Title: CATHETER OR GUIDEWIRE DEVICE INCLUDING FLOW SENSING AND USE THEREOF

Abstract: Devices and methods are provided for performing procedure on tissue with flow monitoring using flow sensors. The devices include an elongated member, and at least one flow sensor disposed on the elongated member. The flow sensor includes at least one temperature sensor and at least one heating element having a cavity. At least a portion of the at least one temperature sensor is housed in the cavity. A temperature measurement of the temperature sensor provides an indication of the flow rate of a fluid proximate to the flow sensor.

FIG. 1
INTERNATIONAL SEARCH REPORT

PCT/US 14/71516

A CLASSIFICATION OF SUBJECT MATTER

IPC (B) - A61B 18/02, 18/18 (2015.01)

CPC - A61B 2018/00434, 18/22: A61N 7/02

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)
CPC: A61B 2018/00434, 18/22: A61N 7/02

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)
PubWEST (USPT.OPGBJPAB,EPAB): Google

Search Terms: Catheter device flow rate ablation blood volume tissue sensor temperature pressure member proximal distal elongated detect heat thermal energy RF electrode signal display housing cavity heating element inflate expand deflate stretch circuitry active
dener

C DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>US 201210101413 A1 (Beetel et al.) 26 April 2012 (26.04.2012), entire document especially abstract; fig. 34, 6-9, 38; Para [0057], [0064]-[0067], [0072], [0082], [0096]-[0097], [0105J; 10137]</td>
<td>1-23 and 34-70</td>
</tr>
<tr>
<td>Y</td>
<td>US 6,387,052 B1 (Quinn et al.) 14 May 2002 (14.05.2002), entire document especially abstract; fig. 1; col 9, In 40-60</td>
<td>1-23 and 34-70</td>
</tr>
<tr>
<td>Y</td>
<td>US 2011/0034912 A1 (de Graff et al.) 10 February 2011 (10.02.2011), entire document especially abstract; fig. 3A-34C, 34, 35, 3840 Para (0079), (0098)- (0099), (0190)-(0194), (0314)</td>
<td>3-6 and 70</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C.

+ 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 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

"Z" document member of the same patent family

Date of the actual completion of the international search: 07 May 2015 (07.05.2015)

Date of mailing of the international search report: 04 JUN 2015

Authorized officer: Lee W. Young

PCT Application No. 571-272-0300
PCT DS No. 571-272-7774

Form PCT/ISA/2 10 (second sheet) (January 2015)
### 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.: 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:

--- See Continuation Sheet ---

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 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.

Form PCT/ISA/210 (continuation of first sheet (2)) (January 2015)
INTERNATIONAL SEARCH REPORT

Box III: Observations where unity of invention is lacking:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: claims 1-23: directed to a device for determining a flow rate of a fluid proximate to a portion of a tissue.

Group II: claims 24-33: directed to an apparatus for displaying representations of parameters of an inflatable and/or expandable body.

Group III: claims 34-48: directed to a method of performing a medical treatment procedure on a tissue.

Group IV: claims 49-70: directed to a method of determining an efficacy of a medical treatment procedure performed on a tissue.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I includes the special technical features of at least a portion of the at least one heating element forming a cavity, wherein: at least a portion of the at least one temperature sensor is housed in a portion of the cavity; and a temperature measurement of the temperature sensor provides a first indication of a flow rate of the fluid proximate to the flow sensor, which are not required by Groups II-IV.

Group II includes the special technical features of a user interface; at least one memory to store processor-executable instructions; and at least one processing unit communicatively coupled to the at least one memory, wherein, upon execution of the processor-executable instructions, the at least one processing unit: controls the user interface to display at least one representation of the parameters, the at least one representation comprising: (A) a first representation of a state of the inflatable body and/or expandable body, the first representation comprising: (i) a first form indicator to indicate that the inflatable body and/or expandable body is in an inflated and/or an expanded state; and (ii) a second form indicator to indicate that the inflatable body and/or expandable body is in a deflated and/or a collapsed state; and (B) a second representation of a state of at least one sensor of the plurality of sensors, the second representation comprising: (i) a first activation indicator to indicate that the at least one sensor of the plurality of sensors measures a signal below a threshold value; or (ii) a second activation indicator to indicate that the at least one sensor of the plurality of sensors measures a signal above or about equal to the threshold value, which are not required by Groups I and III-IV.

Group III includes the special technical features of a reference temperature sensor disposed on a proximal portion of the elongated member; and a control module coupled to the at least one flow sensor and the reference temperature sensor; using the control module to maintain a temperature difference between the reference temperature sensor and the temperature sensor of the at least one flow sensor at a stage of performance of the medical treatment procedure, comprising: monitoring a value of a temperature measurement of the reference temperature sensor and a temperature measurement of the temperature sensor of the at least one flow sensor; controlling a first signal to the at least one heating element to cause the at least one heating element to emit heat or discontinue emitting heat, such that the temperature difference is maintained, which are not required by Groups I-III and IV.

Group IV includes the special technical features of activating the at least one component, coupled to the elongated member to perform a treatment procedure on a portion of the tissue proximate to the elongated member, to perform the treatment procedure on the portion of the tissue; using the at least one flow sensor to perform at least one flow measurement, the at least one flow measurement providing data indicative of a change in the flow subsequent to the treatment procedure of a fluid proximate to the apparatus; analyzing the data indicative of the flow of the fluid to determine at least one timeconstant associated with the data; and comparing the at least one timeconstant associated with the data to a timeconstant indicative of the flow of the fluid prior to performance of the treatment procedure, wherein a difference provides an indication of the efficacy of the treatment procedure, which are not required by Groups I-III.

Groups I and III-IV share the technical feature of a device disposed proximate to a portion of a tissue.

Groups I and III-IV share the technical features of an elongated member having a proximal portion and a distal portion; and at least one flow sensor disposed proximate to the distal portion of the elongated member.

Groups I and III share the technical features of an elongated member having a proximal portion and a distal portion; at least one flow sensor disposed proximate to a distal portion of the elongated member, each of the at least one flow sensor comprising at least one temperature sensor; and at least one heating element disposed proximate to the at least one temperature sensor.

However, these shared technical features do not represent a contribution over the prior art of US 6,387,052 B1 to Quinn et al. (hereinafter ‘Quinn’).

Quinn discloses a device disposed proximate to a portion of a tissue (abstract, claim 1), the device comprising an elongated member having a proximal portion and a distal portion (claim 1; fig. 1); at least one flow sensor disposed proximate to the distal portion of the elongated member, each of the at least one flow sensor comprising at least one temperature sensor (col 9, ln 40-60; fig. 1, catheter having flow directed measurement and temperature sensor disposed at distal end); and at least one heating element disposed proximate to the at least one temperature sensor (col 10, ln 30-60 and claim 1, heater filament disposed near temperature sensor).

As the above device was known, as evidenced by the teaching of Quinn this cannot be considered a special technical feature that would otherwise unify the groups. Groups I-IV therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.