IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:	Examiner: Daniel Nile
Felix Ridi	Group Art Unit: 3683
Application No.: 17/000,000	Attorney Docket No.: 2228
Filed: April 3, 2020	Confirmation No.: 1234
For: A SYSTEM AND METHOD FOR NONINVASIVE VAGUS NERVE STIMULATION	

AMENDMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Examiner Nile:

This Amendment is in response to the Office Action mailed April 10, 2020. This Amendment is timely because it is being submitted within the period for reply which expires July 10, 2020. Please enter and consider the following:

— Compliant

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the

application:

LISTING OF CLAIMS

1. (Currently Amended)   A system for Vagus nerve stimulation, said system

including:

a sensor unit, wherein said sensor unit detects heart beats in a user ~~and generates~~

~~RR interval data, wherein said RR interval data represents intervals between said heart~~

~~beats~~ to determine a heart rate variability (HRV) data, wherein said HRV data represents

a HRV value; *Variation in the interval between Heartbeats*
said

a mobile device, wherein said mobile device receives ~~said RR interval data from~~

~~said sensor unit, wherein said mobile device calculates a heart rate variability (HRV)~~

~~data, wherein said HRV data represents a HRV value,~~ said HRV data from said sensor

Undefined, so is any HRV value

unit, wherein said mobile device retrieves a (baseline) HRV data from a memory, wherein

needed?

said baseline HRV data represents a previously (calculated) and stored baseline HRV

value, wherein said mobile device compares said HRV value to said baseline HRV value

and transmits a signal when said mobile device detects that said HRV value is below said

baseline HRV value; and

a stimulator, wherein said stimulator receives said signal from said mobile device and emits an electrical impulse in response to said signal and~~to~~ stimulates the Vagus nerve in said user.

2. (Original)   The system of claim 1, wherein said stimulator is external to said user and stimulates the Vagus nerve in said user when said user causes said stimulator to contact said user's skin.

3. (Original)   The system of claim 1, wherein said mobile device is a smart phone.

4. (Original)   The system of claim 1, wherein said mobile device determines an intensity for said electrical impulse emitted by said stimulator.

5. (Original)   The system of claim 1, wherein said mobile device determines a duration for said electrical impulse emitted by said stimulator.

6. (Original)   The system of claim 1, wherein said stimulator transmits data pertaining to duration of said electrical impulse emitted by said stimulator to said mobile device.

7. (Original)   The system of claim 1, wherein said stimulator transmits data pertaining to intensity of said electrical impulse emitted by said stimulator to said mobile device.

8. (Original)   The system of claim 1, wherein said memory is a server external to said mobile device.

9. (Currently Amended)   A method for <u>determining a change in a user's heart rate variability and generating a stimulation signal in response</u> ~~determining a baseline heart rate variability (HRV) reading~~, said method including:

detecting, by a sensor unit, intervals between heart beats in a user as interval data *wherein variation is the length of said interval, ...* <u>and using said interval data to calculate a HRV data, wherein said HRV data represents a HRV value for said user;</u>

transmitting said ~~interval data~~ <u>HRV data</u> from said sensor unit to a mobile device, wherein said mobile device includes a processor and a user interface;

<u>retrieving, by said processor, a baseline HRV data from a memory, wherein said baseline HRV data represents an average HRV value, wherein said average HRV value is calculated by averaging, by said processor, adjusted HRV data, wherein said adjusted HRV data is calculated, by said processor, by increasing or decreasing a baseline HRV reading in response to a user input data, wherein said baseline HRV reading represents an HRV value for said user obtained for the purpose of calculating said baseline HRV data, wherein said user input data is entered by said user in said user interface, wherein said user input data represents a perceived emotional state for said user chosen by said user, wherein said user input data is transmitted from said user interface to said processor;</u>

when? <u>determining, by said processor, said HRV data is below said baseline HRV data by determining the difference between said HRV value and said average HRV value;</u>

<u>retrieving, in response to said HRV value being below said average HRV value, by said processor, stimulation instructions stored on said memory; and</u>

HMM

OK, this would not be clear enough for an Examiner, still — I can see you are trying, though

generating, by said processor, a stimulation signal, said stimulation signal containing information related to intensity and duration for a stimulation.

~~calculating a HRV data using said interval data, wherein said HRV data represents a HRV value for said user;~~

~~adjusting said HRV value using a user input data to create an adjusted HRV data, wherein said user input data is entered by said user in said user interface, wherein said user input data represents psychological information, wherein said user input data is transmitted from said user interface to said processor; and~~

~~storing said adjusted HRV data on a memory.~~

10.   (Currently Amended) The method of claim 9, wherein said <u>memory is a</u> ~~adjusted HRV data is stored on a~~ server external to said mobile device.

11.   (Cancelled)

12.   (Cancelled)

13.   (Currently Amended)   A method for Vagus nerve stimulation, said method including:

detecting, by a sensor unit, the time intervals between heart beats of a user ~~as heartbeat data~~ <u>to determine a HRV data, wherein said HRV data represents a HRV value for said user;</u>

transmitting said ~~heartbeat~~ <u>HRV</u> data to a mobile device;

~~calculating heart rate variability (HRV) data, wherein said HRV data is calculated by said mobile device using said heartbeat data, wherein said HRV data represents a HRV value for said user;~~

retrieving a baseline HRV value from a memory, wherein said baseline HRV data represents a previously calculated and stored baseline HRV value; *see above*

~~comparing~~ calculating the difference between said HRV value [[to]] and said baseline HRV value ~~to determine that~~ *[include]* said HRV value is below said baseline HRV value; *you need !*

~~determining said HRV value is below said baseline HRV value;~~

generating, by said mobile device, in response to said mobile device determining *when* said HRV value is below said baseline HRV value, a command signal, wherein said command signal contains data representing a duration and intensity for an electrical stimulus; and *not defined — and not used in rest of claim*

transmitting said command signal from said mobile device to a stimulator which emits an electrical impulse to stimulate a Vagus nerve in said user in response to receiving said signal.

14. (Original) The method of claim 13, wherein duration data and intensity data for said electrical impulse emitted by said stimulator is transmitted from said stimulator to said mobile device.

15. (Original) The method of claim 14, wherein said heart rate variability data, said baseline heart rate variability data, said duration data, and said intensity data are stored on a server external to said mobile device.

REMARKS

The present application includes claims 1-15. Claims 1-15 were rejected by the examiner. By this Amendment, claims 11 and 12 have been canceled, claims 1, 9, 10 and 13 have been amended.

Claims 1-15 were rejected under 35 U.S.C. § 112(b) as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor regards as the invention. More specifically, claims 1-15 recited that HRV is determined at the mobile device rather than at the sensor. Claims 1, 9, and 13 have been amended to correct the concerns identified by the Examiner. First, claim 1 has been amended to recite "said sensor unit detects heart beats in a user to determine a heart rate variability (HRV) data" and "said mobile device receives said HRV data from said sensor unit". Next, claim 9 has been amended to recite "detecting, by a sensor unit, intervals between heart beats in a user as interval data and using said interval data to calculate a HRV data" and "transmitting said HRV data from said sensor unit to a mobile device". Lastly, claim 13 has been amended to recite "detecting, by a sensor unit, the time intervals between heart beats of a user to determine a HRV data" and "transmitting said HRV data to a mobile device".

Next, claims 9-12 included the limitation "adjusting HRV value", which the Examiner found to be indefinite. Claim 9 has been amended to recite "adjusted HRV data

is calculated, by said processor, by increasing or decreasing a baseline HRV reading in response to a user input data". Additionally, claims 9-12 recited "psychological information". Claim 9 has been amended to recite "wherein said user input data represents a perceived emotional state for said user chosen by said user".

Claims 13-15 recited the limitation "determining said HRV value is below said baseline HVE value", which the Examiner found to be indefinite. Claim 13 has been amended to recite "calculating the difference between said HRV value and said baseline HRV value to determine that said HRV value is below said baseline HRV value". Additionally, claim 13 was rejected by the Examiner due to the lack of functional connection within the claim to the last two limitations of the claim. The lack of connection from the original claim 13 was between a claim limitation reciting that HRV value is determined to be below baseline HRV value and a claim limitation reciting that a signal command is generated. Claim 13 has been amended to recite "generating, by said mobile device, in response to said mobile device determining said HRV value is below said baseline HRV value, a command signal".

The remaining claims identified int his rejection were included due to their dependence from claims 1, 9, and 13. Consequently, independent claims 1, 9, and 13, as amended are respectfully submitted to be in compliance with 35 U.S.C. § 112(b), as are their respective dependent claims 2-8, 10, and 14-15.

Claims 9-12 were rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

Claims 1-15 were rejected under 35 U.S.C. § 102(a)(1) as being anticipated by Siegle, U.S. Pat. App. Pub. No. 2020/0061377.

Claims 1-15 were rejected under 35 U.S.C. § 102(a)(2) as being anticipated by Osorio, U.S. Pat. App. Pub. No. 2019/0000378.

The Applicant now turns to the rejection of claims 9-12 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. The Examiner found that the claims were directed toward the abstract idea of merely detecting, storing, and transmitting data. Claim 9, as originally presented, recited collecting HRV data from a sensor and psychological data from a user interface and using these data to calculate an adjusted HRV data. Claim 9, as amended, now recites a method for determining a change in HRV and generating a stimulation signal in response to a detected change. The claim recites, as before, collecting HRV data and psychological data to calculate adjusted HRV data, but continues to recite how the calculated adjusted HRV data is used to generate baseline HRV data which is further used to compare with later HRV readings. Additionally, amended claim 9 recites new limitations: "retrieving, in response to said HRV value

being below said average HRV value, by said processor, stimulation instructions stored on said memory; and generating, by said processor, a stimulation signal, said stimulation signal containing information related to intensity and duration for a stimulation". The addition of the listed limitations specifies a use for the calculated data which is "significantly more" than the abstract idea of detecting, storing, and transmitting data.

Not bad = go with "integrated into a practical application"

Claims 11 and 12 have been cancelled. Dependent claim 10 is amended to reflect the changes to claim 9, to identify that the "memory" described in claim 9 may be a server external to the mobile device. Consequently, the Applicant respectfully submits that independent claim 9 complies with the requirements of 35 U.S.C. § 101 and is allowable, as is dependent claim 10.

The Applicant now turns to the rejection of claims 1-15 under 35 U.S.C. § 102(a)(1) as being anticipated by Siegle. Siegle teaches a regulatory device and associated method for treating depression, wherein the regulatory device delivers stimulation primarily in the form of vibration. Paragraphs [0016] – [0018] of the Siegle reference specifically disclose the levels of vibration stimulation enabled, describing "a first frequency that is in the range of 20-300 Hz and a second oscillation at a second frequency that differs from the first frequency by 0.01-10 Hz". This same vibration limitation is again recited in paragraph [0030] and Claim 1 of the Siege reference.

Siegle does not teach a system to compare an HRV reading within a user to a pre-calculated baseline HRV. Siegle paragraphs [0044] – [0045] does teach a method for detecting physiological stress, presenting a calculation for comparing galvanic skin response (GSR) data with HRV data, but no similar calculation for comparing HRV to a pre-calculated HRV. Additionally, Sielge does not teach to administer electrical stimulation in response to a detected change in HRV value.

[handwritten margin note: You would want to emphasize / clarify this]

Claims 1-15 include independent claims 1, 9, and 13. Claim 1, as amended, recites a mobile device, which receives an HRV data from a sensor unit and retrieves a baseline HRV data from a memory, wherein the baseline HRV data represents a previously calculated and stored baseline HRV value. Claim 1 further recites that the mobile device compares the HRV value to the baseline HRV value and transmits a signal when it detects that the HRV value is below the baseline HRV value. Siegle does not teach comparing a currently measured HRV value to a previously-calculated baseline HRV. Siegle paragraph [0046] mentions a calibration operation which includes brief exposures to stress induction to build a "stress profile" to be consequently stored. Although, as discussed above, Siegle briefly mentions consideration of HRV as part of a method for detecting psychological stress, all that Siegle discloses is a calculation in paragraph [0045] comparing GSR data and HRV data. Claim 1 does not consider GSR.

[handwritten margin note: good, but even more so]

[handwritten note: Does not help claim 1]

Claim 9, as amended, recites a method for taking a baseline HRV reading for a user including wherein a mobile device receives a user input data, wherein the user input data is entered by a user in a user interface, and the user input data represents a perceived psychological state for said user. Claim 9 additionally recites that the user input data is transmitted to a mobile device processor, which increases a collected HRV value in response to said user input data to create an adjusted HRV data. Siegle does teach a method for obtaining calibration readings wherein a user obtains physiological readings at rest and after a stimulus is administered to cause a stress response, as described in paragraphs [0046] and [0075]. Siegle does not teach using a user-input psychological state to adjust a physiological reading as claimed in claim 9.

Claim 13, as amended, recites, as part of a method for determining when to administer a Vagus nerve stimulation to a user, calculating the difference between said HRV value and said baseline HRV value to determine that said HRV value is below said baseline HRV value. As discussed above, Siegle does not teach comparing a currently measured HRV value to a previously-calculated baseline HRV.

Consequently, independent claims 1, 9, and 13 are respectfully submitted to be free of the prior art and allowable, as are their respective dependent claims 2-8, 10, and 14-15.

The Applicant now turns to the rejection of claims 1-15 under 35 U.S.C. §

102(a)(2) as being anticipated by Osorio. Osorio teaches a system and method for

assessing an epilepsy disease state. The Osorio reference shows a system comprising an

implantable medical device, with leads connecting the medical device to electrodes and a

physiological sensor, and a monitoring unit. This system is shown by Figures 4 and 5 in

the Osorio reference. In particular, the implantable signal generator is described in

paragraphs [0107] – [0109] and paragraph [0121] describes the connection between the

physiological sensor and the implanted medical device by leads. Osorio does not teach

connecting a sensor to a mobile device through a wireless connection. Additionally,

Osorio paragraphs [0100] – [0103] disclose a method for comparing an index value, such

as heart rate variability, to a reference value. Osorio does not show how a system

determines to administer a stimulus in response to this comparison.

Claims 1-15 include independent claims 1, 9, and 13. Claim 1, as amended,

recites that a mobile device receives a HRV data from a sensor unit. As discussed above,

Osorio shows a system in which a sensor unit is connected to an implanted medical

device by leads, and does not show a system in which a sensor unit is connected to the

external computing device, such as the mobile device claimed in claim 1. Claim 1 further

recites a mobile device transmitting a signal to a stimulator when the mobile device

detects that a HRV value is below a baseline HRV value, and the stimulator emits an

electrical impulse in response to receiving that signal. Osorio does discuss comparing an

index value to a reference value, but Osorio does not describe what the expected result of this comparison should be. The Osorio reference shows that a HRV value can be compared to a reference HRV value, but does not teach if or when a stimulus should be administered in response to that comparison, as is claimed by claim 1.

Claim 9, as amended, recites a method for taking a baseline HRV reading for a user including wherein a mobile device receives a user input data, wherein the user input data is entered by a user in a user interface, and the user input data represents a perceived psychological state for said user. Osorio paragraphs [0100] – [0103] show that a reference value may be determined from a patient's history and may be an HRV calculated from data collected over a period time. Additionally, Osorio paragraphs [0085] – [0087] discuss collection of user psychological data. However, Osorio does not teach to use collected psychological data to adjust an HRV reading to obtain a baseline HRV reading as described in claim 9.

Claim 13, as amended, recites determining a HRV data in a sensor unit and transmitting the HRV data to a mobile device. Osorio shows a system in which a sensor unit is connected to an implanted medical device by leads, and does not show a system in which a sensor unit is connected to the external computing device, such as the mobile device claimed in claim 13. Claim 13 additionally recites generating, in response to the mobile device determining the HRV value is below the baseline HRV value, a command

signal, wherein the command signal contains data representing a duration and intensity for an electrical stimulus. As previously discussed, Osorio shows that a HRV value can be compared to a reference HRV value, but does not teach if or when a stimulus should be administered in response to that comparison, as is claimed by claim 13.

Consequently, independent claims 1, 9, and 13 are respectfully submitted to be free of the prior art and allowable, as are their respective dependent claims 2-8, 10, and 14-15.

Application No. 17/000,000
Attorney Docket No. 2228

CONCLUSION

If the Examiner has any questions or the Applicant can be of any assistance, the

Examiner is invited and encouraged to contact the Applicant at the number below.

The Commissioner is authorized to charge any necessary fees or credit any

overpayment to the Deposit Account of 2228, Account No. 2228.

Respectfully submitted,

Date: 04/17/20   /2228/

2228
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