(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization

International Bureau





(10) International Publication Number WO 2016/069143 A1

- (43) International Publication Date 6 May 2016 (06.05.2016)
- (51) International Patent Classification: A61M 21/00 (2006.01) G09B 19/00 (2006.01)
- (21) International Application Number:

PCT/US2015/051895

(22) International Filing Date:

24 September 2015 (24.09.2015)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/072,401 29 October 2014 (29.10.2014) US 62/138,361 25 March 2015 (25.03.2015) US 62/152,776 24 April 2015 (24.04.2015) US

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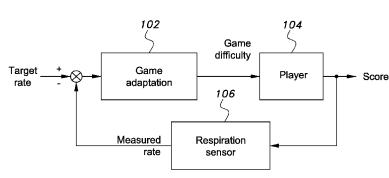
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- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,

[Continued on next page]

(54) Title: STRESS RELIEF TRAINING METHOD AND DEVICE

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(57) Abstract: The stress relief training method and device (100) include an embodiment that relates to a combination of biofeedback and an adaptive game (102) that encourages deep breathing (DB) or other desired behavior. This approach combines an open source casual game (102) (e.g., Frozen Bubble) with a positive feedback controller. A second embodiment encourages DB through the use of an adaptation of the game of Dodge. A third embodiment of a stress relief training method and device relates to a combination of biofeedback and the playback of variable quality music while engaging in deep breathing exercises and simultaneously engaging in a visually demanding task (e.g., driving, reading, etc.) using a positive feedback controller to vary the playback quality of music based on variations in the biofeedback signal.

Fig. 7



SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, Published: GW, KM, ML, MR, NE, SN, TD, TG).

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STRESS RELIEF TRAINING METHOD AND DEVICE TECHNICAL FIELD

The present invention relates to biofeedback methods, and particularly to a stress relief training method and device that uses a biofeedback sensor to monitor stress levels of a subject and provides positive feedback on an electronic device in response to monitoring signals from the sensor when the subject maintains a low level of stress.

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BACKGROUND ART

The World Health Organization has deemed job stress a global epidemic. Job stress can have serious health consequences; it contributes to the obesity epidemic worldwide and promotes a host of chronic diseases, specifically, cardiovascular disease – the leading cause of death in the developed world. Stress can also have a profoundly negative effect on mental health, an under-acknowledged growing health problem around the world. Thus, reducing job stress could help reduce a number of negative health outcomes, increase the quality of life for workers, and result in an economic benefit for employers, e.g., increased worker productivity, reduced healthcare costs. As an example, workplace stress has been estimated to cost \$150-300 billion to the US economy alone.

A number of techniques have been developed to help individuals self-regulate the impact of stress, including various forms of meditation, deep breathing and biofeedback. Deep or diaphragmatic breathing (DB) is among the easiest and most intuitive evidence-based methods for reducing stress. Essentially, DB addresses the autonomic nervous system imbalance that arises following exposure to a stressor and activation of the sympathetic nervous system. As DB recruits the parasympathetic nervous system, action of the sympathetic nervous system becomes inhibited, leading to a calmer, more relaxed state.

Many of the stress management programs delivered in workplace settings demonstrate that DB substantially reduces the symptoms of stress. Biofeedback techniques are also used frequently as components of worksite stress management programs. Biofeedback allows patients to see changes in their physiology (e.g., skin conductance, heart rate) while they perform relaxation exercises, and can be effective provided that the patient adheres to the training regime. Although beneficial, however, these traditional programs may not be sustainable since they require prolonged and substantial commitments of time and other resources from both workers and employers. In addition, these techniques teach subjects to

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regulate their stress response in a quiet, relaxed environment, a skill that may not transfer to stressful, high-stakes scenarios, where it is really needed.

Thus, a stress relief training method and device solving the aforementioned problems are desired.

DISCLOSURE OF INVENTION

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The stress relief training method and device include an embodiment that relates to a combination of biofeedback and an adaptive game to encourage desirable behaviors (e.g., lowering heart rate, reducing muscle tension, reducing/increasing certain brain waves, or encouraging deep breathing (DB)) or improve perception of certain visceral events (e.g. states of high arousal) through positive feedback. This approach combines an open source casual game (e.g., Frozen Bubble) with a positive feedback controller. A second embodiment encourages DB through the use of an adaptation of the game of Dodge. The approach in the first two embodiments includes monitoring physiological signals (variables) during gameplay of an arousing game and adapting the game in a way that encourages relaxing behaviors. A third embodiment of a stress relief training method and device relates to a combination of biofeedback and the playback of variable quality music while simultaneously engaging in deep breathing exercises or simultaneously engaging in a visually demanding task (e.g., driving, reading, etc.), and using a positive feedback controller to degrade the quality of the music when, for example, a subject's breathing deviates from a pre-determined relaxed breathing rate. The quality of the music is restored when, for example, the subject's breathing rate returns to the relaxed breathing rate.

These and other features of the present invention will become readily apparent upon further review of the following specification and drawings.

BRIEF DESCRIPTION OF DRAWINGS

Fig. 1 is a block diagram illustrating adaptation of classical control theory to embodiments of a stress relief training method and device according to the present invention that utilize an electronic video game.

Fig. 2A is a first screenshot of the frozen bubble game that may be used in a first embodiment of a stress relief training method and device according to the present invention.

Fig. 2B is a second screenshot of the frozen bubble game of Fig. 2A.

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Fig. 2C is a first screenshot of a modified Stroop CWT (color word test) used in pretask and post-task testing of some embodiments of a stress relief training method and device according to the present invention.

Fig. 2D is a second screenshot of the modified Stroop cwt used in pre-task and posttask testing of some embodiments of a stress relief training method and device according to the present invention.

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- Fig. 3A is a plot of pre-task and post-task breathing power spectral density used in testing of some embodiments of a stress relief training method and device according to the present invention.
- Fig. 3B is a plot of breathing rate used in testing of some embodiments of a stress relief training method and device according to the present invention, showing the evolution of the breathing rate during testing.
- Fig. 4A is a plot of the physiological arousal, both pre-test and post-test, as measured by electrodermal activity (EDA) in testing of some embodiments of a stress relief training method and device according to the present invention.
- Fig. 4B is a plot of the physiological arousal, both pre-test and post-test, as measured by heart rate variability (HRV) in testing of some embodiments of a stress relief training method and device according to the present invention.
- Fig. 4C is a plot of the CWT scores in testing of some embodiments of a stress relief training method and device according to the present invention.
 - Fig. 5A is an exemplary screenshot showing a Dodge game that may be used in a second embodiment of a stress relief training method and device according to the present invention.
 - Fig. 5B is a plot showing the relation between respiratory rate and game difficulty implemented in the Dodge game used in the second embodiment of a stress relief training method and device according to the present invention.
 - Fig. 6 is a plot comparing pre-task and post-task electrodermal activity (EDA) in testing the Dodge game used in the second embodiment of a stress relief training method and device according to the present invention.
 - Fig. 7 is a plot comparing pre-task and post-task heart rate variability (HRV) in testing the Dodge game used in the second embodiment of a stress relief training method and device according to the present invention.

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Fig. 8 is a chart showing the relation between respiration and game difficulty for a subject in testing the Dodge game used in the second embodiment of a stress relief training method and device according to the present invention.

Fig. 9 is a schematic diagram showing an exemplary system for testing a third embodiment of a stress relief training method and device according to the present invention.

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- Fig. 10 is a plot showing the breathing rate vs noise level in a third embodiment of a stress relief training method and device according to the present invention.
- Fig. 11 is a chart comparing average respiration rate of four test groups in three stages of testing the third embodiment of a stress relief training method and device according to the present invention.
- Fig. 12 is a chart showing percent reduction in electrodermal activity (EDA) of four test groups in two stages of testing the third embodiment of a stress relief training method and device according to the present invention.
- Fig. 13 is a chart showing percent increase in heart rate variability (HRV) of four test groups in two stages of testing the third embodiment of a stress relief training method and device according to the present invention.
- Fig. 14 is a chart showing task performance of four test groups in testing the third embodiment of a stress relief training method and device according to the present invention.
- Fig. 15 is a schematic diagram showing operation of an exemplary system in a third embodiment of a stress relief training method and device according to the present invention.
 - Fig. 16 is a plot showing relationship between breathing rate and audio quality in two variations of the third embodiment of a stress relief training method and device according to the present invention.
 - Fig. 17 is a plot showing the temporal evolution of respiration rate for one of the subjects in testing a variation of the third embodiment of a stress relief training method and device according to the present invention.
 - Fig. 18 is a plot showing the temporal evolution of respiration rate for another one of the subjects in testing a variation of the third embodiment of a stress relief training method and device according to the present invention.
 - Fig. 19 is a block diagram of an exemplary stress relief training method device according to the present invention.

Similar reference characters denote corresponding features consistently throughout the attached drawings.

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BEST MODES FOR CARRYING OUT THE INVENTION

The stress relief training method and device include an embodiment that relates to a combination of biofeedback and an interactive stimulus, such as an adaptive game. This approach combines an open-source casual game (Frozen Bubble) with a positive feedback controller. Another embodiment of the stress relief training method relates to a combination of biofeedback and the playback of variable quality music. A positive feedback controller degrades the quality of the music when a physiological variable of a subject deviates from a pre-determined target indication (sensor reading) of the physiological variable. Exemplary physiological variables include, but are not limited to, breathing rate, skin conductance, and heart rate. For example, the quality of the music may be restored when the subject's breathing rate returns to a relaxed breathing rate.

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In the adaptive game embodiment, game difficulty is modulated to reward slow breathing patterns and penalize high or increasing breathing rates. Slow breathing is one of several relaxation-inducing behaviors that could be targeted. This approach leads to better transfer of deep breathing (DB) skills. Moreover, physiological arousal is reduced while performance of a stress-inducing task is improved.

In the adaptive game embodiment, the present stress relief training method relies on concepts from classical control theory to model the process of adapting the videogame in response to the player's breathing rate. As known by practitioners having ordinary skill in the art, a control loop consists of (i) the plant to be controlled, (ii) a sensor that measures the plant's output, and (iii) a controller that seeks to minimize the difference between the desired and actual output. When applied to the present game adaptation, the plant becomes the player, whose breathing rate we seek to regulate, the feedback loop includes a respiratory sensor, and the controller is an algorithm that modulates the game's difficulty accordingly. Thus, as shown in Fig. 1, the game adaptation system 100 is comprised of the specific game adaptation 102 interfaced with the game player 104 whose respiration rate is monitored by respiration sensor 106 that feeds back a measured respiration rate from which the target rate is subtracted, the result being an error signal which is fed back to an input to the game adaptation 102.

In one instantiation (example) of the present method, a positive feedback control law is used where states of non-relaxation are defined as those with breathing rates higher than 6 breaths per minute (BRPM) and increasing (BR > 6 $\land \Delta BR > 0$) are penalized by increasing the game difficulty level. Breathing rates lower than 6 BRPM or decreasing are

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not penalized. The aforementioned breathing rates are exemplary only and not intended to be restrictive. An exemplary proportional-integral-derivative (PID) control law of equations (1) and (2) may be used to adapt the game.

$$d(t) = K_p \varepsilon(t) + K_d \ d\varepsilon(t) / d(t) + K_i \int_0^t \varepsilon(t) d\tau$$
 (1)

$$\varepsilon(t) = \begin{cases} b(t) - b_0 & (b(t) > b_0) \land (b(t) > b(t-1)) \\ 0 & \text{otherwise} \end{cases}$$
 (2)

where d(t) is the game's difficulty level, and $\varepsilon(t)$ is the error in the current breathing rate b(t) relative to the desired rate $b_0 = 6$. The term K_p is a proportional gain that causes the game difficulty to increase when the respiratory rate is higher than the desired value. Note that it should be obvious to persons having ordinary skill in the art that breathing rate as expressed in (2) could be replaced with arousal or stress, or the like, and that the error expression of (2) is exemplary only, i.e., many other functions to calculate the error may successfully be employed. Likewise, the term K_d is a derivative gain that adjusts the game difficulty based on the rate of change in respiration. Adding a derivative term reduces overshoot and helps stabilize the process. Similarly, K_i is an integral gain constant that adjusts the game difficulty based on the accumulated error in respiration rate over time. It

should be understood that for some applications (e.g., first-responder training) a very

immersive videogame may be used, e.g., one that takes more than a few minutes to play or

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that depicts realistic scenarios.

Based on these considerations, the present method may, e.g., adopt Frozen Bubble, a very popular casual game that is also available through a GNU General Public License. Figs 2A and 2B show screenshots 200a and 200b of the Frozen Bubble game. The user controls a small cannon that shoots bubbles of different colors into a playing area. The objective of the game is to eliminate all the hanging bubbles before the ceiling collapses. To do so, the player has to group three or more bubbles of the same color, which causes them to collapse. Frozen Bubble provides a few parameters that are amenable to adaptation, such as auto-shooting rate, how fast the ceiling drops, or angular rate and lag of the cannon. Out of these, the present adaptive game embodiment chooses the auto-shooting frequency as the game difficulty to be adapted, i.e., parameter d(t) in equation (1) is modulated, as it demands immediate action from the player. As the breathing rate crosses the threshold $(BR > 6 \land \Delta BR > 0)$, the autoshooting frequency increases, making it harder to play the game. Hence, to make progress on

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the game, the user is rewarded with a lower auto-shooting frequency, a desired characteristic, if the user maintains a slow and sustained breathing pattern.

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We validated the approach using an experimental protocol with three phases. During the first phase (pre-task), participants performed a modified Stroop color word test (CWT1) for four minutes. The CWT is widely used in psychophysiology to increase arousal. In the conventional CWT, participants are shown one of four words (red, blue, green, and yellow) displayed in different ink color, and are asked to choose the ink color of the displayed word. See the screenshot of a modified pre-task CWT 200c in Fig. 2C. To make the task more challenging, our implementation switched between asking for the ink color or the text of the word, and also switched between two modes (congruent and incongruent) every 30 seconds. See the screenshot of a modified post-task CWT 200d in Fig. 2D. In congruent mode, the concept and the ink color were the same, e.g., the word "red" in red ink. In incongruent mode, the concept and ink color were different, e.g., the word "blue" in red ink. During pretest, the stimulus was displayed for 1 second, and the participant had 3 seconds to respond. The response time was reduced to 2.5 seconds during post-test to ensure the task remained challenging, despite any learning effects from the pre-test. During the second phase (treatment), participants were randomly assigned into one of three groups, which included a group that played the biofeedback game (GBF), a baseline group that performed deep breathing (DB), and a control group that played the original Frozen Bubble game without adaptation or respiratory feedback (game only - GO). Participants in the DB condition were asked to follow an audio pacing signal that guided them to inspire/expire at a rate of 6 breaths per minute. None of the participants received prior training in DB. The game difficulty level in the GO condition was the lowest level (i.e., easiest) in the GBF condition, which GBF participants could only achieve under slow and sustained breathing. The duration of the treatment was eight minutes for the three groups. During the final phase (post-test), participants repeated the CWT for an additional four minutes. We adopted this betweensubjects experimental design to avoid an ordering effect due to learning or fatigue. Nine participants, (seven male two female; age range 22-33 years) participated in the study. Subjects reported that they were in good health, and none reported excessive drinking or smoking habits. We received approval from the Institutional Review Board (IRB) prior to the study and consent from individual participants before the session.

A Google Nexus-1 smartphone running Android 2.3.6 was used for the game, preand post-CWT, and guided DB. To compare the effectiveness of the adaptive game in managing stress levels, heart rate variability (HRV) and electrodermal activity (EDA), two

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commonly used physiological measures, were extracted. When used in combination, these two measures provide a robust index of arousal. Changes in EDA and HRV are generally in opposite directions with increasing task demands (e.g., EDA increases, while HRV decreases), so simultaneous increases (or decrements) in both variables can be dismissed as noise or motion artifacts. With respect to the game platform, it should be understood that the Google Nexus-1 is exemplary, and any suitable processor with suitable memory, suitable Operating System (OS), and suitable display may be used. This applies to all embodiments of the stress relief training method. For example, the mobile computing platform shown in Fig. 19 is a smartphone that includes a microprocessor 26 in operable communication with memory 27 as part of a mobile device subsystem 23. This mobile computing platform is equipped with a wireless transceiver 28 connected to an antenna as part of a communication subsystem 24. The subject (user) may interface with the device via LCD 25, which may include touch inputs as part of the interface with the user. Measurement module 22 may include whatever necessary data conversion is required to accept inputs from an exemplary BioharnessTM sensor 21 for input of breathing and other physiological data that will be processed by the mobile device subsystem 23. Moreover, it should be understood by one of ordinary skill in the art that embodiments of the stress relief training method disclosed herein can comprise software or firmware code executing on a computer, a microcontroller, a microprocessor, or a DSP processor; state machines implemented in application specific or programmable logic; or numerous other forms without departing from the spirit and scope of the method described herein. The present method can be provided as computer programs, which include a non-transitory machine-readable medium having stored thereon instructions that can be used to program a computer (or other electronic devices) to perform processes according to the methods. The machine-readable medium can include, but is not limited to, floppy diskettes, optical disks, CD-ROMs, and magneto-optical disks, ROMs, RAMs, EPROMs, EEPROMs, magnetic or optical cards, flash memory, or other type of media or machine-readable medium suitable for storing electronic instructions.

Using the aforementioned Google Nexus-1 smartphone, HRV was extracted from a BioharnessTM BT sensor (ZephyrTM Tech.), which also provided the respiratory signal for game adaptation. The measure of HRV was the root mean square of successive differences (RMSSD) in R-R intervals, computed over a thirty second window. EDA was monitored with a FlexComp InfinityTM encoder (Thought Technology Ltd.) and disposable AgCl electrodes placed at the palmar and hypothenar eminences of the player's non-dominant hand. From this, the phasic response (number of skin conductance responses) was extracted

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over a window of thirty seconds using a peak detection algorithm with a threshold of 1 millisecond. It should be understood by persons having ordinary skill in the art that any other physiological sensor (e.g., breathing, skin conductance, heart rate) can be used for this application.

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We compared the three treatments (GBF, GO, and DB) by their ability to transfer the relaxation skill. For this purpose, we analyzed the respiratory signal during pre- and post-tests intervals. Plot 300a of Fig. 3A shows the power spectrum density (PSD) of the breathing waveform for the 9 subjects (pre-test and post-test). For subjects in the GBF condition, there is a marked difference in the respiratory PSD before and after game play. The pre-task breathing spectra is broad and shifted towards high breathing rates, whereas the post-task breathing spectra is narrowband and centered on 0.1Hz (6 BRPM), the breathing rate rewarded during gameplay. Finally, subjects in the GO condition displayed a high breathing rate pre- and post-test, showing that playing a casual game alone does not encourage a relaxing respiratory behavior.

Similar conclusions can be extracted by analyzing the breathing rate in the time domain over the duration of the experiment (see plot 300b of Fig. 3B). Subjects in the GBF class lower their breathing rate during the treatment phase from its initial high value at pretest, and more importantly, maintain that slow breathing rate during post-test, an indication that the deep breathing skill transferred successfully. Subjects in the DB class also lower their breathing rate while performing the treatment, but unlike GBF subjects, revert during post-test to the high breathing rate shown at pre-test. This is particularly noticeable for subject #4. Finally, the breathing rate for subjects in the GO class does not change significantly over the duration of the experiment, and never reaches the deep breathing zone.

With respect to physiological arousal, we also analyzed the subjects' arousal levels, as measured by EDA and HRV. It is important to note that these indirect measures were collected for monitoring purposes, and were not used for biofeedback in any way. EDA results for all subjects in the experiments are shown in plot 400a Fig. 4A. For subjects in the GBF class, there is sharp decrease in EDA when going from pre-test to post-test, which indicates that playing the biofeedback game led to a significant reduction in arousal at post-test. In contrast, only 2/3rd of the subjects in the DB and GO classes had a decrease in EDA, and the remaining 1/3rd experienced an increase in EDA. A 1-way ANOVA of the difference in EDA between pre-test and post-test with treatment (GBF, GO, and DB) as the factor shows statistically significant differences among the three protocols (p = 0.02).

Plot 400b shows the average HRV computed over the duration of the pre-test and post-test segments. HRV increased significantly for subjects in the GBF class, corroborating results from EDA that indicate lower arousal after completion of the biofeedback game. Two of the subjects in the DB class also had higher HRV post-test, but the increase is not as marked. HRV for subjects in the GO class remained largely unaltered. A 1-way ANOVA on the HRV difference between pre-test and post-test with the three treatments as factors also shows a statistically significant difference (p = 0.01).

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Regarding task performance, we analyzed whether the treatment had an effect on performance, measured as the difference in CWT scores between pre-test and post-test. Results are shown in plot 400c of Fig. 4C for 8 subjects. Subjects in the GBF and DB classes had higher CWT scores in the post-task, whereas subjects in the GO class had mixed results. In this case, a 1-way ANOVA shows that the differences among treatments were not statistically significant (p = 0.40).

An embodiment of the present method teaches relaxation skills that leverages the broad appeal of casual games. To test the feasibility of this approach Chill-Out, a casual game for mobile phones that trains players to relax by penalizing high breathing rates with increased game difficulty and adapting in response to respiratory rate to reward sustained slow breathing was developed. Chill-Out was tested against traditional deep breathing and a non-adaptive, non-biofeedback version of the game. Results show that Chill-Out is more effective than either alternative in transferring deep breathing skills to a subsequent stress-inducing task, and it also leads to significantly lower arousal, as measured by electrodermal activity and heart rate variability.

Chill-Out teaches relaxation techniques while performing a task (i.e., a game) that is designed to increase the user's arousal level. As a result, the present method may lead to better transfer of relaxation skills to other stressful tasks, as demonstrated in our study. This hypothesis is also supported by prior research on stress exposure training in military settings, which shows that (for many tasks) normal training procedures do not improve performance when the task is later to be performed under stress.

In the second embodiment, Dodging Stress, a biofeedback game is presented where subjects are trained to slow down their breathing (i.e., breathe deeply) to induce relaxation by modulating game difficulty. The game is then personalized by further adapting game difficulty based on the subject's skill level to maintain engagement.

Dodging Stress is an adaptation of Dodge, an open source Android game under GNU-GPL. Shown in screenshot 500a of Fig. 5A, the goal in Dodge is to steer a ball from one side

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of the field to the other side without hitting any obstacles as many times as possible. Dodge is adapted for game-biofeedback purposes by introducing a positive feedback control law that increases the game difficulty in proportion to the player's breathing rate deviating from the ideal of five breaths per minute. Namely, given the player's breathing rate, b(t), game difficulty, d(t), at time t follows a piecewise linear U curve, as shown in plot 500b of Fig. 5B. The game difficulty is not tied to an intrinsic parameter of the game, but to the player's skill level, as measured during gameplay. This allows the game to adapt to each player, keeping them engaged regardless of their skill levels. Namely, the game maintains an estimate of the player's probability of success (p = successful/overall attempts) over a 45-second window, and then adjusts the number of obstacles n_t as:

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$$n_{t} = \begin{cases} n_{0} + 2 \times d_{t} & 3 > b_{t} \vee b_{t} > 7 \\ n_{t-1} + 2 & 3 < b_{t} < 7 \wedge p_{t} > \tau + 0.05 \\ n_{t-1} - 2 & 3 < b_{t} < 7 \wedge p_{t} < \tau - 0.05 \\ n_{t-1} & \text{otherwise} \end{cases}$$
(3)

where $n_0 = 10$ is the initial number of obstacles and $\tau = 0.75$ is the threshold (i.e., 75% chance of success). This is a very specific way of adapting the game. However, it should be understood by persons having ordinary skill in the art that other game adaption algorithms may be used without deviating from the scope of the present method.

In a pilot user study, Dodging Stress was evaluated through a user study (N=5 male participants, ages 20–23 years) with the protocol shown in Table 1.

Table 1: Stressor Protocol

STEP	Protocol
Training (4 min)	Subjects watched a video describing deep breathing (DB), and then practiced DB with an auditory pacing signal at 6 BRPM for 2 minutes.
Stressor (4 min)	Subjects performed a modified Stroop color word test (CWT) as a pre-treatment stressor
Treatment (8 min):	Subjects played Dodging Stress
Stressor (4 min)	Subjects repeated CWT post-treatment

To evaluate the game's effectiveness in teaching relaxation, we recorded heart rate variability (HRV) and electrodermal activity (EDA), both of which are proven physiological

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indicators of stress. EDA was measured with a ShimmerTM Galvanic Skin Response (GSR) sensor, whereas heart and respiration rate were measured with a ZephyrTM BioHarnessTM.

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Results are shown in plots 600, 700, and 800 of Figs 6, 7 and 8, respectively. Plots 600 and 700 show the HRV and EDA pre-task and post-task for all participants in the study. Overall, subjects showed a decrease in EDA and an increase in HRV between the pre-task and post-task (both measures indicative of relaxation), except for subject 5. Plot 800 shows the trajectory of game difficulty and breathing rate for one exemplary subject in the study. Game difficulty closely follows changes in respiration rate, peaking at the 50-second mark, when b > 7. Between 170 - 425 seconds, the difficulty level tracks the subject's success rate while 3 < b < 7. User feedback was also positive, with subjects expressing an interest in continuing to play the game. Thus it is feasible to use biofeedback games to acquire relaxation skills while performing an engaging activity. Alternative measures of stress (i.e. salivary cortisol) and game effectiveness (i.e., subjective experience) are being investigated at this time. Personalization may also be improved by tracking performance over repeated attempts to better predict the subject's optimal level. This will maintain game appeal over longer periods, thus reducing attrition rates and enabling continuous improvement in relaxation skills.

In a third embodiment, biofeedback that encourages slow breathing by adjusting the quality of music in response to the user's breathing rate is presented. An intervention that combines the benefits of biofeedback and music is employed to teach deep breathing skills. The present method's intervention includes monitoring the respiration rate of the user and adapting the quality of the music (e.g., signal-to-noise ratio) to promote slow, deep breathing, an exercise with known therapeutic benefits. Biofeedback intervention is illustrated schematically in Fig. 9, which shows system 900 where un-modified music is fed into the input of audio modification block, the modified output being heard by the subject who has a chest strap for monitoring breathing rate. The breathing rate is compared with the target respiration rate and the error signal is fed back to the audio modification block. In the event of a mobile application of this technique, the chest strap measures a driver's respiration rate and sends it to the audio modification application, where it is compared against the target range. If the driver's respiration is below the target rate (8 breaths/min), the musical piece is played without applying any modification. However, if the driver's breathing exceeds the target rate, the audio modification application adds white noise to the musical piece according to the piece-wise linear function shown in plot 1000 of Fig. 10. At 12 breaths/min, the noise amplitude is 50% of the average amplitude of the music track. At or above 20 breaths/min,

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the noise has the same amplitude as the music. The target breathing rate was chosen based on prior studies showing that heart rate variability, a physiological indicator of relaxation, is maximized at breathing rates around 0.1Hz (6 breaths/min). Reaching this breathing rate requires familiarity with deep breathing practice, and for this reason, a slightly higher rate (8 breaths/min) is chosen to ensure that study participants would be able to achieve it, yet enjoy the calming benefits of slow breathing.

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The present audio modification tool may be implemented as a mobile app on a Nexus 5 smartphone running Android 4.4 (KitKat). Breathing rate may be measured from a Bluetooth thoracic respiratory sensor (BioharnessTM BT, ZephyrTM Tech.). These details are presented as an example only and it should be understood by persons having ordinary skill in the art that a plethora of alternative hardware devices may be substituted for the aforementioned exemplary hardware without deviating from the scope of the present invention. The mobile app allows users to select a particular song from their personal music library. Once a song is selected the app modifies the audio as described by plot 1000 of Fig. 10. To simulate a visually demanding task, we used an open-source car racing simulator, displayed on a 22" LCD and integrated with a Logitech G27 racing wheel. To reduce variance across participants and experimental conditions, the game was modified such that the player was only required to control the car steering. The speed of the car at each position in the track was predetermined. The nominal speed profile for the track was obtained by recording game plays of a proficient player in a prior study. To measure task performance, the number of crashes during the race was recorded.

We measured arousal with two well-known physiological indices, viz., electrodermal activity (EDA) and heart rate variability (HRV). EDA consists of two components, including a slow changing tonic skin conductance level (SCL) and phasic changes (spikes) known as skin conductance responses (SCRs). SCL are highly subject-dependent and measurement of baseline SCL is difficult in the presence of SCRs. For this reason, we used SCRs as the EDA measure of arousal. Following prior work, we computed SCRs using a peak detection algorithm over a time window of 30 seconds sliding by 1 second. We measured EDA using a FlexComp InfinityTM encoder (Thought Technology Ltd.) with disposable AgCl electrodes attached on the palmar region of the subject's non-dominant hand.

HRV is the physiological phenomenon of variation in beat-to-beat (R-R) intervals. We computed HRV as the root mean square of successive differences (RMSSD) in R-R intervals over a 30-second window sliding by 1 second. We measured HRV with the same BioharnessTM BT chest strap from which we measure respiration rate. It is important to note

that these two physiological measures were collected for monitoring purposes and were not used in any way for biofeedback purposes. When used in combination, EDA and HRV provide a robust index of arousal. Changes in EDA and HRV are generally in opposite directions with increasing arousal (e.g., EDA increases while HRV decreases), so simultaneous increases (or decrements) in both variables can be dismissed as noise or motion artifacts.

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We evaluated our intervention on a study design with music and auditory biofeedback as independent effects. There were twenty (20) participants in the study. The protocol consisted of three phases, each lasting 5 minutes, including Driving: Participants played a race car simulator to measure physiological baseline during driving; Treatment: participants were randomly assigned one of the four conditions summarized in Table 2; and Driving + treatment: participants repeated their assigned condition while driving the simulator.

Participants in the MBF group (music biofeedback group) were provided the mobile app to practice deep breathing while listening to music. Participants in the ABF group (auditory biofeedback group) also used the mobile app, with the exception that the music track was replaced with silence. Thus, these participants heard audio (white noise), and then only if their breathing rate was higher than the target. Participants in the MUS group listened to music without biofeedback. Those in the CTRL group were asked to relax without any assistance (app or music). Music was delivered with stereo headphones.

Table 2: 2×2 Study Design

	No Biofeedback	Biofeedback
No Music	Control (CTRL)	Auditory biofeedback (ABF)
Music	Music only (MUS)	Music biofeedback (MBF)

Prior to the experiments, participants in the MBF and MUS groups were asked to select two songs of the same composer from a predetermined music library, summarized in Table 3. All songs had a slow tempo and were instrumental. Such compositions have been associated with lowering physiological responses. We received approval from the Institutional Review Board (IRB) prior to the study and consent from participants before the session.

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Table 3: List of Pre-Selected Musical Compositions

Composer	Song 1	Song 2
Beethoven	Concerto No. 5	Fur Elise
Mozart	Andante	Andantino
Enya	Caribbean Blue	Watermark
Einaudi	Nuvole Bianche	I Giorni
Yo Yo Ma	Cello Suite No. 1	Meditation

Plot 1100 of Fig.11 shows the average breathing rate for each of the four groups at each stage in the protocol. Breathing rates for participants in the non-biofeedback groups (CRTL, MUS) decreased moderately during the Treatment phase, but returned to the original levels during the Driving+Treatment phase. In contrast, breathing rates for participants in the biofeedback groups (ABF, MBF) dropped below the 8 bpm target during the Treatment phase, and more importantly, remained at that level during the Driving+Treatment phase. Thus, both biofeedback interventions appear to be equally effective at encouraging slow breathing during visually demanding tasks.

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Plot 1300 of Fig. 13 shows the percent increase in HRV (relative to their levels during driving) for each of the four groups. Participants in the non-biofeedback groups showed similar HRV during the Treatment phase (or Driving+Treatment phase) than during the Driving phase, suggesting that neither music (MUS) nor the control (CTRL) group were able to reduce the participants' arousal levels. In contrast, participants in the two biofeedback groups had a large increase in HRV during the Treatment phase, and these levels were sustained during the Driving+Treatment phase.

These results must be interpreted with caution, since the two biofeedback groups manipulate respiration, and HRV tends to increase at low breathing rates because of respiratory sinus arrhythmia. For this reason, EDA is a better measure of arousal, since it has no direct connection with respiration, unless the breathing exercise does lead to relaxation. Plot 1200 of Fig. 12 shows the percent reduction in EDA (relative to its level during the Driving phase). Participants in the four groups (but particularly those undergoing biofeedback) showed a large reduction in EDA during the Treatment phase, which suggests that the four groups were successful in reducing arousal. Arousal levels during the Driving+Treatment phase return close to their values during the Driving phase for all groups except for MBF (music biofeedback), which still shows a large (40%) reduction in EDA. This result suggests that music biofeedback is more effective than auditory biofeedback

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(white noise when respiratory rate exceeds threshold) at lowering arousal during visually demanding tasks.

As a final measure, we compared task performance for each of the four groups. Results are shown in plot 1400 of Fig. 14 in terms of the reduction in the number of collisions during the Driving+Treatment phase (relative to their values during the Driving phase). Participants in the two music groups (MUS and MBF) had fewer collisions than those in the non-music groups (CTRL and ABF). Note the large error bar for the MUS condition, which indicates that the effects of music-biofeedback are more consistent across subjects than music alone.

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We have presented a tool for practicing relaxation exercises during visually demanding tasks. The tool allows the user to listen to their favorite music, and adapts it to encourage slow, deep breathing. We compared this music-biofeedback tool against auditory biofeedback (music without noise when target respiration rate achieved and with noise when target respiration rate not achieved vs. only white noise when target respiration rate not achieved), music and a control condition, with three physiological measures and performance on a car-racing simulation as dependent variables. When compared to the two non-biofeedback conditions, music biofeedback leads to fewer collisions during the Driving+Treatment phase and lower arousal levels across the three physiological measures. Music biofeedback and auditory biofeedback were comparable in terms of respiration, HRV and collisions. However, music biofeedback led to lower EDA levels (i.e., lower arousal) and led to more consistent performance across participants than auditory biofeedback. This suggests that music biofeedback is a viable stress-management intervention during driving and other visually demanding tasks.

Our results are based on a small sample size of college students (N=28), so further work is also needed to test the intervention on different demographics, particularly older adults and novice vs. experienced drivers. Further studies will also require more realistic and complex driving tasks (e.g., urban driving, unexpected events) than those afforded by the car racing simulator described herein.

For this study we used a sensor chest strap, but less cumbersome respiratory measurements are also possible. As an example, respiration rates can be measured with contact-free sensors (e.g., Doppler ultrasound) or estimated from webcams or smartphone cameras. In driving scenarios, respiratory sensors could also be integrated on car seats, and the music adaptation could be implemented on the car audio system.

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In a fourth embodiment, an auditory biofeedback method 1500, modelled schematically in Fig. 15, is used as a tool for stress management biofeedback that encourages slow breathing by adjusting the quality of a music recording in proportion to the user's respiration rate. A first form of acoustic degradation adds white noise to the recording if the user's breathing deviates from the target rate. A second form of acoustic degradation reduces the number of channels in a multi-track recording if the user's breathing deviates from the target rate. Other forms of acoustic degradation may be, for example, bandwidth of the music, tempo of the music, key of the music, intermittency during playback of the music, and pausing during playback of the music. Validation on a small user study indicates that both techniques are equally effective at reducing respiration rates while performing a secondary task, although user feedback indicates that additive noise is a more intuitive form of sonification.

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Several techniques may be used to help individuals reduce the impact of stress, such as meditation, deep breathing and biofeedback. Among these, deep or diaphragmatic breathing (DB) is an easy and intuitive evidence-based method for stress management. DB addresses the autonomic nervous system (ANS) imbalance that arises following exposure to a stressor and activation of the sympathetic 'fight-or-flight' response. As DB recruits the parasympathetic ANS branch, action of the sympathetic branch becomes inhibited, leading to a calmer, more relaxed state. Many of the stress management programs delivered in workplace settings demonstrate that DB substantially reduces the symptoms of stress. As with many other stress-management interventions, however, DB requires a substantial time commitment.

The present Sonic Respiration method is a biofeedback tool that may be used to make the DB practice more appealing and pleasant to the user. Sonic Respiration allows the user to perform DB while enjoying their favorite sound track. As their respiration approaches a breathing rate with known therapeutic benefits (e.g., 6 breaths per minute), the quality of the sound improves. In this fashion, users are encouraged to slow down their breathing and maintain it. We tested two implementations of the approach, one that increases the amount of additive white noise as the user's breathing deviates from the target rate, and a second implementation that reduces the fullness of the audio track by eliminating channels in a multi-track recording.

Using the method 1500, Sonic Respiration teaches users to slow down their breathing while they enjoy their favorite tunes. Rather than using a pacing signal, Sonic Respiration manipulates the quality of the music to guide users towards a breathing rate that maximizes

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their heart rate variability (HRV). The method would not require external hardware beyond an inconspicuous wearable sensor, it could be used anytime/anywhere, and it would allow users to personalize auditory feedback to match their music preferences.

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The present design, Sonic Respiration, includes an Android app running on a smartphone (HTC EVO 4G) with Android 2.3.3 that communicates with a Bluetooth-based thoracic respiratory sensor (BioHarnessTM, ZephyrTM Technology Corp). The app provides audio output that is modified, depending on the user's breathing rate. The relationship between the user's breathing rate and the two audio modifications is illustrated in plot 1600 of Fig. 16.

The track-layering technique phases audio channels in/out from a multi-track recording. When the user breathes at a target slow rate (defined as 5.5–6.5 bpm) the audio contains all the channels in the recording. As the user gets further from this rate, channels are incrementally phased out, reducing the richness of the audio. These channels are added back as the user returns to the proper breathing rate. The phasing is done seamlessly without any noticeable audio artifacts. Track layering requires multi-track recordings, where each instrument is recorded in a separate track. This makes the technique ill-suited for personal audio collections, which generally consist of commercial stereo recordings.

As the name suggests, noise-addition adds white noise to the audio recording. When the user is at the target breathing rate, the audio contains no white noise. The more the user deviates from this rate, the higher the amplitude of the white noise, which, in turn, reduces the perceived quality of the recording. In contrast with track layering, noise-addition can work with any recordings in the user's personal music library. This provides maximum customization and the ability to practice for long periods without repeating the same audio track(s) over and over.

Our choice of a target rate of 6 bpm is motivated by prior psychophysiological studies that indicate that heart rate variability is maximized when the breathing cycle has a duration of 10 seconds (i.e., a breathing rate of 0.1 Hz or 6 bpm). Our prior work has also shown that this target breathing rate reduces arousal levels, as measured by heart rate variability (HRV) and electrodermal activity (EDA).

We administered a user study to evaluate the effectiveness of the two audio manipulation techniques at lowering respiration rates. We compared these results against the initial respiration rate of the users, which served as the baseline.

For the study, we used the same song for both auditory feedback modes and for all subjects. The song chosen was 'On the Line' by James May. The recording contained 14

tracks, of which two were vocal and were omitted to ensure that the song did not interfere with a secondary task (reading). The full track (remaining 12 channels) was used for the noise-addition manipulation. To simulate a typical work scenario, users were given a piece of literature to read while using Sonic Respiration.

For this study, the book "Sweets: A History of Candy" was provided, which was chosen as to not cause any external arousal.

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Participants (N=6; 2 males; ages 20-59) were informed of the process of the study, and then completed a consent form if they were willing to participate. The experimental protocol consisted of a calibration (2 minute) step where participants were allowed to practice slow breathing at the optimal rate of 6 bpm using a free Android app (Paced Breathing) that provides an audiovisual pacing signal, a baseline (5 minute) step where participants were asked to read the provided literature while their baseline respiration rate was collected, a treatment #1 (5 minute) step where participants used one of the two Sonic Respiration modifications while they continued to read the provided literature, a break (2 minute) step where participants took a break from the reading and the Sonic Respiration app, and a treatment #2 (5 minute) step where participants used the second Sonic Respiration modification while they resumed reading of the provided literature.

The order of presentation of the two modifications was counterbalanced across participants. Users completed a short survey regarding their perceived effectiveness of the app, and their attitude toward each audio manipulation technique. This survey also contained basic health data, familiarity with relaxation techniques, and the user's opinion toward the study, biofeedback, procedure, and choice of wearable sensor.

The first research question our analysis serves to answer is "Does Sonic Respiration feedback lead to a reduction in breathing rates?" Experimental results are summarized in Table 4.

Table 4: Average Breathing Rate and Standard Deviation

Mode	Breathing Rate
Baseline	13.54 (2.38)
Noise addition	8.47 (2.81)
Track layering	8.18 (2.30)

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Respiration rates with Sonic Respiration were lower than those at baseline, regardless of the auditory manipulation. Differences between baseline and either manipulation were statistically significant (BSLN-NA:p=0.007; BSLN-TL:p=0.010; paired t-tests).

The second research question was, "Which audio manipulation leads to the lowest respiration rates?" Respiration rates for the track-layering condition were lower than those in the noise-addition condition, but the difference was not statistically significant (BSLN-TL:p=0.68; paired t-test). As we will see, however, most users felt that Additive Noise was more effective than Track Layering.

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Plots 1700 and 1800 of Figs 17 and 18, respectively, show the evolution of the respiration rate for two of the study participants. During the baseline phase, the breathing rate doubles and triples from the optimal rate of 6 bpm (as practiced during the initial calibration phase). During the second phase, both participants are able to bring their respiration to the optimal rate and maintain it. The same result is observed during the third phase. The spike at the beginning of the three phases suggests that the participants are not used to breathing at the slower rate, so in the absence of a pacing signal (as is the case during baseline or the breaks), their breathing tends to return to a higher rate.

Analysis of the surveys shows that most participants preferred Noise Addition over Track Layering. Participant P2 wrote: "The white noise was more noticeable and was more effective in helping me regulate my deep breathing". Participant P1 shared this sentiment: "I felt that the 2nd (white noise) was more effective. This one was clearer in alerting me of poor breathing. The other was easy to be confused with thinking what was playing with bad breathing was simply the normal song."

When asked if using the app made users feel good, participant P2 commented: "Yes. More relaxed", which was similar to participant P1's response: "Yes the app makes me focus on my breathing, calming me down". Similarly, participant P4 noted: "Yes, I felt good by breathing correctly, calm, relaxed."

Most participants reported that they would use the app regularly, with timeframes ranging from P3's "4-6 times daily" to P4's "Maybe every couple of weeks," with "daily" being the most common answer. Participant P1suggested using the app "...at work, to improve my productivity", whereas P3 would use it "before meetings, short work breaks, before driving," and P6 "while running," the latter an application scenario that we had not considered.

Preliminary results have been presented that suggest Sonic Respiration may be an effective tool to help users lower their respiration rates. The results show that users were able

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to reduce their respiration by over 40%, in many cases reaching the target rate of 6 breaths per minute. The two acoustic manipulations appear equally effective at lowering respiration rates, although user feedback indicates that Noise Addition is a more intuitive form of respiratory sonification. As noted by the participants, the Track Layering technique requires familiarity with the song in order to determine whether all the tracks are being played.

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Additional work is needed to validate the approach on a larger sample size, and to establish dosage and persistence effects. Although slow/deep breathing often leads to relaxation, future experiments will need to assess the effectiveness of Sonic Respiration by measuring changes in HRV and EDA, as we have done in prior studies. Future work will also test the effectiveness of different music genres in eliciting slow breathing patterns. A few participants indicated that the wearable sensor was bulky and inconvenient. Work is underway to eliminate the need for an external sensor by measuring respiration directly from the smartphone camera via photoplethysmography.

It is to be understood that the present invention is not limited to the embodiments described above, but encompasses any and all embodiments within the scope of the following claims.

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CLAIMS

We claim:

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1. A training device for reducing stress, comprising:

a housing;

an electronic display mounted in the housing;

a processor mounted in the housing, the processor being connected to the display;

a computer readable medium mounted in the housing, the computer readable medium being connected to the processor, the computer readable medium having software stored thereon executable by the processor, the software including:

means for conducting an electronic video game on the electronic display; and means for adjusting a parameter of the game to increase the difficulty of winning the game;

means for continuously receiving a signal from a biofeedback sensor configured for measuring a stress-related physiological variable of a trainee using the training device; and

a proportional-integral-derivative controller connected to the means for receiving the signal from the biofeedback sensor and connected to the processor, the proportional-integral-derivative controller having means for automatically activating the means for adjusting the game parameter to increase the difficulty of the game when the signal from the biofeedback sensor does not meet a targeted level of the stress-related physiological sign consistent with relaxation.

- 2. The training device according to claim 1, further comprising the biofeedback sensor configured for measuring a stress-related physiological sign of a trainee using the training device.
- 3. The training device according to claim 1, wherein the stress-related physiological sign comprises the trainee's breathing rate.
- 4. The training device according to claim 3, wherein said proportional-integralderivative controller is programmed to activate the means for adjusting the game parameter to proportionally increase the difficulty of winning the game when the signal from the biofeedback sensor corresponds to a breathing rate greater than about six breaths per minute.
- 5. The training device according to claim 1, wherein said means for continuously receiving a signal from a biofeedback sensor comprises a Bluetooth module.
- 6. The training device according to claim 1, wherein said training device comprises a smartphone.

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7. The training device according to claim 1, where said proportional-integralderivative controller comprises means for adjusting the difficulty of the game according to a formula characterized by:

$$d(t) = K_p \varepsilon(t) + K_d d\varepsilon(t) / d(t) + K_i \int_0^t \varepsilon(t) d\tau$$

$$\varepsilon(t) = \begin{cases} b(t) - b_0 & (b(t) > b_0) \land (b(t) > b(t-1)), \\ 0 & \text{otherwise} \end{cases}$$

- where d(t) is a difficulty level in the game, and $\varepsilon(t)$ is an error in a current respiratory rate b(t) of the trainee relative to a desired rate b_0 , K_p is a proportional gain increasing the game difficulty when the respiratory rate is higher than the desired rate, K_d is a derivative gain adjusting the game difficulty based on a rate of change in the subject's respiration, and K_i is an integral gain that adjusts the game difficulty based on the accumulated error in respiration rate over time.
 - 8. A stress relief training method, comprising the steps of:

attaching at least one biofeedback sensor to a human subject, the biofeedback sensor producing a signal corresponding to a physiological response to stress;

providing the human subject with an audio transducer connected to a music playback device;

providing a processing device having means for selectively altering sound quality of music played back by the music playback device;

playing music on the music playback device while the subject engages in an unrelated task;

continuously receiving the signal corresponding to the physiological response to stress at the processing device while the subject is engaging in the unrelated task;

comparing the received signal with reference values to determine stress levels associated with the physiological response, the comparing being done automatically by the processing device;

degrading the sound quality of the music being played back to the human subject in proportion to the stress level when the stress level is elevated, the degrading being done automatically by the processing device; and

enhancing the sound quality of the music being played back to the human subject in proportion to the stress level when the stress level is relaxed, the enhancing being done automatically by the processing device.

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- 9. The stress relief training method according to claim 8, wherein said biofeedback sensor comprises a respiratory sensor for monitoring the human subject's breathing rate.
- 10. The stress relief training method according to claim 9, wherein said stress level is elevated when the human subject's breathing rate is greater than about 6 breaths per minute and said stress level is relaxed when the human subject's breathing rate is up to about 6 breaths per minute
- 11. The stress relief training method according to claim 9, wherein said step of producing a signal corresponding to a physiological response to stress further comprises the step of transmitting the signal by a wireless transmission protocol.
- 12. The stress relief training method according to claim 11, wherein said wireless transmission protocol comprises Bluetooth.
- 13. The stress relief training method according to claim 8, wherein said unrelated task comprises performing deep breathing exercises.
- 14. The stress relief training method according to claim 8, wherein said unrelated task comprises a visually demanding task.
- 15. The stress relief training method according to claim 14, wherein said visually demanding task comprises reading.
- 16. The stress relief training method according to claim 14, wherein said visually demanding task comprises driving.
- 17. The stress relief training method according to claim 8, wherein said means for selectively altering sound quality comprises means for selectively increasing and decreasing signal-to-noise ratio, thereby selectively removing white noise from the music playback to enhance the sound quality and selectively adding white noise to the music playback to degrade the sound quality.
- 18. The stress relief training method according to claim 8, wherein said means for selectively altering sound quality comprises means for selectively increasing and decreasing channels being played back from a multi-track recording, thereby increasing the channels to enhance the sound quality and decreasing the channels to degrade the sound quality.
- 19. The stress relief training method according to claim 8, wherein said processing device is housed within a smartphone.

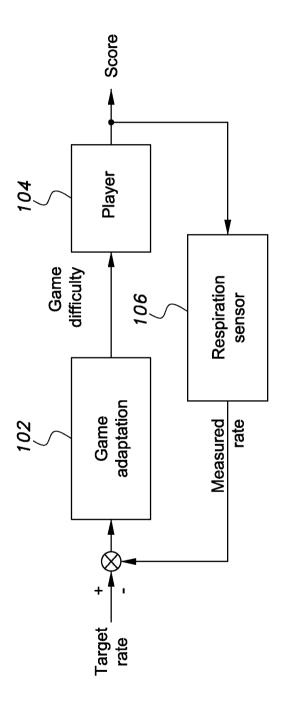
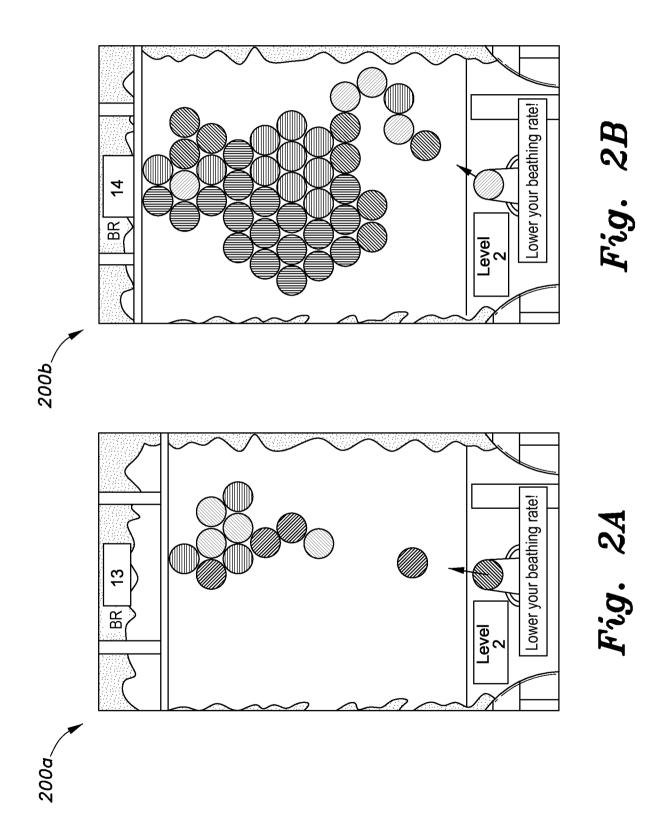
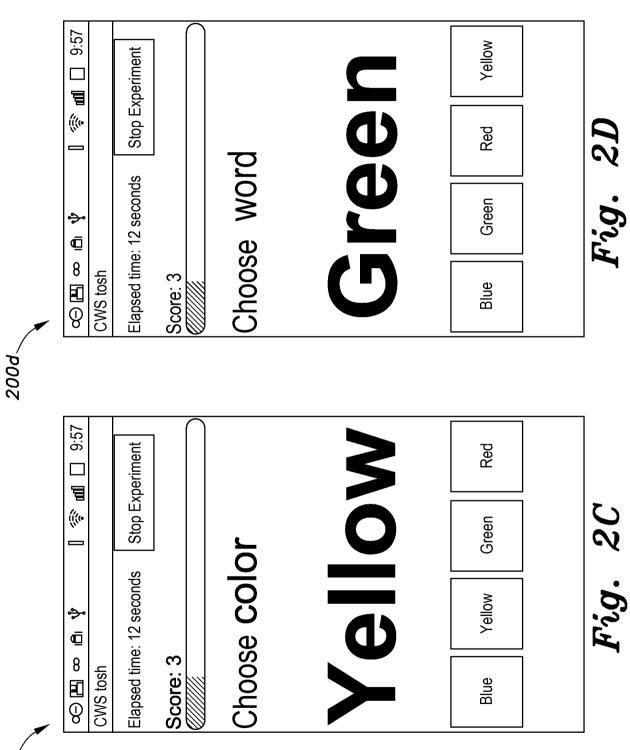
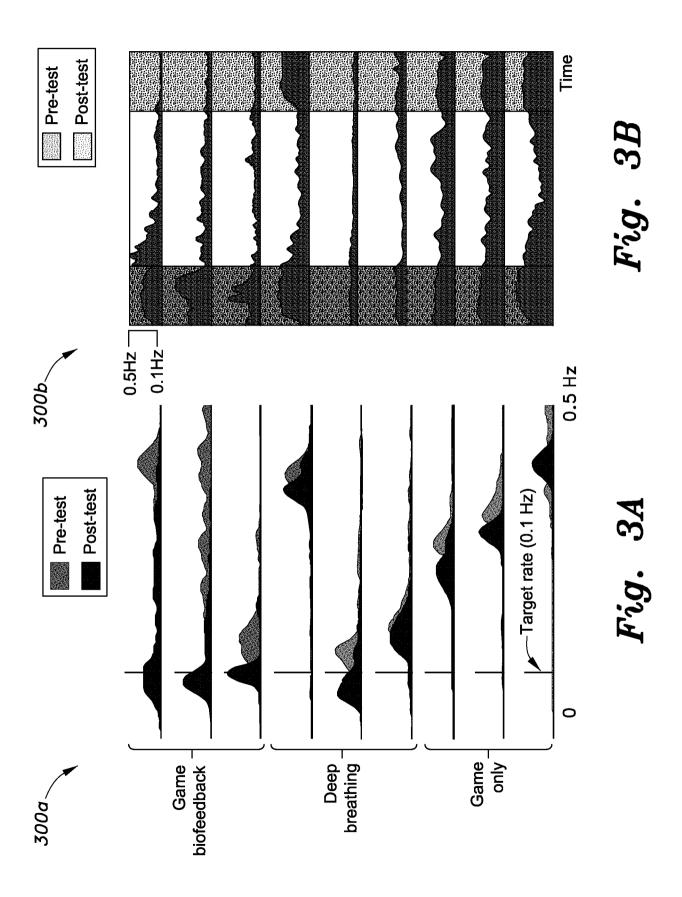


Fig. 1







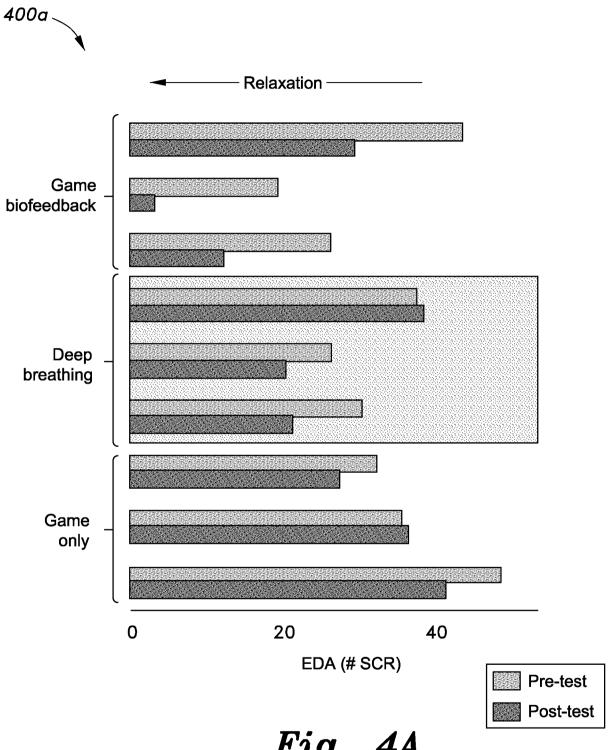


Fig. 4A

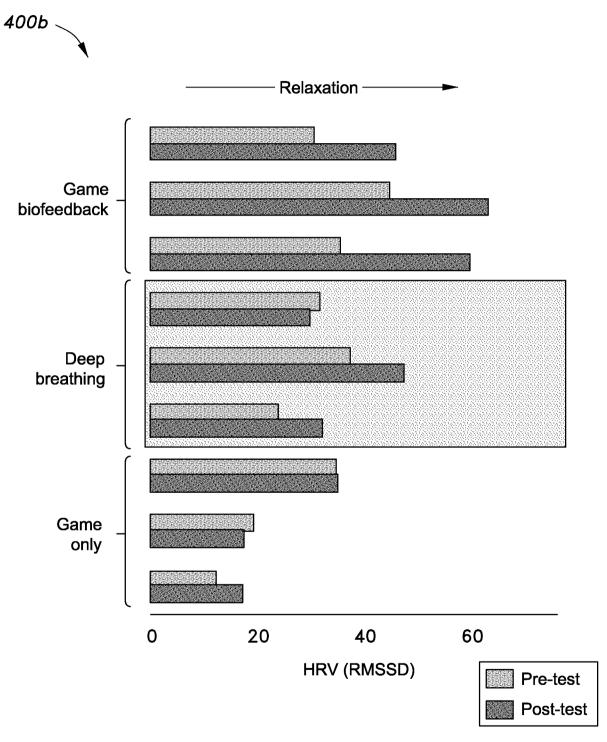


Fig. 4B



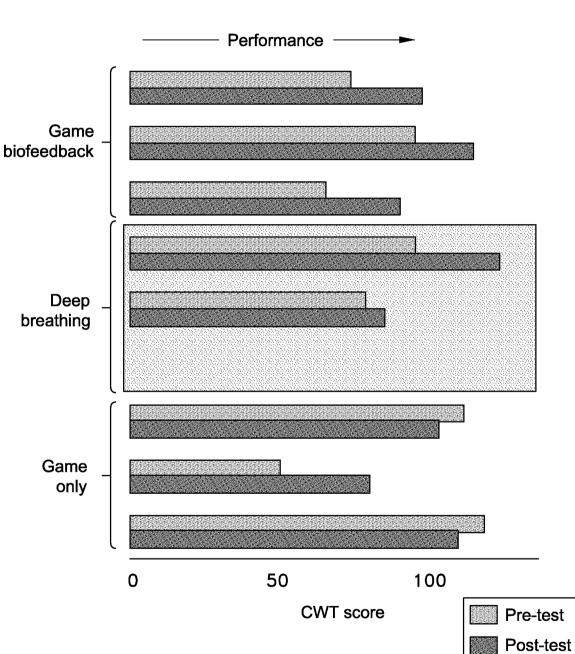
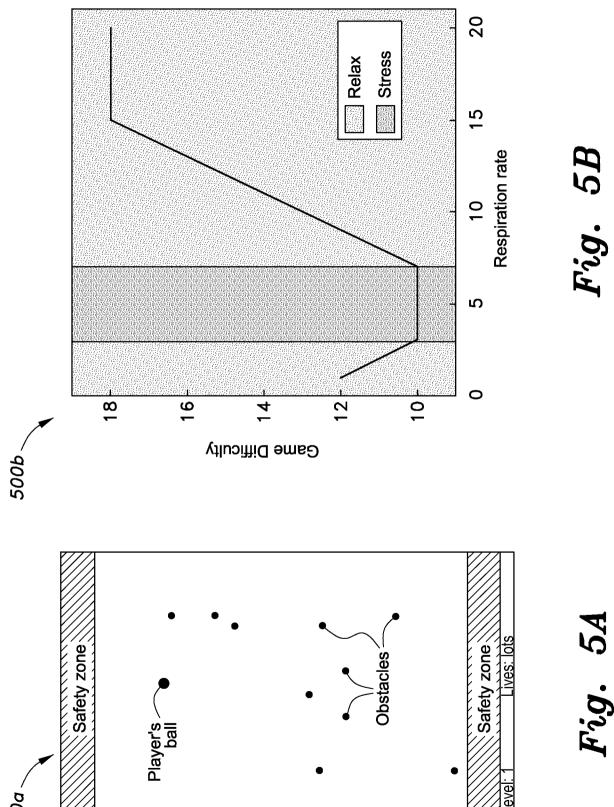
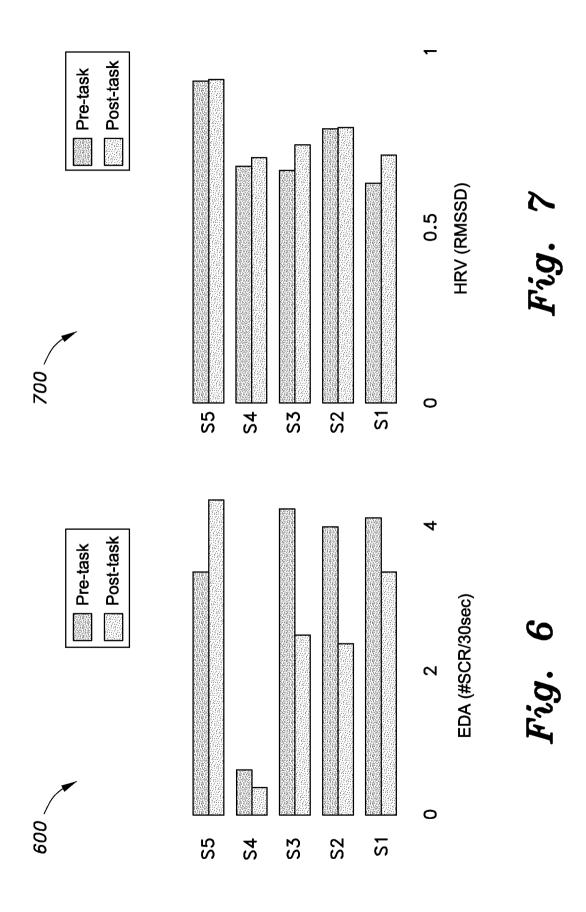
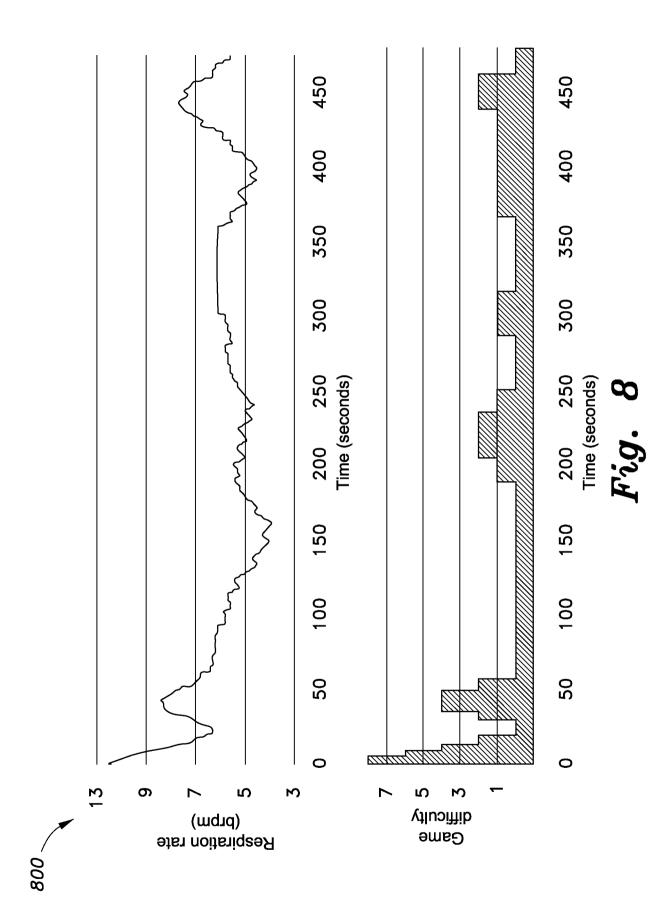


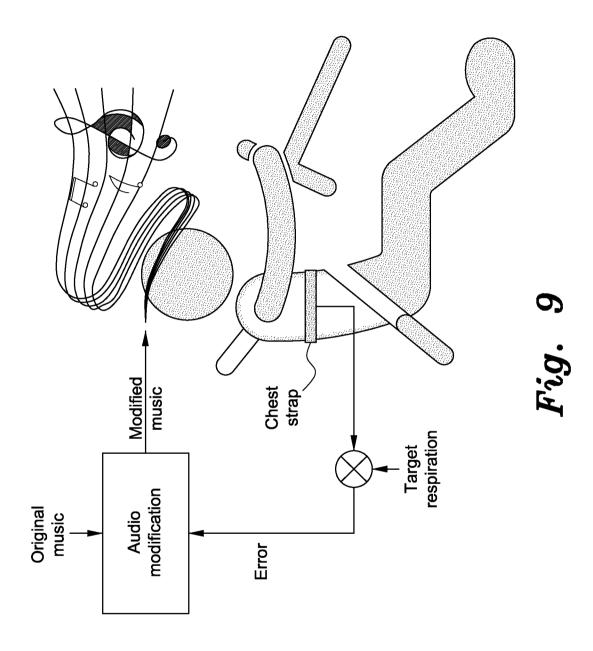
Fig. 4C



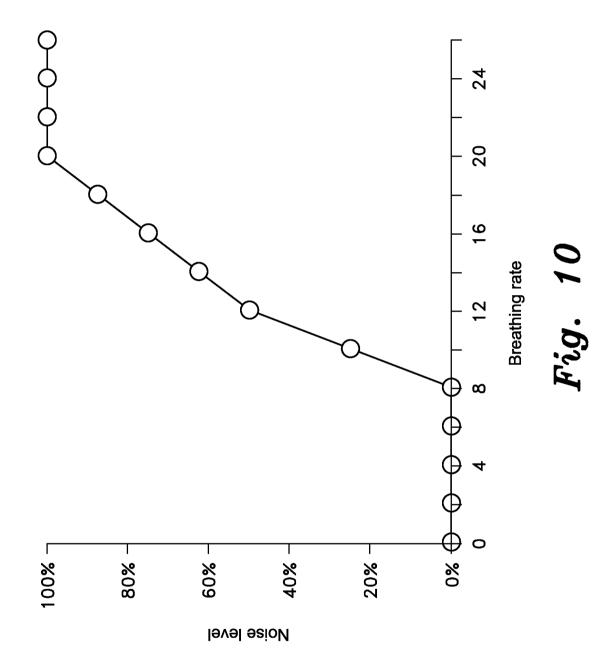
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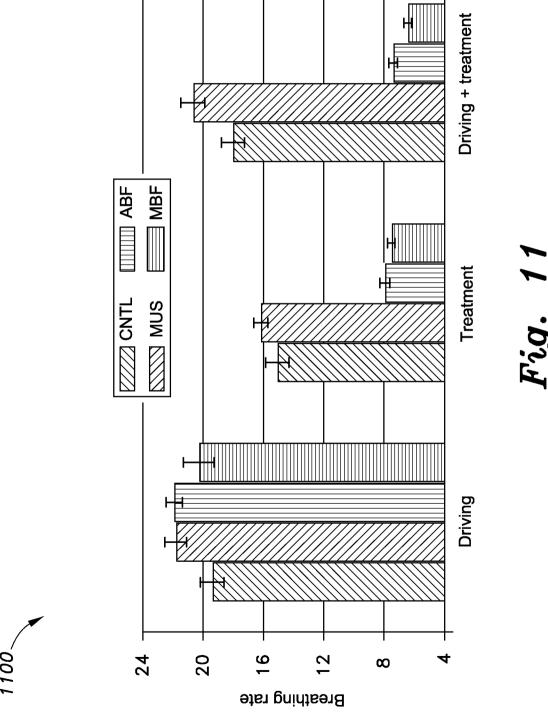


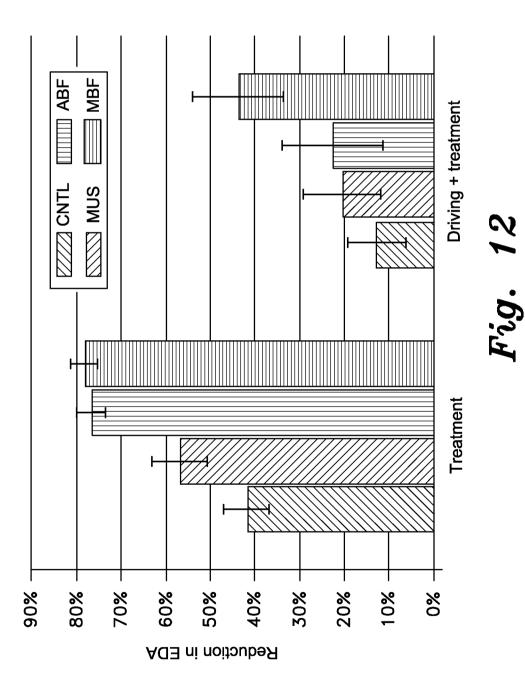




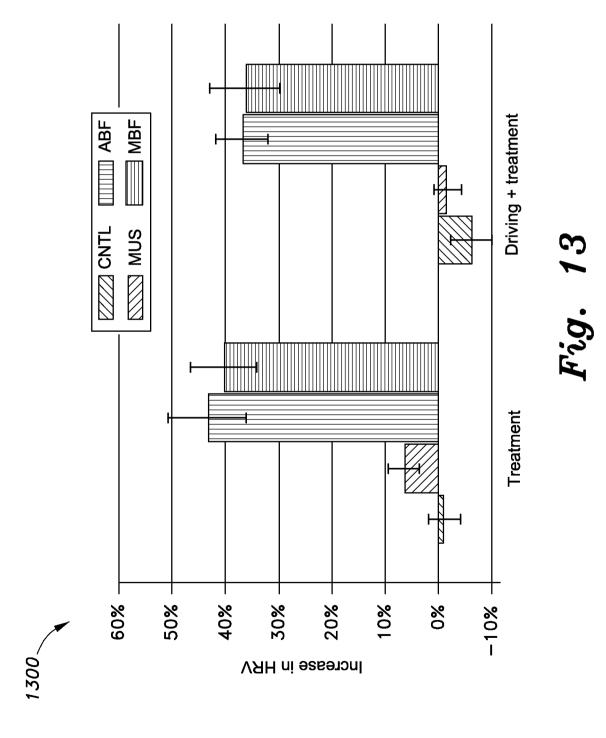


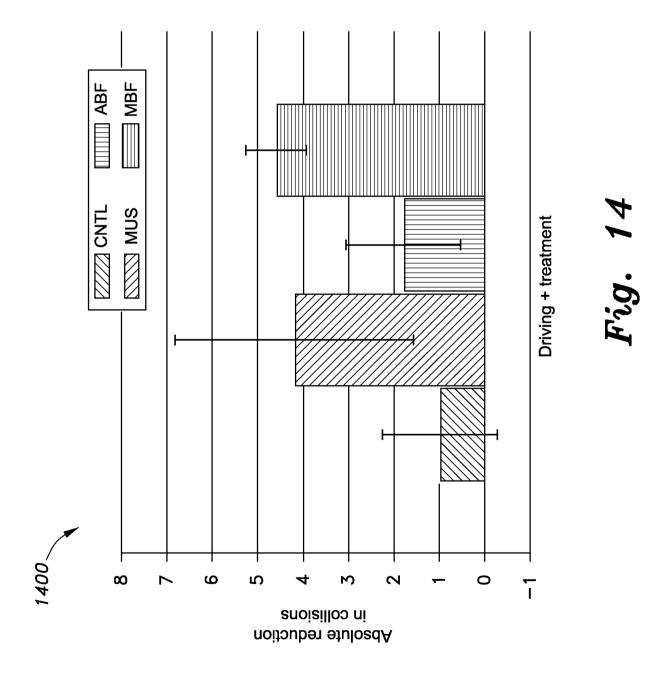


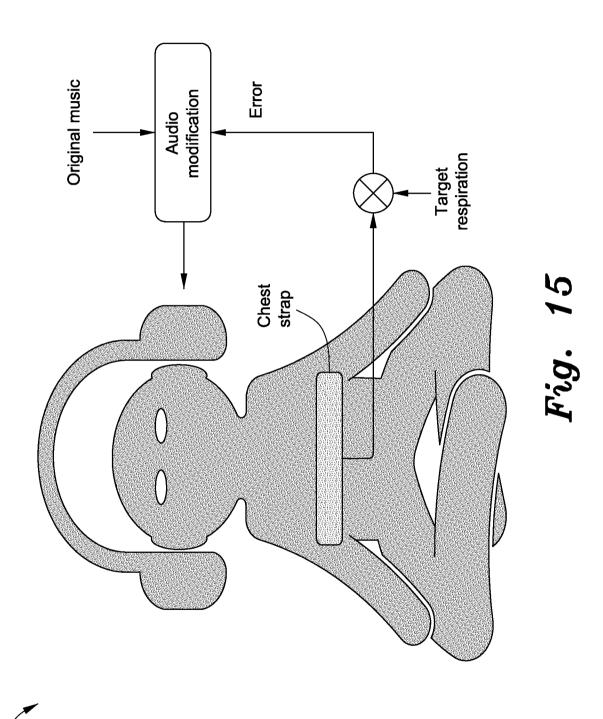




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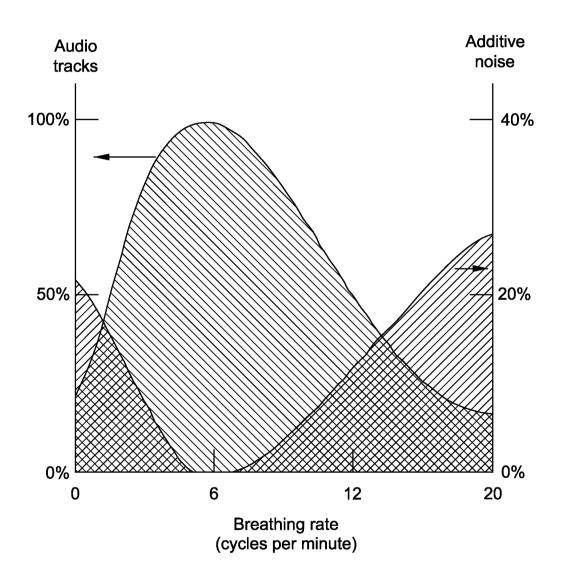
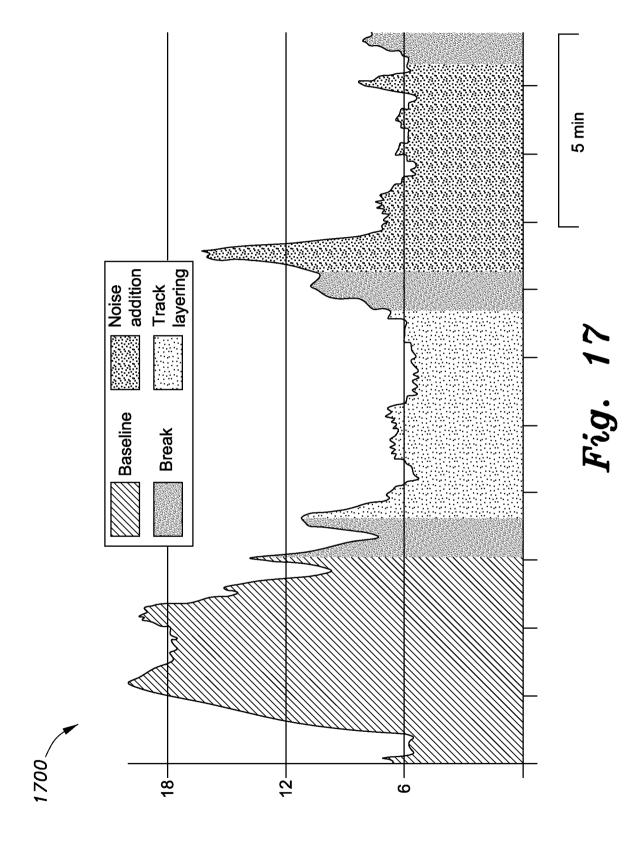
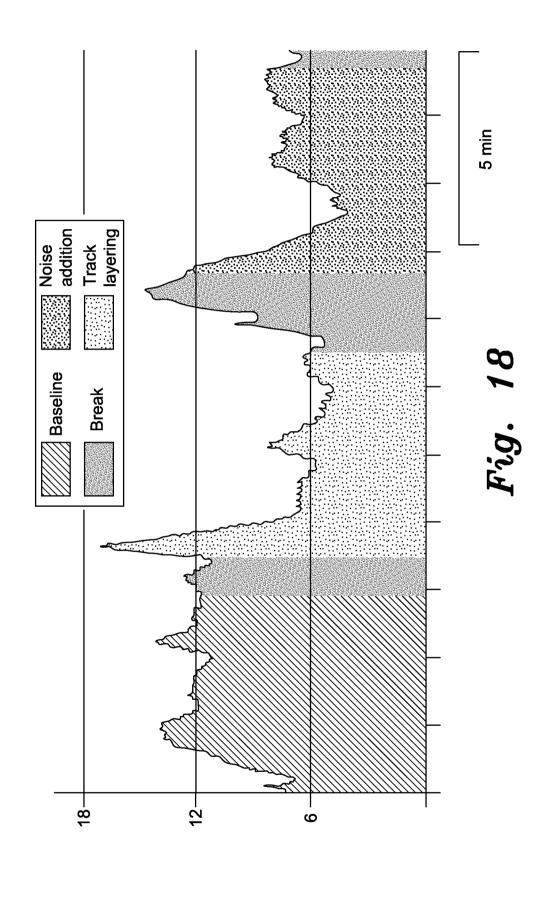


Fig. 16





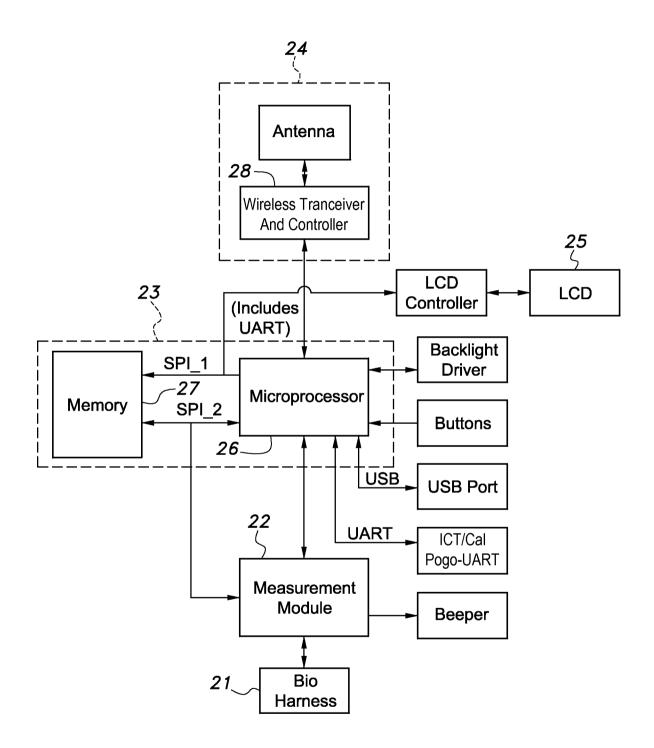


Fig. 19

International application No. **PCT/US2015/051895**

A. CLASSIFICATION OF SUBJECT MATTER

A61M 21/00(2006.01)i, G09B 19/00(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) A61M 21/00; H04R 1/02; G06F 17/00; A63F 9/24; A61B 19/00; A61B 5/00; G09B 19/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) eKOMPASS(KIPO internal) & Keywords: stress relief, housing, display, processor, computer readable medium, means for receiving signal, controller

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014-0141395 A1 (INTERCURE LTD.) 22 May 2014 See paragraphs [0319], [0322], [0333], [0343]-[0348]; figures 7-10.	1-3,5,6
A	see paragraphs [0013], [0022], [0033], [0040], [10040], figures 1 10.	4,7
A	US 2003-0149344 A1 (NIZAN, Y.) 7 August 2003 See entire document.	1-7
A	US 5678571 A (BROWN, S. J.) 21 October 1997 See entire document.	1-7
A	US 6144954 A (LI, C. H.) 7 November 2000 See entire document.	1-7
A	US 2012-0051579 A1 (COHEN, D. E.) 1 March 2012 See entire document.	1-7

	l .			
	Further documents are listed in the continuation of Box C.		See patent family annex.	
*	Special categories of cited documents:	"T"	later document published after the international	al filing date or priority
"A"	document defining the general state of the art which is not considered		date and not in conflict with the application	
	to be of particular relevance		the principle or theory underlying the invention	on
"E"	earlier application or patent but published on or after the international	"X"	document of particular relevance; the claimed	invention cannot be
	filing date		considered novel or cannot be considered to	involve an inventive
"L"	document which may throw doubts on priority claim(s) or which is		step when the document is taken alone	
	cited to establish the publication date of another citation or other	"Y"	document of particular relevance; the claimed	l invention cannot be
	special reason (as specified)		considered to involve an inventive step whe	en the document is
"O"	document referring to an oral disclosure, use, exhibition or other		combined with one or more other such docum	nents, such combination
	means		being obvious to a person skilled in the art	
	document published prior to the international filing date but later	"&"	document member of the same patent family	
	than the priority date claimed			
Date	of the actual completion of the international search	Date	e of mailing of the international search repo	ort
	30 November 2015 (30,11,2015)		05 January 2016 (05.0	11 2016)
	30 November 2013 (30.11,2013)		03 January 2010 (03.0	1.2010)
Nam	e and mailing address of the ISA/KR	Autl	horized officer	The same of the sa

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Form PCT/ISA/210 (second sheet) (January 2015)

Facsimile No. +82-42-472-7140

International Application Division Korean Intellectual Property Office

189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea

International application No.

Box No. II	Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)
This interna	tional search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
beo C	aims Nos.: 8-19 cause they relate to subject matter not required to be searched by this Authority, namely: laims 8-19 pertain to methods for treatment of the human body and thus relate to a subject-matter which this International earching Authority is not required under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv) to search.
□ be	aims Nos.: cause they relate to parts of the international application that do not comply with the prescribed requirements to such an tent that no meaningful international search can be carried out, specifically:
	aims Nos.: cause they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box No. III	Observations where unity of invention is lacking (Continuation of item 3 of first sheet)
This Interna	tional Searching Authority found multiple inventions in this international application, as follows:
1 \square As	all required addtional search fees were timely paid by the applicant, this international search report covers all searchable
	ims.
	all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment any additional fees.
	only some of the required additional search fees were timely paid by the applicant, this international search report covers ly those claims for which fees were paid, specifically claims Nos.:
	required additional search fees were timely paid by the applicant. Consequently, this international search report is tricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark or	The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee. The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation. No protest accompanied the payment of additional search fees.

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