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| 1  | UNITED STATES PATENT AND TRADEMARK OFFICE             |
| 2  | BEFORE THE PATENT TRIAL AND APPEAL BOARD              |
| 3  | RESMED CORP,                                          |
| 4  | PETITIONER,                                           |
| 5  | V.                                                    |
| 6  | CLEVELAND MEDICAL                                     |
| 7  | DEVICES, INC.,                                        |
| 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>Page 4</p> <p>1 JASON P. KIRKNESS, Ph.D.,<br/>2 having been first duly sworn,<br/>3 was examined and testified as follows:<br/>4 DIRECT EXAMINATION<br/>5 BY MR. LAYDEN:<br/>6 Q. Good afternoon, Dr. Kirkness. Good to<br/>7 see you again. You submitted a reply<br/>8 declaration in this IPR; is that correct?<br/>9 A. I did.<br/>10 Q. And that's Exhibit 1071. Do you have<br/>11 that before you?<br/>12 A. Yes, I do.<br/>13 Q. Do you have any other paper copies of<br/>14 exhibits?<br/>15 A. I have the copies of any of the<br/>16 exhibits that were referred to in the<br/>17 declaration.<br/>18 Q. Okay. And what about the previous<br/>19 exhibits from the petition?<br/>20 A. Previous exhibits from the petition.<br/>21 Could you give me a specific example?<br/>22 Q. Any other references, anything of that<br/>23 nature?<br/>24 A. So the references -- I don't have an<br/>25 extensive list of everything that was referred</p>                                                         | <p>Page 6</p> <p>1 A. 1004. CV. Let me see. Yes, I do.<br/>2 Q. If you could pull that out for me,<br/>3 please.<br/>4 A. Yes, sir.<br/>5 Q. And previously when we discussed for<br/>6 the IPR against the '512 patent, we went through<br/>7 some of your engagements, and just a couple of<br/>8 quick questions on that topic. On Page 1 in the<br/>9 bullet points you have listed there, it says<br/>10 novel device -- novel medical devices and<br/>11 treatment approaches for chronic respiratory<br/>12 disease. Research awards from industry.<br/>13 A. Yes.<br/>14 Q. What was the award that Resmed gave<br/>15 you?<br/>16 A. So those are described in detail in<br/>17 pages 6 to 8 under the banners, Extramural<br/>18 Sponsorship and Contracts. And under there, if<br/>19 there was anything that mentioned the word<br/>20 Resmed. So I'm just scrolling through under the<br/>21 section Contracts from 2013 is the first line<br/>22 item, high nasal airflow for treatment of COPD<br/>23 from Resmed. Nasal high-flow -- sorry -- high<br/>24 nasal airflow for treatment of COPD 2014. High<br/>25 nasal airflow for treatment of obstructive sleep</p>                                                        |
| <p>Page 5</p> <p>1 to in the previous iteration in front of me.<br/>2 Q. If we get to that point and you don't<br/>3 have an exhibit before you, I could drop it in<br/>4 the chat and we can go from there, if that<br/>5 works.<br/>6 A. Okay.<br/>7 Q. Looking at your declaration,<br/>8 Exhibit 1070 --<br/>9 A. Yes.<br/>10 Q. -- the final page, Page 17, that's<br/>11 your signature; correct?<br/>12 A. That is correct.<br/>13 Q. And roughly how long did you spend<br/>14 working on this declaration?<br/>15 A. I don't know exactly how long I spent<br/>16 working on it. Sometime from when I was asked<br/>17 to look at it based on the order in which -- you<br/>18 know, in reply to the -- so I don't have that in<br/>19 front of me exactly how long I spent.<br/>20 Q. Are you able to estimate how long?<br/>21 A. I'd basically have to go back to a<br/>22 calendar and look at the days and -- could be<br/>23 done.<br/>24 Q. Okay. Do you have Exhibit 1004, which<br/>25 was your CV?</p> | <p>Page 7</p> <p>1 apnea, 2009 to 2010. High nasal airflow<br/>2 treatment for COPD, 2010 to 2012. Those are the<br/>3 ones that are listed.<br/>4 Q. So the rewards referenced on that<br/>5 first bullet point on Page 1 is in reference to<br/>6 the contracts you've received from Resmed?<br/>7 A. So the bullet points on Page 1 are<br/>8 not -- refers to various research awards from<br/>9 industry for various novel medical devices and<br/>10 treatment approaches for various chronic<br/>11 respiratory diseases.<br/>12 Q. And then within that statement you<br/>13 have listed Resmed and sleep health and ImThera?<br/>14 A. ImThera, yes.<br/>15 Q. And the research awards from industry<br/>16 where you have Resmed, are those research awards<br/>17 description, is that your description of the<br/>18 contracts you received from Resmed or is there<br/>19 an actual award that you received from Resmed?<br/>20 A. So these are research contracts that<br/>21 were -- research contracts conducted at Johns<br/>22 Hopkins University, administered through the<br/>23 Office of External Engagement.<br/>24 So also my belief is that during that<br/>25 time there are awards also at the University of</p> |

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

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

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

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| <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> |

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| <p>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>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>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>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> |

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

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| <p style="text-align: right;">Page 32</p> <p>1 variable. That would be one way that you could<br/>2 examine that. So I don't know if a 10-second<br/>3 apnea creates a different physiological response<br/>4 in a person to a 30-second apnea.<br/>5       So in some individuals a 10- and a<br/>6 30-second apnea may not elicit a different<br/>7 response, and there may be other individuals<br/>8 that have different physiological responses to a<br/>9 10- versus a 30-second apnea.<br/>10       So it would depend on whether you're<br/>11 talking about with an individual, who that<br/>12 individual is, the circumstances under which the<br/>13 apnea occurs, in order to opine on the<br/>14 different -- if there is a difference between a<br/>15 10- and a 30-second apnea.<br/>16       Q. So just to be clear, then, you don't<br/>17 have an opinion on whether or not a 10-second<br/>18 apnea is more or less severe than a 30-second<br/>19 apnea? Do I understand that correctly?<br/>20       A. So if, for example, you're asking me<br/>21 whether within an individual there is a<br/>22 difference in the severity between a 10- and a<br/>23 30-second apnea, what I'm saying is that you<br/>24 would -- we would need to examine something else<br/>25 in order to determine whether the response to</p> | <p style="text-align: right;">Page 34</p> <p>1 there's a number of different physiological<br/>2 variables that could go into determining whether<br/>3 a longer apnea results in some other<br/>4 physiological response.<br/>5       Q. What type of response would a<br/>6 10-second apnea elicit from a CPAP machine on<br/>7 auto-titration mode as opposed to a 30-second<br/>8 apnea?<br/>9       MS. ALEXANDER: Objection; vague.<br/>10       THE WITNESS: Yeah, I would have<br/>11 to -- if you want to point me to somewhere where<br/>12 we could go into that, I could certainly -- if<br/>13 there was a point that you could point me to.<br/>14 BY MR. LAYDEN:<br/>15       Q. Well, Paragraph 15 you state that<br/>16 Truitt's device is not limited to operating in a<br/>17 CPAP, bilevel, or auto-titration type of<br/>18 pressure support mode. Instead, the sensing<br/>19 assembly can be used in conjunction with any<br/>20 type of pressure support or ventilatory system.<br/>21 Do you see that?<br/>22       A. Mm-hmm, yes. So to begin with, I note<br/>23 that Truitt's device is not limited to operating<br/>24 in a CPAP, BiPAP, or auto-titration mode or<br/>25 pressure support. Instead, the sensing assembly</p>                  |
| <p style="text-align: right;">Page 33</p> <p>1 that apnea created something that you would<br/>2 determine as sufficient to be able to<br/>3 discriminate severity. That's what I'm saying.<br/>4       I'm not saying that a 30-second apnea<br/>5 has a physiological -- I'm saying it's longer,<br/>6 but in terms of whether it creates a<br/>7 physiological response that's different, we<br/>8 couldn't say that unless we were looking at some<br/>9 data.<br/>10       Q. What other data would you need?<br/>11       A. So in order to look at -- determine<br/>12 the severity, there's a bunch of different<br/>13 variables that you could look at. You could<br/>14 look at heart rate response, you could look<br/>15 at -- as I mentioned to you before, you could<br/>16 look at cortical arousal. You could look at<br/>17 blood pressure responses. You could look at<br/>18 daytime symptoms.<br/>19       So, for example, if somebody has<br/>20 longer -- a longer apnea versus shorter apnea,<br/>21 you could look and see whether they're sleepy,<br/>22 is there any objective sleepiness. Do they<br/>23 have -- do they require more or less pressure<br/>24 support in order to overcome an apnea. So is<br/>25 their airway more collapsable. So, yeah,</p>                                                  | <p style="text-align: right;">Page 35</p> <p>1 can be used in conjunction with any type of<br/>2 pressure support or ventilatory system where the<br/>3 flow and/or volume of fluid is to be measured.<br/>4 Yes.<br/>5       Q. And then in Paragraph 16 you state<br/>6 that but in the event that Truitt's CPAP is used<br/>7 in a bilevel or auto-titration mode, a POSITA<br/>8 would have still utilized Truitt's severity and<br/>9 usage device data to calculate an index.<br/>10       A. Mm-hmm, yes.<br/>11       Q. So the severity you're referencing<br/>12 there, that's the identification of the apnea,<br/>13 hypopnea, or snores; is that accurate?<br/>14       A. Yes. So exactly, apneas, hypopneas,<br/>15 and/or snores in Truitt would be used whether it<br/>16 was in a bilevel or auto-titration mode.<br/>17       Q. And so when in auto-titration mode,<br/>18 how would Truitt CPAP respond to a 10-second<br/>19 apnea versus a 30-second apnea? Would the<br/>20 response be the same?<br/>21       A. So is there somewhere where I describe<br/>22 the -- in my declaration do I describe how<br/>23 Truitt describes its response to a change in the<br/>24 length of apnea?<br/>25       Q. Well, next sentence you say: Realtime</p> |

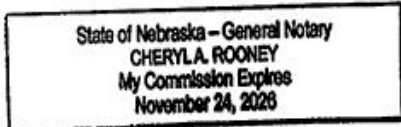
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| <p style="text-align: right;">Page 36</p> <p>1 intervention does not preclude the use of an<br/>2 index calculated over time.<br/>3 A. Yeah, that does not relate -- that's<br/>4 the -- that's saying it does not preclude the<br/>5 use of using apneas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

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

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

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

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| <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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|----|---------------------------------------------------------------------------------------|
| 1  | C E R T I F I C A T E                                                                 |
| 2  | STATE OF NEBRASKA )                                                                   |
| 3  | COUNTY OF DOUGLAS )                                                                   |
| 4  | I, Cheryl A. Rooney, Registered                                                       |
| 5  | Professional Reporter, General Notary Public                                          |
| 6  | within and for the State of Nebraska, do hereby                                       |
| 7  | certify that the foregoing testimony of JASON P.                                      |
| 8  | KIRKNESS, Ph.D. was taken by me in shorthand and                                      |
| 9  | thereafter reduced to typewriting by use of                                           |
| 10 | Computer-Aided Transcription, and the fifty-six                                       |
| 11 | (56) pages contain a full, true and correct                                           |
| 12 | transcription of all the testimony of said                                            |
| 13 | witness, to the best of my ability;                                                   |
| 14 | That I am not a kin or in any way                                                     |
| 15 | associated with any of the parties to said cause                                      |
| 16 | of action, or their counsel, and that I am not                                        |
| 17 | interested in the event thereof.                                                      |
| 18 | IN WITNESS WHEREOF, I hereunto affix                                                  |
| 19 | my signature and seal this 18th of February,                                          |
| 20 | 2026.                                                                                 |
| 21 |                                                                                       |
| 22 |    |
| 23 | CHERYL A. ROONEY, RPR                                                                 |
| 24 | GENERAL NOTARY PUBLIC                                                                 |
| 25 | Registered Professional Reporter                                                      |
|    |  |
|    | My Commission Expires: November 24, 2026                                              |

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