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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 September 2014 (18.09.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/140750 A1

(51) International Patent Classification:
A61F 5/00 (2006.01) *A61H 23/04* (2006.01)

(21) International Application Number:
PCT/IB2014/000327

(22) International Filing Date:
13 March 2014 (13.03.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/794,047 15 March 2013 (15.03.2013) US

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

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) Title: ORAL MOUTHPIECE AND METHOD FOR THE USE THEREOF

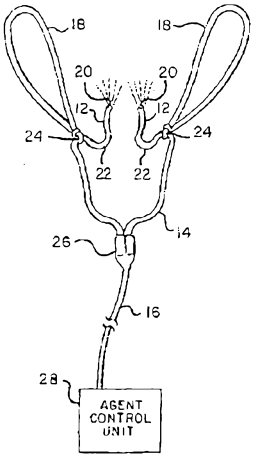

FIG.1

(57) Abstract: The present invention relates generally to an oral device, or mouthpiece, for delivering a fluid to the mouth or oropharynx of a user. In one embodiment, the oral device includes an intraoral portion defining intraoral conduits and an extraoral portion. The extraoral portion defines at least one extraoral conduit in flow communication with the intraoral conduits. The extraoral portion is connectable to a fluid supply, wherein the intraoral portions and extraoral portion form a delivery conduit. The delivery conduit includes a one-way valve permitting one directional flow from the extraoral conduit to the intraoral conduits. A method of dispensing a fluid using the oral device is also provided.

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ORAL MOUTHPIECE AND METHOD FOR USE THEREOF

[0001] This application claims the benefit of U.S. Provisional Application No. 61/794,047, filed March 15, 2013, the entire disclosure of which is hereby incorporated herein by reference.

FIELD OF THE INVENTION

[0002] This invention relates to oral appliances and in particular a mouthpiece used to deliver at least one substance or stimulus.

BACKGROUND OF THE INVENTION

[0003] Swallowing is a complex behavior in which the output of an integrative brainstem network gives rise to a patterned movement sequence described as the pharyngeal stage of swallowing. While several lines of evidence have demonstrated the importance of oropharyngeal sensory inputs in activating this medullary swallowing network, the range of afferent patterns that are both necessary and sufficient to evoke swallowing has not been fully elucidated. Stimulation of receptive fields innervated by the superior laryngeal nerve (SLN) or the pharyngeal branch of the glossopharyngeal nerve (GPNph) appear to be particularly effective in evoking or modulating the pharyngeal swallow; these "reflexogenic" areas correspond to the laryngeal mucosa, including the epiglottis and arytenoids, the lateral pharyngeal wall, posterior tonsillar pillar and peritonsillar areas.

[0004] In humans, the anterior faucial pillar historically has been considered the most reflexogenic site for swallowing. However, the recent

finding that the pharyngeal swallow may begin after the bolus head passes the anterior faucial pillars in healthy adults, including geriatric adults, suggests that stimulation of more posterior pharyngeal regions may help facilitate the initiation of swallowing. The importance of more posterior oropharyngeal areas in swallowing elicitation is also suggested by anatomic evidence that the human posterior tonsillar pillar, as well as discrete regions of the palate, pharynx and epiglottis are innervated by a dense plexus formed from the GPNph and the internal branch of the SLN. The spatial correspondence between these areas of dual SLN/GPNph innervation and reflexogenic areas for swallowing has lead to the hypothesis that swallowing is elicited most readily by stimulation of areas innervated by both the GPNph and SLN. Dynamic stimuli that excite primary afferents within a number of receptive fields over time appear to elicit swallowing more readily than do static stimuli.

[0005] A variety of stimulus modalities have been applied in attempts to evoke swallowing (for review, see Miller, 1999). Repetitive electrical stimulation of the SLN or the GPN, particularly at stimulation frequencies between 30 and 50 Hz, evokes swallowing in a number of animal species. This suggests that the repetitive nature of the stimulus, and the repetition rate, are critical variables in swallowing elicitation. More recently, electrical stimulation of the pharynx has been reported to increase both the excitability and size of the pharyngeal motor cortex representation in humans (14), and facilitate swallowing in dysphagic patients following stroke. Mechanical and chemical stimuli can evoke swallowing in animal species. In humans, reports of the effects of cold mechanical stimulation of the anterior tonsillar pillar have

been variable, some authors reporting decreases in swallowing latency and increases in swallowing frequency (16), and others failing to find an effect of this type of stimulation on oropharyngeal bolus transit, esophageal coordination, or the temporal pattern of swallowing. Three studies have examined the effects of cold mechanical stimulation applied to the anterior tonsillar pillars in small samples of dysphagic stroke patients. They reported a short-term facilitation of swallowing, measured in terms of reduced delay of the pharyngeal swallow, in some patients, with no related reduction in aspiration. Longitudinal studies, examining the potential long-term effects of oropharyngeal sensitisation on not only swallowing physiology but also on nutritional and respiratory health, have not been reported. Reports on the effects of gustatory stimuli also have been variable. A sour bolus has been reported to facilitate swallowing in stroke. Whereas some authors have reported that swallowing latency is significantly reduced by a combination of mechanical, cold, and gustatory (sour) stimulation, others have reported that a cold plus sour bolus reduces the speed of swallowing.

[0006] Air-pulse trains also have been considered as a stimulus that may faciliate the pharyngeal swallow. For example, a single air pulse is a dynamic stimulus that could be applied to a number of receptive fields including regions innervated by both the GPNph and SLN. Furthermore, an air-pulse train represents a repetitive stimulus that can be applied at specific frequencies and pressures. Some devices have been suggested for delivering such air-pulse trains, as disclosed for example in US patent

application 2010/0016908, the entire disclosure of which is hereby incorporated herein by reference. The air pulse trains are directed to the oral cavity by way of an oral device, which is positioned and secured through various devices. For example, the '908 publication describes, in one embodiment, an "over-the-ear" oral device configured such that the flexible tubing that delivers the air pulse trains wraps around the ears of the user.

SUMMARY

[0007] The present invention is defined by the following claims, and nothing in this section should be considered to be a limitation on those claims.

[0008] In one aspect, an oral device, or mouthpiece, is provided for delivering a stimulus, for example and without limitation a fluid, to the mouth or oropharynx of a user. In one embodiment, the oral device includes three portions: an intraoral portion, an extraoral portion, and an auxiliary support device. The auxiliary support device may include two ear loops (i.e., located on the right and left sides of the mouthpiece), or a band that surrounds the user's head, and which serve to stabilize the oral device. In one embodiment, the ear loops are knitted elastic. The intraoral portion generally includes at least one outlet port through which at least one agent or stimulus is delivered to the oral cavity or oropharynx. In one embodiment, the extraoral portion generally includes at least one (proximal) inlet port (or connector) that is connected to a control system

(i.e., that generates the "agent(s)"), and at least one distal end that is continuous with the intraoral portion of the oral device.

[0009] In other embodiments, the auxiliary support device may include one or more support frames or members, including without limitation a Y-shaped yoke, a U-shaped frame, or a laterally extending support member that engages the user's face above or at an upper lip.

[0010] In other embodiments, an oral mouthpiece includes a pair of laterally spaced intraoral portions defining intraoral conduits each having at least one outlet port adapted to dispense at least one fluid pulse and an extraoral portion integrally formed with each of the intraoral portions. The extraoral portions include a pair of spaced apart lip bends communicating with the intraoral portions and a pair of chin portions extending downwardly from the lip bends, with the chin portions forming a loop positionable under the user's chin. The oral mouthpiece may be deployed with or without an auxiliary support device.

[0011] In another aspect, a method of delivering a fluid to a predetermined location in a user's mouth includes disposing a flexible tube between an outer side of a row of teeth and an inner surface of a cheek, securing the flexible tube to the user with an auxiliary support device separate from the tube and formed from a different material than the flexible tube, and dispensing the fluid through the exit port.

[0012] The various oral devices and methods for the user thereof provide various advantages. For example and without limitation, the oral

device may be easily and securely positioned on the user in a reliable manner without impinging on the face of the user, and without interfering with other accessories, such as eyeglasses or hearing aids, positioned on the user.

[0013] The foregoing paragraphs have been provided by way of general introduction, and are not intended to limit the scope of the following claims. The various preferred embodiments, together with further advantages, will be best understood by reference to the following detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The invention will now be described by way of example only, with reference to the accompanying drawings, in which:

[0015] Fig. 1 is a plan view of the oral mouthpiece of the present invention;

[0016] Fig. 2 is front view of a user with the oral mouthpiece of figure 1 located in an operational position;

[0017] Fig. 3 is a plan view of an alternate embodiment of the oral mouthpiece of the present invention;

[0018] Fig. 4 is a front view of a user with the oral mouthpiece of figure 3 located in an operational position;

[0019] Fig. 5 is a side view of the user of figure 4;

[0020] Fig. 6 is a plan view of an alternate embodiment of the oral mouthpiece of the present invention similar to that shown in figure 1 but showing a plurality of ports;

[0021] Fig. 7 is a perspective view of another embodiment of the oral mouthpiece of the present invention;

[0022] Fig. 8 is a schematic representation of the experimental protocols;

[0023] Fig. 9 is a graph showing the supply pressure versus the surface pressure as measured at a plurality of distances form the distal tip of the mouthpiece;

[0024] Fig. 10 is a graph showing supply pressure versus volume delivered for 5 ms pulse;

[0025] Fig. 11 is a graph showing the saliva swallowing rate;

[0026] Fig. 12 is a graph showing the effect of air-pulse train duration;

[0027] Fig. 13 is a graph showing air-pulse train duration versus sham;

[0028] Fig. 14 is a graph showing the effect of air-pulse amplitude;

[0029] Fig. 15 is a graph showing air-pulse amplitude versus sham;

[0030] Fig. 16 is a graph showing the effect of air-pulse frequency;

[0031] Fig. 17 is a graph showing air-pulse frequency versus sham; and

[0032] Fig. 18 is a histogram showing the group swallowing rates.

[0033] FIG. 19 is a plan view of an alternative embodiment oral device.

[0034] FIG. 20 is a perspective view of the yoke shown in Figure 19.

[0035] FIG. 21 is a front view of the yoke shown in Figure 20.

[0036] FIG. 22 is a top, perspective of the yoke shown in Figure 20.

[0037] FIG. 23 is a side view of the yoke shown in Figure 20.

[0038] FIG. 24 is a partial, perspective view of an alternative embodiment oral device.

[0039] FIG. 25 is a side view of the oral device shown in Figure 24 applied to a user.

[0040] FIG. 26 is a front view of the oral device shown in Figure 24 applied to a user.

[0041] FIG. 27 is a partial, perspective view of an alternative embodiment oral device.

[0042] FIG. 28 is a perspective view of the oral device shown in Figure 27 applied to a user.

[0043] FIG. 29 is a perspective view of an alternative embodiment of a yoke.

[0044] FIG. 30 is a partial end view of one side of the yoke shown in Figure 29.

[0045] FIG. 31 is a perspective view of an alternative embodiment oral device.

[0046] FIG. 32 is a front, perspective view of the oral mouthpiece shown in Figure 3.

[0047] FIG. 33 is a top view o the oral mouthpiece shown in Figure 32.

[0048] FIG. 34 is a front view of the oral mouthpiece shown in Figure 32 applied to a user.

[0049] FIG. 35 is a side view of the oral mouthpiece shown in Figure 32 applied to a user.

[0050] FIG. 36 is an alternative to view of the oral mouthpiece shown in Figure 33.

[0051] FIG. 37 is a top view of the oral mouthpiece shown in Figure 7.

[0052] FIG. 38 is a side view of the oral mouthpiece shown in Figure 37 as applied to as user.

[0053] FIG. 39 is a front view of the oral mouthpiece shown in Figure 1 as applied to a user.

[0054] FIG. 40 is a side view of the oral mouthpiece shown in Figure 29 as applied to a user.

[0055] FIG. 41 is a side view of the oral mouthpiece shown in Figure 1 without an auxiliary support device secured thereto.

[0056] FIG. 42 is a front view of the oral mouthpiece shown in Figure 41.

[0057] FIG. 43 is a front view of the oral mouthpiece shown in Figure 42 with an auxiliary support device secured thereto.

[0058] FIG. 44 is a perspective view of one embodiment of an oral mouthpiece.

[0059] FIGS. 45-49 show various views of another embodiment of an oral mouthpiece.

[0060] FIGS. 50A-D show various views of a vibrating element shell.

[0061] FIGS. 51A-D show various views of a vibrating element.

[0062] FIG. 52 shows an oral device kit and assembly.

[0063] FIG. 53 shows a pair of vibrating elements applied to a user.

DETAILED DESCRIPTION OF THE DRAWINGS

[0064] Referring to Figures 1, 2 and 39-43, one embodiment of an oral mouthpiece is shown generally at 10. The oral mouthpiece 10 includes intraoral portions 12, extraoral portions 14 and an auxiliary support device, configured in this embodiment as ear connectors 18. The extraoral portions 14 include a supply portion 16. The intraoral portions 12 define intraoral conduits. The extraoral portions 14 define an extraoral conduit. The intraoral conduit is in flow communication with the extraoral conduit.

[0065] The intraoral portion 12 of the mouthpiece 10 enters the mouth at the angle or corner of the mouth on the user's right and left sides. The intraoral portion 12 extends along the buccal cavity, or vestibule, lateral to the teeth and medial to the cheek, on the right and left sides of the mouth. The length of the intraoral aspect is typically between 20 mm and 50 mm for human adult users, and may be less for pediatric users. The lengths of the intraoral portions may be modified by the user by advancing, or retracting, the intraoral segment that is in flow communication with the extraoral segment, relative to the auxiliary support device. This is an advantage of the device in that the intraoral segments may be modified to accommodate the user's specific oral anatomy. The intraoral portion or aspect 12 ends caudally with an output port 20 such that an agent or substance or stimulus can be delivered from this output port 20 in the general region of the posterior mouth or oropharynx on the right and left sides.

[0066] In one embodiment, the intraoral portion 12 is oriented superiorly and caudally within the buccal cavity such that the output port 20 is situated lateral to the maxillary premolars or molars during use. One advantage of having the intraoral portion or aspect 12 angled superiorly from its origin at the corner of the mouth is that the output port 20 of the mouthpiece does not come in contact with pooled saliva that may accumulate in the region of the mandibular dental arch. However, the intraoral portion 12 of the mouthpiece may be oriented along a variety of angles, relative to the horizontal plane, providing a means for positioning the output port 20 lateral to the mandibular molars, or along the occlusal plane, depending upon the specific conditions and requirements of the user including the oral anatomy and the dentition.

[0067] In another aspect, the intraoral portion 12 of the mouthpiece 10 may be oriented along a variety of angles, relative to the user's sagittal plane, and be gently curved, along this principal off-sagittal orientation, such that it follows the natural contour of the buccal cavity and maxillary or mandibular dental arches, thereby providing optimal comfort for the user. The general orientation and local curvature of the intraoral portion 12 can be provided as manufactured aspects of the mouthpiece 10. Alternatively, the mouthpiece can be provided such that these aspects of the intraoral portion 12 can be manually molded by the clinician, caregiver, or user. The capacity to orient and curve the intraoral aspect of the mouthpiece can be provided by a length of fine malleable wire being embedded within the

intraoral portion 12 of the mouthpiece on the left and right sides of the mouth. This may represent an advantage in that the user, or caregiver, would be provided a means of molding the mouthpiece to the specific anatomy of the individual user.

[0068] In another aspect, the intraoral 12 and extraoral 14 portions of the mouthpiece are continuous as right and left or pair of first looped regions 22 of mouthpiece that are positioned at the right and left angles or corners of the user's mouth during use. These two looped regions, which form lip bends, are oriented approximately in parallel with the user's axial or horizontal plane, at the level of the angles of the mouth.

[0069] The looped regions 22 where the intraoral 12 and extraoral 14 portions of the mouthpiece meet at the angles of the mouth are contiguous with a second, extraoral looped or curved region 24 that provides a site of attachment or site of origin for an auxiliary support device. In other embodiments, the looped region 24 may be omitted. In one embodiment, the auxiliary support device is configured as ear connectors 18 that are attached on the right and left sides of the mouthpiece 10. The ear connectors 18 may be ear loops that are made of a different material than the intraoral or extraoral portions. In one embodiment, the ear loops are knitted elastic ear loops. The second looped region 24 is oriented at approximately 45 degrees relative to the sagittal plane of the user on the right and left sides of the mouthpiece. In use the second looped regions 24 sit over the face, immediately lateral to the angle of the mouth on the

right and left sides, and does not extend rearwardly and/or upwardly for connection to the ears of the user. Rather, these looped regions 24 provide a point of origin for the auxiliary support device, such as the around-the-ear soft elastic ear loops 18 on the right and left sides of the mouthpiece. By virtue of their orientation relative to the intraoral portions, these ear loop origin sites and associated ear loops provide a means of stabilizing the intraoral segments 12, without the elastic tending to pull the intraoral segment 12 out of the mouth. These looped regions 22 and 24 are continuous with a communicating region that extends inferiorly from the inferior aspect of the second looped portion for approximately 30 mm to 100 mm and then curves medially toward the user's midline plane so as to form a chin loop. As the right and left portions of the mouthpiece approach the midline, they articulate with a Y-connector 26, providing a means of delivering an agent from a single input post to right and left intraoral aspects of the mouthpiece.

[0070] In one embodiment, the Y-connector 26 is connected to the supply portion 16 of the mouthpiece 10, which supply portion continues for approximately 90 cm. The length of the supply portion 16 may extend from 0.50 meters to about 2.0 meters as shown in FIG. 44. A longer supply portion 16 is an advantage in that the mouthpiece user may move fairly freely in relation to the fluid control unit. For example, the mouthpiece use could move between lying and sitting in a hospital bed with the fluid control unit mounted on the head or side rail of the bed. This feature increases

the clinical utility of the mouthpiece system in the health care and home settings. At the end of the supply portion tube, a male luer connector may be provided. Alternatively, a low pressure one-way check valve luer connector 17 is provided. This is to prevent contamination of the control unit by any fluids, bodily or otherwise, that may traverse the tubing 16. The check valve 17, 720 may reduce the flow into the mouthpiece, dropping the flow rate to 2.4 to 2.5 L/min. The flow may be maintained above 2.0 L/min. The frequency and amplitude are not affected by the inclusion of the check valve 17.

[0071] Referring to FIGS. 45-49, one embodiment of the mouthpiece 700 may be formed as a one-piece component, including a Y-shaped intraoral tubing 702, inlet tube 704 with a check valve 720, a pair of ear loops 706, or other support device. The ear loops 706 may have on end molded to a lip contour wing 708 defining a lip-receiving portion 730, and have a free end 710, which may be inserted into and captured by a receptacle 712 on the wing 708. In this way, the length of the ear loop 706 may be adjusted by moving the free end 710 into and out of the receptacle. 712. Alternatively, the ear loop may be configured as a continuous non-adjustable loop. Engagement members, such as detents 714, may be molded into the loops to provide additional positional holding power. The engagement members may be configured, for example, as grooves or bumps along the length of the loops.

[0072] In one embodiment, the one-piece silicone component may be manufactured using a dual-shot dual-material-durometer, and/or an overmold process. In the first shot the majority of the components 702, 704, 708 will be formed, with the exceptions being the ear loops 706 and an opening 716 along the length of the outlet tubing (and corresponding Y) areas. The second show will mold the ear loops 706 in a low-durometer silicone as well as close the gap 716 in the outlet tubing. The ear loops may be formed of a lower durometer material. Depending upon the stiffness of the part required to allow the check valve 720 to operate properly, an additional molded-in component, such as a stiffening member 722, may be provided to provide additional rigidity. The check valve 704 is disposed in housing 724. The main body of the mouthpiece may be molded from ~60A durometer silicone rubber. The ear loop portions may be molded from 10-20A durometer silicone rubber. The optional stiffening membe r722 may be made from any hard plastic or metal that is compatible with a silicone over-mold process.

[0073] A control unit 28, shown in FIGS. 1-3 and 53 for example, is connected to the distal end of the supply portion 16 of the mouthpiece 10. The control unit 28 generates at least one agent, or delivers at least one agent to the supply portion 16 of the mouthpiece 10. Preferably the Y-connector is adjustable so that it can extend past the cheek/jaw thereby minimizing a patient's tendency to dislodge the mouthpiece. However,

there may be instances when a longer portion 14 is desirable, for example, in patients who are very sensitive to contact about the face and mouth.

[0074] In another embodiment shown in figures 3- 5 and 32-36, a continuous chin loop or region 30 is provided, extending from the right elastic attachment loop 24 (shown in figures 3 to 5) and, running inferiorly to the level of the user's chin, crossing the midline immediately anterior to the chin, and extending to the other side of the face where it runs superiorly and continues as the left elastic attachment loop 24 as best seen in figures 4 and 32.

[0075] In another aspect, one embodiment of the auxiliary support device is configured as ear loops 18 attached to the second looped 24 aspect of the extraoral portion 14 of the mouthpiece 10, described above. In one embodiment, the ear loops 18 are made of knitted nylon polyester elastic and are between 4 cm and 25 cm in length and between 1 mm and 7 mm in width. The ear loops 18 originate from a single site on the second curved portion 24 of the mouthpiece 10. There are several advantages afforded by the ear loops 24. In one embodiment, the auxiliary support device, and in particular the ear loops or head band, are more compliant or flexible (less stiff) than the extraoral and /or intraoral portions. For example, the ear loops or head band may have a much lower modulus of elasticity than the intraoral and extraoral portions, made for example of thermoformed tubing. The ear loops or head band provide a means of stablilizing the mouthpiece during use. Being made of soft, knitted elastic

material such as nylon polyester, the ear loops stretch substantially such that the mouthpiece can be effectively and comfortably stabilized and worn by individuals with different cranial and facial anatomy. The soft knitted material reduces the likelihood that the mouthpiece will cause discomfort or tissue damage to the hairy skin of the face or pinna. The narrow width and malleability/flexibility of the knitted elastic ear loops is another advantage in that the ear loops do not interfere with over-the-ear hearing aids or the over-the-ear portion of eyeglasses. This is particularly important since users of the mouthpiece will include older adults, as well as pediatric users who require eyeglasses and hearing aids as the result of congenital syndromes or conditions. The soft, knitted ear loops provide user comfort, even when the mouthpiece is used for extended periods of time.

[0076] In use, some flexibility at points 20, 22, and 24 provide a means of improving the fit, efficacy, and comfort of the mouthpiece for faces of various shapes and sizes. Some degree of malleability in the chin piece 30 (shown in figures 3 to 5) and extraoral portions 14 (shown in figures 1 and 2) is also advantageous in that this allows improved positioning of the two sections that rise up toward the angles of the mouth.

[0077] Another advantage of the knitted ear loops 18 is that many users, caregivers, and clinicians are familiar with them based on previous experience with ear loops on medical masks. Thus, the ear loops 18 will facilitate easy positioning of the mouthpiece by users by virtue of their

general familiarity with the procedures around knitted ear loops. Even for users who have not previously used knitted ear loops, there is an intuitive element around ear loops that would increase the likelihood that a naive user would position them correctly around the ears.

[0078] The mouthpiece 10 may be made of flexible tubing, for example, a pair of flexible tubes configured to be positioned on opposite sides of the face of a user. The oral device may include only a single tube positioned on one side of the user's face, for example, for the purpose of delivering an agent to one side of the mouth or oropharynx. This may be advantageous, for example, in patients who have undergone unilateral surgery for oral cancer, or in the case of a unilateral sensorimotor impairment of the face, mouth, or oropharynx.

[0079] The flexible tubes may be made of tubing which can be shaped into a given configuration but which has some flexibility and ability to conform to the face and mouth of the user. The tubes may have a 1/8th inch outer diameter and a 1/16th inner diameter forming a lumen. In various embodiments, the intraoral and/or extraoral portions may be made of various materials, including without limitation, polyurethane, polyethylene, PVC, silicone, rubber, or other suitable and biocompatible materials, and/or combinations thereof. In one embodiment, the tubing is 1.6mm ID x 3.2mm OD tubing made of TYGON® MPF-100 available from Saint-Gobain, Akron , Ohio.

[0080] It will be appreciated by those skilled in the art that the intraoral portions 12 may have a plurality of ports 40 formed therein in addition to the ports 20 positioned at the distal end of the intraoral portions 12.

[0081] Referring to figures 7, 37 and 38, the oral device 50 shown herein and fully described in US 2010/0016908 and WO 2009/127947, both of which are hereby incorporated herein by reference, may be improved upon by adding an auxiliary support device, shown as ear loops 52. Ear loops 52 are similar to those described above but are attached to the extraoral portion 54 proximate to where the extraoral portion 54 meets the intraoral portion 56. While the ear loops 52 serve to secure the oral device 50 to a user in a secure fashion. In the absence of earloops, this embodiment has the shortcoming that it can move out of position when the subject opens his/her mouth, or in patients with mouth/lip weakness the mouthpiece 50 could move out of position during use.

[0082] Referring to FIGS. 19-23, 29-30, 44 and 52, another embodiment of an oral device is shown. The oral device includes a pair of laterally spaced intraoral portions 112 defining intraoral conduits each having at least one outlet port 120 adapted to dispense at least one fluid pulse. An extraoral portion 114 is integrally formed with each of the intraoral portions. The extraoral portions define extraoral conduits in flow communication with the intraoral conduits. An auxiliary support device includes a yoke. In one embodiment, the yoke is configured as a Y-shaped frame 132 having a pair of arm portions 134 and an inlet portion 136, each configured with grooves or channels in which the extraoral portions are disposed and secured. As shown

in FIG. 23, the arm portions curve rearwardly from the inlet portion. In one embodiment, the arm portions extend at an angle α of about 20-60 degrees, and in one embodiment at an angle α of about 30-45 degrees, and in one embodiment at an angle α of 38.5 degrees. The frame shapes and holds the extraoral portions. In addition, each of the pair of arm portions 134 includes a wing with an attachment member 140. At least one securing member 142, configured for example and without limitation as an elastic band, may be secured to the attachment members 140. The band may be configured as a pair of ear loops, or as a single headband that encircles the user's head and locates and holds the yoke in position.

[0083] Referring to FIGS. 29 and 30, in one embodiment, wing portions 440 have a concave curved portion 444 that interfaces with the lips, or corner of the user's mouth, with the end portions 442 of the yoke arms extending into, and positioning intraoral portions of the tubing, in the mouth of the user. In essence, the end portions 442 and the attachment member 140 have a recess 446 formed therebetween so as to locate the yoke relative to the user, and the lips/mouth in particular, with the force applied by the securing member 18 urging the yoke against the user's lips/mouth. Referring to FIG. 30, the width (W) of the wing 440 may be widened at the junction 448 of the end portions 442 and the wings 440 at the area of contact with the user's lips/mouth so as to reduce the tissue contact pressure.

[0084] Referring to FIGS. 24-26, another embodiment of the oral device includes a pair of tubes 200, each defining intraoral and extraoral portions, and which may be configured as substantially straight, flexible tubes, or may

include lip bends as described above. A laterally extending support member 230 extends transversely to the tubes 200 and is positioned above an extraoral portion 214. The support member 230 may engage the user's face above or on/at an upper lip thereof. The support member 230 may be made of a cloth-like material, and may be elastic or non-elastic. The support member is coupled to the tubes 200 with a pair of clips 232. The clips 232 may be wrapped around the tubes, and are secured to the support member with fasteners, adhesives or combinations thereof. The clips 232 may include a lip bend portion that wraps around the upper lip of the user. At least one securing member 242 is coupled to opposite ends of the support member. The securing member may be configured as a pair of ear loops, or as a single head band. In use, the intraoral portions 212 are disposed in the user's mouth, with the support member 230 supported by the user's upper lip and securely held thereto with the securing member 242. This device may be particularly well suited for individuals that may have particular ailments or sensitivities around and under the chin.

[0085] Referring to FIGS. 27 and 28, another embodiment of an auxiliary support device includes a U-shaped frame 330 shaped and configured to be positioned under the user's chin. The frame has opposite end portions 332 coupled to an extraoral portion 314, and at least one securing member 342 coupled to the opposite end portions 332. For example, the tubes making up the extraoral portions may extend through openings 344 formed in the end portions. The U-shaped frame may be made from a flexible, but semi-rigid material, such as a plastic strip. The extraoral portions 314 may include ear

loop portions 316, thereby forming an integral securing member, or may extend downwardly along the chin as shown for example in the embodiment of FIG. 1. At least one securing member 342, configured as individual ear loops or as a head band may be additionally secured to the end portions, or may be the sole support for the end portions. The securing member locates and holds the support device firmly in position.

[0086] Referring to FIG. 31, another embodiment of an oral device 500 includes a pair of downwardly extending extraoral inlet portions 502, each configured with an attachment member 504, or loop, that may be coupled to a securing member, such as an ear loop or head band. The inlet portions have an opening 508 shaped and dimensioned to receive an auxiliary extraoral tube 506. The oral device further includes integrally formed intraoral portions 510, which are shaped and contoured to be positioned in the vestibule of the user's mouth between the teeth and inner cheek/lips. The intraoral portions are in fluid communication with the extraoral inlet portions, and thereby with the tubes 506 positioned in the inlet portions. The ends of the intraoral portions are each configured with a fluid exit port 512. An intraoral bridge 514 extends between the opposing pairs of inlet portions/intraoral portions. The bridge 514 is curved and shaped/dimensioned to be positioned in the vestibule. A cutout 516, or clearance opening, is formed in a mid/intermediate portion of the bridge to provide clearance for the maxillary labial frenulum. In one embodiment, the intraoral portions and bridge 510, 514 are positioned between the upper teeth and the user's cheek, with the inlet portions 502 extending downwardly. In another embodiment, the intraoral portions are

positioned between the lower teeth and cheeks, with the inlet portions extending upwardly. A securing member 18, e.g., ear loops or head band, is coupled to the attachment members and secures the oral device to the user. The oral device may be made of a molded rubber compound, or of various polymers otherwise herein described.

[0087] Referring to FIGS. 50A-53, another embodiment of an oral device includes a vibrating element assembly 800 that converts pulsing pneumatic pressure to a mechanical pressure. The vibrating element is placed directly on the skin, as shown in FIG. 53, causing vibration in the neck, muscles nad nerves of the user. The pneumatic pressure eliminates the need for electrical leads, and avoids heat build up and potential burns. The vibrating element may be used by itself, or in combination with the various oral devices shown and describe herein. In one embodiment, the vibrating element is connected to the controller, and the positive displacement pump incorporated therein, and responds to the air flow delivered by the pump. Alternatively, a syringe-type pump or diaphragm pump may be coupled to the vibrating element in a closed/sealed system. The net air flow is zero in such a system, with the vibrating element being operated without an oral device. In another embodiment, the vibrating element is coupled to a vacuum pump configured with a solenoid valve, operating the vibrating element in a reverse mode.

[0088] Referring to FIGS. 50A-53, the vibrating element assembly 800 includes a shell 802, which may be made of a suitable rigid polymeric material such as polypropylene or ABS. The shell may include a patient interface portion, which may have a circular profile, or some other shape such as

oblong or oval, or any polygonal shape. In one embodiment, having rounded edges minimizes the potential for irritation of the user's skin. A back side 812 may have a domed shape, and forms an interior cavity 810. An inlet port 814 extends from the back side and is in fluid communication with the cavity 810. The shell 802 may have a diameter of between about 20 and 25mm, or may be other sizes.

[0089] A membrane 804 is secured over the opening of the shell, closing the cavity. The membrane may be secured using adhesive, or other attachment devices. The membrane may be made of an elastomeric material, such as nitrile or silicone. The membrane is in contact with the user's skin and applies a force to the neck tissues. The membrane may be omitted, with the shell applying a force directly to the tissues, but such an application requires a good seal between the shell and the surface of the skin. A pneumatic tube 816 is coupled to the inlet port 814. The tube 816 may be made of a flexible material, such as flexible PVC or Tygon. The tubing may be from 3mm OD to 5mm OD, with a corresponding ID sufficient to deliver pneumatic pulses.

[0090] Referring to FIG. 52, an opposite end of tube 816 is coupled to the supply line 16, for example with a T-connector, preferably downstream of the check valve 720 and Y-connector 26. One or more (shown as two) vibrating elements may be coupled to the supply line 16. It should be understood that more than two vibrating elements may be coupled to the line. The various interfaces between the membrane, shell, and supply lines are sealed and leak

free. The vibrating element is coupled to a pressure source, for example controller 28, by line 16, with the controller supplying air pulses from a pump.

[0091] Referring to FIGS. 51A-D, an alternative vibrating element 830 includes a pressure plate 820, made of a rigid material such as thermoplastic, coupled to the shell 802 with an intermediate flexible member 822, such as a bellows made of thermoplastic elastomer or silicone. The shell, flexible member and pressure plate are nominally sealed and lead-free. If used with a vacuum source and solenoid valve, the vibrating element 830 includes an internal spring, for example made of stainless steel, to maintain the shell 802 and pressure plate 820 in a normally, biased and spaced apart relationship, extended against the restraining force of the bellows 822 or other catch mechanism. The vacuum pulse would act to pull the pressure plate toward the shell against the force of the spring, with the spring then expanding the bellows upon removal of the vacuum pulse, thereby expanding the bellows and creating a pressure force on the skin.

[0092] In operation, the vibrating element is applied to the user, with the membrane or pressure plate engaging the skin. The vibrating element may be held in place by adhesive, such as tape, with a hook/loop fastener strap or other suitable device. When used in combination with the oral device, the intraoral portions 112 are positioned in the mouth of the user, with the securing member 18 holding the device in the proper position. As discussed, the vibrating elements may be used independently, or in combination with, the oral device. The line 16 is connected to the controller, which is turned on to initiate a therapy regimen. The controller 28 supplies the pneumatic signal, or

air pulses, which causes vibration in the vibration element 800, which is communicated to the user. As mentioned, a single vibrating element may be used, or more than two elements may be used. When a plurality (two or more) of vibration elements 800 are used, different pressure signals may be supplied to the elements 800. The vibration elements 800 may be operated simultaneously, or out of phase in alternating sequence. The controller 28, or pressure source, may be configured with two or more internal pumps, or valving arrangements, providing for the alternative sequencing, and also differences in frequency, duration, and pressure magnitude.

[0093] An RFID tag and reader, or other communication device, may be incorporated into the oral device or vibration element, to ensure the proper mouthpiece and vibration element are being used for the particular application of pressure pulse pattern/timing/etc. In addition, a pressure sensor may be positioned in the oral device, vibration element or control circuit to detect movement of the user's throat and thereby determine if the user is swallowing. Vibratory elements may also be incorporated into the oral device, and the intraoral portions thereof, so as to provide vibration therapy to specific areas of the oral cavity.

[0094] In any of the embodiments, a wire may run along a length of at least a portion of the flexible tubing forming either or both of the intraoral and extraoral portions. The wire provides further shape memory to the flexible tubing. For example, the oral devices disclosed herein may be shaped by inserting a length of fine wire into the tubing and then bending the wire.

[0095] There are a number of advantages realized with the different embodiments of the oral mouthpiece of the present invention. Specifically the mouthpiece is stabilized during use by the user by the auxiliary support devices, including for example and without limitation the soft elastic loops that fit around the ears. This advantage provides a means of maintaining the intraoral aspects of the mouthpiece in appropriate position, even when the lips are open (as in the case of a patient with lip weakness), during talking, and during other behaviours such as yawning, eating, chewing, and drinking from a glass or straw. Importantly, this feature of the mouthpiece prevents the intraoral portions of the mouthpiece from migrating toward the pharynx, or in other directions, during use by a person, thus enhancing the safety aspect of the device.

[0096] Use of the auxiliary support devices stabilizes the mouthpiece so as to reduce the likelihood that the stabilization component of the mouthpiece will be perceived as irritating by the user and cause tissue damage with prolonged use.

[0097] The head band and soft, elastic ear loops are intuitive in terms of positioning, since they are used in other devices with which the user has likely had previous experience, for example, a medical face mask. The head band and soft elastic ear loops are straightforward to manipulate, thereby facilitating correct positioning by patients. The elastic bands are also narrow, occupying very little area over and around the pinna of the ear or rear of the skull, thus allowing easy positioning and use by persons who wear glasses or over-the-ear hearing aids.

[0098] In the various embodiments, there is no mouthpiece material occupying the midline region of the mouth. Rather, the intraoral portions of the mouthpiece enter the mouth as the angles of the mouth on the left and right sides, leaving the midline oral region free to engage in talking, eating, drinking, and other oral behaviours, and providing a situation in which the appearance of the mouthpiece is considered more socially appropriate than with devices that occupy the midline oral region. Of course, it should be understood that the conduit may extend along the midline of the chin, and then diverge to the left and right sides of the mouth.

[0099] The tubing comprising the mouthpiece is molded such that the left and right intraoral portions extend outside the mouth at the angles as an extraoral portion that is continuous between the right and left sides, and that extends inferiorly to run laterally at the level of the chin. An important advantage of this aspect of the mouthpiece is that it prevents the mouthpiece from being swallowed. In one embodiment, this extraoral portion of the mouthpiece can be used to further tether the mouthpiece, or to attach other devices.

[00100] The mouthpiece is relatively small and light-weight. In one preferred embodiment, it is envisaged that the mouthpiece can be readily manufactured at minimal cost, given the simplicity of the design, the small length of tubing required, and the low costs of the other required materials such as the elastic.

[00101] The mouthpiece can be easily connected to the output of an air-pressure regulator through a length of tubing that extends from the extraoral portion of the mouthpiece in the region of the mandible.

[00102] The mouthpiece comes manufactured with a looped configuration, oriented on the horizontal plane that fits around the angle of the mouth. This aspect of the tubing is contiguous with a second loop that is situated extraorally, immediately lateral to the angle of the mouth and oriented approximately 45 degrees relative to the user's midsagittal plane. The soft elastic ear loops originate at this second looped region and extend over and around the pinna of the ears. With this design, the elastic ear loops do not pull directly on the intraoral portions of the mouthpiece, causing them to migrate. Rather, the elastic ear loops pull on the second looped area (described above) with the result that the intraoral portions of the mouthpiece remain stable during use.

[00103] The mouthpiece can provide an attachment platform for other oral device(s), or oral device components.

[00104] The mouthpiece can be used as an oral suction catheter.

[00105] The intraoral portions of the mouthpiece can be provided as colored elements, providing a cue to the user regarding the portion of the device that is to be inserted into the mouth; by coloring the two intraoral and/or extraoral segments different colors, and providing associated written instructions (e.g., green = right, red = left), the mouthpiece provides increased assurance that the mouthpiece will be positioned accurately and not positioned upside down.

"Right" and "left" icons can also be provided, as well as "finger icons" showing the positions where the fingers should be placed during placement.

[00106] The user can close the lips while the mouthpiece is in position, allowing the user to maintain a typical facial rest position during use.

[00107] Importantly, there is no mouthpiece material disposed between the contacting surfaces of the upper and lower teeth. This is advantageous since a significant distance between the upper and lower teeth may reduce the user's ability to swallow with the device in position.

[00108] There is no material between the superior surface of the tongue, and the palate. This is also an advantage in terms of swallowing since swallowing requires approximation of the superior tongue surface and the palate to transport ingested material from the mouth to the pharynx.

[00109] The mouthpiece can be provided with a flavored element within the intraoral portion, on the surface of the intraoral portion, or on or within the extraoral portion that runs outwardly between the user's upper and lower lips. This flavoring may increase the acceptability of the mouthpiece, as well as promote salivary flow, and swallowing.

[00110] The mouthpiece is small and portable. It can be fit into a purse or small carrying bag, or into a typical "sandwich baggie" for easy and clean transport.

[00111] The agent(s) delivered to the mouth and oropharynx via the mouthpiece described herein may include, but are not limited to, a fluid, including a gas or liquid. For example, air may be delivered to the posterior oral cavity and oropharynx via the mouthpiece. In this regard, our previous

studies, as well as those from other laboratories, have shown that application of air-pulse trains to the oropharynx increases saliva swallowing rates in young and older adults, and activates regions of the human cerebral cortex. Tests were undertaken to determine the effects of oropharyngeal air-pulse: train duration, amplitude, and frequency on saliva swallowing rates in dysphagic stroke and to determine saliva swallowing rates associated with air-pulse application different from swallowing rates associated with a sham condition, in dysphagic stroke.

[00112] In the first of two experiments, twenty three (23) hospitalized individuals who had dysphagia secondary to a stroke volunteered as subjects. Their median age was 69, and 15 were male. The majority had suffered a stroke involving the right middle cerebral artery territory, however other stroke locations were also represented in the sample. The median days post-stroke at the time of testing was 12 days. Study enrolment was limited to patients who were dependent on tube feeding to some degree; thus, the median FOIS score for the sample was 1.5, with a range of 1 to 3. The experimental protocol is shown in figure 8.

[00113] Air-pulse trains were delivered bilaterally to the posterior oral cavity and oropharynx via a prototype buccal mouthpiece which was positioned between the subject's upper teeth and the cheek.

[00114] The air-pulse trains were controlled with an Agilent signal generator and LABneb air-pressure regulator, attached to a hospital wall-mounted compressed medical air source. We examined 4 levels of air-pulse train duration: a single pulse, a doublet or two successive pulses, a 2 second train,

and a 3 second train; 4 levels of air-pulse amplitude were defined in terms of supply pressures of 2, 4, 6, and 8 psi; and finally, 4 levels of pulse frequency, 2, 4, 8, and 12 Hz, were examined. Based on bench testing, this range of supply pressures corresponded to tip pressures, measured 2 mm to 8 mm from the distal tip of the mouthpiece, of no greater than 2 mm Hg, as shown in figure 9.

[00115] The air volume delivered with a single pulse in this supply pressure range was 1.2 ml to 4.2 ml, as shown by the tables provided below and the graph of figure 10.

SINGLE 50 ms	Volume Collected [mL] Source Pressure [psi]					
	0	**2**	**4**	**6**	**8**	**12**
1 Hz	0	1.2	2.3	3.1	4.2	5.8
	0	1.3	2.3	3.2	4.4	6.1
	0	1.2	2.2	3.2	3.9	6
Mean	0.00	1.23	2.27	3.17	4.17	5.97
SD	0.00	0.06	0.06	0.06	0.25	0.15

2 Sec	Volume Collected [mL]			
	2 PSI	**4 PSI**	**6 PSI**	**8 PSI**
2 Hz	3.8	7.5	12.1	15.6
	4	7.4	11.8	15.8
	4.2	7.7	11.9	15.5
Mean	4.00	7.53	11.93	15.63
SD	0.20	0.15	0.15	0.15
4 Hz	6	14.4	23.5	31.4
	6	15.1	23.7	31.6
	6.1	14.5	23.4	30.8
Mean	6.03	14.67	23.53	31.27
SD	0.06	0.38	0.15	0.42

6 Hz	12	25.1	36.4	45
	11.8	25.2	36.3	47
	11.6	24.8	36	48
Mean	11.80	25.03	36.23	46.67
SD	0.20	0.21	0.21	1.53
8 Hz	14	32.4	50	62
	14.1	32.7	49	62
	13.7	32.8	50	62
Mean	13.93	32.63	49.67	62.00
SD	0.21	0.21	0.58	0.00
12 Hz	20.6	44	68	90
	20.4	46	68	89
	20.7	46	68	90
Mean	20.57	45.33	68.00	89.67
SD	0.15	1.15	0.00	0.58

3 Sec	**Volume Collected [mL]**			
	2 PSI	**4 PSI**	**6 PSI**	**8 PSI**
2 Hz	5	12	22	26
	4	12	22	28
	4	12	22	27
Mean	4.33	12.00	22.00	27.00
SD	0.58	0.00	0.00	1.00

4 Hz	8	28	38	48
	8	27	38	50
	8	29	36	50
Mean	8.00	28.00	37.33	49.33
SD	0.00	1.00	1.15	1.15

6 Hz	14	36	54	70
	18	38	54	70
	16	38	55	68
Mean	16.00	37.33	54.33	69.33
SD	2.00	1.15	0.58	1.15

8 Hz	20	44	70	90

	22 24	46 46	72 72	92 90
Mean **SD**	22.00 2.00	45.33 1.15	71.33 1.15	90.67 1.15
12 Hz	30	62	92	130
	28	62	92	130
	29	60	94	130
Mean	29.00	61.33	92.67	130.00
SD	1.00	1.15	1.15	0.00

[00116] Pulse duration was 50 msec throughout.

[00117] Air pulse types were presented in blocks of train duration and sham conditions, that is, there were a total of 5 blocks: single pulse, doublet, 2-sec pulse train, 3-sec pulse train, and sham, two of which are shown here. Successive duration blocks were separated by a 1 min baseline period.

[00118] Their order was randomized across subjects. The four air-pulse amplitude conditions were nested as blocks within train duration; and the four levels of air-pulse frequency were further nested within amplitude blocks. There were two orders of each of the amplitude and frequency conditions across subjects. The duration between the onsets of successive pulse trains was approximately 20 sec.

[00119] During the sham condition, the air pressure regulator was turned to "0" but the signal generator operated such that the subjects, and experimenters, heard the same noise of the solenoids during the air-pulse and sham conditions.

[00120] Dry swallows were identified from the output signals of a Grass throat microphone, a laryngeal movement sensor, and respiratory movement sensor. Two swallows are shown here in relation to three single air-pulse

trials. One experimenter observed the subject throughout the session and marked the computer file for swallows and other behaviors. Swallowing rates were computed as number of swallows over duration of the air-pulse condition, from the onset of 1 trial to the onset of the following trial.

[00121] A repeated measures 1-way ANOVA indicated that there was a main effect of Train Duration on saliva swallowing rate ($p<0.05$). Post-hoc comparisons, with Bonferroni correction, indicated that mean swallowing rates associated with the 2 sec, and the 3 sec train duration conditions were significantly greater than the mean swallowing rate associated with the single pulse condition ($p<0.008$) as shown in figure 11.

[00122] In relation to the sham condition, paired t-tests, again Bonferroni corrected, indicated that the mean swallowing rate associated with the 2 sec train duration condition was significantly greater than the swallowing rate associated with the sham condition ($p<0.013$) as shown in figures 12 and 13.

[00123] Turning now to air-pulse amplitude, there was no main effect of air-pulse AMPLITUDE on dry swallowing rate. Compared with the SHAM condition, the 6 psi condition approached the corrected significance level of 0.013 ($p=0.015$). And, the average swallowing rate across the 4 levels of amplitude was significantly greater than the mean swallowing rate associated with the SHAM condition ($p<0.05$) as shown in figures 14 and 15.

[00124] Looking now at air-pulse frequency, there was no mean effect of air-pulse FREQUENCY on dry swallowing rate. Compared with the SHAM condition, the 12 Hz condition approached the corrected significance level ($p=0.018$). The average swallowing rate across the 4 levels of air-pulse

frequency was significantly greater than the mean swallowing rate associated with the SHAM condition ($p<0.05$) as shown in figures 16 and 17.

[00125] For the air-pulse Duration, Amplitude and Frequency conditions examined, there was considerable variability in dry swallowing rates, as illustrated by the large standard deviations.

[00126] In summary, it was determined that swallowing rates showed substantial variability for the air-pulse types examined. Longer air-pulse trains were associated with greater swallowing rates compared with single pulses; swallowing rates associated with 2 sec air-pulse trains were significantly greater than sham. While swallowing rates were not significantly different as a function of air-pulse (i) amplitude, and (ii) frequency conditions, swallowing rates pooled across amplitude or frequency levels were significantly greater than sham. Air-pulse trains, delivered to the posterior mouth and oropharynx via a buccal mouthpiece, were associated with increased saliva swallowing rates in dysphagic stroke.

[00127] Dry swallowing rates are influenced by the specific properties of air-pulse trains delivered to the posterior mouth and oropharynx in dysphagia stroke. Air-pulse application is associated with increased dry swallowing rates in dysphagic stroke, supporting the potential of the air-pulse approach in swallowing rehabilitation.

[00128] Although there were some significant effects of the air-pulse parameters under study, the effects of air-pulse frequency and amplitude were not marked. With regards to pulse-train duration, the 2-second pulse train appears to be superior to the other pulse types in terms of facilitating

swallowing in patients with dysphagia. However, even in the case of duration, there was not a single setting that proved to be categorically superior to the others in terms of associated swallowing rates. This suggests that air pulses that fall within a range of pulse types can be associated with increased swallowing in patients with swallowing impairment. This is an advantage of the air-pulse approach in that the phenomenon does not appear to be limited to a very narrow set of pulse types.

[00129] The present finding that air-pulse amplitude and frequency did not have more pronounced effects on swallowing rates suggests the possibility that factors other than air pressure may be important in determining the swallowing response.

[00130] Based on this study, air-pulse trains of 2 sec appear to be particularly effective in evoking swallowing in patients with dysphagia following brain injury. Air-pulse trains involving a supply pressure of 6 psi, and involving a frequency of 12 Hz, i.e., involving flow values in the range of 68 mls, also appear to be particularly effective, based on the current testing results in dysphagic patients.

[00131] This study demonstrates that oropharyngeal air-pulse trains delivered via a buccal mouthpiece and involving tip pressures (i.e., measured at 2mm to 8 mm from the tip through bench testing) of less than or equal to 2 mm Hg are effective in increasing saliva swallowing rates in patients with dysphgia following stroke.

[00132] The subjects in the current study participated in testing sessions that were approximately 75 minutes in duration. During that period, air-pulse

trains were delivered for a period of approximately 20 minutes in 6 minute blocks based on air-pulse train duration, the order of which was randomized across subjects. Subjects were observed to swallow during the various air-pulse duration blocks. There was no trend for swallowing to decrease over the course of the testing session. Based on this experience, an air-pulse application period of approximately 20 minutes is appropriate and preferred in terms of increasing swallowing rates in patients with dysphgia following stroke.

[00133] The time between successive air-pulse trains should be (i) short enough that the patient receives an adequate number of bursts per session, but (ii) long enough that the patient does not risk desaturation because of an excessive number of swallowing apneas. Based on the experiment described above, preferred air pulse trains of bursts of 2 sec, 6 psi and 12Hz, and an inter-stimulus time of 20 sec, the mean + 1 sd swallowing rate is less that 3 per min.

Therefore, even patients who respond quite well to the air pulses would not be expected to swallow more than 3 times per minute with an interburst time of 20 sec. A swallowing rate of 3 per min is less than typical swallowing rates for cup drinking, or mealtime eating. Based on this logic, a 20 sec period between the onsets of successive air-pulse trains may be appropriate and thus preferred.

[00134] Based on our finding that air-pulse trains of 12 Hz are particularly effective, as well as our hypotheses on air flow, a second study was designed to examine higher frequencies, and different air flows, as follows:

Oropharyngeal air pulses in the 2 to 12 Hz range are associated with increased swallowing rates in controls and dysphagic patients. However, the effects of higher frequency air pulses, and air flow, are unknown. Therefore, the effects of oropharyngeal air-pulse frequency, and air flow on dry swallowing rates in healthy adults was examined, and compared with a lower frequency air-pulse train employed previously. Methods: Air-pulse trains (duration = 3 sec) were delivered to the oropharynx via a prototype buccal over-the-ear mouthpiece in 25 adults (mean ± sd age: 26.7 ± 7.9 years; 18 female). Laryngeal, respiratory, and acoustic signals were recorded while six air-pulse conditions were randomly administered to each subject: three Frequency conditions (i.e., 26 Hz, 40 Hz, 59 Hz); crossed with two Flow conditions (i.e., Low Air Flow, High Air Flow) as shown in figure 18. A Sham condition, and an 8 Hz air-pulse train previously associated with swallowing, were also examined. Results: While main effects of Frequency, Air Flow, and the Frequency x Air-Flow interaction were not statistically significant (Repeated Measures 2-way ANOVA, pcrit<0.05), Air Flow approached significance (pobs=0.056). When the data were averaged across Frequency conditions, the mean swallowing rate during the 8 Hz condition was significantly greater than that during the Low Flow condition; however, the 8 Hz and High Flow conditions were not significantly different (paired t-test, pcrit<0.025). Moreover, swallowing rates during the High Flow and 8 Hz conditions were significantly greater than the Sham swallowing rate, whereas the Low Flow and Sham conditions were not significantly different (paired t-test, pcrit<0.016). Conclusion: Oropharyngeal air-pulse trains delivered

across a range of frequencies, particularly at higher air flows, increase dry swallowing rates in healthy adults, supporting their potential in dysphagia rehabilitation.

[00135] In addition to increased dry swallowing during the air-pulse application periods, some subjects were observed to display increased overall arousal, and increased overall motor behaviour, in relation to the air-pulse application. For example, some patients opened their eyes, moved their arms and legs, changed position in their chair, etc, in relation to the air-pulse application. Based on the observation, air-pulse application to the back of the mouth and/or the oropharynx appears to provide a method on increasing overall arousal in individuals with brain damage, and further appears to provide a method of increasing motor behaviour in individuals with brain damage. These methods are particularly important in patients with brain damage, for example, in stroke, where decreased arousal and lack of motor behaviour can be significant challenges during the stroke recovery period that may limit gains in rehabilitation. Thus, the air-pulse approach may be employed in the rehabilitation of patients with brain injury, or possibly dementia, to increase arousal and motor behaviour, in addition to increasing swallowing.

[00136] The increased arousal and motor behaviour observed in patients with stroke in association with air-pulse application to the posterior mouth and oropharynx in consistent with our previous finding that oropharyngeal air-pulse application activates the cerebral cortex in healthy control subjects. Various aspects of those findings are further disclosed in U.S. Publication No.

2010/0010400A1, entitled Method of Brain Activation, the entire disclosure of which is hereby incorporated herein by reference. Therefore, for example, cortical activation secondary to air-pulse application may mediate the increases in arousal and motor behaviour observed among stroke patients in the current study.

[00137] Generally speaking, the systems described herein are directed to oral mouthpieces. As required, embodiments of the present invention are disclosed herein. However, the disclosed embodiments are merely exemplary, and it should be understood that the invention may be embodied in many various and alternative forms. The Figures are not to scale and some features may be exaggerated or minimized to show details of particular elements while related elements may have been eliminated to prevent obscuring novel aspects. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention. For purposes of teaching and not limitation, the illustrated embodiments are directed to oral mouthpieces.

[00138] As used herein, the terms "comprises" and "comprising" are to construed as being inclusive and open ended rather than exclusive. Specifically, when used in this specification including the claims, the terms "comprises" and "comprising" and variations thereof mean that the specified features, steps or components are included. The terms are not to be interpreted to exclude the presence of other features, steps or components.

WHAT IS CLAIMED IS:

1. An oral mouthpiece comprising:

a pair of laterally spaced intraoral portions defining intraoral conduits each having at least one outlet port adapted to dispense at least one fluid pulse;

an extraoral portion coupled to said intraoral portions, said extraoral portion defining at least one extraoral conduit in flow communication with said intraoral conduits, said extraoral portion being connectable to a fluid supply, wherein said intraoral portions and said extraoral portion form a delivery conduit, and wherein said delivery conduit comprises a one-way valve permitting one directional flow from said extraoral conduit to said intraoral conduits.

2. The oral mouthpiece of claim 1 wherein said intraoral and extraoral portions are integrally formed.

3. The oral mouthpiece of claim 1 wherein said extraoral portion comprises a wing forming a lip-receiving portion.

4. The oral mouthpiece of claim 3 further comprising an ear loop connected to said wing.

5. The oral mouthpiece of claim 4 wherein a length of said ear loop is adjustable.

6. The oral mouthpiece of claim 5 wherein said ear loop comprises a free end, and wherein said wing comprises a receptacle, wherein said free end of said ear loop is captured by said receptacle.

7. A method of manufacturing an oral mouthpiece comprising:

molding an intraoral tube and an inlet tube having a check valve from a first material; and

overmolding said intraoral tube and said inlet tube with a second material and forming a securing member from said second material.

8. The method of claim 7 wherein said securing member comprises an ear loop.

9. The method of claim 7 wherein said molding said intraoral tube and said inlet tube comprises forming an opening along said length of said intraoral tube, and wherein said overmolding said intraoral tube comprises closing said opening with said second material.

10. The method of claim 7 further wherein said molding said inlet tube further comprises molding a wing forming a lip-receiving portion.

11. The method of claim 10 wherein said forming said securing member comprises further overmolding said securing member with said wing.

12. The method of claim 10 wherein a length of said securing member is adjustable.

13. The method of claim 12 wherein said securing member comprises a free end, and wherein said wing comprises a receptacle, wherein said free end of said securing member is captured by said receptacle.

14. A pneumatic vibrating element comprising:

a shell defining a cavity and comprising an inlet portion in fluid communication with the cavity;

a user interface coupled to said shell and closing said cavity; and

an inlet line adapted to supply a pneumatic pulse to said inlet port.

15. The pneumatic vibrating element of claim 14 wherein said user interface comprises a flexible membrane.

16. The pneumatic vibrating element of claim 14 wherein said user interface comprises a pressure plate and a flexible bellows connected between the pressure plate and the shell.

17. An oral device comprising:

an intraoral portion defining an intraoral conduit having at least one outlet port adapted to dispense at least one fluid pulse;

an inlet line in fluid communication with the intraoral portion and adapted to supply the at least one fluid pulse to the intraoral portion; and

a pneumatic vibrating element comprising:

a shell defining a cavity had comprising an inlet portion in fluid communication with the cavity, said inlet portion in fluid communication with said inlet line; and

a user interface coupled to said shell and closing said cavity.

18. The oral device of claim 17 wherein said user interface comprises a flexible membrane.

19. The oral device of claim 17 wherein said user interface comprises a pressure plate and a flexible bellows connected between the pressure plate and the shell.

20. The oral device of claim 17 wherein said inlet line comprises a one-way check valve.

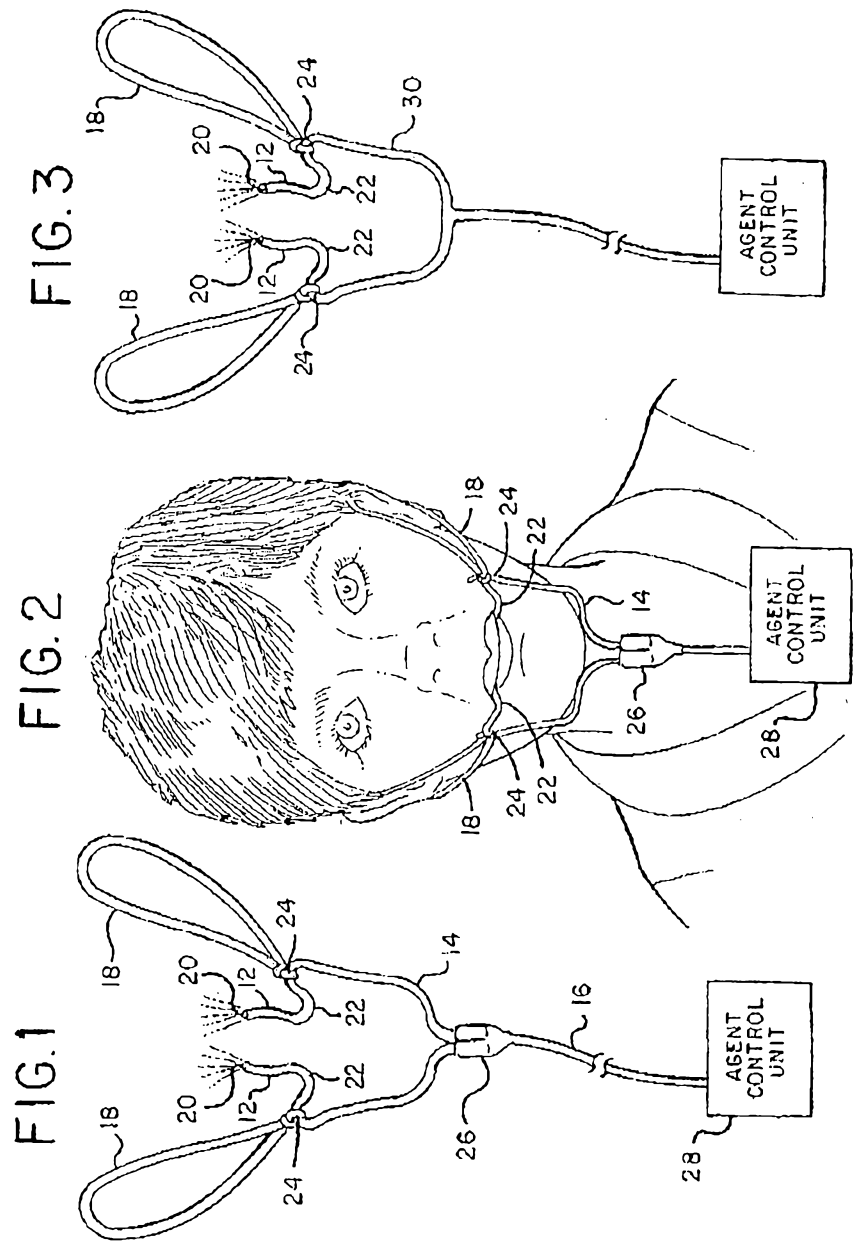


FIG. 1
FIG. 2
FIG. 3
AGENT CONTROL UNIT
AGENT CONTROL UNIT
AGENT CONTROL UNIT
18
20
12
22
24
14
16
26
28
30

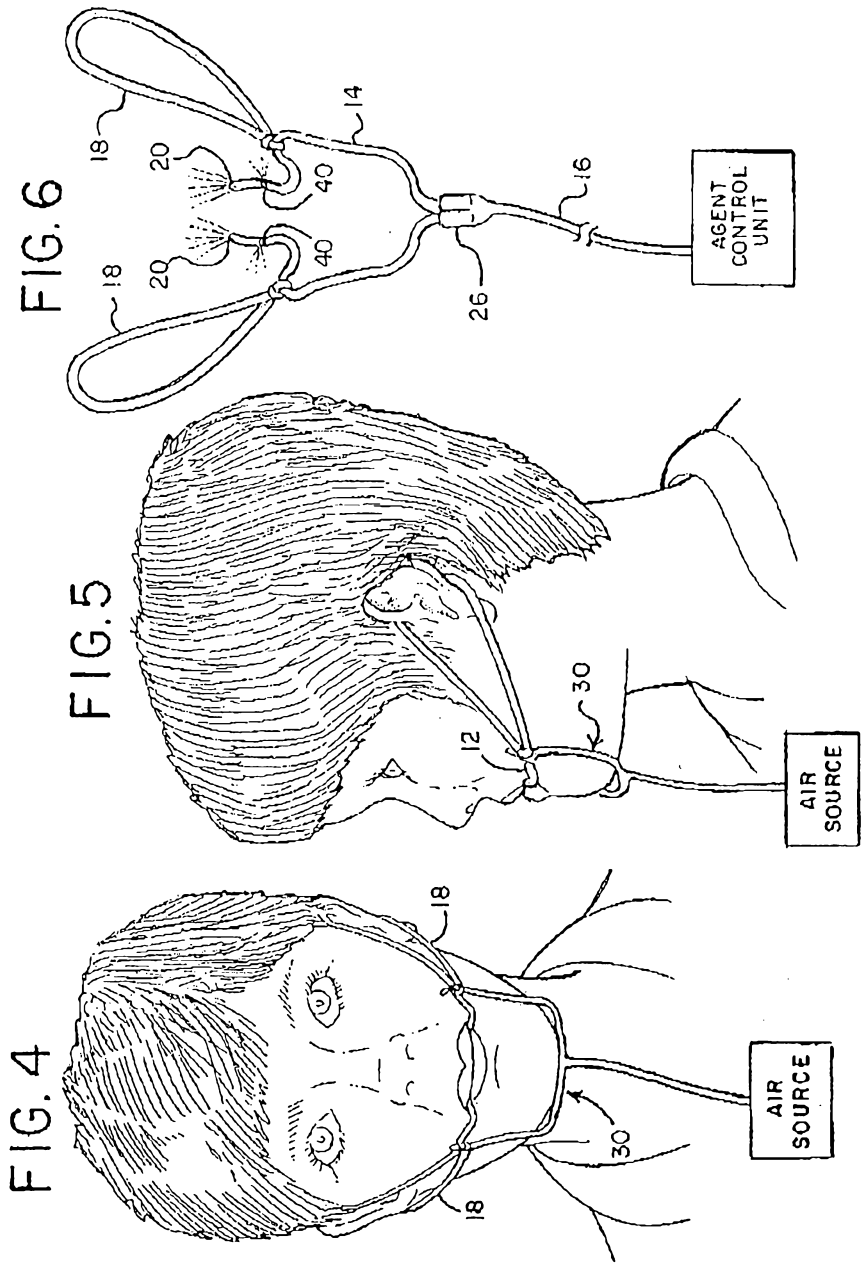


FIG. 6
18
20
20
18
14
40
40
16
26
AGENT CONTROL UNIT
FIG. 5
12
30
AIR SOURCE
FIG. 4
18
18
30
AIR SOURCE

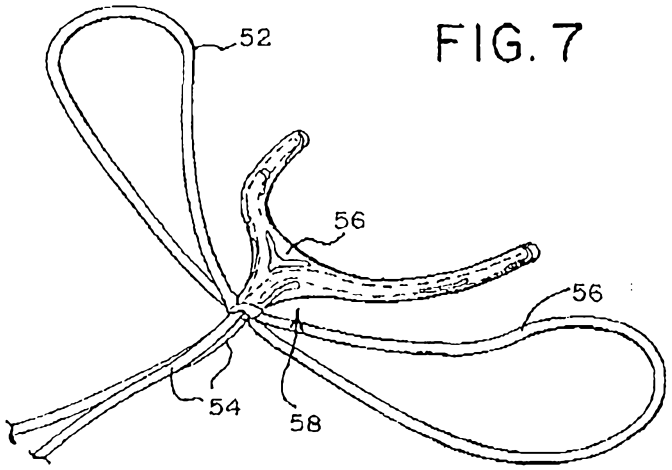

52
56
56
54
58

FIG. 7

FIG. 8

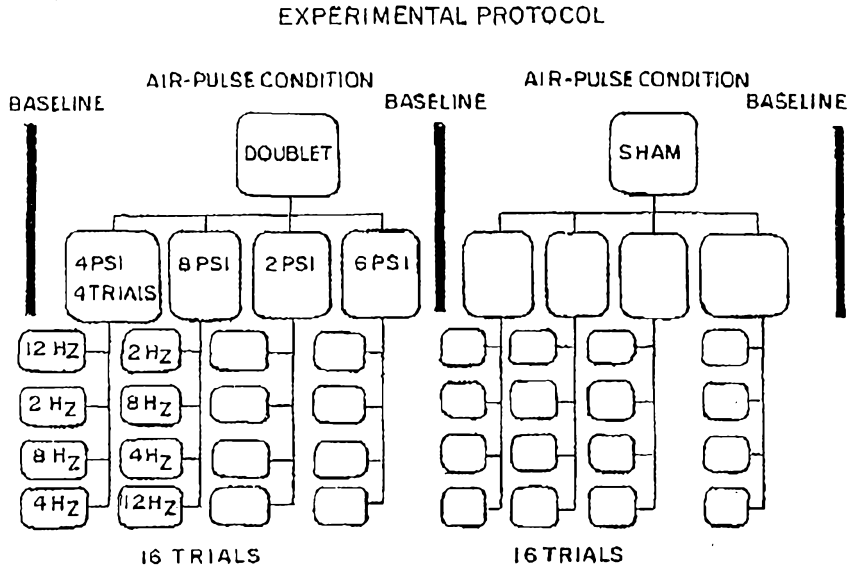

EXPERIMENTAL PROTOCOL
BASELINE
AIR-PULSE CONDITION
BASELINE
AIR-PULSE CONDITION
BASELINE
DOUBLET
SHAM
4PSI 4TRIALS
8PSI
2PSI
6PSI
12 HZ
2 HZ
8 HZ
4 HZ
2 HZ
8 HZ
4 HZ
12 HZ
16 TRIALS
16 TRIALS

FIG. 9

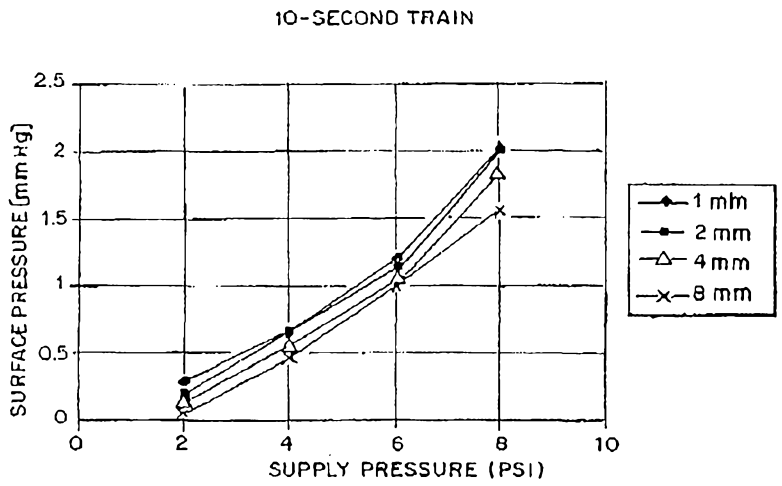

10-SECOND TRAIN
SURFACE PRESSURE (mm Hg)
2.5
2
1.5
1
0.5
0
0
2
4
6
8
10
SUPPLY PRESSURE (PSI)
1 mm
2 mm
4 mm
8 mm

FIG. 10

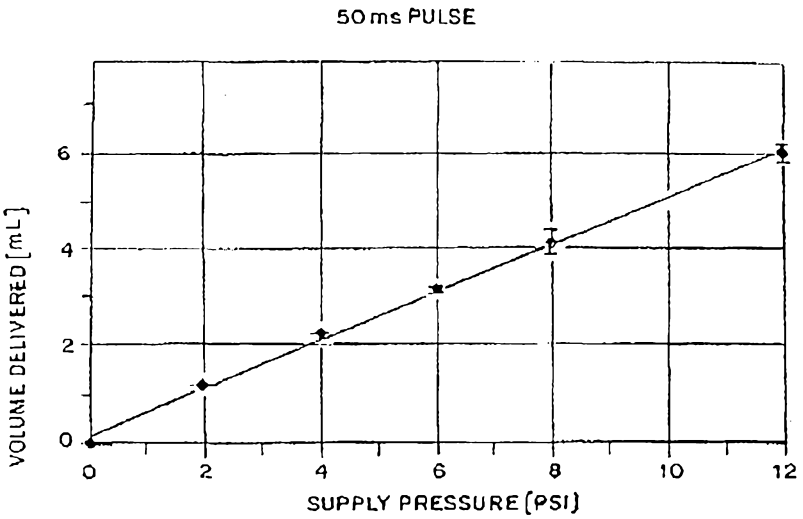

50 ms PULSE
VOLUME DELIVERED (mL)
6
4
2
0
0
2
4
6
8
10
12
SUPPLY PRESSURE (PSI)

FIG.11

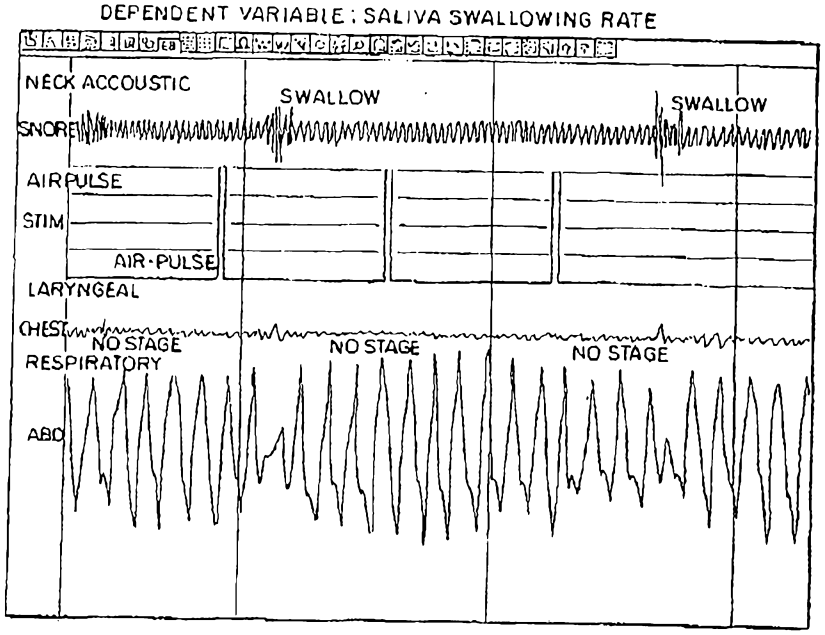

DEPENDENT VARIABLE : SALIVA SWALLOWING RATE
NECK ACCOUSTIC
SNORE
SWALLOW
SWALLOW
AIRPULSE
STIM
AIR-PULSE
LARYNGEAL
CHEST
NO STAGE
NO STAGE
NO STAGE
RESPIRATORY
ABD

FIG.12

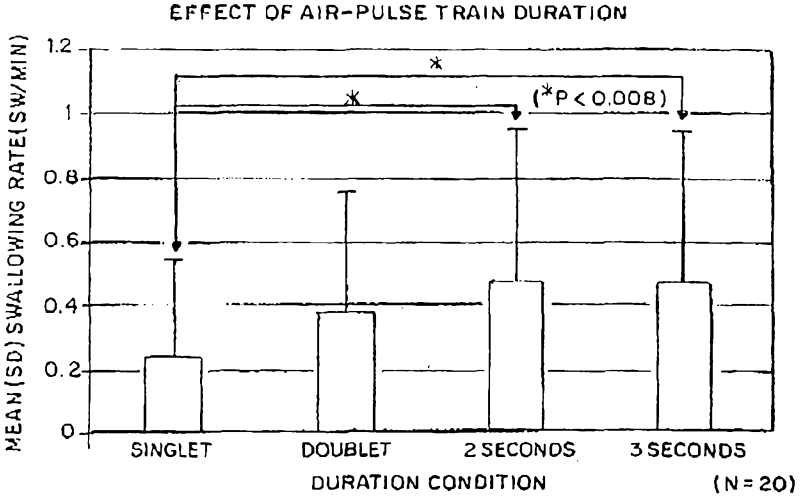

EFFECT OF AIR-PULSE TRAIN DURATION
MEAN(SD) SWALLOWING RATE(SW/MIN)
1.2
1
0.8
0.6
0.4
0.2
0
*
*
(*P < 0.008)
SINGLET
DOUBLET
2 SECONDS
3 SECONDS
DURATION CONDITION
(N = 20)

FIG. 13

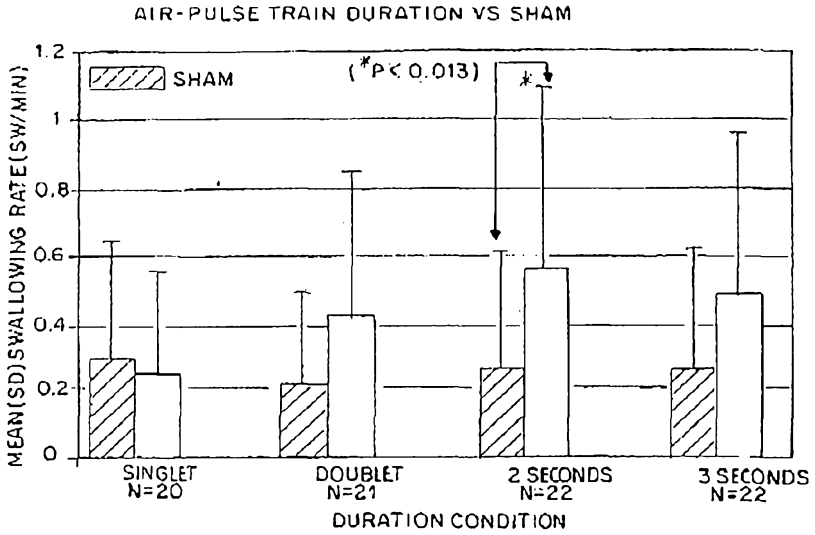

AIR-PULSE TRAIN DURATION VS SHAM
SHAM
(*P< 0.013)
MEAN(SD) SWALLOWING RATE(SW/MIN)
1.2
1
0.8
0.6
0.4
0.2
0
SINGLET N=20
DOUBLET N=21
2 SECONDS N=22
3 SECONDS N=22
DURATION CONDITION

FIG. 14

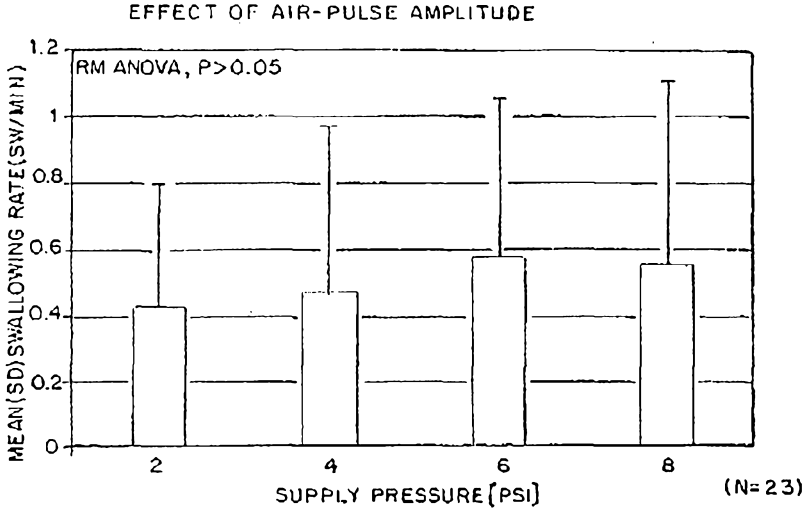

EFFECT OF AIR-PULSE AMPLITUDE
RM ANOVA, P>0.05
MEAN(SD) SWALLOWING RATE(SW/MIN)
1.2
1
0.8
0.6
0.4
0.2
0
2
4
6
8
SUPPLY PRESSURE (PSI)
(N=23)

FIG. 15

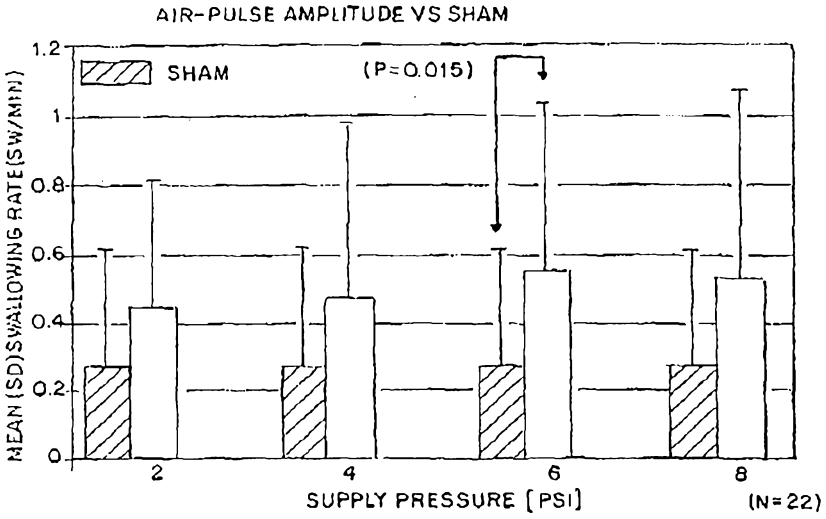

AIR-PULSE AMPLITUDE VS SHAM
SHAM
(P=0.015)
MEAN (SD) SWALLOWING RATE (SW/MIN)
1.2
1
0.8
0.6
0.4
0.2
0
2
4
6
8
SUPPLY PRESSURE [PSI]
(N=22)

FIG. 16

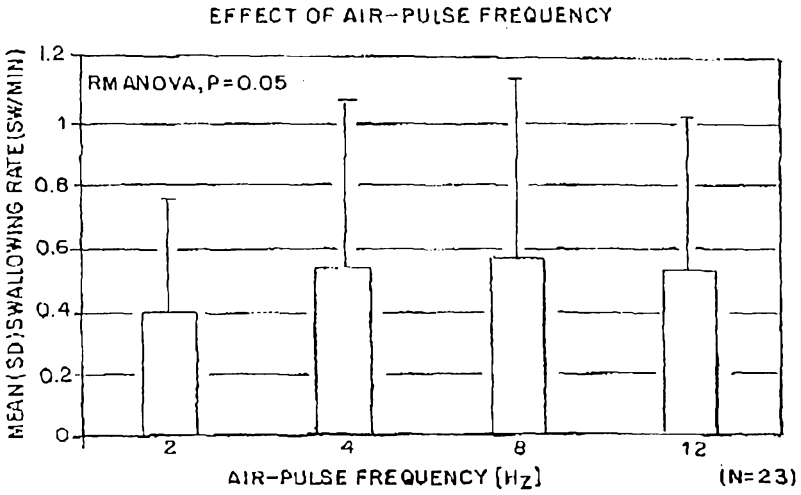

EFFECT OF AIR-PULSE FREQUENCY
RM ANOVA, P=0.05
MEAN (SD) SWALLOWING RATE (SW/MIN)
1.2
1
0.8
0.6
0.4
0.2
0
2
4
8
12
AIR-PULSE FREQUENCY [Hz]
(N=23)

FIG. 17

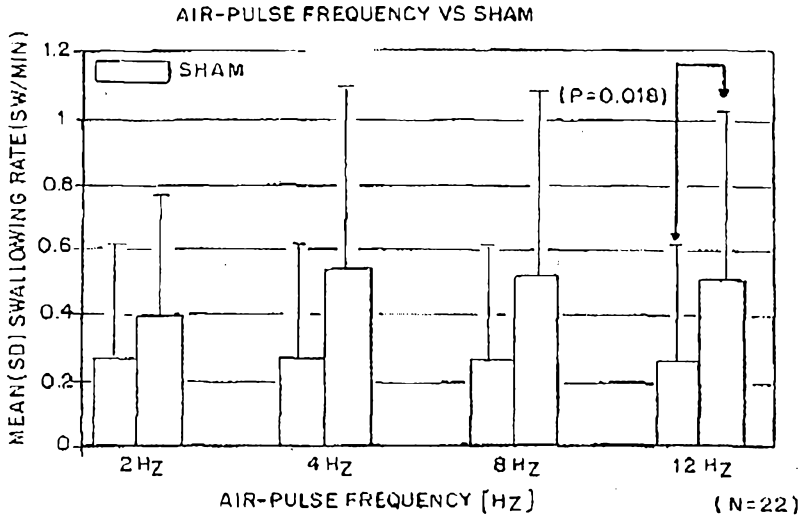

AIR-PULSE FREQUENCY VS SHAM
SHAM
(P=0.018)
MEAN(SD) SWALLOWING RATE(SW/MIN)
1.2
1
0.8
0.6
0.4
0.2
0
2 Hz
4 Hz
8 Hz
12 Hz
AIR-PULSE FREQUENCY (HZ)
(N=22)

FIG. 18

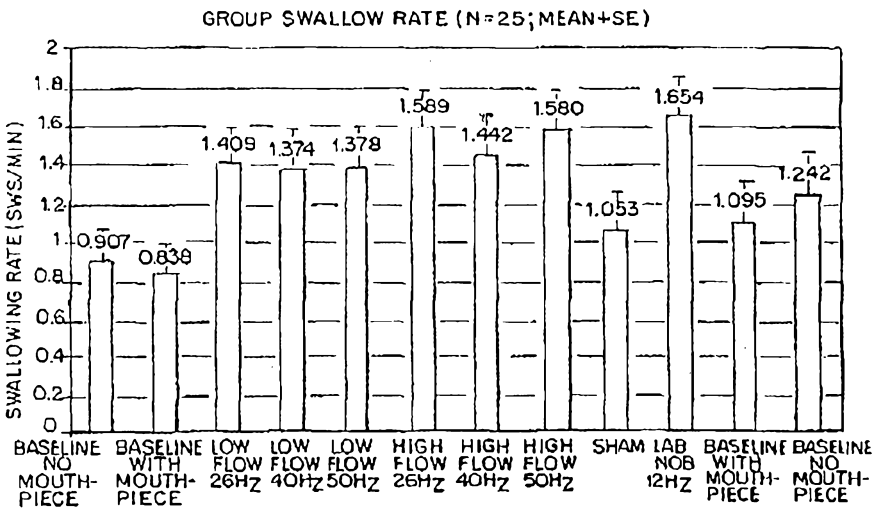

GROUP SWALLOW RATE (N=25; MEAN+SE)
SWALLOWING RATE (SWS/MIN)
2
1.8
1.6
1.4
1.2
1
0.8
0.6
0.4
0.2
0
0.907
0.838
1.409
1.374
1.378
1.589
1.442
1.580
1.053
1.654
1.095
1.242
BASELINE NO MOUTH-PIECE
BASELINE WITH MOUTH-PIECE
LOW FLOW 26HZ
LOW FLOW 40HZ
LOW FLOW 50HZ
HIGH FLOW 26HZ
HIGH FLOW 40HZ
HIGH FLOW 50HZ
SHAM
LAB NOB 12HZ
BASELINE WITH MOUTH-PIECE
BASELINE NO MOUTH-PIECE

FIG. 19

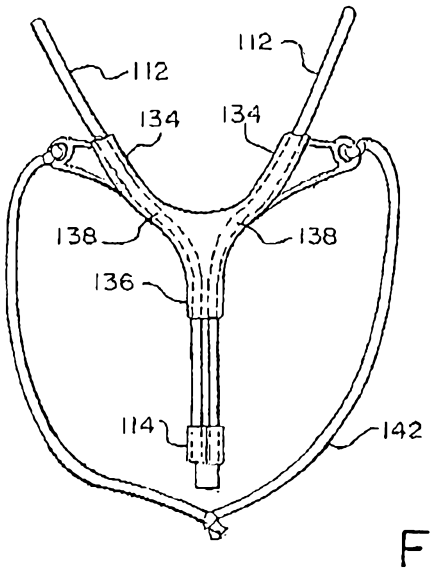


FIG. 21

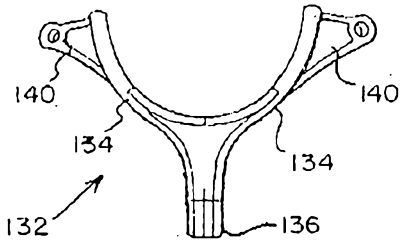


FIG. 23

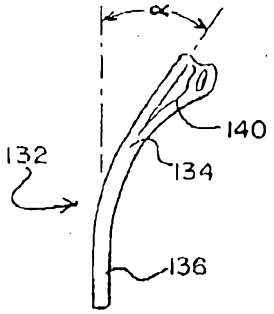


FIG. 22

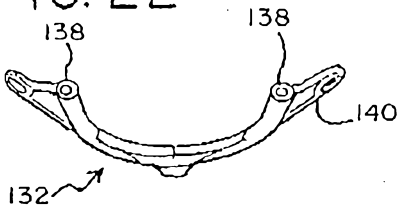


FIG. 20

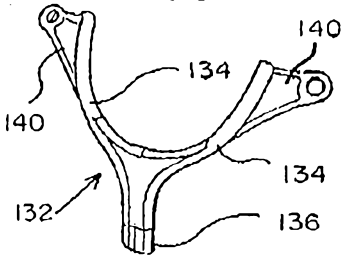


FIG. 24

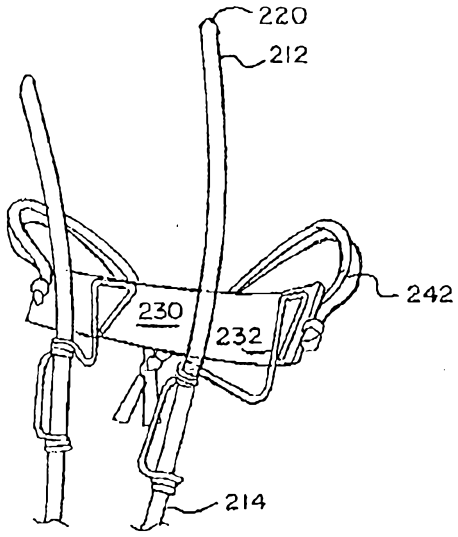


FIG. 25

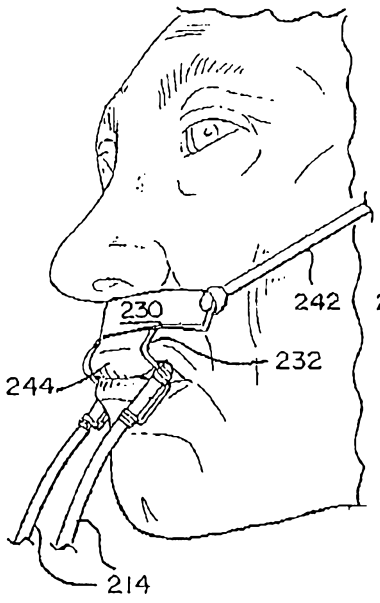
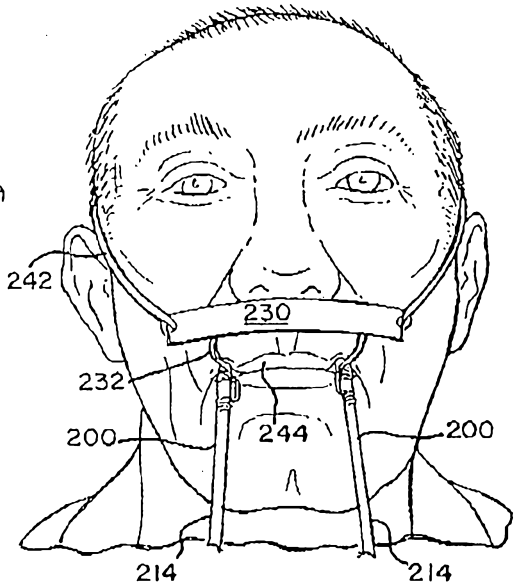


FIG. 26



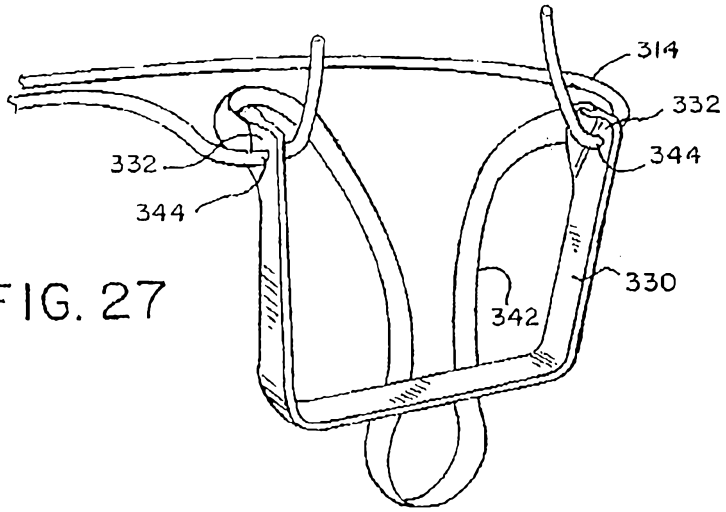


FIG. 27

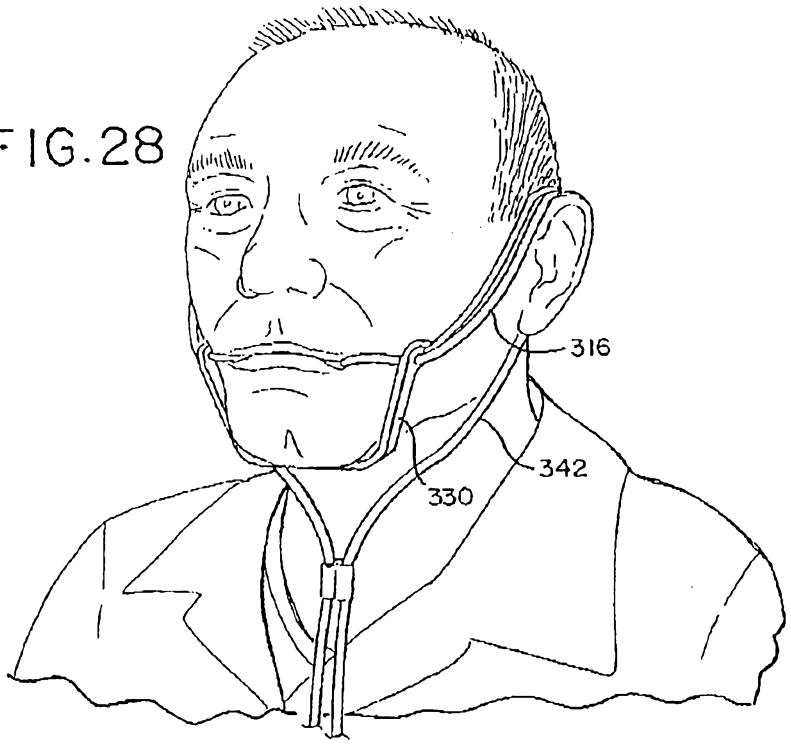


FIG. 28

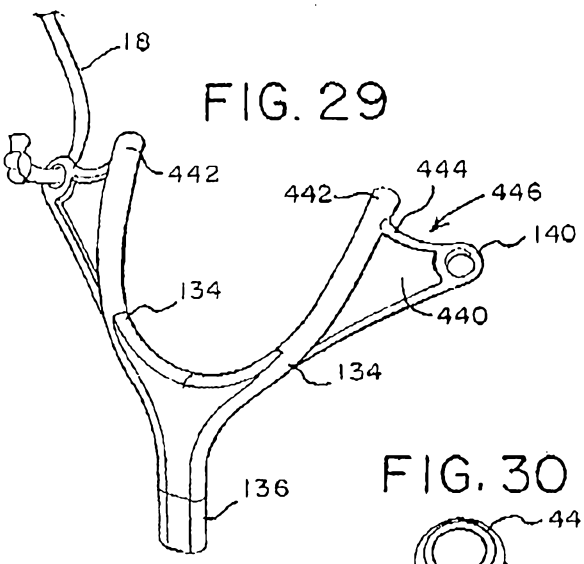


FIG. 29

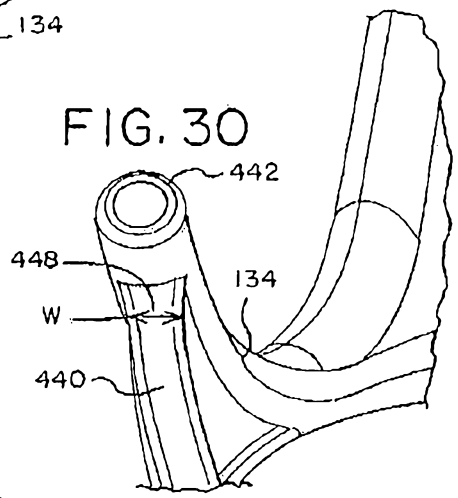


FIG. 30

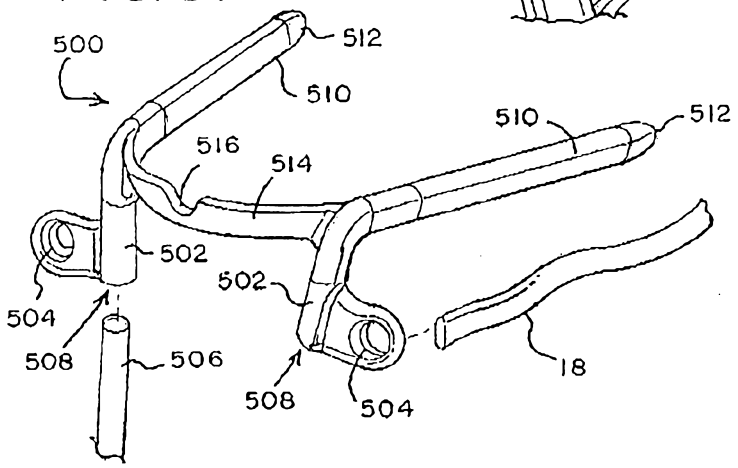


FIG. 31

FIG. 32

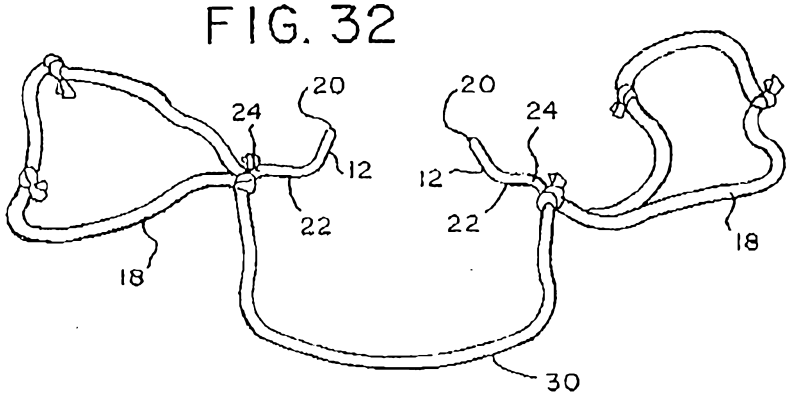


FIG. 33

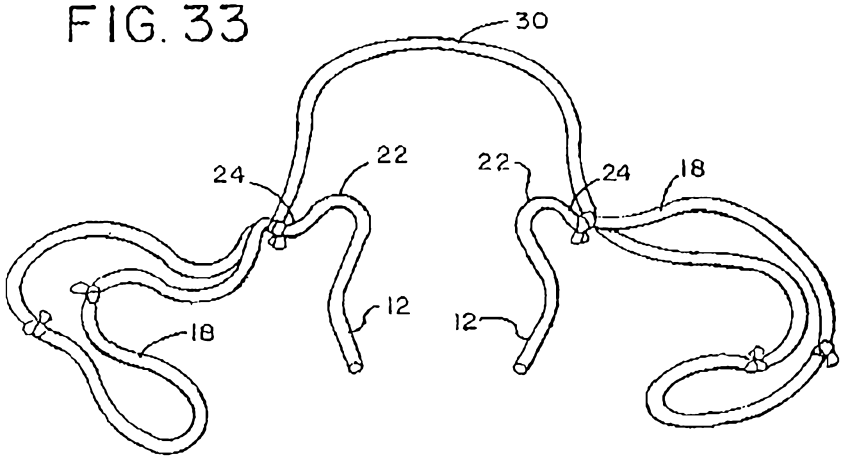


FIG. 34

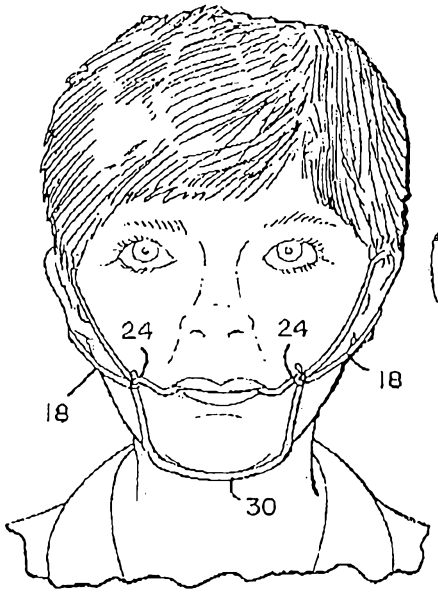


FIG. 35

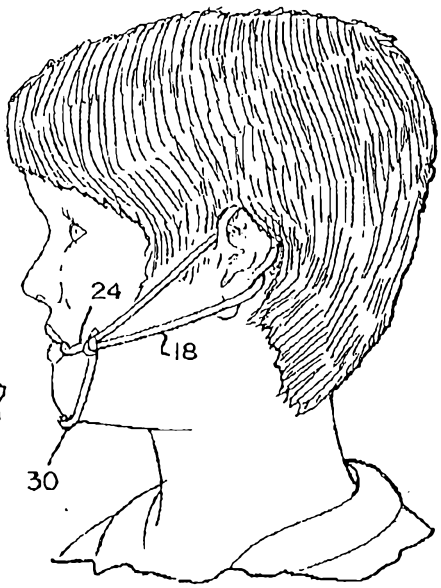


FIG. 36

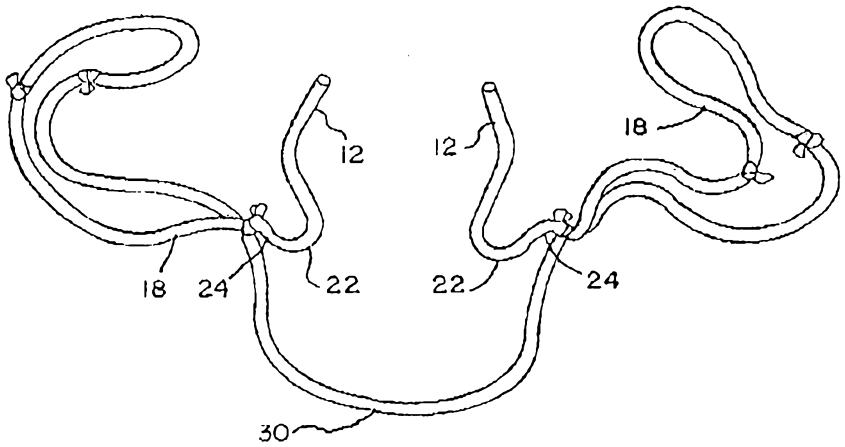
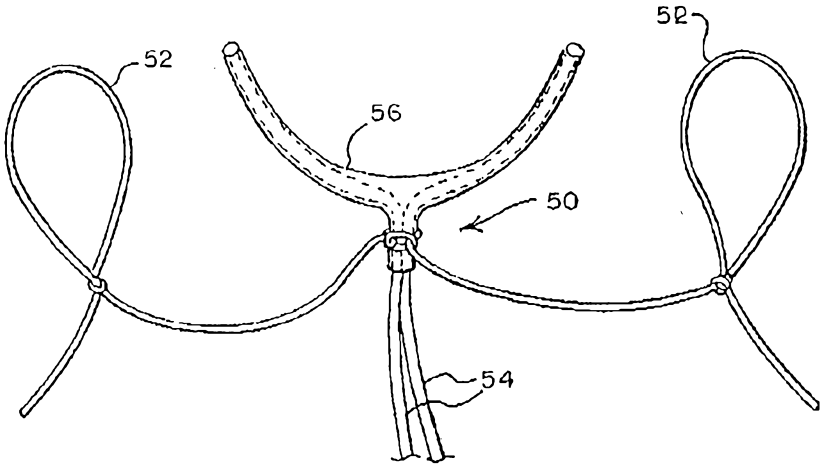


FIG. 37



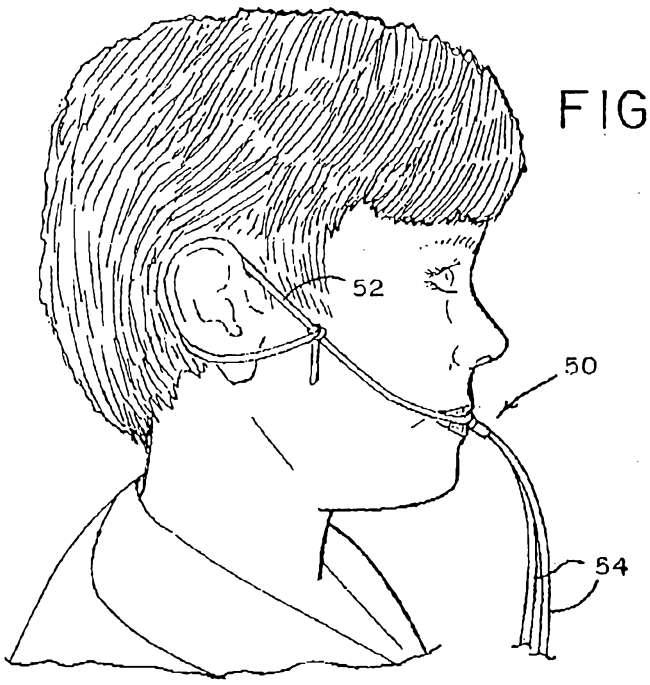


FIG. 38

FIG. 40

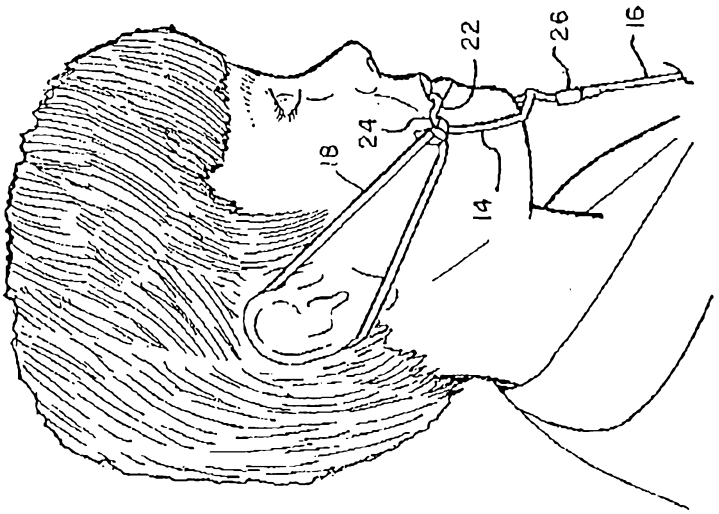


FIG. 39

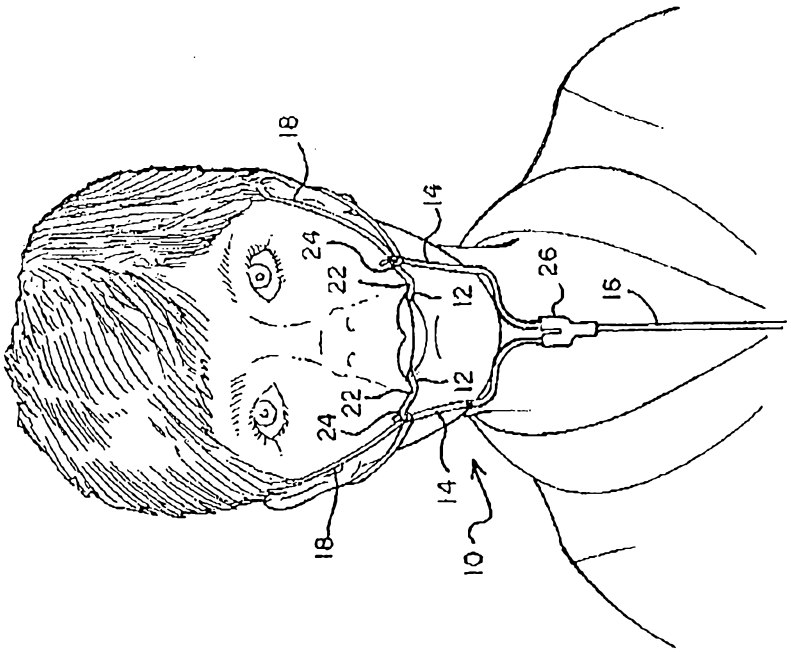


FIG. 41

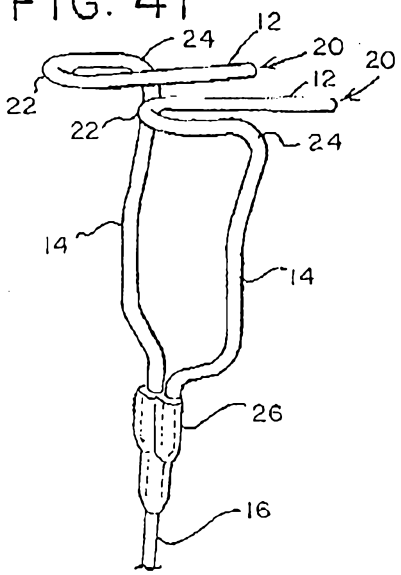


FIG. 42

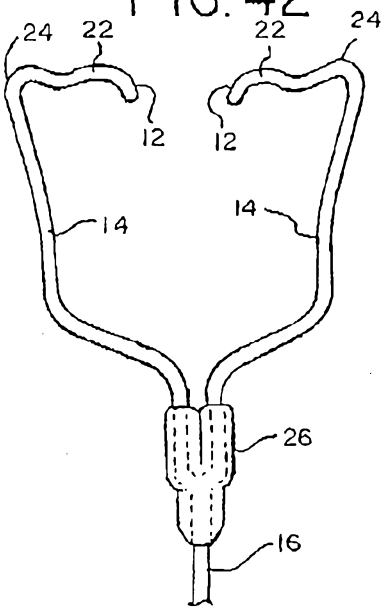
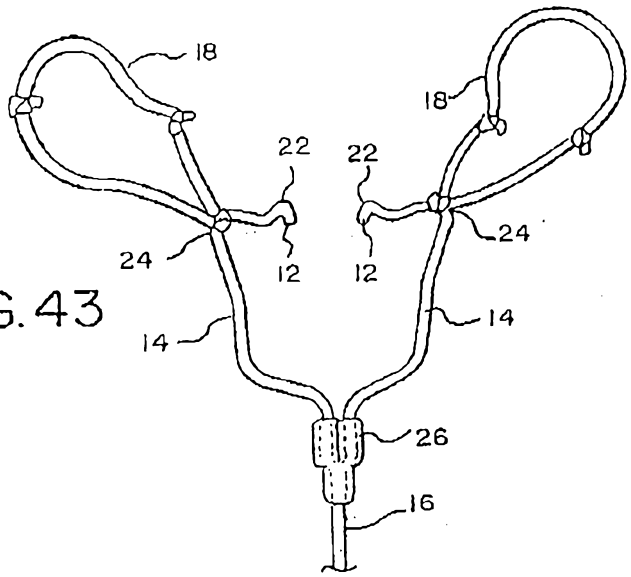


FIG. 43



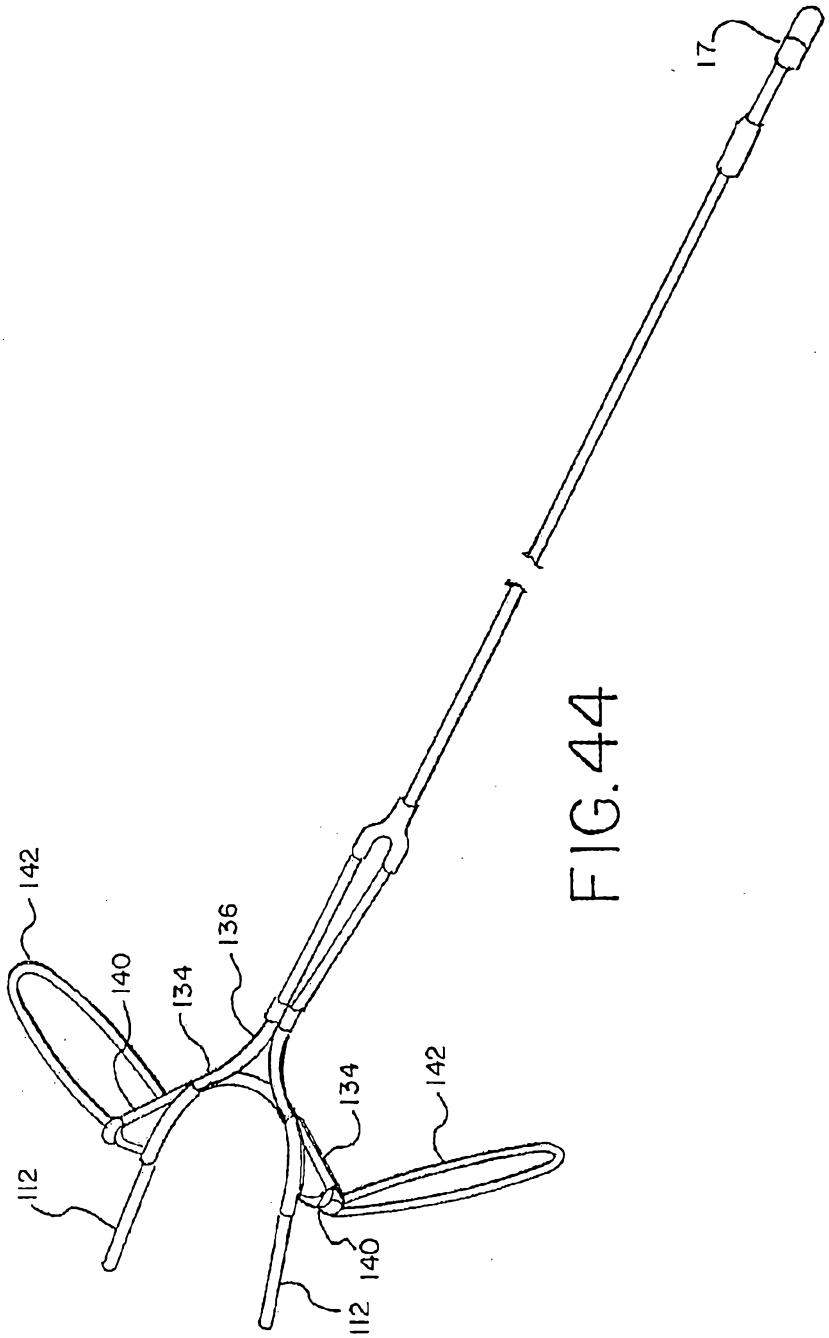


FIG.44

FIG. 45

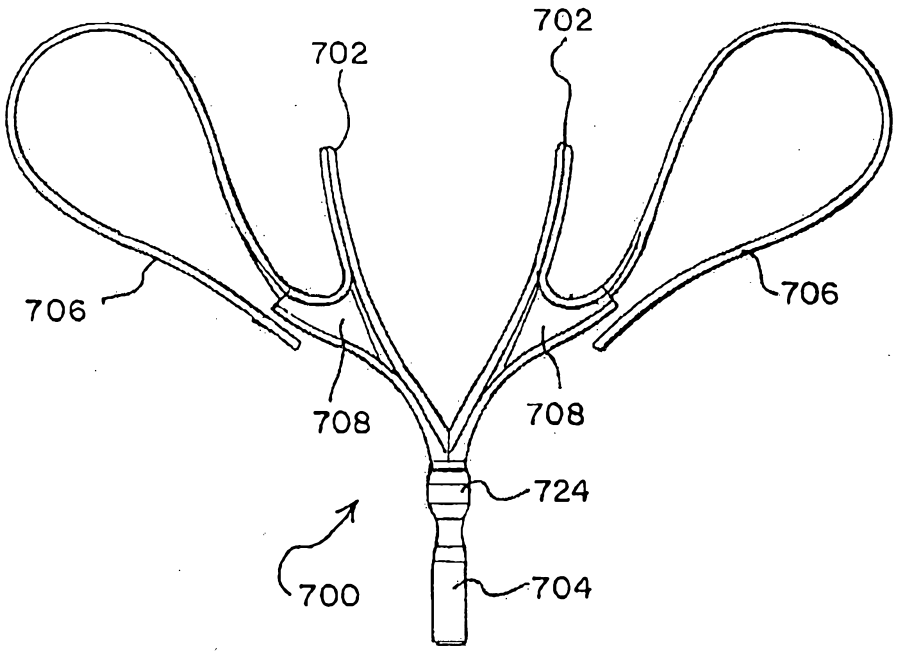


FIG. 46

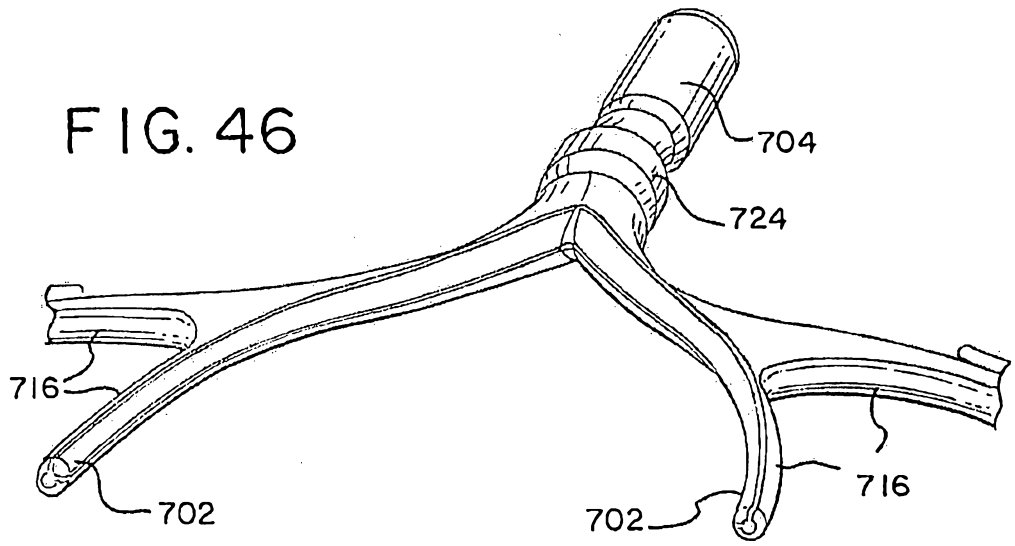


FIG. 47

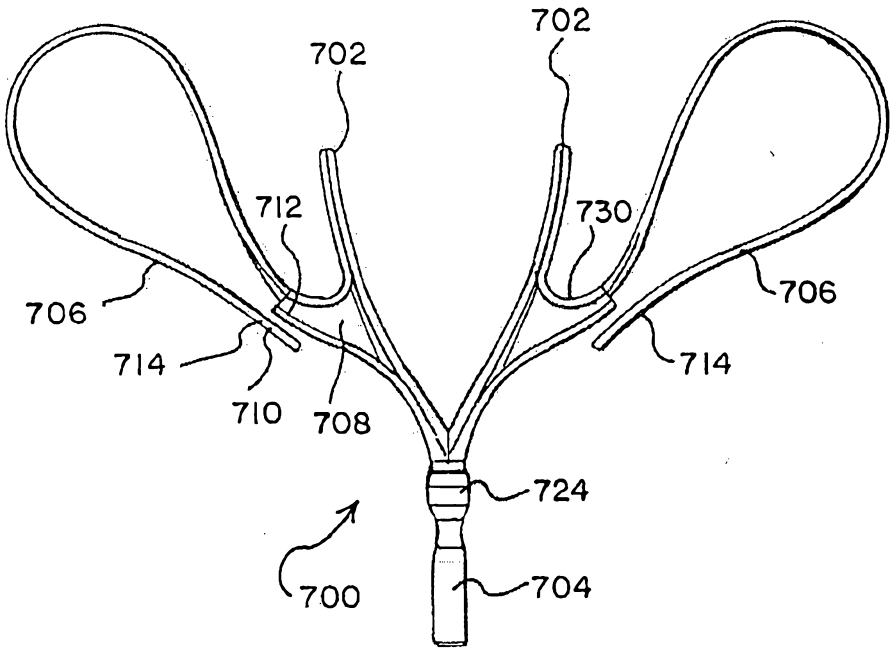

702
702
712
730
706
706
714
714
710
708
724
700
704

FIG. 48

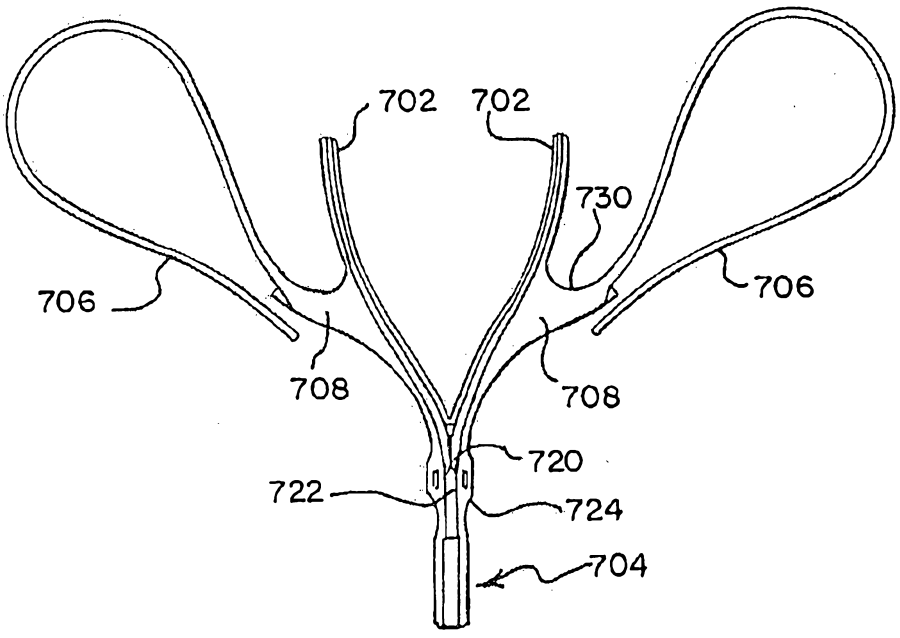

702
702
730
706
706
708
708
720
722
724
704

FIG. 49

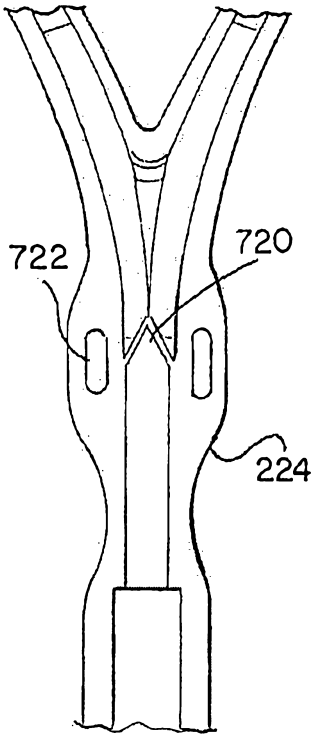


FIG. 50B

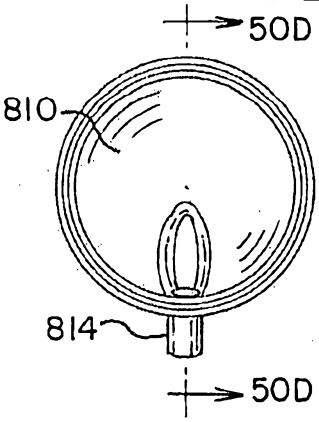


FIG. 50C

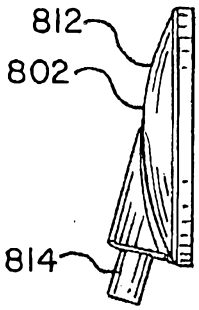


FIG. 50A

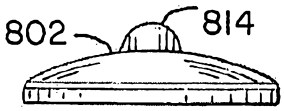


FIG. 50D

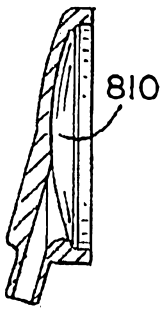


FIG. 51B

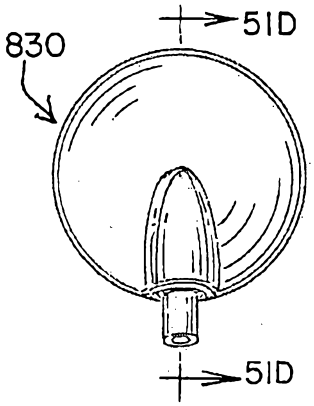


FIG. 51C

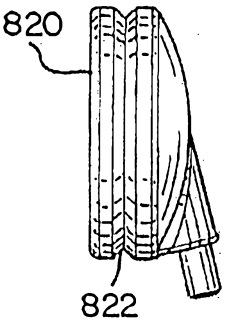


FIG. 51D

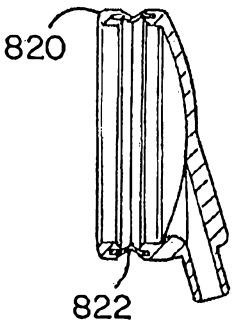


FIG. 51A

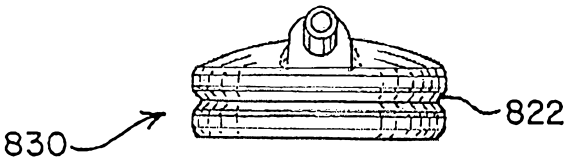
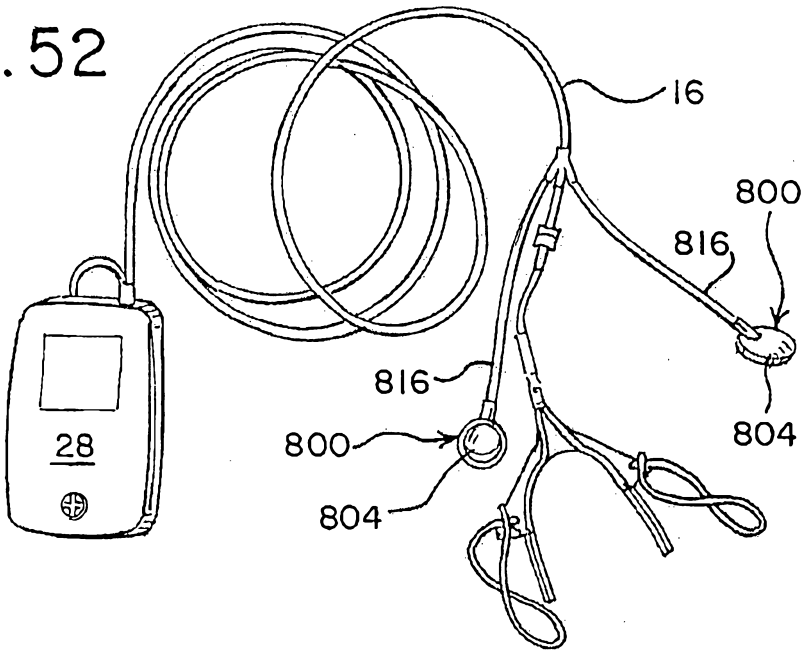


FIG. 52



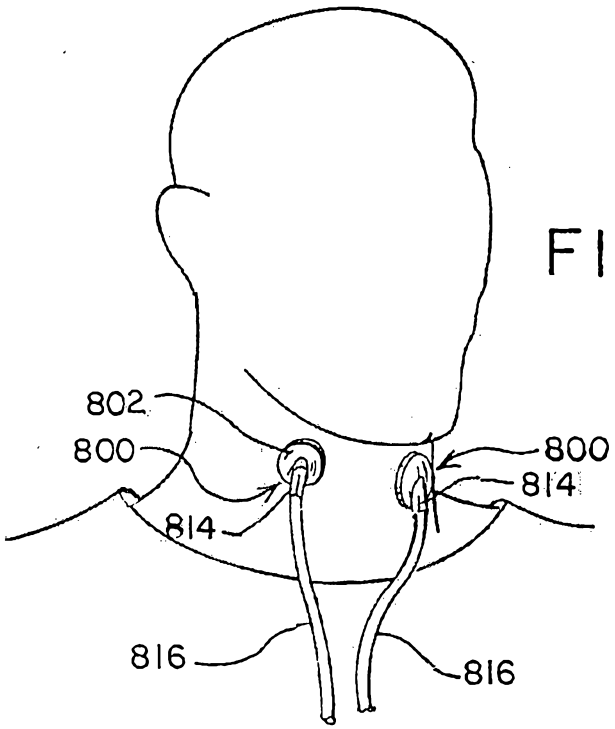


FIG. 53