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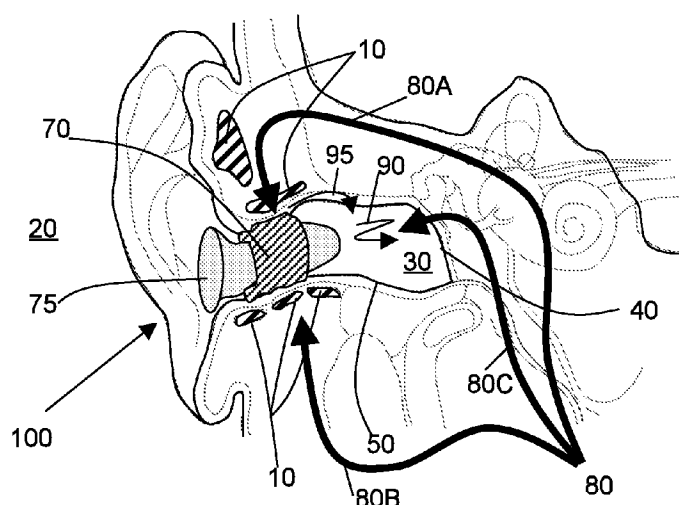


FIG. 1

(57) Abstract: At least one exemplary embodiment is directed to a sound isolation device comprising: an expandable element; and an insertion element, where the expandable element is operatively attached to the insertion element, where the expandable element includes an expanding medium, where the pressure of the expanding medium is varied to vary sound isolation across the expandable element.

## OCCLUSION EFFECT MITIGATION AND SOUND ISOLATION DEVICE FOR ORIFICE INSERTED SYSTEMS

### CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application claims the benefit of U.S. provisional patent application No. 61/076,122 filed on 26 June 2008. The disclosure of which is incorporated herein by reference in its entirety.

### FIELD OF THE INVENTION

**[0002]** The present invention relates to devices that can be inserted into orifices and sealed, and more particularly although not exclusively related to earpieces with expandable systems.

### BACKGROUND OF THE INVENTION

**[0003]** The Occlusion Effect is generally described as the sensation of increased loudness (sound pressure level), especially in the low frequencies, that a person experiences to self-generated sounds (vocalization, chewing, swallowing, walking, and the like), when the ears are covered (occluded). Note that this resonance amplification can occur in tubes that have a sealed volume and have acoustic leakage into the volume. The Occlusion Effect has been identified as a major obstacle to successful hearing aid use and shallow (within the first  $\frac{1}{2}$  of the channel) inserted earpieces. The theories of why the Occlusion Effect forms and what it is are numerous and diverse and to date no single explanation has been totally accepted.

**[0004]** Figure 3 illustrates typical occlusion effect levels as a function of frequency for various in-ear devices.

**[0005]** There are several theories of occlusion effect, they include Outflow theory (Mach, 1863): Occlusion of ear canal results in an increase in middle ear impedance, and hence to a decrease in energy lost from inner ear via ossicular chain. Resonance theory (Huizing, 1923): Increased perception of sound is brought about by the walls of this artificially closed

cavity acting as resonators. Masking theory (Pohlman, 1930; Hallpike, 1930): Occlusion of ear canal eliminates masking influence of ambient noise. Inertial/osseotympanic theory (von Békésy, 1932): Occlusion effect results from sound pressure increase in auditory canal with occlusion. Inertia of mandible to skull sets up pressure variations in EAM. Impedance theory (Huizing, 1960): Occlusion alters the impedance of the column of air in the canal (increasing it), resulting in improved coupling of the air in the canal to the middle ear.

**[0006]** Figure 4 illustrates several occlusion effect studies and their values at various frequencies for earphones, while Figure 5 illustrates several occlusion effect studies for earmolds. Roughly the occlusion effect is in the range of 13-25dB between 250-500Hz. Roughly from Killian, Wilber, and Gudmundsen (1988) a shallow insertion has an occlusion effect of about 13 to 21 dB, while a deep insertion has an occlusion effect of about 20dB for a tapered tip, and about -9 to 4dB for a bony contact ear inserted device. Related art solutions involve acoustic vents between the sealed region (now unsealed) and the outside environment of about 3mm in diameters, however venting has limitations as well, for example ringing. Another solution is deep insertion with contact in the Bony section of the ear canal.

**[0007]** Thus for shallowly inserted systems (e.g.,  $< \frac{1}{2}$  the ear canal length), the occlusion effect can be an issue (e.g.,  $>5$ dB).

## SUMMARY OF THE INVENTION

**[0008]** At least one exemplary embodiment is directed to an occlusion effect mitigation device comprising: an insertion element; and an expandable element operatively attached to the insertion element, where the expandable element is configured to expand against a portion of the walls of a flexible channel forming a sealed chamber in the channel, where the expansion reduces the occlusion effect in the sealed chamber.

**[0009]** At least one exemplary embodiment is directed to a sound isolation device comprising: an expandable element; and an insertion element, where the expandable element is operatively attached to the insertion element, where the expandable element includes an

expanding medium, where the pressure of the expanding medium is varied to vary sound isolation across the expandable element.

**[0010]** At least one exemplary embodiment is directed to a method of sound isolation comprising: expanding an element to a first pressure where the expanded element varies the sound isolation across the element as the pressure exerted by the expanding element is varied.

**[0011]** At least one exemplary embodiment is directed to a method of occlusion effect reduction comprising: inserting an insertion element into a flexible channel; and expanding an expanding element, where upon insertion of the insertion element and expansion of the expanding element a sealed chamber is formed, where when the expanding element presses against a portion of a wall of the flexible channel, the occlusion effect in the sealed chamber is reduced.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

**[0012]** Exemplary embodiments of present invention will become more fully understood from the detailed description and the accompanying drawings, wherein:

**[0013]** Figure 1 illustrates an ear canal as a non-limiting example of an orifice that can be sealed forming a resonance chamber;

**[0014]** Figure 2 illustrates occlusion effect values of at least one exemplary embodiment when the device is sealed at various sound isolation values;

**[0015]** Figures 3-5 illustrates various values of the occlusion effect according to several scientific studies;

**[0016]** Figure 6 illustrates sound isolation values (e.g., acoustic energy absorption and reflection) for an inflatable system according to at least one exemplary embodiment;

**[0017]** Figure 7 illustrates an inflatable device in accordance with at least one exemplary embodiment;

**[0018]** Figures 8-13, and 15 illustrate at least one method of inflating an inflatable device in accordance with at least one exemplary embodiment; and

**[0019]** Figures 14A, 14B, and 14C illustrate various non-limiting examples of electrode configurations in accordance with at least one exemplary embodiment.

#### **DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS OF THE PRESENT INVENTION**

**[0020]** The following description of exemplary embodiment(s) is merely illustrative in nature and is in no way intended to limit the invention, its application, or uses.

**[0021]** At least several exemplary embodiments are directed to or can be operatively used on various wired or wireless earpiece devices (e.g., earbuds, headphones, ear terminal, hearing aids, behind the ear devices, or other acoustic devices as known by one of ordinary skill in the art, and equivalents).

**[0022]** Processes, techniques, apparatus, and materials as known by one of ordinary skill in the art may not be discussed in detail but are intended to be part of the enabling description where appropriate. For example material fabrication may not be disclosed, nor attachment procedures (e.g., adhesive attaching of separate ridge structures), but such, as known by one of ordinary skill in such arts is intended to be included in the discussion herein when necessary.

**[0023]** Notice that similar reference numerals and letters refer to similar items in the following figures, and thus once an item is defined in one figure, it may not be discussed or further defined in the following figures.

**[0024]** Figure 1 illustrates a sealed (occluded) ear canal 50, with a sealed volume 30. Voice can leak 80 into the sealed volume 30 from various source paths 80A, 80B, and 80C. In one explanation, the leaked acoustic energy results in an amplification (e.g., by resonance) at certain frequencies within the sealed volume, resulting in the Occlusion Effect. If the ear canal (a non-limiting example of an orifice) was unsealed then no resonance could build and hence there would be no Occlusion Effect. While the present invention has been described with reference to exemplary embodiments, it is to be understood that the invention is not limited to

the disclosed exemplary embodiments. The scope of the following claims is to be accorded the broadest interpretation so as to encompass all modifications, equivalent structures and functions of the relevant exemplary embodiments. For example exemplary embodiments do not require the formation of a sealed chamber in the channel, exemplary embodiments can increase the sound isolation across the sealed section of the channel.

**[0025]** Figure 1 illustrates at least one exemplary embodiment. An earpiece 100 can include an insertion element 75 operatively connected to a sealing section. The sealing section can include an expandable element 70 (e.g., expanding polymers, inflatable systems, mechanically expanded systems, balloons of various shapes, sizes and materials, for example constant volume balloons (low elasticity  $\leq 50\%$  elongation under pressure or stress) and variable volume (high elastic  $> 50\%$  elongation under pressure or stress) balloons). Many materials can be used for the expandable element 70. For example if the interior medium is air then the material (e.g., membrane) for the expandable element can be chosen so that the pressurized air (e.g., 0.1 bar gauge to 2 bar gauge) leaks through the membrane in a chosen period of time (e.g., 5% pressure decrease in 8 hours). Additionally other fluids (e.g., air, water, oil, glycerin) can be used as the interior medium. A pumping mechanism can be used to pressurize the interior medium. For example a manual pump, electrical pumps, and chemical pumps (e.g., electrolysis).

**[0026]** Figure 6 illustrates sound isolation (attenuation + reflection) results as a function of inflation plotted in semi-log scale. Note that the inflation can be varied to obtain a variation in the attenuation and/or acoustic reflection. Additionally the inflation medium (interior medium) can be either a liquid (e.g., water, baby oil, mineral oil, ) , a gas (e.g., H<sub>2</sub>O vapor, H<sub>2</sub>, O<sub>2</sub> gas), or a combination of both. Thus in accordance with at least one exemplary embodiment sound isolation can be increased as the pressure is increased above a particular seal pressure value. However if the expandable element is a stressed membrane, then there can be an elongation % where the acoustic transmission through the membrane is higher than at larger or lower elongation %. For example if the stressed membrane is stretched to 50% elongation in

one dimension the acoustic transmission can be lower than unstretched or 150% elongation stretched (stressed) membranes. The seal pressure value is the pressure at which the inflatable system (an example of an expandable element) has conformed to the inside of the orifice (e.g., whether regular or irregular) such that a drop between the sound pressure level on one side of the inflatable system is different from the sound pressure level on the opposite side of the inflatable system by a drop value in a short period of time. For example when a sudden (e.g., 1 second) drop (e.g., 3dB) occurs by at a particular seal pressure level (e.g., 2 bar). For example if a balloon is used where the medium is air, an internal pressure of 1.2 bar absolute (0.2 bar gauge) can result in a sound isolation of 20+ dB across the balloon. For permeability consideration, for example suppose one wishes inflation to last for 8 hours with less than 5% internal loss of pressure, the permeability will have to be much better than silicon, for example Teflon. For variable volume balloons (such as silicon balloon) various high elongation materials (some over 1000%) can have the requisite permeability.

**[0027]** Figure 7 illustrates an inflatable system 300 comprising an insertion element (e.g., 320, multi-lumen tube) and an expandable element (e.g., 330, urethane balloon, nylon balloon). The expandable element can be filled with an expanding medium (e.g., gas, liquid, electroactive polymer or gell) fed via a supply tube (e.g., 340). The device illustrated in Figure 7 illustrates a flange 310 (e.g., made of plastic, foam, rubber) designed to stop at a designated position in the orifice (e.g., at the opening of the orifice), and an instrument package (e.g., 350) can include additional devices and equipment to support expansion control (e.g., power supply and leads, gas and/or fluid generation systems).

**[0028]** Figure 8 illustrate at least one exemplary embodiment for pressure generation and control. The non-limiting example illustrated includes a balloon (e.g., 430), at least one pressure control valve (e.g., 420A, 420B); electrodes 410, a porous plug (e.g. 440, micro pore plastics that allow gas to pass but block fluid motion), and optionally a membrane (e.g., 415, Nafion<sup>TM</sup>) that absorbs the electrolysis medium (e.g., H<sub>2</sub>O with NaCl dissolved at 0.001mole/liter) allowing a current to pass between the electrodes as if the electrodes were

essentially in free electrolysis material, and at the same time preventing the electrodes from touching. The membrane facilitates close placement of the electrodes increasing the electric field and hence the current. As illustrated the seal pressure value is as discussed above, the operating pressure is some value greater than the seal pressure value (e.g., 20% greater) at which an expandable element operates for a given condition. Figure 8 illustrates an electrolysis system where the gas generated passes through a porous plug into a chamber that has control valves. The control valves are designed to allow a certain gauge pressure value to be reached inside the chamber (e.g., 0.25 bar, 0.5 bar gauge) while allowing gas from the outside of the chamber to enter if the gauge pressure value drops below a value (e.g., -0.5 bar gauge), where the gauge pressure in this instance is calculated as the pressure inside the chamber minus the pressure outside the chamber. A non-limiting example of sealing time is 12 seconds for a balloon volume of  $1000\text{mm}^3$  using  $< 12$  volts and less than 300 mamps.

**[0029]** An example of electrolysis conversion efficiency is conversion at 75% efficient, roughly 4.0 J/per inflation, or roughly 0.0002823 grams  $\text{H}_2\text{O}$  for roughly  $0.2823\text{ mm}^3$   $\text{H}_2\text{O}$ .

**[0030]** Figure 9 is another exemplary embodiment of a pressure generation and management system in accordance with at least one exemplary embodiment. In this exemplary embodiment the gas formation is controlled by controlling the size of the electric field (e.g., by relative placement of the electrodes (e.g., platinum cylinders)) As the gas is generated fluid must be displaced and a partially filled balloon can start to fill. Near the gas formation region a porous plug can be used to let the gas generated pass and a valve (e.g., duckbill, for example from VERNAY<sup>TM</sup> or a MINIVALVE<sup>TM</sup>), or other types of valves, such as flapper valves, umbrella valves, spring and ball valves, and any other valves that have low leak rates (loss of less than 5% internal pressure in 8-16 hours)), can be used to control the amount of pressure generated. Note that the fluid moves 550 by being displaced by controlling where the bubble formation 560 occurs (e.g., by placing the electrodes closer at the first desired bubble formation point).



**[0031]** Figure 10 illustrates another pressure generation and management system, which includes a manual depression balder (e.g., 680). When depressed the gas and/or fluid in the volume defined by the depression balder (e.g., 680) can be encouraged (e.g., by correctly placed one-way valves (e.g., 620B, 620C)) to move the evacuated gas and/or fluid along a tube to further inflate or pressurize an expandable element (e.g., 630 Balloon). Another valve (e.g., 620A) can control the largest value of the pressure.

**[0032]** Figure 11 illustrates another non-limiting example of a pressure generation and management system 700. In the illustrated system an elastic bladder (e.g., 765) provides a bladder force 775 that can aid in forcing any formed gas through the porous plug 740.

**[0033]** Figure 12 illustrates yet another exemplary embodiment of a pressure generation and management system 800. In the system illustrated as gas is formed water is displaced expanding the elastic bladder 865. The expanding elastic bladder (e.g., compliant urethane) displaces medium (e.g., 837) in a chamber, where the displaced medium can further inflate an expanding element (e.g., Balloon 830).

**[0034]** Figure 13 illustrates yet another pressure generation and management system 900 according to at least one exemplary embodiment. As in Figure 12 the gas is forced through the porous plug (e.g., 940), however in the configuration illustrated a smaller chamber is constructed with it's own inflation bladder (e.g., 985) and the pressure control system (e.g., valves 920A and 920B) are operatively connected to the smaller chamber.

**[0035]** Although not mentioned to this point, the electrodes can vary in shape and relative size. For example the electrode producing more gas (e.g., the – electrode associated with H formation in water) can be made large in surface area facilitating more formation area. Additionally the electrodes can be separated by an electrolysis medium absorber (e.g., Nafion<sup>TM</sup>, 1020). Figures 14A through 14C illustrate several non-limiting arrangement of electrodes. Note that electrode material can vary for example conductive material that will not oxidize in the electrolysis medium (e.g., stainless steel, platinum, gold). The spacer 1020 that allows current to flow between electrodes at a level similar to the current without the spacer but separates the

electrodes so there is no shorting (e.g., Nafion<sup>TM</sup>) This configuration can also keep air in but not water.

**[0036]** Figure 15 illustrates at least one pressure generation and management system in accordance with at least exemplary embodiment. In this system the electrodes are surrounded by a water soluble (porous) membrane (e.g., Nafion<sup>TM</sup>), so that when gas is produced water is forced through the membrane while gas is still trapped inside the enclosed membrane chamber. An opening connected to a porous plug can allow the gas trapped to escape, and the pressure can be controlled by placing a valve after the porous plug. Note that the electrodes can position relative to each other to control the gas formation.

**[0037]** Note that several configuration illustrate gas as the expanding and/or displaced medium, note that other exemplary embodiment can use the same configuration for liquids. For example the displaced medium (e.g., 937) in Figure 13 could be a fluid (gas or liquid).

**[0038]** At least one exemplary embodiment is directed to a device (e.g., an occlusion effect mitigation device, a sound isolation device, an earpiece) comprising: an insertion element (e.g., catheter, catheter with multiple interior channels, tube, body of an earpiece (thus possible irregular)); and an expandable element (e.g., stressed membrane, balloon, electroactive membrane, stressed foam or a combination of these) operatively attached to the insertion element, where the expandable element is configured to expand against a portion of the walls of a channel (e.g., an ear canal, nose pipe,) where the device is configured to seal the channel when expanded (e.g., inflated). Upon sealing the device can reduce sound transmission and/or the occlusion effect in any sealed chamber. Note that the catheter can have at least one interior channel and the interior channel can transmit acoustic energy. In at least one exemplary embodiment the expandable element is a balloon, with an expanding medium inside the balloon, where the expanding medium is at an operating pressure. The balloon can be variable volume (e.g., made of a material with an linear elongation > 50% at operating pressure) or a constant volume balloon (e.g., a balloon made to a certain shape where upon inflation at an operating

pressure does not expand more than 100% by volume from its shape volume). Note that the balloon shape can vary and be irregular or regular, for example disk shaped, conical, and/or spherical. Note that the operating pressure can be between 0.15 and 1 bar gauge pressure. Also note that the fluid can be ambient air.

**[0039]** Thus, the description of the invention is merely exemplary in nature and, thus, variations that do not depart from the gist of the invention are intended to be within the scope of the exemplary embodiments of the present invention. Such variations are not to be regarded as a departure from the spirit and scope of the present invention.

**CLAIMS**

What is claimed is:

1. An occlusion effect mitigation device comprising:

an insertion element; and

an expandable element operatively attached to the insertion element, where the expandable element is configured to expand against a portion of the walls of a channel forming a sealed chamber in the channel, where the expansion reduces the occlusion effect in the sealed chamber.

2. The device according to claim 1 where the channel is a flexible channel.

3. The device according to claim 1, where the insertion element is a catheter.

4. The device according to claim 3, where the catheter has at least one interior channel

5. The device according to claim 4, where the at least one interior channel is configured to transmit acoustic energy.

6. The device according to claim 1, where the expandable element is a balloon, with an expanding medium inside the balloon, where the expanding medium is at an operating pressure.

7. The device according to claim 6, where the balloon is at least one of disk shaped, conical, spherical.

8. The device according to claim 7, where the balloon is configured so that it can have a linear elongation greater than 50% when inflated at an operating pressure.

9. The device according to claim 8, where the operating pressure is between 0.15 and 1 bar gauge pressure.
10. The device according to claim 9, where the interior medium is air.
11. A sound isolation device comprising:
  - an expandable element; and
  - an insertion element, where the expandable element is operatively attached to the insertion element, where the expandable element includes an expanding medium, where the pressure of the expanding medium is varied to vary sound isolation across the expandable element.
12. The device according to claim 11 where the channel is a flexible channel.
13. The device according to claim 11, where the insertion element is a catheter.
14. The device according to claim 13, where the catheter has at least one interior channel
15. The device according to claim 14, where the at least one interior channel is configured to transmit acoustic energy.
16. The device according to claim 11, where the expandable element is a balloon, with an expanding medium inside the balloon, where the expanding medium is at an operating pressure.
17. The device according to claim 16, where the balloon is at least one of disk shaped, conical, spherical.

18. The device according to claim 17, where the balloon is configured so that it can have a linear elongation greater than 50% when inflated at an operating pressure.

19. The device according to claim 18, where the operating pressure is between 0.15 and 1 bar gauge pressure.

20. The device according to claim 19, where the interior medium is air.

21. A method of sound isolation comprising:

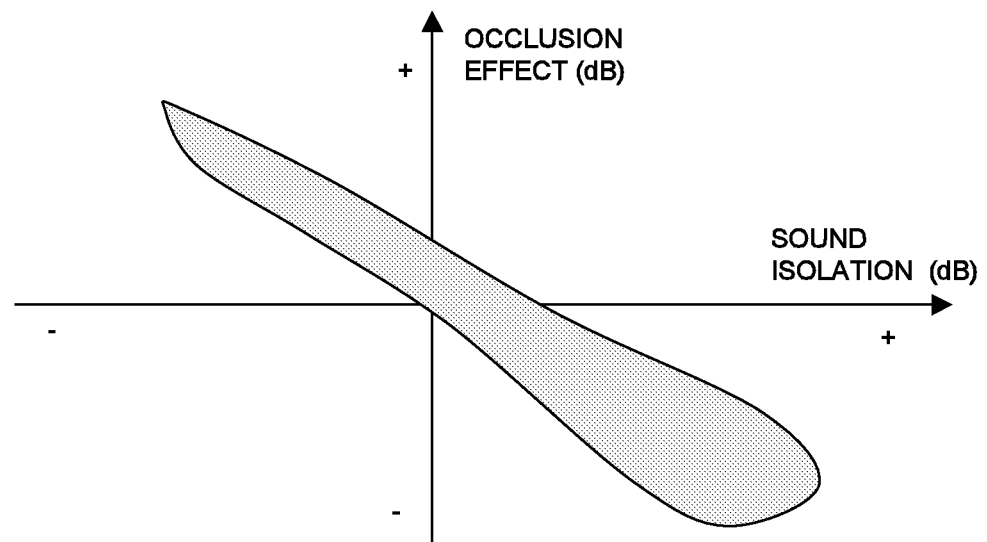
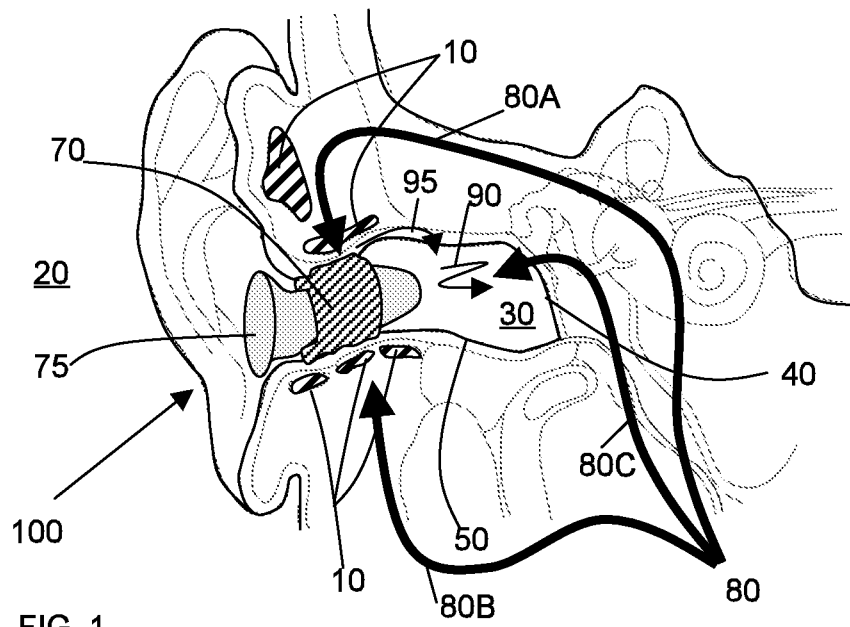
expanding an element to a first pressure where the expanded element varies the sound isolation across the element as the pressure exerted by the expanding element is varied.

22. A method of occlusion effect reduction comprising:

inserting an insertion element into a flexible channel; and

expanding an expanding element , where upon insertion of the insertion element and expansion of the expanding element a sealed chamber is formed, where when the expanding element presses against a portion of a wall of the flexible channel, the occlusion effect in the sealed chamber is reduced.

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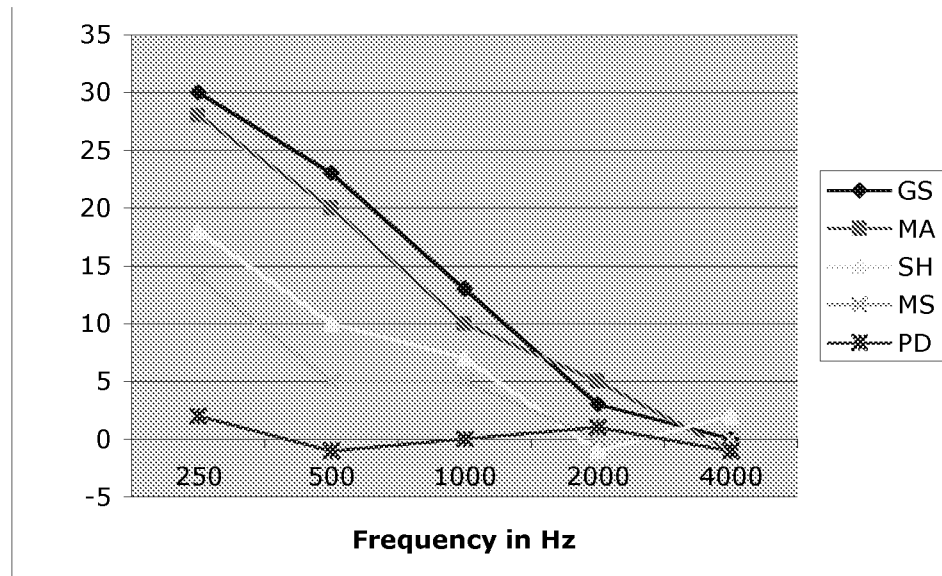


FIG. 3

GS = PDR10  
 MA = TDH39  
 SH = Circumaural  
 MS = Noise Foe Mark II  
 PD = Loudspeakers in spheres

Author Mode of Occlusion	250 Hz		500 Hz		1000 Hz		2000 Hz	
	Occlusion		Occlusion		Occlusion		Occlusion	
	Shift	SD	Shift	SD	Shift	SD	Shift	SD
Elpern & Naunton (TDH 39 MX41/AR)			20	4	9	4.5	0	4.5
Goldstein & Hayes (1965) (TDH 39 MX41/AR - Mastoid)			12.57	9.65	5.71	7.05	1.07	3.83
Goldstein & Hayes (1965) (TDH 39 MX41/AR - Forehead)			13.11	6.58	4.86	3.52	0.43	2.99
Dirks & Swindeman (TDH 39 MX41/AR)			20.2	5.1	8.8	4.5	.5	2.9
Hodgson & Tillman** (TDH 39 MX41/AR)			23.0	*	10	*	-1	*
Feldman, Grimes & Shur (TDH 39 MX41/AR)			23.0	7.4	8.1	3.6	-.1	6.9

FIG. 4



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Author Mode of Occlusion	250 Hz		500 Hz		1000 Hz		2000 Hz	
	Occlusion		Occlusion		Occlusion		Occlusion	
	Shift	SD	Shift	SD	Shift	SD	Shift	SD
Huizing (1960) - Mastoid (Plug: Drum & 1/4 wave back)			15	*	8	*	1	*
Tyszka & Goldstein (Earmold - depth not noted)			9.5	*	11.2	*	*	*
Wimmer (1986) (Earmold - Std. Depth)		22			17			9

FIG. 5

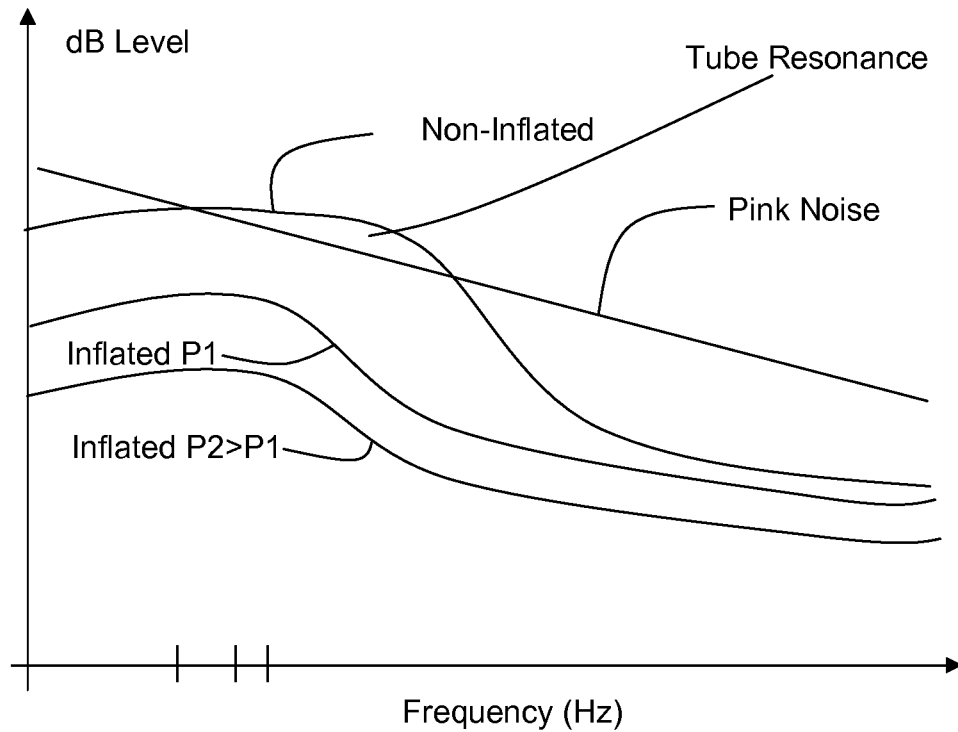
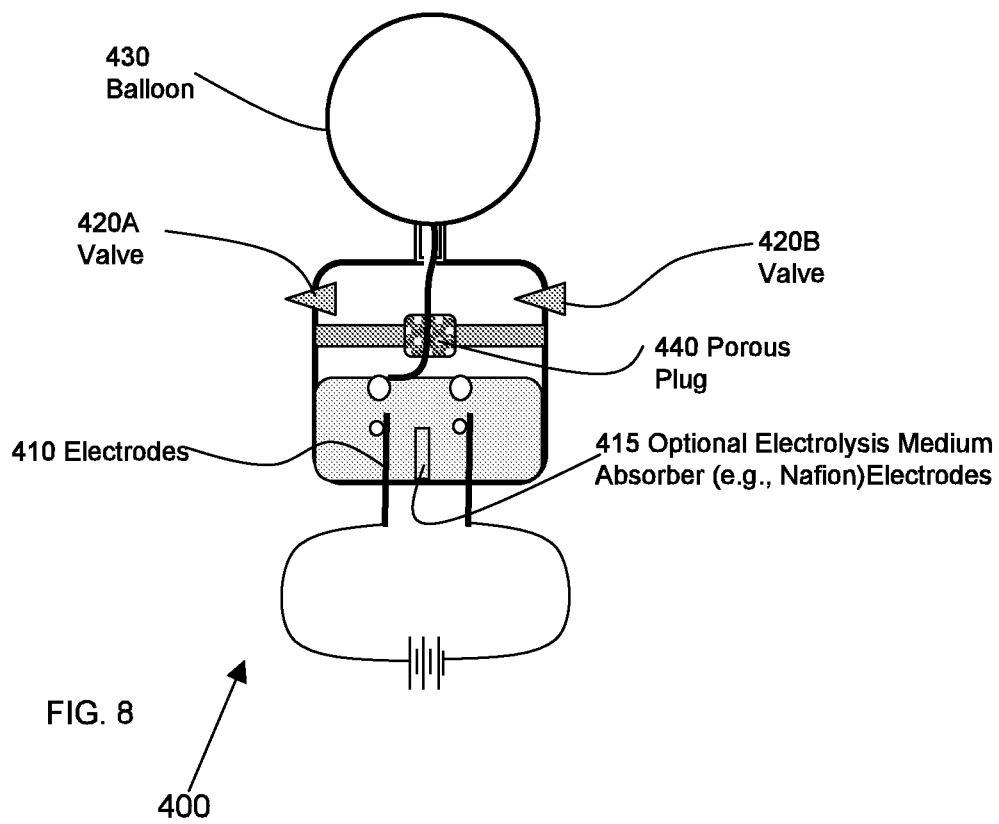
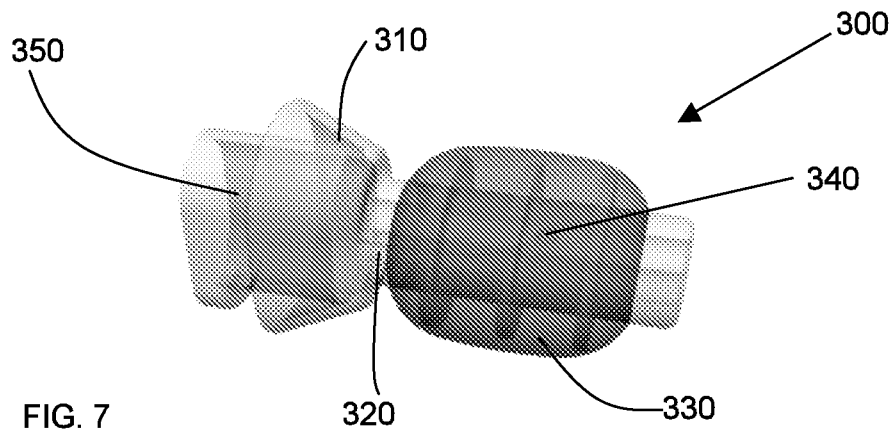


FIG. 6 semi-log plot

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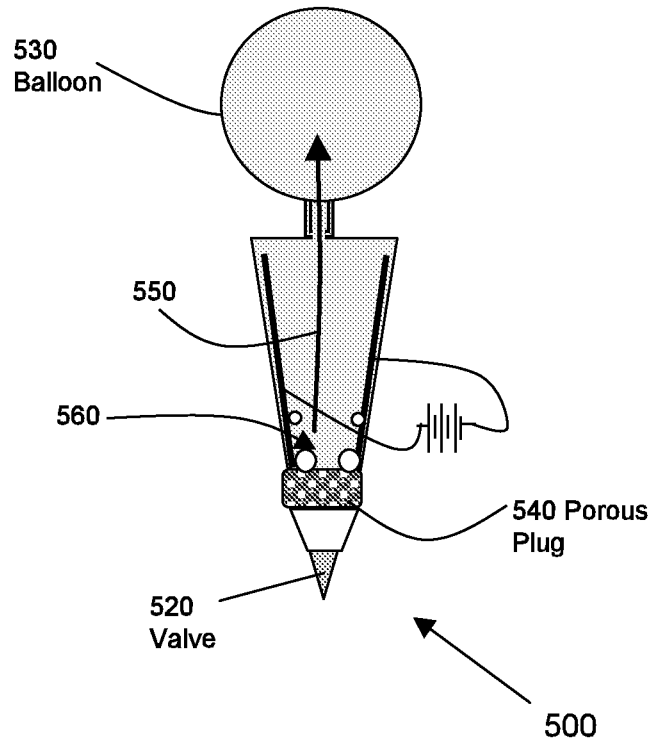


FIG. 9

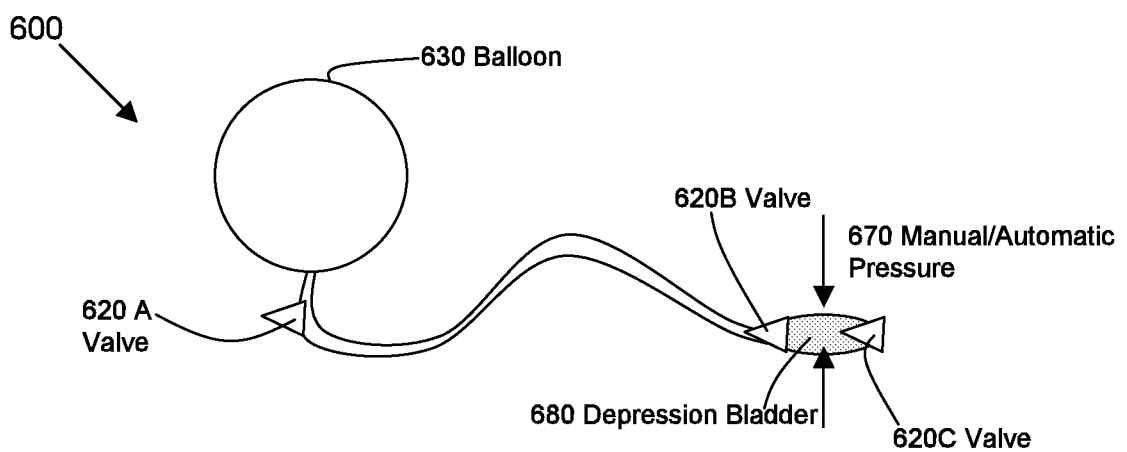


FIG. 10

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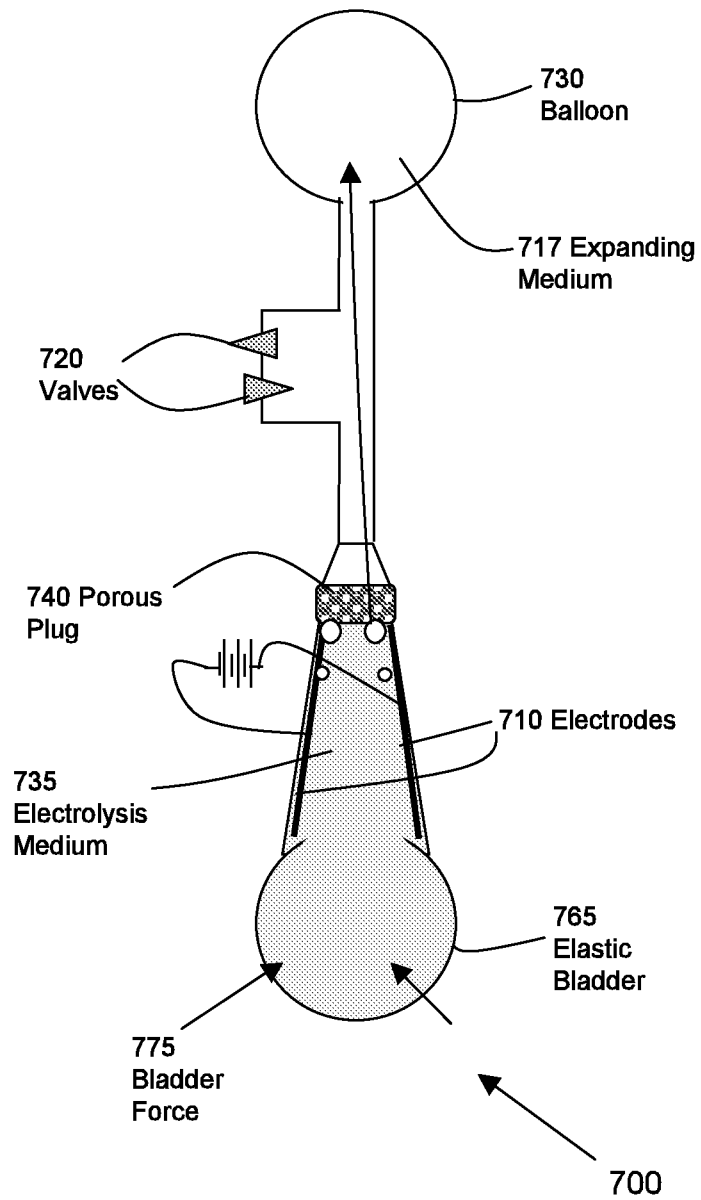
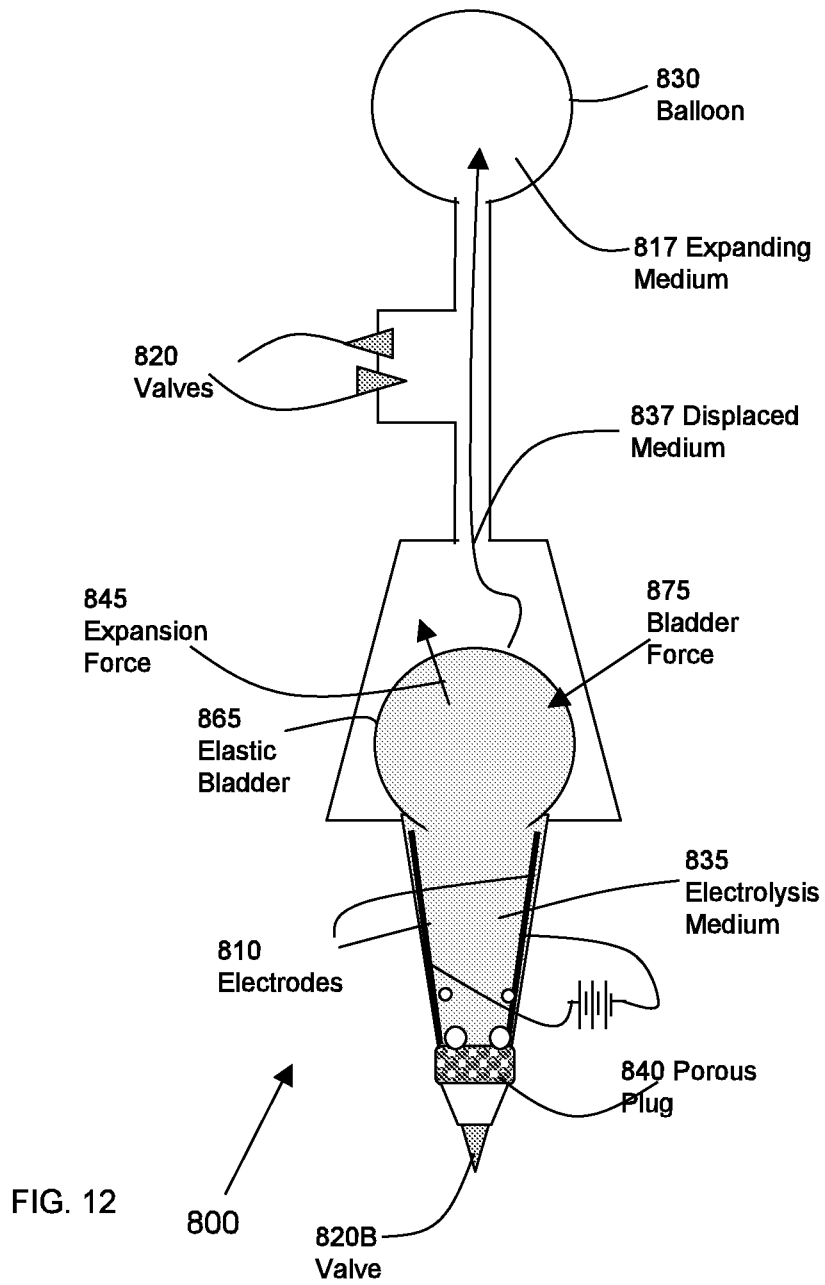


FIG. 11

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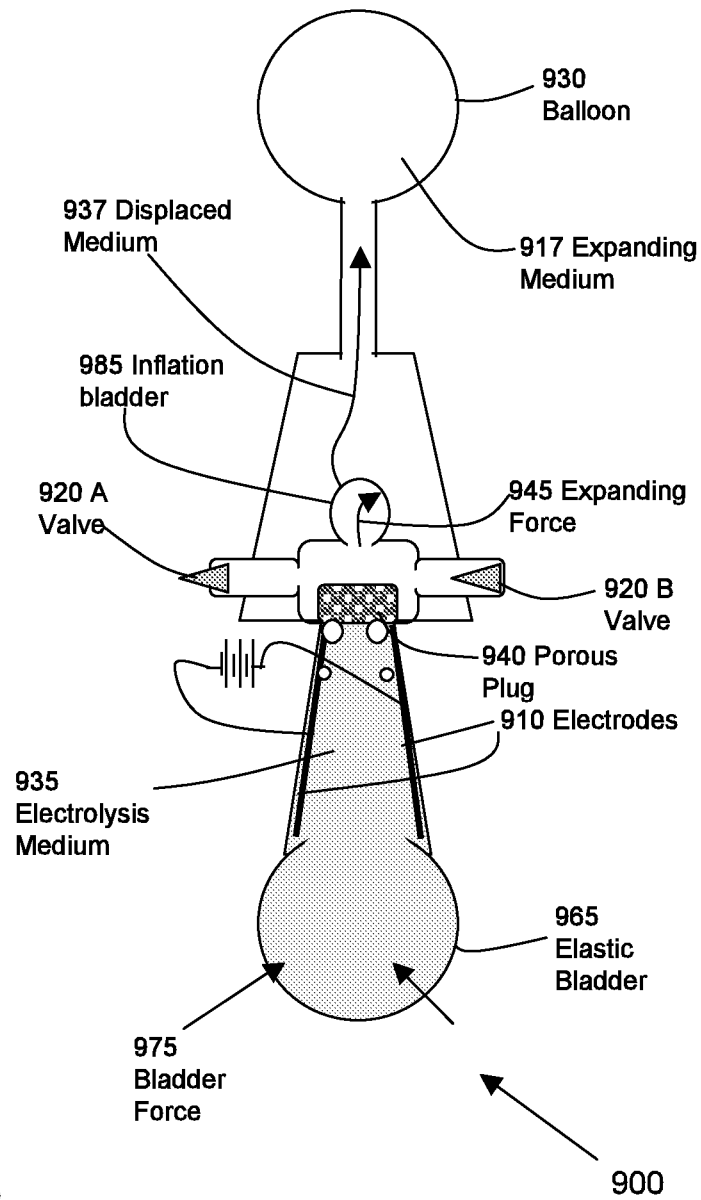


FIG. 13

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FIG. 14A

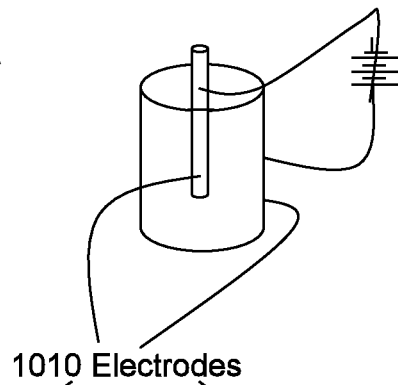


FIG. 14B

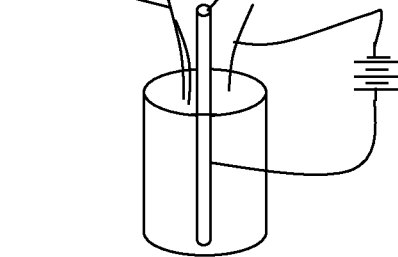
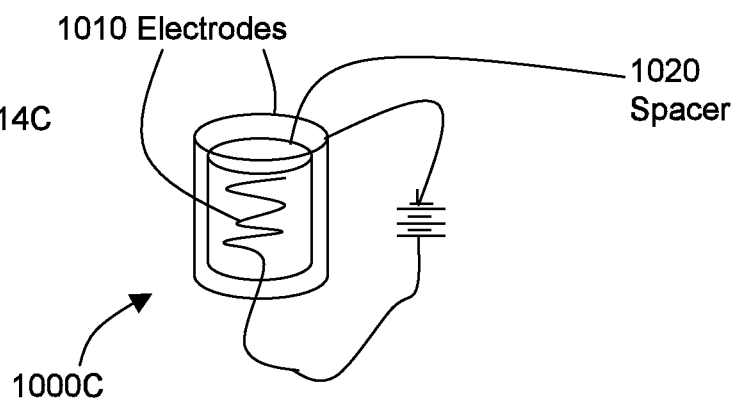
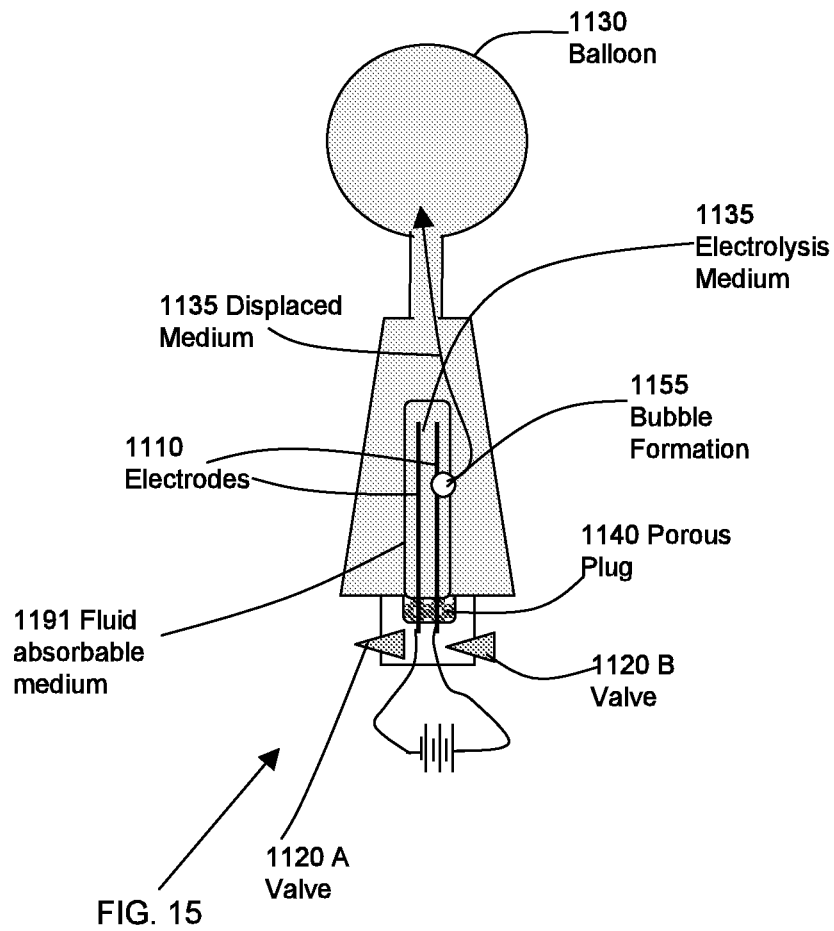


FIG. 14C



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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2009/048869

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 11/00 (2009.01)

USPC - 381/72

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)

IPC(8) - A61F 11/00 (2009.01)

USPC - 128/864, 865, 898; 181/130, 135; 381/72; 600/559; 604/264; 606/108; 607/57; 623/1.11

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)

PatBase

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2,824,558 A (MICHAEL et al) 25 February 1958 (25.02.1958) entire document	1-22
A	GB 643,927 A (ZWISLOCKI) 27 September 1950 (27.09.1950) entire document	1-22
A	US 3,275,001 A (ROSECRANS) 27 September 1966 (27.09.1966) entire document	1-22
A	US 2001/0040973 A1 (FRITZ et al) 15 November 2001 (15.11.2001) entire document	1-22

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Further documents are listed in the continuation of Box C.

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\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&amp;" document member of the same patent family

Date of the actual completion of the international search

13 November 2009

Date of mailing of the international search report

25 NOV 2009

Name and mailing address of the ISA/US

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