



US009037266B2

(12) **United States Patent**
Barlow et al.

(10) **Patent No.:** **US 9,037,266 B2**
(45) **Date of Patent:** **May 19, 2015**

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

(75) Inventors: **Steven M. Barlow**, Lawrence, KS (US);
David L. Stalling, Shawnee, KS (US);
Kenneth Aron, Shawnee, KS (US)

(73) Assignee: **Innara Health, Inc.**, Olathe, KS (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 505 days.

(21) Appl. No.: **13/457,203**

(22) Filed: **Apr. 26, 2012**

(65) **Prior Publication Data**
US 2012/0209148 A1 Aug. 16, 2012

Related U.S. Application Data

(63) Continuation-in-part of application No. 12/390,142, filed on Feb. 20, 2009, now Pat. No. 8,226,579.

(60) Provisional application No. 61/036,304, filed on Mar. 13, 2008, provisional application No. 61/030,484, filed on Feb. 21, 2008.

(51) **Int. Cl.**
A61N 1/00 (2006.01)
A61B 5/03 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC **A61B 5/038** (2013.01); **A61B 5/486** (2013.01); **A61B 5/682** (2013.01); **A61B 5/6896** (2013.01); **A61H 23/02** (2013.01); **A61H 2201/5005** (2013.01); **A61H 2201/5007** (2013.01); **A61H 2201/5071** (2013.01); **A61H 2205/022** (2013.01)

(58) **Field of Classification Search**
CPC . A61N 1/0548; A61N 1/3601; A61N 1/3611; A61N 1/3605
USPC 607/134, 142; 600/590
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,232,687 A 11/1980 Anderson-Shanklin
5,830,235 A 11/1998 Standley
6,033,367 A 3/2000 Goldfield
(Continued)

FOREIGN PATENT DOCUMENTS

CN 101080195 B1 11/2012
EP 1786319 B1 10/2012

(Continued)

OTHER PUBLICATIONS

Barlow et al, "Synthetic orocutaneous stimulation entrains preterm infants with feeding difficulties to suck." J Perinatol, 2008, pp. 541-548, vol. 28, No. 8.

(Continued)

Primary Examiner — Christopher D Koharski

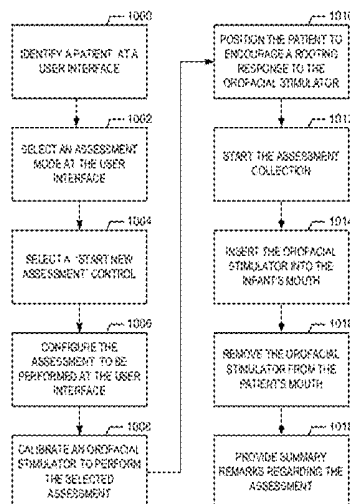
Assistant Examiner — Philip Edwards

(74) *Attorney, Agent, or Firm* — Polsinelli PC

(57) **ABSTRACT**

The present invention relates to a system and method for using the system. In particular, the present invention relates to an application, executable by a processing device to assess the organization of a non-nutritive suck (NNS) pattern of a patient and to entrain an organized NNS pattern in the patient. The software system receives data from an orofacial stimulation appliance to assess the patient's natural NNS pattern and generates a precise therapeutic pulse profile that is actuated as a tactile stimulus via the orofacial stimulation appliance to entrain an organized NNS pattern.

46 Claims, 22 Drawing Sheets



- (51) **Int. Cl.**
A61B 5/00 (2006.01)
A61H 23/02 (2006.01)

(56) **References Cited**

U.S. PATENT DOCUMENTS

7,435,232	B2	10/2008	Liebschner
7,917,201	B2	3/2011	Gozani et al.
8,157,731	B2	4/2012	Teller et al.
8,226,579	B2	7/2012	Barlow et al.
8,251,926	B2	8/2012	Barlow et al.
2004/0019382	A1	1/2004	Amirouche et al.
2006/0074354	A1	4/2006	Barlow et al.
2006/0079814	A1	4/2006	Barlow et al.
2009/0156967	A1	6/2009	Cohen
2009/0222214	A1	9/2009	Barlow et al.
2010/0075285	A1	3/2010	Stalling et al.
2011/0060252	A1	3/2011	Simonsen et al.

FOREIGN PATENT DOCUMENTS

GB	1206014	A	9/1970
WO	2006026623	A2	3/2006
WO	2006081376	A1	8/2006
WO	2008067607	A1	6/2008

OTHER PUBLICATIONS

Barlow et al, "Mechanically evoked perioral reflexes in infants." *Brain Res.*, 1992, pp. 158-160, vol. 599, No. 1.

Finan et al, "The actifier: a device for neurophysiological studies of orofacial control in human infants." *J Speech Hear Res*, 1996, pp. 833-838, vol. 39, No. 4.

Chinese Application Serial No. 200910008046.7, Response filed Apr. 28, 2012 to Office Action mailed Dec. 13, 2011, 4 pgs.

Chinese Application Serial No. 200910008046.7, Office Action mailed Dec. 13, 2011, 5 pgs.

European Application Serial No. 09250464.6, Office Action mailed Mar. 22, 2012, 11 pgs.

Estep et al., "Non-Nutritive Suck Parameter in Preterm Infants with RDS." *J Neonatal Nurs*, 2008, pp. 28-34, vol. 14, No. 1.

Poore et al., "Respiratory treatment history predicts suck pattern stability in preterm infants." *J Neonatal Nurs*, 2008, pp. 185-192, vol. 14, No. 6.

Popescu et al., "Non-nutritive sucking recorded in utero via fetal magnetography." *Physiol Meas*, 2008, pp. 127-139, vol. 29, No. 1.

Stumm et al., "Respiratory Distress Syndrome Degrades the Fine Structure of the Non-Nutritive Suck in Preterm Infants." *J Neonatal Nurs*, 2008, pp. 9-16, vol. 14, No. 1.

Vantipalli et al.; Somatosensory entrainment of suck in preterm infants: NTrainer CNL Technical Research Report; 2006; 3:1-23 entire document.

Goldfield et al.; "Coordination of Sucking, Swallowing, and Breathing and Oxygen Saturation During Early Infant Breast-feeding and Bottle-feeding"; *Pediatric Research*; vol. 60; No. 4; pp. 450-455; Oct. 2006.

PCT/US2013/038405 International Search Report and Written Opinion mailed Jul. 11, 2013; (10 pages).

PCT/US2013/038410 International Search Report and Written Opinion mailed Jul. 15, 2013 (8 pages).

PCT/US13/38400 International Search Report and Written Opinion mailed Jul. 19, 2013 (15 pages).

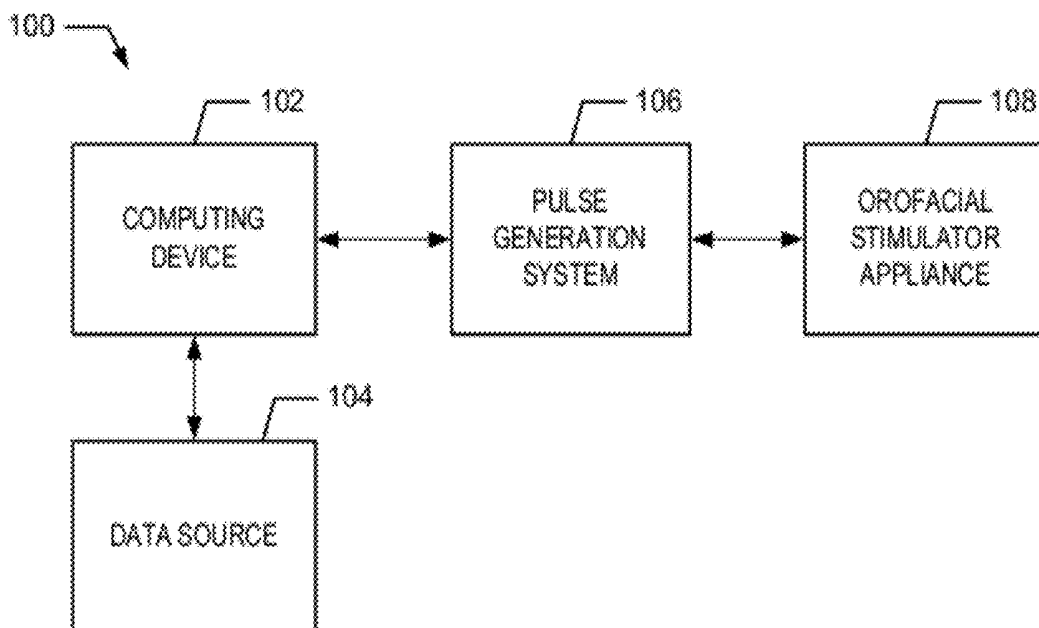


FIG. 1

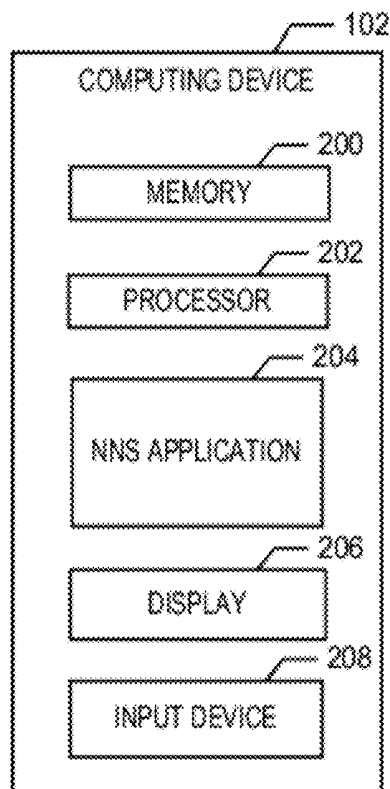


FIG. 2

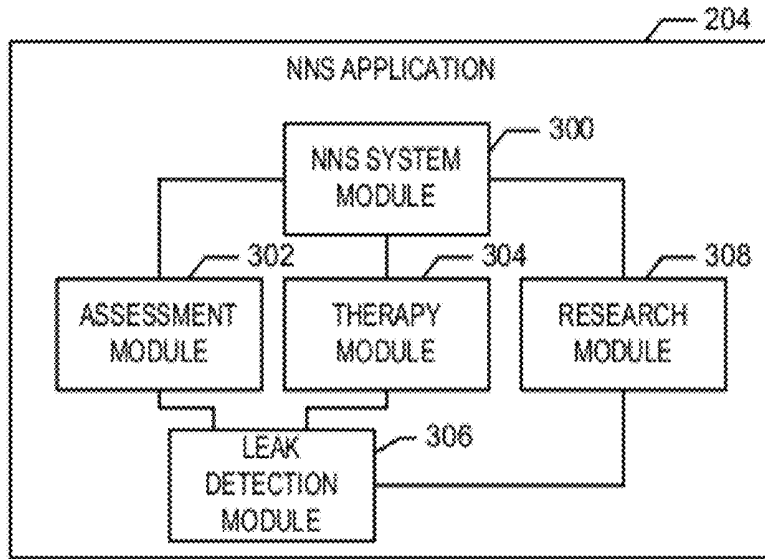


FIG. 3

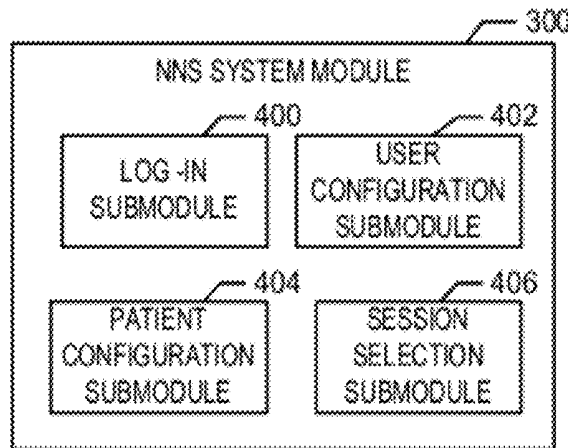


FIG. 4

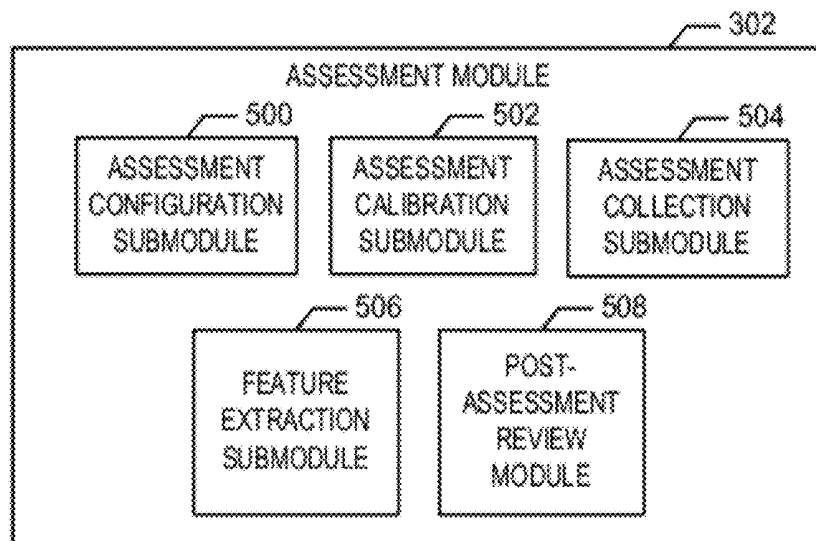


FIG. 5

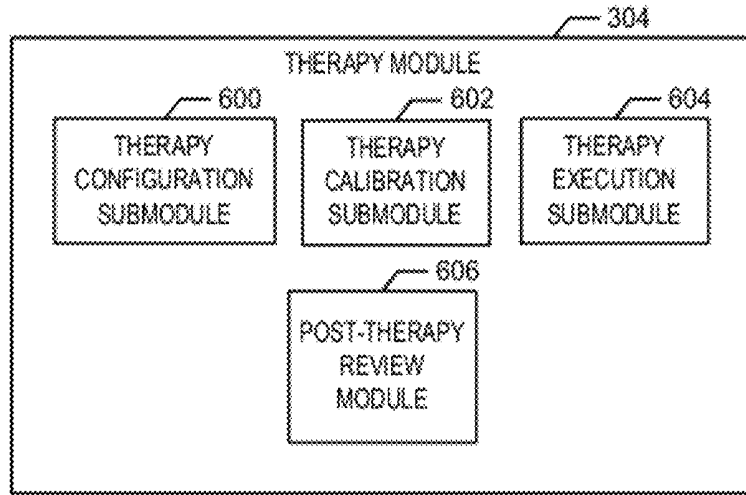


FIG. 6

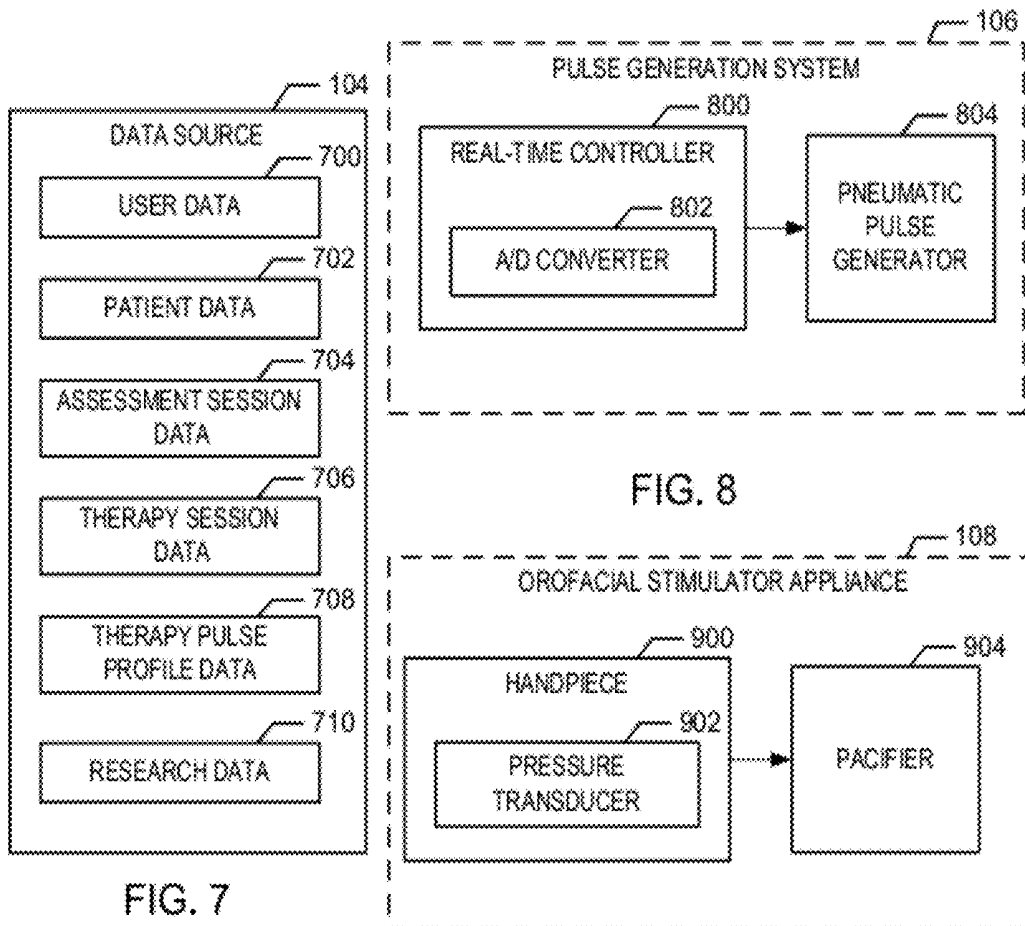


FIG. 8

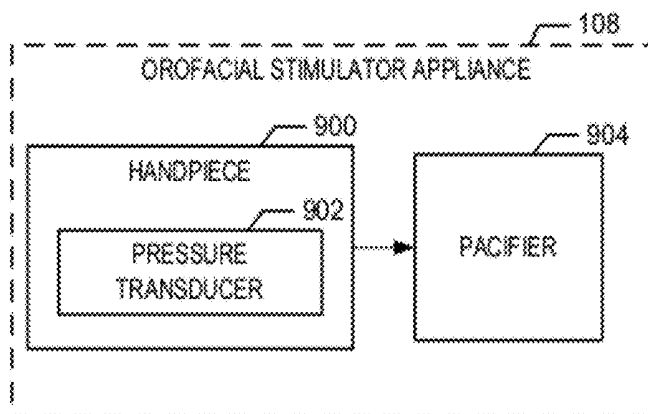


FIG. 9

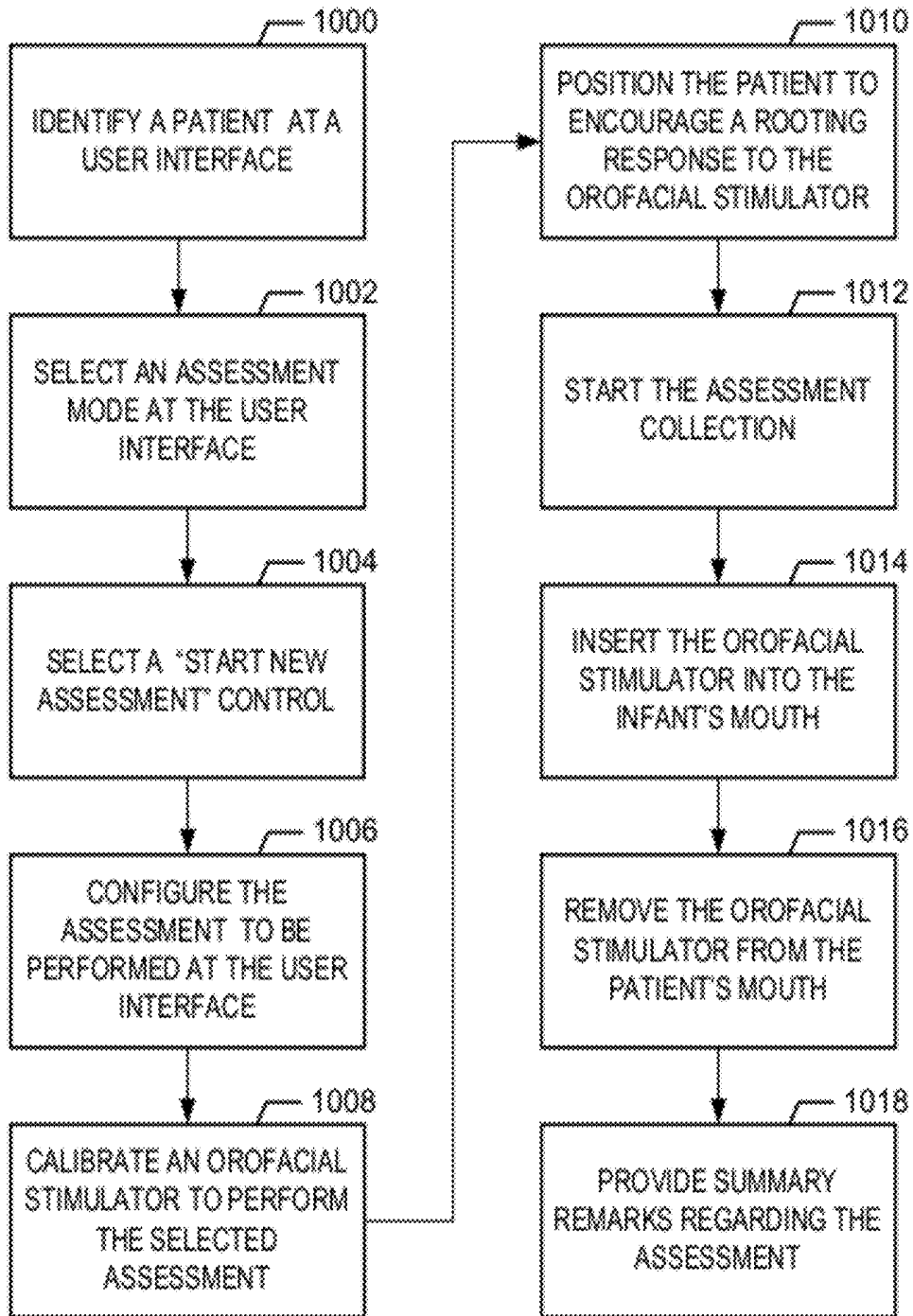


FIG. 10

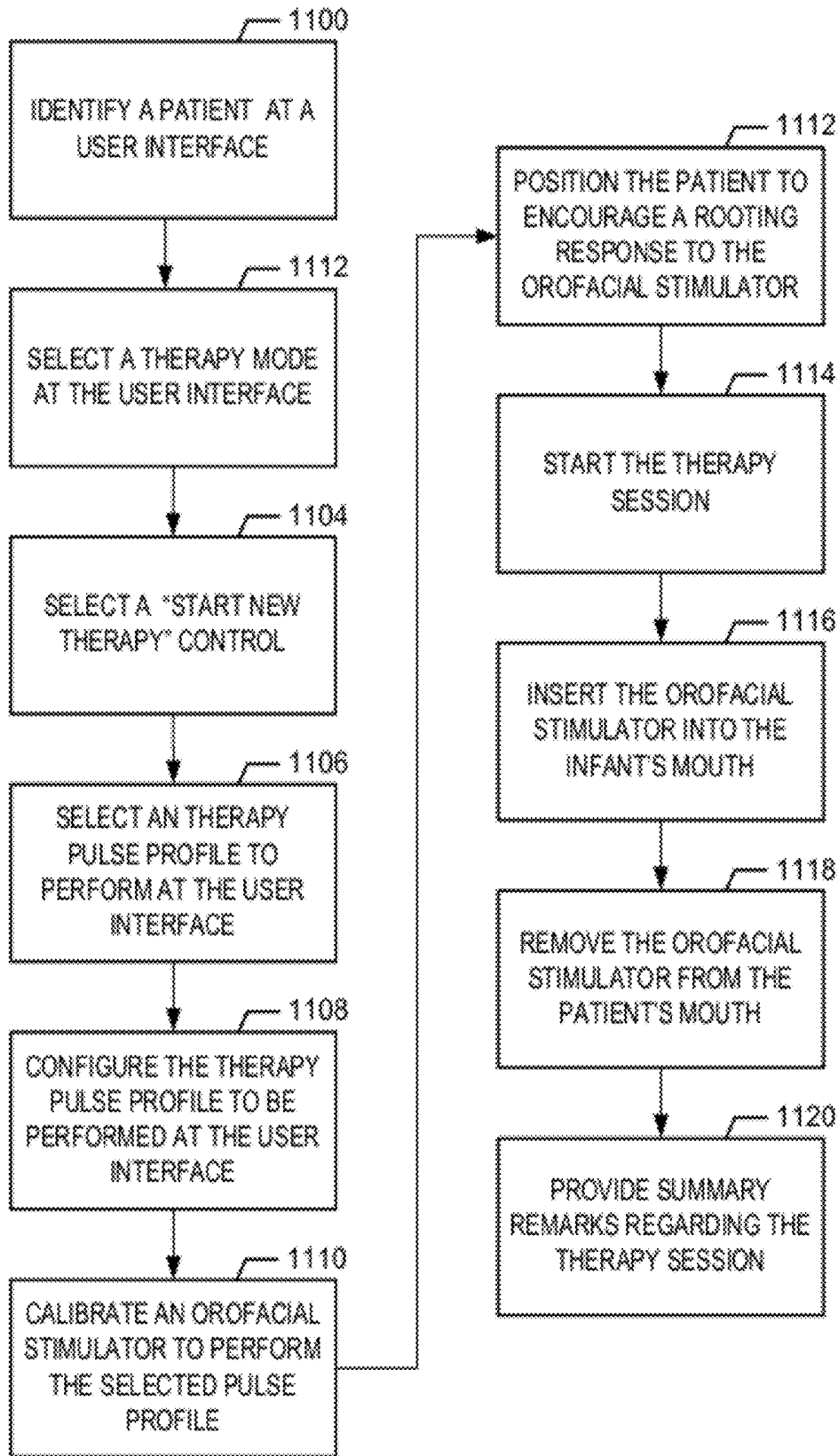


FIG. 11

User Login : Entering Password ↖ 1202

User: Simpson, Homer

Password:

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

FIG. 14

1206

The screenshot shows a web application interface titled "Editing Users". On the left, there is a table with columns: "Lock", "User Name", "Admin", "Super", "Therapist", and "Trainer". The table contains three rows: "Katharina, Katharina", "Stephan, Trainer", and "Therapist, A". The "Therapist, A" row is selected. Below the table is a large empty text area. On the right, there is a form for editing the selected user. The form is divided into sections: "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), and "Lock Account" (checked). At the bottom right are "Cancel" and "Save" buttons.

Lock	User Name	Admin	Super	Therapist	Trainer
<input type="checkbox"/>	Katharina, Katharina	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Stephan, Trainer	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	Therapist, A	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Hospital ID	Birthdate	GA at Birth
<input type="text"/>	11/11/1111	<input type="text"/> weeks <input type="text"/> days

Primary Clinician	Weight (grams)	Gender
<unknown>	<input type="text"/>	<input type="radio"/> Male <input type="radio"/> Female

Assessment Schedule	Therapy Schedule
<input type="text"/> Assessments / week	<input type="text"/> Therapies / day
<input type="text"/> Number of weeks	<input type="text"/> Number of weeks
<input type="text"/> Number of sessions	<input type="text"/> Number of sessions

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>	<input checked="" type="radio"/> Male <input type="radio"/> Female	

Assessment Schedule		Therapy Schedule	
0 Assessments / week	0 Therapies / day	0 Number of weeks	0 Number of sessions
0 Number of weeks			
0 Number of sessions			

? Cancel Save

FIG. 17

1212

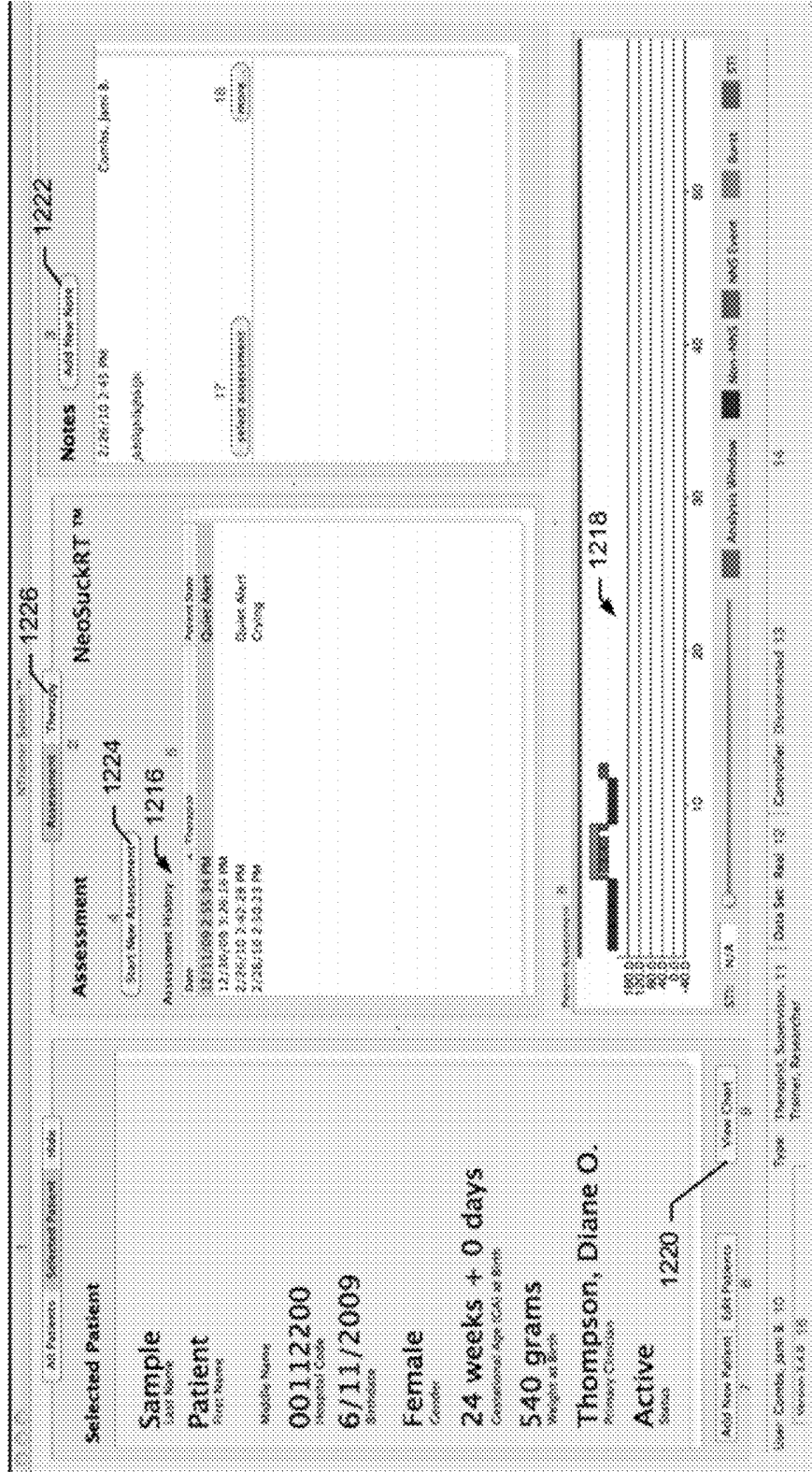


FIG. 18

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

1240 1242

1228

FIG. 19

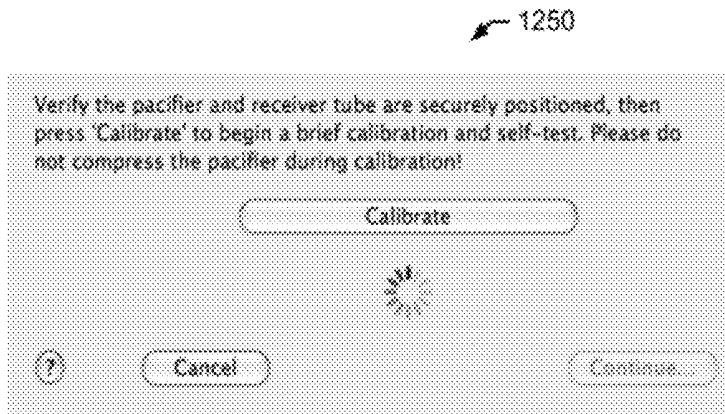


FIG. 20

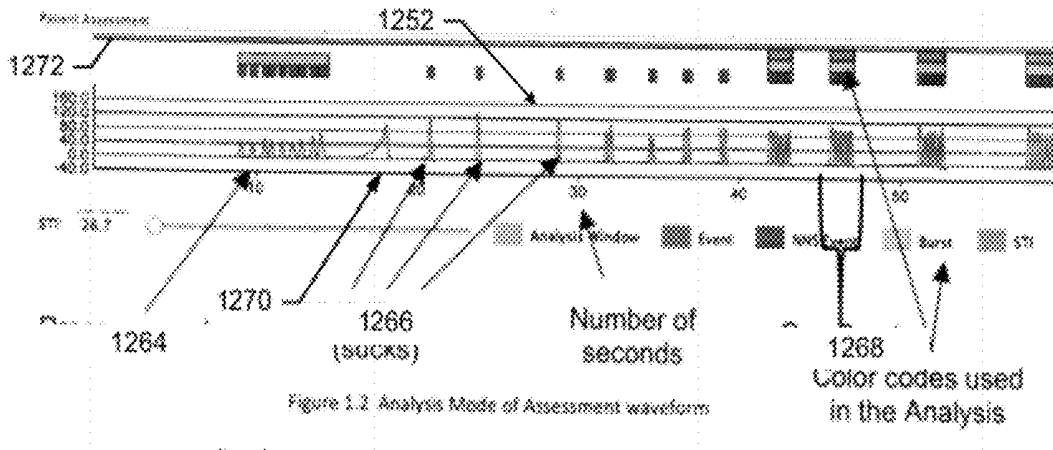


FIG. 21

1254

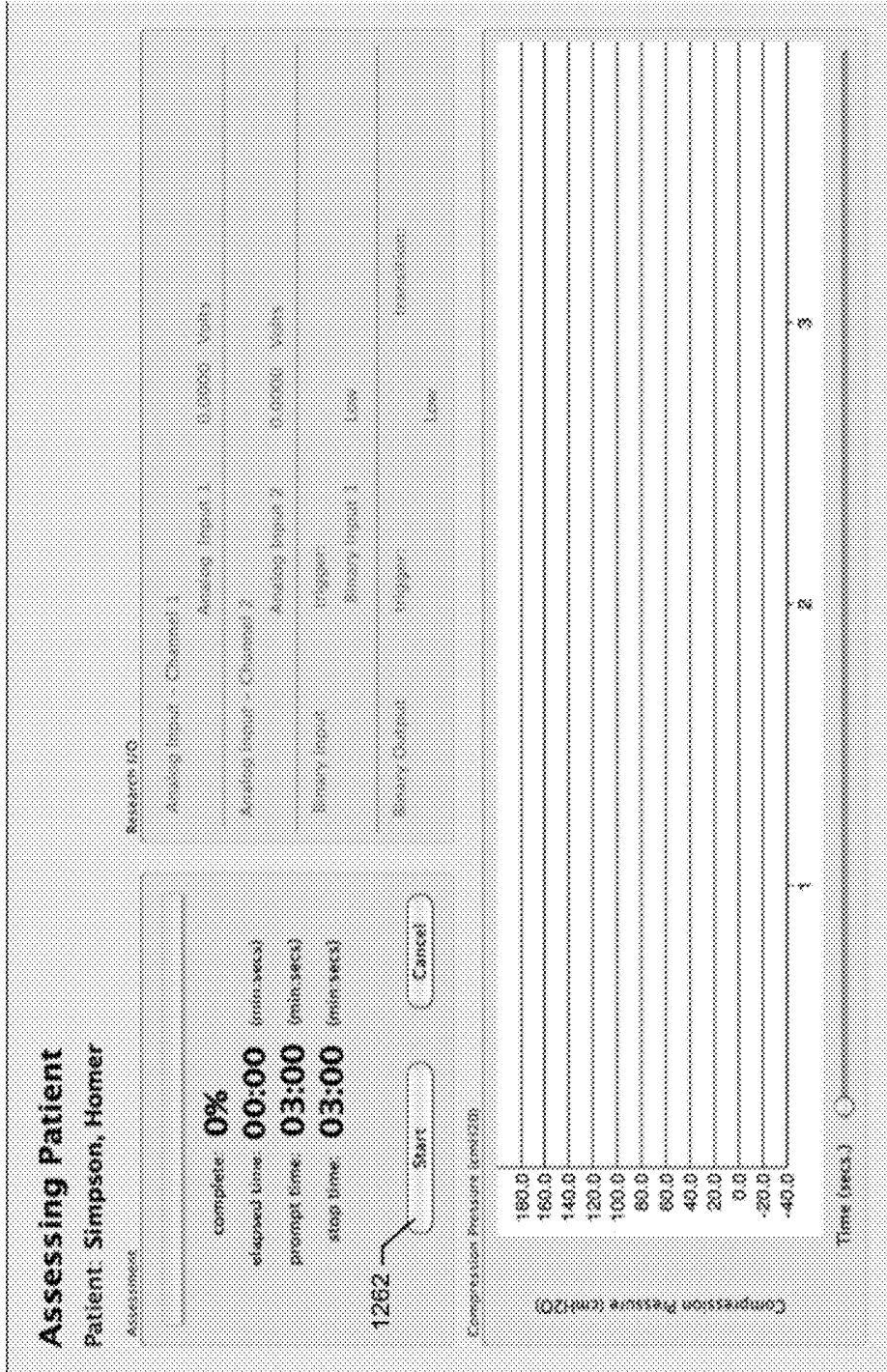


FIG. 22

1256

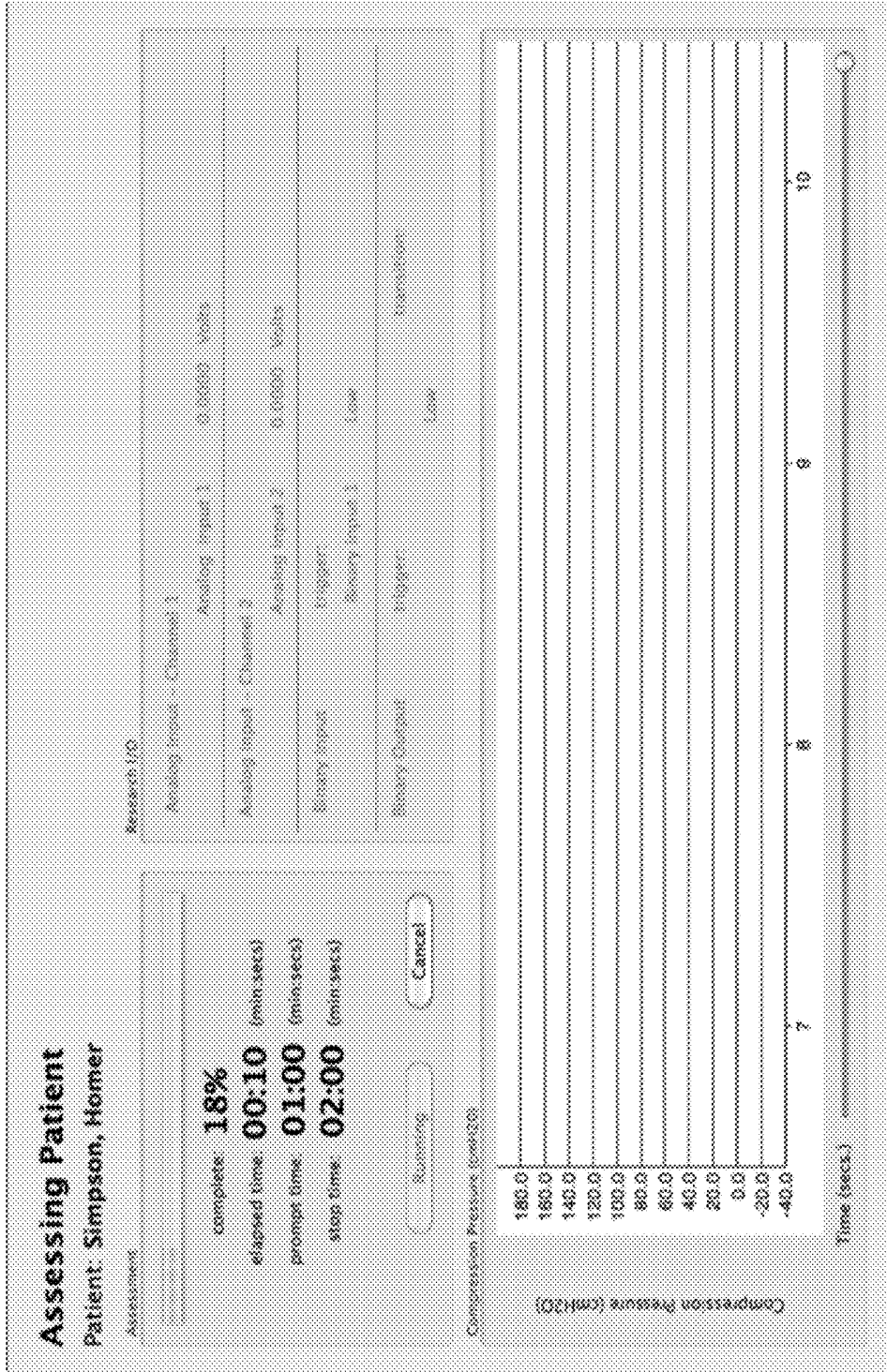


FIG. 23

1258

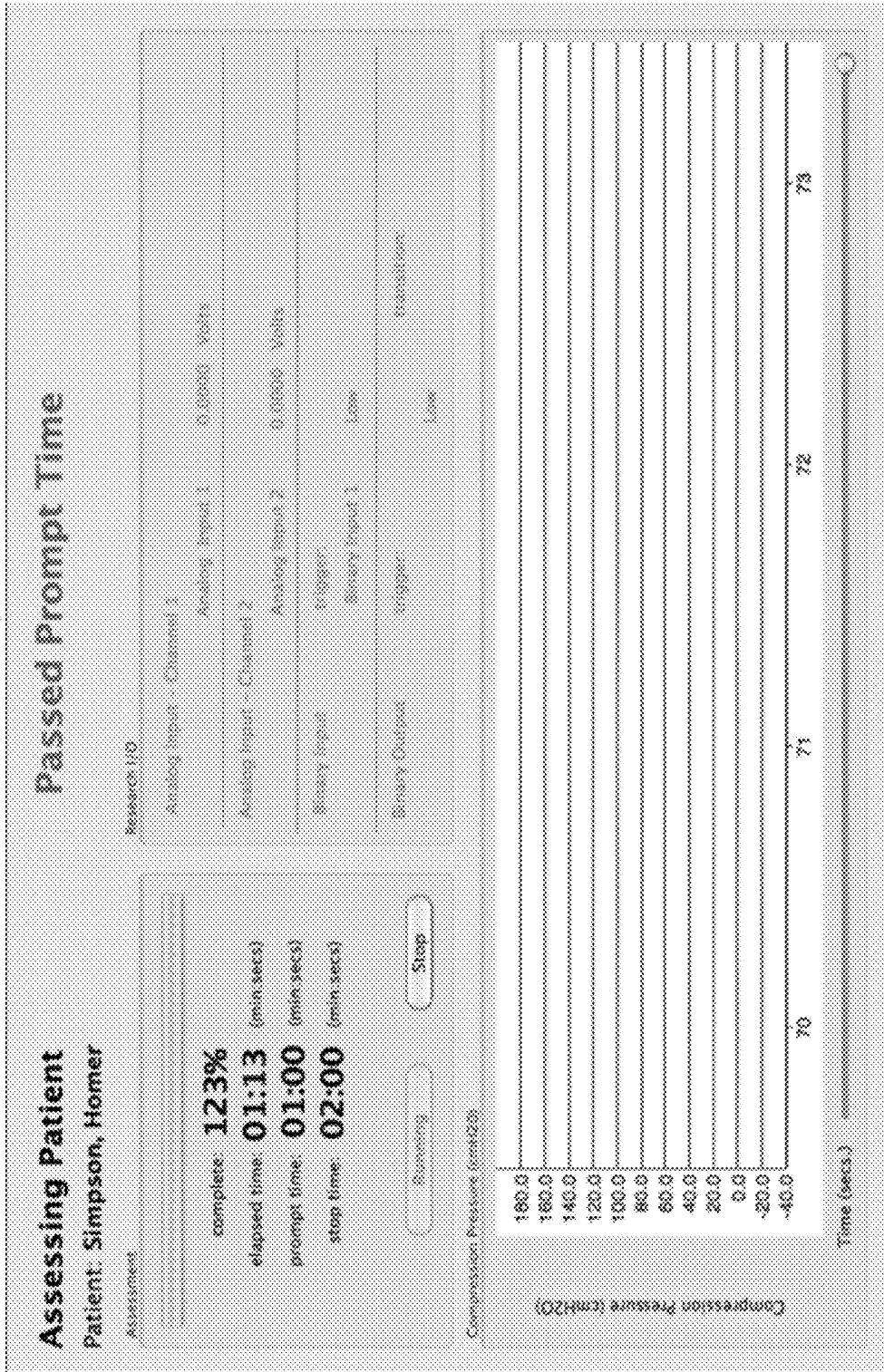


FIG. 24

1260

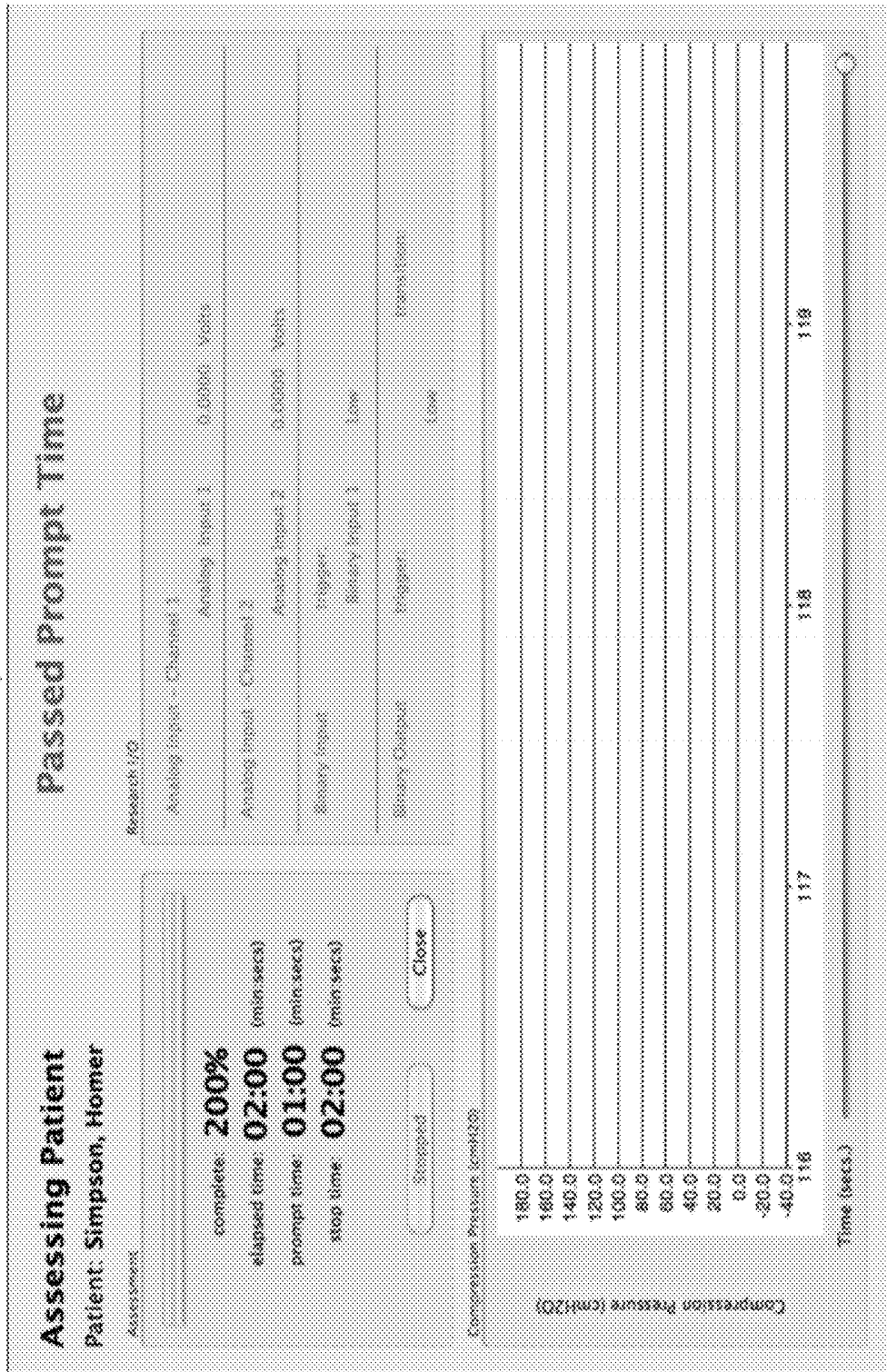


FIG. 25

1274

Please describe the dominant patient state for the session

Patient State:

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

1280

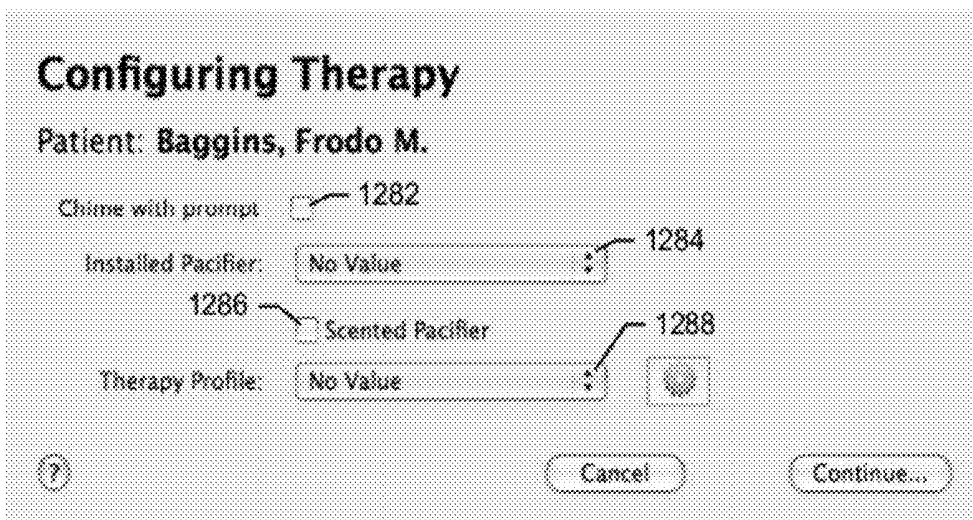


FIG. 28

1292

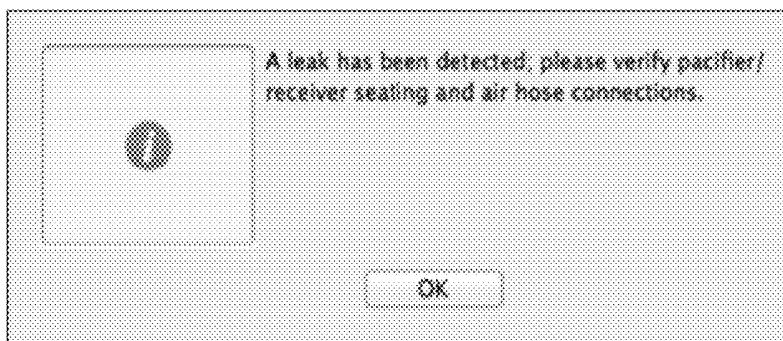


FIG. 30

1290

Performing Patient Therapy

Profile: pre-oral feed short

Patient: Simpson, Bart B.

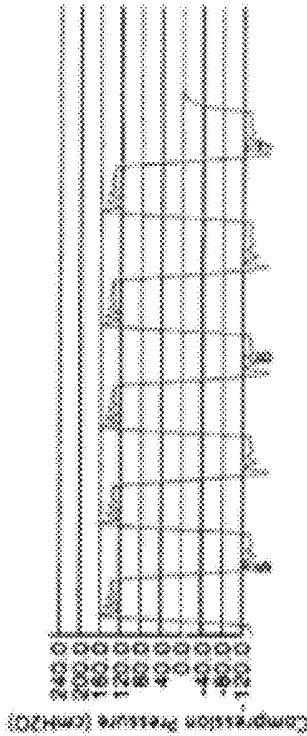
Therapy Progress

complete: **17%**

elapsed time: **00:09** (min:secs)

total time: **00:54** (min:secs)

Pause



Internal Research Therapy

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

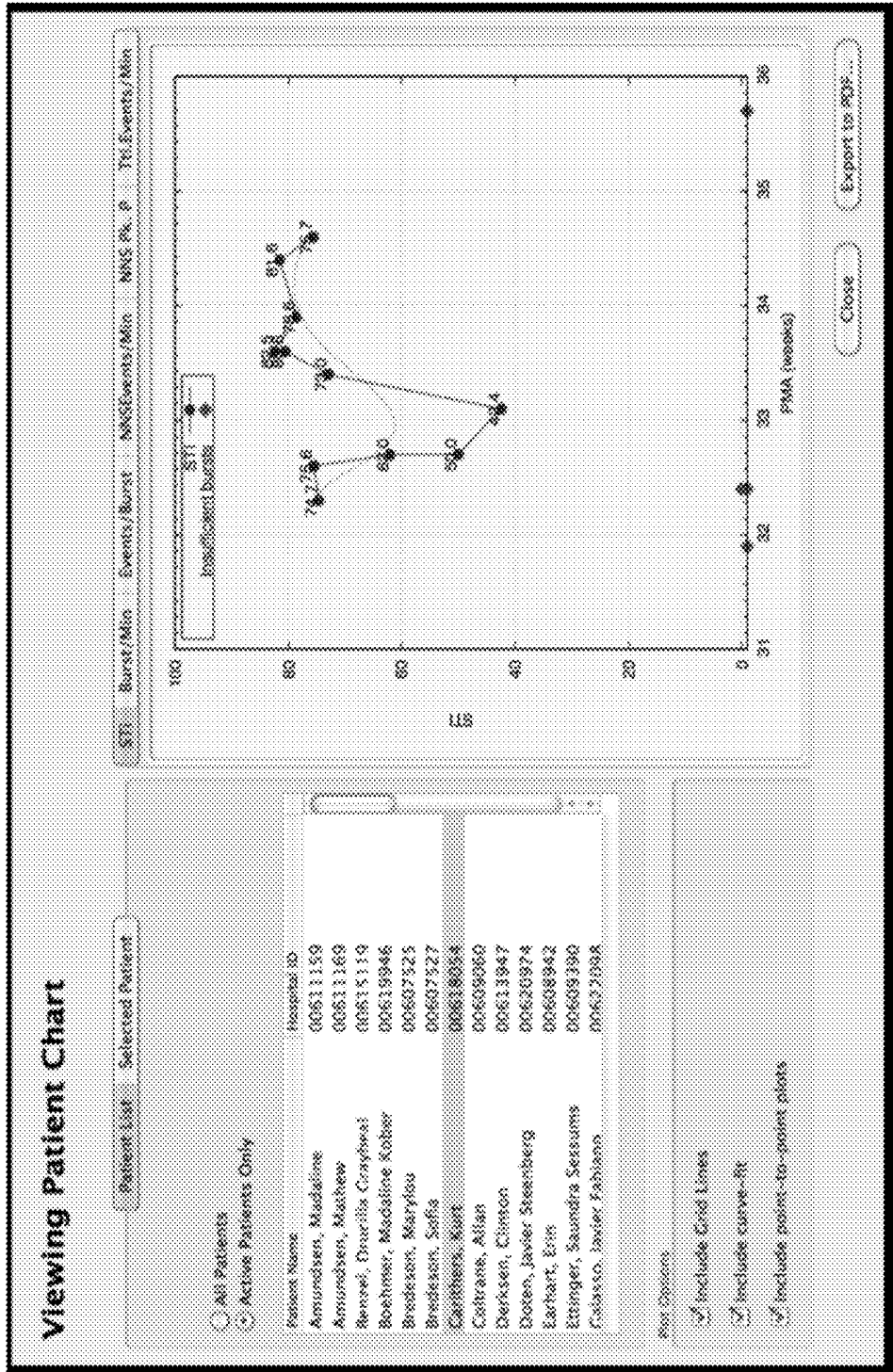


FIG. 31

ENHANCED THERAPEUTIC STIMULUS FOR NON-NUTRITIVE SUCK ENTRAINMENT SYSTEM AND METHOD

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 12/390,142, entitled "Method and Apparatus for Measuring Non-Nutritive Suck Pattern Stability" filed on Feb. 20, 2009, which claims priority to U.S. Provisional Application No. 61/036,304 filed on Mar. 13, 2008 and U.S. Provisional Application No. 61/030,484 filed on Feb. 21, 2008, all of which are incorporated by reference in their entireties.

FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

This 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

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

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.

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.

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.

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.

SUMMARY OF THE INVENTION

The present invention relates to a system and method 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.

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.

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.

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 $\frac{1}{2}$. The pressure transducer generates an analog pressure signal in response to pressure applied to the orofacial stimulator appliance.

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 spa-

tiotemporal 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.

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.

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. The present invention also relates methods of using the software system. Related objects and advantages of the present invention will be apparent from the following description.

DESCRIPTION OF FIGURES

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

The present invention relates to a system for assessing and the neural entrainment of a Non-Nutritive Suck (NNS) pattern in a patient. Typically, the patient is a premature infant; however, the system may also be used for patients unable to properly suck or swallow to receive nourishment, 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.

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.

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.

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 may be useful in configuring a tactile stimulus that may be applied to patients to modify or correct a deficient NNS pattern.

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.

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**.

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**.

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**.

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**.

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.

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**.

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.

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**.

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.

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**.

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 **500-508** 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.

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.

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.

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.

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.

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**.

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**.

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.

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.

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.

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.

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**.

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.

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.

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.

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.

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.

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 ± 3 ms, 526 ± 3 ms, 551 ± 3 ms, 580 ± 3 ms, and 626 ± 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.

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 ± 0.5 Hz, 5.5 ± 0.5 Hz, 9.0 ± 0.5 Hz, 12.5 ± 0.5 Hz, and 16.5 ± 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 $\frac{1}{2}$. As such, the relative high frequency of the rising and falling edges of the therapy pulse helps to achieve stimulus salience in the patient.

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**.

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.

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**.

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.

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**.

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.

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.

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.

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.

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.

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.

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.

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.

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.

It will be appreciated that the device and method of the present invention are capable of being incorporated in the form of a variety of embodiments, only a few of which have been illustrated and described above. The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments

are to be considered in all respects only as illustrative and not restrictive and the scope of the invention is, therefore indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A non-transitory system executable by a processor 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 comprising:

an assessment module to:

record a pressure signal received from a pressure transducer in an orofacial stimulator; and,

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

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; and,

a therapy module to:

generate a therapeutic pressure pulse signal comprising a base frequency signal further comprising two or more pressure pulses, wherein each pressure pulse causes a 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 a square wave profile and are separated by an interval between 500 milliseconds and 650 milliseconds in duration;

generate a 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.

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

3. The system of claim 2, 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.

4. The system of claim 3, wherein the therapeutic pressure profile comprises at least 6 pressure pulses in succession contacted with the patient for at least two minutes, at least twice a day.

5. The system of claim 2, wherein each of the two or more pressure pulses comprises a higher order harmonic of the base frequency.

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

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

8. The system of claim 2, wherein each of the two or more pressure pulses has a first order under damped response square wave profile.

13

9. The system of claim 8, wherein the under damped square wave profile of the two or more pressure pulses has a Q factor greater than or equal to $\frac{1}{2}$.

10. The system of claim 1, wherein the pressure transducer generates the pressure signal in response to pressure applied to the orofacial stimulator.

11. The system of claim 1, wherein the display signal contains waveform data, wherein the waveform data indicates at least one event in the pressure signal.

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

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

14. The system of claim 1, wherein the system further comprises a calibration module to calibrate the orofacial stimulator.

15. The system of claim 14, wherein the orofacial stimulator appliance is calibrated prior to: receiving pressure signals at the assessment module, generating the therapeutic pressure pulse signal, or both.

16. The system of claim 14, wherein the orofacial stimulator appliance is calibrated after: receiving pressure signals at the assessment module, generating the therapeutic pressure pulse signal, or both.

17. The system of claim 14, wherein the orofacial stimulator appliance is calibrated prior to and after: receiving pressure signals at the assessment module, generating the therapeutic pressure pulse signal, or both.

18. The system of claim 1, wherein the system further comprises a review module to review at least one of the assessment data, the generated therapeutic pressure profile, or both.

19. The system of claim 1, wherein the transmitted therapeutic pressure pulse profile signal is received at at least one of the pneumatic pressure transducer and the orofacial stimulator appliance.

20. A processing system 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;

memory; and,

the application, executable by the processor, further comprising instructions to:

record a pressure signal received from a pressure transducer in an orofacial stimulator;

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

14

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 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.

21. The system of claim 20, wherein the base frequency is between 1.5 Hz and 5 Hz.

22. The system of claim 21, 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.

23. The system of claim 22, wherein the therapeutic pressure profile comprises at least 6 pressure pulses in succession contacted with the patient for at least two minutes, at least twice a day.

24. The system of claim 21, wherein each of the two or more pressure pulse is a higher order harmonic decay of the base frequency.

25. The system of claim 24, wherein the higher order harmonic for the two or more pressure pulses varies in an amplitude and a frequency.

26. The system of claim 24, wherein the higher order harmonic for the two or more pressure pulses is identical in an amplitude and a frequency.

27. The system of claim 21, wherein each of the two or more pressure pulses has an under damped square wave profile.

28. The system of claim 27, wherein the under damped square wave profile of the two or more pressure pulses has a Q factor greater than or equal to $\frac{1}{2}$.

29. The system of claim 20, wherein the pressure transducer generates the pressure signal in response to pressure applied to the orofacial stimulator.

30. The system of claim 20, wherein the display signal contains waveform data, wherein the waveform data indicates at least one event in the pressure signal.

31. The system of claim 30, wherein the at least one event is identified as a pressure peak, a non-nutritive suck event, a burst, a chew, or combinations thereof.

32. The system of claim 20, 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.

33. The system of claim 20, wherein the system further comprises a calibration module to calibrate the orofacial stimulator.

34. The system of claim 33, wherein the orofacial stimulator appliance is calibrated prior to: receiving pressure signals at the assessment module, generating the therapeutic pressure pulse signal, or both.

35. The system of claim 33, wherein the orofacial stimulator appliance is calibrated after: receiving pressure signals at the assessment module, generating the therapeutic pressure pulse signal, or both.

36. The system of claim 33, wherein the orofacial stimulator appliance is calibrated prior to and after: receiving pressure signals at the assessment module, generating the therapeutic pressure pulse signal, or both.

37. The system of claim 20, wherein the system further comprises a review module to review at least one of the assessment data, the generated therapeutic pressure profile, or both.

38. The system of claim 20, wherein the transmitted therapeutic pressure pulse profile signal is received at a pressure transducer.

39. A non-transitory computer readable medium encoded with instructions for operating a system for delivering a non-nutritive suck stimulus to a patient, the instructions executable by a processor in communication with memory and comprising:

- receiving, at the processor, a pressure signal received from a pressure transducer in an orofacial stimulator appliance;
- generating a display signal to display assessment data based on the received pressure signal;
- identifying one or more components of the patient's non-nutritive suck pattern in the pressure signal;
- determining a symmetry of the patient's non-nutritive suck pattern;
- determining a repetition of the patient's non-nutritive suck pattern;
- assigning 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;
- generating a therapeutic pressure pulse signal;
- generating a therapeutic pressure profile signal comprising at least one of the therapeutic pressure pulse signals; and,
- transmitting the therapeutic pressure pulse profile signal to the orofacial stimulator appliance.

40. A non-transitory system executable by a processor for stimulating a human brain to organize a patient's non-nutritive suck pattern, the system comprising:

- an assessment module to:
 - record a pressure signal received from a pressure transducer in an orofacial stimulator appliance;
- a feature extraction module to:
 - identify one or more components of the patient's non-nutritive suck pattern in the pressure signal; and
 - assign a spatiotemporal index value to the patient's non-nutritive suck pattern; and,
- a therapy module to:
 - generate a therapeutic pressure pulse signal comprising a damped square wave profile;
 - transmit the therapeutic pressure pulse profile signal to the orofacial stimulator appliance.

41. A processing system encoded with an application for stimulating a human brain to organize a patient's non-nutritive suck pattern, the system comprising:

- a processor;
- memory; and,
- the application, executable by the processor, further comprising instructions to:
 - record a pressure signal received from a pressure transducer in an orofacial stimulator appliance;

identify one or more components of a patient's non-nutritive suck pattern in the pressure signal;

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 damped square wave; and,

transmit the therapeutic pressure pulse profile signal to the orofacial stimulator appliance.

42. A non-transitory computer readable medium encoded with instructions for operating a system for delivering a non-nutritive suck stimulus to a patient, the instructions executable by a processor in communication with memory and comprising:

- receiving, at the processor, a pressure signal received from a pressure transducer in an orofacial stimulator appliance;
- identifying one or more components of the patient's non-nutritive suck pattern in the pressure signal;
- determining a symmetry of the patient's non-nutritive suck pattern;
- determining a repetition of the patient's non-nutritive suck pattern;
- assigning 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;
- generating a therapeutic pressure pulse signal; and,
- transmitting the therapeutic pressure pulse profile signal to the orofacial stimulator appliance.

43. The system of claim 42, wherein the instructions further comprise:

- verify an expansion characteristic of the orofacial stimulator appliance in response to the therapeutic pressure pulse profile signal, wherein verification is performed by measuring a frequency and an amplitude component of a motion of the orofacial stimulator appliance.

44. The system of claim 43, wherein the instructions further comprise digitizing and recording the frequency and amplitude components.

45. The system of claim 43, wherein the frequency and the amplitude are measured by a laser micrometer.

46. A processing system encoded with an application for stimulating a human brain to organize a patient's non-nutritive suck pattern, the system comprising:

- a processor;
- memory; and,
- the application, executable by the processor, further comprising instructions to:
 - record a pressure signal received from a pressure transducer in an orofacial stimulator appliance;
 - identify one or more components of a patient's non-nutritive suck pattern in the pressure signal;
 - generate a therapeutic pressure pulse signal; and,
 - transmit the therapeutic pressure pulse profile signal to the orofacial stimulator appliance.

* * * * *

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	US9037266	公开(公告)日	2015-05-19
申请号	US13/457203	申请日	2012-04-26
[标]申请(专利权)人(译)	BARLOW史蒂芬中号 拖延DAVID大号 ARON KENNETH		
申请(专利权)人(译)	BARLOW史蒂芬M. 拖延DAVID L. ARON KENNETH		
当前申请(专利权)人(译)	堪萨斯大学 INNARA HEALTH , INC.		
[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	A61N1/00 A61B5/00 A61B5/03 A61H23/02		
CPC分类号	A61B5/038 A61B5/486 A61B5/682 A61B5/6896 A61H23/02 A61H2201/5005 A61H2201/5007 A61H2201/5071 A61H2205/022		
助理审查员(译)	EDWARDS , PHILIP		
优先权	61/030484 2008-02-21 US 61/036304 2008-03-13 US		
其他公开文献	US20120209148A1		
外部链接	Espacenet USPTO		

摘要(译)

本发明涉及使用该系统的系统和方法。特别地，本发明涉及一种应用程序，其可由处理设备执行以评估患者的非营养性吮吸（NNS）模式的组织并且在患者体内夹带有组织的NNS模式。软件系统从口面刺激器具接收数据以评估患者的自然NNS图案并产生精确的治疗脉冲轮廓，其通过口面刺激器具作为触觉刺激被致动以夹带有组织的NNS图案。

