

1	UNITED STATES PATENT AND TRADEMARK OFFICE
2	BEFORE THE PATENT TRIAL AND APPEAL BOARD
3	RESMED CORP, )CASE IPR2025-00247
4	PETITIONER, )U.S. PATENT NO. 11,872,029
5	V. )MOBILE VIDEOCONFERENCE
6	CLEVELAND MEDICAL )DEPOSITION OF
7	DEVICES, INC., )JASON P. KIRKNESS, Ph.D.
8	PATENT OWNER. )
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13	MOBILE VIDEOCONFERENCE DEPOSITION OF JASON P.
14	KIRKNESS, Ph.D., taken remotely before Cheryl A.
15	Rooney, RPR, CRR, Online General Notary Public within
16	and for the State of Nebraska, beginning at 1:00 p.m.
17	PST, on February 4, 2026.
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<p style="text-align: right;">Page 4</p> <p>1 JASON P. KIRKNESS, Ph.D., 2 having been first duly sworn, 3 was examined and testified as follows: 4 DIRECT EXAMINATION 5 BY MR. LAYDEN: 6 Q. Good afternoon, Dr. Kirkness. Good to 7 see you again. You submitted a reply 8 declaration in this IPR; is that correct? 9 A. I did. 10 Q. And that's Exhibit 1071. Do you have 11 that before you? 12 A. Yes, I do. 13 Q. Do you have any other paper copies of 14 exhibits? 15 A. I have the copies of any of the 16 exhibits that were referred to in the 17 declaration. 18 Q. Okay. And what about the previous 19 exhibits from the petition? 20 A. Previous exhibits from the petition. 21 Could you give me a specific example? 22 Q. Any other references, anything of that 23 nature? 24 A. So the references -- I don't have an 25 extensive list of everything that was referred</p>	<p style="text-align: right;">Page 6</p> <p>1 A. 1004. CV. Let me see. Yes, I do. 2 Q. If you could pull that out for me, 3 please. 4 A. Yes, sir. 5 Q. And previously when we discussed for 6 the IPR against the '512 patent, we went through 7 some of your engagements, and just a couple of 8 quick questions on that topic. On Page 1 in the 9 bullet points you have listed there, it says 10 novel device -- novel medical devices and 11 treatment approaches for chronic respiratory 12 disease. Research awards from industry. 13 A. Yes. 14 Q. What was the award that Resmed gave 15 you? 16 A. So those are described in detail in 17 pages 6 to 8 under the banners, Extramural 18 Sponsorship and Contracts. And under there, if 19 there was anything that mentioned the word 20 Resmed. So I'm just scrolling through under the 21 section Contracts from 2013 is the first line 22 item, high nasal airflow for treatment of COPD 23 from Resmed. Nasal high-flow -- sorry -- high 24 nasal airflow for treatment of COPD 2014. High 25 nasal airflow for treatment of obstructive sleep</p>
<p style="text-align: right;">Page 5</p> <p>1 to in the previous iteration in front of me. 2 Q. If we get to that point and you don't 3 have an exhibit before you, I could drop it in 4 the chat and we can go from there, if that 5 works. 6 A. Okay. 7 Q. Looking at your declaration, 8 Exhibit 1070 -- 9 A. Yes. 10 Q. -- the final page, Page 17, that's 11 your signature; correct? 12 A. That is correct. 13 Q. And roughly how long did you spend 14 working on this declaration? 15 A. I don't know exactly how long I spent 16 working on it. Sometime from when I was asked 17 to look at it based on the order in which -- you 18 know, in reply to the -- so I don't have that in 19 front of me exactly how long I spent. 20 Q. Are you able to estimate how long? 21 A. I'd basically have to go back to a 22 calendar and look at the days and -- could be 23 done. 24 Q. Okay. Do you have Exhibit 1004, which 25 was your CV?</p>	<p style="text-align: right;">Page 7</p> <p>1 apnea, 2009 to 2010. High nasal airflow 2 treatment for COPD, 2010 to 2012. Those are the 3 ones that are listed. 4 Q. So the rewards referenced on that 5 first bullet point on Page 1 is in reference to 6 the contracts you've received from Resmed? 7 A. So the bullet points on Page 1 are 8 not -- refers to various research awards from 9 industry for various novel medical devices and 10 treatment approaches for various chronic 11 respiratory diseases. 12 Q. And then within that statement you 13 have listed Resmed and sleep health and ImThera? 14 A. ImThera, yes. 15 Q. And the research awards from industry 16 where you have Resmed, are those research awards 17 description, is that your description of the 18 contracts you received from Resmed or is there 19 an actual award that you received from Resmed? 20 A. So these are research contracts that 21 were -- research contracts conducted at Johns 22 Hopkins University, administered through the 23 Office of External Engagement. 24 So also my belief is that during that 25 time there are awards also at the University of</p>

<p style="text-align: right;">Page 8</p> <p>1 Western Australia and the Sir Charles Gairdner 2 Hospital. So any of that work or that contract 3 work awarded would have been administered 4 through the relevant research office. 5 Q. And the contracts you received from 6 Resmed, those are through Resmed, Inc.? 7 A. I would -- I'd have to -- I wouldn't 8 be able to say the corporate entity that I -- I 9 didn't actually sign the contract myself, so I 10 probably wouldn't be able to tell you. 11 Q. On several of the contracts you have 12 listed here, you have Resmed, Inc. as the entity 13 awarding you the contract. 14 A. Yes. 15 Q. Have you ever been awarded a contract 16 from Resmed that didn't come from Resmed, Inc.? 17 A. Yeah, so I would have to -- I would 18 have to go back and actually review and look at 19 the contracts to be able to verify -- you know, 20 I would have to verify that it was exactly 21 Resmed, Inc. and that was the way that it was 22 written. Yeah, if there's -- actually, you 23 brought up a good point, and I can go back and 24 have a look at that. 25 Q. So are you saying that possibly the</p>	<p style="text-align: right;">Page 10</p> <p>1 written in terms of the entity. The Resmed 2 corporation -- in my understanding, there's an 3 amalgam of organizations that make up Resmed, 4 Inc., and I'm unclear at this stage exactly 5 which legal entity I've represented there as 6 Resmed, Inc. 7 Q. So then what compelled you to put 8 Resmed, Inc. into your CV and not just a generic 9 Resmed or some other Resmed corporation? 10 A. Well, in my opinion some of the work 11 that I was doing was related to work with 12 Resmed, Inc., and if there was -- if any of that 13 work was from or through any other organization, 14 because I know that -- well, I don't actually 15 know, but Resmed also has corporations in 16 Australia. And during this time period I was 17 working in the U.S. and Australia, and also I 18 think this is probably the best explanation I 19 can give you why I wrote Resmed, Inc. in my 20 resumé. 21 Q. What work were you doing that you 22 believe to be associated with Resmed, Inc.? 23 A. So as I had put in -- written here, 24 various engagements with medical affairs, 25 applied research, product development department</p>
<p style="text-align: right;">Page 9</p> <p>1 information in your CV is incorrect? 2 A. What I'm saying is that the 3 information regarding the exact entity that was 4 signed for by the contract agent at the 5 university, I would have to review that in order 6 to determine if that was -- if it was exactly 7 written like that on the contract. 8 Q. And if you could turn to Page 15 of 9 your CV. There you have a paragraph stating 10 that from between 2007 to 2016 you were a 11 consultant investigator for Resmed, Inc.? 12 A. Yes. 13 Q. Is that accurate? 14 A. So with respect to your previous 15 comment, I would have to go back and determine 16 if it's listed exactly the same as spelled here 17 in the CV as it's spelled on the contract. But 18 yes, I was a consultant or received consulting 19 funds as a consultant for various activities in 20 that region -- sorry, in that time frame, yes. 21 Q. And you're not sure if that was 22 actually Resmed, Inc., as you have listed on 23 your CV or some other Resmed corporation? 24 A. So again, you're correct in your 25 assertion. I don't know exactly what was</p>	<p style="text-align: right;">Page 11</p> <p>1 at Resmed. Well known at Resmed for research 2 development of a respiratory therapy referred to 3 as high-flow therapy. High-flow therapy is a 4 cannula-based therapy that reduces ventilation 5 via reduction in dead space ventilation and 6 vascular sympathetic activity during sleep in 7 COPD. 8 The most important studies I've 9 conducted for Resmed include cannula usability 10 study. From conception IRB to data 11 acquisition and -- 12 COURT REPORTER: (Requests 13 clarification.) 14 THE WITNESS: From conception IRB 15 approval to data acquisition and report for FDA 16 in three months. Evaluation of competitor's 17 products or assessment of products for due 18 diligence. 19 In addition, I've had various roles in 20 evaluating patents. That's it. 21 BY MR. LAYDEN: 22 Q. What patents did you evaluate while at 23 Resmed? 24 A. So we had some patents that were 25 associated with nasal high-flow. So this is</p>

<p style="text-align: right;">Page 12</p> <p>1 basically a therapy that delivers a high volume 2 or a high-flow rate of air into the nose. And 3 as I put there, therapy referred to as nasal 4 high-flow therapy, it's a cannula-based therapy 5 that reduces ventilation via reduction in dead 6 space ventilation. 7 Q. And who did you report your patent 8 findings to at Resmed? 9 A. So the -- I can tell you who I was 10 working with. I was working with a scientist by 11 the name of Adam Benjafield. And he was 12 working -- although I didn't work directly with 13 him, I definitely conversed with him. But the 14 other person was Glen Richards. Dr. Glen 15 Richards and Dr. Adam Benjafield would be the 16 two people I primarily engaged with at Resmed. 17 Q. If you could turn down to Page 18 of 18 your CV. 19 A. Yes. 20 Q. And under the heading Consultantship 21 and Board of Directors, from 2007 to 2009 you 22 have listed Resmed, Inc., specific scientific 23 advisory meetings for collaborative study. Do 24 you see that? 25 A. Yes.</p>	<p style="text-align: right;">Page 14</p> <p>1 Unless I have that paperwork in front of me, I 2 wouldn't want to misrepresent that. 3 Q. Thank you. And if we could turn back 4 to Exhibit 1071, your reply declaration. 5 A. Sure. I have that in front of me. 6 Q. Okay. If you could turn to Page 2 of 7 your declaration, Paragraph 5. 8 A. Yes. 9 Q. Beginning sentence you state that 10 Truitt describes that a pressure center that 11 measures the pressure at the patient by 12 providing a pressure pick-off port in or near 13 the patient interface device. Can you describe 14 for me what a pick-off port is? 15 A. So it's almost exactly as it's 16 written. It's a port on a mask or a circuit 17 used to extract a pressure reading at the 18 location in which the pressure is being 19 measured. 20 Q. And is it your understanding that a 21 patient interface device is equivalent to a 22 mask? 23 A. So a patient interface device can be a 24 mask, and as mentioned to you just previously, 25 there's a number of other types of interfaces</p>
<p style="text-align: right;">Page 13</p> <p>1 Q. Were you working with the board of 2 directors for Resmed, Inc. during this time? 3 A. No, I was not. 4 Q. Who were you working with at Resmed 5 during this time? 6 A. So during this time I was working with 7 Dr. Adam Benjafield and Dr. Glen Richards. 8 Q. And what was the collaborative study 9 you were advising on? 10 A. So we were working towards the nasal 11 high-flow study for -- it was a couple of 12 studies and I've described them in a way -- 13 studies related to the use of nasal high-flow. 14 One for the treatment of obstructive sleep 15 apnea, so obstructive sleep apnea. And the 16 other one, the use of nasal high-flow therapy 17 for the treatment of chronic obstructive 18 pulmonary disease. 19 Q. And in regards for whose -- or the 20 entity that's paying your fees today, is that 21 Resmed, Inc., or Resmed Corp? 22 A. Once again, you know, I probably would 23 have to look at that contract now that you've 24 brought that up to see the exact entity that's 25 on that agreement. Yeah, so I apologize.</p>	<p style="text-align: right;">Page 15</p> <p>1 that can be used. There's different 2 configurations that a patient interface may 3 encompass, and that may include the mask. 4 Q. I'm going through Paragraph 5 towards 5 the middle. You have a sentence that begins, 6 for instance, and you have claims 2 and 12 7 recite. Do you see that sentence? 8 A. Yes. 9 Q. At the end of that sentence you have 10 citations to claims 2 and 12, and then also 11 Column 7 Line 65 through Column 8 Line 2 of 12 Truitt. Do you see that? 13 A. I do see that. 14 Q. Do you have Exhibit 1007 handy? 15 A. Yes, I do. 16 Q. If you can turn to that section, 17 Column 10 -- or Column 7 Line 65. 18 A. Yes. 19 Q. That first sentence beginning on 20 Column 7 Line 65 states: The present invention 21 also contemplates providing the flow volume 22 sensing assembly at a modular attachment at the 23 outlet of housing 58. 24 Dr. Kirkness, do you understand -- 25 A. Yes, sorry. Just let me make sure</p>

<p style="text-align: right;">Page 16</p> <p>1 I've found the correct segment. So, sorry, you 2 said column -- we're in Exhibit 1007, Column 7 3 Line 65. 4 Q. Mm-hmm. 5 A. And it starts: The present invention 6 also contemplates. Is that correct? 7 Q. Yes. 8 A. Okay. 9 Q. That modular -- where it states a 10 modular attachment at the outlet of housing 58, 11 do you understand that to be describing an 12 external attachment to the CPAP device? 13 A. Yes. 14 Q. If we can continue down in your 15 declaration to Paragraph 9, beginning on Page 4. 16 A. There's one comment that I'd like to 17 just make prior to your next comment, about the 18 previous statement. So when the -- in this 19 section of the -- of Truitt that you referred to 20 Line 65 Column 7, in reference to the embodiment 21 that they're describing, they use the term 22 contemplating, and contemplating a modular 23 attachment at the outset -- outlet of housing. 24 So to be -- just to make sure that you 25 understand that there are multiple</p>	<p style="text-align: right;">Page 18</p> <p>1 therefore, there are other -- within the patent 2 there are other configurations that are 3 described. 4 Q. Correct. And which configuration 5 described in Truitt is the one you're relying on 6 for your opinions? 7 A. Yeah, and which opinion are you 8 referring to in the declaration? So I've put 9 forth multiple opinions in the declaration, and 10 I'm just trying to find out which opinion you're 11 referring to. 12 Q. Well, do you rely on multiple 13 configurations of Truitt in your opinions, or do 14 you rely on the same configuration? 15 MS. ALEXANDER: Objection; vague. 16 THE WITNESS: Is there a place in 17 the declaration that you can point me to where 18 we could discuss that? 19 BY MR. LAYDEN: 20 Q. We'll get there. 21 What are the sensors in Truitt that 22 you're relying upon in your configuration? 23 A. So, once again, is there a place in 24 the declaration where I could -- where you could 25 point me to that opinion?</p>
<p style="text-align: right;">Page 17</p> <p>1 configurations that were described in Truitt. 2 And if you'd like to move on to Paragraph 9 in 3 the -- 4 Q. Well, before we get to that, expanding 5 on what you just said -- 6 A. Sure. 7 Q. -- you said that Truitt has multiple 8 configurations. Which configuration is it, in 9 your opinion, the one that invalidates the '029 10 patent? 11 A. So with regard to your statement 12 there -- 13 Q. Not my statement. I'm asking -- 14 A. Your question, your question, are you 15 pointing to part of my declaration? 16 Q. I'll restate my question. 17 Which configuration of Truitt is it 18 your opinions are relying on? 19 A. So what I said in response to your 20 question about a -- the description of a modular 21 attachment at the outlet of -- the outlet of 22 housing was that that is part of a sentence that 23 says the present invention also contemplates 24 providing flow volume sensing assembly at a 25 modular attachment at the outlet of the housing;</p>	<p style="text-align: right;">Page 19</p> <p>1 Q. Well, before we get there, do you rely 2 on the same configuration of Truitt, or do you 3 rely on different configurations, depending on 4 what you're opining on? 5 MS. ALEXANDER: Objection; vague. 6 THE WITNESS: Yeah, so if there's 7 a place in the declaration where we can have 8 that discussion, if I've discussed it, I would 9 happily expand. 10 BY MR. LAYDEN: 11 Q. Well, let's go to Paragraph 28, if you 12 could. In the second sentence of Paragraph 28 13 you say: The Truitt discloses the use of more 14 than one sensor in its CPAP system. 15 Do you see that? 16 A. Yes. 17 Q. Later on towards the end of 18 Paragraph 28, second-to-the-final sentence you 19 have: Contrary to Dr. Burkholder's assertion, 20 then Truitt's CPAP is not solely a mechanical 21 device that determines airflow with just one 22 flow sensor. 23 Do you see that? 24 A. Yes. 25 Q. What are the other sensors in Truitt</p>

<p style="text-align: right;">Page 20</p> <p>1 that you're relying on?</p> <p>2 A. So in the declaration, and I've</p> <p>3 described this in -- so I just want to make sure</p> <p>4 I get the exact reference right -- so in Truitt,</p> <p>5 Page 5 Lines 60 to 67, Column 6 Lines 1 to 10,</p> <p>6 and so on in that paragraph, in Paragraph 28 of</p> <p>7 my declaration I describe multiple sensors,</p> <p>8 pressure sensors, flow sensors, pressure sensors</p> <p>9 in different operational modes, pressure or flow</p> <p>10 sensors, and in Columns 6, 60 to 63, any other</p> <p>11 sensors as described.</p> <p>12 So that -- as I mentioned before, that</p> <p>13 is in the section Column 6, Paragraph --</p> <p>14 Column 6, Lines 51 through 64 -- 63, sorry, and</p> <p>15 describes the -- by controlling the valve, the</p> <p>16 motor, or combination thereof, it's further</p> <p>17 understood that other sensors can be provided to</p> <p>18 provide additional information to the</p> <p>19 controller.</p> <p>20 Q. And what other sensors are you</p> <p>21 providing in Truitt?</p> <p>22 A. So I have not provided an opinion on</p> <p>23 the other sensors.</p> <p>24 Q. So your opinions rely on the flow and</p> <p>25 pressure sensor in Truitt and no other sensors?</p>	<p style="text-align: right;">Page 22</p> <p>1 necessary for your opinions as given in the</p> <p>2 declaration?</p> <p>3 A. So at this stage, if there are other</p> <p>4 sensors that are required, if I haven't provided</p> <p>5 them in the declaration, that's just what it is.</p> <p>6 Q. Okay. Back to Paragraph 9, if we</p> <p>7 could, beginning on Page 4.</p> <p>8 A. Yes.</p> <p>9 Q. In Paragraph 9 it has the heading,</p> <p>10 Number 1 above it, The apneas, hypopneas and</p> <p>11 snores depicted in Truitt represent data of</p> <p>12 severity.</p> <p>13 Do you see that?</p> <p>14 A. So can you direct me again to the</p> <p>15 right paragraph?</p> <p>16 Q. Paragraph 9 on Page 4, heading 1,</p> <p>17 preceding Paragraph 9.</p> <p>18 A. Yes, I see that.</p> <p>19 Q. You have the heading: The apnea,</p> <p>20 hypopneas, and snores depicted in Truitt</p> <p>21 represent data of severity.</p> <p>22 A. I see that.</p> <p>23 Q. Can you explain how detecting apnea,</p> <p>24 hypopnea, and snores equates to data of</p> <p>25 severity?</p>
<p style="text-align: right;">Page 21</p> <p>1 A. That is correct.</p> <p>2 Q. If we can go back to Paragraph 9.</p> <p>3 A. So it's correct that this declaration</p> <p>4 that I've written, I have only included an</p> <p>5 opinion on the pressure and flow sensors, but if</p> <p>6 there were other sensors that we needed to</p> <p>7 discuss that were listed, I would happily do so.</p> <p>8 Q. Are there other sensors in your</p> <p>9 opinions outside of the flow and pressure sensor</p> <p>10 that are required for you to opine on?</p> <p>11 A. So the other sensors in my opinion are</p> <p>12 described in the combination of Truitt and</p> <p>13 Kumar, and further, in view of Mumford, which</p> <p>14 I've stated here, would render obvious being</p> <p>15 able to calculate the data or the usage of the</p> <p>16 PAP device by the subject. The data of severity</p> <p>17 of sleep disorder symptoms of the subject and/or</p> <p>18 the index of treatment efficacy data, together</p> <p>19 with the therapy efficacy data.</p> <p>20 So as I had mentioned to you before,</p> <p>21 any -- the Truitt does describe the flow and</p> <p>22 pressure sensors, but if there are other sensors</p> <p>23 that -- and also anticipates the use of any</p> <p>24 other sensors.</p> <p>25 Q. Are there other sensors that are</p>	<p style="text-align: right;">Page 23</p> <p>1 A. Certainly. As I have listed in my</p> <p>2 declaration here, that the various definitions</p> <p>3 of the sleep-related breathing conditions, such</p> <p>4 as apnea and hypopnea themselves describe a --</p> <p>5 describe the severity of sleep disordered</p> <p>6 symptoms.</p> <p>7 So in apnea, by definition, is a near</p> <p>8 complete drop of the patient's airflow over a</p> <p>9 period of time. Whereas in contrast, a hypopnea</p> <p>10 is only a partial reduction in airflow.</p> <p>11 Therefore, an apnea is a more severe airflow</p> <p>12 reduction than a hypopnea. And a reduction in</p> <p>13 airflow is a result of a sleep disordered --</p> <p>14 sleep disordered breathing.</p> <p>15 So therefore, what you can see is that</p> <p>16 the different kinds of reduction in airflow, or</p> <p>17 symptoms of a sleep disordered breathing, can be</p> <p>18 defined by the severity in the reduction in</p> <p>19 airflow.</p> <p>20 Q. And I believe for the definitions you</p> <p>21 gave you cited to Exhibit 1070, the AASM manual.</p> <p>22 Could you pull that up for me?</p> <p>23 A. Yes, I do.</p> <p>24 Q. And Exhibit 1070 is the AASM manual</p> <p>25 for the scoring of sleep and associated events?</p>

<p style="text-align: right;">Page 24</p> <p>1 A. Correct.</p> <p>2 Q. And this is Version 3. Correct?</p> <p>3 A. Yes.</p> <p>4 Q. Do you know when Version 1 was</p> <p>5 released?</p> <p>6 A. Version 1, not exactly, no. So I know</p> <p>7 that there was the American Academy of Sleep</p> <p>8 Disorders that held a consensus meeting in</p> <p>9 Chicago to agree on various sleep-disordered</p> <p>10 breathing classifications in 1998. That was the</p> <p>11 first -- that was probably one of the first</p> <p>12 times that I was familiar with the description</p> <p>13 of the various sleep disordered associated --</p> <p>14 associations of sleep medicine. And I think</p> <p>15 that it must have been sometime between 1998 and</p> <p>16 whenever this one was, which is in --</p> <p>17 Q. You can go down to Page 2. Copyright</p> <p>18 is 2023.</p> <p>19 A. 2023, yeah.</p> <p>20 Q. And then below that it says: Copies</p> <p>21 of this manual are available at <a href="http://www.aasm.org">www.aasm.org</a>,</p> <p>22 and corrections to the online and print copies</p> <p>23 of Version 3 were made in February of 2024.</p> <p>24 A. Yes.</p> <p>25 Q. Do you know what corrections were made</p>	<p style="text-align: right;">Page 26</p> <p>1 appears in this manual from 2023?</p> <p>2 A. Well, I don't have that manual in</p> <p>3 front of me, so I wouldn't be able to compare</p> <p>4 those two.</p> <p>5 Q. And looking at Exhibit 1070, it is</p> <p>6 currently seven pages long, including the front</p> <p>7 and back cover.</p> <p>8 A. Sorry, which one?</p> <p>9 Q. Exhibit 1070, the manual.</p> <p>10 A. Oh, yeah.</p> <p>11 Q. You have in here seven pages. How big</p> <p>12 is the manual and any of the excerpts?</p> <p>13 A. The manual, it could be up to -- I</p> <p>14 could pull it up. I don't know exactly. I</p> <p>15 don't have the exact number of pages, and I</p> <p>16 don't have the exact number of pages in this</p> <p>17 exhibit.</p> <p>18 Q. Why didn't you include the whole</p> <p>19 manual as an exhibit?</p> <p>20 A. So the only reasons that I think that</p> <p>21 the whole manual is not included here is because</p> <p>22 there are references to other sleep-disordered</p> <p>23 breathing -- sorry, sleep disorders that do not</p> <p>24 include breathing, that do not refer to apnea,</p> <p>25 do not refer to hypopnea, and it was a matter of</p>
<p style="text-align: right;">Page 25</p> <p>1 in February of 2024 to this manual?</p> <p>2 A. I don't have a list of those</p> <p>3 corrections in front of me.</p> <p>4 Q. Do you know what updates would have</p> <p>5 occurred from 1999 to the release of this manual</p> <p>6 in 2023?</p> <p>7 A. Again, I don't have any of those in</p> <p>8 front of me. So I wouldn't want to speculate.</p> <p>9 Q. Can you tell me how a person of</p> <p>10 ordinary skill in 2005 would have been able to</p> <p>11 use this manual to their benefit?</p> <p>12 A. So a person of ordinary skill in the</p> <p>13 art would have been able to look at or know a</p> <p>14 definition of an apnea and a hypopnea. So it</p> <p>15 would be -- the definitions of apneas and</p> <p>16 hypopneas in terms of the reduction in airflow.</p> <p>17 So an apnea being a complete or cessation of</p> <p>18 airflow versus a reduction in airflow, those are</p> <p>19 definitions that would -- that would have been</p> <p>20 available well before 2025. They're</p> <p>21 described -- and a person of ordinary skill in</p> <p>22 the art would know how to define an apnea and</p> <p>23 hypopnea.</p> <p>24 Q. And that definition that they would</p> <p>25 have known to apply, is that the same that</p>	<p style="text-align: right;">Page 27</p> <p>1 being concise. I would say that that's the only</p> <p>2 reason.</p> <p>3 Q. So in the entire manual it only has</p> <p>4 essentially a half page on the scoring of apneas</p> <p>5 and a half page on the scoring of hypopneas; is</p> <p>6 that accurate?</p> <p>7 A. The scoring of apneas and the scoring</p> <p>8 of hypopneas, that's what appears in front of</p> <p>9 me, and I do not know whether apneas or</p> <p>10 hypopneas appears anywhere else in the manual.</p> <p>11 Q. Have the scoring standards changed for</p> <p>12 identification of sleep apnea and hypopneas from</p> <p>13 1998 to 2023?</p> <p>14 A. So in regards to the reductions in</p> <p>15 airflow, the standards have been reasonably</p> <p>16 consistent. When it comes to the scoring of</p> <p>17 sleep-related disturbances, so sleep-related</p> <p>18 disturbances listed here as respiratory-related</p> <p>19 arousals, there has been a change in terms of</p> <p>20 the associated reductions in oxygen desaturation</p> <p>21 that would be -- that would accompany the</p> <p>22 arousals, and arousal being a change in the</p> <p>23 cortical activity of brain waves.</p> <p>24 Q. Can you tell me what you mean by</p> <p>25 reasonably consistent when describing the</p>

<p style="text-align: right;">Page 28</p> <p>1 scoring standards? 2 A. So there -- so a hypopnea is a 3 reduction in airflow. And the -- some people, 4 for some definitions, may define a hypopnea as 5 between a reduction of airflow from 70 down to 6 10 percent, and once again, I don't have this in 7 front of me but there may have been definitions 8 that included a 50 percent reduction rather than 9 a 70 percent reduction. And my belief is that 10 that is due to the different equipment used for 11 detection of a reduction in airflow. So whether 12 it be from a cannula or a nasal flow-mister. 13 So once again, this is a little bit 14 out of the scope of where I've described in my 15 declaration the simple definitions that would be 16 commonly understood as an apnea, which is a near 17 complete reduction in airflow, in contrast with 18 a hypopnea, which would be commonly understood 19 to be at least a 30 percent reduction in airflow 20 for 10 seconds long. 21 Q. Do you have an understanding of when 22 the scoring standards may have changed based on 23 the technology used to identify apneas, at what 24 point in time that would have occurred? 25 MS. ALEXANDER: Objection.</p>	<p style="text-align: right;">Page 30</p> <p>1 A. So the pressure of -- again, the 2 pressure, pressure sensors -- once again, I 3 think this is probably a little bit out of the 4 scope of what the declaration has -- what I've 5 written about, but pressure sensors would -- the 6 dynamics would be similar today as they were 7 20 years ago at the time of this patent. 8 Q. Why didn't you use a manual from 2005 9 or earlier to support your opinions here? 10 A. The AASM no longer publishes the 11 earlier manual. 12 Q. And you don't have a previous copy of 13 the manual? 14 A. I didn't have a previous copy on hand, 15 so I used the manual that was available to me. 16 Q. And just to get back to how we kind of 17 started, it's your opinion that identification 18 of a snore, an apnea, or hypopnea is data of 19 severity as described and used in the '029 20 patent? 21 A. So whereabouts in the '029 patent are 22 you referring to? 23 Q. Claim 1. 24 A. So yes, I've described that the apneas 25 and hypopneas in that section -- so the terms</p>
<p style="text-align: right;">Page 29</p> <p>1 Mischaracterizes his testimony. 2 THE WITNESS: I could not -- I 3 could not, without having that -- having 4 described that or looked at that, being able to 5 come up with a time off the top of my head. 6 BY MR. LAYDEN: 7 Q. Was the technology available for 8 identification of apneas and hypopneas in 2005 9 better or worse than it is today? 10 A. So I would say that the -- once again, 11 I'm not specifically referring to any reference 12 here. You know, I'm not looking at your -- this 13 is not in my declaration. I'm doing my best 14 honest answer to provide you answer to your 15 question, is that the technologies in 2005, 16 which would have included a nasal cannula and -- 17 or nasal thermistors and various thermocouples 18 that are used, a lot of that technology, the 19 interfaces have not changed much in 20 years. 20 So I would say that the technologies 21 of nasal cannula in 2005 is very, very similar 22 and perform very similar to a nasal cannula in 23 2025, '26. 24 Q. What about the sensors determining the 25 pressure within the nasal cannula?</p>	<p style="text-align: right;">Page 31</p> <p>1 apneas, hypopneas, and snores characterize the 2 severity of a patient's reduction in airflow, 3 and a person of ordinary skill in the art would 4 understand that measuring, detecting the events 5 that represent -- that the event represents a 6 calculating the data of a severity of the sleep 7 disorder symptom. 8 Q. Can apneas come with a range of 9 severity, or is every apnea equal? 10 A. So the duration of an apnea can 11 change. So the -- an apnea could be 10 seconds 12 or an apnea could be 30 seconds. 13 Q. And is one more severe than the other? 14 A. One is longer than the other. So a 15 30-second apnea is longer than a 10-second 16 apnea. 17 Q. But as far as the severity of the 18 apnea, the 10-second apnea is equivalent to a 19 30-second apnea? 20 A. So in terms of the apnea, there would 21 be other -- so to determine if one apnea that 22 was a certain length and another apnea was a 23 different length had any -- were comparable or 24 different in some way, you would probably have 25 to compare their impact on another physiological</p>

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1 variable. That would be one way that you could  
2 examine that. So I don't know if a 10-second  
3 apnea creates a different physiological response  
4 in a person to a 30-second apnea.  
5       So in some individuals a 10- and a  
6 30-second apnea may not elicit a different  
7 response, and there may be other individuals  
8 that have different physiological responses to a  
9 10- versus a 30-second apnea.  
10       So it would depend on whether you're  
11 talking about with an individual, who that  
12 individual is, the circumstances under which the  
13 apnea occurs, in order to opine on the  
14 different -- if there is a difference between a  
15 10- and a 30-second apnea.  
16       Q. So just to be clear, then, you don't  
17 have an opinion on whether or not a 10-second  
18 apnea is more or less severe than a 30-second  
19 apnea? Do I understand that correctly?  
20       A. So if, for example, you're asking me  
21 whether within an individual there is a  
22 difference in the severity between a 10- and a  
23 30-second apnea, what I'm saying is that you  
24 would -- we would need to examine something else  
25 in order to determine whether the response to

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1 that apnea created something that you would  
2 determine as sufficient to be able to  
3 discriminate severity. That's what I'm saying.  
4       I'm not saying that a 30-second apnea  
5 has a physiological -- I'm saying it's longer,  
6 but in terms of whether it creates a  
7 physiological response that's different, we  
8 couldn't say that unless we were looking at some  
9 data.  
10       Q. What other data would you need?  
11       A. So in order to look at -- determine  
12 the severity, there's a bunch of different  
13 variables that you could look at. You could  
14 look at heart rate response, you could look  
15 at -- as I mentioned to you before, you could  
16 look at cortical arousal. You could look at  
17 blood pressure responses. You could look at  
18 daytime symptoms.  
19       So, for example, if somebody has  
20 longer -- a longer apnea versus shorter apnea,  
21 you could look and see whether they're sleepy,  
22 is there any objective sleepiness. Do they  
23 have -- do they require more or less pressure  
24 support in order to overcome an apnea. So is  
25 their airway more collapsable. So, yeah,

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1 there's a number of different physiological  
2 variables that could go into determining whether  
3 a longer apnea results in some other  
4 physiological response.  
5       Q. What type of response would a  
6 10-second apnea elicit from a CPAP machine on  
7 auto-titration mode as opposed to a 30-second  
8 apnea?  
9       MS. ALEXANDER: Objection; vague.  
10       THE WITNESS: Yeah, I would have  
11 to -- if you want to point me to somewhere where  
12 we could go into that, I could certainly -- if  
13 there was a point that you could point me to.  
14 BY MR. LAYDEN:  
15       Q. Well, Paragraph 15 you state that  
16 Truitt's device is not limited to operating in a  
17 CPAP, bilevel, or auto-titration type of  
18 pressure support mode. Instead, the sensing  
19 assembly can be used in conjunction with any  
20 type of pressure support or ventilatory system.  
21 Do you see that?  
22       A. Mm-hmm, yes. So to begin with, I note  
23 that Truitt's device is not limited to operating  
24 in a CPAP, BiPAP, or auto-titration mode or  
25 pressure support. Instead, the sensing assembly

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1 can be used in conjunction with any type of  
2 pressure support or ventilatory system where the  
3 flow and/or volume of fluid is to be measured.  
4 Yes.  
5       Q. And then in Paragraph 16 you state  
6 that but in the event that Truitt's CPAP is used  
7 in a bilevel or auto-titration mode, a POSITA  
8 would have still utilized Truitt's severity and  
9 usage device data to calculate an index.  
10       A. Mm-hmm, yes.  
11       Q. So the severity you're referencing  
12 there, that's the identification of the apnea,  
13 hypopnea, or snores; is that accurate?  
14       A. Yes. So exactly, apneas, hypopneas,  
15 and/or snores in Truitt would be used whether it  
16 was in a bilevel or auto-titration mode.  
17       Q. And so when in auto-titration mode,  
18 how would Truitt CPAP respond to a 10-second  
19 apnea versus a 30-second apnea? Would the  
20 response be the same?  
21       A. So is there somewhere where I describe  
22 the -- in my declaration do I describe how  
23 Truitt describes its response to a change in the  
24 length of apnea?  
25       Q. Well, next sentence you say: Realtime

<p style="text-align: right;">Page 36</p> <p>1 intervention does not preclude the use of an 2 index calculated over time. 3 A. Yeah, that does not relate -- that's 4 the -- that's saying it does not preclude the 5 use of using apneas to calculate the number of 6 apneas over time. That does not say or even ask 7 the same question. 8 Q. Well, following that, you then state 9 that the controller can compute a running 10 severity indicator, for example, a rolling event 11 burden or rolling flow limitation severity that 12 updates continuously and still drives immediate 13 changes in therapy. So the immediate changes in 14 therapy -- 15 A. Correct. 16 Q. -- how would that respond to a 17 10-second apnea versus a 30-second apnea? 18 A. Correct. So an apnea, being the 19 cessation of airflow, would result in an 20 increase in CPAP pressure to overcome the 21 airway -- so if we're talking about an 22 obstructive sleep disordered event, so we have a 23 person that has obstructive sleep apnea, and 24 they're receiving CPAP in the auto-titration 25 mode, and an event, which is an apneic event</p>	<p style="text-align: right;">Page 38</p> <p>1 (At 2:15 p.m. PST with parties present 2 as before, the following proceedings were had, 3 to-wit:) 4 BY MR. LAYDEN: 5 Q. Dr. Kirkness, if you could turn down 6 to Page 12 of your declaration, Paragraph 23. 7 The sentence beginning on the last line of 8 Page 12, carries on to Page 13: A POSITA would 9 have well known that a person would not sleep 10 the same in a hospital or a lab. 11 Do you see that? 12 A. Yes, I do. 13 Q. That description there, are you 14 describing the process for home sleep testing or 15 CPAP therapy? 16 A. So I think -- so let me just read what 17 I've said. So a person of ordinary skill in the 18 art would have understood and recognized the 19 advantages of remotely monitoring and treating a 20 patient in their own home as opposed to in a 21 sleep laboratory or hospital. 22 So it's been very clear for many 23 years, as long as, you know, in the late '90s 24 when sleep laboratories became more common, and 25 some treatments or diagnostics were conducted in</p>
<p style="text-align: right;">Page 37</p> <p>1 occurred, this would indicate that the pressure 2 supplying the airway is insufficient, such that 3 you would require an increase in pressure. So 4 that's how generally it -- the response into the 5 delivering of pressure in an auto-titration 6 device is used to overcome an airway obstruction 7 due to an apnea. 8 Now, so that's what I believe, in my 9 opinion. 10 MS. ALEXANDER: Counsel, we've 11 been going for over an hour. Are you close to a 12 point where you could take a break? 13 MR. LAYDEN: Sure. Ten minutes? 14 MS. ALEXANDER: Now is good? 15 Thank you. 16 (2:05 p.m. PST - Recess taken.) 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 39</p> <p>1 hospital beds as well, and it's very clear that 2 people do not, or often, feel as comfortable in 3 a bed that's not their own or in a room that's 4 not their own, as opposed to in a hospital or 5 laboratory. 6 So therefore, either monitoring or 7 treating a patient in their own home compared to 8 in a laboratory, this addresses the advantages 9 of both diagnostics and treatment. 10 Q. Are you aware of when the first CPAPs 11 were released for in-home use by patients? 12 A. Well, no is the answer, but it must 13 have been before 1997 because that's -- and 14 actually, it must have been before 1995 because 15 I was working in a sleep disorder center in and 16 around that time. 17 Q. And were those devices incapable of 18 recording usage and patient symptom data? 19 A. So there are definitely CPAP machines 20 that were able to have a SMART card or a storage 21 device that was capable of measuring usage, and 22 some of that usage may have included the 23 pressure level, some of that usage may have 24 included the airflow in the device. That data 25 most likely at the earlier devices might have</p>

<p style="text-align: right;">Page 40</p> <p>1 required analysis -- additional analysis as 2 well. 3 Q. And were doctors unable to obtain that 4 data? 5 A. So again, I think that doctors were 6 primarily the ones that were receiving patient 7 data. So anything from -- any data from the 8 treatment of a patient would be the data that 9 was privileged by their treating physician. 10 Q. Dr. Kirkness, do you personally use a 11 CPAP? 12 A. Is that an important question that I 13 have to answer? It's part of a -- for example, 14 if this is a public record, am I required to 15 answer whether I'm currently using any specific 16 medical treatment? 17 Q. You can answer however you wish. 18 A. So unless I'm required to answer, I'll 19 just say I prefer not to answer. 20 Q. Do you know anybody in your family who 21 uses a CPAP? 22 A. I know some people who have used CPAP. 23 Q. And how did they get that CPAP? 24 A. So the -- a person who has some 25 symptoms of -- that would be recognized as a</p>	<p style="text-align: right;">Page 42</p> <p>1 Q. Paragraph 25, third sentence, middle 2 of the paragraph, you state: A POSITA would use 3 a CPAP in the further diagnosis of prospective 4 patients to detect and modify any sleep disorder 5 events, and would do so based on that person's 6 probability of having sleep apnea. 7 So my question is, would a person be 8 given a CPAP or undergoing any of the diagnostic 9 testing that you just described, in order to 10 diagnose them as having sleep apnea? 11 A. So a CPAP that's -- so here in the 12 declaration I said: A POSITA would use a CPAP 13 in the further diagnosis of prospective patients 14 to detect and modify any sleep disorder events, 15 and would do so based on that person's 16 probability of having sleep apnea. Okay. So 17 what that means, the question you've asked, is 18 can you use -- can you determine if somebody has 19 a sleep disorder whilst they're using CPAP? 20 Q. No, that's not my question. My 21 question is would a CPAP be given to a patient 22 prior to any sort of diagnostic testing that you 23 just described before, based on the probability 24 that they have sleep apnea? 25 A. So, as you might know, I'm not a</p>
<p style="text-align: right;">Page 41</p> <p>1 symptom of a sleep disorder would be -- would 2 approach a relevant healthcare provider that is 3 able to either refer to a diagnostic center or 4 refer to a physician who is able to order from a 5 diagnostic center, and then at that stage when a 6 physician who agrees that a diagnostic test for 7 a given condition would be justifiable, that 8 they would receive a diagnostic test that could 9 be interpreted. 10 And from there, if they had received a 11 diagnosis that was compatible with a given 12 treatment, that treatment would be prescribed. 13 And if that treatment was CPAP, the treatment 14 would be fulfilled based on who a -- a provider 15 that is able to legally supply under that 16 prescription order. That's how they would go 17 about obtaining treatment with CPAP. 18 Q. Would a person be diagnosed with a 19 sleep disorder -- strike that. 20 Would a person receive a CPAP in order 21 to diagnose his sleeping disorder? 22 A. So there -- if, for example -- I'd 23 like to bring this back to the declaration at 24 hand, and so that you could point me to where 25 we've discussed that.</p>	<p style="text-align: right;">Page 43</p> <p>1 licensed physician, and I don't prescribe CPAP. 2 So what I would say is that I have -- I wouldn't 3 be able to determine if a specific person or 4 physician is able to prescribe CPAP to an 5 individual prior to a diagnostic test. 6 Now, having said that, it is possible 7 for a person to be prescribed based on the 8 symptoms that may be overt for obstructive sleep 9 apnea, and a physician does have the authority 10 to do so. 11 Q. And can you describe for me what you 12 mean when you stated: A POSITA would use a CPAP 13 in the further diagnosis of prospective patients 14 to detect and modify sleep disorder events? 15 What do you mean by "further diagnosis"? 16 A. So in this case what we're talking 17 about is, for example -- so there was a long -- 18 some people have long waiting lines at sleep 19 labs. So there was a time where it was taking 20 months and waiting times of six months or nine 21 months in order to get in to have a 22 polysomnographic sleep study in order to 23 determine if somebody had a sleep disorder based 24 on polysomnography. 25 A person of ordinary skill in the art</p>

<p style="text-align: right;">Page 44</p> <p>1 would understand that somebody had witnessed 2 apnea, snoring, obesity, and other very common 3 symptoms or signs associated with sleep apnea, 4 may benefit from early usage of CPAP to 5 determine if, for example, morning headaches 6 resolve, if their daytime alertness was able to 7 be resolved. And in that case the use of CPAP 8 amongst people with extremely high likelihood of 9 sleep apnea and the resolution of the symptoms 10 would be beneficial to improve the health and 11 improve the efficiency of the ability to treat 12 more people. So that's what I mean by a 13 POSITA -- that when I stated here, a POSITA 14 would use CPAP in a further -- in the further 15 diagnosis of prospective patients to detect and 16 modify any sleep disorders that would be based 17 on a person's probability of having sleep apnea. 18 There are other conditions, for 19 example, that may co-associate with sleep apnea. 20 There may be other circumstances where early use 21 of a CPAP may be required. For example, if 22 people have hypoventilation, which decreases the 23 amount of ventilation that they have, even 24 during wakefulness. So some people may even 25 require a CPAP prior to -- that's not even a</p>	<p style="text-align: right;">Page 46</p> <p>1 to the -- prior to a diagnosis. 2 Subsequently, if it was found to be -- 3 the CPAP pressure was found to be low based on 4 the presence of subsequent hypopneas and/or 5 apneas, that might indicate whether the 6 pressure, CPAP pressure was too low and needed 7 to be raised. 8 Q. Is it fair to say that without a 9 diagnostic test, though, a person of ordinary 10 skill would just be guessing at what pressure 11 works best in the initial setup? 12 MS. ALEXANDER: Objection; 13 mischaracterizes his testimony. 14 THE WITNESS: So that's not what 15 I said, but what I would say is that the 16 judgment -- it's a clinical judgment that it 17 would be required, and I described in detail 18 some of the factors that might entail that 19 clinical judgment, amongst others. 20 BY MR. LAYDEN: 21 Q. And how would a person of ordinary 22 skill set the -- or determine the patient's 23 baseline without a diagnostic test? 24 A. Could you tell me what you're 25 referring to when you say baseline?</p>
<p style="text-align: right;">Page 45</p> <p>1 sleep related disorder. So CPAP might be used 2 in other conditions as well. 3 Q. How would a POSITA know what pressure 4 to set the CPAP at in the actions of a 5 diagnostic test? 6 A. So the CPAP pressure, that would be 7 very difficult. And I would say that that would 8 have to be a clinical judgment. So a treating 9 physician might have to do a few things. They 10 might have to, for example, look at somebody's 11 weight, look at somebody's size, look at 12 somebody's -- and then when they're being set 13 up. So these things aren't just delivered and 14 show up at the door. The patient has to have 15 a -- in order to get a CPAP machine, has to show 16 up, talk to a either respiratory therapist or a 17 respiratory nurse, and have an education 18 session, understand how to use the device. They 19 might have to try on different masks at the 20 order of the physician and/or potentially at the 21 discretion and discussion with the healthcare 22 provider, may determine a pressure based on 23 comfort during wakefulness, for example, that 24 might be an initial pressure that allows an 25 individual to get a CPAP that is provided prior</p>	<p style="text-align: right;">Page 47</p> <p>1 Q. Well, I believe -- Page 5 you have a 2 footnote, you have baseline in here a couple of 3 times but it says: Typically, the 4 quantification of how far airflow drops from the 5 patient's baseline and/or how obstructed the 6 airflow waveform or snore intensity is over a 7 short window of time. 8 How would a person of ordinary skill 9 determine the patient's baseline without a 10 diagnostic test? 11 A. So in the situation where I had 12 described somebody receiving CPAP prior to 13 the -- prior to a diagnosis, a baseline would 14 refer -- so the pressure that they're receiving 15 without CPAP, if you would consider that, that 16 would be zero, okay, zero pressure. 17 Now, the baseline is a baseline 18 airflow, not a baseline pressure. So are you 19 trying to have me determine how a POSITA would 20 determine the baseline airflow or the baseline 21 pressure? 22 Q. I'm asking about the baseline 23 characteristics of a patient. So if you look at 24 Paragraph 13, and the part on Page 8. The 25 second full sentence there you say: To assess</p>

<p style="text-align: right;">Page 48</p> <p>1 and treat a particular patient's sleep disorder 2 symptoms, a POSITA would typically use that 3 patient as their own baseline. 4 A. And I apologize, you skipped a bit 5 fast for me. Could you tell me which 6 paragraph -- 7 Q. Paragraph 13, on Page 8. It carries 8 over. 9 A. Okay. And so are you -- and the 10 sentence says: The baseline characteristics of 11 a generic patient without sleep-disordered 12 symptoms? 13 Q. Two sentences before that, but yeah, 14 it can carry down through there. 15 A. Oh, okay. 16 Q. How would a person of ordinary skill 17 determine the baseline characteristics of a 18 patient without a diagnostic test? 19 A. Oh, so this baseline is -- this 20 baseline would refer to the sleep-disordered 21 breathing and the symptoms of sleep-disordered 22 breathing, express themselves in terms of apnea, 23 hypopnea, and other respiratory-related 24 characteristics at night when -- sorry, I 25 shouldn't say at night -- during sleep.</p>	<p style="text-align: right;">Page 50</p> <p>1 A. So if, for example, we're referring 2 back to the -- the use of a device, the use of a 3 device that you're going to use at night, so I 4 think what you're referring to is how would you 5 characterize baseline during the use of CPAP? 6 No? 7 Q. No, not how you would characterize. 8 How would you determine the baseline, right, 9 when you give the person the CPAP, to determine 10 the thresholds for apneas? 11 A. So they do have a CPAP or are they 12 using CPAP or not? 13 Q. They're using CPAP. They received the 14 CPAP without a diagnostic test. 15 A. Oh, I see. 16 Q. How would you determine that baseline, 17 that threshold baseline without a diagnostic 18 test? 19 A. So when the airflow measurements 20 obtained from the CPAP device prior to onset of 21 sleep, as I mentioned before, so now we have an 22 individual measuring the airflow via the CPAP 23 and the circuit that they're wearing, so they 24 have -- they're wearing equipment and a device 25 that measures airflow. And you measure the</p>
<p style="text-align: right;">Page 49</p> <p>1 So when a person is in the wake state, 2 those people do not have apneas and hypopneas. 3 So during the wake state, prior to sleep, the 4 breathing -- so if we're talking about airflow, 5 and this is essentially what we're talking 6 about, we're talking about the airflow level 7 that you and I would be respiring or breathing 8 at right now during wakefulness. And this also 9 occurs when we lay down prior to sleep. So 10 prior to sleep, whilst you're still awake 11 preparing for sleep, there is a period of 12 restfulness that is not sleep and it is a 13 baseline period. This is well characterized and 14 used in many situations to look at the baseline 15 breathing characteristics of an individual. 16 And those are the baseline 17 characteristics that would be used in order to 18 make a comparison to a subsequent state where an 19 individual would, during sleepfulness, 20 experience the symptoms that express themselves 21 as apnea, hypopnea, snoring, upper airway 22 resistance syndromes, other sleep-related 23 events, such as arousal, et cetera. 24 Q. How would you determine the baseline 25 in a wakeful state without a diagnosis test?</p>	<p style="text-align: right;">Page 51</p> <p>1 baseline at the portion of time as their -- when 2 they start using the device. Because they're 3 not asleep when you start using the device. 4 Q. Is that baseline determination a 5 factor in determining the pressure settings? 6 A. In CPAP the pressure is constant. 7 Q. Are there different modes of positive 8 airway pressure devices that operate outside of 9 just constant? 10 MS. ALEXANDER: Objection; 11 outside the scope. 12 THE WITNESS: So if you point to 13 me where we discuss that, I could certainly -- 14 BY MR. LAYDEN: 15 Q. I mean, previously we discussed 16 bilevel and auto-titration devices. 17 A. And they may be examples of other 18 modes of pressure devices. 19 Q. Would those other modes be given to a 20 patient without a diagnostic test first? 21 A. So I would, again, refer to my 22 previous answer where I said you would require a 23 clinician to make a clinical judgment as to 24 whether a specific medical device was prescribed 25 to an individual for a certain -- for a specific</p>

<p style="text-align: right;">Page 52</p> <p>1 reason.</p> <p>2 Q. And previously when you were</p> <p>3 discussing the baseline, you said that the</p> <p>4 baseline can be determined just prior to sleep</p> <p>5 through the airflow sensor. Is that accurate?</p> <p>6 A. So I previously said that if a person</p> <p>7 is wearing CPAP in the state where they're not</p> <p>8 experiencing apneas or hypopneas such as occurs</p> <p>9 during the time prior to onset of sleep, this</p> <p>10 would constitute a baseline.</p> <p>11 Q. Would that baseline need to be</p> <p>12 programmed into the device?</p> <p>13 A. So it wouldn't have to be programmed</p> <p>14 into the device. I don't see why it would have</p> <p>15 to be programmed into the device.</p> <p>16 Q. How would the device detect the onset</p> <p>17 of an apnea or hypopnea then?</p> <p>18 A. So that's probably -- I don't see that</p> <p>19 that is -- that I've described that in this</p> <p>20 declaration at all.</p> <p>21 Q. Previously you described apneas and</p> <p>22 hypopneas as the reduction in the breathing</p> <p>23 threshold; do you recall that?</p> <p>24 A. So previously we were talking about --</p> <p>25 we were talking about the data of a severity of</p>	<p style="text-align: right;">Page 54</p> <p>1 medicine. Have you ever experienced a patient</p> <p>2 being given either a CPAP, a bilevel positive</p> <p>3 airway pressure device, or an auto-titration</p> <p>4 positive airway pressure device without first</p> <p>5 having undergone a diagnostic sleep test?</p> <p>6 MS. ALEXANDER: Objection; vague.</p> <p>7 THE WITNESS: So in my career</p> <p>8 I've seen hundreds if not thousands of people</p> <p>9 who have had sleep-disordered breathing. Now,</p> <p>10 whether any of those specific ones had had the</p> <p>11 CPAP before or after a diagnosis, I just</p> <p>12 couldn't recall off the top of my head.</p> <p>13 MR. LAYDEN: Why don't we take a</p> <p>14 five-minute break.</p> <p>15 (2:48 p.m. PST - Recess taken.)</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 53</p> <p>1 sleep-disordered symptoms of subject, and I</p> <p>2 described how apneas and hypopneas, as well as</p> <p>3 snoring, characterize levels of severity of</p> <p>4 those symptoms.</p> <p>5 Q. And you said that they were identified</p> <p>6 by a reduction in airflow; is that accurate?</p> <p>7 A. So if I -- in that discussion we were</p> <p>8 discussing the various levels of airflow, and</p> <p>9 that was on Page -- oh, excuse me -- 4 -- it was</p> <p>10 on Page 5 -- Page 4 and 5 of my declaration</p> <p>11 relating to the description of those and briefly</p> <p>12 I had -- so this is in Paragraph 9 of my</p> <p>13 declaration -- described severity in airflow</p> <p>14 reduction from apneas and hypopneas.</p> <p>15 Q. In your experience have you ever seen</p> <p>16 a patient given a CPAP, bilevel, or</p> <p>17 auto-titration device prior to the conducting of</p> <p>18 a home sleep test or diagnostic test?</p> <p>19 MS. ALEXANDER: Objection; vague.</p> <p>20 THE WITNESS: So can you be more</p> <p>21 specific or can you point to where we discussed</p> <p>22 that?</p> <p>23 BY MR. LAYDEN:</p> <p>24 Q. I'm asking about your personal</p> <p>25 experiences working in the field of sleep</p>	<p style="text-align: right;">Page 55</p> <p>1 (At 2:57 p.m. PST, with parties</p> <p>2 present as before, the following proceedings</p> <p>3 were had, to-wit:)</p> <p>4 MR. LAYDEN: Dr. Kirkness, I</p> <p>5 appreciate you taking the time. I have no</p> <p>6 further questions.</p> <p>7 THE WITNESS: Thank you.</p> <p>8 MS. ALEXANDER: I don't have any</p> <p>9 questions.</p> <p>10 COURT REPORTER: Previous orders,</p> <p>11 Counsel?</p> <p>12 MR. LAYDEN: Yes.</p> <p>13 MS. ALEXANDER: That's fine.</p> <p>14 (2:57 p.m. PST - Adjournment.)</p> <p>15 ** * * * *</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>



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