

1. An apparatus comprising:
 - an SPO2 subsystem including a first exterior housing and a photoplethysmogram sensor in the first exterior housing;
 - a micro dynamic light scattering sensor;
 - 5 a pneumatic engine in a second exterior housing;
 - ~~a cuff bladder~~ a finger occlusion cuff including a third exterior housing and a cuff bladder,
the cuff bladder being in the third exterior housing and that is operably coupled to
the pneumatic engine and that expands and contracts in response to air pressure
from the pneumatic engine, wherein the micro dynamic light scattering sensor is in
10 the cuff bladder and a longitudinal axis of the third exterior housing is about in line
with a longitudinal axis of the second exterior housing;
 - a first circuit board in the second exterior housing, the first circuit board including:
 - a first microprocessor;
 - the first microprocessor operably coupled to the pneumatic engine, the cuff
 - 15 bladder, the photoplethysmogram sensor and the micro dynamic light
 - scattering sensor, the first microprocessor being configured to control and
guide concurrent measurement processes for all measurements of the cuff
bladder, the photoplethysmogram sensor and the micro dynamic light
scattering sensor to generate a plurality of vital signs; and
 - 20 a first digital interface that is operably coupled to the first microprocessor;
 - ~~a second circuit board in a smartphone including:~~
 - ~~a second digital interface, the second digital interface being operably coupled to~~
~~the first digital interface; and~~
 - ~~a second microprocessor operably coupled to the second digital interface, the~~
25 ~~second microprocessor being configured to estimate a plurality of vital~~
~~signs.~~
2. The apparatus of claim 1 further comprising a display device that further comprises:
 - a green traffic light that is associated with a first vital sign of the plurality of vital signs and
that is configured to indicate that the first vital sign is good;
 - 30 an amber traffic light that is associated with the first vital sign of the plurality of vital signs
and that is configured to indicate that the first vital sign is low; and
 - a red traffic light that is associated with the first vital sign of the plurality of vital signs and
that is configured to indicate that the first vital sign is high.

3. The apparatus of claim 1 further comprising a digital infrared sensor having no analog sensor readout ports, the digital infrared sensor including a Faraday cage surrounding a single thermopile sensor, a central processing unit and a control block.
4. The apparatus of claim 1 further comprising:
 - 5 a camera that is operably coupled to ~~[[the]]~~a second microprocessor and configured to provide a plurality of images to the second microprocessor; and
 - the first microprocessor including a cropper module that is configured to receive the plurality of images and configured to crop the plurality of images to exclude a border area of the plurality of images, generating a plurality of cropped images, the second
 - 10 microprocessor also including a temporal-variation-amplifier of the plurality of cropped images that is configured to generate a temporal variation, the second microprocessor also including a biological vital sign generator that is operably coupled to the temporal-variation-amplifier that is configured to generate a biological vital sign from the temporal variation.
- 15 5. The apparatus of claim 4, wherein the temporal-variation-amplifier further comprises a skin-pixel-identification module.
6. The apparatus of claim 4, wherein the temporal-variation-amplifier further comprises a regional facial clusterial module.
7. The apparatus of claim 4, wherein the temporal-variation-amplifier further comprises a first
- 20 frequency filter module.
8. The apparatus of claim 4 wherein a heart rate at rest is estimated from data from ~~[[a]]~~the photoplethysmogram sensor, a respiration rate and a heart rate variability and a blood pressure diastolic is estimated from data from ~~[[a]]~~the micro dynamic light scattering sensor and the photoplethysmogram sensor.
- 25 9. The apparatus of claim 4 further comprising:
 - wherein a blood pressure systolic is estimated from data from ~~[[a]]~~the micro dynamic light scattering sensor.
10. The apparatus of claim 4 further comprising a storage device that is operably coupled to the biological vital sign generator and that is configured to store the plurality of vital signs.
- 30 11. The apparatus of claim 4 wherein a wireless communication subsystem is operably coupled to the second microprocessor and the wireless communication subsystem is configured to transmit a representation of the biological vital sign via a short distance wireless communication path.
12. The apparatus of claim 11 wherein the apparatus is verified by a second apparatus as

known by the second apparatus and as allowed by the second apparatus to transfer information to the second apparatus.

13. The apparatus of claim 11 wherein a connection is established and the plurality of vital signs are pushed from the apparatus through the wireless communication subsystem, thereafter an
5 external device controls flow of the plurality of vital signs between the apparatus and the external device, wherein the connection further comprises an authenticated communication channel.

14. The apparatus of claim 11, wherein a digital infrared sensor further comprises an analog-to-digital sensor.

15. The apparatus of claim 11, wherein the wireless communication subsystem further
10 comprises a component that is configured to transmit a representation of date and time, operator identification, patient identification, manufacturer and model number of the apparatus.

16-2027. (canceled)

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REMARKS ACCOMPANYING AMENDMENTS

The Applicant, having considered the Written Opinion of the IPEA dated 03.09.2018, respectfully submits an amended set of claims 1 – 15, to take into due account the objections raised in said Written Opinion, along with arguments in support of patentability of the claimed invention.

1) Amendments

Amended claim 1 is based on claim 1 as filed and also on description and drawings as filed:

“an SPO2 subsystem having a photoplethysmogram sensor;” is supported for example by Fig. 3-5 and related description;

“a finger occlusion cuff having a cuff bladder” is supported for example by Fig. 57 and related description;

“the micro dynamic light scattering sensor is in the cuff bladder” is supported for example by Fig. 57;

“a longitudinal axis of the finger occlusion cuff is about in line with a longitudinal axis of the SPO2 subsystem” is supported for example by Fig. 52 and related description;

“the first microprocessor being configured to control and guide concurrent measurement processes for all measurements of the cuff bladder, the photoplethysmogram sensor and the micro dynamic light scattering sensor, in which the measurements are sequenced and configured to minimize time required to complete all measurements” is supported for example by original paragraph [0084] of the specification (“...*The measurements are sequenced and configured to minimize time required to complete all measurements...*”)

The second microprocessor “being configured to transmit the plurality of vital signs to a smartphone” is supported for example by Fig. 4 and Fig. 5 and related description.

Amended claims 2 to 15 substantially correspond to claims 2 to 15 as filed. We believe that amended claim 12 should be considered as clear, see also amended claim 11 and amended claim 4 from which amended claim 12 directly and indirectly depends.

Claims 16 to 2027 have been cancelled.

2) Inventive step

Document D1 (WO-A-2011/013132) and document D2 (WO-A-2016/040540) were considered as relevant with regard to the inventive step of claim 1 as filed.

Now, amended claim 1 relates to an apparatus provided, inter alia, with:

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SAN MARINO

21/12/2018

a finger occlusion cuff having a cuff bladder that is operably coupled to the pneumatic engine and that expands and contracts in response to air pressure from the pneumatic engine, wherein the micro dynamic light scattering sensor is in the cuff bladder and a longitudinal axis of the finger occlusion cuff is about in line with a longitudinal axis of the SPO2 subsystem;

a first microprocessor being configured to control and guide concurrent measurement processes for all measurements of the cuff bladder, the photoplethysmogram sensor and the micro dynamic light scattering sensor, in which the measurements are sequenced and configured to minimize time required to complete all measurements;

a second microprocessor configured to transmit the plurality of vital signs to a smartphone.

Document D1, which is considered as the closest prior art, describes a photoplethysmography device in which the PPG device and the DLS device are shown as being inside a detection apparatus 200, see for example figure 7B of D1.

However in D1 there is no indication that the DLS device is in the cuff bladder as recited in amended claim 1 (*"the micro dynamic light scattering sensor is in the cuff bladder"*).

In addition D1 does not disclose any indication that the *"longitudinal axis of the finger occlusion cuff is about in line with a longitudinal axis of the SPO2 subsystem"* as also recited in amended claim 1.

Further, D1 does not disclose any indication that the *"the first microprocessor being configured to control and guide concurrent measurement processes for all measurements of the cuff bladder, the photoplethysmogram sensor and the micro dynamic light scattering sensor, in which the measurements are sequenced and configured to minimize time required to complete all measurements"* recited in amended claim 1.

In addition, D1 does not disclose any indication of *"transmit the plurality of vital signs to a smartphone"* as recited in amended claim 1.

Document D2 relates to a known apparatus for the non-touch detection of body core temperature and in our opinion also D2 does not describe the above combination of features now specified in amended claim 1.

As described in the application as filed, prior techniques of capturing multiple vital signs from human subjects have implemented problematic sensors and have been very cumbersome in terms of affixing the sensors to the patient, recording, storing and forwarding the vital signs to appropriate parties.

The apparatus according to amended claim 1 can effectively and precisely measures temperature, heart rate at rest, heart rate variability, respiration, SpO2, blood flow, blood pressure, total hemoglobin (SpHb), PVi, methemoglobin (SpMet), acoustic respiration rate (RRa), carboxyhemoglobin (SpCO), oxygen reserve index (ORi), oxygen content (SpOC) and/or EEG of a human.

As also originally described, see for example par. [00593], a multi-vital-sign smartphone system according to the application senses temperature, heart rate at rest, heart rate variability, respiration, SpO2, blood flow and blood pressure through a device, and transmits the vital signs to an electronic medical record system through a smartphone. A technical effect of the apparatus and methods disclosed in the application is electronic transmission of a body core

The logo consists of the lowercase letters 'glp' in a bold, sans-serif font. The 'g' and 'l' are connected, and the 'p' has a small registered trademark symbol (®) to its upper right.

temperature that is estimated from signals from the non-touch electromagnetic sensor to a smartphone and then to an electronic medical record system and combination of sensing heart rate at rest, heart rate variability, respiration, SpO2, blood flow and blood pressure.

Another technical effect of the apparatus and methods disclosed in the application is generating a temporal variation of images from which a biological vital sign can be transmitted to a smartphone and then to an electronic medical record system.

In conclusion, since the cited relevant documents D1 and D2, taken alone or in combination, do not describe the combination of features of amended claim 1, we believe that the combination of features of the amended claim 1 should be considered inventive over said prior art documents, since it is neither disclosed nor suggested in such documents cited in the International Search Report. Amended claims 2 to 15 are also inventive, accordingly.

Therefore, we believe that the present application fulfils the requirements of novelty and also inventive step over the prior art documents cited in the ISR.

Looking forward to hearing from you on the prosecution of this case, we thank you in advance for your collaboration and remain,

Yours faithfully,
GLP Srl
Lorenzo Fabro

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1. An apparatus comprising:
 - an SPO2 subsystem having a photoplethysmogram sensor;
 - a micro dynamic light scattering sensor;
 - a pneumatic engine;
 - a finger occlusion cuff having a cuff bladder that is operably coupled to the pneumatic engine and that expands and contracts in response to air pressure from the pneumatic engine, wherein the micro dynamic light scattering sensor is in the cuff bladder and a longitudinal axis of the finger occlusion cuff is about in line with a longitudinal axis of the SPO2 subsystem;
 - a first circuit board including:
 - a first microprocessor;
 - the first microprocessor operably coupled to the pneumatic engine, the cuff bladder, the photoplethysmogram sensor and the micro dynamic light scattering sensor, the first microprocessor being configured to control and guide concurrent measurement processes for all measurements of the cuff bladder, the photoplethysmogram sensor and the micro dynamic light scattering sensor, in which the measurements are sequenced and configured to minimize time required to complete all measurements; and
 - a first digital interface that is operably coupled to the first microprocessor;
 - a second circuit board:
 - a second digital interface, the second digital interface being operably coupled to the first digital interface; and
 - a second microprocessor operably coupled to the second digital

interface, the second microprocessor being configured to estimate a plurality of vital signs and to transmit the plurality of vital signs to a smartphone.

2. The apparatus of claim 1 further comprising a display device that further comprises:

a green traffic light that is associated with a first vital sign of the plurality of vital signs and that is configured to indicate that the first vital sign is good;

an amber traffic light that is associated with the first vital sign of the plurality of vital signs and that is configured to indicate that the first vital sign is low; and

a red traffic light that is associated with the first vital sign of the plurality of vital signs and that is configured to indicate that the first vital sign is high.

3. The apparatus of claim 1 further comprising a digital infrared sensor having no analog sensor readout ports, the digital infrared sensor including a Faraday cage surrounding a single thermopile sensor, a central processing unit and a control block.

4. The apparatus of claim 1 further comprising:

a camera that is operably coupled to the second microprocessor and configured to provide a plurality of images to the second microprocessor; and

the first microprocessor including a cropper module that is configured to receive the plurality of images and configured to crop the plurality of images to exclude a border area of the plurality of images, generating a plurality of cropped images, the second microprocessor also including a temporal-variation-amplifier of the plurality of cropped images that is

configured to generate a temporal variation, the second microprocessor also including a biological vital sign generator that is operably coupled to the temporal-variation-amplifier that is configured to generate a biological vital sign from the temporal variation.

5. The apparatus of claim 4, wherein the temporal-variation-amplifier further comprises a skin-pixel-identification module.
6. The apparatus of claim 4, wherein the temporal-variation-amplifier further comprises a regional facial clusterial module.
7. The apparatus of claim 4, wherein the temporal-variation-amplifier further comprises a first frequency filter module.
8. The apparatus of claim 4 wherein a heart rate at rest is estimated from data from the photoplethysmogram sensor, a respiration rate and a heart rate variability and a blood pressure diastolic is estimated from data from the micro dynamic light scattering sensor and the photoplethysmogram sensor.
9. The apparatus of claim 4 further comprising:
wherein a blood pressure systolic is estimated from data from the micro dynamic light scattering sensor.
10. The apparatus of claim 4 further comprising a storage device that is operably coupled to the biological vital sign generator and that is configured to store the plurality of vital signs.
11. The apparatus of claim 4 wherein a wireless communication subsystem is operably coupled to the second microprocessor and the wireless communication subsystem is configured to transmit a representation of the biological vital sign via a short distance wireless communication path.
12. The apparatus of claim 11 wherein the apparatus is verified by a second apparatus as known by the second apparatus and as allowed by the

second apparatus to transfer information to the second apparatus.

13. The apparatus of claim 11 wherein a connection is established and the plurality of vital signs are pushed from the apparatus through the wireless communication subsystem, thereafter an external device controls flow of the plurality of vital signs between the apparatus and the external device, wherein the connection further comprises an authenticated communication channel.
14. The apparatus of claim 11, wherein a digital infrared sensor further comprises an analog-to-digital sensor.
15. The apparatus of claim 11, wherein the wireless communication subsystem further comprises a component that is configured to transmit a representation of date and time, operator identification, patient identification, manufacturer and model number of the apparatus.

16-2027. (*canceled*)

Re Item I

Basis of the report

The amendment filed with the International Bureau under Article 19(1) introduces subject-matter which extends beyond the content of the application as filed, contrary to Article 19(2) PCT. The amendment concerned is the following passages in claim 1:

- the micro dynamic light scattering sensor is in the cuff bladder and a longitudinal axis of the finger occlusion cuff is about in line with a longitudinal axis of the SP02 subsystem: figure 52 and related description does not provide clear and unambiguous basis for this feature;
- the first microprocessor being configured to control and guide concurrent measurement processes for all measurements of the cuff bladder, the photoplethysmogram sensor and the micro dynamic light scattering sensor, in which the measurements are sequenced and configured to minimize time required to complete all measurements: first of all paragraph 84 does not provide clear and unambiguous basis for this feature in isolation; secondly this aspect is somehow mentioned in general terms in paragraph 84 but in a specific context, which is not present in the present claim, leading to an intermediate generalisation of this aspect;
- to transmit the plurality of vital signs to a smartphone: figure 4. 5 and related description does not provide clear and unambiguous basis for this feature; and if so, only in a particular context which is now omitted from claim 1 (intermediate generalisation).

Re Item V

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

1 Reference is made to the following documents:

- | | |
|----|---|
| D1 | WO 2011/013132 A1 (OXITONE MEDICAL LTD [IL]; EISEN LEON [IL]; KAMINSKY ALEXANDER [IL]; FI) 3 February 2011 (2011-02-03) |
| D2 | WO 2016/040540 A1 (ARC DEVICES INC USA [US]) 17 March 2016 (2016-03-17) |

- D3 US 2012/179011 A1 (MOON JIM [US] ET AL) 12 July 2012
(2012-07-12)
- D4 WO 2008/053474 A2 (ELFI TECH LTD [IL]; FINE ILYA [IL]) 8
May 2008 (2008-05-08)
- D5 WO 2016/120870 A1 (GEVA NIR [IL]; GEVA YACOV [GB]) 4
August 2016 (2016-08-04)

2 CLAIM 1

2.1

As the amended claim 1 filed under Article 19(1) introduces subject-matter which extends beyond the content of the application as filed, contrary to Article 19(2) PCT, the below statement with regard to novelty and inventive step refers to original claim 1.

2.2

The present application does not meet the criteria of Article 33(3) PCT, because the subject-matter of claim 1 does not involve an inventive step.

D1 may be regarded as being the prior art closest to the subject-matter of claim 1, and discloses an apparatus comprising:

a photoplethysmogram sensor (210) (*see abstract; page 17, 2nd paragraph*);

a micro dynamic light scattering sensor (214) (*see abstract; page 17, 2nd paragraph*);

~~a pneumatic engine;~~

~~a cuff bladder that is operably coupled to the pneumatic engine and that expands and contracts in response to air pressure from the pneumatic engine;~~

a first circuit board (218) including:

a first microprocessor (*implicit*);

the first microprocessor operably coupled to ~~the pneumatic engine, the cuff bladder,~~ the photoplethysmogram sensor and the micro dynamic light scattering sensor (*page 17, 2nd paragraph*); and

~~—a first digital interface that is operably coupled to the first microprocessor;~~

~~a second circuit board including:~~

~~—a second digital interface, the second digital interface being operably coupled to the first digital interface; and~~

~~—a second microprocessor operably coupled to the second digital interface, the second microprocessor being configured to estimate a plurality of vital signs (e.g. page 5, last paragraph: deriving blood dynamic parameters).~~

The subject-matter of claim 1 therefore differs from this known apparatus in

- a) a pneumatic engine; and a cuff bladder that is operably coupled to the pneumatic engine and that expands and contracts in response to air pressure from the pneumatic engine; and
- b) a first digital interface that is operably coupled to the first microprocessor; a second circuit board including:
 - a second digital interface, the second digital interface being operably coupled to the first digital interface; and
 - a second microprocessor operably coupled to the second digital interface, the second microprocessor being configured to estimate the plurality of vital signs.

The problem to be solved by this missing feature a) may be regarded as how to increase the accuracy of vital sign monitoring (see application's description, §94).

The problem to be solved by this missing feature b) may be regarded as how to reduce heat transfer in a multi-vital sign monitor (see application's description, §377-§378).

These two problems are not relate to each other and merely amount to a juxtaposition of features.

feature a)

Document D1 already states that DLS should be measured during *occlusion* (see e.g. page 5, 2nd paragraph; reference is made in this paragraph to D4, figure 5, showing DLS measurement at the finger tip during occlusion). It thus is (if not already implicit) very straight-forward for the skilled person to use a cuff bladder and a pneumatic engine for expanding the cuff bladder, as this is a very well known method in the art to create occlusion.

For completeness sake it is pointed out that D1 also mentions that a traditional PPG location is e.g. the finger tip (page 16, 5th paragraph).

feature b)

D1 already states (page 17, 2nd paragraph) that different electronic circuitry can be provided for the different sensors (in casu PPG and DLS).

D2 deals with a multi-vital sign monitor and explicitly states (§141-§142) that to prevent or reduce heat transfer between a sensor and a microprocessor, a separate printed circuit board (PCB) should be provided. The skilled person thus not need inventive skills to apply this teaching to the device of D1.

The solution proposed in claim 1 of the present application can therefore not be considered as involving an inventive step (Article 33(3) PCT).

2.3

Nevertheless in view of the amendments which were made under Article 19(1) the following is pointed out:

- D1 discloses an SPO2 subsystem having a PPG sensor, see e.g. page 16, last paragraph;
- D1 discloses a finger cuff, see page 16, last but one paragraph;
- D1 discloses at least a temporal correlation between the measured signals, see e.g. page 17, first paragraph;
- transmission of vital signs to a cell phone is commonly known in the art, as is also e.g. shown in D5, §87.

3 CLAIMS 2-15

Dependent claims 2-15 do not contain any 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/or inventive step, for the following reasons:

- claim 2: see e.g. D2, claims 6-8;
- claim 3: see e.g. D2, claims 4-5;
- claim 4: see e.g. D2, §319-§320;
- claim 5-7: see e.g. D2, claim 11;
- claim 8, 9: commonly known in the art to use PPG and DLS for deriving these parameters, see also D4, page 16, last paragraph;

- claim 10: well known option;
- claim 11, 13, 15: well known option, see also e.g. D5, §112-§116;
- claim 12: as far as can be understood: well known option, see also e.g. D2, §356, §365-§366;
- claim 14: straight-forward option.

Re Item VIII

Claim 12 is not clear (Art. 6 PCT) as it is not understood what a second apparatus "as known by the second apparatus and as allowed by the second apparatus to transfer information" refers to.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IB2018/000527

Box No. I Basis of the report

1. With regard to the **language**, this report is based on
- ☒ 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 (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a) and (b))
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-131 as originally filed

Claims, Numbers

1-15 filed with the demand for preliminary international examination

Drawings, Sheets

1/59-59/59 as originally filed

- ☐ a sequence listing - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since either they are considered to go beyond the disclosure as filed, or they were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in the Supplemental Box (Rules 70.2(c) and (c-bis)):
- ☐ the description, pages
 - ☒ the claims, Nos. 1 (partly)
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
5. ☐ This report has been established:
- ☐ taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rules 66.1(d-bis) and 70.2(e)).
 - ☐ without taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91(Rules 66.4bis and 70.2(e)).

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IB2018/000527

6. ☒ With regard to top-up searches (Rules 66.1 *ter* and 70.2(f)):
- ☒ A top-up search was carried out by this Authority on 18.01.2019 (all discovered documents are listed in the Supplemental Box Relating to Top-up Search).
 - ☐ Additional relevant documents have been discovered during the top-up search.
 - ☐ No top-up search was carried out by this Authority because it would serve no useful purpose.
7. ☐ Supplementary international search report(s) from Authority(ies) has/have been received and taken into account in establishing this report (Rule 45bis.8(b) and (c)).

* If item 4 applies, some or all of those sheets may be marked "superseded".

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-15</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-15</u>
Industrial applicability (IA)	Yes: Claims	<u>1-15</u>
	No: Claims	

2. Citations and explanations (Rule 70.7):

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

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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33100 Udine
ITALIE

PCT

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY
EXAMINING AUTHORITY

(PCT Rule 66)

Date of mailing
(day/month/year)

28.01.2019

Applicant's or agent's file reference
H5-3631

REPLY DUE
within 2 month(s) from the above date of mailing

International application No.
PCT/IB2018/000527

International filing date (day/month/year)
21.02.2018

Priority date (day/month/year)
21.02.2017

International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/024

Applicant
VVV Holdings Limited

1. ☒ The written opinion established by the International Searching Authority:
☒ is ☐ is not
considered to be a written opinion of the International Preliminary Examining Authority.
2. This second 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 66.2(a)(ii) 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
3. The applicant is hereby **invited to reply** to this opinion.
When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(e).
How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 55.3 and 66.8.
Also: For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis. For an informal communication with the examiner, see Rule 66.6. For an additional opportunity to submit amendments, see Rule 66.4.
If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary report on patentability (Chapter II of the PCT) must be established according to Rule 69.2 is: 21.06.2019

Name and mailing address of the international
preliminary examining authority:



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Re Item I

Basis of the report

The amendment filed with the International Bureau under Article 19(1) introduces subject-matter which extends beyond the content of the application as filed, contrary to Article 19(2) PCT. The amendment concerned is the following passages in claim 1:

- the micro dynamic light scattering sensor is in the cuff bladder and a longitudinal axis of the finger occlusion cuff is about in line with a longitudinal axis of the SP02 subsystem: figure 52 and related description does not provide clear and unambiguous basis for this feature;
- the first microprocessor being configured to control and guide concurrent measurement processes for all measurements of the cuff bladder, the photoplethysmogram sensor and the micro dynamic light scattering sensor, in which the measurements are sequenced and configured to minimize time required to complete all measurements: first of all paragraph 84 does not provide clear and unambiguous basis for this feature in isolation; secondly this aspect is somehow mentioned in general terms in paragraph 84 but in a specific context, which is not present in the present claim, leading to an intermediate generalisation of this aspect;
- to transmit the plurality of vital signs to a smartphone: figure 4. 5 and related description does not provide clear and unambiguous basis for this feature; and if so, only in a particular context which is now omitted from claim 1 (intermediate generalisation).

Re Item V

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

1 Reference is made to the following documents:

- | | |
|----|---|
| D1 | WO 2011/013132 A1 (OXITONE MEDICAL LTD [IL]; EISEN LEON [IL]; KAMINSKY ALEXANDER [IL]; FI) 3 February 2011 (2011-02-03) |
| D2 | WO 2016/040540 A1 (ARC DEVICES INC USA [US]) 17 March 2016 (2016-03-17) |

- D3 US 2012/179011 A1 (MOON JIM [US] ET AL) 12 July 2012
(2012-07-12)
- D4 WO 2008/053474 A2 (ELFI TECH LTD [IL]; FINE ILYA [IL]) 8
May 2008 (2008-05-08)
- D5 WO 2016/120870 A1 (GEVA NIR [IL]; GEVA YACOV [GB]) 4
August 2016 (2016-08-04)

2 CLAIM 1

2.1

As the amended claim 1 filed under Article 19(1) introduces subject-matter which extends beyond the content of the application as filed, contrary to Article 19(2) PCT, the below statement with regard to novelty and inventive step refers to original claim 1.

2.2

The present application does not meet the criteria of Article 33(3) PCT, because the subject-matter of claim 1 does not involve an inventive step.

D1 may be regarded as being the prior art closest to the subject-matter of claim 1, and discloses an apparatus comprising:

a photoplethysmogram sensor (210) (*see abstract; page 17, 2nd paragraph*);

a micro dynamic light scattering sensor (214) (*see abstract; page 17, 2nd paragraph*);

~~a pneumatic engine;~~

~~a cuff bladder that is operably coupled to the pneumatic engine and that expands and contracts in response to air pressure from the pneumatic engine;~~

a first circuit board (218) including:

a first microprocessor (*implicit*);

the first microprocessor operably coupled to ~~the pneumatic engine, the cuff bladder~~, the photoplethysmogram sensor and the micro dynamic light scattering sensor (*page 17, 2nd paragraph*); and

~~—a first digital interface that is operably coupled to the first microprocessor;~~

~~a second circuit board including:~~

~~—a second digital interface, the second digital interface being operably coupled to the first digital interface; and~~

~~—a second microprocessor operably coupled to the second digital interface, the second microprocessor being configured to estimate a plurality of vital signs (e.g. page 5, last paragraph: deriving blood dynamic parameters).~~

The subject-matter of claim 1 therefore differs from this known apparatus in

- a) a pneumatic engine; and a cuff bladder that is operably coupled to the pneumatic engine and that expands and contracts in response to air pressure from the pneumatic engine; and
- b) a first digital interface that is operably coupled to the first microprocessor; a second circuit board including:
 - a second digital interface, the second digital interface being operably coupled to the first digital interface; and
 - a second microprocessor operably coupled to the second digital interface, the second microprocessor being configured to estimate the plurality of vital signs.

The problem to be solved by this missing feature a) may be regarded as how to increase the accuracy of vital sign monitoring (see application's description, §94).

The problem to be solved by this missing feature b) may be regarded as how to reduce heat transfer in a multi-vital sign monitor (see application's description, §377-§378).

These two problems are not relate to each other and merely amount to a juxtaposition of features.

feature a)

Document D1 already states that DLS should be measured during *occlusion* (see e.g. page 5, 2nd paragraph; reference is made in this paragraph to D4, figure 5, showing DLS measurement at the finger tip during occlusion). It thus is (if not already implicit) very straight-forward for the skilled person to use a cuff bladder and a pneumatic engine for expanding the cuff bladder, as this is a very well known method in the art to create occlusion.

For completeness sake it is pointed out that D1 also mentions that a traditional PPG location is e.g. the finger tip (page 16, 5th paragraph).

feature b)

D1 already states (page 17, 2nd paragraph) that different electronic circuitry can be provided for the different sensors (in casu PPG and DLS).

D2 deals with a multi-vital sign monitor and explicitly states (§141-§142) that to prevent or reduce heat transfer between a sensor and a microprocessor, a separate printed circuit board (PCB) should be provided. The skilled person thus not need inventive skills to apply this teaching to the device of D1.

The solution proposed in claim 1 of the present application can therefore not be considered as involving an inventive step (Article 33(3) PCT).

2.3

Nevertheless in view of the amendments which were made under Article 19(1) the following is pointed out:

- D1 discloses an SPO2 subsystem having a PPG sensor, see e.g. page 16, last paragraph;
- D1 discloses a finger cuff, see page 16, last but one paragraph;
- D1 discloses at least a temporal correlation between the measured signals, see e.g. page 17, first paragraph;
- transmission of vital signs to a cell phone is commonly known in the art, as is also e.g. shown in D5, §87.

3 CLAIMS 2-15

Dependent claims 2-15 do not contain any 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/or inventive step, for the following reasons:

- claim 2: see e.g. D2, claims 6-8;
- claim 3: see e.g. D2, claims 4-5;
- claim 4: see e.g. D2, §319-§320;
- claim 5-7: see e.g. D2, claim 11;
- claim 8, 9: commonly known in the art to use PPG and DLS for deriving these parameters, see also D4, page 16, last paragraph;

- claim 10: well known option;
- claim 11, 13, 15: well known option, see also e.g. D5, §112-§116;
- claim 12: as far as can be understood: well known option, see also e.g. D2, §356, §365-§366;
- claim 14: straight-forward option.

Re Item VIII

Claim 12 is not clear (Art. 6 PCT) as it is not understood what a second apparatus "as known by the second apparatus and as allowed by the second apparatus to transfer information" refers to.

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 (under Rules 12.3(a) and 23.1(b)).
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a) and (b))
2. With regard to the elements of the international application, this opinion has been established on the basis of
(*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

Description, Pages

1-131 as originally filed

Claims, Numbers

1-15 as amended (together with any statement) under Art. 19 PCT

Drawings, Sheets

1/59-59/59 as originally filed

- ☐ a sequence listing - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
4. ☒ This opinion has been established as if (some of) the amendments listed below had not been made, since either they are considered to go beyond the disclosure as filed, or they were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in the Supplemental Box (Rules 70.2(c) and (c-bis)):
- ☐ the description, pages
 - ☒ the claims, Nos. 1 (partly)
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
5. ☐ 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 66.1(d-bis)).
 - ☐ without taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 66.4bis).

6. ☐ Supplementary international search report(s) from Authority(ies) have been received and taken into account in drawing up this opinion (Rule 45*bis*.8(b) and (c)).

Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	No:	Claims
Inventive step (IS)	No:	Claims 1-15
Industrial applicability (IA)	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

**PCT DEMAND FOR INTERNATIONAL
PRELIMINARY EXAMINATION (CHAPTER II)**

0	For International Preliminary Examining Authority use only	
0-1	Identification of IPEA	IPEA/EP
0-2	Date of receipt of DEMAND	21.12.2018
0-3	Form - PCT/IPEA/401 PCT Demand	
0-3-1	Prepared Using	eOLF Version: FMMNGR5168, IBR4015168, FM_FOP0205
0-4	Demand under Article 31 of the Patent Cooperation Treaty: The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).	
0-5	International Preliminary Examining Authority (specified by the applicant)	IPEA/EP
I	Identification of the International application	
I-1	International Application No.	PCT/IB2018/000527
I-2	International Filing Date	21 February 2018 (21.02.2018)
I-3	(Earliest) Priority Date	21 February 2017 (21.02.2017)
I-4	Applicant's or agent's file reference	H5-3631
I-5	Title of Invention	A MULTI-VITAL-SIGN SMARTPHONE SYSTEM IN AN ELECTRONIC MEDICAL RECORDS SYSTEM

**PCT DEMAND FOR INTERNATIONAL
PRELIMINARY EXAMINATION (CHAPTER II)**

II-1	Applicant	
II-1-1	Name	VVV HOLDINGS LIMITED
II-1-1a	Attn., c/o	c/o DLI Law
II-1-2	Address	2 Merrion Square D02 E778 DUBLIN Ireland
II-1-3	State of nationality	IE
II-1-4	State of residence	IE
II-1-5	Telephone No.	
II-1-6	Facsimile No.	
II-1-7	e-mail	
II-1-8	Applicant's registration No. with the Office	
III-1	Agent or common representative; or address for correspondence	
	The person identified below is hereby/ has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:	Agent (appointed earlier)
III-1-1	Name (LAST, First)	FABRO, Lorenzo
III-1-2	Address	Viale Europa Unita, 171 33100 Udine Italy
III-1-3	Telephone No.	0432-506388
III-1-4	Facsimile No.	0432-507735
III-1-5	e-mail	glp@glp.it
III-1-6	Agent's registration No.	

**PCT DEMAND FOR INTERNATIONAL
PRELIMINARY EXAMINATION (CHAPTER II)**

IV	Basis for International Preliminary Examination			
IV-1-1	Statement concerning amendments: The applicant wishes the International Preliminary Examination to start on the basis of:	-the description as originally filed -the claims as amended under Article 34 -the drawings as originally filed		
IV-2	Language for the purposes of international preliminary examination:	English -(which is the language of publication of the international application)		
V	Election of States	The filing of this demand constitutes the election of all Contracting States which are designated and are bound by Chapter II of the PCT.		
VI	Check list	Number of sheets	Electronic file(s) attached	Received Y/N (For IPEA use only)
	The demand is accompanied by the following elements, in the language referred to under item IV-2 for the purposes of international preliminary examination:			
VI-2 (1)	Amendments under Art. 34	4	AMDA34-1	
VI-6	Letter accompanying the amendments under Article 34 (Rule 66.8)	3	LETT.pdf	
VI-7	Other : Amended claims_marked-up version	4	OTHERDOC-1.pdf	
	Accompanying Items	Details	Electronic file(s) attached	Received Y/N (For IPEA use only)
	The demand is also accompanied by the following item(s):			
VI-8	Fee calculation sheet	1	fees.pdf	
VII-1	Signature of applicant, agent or common representative	PKCS7 Digital Signature: Lorenzo Fabro 23120		
VII-1-1	Name (First, Last)	Lorenzo Fabro		
VII-1-2	Capacity	Representative		
VIII	Note(s) to IPEA/EP			

PCT DEMAND FOR INTERNATIONAL
PRELIMINARY EXAMINATION (CHAPTER II)

FOR INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY USE ONLY

8-1	Date of actual receipt of DEMAND	21.12.2018
8-2	Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b)	
8-3	The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and items 8-4 and 8-5 below do not apply.	✓
8-3-1	The applicant has been informed accordingly	
8-4	The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.	
8-5	Although the date of receipt of the demand is after the expiration of the 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.	
8-6	The date of receipt of the demand is AFTER the expiration of the time limit under Rule 54bis, 1(a) and item 7 or 8, below, does not apply.	
8-7	The date of receipt of the demand is WITHIN the time limit under Rule 54bis.1(a) as extended by virtue of Rule 80.5.	
8-8	Although the date of receipt of the demand is after the expiration of the time limit under Rule 54bis.1(a), the delay in arrival is EXCUSED pursuant to Rule 82.	

FOR INTERNATIONAL BUREAU USE ONLY

9-1	Demand received from IPEA on	
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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2018/000527

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/024 A61B5/1455 A61B5/026 A61B5/0295 A61B5/01
ADD. G01N15/02 A61B5/022

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)

G01N A61B

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 practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2011/013132 A1 (OXITONE MEDICAL LTD [IL]; EISEN LEON [IL]; KAMINSKY ALEXANDER [IL]; FI) 3 February 2011 (2011-02-03) page 4, paragraph 3 - page 5, paragraph 5 page 16, paragraph 5 - page 17, paragraph 2; figure 7	1-15
Y	WO 2016/040540 A1 (ARC DEVICES INC USA [US]) 17 March 2016 (2016-03-17) paragraphs [1441] - [0142] paragraphs [0319] - [0320] paragraphs [0356], [0365] - [0366] claims 1-11	1-15
	----- -/--	



Further documents are listed in the continuation of Box C.



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 application or patent 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

23 August 2018

Date of mailing of the international search report

03/09/2018

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Loveniers, Kris

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2018/000527

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 2012/179011 A1 (MOON JIM [US] ET AL) 12 July 2012 (2012-07-12) paragraphs [0010] - [0023] paragraphs [0060] - [0061] paragraphs [0127] - [0131] -----	1-15
A	WO 2008/053474 A2 (ELFI TECH LTD [IL]; FINE ILYA [IL]) 8 May 2008 (2008-05-08) page 3, lines 26-34 -----	1-15
A	WO 2016/120870 A1 (GEVA NIR [IL]; GEVA YACOV [GB]) 4 August 2016 (2016-08-04) paragraphs [0059] - [0082] paragraphs [0104] - [0116] -----	1-15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2018/000527

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. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 16-2027
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:
see FURTHER INFORMATION sheet PCT/ISA/210
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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 16-2027

The various definitions of the subject-matter given in the plurality of the 2027 claims (with many independent claims of the same category), each reciting a different combination of limitations expressed at different levels of generalizations and largely repetitive, are such that the claims as whole are not clear and concise. The requirements of Article 6 PCT therefore are not met.

Consequently, the different combinations of features recited in the plurality of independent claims do not allow to correctly identify "the claimed invention" on which an opinion in the sense of Article 33.1 PCT should be based. Therefore, this number of claims makes it difficult, if at all possible, to determine the matter for which protection is sought and places an undue burden on others seeking to establish the extent of monopoly requested. For this reason a full substantive preliminary examination cannot be carried out.

In response to the request for clarifying the subject-matter that needs to be searched (see also PCT Guidelines, 9.34), the Applicant indicated claims 1-15. The search and corresponding opinion is correspondingly limited to claims 1-15.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2018/000527

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2011013132 A1	03-02-2011	US 2011082355 A1 WO 2011013132 A1	07-04-2011 03-02-2011
WO 2016040540 A1	17-03-2016	NONE	
US 2012179011 A1	12-07-2012	CN 104114089 A EP 2775917 A2 HK 1200078 A1 JP 2015502197 A SG 11201402137Q A US 2012179011 A1 WO 2013071014 A2	22-10-2014 17-09-2014 31-07-2015 22-01-2015 27-06-2014 12-07-2012 16-05-2013
WO 2008053474 A2	08-05-2008	EP 2079363 A2 JP 2010508056 A US 2009209834 A1 WO 2008053474 A2	22-07-2009 18-03-2010 20-08-2009 08-05-2008
WO 2016120870 A1	04-08-2016	AU 2016210792 A1 BR 112017015881 A2 CN 107405085 A EP 3250118 A1 JP 2018507080 A KR 20170120114 A US 2017079586 A1 WO 2016120870 A1	03-08-2017 27-03-2018 28-11-2017 06-12-2017 15-03-2018 30-10-2017 23-03-2017 04-08-2016

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2018/000527

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. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 16-2027
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:
see FURTHER INFORMATION sheet PCT/ISA/210

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

International application No
PCT/IB2018/000527

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B5/024 A61B5/1455 A61B5/026 A61B5/0295 A61B5/01 ADD. G01N15/02 A61B5/022		
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) G01N A61B 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 practicable, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2011/013132 A1 (OXITONE MEDICAL LTD [IL]; EISEN LEON [IL]; KAMINSKY ALEXANDER [IL]; FI) 3 February 2011 (2011-02-03) page 4, paragraph 3 - page 5, paragraph 5 page 16, paragraph 5 - page 17, paragraph 2; figure 7 -----	1-15
Y	WO 2016/040540 A1 (ARC DEVICES INC USA [US]) 17 March 2016 (2016-03-17) paragraphs [1441] - [0142] paragraphs [0319] - [0320] paragraphs [0356], [0365] - [0366] claims 1-11 ----- -/--	1-15
☒ Further documents are listed in the continuation of Box C. ☒ 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 application or patent 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 23 August 2018		Date of mailing of the international search report 03/09/2018
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Loveniers, Kris

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2018/000527

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 2012/179011 A1 (MOON JIM [US] ET AL) 12 July 2012 (2012-07-12) paragraphs [0010] - [0023] paragraphs [0060] - [0061] paragraphs [0127] - [0131] -----	1-15
A	WO 2008/053474 A2 (ELFI TECH LTD [IL]; FINE ILYA [IL]) 8 May 2008 (2008-05-08) page 3, lines 26-34 -----	1-15
A	WO 2016/120870 A1 (GEVA NIR [IL]; GEVA YACOV [GB]) 4 August 2016 (2016-08-04) paragraphs [0059] - [0082] paragraphs [0104] - [0116] -----	1-15

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2018/000527

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2011013132 A1	03-02-2011	US 2011082355 A1 WO 2011013132 A1	07-04-2011 03-02-2011
WO 2016040540 A1	17-03-2016	NONE	
US 2012179011 A1	12-07-2012	CN 104114089 A EP 2775917 A2 HK 1200078 A1 JP 2015502197 A SG 11201402137Q A US 2012179011 A1 WO 2013071014 A2	22-10-2014 17-09-2014 31-07-2015 22-01-2015 27-06-2014 12-07-2012 16-05-2013
WO 2008053474 A2	08-05-2008	EP 2079363 A2 JP 2010508056 A US 2009209834 A1 WO 2008053474 A2	22-07-2009 18-03-2010 20-08-2009 08-05-2008
WO 2016120870 A1	04-08-2016	AU 2016210792 A1 BR 112017015881 A2 CN 107405085 A EP 3250118 A1 JP 2018507080 A KR 20170120114 A US 2017079586 A1 WO 2016120870 A1	03-08-2017 27-03-2018 28-11-2017 06-12-2017 15-03-2018 30-10-2017 23-03-2017 04-08-2016

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 16-2027

The various definitions of the subject-matter given in the plurality of the 2027 claims (with many independent claims of the same category), each reciting a different combination of limitations expressed at different levels of generalizations and largely repetitive, are such that the claims as whole are not clear and concise. The requirements of Article 6 PCT therefore are not met.

Consequently, the different combinations of features recited in the plurality of independent claims do not allow to correctly identify "the claimed invention" on which an opinion in the sense of Article 33.1 PCT should be based. Therefore, this number of claims makes it difficult, if at all possible, to determine the matter for which protection is sought and places an undue burden on others seeking to establish the extent of monopoly requested. For this reason a full substantive preliminary examination cannot be carried out.

In response to the request for clarifying the subject-matter that needs to be searched (see also PCT Guidelines, 9.34), the Applicant indicated claims 1-15. The search and corresponding opinion is correspondingly limited to claims 1-15.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

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 43bis.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 13ter.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 13ter.1(a)).
 - ☐ on paper or in the form of an image file (Rule 13ter.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. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 16-2027

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 16-2027 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 16-2027

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13~~ter~~.1(a) or (b).

☒ See Supplemental Box for further details

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

1. Statement

Novelty (N)	Yes: Claims	<u>1-15</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-15</u>
Industrial applicability (IA)	Yes: Claims	<u>1-15</u>
	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

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.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. PCT/IB2018/000527	International filing date (day/month/year) 21.02.2018	Priority date (day/month/year) 21.02.2017
International Patent Classification (IPC) or both national classification and IPC INV. A61B5/024 A61B5/1455 A61B5/026 A61B5/0295 A61B5/01 ADD. G01N15/02 A61B5/022		
Applicant VVV HOLDINGS 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 43bis.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 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.

Name and mailing address of the ISA:  European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	Date of completion of this opinion see form PCT/ISA/210	Authorized Officer Loveniers, Kris Telephone No. +31 70 340-0	
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Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The various definitions of the subject-matter given in the plurality of the 2027 claims (with many independent claims of the same category), each reciting a different combination of limitations expressed at different levels of generalizations and largely repetitive, are such that the claims as whole are not clear and concise. The requirements of Article 6 PCT therefore are not met.

Consequently, the different combinations of features recited in the plurality of independent claims do not allow to correctly identify "the claimed invention" on which an opinion in the sense of Article 33.1 PCT should be based. Therefore, this number of claims makes it difficult, if at all possible, to determine the matter for which protection is sought and places an undue burden on others seeking to establish the extent of monopoly requested. For this reason a full substantive preliminary examination cannot be carried out.

In response to the request for clarifying the subject-matter that needs to be searched (see also PCT Guidelines, 9.34), the Applicant indicated claims 1-15. The search and corresponding opinion is correspondingly limited to claims 1-15.

Re Item V

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

1 Reference is made to the following documents:

- | | |
|----|---|
| D1 | WO 2011/013132 A1 (OXITONE MEDICAL LTD [IL]; EISEN LEON [IL]; KAMINSKY ALEXANDER [IL]; FI) 3 February 2011 (2011-02-03) |
| D2 | WO 2016/040540 A1 (ARC DEVICES INC USA [US]) 17 March 2016 (2016-03-17) |
| D3 | US 2012/179011 A1 (MOON JIM [US] ET AL) 12 July 2012 (2012-07-12) |
| D4 | WO 2008/053474 A2 (ELFI TECH LTD [IL]; FINE ILYA [IL]) 8 May 2008 (2008-05-08) |

D5

WO 2016/120870 A1 (GEVA NIR [IL]; GEVA YACOV [GB]) 4
August 2016 (2016-08-04)

2 CLAIM 1

The present application does not meet the criteria of Article 33(3) PCT, because the subject-matter of claim 1 does not involve an inventive step.

D1 may be regarded as being the prior art closest to the subject-matter of claim 1, and discloses an apparatus comprising:

a photoplethysmogram sensor (210) (*see abstract; page 17, 2nd paragraph*);

a micro dynamic light scattering sensor (214) (*see abstract; page 17, 2nd paragraph*);

~~a pneumatic engine;~~

~~a cuff bladder that is operably coupled to the pneumatic engine and that expands and contracts in response to air pressure from the pneumatic engine;~~

a first circuit board (218) including:

a first microprocessor (*implicit*);

the first microprocessor operably coupled to ~~the pneumatic engine, the cuff bladder,~~ the photoplethysmogram sensor and the micro dynamic light scattering sensor (*page 17, 2nd paragraph*); and

~~—a first digital interface that is operably coupled to the first microprocessor;~~

~~a second circuit board including:~~

~~—a second digital interface, the second digital interface being operably coupled to the first digital interface; and~~

~~—a second microprocessor operably coupled to the second digital interface, the second microprocessor being configured to estimate a plurality of vital signs (e.g. *page 5, last paragraph: deriving blood dynamic parameters*).~~

The subject-matter of claim 1 therefore differs from this known apparatus in

a) a pneumatic engine; and a cuff bladder that is operably coupled to the pneumatic engine and that expands and contracts in response to air pressure from the pneumatic engine; and

b) a first digital interface that is operably coupled to the first microprocessor;

a second circuit board including:

a second digital interface, the second digital interface being operably coupled to the first digital interface; and

a second microprocessor operably coupled to the second digital interface, the second microprocessor being configured to estimate the plurality of vital signs.

The problem to be solved by this missing feature a) may be regarded as how to increase the accuracy of vital sign monitoring (see application's description, §94).

The problem to be solved by this missing feature b) may be regarded as how to reduce heat transfer in a multi-vital sign monitor (see application's description, §377-§378).

These two problems are not relate to each other and merely amount to a juxtaposition of features.

feature a)

Document D1 already states that DLS should be measured during *occlusion* (see e.g. page 5, 2nd paragraph; reference is made in this paragraph to D4, figure 5, showing DLS measurement at the finger tip during occlusion). It thus is (if not already implicit) very straight-forward for the skilled person to use a cuff bladder and a pneumatic engine for expanding the cuff bladder, as this is a very well known method in the art to create occlusion.

For completeness sake it is pointed out that D1 also mentions that a traditional PPG location is e.g. the finger tip (page 16, 5th paragraph).

feature b)

D1 already states (page 17, 2nd paragraph) that different electronic circuitry can be provided for the different sensors (in casu PPG and DLS).

D2 deals with a multi-vital sign monitor and explicitly states (§141-§142) that to prevent or reduce heat transfer between a sensor and a microprocessor, a separate printed circuit board (PCB) should be provided. The skilled person thus not need inventive skills to apply this teaching to the device of D1.

The solution proposed in claim 1 of the present application can therefore not be considered as involving an inventive step (Article 33(3) PCT).

3 CLAIMS 2-15

Dependent claims 2-15 do not contain any 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/or inventive step, for the following reasons:

- claim 2: see e.g. D2, claims 6-8;
- claim 3: see e.g. D2, claims 4-5;
- claim 4: see e.g. D2, §319-§320;
- claim 5-7: see e.g. D2, claim 11;
- claim 8, 9: commonly known in the art to use PPG and DLS for deriving these parameters, see also D4, page 16, last paragraph;
- claim 10: well known option;
- claim 11, 13, 15: well known option, see also e.g. D5, §112-§116;
- claim 12: as far as can be understood: well known option, see also e.g. D2, §356, §365-§366;
- claim 14: straight-forward option.

Re Item VIII

1

The application contains an exceptional amount of independent independent claims, some of which appearing to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

2

Claim 12 is not clear (Art. 6 PCT) as it is not understood what a second apparatus "as known by the second apparatus and as allowed by the second apparatus to transfer information" refers to.