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(71) Applicant (for all designated States except US): **COMPUMEDICS MEDICAL INNOVATION PTY LTD** [AU/AU]; 30-40 Flockhart Street, Abbotsford, Victoria 3067 (AU).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **ZIV, Hedi** [IL/AU]; 27 Peacock Street, Burwood, Victoria 3125 (AU). **MC-COOEY, Conor** [AU/AU]; 95 Asling Street, Brighton, Victoria 3186 (AU). **SLABBERT, Rikus** [ZA/AU]; 6A Mount Ida Avenue, Hawthorn East, Victoria 3123 (AU).

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(54) Title: MULTIPLE CHAMBERS MASK

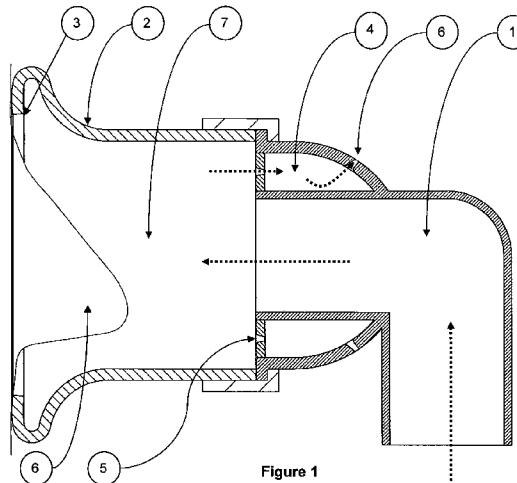


Figure 1

(57) Abstract: The present invention provides a methods and apparatus for gas delivery, in particular, a mask including at least one porous barrier defining at least two chambers in gaseous communication. The porous barrier may include a plurality of pores, which preferably define a tapered shape. The mask may include a pliable nasal cushion. The invention provides a method for providing pressurised gas to a subject by supplying gas from a pressurised source to a mask, transmitting the gas into a first chamber at a first pressure, transmitting the gas into a second chamber at a second pressure through a plurality of pores, and transmitting the gas from the second chamber through a mask exit.

WO 2011/003130 A1

Multiple Chambers Mask

Field of the Invention

The present invention relates to masks for the provision of gases to subjects, in particular, masks for delivery of pressurised gas to the airways of a subject.

Background

There are a number of treatments that require the use of a mask for the delivery of gas or air to a subject. For example, in the treatment of sleep apnoea, gas is often delivered at continuous positive airway pressure (CPAP) wherein gas is supplied continuously at a pressure greater than ambient, or variable positive airway pressure (VPAP) wherein gas is supplied at varying pressures, or other such methods such as BiPAP wherein gas is supplied at two pressures, or APAP wherein gas is supplied at pressures determined automatically by the delivery system to a sleeping subject through a mask to keep the patient's airways open for effective respiration. Often gas must be delivered through a mask for sustained time periods, for example, through a whole overnight period of sleep.

It is important for continuous therapeutic benefit from pressurised gas or air that a mask assembly be comfortable and relatively leak-proof when positioned for gas delivery. The mask must be comfortable so that a subject achieves the therapeutic benefit of relatively unbroken sleep periods. Masks known in the art often incorporate an interface such as a cushion or pillow, made of soft material to be most comfortable for a subject during long periods of use, but are capable of sealing adequately to minimise leaks. A nasal cushion, for example, is sealingly engaged with the bridge and sides of the nose, and the upper lip to provide a leak-proof conduit for pressurised gas delivery.

Prior art mask assemblies have been designed to allow some gas leakage from the mask assembly during gas delivery. An unfortunate consequence is the acoustic noise attributable to these leaks may cause a subject to have difficulty falling asleep and then being aroused from sleep during positive airway pressure treatment. Arousals, in turn, may limit the efficacy of the treatment. Further, the acoustic noise also may affect the sleeping of nearby persons. What is needed is an interface for pressurised gas delivery in any of CPAP/VPAP/BiPAP/APAP system wherein the interface delivers gas to the airways of a subject with reduced acoustic noise.

Summary of the Invention

It is an object of the invention to provide an interface for a gas-delivery mask that generates reduced acoustic noise during gas delivery. The present invention most advantageously provides solutions to the problem of noisy masks when pressurised air or gases is provided to a subject. The mask is both comfortable and less noisy than masks currently found in the art. The invention provides an interface for a mask for delivery of pressurised gas to a subject incorporating means to reduce the acoustic noise generated from the pressurised gas. The interface may be a nasal cushion or other means, such as a face cushion. The noise reduction means comprises of a baffling means. The baffling means preferably comprises of a porous barrier defining volumes in gaseous communication within the nasal interface. Preferably there are two adjacent volumes defined by a porous barrier.

Surprisingly, the acoustic noise of multiple adjacent volumes is reduced compared with a single volume. The invention has many possibilities for uses in different applications whenever pressurised gas is delivered to a subject. Some examples are for delivering oxygen in aircraft, or for delivering gaseous anaesthetics or therapeutic substances suitable for gas delivery. In particular, the invention will be most advantageously used for gas delivery for application of CPAP therapy. The reduced acoustic noise generated by a gas-delivery mask according to the invention enables a more efficient sleep with fewer arousals.

In one aspect, the invention provides a mask comprising of a gas supply, a gas output, and at least one porous barrier defining at least two chambers in gaseous communication. Preferably the mask incorporates a first chamber in gaseous communication with the gas supply and the second chamber, the communication being through apertures for gaseous flow into the ambient air. In another aspect, the invention provides a mask for delivering pressurised gas to a subject, the mask comprising a first aperture in gaseous communication with a pressurised gas supply, a second aperture for efflux of pressurised gas, and at least one porous barrier defining at least two chambers, wherein the chambers are in gaseous communication. Preferably, the mask includes a conduit in communication with the gas supply and the mask. Preferably, the porous barrier includes a plurality of apertures in communication with the chambers. Preferably, the apertures define a tapered shape. Most preferably, the mask includes a nasal cushion. Preferably, the nasal cushion comprises of a pliable material.

In another aspect, the invention provides a method of providing pressurised gas to a subject, comprising the steps of supplying gas from a pressurised source to a mask, transmitting the gas into a first chamber at a first pressure, transmitting the gas into a second chamber at a second

pressure, and transmitting the gas from the second chamber through an exit. Preferably, the step of transmitting the gas to second chamber or through the exit occurs through a plurality of apertures. In another aspect, the invention provides a mask comprising of a first chamber for engagement with the face of a subject, a second chamber in gaseous communication with the first chamber, and a porous baffle defining the boundary between the chambers.

Brief Description of the Figures

Figure 1 shows a longitudinal transverse view through a mask assembly having a nasal cushion interface according to the invention.

Figure 2 shows a transverse view of a few slot leak aperture design of a mask assembly having a nasal cushion according to the invention.

Figure 3 shows a transverse view of multiple leak apertures design of a mask assembly having a nasal cushion according to the invention.

Figure 4 shows a comparison between a parallel wall pore (a) and a tapered pore (b).

Detailed Description of the Invention and Most Preferred Embodiment

The invention advantageously exploits the acoustic muffling effect of adjacent chambers in gaseous communication, the chambers defined by a baffling means. The baffle means comprises of a barrier incorporating pores of defined cross-sectional areas. Preferably the baffle incorporates a plurality of small pores which cooperate to decrease the acoustic noise attributable to the gas flow. More preferably, the pores are tapered. The pores may be frusto-conical in shape. The baffling means may comprise of multiple small tapered pores. Surprisingly, the acoustic noise of the multiple small tapered pores is reduced compared with fewer, larger pores creating the same total cross-sectional area. The acoustic noise of the tapered pores or frusto-conical pores may be reduced compared with cylindrical pores. The reduced acoustic noise enables a more efficient sleep with fewer arousals.

It is known in the art that for two pores in series design, compared to a single pore design, having the same overall pressure drop at the same flow rate, the two pores should have a diameter of about $2^{1/4} d = 1.19 d$, where d is the diameter of a single pore. The velocity of gas movement through the pores reduces to $8\sqrt{2}V$ where V is the original mean velocity. Given that the sound power is proportional to the product of pore area and velocity to the 8th power, the acoustic power

emission per pore should be reduced by a factor of $8\sqrt{2} = 11.3$ or about 10 dB. In practice, the internal pore noise is not fully absorbed. A further advantage is that the reduction in velocity attributable to chambers in gaseous communication would be expected to reduce the external draught effect at the leak site.

The pressure difference of gas in volumes in gaseous communication is proportional to the cross-sectional area defined by the apertures of the pores. Optimal noise suppression may be effected by reducing the magnitude of pressure drop, by introducing intermediate pressure drops in multiple intermediate chambers, and implementing multiple small tapered pores, although either feature may be incorporated in an embodiment to achieve some noise suppression.

The figures illustrate embodiments of the invention. It will be understood that there are many other possible embodiments of the invention and that the invention is limited only by the scope of the claims appended hereto.

Figure 1 shows an embodiment of the invention as a dual chamber gas-delivery mask. The left side of the drawing shows a nasal mask in operative position on the face of a subject, with the subject's nose (6) extending into a first chamber (7) defined by the nasal interface. In this embodiment, the interface is a nasal cushion (2). Alternative embodiments such as facial cushions or pillows may also be used. The PAP (positive airway gas pressure) is supplied via a hose (1) into the nasal cushion defining a chamber (7), the nasal cushion engaging the subject's face with a flexible sealing membrane (3). The pressure differential between the above-ambient pressure gas from the hose (1) flowing into the nasal chamber (7) and a second chamber (4) in gaseous communication with the first chamber (7) results in gas flux between the chambers.

A further gas pressure differential between the second chamber (4) and the ambient air results in gas flux into the air. The pressurised gas from the second chamber (4) flows to the ambient air via pores (6) which are preferably tapered or frusto-conical in shape, but may also take other shapes as necessary, such as being cylindrical. The gas may flow through pores (5) in a porous baffle defining the boundary between the chambers (7),(4). Figure 1 shows two chambers in gaseous communication but further chambers may be incorporated into the mask. The invention includes more than two chambers, if necessary, according to the application. The pathway of the PAP through the supply hose and interface is shown by the dotted lines in Figure 1. The total area of pores (5) between the main chamber (7) and the secondary chamber (4); and the total area of pores (6) between the secondary chamber (4) and the ambient air determines the pressure difference between the main chamber (7) and the secondary chamber (4), as well as the pressure

difference between the secondary chamber (4) and the ambient air. The reduction of pressure difference between the two chambers or the secondary chamber and the ambient air, generates a lower flow through the pores and thus creates less turbulence, resulting in a reduced acoustic noise level.

Figure 2 shows an embodiment of the invention having multiple large pores for the gas leak.

Figure 3 displays small multiple tapered pores for the gas leak.

Figure 4a shows an embodiment of the invention having a cylindrical pore. Figure 4b a further embodiment having a tapered pore. The smooth entrance to the aperture reduces turbulence of the gas being released; the tapered shape decelerates the gas flow, resulting in a reduced acoustic noise level.

We claim:

1. A mask comprising of:
 - a gas supply;
 - a gas output; andat least one porous barrier between at least two chambers in gaseous communication.
2. A mask for delivering pressurised gas to a subject, the mask comprising:
 - a first aperture in gaseous communication with a pressurised gas supply;
 - a second aperture for efflux of pressurised gas; andat least one porous barrier defining at least two chambers, wherein the chambers are in gaseous communication.
3. The mask of claim 1 or claim 2 further comprising a conduit in communication with the gas supply and the mask.
4. The mask of claim 1 or claim 2 wherein the porous barrier includes a plurality of pores in communication with said chambers.
5. The mask of claim 4 wherein the pores define a tapered or frusto-conical shape.
6. The mask of claim any one of claims 1 to 4 further comprising of a nasal cushion.
7. The mask of claim 1 wherein a first chamber is in gaseous communication with the gas supply and the second chamber includes pores in gaseous communication with the ambient air.
8. A mask comprising of:
 - a first chamber for engagement with at least a portion of the face of a subject;
 - a second chamber in gaseous communication with said first chamber; anda porous baffle between the chambers.
9. A mask according to claim 8, wherein the porous baffle comprises of tapered or frusto-conical pores.
10. The mask according to claim 8 wherein the first chamber comprises of a pliable material.
11. A mask according to any one of claims 1 to 10 for use with anaesthetics in gaseous delivery.

12. A method of providing pressurised gas to a subject, the method comprising the steps of:
supplying gas from a pressurised source to a mask;
transmitting the gas into a first chamber at a first pressure;
transmitting the gas into a second chamber at a second pressure; and
transmitting the gas from the second chamber through an exit.
13. The method of claim 12 wherein the step of transmitting the gas to second chamber or through the exit occurs through a plurality of pores.
14. The method of claim 12 wherein the gas incorporates an anaesthetic substance.
15. The method of claim 12 wherein the gas incorporates a therapeutic substance.
16. The method of claim 12 wherein the gas includes oxygen at a concentration greater than ambient.

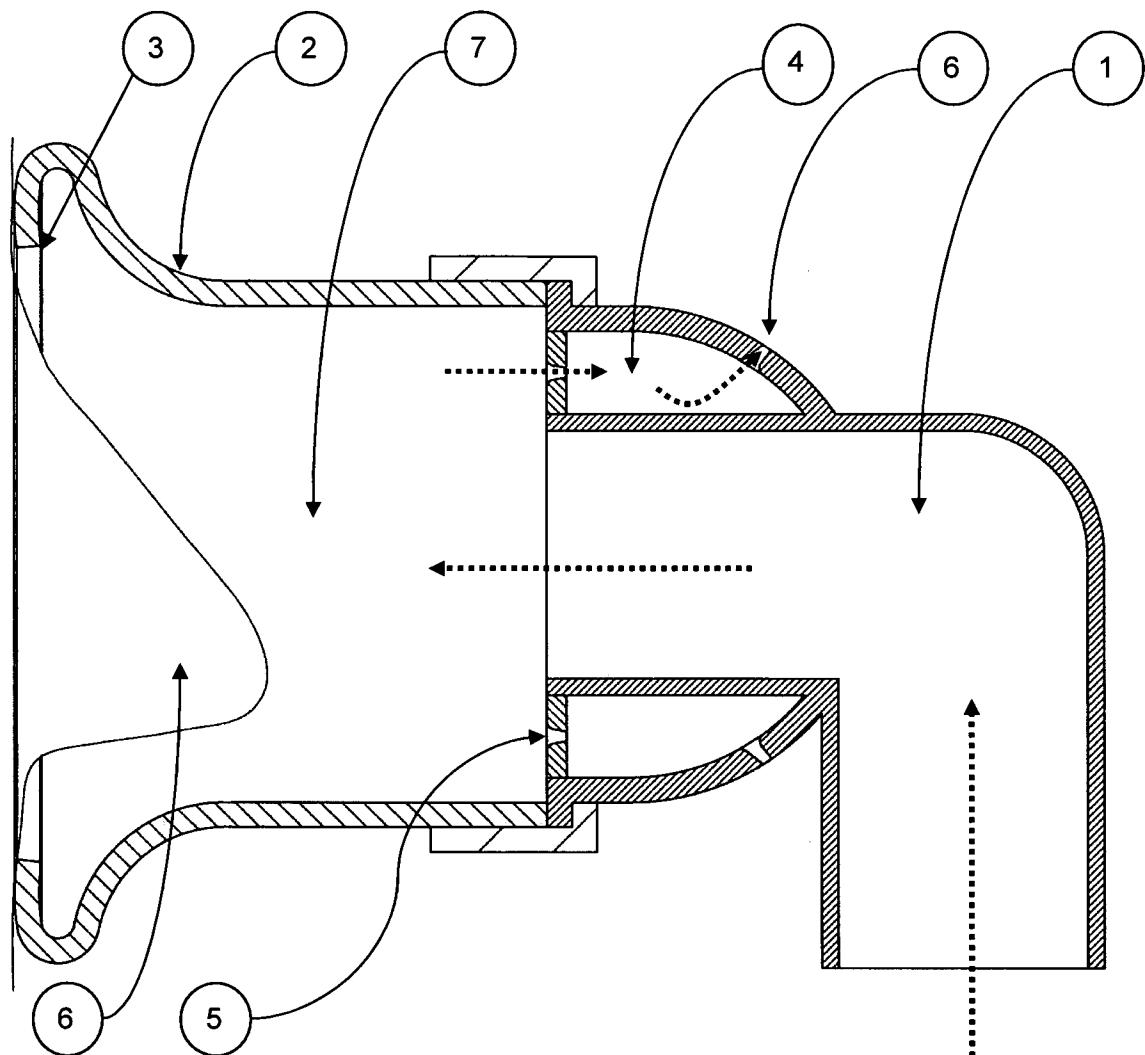
Figure 1

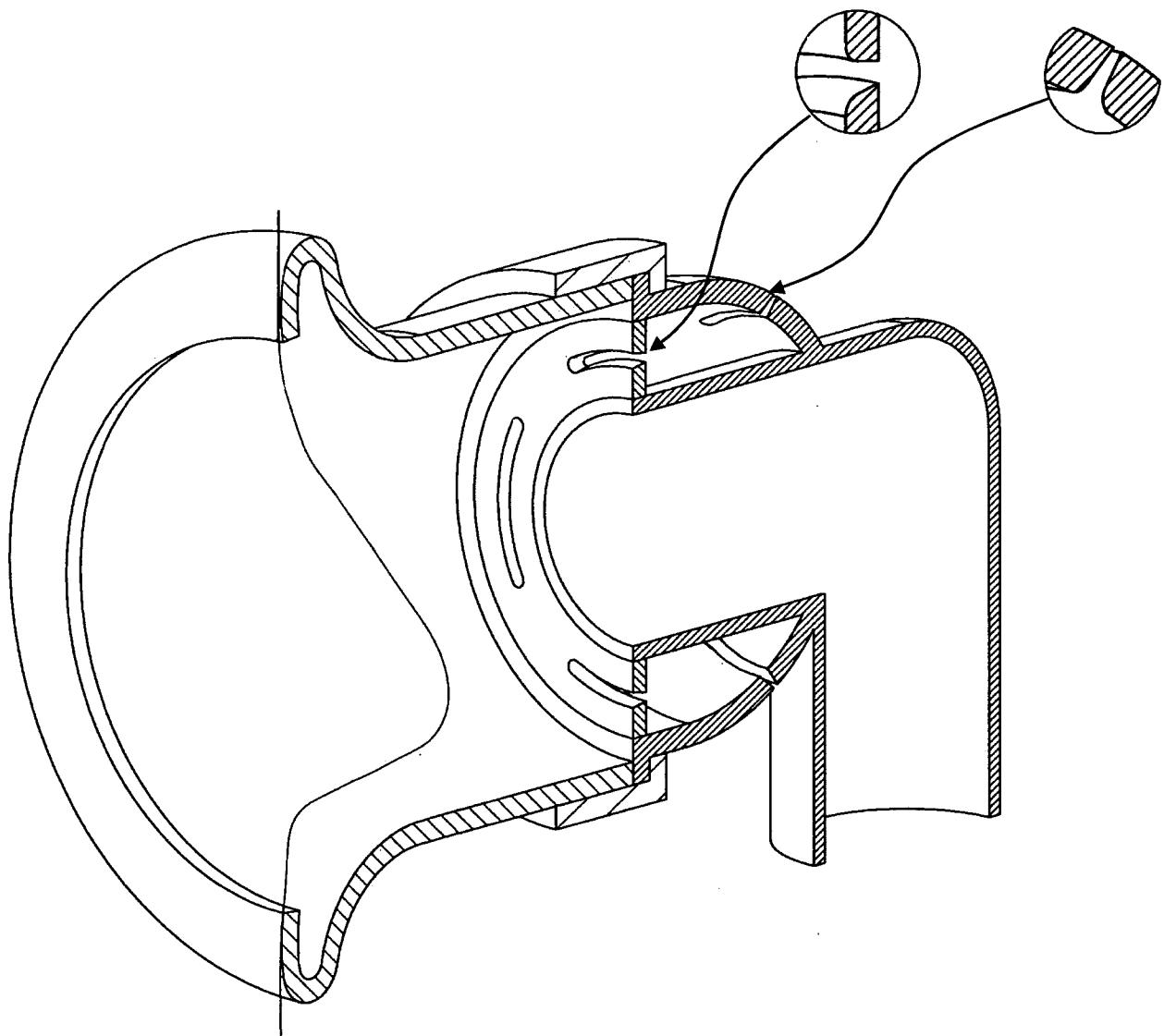
Figure 2

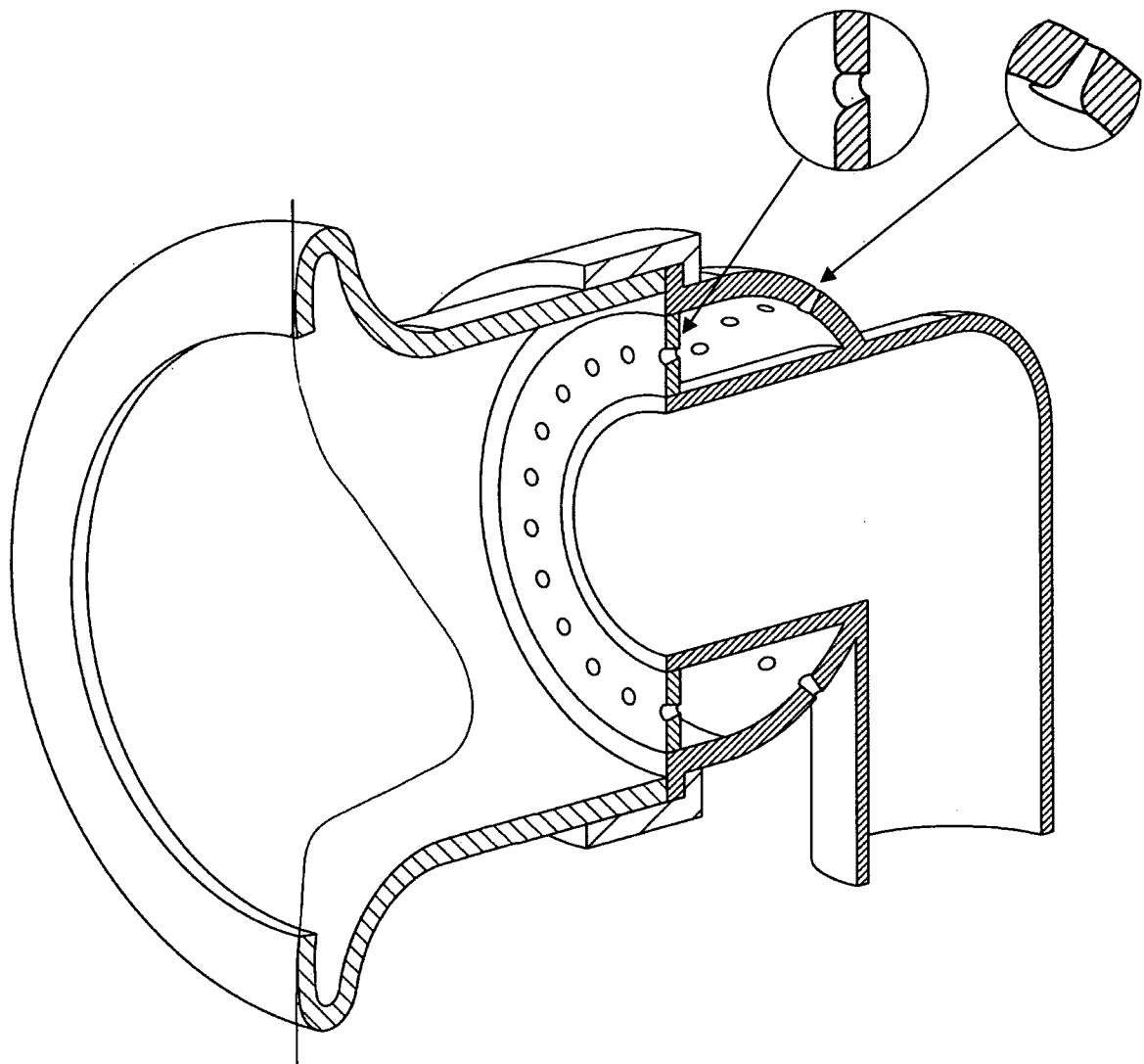
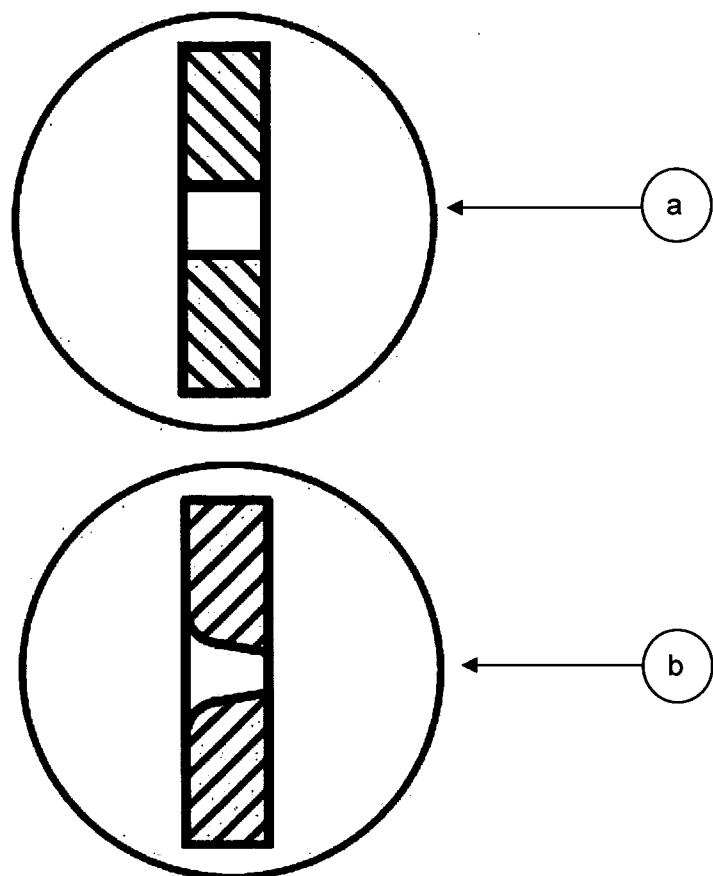
Figure 3

Figure 4

INTERNATIONAL SEARCH REPORT

International application No.

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A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 16/06 (2006.01)

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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)

WPI, EPODOC; IPC and EC A61M 16/-, A62B and keywords; mask, interface, noise, squeak, attenuate, reduce, suppress, diffuse, chamber, multi, baffle, barrier, pore, aperture, opening; and like terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/0006879 A1 (THORNTON) 11 January 2007 Abstract; Figures 2A, 2B; paragraphs [0013]-[0021]	1-5, 7-16
X	GB 1379429.A (INDUSTRIE PIRELLI SPA) 2 January 1975 Figures 1-3; page 1, line 74-page 2, line 49	1-4, 7, 8, 10-16
X	US 2007/0089749 A1 (HO et al.) 26 April 2007 Figure 5; paragraphs [0028]-[0031]	1-4, 6-8, 10-16

Further documents are listed in the continuation of Box C

See patent family annex

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 08 September 2010	Date of mailing of the international search report 14 SEP 2010
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. +61 2 6283 7999	Authorized officer A. ALI AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : +61 2 6283 2607

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2010/000842

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					
US	20070006879	WO	2007008725				
GB	1379429	BE	791431				
US	20070089749	AU	2006306317	CA	2626991	CN	101541380
		EP	1945311	US	7556043	US	2009120442
		WO	2007050557				

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX