

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year)

29/01/2019

Applicant's or agent's file reference

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/IB2018/058635

International Filing Date (day/month/year)

02/11/2018

Priority Date(day/month/year)

06/11/2017

International Patent Classification (IPC) or both national classification and IPC

IPC: A61B5/03, A61B5/00, G06F19/00 ; CPC: A61B5/031, A61B5/6814, A61B5/002, G06F19/00, A61B2562/0219

Applicant

BRAIN CARE DESENVOLVIMENTO E INOVAÇÃO TECNOLÓGICA S.A.

1. This opinion contains indications relating to the following items:

- | | |
|--|--|
| ☒ Box No. I | Basis of the opinion |
| ☐ Box No. II | Priority |
| ☐ Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| ☐ Box No. IV | Lack of unity of invention |
| ☒ Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| ☐ Box No. VI | Certain documents cited |
| ☒ Box No. VII | Certain defects in the international application |
| ☒ Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/BR:



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Date of completion of this opinion

29 January 2019

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application N°

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Box No. I **Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of:
 - a. (means)
 - ☐ on paper
 - ☐ in electronic form
 - b. (time)
 - ☐ in the international application as filed
 - ☐ together with the international application in electronic form
 - ☐ subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1 - 26	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1 - 26	NO
Industrial applicability (IA)	Claims	1 - 26	YES
	Claims	None	NO

2. Citations and explanations:

I) Cited Documents:

D1: US 2008077023 A1 - published in 27-03-2008 - "*Method and system for monitoring intracranial pressure*"

D2: US 2004015058 A1 - published in 22-01-2004 - "*Wireless medical diagnosis and monitoring equipment*"

II) Application abstract:

The application refers to a method, a system, and a device to monitor the intracranial pressure (ICP) through a measurement of the expansion of the skull. The measured signals are digitalize and transmitted wirelessly to the monitor device.

III) Novelty/Inventive Step (Article 33 (2)/(3) of PCT):

The invention defined in claims 1 – 26 is novel and therefore complies with PCT Article 33(2) because the cited documents of prior art do not disclose the invention as it is claimed.

D1 (abstract; Figs. 1 – 4; par. [0019], [0022], [0024] - [0026]) presents a system, a method, and a device that detect analogue signals from a patient by a detection device, receive the detected analogue signals on a receiver, each of the signals being related to the intracranial pressure of the user, process the detected analogue signals generating processed signals; and transmit the processed signals through a transmitter to a pre-configured receiver, wherein the transmitter and the pre-configured receiver are communicating wirelessly. **D1** also mentions using compensating signals to remove interferences on the measurements related to skull's volumetric variations in order to filter the most relevant information from the signals (par. [0024]: "correlations between venous pulsation and pressure measurements"). **D1** uses more than one measurement to estimates the ICP (e.g. Fig. 2, par. [0024]). In this way, claim 1 does not involve inventive step.

It is considered that the construction details present in clam 9 do not aggregate inventive step to clam 1.

It is considered that the monitoring in **D1** is done in real time (subject matter of claim 10), since it is for using to monitor patients. Anything gives a hint that it is not the case.

Thus, it is considered that the subject matter of claims 1, 9, and 10 does not involve an inventive step based in **D1**.

Although **D1** mentions the wireless transmission between the sensor device and the monitor device, it is not clear if the signals are digitalized before transmission (subject matter of claim 3). However, **D2** (abstract; Figures 1 – 7b; par. [0014] – [0016], [0045], [0080] – [0085], [0133], [0136]; claim 1) presents lots of sensors (including motion and temperature sensors) that transmit digitalized signals to a monitor device wirelessly, also mentioning some digital modulation techniques. It is considered that the use of any sensor of **D2** (or other kind of environment or motion sensor) in the system of **D1** is straightforward to a person skilled in the art. In this way, the step of digitalize the signals before transmission wirelessly is anticipated by the combination of **D1** and **D2**.

Thus, it is considered that the subject matter of claims 2 and its dependants 3 – 8 does not involve an inventive step.

The same arguments used to claims 1 and 9 can be used *mutatis mutandis* to the systems of claims 11 and 17, since the last ones claim the systems that merely implement the methods of claims 1 and 9. The same can be said for claims 12 – 16, 18, and 19 considering the arguments used to claims 2 – 8.

The construction details of the device defined in claims 20 – 26 does not involve inventive step based on the device disclosed by **D1**, since, in **D1**, the device has a transducer that detect a kind of skull volumetric variations (Fig. 1, par. [0019]; pressure sheet 20) and a housing, and it is put on the patient's forehead as in the present application.

Accordingly the overall discussion made above, the invention defined in claims 1 – 26 does not involve an inventive step and therefore does not comply with PCT Article 33(3).

IV) Industrial Application:

The subject matter in claims 1 – 26 is considered to be industrially applicable and thus complies with the PCT Article 33(4).

**WRITTEN OPINION OF THE
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International application N°
PCT/IB2018/058635

Box No. VII **Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

The features of the claim/s are not provided with reference signs placed in parentheses, according to PCT Rule 6.2(b).

**WRITTEN OPINION OF THE
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International application N°

PCT/IB2018/058635

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The claims 4 – 6, 12, and 13 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result. In fact, those claims define the filtering and the compensation procedure by their technical effects and not by the technical features needed to reach those effects.