IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CLEVELAND MEDICAL DEVICES INC., an Ohio Corporation,	)	
Plaintiff,	)	C.A. No.
v.	)	**DEMAND FOR JURY TRIAL**
RESMED INC., a Delaware Corporation,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Cleveland Medical Devices Inc. ("CleveMed") files this Complaint for Patent Infringement and Demand for Jury Trial against ResMed Inc. ("Defendant" or "ResMed") and alleges as follows:

THE PARTIES

1. CleveMed is an Ohio corporation with its principal place of business at 4415 Euclid Ave, Cleveland, Ohio 44103.

2. ResMed is a Delaware corporation with its principal place of business at 9001 Spectrum Center Boulevard**,** San Diego**,** California 92123. ResMed can be served through its agent for service of process, Corporation Service Company, at 251 Little Falls Drive, Wilmington, Delaware, 19808.

JURISDICTION AND VENUE

3. This action for patent infringement arises under the patent laws of the United States, 35 U.S.C. § 101 *et seq*. This court has original jurisdiction over this controversy pursuant to 28 U.S.C. §§ 1331 and 1338.

4. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

5. This Court has personal jurisdiction over ResMed because ResMed is incorporated within this District and has committed acts of direct and indirect infringement in this District, including through selling infringing products and services in this District. Further, ResMed has submitted to the jurisdiction of this Court in at least one other instance involving a claim of patent infringement. *See New York University v. ResMed, Inc*., Case No. 21-cv-00813, D.I. 14 (D. Del. Sept. 30, 2021). Given the above, this Court's exercise of jurisdiction over ResMed in this action would be reasonable. Further, because ResMed is a Delaware corporation, Delaware is a convenient forum for the resolution of the parties' dispute.

CLEVEMED'S INNOVATIONS

6. CleveMed was founded in 1990 by its Chairman Robert N. Schmidt. CleveMed's core mission is to lead the world in maximizing clinical quality and patient access to diagnostics and particularly to sleep disorder testing and therapy through innovative technologies and services. CleveMed recognized that a better solution was needed to diagnose and treat the nearly one in seven people in the United States who suffer from some type of chronic sleep disorder that negatively impacts their health and quality of life.

7. CleveMed spent years researching and developing its services and devices aimed at providing portable sleep testing and treatment solutions to the over 32 million patients in the United States suspected of suffering from undiagnosed and untreated obstructive sleep apnea ("OSA"). OSA is one of the most prevalent sleep disorders that leads a sufferer to experience excessive sleepiness that can deteriorate their quality of life, and negatively impact their employment, higher earning and job promotion opportunities, education, and personal life. It also impacts workplace and driving safety, jeopardizing not only people with OSA but those around them as well. To provide a cohesive solution to this long-standing problem, CleveMed

focused its research and development efforts on technologies that provided testing and therapy solutions that could be used at home by a subject, which were technologies that were not possible previously.

8. After developing its innovative technologies, CleveMed offered for sale its sleep diagnostic devices designed to treat those suffering from breathing related sleep disorders, such as OSA. These diagnostic devices provided both the subject and health care provider with real-time or near real-time metrics that were incredibly useful for addressing the subject's symptoms at different points in time. Additionally, by designing technologies for the subject to self-monitor their use of the device and the results of their treatment, CleveMed's novel technologies increased the frequency that subjects used their therapy devices and their engagement with their therapy and treatment device.

9. Around 2007, CleveMed began development of portable home sleep testing solutions that were later offered commercially as its SleepView and SleepScout product lines. Today, CleveMed's novel SleepView product line detects sleep-disorder breathing and a subject's movements while they sleep at home. As the test is conducted entirely in a subject's home, CleveMed's products are more accurate and meaningful because they account for environmental conditions that may affect a subject's sleep at home, as well as eliminate any disturbances that may result from a subject sleeping away from home. These devices communicate with CleveMed's Crystal PSG software and SleepView's Web Portal that receive and analyze the physiological data recorded during the home sleep test and compile the results in reports to be used in diagnosing a sleeping disorder. SleepView's Web Portal also interprets the physiological data recorded and creates reports that can be transmitted to other medical professionals.

10. In addition to its SleepView product line, CleveMed developed its Sapphire product that uses CleveMed's Web Portal. The unique Web Portal of Sapphire and SleepView offers a secure online data management platform, providing medical professionals the benefit of increasing the number of subjects they can accurately monitor and treat. CleveMed's novel solutions offer a wide range of sleep testing capabilities that could never before be conducted while a subject sleeps at home.

11. CleveMed is leading the way in services and devices for home sleep disorder testing through its innovative technology for sleep apnea testing that are portable and easy-to-use at home. Its novel technologies also streamline operations for healthcare providers, and offers cost-efficient testing solutions for customers.

12. The breadth of CleveMed's novel offerings filled a long-felt need for a more effective delivery of care solution that can be administered in a subject's home. The unexpected results of CleveMed's technologies and products included improved outcomes for sufferers of sleep related breathing disorders in their treatment and overall health.

13. In recognition of its innovation and expertise, the United States Patent and Trademark Office ("USPTO") awarded CleveMed 37 patents that disclose, *inter alia*, novel technologies for sleep apnea diagnosis and follow-up, as well as therapy procedures and applications. These technologies are now central to the outcome-based initiatives the healthcare industry is initiating to manage chronic diseases.

CLEVEMED'S ASSERTED PATENTS

14. On September 18, 2018, the USPTO issued U.S. Patent No. 10,076,269 (the "'269 Patent"), entitled "Devices and Methods for Sleep Disorder Diagnosis and Treatment." The '269 Patent lists Hani Kayyali, Robert Schmidt, Mohammad Modarres-Zadeh, and Brian Kolkowski

as its inventors and states that it was assigned to Cleveland Medical Devices Inc. Attached hereto as Exhibit 1 is a true and correct copy of the ’269 Patent.

15. The ’269 Patent generally discloses a sleep diagnostic and treatment device and method. In particular, it relates to an apnea diagnosis and treatment device.

16. On October 1, 2019, the USPTO issued U.S. Patent No. 10,426,399 (the “’399 Patent”), entitled “Method and Device for In-Home Sleep and Signal Analysis.” The ’399 Patent lists Hani Kayyali, Craig A. Frederick, Christian Martin, Robert N. Schmidt, and Brian Kolkowski as its inventors and states that it was assigned to Cleveland Medical Devices Inc. Attached hereto as Exhibit 2 is a true and correct copy of the ’399 Patent.

17. The ’399 Patent generally discloses methods for conducting home sleep tests. In particular, it relates to collecting physiologic and kinetic data from a subject, preferably via an in-home data acquisition system, while the subject attempts to sleep at home.

18. On February 23, 2021, the USPTO issued U.S. Patent No. 10,925,535 (the “’535 Patent”), entitled “Method and Device for In-Home Sleep and Signal Analysis.” The ’535 Patent lists Hani Kayyali, Craig A. Frederick, Christian Martin, Robert N. Schmidt, and Brian Kolkowski as its inventors and states that it was assigned to Cleveland Medical Devices Inc. Attached hereto as Exhibit 3 is a true and correct copy of the ’535 Patent.

19. The ’535 Patent generally discloses systems for conducting at-home sleep testing that has a kinetic sensor and at least three sensors to be applied to a subject that record physiological and kinetic events occurring while a patient sleeps and software that identifies physiological and technological events in the data indicative of a sleeping disorder and that analyzes the data.

20. On July 20, 2021, the USPTO issued U.S. Patent No. 11,064,937 (the “’937

Patent"), entitled "Method and Device for In-Home Sleep and Signal Analysis." The '937 Patent lists Hani Kayyali, Craig A. Frederick, Christian Martin, Robert N. Schmidt, and Brian Kolkowski as its inventors and states that it was assigned to Cleveland Medical Devices Inc. Attached hereto as Exhibit 4 is a true and correct copy of the '937 Patent.

21. The '937 Patent generally discloses systems for remote sleep testing using (a) a nasal cannula or facemask, (b) a respiratory effort belt sensor, (c) a fingertip pulse oximeter, (d) a portable interface box that has a processor for digitizing data and memory for storing the data, (e) a database that is remote for receiving the collected data, and (f) software that can analyze and identify events indicative of a sleeping disorder and (g) can transfer the collected data and/or identify physiological and technological events.

22. On July 24, 2018, the USPTO issued U.S. Patent No. 10,028,698 (the "'698 Patent"), entitled "Method and Device for Sleep Analysis." The '698 Patent lists Craig A. Frederick, Hani Kayyali, Robert N. Schmidt, and Brian Kolkowski as its inventors and states that it was assigned to Cleveland Medical Devices Inc. Attached hereto as Exhibit 5 is a true and correct copy of the '698 Patent.

23. The '698 Patent is generally directed toward methods for remote sleep analysis and diagnosis, that involve applying at least two sensors to a subject that connect to an interface box that can collect and transmit data for medical personnel in a remote location from the subject, and the data is analyzed to identify physiological and technological events to medically diagnose the patient.

24. On November 19, 2019, the USPTO issued U.S. Patent No. 10,478,118 (the "'118 Patent"), entitled "Method and Device for Sleep Analysis." The '118 Patent lists Craig A. Frederick, Hani Kayyali, Robert N. Schmidt, and Brian Kolkowski as its inventors and states that

it was assigned to Cleveland Medical Devices Inc. Attached hereto as Exhibit 6 is a true and correct copy of the ’118 Patent.

25. The ’118 Patent is generally directed toward methods of remote sleep analysis and diagnosis by providing a subject with a portable interface box with a nasal cannula, respiratory effort belt sensor, and a fingertip pulse oximeter for measuring and collecting the subject’s physiological state while the subject is attempting to sleep. This data is digitized, stored in memory, and sent to a sleep analysis lab or database for analysis to determine whether the subject suffers from a sleeping disorder.

26. On December 21, 2021, the USPTO issued U.S. Patent No. 11,202,603 (the “’603 Patent”), entitled “Method and Device for Sleep Analysis.” The ’603 Patent lists Craig A. Frederick, Hani Kayyali, Robert N. Schmidt, and Brian Kolkowski as its inventors and states that it was assigned to Cleveland Medical Devices Inc. Attached hereto as Exhibit 7 is a true and correct copy of the ’603 Patent.

27. The ’603 Patent is generally directed toward sleep diagnostic systems and methods of remote sleep analysis and diagnosis involving sensors that can measure or derive the subject’s airflow or snore, respiratory effort and blood oxygenation and analyze the data for a medical professional.

28. On February 1, 2022, the USPTO issued U.S. Patent No. 11,234,637 (the “’637 Patent”), entitled “Method and Device for In-Home Sleep and Signal Analysis.” The ’637 Patent lists Hani Kayyali, Craig A. Frederick, Christian Martin, Robert N. Schmidt, and Brian Kolkowski as its inventors and states that it was assigned to Cleveland Medical Devices Inc. Attached hereto as Exhibit 8 is a true and correct copy of the ’637 Patent.

29. The ’637 Patent generally discloses systems for conducting home sleep analysis

of a subject using devices to obtain airflow data, respiratory effort data, blood oxygenation data, and body position data, that can transmit the data and has software that identifies events indicative of a sleeping disorder.

30. CleveMed owns all rights, title, and interest in and to the '269 Patent, '399 Patent, '535 Patent, '937 Patent, '698 Patent, '118 Patent, '603 Patent, and '637 Patent (collectively "the Asserted Patents"). The '399 Patent, '535 Patent, '937 Patent, '698 Patent, '118 Patent, '603 Patent, and '637 Patent are collectively referred to as the Home Sleep Testing Patents ("HST Patents").

31. CleveMed marks its products and services with its patents in compliance with 35 U.S.C. § 287. Exs. 1-8; *see also, e.g.*, Ex. 29. Further, CleveMed's public website identifies CleveMed's issued patents in compliance with 35 U.S.C. § 287.

32. All of the Asserted Patents are valid and enforceable. The Asserted Patents disclose and specifically claim inventive concepts that represent significant improvements over conventional systems. Specifically, each of the Asserted Patents describes various techniques, enhancing the ability of medical professionals to conduct a remote sleep test and provide treatment to a subject while the subject sleeps at their home or another remote environment. By allowing the testing and treatment to be conducted in a subject's home environment or outside a traditional sleep laboratory, the claimed inventions increase the quality and accuracy of the subject's diagnosis and treatment. Furthermore, these systems and methods reduce the burden on both the subject and the clinician.

33. The claims of the '269 Patent, when read in light of the specification, generally disclose various systems for enabling sleep disorder treatment systems that record, calculate, analyze, and transmit a subject's physiological signals to inform not only the subject but their

clinician of their therapy's efficacy, but to also potentially adjust a treatment device in order to provide the specific therapy that matches the subject's current physiological condition.

34. The '269 Patent provides a novel enhancement by using a system to connect a positive airway pressure treatment device consisting of at least a hose and blower with sensors that record physiological signals, a cellular phone or a base station, and a remote internet site. The system also uses software that allows for instant or near instant analysis of the physiological signals received. The '269 Patent teaches one to use a processor that receives the physiological signals to analyze those signals to determine the severity of the subject's symptoms, a transceiver to receive and transmit the data with the calculated severity levels, and a base station or cellular phone with a display and software capable of displaying the received data and retransmitting that data to a remote site so the treatment device may be adjusted, if necessary.

35. The result of the treatment system disclosed in the '269 Patent is non-abstract and yields real-world concrete results improving the functionality of sleep breathing disorder treatment devices by altering the treatment administered based upon the present physiological state of the subject. This functionality was beyond any solution previously available.

36. The claims of the '269 Patent are rooted in computer technology and present a specific and non-conventional solution for the computers and processors used to record physiological conditions to test and treat subjects with sleep related breathing disorders. Prior to the filing of the '269 Patent, no at-home sleep breathing disorder treatment device could: (i) adjust a subject's treatment based in part on the subject's current physiological state in their regular or home use environment; (ii) monitor and/or adjust the treatment device based on data transmitted to a remote internet site; (iii) wirelessly transmit analyzed physiological signal data to the subject for better therapy compliance by the subject; and/or (iv) allow for remote

adjustment of the treatment device based on the transmitted usage data, an index of the subject's symptoms and/or the calculated symptom severity levels.

37. The claims of the '269 Patent contain innovative concepts that were not routine, well-known, or understood in the art at the time of its filing. For example, the claims' unconventional positive airway pressure devices with signal processing modules, internal and/or external sensors, a processor, and transceiver, allowed for the first time the ability to record and analyze airflow and/or pulse oximetry data, transmit the recorded and analyzed data, and use additional computers to further analyze, display, and retransmit the recorded and analyzed data. The simultaneous capture of physiological metrics, such as measuring airflow, the digitization of the signals, the application of signal processing techniques, and instant calculation of these metrics from these processed signals into indices showing the severity of events captured are beyond human capability. Further, a human is unable to extract and send the recorded data and calculated indices wirelessly to remote computer processing devices instantly. As such, the '269 Patent meets the standards for patent eligibility.

38. The HST Patents disclose specific methods and systems that go beyond combining generic components to perform conventional activities. The claimed inventions improve the functionality and capabilities of computers and processors used in the recording, analysis, and diagnosis of sleep breathing disorders. They do so by enabling the detection and recording of different breathing disorders that occur while a subject sleeps at home or a location remote to a sleep lab, as well as the transfer of that recording data to locations running software and using a database (now sometimes known as the "cloud") that can automatically analyze, score, and present the recording data in an unconventional manner to highlight specific events indicative of sleep breathing disorders. They further reduce the footprint of the testing devices,

making the device truly wearable and portable, as well as easy for the user to apply. This results in increased access and a more accurate diagnosis for the subject and an efficient and streamlined work platform for medical professionals.

39. The HST Patents include specific, non-conventional steps and concepts which are rooted in computer technology that make the claimed inventions concrete and non-abstract. For example, certain claims of the HST Patents variously recite: attaching to the subject and connecting to the pressure sensors within the wireless portable testing device, a nasal cannula, a pulse oximeter, and a respiratory effort belt and sensor; simultaneously recording and storing the physiological data collected by at least those sensors; transmitting the physiological data collected to a remote database with a computer processor running software to: analyze the recorded and stored data, determine the severity of the subjects' sleep breathing disorder, and transmit the results and determinations of the analyzed data to a location remote from the test site. These steps cannot be simultaneously conducted by a human nor done by a human with an acceptable level of accuracy.

40. The claims of the HST Patents are not routine or conventional in the art because at the time of their filing, the conventional sleep testing methods involved using devices and systems located within a sleep lab or medical facility. In fact, at the time of filing for the earliest HST Patents, there was one general method for diagnosing sleep apnea: use of a questionnaire and an all-night polysomnography evaluation in a sleep lab that could then be followed by an all-day test, such as the Multiple Sleep Latency Test. This method produced results less efficiently than the systems and methods disclosed in the HST Patents, and due to subjects sleeping in a familiar location, the results of the methods and systems disclosed and claimed in the HST Patents are more representative of the subject's actual sleep disorder.

41. In addition, the claims are rooted in computer technology as they specifically disclose systems and methods for efficiently and accurately conducting a home sleep test, analyzing the outcomes of that test, and sharing those results with others in the medical community to produce a more accurate diagnosis. Thus, the claims of the HST Patents recite specific steps to accomplish the desired result and go beyond simply claiming a result.

42. Accordingly, the inventions of the HST Patents allow for a new kind of system that was not previously possible, enabling an in-depth home sleep test and analysis of multiple data points that can be stored and shared with members of the medical community.

RESMED'S PRODUCTS

43. ResMed makes, uses, sells, offers for sale, and/or imports into the United States and this District products and services, including but not limited to, its sleep solutions utilizing devices and software technologies to provide at-home or remote sleep-disordered breathing or apnea testing, and treatment monitoring and/or adjustment (the "Accused Products"). Ex. 9 at 1-3. ResMed's accused products are found in two solutions: Home Sleep Testing Solution ("HST Solution") and Positive Airway Pressure Solution ("PAP Solution").

44. ResMed's solutions use ResMed's software and data management platforms that they provide to its customers, such as AirView, Rescan, myAir, U-Sleep, Brightree, and its AirMini app. Each of these platforms receive data from the devices, and displays and transfers it to various parties, such as customers who are home medical equipment providers, medical professionals, and subjects who want the data. *See* Ex. 10.

45. Some of ResMed's solutions have a pulse oximeter manufactured by NONIN Medical ("NONIN") that ResMed sells and offers for sale. Ex. 52 at 5 (showing NONIN oximeter components as part of the "ApneaLink Air complete kit"); Ex. 35 at 8 ("Only use

compatible NONIN™ finger pulse oximeters").

46. To help leverage the data from its solutions, ResMed uses platforms such as U-Sleep, a "cloud-based solution" that allows home medical equipment providers to "receive detailed reports about patient performance and help coach sleep patients based on compliance with defined therapy programs." Ex. 11 at 2; *see also* Ex. 12 at 2-5 (showing U-Sleep connection with AirView and myAir).

47. ResMed also utilizes Brightree to further monetize the data it captures from its devices as the industry moves from a "fee-for-service" model to that of an "outcomes based reimbursement model." ResMed accomplishes this by integrating its AirView platform with the platform they provide through Brightree. Ex. 13 at 1; *see also* Ex. 14 at 2 (Advanced Analytics from Brightree automatically runs reports and analyzes data); Ex. 15 at 1-4 (showing Brightree integrates with sleep testing and therapy data reports and can provide these reports to medical professionals); Ex. 16 at 1-2 (announcing the integration of AirView and Brightree platforms).

48. In early 2016, ResMed acquired Brightree, further "expanding ResMed's offering to customer[s] of its sleep apnea humidifiers and other devices." Ex. 17 at 1-2.

RESMED'S POSITIVE AIRWAY PRESSURE SOLUTION

49. ResMed's PAP Solutions consist of its PAP devices, its user applications, and in some instances, modules for oximetry data collection or wireless connectivity. ResMed's PAP devices (herein collectively referred to as the "Accused PAP Devices") include:

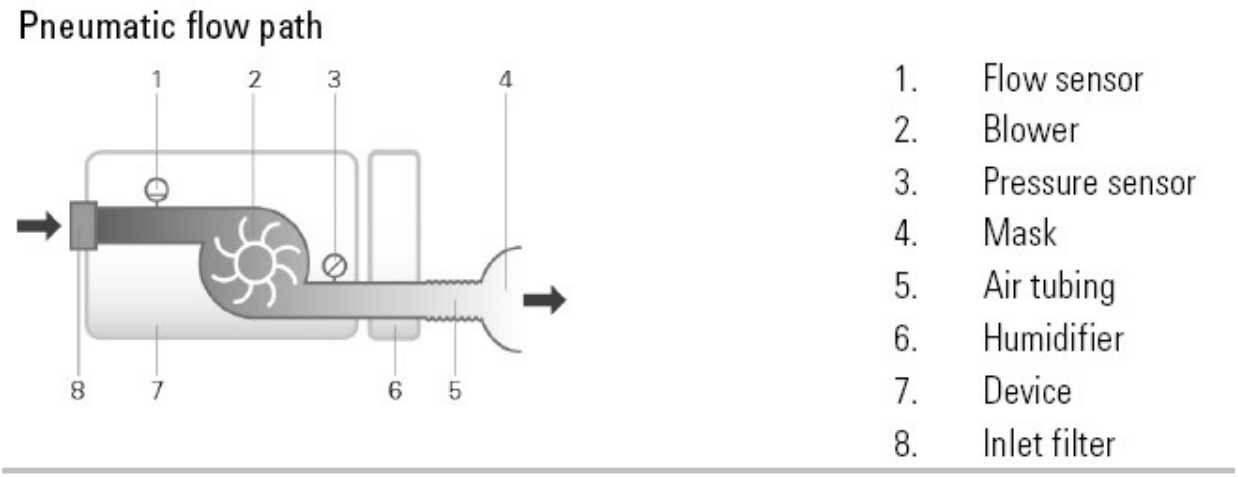
- the AirSense 10 CPAP, Elite, AutoSet, and AutoSet for Her devices (collectively "AirSense 10 devices");
- the AirSense 11 CPAP, Elite, and AutoSet devices (collectively "AirSense 11");
- the AirCurve 10 S, ST, VAuto, and ASV devices (collectively "AirCurve 10 devices");
- the Stellar 100 and 150 devices;

- the Astral 100 and 150 devices; and
- the AirMini CPAP, AutoSet, and AutoSet for Her devices.

Ex. 18 at 1; Ex. 19 at 1; Ex. 20 at 6; Ex. 21 at 2-4; Ex. 22 at 1; Ex. 23 at 1-2; Ex. 24 at 1-2. An image of the AirSense 11 is reproduced below:

Ex. 19 at 1.

50. As shown below, the Accused PAP Devices include a blower, mask, and airflow and pressure sensors.



Ex. 25 at 23 (showing the flow and pressure sensors, the blower, and mask); Ex. 26 at 36 (same); Ex. 27 at 18 (same); Ex. 28 at 18 (same); Ex. 30 at 26 (same); Ex. 38 at 37-38 (discussing use of a mask and the existence of a blower, a airflow sensor, and a pressure sensor); Ex. 39 at 2-4

(discussing use of a mask and the existence of a blower, a airflow sensor, and a pressure sensor).

51. The Accused PAP Devices contain a transceiver for transmitting and memory for storing usage, therapy, and detailed data. Ex. 31 at 14 (indicating Bluetooth and cellular connectivity); *id.* at 32 (showing wireless connectivity and SD card storage); Ex. 32 at 2 (showing cellular connectivity and SD card storage for AirSense 10 and AirCurve 10 devices); Ex. 30 at 8-10 (showing the AirMini uses Bluetooth to connect with the AirMini App); Ex. 33 at 2 (showing Astral devices use the ResMed Connectivity Module); Ex. 34 at 1 (showing Stellar devices use the ResMed Connectivity Module).

52. The Stellar 100 and 150 devices and the Astral 100 and 150 devices are capable of filtering, processing, and outputting pulse oximeter sensor signals. Likewise, the AirSense 10 devices and AirCurve 10 devices connect with and receive pulse oximeter sensor signal using the Air 10 Oximetry Module. Ex. 35 at 1; Ex. 36 at 2.

53. The Accused PAP Devices have both internal and external processors responsible for processing the data collected by the Accused PAP Device and calculating the severity of a subject's symptoms. For example, as shown below, the Accused PAP Devices have an internal processor capable of calculating and displaying therapy data such as an AHI index, usage data, and leak data.

Sleep View Parameters:

Parameter	Description
Used Hrs	Number of hours the device has been used since last session
Pressure	Average Pressure during the selected period (95th percentile for each day, average of the 95th percentile values for periods >1 day)
Leak	Average of the 95th percentile values of leak during the selected period.
AHI	Apnea-Hypopnea Index - average AHI during the selected period.
Total AI	Apnea Index - average total AI during the selected period
Central AI	Central Apnea Index - average CAI of the Days Used in the selected period.

Ex. 31 at 22; Ex. 26 at 19 (same); Ex. 37 at 28-29 (same); Ex. 30 at 3 (the AirMini device and

AirMini App allow a user to transfer, analyze and display usage and therapeutic information); Ex. 38 at 123 (chart showing AHI calculated); Ex. 39 at 2 (chart showing AHI calculated).

54. The Accused PAP Devices transmit usage, therapy, and detailed data to a number of external processors running such as AirView and ResScan.

Type of data	Transmission method			Sessions stored
	Cellular communication to AirView	SD card to ResScan	SD Card to AirView (card-to-cloud)	
Summary data (compliance data)	✓	✓	✓	365
Detailed data	✓	✓	✓	Limited by usage and SD card storage capacity
High resolution flow (25 Hz - every 40 ms)		✓		

Ex. 31 at 33; Ex. 40 at 1-2 (chart showing all Accused PAP Devices send data to AirView and all but the AirMini send data to ResScan).

55. AirView is ResMed's "cloud-based solution for managing patients with sleep apnea." Within AirView, the data received is automatically analyzed and scored "provid[ing] detailed views of respiratory events and oxygen saturation." AirView is also capable of generating reports and sharing the data received and analyzed with clinical users found in different locations. In AirView the data is analyzed, severity levels are calculated, and reports are generated. These reports can then be accessed by other members of the medical community. AirView also connects ResMed device data to systems used by physicians, hospitals, and home care provider customers such as Brightree and U-Sleep.

AirView - enabling efficient and secure access to patient therapy.

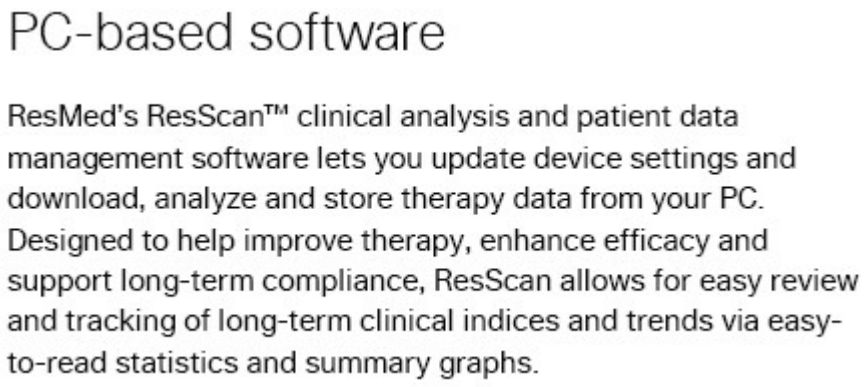
AirView is a secure cloud-based solution from ResMed for patient home testing and therapy management in both sleep and ventilation patients. It allows timely remote access to home sleep tests as well as to sleep and ventilation therapy and device information. You can securely share information and collaborate to help optimise patient management.

Ex. 41 at 2-3 (showing AirView's therapy management and reports for sleep devices);

Therapy report: CPAP/APAP

Ex. 42 at 1-4; Ex. 43 at 1-4 (explaining AirView connects a patient's sleep data and analysis with systems used by medical professionals); Ex. 44 at 1 (showing that reports can be produced for each patient within AirView); Ex. 12 at 2-3 (showing U-Sleep automatically connects with CPAP data and monitors therapy data); Ex. 45 at 1-2 (showing AirView integrates with Brightree); Ex. 16 at 1-3 (showing AirView "integrates directly with Brightree").

56. ResScan is ResMed's on-premise clinical analysis and patient data management software that runs on a computer that allows for clinical analysis of data received from the PAP Device using detailed statistics and summary graphs. Within ResScan, a clinician can compile these calculated results into reports that can then be shared with other medical professionals in remote locations. As described in the image below, ResScan allows the user to view summary and detailed graphs based on the data received from the PAP Device as well as create a report based on that data.



Ex. 46 at 1-2; Ex. 47 at 15-17 (showing how to download therapy data into ResScan); *id.* at 26-38 (showing how the data is displayed and analyzed).

57. The Accused PAP Devices also connect with multiple applications found on cellular phones or PDAs. For example, ResMed's myAir Application provides the user with a display of nightly sleep data and a calculation of the user's sleep score and AHI.

Ex. 48 at 1-9 (showing connectivity with AirSense 11); Ex. 18 at 2 (showing connectivity with AirSense 10 Devices; Ex. 49 at 1-2 (showing connectivity with AirCurve 10 Devices).

58. The AirMini device connects with the AirMini Application, a mobile application used for remote operation of the AirMini device and allows for the transfer, analysis, and display of usage and therapeutic data.

About AirMini app Patient eHelp

This easy-to-use app syncs up with your machine to let you start and stop therapy and change comfort features. It also lets you know how you slept the night before, and helps you stay on track throughout your sleep apnea treatment journey.

Ex. 50 at 3 (The AirMini App "syncs up with your machine" and "lets you know how you slept the night before"); *id.* at 11 (showing the AirMini App displays therapy data to the user).

RESMED'S HOME SLEEP TESTING SOLUTION

59. ResMed's Accused HST Solution products are ResMed's ApneaLink Air device, ApneaLink Software and the AirView Cloud Platform.

The below is an image of the ApneaLink Air device.

Ex. 51 at 1; Ex. 52 at 2-5.

60. The ApneaLink Air device, which a subject wears around their torso while they sleep at home (as shown below), is used to detect technological and physiological events indicative of OSA, central sleep apnea, and/or Cheyne-Stokes respiration.

Ex. 53 at 2;

The following table shows a list of all default event types automatically detected by the ApneaLink program and displayed in the signal curves:

Event type	Abbreviation	Channel
Unclassified apnea	UA	Flow
Obstructive apnea	OA	Flow
Mixed apnea	MA	Flow
Central apnea	CA	Flow
Hypopnea	H	Flow
Flow limitation	FL	Flow
Snoring	Sn	Snoring
Inspiratory flow	If	Flow
Flow limitation and snoring	FS	Flow
Baseline saturation	Bs[1]	Saturation
Desaturation	Ds[1]	Saturation
Invalid data	ID	Flow, battery, snoring, saturation, pulse
Start of evaluation	S	Flow, effort, snoring, saturation, pulse
End of evaluation	E	Flow, effort, snoring
Exclusion from analysis	Ae	Flow, effort, battery, snoring, saturation
Missing oximeter finger sensor/XPod	Ms[1]	Saturation, pulse
Signal too small	Sts	Flow, effort
Cheyne-Stokes	CSR	Flow

1. Only for recordings with pulse oximetry

Ex. 54 at 26 (table showing "a list of all default event types automatically detected by the

ApneaLink program and displayed in the signal curves," including physiological events (i.e. various types of apnea) and technological events (i.e. invalid data, missing sensors, and insufficient signals)).

61. The ApneaLink Air device comes as part of a kit provided by ResMed that includes at least the device, a nasal cannula, a belt and respirator effort sensor, a pulse oximeter, batteries, instructions, a USB cable, and a software CD for installation on a computer.

Ex. 52 at 3; *id.* at 5 (listing the software CD as part of the ApneaLink Air complete kit); Ex. 55 at 2 (showing the three sensors, nasal cannula, respiratory effort belt, and a fingertip pulse oximeter); Ex. 54 at 3 (same).

62. The ApneaLink Air device has at least internal batteries, non-volatile digital

memory, a processor, a transceiver, pressure sensors that connect to the nasal cannula and respiratory effort sensor, and a kinetic sensor.

ApneaLink Air Technical Specifications

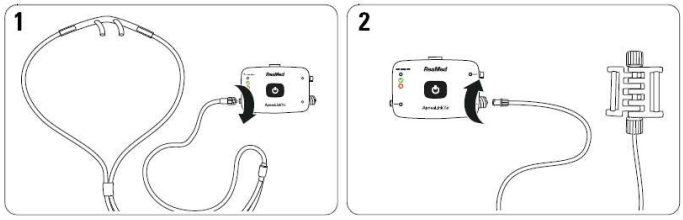
Recorder
Enhanced hardware
EasySense respiratory effort sensor
Oximetry
Light indicators - Test complete indicator - Respiratory flow indicator - Effort sensor connection indicator - Oximetry connection indicator
Signal Recording
Respiratory effort
Respiratory flow
Snore
Blood oxygen saturation
Pulse
Battery voltage

Download application
PC download
Internal battery
AAA alkaline batteries
Internal memory
Recording period: 48 hours
Internal clock
Dimensions
Recorder: 62 x 102 x 30 mm (2.4" x 4" x 1.2")
Pulse oximeter: 53 x 20 x 15 mm (2.1" x 0.8" x 0.6")
Recorder weight: 66 g (2.3 oz)

Ex. 52 at 6 (showing the internal memory, effort sensor, batteries, and signal recordings); Ex. 54 at 9 (discussing the pressure sensors and their connections to the nasal cannula and effort sensor); *id.* at 18 (discussing data transfer for the ApneaAir Link); *id.* at 61-62 (showing the sensor for determining body position and movement).

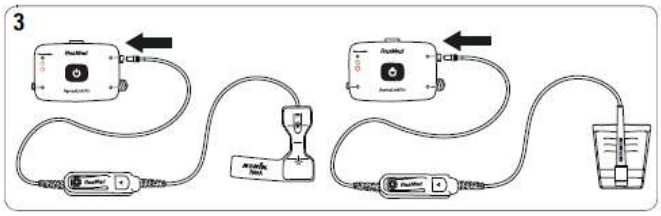
63. The ApneaLink Air device connects the nasal cannula and respiratory effort sensor to their respective pressure sensors via an air port. The ApneaLink Air device also connects with the pulse oximeter.

Connecting the nasal cannula and the effort sensor



1. Insert the connector end of the nasal cannula into the nasal cannula connector on the device. Turn clockwise until the connector is secure.
2. Insert the connector end of the effort sensor into the effort sensor connector on the device. Turn clockwise until the connector is secure.

* * *



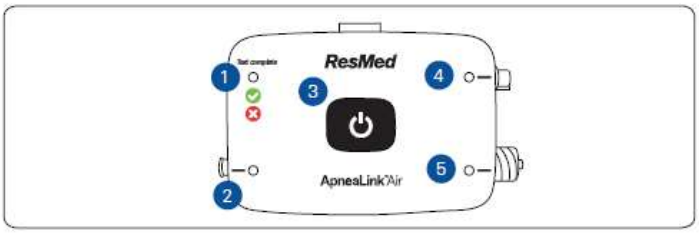
3. Attach the oximeter to the oximeter connector on the device by pushing it on.

Ex. 54 at 7.

Device

The ApneaLink Air device has the following lights, connectors and button:

1 Test complete light
2 Nasal cannula connector and accessory light
3 Power button
4 Oximeter connector and accessory light
5 Effort sensor connector and accessory light



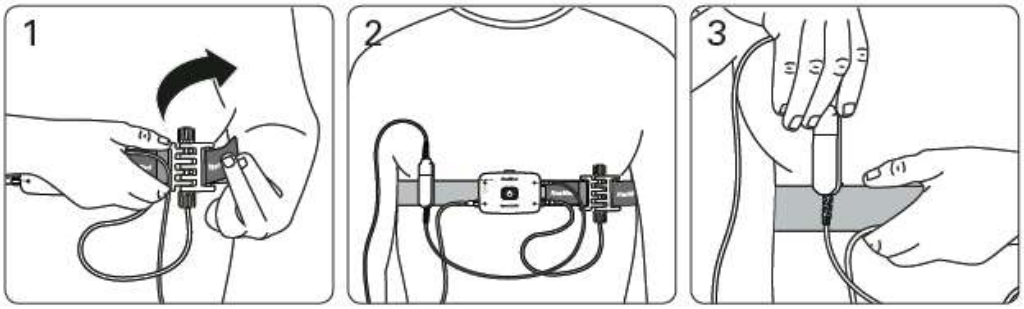
Id. at 4 (showing the portable patient interface box adapted to connect the at least three sensors to the patient).

64. ResMed provides instructions for how the nasal cannula, respiratory effort sensor and belt, and pulse oximeter are applied to the subject.

Fitting the belt

CAUTION

To avoid irritation or allergic reactions, wear the belt and device over a long-sleeved shirt.



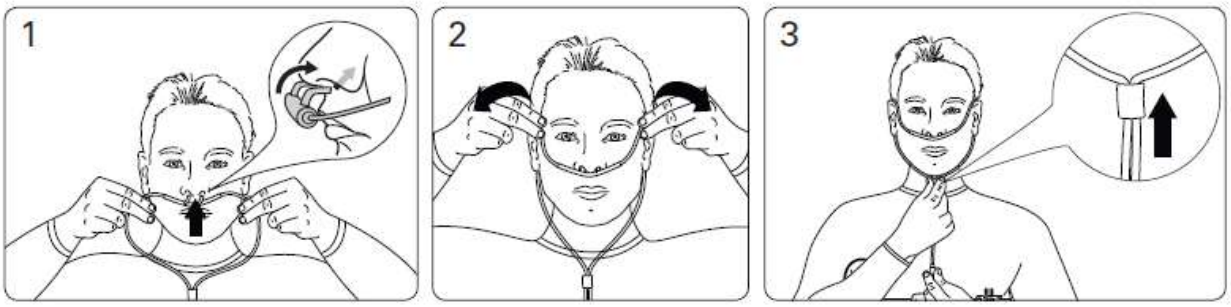
1. Pull the belt around your body. Thread the end of the belt through the slot on the effort sensor (if used) and fasten the tab to the belt. If you are not using the effort sensor, attach the tab to the belt.
2. Check that the belt is secure and comfortable and that the device is positioned over the centre of your chest.
3. If using an oximeter, slide the clip onto the belt. The clip should be worn on the same side of your body as the oximeter finger sensor.

Ex. 55 at 4.

Nasal cannula

WARNING

Ensure that the cannula is fitted as described so as not to pose a strangulation risk.



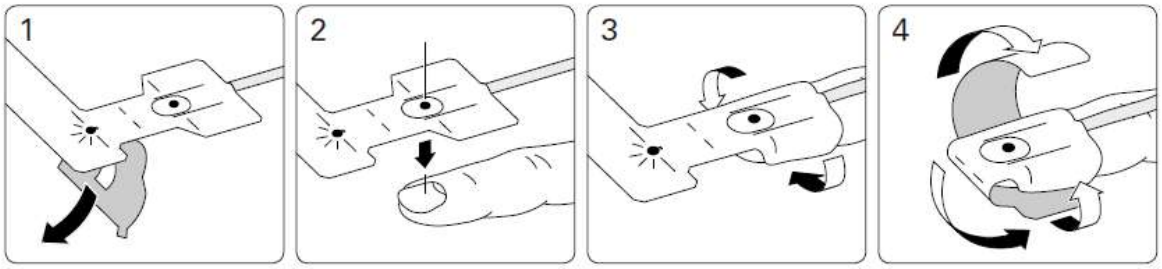
1. Insert the prongs into your nostrils. Make sure the curved side is pointing towards the back of your nose.
2. Loop the plastic tubing around your ears.
3. Pull the slider up towards your chin until the plastic tubing is secure and comfortable.

Id. at 5.

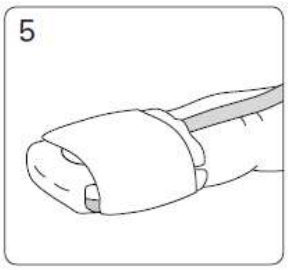
Disposable finger sensor (if used)

⚠ WARNING

Ensure that the oximeter clip is positioned on the same side of the body as the finger sensor so as not to pose a strangulation risk.



1. Remove the backing from the sensor.
2. Place the sensor over the fourth finger on your non-dominant hand. Line up the picture of the fingernail on the finger sensor with your own fingernail.
3. Fold the tabs around the sides of your finger.
4. Fold the top flap under your finger and wrap it around your finger.



5. The sensor should be positioned as shown.

Id. at 6.

65. The ApneaLink Air device records information on a subject's respiratory effort using the respiratory effort sensor, their pulse and oxygen saturation with the pulse oximeter, their nasal flow with the nasal cannula, and body position with a kinetic sensor.

Device, pulse oximeter and effort sensor

Signal recording	Respiratory flow Respiratory effort Blood oxygen saturation Pulse Body position Battery voltage

Ex. 54 at 60 (showing signal recordings and body position measurement sensor configuration); Ex. 52 at 6.

66. The ApneaLink Air device has a transceiver for transmitting the data collected

from the sensors to a computer running the ApneaLink Software and/or AirView.

Downloading data from the device

1. Plug the USB cable into the mini USB connector on the device and into an available USB port of your computer.
2. Run the ApneaLink program.
3. Click **Download ApneaLink** .

Notes:

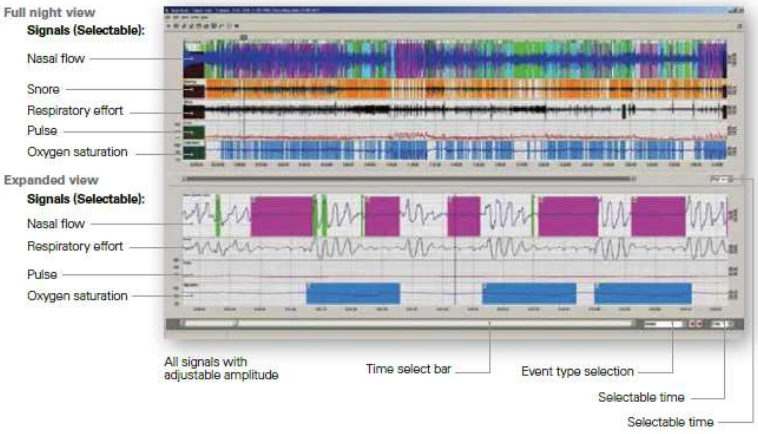
- *If the device was not allocated to a patient during customisation, the download procedure is interrupted and a patient record card appears.*
- *Data transfer and analysis are complete when the report is displayed.*
- *Each recording needs up to 15 MB free computer hard disk space. Before downloading, ensure there is enough space available. The available space is displayed in the status bar of the ApneaLink program.*
- *The download procedure may take up to five minutes.*
- *Recordings shorter than ten seconds are not stored.*
- *For recordings with less than 60 minutes of valid data, the analysis time is considered too short for performing a reliable screening result. A note is posted on the report: "Attention: Evaluation period too short!." Any data that is captured by the device can be manually scored.*
- *If there are several recordings on the device, all the recordings are downloaded and analysed, and a report is produced for each. The report for the longest recording is displayed automatically. The other recordings and reports are also available in the database. All recordings that are transferred during a download have the same patient data.*
- *If the data has been downloaded successfully, both the recording and the patient data in the device are deleted automatically.*

Ex. 54 at 18 (describing a USB transceiver for uploading the collected data), 19 (describing downloading and displaying collected data (recordings) from the device), 47 (describing recordings, which "are accessible on your computer via USB connection").

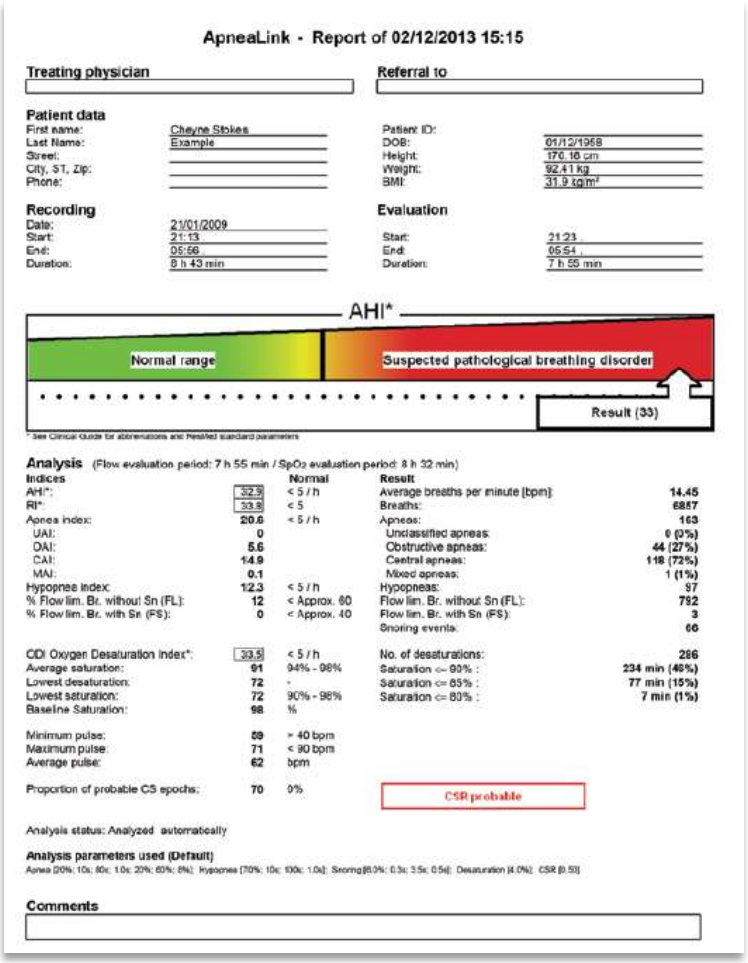
67. ApneaLink Software automatically analyzes the received data to determine a number of sleep disorder related events including "AHI [apnea-hypopnea index], flow limitation and snoring and later automatically generates a simple, easy-to-interpret report with a color-keyed AHI or Risk Indicator [among other indices] for the clinician to review." Ex. 52 at 4; Ex. 54 at 16-52.

Access to detailed signals overnight

ApneaLink Air software provides clinicians access to a more in-depth view of their patients' recordings.



Ex. 52 at 2.



ApneaLink - Report of 02/12/2013 15:15

Treating physician | **Referral to**

Patient data

First name:	Cheyne Stokes	Patient ID:	
Last Name:	Example	DOB:	01/12/1968
Street:		Height:	176.16 cm
City, ST, Zip:		Weight:	92.41 kg
Phone:		BMI:	31.9 kg/m²

Recording

Date:	21/01/2009
Start:	21:13
End:	05:56
Duration:	8 h 43 min

Evaluation

Start:	21:23
End:	05:54
Duration:	7 h 55 min

AHI*

Normal range | Suspected pathological breathing disorder

Result (33)

* See Clinical Guide for abbreviations and Resmed standard parameters

Analysis (Flow evaluation period: 7 h 55 min / SpO_2 evaluation period: 8 h 32 min)

Indices		Normal	Result	
AHI*:	32.9	< 5 / h	Average breaths per minute [bpm]:	14.45
RI*:	33.8	< 5	Breaths:	6857
Apnea index:	20.6	< 5 / h	Apneas:	163
UAI:	0		Unclassified apneas:	0 (0%)
OAI:	5.6		Obstructive apneas:	44 (27%)
CAI:	14.9		Central apneas:	118 (72%)
MAI:	0.1		Mixed apneas:	1 (1%)
Hypopnea index:	12.3	< 5 / h	Hypopneas:	97
% Flow lim. Br. without Sn (FL):	12	< Approx. 60	Flow lim. Br. without Sn (FL):	792
% Flow lim. Br. with Sn (FS):	0	< Approx. 40	Flow lim. Br. with Sn (FS):	3
			Snoring events:	66
CDI Oxygen Desaturation Index*:	33.5	< 5 / h	No. of desaturations:	266
Average saturation:	91	94% - 98%	Saturation <= 90% :	234 min (46%)
Lowest desaturation:	72	-	Saturation <= 85% :	77 min (15%)
Lowest saturation:	72	90% - 98%	Saturation <= 80% :	7 min (1%)
Baseline Saturation:	98	%		
Minimum pulse:	59	> 40 bpm		
Maximum pulse:	71	< 90 bpm		
Average pulse:	62	bpm		
Proportion of probable CS epochs:	70	0%	CSR probable	

Analysis status: Analyzed automatically

Analysis parameters used (Default)

Apnea [20%; 10s; 80s; 1.0x; 20%; 60%; 8%]; Hypopnea [70%; 10s; 100s; 1.0x]; Snoring [0.3%; 0.3s; 3.5s; 0.5s]; Desaturation [4.0%]; CSR [0.53]

Comments

Ex. 52 at 4.

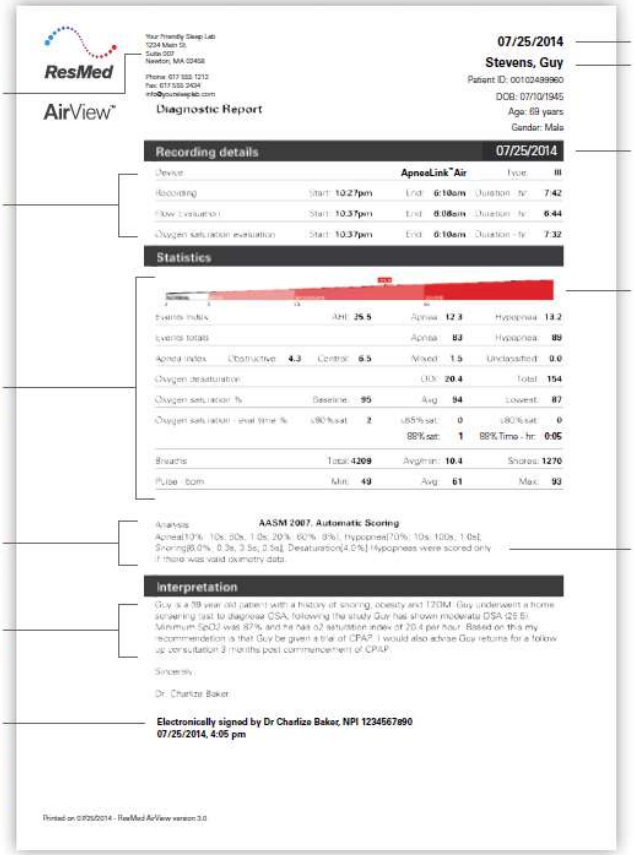
68. ApneaLink Air Software allows for transfer of the received and analyzed data from the ApneaLink Air device to a location remote location. Ex. 54 at 47-52 (explaining how to use ApneaLink Software to archive, export, and email generated reports and received signal recording data).

69. ApneaLink Air also sends data to AirView. *See supra* at ¶ 55. Within AirView, data received from ApneaLink Air is automatically scored and "provides detailed views of respiratory events and oxygen saturation." AirView is also capable of sharing the data received from ApneaLink Air and the generated reports with clinical users found in different locations. Ex. 41 at 2.

AirView™ Report Guide

AirView™ allows you to access your patient data online. Data can now be gathered from a home sleep testing device and displayed on your screen. Your patient therapy data can be viewed via remote wireless monitoring, or downloaded from an SD card. Each report is formatted to help you quickly identify the data you need, so you can provide quality care for your patients and manage their adherence to therapy.[1]

Home sleep testing diagnostic report



This is a sample report. Patient identification and therapy data is representative only.

Ex. 42 at 1-2.

Ex. 53 at 2.

RESMED'S KNOWLEDGE OF CLEVEMED'S PATENTS

70. CleveMed is informed and believes that ResMed is aware of the Asserted Patents because CleveMed discussed with ResMed and sent ResMed some of the Asserted Patents and patents related to the Asserted Patents. CleveMed is further informed and believes that ResMed has done nothing to curtail its infringement.

71. Starting in 2017, CleveMed's Executive Vice President and General Counsel had several meetings with Michael Pinczuk, ResMed's Vice President of Patents, and Paul Green, ResMed's Chief Patent Counsel, to explore potential partnership opportunities between CleveMed and ResMed. Ex. 56; Ex. 57. During these conversations, CleveMed provided ResMed an overview of its patented technology and discussed its issued and pending patents, including many of the Asserted Patents. Pursuant to these conversations, ResMed requested that CleveMed keep ResMed up-to-date with any new developments concerning CleveMed's patented technology.

72. In response to ResMed's request, CleveMed informed ResMed on an ongoing basis about its patent portfolio. For example, CleveMed informed ResMed that it received a Notice of Allowance from the United States Patent Office for a patent application covering a system for displaying a subject's data to be forwarded to the cloud, including apnea symptoms and PAP device usage, and that other claims of the application cover the use of a pulse oximetry module in combination with a PAP device flow sensor that collects sleep disorder symptoms that are forwarded to the cloud.

73. ResMed had discussions with CleveMed about licensing CleveMed's technology and patents. CleveMed is informed and believes that ResMed studied CleveMed's patents and discussed CleveMed's technology with ResMed's management, and in turn, expressed interest in purchasing or licensing CleveMed's patents that related to sleep therapy. In 2018, CleveMed sent ResMed a list of CleveMed's then-issued patents and pending patent applications from the PAP family chart, including the '269 Patent. Ex. 58 (providing notice for the '269 Patent). In 2019, CleveMed wrote to ResMed informing it that CleveMed received three additional Notices of Allowance for patents in the integrated diagnostics and therapy family. Ex. 59.

74. In November of 2019, CleveMed again reached out to Mr. Green and Mr. Pinczuk to introduce them to CleveMed's outside patent counsel and inform them that CleveMed received three Notices of Allowance for the '399 and '118 Patents and their associated families. Ex. 59.

75. CleveMed is informed and believes that, despite ResMed's notice and knowledge of the Asserted Patents and CleveMed's patented technology, ResMed made the deliberate decision to sell products and services that it knew infringes CleveMed's Asserted Patents.

76. CleveMed is informed and believes that ResMed has undertaken no efforts to avoid infringement of the Asserted Patents, despite ResMed's knowledge and understanding that its products and services infringe these patents. Thus, ResMed's infringement of Asserted Patents is willful and in egregious, warranting enhancement of damages.

77. CleveMed is informed and believes that ResMed knew or was willfully blind to CleveMed's patented technology. Despite this knowledge and/or willful blindness, ResMed has acted with blatant and in egregious disregard for CleveMed's patent rights with an objectively high likelihood of infringement.

78. ResMed has been and is now infringing, and will continue to infringe, the Asserted Patents in this Judicial District and elsewhere in the United States by, among other things, making, using, importing, selling, and/or offering for sale the Accused Products.

79. In addition to directly infringing the Asserted Patents pursuant to 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, or both, ResMed also indirectly infringes all the Asserted Patents by instructing, directing, and/or requiring others, including its customers, purchasers, and users, to perform all or some of the steps of the method claims, either literally or under the doctrine of equivalents, or both, of the Asserted Patents.

COUNT I
(Direct Infringement of the '269 Patent)

80. CleveMed repeats, realleges, and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs, as set forth above.

81. ResMed has infringed and continues to infringe at least Claim 15 of the '269 Patent in violation of 35 U.S.C. § 271(a).

82. ResMed's infringement is based upon literal infringement or infringement under the doctrine of equivalents, or both.

83. ResMed's acts of making, using, importing, selling, and/or offering for sale infringing products and services have been without the permission, consent, authorization, or license of CleveMed.

84. ResMed's infringement includes, but is not limited to, the manufacture, use, sale, importation and/or offer for sale of ResMed's products and services incorporating the PAP system described in the '269 Patent, which includes, but is not limited to, the Accused PAP Devices that have the ResMed Connectivity Module, the Air10 Oximetry Module, AirView, ResScan, myAir App, and/or the AirMini App (collectively the "'269 Accused Products"). To the extent any components of the claimed systems are provided by ResMed's customers, ResMed directly infringes by acting as the final assembler of the infringing system. ResMed configures the infringing system that requires the use of the infringing components. *See, e.g.,* Ex. 25 at 6-10.

85. The '269 Accused Products embody the patented invention of the '269 Patent and infringe the '269 Patent because they function as a positive airway pressure sleep disorder treatment system. For example, every accused PAP Device consists of a blower having an air output, a mask or nasal cannula, and an internal sensor adapted for measuring the respiratory airflow of the subject and outputting airflow sensor data. *See supra* at ¶ 49.

86. The Accused PAP Devices are also capable of filtering, processing, and outputting pulse oximeter sensor signals for at least the AirSense 10 CPAP, Elite, AutoSet, and AutoSet for Her devices; the AirCurve 10 S, ST, VAuto, and ASV devices; the Stellar 100 and 150 devices; and the Astral 100 and 150 devices. *See supra* at ¶ 52.

87. The Accused PAP Devices also contain a transceiver that receives and transmits the therapy data and detailed data related to a subject's sleeping disorder symptoms and its severity to a remote location. *See supra* at ¶¶ 51, 53.

88. The Accused PAP Devices have both internal and external processors responsible for receiving airflow sensor data and calculating the severity of the subject's sleep related breathing symptoms and/or an index of the subject's symptoms determined while the subject used the Accused PAP Device. *See supra* at ¶¶ 53-58.

89. The Accused PAP Devices are capable of wirelessly sending a subject's symptom data and/or the index of the subject's symptoms to a base station, cellular phone, or PDA running ResMed's software and/or applications. *See supra* at ¶ 51.

90. The base station, cellular phone, or PDA comprising a wireless module transceiver, a processor, a display, and software. The base station, cellular phone, or PDA are further adapted to display and retransmit the subject's symptom data and/or the index of the subject's symptoms to a remote internet site using the wireless transceiver of the base station, cellular phone, or PDA. *See supra* at ¶¶ 54-58.

91. ResMed's infringement of the '269 Patent has injured and continues to injure CleveMed in an amount to be proven at trial, but not less than a reasonable royalty.

92. CleveMed is informed and believes ResMed has had knowledge of CleveMed's patented technology at least as early as September 4, 2018. ResMed's actions are willful, blatant and in egregious disregard for CleveMed's patent rights. ResMed's infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

93. ResMed acted recklessly, willfully, wantonly, and deliberately engaged in acts of infringement of the ’269 Patent, justifying an award to CleveMed of increased damages under 35 U.S.C. § 284, and attorney’s fees and costs incurred under 35 U.S.C. § 285.

COUNT II
(Indirect Infringement of the ’269 Patent)

94. CleveMed repeats, realleges, and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs.

95. CleveMed is informed and believes ResMed has induced infringement of at least Claim 15 of the ’269 Patent under 35 U.S.C. § 271(b). Further, CleveMed is informed and believes ResMed has also contributorily infringed at least Claim 15 of the ’269 Patent under 35 U.S.C. § 271(c).

96. CleveMed is informed and believes ResMed had knowledge of the ’269 Patent and the ’269 Accused Products’ infringement of the Asserted Patents because in 2018, CleveMed sent ResMed a list of CleveMed’s then issued and pending patents from the PAP family chart, including the ’269 Patent.

97. CleveMed is informed and believes ResMed has induced infringement of the ’269 Patent pursuant to 35 U.S.C. § 271(b) by instructing, directing and/or requiring others, including its customers, partners, purchasers, and users to provide one or more components of the patented system either literally or under the doctrine of equivalents. All the elements of the claims are used by either ResMed, its customers, partners, purchasers, and/or users, or some combination thereof. CleveMed is informed and believes ResMed has known or was willfully blind to the fact that it is inducing others to infringe by practicing, either themselves or in conjunction with ResMed, one or more claims of the ’269 Patent, including Claim 15.

98. CleveMed is informed and believes ResMed knowingly and actively aided and abetted the direct infringement of the ’269 Patent by instructing and encouraging its customers, purchasers, and/or users, and/or partners to meet the elements of the ’269 Patent with the ’269 Accused Products, despite knowing or remaining willfully blind to the fact that the encouraged acts caused infringement. Such instructions and encouragement include, but are not limited to, advising third parties to use the ’269 Accused Products in an infringing manner through direct communications; training and support contracts, sales calls between ResMed employees and its customers; directing distributors, partners, and manufacturers how to install and configure the Accused Products; and by advertising and promoting the use of the ’269 Accused Products in an infringing manner, including the material cited herein and above in the direct infringement allegations. Further, ResMed distributes release notes, webinars, guidelines, videos, manuals, white papers, and trainings to third parties on how the ’269 Accused Products must be used, and shows them being used in an infringing manner.

99. CleveMed is informed and believes ResMed contributorily infringes the ’269 Patent pursuant to 35 U.S.C. § 271(c) because it has provided software such as AirView, ResScan, myAir App, and the AirMini App, as well as computer systems with software installed such as the Accused PAP Devices, that act as a material component of the claims of the ’269 Patent. CleveMed is informed and believes ResMed knows that its products are particularly suited to be used in an infringing manner and that ResMed is aware that its products are not staple articles suitable for substantial non-infringing use. CleveMed is informed and believes ResMed has known or was willfully blind to the fact that it is contributing to the direct infringement of one or more claims of the ’269 Patent by its customers, partners, purchasers, and users, including Claim 15.

100. In particular, ResMed has at least provided the ’269 Accused Products to others as positive airway pressure devices and computer technologies and these products are a material part and/or component of the claims of the ’269 Patent. CleveMed is informed and believes ResMed knows that its products are particularly suited to be used on or in combination with ResMed’s PAP Devices and computer technologies, and that these products are made and adapted for this use, even if some of these components are not sold by ResMed with, or as part of, the ’269 Accused Products. In fact, in many cases, the ’269 Accused Products can only function when used with these computer technologies. For example, ResMed markets the PAP devices and each of the myAir and AirView software together, stating first, “[u]sers of AirSense 11 will have access to enhanced myAir features like Personal Therapy Assistant and Care Check-In,” (Ex. 48 at 1) and second, “[a]ll AirSense 11 devices are supported with Air Solutions, our robust sleep therapy system. This includes our digital health technologies, ResMed AirView™ and myAir” (Ex. 20 at 7).

101. CleveMed is informed and believes ResMed has knowingly and actively contributed to the direct infringement of the ’269 Patent by its manufacture, use, offer to sell, sale, and importation of the ’269 Accused Products together with its customers, partners, purchasers, and/or users to meet the elements of the ’269 Patent, as described above and incorporated by reference here.

102. ResMed’s indirect infringement of the ’269 Patent has injured and continues to injure CleveMed in an amount to be proven at trial, but not less than a reasonable royalty.

103. ResMed’s indirect infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

104. CleveMed is entitled to injunctive relief, damages and any other relief in accordance with 35 U.S.C. §§ 283, 284, and 285.

105. ResMed has had knowledge of CleveMed's '269 Patent since at least as early as September 4, 2018. ResMed's actions are willful, blatant and in egregious disregard for CleveMed's patent rights. ResMed's infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

106. ResMed acted recklessly, willfully, wantonly, and deliberately engaged in acts of infringement of the '269 Patent, justifying an award to CleveMed of increased damages under 35 U.S.C. § 284, and attorney's fees and costs incurred under 35 U.S.C. § 285.

COUNT III
(Direct Infringement of the '399 Patent)

107. CleveMed repeats, realleges, and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs, as set forth above.

108. ResMed has infringed and continues to infringe at least Claim 1 of the '399 Patent in violation of 35 U.S.C. § 271(a).

109. ResMed's infringement is based upon literal infringement or infringement under the doctrine of equivalents, or both.

110. ResMed's acts of making, using, importing, selling, and/or offering for sale infringing products and services have been without the permission, consent, authorization, or license of CleveMed.

111. ResMed's infringement includes, but is not limited to, the manufacture, use, sale, importation and/or offer for sale of ResMed's products and services incorporating the HST solution described in the '399 Patent, which includes, but is not limited to, the Accused HST

Solution: the ApneaLink Air device that has ApneaLink Software and/or AirView (collectively, the "'399 Accused Products").

112. CleveMed is informed and believes ResMed directs and controls the methods in the claims and obtains benefits from the control of the system as a whole. CleveMed is informed and believes ResMed conditions participation in the infringing activity and establishes the manner or timing of that performance, as described below, by instructing and encouraging users to use the '399 Accused Products in an infringing manner. ResMed and its customers, partners, purchasers, and/or users put the article of manufacture and methods described in the claims into service to the benefit of ResMed's ability to further enhance its sleep therapy capabilities. *See*, *e.g.*, Ex. 13 at 1-2.

113. The '399 Accused Products embody the patented invention of the '399 Patent and infringe the '399 Patent because through their use, ResMed provides a method for conducting home sleep testing. For example, ResMed provides a subject with the ApneaLink Air device which is a portable patient interface box worn around the subject's torso, a nasal cannula or facemask to measure airflow, a respiratory effort belt sensor to measure the respiratory effort of the subject, and a fingertip pulse oximeter for measuring the oxygenation of the subject. *See supra* at ¶¶ 59-64.

114. The ApneaLink Air comprises a battery, at least one kinetic sensor for measuring body position, a nonvolatile digital memory, a pressure transducer, an air port adapted for connecting the nasal cannula or facemask to the pressure transducer within the interface box and releasable connectors to connect and disconnect the respiratory effort belt sensor and fingertip pulse oximeter. *See supra* at ¶¶ 61-63.

115. The ApneaLink Air further applies and connects the nasal cannula or facemask, the respiratory effort belt, and the fingertip pulse oximeter to the subject, and the interface box to the subject's torso. *See supra* at ¶¶ 63-64.

116. The ApneaLink Air measures and collects data through the interface box of the airflow, respiratory effort, body position, or orientation and oxygenation of the subject while the subject attempts to sleep at home. *See supra* at ¶ 65.

117. The ApneaLink Air digitizes and stores the collected data from the subject in the nonvolatile digital memory of the interface box. *See supra* at ¶ 62 (showing a 48 hour recording period is stored on the ApneaLink Air's internal memory).

118. The ApneaLink Air transfers the collected data to a location remote from the subject's home. *See supra* at ¶¶ 66-69.

119. The '399 Accused Products additionally use a computer or a processor that runs AirView and/or ApneaLink Software at the remote location for analyzing the transferred collected data to identify and draw attention to physiological or technological events in the data indicative of a sleeping disorder. *See supra* at ¶¶ 59, 67, 69.

120. The ApneaLink Software and AirView provide for further analysis of the transferred collected data and/or the identified physiological and technological events in the data at the remote location to determine whether the subject suffers from a sleeping disorder. For example, the ApneaLink Software has a Re-analyze tool "that repeats the analysis of a recording based on the set analysis parameters" and "modif[ies] the report, the patient record or the records (waveform data)." AirView also allows a user to customize the types of reports generated. *See* Ex. 54 at 21; Ex. 42 at 1-2.

121. ResMed's infringement of the '399 Patent has injured and continues to injure CleveMed in an amount to be proven at trial, but not less than a reasonable royalty.

122. CleveMed is informed and believes ResMed has had knowledge of CleveMed's patented technology at least as early as November 2019. ResMed's actions are willful, blatant and in egregious disregard for CleveMed's patent rights. ResMed's infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

123. ResMed acted recklessly, willfully, wantonly, and deliberately engaged in acts of infringement of the '399 Patent, justifying an award to CleveMed of increased damages under 35 U.S.C. § 284, and attorney's fees and costs incurred under 35 U.S.C. § 285.

COUNT IV
(Indirect Infringement of the '399 Patent)

124. CleveMed repeats, realleges, and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs.

125. CleveMed is informed and believes ResMed has induced infringement of at least Claim 1 of the '399 Patent under 35 U.S.C. § 271(b). Further, CleveMed is informed and believes ResMed has also contributorily infringed at least Claim 1 of the '399 Patent under 35 U.S.C. § 271(c).

126. CleveMed is informed and believes ResMed had knowledge of the '399 Patent and the '399 Accused Products' infringement of the Asserted Patents because in November 2019, CleveMed informed ResMed that CleveMed received Notices of Allowance for the '399 Patent and its associated families.

127. CleveMed is informed and believes ResMed has induced infringement of the ’399 Patent pursuant to 35 U.S.C. § 271(b) by instructing, directing and/or requiring others, including its customers, partners, purchasers, and users to perform one or more of the steps of the method claims either literally or under the doctrine of equivalents. All the elements of the claims are used by either ResMed, its customers, partners, purchasers, and/or users or some combination thereof. CleveMed is informed and believes ResMed has known or was willfully blind to the fact that it is inducing others to infringe by practicing, either themselves or in conjunction with ResMed, one or more claims of the ’399 Patent, including Claim 1.

128. CleveMed is informed and believes ResMed knowingly and actively aided and abetted the direct infringement of the ’399 Patent by instructing and encouraging its customers, purchasers, partners, and/or users to meet the elements of the ’399 Patent with the Accused Products, despite knowing or remaining willfully blind to the fact that the encouraged acts caused infringement. Such instructions and encouragement includes, but are not limited to, advising third parties to use the ’399 Accused Products in an infringing manner through direct communications; training and support contracts, sales calls between ResMed employees and its customers; directing distributors, partners, and manufacturers how to install and configure the Accused Products; and by advertising and promoting the use of the ’399 Accused Products in an infringing manner, including the material cited herein and above in the direct infringement allegations. Further, ResMed distributes release notes, webinars, guidelines, videos, manuals, white papers, and trainings to third parties on how the ’399 Accused Products must be used and shows them being used in an infringing manner.

129. CleveMed is informed and believes ResMed contributorily infringes the ’399 Patent pursuant to 35 U.S.C. § 271(c) because it has provided software such as AirView and

ApneaLink Software and computer systems with software installed such as the ApneaLink Air device, that act as a material component of the claims of the ’399 Patent. In particular, CleveMed is informed and believes ResMed knows that its products are particularly suited to be used in an infringing manner and that ResMed is aware that its products are not staple articles suitable for substantial non-infringing use. CleveMed is informed and believes ResMed has known or was willfully blind to the fact that it is contributing to the direct infringement of one or more claims of the ’399 Patent by its customers, partners, purchasers, and users, including Claim 1.

130. In particular, CleveMed is informed and believes ResMed has at least provided the ’399 Accused Products to others as home sleep testing devices and computer technologies and these products are a material part and/or component of the claims of the ’399 Patent. ResMed knows that its products are particularly suited to be used on, or in combination with ResMed’s HST Devices and computer technologies and that these products are made and adapted for this use, even if some of these components are not sold by ResMed with, or as part of, the ’399 Accused Products. In fact, in many cases, the ’399 Accused Products can only function when used with these computer technologies. For example, ResMed markets the ApneaLink Air and ApneaLink Air Software together, stating “ApneaLink Air software provides clinicians access to a more in-depth view of their patients’ recordings.” Ex. 52 at 2. Further, ResMed markets the ApneaLink Air and AirView together, stating, “[t]est results from the ApneaLink Air are saved to a secure database in the cloud [AirView] giving your sleep lab online access anytime and improving collaboration across your business.” Ex. 53 at 3.

131. CleveMed is informed and believes ResMed has knowingly and actively contributed to the direct infringement of the ’399 Patent by its manufacture, use, offer to sell,

sale, and importation of the ’399 Accused Products together with its customers, partners, purchasers, and/or users to meet the elements of the ’399 Patent, as described above and incorporated by reference here.

132. ResMed’s indirect infringement of the ’399 Patent has injured and continues to injure CleveMed in an amount to be proven at trial, but not less than a reasonable royalty.

133. ResMed’s indirect infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

134. CleveMed is entitled to injunctive relief, damages and any other relief in accordance with 35 U.S.C. §§ 283, 284, and 285.

135. ResMed has had knowledge of CleveMed’s ’399 Patent since at least as early as November 2019. ResMed’s actions are willful, blatant and in egregious disregard for CleveMed’s patent rights. ResMed’s infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

136. ResMed acted recklessly, willfully, wantonly, and deliberately engaged in acts of infringement of the ’399 Patent, justifying an award to CleveMed of increased damages under 35 U.S.C. § 284, and attorney’s fees and costs incurred under 35 U.S.C. § 285.

COUNT V
(Direct Infringement of the ’535 Patent)

137. CleveMed repeats, realleges, and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs, as set forth above.

138. ResMed has infringed and continues to infringe at least Claim 15 of the ’535 Patent in violation of 35 U.S.C. § 271(a).

139. ResMed's infringement is based upon literal infringement or infringement under the doctrine of equivalents, or both.

140. ResMed's acts of making, using, importing, selling, and/or offering for sale infringing products and services have been without the permission, consent, authorization, or license of CleveMed.

141. ResMed's infringement includes, but is not limited to, the manufacture, use, sale, importation and/or offer for sale of ResMed's products and services incorporating the HST solution described in the '535 Patent, which includes, but is not limited to, the Accused HST Solution: the ApneaLink Air device that has ApneaLink Software and/or AirView (collectively, the "'535 Accused Products"). To the extent any components of the claimed systems are provided by ResMed's customers, ResMed directly infringes by acting as the final assembler of the infringing system. ResMed configures the infringing system that requires the use of the infringing components. *See, e.g.,* Ex. 54 at 5-15.

142. The '535 Accused Products embody the patented invention of the '535 Patent and infringe the '535 Patent because they function as a system for conducting an at-home sleep analysis. For example, the ApneaLink Air is a portable interface box worn on a subject's torso that connects to at least three sensors, a nasal cannula or facemask for measuring airflow of the subject, a respiratory effort belt for measuring respiratory effort, and a fingertip pulse oximeter for measuring oxygenation of the subject while they sleep or attempt to sleep. *See supra* at ¶¶ 59-63.

143. The ApneaLink Air comprises a battery, at least one kinetic sensor for measuring body position, a nonvolatile digital memory, a pressure transducer, an air port adapted for connecting the nasal cannula or facemask to the pressure transducer within the interface box, and

a processor adapted for collecting, measuring, digitizing, and storing collected data to the nonvolatile digital memory from the airflow, respiratory effort, blood oxygenation, and body position of the subject. *See supra* at ¶¶ 62-63.

144. The ApneaLink Air further comprises a transceiver adapted for uploading the collected data from the memory, and releasable connector sensor inputs adapted to electrically connect and disconnect the respiratory effort belt sensor and the fingertip pulse oximeter. *See supra* at ¶¶ 63-64, 66 .

145. The ApneaLink Software and AirView contain a database that is remote from the subject and adapted for receiving the collected data transferring from the transceiver. *See* Ex. 54 at 18 (describing running the ApneaLink software to complete data transfer and analysis, and having a database containing collected data, including recordings and reports), *id.* at 20 (showing a database containing "[p]atient details, recordings, and reports"); *see also* Ex. 54 at 3 ("Test results from the ApneaLink Air are saved to a secure database in the cloud, giving your sleep lab online access anytime and improving collaboration across your business.").

146. The ApneaLink Air Software and AirView automatically analyzes the collected data from the database to identify and draw attention to physiological or technological events in the data indicative of a sleeping disorder. *See supra* at ¶¶ 59, 67-69; *see also* Ex. 54 at 41 (the ApneaLink software uses a number of "[a]nalysis indices" to further analyze the data, e.g. "apnea-hypopnea index," "risk indicator," "% Flow limited breaths without Sn (FL)," "SpO_2 evaluation period," "Oxygen Desaturation Index," "Pulse," and "Proportion of probable Cheyne-Stokes epochs."); Ex. 60 at 1-2 (AirView's report guide "outlines the types of reports that you can generate in . . . AirView" and describes common graphs used in the various AirView reports, including those showing "Usage, Leak, Events and SpO_2").

147. The ApneaLink Software and AirView provide for further analysis and displaying and/or printing of the transferred collected data and/or the identified physiological and technological events in the data at the remote location to determine whether the subject suffers from a sleeping disorder. For example, the ApneaLink Software has a Re-analyze tool "that repeats the analysis of a recording based on the set analysis parameters" and "modif[ies] the report, the patient record or the records (waveform data)." AirView also allows a user to customize the types of reports generated. *See* Ex. 54 at 21; Ex. 42 at 1-2.

148. ResMed's infringement of the '535 Patent has injured and continues to injure CleveMed in an amount to be proven at trial, but not less than a reasonable royalty.

149. CleveMed is informed and believes ResMed has had knowledge of CleveMed's patented technology since at least as of the date of this Complaint, if not earlier. ResMed's actions are willful, blatant and in egregious disregard for CleveMed's patent rights. ResMed's infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

150. ResMed acted recklessly, willfully, wantonly, and deliberately engaged in acts of infringement of the '535 Patent, justifying an award to CleveMed of increased damages under 35 U.S.C. § 284, and attorney's fees and costs incurred under 35 U.S.C. § 285.

COUNT VI
(Indirect Infringement of the '535 Patent)

151. CleveMed repeats, realleges, and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs.

152. CleveMed is informed and believes ResMed has induced infringement of at least Claim 15 of the '535 Patent under 35 U.S.C. § 271(b). Further, CleveMed is informed and

believes ResMed has also contributorily infringed at least Claim 15 of the ’535 Patent under 35 U.S.C. § 271(c).

153. CleveMed is informed and believes ResMed has had knowledge of CleveMed’s patented technology since at least as of the date of this Complaint, if not earlier.

154. CleveMed is informed and believes ResMed has induced infringement of the ’535 Patent pursuant to 35 U.S.C. § 271(b) by instructing, directing and/or requiring others, including its customers, partners, purchasers, and users to provide one or more components of the article of manufacturing, either literally or under the doctrine of equivalents. All the elements of the claims are used by either ResMed, its customers, partners, purchasers, and/or users or some combination thereof. CleveMed is informed and believes ResMed has known or was willfully blind to the fact that it is inducing others to infringe by practicing, either themselves or in conjunction with ResMed, one or more claims of the ’535 Patent, including Claim 15.

155. CleveMed is informed and believes ResMed knowingly and actively aided and abetted the direct infringement of the ’535 Patent by instructing and encouraging its customers, purchasers, partners, and/or users to meet the elements of the ’535 Patent with the Accused Products, despite knowing or remaining willfully blind to the fact that the encouraged acts caused infringement. Such instructions and encouragement include, but are not limited to, advising third parties to use the ’535 Accused Products in an infringing manner through direct communications; training and support contracts, sales calls between ResMed employees and its customers; directing distributors, and partners how to install and configure the Accused Products; and by advertising and promoting the use of the ’535 Accused Products in an infringing manner, including the material cited herein and above in the direct infringement allegations. Further, ResMed distributes release notes, webinars, guidelines, videos, manuals,

white papers, and trainings to third parties on how the ’535 Accused Products must be used and shows them being used in an infringing manner.

156. CleveMed is informed and believes ResMed contributorily infringes the ’535 Patent pursuant to 35 U.S.C. § 271(c) because it has provided software such as AirView and ApneaLink Software and computer systems with software installed such as the ApneaLink Air device, that act as a material component of the claims of the ’535 Patent. In particular, ResMed knows that its products are particularly suited to be used in an infringing manner and ResMed is aware that its products are not staple articles suitable for substantial non-infringing use. CleveMed is informed and believes ResMed has known or was willfully blind to the fact that it is contributing to the direct infringement of one or more claims of the ’535 Patent by its customers, partners, purchasers, and users, including Claim 15.

157. In particular, ResMed has at least provided the ’535 Accused Products to others as home sleep testing devices and computer technologies and these products are a material part and/or component of the claims of the ’535 Patent. ResMed knows that its products are particularly suited to be used on, or in combination with ResMed’s HST Devices and computer technologies and that these products are made and adapted for this use, even if some of these components are not sold by ResMed with, or as part of, the ’535 Accused Products. In fact, in many cases, the ’535 Accused Products can only function when used with these computer technologies. For example, ResMed markets the ApneaLink Air and ApneaLink Air Software together, stating “ApneaLink Air software provides clinicians access to a more in-depth view of their patients’ recordings.” Ex. 52 at 2. Further, ResMed markets the ApneaLink Air and AirView together, stating, “[t]est results from the ApneaLink Air are saved to a secure database

in the cloud [AirView] giving your sleep lab online access anytime and improving collaboration across your business." Ex. 53 at 3.

158. CleveMed is informed and believes ResMed has knowingly and actively contributed to the direct infringement of the '535 Patent by its manufacture, use, offer to sell, sale, and importation of the '535 Accused Products together with its customers, partners, purchasers, and/or users to meet the elements of the '535 Patent, as described above and incorporated by reference here.

159. ResMed's indirect infringement of the '535 Patent has injured and continues to injure CleveMed in an amount to be proven at trial, but not less than a reasonable royalty.

160. ResMed's indirect infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

161. CleveMed is entitled to injunctive relief, damages and any other relief in accordance with 35 U.S.C. §§ 283, 284, and 285.

162. ResMed's actions are willful, blatant and in egregious disregard for CleveMed's patent rights. ResMed's infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

163. ResMed acted recklessly, willfully, wantonly, and deliberately engaged in acts of infringement of the '535 Patent, justifying an award to CleveMed of increased damages under 35 U.S.C. § 284, and attorney's fees and costs incurred under 35 U.S.C. § 285.

COUNT VII
(Direct Infringement of the '937 Patent)

164. CleveMed repeats, realleges, and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs, as set forth above.

165. ResMed has infringed and continues to infringe at least Claim 1 of the '937 Patent in violation of 35 U.S.C. § 271(a).

166. ResMed's infringement is based upon literal infringement or infringement under the doctrine of equivalents, or both.

167. ResMed's acts of making, using, importing, selling, and/or offering for sale infringing products and services have been without the permission, consent, authorization, or license of CleveMed.

168. ResMed's infringement includes, but is not limited to, the manufacture, use, sale, importation and/or offer for sale of ResMed's products and services incorporating the HST solution described in the '937 Patent, which includes, but is not limited to, the Accused HST Solution: the ApneaLink Air device that has ApneaLink Software and/or AirView (collectively, the "'937 Accused Products"). To the extent any components of the claimed systems are provided by ResMed's customers, ResMed directly infringes by acting as the final assembler of the infringing system. ResMed configures the infringing system that requires the use of the infringing components. *See, e.g.,* Ex. 54 at 5-15.

169. The '937 Accused Products embody the patented invention of the '937 Patent and infringe the '937 Patent because they function as a system for conducting a remote sleep analysis of a subject. For example, the ApneaLink Air device is a portable interface box adapted for connecting to (1) a nasal cannula or facemask adapted to be applied to a subject for measuring airflow; (2) a respiratory effort belt adapted to be applied to a subject for measuring respiratory

effort; and (3) a fingertip pulse oximeter adapted to be applied to a subject, for measuring blood oxygenation and electrically connects to the ApneaLink Air device. *See supra* at ¶¶ 59-64.

170. The ApneaLink Air device comprises a battery, at least one kinetic sensor, a processor adapted for collecting, measuring, and digitizing data corresponding to the airflow, respiratory effort and blood oxygenation of the subject, and non-volatile memory for receiving and storing the data from the processor. *See supra* at ¶¶ 61-62.

171. ApneaLink Air further comprises a transceiver adapted for uploading the collected data, releasable connector sensor inputs adapted to electrically connect and disconnect the respiratory effort belt and the fingertip pulse oximeter, and a sensor input adapted to electrically connect the fingertip pulse oximeter. *See supra* at ¶¶ 63-66

172. The ApneaLink Air device has a first pressure transducer that connects the nasal cannula or face mask via an air port. *See supra* at ¶ 62; *see also* Ex. 54 at 6 (describing a first pressure transducer (i.e. pressure sensor)'s ability to record a pressure change).

173. The ApneaLink Air additionally comprises a second pressure transducer and a second air port adapted for connecting the respiratory effort sensor to the second pressure transducer. *See supra* at ¶ 62; *see also* Ex. 54 at 6 (describing a second pressure transducer (i.e. pressure sensor)'s ability to record a pressure change).

174. The ApneaLink Software and AirView contain a database that is remote from the subject and adapted for receiving the collected data transferring from the transceiver. *See* Ex. 54 at 18 (describing running the ApneaLink software to complete data transfer and analysis, and having a database containing collected data, including recordings and reports), *id.* at 20 (showing a database containing "[p]atient details, recordings, and reports"); *see also* Ex. 53 at 3 ("Test

results from the ApneaLink Air are saved to a secure database in the cloud, giving your sleep lab online access anytime and improving collaboration across your business.").

175. ApneaLink Air Software and AirView are software programs that are stored on computer readable storage media and when executed by a computing device, automatically analyze the collected data from the database to identify and draw attention to physiological or technological events in the data indicative of a sleeping disorder. *See supra* at ¶¶ 59, 67-69; *see also* Ex. 54 at 41 (the ApneaLink software uses a number of "[a]nalysis indices" to further analyze the data, e.g. "apnea-hypopnea index," "risk indicator," "% Flow limited breaths without Sn (FL)," "SpO_2 evaluation period," "Oxygen Desaturation Index," "Pulse," and "Proportion of probable Cheyne-Stokes epochs."); Ex. 60 at 1-2 (AirView's report guide "outlines the types of reports that you can generate in . . . AirView" and describes common graphs used in the various AirView reports, including those showing "Usage, Leak, Events and SpO_2").

176. ApneaLink Air Software and AirView are additionally adapted for outputting at least: (i) the transferred collected data, (ii) the identified physiological and technological events, or (iii) both (i) and (ii) to determine whether the subject suffers from a sleeping disorder. *See supra* at ¶¶ 68-69.

177. ResMed's infringement of the '937 Patent has injured and continues to injure CleveMed in an amount to be proven at trial, but not less than a reasonable royalty.

178. CleveMed is informed and believes ResMed has had knowledge of CleveMed's patented technology since at least as of the date of this Complaint, if not earlier. ResMed's actions are willful, blatant and in egregious disregard for CleveMed's patent rights. ResMed's infringement has caused and is continuing to cause damage and irreparable injury to CleveMed,

and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

179. ResMed acted recklessly, willfully, wantonly, and deliberately engaged in acts of infringement of the ’937 Patent, justifying an award to CleveMed of increased damages under 35 U.S.C. § 284, and attorney’s fees and costs incurred under 35 U.S.C. § 285.

COUNT VIII
(Indirect Infringement of the ’937 Patent)

180. CleveMed repeats, realleges, and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs.

181. CleveMed is informed and believes ResMed has induced infringement of at least Claim 1 of the ’937 Patent under 35 U.S.C. § 271(b). Further, CleveMed is informed and believes ResMed has also contributorily infringed at least Claim 1 of the ’937 Patent under 35 U.S.C. § 271(c).

182. CleveMed is informed and believes ResMed has had knowledge of CleveMed’s patented technology since at least as of the date of this Complaint, if not earlier.

183. CleveMed is informed and believes ResMed has induced infringement of the ’937 Patent pursuant to 35 U.S.C. § 271(b) by instructing, directing and/or requiring others, including its customers, partners, purchasers, and users to provide one or more components of the article of manufacturing, either literally or under the doctrine of equivalents. All the elements of the claims are used by either ResMed, its customers, partners, purchasers, and/or users or some combination thereof. CleveMed is informed and believes ResMed has known or was willfully blind to the fact that it is inducing others to infringe by practicing, either themselves or in conjunction with ResMed, one or more claims of the ’937 Patent, including Claim 1.

184. CleveMed is informed and believes ResMed knowingly and actively aided and abetted the direct infringement of the ’937 Patent by instructing and encouraging its customers, purchasers, partners, and/or users to meet the elements of the ’937 Patent with the ’937 Accused Products, despite knowing or remaining willfully blind to the fact that the encouraged acts caused infringement. Such instructions and encouragement include, but are not limited to, advising third parties to use the ’937 Accused Products in an infringing manner through direct communications; training and support contracts, sales calls between ResMed employees and its customers; directing distributors, partners, and manufacturers how to install and configure the Accused Products; and by advertising and promoting the use of the ’937 Accused Products in an infringing manner, including the material cited herein and above in the direct infringement allegations. Further, ResMed distributes release notes, webinars, guidelines, videos, manuals, white papers, and trainings to third parties on how the ’937 Accused Products must be used and shows them being used in an infringing manner.

185. CleveMed is informed and believes ResMed contributorily infringes the ’937 Patent pursuant to 35 U.S.C. § 271(c) because it has provided software such as AirView and ApneaLink Software and computer systems with software installed such as the ApneaLink Air device, that act as a material component of the claims of the ’937 Patent. In particular, ResMed knows that its products are particularly suited to be used in an infringing manner and that ResMed is aware that its products are not staple articles suitable for substantial non-infringing use. CleveMed is informed and believes ResMed has known or was willfully blind to the fact that it is contributing to the direct infringement of one or more claims of the ’937 Patent by its customers, partners, purchasers, and users, including Claim 1.

186. In particular, ResMed has at least provided the ’937 Accused Products to others as home sleep testing devices and computer technologies and these products are a material part and/or component of the claims of the ’937 Patent. ResMed knows that its products are particularly suited to be used on, or in combination with ResMed’s HST Devices and computer technologies and that these products are made and adapted for this use, even if some of these components are not sold by ResMed with, or as part of, the ’937 Accused Products. In fact, in many cases, the ’937 Accused Products can only function when used with these computer technologies. For example, ResMed markets the ApneaLink Air and ApneaLink Air Software together, stating “ApneaLink Air software provides clinicians access to a more in-depth view of their patients’ recordings.” Ex. 52 at 2. Further, ResMed markets the ApneaLink Air and AirView together, stating, “[t]est results from the ApneaLink Air are saved to a secure database in the cloud [AirView] giving your sleep lab online access anytime and improving collaboration across your business.” Ex. 53 at 3.

187. CleveMed is informed and believes ResMed has knowingly and actively contributed to the direct infringement of the ’937 Patent by its manufacture, use, offer to sell, sale, and importation of the ’937 Accused Products together with its customers, partners, purchasers, and/or users to meet the elements of the ’937 Patent, as described above and incorporated by reference here.

188. ResMed’s indirect infringement of the ’937 Patent has injured and continues to injure CleveMed in an amount to be proven at trial, but not less than a reasonable royalty.

189. ResMed’s indirect infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

190. CleveMed is entitled to injunctive relief, damages and any other relief in accordance with 35 U.S.C. §§ 283, 284, and 285.

191. ResMed's actions are willful, blatant and in egregious disregard for CleveMed's patent rights. ResMed's infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

192. ResMed acted recklessly, willfully, wantonly, and deliberately engaged in acts of infringement of the '937 Patent, justifying an award to CleveMed of increased damages under 35 U.S.C. § 284, and attorney's fees and costs incurred under 35 U.S.C. § 285.

COUNT IX
(Direct Infringement of the '698 Patent)

193. CleveMed repeats, realleges, and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs, as set forth above.

194. ResMed has infringed and continues to infringe at least Claim 14 of the '698 Patent in violation of 35 U.S.C. § 271(a).

195. ResMed's infringement is based upon literal infringement or infringement under the doctrine of equivalents, or both.

196. ResMed's acts of making, using, importing, selling, and/or offering for sale infringing products and services have been without the permission, consent, authorization, or license of CleveMed.

197. ResMed's infringement includes, but is not limited to, the manufacture, use, sale, importation and/or offer for sale of ResMed's products and services incorporating the HST solution described in the '698 Patent, which includes, but is not limited to, the Accused HST

Solution: the ApneaLink Air device that has ApneaLink Software and/or the AirView (collectively, the "'698 Accused Products").

198. CleveMed is informed and believes ResMed directs and controls the systems and methods in the claims and obtains benefits from the control of the system as a whole. CleveMed is informed and believes ResMed conditions participation in the infringing activity and establishes the manner or timing of that performance, as described below, by instructing and encouraging users to use the '698 Accused Products in an infringing manner. ResMed and its customers, partners, purchasers, and/or users put the article of manufacture and methods described in the claims into service to the benefit of ResMed's ability to further enhance its sleep therapy capabilities. *See*, *e.g.*, Ex. 13 at 1-2.

199. The '698 Accused Products embody the patented invention of the '698 Patent and infringe the '698 Patent because they function as a method of remote sleep analysis and diagnosis. For example, ResMed instructs subjects to apply at least two sensors to a subject located in a facility remote to a sleep analysis unit or lab, the at least two sensors including a respiratory belt sensor and an airflow sensor, the respiratory belt sensor being electrically hardwired and releasably connected to the ApneaLink Air device which is a portable interface box worn or carried by the subject, and the airflow sensor internal to the same interface box and adapted to be applied to the subject through a nasal cannula or breathing mask. *See supra* at ¶¶ 59-63.

200. The ApneaLink Air connects directly to both the respiratory effort sensor and the nasal cannula. *See supra* at ¶ 63.

201. The ApneaLink Air device comprises a memory device, a battery, and electronics, which are programmed to collect and transmit data to an electronic interface for receiving the data for review by medical personnel. *See supra* at ¶ 62 (showing ApneaLink Air has internal

memory, a battery, and electronics (*i.e.* "enhanced hardware," sensors) that collect data); *id.* at ¶ 66 (showing ApneaLink Air has a transceiver to transmit data to an electronic interface).

202. The ApneaLink Air device transmits the data collected on the device to an electronic interface (i.e. the computer running the ApneaLink Software and/or AirView) for receiving the data for review by health care professionals. *See supra* at ¶¶ 64-65, 67.

203. The ApneaLink Air device also collects data in real-time from the respiratory effort sensor worn on the belt and the air flow sensor and stores the data on the memory device of the ApneaLink Air device. *See supra* at ¶¶ 62, 65.

204. The ApneaLink Air device transmits the data from the device to the electronic interface at a sleep unit, lab, or a database accessible to health care professionals running ApneaLink Software and/or AirView. *See supra* at ¶ 66.

205. The ApneaLink Software and AirView are software that runs on a computer that identifies and draws attention to physiological or technological events in the data. *See supra* at ¶¶ 59, 67-69.

206. The ApneaLink Software and AirView provide for further analysis and of the transmitted data and the identified physiological and technological events to medically diagnose whether a subject suffers from a sleep disorder. For example, the ApneaLink Software has a Re-analyze tool "that repeats the analysis of a recording based on the set analysis parameters" and "modif[ies] the report, the patient record or the records (waveform data)." AirView also allows a user to customize the types of reports generated. *See* Ex. 54 at 21; Ex. 42 at 1-2.

207. Through ApneaLink Software and/or AirView the diagnosis can be communicated to the subject. *See supra* at ¶¶ 68-69.

208. ResMed's infringement of the '698 Patent has injured and continues to injure CleveMed in an amount to be proven at trial, but not less than a reasonable royalty.

209. CleveMed is informed and believes ResMed has had knowledge of CleveMed's patented technology since at least as of the date of this Complaint, if not earlier. ResMed's actions are willful, blatant and in egregious disregard for CleveMed's patent rights. ResMed's infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

210. ResMed acted recklessly, willfully, wantonly, and deliberately engaged in acts of infringement of the '698 Patent, justifying an award to CleveMed of increased damages under 35 U.S.C. § 284, and attorney's fees and costs incurred under 35 U.S.C. § 285.

COUNT X
(Indirect Infringement of the '698 Patent)

211. CleveMed repeats, realleges, and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs.

212. CleveMed is informed and believes ResMed has induced infringement of at least Claim 14 of the '698 Patent under 35 U.S.C. § 271(b). Further, CleveMed is informed and believes ResMed has also contributorily infringed at least Claim 14 of the '698 Patent under 35 U.S.C. § 271(c).

213. CleveMed is informed and believes ResMed has had knowledge of CleveMed's patented technology since at least as of the date of this Complaint, if not earlier.

214. CleveMed is informed and believes ResMed has induced infringement of the '698 Patent pursuant to 35 U.S.C. § 271(b) by instructing, directing and/or requiring others, including its customers, partners, purchasers, and users to perform one or more of the steps of the method

claims either literally or under the doctrine of equivalents. All the elements of the claims are used by either ResMed, its customers, partners, purchasers, and/or users or some combination thereof. CleveMed is informed and believes ResMed has known or was willfully blind to the fact that it is inducing others to infringe by practicing, either themselves or in conjunction with ResMed, one or more claims of the '698 Patent, including Claim 14.

215. CleveMed is informed and believes ResMed knowingly and actively aided and abetted the direct infringement of the '698 Patent by instructing and encouraging its customers, purchasers, partners, and/or users to meet the elements of the '698 Patent with the '698 Accused Products, despite knowing or remaining willfully blind to the fact that the encouraged acts caused infringement. Such instructions and encouragement included, but is not limited to, advising third parties to use the '698 Accused Products in an infringing manner through direct communications; training and support contracts, sales calls between ResMed employees and its customers; directing distributors, partners, and manufacturers how to install and configure the Accused Products; and by advertising and promoting the use of the '698 Accused Products in an infringing manner, including the material cited herein and above in the direct infringement allegations. Further, ResMed distributes release notes, webinars, guidelines, videos, manuals, white papers, and trainings to third parties on how the '698 Accused Products must be used and shows them being used in an infringing manner.

216. CleveMed is informed and believes ResMed contributorily infringes the '698 Patent pursuant to 35 U.S.C. § 271(c) because it has provided software such as AirView and ApneaLink Software and computer systems with software installed such as the ApneaLink Air device, that act as a material component of the claims of the '698 Patent. In particular, ResMed knows that its products are particularly suited to be used in an infringing manner and that

ResMed is aware that its products are not staple articles suitable for substantial non-infringing use. CleveMed is informed and believes ResMed has known or was willfully blind to the fact that it is contributing to the direct infringement of one or more claims of the '698 Patent by its customers, partners, purchasers, and users, including Claim 14.

217. In particular, ResMed has at least provided the '698 Accused Products to others as home sleep testing devices and computer technologies and these products are a material part and/or component of the claims of the '698 Patent. ResMed knows that its products are particularly suited to be used on, or in combination with ResMed's HST Devices and computer technologies and that these products are made and adapted for this use, even if some of these components are not sold by ResMed with, or as part of, the '698 Accused Products. In fact, in many cases, the '698 Accused Products can only function when used with these computer technologies. For example, ResMed markets the ApneaLink Air and ApneaLink Air Software together, stating "ApneaLink Air software provides clinicians access to a more in-depth view of their patients' recordings." Ex. 52 at 2. Further, ResMed markets the ApneaLink Air and AirView together, stating, "[t]est results from the ApneaLink Air are saved to a secure database in the cloud [AirView] giving your sleep lab online access anytime and improving collaboration across your business." Ex. 53 at 3.

218. CleveMed is informed and believes ResMed has knowingly and actively contributed to the direct infringement of the '698 Patent by its manufacture, use, offer to sell, sale, and importation of the '698 Accused Products together with its customers, partners, purchasers, and/or users to meet the elements of the '698 Patent, as described above and incorporated by reference here.

219. ResMed's indirect infringement of the '698 Patent has injured and continues to injure CleveMed in an amount to be proven at trial, but not less than a reasonable royalty.

220. ResMed's indirect infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

221. CleveMed is entitled to injunctive relief, damages and any other relief in accordance with 35 U.S.C. §§ 283, 284, and 285.

222. ResMed's actions are willful, blatant and in egregious disregard for CleveMed's patent rights. ResMed's infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

223. ResMed acted recklessly, willfully, wantonly, and deliberately engaged in acts of infringement of the '698 Patent, justifying an award to CleveMed of increased damages under 35 U.S.C. § 284, and attorney's fees and costs incurred under 35 U.S.C. § 285.

COUNT XI
(Direct Infringement of the '118 Patent)

224. CleveMed repeats, realleges, and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs, as set forth above.

225. ResMed has infringed and continues to infringe at least Claim 1 of the '118 Patent in violation of 35 U.S.C. § 271(a).

226. ResMed's infringement is based upon literal infringement or infringement under the doctrine of equivalents, or both.

227. ResMed's acts of making, using, importing, selling, and/or offering for sale infringing products and services have been without the permission, consent, authorization, or license of CleveMed.

228. ResMed's infringement includes, but is not limited to, the manufacture, use, sale, importation and/or offer for sale of ResMed's products and services incorporating the HST solution described in the '118 Patent, which includes, but is not limited to, the Accused HST Solution: the ApneaLink Air device that has ApneaLink Software and/or the AirView (collectively, the "'118 Accused Products").

229. CleveMed is informed and believes ResMed directs and controls the systems and methods in the claims and obtains benefits from the control of the system as a whole. CleveMed is informed and believes ResMed conditions participation in the infringing activity and establishes the manner or timing of that performance, as described below, by instructing and encouraging users to use the '118 Accused Products in an infringing manner. ResMed and its customers, partners, purchasers, and/or users put the article of manufacture and methods described in the claims into service to the benefit of ResMed's ability to further enhance its sleep therapy capabilities. *See*, *e.g.*, Ex. 13 at 1-2.

230. The '118 Accused Products embody the patented invention of the '118 Patent and infringe the '118 Patent because they function as a method of remote sleep analysis and diagnosis. For example, ResMed provides a subject with the ApneaLink Air device which is a portable patient interface device, a nasal cannula for measuring respiratory airflow, a respiratory effort belt sensor for measuring respiratory effort, and a fingertip pulse oximeter for measuring the oxygenation of the subject. *See supra* at ¶¶ 59-64.

231. The ApneaLink Air device comprises a battery, at least one kinetic sensor for measuring body position, and a non-volatile digital memory. *See supra* at ¶¶ 62, 65.

232. The ApneaLink Air also comprises first and second pressure transducers, a first air port for connecting the nasal cannula to the first pressure transducer, and a second air port for connecting respiratory effort belt to the second pressure transducer. The ApneaLink Air device also comprises a releasable connector sensor input to electrically connect and disconnect the fingertip pulse oximeter. *See supra* at ¶¶ 63-64.

233. ResMed instructs a subject to apply and connect the nasal cannula, the respiratory effort belt, the pulse oximeter, to the subject and the ApneaLink Air device. *See supra* at ¶¶ 63-64.

234. The ApneaLink Air measures and collects data from the sensors though the portable interface box of the airflow, respiratory effort, body position or orientation and oxygenation of the subject in a remote sleep location. *See supra* at ¶ 65.

235. The ApneaLink Air digitizes and stores the collected data from the subject in its non-volatile digital memory. *See supra* at ¶ 62.

236. The ApneaLink Software and AirView contain a database accessible to individuals of a sleep analysis unit or lab that is adapted for receiving the collected data transferred from the ApneaLink Air device. *See* Ex. 54 at 18 (describing running the ApneaLink software to complete data transfer and analysis, and having a database containing collected data, including recordings and reports), *id.* at 20 (showing a database containing "[p]atient details, recordings, and reports"); *see also* Ex. 53 at 3 ("Test results from the ApneaLink Air are saved to a secure database in the cloud, giving your sleep lab online access anytime and improving collaboration across your business.").

237. The ApneaLink Software and AirView run on a computer or processor and automatically analyzes the received data to identify and draw attention to physiological or technological events indicative of a sleeping disorder. *See supra* at ¶¶ 59, 67, 69.

238. The ApneaLink Software and AirView provide for further analysis of the transferred collected data and/or the identified physiological and technological events in the data at the remote location to determine whether the subject suffers from a sleeping disorder. For example, the ApneaLink Software has a Re-analyze tool "that repeats the analysis of a recording based on the set analysis parameters" and "modif[ies] the report, the patient record or the records (waveform data)." AirView also allows a user to customize the types of reports generated. *See* Ex. 54 at 21; Ex. 42 at 1-2.

239. ResMed's infringement of the '118 Patent has injured and continues to injure CleveMed in an amount to be proven at trial, but not less than a reasonable royalty.

240. CleveMed is informed and believes ResMed has had knowledge of CleveMed's patented technology since at least as of November 2019. ResMed's actions are willful, blatant and in egregious disregard for CleveMed's patent rights. ResMed's infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

241. ResMed acted recklessly, willfully, wantonly, and deliberately engaged in acts of infringement of the '118 Patent, justifying an award to CleveMed of increased damages under 35 U.S.C. § 284, and attorney's fees and costs incurred under 35 U.S.C. § 285.

COUNT XII
(Indirect Infringement of the ’118 Patent)

242. CleveMed repeats, realleges, and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs.

243. CleveMed is informed and believes ResMed has induced infringement of at least Claim 1 of the ’118 Patent under 35 U.S.C. § 271(b). Further, CleveMed is informed and believes ResMed has also contributorily infringed at least Claim 1 of the ’118 Patent under 35 U.S.C. § 271(c). ResMed has had knowledge of CleveMed’s ’118 Patent since at least as early as November 2019.

244. CleveMed is informed and believes ResMed had knowledge of the ’118 Patent and the ’118 Accused Products’ infringement of the Asserted Patents because in November 2019, CleveMed informed ResMed that CleveMed received Notices of Allowance for the ’118 Patent and its associated families.

245. CleveMed is informed and believes ResMed has induced infringement of the ’118 Patent pursuant to 35 U.S.C. § 271(b) by instructing, directing and/or requiring others, including its customers, partners, purchasers, and users to perform one or more of the steps of the method claims either literally or under the doctrine of equivalents. All the elements of the claims are used by either ResMed, its customers, partners, purchasers, and users, or some combination thereof. CleveMed is informed and believes ResMed has known or was willfully blind to the fact that it is inducing others to infringe by practicing, either themselves or in conjunction with ResMed, one or more claims of the ’118 Patent, including Claim 1.

246. CleveMed is informed and believes ResMed knowingly and actively aided and abetted the direct infringement of the ’118 Patent by instructing and encouraging its customers, purchasers, partners, and/or users to meet the elements of the ’118 Patent with the ’118 Accused

Products, despite knowing or remaining willfully blind to the fact that the encouraged acts caused infringement. Such instructions and encouragement include, but are not limited to, advising third parties to use the '118 Accused Products in an infringing manner through direct communications; training and support contracts, sales calls between ResMed employees and its customers; directing distributors, partners, and manufacturers how to install and configure the Accused Products; and by advertising and promoting the use of the '118 Accused Products in an infringing manner, including the material cited herein and above in the direct infringement allegations. Further, ResMed distributes release notes, webinars, guidelines, videos, manuals, white papers, and trainings to third parties on how the '118 Accused Products must be used and shows them being used in an infringing manner.

247. CleveMed is informed and believes ResMed contributorily infringes the '118 Patent pursuant to 35 U.S.C. § 271(c) because it has provided software such as AirView and ApneaLink Software and computer systems with software installed such as the ApneaLink Air device, that act as a material component of the claims of the '118 Patent. In particular, ResMed knows that its products are particularly suited to be used in an infringing manner and that ResMed is aware that its products are not staple articles suitable for substantial non-infringing use. CleveMed is informed and believes ResMed has known or was willfully blind to the fact that it is contributing to the direct infringement of one or more claims of the '118 Patent by its customers, partners, purchasers, and users, including Claim 1.

248. In particular, ResMed has at least provided the '118 Accused Products to others as home sleep testing devices and computer technologies and these products are a material part and/or component of the claims of the '118 Patent. ResMed knows that its products are particularly suited to be used on, or in combination with ResMed's HST Devices and computer

technologies and that these products are made and adapted for this use, even if some of these components are not sold by ResMed with, or as part of, the '118 Accused Products. In fact, in many cases, the '118 Accused Products can only function when used with these computer technologies. For example, ResMed markets the ApneaLink Air and ApneaLink Air Software together, stating "ApneaLink Air software provides clinicians access to a more in-depth view of their patients' recordings." Ex. 52 at 2. Further, ResMed markets the ApneaLink Air and AirView together, stating, "[t]est results from the ApneaLink Air are saved to a secure database in the cloud [AirView] giving your sleep lab online access anytime and improving collaboration across your business." Ex. 53 at 3.

249. CleveMed is informed and believes ResMed has knowingly and actively contributed to the direct infringement of the '118 Patent by its manufacture, use, offer to sell, sale, and importation of the '118 Accused Products together with its customers, partners, purchasers, and/or users to meet the elements of the '118 Patent, as described above and incorporated by reference here.

250. ResMed's indirect infringement of the '118 Patent has injured and continues to injure CleveMed in an amount to be proven at trial, but not less than a reasonable royalty.

251. ResMed's indirect infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

252. CleveMed is entitled to injunctive relief, damages and any other relief in accordance with 35 U.S.C. §§ 283, 284, and 285.

253. ResMed has had knowledge of CleveMed's '118 Patent since at least as early as November 2019. ResMed's actions are willful, blatant and in egregious disregard for

CleveMed's patent rights. ResMed's infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

254. ResMed acted recklessly, willfully, wantonly, and deliberately engaged in acts of infringement of the '118 Patent, justifying an award to CleveMed of increased damages under 35 U.S.C. § 284, and attorney's fees and costs incurred under 35 U.S.C. § 285.

COUNT XIII
(Direct Infringement of the '603 Patent)

255. CleveMed repeats, realleges, and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs, as set forth above.

256. ResMed has infringed and continues to infringe at least Claim 1 of the '603 Patent in violation of 35 U.S.C. § 271(a).

257. ResMed's infringement is based upon literal infringement or infringement under the doctrine of equivalents, or both.

258. ResMed's acts of making, using, importing, selling, and/or offering for sale infringing products and services have been without the permission, consent, authorization, or license of CleveMed.

259. ResMed's infringement includes, but is not limited to, the manufacture, use, sale, importation and/or offer for sale of ResMed's products and services incorporating the HST solution described in the '603 Patent, which includes, but is not limited to, the Accused HST Solution: the ApneaLink Air device that has ApneaLink Software and/or AirView (collectively, the "'603 Accused Products").

260. CleveMed is informed and believes ResMed directs and controls the systems and methods in the claims and obtains benefits from the control of the system as a whole. CleveMed

is informed and believes ResMed conditions participation in the infringing activity and establishes the manner or timing of that performance, as described below, by instructing and encouraging users to use the '603 Accused Products in an infringing manner. ResMed and its customers, partners, purchasers, and/or users put the article of manufacture and methods described in the claims into service to the benefit of ResMed's ability to further enhance its sleep therapy capabilities. *See*, *e.g.*, Ex. 13 at 1-2. To the extent any components of the claimed systems are provided by ResMed's customers, ResMed directly infringes by acting as the final assembler of the infringing system. ResMed configures the infringing system that requires the use of the infringing components. *See, e.g.,* Ex. 54 at 5-15.

261. The '603 Accused Products embody the patented invention of the '603 Patent and infringe the '603 Patent because they function as a sleep diagnostic system. For example, the ApneaLink Air device is a portable, wearable patient interface box that is worn by the subject during a sleep test. *See supra* at ¶ 59.

262. The ApneaLink Air device comprises a battery, nonvolatile digital memory, electronics including at least three input channels programmed to receive collected data in real-time from at least three sensors at a remote sleep location in the nonvolatile digital memory, and at least two sensor connectors adapted to electrically connect the at least three sensors directly to the at least three input channels of the portable, wearable interface box. *See supra* at ¶¶ 59-64

263. The ApneaLink Air device has a transceiver to upload the collected data to the database, the database adapted to operate at a first location which is different from the remote sleep location where the subject is tested. *See supra* at ¶¶ 66-69.

264. The ApneaLink Air device has at least three sensors consisting of: a fingertip pulse oximeter, a pressure sensor, and transducers. *See supra* at ¶¶ 61-64.

265. The ApneaLink Air device's three sensors are adapted to be applied to a finger and a torso of the subject tested during sleep while located in a remote sleep location and measure or derive at least the subject's respiratory effort, snore and bloody oxygenation during testing. *See supra* at ¶ 62 (showing respiratory effort, snore and bloody oxygenation signals are recorded); *id.* at ¶ 64.

266. The at least three sensors are also electrically hardwired and/or releasable connected to the three input channels on the interface box worn by the subject. *See supra* at ¶¶ 61-63.

267. The ApneaLink Software and AirView contain databases, accessible to individuals from the sleep analysis unit or lab that receive the data collected from the ApneaLink Air device's memory and uploaded to the database by the transceiver. *See supra* at ¶ 66; *see also* Ex. 54 at 18 (describing running the ApneaLink software to complete data transfer and analysis, and having a database containing collected data, including recordings and reports), *id.* at 20 (showing a database containing "[p]atient details, recordings, and reports"); *see also* Ex. 53 at 3 ("Test results from the ApneaLink Air are saved to a secure database in the cloud, giving your sleep lab online access anytime and improving collaboration across your business.").

268. The ApneaLink Software and AirView are software that run on a computer or processor adapted to operate at the first or a second location other than the remote sleep location and automatically analyzes the received data to identify and draw attention to physiological events indicative of a sleeping disorder in one or more of the respiratory effort, snore and blood oxygenation from the data. *See supra* at ¶¶59, 67, 69; *see also* Ex. 54 at 21; Ex. 42 at 1-2.

269. The ApneaLink Software and AirView also consists of a two-way communication link adapted output the i) respiratory effort, snore and blood oxygenation data from the database,

ii) the identified and quantified physiological events in the data, or both i) and ii) in a form adapted for a professional medical diagnosis of whether the subject suffers from a sleeping disorder. *See supra* at ¶¶ 68-69.

270. ResMed's infringement of the '603 Patent has injured and continues to injure CleveMed in an amount to be proven at trial, but not less than a reasonable royalty.

271. CleveMed is informed and believes ResMed has had knowledge of CleveMed's patented technology since at least as of the date of this Complaint, if not earlier. ResMed's actions are willful, blatant and in egregious disregard for CleveMed's patent rights. ResMed's infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

272. ResMed acted recklessly, willfully, wantonly, and deliberately engaged in acts of infringement of the '603 Patent, justifying an award to CleveMed of increased damages under 35 U.S.C. § 284, and attorney's fees and costs incurred under 35 U.S.C. § 285.

COUNT XIV
(Indirect Infringement of the '603 Patent)

273. CleveMed repeats, realleges, and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs.

274. CleveMed is informed and believes ResMed has induced infringement of at least Claim 1 of the '603 Patent under 35 U.S.C. § 271(b). Further, CleveMed is informed and believes ResMed has also contributorily infringed at least Claim 1 of the '603 Patent under 35 U.S.C. § 271(c).

275. CleveMed is informed and believes ResMed has had knowledge of CleveMed's patented technology since at least as of the date of this Complaint, if not earlier.

276. CleveMed is informed and believes ResMed has induced infringement of the ’603 Patent pursuant to 35 U.S.C. § 271(b) by instructing, directing and/or requiring others, including its customers, partners, purchasers, and users to provide one or more components of the article of manufacturing, either literally or under the doctrine of equivalents. All the elements of the claims are used by either ResMed, its customers, partners, purchasers, and users, or some combination thereof. CleveMed is informed and believes ResMed has known or was willfully blind to the fact that it is inducing others to infringe by practicing, either themselves or in conjunction with ResMed, one or more claims of the ’603 Patent, including Claim 1.

277. CleveMed is informed and believes ResMed knowingly and actively aided and abetted the direct infringement of the ’603 Patent by instructing and encouraging its customers, purchasers, partners, and/or users to meet the elements of the ’603 Patent with the ‘603 Accused Products, despite knowing or remaining willfully blind to the fact that the encouraged acts caused infringement. Such instructions and encouragement include, but are not limited to, advising third parties to use the ’603 Accused Products in an infringing manner through direct communications; training and support contracts, sales calls between ResMed employees and its customers; directing distributors, partners, and manufacturers how to install and configure the Accused Products; and by advertising and promoting the use of the ’603 Accused Products in an infringing manner, including the material cited herein and above in the direct infringement allegations. Further, ResMed distributes release notes, webinars, guidelines, videos, manuals, white papers, and trainings to third parties on how the ’603 Accused Products must be used and shows them being used in an infringing manner.

278. CleveMed is informed and believes ResMed contributorily infringes the ’603 Patent pursuant to 35 U.S.C. § 271(c) because it has provided software such as AirView and

ApneaLink Software and computer systems with software installed such as the ApneaLink Air device, that act as a material component of the claims of the ’603 Patent. In particular, ResMed knows that its products are particularly suited to be used in an infringing manner and that ResMed is aware that its products are not staple articles suitable for substantial non-infringing use. CleveMed is informed and believes ResMed has known or was willfully blind to the fact that it is contributing to the direct infringement of one or more claims of the ’603 Patent by its customers, partners, purchasers, and users, including Claim 1.

279. In particular, ResMed has at least provided the ’603 Accused Products to others as home sleep testing devices and computer technologies and these products are a material part and/or component of the claims of the ’603 Patent. ResMed knows that its products are particularly suited to be used on, or in combination with ResMed’s HST Devices and computer technologies and that these products are made and adapted for this use, even if some of these components are not sold by ResMed with, or as part of, the ’603 Accused Products. In fact, in many cases, the ’603 Accused Products can only function when used with these computer technologies. For example, ResMed markets the ApneaLink Air and ApneaLink Air Software together, stating “ApneaLink Air software provides clinicians access to a more in-depth view of their patients’ recordings.” Ex. 52 at 2. Further, ResMed markets the ApneaLink Air and AirView together, stating, “[t]est results from the ApneaLink Air are saved to a secure database in the cloud [AirView] giving your sleep lab online access anytime and improving collaboration across your business.” Ex. 53 at 3.

280. CleveMed is informed and believes ResMed has knowingly and actively contributed to the direct infringement of the ’603 Patent by its manufacture, use, offer to sell, sale, and importation of the ’603 Accused Products together with its customers, partners,

purchasers, and/or users to meet the elements of the ’603 Patent, as described above and incorporated by reference here.

281. ResMed’s indirect infringement of the ’603 Patent has injured and continues to injure CleveMed in an amount to be proven at trial, but not less than a reasonable royalty.

282. ResMed’s indirect infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

283. CleveMed is entitled to injunctive relief, damages and any other relief in accordance with 35 U.S.C. §§ 283, 284, and 285.

284. ResMed’s actions are willful, blatant and in egregious disregard for CleveMed’s patent rights. ResMed’s infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

285. ResMed acted recklessly, willfully, wantonly, and deliberately engaged in acts of infringement of the ’603 Patent, justifying an award to CleveMed of increased damages under 35 U.S.C. § 284, and attorney’s fees and costs incurred under 35 U.S.C. § 285.

COUNT XV
(Direct Infringement of the ’637 Patent)

286. CleveMed repeats, realleges, and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs, as set forth above.

287. ResMed has infringed and continues to infringe at least Claim 1 of the ’637 Patent in violation of 35 U.S.C. § 271(a).

288. ResMed’s infringement is based upon literal infringement or infringement under the doctrine of equivalents, or both.

289. ResMed's acts of making, using, importing, selling, and/or offering for sale infringing products and services have been without the permission, consent, authorization, or license of CleveMed.

290. ResMed's infringement includes, but is not limited to, the manufacture, use, sale, importation and/or offer for sale of ResMed's products and services incorporating the HST solution described in the '637 Patent, which includes, but is not limited to, the Accused HST Solution: the ApneaLink Air device that has ApneaLink Software and/or the AirView (collectively, the "'637 Accused Products").

291. To the extent any components of the claimed systems are provided by ResMed's customers, ResMed directly infringes by acting as the final assembler of the infringing system. ResMed configures the infringing system that requires the use of the infringing components. *See, e.g.,* Ex. 54 at 5-15.

292. CleveMed is informed and believes ResMed directs and controls the systems and methods in the claims and obtains benefits from the control of the system as a whole. ResMed and its customers, partners, purchasers, and/or users put the article of manufacture and methods described in the claims into service to the benefit of ResMed's ability to further enhance its sleep therapy capabilities. *See*, *e.g.*, Ex. 13 at 1-2.

293. The '637 Accused Products embody the patented invention of the '637 Patent and infringe the '637 Patent because they are a system for conducting a home sleep analysis of a subject. For example, the ApneaLink Air device is a portable patient interface box that connects with a snore sensor and/or a nasal cannula that is worn by the subject, a respiratory effort sensor attached to a belt that is worn by the subject and measures respiratory effort, and a fingertip pulse

oximeter that is applied to the subject's fingertip and measures blood oxygenation of the subject. *See supra* at ¶¶ 59-64.

294. The ApneaLink Air device additionally has a kinetic sensor that measures body position. *See supra* at ¶ 65.

295. The ApneaLink Air device also has a wearable portable interface box that connects to a nasal cannula, the respiratory effort sensor, and the fingertip pulse oximeter. *See supra* at ¶¶ 59 and 62.

296. The ApneaLink Air device comprises a processor, memory, battery, a transceiver or transmitter, first and second pressure transducers, a first air port for connecting the nasal cannula to the first pressure transducer, and a second air port for connecting respiratory effort belt to the second pressure transducer. *See supra* at ¶¶ 62-66.

297. The ApneaLink Air device obtains airflow and/or snore data from the snore sensor and/or the airflow sensor for the nasal cannula, respiratory effort data from the output of the respiratory effort sensor, blood oxygenation data from the output of the fingertip pulse oximeter, and body position or orientation data from the kinetic sensor. *See supra* at ¶ 65.

298. The ApneaLink Air device further consists of a transceiver to upload the obtained data to a remote database for analysis by a software stored on a processor. *See supra* at ¶¶ 66-69.

299. The ApneaLink Software and AirView are software that is stored on a processor and configured to automatically analyze the obtained data to identify one or more physiological or technological indicative of a sleeping disorder. *See supra* at ¶¶ 59, 67, 69; *see also* Ex. 54 at 21; Ex. 42 at 1-2.

300. ApneaLink Air Software and AirView are additionally adapted for outputting at least: (i) one or more of the airflow data, snore data, respiratory effort data, blood oxygenation

data, and body position data, and/or (ii) the identified physiological and technological events, to facilitate a determination as to whether the subject suffers from a sleeping disorder. *See supra* at ¶¶ 68-69.

301. ResMed's infringement of the '637 Patent has injured and continues to injure CleveMed in an amount to be proven at trial, but not less than a reasonable royalty.

302. CleveMed is informed and believes ResMed has had knowledge of CleveMed's patented technology since at least as of the date of this Complaint, if not earlier. ResMed's actions are willful, blatant and in egregious disregard for CleveMed's patent rights. ResMed's infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

303. ResMed acted recklessly, willfully, wantonly, and deliberately engaged in acts of infringement of the '637 Patent, justifying an award to CleveMed of increased damages under 35 U.S.C. § 284, and attorney's fees and costs incurred under 35 U.S.C. § 285.

COUNT XVI
(Indirect Infringement of the '637 Patent)

304. CleveMed repeats, realleges, and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs.

305. CleveMed is informed and believes ResMed has induced infringement of at least Claim 1 of the '637 Patent under 35 U.S.C. § 271(b). Further, CleveMed is informed and believes ResMed has also contributorily infringed at least Claim 1 of the '637 Patent under 35 U.S.C. § 271(c).

306. CleveMed is informed and believes ResMed has had knowledge of CleveMed's patented technology since at least as of the date of this Complaint, if not earlier.

307. CleveMed is informed and believes ResMed has induced infringement of the ’637 Patent pursuant to 35 U.S.C. § 271(b) by instructing, directing and/or requiring others, including its customers, partners, purchasers, and users to provide one or more components of the article of manufacturing, either literally or under the doctrine of equivalents. All the elements of the claims are used by either ResMed, its customers, partners, purchasers, and users, or some combination thereof. CleveMed is informed and believes ResMed has known or was willfully blind to the fact that it is inducing others to infringe by practicing, either themselves or in conjunction with ResMed, one or more claims of the ’637 Patent, including Claim 1.

308. CleveMed is informed and believes ResMed knowingly and actively aided and abetted the direct infringement of the ’637 Patent by instructing and encouraging its customers, purchasers, partners, and/or users to meet the elements of the ’637 Patent with the ’637 Accused Products, despite knowing or remaining willfully blind to the fact that the encouraged acts caused infringement. Such instructions and encouragement include, but are not limited to, advising third parties to use the ’637 Accused Products in an infringing manner through direct communications; training and support contracts, sales calls between ResMed employees and its customers; directing distributors, partners, and manufacturers how to install and configure the Accused Products; and by advertising and promoting the use of the ’637 Accused Products in an infringing manner, including the material cited herein and above in the direct infringement allegations. Further, ResMed distributes release notes, webinars, guidelines, videos, manuals, white papers, and trainings to third parties on how the ’637 Accused Products must be used and shows them being used in an infringing manner.

309. CleveMed is informed and believes ResMed contributorily infringes the ’637 Patent pursuant to 35 U.S.C. § 271(c) because it has provided software such as AirView and

ApneaLink Software and computer systems with software installed such as the ApneaLink Air device, that act as a material component of the claims of the ’637 Patent. In particular, ResMed knows that its products are particularly suited to be used in an infringing manner and that ResMed is aware that its products are not staple articles suitable for substantial non-infringing use. ResMed has known or was willfully blind to the fact that it is contributing to the direct infringement of one or more claims of the ’637 Patent by its customers, partners, purchasers, and users, including Claim 1.

310. In particular, ResMed has at least provided the ’637 Accused Products to others as home sleep testing devices and computer technologies and these products are a material part and/or component of the claims of the ’637 Patent. ResMed knows that its products are particularly suited to be used on, or in combination with ResMed’s HST Devices and computer technologies and that these products are made and adapted for this use, even if some of these components are not sold by ResMed with, or as part of, the ’637 Accused Products. In fact, in many cases, the ’637 Accused Products can only function when used with these computer technologies. For example, ResMed markets the ApneaLink Air and ApneaLink Air Software together, stating “ApneaLink Air software provides clinicians access to a more in-depth view of their patients’ recordings.” Ex. 52 at 2. Further, ResMed markets the ApneaLink Air and AirView together, stating, “[t]est results from the ApneaLink Air are saved to a secure database in the cloud [AirView] giving your sleep lab online access anytime and improving collaboration across your business.” Ex. 53 at 3.

311. CleveMed is informed and believes ResMed has knowingly and actively contributed to the direct infringement of the ’637 Patent by its manufacture, use, offer to sell, sale, and importation of the ’637 Accused Products together with its customers, partners,

purchasers, and/or users to meet the elements of the ’637 Patent, as described above and incorporated by reference here.

312. ResMed’s indirect infringement of the ’637 Patent has injured and continues to injure CleveMed in an amount to be proven at trial, but not less than a reasonable royalty.

313. ResMed’s indirect infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

314. CleveMed is entitled to injunctive relief, damages and any other relief in accordance with 35 U.S.C. §§ 283, 284, and 285.

315. ResMed’s actions are willful, blatant and in egregious disregard for CleveMed’s patent rights. ResMed’s infringement has caused and is continuing to cause damage and irreparable injury to CleveMed, and CleveMed will continue to suffer damage and irreparable injury unless and until such infringement is enjoined by this Court.

316. ResMed acted recklessly, willfully, wantonly, and deliberately engaged in acts of infringement of the ’637 Patent, justifying an award to CleveMed of increased damages under 35 U.S.C. § 284, and attorney’s fees and costs incurred under 35 U.S.C. § 285.

DEMAND FOR JURY TRIAL

317. In accordance with Rule 38.1 of the Federal Rule of Civil Procedure, CleveMed demands a jury trial on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, CleveMed prays for judgment and relief as follows:

A. An entry of judgment holding that ResMed has infringed and is infringing the ’269, ’399, ’535, ’937, ’698, ’118, ’603, and ’637 Patents; and has induced infringement and is

inducing infringement of the ’269, ’399, ’535, ’937, ’698, ’118, ’603, and ’637 Patents; and/or has contributorily infringed and continues to contribute to infringement of the ’269, ’399, ’535, ’937, ’698, ’118, ’603, and ’637 Patents.

B. A preliminary and permanent injunction against ResMed and its officers, employees, agents, servants, attorneys, instrumentalities, and/or those in privity with them, from infringing, or inducing the infringement of the ’269, ’399, ’535, ’937, ’698, ’118, ’603, and ’637 Patents and for all further and proper injunctive relief pursuant to 35 U.S.C. § 283;

C. An award to CleveMed of such damages as it shall prove at trial against ResMed that is adequate to fully compensate CleveMed for ResMed’s infringement of the ’269, ’399, ’535, ’937, ’698, ’118, ’603, and ’637 Patents said damages to be no less than a reasonable royalty;

D. An award to CleveMed of increased damages under 35 U.S.C. § 284, including that ResMed willfully infringed the ’269, ’399, ’535, ’937, ’698, ’118, ’603, and ’637 Patents;

E. A finding that this case is “exceptional” and an award to CleveMed of its costs and reasonable attorneys’ fees, as provided by 35 U.S.C. § 285;

F. An accounting of all infringing sales and revenues, together with post judgment interest and prejudgment interest from the first date of infringement of the ’269, ’399, ’535, ’937, ’698, ’118, ’603, and ’637 Patents; and

G. Such further and other relief as the Court may deem proper and just.

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