PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

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/EP2018/072951	27.08.2018	05.09.2017

International Patent Classification (IPC) or both national classification and IPC
INV. A61B90/00 A61B34/20 A61B8/08 A61B5/02 A61B5/00 A61B17/34 A61M5/42

Applicant
KONINKLIJKE PHILIPS N.V.

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
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465	see form PCT/ISA/210	Croatto, Loredana Telephone No. +49 89 2399-0

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	3-8, 12-20
	No:	Claims	1, 2, 9-11
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-20
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

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

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1 US 2015/065916 A1 (MAGUIRE TIM [US] ET AL) 5 March 2015

D2 US 2016/324580 A1 (ESTERBERG JUSTIN [US]) 10 November 2016

D3 WO 2012/088471 A1 (VEEBOT LLC [US]; HARRIS RICHARD J [US]; MYGATT JOSEPH B [US]; HARRIS S) 28 June 2012

D4 EP 2 289 578 A1 (NORY CO LTD [JP]) 2 March 2011

1. Independent claim 1

1.1. The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claim 1 is not new. Document D1 discloses (references in parenthesis refer to this document):

A needle placement assistance device for assisting in venipuncture or arterial line placement, the device comprising:
a stereo camera (§95) configured to acquire stereo images of a target portion of a patient;
a needle tracker (§116-§117) configured to track a current position of an associated needle (13);
at least one electronic processor; and
a non-transitory storage medium storing data related to one or more of target needle depth, target needle angle, and target needle speed, and instructions readable and executable by the at least one electronic processor to perform a needle placement assistance method including:
performing machine vision processing of the stereo images to generate a three-dimensional map of the target portion (§97, §98);
detect a blood vessel in the 3D map of the target portion (§98);
determining a target needle position relative to the blood vessel detected by the machine vision processing based on the data related to one or more of target depth, target angle, and target speed; and
identifying corrective action to align a current position of the needle with the target needle position (§100-§114).

1.2. The attention of the applicant is drawn to the fact that, also, each of the documents D3, D4 disclose the subject-matter of claim 1 (see for D3: p. 6, l. 6 - p. 59, l. 4, for D4: §28-57).

2. Dependent claims 2-12

Dependent claims 2-12 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and inventive step, the reasons being as follows:

Document D1 discloses all the technical features of claims 2, 9-11 (see §115-1121).

The feature of an augmented reality heads -up display (AR-HUD) (as claimed in claim 3, 4) is described in document D2 as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include this feature in the needle placement assistance device described in D1 in order to provide for the acquisition of the stereo images.

The features of claims 5-8 are merely several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to provide feedback, in addition or in stead of the haptic feedback described in D1.

The features of claim 12 is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to provide track the needle of D1.

2. Independent claim 13

2.1. The present application does not meet the criteria of Article 33(3) PCT, because the subject-matter of claim 13 does not involve an inventive step. Document D1 is regarded as being the closest prior art to the subject-matter of claim 13, and discloses (references in parenthesis applying to this document):

A needle placement assistance device for assisting in venipuncture or arterial line placement, the device comprising:
a stereo camera configured to acquire stereo images of a target portion of a patient (§95);
a needle tracker (§116-§117) configured to track a current position of an associated needle (13);
a feedback mechanism (§115-121) configured to present the corrective action to a user during insertion of the needle (13) into the detected blood vessel,
at least one electronic processor; and
a non-transitory storage medium storing data related to one or more of target needle

depth, target needle angle, and target needle speed, and instructions readable and executable by the at least one electronic processor to perform a needle placement assistance method including:
performing machine vision processing of the stereo images to generate a three-dimensional map of the target portion (§97, §98);
detect a blood vessel in the 3D map of the target portion (§98);
determining a target needle position relative to the blood vessel detected by the machine vision processing based on the data related to one or more of target depth, target angle, and target speed; and
identifying corrective action to align a current position of the needle with the target needle position (§100-§114);
wherein the needle tracker comprises the at least one electronic processor and the non-transitory storage medium, wherein the needle placement assistance method further includes:
performing needle tracking machine vision processing of the stereo images to determine the current position of the needle (13) relative to the detected blood vessel (§103--114).

The subject-matter of claim 13 therefore differs from this known needle placement assisting device in that the feedback mechanism including at least an augmented-reality heads-up display (AR-HUD) device including an AR-HUD display, the stereo camera being mounted to the AR-HUD device and is therefore new.

The problem to be solved by the present invention may therefore be regarded as how to provide an alternative way of fixing the stereo camera with respect to the surgical site.

The solution proposed in claim 13 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

The feature of an augmented reality heads -up display (AR-HUD) (as claimed in claim 3, 4) is described in document D2 as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include this feature in the needle placement assistance device described in D1 in order to provide for the acquisition of the stereo images.

3. Dependent claims

Dependent claims 14-16 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT), the reasons being as follows:

The features of claim 14 are already disclosed by D2 (§159-160).

The provision of the LEDs or visual markers (as claimed in claims 15, 16) in order to provide feedback or to track the needle are normal choices the person skilled in the art would choose without any inventive step, in order to provide adequate tracking or feedback. The method steps of claim 15 are also disclosed in D1 (see §100-114).

4. Independent claim 17

The present application does not meet the criteria of Article 33(3) PCT, because the subject-matter of claim 17 does not involve an inventive step. Document D1 is regarded as being the closest prior art to the subject-matter of claim 17, and discloses (references in parenthesis applying to this document):

A needle placement assistance device for assisting in venipuncture or arterial line placement, the device comprising:
a stereo camera (§95) configured to acquire stereo images of a target portion of a patient;
a needle tracker (§116-§117) configured to track a current position of an associated needle (13);
a feedback mechanism (§115-121) configured to present the corrective action to a user during insertion of the needle into the detected blood vessel,
at least one electronic processor; and
a non-transitory storage medium storing data related to one or more of target needle depth, target needle angle, and target needle speed, and instructions readable and executable by the at least one electronic processor to perform a needle placement assistance method including:
performing machine vision processing of the stereo images to generate a three-dimensional map of the target portion(§97-§98);
detect a blood vessel in the 3D map of the target portion (§98);
determining a target needle position relative to the blood vessel detected by the machine vision processing based on the data related to one or more of target depth, target angle, and target speed; and
identifying corrective action to align a current position of the needle with the target needle position(§100-114).

The subject-matter of claim 17 therefore differs from this known needle placement assisting device in that the feedback mechanism includes at least a speaker configured to provide audio instructions to a user presenting the corrective action and is therefore new.

The problem to be solved by the present invention may therefore be regarded as how to provide an auxiliary or alternate type of feedback to the user.

The solution proposed in claim 17 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

Audible feedback by means of a speaker is long known in the art and would be a normal constructional choice for the skilled person to provide the device of D1 with such speakers in order to provide the user with feedback.

5. Dependent claims 18-20

Dependent claims 18-20 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT), the reasons being as follows:

Providing light emitting diodes to provide feedback or visual markers, accelerometers, gyroscopes or electromagnetic tracking system to track the needle are normal features, well known in the field of tracking of instruments. The corrective actions defined in claim 18 are known from D1 (§100-114).

Re Item VII

Certain defects in the international application

6. Independent claims are not in the two-part form in accordance to Rule 6.3 (b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being placed in the characterising part (Rule 6.3(b)(ii) PCT).

7. Claims 13 and 17 comprise all the features of claim 1 and are therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT).