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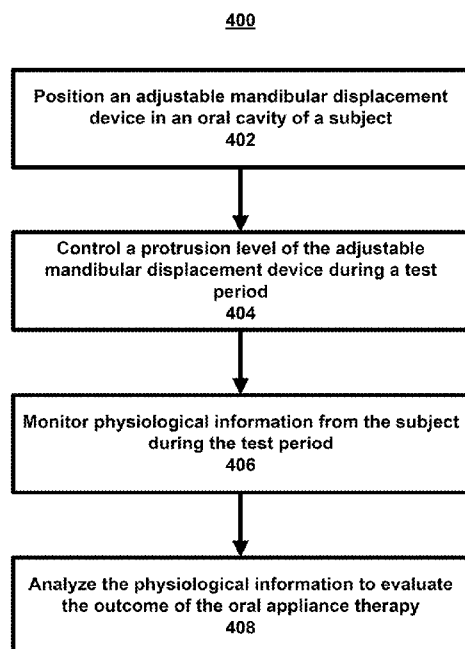
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[Continued on next page]

(54) Title: SYSTEMS AND METHODS FOR PROVIDING AN AUTOMATED TITRATION FOR ORAL APPLIANCE THER-  
APY**FIG. 4**

(57) Abstract: Provided herein are systems, methods and devices for performing one or more titrations for oral appliance therapy. For example, a method for evaluating an outcome of oral appliance therapy in a subject is discussed herein. The method can include positioning an adjustable mandibular displacement device in an oral cavity of a subject and implementing an automatic titration protocol. The protocol can include controlling a protrusion level of the adjustable mandibular displacement device during a test period, monitoring physiological information from the subject during the test period, and analyzing the physiological information to evaluate the outcome of oral appliance therapy.



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SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,  
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## INTERNATIONAL SEARCH REPORT

International application No.

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| <b>A. CLASSIFICATION OF SUBJECT MATTER</b><br>IPC(8) - A61F 5/56 (2015.01)<br>CPC - A61F 5/566<br>According to International Patent Classification (IPC) or to both national classification and IPC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                      |                                                                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| <b>B. FIELDS SEARCHED</b><br>Minimum documentation searched (classification system followed by classification symbols)<br>CPC: A61F 5/566 IPC(8): A61F 5/56 (2015.01)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                      |                                                                                            |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched<br>USPC: 128/204.26, 848; 600/590 (keyword limited; terms below)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                      |                                                                                            |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)<br>PatBase; Google Patents; Google<br>Search Terms Used: mandible, position*, reposition*, adjust*, monitor*, evaluat*, analyz*, titrat*, mouthguard, mouth guard, dental appliance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                      |                                                                                            |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                      |                                                                                            |
| Category*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Citation of document, with indication, where appropriate, of the relevant passages                                   | Relevant to claim No.                                                                      |
| X                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | US 2010/0316973 A1 (REMMERS et al) 16 December 2010 (16.12.2010) fig 11, para [0102], [0104], [0107], [0109], [0112] | 1, 3-4, 25, 36-37, 40-42, 46-47, 51                                                        |
| -----<br>Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                      | 2, 35, 38-39, 43-45, 52-56                                                                 |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | US 2011/0232652 A1 (LEVENDOWSKI et al) 29 September 2011 (29.09.2011) para [0016]                                    | 2, 35                                                                                      |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | US 5,921,942 A (REMMERS et al) 13 July 1999 (13.07.1999) col 6, ln 51-55                                             | 38-39, 43-45                                                                               |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | US 2010/0018538 A1 (SOTOS et al) 28 January 2010 (28.01.2010) para [0083]                                            | 52-56                                                                                      |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                      |                                                                                            |
| * Special categories of cited documents:<br>"A" document defining the general state of the art which is not considered to be of particular relevance<br>"E" earlier application or patent but published on or after the international filing date<br>"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)<br>"O" document referring to an oral disclosure, use, exhibition or other means<br>"P" document published prior to the international filing date but later than the priority date claimed<br>"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<br>"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<br>"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<br>"&" document member of the same patent family |                                                                                                                      |                                                                                            |
| Date of the actual completion of the international search<br>02 February 2015 (02.02.2015)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                      | Date of mailing of the international search report<br><b>06 FEB 2015</b>                   |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-3201                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                      | Authorized officer:<br>Lee W. Young<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 14/22638

## 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:  
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 1-4, 25, 35-47, 51-56 directed to analyzing/evaluating physiological information.  
Group II: Claims 1, 6-12, 25-33, 48-56, 58-79 directed to monitoring physiological information from the subject during the test period.  
Group III: Claims 1, 5, 25, 34, 51-57 directed to controlling a protrusion level of the adjustable mandibular displacement device.  
Group IV: Claims 13-24, 89-152, 179-204 directed to systems for performing a titration for oral appliance therapy.  
Group V: Claims 80-88 directed to a method for performing a titration for oral appliance therapy based on data collected at a plurality of protrusion levels of an adjustable mandibular displacement device  
Group VI: Claims 153-178 directed to a method for performing a titration for oral appliance therapy in a non-clinical setting

----See Supplemental Page----

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.:  
1-4, 25, 35-47, 51-56

### 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/US 14/22638

Continuation of Box III: Observations where unity of invention is lacking

Group VII: Claims 205-244 directed to methods and systems for automatically controlling an adjustable mandibular displacement device while performing a titration for oral appliance therapy.

Group VIII: Claims 245-267 and 291-295 directed to methods and systems for detecting respiratory events.

Group IX: Claim 268-269 directed to a method for treating hypertension.

Group X: Claims 270-290 directed to a system for detecting respiratory events

Group XI: Claims 296-303 directed to methods and a system for identifying a candidate for oral appliance therapy.

Group XII: Claim 304-351 directed to methods and systems for performing a titration for oral appliance therapy.

\* Claims 1, 25 and 51-56 are generic to Groups I-III.

The inventions listed as Groups I-XII 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:

**Special Technical Features**

The special technical feature of each species (Groups I-III) is provided in the group descriptions above. None of these special technical features are common to the other species, nor do they correspond to a special technical feature in the other species.

The invention of Group IV includes the special technical feature of a control unit comprising a processing unit and a memory operatively coupled to the processing unit, the memory having computer-executable instructions stored thereon that, when executed by the processing unit, cause the system to:

control a protrusion level of the adjustable mandibular displacement device during a test period;

monitor physiological information from the subject during the test period; and

analyze the physiological information to evaluate the outcome of oral appliance therapy, not required in Groups I-III or V-XII.

The invention of Group V includes the special technical feature of receiving data related to a protrusion level of the adjustable mandibular displacement device during the test period, not required in Groups I-IV or VI-XII.

The invention of Group VI includes the special technical feature of collecting one or more physiological inputs from the subject during the test period, not required in Groups I-V or VII-XII.

The invention of Group VII includes the special technical feature of the test period including at least one event period and at least one non-event period, analyzing the monitored physiological information to determine if the subject is in the at least one event period or the at least one non-event period;

controlling a protrusion level of the adjustable mandibular displacement device during the at least one event period;

controlling the protrusion level of the adjustable mandibular displacement device during the at least one non-event period; and

collecting data during the at least one event period and the at least one non-event period, not required in Groups I-VI or VIII-XII.

The invention of Group VIII includes the special technical feature of an oxygen saturation monitor configured to sense oxygen saturation of a subject, not required in Groups I-VII or IX-XII.

The invention of Group IX includes the special technical feature of for detecting respiratory events, comprising: receiving at least one physiological input from a subject, the at least one physiological input comprising oxygen saturation; detecting at least one oxygen saturation event based on the received physiological input; and classifying the oxygen saturation event as a respiratory event if a decrease in oxygen saturation of at least a predefined amount from real-time or baseline oxygen saturation is detected, not required in Groups I-VIII or X-XII.

The invention of Group X includes the special technical feature of memory having computer-executable instructions stored thereon that, when executed by the processing unit, cause the system to detect at least one oxygen saturation event based on the received physiological inputs; detect at least one respiratory airflow event based on the received physiological inputs; match the oxygen saturation event and the respiratory airflow event; and classify the matched oxygen saturation event and respiratory airflow event as a respiratory event if the oxygen saturation event and the respiratory airflow event are detected within a period of time., not required in Groups I-IX or XI-XII.

The invention of Group XI includes the special technical feature of identifying an attractor protrusion level where a small increase in the protrusion level results in an insignificant change in respiratory airflow and a small decrease in the protrusion level results in a significant change in respiratory airflow; and in response to identifying an attractor protrusion level, determining that the subject is a favorable candidate for oral appliance therapy, not required in Groups I-X or XII.

The invention of Group XII includes the special technical feature of monitor the subject for one or more respiratory events during a first test period; adjust a protrusion level of the adjustable mandibular displacement device during the first test period; and test the recommendation for oral appliance therapy during a second test period, not required in Groups I-XI.

----Continued on Supplemental Page----

Continuation of Box III: Observations where unity of invention is lacking

#### Common Technical Features

Groups I-IV share the technical features of independent claims 13 and 89. Furthermore, Groups I-III are species of generic independent claims 1 and 25. Groups I-IV are related as methods (Groups I-III) and an apparatus (Group IV). The apparatus is known in prior art as shown by US 2010/0316973 A1 to Remmers, et al. (hereinafter 'Remmers').

Regarding claim 13, Remmers discloses a system for evaluating an outcome of oral appliance therapy in a subject, comprising: an adjustable mandibular displacement device (10, which comprises trays 58, 60) configured to be positioned in an oral cavity of the subject (fig 11, para [0107]); a monitoring unit (96) configured to sense physiological information from the subject (fig 11); and a control unit (92, 94) comprising a processing unit and a memory operatively coupled to the processing unit, the memory having computer-executable instructions stored thereon that, when executed by the processing unit (inherent in computer workstation; also see para [0112]), cause the system to: control a protrusion level of the adjustable mandibular displacement device during a test period (para [0109]); monitor physiological information from the subject during the test period (para [0109]); and analyze the physiological information to evaluate the outcome of oral appliance therapy (para [0109]).

Groups I-III additionally share the technical features of generic independent claims 1 and 25, which are known in the art as shown by Remmers.

Regarding claim 1, Remmers discloses a method for evaluating an outcome of oral appliance therapy in a subject, comprising: positioning an adjustable mandibular displacement device (10, which comprises trays 58, 60) in an oral cavity of the subject (fig 11, para [0107]); and implementing an automatic titration protocol (para [0109]), the protocol comprising: controlling a protrusion level of the adjustable mandibular displacement device during a test period (para [0109]); monitoring physiological information from the subject during the test period (via PSG 96, para [0109]); and analyzing the physiological information to evaluate the outcome of oral appliance therapy (para [0109]).

Regarding claim 25, Remmers discloses a method for performing a titration for oral appliance therapy, comprising: positioning an adjustable mandibular displacement device (10, which comprises trays 58, 60) in an oral cavity of a subject during a test period (fig 11, para [0107]); monitoring physiological information (via PSG 96) from the subject during the test period (para [0109]); controlling a protrusion level of the adjustable mandibular displacement device during the test period (para [0109]); and evaluating the outcome of oral appliance therapy based on a history of movement of the adjustable mandibular displacement device and the physiological information during the test period (para [0104], [0109]).

Groups I-XII share at least some of the following elements: an adjustable mandibular displacement device, a monitoring unit configured to sense physiological information from the subject during a test period and a control unit comprising a processing unit and a memory operatively coupled to the processing unit, the memory having computer-executable instructions stored thereon that, when executed by the processing unit, which are known in the prior art as shown in Remmers, which teaches an adjustable mandibular displacement device (10, fig 11, para [0109], a monitoring unit (96) configured to sense physiological information from the subject (fig 11); and a control unit (92, 94) comprising a processing unit and a memory operatively coupled to the processing unit, the memory having computer-executable instructions stored thereon that, when executed by the processing unit (inherent in computer workstation; also see para [0112]).

As the common features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

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