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(54) **Title**: INTRA-ORAL ELECTRONIC THERAPY DEVICES FOR TREATMENT OF SLEEP-BREATHING DISORDERS, BRUXING DISORDERS, AND TMJ DISORDERS, AND ASSOCIATED METHODS

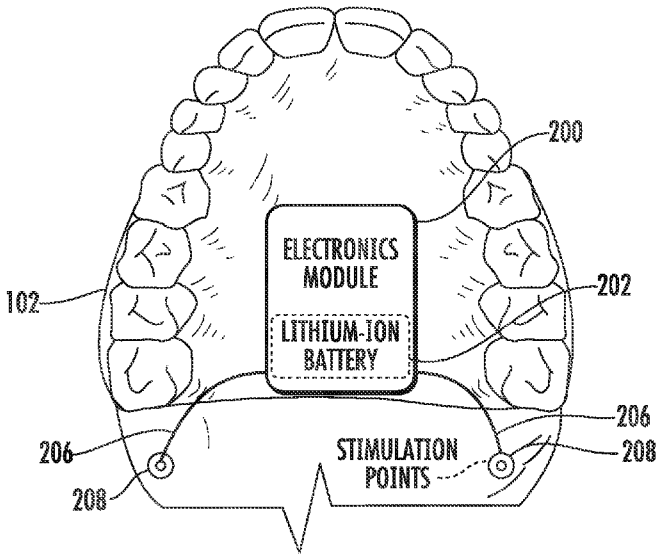


FIG. 2

(57) **Abstract**: The intra-oral electronic therapy device includes a substrate to be positioned in a patient's mouth, a rechargeable battery carried by the substrate, and at least one tissue contact electrode, e.g. a hamular notch contact electrode, extending outwardly from the substrate to contact at least one tissue area in the patient's mouth. A controller is carried by the substrate and cooperates with the rechargeable battery and the at least one tissue contact electrode to provide an electrical stimulation to the at least one tissue area in the patient's mouth. The substrate includes first and second thermoplastic layers sealing therebetween the rechargeable battery and controller.

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# INTRA-ORAL ELECTRONIC THERAPY DEVICES FOR TREATMENT OF SLEEP-BREATHING DISORDERS, BRUXING DISORDERS, AND TMJ DISORDERS, AND ASSOCIATED METHODS

## Field of the Invention

**[0001]** The present invention relates to the treatment of sleep disordered breathing, and, more particularly, to devices and methods for intra-oral stimulation in the treatment of snoring, sleep apnea, bruxing and temporomandibular joint disorders.

## Background of the Invention

**[0002]** Snoring and Obstructive Sleep Apnea (OSA) are a relatively common sleep disorders that affect from 15 million to as many as 70 million people just in the United States. A patient suffering from OSA literally stops breathing while sleeping possibly for a period of one minute or longer with many patients having hundreds of apneic episodes during the night.

**[0003]** The exact cause of OSA is unclear although when a patient's airway blockage occurs, there is a drop in blood oxygen level with an increase in blood carbon dioxide. As the blood oxygen level decreases, the heart will beat faster trying to compensate for the decrease in blood oxygen to body tissues. Snoring has been reported in the literature to precede OSA. According to a 2006 report from the Institute of Medicine, sleep disorders and sleep deprivation represent a major unmet public health problem in America, with 50 to70 million people chronically suffering from a disorder of sleep that results in

a wide range of deleterious health consequences, including increased risk of hypertension, diabetes, obesity, depression, heart attack, and stroke. Almost 20% of all serious car crash injuries in the general population are associated with driver sleepiness, independent of alcohol effects. It has been reported that the 90% of sleep problem patients are yet undiagnosed.

**[0004]** Current treatments for snoring and OSA include behavioral changes such as losing weight, avoiding alcohol, tobacco, sleeping pills, and attempting to adjust sleeping position. Continuous Positive Airway Pressure (CPAP) can be effective but very uncomfortable and noisy to wear during the night with only 50% patient compliance. Oral appliance therapy is available but many times can cause facial pain, TMD symptoms, and changes in tooth position and occlusion. Surgical approaches are available but most are quite drastic requiring patients to undergo unwanted procedures.

**[0005]** Bruxism is a serious dental problem that involves grinding, gnashing, or clenching of teeth affecting 50% - 90% of people. In most adults, stress is a major contributing factor along with anger, frustration, and competition that occur in everyday life. Long term bruxism results in irreversible damage to teeth, both in appearance and function with increasing sensitivity to temperature, possible alveolar bone loss, and eventual loss of teeth. The status of current treatment includes a nightguard to wear while sleeping to protect the teeth from bruxing, but the bruxing continues refocusing destruction on the nightguard. The preferred embodiment of the present invention will mitigate the action of bruxing with electronic stimulation at a subconscious level and not disrupt sleep.

**[0006]** TMD (Temporomandibular Disfunction) is a condition including pain, tenderness, and mal-function of one or both temporomandibular joints (TMJ). This condition reportedly affects 5% - 15% of people. Symptoms include; pain in jaw, ear, and or face, clicking, popping, and or locking of the jaw, headache, and uncomfortable or uneven bite. Barring treatment, patients get progressively worse causing irreversible damage to the joint parts. Surgical treatment results have been controversial due to significant risks and

unpredictable results. Early non-invasive treatment to prevent irreversible damage to the TMJ with electronic balancing of muscle activity will be provided with this invention.

**[0007]** An example of one approach is presented in U.S. Pat. No. 5,792,067 to Karell which is directed to a device and method for addressing sleep and other disorders through electromuscular stimulation within specific areas of a patient's mouth. A mouthpiece includes an electrode for stimulating either the hard palate, soft palate or the pharynx. The mouthpiece includes a denture-like plate to which the control unit and electrodes may be attached.

## Summary of the Invention

**[0008]** In view of the foregoing background, it is therefore an object of the present invention to provide effective treatment for snoring, OSA, bruxism and/or TMJ in a patient via an electronic continuous or periodic airway therapy device (ECAT).

**[0009]** This and other objects, features, and advantages in accordance with the present invention are provided by an intra-oral electronic therapy device including a substrate to be positioned in a patient's mouth, a rechargeable battery carried by the substrate, and at least one tissue contact electrode, e.g. a hamular notch contact electrode, extending outwardly from the substrate to contact at least one tissue area in the patient's mouth. A controller is carried by the substrate and cooperates with the rechargeable battery and the at least one tissue contact electrode to provide an electrical stimulation to the at least one tissue area in the patient's mouth. The substrate includes first and second thermoplastic layers sealing therebetween the rechargeable battery and controller.

**[0010]** An adhesive layer is preferably between the first and second thermoplastic layers. The substrate may be adapted to fit within an upper portion of the patient's mouth, and may comprise a U-shaped teeth engaging portion and palate engaging portion extending therebetween. As such, the rechargeable battery and controller may be carried by the palate engaging portion of the substrate. The substrate may be adapted to fit within a lower

portion of the patient's mouth, and the substrate may have a U-shape for engaging teeth of the patient.

**[0011]** The controller may be configured so that the electrical simulation comprises a predetermined electrical stimulation pattern. A programming interface may be carried by the substrate and coupled to the controller to permit programming of the predetermined stimulation pattern therein. The programming interface may also be configured to provide recharging of the rechargeable battery. The programming interface may be a wired and/or wireless programming interface.

**[0012]** At least one pressure sensor may be carried by the substrate and coupled to the controller. As such, the controller activates the electrical stimulation based upon the at least one pressure sensor.

**[0013]** The controller may further comprise a voltage booster and waveform generator coupled thereto to generate the electrical stimulation. The controller may further comprise a battery manager configured to monitor battery conditions.

**[0014]** A method aspect is directed to a method for providing intra-oral electronic therapy including providing a substrate to be positioned in a patient's mouth, positioning a rechargeable battery on the substrate, and extending at least one tissue contact electrode extending outwardly from the substrate to contact at least one tissue area in the patient's mouth.
The method includes providing a controller carried by the substrate and cooperating with the rechargeable battery and the at least one tissue contact electrode to provide an electrical stimulation to the at least one tissue area in the patient's mouth. The substrate comprises first and second thermoplastic layers sealing therebetween the rechargeable battery and controller.

**[0015]** Thus, effective treatment is provided for snoring and OSA in a patient by opening the airway via flexing or restoring normal muscle tone to the soft palate (e.g. levator veli palatini and tensor veli palatini) along with the uvula, tongue, and throat. This action is the result of the delivery of a mild current to the hamular notch by an electronic continuous or periodic airway

therapy device (ECAT) for treatment of sleep breathing disorders, bruxism and/or TMJ.

## Brief Description of the Drawings

**[0016]** FIG. 1 is a schematic diagram illustrating a maxillary stone cast with a thin plastic sheet adapted to it and used to fabricate the maxillary plastic arch form for the electronic components of the intra-oral appliance in accordance with the present invention.

**[0017]** FIG. 2 is a schematic diagram illustrating the rechargeable battery and controller located in the palatal aspect of the intra-oral appliance, and the circuit extension leads and contacts which stimulate the hamular notches in accordance with features of the present invention.

**[0018]** FIG. 3A is a bottom view of the intra-oral appliance of FIG. 2 including the electronics being sandwiched between thin protective layers.

**[0019]** FIG. 3B is a cross-sectional view of the intra-oral appliance taken along the line B-B of FIG. 3A.

**[0020]** FIG. 4 is a schematic block diagram illustrating the components of the intra-oral appliance of FIG. 2.

**[0021]** FIG. 5 is a schematic block diagram illustrating features of the programming unit used in cooperation with the intra-oral appliance of FIG. 2.

**[0022]** FIG. 6 is a front view of the exterior of the programming unit of FIG. 5.

**[0023]** FIG. 7 is a back view of the exterior of the programming unit of FIG. 5.

**[0024]** FIG. 8 is a timing diagram illustrating an example of a biphasic square-wave stimuation used in the appliance of FIG. 2.

**[0025]** FIG. 9 is a timing diagram illustrating a rolling intensity stimulation level used in the appliance of FIG. 2.

**[0026]** FIG. 10 is a schematic diagram illustrating another embodiment of the intra-oral appliance for bruxism.

**[0027]** FIG. 11 is a schematic diagram illustrating another embodiment of the intra-oral appliance for TMJ.

**[0028]** FIG. 12 is a schematic diagram illustrating another embodiment of the intra-oral appliance for use on the lower portion of the patient's mouth.

**[0029]** FIG. 13 is a perspective view of a vacuum thermoforming machine used to fabricate the substrate for the appliances of FIGs. 2 and 10-12.

**[0030]** FIG. 14 is a flowchart illustrating various portions of a method of making the appliances of FIGs. 2 and 10-12.

## Detailed Description of the Preferred Embodiments

**[0031]** The present invention will now be described more fully hereinafter with reference to the accompanying drawings, in which preferred embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. Like numbers refer to like elements throughout.

**[0032]** Referring initially to FIG. 1, an illustration of a patient's maxillary teeth is shown. The cast 100 is fabricated by the dentist or dental assistant making impressions (e.g. alginate) of the maxillary and mandibular arches in the usual way impressions are made as would be appreciated by those skilled in the art. A vacuum thermoforming machine (such as manufactured by Raintree Essix Inc., Metairie, La.) can be used to pull down sufficiently heated plastic **102** onto the maxillary model. This plastic material **102** will become the first protective layer upon which components will be mounted. After these components are mounted in the palatal aspect of the arch, a second "sandwiching" piece of thin plastic will be vacuum formed over the electronic components to protect them from saliva as will be described in further detail below.

**[0033]** Referring to FIG. 2, an electronics module **200** is positioned on the formed plastic material **102**, and includes a rechargeable battery **202**, and circuit extension leads **206** and associated tissues contacts **208** which contact

the hamular notches bilaterally in the patient's mouth. The battery **202** is preferably of a sufficient voltage to create the necessary tone in the musculature involved with soft palate flexing or stiffening (tensor veli palatini muscles and the levator veli palatini muscles). Wire leads **206** from the electronics module **200** are preferably 28 gauge wire and run between the "sandwiched" plastic arch form distal to the maxillary 2nd molars and terminate with the circuit extension contacts **208**, such as stainless orthodontic ballclamps (0.28 in (0.7 mm)) which contact in the hamular notch.

**[0034]** An example of the intra-oral appliance or mouthpiece **300** is illustrated in FIGS. 3A and 3B. The electronics module **200** and battery 202 is sandwiched between upper and lower protective layers **304**, **305** (e.g. such as thermoformed plastic layers) for protection of the circuitry from saliva and associated corrosion. Also, an adhesive layer **306** (e.g. a bonded, light-cured, acrylic gel, such as Triad Gel from the Dentsply International of York, Pa.) is preferably applied between the protective layers, e.g. at a periphery thereof, to further aid in the corrosion prevention. An interface 308, such as an electrical connector, is also sealed between the layers **304**, **305** and exposed at a periphery thereof.

**[0035]** Accordingly, the appliance **300** defines an intra-oral electronic therapy device including a substrate **304/305** to be positioned in a patient's mouth, a rechargeable battery **202** carried by the substrate, and one or more hamular notch tissue contact electrodes **206/208** extending outwardly from the substrate to contact at least one hamular notch in the patient's mouth. A controller **400** (e.g. referring to FIG. 4) is defined by the electronics module **200** and is carried by the substrate **304/305** and cooperates with the rechargeable battery **202** and the hamular notch tissue contact electrodes **206/208** to provide a predetermined electrical stimulation pattern to a hamular notch in the patient's mouth. A microcontroller **401** and associated programming interface **308** is carried by the substrate **304/305** to permit programming of the predetermined stimulation pattern therein.

**[0036]** The controller **400** may further comprise a voltage booster **402** and waveform generator **404** coupled thereto to generate the predetermined electrical stimulation pattern. The controller may also include a battery manager **406** configured to monitor battery conditions. Illustratively, a lithium-ion battery management IC monitors the battery conditions during charging and use. The charging cycle may be accurately controlled in a constant current mode followed by a constant voltage mode until the battery has been fully recharged. The battery may also be protected against over-voltage, over-current, and under-voltage situations.

**[0037]** The predetermined electrical stimulation pattern may be a biphasic electrical stimulation pattern and may include a series of pulses with successive pulses progressively changing in intensity as will be described with reference to FIGs. 8 and 9. A low voltage electrical stimulation may be provided by the waveform generator, e.g. via dual push-pull output stages which allow for the creation of a biphasic waveform **500**. The biphasic waveform **500** includes alternating, symmetrical positive and negative pulses. Using this type of balanced stimulation may decrease the chance for electrode deterioration and tissue damage.

**[0038]** The waveform generator, e.g. dual push-pull output stages, are supplied with the stimulation voltage level from the voltage boost stage **402**. Depending on the mouthpiece settings, a voltage greater than the battery voltage may be required. This may be accomplished with a switching-mode power supply using a boost converter topology. The output of the voltage boost stage may range from 3.5 - 12.5 volts.

**[0039]** The control of the waveform generator stage **404** and voltage boost stage **402** is managed by the microprocessor **401**. This allows for programming of any wave shape with positive and negative components to be generated. The waveform may be bounded by +/- the maximum voltage boost and operating frequency of the microprocessor. An effective waveform has been shown to be a biphasic square-wave **500** at a frequency of 1 kilohertz

and 50% duty cycle. The shape, frequency, and duty cycle may all be adjustable.

**[0040]** The stimulation may be applied at periodic intervals ranging from 1-60 seconds. Each stimulation event may have a duration ranging from 100-1000 milliseconds. The microprocessor **401** handles timing of all events based on the settings programmed.

**[0041]** With reference to FIG. 9, the stimulation may use a rolling intensity. This means that each stimulation event is at a different level of intensity. The level of intensity increases or decreases after each stimulation event, staying within the bounds programmed into the microprocessor **401**. This has shown to be an effective stimulation event pattern, but any pattern of intensity levels can be programmed into the microprocessor **401**.

**[0042]** Features of a re-programming unit 420 will be described with reference to FIGs. 5-7. The re-programming unit **420** may include a microcontroller **422** and associated appliance link **426**. The re-programming unit **422** allows the user to re-configure settings of the electrical stimulation for the intra-oral appliance **300**. The re-programming unit **420** may include user interface **424**, e.g. an LCD screen for displaying information, buttons for user input, and various connectors for re-charging and re-programming the appliance. The re-programming unit **420** may also allow the appliance to display its current settings.

**[0043]** The battery **202** may be charged by a physical connection or also by inductive or capacitive charging. The inductive charging requires a pair of coils and capacitors that are tuned to a resonant frequency. A base station coil, e.g. at the re-programming unit **420**, is supplied with a signal at its resonant frequency. The coil within the mouthpiece is also tuned to resonate at the same frequency and will receive the signal from the base station coil. The received signal may be rectified to DC and then regulated to 5 volts for the battery charger circuitry.

**[0044]** The intra-oral appliance **300** settings can be transmitted by a direct physical connection, infrared communications or other wireless

methods. Communication over the inductive charging coils can be accomplished by using the charging signal as a carrier and modulating data onto that signal. The signal can then be demodulated in the intra-oral appliance **300** to receive the data. As such, the programming interface **308** may also be configured to provide recharging of the rechargeable battery.

**[0045]** A data recorder may be provided in the re=programming unit **420** to monitor snoring/gasping frequency throughout the night. The battery charger feature of the re-programming unit **420** and the associated battery **202** of the intra-oral appliance **300** may utilize connectors manufactured such as 0.100" pin strip headers and 0.100" board mount sockets. The socket may be used in the appliance **300** and sealed within the protective thin plastic layers by applying bonded, light-cured, acrylic gel, such as Triad Gel from the Dentsply International of York, Pa., to prevent moisture from entering the mouthpiece. As discussed above, contactless charging, such as electromagnetic, capacitive and/or inductive charging may also be provided instead of the connectors.

**[0046]** Thus, as described, the substrate may be defined by the first and second protective layers **304/305**, e.g. thermoplastic layers, sealing therebetween the rechargeable battery **202**, controller **400**, and programming interface **308**. The adhesive layer **306** is between the first and second protective layers. The substrate **304/306** may be adapted to fit within an upper portion of the patient's mouth. Furthermore, the programming interface **308** may be a wired programming interface **308A**, such as an electrical connector exposed on the substrate **304/305** (FIG. 4). The programming interface **308** may be a wireless programming interface **308B** such as an inductive coupler, a capacitive coupler, an optical or infrared coupler and/or an RF wireless transceiver.

**[0047]** Another aspect of the present invention is directed to the treatment of bruxism. FIG. 10 is an illustration of the intra-oral appliance **600** for treatment of bruxism. This electronic orthosis works as a gnathologic appliance to protect teeth from damage during excursive movements. In

addition, the electronics package 602 detects bruxing activity using a pressure electro-conductive rubber sensor or pressure receptor switch **604** such as made by Bridgestone in Tokyo, Japan and stops it with electronic stimulation, via tissue contact **606**, to the intra-oral mucosa at a subconscious level without sleep interruption. Patient adjustability is available with the reprogramming unit **420**, discussed above, that may be connected, e.g. via wired or wireless communication link, with the intra-oral appliance **600**.

**[0048]** Another aspect of the present invention is directed to the treatment of TMJ or TMD. FIG. 11 is an illustration of the intra-oral appliance **700** for treatment of TMJ or TMD. Temporomandibular disorder (TMD), or TMJ syndrome, is a term covering acute or chronic inflammation of the temporomandibular joint, which connects the lower jaw to the skull. This orthotic type appliance **700** detects oral para-functional activity through the use of pressure sensors **704** and an electronics package **702** in the appliance. A para-functional habit or parafunctional habit is the habitual exercise of a body part in a way that is other than the most common use of that body part. The term is most commonly used by dentists, orthodontists, or maxillofacial specialists to refer to parafunctional uses of the mouth, tongue and jaw. Oral para-functional habits may include bruxism (tooth-clenching or grinding), tongue tension, mouth-breathing, and any other habitual use of the mouth unrelated to eating, drinking, or speaking. Treatment includes electronic stimulation, via tissue contact 706 in response to detected pressure.

**[0049]** Another aspect of the present invention is directed to an intra-oral appliance **800** (FIG. 12) for use in the lower portion of the patient's mouth. The appliance **800** is again fabricated using a bi-laminate plastic sandwich technique but designed to fit on the lower teeth instead of the upper(maxillary) teeth. All electronic components, e.g. electronic circuit **801** and battery **802**, are sandwiched between the plastic layers and located on the lateral aspect of the appliance **800**. The electronic function is the same as described above, except that the stimulation points may be the tissues in the floor of the mouth near the retro-mylohoid area and under the tongue. The electronic stimulation

may restore muscle tone in the tongue, genioglossus, geniohyoid, and palato-pharyngeal muscles to maintain the airway. This lower ECAT appliance **800** can be used in place of the upper ECAT appliance for patients that have an exaggerated gag reflex, very narrow palate, or just cannot tolerate coverage of the roof of the mouth.

**[0050]** A method aspect will be described with reference to the flowchart in FIG. 14. The method is for making an intra-oral electronic therapy device, e.g. such as illustrated and described with reference to FIGs. 2 and 10-12. The method begins at block **1000** and includes thermoforming a first thermoplastic layer on a patient's dental cast (block **1002**), e.g. as received from a patient's dentist, positioning components on the first thermoplastic layer (block **1004**), and thermoforming a second thermoplastic layer (block **1006**) on the first thermoplastic layer to define a substrate with the components therein. The components include a rechargeable battery **202** (e.g. FIG. 2), at least one tissue contact electrode **206/208** extending outwardly from the substrate to contact at least one tissue area in the patient's mouth, and a controller **400** to cooperate with the rechargeable battery and the at least one tissue contact electrode to provide an electrical stimulation to the at least one tissue area in the patient's mouth. The method includes separating the substrate with the components therein from the dental cast, at block **1008**.

**[0051]** The first thermoplastic layer may be trimmed prior to positioning the components thereon (block **1003**). Positioning the components may further comprise forming an adhesive layer on the first thermoplastic layer to mount the components (block **1005**). The adhesive may comprise a light-curable adhesive, and the method may also comprise curing the light-curable adhesive via a dental curing light (block **1007**) after thermoforming the second thermoplastic layer on the first thermoplastic layer.

**[0052]** Additional details of exemplary fabrication techniques for the various embodiments will now be described. First, the fabrication details for the ECAT Snoring/Sleep Apnea Appliance (Upper Teeth) may include the following steps. Upon accurate casts of the patient's teeth, a 2mm thick foil of

Erkoloc Pro bilaminate is thermoformed on the upper teeth using an Erkoform 3-D machine, the occlusion is recorded in this layer by gently closing the cast of the lower teeth into the material while it is soft using the Occluform attachment from Erkodent. This first layer is recovered and excess material is removed with contouring of the base layer with twist drill and acrylic burs. This trimmed first layer is repositioned on the cast to verify fit. An electronics package that may include a circuit board, lithium ion battery, tissue contacts, recharging/re-programming contacts, inductive coil, infra-red receptor, and connecting wires are positioned in the palatal area for best fit. 28 gauge Stainless steel wire is custom bent to the palatal contours and positioned for correct soft tissue contact in the hamular notches bilaterally. A #8 round bur is used to "dimple" the hamular notches to allow for slight compression of the tissue in the mouth. A tight loop is formed in the end of the stainless steel wire to fit the "dimple" in the hamular notches.

**[0053]** The electronics package is set aside and the surface of the first layer is cleaned with an alcohol wipe to remove any contaminates. A thin layer of Triad VLC bonding agents is applied to the surface of this layer and light cured. Triad Clear Gel is applied to circuit board prior to positioning it onto the first layer and light cured. The same sequence is used to permanently place the other parts onto the first layer. A 4mm ball of hot glue is used to hold the tissue contact loop in the hamular notch so that the wire leads can be covered with gel. The upper cast along with the first layer and the attached electronics is replaced in the Erkoform machine. Another alcohol wipe is used to clean the surface again. Triad VLC Bonding is applied to the surface, and a 1mm thick foil of Erkodur is thermoformed over this. The occlusion is recorded into this second layer while soft, using the Occluform attachment again. A high intensity curing light is applied to the entire appliance immediately. When cool, the appliance is removed, trimmed and shaped anatomically, and polished.

**[0054]** The fabrication details for ECAT Snoring/Sleep Apnea Appliance (Lower Teeth) may include the following steps. Upon accurate casts of the patient's teeth, a 2mm thick foil of Erkoloc Pro bilaminate is thermoformed on

the lower teeth using an Erkoform 3-D machine. The occlusion is recorded in this layer by gently closing the cast of the lower teeth into the material while it is soft using the Occluform attachment from Erkodent. This first layer is recovered and excess material is removed with contouring of the base layer with twist drill and acrylic burs. This trimmed first layer is repositioned on the cast to verify fit.

**[0055]** An electronics package that may include a circuit board, lithium ion battery, tissue contacts, recharging/re-programming contacts, inductive coil, infra-red receptor, and connecting wires are positioned in the posterior buccal or lingual vestibule area for best fit. 28 gauge Stainless steel wire is custom bent to the oral contours and positioned for correct soft tissue contact in the retro-mylohyoid area and temporarily fixed in position with hot glue. The electronics package is set aside and the surface of the first layer is cleaned with an alcohol wipe to remove any contaminates. A thin layer of Triad VLC bonding agents is applied to the surface of this layer and light cured. Triad Clear Gel is applied to circuit board prior to positioning it onto the first layer and light cured. The same sequence is used to permanently place the other parts onto the first layer. The lower cast along with the first layer and the attached electronics is replaced in the Erkoform machine. Another alcohol wipe is used to clean the surface again. Triad VLC Bonding is applied to the surface, and a 1mm thick foil of Erkodur is thermoformed over this. The occlusion is recorded into this second layer while soft, using the Occluform attachment again. A high intensity curing light is applied to the entire appliance immediately. When cool, the appliance is removed, trimmed and shaped anatomically, and polished.

**[0056]** The fabrication details for the anti-bruxing appliance may include the following steps. Upon accurate casts of the patient's teeth, a 2mm thick foil of Erkoloc Pro bilaminate is thermoformed on the upper teeth using an Erkoform 3-D machine. The occlusion is recorded in this layer by gently closing the cast of the lower teeth into the material while it is soft using the Occluform attachment from Erkodent. This first layer is recovered and excess

material is removed with contouring of the base layer with twist drill and acrylic burs. This trimmed first layer is repositioned on the cast to verify fit.

**[0057]** An electronics package that may include a circuit board, lithium ion battery, tissue contacts, recharging/re-programming contacts, inductive coil, infra-red receptor, and connecting wires are positioned in the palatal area for best fit. Also, two pressure sensing strips are included in the electronics package which is positioned up the lingual surface of the canines. 28 gauge Stainless steel wire is custom bent to the palatal contours and positioned for correct soft tissue contact in the labial vestibule adjacent to the canines bilaterally. A tight loop is formed in the end of the stainless steel wire to act as the tissue contact and held in place temporarily with a little hot glue.

**[0058]** The electronics package is set aside and the surface of the first layer is cleaned with an alcohol wipe to remove any contaminates. A thin layer of Triad VLC bonding agents is applied to the surface of this layer and light cured. Triad Clear Gel is applied to circuit board prior to positioning it onto the first layer and light cured. The same sequence is used to permanently place the other parts onto the first layer. The upper cast along with the first layer and the attached electronics is replaced in the Erkoform machine. Another alcohol wipe is used to clean the surface again. Triad VLC Bonding is applied to the surface, and a 1mm thick foil of Erkodur is thermoformed over this. The occlusion is recorded into this second layer while soft, using the Occluform attachment again. A high intensity curing light is applied to the entire appliance immediately. When cool, the appliance is removed, trimmed and shaped anatomically, and polished.

**[0059]** The fabrication details for TMD Appliance may include the following steps. Upon accurate casts of the patient's teeth, a 2mm thick foil of Erkoloc Pro bilaminate is thermoformed on the upper teeth using an Erkoform 3-D machine. The occlusion is recorded in this layer by gently closing the cast of the lower teeth into the material while it is soft using the Occluform attachment from Erkodent. This first layer is recovered and excess material is

removed with contouring of the base layer with twist drill and acrylic burs. This trimmed first layer is repositioned on the cast to verify fit.

**[0060]** An electronics package that may include a circuit board, lithium ion battery, tissue contacts, recharging/re-programming contacts, inductive coil, infra-red receptor, and connecting wires are positioned in the palatal area for best fit. Also, two pressure sensing strips are included in the electronics package which are positioned on the occlusal surfaces from premolar to molar bilaterally. 28 gauge Stainless steel wire is custom bent to the palatal contours and positioned for correct soft tissue contact in the labial vestibule adjacent to the molars bilaterally. A tight loop is formed in the end of the stainless steel wire to act as the tissue contact and held in place temporarily with a little hot glue.

**[0061]** The electronics package is set aside and the surface of the first layer is cleaned with an alcohol wipe to remove any contaminates. A thin layer of Triad VLC bonding agents is applied to the surface of this layer and light cured. Triad Clear Gel is applied to circuit board prior to positioning it onto the first layer and light cured. The same sequence is used to permanently place the other parts onto the first layer. The upper cast along with the first layer and the attached electronics is replaced in the Erkoform machine. Another alcohol wipe is used to clean the surface again. Triad VLC Bonding is applied to the surface, and a 1mm thick foil of Erkodur is thermoformed over this. The occlusion is recorded into this second layer while soft, using the Occluform attachment again. A high intensity curing light is applied to the entire appliance immediately. When cool, the appliance is removed, trimmed and shaped anatomically, and polished.

**[0062]** Thus, devices and methods are disclosed for intra-oral stimulation in the treatment of snoring, sleep apnea, bruxing and temporomandibular joint disorders.

**[0063]** Many modifications and other embodiments of the invention will come to the mind of one skilled in the art having the benefit of the teachings presented in the foregoing descriptions and the associated drawings.

Therefore, it is understood that the invention is not to be limited to the specific embodiments disclosed, and that modifications and embodiments are intended to be included within the scope of the appended claims.

**THAT WHICH IS CLAIMED IS:**

1. An intra-oral electronic therapy device comprising:

a substrate to be positioned in a patient's mouth;

a rechargeable battery carried by said substrate;

at least one tissue contact electrode extending outwardly from said substrate to contact at least one tissue area in the patient's mouth; and

a controller carried by said substrate and cooperating with said rechargeable battery and said at least one tissue contact electrode to provide an electrical stimulation to the at least one tissue area in the patient's mouth;

said substrate comprising first and second thermoplastic layers sealing therebetween said rechargeable battery, and controller.

2. The intra-oral electronic therapy device of Claim 1, further comprising an adhesive layer between the first and second thermoplastic layers.

3. The intra-oral electronic therapy device of Claim 1, wherein said substrate is adapted to fit within an upper portion of the patient's mouth.

4. The intra-oral electronic therapy device of Claim 3, wherein said substrate comprises a U-shaped teeth engaging portion and palate engaging portion extending therebetween; and wherein said rechargeable battery and controller are carried by the palate engaging portion of said substrate.

5. The intra-oral electronic therapy device of Claim 1, wherein said substrate is adapted to fit within a lower portion of the patient's mouth.

6. The intra-oral electronic therapy device of Claim 5, wherein said substrate has a U-shape for engaging teeth of the patient.

7. The intra-oral electronic therapy device of Claim 1, wherein said at least one tissue contact electrode comprises at least one hamular notch contact electrode.

8. The intra-oral electronic therapy device of Claim 1, wherein said controller is configured so that the electrical simulation comprises a predetermined electrical stimulation pattern.

9. The intra-oral electronic therapy device of Claim 8, further comprising a programming interface carried by said substrate and coupled to said controller to permit programming of the predetermined stimulation pattern therein.

10. The intra-oral electronic therapy device of Claim 9, wherein said programming interface is also configured to provide recharging of said rechargeable battery.

11. The intra-oral electronic therapy device of Claim 9, wherein said programming interface comprises a wired programming interface.

12. The intra-oral electronic therapy device of Claim 9, wherein said programming interface comprises a wireless programming interface.

13. The intra-oral electronic therapy device of Claim 1, further comprising at least one pressure sensor carried by said substrate and coupled to said controller; and wherein said controller activates the electrical stimulation based upon said at least one pressure sensor.

14. The intra-oral electronic therapy device of Claim 1, wherein said controller further comprises a voltage booster and waveform generator coupled thereto to generate the electrical stimulation.

15. The intra-oral electronic therapy device of Claim 1, wherein said controller further comprises a battery manager configured to monitor battery conditions.

16. An intra-oral electronic therapy device comprising:

a substrate to be positioned in a patient's mouth;

a rechargeable battery carried by said substrate;

a plurality of tissue contact electrodes extending outwardly from said substrate to contact respective tissue areas in the patient's mouth; and

a controller, including a voltage booster and waveform generator coupled thereto, carried by said substrate and cooperating with said rechargeable battery and said tissue contact electrodes to provide an electrical stimulation in a predetermined electrical stimulation pattern to the tissue areas in the patient's mouth;

said substrate comprising first and second thermoplastic layers sealing therebetween said rechargeable battery and controller; and

an adhesive layer between the first and second thermoplastic layers.

17. The intra-oral electronic therapy device of Claim 16, wherein said substrate is adapted to fit within an upper portion of the patient's mouth.

18. The intra-oral electronic therapy device of Claim 17, wherein said substrate comprises a U-shaped teeth engaging portion and palate engaging portion extending therebetween; and wherein said rechargeable battery and controller are carried by the palate engaging portion of said substrate.

19. The intra-oral electronic therapy device of Claim 16, wherein said substrate is adapted to fit within a lower portion of the patient's mouth.

20. The intra-oral electronic therapy device of Claim 19, wherein said substrate has a U-shape for engaging teeth of the patient.

21. The intra-oral electronic therapy device of Claim 16, wherein said tissue contact electrodes comprise hamular notch contact electrodes.

22. The intra-oral electronic therapy device of Claim 16, further comprising a programming interface carried by said substrate and coupled to said controller to permit programming of the predetermined stimulation pattern therein.

23. The intra-oral electronic therapy device of Claim 22, wherein said programming interface is also configured to provide recharging of said rechargeable battery.

24. The intra-oral electronic therapy device of Claim 16, further comprising at least one pressure sensor carried by said substrate and coupled to said controller; and wherein said controller activates the electrical stimulation based upon said at least one pressure sensor.

25. A method for providing intra-oral electronic therapy comprising:

providing a substrate to be positioned in a patient's mouth;

positioning a rechargeable battery on said substrate;

extending at least one tissue contact electrode extending outwardly from said substrate to contact at least one tissue area in the patient's mouth; and

providing a controller carried by said substrate and cooperating with said rechargeable battery and said at least one tissue contact electrode to provide an electrical stimulation to the at least one tissue area in the patient's mouth;

said substrate comprising first and second thermoplastic layers sealing therebetween said rechargeable battery and controller.

26. The method of Claim 25, further comprising an adhesive layer between the first and second thermoplastic layers.

27. The method of Claim 25, wherein said substrate is adapted to fit within an upper portion of the patient's mouth; wherein said substrate comprises a U-shaped teeth engaging portion and palate engaging portion extending therebetween; and wherein said rechargeable battery and controller are carried by the palate engaging portion of said substrate.

28. The method of Claim 25, wherein said substrate is adapted to fit within a lower portion of the patient's mouth; and wherein said substrate has a U-shape for engaging teeth of the patient.

29. The method of Claim 25, wherein said at least one tissue contact electrode comprises at least one hamular notch contact electrode.

30. The method of Claim 25, wherein said controller is configured so that the electrical simulation comprises a predetermined electrical stimulation pattern.

31. The method of Claim 30, further comprising coupling a programming interface, carried by said substrate, to said controller to permit programming of the predetermined stimulation pattern therein.

32. The method of Claim 31, wherein said programming interface is also configured to provide recharging of said rechargeable battery.

33. The method of Claim 31, wherein said programming interface comprises a wired programming interface.

34. The method of Claim 31, wherein said programming interface comprises a wireless programming interface.

35. The method of Claim 25, further comprising coupling at least one pressure sensor, carried by said substrate, to said controller; and wherein said controller activates the electrical stimulation based upon said at least one pressure sensor.

36. The method of Claim 25, wherein said controller further comprises a voltage booster and waveform generator coupled thereto to generate the electrical stimulation.

37. The method of Claim 25, wherein said controller further comprises a battery manager configured to monitor battery conditions.

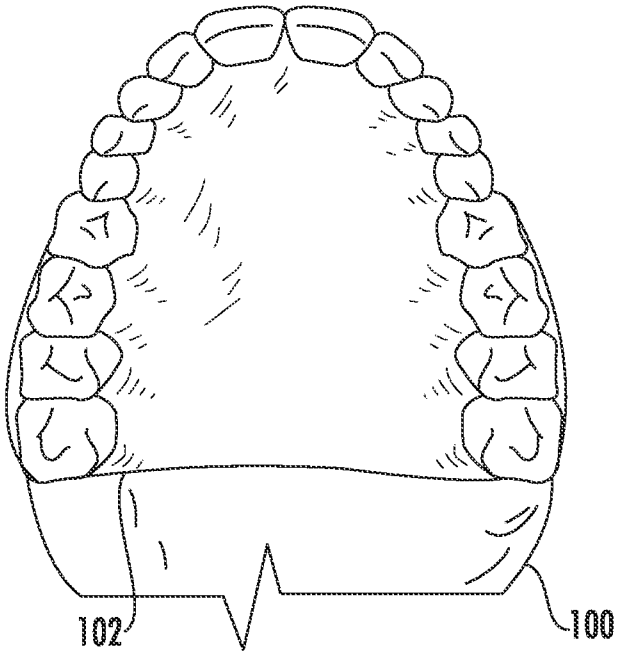
102
100

FIG. 1

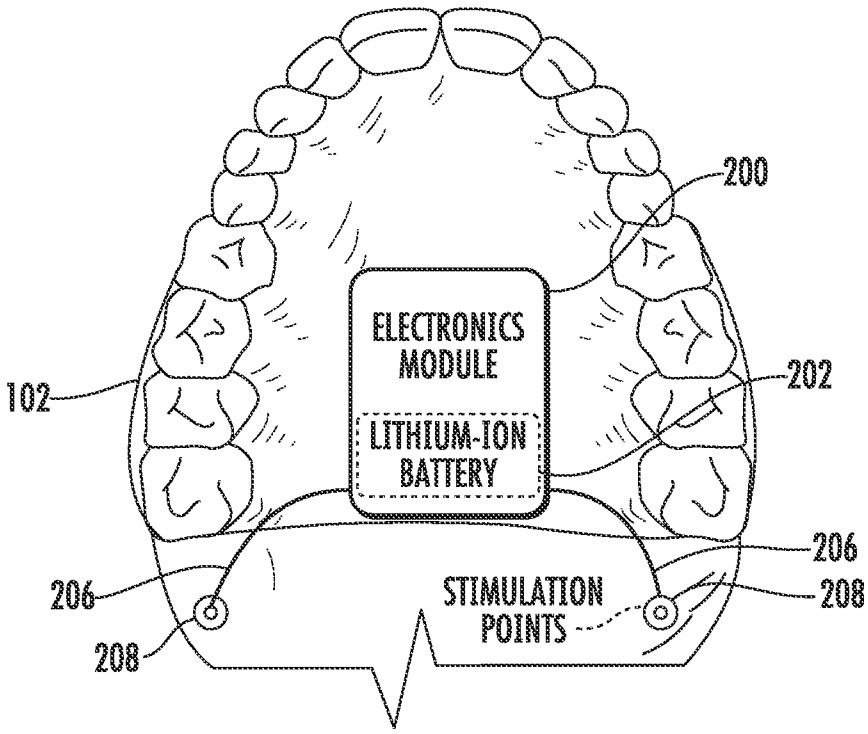
200
ELECTRONICS MODULE
LITHIUM-ION BATTERY
102
202
206
206
208
STIMULATION POINTS
208

FIG. 2

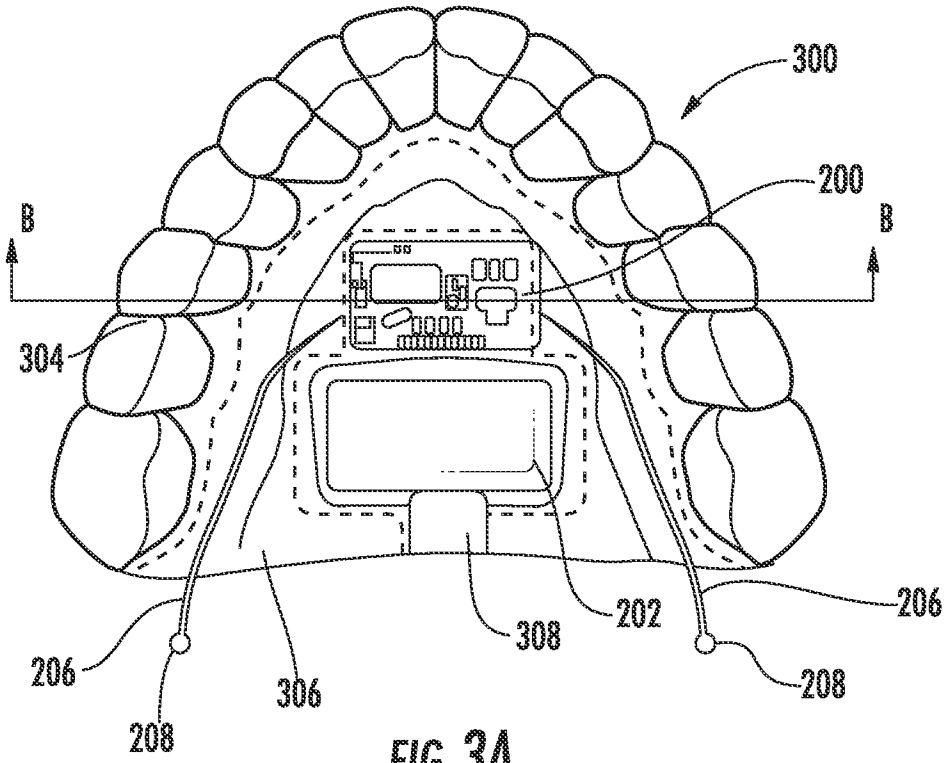
300
200
B
B
304
206
206
208
306
308
202
206
208

FIG. 3A

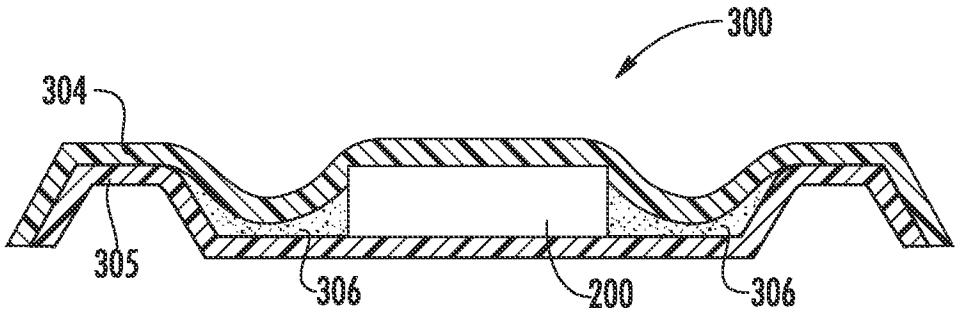
300
304
305
306
200
306

FIG. 3B

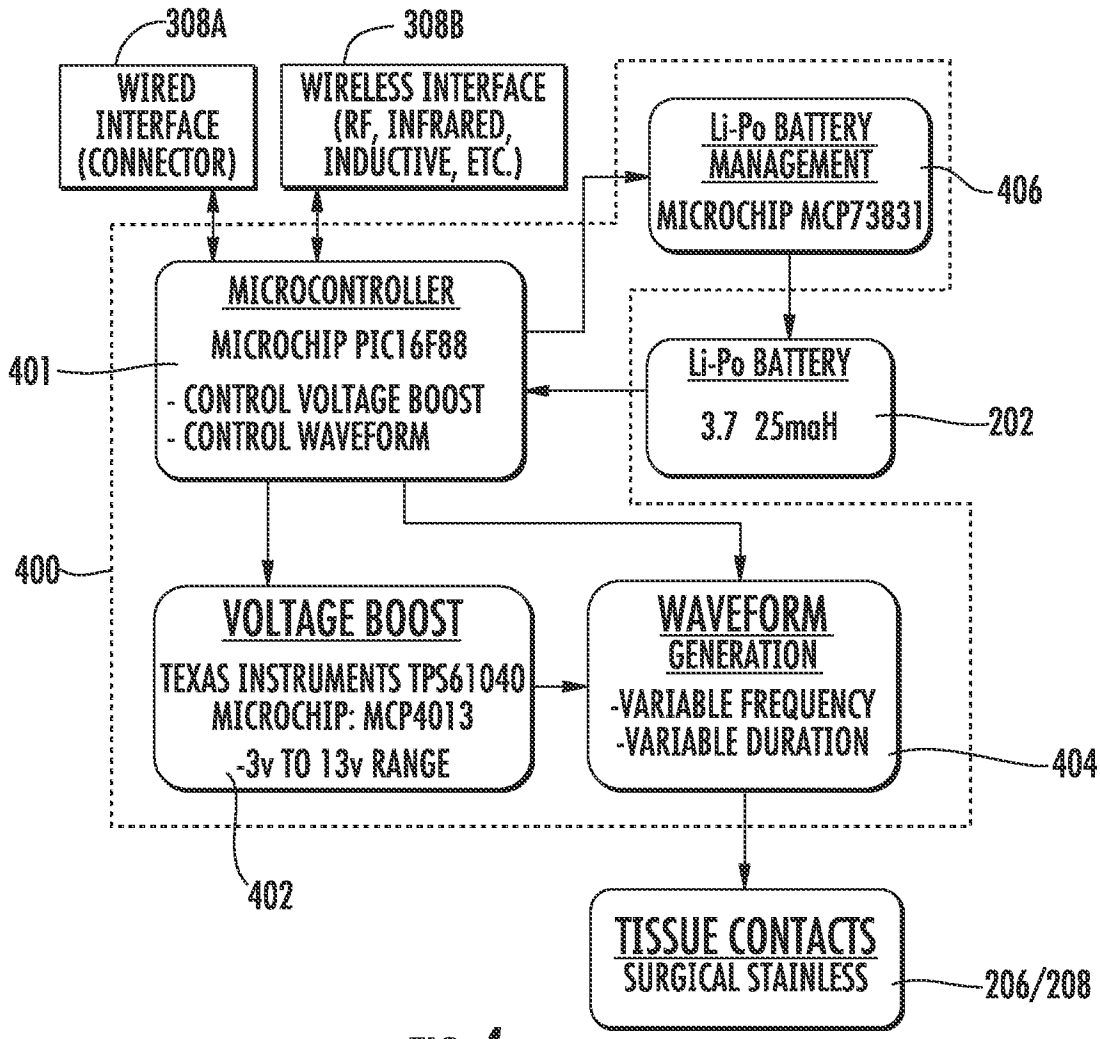
308A
308B
WIRED INTERFACE (CONNECTOR)
WIRELESS INTERFACE (RF, INFRARED, INDUCTIVE, ETC.)
Li-Po BATTERY MANAGEMENT
MICROCHIP MCP73831
406
MICROCONTROLLER
MICROCHIP PIC16F88
- CONTROL VOLTAGE BOOST
- CONTROL WAVEFORM
401
Li-Po BATTERY
3.7 25maH
202
400
VOLTAGE BOOST
TEXAS INSTRUMENTS TPS61040
MICROCHIP: MCP4013
-3v TO 13v RANGE
WAVEFORM GENERATION
-VARIABLE FREQUENCY
-VARIABLE DURATION
404
402
TISSUE CONTACTS
SURGICAL STAINLESS
206/208

FIG. 4

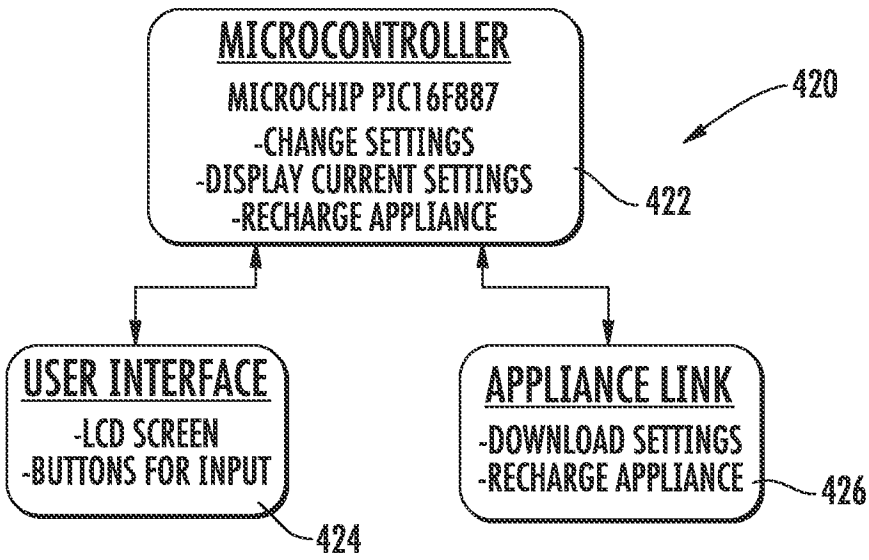
MICROCONTROLLER
MICROCHIP PIC16F887
-CHANGE SETTINGS
-DISPLAY CURRENT SETTINGS
-RECHARGE APPLIANCE
420
422
USER INTERFACE
-LCD SCREEN
-BUTTONS FOR INPUT
424
APPLIANCE LINK
-DOWNLOAD SETTINGS
-RECHARGE APPLIANCE
426

FIG. 5

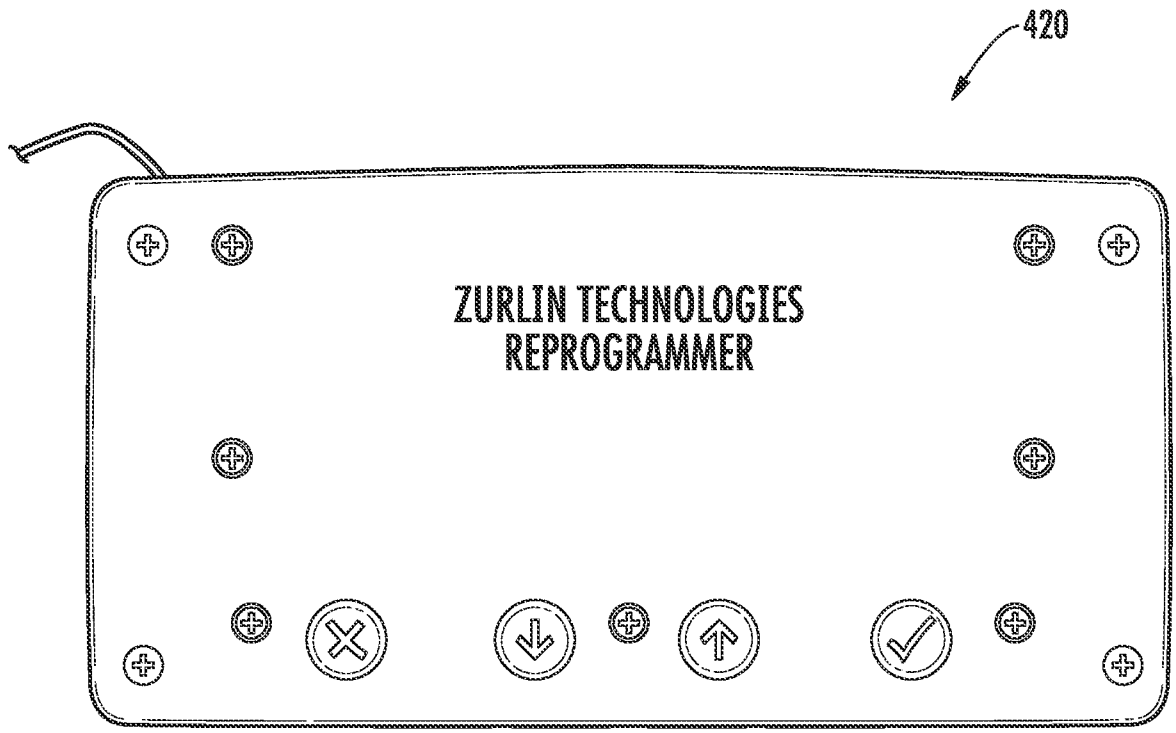
420
ZURLIN TECHNOLOGIES
REPROGRAMMER

FIG. 6

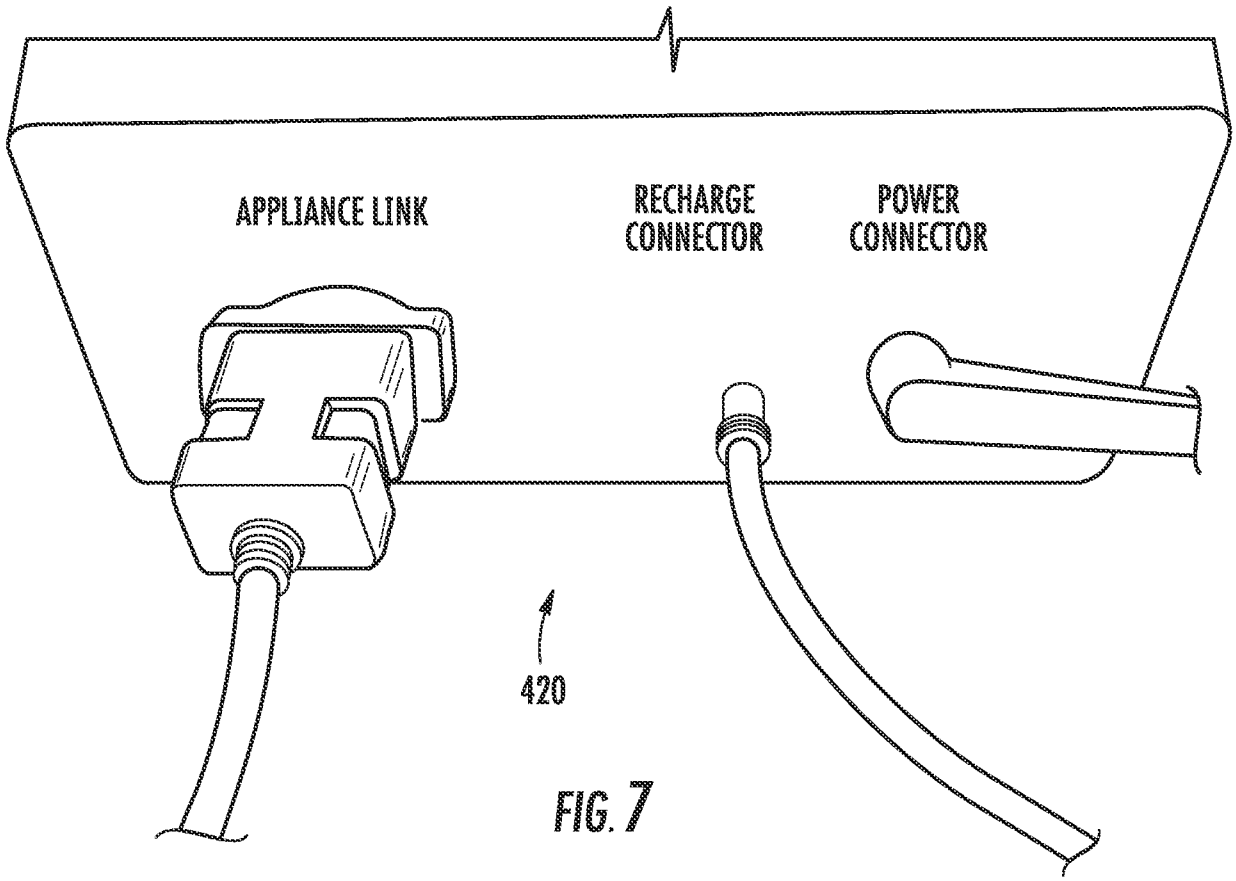
APPLIANCE LINK
RECHARGE CONNECTOR
POWER CONNECTOR
420

FIG. 7

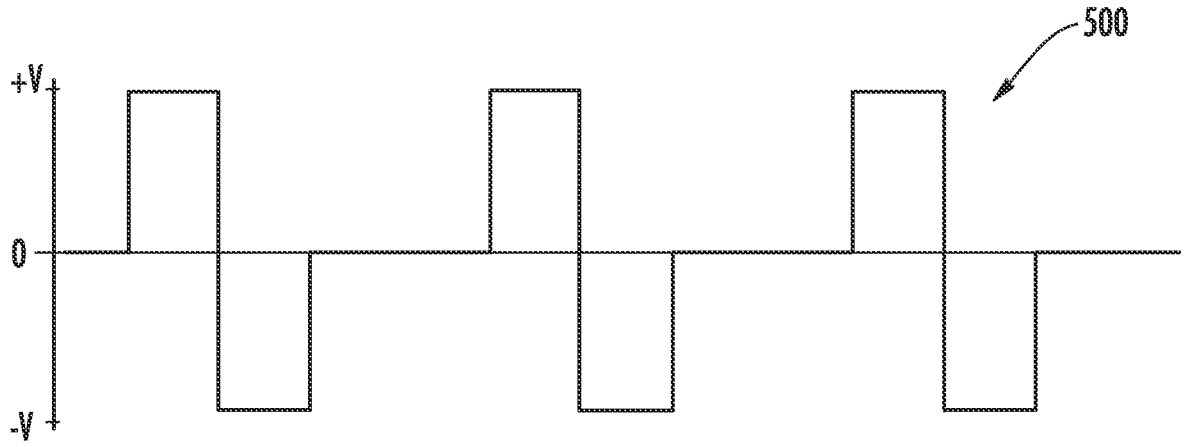
500
+V
0
-V

FIG. 8

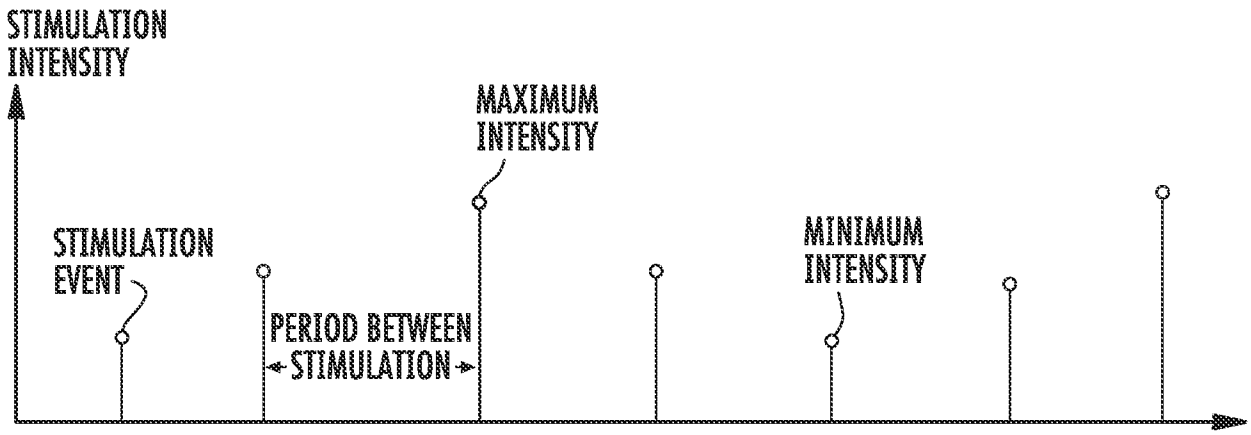
STIMULATION INTENSITY
MAXIMUM INTENSITY
STIMULATION EVENT
MINIMUM INTENSITY
PERIOD BETWEEN STIMULATION

FIG. 9

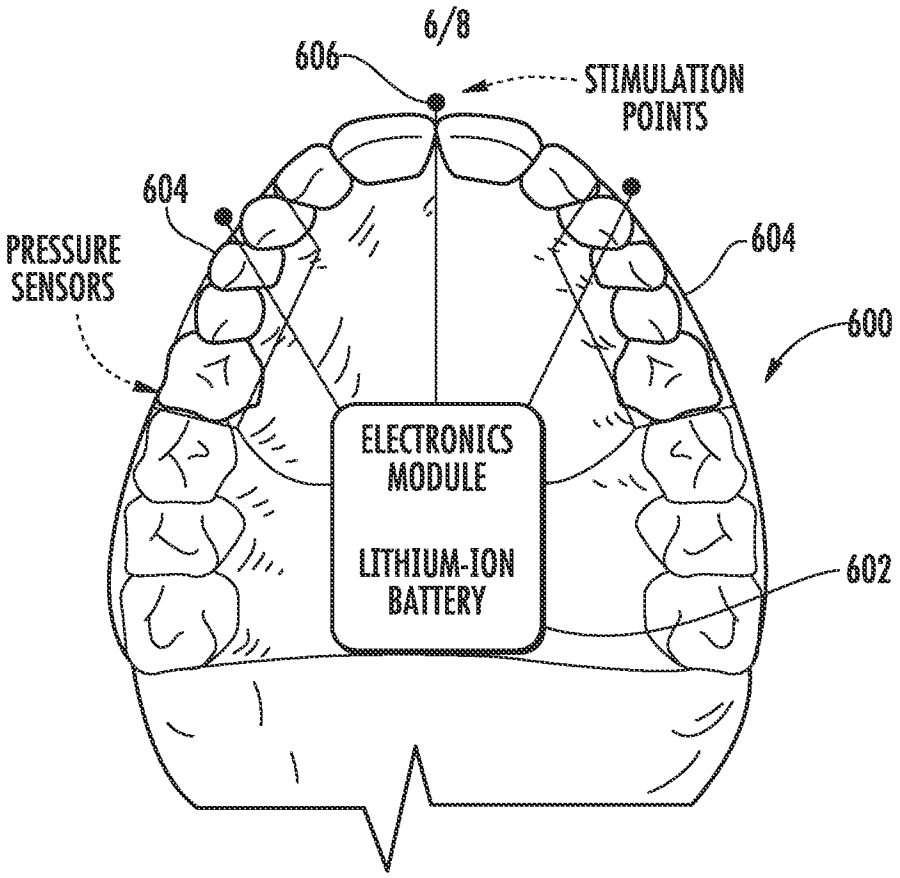
606
STIMULATION POINTS
604
604
PRESSURE SENSORS
600
ELECTRONICS MODULE
LITHIUM-ION BATTERY
602

FIG. 10

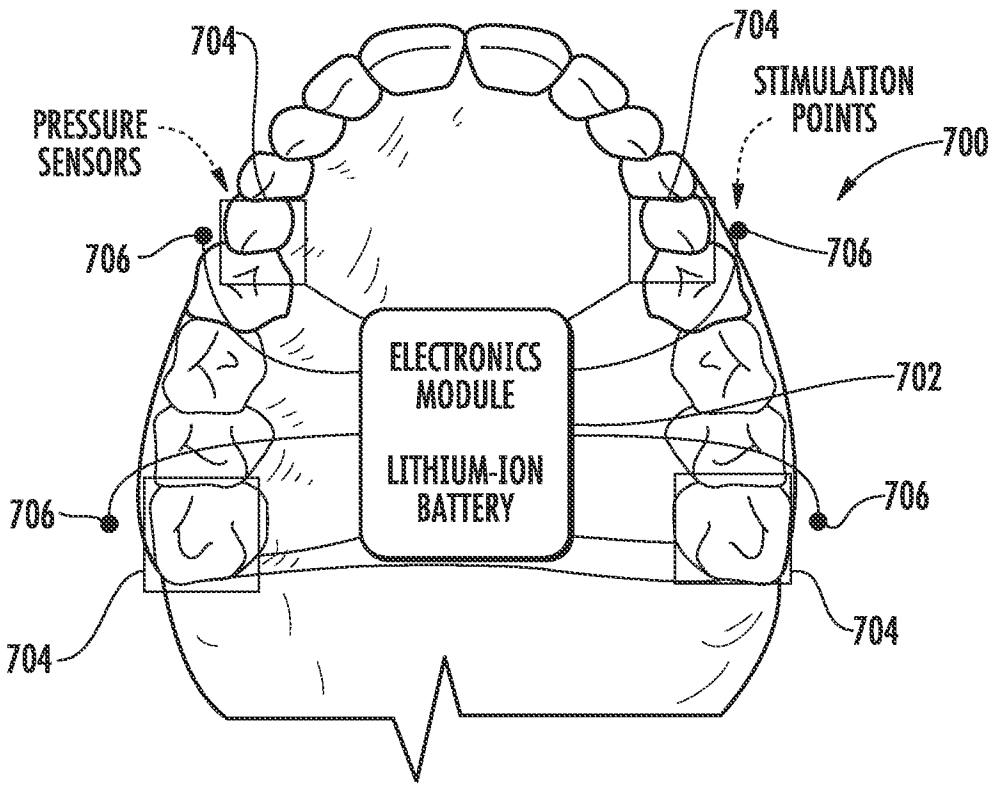
704
704
STIMULATION POINTS
PRESSURE SENSORS
700
706
706
ELECTRONICS MODULE
LITHIUM-ION BATTERY
702
706
706
704
704

FIG. 11

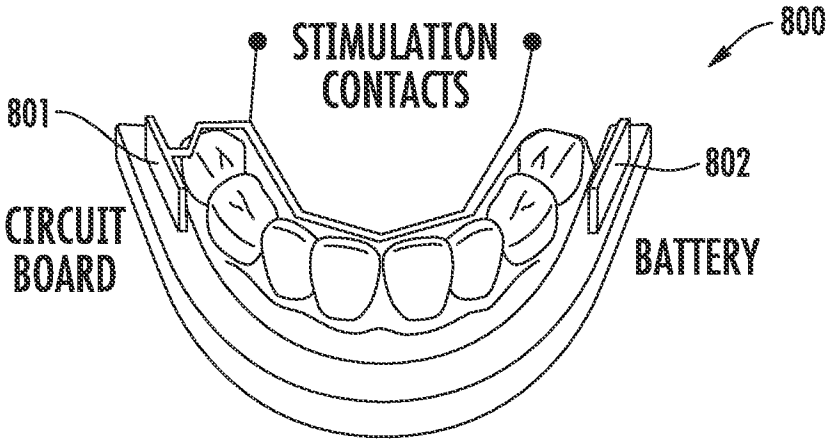
STIMULATION CONTACTS
800
801
802
CIRCUIT BOARD
BATTERY

FIG. 12

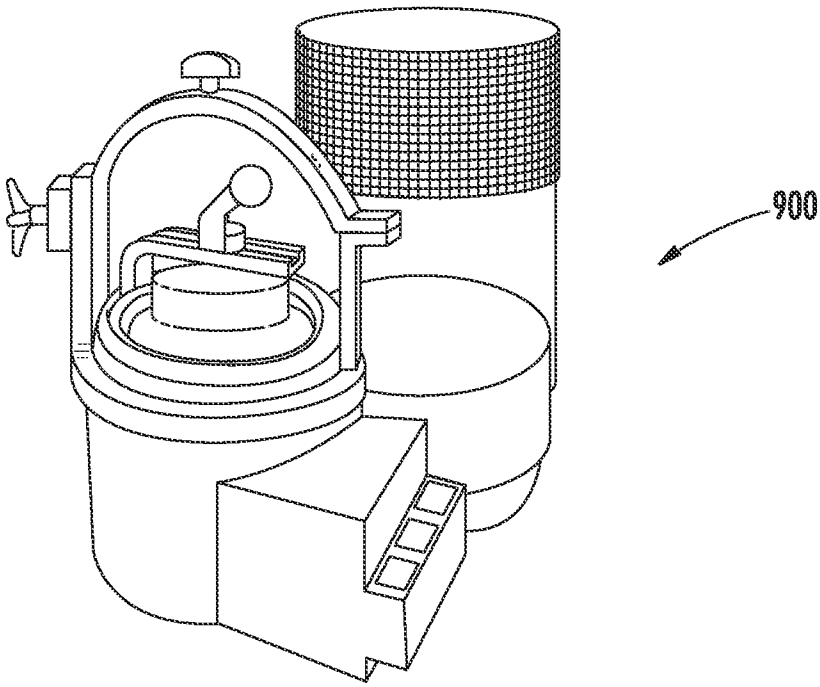
900

FIG. 13

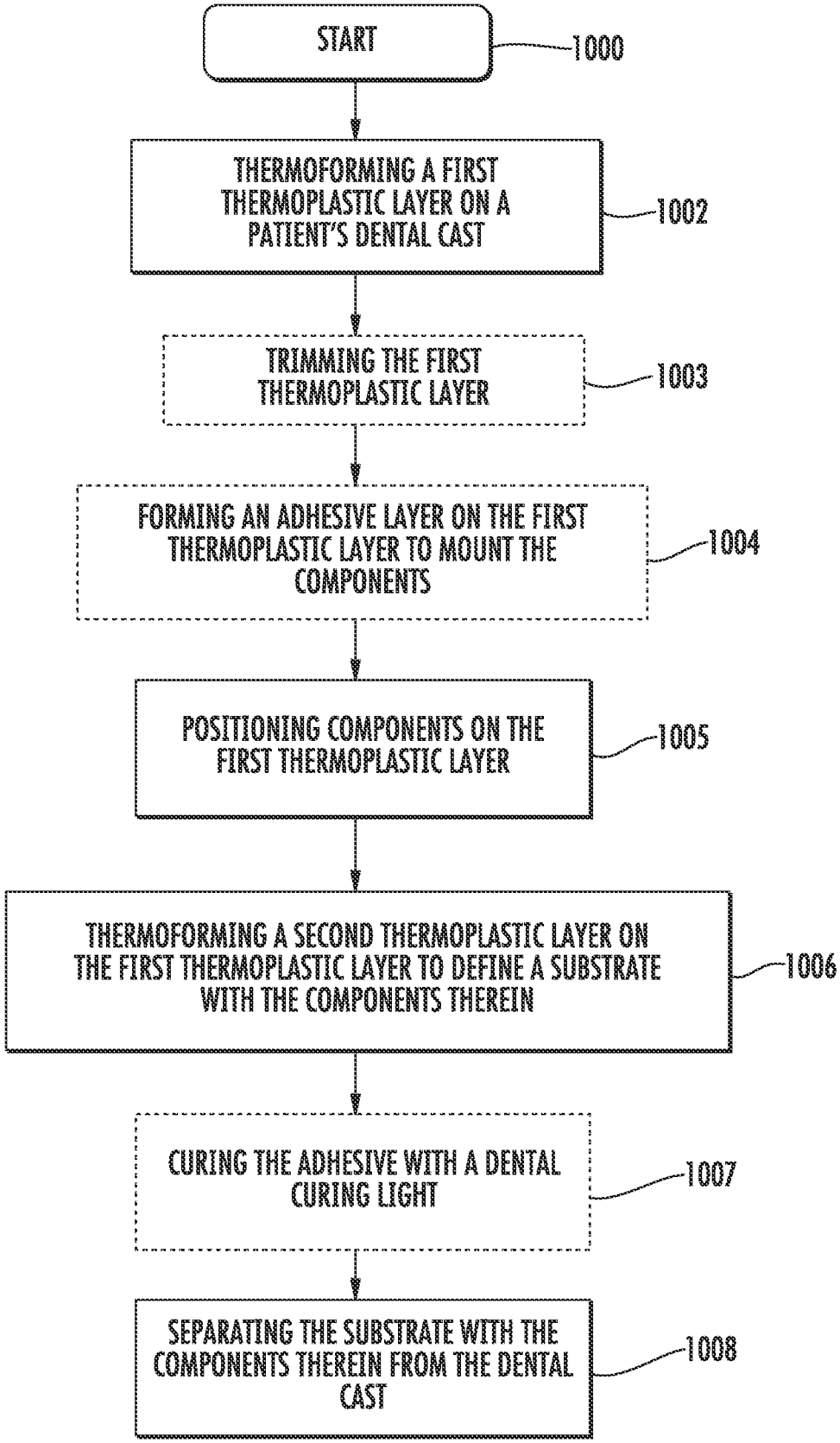
START
1000
THERMOFORMING A FIRST THERMOPLASTIC LAYER ON A PATIENT'S DENTAL CAST
1002
TRIMMING THE FIRST THERMOPLASTIC LAYER
1003
FORMING AN ADHESIVE LAYER ON THE FIRST THERMOPLASTIC LAYER TO MOUNT THE COMPONENTS
1004
POSITIONING COMPONENTS ON THE FIRST THERMOPLASTIC LAYER
1005
THERMOFORMING A SECOND THERMOPLASTIC LAYER ON THE FIRST THERMOPLASTIC LAYER TO DEFINE A SUBSTRATE WITH THE COMPONENTS THEREIN
1006
CURING THE ADHESIVE WITH A DENTAL CURING LIGHT
1007
SEPARATING THE SUBSTRATE WITH THE COMPONENTS THEREIN FROM THE DENTAL CAST
1008

FIG. 14

# INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/021590

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/36
ADD. A61F5/56

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>Y | US 2009/082839 A1 (LINDQUIST SHERRILL F [US] ET AL) 26 March 2009 (2009-03-26)<br>the whole document | 1-10, 12-24<br>11 |
| Y | WO 97/18854 A1 (RESPIRONICS INC [US])<br>29 May 1997 (1997-05-29)<br>page 5, line 17 - page 13, line 29;<br>figures 1-8 | 11 |
| A | US 6 598 006 B1 (HONDA KIYOSHI [JP] ET AL)<br>22 July 2003 (2003-07-22)<br>the whole document | 1-24 |

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 26 March 2010 | 09/04/2010 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Monogyiou, Efstratia |

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/021590

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 25-37
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2010/021590

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| US 2009082839 A1 | 26-03-2009 | NONE | |
| WO 9718854 A1 | 29-05-1997 | AU 1120297 A | 11-06-1997 |
| | | EP 0874662 A1 | 04-11-1998 |
| | | US 5792067 A | 11-08-1998 |
| US 6598006 B1 | 22-07-2003 | JP 3894691 B2 | 22-03-2007 |
| | | JP 2001117699 A | 27-04-2001 |