# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:

    Felix Ridi

Application No.:    17/000,000

Filed:    4/3/2020

For:    VAGUS NERVE
        STIMULATION SYSTEM FOR
        INCREASING HEART RATE
        VARIABILITY

Examiner:    Daniel Nile

Group Art Unit:    3683

Attorney Docket No.: 946

Confirmation No.:    1234

## AMENDMENT

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

Dear Examiner Nile:

    This Amendment is in response to the Office Action mailed on April 24, 2020.

This Amendment is timely because it is being submitted within the period for reply which

expires on July 24, 2020. Please enter and consider the following:

*[Handwritten notes:]*

*- Would have been better to just go w/ 1 claim*

*- Note: This would not quite be at work in a practice setting, but it is the best in the class so I am curving grades to yours*

*- Overall good effort*

*[Handwritten "A" circled in the margin]*

## 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 applying ~~a~~ vagus nerve stimulation, said system including:

a heart rate variability (HRV) detecting device, wherein said HRV detecting device detects <u>a plurality of</u> a user's ~~heartbeat~~ heartbeats, senses ~~the~~ intervals between ~~each heartbeat~~ <u>said user's heartbeats,</u> <u>and</u> calculates an HRV score ~~based on said intervals between each heartbeat using the root mean square of successive differences (RMSSD)~~ <u>by applying a root mean square of successive differences (RMSSD) calculation to said</u> <u>intervals between heartbeats;</u>

a computer, wherein said computer receives said HRV score from said HRV detecting device, compares said HRV score to a predetermined HRV score, and ~~send~~ sends a stimulation initiation command when said HRV score is lower than said predetermined HRV score; and

a <u>non-invasive</u> vagus nerve stimulator, wherein said stimulator receives said stimulation initiation command and applies <u>non-invasive</u> vagus nerve stimulation <u>in</u> <u>response to said stimulation initiation command.</u>

2.      (Original) The system of claim 1, wherein said system further includes a server, said server stores said predetermined HRV score.

3.      (Original) The system of claim 1, wherein said stimulator further includes a wireless communication module.

4.      (Original) The system of claim 1, wherein said HRV detecting device further includes a wireless communication module.

5.      (Currently Amended) The system of claim 1, wherein said computer further includes a user interface, said user interface notifies the user before applying ~~the~~ said non-invasive stimulation.

6.      (Currently Amended) A system for determining a predetermined heart rate variability (HRV) score, said system including:

an HRV detecting device, wherein said HRV detecting device repeatedly detects a plurality of a user's ~~heartbeat~~ heartbeats, senses ~~the~~ intervals between ~~each~~ said user's ~~heartbeat~~ heartbeats, ~~and~~ calculates an HRV score ~~based on said intervals between each heartbeat using the root mean square of successive differences (RMSSD)~~ by applying a root mean square of successive differences (RMSSD) calculation to said intervals between heartbeats, and generates a plurality of said HRV scores; and

*[handwritten annotations: "You are actually reciting detecting the same heartbeats a plurality of times", "chuck"]*

a computer ~~receiver~~, wherein said computer ~~receiver receives said HRV score from said HRV detecting device;~~ receives a plurality of said HRV scores from said HRV detecting device, displays said HRV scores to said user, requests psychological state inputs representing said user's psychological states at the time when each said HRV score is generated, receives said psychological state inputs from said user, calculates a plurality of adjusted HRV scores based on said psychological state inputs, and generates a predetermined HRV score by calculating the average of said adjusted HRV scores.

~~a computer transmitter, wherein said computer transmitter~~

~~a user interface, wherein said user interface includes a psychological state dropdown menu and receives psychological state input from the same user as the one who receives said HRV score; and~~

~~a computer processor and a computer memory, wherein said computer processor receives said HRV score from said computer receiver and receives said psychological state input from said user interface, calculates an adjusted HRV score by increasing said HRV score when said psychological state input indicates the user is sad, saves said adjusted HRV score to said computer memory, calculates an average HRV score by calculating the average of a plurality of said adjusted HRV scores saved on said computer memory, and saves said average HRV score as a predetermined HRV score in said computer memory.~~

7. (Original) The system of claim 6, wherein said system further includes a server, wherein said server stores said predetermined HRV score.

8. (Original) The system of claim 6, wherein said HRV detecting device further includes a wireless communication module.

9. (Cancelled)

10. (Currently Amended) A method of increasing heart rate viability (HRV), said method including:

detecting a plurality of a user's ~~heartbeat~~ heartbeats, senses ~~the~~ intervals between ~~each~~ said user's heartbeats ~~through~~ using an HRV detecting device;

calculating an HRV score ~~based on the~~ by applying a root mean square of successive differences (RMSSD) calculation to ~~using~~ said ~~beat-to-beat~~ intervals ~~through~~ using said HRV detecting device;

comparing said HRV score to a predetermined HRV score ~~through~~ using a computer; and

applying non-invasive vagus nerve stimulation at a predetermined default initial intensity when said HRV score is lower than said predetermined HRV score ~~through~~ using a non-invasive vagus nerve stimulator.

11.    (Currently Amended) The method of claim 10, wherein said method comprises calculating an HRV score based on another HRV time-domain measure ~~through~~ <u>using</u> said HRV detecting device, such as the standard deviation of NN intervals.


12.    (Currently Amended) The method of claim 10, wherein said method further includes adjusting said default initial intensity according to a predetermined adjustment value based on height, body mass index and gender ~~through~~ <u>using</u> said computer.

**REMARKS**

The present application includes claims 1-12. Claims 1-12 were rejected. By this Amendment, claims 1, 5, 6, and 10-12 have been amended. Claim 9 has been cancelled.

Claims 6-12 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.

Claims 6-12 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter.

Claims 1-12 were rejected under 35 U.S.C. §103(a) as being unpatentable over the U.S. Pat. App. Pub. No. 2019/0000378 to Osorio (hereinafter "Osorio") in light of the Corsense device by Elite HRV (hereinafter Corsense).

The Applicant now turns to the rejection of claims 6-12 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, the examiner claimed that the following limitations in claim 6 were indefinite: "same user as the one who receives said HRV score", "indicates said user is sad", "said average HRV score", "a predetermined HRV score". Additionally, the examiner pointed out that

*[handwritten: claim 6 would still not be clear to an Examiner, see claim]*

claim 6 recites "calculating the average of a plurality of said adjusted HRV score" while only one adjusted HRV score is recited. Claim 6 has been amended to recite an HRV detecting device that "*repeatedly* detects a plurality of a user's heartbeats and senses intervals between said user's heartbeats, calculates an HRV score by applying a root mean square of successive differences (RMSSD) calculation to said intervals between heartbeats, and *generates a plurality of said HRV scores*", and a computer that "receives *a plurality of said HRV scores from said HRV detecting device*, displays said HRV scores to said user, requests psychological state inputs representing said user's psychological state at the time when each said HRV score is generated, receives said psychological state inputs from said user, *calculates a plurality of adjusted HRV scores based on said psychological state inputs, and generates a predetermined HRV score by calculating the average of said adjusted HRV scores*". As amended, claim 6 recites a plurality of adjusted HRV scores, which further clarifies how the predetermined HRV score is calculated. Additionally, claim 6 no longer includes the limitation "same user as the one who receives said HRV score" and "indicates said user is sad", and claim 9 has been cancelled. Claim 10 has been similarly amended to recite an HRV detecting device that "detects *a plurality of* a user's heartbeats".

Additionally, claim 10 was rejected since it recites "through said HRV detecting device" and "through a computer". Claim 10 has been amended to recite "using said HRV detecting device" and "using a computer". Consequently, claims 6 and 10, along

with claims 7-8 and 11-12 which depend from claims 6 and 10, are respectfully submitted

to be allowable under 35 U.S.C. §112(b).

The Applicant now turns to the rejection of claims 6-12 under 35 U.S.C. §101 as

being directed to non-statutory subject matter. Specifically, the examiner pointed out that

the claims were drawn to an abstract idea and did not recite limitations that are

"significantly more" than the abstract idea. Based on 2019 Revised Patent Subject Matter

Eligibility Guidance (hereinafter 2019 PEG), even if claim 6 is directed to an abstract

idea, it is still allowable when it recites additional elements that integrate the judicial

exception into a practical application. According to the 2019 PEG, one way of integrating

the judicial exception into a practical application is to "applying the judicial exception

with, or by use of, a particular machine." Claim 6 recites the HRV detecting device,

which is a particular machine. Additionally, claim 6 recites a computer, which is

specifically designed to have functions to carry out the purpose of the invention. For

example, the computer can display HRV scores to user, request psychological inputs

from user, and calculate adjusted HRV scores based on the psychological inputs. These

functions cannot be performed by a generic computer and require specific design and

programming. Similarly, claim 10 recites an HRV detecting device, a computer that is

designed to perform specific tasks, and a vagus nerve stimulator that is designed and

programmed to receive command signals from the computer.

Additionally, claim 6 recites "psychological state input indicating the user is sad", which was claimed to be non-statutory under 35 U.S.C. §101. Claim 6 has been amended and no longer recites this limitation, and claim 9 has been cancelled. Consequently, claims 6 and 10, and claims 7-8, 11-12 which depend from claims 6 and 10, are respectfully submitted to be allowable under 35 U.S.C. §101.

The Applicant now turns to the rejection of claims 1-12 under 35 U.S.C. § 103 as being unpatentable over Osorio in light of Corsense. Paragraphs 99-105 in Osorio teach a method of comparing user's HRV value to a predetermined reference HRV value. This method can be used to assess a state of a disease. Paragraphs 172, 181-182 teach a medical device system that applies stimulation in response to the assessment. In one embodiment, this system includes a therapy unit that delivers therapy for a disease of patient. In another embodiment, the system includes at least one electrode that is coupled to user's vagus nerve and performs electrical therapy. Paragraph 196 disclosed that the system can be used for treating patients having depression.

Corsense teaches an HRV monitor that generates HRV scores by detecting user's heartbeats, capturing intervals between user's heartbeats, and applying root mean square of successive differences (RMSSD) calculation to the intervals.

Claims 1 and 10 have been amended to recite a non-invasive vagus stimulator and non-invasive vagus stimulation. Corsense does not include any teaching of non-invasive vagus stimulation. Osorio only teaches a method of electrical therapy by coupling at least one electrode to user's vagus nerve, which can be referred to both traditional vagus nerve stimulation and non-invasive vagus stimulation, since both methods require coupling at least one electrode to at least one of the vagus nerves. In other words, Osorio does not specifically teach non-invasive vagus nerve stimulation, or a non-invasive vagus stimulator. Therefore, neither Osorio nor Corsense teaches non-invasive vagus stimulator or non-invasive vagus stimulation. Consequently, claims 1 and 10, along with claims 2-4 and 11-12 which depend from claims 1 and 10 and thus include all the limitations of claims 1 and 10, are respectfully submitted to be allowable under 35 U.S.C. § 103.

Claim 6, on the other hand, recites a system that determines a reference HRV score based on user's HRV scores and psychological states when each score is generated. Corsense does not teach how a reference HRV score is determined. Osorio mentions in paragraph 100 that "if the index value is heart rate variability (HRV), the corresponding reference value can be a single value defined by a physician in view of the patient's age, sex, fitness level, body mass index, physical fitness level at the time of the measurement, initial disease state, or other values; it can be a value chosen from a set of predetermined options relating to different typical initial disease states or the like; or it can be dynamically recalculated, such as from an indicator of central tendency (e.g., a mean, a

median, or a percentile value) of HRV data over one or more timescales, such as the past hour, day, week, month, or year, among others, to account for ultradian, circadian, catamenial, lunar, and seasonal variations." This description does not teach a method or system that determines a reference HRV value by using both user's HRV scores and psychological states when each score is generated. Specifically, the first part of the description teaches that the reference value "can be a single value *defined by a physician*", which teaches away from determining the reference value by using user's own HRV scores and psychological inputs. Other methods mentioned in Osorio, such as determining the reference value by choosing it from "a set of predetermined options relating to different typical initial disease states or the like", also do not specifically include a method that determines the reference value by generating user's HRV scores, adjusting the scores and determining the reference value by calculating the average of the adjusted scores. Therefore, neither Corsense nor Osorio teaches a system of determining the reference HRV value based on user's HRV scores and psychological states when each score is generated, which is recited in claim 6. Consequently, claims 6, along with claims 7-8 which depend from claims 6 and thus include all the limitations of claim 6, are respectfully submitted to be allowable under 35 U.S.C. § 103.

*[handwritten annotation: not clear in claim]*

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Attorney Docket No. 946

## 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 Pat, Ent & Win, Account No. 12345.

Respectfully submitted,

Date: _____May 1, 2020_____     _____/946/_____
                                    946
                                    Registration No. 946

PAT, ENT & WIN
504 East Pennsylvania Avenue,
Champaign, IL 61820

Telephone:    555-555-5555
Facsimile:    555-555-5555