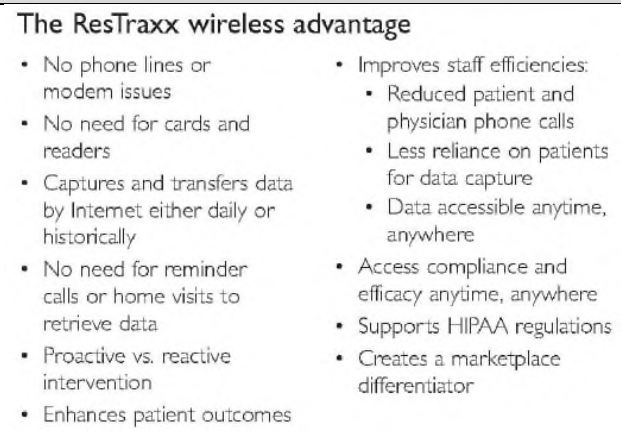
IPR2023-00565 - ResMed
Exhibit 1024 - Page 131

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted] ResTraxx is a first-of-its-kind wireless communication device that attaches easily to the back of ResMed flow generators. The ResTraxx system captures, transfers, and stores compliance and efficacy data without wires, phone lines, modems, or data cards. ResTraxx is an elegant system that brings patient usage and treatment efficacy data to your fingertips instantly. RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

Claim Language [1pre]	ResMed Prior Art ("RPA")
	 RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

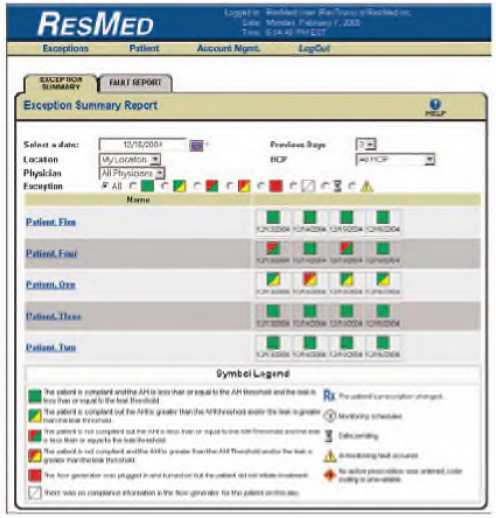
[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")

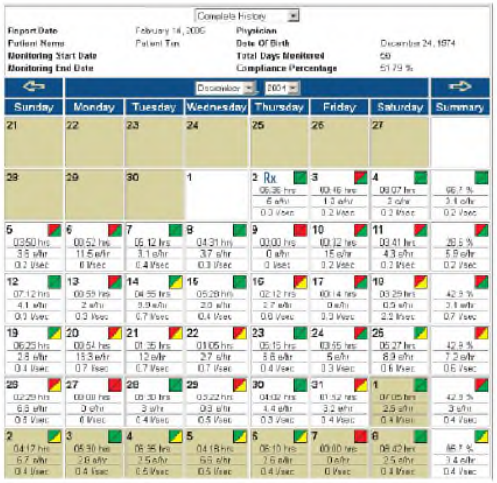
Exception Reporting

Enhance productivity and manage patients more efficiently. **Exception Reporting identifies and highlights those patients who fall below desired usage thresholds or have issues with mask leak or AHI.** This feature enables you to focus your efforts only on those patients who require intervention and respond proactively to potential problems. The simple color-coded alert system helps you identify exception patients quickly and easily.



Efficacy + Leak + Usage Data

The ResTraxx Data Center displays data on a daily basis in a calendar format enabling you to see daily or weekly trends of adherence problems before compliance is truly compromised. Early intervention and ongoing follow-up is considered critical, especially during the first month of CPAP acclimation, to determine long-term compliance rates.[1,2]



Want more details on therapy results? Click on the calendar day in question, and a therapeutic report will display additional clinical data regarding the patient's usage for that day.

RMD-063327 (ResTraxx Patient Management Brochure) at -3328.

[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted]

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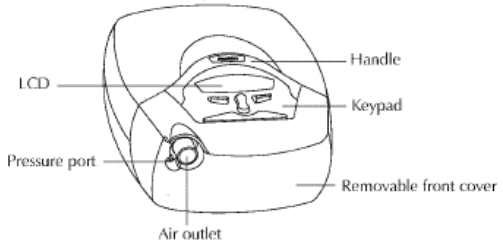
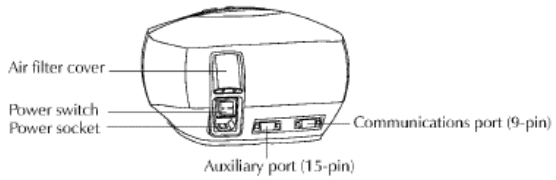
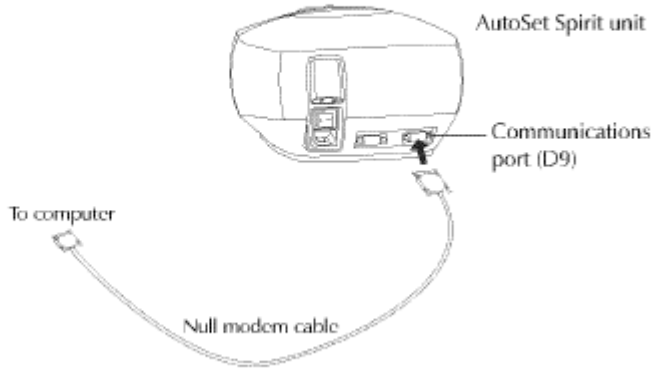
Exhibit 1024 - Page 141

Claim Language [1pre]	ResMed Prior Art ("RPA")
	[redacted] **Additional Citations** "*CPAP technology*" "All subjects were set up using commercially available CPAP devices with an integrated computer chip that collects compliance data. This method for the collection of compliance data is a proven and accepted approach that has been in widespread use for several years. The present study used these data, rather than a created data set, because the wireless data transmission device was developed to access existing data sets stored in the internal flow generator's computer chip. "Fourteen of the patients utilized a CPAP device that collects both compliance and efficacy data. At the Atlanta site, all patients used a Resmed S6 Elite Flow Generator that collects compliance and usage-related data. In Boston and Buffalo, the patients used a Resmed Auto Set T Flow Generator,

Claim Language [1pre]	ResMed Prior Art ("RPA")
	which collects usage/ compliance data as well as therapeutic data that measure efficacy. The S6 Elite provides continuous positive airway pressure at a preset level determined by titration. The Auto-Set T provides either fixed pressure in CPAP mode or delivers variable pressure levels that are determined using an algorithm that adjusts pressure according to inspiratory flow. As a result, users will experience variations in pressure on a night-to-night basis, as well as throughout the night depending on changes in sleep staging and position. For purposes of this study, the Auto-Set T devices were used in fixed pressure CPAP mode only. "Both devices deliver pressure to the upper airway through a patient interface. In all cases, the patients were previously fitted with a nasal mask during initial set up and were sent home with the mask. A variety of mask types and sizes were used. Each flow generator was uniquely assigned to an individual patient throughout the trial. The patients were identified by number only. "At the start of the trial, each unit had the internal clock and date set to the current date and time, and existing data in the flow generator chips were set at zero. "*Wireless and Internet-based technologies"* "For data downloading at the end of the trial, an investigational wireless-to-Internet data collection/transmission system, being developed by ResMed, and named the "Spectrum System," was employed in this trial. The Spectrum System consists of the flow generator, a wireless communication device, code-named "Cyrcat," and a secure Web server located in a remote location. The secure Web server receives patient-related clinical data (compliance and efficacy parameters) from the Cyrcat wireless transmitter and it stores the information for clinician viewing, analysis, and reporting through a secure Web browser." Lankford, 164.

Claim Language [1.a]	ResMed Prior Art ("RPA")
[1.a] a signal processing module comprising a first input adapted for connecting to a pulse oximeter sensor with a signal, electronics adapted for filtering and processing	RPA discloses, or at least renders obvious, a signal processing module comprising a first input adapted for connecting to a pulse oximeter sensor with a signal, electronics adapted for filtering and processing the signal, and an output adapted for outputting pulse oximetry sensor data. RPA System 1 discloses this limitation, or alternatively renders it obvious in view of the knowledge of a POSITA. The NONIN Xpod is a "a signal processing module comprising a first input adapted for connecting to a pulse oximeter sensor with a signal, electronics adapted for filtering and processing the signal, and an output adapted for outputting pulse oximetry sensor data," where the

Claim Language [1.a]	ResMed Prior Art ("RPA")
the signal, and an output adapted for outputting pulse oximetry sensor data;	pulse oximeter is an instrument used to measure the blood oxygenation. Alternatively, the ResLink is a "a signal processing module comprising a first input adapted for connecting to a pulse oximeter sensor with a signal, electronics adapted for filtering and processing the signal, and an output adapted for outputting pulse oximetry sensor data" under CleveMed's infringement contention theory for this limitation. RPA System 2 renders this limitation obvious in view of the knowledge of a POSITA, and alternatively also in view of System 1. Alternatively, RPA Systems 1-2 in combination with Schmidt and the knowledge of a POSITA render this limitation obvious. Schmidt discloses this limitation. *See, e.g.*, 1.pre. For example, RPA discloses: **ResMed AutoSet Spirit (System 1-2)** COMPONENTS OF THE AUTOSET® SPIRIT™ SYSTEM The following are supplied as part of an AUTOSET SPIRIT system. **AutoSet Spirit unit** **Front view**  **Rear view** 

Claim Language [1.a]	ResMed Prior Art ("RPA")
	RMD-063968 (AutoSet Spirit Clinician's Manual) at -3983. AUTOSCAN™ SOFTWARE AUTOSCAN is designed to enable review of the data stored in an AUTOSET SPIRIT unit. Data from up to 365 sessions may be stored and downloaded. Refer to the *AutoScan Clinician's Manual* or *Help* for details.  RMD-063968 (AutoSet Spirit Clinician's Manual) at -3986. REMOTE DATA ACCESS You can download data from an AUTOSET SPIRIT unit in your patient's home to AUTOSCAN software on your computer using modems. Both you and your patient require a modem set up for this purpose. The patient attaches the modem to the right communications port on the AUTOSET SPIRIT unit and to a phone line. You attach your modem to the serial port on your computer and a phone line. Refer to complete instructions for modem use in the *AutoScan Clinician's Manual*. RMD-063968 (AutoSet Spirit Clinician's Manual) at -4015.

Claim Language [1.a]	ResMed Prior Art ("RPA")
	[redacted] **ResLink (System 1)** The NONIN Xpod is a "a signal processing module comprising a first input adapted for connecting to a pulse oximeter sensor with a signal, electronics adapted for filtering and processing the signal, and an output adapted for outputting pulse oximetry sensor data." The RESLINK is intended to be used with the ResMed AUTOSET® SPIRIT™ and S7™ ELITE systems. The RESLINK has two distinct functions: • enhanced collection, storage and transfer of data (including pulse oximetry data), and • upgrade of the AUTOSET SPIRIT and S7 ELITE software. RMD-063198 (ResLink Clinician's Guide) at -3199.

Claim Language [1.a]	ResMed Prior Art ("RPA")

THE RESLINK SYSTEM

The following are supplied as part of the RESLINK system:

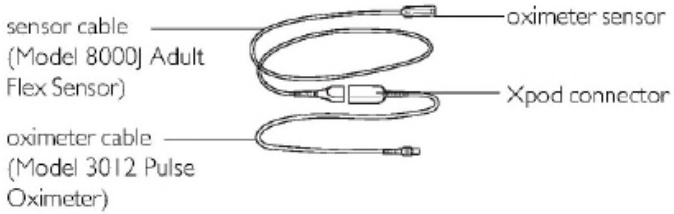
- RESLINK device

- SmartMedia card

The RESLINK pouch also contains the *ResLink User's Manual* and the SmartMedia card Mailback card.

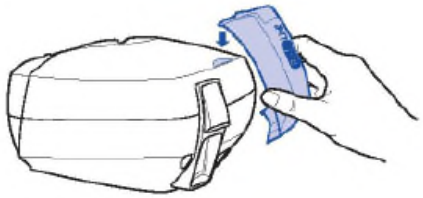
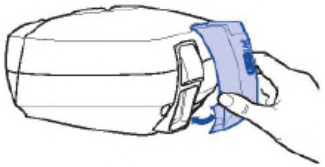
ACCESSORIES

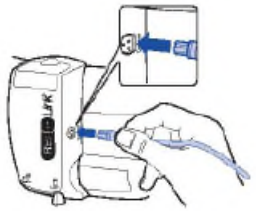
The NONIN ® Model 3012 Pulse Oximeter and Model 8000J Adult Flex Sensor (available from ResMed) are compatible for use with the RESLINK.



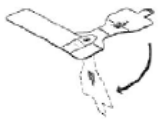
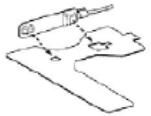
RESMED

RMD-063198 (ResLink Clinician's Guide) at -3199; ResLink User's Manual (RMD-063203) at 4, 17 (SpO2 "70-100% ± 3 digits", Pulse rate "18-200 pulses ± 3% ± 1 digit); *see also* ResLink Clinician's Guide (RMD-063198) at 63199; [redacted]

Claim Language [1.a]	ResMed Prior Art ("RPA")
	Connecting the ResLink to the flow generator The flow generator should be set up according to the instructions in the user's manual. **WARNING** **Before connecting the RESLINK, make sure that the flow generator is switched off.** 1. Place the top catch of the RESLINK onto the notch at the back of the flow generator.  2. Push the bottom of the RESLINK onto the auxiliary port at the back of the flow generator.  3. Slide the lever at the back of the RESLINK to the right, to lock the RESLINK in place. RMD-063198 (ResLink User's Manual) at -3211-12.

Claim Language [1.a]	ResMed Prior Art ("RPA")
	USING THE RESLINK Connecting an Oximeter (optional) Your clinician may have supplied an oximeter for use with the RESLINK. Connecting an oximeter to the RESLINK allows collection and storage of oximetry data (oxygen saturation and pulse rate). 1. Ensure that the sensor cable is properly connected to the Xpod connector. 2. Insert the oximeter plug into the RESLINK oximeter port. The 'Oximeter Connected' message will be displayed on the LCD indicating successful connection of the oximeter to the RESLINK.  RMD-063198 (ResLink User's Manual) at -3213-14.

Claim Language [1.a]	ResMed Prior Art ("RPA")
	 RMD-0318396 at -0318407, *see also* -0318406.

Claim Language [1.a]	ResMed Prior Art ("RPA")
	Attaching the Oximeter Sensor (optional) **CAUTION** **The oximeter sensor will not function properly if there is nail polish on your fingernails.** 1. Peel the paper backing away from the FlexiWrap.  2. Firmly press the oximeter sensor onto the adhesive side of the FlexiWrap.  3. Carefully position any one of your fingers (not the thumb) on the adhesive side of the FlexiWrap. Ensure that the dotted line is at the tip of your finger. Wrap the flaps around your finger. 4. Carefully fold the FlexiWrap over the tip of your finger so that the two diodes are vertically aligned. Wrap the short flap around your finger. 5. Wrap the long flap around your finger to secure the sensor. 6. Secure the sensor wire to the base of the finger or wrist using medical tape. RMD-063198 (ResLink User's Manual) at -3214-15.

[redacted]

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ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.a]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
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Claim Language [1.a]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.a]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.a]	ResMed Prior Art ("RPA")
	[redacted] *See also* [redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.a]	ResMed Prior Art ("RPA")
	[redacted]

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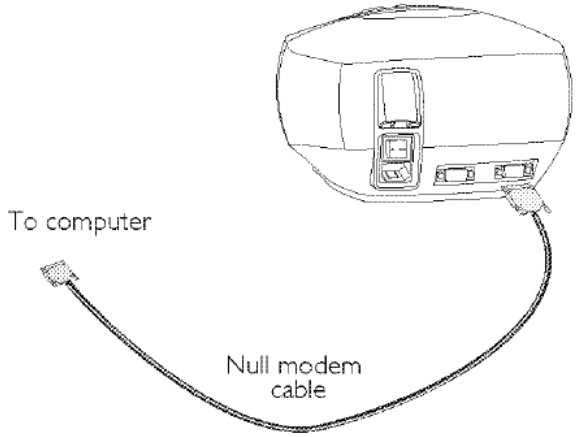
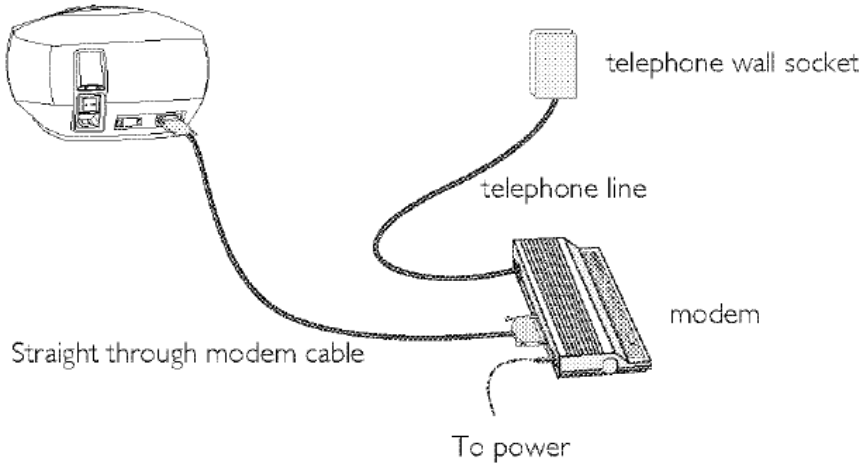
Claim Language [1.a]	ResMed Prior Art ("RPA")
	 RMD-289749 (ResLink Launch Brochure) at -9749 and -9756. ResMed introduces ResLink™–the first truly modular sleep-disordered breathing (SDB) therapy management tool with significant benefits for the patient, sleep laboratory, prescribing physician, and equipment provider. The portable ResLink module simply clips onto ResMed's AutoSet Spirit™ system. ResLink captures and stores high-resolution patient compliance and efficacy data, including oximetry. This information is easily accessed and transferred via a 32MB SmartMedia™ card and then downloaded to a PC using ResMed's AutoScan™ software. RMD-289749 (ResLink Launch Brochure) at -9750. **Comprehensive efficacy data with oximetry** ResLink reports on significant parameters such as minute ventilation, snore, flattening, SpO_2, pulse rate, pressure response, leak, events, and AHI, providing visible insights into treatment efficacy. ResLink presents this efficacy information along with integrated oximetry data for simultaneous onscreen viewing and analysis. RMD-289749 (ResLink Launch Brochure) at -9751.

Claim Language [1.a]	ResMed Prior Art ("RPA")
	 RMD-289749 (ResLink Launch Brochure) at -9755. **AutoScan 5.4 (System 1)** AUTOSCAN™ 5.4 has been developed to view summary data and detailed data obtained from the RESLINK™ via the SmartMedia™ card. Summary data and Night profile data obtained from the flow generator can also be viewed as in previous versions of AUTOSCAN. AUTOSCAN 5.4 has data collection and management capabilities that provide an adjunct for patient management. The flow generator systems intended to be used with AUTOSCAN 5.4 are the ResMed AUTOSET® SPIRIT™, S7™ ELITE, VPAP® III, VPAP III ST, VPAP III ST-A, and AUTOSET RESPOND™. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1269.

Claim Language [1.a]	ResMed Prior Art ("RPA")
	FLOW GENERATOR COMPATIBILITY The following flow generators are compatible with AUTOSCAN 5.4: • AUTOSET SPIRIT • AUTOSET RESPOND • VPAP III, VPAP III ST, VPAP III ST-A, • S7 ELITE. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277. CONNECTING THE FLOW GENERATOR TO THE COMPUTER In order to download data into AUTOSCAN 5.4, your computer must be connected by cable to the flow generator. NOTES *If your flow generator is connected to a ResControl, you must disconnect the ResControl before connecting the flow generator to your computer for interfacing to AutoScan 5.4.* Plug the null modem cable into the PC connection port on the flow generator and into an available serial port at the back of your computer (COM1, COM2, COM3 or COM4).

Claim Language [1.a]	ResMed Prior Art ("RPA")
	 Figure 2: Connecting the flow generator to the computer RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277 – 78. USING MODEMS You can download summary and Night Profile data on your flow generator remotely via modem. We recommend *Windows NT 4.0 SP6* and 3Com U.S. Robotics 56k Voice Faxmodems for this purpose. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1279. USING MODEMS TO DOWNLOAD DATA You may download summary and Night Profile data remotely via modem. These operations require that both you and the patient have modems. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1290.

Claim Language [1.a]	ResMed Prior Art ("RPA")



RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1290.

MANAGING PATIENT INFORMATION

AUTOSCAN 5.4 allows you to record patient information, clinical details and notes in the patient file.

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1297.

Detailed and summary data from a patient's flow generator are stored on a SmartMedia card by the RESLINK. The SmartMedia card is removed and sent to the clinician at the end of the study period. The SmartMedia card is inserted into a SmartMedia card reader attached to the clinician's computer, and the data can then be downloaded and viewed in AUTOSCAN 5.4.

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1301.

The Detailed Data screen displays nine traces of data downloaded via the RESLINK from the flow generator. You can view data in the Detailed Data screen in increased detail or as a compact overview.

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1303.

Claim Language [1.a]	ResMed Prior Art ("RPA")
	The Detailed Data screen for that session will be displayed. The graph display area shows the downloaded data in the trace panels: • Events (s) • Minute Ventilation (L/min) • Leak (L/s) • Pulse Rate (bpm) • SpO_2 (%) • AHI (Events/hr) • Pressure (cm H_2O)[a] • Snore (Quiet to Loud)[a] • Flattening (Round to Flat)[a] • Respiratory rate (BPM).[b] [a] AUTOSET SPIRIT and S7 ELITE only [b] VPAP III series only NOTE *Pulse rate and SpO_2 are derived from the oximeter reading.* RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1304. **ResTraxx (including RDC) (System 2)** ResTraxx™ allows the wireless transfer of information from a continuous positive airway pressure (CPAP) unit to a clinician at a remote location via a two-way pager network. ResTraxx is intended to be used with ResMed S7™ Elite, AutoSet® Spirit™ , AutoSet® Respond™ , and VPAP® III flow generator systems on adults with obstructive sleep apnea. RMD-062642 (ResTraxx Quick Reference Guide) at -2642.

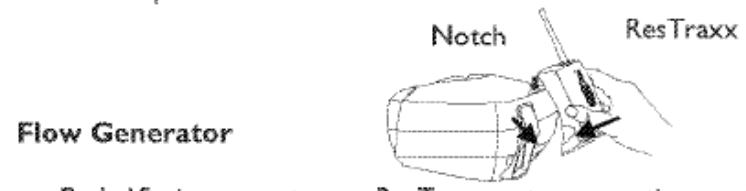
[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.a]	ResMed Prior Art ("RPA")

Attaching the ResTraxx

1. Turn the flow generator to OFF.
2. Slide lever on back of ResTraxx to the left.
3. Place top catch on ResTraxx onto notch at back of unit.



4. Push 15-pin connector on ResTraxx onto connection port on back of unit.
5. Slide lever on back of ResTraxx to the right to lock it into place.
6. Turn the main power switch at the back of flow generator to the ON position.
7. A green LED on top of ResTraxx will light up 15 - 20 seconds after unit is turned on, then begin to flash.
8. After about 15 seconds, a series of messages will appear on the flow generator display, indicating the unit's initialization and registration status of unit.
9. After initialization, the standby screen appears on the flow generator display and the unit begins transmitting information.

RMD-062642 (ResTraxx Quick Reference Guide) at -2642.

[redacted]

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Claim Language [1.a]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.a]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
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Claim Language [1.a]	ResMed Prior Art ("RPA")
	[redacted]

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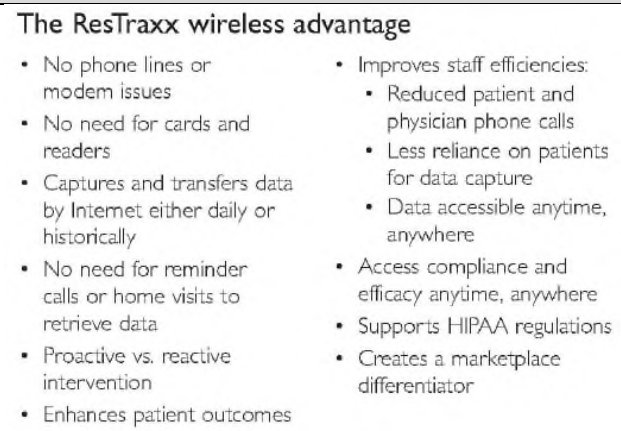
Claim Language [1.a]	ResMed Prior Art ("RPA")
	[redacted] ResTraxx is a first-of-its-kind wireless communication device that attaches easily to the back of ResMed flow generators. The ResTraxx system captures, transfers, and stores compliance and efficacy data without wires, phone lines, modems, or data cards. ResTraxx is an elegant system that brings patient usage and treatment efficacy data to your fingertips instantly. RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

Claim Language [1.a]	ResMed Prior Art ("RPA")
	 RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

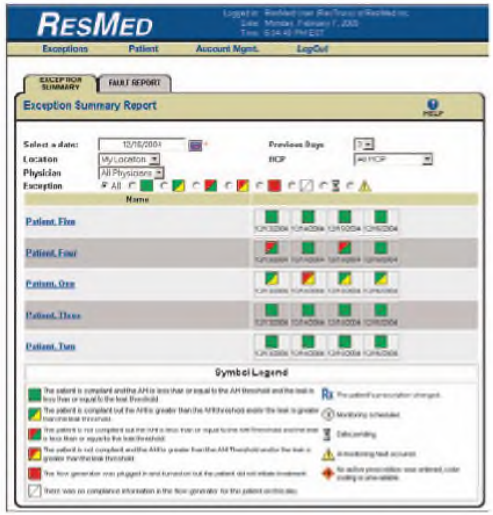
[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.a]	ResMed Prior Art ("RPA")

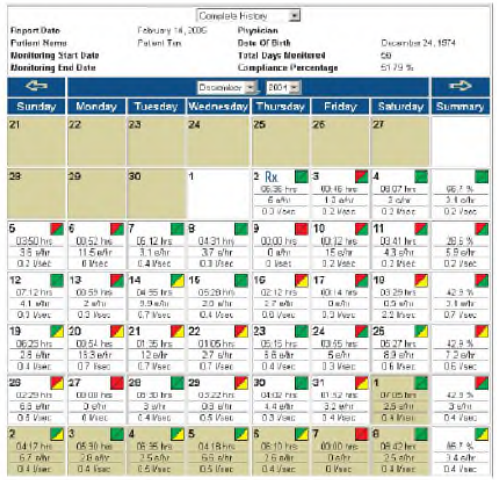
Exception Reporting

Enhance productivity and manage patients more efficiently. **Exception Reporting identifies and highlights those patients who fall below desired usage thresholds or have issues with mask leak or AHI.** This feature enables you to focus your efforts only on those patients who require intervention and respond proactively to potential problems. The simple color-coded alert system helps you identify exception patients quickly and easily.



Efficacy + Leak + Usage Data

The ResTraxx Data Center displays data on a daily basis in a calendar format enabling you to see daily or weekly trends of adherence problems before compliance is truly compromised. Early intervention and ongoing follow-up is considered critical, especially during the first month of CPAP acclimation, to determine long-term compliance rates.[2]



Want more details on therapy results? Click on the calendar day in question, and a therapeutic report will display additional clinical data regarding the patient's usage for that day.

RMD-063327 (ResTraxx Patient Management Brochure) at -3328.

[redacted]

[redacted]

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Claim Language [1.a]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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Claim Language [1.a]	ResMed Prior Art ("RPA")
	[redacted]

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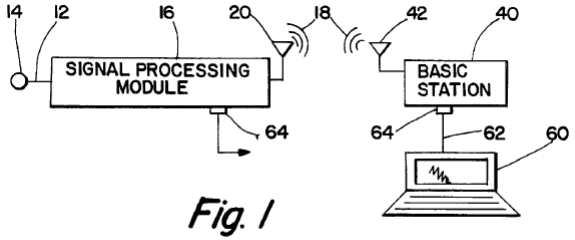
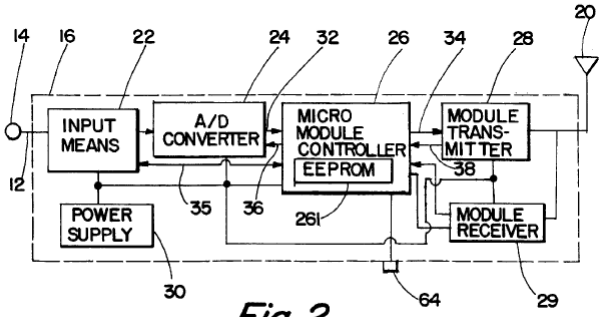
Claim Language [1.a]	ResMed Prior Art ("RPA")
	[redacted] If the Judge or Jury finds that RPA does not disclose this claim limitation, this claim is still rendered obvious by modifying or combining RPA with the knowledge of POSITA. It would have been obvious, for example, to combine a pulse oximeter and its associated signal processing module with the AutoSet Spirit flow generator in System 2. It was well-known to a POSITA that oxygen

Claim Language [1.a]	ResMed Prior Art ("RPA")
	desaturation information (SaO2 or SpO2) reported by a pulse oximeter that is an instrument used to measure the blood oxygenation, like the NONIN Xpod and pulse oximeter sensor, was useful to identify sleep disordered breathing events like hypopneas. Pulse oximeters that are instruments used to measure the blood oxygenation were well known and commonly used sensors for measuring the oxygenation of the subject's blood. Such sensors were readily available in the industry to incorporate, off-the-shelf, into systems like ResMed's CPAP systems. It was well known that such sensors included or connected to a signal processing module for filtering and processing the sensed signal and data recorded by the pulse oximeter (which typically uses light absorption) into a format to calculate a blood oxygenation level. A POSITA would have been motivated to incorporate a typical pulse oximeter device with ResMed PAP devices, at least because the ResLink with oximeter was used to collect and report sleep events, including apneas and hypopneas, to a medical professional for review. It would have been obvious to use a pulse oximeter sensor and its corresponding processing module, like the NONIN Xpod processing module and its corresponding pulse oximeter sensor that were well-known in the art as off-the shelf components, to provide pulse oximeter, and particularly oxygen saturation, information directly to the AutoSet Spirit flow generator, for example, in RPA System 2 and also Systems 1. For example, the AutoSet Spirit is already configured to receive pulse oximetry data through the ResLink module of System 1. It would have been obvious to modify the AutoSet Spirit to receive pulse oximetry signal data from the off-the-shelf NONIN components directly rather than through a ResLink module. This was already implemented in the ResMed Sullivan Portable II. *See, e.g.*, [redacted] Lankford also discloses incorporating pulse oximetry into the remote wireless ResMed CPAP device monitoring system that included the ResMed AutoSet T CPAP devices, which were the precursors to the AutoSet Spirit and other ResMed AutoSet PAP devices. Lankford, 168. Westbrook also teaches the desirability of this limitation (*see, e.g.*, Fig. 2, ¶¶100-105, 164-167, 34). Roux also presented a collection of multiple studies evaluating automatic PAP ("APAP") devices on the market, some of which measured and recorded oxygenation. See, e.g., Roux, at 326-330. A POSITA would have recognized that the signal processing module's main function is to condition the signal from a sensor(s) before it is ready to be transmitted or input to a processor for analysis and further processing of the sensed data. For example, a temperature sensor or an oximeter outputs an

Claim Language [1.a]	ResMed Prior Art ("RPA")
	analog signal that would typically need to be digitized (using A/D converter) and encoded. As known in the art, Kirianaki teaches, for example: "According to [7] 'Data Acquisition (DAQ) is collecting and measuring electrical signals from sensors and transducers and inputting them to a computer for processing.' Further processing can include the sensors' characteristic transformation, joint processing for many parameters as well as statistical calculation of results and presenting them in a user-friendly manner." Kirianaki, at 22. As yet another example, Schmidt, the disclosure of which was copied into the '269 patent's specification, appears to disclose this limitation in its entirety. For example, Schmidt discloses: "All data acquisition systems generally operate in a similar fashion. They receive an external input from some type of sensing device, condition and/or convert the input to a format suitable for transmission, as necessary, and transmit it to another piece of equipment usually a monitor or controller, which may be a computer, and more specifically, a personal computer. The external input is generally an analog signal, although digital signals, frequently on-off switching, pulse-width modulation, or serial data protocols, are also involved. The inputs, though, come in many forms with many different characteristics, be they pneumatic, hydraulic or electronic, to list a few. Modern applications, control schemes and devices usually necessitate the use of electronic inputs in one form or another. For example, electronic analog inputs may have ranges of 4-20 mA, +/-5 volts, +/-15 volts, or microvolts to millivolts. "In the case of a wired system the analog input can be transmitted directly over interconnecting wiring with the major concern being that the interconnecting wires be suitably shielded to prevent interference by nearby electromagnetic sources. Signal conditioning becomes critically important for wireless systems, though. This is especially so when considering power consumption, size and cost factors. Because electronic inputs can have different characteristics (e.g.: high frequency or low frequency) and ranges (e.g.: microvolts to many volts), data acquisition systems are either application specific, i.e. designed to accept and condition a particular type of signal, i.e.: current, with a range of 4-20 mA for instance, or include separate discrete signal conditioning devices which consume a large amount of power and add considerable size. "Radio frequency (RF) wireless data acquisition systems can convert the input to a conditioned electronic signal which is used to modulate a carrier frequency which is then transmitted as a radio frequency signal to equipment in another location. The conditioned signal is encoded with data

Claim Language [1.a]	ResMed Prior Art ("RPA")
	corresponding to the status of the input. The radio frequency signal is received, demodulated and decoded and the data is read, displayed, stored, and/or acted upon, i.e. monitored, analyzed, by equipment at the receiving point. In the United States the Federal Communications Commission (FCC) regulations govern RF transmissions, and similar agencies regulate RF transmissions in other countries, specifically as to the frequency band that can be utilized to transmit the signal and the strength of the signal. Other data transmission means, such as infrared, optical, or any means which does not require a mechanical connection is understood to offer similar advantages as RF transmission. "Wireless data acquisition systems are well known in the art. In the biomedical area, U.S. Pat. No. 5,704,351 to Mortara discloses a multiple channel biomedical digital telemetry transmitter. Mortara teaches an 8 channel biomedical transmitter specifically directed to electrocardiogram (EKG) signal transmission in the 902 to 928 MHz band. The Mortara device includes input circuitry and an analog-to-digital converter which receives the input signal from an EKG electrode and converts it to a digital signal which is inputted to a microprocessor. The microprocessor then converts the digital signal to a serial digital output signal which is used to frequency modulate the radio frequency carrier signal for telemetry transmission. The carrier frequency is adjustable within the 902 to 928 MHz band by two manual frequency setting switches. The use of these manual switches is the only adjustment available on the Mortara device and only to manually set the frequency within the 902 to 928 MHz band. The input circuitry and analog-to-digital converter are not adjustable nor adaptable to accept different input signal characteristics. In addition, the Mortara device cannot be adjusted, by programming or otherwise, to operate in any other frequency band. Finally, the Mortara device is just a transmitter and, therefore, is not able to receive RF or other signals to control its operation." Schmidt, 1:22-31. "In yet another aspect, the present invention relates to a programmable wireless data acquisition system, comprising a signal processing module comprising a module microcontroller having a memory. The signal processing module operation includes inputting, conditioning and processing at least one external input and transmitting by wireless means a signal encoded with data corresponding to the external input. The at least one external input comprising at least one physiological signal wherein the physiological signal is from the group of physiological signals consisting of EEG, EKG, EOG, ***SpO2***, PO2, PCO2 EMG, blood pressure, heart rate, ***pulse***, body temperature, air flow and respiration. The module microcontroller adapts the signal processing module in response to variation

Claim Language [1.a]	ResMed Prior Art ("RPA")
	in the range, character and type of the physiological signal such that the adaptation occurs during signal processing module operation." Schmidt, 4:7-22 (emphasis added). "Referring now to the drawings and, in particular to FIG. 1, there is shown a block diagram of the present invention. An ***external input 12 from sensor 14 is inputted to signal processing module 16***. Although, one sensor 14 and one external input 12 are shown, the signal processing module 16 is capable of accepting multiple external inputs 12 from multiple sensors 14. The signal processing module 16 generates a signal 18 encoded with data corresponding to the external input 12. The signal processing module 16 transmits the signal 18 by wireless means. to base station 40 In FIG. 1, the wireless means is shown as radio frequency (RF). In this case, the signal processing module generates a radio frequency signal 18 by frequency modulating a frequency carrier and transmits the radio frequency signal through module antenna 20. The base station 40 receives the radio frequency signal 18 through base antenna 42, demodulates the radio frequency signal 18, and decodes the data. It is understood that other wireless means can be utilized with the present invention, such as infrared and optical, for example. Although one module antenna 20 and one base antenna 42 is shown in this embodiment, it is understood that two or more diversity antennas can be used and are included in the present invention. An external programming means 60, shown in FIG. 1 as a personal computer, contains software which is used to program the signal processing module 16 and the base station 40 through data interface cable 62. The data interface cable 62 is connected to the base station 40 and signal processing module 16 by respective connectors 64. The same data interface cable 62 or two different interface cables 62 can be used, one for the base station 40 and one for the signal processing module 16. The signal processing module 16 and the base station 40 can be programmed by connecting a data interface cable 62 between it and an external programming means 60 or by radio frequency (or other type) of signals transmitted between a base station 40 to the signal processing module 16 or to another base station 40. RF signals, therefore, can be both transmitted and received by both signal processing module 16 and base station 40. In this event the signal processing module 16 also includes a module receiver 29 while the base station 40 also includes a base transmitter 84, in effect making both the signal processing module 16 and the base station 40 into transceivers. In addition, the data interface cable 62 also can be used to convey data from the base station 40 to the external programming means 60. If a personal computer is the external programming means 60, it can monitor, analyze and display the data in addition to its programming functions. The base receiver 80 and module receiver 29 can be any appropriate receivers, such as direct or single conversion types., The base receiver 80 preferably is a double conversion superheterodyne receiver while the

Claim Language [1.a]	ResMed Prior Art ("RPA")
	module receiver 29 preferably is a single conversion receiver. Advantageously, the receiver employed will have automatic frequency control to facilitate accurate and consistent tuning of the radio frequency signal 18 received thereby. "Referring now to FIG. 2, there is shown a block diagram of the signal processing module 16 with the sensor 14 and the module antenna 20. The ***signal processing module 16 comprises input means 22, analog-to-digital (A/D) means 24, a module microcontroller 26*** with a nonvolatile memory, advantageously, an EEPROM 261, a module transmitter 28, a module receiver 29 and a module power supply 30. Although the module antenna 20 is shown externally located from the signal processing module 16, it can also be incorporated therein. The module antenna 20 may be a printed spiral antenna printed on a circuit board or on the case of the signal processing module 16 or other type of antenna. A module power supply 30 provides electrical power to the signal processing module 16 which includes the input means 22, A/D means 24, module microcontroller 26 module transmitter 28 and module receiver 29." Schmidt, 4:63-5:67 (emphasis added); *see also, e.g.*, 12:26-48 (digital filter).  Fig. 1  Fig. 2

Claim Language [1.a]	ResMed Prior Art ("RPA")
	Schmidt, FIGs. 1-2, *see also* FIG. 4. A POSITA would have recognized the "SpO2," "heart rate, pulse" would be sensed by a pulse oximeter that is an "instrument used to measure the blood oxygenation. It would have been obvious to a POSITA to incorporate the signal processing module disclosed by Schmidt into RPA's system to perform the claimed signal processing and provide filtered and processed data to the CPAP apparatus. As was known in the art, and recognized, for example, by Westbrook, the diagnosis of sleep disorders was known to include the use of oxygen saturation data. Similarly, it was well known for pulse oximeters to be implemented with commercially available equipment that included signal processing functionality in order to process the received sensor signals. It would have been obvious, to the extent not expressly disclosed by RPA, to incorporate the claimed signal processing module (as disclosed, e.g., by Schmidt) into the RPA to perform the processing of sensor data for use by the CPAP device, and such an addition or modification would have merely been an implementation detail known to a POSITA. It would have been obvious to combine the Schmidt disclosure with the RPA Systems 1 and 2 at least because a POSITA would have looked to details for signal processing of the pulse oximeter sensor to the extent not disclosed by RPA System 1. **<u>CleveMed's Infringement Contentions</u>** Moreover, CleveMed's infringement contentions allege that this claim limitation is met by the following: [redacted]

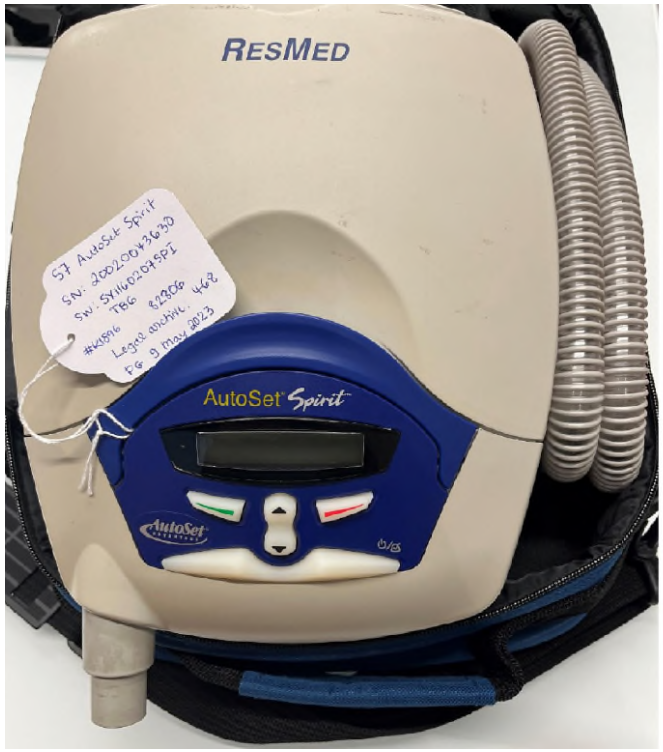
Claim Language [1.a]	ResMed Prior Art ("RPA")
	As explained and identified above, pulse oximeters, including those developed and sold by NONIN, were well known to a POSITA, and in fact disclosed as RPA in combination with CPAP devices such as the AutoSet Spirit. For at least the same reasons the accused "adapter" practices this claim, the NONIN Xpod and associated components or alternatively the ResLink also disclose this claim. Moreover, it would have been at least obvious to include such an "adapter" connected to a pulse oximeter sensor and adapted to output pulse oximetry sensor data to the disclosed RPA PAP devices, at least for the basic reason that the data communicated would need to be in a format for reception and processing by the PAP device. It was well-known, for example, that PAP devices were developed with specific communications protocols in order to interface with, and "PUT" or "GET" data, for example to and from the PAP device's microprocessor and memory. The accused communication protocol translation would have been an obvious implementation detail well known to those skilled in the art to achieve this interface. *See also, e.g.*, RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures; RMD-0318396 Specimen Photographs; [redacted]

Claim Language [1.b]	ResMed Prior Art ("RPA")
[1.b] a PAP device adapted for treating a subject's sleep disorder, the PAP device with a separate enclosure from the signal processing module further comprising:	RPA discloses, or at least renders obvious, a PAP device adapted for treating a subject's sleep disorder, the PAP device with a separate enclosure from the signal processing module. *See, e.g.*, limitations 1pre, 1.a. The AutoSet Spirit flow generator is a PAP device for treating a subject's sleep disorder. The AutoSet Spirit flow generator has a separate enclosure from the Nonin Xpod. Alternatively, it would have been obvious that the signal processing module addressed for limitation 1.a would have a separate enclosure from the AutoSet Spirit flow generator. RPA System 1 discloses this limitation. RPA System 1 in combination with Schmidt render this limitation obvious. RPA System 2 renders this limitation obvious in view of the knowledge of a POSITA, and/or in view of RPA System 1, and/or in combination with Schmidt for at least the reasons expressed for limitation 1.a. *See, e.g.*, 1.pre. For example, RPA discloses:

ResMed AutoSet Spirit (System 1-2)

> The AUTOSET SPIRIT system is designed for clinical use and home treatment of adult patients with obstructive sleep apnea (OSA). The system has two therapy modes for treating OSA: **CPAP** mode and **AutoSet** mode.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.



RMD-0318396 at -0318396-402.

Claim Language [1.b]	ResMed Prior Art ("RPA")

CPAP MODE

In CPAP mode, the AUTOSET SPIRIT unit provides fixed-pressure room air via tubing to the mask worn by your patient. The continuous air stream "splints" open the upper airway, preventing airway collapse.

AUTOSET SPIRIT delivers pressure within the range 4 to 20 cm H_2O. To make the beginning of treatment more comfortable, you may set a ramp so the pressure starts low and gradually increases to full treatment pressure over the ramp time.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.

AUTOSET® MODE

The treatment pressure required by your patient may vary through the night, and from night to night, due to changes in sleep state, body position, and airway resistance. In AutoSet mode AUTOSET SPIRIT provides only sufficient pressure to maintain upper airway patency.

You can set the minimum and maximum allowable treatment pressures. The unit analyzes the state of the patient's upper airway on a breath-by-breath basis and delivers pressure within the allowed range according to the degree of obstruction. The AutoSet algorithm adjusts treatment pressure as a function of three parameters: inspiratory flow limitation, snore, and apnea.

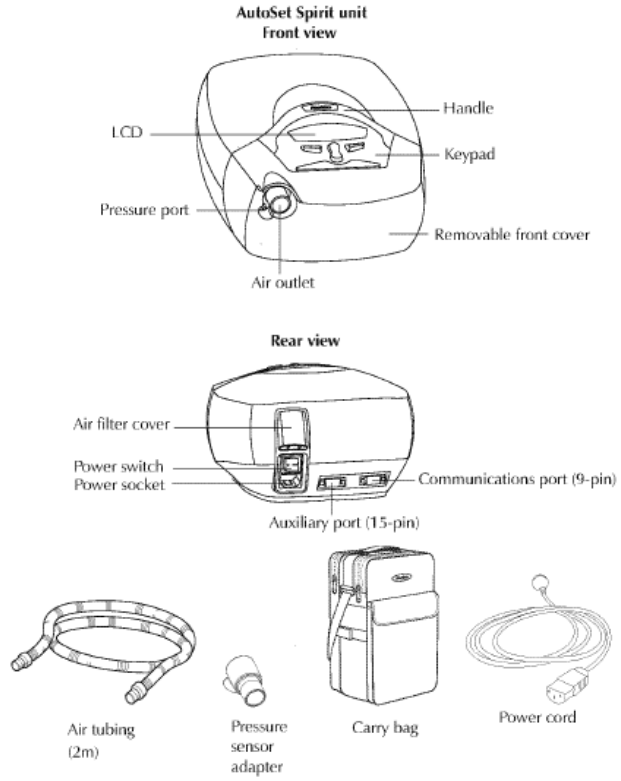
The flow sensor, located in the AUTOSET SPIRIT unit, enables detection of inspiratory flow limitation and apneas. The pressure sensor, also located in the unit, enables measurement of pressure and snore.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.

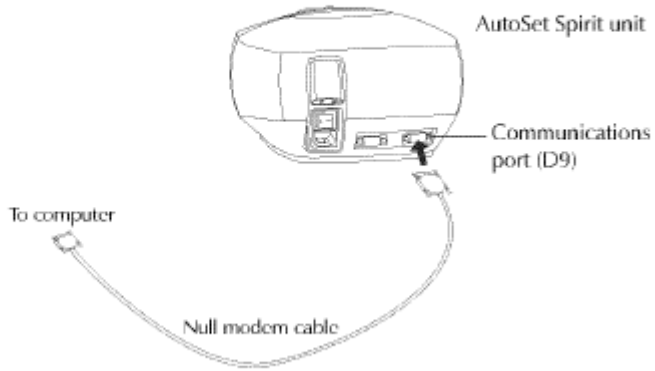
REMOTE DATA ACCESS

You can download data from an AUTOSET SPIRIT unit in your patient's home to AUTOSCAN software on your computer using modems. Both you and your patient require a modem set up for this purpose. The patient attaches the modem to the right communications port on the AUTOSET SPIRIT unit and to a phone line. You attach your modem to the serial port on your computer and a phone line. Refer to complete instructions for modem use in the *AutoScan Clinician's Manual*.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -4015.

Claim Language [1.b]	ResMed Prior Art ("RPA")
	COMPONENTS OF THE AUTOSET® SPIRIT™ SYSTEM The following are supplied as part of an AUTOSET SPIRIT system.  Figure 4: AutoSet Spirit system components RMD-063968 (AutoSet Spirit Clinician's Manual) at -3983.

Claim Language [1.b]	ResMed Prior Art ("RPA")
	HUMIDIFIERS A humidifier may be required if your patient experiences dryness of the nose, mouth, or throat. The following humidifiers (supplied separately) are compatible for use with AUTOSET SPIRIT units. HUMIDAIRE 2i heated humidifier HUMIDAIRE™ heated humidifier ResMed PASSOVER humidifier RMD-063968 (AutoSet Spirit Clinician's Manual) at -3984.

Claim Language [1.b]	ResMed Prior Art ("RPA")
	AUTOSCAN™ SOFTWARE AUTOSCAN is designed to enable review of the data stored in an AUTOSET SPIRIT unit. Data from up to 365 sessions may be stored and downloaded. Refer to the *AutoScan Clinician's Manual* or *Help* for details.  RMD-063968 (AutoSet Spirit Clinician's Manual) at -3986.

ResLink (System 1)

THE RESLINK SYSTEM

The following are supplied as part of the RESLINK system:

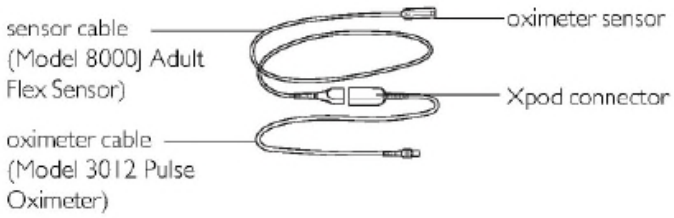
- RESLINK device

- SmartMedia card

The RESLINK pouch also contains the *ResLink User's Manual* and the SmartMedia card Mailback card.

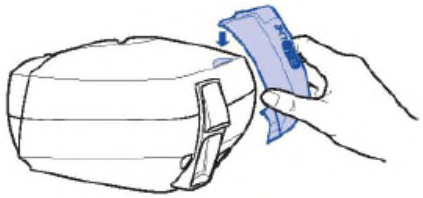
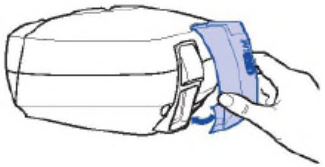
ACCESSORIES

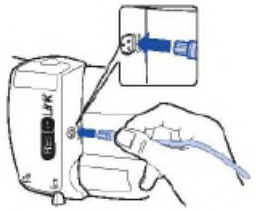
The NONIN ® Model 3012 Pulse Oximeter and Model 8000J Adult Flex Sensor (available from ResMed) are compatible for use with the RESLINK.



RESMED

RMD-063198 (ResLink Clinician's Guide) at -3199.

Claim Language [1.b]	ResMed Prior Art ("RPA")
	Connecting the ResLink to the flow generator The flow generator should be set up according to the instructions in the user's manual. **WARNING** **Before connecting the RESLINK, make sure that the flow generator is switched off.** 1. Place the top catch of the RESLINK onto the notch at the back of the flow generator.  2. Push the bottom of the RESLINK onto the auxiliary port at the back of the flow generator.  3. Slide the lever at the back of the RESLINK to the right, to lock the RESLINK in place. RMD-063198 (ResLink User's Manual) at -3211-12.

Claim Language [1.b]	ResMed Prior Art ("RPA")
	USING THE RESLINK Connecting an Oximeter (optional) Your clinician may have supplied an oximeter for use with the RESLINK. Connecting an oximeter to the RESLINK allows collection and storage of oximetry data (oxygen saturation and pulse rate). 1. Ensure that the sensor cable is properly connected to the Xpod connector. 2. Insert the oximeter plug into the RESLINK oximeter port. The 'Oximeter Connected' message will be displayed on the LCD indicating successful connection of the oximeter to the RESLINK.  RMD-063198 (ResLink User's Manual) at -3213-14.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b]	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b]	ResMed Prior Art ("RPA")
	[redacted]

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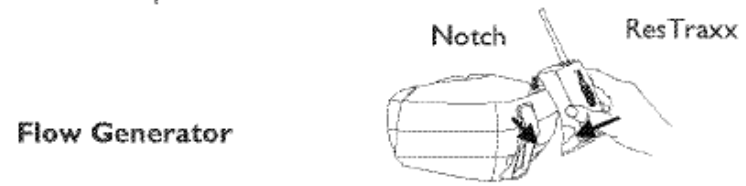
[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b]	ResMed Prior Art ("RPA")
	[redacted] RMD-289749 (ResLink Launch Brochure) at -9749 and -9756.

Claim Language [1.b]	ResMed Prior Art ("RPA")
	 RMD-289749 (ResLink Launch Brochure) at -9755. **ResTraxx (including RDC) (System 2)**

Claim Language [1.b]	ResMed Prior Art ("RPA")
	Attaching the ResTraxx 1. Turn the flow generator to OFF. 2. Slide lever on back of ResTraxx to the left. 3. Place top catch on ResTraxx onto notch at back of unit.  4. Push 15-pin connector on ResTraxx onto connection port on back of unit. 5. Slide lever on back of ResTraxx to the right to lock it into place. 6. Turn the main power switch at the back of flow generator to the ON position. 7. A green LED on top of ResTraxx will light up 15 - 20 seconds after unit is turned on, then begin to flash. 8. After about 15 seconds, a series of messages will appear on the flow generator display, indicating the unit's initialization and registration status of unit. 9. After initialization, the standby screen appears on the flow generator display and the unit begins transmitting information. RMD-062642 (ResTraxx Quick Reference Guide) at -2642.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b]	ResMed Prior Art ("RPA")
	[redacted]

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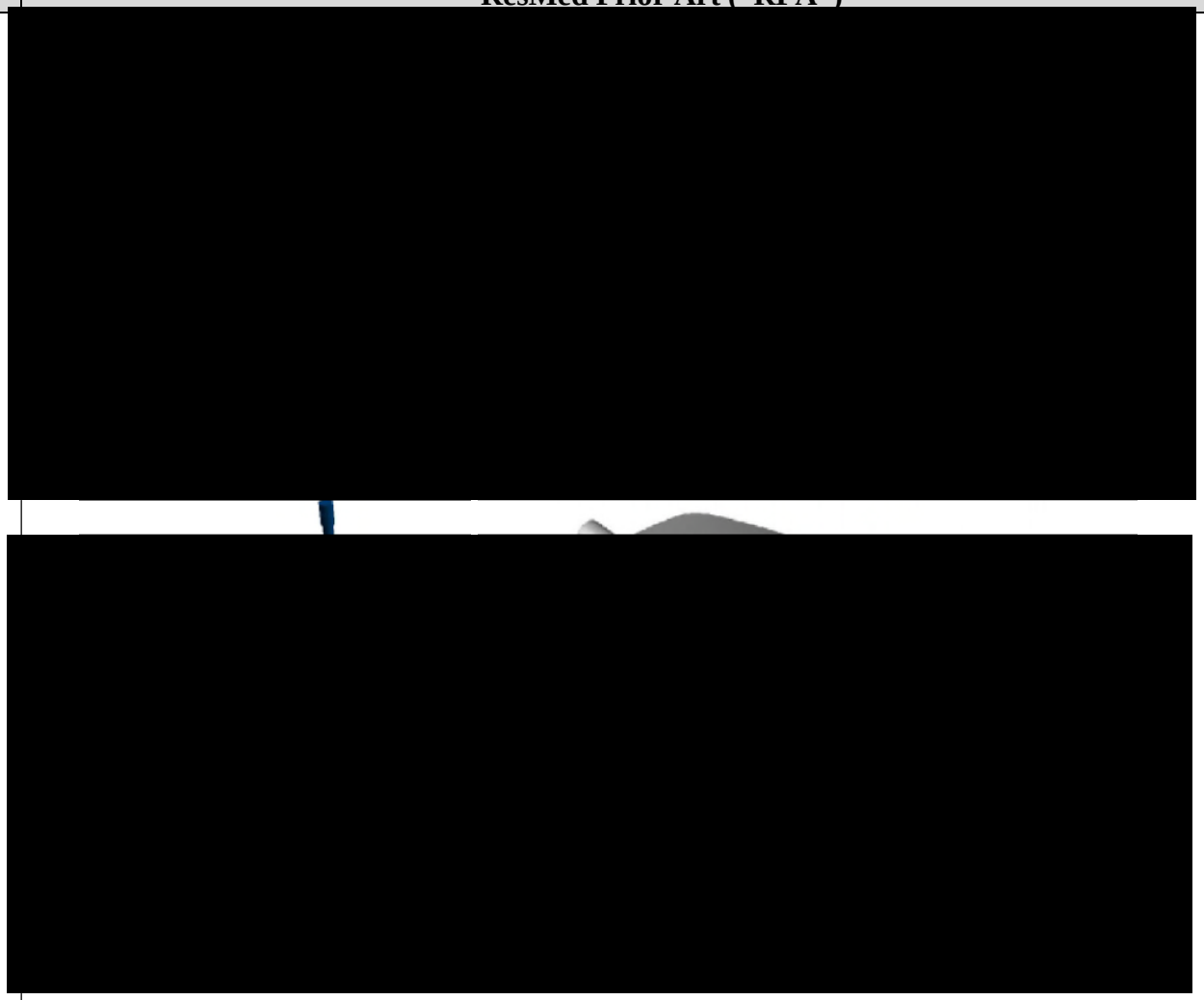
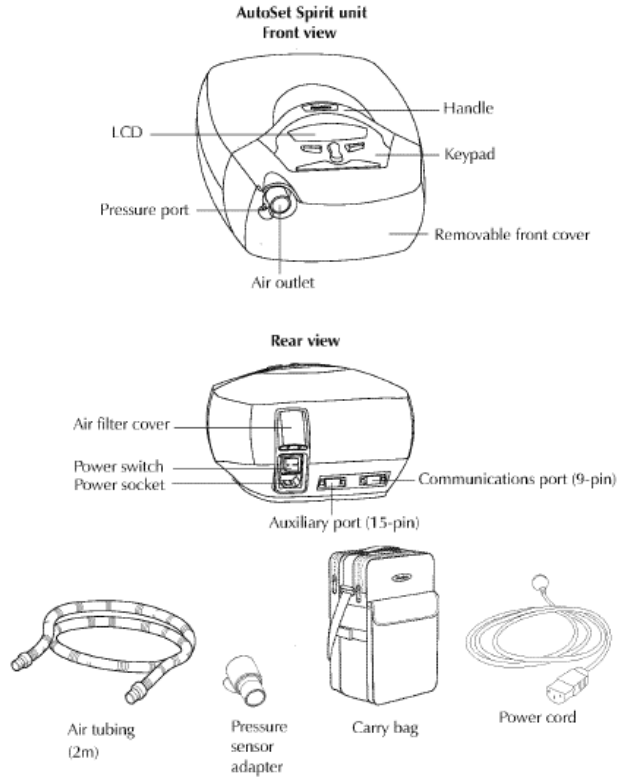
Claim Language [1.b]	ResMed Prior Art ("RPA")
	[redacted] ResTraxx is a first-of-its-kind wireless communication device that attaches easily to the back of ResMed flow generators. The ResTraxx system captures, transfers, and stores compliance and efficacy data without wires, phone lines, modems, or data cards. ResTraxx is an elegant system that brings patient usage and treatment efficacy data to your fingertips instantly. RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

Claim Language [1.b]	ResMed Prior Art ("RPA")
	 As an additional example, it was known to a POSITA and disclosed in both RPA Systems 1 and 2 to enclose discrete processing features in housing separate from the enclosure of the AutoSet Spirit. This is demonstrated by both the ResLink and the [redacted] that provide additional functionality to the AutoSet Spirit flow generator within their own enclosure separate from the enclosure of the

Claim Language [1.b]	ResMed Prior Art ("RPA")
	AutoSet Spirit flow generator (PAP device). A POSITA would have known or at least been motivated, as implemented with these specific components, to implement the signal processing module for the pulse oximeter within its own housing separate from the enclosure of the AutoSet Spirit. *See also, e.g.*, RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures; RMD-0318396 Specimen Photographs; [redacted]

Claim Language [1.b.1]	ResMed Prior Art ("RPA")
[1.b.1] a blower having an air output,	RPA discloses that the AutoSet Spirit flow generator (part of Systems 1-2) comprises a blower having an air output. *See, e.g.*, 1.pre. For example, RPA discloses: The ResMed AUTOSET® SPIRIT™ system is designed to provide continuous positive airway pressure (CPAP) therapy to patients with obstructive sleep apnea (OSA). Patients with OSA experience recurrent obstruction of their upper airway (apneas) due to relaxation of the tongue and soft palate while they sleep. Common symptoms are associated with poor sleep quality and may include excessive daytime sleepiness and tiredness, as well as diminished concentration and memory loss. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3974. [redacted] The AUTOSET SPIRIT system is designed for clinical use and home treatment of adult patients with obstructive sleep apnea (OSA). The system has two therapy modes for treating OSA: **CPAP** mode and **AutoSet** mode. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.

Claim Language [1.b.1]	ResMed Prior Art ("RPA")
	CPAP MODE In CPAP mode, the AUTOSET SPIRIT unit provides fixed-pressure room air via tubing to the mask worn by your patient. The continuous air stream "splints" open the upper airway, preventing airway collapse. AUTOSET SPIRIT delivers pressure within the range 4 to 20 cm H_2O. To make the beginning of treatment more comfortable, you may set a ramp so the pressure starts low and gradually increases to full treatment pressure over the ramp time. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980. AUTOSET® MODE The treatment pressure required by your patient may vary through the night, and from night to night, due to changes in sleep state, body position, and airway resistance. In AutoSet mode AUTOSET SPIRIT provides only sufficient pressure to maintain upper airway patency. You can set the minimum and maximum allowable treatment pressures. The unit analyzes the state of the patient's upper airway on a breath-by-breath basis and delivers pressure within the allowed range according to the degree of obstruction. The AutoSet algorithm adjusts treatment pressure as a function of three parameters: inspiratory flow limitation, snore, and apnea. The flow sensor, located in the AUTOSET SPIRIT unit, enables detection of inspiratory flow limitation and apneas. The pressure sensor, also located in the unit, enables measurement of pressure and snore. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.

Claim Language [1.b.1]	ResMed Prior Art ("RPA")
	COMPONENTS OF THE AUTOSET® SPIRIT™ SYSTEM The following are supplied as part of an AUTOSET SPIRIT system.  Figure 4: AutoSet Spirit system components RMD-063968 (AutoSet Spirit Clinician's Manual) at -3983.

Claim Language [1.b.1]	ResMed Prior Art ("RPA")
	ACCESSORIES The following accessories may be purchased separately. AUTOSET SPIRIT ACCESSORIES Air tubing 9ft10in (3m) HUMIDIFIER ACCESSORIES (HUMIDAIRE and ResMed PASSOVER only) Pressure sensor line Short air tubing 7.5in (19cm) for HumidAire connection Medium air tubing 21in (52cm) for humidifier connection RMD-063968 (AutoSet Spirit Clinician's Manual) at -3984.

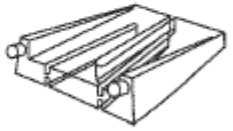
Claim Language [1.b.1]	ResMed Prior Art ("RPA")

HUMIDIFIERS

A humidifier may be required if your patient experiences dryness of the nose, mouth, or throat. The following humidifiers (supplied separately) are compatible for use with AUTOSET SPIRIT units.

HUMIDAIRE 2i heated humidifier

HUMIDAIRE™ heated humidifier



ResMed PASSOVER humidifier

RMD-063968 (AutoSet Spirit Clinician's Manual) at -3984.

[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.1]	ResMed Prior Art ("RPA")
	SlipStream System Components [redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.1]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.b.1]	ResMed Prior Art ("RPA")
	[redacted]
	If the Judge or Jury finds that RPA does not disclose this claim limitation, this claim is alternatively rendered obvious in view of the knowledge of a POSITA. For example, a POSITA would have recognized that a system for applying a continuous positive airway pressure to a person was well

Claim Language [1.b.1]	ResMed Prior Art ("RPA")
	known in the art prior to the '269 patent. Indeed, the '269 patent admits that "conventional pressure support system[s] … include[] a pressure generator 312, a blower, piston or bellows, that receives a supply of gas from a gas source, such as ambient atmosphere, … or pressured gas tanks … and creates a flow of breathing gas … having a pressure greater than the ambient atmospheric pressure." '269 patent, 22:45-54. A POSITA would have therefore recognized, or at least found it obvious, that the RPA discloses the claimed blower. *See also, e.g.*, RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures; RMD-0318396 Specimen Photographs; [redacted]

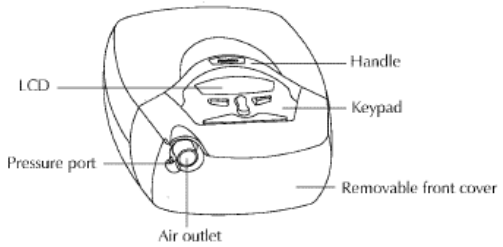
Claim Language [1.b.2]	ResMed Prior Art ("RPA")
[1.b.2] a second input adapted for receiving the pulse oximetry sensor data from the output of the signal processing module,	RPA discloses, or at least renders obvious, a second input adapted for receiving the pulse oximetry sensor data from the output of the signal processing module. *See, e.g.*, 1.pre. RPA System 1 discloses this limitation, or alternatively renders it obvious in view of the knowledge of a POSITA. For example, the AutoSet Spirit flow generator includes an auxiliary input port for receiving pulse oximetry sensor data (via the ResLink) from the output of the Xpod (signal processing module). RPA System 2 renders this limitation obvious in view of the knowledge of a POSITA, and alternatively also in view of System 1. Alternatively, RPA Systems 1-2 in combination with Schmidt and the knowledge of a POSITA render this limitation obvious. For example, the AutoSet Spirit flow generator (PAP device of Systems 1-2) includes an auxiliary input port (second input) adapted for receiving pulse oximetry sensor data (via the ResLink) from the output of the Xpod (signal processing module). *See, e.g.*, limitation 1.a. For example, RPA discloses: **ResMed AutoSet Spirit (System 1-2)**

Claim Language [1.b.2]	ResMed Prior Art ("RPA")

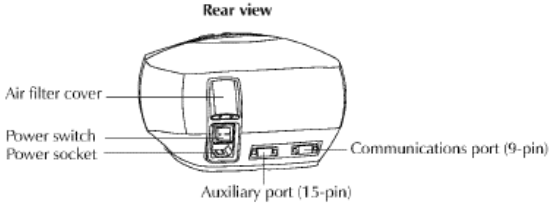
COMPONENTS OF THE AUTOSET® SPIRIT™ SYSTEM

The following are supplied as part of an AUTOSET SPIRIT system.

AutoSet Spirit unit
Front view



Rear view



RMD-063968 (AutoSet Spirit Clinician's Manual) at -3983.

RMD-0318396 at -0318398, *see also* 0318401.

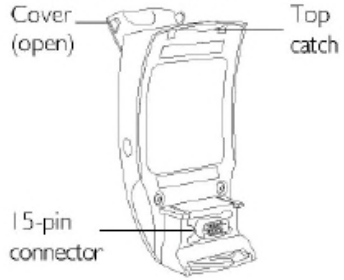
Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	[redacted] **ResLink (System 1, 2)** The RESLINK is intended to be used with the ResMed AUTOSET® SPIRIT™ and S7™ ELITE systems. The RESLINK has two distinct functions: • enhanced collection, storage and transfer of data (including pulse oximetry data), and • upgrade of the AUTOSET SPIRIT and S7 ELITE software. RMD-063198 (ResLink Clinician's Guide) at -3199.

Claim Language [1.b.2]	ResMed Prior Art ("RPA")

THE RESLINK SYSTEM

The following are supplied as part of the RESLINK system:

- RESLINK device



ResLink (front view)

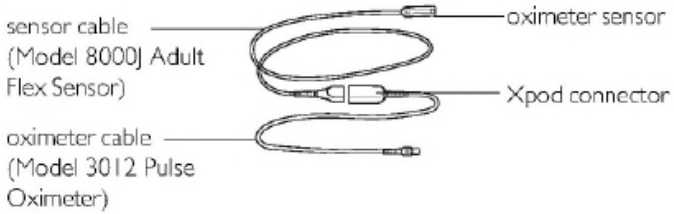
ResLink (back view)

- SmartMedia card

The RESLINK pouch also contains the *ResLink User's Manual* and the SmartMedia card Mailback card.

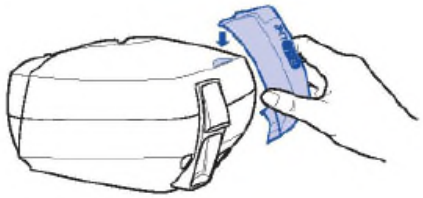
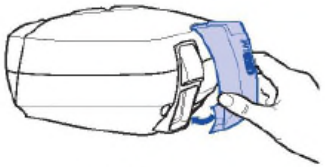
ACCESSORIES

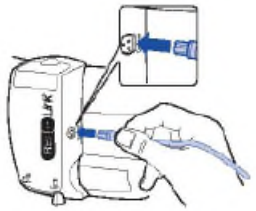
The NONIN ® Model 3012 Pulse Oximeter and Model 8000J Adult Flex Sensor (available from ResMed) are compatible for use with the RESLINK.

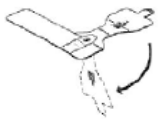
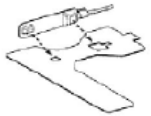


RESMED

RMD-063198 (ResLink Clinician's Guide) at -3199.

Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	Connecting the ResLink to the flow generator The flow generator should be set up according to the instructions in the user's manual. **WARNING** **Before connecting the RESLINK, make sure that the flow generator is switched off.** 1. Place the top catch of the RESLINK onto the notch at the back of the flow generator.  2. Push the bottom of the RESLINK onto the auxiliary port at the back of the flow generator.  3. Slide the lever at the back of the RESLINK to the right, to lock the RESLINK in place. RMD-063198 (ResLink User's Manual) at -3211-12.

Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	USING THE RESLINK Connecting an Oximeter (optional) Your clinician may have supplied an oximeter for use with the RESLINK. Connecting an oximeter to the RESLINK allows collection and storage of oximetry data (oxygen saturation and pulse rate). 1. Ensure that the sensor cable is properly connected to the Xpod connector. 2. Insert the oximeter plug into the RESLINK oximeter port. The 'Oximeter Connected' message will be displayed on the LCD indicating successful connection of the oximeter to the RESLINK.  RMD-063198 (ResLink User's Manual) at -3213-14.

Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	Attaching the Oximeter Sensor (optional) **CAUTION** **The oximeter sensor will not function properly if there is nail polish on your fingernails.** 1. Peel the paper backing away from the FlexiWrap.  2. Firmly press the oximeter sensor onto the adhesive side of the FlexiWrap.  3. Carefully position any one of your fingers (not the thumb) on the adhesive side of the FlexiWrap. Ensure that the dotted line is at the tip of your finger. Wrap the flaps around your finger. 4. Carefully fold the FlexiWrap over the tip of your finger so that the two diodes are vertically aligned. Wrap the short flap around your finger. 5. Wrap the long flap around your finger to secure the sensor. 6. Secure the sensor wire to the base of the finger or wrist using medical tape. RMD-063198 (ResLink User's Manual) at -3214-15.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	 RMD-289749 (ResLink Launch Brochure) at -9749 and -9756. ResMed introduces ResLink™–the first truly modular sleep-disordered breathing (SDB) therapy management tool with significant benefits for the patient, sleep laboratory, prescribing physician, and equipment provider. The portable ResLink module simply clips onto ResMed's AutoSet Spirit™ system. ResLink captures and stores high-resolution patient compliance and efficacy data, including oximetry. This information is easily accessed and transferred via a 32MB SmartMedia™ card and then downloaded to a PC using ResMed's AutoScan™ software. RMD-289749 (ResLink Launch Brochure) at -9750. **Comprehensive efficacy data with oximetry** ResLink reports on significant parameters such as minute ventilation, snore, flattening, SpO_2, pulse rate, pressure response, leak, events, and AHI, providing visible insights into treatment efficacy. ResLink presents this efficacy information along with integrated oximetry data for simultaneous onscreen viewing and analysis. RMD-289749 (ResLink Launch Brochure) at -9751.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	 RMD-289749 (ResLink Launch Brochure) at -9755. *See also* [redacted] ResLink User's Manual (RMD-063203) at 8-9; [redacted]

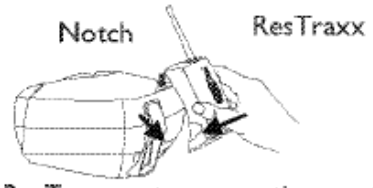
	AutoScan 5.4 (System 1) MANAGING PATIENT INFORMATION AUTOSCAN 5.4 allows you to record patient information, clinical details and notes in the patient file. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1297. Detailed and summary data from a patient's flow generator are stored on a SmartMedia card by the RESLINK. The SmartMedia card is removed and sent to the clinician at the end of the study period. The SmartMedia card is inserted into a SmartMedia card reader attached to the clinician's computer, and the data can then be downloaded and viewed in AUTOSCAN 5.4. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1301. The Detailed Data screen displays nine traces of data downloaded via the RESLINK from the flow generator. You can view data in the Detailed Data screen in increased detail or as a compact overview. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1303.

Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	The Detailed Data screen for that session will be displayed. The graph display area shows the downloaded data in the trace panels: • Events (s) • Minute Ventilation (L/min) • Leak (L/s) • Pulse Rate (bpm) • SpO_2 (%) • AHI (Events/hr) • Pressure (cm H_2O)[a] • Snore (Quiet to Loud)[a] • Flattening (Round to Flat)[a] • Respiratory rate (BPM).[b] [a] AUTOSET SPIRIT and S7 ELITE only [b] VPAP III series only NOTE *Pulse rate and SpO_2 are derived from the oximeter reading.* RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1304. **ResTraxx (including RDC) (System 2)** ResTraxx™ allows the wireless transfer of information from a continuous positive airway pressure (CPAP) unit to a clinician at a remote location via a two-way pager network. ResTraxx is intended to be used with ResMed S7™ Elite, AutoSet® Spirit™ , AutoSet® Respond™ , and VPAP® III flow generator systems on adults with obstructive sleep apnea. RMD-062642 (ResTraxx Quick Reference Guide) at -2642.

Claim Language [1.b.2]	ResMed Prior Art ("RPA")

Attaching the ResTraxx

1. Turn the flow generator to OFF.
2. Slide lever on back of ResTraxx to the left.
3. Place top catch on ResTraxx onto notch at back of unit.



4. Push 15-pin connector on ResTraxx onto connection port on back of unit.
5. Slide lever on back of ResTraxx to the right to lock it into place.
6. Turn the main power switch at the back of flow generator to the ON position.
7. A green LED on top of ResTraxx will light up 15 - 20 seconds after unit is turned on, then begin to flash.
8. After about 15 seconds, a series of messages will appear on the flow generator display, indicating the unit's initialization and registration status of unit.
9. After initialization, the standby screen appears on the flow generator display and the unit begins transmitting information.

RMD-062642 (ResTraxx Quick Reference Guide) at -2642.

[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	[redacted]

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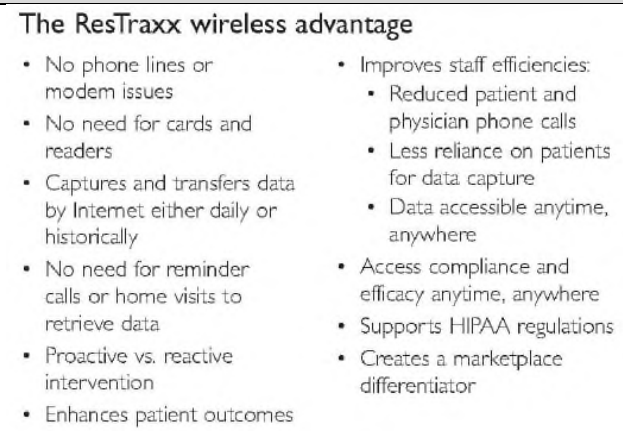
Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	[redacted]

ResTraxx is a first-of-its-kind wireless communication device that attaches easily to the back of ResMed flow generators. The ResTraxx system captures, transfers, and stores compliance and efficacy data without wires, phone lines, modems, or data cards. ResTraxx is an elegant system that brings patient usage and treatment efficacy data to your fingertips instantly.

RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	 RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

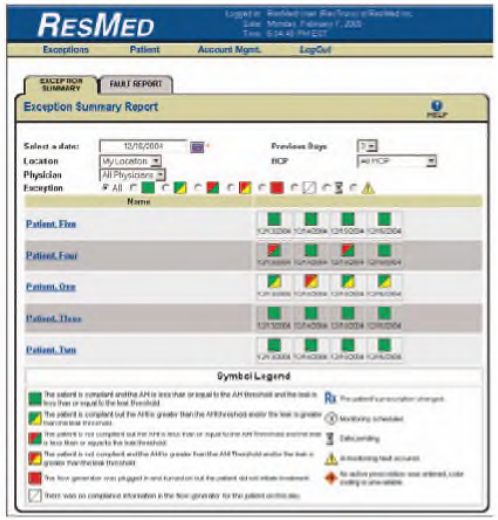
[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.2]	ResMed Prior Art ("RPA")

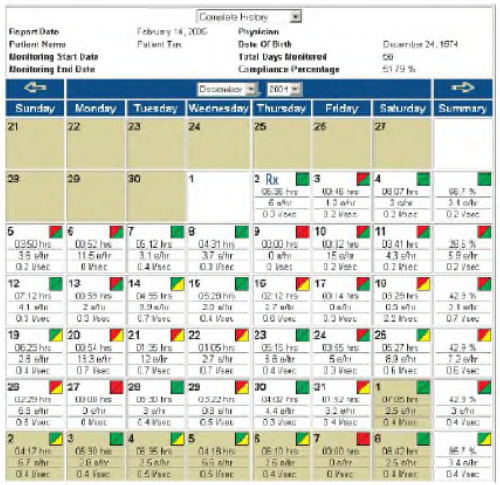
Exception Reporting

Enhance productivity and manage patients more efficiently. **Exception Reporting identifies and highlights those patients who fall below desired usage thresholds or have issues with mask leak or AHI.** This feature enables you to focus your efforts only on those patients who require intervention and respond proactively to potential problems. The simple color-coded alert system helps you identify exception patients quickly and easily.



Efficacy + Leak + Usage Data

The ResTraxx Data Center displays data on a daily basis in a calendar format enabling you to see daily or weekly trends of adherence problems before compliance is truly compromised. Early intervention and ongoing follow-up is considered critical, especially during the first month of CPAP acclimation, to determine long-term compliance rates.[2]



Want more details on therapy results? Click on the calendar day in question, and a therapeutic report will display additional clinical data regarding the patient's usage for that day.

RMD-063327 (ResTraxx Patient Management Brochure) at -3328.

[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.2]	[redacted]

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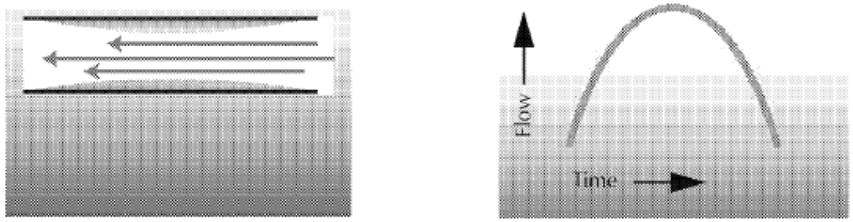
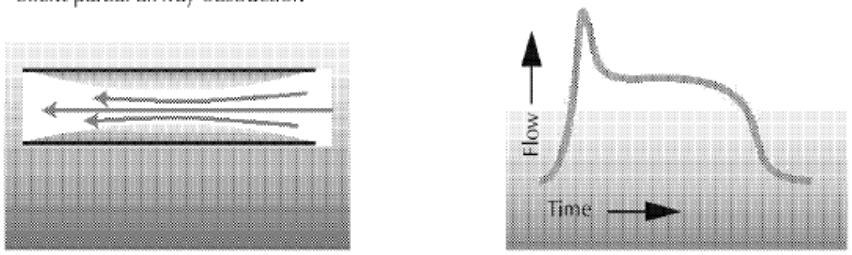
Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	[redacted]
	To the extent the Xpod module practices the "signal processing module" of limitation 1.a, the ResLink oximeter port and/or the auxiliary port of the AutoSet Spirit flow generator practices this claim limitation. Both are "an input adapted for receiving the pulse oximetry sensor data form the

Claim Language [1.b.2]	ResMed Prior Art ("RPA")
	output of the signal processing module," at least based on CleveMed's contentions that appear to allege there does not to be a direct interface between the input and the output. If the Judge or Jury finds that RPA does not disclose this claim limitation, this claim is still rendered obvious by modifying or combining RPA with the knowledge of a POSITA. A POSITA would have found it obvious, for example, that the AutoSet Spirit flow generator (PAP device) would include an input for receiving the pulse oximetry sensor data from the output of the signal processing module discussed for limitation 1.a. If the combination of the PAP device and ResLink are found to not practice this claim, it would have at least been obvious to modify the PAP device to directly receive the pulse oximetry sensor data from the output of the Xpod. As an example, other prior art commercial ResMed PAP devices disclosed this configuration. This is addressed for limitation 1.a. *See also, e.g.*, RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures; RMD-0318396 Specimen Photographs; [redacted]

Claim Language [1.b.3]	ResMed Prior Art ("RPA")
[1.b.3] an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow data of a subject using the PAP device, and	RPA discloses, or at least renders obvious, an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow data of a subject using the PAP device. *See, e.g.*, 1.pre. RPA Systems 1-2 disclose this limitation at least for the same reasons CleveMed alleges the Accused Products infringe this claim. ResMed reserves the right to contend the accused functionality does not practice the claim; if the accused functionality is found to practice the claim, then the same functionality is disclosed in RPA Systems 1-2. Alternatively, RPA Systems 1-2 render this limitation obvious in view of the knowledge of a POSITA, and/or Westbrook. For example, the AutoSet Spirit flow generator (PAP device) comprises an airflow sensor internal to the flow generator. For example, RPA discloses: **ResMed AutoSet Spirit (System 1-2)**

Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	The ResMed AUTOSET® SPIRIT™ system is designed to provide continuous positive airway pressure (CPAP) therapy to patients with obstructive sleep apnea (OSA). Patients with OSA experience recurrent obstruction of their upper airway (apneas) due to relaxation of the tongue and soft palate while they sleep. Common symptoms are associated with poor sleep quality and may include excessive daytime sleepiness and tiredness, as well as diminished concentration and memory loss. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3974. The AUTOSET SPIRIT system is intended for the treatment of obstructive sleep apnea (OSA) in adult patients. Data collection capabilities also assist in the management of continuous positive airway pressure (CPAP) treatment. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3976. [redacted] The AUTOSET SPIRIT system is designed for clinical use and home treatment of adult patients with obstructive sleep apnea (OSA). The system has two therapy modes for treating OSA: **CPAP** mode and **AutoSet** mode. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.

Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	CPAP MODE In CPAP mode, the AUTOSET SPIRIT unit provides fixed-pressure room air via tubing to the mask worn by your patient. The continuous air stream "splints" open the upper airway, preventing airway collapse. AUTOSET SPIRIT delivers pressure within the range 4 to 20 cm H_2O. To make the beginning of treatment more comfortable, you may set a ramp so the pressure starts low and gradually increases to full treatment pressure over the ramp time. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980. AUTOSET® MODE The treatment pressure required by your patient may vary through the night, and from night to night, due to changes in sleep state, body position, and airway resistance. In AutoSet mode AUTOSET SPIRIT provides only sufficient pressure to maintain upper airway patency. You can set the minimum and maximum allowable treatment pressures. The unit analyzes the state of the patient's upper airway on a breath-by-breath basis and delivers pressure within the allowed range according to the degree of obstruction. The AutoSet algorithm adjusts treatment pressure as a function of three parameters: inspiratory flow limitation, snore, and apnea. The flow sensor, located in the AUTOSET SPIRIT unit, enables detection of inspiratory flow limitation and apneas. The pressure sensor, also located in the unit, enables measurement of pressure and snore. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980. **Inspiratory flow limitation** indicates silent partial obstruction. When your patient is breathing normally, the inspiratory flow measured by the unit as a function of time shows a typically rounded curve for each breath. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.

Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	Open unrestricted airway  Figure 1: Inspiratory flow-time curve for an unrestricted airway As the upper airway begins to collapse, the shape of the inspiratory flow/time curve changes and the central section flattens. Silent partial airway obstruction  Figure 2: Inspiratory flow/time curve for a partially obstructed airway The AutoSet algorithm analyzes the shape of the central part of the curve for each breath and assigns a value as the amount of flattening. Inspiratory flow limitation, or partial airway closure, usually precedes snoring and obstruction. Detection of this flow limitation enables the unit to increase the pressure *before* obstruction occurs, making treatment pre-emptive. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3981.

Claim Language [1.b.3]	ResMed Prior Art ("RPA")

The Flattening Index is a measure of silent inspiratory airflow limitation. Flow limitation with loud snoring is handled by the snore detector. When a patient **snores**, sound is generated and the inspiratory flow/time curve is distorted by the frequency of the sound.

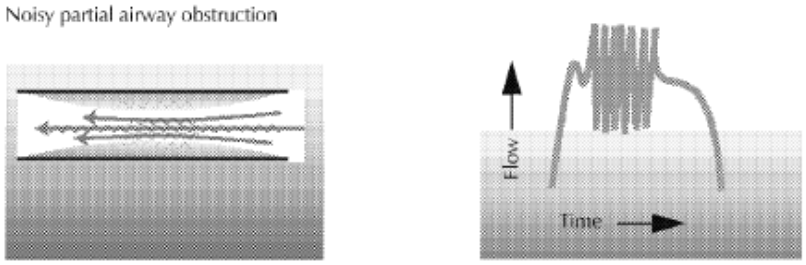


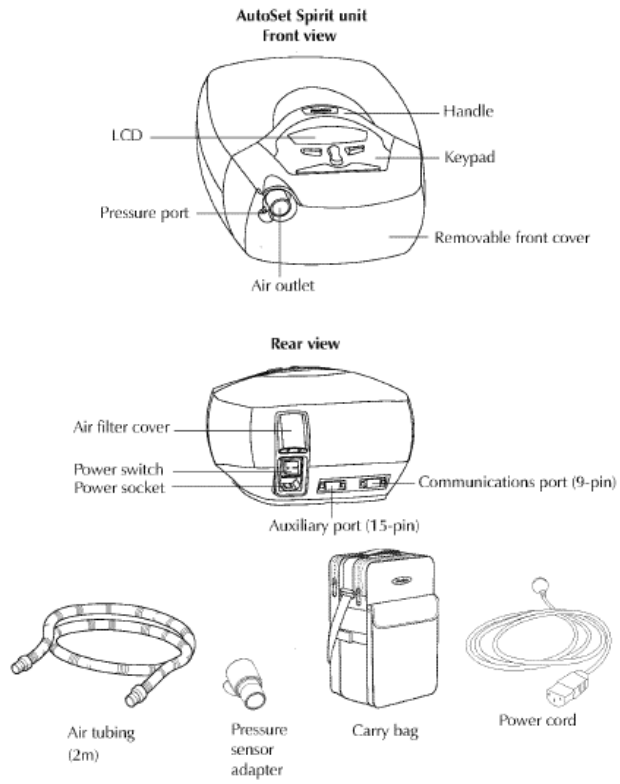
Figure 3: Inspiratory flow/time curve affected by snore

The AutoSet algorithm assigns an arbitrary value between 0.0 and 2.0 to the average amplitude of the snoring detected for the past 5 breaths. A value of 1.0 is equivalent to approximately 75dBA measured 10cm from the nares. Treatment pressure increases by up to 0.2 cm H_2O per second (proportional to the severity of the snore) for snore above 0.2 snore units. When snore is less than 0.2 snore units, therapy is reduced towards the minimum pressure with a 20-minute time constant.

An **apnea** is defined as a greater than 75% decrease in ventilation. The AutoSet algorithm scores an apnea if the 2-second moving average ventilation drops below 25% of the recent time average (time constant 100 seconds) for at least 10 consecutive seconds. Treatment pressure increases based on the duration of the apnea. The pressure will not rise above 10 cm H_2O when an apnea is detected, to prevent an inappropriate response to central apneas. Initial pressure increases are rapid, but the rate of increase diminishes as the pressure approaches 10 cm H_2O. When no further apneas are detected, therapy is reduced towards the minimum pressure with a 20-minute time constant.

A **hypopnea** is defined as a 50 to 75% drop in ventilation. A hypopnea is scored if the 8-second moving average ventilation drops below 50%, but not below 25%, of the recent average for 15 consecutive seconds. In order to avoid falsely responding to central hypopneas, the AutoSet algorithm does not respond to hypopneas but rather to the associated snore or flow limitation.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -3982.

Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	COMPONENTS OF THE AUTOSET® SPIRIT™ SYSTEM The following are supplied as part of an AUTOSET SPIRIT system.  Figure 4: AutoSet Spirit system components RMD-063968 (AutoSet Spirit Clinician's Manual) at -3983.

Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	ACCESSORIES The following accessories may be purchased separately. AUTOSET SPIRIT ACCESSORIES Air tubing 9ft10in (3m) HUMIDIFIER ACCESSORIES (HUMIDAIRE and ResMed PASSOVER only) Pressure sensor line Short air tubing 7.5in (19cm) for HumidAire connection Medium air tubing 21in (52cm) for humidifier connection RMD-063968 (AutoSet Spirit Clinician's Manual) at -3984.

Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	HUMIDIFIERS A humidifier may be required if your patient experiences dryness of the nose, mouth, or throat. The following humidifiers (supplied separately) are compatible for use with AUTOSET SPIRIT units. HUMIDAIRE 2i heated humidifier HUMIDAIRE™ heated humidifier ResMed PASSOVER humidifier RMD-063968 (AutoSet Spirit Clinician's Manual) at -3984.

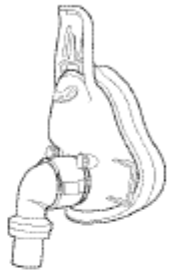
Claim Language [1.b.3]	ResMed Prior Art ("RPA")

MASK SYSTEMS

The following ResMed mask systems (supplied separately) are recommended for use with the AUTOSET SPIRIT system.

ULTRA MIRAGE™ MASK

MIRAGE® FULL FACE MASK



FULL FACE MASK SERIES 2

MIRAGE® MASK

MODULAR MASK

WARNING

For therapy in **AutoSet** mode, use one of the recommended ResMed masks. The AutoSet algorithm has appropriate parameters for these masks.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -3985.

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Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	[redacted]

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FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.b.3]	ResMed Prior Art ("RPA")

Menu	Parameter	Description
Results	Efficacy data	Displays pressure, leak, AHI (apnea + hypopnea index), AI (apnea index), and HI (hypopnea index) data for a range of time intervals. For details, see "Clinical Menu Results" on page 39.
	Usage data	Displays usage data for a range of time intervals. For details, see "Clinical Menu Results" on page 39.
	Mask Fit* (Smart Data)	Displays a star rating corresponding to the 70th centile leak from the previous session, if enabled in Clinical Menu, Options, Smart Data.
	Pressure* (Smart Data)	Displays 95th centile pressure from the previous session, if enabled in Clinical Menu, Options, Smart Data.
	Usage* (Smart Data)	Displays usage hours from the previous session, if enabled in Clinical Menu, Options, Smart Data.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -4004.

PRESSURE

The pressure transducer located in the unit measures treatment pressure; the average pressure is calculated and recorded each minute. The pressure reported in the Efficacy Data submenu (see Figure 9, The Clinical Menu Results series, on page 40) for a single session is the 95th centile pressure for mask-on time, excluding periods when the leak has exceeded 0.4 L/s (24 L/min). For selected time intervals (last week, last month, last 6 months or last year), the median of the daily 95th centile values is reported. Non-usage days are not included in calculations.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -4010.

Claim Language [1.b.3]	ResMed Prior Art ("RPA")

LEAK

Leak is derived by analyzing inspiratory and expiratory airflows (via the flow sensor located in the unit). Theoretically, inspiratory and expiratory volumes should be equal. A net airflow greater than the expected mask vent flow is equal to the leak. Generally, a leak rate of more than 0.4 L/s (24 L/min) is associated with patient discomfort, disturbed sleep, and reduced efficacy of treatment.

If the leak exceeded 0.4 L/s (24 L/min) for more than 30% of the previous session, the following message will appear on the LCD: **`High leak in last session.`**

The Leak Alert feature, if enabled, will alert the patient when mask leak exceeds 0.7 L/s (42 L/min) for more than 20 seconds. When the leak exceeds this level, the autotitrating algorithm ceases to perform optimally.

The leak reported in the Efficacy Data submenu (see Figure 9, The Clinical Menu Results series, on page 40) is the 95th centile value for mask-on time for each session, or the median 95th centile value for a selected time interval (last week, last month, last 6 months, or last year). Non-usage days are not included in calculations.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -4010.

[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	[redacted] **AutoScan 5.4 (System 1)** AUTOSCAN™ 5.4 has been developed to view summary data and detailed data obtained from the RESLINK™ via the SmartMedia™ card. Summary data and Night profile data obtained from the flow generator can also be viewed as in previous versions of AUTOSCAN. AUTOSCAN 5.4 has data collection and management capabilities that provide an adjunct for patient management. The flow generator systems intended to be used with AUTOSCAN 5.4 are the ResMed AUTOSET® SPIRIT™, S7™ ELITE, VPAP® III, VPAP III ST, VPAP III ST-A, and AUTOSET RESPOND™. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1269. FLOW GENERATOR COMPATIBILITY The following flow generators are compatible with AUTOSCAN 5.4: • AUTOSET SPIRIT • AUTOSET RESPOND • VPAP III, VPAP III ST, VPAP III ST-A, • S7 ELITE. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277. MANAGING PATIENT INFORMATION AUTOSCAN 5.4 allows you to record patient information, clinical details and notes in the patient file. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1297.

Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	Detailed and summary data from a patient's flow generator are stored on a SmartMedia card by the RESLINK. The SmartMedia card is removed and sent to the clinician at the end of the study period. The SmartMedia card is inserted into a SmartMedia card reader attached to the clinician's computer, and the data can then be downloaded and viewed in AUTOSCAN 5.4. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1301. The Detailed Data screen displays nine traces of data downloaded via the RESLINK from the flow generator. You can view data in the Detailed Data screen in increased detail or as a compact overview. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1303. The Detailed Data screen for that session will be displayed. The graph display area shows the downloaded data in the trace panels: • Events (s) • Minute Ventilation (L/min) • Leak (L/s) • Pulse Rate (bpm) • SpO_2 (%) • AHI (Events/hr) • Pressure (cm H_2O)[a] • Snore (Quiet to Loud)[a] • Flattening (Round to Flat)[a] • Respiratory rate (BPM).[b] [a] AUTOSET SPIRIT and S7 ELITE only [b] VPAP III series only NOTE *Pulse rate and SpO_2 are derived from the oximeter reading.* RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1304.

Claim Language [1.b.3]	ResMed Prior Art ("RPA")

PRESSURE (AUTOSET SPIRIT AND S7 ELITE ONLY)

The RESLINK samples pressure every 2 seconds. The trace displayed in the Detailed Data screen is the calculated delivered pressure. If this differs markedly from the pressure set on the flow generator, check that the device is functioning correctly.

The trace for Pressure will show any changes to the pressure setting on the flow generator. In Autoset mode, the trace will show increases or decreases in line with apnea or hypopnea events, or snore.

If the pressure trace is constant, this would indicate that the flow generator is in CPAP mode. If the pressure trace is changing with time, this would indicate that the flow generator is in Autoset mode.

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1308.

LEAK MEASUREMENT

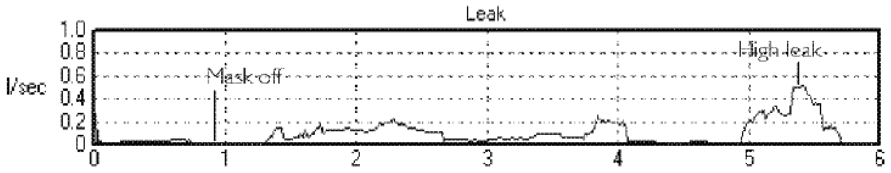
NOTE *When assessing results, it is best to check the leak data first. Leaks greater than 0.4 L/sec affect the accuracy of other measurements.*

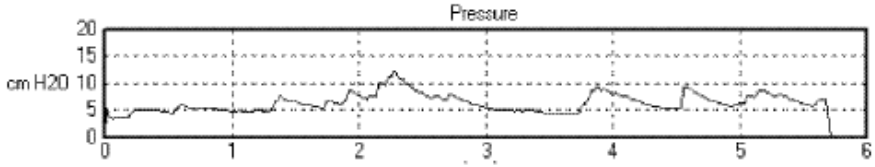
Leak is measured by analysing inspiratory and expiratory volumes, which should be approximately equal, yielding an average airflow of 0 L/sec in the absence of mask leak. An average airflow greater than 0 L/sec is due to leak.

Generally, a leak rate of more than 0.4 L/sec is associated with patient discomfort, disturbed sleep and reduced efficacy of treatment. A leak rate of 0.2 L/sec or less for the majority of a session signals a well-fitting mask.

The median, maximum and 95th percentile leak for each session in a series are displayed in the *Treatment Profile* (see Figure 38).

Median, 95th percentile and maximum leak are displayed for the nominated time interval in the *Statistics* tab of AUTOSCAN 5.4. A graph of leak as a function of time for each night is shown in the *Night Profile*.



Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1326 – 27. PRESSURE MEASUREMENT The pressure transducer located in the AUTOSET SPIRIT and S7 ELITE calculates pressure at the mask. The median, maximum and 95th percentile pressure delivered during each night in a series are displayed in the *Treatment Profile* (see Figure 38). The AUTOSET SPIRIT and S7 ELITE continuously titrate the pressure delivered, based on inspiratory flow limitation, snore, and apnea. The median, 95th percentile and maximum pressure data are displayed for the nominated time interval in the *Statistics* tab of AUTOSCAN 5.4. The pressure delivered to the patient each night is reported as a function of time in the pressure graph in the *Night Profile*.  RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1327. **ResTraxx (including RDC) (System 2)** ResTraxx™ allows the wireless transfer of information from a continuous positive airway pressure (CPAP) unit to a clinician at a remote location via a two-way pager network. ResTraxx is intended to be used with ResMed S7™ Elite, AutoSet® Spirit™ , AutoSet® Respond™ , and VPAP® III flow generator systems on adults with obstructive sleep apnea. RMD-062642 (ResTraxx Quick Reference Guide) at -2642. [redacted]

[redacted]

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Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.b.3]	ResMed Prior Art ("RPA")

ResTraxx is a first-of-its-kind wireless communication device that attaches easily to the back of ResMed flow generators. The ResTraxx system captures, transfers, and stores compliance and efficacy data without wires, phone lines, modems, or data cards. ResTraxx is an elegant system that brings patient usage and treatment efficacy data to your fingertips instantly.

RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

The ResTraxx wireless advantage

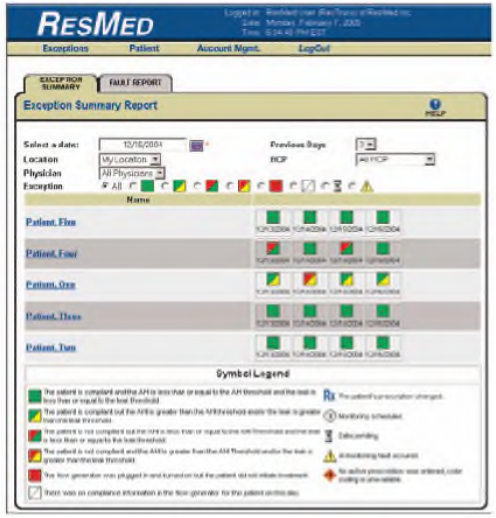
- No phone lines or modem issues
- No need for cards and readers
- Captures and transfers data by Internet either daily or historically
- No need for reminder calls or home visits to retrieve data
- Proactive vs. reactive intervention
- Enhances patient outcomes
- Improves staff efficiencies:
  - Reduced patient and physician phone calls
  - Less reliance on patients for data capture
  - Data accessible anytime, anywhere
- Access compliance and efficacy anytime, anywhere
- Supports HIPAA regulations
- Creates a marketplace differentiator

RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

Claim Language [1.b.3]	ResMed Prior Art ("RPA")

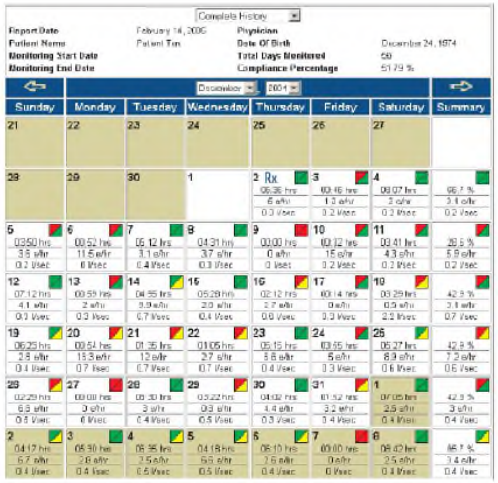
Exception Reporting

Enhance productivity and manage patients more efficiently. **Exception Reporting identifies and highlights those patients who fall below desired usage thresholds or have issues with mask leak or AHI.** This feature enables you to focus your efforts only on those patients who require intervention and respond proactively to potential problems. The simple color-coded alert system helps you identify exception patients quickly and easily.



Efficacy + Leak + Usage Data

The ResTraxx Data Center displays data on a daily basis in a calendar format enabling you to see daily or weekly trends of adherence problems before compliance is truly compromised. Early intervention and ongoing follow-up is considered critical, especially during the first month of CPAP acclimation, to determine long-term compliance rates.[2]



Want more details on therapy results? Click on the calendar day in question, and a therapeutic report will display additional clinical data regarding the patient's usage for that day.

RMD-063327 (ResTraxx Patient Management Brochure) at -3328.

[redacted]

[redacted]

FINAL Exhibit G05
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Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	[redacted]
	Additional Citations "*CPAP technology* "All subjects were set up using commercially available CPAP devices with an integrated computer chip that collects compliance data. This method for the collection of compliance data is a proven and accepted approach that has been in widespread use for several years. The present study used these data, rather than a created data set, because the wireless data transmission device was developed to access existing data sets stored in the internal flow generator's computer chip. "Fourteen of the patients utilized a CPAP device that collects both compliance and efficacy data. At the Atlanta site, all patients used a Resmed S6 Elite Flow Generator that collects compliance and

Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	usage-related data. In Boston and Buffalo, the patients used a Resmed Auto Set T Flow Generator, which collects usage/ compliance data as well as therapeutic data that measure efficacy. The S6 Elite provides continuous positive airway pressure at a preset level determined by titration. The Auto-Set T provides either fixed pressure in CPAP mode or delivers variable pressure levels that are determined using an algorithm that adjusts pressure according to inspiratory flow. As a result, users will experience variations in pressure on a night-to-night basis, as well as throughout the night depending on changes in sleep staging and position. For purposes of this study, the Auto-Set T devices were used in fixed pressure CPAP mode only." Lankford, 164. If the Judge or Jury finds that RPA does not disclose this claim limitation under CleveMed's theory of infringement for the accused products, this claim is still rendered obvious by modifying or combining RPA with other references or the knowledge of a POSITA. It was well-known to a POSITA, for example, to use an airflow sensor in order to provide feedback to the PAP device to ensure the desired pressure is being applied. A POSITA would have recognized there were only a handful of commonly known solutions for monitoring the condition of the patient and controlling the pressure of the PAP system that included an airflow sensor. A POSITA would have recognized that there were only a handful of locations within the system to place the airflow sensor, including internal to the PAP device as claimed, or at or near the mask. *See, e.g.*, Berthon-Jones, 8:31-36 ("Further, it may not be convenient to mount the flow transducer 44 at or near the mask 30, nor to measure the mask pressure at or near the mask. An alternative arrangement, where the flow and pressure transducers are mounted at or near the air pressure generator (in the embodiment being the turbine 34) is shown in FIG. 3.") **Westbrook** discloses a combination of an airflow *physiological* sensor and a pulse oximeter that detects and records pulse rate and oximetry, and discloses that the airflow connecter is provided *within* the enclosure of the PAP device: "As discussed above, the PSG detects a number of signals. The present inventors, however, have found that not all signals are necessary to accurately detect sleep apnea. A reduction in the number of signals, as compared to PSG, is helpful in obtaining high quality data when the user is responsible for applying the device without assistance. Accordingly, the ***physiological monitor 12 in accordance with the preferred embodiment detects and records the pulse rate, oximetry***, snoring sounds, and head position of a patient. ***In addition to these signals, the physiological monitor may also incorporate a number of additional signals without substantially increasing its weight, size, or***

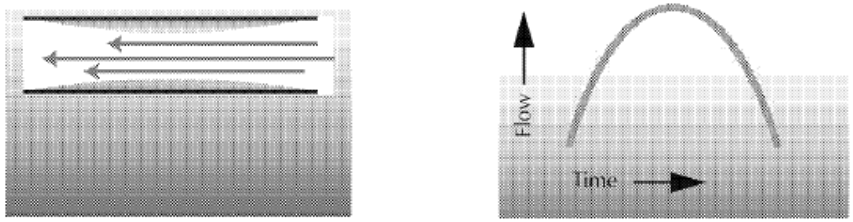
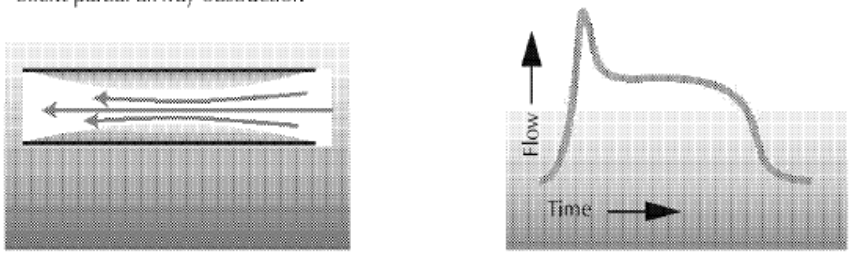
Claim Language [1.b.3]	ResMed Prior Art ("RPA")
	power consumption. Note, however, that while additional signals may improve the accuracy of detecting respiratory events, these additional signals are not required. The inclusion of these additional signals could increase the complexity of system thereby affecting its ease of use. ***An airflow signal could be added to the physiological monitor with minimal intrusiveness***. In this configuration, the amplifier and filtering circuitry for the airflow channel can be incorporated into the design with a connector ***provided in the enclosure for the termination of the sensor*** (see FIG. 16). A short wire or tube would then extend from the terminal connector to the sensor 100 positioned over the airway opening. The advantage of the forehead-mounted physiological monitor to acquire airflow would be to decrease the length of the connection between the sensor and recording device in order, thereby improving the reliability of the signal." Westbrook [0161] (emphasis added). Thus, in view of the teachings of Westbrook, it would have been obvious to a POSITA, to the extent not disclosed expressly in RPA, to incorporate a flow sensor within the PAP device enclosure (at least because this is disclosed by RPA) to measure physiological flow of the subject, such as respiratory airflow data, in combination with a sensor that detects and records the pulse rate and oximetry, such as a pulse oximeter, which is external to the PAP device enclosure. It would have been obvious to configure the system in such a manner at least based on the knowledge of a POSITA, and also in view of the disclosures of Westbrook. *See also, e.g.*, RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures; RMD-0318396 Specimen Photographs; [redacted]

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
[1.b.4] 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	RPA discloses, or at least renders obvious, 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. *See, e.g.,* 1.pre. Based on CleveMed's infringement contentions, RPA Systems 1-2 render this limitation obvious. Alternatively, RPA Systems 1-2 render this limitation obvious in view of the knowledge of a POSTIA, and/or Westbrook. *See, e.g.*, limitations 1.a, 1.b, 1.b.2, 1.b.3.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
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;	The AutoSet Spirit comprises a microprocessor (processor) "adapted for receiving the … data from [an] airflow sensor and calculating, based in part" on the sensor data from the flow and/or pressure sensor, certain data parameters discussed below. *See, e.g.*, [redacted] CleveMed's contentions, both its final contentions and preliminary contentions, alleged that the same parameters calculated by the AutoSet Spirit's microprocessor practice the claimed "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." [redacted] In RPA System 1, the microprocessor of the AutoSet Spirit also receives the oxygen saturation and pulse data from the pulse oximeter. [redacted] It would have been obvious for the microprocessor of the AutoSet Spirit to also calculate "95th percentile, max and median of the 1-minute average value of SpO2" like the accused products. For example, the microprocessor of the AutoSet Spirit is already programmed to calculate centile statistics for leak and pressure. It would have been obvious, and a mere design implementation detail that would require only a few lines of code, to calculate the same statistics for the SpO2 data that is input via the ResLink, or, as an obvious variant, input directly to the PAP device rather than through the ResLink. For example, RPA discloses:

	ResMed AutoSet Spirit (System 1, 2, 3) The ResMed AUTOSET® SPIRIT™ system is designed to provide continuous positive airway pressure (CPAP) therapy to patients with obstructive sleep apnea (OSA). Patients with OSA experience recurrent obstruction of their upper airway (apneas) due to relaxation of the tongue and soft palate while they sleep. Common symptoms are associated with poor sleep quality and may include excessive daytime sleepiness and tiredness, as well as diminished concentration and memory loss. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3974. The AUTOSET SPIRIT system is intended for the treatment of obstructive sleep apnea (OSA) in adult patients. Data collection capabilities also assist in the management of continuous positive airway pressure (CPAP) treatment. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3976. [redacted] The AUTOSET SPIRIT system is designed for clinical use and home treatment of adult patients with obstructive sleep apnea (OSA). The system has two therapy modes for treating OSA: **CPAP** mode and **AutoSet** mode. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	CPAP MODE In CPAP mode, the AUTOSET SPIRIT unit provides fixed-pressure room air via tubing to the mask worn by your patient. The continuous air stream "splints" open the upper airway, preventing airway collapse. AUTOSET SPIRIT delivers pressure within the range 4 to 20 cm H_2O. To make the beginning of treatment more comfortable, you may set a ramp so the pressure starts low and gradually increases to full treatment pressure over the ramp time. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980. AUTOSET® MODE The treatment pressure required by your patient may vary through the night, and from night to night, due to changes in sleep state, body position, and airway resistance. In AutoSet mode AUTOSET SPIRIT provides only sufficient pressure to maintain upper airway patency. You can set the minimum and maximum allowable treatment pressures. The unit analyzes the state of the patient's upper airway on a breath-by-breath basis and delivers pressure within the allowed range according to the degree of obstruction. The AutoSet algorithm adjusts treatment pressure as a function of three parameters: inspiratory flow limitation, snore, and apnea. The flow sensor, located in the AUTOSET SPIRIT unit, enables detection of inspiratory flow limitation and apneas. The pressure sensor, also located in the unit, enables measurement of pressure and snore. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980. **Inspiratory flow limitation** indicates silent partial obstruction. When your patient is breathing normally, the inspiratory flow measured by the unit as a function of time shows a typically rounded curve for each breath. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	Open unrestricted airway  Figure 1: Inspiratory flow-time curve for an unrestricted airway As the upper airway begins to collapse, the shape of the inspiratory flow/time curve changes and the central section flattens. Silent partial airway obstruction  Figure 2: Inspiratory flow/time curve for a partially obstructed airway The AutoSet algorithm analyzes the shape of the central part of the curve for each breath and assigns a value as the amount of flattening. Inspiratory flow limitation, or partial airway closure, usually precedes snoring and obstruction. Detection of this flow limitation enables the unit to increase the pressure *before* obstruction occurs, making treatment pre-emptive. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3981.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")

The Flattening Index is a measure of silent inspiratory airflow limitation. Flow limitation with loud snoring is handled by the snore detector. When a patient **snores**, sound is generated and the inspiratory flow/time curve is distorted by the frequency of the sound.

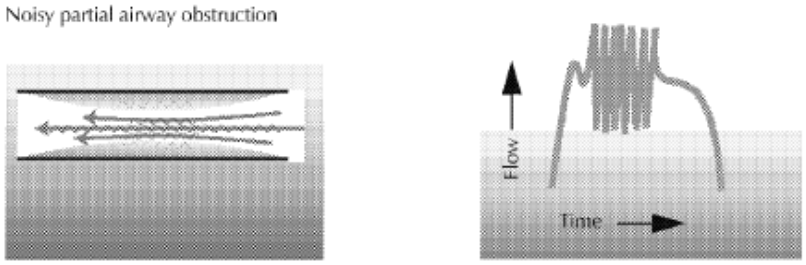


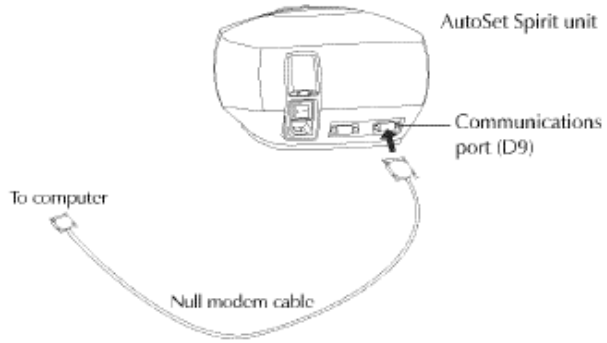
Figure 3: Inspiratory flow/time curve affected by snore

The AutoSet algorithm assigns an arbitrary value between 0.0 and 2.0 to the average amplitude of the snoring detected for the past 5 breaths. A value of 1.0 is equivalent to approximately 75dBA measured 10cm from the nares. Treatment pressure increases by up to 0.2 cm H_2O per second (proportional to the severity of the snore) for snore above 0.2 snore units. When snore is less than 0.2 snore units, therapy is reduced towards the minimum pressure with a 20-minute time constant.

An **apnea** is defined as a greater than 75% decrease in ventilation. The AutoSet algorithm scores an apnea if the 2-second moving average ventilation drops below 25% of the recent time average (time constant 100 seconds) for at least 10 consecutive seconds. Treatment pressure increases based on the duration of the apnea. The pressure will not rise above 10 cm H_2O when an apnea is detected, to prevent an inappropriate response to central apneas. Initial pressure increases are rapid, but the rate of increase diminishes as the pressure approaches 10 cm H_2O. When no further apneas are detected, therapy is reduced towards the minimum pressure with a 20-minute time constant.

A **hypopnea** is defined as a 50 to 75% drop in ventilation. A hypopnea is scored if the 8-second moving average ventilation drops below 50%, but not below 25%, of the recent average for 15 consecutive seconds. In order to avoid falsely responding to central hypopneas, the AutoSet algorithm does not respond to hypopneas but rather to the associated snore or flow limitation.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -3982.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	AUTOSCAN™ SOFTWARE AUTOSCAN is designed to enable review of the data stored in an AUTOSET SPIRIT unit. Data from up to 365 sessions may be stored and downloaded. Refer to the *AutoScan Clinician's Manual* or *Help* for details.  RMD-063968 (AutoSet Spirit Clinician's Manual) at -3986.

[redacted]

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ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]

[redacted]

FINAL Exhibit G05
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Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]
	[redacted]

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[redacted]

FINAL Exhibit G05
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Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.b.4]	[redacted]

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[redacted]

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Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.b.4]	ResMed Prior Art ("RPA")

Menu	Parameter	Description
Results	Efficacy data	Displays pressure, leak, AHI (apnea + hypopnea index), AI (apnea index), and HI (hypopnea index) data for a range of time intervals. For details, see "Clinical Menu Results" on page 39.
	Usage data	Displays usage data for a range of time intervals. For details, see "Clinical Menu Results" on page 39.
	Mask Fit* (Smart Data)	Displays a star rating corresponding to the 70th centile leak from the previous session, if enabled in Clinical Menu, Options, Smart Data.
	Pressure* (Smart Data)	Displays 95th centile pressure from the previous session, if enabled in Clinical Menu, Options, Smart Data.
	Usage* (Smart Data)	Displays usage hours from the previous session, if enabled in Clinical Menu, Options, Smart Data.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -4004.

PRESSURE

The pressure transducer located in the unit measures treatment pressure; the average pressure is calculated and recorded each minute. The pressure reported in the Efficacy Data submenu (see Figure 9, The Clinical Menu Results series, on page 40) for a single session is the 95th centile pressure for mask-on time, excluding periods when the leak has exceeded 0.4 L/s (24 L/min). For selected time intervals (last week, last month, last 6 months or last year), the median of the daily 95th centile values is reported. Non-usage days are not included in calculations.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -4010.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	LEAK Leak is derived by analyzing inspiratory and expiratory airflows (via the flow sensor located in the unit). Theoretically, inspiratory and expiratory volumes should be equal. A net airflow greater than the expected mask vent flow is equal to the leak. Generally, a leak rate of more than 0.4 L/s (24 L/min) is associated with patient discomfort, disturbed sleep, and reduced efficacy of treatment. *If the leak exceeded 0.4 L/s (24 L/min) for more than 30% of the previous session, the following message will appear on the LCD:* **`High leak in last session.`** *The Leak Alert feature, if enabled, will alert the patient when mask leak exceeds 0.7 L/s (42 L/min) for more than 20 seconds. When the leak exceeds this level, the autotitrating algorithm ceases to perform optimally.* The leak reported in the Efficacy Data submenu (see Figure 9, The Clinical Menu Results series, on page 40) is the 95th centile value for mask-on time for each session, or the median 95th centile value for a selected time interval (last week, last month, last 6 months, or last year). Non-usage days are not included in calculations. RMD-063968 (AutoSet Spirit Clinician's Manual) at -4010.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	CLINICAL MENU RESULTS A comprehensive set of data is available in Clinical Menu, Results (Efficacy Data and Usage Data), as shown in Figure 9, The Clinical Menu Results series, on page 40. To navigate within the Efficacy or Usage Data sections, use: • the **Up/Down** key to scroll through items within a time series • the **Left** key to navigate between time series. The Used screen reports total hours the device has been used and the number of days the device was used compared to the total days since the hourmeter was last reset. Other statistics quoted include: • usage • pressure (95th centile value for mask-on time only) • leak (95th centile value for mask-on time only) • AHI, or apnea + hypopnea index (calculated per session) • AI, or apnea index (calculated per session) • HI, or hypopnea index (calculated per session). RMD-063968 (AutoSet Spirit Clinician's Manual) at -4012.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")

DOWNLOADING AND REVIEWING DATA USING AUTOSCAN

Data collected by the AUTOSET SPIRIT unit may be downloaded to AUTOSCAN software (available in the AUTOSCAN clinical interface kit) for review. Refer to the instructions in the *AutoScan Clinician's Manual* for details of downloading and reviewing data.

Data from an AUTOSET SPIRIT unit are presented in AUTOSCAN in the following ways:

- graphical display of usage data (time/date stamped) showing mask on/off events (Usage graph)
- 95th centile, median, and maximum values plus average and standard deviation values for leak and pressure for each session, with median values quoted for all parameters for nominated time intervals (Treatment Profile and Statistics display)
- apneas, hypopneas, AI, HI, and AHI on a per hour basis (Treatment Profile and Statistics display).
- 5 nights of Night Profile Data.

NOTE

The AutoSet Spirit clock resets at midday. To ensure that 5 nights of Night Profile Data are available, you must download the data before midday on the fifth day.

Additionally, use AUTOSCAN to:

- document patient notes
- generate and print reports.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -4015.

REMOTE DATA ACCESS

You can download data from an AUTOSET SPIRIT unit in your patient's home to AUTOSCAN software on your computer using modems. Both you and your patient require a modem set up for this purpose. The patient attaches the modem to the right communications port on the AUTOSET SPIRIT unit and to a phone line. You attach your modem to the serial port on your computer and a phone line. Refer to complete instructions for modem use in the *AutoScan Clinician's Manual*.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -4015.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 285

Claim Language [1.b.4]	
	[redacted] **ResLink (System 1)**

Claim Language [1.b.4]	ResMed Prior Art ("RPA")

The RESLINK is intended to be used with the ResMed AUTOSET® SPIRIT™ and S7™ ELITE systems. The RESLINK has two distinct functions:

- enhanced collection, storage and transfer of data (including pulse oximetry data), and
- upgrade of the AUTOSET SPIRIT and S7 ELITE software.

RMD-063198 (ResLink Clinician's Guide) at -3199.

Detailed Data

The following table sets out the detailed data available for viewing in AutoScan. A ninth parameter, the Apnea / Hypopnea Index (AHI) is also displayed. The AHI is calculated by adding together the total number of apneas and hypopneas that occurred in the preceding hour. The AHI is updated with each event, and reset every hour, increasing with the number of apneas.

The Pulse rate and SpO_2 readings are obtained from the oximeter.

Parameter	Minimum resolution	Range	Sampling frequency (hz)
Events	1 sec	0–180 sec	as each event occurs (maximum 2000 events/session)
Minute ventilation	0.1 L/min	0–180 L/min	0.5
Leak	0.02 L/sec	0–5 L/sec	0.5
Pulse rate	1 bpm	20–220	0.2
SpO_2	1%	40%–100%	1.0
Pressure	0.2 cmH_2O	-5–40 cmH_2O	0.5
Snore	n/a	Quiet–Loud	per breath
Flattening	n/a	Round–Flat	per breath

RMD-063198 (ResLink Clinician's Guide) at -3200.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")

DATA COLLECTION

To collect data from the AUTOSET SPIRIT or S7 ELITE, insert the SmartMedia card into the RESLINK.

***Note**: When you use the SmartMedia card with a new patient's flow generator, the ResLink deletes all information currently on the SmartMedia card.*

In addition to the comprehensive set of data available in the flow generator, the RESLINK collects and stores *Detailed Data*. Collection and storage of data occurs automatically during therapy. The 32-megabyte SmartMedia card (supplied with the RESLINK), can record and store up to 30 sessions of detailed data. If the one SmartMedia card is used for more than 30 sessions, the oldest data will be overwritten.

A maximum of 10 hours per session is recorded. If the duration of therapy is greater than 10 hours, the first 10 hours is retained. Each session is defined as taking place between noon of one day and noon of the following day.

After therapy, the patient can return the card to the clinician using the Mailback card provided with the RESLINK. Data stored on the SmartMedia card can be downloaded by the clinician for review and analysis. See the *AutoScan Clinician's Manual* for information on downloading and viewing detailed data.

RMD-063198 (ResLink Clinician's Guide) at -3200.

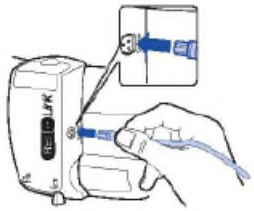
USING THE RESLINK

Connecting an Oximeter (optional)

Your clinician may have supplied an oximeter for use with the RESLINK. Connecting an oximeter to the RESLINK allows collection and storage of oximetry data (oxygen saturation and pulse rate).

1. Ensure that the sensor cable is properly connected to the Xpod connector.

2. Insert the oximeter plug into the RESLINK oximeter port.



The 'Oximeter Connected' message will be displayed on the LCD indicating successful connection of the oximeter to the RESLINK.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	RMD-063198 (ResLink User's Manual) at -3213-14. [redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 290

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]

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Exhibit 1024 - Page 291

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]

[redacted]

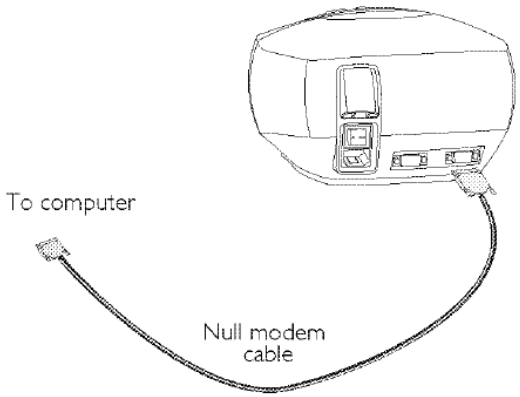
FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 293

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	 RMD-289749 (ResLink Launch Brochure) at -9749 and -9756. ResMed introduces ResLink™–the first truly modular sleep-disordered breathing (SDB) therapy management tool with significant benefits for the patient, sleep laboratory, prescribing physician, and equipment provider. The portable ResLink module simply clips onto ResMed's AutoSet Spirit™ system. ResLink captures and stores high-resolution patient compliance and efficacy data, including oximetry. This information is easily accessed and transferred via a 32MB SmartMedia™ card and then downloaded to a PC using ResMed's AutoScan™ software. RMD-289749 (ResLink Launch Brochure) at -9750. **Comprehensive efficacy data with oximetry** ResLink reports on significant parameters such as minute ventilation, snore, flattening, SpO_2, pulse rate, pressure response, leak, events, and AHI, providing visible insights into treatment efficacy. ResLink presents this efficacy information along with integrated oximetry data for simultaneous onscreen viewing and analysis. RMD-289749 (ResLink Launch Brochure) at -9751.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	 RMD-289749 (ResLink Launch Brochure) at -9755. **AutoScan 5.4 (System 1)** AUTOSCAN™ 5.4 has been developed to view summary data and detailed data obtained from the RESLINK™ via the SmartMedia™ card. Summary data and Night profile data obtained from the flow generator can also be viewed as in previous versions of AUTOSCAN. AUTOSCAN 5.4 has data collection and management capabilities that provide an adjunct for patient management. The flow generator systems intended to be used with AUTOSCAN 5.4 are the ResMed AUTOSET® SPIRIT™, S7™ ELITE, VPAP® III, VPAP III ST, VPAP III ST-A, and AUTOSET RESPOND™. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1269.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	FLOW GENERATOR COMPATIBILITY The following flow generators are compatible with AUTOSCAN 5.4: • AUTOSET SPIRIT • AUTOSET RESPOND • VPAP III, VPAP III ST, VPAP III ST-A, • S7 ELITE. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277. CONNECTING THE FLOW GENERATOR TO THE COMPUTER In order to download data into AUTOSCAN 5.4, your computer must be connected by cable to the flow generator. NOTES *If your flow generator is connected to a ResControl, you must disconnect the ResControl before connecting the flow generator to your computer for interfacing to AutoScan 5.4.* Plug the null modem cable into the PC connection port on the flow generator and into an available serial port at the back of your computer (COM1, COM2, COM3 or COM4).  Figure 2: Connecting the flow generator to the computer RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277 – 78.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	MANAGING PATIENT INFORMATION AUTOSCAN 5.4 allows you to record patient information, clinical details and notes in the patient file. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1297. Detailed and summary data from a patient's flow generator are stored on a SmartMedia card by the RESLINK. The SmartMedia card is removed and sent to the clinician at the end of the study period. The SmartMedia card is inserted into a SmartMedia card reader attached to the clinician's computer, and the data can then be downloaded and viewed in AUTOSCAN 5.4. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1301. The Detailed Data screen displays nine traces of data downloaded via the RESLINK from the flow generator. You can view data in the Detailed Data screen in increased detail or as a compact overview. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1303.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	The Detailed Data screen for that session will be displayed. The graph display area shows the downloaded data in the trace panels: • Events (s) • Minute Ventilation (L/min) • Leak (L/s) • Pulse Rate (bpm) • SpO_2 (%) • AHI (Events/hr) • Pressure (cm H_2O)[a] • Snore (Quiet to Loud)[a] • Flattening (Round to Flat)[a] • Respiratory rate (BPM).[b] a AUTOSET SPIRIT and S7 ELITE only [b] VPAP III series only NOTE *Pulse rate and SpO_2 are derived from the oximeter reading.* RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1304.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")

INTERPRETING AUTOSET DATA

NOTE *AutoSet Respond displays data only in the Usage Profile.*

APNEAS AND HYPOPNEAS

The AutoSet algorithm defines an apnea as a greater than 75% decrease in nasal ventilation for at least 10 seconds. An apnea is scored if the 2-second moving average ventilation drops below 25% of the recent average (time constant 100 seconds) for at least 10 consecutive seconds.

An Apnea Index (AI), shown in the *Treatment Profile* as a red bar, is derived for each session by dividing the total number of apneas that occurred by the total mask-on time.

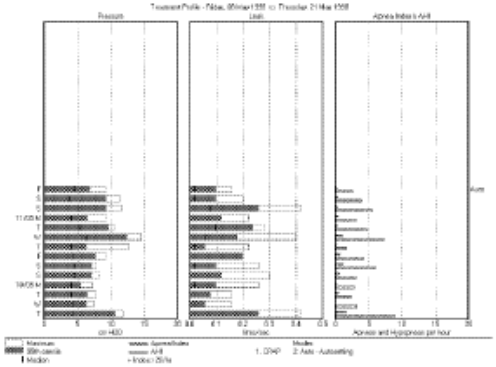


Figure 38: Treatment Profile details

The AI for a session or group of sessions may be viewed in the *Statistics* tab of AUTOSCAN 5.4.

Information on apneas is stored for the most recently accumulated five nights of data. They log the time during the session and duration of each apnea and display these as red "lollipops" on the Apnea Events and Duration graph in the *Night Profile*.

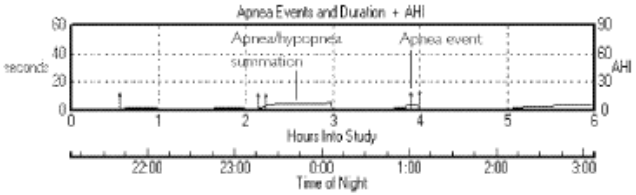


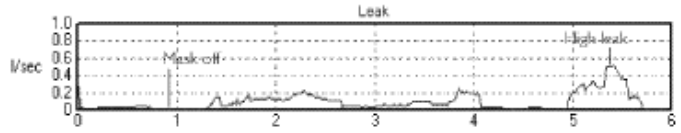
Figure 39: Apnea Events and Duration and AHI in the Night Profile

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1325.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	The AutoSet algorithm defines a hypopnea as a 50 to 75% decrease in nasal ventilation. A hypopnea is scored if the 8-second moving average ventilation drops below 50%, but not below 25%, of the recent average for 15 consecutive seconds. The recent average ventilation is calculated using a time constant of 100 seconds. Information on individual hypopneas is not displayed in the *Treatment Profile* but an apnea/hypopnea index (AHI) is calculated by dividing the total number of apneas + hypopneas that occurred in a session by the total mask-on time. The AHI for a given session is displayed as a blue bar in the *Treatment Profile* (see Figure 38). The AHI value for a session (or group of sessions) can also be viewed in *Statistics*. The *Statistics* tab in AUTOSCAN 5.4 displays hypopnea index (HI) values, in addition to AI and AHI values, for the nominated time interval. For the most recently accumulated five nights of data, a series of apnea/hypopnea summations is saved for each session. Each of these is the sum of the number of apneas and hypopneas the patient experienced within a one-hour interval. At the end of each hour of data collection, the maximum value of the summation is equivalent to an AHI for that hour as it is equal to the total number of apneas + hypopneas divided by one hour. The flow generator then resets the apnea + hypopnea count to zero. The apnea/hypopnea summation is plotted as a blue line on the Apnea Events graph in the *Night Profile* (Figure 39). At the end of the session, an AHI is calculated and displayed in the *Statistics* screen. NOTE *The AutoSet algorithm does not distinguish between a closed airway apnea (obstructive apnea) and an open airway apnea (central apnea). For this reason, it will not increase pressure in response to apneas once pressure has reached 10 cm H_2O. Pressure increases beyond 10 cm H_2O, in response to apnea alone, may invoke more apneas if they are central in nature by triggering the Hering-Breuer reflex.* LEAK MEASUREMENT NOTE *When assessing results, it is best to check the leak data first. Leaks greater than 0.4 L/sec affect the accuracy of other measurements.* Leak is measured by analysing inspiratory and expiratory volumes, which should be approximately equal, yielding an average airflow of 0 L/sec in the absence of mask leak. An average airflow greater than 0 L/sec is due to leak. Generally, a leak rate of more than 0.4 L/sec is associated with patient discomfort, disturbed sleep and reduced efficacy of treatment. A leak rate of 0.2 L/sec or less for the majority of a session signals a well-fitting mask. The median, maximum and 95th percentile leak for each session in a series are displayed in the *Treatment Profile* (see Figure 38). RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1326.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")

Median, 95th percentile and maximum leak are displayed for the nominated time interval in the *Statistics* tab of AUTOSCAN 5.4. A graph of leak as a function of time for each night is shown in the *Night Profile*.



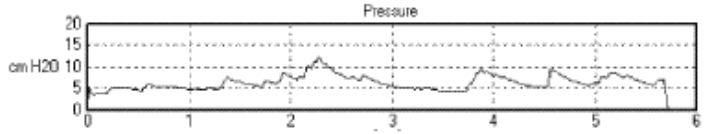
PRESSURE MEASUREMENT

The pressure transducer located in the AUTOSET SPIRIT and S7 ELITE calculates pressure at the mask.

The median, maximum and 95th percentile pressure delivered during each night in a series are displayed in the *Treatment Profile* (see Figure 38).

The AUTOSET SPIRIT and S7 ELITE continuously titrate the pressure delivered, based on inspiratory flow limitation, snore, and apnea.

The median, 95th percentile and maximum pressure data are displayed for the nominated time interval in the *Statistics* tab of AUTOSCAN 5.4. The pressure delivered to the patient each night is reported as a function of time in the pressure graph in the *Night Profile*.



MINUTE VENTILATION

Information from the VPAP III, VPAP III ST or VPAP III ST-A flow transducer, modified by an internal model of the mask vent flow, is used to calculate the minute ventilation. This is displayed as a 5-breath moving average.

The median, maximum and 95th percentile minute ventilation for each night in a series are displayed in the Treatment Profile, and for the nominated time interval in the Statistics tab.

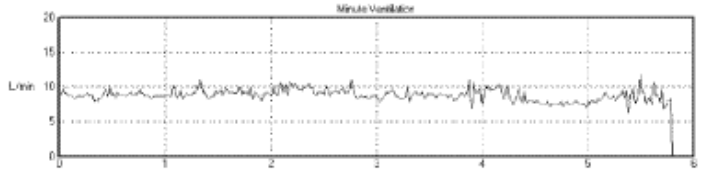


Figure 40 : Minute Ventilation graph in Night Profile screen

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1327.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")

INTERPRETING DETAILED DATA

Detailed data obtained from the SmartMedia card is displayed at the AUTOSCAN 5.4 Detailed Data tab. Each of the graphs in the Detailed Data screen represents a set of measurements of a different aspect of the patient's breathing. If there is no data in a section of the graph, the flow generator was not being used at that time. If the oximeter falls off or fails to make contact with the patient at any stage, the Pulse Rate and SpO_2 traces will be empty or show a zero reading. You will be alerted to this by a message during download (see Figure 21 above).

Session statistics for SpO_2, Pulse rate and Minute ventilation are included in the printed detailed data report.

AHI (APNEA/HYPOPNEA INDEX)

The apnea / hypopnea index for the AUTOSCAN 5.4 *Detailed Data* screen is calculated by adding together the total number of apneas and hypopneas that occurred in the preceding hour. The AHI is updated with each event, and reset every hour, increasing with the number of apneas. If it rises above 10 events/hr, check the leak and pressure. It may be that the patient is having a lot of central apneas.

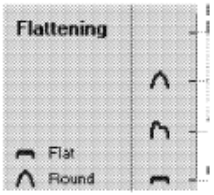
EVENTS

The *Events* graph displays the patient's apneas and hypopneas with an indicator at the point where they commence, and a number that indicates the duration (in seconds) of the event. AUTOSCAN 5.4 can log up to 2000 events per session.

Apneas are indicated with a red ball, and hypopneas with blue.

FLATTENING INDEX (AUTOSET SPIRIT AND S7 ELITE ONLY)

The Flattening Index graph is an indicator of trends in the patient's breathing. The Flattening Index graph in AUTOSCAN 5.4 displays measurements as being Flat, Flattening or Round



It is desirable that the results are rounded rather than flat. If the trace is too flat, check the leak and the pressure. If the patient is currently on CPAP mode, it is possible that they may benefit from changing to Autoset mode.

LEAK

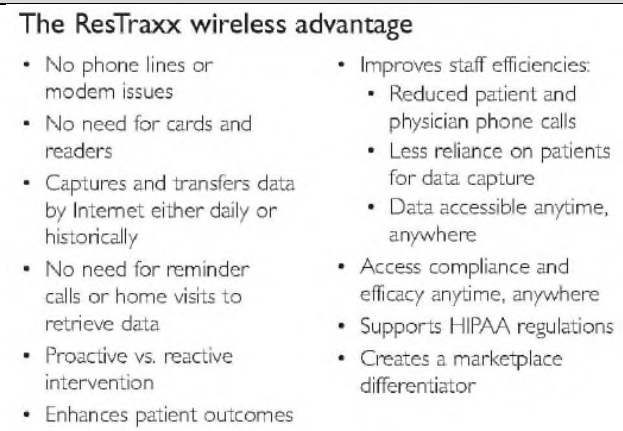
The RESLINK samples for leak every 2 seconds. While some leak is a natural part of therapy, it is recommended that the level of leak is below 0.4 L/sec. Higher leak will

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1307.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	affect treatment and compliance. A red line in the Leak graph indicates the 0.4 L/sec level. MINUTE VENTILATION Minute ventilation is a measure of the total volume breathed in (or out) within any 60 second period. It is calculated from respiratory rate x tidal volume. The RESLINK samples this information every 2 seconds. A normal range is from 6–12 L/min. Minute ventilation is used mainly to manage arterial CO_2 tension ($PaCO_2$) during therapy. For example, a patient with a $PaCO_2$ of 50mmHg and a Minute Ventilation of 5 L/min can be reduced to 45 mmHg (10% reduction) by raising Minute Ventilation to 5.5 L/min (10% increase). NOTE *Respiratory rate is the number of breaths per minute. Tidal volume is the volume of air breathed in or out in one breath.* PRESSURE (AUTOSET SPIRIT AND S7 ELITE ONLY) The RESLINK samples pressure every 2 seconds. The trace displayed in the Detailed Data screen is the calculated delivered pressure. If this differs markedly from the pressure set on the flow generator, check that the device is functioning correctly. The trace for Pressure will show any changes to the pressure setting on the flow generator. In Autoset mode, the trace will show increases or decreases in line with apnea or hypopnea events, or snore. If the pressure trace is constant, this would indicate that the flow generator is in CPAP mode. If the pressure trace is changing with time, this would indicate that the flow generator is in Autoset mode. PULSE RATE An average pulse rate should be between 60–80 bpm. Typically, an apnoea will increase the patient's pulse rate. Zoom in on any part of the trace (see "Changing the scale" above) to see the cardiac response in detail. The pulse rate is sampled every second by the RESLINK. RESPIRATORY RATE (VPAP III SERIES ONLY) Respiratory rate is sampled once every 2 seconds. The displayed rate is an average of the previous 5 breaths. The range is 0–60 bpm (breaths per minute). SNORE (AUTOSET SPIRIT AND S7 ELITE ONLY) Every breath is monitored for snore. However, the trace shows the rolling average for the last 5 breaths as the *Snore* graph is concerned with trends rather than measuring the individual snore. If the flow generator is functioning properly, there should not be much occurrence of snore. Snore is measured in AUTOSCAN 5.4 on a scale of Quiet to Loud. SpO_2 SpO_2 measures oxygen saturation in the patient's blood. The SpO_2 trace in AUTOSCAN 5.4 has a red indicator line at 90% to show at a glance if the patient is within acceptable limits. This line makes it easy to see where desaturations are occurring, and to connect their occurrence with apnea events. SpO_2 is measured every second by the RESLINK. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1308.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	ResTraxx (including RDC) (System 2) ResTraxx™ allows the wireless transfer of information from a continuous positive airway pressure (CPAP) unit to a clinician at a remote location via a two-way pager network. ResTraxx is intended to be used with ResMed S7™ Elite, AutoSet® Spirit™ , AutoSet® Respond™ , and VPAP® III flow generator systems on adults with obstructive sleep apnea. RMD-062642 (ResTraxx Quick Reference Guide) at -2642. [redacted]

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted] ResTraxx is a first-of-its-kind wireless communication device that attaches easily to the back of ResMed flow generators. The ResTraxx system captures, transfers, and stores compliance and efficacy data without wires, phone lines, modems, or data cards. ResTraxx is an elegant system that brings patient usage and treatment efficacy data to your fingertips instantly. RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	 RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

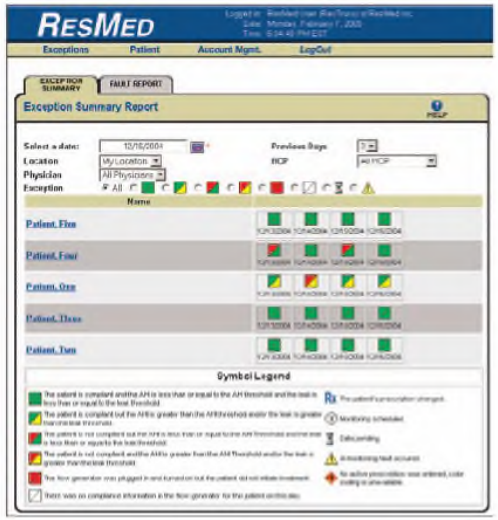
[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.4]	ResMed Prior Art ("RPA")

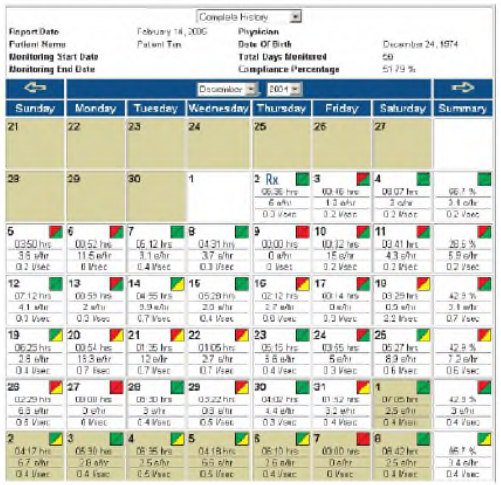
Exception Reporting

Enhance productivity and manage patients more efficiently. **Exception Reporting identifies and highlights those patients who fall below desired usage thresholds or have issues with mask leak or AHI.** This feature enables you to focus your efforts only on those patients who require intervention and respond proactively to potential problems. The simple color-coded alert system helps you identify exception patients quickly and easily.



Efficacy + Leak + Usage Data

The ResTraxx Data Center displays data on a daily basis in a calendar format enabling you to see daily or weekly trends of adherence problems before compliance is truly compromised. Early intervention and ongoing follow-up is considered critical, especially during the first month of CPAP acclimation, to determine long-term compliance rates.[2]



Want more details on therapy results? Click on the calendar day in question, and a therapeutic report will display additional clinical data regarding the patient's usage for that day.

RMD-063327 (ResTraxx Patient Management Brochure) at -3328.

[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	[redacted]
	Additional Citations "Several factors have been identified as important in attempting to maximize long-term compliance. Apparently, self-reported hours of use often overestimate actual hours of use,4 measured by hour meters integrated with the CPAP unit. Improvements have taken place over the years, including the

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	development of hour meters that measure not just time on of the unit, but actual hours at "mask on" pressure, to ascertain hours of use at the most effective pressure. Further attempts at documenting compliance rates have focused on integral chips within the CPAP units, which collect data on a nightly basis at effective pressures, and store these data over a 1- to 12-month period. Subsequently, the data can be downloaded by the appropriate treatment professional for evaluation, and appropriate steps taken to maximize use." Lankford, 163. "The present study evaluates a further innovative and evolutionary development in the collection and reporting of compliance data, using wireless and Internet technologies to transmit clinical data. Several parameters of this wireless reporting technology are assessed to determine the accuracy of transmitting data in this modality as compared to the internal chips in CPAP units. In some cases, clinical measures for evaluation included therapeutic data collected by the CPAP units, such as time, median leak, and the apnea-hypopnea index. Although primarily collected to evaluate transmission accuracy, these data are potentially available to evaluate therapeutic efficacy, although this was not undertaken here. "In brief, the purpose of this study was to examine the accuracy and reproducibility of subject data wirelessly transmitted to a remote site and to compare the data to traditionally collected data either from the ResMed S6 CPAP (K#961783) or the ResMed AutoSet T (K#980721) via download." Lankford, 163. "*CPAP technology* "All subjects were set up using commercially available CPAP devices with an integrated computer chip that collects compliance data. This method for the collection of compliance data is a proven and accepted approach that has been in widespread use for several years. The present study used these data, rather than a created data set, because the wireless data transmission device was developed to access existing data sets stored in the internal flow generator's computer chip. "Fourteen of the patients utilized a CPAP device that collects both compliance and efficacy data. At the Atlanta site, all patients used a Resmed S6 Elite Flow Generator that collects compliance and usage-related data. In Boston and Buffalo, the patients used a Resmed Auto Set T Flow Generator, which collects usage/ compliance data as well as therapeutic data that measure efficacy. The S6 Elite provides continuous positive airway pressure at a preset

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	level determined by titration. The Auto-Set T provides either fixed pressure in CPAP mode or delivers variable pressure levels that are determined using an algorithm that adjusts pressure according to inspiratory flow. As a result, users will experience variations in pressure on a night-to-night basis, as well as throughout the night depending on changes in sleep staging and position. For purposes of this study, the Auto-Set T devices were used in fixed pressure CPAP mode only." Lankford, 164. "Efficacy measures included indices of mask leak, along with the apnea–hypopnea index, among others. Efficacy data are available only from the ResMed's Auto-Set T flow generator, which was not used for 7 of the subjects. A complete list of all compliance and efficacy parameters is found in the Results section." Lankford, 166. "Other potential uses include ambulatory blood pressure monitoring and pulse oximetry." Lankford, 168. If the Judge or Jury finds that RPA does not disclose this claim limitation, this claim is still rendered obvious by modifying or combining RPA with other references or the knowledge of a POSITA. A POSITA would have recognized, or at least found it obvious, that the RPA includes a processor for calculating, among other things, apneas, hypopneas, and AHI, and various statistics within the collected sensor data, such as 95th percentile, maximum, minimums, and median values as was known in the art. Also, to the extent not disclosed, it would have been obvious to incorporate the processing of pulse oximetry sensor data received via ResLink into the main processor of the PAP device to which it is connected. Such a modification would have been an obvious implementation detail to avoid the need for the additional processor and connectors of the ResLink component, and simplification of the overall system. It was also well-known, as established for limitations 1.a and 1.b.3, for a processor of a CPAP device to receive both airflow and pulse oximetry sensor data. *See, e.g.*, Westbrook [0161]. As an example of the knowledge of a POSITA, U.S. Patent No. 5,704,345 to Berthon-Jones, discloses embodiments of a CPAP machine having a flow sensor, and use of the flow sensor data to detect and monitor apneas, airway patency, and obstruction, and adjustment of CPAP treatment in response to the detected events. *See, e.g.*, Berthon-Jones, FIGs 1-3, 16, 1:6-15, 7:37-8:4, 8:31-40 (flow sensor at output of turbine), 8:65-9:58, claim 1. Berthon-Jones also discloses that the CPAP device can be used for treatment or purely a diagnostic implementation in which measurements of

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	apneas, patency, and partial obstruction are logged, and the data "provides the physician with the ability to diagnose conditions such as Obstructive Sleep Apnea Syndrome and Upper Airway Resistance syndrome." *Id.*, 7:31-35, 18:3-17. Berthon-Jones discloses, for example: "The dangers of obstructed breathing during sleep are well known in relation to the Obstructive Sleep Apnea (OSA) syndrome. Apnea, hypopnea and heavy snoring are recognised as causes of sleep disruption and risk factors in certain types of heart disease. More recently it has been found that increased upper airway resistance (Upper Airway Resistance syndrome) during sleep without snoring or sleep apnea also can cause sleep fragmentation and daytime sleepiness. It is possible there is an evolution from upper airway resistance syndrome to sleep apnea, accompanied by a worsening of clinical symptoms and damage to the cardiovascular system. "The common form of treatment of these syndromes is the administering of Continuous Positive Airway Pressure (CPAP). The procedure for administering CPAP treatment has been well documented in both the technical and patent literature. Briefly stated, CPAP treatment acts as a pneumatic splint of the airway by the provision of a positive pressure, usually in the range 4-20 cm H2 O. The air is supplied to the airway by a motor driven blower whose outlet passes via an air delivery hose to a nose (or nose and/or mouth) mask sealingly engaged to a patient's face. An exhaust port is provided in the delivery tube proximate to the mask. More sophisticated forms of CPAP, such as bi-level CPAP and autosetting CPAP, are described in U.S. Pat. Nos. 5,148,802 and 5,245,995 respectively. "Various techniques are known for sensing and detecting abnormal breathing patterns indicative of obstructed breathing. U.S. Pat. No. 5,245,995, for example, describes how snoring and abnormal breathing patterns can be detected by inspiration and expiration pressure measurements while sleeping, thereby leading to early indication of preobstructive episodes or other forms of breathing disorder. Particularly, patterns of respiratory parameters are monitored, and CPAP pressure is raised on the detection of pre-defined patterns to provide increased airway pressure to, ideally, subvert the occurrence of the obstructive episodes and the other forms of breathing disorder." Berthon-Jones, 1:41-2:10. "FIG. 1 is a flow diagram of the basic methodology of one embodiment. The first step 10 is the measurement of respiratory flow (rate) over time. This information is processed in step 12 to

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	generate Index values to be used as qualitative measures for subsequent processing. Step 14 detects whether an apnea is occurring by comparison of the Breathing Index with a Threshold value. "If the answer in step 14 is "Yes", an apnea is in progress and there then follows a determination of patency in step 20. If there is patency of the airway, a central apnea with an open airway is occurring, and, if desired, the event is logged in step 22. If the result of step 20 is that the airway is not patent, then a total obstructive apnea or a central apnea with closed airway is occurring, which results in the commencement or increase in CPAP treatment pressure in step 18. If desired, step 18 may include the optional logging of the detected abnormality. "If the answer in step 14 is "No", the Obstruction Index is compared with another Threshold value in step 16, by which the determination of obstruction of the airway is obtained. If "Yes" in step 16, then there is a partial obstruction, and if "No", there is no obstruction (normalcy). "Thus step 18 applies in the case of a complete or partial obstruction of the airway with a consequential increase in CPAP treatment pressure. In the instance of a central apnea with patent airway (steps 20, 22) or normal breathing with no obstruction, the CPAP treatment pressure rather is reduced, in accordance with usual methodologies that seek to set the minimal pressure required to obviate, or at least reduce, the occurrence of apneas. The amount of reduction in step 17 may, if desired, be zero." Berthon-Jones, 6:66-7:29, FIG. 1. *See also* limitation 1.a and use of sensor data from the pulse oximeter for determination of sleep disorder related information. RPA Systems 1-2 disclose a processor that calculates various parameters based on data from a flow sensor and data from a pressure sensor. To the extent not disclosed by RPA Systems 1-2, it would have been obvious to calculate centile statistics for the oxygen saturation data (which CleveMed has alleged practice this limitation). It would have also been obvious to a POSITA, given the RPA disclosures to look to disclosures like Westbrook for implementation details for sleep event calculations and collection of efficacy data. As recognized in Westbrook, "the 'gold standard' for diagnosis of sleep disorders" uses sensor signals including respiratory airflow, measured by an airflow sensor, for example, and oxygen saturation, measured by a pulse oximeter, for example. Westbrook, [0010]. A POSITA implementing the RPA systems would have been motivated to strive for this "gold standard" to assist the monitoring health care provider by incorporating both an airflow sensor and pulse oximeter sensor, and using the signals from both sensors to "calculat[e], based in

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	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." *See also* Roux, 321 ("level I PSG is the gold standard for diagnosing OSA and guiding treatment options, and it is against this standard that other options must be compared."), Table 3 (showing APAP studies including calculation of AHI and oxygenation). **'269 Patent** In addition, the '269 patent does not disclose how to "calculate[e], 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." For example, the '269 patent disclosure merely provides: "One or more sensors are used to develop the data or signals used in the present invention for determining a quantitative level of severity of a subject's sleeping disorder and/or symptoms." '269 patent, 18:51-54. "The signals from the one or more sensors used in various embodiments of the present invention are preferably analyzed using a processor and software that can quantitatively estimate or determine the severity of the subject's sleeping disorder or symptoms." '269 patent, 18:60-64; see also 19:46-49 ("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 more sensors described herein.") The '269 patent does not mention calculating an "index of a level of severity of the subject's sleep disorder symptoms," and only makes a passing reference to "obtaining respiratory disturbance index to diagnose sleep apnea" in the Background section. '269 patent, 1:51-54. In addition, neither "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" are terms of art, nor would a POSITA recognize these terms to have well-defined boundaries. As noted above, the '269 patent fails to provide even a single example of a parameter within the scope of these terms, or how to calculate one.

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	Thus, at least commensurate in scope with the '269 patent that discloses that the level of severity of a subject's sleeping disorder or symptoms is determined using signals or data from the sensors, RPA discloses or renders obvious this limitation. **Additional Prior Art – Knowledge of a POSITA** Alternatively, this claim limitation would have been obvious because it would have been obvious to use the oxygenation information from the pulse oximeter in combination with the respiratory flow parameters to identify hypopneas, which are part of the hypopnea index and apnea-hypopnea index (AHI) already calculated by the microprocessor of the AutoSet Spirit. This obvious modification would result in a calculation of AHI that is based in part ***on both*** respiratory airflow data and pulse oximetry sensor data measured during use of the PAP device. Such a modification would have been obvious in view of the knowledge of a POSITA, and also as disclosed by Westbrook, regarding the benefits of using oxygen desaturation as an additional check on hypopnea identification. Such a modification would have also been obvious to a POSITA where having an additional sensor input to corroborate the sensor data from another sensor would have been desirable in a system like a PAP device that is collecting data that might impact a patient's medical treatment. A POSITA would have been familiar with the history, development, and research in the field of sleep apnea, including the varying definitions of apneas, hypopneas, and indices including "apnea index," "apnea-hypopnea index," and "respiratory disturbance index," the use of a commonly known handful of types of sensor data to identify, determine, or calculate such parameters, and the types of well-known sensors to obtain such data. For example, Guilleminault was considered a leading clinician and researcher on sleep apnea, and published numerous well-known papers and studies that a POSITA would have been familiar with. Guilleminault explained that "[a]n apnea has been defined as a cessation of airflow at the level of the nostrils and mouth lasting at least ten seconds," and that a "sleep apnea syndrome is diagnosed if, during seven hours of nocturnal sleep, at least 30 apneic episodes are observed in both [REM] and [NREM] sleep … ." Guilleminault 1978, at 2; *see also* Guilleminault 2004. Guilleminault also taught that "the use of an 'Apnea Index,' ie, the number of sleep apneas per sleep-hour, frequently gives a better indication of the seriousness of the disorder," and that "Patients diagnosed with 'sleep apnea syndrome' always presented an abnormally elevated apnea index and a similar predominant type of apnea (central, mixed, or obstructive)." *Id.* In 2004, Guilleminault observed that "[v]arious criteria have been utilized to define hypopnea, including (1) greater than 50% reduction in the amplitude of breathing from baseline during sleep, or

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	(2) less than 50% reduction in the amplitude of breathing during sleep *associated with either greater than 3% oxygen desaturation* or an arousal, or (3) greater than 30% reduction in the amplitude of breathing during sleep or 30% reduction in the nasal cannula-pressure transducer curve *associated with oxygen desaturation greater than or equal to 4%*, and (4) event duration greater than or equal to 10 seconds." Guilleminault 2004, at 615. A POSITA would have known that oxygen desaturation and arousals could be determined (and typically were determined) using pulse oximetry sensor data. *See, e.g.*, AASM Manual, page 45 ("The sensor for detection of blood oxygen is pulse oximetry"). According to Guilleminault, "OSA can be classified based on the apneas plus hypopneas per hour of sleep index (AHI) or respiratory disturbance index ([RDI] apneas plus hypopneas plus respiratory event-related arousals per hour of sleep) into mild (5<AHI or RDI<15); moderate (15<AHI or RDI<30); or severe (AHI or RDI>30)." *Id.* at 615-616. As was also known in the art, and recognized for example, in Westbrook, discussed above, polysymnography was known as the standard and routine methodology for diagnosing obstructive sleep apnea. Guilleminault 2004, at 616. Guilleminault also describes the approach of "split-night full-night polysymnography" in which "the first half of the night is spent in diagnostic recording, with the second half of the night used for CPAP titration." *Id.* This "split-night study requires the recording and analysis of the same parameters as a standard diagnostic full-night polysymnography" (Guilleminault 2004, at 616) which a POSITA would have recognized includes both pulse oximetry sensor data to track oxygen desaturation, and air flow sensor data, as shown in the below graph:

Claim Language [1.b.4]	ResMed Prior Art ("RPA")

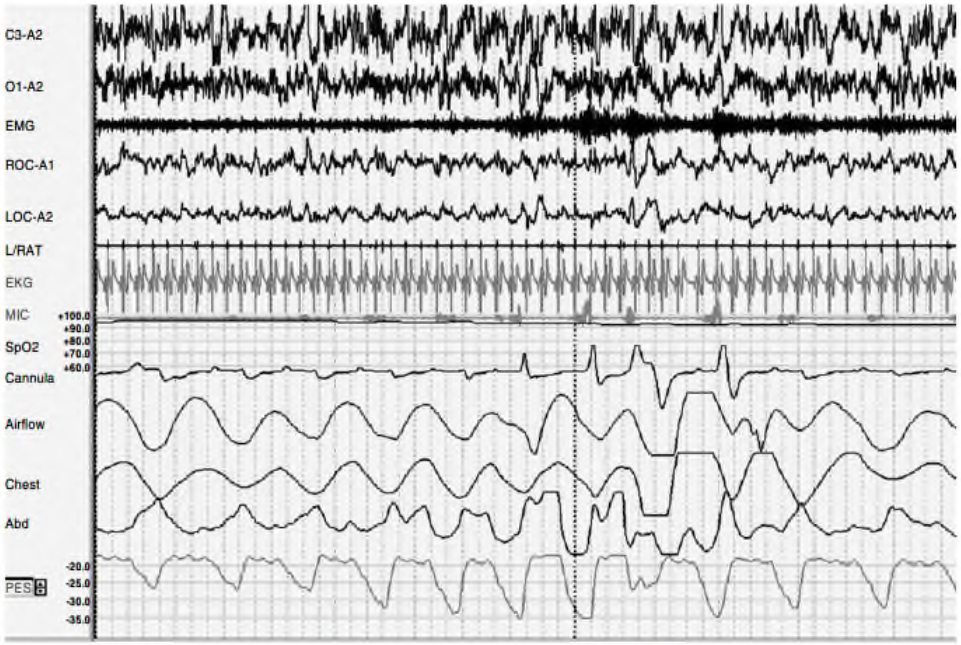


Fig. 1. Polysomnogram of a patient with OSA. The cannula and airflow channels demonstrate reduction in oronasal airflow consistent with a hypopnea. Paradoxical respiration is noted on the chest and abdominal effort channels. Esophageal pressure crescendo with Pes reversal associated with an arousal is seen.

Guilleminault 2004, at 617 (showing SpO2 and Airflow sensor data).

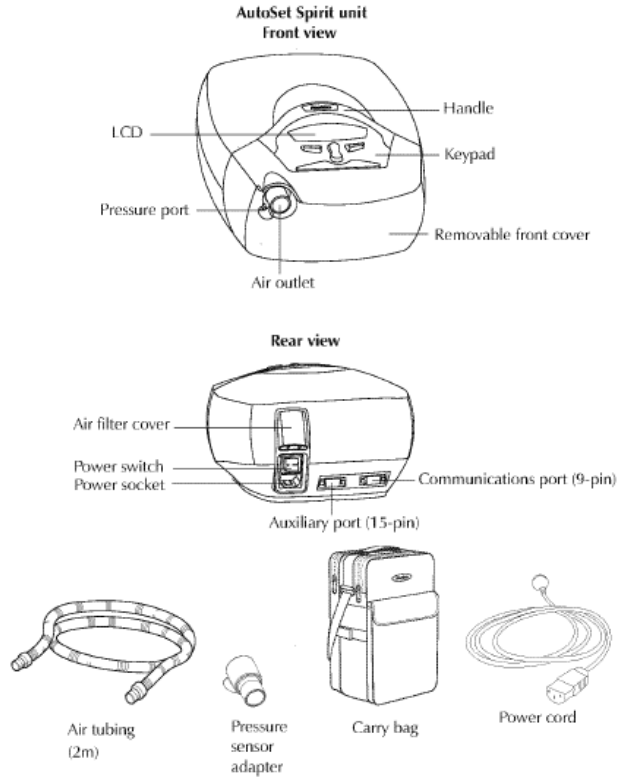
Guilleminault also recognized, as was known in the art, that "Autotitrating positive airway pressure devices detect snoring, apneas, hypopneas, flow limitation, and changes in airway resistance or impedance, which are then interpreted by a central processing unit based on specific diagnostic algorithms to determine the resultant voltage for the autotitrating positive airway pressure blower in response to these signals." Guilleminault 2004, at 622. It was well-known to a POSITA that the handful of known sensors and their corresponding data used to detect apneas and hypopneas, for example, included flow sensors and blood oxygen level sensors, such as pulse oximeters. In particular, a POSITA would have recognized or at least found it obvious to include sensors and

Claim Language [1.b.4]	ResMed Prior Art ("RPA")
	processing features for the detection of hypopneas, which (as discussed above) relied on oxygen desaturation information that a POSITA would have found it obvious to obtain from a pulse oximeter, as was well-known in the art. *See, e.g.,* AASM Manual, Section 4. As discussed above for limitations 1.a and 1.b.3, Westbrook discloses the claimed combination of an airflow sensor and a pulse oximeter sensor, along with calculation of parameters such as those CleveMed has allege in its contentions practice this limitation. It would have been obvious to arrive at this claim in view of the knowledge of a POSITA as discussed above, and further in view of Westbrook for the reasons discussed for limitations 1.a and 1.b.3. **CleveMed's Infringement Contentions** CleveMed's infringement contentions allege that this claim limitation is practiced by recording "95th percentile, max and median of the 1-minute average value of SpO2." Final Infr. Cont., Chart I, 21-22. CleveMed's contentions, for example, do not identify a single parameter calculated "based in part on *both* the respiratory airflow data and the pulse oximetry sensor data" as required by the claim. However, if it is determined that merely determining mathematical statistics from the pulse oximetry data alone satisfies this claim limitation, the RPA discloses or at least renders obvious such a feature. *See, e.g.,* AutoScan 5.4 Clinician's Manual (RMD-311263) at 1-4, 7-8, 27, 33-34 (Detailed Data), 35-36, 39, 45-47 (Summary Data), 52-55; ResLink User's Manual (RMD-063203) at 5-6; ResLink Launch Brochure (RMD-289749) at 289751; [redacted] If a judge or jury determines RPA does not disclose this limitation, it would have been a mere implementation detail to determine statistics from collected pulse oximetry data, and would have been an obvious process to apply to the collected pulse oximeter data by a processor both within a PAP device and an external processor. For example, a POSITA would have recognized that the collected pulse oximeter data alone would be most useful in the form of statistics such as max, median, and 95th percentile to the monitoring health care provider, as opposed to viewing only the raw sensor data points. A POSITA would have also found it useful to calculate such statistics at the flow generator, for example, such that the subject could view such statistics in the menus provided at the flow generator. *See also, e.g.*, RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures; RMD-0318396 Specimen Photographs; [redacted]

Claim Language [1.c]	ResMed Prior Art ("RPA")
[1.c] a mask or a nasal cannula; and	RPA Systems 1-2 disclose a mask. *See, e.g.*, 1.pre. For example, RPA discloses: RMD-0318396 at -0318411, *see also* -0318412-13. **ResMed AutoSet Spirit (System 1-2)** The ResMed AUTOSET® SPIRIT™ system is designed to provide continuous positive airway pressure (CPAP) therapy to patients with obstructive sleep apnea (OSA). Patients with OSA experience recurrent obstruction of their upper airway (apneas) due to relaxation of the tongue and soft palate while they sleep. Common symptoms are associated with poor sleep quality and may include excessive daytime sleepiness and tiredness, as well as diminished concentration and memory loss. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3974.

Claim Language [1.c]	ResMed Prior Art ("RPA")
	The AUTOSET SPIRIT system is intended for the treatment of obstructive sleep apnea (OSA) in adult patients. Data collection capabilities also assist in the management of continuous positive airway pressure (CPAP) treatment. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3976. [redacted] The AUTOSET SPIRIT system is designed for clinical use and home treatment of adult patients with obstructive sleep apnea (OSA). The system has two therapy modes for treating OSA: **CPAP** mode and **AutoSet** mode. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980. CPAP MODE In CPAP mode, the AUTOSET SPIRIT unit provides fixed-pressure room air via tubing to the mask worn by your patient. The continuous air stream "splints" open the upper airway, preventing airway collapse. AUTOSET SPIRIT delivers pressure within the range 4 to 20 cm H_2O. To make the beginning of treatment more comfortable, you may set a ramp so the pressure starts low and gradually increases to full treatment pressure over the ramp time. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.

Claim Language [1.c]	ResMed Prior Art ("RPA")
	AUTOSET® MODE The treatment pressure required by your patient may vary through the night, and from night to night, due to changes in sleep state, body position, and airway resistance. In AutoSet mode AUTOSET SPIRIT provides only sufficient pressure to maintain upper airway patency. You can set the minimum and maximum allowable treatment pressures. The unit analyzes the state of the patient's upper airway on a breath-by-breath basis and delivers pressure within the allowed range according to the degree of obstruction. The AutoSet algorithm adjusts treatment pressure as a function of three parameters: inspiratory flow limitation, snore, and apnea. The flow sensor, located in the AUTOSET SPIRIT unit, enables detection of inspiratory flow limitation and apneas. The pressure sensor, also located in the unit, enables measurement of pressure and snore. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.

Claim Language [1.c]	ResMed Prior Art ("RPA")
	COMPONENTS OF THE AUTOSET® SPIRIT™ SYSTEM The following are supplied as part of an AUTOSET SPIRIT system.  Figure 4: AutoSet Spirit system components RMD-063968 (AutoSet Spirit Clinician's Manual) at -3983.

Claim Language [1.c]	ResMed Prior Art ("RPA")
	ACCESSORIES The following accessories may be purchased separately. AUTOSET SPIRIT ACCESSORIES Air tubing 9ft10in (3m) HUMIDIFIER ACCESSORIES (HUMIDAIRE and ResMed PASSOVER only) Pressure sensor line Short air tubing 7.5in (19cm) for HumidAire connection Medium air tubing 21in (52cm) for humidifier connection RMD-063968 (AutoSet Spirit Clinician's Manual) at -3984.

Claim Language [1.c]	ResMed Prior Art ("RPA")
	HUMIDIFIERS A humidifier may be required if your patient experiences dryness of the nose, mouth, or throat. The following humidifiers (supplied separately) are compatible for use with AUTOSET SPIRIT units. HUMIDAIRE 2i heated humidifier HUMIDAIRE™ heated humidifier ResMed PASSOVER humidifier RMD-063968 (AutoSet Spirit Clinician's Manual) at -3984.

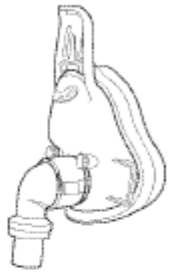
Claim Language [1.c]	ResMed Prior Art ("RPA")

MASK SYSTEMS

The following ResMed mask systems (supplied separately) are recommended for use with the AUTOSET SPIRIT system.

ULTRA MIRAGE™ MASK

MIRAGE® FULL FACE MASK



FULL FACE MASK SERIES 2

MIRAGE® MASK

MODULAR MASK

WARNING

For therapy in **AutoSet** mode, use one of the recommended ResMed masks. The AutoSet algorithm has appropriate parameters for these masks.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -3985.

[redacted]

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Claim Language [1.c]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
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Claim Language [1.c]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
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Claim Language [1.c]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.c]	ResMed Prior Art ("RPA")
	[redacted] **ResLink (System 1)** The RESLINK is intended to be used with the ResMed AUTOSET® SPIRIT™ and S7™ ELITE systems. The RESLINK has two distinct functions: • enhanced collection, storage and transfer of data (including pulse oximetry data), and • upgrade of the AUTOSET SPIRIT and S7 ELITE software. RMD-063198 (ResLink Clinician's Guide) at -3199. [redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.c]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.c]	ResMed Prior Art ("RPA")
	ResMed introduces ResLink™–the first truly modular sleep-disordered breathing (SDB) therapy management tool with significant benefits for the patient, sleep laboratory, prescribing physician, and equipment provider. The portable ResLink module simply clips onto ResMed's AutoSet Spirit™ system. ResLink captures and stores high-resolution patient compliance and efficacy data, including oximetry. This information is easily accessed and transferred via a 32MB SmartMedia™ card and then downloaded to a PC using ResMed's AutoScan™ software. RMD-289749 (ResLink Launch Brochure) at -9750. **Comprehensive efficacy data with oximetry** ResLink reports on significant parameters such as minute ventilation, snore, flattening, SpO_2, pulse rate, pressure response, leak, events, and AHI, providing visible insights into treatment efficacy. ResLink presents this efficacy information along with integrated oximetry data for simultaneous onscreen viewing and analysis. RMD-289749 (ResLink Launch Brochure) at -9751.

Claim Language [1.c]	ResMed Prior Art ("RPA")
	 RMD-289749 (ResLink Launch Brochure) at -9755. **AutoScan 5.4 (System 1)** AUTOSCAN™ 5.4 has been developed to view summary data and detailed data obtained from the RESLINK™ via the SmartMedia™ card. Summary data and Night profile data obtained from the flow generator can also be viewed as in previous versions of AUTOSCAN. AUTOSCAN 5.4 has data collection and management capabilities that provide an adjunct for patient management. The flow generator systems intended to be used with AUTOSCAN 5.4 are the ResMed AUTOSET® SPIRIT™, S7™ ELITE, VPAP® III, VPAP III ST, VPAP III ST-A, and AUTOSET RESPOND™. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1269.

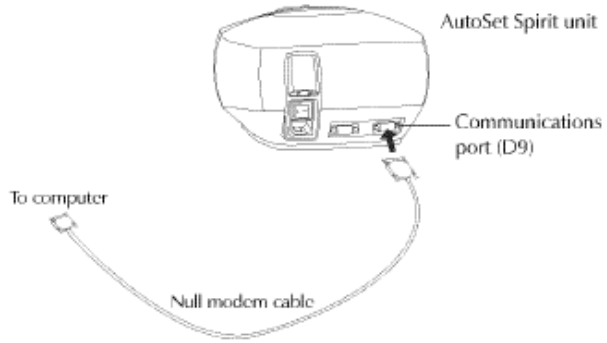
Claim Language [1.c]	ResMed Prior Art ("RPA")
	FLOW GENERATOR COMPATIBILITY The following flow generators are compatible with AUTOSCAN 5.4: • AUTOSET SPIRIT • AUTOSET RESPOND • VPAP III, VPAP III ST, VPAP III ST-A, • S7 ELITE. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277. **ResTraxx (including RDC) (System 2)** ResTraxx™ allows the wireless transfer of information from a continuous positive airway pressure (CPAP) unit to a clinician at a remote location via a two-way pager network. ResTraxx is intended to be used with ResMed S7™ Elite, AutoSet® Spirit™ , AutoSet® Respond™ , and VPAP® III flow generator systems on adults with obstructive sleep apnea. RMD-062642 (ResTraxx Quick Reference Guide) at -2642. [redacted]

Claim Language [1.c]	ResMed Prior Art ("RPA")
	[redacted] *See also*, e.g., RMD-0318396 Specimen Photographs; [redacted] *see, e.g.*, limitation 1.b.3, 1.b.4).

Claim Language [1.d]	ResMed Prior Art ("RPA")
[1.d] a module transceiver adapted for receiving and transmitting the sleep disorder symptom data of the level of severity and/or the index of the level of severity of the subject's sleep disorder symptoms to a remote location.	RPA discloses, or at least renders obvious, a module transceiver adapted for receiving and transmitting the sleep disorder symptom data of the level of severity and/or the index of the level of severity of the subject's sleep disorder symptoms to a remote location. *See, e.g.*, limitation 1.pre, 1.b.4. RPA System 1 (AutoScan 5) discloses, or at least renders obvious, this limitation for at least the same reasons CleveMed alleges the accused products practice this limitation. RPA System 1 discloses, for example, the modem is a "module transceiver adapted for receiving and transmitting [data calculated by the processor] to a remote location." *See, e.g.*, [redacted] AutoScan 5.4 Clinician's Manual (RMD-311263) at 2-5, 11-23, 27, 45-47, 53-55, 66 ("Modem Instructions For the Patient"); [redacted] AutoSet Spirit Clinician's Manual (RMD-063968) at 42. The RPA System 1 discloses at least under CleveMed's infringement allegations for this limitation that the received and transmitted data is "the sleep disorder symptom data of the level of

Claim Language [1.d]	ResMed Prior Art ("RPA")
	severity and/or the index of the level of severity of the subject's sleep disorder symptoms." *See* limitation 1.b.4. RPA System 2 (ResTraxx) renders this limitation obvious. RPA System 2 discloses "a module transceiver adapted for receiving and transmitting [data calculated by the processor] to a remote location. For example, the Restraxx module ([redacted] 1) is "a module transceiver adapted for receiving and transmitting the sleep disorder symptom data of the level of severity and/or the index of the level of severity of the subject's sleep disorder symptoms to a remote location." *See, e.g.*, RDC User's Manual (RMD-306688) at 4-6; [redacted] ResTraxx Patient Management Brochure (RMD-063327) at 1; *see also* ResTraxx Wireless Patient Monitoring Atlas (RMD-063341)(RMD-129625); [redacted] The RPA System 2 renders obvious, at least under CleveMed's infringement allegations for this limitation, that the received and transmitted data is "the sleep disorder symptom data of the level of severity and/or the index of the level of severity of the subject's sleep disorder symptoms." *See* limitations 1.a, 1.b.4. For example, RPA discloses: **ResMed AutoSet Spirit (System 1-2)** The ResMed AUTOSET® SPIRIT™ system is designed to provide continuous positive airway pressure (CPAP) therapy to patients with obstructive sleep apnea (OSA). Patients with OSA experience recurrent obstruction of their upper airway (apneas) due to relaxation of the tongue and soft palate while they sleep. Common symptoms are associated with poor sleep quality and may include excessive daytime sleepiness and tiredness, as well as diminished concentration and memory loss. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3974.

Claim Language [1.d]	ResMed Prior Art ("RPA")
	The AUTOSET SPIRIT system is intended for the treatment of obstructive sleep apnea (OSA) in adult patients. Data collection capabilities also assist in the management of continuous positive airway pressure (CPAP) treatment. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3976. [redacted] REMOTE DATA ACCESS You can download data from an AUTOSET SPIRIT unit in your patient's home to AUTOSCAN software on your computer using modems. Both you and your patient require a modem set up for this purpose. The patient attaches the modem to the right communications port on the AUTOSET SPIRIT unit and to a phone line. You attach your modem to the serial port on your computer and a phone line. Refer to complete instructions for modem use in the *AutoScan Clinician's Manual*. RMD-063968 (AutoSet Spirit Clinician's Manual) at -4015.

Claim Language [1.d]	ResMed Prior Art ("RPA")
	AUTOSCAN™ SOFTWARE AUTOSCAN is designed to enable review of the data stored in an AUTOSET SPIRIT unit. Data from up to 365 sessions may be stored and downloaded. Refer to the *AutoScan Clinician's Manual* or *Help* for details.  RMD-063968 (AutoSet Spirit Clinician's Manual) at -3986.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.d]	ResMed Prior Art ("RPA")

Menu	Parameter	Description
Results	Efficacy data	Displays pressure, leak, AHI (apnea + hypopnea index), AI (apnea index), and HI (hypopnea index) data for a range of time intervals. For details, see "Clinical Menu Results" on page 39.
	Usage data	Displays usage data for a range of time intervals. For details, see "Clinical Menu Results" on page 39.
	Mask Fit* (Smart Data)	Displays a star rating corresponding to the 70th centile leak from the previous session, if enabled in Clinical Menu, Options, Smart Data.
	Pressure* (Smart Data)	Displays 95th centile pressure from the previous session, if enabled in Clinical Menu, Options, Smart Data.
	Usage* (Smart Data)	Displays usage hours from the previous session, if enabled in Clinical Menu, Options, Smart Data.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -4004.

PRESSURE

The pressure transducer located in the unit measures treatment pressure; the average pressure is calculated and recorded each minute. The pressure reported in the Efficacy Data submenu (see Figure 9, The Clinical Menu Results series, on page 40) for a single session is the 95th centile pressure for mask-on time, excluding periods when the leak has exceeded 0.4 L/s (24 L/min). For selected time intervals (last week, last month, last 6 months or last year), the median of the daily 95th centile values is reported. Non-usage days are not included in calculations.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -4010.

Claim Language [1.d]	ResMed Prior Art ("RPA")
	LEAK Leak is derived by analyzing inspiratory and expiratory airflows (via the flow sensor located in the unit). Theoretically, inspiratory and expiratory volumes should be equal. A net airflow greater than the expected mask vent flow is equal to the leak. Generally, a leak rate of more than 0.4 L/s (24 L/min) is associated with patient discomfort, disturbed sleep, and reduced efficacy of treatment. *If the leak exceeded 0.4 L/s (24 L/min) for more than 30% of the previous session, the following message will appear on the LCD:* **`High leak in last session.`** *The Leak Alert feature, if enabled, will alert the patient when mask leak exceeds 0.7 L/s (42 L/min) for more than 20 seconds. When the leak exceeds this level, the autotitrating algorithm ceases to perform optimally.* The leak reported in the Efficacy Data submenu (see Figure 9, The Clinical Menu Results series, on page 40) is the 95th centile value for mask-on time for each session, or the median 95th centile value for a selected time interval (last week, last month, last 6 months, or last year). Non-usage days are not included in calculations. RMD-063968 (AutoSet Spirit Clinician's Manual) at -4010.

Claim Language [1.d]	ResMed Prior Art ("RPA")
	CLINICAL MENU RESULTS A comprehensive set of data is available in Clinical Menu, Results (Efficacy Data and Usage Data), as shown in Figure 9, The Clinical Menu Results series, on page 40. To navigate within the Efficacy or Usage Data sections, use: • the **Up/Down** key to scroll through items within a time series • the **Left** key to navigate between time series. The Used screen reports total hours the device has been used and the number of days the device was used compared to the total days since the hourmeter was last reset. Other statistics quoted include: • usage • pressure (95th centile value for mask-on time only) • leak (95th centile value for mask-on time only) • AHI, or apnea + hypopnea index (calculated per session) • AI, or apnea index (calculated per session) • HI, or hypopnea index (calculated per session). RMD-063968 (AutoSet Spirit Clinician's Manual) at -4012.

Claim Language [1.d]	ResMed Prior Art ("RPA")

DOWNLOADING AND REVIEWING DATA USING AUTOSCAN

Data collected by the AUTOSET SPIRIT unit may be downloaded to AUTOSCAN software (available in the AUTOSCAN clinical interface kit) for review. Refer to the instructions in the *AutoScan Clinician's Manual* for details of downloading and reviewing data.

Data from an AUTOSET SPIRIT unit are presented in AUTOSCAN in the following ways:

- graphical display of usage data (time/date stamped) showing mask on/off events (Usage graph)
- 95th centile, median, and maximum values plus average and standard deviation values for leak and pressure for each session, with median values quoted for all parameters for nominated time intervals (Treatment Profile and Statistics display)
- apneas, hypopneas, AI, HI, and AHI on a per hour basis (Treatment Profile and Statistics display).
- 5 nights of Night Profile Data.

NOTE

The AutoSet Spirit clock resets at midday. To ensure that 5 nights of Night Profile Data are available, you must download the data before midday on the fifth day.

Additionally, use AUTOSCAN to:

- document patient notes
- generate and print reports.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -4015.

REMOTE DATA ACCESS

You can download data from an AUTOSET SPIRIT unit in your patient's home to AUTOSCAN software on your computer using modems. Both you and your patient require a modem set up for this purpose. The patient attaches the modem to the right communications port on the AUTOSET SPIRIT unit and to a phone line. You attach your modem to the serial port on your computer and a phone line. Refer to complete instructions for modem use in the *AutoScan Clinician's Manual*.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -4015.

[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted] **ResLink (System 1)** The RESLINK is intended to be used with the ResMed AUTOSET® SPIRIT™ and S7™ ELITE systems. The RESLINK has two distinct functions: • enhanced collection, storage and transfer of data (including pulse oximetry data), and • upgrade of the AUTOSET SPIRIT and S7 ELITE software. RMD-063198 (ResLink Clinician's Guide) at -3199.

Claim Language [1.d]	ResMed Prior Art ("RPA")

Detailed Data

The following table sets out the detailed data available for viewing in AutoScan. A ninth parameter, the Apnea / Hypopnea Index (AHI) is also displayed. The AHI is calculated by adding together the total number of apneas and hypopneas that occurred in the preceding hour. The AHI is updated with each event, and reset every hour, increasing with the number of apneas.

The Pulse rate and SpO_2 readings are obtained from the oximeter.

Parameter	Minimum resolution	Range	Sampling frequency (hz)
Events	1 sec	0–180 sec	as each event occurs (maximum 2000 events/session)
Minute ventilation	0.1 L/min	0–180 L/min	0.5
Leak	0.02 L/sec	0–5 L/sec	0.5
Pulse rate	1 bpm	20–220	0.2
SpO_2	1%	40%–100%	1.0
Pressure	0.2 cmH_2O	-5–40 cmH_2O	0.5
Snore	n/a	Quiet–Loud	per breath
Flattening	n/a	Round–Flat	per breath

RMD-063198 (ResLink Clinician's Guide) at -3200.

Data Collection

To collect data from the AutoSet Spirit or S7 Elite, insert the SmartMedia card into the ResLink.

Note: *When you use the SmartMedia card with a new patient's flow generator, the ResLink deletes all information currently on the SmartMedia card.*

In addition to the comprehensive set of data available in the flow generator, the ResLink collects and stores *Detailed Data*. Collection and storage of data occurs automatically during therapy. The 32-megabyte SmartMedia card (supplied with the ResLink), can record and store up to 30 sessions of detailed data. If the one SmartMedia card is used for more than 30 sessions, the oldest data will be overwritten.

A maximum of 10 hours per session is recorded. If the duration of therapy is greater than 10 hours, the first 10 hours is retained. Each session is defined as taking place between noon of one day and noon of the following day.

After therapy, the patient can return the card to the clinician using the Mailback card provided with the ResLink. Data stored on the SmartMedia card can be downloaded by the clinician for review and analysis. See the *AutoScan Clinician's Manual* for information on downloading and viewing detailed data.

RMD-063198 (ResLink Clinician's Guide) at -3200.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	[redacted] A")

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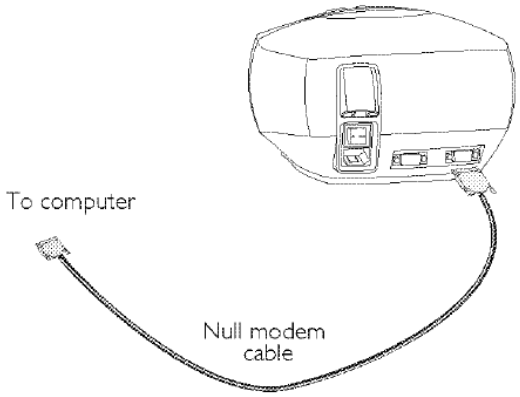
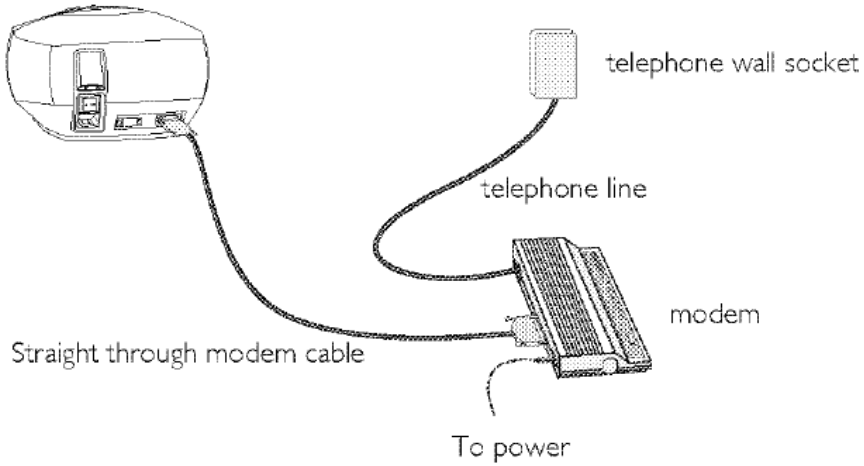
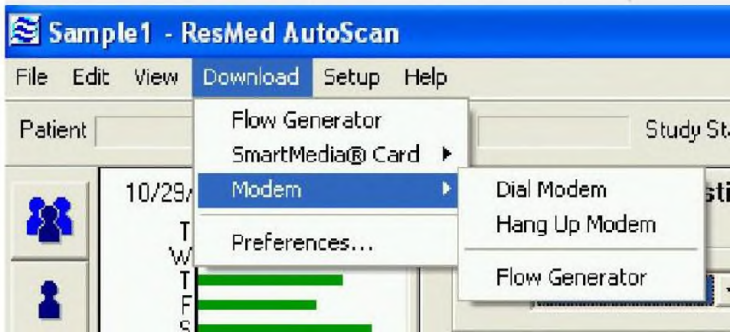
Claim Language [1.d]	ResMed Prior Art ("RPA")
	ResMed introduces ResLink™–the first truly modular sleep-disordered breathing (SDB) therapy management tool with significant benefits for the patient, sleep laboratory, prescribing physician, and equipment provider. The portable ResLink module simply clips onto ResMed's AutoSet Spirit™ system. ResLink captures and stores high-resolution patient compliance and efficacy data, including oximetry. This information is easily accessed and transferred via a 32MB SmartMedia™ card and then downloaded to a PC using ResMed's AutoScan™ software. RMD-289749 (ResLink Launch Brochure) at -9750. **Comprehensive efficacy data with oximetry** ResLink reports on significant parameters such as minute ventilation, snore, flattening, SpO_2, pulse rate, pressure response, leak, events, and AHI, providing visible insights into treatment efficacy. ResLink presents this efficacy information along with integrated oximetry data for simultaneous onscreen viewing and analysis. RMD-289749 (ResLink Launch Brochure) at -9751.

Claim Language [1.d]	ResMed Prior Art ("RPA")
	RMD-0318396 at -0318405, *see also* 0318404-407. **AutoScan 5.4 (System 1)** AUTOSCAN™ 5.4 has been developed to view summary data and detailed data obtained from the RESLINK™ via the SmartMedia™ card. Summary data and Night profile data obtained from the flow generator can also be viewed as in previous versions of AUTOSCAN. AUTOSCAN 5.4 has data collection and management capabilities that provide an adjunct for patient management. The flow generator systems intended to be used with AUTOSCAN 5.4 are the ResMed AUTOSET® SPIRIT™, S7™ ELITE, VPAP® III, VPAP III ST, VPAP III ST-A, and AUTOSET RESPOND™. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1269. FLOW GENERATOR COMPATIBILITY The following flow generators are compatible with AUTOSCAN 5.4: • AUTOSET SPIRIT • AUTOSET RESPOND • VPAP III, VPAP III ST, VPAP III ST-A, • S7 ELITE. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277. CONNECTING THE FLOW GENERATOR TO THE COMPUTER In order to download data into AUTOSCAN 5.4, your computer must be connected by cable to the flow generator. NOTES *If your flow generator is connected to a ResControl, you must disconnect the ResControl before connecting the flow generator to your computer for interfacing to AutoScan 5.4.* Plug the null modem cable into the PC connection port on the flow generator and into an available serial port at the back of your computer (COM1, COM2, COM3 or COM4).

Claim Language [1.d]	ResMed Prior Art ("RPA")
	 Figure 2: Connecting the flow generator to the computer RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277 – 78. USING MODEMS You can download summary and Night Profile data on your flow generator remotely via modem. We recommend *Windows NT 4.0 SP6* and 3Com U.S. Robotics 56k Voice Faxmodems for this purpose. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1279. USING MODEMS TO DOWNLOAD DATA You may download summary and Night Profile data remotely via modem. These operations require that both you and the patient have modems. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1290.

Claim Language [1.d]	ResMed Prior Art ("RPA")
	 RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1290. RMD-0318396 at -0318408.

Claim Language [1.d]	ResMed Prior Art ("RPA")
	 RMD-0318346 at -0318351, *see also* 0318355. MANAGING PATIENT INFORMATION AUTOSCAN 5.4 allows you to record patient information, clinical details and notes in the patient file. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1297. Detailed and summary data from a patient's flow generator are stored on a SmartMedia card by the RESLINK. The SmartMedia card is removed and sent to the clinician at the end of the study period. The SmartMedia card is inserted into a SmartMedia card reader attached to the clinician's computer, and the data can then be downloaded and viewed in AUTOSCAN 5.4. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1301. The Detailed Data screen displays nine traces of data downloaded via the RESLINK from the flow generator. You can view data in the Detailed Data screen in increased detail or as a compact overview. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1303.

Claim Language [1.d]	ResMed Prior Art ("RPA")
	The Detailed Data screen for that session will be displayed. The graph display area shows the downloaded data in the trace panels: • Events (s) • Minute Ventilation (L/min) • Leak (L/s) • Pulse Rate (bpm) • SpO_2 (%) • AHI (Events/hr) • Pressure (cm H_2O)[a] • Snore (Quiet to Loud)[a] • Flattening (Round to Flat)[a] • Respiratory rate (BPM).[b] a AUTOSET SPIRIT and S7 ELITE only [b] VPAP III series only NOTE *Pulse rate and SpO_2 are derived from the oximeter reading.* RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1304.

Claim Language [1.d]	ResMed Prior Art ("RPA")

INTERPRETING AUTOSET DATA

NOTE *AutoSet Respond displays data only in the Usage Profile.*

APNEAS AND HYPOPNEAS

The AutoSet algorithm defines an apnea as a greater than 75% decrease in nasal ventilation for at least 10 seconds. An apnea is scored if the 2-second moving average ventilation drops below 25% of the recent average (time constant 100 seconds) for at least 10 consecutive seconds.

An Apnea Index (AI), shown in the *Treatment Profile* as a red bar, is derived for each session by dividing the total number of apneas that occurred by the total mask-on time.

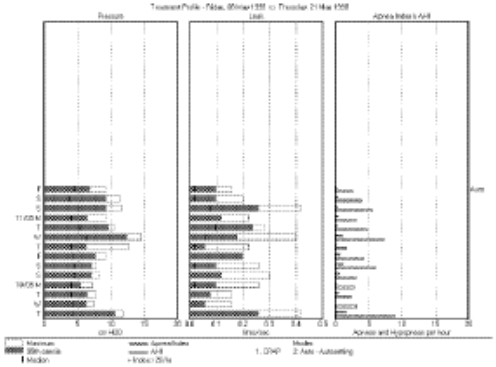


Figure 38: Treatment Profile details

The AI for a session or group of sessions may be viewed in the *Statistics* tab of AUTOSCAN 5.4.

Information on apneas is stored for the most recently accumulated five nights of data. They log the time during the session and duration of each apnea and display these as red "lollipops" on the Apnea Events and Duration graph in the *Night Profile*.

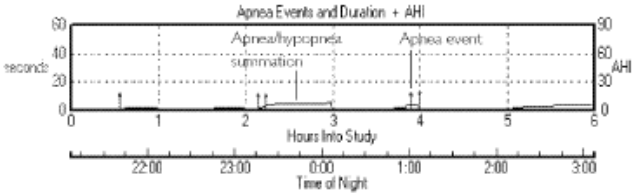


Figure 39: Apnea Events and Duration and AHI in the Night Profile

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1325.

Claim Language [1.d]	ResMed Prior Art ("RPA")

The AutoSet algorithm defines a hypopnea as a 50 to 75% decrease in nasal ventilation. A hypopnea is scored if the 8-second moving average ventilation drops below 50%, but not below 25%, of the recent average for 15 consecutive seconds. The recent average ventilation is calculated using a time constant of 100 seconds.

Information on individual hypopneas is not displayed in the *Treatment Profile* but an apnea/hypopnea index (AHI) is calculated by dividing the total number of apneas + hypopneas that occurred in a session by the total mask-on time. The AHI for a given session is displayed as a blue bar in the *Treatment Profile* (see Figure 38). The AHI value for a session (or group of sessions) can also be viewed in *Statistics*.

The *Statistics* tab in AUTOSCAN 5.4 displays hypopnea index (HI) values, in addition to AI and AHI values, for the nominated time interval.

For the most recently accumulated five nights of data, a series of apnea/hypopnea summations is saved for each session. Each of these is the sum of the number of apneas and hypopneas the patient experienced within a one-hour interval. At the end of each hour of data collection, the maximum value of the summation is equivalent to an AHI for that hour as it is equal to the total number of apneas + hypopneas divided by one hour. The flow generator then resets the apnea + hypopnea count to zero. The apnea/hypopnea summation is plotted as a blue line on the Apnea Events graph in the *Night Profile* (Figure 39). At the end of the session, an AHI is calculated and displayed in the *Statistics* screen.

NOTE *The AutoSet algorithm does not distinguish between a closed airway apnea (obstructive apnea) and an open airway apnea (central apnea). For this reason, it will not increase pressure in response to apneas once pressure has reached 10 cm H_2O. Pressure increases beyond 10 cm H_2O, in response to apnea alone, may invoke more apneas if they are central in nature by triggering the Hering-Breuer reflex.*

LEAK MEASUREMENT

NOTE *When assessing results, it is best to check the leak data first. Leaks greater than 0.4 L/sec affect the accuracy of other measurements.*

Leak is measured by analysing inspiratory and expiratory volumes, which should be approximately equal, yielding an average airflow of 0 L/sec in the absence of mask leak. An average airflow greater than 0 L/sec is due to leak.

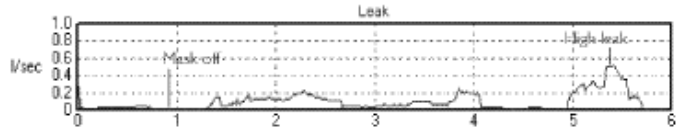
Generally, a leak rate of more than 0.4 L/sec is associated with patient discomfort, disturbed sleep and reduced efficacy of treatment. A leak rate of 0.2 L/sec or less for the majority of a session signals a well-fitting mask.

The median, maximum and 95th percentile leak for each session in a series are displayed in the *Treatment Profile* (see Figure 38).

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1326.

Claim Language [1.d]	ResMed Prior Art ("RPA")

Median, 95th percentile and maximum leak are displayed for the nominated time interval in the *Statistics* tab of AUTOSCAN 5.4. A graph of leak as a function of time for each night is shown in the *Night Profile*.



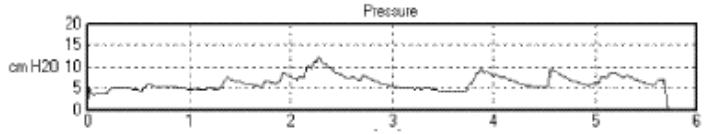
PRESSURE MEASUREMENT

The pressure transducer located in the AUTOSET SPIRIT and S7 ELITE calculates pressure at the mask.

The median, maximum and 95th percentile pressure delivered during each night in a series are displayed in the *Treatment Profile* (see Figure 38).

The AUTOSET SPIRIT and S7 ELITE continuously titrate the pressure delivered, based on inspiratory flow limitation, snore, and apnea.

The median, 95th percentile and maximum pressure data are displayed for the nominated time interval in the *Statistics* tab of AUTOSCAN 5.4. The pressure delivered to the patient each night is reported as a function of time in the pressure graph in the *Night Profile*.



MINUTE VENTILATION

Information from the VPAP III, VPAP III ST or VPAP III ST-A flow transducer, modified by an internal model of the mask vent flow, is used to calculate the minute ventilation. This is displayed as a 5-breath moving average.

The median, maximum and 95th percentile minute ventilation for each night in a series are displayed in the Treatment Profile, and for the nominated time interval in the Statistics tab.

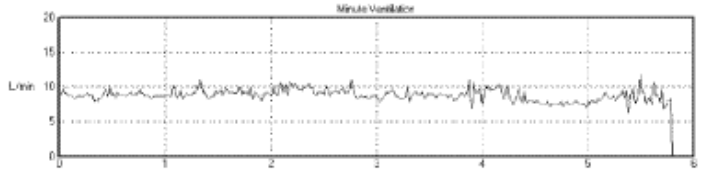


Figure 40 : Minute Ventilation graph in Night Profile screen

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1327.

Claim Language [1.d]	ResMed Prior Art ("RPA")

INTERPRETING DETAILED DATA

Detailed data obtained from the SmartMedia card is displayed at the AUTOSCAN 5.4 Detailed Data tab. Each of the graphs in the Detailed Data screen represents a set of measurements of a different aspect of the patient's breathing. If there is no data in a section of the graph, the flow generator was not being used at that time. If the oximeter falls off or fails to make contact with the patient at any stage, the Pulse Rate and SpO_2 traces will be empty or show a zero reading. You will be alerted to this by a message during download (see Figure 21 above).

Session statistics for SpO_2, Pulse rate and Minute ventilation are included in the printed detailed data report.

AHI (APNEA/HYPOPNEA INDEX)

The apnea / hypopnea index for the AUTOSCAN 5.4 *Detailed Data* screen is calculated by adding together the total number of apneas and hypopneas that occurred in the preceding hour. The AHI is updated with each event, and reset every hour, increasing with the number of apneas. If it rises above 10 events/hr, check the leak and pressure. It may be that the patient is having a lot of central apneas.

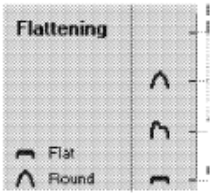
EVENTS

The *Events* graph displays the patient's apneas and hypopneas with an indicator at the point where they commence, and a number that indicates the duration (in seconds) of the event. AUTOSCAN 5.4 can log up to 2000 events per session.

Apneas are indicated with a red ball, and hypopneas with blue.

FLATTENING INDEX (AUTOSET SPIRIT AND S7 ELITE ONLY)

The Flattening Index graph is an indicator of trends in the patient's breathing. The Flattening Index graph in AUTOSCAN 5.4 displays measurements as being Flat, Flattening or Round



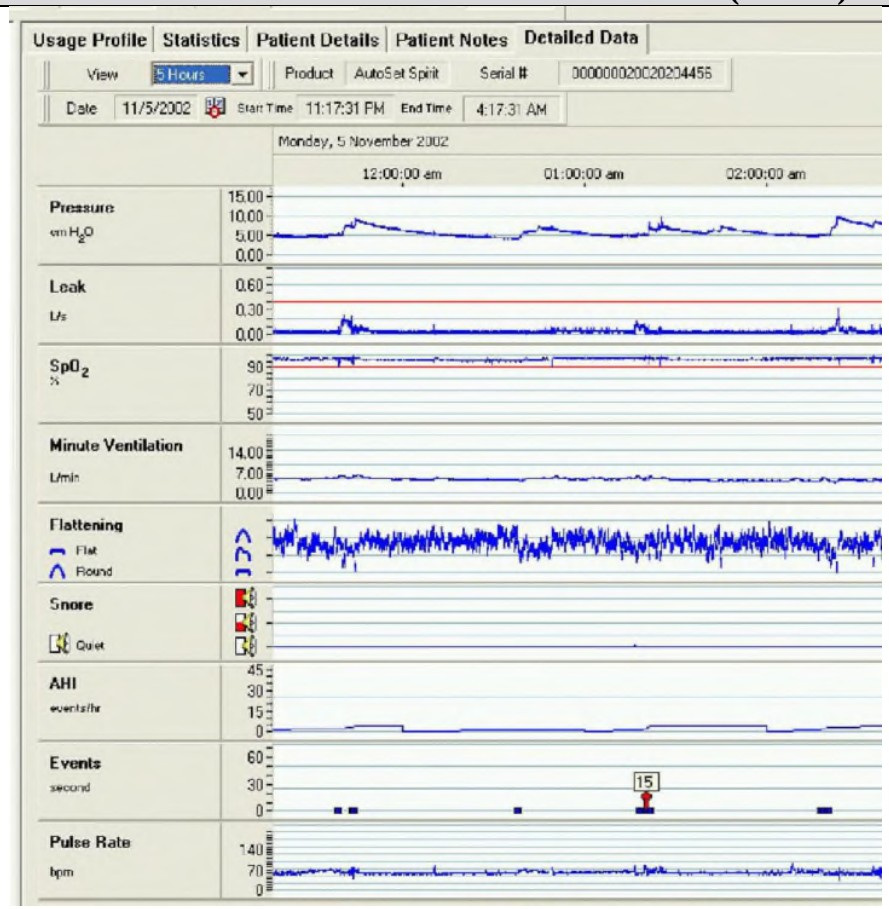
It is desirable that the results are rounded rather than flat. If the trace is too flat, check the leak and the pressure. If the patient is currently on CPAP mode, it is possible that they may benefit from changing to Autoset mode.

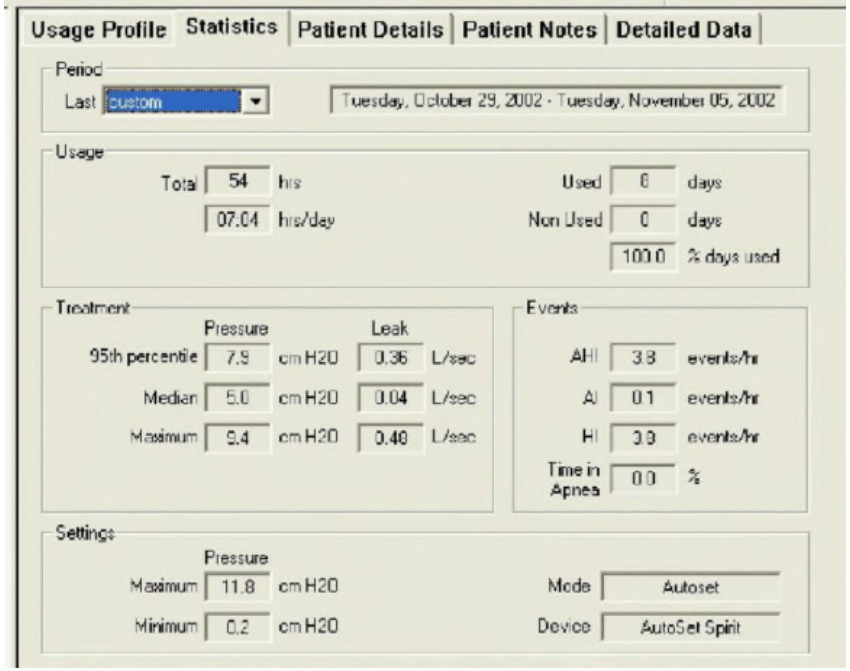
LEAK

The RESLINK samples for leak every 2 seconds. While some leak is a natural part of therapy, it is recommended that the level of leak is below 0.4 L/sec. Higher leak will

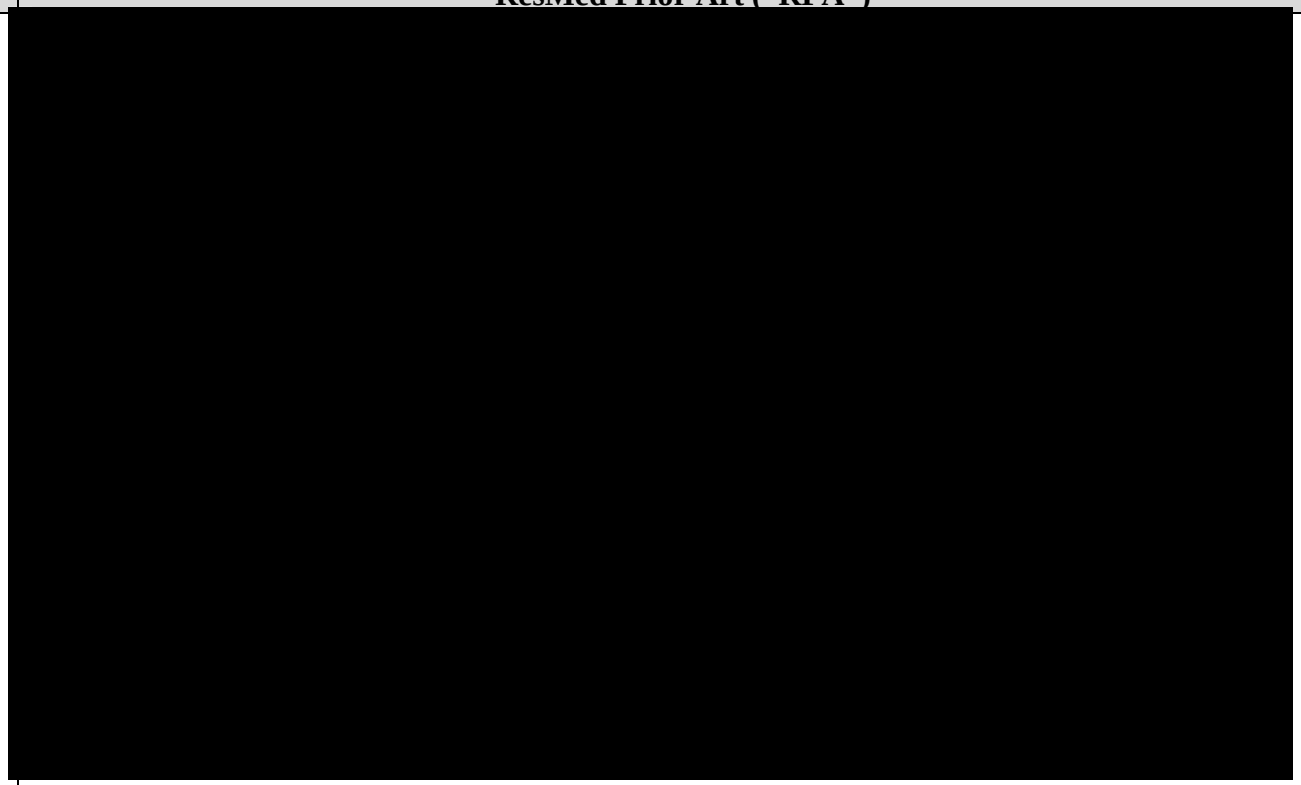
RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1307.

Claim Language [1.d]	ResMed Prior Art ("RPA")
	affect treatment and compliance. A red line in the Leak graph indicates the 0.4 L/sec level. MINUTE VENTILATION Minute ventilation is a measure of the total volume breathed in (or out) within any 60 second period. It is calculated from respiratory rate x tidal volume. The RESLINK samples this information every 2 seconds. A normal range is from 6–12 L/min. Minute ventilation is used mainly to manage arterial CO_2 tension ($PaCO_2$) during therapy. For example, a patient with a $PaCO_2$ of 50mmHg and a Minute Ventilation of 5 L/min can be reduced to 45 mmHg (10% reduction) by raising Minute Ventilation to 5.5 L/min (10% increase). NOTE *Respiratory rate is the number of breaths per minute. Tidal volume is the volume of air breathed in or out in one breath.* PRESSURE (AUTOSET SPIRIT AND S7 ELITE ONLY) The RESLINK samples pressure every 2 seconds. The trace displayed in the Detailed Data screen is the calculated delivered pressure. If this differs markedly from the pressure set on the flow generator, check that the device is functioning correctly. The trace for Pressure will show any changes to the pressure setting on the flow generator. In Autoset mode, the trace will show increases or decreases in line with apnea or hypopnea events, or snore. If the pressure trace is constant, this would indicate that the flow generator is in CPAP mode. If the pressure trace is changing with time, this would indicate that the flow generator is in Autoset mode. PULSE RATE An average pulse rate should be between 60–80 bpm. Typically, an apnoea will increase the patient's pulse rate. Zoom in on any part of the trace (see "Changing the scale" above) to see the cardiac response in detail. The pulse rate is sampled every second by the RESLINK. RESPIRATORY RATE (VPAP III SERIES ONLY) Respiratory rate is sampled once every 2 seconds. The displayed rate is an average of the previous 5 breaths. The range is 0–60 bpm (breaths per minute). SNORE (AUTOSET SPIRIT AND S7 ELITE ONLY) Every breath is monitored for snore. However, the trace shows the rolling average for the last 5 breaths as the *Snore* graph is concerned with trends rather than measuring the individual snore. If the flow generator is functioning properly, there should not be much occurrence of snore. Snore is measured in AUTOSCAN 5.4 on a scale of Quiet to Loud. SpO_2 SpO_2 measures oxygen saturation in the patient's blood. The SpO_2 trace in AUTOSCAN 5.4 has a red indicator line at 90% to show at a glance if the patient is within acceptable limits. This line makes it easy to see where desaturations are occurring, and to connect their occurrence with apnea events. SpO_2 is measured every second by the RESLINK. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1308.

Claim Language [1.d]	ResMed Prior Art ("RPA")
	 RMD-0318346 at -0318369.

Claim Language [1.d]	ResMed Prior Art ("RPA")
	 RMD-0318346 at -0318366. **ResTraxx (including RDC) (System 2)** *See, e.g.*, limitation 1.pre; [redacted]

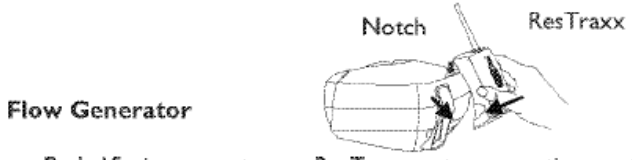
Claim Language [1.d]	ResMed Prior Art ("RPA")
	 RMD-0318396 at -0318410, *see also* 0318409.

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]  ResTraxx™ allows the wireless transfer of information from a continuous positive airway pressure (CPAP) unit to a clinician at a remote location via a two-way pager network. ResTraxx is intended to be used with ResMed S7™ Elite, AutoSet® Spirit™, AutoSet® Respond™, and VPAP® III flow generator systems on adults with obstructive sleep apnea. RMD-062642 (ResTraxx Quick Reference Guide) at -2642.

Claim Language [1.d]	ResMed Prior Art ("RPA")

Attaching the ResTraxx

1. Turn the flow generator to OFF.
2. Slide lever on back of ResTraxx to the left.
3. Place top catch on ResTraxx onto notch at back of unit.



4. Push 15-pin connector on ResTraxx onto connection port on back of unit.
5. Slide lever on back of ResTraxx to the right to lock it into place.
6. Turn the main power switch at the back of flow generator to the ON position.
7. A green LED on top of ResTraxx will light up 15 - 20 seconds after unit is turned on, then begin to flash.
8. After about 15 seconds, a series of messages will appear on the flow generator display, indicating the unit's initialization and registration status of unit.
9. After initialization, the standby screen appears on the flow generator display and the unit begins transmitting information.

RMD-062642 (ResTraxx Quick Reference Guide) at -2642.

[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]

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Exhibit 1024 - Page 369

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]

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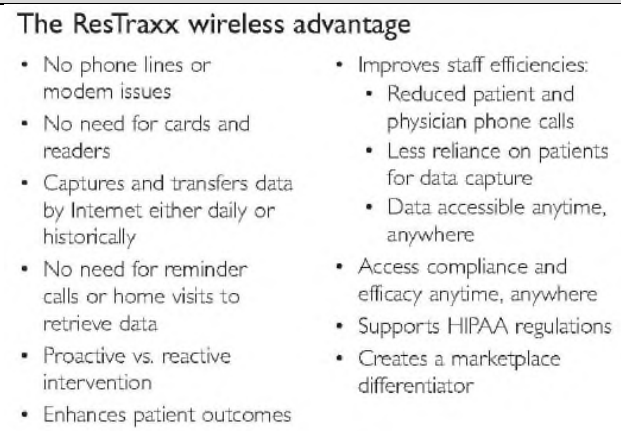
Exhibit 1024 - Page 370

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted] ResTraxx is a first-of-its-kind wireless communication device that attaches easily to the back of ResMed flow generators. The ResTraxx system captures, transfers, and stores compliance and efficacy data without wires, phone lines, modems, or data cards. ResTraxx is an elegant system that brings patient usage and treatment efficacy data to your fingertips instantly. RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

Claim Language [1.d]	ResMed Prior Art ("RPA")
	 RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

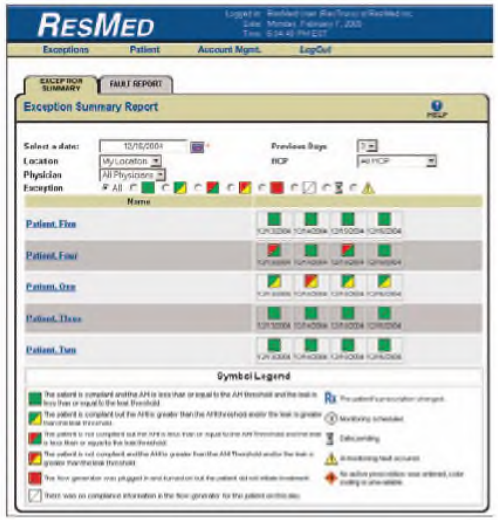
[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")

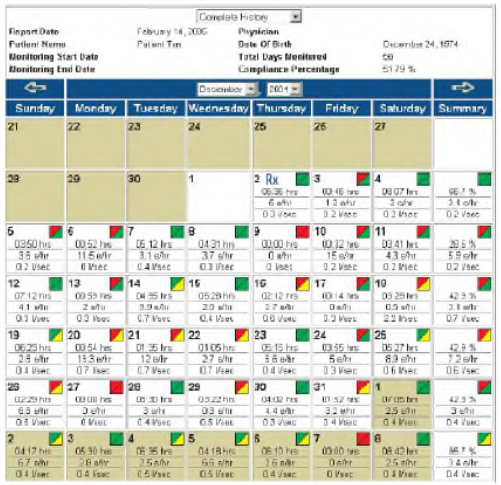
Exception Reporting

Enhance productivity and manage patients more efficiently. **Exception Reporting identifies and highlights those patients who fall below desired usage thresholds or have issues with mask leak or AHI.** This feature enables you to focus your efforts only on those patients who require intervention and respond proactively to potential problems. The simple color-coded alert system helps you identify exception patients quickly and easily.



Efficacy + Leak + Usage Data

The ResTraxx Data Center displays data on a daily basis in a calendar format enabling you to see daily or weekly trends of adherence problems before compliance is truly compromised. Early intervention and ongoing follow-up is considered critical, especially during the first month of CPAP acclimation, to determine long-term compliance rates.[2]



Want more details on therapy results? Click on the calendar day in question, and a therapeutic report will display additional clinical data regarding the patient's usage for that day.

RMD-063327 (ResTraxx Patient Management Brochure) at -3328.

[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]

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Exhibit 1024 - Page 376

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]

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Exhibit 1024 - Page 377

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]

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Exhibit 1024 - Page 378

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted] "Various approaches have been developed to expedite the collection and analysis of these data. Current CPAP devices can be interfaced with a computer in the office or home setting to download data. Newer modems can interface with the CPAP unit and the integrated chip to facilitate the reporting of remote data and reduce the need for face-to-face visits. Also, smart cards can be inserted into slots in the CPAP units to imprint the data. These cards are then transported to the appropriate professional in a variety of ways, including the use of mail carriers or other modes, to reduce the need for direct patient travel for regular compliance reporting." Lankford, 163. "Wireless data transmission was accomplished by first attaching a transmission device, described below, to the flow generator. Then, by accessing a secure Web site, a request for data was sent from a secure sever, located in Peachtree City, Georgia, through land lines to the carrier's local transmission antenna, located within several miles of the device and location set up, where it is transmitted wirelessly to the device. Once the device received the request, the data were retrieved from the memory of the flow generator, transmitted wirelessly to a receiving antenna, located within several miles of the device. Then, through land lines back to the secure server, the data became available on the aforementioned Web site." Lankford, 164. "*Wireless and Internet-based technologies* "For data downloading at the end of the trial, an investigational wireless-to-Internet data collection/transmission system, being developed by ResMed, and named the "Spectrum System," was employed in this trial. The Spectrum System consists of the flow generator, a wireless communication device, code-named "Cyrcat," and a secure Web server located in a remote location. The secure Web server receives patient-related clinical data (compliance and efficacy parameters) from the Cyrcat wireless transmitter and it stores the information for clinician viewing, analysis, and reporting through a secure Web browser." Lankford, 164.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	"*Data collection methods* "Patients were asked to return with their CPAP unit to their respective set-up locations. Data were wirelessly transmitted using the Spectrum System to the secure Web server. These data were then downloaded onto a storage disk using a predetermined Microsoft Excel format for later comparison with the same base set that was manually downloaded from the flow generators using the same format. All disks were marked with patient codes to assure anonymity. In the tables that follow, the terms 'wireless' and 'autoscan' refer to the wireless and base data sets, respectively." Lankford, 165. [redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]

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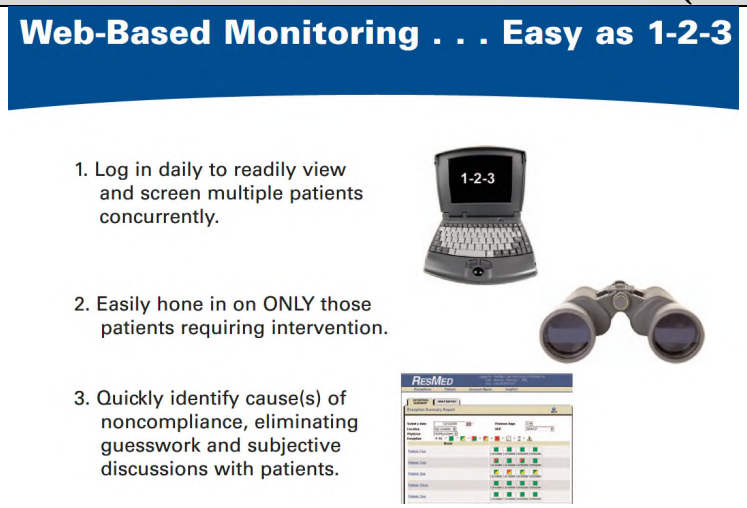
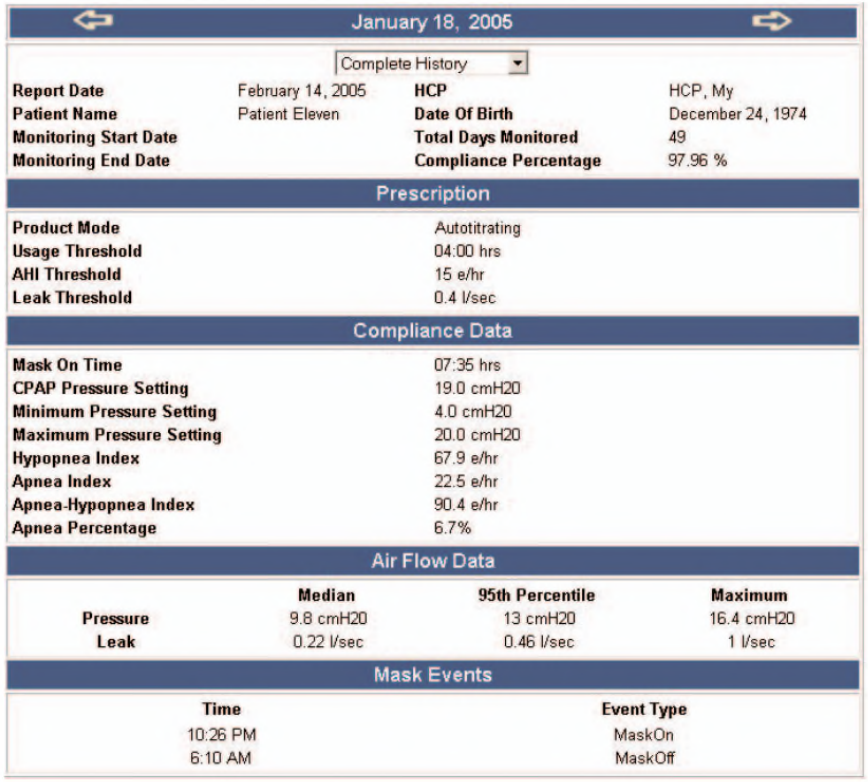
Claim Language [1.d]	ResMed Prior Art ("RPA")
	 RMD-063341 (ResTraxx Wireless Patient Monitoring Atlas) at -3343.

Claim Language [1.d]	ResMed Prior Art ("RPA")



January 18, 2005

Complete History

Report Date	February 14, 2005	**HCP**	HCP, My
Patient Name	Patient Eleven	**Date Of Birth**	December 24, 1974
Monitoring Start Date		**Total Days Monitored**	49
Monitoring End Date		**Compliance Percentage**	97.96 %

Prescription

Product Mode	Autotitrating
Usage Threshold	04:00 hrs
AHI Threshold	15 e/hr
Leak Threshold	0.4 l/sec

Compliance Data

Mask On Time	07:35 hrs
CPAP Pressure Setting	19.0 cmH20
Minimum Pressure Setting	4.0 cmH20
Maximum Pressure Setting	20.0 cmH20
Hypopnea Index	67.9 e/hr
Apnea Index	22.5 e/hr
Apnea-Hypopnea Index	90.4 e/hr
Apnea Percentage	6.7%

Air Flow Data

	Median	**95th Percentile**	**Maximum**
Pressure	9.8 cmH20	13 cmH20	16.4 cmH20
Leak	0.22 l/sec	0.46 l/sec	1 l/sec

Mask Events

Time	**Event Type**
10:26 PM	MaskOn
6:10 AM	MaskOff

RMD-063341 (ResTraxx Wireless Patient Monitoring Atlas) at -3365.

> A drill-down into a specific date on Jan 18th **shows the relevance of the Compliance Data demonstrating that the AHI is 90.4 with a breakdown of Apneas of 22.5 and hypopneas of 67.9%.** The clinician now has the data required to make appropriate therapeutic intervention.

RMD-063341 (ResTraxx Wireless Patient Monitoring Atlas) at -3372.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted]
	If the Judge or Jury finds that RPA does not disclose this claim limitation, this claim is still rendered obvious by modifying or combining RPA with the knowledge of a POSITA. For example, a POSITA would have recognized that RPA discloses, or at least renders obvious, the claimed "module transceiver," at least for the same reasons CleveMed alleges the accused products practice this claim limitation. It would have been obvious to include pulse oximeter sensor data or the obvious AHI calculated in connection with limitation 1.b.4 with the data transmitted by the modem for RPA System 1 or the [redacted] in RPA System 2. The AutoSet Spirit was capable of receiving and transmitting oxygen saturation data over the modem/serial port and modem. [redacted]

Claim Language [1.d]	ResMed Prior Art ("RPA")
	[redacted] If a judge or jury determines this claim limitation is not expressly disclosed by RPA System 1, it would have been at least obvious because the AutoSet Spirit's modem port supports transmission of other statistics such as leak and pressure by the modem (which is generally capable of receiving and transmitting data from the Spirit in the correct format, regardless of content), and ResMed had already contemplated this feature would be supported by the AutoSet Spirit, even if not enabled or employed by AutoScan software. Including oxygen saturation statistics would not have been limited in terms of the amount of data or bandwidth because they would merely be centile statistic numbers rather than periodic data. **'269 Patent** Furthermore, as noted for limitation 1.b.4, the '269 patent does not disclose how to "calculate[e], 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." Thus, at least commensurate in scope with the '269 patent that discloses that the level of severity of a subject's sleeping disorder or symptoms is determined using signals or data from the sensors, RPA (either alone or in combination with other prior art) discloses or renders obvious this limitation. *See also, e.g.*, RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures; RMD-0318396 Specimen Photographs; [redacted]

Claim Language [5pre]	ResMed Prior Art ("RPA")
[5pre] A sleep disorder treatment system comprising:	To the extent the preamble is limiting, RPA discloses a sleep disorder treatment system. *See, e.g.*, limitation 1pre.

Claim Language [5.a]	ResMed Prior Art ("RPA")
[5.a] a data acquisition system;	RPA discloses a data acquisition system. *See, e.g.*, limitation 1.a. RPA System 1 discloses this limitation, or alternatively renders it obvious in view of the knowledge of a POSITA. The NONIN Xpod is "a data acquisition system." Alternatively, the ResLink is "a data acquisition system" under CleveMed's infringement contention theory for this limitation. RPA System 2 renders this limitation obvious in view of the knowledge of a POSITA, and alternatively also in view of System 1. Alternatively, RPA Systems 1-2 in combination with Schmidt and the knowledge of a POSITA render this limitation obvious. If the Judge or Jury finds that RPA does not disclose this claim limitation, this claim is still rendered obvious by modifying or combining RPA with the knowledge of a POSITA, and/or Schmidt. An example in the prior art is Schmidt, which discloses: "All data acquisition systems generally operate in a similar fashion. They receive an external input from some type of sensing device, condition and/or convert the input to a format suitable for transmission, as necessary, and transmit it to another piece of equipment usually a monitor or controller, which may be a computer, and more specifically, a personal computer. The external input is generally an analog signal, although digital signals, frequently on-off switching, pulse-width modulation, or serial data protocols, are also involved. The inputs, though, come in many forms with many different characteristics, be they pneumatic, hydraulic or electronic, to list a few. Modern applications, control schemes and devices usually necessitate the use of electronic inputs in one form or another. For example, electronic analog inputs may have ranges of 4-20 mA, +/-5 volts, +/-15 volts, or microvolts to millivolts. "In the case of a wired system the analog input can be transmitted directly over interconnecting wiring with the major concern being that the interconnecting wires be suitably shielded to prevent interference by nearby electromagnetic sources. Signal conditioning becomes critically important for

Claim Language [5.a]	ResMed Prior Art ("RPA")
	wireless systems, though. This is especially so when considering power consumption, size and cost factors. Because electronic inputs can have different characteristics (e.g.: high frequency or low frequency) and ranges (e.g.: microvolts to many volts), data acquisition systems are either application specific, i.e. designed to accept and condition a particular type of signal, i.e.: current, with a range of 4-20 mA for instance, or include separate discrete signal conditioning devices which consume a large amount of power and add considerable size. "Radio frequency (RF) wireless data acquisition systems can convert the input to a conditioned electronic signal which is used to modulate a carrier frequency which is then transmitted as a radio frequency signal to equipment in another location. The conditioned signal is encoded with data corresponding to the status of the input. The radio frequency signal is received, demodulated and decoded and the data is read, displayed, stored, and/or acted upon, i.e. monitored, analyzed, by equipment at the receiving point. In the United States the Federal Communications Commission (FCC) regulations govern RF transmissions, and similar agencies regulate RF transmissions in other countries, specifically as to the frequency band that can be utilized to transmit the signal and the strength of the signal. Other data transmission means, such as infrared, optical, or any means which does not require a mechanical connection is understood to offer similar advantages as RF transmission. "Wireless data acquisition systems are well known in the art. In the biomedical area, U.S. Pat. No. 5,704,351 to Mortara discloses a multiple channel biomedical digital telemetry transmitter. Mortara teaches an 8 channel biomedical transmitter specifically directed to electrocardiogram (EKG) signal transmission in the 902 to 928 MHz band. The Mortara device includes input circuitry and an analog-to-digital converter which receives the input signal from an EKG electrode and converts it to a digital signal which is inputted to a microprocessor. The microprocessor then converts the digital signal to a serial digital output signal which is used to frequency modulate the radio frequency carrier signal for telemetry transmission. The carrier frequency is adjustable within the 902 to 928 MHz band by two manual frequency setting switches. The use of these manual switches is the only adjustment available on the Mortara device and only to manually set the frequency within the 902 to 928 MHz band. The input circuitry and analog-to-digital converter are not adjustable nor adaptable to accept different input signal characteristics. In addition, the Mortara device cannot be adjusted, by programming or otherwise, to operate in any other frequency band. Finally, the Mortara device is just a transmitter and, therefore, is not able to receive RF or other signals to control its operation." Schmidt, 1:22-31.

Claim Language [5.a]	ResMed Prior Art ("RPA")
	"In yet another aspect, the present invention relates to a programmable wireless data acquisition system, comprising a signal processing module comprising a module microcontroller having a memory. The signal processing module operation includes inputting, conditioning and processing at least one external input and transmitting by wireless means a signal encoded with data corresponding to the external input. The at least one external input comprising at least one physiological signal wherein the physiological signal is from the group of physiological signals consisting of EEG, EKG, EOG, SpO2, PO2, PCO2 EMG, blood pressure, heart rate, pulse, body temperature, air flow and respiration. The module microcontroller adapts the signal processing module in response to variation in the range, character and type of the physiological signal such that the adaptation occurs during signal processing module operation." Schmidt, 4:7-22. Additionally, Kirianaki discloses data acquisition systems known in the art: "The processing and interpretation of information arriving from the outside are the main tasks of data acquisition systems and measuring instruments based on computers. Data acquisition and control systems need to get real-world signals into the computer. These signals come from a diverse range of transducers and sensors. According to [7] 'Data Acquisition (DAQ) is collecting and measuring electrical signals from sensors and transducers and inputting them to a computer for processing.' Further processing can include the sensors' characteristic transformation, joint processing for many parameters as well as statistical calculation of results and presenting them in a user-friendly manner." Kirianaki, at 22. As recognized by Schmidt and Kirianaki, data acquisition systems were well known in the art. It would have been obvious to a POSITA to incorporate one as known in the art or taught by Schmidt (or the other disclosures discussed in reference to limitation 1.a) into RPA's system to arrive at the claimed system. **<u>CleveMed's Infringement Contentions and Additional Prior Art Disclosures</u>** Moreover, CleveMed's infringement contentions allege the claimed "data acquisition system" is practiced as follows: The Air 10 Oximetry Module is a data acquisition system from ResMed. As shown below, the Air10 Oximeter Module has an oximeter port that connects with and acquires data from a Nonin Xpod Oximeter, which is a pulse oximeter sensor, to send to the AirSense 10." Final Inf. Cont., Chart I, 38-39. If such an adapter satisfies this limitation, and also limitation 5.d below as

Claim Language [5.a]	ResMed Prior Art ("RPA")
	CleveMed alleges, the prior art discloses or at least renders obvious such a feature. *See* limitation 1.b. *See also*, e.g., RMD-0318396 Specimen Photographs; [redacted]

Claim Language [5.b]	ResMed Prior Art ("RPA")
[5.b] a positive airway pressure (PAP) device; and	RPA Systems 1-2 disclose a positive airway pressure (PAP) device. The AutoSet Spirit flow generator is a PAP device. *See, e.g.*, limitation 1.b. *See also*, e.g., RMD-0318396 Specimen Photographs; [redacted]

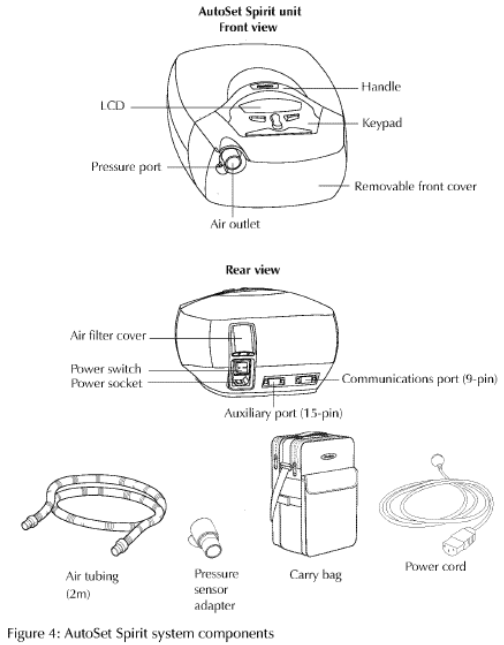
Claim Language [5.c]	ResMed Prior Art ("RPA")
[5.c] a processor;	RPA Systems 1-2 disclose a processor. The AutoSet Spirit flow generator PAP device has a microprocessor (processor). *See, e.g.*, limitations 1.b.4, 15.b.

Claim Language [5.d]	ResMed Prior Art ("RPA")
[5.d] 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	RPA discloses, or at least renders obvious, 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. RPA Systems 1 discloses this limitation. The NONIN Xpod, alone or in combination with the ResLink, is a "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." RPA System 2 renders this limitation obvious in view of the knowledge of a POSITA, and alternatively also in view of RPA System 1.

Claim Language [5.d]	ResMed Prior Art ("RPA")
from the pulse oximeter sensor to the PAP device;	Alternatively, as discussed for limitation 1.a, this limitation is also rendered obvious by RPA Systems 1-2 in combination with Schmidt and the knowledge of a POSITA. *See, e.g.*, limitations 5.a, 1.a, 1.b.2. Also, the written description of the '269 patent does not appear to disclose processing a first signal from the pulse oximeter sensor to remove artifacts. To the extent the '269 patent is relying on related signal processing disclosures to provide a written description of this limitation, the same disclosure was known in the art and disclosed, for example, in Schmidt, and would have been an obvious element for a POSITA to use in implementing RPA's system to arrive at the claimed system. Schmidt, which was copied into the '269 patent appears to disclose this limitation at least for the same reasons the '269 patent might provide a written description for this limitation. *See* Schmidt at Figures 1-6, 4:7-22, 4:63-5:67, 12:26-48 (digital filter). If it is determined that RPA System 1 and/or 2 fail to disclose this limitation, the limitation would have been obvious at least in view of the disclosure of Schmidt that provides details with regard to a data acquisition device that performs signal processing for physiological sensor signals such as pulse oximeter sensor signals. It would have been obvious to combine the Schmidt disclosure with the RPA Systems 1 and 2 at least because a POSITA would have looked to details for signal processing of the pulse oximeter sensor to the extent not disclosed by RPA System 1/2. A POSITA would have recognized that the Xpod performs filtering and processing of the pulse oximeter sensor signal to remove artifacts from the sensor signal. If this is not expressly disclosed or inherent in the Xpod, filtering and processing to remove artifacts would have been an obvious feature to include with the filtering and processing that is performed by the Xpod. It would have been obvious, for example, to remove artifacts induced by the subject, such as due to movement and a poor or interrupted interface with the sensor, or due to environmental factors such as interference. These would have been obvious processing steps to a POSITA to include, and within the level of ordinary knowledge and skill in the art because it was a common operation to apply to pulse oximeter sensor signal and it would have been obvious to incorporate it into the Xpod, to the extent it is not already incorporated. As another example, it would have obvious to discard data packets that might have a oxygen saturation or heart rate value outside the acceptable range for valid data. This was a well known feature of sensor signal processing and, to the extent not disclosed by the Xpod, would have been obvious to include as a common feature to discard data values that are likely errors.

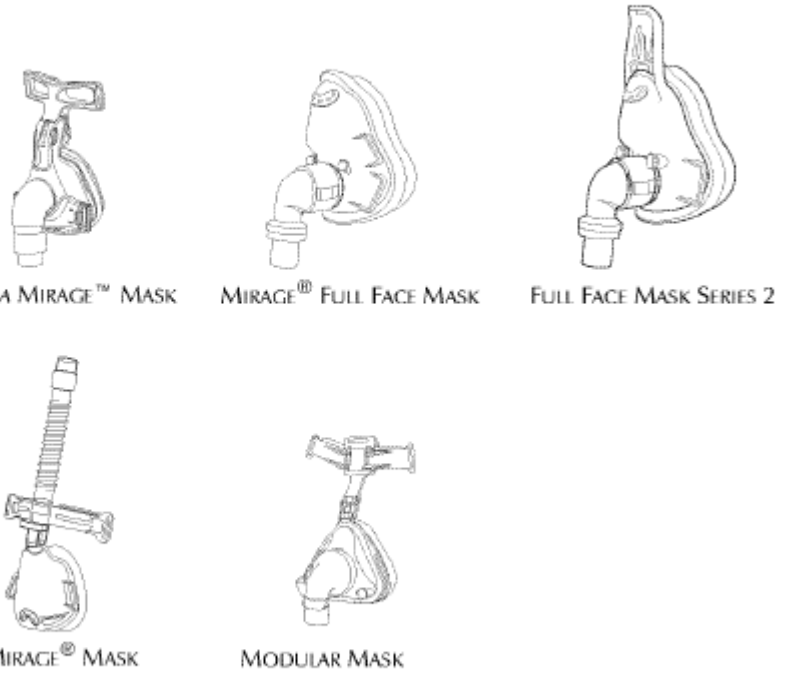
Claim Language [5.d]	ResMed Prior Art ("RPA")
	CleveMed's Infringement Contentions CleveMed's contentions for these limitations do not identify specifically which components of the accused products allegedly are the "data acquisition system." If CleveMed clarifies its contentions, ResMed reserves the right to supplement its invalidity contentions to rely on the same or similar components in the ResMed prior art. Furthermore, the '269 patent does not mention filtering and processing a sensor signal, or particularly a pulse oximeter sensor signal, to remove artifacts. It is therefore unclear what types of artifacts the claim is referring to, and the processing to remove artifacts might be different depending on the type or source of the artifact. CleveMed's infringement contentions for this limitation allege that the limitation is practiced as follows: "ResMed's Air10 Oximeter Module serves as the interface between the AirSense 10 and the pulse oximeter allowing the AirSense 10 to monitor and log pulse and oximetry data. The Air10 Oximetry Module receives the signal from the XPOD and converts it to a suitable format for transfer to the AirSense 10. [redacted] Final Infr. Cont., Chart I, 43. If the Xpod does not disclose these features, it would have been obvious to incorporate the *accused* features into the Xpod so as to remove data points that are likely errors or gaps in the data. This would have been an obvious, basic feature to include the design of the processing of a pulse oximeter sensor signal. *See also*, e.g., RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures; RMD-0318396 Specimen Photographs; [redacted]

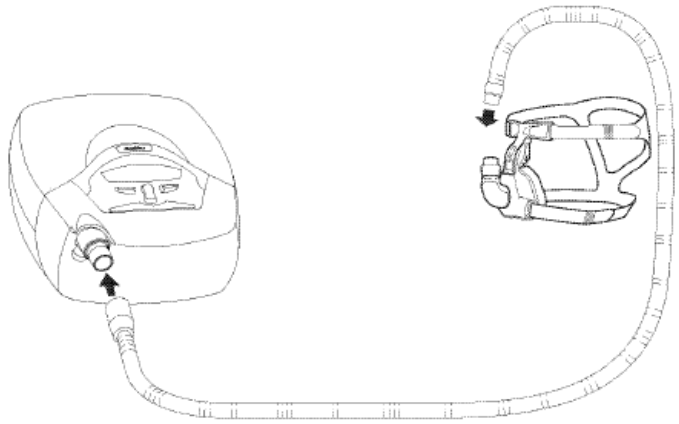
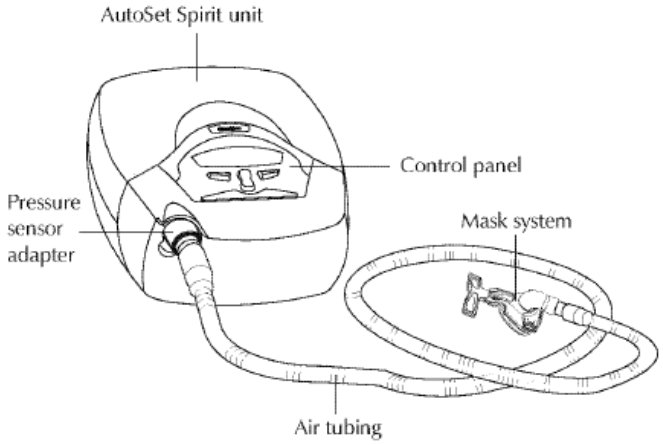
Claim Language [5.e.1]	ResMed Prior Art ("RPA")
[5.e.1] the PAP device comprising: a hose,	RPA discloses the AutoSet Spirit (PAP device) comprises a hose. For example, RPA discloses: **ResMed AutoSet Spirit (System 1-2)**

Claim Language [5.e.1]	ResMed Prior Art ("RPA")
	COMPONENTS OF THE AUTOSET® SPIRIT™ SYSTEM The following are supplied as part of an AUTOSET SPIRIT system.  Figure 4: AutoSet Spirit system components RMD-063968 (AutoSet Spirit Clinician's Manual) at -3983.

Claim Language [5.e.1]	ResMed Prior Art ("RPA")
	ACCESSORIES The following accessories may be purchased separately. AUTOSET SPIRIT ACCESSORIES Air tubing 9ft10in (3m) HUMIDIFIER ACCESSORIES (HUMIDAIRE and ResMed PASSOVER only) Pressure sensor line Short air tubing 7.5in (19cm) for HumidAire connection Medium air tubing 21in (52cm) for humidifier connection RMD-063968 (AutoSet Spirit Clinician's Manual) at -3984.

Claim Language [5.e.1]	ResMed Prior Art ("RPA")
	HUMIDIFIERS A humidifier may be required if your patient experiences dryness of the nose, mouth, or throat. The following humidifiers (supplied separately) are compatible for use with AUTOSET SPIRIT units. HUMIDAIRE 2i heated humidifier HUMIDAIRE™ heated humidifier ResMed PASSOVER humidifier RMD-063968 (AutoSet Spirit Clinician's Manual) at -3984.

Claim Language [5.e.1]	ResMed Prior Art ("RPA")
	MASK SYSTEMS The following ResMed mask systems (supplied separately) are recommended for use with the AUTOSET SPIRIT system.  *ULTRA* MIRAGE™ MASK MIRAGE® FULL FACE MASK FULL FACE MASK SERIES 2 MIRAGE® MASK MODULAR MASK WARNING For therapy in **AutoSet** mode, use one of the recommended ResMed masks. The AutoSet algorithm has appropriate parameters for these masks. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3985.

Claim Language [5.e.1]	ResMed Prior Art ("RPA")
	 RMD-063968 (AutoSet Spirit Clinician's Manual) at -3988.  RMD-063968 (AutoSet Spirit Clinician's Manual) at -3987.

Claim Language [5.e.1]	ResMed Prior Art ("RPA")
	[redacted] *See also*, *e.g.*, RMD-0318396 Specimen Photographs; [redacted].

Claim Language [5.e.2]	ResMed Prior Art ("RPA")
[5.e.2] a blower,	RPA discloses that the AutoSet Spirit flow generator (PAP device) comprises a blower. *See, e.g.,* limitation 1.b.1.

Claim Language [5.e.3]	ResMed Prior Art ("RPA")
[5.e.3] an airflow sensor with a second signal adapted for measuring respiratory airflow of a subject,	RPA discloses, or at least renders obvious, an airflow sensor with a second signal adapted for measuring respiratory airflow of a subject. RPA Systems 1-2 disclose this limitation at least for the same reasons CleveMed alleges the Accused Products infringe this claim. Alternatively, RPA Systems 1-2 render this limitation obvious in view of the knowledge of a POSITA, and/or Westbrook. *See, e.g.*, limitation 1.b.3. *See also*, *e.g.*, RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures; [redacted]

Claim Language [5.e.4]	ResMed Prior Art ("RPA")
[5.e.4] a second input for receiving pulse oximetry sensor data from the data acquisition device; and	RPA discloses, or at least renders obvious, a second input for receiving pulse oximetry sensor data from the data acquisition device. The AutoSet Spirit flow generator comprises an auxiliary input for receiving pulse oximetry sensor data from the NONIN Xpod via the ResLink. RPA System 1 discloses this limitation, or alternatively render it obvious in view of the knowledge of a POSITA. RPA System 2 renders this limitation obvious in view of the knowledge of a POSITA, and alternatively also in view of System 1. Alternatively, RPA Systems 1-2 in combination with Schmidt and the knowledge of a POSITA render this limitation obvious. *See, e.g.*, limitation 1.a, 1.b.2. *See also, e.g.*, RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures; RMD-0318396 Specimen Photographs; [redacted]

Claim Language [5.e.5]	ResMed Prior Art ("RPA")
[5.e.5] a mask or nasal cannula for treating a subject's sleep disorder symptoms; and	RPA discloses a mask for treating a subject's sleep disorder symptoms. *See, e.g.*, limitations 1.c.

Claim Language [5.f]	ResMed Prior Art ("RPA")
[5.f] the processor adapted for receiving pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor, the processor further adapted for calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom	RPA discloses, or at least renders obvious, the processor adapted for receiving pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor, 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, the processor adapted to be either part of or external to the PAP device and having a second output, the second output adapted for providing sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a nonvolatile memory to be used for later transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a remote location. *See, e.g.*, limitations 1.a, 1.b.4, 1.d, 5.d. RPA System 1 renders this limitation obvious, and RPA System 2 renders this limitation obvious for at least the reasons discussed for limitation 1.b.4 "the processor further adapted for calculating, based

Claim Language [5.f]	ResMed Prior Art ("RPA")
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, the processor adapted to be either part of or external to the PAP device and having a second output, the second output adapted for providing sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a nonvolatile memory to be used for later transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a remote location.	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." RPA Systems 1-2 disclose "the processor adapted to be either part of or external to the PAP device and having a second output, the second output adapted for providing [the calculated data] to a nonvolatile memory." To the extent the phrase "to be used for later transmission … to a remote location" is a further limitation on the claim, RPA Systems 1 and 2 disclose it or render it obvious. RPA System 1 (AutoScan 5) discloses the limitation "to be used for later transmission … to a remote location," or at least renders it obvious. *See* limitation 1.d. RPA System 2 (ResTraxx) renders the limitation "to be used for later transmission … to a remote location" obvious for the reasons presented for limitation 1.d. For example, RPA discloses: **ResMed AutoSet Spirit (System 1-2)** The ResMed AUTOSET® SPIRIT™ system is designed to provide continuous positive airway pressure (CPAP) therapy to patients with obstructive sleep apnea (OSA). Patients with OSA experience recurrent obstruction of their upper airway (apneas) due to relaxation of the tongue and soft palate while they sleep. Common symptoms are associated with poor sleep quality and may include excessive daytime sleepiness and tiredness, as well as diminished concentration and memory loss. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3974. The AUTOSET SPIRIT system is intended for the treatment of obstructive sleep apnea (OSA) in adult patients. Data collection capabilities also assist in the management of continuous positive airway pressure (CPAP) treatment. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3976.

Claim Language [5.f]	ResMed Prior Art ("RPA")

[redacted]

The AUTOSET SPIRIT system is designed for clinical use and home treatment of adult patients with obstructive sleep apnea (OSA). The system has two therapy modes for treating OSA: **CPAP** mode and **AutoSet** mode.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.

CPAP MODE

In CPAP mode, the AUTOSET SPIRIT unit provides fixed-pressure room air via tubing to the mask worn by your patient. The continuous air stream "splints" open the upper airway, preventing airway collapse.

AUTOSET SPIRIT delivers pressure within the range 4 to 20 cm H_2O. To make the beginning of treatment more comfortable, you may set a ramp so the pressure starts low and gradually increases to full treatment pressure over the ramp time.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.

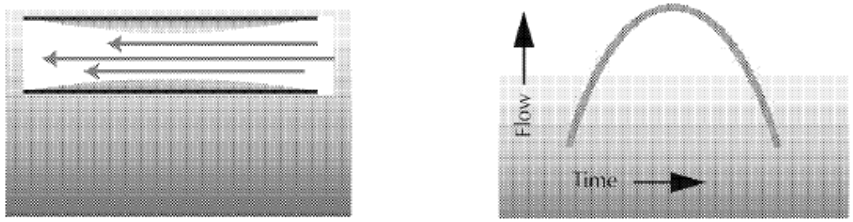
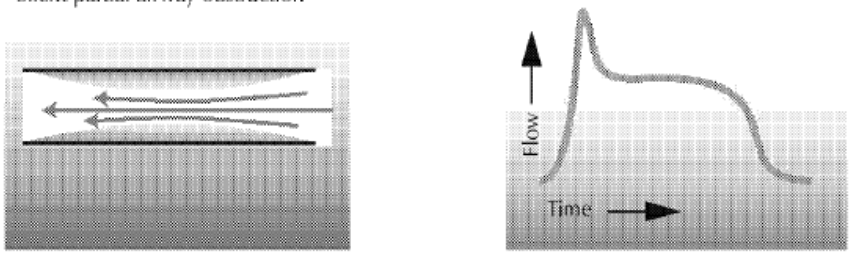
AUTOSET® MODE

The treatment pressure required by your patient may vary through the night, and from night to night, due to changes in sleep state, body position, and airway resistance. In AutoSet mode AUTOSET SPIRIT provides only sufficient pressure to maintain upper airway patency.

You can set the minimum and maximum allowable treatment pressures. The unit analyzes the state of the patient's upper airway on a breath-by-breath basis and delivers pressure within the allowed range according to the degree of obstruction. The AutoSet algorithm adjusts treatment pressure as a function of three parameters: inspiratory flow limitation, snore, and apnea.

The flow sensor, located in the AUTOSET SPIRIT unit, enables detection of inspiratory flow limitation and apneas. The pressure sensor, also located in the unit, enables measurement of pressure and snore.

Claim Language [5.f]	ResMed Prior Art ("RPA")
	RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980. **Inspiratory flow limitation** indicates silent partial obstruction. When your patient is breathing normally, the inspiratory flow measured by the unit as a function of time shows a typically rounded curve for each breath. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980. REMOTE DATA ACCESS You can download data from an AUTOSET SPIRIT unit in your patient's home to AUTOSCAN software on your computer using modems. Both you and your patient require a modem set up for this purpose. The patient attaches the modem to the right communications port on the AUTOSET SPIRIT unit and to a phone line. You attach your modem to the serial port on your computer and a phone line. Refer to complete instructions for modem use in the *AutoScan Clinician's Manual*. RMD-063968 (AutoSet Spirit Clinician's Manual) at -4015.

Claim Language [5.f]	ResMed Prior Art ("RPA")
	Open unrestricted airway  Figure 1: Inspiratory flow-time curve for an unrestricted airway As the upper airway begins to collapse, the shape of the inspiratory flow/time curve changes and the central section flattens. Silent partial airway obstruction  Figure 2: Inspiratory flow/time curve for a partially obstructed airway The AutoSet algorithm analyzes the shape of the central part of the curve for each breath and assigns a value as the amount of flattening. Inspiratory flow limitation, or partial airway closure, usually precedes snoring and obstruction. Detection of this flow limitation enables the unit to increase the pressure *before* obstruction occurs, making treatment pre-emptive. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3981.

Claim Language [5.f]	ResMed Prior Art ("RPA")

The Flattening Index is a measure of silent inspiratory airflow limitation. Flow limitation with loud snoring is handled by the snore detector. When a patient **snores**, sound is generated and the inspiratory flow/time curve is distorted by the frequency of the sound.

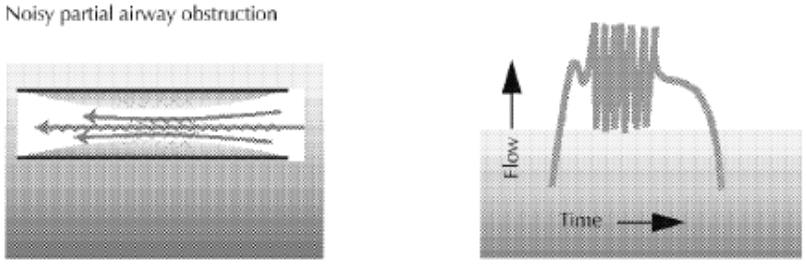


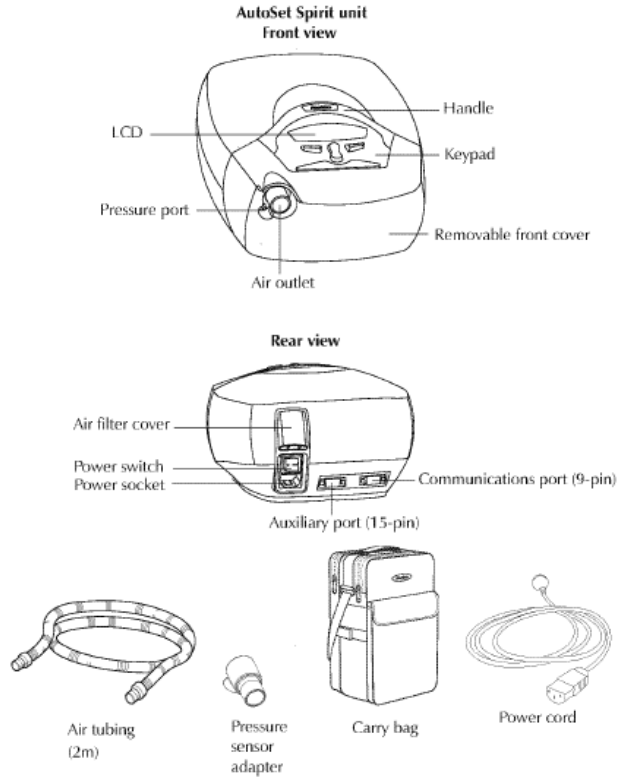
Figure 3: Inspiratory flow/time curve affected by snore

The AutoSet algorithm assigns an arbitrary value between 0.0 and 2.0 to the average amplitude of the snoring detected for the past 5 breaths. A value of 1.0 is equivalent to approximately 75dBA measured 10cm from the nares. Treatment pressure increases by up to 0.2 cm H_2O per second (proportional to the severity of the snore) for snore above 0.2 snore units. When snore is less than 0.2 snore units, therapy is reduced towards the minimum pressure with a 20-minute time constant.

An **apnea** is defined as a greater than 75% decrease in ventilation. The AutoSet algorithm scores an apnea if the 2-second moving average ventilation drops below 25% of the recent time average (time constant 100 seconds) for at least 10 consecutive seconds. Treatment pressure increases based on the duration of the apnea. The pressure will not rise above 10 cm H_2O when an apnea is detected, to prevent an inappropriate response to central apneas. Initial pressure increases are rapid, but the rate of increase diminishes as the pressure approaches 10 cm H_2O. When no further apneas are detected, therapy is reduced towards the minimum pressure with a 20-minute time constant.

A **hypopnea** is defined as a 50 to 75% drop in ventilation. A hypopnea is scored if the 8-second moving average ventilation drops below 50%, but not below 25%, of the recent average for 15 consecutive seconds. In order to avoid falsely responding to central hypopneas, the AutoSet algorithm does not respond to hypopneas but rather to the associated snore or flow limitation.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -3982.

Claim Language [5.f]	ResMed Prior Art ("RPA")
	COMPONENTS OF THE AUTOSET® SPIRIT™ SYSTEM The following are supplied as part of an AUTOSET SPIRIT system.  Figure 4: AutoSet Spirit system components RMD-063968 (AutoSet Spirit Clinician's Manual) at -3983.

Claim Language [5.f]	ResMed Prior Art ("RPA")

ACCESSORIES

The following accessories may be purchased separately.

AUTOSET SPIRIT ACCESSORIES

Air tubing
9ft10in (3m)

HUMIDIFIER ACCESSORIES

(HUMIDAIRE and ResMed PASSOVER only)

Pressure sensor line

Short air tubing
7.5in (19cm) for HumidAire connection

Medium air tubing
21in (52cm) for humidifier connection

RMD-063968 (AutoSet Spirit Clinician's Manual) at -3984.

Claim Language [5.f]	ResMed Prior Art ("RPA")
	HUMIDIFIERS A humidifier may be required if your patient experiences dryness of the nose, mouth, or throat. The following humidifiers (supplied separately) are compatible for use with AUTOSET SPIRIT units. HUMIDAIRE 2i heated humidifier HUMIDAIRE™ heated humidifier ResMed PASSOVER humidifier RMD-063968 (AutoSet Spirit Clinician's Manual) at -3984.

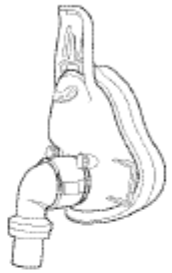
Claim Language [5.f]	ResMed Prior Art ("RPA")

MASK SYSTEMS

The following ResMed mask systems (supplied separately) are recommended for use with the AUTOSET SPIRIT system.

ULTRA MIRAGE™ MASK

MIRAGE® FULL FACE MASK



FULL FACE MASK SERIES 2

MIRAGE® MASK

MODULAR MASK

WARNING

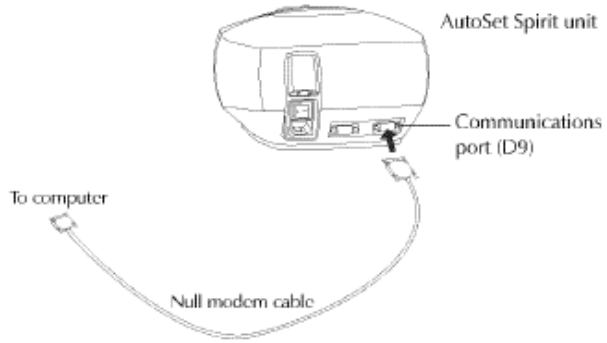
For therapy in **AutoSet** mode, use one of the recommended ResMed masks. The AutoSet algorithm has appropriate parameters for these masks.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -3985.

Claim Language [5.f]	ResMed Prior Art ("RPA")

AUTOSCAN™ SOFTWARE

AUTOSCAN is designed to enable review of the data stored in an AUTOSET SPIRIT unit. Data from up to 365 sessions may be stored and downloaded. Refer to the *AutoScan Clinician's Manual* or *Help* for details.



RMD-063968 (AutoSet Spirit Clinician's Manual) at -3986.

[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 410

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 411

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 412

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 413

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 414

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 415

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 416

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 418

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 419

Claim Language [5.f]	ResMed Prior Art ("RPA")

Menu	Parameter	Description
Results	Efficacy data	Displays pressure, leak, AHI (apnea + hypopnea index), AI (apnea index), and HI (hypopnea index) data for a range of time intervals. For details, see "Clinical Menu Results" on page 39.
	Usage data	Displays usage data for a range of time intervals. For details, see "Clinical Menu Results" on page 39.
	Mask Fit* (Smart Data)	Displays a star rating corresponding to the 70th centile leak from the previous session, if enabled in Clinical Menu, Options, Smart Data.
	Pressure* (Smart Data)	Displays 95th centile pressure from the previous session, if enabled in Clinical Menu, Options, Smart Data.
	Usage* (Smart Data)	Displays usage hours from the previous session, if enabled in Clinical Menu, Options, Smart Data.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -4004.

PRESSURE

The pressure transducer located in the unit measures treatment pressure; the average pressure is calculated and recorded each minute. The pressure reported in the Efficacy Data submenu (see Figure 9, The Clinical Menu Results series, on page 40) for a single session is the 95th centile pressure for mask-on time, excluding periods when the leak has exceeded 0.4 L/s (24 L/min). For selected time intervals (last week, last month, last 6 months or last year), the median of the daily 95th centile values is reported. Non-usage days are not included in calculations.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -4010.

Claim Language [5.f]	ResMed Prior Art ("RPA")
	LEAK Leak is derived by analyzing inspiratory and expiratory airflows (via the flow sensor located in the unit). Theoretically, inspiratory and expiratory volumes should be equal. A net airflow greater than the expected mask vent flow is equal to the leak. Generally, a leak rate of more than 0.4 L/s (24 L/min) is associated with patient discomfort, disturbed sleep, and reduced efficacy of treatment. *If the leak exceeded 0.4 L/s (24 L/min) for more than 30% of the previous session, the following message will appear on the LCD:* **`High leak in last session.`** *The Leak Alert feature, if enabled, will alert the patient when mask leak exceeds 0.7 L/s (42 L/min) for more than 20 seconds. When the leak exceeds this level, the autotitrating algorithm ceases to perform optimally.* The leak reported in the Efficacy Data submenu (see Figure 9, The Clinical Menu Results series, on page 40) is the 95th centile value for mask-on time for each session, or the median 95th centile value for a selected time interval (last week, last month, last 6 months, or last year). Non-usage days are not included in calculations. RMD-063968 (AutoSet Spirit Clinician's Manual) at -4010.

Claim Language [5.f]	ResMed Prior Art ("RPA")
	CLINICAL MENU RESULTS A comprehensive set of data is available in Clinical Menu, Results (Efficacy Data and Usage Data), as shown in Figure 9, The Clinical Menu Results series, on page 40. To navigate within the Efficacy or Usage Data sections, use: • the **Up/Down** key to scroll through items within a time series • the **Left** key to navigate between time series. The Used screen reports total hours the device has been used and the number of days the device was used compared to the total days since the hourmeter was last reset. Other statistics quoted include: • usage • pressure (95th centile value for mask-on time only) • leak (95th centile value for mask-on time only) • AHI, or apnea + hypopnea index (calculated per session) • AI, or apnea index (calculated per session) • HI, or hypopnea index (calculated per session). RMD-063968 (AutoSet Spirit Clinician's Manual) at -4012.

Claim Language [5.f]	ResMed Prior Art ("RPA")

DOWNLOADING AND REVIEWING DATA USING AUTOSCAN

Data collected by the AUTOSET SPIRIT unit may be downloaded to AUTOSCAN software (available in the AUTOSCAN clinical interface kit) for review. Refer to the instructions in the *AutoScan Clinician's Manual* for details of downloading and reviewing data.

Data from an AUTOSET SPIRIT unit are presented in AUTOSCAN in the following ways:

- graphical display of usage data (time/date stamped) showing mask on/off events (Usage graph)
- 95th centile, median, and maximum values plus average and standard deviation values for leak and pressure for each session, with median values quoted for all parameters for nominated time intervals (Treatment Profile and Statistics display)
- apneas, hypopneas, AI, HI, and AHI on a per hour basis (Treatment Profile and Statistics display).
- 5 nights of Night Profile Data.

NOTE

The AutoSet Spirit clock resets at midday. To ensure that 5 nights of Night Profile Data are available, you must download the data before midday on the fifth day.

Additionally, use AUTOSCAN to:

- document patient notes
- generate and print reports.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -4015.

REMOTE DATA ACCESS

You can download data from an AUTOSET SPIRIT unit in your patient's home to AUTOSCAN software on your computer using modems. Both you and your patient require a modem set up for this purpose. The patient attaches the modem to the right communications port on the AUTOSET SPIRIT unit and to a phone line. You attach your modem to the serial port on your computer and a phone line. Refer to complete instructions for modem use in the *AutoScan Clinician's Manual*.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -4015.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 424

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted] **ResLink (System 1, 2)** The RESLINK is intended to be used with the ResMed AUTOSET® SPIRIT™ and S7™ ELITE systems. The RESLINK has two distinct functions: • enhanced collection, storage and transfer of data (including pulse oximetry data), and • upgrade of the AUTOSET SPIRIT and S7 ELITE software. RMD-063198 (ResLink Clinician's Guide) at -3199.

Claim Language [5.f]	ResMed Prior Art ("RPA")

THE RESLINK SYSTEM

The following are supplied as part of the RESLINK system:

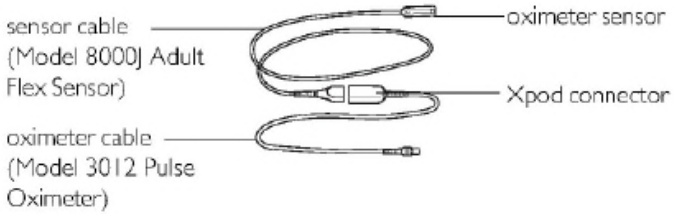
- RESLINK device

- SmartMedia card

The RESLINK pouch also contains the *ResLink User's Manual* and the SmartMedia card Mailback card.

ACCESSORIES

The NONIN ® Model 3012 Pulse Oximeter and Model 8000J Adult Flex Sensor (available from ResMed) are compatible for use with the RESLINK.



RESMED

RMD-063198 (ResLink Clinician's Guide) at -3199.

Claim Language [5.f]	ResMed Prior Art ("RPA")

Detailed Data

The following table sets out the detailed data available for viewing in AutoScan. A ninth parameter, the Apnea / Hypopnea Index (AHI) is also displayed. The AHI is calculated by adding together the total number of apneas and hypopneas that occurred in the preceding hour. The AHI is updated with each event, and reset every hour, increasing with the number of apneas.

The Pulse rate and SpO_2 readings are obtained from the oximeter.

Parameter	Minimum resolution	Range	Sampling frequency (hz)
Events	1 sec	0–180 sec	as each event occurs (maximum 2000 events/session)
Minute ventilation	0.1 L/min	0–180 L/min	0.5
Leak	0.02 L/sec	0–5 L/sec	0.5
Pulse rate	1 bpm	20–220	0.2
SpO_2	1%	40%–100%	1.0
Pressure	0.2 cmH_2O	5–40 cmH_2O	0.5
Snore	n/a	Quiet–Loud	per breath
Flattening	n/a	Round–Flat	per breath

RMD-063198 (ResLink Clinician's Guide) at -3200.

Data Collection

To collect data from the AutoSet Spirit or S7 Elite, insert the SmartMedia card into the ResLink.

Note: *When you use the SmartMedia card with a new patient's flow generator, the ResLink deletes all information currently on the SmartMedia card.*

In addition to the comprehensive set of data available in the flow generator, the ResLink collects and stores *Detailed Data*. Collection and storage of data occurs automatically during therapy. The 32-megabyte SmartMedia card (supplied with the ResLink), can record and store up to 30 sessions of detailed data. If the one SmartMedia card is used for more than 30 sessions, the oldest data will be overwritten.

A maximum of 10 hours per session is recorded. If the duration of therapy is greater than 10 hours, the first 10 hours is retained. Each session is defined as taking place between noon of one day and noon of the following day.

After therapy, the patient can return the card to the clinician using the Mailback card provided with the ResLink. Data stored on the SmartMedia card can be downloaded by the clinician for review and analysis. See the *AutoScan Clinician's Manual* for information on downloading and viewing detailed data.

RMD-063198 (ResLink Clinician's Guide) at -3200.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

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Exhibit 1024 - Page 429

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

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Exhibit 1024 - Page 430

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 431

[redacted]

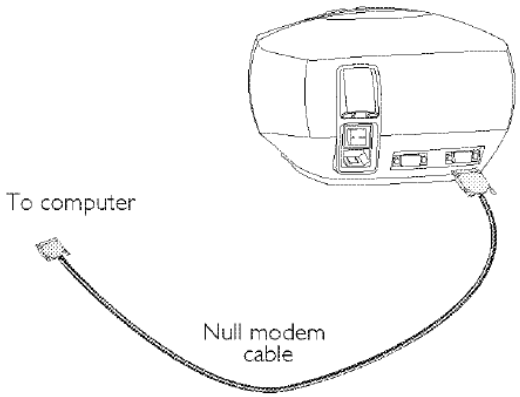
FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

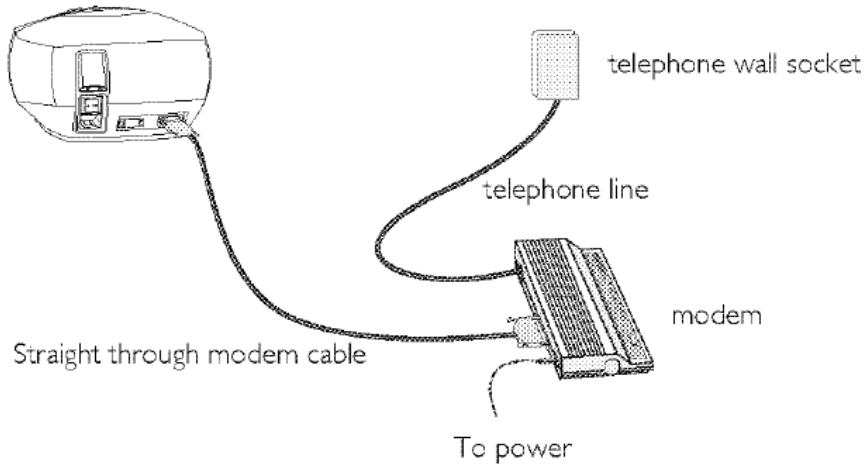
Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 432

Claim Language [5.f]	ResMed Prior Art ("RPA")
	 RMD-289749 (ResLink Launch Brochure) at -9749 and -9756. ResMed introduces ResLink™–the first truly modular sleep-disordered breathing (SDB) therapy management tool with significant benefits for the patient, sleep laboratory, prescribing physician, and equipment provider. The portable ResLink module simply clips onto ResMed's AutoSet Spirit™ system. ResLink captures and stores high-resolution patient compliance and efficacy data, including oximetry. This information is easily accessed and transferred via a 32MB SmartMedia™ card and then downloaded to a PC using ResMed's AutoScan™ software. RMD-289749 (ResLink Launch Brochure) at -9750. **Comprehensive efficacy data with oximetry** ResLink reports on significant parameters such as minute ventilation, snore, flattening, SpO_2, pulse rate, pressure response, leak, events, and AHI, providing visible insights into treatment efficacy. ResLink presents this efficacy information along with integrated oximetry data for simultaneous onscreen viewing and analysis. RMD-289749 (ResLink Launch Brochure) at -9751.

Claim Language [5.f]	ResMed Prior Art ("RPA")
	 RMD-289749 (ResLink Launch Brochure) at -9755. **AutoScan 5.4 (System 1)** AUTOSCAN™ 5.4 has been developed to view summary data and detailed data obtained from the RESLINK™ via the SmartMedia™ card. Summary data and Night profile data obtained from the flow generator can also be viewed as in previous versions of AUTOSCAN. AUTOSCAN 5.4 has data collection and management capabilities that provide an adjunct for patient management. The flow generator systems intended to be used with AUTOSCAN 5.4 are the ResMed AUTOSET® SPIRIT™, S7™ ELITE, VPAP® III, VPAP III ST, VPAP III ST-A, and AUTOSET RESPOND™. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1269.

Claim Language [5.f]	ResMed Prior Art ("RPA")
	FLOW GENERATOR COMPATIBILITY The following flow generators are compatible with AUTOSCAN 5.4: • AUTOSET SPIRIT • AUTOSET RESPOND • VPAP III, VPAP III ST, VPAP III ST-A, • S7 ELITE. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277. CONNECTING THE FLOW GENERATOR TO THE COMPUTER In order to download data into AUTOSCAN 5.4, your computer must be connected by cable to the flow generator. NOTES *If your flow generator is connected to a ResControl, you must disconnect the ResControl before connecting the flow generator to your computer for interfacing to AutoScan 5.4.* Plug the null modem cable into the PC connection port on the flow generator and into an available serial port at the back of your computer (COM1, COM2, COM3 or COM4).  Figure 2: Connecting the flow generator to the computer RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277 – 78.

Claim Language [5.f]	ResMed Prior Art ("RPA")
	USING MODEMS You can download summary and Night Profile data on your flow generator remotely via modem. We recommend *Windows NT 4.0 SP6* and 3Com U.S. Robotics 56k Voice Faxmodems for this purpose. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1279. USING MODEMS TO DOWNLOAD DATA You may download summary and Night Profile data remotely via modem. These operations require that both you and the patient have modems. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1290.  RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1290. MANAGING PATIENT INFORMATION AUTOSCAN 5.4 allows you to record patient information, clinical details and notes in the patient file. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1297.

Claim Language [5.f]	ResMed Prior Art ("RPA")

Detailed and summary data from a patient's flow generator are stored on a SmartMedia card by the RESLINK. The SmartMedia card is removed and sent to the clinician at the end of the study period. The SmartMedia card is inserted into a SmartMedia card reader attached to the clinician's computer, and the data can then be downloaded and viewed in AUTOSCAN 5.4.

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1301.

The Detailed Data screen displays nine traces of data downloaded via the RESLINK from the flow generator. You can view data in the Detailed Data screen in increased detail or as a compact overview.

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1303.

The Detailed Data screen for that session will be displayed.

The graph display area shows the downloaded data in the trace panels:

- Events (s)
- Minute Ventilation (L/min)
- Leak (L/s)
- Pulse Rate (bpm)
- SpO_2 (%)
- AHI (Events/hr)
- Pressure (cm H_2O)[a]
- Snore (Quiet to Loud)[a]
- Flattening (Round to Flat)[a]
- Respiratory rate (BPM).[b]

[a] AUTOSET SPIRIT and S7 ELITE only
[b] VPAP III series only

NOTE *Pulse rate and SpO_2 are derived from the oximeter reading.*

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1304.

Claim Language [5.f]	ResMed Prior Art ("RPA")

INTERPRETING AUTOSET DATA

NOTE *AutoSet Respond displays data only in the Usage Profile.*

APNEAS AND HYPOPNEAS

The AutoSet algorithm defines an apnea as a greater than 75% decrease in nasal ventilation for at least 10 seconds. An apnea is scored if the 2-second moving average ventilation drops below 25% of the recent average (time constant 100 seconds) for at least 10 consecutive seconds.

An Apnea Index (AI), shown in the *Treatment Profile* as a red bar, is derived for each session by dividing the total number of apneas that occurred by the total mask-on time.

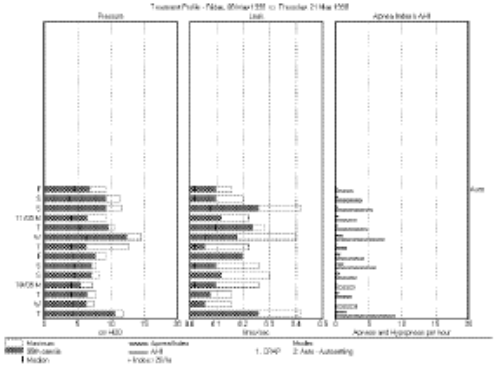


Figure 38: Treatment Profile details

The AI for a session or group of sessions may be viewed in the *Statistics* tab of AUTOSCAN 5.4.

Information on apneas is stored for the most recently accumulated five nights of data. They log the time during the session and duration of each apnea and display these as red "lollipops" on the Apnea Events and Duration graph in the *Night Profile*.

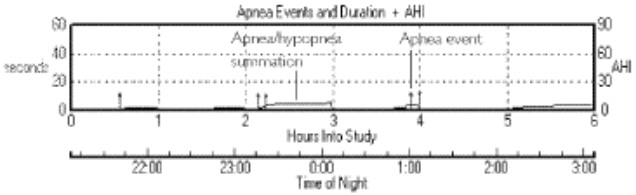


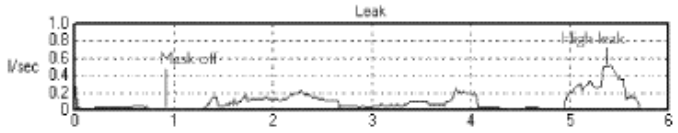
Figure 39: Apnea Events and Duration and AHI in the Night Profile

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1325.

Claim Language [5.f]	ResMed Prior Art ("RPA")
	The AutoSet algorithm defines a hypopnea as a 50 to 75% decrease in nasal ventilation. A hypopnea is scored if the 8-second moving average ventilation drops below 50%, but not below 25%, of the recent average for 15 consecutive seconds. The recent average ventilation is calculated using a time constant of 100 seconds. Information on individual hypopneas is not displayed in the *Treatment Profile* but an apnea/hypopnea index (AHI) is calculated by dividing the total number of apneas + hypopneas that occurred in a session by the total mask-on time. The AHI for a given session is displayed as a blue bar in the *Treatment Profile* (see Figure 38). The AHI value for a session (or group of sessions) can also be viewed in *Statistics*. The *Statistics* tab in AUTOSCAN 5.4 displays hypopnea index (HI) values, in addition to AI and AHI values, for the nominated time interval. For the most recently accumulated five nights of data, a series of apnea/hypopnea summations is saved for each session. Each of these is the sum of the number of apneas and hypopneas the patient experienced within a one-hour interval. At the end of each hour of data collection, the maximum value of the summation is equivalent to an AHI for that hour as it is equal to the total number of apneas + hypopneas divided by one hour. The flow generator then resets the apnea + hypopnea count to zero. The apnea/hypopnea summation is plotted as a blue line on the Apnea Events graph in the *Night Profile* (Figure 39). At the end of the session, an AHI is calculated and displayed in the *Statistics* screen. NOTE *The AutoSet algorithm does not distinguish between a closed airway apnea (obstructive apnea) and an open airway apnea (central apnea). For this reason, it will not increase pressure in response to apneas once pressure has reached 10 cm H_2O. Pressure increases beyond 10 cm H_2O, in response to apnea alone, may invoke more apneas if they are central in nature by triggering the Hering-Breuer reflex.* LEAK MEASUREMENT NOTE *When assessing results, it is best to check the leak data first. Leaks greater than 0.4 L/sec affect the accuracy of other measurements.* Leak is measured by analysing inspiratory and expiratory volumes, which should be approximately equal, yielding an average airflow of 0 L/sec in the absence of mask leak. An average airflow greater than 0 L/sec is due to leak. Generally, a leak rate of more than 0.4 L/sec is associated with patient discomfort, disturbed sleep and reduced efficacy of treatment. A leak rate of 0.2 L/sec or less for the majority of a session signals a well-fitting mask. The median, maximum and 95th percentile leak for each session in a series are displayed in the *Treatment Profile* (see Figure 38). RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1326.

Claim Language [5.f]	ResMed Prior Art ("RPA")

Median, 95th percentile and maximum leak are displayed for the nominated time interval in the *Statistics* tab of AUTOSCAN 5.4. A graph of leak as a function of time for each night is shown in the *Night Profile*.



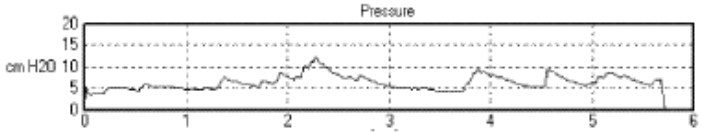
PRESSURE MEASUREMENT

The pressure transducer located in the AUTOSET SPIRIT and S7 ELITE calculates pressure at the mask.

The median, maximum and 95th percentile pressure delivered during each night in a series are displayed in the *Treatment Profile* (see Figure 38).

The AUTOSET SPIRIT and S7 ELITE continuously titrate the pressure delivered, based on inspiratory flow limitation, snore, and apnea.

The median, 95th percentile and maximum pressure data are displayed for the nominated time interval in the *Statistics* tab of AUTOSCAN 5.4. The pressure delivered to the patient each night is reported as a function of time in the pressure graph in the *Night Profile*.



MINUTE VENTILATION

Information from the VPAP III, VPAP III ST or VPAP III ST-A flow transducer, modified by an internal model of the mask vent flow, is used to calculate the minute ventilation. This is displayed as a 5-breath moving average.

The median, maximum and 95th percentile minute ventilation for each night in a series are displayed in the Treatment Profile, and for the nominated time interval in the Statistics tab.

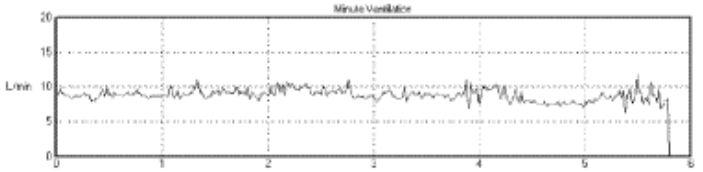


Figure 40 : Minute Ventilation graph in Night Profile screen

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1327.

Claim Language [5.f]	ResMed Prior Art ("RPA")

INTERPRETING DETAILED DATA

Detailed data obtained from the SmartMedia card is displayed at the AUTOSCAN 5.4 Detailed Data tab. Each of the graphs in the Detailed Data screen represents a set of measurements of a different aspect of the patient's breathing. If there is no data in a section of the graph, the flow generator was not being used at that time. If the oximeter falls off or fails to make contact with the patient at any stage, the Pulse Rate and SpO_2 traces will be empty or show a zero reading. You will be alerted to this by a message during download (see Figure 21 above).

Session statistics for SpO_2, Pulse rate and Minute ventilation are included in the printed detailed data report.

AHI (APNEA/HYPOPNEA INDEX)

The apnea / hypopnea index for the AUTOSCAN 5.4 *Detailed Data* screen is calculated by adding together the total number of apneas and hypopneas that occurred in the preceding hour. The AHI is updated with each event, and reset every hour, increasing with the number of apneas. If it rises above 10 events/hr, check the leak and pressure. It may be that the patient is having a lot of central apneas.

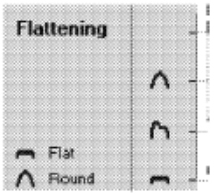
EVENTS

The *Events* graph displays the patient's apneas and hypopneas with an indicator at the point where they commence, and a number that indicates the duration (in seconds) of the event. AUTOSCAN 5.4 can log up to 2000 events per session.

Apneas are indicated with a red ball, and hypopneas with blue.

FLATTENING INDEX (AUTOSET SPIRIT AND S7 ELITE ONLY)

The Flattening Index graph is an indicator of trends in the patient's breathing. The Flattening Index graph in AUTOSCAN 5.4 displays measurements as being Flat, Flattening or Round



It is desirable that the results are rounded rather than flat. If the trace is too flat, check the leak and the pressure. If the patient is currently on CPAP mode, it is possible that they may benefit from changing to Autoset mode.

LEAK

The RESLINK samples for leak every 2 seconds. While some leak is a natural part of therapy, it is recommended that the level of leak is below 0.4 L/sec. Higher leak will

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1307.

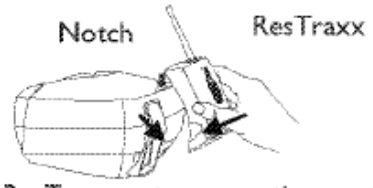
Claim Language [5.f]	ResMed Prior Art ("RPA")
	affect treatment and compliance. A red line in the Leak graph indicates the 0.4 L/sec level. MINUTE VENTILATION Minute ventilation is a measure of the total volume breathed in (or out) within any 60 second period. It is calculated from respiratory rate x tidal volume. The RESLINK samples this information every 2 seconds. A normal range is from 6–12 L/min. Minute ventilation is used mainly to manage arterial CO_2 tension ($PaCO_2$) during therapy. For example, a patient with a $PaCO_2$ of 50mmHg and a Minute Ventilation of 5 L/min can be reduced to 45 mmHg (10% reduction) by raising Minute Ventilation to 5.5 L/min (10% increase). NOTE *Respiratory rate is the number of breaths per minute. Tidal volume is the volume of air breathed in or out in one breath.* PRESSURE (AUTOSET SPIRIT AND S7 ELITE ONLY) The RESLINK samples pressure every 2 seconds. The trace displayed in the Detailed Data screen is the calculated delivered pressure. If this differs markedly from the pressure set on the flow generator, check that the device is functioning correctly. The trace for Pressure will show any changes to the pressure setting on the flow generator. In Autoset mode, the trace will show increases or decreases in line with apnea or hypopnea events, or snore. If the pressure trace is constant, this would indicate that the flow generator is in CPAP mode. If the pressure trace is changing with time, this would indicate that the flow generator is in Autoset mode. PULSE RATE An average pulse rate should be between 60–80 bpm. Typically, an apnoea will increase the patient's pulse rate. Zoom in on any part of the trace (see "Changing the scale" above) to see the cardiac response in detail. The pulse rate is sampled every second by the RESLINK. RESPIRATORY RATE (VPAP III SERIES ONLY) Respiratory rate is sampled once every 2 seconds. The displayed rate is an average of the previous 5 breaths. The range is 0–60 bpm (breaths per minute). SNORE (AUTOSET SPIRIT AND S7 ELITE ONLY) Every breath is monitored for snore. However, the trace shows the rolling average for the last 5 breaths as the *Snore* graph is concerned with trends rather than measuring the individual snore. If the flow generator is functioning properly, there should not be much occurrence of snore. Snore is measured in AUTOSCAN 5.4 on a scale of Quiet to Loud. SpO_2 SpO_2 measures oxygen saturation in the patient's blood. The SpO_2 trace in AUTOSCAN 5.4 has a red indicator line at 90% to show at a glance if the patient is within acceptable limits. This line makes it easy to see where desaturations are occurring, and to connect their occurrence with apnea events. SpO_2 is measured every second by the RESLINK. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1308.

Claim Language [5.f]	ResMed Prior Art ("RPA")
	ResTraxx (including RDC) (System 2) ResTraxx™ allows the wireless transfer of information from a continuous positive airway pressure (CPAP) unit to a clinician at a remote location via a two-way pager network. ResTraxx is intended to be used with ResMed S7™ Elite, AutoSet® Spirit™ , AutoSet® Respond™ , and VPAP® III flow generator systems on adults with obstructive sleep apnea. RMD-062642 (ResTraxx Quick Reference Guide) at -2642.

Claim Language [5.f]	ResMed Prior Art ("RPA")

Attaching the ResTraxx

1. Turn the flow generator to OFF.
2. Slide lever on back of ResTraxx to the left.
3. Place top catch on ResTraxx onto notch at back of unit.



4. Push 15-pin connector on ResTraxx onto connection port on back of unit.
5. Slide lever on back of ResTraxx to the right to lock it into place.
6. Turn the main power switch at the back of flow generator to the ON position.
7. A green LED on top of ResTraxx will light up 15 - 20 seconds after unit is turned on, then begin to flash.
8. After about 15 seconds, a series of messages will appear on the flow generator display, indicating the unit's initialization and registration status of unit.
9. After initialization, the standby screen appears on the flow generator display and the unit begins transmitting information.

RMD-062642 (ResTraxx Quick Reference Guide) at -2642.

[redacted]

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FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

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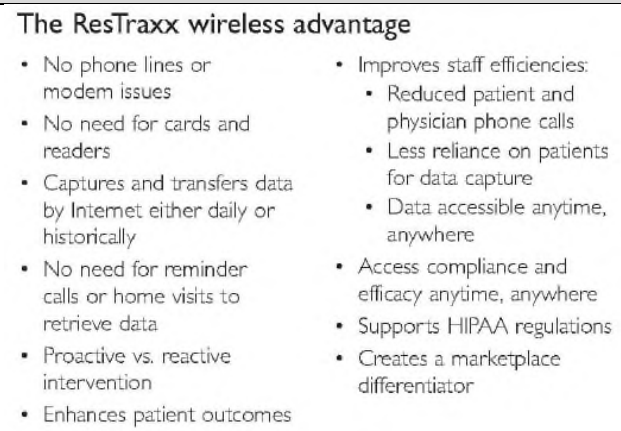
Exhibit 1024 - Page 447

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted] ResTraxx is a first-of-its-kind wireless communication device that attaches easily to the back of ResMed flow generators. The ResTraxx system captures, transfers, and stores compliance and efficacy data without wires, phone lines, modems, or data cards. ResTraxx is an elegant system that brings patient usage and treatment efficacy data to your fingertips instantly. RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

Claim Language [5.f]	ResMed Prior Art ("RPA")
	 RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

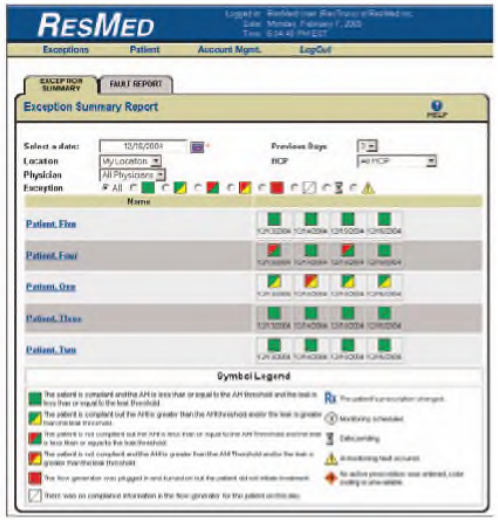
[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")

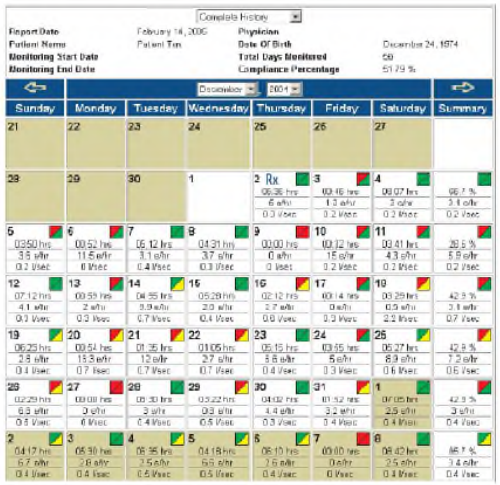
Exception Reporting

Enhance productivity and manage patients more efficiently. **Exception Reporting identifies and highlights those patients who fall below desired usage thresholds or have issues with mask leak or AHI.** This feature enables you to focus your efforts only on those patients who require intervention and respond proactively to potential problems. The simple color-coded alert system helps you identify exception patients quickly and easily.



Efficacy + Leak + Usage Data

The ResTraxx Data Center displays data on a daily basis in a calendar format enabling you to see daily or weekly trends of adherence problems before compliance is truly compromised. Early intervention and ongoing follow-up is considered critical, especially during the first month of CPAP acclimation, to determine long-term compliance rates.[2]



Want more details on therapy results? Click on the calendar day in question, and a therapeutic report will display additional clinical data regarding the patient's usage for that day.

RMD-063327 (ResTraxx Patient Management Brochure) at -3328.

[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [5.f]	ResMed Prior Art ("RPA")
	[redacted]

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Claim Language [5.f]	
	[redacted] If the Judge or Jury finds that RPA does not disclose this claim limitation, this claim is still rendered obvious by modifying or combining RPA with other references or the knowledge of a POSITA. For example, it would have been obvious to a POSITA to store sleep disorder symptom data and/or an

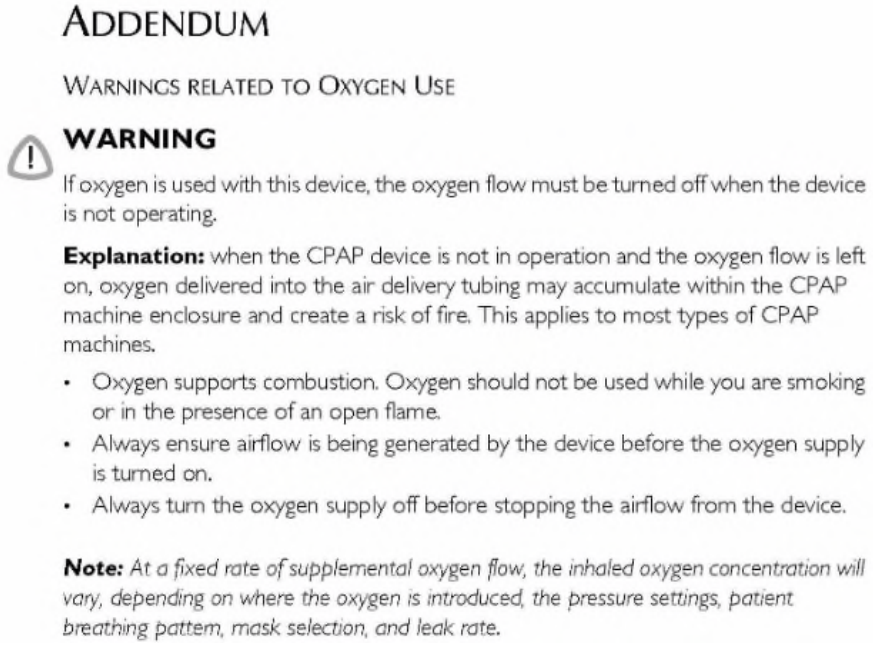
Claim Language [5.f]	ResMed Prior Art ("RPA")
	index of the level of severity of the subject's symptom, along with the information collected by RPA's CPAP device, in a nonvolatile memory for later transmission. As one example, Schmidt discloses: "Referring now to FIG. 2, there is shown a block diagram of the signal processing module 16 with the sensor 14 and the module antenna 20. The signal processing module 16 comprises input means 22, analog-to-digital (A/D) means 24, a ***module microcontroller 26 with a nonvolatile memory***, advantageously, an EEPROM 261, a module transmitter 28, a module receiver 29 and a module power supply 30." Schmidt, 5:52-58 (emphasis added); *see also* 7:4-9, 8:47-55. The disclosure in Schmidt appears to be identical to the only disclosure in the '269 patent that references a nonvolatile memory. Accordingly, for at least the same reasons that the '269 patent may be considered to provide a written description of this claim limitation, it is disclosed by Schmidt and would have been on obvious feature to a POSITA to incorporate into the RPA system to arrive at the claimed system. *See* limitation 1.a. *See also, e.g.*, RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures; RMD-0318396 Specimen Photographs; [redacted]

Claim Language [8pre]	ResMed Prior Art ("RPA")
[8pre] A sleep disorder treatment system comprising:	To the extent the preamble is limiting, RPA discloses a sleep disorder treatment system. *See, e.g.*, limitation 1pre.

Claim Language [8.a]	ResMed Prior Art ("RPA")
[8.a] a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals	RPA discloses, or at least renders obvious, a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the at least one physiological sensor. For at least the same reasons, RPA discloses this limitation. For example, for at least the

Claim Language [8.a]	ResMed Prior Art ("RPA")
from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the at least one physiological sensor; and	same reasons CleveMed alleges the accused flow generator devices satisfy this limitation, the prior art AutoSet Spirit flow generator discloses this limitation. *See, e.g.*, limitations 1.pre, 1.a, 1.b.3, 1.b.4, 5.a. Alternatively, if the Judge or Jury finds that RPA does not disclose this claim limitation, this claim is still rendered obvious by modifying or combining RPA with the knowledge of a POSITA. For example, CleveMed's infringement contentions for this limitation allege the following: [redacted] Final Infr. Cont., Chart I, 69. [redacted] Final Infr. Cont., Chart I, 70. CleveMed's infringement contentions for this limitation do not point to any specific structure within the accused PAP devices as the "data acquisition system" or "device," therefore CleveMed appears to allege that any structure that has inputs for receiving signals from at least one physiological sensor satisfies this limitation. If CleveMed clarifies its contentions for this claim limitation, ResMed reserves the right to supplement its contentions accordingly. The AutoSet Spirit flow generator discloses the same features as those accused by CleveMed.

Claim Language [8.a]	ResMed Prior Art ("RPA")
	The AutoSet Spirit flow generator comprises inputs, e.g., at the microprocessor, for receiving signals [redacted].
	The AutoSet Spirit flow generator's microprocessor calculates and derives parameters based in part on the signals from the at least one physiological sensor. *See* limitation 1.b.4. CleveMed's infringement contentions for this limitation allege that a handful of statistics and parameters allegedly practice the claimed "an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the at least one physiological sensor," as shown in the above excerpt, and also at the cited chart in excerpts from ResMed accused product documentation. In some cases, the same parameters that are accused are also calculated by the prior art AutoSet Spirit flow generator. As established for limitation 1.b.4, the microprocessor derives parameters such as respiratory flow, flow limitation, and flattening index based at least in part on data from the flow sensor, and detects apneas and hypopneas based at least in part on the data from the flow sensor; and derives pressure parameters and a snore index based at least in part on data from the pressure sensor. *See, e.g.*, limitation 1.b.4; AutoSet Spirit Clinician's Manual at 7-9; see also [redacted] AutoScan 5.4 Clinician's Manual (RMD-311263) at 57-58. *See also, e.g.*, RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures; RMD-0318396 Specimen Photographs; [redacted]

Claim Language [8.b]	ResMed Prior Art ("RPA")
[8.b] a positive airway pressure apparatus for providing pressurized air and dosing and chemically treating a subject's sleep disorder or symptoms with a pharmaceutical agent, the positive airway pressure apparatus comprising a controller adapted to adjust the pharmaceutical agent, at least in part, using the output of the level of severity of the subject's sleep disorder from the data acquisition system.	RPA discloses, or at least renders obvious, this limitation for the same reasons CleveMed alleges the accused products practice this claim limitation. *See, e.g.*, limitations 1pre, 1.b, 1.c (showing masks with connector ports for supplemental oxygen), 1.b.3, 15.b. Moreover, CleveMed's infringement contentions allege this limitation is practiced by a PAP device "that can be fitted to provide … supplemental oxygen." Final Infr. Cont., Chart I, 72-73. RPA Systems 1-2 disclose this limitation for at least the same reasons. For example, RPA discloses:  ADDENDUM WARNINGS RELATED TO OXYGEN USE **WARNING** If oxygen is used with this device, the oxygen flow must be turned off when the device is not operating. **Explanation:** when the CPAP device is not in operation and the oxygen flow is left on, oxygen delivered into the air delivery tubing may accumulate within the CPAP machine enclosure and create a risk of fire. This applies to most types of CPAP machines. • Oxygen supports combustion. Oxygen should not be used while you are smoking or in the presence of an open flame. • Always ensure airflow is being generated by the device before the oxygen supply is turned on. • Always turn the oxygen supply off before stopping the airflow from the device. ***Note:*** *At a fixed rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on where the oxygen is introduced, the pressure settings, patient breathing pattern, mask selection, and leak rate.* RMD-307134 (AutoSet Spirit Supplemental Oxygen Addendum) at -7135.

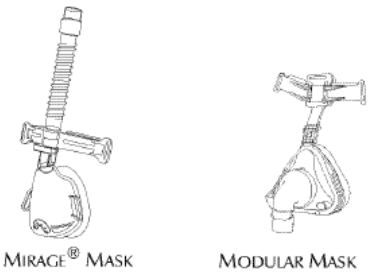
Claim Language [8.b]	ResMed Prior Art ("RPA")
	 RMD-0318396 at -0318403 (showing adapter for supplemental oxygen inline between the AutoSet Spirit outlet and hose).

Claim Language [8.b]	ResMed Prior Art ("RPA")

MASK SYSTEMS

The following ResMed mask systems (supplied separately) are recommended for use with the AUTOSET SPIRIT system.

ULTRA MIRAGE™ MASK | MIRAGE® FULL FACE MASK | FULL FACE MASK SERIES 2



MIRAGE® MASK | MODULAR MASK

WARNING

For therapy in **AutoSet** mode, use one of the recommended ResMed masks. The AutoSet algorithm has appropriate parameters for these masks.

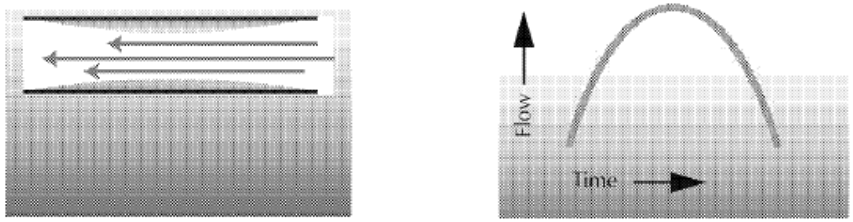
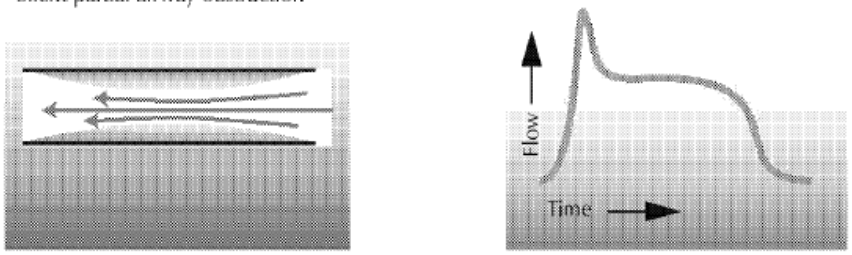
RMD-063968 (AutoSet Spirit Clinician's Manual) at -3985.

- If supplemental oxygen is used, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate.

RMD-271110 (Mirage Mask User Manual) at -1118.

Claim Language [8.b]	ResMed Prior Art ("RPA")
	• At a fixed flow rate of supplemental oxygen (if used), the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. RMD-271027 (Mirage Full Face Mask Series 2 User Instructions) at -1044. **Note:** *At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate.* RMD-271159 (Ultra Mirage Full Face Mask User's Guide) at -1164. A POSITA would have also known that, for RPA Systems 1-2, the configuration to introduce supplemental oxygen into the system included attachment to a mask port (as shown in the ResMed Mask Systems documentation), or use of an adapter attached to the output of the flow generator between the outlet and the tubing (like that accused in CleveMed's infringement contentions). Such an adapter was well-known in the art and would have been a common component readily available for the prior art systems. To the extent these features are found to not be expressly disclosed, it would have at least been obvious to a POSITA based on known methods to introduce supplemental oxygen into a PAP treatment system like RPA Systems 1-2.

Claim Language [8.b]	ResMed Prior Art ("RPA")
	AUTOSET® MODE The treatment pressure required by your patient may vary through the night, and from night to night, due to changes in sleep state, body position, and airway resistance. In AutoSet mode AUTOSET SPIRIT provides only sufficient pressure to maintain upper airway patency. You can set the minimum and maximum allowable treatment pressures. The unit analyzes the state of the patient's upper airway on a breath-by-breath basis and delivers pressure within the allowed range according to the degree of obstruction. The AutoSet algorithm adjusts treatment pressure as a function of three parameters: inspiratory flow limitation, snore, and apnea. The flow sensor, located in the AUTOSET SPIRIT unit, enables detection of inspiratory flow limitation and apneas. The pressure sensor, also located in the unit, enables measurement of pressure and snore. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980. **Inspiratory flow limitation** indicates silent partial obstruction. When your patient is breathing normally, the inspiratory flow measured by the unit as a function of time shows a typically rounded curve for each breath. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.

Claim Language [8.b]	ResMed Prior Art ("RPA")
	Open unrestricted airway  Figure 1: Inspiratory flow-time curve for an unrestricted airway As the upper airway begins to collapse, the shape of the inspiratory flow/time curve changes and the central section flattens. Silent partial airway obstruction  Figure 2: Inspiratory flow/time curve for a partially obstructed airway The AutoSet algorithm analyzes the shape of the central part of the curve for each breath and assigns a value as the amount of flattening. Inspiratory flow limitation, or partial airway closure, usually precedes snoring and obstruction. Detection of this flow limitation enables the unit to increase the pressure *before* obstruction occurs, making treatment pre-emptive. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3981.

Claim Language [8.b]	ResMed Prior Art ("RPA")

The Flattening Index is a measure of silent inspiratory airflow limitation. Flow limitation with loud snoring is handled by the snore detector. When a patient **snores**, sound is generated and the inspiratory flow/time curve is distorted by the frequency of the sound.

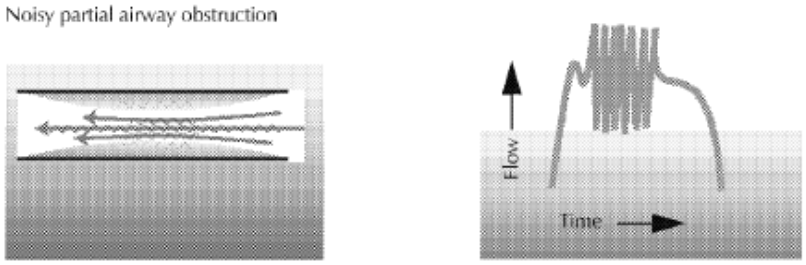


Figure 3: Inspiratory flow/time curve affected by snore

The AutoSet algorithm assigns an arbitrary value between 0.0 and 2.0 to the average amplitude of the snoring detected for the past 5 breaths. A value of 1.0 is equivalent to approximately 75dBA measured 10cm from the nares. Treatment pressure increases by up to 0.2 cm H_2O per second (proportional to the severity of the snore) for snore above 0.2 snore units. When snore is less than 0.2 snore units, therapy is reduced towards the minimum pressure with a 20-minute time constant.

An **apnea** is defined as a greater than 75% decrease in ventilation. The AutoSet algorithm scores an apnea if the 2-second moving average ventilation drops below 25% of the recent time average (time constant 100 seconds) for at least 10 consecutive seconds. Treatment pressure increases based on the duration of the apnea. The pressure will not rise above 10 cm H_2O when an apnea is detected, to prevent an inappropriate response to central apneas. Initial pressure increases are rapid, but the rate of increase diminishes as the pressure approaches 10 cm H_2O. When no further apneas are detected, therapy is reduced towards the minimum pressure with a 20-minute time constant.

A **hypopnea** is defined as a 50 to 75% drop in ventilation. A hypopnea is scored if the 8-second moving average ventilation drops below 50%, but not below 25%, of the recent average for 15 consecutive seconds. In order to avoid falsely responding to central hypopneas, the AutoSet algorithm does not respond to hypopneas but rather to the associated snore or flow limitation.

RMD-063968 (AutoSet Spirit Clinician's Manual) at -3982.

Claim Language [8.b]	ResMed Prior Art ("RPA")
	See also [redacted] AutoScan 5.4 Clinician's Manual (RMD-311263) at 57-58. For example, the algorithm uses the flow sensor signal to identify flow limitations, calculate a flattening index, and calculate a snore index, which are used to adjust the pressure supplied to the patient by sending a control signal to the motor controlling the blower. AutoSet Spirit Clinician's Manual at 7-9; AutoScan 5.4 Clinician's Manual (RMD-311263) at 57-58; [redacted] Alternatively, it would have been obvious to combine RPA Systems 1-2 with Hoffman. Hoffman discloses: "Another preferred embodiment of the present invention to measure clinical obstructions and response to treatments, such as the administration of bronchodilation medication, features obtaining a signal indicative of the effort required to breathe and a signal indicative of airflow through the respiration system and processing the two signals to obtain a signal indicative any respiration restriction of the subject. In another embodiment, the present invention can be used as a monitoring system for respiration functions. The advantage of the present invention in terms of its lack of obtrusiveness allows the subject to adopt normal body posture and yet be monitored. The monitoring application of the present invention is well suited for continuous or intermittent home or hospital monitoring of adults, children, infants and animal subjects. In particular, for patients on continuous positive airway pressure (CPAP) or assisted ventilation, the system of the present invention can be coupled to a CPAP delivery device or ventilator. The present invention triggers the use of the ventilators upon detecting respiratory restriction. ***Similarly, an oxygen delivery system can be***

Claim Language [8.b]	ResMed Prior Art ("RPA")
	coupled to the respiration function measurement system of the present invention." Hoffman, 3:38-59 (emphasis added). "The analog signal 826 that is outputted from the bedside or centrally located workstation 812 incorporating the system to measure respiratory function, in conjunction with the output 840 of the airflow sensor 808, form inputs to a flow rate adjuster 842 of the ventilator 828. The analog signal also forms an input into a ventilator valve adjuster 844 which in turn adjusts an exhalation valve 846 located on the exhalation segment 848 of the ventilator tubing. An exhalation flowmeter or volume sensor 850 is located downstream of the exhalation valve. The exhalation flowmeter 850 provides a check of the ventilation system against system leaks by checking if the amount of gas inputted by the ventilator is equivalent to the amount exhaled. The analog signal 826 indicative of the difference between the effort and airflow signal affects the CPAP flow rate and the resistance of the exhalation valve 846 to increase or decrease CPAP or change the oxygen percentage supplied to the patient requiring assist ventilation. Thus, the ventilator pump 852 provides, using the continuous fresh gas source for CPAP 854 and an oxygen source 856, the required amount of oxygen to the patient via the inhalation segment 858 of the ventilation tubing." Hoffman, 16:54-17:8; *see also* Figure 17 (showing oxygen source 856 coupled to the Flow Rate Adjust component 842 in the CPAP component). In addition, Hoffman discloses using the disclosed treatment system to dose the subject with a histamine or other chemical. *See, e.g.*, Hoffman, 2:31-46, 13:52-14:31. It would have been obvious to combine the teachings of Hoffman with RPA Systems 1-2 to incorporate oxygen delivery or a histamine or chemical to arrive at the claimed system. **<u>CleveMed's Infringement Contentions</u>** CleveMed's infringement contentions for this limitation allege that the limitation is practiced by the following use of ResMed accused products with supplemental oxygen:

Claim Language [8.b]	ResMed Prior Art ("RPA")
	[redacted]
	However, CleveMed's contentions do not identify what is the alleged created "output of the level of severity of the subject's sleep disorder" that is allegedly used to adjust "the pharmaceutical agent." If CleveMed supplements its contentions, ResMed reserves the right to supplement its contentions accordingly.

Claim Language [8.b]	ResMed Prior Art ("RPA")
	If the accused functionality is determined to practice this claim, then RPA discloses this claim for at least the same reasons, as established above. *See also, e.g.,* RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures; RMD-0318396 Specimen Photographs; [redacted]

Claim Language [15pre]	ResMed Prior Art ("RPA")
[15pre] A positive airway pressure (PAP) sleep disorder treatment system comprising:	To the extent the preamble is limiting, RPA Systems 1-2 disclose a positive airway pressure (PAP) sleep disorder treatment system. *See, e.g.*, limitation 1pre.

Claim Language [15.a]	ResMed Prior Art ("RPA")
[15.a] a PAP device with an enclosure further comprising:	RPA Systems 1-2, disclose a PAP device with an enclosure. *See, e.g.*, limitation 1.b, 1.pre.

Claim Language [15.a.1]	ResMed Prior Art ("RPA")
[15.a.1] a blower having an air output,	RPA Systems 1-2 disclose a blower having an air output. *See, e.g.*, limitation 1.b.1, 1.pre.

Claim Language [15.a.2]	ResMed Prior Art ("RPA")
[15.a.2] an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject while using the PAP and outputting airflow sensor data;	RPA Systems 1-2, disclose an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject while using the PAP and outputting airflow sensor data, at least based on CleveMed's infringement contentions. *See, e.g.*, limitation 1.b.3, 1.pre; Final Infr. Cont., Chart I, 84-87.

Claim Language [15.b]	ResMed Prior Art ("RPA")
[15.b] 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;	RPA Systems 1-2, disclose, or at least renders obvious, for at least the same reasons CleveMed alleges the accused products practice this limitation, 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. RPA Systems 1-2 disclose a processor adapted for receiving airflow sensor data. *See, e.g.,* limitation 1.b.4. For at least the same reasons CleveMed alleges the accused products practice this limitation, RPA Systems 1-2 disclose that the airflow sensor data is respiratory airflow data. *See, e.g.,* Final Infr. Cont., Chart I, 87-88. For at least the same reasons CleveMed alleges the accused products practice "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,) RPA Systems 1-2 disclose this feature because the AutoSet Spirit flow generator calculates the same parameters CleveMed alleges practice this limitation, including flow, pressure, leak parameters, detects the same respiratory events like apneas and hypopneas, and derives indexes like AI and AHI. *See, e.g.,* [redacted] AutoScan 5.4 Clinician's Manual (RMD-311263) at 2-4 ("Summary Data" and "Night Profile Data" are downloaded from the AutoSet Spirit to a clinician's computer running AutoScan 5.4 using either the cable or modem methods), 27, 45-47 ("data currently stored in the flow generator will download to your computer"), 53-55 (identifying Statistics recorded by the AutoSet Spirit that AutoScan can download from the flow generator device over the modem); [redacted] RPA Systems 1-2 disclose a processor adapted for calculating "data of usage." [redacted] *See, e.g.,* limitation 1.b.4, 5.c, 5.f, 1.pre.

Claim Language [15.b]	ResMed Prior Art ("RPA")
	'269 Patent The '269 patent does not disclose how to "calculate[e] … 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." For example, the '269 patent disclosure merely provides: "The signals from the one or more sensors used in various embodiments of the present invention are preferably analyzed using a processor and software that can quantitatively estimate or determine the severity of the subject's sleeping disorder or symptoms." '269 patent, 18:60-64; see also 19:46-49 ("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 more sensors described herein.") The '269 patent does not mention calculating an "index of a subject's symptoms," and only makes a passing reference to "obtaining respiratory disturbance index to diagnose sleep apnea" in the Background section. '269 patent, 1:51-54. Thus, at least commensurate in scope with the '269 patent that discloses that the level of severity of a subject's sleeping disorder or symptoms is determined using signals or data from the sensors, RPA discloses or renders obvious this limitation. Furthermore, claim 15 does not specify the location of the processor, and the '269 patent fails to articulate any specific benefit or unexpected result in performing the claimed "calculating" at a processor, receiving the calculated parameters at a first radio frequency wireless module transceiver, transmitting the calculated parameters to a base station, cellular phone or PDA adapted to display the calculated parameters, and the base station/cellular phone/PDA further retransmitting the calculated parameters to a remote internet site. Instead, the '269 patent merely lists a variety of different configurations of a system employing RF communication, noting that "[p]referably, the remote communication station or base station can be any device known to receive RF transmissions." '269 patent, 19:8-45. Thus, the '269 patent appears to recognize there was no inventive or non-obvious aspect to the claimed configuration (to the extent even disclosed by the '269 patent), thereby confirming a POSITA would have found the claimed configuration at least obvious as amongst those known in the art and obvious to try.

Claim Language [15.c]	ResMed Prior Art ("RPA")
[15.c] a mask or a nasal cannula;	RPA Systems 1-2 disclose a mask. *See, e.g.,* limitation 1.c, 1.pre.

Claim Language [15.d]	ResMed Prior Art ("RPA")
[15.d] a first radio frequency wireless module transceiver; and	RPA discloses, or at least renders obvious, a first radio frequency wireless module transceiver. *See, e.g.,* limitation 1.d, 1.pre, above, and also limitation 15.f below. RPA System 2 discloses a first radio frequency wireless module transceiver. The [redacted] is a radio frequency wireless module transceiver. Alternatively, RPA System 2 renders this limitation obvious in view of the knowledge of a POSITA and/or in view of Rasid. RPA System 1 renders obvious a first radio frequency wireless module transceiver, either in view of the knowledge of a POSITA and/or RPA System 2 and/or in view of Rasid. For example, it would have been obvious to replace the modem of RPA System 1 with a radio frequency wireless module transceiver as claimed. *See, e.g.,* Final Infr. Cont., Chart A, 70-73. For example, RPA discloses:

ResMed AutoSet Spirit (System 1-2)

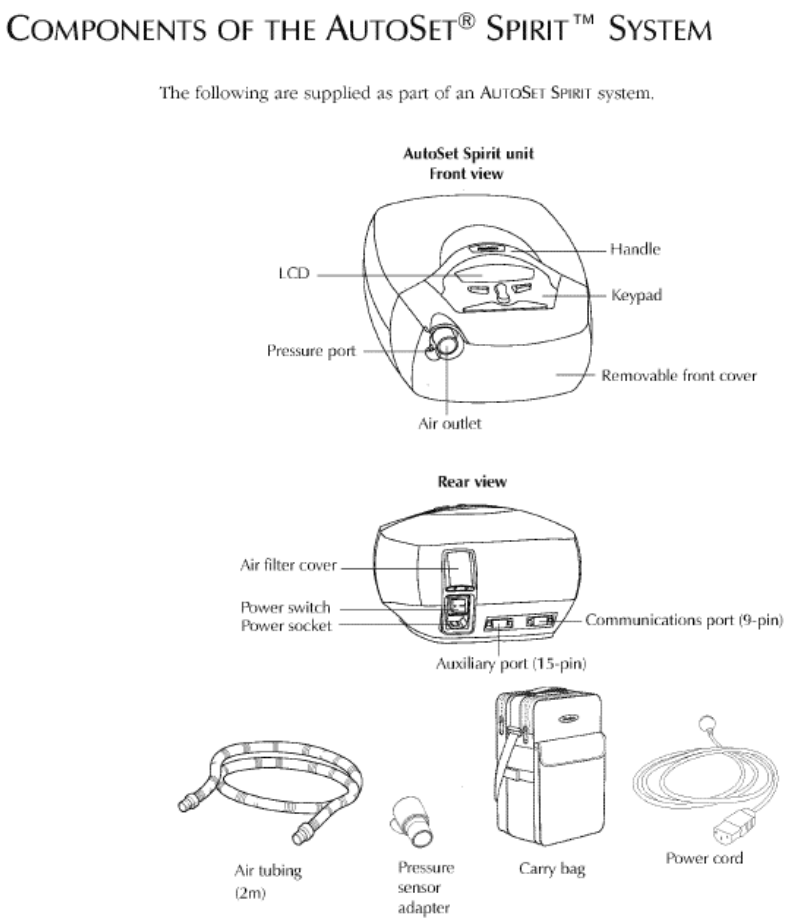
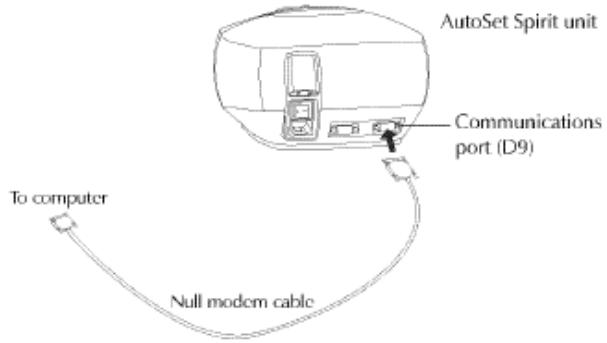


Figure 4: AutoSet Spirit system components

RMD-063968 (AutoSet Spirit Clinician's Manual) at -3983.

Claim Language [15.d]	ResMed Prior Art ("RPA")
	AUTOSCAN™ SOFTWARE AUTOSCAN is designed to enable review of the data stored in an AUTOSET SPIRIT unit. Data from up to 365 sessions may be stored and downloaded. Refer to the *AutoScan Clinician's Manual* or *Help* for details.  RMD-063968 (AutoSet Spirit Clinician's Manual) at -3986. REMOTE DATA ACCESS You can download data from an AUTOSET SPIRIT unit in your patient's home to AUTOSCAN software on your computer using modems. Both you and your patient require a modem set up for this purpose. The patient attaches the modem to the right communications port on the AUTOSET SPIRIT unit and to a phone line. You attach your modem to the serial port on your computer and a phone line. Refer to complete instructions for modem use in the *AutoScan Clinician's Manual*. RMD-063968 (AutoSet Spirit Clinician's Manual) at -4015.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.d]	ResMed Prior Art ("RPA")
	[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.d]	ResMed Prior Art ("RPA")
	[redacted]

Claim Language [15.d]	ResMed Prior Art ("RPA")
	[redacted] **AutoScan 5.4 (System 1)** AUTOSCAN™ 5.4 has been developed to view summary data and detailed data obtained from the RESLINK™ via the SmartMedia™ card. Summary data and Night profile data obtained from the flow generator can also be viewed as in previous versions of AUTOSCAN. AUTOSCAN 5.4 has data collection and management capabilities that provide an adjunct for patient management. The flow generator systems intended to be used with AUTOSCAN 5.4 are the ResMed AUTOSET® SPIRIT™, S7™ ELITE, VPAP® III, VPAP III ST, VPAP III ST-A, and AUTOSET RESPOND™. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1269. FLOW GENERATOR COMPATIBILITY The following flow generators are compatible with AUTOSCAN 5.4: • AUTOSET SPIRIT • AUTOSET RESPOND • VPAP III, VPAP III ST, VPAP III ST-A, • S7 ELITE. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277.

Claim Language [15.d]	ResMed Prior Art ("RPA")

CONNECTING THE FLOW GENERATOR TO THE COMPUTER

In order to download data into AUTOSCAN 5.4, your computer must be connected by cable to the flow generator.

NOTES *If your flow generator is connected to a ResControl, you must disconnect the ResControl before connecting the flow generator to your computer for interfacing to AutoScan 5.4.*

Plug the null modem cable into the PC connection port on the flow generator and into an available serial port at the back of your computer (**COM1, COM2, COM3** or **COM4**).

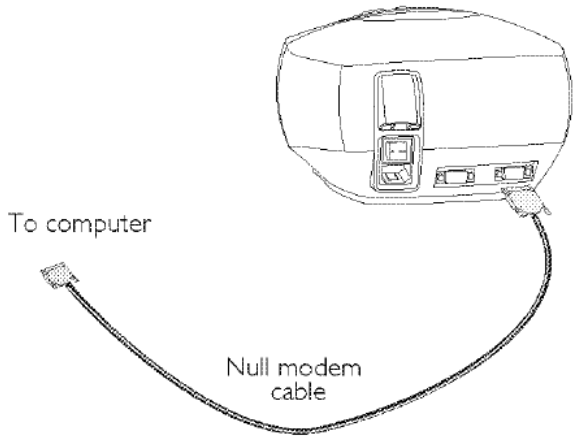


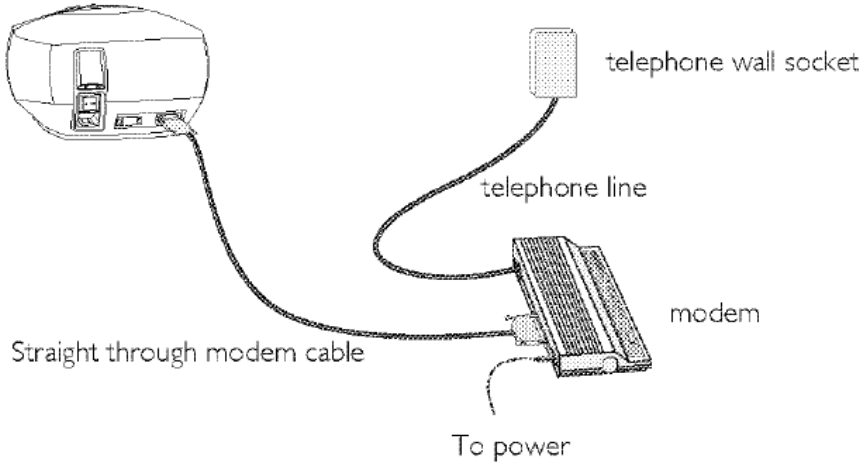
Figure 2: Connecting the flow generator to the computer

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277 – 78.

USING MODEMS

You can download summary and Night Profile data on your flow generator remotely via modem. We recommend *Windows NT 4.0 SP6* and 3Com U.S. Robotics 56k Voice Faxmodems for this purpose.

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1279.

Claim Language [15.d]	ResMed Prior Art ("RPA")
	USING MODEMS TO DOWNLOAD DATA You may download summary and Night Profile data remotely via modem. These operations require that both you and the patient have modems. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1290.  RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1290. MANAGING PATIENT INFORMATION AUTOSCAN 5.4 allows you to record patient information, clinical details and notes in the patient file. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1297. Detailed and summary data from a patient's flow generator are stored on a SmartMedia card by the RESLINK. The SmartMedia card is removed and sent to the clinician at the end of the study period. The SmartMedia card is inserted into a SmartMedia card reader attached to the clinician's computer, and the data can then be downloaded and viewed in AUTOSCAN 5.4. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1301.

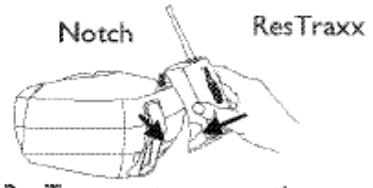
Claim Language [15.d]	ResMed Prior Art ("RPA")
	The Detailed Data screen displays nine traces of data downloaded via the RESLINK from the flow generator. You can view data in the Detailed Data screen in increased detail or as a compact overview. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1303. The Detailed Data screen for that session will be displayed. The graph display area shows the downloaded data in the trace panels: • Events (s) • Minute Ventilation (L/min) • Leak (L/s) • Pulse Rate (bpm) • SpO_2 (%) • AHI (Events/hr) • Pressure (cm H_2O)[a] • Snore (Quiet to Loud)[a] • Flattening (Round to Flat)[a] • Respiratory rate (BPM).[b] [a] AUTOSET SPIRIT and S7 ELITE only [b] VPAP III series only NOTE *Pulse rate and SpO_2 are derived from the oximeter reading.* RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1304. A POSITA would have found it obvious to replace the wired modem with a wireless networking card or other WiFi radio frequency wireless module transceiver capable of communicating without the need for wires. It was within the knowledge of a POSITA that modems like those disclosed for use in RPA System 1 were commonly being replaced in 2004-2005 by wireless systems including wireless networking cards. *See, e.g.*, RMD-0318504 RadioShack 2003-2004 Reference Guide at 66 (showing "Wireless networking for home or small office" including wireless networking cards and laptop); RMD-0318394 Oct. 11, 2004 Archive of BestBuy "Wireless Network" page listing wireless cards and routers. A POSITA would have found it obvious to use a wireless system to avoid cables like those used with the modem, for example, so that the patient would not need to move their flow

Claim Language [15.d]	ResMed Prior Art ("RPA")
	generator to a location with a wall telephone jack for connection of the modem. A modification to replace the modem with a wireless networking module would have merely required off the shelf components to replace the off-the-shelf modem already incorporated into RPA System 1. **ResTraxx (including RDC) (System 2)** ResTraxx™ allows the wireless transfer of information from a continuous positive airway pressure (CPAP) unit to a clinician at a remote location via a two-way pager network. ResTraxx is intended to be used with ResMed S7™ Elite, AutoSet® Spirit™, AutoSet® Respond™, and VPAP® III flow generator systems on adults with obstructive sleep apnea. RMD-062642 (ResTraxx Quick Reference Guide) at -2642.

Claim Language [15.d]	ResMed Prior Art ("RPA")

Attaching the ResTraxx

1. Turn the flow generator to OFF.
2. Slide lever on back of ResTraxx to the left.
3. Place top catch on ResTraxx onto notch at back of unit.



4. Push 15-pin connector on ResTraxx onto connection port on back of unit.
5. Slide lever on back of ResTraxx to the right to lock it into place.
6. Turn the main power switch at the back of flow generator to the ON position.
7. A green LED on top of ResTraxx will light up 15 - 20 seconds after unit is turned on, then begin to flash.
8. After about 15 seconds, a series of messages will appear on the flow generator display, indicating the unit's initialization and registration status of unit.
9. After initialization, the standby screen appears on the flow generator display and the unit begins transmitting information.

RMD-062642 (ResTraxx Quick Reference Guide) at -2642.

[redacted]

[redacted]

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ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.d]	ResMed Prior Art ("RPA")
	[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.d]	ResMed Prior Art ("RPA")
	[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.d]	ResMed Prior Art ("RPA")
[redacted]	

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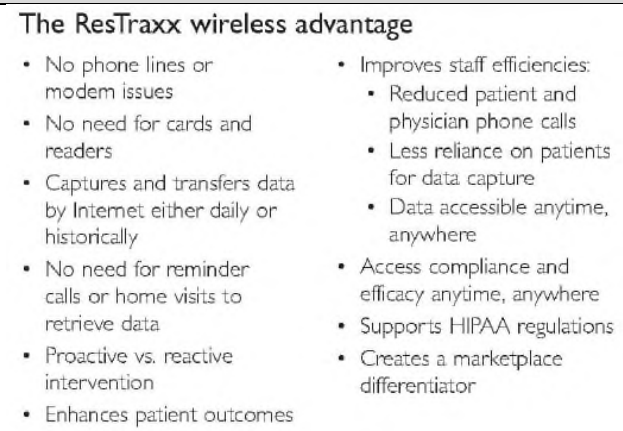
Claim Language [15.d]	ResMed Prior Art ("RPA")
	[redacted] ResTraxx is a first-of-its-kind wireless communication device that attaches easily to the back of ResMed flow generators. The ResTraxx system captures, transfers, and stores compliance and efficacy data without wires, phone lines, modems, or data cards. ResTraxx is an elegant system that brings patient usage and treatment efficacy data to your fingertips instantly. RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

Claim Language [15.d]	ResMed Prior Art ("RPA")
	 RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

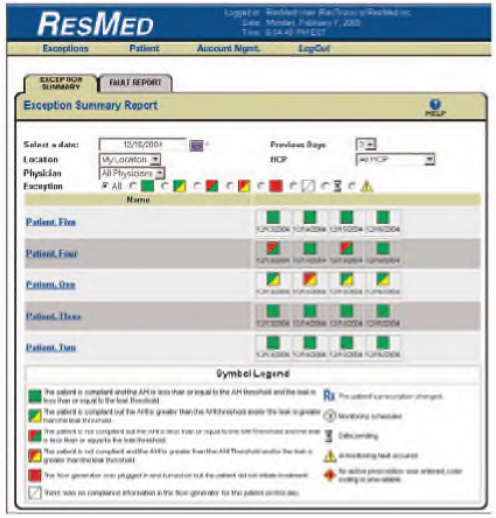
[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.d]	ResMed Prior Art ("RPA")

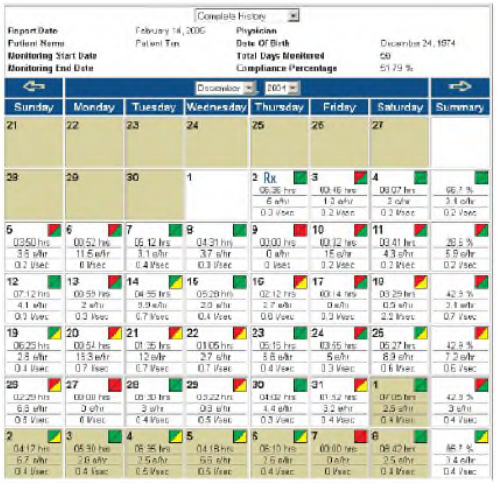
Exception Reporting

Enhance productivity and manage patients more efficiently. **Exception Reporting identifies and highlights those patients who fall below desired usage thresholds or have issues with mask leak or AHI.** This feature enables you to focus your efforts only on those patients who require intervention and respond proactively to potential problems. The simple color-coded alert system helps you identify exception patients quickly and easily.



Efficacy + Leak + Usage Data

The ResTraxx Data Center displays data on a daily basis in a calendar format enabling you to see daily or weekly trends of adherence problems before compliance is truly compromised. Early intervention and ongoing follow-up is considered critical, especially during the first month of CPAP acclimation, to determine long-term compliance rates.[2]



Want more details on therapy results? Click on the calendar day in question, and a therapeutic report will display additional clinical data regarding the patient's usage for that day.

RMD-063327 (ResTraxx Patient Management Brochure) at -3328.

[redacted]

[redacted]

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Claim Language [15.d]	[redacted]

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[redacted]

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Claim Language [15.d]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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Claim Language [15.d]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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Claim Language [15.d]	ResMed Prior Art ("RPA")
	[redacted]

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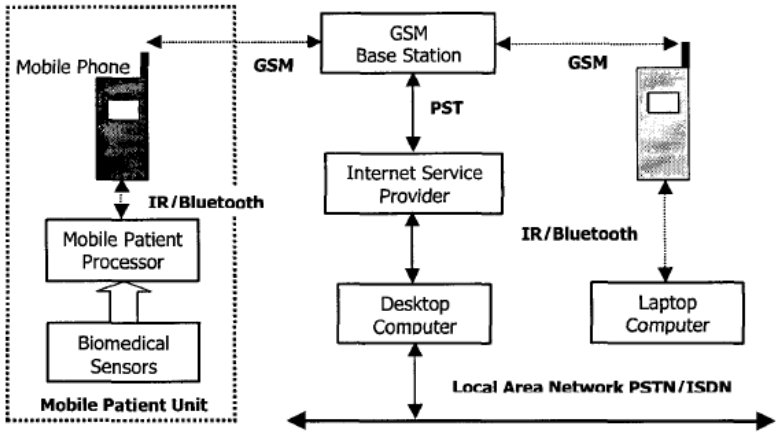
[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

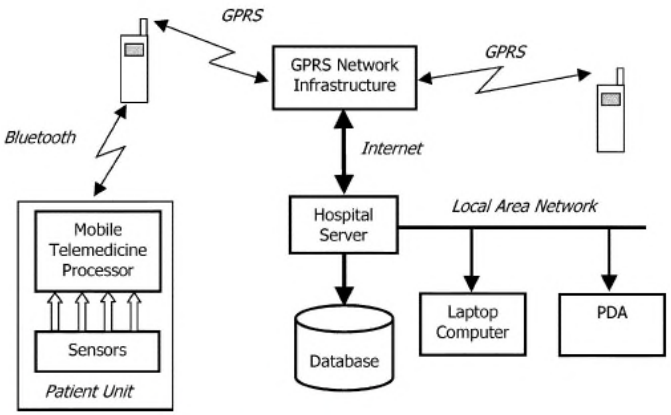
Claim Language [15.d]	ResMed Prior Art ("RPA")
	[redacted]
	See also ResTraxx Quick Reference Guide (RMD-062642) at 1; ResTraxx Patient Management Brochure (RMD-063327) at 2; [redacted] RDC User's Manual (RMD-306688) at 4 (RDC wireless, web-based,

Claim Language [15.d]	ResMed Prior Art ("RPA")
	data management application designed for healthcare professionals involved in the care and management of adult, sleep-disordered breathing patients," and "provides healthcare professionals with the ability to remotely monitor patients' usage of ResMed Positive Airway Pressure (PAP) flow generators via the internet."), 5, 8-10, 15, 27 (Windows XP, Internet Explorer 6.0); ResTraxx Wireless Patient Monitoring Atlas (RMD-063341) at 63343-48. "Various approaches have been developed to expedite the collection and analysis of these data. Current CPAP devices can be interfaced with a computer in the office or home setting to download data. Newer modems can interface with the CPAP unit and the integrated chip to facilitate the reporting of remote data and reduce the need for face-to-face visits. Also, smart cards can be inserted into slots in the CPAP units to imprint the data. These cards are then transported to the appropriate professional in a variety of ways, including the use of mail carriers or other modes, to reduce the need for direct patient travel for regular compliance reporting." Lankford, 163. "Wireless data transmission was accomplished by first attaching a transmission device, described below, to the flow generator. Then, by accessing a secure Web site, a request for data was sent from a secure sever, located in Peachtree City, Georgia, through land lines to the carrier's local transmission antenna, located within several miles of the device and location set up, where it is transmitted wirelessly to the device. Once the device received the request, the data were retrieved from the memory of the flow generator, transmitted wirelessly to a receiving antenna, located within several miles of the device. Then, through land lines back to the secure server, the data became available on the aforementioned Web site." Lankford, 164. "*Wireless and Internet-based technologies* "For data downloading at the end of the trial, an investigational wireless-to-Internet data collection/transmission system, being developed by ResMed, and named the "Spectrum System," was employed in this trial. The Spectrum System consists of the flow generator, a wireless communication device, code-named "Cyrcat," and a secure Web server located in a remote location. The secure Web server receives patient-related clinical data (compliance and efficacy parameters) from the Cyrcat wireless transmitter and it stores the information for clinician viewing, analysis, and reporting through a secure Web browser." Lankford, 164. "*Data collection methods*

Claim Language [15.d]	ResMed Prior Art ("RPA")
	"Patients were asked to return with their CPAP unit to their respective set-up locations. Data were wirelessly transmitted using the Spectrum System to the secure Web server. These data were then downloaded onto a storage disk using a predetermined Microsoft Excel format for later comparison with the same base set that was manually downloaded from the flow generators using the same format. All disks were marked with patient codes to assure anonymity. In the tables that follow, the terms 'wireless' and 'autoscan' refer to the wireless and base data sets, respectively." Lankford, 165. If the Judge or Jury finds that RPA does not disclose this claim limitation, this claim is still rendered obvious by modifying or combining RPA Systems 1-2 with Rasid or the knowledge of a POSITA. For example, a POSITA would have recognized that it was well known in the art by the alleged date of invention of the '269 patent to implement the disclosed communication between the RPA PAP devices and the servers running AutoScan with a wireless communication link as disclosed for ResTraxx/RDC for System 2. In one example, it would have been obvious to implement the modem of RPA System 1 or the [redacted] of System 2 with a "radio frequency wireless module transceiver" for short range communication between a medical device, such as the disclosed PAP devices, and a cellular device or PDA at the patient's location. For example, Bluetooth was a well-known communication protocol that could be implemented by incorporating a Bluetooth wireless module transceiver into devices such as the PAP devices disclosed by RPA in order to communicate with the disclosed computer, which in turn communicates with the server running AutoScan. A POSITA would have recognized, for example, that the disclosed "modem" could be implemented with an RF transceiver module as claimed, using for example, a Bluetooth, PAN, WLAN, or cellular modem that includes an RF wireless transceiver as known in the art. A POSITA would have recognized, at the time of the application for the '269 patent, that available communication channels included RF wireless communication channels in addition to the pager network employed by ResTraxx, such as using PAN's including the well-known Bluetooth protocol. Woodward discloses a telemedicine system:

Claim Language [15.d]	ResMed Prior Art ("RPA")
	 Fig. 1 Telemedicine system with mobile telephone and PSTN communications links "This paper reviews a number of recent wireless telemedicine projects that have been carried out around the world, then focuses on the design and development of a wireless telemedicine system using a conventional mobile telephone. The system is capable of transmitting up to four sets of biomedical data from a patient via the Global System for Mobile communications (GSM) cellular network to a hospital or surgery. It is designed to be generic, so it may also be used for non-medical applications, and to be "future-proofed" in view of constantly evolving telecommunications technology, including the introduction of the Third Generation (3G) protocol as a replacement for the present GSM protocol." Woodward, 43. "While the transmission of biomedical data by satellite is demonstrably feasible for long-range wireless links, it is more likely that mobile telephones using cellular networks will be adopted for transmission over shorter ranges. Among the technical problems is the issue of how to link the data from the patient (via a mini-processor) to the phone. This may possibly be done by a direct connection, or by a wireless connection such as an acoustic, infra-red or Bluetooth radio link [l8]. It is only recently that the potential advantages of Bluetooth and other wireless technologies have been

Claim Language [15.d]	ResMed Prior Art ("RPA")
	recognized, including the Wireless Application Protocol (WAP) for cell phones [19], and Personal Digital Assistants (PDA) [20,21]." Woodward, 44. "The main contribution of this paper has been to describe the present scope and future potential of mobile communications in telemedicine. A modular-structured system has been used to illustrate the concept. The mobile patient unit comprises a processing unit, which accepts signals from one or more sets of sensors, linked by a wireless channel to a mobile telephone. The prototype version is designed to transmit digitised electrocardiogram signals to a hospital via the GSM mobile telephone cellular network. New compression and signal processing algorithms, such as wavelet techniques, can be integrated to optimise the performance of the system under different mobile conditions. The modular design of the system should enable telemedicine providers to adapt to future technology advances." Woodward, 45. Rasid, a later publication directed to the same work described in Woodward, recognized as was known in the art that telemedicine systems for transmitting physiological and compliance data to health care providers were well-known in the art by 2004-2005. It would have been obvious to modify RPA Systems 1 and 2 according to such known systems, like that discloses by Rasid, to replace the modem of System 1 and the [redacted] of System 2 with Rasid's Bluetooth transceiver at the Patient Unit ("first radio frequency wireless module transceiver adapted for receiving and transmitting" physiological sensor data). Rasid's system included a Bluetooth wireless RF transceiver at a patient unit that transmitted physiological sensor data to a cell phone; the cell phone then transmitted the data, via the GPRS cellular network, to a hospital server that made the data available to clinician via devices including a personal computer, laptop, or PDA. See, e.g., Rasid, Figure 2, §§ I.C, III.A (sensor inputs included SpO). Figure 2 from Rasid is reproduced below:

Claim Language [15.d]	ResMed Prior Art ("RPA")
	 Fig. 2. Mobile telemedicine system. Rasid, Fig. 2; see also Rasid Thesis at Figures 6.1, 6.20.; *see also* Rasid, Abstract, §§ I.B, IV, Figs. 2, 4. The system disclosed by Rasid was a common configuration being investigated for telemedicine in the 2004-2005 time frame due to the adoption of cellular phones and common cellular support for data transmission. It would have been obvious, given RPA System 1, for example, to incorporate a Bluetooth wireless RF transceiver that were commonly being investigated in the art at the time and used by Rasid, into RPA System 1 for at least these reasons to transmit the data for download to the clinician's computer running the AutoScan 5.4 software to a cellular phone (base station) that then uses the cellular network to transmit the data to the physician's computer running the AutoScan software. Such a configuration would have been desirable such to provide a wireless connection between the flow generator and the transmitter (the cell phone), thereby avoiding the cable connection discussed above for the modem. Alternatively, it would have been obvious to modify RPA System 2 in view of known telemedicine systems like that disclosed by Rasid. It would have been obvious to replace the [redacted] with a Bluetooth or other short range wireless technology protocol to communicate with a cellular phone, which then transmitted the data transmitted from the [redacted] to the backend components of the ResTraxx Data Center like the system disclosed by Rasid. This would have been obvious at least for the same reasons discussed above for RPA System 1.

Claim Language [15.d]	ResMed Prior Art ("RPA")
	RPA already discloses the use of a modem to transmit data to AutoScan and the [redacted] module to transmit data to a pager network and on to the RDC web components. It would have been obvious to implement the modem with a cellular phone having a short range RF connection to the PAP device. Rasid/Woodward provide implementation details that would have been known to a POSITA for incorporating such functionality into RPA Systems 1 and 2. *See also, e.g.,* RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures; RMD-0318396 Specimen Photographs; [redacted]

Claim Language [15.e]	ResMed Prior Art ("RPA")
[15.e] a base station, cellular phone, or PDA;	RPA Systems 1-2 disclose, or at least renders obvious, a base station, cellular phone, or PDA. *See, e.g.,* limitations 1.d, 15.d. CleveMed's infringement contentions allege this limitation and limitation 15.g are practiced by the following: [redacted]

[redacted]

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Claim Language [15.e]	ResMed Prior Art ("RPA")
	CleveMed's infringement contentions also allege this limitation and limitation 15.g are practiced by [redacted]

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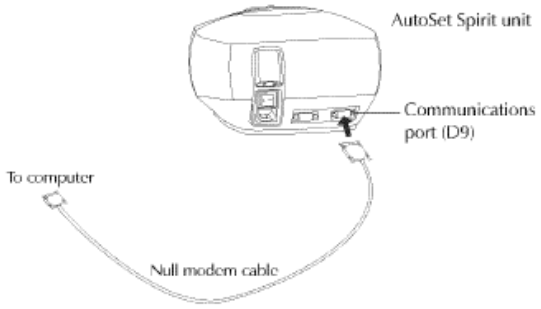
Claim Language [15.e]	ResMed Prior Art ("RPA")
	[redacted]
	If the accused functionality is found to practice these limitations, then RPA Systems 1-2 disclose (or at least renders them obvious) the claimed "base station" for at least the same reasons. If CleveMed

Claim Language [15.e]	ResMed Prior Art ("RPA")
	clarifies the component that it alleges is the computer running AirView, ResMed reserves the right to modify its contentions accordingly. Consistent with CleveMed's infringement contentions, as one example, RPA System 1 discloses a computer running AutoScan (a computer that can communicate with other devices), and RPA System 2 discloses a clinician's computer (a computer that can communicate with other devices) accessing the RDC web application. Alternatively, under CleveMed's vague infringement allegations, in the same way that any AirView component could be *part of* the claimed "base station," at least in the same way, any component of RDC is also part of the claimed "base station" for at least the same reasons. For example, RPA discloses: **ResMed AutoSet Spirit (System 1-2)** The AUTOSET SPIRIT system is intended for the treatment of obstructive sleep apnea (OSA) in adult patients. Data collection capabilities also assist in the management of continuous positive airway pressure (CPAP) treatment. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3976. REMOTE DATA ACCESS You can download data from an AUTOSET SPIRIT unit in your patient's home to AUTOSCAN software on your computer using modems. Both you and your patient require a modem set up for this purpose. The patient attaches the modem to the right communications port on the AUTOSET SPIRIT unit and to a phone line. You attach your modem to the serial port on your computer and a phone line. Refer to complete instructions for modem use in the *AutoScan Clinician's Manual*. RMD-063968 (AutoSet Spirit Clinician's Manual) at -4015.

Claim Language [15.e]	ResMed Prior Art ("RPA")
	AUTOSCAN™ SOFTWARE AUTOSCAN is designed to enable review of the data stored in an AUTOSET SPIRIT unit. Data from up to 365 sessions may be stored and downloaded. Refer to the *AutoScan Clinician's Manual* or *Help* for details.  RMD-063968 (AutoSet Spirit Clinician's Manual) at -3986. [redacted]

[redacted]

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Claim Language [15.e]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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Claim Language [15.e]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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Claim Language [15.e]	ResMed Prior Art ("RPA")
	[redacted]

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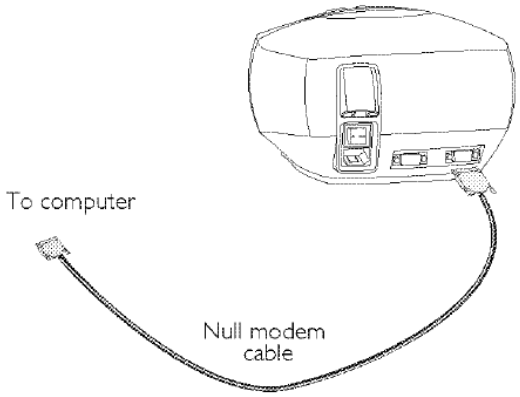
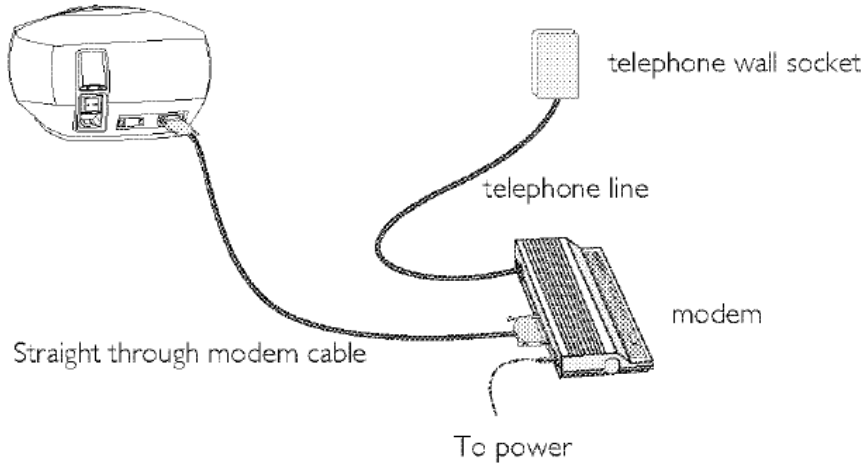
Claim Language [15.e]	ResMed Prior Art ("RPA")
	DOWNLOADING AND REVIEWING DATA USING AUTOSCAN Data collected by the AUTOSET SPIRIT unit may be downloaded to AUTOSCAN software (available in the AUTOSCAN clinical interface kit) for review. Refer to the instructions in the *AutoScan Clinician's Manual* for details of downloading and reviewing data. Data from an AUTOSET SPIRIT unit are presented in AUTOSCAN in the following ways: • graphical display of usage data (time/date stamped) showing mask on/off events (Usage graph) • 95th centile, median, and maximum values plus average and standard deviation values for leak and pressure for each session, with median values quoted for all parameters for nominated time intervals (Treatment Profile and Statistics display) • apneas, hypopneas, AI, HI, and AHI on a per hour basis (Treatment Profile and Statistics display). • 5 nights of Night Profile Data. NOTE *The AutoSet Spirit clock resets at midday. To ensure that 5 nights of Night Profile Data are available, you must download the data before midday on the fifth day.* Additionally, use AUTOSCAN to: • document patient notes • generate and print reports. RMD-063968 (AutoSet Spirit Clinician's Manual) at -4015. **AutoScan 5.4 (System 1)**

Claim Language [15.e]	ResMed Prior Art ("RPA")
	AUTOSCAN™ 5.4 has been developed to view summary data and detailed data obtained from the RESLINK™ via the SmartMedia™ card. Summary data and Night profile data obtained from the flow generator can also be viewed as in previous versions of AUTOSCAN. AUTOSCAN 5.4 has data collection and management capabilities that provide an adjunct for patient management. The flow generator systems intended to be used with AUTOSCAN 5.4 are the ResMed AUTOSET® SPIRIT™, S7™ ELITE, VPAP® III, VPAP III ST, VPAP III ST-A, and AUTOSET RESPOND™. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1269. FLOW GENERATOR COMPATIBILITY The following flow generators are compatible with AUTOSCAN 5.4: • AUTOSET SPIRIT • AUTOSET RESPOND • VPAP III, VPAP III ST, VPAP III ST-A, • S7 ELITE. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277. CONNECTING THE FLOW GENERATOR TO THE COMPUTER In order to download data into AUTOSCAN 5.4, your computer must be connected by cable to the flow generator. NOTES *If your flow generator is connected to a ResControl, you must disconnect the ResControl before connecting the flow generator to your computer for interfacing to AutoScan 5.4.* Plug the null modem cable into the PC connection port on the flow generator and into an available serial port at the back of your computer (COM1, COM2, COM3 or COM4).

Claim Language [15.e]	ResMed Prior Art ("RPA")
	 Figure 2: Connecting the flow generator to the computer RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277 – 78. USING MODEMS You can download summary and Night Profile data on your flow generator remotely via modem. We recommend *Windows NT 4.0 SP6* and 3Com U.S. Robotics 56k Voice Faxmodems for this purpose. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1279. USING MODEMS TO DOWNLOAD DATA You may download summary and Night Profile data remotely via modem. These operations require that both you and the patient have modems. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1290.

Claim Language [15.e]	ResMed Prior Art ("RPA")



RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1290.

MANAGING PATIENT INFORMATION

AUTOSCAN 5.4 allows you to record patient information, clinical details and notes in the patient file.

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1297.

Detailed and summary data from a patient's flow generator are stored on a SmartMedia card by the RESLINK. The SmartMedia card is removed and sent to the clinician at the end of the study period. The SmartMedia card is inserted into a SmartMedia card reader attached to the clinician's computer, and the data can then be downloaded and viewed in AUTOSCAN 5.4.

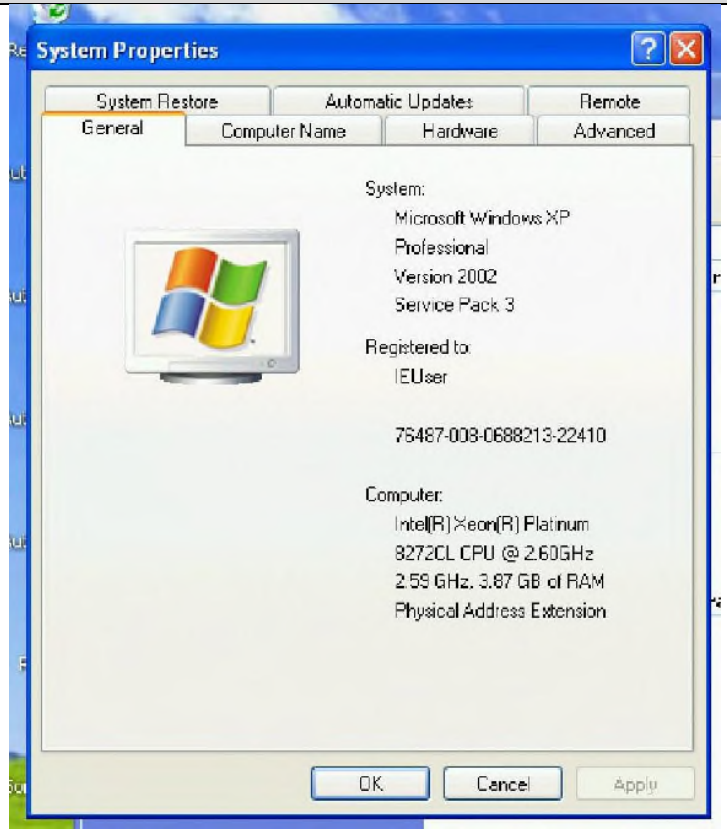
RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1301.

The Detailed Data screen displays nine traces of data downloaded via the RESLINK from the flow generator. You can view data in the Detailed Data screen in increased detail or as a compact overview.

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1303.

Claim Language [15.e]	ResMed Prior Art ("RPA")
	The Detailed Data screen for that session will be displayed. The graph display area shows the downloaded data in the trace panels: • Events (s) • Minute Ventilation (L/min) • Leak (L/s) • Pulse Rate (bpm) • SpO_2 (%) • AHI (Events/hr) • Pressure (cm H_2O)[a] • Snore (Quiet to Loud)[a] • Flattening (Round to Flat)[a] • Respiratory rate (BPM).[b] [a] AUTOSET SPIRIT and S7 ELITE only [b] VPAP III series only NOTE *Pulse rate and SpO_2 are derived from the oximeter reading.* RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1304. *See also* AutoScan 5.4 Clinician's Manual (RMD-311263) at 7-8 ("minimum computer requirements in order to configure the system and to transfer and print the stored data.").

Claim Language [15.e]	ResMed Prior Art ("RPA")



RMD-0318346 at -0318346.

ResTraxx (including RDC) (System 2)

ResTraxx™ allows the wireless transfer of information from a continuous positive airway pressure (CPAP) unit to a clinician at a remote location via a two-way pager network. ResTraxx is intended to be used with ResMed S7™ Elite, AutoSet® Spirit™, AutoSet® Respond™, and VPAP® III flow generator systems on adults with obstructive sleep apnea.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.e]	ResMed Prior Art ("RPA")
	RMD-062642 (ResTraxx Quick Reference Guide) at -2642. [redacted]

Claim Language [15.e]	ResMed Prior Art ("RPA")

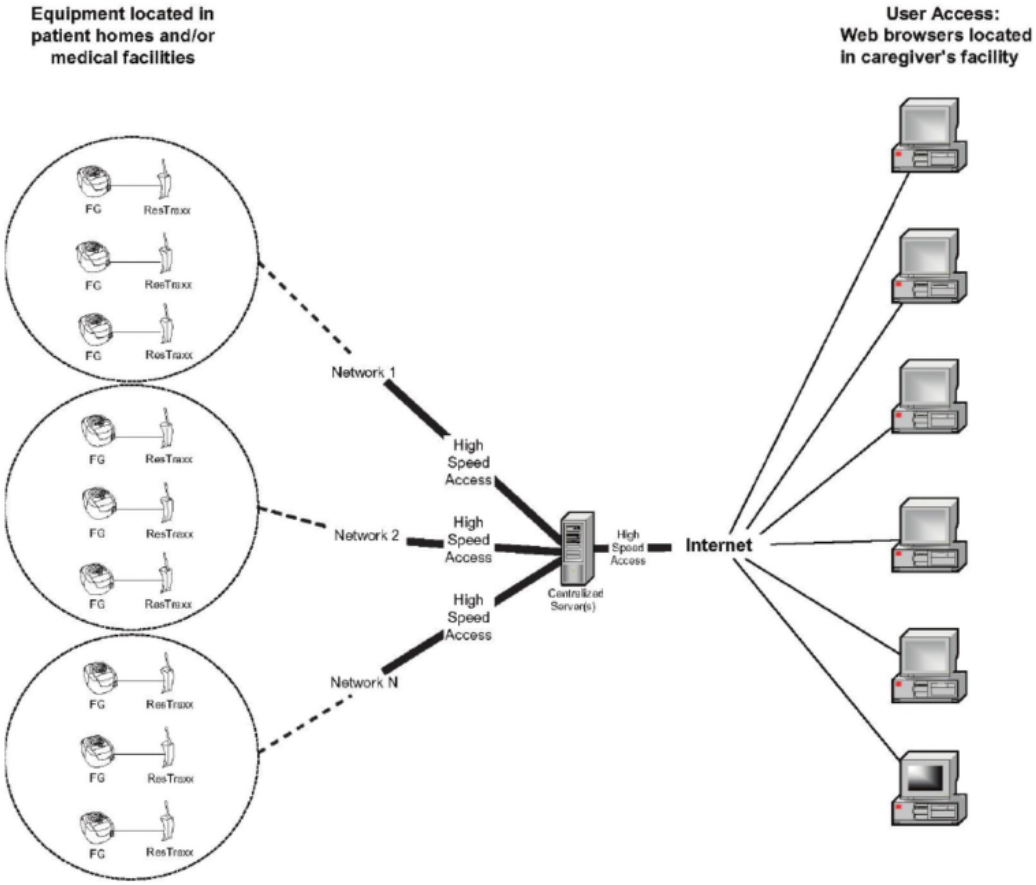


Figure 1: System configuration

RDC User's Manual (RMD-306688) at 5.

[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.e]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.e]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 514

Claim Language [15.e]	ResMed Prior Art ("RPA")

ResTraxx is a first-of-its-kind wireless communication device that attaches easily to the back of ResMed flow generators. The ResTraxx system captures, transfers, and stores compliance and efficacy data without wires, phone lines, modems, or data cards. ResTraxx is an elegant system that brings patient usage and treatment efficacy data to your fingertips instantly.

RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

The ResTraxx wireless advantage

- No phone lines or modem issues
- No need for cards and readers
- Captures and transfers data by Internet either daily or historically
- No need for reminder calls or home visits to retrieve data
- Proactive vs. reactive intervention
- Enhances patient outcomes
- Improves staff efficiencies:
  - Reduced patient and physician phone calls
  - Less reliance on patients for data capture
  - Data accessible anytime, anywhere
- Access compliance and efficacy anytime, anywhere
- Supports HIPAA regulations
- Creates a marketplace differentiator

RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

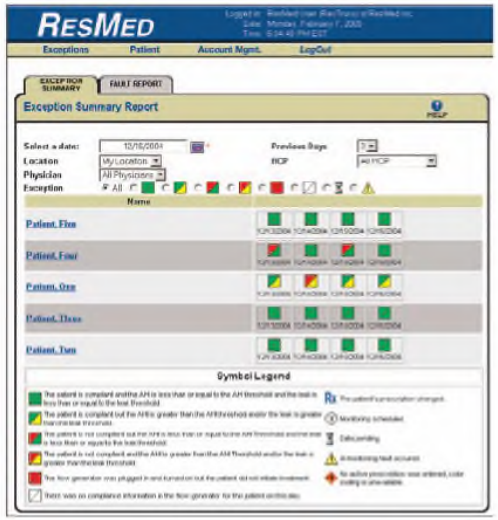
[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.e]	ResMed Prior Art ("RPA")

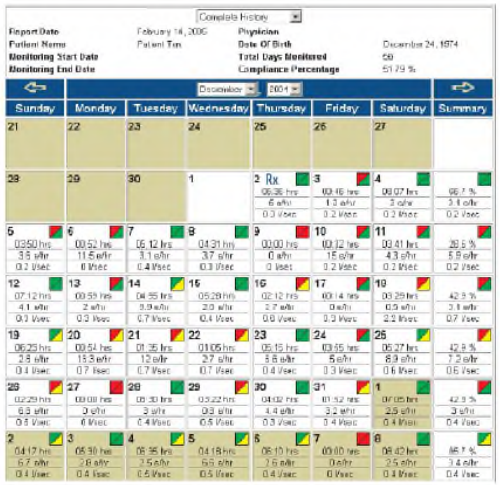
Exception Reporting

Enhance productivity and manage patients more efficiently. **Exception Reporting identifies and highlights those patients who fall below desired usage thresholds or have issues with mask leak or AHI.** This feature enables you to focus your efforts only on those patients who require intervention and respond proactively to potential problems. The simple color-coded alert system helps you identify exception patients quickly and easily.



Efficacy + Leak + Usage Data

The ResTraxx Data Center displays data on a daily basis in a calendar format enabling you to see daily or weekly trends of adherence problems before compliance is truly compromised. Early intervention and ongoing follow-up is considered critical, especially during the first month of CPAP acclimation, to determine long-term compliance rates.[2]



Want more details on therapy results? Click on the calendar day in question, and a therapeutic report will display additional clinical data regarding the patient's usage for that day.

RMD-063327 (ResTraxx Patient Management Brochure) at -3328.

[redacted]

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.e]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 517

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.e]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.e]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 519

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.e]	ResMed Prior Art ("RPA")
	[redacted]

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Exhibit 1024 - Page 520

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

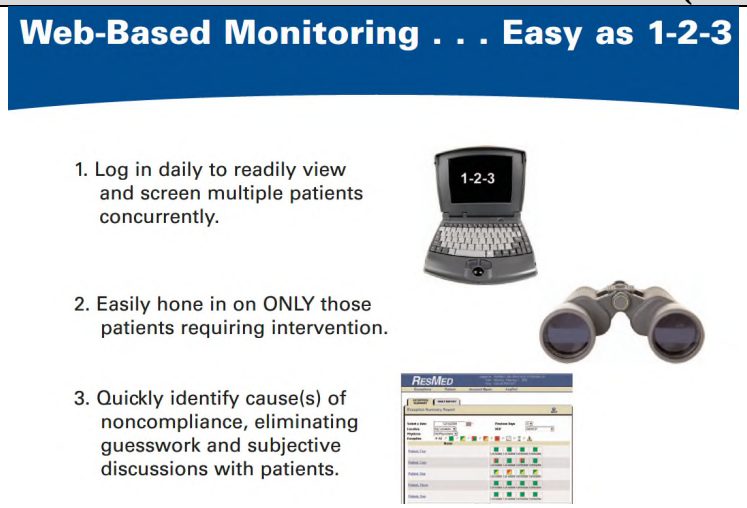
Claim Language [15.e]	ResMed Prior Art ("RPA")
	[redacted]

[redacted]

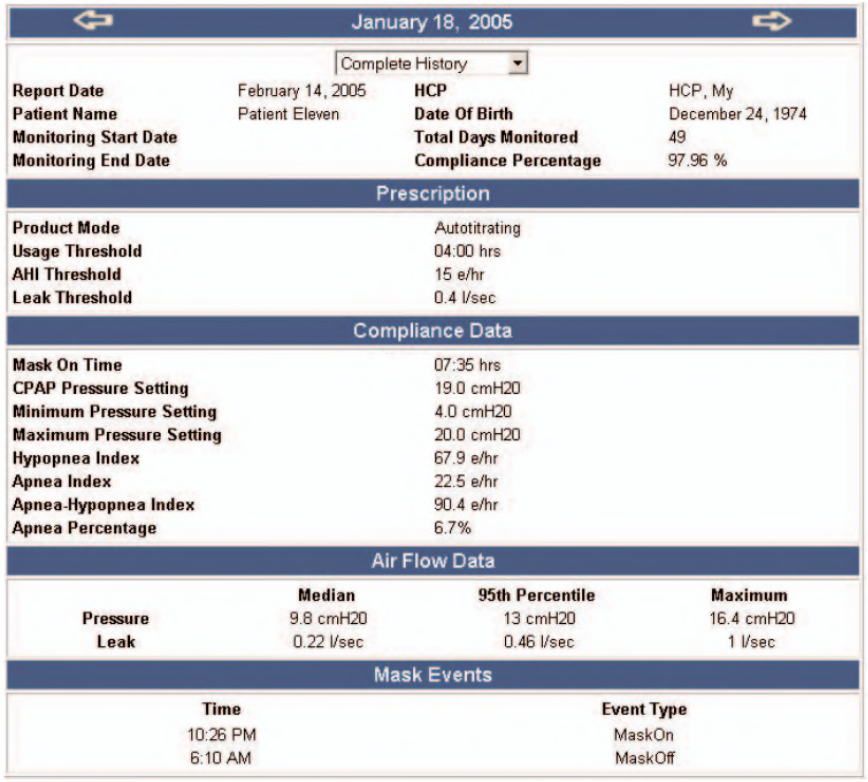
FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.e]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 522

Claim Language [15.e]	ResMed Prior Art ("RPA")
	 RMD-063341 (ResTraxx Wireless Patient Monitoring Atlas) at -3343.

Claim Language [15.e]	ResMed Prior Art ("RPA")



January 18, 2005

Complete History

Report Date	February 14, 2005	**HCP**	HCP, My
Patient Name	Patient Eleven	**Date Of Birth**	December 24, 1974
Monitoring Start Date		**Total Days Monitored**	49
Monitoring End Date		**Compliance Percentage**	97.96 %

Prescription

Product Mode	Autotitrating
Usage Threshold	04:00 hrs
AHI Threshold	15 e/hr
Leak Threshold	0.4 l/sec

Compliance Data

Mask On Time	07:35 hrs
CPAP Pressure Setting	19.0 cmH20
Minimum Pressure Setting	4.0 cmH20
Maximum Pressure Setting	20.0 cmH20
Hypopnea Index	67.9 e/hr
Apnea Index	22.5 e/hr
Apnea-Hypopnea Index	90.4 e/hr
Apnea Percentage	6.7%

Air Flow Data

	Median	**95th Percentile**	**Maximum**
Pressure	9.8 cmH20	13 cmH20	16.4 cmH20
Leak	0.22 l/sec	0.46 l/sec	1 l/sec

Mask Events

Time	**Event Type**
10:26 PM	MaskOn
6:10 AM	MaskOff

RMD-063341 (ResTraxx Wireless Patient Monitoring Atlas) at -3365.

> A drill-down into a specific date on Jan 18th **shows the relevance of the Compliance Data demonstrating that the AHI is 90.4 with a breakdown of Apneas of 22.5 and hypopneas of 67.9%.** The clinician now has the data required to make appropriate therapeutic intervention.

RMD-063341 (ResTraxx Wireless Patient Monitoring Atlas) at -3372.

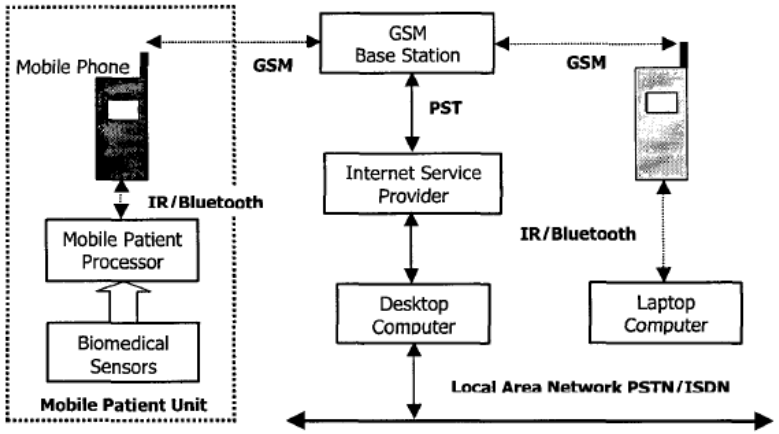
[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.e]	ResMed Prior Art ("RPA")
	[redacted]

IPR2023-00565 - ResMed
Exhibit 1024 - Page 525

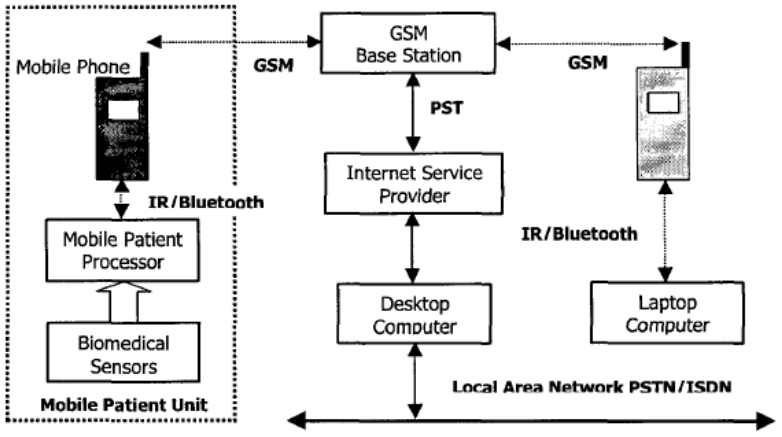
Claim Language [15.e]	ResMed Prior Art ("RPA")
	[redacted] *See also* RDC User's Manual (RMD-306688); [redacted] Alternatively, if the Judge or Jury finds that RPA Systems 1-2 does not disclose this claim limitation, this claim is still rendered obvious by modifying or combining RPA Systems 1-2 with knowledge of a POSITA and/or Rasid. For example, telemedicine systems were known in the art for transmitting data collected at biomedical monitoring devices, such as CPAP devices, using PDAs and mobile phones. A POSITA would have recognized this to suggest the use of short range, low power communications at the CPAP device, such as the well-known Bluetooth protocol, for wireless transmission to a device with longer range communication capability and ability for technological updates (such as advancements and updates in cellular communication), such as a PDA or cell phone. This configuration was known in the art. Woodward discloses an exemplary telemedicine system as was known to a POSITA:

Claim Language [15.e]	ResMed Prior Art ("RPA")
	 Fig. 1 Telemedicine system with mobile telephone and PSTN communications links "This paper reviews a number of recent wireless telemedicine projects that have been carried out around the world, then focuses on the design and development of a wireless telemedicine system using a conventional mobile telephone. The system is capable of transmitting up to four sets of biomedical data from a patient via the Global System for Mobile communications (GSM) cellular network to a hospital or surgery. It is designed to be generic, so it may also be used for non-medical applications, and to be "future-proofed" in view of constantly evolving telecommunications technology, including the introduction of the Third Generation (3G) protocol as a replacement for the present GSM protocol." Woodward, 43. "While the transmission of biomedical data by satellite is demonstrably feasible for long-range wireless links, it is more likely that mobile telephones using cellular networks will be adopted for transmission over shorter ranges. Among the technical problems is the issue of how to link the data from the patient (via a mini-processor) to the phone. This may possibly be done by a direct connection, or by a wireless connection such as an acoustic, infra-red or Bluetooth radio link [l8]. It is only recently that the potential advantages of Bluetooth and other wireless technologies have been recognized, including the Wireless Application Protocol (WAP) for cell phones [19], and Personal Digital Assistants (PDA) [20,21]." Woodward, 44.

Claim Language [15.e]	ResMed Prior Art ("RPA")
	"The main contribution of this paper has been to describe the present scope and future potential of mobile communications in telemedicine. A modular-structured system has been used to illustrate the concept. The mobile patient unit comprises a processing unit, which accepts signals from one or more sets of sensors, linked by a wireless channel to a mobile telephone. The prototype version is designed to transmit digitised electrocardiogram signals to a hospital via the GSM mobile telephone cellular network. New compression and signal processing algorithms, such as wavelet techniques, can be integrated to optimise the performance of the system under different mobile conditions. The modular design of the system should enable telemedicine providers to adapt to future technology advances." Woodward, 45. This is also disclosed by Rasid. *See* Abstract ("a system to transmit a patient's biomedical signals directly to a hospital for monitoring or diagnosis, using an unmodified mobile telephone"), §§ I.B, III.A, IV, Figs. 2, 4. It would have been obvious to modify RPA Systems 1-2 to incorporate use of the mobile phones (cellular phone) of Rasid or otherwise combine such reference teachings to arrive at the claimed system having a "a base station, cellular phone, or PDA." The Rasid disclosure demonstrates the implementation details as known in the art for doing so. It would have been obvious, for example, to implement the RPA System disclosed wired modem transmission or RPA System 2 pager network transmission function with a cellular phone as disclosed by Rasid to wirelessly transmit the collected physiological sensor data to a server like that disclosed by Rasid such that a health care professional could review and analyze the data. *See also* limitation 15.g.

Claim Language [15.f]	ResMed Prior Art ("RPA")
[15.f] the first radio frequency wireless module transceiver adapted for receiving and transmitting the symptom data of the severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms	At least based on CleveMed's infringement contentions, RPA Systems 1 and 2 disclose a "base station" for the same reasons CleveMed alleges the accused products practice the "base station" limitation. RPA System 2 discloses the remainder of this limitations for the same reasons CleveMed alleges the accused products practice this limitation. For example, RPA System 1 discloses a modem "adapted for receiving and transmitting [data calculated by the PAP device processor] and the data of usage to the" clinician's computer running AutoScan 5.4 software (a "base station" according to CleveMed's contentions). As discussed, e.g.,

Claim Language [15.f]	ResMed Prior Art ("RPA")
measured during use of the PAP device and the data of usage to the base station, cellular phone or PDA;	for limitation 15.d-e, it would have been obvious to modify the modem to practice the system of claim 15. RPA System 2 discloses the [redacted] that is "adapted for receiving and transmitting [data calculated by the PAP device processor] to the" RDC system and clinician's computer accessing the RDC web application (a "base station" according to CleveMed's contentions). RPA Systems 1-2 transmit the data calculated by the processor that CleveMed has alleged is symptom data of the severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device. *See* limitations 1.b.4, 1.d, 15.b. Alternatively, RPA Systems 1 and 2 render these limitations obvious either alone or in combination with the knowledge of a POSITA, and/or Rasid. *See, e.g.*, limitations 1.d, 15.b, 15.d. "Wireless data transmission was accomplished by first attaching a transmission device, described below, to the flow generator. Then, by accessing a secure Web site, a request for data was sent from a secure sever, located in Peachtree City, Georgia, through land lines to the carrier's local transmission antenna, located within several miles of the device and location set up, where it is transmitted wirelessly to the device. Once the device received the request, the data were retrieved from the memory of the flow generator, transmitted wirelessly to a receiving antenna, located within several miles of the device. Then, through land lines back to the secure server, the data became available on the aforementioned Web site." Lankford, 164. "*Wireless and Internet-based technologies* "For data downloading at the end of the trial, an investigational wireless-to-Internet data collection/transmission system, being developed by ResMed, and named the "Spectrum System," was employed in this trial. The Spectrum System consists of the flow generator, a wireless communication device, code-named "Cyrcat," and a secure Web server located in a remote location. The secure Web server receives patient-related clinical data (compliance and efficacy parameters) from the Cyrcat wireless transmitter and it stores the information for clinician viewing, analysis, and reporting through a secure Web browser." Lankford, 164. "*Data collection methods* "Patients were asked to return with their CPAP unit to their respective set-up locations. Data were wirelessly transmitted using the Spectrum System to the secure Web server. These data were then

Claim Language [15.f]	ResMed Prior Art ("RPA")
	downloaded onto a storage disk using a predetermined Microsoft Excel format for later comparison with the same base set that was manually downloaded from the flow generators using the same format. All disks were marked with patient codes to assure anonymity. In the tables that follow, the terms 'wireless' and 'autoscan' refer to the wireless and base data sets, respectively." Lankford, 165, *see also* 166. Alternatively, this claim is still rendered obvious by modifying or combining RPA with the knowledge of a POSITA and/or Rasid. *See* limitation 15.d, 15.g. For example, telemedicine systems were well known in the art that used short range wireless transmission from a device such as the RPA PAP devices, to a mobile phone. *See, e.g.*, Rasid, § II.A ("Bluetooth is a universal short-range low-power radio protocol operating in the unlicensed industrial, scientific, and medical frequency band.") It would have been at least obvious to transfer the data collected and calculated by the RPA PAP device (AutoSet Spirit flow generator) to the handheld devices known to a POSITA. A POSITA would have therefore been motivated to at least try a configuration like those known in the art, and expressly disclosed in the below examples, to arrive at the claimed system configuration. Woodward discloses a telemedicine system:  Fig. 1 Telemedicine system with mobile telephone and PSTN communications links

Claim Language [15.f]	ResMed Prior Art ("RPA")
	"This paper reviews a number of recent wireless telemedicine projects that have been carried out around the world, then focuses on the design and development of a wireless telemedicine system using a conventional mobile telephone. The system is capable of transmitting up to four sets of biomedical data from a patient via the Global System for Mobile communications (GSM) cellular network to a hospital or surgery. It is designed to be generic, so it may also be used for non-medical applications, and to be "future-proofed" in view of constantly evolving telecommunications technology, including the introduction of the Third Generation (3G) protocol as a replacement for the present GSM protocol." Woodward, 43. "While the transmission of biomedical data by satellite is demonstrably feasible for long-range wireless links, it is more likely that mobile telephones using cellular networks will be adopted for transmission over shorter ranges. Among the technical problems is the issue of how to link the data from the patient (via a mini-processor) to the phone. This may possibly be done by a direct connection, or by a wireless connection such as an acoustic, infra-red or Bluetooth radio link [l8]. It is only recently that the potential advantages of Bluetooth and other wireless technologies have been recognized, including the Wireless Application Protocol (WAP) for cell phones [19], and Personal Digital Assistants (PDA) [20,21]." Woodward, 44. "The main contribution of this paper has been to describe the present scope and future potential of mobile communications in telemedicine. A modular-structured system has been used to illustrate the concept. The mobile patient unit comprises a processing unit, which accepts signals from one or more sets of sensors, linked by a wireless channel to a mobile telephone. The prototype version is designed to transmit digitised electrocardiogram signals to a hospital via the GSM mobile telephone cellular network. New compression and signal processing algorithms, such as wavelet techniques, can be integrated to optimise the performance of the system under different mobile conditions. The modular design of the system should enable telemedicine providers to adapt to future technology advances." Woodward, 45. Rasid discloses a similar system with additional advancements. *See* Rasid, Abstract ("a system to transmit a patient's biomedical signals directly to a hospital for monitoring or diagnosis, using an unmodified mobile telephone"), §§ I.B, III.A, IV, Figs. 2, 4. It would have been obvious to incorporate the Bluetooth module and cellular phone of Rasid into RPA System 1 or 2, or otherwise combine such reference teachings to arrive at the claimed system having a first wireless module, such as a Bluetooth module implemented at RPA's PAP device

Claim Language [15.f]	ResMed Prior Art ("RPA")
	(AutoSet Spirit flow generator), adapted for receiving and transmitting symptom data of the severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device along with the disclosed compliance data to a cellular phone as disclosed by Rasid. Furthermore, RPA Systems 1 and 2 disclose that the parameters "calculated" by the processor in accordance with limitation 15.b are received and transmitted by the modem of System 1 and the [redacted] of System 2 for at least the same reasons CleveMed alleges the data received and transmitted by the accused products is the claimed "symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms, and to retransmit the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms and the data of usage received from the PAP."

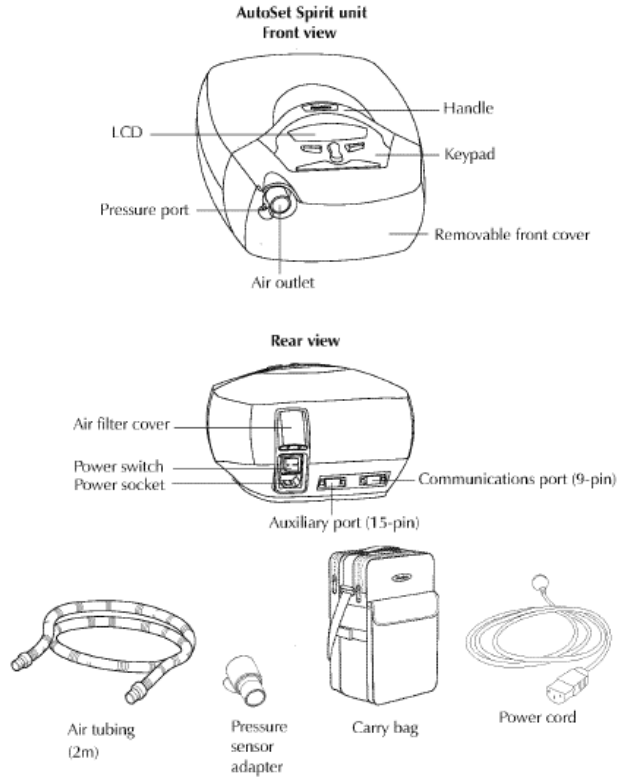
Claim Language [15.g]	ResMed Prior Art ("RPA")
[15.g] the base station, cellular phone, or PDA comprising a second radio frequency wireless module transceiver, a processor, a software, and a display, the base station, cellular phone, or PDA adapted to display the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms, and to retransmit the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms and the data of usage	At least based on CleveMed's infringement contentions, RPA System 2 discloses this limitation. Otherwise RPA Systems 1 and 2 render this limitation obvious either alone or in combination with the knowledge of a POSITA, and/or Rasid. *See, e.g.*, limitations 1.pre, 1.d, 5.f, 15.b, 15.d, 15.e, 15.f. **CleveMed's Infringement Contentions** CleveMed's infringement contentions allege that this limitation is practiced as follows: [redacted]

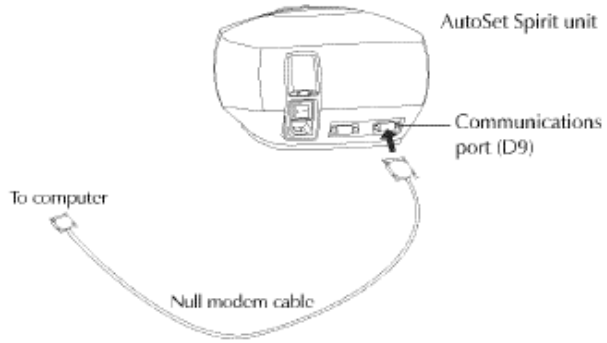
Claim Language [15.g]	ResMed Prior Art ("RPA")
received from the PAP device to a remote internet site.	platform, as well as other third-party integrators. RMD-014240; RMD-059017-018; RMD-207340. [redacted] Final Infr. Cont., Chart I, 107-108. CleveMed's contentions, however, like those for limitation 15.e (the discussion of which is incorporated by reference here), again do not specify what CleveMed contends is the "computer(s) running AirView" that allegedly comprises "a second radio frequency wireless module transceiver, a processor, a software, and a display," and are "adapted to display … and to retransmit" the data calculated by the processor of limitation 15.b. If this configuration is found to practice the asserted claim, as best CleveMed's contentions can be understood, RPA discloses (or at least renders it obvious) for at least the same reasons. For example, as established for limitations 15.b, 15.d, and 15.e, a POSITA would have recognized, or at least found it obvious, that computers running software to access the RDC web application (RPA System 2) and view the data transmitted from the PAP device using the ResTraxx module comprised a processor and display, and that the computer was adapted to display usage data and calculated data transmitted from the PAP device (including, *e.g.*, Apnea Index, Hypopnea Index, Apnea-hypopnea index, Apnea Percentage, Pressure statistics, Leak statistics, pressure settings, and Mask On Time). Likewise, the computer running the AutoScan 5.4 software (RPA System 1) comprised a processor and display for viewing the data transmitted via modem from the PAP device, including Usage, Pressure and Leak Statistics, AHI, AI, time in apnea, and pressure settings. For at least the same reasons CleveMed alleges the "AirView computers can … retransmit" the data displayed at the

[2] This is a new theory of infringement not disclosed prior to CleveMed's Final Infringement Contentions. CleveMed's late disclosure of this theory has prejudiced ResMed's ability to develop its defenses in view of this newly minted theory and ResMed reserves the right to move to strike this theory from CleveMed's contentions and any corresponding opinion or analysis in expert reports.

Claim Language [15.g]	ResMed Prior Art ("RPA")
	computer, the computer displaying data from the RDC (RPA System 2) or AutoScan (RPA System 1) could also retransmit the displayed data to a remote location. *See, e.g.*, limitations 1.d, 5.f. Furthermore, a POSITA would have recognized, or at least found it obvious, that the computer adapted to display data collected at the RPA PAP devices through RDC or AutoScan would include a laptop device or PC with a "radio frequency wireless module transceiver." Such a feature was merely an implementation detail where laptops or PCs having wireless modems (e.g., wireless network cards), for example, would have been an obvious design choice for the implementer, and more generally, would have been a choice by the user as a generic component of their laptop device that is mobile, or PC, as known in the art. Alternatively, in view of CleveMed's new theory that a "cell tower" is "AirView's wireless module transceiver," for at least the same reasons the RF pager network "tower" is "RDC's wireless module transceiver." **ResMed AutoSet Spirit (System 1-2)** The ResMed AUTOSET® SPIRIT™ system is designed to provide continuous positive airway pressure (CPAP) therapy to patients with obstructive sleep apnea (OSA). Patients with OSA experience recurrent obstruction of their upper airway (apneas) due to relaxation of the tongue and soft palate while they sleep. Common symptoms are associated with poor sleep quality and may include excessive daytime sleepiness and tiredness, as well as diminished concentration and memory loss. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3974. The AUTOSET SPIRIT system is designed for clinical use and home treatment of adult patients with obstructive sleep apnea (OSA). The system has two therapy modes for treating OSA: **CPAP** mode and **AutoSet** mode. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.

Claim Language [15.g]	ResMed Prior Art ("RPA")
	AUTOSET® MODE The treatment pressure required by your patient may vary through the night, and from night to night, due to changes in sleep state, body position, and airway resistance. In AutoSet mode AUTOSET SPIRIT provides only sufficient pressure to maintain upper airway patency. You can set the minimum and maximum allowable treatment pressures. The unit analyzes the state of the patient's upper airway on a breath-by-breath basis and delivers pressure within the allowed range according to the degree of obstruction. The AutoSet algorithm adjusts treatment pressure as a function of three parameters: inspiratory flow limitation, snore, and apnea. The flow sensor, located in the AUTOSET SPIRIT unit, enables detection of inspiratory flow limitation and apneas. The pressure sensor, also located in the unit, enables measurement of pressure and snore. RMD-063968 (AutoSet Spirit Clinician's Manual) at -3980.

Claim Language [15.g]	ResMed Prior Art ("RPA")
	COMPONENTS OF THE AUTOSET® SPIRIT™ SYSTEM The following are supplied as part of an AUTOSET SPIRIT system.  Figure 4: AutoSet Spirit system components RMD-063968 (AutoSet Spirit Clinician's Manual) at -3983.

Claim Language [15.g]	ResMed Prior Art ("RPA")
	AUTOSCAN™ SOFTWARE AUTOSCAN is designed to enable review of the data stored in an AUTOSET SPIRIT unit. Data from up to 365 sessions may be stored and downloaded. Refer to the *AutoScan Clinician's Manual* or *Help* for details.  RMD-063968 (AutoSet Spirit Clinician's Manual) at -3986. REMOTE DATA ACCESS You can download data from an AUTOSET SPIRIT unit in your patient's home to AUTOSCAN software on your computer using modems. Both you and your patient require a modem set up for this purpose. The patient attaches the modem to the right communications port on the AUTOSET SPIRIT unit and to a phone line. You attach your modem to the serial port on your computer and a phone line. Refer to complete instructions for modem use in the *AutoScan Clinician's Manual*. RMD-063968 (AutoSet Spirit Clinician's Manual) at -4015.

[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.g]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.g]	ResMed Prior Art ("RPA")
	[redacted]

Claim Language [15.g]	ResMed Prior Art ("RPA")
	[redacted] **AutoScan 5.4 (System 1)** AUTOSCAN™ 5.4 has been developed to view summary data and detailed data obtained from the RESLINK™ via the SmartMedia™ card. Summary data and Night profile data obtained from the flow generator can also be viewed as in previous versions of AUTOSCAN. AUTOSCAN 5.4 has data collection and management capabilities that provide an adjunct for patient management. The flow generator systems intended to be used with AUTOSCAN 5.4 are the ResMed AUTOSET® SPIRIT™, S7™ ELITE, VPAP® III, VPAP III ST, VPAP III ST-A, and AUTOSET RESPOND™. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1269. FLOW GENERATOR COMPATIBILITY The following flow generators are compatible with AUTOSCAN 5.4: • AUTOSET SPIRIT • AUTOSET RESPOND • VPAP III, VPAP III ST, VPAP III ST-A, • S7 ELITE. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277.

Claim Language [15.g]	ResMed Prior Art ("RPA")

CONNECTING THE FLOW GENERATOR TO THE COMPUTER

In order to download data into AUTOSCAN 5.4, your computer must be connected by cable to the flow generator.

NOTES *If your flow generator is connected to a ResControl, you must disconnect the ResControl before connecting the flow generator to your computer for interfacing to AutoScan 5.4.*

Plug the null modem cable into the PC connection port on the flow generator and into an available serial port at the back of your computer (**COM1, COM2, COM3** or **COM4**).

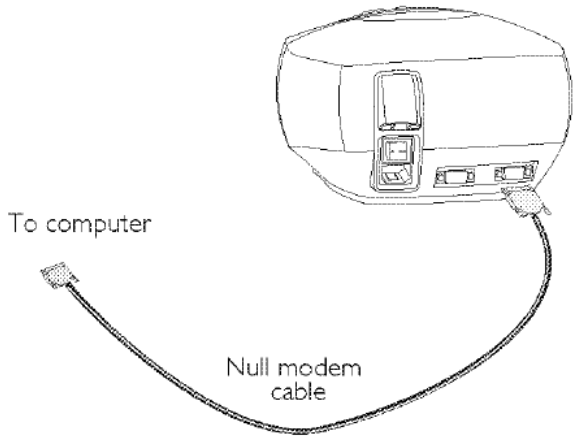


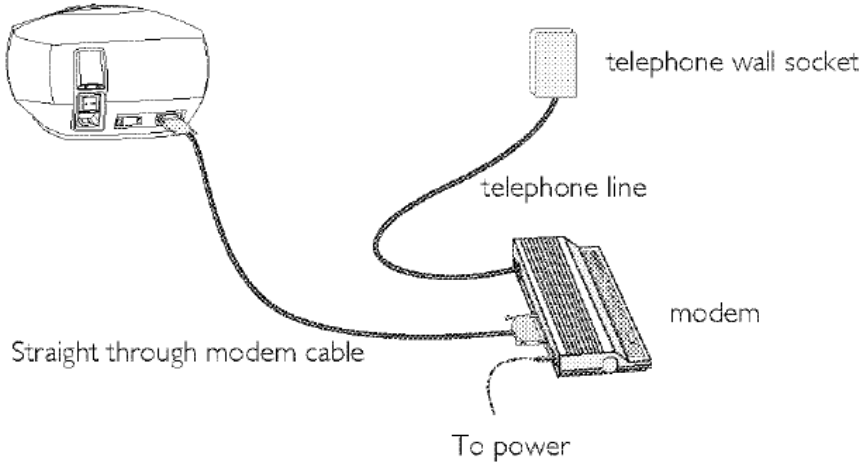
Figure 2: Connecting the flow generator to the computer

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1277 – 78.

USING MODEMS

You can download summary and Night Profile data on your flow generator remotely via modem. We recommend *Windows NT 4.0 SP6* and 3Com U.S. Robotics 56k Voice Faxmodems for this purpose.

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1279.

Claim Language [15.g]	ResMed Prior Art ("RPA")
	USING MODEMS TO DOWNLOAD DATA You may download summary and Night Profile data remotely via modem. These operations require that both you and the patient have modems. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1290.  RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1290. MANAGING PATIENT INFORMATION AUTOSCAN 5.4 allows you to record patient information, clinical details and notes in the patient file. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1297. Detailed and summary data from a patient's flow generator are stored on a SmartMedia card by the RESLINK. The SmartMedia card is removed and sent to the clinician at the end of the study period. The SmartMedia card is inserted into a SmartMedia card reader attached to the clinician's computer, and the data can then be downloaded and viewed in AUTOSCAN 5.4. RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1301.

Claim Language [15.g]	ResMed Prior Art ("RPA")

The Detailed Data screen displays nine traces of data downloaded via the RESLINK from the flow generator. You can view data in the Detailed Data screen in increased detail or as a compact overview.

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1303.

The Detailed Data screen for that session will be displayed.

The graph display area shows the downloaded data in the trace panels:

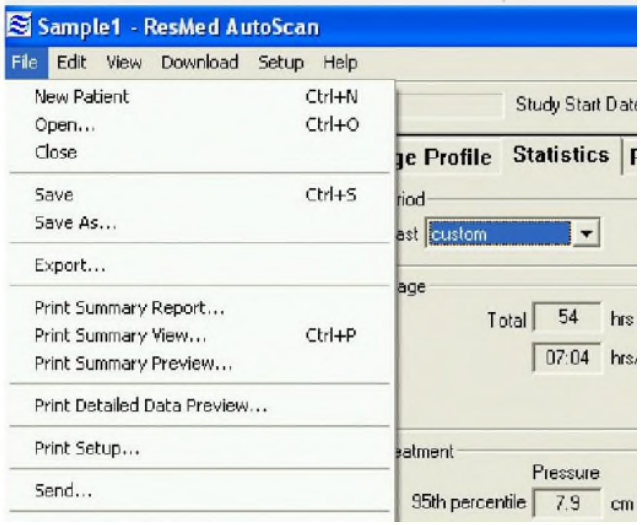
- Events (s)
- Minute Ventilation (L/min)
- Leak (L/s)
- Pulse Rate (bpm)
- SpO_2 (%)
- AHI (Events/hr)
- Pressure (cm H_2O)[a]
- Snore (Quiet to Loud)[a]
- Flattening (Round to Flat)[a]
- Respiratory rate (BPM).[b]

[a] AUTOSET SPIRIT and S7 ELITE only
[b] VPAP III series only

NOTE *Pulse rate and SpO_2 are derived from the oximeter reading.*

RMD-311263 (AutoScan 5.4 Clinician's Manual) at -1304.

See also AutoSet Spirit Clinician's Manual (RMD-063968) at 42; AutoScan 5.4 Clinician's Manual (RMD-311263) at 25-26, 61-62 ("Printing a Full Report" and "Printing Night Profiles"); [redacted]

Claim Language [15.g]	ResMed Prior Art ("RPA")
	[redacted]  RMD-0318346 at -0318350, *see also* -0318362-364. A POSITA would have found it obvious to "retransmit" the generated report, for example, to incorporate it into the patient's medical record or send it to an insurance provider or other recipient in the health care network, as was known in the art. It would have been known, or at least obvious, that such a practice would have included transmission of the report to a remote internet site that maintains records or communications for the receiving party. The AutoScan 5.4 software can "send an email with the currently open patient file as an attachment … ." AutoScan 5.4 Clinician's Manual (RMD-311263) at 25-26; [redacted] ResScan 3.0 Clinician's Manual (RMD-063018) at 47; RMD-0318346 at -0318350, see also 0318370-372. CleveMed's infringement contentions allege that emailing a report in this manner practices the limitation "retransmit the symptom data of the severity of the subject's sleep disorder symp-toms and/or the index of the subject's symptoms and the data of usage received from

Claim Language [15.g]	ResMed Prior Art ("RPA")
	the PAP device to a remote internet site." The same or similar functionality in RPA System 1 therefore practices the limitation for the same reasons. **ResTraxx (including RDC) (System 2)** ResTraxx™ allows the wireless transfer of information from a continuous positive airway pressure (CPAP) unit to a clinician at a remote location via a two-way pager network. ResTraxx is intended to be used with ResMed S7™ Elite, AutoSet® Spirit™, AutoSet® Respond™, and VPAP® III flow generator systems on adults with obstructive sleep apnea. RMD-062642 (ResTraxx Quick Reference Guide) at -2642. [redacted]

[redacted]

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Claim Language [15.g]	[redacted]

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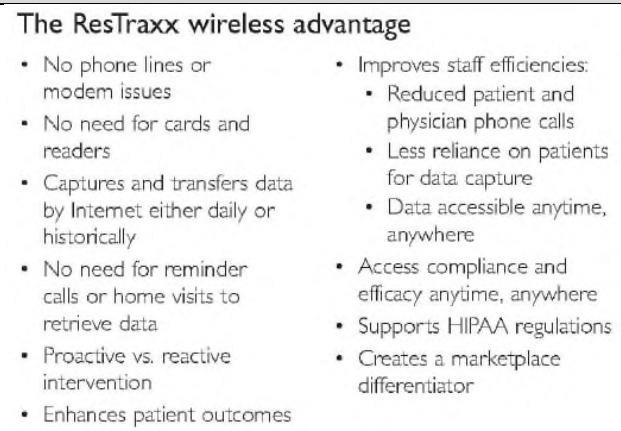
Claim Language [15.g]	ResMed Prior Art ("RPA")
	[redacted]

ResTraxx is a first-of-its-kind wireless communication device that attaches easily to the back of ResMed flow generators. The ResTraxx system captures, transfers, and stores compliance and efficacy data without wires, phone lines, modems, or data cards. ResTraxx is an elegant system that brings patient usage and treatment efficacy data to your fingertips instantly.

RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

Claim Language [15.g]	ResMed Prior Art ("RPA")
	 RMD-063327 (ResTraxx Patient Management Brochure) at -3327.

[redacted]

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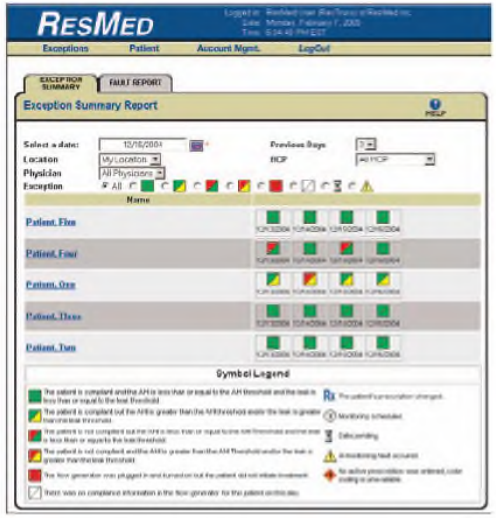
Claim Language [15.g]	ResMed Prior Art ("RPA")

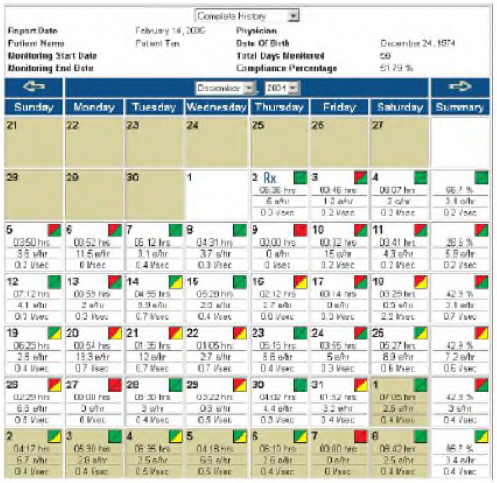
Exception Reporting

Enhance productivity and manage patients more efficiently. **Exception Reporting identifies and highlights those patients who fall below desired usage thresholds or have issues with mask leak or AHI.** This feature enables you to focus your efforts only on those patients who require intervention and respond proactively to potential problems. The simple color-coded alert system helps you identify exception patients quickly and easily.



Efficacy + Leak + Usage Data

The ResTraxx Data Center displays data on a daily basis in a calendar format enabling you to see daily or weekly trends of adherence problems before compliance is truly compromised. Early intervention and ongoing follow-up is considered critical, especially during the first month of CPAP acclimation, to determine long-term compliance rates.[2]



Want more details on therapy results? Click on the calendar day in question, and a therapeutic report will display additional clinical data regarding the patient's usage for that day.

RMD-063327 (ResTraxx Patient Management Brochure) at -3328.

[redacted]

[redacted]

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Claim Language [15.g]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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Claim Language [15.g]	ResMed Prior Art ("RPA")
	[redacted]

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[redacted]

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Claim Language [15.g]	ResMed Prior Art ("RPA")
	[redacted]

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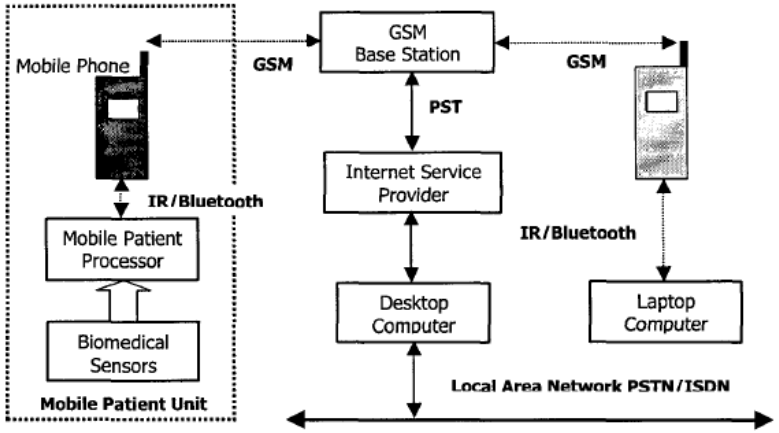
[redacted]

FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent

Claim Language [15.g]	ResMed Prior Art ("RPA")
	[redacted]

Claim Language [15.g]	ResMed Prior Art ("RPA")
	[redacted] If the Judge or Jury finds that RPA does not disclose this claim limitation, this claim is still rendered obvious by modifying or combining RPA with the knowledge of a POSITA. For example, A POSITA would have recognized, or at least found it obvious, that the "computer" running the AutoScan software comprises a processor, software, and a display as claimed. A POSITA would have also found it obvious, as established for limitations 15.d-f, to implement the modem at the RPA PAP device location with wireless networking component or (according to Rasid) a short range (e.g., Bluetooth) connection to a cellular phone or PDA having an RF wireless module transceiver for retransmitting the data collected at the PAP device to a remote location, e.g., for viewing using AutoScan, or to the RDC database. A POSITA would have recognized, or at least found it obvious, that a cellular phone or PDA includes a processor, software, and display adapted for displaying the data collected by the PAP device, to the extent not disclosed by Rasid.

Claim Language [15.g]	ResMed Prior Art ("RPA")
	Woodward discloses an exemplary telemedicine system:  Fig. 1 Telemedicine system with mobile telephone and PSTN communications links "This paper reviews a number of recent wireless telemedicine projects that have been carried out around the world, then focuses on the design and development of a wireless telemedicine system using a conventional mobile telephone. The system is capable of transmitting up to four sets of biomedical data from a patient via the Global System for Mobile communications (GSM) cellular network to a hospital or surgery. It is designed to be generic, so it may also be used for non-medical applications, and to be "future-proofed" in view of constantly evolving telecommunications technology, including the introduction of the Third Generation (3G) protocol as a replacement for the present GSM protocol." Woodward, 43. "While the transmission of biomedical data by satellite is demonstrably feasible for long-range wireless links, it is more likely that mobile telephones using cellular networks will be adopted for transmission over shorter ranges. Among the technical problems is the issue of how to link the data from the patient (via a mini-processor) to the phone. This may possibly be done by a direct connection, or by a wireless connection such as an acoustic, infra-red or Bluetooth radio link [l8]. It is only recently that the potential advantages of Bluetooth and other wireless technologies have been

Claim Language [15.g]	ResMed Prior Art ("RPA")
	recognized, including the Wireless Application Protocol (WAP) for cell phones [19], and Personal Digital Assistants (PDA) [20,21]." Woodward, 44. "The main contribution of this paper has been to describe the present scope and future potential of mobile communications in telemedicine. A modular-structured system has been used to illustrate the concept. The mobile patient unit comprises a processing unit, which accepts signals from one or more sets of sensors, linked by a wireless channel to a mobile telephone. The prototype version is designed to transmit digitised electrocardiogram signals to a hospital via the GSM mobile telephone cellular network. New compression and signal processing algorithms, such as wavelet techniques, can be integrated to optimise the performance of the system under different mobile conditions. The modular design of the system should enable telemedicine providers to adapt to future technology advances." Woodward, 45. As another example, Rasid discloses: "One of the emerging issues in m-Health is how best to exploit the mobile communications technologies that are now almost globally available. The challenge is to produce a system to transmit a patient's biomedical signals directly to a hospital for monitoring or diagnosis, using an unmodified mobile telephone. The paper focuses on the design of a processor, which samples signals from sensors on the patient. It then transmits digital data over a Bluetooth link to a mobile telephone that uses the General Packet Radio Service. The modular design adopted is intended to provide a "future-proofed" system, whose functionality may be upgraded by modifying the software." Rasid, Abstract; *see also* Rasid Thesis, Abstract. "The system presented here contains the following links, as shown in Fig. 2: 1) short-range Bluetooth link between patient and telephone; 2) GPRS to a base station and to other mobile telephones; 3) land lines (PSTN) and an Internet service provider (ISP) to a hospital server and database; 4) LAN to clinicians." Rasid, § I.C.

Claim Language [15.g]	ResMed Prior Art ("RPA")

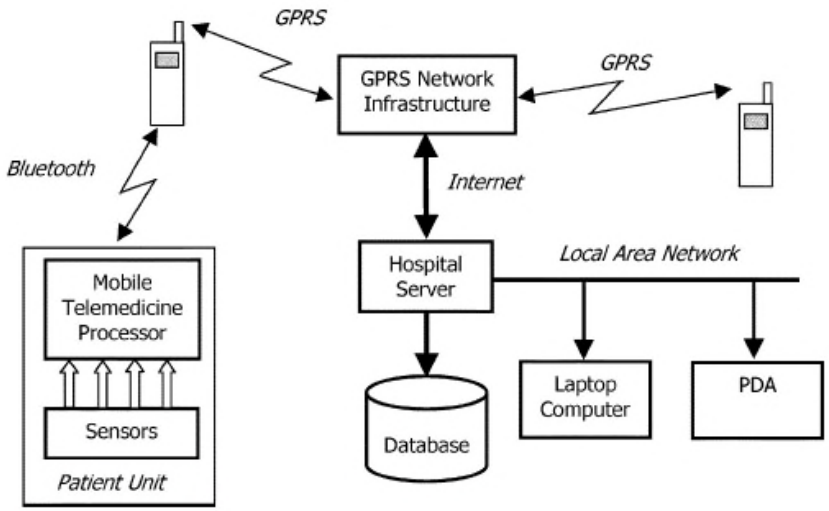


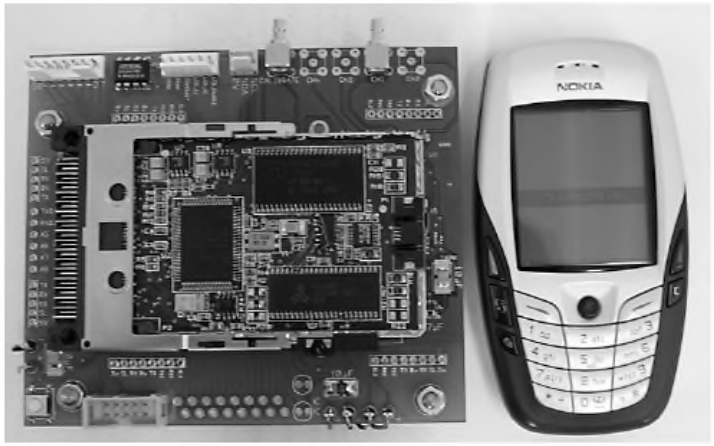
Fig. 2. Mobile telemedicine system.

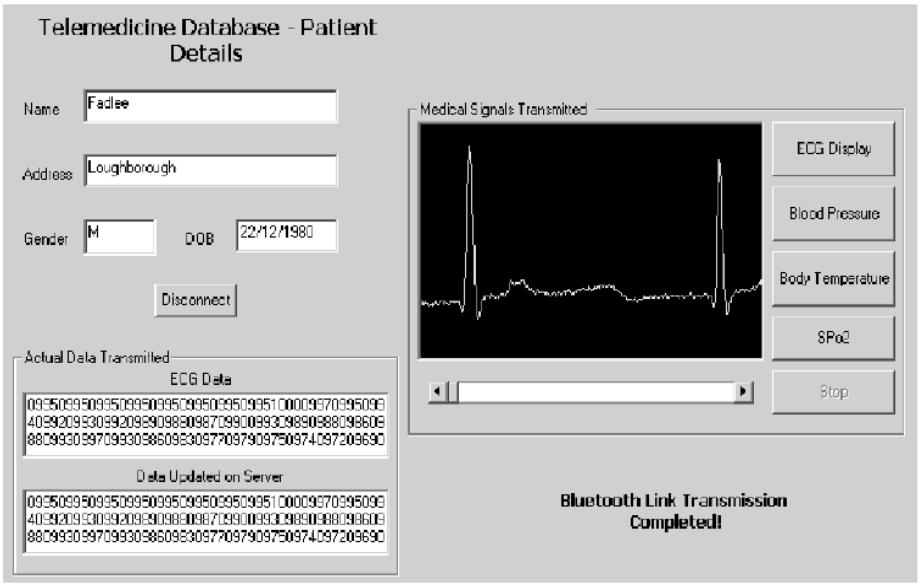
Rasid, Fig. 2; *see also* Rasid Thesis at Figures 6.1, 6.20.

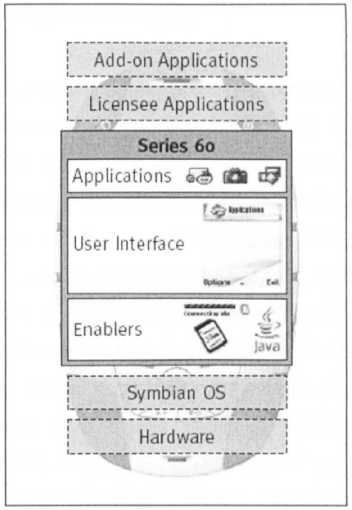
TABLE VI
BIOMEDICAL SIGNAL CHARACTERISTICS [46]

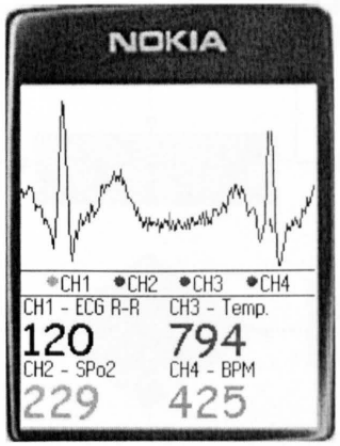
Signal	Frequency range	Signal Range
Electrocardiogram (ECG)	0.05 – 100 Hz	10 μV – 5 mV
Electroencephalogram (EEG)	0.5 – 60 Hz	15 – 100 mV
Heart Rate	45 – 200 beats/min	N/A
Breathing Rate	12 – 40 breaths/min	N/A
Blood Pressure	dc – 60 Hz	40 – 300 mm Hg (arterial) 0 – 15 mm Hg (venous)

Rasid, Table VI; § II.C ("There is some variation in the amount and type of clinical data that can be transmitted, as shown in Table V [45]. In our system, the type of data is applicable to monitoring and routine checkups. Typical signals monitored are shown in Table VI [46].")

Claim Language [15.g]	ResMed Prior Art ("RPA")
	"The complete system is shown in Fig. 2. Signal inputs from the patient are those normally used for monitoring purposes, such as the ECG (and heart rate), blood pressure, body temperature, and SpO . These signals are fed to the Bluetooth-enabled processor unit, where they are digitized and stored in memory. Next, the digitized data are transmitted to a Bluetooth mobile telephone and subsequently via the GPRS cellular network to a base station, then to a hospital via conventional PSTN lines or a cellular network. The data received at the hospital server are available to a clinician via the hospital's LAN, either through the personal computer (PC), laptop, or personal digital assistant (PDA). Alternatively, the clinician away from the vicinity of the hospital may receive a patient's data via a mobile telephone and a PDA." Rasid, § III.A.  Fig. 4. Layout of mobile telemedicine processor. Rasid, Fig. 4. "Patient data are recorded and stored in the processor's memory module, typically for 10 min, then the processor transmits an AT-command to the mobile phone to initiate data transmission via the GPRS network." Rasid, § IV. "For test purposes, the patient interface to the mobile telephone has been simulated by programming the mobile telemedicine processor to transmit the digitized ECG signals via a Bluetooth link to a PC, which is programmed to represent the hospital server." Rasid, § IV.

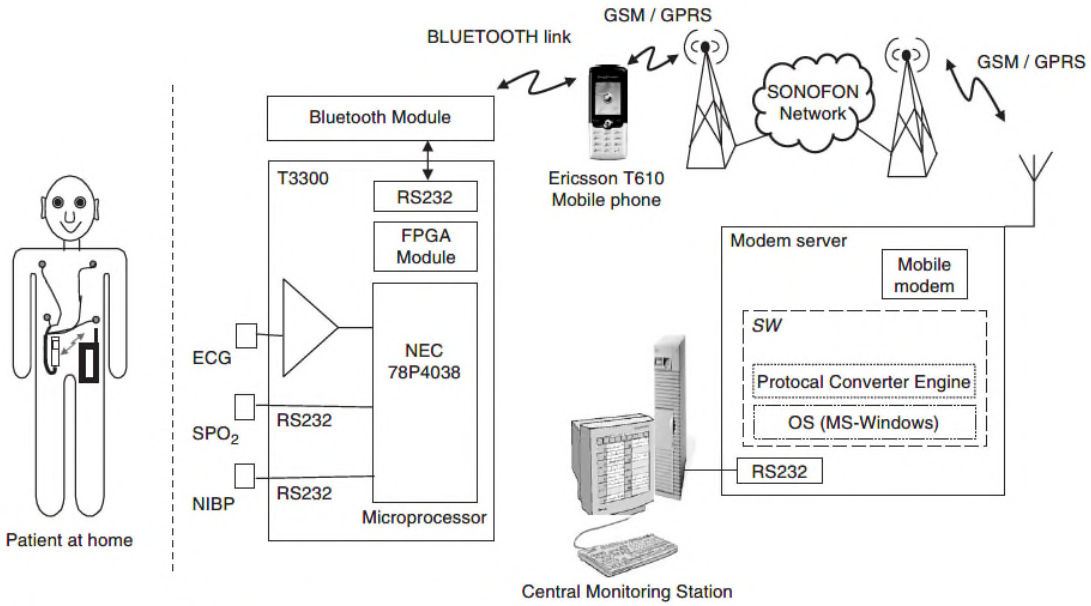
Claim Language [15.g]	ResMed Prior Art ("RPA")
	 Rasid, FIG. 9. It would have been obvious to incorporate the mobile phone of Rasid, or otherwise combine such reference teachings with RPA System 1 or RPA System 2 to arrive at the claimed system. Namely it would have been obvious to incorporate a wireless module such as a Bluetooth module as disclosed by Rasid, into the RPA CPAP devices, and to use a mobile phone or PDA as the "computer" to receive and display compliance and parameter data from the CPAP device, and retransmit such information to a remote internet site, such as the website disclosed by AutoScan for clinician review. Furthermore, to the extent transmission of the RPA PAP collected data from a device accessing the RDC, or using the AutoScan software, to a medical/health care or insurance provider, is determined to practice the "retransmit … to a remote internet site" part of this limitation, this was known in the art and would have been an obvious modification to RPA to the extent not disclosed. For example, as established for limitation 5.f, AutoScan were adapted to generate reports that could be emailed from the computer running AutoScan.

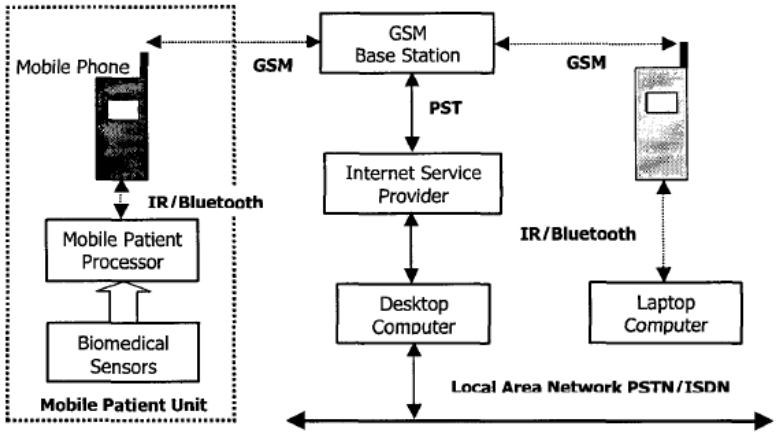
Claim Language [15.g]	ResMed Prior Art ("RPA")
	As an additional example in the art demonstrating the knowledge of a POSITA of a cellular phone that displays physiological or biometric data, the Rasid thesis discloses, for example:  Figure 5.10 The Series 60 platform architecture Rasid Thesis, 98. The Enablers layer is the layer responsible for application execution and supports either Symbian C++ or Java virtual machine environment. The Java application environment in the Series 60 platform is utilised for the research that supports, among other things, the MIDP 2.0 profile (JSR 118), the CLDC (JSR 30) and the Bluetooth API (JSR 82) for J2ME applications. The Nokia 6600 mobile phone model used for the research is based on the Series 60 platform, as given by the specifications listed in Chapter 4, section 4.3.1. Some other Series 60 mobile phone models are Nokia 6630, Panasonic X700, Siemens SX1. An up to date list of Series 60 mobile phones is available from Series 60 platform official website [5.38]. Rasid Thesis, 98.

Claim Language [15.g]	ResMed Prior Art ("RPA")
	 Figure 6.15 (b) Mobile phone patient program- Test mode [6.9] Rasid Thesis, 133. This claim is also further rendered obvious, also in view of CleveMed's infringement contentions regarding the creation and forwarding of reports. *See, e.g.*, Final Infr. Cont., Chart I, 107-117. It would have been obvious to modify the RPA such that the PAP collected data reviewed at a "computer" accessing the RDC, or running AutoScan, could forward the report reviewed by the clinician, including notes from the clinician, to the health care or insurance provider. Such a modification would have been a simple design choice known to a POSITA. For example, in accordance with CleveMed's infringement theories, it would have been obvious that the "laptop computer" disclosed in Rasid's system practices the claimed "base station" limitation, or the PDA satisfies the claim as well. It is inherent or at least obvious that both of these devices would include a processor, software, and display for displaying the data transmitted by the Bluetooth and cell phone to the hospital server, and accessed by the laptop or PDA. It would have been obvious for the laptop and PDA to use a RF wireless module transceiver to connect to the hospital server for at least the same reasons discussed above for limitations 15.d-f to use a wireless networking card or similar wireless network access module in place of wired connections to a local area network as was known in the art. A POSITA would have recognized, or at least found it obvious, for at least the reasons

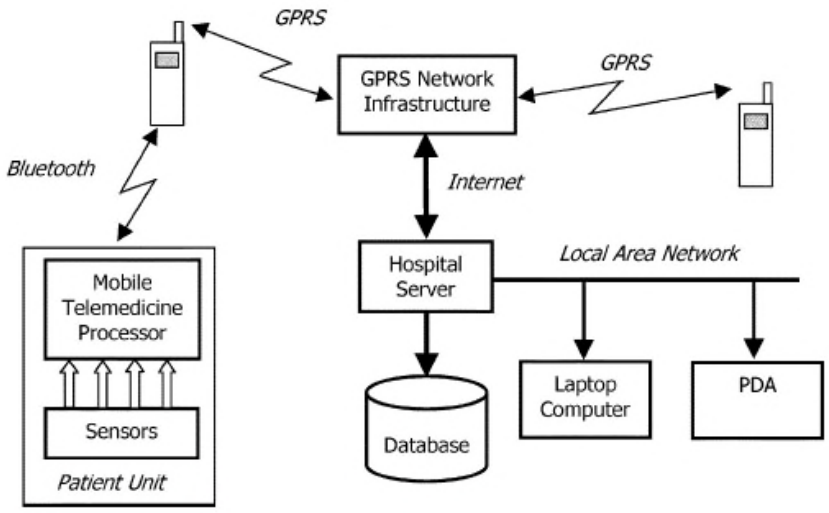
Claim Language [15.g]	ResMed Prior Art ("RPA")
	discussed above, that the laptop or PDA could retransmit reports or data displayed at the laptop and PDA to a remote location, such as back to the server for saving in the patient's medical record file, or to an insurance provider. **<u>CleveMed's New DOE Argument</u>** CleveMed's Final Contentions present a DOE argument for the first time for this claim: "To the extent that AirSense 10 is found to not meet this element literally, AirSense 10 also meets this element under the Doctrine of Equivalents because it performs substantially the same function, where AirSense 10 transmits the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms and AirView, as a base station, retransmits the symptom data of the severity of the subject's sleep disorder symptoms, in substantially the same way, where AirView intended to receive wireless the symptom data of the severity of the subject's sleep disorder symptoms from AirSense 10, to achieve substantially the same result of receiving the symptom data of the severity of the subject's sleep disorder symptoms and retransmitting the symptom data of the severity of the subject's sleep disorder symptoms to a remote internet site. Any difference between AirSense 10 in its transfer of data to the base station and the base station claim element (e.g. having a second wireless module transceiver) is insubstantial." Final Infr. Cont., Chart I, 117-118. To the extent this new argument can be understood, RPA Systems 1-2 render claim 15 obvious for at least the same reasons CleveMed alleges the accused products practice this limitation in an equivalent manner. For example, CleveMed's arguments that any differences between the accused products and the claim are insubstantial is an admission that the claim is obvious in view of at least RPA Systems 1 and/or 2. Furthermore, CleveMed is estopped from relying on the doctrine of equivalents for this claim limitation at least because it was expressly added during prosecution to overcome a rejection of the claim. *See, e.g.*, '269 patent FH, 3/27/2018 Amendment at 7.

Claim Language [16]	ResMed Prior Art ("RPA")
16. The system of claim 15, wherein the first radio frequency wireless module transceiver of the PAP device and the second radio frequency wireless module transceiver of the base station, cellular phone or PDA communicate using Bluetooth wireless protocol.	RPA discloses, or at least renders obvious, the system of claim 15, wherein the first radio frequency wireless module transceiver of the PAP device and the second radio frequency wireless module transceiver of the base station, cellular phone or PDA communicate using Bluetooth wireless protocol. *See, e.g.*, claim 15, also specifically limitations 15.d, 15.g. This claim is at least rendered obvious by modifying or combining RPA Systems 1-2 with the knowledge of a POSITA and Rasid. For example, telemedicine systems were well known in the art that used Bluetooth communication from a device such as the RPA PAP devices to a cellular/mobile phone. *See, e.g.*, Rasid, § II.A ("Bluetooth is a universal short-range low-power radio protocol operating in the unlicensed industrial, scientific, and medical frequency band.") In a further example, demonstrating the knowledge of a POSITA, Jasemian discloses a telemedicine "system based on the Bluetooth protocol … and the general packet radio service (GPRS) for GSM mobile phones. The patient unit contained a telemetry device (T3300, Danica Biomedical), a Bluetooth module (ROK 101 800, Ericsson) and a mobile phone (T610, Ericsson). The Bluetooth module is a short-range (10m) device that enables the telemetry unit to communicate with the mobile phone wirelessly. The mobile phone used the GSM/GPRS Network (Sonofon, Denmark) to communicate with a modem server and a central monitoring station." Jasemian, 256.

Claim Language [16]	ResMed Prior Art ("RPA")
	 **Figure 1** System architecture Jasemian, Figure 1. Woodward and Rasid discloses a similar telemedicine system:

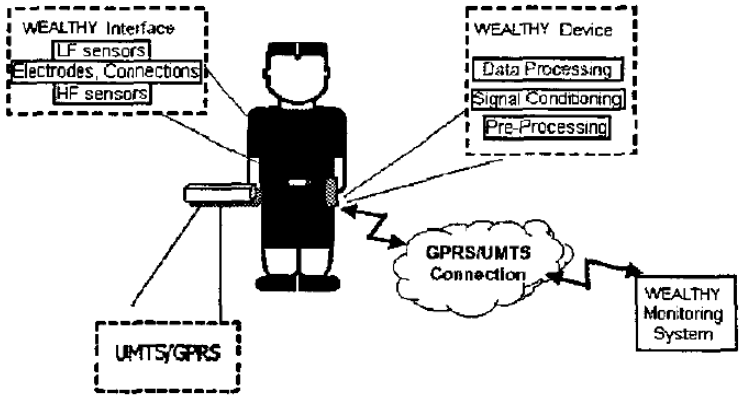
Claim Language [16]	ResMed Prior Art ("RPA")
	 Fig. 1 Telemedicine system with mobile telephone and PSTN communications links "While the transmission of biomedical data by satellite is demonstrably feasible for long-range wireless links, it is more likely that mobile telephones using cellular networks will be adopted for transmission over shorter ranges. Among the technical problems is the issue of how to link the data from the patient (via a mini-processor) to the phone. This may possibly be done by a direct connection, or by a wireless connection such as an acoustic, infra-red or Bluetooth radio link [l8]. It is only recently that the potential advantages of Bluetooth and other wireless technologies have been recognized, including the Wireless Application Protocol (WAP) for cell phones [19], and Personal Digital Assistants (PDA) [20,21]." Woodward, 44. "The main contribution of this paper has been to describe the present scope and future potential of mobile communications in telemedicine. A modular-structured system has been used to illustrate the concept. The mobile patient unit comprises a processing unit, which accepts signals from one or more sets of sensors, linked by a wireless channel to a mobile telephone. The prototype version is designed to transmit digitised electrocardiogram signals to a hospital via the GSM mobile telephone cellular network. New compression and signal processing algorithms, such as wavelet techniques, can be integrated to optimise the performance of the system under different mobile conditions. The modular design of the system should enable telemedicine providers to adapt to future technology advances." Woodward, 45; *see also* Rasid, Abstract ("a system to transmit a patient's biomedical

Claim Language [16]	ResMed Prior Art ("RPA")
	signals directly to a hospital for monitoring or diagnosis, using an unmodified mobile telephone"), §§ I.B, III.A, IV, Figs. 2, 4. "One of the emerging issues in m-Health is how best to exploit the mobile communications technologies that are now almost globally available. The challenge is to produce a system to transmit a patient's biomedical signals directly to a hospital for monitoring or diagnosis, using an unmodified mobile telephone. The paper focuses on the design of a processor, which samples signals from sensors on the patient. It then transmits digital data over a Bluetooth link to a mobile telephone that uses the General Packet Radio Service. The modular design adopted is intended to provide a "future-proofed" system, whose functionality may be upgraded by modifying the software." Rasid, Abstract. "The system presented here contains the following links, as shown in Fig. 2: 1) short-range Bluetooth link between patient and telephone; 2) GPRS to a base station and to other mobile telephones; 3) land lines (PSTN) and an Internet service provider (ISP) to a hospital server and database; 4) LAN to clinicians." Rasid, § I.C.

Claim Language [16]	ResMed Prior Art ("RPA")
	 Fig. 2. Mobile telemedicine system. Rasid, Fig. 2. "The complete system is shown in Fig. 2. Signal inputs from the patient are those normally used for monitoring purposes, such as the ECG (and heart rate), blood pressure, body temperature, and SpO . These signals are fed to the Bluetooth-enabled processor unit, where they are digitized and stored in memory. Next, the digitized data are transmitted to a Bluetooth mobile telephone and subsequently via the GPRS cellular network to a base station, then to a hospital via conventional PSTN lines or a cellular network. The data received at the hospital server are available to a clinician via the hospital's LAN, either through the personal computer (PC), laptop, or personal digital assistant (PDA). Alternatively, the clinician away from the vicinity of the hospital may receive a patient's data via a mobile telephone and a PDA." Rasid, § III.A. For the reasons discussed for limitations 15.e-15.g, it would have been obvious to implement the CPAP device's modem disclosed by RPA as a Bluetooth module, as known in the art and disclosed, for example, by Rasid.

Claim Language [16]	ResMed Prior Art ("RPA")
	'269 Patent Moreover, the '269 patent fails to identify any specific benefit or advancement by using the "Bluetooth wireless protocol," mentioning Bluetooth only once and only generally stating that "IR or Bluetooth wireless technology can be used for data transmission." '269 patent, 8:46-48. Thus, the '269 patent appears to rely on the knowledge of a POSITA to apply Bluetooth wireless technology generally to the disclosed system. A POSITA would have found it at least obvious to similarly use their knowledge of Bluetooth wireless technology in combination with RPA to arrive at the claimed system.

Claim Language [20]	ResMed Prior Art ("RPA")
20. The system of claim 15, wherein the airflow sensor data is processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis.	RPA Systems 1-2 disclose, or at least renders obvious, the system of claim 15, wherein the airflow sensor data is processed using one or more of the signal processing techniques from the group consisting of a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis. *See* claim 15. For example, the AutoSet Spirit uses a standard deviation technique to analyze flow sensor data. *See, e.g.*, [redacted] AutoSet Spirit Clinician's Manual at 7-9; [redacted] AutoScan 5.4 Clinician's Manual (RMD-311263) at 57-58. Alternatively, for at least the same reasons CleveMed alleges the accused products practice this limitation, RPA Systems 1 and 2 perform the same or similar "waveform" analysis. *See, e.g., id.* If the Judge or Jury finds that RPA does not disclose this claim limitation, this claim is still rendered obvious by modifying or combining RPA with the knowledge of a POSITA. For example, it would have been obvious to a POSITA to incorporate one or more of the claimed signal processing techniques, all of which were well-known to a POSITA for use in processing physiological sensor signals in the medical environment by the time of the application for the '269 patent, into RPA's CPAP system.

Claim Language [20]	ResMed Prior Art ("RPA")
	As one example, Woodward/Rasid disclosed in 2003 for the telemedicine system that "compression and signal processing algorithms, such as ***wavelet techniques***, can be integrated to optimise the performance of the system under different mobile conditions." Woodward, 45 (emphasis added); *see also* Rasid, § V. As another example from the prior art, Paradiso discloses a biomedical monitoring and communication system, and teaches, consistent with the knowledge of a POSITA: "One of the main goals of the digital processing stage is to compress or even directly extract the most appropriate features to reduce communication data rates and expenses for the selected physiological parameters. This processing may typically make use of neuro-fuzzy or other advanced processing techniques like wavelet processing, particularly suited to extract weak biomedical signals from a noisy environment (due to the user movements and activities) and to dramatically reduce the data volume." Paradiso, 283. An overview of the technology in WEALTHY is shown below in Fig. 1, where the main phases of the process are shown, namely: sensing, pre-processing, transmission, processing and data management.  Fig. 1: The processing and communication mechanism Paradiso, 283.

Claim Language [20]	ResMed Prior Art ("RPA")
	For at least the reasons expressed by Paradiso, which were known to a POSITA, it would have been obvious to use signal processing techniques for the sensor signals at the CPAP device, including the air flow sensor signal. **'269 Patent** In addition, the '269 patent appears to rely generally on the knowledge of a POSITA to implement this well-known feature. For example, the '269 patent states: "Various sleeping disorders have symptoms that can be predicted based on various combinations of physiological signals or data. Various embodiments of the present invention include the approach to identifying these symptoms prior to onset by identifying various characteristic shifts in the power spectrum of the sensors being used to monitor these physiological conditions. This characteristic shift in these signals or data can be identified and used to trigger an actuator on the physical or chemical treatment device(s) to provide for delivery of a certain level of treatment. The various embodiments of the present invention include but are not limited to the following signal-processing techniques that are utilized to predict the onset of these symptoms. These are: (i) the standard deviation technique, (ii) a recursively fit ARMAX system identification model, (iii) the Short-Time Fourier Transform (SFFT) technique, and (iv) time-frequency signal analysis with a variety of different kernels. The present invention would also include other on-line signal processing algorithms known to those skilled in the art, such as wavelet analysis, which is similar to time-frequency analysis with a particular kernel function, to identify the shift in power spectrum associated with imminent flow separation that is discussed herein." '269 patent, 20:9-31. For at least the same reasons a POSITA would have known how to implement one or more of these techniques, it would have been obvious to use them in RPA's CPAP system to arrive at the claimed system.

[redacted]

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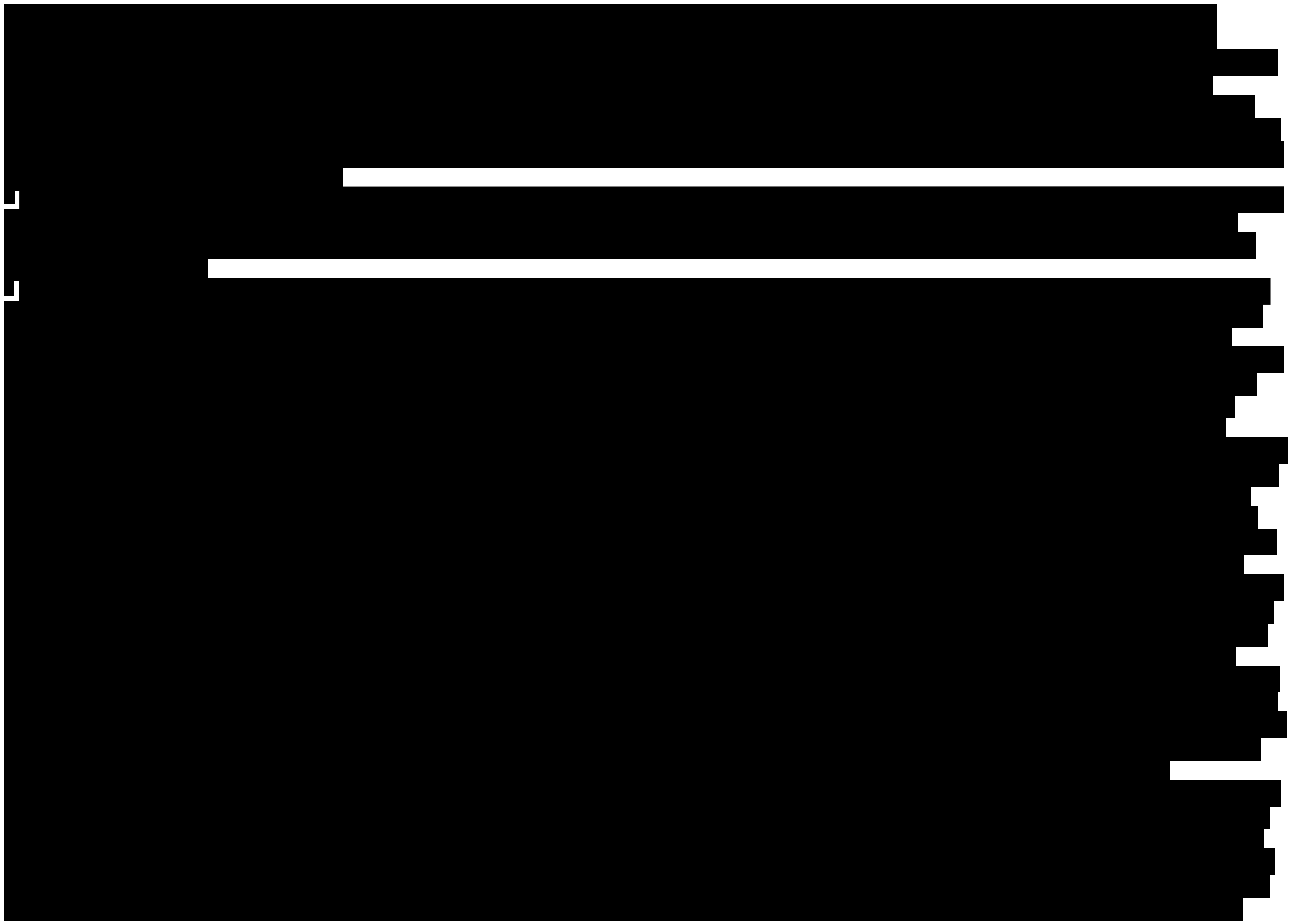
FINAL Exhibit G05
ResMed Prior Art ("RPA") v. '269 Patent



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[redacted]

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