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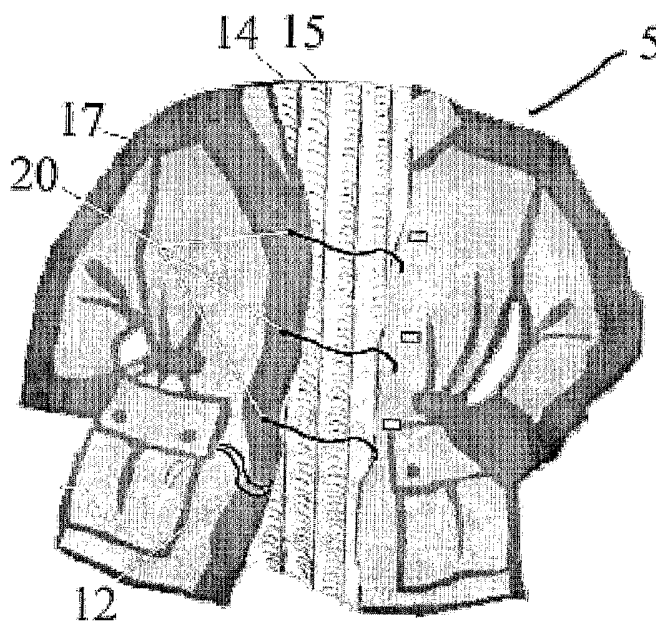
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(54) Title: WEARABLE SOOTHING SYSTEM



(57) Abstract: The invention provides a system for reducing and/or preventing anxiety in an individual in need comprising: a non-restraining apparel adapted for applying varying pressure to at least one selected body part of the individual; means measuring at least one physiological parameter indicative of the individual's anxiety level; and means for applying pressure by the apparel in varying degrees and for varying periods of time to at least one selected body part of the individual. The system is particularly useful for soothing and pacifying individuals suffering from a sensory modulation disorder such as autism.

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WEARABLE SOOTHING SYSTEM

FIELD OF THE INVENTION

The present invention relates to a wearable system for reducing anxiety,
5 particularly in individuals affected with a sensory modulation disorder, e.g. autism,
by application of a controlled pressure on selected body parts.

BACKGROUND OF THE INVENTION

Generally, subjects who are diagnosed with Pervasive Developmental
Disorders (PDD), Attention Deficit Disorder (ADD) and Attention Deficit
10 Hyperactivity Disorder (ADHD), have a Sensory Modulation Disorder (SMD) (see.
Baranek, G.T., Foster, L.G., & Berkson, G. (1997). Sensory defensiveness in
persons with developmental disabilities. *Occupational Therapy Journal of
Research*, 17, 173-185; Case-Smith, J., & Bryan, T. (1999). The effects of
occupational therapy with sensory integration emphasis on preschool age children
15 with autism. *American Journal of Occupational Therapy*, 53, 489-497; Case-Smith,
J. & Miller, H. (1999). Occupational therapy with children with pervasive
developmental disorders. *American Journal of Occupational Therapy*, 53, 506-513).

Five disorders are identified under the category of Pervasive Developmental
Disorders: (1) Autistic Disorder, (2) Rett's Disorder, (3) Childhood Disintegrative
20 Disorder, (4) Asperger's Disorder, and (5) Pervasive Developmental Disorder Not
Otherwise Specified, or PDDNOS. Autism is a condition manifesting in early
childhood and characterized by marked abnormalities in communication and social
interactions and a restricted and socially atypical range of interests. Autism and
PDD are developmental disabilities that share many of the same characteristics.
25 Usually evident by age three, autism and PDD are neurological disorders that affect
a child's ability to communicate, understand language, play, and relate to others.
Many children may seem underresponsive or overresponsive to sensory stimuli.
Some children avoid gentle physical contact, yet react with pleasure to rough-and-
tumble games. Asperger disorder is another form of pervasive developmental

disorder characterized by severe persistent impairment in social interactions, repetitive behavior patterns, and restricted interests

Autism (sometimes called “classical autism”) is the most common condition in a group of developmental disorders known as the autism spectrum disorders (ASDs). Many children with autism have a reduced sensitivity to pain, but are abnormally sensitive to sound, touch, or other sensory stimulation. These unusual reactions may contribute to behavioral symptoms such as a resistance to being cuddled or hugged.

There is no known cure for PDD. Medications are used to address specific behavioral problems; therapy for children with PDD should be specialized according to need. During adolescence, some children with autism may become depressed or experience behavioral problems. Doctors often prescribe an antidepressant medication to handle symptoms of anxiety, depression, or obsessive-compulsive disorder. Anti-psychotic medications are used to treat severe behavioral problems. Seizures can be treated with one or more of the anticonvulsant drugs. Stimulant drugs, such as those used for children with attention deficit disorder (ADD), are sometimes used effectively to help decrease impulsivity and hyperactivity.

It is commonly held that we have five senses: touch - taste - smell - hearing - vision. These basic senses or “far senses” respond to external stimuli from the environment. The truth is, we have many more senses than that. Some hold that we can divide the senses into internal and external senses: that the “sense of well-being” is a sense too, but an internal one. So too “homeostasis” or the sense of having returned to even keel, essential for the regulation of temperature, heart rate, and breathing.

The therapy approach that is more commonly used with children with PDD and autism – estimated over 80% of occupational therapy clinical treatments today - is based on Sensory Integration (SI) principles, but is more correctly called sensory modulation or sensory processing therapy. It differs in that the focus is more on altering the child's sensory environment to help them to modulate the sensory input

they are receiving and to maximize their performance. This may include changes such as: modification of the child's clothing, altering room configurations, noise or light levels or experimenting with food textures. There are also treatment protocols that take a more active approach such as those developed by Wilbarger (1995) that
5 promote the use of increased sensory input e.g., deep pressure to reduce hypersensitivity in addition to the modifications in the child's environment.

Several devices and methods are known in the art in order to apply pressure to the body of the patient. Holding or squeezing techniques can be used by a therapist or caretaker. The therapist holds the patient and squeezes him or her firmly
10 but in a controlled manner. This technique involves human touch, application of force and some elements of control. Application of human touch between a therapist and patient raises strong ethical issues.

Restraining devices are used mostly when a person might cause damage to himself or his surroundings. These devices do not soothe the user, they just limit his
15 movements and their usage requires permits.

Dr. Temple Grandin, an Associate Professor of Animal Science at Colorado State University, is an adult with autism, who has described her severe anxiety and how her discovery of deep pressure ultimately helped her reduce the anxiety's debilitating effects. During her childhood years, Temple would crave deep pressure
20 and would crawl under sofa cushions or wrap herself in blankets to provide pressure. She stated that she could not obtain the 'right' amount of pressure from people because they either gave her too much deep pressure or too little. As a teenager, Temple observed cattle being branded in a squeeze chute at a relative's farm and noticed that they immediately calmed down after pressure was
25 administered to them in the chute. She then reasoned that the deep pressure from the chute led to an overall calming effect and thought it might be able to settle her 'over-stimulated nerves.' She then built her own device which is referred to as the 'Hug Box,' the 'Hug Machine,' the 'Squeeze Machine,' or the 'Squeeze Box.' (see Edelson, S. M., Edelson, M.G., Kerr, D., & Grandin, T. (1999). Behavioural and
30 physiological effects of deep pressure on children with autism: A pilot study

evaluating the efficacy of Grandin's hug machine. *American Journal of Occupational Therapy*, 53, 145-152). Temple also developed devices designed to apply pressure and reduce anxiety in animals (US 5,906,540).

The Squeeze Machine is made of two padded side-boards which are hinged near the bottom to form a V- shape. The user needs to crawl in the machine and then lie down or squat inside the V. By using a lever, the user or caretaker engage an air cylinder, which pushes the side-boards together. This action provides the deep pressure stimulation evenly across the lateral parts of the body. Some individuals prefer long squeezes while others prefer rather short squeezes.

The Squeeze Machine or Hug Box is a stationary, heavy, expensive device that is typically only available at a clinic. It also requires the user to remain in an awkward position. It would be desired to provide a portable and affordable device that can be acquired and used by each patient whenever the need arises.

It has been demonstrated that stimulating the nervous system at periodic low frequencies (below 3Hz) can create sleep, relaxation and other effects in any subject (as described for example, in US Patent No. 5,782,874).

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a non-restraining, lightweight, low cost wearable device that uses mildly applied pressure to soothe and pacify individuals suffering from anxiety, in particular individuals suffering from a sensory modulation disorder such as autism.

The present invention thus relates to a system for reducing and/or preventing anxiety in an individual in need, said system comprising:

- (i) a non-restraining apparel adapted for applying varying pressure to at least one selected body part of said individual;
- (ii) means measuring at least one physiological parameter indicative of said individual's anxiety level; and

- (iii) means for applying pressure by said apparel in varying degrees and for varying periods of time to at least one selected body part of said individual, wherein the degree of pressure applied and the time period said pressure is applied are wholly or partially based on the value of said measured at least one physiological parameter, in order to reduce and /or prevent the anxiety level in said individual in need.

The apparel is typically an inflatable vest worn including a plurality of cells applying pressure to the right and left sides of the individual's torso. Pressure is applied rhythmically with alternating periods of pressure and rest. It is important for the apparel not to be a restraining apparel, so that usage of the apparel does not require legal authorization.

According to the invention, it is important to be able to scientifically measure or appreciate the degree of anxiety of a person in need, and the effectiveness of the pressure applied. The present invention encompasses measurement of one or more physiological parameters that are indicative of a person's stress or anxiety level. Such physiological parameters include, but are not limited to, heart rate, body temperature, galvanic skin response, differences in finger temperature, frontalis muscle activity, cardiovascular activity, blood pressure, pupils expansion, sweat, electrodermal responses, muscle tension, respiratory rate and amplitude, brain wave or any combination thereof.

When the individual in need wears the apparel, pressure is applied with varying degrees of strength and for varying degrees of time. The apparel can be made of multiple cells, wherein each cell can be regulated with its individual degree of pressure, and its individual time period for which said pressure is applied.

The system calculates the degree of pressure to be applied and its length of time based partially or wholly on at least one of the physiological measures obtained. Additionally, the system can take into consideration other personal parameters such as the person in need's age, gender, weight, height, medical history,

treatment history, individual preference or any other parameter that has a relation to the level of anxiety or to the effectiveness of the pressure applied. The pressure level and the time period are responsive to said one or more physiological parameters such as to provide the individual with a sense of well-being and
5 soothing him as needed.

Pressure can be applied using means including gas, liquid, solid mechanical means or any combination thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

10 **Fig. 1** illustrates a system for applying pressure to the upper body of a human being.

Fig. 2 is a schematic illustration of an outer layer and inflatable cells of the system.

Fig. 3 is a schematic illustration of an end view of the outer layer and the
15 inflatable cells of Fig 2.

Fig. 4 is a flow diagram showing how pressure is applied based on reading of the pulse.

DETAILED DESCRIPTION OF THE INVENTION

In the following detailed description of various embodiments, reference is
20 made to the accompanying drawings that form a part thereof, and in which are shown by way of illustration specific embodiments in which the invention may be practiced. It is understood that other embodiments may be utilized and structural changes may be made without departing from the scope of the present invention.

The present invention relates to a system for reducing and / or preventing
25 anxiety in an individual in need, said system comprising:

- (i) a non-restraining apparel adapted for applying varying pressure to at least one selected body part of said individual in need;

- (ii) means measuring at least one physiological parameter indicative of said individual in need's anxiety level; and
- (iii) means for applying pressure by said apparel in varying degrees and for varying periods of time to at least one selected body part of said individual, wherein the degree of pressure applied and the time period said pressure is applied are wholly or partially based on the value of said measured at least one physiological parameter, in order to reduce and /or prevent the anxiety level in said individual in need.

The present invention can be used to reduce anxiety in an individual in need. It is based on the well-observed fact that mildly applied pressure on a person's body has a pleasant, soothing effect. This pressure has a relaxing effect and is helpful in alleviating anxieties when said individuals are anxious or under stress. Alternatively, the invention can also be used to prevent anxiety when said individual in need will experience an event that can be stressful, for example, when visiting a dentist.

The invention is particularly useful for preventing or reducing anxiety in patients suffering from autism as well as other in other anxiety-prone individuals such as hyperactive or overstimulated individuals that may need temporary soothing. The target population can also include anyone who is not handicapped but is temporarily placed in an unusual situation, e.g., some air travellers.

Fig. 1 illustrates an apparel of the invention adapted for applying varying pressure to selected body parts of an individual in need. The jacket **5** of **Fig. 1** is inflatable, and can be inflated and deflated using a compact air compressor **10** integrated into the jacket **5**. The invention can also use an external air compressor. The compact air compressor **10** is connected via air conducts **12** to a plurality of inflatable cells **14** and **15**.

In order to improve the quality of the treatment and its accuracy, the system measures one or more physiological parameters that are indicative of a person's stress or anxiety level.

5 Examples of physiological parameter include: heart rate, body temperature, galvanic skin response, differences in finger temperature, frontalis muscle activity, cardiovascular activity (the electrocardiogram [ECG], relative pulse volume [RPV], and digit skin temperature), blood pressure, pupils expansion, sweat, electrodermal responses (skin conductance), muscle tension, respiratory rate and amplitude, brain wave or any combination thereof. Multiple measures and indicator can be
10 associated with each physiological parameter. It is preferred to work with physiological parameters that can be easily measured and that are non-invasive.

The system comprises means for applying varying pressure by the apparel of the invention to selected body parts of the individual in need. The pressure can vary both by the degree of strength and by the length of time it is applied.

15 In order to administer an effective as possible treatment, the degree of pressure applied by the system and the period of time for which said pressure is applied are wholly or partially based on the value or values of at least one physiological parameter measured. The value of the anxiety parameters can be combined in a multivariate manner in order to best determine the individual in
20 need's anxiety level.

In one embodiment of the present invention, the degree of pressure applied and the time period said pressure is applied also take into consideration personal parameters of said individual in need. The same physiological parameter value can have a different interpretation according to personal parameters of the person.
25 Personal parameters include, but are not limited to: age, gender, weight, height, medical history, medication intake, treatment history, physical fitness, individual preference or any combination thereof. For example, a given heart rate at rest is interpreted differently whether the person is young or old, overweight, physically fit, is currently taking medication that affects the heart rate, etc.

It is important for the apparel of the invention to be non-restraining, since restraining devices cannot be used without legal authorization.

In another embodiment of the present invention, the apparel includes an outer layer 17 and a plurality of cells 14 and 15 coupled with an inner surface of said outer layer 17, said outer layer 17 having such an elasticity that when the pressure in said cells is increased 14 and 15, said apparel applies said pressure to said at least one selected body part of said individual in need.

In yet another embodiment of the present invention, the apparel includes means for tightening the external layer 17 of said apparel. These means include, but are not limited to: a belt, strapped loops, a fastener such as Velcro™, snap links 20 or a band.

Fig. 2 is a schematic illustration of an outer layer 17 and inflatable cells 14 and 15 of the system of Fig. 1.

Fig. 3 is a schematic illustration of an end view of the outer layer 17 and the inflatable cells 14 and 15 of Fig. 2.

Fig. 4 is a flowchart of a simple process controlling the frequency of the applied pressure based on a measurement of the pulse. In this implementation of the invention, the system takes a pulse measure every ten seconds. If the pulse measure is higher than the previous pulse measure, or lower than the pulse measure taken two cycles ago, then the frequency is lowered. If the pulse value taken is higher than the pulse value taken two measures before, then the frequency is kept the same.

Pressure can be applied to any body part except for the head, chest, abdomen and genitals. In yet another embodiment of the present invention, each of the cells can be pressurized individually with an individual degree of pressure, for an individual time period. By controlling the pressure applied to each individual cell, the quality and effectiveness of the treatment can be increased.

The outer layer 17 fabric is flexible enough to adapt itself to the individual's body and yet sturdy enough so that the pressure is directed solely to the individual's body.

Several means are known in order to apply and regulate the pressure applied to each cell. In one embodiment of the invention, the apparel is inflatable and pressure in said cells is obtained by inflating or deflating said cells. The system can use gas in order to inflate and increase the pressure in a cell. The term "gas" as used
5 herein means a single gas, a combination of more than one gas, and includes the air. Pressure can also be applied by using fluids or solid mechanical means.

The system can operate in a manual mode wherein the individual in need regulates the pressure administered to him and the time of administration on his own.

10 In another embodiment of the present invention, a caretaker regulates the degree and length of time pressure applied to selected body parts of the individual. The term "caretaker" as referred to herewith means a doctor, an occupational therapist, a nurse, a trainer, a coach, a physiotherapist, a healthcare professional, a family member, a friend or any person assuming such tasks. The caretaker watches
15 the values measured for the different physiological parameters, and based on these values and the individual parameters of the person in need, the caretaker makes a decision how to regulate the pressure in order to prevent and/or reduce the anxiety level of the individual in need. Naturally, the caretaker can also base his/her decisions of how to regulate the pressure on his/her personal experience and
20 knowledge and on his/her evaluation of how the individual in need is responding.

Under normal conditions, the pressure applied should be set from 1PSI and should not exceed 5-6 PSI (i.e., from 52 to 250-300 mm Hg) that is twice the blood pressure of a normal individual.

In another embodiment of the present invention, the apparel includes means
25 for tightening the external layer 17 of said apparel. The tightening mechanism assures that the apparel fits close to the individual in need's body. The tightening may already apply a first pressure. In addition, by using a tightening mechanism, the apparel can fit people with different sizes since even if the apparel is a little to big initially for a person, after tightening it, the apparel may fit close to that

person's body. The tightening means include but are not limited to: a belt, strapped loops, a fastener such as Velcro™, snap links **20** or a band.

Preferably, all the parts of the system are small and light so the system can be easily worn or folded into a backpack.

5 In yet another embodiment of the present invention, the system further comprises electric neurostimulation means. The term "neurostimulation" as used herein refers to the effect obtained when electric currents are passed through the brain, the spinal cord, an organ or peripheral nerves. The electric current is usually delivered by contact electrodes i.e., electrodes that are in ohmic contact with the
10 biological tissue. Research has shown that weak electric fields of frequency near $\frac{1}{2}$ Hz applied externally to the skin of an individual can cause relaxation and dozing. In the experiments performed, the electric field was applied predominantly to skin areas away from the head, thereby avoiding substantial polarization current densities in the brain.

15 Apparently, the external electric field somehow influences somatosensory or visceral afferent nerves, which report the effect to the brain. Although the mechanism whereby the field acts on the afferents is unknown, the effect must take the form of a slight modulation of the firing patterns of the nerves, because the polarization current densities induced by the field are much too small to cause firing
20 of the nerves. If the applied external field is periodic, so will be the modulation of the firing patterns of affected afferent fibers, and the brain is then exposed to an evoked periodic signal input. Apparently, this signal input influences certain resonant neural circuits, the state of which has observable consequences.

25 The excitation of sensory resonances through modulation of afferents allows the use of small electric field generators that may be battery-operated. To be effective, the fluctuating electric field need not be sinusoidal or even periodic. The field may have a complicated spectral power density, as long as the dominant frequency is close to the resonant frequency of the sensory resonance of interest.

30 Although the invention has been described in detail, nevertheless changes and modifications, which do not depart from the teachings of the present invention

will be evident to those skilled in the art. Such changes and modifications are deemed to come within the purview of the present invention and the appended claims.

CLAIMS

1. A system for reducing and/or preventing anxiety in an individual in need, said system comprising:

5 (i) a non-restraining apparel adapted for applying varying pressure to at least one selected body part of said individual in need;

(ii) means measuring at least one physiological parameter indicative of said individual in need's anxiety level; and

10 (iii) means for applying pressure by said apparel in varying degrees and for varying periods of time to at least one selected body part of said individual, wherein the degree of pressure applied and the time period said pressure is applied are wholly or partially based on the value of said measured at least one physiological parameter, in order
15 to reduce and /or prevent the anxiety level in said individual in need.

2. The system of claim 1, wherein said physiological parameter includes: heart rate, body temperature, galvanic skin response, differences in finger temperature, frontalis muscle activity, cardiovascular activity, electro cardiac activity, blood
20 pressure, pupils expansion, sweat, electrodermal responses, muscle tension, respiratory rate and amplitude, brain wave or any combination thereof.

3. The system according to claim 1 or 2, wherein said degree of pressure applied and the time period said pressure is applied take into consideration personal parameters of said individual in need.

25 4. The system according to claim 3, wherein said individual parameter includes: age, gender, weight, height, medical history, medication intake, treatment history, physical fitness, individual preference or any combination thereof.

5 5. The system according to claim 1, wherein said apparel includes an outer layer and a plurality of cells coupled with an inner surface of said outer layer, said outer layer having such an elasticity that when the pressure in said cells is increased, said apparel applies said pressure to said at least one selected body part of said individual in need.

6. The system according to claim 5, wherein each of said cells can be pressurized individually with an individual degree of pressure.

7. The system according to claim 6, wherein said apparel is inflatable.

8. The system according to claim 7, wherein said apparel is inflated using a gas.

10 9. The system according to claim 7, wherein said pressure is applied using fluids.

10. The system according to claim 6, wherein said pressure is applied using solid mechanical means.

15 11. The system according to claim 6, wherein said pressure is regulated by a caretaker.

12. The system according to claim 6, wherein said pressure is regulated by said individual in need.

13. The system according to claim 6, wherein said apparel includes means for tightening the external layer of said apparel.

20 14. The system of claim 13, wherein said means include: a belt, strapped loops, a fastener, snap links or a band.

15. The system according to claim 1, further comprising electrical neurostimulation means.

16. The system of claim 15, wherein said means include applying a weak, fluctuating electric field, tuned to a frequency such as to excite a resonance in certain neural circuits in order to cause relaxation, sleepiness or slowing of targeted cortical processes in said individual in need.
- 5 17. The system according to claim 1, wherein said individual in need is an individual suffering from a sensory modulation disorder.
18. The system according to claim 18, wherein said sensory modulation disorder is autism.

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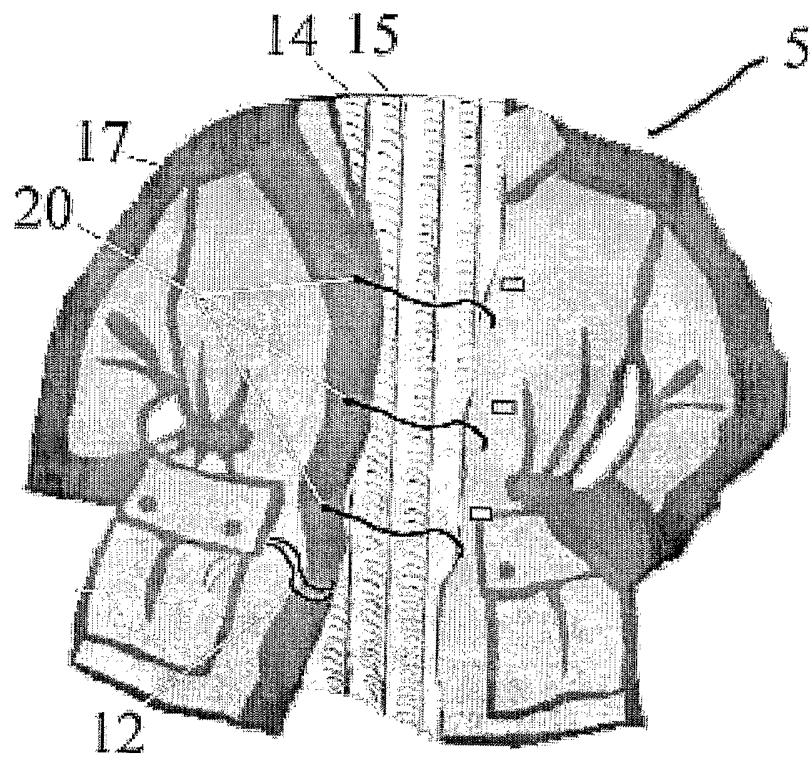


Fig. 1

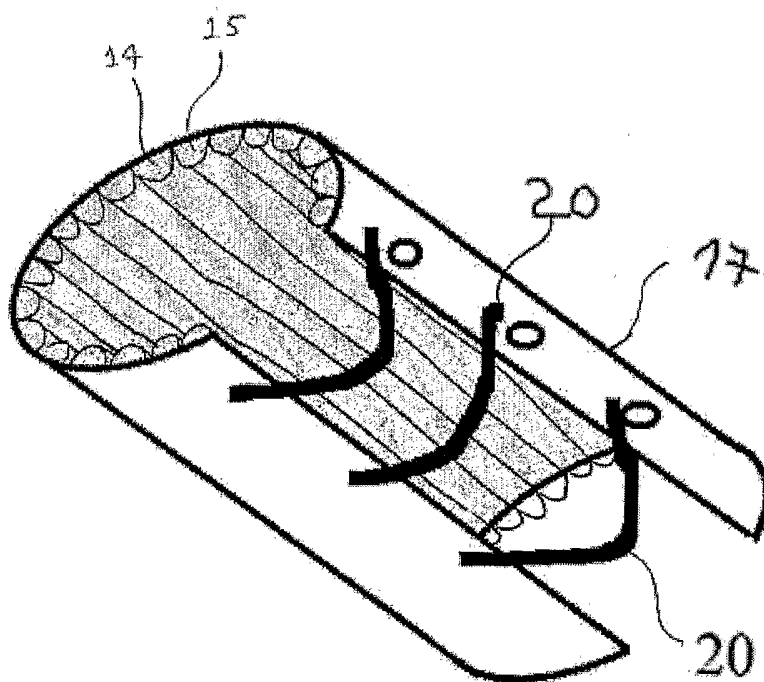


Fig. 2

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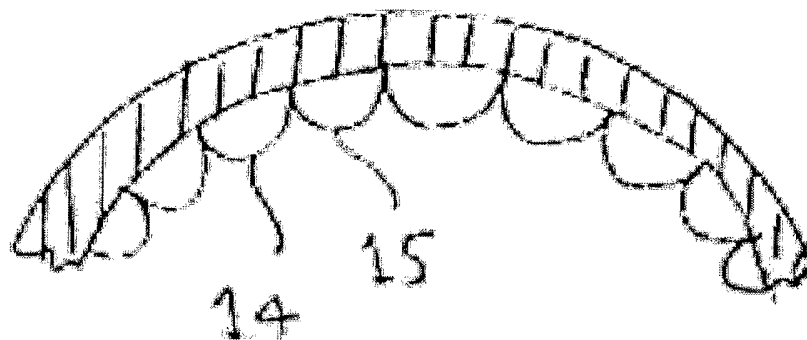


Fig. 3

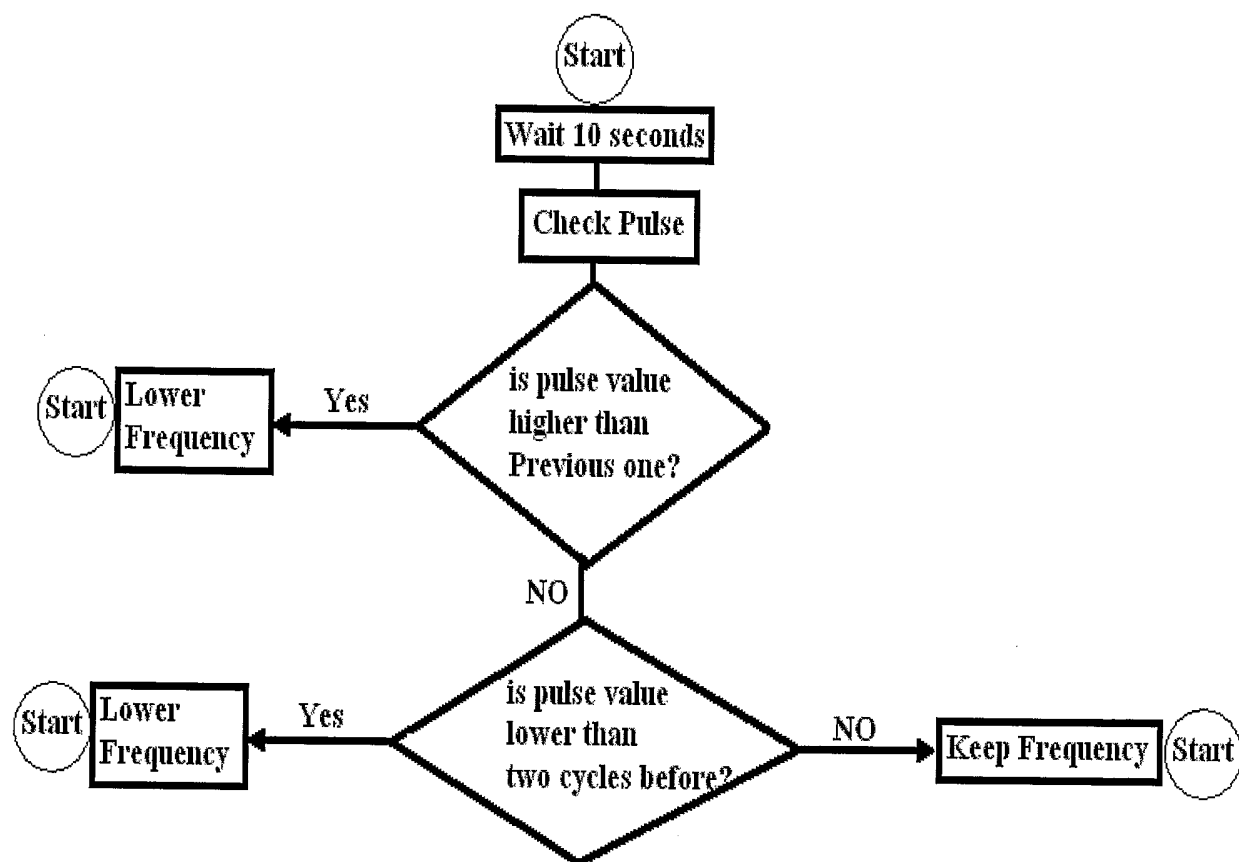


Fig. 4