(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) **EP 2 840 969 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
10.06.2020 Bulletin 2020/24

(21) Application number: **13780650.1**

(22) Date of filing: **26.04.2013**

(51) Int Cl.:
A61B 5/11 *(2006.01)* ***A61H 7/00*** *(2006.01)*
A61B 5/00 *(2006.01)* ***A61H 39/00*** *(2006.01)*
A61B 5/03 *(2006.01)* ***G16H 15/00*** *(2018.01)*
G16H 40/40 *(2018.01)* ***G16H 40/63*** *(2018.01)*
A61M 21/00 *(2006.01)*

(86) International application number:
PCT/US2013/038405

(87) International publication number:
WO 2013/163541 (31.10.2013 Gazette 2013/44)

(54) **ENHANCED THERAPEUTIC STIMULUS FOR NON-NUTRITIVE SUCK ENTRAINMENT SYSTEM**

VERBESSERTER THERAPEUTISCHER STIMULUS FÜR EIN SYSTEM FÜR NÄHRSTOFFLOSEN SAUGBEWEGUNGSBEGINN

STIMULUS THÉRAPEUTIQUE AMÉLIORÉ POUR SYSTÈME D'ENTRAÎNEMENT À LA SUCCION NON NUTRITIVE

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **26.04.2012 US 201213457203**

(43) Date of publication of application:
04.03.2015 Bulletin 2015/10

(73) Proprietors:
- **Innara Health, Inc.**
  Shawnee, Kansas 66227 (US)
- **University of Kansas**
  Lawrence, KS 66045 (US)

(72) Inventors:
- **BARLOW, Steven M.**
  Lawrence, Kansas 66045 (US)
- **STALLING, David L.**
  Lenexa, KS 66220 (US)
- **ARON, Kenneth**
  Iowa City, IA 52245 (US)

(74) Representative: **Greaves Brewster LLP**
Copa House
Station Road
Cheddar, Somerset BS27 3AH (GB)

(56) References cited:
US-A1- 2009 222 214 **US-A1- 2010 075 285**

- **M POORE ET AL: "Patterned orocutaneous therapy improves sucking and oral feeding in preterm infants", ACTA PAEDIATRICA, vol. 97, no. 7, 1 July 2008 (2008-07-01), pages 920-927, XP055257387, NO ISSN: 0803-5253, DOI: 10.1111/j.1651-2227.2008.00825.x**
- **FINAN D S ET AL: "The Actifier: A Device for Neurophysiological Studies of Orofacial Control in Human Infants", JOURNAL OF SPEECH AND HEARING RESEARCH, AMERICAN SPEECH-LANGUAGE-HEARING ASSOCIATION, US, vol. 39, 1 August 1996 (1996-08-01), pages 833-838, XP002123313, ISSN: 0022-4685**
- **BARLOW ET AL.: 'Synthetic orocutaneous stimulation entrains preterm infants with feeding difficulties to suck.' JOURNAL OF PERINATOLOGY vol. 28, 12 June 2008, pages 541 - 548, XP002556385**
- **VANTIPALLI ET AL.: 'Somatosensory entrainment of suck in preterm infants: NTrainer' CNL TECHNICAL RESEARCH REPORT vol. 3, 2006, pages 1 - 23, XP055174998**

EP 2 840 969 B1

Description

FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0001] The subject matter discussed in this patent application was funded in part by United States Grant No. R01-DC003311 from the National Institute of Health (NIH). The government may have certain rights to the subject matter discussed herein.

FIELD OF THE INVENTION

[0002] The invention relates generally to a software system and processing devices or appliances incorporating the software system to assess the organization of a non-nutritive suck (NNS) pattern of a patient and to entrain an organized NNS pattern in the patient. More specifically, the present invention relates to a software system that receives data from an orofacial stimulation appliance to assess the patient's natural NNS pattern and generates a tactile stimulus via the orofacial stimulation appliance to entrain an organized NNS pattern.

BACKGROUND OF THE INVENTION

[0003] Premature birth places infants at increased risk for learning disabilities, delayed development of speech, language and motor skills, and mortality. The premature infant often has difficulties with respiration and feeding and therefore may remain in the hospital for prolonged periods of time. The non-nutritive suck (NNS) is a motor behavior which can be observed and used to make inference about brain development and organization in this young population.

[0004] Oral stimulation therapy is a common practice, in which feeding therapists manually apply a stimulation using their fingertip. Manually applying stimulation, however, has a number of drawbacks. One such drawback includes the variance and limitation in the amount of motion (amplitude) and rhythm (frequency) from therapist to therapist, or even by the same individual. As a result, extensive and costly training and experience are required for a therapist to be proficient at providing manual stimulation and assessment.

[0005] In addition, manual stimulation is given essentially blind, as patients can respond by producing a variety of undesirable motor actions, including but not limited to clenching the jaws, tongue compression, tongue thrusting, or other reactions that may be confused with desirable NNS events. As such, it can be difficult to determine if the manual stimulation is beneficial to the patient.

[0006] Therefore, a need exists for an automated system and method to assess a patient's natural NNS pattern and to provide precise and beneficial tactile stimulus to correct and organize the patients NNS pattern.

[0007] Poore M., Zimmerman E., Barlow S.M., Wang J. and Gu F.. 2008. Patterned orocutaneous therapy improves sucking and oral feeding in preterm infants. Acta Paediatrica 97: 920-927 relates to a study of patterned orocutaneous therapy on preterm infants and studies their non-nutritive suck and/or oral feeding success.

[0008] Finan D.S and Barlow S.M. 1996. The Actifier: A Device for Neurophysiological Studies of Orofacial Control in Human Infants. Journal of Speech and Hearing Research, Volume 39: 833-838 describes a device for the stimulation of intraoral tissues in human neonates, used to investigate the responsiveness of the sucking central pattern generator in human infants to mechanical perturbation.

SUMMARY OF THE INVENTION

[0009] The present invention relates to a system for assessing and entraining a non-nutritive suck (NNS) pattern in a patient. In one aspect, the system is executable by a processor for stimulating a central pattern generator and a trigeminal nerve in a human brain, where such stimulation influences brain response or development including repair, control of respiration, control of NNS, mastication, and combinations thereof, in a human brain. The system includes an assessment module to record a pressure signal received from a pressure transducer in an orofacial stimulator appliance and generate a display signal to display assessment data based on the received pressure signal. The system also includes a feature extraction module to identify one or more components of a patient's non-nutritive suck pattern in the pressure signal, determine a symmetry of the patient's non-nutritive suck pattern, determine a repetition of the patient's non-nutritive suck pattern, and assign a spatiotemporal index value to the patient's non-nutritive suck pattern, the spatiotemporal index value indicating an overall rating of the patient's non-nutritive suck pattern.

[0010] The system further includes a therapy module to generate a therapeutic pressure pulse signal comprising a base frequency signal further comprising two or more pressure pulses, wherein each pulse period consists of a positive and negative displacement contacted by the lip and the mouth of the patient. Pulses are administered in a series of two or more pulses, and each of the two or more pressure pulses has a damped harmonic oscillating square wave profile and are separated by an interval between 500 milliseconds and 650 milliseconds in duration. The therapy module also generates a therapeutic pressure profile signal comprising at least one of the therapeutic pressure pulse signals and transmits the therapeutic pressure pulse profile signal to the orofacial stimulator appliance.

[0011] In various aspects, the base frequency is between 1.5 Hz and 5 Hz and the two or more pressure pulses causes surface motion of between about 260 microns and 300 microns, with a maximum transition interval of 20 milliseconds to 50 milliseconds. The therapeutic pressure profile may include at least 6 pressure pulses in succession contacted with the patient for at least two

minutes, at least twice a day. Further, each of the two or more pressure pulse is composed of higher order harmonics of the base frequency and each pressure pulse has a square wave peak.

[0012] In other aspects, the amplitude of the higher order harmonic decay is greatest at a beginning of each pressure pulse and the higher order harmonic decay for the two or more pressure pulses vary in amplitude and a frequency. Further, in one aspect, the higher order harmonic decay for the two or more pressure pulses are identical in amplitude and a frequency. Each of the two or more pressure pulses may have a first order damped overshoot square wave profile, wherein the damped overshoot square wave profile of the two or more pressure pulses has a Q factor greater than or equal to ½. The pressure transducer generates an analog pressure signal in response to pressure applied to the orofacial stimulator appliance.

[0013] In one aspect, the display signal contains waveform data, wherein the waveform data indicates at least one event in the pressure signal. Further, the signal may contain at least one event. An event may be a pressure peak, a non-nutritive suck event, a burst, a chew, or combinations thereof. NNS values assigned to the waveform data may be based upon a suck symmetry, a suck quantity, a suck magnitude, and a burst timing of the patient's non-nutritive suck pattern. A spatiotemporal index value may be calculated that relates to the regularity of repetitive suck burst. For example, the spatiotemporal index value may measure the similarity in up to five repetitive suck bursts detected within an assessment as a measure of the reproducibility of the infant's suck.

[0014] In one aspect, the system further includes a calibration module to calibrate the orofacial stimulator appliance. The orofacial stimulator appliance is calibrated prior to receiving pressure signals at the assessment module, generating the therapeutic pressure pulse signal, or both. Alternately, the orofacial stimulator appliance may be calibrated after receiving pressure signals at the assessment module, generating the therapeutic pressure pulse signal, or both. Further, the orofacial stimulator appliance may be calibrated prior to and after receiving pressure signals at the assessment module, generating the therapeutic pressure pulse signal, or both. For example, the calibration module may verify the expansion characteristics of the pacifier. Verification is performed by measuring the frequency and amplitude of changes in the pacifier by a laser micrometer in communication with the system. The system may then digitize and record the frequency and amplitude of changes in the pacifier shape to verify that the desired therapy pulse is applied. In various other aspects, the system further includes a review module to review at least one of the assessment data, the generated therapeutic pressure profile, or both.

[0015] In various other embodiments, the system may be encoded on a non-transitory computer readable medium that is further encoded with instructions for operating a non-nutritive system for generating non-nutritive stimulus for a patient. The instructions are executable by a processor in communication with memory. Related objects and advantages of the present invention will be apparent from the following description.

DESCRIPTION OF FIGURES

[0016]

FIG. 1 is a block diagram of a non-nutritive suck assessment and entrainment system according to one aspect.

FIG. 2 is a block diagram of computing environment according to one aspect of the non-nutritive suck assessment and entrainment system.

FIG. 3 is a block diagram of data source according to one aspect of the non-nutritive suck assessment and entrainment system.

FIG. 4 is a block diagram of a non-nutritive suck entrainment application according to one aspect of the non-nutritive suck assessment and entrainment system.

FIG. 5 is a block diagram of a system module according to one aspect of the non-nutritive suck assessment and entrainment system.

FIG. 6 is a block diagram of an assessment module according to one aspect of the non-nutritive suck assessment and entrainment system.

FIG. 7 is a block diagram of a therapy module according to one aspect of the non-nutritive suck assessment and entrainment system.

FIG. 8 is a block diagram of a therapeutic pulse generation system according to one aspect of the non-nutritive suck assessment and entrainment system.

FIG. 9 is a block diagram of an orofacial stimulator appliance according to one aspect of the non-nutritive suck assessment and entrainment system.

FIG. 10 illustrates a method for assessing a non-nutritive suck pattern according to one aspect of the non-nutritive suck assessment and entrainment system.

FIG. 11 illustrates a method for stimulating a patient to entrain an organized non-nutritive suck pattern according to one aspect of the non-nutritive suck assessment and entrainment system.

FIGS. 12-31 are screenshots of various graphic user interface displays according to aspects of the non-nutritive suck assessment and entrainment system.

DETAILED DESCRIPTION OF THE INVENTION

[0017] The present invention relates to a processing system for assessing and the neural entrainment of a Non-Nutritive Suck (NNS) pattern in a patient as defined in appended claim 1. Typically, the patient is a premature infant; however, the system may also be used for patients unable to properly suck or swallow to receive nourish-

ment, including but not limited to full-term infants, toddlers, adolescents, and adults. For example, the system may be used to treat those that have been debilitated by strokes, hemorrhages, or other conditions that correlate with an impairment in neurological development or function.

[0018] The NNS pattern of a patient is generated by the patient's suck central pattern generator (sCPG). A central pattern generator (CPGs) is a neural circuit or combination of neural circuits located in the patient's cerebral cortex, brainstem, and/or spinal cord that drives rhythmic motor behaviors such as sucking, breathing, mastication, and locomotion. The patterns generated by the CPGs can be modulated by a variety of external stimuli. As such, the most beneficial therapeutic results are manifested when the therapy consistently mimics the intrinsic frequency of sCPG.

[0019] It is often difficult for therapists to model the fine temporal structure of an organized NNS burst pattern, which involves a frequency-modulated (FM) burst structure, using manual stimulation. The FM burst structure is characterized by a series of suck cycles that successively decrease in frequency from the first compression cycle of the lips and mouth to the last compression cycle. The FM burst structure typically modulates between 1.5 Hz and 3 Hz. The structure of the FM burst is very difficult if not impossible to produce manually in a repeated pattern by even the most experienced therapist.

[0020] The present invention relates to the identification of particular characteristics of the FM burst structure and provides criteria or descriptions of features of the NNS pattern that may be used as diagnostic indicators for gauging the development of oromotor control among patients. Further, the identified characteristics are useful in configuring a tactile stimulus that may be applied to patients to modify or correct a deficient NNS pattern.

[0021] FIG. 1 is a block diagram of a non-nutritive suck (NNS) assessment and entrainment system (NNS system) 100 for assessing a patient's natural NNS pattern and for providing a tactile stimulus that will stimulate the suck central pattern generator (sCPG) and trigeminal nerve of a human brain to entrain a proper NNS pattern. Further, the NNS system 100 may be used to assess and entrain brain activity for controlling respiration, mastication, or combinations thereof. The NNS system 100 includes a computing device 102 to process data and execute one or more applications, a data source 104 to store data, a pulse generation system 106 to generate pneumatic pulses in response to input signals, and an orofacial stimulator appliance 108 to transfer the pneumatic pulses to a patient as a tactile stimulus.

[0022] According to one aspect, the computing device 102 includes memory 200 and at least one processor 202 to execute a NNS assessment and therapy application (NNS application) 204, as shown in FIG. 2. The computing device 102 also includes a display 206, such as a computer monitor, for displaying data stored in the data source 104, data received from the pulse generation system 106 or the orofacial stimulator appliance 108, and data input by a user of the NNS system 100. The display device 206 also displays one or more graphical user interfaces (GUIs) input forms or displays, generated by the NNS application 204, as shown in FIGS. 12-31. The GUI input forms and displays enable a user of the NNS system 100 to input, view, and/or interact with the various modules of the system. The GUI input forms and displays also allow a user to input, view, and/or interact with patient data, NNS assessment data, NNS therapy data, and/or other data related to the assessment and therapeutic stimulation of the patient. Further, the GUI input forms and displays permit a user to configure and interact with the pulse generation system 106 and the orofacial stimulator appliance 108.

[0023] The computing device 102 may also include an input device 208, such as a keyboard or a pointing device (e.g., a mouse, trackball, pen, or touch screen) to enter data or configure a feature of the NNS system 100 using the GUI input forms and displays. The computing device 102 may further include, or at least be in communication with, the data source 104.

[0024] The data source 104 may be a database stored on a local hard disk drive (HDD) incorporated into the computing device 102. Alternately, the data source 104 may be a database or other data structure stored remotely from the computing device 102. For example, the computing device 102 may be in communication with the data source 104 over a network, including but not limited to the Internet. As shown in FIG. 7, the data source may store a variety of data. For example, the data source 104 may store user data 700 that includes profiles and login information, such as passwords, for users of the NNS system 100. The data source 104 may also contain patient data 702 including patient charts and historical assessment and therapy session data 704 and 706, respectively. The data source 104 also stores data for therapy pulse profiles 708 that may be used to entrain a variety of patients, as well as, other data 710 gathered from experiments or research trials conducted using the NNS system 100.

[0025] According to one aspect, as shown in FIG. 3, the NNS assessment and therapy application 204 includes a number of instructions, applets, modules 300-308, and submodules to receive, process, and generate data and/or signals for the assessment of a NNS pattern and the therapeutic stimulation of a patient's mouth and lips to entrain a proper NNS pattern. The modules of the NNS assessment and therapy application 204 include an NNS application system module 300, an assessment module 302, a therapy module 304, a leak detection module 306, and a research module 308.

[0026] The NNS application system module 300 includes various submodules 400-406 to provide access to various features and functionality of the NNS assessment and therapy application 204. For example, the NNS application system module 300 includes a user login submodule 400 that allows a user of the NNS system 100 to

login into the NNS application 204. In one aspect, the NNS application system module 300 generates GUI input forms 1200 and 1202, as shown in FIGS. 12-13, where the user may select a user account and log in to the NNS application 204 after entering a valid password for the selected user.

[0027] The NNS application system module 300 includes a user configuration submodule 402 that allows users of the NNS system 100 with sufficient privileges to add, edit, or delete user accounts. By way of example and not limitation, an administrator may input data into GUI input forms 1204 and 1206, as shown in FIGS. 14-15 to create, modify, or delete a user profile to grant or restrict access to the NNS application 204.

[0028] Similarly, the NNS application system module 300 includes a patient configuration submodule 404 that allows users of the NNS system 100 with sufficient privileges to add, edit, or delete patients. By way of example and not limitation, an administrator may input data into input forms 1208 and 1210, as shown in FIGS. 16-17, to create, modify, or delete a profile for a patient that may receive an NNS assessment or therapy using the NNS system 100. The NNS application system module 300 also includes a session selection submodule 406 that allows users of the NNS system 100 to select whether the NNS system will be used to assess a patient's naturally generated NNS pattern or to provide therapeutic stimulus to the patient. As such, the session selection submodule 406 sends requests to the assessment module 302 and the therapy module 404 in response to type of session selected by the user.

[0029] When an assessment request is generated, the NNS application system module 300 generates a main assessment input form 1212 to allow the user to input data and interact with the NNS application 204 during the assessment session. By way of example, and not limitation, an embodiment of the main assessment input form 1212 is shown in FIG. 18. In one aspect, the main assessment input form 1212 includes one or more control buttons 1214 to access a list of all the patients actively associated with the NNS application 204. When a patient is selected, the main assessment input form 1212 displays a history 1216 of assessments for the selected patient, and is capable of displaying waveforms from the previous assessments in a waveform frame 1218. In one aspect, the prior waveforms and assessment histories 1216 may be stored as assessment session data 704 in the data source 104.

[0030] The main assessment input form 1212 also includes a control button 1220 to permit a user to view a patient's medical chart 1294, an example of which is shown in FIG. 31. In addition, the control button 1220 allows the user to add or edit patient data, while control button 1222 allows the user to add notes to the patient assessment data. In addition, the user may select control button 1224 to start a new assessment session for the selected patient or select control button 1226 to switch directly to a therapy session for the selected patient.

[0031] In one aspect, an assessment session consists of recording and displaying a signal received at the computing device 102 from a pressure transducer 902 of the orofacial stimulator appliance 108, as shown in FIG. 9. The transducer 902 translates pressure changes caused by sucking and mouthing movements of the patient into an analog signal that tracks the pressure applied to a pacifier 904 versus time. The analog pressure signal is converted to a digital signal at an analog-to-digital converter 802 of the pulse generation system 106. The analog-to-digital converter 802 is incorporated into a real-time controller 800, that receives and modifies received and/or generated pressure signals in real-time. The digital pressure signal is then received, recorded, and displayed by the assessment module 302.

[0032] In one aspect, the assessment module 302 includes a number of submodules 500-508, including but not limited to an assessment configuration submodule 500, an assessment calibration submodule 502, an assessment capture module 504, a feature extraction submodule 506, and a post assessment review module 508. The various submodules 500-58 generate and display one or more GUI input forms as shown in FIGS. 19-26 that allow the user to configure, initiate, and review an assessment session.

[0033] The assessment configuration submodule 500, for example, generates an assessment configuration input form 1228. The assessment configuration GUI input form 1228 includes one or more controls 1230-1242 and data fields 1244-1248 to input data related to a total assessment time 1246, an intermediate assessment prompt 1244, a type and configuration 1236 of the pacifier 904, and optionally, the patient's weight 1248. As the behavior and mood of a patient is often unpredictable, it's difficult for the user to know in advance how long the assessment session may take. Therefore, the intermediate assessment prompt is selected as a 'best estimate' for the actual time that it may take to capture enough NNS pattern activity to assess the patient. As such, the total assessment time permits the user to continue to collect data, if desired, after intermediate assessment prompt. In one aspect, the assessment collection submodule 504 halts the capture of assessment data at the intermediate assessment prompt.

[0034] The assessment calibration submodule 502 generates an assessment calibration GUI input form 1250. In one aspect, the calibration input form 1250 allows the user to communicate with and configure the pulse generation system 106 and the orofacial stimulator appliance 108 to verify the intended function and calibration for the components of the pulse generation system and the orofacial stimulator appliance prior to the initiation of an assessment session.

[0035] The assessment capture submodule 504 receives the digital pressure signal from the pulse generation system 106. In one aspect, the assessment capture submodule 504 records and displays the patient's NNS pattern activity as a waveform 1252. In other aspects,

the assessment capture submodule 504 may receive and store the digital pressure signal without displaying the NNS pattern activity. In another aspect, the assessment capture submodule 504 may display the NNS pattern activity in another form, such as a chart, graph, or table.

[0036] The assessment capture submodule 504 may further generate a number of displays during the assessment capture session. For example, FIGS. 22-25 are screen displays that show the progress of the assessment session at the start of the session 1254, at the intermediate prompt interval 1256, at the user input duration time 1258, and at the conclusion of the assessment session 1260. In other aspects, fewer or a greater number of displays 1254-1260 may be provided during the assessment session.

[0037] In one aspect, the assessment data capture session may be initiated by input received through a start control button 1262 shown on the display 206. Alternately, the assessment data capture session may be initiated by a switch on a handpiece 900 of the orofacial stimulator appliance 108.

[0038] During or subsequent to an assessment session, the feature extraction submodule 506 analyzes the digital pressure signal received by the assessment capture submodule 504. In particular, the feature extraction submodule 506 identifies various components of the patient's generated NNS pattern. For example, in the waveform 1252 of FIG. 21, the feature extraction submodule 506 identifies pressure peaks 1264, individual suck events 1266, as well as bursts 1268, which are defined as two or more suck events in less than about 1.2 seconds. In addition, the feature extraction submodule 506 also identifies a number of non-NNS events 1270, such as chewing motions made by the patient. In one aspect, the feature extraction submodule 506 may provide annotations, including color-coding, to identify the various NNS events 1264-1268.

[0039] In one aspect, the feature extraction submodule 506 quantifies the overall performance of the patient's generated NNS pattern by assigning a Spatiotemporal Index (STI) value to the pattern. For example, the STI value may be derived by calculating the similarity of up to five individual suck bursts. The STI value measures the symmetrical and repetition of the patient's generated NNS burst pattern by integrating the symmetry and quantity of selected NNS events 1264-1268 in the patient's NNS pattern.

[0040] In another aspect, the feature extraction submodule 506 automatically determines a number of parameters that are desirable for evaluating the patient's generated NNS pattern and determining the best course of therapy to treat the patient. For example, the evaluation parameters may include the STI value for the waveform, the number of bursts per minute, the number of events per burst, the number of NNS events per minute, an average peak pressure, as well as the total number of events per minute. In other examples, a fewer or greater number of parameters as well as different parameters may be considered when evaluating the patient's generated NNS pattern.

[0041] The evaluation parameters may be determined using a portion or subset of the collected assessment data. For example, a "most active" two-minute window having the most number of NNS events is identified by the feature extraction submodule 506. The most-active window is generally indicated by a bar 1272 on the displayed waveform 1252. When calculating the six evaluation parameters, the feature extraction submodule 506 may ignore any NNS activity outside of the most-active window.

[0042] After capturing the patient's generated NNS pattern and determining the evaluation parameters, the post assessment review module 508 generates a post-session GUI input form 1274 where the user may confirm the identify of the patient that underwent the assessment session and input notes regarding the assessment session. By way of example and not limitation, the user may indicate the state of alertness for the patient, by inputting terms such as alert, crying, drowsy, sleepy, or any other term that identifies the patient's level of alertness during the assessment session. The user may further quantify the patient's state of alertness as active or quiet, as the patient's STI value may fluctuate between assessment sessions due to the patient drifting off to sleep during the capture period.

[0043] Once a patient has been diagnosed or characterized as having a disorganized NNS pattern, it is often desirable for the patient to undergo a therapy session to entrain the patient's sCPG to produce an organized NNS pattern. Typically, a therapy session consists of applying an external stimulus to or near the lips and mouth of the patient in order to modify the NNS pattern generated by the sCPG. The orofacial stimulator appliance 108 contacts the patient on or near the lips and mouth to deliver therapeutic stimulation, provided by the pacifier's motion as caused by the pressure pulses, to the patient's orofacial nerves via regulated changes in the surface diameter of the pacifier 904. The pressure pulses conveyed by the orofacial stimulator appliance 108 are actuated at the pulse generator 104 system in response to a therapy pulse profile generated by the therapy module 304.

[0044] When a therapy session is to be performed, the NNS application system module 300 generates a main therapy GUI input form 1276, as shown in FIG. 27. The main therapy GUI input form 1276 includes a control button 1278 to allow a user to start new therapy session. The main therapy GUI input form 1276 also includes a control button to display previous therapy session data 706 stored in the data source 104, the therapy sessions data 706 includes summaries and detailed information for previous therapy sessions.

[0045] In one aspect, the therapy module 304 includes a number of submodules 600-606, including but not limited to a therapy configuration submodule 600, a therapy calibration submodule 602, a therapy execution submodule 604, and a post-therapy review submodule 606. The

various submodules 600-606 generate one or more GUI input forms for display that allow the user to configure, execute, and review a therapy session.

[0046] The therapy configuration submodule 600, for example, generates a therapy configuration input form 1280. The assessment configuration GUI input form 1280 includes a number controls 1282-1286 related to the therapy session and the pacifier 904 of the orofacial stimulator appliance 108. The assessment configuration GUI input form 1280 also includes a control button 1288 that allows the user to select or modify one or more therapy pulse profiles.

[0047] A therapy pulse profile consists of one or more therapeutic waveforms that result in variable but controlled radial displacements of the outer surface of the pacifier 904. The surface displacements of the pacifier 904 provide a tactile stimulus to or near the lips and mouth (e.g., intraoral tissues, anterior tongue blade, anterior tongue dorsum) of the patient to entrain the patient's sCPG to naturally produce an NNS pattern that mimics the generated therapy waveforms.

[0048] Preferably, the therapy waveform consists of one or more salient therapeutic bursts and each burst contains two or more square wave pulses. Typically, the bursts are separated by a configurable and variable delay interval.

[0049] According to one aspect, the nominal number of pulses in a desired therapeutic burst is six, while the actual number is configurable by users of the NNS system 100. Preferably, each pulse in a therapeutic burst is a square wave pulse having the same configurable amplitude. Further, the period of each pulse increases sequentially thereby, causing the waveform frequency to slow down from the start of the therapeutic burst to the end of the therapeutic burst. A desirable decelerating sequence pulse sequence has periods of approximately 510 $\pm$ 3 ms, 526 $\pm$ 3 ms, 551 $\pm$ 3 ms, 580 $\pm$ 3 ms, and 626 $\pm$ 3 ms between therapeutic bursts. When more than five pulses are used in the therapeutic burst, the sixth and all subsequent pulses have an periodic interval of approximately 626 ms.

[0050] Preferably, each square wave pulse period is shaped to minimize the positive and negative rise/fall times. For example, the transition intervals of each pulse's leading or trailing edges between each pulse may be tuned to create harmonics of 1.7 $\pm$ 0.5 Hz, 5.5 $\pm$ 0.5 Hz, 9.0 $\pm$ 0.5 Hz, 12.5 $\pm$ 0.5 Hz, and 16.5 $\pm$ 0.5 Hz. It is desired that the therapy waveform have minimal ringing or flutter at the square wave peaks, in order to be perceived as a "clean" square waves. As the therapy pulse profiles may be modified in the amplitude and frequency domains, a power spectrum analysis shows that the preferred therapy waveform generates displacement of the pacifier 904 at a fundamental frequency of approximately 1.7 Hz and higher orders. This fundamental frequency is preferred to entrain the patient's nervous system through cutaneous signal detection. Further, the preferred therapy waveform has a Q factor greater than or equal to 1/2. As such, the relative high frequency of the rising and falling edges of the therapy pulse helps to achieve stimulus salience in the patient.

[0051] In all aspects, the number of square wave pulses per therapeutic burst, the number of therapeutic bursts per therapy session, and the amplitude of the square wave pulses are configurable by the user to account for variability in the patients. For example, the age, endurance, and/or aptitude of the patients may vary, thereby requiring the user to select or modify a therapy pulse profile via the therapy configuration submodule 600.

[0052] The therapy calibration submodule 604 functions similar to the assessment calibration submodule 502 and generates a therapy calibration GUI input form similar to the assessment calibration GUI input form 1250. In one aspect, the calibration GUI input form allows the user to communicate with and configure the pulse generation system 106 and the orofacial stimulator appliance 108 to verify the intended function and calibration of the instruments prior to the start of the therapy session.

[0053] In one aspect, the expansion characteristics of the therapy pulses as delivered by expansion of the pacifier are verified using a laser micrometer (not shown) in communication with the therapy calibration submodule 604. The data from the laser micrometer regarding the frequency and amplitude components of the therapy pulse at the pacifier 904 may be digitized, recorded, and analyzed by the NNS application 204.

[0054] The therapy execution submodule 604 captures and displays the patient's NNS pattern activity during a therapy session. The therapy execution submodule 604 may generate a display 1290, as shown in FIG. 29, that shows progress of the therapy session at the start of the session, during the therapy session, at a rest interval, and at the conclusion of the therapy session, respectively. In other aspects, fewer or a greater number of displays may be provided during the therapy session.

[0055] Similar to an assessment session, the therapy session may be initiated by input received through the start control button 1278 of the GUI input form 1276. Alternately, the therapy session may be initiated by a switch on a handpiece 900 of the orofacial stimulator appliance 108.

[0056] After a therapy session, the post-therapy review submodule 606 generates a post-session GUI input form similar to the assessment post session GUI input form 1274 where the user inputs notes regarding the therapy session. The user may indicate the state of alertness for the patient, such as alert, crying, drowsy, or sleepy.

[0057] The NNS application 204 further includes a leak detection module 306. The leak detection module 306 continuously monitors the performance of pneumatic subsystems within the pulse generator system 104 and the pneumatic lines and connections of the orofacial stimulator appliance 108 to detect air leaks.

[0058] In one aspect, the leak detection module 306 determines that there may be an air leak by identifying reduced pulse amplitudes, increased pulse roll-offs,

and/or the need for a greater stroke length in an air pump or pneumatic pulse generator 804 to generate the requested pressure. Further, the leak detection module 306 can identify air leaks caused by disconnected air lines, and poorly seated receiver tubes or pacifiers. The module 306 will display a warning 1292, as shown in FIG. 30, requiring the user to address the leak. The leak detection module 306 may monitor the NNS system 100 automatically and continuously during both assessment and therapy sessions.

[0059] The NNS application 204 also includes the research module 308 that allows a user of NNS system 100 to conduct various research experiments and protocols. In particular, the research module 308 receives and transmits data to an input/output (I/O) port of the computing device 102 or the real-time controller 800 of the pulse generation system 106. The I/O port, in turn, may be in communication with any of a variety of external instruments for conducting research.

[0060] In various other aspects, the NNS assessment and therapy application 204 may include additional modules for other functions, including those typically associated with medical or rehabilitation facilities. By way of example and not limitation, the NNS application 204 may also include a billing module to interface with an existing billing system or a printing module for printing various data, charts, or reports.

[0061] FIG. 10 illustrates a method for performing an assessment session to capture and analyze a patient's NNS pattern in accordance with an aspect of the NNS system 100. At step 1000, a user of the NNS system 100 selects a patient from a displayed list of patients. The user then selects a control button to enter the assessment mode of the NNS application 204 at step 1002 and selects the "start new assessment" control button 1224 at step 1004. The assessment session is configured as desired at step 1006 based upon the patient's age, injury, or other patient data 702 and optionally, data 704 regarding the patient's assessment history. The orofacial stimulator appliance 108 is calibrated at step 1008, while the patient is positioned to encourage a rooting response to the orofacial stimulator appliance at step 1010. At step 1012, the assessment session is started, while the orofacial stimulator appliance is contacted with the patient's lips and mouth at step 1014. In other aspects, the orofacial stimulator appliance 108 is inserted into the patient's mouth at step 1014. Similarly, in other aspects, the steps 1012 and 1014 may be reversed.

[0062] Once the assessment session is completed, the orofacial stimulator appliance 108 is removed from the patient at step 1016. After the feature extraction submodule 406 analyzes the collected assessment data, using the input form 1274 generated by the post-assessment review module 508. After the assessment session, the user may initiate another assessment session for the same patient or a different patient. Alternatively, the user may instead exit the NNS application 204.

[0063] FIG. 11 illustrates a method for performing a therapy session to entrain a patient's sCPG to generate an organized NNS pattern in accordance with an aspect of the NNS system 100. At step 1110, a user of the NNS system 100 selects a patient from a list of patients. The user then selects a control button to enter the therapy mode of the NNS application 204 at step 1102 and the selects a "start new therapy" control button 1278 at step 1104. The therapy pulse profile to be generated during the therapy session is selected from the therapy pulse profile data 708 at step 1106 and at step 1108, the therapy pulse profile is configured as desired based upon the patient's age, injury, or other patient data 702 and any of the patients NNS assessment data 704. The orofacial stimulator appliance 108 is calibrated at step 1110, while the patient is positioned to encourage a rooting response to the orofacial stimulator appliance at step 1112. At step 1114, the therapy session is started, while the orofacial stimulator appliance is contacted with the patient's lips and mouth at step 1116. In other aspects, the orofacial stimulator appliance 108 is inserted into the patient's mouth at step 1116. Similarly, in other aspects, the steps 1114 and 1116 may be reversed. During the therapy session, the user may attempt to hold the patient as still as possible.

[0064] Once the therapy session is completed, the orofacial stimulator appliance 108 is removed from the patient at step 1118. The user may provide summary remarks regarding the therapy session at step 1120 using the GUI input form 1274 generated by the post-therapy review module 606. After the therapy session, the user may initiate another therapy session for the same patient or a different patient. Alternatively, the user may instead exit the NNS application 204.

[0065] It will be appreciated that the device of the present invention is capable of being incorporated in the form of a variety of embodiments, only a few of which have been illustrated and described above.

Claims

1. A processing system (100) encoded with an application for stimulating a CPG and a trigeminal nerve in a human brain, such stimulation influencing brain response or development including repair, control of respiration, control of NNS, mastication, and combinations thereof, in a human brain, the system comprising:

a processor (202); memory (200) and, the application, executable by the processor (202) further comprising instructions to:

record a pressure signal received from a pressure transducer (902) in an orofacial stimulator (108);

generate a display signal to display assessment data based on the received pressure signal;

identify one or more components of a patient's

non-nutritive suck pattern in the pressure signal;
determine a symmetry of the patient's non-nutritive suck pattern;
determine a repetition of the patient's non-nutritive suck pattern;
assign a spatiotemporal index value to the patient's non-nutritive suck pattern, the spatiotemporal index value indicating an overall rating of the patient's non-nutritive suck pattern;
generate a therapeutic pressure pulse signal comprising a base frequency signal further comprising two or more pressure pulses, wherein a first pressure pulse causes a positive displacement of a pacifier surface contacted by a lip and a mouth of the patient and a second pressure pulse causes a negative displacement of the pacifier surface contacted by the lip and the mouth of the patient, wherein each of the two or more pressure pulses has a damped square wave profile and are separated by an interval between 500 milliseconds and 650 milliseconds in duration;
generate a variable therapeutic pressure profile signal based on the pressure signal and the spatiotemporal index value, the variable therapeutic pressure profile signal comprising at least one of the therapeutic pressure pulse signals; and,
transmit the therapeutic pressure pulse profile signal to the orofacial stimulator (108).

2. The system according to claim 1, wherein the application further comprises:

an assessment module (302) to:

record the pressure signal received from the pressure transducer in the orofacial stimulator; and,
generate the display signal to display assessment data based on the received pressure signal;

a feature extraction module (506) to:

identify one or more components of the patient's non-nutritive suck pattern in the pressure signal;
determine the symmetry of the patient's non-nutritive suck pattern;
determine the repetition of the patient's non-nutritive suck pattern; and,
assign the spatiotemporal index value to the patient's non-nutritive suck pattern, the spatiotemporal index value indicating an overall rating of the patient's non-nutritive suck pattern; and,

a therapy module (304) to:

generate the variable therapeutic pressure pulse signal based on the pressure signal and spatiotemporal index value comprising the base frequency signal further comprising two or more pressure pulses, wherein each pressure pulse causes the displacement of a pacifier surface contacted by the lip and the mouth of the patient, wherein each of the two or more pressure pulses has the square wave profile and are separated by the interval between 500 milliseconds and 650 milliseconds in duration;
generate the therapeutic pressure profile signal comprising at least one of the therapeutic pressure pulse signals; and,
transmit the therapeutic pressure pulse profile signal to the orofacial stimulator.

3. The system of claim 1 or 2, wherein the base frequency is between 1.5 Hz and 5 Hz.

4. The system of claim 2 or 3, wherein the two or more pressure pulses causes surface motion of between about 260 microns and 300 microns, with changes in the motion occurring at an interval between 20 milliseconds and 50 milliseconds.

5. The system of claim 3 or 4, wherein the therapeutic pressure profile comprises at least six pressure pulses in succession contacted with the patient for at least two minutes, at least twice a day.

6. The system of claim 2 or 3, wherein each of the two or more pressure pulses is a higher order harmonic decay of the base frequency.

7. The system of claim 5 or 6, wherein the higher order harmonic for the two or more pressure pulses varies in an amplitude and a frequency.

8. The system of claim 5 or 6, wherein the higher order harmonic for the two or more pressure pulses is identical in an amplitude and a frequency.

9. The system of claim 2 or 3, wherein each of the two or more pressure pulses has an under damped square wave profile.

10. The system of claim 8 or 9, wherein the under damped square wave profile of the two or more pressure pulses has a Q factor greater than or equal to ½.

11. The system of claim 20, wherein the pressure transducer (902) is configured to generate the pressure signal in response to pressure applied to the orofacial stimulator.

12. The system of claim 1 or 2, wherein the display signal

contains waveform data, wherein the waveform data indicates at least one event in the pressure signal.

13. The system of claim 11 or 12, wherein the at least one event is identified as a pressure peak, a non-nutritive suck event, a burst, a chew, or combinations thereof.

14. The system of claim 1 or 2, wherein the spatiotemporal index value is based upon a suck symmetry, a suck quantity, and a burst timing of the patient's non-nutritive suck pattern.

15. The system of claim 1 or 2, wherein the system further comprises a calibration module (502) to calibrate the orofacial stimulator.

16. The system of claim 15, wherein the calibration module is adapted to calibrate the orofacial stimulator appliance prior to: receiving pressure signals at the assessment module, generating the therapeutic pressure pulse signal, or both.

17. The system of claim 15, wherein the calibration module is adapted to calibrate the orofacial stimulator appliance after: receiving pressure signals at the assessment module, generating the therapeutic pressure pulse signal, or both.

18. The system of claim 15, wherein the calibration module is adapted to calibrate the orofacial stimulator appliance prior to and after: receiving pressure signals at the assessment module, generating the therapeutic pressure pulse signal, or both.

19. The system of claim 1 or 2, further comprising a review module (508) to generate a display comprising at least one of the assessment data or the generated therapeutic pressure profile for review, or both.

20. The system of claim 1 or 2, further comprising a pressure transducer (902) adapted to receive the transmitted therapeutic pressure pulse profile signal.

Patentansprüche

1. Verarbeitungssystem (100), codiert mit einer Anwendung zur Stimulation eines CPG und eines Trigeminus in einem menschlichen Gehirn, wobei die Stimulation eine Gehirn-Antwort oder -Entwicklung, einschließlich Reparatur, Atmungssteuerung, Steuerung des NNS, Mastikation und Kombinationen derselben, im menschlichen Gehirn einschließt, wobei das System umfasst:

einen Prozessor (202),
einen Speicher (200), und
wobei die von dem Prozessor (202) ausführbare Anwendung weiter Befehle umfasst, um:

ein von einem Druckfühler (902) in einem orofazialen Stimulator (108) empfangenes Drucksignal aufzuzeichnen,
ein Anzeigesignal zu erzeugen, um Auswertungsdaten, basierend auf dem empfangenen Drucksignal, anzuzeigen,
eine oder mehrere Komponenten eines nicht-nutriven Saugmusters eines Patienten in dem Drucksignal zu identifizieren,
eine Symmetrie des nicht-nutriven Saugmusters des Patienten zu bestimmen,
eine Wiederholung des nicht-nutriven Saugmusters des Patienten zu bestimmen,
einen Raum-Zeit-Index-Wert für das nicht-nutrive Saugmuster des Patienten zu vergeben, wobei der Raum-Zeit-Index-Wert eine Gesamtbewertung des nicht-nutriven Saugmusters des Patienten anzeigt,
ein therapeutisches Druckpulssignal zu erzeugen, das ein Basisfrequenzsignal umfasst, weiter zwei oder mehr Druckpulse aufweisend, wobei ein erster Druckpuls eine positive Verlagerung einer Beruhigungssaugeroberfläche bewirkt, die von einer Lippe und einem Mund des Patienten kontaktiert wird, und ein zweiter Druckpuls eine negative Verlagerung der Beruhigungssaugeroberfläche bewirkt, die von der Lippe und dem Mund des Patienten kontaktiert wird, wobei jeder der zwei oder mehr Druckpulse ein gedämpftes Rechteckwellen-Profil aufweist und sie durch ein Intervall von 500 ms bis 600 ms Dauer voneinander getrennt sind,
ein variables therapeutisches Druckprofilsignal, basierend auf dem Drucksignal und dem Raum-Zeit-Index-Wert, zu erzeugen, wobei das variable therapeutische Druckprofilsignal wenigstens eines der therapeutischen Druckpulssignale umfasst, und
das therapeutische Druckpulsprofilsignal an den orofazialen Stimulator (108) zu übermitteln.

2. System nach Anspruch 1, worin die Anwendung weiter umfasst:
ein Auswertungsmodul (302), um:

das von dem Druckfühler in dem orofazialen Stimulator empfangene Drucksignal aufzuzeichnen und
das Anzeigesignal zu erzeugen, um Auswertungsdaten, basierend auf dem empfangenen Drucksignal, anzuzeigen,
ein Merkmalsextraktionsmodul (506), um:

ein oder mehrere Komponenten des nicht-nutriven Saugmusters des Patienten in dem Drucksignal zu identifizieren,
die Symmetrie des nicht-nutriven Saugmusters des Patienten zu bestimmen,
die Wiederholung des nicht-nutriven Saugmusters des Patienten zu bestimmen, und
dem nicht-nutriven Saugmuster des Patienten den Raum-Zeit-Index-Wert zuzuweisen, wobei der Raum-Zeit-Index-Wert eine Gesamtbewertung des nicht-nutriven Saugmusters des Patienten anzeigt, und
ein Therapiemodul (304), um:

basierend auf dem Drucksignal und dem Raum-Zeit-Index-Wert, das variable therapeutische Druckpulssignal zu erzeugen, das das Basisfrequenzsignal umfasst, weiter zwei oder mehr Druckpulse aufweisend, wobei jeder Druckpuls die Verlagerung einer Beruhigungssaugeroberfläche bewirkt, die von der Lippe und dem Mund des Patienten kontaktiert wird, wobei jeder der zwei oder mehr Druckpulse das Rechteckwellen-Profil aufweist und sie durch das Intervall von 500 ms bis 600 ms Dauer voneinander getrennt sind,
das wenigstens eines der therapeutischen Druckpulssignale umfassende therapeutische Druckprofilsignal zu erzeugen, und
das therapeutische Druckpulsprofilsignal an den orofazialen Stimulator zu übermitteln.

3. System nach Anspruch 1 oder 2, worin die Basisfrequenz zwischen 1,5 Hz und 5 Hz beträgt.

4. System nach Anspruch 2 oder 3, worin die zwei oder mehr Druckpulse eine Oberflächenbewegung von zwischen etwa 260 μm und 300 μm verursachen, wobei die Bewegungsänderungen mit einem Intervall von 20 ms bis 50 ms stattfinden.

5. System nach Anspruch 3 oder 4, worin das therapeutische Druckprofil wenigstens sechs Druckpulse in Folge in Kontakt mit dem Patienten für wenigstens zwei Minuten, wenigstens zweimal am Tag, umfasst.

6. System nach Anspruch 2 oder 3, worin jeder der zwei oder mehr Druckpulse ein harmonisches Abklingen höherer Ordnung der Basisfrequenz ist.

7. System nach Anspruch 5 oder 6, worin die harmonische Schwingung höherer Ordnung für die zwei oder mehr Druckpulse in einer Amplitude oder einer Frequenz variiert.

8. System nach Anspruch 5 oder 6, worin die harmonische Schwingung höherer Ordnung für die zwei oder mehr Druckpulse in einer Amplitude oder einer Frequenz identisch ist.

9. System nach Anspruch 2 oder 3, worin jeder der zwei oder mehr Druckpulse ein unterdämpftes Rechteckwellen-Profil aufweist.

10. System nach Anspruch 8 oder 9, worin das unterdämpfte Rechteckwellenprofil der zwei oder mehr Druckpulse einen Q-Faktor von größer oder gleich 1/2 aufweist.

11. System nach Anspruch 20, worin der Druckfühler (902) ausgebildet ist, das Drucksignal in Antwort auf an den orofazialen Stimulator angelegten Druck zu erzeugen.

12. System nach Anspruch 1 oder 2, worin das Anzeigesignal Wellenformdaten enthält, wobei die Wellenformdaten wenigstens ein Ereignis im Drucksignal anzeigen.

13. System nach Anspruch 11 oder 12, worin das wenigstens eine Ereignis als Druckpeak, nicht-nutrives Saugereignis, eine Saugepisode, ein Kauen oder Kombinationen derselben identifiziert ist.

14. System nach Anspruch 1 oder 2, worin der Raum-Zeit-Index-Wert auf einer Saugsymmetrie, einer Saugmenge und einem Saugepisoden-Timing des nicht-nutriven Saugmusters des Patienten basiert ist.

15. System nach Anspruch 1 oder 2, worin das System weiter ein Kalibrierungsmodul (502) umfasst, um den orofazialen Stimulator zu kalibrieren.

16. System nach Anspruch 15, worin das Kalibrierungsmodul ausgebildet ist, das Orofazialstimulator-Gerät vor dem Empfang von Drucksignalen am Auswertungsmodul, dem Erzeugen des therapeutischen Druckpulssignals oder beidem zu kalibrieren.

17. System nach Anspruch 15, worin das Kalibrierungsmodul ausgebildet ist, das Orofazialstimulator-Gerät nach dem Empfang von Drucksignalen am Auswertungsmodul, dem Erzeugen des therapeutischen Druckpulssignals oder beidem zu kalibrieren.

18. System nach Anspruch 15, worin das Kalibrierungsmodul ausgebildet ist, das Orofazialstimulator-Gerät vor und nach dem Empfang von Drucksignalen am Auswertungsmodul, dem Erzeugen des therapeutischen Druckpulssignals oder beidem zu kalibrieren.

19. System nach Anspruch 1 oder 2, weiter umfassend

ein Überprüfungsmodul (508), um eine Anzeige zu erzeugen, die wenigstens eines der Auswertungsdaten oder des erzeugten therapeutischen Druckprofils zur Überprüfung oder beides umfasst.

20. System nach Anspruch 1 oder 2, weiter umfassend einen Druckfühler (902), ausgebildet, ein übermitteltes therapeutisches Druckpulsprofilsignal zu empfangen.

Revendications

1. Système de traitement (100) codé avec une application pour stimuler un CPG et un nerf trijumeau dans un cerveau humain, ladite stimulation influençant la réponse ou le développement du cerveau, y compris la réparation, le contrôle de la respiration, le contrôle du NNS, la mastication, et des combinaisons de ceux-ci, dans un cerveau humain, le système comprenant :

un processeur (202) ;
une mémoire (200) et,
l'application, exécutable par le processeur (202) comprenant en outre des instructions pour :

enregistrer un signal de pression reçu d'un transducteur de pression (902) dans un stimulateur orofacial (108) ;
générer un signal d'affichage pour afficher les données d'évaluation basées sur le signal de pression reçu ;
identifier au moins un composant du schéma de succion non nutritive d'un patient dans le signal de pression ;
déterminer une symétrie du schéma de succion non nutritive du patient ;
déterminer une répétition du schéma de succion non nutritive du patient ;
attribuer une valeur d'indice spatiotemporel au schéma de succion non nutritive du patient, la valeur d'indice spatiotemporel indiquant une évaluation globale du schéma de succion non nutritive du patient ;
générer un signal d'impulsion de pression thérapeutique comprenant un signal de fréquence de base comprenant en outre au moins deux impulsions de pression, une première impulsion de pression provoquant un déplacement positif d'une surface de tétine en contact avec une lèvre et une bouche du patient et une seconde impulsion de pression provoquant un déplacement négatif de la surface de tétine en contact avec la lèvre et la bouche du patient, chacune des au moins deux impulsions de pression ayant un profil d'onde carrée amortie et étant séparée par un intervalle d'une durée comprise entre 500 millisecondes et 650 millisecondes ;
générer un signal de profil de pression thérapeutique variable basé sur le signal de pression et la valeur d'indice spatiotemporel, le signal de profil de pression thérapeutique variable comprenant au moins un des signaux d'impulsion de pression thérapeutique ; et,
transmettre le signal de profil de pression thérapeutique au stimulateur orofacial (108).

2. Système selon la revendication 1, l'application comprenant en outre :

un module d'évaluation (302) pour :

enregistrer le signal de pression reçu du transducteur de pression dans le stimulateur orofacial ; et,
générer le signal d'affichage pour afficher les données d'évaluation basées sur le signal de pression reçu ;

un module d'extraction de caractéristique (506) pour :

identifier au moins un composant du schéma de succion non nutritive du patient dans le signal de pression ;
déterminer la symétrie du schéma de succion non nutritive du patient ;
déterminer la répétition du schéma de succion non nutritive du patient ; et,
attribuer la valeur d'indice spatiotemporel au schéma de succion non nutritive du patient, la valeur d'indice spatiotemporel indiquant une évaluation globale du schéma de succion non nutritive du patient ; et,

un module de thérapie (304) pour :

générer le signal d'impulsion de pression thérapeutique variable sur la base du signal de pression et de la valeur d'indice spatiotemporel comprenant le signal de fréquence de base comprenant en outre au moins deux impulsions de pression, chaque impulsion de pression provoquant le déplacement d'une surface de tétine en contact avec la lèvre et la bouche du patient, chacune des au moins deux impulsions de pression ayant le profil d'onde carrée et étant séparée par un intervalle d'une durée comprise entre 500 millisecondes et 650 millisecondes ;

générer le signal de profil de pression thérapeutique comprenant au moins un des signaux d'impulsion de pression thérapeutique ; et,
transmettre le signal de profil de pression thérapeutique au stimulateur orofacial.

3. Système selon la revendication 1 ou 2, la fréquence de base étant comprise entre 1,5 Hz et 5 Hz.

4. Système selon la revendication 2 ou 3, les au moins deux impulsions de pression provoquant un mouvement de surface compris entre environ 260 microns et 300 microns, des changements de mouvement se produisant à un intervalle compris entre 20 millisecondes et 50 millisecondes.

5. Système selon la revendication 3 ou 4, le profil de pression thérapeutique comprenant au moins six impulsions de pression successives en contact avec le patient pendant au moins deux minutes, au moins deux fois par jour.

6. Système selon la revendication 2 ou 3, chacune des au moins deux impulsions de pression étant une décroissance harmonique d'ordre supérieur de la fréquence de base.

7. Système selon la revendication 5 ou 6, l'harmonique d'ordre supérieur pour les au moins deux impulsions de pression variant en amplitude et en fréquence.

8. Système selon la revendication 5 ou 6, l'harmonique d'ordre supérieur pour les au moins deux impulsions de pression étant identique en amplitude et en fréquence.

9. Système selon la revendication 2 ou 3, chacune des au moins deux impulsions de pression ayant un profil d'onde carré sous-amorti.

10. Système selon la revendication 8 ou 9, le profil d'onde carré sous-amorti des au moins deux impulsions de pression ayant un facteur Q supérieur ou égal à ½.

11. Système selon la revendication 20, le transducteur de pression (902) étant conçu pour générer le signal de pression en réponse à la pression appliquée au stimulateur orofacial.

12. Système selon la revendication 1 ou 2, le signal d'affichage contenant des données de forme d'onde, les données de forme d'onde indiquant au moins un événement dans le signal de pression.

13. Système selon la revendication 11 ou 12, l'au moins un événement étant identifié comme un pic de pression, un événement de succion non nutritive, un éclatement, une mastication, ou des combinaisons de ceux-ci.

14. Système selon la revendication 1 ou 2, la valeur d'indice spatiotemporel étant basée sur une symétrie de succion, une quantité de succion et une synchronisation d'éclatement du schéma de succion non nutritive du patient.

15. Système selon la revendication 1 ou 2, le système comprenant en outre un module d'étalonnage (502) pour étalonner le stimulateur orofacial.

16. Système selon la revendication 15, le module d'étalonnage étant conçu pour étalonner l'appareil de stimulation orofaciale avant : la réception des signaux de pression au niveau du module d'évaluation, la génération du signal d'impulsion de pression thérapeutique, ou les deux.

17. Système selon la revendication 15, le module d'étalonnage étant conçu pour étalonner l'appareil de stimulation orofaciale après : la réception des signaux de pression au niveau du module d'évaluation, la génération du signal d'impulsion de pression thérapeutique, ou les deux.

18. Système selon la revendication 15, le module d'étalonnage étant conçu pour étalonner l'appareil de stimulation orofaciale avant et après : la réception des signaux de pression au niveau du module d'évaluation, la génération du signal d'impulsion de pression thérapeutique, ou les deux.

19. Système selon la revendication 1 ou 2, comprenant en outre un module d'examen (508) pour générer un affichage comprenant au moins une des données d'évaluation ou le profil de pression thérapeutique généré pour l'examen, ou les deux.

20. Système selon la revendication 1 ou 2, comprenant en outre un transducteur de pression (902) conçu pour recevoir le signal de profil de pression thérapeutique transmis.

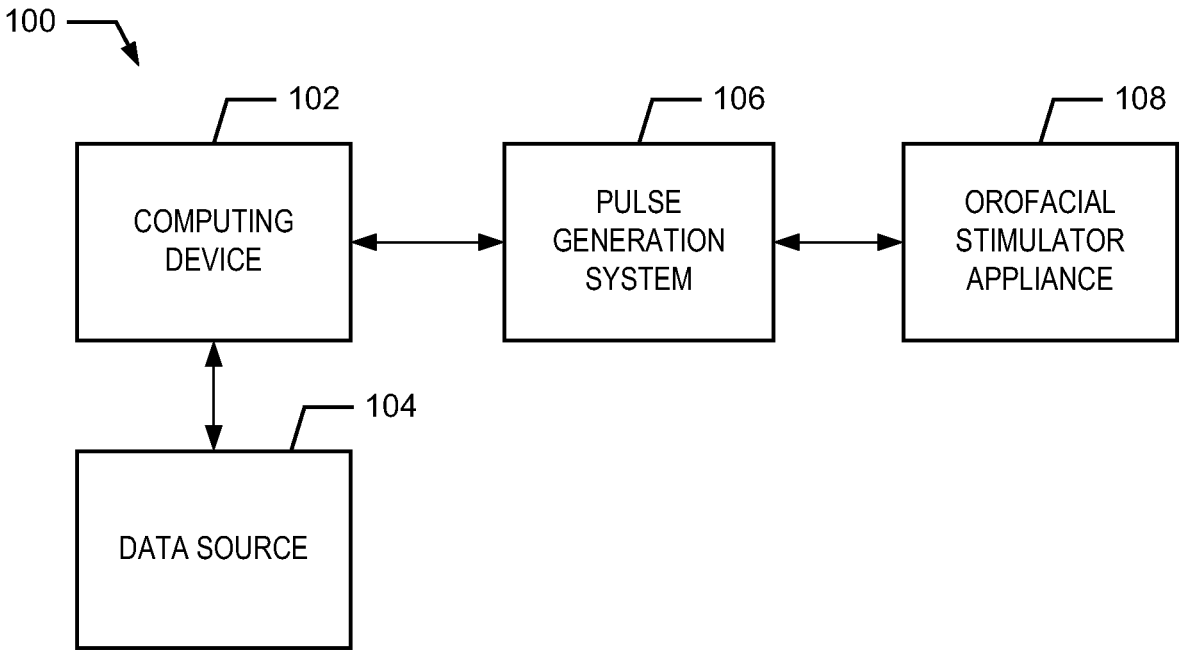

100
102
106
108
COMPUTING DEVICE
PULSE GENERATION SYSTEM
OROFACIAL STIMULATOR APPLIANCE
104
DATA SOURCE

FIG. 1

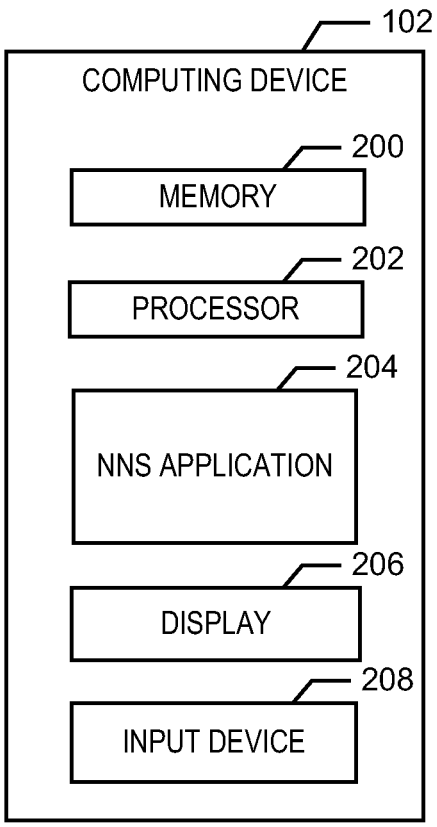

102
COMPUTING DEVICE
200
MEMORY
202
PROCESSOR
204
NNS APPLICATION
206
DISPLAY
208
INPUT DEVICE

FIG. 2

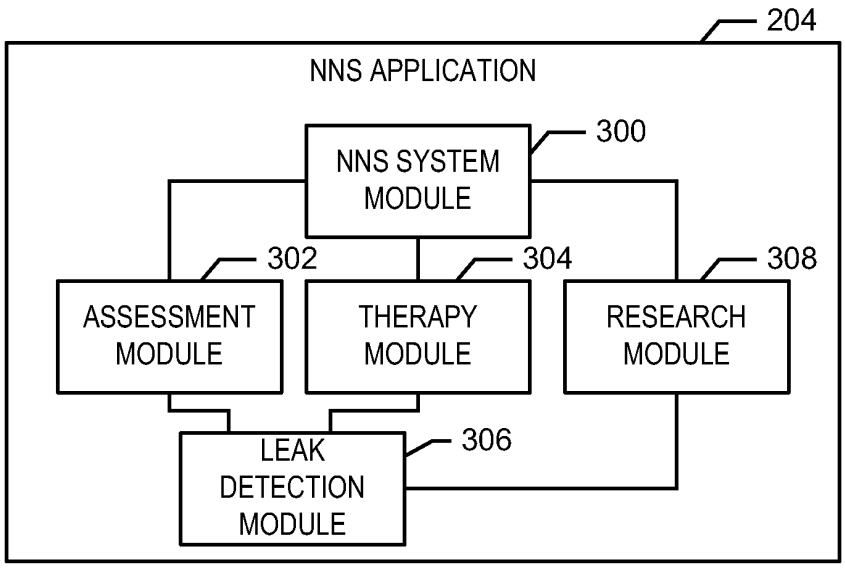


FIG. 3

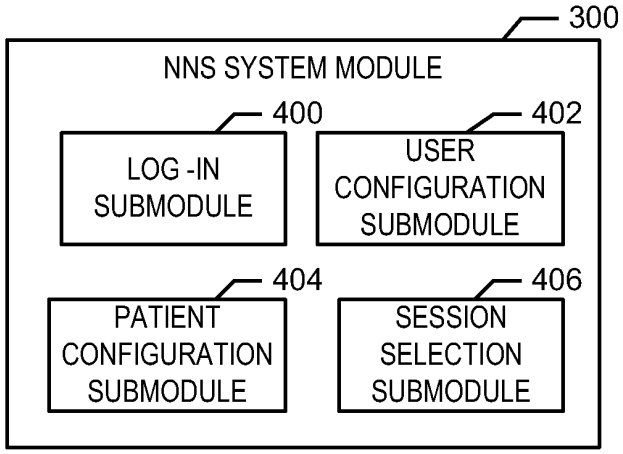


FIG. 4

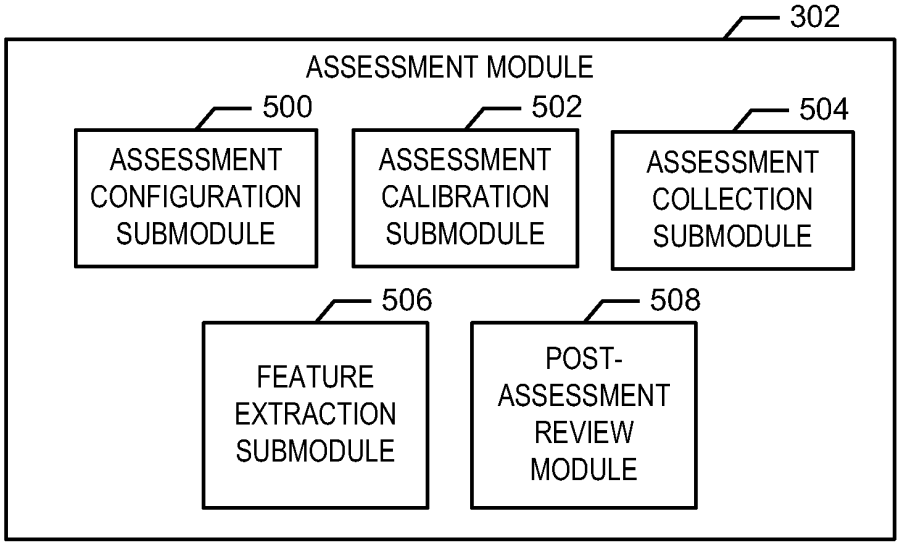


FIG. 5

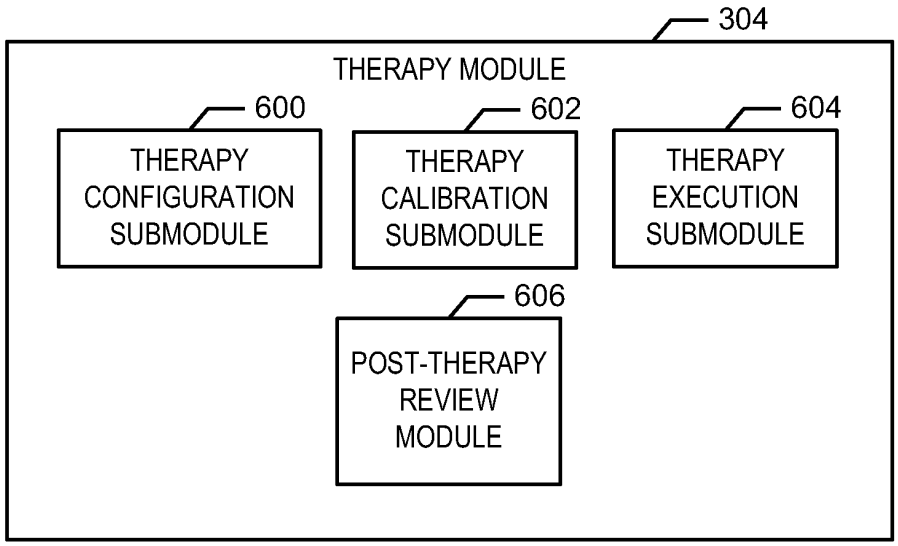


FIG. 6

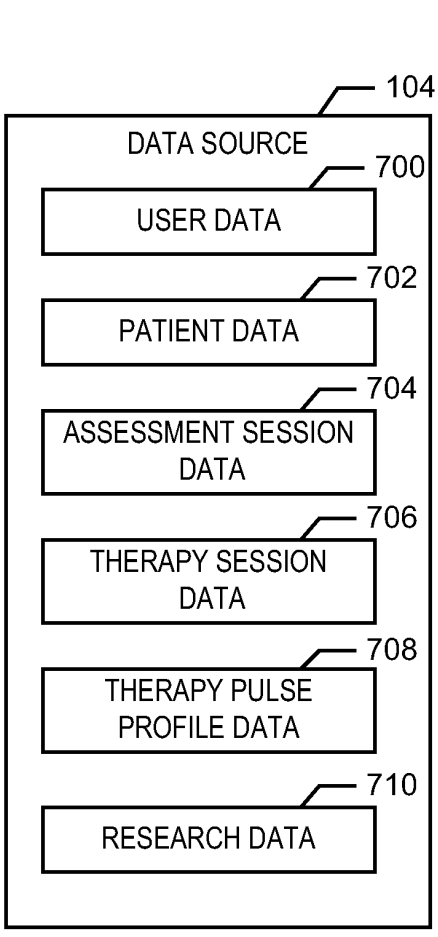


FIG. 7

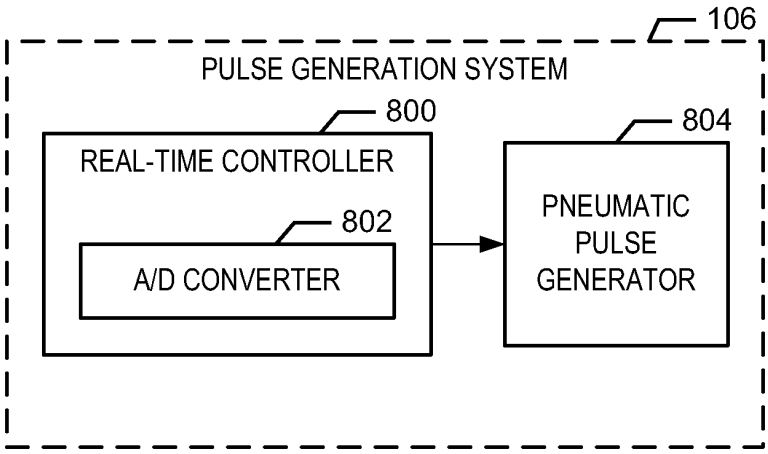


FIG. 8

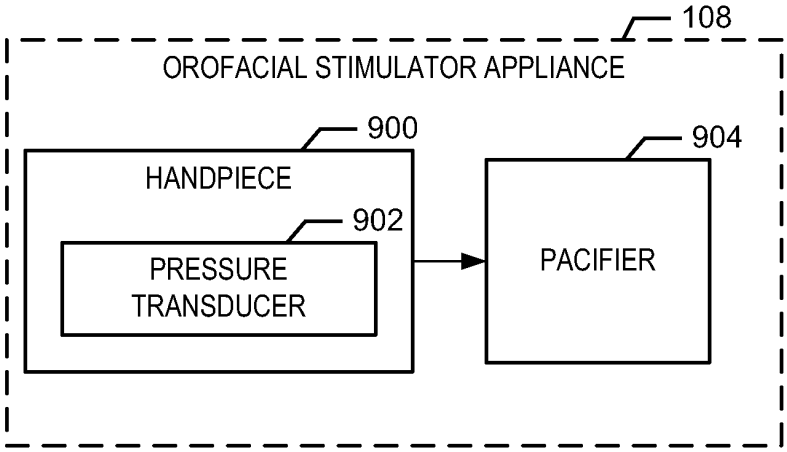


FIG. 9

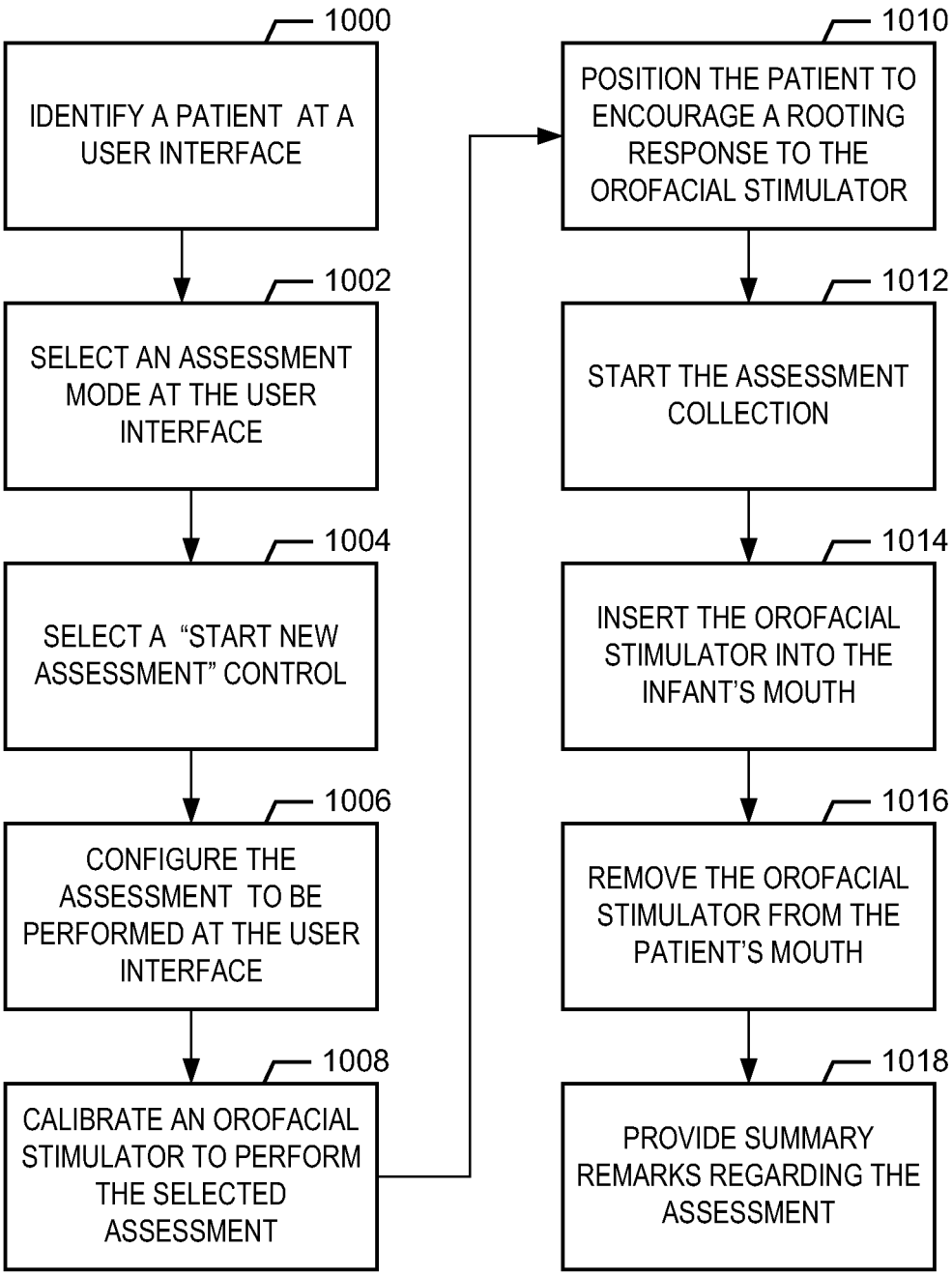

1000
IDENTIFY A PATIENT AT A USER INTERFACE
1002
SELECT AN ASSESSMENT MODE AT THE USER INTERFACE
1004
SELECT A "START NEW ASSESSMENT" CONTROL
1006
CONFIGURE THE ASSESSMENT TO BE PERFORMED AT THE USER INTERFACE
1008
CALIBRATE AN OROFACIAL STIMULATOR TO PERFORM THE SELECTED ASSESSMENT
1010
POSITION THE PATIENT TO ENCOURAGE A ROOTING RESPONSE TO THE OROFACIAL STIMULATOR
1012
START THE ASSESSMENT COLLECTION
1014
INSERT THE OROFACIAL STIMULATOR INTO THE INFANT'S MOUTH
1016
REMOVE THE OROFACIAL STIMULATOR FROM THE PATIENT'S MOUTH
1018
PROVIDE SUMMARY REMARKS REGARDING THE ASSESSMENT

FIG. 10

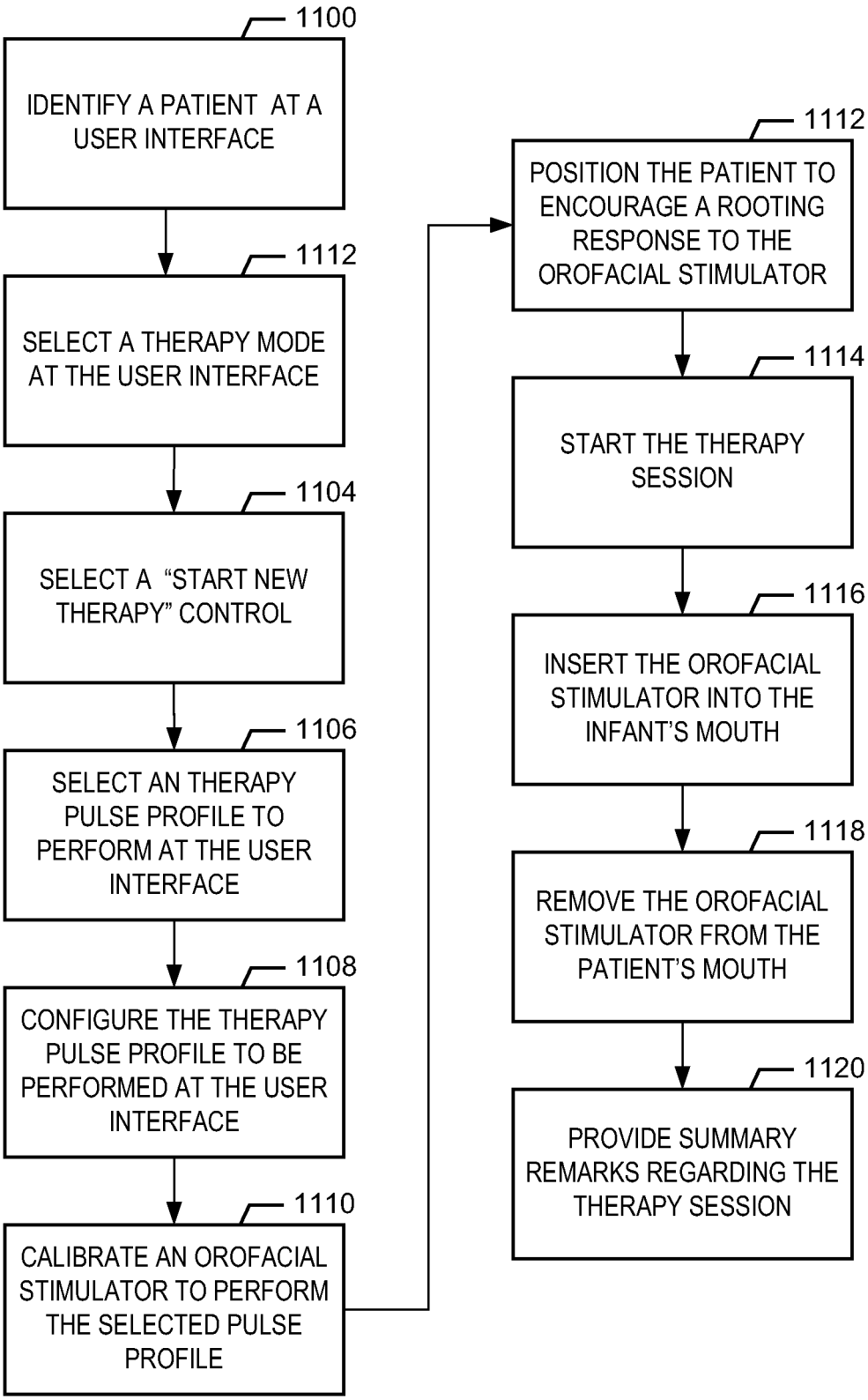

1100
IDENTIFY A PATIENT AT A USER INTERFACE
1112
SELECT A THERAPY MODE AT THE USER INTERFACE
1104
SELECT A "START NEW THERAPY" CONTROL
1106
SELECT AN THERAPY PULSE PROFILE TO PERFORM AT THE USER INTERFACE
1108
CONFIGURE THE THERAPY PULSE PROFILE TO BE PERFORMED AT THE USER INTERFACE
1110
CALIBRATE AN OROFACIAL STIMULATOR TO PERFORM THE SELECTED PULSE PROFILE
1112
POSITION THE PATIENT TO ENCOURAGE A ROOTING RESPONSE TO THE OROFACIAL STIMULATOR
1114
START THE THERAPY SESSION
1116
INSERT THE OROFACIAL STIMULATOR INTO THE INFANT'S MOUTH
1118
REMOVE THE OROFACIAL STIMULATOR FROM THE PATIENT'S MOUTH
1120
PROVIDE SUMMARY REMARKS REGARDING THE THERAPY SESSION

FIG. 11

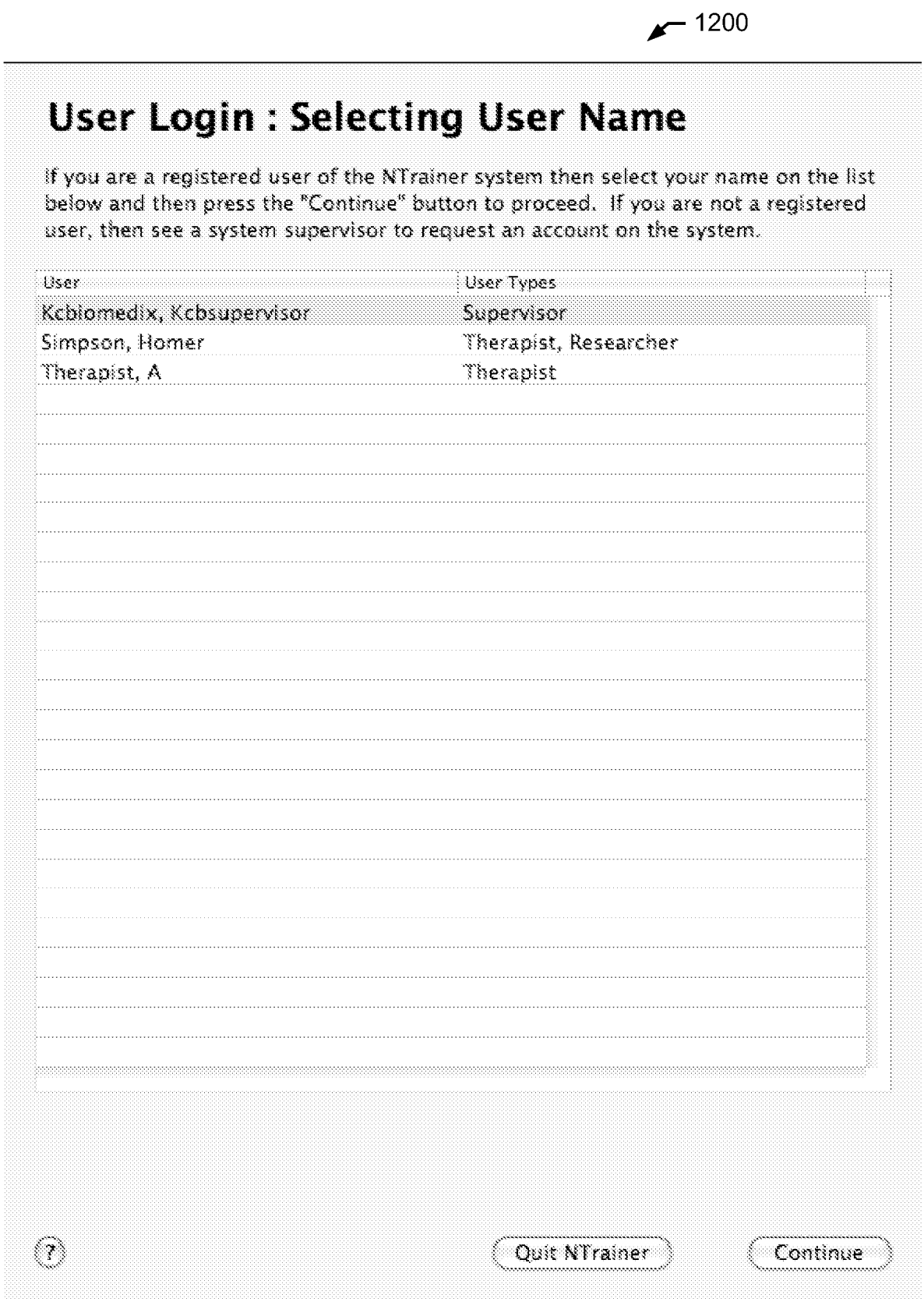

1200
User Login : Selecting User Name
If you are a registered user of the NTrainer system then select your name on the list below and then press the "Continue" button to proceed. If you are not a registered user, then see a system supervisor to request an account on the system.
User
User Types
Kcbiomedix, Kcbsupervisor
Supervisor
Simpson, Homer
Therapist, Researcher
Therapist, A
Therapist
?
Quit NTrainer
Continue

FIG. 12


User Login : Entering Password
User: Simpson, Homer
Password: •••
Cancel
Login
1202

FIG. 13

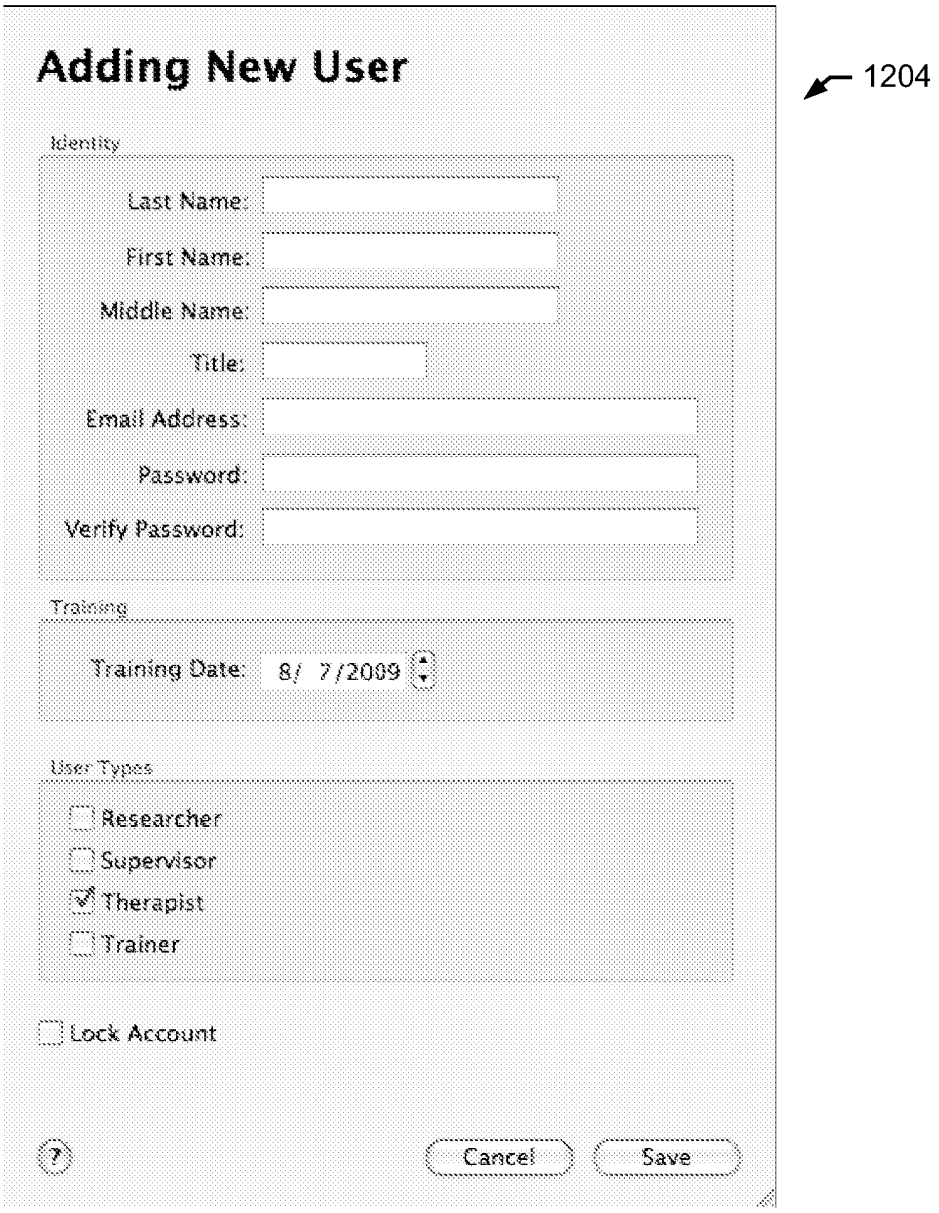

Adding New User
1204
Identity
Last Name:
First Name:
Middle Name:
Title:
Email Address:
Password:
Verify Password:
Training
Training Date: 8/ 7/2009
User Types
Researcher
Supervisor
Therapist
Trainer
Lock Account
Cancel
Save

FIG. 14

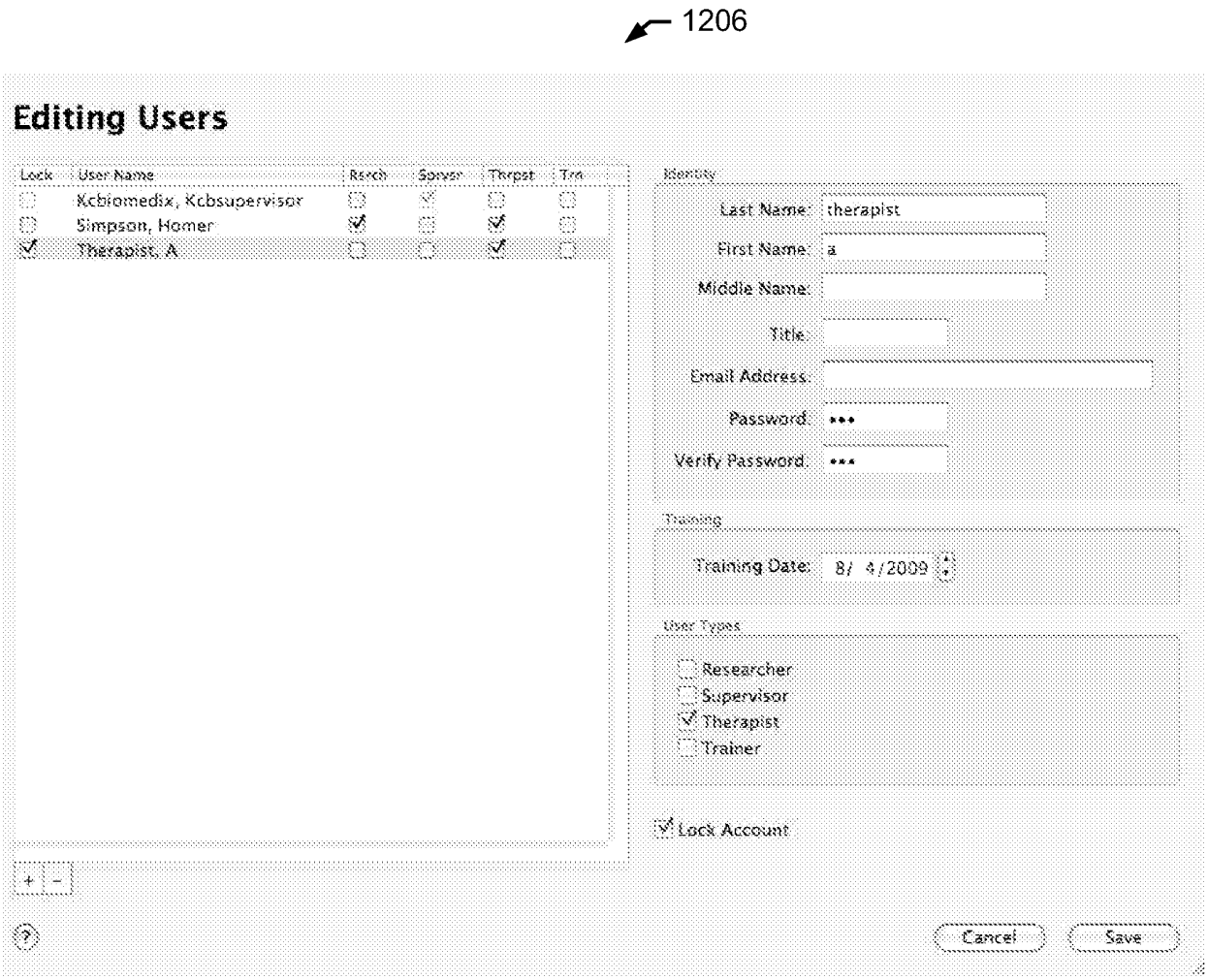

1206
Editing Users
Lock
User Name
Rsrch
Spvsr
Thrpst
Trn
Kcbiomedix, Kcbsupervisor
Simpson, Homer
Therapist, A
Identity
Last Name: therapist
First Name: a
Middle Name:
Title:
Email Address:
Password: •••
Verify Password: •••
Training
Training Date: 8/ 4/2009
User Types
Researcher
Supervisor
Therapist
Trainer
Lock Account
+
-
Cancel
Save

FIG. 15

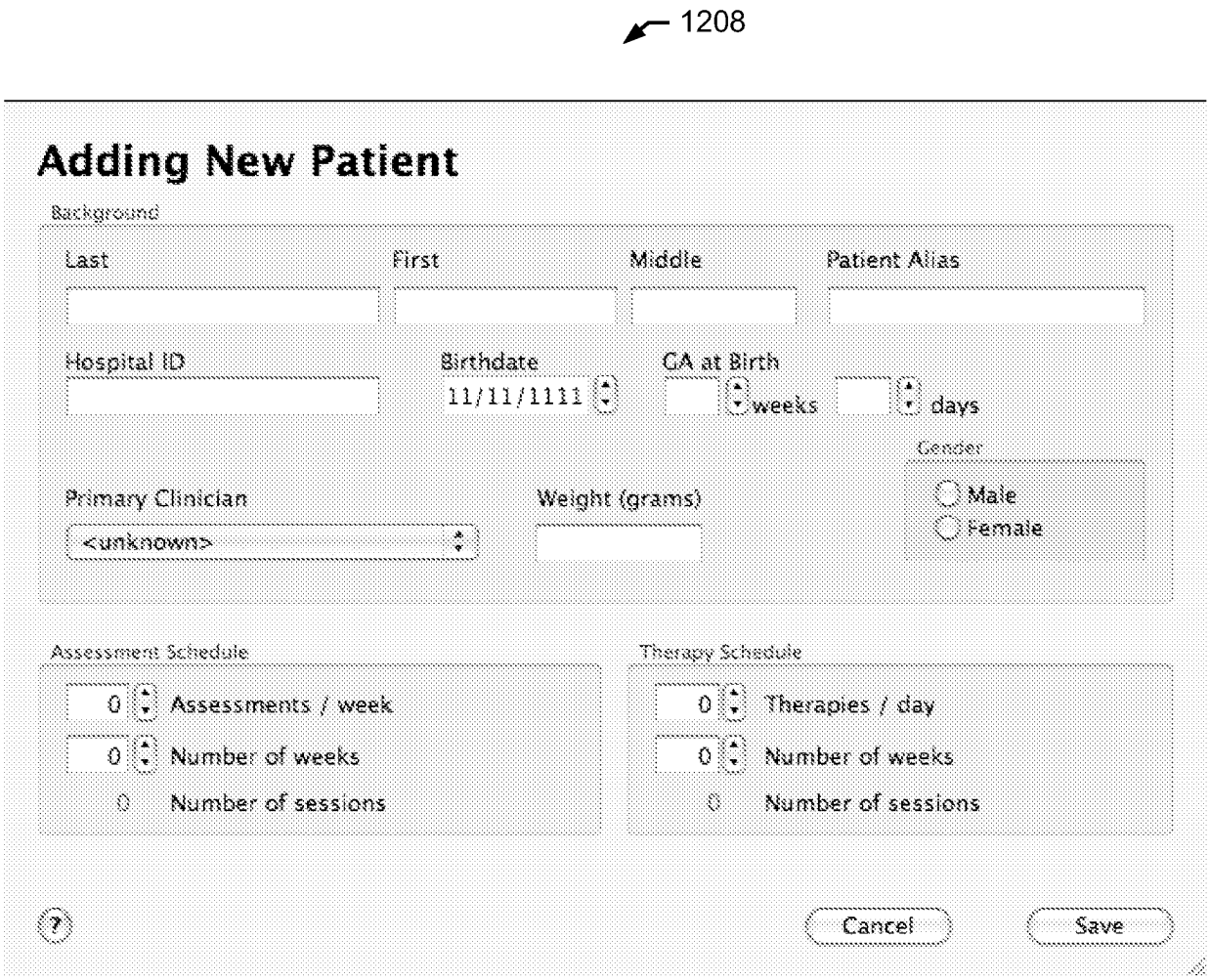

1208
Adding New Patient
Background
Last
First
Middle
Patient Alias
Hospital ID
Birthdate
11/11/1111
GA at Birth
weeks
days
Gender
Male
Female
Primary Clinician
<unknown>
Weight (grams)
Assessment Schedule
0
Assessments / week
0
Number of weeks
0
Number of sessions
Therapy Schedule
0
Therapies / day
0
Number of weeks
0
Number of sessions
?
Cancel
Save

FIG. 16


1210
Editing Patients
Patients
Name
Hospital ID
Gender
Status
Primary Clinician
Van Houten, Milhouse R.
nicu1234
Male
Active
+
-
Background
Last
First
Middle
Patient Alias
Van Houten
Milhouse
R
nicu1234
Hospital ID
Birthdate
GA at birth
Weight (grams)
nicu1234
8/ 3/2009
30
weeks
3
days
1500
Patient Status
Primary Clinician
Gender
Active
<unknown>
Male
Female
Assessment Schedule
0
Assessments / week
0
Number of weeks
0
Number of sessions
Therapy Schedule
0
Therapies / day
0
Number of weeks
0
Number of sessions
?
Cancel
Save

FIG. 17

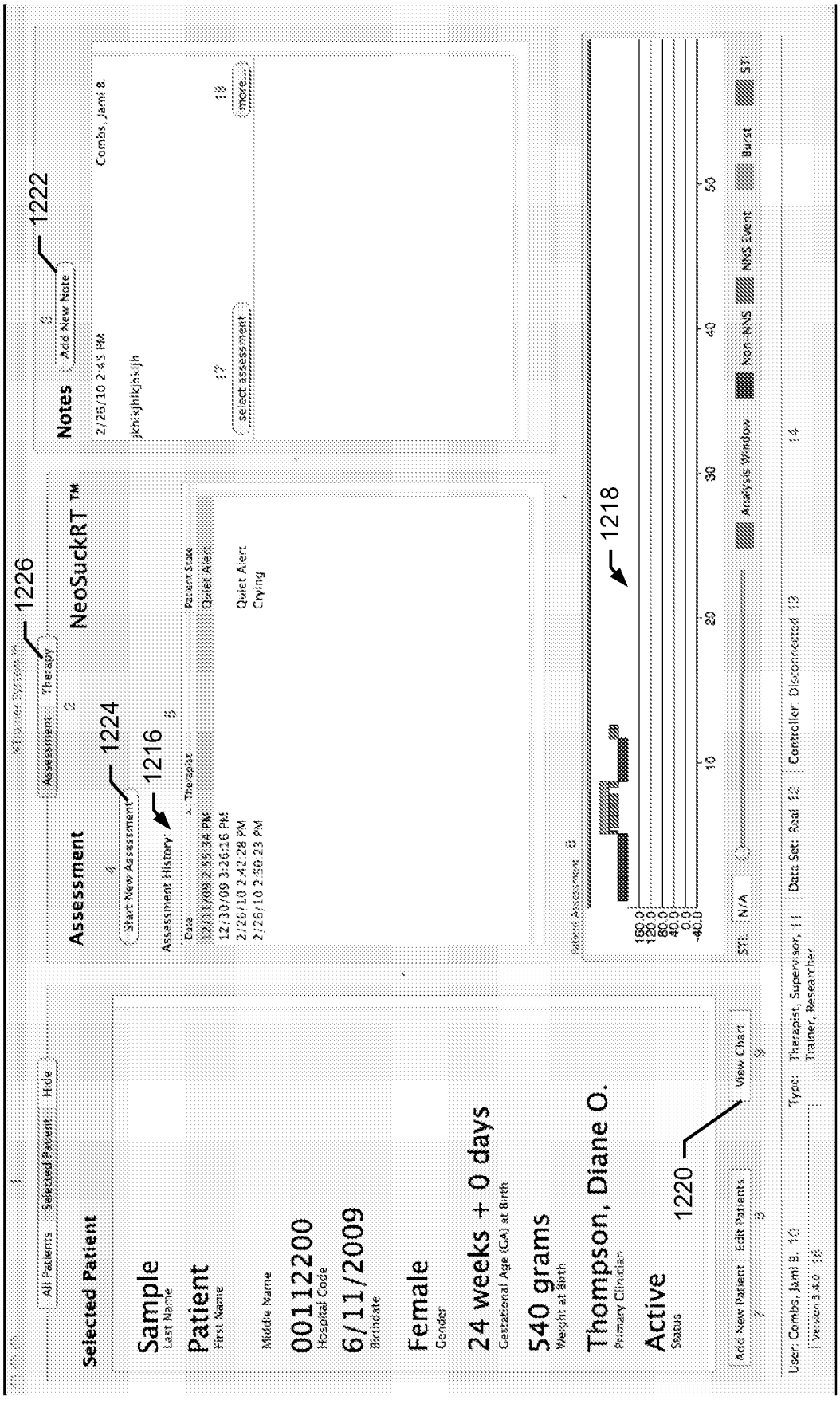

1212
1226
1222
1224
1216
1218
1220
All Patients
Selected Patient
Hide
Selected Patient
Sample
Last Name
Patient
First Name
Middle Name
00112200
Hospital Code
6/11/2009
Birthdate
Female
Gender
24 weeks + 0 days
Gestational Age (GA) at Birth
540 grams
Weight at Birth
Thompson, Diane O.
Primary Clinician
Active
Status
Add New Patient
Edit Patients
View Chart
Assessment
Therapy
Assessment
Start New Assessment
Assessment History
Date
Therapist
Patient State
12/30/09 3:26:16 PM
Quiet Alert
2/26/10 2:42:28 PM
Quiet Alert
2/26/10 2:39:23 PM
Crying
NeoSuckRT ™
Notes
Add New Note
2/26/10 2:45 PM
Combs, Jami B.
jkhkjhkjhkjh
select assessment
more
Patient Assessment
160.0
120.0
80.0
40.0
0.0
-40.0
10
20
30
40
50
STI: N/A
Analysis Window
Non-NNS
NNS Event
Burst
STI
User: Combs, Jami B. 10
Type: Therapist, Supervisor, 11
Trainer, Researcher
Data Set: Real 12
Controller Disconnected 13
Version 3.4.0 15
14

FIG. 18

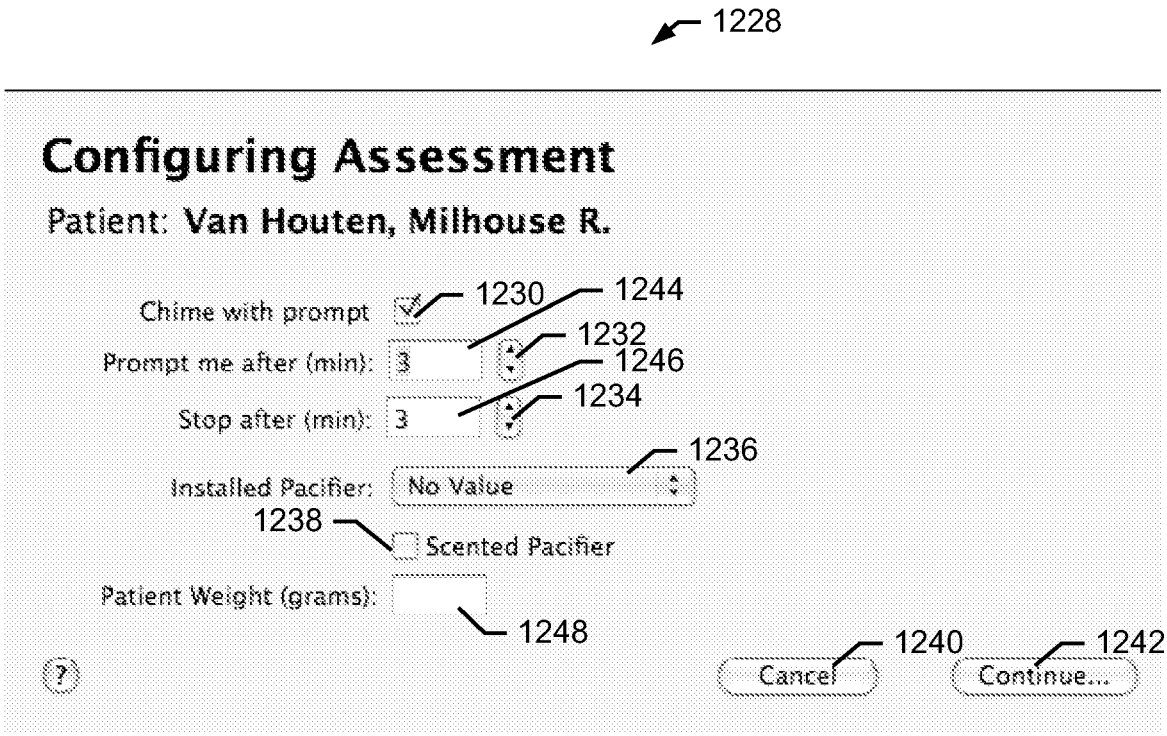

1228
Configuring Assessment
Patient: Van Houten, Milhouse R.
Chime with prompt
1230
1244
Prompt me after (min):
3
1232
1246
Stop after (min):
3
1234
Installed Pacifier:
No Value
1236
1238
Scented Pacifier
Patient Weight (grams):
1248
?
Cancel
1240
Continue...
1242

FIG. 19

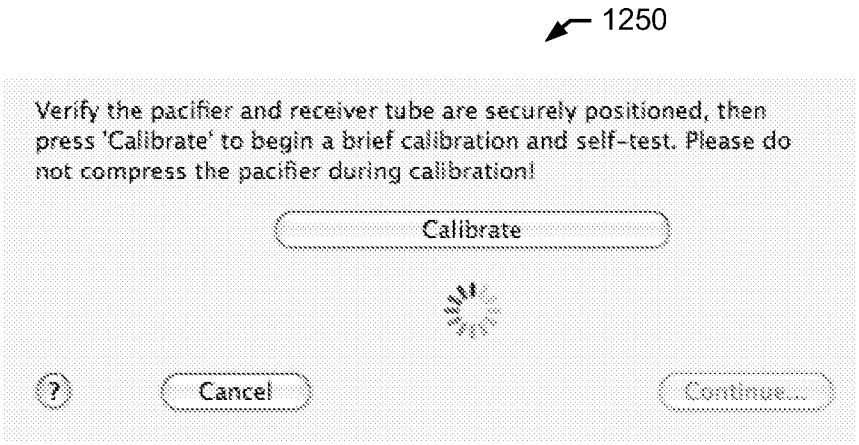

1250
Verify the pacifier and receiver tube are securely positioned, then press 'Calibrate' to begin a brief calibration and self-test. Please do not compress the pacifier during calibration!
Calibrate
Cancel
Continue...

FIG. 20

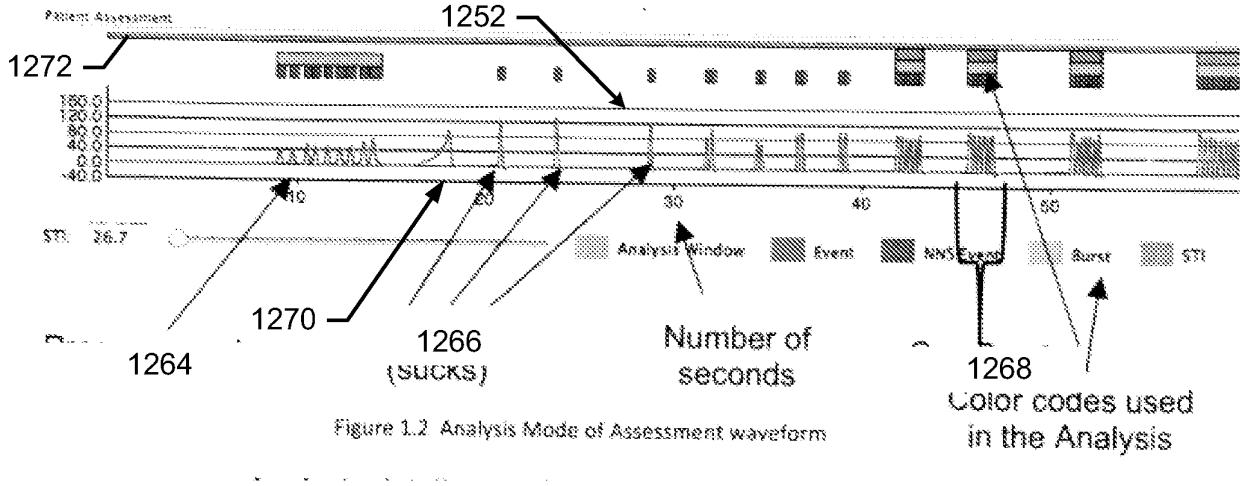

1252
1272
1264
1270
1266
(SUCKS)
Number of seconds
1268
Color codes used in the Analysis
Figure 1.2 Analysis Mode of Assessment waveform

FIG. 21

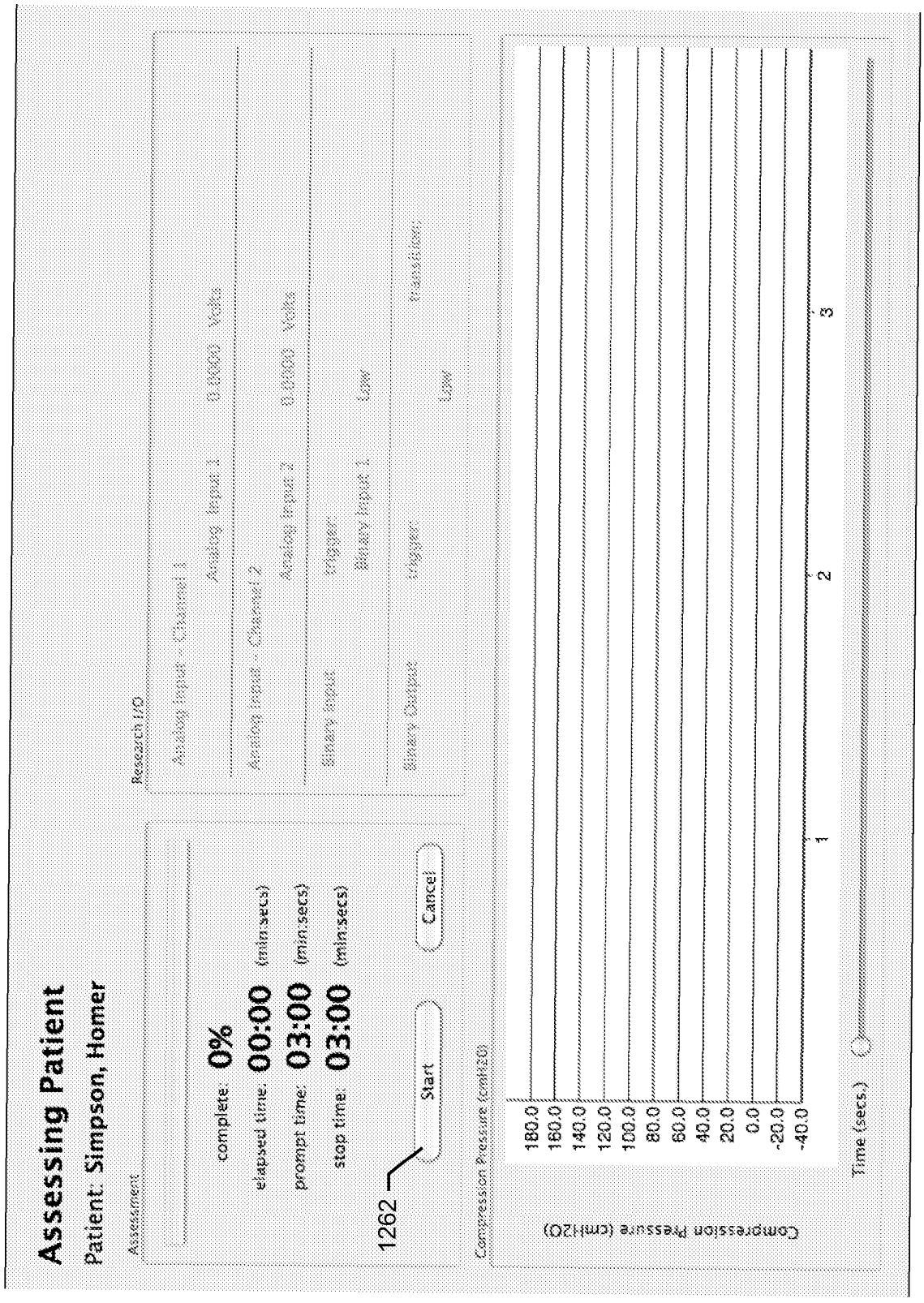

1254
Assessing Patient
Patient: Simpson, Homer
Assessment
complete: 0%
elapsed time: 00:00 (min:secs)
prompt time: 03:00 (min:secs)
stop time: 03:00 (min:secs)
1262
Start
Cancel
Research I/O
Analog Input - Channel 1
Analog Input 1 0.0000 Volts
Analog Input - Channel 2
Analog Input 2 0.0000 Volts
Binary Input
trigger
Binary Input 1 Low
Binary Output
trigger
transition
Low
Compression Pressure (cmH20)
Compression Pressure (cmH2O)
180.0
160.0
140.0
120.0
100.0
80.0
60.0
40.0
20.0
0.0
-20.0
-40.0
1
2
3
Time (secs.)

FIG. 22

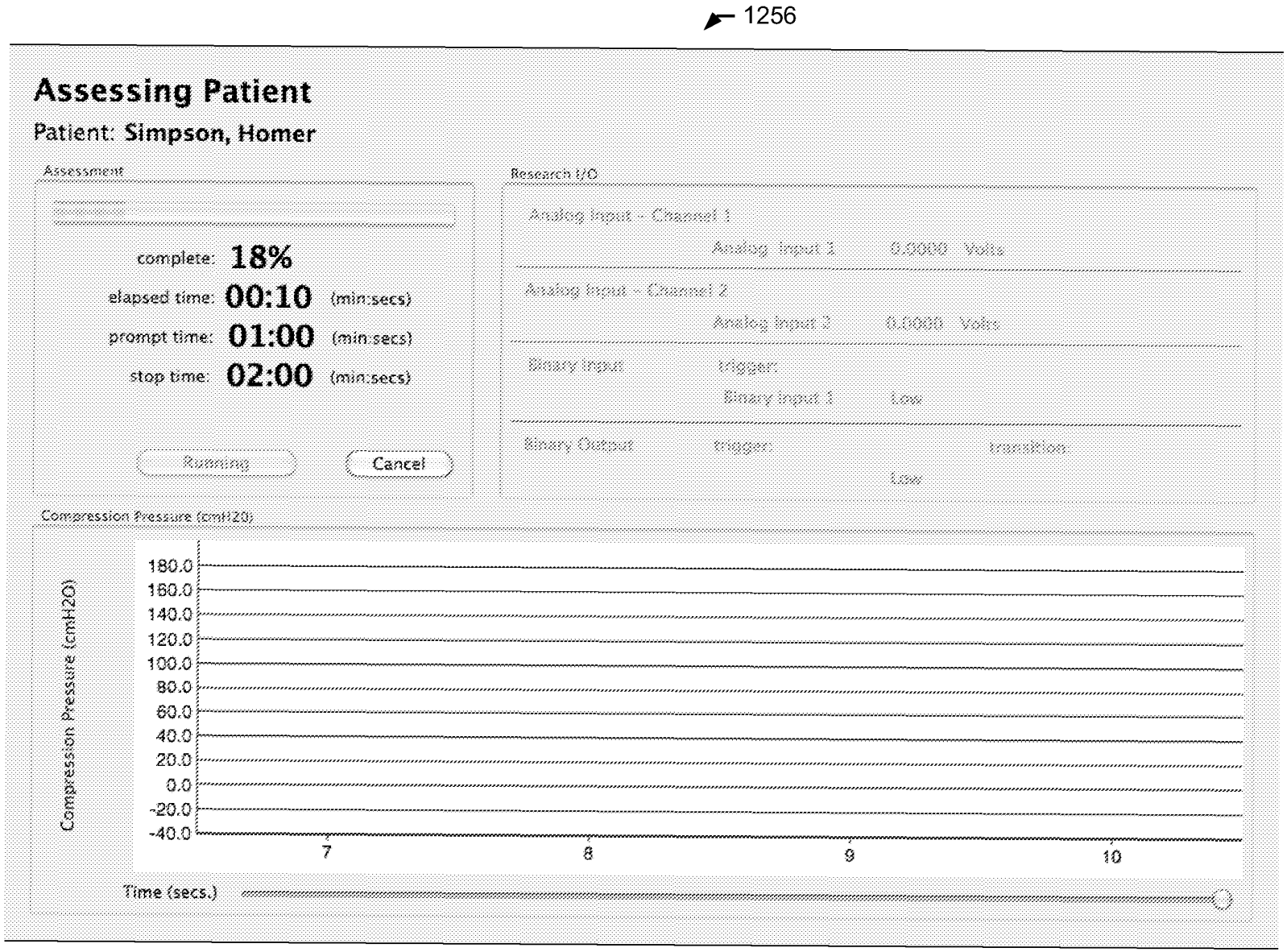

1256
Assessing Patient
Patient: Simpson, Homer
Assessment
complete: 18%
elapsed time: 00:10 (min:secs)
prompt time: 01:00 (min:secs)
stop time: 02:00 (min:secs)
Running
Cancel
Research I/O
Analog Input - Channel 1
Analog Input 1 0.0000 Volts
Analog Input - Channel 2
Analog Input 2 0.0000 Volts
Binary Input trigger:
Binary Input 1 Low
Binary Output trigger: transition:
Low
Compression Pressure (cmH2O)
Compression Pressure (cmH2O)
180.0
160.0
140.0
120.0
100.0
80.0
60.0
40.0
20.0
0.0
-20.0
-40.0
7
8
9
10
Time (secs.)

FIG. 23

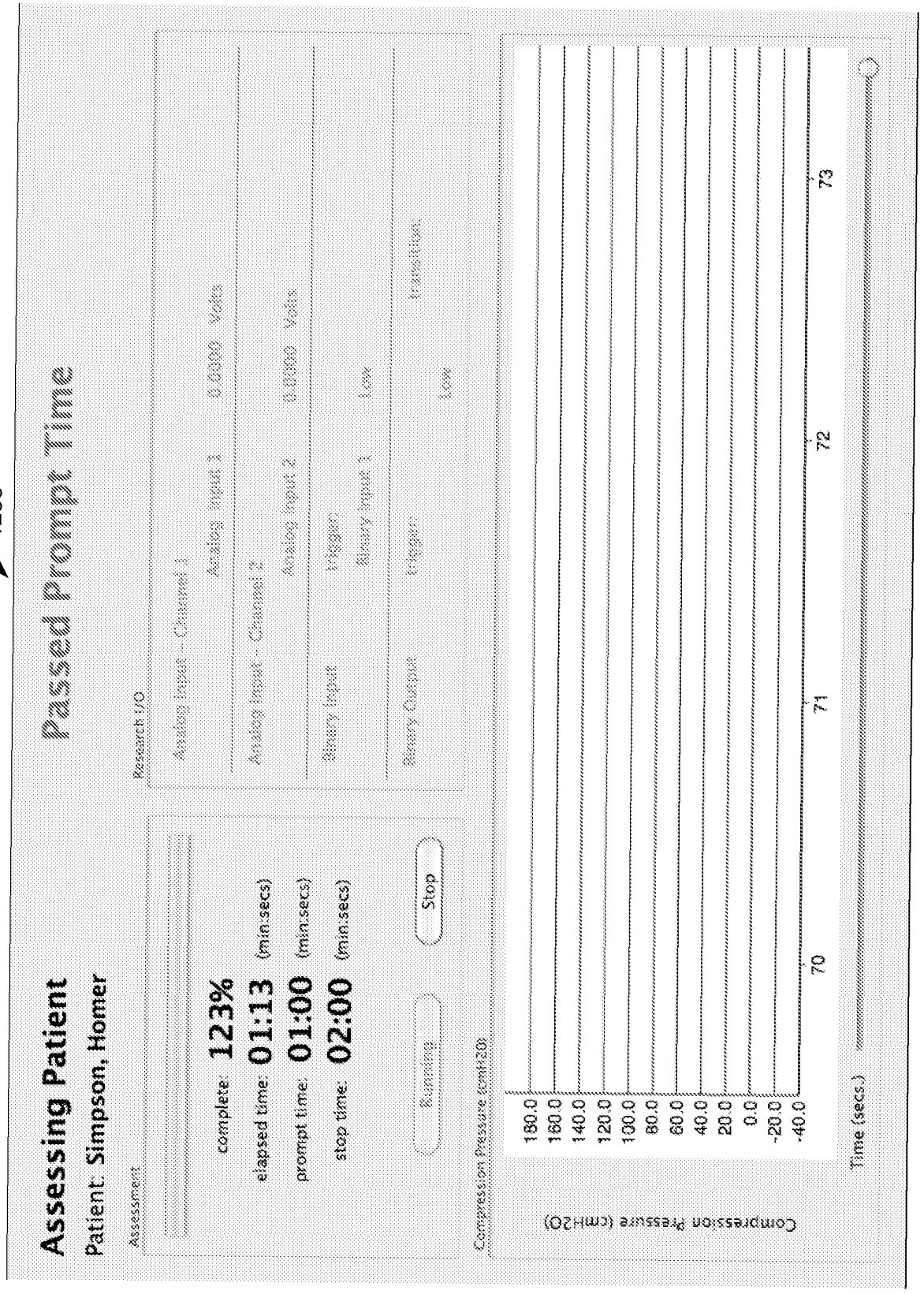

1258
Assessing Patient
Patient: Simpson, Homer
Passed Prompt Time
Assessment
Research I/O
Analog Input - Channel 1
Analog Input 3
0.0000 Volts
Analog Input - Channel 2
Analog Input 2
0.0000 Volts
complete: 123%
elapsed time: 01:13 (min:secs)
prompt time: 01:00 (min:secs)
stop time: 02:00 (min:secs)
Binary Input
trigger
Binary Input 1
Low
Binary Output
trigger
transition
Low
Running
Stop
Compression Pressure (cmH2O)
180.0
160.0
140.0
120.0
100.0
80.0
60.0
40.0
20.0
0.0
-20.0
-40.0
Compression Pressure (cmH2O)
70
71
72
73
Time (secs.)

FIG. 24

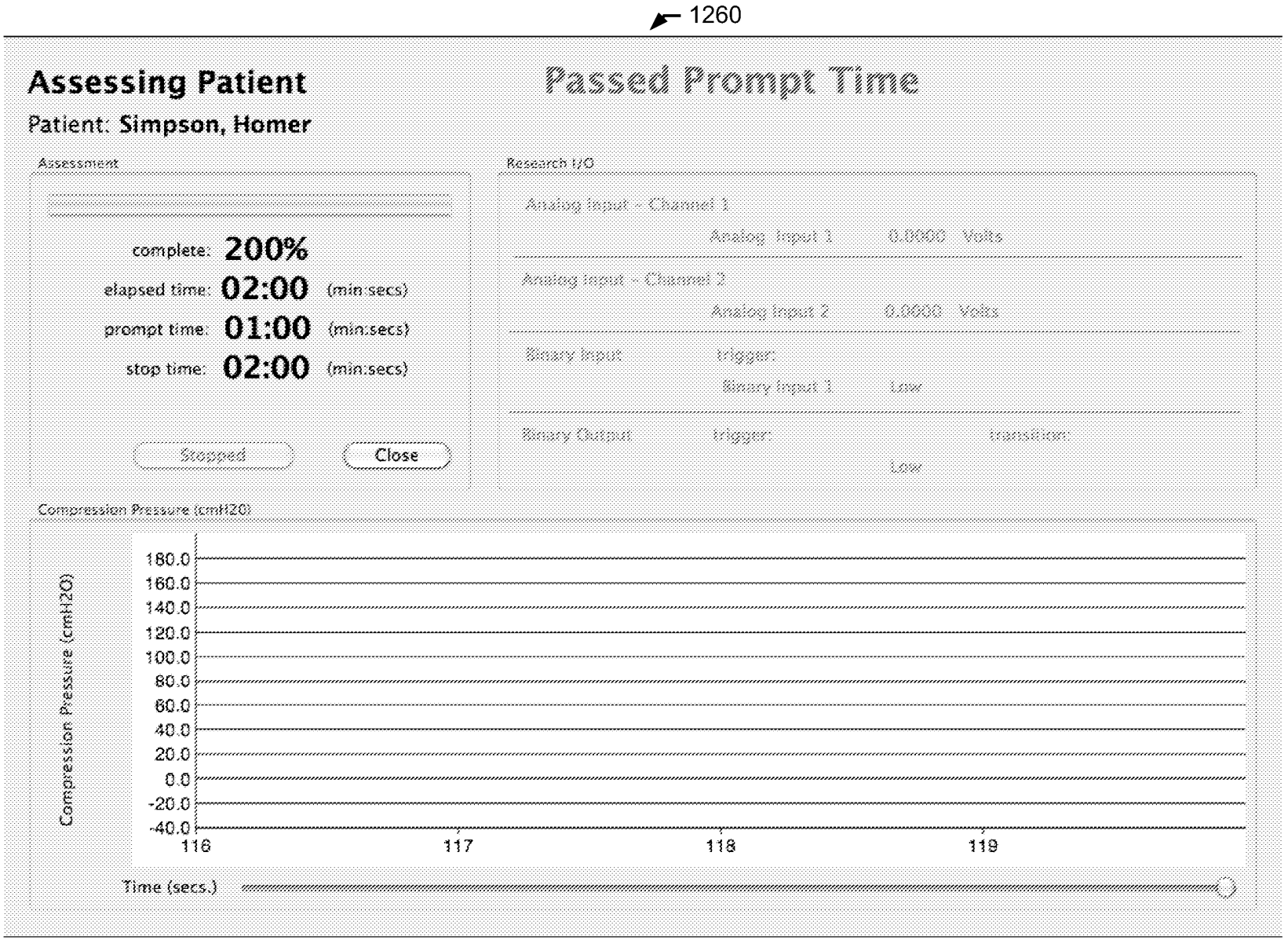

1260
Assessing Patient
Patient: Simpson, Homer
Passed Prompt Time
Assessment
complete: 200%
elapsed time: 02:00 (min:secs)
prompt time: 01:00 (min:secs)
stop time: 02:00 (min:secs)
Stopped
Close
Research I/O
Analog Input - Channel 1
Analog Input 1 0.0000 Volts
Analog Input - Channel 2
Analog Input 2 0.0000 Volts
Binary Input trigger:
Binary Input 1 Low
Binary Output trigger: transition:
Low
Compression Pressure (cmH2O)
Compression Pressure (cmH2O)
180.0
160.0
140.0
120.0
100.0
80.0
60.0
40.0
20.0
0.0
-20.0
-40.0
116
117
118
119
Time (secs.)

FIG. 25


1274
Please describe the dominant patient state for the session
Patient State:
No Value
Please verify that the completed assessment is assigned to the correct patient
correct, assigned to patient: Simpson, Homer
incorrect, reassign to patient
Add optional notes
Ok

FIG. 26

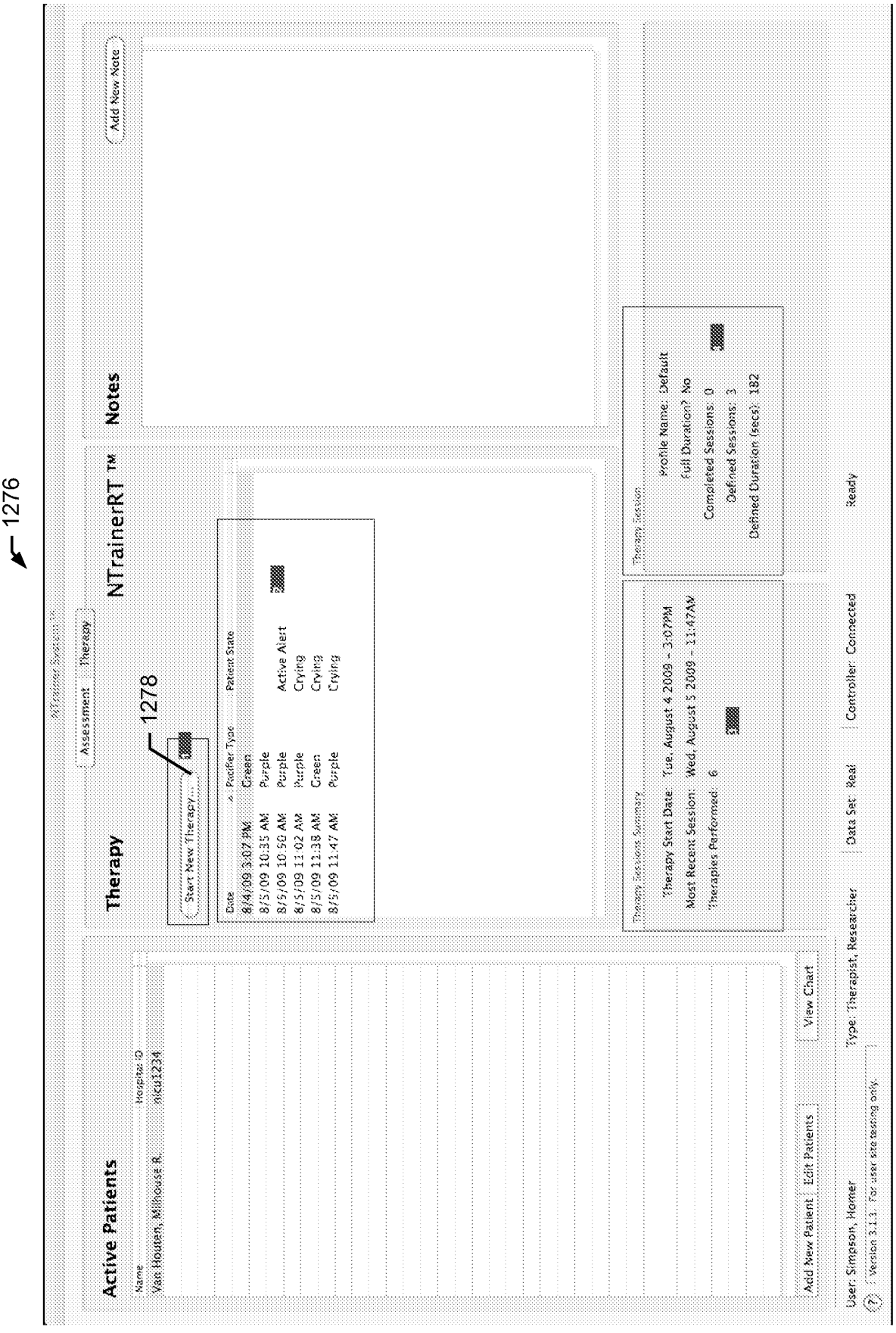

1276
1278
Active Patients
Name
Hospital ID
Van Houten, Millhouse R.
nicu1234
Add New Patient
Edit Patients
View Chart
Therapy
NTrainerRT ™
Assessment
Therapy
Start New Therapy...
Date
Pacifier Type
Patient State
8/4/09 3:07 PM
Green
8/5/09 10:35 AM
Purple
8/5/09 10:50 AM
Purple
Active Alert
8/5/09 11:02 AM
Purple
Crying
8/5/09 11:38 AM
Green
Crying
8/5/09 11:47 AM
Purple
Crying
Therapy Session Summary
Therapy Start Date: Tue, August 4 2009 - 3:07PM
Most Recent Session: Wed, August 5 2009 - 11:47AM
Therapies Performed: 6
Therapy Session
Profile Name: Default
Full Duration? No
Completed Sessions: 0
Defined Sessions: 3
Defined Duration (secs): 182
Notes
Add New Note
User: Simpson, Homer
Type: Therapist, Researcher
Data Set: Read
Controller: Connected
Ready
Version 3.1.1 For user site testing only.

FIG. 27

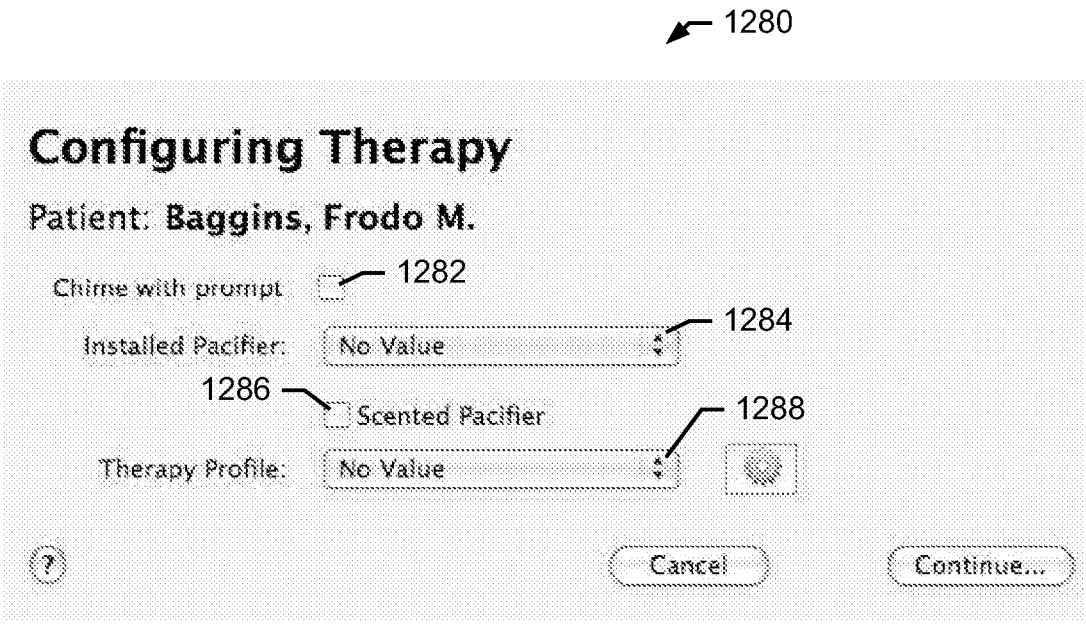

1280
Configuring Therapy
Patient: Baggins, Frodo M.
Chime with prompt
1282
Installed Pacifier:
No Value
1284
1286
Scented Pacifier
1288
Therapy Profile:
No Value
Cancel
Continue...

FIG. 28

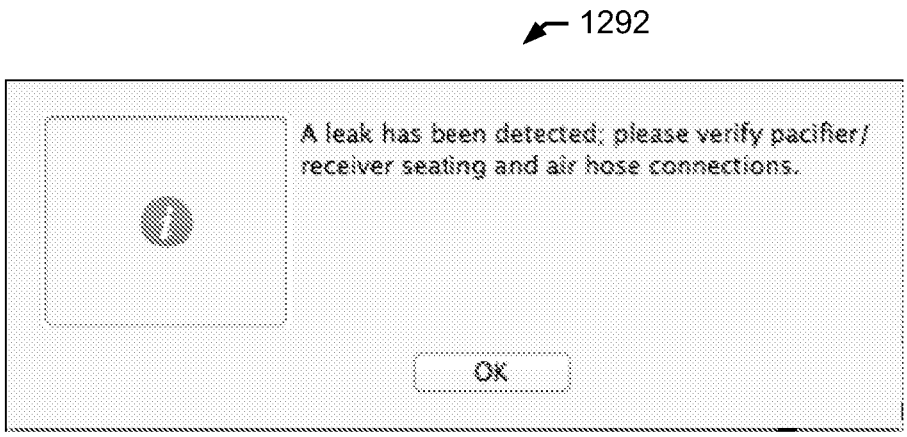

1292
A leak has been detected; please verify pacifier/ receiver seating and air hose connections.
OK

FIG. 30

1290

Performing Patient Therapy

Profile: pre-oral feed short

Patient: Simpson, Bart B.

Therapy Progress

complete: 17%

elapsed time: 00:09 (min:secs)

total time: 00:54 (min:secs)

Pause

Interval Between Therapies

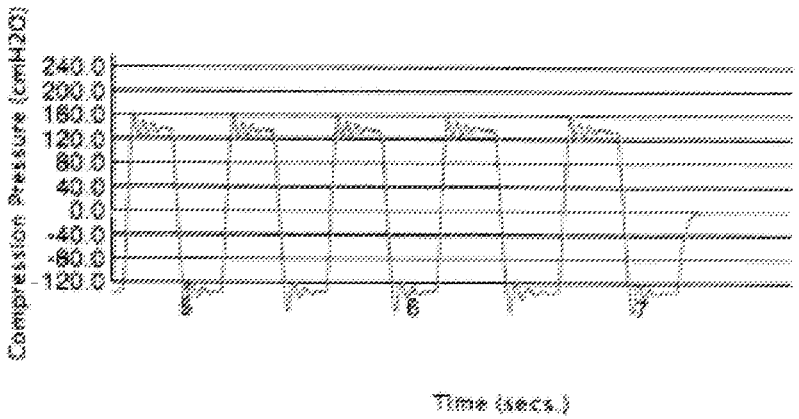
Complete: 0%

Elapsed time: 00:00 (min:secs)

Total time: 05:30 (min:secs)

Completed Sessions:

Completed Sessions: 0 Total Sessions: 1



Research I/O

Analog Input - Channel 1

Analog Input 1 0.3093 Volts

Analog Input - Channel 1

Analog Input 1 0.3093 Volts

Binary Output trigger

Transition:

none

Cancel

FIG. 29

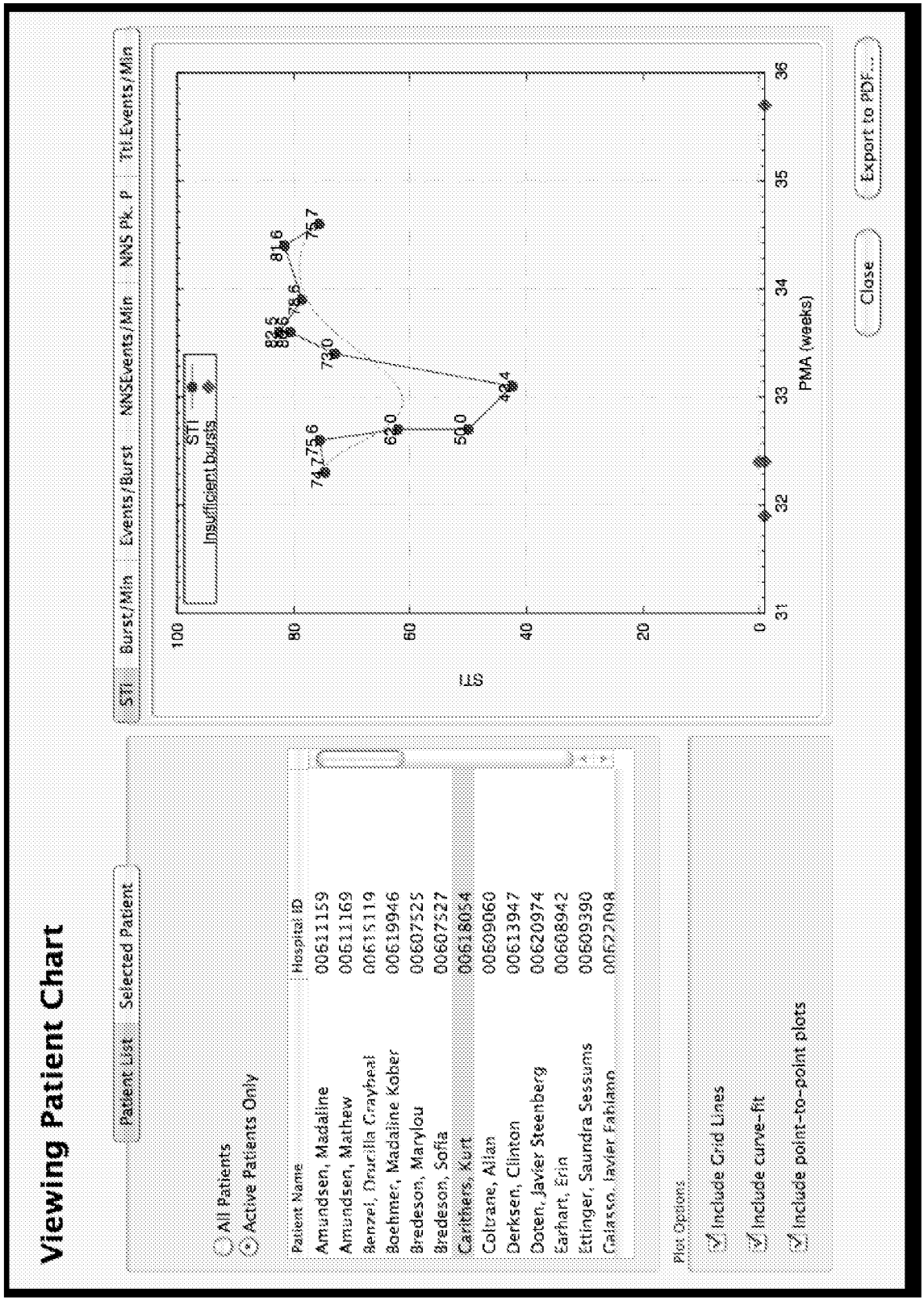

1294
Viewing Patient Chart
Patient List
Selected Patient
All Patients
Active Patients Only
Patient Name
Hospital ID
Amundsen, Madaline 00611159
Amundsen, Mathew 00611169
Benzel, Drucilla Crayhead 00615119
Boehmer, Madaline Kober 00619946
Bredeson, Marylou 00607525
Bredeson, Sofia 00607527
Carithers, Kurt 00618054
Coltrane, Allan 00609060
Derksen, Clinton 00613947
Doten, Javier Steenberg 00620974
Earhart, Erin 00608942
Ettinger, Saundra Sessums 00609390
Galasso, Javier Fabiano 00622098
Plot Options
Include Grid Lines
Include curve-fit
Include point-to-point plots
STI
Burst/Min
Events/Burst
NNSEvents/Min
NNS Pk. P
Tit.Events/Min
STI
Insufficient bursts
100
80
60
40
20
0
31
32
33
34
35
36
PMA (weeks)
Close
Export to PDF...

FIG. 31

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Non-patent literature cited in the description

- **POORE M. ; ZIMMERMAN E. ; BARLOW S.M. ; WANG J. ; GU F.** Patterned orocutaneous therapy improves sucking and oral feeding in preterm infants. *Acta Paediatrica,* 2008, vol. 97, 920-927 **[0007]**
- **FINAN D.S ; BARLOW S.M.** A Device for Neuro-physiological Studies of Orofacial Control in Human Infants. *Journal of Speech and Hearing Research,* 1996, vol. 39, 833-838 **[0008]**

专利名称(译)	增强对非营养性吸吮夹带系统和方法的治疗刺激		
公开(公告)号	EP2840969A1	公开(公告)日	2015-03-04
申请号	EP2013780650	申请日	2013-04-26
[标]申请(专利权)人(译)	新KCBX 堪萨斯大学		
申请(专利权)人(译)	新KCBX INC. 堪萨斯大学		
当前申请(专利权)人(译)	新KCBX INC. 堪萨斯大学		
[标]发明人	BARLOW STEVEN M STALLING DAVID L ARON KENNETH		
发明人	BARLOW, STEVEN M. STALLING, DAVID L. ARON, KENNETH		
IPC分类号	A61B5/11 A61B5/00 A61B5/03 A61H7/00 A61H39/00 A61M21/00 G16H15/00 G16H40/40 G16H40/63		
CPC分类号	A61B5/038 A61B5/4836 A61B5/486 A61B5/682 A61B5/6896 A61B5/7435 A61B2503/045 G06F19/3481 G16H15/00 G16H40/40 G16H40/63		
优先权	13/457203 2012-04-26 US		
其他公开文献	EP2840969A4 EP2840969B1		
外部链接	Espacenet		

摘要(译)

本发明涉及一种系统和使用该系统的方法。 特别地，本发明涉及一种可由处理设备执行的应用，以评估患者的非营养性吮吸（NNS）模式的组织并在患者体内携带有组织的NNS模式。 该软件系统从口腔刺激设备接收数据以评估患者的自然NNS模式，并生成一个精确的治疗脉冲图，通过口腔刺激设备将其作为触觉刺激进行激活，以带走有组织的NNS模式。