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(54) Title: USE OF SCALAR VALUE TO ASSESS NEUROLOGICAL STATUS

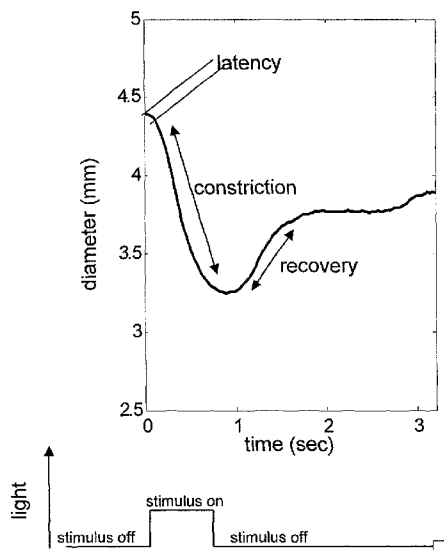


Figure 1

(57) Abstract: Methods, systems and devices for determining whether a patient has an abnormally high level of intracranial pressure is described. The method includes using a pupillometer to obtain pupillary response data from the patient. The pupillary response data can be representative of one or more pupillary response characteristics of the patient. The method further includes providing a data analysis system comprising a microprocessor that is in communication with the pupillometer. The microprocessor includes an algorithm that converts the pupillary response data to a scalar value that is indicative of the patient's level of intracranial pressure. The microprocessor can be a stand-alone computer connected to the pupillometer or it can be integral with the pupillometer. The method further includes using the data analysis system to derive a scalar value based on the pupillary response data from the patient, wherein the scalar value is indicative of the patient's level of intracranial pressure. The scalar value can be represented by a numerical value, graphical depiction, color, sound, or other visual or audio means that indicates a value. The scalar value can be a Scalar value that indicates that the patient's pupillary response characteristics indicate that the patient's intracranial pressure is within a normal range, an abnormal range, or that the pupillary response characteristics indicate that the pupil is non-responsive.



WO 2009/137614 A3

**INTERNATIONAL SEARCH REPORT**

International application No  
PCT/US2009/043030

**A. CLASSIFICATION OF SUBJECT MATTER**  
INV. A61B3/11 A61B5/03

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

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)

EP0-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>TAYLOR WILLIAM R ET AL: "Quantitative pupillometry, a new technology: normative data and preliminary observations in patients with acute head injury. Technical note." JOURNAL OF NEUROSURGERY JAN 2003, vol. 98, no. 1, January 2003 (2003-01), pages 205-213, XP002559199 ISSN: 0022-3085 page 206, right-hand column, last paragraph - page 207, left-hand column, paragraph 4 page 210, right-hand column, paragraph 2 - page 212, left-hand column, paragraph 3 table 1 figures 1,4,5</p> <p align="center">----- -/--</p>	1-34

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 document 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

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## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2009/043030

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>US 6 820 979 B1 (STARK LAWRENCE W [US] ET AL) 23 November 2004 (2004-11-23)  cited in the application  column 1, line 66 - column 2, line 29  column 15, line 47 - column 16, line 13  column 21, lines 6-42  figures 1,2</p> <p style="text-align: center;">-----</p>	1-34
X	<p>US 2006/030760 A1 (GEIGER MARK A [US])  9 February 2006 (2006-02-09)</p> <p>paragraph [0004]  paragraph [0010]  paragraphs [0024] - [0026]  paragraphs [0036], [0037]  paragraph [0045]  figures 1,4,6</p> <p style="text-align: center;">-----</p>	1-9, 12-26, 29-34
P,X	<p>"Instruction Manual NeuroOptics(TM)  NPi(TM)-100 Pupillometer" [Online]  4 May 2009 (2009-05-04), NEUROPTICS , USA  , XP002559248  Retrieved from the Internet:  URL: <a href="http://www.neuroptics.com/uploads/NPi_IFU%20Rev%20C%20single%20sided.pdf">http://www.neuroptics.com/uploads/NPi_IFU%20Rev%20C%20single%20sided.pdf</a>  [retrieved on 2009-12-08]  page 19 - page 24</p> <p style="text-align: center;">-----</p>	1-34
A	<p>US 2002/099305 A1 (FUKUSHIMA SHOGO [JP] ET AL) 25 July 2002 (2002-07-25)</p> <p>paragraph [0002]  paragraphs [0011] - [0013]  paragraphs [0070] - [0081]  paragraph [0114]  figure 4</p> <p style="text-align: center;">-----</p>	1-9, 12-26, 29-34

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2009/043030

## 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.: **35-50**  
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

Continuation of Box II.1

Claims Nos.: 35-50

Rule 39.1(iv) PCT - Diagnostic method practised on the human or animal body

This International Searching Authority considers a claim to be directed to a diagnostic method practised on the human or animal body if the claim includes method steps relating to all of the following phases:  
(i) the examination phase, involving the collection of data,  
(ii) the comparison of these data with standard values,  
(iii) the finding of any significant deviation, i.e. a symptom, during the comparison,  
(iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase (diagnosis for curative purposes stricto sensu).

Furthermore, it is required that any method step relating to phases (i) to (iii) which has a technical character must be performed on a human or animal body.

Independent claim 35 includes method steps relating to all of those phases:  
phase (i): using a pupillometer, obtaining pupillary response data from a patient;  
phase (iv): assessing the neurological status of the patient based on the scalar value;  
phases (ii) - (iii): are implicitly present because the assessment based on the scalar value inevitably requires the comparison of the scalar value with standard values and the finding of any significant deviation from the standard values.

Moreover, the only step of technical character, the measurement of pupillary response data, is performed on a human body (see paragraph 23 of the description).

The method defined in claim 35 therefore relates to a diagnostic method practised on the human body. Claims 36 - 50 are dependent on claim 35 and therefore, too, relate to a diagnostic method practised on the human or animal body.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2009/043030

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6820979	B1	23-11-2004	NONE
US 2006030760	A1	09-02-2006	NONE
US 2002099305	A1	25-07-2002	EP 1219243 A1 03-07-2002