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(54) Title: RESPIRATORY ASSISTANCE DEVICE AND SYSTEM AND METHOD

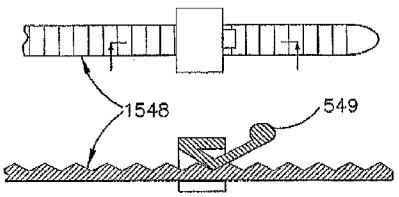

FIG. 6

(57) Abstract: A pressurized air delivery device, system and method provide respiratory assistance to individuals, particularly infant humans. The device comprises nasal conduits or prongs which are in fluid communication with respective supply conduits separately supply each nasal conduit with a breathable gas such as air or oxygen. The size of the nasal conduits or prongs may be chosen according to the size of the individual's nares and the spacing between nasal conduits or prongs may be adjustable.

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RESPIRATORY ASSISTANCE DEVICE AND SYSTEM AND METHOD

FIELD OF THE INVENTION

THIS INVENTION relates to delivery of continuous positive airway pressure to an individual, such as an infant, to thereby provide respiratory assistance.

BACKGROUND

Newborn infants particularly those born premature often have a need for respiratory support, ranging from increased ambient oxygen, through continuous positive airways pressure (CPAP) and endotracheal ventilation to, rarely, extracorporeal membrane oxygenation (ECMO). Infants born before 30 weeks of completed gestation almost invariably need a period of CPAP or ventilation to survive.

The commonest reason for premature newborn infants to require respiratory support is due to a lack of surfactant, a protein which helps to keep the smallest of the lungs air spaces open. Treatment for this disease process has consisted of CPAP since it was realised in the mid 1970's that CPAP treatment greatly improved infants rates of survival.

Whilst replacement of surfactant via an endotracheal tube has been available in Australia since the early 1990's, this requires infants to be intubated and ventilated. However intubation and ventilation, itself, can damage infants' lungs and there has been a shift in the last 5 – 10 years towards CPAP, both as a modality of support post extubation and a primary support in its own right, for the majority of infants with respiratory distress.

CPAP may be delivered via a multitude of machine – patient interfaces. The best devices utilise "short binasal" prongs designed to snugly fit into the nares of infants, thereby allowing the pressure to be delivered to the infant whilst minimising the resistance of the device to the infants' work of breathing.

Current "short binasal" prongs are designed with a connection between the two prongs which insert into the infants nose. This connection may cause pressure on the nasal septum, which in extreme cases can lead to necrosis and require plastic surgery to

correct. This problem is exacerbated by the mechanism by which these prongs are fixed to the infants head and face by means of hats, bonnets or headbands and the relatively bulky tubing and prongs in use.

Although the currently available devices come in a variety of sizes, both for prong size and separation between the prongs, each prong set is typically of a fixed prong size and separation.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

SUMMARY

The invention is broadly directed to providing respiratory assistance to an individual, typically an infant, by way of a device, system and/or method that delivers pressurized air to the nares of the individual, to alleviate one or more of the aforementioned deficiencies of the prior art.

In one aspect, the invention provides a pressurized air delivery device for providing respiratory assistance to an individual, said device comprising a plurality of nasal conduits in fluid communication with respective supply conduits connectable to a source of pressurized, breathable gas.

In another aspect, the invention provides a pressurized air delivery system for providing respiratory assistance to an individual, said system comprising a plurality of flexible nasal conduits in fluid communication with respective supply conduits connected to a source of pressurized, breathable gas.

In yet another aspect, the invention provides a method of providing respiratory assistance to an individual, said method including the step of delivering pressurized air to the nose of said individual through a plurality of nasal conduits in fluid communication with respective supply conduits connected to a source of pressurized, breathable gas.

Preferably, according to the aforementioned aspects, the individual is an infant human.

Suitably, continuous positive airway pressure is delivered to an individual by way of a plurality of conduits respectively locatable in the nares of an individual, without engaging, bearing against or otherwise contacting the nasal septum. Advantageously, continuous positive airway pressure is delivered to the individual without providing a hat, bonnet, headband or other separate means for attachment to the individual.

In a preferred embodiment, the nasal conduits are of a size adapted to fit the nares of the individual. In a particularly preferred embodiment the nasal conduits are interchangeable in size.

Preferably the nasal conduits are formed of a material that is more rigid than the supply conduits.

In certain embodiments, the nasal conduits may each comprise an inlet and an outlet, said outlet facilitating exhaust of exhaled gas to atmosphere.

Preferably, the nasal conduits further comprise respective valves to control oxygen flow to the user.

Suitably, the device and/or system further comprises a spacer to maintain a desired spacing or distance between the nasal conduits.

Preferably, the spacer is adjustable in order to select a desired spacing or distance between the nasal conduits.

In one preferred embodiment, said respective nasal prongs are maintained at a desired distance apart by an adjustable spacer that comprises a sliding rod or a band that comprises teeth or serrations. Typically, the adjustable spacer comprises an adjustment member, such as a lever, ratchet, turnbuckle, or cam, although without limitation thereto.

In a particularly preferred embodiment, the spaces comprises a band comprising teeth, ridges or serrations releasably engageable by a cam or lever.

Throughout this specification, unless the context requires otherwise, the words "comprise", "comprises" and "comprising" will be understood to imply the inclusion of

a stated integer or group of integers but not the exclusion of any other integer or group of integers.

BRIEF DESCRIPTION OF THE DRAWINGS

A preferred embodiment of the invention will now be described by way of example only, with reference to the accompanying figures in which:

FIG. 1 shows an embodiment where nasal prongs being held at a desired distance apart by rare earth magnets;

FIG. 2 shows an embodiment where nasal prongs are held at a desired distance apart by a ratchet mechanism;

FIG. 3 shows an embodiment where nasal prongs are held at a desired distance apart by a turnbuckle system;

FIG. 4 shows an embodiment where nasal prongs are spaced apart by a sliding rod mechanism;

FIG. 5 shows side and top views of different sized nasal prongs spaced apart by a sliding rod mechanism;

FIG. 6 shows side and top views of different sized prongs spaced apart by a sliding locking flat band mechanism;

FIG. 7 shows nasal prongs spaced apart by a sliding locking flat band mechanism that is adjustable by a cam mechanism;

FIG. 8 shows an example of the attachment of nasal prongs to an air supply conduit; and

FIG. 9 shows a nasal prong comprising and inlet and outlet for exhalation.

DETAILED DESCRIPTION

Referring to FIG. 1, device 10 comprises respective nasal conduits 20A, 20B in fluid communication with respective air and/or oxygen supply conduits 30A, 30B. Nasal conduits 20A, 20B respectively comprise arms 21A, 21B normal to air supply conduits 30A, 30B and elbows 22A, 22B which respectively terminate in nasal prongs 23A, 23B. Preferably nasal conduits 20A, 20B are formed of a material that is more

rigid (e.g. polymethylmethacrylate or polycarbonate) than the supply conduits which are of a relatively flexible tubing material (*e.g.* polyurethane).

In use, air and/or oxygen supply conduits 30A, 30B are connected to a source of pressurized air, oxygen or other gas suitable for assisting human respiration (not shown). The direction of pressurized air flow from the source is indicated by solid arrows.

According to this embodiment, spacer 40 comprises magnetic poles 41A, 41B on bridge 42, which respectively interact with magnetic poles 24A, 24B on nasal prongs 23A, 23B to maintain nasal prongs 23A, 23B at a desired separation. Typically, although not exclusively, magnetic poles 41A, 41B, 24A and 24B are produced by rare earth magnets (*e.g.* lanthanides such as neodymium or samarium, although without limitation thereto) located on the outside of the nares.

Referring to an embodiment shown in FIG. 2, device 110 comprises spacer 140 comprising adjustable ratchet 142 which maintains nasal prongs 123A, 123B at a desired separation.

An embodiment shown in FIG. 3 shows nasal prongs 223A, 223B adjustably movable (indicated by solid horizontal arrows) to a desired distance apart by spacer 240 comprising turnbuckle 243 that is adjustable by winding wheel 244 in either direction (indicated by solid arrows).

In another embodiment of device 310 shown in FIG. 4, nasal prongs 323A, 323B are held at a desired distance apart by spacer 340 that is adjustable by way of sliding rod mechanism 345 that is adjustable by pushing button 346 to release sliding rod 347 and thereby finding the correct distance between nasal prongs 323A, 323B.

Referring now to FIG. 5, an embodiment of device 410 is shown similar to that shown in FIG. 4, wherein nasal prongs 423A, 423B are of reduced diameter compared to those in FIG. 4, demonstrating that nasal prongs 23A, 23B may be of varying, interchangeable sizes.

FIG. 6 shows an embodiment where nasal prongs 523A, 523B are held at a desired distance apart by spacer 540 comprising slidable band 548 that comprises teeth, serrations or ridges 1548 releasably engageable by lever 549. Lever 549 engages teeth, serrations or ridges 1548 of flat band 548 to releasably maintain the desired distance

between prongs 523A, 523B and thereby allow adjustment of the spacing between prongs 523A, 523B. Preferably, slidable band 548 is located underneath arms 521A, 521B of nasal conduits 520A, 520B (relative to an individual's nares) to maximize the distance between slidable band 548 and the individual's nasal septum. This should eliminate or at least minimize any potential contact between slidable flat band 548 and the individual's nasal septum.

In an embodiment shown in FIG. 7, nasal prongs 623A, 623B are held at an appropriate distance apart by spacer 640 comprising slidable t band 648 that comprises teeth, serrations or ridges 1648 releasably engageable by cam 650. Cam 650 releasably engages teeth, serrations or ridges 1648 of slidable band 648 to releasably maintain the desired distance between prongs 623A, 623B and thereby allow adjustment of the spacing between prongs 623A, 623B. As in the embodiment described in FIG. 6, slidable band 648 is ideally located underneath arms 621A, 621B of nasal conduits 620A, 620B (relative to an individual's nares) to maximize the distance between slidable band 648 and the individual's nasal septum.

It should also be appreciated that slidable band 540, 640 is shown as a "flat" band in FIGS 6 and 7. However, in certain embodiments slidable band 540, 640 may be curved to facilitate a more comfortable fit on the individual.

FIG. 8 shows an example of one way in which nasal conduit 720A is attached to air supply conduit 730A. In this example, arm 721A is pushed onto air supply conduit 730A and barbs770A, 770B are employed to hold arm 721A in place on air supply conduit 730A.

Referring to FIG. 9, there is shown an embodiment wherein device 810 comprises nasal prong 823 having inlet 870 and outlet 880, which each operate as "one-way" valves. Inlet 870 comprises leaflet 871 which moves between open position 872 and closed position 873 to enable a one-way flow of air to the nares. Outlet 880 comprises leaflet 881 which moves between closed position 882 and open position 883 to enable a one-way flow of exhaled gas from the nares to atmosphere via aperture 884. Screen 890 may also be provided to prevent accidental inhalation of leaflets 871 and/or 881.

It will be appreciated the present invention provides continuous positive airway pressure to an individual, typically an infant human, without engaging or otherwise contacting the nasal septum in a manner that causes irritation or discomfort to the user. Air, oxygen or other breathable gas is supplied via separate air supply conduits and nasal conduits, rather than via a common air supply conduit into separate nasal conduits. This eliminates the portion of the common air supply conduit that contacts and irritates the nasal septum. Furthermore, the nasal prongs may be provided in a variety of interchangeably different sizes to suit the size of the nares of the user, which also assists the objective of reducing the level of irritation and discomfort..

Another advantage of the present invention is that the device needs limited fixation, (even just a piece of tape may suffice) rather than the bonnets, hats, head-bands *etc.* required with prior art devices. Furthermore, many prior art devices require significant nursing expertise to attach and supervise in use. The present invention can be fitted and supervised by any person familiar with standard nasal cannulae.

In summary, the present invention provides improved nasal septal protection, ease of attachment, ease of nursing care, reduced weight and bulk, the ability to adapt nasal conduit size to different nare sizes (sometimes if a child has been nasally intubated, one nare is larger than the other), and variable separation between respective conduits.

Throughout this specification, the aim has been to describe the preferred embodiments of the invention without limiting the invention to any one embodiment or specific collection of features. Various changes and modifications may be made to the embodiments described and illustrated without departing from the present invention.

CLAIMS

1. A pressurized air delivery device for providing respiratory assistance to an individual, said device comprising a plurality of nasal conduits in fluid communication with respective supply conduits connectable to a source of pressurized, breathable gas.

2. A pressurized air delivery system for providing respiratory assistance to an individual, said system comprising a plurality of flexible nasal conduits in fluid communication with respective supply conduits connected to a source of pressurized, breathable gas.

3. The device of Claim 1 or the system of Claim 2, further comprising a spacer to maintain a desired spacing or distance between the nasal conduits.

4. The device or system of Claim 3, wherein the spacer is adjustable in order to select a desired spacing or distance between the nasal conduits.

5. The device or system of Claim 4, wherein said adjustable spacer comprises an adjustment member.

6. The device or system of Claim 4, wherein the adjustment member comprises a lever, ratchet or cam.

7. The device or system of any one of Claims 1-6, wherein the nasal conduits are formed of a material that is more rigid than the supply conduits.

8. The device or system of any one of Claims 1-7, wherein the nasal conduits are of interchangeable sizes.

9. The device or system of any one of Claims 1-8, wherein the nasal conduits each further comprise a valve.

10. The device of any one of Claims 1-9, wherein each said nasal conduit comprises an inlet and an outlet, said outlet facilitating exhaust of exhaled gas to atmosphere.

11. The device or system of any preceding claim, wherein the breathable gas is air or oxygen.

12. A method of providing respiratory assistance to an individual, said method including the step of delivering pressurized air to the nose of said individual through a

plurality of nasal conduits in fluid communication with respective conduits connected to a source of pressurized, breathable gas.

13. The method of Claim 12, wherein the individual is an infant human.

14. The method of Claim 12 or Claim 13, wherein continuous positive airway pressure is delivered to an individual by way of a plurality of conduits respectively locatable in the nares of an individual, without engaging or otherwise contacting the nasal septum.

15. The method of any one of Claims 12-14, using the device or system of any one of Claims 1-11.

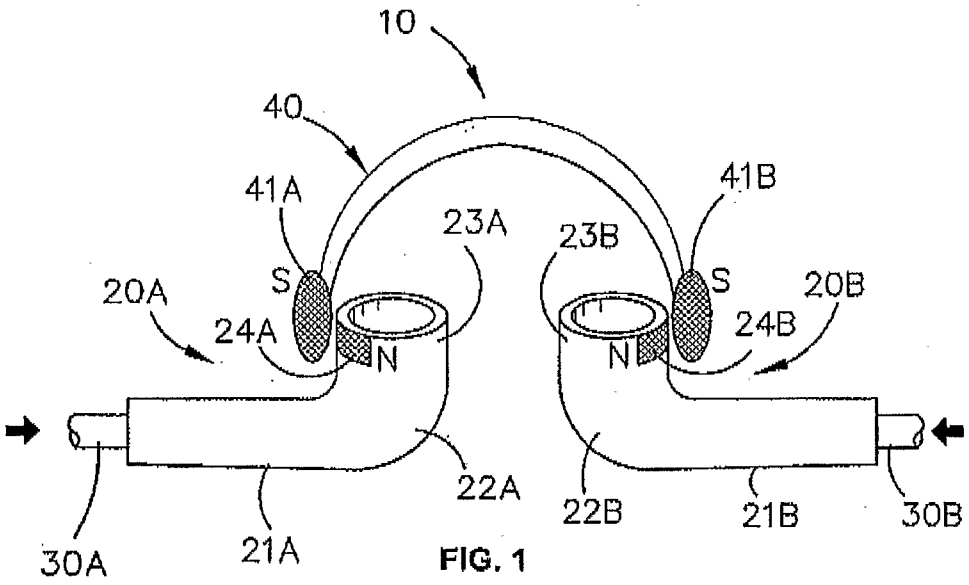
10
40
41A
41B
23A
23B
20A
S
S
20B
24A
24B
N
N
22A
22B
21B
30B
30A
21A

FIG. 1

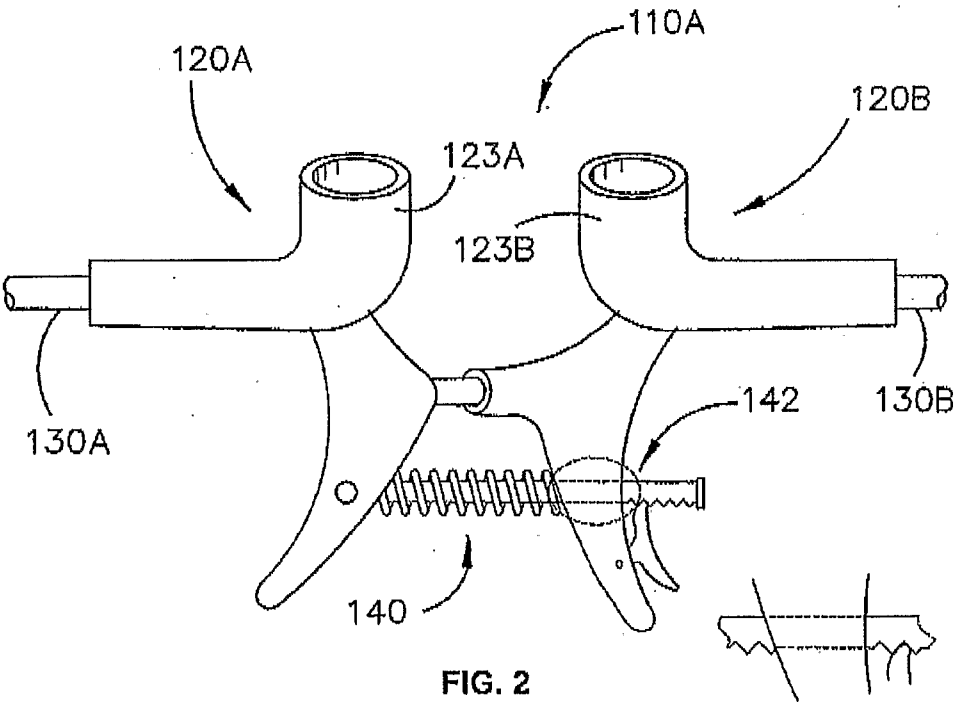
110A
120A
120B
123A
123B
130A
130B
142
140

FIG. 2

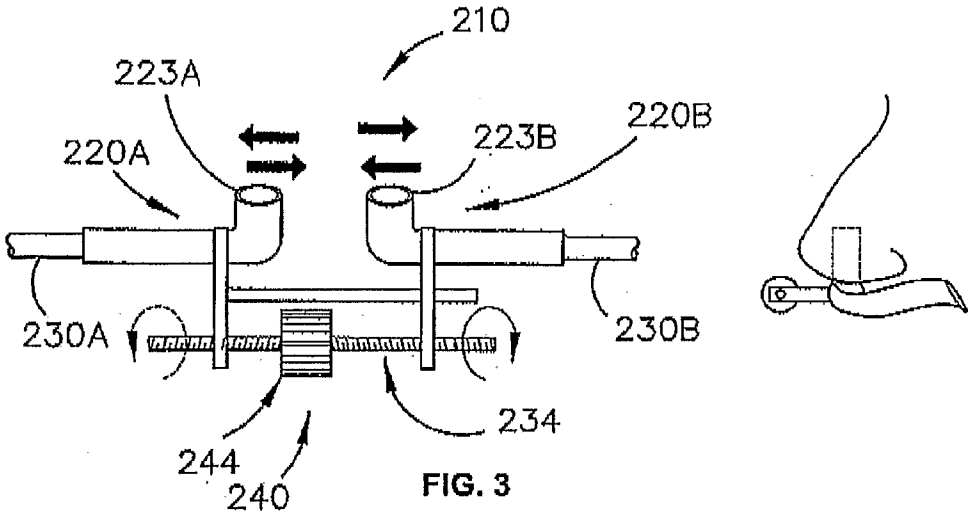
210
223A
220A
223B
220B
230A
230B
234
244
240

FIG. 3

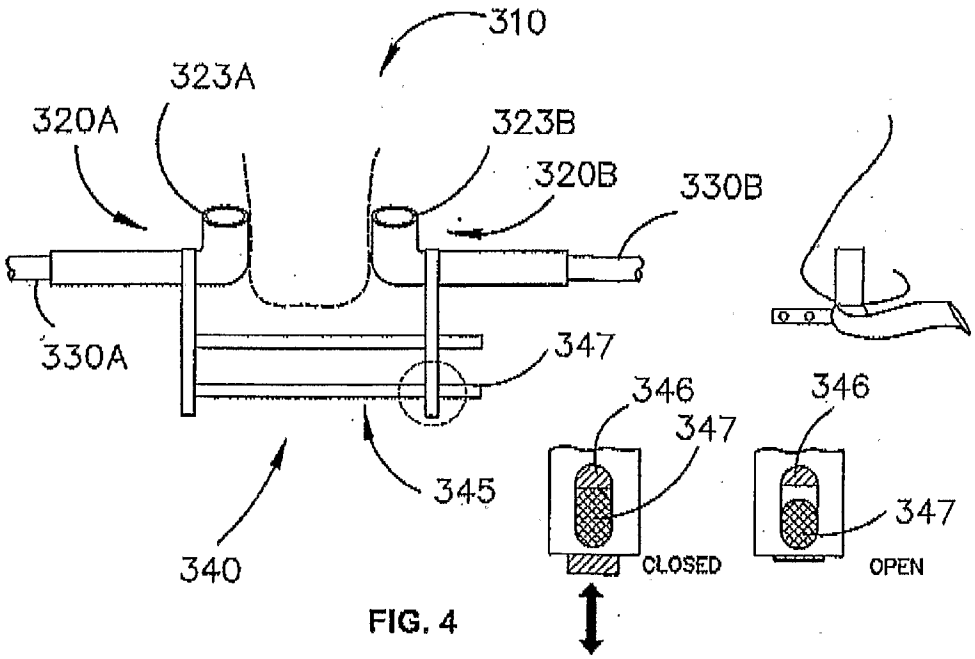
310
323A
320A
323B
320B
330B
330A
347
346
347
346
345
340
CLOSED
347
OPEN

FIG. 4

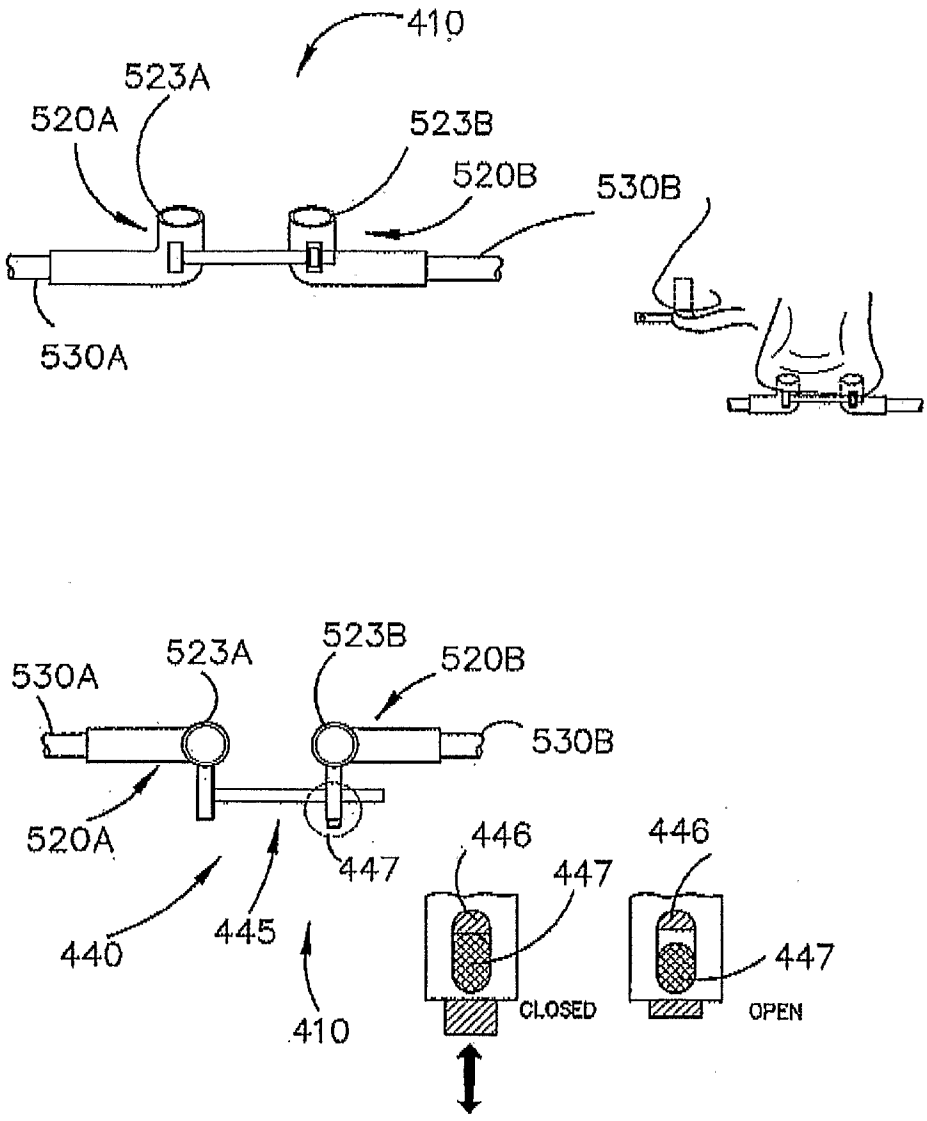
410
523A
520A
523B
520B
530B
530A
523A
523B
520B
530A
530B
520A
447
446
446
447
440
445
447
410
CLOSED
OPEN

FIG. 5

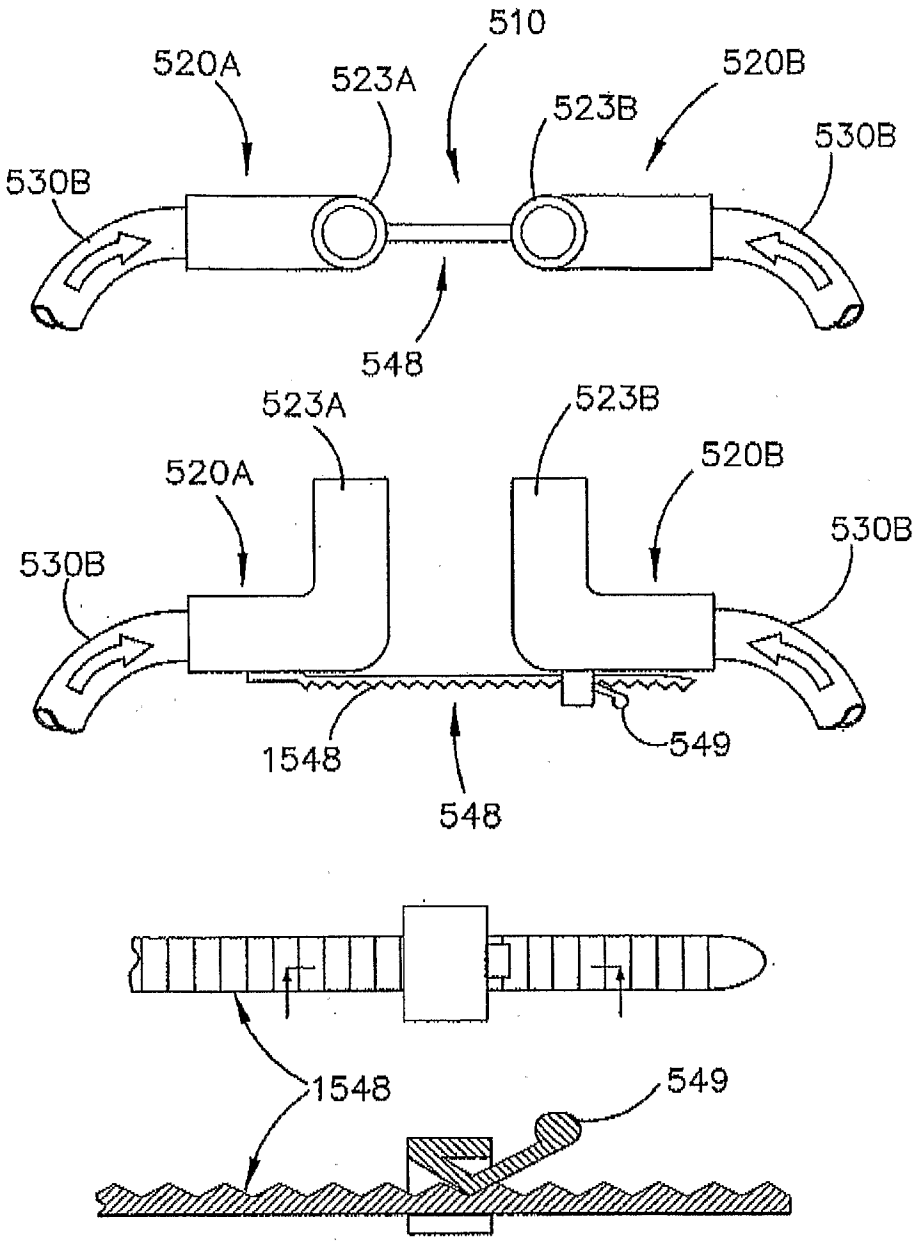
510
520A
523A
520B
523B
530B
530B
548
523A
523B
520A
520B
530B
530B
1548
549
548
1548
549

FIG. 6

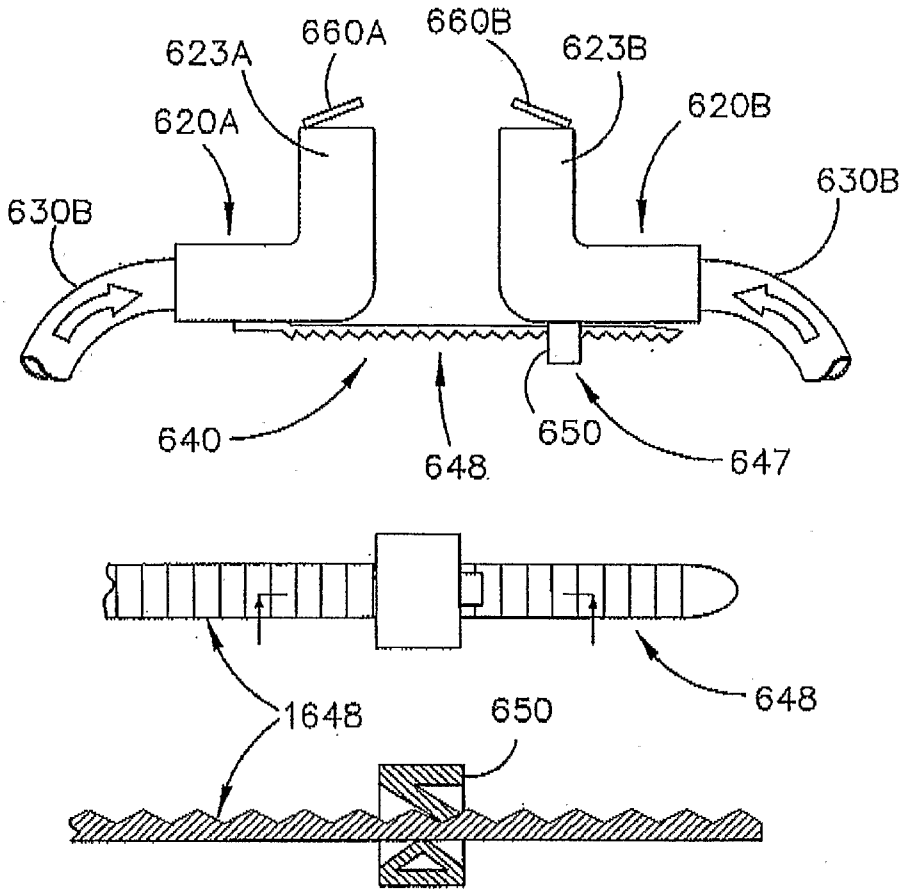
623A
660A
660B
623B
620A
620B
630B
630B
640
648
650
647
1648
650
648

FIG. 7

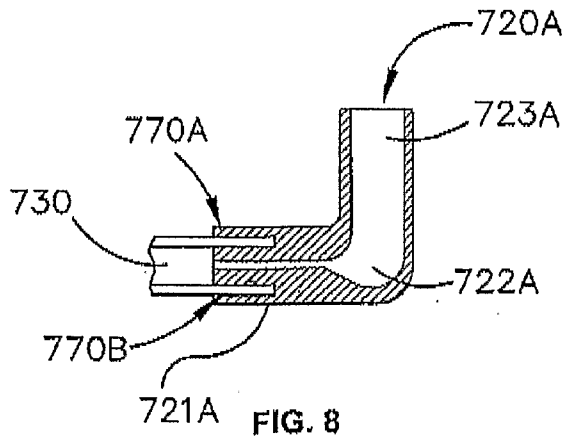
720A
723A
770A
730
722A
770B
721A

FIG. 8

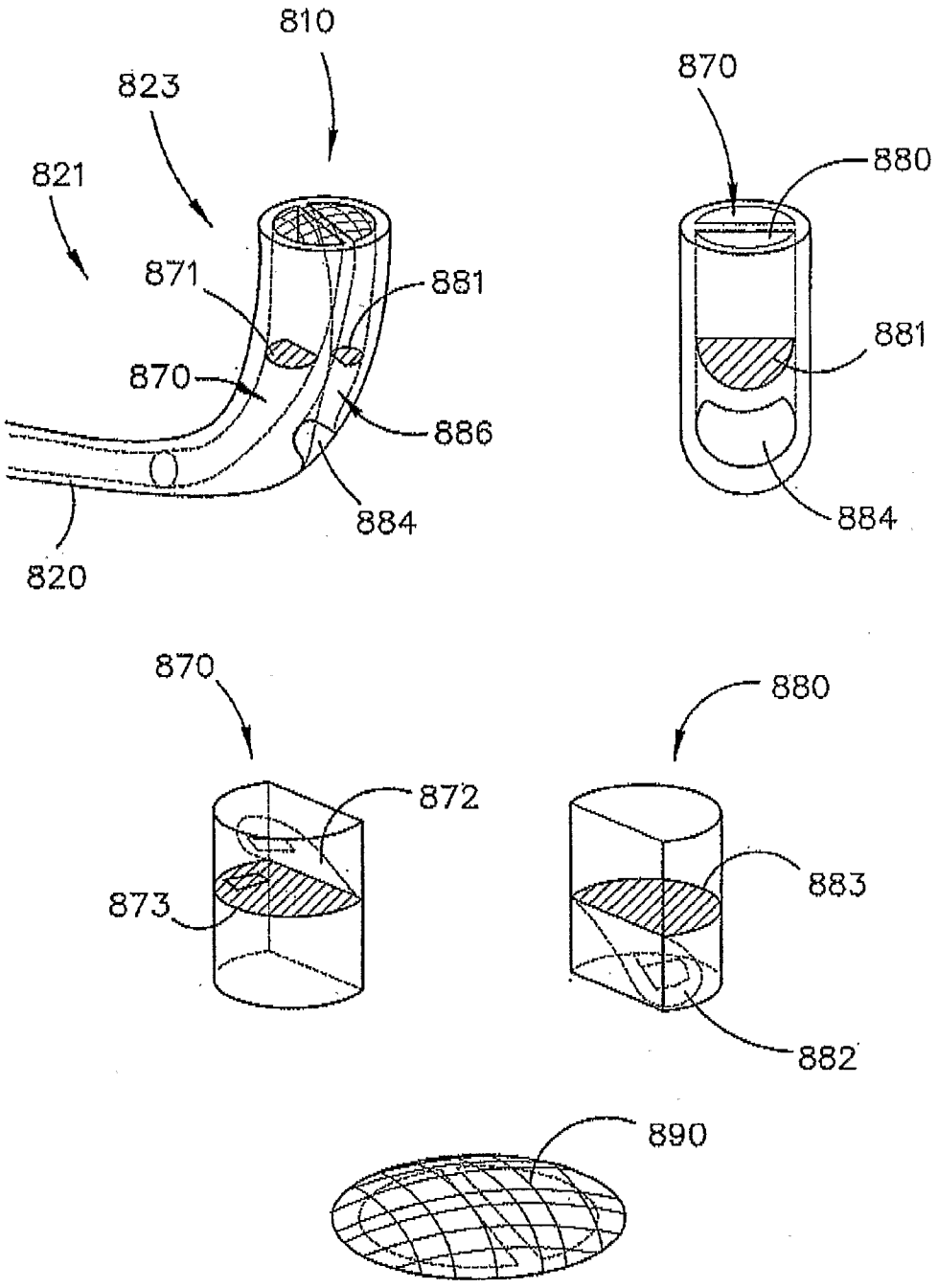
810
823
821
871
881
870
886
884
820
870
880
881
884
870
872
873
880
883
882
890

FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2009/001519

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 16/00 (2006.01)

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)

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)
EPODOC, WPI - IPC A61M16/-, A62B7/-, A62B9/-, and NASAL, NOSTRIL, NARE, CONDUIT, CANNULA, ADJUST, CHANGE and like keywords.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 191406973 (HUMPHRIES) 30 July 1914 Page 1, lines 5-7, 34-40; page 2, lines 1-3, 9-10, 14-25	1, 3-5, 8-12, 15
Y	Figure 4	6, 9
X	US 4278082 A (BLACKMER) 14 July 1981 Column 1, lines 6-10; column 3, lines 34-64 Figures 3, 4, 7, 8	1-4, 11, 12, 15
X	WO 1992/020392 A1 (CALOR AIR SEPARATION LIMITED) 26 November 1992 Page 1, lines 1-2; page 3, lines 4-10; Page 14, lines 13-23 Figure 8	1-5, 11, 12, 15
X	US 5269296 A (LANDIS) 14 December 1993 Abstract; column 1, 5, 6, 9 Figures 2, 3	1, 3, 4, 7, 11-13, 15

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 January 2010	29 JAN 2010
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. +61 2 6283 7999	Authorized officer **Wan Kit Chan** AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : +61 2 6283 2974

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2009/001519

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0821978 A2 (HART-ELLERETH MEDICAL INC.) 4 February 1998 Abstract; column 2, 5, 6 Figure 2	1, 3, 7, 8, 10-12, 14, 15
X	US 2002/0046755 A1 (De VOSS) 25 April 2002 Abstract; paragraph [0018, 0024, 0027, 0061, 0064] Figures 5, 7, 13	1-5, 10-13, 15
X	US 2004/0244804 A1 (OLSEN et al.) 9 December 2004 Abstract Paragraph [0056, 0057, 0059]	1, 2, 8, 11-15
Y	US 5097827 A (IZUMI) 24 March 1992 Column 1, 2, 5 Figures 7-9	6
Y	WO 2006/063339 A2 (VENTUS MEDICAL. INC.) 15 June 2006 Abstract; paragraph [0141] Figure 4, 23	9

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2009/001519

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
GB	191406973	NONE					
US	4278082	NONE					
WO	9220392	NONE					
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		CA	2589922	CA	2658966	CN	101166555
		CN	101489630	EP	1824544	EP	2032213
		EP	2032214	KR	20070106995	KR	20090024783
		MX	2007006738	RU	2007125634	US	7506649

US	2006144398	US	2006150978	US	2006150979
US	2007283962	US	2007295338	US	2008041373
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US	2009308398	WO	2007146133	WO	2007146189
WO	2007146207	WO	2008061250	WO	2008061252
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Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX