Title: INGESTIBLE DEVICES AND METHODS FOR PHYSIOLOGICAL STATUS MONITORING

Abstract: Reliable, real-time heart and respiratory rates are key vital signs used in evaluating the physiological status in many clinical and non-clinical settings. Measuring these vital signs generally requires superficial attachment of physically or logistically obtrusive sensors to subjects that may result in skin irritation or adversely influence subject performance. Given the broad acceptance of ingestible electronics, the approach disclosed here enables vital sign monitoring internally from the gastrointestinal tract. The large animal (porcine) experiments and a robust processing disclosed herein demonstrate the feasibility of this approach. Implementing vital sign monitoring as a stand-alone technology or in conjunction with other ingestible devices has the capacity to significantly aid telemedicine, optimize performance monitoring of athletes, military service members, and first-responders, as well as provide a facile method for rapid clinical evaluation and triage.

FIG. 2A
Published:
— with international search report (Art. 21(3))
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(88) Date of publication of the international search report:
6 My 2017

Declarations under Rule 4.17:
— as to applicant’s entitlement to apply for and be granted a patent (Rule 4.17(H))
### INTERNATIONAL SEARCH REPORT

**International application No:**
PCT/US2016/047047

### A. CLASSIFICATION OF SUBJECT MATTER

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<th>INV.</th>
<th>A61B5/00</th>
<th>A61B5/07</th>
<th>A61B5/0205</th>
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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):**

A61B, G06F

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 practical, search terms used):**

EPO-Internal, WPI Data

### C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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Further documents are listed in the continuation of Box C.

See patent family annex.

- **X** 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
- **Y** 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
- **Z** 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
- **A** document member of the same patent family

**Date of the actual completion of the international search:**
8 May 2017

**Date of mailing of the international search report:**
12/05/2017

**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: Carta, R. C. Cardo
INTERNATIONAL SEARCH REPORT

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. **X** claims Nos.: 23, 24 (completely); 17-22 (partially) because they relate to subject matter not required to be searched by this Authority, namely:
   
   see FURTHER INFORMATION sheet PCT/ISA/210

2. **☐** Claims Nos.: 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:

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

Claims Nos.: 23, 24(compl etely) ; 17-22 (parti ally)

Excepti on to Patentabi lity: Rule 39.1(iv) PCT

The subject-matter of claim 17 is regarded as a diagnosi c method practi ced on the human or animal body insofar rel ates to "estimating an indicator of a pathologi cal event of the mammal based on the digital representa ti on". As such, claim 17 is not patentable according to Rule 39.1(iv) PCT. A diagnosi c method in the sense of Rule 39.1(iv) PCT has to comprise the followi ng steps (see PCT-EPO Gui delines, B-VII, 2.1-2.2) : (a) The examinati on phase involvi ng the collecti on of data; (b) the compari son of these data with standard values; (c) the finding of any specific devi atio n, i.e. a symptom, during the compari son; (d) the attibi ti on of the devi ati on to a parti cul ar clinical picture, i.e. the deducti ve medical or veteri nary deci sion phase; wherein the steps of a techni cal nature belogni ng to steps (a) to (c) must sati sfy the cri teri on on "practi ced on the human or animal body". It should be noted that Rule 39.1(iv) PCT does not require a specific type and intensi ty of interaction with the human or animal body; a precedi ng step of a techni cal nature thus sati sfy the cri teri on on "practi ced on the human or animal body" if its performance implies any interacti on with the human or animal body, necessi ti ng the presence of the latter (see PCT-EPO Gui delines, B-VII, 2.1-2.2). In the case of claim 17, the above menti oned phases are identi fi ed as follows: (a) "transducing, with an accoustic sensor disposed within an ingestible pill ingested by the mammal, at least one accoustic wave propagati ng withi n the mammal into an analog signal", see claim 17: p. 32, 1. 6-7; (b) "generati ng, with an anal og-to-digital control ler (ADC) operably coupled to the accoustic sensor, a digital representa ti on of the analog signal; estima ti ng an indicator of a pathologi cal event of the mammal based on the digital representa ti on", see claim 17: p. 32, 1. 8-11; Note that the compari son of the acquired data with standard values is regarded as implicit, see for instance descri pti on, par. 15, 66; (c) "estima ti ng an indicator of a pathologi cal event of the mammal based on the digital representa ti on", see claim 17: p. 32, 1. 10-11; Note that the finding of a devi ati on during the compari son is regarded as implicit, see for instance descri pti on, par. 15, 36-40, 59; (d) "estima ti ng an indicator of a pathologi cal event of the mammal based on the digital representa ti on", see claim 17: p. 32, 1. 10-11. Steps (b) and (c) are confi gured as hav i ng a techni cal nature since claim 17 explicitly menti oned that these steps are executed by an accoustic sensor and an ADC respecti vel y. As these components are withi n the ingestible device (see cl. 17, p. 32, 1. 6-9), steps (a) and (b) sati sfy the condi ti on of being practi ced on the human or animal body (see PCT-EPO Gui delines, B-VII, 2.1-2.2). Claims 18-24, di rectly or indirectly dependent from claim 17 are also regarded as diagnosi c methods practi ced on the human or animal body insofar their subject-matter relates to further deta ils of estimating the indicator of a pathologi cal event of the mammal. As such claims 18-24 are also not patentable according to Rule 39.1(iv) PCT. The attenti on of the applicant is drawn on the fact that although claims 17-22 only par ti ally relate to diagnosi c methods practi ced on the human or animal body, claims 23 and 24 excl u sively relate to further processi ng on identi fi ed pathologi cal
events and are therefore entirely not patentable according to Rule 39.1(iv) PCT (see PCT-EPO Guidelines, B-VIII, 2.1-2.2). For this reason claims 17-22 were partially searched whereas claims 23 and 24 were not searched.
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