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Declarations under Rule 4.17:

— of inventorship (Rule 4.17(iv))

Published:

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

[Continued on next page]

(54) Title: ADAPTIVE CYCLING FOR RESPIRATORY TREATMENT APPARATUS

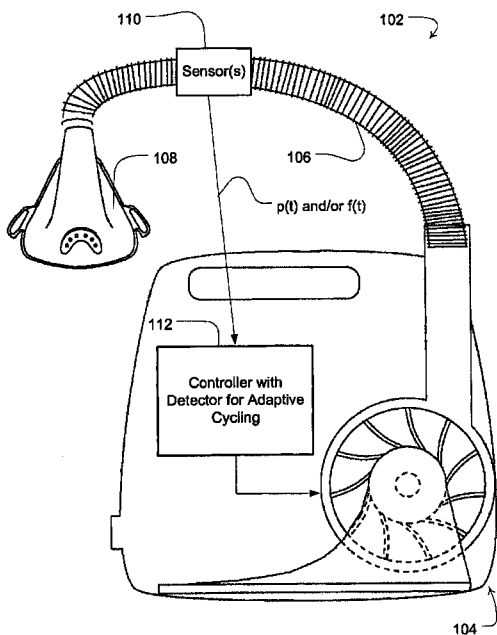


Fig. 1

(57) Abstract: A controller or processor (s) implements detection of respiratory related conditions that may serve as control logic to synchronize pressure treatment delivery with a patient's respiratory cycle. Based on data derived from sensor signals associated with the respiratory treatment, a monitoring device, detector or respiratory treatment apparatus may evaluate flow measures from a flow sensor and distinguish flow attributable to the respiratory treatment apparatus and flow attributable to patient respiratory muscles. The determination may serve as a basis of synchronization criteria that controls pressure levels from a pressure treatment apparatus, such as by evaluating the determined patient generated flow or a relationship between total flow and apparatus flow. In some embodiments, data for the cycling conditions is determined in preliminary treatment cycles during which synchronized pressure changes are controlled according to other cycling criteria. The new cycling conditions are then automatically initiated for control of synchronization in subsequent cycles.





— *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))*

(88) Date of publication of the international search report:
24 May 2012

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2011/001093**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 and keywords (pressure, expiration, inspiration, control, calibrate, session, learn, additional, sensor, muscle, effort and similar 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 2009/0229611 (MARTIN et al.) 17 September 2009 Paragraphs [0015-0017, 0020, 0025, 0039, 0045, 0053]	67-71, 74- 78, 81- 85, 87, 88, 91- 94, 96, 97
A	US 2003/0168066 A1 (SALLVIN) 11 September 2003 Whole document	1-30
A	US 6532960 B1 (YURKO) 18 March 2003 Whole document	67-99
A	US 2003/0221689 A1 (BERTHON-JONES) 04 December 2003 Whole document	1-30

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

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

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

"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
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15 March 2012Name and mailing address of the ISA/AU
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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
[See Supplemental Box]

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

1-30 and 67-99
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

Supplemental Box

(To be used when the space in any of Boxes I to IV is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Claims 1-30 are directed to a respiratory treatment apparatus and associated method. The feature of controlling generation of inspiratory and expiratory pressure over a first and second plurality of cycles, wherein the setting of the expiratory pressure is based on a first and second cycling criteria, the second criteria being different from the first and being initiated for operation subsequent to the first plurality of cycles is specific to this group of claims.
- Claims 31-66 are directed to a respiratory treatment apparatus and associated method. The feature of determining a first flow measure with a flow sensor, determining a second flow measure attributable to the respiratory treatment apparatus and evaluating with a processor a cycling criteria as a function of the first flow measure and the second flow measure is specific to this group of claims.
- Claims 67-81 are directed to a monitoring apparatus and associated method. The feature of determining a first inspiratory flow measure with a flow sensor, determining a second inspiratory flow measure, and determining a patient respiration measure as a function of the first and second inspiratory flow measures and an estimate of resistance and compliance derived from an expiratory portion of a flow measure of the flow sensor, the patient respiratory measure representing patient respiratory muscles effort, and determining a timing for switching a pressure treatment based on the respiration measure is specific to this group of claims.
- Claims 82-99 are directed to a respiratory treatment apparatus and associated method. The feature of determining a flow measure with a flow sensor, determining a pressure measure with a pressure sensor, determining, with a processor, an estimate of muscle effort as a function of the flow measure and pressure measure, and deriving with the processor a cycling control signal as a function of the estimate of muscle effort is specific to this group of claims.
- Claims 100-106 are directed to a respiratory treatment apparatus. The feature of the electro-optical sensor for non-invasively measuring diaphragmatic muscle activity, processor configured to control a determination of muscle effort signal with the sensor, and a derivation of a switch control signal as a function of the muscle effort signal is specific to this group of claims.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied *a priori*.

Claims 31-99 share the feature of determining first and second measures (which may relate to either flow or pressure) and deriving a criteria of some form from these measures. However it is considered that this feature is generic in the art. As such, these 3 groups of claims lack unity *a posteriori*.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2011/001093

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	2009229611	NONE					
US	2003168066	US	7086098				
US	6532960	US	2003127097	US	6640806		
US	2003221689	CN	1553819	EP	1418968	JP	2009153991
		JP	2004534621	US	7520279	US	2009173347
		WO	03008027				

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

END OF ANNEX