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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

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

(54) Title: METHOD AND DEVICE FOR AIRWAY CLEARANCE

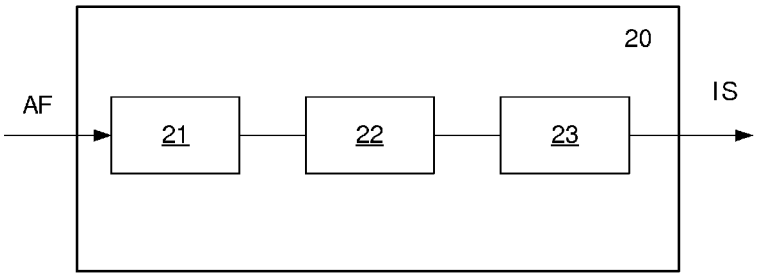

FIG. 2

(57) Abstract: The invention provides an airway clearance device. The airway clearance device comprises a vibrating unit (10) for making an airway vibrate so as to cause an oscillating airflow in the airway, based on a set of vibration parameters, and comprises a monitoring unit (20) for monitoring the validity of the set of vibration parameters. The monitoring unit (20) comprises: - a detecting unit (21) for detecting the velocity of the oscillating airflow in the airway, - a determining unit (22) for determining that the velocity is not in a pre-defined velocity range, and - a generating unit (23) for generating an indication signal to indicate that the set of vibration parameters is invalid.

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METHOD AND DEVICE FOR AIRWAY CLEARANCE

FIELD OF THE INVENTION

The invention relates to a method and a device for airway treatment, in particular, to a method and a device for airway clearance.

BACKGROUND OF THE INVENTION

For a patient with Chronic Obstructive Pulmonary Disease (COPD), Asthma, or Cystic Fibrosis (CF), an excessive volume of visco-elastic material, which is called mucus, may be built up in an airway of a lung system. Mucus hyper-secretion combined with a decreased ability of the lung system results in an increased chance of lung infection, increased risk of death, and a decreased effect of inhaled medicine.

Removing excessive mucus from an airway of a lung system is therefore highly beneficial to the health status of a patient. Currently, vibration therapy is an accepted treatment for mucus retention. For example, based on a vibration frequency, a home-use vibration device may be used to cause a resonance in an airway for enhancing mucus expectoration, and the vibration frequency is stored in the home-use vibration device. The vibration frequency for causing a resonance in an airway is influenced by lung properties of a lung system. For a patient of COPD or CF, the properties of his/her lung system change over time, thus, the vibration frequency for causing a resonance in airways of the lung system must be changed correspondingly.

However, only specific expensive equipment available in big hospitals can be used to test changes of lung properties of a lung system, and then provide a corresponding vibration

frequency for causing a resonance in an airway of the lung system, based on the changed lung properties. The home-use device cannot change the stored vibration frequency automatically, and furthermore, a user does not know when lung properties change and when the stored vibration frequency of a home-use device needs to be changed correspondingly.

Thus, it is still difficult to enhance mucus expectoration effectively, based on the current home-use device.

SUMMARY OF THE INVENTION

An object of this invention is to provide an improved airway clearance device.

The airway clearance device comprises a vibrating unit for making an airway vibrate so as to cause an oscillating airflow in the airway, based on a set of vibration parameters, and comprises a monitoring unit for monitoring the validity of the set of vibration parameters. The monitoring unit comprises a detecting unit for detecting the velocity of the oscillating airflow in the airway, a determining unit for determining that the velocity is not in a pre-defined velocity range, and a generating unit for generating an indication signal to indicate that the set of vibration parameters is invalid.

The advantage is that the airway clearance device of the invention can automatically indicate the validity of the vibration parameters used for causing vibration of an airway.

In an embodiment of the invention, the vibrating unit is further intended to cause a vibration pressure in the airway, and the detecting unit is also intended to divide the velocity by the vibration pressure.

A further advantage is that the airway clearance device of the invention can more accurately indicate the validity of the vibration parameters used for causing automatic vibration of an airway.

According to another object, the invention also provides a monitoring unit for monitoring the validity of a set of vibration parameters.

The monitoring unit is used for monitoring the validity of a set of vibration parameters. The set of vibration parameters is used for causing vibration of an airway so as to cause an oscillating airflow in the airway. The monitoring unit comprises a detecting unit for detecting the velocity of the oscillating airflow in the airway, a determining unit for determining that the velocity is not in a pre-defined velocity range, and a generating unit for generating an indication signal to indicate that the set of vibration parameters is invalid.

The advantage is that the monitoring unit can accurately monitor the validity of the set of vibration frequencies.

In an embodiment of the invention, the set of vibrating parameters is also used to cause a vibration pressure in the airway, and the detecting unit is also used to divide the velocity by the vibration pressure.

The advantage is that the monitoring unit of the invention can more accurately indicate the validity of the vibration parameters used for causing automatic vibration of an airway.

The invention also provides a method corresponding to the airway clearance device and a method corresponding to the monitoring unit.

The invention further provides a computer program used in the method corresponding to the monitoring unit.

Detailed explanations and other aspects of the invention will be given below.

DESCRIPTION OF THE DRAWINGS

The above and other objects and features of the present invention will become more apparent from the following detailed description considered in connection with the accompanying drawings, in which:

Fig. 1 schematically shows an airway clearance device in accordance with an embodiment of the invention;

Fig. 2 schematically shows a monitoring unit for monitoring the validity of a set of vibration parameters in accordance with an embodiment of the invention;

Fig. 3 is a flowchart illustrating a method of airway clearance in accordance with an embodiment of the invention;

Fig. 4 is a flowchart illustrating a method of monitoring the validity of a set of vibration parameters in accordance with an embodiment of the invention.

The same reference numerals are used to denote similar parts throughout the Figures.

DETAILED DESCRIPTION

Fig. 1 schematically shows an airway clearance device in accordance with an embodiment of the invention.

The device 1 comprises a vibrating unit 10 for causing vibration of an airway of a lung system so as to cause an oscillating airflow in the airway, based on a set of vibration parameters, and comprises a monitoring unit 20 for monitoring the validity of the set of vibration parameters.

The lung system is from a human body or an animal body. The set of vibration parameters may comprise a vibration frequency and a vibration amplitude. The vibrating unit 10 starts to set the airway into vibration according to a start request (shown as SR in Fig. 1) from a user. The user may push a button, press a keyboard, or write on a touch screen to input the start request.

The vibrating unit 10 can be a flutter device for causing vibration of the airway through the mouth. Alternatively, the vibrating unit 10 can be a High Frequency Chest Wall Oscillations (HFCWO) vest for causing vibration of the airway through the chest.

Fig. 2 schematically shows a monitoring unit for monitoring the validity of a set of vibration parameters in accordance with an embodiment of the invention.

The monitoring unit 20 is used for monitoring the validity of the set of vibration parameters. The set of vibration parameters is used by the vibrating unit 10 to cause vibration of the airway for causing the oscillating airflow in the airway.

The monitoring unit 20 comprises a detecting unit 21 for detecting a velocity of the oscillating airflow (shown as AF in Fig. 2) in the airway, a determining unit 22 for determining that the velocity is not in a pre-defined velocity range, and a generating unit 23 for generating an

indication signal (shown as IS in Fig. 1 and Fig. 2) to indicate that the set of vibration parameters is invalid.

The vibrating unit 10 is intended to cause a vibration pressure in the airway, based on the set of vibration parameters, and the detecting unit 21 may be also intended to detect the vibration pressure. The velocity of the oscillating airflow can be a non-processed/raw velocity of the oscillating airflow or a velocity of the oscillating airflow divided by the vibration pressure (the ratio between the velocity and the vibration pressure). Therefore, the detecting unit may be further used to divide the velocity of the oscillating airflow by the vibration pressure. The pre-defined velocity range may be established based on an unprocessed/raw velocity or a velocity divided by the vibration pressure.

The device 1 further comprises a database (not shown in Fig. 1 and Fig. 2) for storing the set of vibration parameters and the pre-defined velocity range. The database may be integrated in the vibrating unit 10 or the monitoring unit 20. Alternatively, the database may be integrated neither in the vibrating unit 10 nor in the monitoring unit 20.

The indication signal also indicates to update the set of vibration parameters and the pre-defined velocity range.

In an example, the set of vibration parameters and the pre-defined velocity range of the database are intended to be updated through an inputting unit (not shown in Fig. 1 and Fig. 2). The inputting unit can be a Universal Serial Bus connector, a touch screen, a keyboard etc. The indication signal can be a light, a voice, one or more words for indicating to a user that the set of vibration parameters and the pre-defined velocity range should be updated from a testing machine (e.g. an impulse oscillation system), and the updated set of vibration parameters and the updated pre-defined velocity inputted to the database through the inputting unit. The testing machine may be placed in a hospital, and controlled by a doctor to test lung properties of the lung system and generate the updated vibration parameters and the updated pre-defined velocity range. The

inputting unit may be integrated in the vibrating unit 10 or the monitoring unit 20. Alternatively, the inputting unit may be integrated neither in the vibrating unit 10 nor in the monitoring unit 20.

In another example, the device 1 may comprise a receiving unit and a transmitting unit (not shown in Fig.1 and Fig. 2). The indication signal may be a wireless signal, and the transmitting unit is intended to transmit the indication signal and the velocity to a server, and the receiving unit is intended to receive an updated set of vibration parameters and an updated pre-defined velocity range from the server. The server may be the testing machine (as mentioned in the previous example) for testing lung properties of the lung system based on the velocity, and for generating the updated vibration parameters and the updated pre-defined velocity range. The receiving unit and the transmitting unit may be integrated in the vibrating unit 10 or the monitoring unit 20. Alternatively, the receiving unit and the transmitting unit may be integrated neither in the vibrating unit 10 nor in the monitoring unit 20.

Fig. 3 is a flowchart illustrating a method of airway clearance in accordance with an embodiment of the invention. The method comprises the steps of:

- causing vibration 30 of an airway so as to cause an oscillating airflow in the airway, based on a set of vibration parameters, and
- monitoring 40 the validity of the set of vibration parameters.

Fig. 4 is a flowchart illustrating a method of monitoring the validity of a set of vibration parameters in accordance with an embodiment of the invention. The set of vibration parameters is used for causing vibration of the airway so as to cause the oscillating airflow in the airway. The method of monitoring comprises the steps of:

- detecting 41 the velocity of the oscillating airflow in the airway,
- determining 42 that the velocity is not in a pre-defined velocity range, and
- generating 43 an indication signal to indicate that the set of vibration parameters is invalid.

The indication signal also indicates to update the set of vibration parameters and the pre-defined velocity range.

The vibrating step 30 is intended to cause a vibration pressure in the airway, based on the set of vibration parameters, and the detecting step 41 may be also intended to detect the vibration pressure. The velocity of the oscillating airflow can be a non-processed/raw velocity of the oscillating airflow or a velocity of the oscillating airflow divided by the vibration pressure (the ratio between the velocity and the vibration pressure). Therefore, detecting step 41 may be further used to divide the velocity of the oscillating airflow by the vibration pressure.

The computer program is used in the method of monitoring the validity of a set of vibration parameters. The set of vibration parameters is used for causing vibration of an airway so as to cause an oscillating airflow in the airway. The method comprises the steps of:

- detecting 41 a velocity of the oscillating airflow in the airway,
- determining 42 that the velocity is not in a pre-defined velocity range, and
- generating 43 an indication signal to indicate that the set of vibration parameters is invalid.

It should be noted that the above-mentioned embodiments illustrate rather than limit the invention and that those skilled in the art will be able to design alternative embodiments without departing from the scope of the appended claims. In the claims, any reference signs placed between parentheses shall not be construed as limiting the claim. The word “comprising” does not exclude the presence of elements or steps not listed in a claim or in the description. The word “a” or “an” preceding an element does not exclude the presence of a plurality of such elements. The invention can be implemented by a unit of hardware comprising several distinct elements and by a unit of a programmed computer. In the system claims enumerating several units, several of these units can be embodied by one and the same item of hardware or software.

The usage of the words first, second and third, et cetera, does not indicate any ordering. These words are to be interpreted as names.

CLAIMS:

1. An airway clearance device comprising:
   - a vibrating unit (10) for causing vibration of an airway so as to cause an oscillating airflow in the airway, based on a set of vibration parameters, and
   - a monitoring unit (20) for monitoring the validity of the set of vibration parameters, comprising:
   - a detecting unit (21) for detecting the velocity of the oscillating airflow in the airway,
   - a determining unit (22) for determining that the velocity is not in a pre-defined velocity range, and
   - a generating unit (23) for generating an indication signal to indicate that the set of vibration parameters is invalid.

2. The device as claimed in claim 1, wherein the vibrating unit (10) is further intended to cause a vibration pressure in the airway, and the detecting unit (21) is also intended to divide the velocity by the vibration pressure.

3. The device as claimed in claim 1, further comprising a database for storing the set of vibration parameters and the pre-defined velocity range therein.

4. The device as claimed in claim 1, wherein the indication signal also indicates to update the set of vibration parameters and the pre-defined velocity range.

5. The device as claimed in claim 1, wherein the set of vibration parameters comprises a vibration frequency and a vibration amplitude.

6. A monitoring unit (20) for monitoring the validity of a set of vibration parameters which are used for causing vibration of an airway so as to cause an oscillating airflow in the airway, comprising:

- a detecting unit (21) for detecting the velocity of the oscillating airflow in the airway,
- a determining unit (22) for determining that the velocity is not in a pre-defined velocity range, and
- a generating unit (23) for generating an indication signal to indicate that the set of vibration parameters is invalid.

7. The monitoring unit as claimed in claim 6, wherein the indication signal also indicates to update the set of vibration parameters and the pre-defined velocity range.

8. The monitoring unit as claimed in claim 6, wherein the set of vibrating parameters is also used to cause a vibration pressure in the airway, and the detecting unit (21) is also intended to divide the velocity by the vibration pressure.

9. A method of airway clearance comprising the steps of:
- causing vibration (30) of an airway so as to cause an oscillating airflow in the airway, based on a set of vibration parameters, and
- monitoring (40) the validity of the set of vibration parameters, wherein the monitoring step (40) comprises the steps of
- detecting (41) the velocity of the oscillating airflow in the airway,
- determining (42) that the velocity is not in a pre-defined velocity range, and
- generating (43) an indication signal to indicate that the set of vibration parameters is invalid.

10. The method as claimed in claim 9, wherein the vibrating step (30) is intended to cause a vibration pressure in the airway, and the detecting step (41) is also intended to divide the velocity by the vibration pressure.

11. The method as claimed in claim 9, wherein the indication signal also indicates to update the set of vibration parameters and the pre-defined velocity range.

12. A method of monitoring the validity of a set of vibration parameters which is used for causing vibration of an airway so as to cause an oscillating airflow in the airway, comprising the steps of:
- detecting (41) the velocity of the oscillating airflow in the airway,
- determining (42) that the velocity is not in a pre-defined velocity range, and
- generating (43) an indication signal to indicate that the set of vibration parameters is invalid.

13. The method as claimed in claim 12, wherein the indication signal also indicates to update the set of vibration parameters and the pre-defined velocity range.

14. The method as claimed in claim 12, wherein the set of vibrating parameters is also used to cause a vibration pressure in the airway, and the detecting step (41) is also intended to divide the velocity by the vibration pressure.

15. The computer program used in a method of monitoring the validity of a set of vibration parameters which are used for causing vibration of an airway so as to cause an oscillating airflow in the airway, the method comprising the steps of:
- detecting (41) the velocity of the oscillating airflow in the airway,
- determining (42) that the velocity is not in a pre-defined velocity range, and
- generating (43) an indication signal to indicate that the set of vibration parameters is invalid.

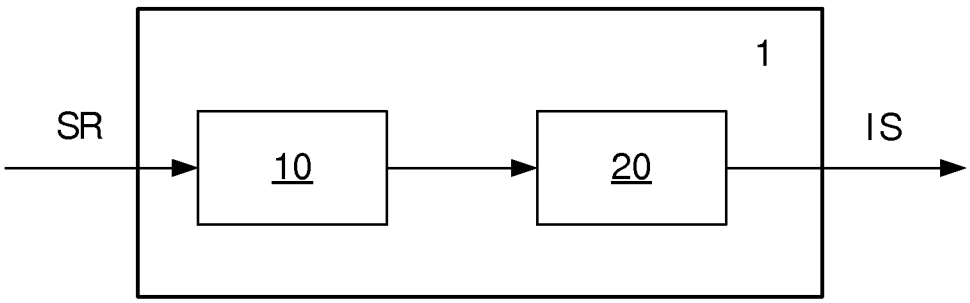

FIG. 1

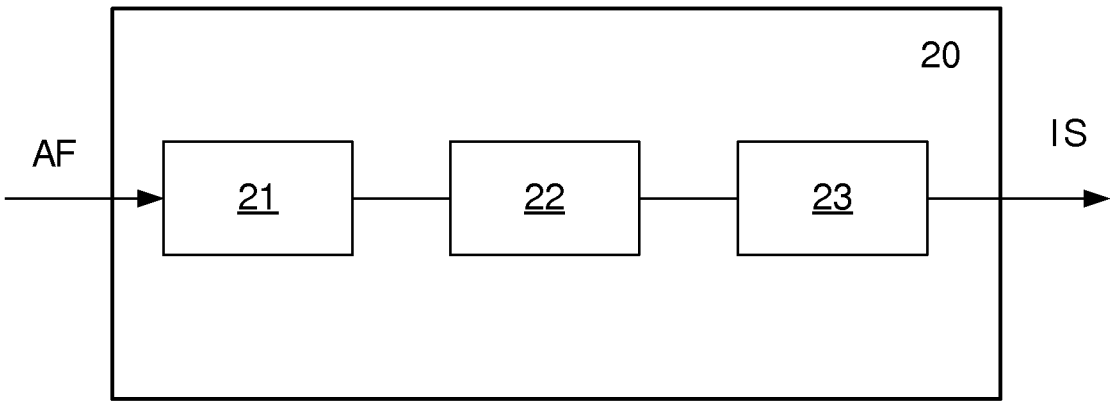

FIG. 2

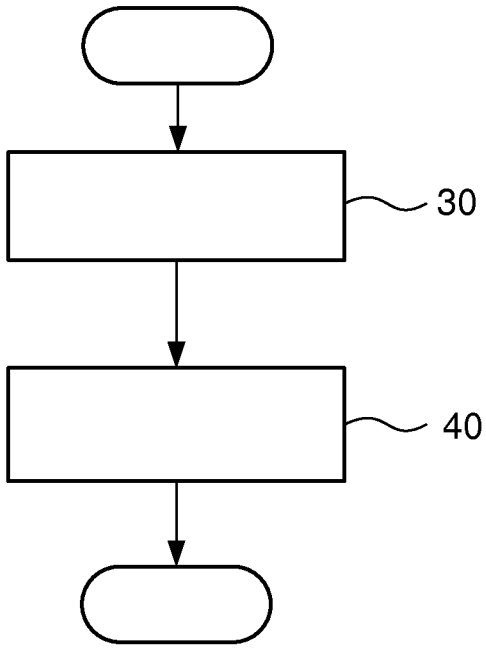

FIG. 3

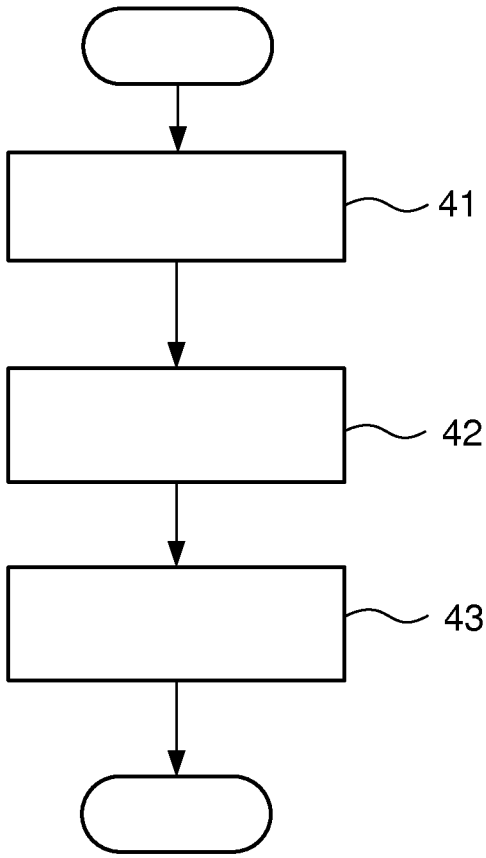

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2010/054831

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/00 A61H23/04 A63B23/18
ADD.

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)
A61M A61H A63B

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 practical, search terms used)
EPO-Internal, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 977 889 A (BUDD JEFFREY R [US]) 18 December 1990 (1990-12-18) The whole document, especially column 7, line 67 - column 10, line 22; Fig. 1	1-8, 12-15
X	US 6 581 596 B1 (TRUITT PATRICK W [US] ET AL) 24 June 2003 (2003-06-24) paragraphs [0072] - [0078]; figure 13	1-8, 12-15
X	WO 2007/106804 A2 (HUSTER KEITH A [US]; BRANSON GREGORY W [US]; O'NEAL TODD P [US]; YERMA) 20 September 2007 (2007-09-20) paragraph [0137]	1-8, 12-15
A	US 6 210 345 B1 (VAN BRUNT NICHOLAS P [US]) 3 April 2001 (2001-04-03) the whole document	1-8, 12-15

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[X] Further documents are listed in the continuation of Box C.

[X] 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

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

"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)

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

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

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

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

"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.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 January 2011	02/02/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Borowski, Aleksander

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2010/054831

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2007/113843 A1 (HUGHES ARTHUR R [US]) 24 May 2007 (2007-05-24) the whole document -----	1-8, 12-15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2010/054831

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. [X] Claims Nos.: 9-11
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy: a method of airway clearance comprising a step of causing vibration of an airway.

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:

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 an 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.:

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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2010/054831

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4977889 A	18-12-1990	AU 6276090 A	16-05-1991
		WO 9105534 A1	02-05-1991
US 6581596 B1	24-06-2003	US 2003192545 A1	16-10-2003
WO 2007106804 A2	20-09-2007	EP 2007461 A2	31-12-2008
US 6210345 B1	03-04-2001	AU 7085900 A	10-05-2001
		EP 1225834 A1	31-07-2002
		JP 2004500905 T	15-01-2004
		WO 0124698 A1	12-04-2001
		US 6415791 B1	09-07-2002
		US 6910479 B1	28-06-2005
		US 6340025 B1	22-01-2002
US 2007113843 A1	24-05-2007	AU 2006316854 A1	31-05-2007
		CA 2628948 A1	31-05-2007
		CN 101312704 A	26-11-2008
		EP 1957027 A2	20-08-2008
		JP 2009517128 T	30-04-2009
		US 2010022923 A1	28-01-2010
		WO 2007061648 A2	31-05-2007
		ZA 200805455 A	25-11-2009