

Internal distribution code:

- (A) Publication in OJ
(B) To Chairmen and Members
(C) To Chairmen
(D) No distribution

**Datasheet for the decision
of 11 March 2013**

Case Number: T 2260/08 - 3.2.02

Application Number: 03778559.9

Publication Number: 1615564

IPC: A61B 8/08, A61N 5/10

Language of the proceedings: EN

Title of invention:
Respiration monitoring process and device

Applicant:
NEORAD AS

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Novelty (yes, after amendment)"
"Inventive step (yes, after amendment)"

Decisions cited:
-

Catchword:
-



Case Number: T 2260/08 - 3.2.02

DECISION
of the Technical Board of Appeal 3.2.02
of 11 March 2013

Appellant: NEORAD AS
(Applicant) Parkveien 53B
N-0256 Oslo (NO)

Representative: Taylor, Adam David
Dehns
St Bride's House
10 Salisbury Square
London EC4Y 8JD (GB)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 15 July 2008
refusing European patent application
No. 03778559.9 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: E. Dufrasne
Members: C. Körber
P. L. P. Weber

Summary of Facts and Submissions

- I. On 15 July 2008 the Examining Division posted its decision to refuse European patent application No. 03778559.9 for lack of novelty of the subject-matter of claim 5 and lack of inventive step of the subject-matter of claim 1.
- II. An appeal was lodged against this decision by the applicant by notice received on 22 September 2008, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 25 November 2008. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of its main request, first auxiliary request or second auxiliary request filed with its statement of grounds of appeal.
- III. By communication of 3 February 2012, the Board informed the appellant of its provisional opinion that the main request was considered to be allowable provided that a number of formal observations were addressed by the appellant.
- IV. With letter dated 22 February 2012 the appellant replaced its main request with an amended version.
- V. The following documents are of importance for the present decision:

D1: EP-A-1 086 652;

D2: WO 02/41 776 A;

D3: EP-A-0 940 158;

D4: EP-A-1 208 796;

D5: O. Etlik et al.: "Demonstrating the effect of theophylline treatment on diaphragmatic movement in chronic obstructive pulmonary disease patients by MR-fluoroscopy", European Journal of Radiology 51 (2004), pages 150-154;

D6: US-A-4 431 007.

VI. Claims 1 and 5 of the main request read:

"1. A method of determining the degree of lung inspiration in a patient (1) comprising the step of non-invasively detecting the position of the patient's diaphragm (4) by means of an array of at least two ultrasound transducer elements (7) on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus (6), wherein: each individual transducer element detects an ultrasound beam which is reflected from tissue adjacent thereto and provides an output signal; and comprising the step of measuring the strength of each output signal to obtain a value for the acoustic impedance of said tissue adjacent to the transducer element; and determining the position of the diaphragm based upon a comparison of the measured acoustic impedance values from each transducer."

"5. An apparatus for monitoring the position of a patient's diaphragm (4) comprising: an array of at least two ultrasound transducer elements (7) for placing on the patient (1) in the direction of the longitudinal (z) axis of the patient to extend over the lung sinus (6), wherein each individual transducer element is arranged to detect an ultrasound beam which is reflected from tissue adjacent thereto and to

provide an output signal; wherein the apparatus is arranged to measure the strength of each output signal to obtain a value for the acoustic impedance of said tissue adjacent to the transducer element, and to determine the position of the diaphragm based upon a comparison of the measured acoustic impedance values."

Claims 2 to 4 and 6 to 9 are dependent claims.

VII. The appellant's arguments are summarised as follows:

D2 did not disclose the measurement of strength of the output signal of a transducer to obtain a value for the acoustic impedance of the adjacent tissue. Nor was there any disclosure of a simple comparison of such impedance values to determine diaphragm position. Accordingly, claim 5 was novel over D2.

Instead of combining the output signals of all the transducers to produce an image and using this image as the basis for determination of a movement of the diaphragm between different MRI procedures as described in D2, the invention utilised measurement of signal strength to obtain values for the impedance of tissue adjacent to each transducer, and compared the impedance values to determine the diaphragm position. The diaphragm position could thus be determined with direct reference to the position of the transducers on the body, without the need for interpretation of an ultrasound image, and this determination was based on data that could be understood by the layman, enabling the patient to obtain a desired degree of lung inspiration without the assistance of medically trained personnel. Accordingly, the skilled person could not

have arrived at the invention of claim 1 or claim 5 without the use of inventive skill.

Reasons for the Decision

1. The appeal is admissible.
2. Amendments

Claims 1 and 5 are based on claims 1, 5, 7 and 8 in combination with the passages at page 4, lines 22 to 33, and page 9, lines 14 to 26, of the original disclosure as published (WO-A-2004/049951). The Board is satisfied that the requirements of Article 123(2) EPC are met.

3. Novelty

In the Board's view, the apparatus disclosed in D2 is not "arranged to measure the strength of each output signal to obtain a value for the acoustic impedance of said tissue adjacent to the transducer element, and to determine the position of the diaphragm based upon a comparison of the measured acoustic impedance values" as defined in independent apparatus claim 5.

The apparatus of D2 processes the ultrasound echoes received at the transducers in a conventional manner to produce an ultrasound image. Such an image typically shows the magnitude of echoes received, and the depth of the tissue that reflected the ultrasound pulse. Whilst this necessarily involves data relating to the impedance of the underlying tissue, at varying depths,

D2 does not disclose any measurement of the strength of the output signals from the transducers signal to obtain, for each transducer, a single value for the impedance of the adjacent tissue, nor does D2 disclose the determination of diaphragm position based on a comparison of such impedance values.

D2 also fails to disclose the corresponding features of the independent method claim 1.

None of the other available prior-art documents discloses in combination the features of claims 1 and 5.

Accordingly, the subject-matter of the independent claims is novel (Article 54 EPC).

4. Inventive step

- 4.1 Document D2 as closest prior art discloses (Figure 10) a method of determining the degree of lung inspiration in a patient comprising the step of non-invasively detecting the position of the patient's diaphragm by means of an array of at least two ultrasound transducer elements on the patient, wherein each individual transducer element detects an ultrasound beam which is reflected from tissue adjacent thereto and provides an output signal (paragraph bridging pages 18 and 19). The ultrasound probes are used to produce images showing the patient's diaphragm and its location relative to a reference point on the MRI apparatus. A movement of the diaphragm in an image compared to the position in an earlier image is then derived from the image data. The thus determined movement of the diaphragm is used to

adjust the MRI apparatus. In the penultimate paragraph of page 9 it is also said to be possible to use the raw ultrasound source data.

- 4.2 The subject-matter of claim 1 is distinguished from D2 in that the array of ultrasound transducer elements extends in the direction of the longitudinal axis of the patient over the lung sinus and in that the method comprises the steps of measuring the strength of each output signal to obtain a value for the acoustic impedance of said tissue adjacent to the transducer element and determining the position of the diaphragm based upon a comparison of the measured acoustic impedance values from each transducer.
- 4.3 The technical effects of the distinguishing features are that the output signals from the transducers can be used such that the patient is presented with simple output data showing the degree of lung inspiration using the acoustic impedance values, and that the patient can assess these data himself, without the assistance of specially trained personnel. Interpretation of an ultrasound image, which requires medical skill, is not required. Nor is it required to determine any relationship between reference points and the image. The invention enables the patient to obtain a desired degree of lung inspiration in a straightforward and readily repeatable way without any assistance.
- 4.4 The objective technical problem solved by the invention is to easily determine and obtain a desired degree of lung inspiration and to allow the patient to carry out this procedure.

- 4.5 Document D2 does not address the above-mentioned problem. As already explained supra, the teaching given with respect to Figure 10 is restricted to an ultrasonic **imaging** technique. The general statement in the penultimate paragraph of page 9 that any of the known ultrasound imaging modes or the raw ultrasound source data can be used cannot be regarded as a hint towards simply measuring the strength of each output signal to obtain a value for the acoustic impedance of the tissue and determining the position of the diaphragm by directly comparing the measured acoustic impedance values.
- 4.6 The other cited prior-art documents are more remote. They neither address the above-mentioned objective technical problem nor do they give a hint towards the solution according to claim 1. D1 discloses measuring respiration by means of an abdominal belt. It is briefly mentioned in paragraph [0026] that ultrasound may also be used for this purpose, but this approach is not further elaborated. D3 deals with a radiation treatment apparatus comprising a physiology monitor (1000) which may be configured to measure respiration and to control a gating signal for controlling the radiation treatment. The document is silent regarding ultrasound transducers. D4 describes an X-ray method for determining the filling state of the lung and detecting the position of the patient's diaphragm, also without addressing ultrasonic techniques. D5, published after the priority date of the present application, was only introduced in order to demonstrate the range of diaphragmatic movement in adults. D6 was merely cited

in order to show that phased array as well as linear array ultrasound imaging were well known in the art.

- 4.7 Since none of the available prior-art documents renders obvious the subject-matter of claim 1 it is based on an inventive step within the meaning of Article 56 EPC. The same applies to claim 5 which corresponds to claim 1 in terms of apparatus features.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order that a patent be granted on the basis of the following documents:

Claims:

No. 1 to 9 filed with letter dated 22 February 2012;

Description:

pages 1 to 11 filed with letter dated 22 February 2012;

Drawings:

sheets 1/4 to 4/4 as published (WO-A-2004/049951).

The Registrar:

The Chairman:

D. Hampe

E. Dufrasne