

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CLEVELAND MEDICAL DEVICES INC., an
Ohio Corporation,

Plaintiff,

v.

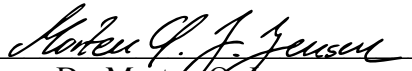
RESMED INC., a Delaware Corporation,

Defendant.

C.A. No. 22-794 – GBW

**EXPERT REPORT OF DR. MORTEN O. JENSEN
REGARDING INVALIDITY ISSUES**

Submitted: December 4, 2023


Dr. Morten O. Jensen



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3. “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), “the PAP device ... further comprising: ... a second input adapted for receiving the pulse oximetry sensor data from the output of the signal processing module” (claim 1), “the PAP device comprising ... a second input adapted for receiving the pulse oximetry sensor data from the output of the data acquisition device” (claim 5);..... 226
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5. “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;” “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” (claim 15)..... 228
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8.	“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).....	230
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I. INTRODUCTION

1. I submit this report on behalf of ResMed, Inc. (“ResMed”).

2. I have been asked by counsel for ResMed to analyze U.S. Patent No. 10,076,269 (the “’269 patent” or the “’269 Asserted Patent”). I was asked to form and express opinions on the validity of each asserted claim of the ’269 Patent, noninfringing alternatives to the accused products and systems, and materiality of certain prior art to the validity of the Asserted Patents. My opinions and related analysis are contained in this report.

3. I am being compensated at my customary hourly rate of \$500 per hour for consulting time and \$550 per hour for deposition and trial time, plus reasonable expenses. My compensation is not dependent upon the opinions I render or the outcome of this investigation. I am working as a private consultant on this matter and the opinions presented here are my own.

4. In forming my opinions, I have relied on my knowledge and experience in biomedical engineering and medicine, which I have summarized below, and on the documents and information described below. I may also review other materials throughout this investigation, including any other documents or testimony that may emerge in this investigation at a future date. Those materials may affect my opinions in this matter.

5. I reserve the right to modify and supplement my analysis and conclusions set forth in this report based upon any additional fact discovery performed by the parties or in response to any reports by experts for Cleveland Medical (“CleveMed”). I also reserve the right to modify and supplement my analysis and conclusions set forth in this report based upon any change to any of the applicable legal standards explained to me by ResMed’s counsel.

6. At trial, I may rely on visual aids and/or analogies concerning elements of the asserted patents, the accused products, or other aspects of my opinions or the material in this report. In connection with my anticipated testimony in this investigation, I may use as exhibits various documents produced in this investigation that refer or relate to the matters discussed in this report. I have not yet selected the particular exhibits that might be used. In addition, I may

[REDACTED]

create or assist in the creation of certain demonstrative evidence to assist me in testifying.

7. As part of my analysis, I have considered the ResMed products that I understand CleveMed has accused of infringing the asserted claims of the '269 patent. I understand CleveMed has accused of infringement the following flow generator devices:¹

- Astral and Stellar ventilators (Chart A);
- AirSense 11 (Chart H);
- AirSense 10 (Chart I);
- AirCurve 10 (Chart J);
- AirMini (Chart K).

8. I understand that certain models of these devices are positive airway pressure devices intended to treat sleeping disorders. I further understand that the above-identified devices are accused of infringing the '269 Patent in combination with (1) ResMed's AirView cloud-based system, (2) mobile device apps, including the AirMini app and the myAir app, and (3) particular accessories, such as the Air 10 Oximeter Adapter for connecting a NONIN Xpod oximeter to an AirSense 10 or AirCurve 10 device (identified, e.g., in CleveMed's Final Infringement Contentions, Chart I at 9-10), and the ResMed Connectivity Module that provides cellular connection between the Astral/Stellar ventilators and the AirView platform. *See, e.g.,* § IX, *infra*.

9. I have also considered as part of my analysis ResMed products that were known and used in the United States before the '269 patent, which I generally refer to herein as "ResMed Prior Art". These include the following components:

- AutoSet Spirit, which is a positive airway pressure device (also referred to as a "flow generator");
- ResLink, which is a module that mounts to the back of the AutoSet Spirit;
- AutoScan software, which is used by a clinician to download and view data collected by the AutoSet Spirit;
- ResTraxx System, which comprises:

¹ CleveMed's Final Infringement Contentions, including Charts A, H-K.

- [REDACTED]
- o ResTraxx module (also called the “[REDACTED]” which is a communication module that mounts to the back of the AutoSet Spirit and communicates wirelessly via a pager network to backend components of the ResTraxx Data Center;
 - o ResTraxx Data Center, which provides a web-based application to view data collected by the AutoSet Spirit and transmitted by the ResTraxx module.

See, e.g., Section X.A, *infra*.

II. QUALIFICATIONS

10. A copy of my curriculum vitae including a list of my publications is attached hereto as **Exhibit 1**.

11. I graduated with honors from The Engineering College of Aarhus in Denmark in July 1997 with a B.Sc. (bachelor’s) degree in electrical and computer engineering with a focus in biomedical engineering. The focus of my early education was system automation, sensor measurements, control, data management, data transfer, biophysics. I graduated from the Georgia Institute of Technology and Emory University School of Medicine (joint program) in May 2000 with a M.Sc. (master’s) degree in biomedical engineering. My research project focused on fluid control, instrumentation, and system design with *in vitro* measurements and models. I graduated from the University of Aarhus School of Medicine in Denmark in November 2008 with a Ph.D (doctorate) in medicine. In March 2015, I was granted a Dr.Med (or *dr.med.*) in medical science from the University of Aarhus School of Medicine in Denmark. The focus of my Ph.D. and Dr.Med degrees continued from my M.Sc. degree to be fluid control, instrumentation, and system design, but now with *in vivo* measurements and models. The Dr.Med degree is a higher-level doctorate degree that is awarded at certain universities in Northern Europe in the field of medicine. Dr.Med. is by law a higher degree than the Ph.D. The Dr.Med degree is awarded after a candidate’s research and publications have proven to make a significant difference in the advancement of science. Historically, the Dr.Med degree has been given only to medical doctors, with rare exceptions. I was the third engineer in Denmark since 1479 to receive this degree.

[REDACTED]

12. From 2000 to 2005 I worked in industry with a company based in Austin, Texas called National Instruments. Most of my activities with the company were with the consulting services department. The company makes sophisticated engineering tools for automation and controls systems to a large variety of industries. These systems are typically electrically controlled by software, embedded into a microcontroller or based on a computer. The systems often control mechanical systems and actuators.

13. I am currently employed as Associate Professor of Biomedical Engineering at the University of Arkansas in Fayetteville, Arkansas. I have held this position since August 2015. I am also a Scholar of the Arkansas Research Alliance, a public-private partnership dedicated to elevating a fundamental belief that “research matters.” This Alliance provides financial support for my research at the university in the field of increasing the understanding of the tissue and fluid mechanics of disease and intervention while creating solutions and dedicated devices.

14. My opinions in this declaration are mine as an individual and an independent expert and not those of the University of Arkansas.

15. I also hold an Adjunct Associate Professorship in the Department of Cardiothoracic Surgery at the University Hospital of Aarhus in Denmark where I teach biomedical engineering to MD/PhD students and advise on cardiovascular projects. I have held that position since July 2009. In 2013-2014, I was an Honorary Clinical Fellow and Senior Lecturer at University College in London, England.

16. In 2021 I became a fellow of the American Heart Association, which is a high honor for a non-clinician. It has been widely recognized that sleep medicine and cardiovascular health are very tightly connected.

17. Over the past two decades, I have developed and taught numerous courses at both the undergraduate and graduate level, as well as in medical schools, in the field of biomedical engineering, including biomechanics, biofluids, pressure and flow measurements, hemodynamics and biomechanical modeling, and bioinstrumentation. As set forth on my CV (Exhibit 1 attached hereto), I have published numerous articles relating to aspects of electronical fluid control device

[REDACTED]

interactions with the soft tissues of the human body, including device design, performance and specific features that allow them to function optimally. I have also received numerous awards for my research work.

18. Observation and participation during clinical procedures and treatment is part of my biomedical research work directed to medical device design and development.

Understanding the biomechanical and device related activities surrounding these procedures and treatments has given me a first-hand experience that would only be relevant after obtaining a deep knowledge of the involved physics and physiologies interacting during the procedures. I consider these experiences highly relevant, and hence, while my focus has always been on medical devices, I have extensive knowledge of the human anatomy, and how soft tissues, nerves, and blood flow and pressure interact with devices and fluids, both implanted and externally operated devices.

19. I have worked with communication systems during my entire career. While I was with National Instruments, some of the consulting services jobs that I worked on was with anesthesiology equipment manufacturers, including ventilation systems. These would measure pressure, flow and volume, and I would be part of both analyzing and displaying the data, as well as transmitting it.

20. My teaching career has spanned over several decades, both in university teaching at undergraduate and graduate levels, medical school, and at the Scandinavian School for Extracorporeal Technology (perfusionist Master's Program). I teach biomechanics, which includes pulmonary mechanics. I also teach bioinstrumentation, and have taught numerous customer education classes while in industry, that includes wireless transmission of physiological signals. I was part of a development team that added features to a software package called "BioBench", which collects, analyzes, stores, and transmits physiological data.

21. All of my PhD and MS students have been working with projects and tasks that are relevant to this case. They work with biomechanics, instrumentation, signal analysis, signal storage, signal transmission. These projects typically have a clinical goal, but with extensive use

[REDACTED]

of a technical toolbox

22. I have also served on various committees and boards and am still serving on many of them. This includes review panels such as the National Institutes of Health (NIH) RO1 Bioengineering, Technology and Surgical Sciences Study Section panel, Center for Scientific Review (CSR). I am also a standing (non-ad hoc) review panel member with the National Science Foundation (NSF) Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Medical Devices programs in the “Implantables & General Medical Devices” section, panel subsections including Implantables and Procedures, General Devices, Rehabilitation, Diagnostics, Instrumentation, Externals, Wearables, Sensors, Medical Technology (materials, manufacturing)

23. Thus far I have published 98 peer reviewed publications (hereof 73 journal papers and 25 refereed conference proceedings), 20 magazine articles, 11 books / book chapters, 164 conference presentations and keynote addresses. I have been invited as a guest speaker to 32 seminars and have 9 publications of Intellectual Property / Patent Applications. Since public knowledge of academic work is important for universities and funding sources, I have also been part of more than 100 public media appearances.

24. All of my publications are in a field that is relevant to this case. I have used signal acquisition from analog sensors, noise filtration, analog to digital conversion, signal transformation, frequency and signal type and character analysis, wireless transmission of physiological signals.

25. All of my paper research publications have been accompanied by conference presentations, both oral and poster formats. The publications listed that are relevant for this work will be equally listed here as well.

26. My publications of and applications for protecting intellectual property are all in relevant fields to this case, such as using alternative methods for more efficient signal analysis, optimizing fluid flow with alternative shapes of conduits, analysis of physiological signals using alternative methods such as deep machine learning.

[REDACTED]

27. As a result of my background, education and experience, I believe that I am qualified to provide opinions from the standpoint of the person of skill in the prior art relating to the technology described in the '269 patent that I discuss in this Declaration.

28. I also have an understanding of what a person of ordinary skill in the art in 2004-2007 was and how that person would understand the terminology used in the Asserted Patents.

III. INFORMATION CONSIDERED IN FORMING OPINION

29. In forming my opinions, I have considered, in addition to my knowledge and experience noted above, the documents and materials identified in this report and listed in **Exhibit 2** to this report. I inspected specimens of the ResMed Prior Art addressed herein, including the AutoSet Spirit flow generator, ResLink (a module that mounts to the back of the flow generator), ResTraxx module (another module that mounts to the back of the flow generator), ResMed masks and tubing, supplemental oxygen adapter, NONIN pulse oximeter and Xpod (a module that performs processing of signals from the pulse oximeter sensor), and modem.² I also inspected the ResMed products CleveMed has accused of infringing the '269 patent, including the following flow generators: AirSense 10, AirSense Curve, AirSense 11, AirMini, Astral. I also inspected the ResMed Connectivity Module that provides cellular communication capability for the Astral flow generator, and a supplemental oxygen adapter. I also inspected the virtual machine running the AutoScan 5.4 software, and the source code for the AutoSet Spirit ([REDACTED]), ResLink, and ResTraxx module. Although I have attempted to make the list of materials in Exhibit 2 as complete as possible, it may not be a completely exhaustive list of materials I have considered during the course of this litigation.

30. In addition to the materials identified in Exhibit 2 and herein, I have considered the expert report and analysis of Dr. Jing Hu on invalidity issues. I also discussed Dr. Hu's analysis with her on November 30, 2023, and confirmed my understanding of her analysis and

² I understand that the physical specimens of the ResMed Prior Art flow generator, modules, and accessories (except the modem) were provided from ResMed's own product library.

[REDACTED]

the support therefore. I have further considered the expert report and analysis of Dr. Alan Schwartz on invalidity issues. I also discussed Dr. Schwartz's analysis with him on November 30, 2023 and confirmed my understanding of his analysis and the support therefore. To the extent I relied on the opinions of Dr. Hu or Dr. Schwartz, I have identified that in the relevant section of my report. I also reserve the right to rely on their reports or opinions not expressly identified herein, for example, as identified in rebuttal and reply reports and at deposition.

IV. LEGAL STANDARDS

31. ResMed counsel has informed me of the legal standards that apply to patent validity and invalidity, identified below, which I have applied in arriving at my conclusions.

A. Claim Construction

32. I understand that a patent validity analysis involves two steps: (1) properly construing the patent claims to ascertain their scope and meaning; and (2) comparing the properly construed claims with the prior art. I understand that terms in patent claims must be construed as a first step in analyzing whether a claim is infringed and/or whether the claim is invalid. I also understand that patent claims must be construed the same way for infringement and invalidity analyses. I understand that claim construction is a legal matter to be decided by the Court.

33. I understand that claims are construed based on the claim language, the specification, and the file history. I understand that "extrinsic evidence" such as dictionaries, general knowledge of one of ordinary skill in the art, prior art patents or publications, etc., is used to help decipher the meaning and construction of the claim terms—as long as the extrinsic evidence does not contradict the claims, specification, or file history.

34. I understand that the Court issued a claim construction Order and Memorandum Opinion on October 30, 2023, henceforth referred to as the "Court's Claim Construction" or the "Claim Construction Order."

[REDACTED]

B. Legal Standards for Prior Art

35. I understand that a patent or other publication must first qualify as prior art before it can be used to invalidate a patent claim. I understand that products and systems, including software, and non-patent printed publications, such as books, may qualify as prior art. I understand that a printed publication, such as a book, qualifies as prior art at least if its publication pre-dates the invention of the asserted patent or if its publication pre-dates the application date of the asserted patent by more than one year. I understand that a product or system, such as software, qualifies as prior art (1) if it was known or used by others in this country (the United States) before the invention of the asserted patent or (2) if it was in public use or on sale in this country more than one year before the application date of the asserted patent. I understand that CleveMed has alleged the “priority date” for the ’269 patent is the November 4, 2005 filing date of patent application no. 11/266,899, which the ’269 patent claims priority to. I also understand that CleveMed has alleged that the claimed “inventions” of the ’269 Patent Asserted Claims were “conceived at least by March 18, 2005” CleveMed Response to ResMed Interrogatory No. 2 (at Third Response).

C. Legal Standards for Priority Date and “Invention” Date

36. I understand that the “priority date” of a patent is the date on which it is filed or the date on which an application to which the issued patent claims priority is filed. I understand that an applicant for a patent may file a continuation, divisional, or continuation-in-part (CIP) application of a prior application, all of which are characterized as “continuing” applications. I also understand that a continuing application is one filed during the pendency of another application which contains at least part of the disclosure of the other application. I further understand that the original application in a sequence of applications is sometimes called the “parent,” and, in the case of a sequence of three applications, the original may be called the “grandparent,” and the subsequent applications may, then, be called a “child” or “grandchild.”

37. I understand that, for certain prior art references, a patentee may attempt to show that the claimed invention was conceived prior to the publication date of the prior art reference in

[REDACTED]

an effort to overcome the prior art reference. I understand that the first person to conceive the subject matter is the first inventor provided he exercises reasonable diligence in reducing to practice from a time just prior to when the first person to reduce to practice enters the field.

38. I have been informed by ResMed counsel that conception is the mental formulation and disclosure by the inventor of a complete idea for a product or process. I understand that the idea must be of specific means, not just a desirable end or result and it must be sufficiently complete so as to enable anyone of ordinary skill in the art to reduce the concept to practice. I understand that a conception must include all the limitations or elements of a patent claim. I also understand that conception of a genus or broad class is not conception of species in the genus or class. I further understand that an inventor is entitled to priority based on conception only as of a date when the complete conception has been manifested or disclosed in some fashion. I also understand that manifestation of a complete conception can be in the form of written descriptions, drawings, or a model.

D. Legal Standards for Anticipation

39. I understand that documents and materials that qualify as prior art can be used to invalidate a patent claim as anticipated or obvious.

40. I understand that, once the claims of a patent have been properly construed, determining anticipation of a patent claim requires a comparison of the properly construed claim language to the prior art on a limitation-by-limitation basis. I understand that a prior art reference “anticipates” a claim, and thus renders the claim invalid, if all elements of the claim are disclosed in that prior art reference, either expressly or inherently (i.e., is necessarily present).

41. I understand that anticipation must be shown by clear and convincing evidence.

E. Legal Standards for Obviousness

42. I understand that even if a patent is not anticipated, it is still invalid if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the invention.

[REDACTED]

43. I understand that a person of ordinary skill in the art (“POSITA”) is a reference point from which the prior art and claimed invention are viewed.

44. I understand that an obviousness determination includes the consideration of factors such as (1) the scope and content of the prior art, (2) the differences between the prior art and the asserted claims, (3) the level of ordinary skill in the pertinent art, and (4) the existence of secondary considerations such as commercial success, long-felt but unresolved needs, failure of others, etc.

45. I understand that an obviousness evaluation can be based on a combination of multiple prior art references. I understand that the prior art references themselves may provide a suggestion, motivation, or reason to combine or modify the base prior art references, but other times the nexus linking two or more prior art references may be simple common sense. I further understand that an obviousness analysis recognizes that market demand, rather than scientific literature, often drives innovation, and that a motivation to combine references may be supplied by the direction of the marketplace.

46. I understand that if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

47. I also understand that practical and common sense considerations should guide a proper obviousness analysis, because familiar items may have obvious uses beyond their primary purposes. I further understand that a person of ordinary skill in the art looking to overcome a problem will often be able to fit together the teachings of multiple publications. I understand that obviousness analysis therefore takes into account the inferences and creative steps that a person of ordinary skill in the art would employ under the circumstances.

48. I understand that a particular combination may be shown to be obvious merely by showing that it was obvious to try the combination. I understand that one example is that, when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known

[REDACTED]

options within his or her technical grasp because the result is likely the product not of innovation but of ordinary skill and common sense.

49. I understand that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, the patent claim is likely obvious.

50. It is further my understanding that a proper obviousness analysis focuses on what was known or obvious to a person of ordinary skill in the art, not just the patentee. Accordingly, I understand that any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

51. I understand that a claim can be obvious in light of a single reference, without the need to combine references, if the elements of the claim that are not found explicitly or inherently in the reference can be supplied by the common sense of one of skill in the art.

52. I understand that secondary indicia of non-obviousness may include (1) a long felt but unmet need in the prior art that was satisfied by the invention of the patent; (2) commercial success of processes covered by the patent; (3) unexpected results achieved by the invention; (4) praise of the invention by others skilled in the art; (5) taking of licenses under the patent by others; (6) deliberate copying of the invention; (7) failure of others to find a solution to the long felt need; and (8) skepticism by experts.

53. I also understand that there must be a relationship between any such secondary considerations and the invention as a whole. I further understand that contemporaneous and independent invention by others is a secondary consideration supporting an obviousness determination.

54. Overall, my understanding is that the teachings of the prior art are properly combined where a person of ordinary skill in the art, having the understanding and knowledge

[REDACTED]

reflected in the prior art and motivated by the general problem facing the inventor, would have been led to make the combination of elements recited in the claims. Under this analysis, the prior art references themselves, or any need or problem known in the field of endeavor at the time of the invention, can provide a reason for combining the elements of multiple prior art references in the claimed manner.

55. I understand that obviousness must be shown by clear and convincing evidence.

F. Adequacy of Disclosure

56. I have been informed by ResMed's counsel that, under the Patent Statute, the named inventor(s) must adequately set forth and describe in their application for patent (1) the claimed invention (the description requirement), and (2) the manner and process of making and using the claimed invention (the enablement requirement).

1. Written Description Requirement

57. I understand that a patent application must describe the claimed invention sufficiently to convey with reasonable clarity to those skilled in the art that the patentee was in possession of the claimed invention at the time of the application for patent. I also understand that the written description requirement is not satisfied if the subject matter actually described in the specification would only render the claimed subject matter obvious, but rather the specification must actually disclose it. I understand that the purpose of the requirement is to ensure that the scope of the right to exclude does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.

2. Enablement Requirement

58. I understand that a patent's specification must adequately disclose to a person skilled in the relevant art how to make and use the claimed invention without undue experimentation. I understand that a patent specification complies with this "enablement" requirement even if a reasonable amount of experimentation is required, but that such experimentation must not be "undue." I also understand that, in determining whether a

[REDACTED]

disclosure would require undue experimentation, the following factors may be considered: (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.

G. Legal Standard for Materiality

59. I have been informed by ResMed’s counsel that an applicant for a patent is under a duty of candor in dealing with the Patent and Trademark Office, and that a breach of that duty constitutes “inequitable conduct” or, in severe form, “fraud.” I have been informed by ResMed’s counsel that a breach may occur by misrepresentation or omission of “material” information.

60. I understand that, as a general matter, the materiality required to establish inequitable conduct is but-for materiality. I understand that when an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. Thus, the relevant materiality question is whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. I also understand that, in making this determination, courts apply the preponderance of the evidence standard and give claims their broadest reasonable construction. I understand that one relevant inquiry is whether the teachings of the reference would have rendered the claimed invention invalid. I understand this would include, as discussed above in the legal standards sections for anticipation and obviousness, whether the teachings of the reference, in combination with other relevant prior art, would have rendered the claimed invention obvious

61. I have been informed by ResMed’s counsel that an exception exists in cases of affirmative egregious misconduct, such as the filing of a false affidavit. In such cases, the misconduct itself is material. I have further been informed that this exception to the general rule requiring but-for proof incorporates elements of early cases dealing with deliberately planned and carefully executed schemes to defraud the PTO and the courts.

62. I also understand that an item of prior art is not material if it is cumulative to other

[REDACTED]

items of prior art that the examiner considered. I further understand that an item is not cumulative if it discloses a feature that is not disclosed in the items considered by the examiner, or suggests a combination of features that is not disclosed in the items considered by the examiner.

H. Patentable Subject Matter

63. I have been informed by counsel that a patent may be invalid under 35 U.S.C. § 101 for lacking eligible subject matter. I understand that anyone who invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof may obtain a patent. I further understand that this patent protection does not extend to claims directed to laws of nature, natural phenomena, and abstract ideas, and that such claims are not patent-eligible. I understand that these exclusions are intended to guard against, among other things, undue preemption of innovation using these basic tools of scientific and technological work.

64. I have been informed by counsel that there is a two-step framework for analyzing whether claims are directed to patent eligible subject matter. In step one, it is determined whether the claims are directed to a patent-ineligible concept such as a natural law or abstract idea. I understand that this determination is based on examining the character of the claims as a whole, which can also be understood as the focus, basic thrust, or fundamental concept of the claims. In making this assessment, one must look at the claimed advance over the prior art to determine if the claim's character as a whole is directed to excluded subject matter.

65. I have been informed by ResMed's counsel that step one of the analysis is a legal determination that will be made by the Court. If it would be helpful to the court, I am able and willing to provide testimony regarding any factual issues related to the step one analysis.

66. I understand that if the first step of the analysis shows that the character of the claims as a whole is directed to patent-ineligible subject matter, the analysis moves to step. I understand that the second step of the analysis involves a search for an inventive concept that transforms the nature of the claim into a patent-eligible application. I understand that this inquiry

[REDACTED]

requires consideration of the elements of each claim both individually and as an ordered combination. I understand that the inventive concept must be an element or combination of elements that is sufficient to ensure that the patent in practice amounts to something significantly more than the abstract idea itself, such that these additional elements or combination of elements transform the nature of the claim to be patent eligible. I understand that an ordered combination of conventional and well-known elements may create an inventive concept only if it claims a specific, unconventional technological solution to a technological problem. I understand that the mere recitation of concrete, tangible components is insufficient; they must involve more than performance of conventional, well-understood, and routine activities. I understand that limiting the application of an abstract idea to a particular field of use or technological environment, or adding token post-solution components, does not render an abstract idea patentable.

67. I have been informed by ResMed's counsel that the Court will rely on the parties' fact and expert discovery to inform its step two analysis relating to inventiveness. I intend my report to provide an overview of the relevant background technology as of CleveMed's alleged priority date to assist with inventiveness determinations.

V. SUMMARY OF OPINIONS

68. It is my opinion that the Asserted Claims (1, 5, 8, 15, 16, 20) of the '269 patent are anticipated or at least rendered obvious by at least the prior art discussed below. *See* § X.C.

69. For at least these reasons, the Asserted Claims of the '269 patent are invalid.

70. It also is my opinion that the '269 patent specification fails to comply with the written description requirement, which I am informed comes from 35 U.S.C. § 112, for those claims. *See* § XIII.

71. For at least these reasons, the Asserted Claims of the '269 patent are invalid.

72. It is also my opinion that certain prior art that was not disclosed to the examiner of the '269 patent would have rendered at least one claim of the '269 patent obvious and therefore invalid. It is my opinion that the prior art not disclosed to the examiner would have therefore been material to the '269 patent claims. *See* § XII.

[REDACTED]

73. It is my opinion that the claims of the '269 patent do not claim any inventive concept that would transform an abstract idea into patent-eligible subject matter. *See* § XV.

VI. OVERVIEW OF THE '269 PATENT

74. I understand that the '269 patent issued from patent application serial number 13/440,116 (the "'116 application"), which was filed April 5, 2012. *See, e.g.,* '269 patent cover sheet. I also understand that the '116 application claimed priority as a continuation application to application serial number 11/266,899 (the "'899 application"), filed November 4, 2005, and that the '899 application issued as U.S. Patent No. 8,172,766 (the "'766 patent") on May 8, 2012. I further understand that additional applications for patent were filed after the '116 application also claiming priority to the '899 and '116 application and relying on the same specification as the '269 patent.

A. The '269 Patent Specification and the Admitted and Copied Prior Art

75. The '269 patent purports to disclose systems and methods, and particularly an "integrated" system, for sleep disorder treatment and diagnosis. *See, e.g.,* '269 Patent, Abstract, 2:55-4:45. However, I note that none of the asserted claims of the '269 patent reference diagnosis. Overall, the majority of the '269 patent's specification, including the figures, have been copied from other prior art references. *See, e.g.,* Exhibit 10 (showing highlighted portions of the '269 patent that were copied from prior art references). I reviewed the '269 patent specification (the figures and written text) with the asserted claims in mind to understand the scope and meaning of the claims. However, the specification does not use many of the terms in the claims and fails to describe many aspects of the claims.

76. Most of the "Technical Background" section of the '269 patent (e.g., 1:27-2:10) was copied from U.S. Patent No. 6,993,380 ("Modarres") at 1:21-2:27. *See, e.g.,* Exhibit 3 at Comparison 1; Exhibit 7. Modarres was filed June 4, 2003, which is before the November 4, 2005 priority date of the '269 patent. Modarres is prior art to the '269 patent, and Mohammad Modarres is also listed as an inventor on the '269 patent. The '269 patent, in the "Technical Background" section, recognized that diagnosis of sleep disorders typically includes "subjective

[REDACTED]

methods such as the Epworth and Stanford Sleepiness Scale, which generally involves questionnaires where the patients answer a series of qualitative questions regarding their sleepiness during the day.” ’269 Patent, 1:40-45. I note that Modarres used the term “symptom,” e.g., in disclosing that “[e]xcessive daytime sleepiness (EDS) is a symptom describing an increased propensity to fall asleep” (Modarres, 1:35-37), but the ’269 patent does not use the term “symptom” in this context. This is notable because the ’269 patent asserted claims use the term “symptom” but not in any clear manner.

77. Polysymnography was Known. The ’269 patent background section admits, which also is copied from Modarres, that the second method for diagnosis “is via physiological based evaluations such as all night polysomnography to evaluate the patients sleep architecture (e.g., obtaining respiratory disturbance index to diagnose sleep apnea) followed by an all day test such as the Multiple Sleep Latency Test (MSLT) or its modified version, Maintenance of Wakefulness Test (MWT).” ’269 Patent, 1:51-56; Exhibit 3 at Comparison 1. This is consistent with many disclosures in the literature that polysymnography was well-known as the “gold standard” for diagnosing sleep disorders, including the monitoring of multiple physiologic signals using a plurality of sensors.

78. CPAP Treatment was Known. The ’269 patent admits that “the most common method of treating the sleeping disorder of sleep apnea is by apply [sic] a continuous positive gas pressure to the patient’s airway, which has the effect of forcing the patient to breath [sic] through application of the pressure.” ’269 Patent, 2:17-21. The ’269 patent admits that CPAP was the “most common method of treating the sleeping disorder of sleep apnea.” The ’269 patent also states “[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. Thus, PAP devices that auto adjust (sometimes called auto-titrating) were well-known in the art, where such devices adjust the supplied pressure using feedback from sensors that “measure gas flow through the device,” such as blower flow. However, the ’269 misrepresents that “[t]hese basic adjustable

[REDACTED]

devices have been found to be expensive and largely ineffective.” ’269 Patent, 2:25-26. Auto-titrating or auto-adjusting PAP devices were common in the market. ResMed’s AutoSet T, for example, was a widely known auto-titrating PAP device. *See, e.g.*, D. Alan Lankford, *Wireless CPAP Patient Monitoring: Accuracy Study*, Telemedicine Journal and e-Health, Vol. 10, No. 2, 2004, 162-169, at 164; *see also*, from the ’269 Patent File History: US 2002/0185130 (“Wright”) at ¶¶ 7, 31; US 5,704,345 (“Berthon-Jones”), referenced in Wright; US 7,878,198 (“Farrell-198”) at 1:34-67.

79. Physiological Signals. The ’269 patent suggests 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,” or “to adjust a treatment device based on the subject’s physiological signals.” ’269 Patent, 2:27-37. The ’269 patent appears to use “physiological signals” to refer to simply sensor signals (or parameters) monitored for polysymnography (“physiological based evaluations”), or a “subject’s physiological signals, e.g., EEG, EKG, EMG, etc.,” or a “subject’s electro-physiological signals.” In other words, the ’269 patent does not describe what the inventors contemplated are the physiological sensor signals or data that the devices on the market allegedly failed to consider to adjust a treatment device. I note that the ’269 Patent Asserted Claims do not recite *adjusting* a patient’s treatment device based on any kind of feedback through the system from sensors, measurements, or algorithms. Claim 18 recites adjustment of the PAP device from a remote location, but CleveMed’s infringement contentions for this limitation rely on input from a medical professional, suggesting that the claim can be practiced by, at least in part, a human.

80. The ’269 Patent Uses Known Sensors. The ’269 Patent admits that “[s]ensors which can be used are known to those skilled in the art.” ’269 Patent, 6:10-11. These include sensors described at 6:16-59. (copied from Modarres at 6:40-7:14). The disclosed sensors include sensors that “can be used to measure various parameters of a subject’s respirations.” ’269 Patent, 7:27-30. According to the ’269 Patent, a “nasal cannula or facemask can be used to *measure the subject’s respiratory airflow*,” e.g., “quantitatively and directly with a

[REDACTED]

pneumotachograph consisting of a standard oxygen nasal cannula or facemask respectively connected to a pressure transducer and placed in the nares or over the subject's mouth and nose respectively." '269 Patent, 7:63-8:2 (emphasis added). I note that the '269 Patent Asserted Claims do not recite a sensor *in a mask* or *use of a cannula* to measure respiratory airflow of a subject; instead, the claims recite an airflow sensor internal to the PAP device. The '269 patent describes that "[a]irflow can be *estimated* by measuring nasal or oral airway pressure that decreases during inspiration and increases during expiration," where "[i]nspiration and expiration produce fluctuations on the pressure transducer's signal that is proportional to airflow." '269 Patent, 8:2-6 (emphasis added). But, again, the '269 Patent Asserted Claims do not recite that the claimed "airflow sensor" estimates airflow, but instead that the airflow sensor internal to the PAP device is itself "adapted for *measuring* the respiratory airflow" of a subject and outputting respiratory airflow data that is received by a processor. *See, e.g.*, claims 1, 5, 15.

81. Signal Processing and Data Acquisition are from the Prior Art. According to the '269 Patent "the signals from one or more of the aforementioned sensors are fed into some form of device with a processor or relayed to a processor for analyzing the one or more signals" '269 Patent, 8:26-30. "One preferable embodiment of this device is a programmable wireless data acquisition system as shown in FIGS. 1-6 and described in more detail herein." '269 Patent, 8:31-33. FIGS. 1-6 and their corresponding description in the '269 Patent (spanning nearly ten columns of the '269 patent) are copied from U.S. Patent No. 6,167,258 ("Schmidt"). *See* Exhibit 3 at Figure comparison, and text Comparisons 2, 4 (comparing Schmidt, FIGS. 1-6, 4:46-59, 4:63-14:54 to '269 Patent, FIGS. 1-6, 4:65-5:18, 8:57-18:50. The Schmidt patent issued Dec. 26, 2000, which is more than one year before the November 4, 2005 priority date CleveMed has claimed for the '269 patent. Schmidt is therefore prior art to the '269 patent.

82. Outputs from Data and Signal Processing. Following the copied portions from the Schmidt reference, the '269 Patent states:

One or more sensors are used to develop the data or signals used in the present invention for determining a quantitative level of

[REDACTED]

severity of a subject's sleeping disorder and/or symptoms. In various embodiments, preferably at least two EEG electrodes are used to develop this data. In other embodiments, preferably, at least two ECG electrodes are used. In still other embodiments, preferably a pulse oximeter is used. In still even other embodiments, preferably, either an O² or CO² blood gas monitor is used.

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. Using either the microcontroller 26 of a data acquisition system, a separate computer, base station or processor, a PDA, a processor on a device for treating the subject's sleeping disorder or a combination of these processors, the severity of the subject's sleeping disorder and/or symptoms is determined and is used at least in part to regulate the physical or chemical treatment of the subject. Also optionally, the one or more sensors used in the system of the present invention can also be tethered to a computer, base station, cell phone, a PDA or some other form of processor or microprocessor.

'269 Patent, 18:51-19:7 (underline added). As noted above, the '269 patent specification does not use many of the terms recited in the asserted claims, including “symptom data of a level of severity of a subject’s sleep disorder symptoms,” “symptom data of a severity of the subject’s sleep disorder symptoms,” “index of a level of severity,” or “index of a subject’s symptoms” as recited in the asserted claims. Instead, the patent uses the terms “level of severity” or “quantitative level of severity.” It is unclear what the inventors intended the term “quantitative level of severity of a subject’s sleeping disorder and/or symptoms” to refer to, and the specification does not provide any example of what this “quantitative level” might be. The same is true of the various “data” and “index” terms recited in the claims. I understand that the apnea-hypopnea index (AHI) is the average number of apneas and hypopneas per hour (an index), which is determined by the sum of all apneas and hypopneas divided by the total sleep time. *See, e.g.,* Christian Guilleminault and Vivien C. Abad, *Obstructive sleep apnea syndromes*, Med. Clin. N. Am. 88, 2004, pp. 611-630 (“Guilleminault 2004”) at 615-616; *see also* US 2002/0165462 to Westbrook et al. (“Westbrook”), ¶19. I understand it was known to use AHI to

[REDACTED]

diagnose a level of severity (e.g., mild, medium, or severe), but the '269 Patent does not link the “quantitative level of severity” to either AHI (which is never mentioned in the patent)³ or the mild, medium, or severe levels of severity generally used in the art, nor does the '269 patent link events such as apneas or hypopneas to the recited “level of severity” or “quantitative level.” Moreover, the '269 patent describes using the determined “severity ... at least in part to regulate the physical or chemical treatment of the subject.” However, the '269 Patent does not explain, if the recited “severity” or “level of severity” or “quantitative level of severity” somehow refers to either AHI or mild, medium or severe, *how* such information is used to “regulate the physical or chemical treatment.” Regarding the “index” terms recited in the claims, the '269 patent only uses the word “index” in reference to “obtaining respiratory disturbance index to diagnose sleep apnea” via polysymnography in the “Technical Background” section of the patent. Nowhere else does the patent discuss calculating an index, or how such an index would be calculated with the airflow and pulse oximeter sensor signals recited in the claims. The '269 Patent also does not disclose calculating “based in part on both the respiratory airflow data and the pulse oximetry sensor data” as recited in the '269 Patent Asserted Claims. For example, the excerpt above from columns 18 through 19 describes using multiple sensors known in the art that were typically used with polysymnography, such as ECG, pulse oximeter, or a blood gas monitor. But the '269 Patent does not describe calculating a parameter based on both (either in whole or in part) pulse oximeter sensor signal data and respiratory airflow. The '269 Patent also does not provide an example of what parameter might be calculated in the claimed manner or how it might be used for feedback to adjust the system, which the specification describes throughout is an objective of the system.

83. Known Algorithms. The '269 Patent admits that “[v]arious algorithms known to those skilled in the art are used to filter out noise from the signal or data, and to then quantify the level of severity of the subject’s sleeping disorder or symptoms.” '269 Patent, 20:1-4. I agree

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[REDACTED]

that algorithms to filter out noise from a sensor signal or data were well-known in the art. I understand that, during the claim construction phase of the case, CleveMed argued that the signal processing techniques recited at 20:11-21:67 were examples of methods for performing the claimed calculations of “data” and/or “index”. *See, e.g.*, Amended Joint CC Brief (D.I. 116), at 14, 50. The signal processing techniques recited at 20:11-21:67 are well-known techniques for processing physiological sensor signals. In addition, this section of the specification was copied from prior art U.S. Patent Application Publication No. 2004/0129838 (“Lisy”) at paragraphs 40-45. *See, e.g.*, Exhibit 3 at Comparison 6; Exhibit 8 (color-coded version of Lisy showing copied section); Exhibit 10 (color-coded version of ’269 patent showing copied portions). Lisy is prior art to the ’269 patent at least because Lisy was published July 8, 2004, which is more than one year before the November 4, 2005 priority date of the ’269 patent. Notably, the Lisy publication is directed to a “flow control device” for “controlling air flow across a surface of an aircraft under certain flight conditions.” Lisy, Abstract. The ’269 Patent does not provide any explanation of how or why the techniques for aircraft wing airflow processing are applicable to or used by the sleep disorder treatment or diagnosis system of the ’269 Patent, but this further demonstrates that the disclosed techniques are well-known, generic signal processing techniques known in the art. ’269 Patent, 20:32-34 (“there is an increase in pressure fluctuation as the flow begins to separate from the surface of an airfoil.”). For example, the ’269 specification does not provide any thresholds or guidance to identify flow limitations that could be used to identify apneas, hypopneas, or other relevant events or to be used as feedback in the system to adjust the operation of the treatment device.

84. The Systems of Copied Figure 7 and Figure 8. Figures 7-8 appear to be the only figures in the ’269 patent that illustrate a PAP sleep disorder treatment system. However, I find that neither Figure 7 nor Figure 8 depict the claimed systems as neither figure illustrates all elements of any one system. For example, Figure 7 does not depict the “processor” or transmission elements of independent claims 1, 5, and 15, or “data acquisition” or “signal

[REDACTED]

processing” elements of independent claims 1, 5, and 8.⁴ Figure 7 and its description (’269 patent, 22:45-23:17) were copied from U.S. Patent No. 6,644,311 (“Truitt”) at Figure 1 and its corresponding description. *See, e.g.*, Exhibit 3 at Figure 1 comparison, Text Comparison 7; Exhibit 6 (color-coded version of Truitt showing copied portion); Exhibit 10 (color-coded version of ’269 patent showing copied portions). The Truitt patent issued November 11, 2003, almost two years before the ’269 patent priority application was filed, and is therefore prior art to the ’269 patent. Figure 1 of Truitt is labeled “PRIOR ART,” but the copied Figure 7 in the ’269 patent is not identified as prior art. The ’269 patent applicants changed the description of the figure to state a “more sophisticated pressure support device” with “a flow sensor 320, pressure sensor 322, or both that monitor the flow and/or pressure of gas passing in the subject circuit” is a “device of the present invention” in the ’269 patent. Compare Truitt, 2:1-5 with ’269 Patent, 23:7-10.

85. The ’269 Patent’s Figure 8 and corresponding description are directed to a system comprising a diagnostic device 441 that (1) receives a signal or data from sensors 418, 420, 424, and 426, (2) processes “the data or signals to determine a level of severity of the subject’s sleeping disorder or symptoms,” and (3) transmits “a signal based on this level of severity by either a tether 444 or radio signal to an actuator (not shown) in the CPAP device 428. ’269 Patent, 23:19-33. The ’269 patent asserted claims, however, do not recite a “diagnostic device.” Neither Figure 8 nor its description disclose an “airflow sensor *internal* to the PAP device adapted for measuring the respiratory airflow data of a subject,” or calculating a parameter “based in part *on both* the respiratory airflow data and the pulse oximetry sensor data” as claimed. In contrast, the description recites that “the treatment device 428 has a sensor in the air hose 416, which can measure the differential pressure 414 and thereby accurately measure air

⁴ I note that Figure 7 includes boxes labeled with numerals 324 and 340, but the text of the patent does not describe these elements. However, the box labeled 324 in Figure 7 of the ’269 patent was labeled “38” in Truitt Figure 1, and element 38 was described in Truitt as a “controller.” *See, e.g.*, Truitt, 2:57-64 (“Controller 38 receives the signals output from sensors 30 and 22 and controls the operation of valve 40, pressure generator 12, or a combination thereof in a feedback fashion based on these received signals.”).

[REDACTED]

flow provided to the patient.” ’269 Patent, 23:36-39 (emphasis added). But this is not an “airflow sensor *internal* to the PAP device.”

86. Transmission, Retransmission, and Remote Components. The description of Figures 7 and 8 and the drawings also do not reference the following aspects of the asserted claims: “module transceiver,” transmission to a “remote internet site,” a “radio frequency wireless module transceiver” adapted for transmitting calculated parameters “to [a] base station, cellular phone, or PDA,” retransmission by a base station, cellular phone, or PDA.

87. The ’269 Patent at column 19, lines 12-45 provides the only reference to a “remote site” or RF transmissions that could be relevant to the claims. But this disclosure is copied from U.S. Patent No. 8,187,209 (“Giuffrida”). See Exhibit 3 at Comparison 5; Exhibit 9 (color-coded version of Giuffrida showing copied portions); Exhibit 10 (color-coded version of ’269 patent showing copied portions). Giuffrida was filed March 17, 2005, which is before the November 4, 2005 priority date for the ’269 patent—Giuffrida is therefore prior art to the ’269 patent. However, neither this portion, nor any other portion of the specification, describes that the base station, cellular phone, or PDA displays any calculated parameters as recited in claim 15.

B. Prosecution History of the ’899 Application (’269 Patent Priority Application)

88. I understand from ResMed’s counsel that statements by the patentee or “Applicant” during prosecution of a patent application and its family members with the patent office can inform the scope and meaning of the patent claims.

89. The original claims of the ’899 Application (the ’269 patent’s parent application) recited a system with two components: “a first device for diagnosing and creating a quantitative output of a level of severity of a subject’s sleeping disorder or symptoms; and a second device for physically or chemically treating a subject’s sleeping disorder of symptoms, which can be adjusted using in part the output of the level of severity of the subject’s sleeping disorder.” ’899 FH, 11/4/2010 Application at 42-44 (claims 7 and 14 recite the second device as a “CPAP

[REDACTED]

device”). In response to a rejection of the claims by the PTO examiner, CleveMed amended the claims, renaming the first device a “data acquisition device” and adding inputs for signals from “a respiration belt and a pulse oximeter sensors for creating an output of the signals or a level of severity ... based in part on the signals from the sensors.” CleveMed argued the prior art did not disclose the claimed combination of sensors and a CPAP device being adjusted using the output of the data acquisition system. ’899 FH, 2/9/2010 Amendment at 2-4, 6. CleveMed also argued that that the “present invention uses a data acquisition device separate from the CPAP to adjust the CPAP.” *Id.* at 7. CleveMed also emphasized that the “benefit of the present invention as claimed in all the independent claims is that it provides a single data acquisition device, external the to patient, which interfaces with sensors including a respiration belt and a pulse oximeter.” *Id.* at 7.

90. CleveMed admitted that, “[w]hile paragraph [0045] of [prior art reference] Wright states that the apparatus disclosed therein can generate an apnea hypopnea index, or AHI, and while AHI is an indicator of the level of severity of a patient’s sleep disordered breathing, one of ordinary skill in the art would recognize that the method of obtaining AHI described in paragraph [0045] does not even require the use of a respiration belt sensor and pulse oximeter sensor as does claim 1.” ’899 FH, 10/28/2011 Amendment, 6-7 (emphasis added), 10. Having considered these statements, a POSITA would have understood CleveMed’s statements as an admission that AHI is “an indicator of the level of severity of a patient’s sleep disordered breathing.” This language is similar to the phrase in the ’269 patent’s claim 8, which recites “creating an output of the level of severity of the subject’s sleep disorder or symptoms, but it does not match the phrases used in the ’269 patent’s claims 1, 5, and 15 for the calculated parameters. However, I do recognize that AHI is “an index,” and CleveMed has accused AHI as a parameter that satisfies the calculated parameters of the asserted claims.

[REDACTED]

C. Prosecution History of the '269 Patent (the '116 Application)⁵

91. I understand that the '116 Application that issued as the '269 patent was filed April 5, 2012, and claimed priority as a “continuation” of the '899 application, relying on the same specification filed in the '899 application. I understand that the '116 Application was filed with a preliminary amendment canceling claims 1-20 and adding new claims 21-40. I understand that examined claim 21 issued (after numerous amendments) as asserted claim 1 of the '269 patent, examined claim 28 issued (after numerous amendments) as asserted claim 5, and examined claim 34 (after numerous amendments) issued as asserted claim 8. *See, e.g.*, '116 FH, 04/05/2012 Preliminary Amendment; '116 FH, 8/7/2018 Notice of Allowability. Like the '899 application, the claims of the '116 application originally presented for examination recited a data acquisition system or processor separate from a PAP or treatment device. '116 FH, 04/05/2012 Preliminary Amendment. The claims were rejected in view of US 7,878,198 to Farrell (“Farrell-198”), and CleveMed responded that “Farrell[-198] makes clear that flow and pressure measurements of the delivered air are used to adjust the PAP device – not respiratory effort ... and pulse oximetry” '166 FH, 5/27/2016 Amendment, at 8. CleveMed also admitted that US 5,704,345 (Berthon-Jones), which is incorporated by reference in Farrell-198, “makes it clear that the discrete ... fourier [sic] transform is ‘performed by the processing element 132, *of the airflow signal fn during the apnea ...* .” *Id.* at 8-9.

92. The examiner identified the subject matter of then-pending claims 24, 25, 31, 39, and 40, which recite the signal processing techniques of issued claims 4, 6, 14 (and later claim 20), as reciting allowable subject matter. '116 FH, 9/6/2016 Office Action, at 13.

93. The examiner also rejected a claim as lacking written description in the specification; CleveMed responded that “[t]he Specification, pgs. 39-41, further describe the processor determining a level of severity of the symptoms or disease state and outputting a signal

⁵ I also address certain statements by CleveMed during prosecution of the claim that issued as claim 8 with regard to the state of the art in section X.A.8 below.

[REDACTED]

to adjust the physical or chemical treatment, specifically including the PAP or chemical methods.” ’116 FH, 4/3/2017 Amendment, at 8 (emphasis added) (where cited pages 39-41 appear to correspond roughly to 22:9-23:48 of the issued patent). But the cited portions of the specification discussing Figures 7 and 8 do not mention a “level of severity” or how a processor calculates or creates an output of a “level of severity.”

94. CleveMed made extensive amendments to the claims on October 12, 2017 that included the addition of “calculating symptom data of level of severity and/or an index of a level of severity of the subject’s symptoms measured during use of the PAP device,” “a module transceiver adapted for receiving and transmitting symptom data and/or the sensor data to a remote location,” and the addition of claims 41-46 that correspond (after additional later amendments) to issued claims 15-20. ’116 FH, 10/12/2017 Amendment, at 2-7.

95. The October 12, 2017 amendments also added the limitation “an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow data of a subject using the PAP” (and similar limitations). ’116 FH, 10/12/2017 Amendment at 2, 4, 6-7 (new claim 41 (issued as claim 15)). The amendment to claim 28 (issued claim 5) made the following changes (additions in underline, deletions stricken) that are instructive in understanding the added “airflow sensor” limitations: “~~the~~ an airflow sensor with a signal adapted for measuring air flow and/or pressure-respiratory airflow of a subject”. *Id.* at 4. In particular, CleveMed appears to have intended the amendment to differentiate the claimed “airflow sensor with a signal adapted for measuring respiratory airflow of a subject” from merely a sensor for measuring flow and/or pressure.

96. CleveMed also 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. In CleveMed’s remarks for that amendment, CleveMed argued that “Bowen does not teach or disclose integrating external sensors with the internal sensors of the PAP device – thereby failing to teach the crux of the present invention, and neither Bowen nor Wright teach the incorporation of pulse oximetry data and internal flow

[REDACTED]

sensors to develop a level of severity or an index of a level of severity of the sleep disorder breathing symptoms of the present invention.” ’116 FH, 3/27/2018 Remarks at 22 (addressing issued claims 15-20) (emphasis added). CleveMed also 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 “for grammatical/typographical errors”).

97. A POSITA having considered the above amendments and statements by CleveMed in the file history 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 index, or flattening index because such measurements or statistics could also be used to determine stroke related parameters as disclosed

[REDACTED]

by the Wright reference. Instead, CleveMed argued the calculated parameters are different from those disclosed by Wright, which a POSITA would understand to 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.

D. Prosecution History of Child Patents

98. I understand that Application No. 17/825,266 (the “’266 Application”) was filed as a continuation of Application No. 16/057,963, which was in turn filed as a continuation of the ’116 Application (issued as the ’269 patent). A September 13, 2022 office action from the examiner rejected claims that recited “an airflow sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data.” The basis for the rejection was US 2007/0161913 (“Farrell-913”), described as “the closest prior art.” The rejection proposed that Farrell-913 disclosed “an airflow sensor (“flow sensor”) 4f internal to the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP and outputting airflow sensor data (see para. [0024]). ’266 FH, 9/13/2022 Office Action, at 10. Thus, the examiner appears to have concluded that Farrell-913 disclosed the airflow sensor limitations that are also recited in the ’269 patent asserted claims.

E. IPR2023-00565 Against the ’269 Patent

99. I understand from counsel that statements by a patentee in an IPR proceeding may operate to disclaim the scope of a claim in a similar manner that statements made during prosecution of an application with a PTO examiner (like those above in §§ VI.B-D).

100. I understand from ResMed’s counsel that ResMed Corp. filed, with the USPTO, a petition for *inter partes* review (IPR) of the ’269 patent on March 22, 2023, requesting cancellation of claims 1-20 of the patent in view of prior art. IPR2023-00565, Paper 1. I further understand that CleveMed filed, on June 28, 2023, a Patent Owner’s Preliminary Response (POPR) to the petition. IPR2023-00565, Paper No. 6. I have considered statements made by

[REDACTED]

CleveMed as the Patent Owner (“PO”) in their Preliminary Response paper with regard to the scope of the ’269 patent asserted claims and the prior art. For example, CleveMed’s statements further inform the scope and meaning of the airflow sensor limitations and the “calculating” limitations of the asserted claims.

101. CleveMed stated that “claimed invention uses a CPAP with sensors that detect the patient’s physiological condition, including parameters related to a patient’s breath, such as respiratory airflow and effort, and blood oxygenation levels,” and that “*diagnostic* readings from pulse oximeters and/or airflow sensors **are combined** to determine sleep disorder symptom data” IPR2023-00565, POPR at 4. As I already noted, the asserted claims do not say anything about “diagnostics,” nor do the claims specify any particular combination / configuration or aspect of the sensors to indicate they are providing “diagnostic readings.” Another of CleveMed’s arguments is that a prior art disclosure of “the oxygen saturation may be averaged over a certain time or the number of apneas in a predetermined period may be determined as trend data” did not disclose calculating “sleep disorder symptom data based on data from respiratory airflow and pulse oximetry sensors.” *Id.* at 28. I understand this to be confirmation that the limitations in claims 1 and 5 that require the parameter be calculated “based in part on both the respiratory airflow data and the pulse oximetry sensor data” requires that the two types of data be combined or both used to calculate the claimed data parameter or index.

102. I understand that the IPR petition relied on WO 2005-096737A2 (“Farrell”) as an example of prior art that disclosed the airflow sensor limitations of the ’269 patent claims: Farrell’s CPAP main unit 2 includes “flow sensor 4f [so] mask flow may be measured using a pneumotachograph and differential pressure transducer or similar device to derive a flow signal F(t)” Farrell, 5:5-7 (quote in IPR Petition (Paper 1) at 34-35). In reference to the airflow sensor limitations, CleveMed argued:

- “In some claimed embodiments, the CPAP machine measures a patient’s respiratory airflow using a pressure sensor located within the device,” and, “[u]nlike the prior art, this airflow sensor is placed within the CPAP device, not attached to the hose or the patient’s mask.” IPR2023-00565, POPR at 5-6.

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- Farrell’s pressure and flow sensors “are used just for determination of the delivered air to the patient ... [and] do not detect physiological information, such as a patient’s respiratory airflow.” *Id.* at 23.
 - “Farrell, which was considered extensively during original prosecution of the ’269 patent, discloses an airflow sensor that measures the *blower output*” (*id.* at 27-28); Farrell does not teach the claimed internal airflow sensor “because Farrell’s pressure sensor measures the output of the CPAP machine’s blower rather than the respiratory airflow of the subject.” *Id.* at 31 (emphasis added).
 - CleveMed repeated these arguments for the Kocinski reference: “[r]ather than measure the respiratory airflow of a subject, both Kocinski and Farrell disclose pressure sensors that measure the pressure that the CPAP machine provides to the patient.” *Id.* at 35, 36 (“The referenced internal pressure transducer [of Kocinski] does not measure the respiratory airflow the [sic] of the subject nor output the subject’s airflow data.”)

103. These statements by CleveMed about the scope of the asserted claims informs a POSITA that the configuration CleveMed has accused in their infringement contentions (discussed more below), that is, a sensor(s) that measure blower flow or pressure output of the machine, does not practice the airflow sensor limitations of the claims. However, since CleveMed continues to allege such a configuration in the accused products practices the claims, the same features in the ResMed prior art products practice the claims for at least the same reasons CleveMed alleges the accused products do so.

VII. ASSERTED CLAIMS AND CONSTRUCTIONS

A. Asserted Claims

104. I understand that the following claims are asserted for the ’269 Patent:⁶ 1, 5, 8, 15, 16, 20.

105. I will refer to these claims collectively as “the ’269 Asserted Claims” or “the Asserted Claims.”

B. Claim Constructions

106. I understand from ResMed’s counsel that the Court issued an opinion construing

⁶ CleveMed’s Final Infringement Contentions and Final Election of Asserted Claims (Nov. 13, 2023) at 2.

certain claim terms, and that the parties agreed to the construction of certain claim terms. Set forth below is a table reflecting these constructions. I understand that certain claims were also disputed as indefinite, but that the court found the disputed terms not indefinite. I have applied these constructions as part of my analysis.

Term	Court's Construction
"base station" ('269 patent, claim 15)	"a computer that can communicate with other devices"
"pulse oximeter" ('269, claims 1, 5, 9) ('399, claims 1, 8) ('535, claim 8) ('937, claims 1, 2, 13) ('603, claims 1, 8) ('637, claim 1)	Plain and ordinary meaning, which is "instrument used to measure the blood oxygenation"
"transferring the collected data to a location remote from the subject's home" ('399 patent, claim 1) "transferring the collected data via cellular systems, internet, satellite, wired-network and/or land lines to a location remote from the subject's home" ('399 patent, claim 8)	Plain and ordinary meaning. No construction necessary.
"oxygenation" ('399, claims 1, 8) ('535, claim 8) ('937, claims 1, 8) ('637, claim 1)	Plain and ordinary meaning, which is "level of oxygen saturation of the blood"

Term	Agreed Construction
"ARMAX system identification model" ('269 patent, claim 4)	"Auto-Regressive Moving Average exogenous system identification model"
"short-time Fourier transform" ('269 patent, claim 4)	Plain and ordinary meaning, which is "a sequence of Fourier transforms of a windowed signal. A Fourier transform is a technique that uses a mathematical operation to convert a signal or data from the time domain to the frequency domain"

Term	Agreed Construction
“nasal cannula” (‘269, claims 1, 5, 15) (‘399, claims 1, 8) (‘535, claim 8) (‘937, claims 1, 2, 13) (‘603, claim 13) (‘698, claim 14) (‘637, claim 1)	Plain and ordinary meaning, which is “a flexible tube having two prongs that extend into a user’s nostrils and leave the nostrils open for free exhalation through the nose”
“pressure transducer” (‘399, claims 1, 8) (‘535, claim 8) (‘937, claims 1, 13) (‘603, claims 1, 8) (‘698, claim 14) (‘637, claim 1)	“device that converts physical pressure into an electrical signal”

107. Where claim language does not have a corresponding proposed construction, I have applied the plain and ordinary meaning of that claim language to one of ordinary skill in the art.

VIII. PERSON OF ORDINARY SKILL IN THE ART (“POSITA”)

108. I understand from ResMed counsel that ResMed has asserted in this investigation that a person of ordinary skill in the art for the Asserted Patents at the time of the alleged invention would have had a bachelor’s degree in mechanical engineering, electrical engineering, computer science or an equivalent field and two years of industry experience working with diagnostic sensor systems and networked data systems, and an increase in experience could compensate for less education and vice versa. I agree that this is an accurate description of the person having ordinary skill in the art of the Asserted Patents.

109. I understand that CleveMed has asserted in this investigation that a person of ordinary skill in the art of the Asserted Patents would be “a person with an undergraduate degree in biomedical engineering, electrical engineering, or a similar field, or who has 3 to 5 years of experience in the relevant medical devices industry.”

110. Adopting CleveMed’s proposal for a person of ordinary skill in the art does not change any of my opinions in this report.

[REDACTED]

111. I was at least a person of ordinary skill in the art under either of the above proposals at the time of the earliest claimed priority date for the '269 Patent (Nov. 4, 2005), and also at the time of the alleged conception (March 2005), and the time of the priority date of the HST Patents (June 2007).

IX. CLEVEMED'S INFRINGEMENT CONTENTIONS

112. I understand from ResMed counsel that claims must be interpreted the same for an infringement analysis as for a validity analysis. I have therefore considered CleveMed's Preliminary Infringement Contentions and supplements thereto, CleveMed's Final Infringement Contentions, and documentation, discovery responses, and relevant deposition transcripts regarding the Accused Products in my invalidity analysis. In particular, I have considered in my analysis what features and functionalities CleveMed has alleged practice the Asserted Claims and in some instances pointed to the same features and functionalities in the prior art. However, this is not an admission or concession that such a feature or functionality practices the claims, and I reserve the right to take a position that the same feature or functionality does not practice the claim in my opinions on noninfringement.

113. If CleveMed amends or supplements their infringement contentions, I reserve the right to supplement my report and my opinions included herein. I also reserve the right to supplement my report and opinions if CleveMed's experts opine on matters of infringement and / or validity which clarify, contradicts, or modifies CleveMed's infringement theories.

114. I understand CleveMed has accused of infringement the following flow generator devices:

- Astral and Stellar ventilators (Chart A);
- AirSense 11 (Chart H);
- AirSense 10 (Chart I);
- AirCurve 10 (Chart J);
- AirMini (Chart K).

115. I further understand that the above-identified flow generators are accused of infringing the '269 Patent Asserted claims in combination with the AirView cloud-based system, apps including the AirMini app and the myAir app, and particular accessories (such as the Air 10

[REDACTED]

Oximeter Adapter for connecting a NONIN Xpod oximeter to an Air10 flow generator, identified in Chart I at 9-10, and the ResMed Connectivity Module that provides cellular connection between the Astral/Stellar ventilators and the AirView platform).

A. CleveMed's '269 Patent Infringement Allegations

116. I understand that CleveMed has accused certain ResMed hardware and software products (identified above) of practicing the '269 Patent Asserted Claims. CleveMed's Infringement Contentions only generally refer to source code functions without specific function or line cites to attempt to show infringement of the elements of the '269 Patent Asserted Claims. CleveMed's contentions also refer in some cases generally to a category of parameters, or in other cases a long list of parameters allegedly calculated by the accused products without identifying which of the parameters allegedly practice the claims. If CleveMed clarifies its infringement contentions on these issues, I reserve the right to supplement my analysis and opinions accordingly.

1. No Continuity of Accused Calculated/Created Parameters

117. I note that the '269 patent asserted claims recite that the same "data," "index," or "output of the level of severity" parameters calculated or created by the processor are further received, transmitted, displayed, or otherwise used by other components of the system. However, CleveMed's Infringement Contentions do identify a single specific parameter that meets all of the elements of the claim that do something with that parameter. As just one example, for claim 15, CleveMed's contentions allege that display of a "Score that is based on the patients data showing severity of their sleep disorder symptoms and/or an index of their symptoms" (Final. Inf. Cont., Chart H, 136; *see also* Chart K, 35)(emphasis added), rather than "display [of] the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms" that was allegedly calculated by the processor.

2. "Airflow Sensor" limitations 1.b.3, 5.e.3, 15.a.2

118. The airflow sensor limitations 1.b.3, 5.e.3, and 15.a.2 (limitations 1g, 5i, and 15d

[REDACTED]

in CleveMed's charts, respectively) require "an airflow sensor" internal to the PAP device "adapted for measuring respiratory airflow [or airflow data] of a subject" where the processor of the system receives "the respiratory airflow data from the airflow sensor." CleveMed's contentions for these limitations do not point to "an airflow sensor" that satisfies these claim

[REDACTED]

[REDACTED]

to be contrary to what CleveMed has argued to the patent office regarding the airflow sensor limitations. As discussed above, I understand that CleveMed has argued that a "pressure sensor [that] measures the output of the CPAP machine's blower rather than the respiratory airflow of the subject" does not practice the airflow sensor limitations. IPR2023-00565, POPR (Paper 6), 31, 35-37. I disagree that the "airflow sensor" identified in CleveMed's contentions meets the airflow sensor limitations. However, if a judge or jury determines that the accused features meet

[REDACTED]

the airflow sensor limitations, the same features were disclosed in the prior art, were part of the knowledge of a POSITA, and also at least would have been obvious to a POSITA, as discussed in more detail below.

3. Calculated and created data, index, and output of limitations 1.b.4, 5.f, 8.a, and 15.b

120. As noted above, CleveMed's contentions for the calculated data, index, and output recited in claims 1, 5, 8, and 15 merely list or excerpt a large number of parameters, do not point to a single one, and do not address whether any particular parameter is the claimed "data" or "index." CleveMed's preliminary contentions for limitations 1.b.4 (limitation 1h in CleveMed's charts) and 5.f (limitation 5l in CleveMed's charts) allege the following parameters are the "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" calculated "based in part both the respiratory airflow data and the pulse oximetry sensor data," and for limitation 15.b (limitation 15e in CleveMed's charts) the calculated "symptoms data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured

[REDACTED]

121. CleveMed's final contentions similarly allege the "data" and/or "index" or "level" of limitations 1.b.4, 5.f, 8.a, and 15.b are practiced by the (1) "Detailed Data" that includes

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

122. CleveMed’s contentions also allege that limitations 1.b.4 and 5.f are met by the following: [REDACTED]

[REDACTED]

[REDACTED]

123. As another example, CleveMed’s contentions for the “calculating” limitation of claims 1, 5, and 15 and the “creating” limitation of claim 8 point to the following as alleged evidence the claim is met by the accused products:



124. CleveMed’s contentions also point to the following as evidence the accused products practice the “creating” limitation of claim 8:

[REDACTED]

125. CleveMed's contentions for limitation 5.f (limitation 5l in CleveMed's charts) also allege that the following parameters are a "calculated level of severity and/or index of the level of severity for a patient's sleep disorder symptoms determined while using the device" that meets the claim limitation: [REDACTED]

[REDACTED]

[REDACTED]

126. CleveMed's contentions for limitation 5.f also allege that the accused products receive and transmit [REDACTED]

[REDACTED]

[REDACTED]

127. CleveMed's contentions do not identify a single parameter allegedly calculated "based in part on both data from the respiratory airflow and pulse oximetry sensors" as claimed—instead, CleveMed's contentions appear to allege that [REDACTED]

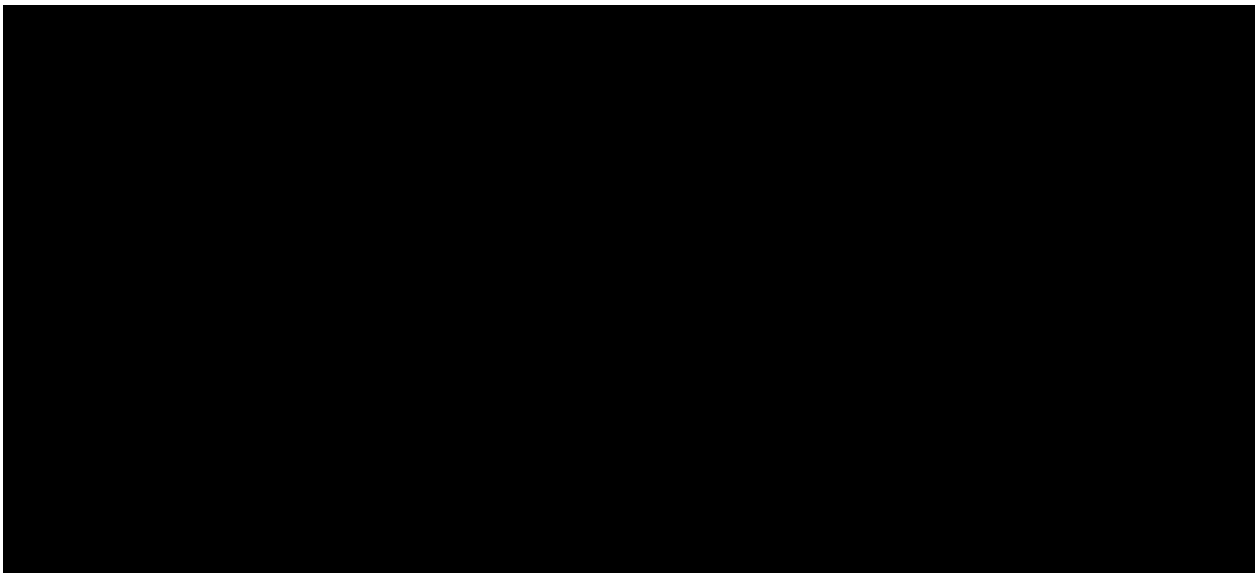
[REDACTED]. If it is determined that the accused functionality meets the claim limitation, the same functionality was also present in the prior art, was part of the knowledge of a POSITA, and also at least would

[REDACTED]

have been obvious to a POSITA, as discussed more below.

128. As also discussed above, CleveMed argued in the IPR in connection with limitations 1.b.4 and 5.f that the following disclosures in the prior art do not meet the “calculating” limitations because they do not include a calculation of “sleep disorder symptom data based on data from respiratory airflow and pulse oximetry sensors:” “the oxygen saturation may be averaged over a certain time or the number of apneas in a predetermined period may be determined as trend data.” IPR2023-00565, POPR (Paper 6), 28. CleveMed’s IPR arguments appear conflict with CleveMed’s infringement contentions that accuse statistical values of oxygen saturation and the number of apnea events or an apnea index. If it is determined that these types of calculations meet the claims, the prior art also discloses such calculations, as discussed below.

129. CleveMed’s final contentions for limitation 8.a (limitation 8b in CleveMed’s charts) further allege that “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” is met by:



130. I note that CleveMed’s final contentions do not identify what it alleges is the “output” created in accordance with limitation 8.a. However, CleveMed’s final contentions for limitation 8.b appear to allege that a “values [] derived from at least the blower pressure and airflow sensors.” Final Infr. Cont., Chart A, 49.

4. Limitation 8.b – “adjust the pharmaceutical agent ... using the output of the level of severity”

132. CleveMed’s contentions for limitation (limitation 8c in CleveMed’s charts) allege the accused product is “adapted to adjust the oxygen based upon the output of the level of severity of the subject’s sleep disorder registered from the pressure and flow sensors,” but CleveMed’s contentions do not identify what parameter CleveMed alleges is the “output of the level of severity” used to adjust the oxygen. Chart A, limitation 8c. CleveMed appears to allege



accused functionality practices the claim, the same functionality was also present in the prior art, was part of the knowledge of a POSITA, and also at least would have been obvious to a POSITA as discussed below.

5. Limitation 5.d – “consisting essentially of” and “processing ... to remove artifacts”

133. I understand from counsel that the phrase “consisting essentially of” has a special meaning in patent law, and that it is a transitional phrase that limits the scope of the claim to the specified components that follow the phrase and those that do not materially affect the basic and novel characteristics of the claimed apparatus. I further understand that, to determine the steps which are included or excluded, the claim must be read in light of the specification. Here, the specification does not instruct a POSITA what elements or components might be excluded from

[REDACTED]

the claim because they “materially affect the basic and novel characteristics” of the claimed system. As expressed in Section X.C below, claim 5 is not novel, and, in particular, claim 5 is not novel when construed according to CleveMed’s contentions. I have considered, for example, whether the prior art comprises additional inputs to the disclosed “data acquisition system,” or components in addition to those used “for filtering and processing the first signal” that might affect its characteristics beyond those recited in the claim. See § X.C at limitation 5.d.

CleveMed’s contentions for limitation 5.d do not appear to address this limiting transitional phrase, but if CleveMed supplements its contentions I reserve the right to supplement my invalidity analysis and opinions accordingly.

134. CleveMed’s contentions for limitation 5.d (limitation 5e in CleveMed’s charts) allege that the accused oximetry module adapter, which is an adapter that plugs into the accused flow generator to translate the communication packets from the pulse oximeter to the protocol language used by the flow generator, practices the claimed “data acquisition system” and the module “removes artifacts as part of its various processing functions, including correcting data errors and/or removing data gaps when, for example, converting the pulse oximeter’s output into a format that can be received by the AirSense 10.” Final Infr. Cont., Chart I at limitation 5e (page 43). If “correcting data errors” or performing other communication processing tasks common to communication processing are determined to meet limitation 5.d, as CleveMed appears to accuse, then the same functionality in the prior art discloses the claim limitation for at least the same reasons.

6. Claim 15 – “base station”

135. CleveMed’s Infringement Contentions for claim 15 allege that a “computer[] ... running AirView” practices the claimed “base station.” See, e.g., Charts H, I at limitation 15h. If a judge or jury determine that the accused “computer[] ... running AirView” practices the claimed “base station,” the prior art anticipates the claims for at least the same reasons.

7. Claim 20

136. CleveMed’s contentions allege that any “waveform” analysis is “wavelet

[REDACTED]

analysis” of “airflow sensor data” as recited in claim 20. I disagree that any wave form analysis is a wavelet analysis. A wavelet analysis may be considered a particular type of waveform analysis, but not all wave form analysis are a “wavelet analysis.” For example, the ’269 patent itself identifies that a wavelet analysis uses “a particular kernel function” that CleveMed fails to address in its contentions. ’269 patent, 20:26-31. If a judge or jury determines that the accused functions practice claim 20, the ResMed prior art discloses claim 20 for the same reasons. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] CleveMed’s contentions are unclear as to what aspect of the AutoSet algorithm allegedly practices the claim. Therefore, I reserve the right to supplement my analysis and rely on the same feature in the ResMed prior art products if CleveMed clarifies its contentions or in response to CleveMed’s expert report on alleged infringement.

X. ANALYSIS OF THE ’269 PATENT PRIOR ART

137. Below is a table of acronyms and terms used herein and in the ResMed documentation with a general description. The below descriptions should not be construed as a “claim construction,” but are merely provided for reference and ease of navigation.

<u>Term</u>	<u>Explanation</u>
510(k)	A premarket submission made to the U.S. Food and Drug Administration (FDA) to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device
Apnea	[REDACTED]
Apnea Index	[REDACTED]
Apnea-Hypopnea	[REDACTED]

Index (AHI)	[REDACTED]
AutoScan	ResMed software for viewing data collected by a compatible ResMed flow generator
AutoSet Spirit	ResMed S7 series flow generator, internally named “[REDACTED]”
BOM	Bill of materials
CMR	Controlled Market Release
[REDACTED]	[REDACTED]
Compliance	[REDACTED]
CPAP	Continuous positive airway pressure
FG – Flow Generator	Device that delivers positive airway pressure (PAP)
LFE	[REDACTED]
NONIN Xpod	A signal processing pod from NONIN that filters and processes signals from a pulse oximeter sensor
OSA	Obstructive sleep apnea
PAP	Positive airway pressure
[REDACTED]	[REDACTED]
ResLink	[REDACTED] ([REDACTED]) that mounts to the back of the AutoSet Spirit flow generator
[REDACTED] / [REDACTED] / [REDACTED] / ResTraxx module	Wireless module that attaches to the flow generator and provides the means to wirelessly send and receive information. [REDACTED] is the development name for the ResTraxx module.
RDC	ResTraxx Data Center – the backend hardware and software that communicate with the ResTraxx module, store the retrieved data, and provide the user interface for the web application
RPA	ResMed Prior Art, including RPA System 1 and RPA System 2
RPA System 1	ResMed Prior Art System, including AutoSet Spirit flow generator, ResLink (module), AutoScan 5.4 software, modem, NONIN Xpod and pulse oximeter
RPA System 2	ResMed Prior Art System, including AutoSet Spirit flow generator, ResTraxx module ([REDACTED]) ResTraxx Data Center (RDC)
[REDACTED]	[REDACTED]
SpO ₂ / SaO ₂	Oxygen saturation, the level of oxygen saturation of the blood
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

A. ResMed Prior Art Systems Overview

138. I understand that the following two ResMed Prior Art (RPA) systems were in

[REDACTED]

public use, on sale, or sold prior to the November 4, 2005 priority date of the '269 patent, and in some cases more than one year prior to the November 4, 2005 priority date.

System 1: ResMed AutoSet Spirit (S7) + ResLink + AutoScan 5.4

System 2: ResMed AutoSet Spirit (S7) + ResTraxx (including RDC)

139. As discussed in more detail below, the ResMed AutoSet Spirit (S7) is a flow generator for PAP treatment, the ResLink is a module that mounts to the back of the flow generator, AutoScan 5.4 is software that runs on a clinician's computer to download and view data collected and derived by the flow generator. The ResTraxx module is a module that mounts to the flow generator (in a similar manner to the ResLink module) and communicates wirelessly via a pager network to back end components of the ResTraxx Data Center, which provides a web-based application for clinician's or health care providers to view the data collected and derived by the flow generator and transmitted to the RDC web components.

140. RPA Systems 1-2 comprise the ResMed AutoSet Spirit flow generator (aka, "FG" or "AutoSet Spirit"). I understand the internal development name for the ResMed AutoSet Spirit flow generator was "[REDACTED]" See, e.g., [REDACTED]
[REDACTED] I understand that the ResMed AutoSet Spirit was offered for sale, sold, and designed and advertised to be used with a hose and mask. See, e.g., [REDACTED]
[REDACTED] AutoSet Spirit Clinician's Manual (RMD-063968) at 10-12, 15, 33 (Mask settings). I also understand that the ResMed AutoSet Spirit was offered for sale, sold, or in public use with a hose and mask before November 4, 2004, which is more than one year before the alleged priority date of the '269 patent. See, e.g., [REDACTED]
[REDACTED]
[REDACTED]

141. RPA System 1 further comprises the ResLink module, [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] The ResMed AutoSet Spirit was offered for sale, sold, and designed and advertised to be used with the ResLink module and also a NONIN pulse oximeter and its corresponding Xpod. *See, e.g.,* [REDACTED]

[REDACTED] ResLink User's Manual (RMD-063203) at 1, 4; ResLink Launch Brochure (RMD-289749); ResLink Clinician's Manual (RMD-063198); [REDACTED]

[REDACTED] I understand that the ResMed AutoSet Spirit in combination with the ResLink module, and also pulse oximeter and NONIN Xpod, was also offered for sale, sold, and designed and advertised to be used with the ResMed AutoScan 5.4 software before November 4, 2004, which is more than year before the claimed priority date of the '269 patent. *See, e.g.,* AutoSet Spirit Clinician's Manual at 1, 13, 42; AutoScan 5.4 Clinician's Manual (RMD-311263) at 1, 7, 33; RMD-311773 (archive of www.cpap.com); *see also* RMD-0318344 (October 14, 2004 archive of CPAP.com) ("Reslink can be attached to all S7 Spirit and S7 Elite machines as well as VPAP III and VPAPIII ST. It records data including oximetry, pressure response, leak, apneas/hypopneas, minute ventilation, flow limitation, snore, SpO2, and pulse rate. This package includes one Reslink, one USB card reader with card, and one oximeter with probe. Auto Scan software version 5.4 sold separately."); [REDACTED]
[REDACTED]
[REDACTED]

I further understand, as described in more detail below, that the AutoSet Spirit as offered for sale or sold before November 4, 2004, was capable of (and described in public documentation, *see, e.g.,* AutoSet Spirit Clinician's Manual (RMD-063968) at 42; AutoScan 5.4 Clinician's Manual (RMD-311263) at 11-23) communicating using a modem connected to the AutoSet Spirit flow generator such that a clinician's computer running the AutoScan 5.4 software could download data remotely from the flow generator. I understand from ResMed's counsel that this means RPA System 1 is prior art to the '269 Patent under 35 U.S.C. § 102(b).

142. For System 2, the ResMed AutoSet Spirit was also offered for sale, sold, and

[REDACTED]

designed and advertised to be used with Restraxx, which includes the Restraxx module that attaches to the back of the AutoSet Spirit, the Restraxx Data Center (“RDC”), along with additional backend components for RDC discussed in more detail below. *See, e.g.,* [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] I understand that this System 2 was offered for sale, sold, and publicly used in the U.S. before November 4, 2005. *See, e.g.,* [REDACTED]

[REDACTED]

[REDACTED] I understand from ResMed’s counsel that this means RPA System 3 is prior art to the ’269 Patent under 35 U.S.C. § 102(a).

143. Below is a table of documents that shows RPA Systems 1-2 were publicly available, offered for sale or sold in the United States as identified above, in addition to the documents identified above and in the detailed description below:

Bates Identifier	Document title / Date
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
RMD-0318396	ResMed Prior Art – Physical Specimen Photographs
RMD-0318346	ResMed Prior Art – Virtual Machine and AutoScan 5.4 Screenshots
[REDACTED]	[REDACTED]
RMD-306740	AutoSet Spirit User Manual BOM Spec [30844] (9-25-2002)
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

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.

AutoSet Spirit Clinician's Manual (RMD-063968) at 1.

145. ResMed documentation further teaches that “[d]ata collection capabilities also assist in the management of continuous positive airway pressure (CPAP) treatment.” AutoSet Spirit Clinician's Manual (RMD-063968) at 3, *see also* 1 (“Data storage and processing capabilities of the AUTOSET SPIRIT system facilitate patient management.”).

[REDACTED]

[REDACTED] *see also* AutoSet Spirit Clinician's Manual (RMD-063968) at 10.

146. As explained by the AutoSet Spirit Clinician's Manual and discussed below in more detail:

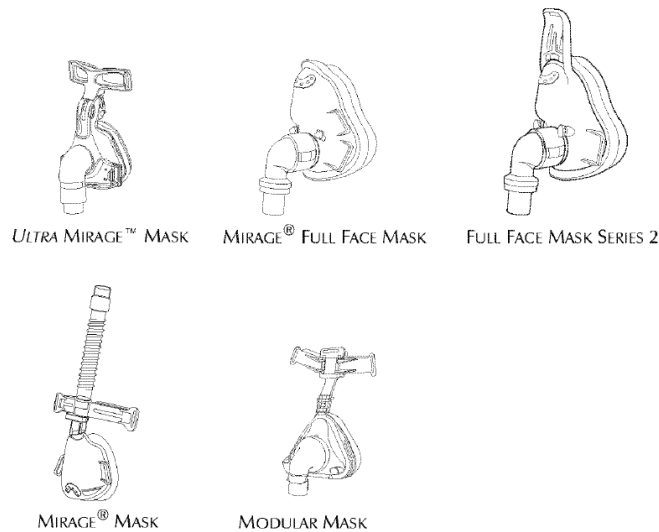
The system provides summary data for a variety of time intervals, which can be viewed via the LCD menus. The patient's usage hours, treatment pressure, mask leak, apnea + hypopnea index (AHI), apnea index (AI), and hypopnea index (HI) are displayed in the Results section of the Clinical Menu. At your discretion, the patient may view mask fit, treatment pressure, and usage hours for the last session. This patient feature is called SMART DATA[™].

[REDACTED]

AUTOscan software is designed for downloading and reviewing the most recent 365 days of data from an AUTOSET SPIRIT unit used in the patient's home.

AutoSet Spirit Clinician's Manual (RMD-063968) at 1, 31 (list of results viewable on menus), 33 (settings options), 40 (results menu diagram).

147. The AutoSet Spirit is designed to be used with tubing and a mask, such as the ResMed Ultra Mirage Mask, Mirage Full Face Mask, Full Face Mask Series 2, Mirage Mask, and Modular Mask. AutoSet Spirit Clinician's Manual (RMD-063968) at 10 (showing "Air tubing"), 12 (identifying recommended masks); *see also* Mirage Vista Mask User's Guide (RMD-270989); Mirage Full Face Mask Series 2 User Instructions (RMD-271027); Mirage Mask User Instructions (RMD-271110); Ultra Mirage Full Face Mask User's Guide (RMD-271159).



AutoSet Spirit Clinician's Manual (RMD-063968) at 12.

[REDACTED]

[REDACTED]

2. AutoSet Spirit (“[REDACTED]”) Hardware and Sensors

150. The AutoSet Spirit comprises a microprocessor [REDACTED] and memory. *See, e.g.,* [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

151. The AutoSet Spirit has [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

a. Blower

152. The AutoSet Spirit comprises a blower, controlled by the microprocessor, that generates the required positive airway pressure in the system. *See, e.g.*, [REDACTED]

[REDACTED] The blower includes a motor and fan combination to take air from the environment and pump it into a patient's mask in a controlled manner. [REDACTED]

The motor speed is controlled according to outputs from the microprocessor.

b. Sensors

153. The AutoSet Spirit has a pressure sensor and a “flow sensor” internal to the device housing. *See, e.g.*, [REDACTED]

AutoSet Spirit Clinician's Manual at 7, ("The flow

[REDACTED]

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.”), 37 (“The pressure transducer located in the unit measures treatment pressure; the average pressure is calculated and recorded each minute;” “Leak is derived by analyzing inspiratory and expiratory airflows (via the flow sensor located in the unit).”).

154. At a detailed level, the “flow sensor,” which would be specifically understood to be a flow sensor system that comprises multiple components, comprises a laminar flow element, which is positioned in the blower module between the blower and the outlet, and a differential pressure transducer [REDACTED] that measures the airflow by detecting the pressure drop across the laminar flow element. Thus, the actual “sensor” in the form of the pressure transducer *measures* differential pressure, but the output of the flow sensor system comprising the flow element, differential pressure transducer, and corresponding circuitry output a data signal that is considered a “flow” data signal within the AutoSet Spirit flow generator. The laminar flow element and the differential pressure transducer are connected with small tubes. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

155. The pressure sensor includes a pressure transducer [REDACTED] to measure the pressure at the output of the flow generator. *See, e.g.,* [REDACTED]

[REDACTED]

[REDACTED]

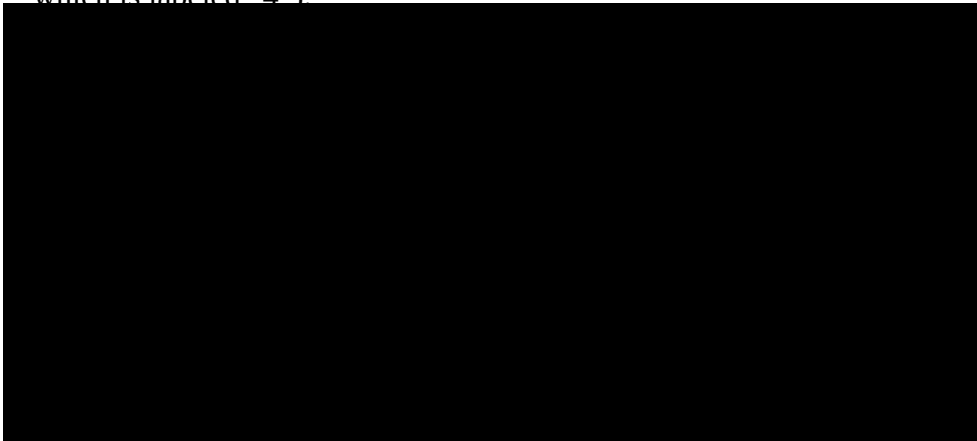
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

156. Below are pictures from the Service Manual showing the sensor tube connections to the transducer components [REDACTED] on the PCB. As shown in the second photograph (bottom) with the labeled tubes, tubes 1 and 2 are connected to the flow sensor and the differential pressure transducer for sensing flow, and tube 3 is connected to the pressure transducer to sense the pressure at the outlet of the flow generator (relative to ambient pressure, which is labeled “4”).



[REDACTED]

[REDACTED]

157. The outputs of the pressure sensor and flow sensor circuits are input to the microprocessor. *See, e.g.*, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

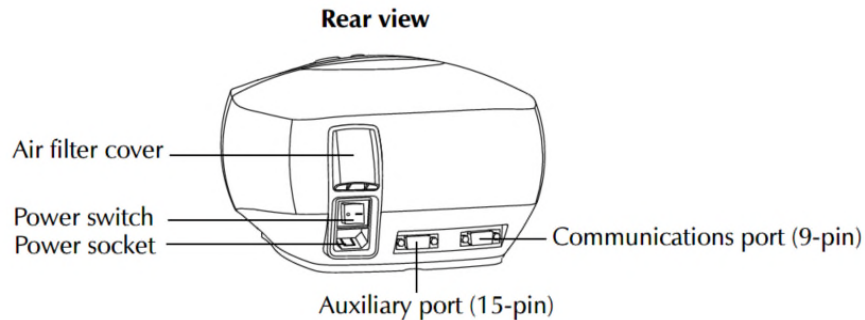
[REDACTED]

[REDACTED]

[REDACTED]

3. AutoSet Spirit ([REDACTED]) Interfaces

158. As shown in the below drawing, the AutoSet Spirit has two physical ports: a serial interface (“Communications port”) and an “Auxiliary port” (aka, “[REDACTED] Port”). [REDACTED]
[REDACTED] In reference to the Figure 2 diagram above from the [REDACTED], the serial interface is used to connect to the RS232 port of a PC running ResMed software, or to a modem that is used to communicate with a PC running ResMed software. [REDACTED]
[REDACTED] AutoSet Spirit Clinician’s Manual at 13 (showing cable from flow generator port to “computer”), 42 (“patient attaches the modem to the right communications port on the AUTOSET SPIRIT unit and to a phone line”).



AutoSet Spirit Clinician’s Manual (RMD-063968) at 10.

[REDACTED]

159. The serial (“Comm’s”) and auxiliary ports are also shown in the above diagram from the Microprocessor and Digital Design Description and described in more detail in section 5.4 of that document. [REDACTED]

[REDACTED]

160. The ResLink ([REDACTED] and [REDACTED] 1 (of the ResTraxx system discussed in more detail below) use [REDACTED] to transfer data on the [REDACTED] port. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

161. The AutoSet Spirit supports communication on the “Modem” port using [REDACTED]

[REDACTED]

[REDACTED] “Data collected by the AUTOSET SPIRIT unit may be downloaded to AUTOSCAN software (available in the AUTOSCAN clinical interface kit) for review,” where the AutoScan software runs on a clinician’s computer. AutoSet Spirit Clinician’s Manual (RMD-063968) at 42. Data can also be downloaded to a clinician’s computer running AutoScan software from the modem port of the AutoScan Spirit using a modem:

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

[REDACTED]

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.

AutoSet Spirit Clinician's Manual (RMD-063968) at 42 (emphasis added); *see also* [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

162. I note that the design documents for the AutoSet Spirit and [REDACTED] contemplated that requests to the FG in standby mode from a device on the Modem port for the download of data not stored on the FG, such as pulse oximeter data, would be routed by the FG to the [REDACTED] and the [REDACTED] response packets would be routed back to the FG and to the modem port. *See, e.g.,* [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In other words, ResMed had contemplated that data such as oxygen saturation and pulse rate could be retrieved on the modem port by a clinician's computer running ResMed software such as AutoScan (discussed in more detail below) either over a direct cable connection or transmitted using a modem.

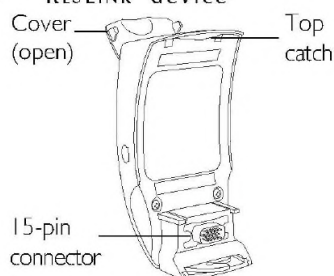
4. ResLink ([REDACTED]) and NONIN Xpod (RPA System 1)

163. ResLink is an accessory module, referred to internally as the [REDACTED] or "[REDACTED]" that is plugged into the auxiliary/[REDACTED] port in the back of the AutoSet Spirit flow generator. *See, e.g.,* ResLink User's Manual (RMD-063203) at 1, 5-6; ResLink Launch Brochure (RMD-289749) at 289751; [REDACTED] The ResLink was "designed for use with the RESMED AUTOSET SPIRIT or S7 Elite flow generators to help your clinician monitor your sleep and ensure that you are receiving optimal treatment." ResLink User's Manual (RMD-063203) at 1; *see also* ResLink Clinician's Manual (RMD-063198) at

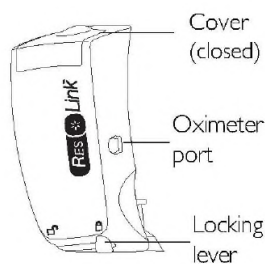
63199;⁷

The following are supplied as part of the ResLINK system:

- **ResLINK device**

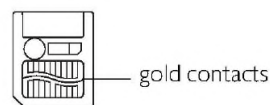


ResLink (front view)



ResLink (back view)

- **SmartMedia card**



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

ResLink Clinician's Guide (RMD-063198) at 63199; *see also* ResLink User's Manual (RMD-063203) at 4.

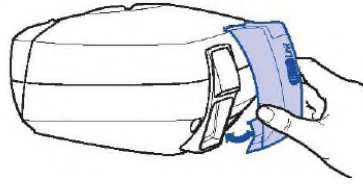


ResLink Launch Brochure (RMD-289749) at 289749 and 289756.

164. The ResMed documentation instructs that the user inserts a SmartMedia Card (SMC) into the card slot on the ResLink, and attaches or docks the ResLink to the back of the AutoSet Spirit by locking the ResLink into the auxiliary port. *See, e.g.,* ResLink User's Manual (RMD-063203) at 5-6; ResLink Launch Brochure (RMD-289749) at 289751; [REDACTED]

⁷ I understand that the ResLink was also used to provide an upgrade to the AutoSet Spirit flow generator's software. *See, e.g.,* ResLink Clinician's Guide (RMD-063198) at 63199.

- [REDACTED]
2. Push the bottom of the RESLINK onto the auxiliary port at the back of the flow generator.



ResLink User's Manual (RMD-063203) at 6.

The first truly modular system



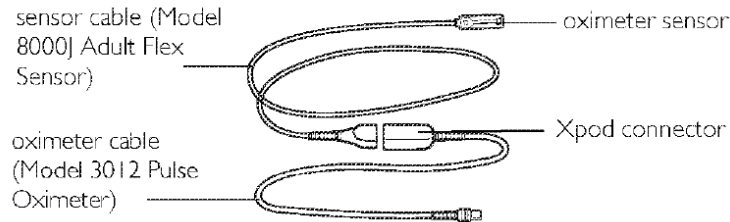
ResLink Launch Brochure (RMD-289749) at 289752.

[REDACTED]

165. An accessory to the ResLink is the NONIN Model 3012 Pulse Oximeter with Xpod connector and corresponding Model 8000 sensor cable that “allows collection and storage of oximetry data (oxygen saturation and pulse rate).” ResLink User's Manual (RMD-063203) at 7; [REDACTED]

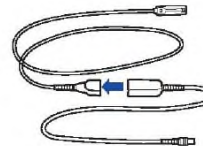
ACCESSORIES

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



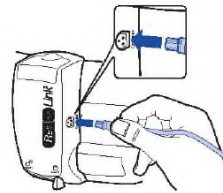
ResLink User's Manual (RMD-063203) at 4, 17 (SpO2 "70-100% $\pm$ 3 digits", Pulse rate "18-200 pulses $\pm$ 3% $\pm$ 1 digit"); *see also* ResLink Clinician's Guide (RMD-063198) at 63199;

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.



Attaching the Oximeter Sensor (optional)

ResLink User's Manual (RMD-063203) at 4;



ResLink Launch Brochure (RMD-289749) at 289755; *see also* ResLink User's Manual (RMD-

[REDACTED]

063203) at 8-9.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

166. The ResLink interface to the oximeter [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

167. The AutoSet Spirit displays various messages to inform the user about the operation of the ResLink, including successful oximeter connection and notification that there is

[REDACTED]

an oximeter fault, in accordance with oximeter information communicated from the ResLink to the flow generator. See, e.g., ResLink User's Manual (RMD-063203) at 10, 14; [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

168. The ResLink “collects and stores Summary and Detailed data,” including data from the AutoSet Spirit, and stores that data on the SmartMedia Card. See, e.g., ResLink Clinician's Guide (RMD-063198) at 63200 (“In addition to the comprehensive set of data available in the flow generator, the RESLINK collects and stores *Detailed Data*.”); [REDACTED]

[REDACTED] ResMed documentation instructs that, “[a]fter 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.” ResLink Clinician's Guide (RMD-063198) at 63200. The *Detailed Data* collected by the ResLink and available for display on the AutoScan software (discussed in more detail below) include the following:

The Pulse rate and SpO₂ 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 ₂ O	-5–40 cmH ₂ O	0.5
Snore	n/a	Quiet–Loud	per breath
Flattening	n/a	Round–Flat	per breath

ResLink Clinician's Guide (RMD-063198) at 63200; see also ResLink Launch Brochure (RMD-

[REDACTED]

289749) at 289751 (“ResLink reports on significant parameters such as minute ventilation, snore, flattening, SpO₂, pulse rate, pressure response, leak, events, and AHI, providing visible insights into treatment efficacy”), 289753 (showing screenshot of AutoScan software); [REDACTED]

[REDACTED]

169. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

170. The ResLink includes a microprocessor, firmware and associated hardware to enable write functions to the SmartMedia Card. [REDACTED]

171. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

172. Details of the Nonin Xpod oximeter are [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

5. AutoSet Spirit (“[REDACTED]”) Operation and Software (Source Code)

173. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

174. The AutoSet Spirit has a CPAP mode and an AutoSet mode. *See, e.g.*, AutoSet Spirit Clinician’s Manual at 1 , 7-9, 33; [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] “The continuous air stream ‘splints’ open the upper airway, preventing airway collapse.” AutoSet Spirit Clinician’s Manual at 7.

175. A patient may require that treatment pressure vary due to changes in sleep state, body position, and airway resistance. AutoSet Spirit Clinician’s Manual at 7. The AutoSet Spirit’s **AutoSet mode** “provides only sufficient pressure to maintain upper airway patency.” AutoSet Spirit Clinician’s Manual at 7, *see also* 1. For the AutoSet Mode, the AutoSet Spirit uses feedback from the sensors and programmed algorithms to adjust the treatment pressure in

[REDACTED]

real time as the subject is using the device. ResMed documentation describes the AutoSet Mode as follows (I note that the description of the “flow sensor,” “pressure sensor,” and “pressure transducer” in the Clinician’s Manuals include the signals from the sensors and also the estimations by the microprocessor):

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.

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.

Open unrestricted airway

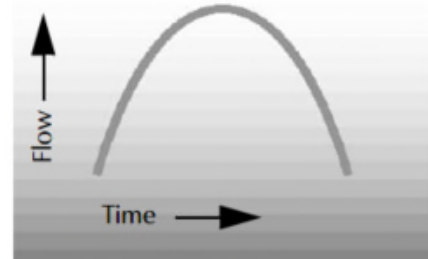
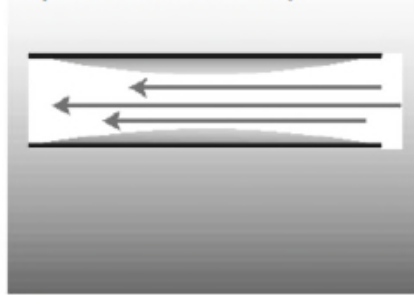


Figure 1: Inspiratory flow-time curve for an unrestricted airway

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

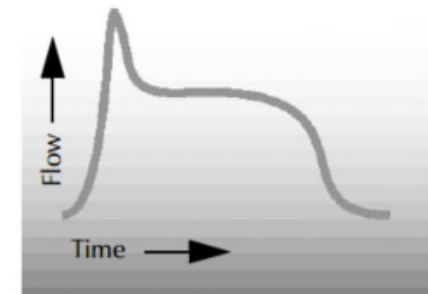
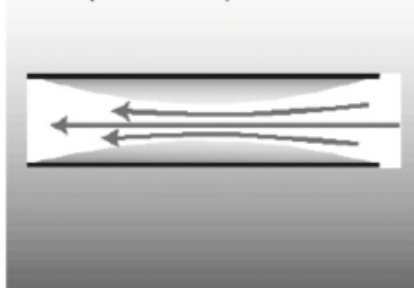


Figure 2: Inspiratory flow/time curve for a partially obstructed airway

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.

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.

Noisy partial airway obstruction

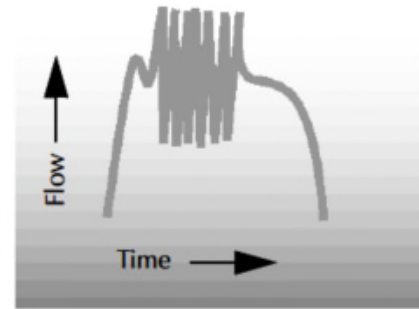
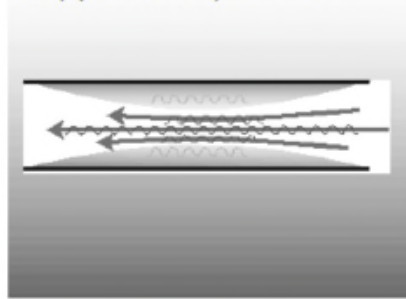


Figure 3: Inspiratory flow/time curve affected by snore

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 H₂O 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 H₂O 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 H₂O. 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.

AutoSet Spirit Clinician's Manual at 7-9; see also

[REDACTED]

[REDACTED]

[REDACTED]

AutoScan 5.4 Clinician's Manual (RMD-311263) at 57-58.

176. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

177. The data output or displayed on the AutoSet Spirit menus include: usage, apnea index (calculated per session), hypopnea index (calculated per session), apnea-hypopnea index (AHI)(calculated per session), 95th percentile leak, 95th percentile pressure (medians for weekly, monthly, 6 monthly and yearly). *See, e.g.,* AutoSet Spirit Clinician's Manual at 31, 38-39, 40 (showing menu series), 41 (statistics are provided for five time intervals (e.g., last day, last week), and statistics calculated are median values); [REDACTED]

[REDACTED]

178. The AutoSet Spirit Clinician's Manual provides the following description of the calculation of Pressure and Leak:

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.

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.

AutoSet Spirit Clinician's Manual at 37 ("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)").

179. The details of how various parameters or statistics are calculated, determined, or

██████████ I have reviewed the expert report of Jing Hu that summarizes her analysis of the AutoSet Spirit flow generator, ResLink (██████████) and ResTraxx (██████████) and CommServer) source code. I also personally reviewed the source code. I agree with and adopt Dr. Hu's analysis, rely on it, in part, for my opinions, in addition to my own independent analysis of the ResMed Prior Art product information (including source code, schematics, and documentation identified herein). I incorporate and cite to exemplary and relevant sections of Dr. Hu's analysis below and in my element-by-element analysis of the Asserted Claims.

[illegible]

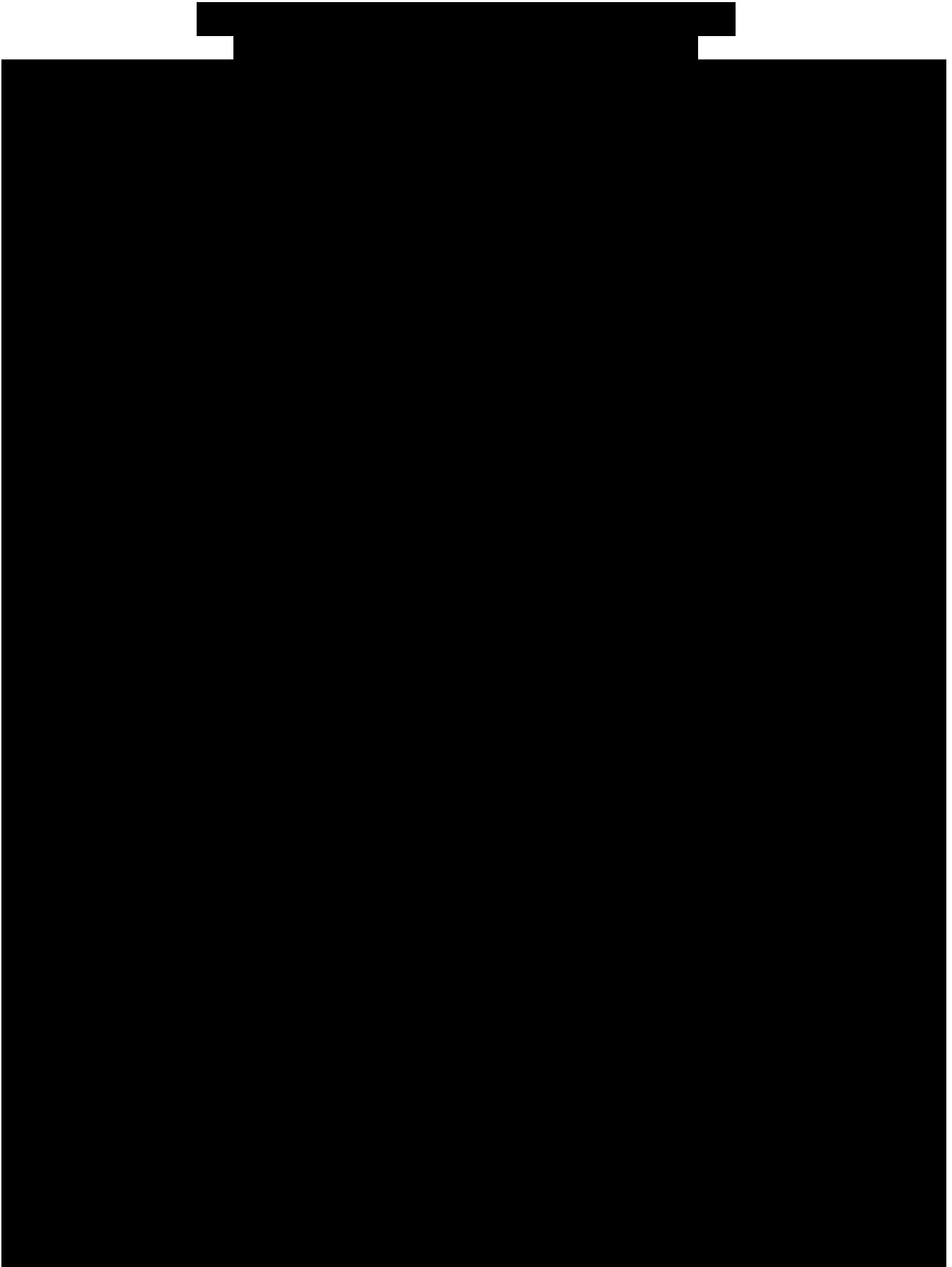
[REDACTED]

[REDACTED]

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[REDACTED]

6. AutoScan 5 Software (RPA System 1)

214. AutoScan is software provided by ResMed that is run on a clinician's computer to transfer and view data collected by a ResMed flow generator. ResMed provided the software on CD-ROM that was used to install the software on the clinician's computer. *See, e.g.,* AutoScan 5.4 Clinician's Manual (RMD-311263) at 7-8; [REDACTED]

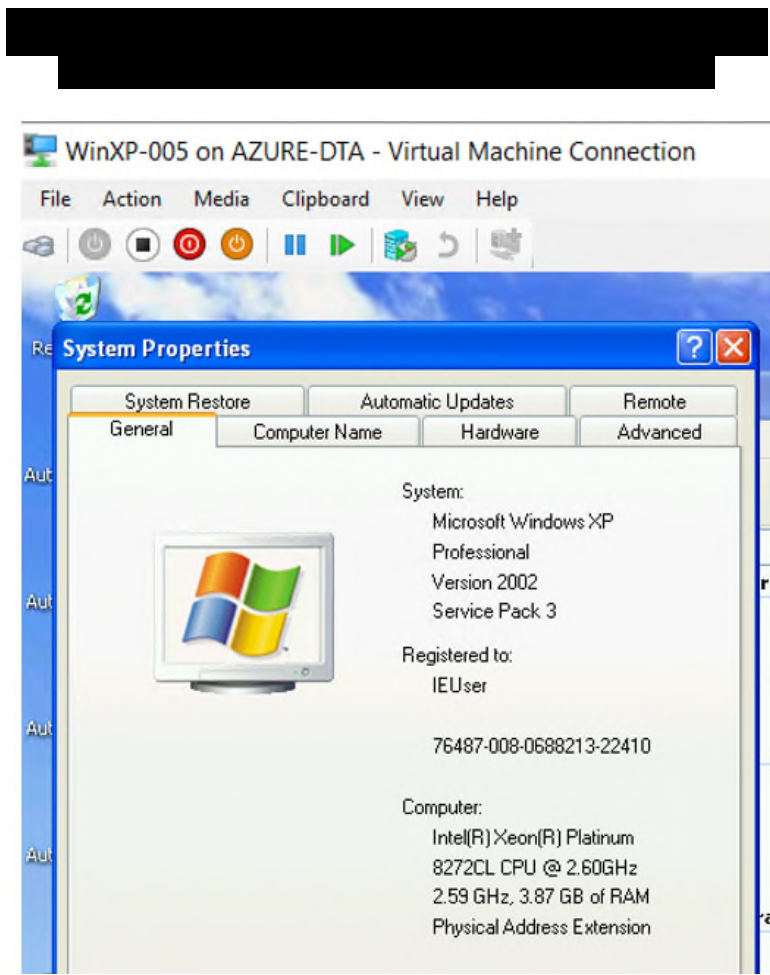
[REDACTED]

[REDACTED]

[REDACTED] The Clinician's Manuals for the software provide the "minimum computer requirements in order to configure the system and to transfer and print the stored data." *See* AutoScan 5.4 Clinician's Manual (RMD-311263) at 7-8.

215. I inspected the AutoScan 5.4 software running on a virtual machine that emulated a Windows XP operating system. I navigated the help screens and tabs, loaded sample data,, for example, and confirmed the information provided therein was consistent with the information provided in the Clinician's Manuals for the respective software versions, including the ability to "download" data from a flow generator via a modem connected to the flow generator, the ability to print reports, and the ability to send a patient file via email.

[REDACTED]



RMD-0318346 at 0318346.



RMD-0318346 at 0318349.

216. The AutoScan 5.4 documentation describes that “AutoScan 5.4 has data collection and management capabilities that provide an adjunct for patient management,” that “AutoScan

[REDACTED]

5.4 has been developed to view summary data and detailed data obtained from the ResLink,” and that “flow generator systems intended to be used with AutoScan 5.4 are the ResMed AutoSet Spirit, S7 Elite, ...” AutoScan 5.4 Clinician’s Manual (RMD-311263) at 1. The AutoScan 5.4 Clinician’s Manual informs that “Summary data and Night profile data obtained from the flow generator can also be viewed as in previous versions of AutoScan. AutoScan 5.4 Clinician’s Manual (RMD-311263) at 1; [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

217. Cable Connection. One method of downloading data from the flow generator to the clinician’s computer running the AutoScan software is to use a direct cable connection (RS232/serial interface) between the computer and the flow generator. *See, e.g.*, AutoScan 5.4 Clinician’s Manual (RMD-311263) at 3, 9-10.

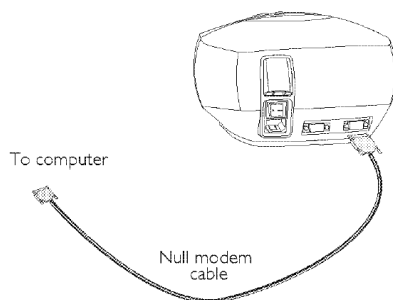


Figure 2: Connecting the flow generator to the computer

AutoScan 5.4 Clinician’s Manual (RMD-311263) at 10.

218. Modem Connection. A second method of downloading data from the AutoSet Spirit to the clinician’s computer running the AutoScan 5.4 software is to use a modem connected to the flow generator’s RS232 (serial) port, and a modem connected to or internal to the clinician’s computer. AutoScan 5.4 Clinician’s Manual (RMD-311263) at 2, 11-23, 66

[REDACTED]

[REDACTED]

(“Modem Instructions For the Patient”); AutoSet Spirit Clinician’s Manual (RMD-063968) at 42.

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.

1. Ensure that both modems have been set up correctly (see “Configuring the modems” on page 18).
2. The patient’s modem should be:
 - Connected to the modem port on the flow generator using a Straight through modem cable (Figure 10).
 - Turned on. The power for the flow generator should also be turned on using the power switch at the back of the unit.
 - Connected to a phone line. Be sure to use the correct socket on the modem if there is more than one (it is often labelled “line”).

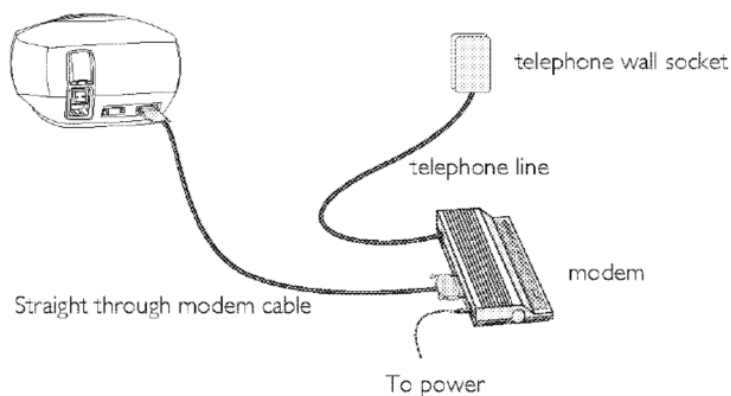
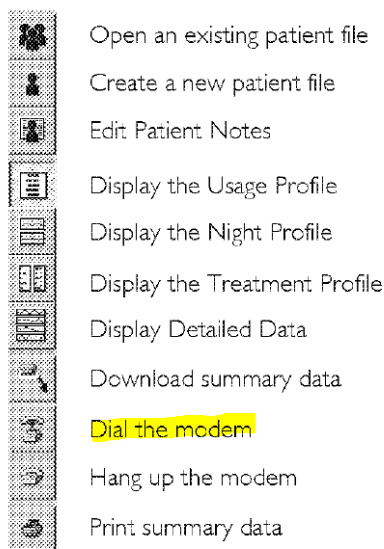


Figure 10: The patient’s flow generator connected to a modem

AutoScan 5.4 Clinician’s Manual (RMD-311263) at 22.

The toolbar:



AutoScan 5.4 Clinician’s Manual (RMD-311263) at 5.

[REDACTED]

219. Card Storage. The third method of importing data collected by a flow generator to a clinician's computer running the AutoScan software is by storing data on a SmartMedia Card in the ResLink attached to the AutoSet Spirit flow generator, and using a card reader at the clinician's computer to download the data from the card to the clinician's computer running the AutoScan 5.4. *See, e.g.*, AutoScan 5.4 Clinician's Manual (RMD-311263) at 1-4, 7-8, 27, 33-34 (Detailed Data), 39, 45-47 (Summary Data); ResLink User's Manual (RMD-063203) at 5-6; ResLink Launch Brochure (RMD-289749) at 289751; [REDACTED]

220. The AutoSet Spirit Clinician's Manual describes that "[d]ata 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.

AutoSet Spirit Clinician's Manual (RMD-063968) at 42.

221. "Summary Data" and "Night Profile Data" are downloaded from the AutoSet Spirit to a clinician's computer running the AutoScan 5.4 using either the cable or modem methods identified above. *See, e.g.*, AutoScan 5.4 Clinician's Manual (RMD-311263) at 2-4, 27, 45-47 ("data currently stored in the flow generator will download to your computer"); [REDACTED]

[REDACTED] Summary Data is also downloaded from the ResLink via the SmartMedia card. AutoScan 5.4 Clinician's Manual (RMD-311263) at 33, 47.

222. In AutoScan, the Summary Data can be viewed in the following AutoScan

screens: Usage Profile, Treatment Profile, Night Profile, and Statistics. AutoScan 5.4 Clinician's Manual (RMD-311263) at 41-42, 47-48. The software can be used to "view a specific range of dates." AutoScan 5.4 Clinician's Manual (RMD-311263) at 41, 43, 48.

223. The **Usage Profile** provides the dates and times spent in therapy for up to 365 nights, the mode in which data was collected (CPAP or Auto) and displays mask-on time plotted as a solid bar, and mask-off time as gaps in the bar. AutoScan 5.4 Clinician's Manual (RMD-311263) at 48-49.

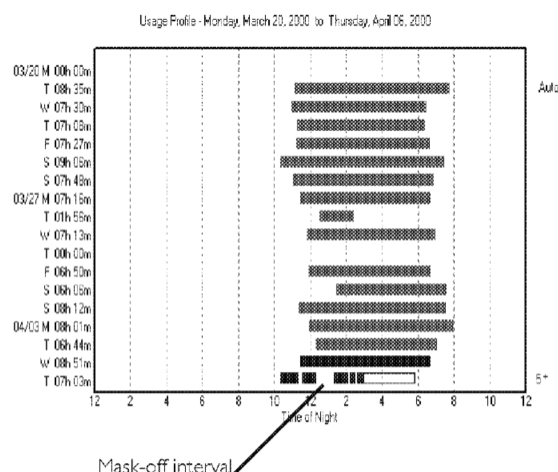


Figure 33: Usage profile detail

AutoScan 5.4 Clinician's Manual (RMD-311263) at 49.

224. The **Treatment Profile** displays pressure, leak, apnea indices, and apnea/hypopnea indices for up to 365 nights, plotted as horizontal bar graphs by session. AutoScan 5.4 Clinician's Manual (RMD-311263) at 50-51.

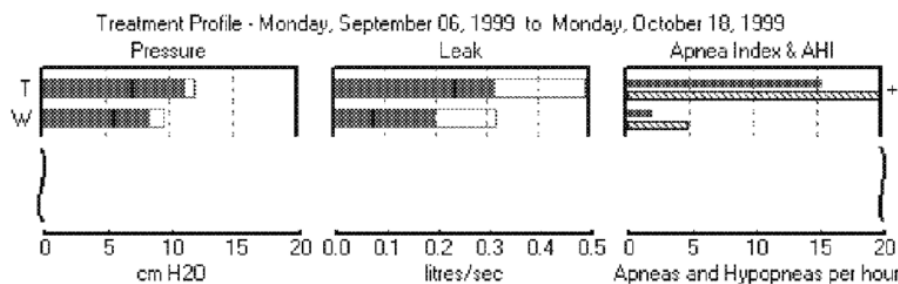


Figure 35: Treatment Profile detail with AHI value out of range

AutoScan 5.4 Clinician's Manual (RMD-311263) at 51.

225. The **Night Profile** screen "displays pressure and leak data, apnea time and

duration, and hourly apnea/hypopnea totals for one night” plotted in three graphs as a function of time. AutoScan 5.4 Clinician’s Manual (RMD-311263) at 51.

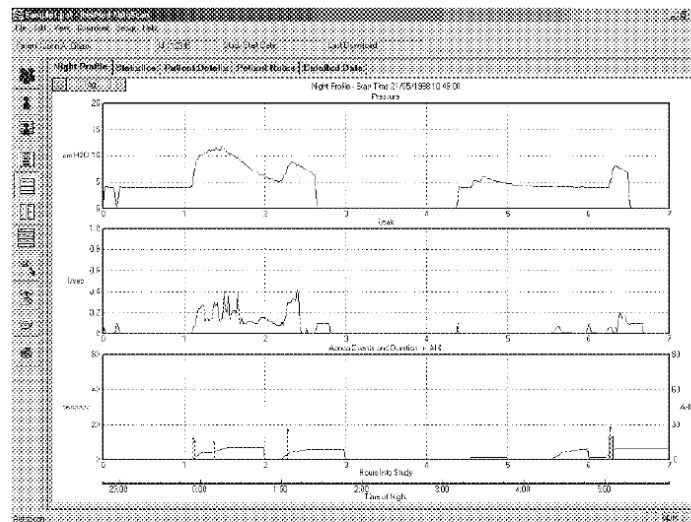


Figure 36: Night Profile display

AutoScan 5.4 Clinician’s Manual (RMD-311263) at 52.

226. The following information is displayed on the **Statistics** tab:

AUTOSET SPIRIT AND S7 ELITE STATISTICS

IN THE PERIOD SECTION

- **Last:** Displays the viewing interval (custom, last day, week, month, 3 months, 6 months, 1 year) selected from the drop down list.
- **Dynamic Date Display:** Displays the date range selected using the Navigation Panel lasso. If this method is used to select the viewing interval, the word “Custom” will appear in the Last drop down box.

IN THE USAGE SECTION

- **Total hrs:** The total number of hours of usage in the data set from the first date of the selected range to the last date.
- **Hrs/day:** The median hours/day the device was used during the selected range. Days when the device was not used are not included in the calculation.
- **Used:** Total days used within the selected range.
- **Non used:** Total days not used within the selected range.
- **% Days Used:** Percentage days used within the selected range.

[REDACTED]

IN THE TREATMENT SECTION
PRESSURE

- **95th Percentile:** The pressure level, in cm H₂O, exceeded during the selected range for 5% of the time.
- **Median:** The median pressure level, in cm H₂O, delivered during the selected range.
- **Maximum:** The highest pressure level, in cm H₂O, delivered during the selected range.

LEAK

- **95th Percentile:** The leak level, in L/sec, exceeded during the selected range for 5% of the time.
- **Median:** The median leak level, in L/sec, recorded during the selected range.
- **Maximum:** The maximum leak level, in L/sec, recorded during the selected range.

IN THE EVENTS SECTION

- **AHI:** The AHI (apnea + hypopnea index) is the total number of apneas + hypopneas that occurred during the selected range divided by the total mask-on time.
- **AI:** The AI (Apnea Index) is the total number of apneas that occurred during the selected range divided by the total mask-on time.
- **HI:** The HI (Hypopnea Index) is the total number of hypopneas that occurred during the selected range divided by the total mask-on time.
- **Time in Apnea:** The time, given as a percentage of mask-on time, during which the patient experienced apneic episodes.

IN THE SETTINGS SECTION

- **Maximum Pressure:** The maximum pressure, in cm H₂O, set in Autoset mode.
- **Minimum Pressure:** The minimum pressure, in cm H₂O, set in Autoset mode.
- **Pressure:** The pressure, in cm H₂O, set in CPAP mode.
- **Mode:** This is the mode in which the unit operated during the treatment sessions. Options for the **AUTOSET SPIRIT** are: *CPAP* in which the supplied pressure is constant and set by the clinician and *AutoSet* in which the CPAP pressure is adjusted automatically. The mode is *CPAP* for an **S7 ELITE** unit.

AutoScan 5.4 Clinician's Manual (RMD-311263) at 53-55.

227. As discussed above, for the AutoSet Spirit, "Detailed and summary data from a patient's flow generator are stored on a SmartMedia card by the ResLink," and the 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." AutoScan 5.4 Clinician's Manual (RMD-311263) at 33; [REDACTED]

[REDACTED]

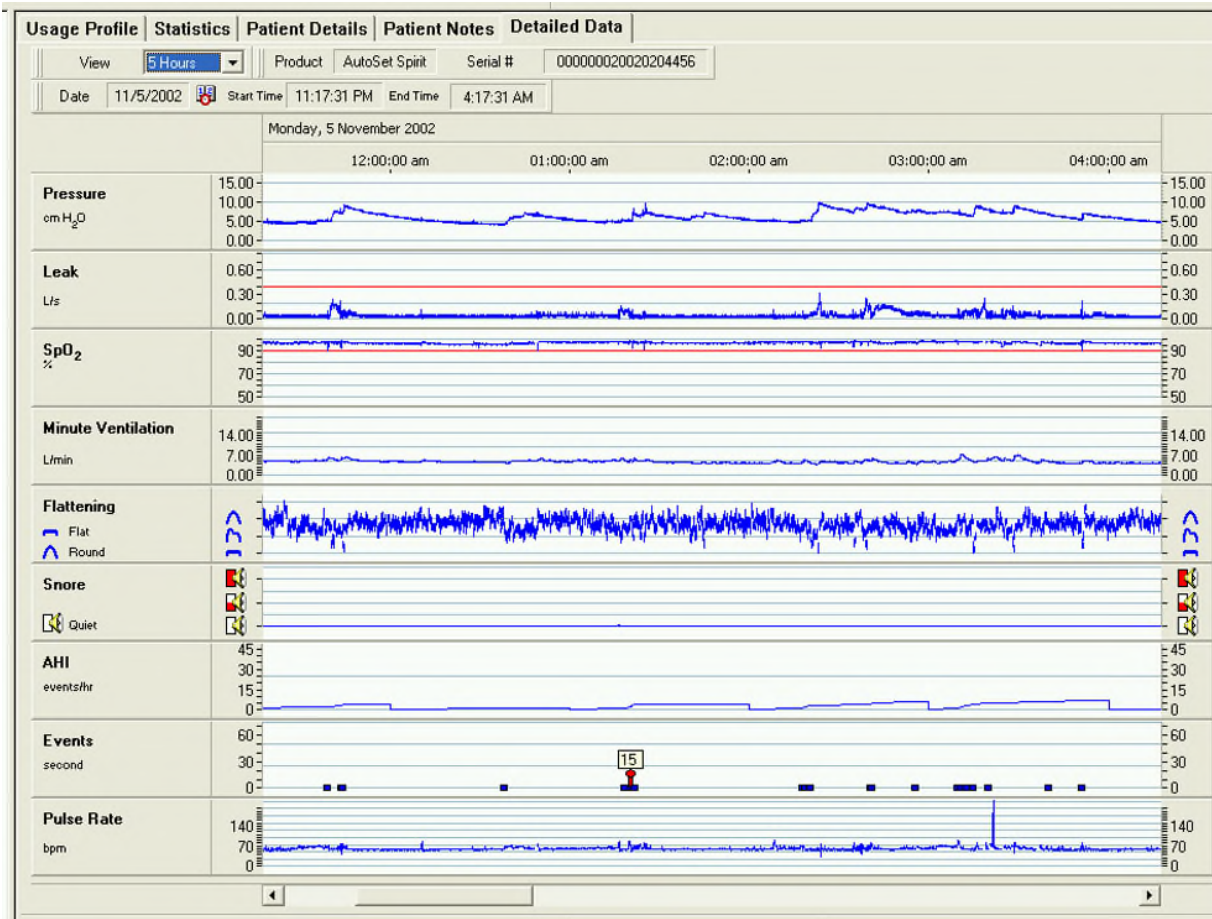
[REDACTED]

228. The “Detailed Data Screen” of AutoScan “displays nine traces of data downloaded via the ResLink from the flow generator.” AutoScan 5.4 Clinician’s Manual (RMD-311263) at 35. The graph shows traces for the following data for AutoSet Spirit:⁷⁵

- Events (s)
- Minute Ventilation (L/min)
- Leak (L/s)
- Pulse Rate (bpm)
- SpO₂ (%)
- AHI (Events/hr)
- Pressure (cm H₂O)
- Snore (Quiet to Loud)
- Flattening (Round to Flat)

AutoScan 5.4 Clinician’s Manual (RMD-311263) at 35-36, 67 (e.g., showing Flattening index graph).

⁷⁵ The Clinician’s Manuals advise that the Snore and Flattening Index parameters are reported for AutoSet Spirit only. AutoScan 5.4 Clinician’s Manual (RMD-311263) at 35-36



RMD-0318346 ResMed Prior Art – Virtual Machine and AutoScan 5.4 Screenshots at 0318369 (showing Detailed Data tab and the ability to display “SpO2” and “Pulse Rate”).

229. The scale for the data can be adjusted. AutoScan 5.4 Clinician’s Manual (RMD-311263) at 37.

230. Reports. The AutoScan software can also be used to “generate and print reports.” 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]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The AutoScan 5.4 software can also be used to “send an email with the currently open patient file as an attachment ...” AutoScan 5.4 Clinician’s Manual (RMD-311263) at 25-26; [REDACTED]

[REDACTED]

[REDACTED]

7. **ResTraxx Module (“[REDACTED]” and ResTraxx Data Center (a.k.a. [REDACTED])⁷⁶ (RPA System 2)**

231. RPA System 2 comprises the AutoSet Spirit flow generator and the ResTraxx system. I understand that RPA System 3 with the ResTraxx system [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

232. The ResTraxx system was described as a “first-of-its-kind wireless communication device that attaches easily to the back of ResMed flow generators” to provide the

[REDACTED]

[REDACTED]

“ResTraxx system [that] captures, transfers, and stores compliance and efficacy data without wires, phone lines, modems, or data cards.” ResTraxx Patient Management Brochure (RMD-063327) at 1-2. Shown below on the left is the ResTraxx module or device that provides wireless communication capability to the flow generator, and the picture on the right illustrates the module mounted to the back of a flow generator.



ResTraxx Patient Management Brochure (RMD-063327) at 1; *see also* ResTraxx Wireless Patient Monitoring Atlas (RMD-063341); RMD-0318396 ResMed Prior Art – Physical Specimen Photographs at 0318410 (showing ResTraxx module ([REDACTED]) mounted to AutoSet Spirit flow generator (PAP device), *see also* 0318409.

233. The ResTraxx module was referred to as “[REDACTED]” or “[REDACTED]” (“Resmed Communications Access Module”) and included the electronics to provide wireless communication capabilities from the AutoSet Spirit ([REDACTED]) flow generator over a pager network: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Similar to the ResLink module, the [REDACTED] attached to the back of the AutoSet Spirit flow generator by engaging a notch in the back of the flow generator and

[REDACTED]

connecting to the flow generator's auxiliary port. *See, e.g.,* ResTraxx Quick Reference Guide (RMD-062642) at 1; RDC User's Manual (RMD-306688) at 5-6 ("System Requirements");

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

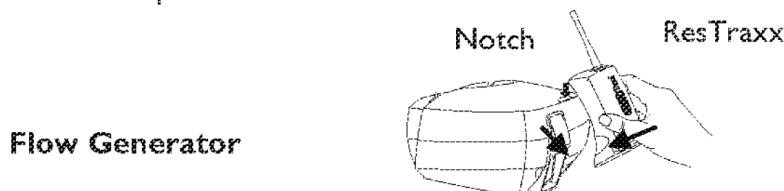
[REDACTED]

[REDACTED]

[REDACTED]

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.

ResTraxx Quick Reference Guide (RMD-062642) at 1; *see also* RDC User's Manual (RMD-306688) at 24-25.

234. [REDACTED] when attached to the AutoSet Spirit flow generator, wirelessly transfers "data from the flow generator through a nationwide message network to a database in a centralized server where it is available to customers via the internet," where the "ResTraxx Data Center system provides the software that enables the transmission and storage of usage data through the ResTraxx." RDC User's Manual (RMD-306688) at 5; *see also* [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

235. ResTraxx Data Center (RDC) “is a wireless, web-based, 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.” RDC User’s Manual (RMD-306688) at 4. The RDC manual describes that the “data collected with this application facilitates timely patient intervention and optimizes patient acceptance of treatment.” RDC User’s Manual (RMD-306688) at 4.

236. The RDC User’s Manual provides the following diagram of the ResTraxx system:

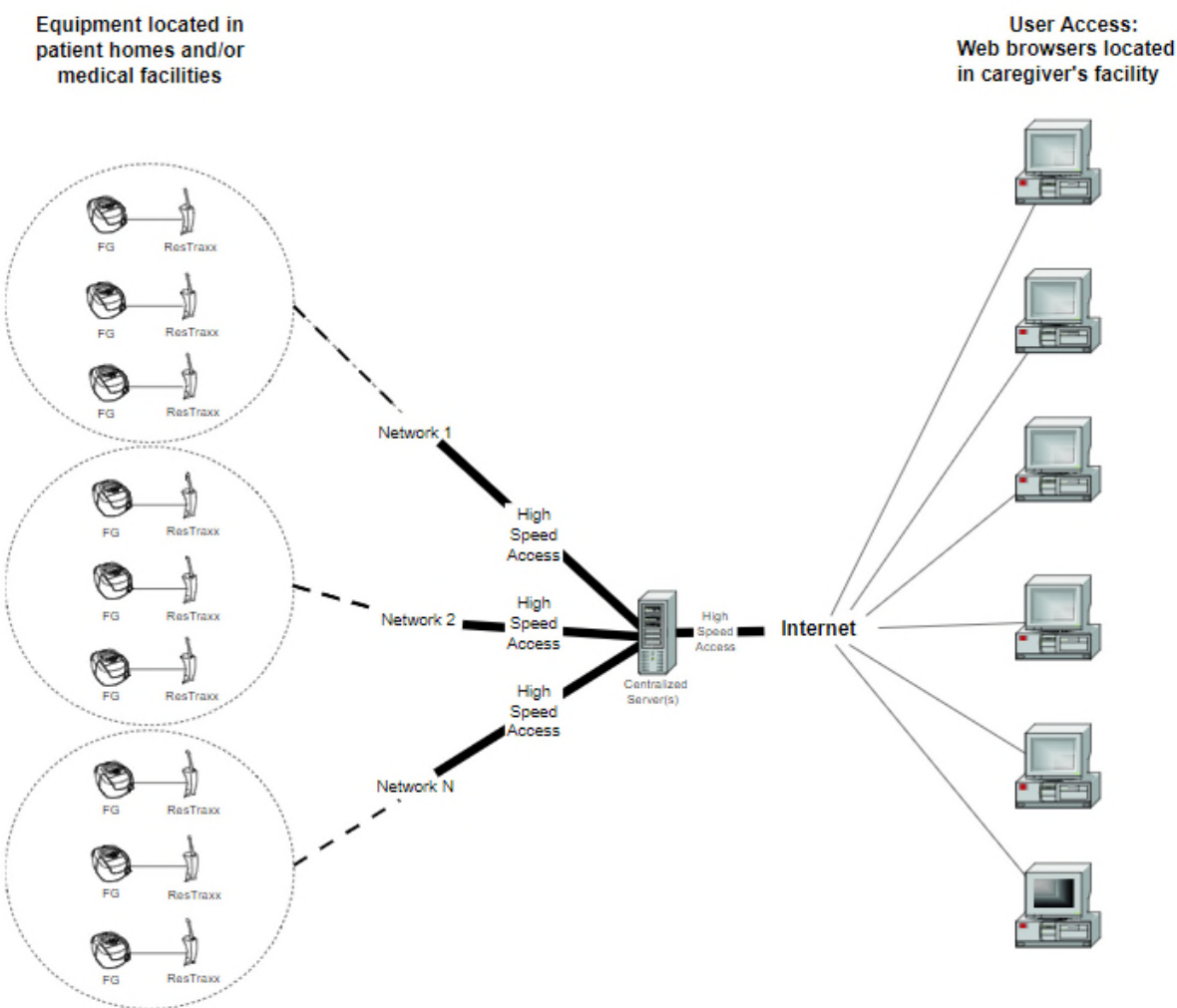


Figure 1: System configuration

[REDACTED]

RDC User's Manual (RMD-306688) at 5.

237. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

242. The RDC web application is used to schedule the retrieval of data from flow generators according to a “monitoring schedule.” RDC User’s Manual (RMD-306688) at 10, 15;

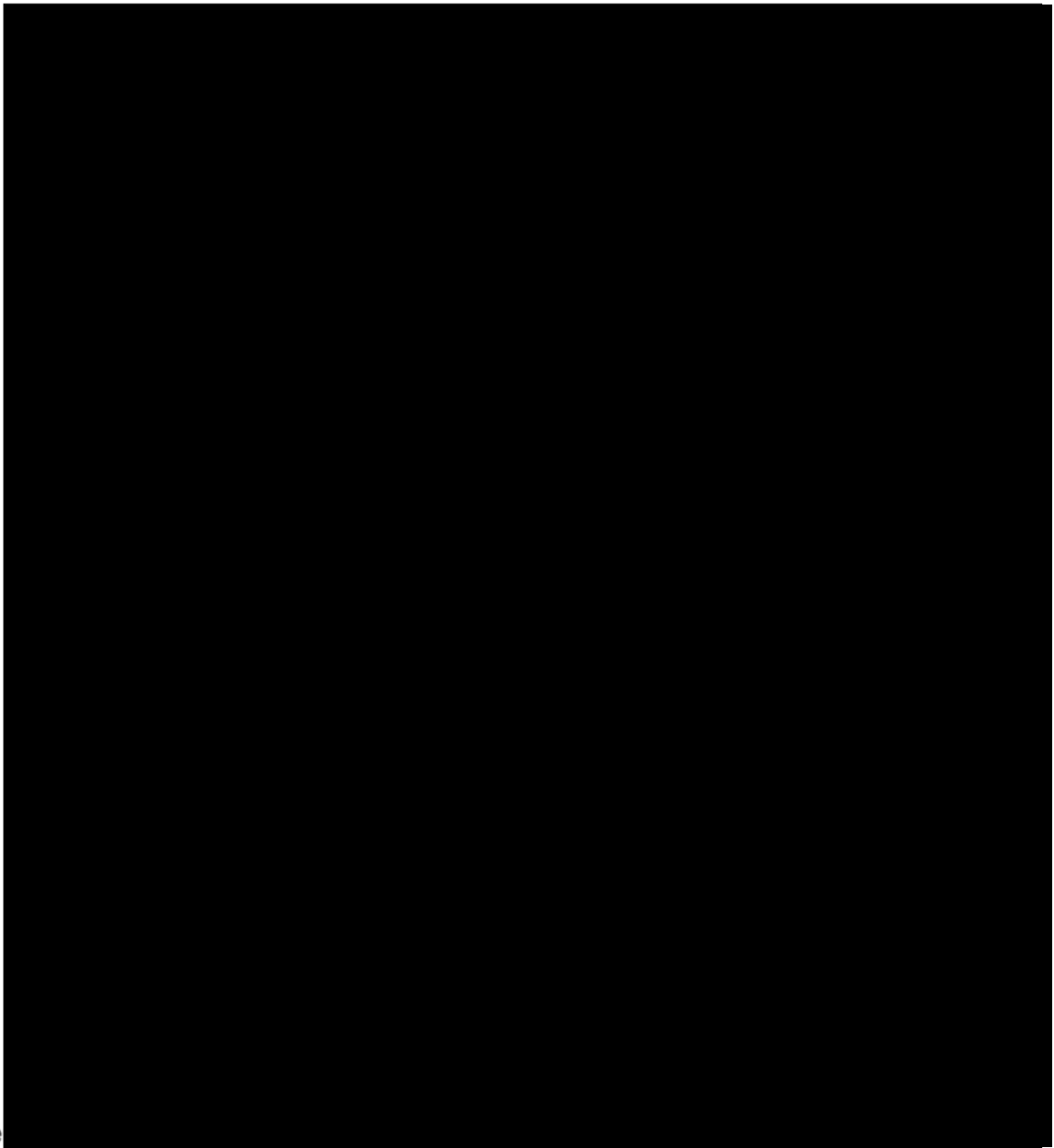
[REDACTED]

[REDACTED] Data is transferred either daily or historically by the [REDACTED] to the centralized server. *See, e.g.*, ResTraxx Patient Management Brochure (RMD-063327) at 2.

243. The RDC [REDACTED]

[REDACTED]

[REDACTED]



Figure

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

245. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[Redacted]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

251. In practice, a healthcare provider user accesses the RDC application using a computer with a web browser, and by navigating to the RDC login page (<https://connect.resmed.com>). *See, e.g.*, [REDACTED] RDC User's Manual (RMD-306688) at 8-9, 27 (Windows XP, Microsoft Internet Explorer 6.0); ResTraxx Wireless Patient Monitoring Atlas (RMD-063341) at 63343-48. Below is a flow diagram illustrating the elements of the RDC web application:

[REDACTED]



252. The data stored on the AutoSet Spirit flow generator and transmitted by the [REDACTED] to the RDC web components ([REDACTED]) are presented by the web server's user interface components in two user interface screens: (1) a "Patient Usage History Report" or "compliance" history displayed in calendar format as shown below, where the different colored boxes provided an easily viewable mechanism to identify days that that were out of compliance or otherwise might require review, and (2) Patient Therapeutic History Report.

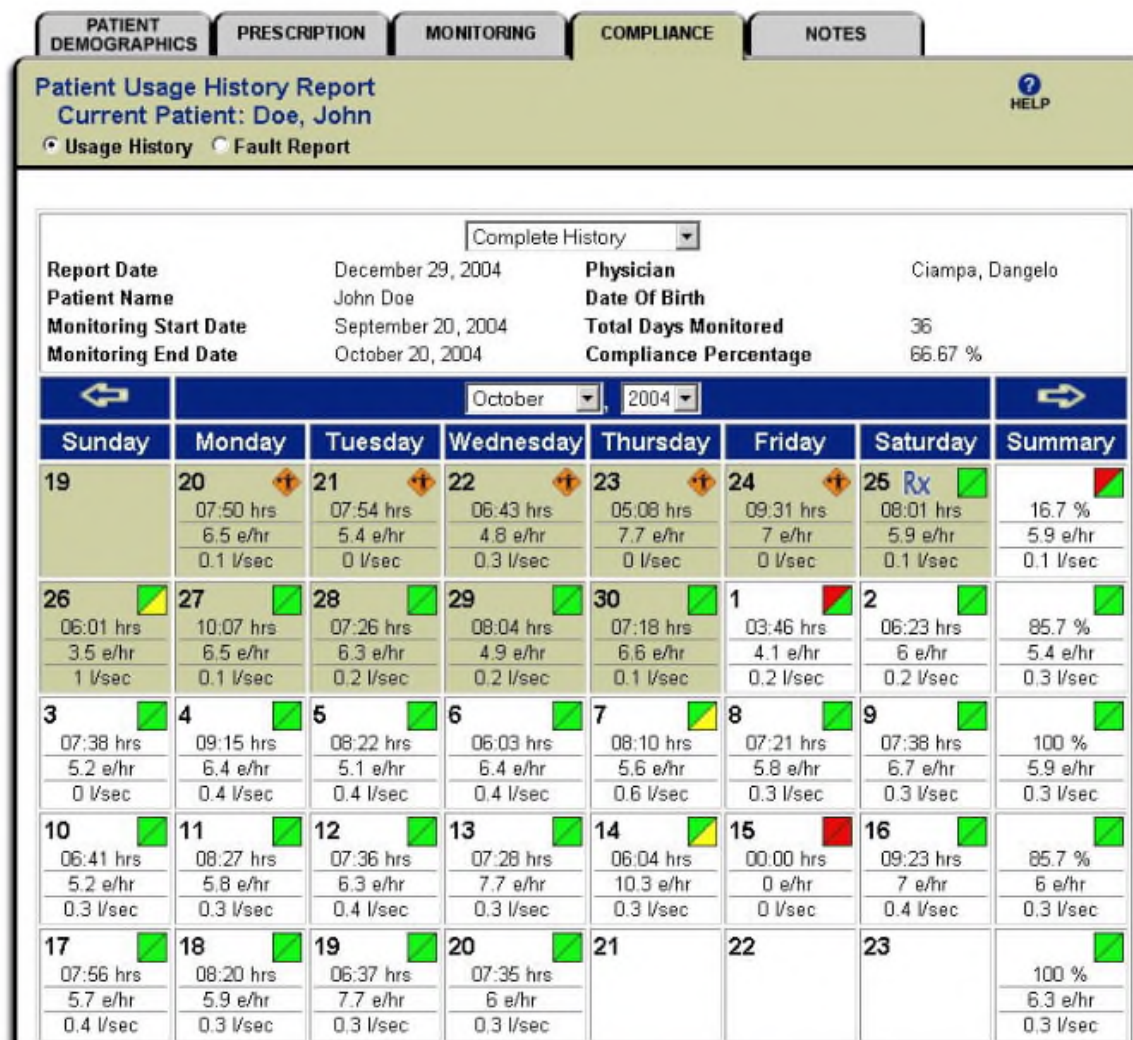


Figure 22: Patient Compliance calendar

RDC User's Manual (RMD-306688) at 16; *see also* ResTraxx Patient Management Brochure (RMD-063327) at 3; [Redacted]

[Redacted] The compliance calendar shows “daily and weekly summary results indicating: actual usage (in hour format), color graphic symbols indicating the patient’s compliance, leak, and AHI compared to the prescription.” RDC User's Manual (RMD-306688) at 16; *see also* ResTraxx Patient Management Brochure (RMD-063327) at 3; ResTraxx Wireless Patient Monitoring Atlas (RMD-063341) at 063358-63.

Usage, Leak, and Apnea/Hypopnea Index (AHI) data are displayed graphically, using the following coding.

-  The patient is compliant and the AHI is less than or equal to the AHI threshold and the leak is less than or equal to the leak threshold.
-  The patient is compliant but the AHI is greater than the AHI threshold and/or the leak is greater than the leak threshold.
-  The patient is not compliant but the AHI is less than or equal to the AHI Threshold and the leak is less than or equal to the leak threshold.
-  The patient is not compliant and the AHI is greater than the AHI Threshold and/or the leak is greater than the leak threshold.
-  The flow generator was plugged in and turned on but the patient did not initiate treatment.
-  There was no compliance information in the flow generator for this patient on this day.

Figure 23: Compliance coding

RDC User's Manual (RMD-306688) at 16; *see also* ResTraxx Patient Management Brochure (RMD-063327) at 3; [REDACTED]

253. The "Patient Therapeutic History Report" shows a specific day of compliance data. RDC User's Manual (RMD-306688) at 16-17.

[REDACTED]

PATIENT DEMOGRAPHICS		PRESCRIPTION		MONITORING		COMPLIANCE		NOTES																	
Patient Therapeutic History Report Current Patient: Luv, Har PRINT HELP 																									
⏪ October 1, 2004 ⏩																									
Complete History <table style="width: 100%; border: none;"> <tr> <td style="width: 25%;">Report Date</td> <td style="width: 25%;">December 29, 2004</td> <td style="width: 25%;">HCP</td> <td style="width: 25%;">P'Simer, Donley R</td> </tr> <tr> <td>Patient Name</td> <td>Har Luv</td> <td>Date Of Birth</td> <td></td> </tr> <tr> <td>Monitoring Start Date</td> <td>September 20, 2004</td> <td>Total Days Monitored</td> <td>36</td> </tr> <tr> <td>Monitoring End Date</td> <td>October 20, 2004</td> <td>Compliance Percentage</td> <td>66.67 %</td> </tr> </table>										Report Date	December 29, 2004	HCP	P'Simer, Donley R	Patient Name	Har Luv	Date Of Birth		Monitoring Start Date	September 20, 2004	Total Days Monitored	36	Monitoring End Date	October 20, 2004	Compliance Percentage	66.67 %
Report Date	December 29, 2004	HCP	P'Simer, Donley R																						
Patient Name	Har Luv	Date Of Birth																							
Monitoring Start Date	September 20, 2004	Total Days Monitored	36																						
Monitoring End Date	October 20, 2004	Compliance Percentage	66.67 %																						
Prescription																									
Product Mode		Autotitrating																							
Usage Threshold		05:00 hrs																							
AHI Threshold		10 e/hr																							
Leak Threshold		0.4 l/sec																							
Compliance Data																									
Mask On Time		03:46 hrs																							
CPAP Pressure Setting		12.0 cmH2O																							
Minimum Pressure Setting		4.0 cmH2O																							
Maximum Pressure Setting		20.0 cmH2O																							
Hypopnea Index		3.9																							
Apnea Index		0.2																							
Apnea Percentage		0.0%																							
Air Flow Data																									
	Median	95th Percentile	Maximum																						
Pressure	12 cmH2O	12.2 cmH2O	12.4 cmH2O																						
Leak	0.04 l/sec	0.16 l/sec	0.6 l/sec																						
Mask Events																									
Time	Event Type																								
11:05 PM	MaskOn																								
3:00 AM	MaskOff																								

Figure 25: Patient Therapeutic History Report by day

RDC User's Manual (RMD-306688) at 17; ResTraxx Wireless Patient Monitoring Atlas (RMD-063341) at 063364-65; [REDACTED]

[REDACTED] The Patient Therapeutic History Report displays the following data calculated and stored by the flow generator and transmitted by the [REDACTED] to RDC:

- Compliance Data: Mask On Time, CPAP Pressure Setting, Minimum Pressure Setting, Maximum Pressure Setting, Hypopnea Index, Apnea Index, and Apnea Percentage;
- Air Flow Data: median, 95th percentile, and maximum pressure and leak values
- Mask Events: time of MaskOn and time of MaskOff

RDC User's Manual (RMD-306688) at 17; *see also* D [REDACTED]

[REDACTED]

[REDACTED]

8. Supplemental Oxygen

254. Documentation for the AutoSet Spirit describes that the flow generator could be used with supplemental oxygen:

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.*

Spirit/S7 O2 Update (RMD-307134) at 1.

255. Also, the documentation for the masks identified above for use with the AutoSet Spirit contemplates use with supplemental oxygen through a port in the mask (see, e.g., drawings of the masks showing ports):

- “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.” Mirage Mask User Instructions (RMD-271110) at 6.
- “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.” Mirage Full Face Mask Series 2 User Instructions (RMD-271027) at 15.
- “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.” Ultra Mirage Full Face Mask User’s Guide (RMD-271159) at 2.

B. Additional Prior Art and State of the Art Overview

256. 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 March 2005 alleged conception date of

[REDACTED]

the '269 patent.⁸³ 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 admits that such features were well known to a POSITA.

257. 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.

258. 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 RPA discussed herein, 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 Janet Hilbert, *Continuous positive airway pressure: new generations*, Clin. Chest Med. 24, 2003, at 315-342 (“Roux”), Table 3.

259. [REDACTED]

[REDACTED]

⁸³ See CleveMed Responses to ResMed Interrogatory No. 2.

[REDACTED]

[REDACTED]

1. Airflow and Pulse Oximeter Sensors

261. Claim 8 simply recites a “physiological sensor,” dependent claim 9 recites a pulse oximeter sensor, claim 15 requires an “airflow sensor,” and claims 1 and 5 recite both an airflow sensor and a pulse oximeter sensor. 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.

a. Airflow sensor configuration and placement

262. The ’269 patent does not identify any preference for the type of airflow sensor (nor do the asserted claims), e.g., amongst those listed above and in the ’269 patent specification,

[REDACTED]

and fails to suggest any specific reason or advantage for selecting a pulse oximeter to use in combination with an internal airflow 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 admits, 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 admits, 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 simple design choice.

263. As known in the art, and disclosed, for example, by Farrell, PAP devices typically included a number of sensors to detect air flow and pressure as feedback to the system to adjust the pressure of treatment provided to the patient, and also oximeters, such as pulse oximeter, to detect oxygenation. *See, e.g.*, WO 2005-096737 (“Farrell”), 5:31-6:5 (pulse oximeter). As another example, Mechlenburg describes, as was known in the art, 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 vice 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].

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

[REDACTED]

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.” US 2002/0022973 (“Sun”), [0060]; *see also* US 2001/0018557 (“Lynn”), ¶¶24-25, 33, 54-56; US 8,069,852 (“Burton”), 5:53-6:4. Sun discloses a flow sensor internal to the PAP device in an almost identical manner as that shown in Figure 7 of the ’269 patent. *See, e.g.*, Sun at FIG. 4 (flow sensor 63). And the ’269 patent admitted that prior art PAP devices included internal flow sensors, e.g., for “measuring gas flow through the device.” ’269 patent, 2:17-25.

265. 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 (incorporated by reference in Farrell) 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 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. Truitt also recognized the variability in design choice for placement and design of the flow sensor. Truitt, 3:21-36, 7:56-12. 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 well-known in the prior art and disclosed, for example, in Berthon-Jones at column 8, lines 31-62 and Truitt at 2:1-42, 6:1-47.

b. Pulse oximeters and oxygenation data

266. A POSITA would have been aware that polysymnography (PSG) was the “gold standard” for the diagnosis of sleep disordered breathing. For example, Westbrook taught:

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).

267. 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 (combination with airflow signal). Westbrook also disclosed integrating the disclosed PSG sensors with a CPAP device. Westbrook, ¶¶164-167.

268. Commercially available, conventional fingertip pulse oximeter sensors were well-known in the art in 2005. CleveMed’s infringement contentions allege the NONIN Xpod oximeter, used 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. As discussed above with regard to the ResLink and predicate devices with pulse oximetry inputs, ResMed had already incorporated a pulse oximeter with its PAP devices by 2003. As was also known in the art, NONIN and other manufacturers had developed Bluetooth enabled pulse oximeters, such as the NONIN wrist-worn module, by 2005. 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, 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

[REDACTED]

also the ubiquity of pulse oximeters commercially available, which would have made incorporation of such a sensor no more than a conventional, implementation detail within the level of ordinary skill in the art.

269. A POSITA would have also recognized the benefit of an additional source of physiological data about the patient during treatment. Each sensor signal is subject to variability. Airflow is subject to leak, 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. 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 airflow sensor. CleveMed admitted during prosecution that the Farrell-198 prior art reference disclosed the use of pulse oximeter sensor data “to provide the physician with more information about the subject’s physiological characteristics during apnea incidents.” See ’269 Patent FH, 5/27/2016 Amendment at 13.

270. 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. Other references also recognized the usefulness of pulse oximeter data with a PAP system. Lankford, 168 (disclosing incorporating pulse oximetry into the remote 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).

271. As one example of a commercial implementation, as discussed above, prior ResMed CPAP devices, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] 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 Brochure (RMD-079581), page 2; *see also* Exhibit 15 AutoSet Portable II Plus Clinician’s Manual, page 15, 50, 55 (showing “Oximetry Analysis dialog group”. The addition of such a sensor, as discussed herein, would have been merely a matter of incorporating off the shelf commercial components.

2. Calculations from Airflow and Pulse Oximeter Sensor Signals

272. The ’269 patent’s claims 1 and 5 recite the following limitations:

- “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” (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” (claim 5).

273. As noted elsewhere, the ’269 patent specification does not use the terms “sleep disorder symptom data” or identify what the inventors understood a “symptom” or “symptom data” to be, or recite an “index of a level of severity.” The discussion above for the prosecution history notes that CleveMed admitted that “AHI is an indicator of the level of severity of a patient’s sleep disordered breathing” in reference to the prior art. However, the ’269 patent specification does not describe calculation of AHI, or whether AHI is calculated “based in part on both” data from the respiratory airflow and pulse oximetry sensors. For example, the specification does not describe calculating a single parameter based on both types of data, and likewise does not describe how to perform such calculation. However, it would have been at least obvious to do so based on the knowledge of a POSITA, and also express teachings in the art.

274. A POSITA would have been familiar with the various diagnostic parameters for sleep disordered breathing, including events such as apneas, hypopneas, and indices including “apnea index,” “apnea-hypopnea index,” and “respiratory disturbance index.” A POSITA would

[REDACTED]

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, as the '269 patent admits. Guilleminault, for example, published numerous well-known and oft-cited 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 “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.*

275. Specifically with regard to hypopneas, 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 (emphasis added). 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

[REDACTED]

respiratory event-related arousals per hour of sleep) into mild ($5 < \text{AHI or RDI} < 15$); moderate ($15 < \text{AHI or RDI} < 30$); or severe ($\text{AHI or RDI} > 30$).” *Id.* at 615-616; *see also* Westbrook, ¶19.

Thus, where a hypopnea is determined using pulse oximetry data to identify an oxygen desaturation or arousal, a consequential AHI or RDI would inherently be based on the underlying pulse oximetry data, in addition to the reduced breathing data that is typically determined based on airflow data.

276. As known in the art and recognized, for example, in Westbrook, discussed above, polysymnography was known as the “gold 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:

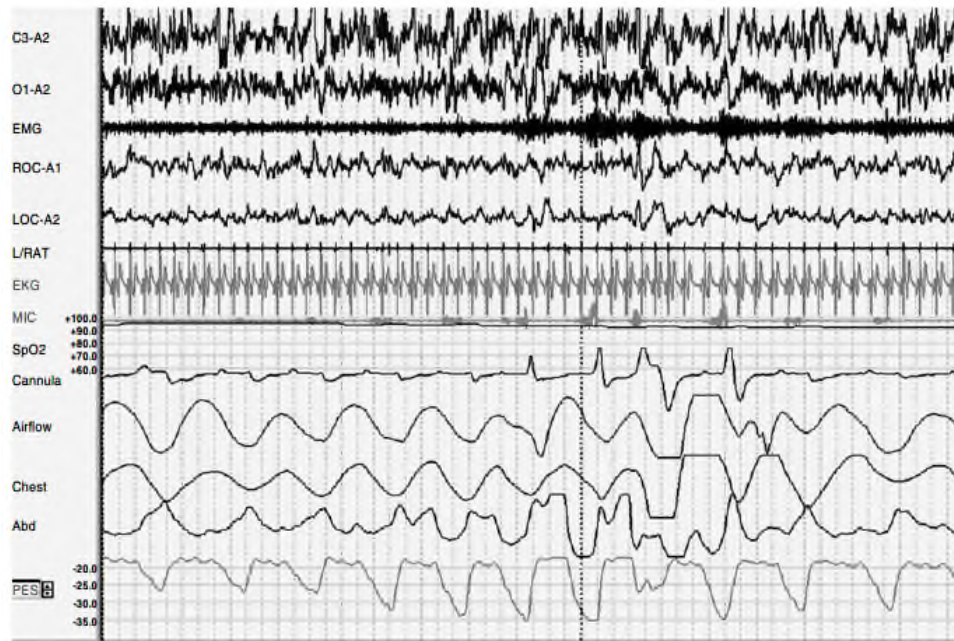


Fig. 1. Polysomnogram of a patient with OSA. The cannula and airflow channels demonstrate reduction in oronasal airflow consistent with a hypopnea. Paradoxical respiration is noted on the chest and abdominal effort channels. Esophageal pressure crescendo with Pes reversal associated with an arousal is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

Guilleminault 2004, at 617 (showing SpO2 and Airflow sensor data as part of “polysomnographic findings in a patient with OSA” (see page 616)).

277. 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. ResMed’s AutoSet devices are an example of an “autotitrating” PAP device. 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 saturation 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 that 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.,* The AASM Manual for the Scoring of Sleep

[REDACTED]

and Associated Events, 2007 (“AASM Manual”), Section 4.

278. As another example similar to Guillemineault, 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 (emphasis added), *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 in these prior art systems using a pulse oximeter. A POSITA would have further been motivated to use the oxygen desaturation information to assist in the identification of hypopneas.

279. In addition, 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 and observed, for example, in Roux. Such a modification would have been a mere design choice known to a POSITA, as also evidenced by Roux.

[REDACTED]

a. CleveMed’s Expert Declaration: “symptom data” and “indexes”

280. I understand that CleveMed relied on a declaration from Dr. D’Ambrosio in support of its briefing in the claim construction phase of this case. See Amended Joint Claim Construction Brief (D.I. 116), at 21-23. CleveMed’s claim construction briefing sections for the ’269 patent did not present any proposed meaning for the data and index terms recited in the claims, but Dr. D’Ambrosio’s declaration appears to do so. 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 SpO2 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).

281. Dr. D’Ambrosio additionally interpreted the relationship of “symptom data” and “severity” or “level of severity” (which I do not find support for 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

[REDACTED]

AHI is the sum of all the apneas and hypopneas divided by the total sleep time. RERAs include arousals from sleep in the definition. 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," or whether the symptoms data must be used to derive a severity to practice the claims. Dr. D'Ambrosio's opinions include that the "symptom data" of the claim include at least the following: respiratory disturbance index (RDI), apnea-hypopnea index (AHI), reduction in airflow, numbers of obstructive sleep apneas, and oxygen saturation. These parameters were disclosed in the prior art.

282. 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). It is unclear from these statements whether Dr. D'Ambrosio 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 '269 patent.

Regardless, calculation of AHI was disclosed in the prior art.

3. Signal Processing, Data Acquisition

283. Claim 1 requires a “signal processing module comprising ... electronics adapted for filtering and processing the [pulse oximeter sensor] signal, and an output adapted for outputting pulse oximetry sensor data,” claim 5 requires a “data acquisition system” including “an electronic component adapted for filtering and processing the first signal from the pulse oximeter sensor to remove artifacts,” and claim 8 requires a “data acquisition system ... for creating an output of the level of severity ... based in part on the signals from the at least one physiological sensor.” Notably, claims 1 and 8 do not specify how the pulse oximeter or physiological signal is processed to create the claimed output, and claim 5 only specifies that filtering and processing is done “to remove artifacts.”

284. As discussed above in the summary of the '269 patent, most of the disclosure of the '269 patent is directed to a system with a data acquisition system that performs signal processing of data from physiological or biometric sensors, such as EEG and ECG. Such systems and processing techniques were known in the art. Also, the description of the signal processing module and data acquisition system in 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 therefore is prior art to the '269 patent). 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. Schmidt also discloses:

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**

[REDACTED]

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, 4:10-22 (emphasis added).

285. A POSITA would have recognized that signals from sensors like pulse oximeters and other physiological sensors would typically be output in analog form and need to be filtered and converted to digital form to enable processing by software, possibly encoded or reformatted to a particular format for communication. Conversion of signals from analog format to digital format has been around for many decades. Pre-conversion filtering stems from traditional analog technology. Prior to Analog to Digital conversion (A/D conversion), filtering out high frequency noise or low frequency noise is necessary in order for the A/D conversion to be successful and represent the actual values of the analog signals. The bit-depth of the A/D conversion determines the level of noise filtration needed prior to A/D conversion. As an example, Elena illustrates and describes a typical signal processing module that conditions and processes signals, such as physiological sensor signals, before output. 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. Figure 2 of Elena is reproduced below., reproduced below, shows a typical signal processing module that conditions and processes signals before output.

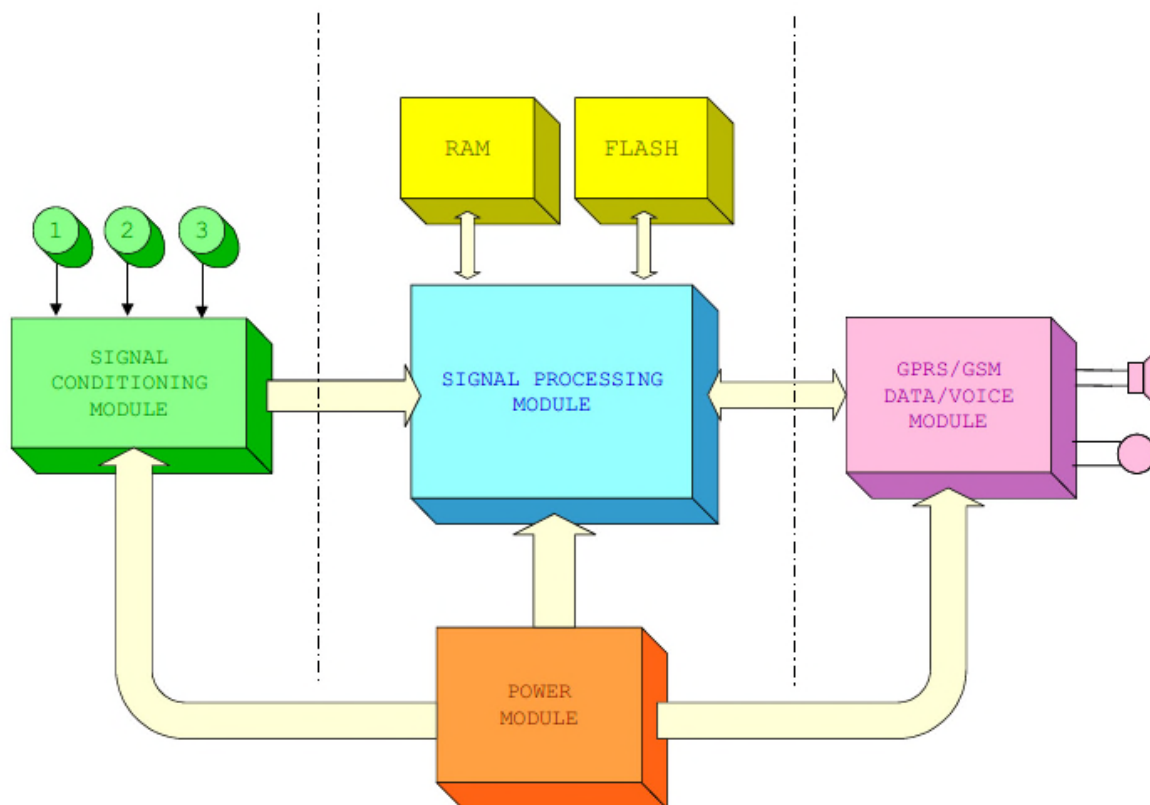


Figure 2. A block diagram of PAC

Elena, FIG. 2. Kirianaki also 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.

286. Schmidt also admitted that “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

[REDACTED]

such knowledge to the PAP systems of the prior art, such as the ResMed prior art, to arrive at the '269 patent claims. Such features would have been minor implementation details that a POSITA would have known to incorporate, as acknowledged by the disclosure of Schmidt. As an additional example, 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.

287. I note that the '269 patent disclosure does not describe processing to “remove artifacts,” or otherwise indicate what types of artifacts are being referred to. For example, subject introduced artifacts might be present, such as from the movement of the subject and/or poor or changing interface of the sensor with the subject. External artifacts might also occur, such as due to electrical interference. Regardless, processing to remove artifacts was known in the art. Also, to the extent the disclosure from Schmidt that was copied into the '269 patent is found to disclose the claimed removal of artifacts, as discussed above, such techniques were prior art and would have been a simple design choice to incorporate into the prior art systems.

288. Some of the '269 patent claims recite certain “signal processing” techniques: 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. These were typical, conventional, and widely known and used signal processing techniques known to a POSITA, and were well-known to be used with physiological sensors like those disclosed in the '269 patent. For example, wavelets were often faster and more efficient than FFT for representing signals at different scales and resolutions. Wavelets can be used in applications such as compression, removing noise, and feature extraction from signals such as ECG. Wavelets became an essential part of signal processing in many and diverse fields

[REDACTED]

such as telecommunications, image and video compression, biomedical signal processing, and more at least by 2004. *See, e.g.*, Exhibit 12, A.W.M. Van Den Enden and N.A.M. Verhoeckx, DISCRETE-TIME SIGNAL PROCESSING – AN INTRODUCTION (1989); Exhibit 13, Stephane Mallat, A WAVELET TOUR OF SIGNAL PROCESSING (1998); Exhibit 14, Gilbert Strang and Truong Nguyen, WAVELETS AND FILTER BANKS (1996).

4. System Configuration, Wireless Transmission, Remote Monitoring

289. As established above with the summary of the ResMed Prior Art, 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 also, e.g.*, United States Patent Application Publication No. 2003/0236450 (“Kocinski”), ¶¶ 9, 12, 28, 45, 49, FIGs. 1, 10. An early prototype of the above-described ResTraxx system is described in a 2004 paper by D. Alan Lankford, referring to the “Spectrum System” used with a “Cyracat” wireless communication device and the ResMed AutoSet T flow generators. D. Alan Lankford, *Wireless CPAP Patient Monitoring: Accuracy Study, Telemedicine Journal and e-Health*, Vol. 10, No. 2, 2004, at 162 (“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.

290. Claim 15 does not specify the location of the “first radio frequency wireless module transceiver,” although I note that dependent claim 16 recites in an antecedent basis manner that the transceiver is “of the PAP device.” The ’269 patent fails to recognize any specific unexpected result or challenge in the particular configuration of the components in a system that employs wireless communications and “retransmits” data. Instead, the ’269 patent merely provides a laundry list of 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 recognizes 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

[REDACTED]

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. 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.

291. Telemedicine was an established field of endeavor by 2005. Many publications had documented already-implemented communication system configurations for collecting information from biomedical systems at the location of a patient, such as a CPAP treatment device in a patient's home, and transmitting data to remote locations. Many of these systems employed cellular phones as part of the transmission data path due to advancements in data transmission, cellular coverage, and the widespread adoption of cellular devices. In some cases, the cellular phone used a short range RF wireless interface to receive data from sensors, monitors, or other sources of data.

292. As one example, 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. Below is a reproduction of a figure from Jasemian that illustrates a typical telemedicine configuration employing a cellular

phone for local short range communications and also cellular communications to a server or monitoring system.

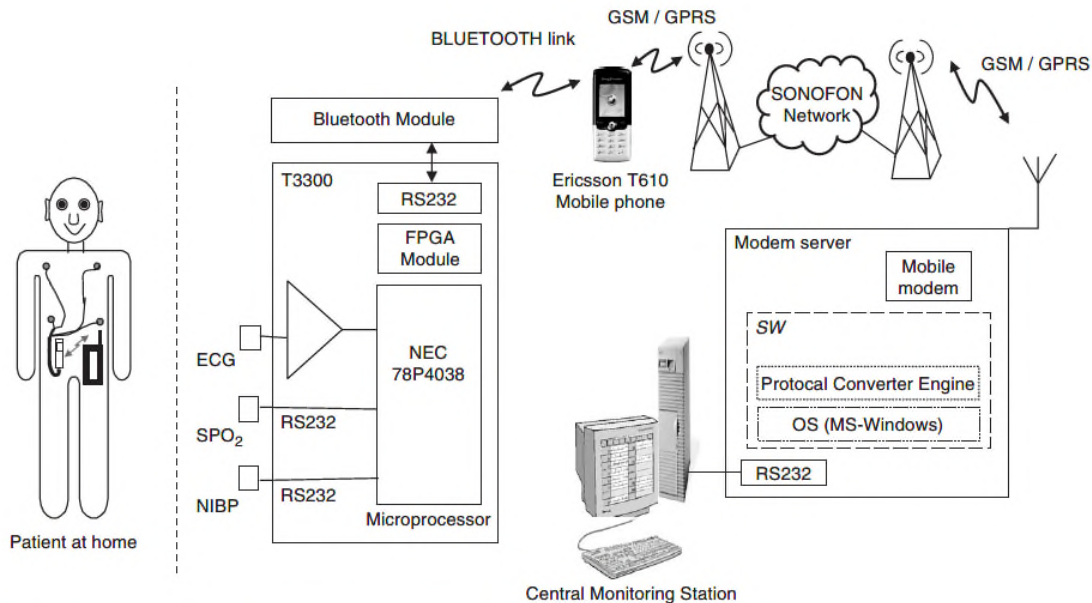


Figure 1 System architecture

Jasemian, Figure 1.

293. Bryan Woodward and Mohd Fadlee Rasid described a similar telemedicine system in 2003, as shown in the below reproduced figure:

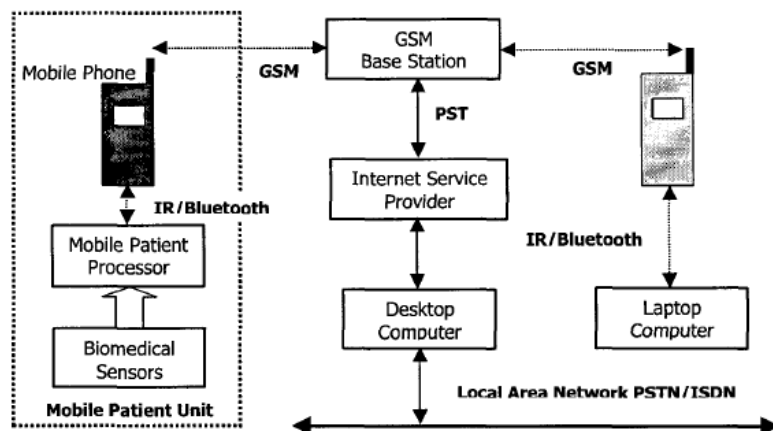


Fig. 1 Telemedicine system with mobile telephone and PSTN communications links

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"). The Woodward paper reviewed multiple wireless telemedicine projects that had

[REDACTED]

been carried out around the world, and further described the design and development of a wireless telemedicine system using a conventional mobile telephone. Id. Woodward described the system as 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. Id. Woodward's system was "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." Id.

294. Woodward described that the transmission of data from the patient monitoring sensors or devices to the phone "may possibly be done by a direct connection, or by a wireless connection such as an acoustic, infra-red or Bluetooth radio link." Woodward at 44. Woodward recognized, as did many in 2003, that "[i]t 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)." Woodward, 44. However, by the 2005 filing of the '269 patent many applications for the Bluetooth protocol, including in the area of telemedicine, had already been explored.

295. In Woodward's system, 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." Woodward, 45. The prototype was "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.

296. Further work by the same authors is disclosed in 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

[REDACTED]

Biomedicine, Vol. 9, No. 1, March 2005, at 35 (“Rasid IEEE Article”). *See, e.g.*, 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. There was significant activity in the area of exploring the use of mobile communications technology that had been widely adopted by 2005, demonstrating the motivation to explore and ability to implement the communication aspects of the ’269 patent claims. The Rasid IEEE Article, published in early 2005, for example, recognized Mthat “[o]ne of the emerging issues in m-Health is how best to exploit the mobile communications technologies that are now almost globally available,” and that 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.” Rasid IEEE Article, Abstract. The disclosed system including a “processor, which samples signals from sensors on the patient,” and “then transmits digital data over a Bluetooth link to a mobile telephone that uses the General Packet Radio Service,” where the “modular design adopted is intended to provide a “future-proofed” system, whose functionality may be upgraded by modifying the software.” Rasid IEEE Article, 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.

297. The system described in Rasid’s IEEE Article included the following communication links, shown in the below-reproduced 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 IEEE Article, § I.C.

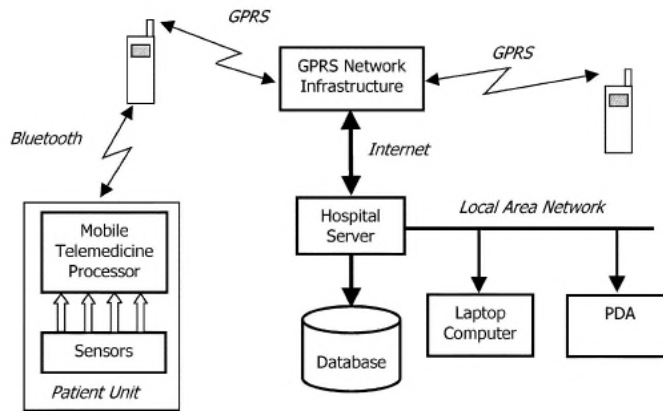


Fig. 2. Mobile telemedicine system.

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

298. In the system of Rasid’s IEEE Article, 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 IEEE Article, § III.A.

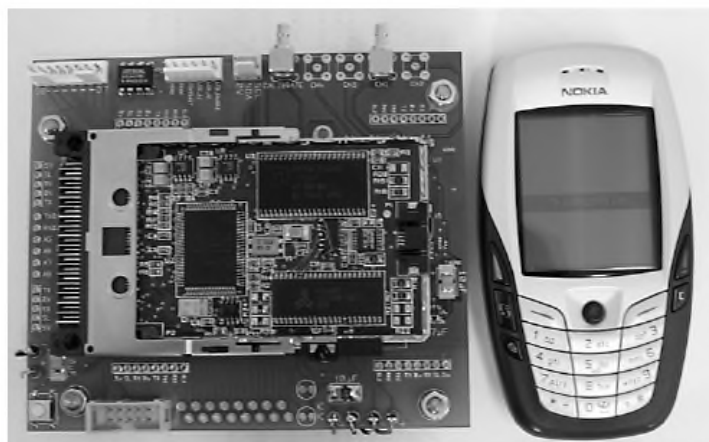
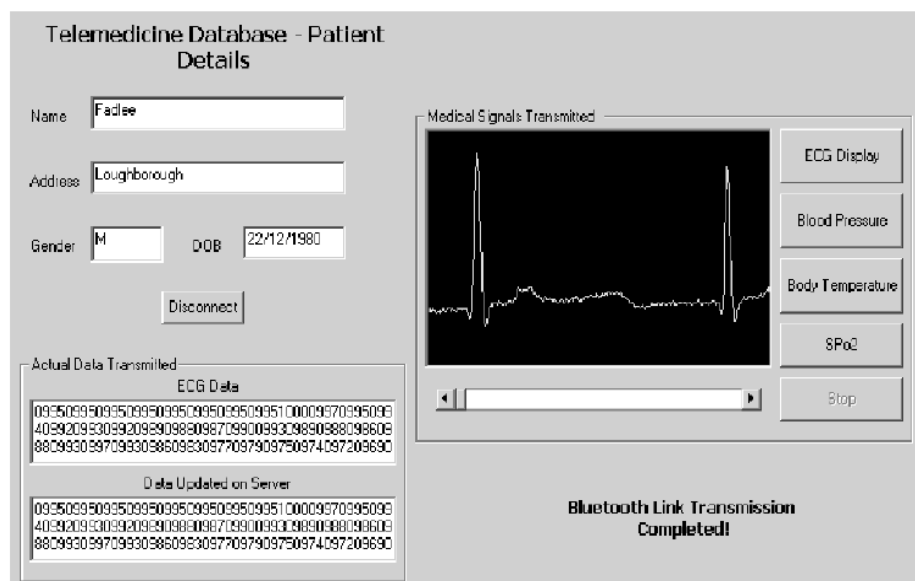


Fig. 4. Layout of mobile telemedicine processor.

Rasid IEEE Article, Fig. 4.

299. The Rasid IEEE Article disclosed that the system was designed to include a patient interface at the mobile device to view the data received by the mobile phone and transmitted to the hospital server. See Rasid IEEE Article, § IV.



Rasid IEEE Article, FIG. 9, see § IV (simulated patient interface to the mobile telephone).

Rasid's later-published thesis demonstrated a user interface on a Nokia mobile phone displayed collected signal data. Rasid Thesis (2005), 98, 133.

300. Thus, it was known in the art and within the level of ordinary skill to select a system configuration including that recited in the '269 patent claims for receiving sensed and

[REDACTED]

calculated biometric data, transmitting that data, *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 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. 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 IEEE Article, § 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 communications link, or to use a different cellular subscription for the user’s PAP device to

[REDACTED]

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 the Rasid IEEE Article, 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.

301. 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 relies on the knowledge of a POSITA to apply Bluetooth wireless technology generally to the disclosed system. As established above, 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.

302. Dependent claim 18 recites that the PAP device can be "adjusted remotely based on the symptom data ... or the index" However, as noted above, this feature was well known in the art, and disclosed, for example, by the ResMed Prior Art, and also patent disclosures by ResMed. *See also, e.g.,* Farrell, 6:22-32. The desirability of incorporating the ability to remotely adjust the PAP device based on reported usage and calculated data was well known in the art, its benefits as discussed above, would have motivated a POSITA to incorporate this feature to the extent not already disclosed by the primary prior art references.

5. Pharmaceutical Agent or Supplemental Oxygen

303. Claim 8 requires a PAP apparatus "for providing pressurized air and dosing and chemically treating a subject's sleep disorder or symptoms with a pharmaceutical agent." CleveMed's infringement contentions have alleged that supplemental oxygen meets the claimed

[REDACTED]

“dosing and chemically treating ... with a pharmaceutical agent.” However, such a system and combination of components was known in the art. The examiner of the application that issued as the '269 patent recognized as much in stating “conventionally, CPAP devices can provide pressurized oxygen, which is a chemical, to the subject. Thus, the scope of this limitation does not distinguish over typical CPAP devices. Examiner suggests narrowing the claim limitation further to specific chemicals other than oxygen and/or other chemical components in air” '269 FH ('116 application), 9/6/2016 Final Rejection at 8. CleveMed responded by amending the claim to recite “additional CO₂ ... or a pharmaceutical agent” (*Id.*, 12/6/2016 Amendment at 5), which the examiner indicated was allowable—this informs a POSITA that the amended language that includes “or a pharmaceutical agent” does not encompass “CPAP devices [that] can provide pressurized oxygen” that the examiner had previously pointed to. *Id.*, 1/3/2017 Non-final Rejection at 21. But CleveMed then amended the claim again to remove the reference to additional CO₂. *Id.*, 4/3/2017 Amendment at 5. The examiner later rejected the claim in view of the Wright reference, but did not repeat the observation that pressurized oxygen is a “pharmaceutical agent” of the claim. *Id.*, 11/27/2017 Non-final Rejection at 10. Thus, the only reasonable inference from these exchanges between CleveMed and the examiner is that both CleveMed and the examiner concluded that pressurized oxygen is not a “pharmaceutical agent,” and CPAP devices that can provide pressurized oxygen are outside the scope of the claim.

304. The '269 patent admits that “[p]hysical and chemical methods to treat sleeping disorders are known to those skilled in the art. ... Chemical methods to therapeutically treat sleeping disorders and symptoms while less common include various pharmaceutical agents with various delivery techniques including oral delivery, injection, transdermal delivery, injection with a controlled pump, inhalation therapy and the like.” '269 patent, 22:13-28. The specification at column 22 and the description of a “conventional pressure support system 10, the disclosure recites a system “that receives a supply of gas from a gas source,” but this section is copied from US 6,644,311 to Truitt. Truitt further teaches, in a section not copied into the '269 patent: “It is to be understood that other sources of gas can be used instead of, or in addition to,

[REDACTED]

the air from the ambient atmosphere. For example, a supply of oxygen or an oxygen mixture can be provided as source of breathing gas.” Truitt, 5:6-9. A POSITA would have recognized that the gas source could include an oxygen tank or supply.

305. The ’269 patent does not provide a written description for the use of “pharmaceutical agent” in combination with a CPAP apparatus, or a PAP device for dosing and chemically treating a subject’s sleep disorder or symptoms with a pharmaceutical agent using an output of a level of severity to adjust the dosing. For example, the specification only recites that a *diagnosis* unit is used to determine the output of the level of severity, but claim 8 does not recite a diagnosis component. However, if the above description copied from and disclosed in Truitt is a disclosure of the system of claim 8, such a system was disclosed in the art, including by Truitt and the ResMed prior art. In addition, the ’269 patent describes signal processing techniques to identify “characteristic shift in these signals or data,” which “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.” ’269 patent, 20:11-18. However, this description is copied from US 6,837,465 to Lisy, which is prior art to the ’269 patent.

306. As discussed above, it was known to use supplemental oxygen with the ResMed prior art systems. As another example, US 6,287,264 to Hoffman discloses the use of a PAP system with physiological sensors with an oxygen delivery system. *See, e.g.*, Hoffman at 15:44-17:46. It would have been obvious to incorporate supplemental oxygen with a PAP device like those known in the art, including those commercialized by ResMed and sold well before the ’269 patent. Incorporating supplemental oxygen would have been a simple design choice that would have been within the level of ordinary skill in the art. Indeed, CleveMed’s infringement contentions allege that an auto-adjusting PAP system that includes an adapter for including supplemental oxygen into the breathing circuit after the output of the PAP device (i.e., through an adapter affixed between the output of the PAP device and the hose) meets the claim, even though the PAP device has no awareness or response to the oxygen flowing into the system. Thus, CleveMed’s allegations confirm that no modification to the PAP device itself is needed in

order to incorporate supplemental oxygen with a PAP device and practice the claim.

307. 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.

C. The ResMed Prior Art Systems 1-2 Anticipate or Render Obvious the '269 Patent Asserted Claims

308. Below is a summary of my invalidity opinions for each '269 Patent Asserted Claim and RPA Systems. I incorporate here by reference the analysis above of CleveMed's '269 Patent Infringement contentions (§ IX), technology background and state of the art § X.B), and overview of the '269 patent (§ VI). I have also reviewed ResMed's Final Invalidity Contentions, including the cover pleading document and Exhibit G05 and incorporate and adopt that analysis here.

Claim	System	Components/ Accessories	Anticipation/Obviousness
Claim 1	System 1: ResMed AutoSet Spirit (S7) + ResLink + AutoScan 5.4	NONIN Xpod, mask, modem	Obvious or alternatively anticipated based on CleveMed's infringement contentions; obvious in view of knowledge of a POSITA and/or Westbrook and/or Schmidt
	System 2: ResMed AutoSet Spirit (S7) + Restraxx (including RDC)	Mask	Obvious in view of knowledge of a POSITA, in combination with System 1 and/or Westbrook and/or Schmidt
Claim 5	System 1: ResMed AutoSet Spirit (S7) + ResLink + AutoScan 5.4	NONIN Xpod, mask, hose	Anticipated and/or obvious based on CleveMed's infringement contentions; obvious in view of knowledge of a POSITA and/or Westbrook and/or Schmidt
	System 2: ResMed AutoSet Spirit (S7) + Restraxx (including RDC)	Mask, hose	Obvious in view of knowledge of a POSITA, in combination with System 1 and/or Westbrook and/or Schmidt

Claim	System	Components/ Accessories	Anticipation/Obviousness
Claim 8	System 1: ResMed AutoSet Spirit (S7) + ResLink + AutoScan 5.4	Mask, supplemental oxygen	Anticipated based on CleveMed's infringement contentions; obvious in view of knowledge of a POSITA, and alternatively in combination with Hoffman
	System 2: ResMed AutoSet Spirit (S7) + Restraxx (including RDC)	Mask, supplemental oxygen	Anticipated based on CleveMed's infringement contentions; obvious in view of knowledge of a POSITA, and alternatively in combination with Hoffman
Claim 15	System 1: ResMed AutoSet Spirit (S7) + ResLink + AutoScan 5.4	Mask, modem	Obvious based on CleveMed's infringement contentions and the knowledge of a POSITA; obvious in view of the knowledge of a POSITA and/or Rasid IEEE Article
	System 2: ResMed AutoSet Spirit (S7) + Restraxx (including RDC)	Mask	Anticipated and/or obvious based on CleveMed's infringement contentions; obvious in view of the knowledge of a POSITA and/or Rasid IEEE Article
Claim 16	System 1: ResMed AutoSet Spirit (S7) + ResLink + AutoScan 5.4	Mask, modem	Obvious in view of knowledge of a POSITA, and/or in combination with Rasid IEEE Article
	System 2: ResMed AutoSet Spirit (S7) + Restraxx (including RDC)	Mask	Obvious in view of knowledge of a POSITA, and/or in combination with Rasid IEEE Article
Claim 20	System 1: ResMed AutoSet Spirit (S7) + ResLink + AutoScan 5.4	Mask, modem	Claim 20 limitation anticipated; claim is obvious for the reasons identified for claim 15
	System 2: ResMed AutoSet Spirit (S7) + Restraxx (including RDC)	Mask	Claim 20 limitation anticipated; claim is obvious for the reasons identified for claim 15

[REDACTED]

Claim 1 [pre] A positive airway pressure (PAP) sleep disorder treatment system comprising:

309. **RPA Systems 1-2** each disclose a PAP sleep disorder treatment system according to claim 1. The AutoSet Spirit has two modes: CPAP mode and AutoSet mode. *See, e.g.,* AutoSet Spirit Clinician's Manual at 1, 7-9, 33; [REDACTED]

[REDACTED] Both modes provide PAP "sleep disorder treatment."

310. "Indications for Use" for the AutoSet Spirit include that the "AUTOSET SPIRIT system is intended for the treatment of obstructive sleep apnea (OSA) in adult patients." AutoSet Spirit Clinician's Manual (RMD-063968) at 3; [REDACTED]

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.

AutoSet Spirit Clinician's Manual (RMD-063968) at 1. The AutoSet Spirit, along with its accessories, including but not limited to a mask and tubing, provide a sleep disorder treatment system. *See also* RMD-0318346 Virtual Machine and AutoScan 5.4 Screen Captures; RMD-0318396 Specimen Photographs; [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

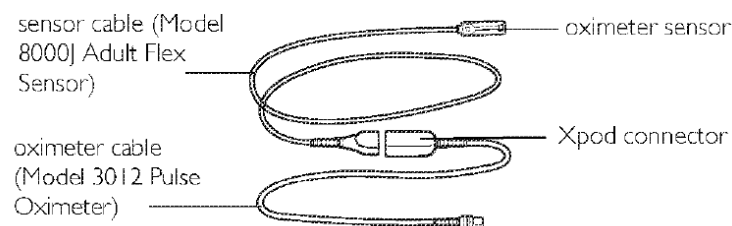
[REDACTED]

[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 the signal, and an output adapted for outputting pulse oximetry sensor data;

311. **RPA System 1** discloses this limitation. *See, e.g.,* § X.A.4. The NONIN Xpod processing module has a first input adapted for connecting to a NONIN pulse oximeter sensor with a signal.

ACCESSORIES

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



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

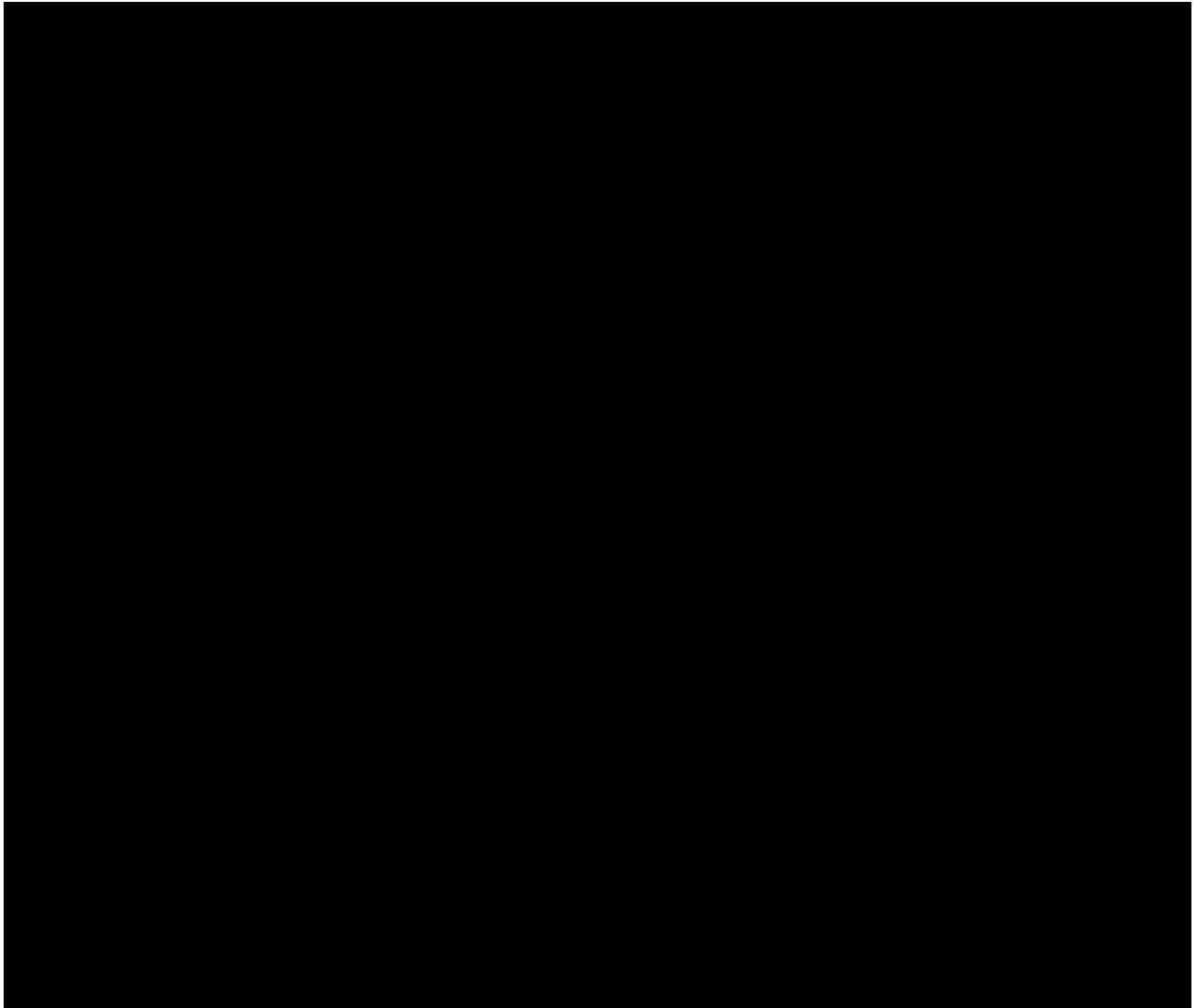
312. The Nonin Xpod [REDACTED]

[REDACTED]

[REDACTED]



RMD-0318396 ResMed Prior Art – Physical Specimen Photographs at -0318406 (showing “NONIN Xpod”).



[REDACTED]

314. **RPA System 2** renders this limitation obvious in view of the knowledge of a POSITA, and alternatively in view of RPA System 1. It would have been obvious to use a pulse oximeter and its corresponding processing module that were well known in the art as part of System 2. The NONIN Xpod processing module and its corresponding pulse oximeter sensor were well-known, off-the shelf components. It would have been obvious to do so, for example, to provide oxygen saturation information directly to the AutoSet Spirit flow generator in System 2. The AutoSet Spirit, as discussed for System 1, is configured to receive pulse oximetry data through the ResLink module.

315. 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 implemented commercially before 2004 in the ResMed Sullivan Portable II. [REDACTED]

[REDACTED]

316. It was well-known in the art that oxygen desaturation information (SaO₂ or SpO₂) reported by a pulse oximeter like the NONIN Xpod and pulse oximeter sensor, was useful to identify sleep disordered breathing events like hypopneas. For at least this reason it would have been obvious to add the pulse oximetry sensor to System 2. As discussed in the prior art section, it was well known that oxygen desaturation was an important parameter for the diagnosis and treatment of sleep disordered breathing, and particularly for identifying hypopneas. Incorporating an off-the-shelf pulse oximeter and its corresponding signal processing module would have been merely a design choice for System 2, e.g., by providing an input port directly to the flow generator from the Xpod cable. Other commercial devices incorporated such a feature, including ResMed's own PAP devices. I note that Roux 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 such a combination of a PAP device with measurement and recording of

[REDACTED]

oxygenation would have typically been done by incorporating an off-the-shelf pulse oximeter that would have necessarily included some type of filtering and processing of the oximeter sensor signal to identify blood oxygenation, and also typically heart rate information. It would have been within the level of ordinary skill to incorporate such an off-the-shelf and well-known feature into System 2 and would have yielded merely predictable results.

317. Alternatively, the Schmidt reference that 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). Schmidt also discloses that the signal processing module receives as an input physiological signal SpO₂ and heart rate, which a POSITA would have recognized are provided by a pulse oximeter. Schmidt, 4:10-22. 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 signal processing module for physiological 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.

[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:

318. **RPA System 1** discloses this limitation. The AutoSet Spirit flow generator is a PAP device adapted for treating a subject's sleep disorder. *See, e.g.*, limitation 1[pre]. The AutoSet Spirit flow generator has an enclosure separate from the NONIN Xpod. *See, e.g.*, ResLink User's Manual (RMD-063203) at 4; ResLink Launch Brochure (RMD-289749) at 289755; [REDACTED]



RMD-0318396 ResMed Prior Art – Physical Specimen Photographs at 0318407 (showing AutoSet Spirit flow generator (PAP device) with separate enclosure from Xpod).

319. **RPA System 2:** The AutoSet Spirit flow generator is a PAP device with an enclosure adapted for treating a subject's sleep disorder. *See, e.g.*, limitation 1[pre], above.



ResLink Launch Brochure (RMD-289749) at 289755; *see also* ResLink User's Manual (RMD-063203) at 8-9. As addressed for limitation 1.a, it would have been obvious to combine the AutoSet Spirit of System 2 with the pulse oximeter and NONIN Xpod (signal processing module) as was known in the art and disclosed by System 1. The Xpod has a separate enclosure from the flow generator (PAP device), as established for System 1.

[REDACTED]

320. 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 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.

[1.b.1] a blower having an air output,

321. **RPA Systems 1-2** each disclose this limitation. The AutoSet Spirit flow generator comprises a blower having an air output. *See, e.g.,* [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[1.b.2] a second input adapted for receiving the pulse oximetry sensor data from the output of the signal processing module,

322. **RPA System 1** discloses this limitation. *See, e.g.,* limitations 1.a, 1.b. As one example, the AutoSet Spirit flow generator includes an auxiliary port that is adapted for receiving the pulse oximetry sensor data from the output of the NONIN Xpod through the Reslink. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



ResLink Launch Brochure (RMD-289749) at 289755; *see also* ResLink User's Manual (RMD-063203) at 8-9. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

323. **RPA Systems 1-2** each render this limitation obvious. *See, e.g.*, limitations 1.a, 1.b. To the extent required by the claims, it would have been obvious to connect the NONIN Xpod (signal processing module) cable directly to the AutoSet Spirit flow generator, as discussed above for the previous limitations, instead of transferring data through the ResLink.

[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

324. As discussed above, CleveMed argued in response to an IPR petition that “Farrell, which was considered extensively during original prosecution of the ’269 patent, discloses an airflow sensor that measures the blower output” (IPR2023-00565, POPR at 27-28), and that Farrell does not teach the claimed internal airflow sensor “because Farrell’s pressure sensor measures the output of the CPAP machine’s blower rather than the respiratory airflow of the subject.” *Id.* At 31. CleveMed’s infringement contentions, however, allege that a flow sensor and/or pressure sensor that measure blower flow, and supplies a sensor signal to a processor that

[REDACTED]

estimates respiratory flow, practices this claim limitation. The *accused* airflow sensor is not a sensor “adapted for measuring the respiratory airflow data of a subject using the PAP device” as claimed—the accused airflow sensor is instead adapted for *measuring* blower flow, or flow within the PAP device that CleveMed argued in the IPR does not practice this claim limitation. Regardless, if a judge or jury determines the air flow and/or pressure sensor configuration of the accused products, which employs estimation of the respiratory airflow by the *microprocessor*, not *measurement* by a sensor, satisfies this limitation, RPA Systems 1-2 disclose this limitation for the same reasons.

325. **RPA Systems 1-2** each disclose this limitation at least for the same reasons CleveMed alleges the Accused Products practice this claim. The AutoSet Spirit flow generator (PAP device) comprises an airflow sensor internal to the flow generator. The AutoSet Spirit has a pressure sensor and a flow sensor internal to the device housing. See, e.g., [REDACTED]

[REDACTED]

AutoSet Spirit Clinician’s Manual at 7, (“The flow sensor, located in the AUTOSSET SPIRIT unit, enables detection of inspiratory flow limitation and apneas. The pressure sensor, also located in the unit, enables measurement of pressure and snore.”), 37 (“The pressure transducer located in the unit measures treatment pressure; the average pressure is calculated and recorded each minute;” “Leak is derived by analyzing inspiratory and expiratory airflows (via the flow sensor located in the unit).”).

326. The flow sensor comprises a laminar flow element, which is positioned in the blower module between the blower and the outlet, and a differential pressure transducer [REDACTED] that measures the airflow by detecting the pressure drop across the laminar flow element. These elements are connected with small tubes. See, e.g., [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

327. The pressure sensor includes a pressure transducer [REDACTED] to measure the pressure at the output of the flow generator. See, e.g., [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

328. The sensor tube connections to the pressure transducer components ([REDACTED]) on the circuit board (reproduced below) are shown in the AutoSet Spirit Service Manual where tubes 1 and 2 connect the flow sensor to the differential pressure transducer, and tube 3 connects the outlet pressure to another pressure transducer.

[REDACTED]

329. As addressed below in reference to the next claim limitation, the AutoSet Spirit flow generator's microprocessor calculates respiratory airflow based on the flow and pressure sensor inputs.

[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 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;

330. RPA Systems 1-2 each render this limitation obvious for at least the same reasons CleveMed's infringement contentions allege the accused products practice this limitation. *See, e.g.,* section X.B.2, *supra*. Alternatively, RPA Systems 1-2 each render this limitation obvious.

331. Alternatively, if CleveMed's infringement allegations are alleging that merely creation of a "transmission file" containing both pulse oximetry sensor data and respiratory airflow data (or parameters derived therefrom, such as respiratory events, flow, pressure, or AHI) practices this claim limitation, then for at least the same reasons the ResMed prior art practices this limitation by creating packet streams that contain both pulse oximeter data (e.g., [REDACTED] and data derived from airflow data (such as respiratory events, flow, pressure, or indexes like AHI).

332. **RPA Systems 1-2.** The AutoSet Spirit flow generator comprises a microprocessor (processor). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

335.

[REDACTED]

[REDACTED]

336. Also, the data output or displayed on the AutoSet Spirit menus include: usage, apnea index (calculated per session), hypopnea index (calculated per session), apnea-hypopnea index (AHI)(calculated per session), 95th percentile leak, 95th percentile pressure (medians for weekly, monthly, 6 monthly and yearly). *See, e.g.*, AutoSet Spirit Clinician's Manual at 31, 38-39, 40 (showing menu series), 41 (statistics are provided for five time intervals (e.g., last day, last week), and statistics calculated are median values); [REDACTED]

337. The microprocessor of the AutoSet Spirit therefore calculates similar if not the same parameters CleveMed has alleged are "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," including an apnea index and AHI, based at least in part on the data

[REDACTED]

from the flow sensor (blower flow), and also based at least in part the respiratory flow parameter that is derived from the flow sensor (blower flow) data.

338. Furthermore, CleveMed's infringement contentions appear to allege that a data structure or file, [REDACTED] that contain both "SpO2 statistics" and "respiratory indices, respiratory rate, pressure, Apnea or Hypopnea events" satisfies the claimed "data" and/or "index" limitation. See § IX.3. To the extent CleveMed is arguing that generating a data structure or file having both pulse oximeter data, or "SpO2 statistics" calculated based on pulse oximeter sensor data, and parameters such as "respiratory indices, respiratory rate, pressure, Apnea or Hypopnea events" calculated based in part on respiratory airflow data" satisfies the claim limitation "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," this is anticipated by or would have been an obvious modification to RPA System 1. The AutoSet Spirit, as discussed above, generates [REDACTED] packets that contain pulse oximeter data, and also, e.g., [REDACTED] that contain parameters derived from airflow sensor data. If this does not anticipate the claim, alternatively, it would have been obvious to include the SpO2 statistics discussed above (calculated similar to the Leak and pressure centile statistics that are part of [REDACTED] logged data packet structure such that all the desired data is in one data structure for ease of transmission. The inclusion of such statistics in the [REDACTED] data structure would have been a simple design implementation choice that would have been obvious to a POSITA to try, where the selection of which data parameters (and their statistics) to include the [REDACTED] data structure was a design choice.

339. **RPA System 1** in combination with the knowledge of a POSITA and/or alternatively Westbrook, renders this limitation obvious. The microprocessor of the AutoSet Spirit flow generator receives the pulse oximetry sensor data from the auxiliary port (second input) of the flow generator (PAP device). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] CleveMed's infringement allegations for limitation 1.b.4 (discussed above) contend that calculation of centile statistics of the pulse oximeter data practices this claim limitation. For the same reasons, this limitation is rendered obvious where it would have been obvious to modify the AutoSet Spirit flow generator microprocessor to "calculate" the same accused oxygenation percentile statistics for the oxygenation values input to the AutoSet Spirit via the ResLink. The AutoSet Spirit microprocessor already is adapted for calculating centile statistics for leak and pressure. It would have been a simple design choice that a POSITA could have easily implemented with a few lines of code to perform the same centile statistics calculations for the oxygenation data presented by the pulse oximeter sensor. Such statistics could thereby be stored by the flow generator and thus available for download to AutoScan. It would have also been desirable to calculate such statistics such that some oxygenation statistics were available for ease of transmission, similar to the leak and pressure statistics.

340. 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 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.

[REDACTED]

341. **RPA System 2** renders this limitation obvious. It would have been obvious to modify RPA System 2 to incorporate a pulse oximeter for the reasons discussed for limitations 1.a and 1.b.2; the microprocessor would be adapted to receive the pulse oximeter data in the same manner it is received in RPA System 1. It would have been obvious for the microprocessor of RPA System 2 to perform the calculations, including under CleveMed's infringement theories and also the combined use of sensor information for calculation of AHI, for the reasons discussed above for this limitation for RPA System 1.

[1.c] a mask or a nasal cannula; and

342. **RPA Systems 1-2** each disclose a mask. The AutoSet Spirit is designed to be used with a mask, such as the ResMed Ultra Mirage Mask, Mirage Full Face Mask, Full Face Mask Series 2, Mirage Mask, and Modular Mask, and also tubing. See, e.g., AutoSet Spirit Clinician's Manual (RMD-063968) at 10 (showing "Air tubing"), 12 (identifying recommended masks); *see also* Mirage Vista Mask User's Guide (RMD-270989); Mirage Full Face Mask Series 2 User Instructions (RMD-271027); Mirage Mask User Instructions (RMD-271110); Ultra Mirage Full Face Mask User's Guide (RMD-271159); ResLink Launch Brochure (RMD-289749) at 289754 (showing the AutoSet Spirit in use with tubing and a nasal mask); RMD-0318396 ResMed Prior Art – Physical Specimen Photographs at 0318411-0318413 (showing Mirage Full Face 2 Mask, Mirage Nasal Mask, Mirage Vista mask).

[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.

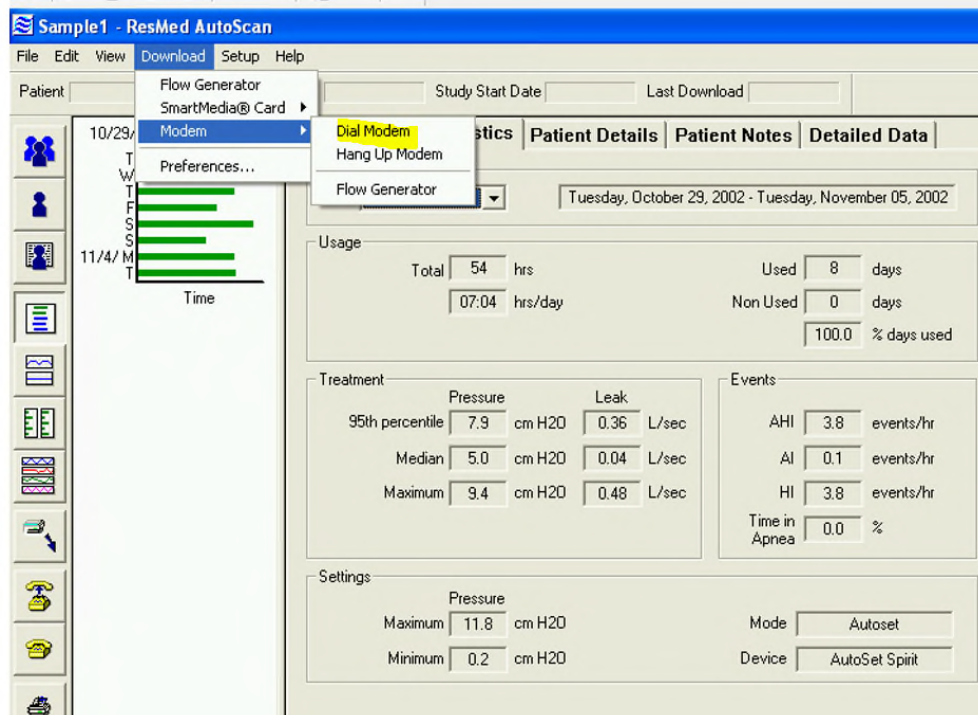
343. **RPA System 1 (AutoScan 5):** This RPA system discloses, or at least renders obvious, this limitation for at least the same reasons CleveMed alleges the accused products practice this limitation. See, e.g., limitation 1pre. RPA System 1 discloses a modem that is a "module transceiver adapted for receiving and transmitting [data calculated by the processor] to a remote location." The modem connects to the AutoSet Spirit flow generator's modem/serial port and is adapted for receiving and transmitting data to a clinician's computer running the AutoScan 5.4 software (remote location). See, e.g., [REDACTED]

[REDACTED]

[REDACTED] AutoScan 5.4 Clinician's Manual (RMD-311263) at 2, 5, 11-23, 66 ("Modem Instructions For the Patient"); [REDACTED]

[REDACTED] AutoSet Spirit Clinician's Manual (RMD-063968) at 42; RMD-0318396 ResMed Prior Art – Physical Specimen Photographs at 0318408 (showing exemplary modem).

[REDACTED]



RMD-0318346 ResMed Prior Art – Virtual Machine and AutoScan 5.4 Screenshots at 0318351

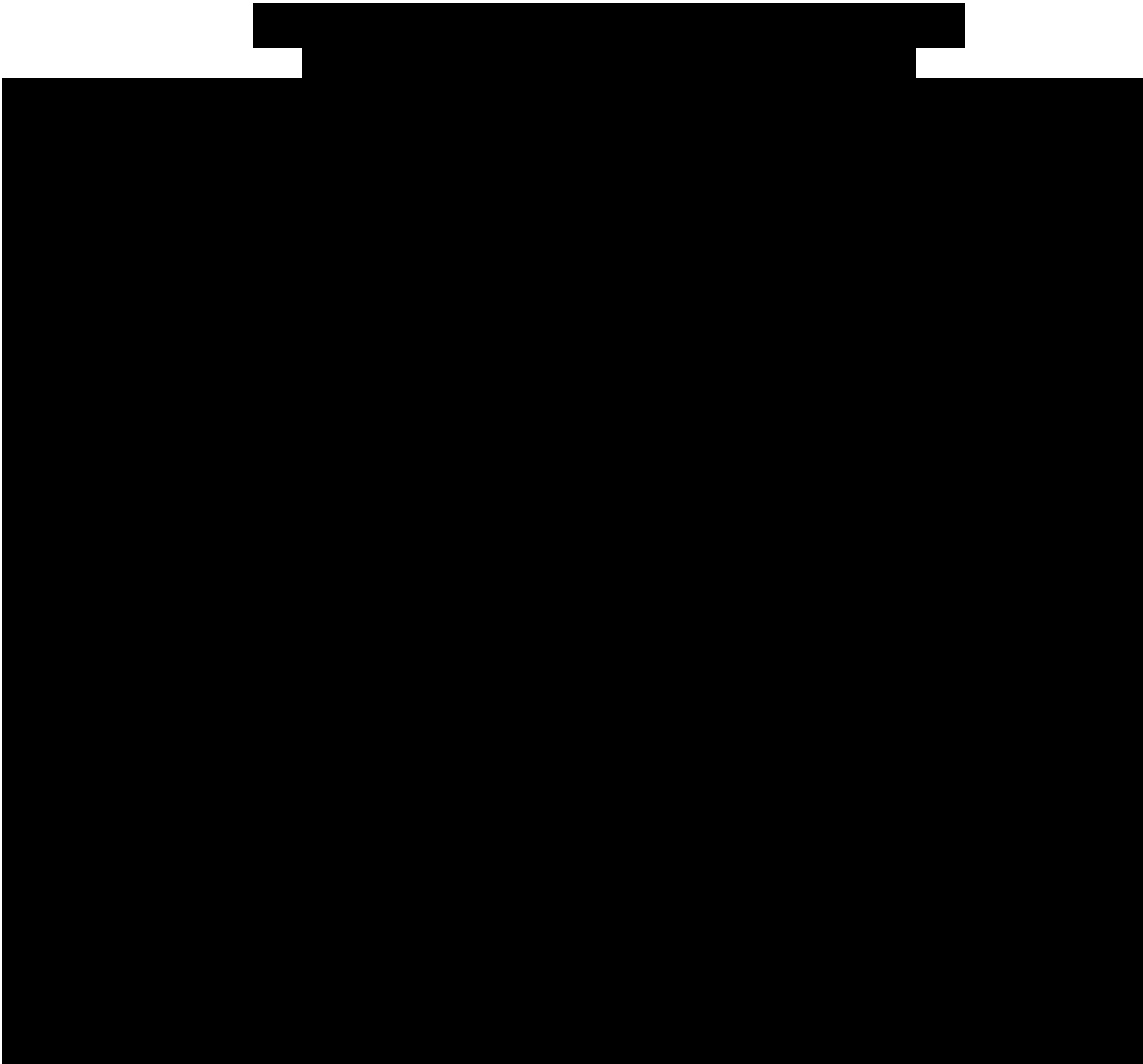
[REDACTED]

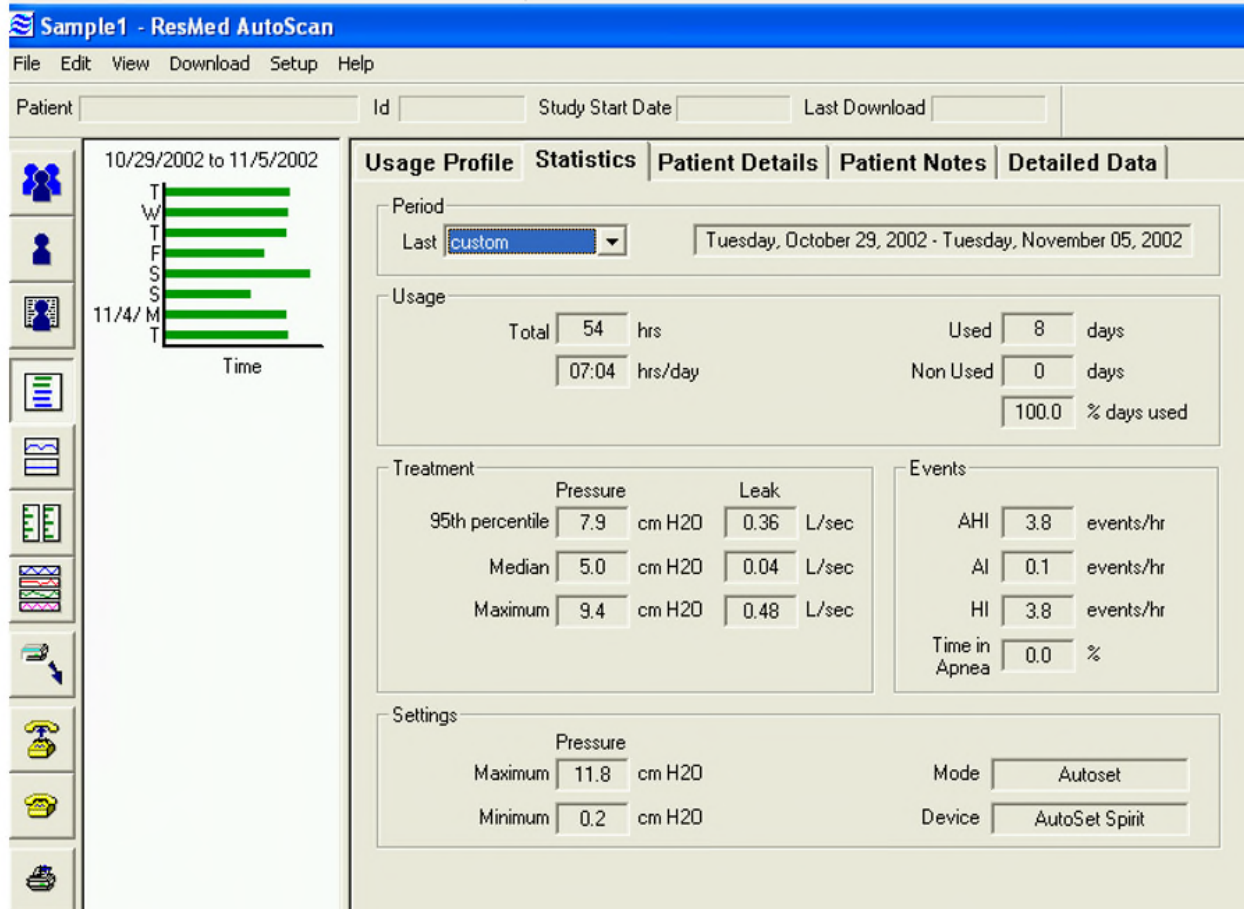
(showing the option to “Dial Modem” to download data from a flow generator), *see also* 0318355 (help screen for “Using modems”).

344. In the same way CleveMed alleges the accused parameters are “symptom data of the level of severity and/or the index of the level of severity of the subject’s sleep disorder symptoms” received and transmitted, the same or similar data, including the summary data, profile data, and event data calculated by the AutoSet Spirit’s microprocessor, are received and transmitted by the modem. *See* limitation 1.b.4; AutoScan 5.4 Clinician’s Manual (RMD-311263) at 2-4, 27, 45-47 (“data currently stored in the flow generator will download to your computer”); [REDACTED]

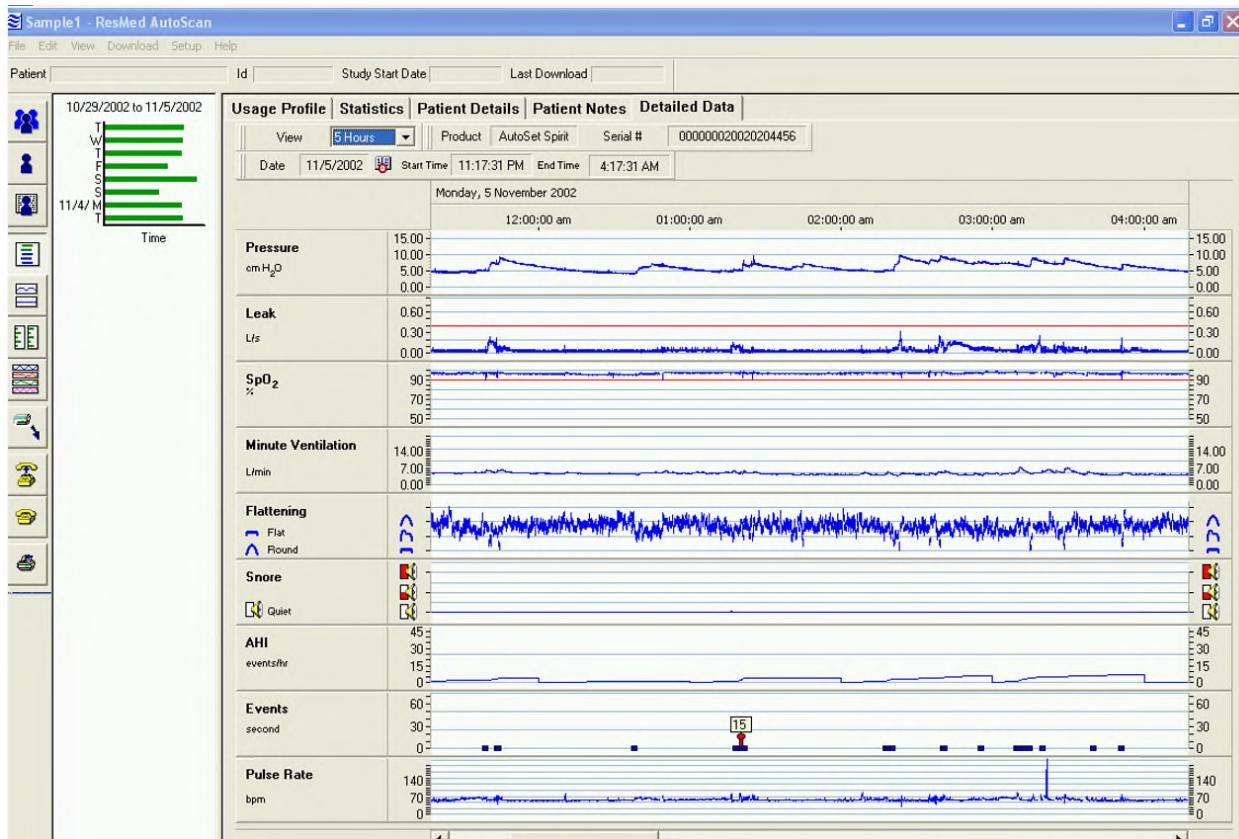
[REDACTED] This includes statistics such as pressure centiles (including max and median), leak centiles (including max and median), AHI and Apnea Index, and Time in Apnea. *See, e.g.*, AutoScan 5.4 Clinician’s Manual (RMD-311263) at 53-55. [REDACTED]

[REDACTED] “Summary Data” and “Night Profile Data” are downloaded from the AutoSet Spirit to a clinician’s computer running the AutoScan 5.4 using either a modem. *See, e.g.*, AutoScan 5.4 Clinician’s Manual (RMD-311263) at 2-4, 27, 45-47 (“data currently stored in the flow generator will download to your computer”), 51-52 (“Night Profile Data”), 53-55 (“Statistics Tab”); [REDACTED]





RMD-0318346 ResMed Prior Art – Virtual Machine and AutoScan 5.4 Screenshots at 0318366.



RMD-0318346 ResMed Prior Art – Virtual Machine and AutoScan 5.4 Screenshots at 0318369 (showing Detailed Data tab and the ability to display “SpO₂” and “Pulse Rate”).

345. The AutoSet Spirit was also capable of receiving and transmitting oxygen saturation data over the modem/serial port and modem.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

346. 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.

347. Also, for the reasons discussed for limitation 1.b.4, it would have been obvious that the AHI received and transmitted by the modem would be an AHI value based on hypopnea events identified using both pulse oximetry sensor and respiratory airflow sensor data.

348. **RPA System 2** (ResTraxx) renders this limitation obvious. *See, e.g.*, limitation 1pre. RPA System 2 discloses "a module transceiver adapted for receiving and transmitting [data calculated by the processor] to a remote location. The [REDACTED] 1 (ResTraxx module) 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."



RMD-0318396 ResMed Prior Art – Physical Specimen Photographs at 0318410 (showing ResTraxx module ([REDACTED] mounted to AutoSet Spirit flow generator (PAP device), *see also* 0318409.

349. The [REDACTED] is adapted to receive data collected and derived by the AutoSet Spirit flow generator from the flow generator and transmit that data to a remote location (the CommServer and RDC web components). *See, e.g.*, RDC User's Manual (RMD-306688) at 4-6;

[REDACTED]

[REDACTED]

[REDACTED]



ResTraxx Patient Management Brochure (RMD-063327) at 1; see also ResTraxx Wireless Patient Monitoring Atlas (RMD-063341). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

350. Data calculated and stored by the AutoSet Spirit flow generator's microprocessor and received and transmitted by the [REDACTED] (ResTraxx module) to RDC, includes

[REDACTED]

Compliance Data: Mask On Time, CPAP Pressure Setting, Minimum Pressure Setting, Maximum Pressure Setting, Hypopnea Index, Apnea Index, and Apnea Percentage; and **Air Flow Data:** median, 95th percentile, and maximum pressure and leak values. RDC User's Manual (RMD-306688) at 17; *see also* [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

351. The Standard/[REDACTED], Event/[REDACTED] and Profile/[REDACTED] logged data generated at the AutoSet Spirit flow generator, identified for limitation 1.b.4, is transmitted to the [REDACTED] for example, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

352. For the reasons discussed in reference to limitation 1.b.4, it would have been

[REDACTED]

obvious to include in this calculated and transmitted data oxygen saturation data from the pulse oximeter sensor data, or centile statistics for such data.

Claim 5 [pre] A sleep disorder treatment system comprising:

353. RPA Systems 1-2 each satisfy this preamble. *See, e.g.*, Claim 1 [pre].

[5.b] a positive airway pressure (PAP) device; and

354. RPA Systems 1-2 each disclose this limitation. *See, e.g.*, limitation 1.b.

[5.c] a processor;

355. RPA Systems 1-2 each disclose this limitation. *See, e.g.*, limitation 1.b.4.

[5.a] a data acquisition system;

[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 from the pulse oximeter sensor to the PAP device;

356. As discussed, 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, I reserve the right to supplement my analysis and rely on the same or similar components in the ResMed prior art for my invalidity analysis. 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.

357. **RPA System 1** discloses this limitation, at least based on CleveMed's infringement allegations. The NONIN Xpod processing module 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." *See* limitation 1.a. A POSITA would have

[REDACTED]

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 been 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.

358. As discussed above at § IX.A.5, this limitation recites the phrase “consisting essentially of.” I have considered, whether RPA System 1 comprises additional inputs to the disclosed “data acquisition system,” or components in addition to those used “for filtering and processing the first signal” that might affect its characteristics beyond those recited in the claim. The NONIN Xpod does not comprise any inputs in addition to the pulse oximeter sensor signal. In addition, the Xpod does not comprise components in addition to those that filter and process the pulse oximeter sensor signal. Therefore, the NONIN Xpod does not comprise additional features or components that might affect its characteristics beyond those recited in the claim, and therefore satisfies the “consisting essentially of” language of the claim.

359. CleveMed’s infringement contentions for this limitation allege the claim is practiced by the accused oximeter adapter by allegedly “correcting data errors and/or removing data gaps when, for example, converting the pulse oximeter’s output into a format that can be received by the AirSense 10.” If the Xpod does not disclose these features, it would have been

[REDACTED]

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.

360. **RPA System 2** renders this limitation obvious in view of the knowledge of a POSITA, and alternatively also in view of RPA System 1. For the reasons discussed for limitation 1.a, it would have been obvious to use a pulse oximeter sensor and its corresponding processing module, such as off-the-shelf components like the NONIN Xpod processing module and its corresponding pulse oximeter sensor, with RPA System 2. For the reasons discussed above for this limitation and RPA System 1, such a system discloses, or renders obvious the claim limitation.

361. Alternatively, the Schmidt reference that 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 Systems 1 and 2.

[5.e] the PAP device comprising:

[5.e.1] a hose,

[5.e.2] a blower,

362. RPA Systems 1-2 each disclose these limitations. *See, e.g.*, limitations 1.b.1, 1.c. *See also* RMD-0318396 ResMed Prior Art – Physical Specimen Photographs at 0318396 (showing AutoSet Spirit flow generator (PAP device) and hose).

[REDACTED]

[5.e.3] an airflow sensor with a second signal adapted for measuring respiratory airflow of a subject,

363. RPA Systems 1-2 each disclose this limitation at least for the same reasons

CleveMed alleges the Accused Products infringe this claim. *See, e.g.*, limitation 1.b.3.

[5.e.4] a second input for receiving pulse oximetry sensor data from the data acquisition device; and

364. RPA System 1 discloses this limitation, and RPA Systems 1-2 each render this limitation obvious. *See, e.g.*, limitation 1.b.2.

[5.e.5] a mask or nasal cannula for treating a subject's sleep disorder symptoms; and

365. RPA Systems 1-2 each disclose this limitation. *See, e.g.*, limitations 1.b, 1.c.

[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 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.

366. For at least the same reasons CleveMed alleges the accused products practice this limitation, RPA Systems 1 and 2 each render this limitation obvious, and RPA System 2 renders this limitation obvious for at least the same reasons CleveMed alleges the accused products practice this limitation. Otherwise, RPA Systems 1-2 each render this limitation obvious.

“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”

367. RPA Systems 1 and 2 each render this limitation obvious, and RPA System 2 renders this limitation obvious for at least the reasons discussed for limitation 1.b.4.

[REDACTED]

“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”

368. RPA Systems 1-2 each 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.” [REDACTED]

[REDACTED]

369. 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 each disclose it.

370. **RPA System 1 (AutoScan 5)** discloses “to be used for later transmission ... to a remote location,” or at least renders it obvious. See limitation 1.d. As another example, I note that CleveMed’s Infringement Contentions for limitation 5.f (limitation 5l in CleveMed’s charts) against the Astral and Stellar ventilator products allege that “Astral and Stellar send the

[REDACTED]

[REDACTED] Final Infr. Cont., Chart A, 37-38. I understand the ResMed Connectivity Module is a module separate from the Astral and Stellar ventilator devices that requests data from the ventilator over a USB port of the ventilator. See *Id.* Similarly, the modem of RPA System 1 is a separate module from the AutoSet Spirit flow generator, and the modem retrieves data from the flow generator in a similar manner to the accused ResMed Connectivity Module for transmission

[REDACTED]

to a remote location (in the case of RPA System 1, the clinician's computer running AutoScan 5.4). If CleveMed alleges the Astral and Stellar ventilators alone without the ResMed Connectivity Module practice this claim limitation, then the AutoSet Spirit practices the claim without the modem for the same reasons. Otherwise, the accused configuration is disclosed by or would have been at least obvious in view of the very similar RPA System 1 configuration, and any relevant differences would have been obvious design choices (such as replacing the telephone line modem connection with a cellular connection).

371. **RPA System 2 (ResTraxx)** renders obvious “to be used for later transmission ... to a remote location” for the reasons discussed for limitation 1.d.

Claim 8 [pre] A sleep disorder treatment system comprising:

372. RPA Systems 1-2 each satisfy this preamble. *See* Claim 1[pre].

[8.a] 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

373. For at least the same reasons CleveMed alleges the accused products practice this limitation, RPA Systems 1-2 each disclose it. The '269 patent and CleveMed's infringement contentions lack clarity as what it means for the claimed system to “create[e] an output.” For example, must the “level” be output from the system, or is the “output” simply a parameter derived by the system that could be consumed within the system. CleveMed's contentions also fail to identify what they contend is the created “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” that is allegedly used according to limitation 8.b to “adjust the pharmaceutical agent.” If CleveMed clarifies its contentions I reserve the right to supplement my analysis accordingly.

374. The AutoSet Spirit flow generator comprises a data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor. 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

[REDACTED]

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, I reserve the right to supplement my analysis accordingly. The AutoSet Spirit flow generator disclose the same features as those accused by CleveMed. The AutoSet Spirit flow generator comprises inputs, e.g., at the microprocessor, for receiving signals from the flow (differential pressure transducer) and pressure (pressure transducer) sensors. *See, e.g.* [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

375. 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." In some cases, the same parameters that are accused are also calculated by the prior art AutoSet Spirit flow generator. *See* discussion of CleveMed's Infringement Contentions, above. For example, as discussed 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; [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] AutoScan 5.4 Clinician's Manual (RMD-311263) at 57-58.

[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.

376. RPA Systems 1-2 each disclose a “positive airway pressure apparatus for providing pressurized air,” the PAP apparatus “comprising a controller.” *See, e.g.*, limitations 1.b, 1.b.4, *supra*.

377. For at least the same reasons CleveMed alleges the accused products practice this limitation, RPA systems 1-2 each disclose this limitation or render it obvious. As discussed above, CleveMed has alleged that supplemental oxygen is a “pharmaceutical agent” within the scope of this claim. CleveMed has alleged that a configuration in which supplemental oxygen is routed into the tubing of the patient circuit through an adapter at the outlet of the flow generator practices this claim limitation. CleveMed has also alleged that the accused products that use an AutoSet algorithm to adjust treatment pressure thereby “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” allegedly because such adjustment may effect “oxygen concentration ... depending on the pressure setting, the patient's breathing pattern, mask selection and leak rate.” However, the same disclosures CleveMed relies on for infringement were disclosed in the AutoSet Spirit systems when used with supplemental oxygen.

378. The AutoSet Spirit flow generator documentation discloses that the flow generator could be used with supplemental oxygen. Spirit/S7 O2 Update (RMD-307134) at 1. This documentation provides the same description CleveMed relies on for its infringement contentions: “[a]t a fixed rate of supplemental oxygen flow, the inhaled oxygen concentration

[REDACTED]

will vary, depending on where the oxygen is introduced, the pressure settings, patient breathing patten, mask selection, and leak rate.” *Id.* ResMed documentation for the masks to be used with the AutoSet Spirit provide the same or similar disclosures. Mirage Mask User Instructions (RMD-271110) at 6; Mirage Full Face Mask Series 2 User Instructions (RMD-271027) at 15; Ultra Mirage Full Face Mask User’s Guide (RMD-271159) at 2.

379. A POSITA would have also known that, for each 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). *See* RMD-0318396 ResMed Prior Art – Physical Specimen Photographs at 0318403 (showing oxygen adapter (with hose to connect to oxygen source) inline between the AutoSet Spirit flow generator (PAP device) and hose). 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.

380. Like the accused products, the microprocessor of the AutoSet Spirit runs an algorithm when in AutoSet mode to adjust the pressure supplied to the patient based at least in part on parameters calculated based on data from the flow and also pressure sensors. *See, e.g.,* limitations 1.b.4, 8.a. The AutoSet Spirit’s 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, and such parameters are used to control the blower motor and thereby adjust the pressure supplied to the patient. *See, e.g.,* limitation 1.b.4; AutoSet Spirit Clinician’s Manual at 7-9; *see also* [REDACTED]

[REDACTED]

[REDACTED]

381. Alternatively, RPA Systems 1-2 each render this limitation obvious in view of Hoffman. Hoffman discloses the introduction of a histamine or chemical into a treatment system like RPA Systems 1-2. *See, e.g.*, Hoffman, 2:31-46, 13:52-14:31. It would have been obvious to incorporate such a chemical treatment into each of RPA Systems 1-2 as necessary to improve and specifically tailor the patient's treatment to their needs. *See, e.g.*, Schwartz Invalidity Report, e.g., at discussion of claim limitation 8.b.

Claim 15 [pre] A positive airway pressure (PAP) sleep disorder treatment system comprising:

382. RPA Systems 1 and 2 satisfy this preamble. *See* Claim 1 [pre], limitation 1.b, *supra*.

[15.a] a PAP device with an enclosure further comprising:

[15.a.1] a blower having an air output,

383. RPA Systems 1 and 2 each disclose these limitations. *See, e.g.*, limitation 1.b, 1.b.1.

[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;

384. For at least the same reasons CleveMed alleges the accused products practice this

[REDACTED]

claim limitation, RPA Systems 1 and 2 each disclose this limitation. *See, e.g.*, limitation 1.b.3.

[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;

385. RPA Systems 1 and 2 each disclose a processor adapted for receiving airflow sensor data. *See, e.g.*, limitation 1.b.4. RPA Systems 1 and 2 each disclose that the airflow sensor data is respiratory airflow data for at least the same reasons CleveMed alleges the accused products practice this limitation.

386. RPA Systems 1 and 2 each disclose that the microprocessor is adapted for calculating data of usage of the PAP device. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

387. RPA Systems 1 and 2 each disclose, for at least the same reasons CleveMed alleges the accused products practice, “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). The AutoSet Spirit's microprocessor is adapted for calculating parameters including Median Pressure, 95% centile pressure, 100% centile pressure, Median Leak, 95% centile Leak, 100% centile Leak, Apnea Index, Apnea/Hypopnea Index, [REDACTED], [REDACTED], mask pressure and mask leak [REDACTED], and respiratory event data [REDACTED]

[REDACTED]

[REDACTED]

[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

[REDACTED]
[REDACTED]
generator device over the modem); [REDACTED]
[REDACTED]
[REDACTED]

[15.c] a mask or a nasal cannula;

388. RPA Systems 1 and 2 each disclose a mask. *See, e.g.*, limitation 1.c.

[15.d] a first radio frequency wireless module transceiver; and

[15.e] a base station, cellular phone, or PDA;

[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 measured during use of the PAP device and the data of usage to the base station, cellular phone or PDA;

389. RPA Systems 1-2 each disclose a “base station” at least based on CleveMed’s infringement contentions. RPA System 2 discloses the remainder of these limitations for the same reasons CleveMed alleges the accused products practice this limitation. RPA Systems 1 and 2 each render these limitations obvious either alone or in combination with the knowledge of a POSITA, or particular art identified below.

390. **RPA System 1** comprises a clinician’s computer running the AutoScan 5.4 software, and a modem for receiving and transmitting data parameters calculated by the AutoSet Spirit flow generator to the clinician’s computer. *See, e.g.*, limitation 1.d. The Clinician’s Manuals for the software provide the “minimum computer requirements in order to configure the system and to transfer and print the stored data.” *See* AutoScan 5.4 Clinician’s Manual (RMD-311263) at 7-8. For at least the same reasons CleveMed alleges the accused products practice this limitation, the modem of RPA System 1 is a “module transceiver” that is “adapted for 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” clinician’s computer running AutoScan 5.4 software. *See, e.g.*, limitations 1.b.4, 1.d. Under the court’s construction of “base station” and according to CleveMed’s infringement contentions, the clinician’s computer running AutoScan software discloses the claimed “base station.”

391. A POSITA would have found it obvious to replace the wired modem with a

[REDACTED]

wireless networking card (WiFi radio frequency wireless module transceiver). 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 Reference Guide (2003-2004) 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. In addition, in the 2004-2005 timeframe, a POSITA would know to use SIM cards or sim card equivalent electronic circuitry, as well as Bluetooth connected to a cell phone that transmits the data over the cellular network. 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 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. It was a common motivation in engineering in 2004-2005 and even present day to replace wired connections with wireless connections, for example, to improve mobility and reduce the need for various tethers/cables between devices, and the need for mechanical/electrical interfaces.

392. In the alternative, 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 System 1 according to such known systems, like that disclose by the Rasid IEEE Article. The system of Rasid’s IEEE Article 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 IEEE Article, Figure 2, §§ I.C, III.A (sensor inputs included SpO). Figure 2 from the Rasid IEEE Article is reproduced below:

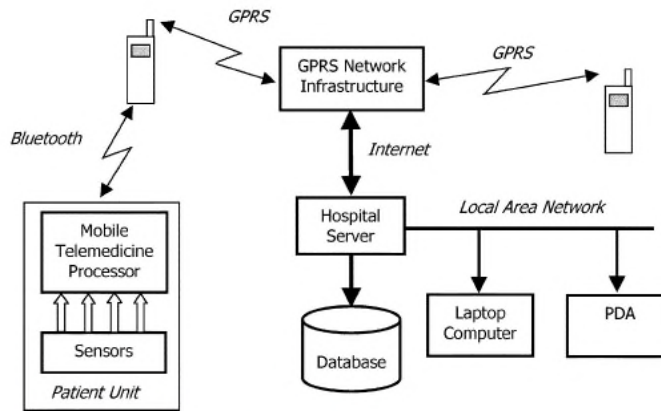


Fig. 2. Mobile telemedicine system.

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

393. The system disclosed by the Rasid IEEE Article 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 in the Rasid IEEE Article, 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 as 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.

394. **RPA System 2:** The [REDACTED] is 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." *See, e.g.*, limitation 1.d. Under the court's construction of "base station" and according to CleveMed's infringement contentions, the clinician's computer accessing the ResTraxx Data Center web application discloses the claimed "base station." For at least the same reasons CleveMed alleges the accused products practice this

[REDACTED]

[REDACTED]

limitation, the [REDACTED] wireless module is “adapted for 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” clinician’s computer accessing the ResTraxx Data Center web application.⁸⁵ *See, e.g.*, ResTraxx Quick Reference Guide (RMD-062642) at 1; ResTraxx Patient Management Brochure (RMD-063327) at 2; [REDACTED]

[REDACTED]

[REDACTED] RDC User’s Manual (RMD-306688) at 5-6 (“System Requirements”), 17 (showing display of parameters calculated by the flow generator and transmitted via the [REDACTED] to the RDC backend, including usage data (“Mask On Time”), AI), 16 (showing display of AHI at clinician’s computer accessing RDC web application); [REDACTED]

[REDACTED]

[REDACTED] RDC User’s Manual (RMD-306688) at 4 (RDC wireless, web-based, 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.

⁸⁵ I reserve the right to offer the opinion that the components (e.g., cellular module) that CleveMed has accused for this claim limitation are not “adapted for ... transmitting ... to the base station, cellular phone or PDA.” As discussed herein, similar to the operation of the accused products, the [REDACTED] transmits data to the RDC backend components; then, a clinician may use a computer and RDC web application to access that data from the RDC backend.



ResTraxx Patient Management Brochure (RMD-063327) at 1; *see also* ResTraxx Wireless Patient Monitoring Atlas (RMD-063341).

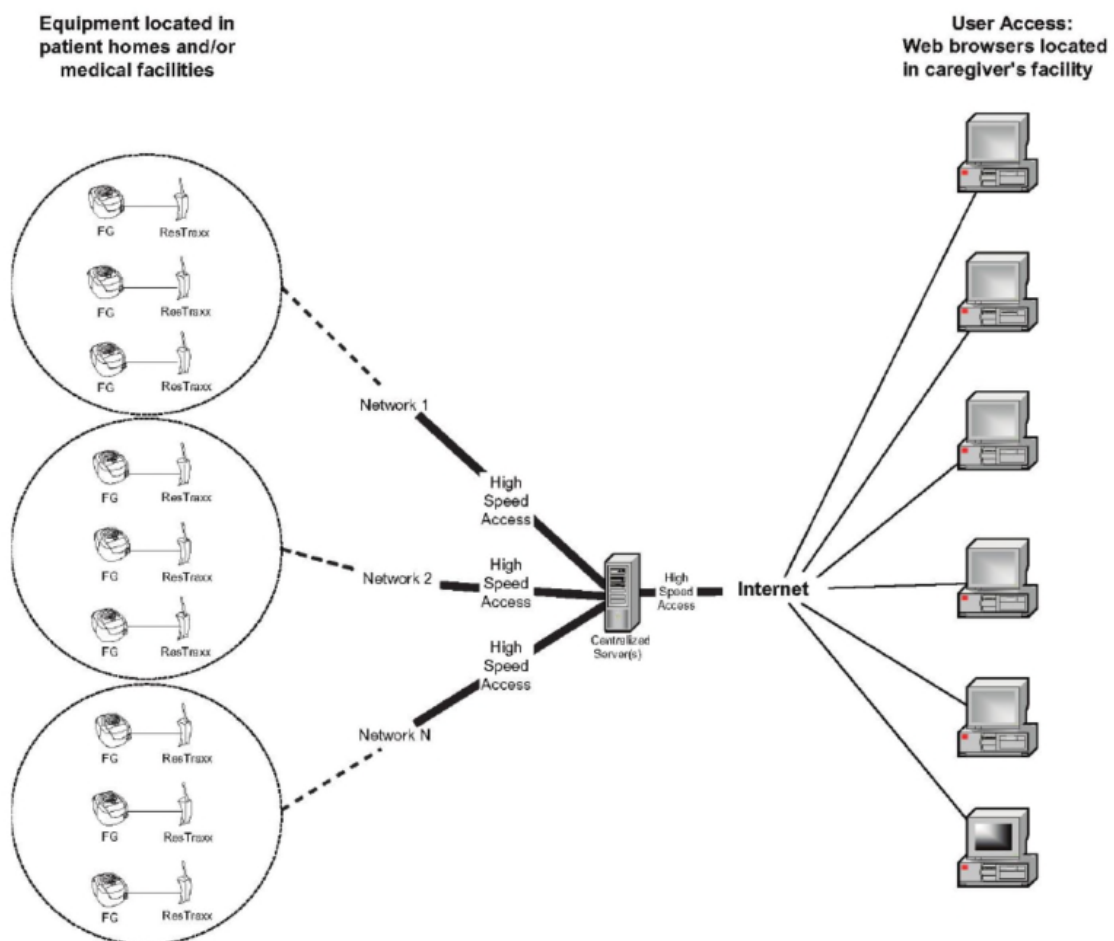


Figure 1: System configuration

[REDACTED]

RDC User's Manual (RMD-306688) at 5.

395. Alternatively, it would have been obvious to modify RPA System 2 in view of known telemedicine systems like that disclosed by the Rasid IEEE Article. 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 the Rasid IEEE Article. This would have been obvious at least for the same reasons discussed above for RPA System 1.

[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 received from the PAP device to a remote internet site.

396. RPA System 2 discloses this limitation at least for the same reasons CleveMed alleges the accused products practice the claim. Alternatively, RPA Systems 1 and 2 render this limitation obvious either alone or in combination with the knowledge of a POSITA, or particular art identified below

397. **RPA System 1:** The clinician's computer running AutoScan 5.4 *software* comprises "a processor, a software, and a display," and is "adapted to display [the data calculated by the processor and usage data], and to retransmit [the same data] to a remote internet site." See, e.g., AutoScan 5.4 Clinician's Manual (RMD-311263) at 7 ("Computer Requirements" identifying "300MHz computer or above"). The display at a clinician's computer of parameters calculated by the AutoSet Spirit as depicted in the AutoScan Clinician's Manual is reproduced below:

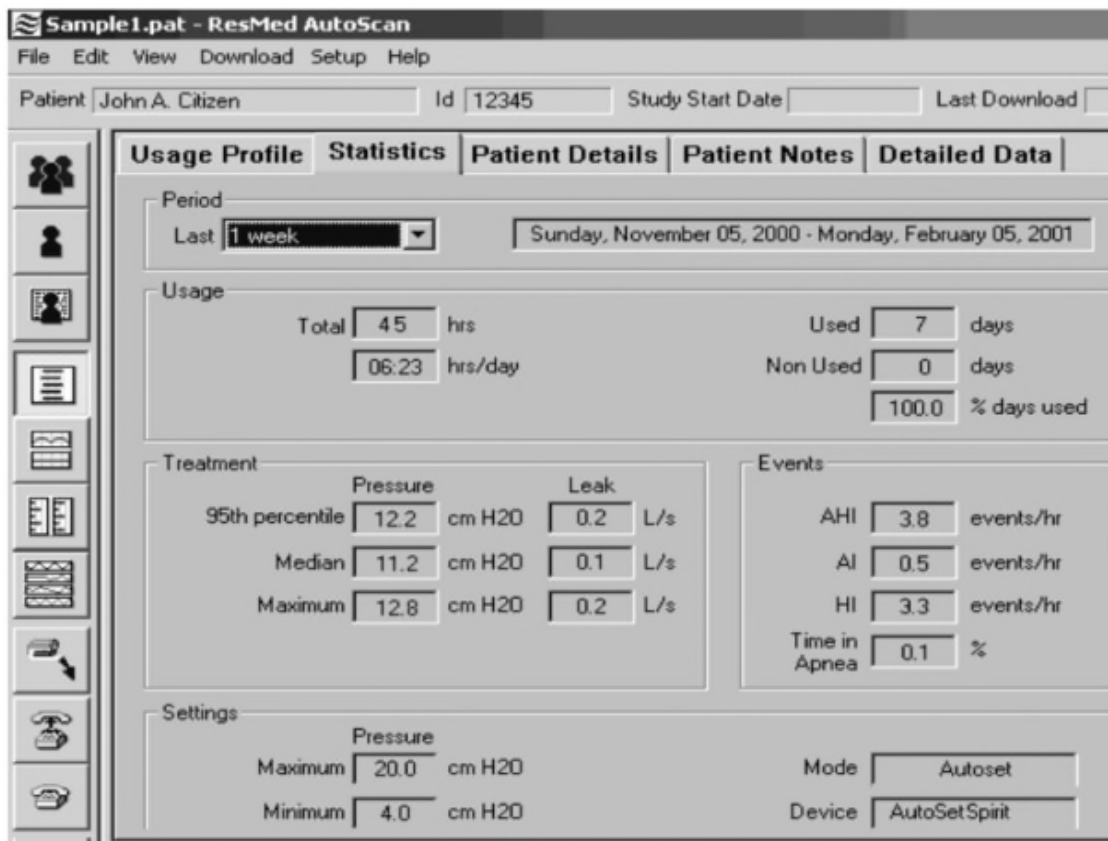
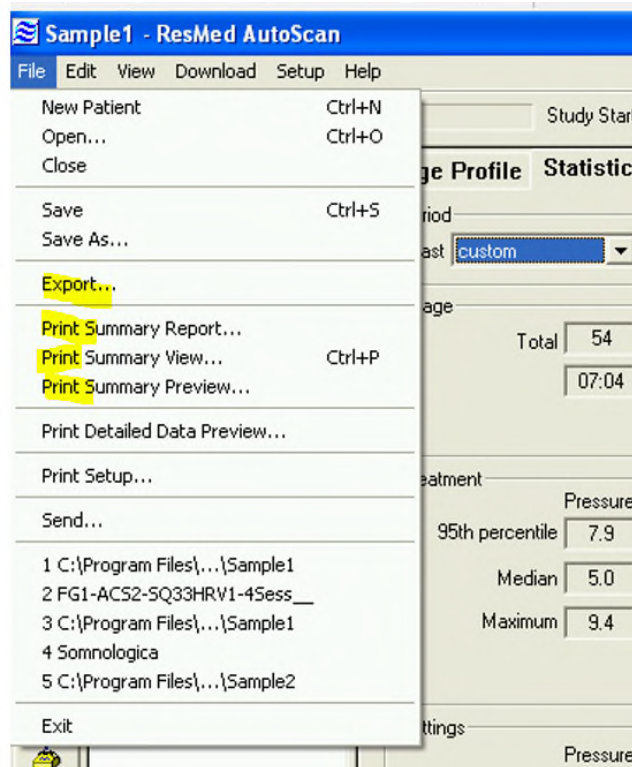


Figure 37 : Statistics display, AutoSet Spirit system

AutoScan 5.4 Clinician's Manual (RMD-311263) at 53; *see also* RMD-0318346 ResMed Prior Art – Virtual Machine and AutoScan 5.4 Screenshots at 0318366. A POSITA would have recognized that the clinician's computer has a processor and display. *See, e.g.*, RMD-0318346 ResMed Prior Art – Virtual Machine and AutoScan 5.4 Screenshots at 0318346 ("Intel Xeon Platinum 8272CL CPU").

398. The clinician's computer running the AutoScan 5.4 software is capable of sending reports in the same or at least similar way that the accused products allegedly send reports from AirView. The AutoScan 5.4 software can be used to "generate and print reports" configured by the clinician. 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]



RMD-0318346 ResMed Prior Art – Virtual Machine and AutoScan 5.4 Screenshots at 0318350.

399. 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, for example, similar to a radiology report being reviewed by a radiologist (specialist) and transmitted/retransmitted to the

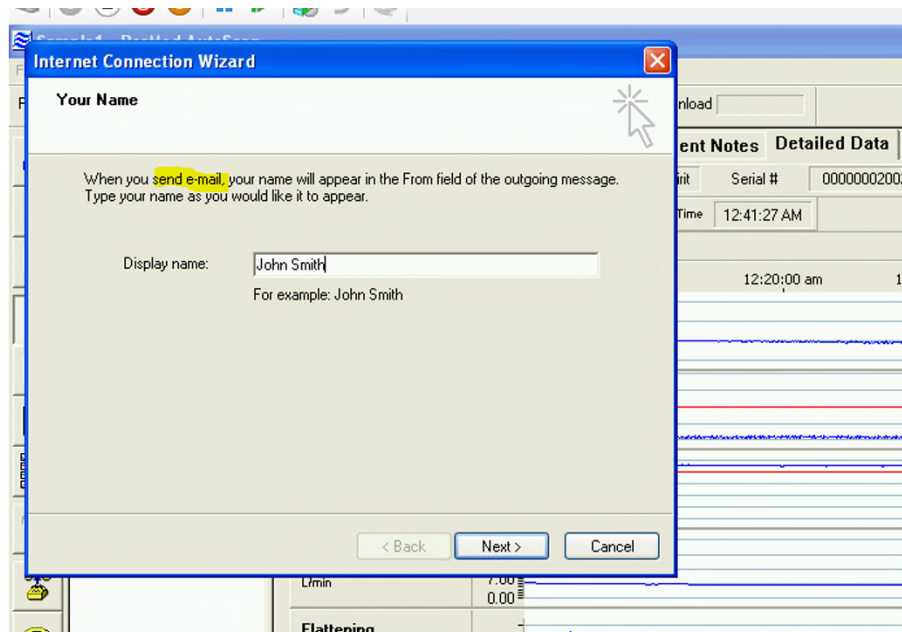
[REDACTED]

treating physician and/or the patient's medical record. 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, such as disclosed in the Rasid IEEE Article, for example.

400. The AutoScan 5.4 software can also “send an email with the currently open patient file as an attachment ...” AutoScan 5.4 Clinician's Manual (RMD-311263) at 25-26;

[REDACTED]

[REDACTED] ResScan 3.0 Clinician's Manual (RMD-063018) at 47.



RMD-0318346 ResMed Prior Art – Virtual Machine and AutoScan 5.4 Screenshots at 0318370, *see also* 0318371-72 (requesting email address and email server (remote internet site) information).

401. 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 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.” The same or similar functionality in RPA System 1 therefore practices the limitation for the same reasons.

[REDACTED]

402. **Obvious Modifications to RPA System 1:** It would have been obvious that the clinician's computer running the AutoScan software would include a wireless networking card (RF wireless RF module transceiver) for sending the email or report generated by the AutoScan software, e.g., instead of a wired modem. *See, e.g.*, AutoScan 5.4 Clinician's Manual at 18 ("Clinician Modem Setup (the PC Modem)). For example, a POSITA would have recognized or found it obvious that the clinician's computer could be a laptop that, due to its mobility, would have been obvious to have included a wireless networking card (wireless RF module transceiver) for communication to the Internet, for example, to send emails. Such a modification would have been an obvious implementation of the clinician's computer running the AutoScan 5.4 software of RPA System 1 requiring no more than off-the-shelf components readily available in consumer electronics.

403. As discussed above, it would have been also obvious to modify RPA System 1 in view of the Rasid IEEE Article. In this modified system, the cellular phone disclosed by the Rasid IEEE Article comprises a second RF wireless transceiver (GPRS cellular transceiver), and "a processor, a software, and a display, the ... cellular phone ... adapted to display the [received sensor data], and to retransmit the [received sensor data] to a remote internet site." *See, e.g.*, Rasid IEEE Article at Abstract, §§ I.B, I.C, III.A, IV, Figs. 2, 4. Figure 4 of the Rasid IEEE Article is reproduced below:



Fig. 4. Layout of mobile telemedicine processor.

Rasid IEEE Article, Fig. 4. The Rasid IEEE Article discloses a system designed to include a patient interface at the mobile device to view the data received by the mobile phone and transmitted to the hospital server via the GPRS cellular network. *See* Rasid IEEE Article, § IV, Figure 9; *see also* Rasid Thesis (2005), 98, 133 (describing Nokia cellular phone user interface for display of the collected signal data). If not expressly disclosed by the Rasid IEEE Article, it would have obvious to display the sensor data at the cellular phone such that the patient could review the physiological sensor statistics collected and transmitted to confirm the validity of the data before it was transmitted to the remote hospital site and for their own information. This feature would have been within the level of ordinary skill as demonstrated by Rasid’s later implementation in connection with his thesis, which was published in 2005.

404. **RPA System 2** (ResTraxx) includes a clinician’s computer capable of accessing the RDC web application. A POSITA would have recognized that the clinician’s computer comprises a processor, software, and display, and is “adapted to display the” data parameters collected and derived at the AutoSet Spirit flow generator and transmitted from the [REDACTED]. *See, e.g.*, RDC User Manual (RMD-306688) at 5 (“ResTraxx Data Center also provides healthcare professionals with the ability to retrieve and view the stored information in an easily interpretable manner using standard web browsers and custom-designed web folders), Figure 1 (showing computers with displays for “User Access: Web browsers located in caregiver’s

facility” accessing the central server via the Internet), 6 (“Any Intel-based PC hardware allowing a connection to the Internet can be used;” “Internet connection software,” and “Browser software”). The Patient Therapeutic History Report that displays specific compliance and air flow data is depicted in Figure 25 of the RDC User’s Manual, reproduced below:

Patient Therapeutic History Report
Current Patient: Luv, Har

Navigation: PATIENT DEMOGRAPHICS | PRESCRIPTION | MONITORING | COMPLIANCE | NOTES

October 1, 2004

Complete History

Report Date	December 29, 2004	HCP	P'Simer, Donley R
Patient Name	Har Luv	Date Of Birth	
Monitoring Start Date	September 20, 2004	Total Days Monitored	36
Monitoring End Date	October 20, 2004	Compliance Percentage	66.67 %

Prescription

Product Mode	Autotitrating
Usage Threshold	05:00 hrs
AHI Threshold	10 a/hr
Leak Threshold	0.4 l/sec

Compliance Data

Mask On Time	03:46 hrs
CPAP Pressure Setting	12.0 cmH2O
Minimum Pressure Setting	4.0 cmH2O
Maximum Pressure Setting	20.0 cmH2O
Hypapnea Index	3.9
Apnea Index	0.2
Apnea Percentage	0.0%

Air Flow Data

	Median	95th Percentile	Maximum
Pressure	12 cmH2O	12.2 cmH2O	12.4 cmH2O
Leak	0.04 l/sec	0.16 l/sec	0.6 l/sec

Mask Events

Time	Event Type
11:05 PM	MaskOn
3:00 AM	MaskOff

Figure 25: Patient Therapeutic History Report by day

RDC User’s Manual (RMD-306688) at 17 (showing display of parameters calculated by the flow generator and transmitted via the [REDACTED] to the RDC backend), 16 (display of AHI); ResTraxx Wireless Patient Monitoring Atlas (RMD-063341) at 063364-65; [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As shown above, the report displayed by the web application includes data calculated and stored by the flow generator, and transmitted by the [REDACTED] (ResTraxx module) to the web components of the ResTraxx Data Center. These parameters include **Compliance Data**, such as Mask On Time, CPAP Pressure Setting, Minimum Pressure Setting, Maximum Pressure Setting, Hypopnea Index, Apnea Index, and Apnea Percentage; and **Air Flow Data**, such as median, 95th percentile, and maximum pressure and leak values.

405. A POSITA would have recognized that the clinician's computer used to access the RDC web application would include a desktop PC using a wireless networking card to access the Internet, or a laptop (as also taught by the Rasid IEEE Article, § III.A), which was known to include a wireless networking card (WiFi radio frequency wireless module transceiver) for Internet connection, e.g., particularly due to its mobility. If this is not expressly disclosed by RPA System 2, this feature would have been an obvious modification to RPA System 2 using conventional commercial computers and components (wireless network cards in the form of WiFi RF module transceiver) known in the art. *See, e.g.*, RMD-0318504 RadioShack Reference Guide (2003-2004) 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 notebook and desktop cards.

406. A POSITA would have been motivated to use a wireless networking connection for the clinician's computer accessing the RDC web application at least for the same reasons the development of computers and networking, and mobility, suggested such features, and would have been merely a design choice by the clinician or health care provider for their preference for network access. Such features could have been easily implemented with commercially available components in their known configurations to achieve no more than predictable results.

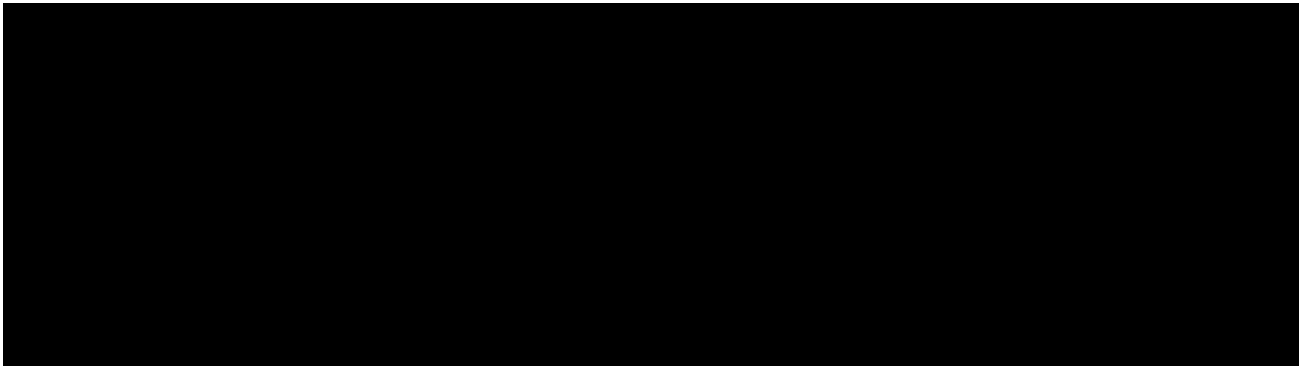
407. A POSITA would have recognized, or would have also found it obvious, that the RDC web application generated reports (shown above) that include the data calculated by the

[REDACTED]

flow generator could be *retransmitted* to a remote internet site maintaining the patient's medical record. It would have been obvious to incorporate this remote transmission feature so as to share the compliance data reported from the flow generator with health care providers to improve the subject's treatment and corresponding settings of the device in the event they were not improving the subject's condition.

408. **Additional Modification to System 2:** It would have also been obvious to modify RPA System 2 in view of telemedicine systems such as the system disclosed by the Rasid IEEE Article to arrive at the claimed system. *See* limitation 15.f. As discussed in reference to RPA System 1 for this limitation, the Rasid IEEE Article discloses a cellular phone comprising a second RF wireless module transceiver (GPRS transceiver), processor, display, and software, where the cellular phone is adapted to display sensor signal data received from the patient monitor and retransmit the data to a hospital server (remote internet site). *See, e.g.*, Rasid IEEE Article at Abstract, §§ I.B, I.C, III.A, IV, Figs. 2, 4. It would have been obvious to modify RPA System 2 for at least the reasons discussed above and also those expressed for limitations 15.d-15.f.

[REDACTED]



411. 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 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 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.

412. Furthermore, a POSITA would have recognized, or at least found it obvious, that

[REDACTED]

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.

413. Alternatively, in view of CleveMed’s 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.”

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.

414. RPA Systems 1-2 each render this claim obvious. As discussed for limitations 15.d-g above, it would have been obvious to modify RPA Systems 1-2 in view of the Rasid IEEE Article such that the AutoSet Spirit flow generator (PAP device) incorporated the off-the-shelf Bluetooth transceiver (first radio frequency wireless module transceiver), which uses the Bluetooth protocol, to communicate with the cellular phone in the system of Rasid’s IEEE Article. See limitations 15.d-g, above.

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.

415. RPA Systems 1-2 each disclose this limitation, and therefore render the claim obvious in view of the discussions above with regard to the independent claim 15.

416. The AutoSet Spirit flow generator (PAP device) processes airflow sensor data using the signal processing technique of a standard deviation technique. See, e.g., [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

XI. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

418. As discussed above in the section regarding legal standards, I understand that certain “secondary considerations” may be examined to determine whether an invention would have been obvious to one of ordinary skill in the art. I understand that secondary indicia of non-obviousness may include:

- 1) a long felt but unmet need in the prior art that was satisfied by the patented invention;
- 2) commercial success of processes covered by the patent;
- 3) unexpected results achieved by the invention;
- 4) praise of the invention by others skilled in the art;
- 5) taking of licenses under the patent by others;
- 6) deliberate copying of the invention;
- 7) failure of others to find a solution to the long felt need; and
- 8) skepticism by experts.

419. I also understand that there must be a relationship between any such secondary considerations and the invention as a whole.

420. I have considered the secondary consideration factors listed above and CleveMed’s Second Supplemental Response to ResMed’s Interrogatory No. 16 (October 3, 2023) regarding secondary considerations of non-obviousness and the documents cited by it. In my opinion, none of these factors show that the ’269 Patent Asserted Claims are not obvious. Overall, CleveMed’s allegations do not link any of the allegations to any asserted claim or claim limitation of the ’269 patent. I reserve the right to supplement my analysis if CleveMed or its expert(s) supplement CleveMed’s allegations.

A. A Long Felt But Unmet Need in the Prior Art

421. Any long felt need allegedly satisfied by the asserted claims (which there are

[REDACTED]

none) was met many times over by the prior art. Accordingly, this secondary consideration does not show that the '269 patent is not obvious.

422. I understand that CleveMed has alleged the following :

The technology claimed in the Patents-in-Suit solved long-felt industry needs. Prior to the technology of the Patents-in-Suit, the sleep industry had no ability to effectively deliver efficient and accurate sleep breathing disorder care solutions that can be administered in a subject's home. Additionally, the Patents-in-Suit solve many longstanding problems arising in the sleep industry's shift from in-lab testing and treatment to the more cost-effective home setting, by providing: an at-home sleep disorder breathing diagnosis and treatment solution that treats a subject's sleeping disorder or symptoms based upon their physiological condition as determined by an internal airflow sensor(s) that measures a patient's airflow; an at-home sleep disorder breathing diagnosis and treatment solution that treats a subject's sleeping disorder or symptoms based upon their physiological condition as determined by an internal airflow sensor(s) that measures a patient's airflow and oximetry data; an at-home sleep disorder breathing diagnosis and treatment solution that treats a subject's sleeping disorder or symptoms and is capable of remote adjustment based upon the calculated symptom data of a severity of the patient's sleeping disorder symptoms and/or an index of a patient's symptoms measured during use of the PAP and transmitted to a remote location; an at-home sleep disorder breathing diagnosis and treatment solution that is capable of calculating of a severity of the patient's sleeping disorder symptoms and/or an index of a patient's symptoms and wirelessly transmitting it to a remote location in order to improve the efficacy of the prescribed treatment; a sleep disorder breathing diagnosis and treatment solution with a monitor that can be easily administered at home, which provides adjunct data, such as respiratory effort, airflow, oximetry and/or body position data, that can be combined with other data from the CPAP for a more comprehensive and extensive data set that is available while a patient is using CPAP at home (where previously there was no such system that could be effectively or easily administered from home or where such a full set of data was available in such a context), which is particularly important and helpful for medical professionals to have when analyzing data for patients with comorbidities; a sleep testing solution that can be prepared and administered by a patient at their home; an at-home sleep testing solution that improves patient mobility while sleeping; an at-home sleep testing solution capable of processing and outputting at-least type III sleep data; and an at-home sleep testing solution capable of recording, displaying, scoring and analyzing physiological signals for sleep studies.

[REDACTED]

Prior to the Patents-in-Suit, the industry for sleep breathing disorder care solutions, led by ResMed and Phillips Respironics, failed to develop any product or solution that solved any of these longstanding problems.⁹¹

423. It is unclear from the above statement what aspects CleveMed alleges is attributable to the '269 patent as opposed to the other patents that I understand are asserted in this litigation. However, as established above, e.g., in section X, not only were the identified features disclosed in the prior art, they were implemented in commercially. Furthermore, CleveMed's allegations above do not link any of the alleged "needs" to any particular claim or claim limitations of the '269 patent asserted claims.

B. Commercial Success of Processes Covered by the Patent

424. I understand from counsel that, in order to support a finding of non-obviousness based on commercial success, there must be a sufficient nexus between the commercial success and the patented subject matter. I understand from counsel that evidence showing merely that a large number of goods were sold supposedly embodying the patent claims does not demonstrate that the invention enjoyed commercial success because it does not satisfy the nexus requirement. I understand from counsel that the success must be due to the claimed features, rather than advertising or superior workmanship, in order to fulfill the nexus requirement.

425. I understand that CleveMed contends that "ResMed copied the technology of the Patents-in-Suit and incorporated this technology into the Accused Products. ResMed was aware of the technology and instead of licensing the technology, ResMed copied it for its own benefit. ... ResMed achieved great commercial success, praise by others, and industry recognition based on the technology in the Patents-in-Suit."⁹² CleveMed's contention does not link any alleged

⁹¹ CleveMed's Second Supplemental Response to ResMed's Interrogatory No. 16 (October 3, 2023).

⁹² *Id.* CleveMed's written response also alleges that Philips Respironics also copied the technology and incorporated this technology into its products. Philips Respironics has also achieved great commercial success, praise by others, and industry recognition based on the technology in the Patents-in-Suit. CleveMed garnered numerous accolades and praise throughout the industry for its innovative technology covered by the Patents-in-Suit." However, I understand CleveMed has not provided any evidence of this. If CleveMed provides any such evidence I reserve the right to consider it and supplement my analysis accordingly.

[REDACTED]

success to any particular claim or claim limitation of the '269 Patent Asserted Claims.

Furthermore, as established above, the accused functionality was implemented by ResMed in the prior art before CleveMed filed its application that the '269 patent claims priority to.

Furthermore, as established above, ResMed had deployed the ResTraxx system, which was an Internet connected system, at least by February 2004. *See, e.g.*, sections X.A, X.A.7.

C. Unexpected Results Achieved by the Alleged Inventions

426. The asserted claims are merely combinations of components well known in the prior art, as discussed above. Each of these components is used in an ordinary and expected way in the asserted claims, and the result of using them in combination is entirely expected and predictable. Accordingly, this secondary consideration does not show that the asserted claims are not obvious.

D. Praise of the Invention By Others of Skill in the Art

427. I understand that praise of the invention by others skilled in the art can support a showing of non-obviousness. CleveMed's general allegation that "ResMed achieved great commercial success, praise by others, and industry recognition based on the technology in the Patents-in-Suit" does not identify any specific feature that was allegedly praised, or was not present in ResMed's own prior art systems or the prior art.

E. Taking of Licenses to the Patents by Others

428. I understand that the mere existence of licenses is insufficient to overcome the conclusion of obviousness. I understand that CleveMed has alleged "[t]he inventions of the Patents-in-Suit are subject to paid-up licenses by the U.S. Government based on highly competitive grants awarded by the National Institute of Health." However, CleveMed has not provided any additional information with regard to these alleged licenses.

F. Deliberate Copying of the Invention

429. Beyond the general allegations identified above with regard to ResMed and Philips Respironics, CleveMed does not provide any specifics for this allegation, particularly

[REDACTED]

with regard to any specific claim or claim limitation of the '269 patent.

E. Failure of Others to Find a Solution to a Long Felt Need

430. I understand that to show non-obviousness based on this secondary consideration, CleveMed must point to evidence of an “articulated identified” problem and failed efforts to solve the problem. I understand that CleveMed must also show that there are more than minimal differences between the prior art and the asserted claims.

431. However, CleveMed has not identified the problem solved by the alleged inventions of the '269 patent, detailed any failed efforts to solve that problem, or shown that the differences between the prior art and the asserted claims are significant.

F. Skepticism by Experts

432. CleveMed has not identified any skepticism in the industry related to the purported inventions. The '269 patent falls within an overwhelmingly crowded field of prior art (as discussed, e.g., in Section X.A-B) and the alleged inventions of the asserted patents were routinely implemented and yielded predictable results. The '269 patent and its claims contributed nothing to the art beyond what was already known.

XII. MATERIALITY AND INEQUITABLE CONDUCT [CleveMed HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY Information]

433. I understand from ResMed counsel that an applicant for a patent is under a duty of candor in dealing with the Patent and Trademark Office, and that a breach of that duty constitutes “inequitable conduct” or, in severe form, “fraud.” I further understand that a breach may occur either by affirmative misrepresentation or by omission of “material” information.

434. I understand that, as a general matter, the materiality required to establish inequitable conduct is but-for materiality. I understand that when an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. Thus, the relevant materiality question is whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. I also understand that, in making this determination, courts apply the preponderance of the evidence

[REDACTED]

standard and give claims their broadest reasonable construction. I understand that one relevant inquiry is whether the teachings of the reference would have rendered the claimed invention invalid. I understand this would include, as discussed above in the legal standards sections for anticipation and obviousness, whether the teachings of the reference, in combination with other relevant prior art, would have rendered the claimed invention obvious

435. I also understand that an exception exists in cases of affirmative egregious misconduct, such as the filing of a false affidavit. In such cases, the misconduct itself is material. I further understand that this exception to the general rule requiring but-for proof incorporates elements of early cases dealing with deliberately planned and carefully executed schemes to defraud the PTO and the courts.

436. I also understand that an item of prior art is not material if it is cumulative to other items of prior art that the examiner considered. I further understand that an item is not cumulative if it discloses a feature that is not disclosed in the items considered by the examiner, or suggests a combination of features that is not disclosed in the items considered by the examiner.

A. Copied Prior Art

437. I have considered the '269 patent claims and whether the following references (collectively the "Copied Prior Art") meet the above "materiality" standard for any of the claims.

- (1) US Patent No. 6,644,311 to Truitt, et al., issued November 11, 2003 ("Truitt");
- (2) US Patent No. 6,167,258 to Schmidt, et al., issued December 26, 2000 ("Schmidt");
- (3) US Patent No. 6,993,380 to Modarres, filed June 4, 2003 and issued January 31, 2006 ("Modarres");
- (4) US Patent No. 8,187,209 to Giuffrida, filed March 17, 2005 and issued May 29, 2012 ("Giuffrida");
- (5) US Patent Application Publication No. 2004/0129838, published July 8, 2004 ("Lisy").

438. Each of these references are prior art to the '269 patent at least because they were filed before, and in some cases published/issued before, the November 4, 2005 priority date claimed for the '269 patent. My analysis is summarized in Exhibit 4, attached hereto.

[REDACTED]

439. As established in Exhibit 4, the five references of the Copied Prior Art, either alone or in combination, would have rendered at least one claim of the '269 patent obvious.

440. Therefore, each of the references of the Copied Prior Art would have rendered at least one claim of the '269 patent invalid.

441. For at least these reasons, each of the references of the Copied Prior Art meet the “materiality” requirement.

442. [REDACTED]

[REDACTED] As discussed above, I understand that the '269 patent claims priority to the '899 application and shares the same specification. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Date	Bates No.	Description/summary
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

⁹³ See, e.g., '899 FH, 11/4/2005 Utility Patent Application Transmittal (identifying “Attorney Docket No. CMD-023”); [REDACTED].

⁹⁴ CleveMed’s Responses to ResMed Interrogatory No. 2.

⁹⁵ See, e.g., [REDACTED]

[REDACTED]

Date	Bates No.	Description/summary
		allow gas, such as expired gas from the subject, to exhaust to the atmosphere, as [REDACTED]
[REDACTED]		[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED]	[REDACTED]	[REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED]	[REDACTED]	[REDACTED] [REDACTED] [REDACTED]

[REDACTED]

Date	Bates No.	Description/summary
[REDACTED]		

[REDACTED]

Date	Bates No.	Description/summary
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[REDACTED]		
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443. The correspondence between the issued text and figures of the '269 patent from the above-identified copying from the Schmidt, Truitt, Modarres, Lisy, and Giuffrida references into the '899 application is summarized in the table below with references to the relevant text in the issued '269 patent. This correspondence is also depicted in the attached color-coded versions of the copied references at Exhibit 5 (Schmidt), Exhibit 6 (Truitt), Exhibit 7 (Modarres), Exhibit 8 (Lisy), and Exhibit 9 (Giuffrida) and the '269 patent at Exhibit 10.

<u>'269 Specification</u>	<u>Copied From</u>
Figs. 1-6	Schmidt Figs. 1-6
Fig. 7	Truitt Fig. 1

<u>'269 Specification</u>	<u>Copied From</u>
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

444. Attached Exhibit 3 is a table with a redline comparison of the above elements of the '269 patent and the copied Schmidt, Truitt, Modarres, Lisy, and Giuffrida references, which shows the deceptive changes the drafter made to the copied portions of the text and also Figure 7.⁹⁶

445. In addition to the materiality of Truitt established in the attached Exhibit 4 chart, CleveMed also emphasized the materiality of the disclosure of Truitt to the purported novelty of the alleged inventions of the '269 patent in the IPR proceeding against the '269 patent (discussed at § VI.E). In its preliminary response to the IPR petition, CleveMed argued 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. *See* IPR2023-00565, POPR, 5-6 (citing '269 patent, 23:7-17 and excerpting FIG. 7), 27 (arguing that the claims are “patentable because the combination of references does not disclose ‘an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject.’”). CleveMed’s arguments in favor of patentability also excerpted Figure 7 of the '269 patent (Truitt’s FIG. 1) and described it as an “exemplary embodiment of the CPAP device” of the

⁹⁶ I also referenced Exhibit 11 for this analysis, which is another color-coded version of the '269 patent showing the portions of the specification that were *not* copied from the five Copied Prior Art references. Exhibits 3 and 5-11 were prepared by ResMed counsel, however I analyzed and confirmed their content and adopt them here in support of my opinions. Similarly, I understand the table provided in the above paragraph comparing the '269 specification to the copied prior art was provided in ResMed’s First Amended Answer to the Complaint in this litigation. I have analyzed, confirmed, and adopted its content here in support of my opinions.

[REDACTED]

“claimed invention.” *Id.* at 4-6 (emphasis added). But CleveMed’s characterization of Figure 7 as CleveMed’s “invention” was untrue—this figure was disclosed in Truitt and characterized *there* as prior art to even the Truitt patent. As established above and in the attached Exhibit 10 (’269 patent – color-coded copied art) and Exhibit 6 (Truitt – color-coded copied portion) the excerpted figure and text CleveMed relied on to try to demonstrate novelty were copied from Truitt.

446. As identified above, I understand that an item of prior art is not material if it is cumulative to other items of prior art that the examiner considered. I further understand that an item is not cumulative if it discloses a feature that is not disclosed in the items considered by the examiner, or suggests a combination of features that is not disclosed in the items considered by the examiner. I understand that CleveMed has not identified any prior art disclosed to the examiner that CleveMed alleges the copied Schmidt, Truitt, Modarres, Lisy, and Giuffrida references might be cumulative to. If CleveMed does present such art or argument, I reserve the right to respond accordingly. However, CleveMed’s arguments during prosecution of the ’269 patent demonstrate that the copied Schmidt, Truitt, Lisy, and Giuffrida references were not cumulative to the prior art considered by the examiner. Regarding Lisy, the Examiner identified dependent claims reciting the signal processing methods copied from Lisy as reciting allowable subject matter because the prior art of record did not disclose the claimed sensor signal processing techniques that are only described in the ’269 patent in the disclosure copied from Lisy. ’269 File History, 9/6/2016 Final Office Action at 13. The dependent claims that later issued as claims 4, and 14 had been added in the previous amendment and CleveMed argued that the prior art of record did not disclose the claimed signal processing techniques. ’269 File History, 5/27/2016 Amendment at 2, 4, 8, 10-11. For Schmidt, CleveMed repeatedly argued during prosecution that the prior art failed to disclose the claimed “signal processing module comprising ... electronics adapted for filtering and processing the signal” and “data acquisition module” that are only described in the disclosure of the ’269 patent in the disclosure copied from Schmidt. *See, e.g.*, ’269 File History, 3/27/2016 Amendment at 10, 17. For Giuffrida,

[REDACTED]

CleveMed argued during prosecution that the prior art of record failed to disclose the claimed transmission to a remote location, a feature that is only discussed in the '269 patent in the disclosure copied from Giuffrida. *See, e.g.*, '269 File History, 3/27/2016 Amendment at 11, 12, 22. For Truitt, CleveMed amended the claims to overcome the prior art by adding the features copied from Truitt that the airflow sensor was “internal to the PAP device” and “adapted for measuring the respiratory airflow data of a subject using the PAP device” (or some variation of this limitation) to the claims that issued as claims 1, 5, and 15. *See, e.g.*, '269 File History, 10/12/2017 Amendment at 2, 4. CleveMed also emphasized the “airflow sensor internal to the PAP device” as a feature missing from the prior art. *See, e.g.*, '269 File History, 3/27/2016 Amendment at 10. These features were not CleveMed’s invention—they were copied from Truitt.

B. ResMed Prior Art

447. I have also considered whether the ResMed Prior Art of RPA System 2, including the S7 AutoSet Spirit flow generator and ResTraxx, was material to the claims of the '269 patent. As established in my analysis above of RPA System 2, ResTraxx (including [REDACTED] and ResTraxx Data Center) at least renders obvious, either alone or in combination with the AutoSet Spirit flow generator, at least the '269 patent Asserted Claims. I have also reviewed documents that show [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] I understand that CleveMed and ResMed had a Product Development and Marketing Agreement in order to promote product development by integrating ResMed devices with CleveMed's products and technology.

[REDACTED]. I further understand that, pursuant to this agreement, ResMed provided information regarding several ResMed prior art systems, including ResTraxx, S7 AutoSet, and S8 AutoSet Vantage. *See, e.g.*, [REDACTED] [REDACTED]

[REDACTED]

[illegible]

[REDACTED]

448. The ResMed Prior Art was also not cumulative to the art considered by the examiner for at least the same reasons Truitt, Lisy, and Giuffrida were not cumulative. The ResMed Prior Art discloses at least the same claimed features disclosed in the copied portions of Truitt, Lisy, and Giuffrida.

449. As established above, the ResMed Prior Art would have rendered at least one claim of the '269 patent obvious.

450. Therefore, the ResMed Prior Art would have rendered at least one claim of the '269 patent invalid.

451. For at least these reasons, the ResMed Prior Art meets the “materiality” requirement.

C. Additional Prior Art

452. [REDACTED]

[REDACTED] I understand that CleveMed’s Crystal Monitor 20S was a monitor that CleveMed had developed and began selling on the market in 2004, more than one year before the filing of the '269 patent priority application. See R.N. Schmidt Dep. Tr. (9/26/2023), 102:1-104:12, 168:12-170:18, 176:14-24. [REDACTED]

[REDACTED] The Crystal Monitor 20-S is also not cumulative, at least because CleveMed argued during prosecution of the '269 patent that the prior art did not disclose, e.g., “the output of the data acquisition system is transmitted wirelessly” to a receiver. See, e.g., '269 Patent ('116 App.) FH, 5/27/2016 Amendment at 11. I

[REDACTED]

understand the Crystal Monitor 20-S provides a data acquisition system that transmits data wirelessly to a receiver. *See* RMD-090625 Crystal Monitor 20-S Brochure.

453. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As discussed above in section X.B and established in section X.C, the ResMed flow generators and their related features and accessories at least rendered the claims of the '269 patent obvious, and therefore were material. Their disclosures are not cumulative for at least the same reasons noted above for the ResMed Prior Art (e.g., System 2) discussed above. *See* Section XII.B, X.C.

XIII. THE '269 SPECIFICATION FAILS TO PROVIDE AN ADEQUATE DISCLOSURE FOR THE ASSERTED CLAIMS

454. The specification of the '269 Patent fails to comply with either the definiteness or enablement requirements for the '269 Patent Asserted Claims, and the '269 Patent Asserted Claims are therefore invalid.

A. Written Description

455. I understand from ResMed counsel that under 35 U.S.C. § 112, first paragraph, in order for a patent claim to be valid, the patent's specification must "contain a written description of the invention, and of the manner and process of making and using it, 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 connected, to make and use the same." I understand from ResMed counsel that a claim is invalid for lack of "written description" if the patent specification fails to adequately describe all elements of the claim such that one of ordinary skill in the art in reading the patent would determine that the inventor possessed the claimed invention.

456. I understand from ResMed counsel that to satisfy the written description requirement of § 112, first paragraph, the description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed. I further understand from

[REDACTED]

ResMed counsel that the test for sufficiency is whether the specification's disclosure reasonably conveys to those skilled in the art that the inventor *had possession of the claimed subject matter* as of the filing date. I understand from ResMed counsel that "possession" means possession as shown in the disclosure, and requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. I also understand from ResMed counsel that one shows that one is in possession of the invention by describing the invention, with all its claimed limitations, not that which merely makes it obvious. I understand from ResMed counsel that one does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. I further understand from ResMed counsel that the specification does not need to describe the subject matter in exactly the same terms as used in the claims, but it must nonetheless contain a description of the claimed subject matter.

457. I have analyzed the asserted claims of the '269 patent with the specification. The specification fails to meet the requirements identified above for at least the following claim terms:⁹⁷

1. **"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)"**

458. The only apparent reference in the '269 patent to the location or placement of the airflow sensor "internal to the PAP device" is the text at 23:7-17 that references Figure 7. As discussed elsewhere in my report, this text and Figure are copied from the Truitt patent. The '269 patent does not describe in this text, or anywhere else, that an airflow sensor *internal* to the PAP device "measur[es] respiratory airflow of a subject." In particular, as discussed in reference

⁹⁷ I also referenced Exhibit 11 for this analysis, which shows the remaining portions of the '269 patent specification that were *not* copied from the five references identified above in the materiality section of my report (Section XII).

[REDACTED]

to CleveMed's statements in the IPR against the '269 patent, CleveMed argued that an airflow sensor internal to the PAP device of the prior art merely measured blower flow and not the physiological state of the subject, and specifically the respiratory airflow of the subject.

459. To the extent CleveMed relies on the recitation that the "information from the flow sensor 320 and/or pressure sensor 322 is used, for example, to ... monitor the condition of the subject" for written description support for these limitations, that statement does not specify or otherwise indicate that the measured "condition" is the respiratory airflow. Moreover, to the extent such disclosure is found to provide a description of the identified claim limitations, such disclosure was copied from the prior art Truitt application. Accordingly, a POSITA would have understood the claimed internal airflow sensor was not something the '269 patent inventors had invented or were in possession of, but instead something they copied from the Truitt patent and the inventors of the Truitt patent. Neither of the inventors named on the Truitt patent (Patrick W. Truitt and Winslow K. Duff) are listed as inventors on the '269 patent.

2. "an electronic component adapted for filtering and processing the first signal from the pulse oximeter sensor to remove artifacts" (claim 5);

460. The '269 patent specification does not describe processing a sensor signal from a pulse oximeter "to remove artifacts." A POSITA would have recognized, as discussed above, that a physiological sensor signal, like that from a pulse oximeter, might include subject introduced artifacts, such as from the movement of the subject and/or poor or changing interface of the sensor with the subject. External artifacts might also be present, such as due to electrical interference. The signal processing techniques used to remove or mitigate artifacts would depend on the type of artifact. The '269 patent specification does not discuss or address artifacts, or which type of processing might be used to "remove artifacts."

461. Furthermore, if CleveMed relies on the disclosure in the '269 patent at 8:57-18:50, or 20:11-21:67 to provide a written description for this claim limitation, those sections of the specification were copied from Schmidt and Lisy (respectively). Accordingly, a POSITA

[REDACTED]

would have understood the claimed feature was not something the '269 patent inventors had invented or were in possession of, but instead something they copied from the prior art disclosures and their named inventors. In addition to Robert N. Schmidt and MoHammad Modarres, the Lisy publication lists as inventors Frederick J. Lisy, Mehul P. Patel, Jack M DiCocco, Reed Carver, and Troy Prince, none of whom are listed as inventors on the '269 patent. The Schmidt patent lists Donald C. Ferencz and Steven P. Hendrix as inventors, but neither of them are listed as inventors on the '269 patent.

3. **“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), “the PAP device ... further comprising: ... a second input adapted for receiving the pulse oximetry sensor data from the output of the signal processing module” (claim 1), “the PAP device comprising ... a second input adapted for receiving the pulse oximetry sensor data from the output of the data acquisition device” (claim 5);**

462. The '269 patent does not describe a signal processing module or data acquisition system that outputs pulse oximetry sensor data to a PAP device input. For example, Figure 8 (which is the only figure not copied from the prior art) and its corresponding text merely show a number of sensors 418, 420, 424, and 426, where it appears sensor 424 is labeled in the figure “Pulse Ox.” '269 patent, 23:18-21, FIG. 8. However, there is no description in this section that the pulse oximeter data is provided to an input of the CPAP device 428.

4. **“the PAP device ... further comprising a processor adapted for ... 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), “the processor 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” (claim 5), “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)**

463. The '269 patent fails to provide a written description for the claimed calculations.

[REDACTED]

First, the patent never mentions “symptom data” or what a “symptom” or “symptom data” might be. Nor does the patent use the terms “index of a level of severity” or “index of a subject’s symptoms.” Although columns 5-6 mention apneas and hypopneas, the patent’s specification makes no link between such events and the claimed “data.” Nor does the patent make any link between the claimed “data” and any of the accused calculated parameters. With regard to the claimed “index[es],” the only “index” mentioned or alluded to by the patent is in the background discussion copied from Modarres that recites a diagnostic method using polysomnography that is used to obtain “respiratory disturbance index to diagnose sleep apnea.” ’269 patent, 1:51-54.

464. The ’269 patent also fails to provide a written description of a processor that calculates the claimed “data” or “index” “based in part on both” respiratory airflow data and pulse oximetry sensor data. At best, the specification describes using signals or data from one or more of the sensors described in the patent. However, as noted in the overview of the patent, the specification merely lists a number of physiological sensors known to those of ordinary skill in the art. There is no description of using specifically the combination of both respiratory airflow sensor data and pulse oximeter sensor data to calculate the claimed “data ... and/or index”.

465. With regard to claim 1, the ’269 patent fails to provide a written description that the *PAP device* comprises a processor that performs any type of calculation that could be “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, in reference to Figure 8, the ’269 patent describes that “a microprocessor 438 for processing the data or signals to determine a level of severity of the subject's sleeping disorder or symptoms; the diagnostic device then transmits a signal based on this level of severity by either a tether 444 or radio signal (not shown) to an actuator (not shown) in the CPAP device 428.” ’269 patent, 23:27-33. In other words, this describes that the microprocessor of the diagnostic device, *not a processor at the PAP device*, determines a level of severity of the subject’s sleeping disorder or symptoms.

466. With regard to claim 15, there is no apparent disclosure in the ’269 patent of a processor that calculates “data of usage of the PAP device.” If CleveMed argues the disclosure

[REDACTED]

at 22:45-23:17 provides written description support for this limitation, such disclosure was copied from the prior art Truitt application. Accordingly, a POSITA would have understood the claimed feature was not something the '269 patent inventors had invented or were in possession of, but instead something they copied from the Truitt patent and the inventors of the Truitt patent.

467. Furthermore, if CleveMed relies on the disclosure at column 20:11-21:67 as allegedly providing a written description of these claim terms, I disagree. The specification of the '269 patent at these columns does not describe calculating symptom data of a level of severity of a subject's sleep disorder symptoms, and instead expressly states the signal processing techniques are used "to *predict the onset* of these symptoms." '269 patent at 20:20-21, *see also* 20:66-67 ("foretells the onset of the symptom"), 21:6-8 ("indicating to the control system that certain critical symptoms are impending"). For example, the specification does not link the claimed symptom data of a level of severity with the prediction of the onset of symptoms. Moreover, these columns of the specification do not describe calculating an index of any kind or in any way link an index with the description of the *prediction of the onset* of symptoms.

5. **"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;" "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" (claim 15)**

468. First, to the extent this claim limitation requires or encompasses a first RF wireless module transceiver located at the PAP device for receiving and transmitting the "symptom data ... and/or index," the '269 patent does not disclose such a feature.

469. Second, there is no disclosure in the '269 patent of the claimed configuration of a

[REDACTED]

“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.” For example, there is no description of a base station, cellular phone, or PDA that displays “symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms.” There is also no description of such a “base station, cellular phone, or PDA” that comprises software. There is also no description of a “base station, cellular phone, or PDA” that receives “symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms” from an RF wireless transceiver of a PAP device.

470. To the extent CleveMed argues that the '269 patent's disclosure at 19:12-45 discloses these limitations, such disclosure was copied from Giuffrida. Therefore, a POSITA would not have concluded the inventors of the '269 patent were in possession of such features, and instead they were in the possession of the inventor, Joseph Giuffrida, of the Giuffrida disclosure, who is not listed as an inventor on the '269 patent. Similarly, to the extent CleveMed argues that the '269 patent's disclosure at Figures 1-6 and/or the text at 8:57-18:50 provides a written description for these limitations, that disclosure was copied from Schmidt. Therefore, a POSITA would not have concluded the inventors of the '269 patent were in possession of the claimed features.

6. “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);

471. The '269 patent does not provide a description that the PAP device and a “base station, cellular phone, or PDA” communicate using Bluetooth wireless protocol.

- [REDACTED]
7. **“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);**

472. The only apparent disclosure of a transceiver adapted for transmitting data to remote location is in the disclosure of the ’269 patent at 19:12-45 copied from Giuffrida. Accordingly, a POSITA would have understood that the inventors of the ’269 patent were not in possession of the claimed feature. Instead the claimed feature, in particular the concept of transmission to a remote location, was copied from Giuffrida and in the possession of its inventor, who is not listed as an inventor on the ’269 patent.

8. **“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)**

473. The only apparent written description for this limitation is the portion copied from Lisy into the ’269 patent at 20:11-21:67. Therefore, a POSITA would have understood the inventors of the ’269 patent were not in possession of these features as part of their “invention,” but instead that they were copied from the Lisy patent and its inventors, who are not listed as inventors on the ’269 patent.

XIV. NONINFRINGEMENT ALTERNATIVES

474. I understand that ResMed has identified alternatives to the accused products and specific functionality that includes the following:

- (1) Use of ResScan software instead of AirView;
- (2) Flow generators that employ card-to-cloud and do not include cellular communication capability;
- (3) Flow generators that do not support pulse oximeters;
- (4) For AirSense 11, removal of Bluetooth communication capability;
- (5) Use of the ResMed prior art technology, including “Restraxx and the corresponding Restraxx Data Center that was the predecessor to EasyCare Online.”

[REDACTED]

ResMed's Suppl. Resp. to Interrogatory No. 3, October 3, 2023. I have reviewed these alternatives and, in my opinion, they do not practice the asserted claims of the '269 patent.

A. ResScan software – No Infringement of Claims 1, 5, and 15

475. I understand that ResScan software is the successor of the AutoScan software discussed above. *See, e.g.*, Roman Dep. Tr. (9/4/2023), 17:24-32:15, 32:18-38:18. Similar to the AutoScan software, the ResScan software is loaded on a clinician's computer like the AutoScan software, and does not include a "cloud" component like that employed by the accused AirView platform. *Id.* I understand that CleveMed's initial infringement contentions accused ResScan of infringing the '269 patent Asserted Claims, but have since withdrawn their allegations.⁹⁸ I understand that ResScan cannot be used to receive and transmit data from an accused flow generator (such as the Astral, Stellar, AirSense 10, AirSense 11, and AirCurve 10), and transmit to a remote location. *See* Roman Dep. Tr. (9/4/2023), 19:20-20:9. Accordingly, configurations of the accused flow generators with ResScan would not practice the "module transceiver" of limitation 1.d, the "'later transmission ... to a remote location" of limitation 5.f, or the "wireless transceiver" or transmission "to a remote internet site" of limitation 15.g. Thus, the accused flow generators used in combination with the ResScan software would not infringe at least claims 1, 5, and 15.

B. Card-to-Cloud Implementations – No Cellular Capability – No Infringement of Claims 1, 5, 15

476. I understand CleveMed has accused the Astral, Stellar, ResMed AirSense 10, AirCurve 10, AirSense 11 flow generators of infringing claims 1, 5, and 15. *See* CleveMed Final Infr. Cont., Charts A, H, I, J; *see also* § IX, *supra*. An alternative to the accused technology (identified in CleveMed's Final Infringement Contentions) would comprise the accused AirSense and AirCurve products without cellular communication capability, and the accused ventilator products (Astral and Stellar (*see* Infr. Cont., Chart A)) without the available ResMed

⁹⁸ *See, e.g.*, CleveMed Initial Infringement Contentions, January 12, 2023, Chart I.

[REDACTED]

Connectivity Module. Such an implementation would not infringe the asserted claims because, for claim 1, the accused products would not comprise the claimed “module transceiver;” for claim 5 the accused products would not have the capability for transmission to a “remote location,” and for claim 15, the accused products would not comprise a “first radio frequency wireless RF transceiver” as claimed. *See, e.g.,* CleveMed Final Infr. Cont., Chart A at limitation 1j (“Cellular Wireless Module”), limitation 5l, limitations 15g at 15i, *see also* Charts H, I, J at limitations 1j, 5l, 15g, and 15i.

C. No Support for Pulse Oximeters – No Infringement of Claims 1, 5

477. Flow generators that do not support the input of pulse oximeter sensor data do not practice claims 1 and 5 at least because the PAP device would not practice the following limitations of claims 1 and 5:

- 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 the signal, and an output adapted for outputting pulse oximetry sensor data”
- 1.b.2 – a PAP device comprising “a second input adapted for receiving the pulse oximetry sensor data from the output of the signal processing module”
- 1.b.4 – “a processor adapted for receiving the pulse oximetry sensor data from the second input ... 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”
- 5.d - 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”
- 5.e.4 – a PAP device further comprising “a second input for receiving pulse oximetry sensor data from the data acquisition device”
- 5.f – “the processor adapted for receiving pulse oximetry sensor data from the second input ... , 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

[REDACTED]

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”

478. For example, I have considered CleveMed’s infringement allegations for these claim limitations. For example, CleveMed’s allegations against the AirSense 10 flow generator at Chart I to their contentions allege the “signal processing module” (limitation 1.a) and “data acquisition module” (limitation 5.d) of the claims is practiced by the Air10 oximeter adapter. CleveMed’s contentions allege: “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 Air 10 Oximetry Module has electronics adapted for filtering and processing the signal from the pulse oximeter sensor, and an output adapted for outputting pulse oximetry sensor data to the AirSense

[REDACTED]

479. However, a flow generator that is not compatible with the Air 10 Oximetry Module would not practice the “signal processing” and “data acquisition” claim limitations (1.a, 5.d). Similarly, a flow generator that does not have an “input adapted for receiving the pulse oximetry sensor data from the output of” the Air 10 Oximetry Module would not practice the “second input” claim limitations (1.b.2, 5.e.4). For at least these reasons, such a flow generator does not infringe claims 1 and 5.

480. A flow generator that does not calculate the accused “95th percentile, max and median of the 1-minute average of value of SpO2” statistics based on pulse oximeter sensor input would not practice the “processor” claim limitations (1.b.4, 5.f). For at least these reasons, such a flow generator does not infringe claims 1 and 5.

D. Practice of the ResMed Prior Art – Claims 1, 5, 15

481. ResMed’s continued use of the ResTraxx system would not infringe the asserted

[REDACTED]

claims. First, the ResTraxx system is prior art to the '269 patent, therefore it cannot infringe the '269 patent that came later. Second, to the extent CleveMed argues RPA System 2 comprising the Restraxx system does not anticipate or render obvious the asserted claims, the claims would not be infringed by the Restraxx system for the same reasons. I also reserve the right to offer an opinion that the same or similar functionality in the ResTraxx system I have relied on above for invalidity, if present in the accused products, does not infringe.

E. AirSense 11 - Removal of Bluetooth communication capability – No Infringement of Claims 1, 5, 15

482. CleveMed's infringement contentions in connection with the AirSense 11 product (see Chart H) allege that the AirSense 11 infringes claims 1, 5, 8, 15, 16, and 20. For claim 1, CleveMed's contentions allege that the "signal processing module" of limitation 1.a is practiced by a NONIN WristOx2 Model 3150 that outputs "pulse oximetry sensor data to the AirSense 11 via Bluetooth" (page 10), and that the AirSense 11 practices the "second input" of limitation 1.b.2 because the device receives "pulse oximetry data from the Bluetooth pulse oximeter via the AirSense 11's Bluetooth transceiver" (page 16). *See also* Chart H, page 50-51 (limitation 5.d), 60 (limitation 5.e.4). For claim 15, CleveMed's infringement contentions allege that claim 15's "first radio frequency wireless module transceiver" is practiced by the Bluetooth transceiver. Chart H, 111, 125-126. However, without the Bluetooth transceiver, the accused products would not practice these claim limitations and therefore not infringe the Asserted Claims of the '269 patent. Moreover, the accused AirSense 11 products would not practice dependent claim 16, which requires the use of Bluetooth wireless protocol, and would therefore not infringe dependent claim 16.

XV. ANALYSIS OF '269 PATENT – PATENTABLE SUBJECT MATTER

A. State of the Art at the Time of the '269 Patent

483. As I described above, 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 March 2005 alleged conception date of the '269 patent. I hereby incorporate by reference my discussion of

[REDACTED]

the state of the art in Section X.B.

484. As I have explained above, the '269 patent did not include any new or inventive component. Further, based on my review of the claims and my knowledge of the state of the art at the time of the invention, the components in the asserted claims were well-known, routine, and/or conventional. The state of the art was full of examples of combinations of these same various well-known elements. *See* Sections X.A-B.

485. The '269 specification discloses that several components claimed by the '269 patent were well known in the prior art. *See* '269 patent at 2:61-63, 3:48-49 ("The treatment device can be any device known to those skilled in the art."); *id.* at 6:10-11 ("Sensors which can be used are known to those skilled in the art."); *id.* at 9:37-38 ("The base receiver 80 and module receiver 29 can be any appropriate receivers"); *id.* at 19:12-14 ("the remote communication station or base station can be any device known to receive RF transmissions."). Further, the specification discloses that the purported invention incorporates off-the-shelf components. *See id.* at 10:45-46 ("This programmable A/D converter may be an AD7714 as manufactured by Analog Devices or similar."); *id.* at 11:5-7 ("the module microcontroller 26 may be PIC16C74A PIC16C74B or a PIC16C77 both manufactured by MicroChip, or an Amtel AT90S8515 or similar."); *id.* at 20:45-47 ("Advantageously, the controller is the ORICA™ controller, an extended horizon, adaptive, predictive controller, produced by Orbital Research, Inc."). Finally, the specification suggests that any generic, conventional component would suffice. *See id.* at 10:66-11:2 ("In the present invention, the module microcontroller 26 includes a serial EEPROM 261 but any nonvolatile memory (or volatile memory if the signal processing module remains powered) can be used."); *id.* at 18:60-19:7 ("Using either the microcontroller 26 of a data acquisition system, a separate computer, base station or processor, a PDA, a processor on a device for treating the subject's sleeping disorder or a combination of these processors, the severity of the subject's sleeping disorder and/or symptoms is determined."). Taken together, these disclosures demonstrate that the purported invention of the '269 patent is comprised of nothing more than conventional hardware components.

[REDACTED]

486. The specification also discloses that some parts of the purported invention depend on techniques and methods known in the art. See '269 patent at 20:1-4 (“Various algorithms known to those skilled in the art are used to filter out noise from the signal or data, and to then quantify the level of severity of the subject’s sleeping disorder or symptoms.”); *id.* at 20:9-31 (“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.”); *id.* at 22:9-28 (“Various embodiments of the present invention include a device for physically or chemically treating a subject’s sleeping disorder Physical and chemical methods to treat sleeping disorders are known to those skilled in the art.”).

487. This is especially true when one considers that the '269 patent copied large portions of U.S. Patent No. 6,167,258 (“Schmidt”), filed on October 9, 1998, and issued on December 26, 2000; U.S. Patent No. 6,644,311 (“Truitt”), filed on December 19, 2001, and issued on November 11, 2003; U.S. Patent Pub. No. 2004/0129838 (“Lisy”), filed on January 3, 2003, published on July 8, 2004; U.S. Patent No. 8,187,209 (“Giuffrida”), filed on March 17, 2005, and issued on May 29, 2012; U.S. Patent No. 6,993,380 (“Modarres”), filed on January 4, 2003, and issued on January 31, 2006 (collectively, the “Copied Prior Art”).

488. The chart below summarizes CleveMed’s extensive copying and demonstrates that significant portions of the '269 patent specification was copied from the prior art, including:

'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 1:44-2:10

489. For instance, Figure 7 of the '269 patent, which is a copy of Figure 1 from Truitt, shows a conventional CPAP device with conventional components. It is clear that the elements in this CPAP device are conventional since Truitt Figure 1 is labelled as “Prior Art” and the disclosure in Truitt about Truitt Figure 1 was included in the “Background of the Invention” section and refers to the device as “conventional.” Truitt, 1:44-2:10. This disclosure from Truitt was copied into the '269 patent and describes the system as “conventional.” '269 patent, 22:45-23:17. The claimed hardware components disclosed in the asserted claims that are identified in Figure 7 of the '269 patent are, thus, conventional components, such as an airflow sensor “internal to the PAP device” and a “blower having an air output” as claimed.

490. 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 Lisy. Lisy, ¶¶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. *See* D.I. 116 at 14, 23, 26-27.

491. These conventional aspects of the Copied Prior Art were also incorporated into the claims of the '269 patent. In the table below, I have indicated the elements of the claims below in **bold** that were either expressly copied from the Copied Prior Art or would have been known to be conventional or generic based on the disclosures in the Copied Prior Art.

'269 Claim	Limitation	Copied From
1	A positive airway pressure (PAP) sleep disorder treatment system comprising:	<i>See, e.g.</i> , Truitt, FIG. 1, 1:24-55; Schmidt, 4:63-9:59.
	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 ;	<i>See, e.g.</i> , Schmidt, FIG. 1, 4:63-5:51, 9:60-12:48; Lisy, ¶¶ 40-45.
	a PAP device adapted for treating a subject's sleep disorder, the PAP device with a separate enclosure from the signal processing module	<i>See, e.g.</i> , Truitt, FIG. 1, 1:24-55.

	further comprising:	
	a blower having an air output,	<i>See, e.g.,</i> 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,	<i>See, e.g.,</i> Schmidt, FIG. 2, 5:52-6:35; Modarres 6:40-7:14.
	an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow data of a subject using the PAP device, and	<i>See, e.g.,</i> 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 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;	<i>See, e.g.,</i> Schmidt, FIG. 2, 5:52-6:35; Modarres, 1:21-2:27; Giuffrida 13:5-36; Lisy, ¶¶ 40-45; knowledge of POSITA as described in D'Ambrosio Decl. at ¶¶ 24-27.
	a mask or a nasal cannula; and	<i>See, e.g.,</i> 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.	<i>See, e.g.,</i> Schmidt, FIG. 2, 5:52-6:35; Modarres, 1:21-2:27; Giuffrida, 13:5-36; Lisy, ¶¶ 40-45; knowledge of POSITA as described in D'Ambrosio Decl. at ¶¶ 24-27.
4 ⁹⁹	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	<i>See, e.g.,</i> Lisy, ¶¶ 40-45.

⁹⁹ 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.

	wavelet analysis.	
5	A sleep disorder treatment system comprising:	<i>See, e.g.</i> , Truitt, FIG. 1, 1:24-55; Schmidt, 4:63-9:59.
	a data acquisition system ;	<i>See, e.g.</i> , Schmidt, FIGS. 1-6; 4:63-14:54.
	a positive airway pressure (PAP) device ; and	<i>See, e.g.</i> , Truitt, FIG. 1, 4:61-5:13.
	a processor ;	<i>See, e.g.</i> , Schmidt, FIG. 2, 5:52-67; Modarres, 1:21-2:27; Giuffrida 13:5-36; Lisy, ¶¶ 40-45.
	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 ;	<i>See, e.g.</i> , Schmidt, FIGS. 1-6; 4:63-14:54; Lisy, ¶¶ 40-45.
	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	<i>See, e.g.</i> , Truitt, FIG. 1, 1:24-2:11.
	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	<i>See, e.g.</i> , Schmidt, FIG. 2, 5:52-6:35; Modarres 1:21-2:27; Giuffrida, 13:5-36; Lisy, ¶¶ 40-45; knowledge of POSITA as described in

	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.	D'Ambrosio Decl. at ¶¶ 24-27.
8	A sleep disorder treatment system comprising:	See, e.g., Truitt, FIG. 1, 1:24-55; Schmidt, 4:63-9:59.
	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, FIGS. 1-6; 4:63-14:54; Giuffrida, 13:5-36; knowledge of POSITA as described in D'Ambrosio Decl. at ¶¶ 24-27.
	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; Schmidt, FIG. 2, 5:52-6:35; Modarres 1:21-2:27; Giuffrida, 13:5-36; Lisy, ¶¶ 40-45; knowledge of POSITA as described in D'Ambrosio Decl. at ¶¶ 24-27.
15	A positive airway pressure (PAP) sleep disorder treatment system comprising:	See, e.g., Truitt, FIG. 1, 1:24-55; Schmidt, 4:63-9:59.
	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	See, e.g., Truitt, FIG. 1; 1:24-2:11.

	a subject while using the PAP and outputting airflow sensor data;	
	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;	<i>See, e.g.,</i> Schmidt, FIG. 2; 5:52-6:35; Modarres, 1:21-2:27; Giuffrida 13:5-36; Lisy, ¶¶ 40-45; knowledge of POSITA as described in D'Ambrosio Decl. at ¶¶ 24-27.
	a mask or a nasal cannula	<i>See, e.g.,</i> Truitt, FIG. 1, 1:44-2:11.
	a first radio frequency wireless module transceiver; and	<i>See, e.g.,</i> Schmidt, FIGS. 1, 2, 4:63-6:35; Giuffrida, 13:5-36.
	a base station, cellular phone, or PDA;	<i>See, e.g.,</i> Schmidt, FIGS. 1, 2, 4:63-6:35; 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;	<i>See, e.g.,</i> Schmidt, FIGS. 1, 2, 4:63-6:35; Modarres 1:21-2:27; Giuffrida, 13:5-36; Lisy, ¶¶ 40-45; knowledge of POSITA as described in D'Ambrosio Decl. at ¶¶ 24-27.
	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.	<i>See, e.g.,</i> Schmidt, FIGS. 1, 2, 4:63-6:35; Modarres 1:21-2:27; Giuffrida, 13:5-36; Lisy, ¶¶ 40-45; knowledge of POSITA as described in D'Ambrosio Decl. at ¶¶ 24-27.

492. The only tangible component in the asserted claims that was not copied from the

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Copied Prior Art is the pulse oximeter, which as I described above was conventional equipment at the time of the invention.

493. The claims recite certain generic hardware, none of which add an inventive concept to the claims. For instance, the “signal processing module” (claim 1), “processor” (claims 1, 5, 15), “data acquisition system” (claims 5, 8), “controller” (claim 8), and “radio frequency wireless module transceiver” (claim 15) are all generic descriptions of conventional hardware that would have been known to POSITA at the time of the invention.

494. The claims do not recite any non-routine components or unique steps. It is my understanding that limiting the claims to the particular technological environment of PAP devices is not a sufficient reason to find that the claims are patent eligible. Therefore, it is my opinion that the claims of the '269 patent do not claim any inventive concept that would transform an abstract idea into patent-eligible subject matter.

495. The claims describe processing, transmitting, receiving, and measuring the data of a subject through the use of a positive airway pressure (PAP) device. To perform these tasks, the claims rely on generic computer hardware (*e.g.*, “non-volatile digital memory,” “nasal cannula or a facemask,” “processor,” “transceiver,” “sensors,” “cellular phone”) performing their usual, conventional, and routine functions (*e.g.*, “transmitting,” “receiving,” “measuring,” “processing”). The claims do not, for example, describe an improvement to a computer system itself, and do not describe any particular processing step. The claims also do not describe any arrangement or sequence of steps in the method that deviates from what is well-known, routine, and conventional.

496. The steps recited are generic and well known, and there is nothing inventive in their ordered combination. It is my understanding that 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 in order to supply and inventive concept. Therefore, it is my opinion that the claims of the '269 patent do not claim any inventive concept that would transform an abstract idea into patent-eligible subject matter.



XVI. CONCLUSION

497. It is my opinion that the asserted claims of the '269 patent are invalid because they are anticipated or rendered obvious by the prior art as outlined above, or because the specification fails to comply with the disclosure requirements for the reasons discussed above.