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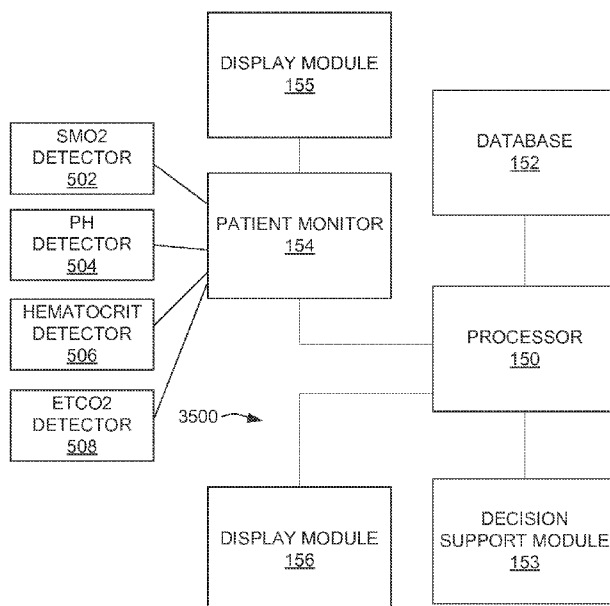
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[Continued on next page]

(54) Title: USE OF MUSCLE OXYGEN SATURATION AND PH IN CLINICAL DECISION SUPPORT

**FIG. 35**

(57) Abstract: Embodiments of the present invention include a system having at least one sensor configured to monitor a muscle oxygen saturation (SmO2) level of a patient who is undergoing cardiac arrest and to generate a signal representing SmO2 level; a user interface device; a processor communicably coupled to the user interface device, the processor configured to cause the user interface device to present an array of two or more possible nodes of a clinical decision support tree, wherein at least one of the nodes indicates cardiopulmonary resuscitation (CPR) treatment of the patient with no ventilation, and wherein at least another of the nodes indicates CPR treatment of the patient with active ventilation; determine which of the two or more possible nodes should be emphasized based on the SmO2 level; and update the array of the two or more possible nodes based on the determination.



— *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))*

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INTERNATIONAL SEARCH REPORT

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International application No.

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A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61B 5/00 (2014.01) CPC - A61B 5/0002 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) IPC(8): A61B 5/00 (2014.01) CPC: A61B 5/0002 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched IPC(8): A61B 5/00 (2014.01); USPC: 600/301, 300; 309, 310, 323; 600/324; 600/326; 600/365; 600/437; 600/473; 600/485; 600/486; 600/509; CPC: A61B 5/0002; G06F 19/3406; A61B 5/0205; G06F 19/3418; G06F 19/322 (keyword limited; terms below) Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) PatBase; Google(Web, Patents); Search terms used: muscle oxygen saturation pH heart attack CPR resuscitate clinical decision support tree node ventilation display		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2009/0275808 A1 (DiMaio et al.) 05 November 2009 (05.11.2009), entire document especially Fig. 3, 6, 7; abstract; para [0008], [0069], [0071], [0076], [0078], [0085]-[0090], [0098]-[0102], [0106], [0107], [0109], [0121]	1-16
Y	US 2010/0174555 A1 (Abraham-Fuchs et al.) 08 July 2010 (08.07.2010), para [0014]-[0022], [0026], [0036], [0050], [0063], [0071], [0076]	1-16
Y	US 2006/0223042 A1 (Epler et al.) 05 October 2006 (05.10.2006), para [0165]-[0167], [0174]	1-16
Y	US 2012/0123223 A1 (Freeman et al.) 17 May 2012 (17.05.2012), para [0078]-[0080]	2, 8, 13-16
☐ 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 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 29 September 2014 (29.09.2014)		Date of mailing of the international search report 03 NOV 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201		Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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 extra 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.:
1-16

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.

Continuation of Box III: Lack of Unity

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 1-16 are drawn to a medical system comprising: at least one sensor configured to muscle oxygen saturation (SmO2) level of a patient who is undergoing cardiac arrest and to generate a signal representing the SmO2 level; determine which of the two or more possible nodes should be emphasized based on the SmO2 level.

Group II: claims 17-21 are drawn to a medical system comprising: at least one sensor configured to monitor end tidal carbon dioxide (ETCO2) level of a patient who is undergoing cardiac arrest and to generate a signal representing the ETCO2 level; determine which of the two or more possible nodes should be emphasized based on the ETCO2 level.

Group III: claims 22-23 are drawn to a medical system comprising: at least one sensor configured to monitor pH level of a patient who is undergoing cardiac arrest and to generate a signal representing the pH level; determine which of the two or more possible nodes should be emphasized based on the pH level.

Group IV: claim 24 is drawn to a medical system comprising: at least one sensor configured to monitor a muscle oxygen saturation (SmO2) level of a patient who is undergoing cardiac arrest and to generate a signal representing the SmO2 level; compare the SmO2 level over time with a predetermined threshold level; and indicate via the user interface device whether further cardiopulmonary resuscitation attempts are likely to be successful, based on the SmO2 level.

Group V: claim 25 is drawn to a medical system comprising: at least one sensor configured to monitor end tidal carbon dioxide (ETCO2) level of a patient who is undergoing cardiac arrest and to generate a signal representing the end tidal carbon dioxide (ETCO2) level; compare the ETCO2 level over time with a predetermined threshold level; and indicate via the user interface device whether further cardiopulmonary resuscitation attempts are likely to be successful, based on the ETCO2 level.

Group VI: claim 26 is drawn to a medical system comprising: at least one sensor configured to monitor a pH level of a patient who is undergoing cardiac arrest and to generate a signal representing the pH level; compare the pH level over time with a predetermined threshold level; and indicate via the user interface device whether further cardiopulmonary resuscitation attempts are likely to be successful, based on the pH level.

Group VII: claim 27 is drawn to a medical system comprising: at least one sensor configured to monitor a hematocrit level of a patient who is undergoing cardiac arrest and to generate a signal representing the hematocrit level; compare the hematocrit level over time with a predetermined threshold level; and indicate via the user interface device whether one or both of a frequency and an intensity of ventilation measures applied to the patient should be adjusted, based on the hematocrit level.

The inventions listed as Groups I through VII 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 technical features for the following reasons:

Special Technical Features

The special technical feature of Group I is a medical system comprising: at least one sensor configured to muscle oxygen saturation (SmO2) level of a patient who is undergoing cardiac arrest and to generate a signal representing the SmO2 level; determine which of the two or more possible nodes should be emphasized based on the SmO2 level, not required in any other group.

The special technical feature of Group II is a medical system comprising: at least one sensor configured to monitor end tidal carbon dioxide (ETCO2) level of a patient who is undergoing cardiac arrest and to generate a signal representing the ETCO2 level; determine which of the two or more possible nodes should be emphasized based on the ETCO2 level, not required in any other group.

The special technical feature of Group III is a medical system comprising: at least one sensor configured to monitor pH level of a patient who is undergoing cardiac arrest and to generate a signal representing the pH level; determine which of the two or more possible nodes should be emphasized based on the pH level, not required in any other group.

The special technical feature of Group IV is a medical system comprising: at least one sensor configured to monitor a muscle oxygen saturation (SmO2) level of a patient who is undergoing cardiac arrest and to generate a signal representing the SmO2 level; compare the SmO2 level over time with a predetermined threshold level; and indicate via the user interface device whether further cardiopulmonary resuscitation attempts are likely to be successful, based on the SmO2 level, not required in any other group.

The special technical feature of Group V is a medical system comprising: at least one sensor configured to monitor end tidal carbon dioxide (ETCO2) level of a patient who is undergoing cardiac arrest and to generate a signal representing the end tidal carbon dioxide (ETCO2) level; compare the ETCO2 level over time with a predetermined threshold level; and indicate via the user interface device whether further cardiopulmonary resuscitation attempts are likely to be successful, based on the ETCO2 level, not a required in any other group.

The special technical feature of Group VI is a medical system comprising: at least one sensor configured to monitor a pH level of a patient who is undergoing cardiac arrest and to generate a signal representing the pH level; compare the pH level over time with a predetermined threshold level; and indicate via the user interface device whether further cardiopulmonary resuscitation attempts are likely to be successful, based on the pH level, not a required in any other group.

The special technical feature of Group VII is a medical system comprising: at least one sensor configured to monitor a hematocrit level of a patient who is undergoing cardiac arrest and to generate a signal representing the hematocrit level; compare the hematocrit level over time with a predetermined threshold level; and indicate via the user interface device whether one or both of a frequency and an intensity of ventilation measures applied to the patient should be adjusted, based on the hematocrit level, not required in any other group.

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Common Technical Features:

-Groups I through III share the technical features of at least one sensor configured to monitor ... level of a patient who is undergoing cardiac arrest and to generate a signal representing the...level; a user interface device; a processor communicably coupled to the user interface device, the processor configured to: cause the user interface device to present an array of two or more possible nodes of a clinical decision support tree, wherein at least one of the two or more possible nodes indicates cardiopulmonary resuscitation (CPR) treatment of the patient with no ventilation, and wherein at least another of the two or more possible nodes indicates CPR treatment of the patient with active ventilation; and determine which of the two or more possible nodes should be emphasized based on the ... level; and update the array of the two or more possible nodes based on the determination. However, these shared technical features do not represent a contribution over the prior art:

US 2012/0123223 A1 (Freeman et al.) (hereinafter Freeman) 17 May 2012 (17.05.2012) in view of

US 2006/0223042 A1 (Epler et al.) (hereafter Epler) 05 October 2006 (05.10.2006)

Freeman teaches at least one sensor configured to monitor... level of a patient who is undergoing cardiac arrest and to generate a signal representing the...level (e.g. analyze the patient's end-tidal waveform, para [0076]; e.g. data received from one or more sensors, para [0072]; e.g. receiving data from sensors ... cardiac distress DTP, the decision support system may be configured to display a cardiac arrest probability at a moment in time, which may be calculated and/or predicated by the decision support system based on selected criteria, para [0085]); a user interface device; a processor communicably coupled to the user interface device, the processor configured to (a user interface device is communicably coupled to a processor, para [0072]): cause the user interface device to present an array of two or more possible nodes of a clinical decision support tree, wherein at least one of the two or more possible nodes indicates cardiopulmonary resuscitation (CPR) treatment of the patient (e.g. Although five diagnosis and treatment pathways are discussed...the differential diagnosis/decision support system may be configured to support decisionmaking and diagnosis with respect to other DTPs, and may be configured to display and support various combinations of one or more DTPs...guides the caregiver through a series of decisions according to a pre-established flow chart...a cardiac distress DTP...the length of the CPR period may be configured by the user to customize the treatment protocol, para [0083]-[0086]; and determine which of the two or more possible nodes should be emphasized based on the...level update the array of the two or more possible nodes based on the determination (e.g. the decision support system may display and/or analyze the patient's end-tidal waveform, and suggest that the patient does not appear to be responding to the treatment, and ask for the caregiver's confirmation. If the caregiver confirms the decision, then the decision support system may continue to guide the caregiver through additional treatment options, para [0076]).

Freeman fails to teach wherein at least one of the two or more possible nodes indicates cardiopulmonary resuscitation (CPR) treatment of the patient with no ventilation, and wherein at least another of the two or more possible nodes indicates CPR treatment of the patient with active ventilation.

However, Epler, in an analogous art, teaches , wherein at least one of the two or more possible nodes indicates cardiopulmonary resuscitation (CPR) treatment of the patient with no ventilation, and wherein at least another of the two or more possible nodes indicates CPR treatment of the patient with active ventilation (e.g. Returning to the instructions 138 and 142...is the resuscitator passing oxygen into and out of the patient's lungs? If yes, the rescuer is given the instruction 160... If no, the rescuer is given the instruction 162...If no ventilation is reported, the rescuer is given the instruction 166, "Insert oral airway." After indicating insertion of the oral airway, another "Ventilate?" question 168 is given. Para [0164]-[0165]; e.g. browsing of decision tree...decision trees can be represented at design time by a flowchart, para [0176]-[0177]). It would have been obvious to one of ordinary skill in the art to have modified the system of Freeman by including at least one of the two or more possible nodes indicates cardiopulmonary resuscitation (CPR) treatment of the patient with no ventilation, and wherein at least another of the two or more possible nodes indicates CPR treatment of the patient with active ventilation as taught by Epler because the modification would allow the system to provide a more accurate treatment based on the condition of the user.

-Group IV through VII share technical features at least one sensor configured to monitor... level of a patient who is undergoing cardiac arrest and to generate a signal representing the ... level; a user interface device; a processor communicably coupled to the user interface device, the processor configured to: compare the... level over time with a predetermined threshold level; and indicate via the user interface device whether further cardiopulmonary resuscitation attempts are likely to be successful, based on the... level. However, these shared technical features does not represent a contribution over the Freeman in view of US 6,171,257 B1 (Weil et al.) (hereinafter Weil) 09 January 2001 (09.01.2001).

Freeman teaches at least one sensor configured to monitor... level of a patient who is undergoing cardiac arrest and to generate a signal representing the...level (e.g. analyze the patient's end-tidal waveform, para [0076]; e.g. data received from one or more sensors, para [0072]; e.g. receiving data from sensors ... cardiac distress DTP, the decision support system may be configured to display a cardiac arrest probability at a moment in time, which may be calculated and/or predicated by the decision support system based on selected criteria, para [0085]); a user interface device; a processor communicably coupled to the user interface device, the processor configured to (a user interface device is communicably coupled to a processor, para [0072]). Freeman fails to teach compare the... level over time with a predetermined threshold level; and indicate via the user interface device whether further cardiopulmonary resuscitation attempts are likely to be successful, based on the... level. However, Weil, in an analogous art, teaches AM, ASA, and PSA are highly correlated With successful resuscitation by defibrillation....ASA (amplitude spectrum area) has the lowest NLL value, it is the best predictor of successful resuscitation....To establish a threshold level at which the probability of resuscitation is favorable, the binary logistic regression model is used to assess the relation between the outcome and the EKG characteristics...Where PS represents the probability of success, X=measured variable, ?a? is a multiplicative constant and ?b? is an additive constant derived from empirical data that provide the best fit, col. 7, ln to col. 8, ln 9). It would have been obvious to one of ordinary skill in the art to have modified the system of Freeman by including compare the...level over time with a predetermined threshold level; and indicate via the user interface device whether further cardiopulmonary resuscitation attempts are likely to be successful, based on the... level as taught by Weil because the modification would predict the immediate success of a defibrillatory shock during cardiac arrest (abstract, Weil).

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-Group I through VII share technical features at least one sensor configured to monitor... level of a patient who is undergoing cardiac arrest and to generate a signal representing the ... level; a user interface device; a processor communicably coupled to the user interface device, the processor configured to. However, these shared technical features does not represent a contribution over the Freeman.

Freeman teaches at least one sensor configured to monitor... level of a patient who is undergoing cardiac arrest and to generate a signal representing the...level (e.g. analyze the patient's end-tidal waveform, para [0076]; e.g. data received from one or more sensors, para [0072]; e.g. receiving data from sensors ... cardiac distress DTP, the decision support system may be configured to display a cardiac arrest probability at a moment in time, which may be calculated and/or predicated by the decision support system based on selected criteria, para [0085]); a user interface device; a processor communicably coupled to the user interface device, the processor configured to (a user interface device is communicably coupled to a processor, para [0072]).

-Group I and IV share technical features at least one sensor configured to monitor a muscle oxygen saturation (SmO2) level of a patient who is undergoing cardiac arrest and to generate a signal representing the SmO2 level. However, these shared technical features does not represent a contribution over the article Freeman in view of "Reflectance Medical CareGuide Oximeter for Muscle Oxygen Saturation Cleared in U.S" by Editors ([online] published Aug. 2, 2012. [Retrieved on 29 July 2014] Retrieved from the Internet <URL: <http://www.medgadget.com/2012/08/reflectance-medical-careguide-oximeter-for-muscle-oxygen-saturation-cleared-in-u-s.html>>)

Freeman teaches at least one sensor configured to monitor... level of a patient who is undergoing cardiac arrest and to generate a signal representing the...level (e.g. analyze the patient's end-tidal waveform, para [0076]; e.g. data received from one or more sensors, para [0072]; e.g. receiving data from sensors ... cardiac distress DTP, the decision support system may be configured to display a cardiac arrest probability at a moment in time, which may be calculated and/or predicated by the decision support system based on selected criteria, para [0085]).

Freeman fails to teach a muscle oxygen saturation (SmO2) level of a patient. However, Editors teaches a muscle oxygen saturation (SmO2) level of a patient (e.g. a hemoglobin oxygen saturation monitor of skeletal muscle tissue (SmO2)...device uses near-infrared light to penetrate muscle tissue and measure the muscle oxygen saturation non-invasively, an indicator of whether a muscle is receiving sufficient oxygen for its labors, pg. 2). It would have been obvious to one of ordinary skill in the art to have modified the system of Freeman by including a muscle oxygen saturation (SmO2) level of a patient as taught by Editors because the modification would use near-infrared light to penetrate muscle tissue and measure the muscle oxygen saturation non-invasively, an indicator of whether a muscle is receiving sufficient oxygen for its labors (Editors, pg. 2).

-Group II and V share the technical features at least one sensor configured to end tidal carbon dioxide (ETCO2) of a patient who is undergoing cardiac arrest and to generate a signal representing the end tidal carbon dioxide (ETCO2). However, these shared technical features does not represent a contribution over Freeman.

Freeman teaches at least one sensor configured to end tidal carbon dioxide (ETCO2) of a patient who is undergoing cardiac arrest and to generate a signal representing the end tidal carbon dioxide (ETCO2) (e.g. analyze the patient's end-tidal waveform, para [0076]; e.g. data received from one or more sensors, para [0072]; e.g. receiving data from sensors ... cardiac distress DTP, the decision support system may be configured to display a cardiac arrest probability at a moment in time, which may be calculated and/or predicated by the decision support system based on selected criteria, para [0085]).

-Group III and VI share technical features at least one sensor configured to pH level of a patient who is undergoing cardiac arrest and to generate a signal representing the pH level. However, these shared technical features does not represent a contribution over Freeman in view of Editors.

Freeman teaches at least one sensor configured to monitor... level of a patient who is undergoing cardiac arrest and to generate a signal representing the...level (e.g. analyze the patient's end-tidal waveform, para [0076]; e.g. data received from one or more sensors, para [0072]; e.g. receiving data from sensors ... cardiac distress DTP, the decision support system may be configured to display a cardiac arrest probability at a moment in time, which may be calculated and/or predicated by the decision support system based on selected criteria, para [0085]). Freeman fails to teach a pH level of a patient. However, Editors teaches a pH level of a patient (e.g. the sensor to simultaneously determine pH (acidosis) and hematocrit within muscle tissue, pg. 2). It would have been obvious to one of ordinary skill in the art to have modified the system of Freeman by including a pH level of a patient as taught by Editors because the modification would provide a very early indication of impaired tissue perfusion, the imbalance between available oxygen and tissue demand, as well as immediate, continuous feedback on the efficacy of therapy aimed at improving tissue perfusion (Editors, pg. 2).

Therefore, Groups I-VII lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.