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(71) Applicant: **WOJER LTD** [IL/IL]; Shimon Hatsadik St. 48/6, 4083949 ELAD (IL).

(72) Inventors: **EFRATI, Mor**; 21 Shtand St, 6437431 TEL-AVIV (IL). **KAREEV, Uri**; 5 Amir Gilboa St., 6967135 TEL AVIV (IL). **BAR LEVAV, Kfir**; Shimon Hatsadik St.

48/6, 4083949 ELAD (IL). **BAR LEVAV, Noam**; Vilesnky Moshe St. 14/3, 4464615 KFAR SABA (IL).

(74) Agent: **SPUNGIN, Ben**; 18 Alexandroni St, 4973617 Petach-Tikva (IL).

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(54) Title: SYSTEM AND METHOD FOR DISPLACING OR REFORMING A MASS WITHIN A BODY MEDIUM

Figures

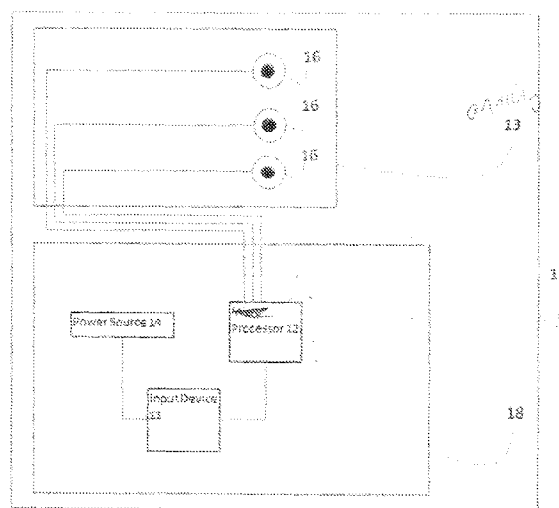


Figure 1

(57) Abstract: A system and method for displacing or reforming a mass within a body medium. The system includes one or more tactile audio transducers. A processor is configured to generate signals that drive the transducers in to generate audio waves in the medium when the transducers are applied to the medium and cause displacement of the mass or reformation of the mass. The method includes applying one or more tactile audio transducers to the medium; and driving one or more of the tactile audio transducers to generate audio waves in the medium to cause displacement of the mass or reformation of the mass.

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

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SYSTEM AND METHOD FOR DISPLACING OR REFORMING A MASS WITHIN A BODY MEDIUM

FIELD OF THE INVENTION

- 5 The present invention relates to medical devices, and more specifically to such devices for applying mechanical energy into a body.

BACKGROUND OF THE INVENTION

The following prior art publication is considered as being relevant for an understanding of the background of the invention:

- 10 U.S. Pat. No. 5,235,967 to Arbisi et al.

There are various medical conditions where applying haptic tactile energy to a body surface may have beneficial effects. For example, it is known to apply a peristaltic pressure effect to the legs in cases of edema in order to promote flow of lymph towards the trunk. As another example, cystic fibrosis has been treated by
15 pounding the back of a patient to promote movement of mucus up the bronchial tree towards the larynx.

Various wearable devices are known that apply haptic tactile energy to a body surface. Such wearable devices, may be, for example, in the form of a vest worn over the torso or a sleeve worn over a body limb. These wearable devices may apply haptic
20 tactile energy to the individual for example, using one or more bladders that are cyclically inflated and deflected to generate a pounding motion on the thorax. Other wearable devices use one or more transducers to transmit pressure waves to the thorax. Wearable devices are also known that administer mechanical impacts or vibrations to the thorax. These devices include one or more electro-mechanical
25 vibrators to produce pulsating impacts. U.S. Pat. No. 5,235,967 to Arbisi et al, describes a vest-like garment with a plurality of movable electrically conductive elements that are actuated by a pulsed magnetic field produced by drive coils that are energized by a drive circuit.

An audio transducer (also known as a "*tactile transducer*") is a device that
30 generates vibrations into various body surfaces. frequencies can be felt as well as heard by an individual, a phenomenon sometimes referred to as "*tactile sound*".

Existing systems use either air waves or motors or speakers to induce vibration. However, these prior art systems do not use lossless tactile haptic induction, by directly applying the inductors on the patient or via a rigid lossless mechanical extension, and do not use designed asymmetrical waveforms or a combination of
5 symmetrical and asymmetrical waves to move and control the movement of masses and materials within the body.

SUMMARY OF THE INVENTION

The present invention provides a system and method for displacing or
10 reforming a body mass within the body. The invention may be used, for example, to displace a blood clot in an occluded blood vessel, to displace mucus within the respiratory tract in cases of cystic fibrosis, to displace a food bolus in the digestive tract in cases of impaired digestive tract peristalsis, or movement of lymph valves in cases of edema. The inventors have found that generating synchronized symmetric or
15 asymmetric sound waveforms in the tissue surrounding the mass can create displacement of the mass. As used herein the term "*asymmetric wave*" is used to refer to a waveform wherein the wave and its inverse are not identical, such as for example either. Such asymmetric waveforms may be created, for example, by (1) one or more transducers executing a cycle with a rapid buildup of pressure followed by a slower
20 release of pressure, (2) a wave train in which a first time interval of constant pressure is followed by a second time interval of less pressure, or (3) where the buildup of the wave is complex comprising a modulated attack form and modulated release.

The invention comprises a device including one or more tactile audio transducers where each tactile audio transducer can be applied to a specific location
25 on a body surface or tissue in a specific orientation so that each tactile audio transducer delivers tactile haptic energy pressure cycles to a specific location in the body. The system may be, for example, in the form of a wearable device such as a vest adapted to be worn around the torso, or a sleeve adapted to be worn on a body limb, or a system of one or more implanted transducers applying the haptic stimuli
30 directly from within the body. The system may be embedded into an object to which a body part of the user is applied, for example, a piece of furniture such as a chair, a bed or a mattress..

The system may further comprise a controller that activates the transducers in a predetermined pattern to generate a temporo-spatial array of transducer activation. As explained below, the temporo-spatial array of the transducer activation and the transducer orientation may be selected to generate directional waves in the targeted body tissue to displace or reform the mass.

Due to the proven relationship between the mental wellbeing of an individual and his or her physical state, the invention may be combined with entertainment media, to allow the individual being treated by the invention to be entertained and have a pleasant experience during the treatment, thus allowing a better overall medical procedure. This is of high importance to patients with chronic diseases for whom treatment is a part of their routine.

Thus, in one of its aspects, the present invention provides a system for displacing or reforming a mass within a body medium comprising:

- (a) one or more tactile audio transducers;
- (b) a processor configured to generate signals that drive the transducers in a predetermined fashion to generate audio waves in the medium when the transducers are applied to the medium and cause displacement of the mass or reformation of the mass.

The transducers may be adapted to be applied to a surface overlying the medium or embedded or implanted in the medium.

One or more of the audio waves may be a symmetric wave. One or more of the audio waves may be an asymmetric wave selected from:

- (a) a waveform having a rapid buildup of pressure followed by a slower release of pressure;
- (b) a wave train in which a first time interval of constant first pressure is followed by a second time interval of a second pressure, the second pressure being lower than the first pressure. and
- (c) a waveform in which buildup of the wave is complex and comprises a modulated attack form and modulated release.

The transducers may be positioned in an array to produce a synergetic effect on the mass to focus the waves on the mass, or to induce directional movement of the mass.

The transducers may be incorporated into a wearable device or may be embedded in a furniture item. .

One or more of the transducers may be adapted to be positioned separated from the body, and the system further comprises one or more rigid elements that
5 convey the audio waves from the transducer to the medium.

One or more of the signals may include entertainment media.

The system may comprise a single transducer .

One or more of the transducers may be adapted to be applied onto the medium.

One or more of the transducers may be adapted to be applied onto a body
10 surface and one or more of the transducers may be activatable to generate the waves in a direction parallel to the body surface.or perpendicular to the body surface.

The system may be configured to activate the transducers at two or more frequencies and waveforms to maintain or manipulate the medium or materials within the medium.

15 In another of its aspects, the present invention provides a method for displacing or reforming a mass within a body medium comprising:

- (a) applying one or more tactile audio transducers to the medium; and
- (b) driving one or more of the tactile audio transducers to generate
audio waves in the medium to cause displacement of the mass or
20 reformation of the mass.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in
25 practice, a preferred embodiment will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Fig. 1 shows a system for applying haptic/tactile audio energy to a body surface in accordance with one embodiment of the invention;

Fig. 2a shows the front and **Fig. 2b** shows the back of a wearable device in the form
30 of a vest for delivering haptic tactile audio energy to a body surface that may be used in the system of Fig. 1;

Fig. 3 shows a wearable device in the form of a sleeve for delivering haptic/tactile audio energy to a body surface or organ that may be used in the system of Fig. 1;

Fig. 4 shows an exploded expanded view of a wearable device that may be used in the system of Fig. 1;

Fig 5A and **Fig. 5B** show two exemplary configurations with the respective effect on signal levels;

5 **Fig 6** shows a symmetric and asymmetric signals that may be used in the invention to generate various in body effects; and

Fig 7 shows an exemplary configuration capable of creating a displacement of an in-body mass along a designated direction, in accordance with one embodiment of the invention.

10 **DESCRIPTION OF THE INVENTION**

Fig. 1 shows a schematic view of a system **19** for displacing or reforming a body mass within the body in accordance with one embodiment of the invention. The system **19** includes a an array **13** of one or more transducers The system **19** also includes a control unit **18**. The control unit **18** comprises a power source **14**, a
15 processor **12**, and an input device **11** such as a keyboard or control panel. The power source **14** may be, for example, a rechargeable battery or means for connection to an AC power source.

Fig. 2 shows a first example of a device that may be used in the system **19** of the invention. The device shown in Fig. 2 is in the exemplary form of a vest **10** that is
20 worn around the torso and may be used, for example, in the treatment of cystic fibrosis or impaired digestive tract motility. Fig. 2a shows the front and Fig. 2b shows the back of the vest **10**. The vest **10** includes a pair of arm openings **20** and a neck opening **22**. Front flaps **24** of the vest **10** can be secured together by separable fasteners that allow the device to be put on and taken off as needed. The controller **18**
25 may be contained in a pouch **28** that may be, for example, attached to the outer surface of the vest **10** or mounted on a belt.

Fig. 3 shows as another example, a wearable device **78** that may be used in the system **19** of the invention. The wearable device **78** shown in Fig. 2 is in the form of a sleeve **32** configured to be worn on a body limb **34** such as a leg or an arm, that may
30 be used, for example, in the treatment of edema.

Fig. 4 shows an expanded view of the layers of a wearable the device (such as the vest **10** or the sleeve **32**) that may be used in the system of the invention. An innermost layer **45** consists of a sheet of a flexible fabric material that is applied,

directly or indirectly, to a body surface to be treated. A frame **44** supports one or more haptic low frequency tactile audio transducers **42**.

An optional rigid backing **43** is positioned behind the frame **44** that opposes the motion of the transducers **42**, so that movement of the transducers is confined to the space between the frame **44** and the body surface. Behind the rigid backing **43** is an outermost layer **45** that may be made from the same material as the innermost layer **46**.

The input device **11** allows programming of the processor **12** including, for example, specifying the characteristics of the operation of each transducer and the pattern of transducer activation. One or more of the transducers may execute an asymmetric cycle or waveform, in which the impact stroke of the cycle is different from the recovery stroke. For example, one or more of the transducers may execute a cycle with a rapid buildup of pressure followed by a slower release of pressure, or an impulse in which a first time interval of constant pressure is followed by a second time interval of less pressure. The input device **11** may also allow specification of the haptic stimulation, the frequency and amplitude of each transducer and or selection of other media that are also to be used in the stimulation.

The processor **12** may be further configured to execute a temporo-spatial array of transducer activity that is selected to create a synergetic effect between the transducers in the array to induce directional displacement waves in the body tissue underlying the transducer array.

In the case that it is desired to move the mass **78** from the position **P1** in the direction of the arrow **78**, the two transducers **72** and **73** may be activated simultaneously, each of the two transducers **72** and **73** may execute a symmetric or asymmetric cycle to displace the mass **71** within the medium **70**. If the mass **78** is confined to the body tube **76**, displacement of the mass **71** will be along the tube **76** in the direction of the arrow **78**. If the mass **71** is not confined to a body tube, displacement of the mass **71** can be directed in the direction of the arrow **78** by activating the transducers **74** and **75** in a way that is symmetric and synchronized with the transducers **72** and **73**. When the mass **71** has arrived at the position **P2**, the process may be repeated by activation of the transducers **74** and **75** as just explained for the transducers **72** and **73**. The process may be repeated any number of times until the mass **71** has arrived at its final destination.

Fig.5 shows two different location configurations and exemplary modifications to the actuation of the transducer driving signals to achieve a desired effect. In Fig.5a, a focal area **50** is located equidistant from transducers **52**, **54**, and **56** so that the three transducers **52**, **54**, and **56** could be operated at the same amplitude.

5 In Fig. 5B, the focal point **58** is closest to the transducer **53**, so the amplitude of the signal driven to the transducer **53** could be lower than the signal amplitude driven to transducers **51** and **55**.

Figure 6 shows exemplary and non-limiting waveforms that may be used to create desired effects on a mass within a body. Waveform **61** is a symmetrical waveform. A mass subjected to waveform **61** will oscillate equally in opposite
10 directions, as indicated in graph **65**. This oscillation can potentially have benefits such as material separation (e.g. separation of mucus in the lungs), material alignment into geometric forms or breakdown but without causing directional displacement of the mass.

15 Waveform **62** shows an exemplary and non-limiting asymmetrical waveform comprising a steep rising edge with a slower falling edge, resulting in gradual pushing waves in one direction relative to the transducer. Such waveforms may result in a gradual directional push of the mass, as indicated in graph **67**.

Waveform **63** shows an exemplary and non-limiting asymmetrical waveform
20 comprising of a steep rising edge with a slower falling edge in a cyclically increasing amplitude, resulting in pushing waves, as indicated in graph **69**, that are stronger than those depicted in the graph **67**, and are in one direction relative to the transducer. Such waveforms may result in a gradual directional push of the mass.

Fig. 7 shows schematically a body mass **71** present in a body tissue **70**,
25 referred to herein as "*the medium*". The mass **71** may or may not be confined to a tube **76**, such as a blood vessel or bronchus. Fig. 7 also shows four transducers **72**, **73**, **74**, and **75**, positioned in an array designed to generate waves in the medium that are focused on the mass or in the medium. The transducers **72**, **73**, **74**, and **75** may or may not be part of a larger transducer array. The transducers **72**, **73**, **74**, and **75** may be
30 embedded in the medium **70** or applied to a surface overlying the medium **70**.

In the case that it is desired to move the mass **71** from the position **P1** in the direction of the arrow **78**, the two transducers **72** and **73** may be activated simultaneously creating a push waveform such as the waveform **77**, each of the two transducers **72** and **73** may execute a symmetric or an asymmetric cycle to displace

the mass **71** within the medium **70**. The transducers **74** and **75** may be further configured to create weak waveforms to help steering the mass towards **P2**. If the mass **71** is confined to the body tube **78**, displacement of the mass **71** will be along the tube **76** in the direction of the arrow **78**. If the mass **71** is not confined to a body tube, displacement of the mass **71** can be directed in the direction of the arrow **78** by activating the transducers **74** and **75** in a way that is symmetric and synchronized with the transducers **72** and **73**. When the mass **71** has arrived at the position **P2**, the process may be repeated by activation of the transducers **75** and **75**, as just explained for the transducers **72** and **73**. The process may be repeated any number of times until the mass **71** has arrived at its final destination.. Transducers **74** and **75** may also be used to induce an additional waveform that manipulate the medium or other materials in the medium to assist with the process.

CLAIMS:

- 5 **1.** A system for displacing or reforming a mass within a body medium comprising:
- (a) one or more tactile audio transducers;
- (b) a processor configured to generate signals that drive the transducers in a predetermined fashion to generate audio waves in the medium when the transducers are applied to the medium and cause
- 10 displacement of the mass or reformation of the mass.
- 2.** The system according to claim 1 wherein one or more of the transducers are adapted to be applied to a surface overlying the medium.
- 3.** The system according to any one of the previous claims wherein one or more of the transducers are adapted to be embedded or implanted in the
- 15 medium .
- 4.** The system according to any one of the previous claims wherein one or more of the audio waves is a symmetric wave.
- 5.** The system according to any one of claims 1 to 4 wherein one or more of the audio waves is an asymmetric wave selected from:
- 20 (a) a waveform having a rapid buildup of pressure followed by a slower release of pressure;
- (b) a wave train in which a first time interval of constant first pressure is followed by a second time interval of a second pressure, the second pressure being lower than the first pressure. and
- 25 (c) a waveform in which buildup of the wave is complex and comprises a modulated attack form and modulated release.
- 6.** The system according to any one of the previous claims comprising a plurality of transducers wherein the transducers are positioned in an array producing a synergetic effect on the mass based on relative positions of the
- 30 transducers in order to focus the waves on the mass .
- 7.** The system according to any one of the previous claims comprising a plurality of transducers wherein the transducers are positioned in an array producing a synergetic effect on the mass based on relative positions of the

transducers applying asymmetric waveforms in order to induce directional movement of the mass.

8. The system according to any one of the previous claims wherein the transducers are incorporated into a wearable device. .

5 9. The system according to any one of the previous claims wherein one or more of the transducers are adapted to be positioned separated from the body, and the system further comprises one or more rigid elements that convey the audio waves from the transducer to the medium.

10 10. The system according to any one of the previous claims wherein one or more of the signals include entertainment media.

11. The system according to any one of claims 1 to 5 comprising a single transducer .

12. The system according to any one of the previous claims wherein one or more of the transducers are embedded in a furniture item.

15 13. The system of any of the previous claims, wherein one or more of the transducers are adapted to be applied onto the medium.

20 14. The system according to any of the previous claims, wherein one or more of the transducers are adapted to be applied onto a body surface and one or more of the transducers is activatable to generate the waves in a direction parallel to the body surface.

15. The system according to any of the previous claims, wherein one or more of the transducers are adapted to be applied onto a body surface and one or more of the transducers is activatable to generate the waves in a direction perpendicular to the body surface.

25 16. The system according to the previous claims configured to activate the transducers at two or more frequencies and waveforms to maintain or manipulate the medium or materials within the medium.

17. A method for displacing or reforming a mass within a body medium comprising:

30 (a) applying one or more tactile audio transducers to the medium; and
(b) driving one or more of the tactile audio transducers to generate audio waves in the medium to cause displacement of the mass or reformation of the mass.

Figures

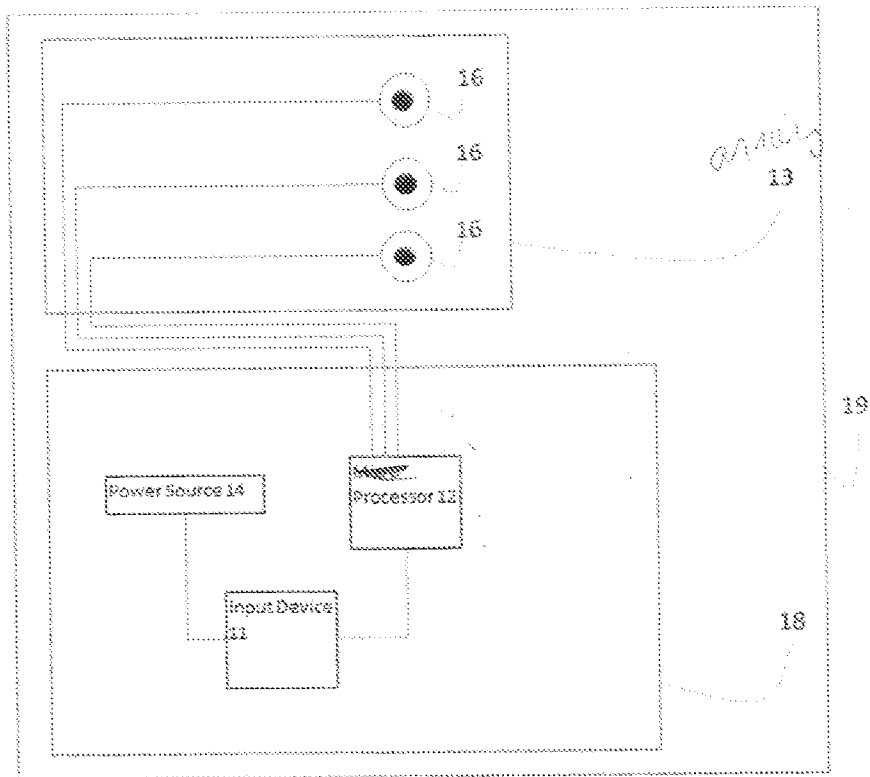


Figure 1

Figures Cont

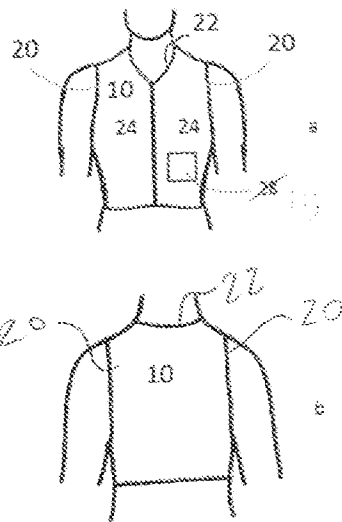


Figure 2

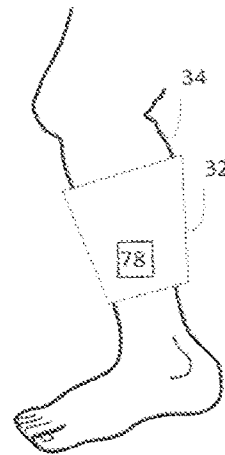


Figure 3

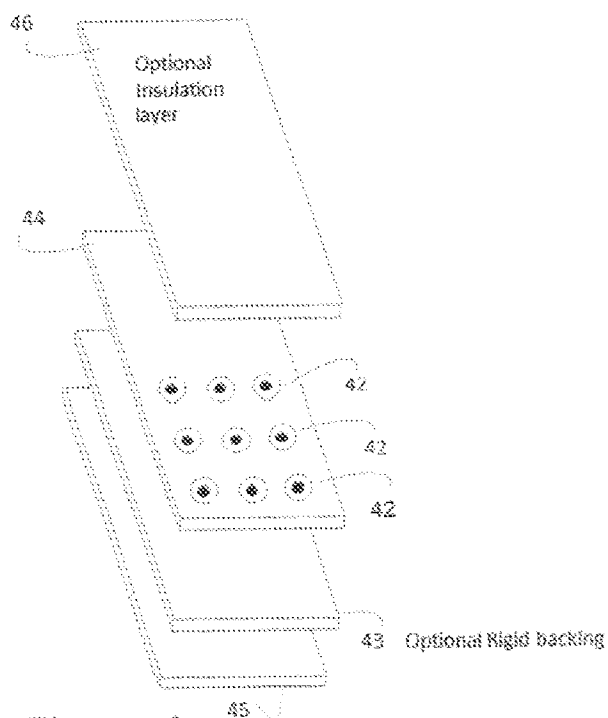


Figure 4

Figures Cont

Figure 5A

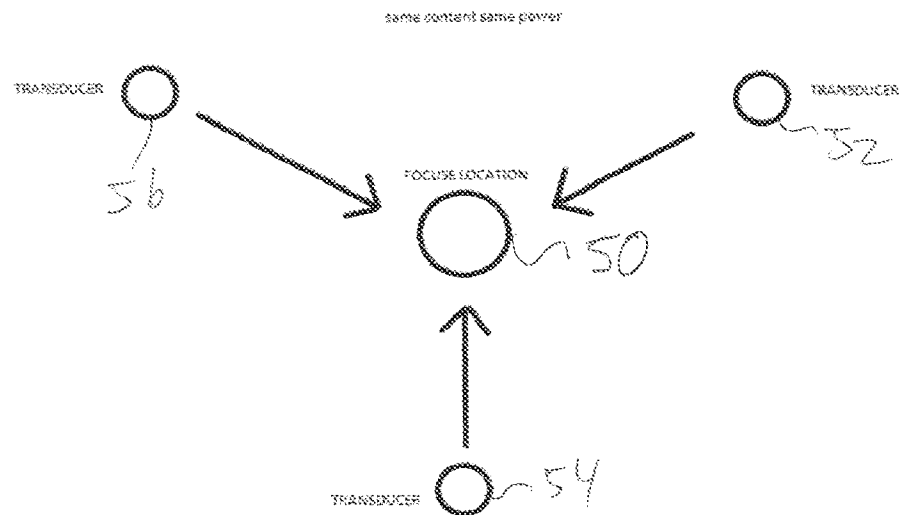


Figure 5B

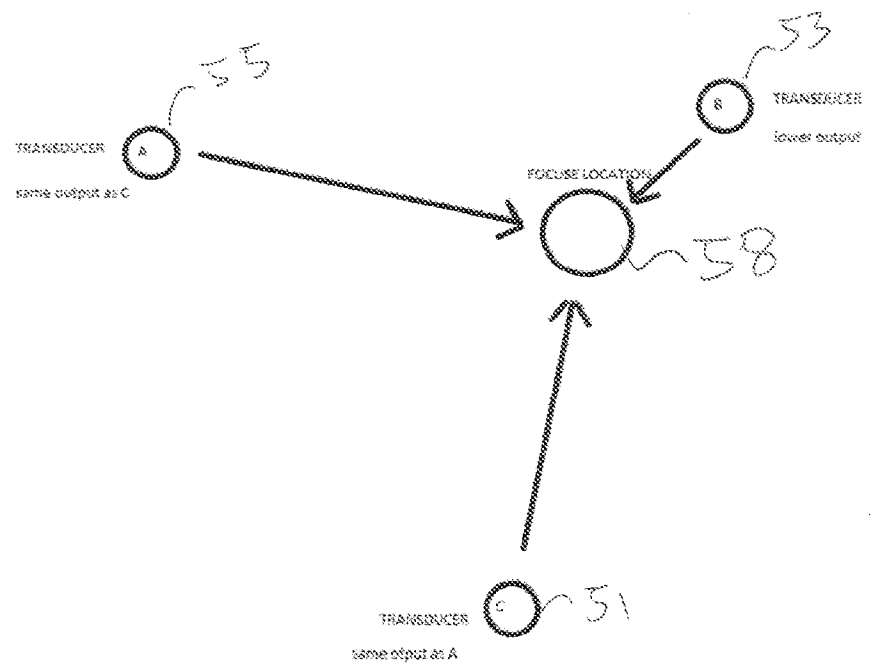


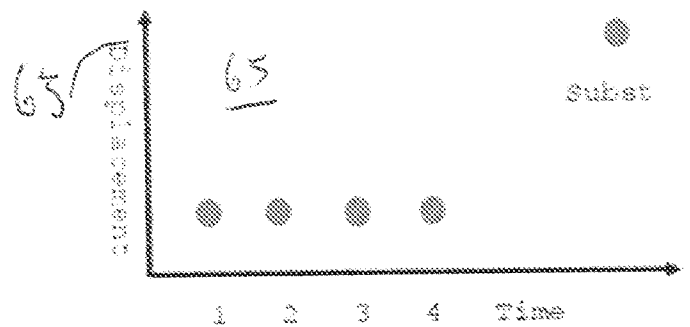
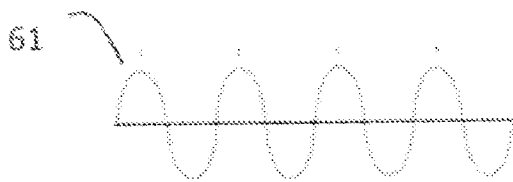
Figure 5

Figures Cont.

BASIC DESCRIPTION OF SUBSTANCE MOVEMENT VIA CYCLES

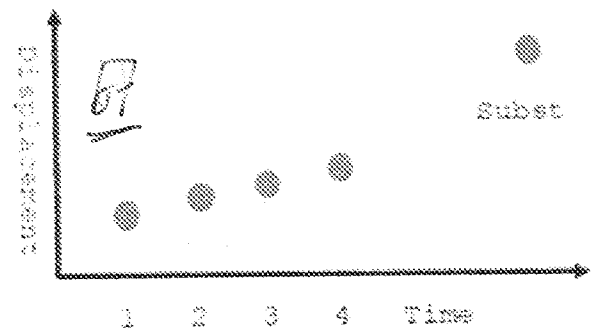
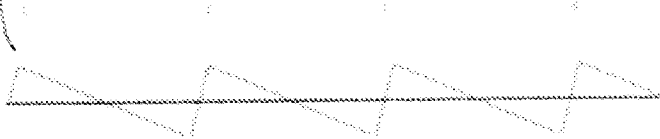
IN A PURE SINE WAVE THE TARGET SUBSTANCE WILL OSCILLATE BETWEEN UP & DOWN

PURE SINE WAVE



62 A FAST YSRONGE WAVE ATTACK FOLLOWED BY A SLOW MODERATED DECAT WILL CAUSE THE SUBSTANCE TO MOVE IN THE UP DIRECTION FASTER THEN THE DOWN

RESULTING IN A MOVEMENT IN THE UP DIRECTION DUE TO THE SLOWER SLOPE AND LOWER POWER OF THE DOWN PHASE ALSO COMBINATION WITH EXTERNAL FORCES ON THE SUBSTANCE



GRADUALLY INCREASING ATTACK WITH LOWER AND WEAKER DECAT WILL PRODUCE A CLEAR DIRECTIONAL MOVEMENT

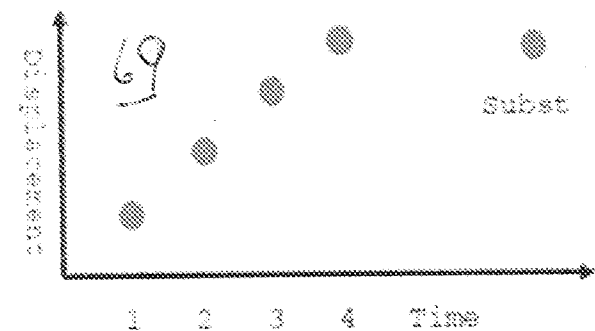
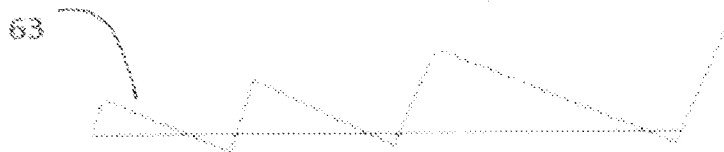


Figure 6

Figures Cont

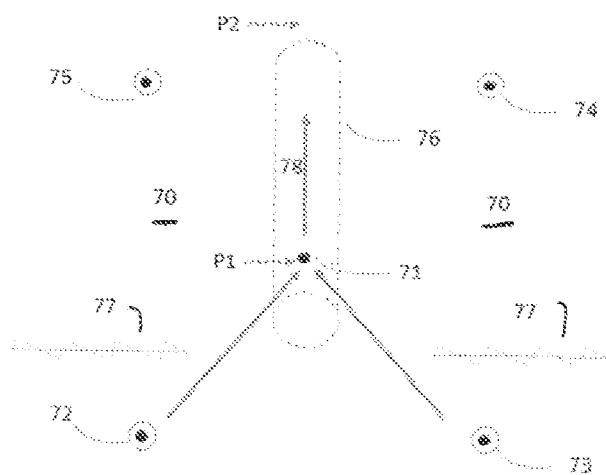


Figure 7

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL2022/050426

A. CLASSIFICATION OF SUBJECT MATTER <i>A61H 23/00</i> (2022.01)i; <i>A61H 23/02</i> (2022.01)i; <i>B06B 1/04</i> (2022.01)i; <i>H04R 1/00</i> (2022.01)i CPC:A61H 23/00; H04R 2400/03; A61H 23/0236; B06B 1/045; H04R 1/00 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) A61H 23/00; A61H 23/02; B06B 1/04; H04R 1/00 CPC:A61H 23/00; H04R 2400/03; A61H 23/0236; B06B 1/045; H04R 1/00 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Databases consulted: Google Patents, Google Scholar, Orbit, Similari (AI-based)														
C. DOCUMENTS CONSIDERED TO BE RELEVANT <table border="1"> <thead> <tr> <th>Category*</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>X</td> <td>US 2014010387 A1 (COHEN DANIEL E [US]) 09 January 2014 (2014-01-09) the whole document especially para. [0010],[0012],[0041]; figures.</td> <td>1-3,9,11-17</td> </tr> <tr> <td>X</td> <td>WO 2020245466 A1 (SYNDERMIX AG [CH]) 10 December 2020 (2020-12-10) the whole document especially: para. "FIELD", page 8, lines 14-25; page 11, lines 6-10;page 35, last line - page 36 1st line; page 39, lines 20-26; page 59, 1st para.;FIG. 23.</td> <td>1-4,9-11,13-17</td> </tr> <tr> <td>X</td> <td>US 2007225685 A1 (DYMEDSO INC [CA]) 27 September 2007 (2007-09-27) the whole document especially: abstract, para. [0028], [0029]-[0031]; fig. 4</td> <td>1-4,8,9,11,13-17</td> </tr> </tbody> </table>			Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	X	US 2014010387 A1 (COHEN DANIEL E [US]) 09 January 2014 (2014-01-09) the whole document especially para. [0010],[0012],[0041]; figures.	1-3,9,11-17	X	WO 2020245466 A1 (SYNDERMIX AG [CH]) 10 December 2020 (2020-12-10) the whole document especially: para. "FIELD", page 8, lines 14-25; page 11, lines 6-10;page 35, last line - page 36 1st line; page 39, lines 20-26; page 59, 1st para.;FIG. 23.	1-4,9-11,13-17	X	US 2007225685 A1 (DYMEDSO INC [CA]) 27 September 2007 (2007-09-27) the whole document especially: abstract, para. [0028], [0029]-[0031]; fig. 4	1-4,8,9,11,13-17
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Date of the actual completion of the international search 03 August 2022		Date of mailing of the international search report 04 August 2022												
Name and mailing address of the ISA/IL Israel Patent Office Technology Park, Bldg.5, Malcha, Jerusalem, 9695101, Israel Israel Telephone No. 972-73-3927214 Email: pctoffice@justice.gov.il		Authorized officer LEVI Moria Telephone No.												

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