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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB2018/053745	21.12.2018	21.12.2017

International Patent Classification (IPC) or both national classification and IPC
INV. G16H50/30 G16H20/00

Applicant
THALAMUS AI LIMITED

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 43*bis*.1(a)(i) with regard to novelty, inventive step and 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 usually 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 notifed the International Bureau under Rule 66.1*bis*(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.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/GB2018/053745

Box No. I Basis of the 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 sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

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 forming part of 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 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-19
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-19
Industrial applicability (IA)	Yes:	Claims	1-19
	No:	Claims	

2. Citations and explanations

see separate sheet

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:

see separate sheet

Re Item V

1 **References**

Reference is made to the following documents:

D1 US 2009/054908 A1 (ZAND JASON MATTHEW [US] ET AL) 26 February 2009 (2009-02-26)

D2 US 2017/231701 A1 (COHEN DVIR [IL] ET AL) 17 August 2017 (2017-08-17)

D3 EP 0 917 078 A1 (SMITHKLINE BEECHAM CORP [US]) 19 May 1999 (1999-05-19)

D4 US 2014/108045 A1 (AFSHAR SALIM [US] ET AL) 17 April 2014 (2014-04-17)

D5 US 2016/055307 A1 (MACOVIAK JOHN A [US] ET AL) 25 February 2016 (2016-02-25)

D6 US 2015/255004 A1 (MANZKE ROBERT [DE] ET AL) 10 September 2015 (2015-09-10)

2 **Inventive step of independent claims**

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 1, 3, 17, 18 and 19** does not involve an inventive step in the sense of Article 33(3) PCT.

2.1 **Claim 1**

Claim 1 comprises technical and non-technical features. The assessment of inventive step is therefore carried out in accordance with the PCT-EPO Guidelines 2018, G-VII, 5.4.

In the case of claims comprising technical and non-technical features, only those features which contribute to the technical character of the invention are taken into account for the assessment of inventive step.

2.1.1 **Closest prior art**

D1 is considered to be the prior art closest to the subject-matter of claim 1 and discloses the following features thereof, whereby features deemed not to be disclosed are ~~struck through~~ (emphases are added):

F1) A medical intervention control system for providing a risk analysis and influencing intervention action on a patient, the system comprising:

D1, paragraph 0008 discloses a "system which generates real time, patient specific procedural guidance for predicting success of a surgical procedure, and avoiding or detecting failure of the procedure", corresponding to a risk analysis. Further, D1, paragraph 0009 discloses that the "expert procedural guidance [is] based upon patient specific data gained from personal medical history, patient status monitoring equipment, surgical instruments incorporating sensors on the instrument's working surface, reference sensors placed about the patient, and implanted sensors placed before, during or after the procedure". Further, D1, paragraph 0093 discloses that in a "robotic-assisted surgery scenario, the sensed information [...] is used to close the control loop for the robot and/or provide warnings or augment the motions of the robot manipulator", corresponding to influencing [an] intervention action.

F2) a database with a data set containing data from at least one data source comprising: a) study data; and b) sensed data;

D1, paragraph 0056 discloses that a "[d]atabase 131 includes information about the current patient and also data from previous patients", corresponding to study data. Further, D1, paragraph 0056 discloses that "sensor data and outcomes from the current procedure are added to database 131".

F3) ~~a waveform detector operable to identify a waveform from a data source, extract the waveform, categorise the waveform, normalise the waveform to a predetermined format and determine waveform characteristics and parameters of the waveform, the waveform detector populating part of the sensed data;~~

F4) a measurement module to derive subject data from the patient;

D1, paragraph 0056 implicitly discloses sensors, i.e., "sensor data", and discloses a "recorder 130 [...] linked to a central repository for patient information", both corresponding to a measurement module.

F5) an analyser operable to analyse the subject data with respect to the data set from the at least one data source and output an associated probability for each of one or more outcomes, wherein the associated probability is affected by an intervention, wherein the analyser takes subject data derived from the patient and tests for outcomes and potential interventions which influence the outcomes;

D1, paragraph 0056 discloses that data from database 131 "is used to make an informed decision about [...] the likelihood of success of a procedure", corresponding to outputting an associated probability for each of one or more outcomes influenced by an intervention, i.e., "procedure".

F6) an action and alert management module to provide feedback to an intervention allocation module and, for respective interventions, being operable to output a direct instruction to an intervention allocation module to perform an intervention or a direct instruction to an intervention allocation module to desist from performing an intervention; and

F7) an intervention allocation module to perform an intervention ror desist from an intervention depending on the direct instruction from the action and alert management module on the current patient.

D1, paragraph 0093 discloses that in a "robotic-assisted surgery scenario, the sensed information [...] is used to close the control loop for the robot and/or provide warnings or augment the motions of the robot manipulator", corresponding to providing feedback to an intervention allocation module, i.e., the "robot". As the the motions are augmented the intervention depend[s] on the direct instruction from the action and alert management module (which corresponds to controller implicitly disclosed in D1, paragraph 0056 which is performing the closed loop control).

2.1.2 **Distinguishing features**

The subject-matter of claim 1 therefore differs from the disclosure of D1 in feature F3.

It is noted that D1, paragraph 0107 discloses that the "[p]atient status sensing includ[es] [...] vital signs monitors which include, [...] pulse rate [...], respiration rate [...], and ECG". Therefore, the technical means to sense waveforms is disclosed by D1. In conclusion, the above difference, which is based on feature F3, relates only the the processing of the waveform data.

2.1.3 **Analysis of the technical character of the distinguishing features**

The distinguishing features when taken in isolation are non-technical as they relate to the processing of data through a computer program. Computer programs are non-technical due to Rule 39.1(vi) PCT (see also PCT-EPO Guidelines 2018, G-II, 3.6, paragraphs 4 to 6). Further, cognitive data, i.e., data which does not serve to control the operation of a device, is non-technical (see also PCT-EPO Guidelines 2018, G-II, 3.6.3, paragraph 2).

2.1.4 **Purpose and effect**

Features which are non-technical when taken in isolation may nevertheless contribute to the technical character of an invention if, in the context of the invention, they contribute to producing a technical effect serving a technical purpose (see PCT-EPO Guidelines 2018, G-VII, 5.4, paragraph 2).

In the present case, the distinguishing features do not contribute to the technical character of the invention for the reasons following.

The purpose which feature F3 allegedly serves in the context of claim 1 is to control an intervention allocation module (which can, according to claim 6, comprise a medical robot).

This purpose is considered to be technical.

However, the claim is not sufficiently limited to ensure that this technical purpose is actually served by the distinguishing features over the whole claim scope, for the following reasons.

The distinguishing features and in general the non-technical features of claim 1 which relate to the processing of data are defined at such a level of abstraction that no technical effect can be derived from them over their whole scope. In particular, the following open questions prevent the skilled person from arriving at a technical effect with the information provided in claim 1:

a. What is the `study data` and the `sensed data`? Basically, this data can be anything. From arbitrary data no meaningful control of an intervention allocation module is possible.

b. How exactly is the `waveform` processed and used to populate the sensed data afterwards? General preprocessing methods for waveforms are known in the art. Therefore, general preprocessing would be obvious to the skilled person. Further, it is not defined why the specific preprocessing is required in order to populate the sensed data.

c. Why is the populating of the sensed data required? Claim 1 does not explicitly refer to the sensed data after the populating step.

d. What is the `subject data`? From arbitrary data no meaningful control of an intervention allocation module is possible.

e. How are the probabilities of the outcomes determined? From an arbitrary probability determination no meaningful control of an intervention allocation module is possible.

It seems that the description does not provide enough detail to sufficiently answer the above questions (in particular, see question (e)).

It follows that in the context of present claim 1 the feature F3, which is as such non-technical, cannot derive a technical character from the technical purpose identified above as it does not actually contribute to serve it. Feature F3 does not contribute to the technical character of the invention.

2.1.5 **Conclusion regarding inventive step**

As claim 1 does not comprise any feature making a technical contribution over the teaching of D1, it cannot be regarded as involving an inventive step (see also PCT-EPO Guidelines 2018, G-VII, 5.4(iii)(b)).

2.2 **Claim 3**

All features of claim 1 are comprised in claim 3, i.e., claim 3 is broader than claim 1. Therefore, also claim 3 does not involve an inventive step based on the arguments provided with respect to claim 1 under point 2.1 above.

2.3 **Claims 17, 18 and 19**

The features of claims 17, 18 and 19 correspond to features of a different category of claim 1. The objections raised in respect of this latter claim, therefore, also apply, mutatis mutandis, to claims 17, 18 and 19, which are thus not allowable for lack of inventive step of their subject-matter.

3 **Inventive step of dependent claims**

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 2, and 4 to 16** does not involve an inventive step in the sense of Article 33(3) PCT.

3.1 **Claims 2, 4, 12, 13, 14, 15 and 16**

Claims 2, 4, 12, 13, 14, 15 and 16 relate to the processing of data through a computer program. At least questions (b) to (e) raised under point 2.1.4 are not sufficiently answered by any of the claims. Therefore, following the argumentation under points 2.1.3 and 2.1.4 above, claims 2, 4, 12, 13, 14, 15 and 16 do not involve an inventive step.

3.2 **Claim 5**

See D1, paragraph 0093.

3.3 **Claim 6**

See D1, paragraph 0093. Additionally, it is well-known that medical robots for security reasons might require authorisation input from a user (e.g., see D2, paragraph 0484). The skilled person would implement authorisation inputs from a user depending on the circumstances.

3.4 **Claims 7 and 8**

See D1, paragraphs 0009 and 0056.

3.5 **Claim 9**

See D1, paragraph 0106.

3.6 **Claim 10**

See D1, paragraph 0108.

3.7 **Claim 11**

See D1, paragraph 0075: "normalization of the signal to allow for consistent readings regardless of optical density of the tissue"

3.8 **Claim 14**

See D1, paragraph 0056. A "likelihood of success of a procedure" corresponds to a `risk`.

4 Further cited documents

D3, paragraph 0005 discloses a "system" using a "prediction model" for "identifying at-risk patients". Further, an "intervention list" is prepared "for at least one at risk patient". However, D3 does not disclose an `intervention allocation module`.

D4, paragraph 0008 discloses a "system" which uses an "epoch of care model to assist in the provision of healthcare services to the patient, such as by generating predictions of healthcare outcomes for the patient and by making recommendations for actions to be taken". However, D4 does not disclose an `intervention allocation module`.

D5, paragraph 0004 discloses "devices" "performing probability calculations, making recommendations, and making outcome predictions to predict a health or economic outcome of a patient or therapy". D5, paragraphs 0108, 0127 and 0129 discloses an "urgent care robot", a "robotic arm" and "robotic controls". However, D5 does not disclose that the "predictions" are directly used to control the "robot".

D6, paragraph 0022 discloses a "system" to "obtain real-time feedback/ reporting on a probability of success of the procedure, e.g., by predicting clinical outcomes". D6, paragraph 0029 discloses that a "medical device" of the system may be a "robot". However, D6 does not disclose that the predictions are directly used to control the "robot".

5 Potential exceptions to patentability

Claim 17 seeks protection for subject-matter which is excluded from patentability in at least some countries (e.g., Article 53(c) EPC).

Claim 17 falls under the exceptions to patentability put forward in Article 53(c) EPC, since they are directed to a method for treatment of the human or animal body by surgery or therapy practised on the human or animal body. The method step related to `outputting [...] a direct instruction to perform an intervention` represents a surgical or therapeutic method step. Further, the method is for `influencing intervention action on a patient`. Therefore, the method is considered to be practised on the human or animal body (see PCT-EPO Guidelines, G-II, 4.2.1.3, paragraph 6; the PCT-EPO Guidelines, G-II, 4.2.1.3

might be directed to diagnostic methods, but the same interpretation for the expression "practised on the human or animal body" holds for surgical or therapy methods; see also PCT-EPO Guidelines, G-II, 4.2.1.1 and 4.2.1.2).

Should the applicant consider to proceed further with this application, objections are to be expected in jurisdictions where such subject-matter is forbidden (e.g., in proceedings under the EPC).

For the sake of completeness, it is mentioned that if the claim was amended to not comprise the `direct instruction to perform an intervention`, the claim would lack a technical purpose and all non-technical features, i.e., features related to the mere processing of data realized through a computer program or features related to the presentation of information (see PCT-EPO Guidelines, G-II, 3.6, paragraphs 4 to 6, and 3.7, paragraphs 1 and 6), would not contribute to the technical character of the invention and, therefore, could not support the presence of an inventive step.

Re Item VIII

6 **Interpretation of claims 1, 17 and 18**

Claims 1, 17 and 18 seek protection for `at least one data source` and `a data source`. These two features are considered to be independent of each other, i.e., the `data source` might be or might not be part of the `at least one data source`.

7 **Clarity**

The application does not meet the requirements of Article 6 PCT, because **claims 1, 2, 3, 13, 16, 17** are not clear or not concise.

7.1 **Claims 1 and 17**

The `study data` and the `sensed data` are introduced as optional features in claim 1. However, claim 1 refers to the `sensed data` in line 11 and claim 8 refers to the `study data`. Therefore, claim 1 is unclear as the `study data` and the `sensed data` should not be optional.

An analogous objection holds for claim 17.

7.2 **Claims 2 and 13**

Claims 2 and 13 seek protection for `a data source`. It is not clear whether this `data source` refers to the data source introduced in claim 1 or claim 13.

7.3 **Claim 3**

Claims 1 and 3 are defined as independent claims. However, all features of claim 1 are comprised in claim 3. Therefore, the set of claims is not concise.

7.4 **Claim 16**

The expression `probability node value` is not clearly defined in the art and the exact meaning cannot be derived from the wording of claim 16 (in particular, the term `node` is unclear in the context of the claim).

Further, it is not clear how values can be `run` in a matrix. Values might be arranged or stored in a matrix (i.e., in a row and column structure). However, the expression to `run` values in a matrix is unclear.

Further, it is not clear how values can be `iterated`. A procedure might be iterated to update a value. However, the expression to `iterate` a value is unclear.