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(54) **INTRAORAL APPLIANCES WITH SENSING**

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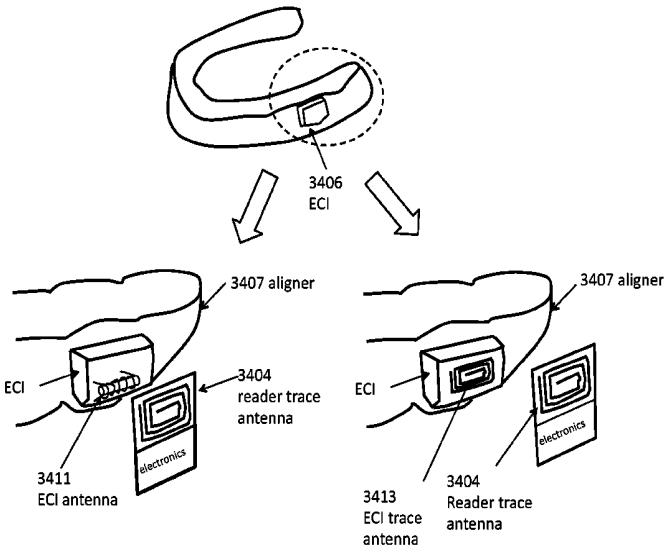
(57) **ABSTRACT**

Detection of placement of dental aligners in patient mouth on teeth for indication of wearing compliance. Described herein are apparatuses and methods for detecting wearing, including compliance, and for reliably transferring data, by wired or wireless direct or indirect communication of electronic compliance information to a smartphone. Also described herein are dental appliances that can detect physiological parameters related to respiration and sleep. Also described herein are aligner cases that enable NFC communication with electronic compliance indicator (ECI) devices and Bluetooth communication with smartphones.

26 Claims, 55 Drawing Sheets



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See application file for complete search history.

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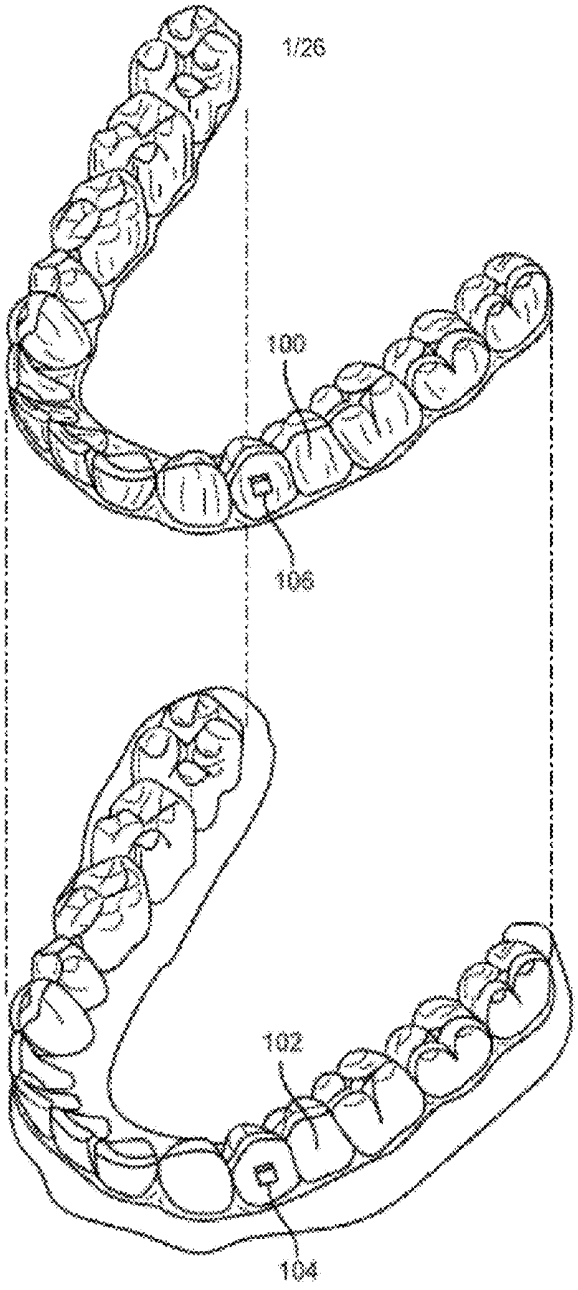


FIG. 1A

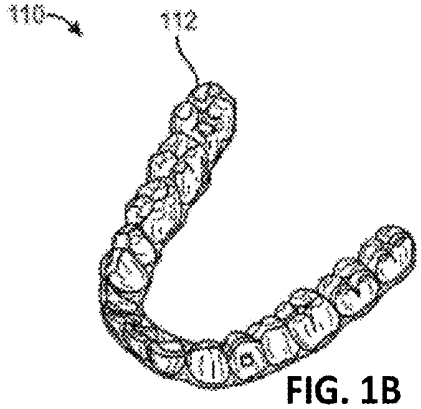


FIG. 1B

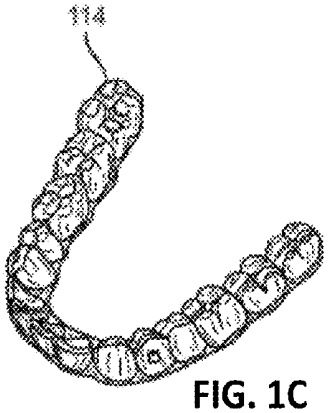


FIG. 1C

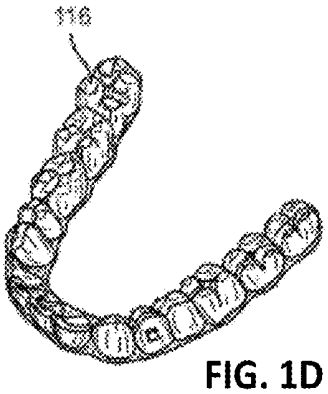


FIG. 1D

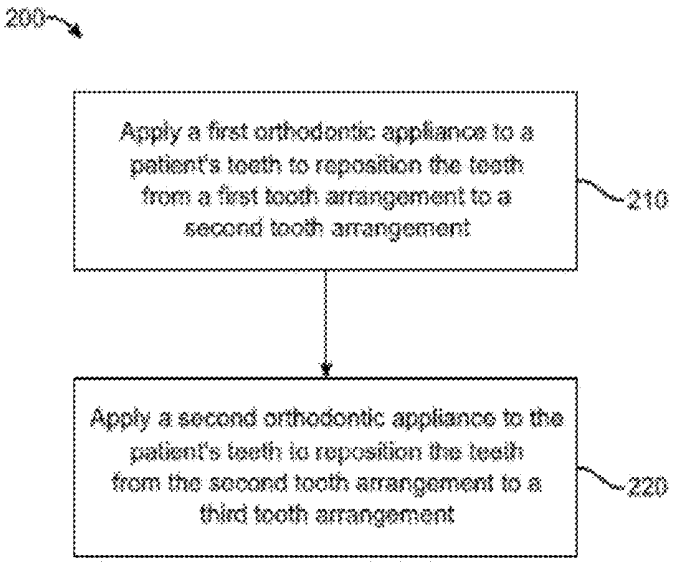

200
Apply a first orthodontic appliance to a patient's teeth to reposition the teeth from a first tooth arrangement to a second tooth arrangement
210
Apply a second orthodontic appliance to the patient's teeth to reposition the teeth from the second tooth arrangement to a third tooth arrangement
220

FIG. 2

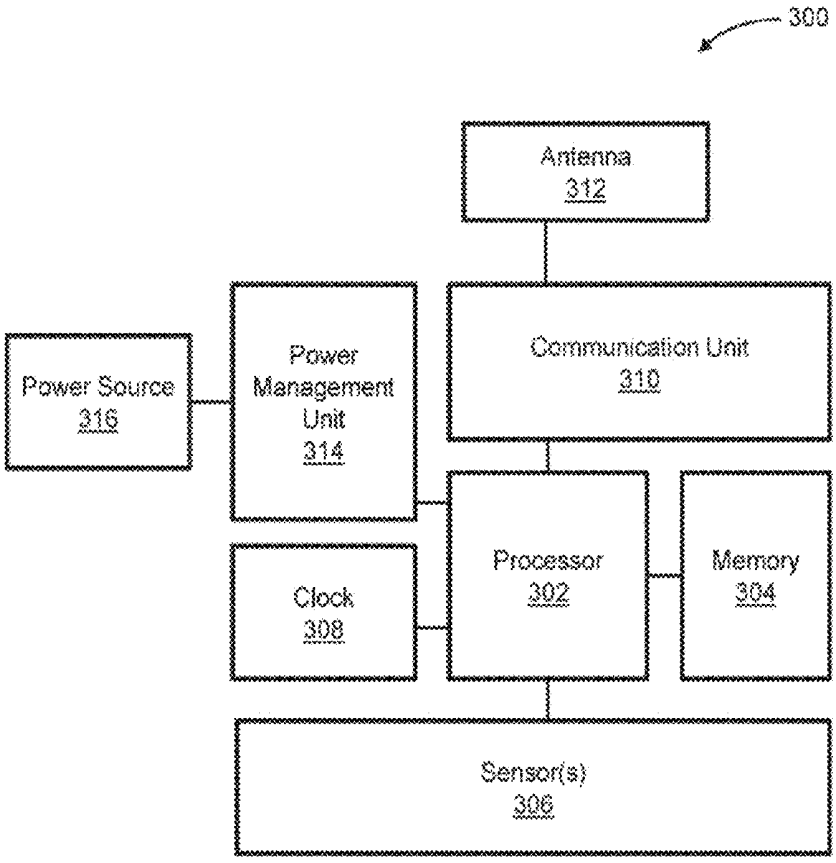

300
Antenna
312
Power Source
316
Power Management Unit
314
Communication Unit
310
Clock
308
Processor
302
Memory
304
Sensor(s)
306

FIG. 3A

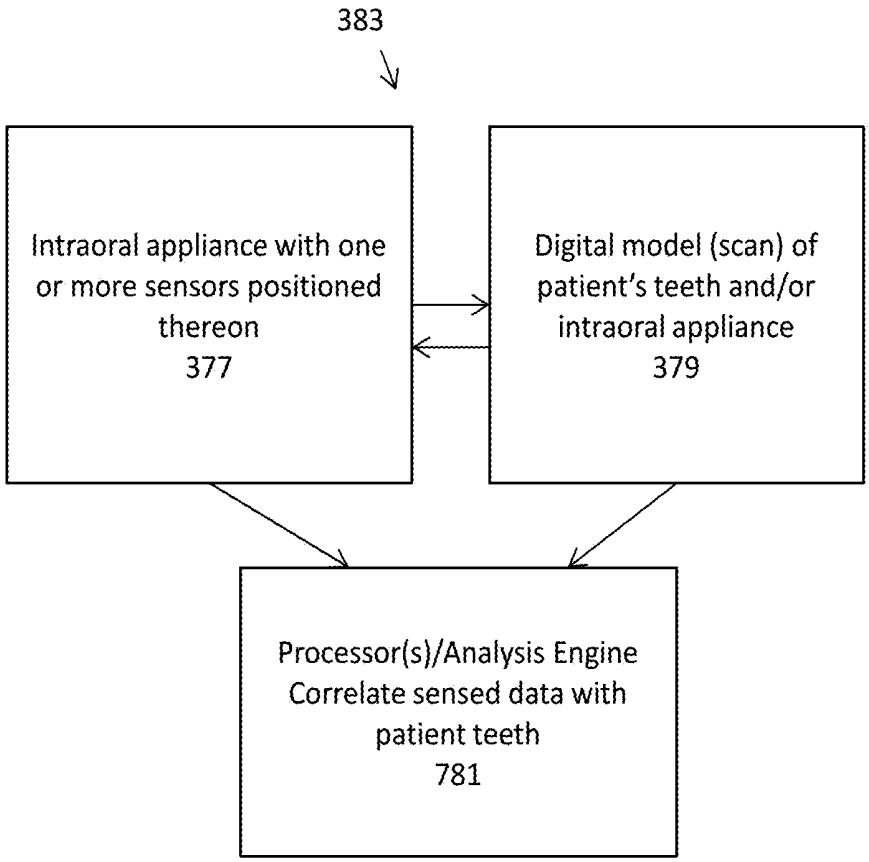

383
Intraoral appliance with one or more sensors positioned thereon
377
Digital model (scan) of patient's teeth and/or intraoral appliance
379
Processor(s)/Analysis Engine
Correlate sensed data with patient teeth
781

FIG. 3B

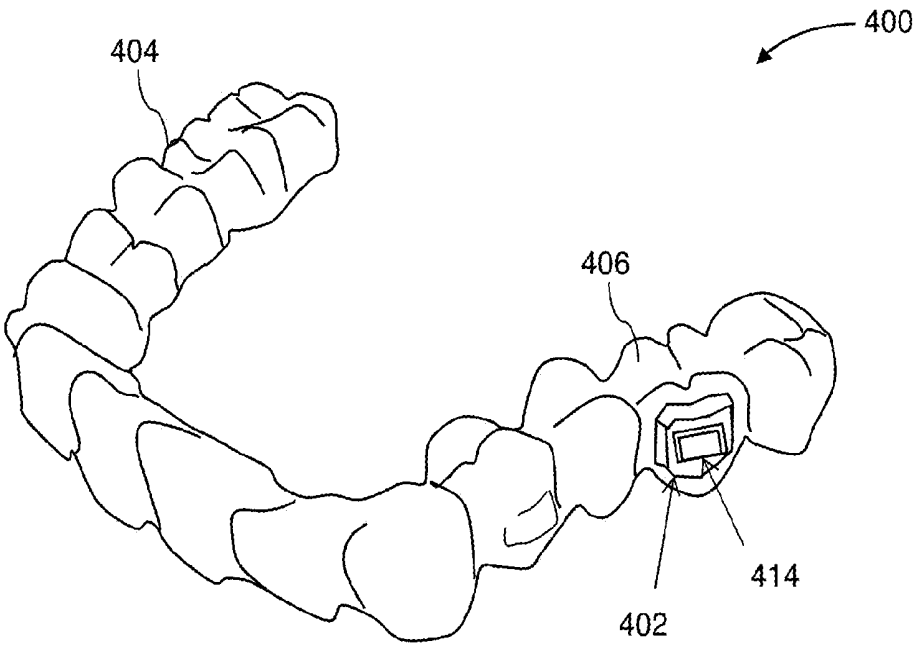


FIG. 4A

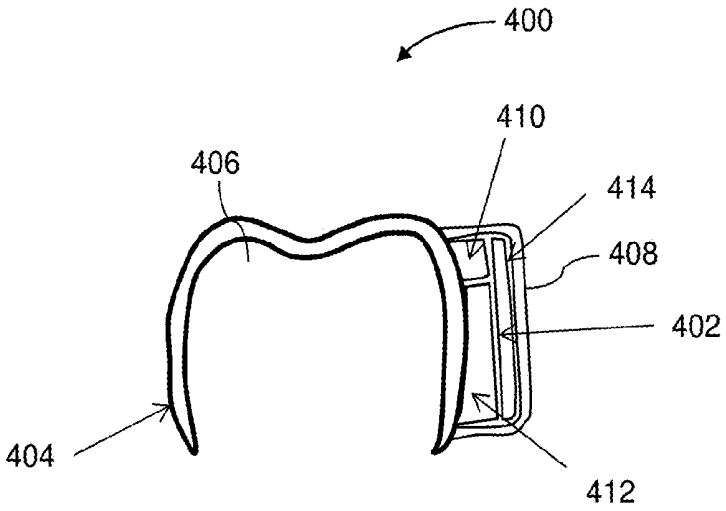


FIG. 4B

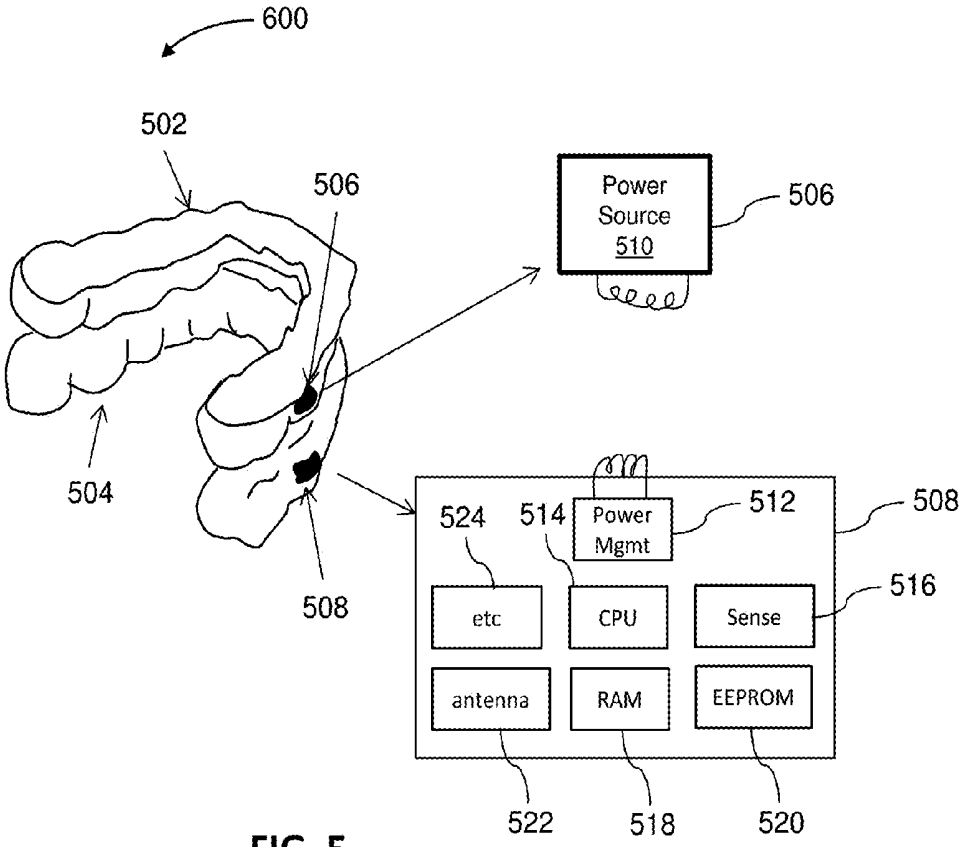

600
502
506
Power Source 510
506
504
508
524
514
Power Mgmt
512
508
516
etc
CPU
Sense
antenna
RAM
EEPROM
522
518
520

FIG. 5

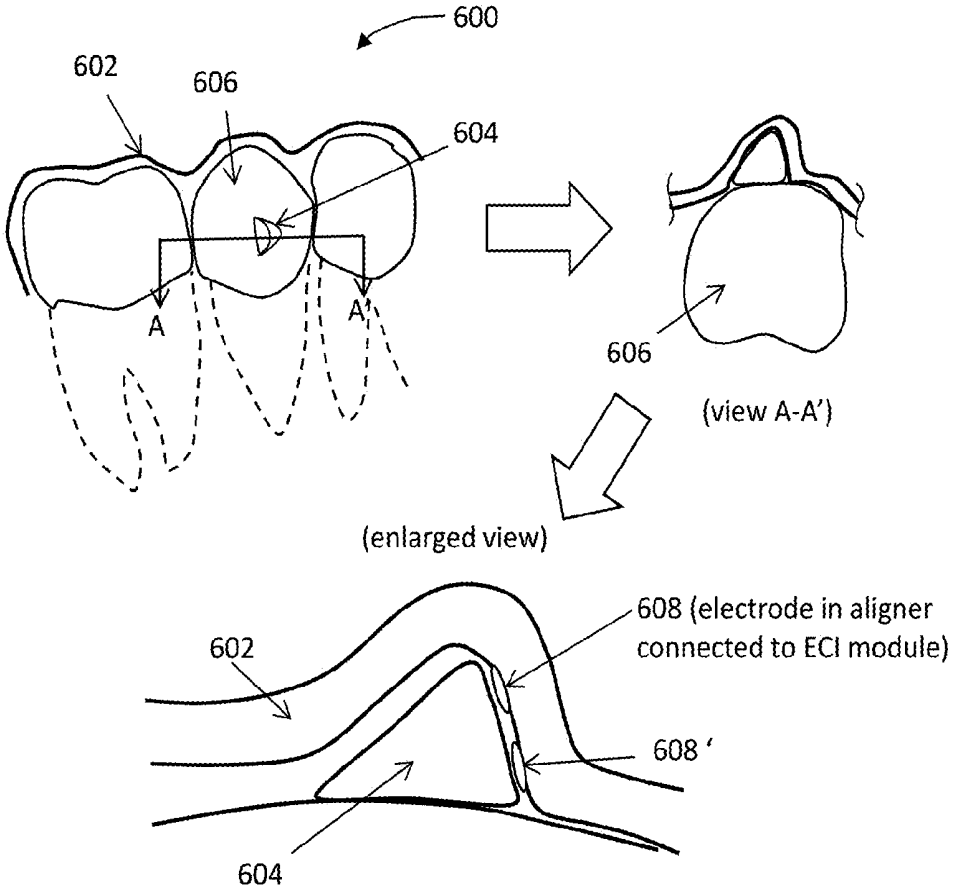

600
602
606
604
A
A'
606
(view A-A')
(enlarged view)
608 (electrode in aligner connected to ECI module)
602
608 '
604

FIG. 6A

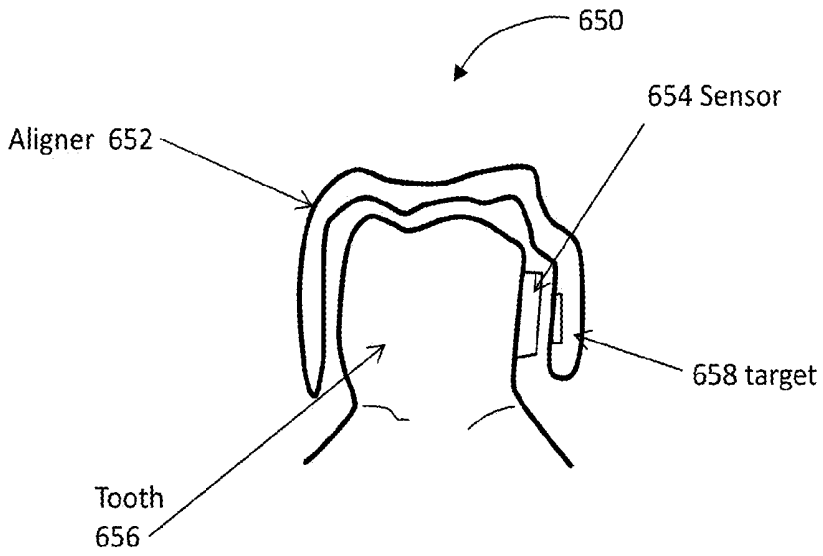

650
654 Sensor
Aligner 652
658 target
Tooth
656

FIG. 6B

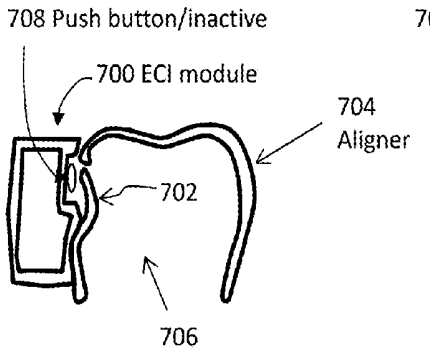


FIG. 7A

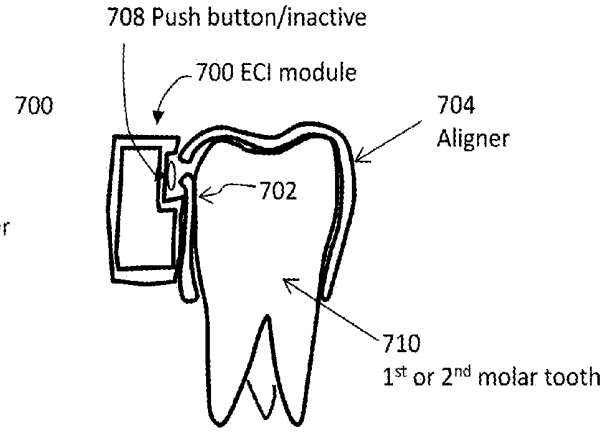


FIG. 7B

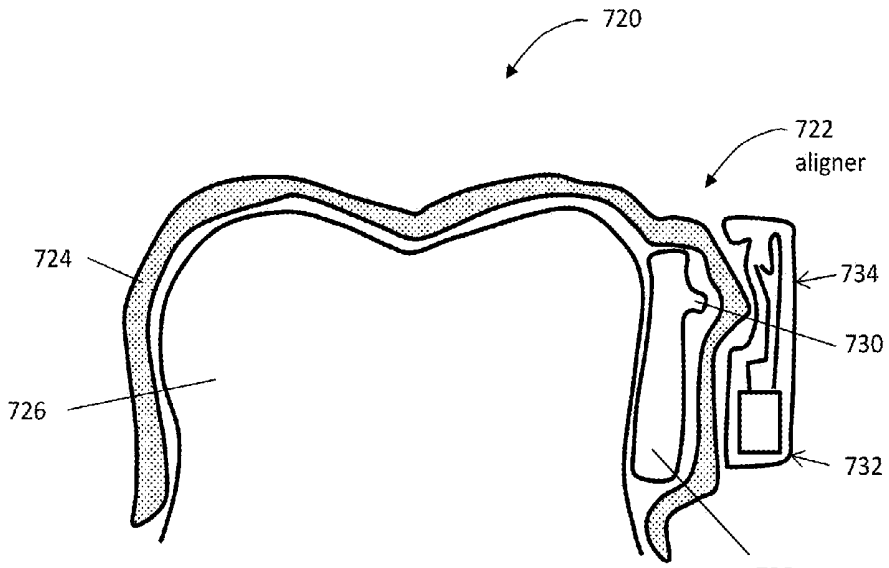


FIG. 7C

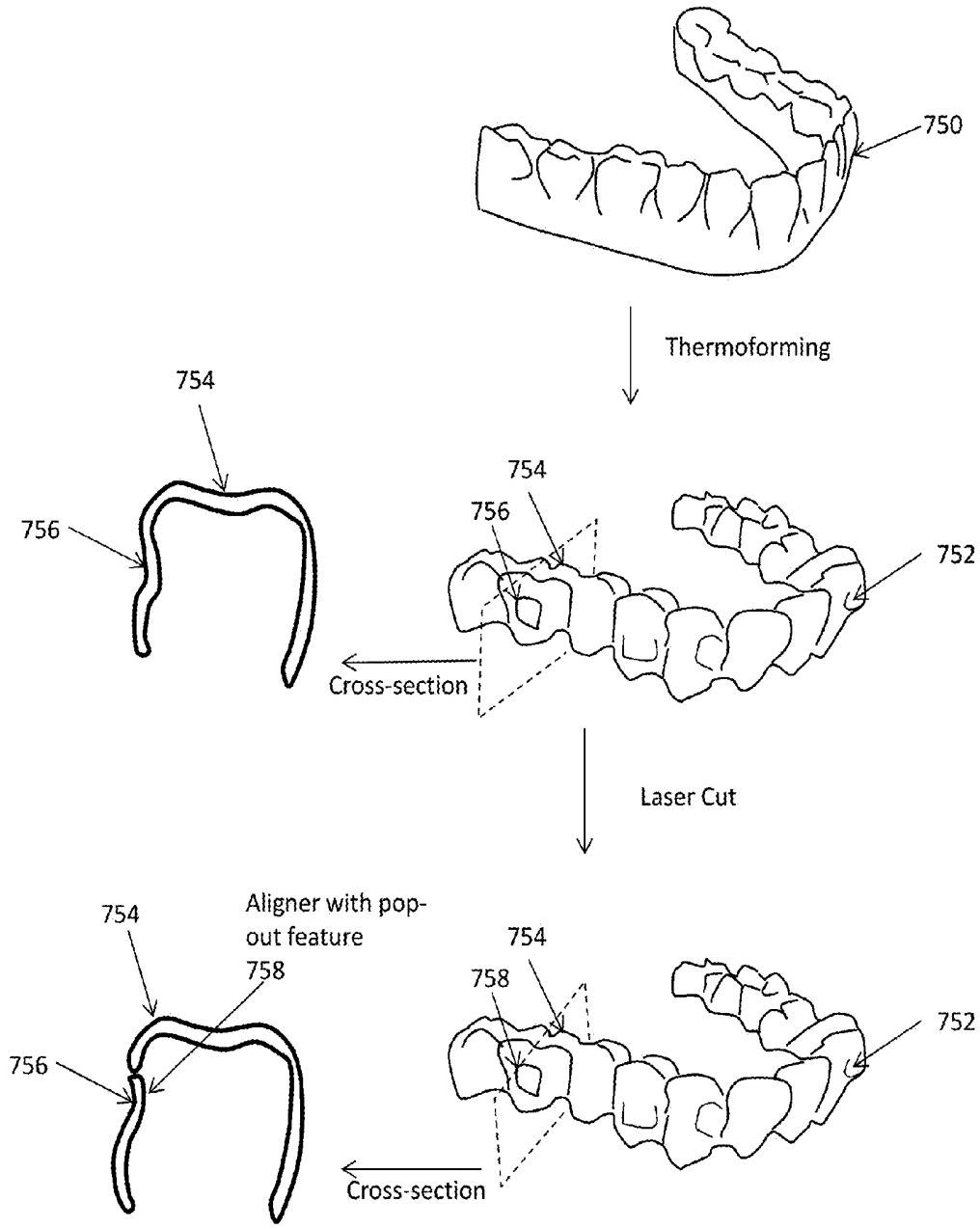

750
Thermoforming
754
756
754
756
752
Cross-section
Laser Cut
754
Aligner with pop-out feature
758
754
758
752
756
Cross-section

FIG. 7D

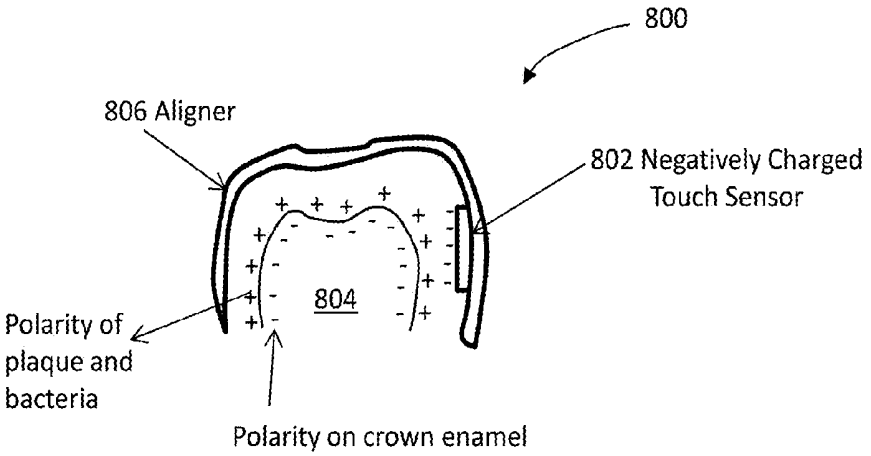

800
806 Aligner
802 Negatively Charged Touch Sensor
804
Polarity of plaque and bacteria
Polarity on crown enamel

FIG. 8A

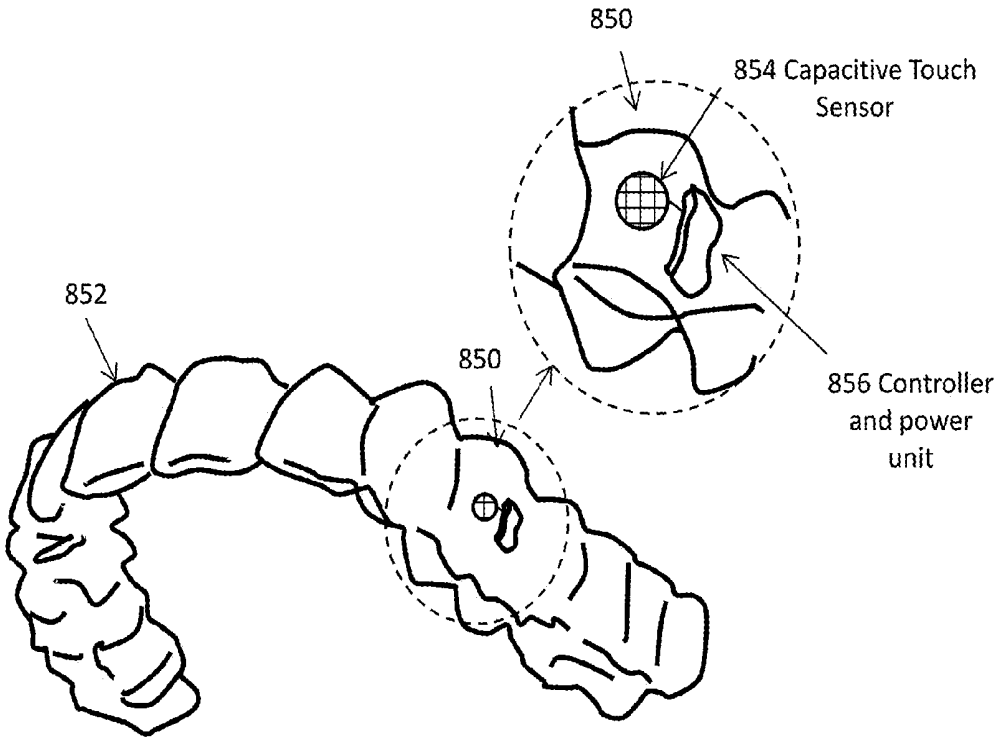

850
854 Capacitive Touch Sensor
852
850
856 Controller and power unit

FIG. 8B

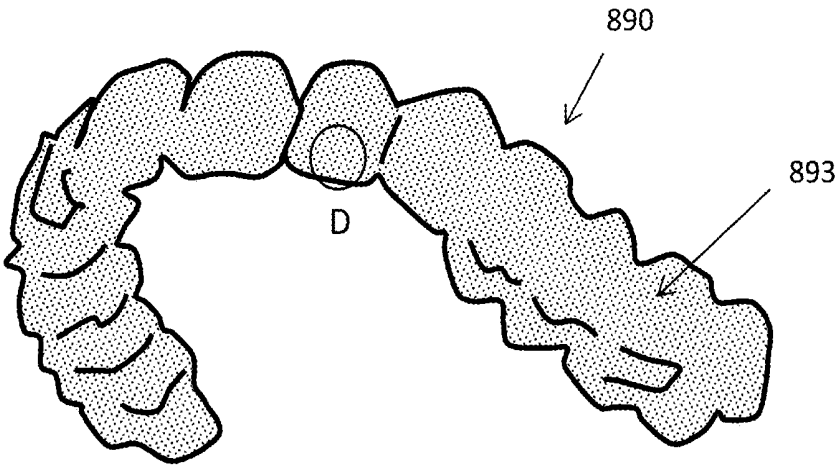


FIG. 8C

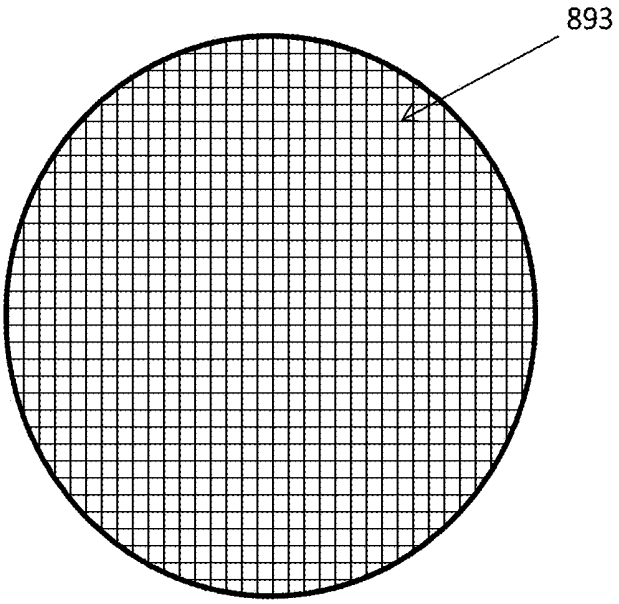


FIG. 8D

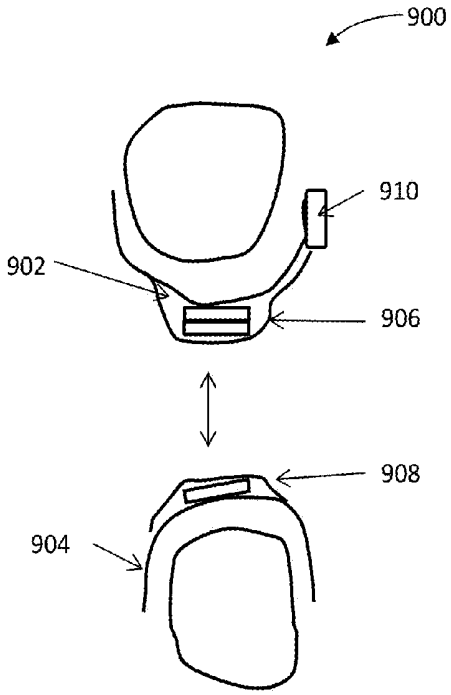


FIG. 9

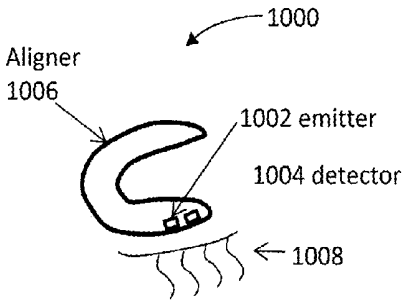


FIG. 10A

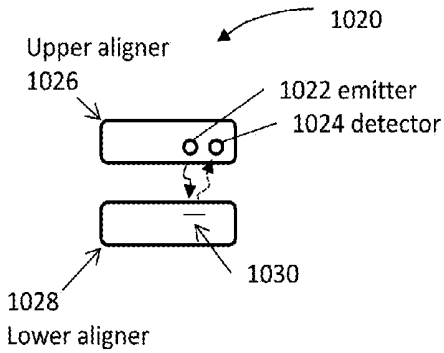


FIG. 10B

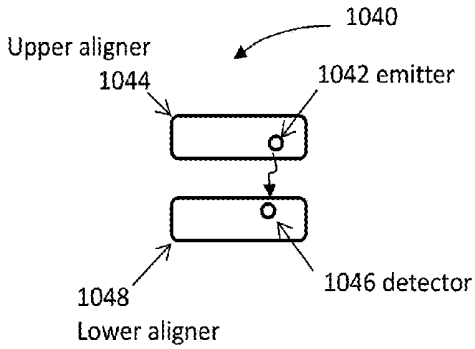


FIG. 10C

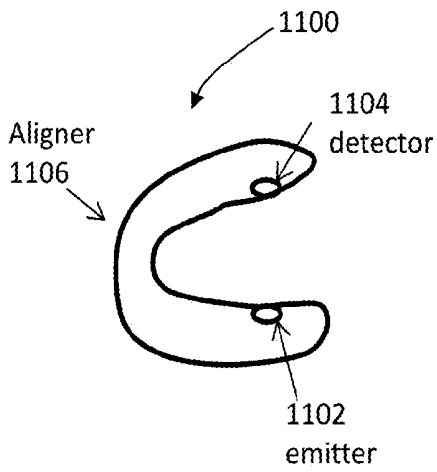


FIG. 11A

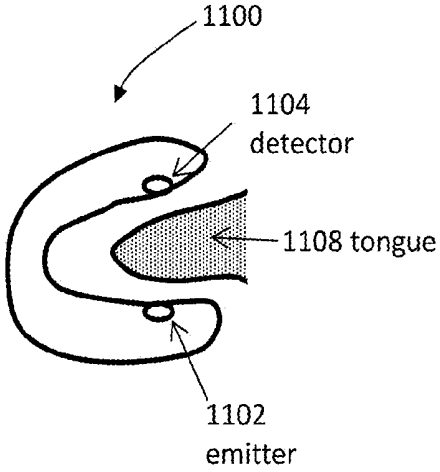


FIG. 11B

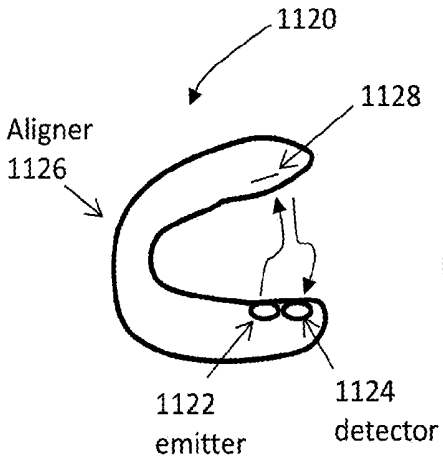


FIG. 11C

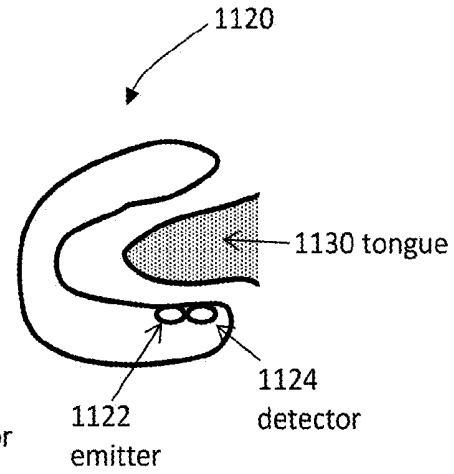


FIG. 11D

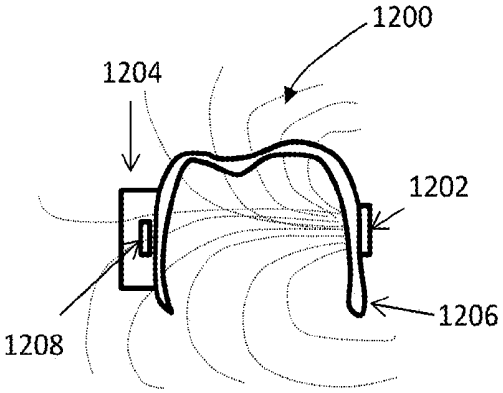


FIG. 12A

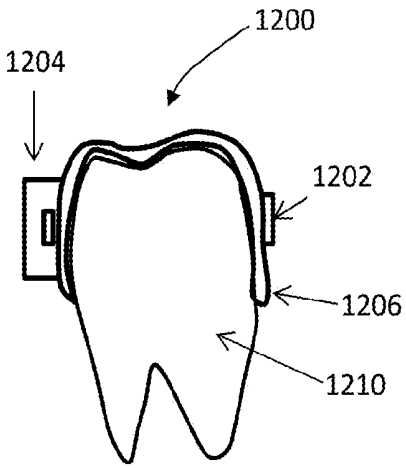


FIG. 12B

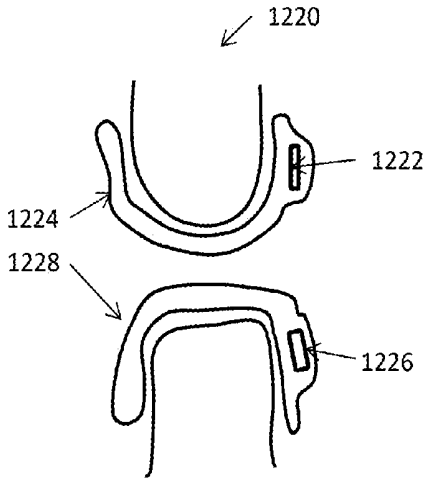


FIG. 12C

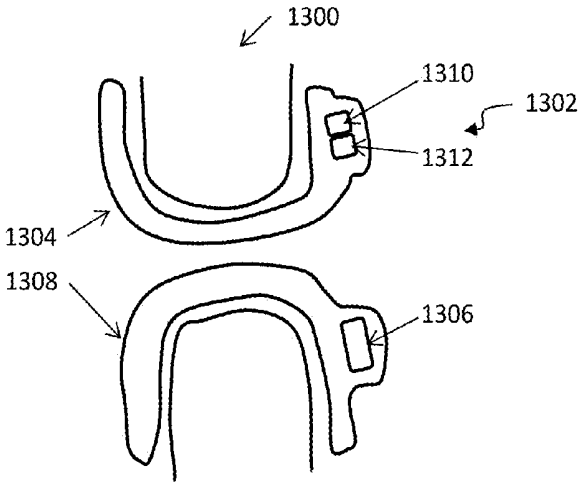


FIG. 13A

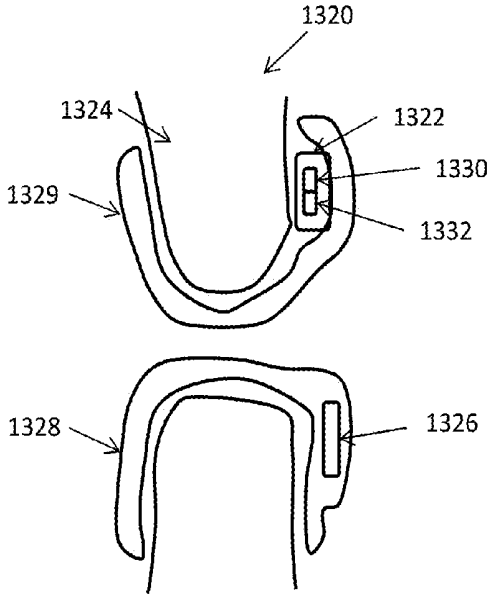


FIG. 13B

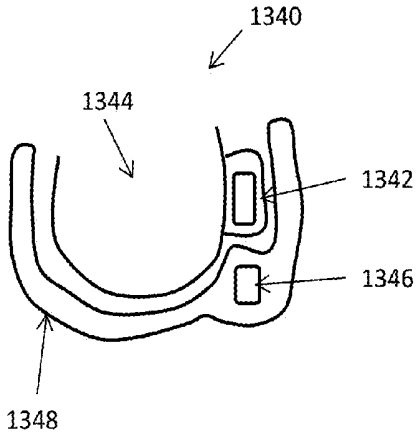


FIG. 13C

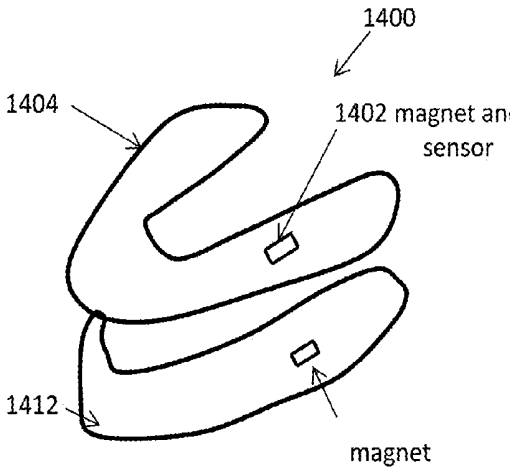


FIG. 14A

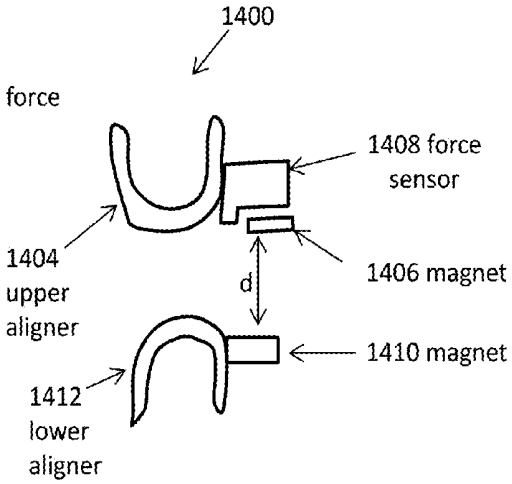


FIG. 14B

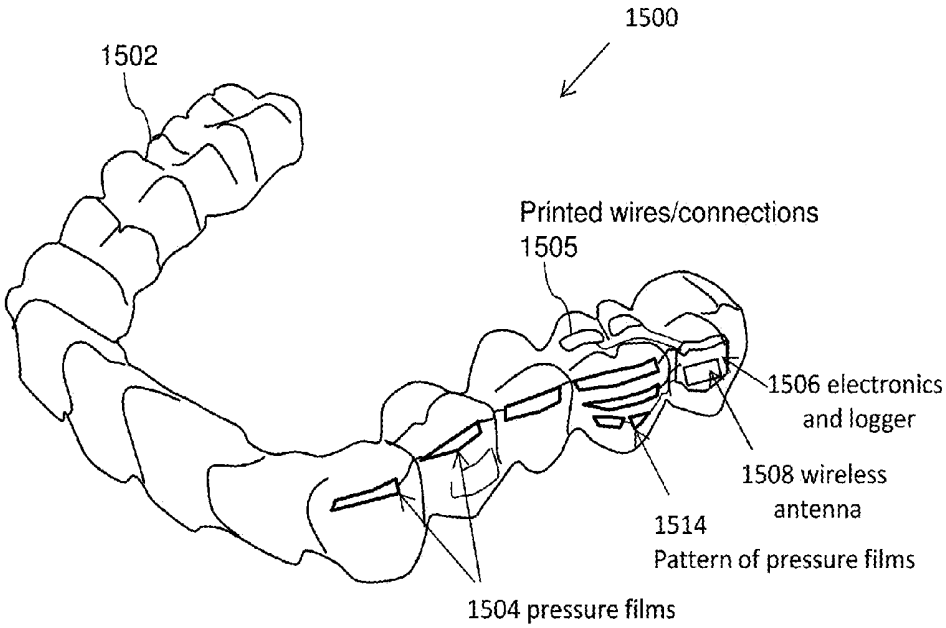


FIG. 15

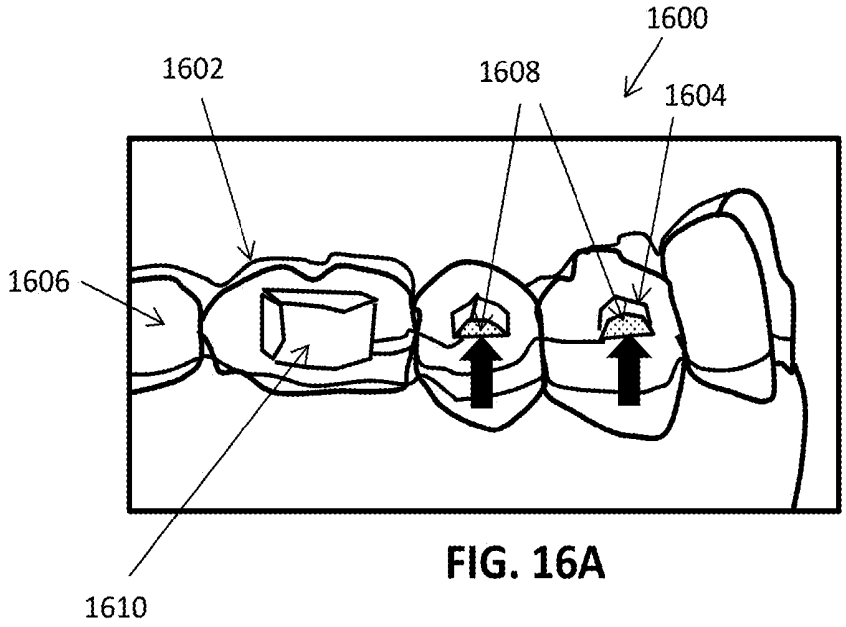


FIG. 16A

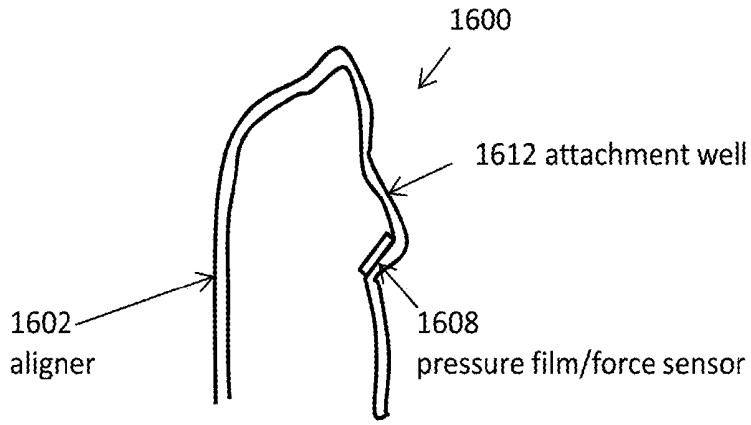


FIG. 16B

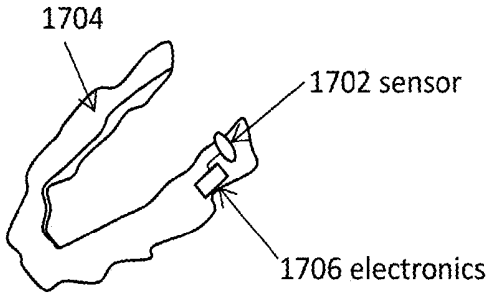


FIG. 17A

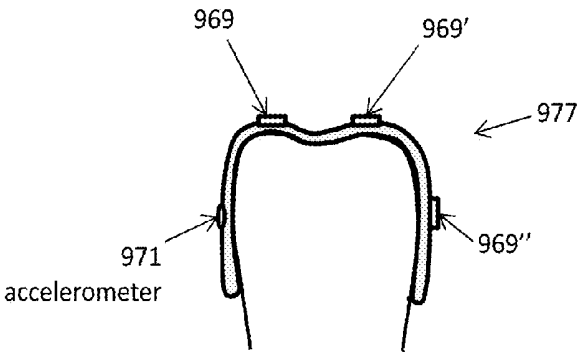


FIG. 16C

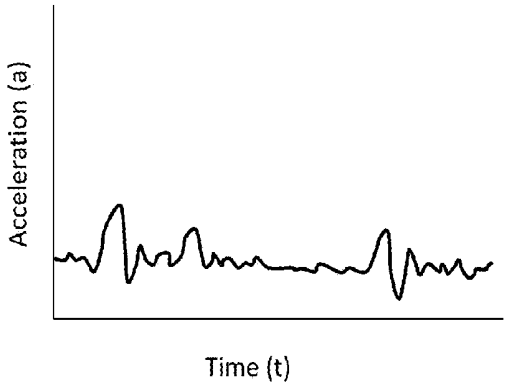


FIG. 16D

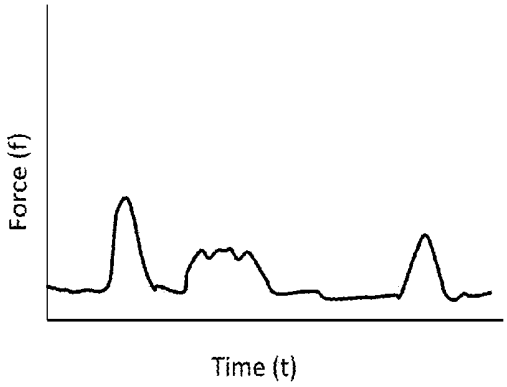


FIG. 16E

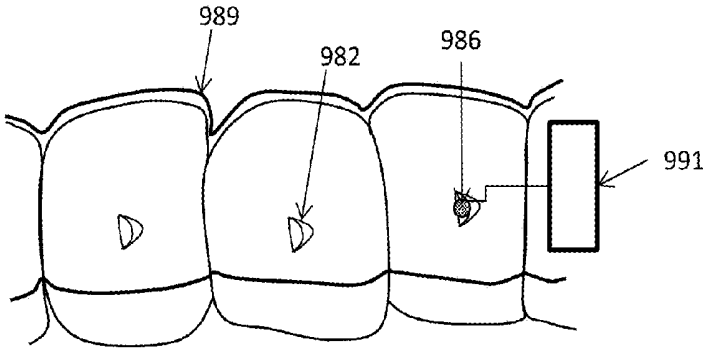


FIG. 16F

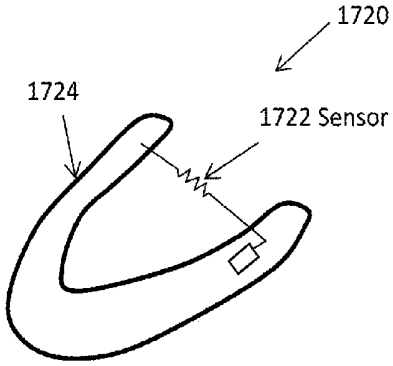


FIG. 17B

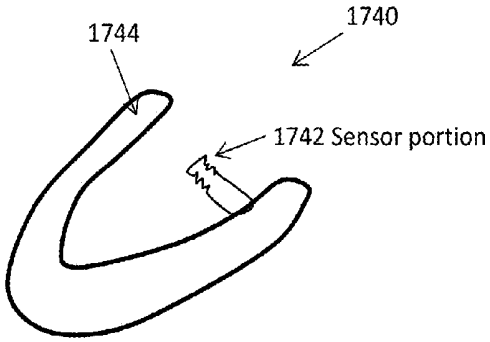


FIG. 17C

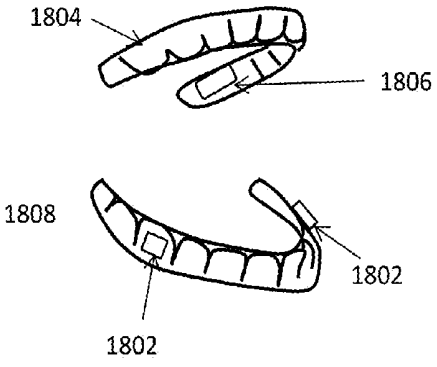


FIG. 18

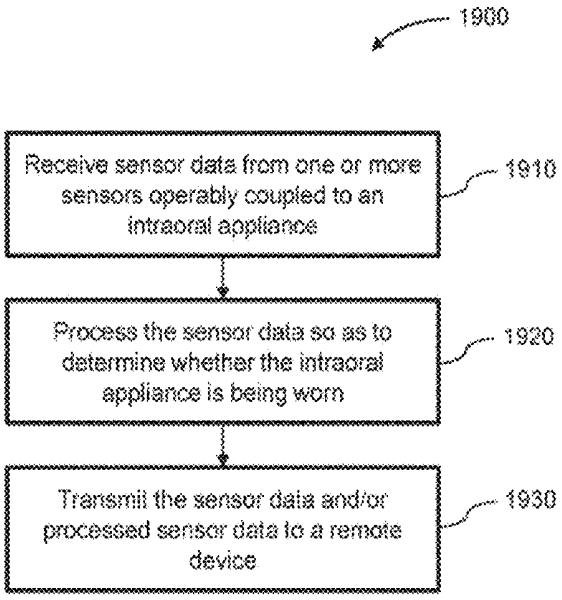
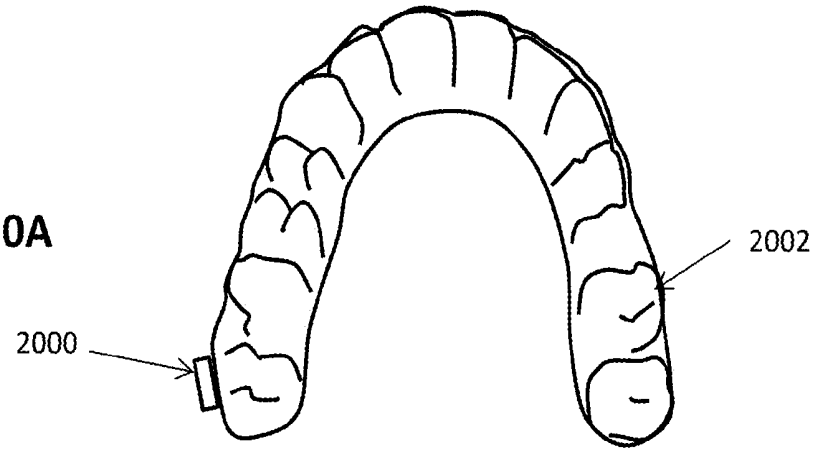


FIG. 19

FIG. 20A



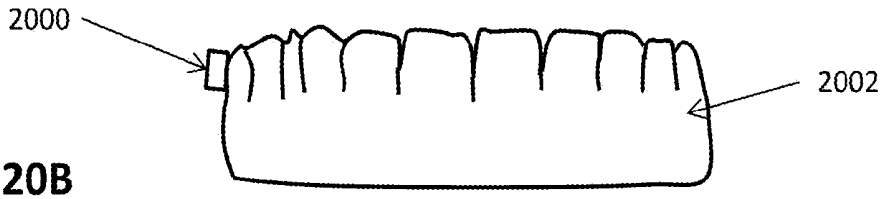


FIG. 20B

FIG. 20C

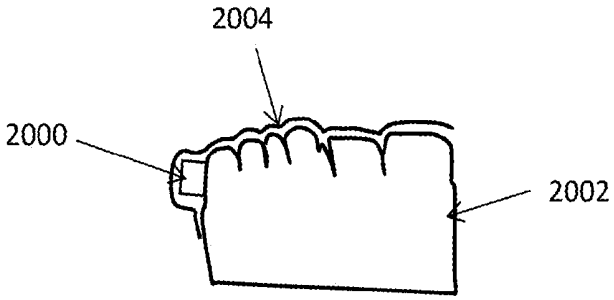
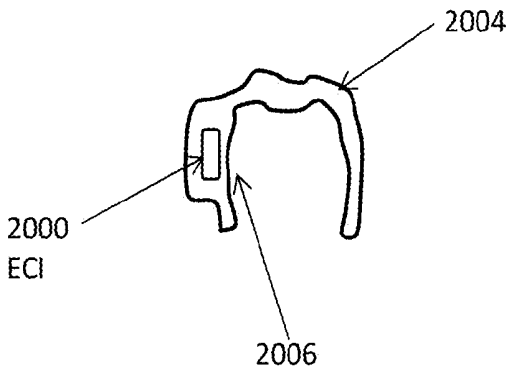


FIG. 20D



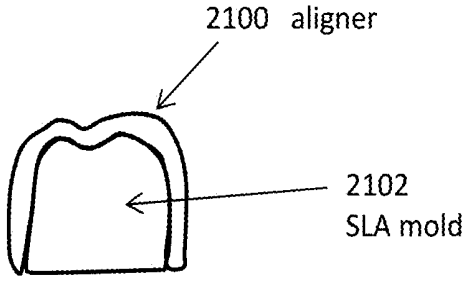


FIG. 21A

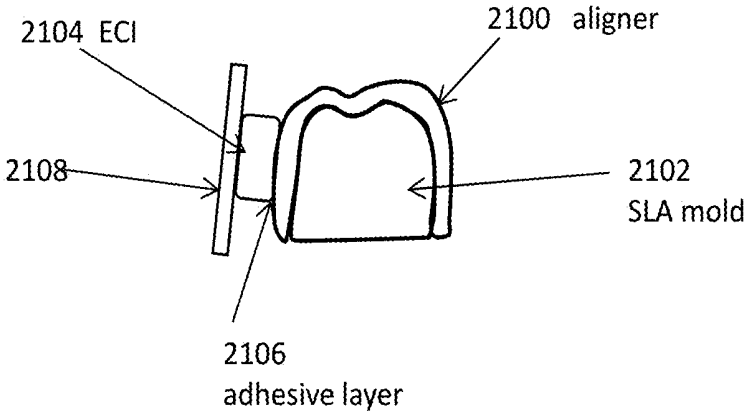


FIG. 21B

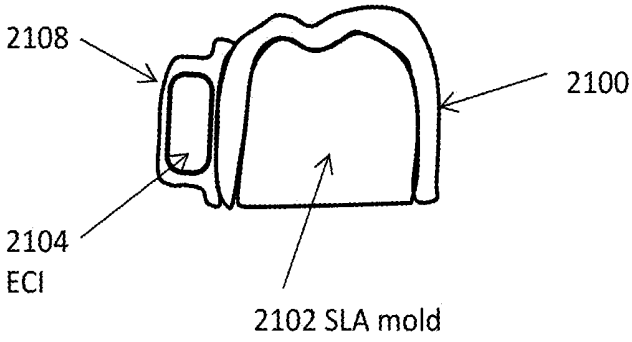


FIG. 21C

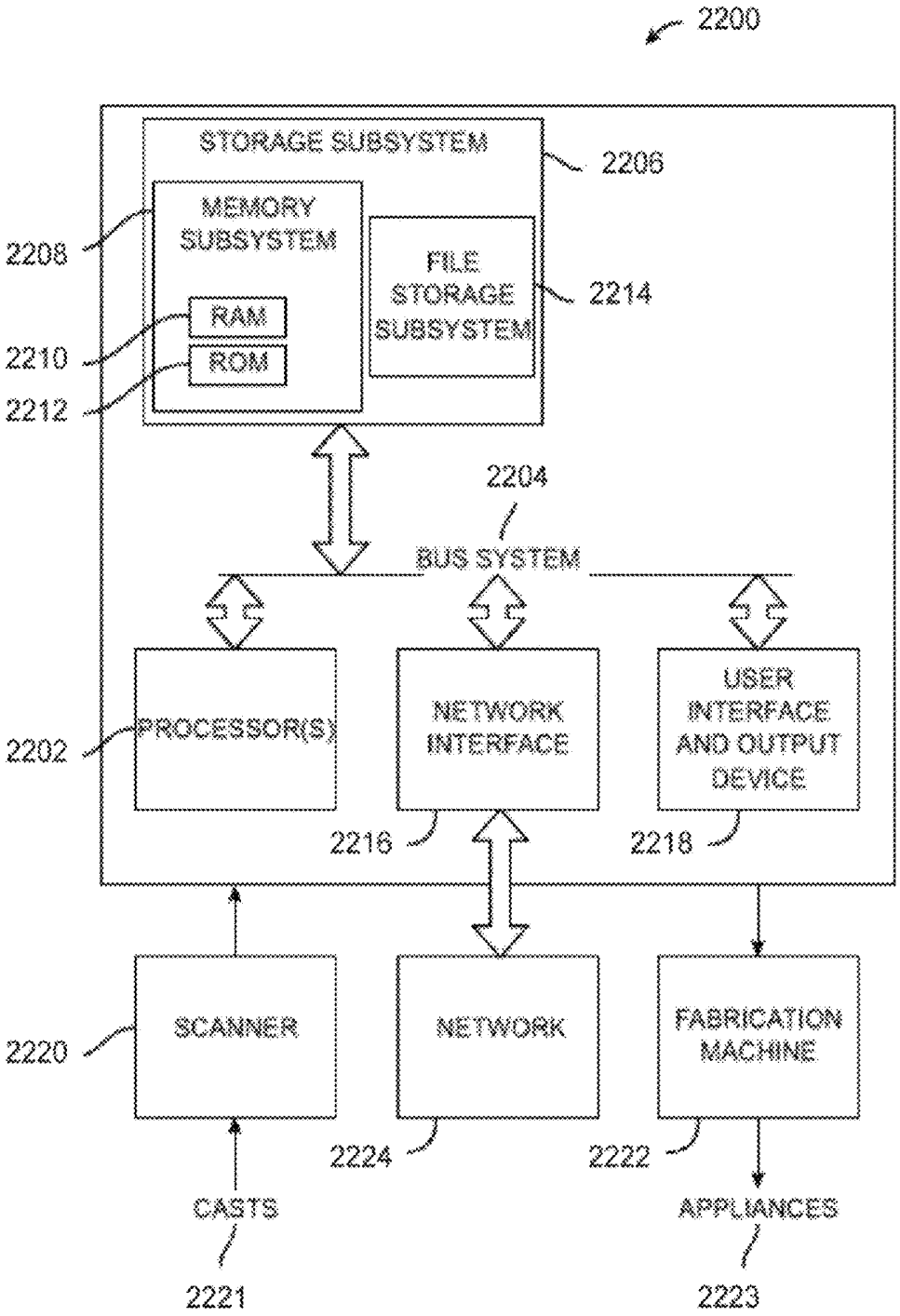

2200
STORAGE SUBSYSTEM
2206
MEMORY SUBSYSTEM
2208
RAM
2210
ROM
2212
FILE STORAGE SUBSYSTEM
2214
2204
BUS SYSTEM
PROCESSOR(S)
2202
NETWORK INTERFACE
2216
USER INTERFACE AND OUTPUT DEVICE
2218
SCANNER
2220
NETWORK
2224
FABRICATION MACHINE
2222
CASTS
2221
APPLIANCES
2223

FIG. 22

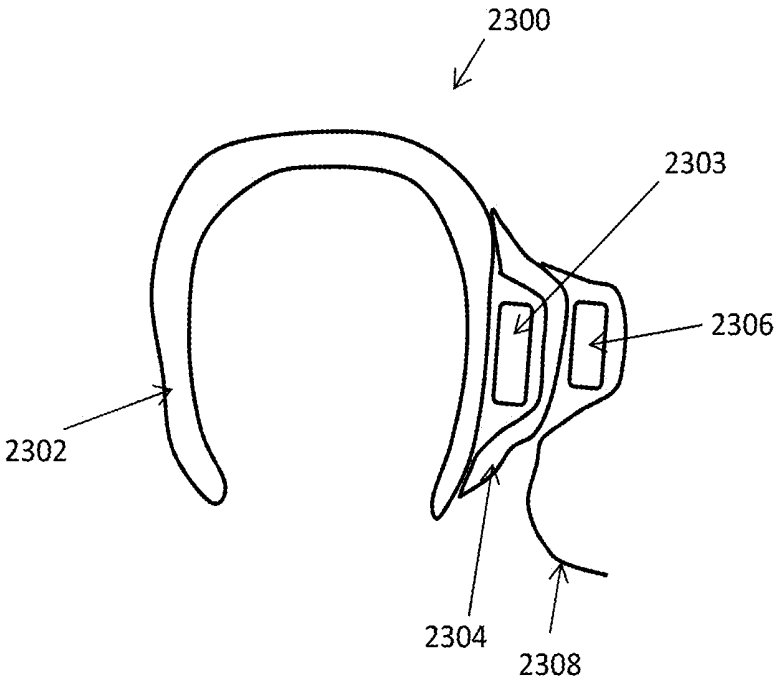


FIG. 23

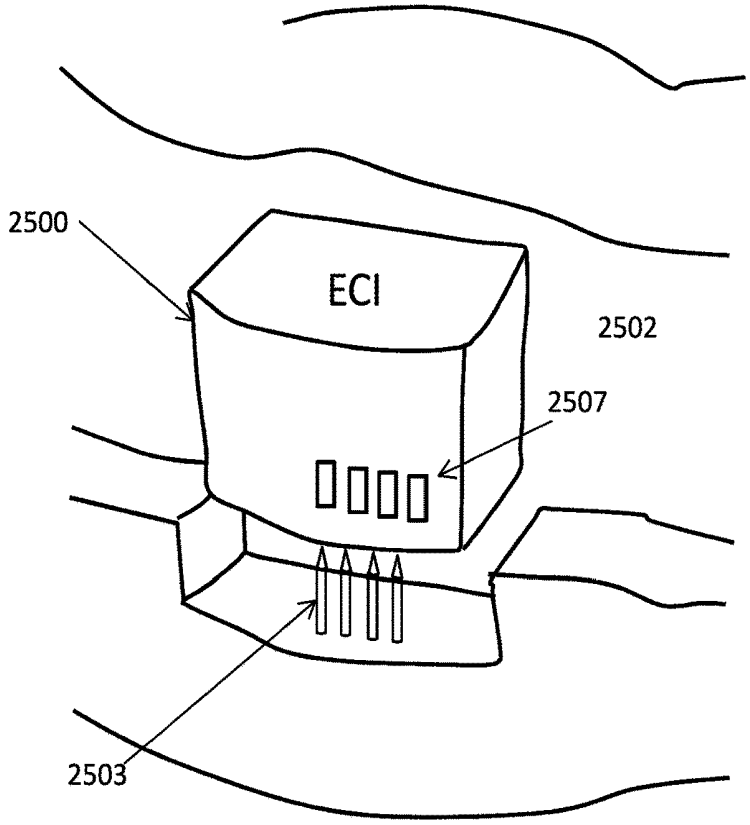


FIG. 24

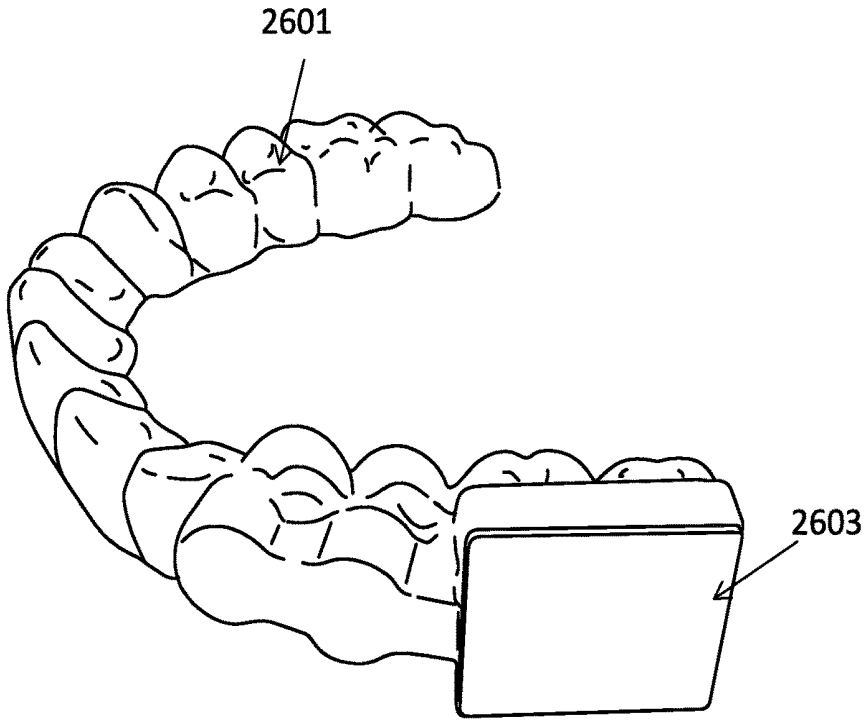


FIG. 25

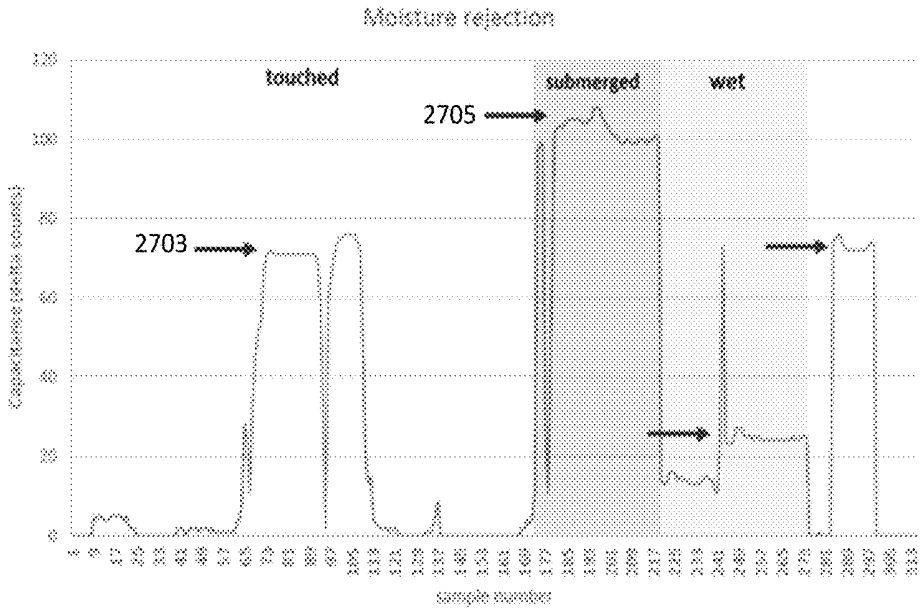

Moisture rejection
touched
submerged
wet
2705
2703

FIG. 26

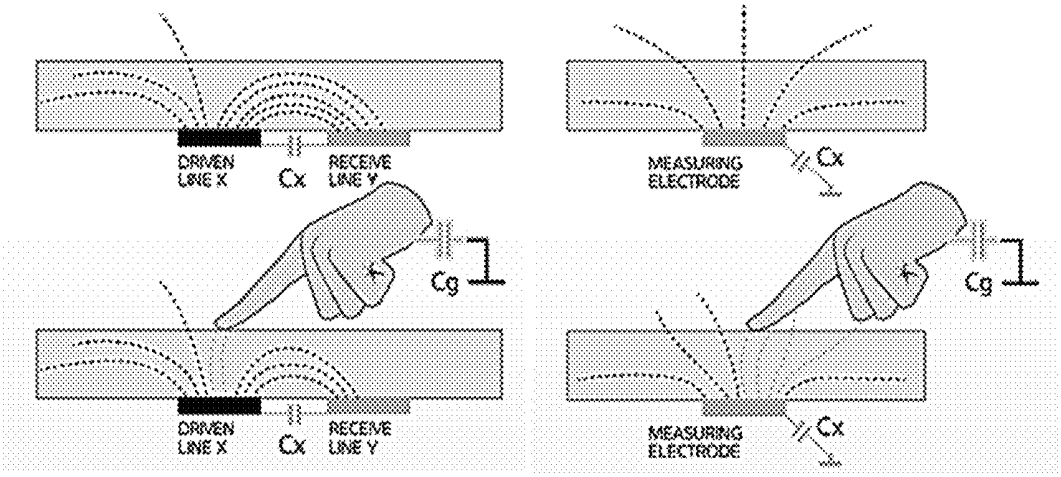

DRIVEN LINE X
Cx
RECEIVE LINE Y
Cg
MEASURING ELECTRODE
Cx
Cg
DRIVEN LINE X
Cx
RECEIVE LINE Y
MEASURING ELECTRODE
Cx
Cg

FIG. 27

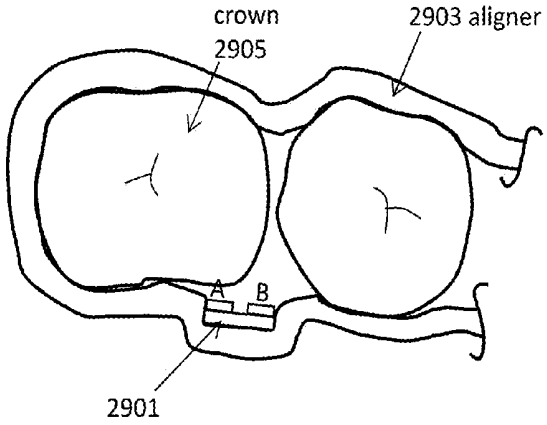


FIG. 28

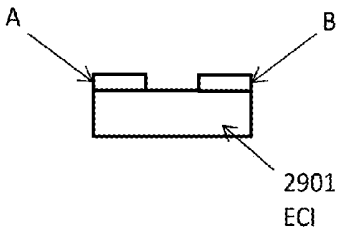


FIG. 29A

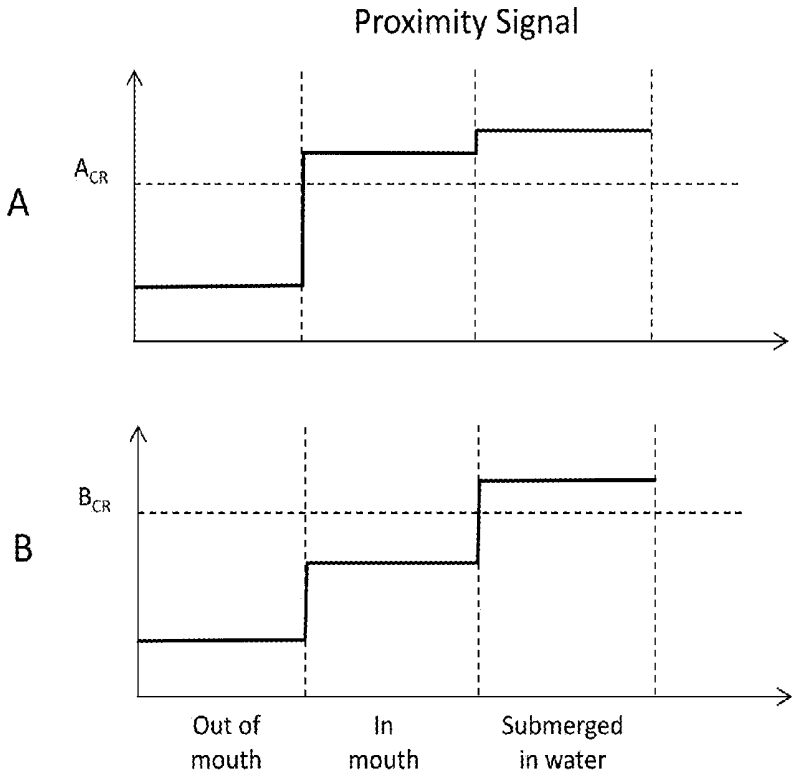
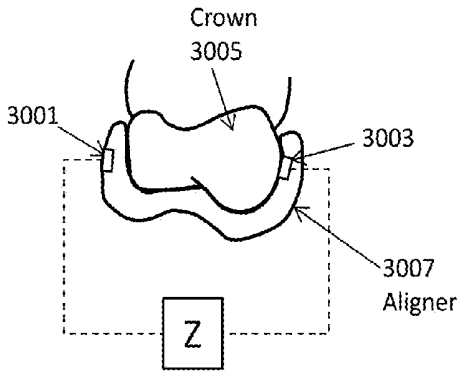
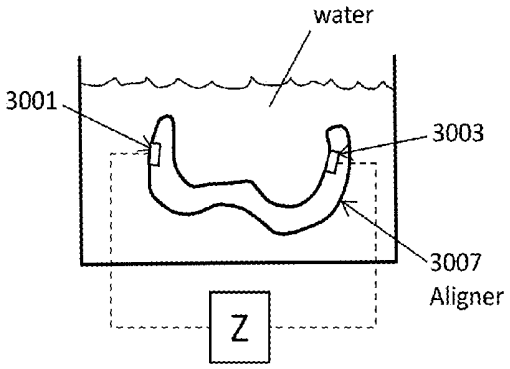


FIG. 29B



(Z is very high or ∞)

FIG. 30A



(Z is near 0)

FIG. 30B

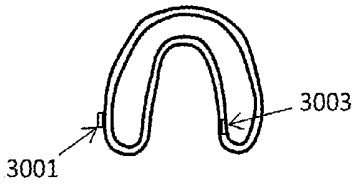


FIG. 30C

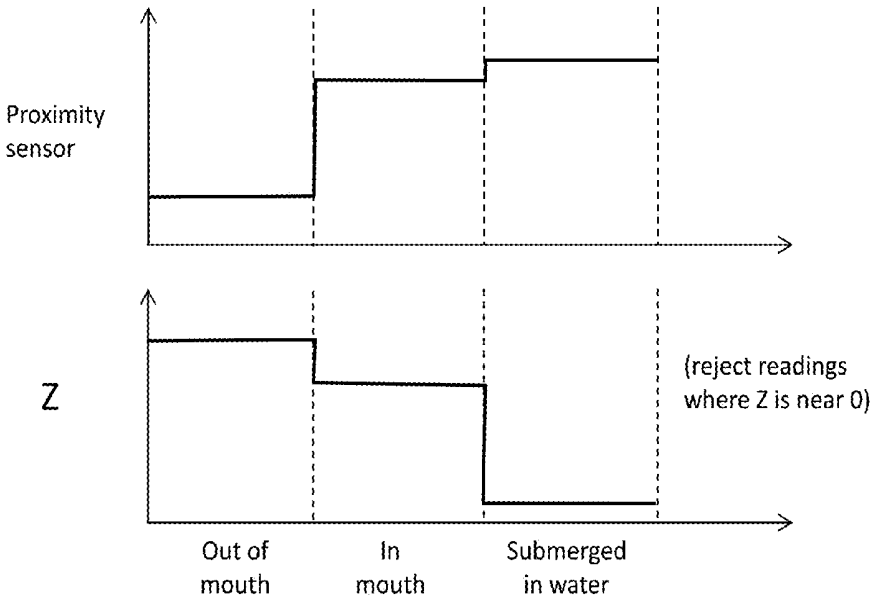


FIG. 30D

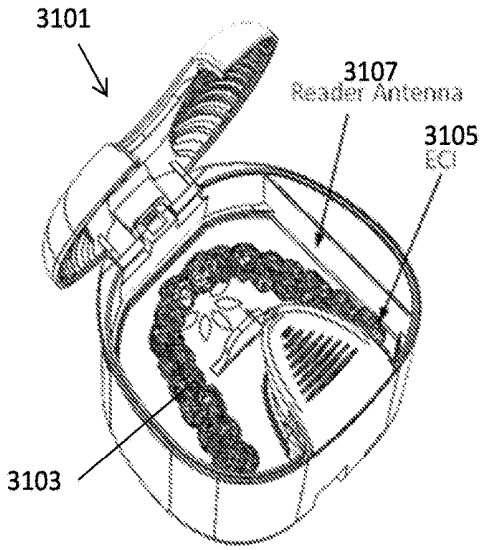


FIG. 31A

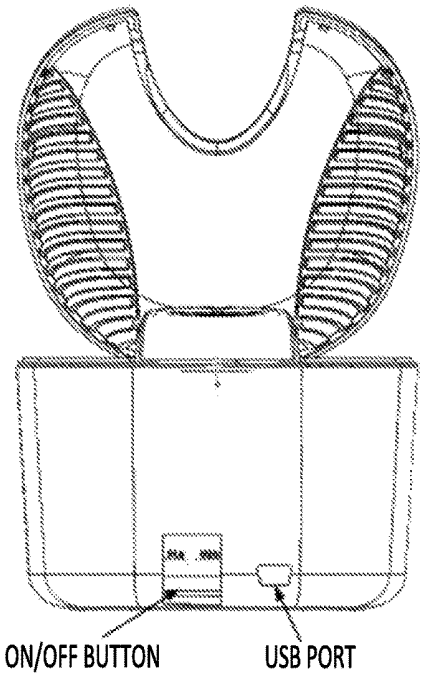


FIG. 31B

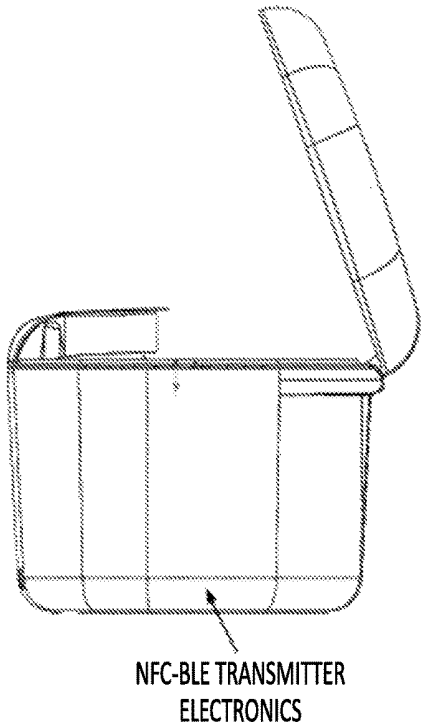


FIG. 31C

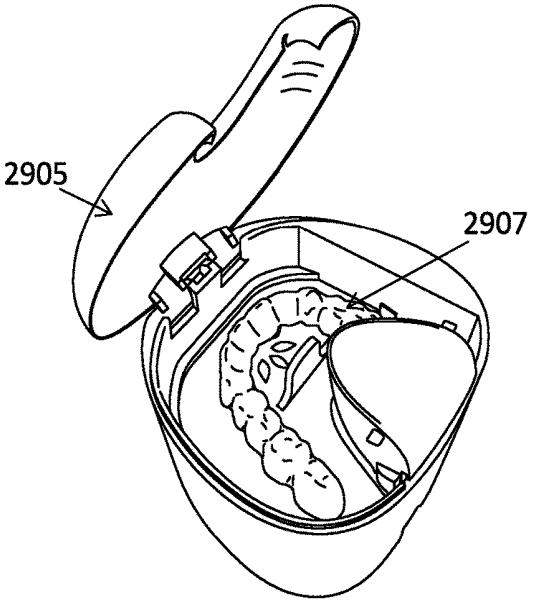


FIG. 31D

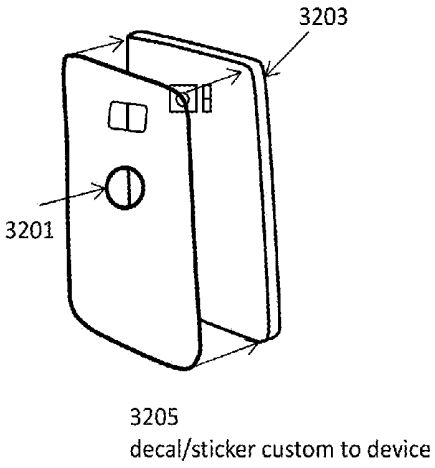


FIG. 32

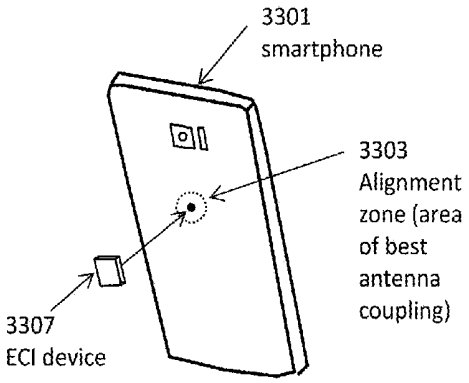


FIG. 33A

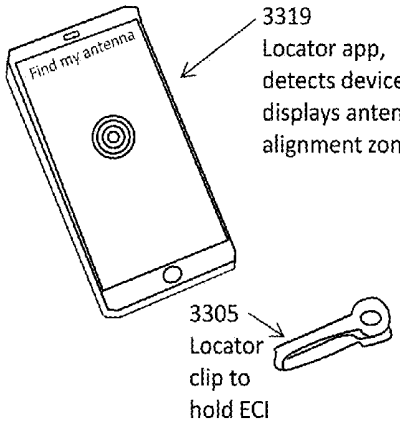


FIG. 33B

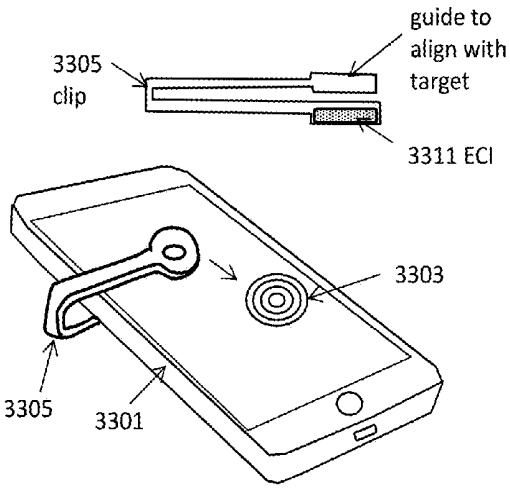


FIG. 33C

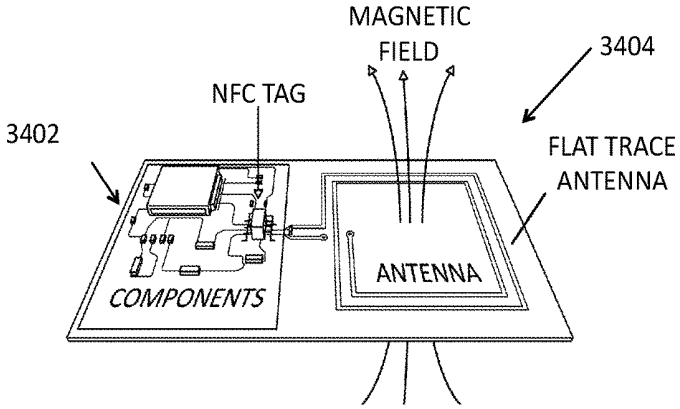


FIG. 34A

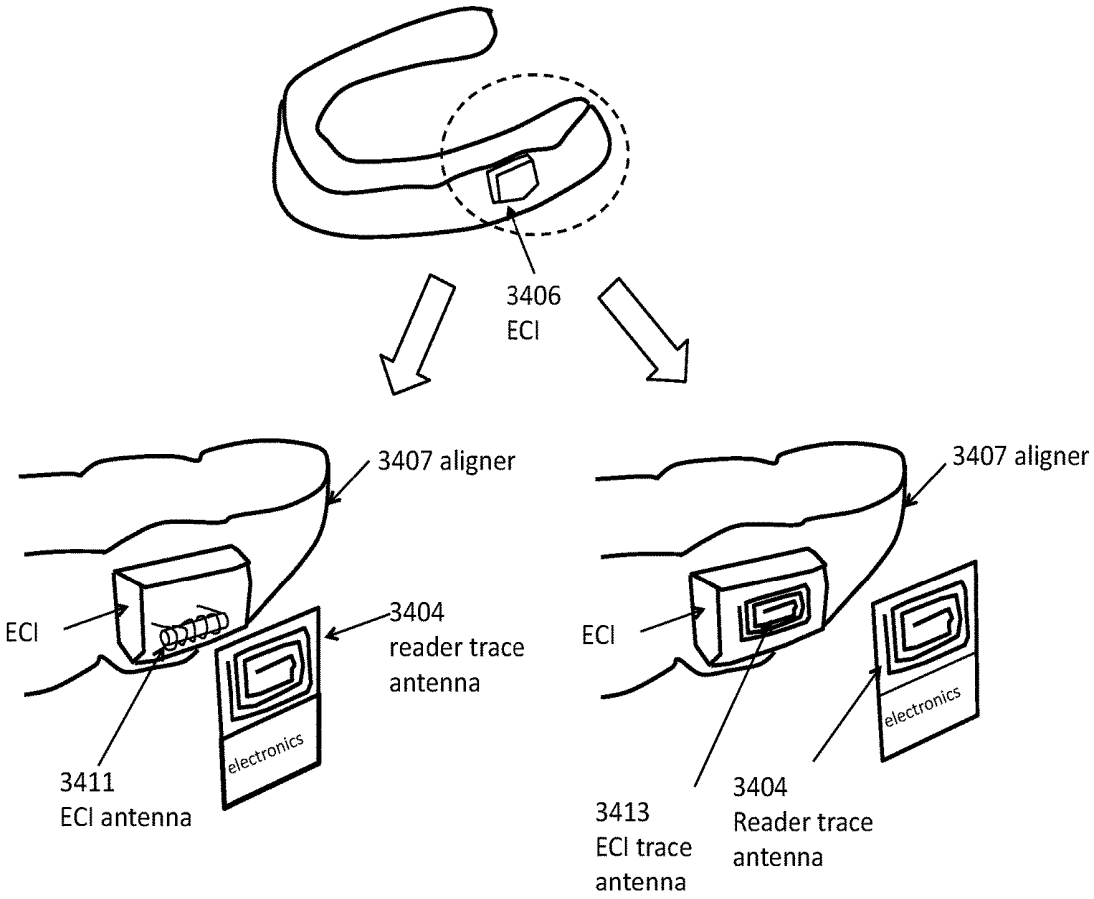


FIG. 34B

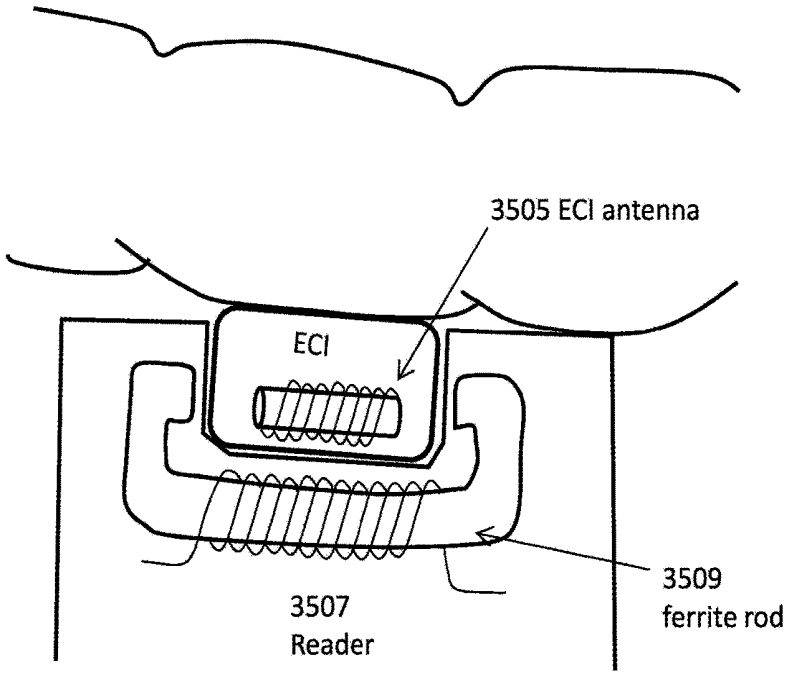
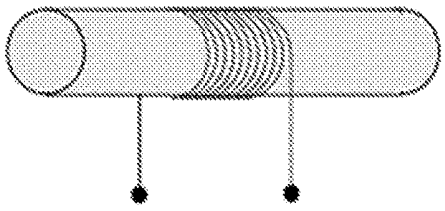


FIG. 35B



COIL WOUND ON A FERRITE ROD

FIG. 35A

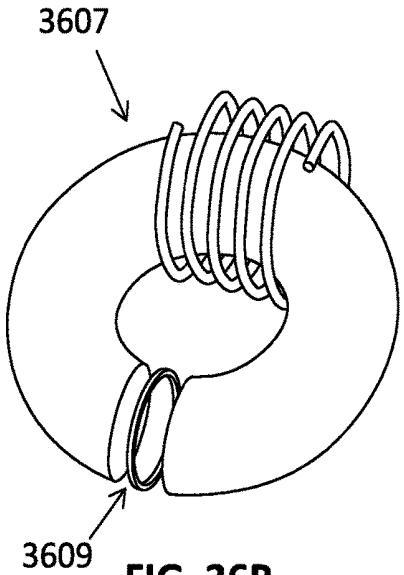


FIG. 36B

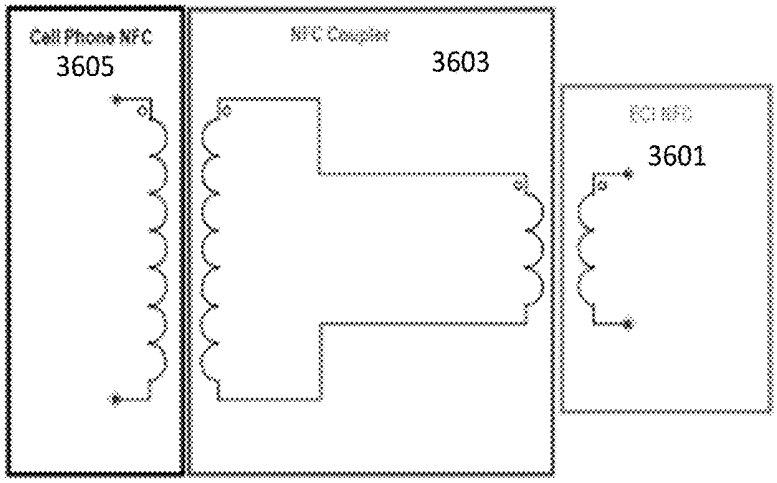


FIG. 36A

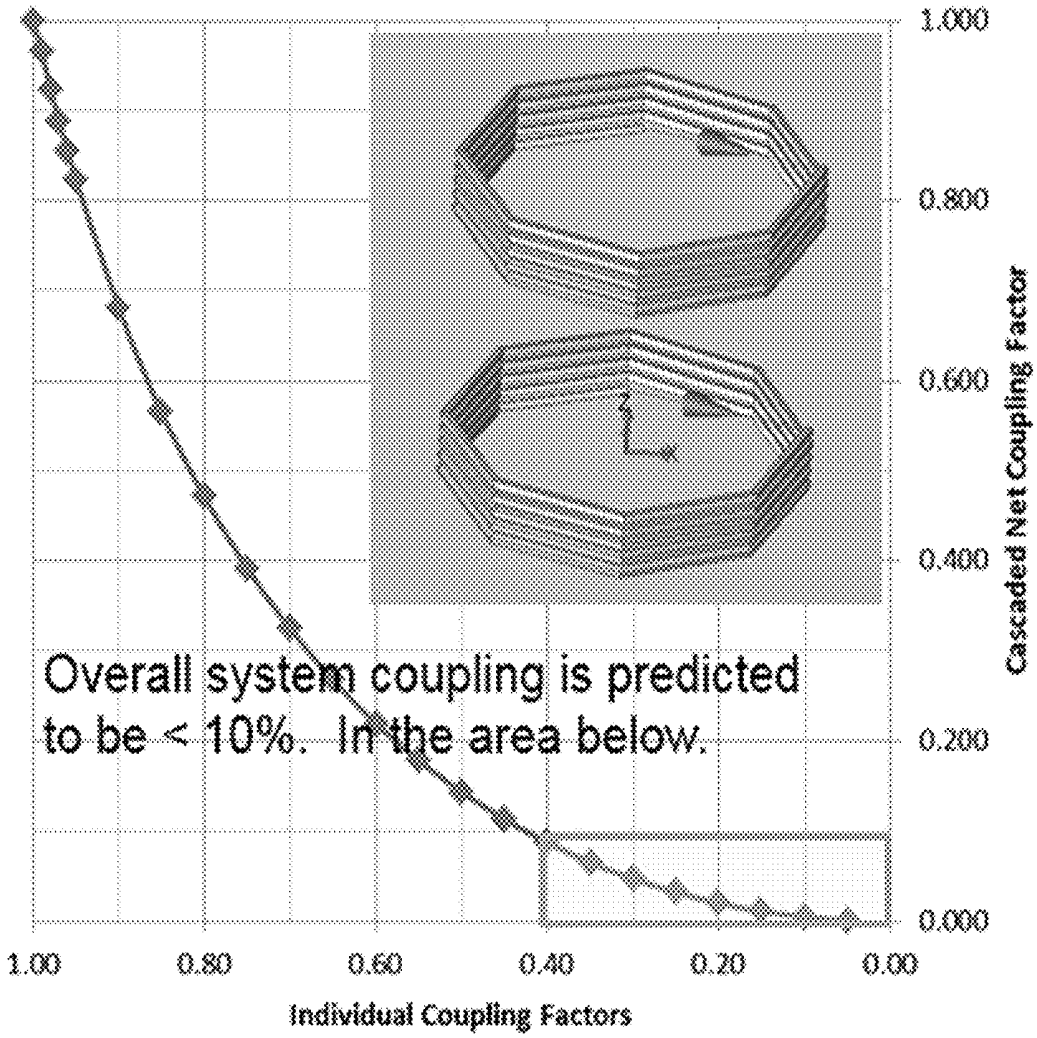


FIG. 36C

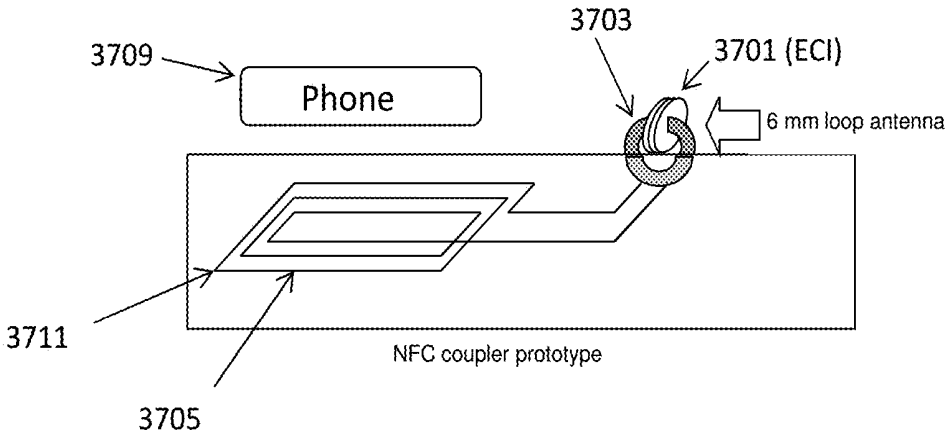


FIG. 37A

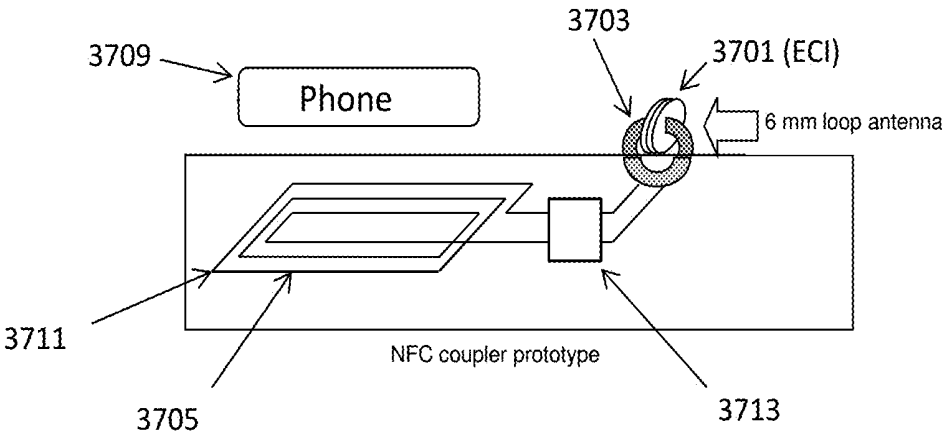


FIG. 37B

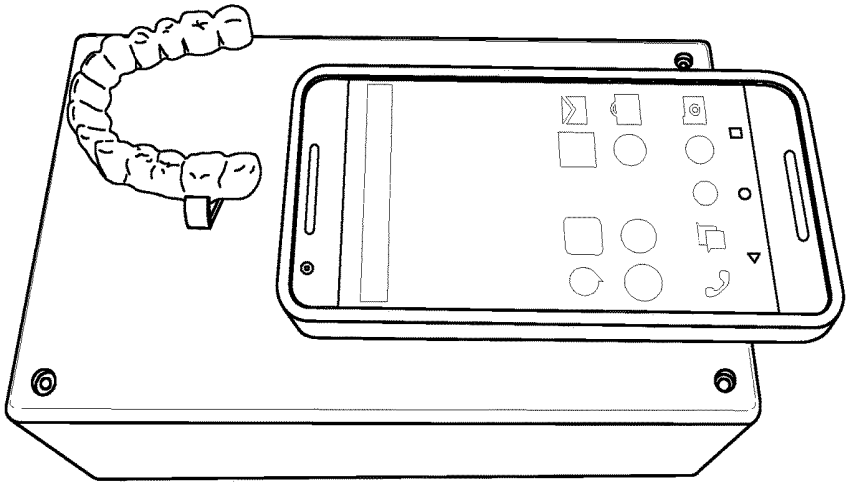


FIG. 38

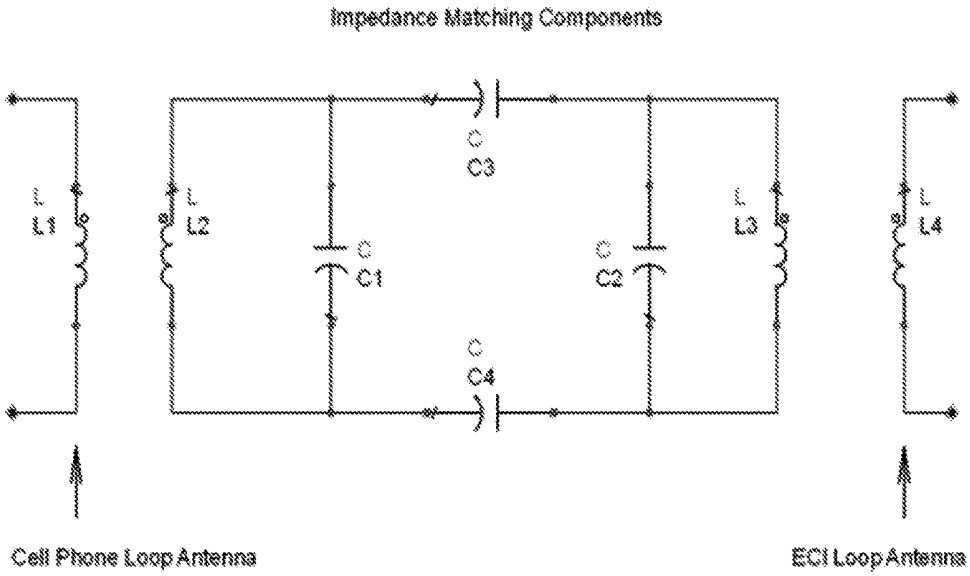

Impedance Matching Components
L
L1
L
L2
C
C3
C
C1
C
C2
L
L3
L
L4
C
C4
Cell Phone Loop Antenna
ECI Loop Antenna

FIG. 39

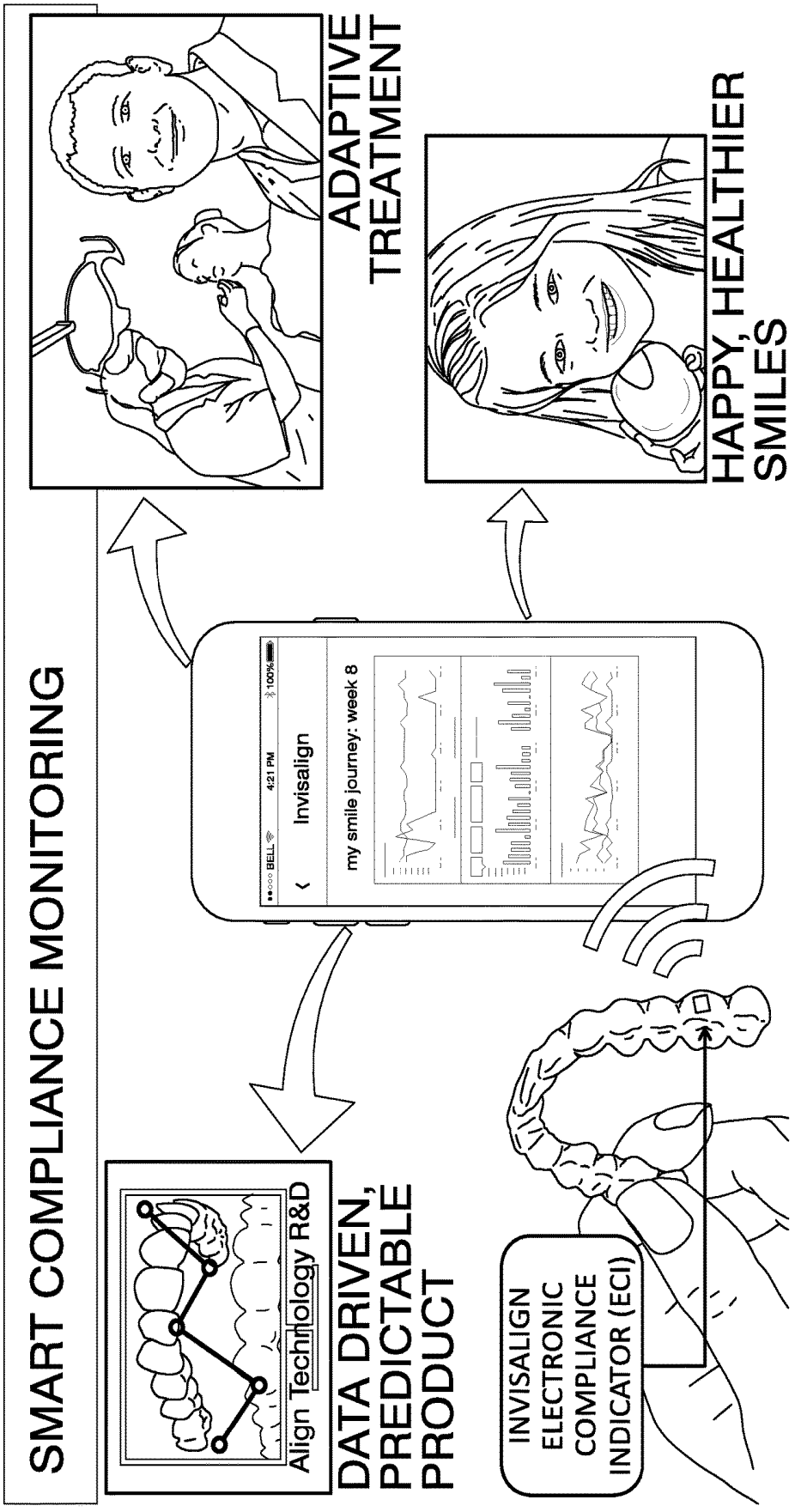

SMART COMPLIANCE MONITORING
DATA DRIVEN, PREDICTABLE PRODUCT
Align Technology R&D
INVISALIGN ELECTRONIC COMPLIANCE INDICATOR (ECI)
Invisalign
my smile journey: week 8
ADAPTIVE TREATMENT
HAPPY, HEALTHIER SMILES

FIG. 40

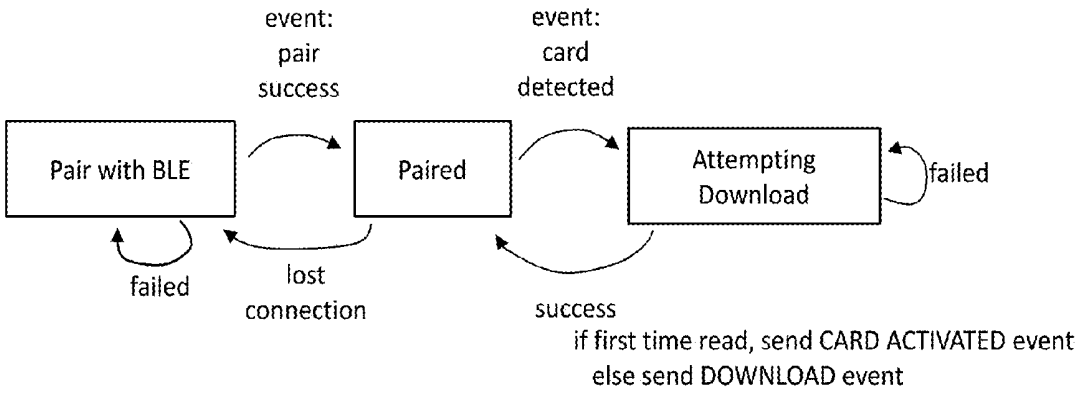


FIG. 41

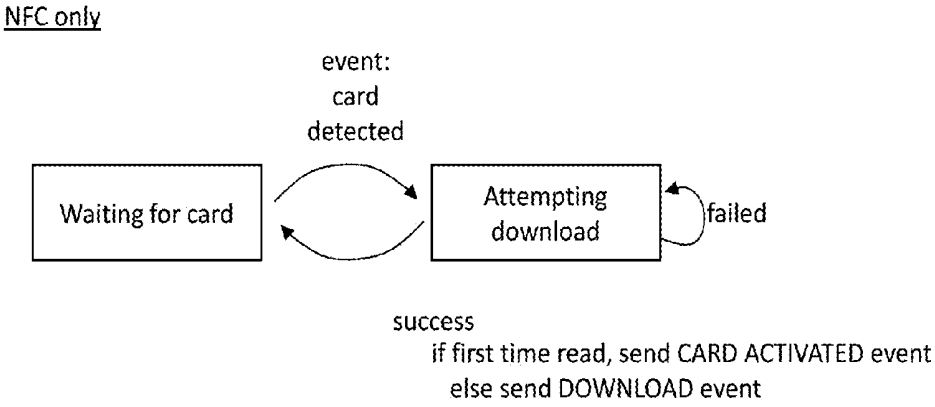


FIG. 42

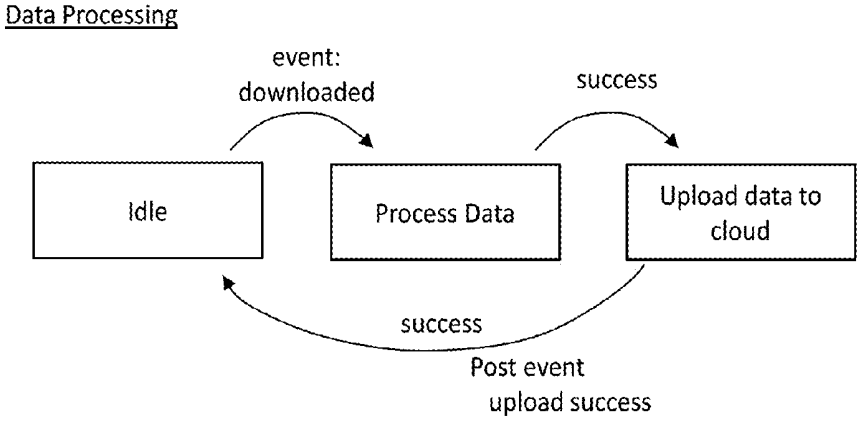


FIG. 43

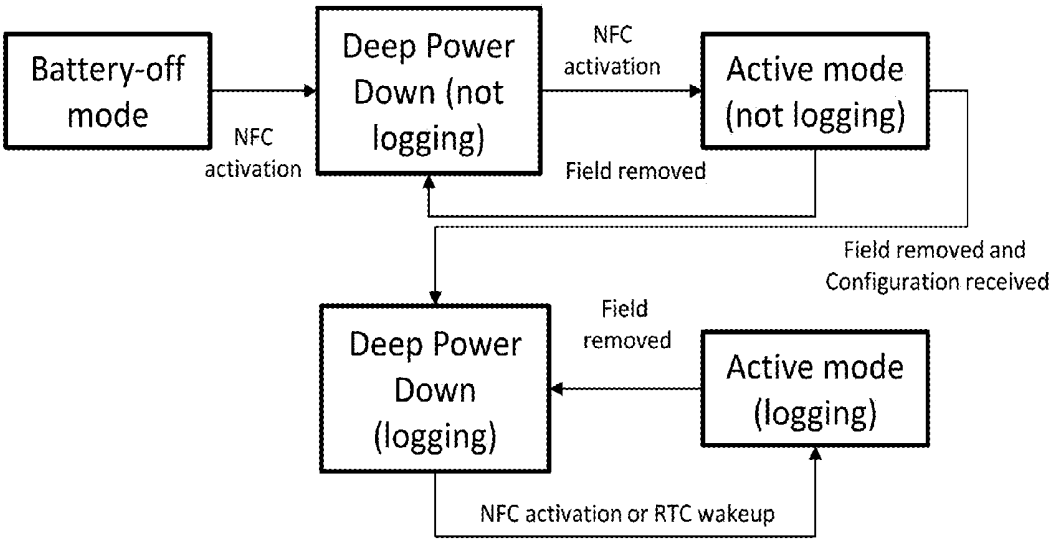

Battery-off mode
NFC activation
Deep Power Down (not logging)
NFC activation
Active mode (not logging)
Field removed
Field removed and Configuration received
Deep Power Down (logging)
Field removed
Active mode (logging)
NFC activation or RTC wakeup

FIG. 44

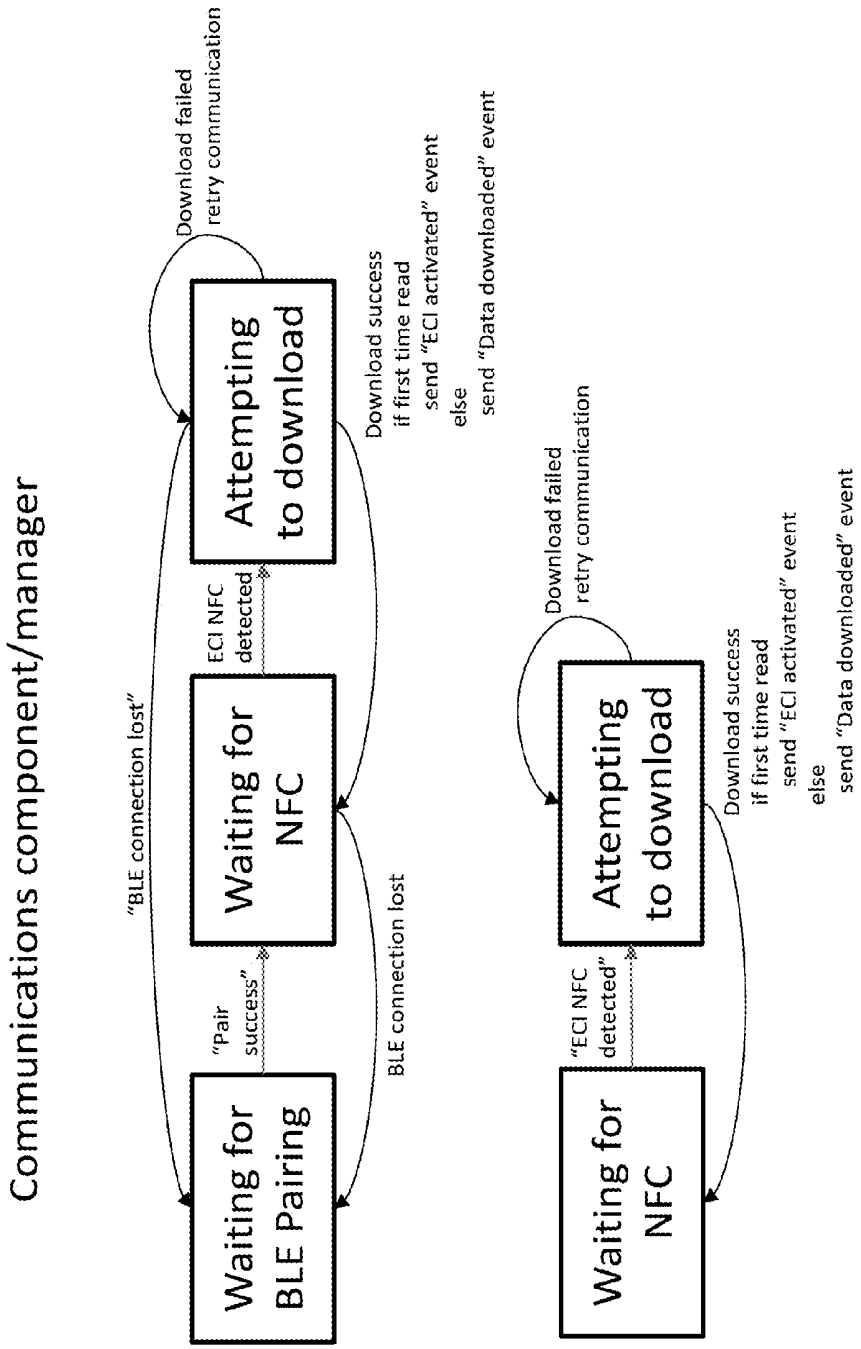

Communications component/manager
Waiting for BLE Pairing
"Pair success"
Waiting for NFC
ECI NFC detected
Attempting to download
Download failed
retry communication
Download success
if first time read
send "ECI activated" event
else
send "Data downloaded" event
"BLE connection lost"
BLE connection lost
Waiting for NFC
"ECI NFC detected"
Attempting to download
Download failed
retry communication
Download success
if first time read
send "ECI activated" event
else
send "Data downloaded" event

FIG. 45

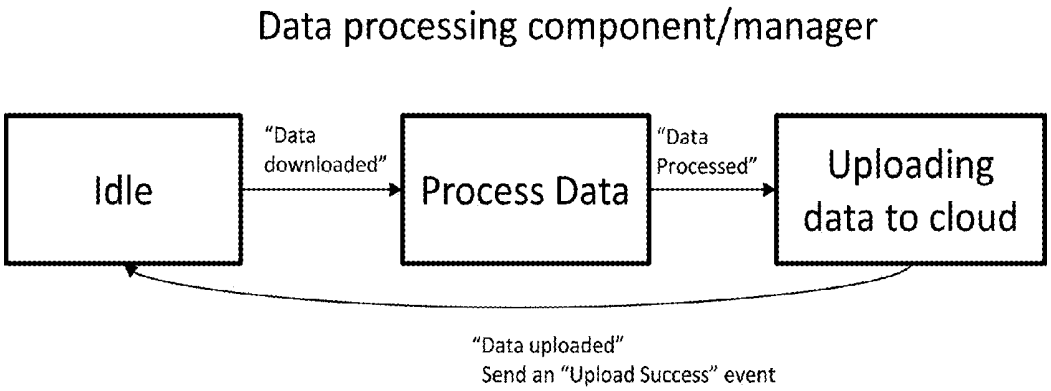

Data processing component/manager
Idle
"Data downloaded"
Process Data
"Data Processed"
Uploading data to cloud
"Data uploaded"
Send an "Upload Success" event

FIG. 46

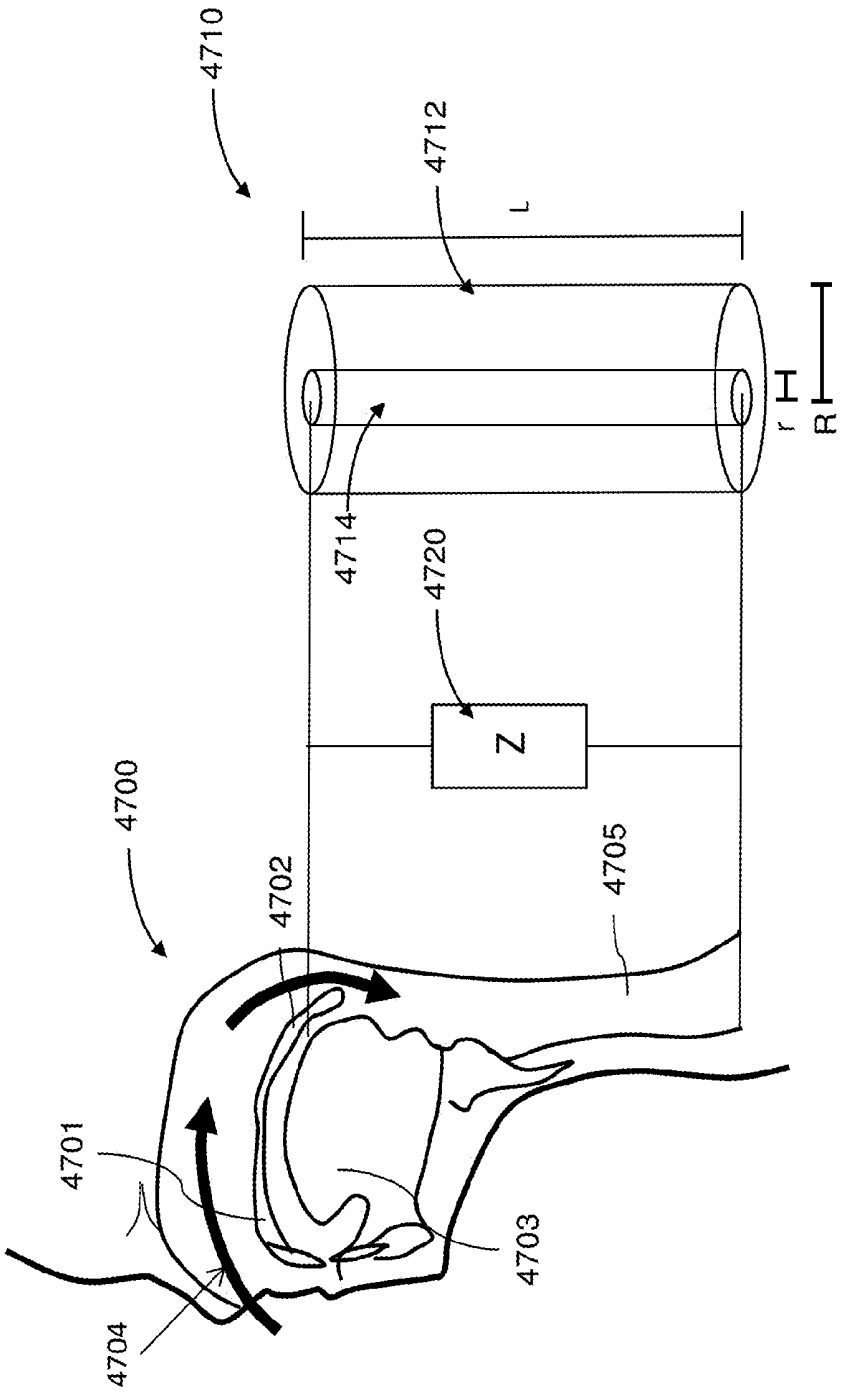


FIG. 47

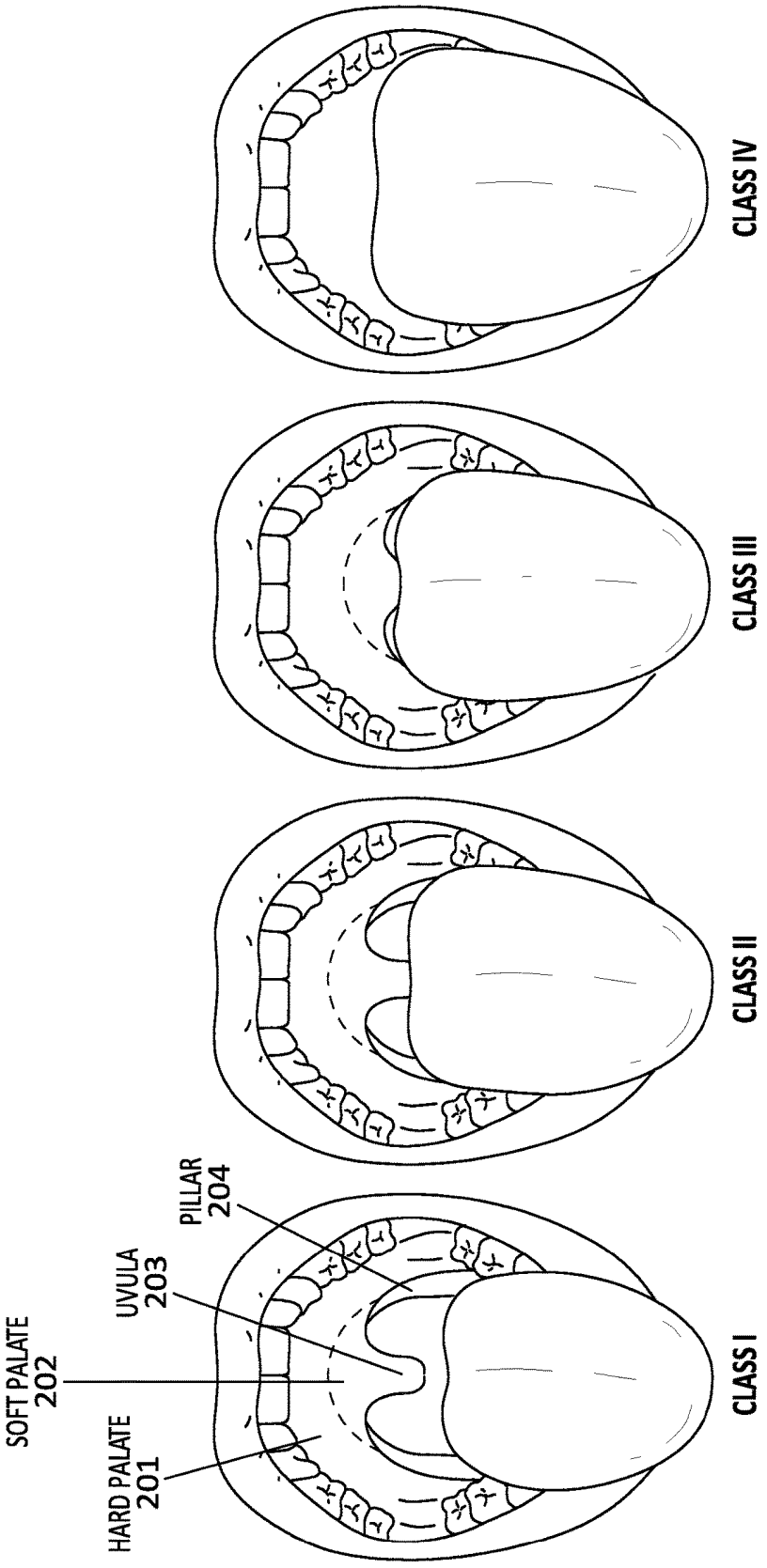

CLASS I
CLASS II
CLASS III
CLASS IV
SOFT PALATE 202
UVULA 203
PILLAR 204
HARD PALATE 201

FIG. 48A

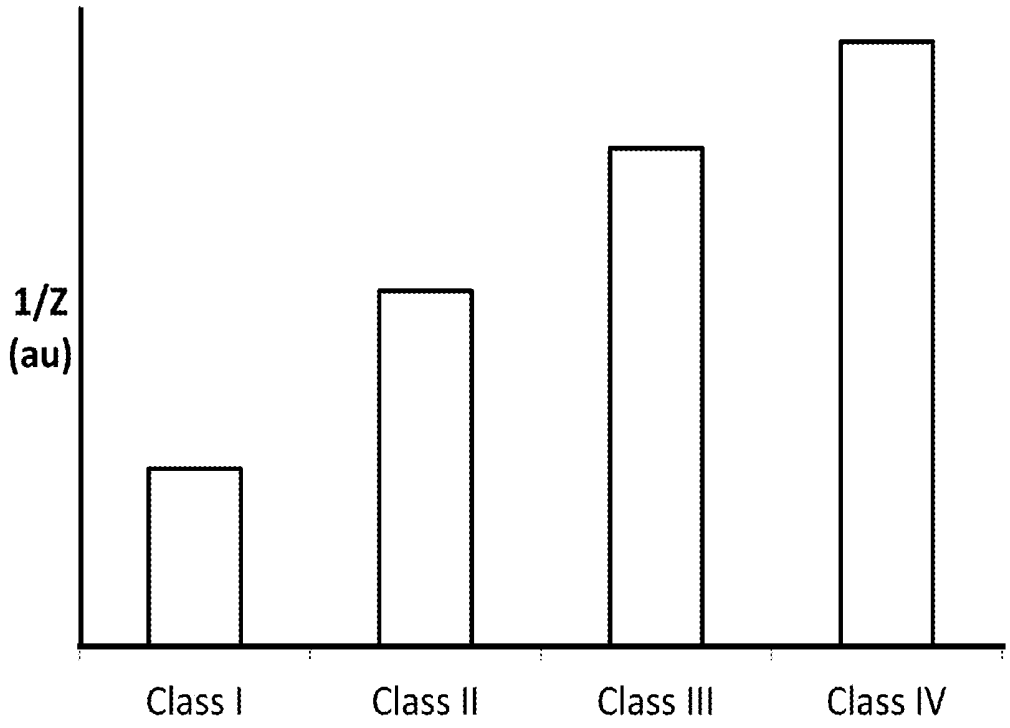


FIG. 48B

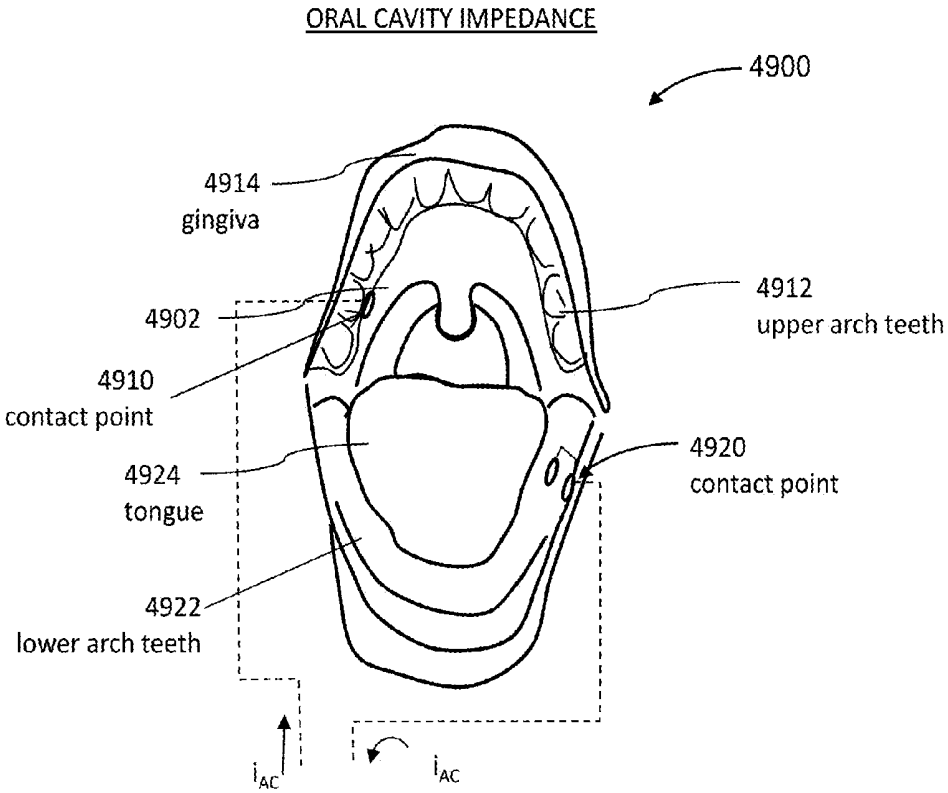

ORAL CAVITY IMPEDANCE
4900
4914
gingiva
4902
4910
contact point
4924
tongue
4922
lower arch teeth
4912
upper arch teeth
4920
contact point
i_{AC}
i_{AC}

FIG. 49A

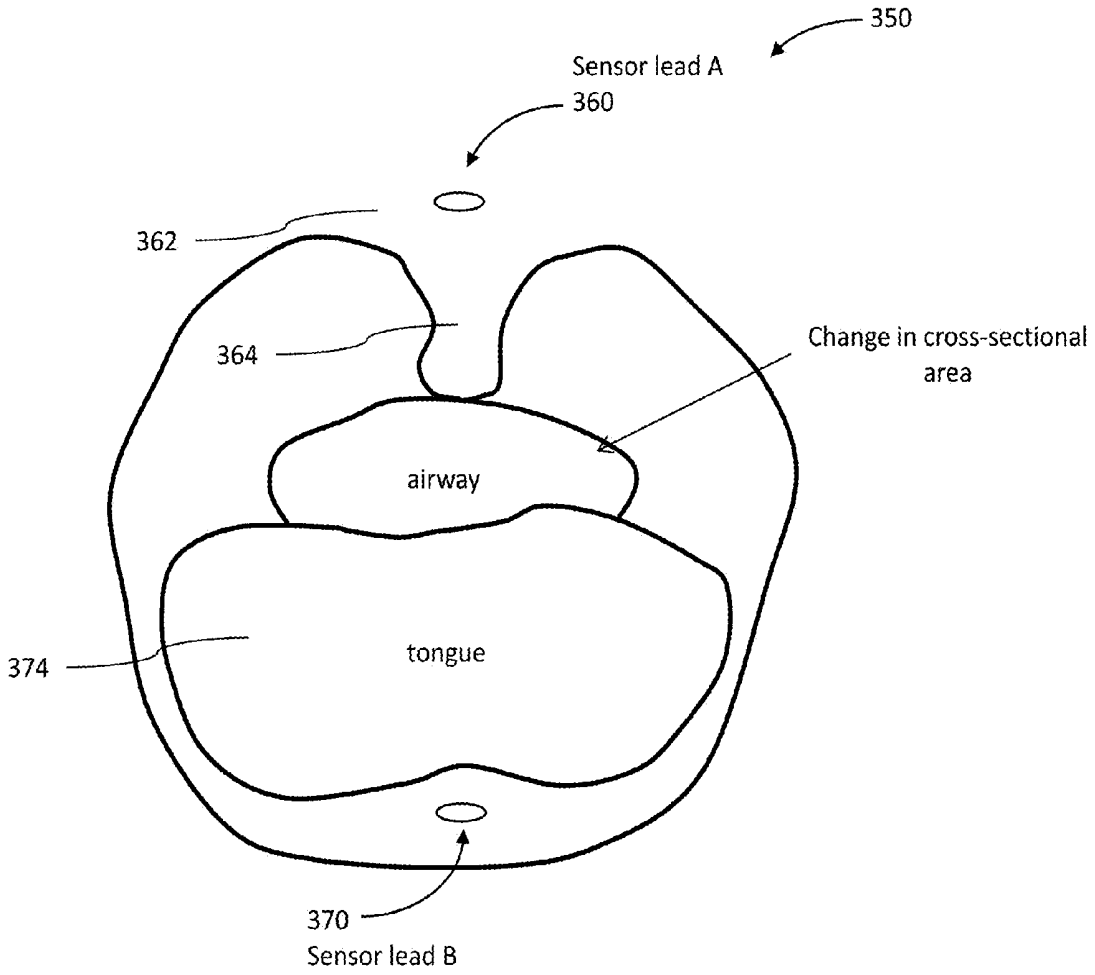

350
Sensor lead A
360
362
364
Change in cross-sectional area
airway
tongue
374
370
Sensor lead B

FIG. 49B

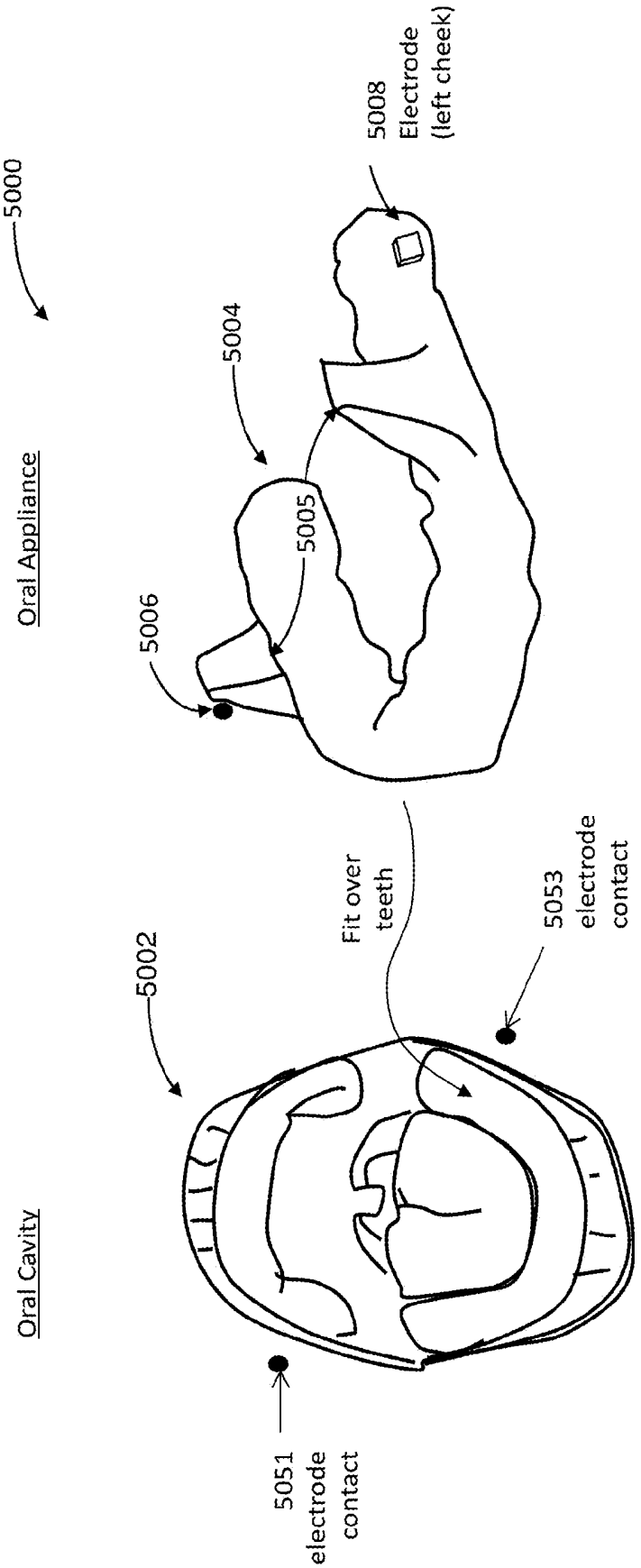

5000
Oral Appliance
5004
5005
5006
5008
Electrode
(left cheek)
Oral Cavity
5002
Fit over
teeth
5053
electrode
contact
5051
electrode
contact

FIG. 50A

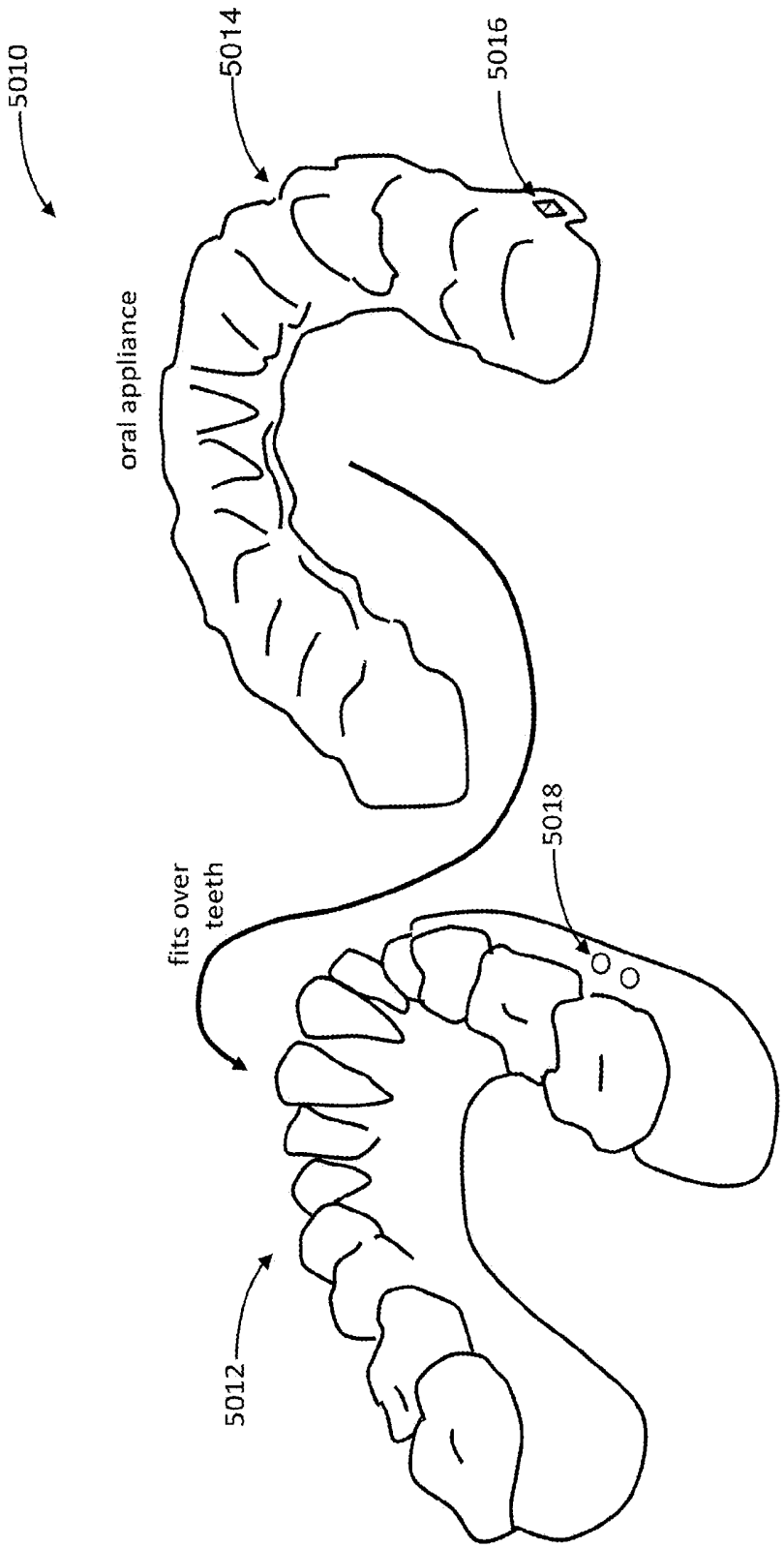


FIG. 50B

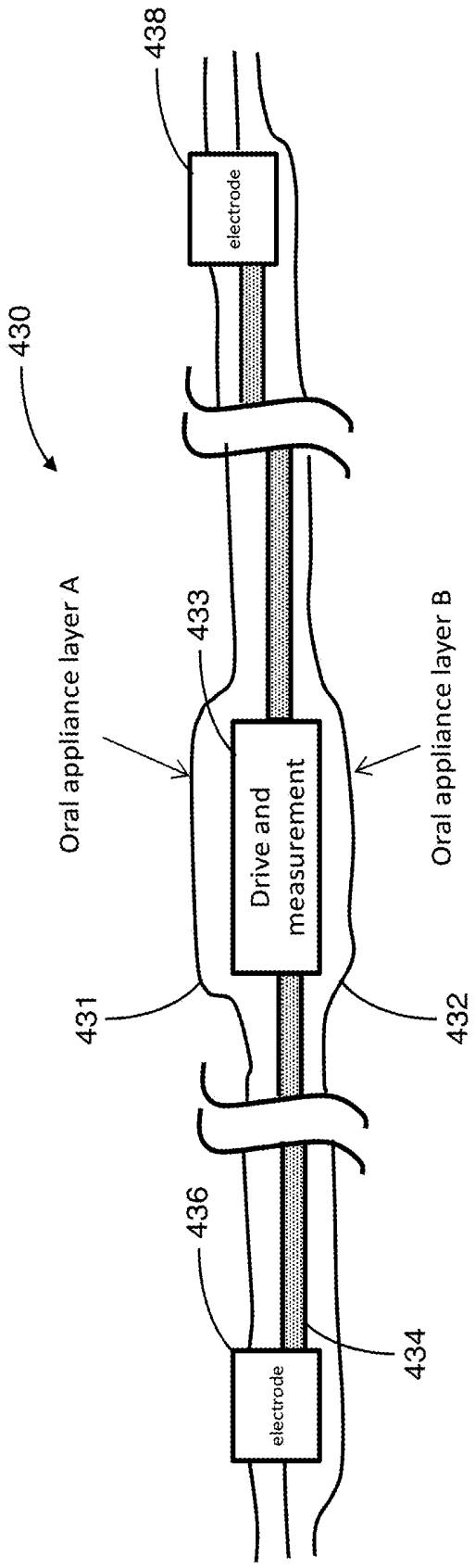

438
electrode
430
Oral appliance layer A
433
Drive and measurement
Oral appliance layer B
431
432
436
434
electrode

FIG. 50C

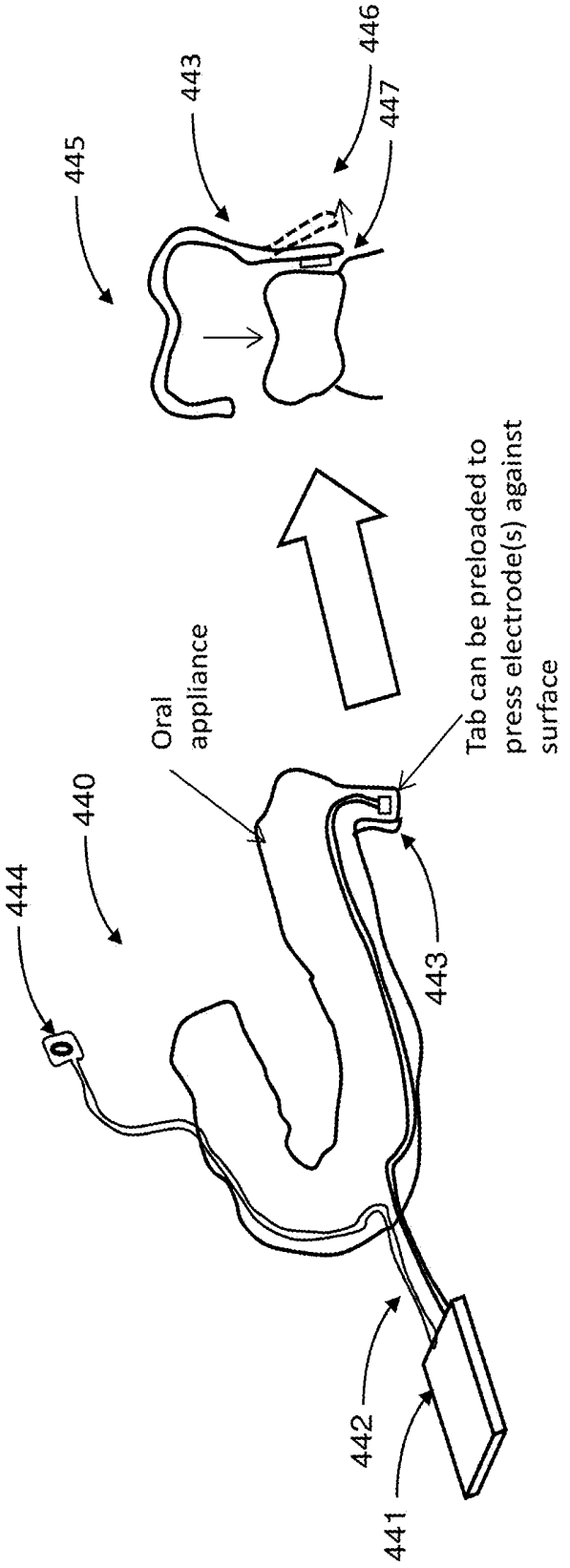

445
443
446
447
Oral appliance
Tab can be preloaded to press electrode(s) against surface
440
444
443
442
441

FIG. 50D

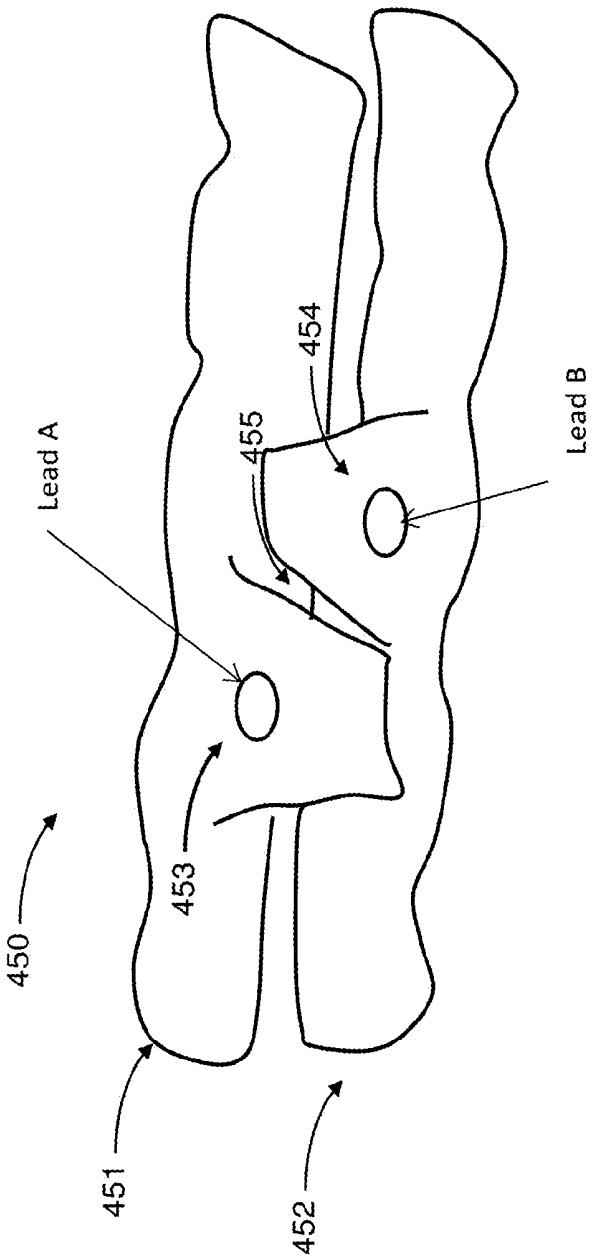


FIG. 50E

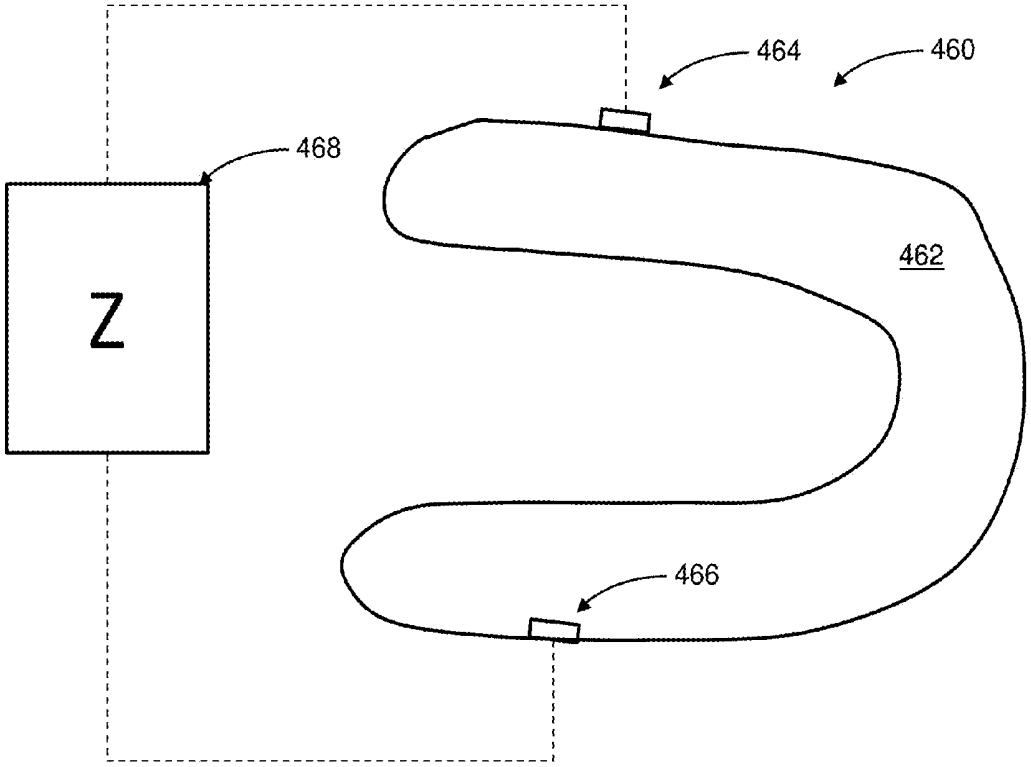


FIG. 50F

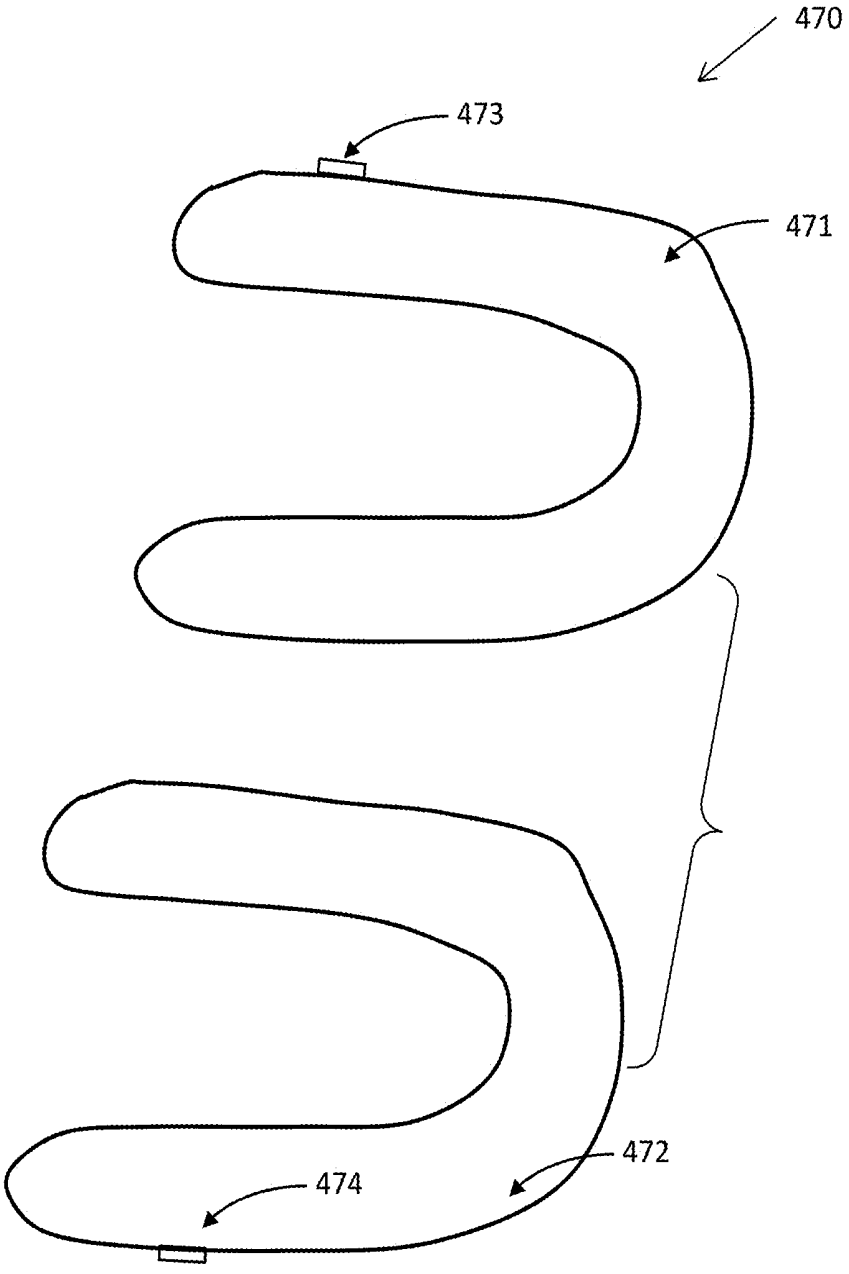


FIG. 50G

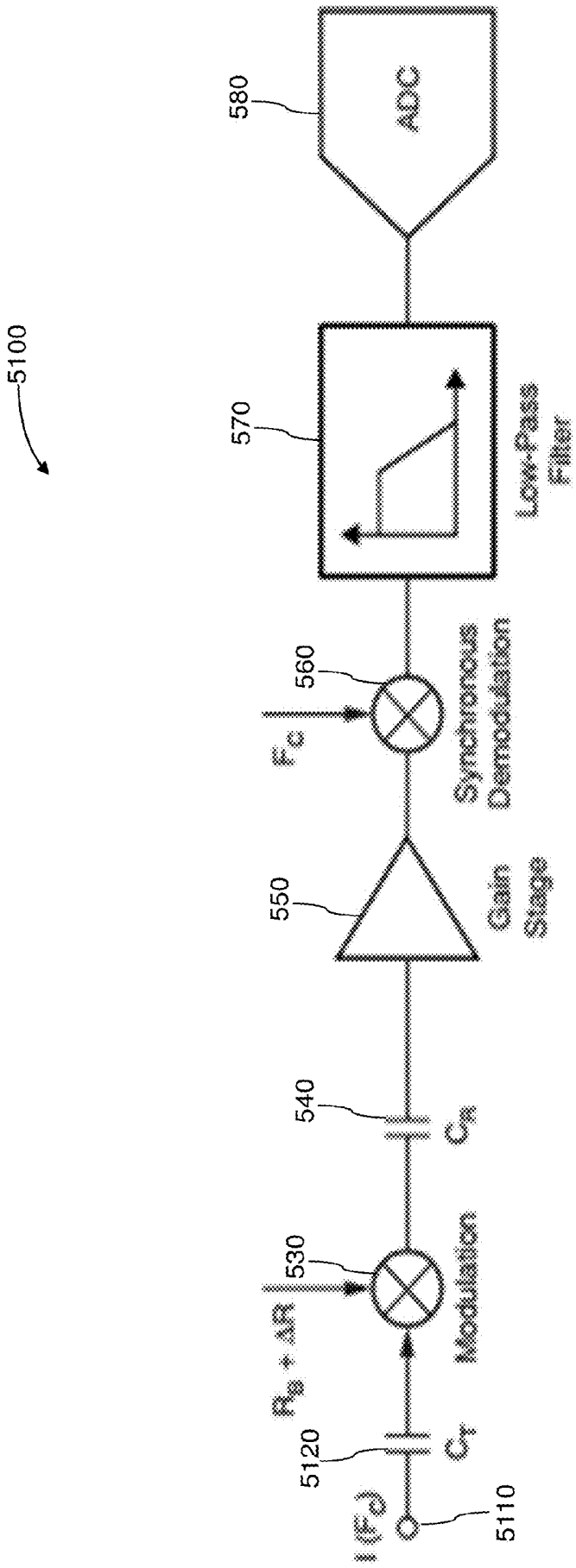

5100
580
ADC
570
Low-Pass Filter
560
F_C
Synchronous Demodulation
550
Gain Stage
540
C_R
530
$R_B + \Delta R$
Modulation
5120
C_T
$I(F_S)$
5110

FIG. 51A

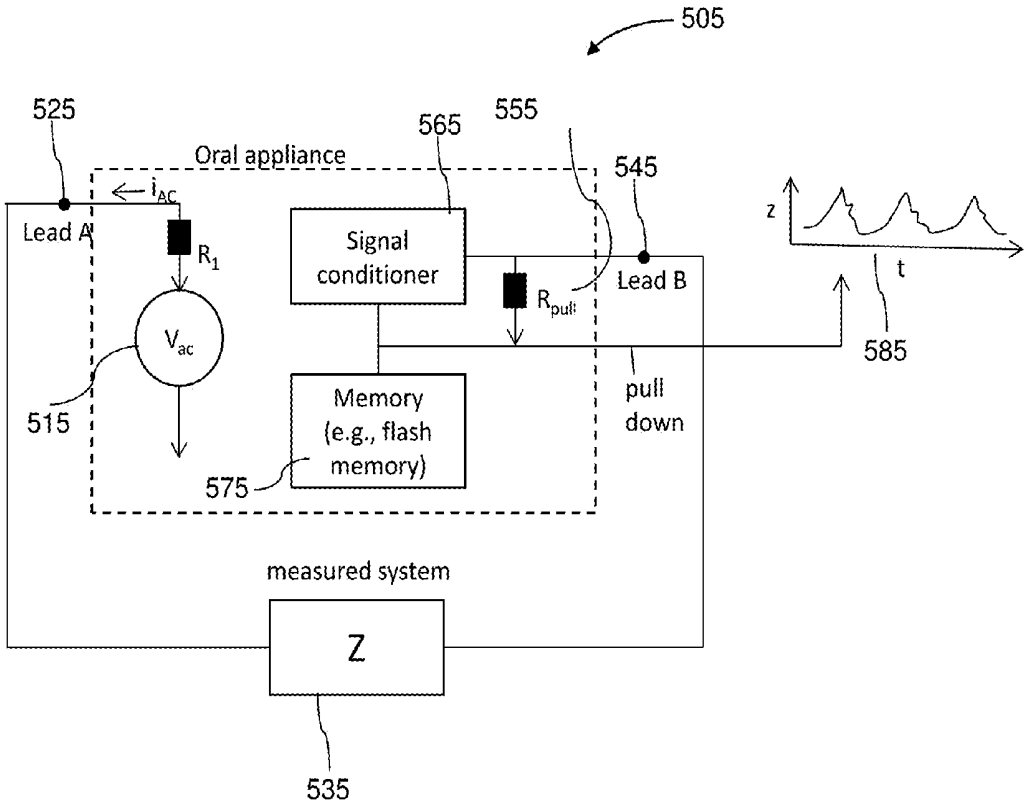

505
525
565
555
Oral appliance
545
i_{AC}
Lead A
R_1
Signal conditioner
R_{pull}
Lead B
z
t
V_{ac}
585
515
pull down
Memory (e.g., flash memory)
575
measured system
Z
535

FIG. 51B

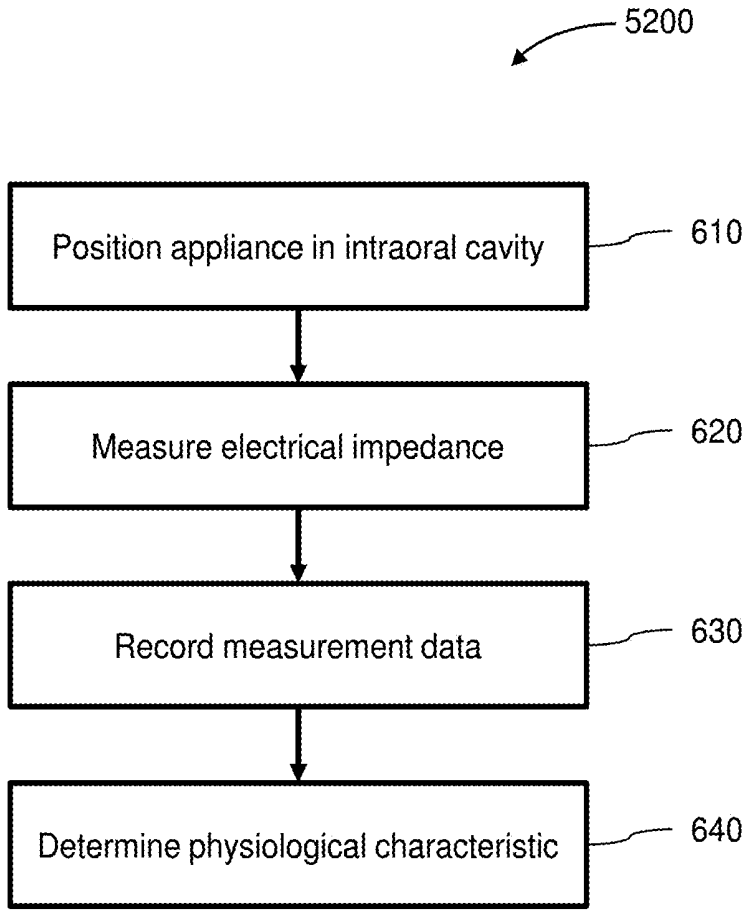

5200
Position appliance in intraoral cavity
610
Measure electrical impedance
620
Record measurement data
630
Determine physiological characteristic
640

FIG. 52

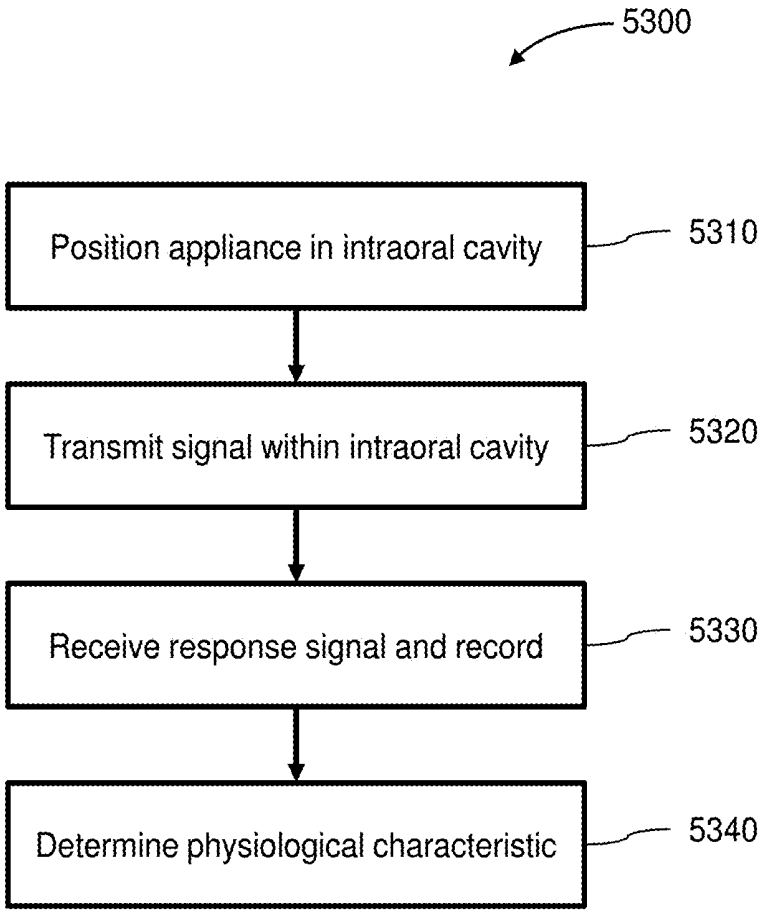

5300
Position appliance in intraoral cavity
5310
Transmit signal within intraoral cavity
5320
Receive response signal and record
5330
Determine physiological characteristic
5340

FIG. 53

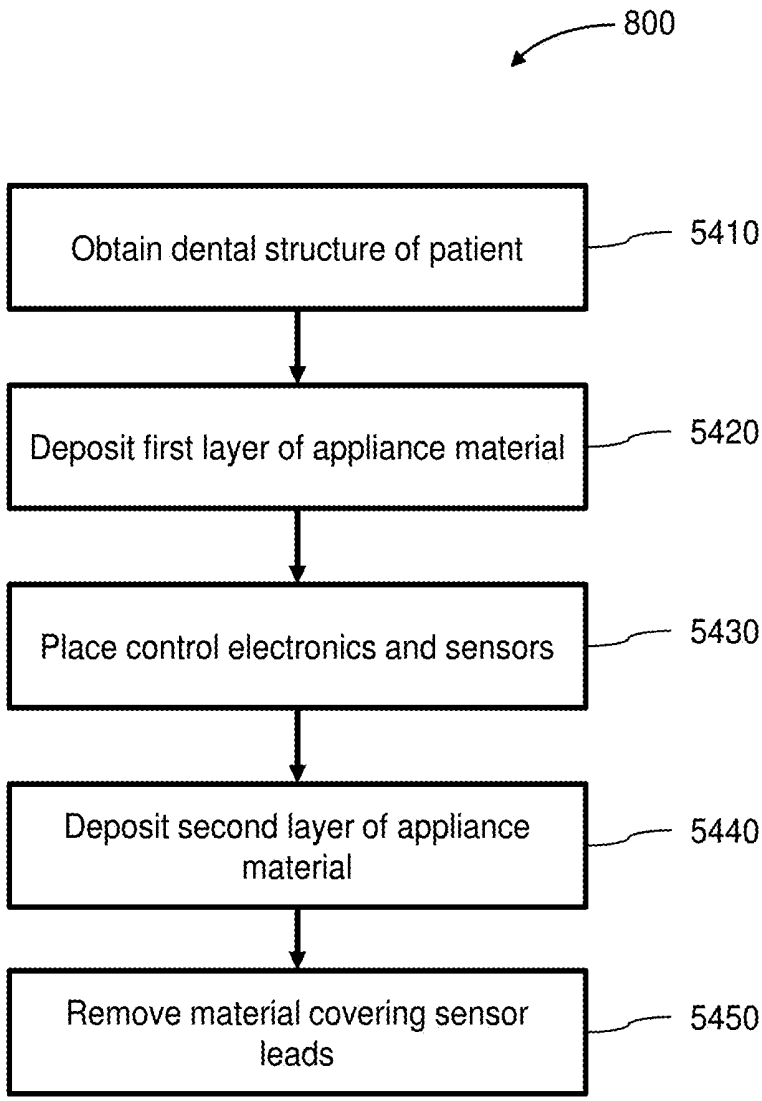

800
Obtain dental structure of patient
5410
Deposit first layer of appliance material
5420
Place control electronics and sensors
5430
Deposit second layer of appliance material
5440
Remove material covering sensor leads
5450

FIG. 54

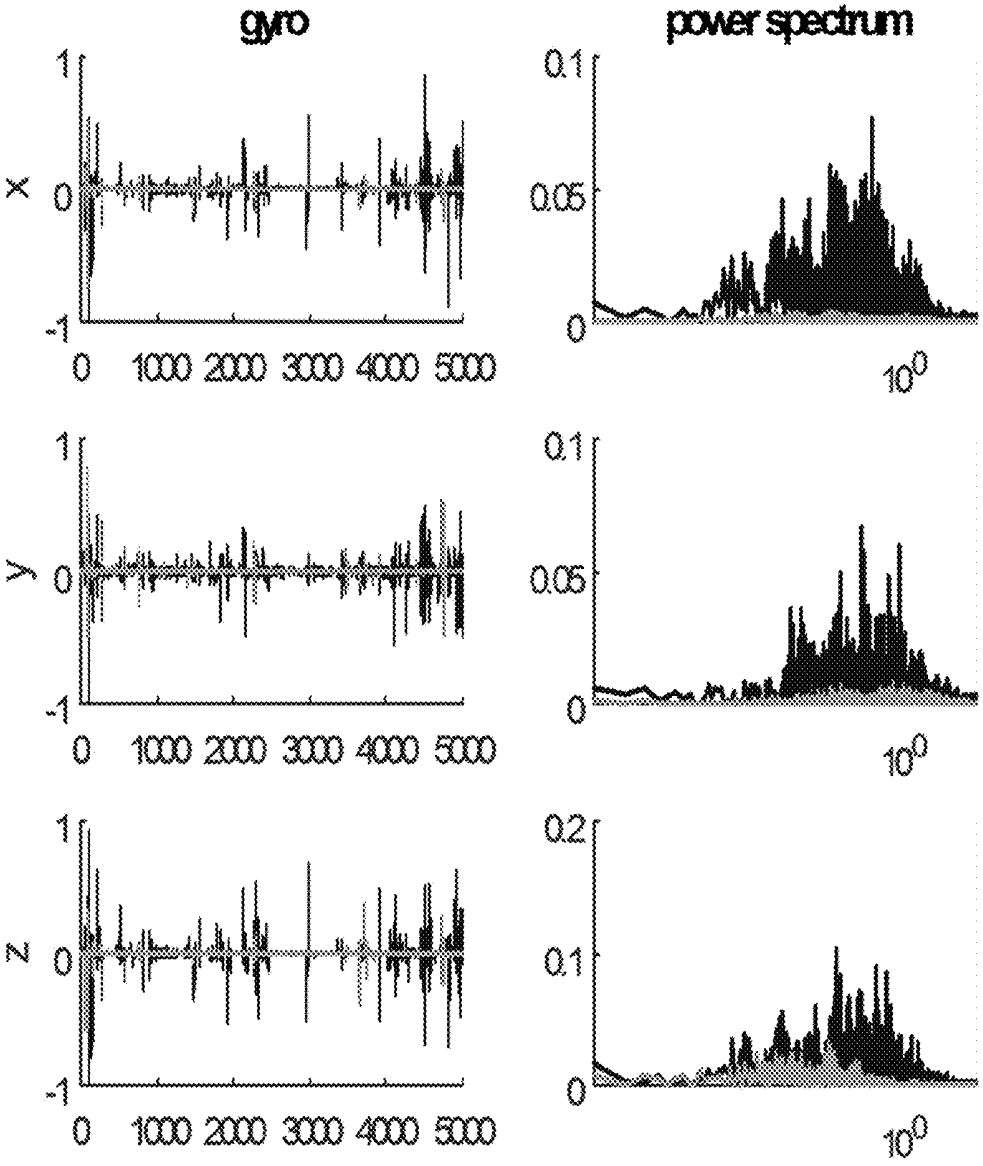

gyro
power spectrum
x
y
z
1
0
-1
0 1000 2000 3000 4000 5000
0.1
0.05
0
0.2
10^0

FIG. 55

INTRAORAL APPLIANCES WITH SENSING

CROSS REFERENCE TO RELATED APPLICATIONS

This Application claims priority to U.S. provisional patent application No. 62/351,516, filed Jun. 17, 2016 (titled "EMBEDDED INTRAORAL SENSING FOR PHYSIOLOGICAL MONITORING AND TREATMENT WITH AN ORAL APPLIANCE"), U.S. provisional patent application No. 62/351,391, filed Jun. 17, 2016 (titled "ELECTRTONIC COMPLIANCE INDICATOR FOR INTRAORAL APPLIANCES") and U.S. provisional patent application No. 62/483,283, filed Apr. 7, 2017 (titled "WIRELESS ELECTRONIC COMPLIANCE INDICATOR, READER CASE AND USER INTERFACE FOR INTRAORAL APPLIANCES").

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BACKGROUND

Orthodontic procedures typically involve repositioning a patient's teeth to a desired arrangement in order to correct malocclusions and/or improve aesthetics. To achieve these objectives, orthodontic appliances such as braces, shell aligners, and the like can be applied to the patient's teeth by an orthodontic practitioner. The appliance can be configured to exert force on one or more teeth in order to effect desired tooth movements according to a treatment plan.

During orthodontic treatment with patient-removable appliances, the practitioner may rely on the patient to comply with the prescribed appliance usage. In some instances, a patient may not wear the orthodontic appliance as prescribed by the practitioner. Extended removal of the appliance, for any reason beyond what is recommended, may interrupt the treatment plan and lengthen the overall period of treatment. There is a need for methods and apparatuses that allow monitoring of the wearing and/or effects of intraoral appliances. Described herein are methods and apparatuses for performing such monitoring.

Obstructive sleep apnea (hereinafter "OSA") is a medical condition characterized by complete or partial blockage of the upper airway during sleep. The obstruction may be related to relaxation of soft tissues and muscles in or around the throat (e.g., the soft palate, back of the tongue, tonsils, uvula, and pharynx) during sleep. OSA episodes may occur multiple times per night and disrupt the patient's sleep cycle. Suffers of chronic OSA may experience sleep deprivation, excessive daytime sleepiness, chronic fatigue, headaches, snoring, and hypoxia.

Prior methods and apparatus for monitoring physiological characteristics of patients with conditions such as sleep disordered breathing can be less than ideal in at least some respects. It would be desirable to provide systems for monitoring physiological characteristics without requiring sensors placed outside of the intraoral cavity. For example, instead of sensors on the body of a patient, implanted within the patient, or disposed within the mouth but connected to external apparatus, it is preferred to have sensors that operate autonomously within the intraoral cavity of the patient. It would be helpful to provide intraoral appliances comprising embedded intraoral sensors, allowing autonomous monitoring of physiological characteristics of patients, thereby providing data useful in the diagnosis of sleep disorders and other oral- and airway-related disorders.

SUMMARY OF THE DISCLOSURE

Described herein are apparatuses, including devices and systems, including in particular appliances (e.g., orthodontic appliances) and methods for monitoring an orthodontic appliance, including, but not limited to monitoring patient compliance with orthodontic treatment. Monitoring may alternatively or additionally include monitoring status, monitoring wear of the appliance, monitoring the geographic/spatial location of the appliance, monitoring the environment of the appliance, etc. In some embodiments, an orthodontic appliance includes one or more sensors configured to obtain sensor data; these sensors may include those that are indicative of patient compliance (e.g., whether the patient is wearing the appliance). The appliance can include one or more processors operably coupled to the sensor(s) and configured to process the sensor data so as to generate patient compliance data, thus enabling electronic monitoring of patient compliance with a prescribed course of orthodontic treatment. Advantageously, the systems, methods, and devices herein may increase patient compliance and improve treatment efficacy, as well as provide patient data useful to the practitioner for designing and monitoring orthodontic treatments.

A device for monitoring usage of an intraoral appliance may include an appliance shell comprising a plurality of teeth receiving cavities; one or more sensors operably coupled to the appliance shell and configured to generate sensor data indicative of appliance usage by a patient; and a processor operably coupled to the one or more sensors and configured to process the sensor data so as to determine whether the intraoral appliance is being worn on the patient's teeth.

The apparatuses and methods described herein may be configured to detect ("smart detection") placement of aligners on a tooth or teeth and may be configured to differentiate from other, similar, events such as water immersion. Also described herein are methods and apparatuses that permit direct communication with cell phones for activation and retrieving data from monitor(s).

As mentioned, the methods and apparatuses described herein may generally be used with or as part of any monitoring devices for monitoring an orthodontic appliance. For example, described herein are Electronic Compliance Indicator (ECI) apparatuses that may be configured to record sensor data from subjects (e.g., patients) wearing or intended/intending to wear an orthodontic aligner such as a shell aligner. However, it should be understood that these methods and apparatuses are not limited to just monitoring compliance and operation on compliance data, but may be used for any type of data, and these monitoring apparatuses (including ECIs) may also be generically referred to as data loggers or embedded data loggers. Thus, in any of the description and examples provided herein, unless the context makes it clear otherwise, when an "ECI" apparatus is described, the apparatus may not be limited to compliance monitoring. Thus, for any of the description, examples, methods and apparatuses described herein, the term "ECI" should be understood to be more broadly referred to as a monitoring apparatus (MA) or performance monitoring apparatus (PMA), and not just an ECI.

For example, in any of these apparatuses, the data may be stored in physical memory on the monitoring apparatus (e.g., the ECI) and may be retrieved by another device in communication with the monitoring apparatus. Retrieval may be done wirelessly, e.g., using near-field communication (NFC) and/or Bluetooth (BLE) technologies to use a smartphone or other hand-held device to retrieve the data. Specifically described herein are monitoring apparatuses (including ECI apparatuses) and orthodontic aligners using them that include temperature and capacitive sensors, a CPU, a NFC communication module, an NFC antenna, a PCB and battery. Also described herein are cases or holders that may boost and/or relay the signals from the small monitoring apparatus to a handheld device such as a smartphone; such cases or holders may be referred to as NFC-BLE enabled Aligner cases.

A monitoring apparatus such as an electronic compliance indicator (ECI) apparatus configured to monitor usage of an intraoral appliance may include a housing enclosing a power source and monitoring circuitry, the monitoring circuitry comprising a processor, a memory, and one or more sensors; a removable mechanical activation interrupt between the power source and the processor, wherein the mechanical activation interrupt has a first position that breaks a connection between the power source and the monitoring circuitry so that no current flows between the power source and the monitoring circuitry and a second position in which there is an electrical connection between the monitoring circuity and the power source; and an elastomeric overmold encapsulating the housing.

The removable mechanical activation interrupt may comprise a magnetic switch, a removable activation rod, a pin, etc. Any of these apparatuses may include the dental appliance (e.g., an aligner such as a shell aligner) to which the monitoring apparatus (e.g., ECI) may be permanently or removably coupled.

In general, any of the monitoring apparatus (e.g., ECI apparatuses) may be sized to fit against or over one tooth. For example the housing may have a maximum diameter of 2 cm or less, 1.5 cm or less, 1.0 cm or less, 0.9 cm or less, 0.8 cm or less, 0.7 cm or less, 0.6 cm or less, etc.). The monitoring apparatus housing may generally be thin (e.g., 1.0 cm or less, 0.9 cm or less, 0.8 cm or less, 0.7 cm or less, 0.6 cm or less, 0.5 cm or less, 0.4 cm or less, etc.). In any of these apparatuses, the monitoring circuitry may be configured for a wired connection, e.g., may include a plurality of data electrodes external to the housing but encapsulated by the elastic overmold. The apparatus may configured to be connect to a plurality of metallic/conductive leads that pierce the (e.g., self-healing) overmold material to contact the otherwise covered contacts.

Also described herein are methods of activating a monitoring apparatus (such as an electronic compliance indicator or ECI) configured to monitor an intraoral appliance. For example, a method may include: moving a mechanical activation interrupt of the monitoring apparatus from a first position that breaks a connection between a power source and a monitoring circuitry of the monitoring apparatus such that no current flows between the power source and the monitoring circuitry to a second position in which there is an electrical connection between the monitoring circuity and the power source; inserting the monitoring apparatus, coupled to an orthodontic appliance, into a patient's oral cavity; and recording data from one or more sensors with the monitoring apparatus. Moving the mechanical activation interrupt may comprise: operating a magnetic switch by removing the monitoring apparatus from a packaging having a permanent magnet; inserting or removing an activation rod; and/or inserting or removing a pin. The method may also include coupling the monitoring apparatus to the orthodontic appliance. Inserting the monitoring apparatus may comprise inserting the monitoring apparatus coupled to a shell aligner. Recording data may comprise recording data from two or more sensors of the monitoring apparatus every 1 to every 30 minutes (e.g., every approximately 10 minutes).

Also described herein are monitoring apparatuses (e.g., electronic compliance indicator apparatuses) configured to monitor usage of an intraoral appliance and provide output via a removable wired connection. A monitoring apparatus may include: a housing enclosing a power source and monitoring circuitry, the monitoring circuitry comprising a processor, a memory, and one or more sensors; a self-healing elastomeric overmold encapsulating the housing; a plurality of data electrodes external to the housing but encapsulated by the elastic overmold; and an attachment configured to secure the monitoring apparatus to an orthodontic appliance. The apparatus may include the orthodontic appliance (e.g., a shell aligner). Any appropriate self-healing material may be used, including an electrically insulating polymeric material.

Also described herein are boosters and/or converters for transferring a signal (such as a NFC signal) from the monitoring apparatus to a signal that can be received by a smartphone, which typically has a much larger (and poorly matched/difficult to match) antenna for receiving the NFC from the monitoring apparatus device. For example, described herein are near field communication (NFC) to Bluetooth communication (BLE) signal coupler devices for relaying monitoring data from an orthodontic Monitoring Apparatus (monitoring apparatus, such as an ECI) to a handheld processor (such as a smartphone). These devices may include: a housing; a first antenna configured for NFC within the housing; a second antenna configured for BLE within the housing; a holder on the housing configured to hold the monitoring apparatus in alignment with the first antenna; and NFC to BLE transmission circuitry configured to receive data from the first antenna and to transmit data from the second antenna. The holder may comprise a case formed at least partially from the housing and configured to hold the monitoring apparatus (or the MA and dental appliance such as an aligner) within the case so that the monitoring apparatus is aligned with the first antenna. The NFC to BLE transmission circuitry may comprise a power source within the housing. The holder may include an indentation on the housing. The first antenna may comprise a trace antenna or a coil antenna; for example, the first antenna comprises a toroidal loop antenna having a gap.

Although the apparatuses and methods described herein include numerous examples of near field communication (NFC), including NFC-to-NFC communication, any of the methods and apparatuses described herein may be used with other types of wireless communication modes, including, without limitation, Wi-Fi, radio (RF, UHF, etc.), infrared (IR), microwave, Bluetooth (including Bluetooth low energy or BLE), magnetic field induction (including NFC), Wimax, Zigbee, ultrasound, etc. In particular, the methods and apparatuses described herein may include apparatuses that convert between these different wireless modes.

Also described herein are methods of relaying monitoring data from an orthodontic Monitoring Apparatus (such as an electronic compliance indicator apparatus) to a handheld processor. For example, a method may comprise: aligning a monitoring apparatus with a first antenna within a housing of

a near field communication (NFC) to Bluetooth communication (e.g., BLE) signal coupler device; transmitting the monitoring data from the monitoring apparatus to the NFC to BLE signal coupler device by NFC; and retransmitting the monitoring data from the NFC to BLE signal coupler device via a Bluetooth signal to a handheld electronics device. The method may also include inserting the monitoring apparatus into the NFC to BLE signal coupler device, wherein the NFC to BLE signal coupler device is configured as a case configured to hold the monitoring apparatus (or MA and a dental appliance to which the monitoring apparatus is coupled). The method may also include receiving the Bluetooth signal in the handheld electronics device, wherein the handheld electronics device comprises a smartphone. The method may also include modifying the monitoring data before retransmitting the data. Transmitting the monitoring data may comprise receiving the NFC signal comprising the monitoring data on a first antenna of the NFC to BLE signal coupler device; alternatively or additionally, retransmitting the monitoring data may comprise transmitting the monitoring data as the Bluetooth data via a second antenna of the NFC to BLE signal coupler device configured for Bluetooth communication.

Also described herein are improved systems, methods, and apparatus for monitoring physiological characteristics of patients, including from a patient's airway. In many embodiments, an orthodontic appliance is provided. The orthodontic appliance comprises one or more intraoral sensors embedded within an appliance shell shaped to receive teeth. In some embodiments, the intraoral sensors comprise a transmitter and a receiver. In some embodiments, the intraoral sensors comprise a plurality of electrodes. The one or more intraoral sensors are coupled to one or more processors. The processors are configured to determine a characteristic of the patient's intraoral cavity or airway based on measurements from the intraoral sensors. In some cases, the measurements include electrical impedance measurements. In some cases, the measurements include return signals from the patient's intraoral cavity or airway in response to emitted signals from a transmitter. Monitoring the physiological characteristics of patients using the appliances disclosed herein allows more precise diagnosis of patient conditions such as OSA. Because the symptoms of diseases such as OSA manifest when the patient is unconscious, autonomous electronic monitoring with an intraoral appliance can provide patient data that would otherwise be difficult or impossible to obtain, thereby facilitating diagnosis and treatment of the underlying condition. The monitoring systems and methods disclosed herein can be combined with a treatment apparatus, such as an appliance applying tooth-moving forces or an appliance for increasing airway clearance in the treatment of OSA.

In one aspect, an apparatus for monitoring a physiological characteristic of a patient is provided. The apparatus comprises an intraoral appliance shaped to receive the patient's teeth. The appliance comprises a plurality of electrodes. The electrodes are positioned to make electrical contact with the patient's intraoral cavity when the intraoral appliance is worn by the patient. The appliance further comprises one or more processors configured to use the electrodes to measure an electrical impedance. The processor uses the measured electrical impedance to determine a physiological characteristic of the patient.

In another aspect, an apparatus for monitoring a characteristic of a patient's intraoral cavity or airway is provided. The apparatus comprises an intraoral appliance shaped to receive the patient's teeth and includes a transmitter and a receiver. The appliance may further comprise one or more processors configured to cause the transmitter to emit a signal within the patient's intraoral cavity; measure a signal returning from the patient's intraoral cavity or airway in response to the emitted signal using the receiver; and determine, based on the measured signal, the characteristic of the patient's intraoral cavity or airway.

Other objects and features of the present invention will become apparent by a review of the specification, claims, and appended figures.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1**A illustrates an example of a tooth repositioning appliance.

FIGS. **1**B-**1**D shows an example of a tooth repositioning system.

FIG. **2** illustrates a method of orthodontic treatment using a plurality of appliances.

FIG. **3**A schematically illustrates an example of a monitoring apparatus (shown as an ECI device).

FIG. **3**B schematically illustrates a system including any of the intraoral appliances with one or more sensors as described herein, and digital scan data of the appliance and/or patient's teeth. An analysis engine (which may be part of the intraoral appliance or separate from the intraoral appliance) may integrate the distal information and the sensor information, and may relate the specific sensor information to the patient's teeth using the digital scan data.

FIG. **4**A illustrates an example of an intraoral appliance including an integrated monitoring device.

FIG. **4**B is a cross-sectional view of the appliance of FIG. **4**A.

FIG. **5** illustrates an example of a monitoring system including a first appliance and a second appliance.

FIG. **6**A illustrates an example of a system including an intraoral appliance and an attachment device mounted on a tooth.

FIG. **6**B shows an example of a system including an intraoral appliance and an attachment device mounted on a tooth.

FIGS. **7**A and **7**B illustrate an example of a monitoring device with a deflectable structure.

FIG. **7**C shows an example of a monitoring device with a deflectable structure.

FIG. **7**D illustrates an exemplary method for fabricating an intraoral appliance with a deflectable structure.

FIG. **8**A illustrates an example of an intraoral appliance including a capacitive sensor.

FIG. **8**B illustrates an example of a monitoring device integrated into an intraoral appliance.

FIG. **8**C illustrates an example of an intraoral appliance in which the majority of the aligner surface comprises a capacitive touch-sensor material.

FIG. **8**D illustrates an enlarged view, showing the grid pattern of the capacitive touch sensor that is distributed across the surface of the intraoral appliance of FIG. **8**C.

FIG. **9** illustrates an example of a monitoring system for detecting proximity between the patient's jaws.

FIG. **10**A shows an example of a monitoring device utilizing optical sensing.

FIG. **10**B illustrates an example of a monitoring device using optical sensing.

FIG. **10**C illustrates an example of a monitoring device using optical sensing.

FIGS. **11**A and **11**B illustrate operation of an example of a monitoring device using optical sensing.

FIGS. **11**C and **11**D illustrate an example of a monitoring device using optical sensing.

FIGS. **12**A and **12**B illustrate an example of a monitoring device using magnetic sensing.

FIG. **12**C shows an example of a monitoring device using magnetic sensing.

FIG. **13**A illustrates an example of a monitoring device using magnetic sensing.

FIG. **13**B illustrates an example of a monitoring device using magnetic sensing.

FIG. **13**C shows an example of a monitoring device using magnetic sensing.

FIG. **14**A illustrates an example of a monitoring device using a plurality of magnets.

FIG. **14**B is a cross-sectional view of the device of FIG. **14**A.

FIG. **15** illustrates an example of a monitoring device configured to measure force and/or pressure between an intraoral appliance and the patient's teeth.

FIG. **16**A illustrates an example of a monitoring device configured to measure force and/or pressure between an intraoral appliance and one or more attachment devices on a patient's teeth.

FIG. **16**B is a cross-sectional view of the device of FIG. **16**A.

FIG. **16**C is an example of an intraoral device configured to measure mechanical impedance of a tooth or teeth.

FIG. **16**D graphically illustrates the detection of acceleration over time at a particular tooth (or an aligner portion corresponding to a particular tooth). FIG. **16**E graphically illustrates the detection of force over time at the same tooth (or aligner region) for which acceleration was determined as shown in FIG. **16**D. An intraoral device configured to measure mechanical impedance such as the apparatus shown in FIG. **16**C may correlate the acceleration over time and the force over time to estimate mechanical impedance for the tooth.

FIG. **16**F shows a portion of an intraoral appliance configured to measure mechanical impedance. In this example, one or more motion sensors (e.g., accelerometers) may be coupled to the tooth (as part of the attachment, as shown) and may communicate with electronic components on the intraoral appliance (e.g., memory, processor, power supply, wireless communications, etc.). The apparatus may also include or may be used in conjunction with a mechanical actuator to provide a known (or measured) perturbing vibration, and the processor may use the known force input with the output from the accelerometer to determine mechanical impedance for the tooth/teeth.

FIG. **17**A shows an example of a monitoring device including a gas flow sensor.

FIG. **17**B illustrates an example of a monitoring device including a gas flow sensor.

FIG. **17**C shows an example of a monitoring device including a gas flow sensor.

FIG. **18** illustrates an example of a monitoring device using motion sensing.

FIG. **19** illustrates an example of a method for monitoring usage of an intraoral appliance.

FIGS. **20**A through **20**D illustrate an exemplary method for fabricating an intraoral appliance with an integrated monitoring device.

FIGS. **21**A through **21**C illustrate an example of a method for fabricating an intraoral appliance with an integrated monitoring device.

FIG. **22** is a simplified block diagram of an example of a data processing system.

FIG. **23** illustrates an example of a monitoring device.

FIG. **24** illustrates one example of coupling an ECI apparatus to an aligner.

FIG. **25** shows an exemplary prototype of an ECI apparatus coupled to an aligner.

FIG. **26** graphically illustrates the use of a capacitance sensor to detect when an aligner is being worn by a user, and/or is submerged in a fluid (e.g., water).

FIG. **27** graphically illustrates mutual capacitance measurements (on left) and self-capacitance measurements (on right).

FIG. **28** shows an example an ECI apparatus having a pair of capacitive electrodes.

FIG. **29**A shows an enlarged view of the sensing electrodes on an ECI apparatus. FIG. **29**B illustrates the use of capacitive signals from different sensing electrodes to distinguish wearing of an appliance including an ECI apparatus as described.

FIG. **30**A shows an example of an ECI apparatus including a pair of guard electrodes; FIG. **30**B illustrates the complex impedance of an ECI apparatus such as that shown in FIG. **30**A when submerged in water; FIG. **30**C is an example of an ECI apparatus including capacitance-sensing electrodes positioned at the end of the aligner appliance. FIG. **30**D illustrates the interpretation of the capacitance-sensing electrode to distinguish false positives when determining if an appliance having an ECI apparatus such as that shown in FIG. **30**A is being worn.

FIGS. **31**A-**31**D illustrate views of one variation of an aligner case configured as an intermediate device for coupling a near-filed signal (NFC) from an ECI apparatus for output as a Bluetooth signal to a phone. FIG. **31**A is a top view with the case cover open. FIG. **31**B shows a back view of the case of FIG. **31**A, and FIG. **31**C is a side view of the case of FIG. **31**A. FIG. **31**D is a top view of a prototype of the case shown in FIG. **31**A.

FIG. **32** illustrates one example of a system for transmitting data directly from an ECI to a smartphone.

FIGS. **33**A-**33**C illustrate an example of a system for transmitting data directly from an ECI to a smartphone using a holder/clip tool to hold the ECI in alignment with the antenna of the phone.

FIGS. **34**A and **34**B illustrate a trace antenna and the use of a trace antenna to read data from an ECI, respectively. FIG. **34**B shows alternative variations of antennas on the aligner.

FIGS. **35**A and **35**B illustrate a coil antenna and the use of a coil antenna as part of a data reader to read data from an ECI, respectively.

FIG. **36**A shows a schematic of a circuit diagram for an NFC coupler coupling between an ECI apparatus and a smartphone. FIG. **36**B illustrates an example of a toroid loop antenna with a gap in the ferrite core that may be used as part of an NFC coupler, such as illustrated in FIG. **36**A, for example. FIG. **36**C illustrate overall system coupling between NFC antennas.

FIGS. **37**A and **37**B illustrate, schematically, an NFC coupling device.

FIG. **38** illustrates a prototype of an NFC coupling device such as the one shown in FIG. **37**A.

FIG. **39** is an exemplary circuit diagram of an NFC coupling device.

FIG. **40** is an example of a user interface for an application program that may coordinate data transfer and/or analysis and/or compliance monitoring.

FIG. **41** is a flow diagram of a communications protocol that may be part of an application program.

FIG. **42** is a flow diagram for a coordinating near field communication between a smartphone and an ECI apparatus.

FIG. **43** is a flow diagram for data processing using an application program processing EIC data.

FIG. **44** is a flow diagram schematically illustrating operational states of an ECI device.

FIG. **45** is a flow chart illustrating the control of communications by a receiving processor (e.g., smartphone) communicating with an ECI device.

FIG. **46** is an example of a process chart for a data processing component/manager.

FIG. **47** illustrates an impedance model of a patient's airway.

FIG. **48**A illustrates the variation of patient airway width for different Mallampati scores, and FIG. **48**B illustrates the corresponding variation of airway resistance as a function of Mallampati score.

FIG. **49**A illustrates a patient's intraoral cavity in conjunction with points from which sensors such as electrodes can be placed to measure characteristics of the intraoral cavity and airway.

FIG. **49**B illustrates alternative positions in which sensors such as electrodes can be placed to measure characteristics of the intraoral cavity and airway.

FIG. **50**A illustrates an appliance wearable over a patient's teeth comprising sensors positioned at diametrically opposed points in a patient's intraoral cavity.

FIG. **50**B illustrates an appliance wearable over a patient's teeth comprising sensors positioned in close proximity to each other.

FIG. **50**C illustrates an interior of an appliance with an embedded measurement system comprising drive electronics and sensors.

FIG. **50**D illustrates examples of alternative, extended positions for sensors and drive electronics.

FIG. **50**E illustrates an appliance comprising an upper shell to fit a patient's upper teeth and a lower shell to fit the patient's lower teeth, each shell comprising an sensor.

FIG. **50**F illustrates an appliance configured to measure impedance between electrodes on opposite sides of the appliance shell.

FIG. **50**G illustrates an appliance with respective sensors on upper and lower shells, in which the sensors are inductively coupled.

FIG. **51**A illustrates a block diagram of a signal chain for performing impedance measurements with the appliances disclosed herein.

FIG. **51**B shows a schematic diagram of an oral appliance comprising a plurality of electrodes for measuring the impedance of a system such as the intraoral cavity or airway of a patient.

FIG. **52** illustrates a method for monitoring a physiological characteristic of a patient using an appliance as disclosed herein.

FIG. **53** illustrates a method for monitoring a characteristic of a patient's intraoral cavity or airway.

FIG. **54** illustrates a method of manufacturing an appliance comprising sensors and control electronics.

FIG. **55** illustrates exemplary rotational velocity data collected with a gyroscopic accelerometer coupled to the maxilla of a patient.

DETAILED DESCRIPTION

The monitoring apparatuses described herein may generally include Electronic Compliance Indicators (ECIs). An ECI may record sensor data from a subject wearing one or more dental appliances, such as dental/orthodontic aligners, including shell aligners. Data recorded by the ECI may be stored in physical memory on the ECI and may be retrieved by another device. In particular, the data described may be retrieved by a hand held electronics communication device such as a smartphone, tablet, or the like. The handheld electronics device may include a user interface to augment communication between the ECI and the device, and may provide feedback to the user (e.g., patient) and/or technician, physician, dentist, orthodontist, or other medical/dental practitioner. Once transmitted to the handheld device, the data may be processed (or further processed) and/or passed on to a remote processor, memory and/or server.

In particular, described herein are apparatuses for monitoring, including ECIs, that are very small and therefore use a relay, such as an appliance case or holder configured to operate as a relay. For example, described herein are apparatuses that use both NFC and BLE communication to transmit data between an ECI and a handheld electronic device (e.g., smartphone). Using NFC and BLE technologies may allow a smartphone to retrieve the data even from a very small ECI that includes only a small antenna, with a reasonably high accuracy and low power.

The apparatuses and methods described herein for monitoring treatment with removable intraoral appliances may generate sensor data related to usage of an intraoral appliance. The sensor data can be processed and analyzed to determine whether the patient is wearing the appliance in accordance with a prescribed treatment plan. Advantageously, the apparatuses and methods described herein provide an integrated electronic sensing and logging system capable of generating more reliable and accurate patient compliance data, which may be used by the treating practitioner to track patient behavior and improve treatment efficacy. Additionally, the monitoring apparatuses described herein may provide high value sensing data useful for appliance design. In some embodiments, the sensing data provided by the monitoring apparatuses described herein may be used as feedback to modify parameters of an ongoing orthodontic treatment, also known as adaptive closed-loop treatment planning.

The ECI apparatuses described herein may detect when the device is worn on a subject's tooth/teeth using any appropriate method, including one or more of those described herein. For example, an apparatuses for monitoring usage of an intraoral appliance (an ECI) may include one or more deflectable structures formed with or coupled to the intraoral appliance. The deflectable structure(s) can be shaped to be deflected when the intraoral appliance is worn on a patient's teeth. The device can comprise a sensor configured to generate sensor data indicative of deflection of the deflectable structure(s). Optionally, the device can comprise a processor operably coupled to the sensor and configured to process the sensor data so as to determine whether the intraoral appliance is being worn.

The intraoral appliance may comprise an appliance shell including a plurality of teeth receiving cavities. The deflectable structure(s) can be located near a tooth receiving cavity of the plurality of teeth receiving cavities so as to be deflected outward when a tooth is positioned within the tooth receiving cavity. The deflectable structure(s) can be formed in a wall of the tooth receiving cavity. The deflectable structure(s) can be deflected outward by at least 25 μm when the tooth is positioned within the tooth receiving cavity.

The deflectable structure(s) may comprise a deflected state when the intraoral appliance is being worn and a resting state when the intraoral appliance is not being worn, and the deflectable structure(s) interact with the sensor when in the deflected state. The sensor can comprise a mechanical switch and the deflectable structure(s) can engage the mechanical switch when in the deflected state. The sensor can comprise an optical switch and the deflectable structure(s) can activate the optical switch when in the deflected state.

The deflectable structure(s) may comprise a cantilever, dimple, concavity, flap, protrusion, or pop-out structure.

The apparatuses may further comprise a communication unit operably coupled to the sensor and configured to transmit one or more of the sensor data or the processed sensor data to a remote device. The sensor may be integrated with the intraoral appliance or coupled to a tooth. The processor may be integrated with the intraoral appliance or coupled to a tooth. Alternatively or additionally, the processor may be located external to the patient's intraoral cavity.

Any of the devices for monitoring usage of an intraoral appliance may comprise an appliance shell comprising a plurality of teeth receiving cavities and one or more proximity sensors operably coupled to the appliance shell and configured to generate sensor data when in proximity with intraoral tissue. The device can comprise a processor operably coupled to the one or more proximity sensors and configured to process the sensor data so as to determine whether the intraoral appliance is being worn on a patient's teeth.

The one or more proximity sensors may comprise one or more touch sensors (similarly the touch sensors described herein may be referred to as proximity sensors and/or proximity/touch sensors). The one or more touch sensors can comprise at least one capacitive touch sensor activated by charges associated with one or more of enamel, gingiva, oral mucosa, saliva, cheeks, lips, or tongue. The one or more touch sensors can comprise at least one capacitive touch sensor activate by positive charges associated with plaque or bacteria on the patient's teeth. The processor may optionally be configured to process the sensor data so as to determine an amount of bacteria on the patient's teeth. The one or more touch sensors can comprise at least one resistive touch sensor.

The one or more touch sensors may comprise at least one capacitive touch sensor configured to use one or more of enamel, gingiva, oral mucosa, saliva, cheeks, lips, or tongue as a ground electrode.

The one or more proximity sensors may comprise one or more of: a capacitive sensor, an eddy-current sensor, a magnetic sensor, an optical sensor, a photoelectric sensor, an ultrasonic sensor, a Hall Effect sensor, an infrared touch sensor, or a surface acoustic wave (SAW) touch sensor. The one or more proximity sensors may be configured to generate sensing data when in proximity to one or more of the patient's enamel, gingiva, oral mucosa, cheeks, lips, or tongue. The one or more proximity sensors may be integrated with the intraoral appliance, coupled to a tooth, or a combination thereof.

The processor may be integrated with the intraoral appliance or coupled to a tooth.

An apparatuses for monitoring usage of an intraoral appliance may include an appliance shell comprising a plurality of teeth receiving cavities and one or more vibration sensors operably coupled to the appliance shell and configured to generate sensor data of intraoral vibration patterns. The device can also comprise a processor operably coupled to the one or more vibration sensors and configured to process the sensor data so as to determine whether the intraoral appliance is being worn on a patient's teeth. The one or more vibration sensors comprise one or more of: a MEMS microphone, an accelerometer, or a piezoelectric sensor. The intraoral vibration patterns may be associated with one or more of: vibrations transferred to the patient's teeth via the patient's jaw bone, teeth grinding, speech, mastication, breathing, or snoring. The processor may determine whether the intraoral appliance is being worn by comparing the intraoral vibration patterns to patient-specific intraoral vibration patterns. The one or more vibration sensors may be integrated with the intraoral appliance, coupled to a tooth, or a combination thereof. The processor is integrated with the intraoral appliance or coupled to a tooth.

The various embodiments described herein can be used in combination with various types of intraoral appliances worn in a patient's mouth. The intraoral appliance may be an orthodontic appliance, such as an aligner or wire-and-bracket appliance, used to reposition one or more of the patient's teeth to a desired arrangement, e.g., to correct a malocclusion. Alternatively or additionally, the intraoral appliance may be used to maintain one or more of the patient's teeth in a current arrangement, such as a retainer. Other examples of intraoral appliances suitable for use in conjunction with the embodiments herein include sleep apnea treatment devices (e.g., mandibular advancement devices or splints), night guards (e.g., for treating bruxism), mouth guards, and palatal expanders.

Appliances having teeth receiving cavities that receive and reposition teeth, e.g., via application of force due to appliance resiliency, are generally illustrated with regard to FIG. **1**A. FIG. **1**A illustrates an exemplary tooth repositioning appliance or aligner **100** that can be worn by a patient in order to achieve an incremental repositioning of individual teeth **102** in the jaw. The appliance can include a shell having teeth-receiving cavities that receive and resiliently reposition the teeth. An appliance or portion(s) thereof may be indirectly fabricated using a physical model of teeth. For example, an appliance (e.g., polymeric appliance) can be formed using a physical model of teeth and a sheet of suitable layers of polymeric material. In some embodiments, a physical appliance is directly fabricated, e.g., using rapid prototyping fabrication techniques, from a digital model of an appliance.

Although reference is made to an appliance comprising a polymeric shell appliance, the embodiments disclosed herein are well suited for use with many appliances that receive teeth, for example appliances without one or more of polymers or shells. The appliance can be fabricated with one or more of many materials such as metal, glass, reinforced fibers, carbon fiber, composites, reinforced composites, aluminum, biological materials, and combinations thereof for example. The appliance can be shaped in many ways, such as with thermoforming or direct fabrication (e.g., 3D print-

ing, additive manufacturing), for example. Alternatively or in combination, the appliance can be fabricated with machining such as an appliance fabricated from a block of material with computer numeric control machining.

An appliance can fit over all teeth present in an upper or lower jaw, or less than all of the teeth. The appliance can be designed specifically to accommodate the teeth of the patient (e.g., the topography of the tooth-receiving cavities matches the topography of the patient's teeth), and may be fabricated based on positive or negative models of the patient's teeth generated by impression, scanning, and the like. Alternatively, the appliance can be a generic appliance configured to receive the teeth, but not necessarily shaped to match the topography of the patient's teeth. In some cases, only certain teeth received by an appliance will be repositioned by the appliance while other teeth can provide a base or anchor region for holding the appliance in place as it applies force against the tooth or teeth targeted for repositioning. In some embodiments, some, most, or even all of the teeth will be repositioned at some point during treatment. Teeth that are moved can also serve as a base or anchor for holding the appliance as it is worn by the patient. Typically, no wires or other means will be provided for holding an appliance in place over the teeth. In some cases, however, it may be desirable or necessary to provide individual attachments or other anchoring elements **104** on teeth **102** with corresponding receptacles or apertures **106** in the appliance **100** so that the appliance can apply a selected force on the tooth. Exemplary appliances, including those utilized in the Invisalign® System, are described in numerous patents and patent applications assigned to Align Technology, Inc. including, for example, in U.S. Pat. Nos. 6,450,807, and 5,975,893, as well as on the company's website, which is accessible on the World Wide Web (see, e.g., the URL "invisalign.com"). Examples of tooth-mounted attachments suitable for use with orthodontic appliances are also described in patents and patent applications assigned to Align Technology, Inc., including, for example, U.S. Pat. Nos. 6,309,215 and 6,830,450.

FIGS. **1**B-**1**D illustrate an example of a tooth repositioning system **110** including a plurality of appliances **112**, **114**, **116**. Any of the appliances described herein can be designed and/or provided as part of a set of a plurality of appliances used in a tooth repositioning system. Each appliance may be configured so a tooth-receiving cavity has a geometry corresponding to an intermediate or final tooth arrangement intended for the appliance. The patient's teeth can be progressively repositioned from an initial tooth arrangement to a target tooth arrangement by placing a series of incremental position adjustment appliances over the patient's teeth. For example, the tooth repositioning system **110** can include a first appliance **112** corresponding to an initial tooth arrangement, one or more intermediate appliances **114** corresponding to one or more intermediate arrangements, and a final appliance **116** corresponding to a target arrangement. A target tooth arrangement can be a planned final tooth arrangement selected for the patient's teeth at the end of all planned orthodontic treatment. Alternatively, a target arrangement can be one of some intermediate arrangements for the patient's teeth during the course of orthodontic treatment, which may include various different treatment scenarios, including, but not limited to, instances where surgery is recommended, where interproximal reduction (IPR) is appropriate, where a progress check is scheduled, where anchor placement is best, where palatal expansion is desirable, where restorative dentistry is involved (e.g., inlays, onlays, crowns, bridges, implants, veneers, and the like), etc. As such, it is understood that a target tooth arrangement can be any planned resulting arrangement for the patient's teeth that follows one or more incremental repositioning stages. Likewise, an initial tooth arrangement can be any initial arrangement for the patient's teeth that is followed by one or more incremental repositioning stages.

The various embodiments of the orthodontic appliances presented herein can be fabricated in a wide variety of ways. As an example, some embodiments of the appliances herein (or portions thereof) can be produced using indirect fabrication techniques, such as by thermoforming over a positive or negative mold. Indirect fabrication of an orthodontic appliance can involve producing a positive or negative mold of the patient's dentition in a target arrangement (e.g., by rapid prototyping, milling, etc.) and thermoforming one or more sheets of material over the mold in order to generate an appliance shell. Alternatively or in combination, some embodiments of the appliances herein may be directly fabricated, e.g., using rapid prototyping, stereolithography, 3D printing, and the like.

The configuration of the orthodontic appliances herein can be determined according to a treatment plan for a patient, e.g., a treatment plan involving successive administration of a plurality of appliances for incrementally repositioning teeth. Computer-based treatment planning and/or appliance manufacturing methods can be used in order to facilitate the design and fabrication of appliances. For instance, one or more of the appliance components described herein can be digitally designed and fabricated with the aid of computer-controlled manufacturing devices (e.g., computer numerical control (CNC) milling, computer-controlled rapid prototyping such as 3D printing, etc.). The computer-based methods presented herein can improve the accuracy, flexibility, and convenience of appliance fabrication.

In some embodiments, orthodontic appliances, such as the appliance illustrated in FIG. **1**A, impart forces to the crown of a tooth and/or an attachment positioned on the tooth at one or more points of contact between a tooth receiving cavity of the appliance and received tooth and/or attachment. The magnitude of each of these forces and/or their distribution on the surface of the tooth can determine the type of orthodontic tooth movement which results. Tooth movements may be in any direction in any plane of space, and may comprise one or more of rotation or translation along one or more axes. Types of tooth movements include extrusion, intrusion, rotation, tipping, translation, and root movement, and combinations thereof, as discussed further herein. Tooth movement of the crown greater than the movement of the root can be referred to as tipping. Equivalent movement of the crown and root can be referred to as translation. Movement of the root greater than the crown can be referred to as root movement.

FIG. **2** illustrates a method **200** of orthodontic treatment using a plurality of appliances, in accordance with embodiments. The method **200** can be practiced using any of the appliances or appliance sets described herein. In step **210**, a first orthodontic appliance is applied to a patient's teeth in order to reposition the teeth from a first tooth arrangement to a second tooth arrangement. In step **220**, a second orthodontic appliance is applied to the patient's teeth in order to reposition the teeth from the second tooth arrangement to a third tooth arrangement. The method **200** can be repeated as necessary using any suitable number and combination of sequential appliances in order to incrementally reposition the patient's teeth from an initial arrangement to a target arrangement. The appliances can be generated all at

the same stage or time point, in sets or batches (e.g., at the beginning of one or more stages of the treatment), or one at a time, and the patient can wear each appliance until the pressure of each appliance on the teeth can no longer be felt or until the maximum amount of expressed tooth movement for that given stage has been achieved. A plurality of different appliances (e.g., a set) can be designed and even fabricated prior to the patient wearing any appliance of the plurality. After wearing an appliance for an appropriate period of time, the patient can replace the current appliance with the next appliance in the series until no more appliances remain. The appliances are generally not affixed to the teeth and the patient may place and replace the appliances at any time during the procedure (e.g., patient-removable appliances). The final appliance or several appliances in the series may have a geometry or geometries selected to overcorrect the tooth arrangement. For instance, one or more appliances may have a geometry that would (if fully achieved) move individual teeth beyond the tooth arrangement that has been selected as the "final." Such over-correction may be desirable in order to offset potential relapse after the repositioning method has been terminated (e.g., permit movement of individual teeth back toward their pre-corrected positions). Over-correction may also be beneficial to speed the rate of correction (e.g., an appliance with a geometry that is positioned beyond a desired intermediate or final position may shift the individual teeth toward the position at a greater rate). In such cases, the use of an appliance can be terminated before the teeth reach the positions defined by the appliance. Furthermore, over-correction may be deliberately applied in order to compensate for any inaccuracies or limitations of the appliance.

An intraoral appliance can be operably coupled to a monitoring device (also referred to herein as an "electronic compliance indicator") configured to provide data related to appliance usage and/or patient compliance, such as data indicative of whether the appliance is being worn, the amount of time the appliance is worn, and/or interaction between the appliance and the intraoral cavity (e.g., contact between the appliance and intraoral tissues, force and/or pressure applied by the appliance to intraoral tissues). Alternatively or in combination, the monitoring device can be configured to provide data indicative of one or more characteristics of the patient's intraoral cavity or a portion thereof (e.g., teeth, gingiva, palate, lips, tongue, cheeks, saliva, airway), such as temperature, color, sound, vibration, motion, pH, conductivity, charge, resistance, capacitance, humidity, or gas flow. The characteristics of the patient's intraoral cavity can optionally be used to determine appliance usage and/or patient compliance, as discussed in greater detail herein.

The monitoring devices described herein can be designed for use in the patient's intraoral cavity. For example, the dimensions of a monitoring device may be limited in order to avoid patient discomfort and/or facilitate integration into an intraoral appliance as discussed below. In some embodiments, a monitoring device has a height or thickness less than or equal to about 1.5 mm, or less than or equal to about 2 mm. In some embodiments, a monitoring device has a length or width less than or equal to about 4 mm, or less than or equal to about 5 mm. The shape of the monitoring device can be varied as desired, e.g., circular, ellipsoidal, triangular, square, rectangular, etc. For instance, in some embodiments, a monitoring device can have a circular shape with a diameter less than or equal to about 5 mm.

A relatively thin and flexible monitoring device can be used to provide a larger surface area while reducing patient discomfort. In some embodiments, the monitoring devices herein are sized to conform to a surface of a tooth crown (e.g., a buccal, lingual, and/or occlusal surface of a tooth crown). For example, a monitoring device having dimensions of about 10 mm by about 5 mm can be used to cover a buccal surface of a molar crown. As another example, a monitoring device having dimensions of about 10 mm by about 20 mm can be used to cover the buccal, occlusal, and lingual surfaces of a tooth crown. A monitoring device can be in contact with a crown of a single tooth, or with crowns of a plurality of teeth, as desired.

The other properties of the monitoring device (e.g., volume, weight) can be designed in order to reduce patient discomfort. For instance, the weight of a monitoring device can be selected not to exceed a level that would exert undesirable forces on the underlying teeth.

FIG. **3**A schematically illustrates a monitoring device **300** (e.g., an ECI). The monitoring device **300** can be used in combination with any embodiment of the systems and devices described herein, and the components of the monitoring device **300** are equally applicable to any other embodiment of the monitoring devices described herein. The monitoring device **300** can be implemented as an application-specific integrated circuit (ASIC) including one or more of the following components: a processor **302**, a memory **304**, one or more sensors **306**, a clock **308**, a communication unit **310**, an antenna **312**, a power management unit **314**, or a power source **316**. The processor **302** (e.g., a central processing unit (CPU), microprocessor, field programmable gate array (FPGA), logic or state machine circuit, etc.), also referred to herein as a controller, can be configured to perform the various methods described herein. The memory **304** encompasses various types of memory known to those of skill in the art, such as RAM (e.g., SRAM, DRAM), ROM (EPROM, PROM, MROM), or hybrid memory (e.g., flash, NVRAM, EEPROM), and the like. The memory **304** can be used to store instructions executable by the processor **302** to perform the methods provided herein. Additionally, the memory can be used to store sensor data obtained by the sensor(s) **306**, as discussed in greater detail below.

The monitoring device **300** can include any number of sensors **306**, such as one, two, three, four, five, or more sensors. In some embodiments, the use of multiple sensors provides redundancy to increase the accuracy and reliability of the resultant data. Some or all of the sensors **306** can be of the same type. Some or all of the sensors **306** can be of different types. Examples of sensor types suitable for use in the monitoring devices described herein include: touch or tactile sensors (e.g., capacitive, resistive), proximity sensors, audio sensors (e.g., microelectromechanical system (MEMS) microphones), color sensors (e.g., RGB color sensors), electromagnetic sensors (e.g., magnetic reed sensors, magnetometer), light sensors, force sensors (e.g., force-dependent resistive materials), pressure sensors, temperature sensors, motion sensors (e.g., accelerometers, gyroscopes), vibration sensors, piezoelectric sensors, strain gauges, pH sensors, conductivity sensors, gas flow sensors, gas detection sensors, humidity or moisture sensors, physiological sensors (e.g., electrocardiography sensors, bio-impedance sensors, photoplethysmography sensors, galvanic skin response sensors), or combinations thereof. In some embodiments, the sensors herein can be configured as a switch that is activated and/or deactivated in response to a particular type of signal (e.g., optical, electrical, magnetic, mechanical, etc.).

A sensor **306** can be located at any portion of an intraoral appliance, such as at or near a distal portion, a mesial portion, a buccal portion, a lingual portion, a gingival portion, an occlusal portion, or a combination thereof. A sensor **306** can be positioned near a tissue of interest when the appliance is worn in the patient's mouth, such as near or adjacent the teeth, gingiva, palate, lips, tongue, cheeks, airway, or a combination thereof. For example, when the appliance is worn, the sensor(s) **306** can cover a single tooth, or a portion of a single tooth. Alternatively, the sensor(s) **306** can cover multiple teeth or portions thereof. In embodiments where multiple sensors **306** are used, some or all of the monitoring devices can be located at different portions of the appliance and/or intraoral cavity. Alternatively, some or all of the sensor **306** can be located at the same portion of the appliance and/or intraoral cavity.

An analog-to-digital converter (ADC) (not shown) can be used to convert analog sensor data into digital format, if desired. The processor **302** can process the sensor data obtained by the sensor(s) **306** in order to determine appliance usage and/or patient compliance, as described herein. The sensor data and/or processing results can be stored in the memory **304**. Optionally, the stored data can be associated with a timestamp generated by the clock **308** (e.g., a real-time clock or counter).

The monitoring device **300** may include a communication unit **310** configured to transmit the data stored in the memory (e.g., sensor data and/or processing results) to a remote device. The communication unit **310** can utilize any suitable communication method, such as wired or wireless communication methods (e.g., RFID, near-field communication, Bluetooth, ZigBee, infrared, etc.). The communication unit **310** can include a transmitter for transmitting data to the remote device and an antenna **312**. Optionally, the communication unit **310** includes a receiver for receiving data from the remote device. In some embodiments, the communication channel utilized by the communication unit **310** can also be used to power the device **300**, e.g., during data transfer or if the device **300** is used passively.

The remote device can be any computing device or system, such as a mobile device (e.g., smartphone), personal computer, laptop, tablet, wearable device, etc. Optionally, the remote device can be a part of or connected to a cloud computing system ("in the cloud"). The remote device can be associated with the patient, the treating practitioner, medical practitioners, researchers, etc. In some embodiments, the remote device is configured to process and analyze the data from the monitoring device **300**, e.g., in order to monitor patient compliance and/or appliance usage, for research purposes, and the like.

The monitoring device **300** can be powered by a power source **316**, such as a battery. In some embodiments, the power source **316** is a printed and/or flexible battery, such as a zinc-carbon flexible battery, a zinc-manganese dioxide printed flexible battery, or a solid-state thin film lithium phosphorus oxynitride battery. The use of printed and/or flexible batteries can be advantageous for reducing the overall size of the monitoring device **300** and avoiding patient discomfort. For example, printed batteries can be fabricated in a wide variety of shapes and can be stacked to make three-dimensional structures, e.g., to conform the appliance and/or teeth geometries. Likewise, flexible batteries can be shaped to lie flush with the surfaces of the appliance and/or teeth. Alternatively or in combination, other types of batteries can be used, such as supercapacitors. In some embodiments, the power source **316** can utilize lower power energy harvesting methods (e.g., thermodynamic, electrodynamic, piezoelectric) in order to generate power for the monitoring device **300**. Optionally, the power source **316** can be rechargeable, for example, using via inductive or wireless methods. In some embodiments, the patient can recharge the power source **316** when the appliance is not in use. For example, the patient can remove the intraoral appliance when brushing the teeth and place the appliance on an inductive power hub to recharge the power source **316**.

Optionally, the monitoring device **300** can include a power management unit **314** connected to the power source **316**. The power management unit **314** can be configured to control when the monitoring device **300** is active (e.g., using power from the power source **316**) and when the device **300** is inactive (e.g., not using power from the power source **316**). In some embodiments, the monitoring device **300** is only active during certain times so as to lower power consumption and reduce the size of the power source **316**, thus allowing for a smaller monitoring device **300**. In some embodiments, the monitoring device **300** includes an activation mechanism (not shown) for controlling when the monitoring device **300** is active (e.g., powered on, monitoring appliance usage) and when the monitoring device **300** is dormant (e.g., powered off, not monitoring appliance usage). The activation mechanism can be provided as a discrete component of the monitoring device **300**, or can be implemented by the processor **302**, the power management unit **314**, or a combination thereof. The activation mechanism can be used to reduce the amount of power used by the monitoring device **300**, e.g., by inactivating the device **300** when not in use, which can be beneficial for reducing the size of the power supply **316** and thus the overall device size.

In some embodiments, the monitoring device **300** is dormant before being delivered to the patient (e.g., during storage, shipment, etc.) and is activated only when ready for use. This approach can be beneficial in conserving power expenditure. For example, the components of the monitoring device **300** can be electrically coupled to the power source **316** at assembly, but may be in a dormant state until activated, e.g., by an external device such as a mobile device, personal computer, laptop, tablet, wearable device, power hub etc. The external device can transmit a signal to the monitoring device **300** that causes the activation mechanism to activate the monitoring device **300**. As another example, the activation mechanism can include a switch (e.g., mechanical, electronic, optical, magnetic, etc.), such that the power source **316** is not electrically coupled to the other components of the monitoring device **300** until the switch is triggered. For example, in some embodiments, the switch is a reed switch or other magnetic sensor that is held open by a magnet. The magnet can be removably attached to the monitoring device **300**, or may be integrated into the packaging for the device **300** or appliance, for example. When the monitoring device is separated from the magnet (e.g., by removing the magnet or removing the device and appliance from the packaging), the switch closes and connects the power source **316**. As another example, the monitoring device **300** can include a mechanical switch such as a push button that is manually actuated in order to connect the power source **316**. In some embodiments, the activation mechanism includes a latching function that locks the switch upon the first actuation to maintain connectivity with the power source so as to maintain activation of the monitoring device **300**. Optionally, the switch for the activation mechanism can be activated by a component in the patient's intraoral cavity (e.g., a magnet coupled to a patient's tooth), such that the monitoring device **300** is active only when the

appliance is worn by the patient, and is inactive when the appliance is removed from the patient's mouth. Alternatively or in combination, the switch can be activated by other types of signals, such as an optical signal.

FIG. **23** illustrates a monitoring device **2300** with an activation mechanism, in accordance with embodiments. The monitoring device **2300**, as with all other monitoring devices described herein, can be similar to the monitoring device **300**, and can include some or all of the components described herein with respect to the monitoring device **300**. The device **2300** is coupled to an intraoral appliance **2302** (e.g., via an encapsulating material **2304**). The device **2300** can include an activation mechanism **2303** including a magnetic switch. Prior to use, the device **2300** can be removably coupled to a magnet **2306** (e.g., using tape **2308**), and the magnet **2306** can hold the magnetic switch in an open position such that the device **2300** is inactive. When the appliance **2302** is ready for use, the user can remove the magnet **2306**, thus closing the magnetic switch and connecting the components of the monitoring device **2300** to a power source. The intraoral appliances and monitoring devices described herein can be configured in many different ways. In some embodiments, an intraoral appliance as described herein is operably coupled to a single monitoring device. Alternatively, the intraoral appliance can be operably coupled to a plurality of monitoring devices, such as at least two, three, four, five, or more monitoring devices. Some or all of the monitoring devices may be of the same type (e.g., collect the same type of data). Alternatively, some or all of the monitoring devices may be of different types (e.g., collect different types of data). Any of the embodiments of monitoring devices described herein can be used in combination with other embodiments in a single intraoral appliance.

A monitoring device can be located at any portion of the appliance, such as at or near a distal portion, a mesial portion, a buccal portion, a lingual portion, a gingival portion, an occlusal portion, or a combination thereof. The monitoring device can be positioned near a tissue of interest when the appliance is worn in the patient's mouth, such as near or adjacent the teeth, gingiva, palate, lips, tongue, cheeks, airway, or a combination thereof. For example, when the appliance is worn, the monitoring device can cover a single tooth, or a portion of a single tooth. Alternatively, the monitoring device can cover multiple teeth or portions thereof. In embodiments where multiple monitoring devices are used, some or all of the monitoring devices can be located at different portions of the appliance. Alternatively, some or all of the monitoring devices can be located at the same portion of the appliance.

A monitoring device can be operably coupled to the intraoral appliance in a variety of ways. For example, the monitoring device can be physically integrated with the intraoral appliance by coupling the monitoring device to a portion of the appliance (e.g., using adhesives, fasteners, latching, laminating, molding, etc.). The coupling may be a releasable coupling allowing for removal of the monitoring device from the appliance, or may be a permanent coupling in which the monitoring device is permanently affixed to the appliance. Alternatively or in combination, the monitoring device can be physically integrated with the intraoral appliance by encapsulating, embedding, printing, or otherwise forming the monitoring device with the appliance. In some embodiments, the appliance includes a shell shaped to receive the patient's teeth, and the monitoring device is physically integrated with the shell. The monitoring device can be located on an inner surface of the shell (e.g., the surface adjacent to the received teeth), an outer surface of the shell (e.g., the surface away from the received teeth), or within a wall of the shell. Optionally, as discussed further herein, the shell can include a receptacle shaped to receive the monitoring device. Exemplary methods for fabricating an appliance with a physically integrated monitoring device (e.g., by incorporating some or all of the components of the monitoring device during direct fabrication of the appliance) are described in further detail herein.

In general any of the apparatuses described herein may be used in conjunction with digital model(s) or scans or the patient's teeth and/or intraoral appliance. For example, FIG. **3**B schematically illustrates a system **383** including an intraoral appliance **377** with one or more sensors, and digital scan data of the appliance and/or patient's teeth **379**. An analysis engine **381** (which may be part of the intraoral appliance or separate from the intraoral appliance) may integrate the distal information and the sensor information, and may relate the specific sensor information to the patient's teeth using the digital scan data.

FIGS. **4**A and **4**B illustrate an intraoral appliance **400** including an integrated monitoring device **402**, in accordance with embodiments. The appliance **400** includes a shell **404** having a plurality of teeth receiving cavities, and the monitoring device **402** is coupled to an outer, buccal surface of the shell **404** adjacent a tooth receiving cavity **406**. In the depicted embodiment, the monitoring device **402** is coupled to a tooth receiving cavity **406** for a molar. It shall be appreciated that in alternative embodiments, the monitoring device **402** can be coupled to other portions of the shell **404**, such as an inner surface, a lingual surface, an occlusal surface, one or more tooth receiving cavities for other types of teeth (e.g., incisor, canine, premolar), etc. The monitoring device **402** can be shaped to conform to the geometry of the corresponding appliance portion (e.g., the wall of the cavity **306**) so as to provide a lower surface profile and reduce patient discomfort. In some embodiments, the appliance **400** includes a receptacle **408** formed on the outer surface of the shell **404** and the monitoring device **402** is positioned within the receptacle. Exemplary methods for forming an appliance with a receptacle **408** and integrated monitoring device **402** are described in detail below.

The monitoring device **402** can include any of the components previously described herein with respect to the monitoring device **300** of FIG. **3**A. For example, the monitoring device **402** can include a sensor **410**, a power source **412** (e.g., a battery), and/or a communication unit **414** (e.g., a wireless antenna). The arrangement of the components of the monitoring device **402** can be varied as desired. In some embodiments, the sensor **408** is located adjacent to the tooth receiving cavity **406**. A gap can be formed in the shell **404** adjacent to the sensor **410** so as to permit direct access to the received tooth. The communication unit **414** (or a component thereof, such as an antenna) can be located adjacent to or on the outer surface of the receptacle **408** so as to facilitate data transmission.

In some embodiments, some of the components of a monitoring device may be packaged and provided separately from other components of the device. For example, a monitoring device can include one or more components that are physically integrated with a first intraoral appliance and one or more components that are physically integrated with a second intraoral appliance. The first and second intraoral appliances can be worn on opposing jaws, for example. Any of the components of a monitoring device (e.g., components of the device **300** of FIG. **3**A) can be located on an appliance for the upper jaw, an appliance for the lower jaw, or a

combination thereof. In some embodiments, it is beneficial to distribute the components of the monitoring device across multiple appliances in order to accommodate space limitations, accommodate power limitations, and/or improve sensing, for example. Additionally, some of the components of a monitoring device can serve as a substrate for other components (e.g., a battery serves as a substrate to an antenna). FIG. **5** illustrates a monitoring system **500** including a first appliance **502** and a second appliance **504**, in accordance with embodiments. The first appliance **502** can be shaped to receive teeth of a patient's upper arch and the second appliance **504** can be shaped to receive teeth of a patient's lower arch. The system **500** can include a monitoring device separated into a first subunit **506** physically integrated with the first appliance **502** and a second subunit **508** physically integrated with the second appliance **508**. In some embodiments, the first subunit **506** is a power supply subunit including a power source **510**, and the second subunit **508** is a sensing subunit including the remaining components of the monitoring device, such as a power management unit **512**, processor (e.g., CPU **514**), sensor **516**, memory (e.g., RAM **518** such as SRAM or DRAM; ROM such as EPROM, PROM, or MROM; or hybrid memory such as EEPROM **520**, flash, or NVRAM), communication unit (e.g., antenna **522**), or any other component **524** described herein (e.g., with respect to the monitoring device **300** of FIG. **3**A). The first subunit **506** and second subunit **508** can be operably coupled to each other via inductive coupling between the power supply **510** and power management unit **512**, e.g., when the first appliance **502** and second appliance **504** are brought into proximity with each other by the closing of the patient's jaws.

The configuration of FIG. **5** can be varied as desired. For example, the first subunit **506** can be physically integrated with the second appliance **504** and the second subunit **508** can be physically integrated with the first appliance **502**. As another example, the distribution of the monitoring device components between the first subunit **506** and second subunit **508** can differ from the depicted embodiment.

Alternatively or in combination, a monitoring device can include one or more components that are physically integrated with an intraoral appliance and one or more components that are physically integrated with another device external to the patient's intraoral cavity. For example, the external device can be a wearable device (e.g., headgear, smart watch, wearable computer, etc.) worn on another portion of the patient's body. As another example, the external device can be a power hub, a mobile device, personal computer, laptop, tablet, etc. Any of the components of a monitoring device (e.g., components of the device **300** of FIG. **3**A) can be located on an external device. In some embodiments, the monitoring device includes a communication unit and antenna integrated into the intraoral appliance that transmits sensor data from the patient's intraoral cavity to the external device, and optionally receives data from the external device. The monitoring device components integrated into the external device can provide additional functionality (e.g., processing and/or analysis capabilities) that augments the functionality of the monitoring device components within the intraoral appliance. The monitoring device components within the intraoral appliance may be capable of operating with or without the augmented functionalities.

Alternatively or in combination, a monitoring device can include one or more components that are physically integrated with an intraoral appliance and one or more components that are located in the patient's intraoral cavity separate from the appliance. The intraoral components can be positioned so as to interact with (e.g., physically contact, communicate with) the integrated components in the appliance when the appliance is worn. In some embodiments, the intraoral components are coupled to a portion of the intraoral cavity, such as a crown of the patient's tooth. For instance, the intraoral components can be physically integrated into an attachment device mounted on a patient's tooth. Alternatively or in combination, the monitoring device can be surgically implanted, e.g., in the bone of the patient's jaw. Any of the components of a monitoring device (e.g., components of the device **300** of FIG. **3**A) can be located in the patient's intraoral cavity rather than in the intraoral appliance. In some embodiments, the appliance and integrated components can be removed from the patient's mouth independently of the intraoral components. Advantageously, this approach may reduce costs by allowing the same device components to be used with multiple different appliances, e.g., when applying a sequence of shell appliances to reposition the patient's teeth.

FIG. **6**A illustrates a system **600** including an intraoral appliance **602** and an attachment device **604** mounted on a tooth **606**, in accordance with embodiments. The appliance **602** can include a shell with a tooth receiving cavity shaped to receive the tooth **606** and a receptacle shaped to accommodate the attachment device **604** on the tooth **606**. In some embodiments, the system **600** includes a monitoring device having a first subunit physically integrated into the appliance **602** (e.g., according to any of the methods described herein) and a second subunit physically integrated into the attachment device **604**. In some embodiments, the second subunit integrated into the attachment device **604** includes the relatively bulky components of the monitoring device, such as the power source, memory, and/or sensors. For example, the attachment device **604** can include a battery or other power source operably coupled to the monitoring device components integrated into the appliance **602**, e.g., via inductive coupling or direct contact using electrodes **608**. In alternative embodiments, this configuration can be reversed, with the power source mounted in the appliance **602** and the remaining monitoring device components located in the attachment device **604**. This approach can reduce costs when multiple appliances are used, since only the power source is replaced with each new appliance. As another example, the attachment device **604** can include a passive sensing element driven by one or more monitoring device components located in the appliance **602**. In yet another example, the attachment device **604** can include a conductive element used to trigger a switch integrated in the appliance **602**.

FIG. **6**B illustrates a system **650** including an intraoral appliance **652** and an attachment device **654** mounted on a tooth **656**, in accordance with embodiments. Similar to the appliance **600**, the appliance **652** can include a shell with a tooth receiving cavity shaped to receive the tooth **656** and a receptacle shaped to accommodate the attachment device **654** on the tooth **656**. In some embodiments, the system **650** includes a monitoring device having a first subunit physically integrated into the appliance **652** (e.g., according to any of the methods described herein) and a second subunit physically integrated into the attachment device **654**. The first subunit in the appliance **652** can include a sensing target **658** and the second subunit in the attachment device **654** can include one or more sensors configured to detect the target. For example, the sensing target **658** can be a mirror or opaque surface and the sensor can be a photodetector. As another example, the sensing target **658** can be a magnet and the sensor can be a magnetometer. In yet another example,

the sensing target **658** can be a metallic element (e.g., foil, coating) and the sensor can be a capacitive sensor. Optionally, the sensing target **658** can be a powered coil generating an AC electromagnetic field, such that the sensor also obtains power from the sensing target **658**. In alternative embodiments, the locations of the first and second subunits can be reversed, such that the sensing target **658** is located in the attachment device **654** and the sensor is located in the appliance **652**.

The monitoring devices of the present disclosure may utilize many different types and configurations of sensors. The description below of certain exemplary monitoring devices is not intended to be limiting, and it shall be appreciated that the features of the various embodiments described herein can be used in combination with features of other embodiments. For example, the monitoring devices discussed below may also include any of the components previously described with respect to the monitoring device **300** of FIG. **3**A. A single monitoring device can include any combination of the sensor types and sensor configurations described herein.

In some embodiments, a monitoring device includes a structure shaped to interact with the sensor when the intraoral appliance is worn on the patient's teeth. The monitoring device can include one or more deflectable structures (e.g., a cantilever, dimple, concavity, flap, protrusion, pop-out structure, etc.) formed with or coupled to the appliance. The deflectable structure can be deflected outward by the patient's tooth or an attachment device coupled to the tooth when the appliance is worn, for example. In some embodiments, the monitoring device includes a sensor (e.g., a mechanical switch such as a push button), an electrical switch, an optical switch, a proximity sensor, a touch sensor, etc., configured to generate sensor data indicative of deflection of the deflectable structure (e.g., whether the structure is deflected, the deflection distance, etc.). The monitoring device can also include a processor operably coupled to the sensor and configured to process the sensor data so as to generate appliance usage and/or compliance data (e.g., information regarding whether the appliance is being worn). Optionally, the sensor can provide more complex data (e.g., force and/or pressure data) regarding the interaction between the appliance and the patient's teeth. In some embodiments, the deflectable structure is in a deflected state when the appliance is being worn and in a resting state when the appliance is not being worn, and the deflectable structure interacts with (e.g., activates) the sensor only when in the deflected state.

FIGS. **7**A and **7**B illustrate a monitoring device **700** with a deflectable structure **702**, in accordance with embodiments. In the depicted embodiment, the deflectable structure **702** is formed in a shell **704** of an intraoral appliance, e.g., in a wall of a tooth receiving cavity **706**. The monitoring device **700** can include a sensor **708** (e.g., push button) configured to detect the deflection of the deflectable structure **702**. When the appliance is not being worn on the patient's teeth (FIG. **7**A), the deflectable structure **702** can be in a resting state such that the sensor **708** is not activated. When the appliance is worn by the patient, the tooth **710** (e.g., a first or second molar) can displace the deflectable structure **702** outwards to activate the sensor **708**. The deflection distance can be varied as desired. For instance, the structure **702** can be deflected outward by a distance of at least about 25 μm, at least about 30 μm, at least about 50 μm, at least about 100 μm, at least about 200 (μm, at least about 300 μm, or a distance within a range from about 25 μm to about 300 μm. The monitoring device **700** can include other components (e.g., as previously described with respect to FIG. **3**A) for storing, processing, analyzing, and/or transmitting the sensor data.

FIG. **7**C illustrates a monitoring device **720** with a deflectable structure **722**, in accordance with embodiments. The deflectable structure **722** is formed in a shell of an intraoral appliance, e.g., in a wall of a tooth receiving cavity **724**. The tooth receiving cavity **724** is shaped to receive a tooth **726** coupled to an attachment device **728**. In some embodiments, the attachment device **728** includes an activator structure **730** that deflects the deflectable structure **722** when the tooth **726** is received in the cavity **724**. The monitoring device **720** includes a sensing subunit **732** mounted to the shell near the deflectable structure **722**. The sensing subunit **732** includes a sensor **734** (e.g., a switch) that is activated by the deflection of the deflectable structure **722**. Optionally, the sensor **732** can be covered with a flexible membrane. The subunit **732** can also include a power source, a processor, and/or any of the other monitoring device components described herein (e.g., with respect to the embodiment of FIG. **3**A).

FIG. **7**D illustrates a method for fabricating an intraoral appliance with a deflectable structure, in accordance with embodiments. In the first step, a mold **750** of a patient's dentition is provided. The mold **750** can represent the patient's teeth in a current or target tooth arrangement, for example. In a second step, an intraoral appliance **752** is formed by forming (e.g., thermoforming) a material over the mold **750**. Alternatively, the intraoral appliance **752** can be formed by direct fabrication (e.g., stereolithography, 3D printing, etc.) without using the mold **750**. The appliance can include a shell with a tooth receiving cavity **754** having a dimple or concavity **756** at the target location for the deflectable structure. In a third step, a deflectable structure **758** is formed in the appliance **752** by cutting the wall of the cavity **754** so as to form a cantilevered portion. Cutting of the appliance **752** can be performed using methods known to those of skill in the art, such as laser cutting or milling. Subsequently, the other components of the monitoring device can be coupled to the appliance **752** adjacent to or near the deflectable structure **758**.

Alternatively or in combination, a monitoring device can include one or more proximity sensors configured to generate sensor data when in proximity to a sensing target. Examples of proximity sensors suitable for use with the embodiments herein include capacitive sensors, resistive sensors, inductive sensors, eddy-current sensors, magnetic sensors, optical sensors, photoelectric sensors, ultrasonic sensors, Hall Effect sensors, infrared touch sensors, or surface acoustic wave (SAW) touch sensors. A proximity sensor can be activated when within a certain distance of the sensing target. The distance can be about less than 1 mm, or within a range from about 1 mm to about 50 mm. In some embodiments, a proximity sensor can be activated without direct contact between the sensor and the sensing target (e.g., the maximum sensing distance is greater than zero).

In some embodiments, a proximity sensor is activated when in direct contact with the sensing target (the sensing distance is zero), also known as a touch or tactile sensor. Examples of touch sensors include capacitive touch sensors, resistive touch sensors, inductive sensors, pressure sensors, and force sensors. In some embodiments, a touch sensor is activated only by direct contact between the sensor and the sensing target (e.g., the maximum sensing distance is zero). Some of the proximity sensor types described herein (e.g., capacitive sensors) may also be touch sensors, such that they are activated both by proximity to the sensing target as well as direct contact with the target.

One or more proximity sensors may be integrated in the intraoral appliance and used to detect whether the appliance is in proximity to one or more sensing targets. The sensing targets can be an intraoral tissue (e.g., the teeth, gingiva, palate, lips, tongue, cheeks, or a combination thereof). For example, proximity sensors can be positioned on the buccal and/or lingual surfaces of an appliance in order to detect appliance usage based on proximity to and/or direct contact with the patient's cheeks and/or tongue. As another example, one or more proximity sensors can be positioned in the appliance so as to detect appliance usage based on proximity to and/or direct contact with the enamel and/or gingiva. In some embodiments, multiple proximity sensors are positioned at different locations appliance so as to detect proximity to and/or direct contact with different portions of the intraoral cavity.

Alternatively or in combination, one or more sensing targets can be coupled to an intraoral tissue (e.g., integrated in an attachment device on a tooth), or can be some other component located in the intraoral cavity (e.g., a metallic filling). Alternatively or in combination, one or more proximity sensors can be located in the intraoral cavity (e.g., integrated in an attachment device on a tooth) and the corresponding sensing target(s) can be integrated in the intraoral appliance. Optionally, a proximity sensor integrated in a first appliance on a patient's upper or lower jaw can be used to detect a sensing target integrated in a second appliance on the opposing jaw or coupled to a portion of the opposing jaw (e.g., attached to a tooth), and thus detect proximity and/or direct contact between the patient's jaws.

The proximity sensor may be a capacitive sensor activated by charges on the sensing target. The capacitive sensor can be activated by charges associated with intraoral tissues or components such as the enamel, gingiva, oral mucosa, saliva, cheeks, lips, and/or tongue. For example, the capacitive sensor can be activated by charges (e.g., positive charges) associated with plaque and/or bacteria on the patient's teeth or other intraoral tissues. In such embodiments, the capacitive sensing data can be used to determine whether the appliance is being worn, and optionally the amount of plaque and/or bacteria on the teeth. As another example, the capacitive sensor can be activated by charges associated with the crowns of teeth, e.g., negative charges due to the presence of ionized carboxyl groups covalently bonded to sialic acid.

Various configurations of capacitive sensors can be used for the monitoring devices described herein. In some embodiments, the electrical charges on the surface of an intraoral tissue can interfere with the electric field of the capacitive sensor. Alternatively or in combination, the intraoral tissue can serve as the ground electrode of the capacitive sensor. Optionally, a shielding mechanism can be used to guide the electric field of the capacitive sensor in a certain location and/or direction for detecting contact with a particular tissue.

FIG. **8**A illustrates an intraoral appliance **800** including a capacitive sensor **802**, in accordance with embodiments. In some embodiments, the sensing target for the capacitive sensor **802** is the surface of the patient's tooth **804**, and the capacitive sensor **802** is coupled to the inner surface of a tooth receiving cavity **806** of an intraoral appliance so as to be adjacent to the tooth **804** when the appliance is worn. The capacitive sensor **802** can be activated by proximity to the tooth **804** and/or direct contact with the tooth **804**. In some embodiments, the capacitive sensor **802** is activated by negative charges on the enamel of the tooth crown. Alternatively or in combination, the capacitive sensor **802** can be activated by positive charges associated with plaque and/or bacteria on the tooth crown. Optionally, the capacitive sensor **802** can be activated by charges associated with minerals in the patient's saliva on the tooth surface, including but not limited to NH4+, Ca2+, PO43", HCO3−, and F.

FIG. **8**B illustrates a monitoring device **850** integrated into an intraoral appliance **852**, in accordance with embodiments. The monitoring device **850** can be located on any suitable portion of the appliance **852**, such as a buccal surface and/or lingual surface of the appliance **852** adjacent a tooth receiving cavity. The device **850** can include a capacitive sensor **854** (e.g., a capacitive touch sensor grid). The capacitive sensor **854** can be similar to the sensor **802** described with respect to FIG. **8**A, for example. In some embodiments, the capacitive sensor **854** is flexible and/or thermoformable so as to conform to the shape of the appliance **852**. The monitoring device **850** can also include a controller and power source **856** coupled to the capacitive sensor **854**, as well as any of the other components described herein with respect to the monitoring device **300** of FIG. **3**A. The controller and power source **856** can be used to power the capacitive sensor **854**, process proximity and/or contact data obtained by the capacitive sensor **854**, store the obtained data and/or processing results, and/or transmit the data and/or processing results to a remote device, for example.

Although FIG. **8**B illustrates a single monitoring device **850** with a single capacitive sensor **854**, other configurations can also be used. For example, in alternative embodiments, the monitoring device **850** can include multiple capacitive sensors located at different sites on the appliance **852** to detect proximity to and/or contact with multiple locations in the intraoral cavity. Optionally, multiple monitoring devices can be used, with each device being coupled to one or more respective capacitive sensors.

In some variations, the majority of (or all of) the intraoral appliance (shown in this example as an aligner, but as mentioned above, may be configured as any other intraoral appliance) may include a capacitive touch-sensor material. In FIG. **8**C, the aligner **890** includes a formed surface of capacitive touch-sensor material **893**. FIG. **8**D shows an enlarged view, showing a grid pattern of the capacitive touch sensor that may be distributed across the surface of the intraoral appliance of FIG. **8**C.

The capacitive touch sensor may relate intensity and location of touch information, and may derive force (force moment, and force direction) on the patient's teeth from the intraoral appliance. In some variations the appliance may include one or more processors for receiving touch information from the grid of capacitive sensors and may correlate this information with applied force on the teeth by the apparatus. For example, the capacitive touch data may be correlate to particular teeth using a digital model of the patient's teeth and/or aligner (as discussed above generally in FIG. **3**B).

FIG. **9** illustrates a monitoring system **900** for detecting proximity between the patient's jaws, in accordance with embodiments. The system **900** includes a first appliance **902** worn on the patient's upper teeth and a second appliance **904** worn on the patient's lower teeth. The system **900** also includes a monitoring device including a first sensing subunit **906** (e.g., a first plate) integrated with the first appliance **902**, a second sensing subunit **908** (e.g., a second plate) integrated with the second appliance **904**, and a controller **910** integrated with the first appliance **902** and coupled to the first sensing subunit **906**. Alternatively, the controller **910** can be integrated with the second appliance **904** and coupled

to the second sensing subunit **908**. In some embodiments, the monitoring device is used to measure the capacitance and/or charge between first sensing subunit **906** and the second sensing subunit **908**, and the measurement data can be used to determine whether the patient's jaws are in proximity to each other.

Alternatively or in combination, a monitoring device can include one or more vibration sensors configured to generate sensor data indicative of intraoral vibration patterns. Examples of vibration sensors include audio sensors (e.g., MEMS microphones), accelerometers, and piezoelectric sensors. The intraoral vibration patterns can be associated with one or more of: vibrations transferred to the patient's teeth via the patient's jaw bone, teeth grinding, speech, mastication, breathing, or snoring. In some embodiments, the intraoral vibration patterns originate from sounds received by the patient's ear drums. The intraoral vibration patterns may also originate from intraoral activities, such as teeth grinding, speech, mastication, breathing, snoring, etc. The sensor data generated by the vibration sensors can be processed to determine appliance usage and/or patient compliance. For instance, the monitoring device can include a processor that compares the detected intraoral vibration patterns to patient-specific intraoral vibration patterns to determine whether the appliance is being worn on a patient's teeth. In some embodiments, the processor is trained using previous data of patient-specific intraoral vibration patterns, and then determines whether the appliance is being worn by matching the measured patterns to the previous patterns. Alternatively or in combination, appliance usage can be determined by comparing the measured vibration patterns to vibration patterns obtained when the appliance is not being worn.

Alternatively or in combination, a monitoring device can include one or more optical sensors configured to detect appliance usage based on optical signals. For example, the optical sensors can be color sensors (e.g., mono-channel color sensors, multi-channel color sensors such as RGB sensors) configured to detect the colors of intraoral tissues. In some embodiments, one or more color sensors can be integrated into the intraoral appliance so as to be positioned adjacent to certain intraoral tissue (e.g., enamel, gingiva, cheeks, tongue, etc.) when the appliance is worn in the mouth. The device can determine whether the appliance is currently being worn based on whether the colors detected by the sensors match the expected colors for the tissues. In such embodiments, the monitoring device can include one or more light sources (e.g., LEDs) providing illumination for the color sensors.

As another example, the monitoring device can include one or more emitters (e.g., a LED) configured to generate optical signals and one or more optical sensors (e.g., a photodetector) configured to measure the optical signals. For example, an emitter can be positioned such that when the appliance is worn, the optical signal is reflected off of a surface (e.g., an intraoral tissue, a portion of an intraoral appliance) in order to reach the corresponding optical sensor. In some embodiments, when the appliance is not being worn, the optical signal is not reflected and does not reach the optical sensor. Accordingly, activation of the optical sensor can indicate that the appliance is currently being worn.

FIG. **10**A illustrates a monitoring device **1000** utilizing optical sensing, in accordance with embodiments. The device **1000** includes an emitter **1002** and an optical sensor **1004** integrated into an intraoral appliance **1006**. In the depicted embodiment, the emitter **1002** and sensor **1004** are both located on a buccal surface of the appliance **1006** such that optical signals from the emitter **1002** are reflected off the patient's cheek **1008** to reach the sensor **1004** when the appliance **1006** is worn. In alternative embodiments, the emitter **1002** and sensor **1004** can be located on a lingual surface of the appliance **1006** such that optical signals from emitter **1002** are reflected off the patient's tongue to reach the sensor **1004**.

FIG. **10**B illustrates a monitoring device **1020** using optical sensing, in accordance with embodiments. The device **1020** includes an emitter **1022** and an optical sensor **1024** integrated into a first intraoral appliance **1026** worn on a jaw of the patient (e.g., upper or lower jaw). The emitter **1022** and sensor **1024** can be arranged such that optical signals from the emitter **1022** reflect off of a second intraoral appliance **1028** worn on the patient's opposing jaw to reach the sensor **1024** when the first appliance **1026** and second appliance **1028** are being worn. Optionally, the second appliance **1028** can include a surface **1030** with optical properties selected to enhance and/or control reflection of the optical signal.

As another example, the emitter can be positioned such that when the appliance is worn, the optical signal is transmitted directly to the optical sensor without requiring any reflection off another surface. In some embodiments, when the appliance is not being worn, the optical signal does not reach the optical sensor. Accordingly, activation of the optical sensor can indicate that the appliance is currently being worn.

FIG. **10**C illustrates a monitoring device **1040** using optical sensing, in accordance with embodiments. The device **1040** includes an emitter **1042** integrated into a first intraoral appliance **1044** worn on a jaw of the patient (e.g., upper or lower jaw) and an optical sensor **1046** integrated into a second intraoral appliance **1048** worn on the patient's opposing jaw. The emitter **1042** and sensor **1046** can be arranged such that the optical signals from the emitter **1042** are transmitted directly to the sensor **1046** when the first appliance **1044** and second appliances **1048** are worn. In yet another example, the emitter can be positioned such that when the appliance is worn, the optical signal is occluded by an intraoral tissue (e.g., the patient's tongue). In some embodiments, when the appliance is not being worn, the optical signal is not occluded and reaches the optical sensor (e.g., via direct transmission or reflection from a surface). Accordingly, activation of the optical sensor can indicate that the appliance is not currently being worn. Optionally, the optical signal can be infrared light in order to be less obtrusive to the patient.

FIGS. **11**A and **11**B illustrate a monitoring device **1100** using optical sensing, in accordance with embodiments. The device **1100** includes an emitter **1102** and optical sensor **1104** integrated into an intraoral appliance **1106**. The emitter **1102** and sensor **1104** can be positioned on opposing sides of the lingual surface of the appliance **1106** such that optical signals are transmitted directly from the emitter **1102** to the sensor **1104** when the appliance **1106** is not being worn (FIG. HA). When the appliance **1106** is worn (FIG. **11**B), the patient's tongue **1108** can occlude the transmission of optical signals between the emitter **1102** and sensor **1104**.

FIGS. **11**C and **11**D illustrate a monitoring device **1120** using optical sensing, in accordance with embodiments. The device **1120** includes an emitter **1122** and optical sensor **1124** integrated into an intraoral appliance **1126**. The emitter **1122** and sensor **1124** can be positioned the same side of the lingual surface of the appliance **1126** such that optical signals generated by the emitter **1122** are reflected off the

opposing lingual surface **1128** to the sensor **1124** when the appliance **1126** is not being worn (FIG. **11**C). Optionally, the optical properties of the surface **1128** can be selected to enhance and/or control the reflection of the optical signal. When the appliance **1126** is worn (FIG. **11**D), the patient's tongue **1130** can occlude the transmission of optical signals between the emitter **1122** and sensor **1124**.

Additionally, the optical sensing-based monitoring devices described herein can also be configured to detect variations in the reflected and/or transmitted optical signal caused by breathing, mastication, or other patient movements. This information can be used to further improve the reliability and accuracy of optical-sensing based compliance monitoring.

Alternatively or in combination, the monitoring devices of the present disclosure can include one or more magnetic sensors configured to detect appliance usage based on changes to a magnetic field. Examples of magnetic sensors suitable for use with the embodiments herein include magnetometers, Hall Effect sensors, magnetic reed switches, and magnetoresistive sensors. In some embodiments, the characteristics of the magnetic field (e.g., magnitude, direction) vary based on whether the appliance is currently being worn, e.g., due to interference from intraoral tissues such as the teeth. Accordingly, the device can determine appliance usage by processing and analyzing the magnetic field detected by the magnetic sensors.

FIGS. **12**A and **12**B illustrate a monitoring device **1200** using magnetic sensing, in accordance with embodiments. The device **1200** includes a magnet **1202** and a sensing subunit **1204** coupled to an intraoral appliance **1206**. For example, the appliance **1206** can include a shell with tooth-receiving cavities and the magnet **1202** and sensing subunit **1204** can be coupled to the outer surface of a tooth receiving cavity. The sensing subunit **1204** includes one or more magnetic sensors **1208** (e.g., three magnetometers) configured to measure the characteristics (e.g., magnetic, direction) of the magnetic field generated by the magnet **1202**. In some embodiments, when the appliance **1206** is worn by the patient, the tooth **1210** received in the cavity interferes with the magnetic field (FIG. **12**B), such that the field characteristics differ from when the appliance is not being worn (FIG. **12**A). The monitoring device **1200** can include a processor (not shown) configured to determine whether the appliance is being worn based on the sensing data produced by the magnetic sensor(s) **1208**.

FIG. **12**C illustrates a monitoring device **1220** using magnetic sensing, in accordance with embodiments. The device **1220** includes a magnetic sensor **1222** (e.g., a Hall Effect sensor or a magnetoresistive sensor) integrated into a first intraoral appliance **1224** worn on a patient's jaw (e.g., upper or lower jaw). The magnetic sensor **1222** is used to detect a magnetic field generated by a magnet **1226** integrated into a second intraoral appliance **1228** worn on the opposing jaw. In some embodiments, the characteristics of the magnetic field vary based on whether the first appliance **1224** and second appliance **1228** are being worn on the patient's teeth. The monitoring device **1220** can include a processor (not shown) configured to determine whether the appliances are being worn based on the sensing data produced by the magnetic sensors **1222**.

A magnetic sensing-based monitoring device may include a ferromagnetic target (e.g., a metal plate) that alters the characteristics of the magnetic field when the appliance is worn. The ferromagnetic target can be integrated into an intraoral appliance or an attachment device mounted on a tooth, or can be an existing element in the intraoral cavity (e.g., a metal filling, implant, etc.). The monitoring device can detect whether the patient is using the appliance by sensing the characteristics of the magnetic field and detecting whether the ferromagnetic target is present.

FIG. **13**A illustrates a monitoring device **1300** using magnetic sensing, in accordance with embodiments. The monitoring device **1300** includes a sensing subunit **1302** integrated into a first intraoral appliance **1304** worn on a patient's jaw (e.g., upper or lower jaw) and a ferromagnetic target **1306** (e.g., a metal plate) integrated into a second intraoral appliance **1308** worn on the opposing jaw. The sensing subunit **1302** can include a magnet **1310** and a magnetic sensor **1312** that detect the magnetic field generated by the magnet **1310**. In some embodiments, when the first appliance **1304** and second appliance **1308** are worn by the patient, the presence of the ferromagnetic target **1306** alters the characteristics of the generated magnetic field. The monitoring device **1300** can include a processor (not shown) configured to determine whether the appliances are being worn based on the sensing data produced by the magnetic sensor **1312**.

FIG. **13**B illustrates a monitoring device **1320** using magnetic sensing, in accordance with embodiments. The monitoring device **1320** includes a sensing subunit **1322** integrated into an attachment device coupled to a tooth **1324** in a patient's jaw (e.g., upper or lower jaw) and a ferromagnetic target **1326** (e.g., a metal plate) integrated into an intraoral appliance **1328** worn on the opposing jaw. Optionally, a second intraoral appliance **1329** including a cavity shaped to receive the tooth **1324** and sensing subunit **1322** can also be worn. The sensing subunit **1322** can include a magnet **1330** and a magnetic sensor **1332** that detects the magnetic field generated by the magnet **1330**. In some embodiments, when the appliance **1328** is worn by the patient, the presence of the ferromagnetic target **1326** alters the characteristics of the generated magnetic field. The monitoring device **1320** can include a processor (not shown) configured to determine whether the appliance **1328** is being worn based on the sensing data produced by the magnetic sensor **1332**. Optionally, the processor and other components of the monitoring device **1320** can also be integrated into the attachment device. This implementation can reduce the costs of the device **1320**, since only the relatively low cost ferromagnetic target would be replaced with each new appliance. FIG. **13**C illustrates a monitoring device **1340** using magnetic sensing, in accordance with embodiments. The monitoring device **1340** includes a sensing subunit **1342** integrated into an attachment device coupled to a tooth **1344** in a patient's jaw (e.g., upper or lower jaw) and a ferromagnetic target **1346** (e.g., a metal plate) integrated into an intraoral appliance **1348** worn on the same jaw. The appliance **1348** can include a cavity shaped to receive the tooth **1344** and the sensing subunit **1342**. The sensing subunit **1342** can include a magnet and a magnetic sensor that detects the magnetic field generated by the magnet. In some embodiments, when the appliance **1348** is worn by the patient, the presence of the ferromagnetic target **1346** alters the characteristics of the generated magnetic field. The monitoring device **1340** can include a processor (not shown) configured to determine whether the appliance **1348** is being worn based on the sensing data produced by the magnetic sensor. Optionally, the processor and other components of the monitoring device **1340** can also be integrated into the attachment device, thus reducing cost when multiple appliances are used.

Alternatively or in combination, a monitoring device can use a magnet to directly activate a magnetic sensor. For

example, a magnet can be attached to an intraoral tissue, such as a tooth surface. The monitoring device can include a magnetic sensor (e.g., a magnetic reed sensor or switch) integrated into an intraoral appliance such that when the appliance is worn, the magnet activates the sensor. In alternative embodiments, the locations of the magnet and magnetic sensor can be switched, such that the magnetic sensor is attached to the intraoral tissue and the magnet is integrated into the appliance. Optionally, the magnet can be integrated into a first intraoral appliance worn on a patient's jaw (e.g., upper or lower jaw) and the magnetic sensor can be integrated into a second intraoral appliance worn on the opposing jaw, such that when both appliances are worn, the magnet activates the sensor.

Alternatively or in combination, a monitoring device can utilize two or more magnets that interact with each other (e.g., by exerting magnetic forces on each other), and a sensor that detects the interaction between the magnets. For example, the sensor can be a mechanical switch coupled to a magnet and actuated by magnetic forces exerted on the magnet. As another example, the sensor can be configured to detect the characteristics (e.g., magnitude, direction) of the magnetic force exerted on a magnet by the other magnets. The magnets and sensor can each be independently integrated in an appliance or coupled to a tooth or other intraoral tissue.

FIGS. **14**A and **14**B illustrate a monitoring device **1400** using a plurality of magnets, in accordance with embodiments. The device **1400** includes a sensing subunit **1402** integrated into a first intraoral appliance **1404** worn on a patient's jaw (e.g., upper or lower jaw). The sensing subunit includes a first magnet **1406** coupled to a force sensor **1408**. A second magnet **1410** is integrated into a second intraoral appliance **1412** worn on the opposing jaw. The force sensor **1408** can measure the magnetic force between the first magnet **1406** and the second magnet **1410**, which varies according to the distance between the magnets. The monitoring device **1400** can include a processor (not shown) configured to determine whether the appliances are being worn based on the measured force. In some embodiments, the magnetic force can also be used to generate power for monitoring device **1400**.

Alternatively or in combination, the monitoring devices of the present disclosure can include one or more force and/or pressure sensors for detecting appliance usage. For example, the monitoring device can include a force- and/or pressure-dependent resistive material, such as a film or sheet. The resistive material can be positioned between two thin electrodes in an intraoral appliance, and the resistance of the material may increase or decrease as force and/or pressure is exerted on the material, e.g., by the interaction between the teeth and the appliance. Other types of force and/or pressure sensors include strain gauges and piezocrystal sensors. In some embodiments, the monitoring device determines whether the patient is wearing the appliance based on the force and/or pressure measurements obtained by the force and/or pressure sensors. The measurement data may be indicative of the force and/or pressure between the appliance and an intraoral tissue, such as one or more of the patient's teeth. Optionally, the measurement data can be based on the force and/or pressure between the appliance and one or more attachment devices mounted on the patient's teeth. The monitoring device can process the data to determine whether the measured force and/or pressure are within the expected range corresponding to the patient wearing the appliance.

A monitoring device can include a single force and/or pressure sensor, or a plurality of force and/or pressure sensors. The sensors can be positioned at any location in the appliance, such on an inner surface, an outer surface, a buccal surface, a lingual surface, an occlusal surface, a mesial portion, a distal portion, a gingival portion, or a combination thereof. In some embodiments, the sensors are positioned to be near certain teeth when the appliance is worn. In embodiments where the appliance is an orthodontic appliance, the sensors can be positioned near teeth to be repositioned, e.g., at locations where the appliance is expected to exert force on the teeth. For example, if the appliance is shaped to engage an attachment device mounted on a tooth in order to exert force onto the tooth, a force and/or pressure sensor can be located at or near the location of engagement between the appliance and the attachment device.

FIG. **15** illustrates a monitoring device **1500** configured to measure force and/or pressure between an intraoral appliance **1502** and the patient's teeth, in accordance with embodiments. The device **1500** includes a plurality of pressure and/or force sensors **1504** (e.g., pressure-dependent resistive films) electrically coupled (e.g., via printed wires **1505** or other connecting elements) to a controller **1506**. The plurality of pressure and/or force sensors **1504** can be patterned on the inner surface of the appliance **1502** so as to generate sensor data indicative of the pressure and/or force between the appliance **1502** and the patient's teeth. In some embodiments, the appliance **1502** includes a plurality of teeth receiving cavities and the pressure and/or force sensors **1504** are located on the buccal, lingual, and/or occlusal surfaces of the cavities. The controller **1506** can include components (e.g., as previously described with respect to FIG. **3**) configured to process the sensor data to determine whether the appliance **1502** is being worn. Optionally, the controller **1506** can include a wireless antenna **1508** for transmitting the sensing data and/or processing results to a remote device, as described herein.

FIGS. **16**A and **16**B illustrate a monitoring device **1600** configured to measure force and/or pressure between an intraoral appliance **1602** and one or more attachment devices **1604** on a patient's teeth **1606**, in accordance with embodiments. The device **1600** includes a plurality of pressure and/or force sensors **1608** (e.g., pressure-dependent resistive films) electrically coupled to a controller **1610**. The plurality of pressure and/or force sensors **1608** can be patterned on the inner surface of the appliance **1602** so as to generate sensor data indicative of the pressure and/or force between the appliance **1602** and the attachment devices **1604** on the patient's teeth **1606**. In some embodiments, the appliance **1602** includes a plurality of teeth receiving cavities formed with one or more receptacles **1612** to receive the corresponding attachment devices **1604** on the patient's teeth, and the pressure and/or force sensors **1608** can be positioned the inner surface of one or more receptacles **1612**. The controller **1610** can include components (e.g., as previously described with respect to FIG. **3**A) configured to process the sensor data to determine whether the appliance **1602** is being worn.

Any of the apparatuses (e.g., monitoring devices) described herein may be configured to determine mechanical impedance of the teeth and/or intraoral appliance. For example, any of the apparatuses described herein may be configured to derive a mechanical impedance of a tooth, multiple or groups of teeth, and/or the appliance. Generally, mechanical impedance may be referred to as the resistance to motion given an applied force:

$$Z(w)=F(w)/v(w)$$

Where F=force, v=velocity and w=angular frequency.

FIG. **16**C illustrates one example of a section through an intraoral appliance **977** (showing in this example as an aligner) including a motion sensor **971** (such as an accelerometer) and one or more force sensors **969**, **969'**, **969"**. Alternatively or additionally, one or more of the motion sensor and force sensor(s) may be positioned directly on the teeth (including on an attachment adapted to secure the intraoral appliance to the teeth) and may communicate with a processor/analysis engine, battery, communications circuitry, etc. on the aligner.

The processor/analysis engine may then use the motion (e.g., acceleration) data over time, an example of which is shown in FIG. **16**D, and corresponding force data over time, an example of which is shown in FIG. **16**E, and may correlate this data to estimate mechanical impedance.

Alternatively of additionally, the system may estimate mechanical impedance based on underdamped second order system (e.g., as a logarithmic decrement of an underdamped second order system). In this case, the apparatus may be configured to measure the teeth (and/or appliance) response to a perturbing force, such as an input vibration or force applied to the teeth. For example, the apparatus may be configured to measure the free vibration response to a mechanical impulse input. The apparatus may then determine the peak-to-peak decay of the underdamped oscillation and the period of the system; from these values, the apparatus may then derive the damped natural frequency, the natural frequency, and a damping ratio. In a second order system, these values may define the impedance.

For linear systems, the apparatus may fit parameter of a parametric model of the mechanical impedance to a measured bode plot. For non-linear system, the apparatus may use generalized frequency response functions to analyze non-linear systems (e.g., forced vibrations response, sinusoidal frequency sweeps, etc., including machine learning).

For example, FIG. **16**F shows a side view of another example of an apparatus for measuring mechanical impedance of a tooth or teeth. In this example, a plurality of attachments **982** are used to secure an orthodontic appliance (e.g., aligner **989**) to the teeth. The aligner includes a processor **991**, wireless communication circuitry, and may include additional hardware, software and/or firmware for detecting sensor data to determine mechanical impedance of the teeth and/or aligner. The attachments may include one or more sensors, including motion (e.g., accelerometers) and/or force sensors; these one or more sensors may communicate directly (e.g., via electrical contact) with the processor **991** on the aligner.

In FIG. **16**F, this configuration may be used as described above, and/or may be used to determine a frequency response to an applied input signal. For example, any of these apparatuses may include an actuator to apply a vibration or force input to the teeth (e.g., a vibration motor, miniature piston, etc.). The force applied by the actuator may be measured or estimated and used in conjunction with the detected response (e.g., motion/acceleration data). Alternatively, the apparatus my take into account naturally occurring force inputs (e.g., masticatory forces), and may measure or estimate them; as mentioned above, using one or more force sensors. The force data as well as the response movement/acceleration data may be used to determine mechanical impedance.

The resulting mechanical impedance data may then be used to assess the health of the tooth movement.

Alternatively or in combination, the monitoring devices described herein can include one or more gas flow sensors configured to detect whether the intraoral appliance is being worn based on intraoral airflow. For instance, the gas flow sensor can be a hot-wire anemometer configured to measure airflow associated with breathing, mastication, speech, snoring, and the like. The embodiments herein can also incorporate microfluidic-based gas flow sensors, as desired. Optionally, gas flow sensors can also be used to measure airflow to determine whether the patient is experiencing a sleep apnea event. For example, the monitoring device can determine whether the measured airflow pattern is similar to airflow patterns that occur when the patient is experiencing sleep apnea. This approach can be used in embodiments where the intraoral appliance is a sleep apnea treatment appliance (e.g., a mandibular advancement device), for example. FIG. **17**A illustrates a monitoring device **1700** including a gas flow sensor **1702**, in accordance with embodiments. The sensor **1702** is integrated into an intraoral appliance **1704**. In some embodiments, the sensing portion of the sensor **1702** (e.g., a wire or conductor) extends from the appliance **1704** (e.g., a lingual surface) so as to be exposed to intraoral airflow. The sensing data obtained by the sensor **1702** can be processed and analyzed by other components of the monitoring device **1700** (e.g., controller **1706**) in order to determine appliance usage and/or whether patient is experiencing a sleep apnea event.

FIG. **17**B illustrates a monitoring device **1720** including a gas flow sensor **1722**, in accordance with embodiments. The device **1720** can be substantially similar to the device **1700**, except that the sensor **1722** extends across the opposite sides of the appliance **1724** such that the sensing portion is located near the middle of the intraoral airflow. This approach may provide improved sensing accuracy.

FIG. **17**C illustrates a monitoring device **1740** including a gas flow sensor **1742**, in accordance with embodiments. The device **1740** can be substantially similar to the device **1720**, except that the sensor **1742** extends only from one side of appliance **1744**. This approach may reduce patient discomfort.

Alternatively or in combination, a monitoring device can include one or more motion sensors configured to detect appliance usage based on movements of one or both of the patient's jaws. Examples of such motion sensors include accelerometers, gyroscopes, piezoelectric film vibration sensors, gravity sensors, and microwave emitters and receivers. The motion sensors can be integrated into an intraoral appliance worn on a patient's upper or lower jaw, or can be distributed across an appliance worn on the upper jaw and an appliance worn on the lower jaw. In some embodiments, the motion sensors are configured to generate data representative of the patient's jaw movement patterns, and the monitoring device processes and analyzes the movement patterns (e.g., using power spectrum and/or kinematic analysis) to determine whether the patterns indicate that the appliance(s) are being worn. Optionally, the monitoring device can distinguish jaw movement patterns associated with different oral activities (e.g., mastication, grinding, speech, etc.).

FIG. **18** illustrates a monitoring device **1800** using motion sensing, in accordance with embodiments. The device **1800** includes one or more motion sensors **1802** integrated into a first intraoral appliance **1804** worn on a patient's jaw (e.g., upper or lower jaw). In some embodiments, the motion sensors **1802** include one or more magnetometers that detect the magnetic field generated by a magnet **1806** integrated into a second intraoral appliance **1808** worn on the opposing jaw. For instance, the device **1800** can include two multi-

axis magnetometers used to obtain a six-axis measurement of the relative movements of the upper and lower jaws. In alternative embodiments, rather than using the magnet **1806**, the magnetometer(s) **1802** can be used to measure the angle of the patient's jaw relative to the earth's magnetic field, and the angle data can be used to determine whether the appliance is being worn. The motion data generated by the motion sensor(s) **1802** can be used to track jaw movement patterns in order to determine whether the appliances are currently being worn. Other types of motion sensors **1802** can also be used, such as accelerometers, gravity sensors, gyroscopes, or microwave emitters and receivers.

Alternatively or in combination, a monitoring device can include one or more temperature sensors, such as sensors detecting temperature based on infrared radiation, conductive thermistor-based sensors, and the like. The motion detector can determine appliance usage based on whether the measured temperature is within the range of body temperature, e.g., oral cavity temperature. Optionally, this determination can involve comparing the measured temperature with ambient temperature measurements obtained while the appliance is not being worn. In some embodiments, the temperature data is recorded as the raw temperature value. Alternatively, the temperature data can be recorded in binary form (e.g., whether the temperature is within the range of body temperature or not), for example, to save memory space.

Alternatively or in combination, a monitoring device can include one or more strain gauges (e.g., resistive or MEMS-based) to detect the stress and/or strain at one or more locations in the intraoral appliance. The monitoring device can determine whether the measured stress and/or strain values are within the expected ranges for appliance usage. The monitoring device can store the actual stress and/or strain values, or can store just binary data indicating whether or not the appliance is being worn.

Alternatively or in combination, a monitoring device can include one or more pH sensors configured to measure the pH values of fluids (e.g., saliva) in the surrounding environment. The monitoring device can determine whether the appliance is being worn based on whether the measured pH values are within the expected pH range for human saliva, for example.

Alternatively or in combination, a monitoring device can include one or more conductivity sensors configured to measure the conductivity of fluids (e.g., saliva) in the surrounding environment. The monitoring device can determine whether the appliance is being worn based on whether the measured conductivity is within the expected range for human saliva, for example. In some embodiments, the conductivity can be measured over a period of time. This approach can be used to prevent the monitoring device from being deceived by immersion into saliva-mimicking fluids, since the conductivity of human saliva may vary over time based on the body's physiological activities.

Alternatively or in combination, a monitoring device can include one or more humidity sensors configured to detect contact with intraoral fluids (e.g., saliva). The monitoring device can determine whether the appliance is being worn based on whether the measured humidity is within the expected humidity range for the intraoral cavity, for example.

The monitoring devices described herein may be used to measure health information for the patient alternatively to or in combination with detecting appliance usage. Such monitoring devices can include one or more physiological sensors, such as electrocardiography sensors, bio-impedance sensors, photoplethysmography sensors, galvanic skin response sensors, or combinations thereof. For example, a photoplethysmography sensor can be used to measure blood volume changes in the patient's intraoral tissues such as the cheeks or gingiva. As another example, a galvanic skin response sensor can be used to measure the conductivity of intraoral tissues, which may vary based on the minerals released onto the outer tissue surfaces from glands, for example. In some embodiments, the monitoring devices described herein are configured to differentiate between sensor data indicative of appliance usage and sensor data produced by other types of patient interactions with the appliance (e.g., the appliance being held in a patient's hand). Such differentiation can be accomplished by training the monitoring device to distinguish between data patterns indicative of appliance usage and data patterns produced by other interactions, e.g., based on a training data set prior to actual patient monitoring and/or data generated during monitoring. Alternatively or in combination, this differentiation can be performed by other devices besides the monitoring device, e.g., by an external processor performing post-processing on the data obtained by the monitoring device.

FIG. **19** illustrates a method **1900** for monitoring usage of an intraoral appliance, in accordance with embodiments. The method **1900** can be performed using any embodiment of the systems and devices described herein. In some embodiments, some or all of the steps are performed using a processor of a monitoring device operably coupled to an intraoral appliance. Alternatively or in combination, some or all of the steps can be performed by a processor of a device external to the patient's intraoral cavity, e.g., a separate computing device or system.

In step **1910**, sensor data is received from one or more sensors operably coupled to an intraoral appliance. The one or more sensors can include any of the sensor types described herein, including but not limited to touch or tactile sensors (e.g., capacitive, resistive), proximity sensors, audio sensors (e.g., microelectromechanical system (MEMS) microphones), color sensors (e.g., RGB color sensors), electromagnetic sensors (e.g., magnetic reed sensors, magnetometer), light sensors, force sensors (e.g., force-dependent resistive materials), pressure sensors, temperature sensors, motion sensors (e.g., accelerometers, gyroscopes), vibration sensors, piezoelectric sensors, strain gauges, pH sensors, conductivity sensors, gas flow sensors, gas detection sensors, humidity or moisture sensors, physiological sensors (e.g., electrocardiography sensors, bio-impedance sensors, photoplethysmography sensors, galvanic skin response sensors), or combinations thereof. The sensor(s) can be physically integrated with (e.g., coupled to, embedded in, formed with, etc.) the intraoral appliance, or can be positioned in the intraoral cavity (e.g., attached to a tooth) so as to interact with the intraoral appliance. The sensor data can be indicative of whether the appliance is currently being worn in the patient's mouth, in accordance with the embodiments described herein.

In step **1920**, the sensor data is processed to determine whether the appliance is being worn. For example, the processing step can involve determining whether the sensor data matches a pattern and/or falls within a range of values indicating that the appliance is being worn. Alternatively or in combination, the processing step can involve determine whether the sensor data is different from a pattern and/or lies outside a range of values indicating that the appliance is not being worn. Optionally, the processing step can involve associating the sensor data with a timestamp representing

when the data was obtained such that temporal appliance usage information can be determined. The processed sensor data can include appliance usage information indicating whether the appliance is currently being worn, the duration of appliance usage, and/or the date-time the appliance was in use. In some embodiments, step **1920** can alternatively or additionally involve processing the sensor data to determine patient health information, as discussed herein.

In step **1930**, the sensor data generated in step **1910** and/or processed sensor data generated in step **1920** is optionally transmitted to a remote device. The remote device can be a mobile device (e.g., smartphone), personal computer, laptop, tablet, wearable device, cloud computing server, or the like. Step **1930** can be performed using wireless or wired communication methods, as desired. Step **1930** can be performed automatically (e.g., at predetermined time intervals) or in response to instructions received from the remote device (e.g., a command to transmit the sensor data and/or appliance usage).

The monitoring devices described herein can be physically integrated into an intraoral appliance in a variety of ways. In some embodiments, the monitoring device is integrated into the appliance during or after fabrication of the appliance. For example, the monitoring device can be attached to an appliance using adhesives, fasteners, a latching mechanism, or a combination thereof after the appliance has been fabricated. Optionally, the appliance can be formed with complementary features or structures (e.g., recesses, receptacles, guides, apertures, etc.) shaped to receive and accommodate the monitoring device or components thereof.

In some embodiments, a monitoring device is coupled to the appliance as a prefabricated unit during or after fabrication of the appliance, such as by being inserted and sealed into a receptacle in the appliance, attached to an appliance (e.g., by a latching mechanism, adhesive, fastener). Alternatively, the monitoring device can be assembled in situ on the appliance during or after appliance fabrication. For instance, in embodiments where the appliance is manufactured by direct fabrication (e.g., 3D printing), the monitoring device can be printed simultaneously with the appliance, inserted into the appliance during fabrication, or after assembled the appliance has been fabricated. Optionally, some of the monitoring device components may be prefabricated and other components may be assembled in situ. It shall be appreciated that the various fabrication methods described herein can be combined in various ways in order to produce an appliance with integrated monitoring device components.

FIGS. **20**A through **20**D illustrate a method for fabricating an intraoral appliance with an integrated monitoring device, in accordance with embodiments. The method can be applied to any embodiment of the monitoring devices and appliances described herein, and can be used in combination with any of the other fabrication methods described herein. In a first step (FIGS. **20**A (top view) and **20**B (side view)), a prefabricated monitoring device **2000** is coupled to a positive model **2002** of a patient's dentition. The monitoring device **2000** can be attached using an adhesive and/or a mechanical fastener, for example. Optionally, the monitoring device **2000** can be hermetically sealed prior to being attached to the model **2002**. In a second step (FIG. **20**C), a material is formed (e.g., thermoformed) over the monitoring device **2000** and model **2002** so as to produce an appliance shell **2004**. In a third step (FIG. **20**D), the mold **2002** is removed, resulting in an appliance shell **2004** with an embedded monitoring device **2000**. Optionally, the monitoring device **2000** can be encapsulated using a biocompatible adhesive **2006** (e.g., a UV-curable glue), a layer of material, or other sealing element.

FIGS. **21**A through **21**C illustrate a method for fabricating an intraoral appliance with an integrated monitoring device, in accordance with embodiments. The method can be applied to any embodiment of the monitoring devices and appliances described herein, and can be used in combination with any of the other fabrication methods described herein. In a first step (FIG. **21**A), an appliance **2100** is formed (e.g., thermoformed) over a positive model **2102** of a patient's dentition. In a second step (FIG. **21**B), a prefabricated monitoring device **2104** is attached to the appliance **2100**, e.g., using an adhesive layer **2106** and/or fastener, and a thermoplastic material **2108** is attached to the outer surface of the monitoring device **2104**. In a third step (FIG. **21**C), the thermoplastic material **2108** is thermoformed so as to form a cover encapsulating the monitoring device **2104** into the appliance **2100**. The positive model **2102** can be removed e.g., before or after the third step.

Alternatively or in combination, the method can involve forming a positive geometry corresponding to the geometry of the monitoring device **2104** on the positive model **2102** (e.g., by 3D printing, CNC milling, etc.), such that the appliance **2100** is thermoformed with a receptacle for the monitoring device **2104**. The monitoring device **2104** can then be placed and sealed into the receptacle.

Alternatively or in combination, an intraoral appliance with an integrated monitoring device can be produced by fabricating the appliance (e.g., by indirect or direct fabrication), then attaching a prefabricated monitoring device to the fabricated appliance, e.g., using adhesives, fasteners, a latching mechanism, etc. Optionally, the monitoring device can be hermetically sealed (e.g., by molding) before being attached to the appliance.

Alternatively or in combination, an intraoral appliance with an integrated monitoring device can be fabricated by coupling flexible and/or printed components of a monitoring device onto the appliance during or after forming the appliance. The components can be coupled in various ways, such as thermoforming, laminating, adhesives, coating, and so on.

Alternatively or in combination, an intraoral appliance with an integrated monitoring device can be fabricated by 3D printing a base for the monitoring device, then building up the electronic components for the monitoring device onto the base. In some embodiments, the base is shaped to conform to the geometry of the tooth receiving cavity and/or target tooth where the monitoring device will be located. The 3D printed portions of the monitoring device can be shaped to lie flush with the surface of the appliance to facilitate integration of the monitoring device with the appliance. Alternatively or in combination, an intraoral appliance with an integrated monitoring device can be fabricated by etching the surface of the appliance (e.g., using a masking process) and then depositing conductive inks, stretchable materials, etc. onto the etched portions to build up the electronic components of the monitoring device (e.g., wires, connections, electrodes, etc.) on the appliance.

FIG. **22** is a simplified block diagram of a data processing system **2200** that may be used in executing methods and processes described herein. The data processing system **2200** typically includes at least one processor **2202** that communicates with one or more peripheral devices via bus subsystem **2204**. These peripheral devices typically include a storage subsystem **2206** (memory subsystem **2208** and file storage subsystem **2214**), a set of user interface input and output devices **2218**, and an interface to outside networks **2216**. This interface is shown schematically as "Network

Interface" block **2216**, and is coupled to corresponding interface devices in other data processing systems via communication network interface **2224**. Data processing system **2200** can include, for example, one or more computers, such as a personal computer, workstation, mainframe, laptop, and the like.

The user interface input devices **2218** are not limited to any particular device, and can typically include, for example, a keyboard, pointing device, mouse, scanner, interactive displays, touchpad, joysticks, etc. Similarly, various user interface output devices can be employed in a system of the invention, and can include, for example, one or more of a printer, display (e.g., visual, non-visual) system/subsystem, controller, projection device, audio output, and the like.

Storage subsystem **2206** maintains the basic required programming, including computer readable media having instructions (e.g., operating instructions, etc.), and data constructs. The program modules discussed herein are typically stored in storage subsystem **2206**. Storage subsystem **2206** typically includes memory subsystem **2208** and file storage subsystem **2214**. Memory subsystem **2208** typically includes a number of memories (e.g., RAM **2210**, ROM **2212**, etc.) including computer readable memory for storage of fixed instructions, instructions and data during program execution, basic input/output system, etc. File storage subsystem **2214** provides persistent (non-volatile) storage for program and data files, and can include one or more removable or fixed drives or media, hard disk, floppy disk, CD-ROM, DVD, optical drives, and the like. One or more of the storage systems, drives, etc. may be located at a remote location, such coupled via a server on a network or via the internet/World Wide Web. In this context, the term "bus subsystem" is used generically so as to include any mechanism for letting the various components and subsystems communicate with each other as intended and can include a variety of suitable components/systems that would be known or recognized as suitable for use therein. It will be recognized that various components of the system can be, but need not necessarily be at the same physical location, but could be connected via various local-area or wide-area network media, transmission systems, etc.

Scanner **2220** includes any means for obtaining a digital representation (e.g., images, surface topography data, etc.) of a patient's teeth (e.g., by scanning physical models of the teeth such as casts **2221**, by scanning impressions taken of the teeth, or by directly scanning the intraoral cavity), which can be obtained either from the patient or from treating professional, such as an orthodontist, and includes means of providing the digital representation to data processing system **2200** for further processing. Scanner **2220** may be located at a location remote with respect to other components of the system and can communicate image data and/or information to data processing system **2200**, for example, via a network interface **2224**. Fabrication system **2222** fabricates appliances **2223** based on a treatment plan, including data set information received from data processing system **2200**. Fabrication machine **2222** can, for example, be located at a remote location and receive data set information from data processing system **2200** via network interface **2224**.

EXAMPLES

Any of the monitoring apparatuses described herein, which may be referred to as ECI's and/or data loggers, may be wirelessly connected or connected by a wire ("wire-connected"), or both. For example, when a wired communication with a monitoring apparatus is used, the apparatus may be connected via one or more pins/contacts on an outer surface of the apparatus, either when worn and/or attached to an orthodontic appliance (such an aligner) or after removing from the appliance. Data communication with the monitoring device may be enabled via a reader having one or more mechanical probes that may act as electrical contacts with electrodes/pads in or on the monitoring apparatus. For example, the probes may be located in a case or housing for holding the appliance, which can then separately communicate with a hand-held electronics device such as a smartphone, via Bluetooth. Thus, for example, the monitoring apparatus may connect via a wired connection to a case, and the case may then transmit the data (either raw or unmodified data or modified, analyzed and/or formatted data) to a separate handheld device, such as a smartphone.

The monitoring apparatus may include one or more (e.g., a plurality of) connection pads which may be encapsulated in a self-healing polymer that opens upon insertion of probes and retract to original shape upon removal of the probes providing water sealing. Alternatively or additionally, the connection pads may be exposed out of ECI but grounded/disabled when aligner and/or ECI is in a mouth or in contact with water/saliva. Upon being energized by reader probes, the ECI pads may switch to communication mode.

Any of the monitoring apparatuses described herein may also be configured to be stored in an inactive configuration, in which some or all of the internal contacts are disabled (e.g., disabling the connection between the battery and the processor or other components by a physical break, gap, pin, barrier, etc. that may be removed (e.g., connecting/reconnecting the power source to the circuitry) manually or automatically prior to use, including prior to removing from a case or packaging, prior inserting the device into a subject's mouth, prior to connecting the monitoring apparatus to a dental appliance, etc. For example, the apparatus may include mechanical activation of the monitoring apparatus via removing a tiny pin.

In any of the ECI apparatuses described herein, a mechanical activation/deactivation connection may be used, as described above. Any of these ECIs (e.g., "data loggers") may be configured for wired (direct mechanical/electrical) connection to a reader. The ECI may include internal circuitry (e.g., an ASIC, and/or any of the circuitry described above) one or more sensors, memory, etc.) and a battery that are enclosed or at least partially enclosed, in a housing. A plurality of data pads may be present outside of this housing, so that an electrical connection can be made to the internal circuitry. As mentioned, the entire device, including the pads, may be covered by a protective elastomer (e.g., a self-healing elastomer). This elastomer may be any appropriate material, typically a biocompatible, electrically insulative material that is self-healing or self-sealing after being pierced.

The monitoring apparatus (ECI) operation may be initiated by the user, e.g., patient, dental technician, etc., including mechanically activating using a pin, rod, or the like. For example, prior to use of the ECI, the user may remove an activation rod. When in place, the rod may breaks connection between the battery and the circuit, ensuring zero off current to the ECI circuitry (e.g., ASIC). When the activation rod is removed, the battery may be connected to the ECI ASIC, initiating the data logging sequence. During operation, the ECI ASIC may acquire raw sensor data, as described above. For example, the apparatus may acquire raw capacitance and temperature data at 10 minute intervals, and store each sample in memory (e.g., EEPPROM). The

sampling intervals may be counted as individual events, translated into desired time interval display format by the intermediate interface device. Thus, any of the apparatuses described herein may have reduced size/footprint, by eliminating the need for a real time clock and related EEPROM memory. The ECI may include a housing (packaging) consists of a rigid material holding the internal circuitry and battery part of the assembly, and may also include an elastomeric coating over the housing and the data pads. Data may be retrieved from the devices even when the battery is completely depleted, such as if the patient fails to deliver the ECI back to the dental professional (e.g., orthodontist) within the small battery's lifetime. As an alternatively variation, the operation of mechanical activating mechanism may be reversed from which is described above, so that the ECI apparatus is activated by inserting, rather than removing, an activating rod, pin, etc.

In other variations, a similar mechanical control or switch may be provided by including a spring contact that is held open by a magnetic field, rather than using an activating rod/pin. In this example, the apparatus may be activated by removing it from a package; when in the packaging a permanent magnet (e.g., built into the packaging/housing) may hold a spring contact away from the circuitry, disconnecting the battery from the rest of the circuitry (e.g., ASIC), breaking the connection between the battery and the rest of the circuit, also ensuring zero off-current to the circuitry. Removing the device from the packaging may allow the spring contact to close, activating the data logging sequence, so that the apparatus can acquire data (e.g., capacitance and/or temperature data at a continuous 10 min intervals, and store the data in the memory for later read-out from the data pads).

Although mechanical activation may be used in the context of an apparatus having data contact pads for making a wired connection, any of the apparatuses, including those configured to operate wirelessly, may be configured to mechanical activation.

In addition, any of the ECI apparatuses described herein may be configured to be inserted/connected to an orthodontic appliance (such as an aligner) by the user or a dental professional. For example, FIG. **24** illustrates an example of an ECI apparatus **2500** that can be inserted onto an aligner **2502**. In this case, the ECI apparatus shown is configured for a wired connection (via the pads **2507**), however wireless ECI apparatuses may be similarly configured for connection onto an aligner **2502**. The aligner may therefore include on or more retaining features, as described above, including pins **2503**, as shown in FIG. **24**. In some variations, the retaining feature on the aligner may make the mechanical connection between the battery and the circuitry. In some variations, the pins may connect to one or more sensors on the aligner. The pins may penetrate an over molding material, which may be present on any of the variations (including the wireless and wired connection devices).

As mentioned, data may be retrieved from any of these apparatuses using an intermediate interface device such as a housing or case. When the ECI apparatus is configured to make a wired connection, the intermediate device may be fitted with sharp probes to penetrate the over mold elastomer and make electrical contact with any data pads on the PCB. The intermediate device may then retrieve, process, calibrate, and encrypt the data as needed, then transmit to a handheld device such as a smart phone, e.g., via Bluetooth. The data can then be displayed on the smartphone or other display medium using custom applications software, which the patient and/or orthodontist may be able to download for execution on the smartphone or other mobile device

In any of the variations described herein, the same pins can be used for connecting and as a conductivity sensing probe for detection of saliva medium.

Although FIGS. **24** and **25** illustrate the connective pads as covered by the over molding material, in some variations the connection pads may be exposed. For example, the connection pads may be exposed out of ECI but grounded/disabled when Aligner and ECI are in the user's mouth or in contact with water/saliva. Upon being energized by reader probes the ECI pads may switch to a communication mode during which data may be transferred.

Any of the devices described herein may also or alternatively be connected by a wireless connection. FIG. **25** illustrates one example of an ECI prototype constructed as described herein, including one or more temperature and capacitive sensors. In this example, the ECI **2603** is connected to an aligner (shell **2601**). In FIG. **25**, the prototype is relatively large; it may be much smaller in practice, for example, by reducing the size of the processor, sensors and other internal components. For example the prototype shown in FIG. **25** may include a Texas Instruments FDC1004 capacitive-to-digital converter (with a footprint of 10×8 mm); this footprint may be significantly reduced in size, e.g., using QFN rather than SOP package. The data logger may include an on-chip temperature sensing data logger (e.g., an NFC type, such as a THOR data logger). The exemplary prototype shown in FIG. **25** may be wirelessly connected to an intermediate device, and therefore a handheld electronics device such as a smartphone.

In any of the apparatuses described herein, the ECI may include a capacitive sensor, which may be configured to accurately determine when the apparatus is present on a tooth/teeth, rather than outside of the mouth, even when submerged in water or other material that may mimic saliva. For example, a prototype such as that shown in FIG. **25** was used as a proof-of-concept to show that capacitance data may be used to determine when an oral appliance was present in the mouth of the user, rather than just submerged (or outside of the mouth). In FIG. **26**, capacitance (and temperature) was recorded using the device of FIG. **25** every 5 minutes for fifty-four hours, while subjecting the device to different conditions and looking at the capacitance. As shown, the apparatus is able to distinguish between being worn ("touched" **2703**) and submerged in saline ("submerged **2705**). As discussed above, the capacitive sensor configuration may be configured to be mutual capacitance measurements or self-capacitance measurements (see, e.g., FIG. **27**, left and right, respectively). The capacitance sensor may saturate, however using the proper frequency range and/or ground size may permit the capacitance detector circuitry to distinguish between saturation due to being in the mouth versus being submerged in a fluid.

For example, FIGS. **28** and **29**A-**29**B illustrate one example of an ECI that is configured to distinguish between being worn and other conditions that may otherwise provide capacitive signals similar to those provided when in a fluid solution but not worn. In FIG. **28**, the ECI **2901** is shown worn on a subject's teeth **2905** as part of an aligner **2903**. The aligner in this case is shown having two sensing electrodes (A and B). The first electrode (A) is configured to be in close proximity to a crown of a tooth when the aligner is worn. The second (B) is configured to be 'far' proximity to the crown of the tooth when worn. FIG. **29**A shows a schematic of the ECI, including the A and B sensing electrodes. FIG. **29**B illustrates how capacitive signals from

these sensing electrodes may be used to distinguish when the device is actually being worn in the mouth, versus when the ECI is out of the mouth or submerged in a saliva-like environment. The logic used to distinguish these conditions may be used to determine a more accurate 'worn' or 'not worn' metric that may be output by the ECI or by software/firmware/hardware in communication with the ECI (e.g., from an application software running on a smartphone, etc.). In FIG. **29**B, the signal from the A contact sensor is shown aligned with the signal from the B contact sensor. In this case, three conditions are shown, as well as rough signal amplitudes. When the ECI is out of the mouth, the signal on the A sensing electrode is low; similarly, the signal on the B sensing electrode is low. When the device is worn as shown in FIG. **28**, the signal on the A sensing electrode is high (greater than a threshold amount, ACR), and the signal on the B sensing electrode is higher than when out of the mouth, but lower than a threshold (BCR). When the device is submerged in water, however, the signals on both the A sensing electrode and B sensing electrode are high, above the ACR and BCR thresholds. Thus, the apparatus may distinguish between in, out and submerged cases, by rejecting readings when A>ACR and B>BCR as false positives. When both A and B are below their thresholds the device is out of the mouth, and when the A signal is above threshold but the B signal is below threshold, the device may be determined to be in the users mouth.

FIGS. **30**A-**30**C illustrate another example of a method for discriminating between these conditions (in mouth, out of the mouth, and submerged). In this example, the apparatus may again include a pair of sensing electrodes "A" **3001** and "B" **3003**, however they are positioned on either side of a tooth on the aligner, and a complex impedance measure, Z, may be taken between them. This "guard" electrode configuration may use short detection pulses to distinguish between false positive readings. This signal may be used in conjunction with proximity sensing to increase the specificity of the detection. The placement of the sensing electrodes may be optimized to minimize the likelihood of false negatives (e.g., shorting by saliva). For example, the electrodes may be placed at the ends of the arch, as shown in FIG. **30**C. In this configuration, the complex impedance, Z, may be 0 when the electrodes are placed in water, rather than against the teeth. As shown in FIG. **30**D, when the proximity sensor shows that the real capacitance is low, the apparatus is out of the mouth; when the proximity sensor shown a high or moderately high capacitance, and the complex impedance measurement is low, the apparatus is likely submerged in a solution (e.g., of water), and thus these measurements can be rejected as false positives.

When the ECI apparatuses described herein wirelessly communicate data (e.g., data output) to a handheld device, such as a smartphone, an intermediate apparatus such as a case or container, which may hold either just the ECI module or apparatus, and/or it may hold the ECI apparatus and an appliance (such as an aligner) to which the ECI apparatus is attached. FIGS. **31**A-**31**D illustrate one example of a container that acts as an intermediary device, receiving near field communication signals from the ECI module, and transmitting these signals to a smartphone or other handheld device by Bluetooth. Because of the relatively small size of the ECI apparatus, any antenna component used for wirelessly transmitting signals must also be small; this may pose a problem for directly communicating with a smartphone or other apparatus, as it may be difficult to align the antenna of the ECI apparatus with the antenna of a smartphone or other hand-held electronics device. In this case, a case or holder such as that shown and described in FIGS. **31**A-**31**D may be used to both securely hold the appliance and ECI and to transfer any data recorded by the ECI from the ECI to the case and then on to a mobile devices such as a smartphone, transferring the data first as NFC from the ECI to the intermediate case, then as BLE from the intermediate case to the smartphone. The case or other intermediate device may hold the ECI in a predetermined position, including in alignment with one or more antenna. Note that data may be transmitted between the ECI, case and mobile device in an ongoing manner or sequentially (e.g., delaying transmission between the case and the mobile device); delaying transmission may be helpful for determining when the receiving device (e.g., mobile device) is ready to receive the data, and the intermediate device may hold onto the data until the receiving device indicates it is ready. In FIG. **31**A, the aligner **3103** fits into the case **3101** so that the ECI **3105** is aligned with a reader antenna **3107** for reliable transmission via NFC. The intermediate device, such as a case, may be passive (e.g., transferring on the data) or it may be active, e.g., modifying, filtering, annotating, analyzing, averaging, etc. the data.

In general, when the ECI apparatus is configure to wirelessly transfer data, the near-field communication antenna (NFC antenna) may be a flat antenna, such as a trace antenna, and/or it may be a coil antenna. FIGS. **34**A and **34**B illustrate a flat (trace) antenna and the user of such an antenna to transfer data from an appliance incorporating an ECI data recorder. In FIG. **34**A, the trace antenna is formed on a substrate (e.g., PCB substrate) and forms a loop **3404** (or multiple loops) and connects to antenna circuitry **3402**. The trace antenna produces a field that is substantially transverse to the plane of the substrate. In FIG. **34**B the aligner **3407** may be aligned with the attached ECI **3406** adjacent to the antenna loop **3404**. In FIG. **34**B, two separate NFC antennas are shown in alternative views of the ECI. In the upper portion, the ECI antenna is a coil antenna **3411**; the antenna in the lower ECI is a trace antenna **3413**.

FIG. **35**A illustrates an enlarged view of a generic coil antenna (e.g., a coil wound around a ferrite rod) that may be used for NFC; FIG. **35**B shows an example of an ECI and reader, both of which use coil antenna. In FIG. **35**B, the ECI antenna **3505** includes a ferrite core, as does the coil antenna on the reader **3507**. Any of the readers (including intermediate devices such as holders, etc.) may use any appropriate antenna, including coil antennas and trace antennas. In FIGS. **34**B and **35**B the readers may be used while the appliance (shown as an aligner) is attached to the ECI.

As mentioned, there is typically a size discrepancy between the NFC antenna in the ECI apparatus and the antenna in a phone (e.g., smartphone) and other handheld electronics device. Thus, the energy transfer efficiency between a relatively large NFC loop antenna such as may be present in a smartphone and the much smaller ECI loop antenna (e.g., typically only as large as a tooth width) maybe extremely low, including less than 1% due to the antenna size mismatch. Thus, it may be beneficial to use an energy coupler, including as part of an intermediate device (e.g., booster, etc.) which may be configured as a case, mount, holder, or otherwise. FIGS. **36**A-**36**C illustrates a passive NFC energy coupler that may be used. In FIG. **36**A, the circuit diagram illustrates the use of a NFC coupler **3603** between an ECI apparatus NFC antenna **3601** and the antenna of a smartphone **3605**. Any appropriate antenna may be used as part of the NFC coupler, including a toroid ferrite coupler **3607** having an air gap **3609** in the ferrite core, as shown in FIG. **36**B; the ECI (or the NFC antenna of the ECI)

may be placed within the air gap. FIG. **36**C illustrate the overall system coupling prediction using an NFC coupler.

FIGS. **37**A and **37**B illustrate the use of an NFC to NFC coupler prototype that may be used as an intermediate device. As shown in FIG. **37**A, an ECI apparatus (shown schematically as having a coil antenna) **3701** is positioned within range of an NFC antenna **3703**, shown in this example a coil antenna having an air gap with a ferrite coil (e.g., a 6 mm loop antenna). The signal received from the NFC antenna is then retransmitted using second antenna **3705** of the NFC coupler to transmit by NFC to a phone **3707** placed in range to the second, larger antenna **3711**. As will be described in FIG. **39**, below, the first antenna may be matched to the ECI antenna and the second antenna may be matched to the antenna in the phone. In addition, the NFC coupler apparatus may provide alignment between the phone antenna and the second antenna **3711** and the ECI antenna and the first antenna, and may hold the phone and/or the ECI securely in the position. The prototype shown in **37**B also includes indicates that additional circuitry (e.g. amplifiers, filters, etc.) **3413** may be used to modify the data signal received from the ECI before it is passed on to the phone. In general, any signal processing may be performed at this stage, or the signal may simply be passed. In one example a 3 dB attenuator is positioned between the first antenna **3703** and the second antenna **2711**.

FIG. **38**A shows a prototype of the NFC coupler similar to that schematically illustrated in FIGS. **37**A and **37**B. In FIG. **38**, an aligner having an ECI is placed on the NFC coupler so that the ECI antenna is aligned with the NFC antenna of the NFC coupler (not visible in FIG. **38**). A phone receiving the signal passed on the NFC coupler is positioned over the phone antenna region of the NFC coupler. FIG. **39** shows a schematic circuit diagram of the apparatus of FIG. **38**. In this example, a pair of shunts (C**1**, C**2**) and a series of capacitors (C**3**, C**4**) transform the inductive impedance of both of the NFC coupler coils to a resistive impedance at the center of the circuit, greatly eliminating the impedance mismatch losses in the system.

In addition to transfer of data from the ECI by an intermediate device such as a case or other relay apparatus, in some variations, the ECI may be configured (in some variations in conjunction with other system components, including hardware, software and/or firmware) for direct transfer of data from the ECI to a mobile, handheld device such as a smartphone (e.g., NFC to NFC communication or alternatively, NFC to Bluetooth or other wireless protocol). For example, FIG. **32** illustrates a first example of a system for transmitting data directly from an ECI to a mobile handheld device. In FIG. **32**, a marker or guide (e.g., sticker, decal, phone cover/case, sleeve, etc.) may indicate a position **3201** or location for placement of an ECI or aligner/appliance and ECI on the phone **3203** to reliably transfer data (e.g., via NFC) from the ECI apparatus to the smartphone. In FIG. **32** the guide markings are part of a decal **3205**.

In some variations the application software on the mobile device (e.g., phone) may also provide guidance for alignment of the ECI, including indicating on the screen where to place the ECI apparatus and/or appliance and ECI. The software may also indicate by visual, audio, or both when the ECI is in good alignment, allowing the user to correct/adjust the alignment. For example, FIG. **33**A illustrates another example of direct communication between the ECI and a smartphone. In this example, the application software for data transfer from the ECI to the phone **3301** indicates by displaying an alignment zone **3303** on the screen of the phone where to position the ECI. In FIGS. **33**B-**33**C, an additional holder or interface **3305** to hold the ECI securely on the phone is shown, and FIG. **33**C illustrates the use of the holder **3305** to hold the ECI on the optimal target for transfer of data. In this example, the data receiver is a mobile/handheld device (e.g., smartphone) that may help align the ECI for transfer of the data, as illustrated in FIGS. **33**B and **33**C. In these illustrations, the screen of the mobile device shows a target that may indicate the position for placement of the ECI relative to the mobile device for best communication between the ECI (e.g., an antenna such as a NFC antenna) in the ECI and an antenna in the smartphone (such as an NFC antenna). In this example, the target (which is drawn as a bullseye, but may be any marker or indicator **3303**) is shown on the screen and the user may manually align the target-matching portion of the 'clip' **3305** for positioning opposite of the target **3303**. This allows an ECI attached or on the clip (see top of FIG. **33**C) to be held optimal alignment. The mobile device may determine the location of the target **3303** based on one or more criterion, including the hardware (e.g., mobile device) configuration, model, etc., such as the known location of the antenna within the device of a particular make and model that may be determined by the application method (e.g., software) operating the mobile device (shown in FIGS. **33**B and **33**C as a "Find my Antenna" application method). In some variations, the application method may calculate the target **3303** position based on feedback between the receiver (mobile device) antenna and the ECI device.

Other alignment mechanisms and techniques may also be used to align and/or hold the ECI apparatus in communication with the phone for wireless transfer of data from the ECI to the smartphone. For example, in some variations a magnetic force may be used to attract the ECI to a target location. Other mechanical alignment mechanisms may be used to secure the ECI apparatus in alignment with the antenna region of the phone. For example, a phone case or cover (e.g., sleeve) may be used that includes a depression/holding region for aligning the ECI with the antenna of the phone. In some variations the mount/cover/sleeve may include one or more pins to hold the ECI device in position.

As mentioned above, any of the apparatuses described herein (including systems) may communicate with a hand-held electronics device such a smartphone via control software running on the smartphone (or other hand-held electronics). This application software may interface with the electronic compliance indicator and may enhance wireless communications between the electronic compliance indicator (ECI) using NFC and BLE protocols. The application can complement or supplement the ECI by incorporating mechanisms for encouraging compliance (e.g., incentives, gamification, etc.), and may also provide data processing, visualization, and/or sharing of the data from the ECI. An ECI apparatus may generally record sensor data from patients wearing an orthodontic appliance such as an aligner. The data may be stored in physical memory on the ECI and retrieved by another device, e.g., using NFC and BLE technologies as described above (or NFC and NFC), so that the smartphone may retrieve the data. The smartphone application (app) may consist of several components, some of which are described in FIGS. **41**, **42** and **43**. For example, in FIG. **41** schematically illustrates an NFC/BLE communication control. In addition, FIGS. **44**, **45** and **46** schematically illustrate operational states of the ECI device, as well as control of communication between the device and a remote processor (e.g., smartphone).

Handling wireless communications and data transfer with the ECI may be coordinated by the application software. The

application can post events to may include other elements of the application, for example: a home screen or user interface (UI) manager that can respond to an event (e.g., a "CARD ACTIVATED" event, as shown in FIGS. **41-42**, when the ECI is first turned on and receives confirmation back) to provide a notification to the user or launch a welcome or instructions screen; and/or a data analysis manager that can respond to data transfer (e.g., an "UPDLOAD SUCCESS" in FIG. **43**) events. The application software may generate displays, including graphs, and may look for patterns in the data to improve accuracy/specificity/sensitivity of the compliance data. It may post events such as "LOW COMPLIANCE," "HIGH COMPLIANCE," etc. See, e.g., FIG. **40** (center), showing a user interface for an exemplary application software including a smart compliance monitoring.

Some components of the application software may not exist or run locally (on the smart phone), but could run on a remote server. For example, data history and data analysis can be hosted on a remote server. In this case, the app may also have a component to upload and download data to and from this server.

The application software may help the user to manage the operation of the appliance and/or the ECI on the appliance, including starting/stopping timing/sensing/recording, and/or transferring data to/from the ECI, activating/de-activating the ECI, etc. Events that are posted from normal use can be used to complement or supplement the ECI system from the application software. For example, the application software may manage notifications or reminders related to the appliance and/or ECI and/or can respond to an event (e.g., a "CARD ACTIVATED" event) by initiating a timer, which can post another event when it expires. One possible response to this event may be to push a notification to the user to remind the user to connect the ECI device to the phone. This notification can be an alarm, email, text message, etc. This service could also respond to a "LOW COMPLIANCE" by notifying other connected users (e.g., parents or doctors).

The application software may also coordinate an incentives system which responds to specific events related to wearing/using the orthodontic appliances described herein. For example, and application software may include or operate a game with virtual rewards (e.g., coins, trophies, RPG elements "level up"/upgrade your smile, points, etc.), monetary rewards (e.g., discounts, coupons, gift cards, etc.), and/or motivational messages. For example when the "CARD ACTIVATED" event occurs by outputting→"You've activated your first aligner! You're on your way to a happy healthy smile." After a DOWNLOADED event, a specific message may be displayed or transmitted to the user depending on the data, e.g., "great job wearing your aligners this week," "just 2 more aligners to go!" or the like.

FIG. **42** illustrates a potential flow diagram for an application software as described herein for controlling NFC, including detecting the ECI. FIG. **43** illustrates a potential control diagram for an application software controlling data processing.

An example of the operational states for an ECI device is shown in FIG. **44**, illustrating the interaction of the communication between the device (e.g., an appliance with monitoring sensors, shown as the ECI) and a remote processor such as a smartphone. In FIG. **44**, the device transitions between various power down and logging states in which NFC is active or removed. Other possible states may include an active mode in which logging is complete, and active mode with live measurements.

FIG. **45** illustrates the management of communications by the receiving processor, such as a smartphone, on which control logic (e.g., software) is operating; FIG. **45** illustrates one example of how the phone/receiver app may behave and interact. For example, in FIG. **45**, the smartphone may toggle between waiting for BLE pairing, waiting for NFC and attempting to download, or waiting for NFC and attempting to download, depending on the communication status between the smartphone and the orthodontic appliance with the sensor (e.g., ECI). A communications manager (e.g., the software/firmware on the smartphone) can be responsible for managing BLE or NFC only communications. It can post events so that external components or managers can act on them (e.g., a Data Manager can act on a "Data Downloaded" event, and another component, not illustrated here, could act on a "Data Uploaded" event). Similarly, FIG. **46** illustrates an example of a process chart for a data processing component/manager.

The present disclosure provides improved systems, methods, and apparatus for monitoring physiological characteristics of a patient's intraoral cavity and airway. Appliances are provided with sensors configured to send, and receive signals, and a processor records those signals to memory. The signals can be analyzed to determine physiological characteristics of the patient. The intraoral appliance may also be a treatment appliance, treating an underlying condition and monitoring physiological characteristics to track the efficacy of that treatment.

As used herein the term "and/or" is used as a functional word to indicate that two words or expressions are to be taken together or individually. For example, A and/or B encompasses A alone, B alone, and A and B together.

The present disclosure provides orthodontic systems, apparatus, and related methods for monitoring physiological characteristics of a patient, as well as for assessing treatment parameters such as appliance efficacy.

In one aspect, a method for monitoring a physiological characteristic of a patient is provided. The method comprises positioning an intraoral appliance in the patient's intraoral cavity. The intraoral appliance is shaped to receive the patient's teeth and comprises a plurality of electrodes each positioned to make electrical contact with a different part of the patient's intraoral cavity. The method further comprises measuring an electrical impedance using the plurality of electrodes and determining the physiological characteristic based on the electrical impedance. In some embodiments, the measuring and determining steps are performed by one or more processors disposed on or within the intraoral appliance.

In some cases, the physiological characteristic comprises one or more of: airway diameter, airway volume, airway resistance, lung fluid level, soft tissue crowding, breathing rate, muscle activity, ionic composition of saliva, or ionic composition of oral mucosa. The physiological characteristic can be related to a sleep disorder of the patient, and the sleep disorder can comprise one or more of sleep apnea, snoring, or bruxism. In some embodiments, the sleep disorder comprises sleep apnea and the intraoral appliance is configured to treat the sleep apnea.

In some cases, the efficacy of the intraoral appliance in treating the sleep apnea is determined based on the determined physiological characteristic. The one or more processors may be configured to make this determination.

In some cases, the electrical impedance comprises a near-field impedance and the physiological characteristic comprises one or more of soft tissue crowding, ionic composition of saliva, or ionic composition of oral mucosa. In

some cases, the electrical impedance comprises a far-field impedance and the physiological characteristic comprises one or more of lung fluid level or airway length.

In another aspect, a method is provided for monitoring a characteristic of a patient's intraoral cavity or airway. The method comprises positioning an intraoral appliance in the patient's intraoral cavity. The intraoral appliance is shaped to receive the patient's teeth and includes a transmitter and a receiver. The method further comprises causing the transmitter to emit a signal within the patient's intraoral cavity, measuring a signal returning from the patient's intraoral cavity or airway in response to the emitted signal using the receiver, and determining the characteristic of the patient's intraoral cavity or airway based on the measured signal. In some embodiments, the measuring and determining steps are performed by one or more processors disposed on or within the intraoral appliance.

Although reference is made to an appliance comprising a polymeric shell appliance, the embodiments disclosed herein are well suited for use with many appliances that receive teeth, for example appliances without one or more of polymers or shells. The appliance can be fabricated with one or more of many materials such as metal, glass, reinforced fibers, carbon fiber, composites, reinforced composites, aluminum, biological materials, and combinations thereof for example. The appliance can be shaped in many ways, such as with thermoforming or direct fabrication (e.g., 3D printing, additive manufacturing), for example. Alternatively or in combination, the appliance can be fabricated with machining such as an appliance fabricated from a block of material with computer numeric control machining.

FIG. **1** illustrates an impedance model of a patient's airway **4700**. The airway **4700** comprises an intraoral cavity bounded on the maxillary side by the hard palate **101** and soft palate **4702**, bounded on the mandibular side by the tongue **4703** and maxilla, and bounded on the lateral sides by the cheeks. As the patient breathes, airflow **4704** passes through the mouth and sinuses and travels down the upper airway **4705** toward the lungs. Obstruction of these passageways can cause sleep apnea, and may be due to conditions such as soft tissue crowding or narrowing of parts of the upper airway, for example. A patient's airway may be modeled as a substantially cylindrical passageway between the intraoral cavity and the lungs. In some embodiments, the patient's trachea is approximated as a cylinder **4710** of length L with an outer shell **4712** of soft tissue and a hollow core **4714** filled with air. The conductivity of soft tissue is much higher than that of air; accordingly, the impedance of the airway can be approximated as the resistance of a hollow cylinder with outer radius R (the radius of the tissue surrounding the airway in the neck), inner radius r (the airway radius), and length L (the airway length). The resistivity ρ can be approximated as that of the airway tissue, and the impedance **4720** can be estimated by the equation $Z=\rho L/A$, where A is the total conductive area—in this case the outer cylinder area minus the inner (substantially non-conductive) cylinder area. This gives a total impedance **4720** of about $Z=\rho L/\pi(R^2-r^2)$. More generally, in some embodiments the impedance will be proportional to the resistivity of soft tissue and the length of the airway, while being inversely proportional to the cross-sectional area of the conductive tissue of the airway. For electrical signals traveling between the intraoral cavity and the lower airway, the upper airway may thus be treated as a circuit element characterized by an impedance Z similar to this equation. The impedance Z depends on the inner radius r—in particular, as r increases, Z increases, and as r decreases, Z decreases. Thus, by measuring the variation of impedance over time, it is possible to determine changes in airway width from corresponding changes in impedance.

Variation of airway width can be particularly important in patients with sleep apnea and related disorders, as sleep disturbance and snoring can result from an insufficiently wide airway. FIG. **48**A illustrates the variation of patient airway width for different Mallampati scores. A patient with a Mallampati score of I has a large, unobstructed airway with hard palate **201**, soft palate **202**, uvula **203**, and pillars **204** visible; a patient with a Mallampati score of II has a smaller airway with pillars no longer visible; a patient with a Mallampati score of III has only the hard and soft palate and base of the uvula visible; and a patient with a Mallampati score of IV has only the hard palate visible. Higher Mallampati score may be associated with greater likelihood of sleep apnea, with class III and class IV especially likely to exhibit sleep apnea.

As can be seen from FIG. **48**A, in some embodiments, the unobstructed cross-sectional area of the patient's airway decreases with increasing Mallampati score, such that a higher Mallampati score is associated with smaller airway area. As discussed with respect to FIG. **1**, smaller airway cross section may correspond to lower electrical impedance. FIG. **48**B illustrates the correlation between Mallampati score and airway impedance, plotting Mallampati score against inverse impedance 1/Z. Because increasing 1/Z corresponds to increasing Mallampati score, a measurement of electrical impedance along the airway can be used to determine Mallampati score. An appliance capable of measuring impedance in continuously or continually when worn by a patient allows for continuous monitoring of airway width, for example while a patient is sleeping. Data generated by such measurements can be used in the diagnosis and treatment of sleep apnea.

In some embodiments, the present disclosure provides systems, methods, and devices for measuring characteristics of the patient's intraoral cavity and/or airway based on electrical impedance. Examples of characteristics that may be measured include airway diameter, airway volume, airway resistance, lung fluid level, soft tissue crowding, breathing rate, muscle activity, the ionic composition of saliva, or the ionic composition of oral mucosa. Measurements can be made based on near field impedance, far field impedance, or combinations thereof. As used herein, near field may refer to measurements of impedance along or around the shortest path between two electrodes. For electrodes within the mouth, for example, a near field impedance may be that portion of the impedance that depends on the resistivity and shape of the tissues of the mouth, or a portion thereof. Near field may be used to measure characteristics such as muscle activity, the ionic composition of saliva, or the ionic composition of oral mucosa, for example. As used herein far field may refer to impedance measurements depending on the characteristics away from the shortest path between two electrodes. For electrodes within the mouth, for example, a far field impedance measurement may measure the effects on impedance due to changes in shape or resistivity of tissues in the upper or lower airway, or in the lungs. Far field may be used to measure characteristics such as airway diameter, airway volume, airway resistance, lung fluid level, soft tissue crowding, breathing rate, for example. Impedance may be measured between two or more points in the patient's intraoral cavity. The location of the measurement points in the intraoral cavity may be varied as desired. For example electrodes may be placed on opposite sides of mouth, at points on the upper and lower jaws, at points on

the same jaw (upper or lower), or contacting tissues such as cheeks, palate, gingiva, teeth. The electrodes may be configured to contact points in the mouth at a separation of about 1 mm, 2 mm, 4 mm, 10 mm, 20 mm 40 mm, 100 mm, or 200 mm, for example. Shorter separations may be more sensitive to near-field measurements, while longer separations may be more sensitive to far-field measurements, for example.

FIG. **49**A illustrates a patient's intraoral cavity **4900** in conjunction with points from which sensors such as electrodes can be placed to measure characteristics of the intraoral cavity and airway. A pair of contact points **4910** and **4920** are located in the intraoral cavity **4900**. One contact point is located along the gingiva of the upper arch **4912**, on the lingual side. Although illustrated on the right lingual side near the back of the mouth in FIG. **49**A, the location of contact point **4910** may be varied; for example, in some embodiments contact point **4910** is on the buccal side of the upper arch, or on the left side of the mouth, or at any point along the upper or lower arch, including optionally on the same arch as contact point **4920**. Contact point **4910** may also be at a point along a cheek of the patient. Similarly, although contact point **4920** is illustrated along the gingiva of the lower arch **4922**, on the buccal side opposite the tongue **4924**, the contact point **4920** may also be varied in the same manner as contact point **4910**, such that any valid contact point for one may be the contact point for the other, including without limitation contact points on the lingual and/or buccal sides of one or more arches, along the hard palate, along the cheek of the patient, or at any other point within the mouth. The position of each contact point pair affects the sensitivities of measurements performed with that pair of points.

For example, referring to the specific choice of contact points illustrated in FIG. **49**A, because the airway of the patient stretches away from the intraoral cavity, the airway passageway may be substantially in the far field with respect to electrical impedance. Accordingly, in some embodiments, it is preferred to keep near field signal as small as reasonably possible so as to maximize the relative size of far-field signal. Thus, in some embodiments points **4910** and **4920** are preferably located far apart in the intraoral cavity, as well as near the back of the mouth; in FIG. **49**A, this is illustrated with point **4910** located near the upper molars on one side of the mouth while point **4920** is located near the lower molars on the other side of the mouth.

Electrical currents can be induced to flow between contact points, such as points **4910** and **4920** by applying an appropriate voltage, and these currents can be measured to determine electrical impedance. The voltage may be an alternating voltage to induce an alternating current, for example. Current pulses comprising many frequencies may be induced to allow the measurement of impedance at each of multiple different frequencies simultaneously and/or sequentially. In some embodiments, although a portion of the electrical impedance between contact points such as points **4910** and **4920** is due to near field impedance, a portion may also be due to far field impedance, including airway impedance. Contact points that are farther apart may tend to be more sensitive to the far field relative to the near field, while points that are closer together may be more sensitive to the near field relative to the far field. This principle may also be applied for measurements performed with sensors other than electrodes, such as transmitter-receiver pairs as disclosed herein: close-by transmitter-receiver pairs may be more sensitive to the near field while separated transmitter-receiver pairs may be more sensitive to the far field.

Measurements such as impedance measurements can be filtered to isolate that portion of the measured quantity and variation thereof that is due to the variable to be measured and variation thereof. For example, current pulses may be induced and thereafter received by applying a voltage pulse between points **4910** and **4920**, then later measuring a return signal. The signal may be tracked as a function of time. The time it takes for a pulse to travel to the lungs and back can correspond to the round trip distance divided by the speed of electrical current, which can be a significant fraction of the speed of light. With sufficient time resolution, such as nanosecond resolution, it is possible to determine how far a pulse has traveled based on its round trip time; by measuring signal strength at the delay time corresponding to a round trip through the airway, a direct measurement of the far field impedance of the airway can be obtained. In some cases, the relative phase of current pulses may be measured to determine the far field impedance, as phase can be affected by time delay.

A portion of the near-field impedance will also depend on the airway width, as the available paths between points **4910** and **4920** along the surface of the intraoral cavity include paths that travel near the airway opening. If the airway opening is smaller, shorter paths are available, which lowers impedance in the near field. Impedance can also be measured repeatedly over longer time periods to allow better filtering of noise sources and isolation of the effect of airway width variation on impedance. For example, as a patient breathes the airway changes shape, so variations in airway impedance correlated with patient respiration can be used to isolate impedance variation caused by airway width variation. Similarly, for other measurements, changes in impedance or other measured properties can be correlated to that particular measurement; for example, changes in ionic saliva content can be determined from near field impedance changes, and physical properties of a tooth or tooth-PDL system can be determined from measured acceleration in response to forces applied by an actuator. It will be appreciated that points **4910** and **4920** may be varied throughout the intraoral cavity to change the measurement sensitivity and specificity; for example, to determine appropriate positions for measurement sensor location, a plurality of point pairs can be tested in the mouth of a patient, and the point pair with highest signal-to-noise ratio for that measurement can be selected for use in that patient or other patients. Other measurements, such as transmitter-receiver measurements, may follow the same pattern for their respective measurement variables and can likewise be placed at variable positions throughout the intraoral cavity to change their sensitivities and specificities for their respective measurements.

FIG. **49**B illustrates alternative positions in which sensors such as electrodes can be placed to measure characteristics of the intraoral cavity and airway. In sensor configuration **350**, a first sensor **360** is located along the maxillary palate near the soft tissue **362** and uvula **364**. A second sensor is located along the mandibular palate between the tongue **374** and the mandibular teeth (not shown). In this embodiment, the sensors are located on opposite sides of the airway, such that the airway lies along the shortest path between the two sensors. In the case that sensors **360** and **370** are electrodes, for example, the impedance between the two sensors will

depend in part on the width of the airway, with lower impedance corresponding to a narrower (and thus more occluded) airway.

In some embodiments, the impedance measurements described herein are performed using electrical sensors coupled to an oral appliance. Examples of such oral appliances include dental retainers, aligners, and mouthguards. In some embodiments, the oral appliance is used to treat sleep apnea, such as a mandibular advancement device. In some embodiments, a mandibular advancement device is worn by the patient in the order to displace the lower jaw anteriorly relative to the upper jaw to treat sleep apnea. The mandibular advancement device can be a patient-removable appliance (e.g., the patient can place and remove the appliance without aid from a practitioner) that is inserted into the patient's mouth prior to sleep so as to maintain the lower jaw in an advanced position during sleep, and is removed from the patient's mouth while the patient is awake to allow for normal activity. In alternative embodiments, the intraoral appliance can include one or more components that are not patient-removable (e.g., attachments or brackets affixed to one or more teeth, anchoring devices positioned in the tissue of the intraoral cavity such as bone). In some embodiments, the intraoral appliance includes at least one appliance shell having a plurality of cavities shaped to receive teeth of a single jaw of the patient.

Any number of sensors can be used, such as electrodes, acoustic transducers, and accelerometers. The sensors can be located in any portion of the appliance, such as adjoining the lingual or buccal sides of the gingiva, adjoining the dental surfaces of teeth, adjoining the cheeks, or along the roof or bottom of the mouth. The sensors can be coupled to the appliance in various ways, such as by adhesives, fasteners, embedding within the appliance material, or insertion into cavities formed in the appliance. The measurements described herein may be obtained using sensors coupled to a single appliance worn on the patient's upper or lower jaw. Alternatively, sensors may be distributed between a pair of appliances worn on the upper and lower jaws, respectively. In some embodiments, the oral appliance(s) and sensors are contained entirely within the patient's intraoral cavity when worn. For example, in some embodiments the appliances can be operated without connection to external power sources, control electronics, or external sensor points. The appliance electronics can comprise a power source such as a battery to store energy for continuous operation. The battery can be rechargeable, for example, by plugging the appliance into a recharger when not in use or by recharging using wireless power transfer—in the latter case the appliance can comprise appropriate antenna(s) to receive transmitted power from a base station. The oral appliance(s) and sensors may be patient-removable, allowing for measurements to be performed without the need for sensor apparatus being implanted within patient tissue or affixed to the mouth or teeth of the patient.

FIGS. **50**A-**50**G illustrate a variety of oral appliances comprising electrical sensors such as electrodes positioned in various configurations to allow measurement of impedance due to airway width variation, as well as other physiological characteristics of a patient, including characteristics of a patient's intraoral cavity or airway. Electrodes can be used to monitor resistance changes within the oral cavity, as in patients with abnormal soft tissue crowding, the conductive paths between electrodes may be shorter. Because stretching of soft tissue during changes in mandibular position can alter the conductive pathways within the intraoral cavity, impedance measurements can be used to detect whether the patient has an open or closed mouth, for example, or whether the mandible is retruded or protruded. While well-separated electrodes may be desirable for increased sensitivity to far-field impedance variation in some embodiments, closely-positioned electrodes can also be used for monitoring of physiological characteristics of the patient. For example, the electrical potential generated by muscle cells during activation may be monitored by appropriately-positioned electrodes. Among the physiological activities that may be detected by monitoring muscle movements in this way are temporomandibular joint articulation, increased masseter activity during parafunctional activity (such as grinding or clenching), and upper airway relaxation due, for example, to upper airway collapse or decrease in activity, which are associated with hypopnea or apnea.

Although electrodes are used herein as exemplary sensors in the illustrated orthodontic appliances, sensors other than electrodes may be used for sensing physiological properties of a patient's intraoral cavity and/or airway, by measuring properties other than impedance, such as piezoelectric pulses, acoustic waves, and acceleration. In some embodiments, the physiological properties can be measured by transmitting a signal into the patient's intraoral cavity and/or airway, and measuring the response signal returning from the intraoral cavity and/or airway. The characteristics of the response signal (e.g., amplitude, frequency, etc.) may vary based on the properties of the patient's intraoral cavity and/or airway.

In such embodiments, the electrodes marked in FIGS. **50**A-**50**G may be replaced with appropriate pairs of sensors, acting as transmitter and receiver respectively. For example, transducers can be used for generating and receiving acoustic waves (e.g., ultrasound), and phase and magnitude information of the response signal can be used to image the oral cavity or upper airway. An actuator (such as a piston, vibration motor, or piezo-electric crystal) and an accelerometer may replace respective electrodes. An impulse signal can be sent to a tooth via the actuator and a response signal can be recorded with an accelerometer in contact with the tooth. This response can be correlated with different phases of tooth movement, such as movement due to orthodontic forces applied by an appliance shell, because the stiffness of the tooth-PDL structure will vary with different stages of tooth movement. The response may also be correlated with tooth, root, and/or PDL health, even if no tooth movement is being induced by the appliance shell. Actuators may also be placed to produce forces that can result in electrical currents (for example, via the piezoelectric effect) in structures of the mouth. For example, compression of bone and collagen results in movement of electrons in the crystal lattice, and application of force on the teeth can result in a short piezoelectric effect on the alveolar bone which may be detected by appropriate receiving sensors such as electrodes. Electrical signals produced by alveolar and periodontal ligaments (PDL) when under load can stimulate changes in bone metabolism—electrical sensors such as electrodes may also be used to detect these electrical signals, for example, by monitoring changes in voltage. These examples of measurements can be combined to perform simultaneous or staggered measurements, including combinations with electrode measurements of impedance and other electrical properties. In some embodiments, multiple measurements are performed and their results compared or combined using sensor fusion techniques, thereby improving resolution of each measured quantity.

FIG. **50**A illustrates an appliance **5000** wearable over a patient's teeth comprising sensors positioned at diametri-

cally opposed points in a patient's intraoral cavity **5002**. The appliance **5000** comprises a shell **5004** with teeth-receiving cavities configured to receive the teeth of a patient when worn in the patient's mouth **5002**. The appliance shell comprises protruding portions **405** configured to extend along the cheeks of the patient when the appliance is worn. The protruding portions can be configured to engage protruding portions of an appliance worn on the opposite jaw to provide forces for mandibular advancement, for example. The appliance further comprises a plurality of sensors such as electrodes, with a first electrode **5006** disposed on a protrusion and positioned to come into contact with the right cheek of the patient when worn. The second electrode **5008** is disposed on the shell and positioned to come into contact with the left cheek of the patient when worn. The illustration of the patient's intraoral cavity **5002** shows the points which are contacted by each electrode when the appliance is worn. The electrodes are positioned to contact substantially opposite points near the rear part of the patient's intraoral cavity, providing electrical contact points in areas similar to those illustrated in FIG. **49**A. As a result, the electrode positions are well-suited to measure far-field impedance, for example. In alternative embodiments, the appliance **5000** can also be used to perform other types of measurements, as discussed herein.

The appliance **5000** further comprises appropriate wiring disposed within shell **5004**, providing electrical contact between sensors, illustrated as electrodes **5006** and **5008** and a processor disposed within the shell. The processor is further connected to a power source such as a battery that provides electrical power. The processor is configured to control voltage values at each electrode to allow the generation of current pulses, alternating current, and/or direct current flow. The circuitry connecting the processor to the electrodes further comprises a current measuring unit, such as an ammeter, so that impedance may be calculated by the processor by a measurement of voltage and current as a function of time. The processor comprises a clock for time measurement, and is connected to memory to allow the recording of sensor data, as well as to contain instructions to be executed by the processor. Optionally, the processor is further connected to a wireless radio transmitter, allowing recorded data to be transmitted to an external receiver for processing by an external computing device. The external receiver may be, for example, a mobile device or WiFi antenna, and the receiver and transmitter may communicate using an appropriate communications protocol such as Bluetooth, cellular, WiFi, or other protocols. FIG. **50**C provides more detail of the internal structure of an appliance such as that illustrated in FIG. **50**A.

FIG. **50**B illustrates an appliance **5010** wearable over a patient's teeth **5012** comprising sensors positioned close proximity to each other. The appliance comprises an appliance shell **5014** and the sensors comprise a plurality of electrodes **5016** in close proximity to each other. Sensors such as electrodes may be in close proximity when, for example, the shortest distance between them is small compared to the width of the airway. Sensors in close proximity may be more sensitive to near-field measurements then more distantly-separated sensors. The electrodes are configured to contact a plurality of nearby points **5018** within the patient's intraoral cavity when the appliance is worn by the patient. In this illustration, the contact points are located on the buccal gingiva; in other embodiments, the contact points may be on the cheeks or lips, or on the lingual side touching the tongue and lingual gingiva. The contact points may also touch the teeth on the lingual and/or buccal side (including one sensor on each side of a tooth). The nearby electrodes are sensitive to near-field variations in impedance; accordingly, they may be used to measure properties such as intraoral impedance caused by changes in saliva quantity or contents. For example, if a patient's mouth becomes more dry, the amount of saliva between electrodes **5016** and around points **5018** will diminish, which can increase the impedance as saliva is not available to carry electrical current. Similarly, changes in contents of saliva, such as pH shifts, can be measured, for example, by their resultant changes in saliva conductivity. These properties may also be measured in combination with far field measurements by providing an appliance with both near-field and far-field electrode configurations, such as by adding near-field electrodes such as illustrated in FIG. **50**B to an appliance with far-field electrodes such as FIG. **50**A. The respective electrode pairs can be separately connected to and controlled by the processor, or may be controlled by separate processors.

FIG. **50**C illustrates an interior of an appliance **430** with an embedded measurement system comprising control electronics and sensors. The appliance **430** comprises oral appliance layers **431** and **432**, which surround control electronics **433**. Control electronics **433** include a power source such as a battery, drive electronics to generate electrical voltage pulses for inducing electrical current, and measurement electronics for measuring electrical current and voltage as a function of time, then recording the resulting data to memory. The control electronics **433** comprise a processor and memory, the memory containing instructions that, when executed, cause the processor to control the drive and measurement electronics to produce electrical pulses and perform measurements such as impedance measurements, according to the methods as disclosed herein. The control electronics are electrically coupled with wires **434** to one or more sensors such as electrodes **436** and **438**. The wires **434** are preferably disposed within the layers of the appliance shell, but may include open connections between shells (see FIG. **50**E, for example). The electrodes are disposed to contact the surfaces of the patient's intraoral cavity when the appliance is worn. The electrodes perform both current generation and electrical measurement, under the direction of the control electronics. The basic schematic layout shown in FIG. **50**C may be used, with appropriate variations in positions of electrodes, driver electronics, and measurement electronics, in any of a variety of appliance shell configurations, including configurations as shown in FIGS. **50**A, **50**B, and **50**D-**50**G.

FIG. **50**D illustrates examples of alternative, extended positions for sensors such as electrodes and drive electronics. The configurations of appliance shells and electrodes as shown in FIGS. **50**A, **50**B, and **50**E-**50**G may be varied to place drive and measurement electronics and electrodes in alternative positions, as needed. For example, FIG. **50**D illustrates an appliance **440** with certain variations of this type. The drive electronics **441** of appliance **440** are located outside of the shell, allowing an extra-oral measurement device to be connected. For example, the lead wires **442** may be connected to an external device while the patient sleeps, allowing the appliance to record impedance and other data without needing an internal power source. Electrodes may be located in a tab **443** extending from the gingival edge of the appliance, or even in a flexible, wired connection, such as electrode **444**. Electrode **444** can be attached to an appliance or dental attachment on the opposite side of the patient's mouth as appliance **440**, for example. This allows a greater flexibility in electrode configuration for performing a variety of measurements within the intraoral cavity of the

patient. The tab **443** may be a preloaded tab with an electrode on an inner surface to allow contact to be maintained. As shown in the cross-section view **445** of a portion of appliance **440**, the tab **443** is configured to elastically bend between a first configuration **446** away from the dentition and gums and a second configuration **447** pressing an electrode against the gums of the patient when the appliance is worn. The tab **443** is configured to apply a preloaded inwards force to keep the tab in the second configuration **447** to maintain electrical contact between the electrode and the gums of the patient. Such an electrode position is useful, for example, in measurements of impedance and other electrical characteristics of the periodontal ligaments (PDL).

FIG. **50**E illustrates an appliance comprising an upper shell to fit a patient's upper teeth and a lower shell to fit the patient's lower teeth, each shell comprising an sensor such as an electrode. The appliance **450** comprises an upper shell **451** comprising an upper electrode **453**, and a lower shell **452** comprising a lower electrode **454**. Each electrode is located on a protrusion of a mandibular advancement device for the treatment of a condition such as OSA, and the protrusions are configured to come into contact when each appliance is worn on the patient's respective upper and lower teeth to advance the mandible, for example. The interface **455** between protrusions can comprise conductive surfaces on each protrusion, such that the protrusions form an electrical contact, allowing each electrode to be controlled by a processor in one of the two shells. It will be understood that the electrodes **453** and **454** do not have to be located on the protrusions, but may instead be located elsewhere on their respective shells (for example, on opposite sides of the patient's mouth). In such a case, wires may be provided within the shells to connect the electrodes, the processor, and the interface **455** together.

FIG. **50**F illustrates an appliance configured to measure physiological properties using electrodes on opposite sides of the appliance shell. The appliance **460** comprises an appliance shell **462** with two electrodes **464** and **466** on opposite sides of the shell. An impedance **468** may be measured between the electrodes, as illustrated in FIG. **50**F in the form of a partial circuit diagram. The appliance shell **462** comprises control electronics including a processor and memory, for example as illustrated in FIG. **50**C. The processor determines the impedance Z between electrodes, which is then used to determine one or more physiological characteristics of the patient; for example, airway cross-sectional area.

FIG. **50**G illustrates an appliance **470** with respective sensors on upper and lower shells, in which the electronic systems of the sensors are inductively coupled. The appliance **470** comprises an upper shell **471** with a sensor **472** and a lower shell **472** with a sensor **474**. The two shells each comprise respective control electronics including respective processors, power sources, and measurement and drive electronics. The two shells are not configured to form direct electrical contact; instead, the electronics of the upper and lower shells are inductively coupled, such that each responds to transient electrical pulses emitted from the other. The sensors of FIG. **50**G can be configured with one sensor being a transmitter and one being a receiver; for example, an acoustic transmitter and receiver may be used. In this manner, measurements may be performed relating signals to and from sensors in each respective shell without requiring an electrical pathway connecting the upper and lower shell electronics.

In cases in which sensors are located on separate upper and lower appliance shells the two shells may be coupled in various ways to enable coordinated measurement. For example, conductive coupling can be achieved in various ways. A wired connection can be made between opposing arches. In some embodiments, a single, monolithic appliance may be more practical than an appliance for both arches. However, where intermittent sensing is acceptable, conductive connectors can be placed on known contact points, such as is illustrated in FIG. **50**E. In another example of coupling, a conductive articulating rod such as a Herbst-style rod can be included between shells to provide a conductive path. Other methods of coupling directly include stretchable conductors, which can function like orthodontic elastics between appropriate hooks or buttons, or implanted wires within the mouth of the patient, such as subcutaneous wires in the cheek or adhesive wires attached on the inner surface of the intraoral cavity.

FIG. **51**A illustrates a block diagram of a signal chain **5100** for performing impedance measurements with the appliances disclosed herein. The driver electronics provide a current **5110** to an electrode characterized by a carrier frequency Fc. To eliminate DC current, the current transmitting electrode is screened from the current source by a high-pass filter in the form of a capacitor **5120**. The electrode contacts the patient's intraoral cavity, which provides modulation **530** at low frequencies, corresponding to variations in electrical impedance. This impedance can be modeled as a baseline impedance RB plus a variable impedance ΔR. The modulation is due to changes in ΔR, for example, arising from changes in airway cross-sectional area as the patient breathes. The modulated signal is received at the receiving electrode, which is also screened by a high-pass filter in the form of a capacitor **540**. The received signal is then amplified by a gain stage **550**. Thereafter, the signal is synchronously demodulated **560** to remove the carrier frequency Fc. Remaining high-frequency components are removed with a low-pass filter **570**, producing the final signal to be measured. An analog-to-digital converter **580** then converts the signal to a digital signal, which is processed by a processor that records the resulting measurement data to a non-transitory computer-readable medium.

When the signal chain disclosed in FIG. **51**A is applied to monitor physiological characteristics within the mouth of a patient, it is important to use signal frequencies and amplitudes that do not irritate or harm the patient. For inductive measurements with electrodes, safe ranges for current may be about 100 μA or less. Carrier frequencies used to modulate the signals can be chosen to appropriately minimize noise; for example, a carrier frequency of about 10 kHz is useful for many applications. The signal chain disclosed in FIG. **51**A may be applied to systems using sensors other than electrodes, replacing the electrodes described above with the appropriate sensor, such as a transducer, a piezo-electric crystal, or an actuator/accelerometer pair. The impedance modulation will correspondingly be replaced with a modulation of the signal to which the particular sensor is sensitive. For systems applying mechanical energy, the mechanical energy applied can be kept less than about 1 N for continuous force. For transient forces such as periodic forces, larger forces may be applied; for example, an amplitude of about 5 N or less can be applied for transient force measurements.

FIG. **51**B shows a schematic diagram of an oral appliance comprising a plurality of electrodes for measuring the impedance of a system such as the intraoral cavity or airway of a patient. A power source **515** supplies an alternating current to a first electrode lead **525**. The electrode lead **525**

can be brought into contact with a system **535** to be measured, such as the intraoral cavity of a patient. The voltage drop between lead **525** and lead **545** varies based on the impedance of the system **535**, in a manner approximated by Ohm's law (V=I*Z); accordingly, the relationship between the voltage drop and current flow between electrodes **525** and **545** can be used to determine the impedance of the system **535**. Each of the voltage and the current can be measured using conventional methods, e.g., with voltmeters and/or ammeters. A pull-up or pull-down resistor **555** can be included to ensure the incoming electrical signal has an appropriate voltage reference. The incoming AC signal from electrode lead **545** is then demodulated at signal conditioner **565**, with gain applied as needed to amplify the signal. Remaining high-frequency elements are removed with a low-pass filter, and the signal is then recorded to memory **575** for analysis. As data are accumulated over time, a data plot **585** of impedance vs time can be generated for analysis by the processor. The data can also be transmitted to an external device such as a mobile device for display and analysis, e.g., by a medical professional.

FIG. **52** illustrates a method **5200** for monitoring a physiological characteristic of a patient using an intraoral appliance as disclosed herein.

In step **610**, the appliance is positioned in the mouth of a patient. The appliance may comprise, for example, an appliance shell, or even a plurality of appliance shells, such as those disclosed herein. The appliance comprises a plurality of electrodes disposed within the one or more shells, and configured to make electrical contact with the patient's intraoral cavity when the intraoral appliance is worn by the patient.

In step **620**, an impedance measurement is performed by a processor coupled to the electrodes. The impedance measurement may, for example, be performed using a signal chain such as signal chain **500**. The variation of impedance due to physiological changes of the patient such as changes in airway occlusion causes a modulation of a current signal. After amplification and demodulation of a carrier frequency of the current signal, the remaining signal can be sent through a low-pass filter to retrieve an analog signal. The variation of that signal corresponds to variation in impedance. An analog-to-digital converter can generate signal data readable by the processor as a sequence of signal values over time, and the sequence contains information from which impedance variation can be determined. For example, variations in impedance due to breathing can be determined by detecting signal variations with substantially similar frequencies to the breathing rate.

In step **630**, the processor records data to memory corresponding to the impedance measurement. Optionally, the processor may cause a transmitter to transmit the data to a remote receiver to be recorded in memory outside the appliance. For example, a mobile device or other computing device may communicate with the processor using wired or wireless technology (such a Bluetooth, WiFi, or cellular communication, for example.)

In step **640**, a physiological characteristic is determined based on the impedance measurement data recorded in memory. For example, the physiological characteristic may be airway diameter, airway volume, airway resistance, lung fluid level, soft tissue crowding, breathing rate, muscle activity, ionic composition of saliva, or ionic composition of oral mucosa, or a combination thereof. Airway diameter, volume, and resistance can be determined by measuring variation in far-field impedance as measured by the electrodes. These size changes can be used as indicators of soft-tissue crowding. The signal can be isolated by detecting impedance variations correlated with patient breathing, for example. Breathing rate may be determined by detecting slow, periodic variations in overall impedance with time periods on the order of seconds. Lung fluid level can be determined by measuring properties of returning electrical current pulses, in particular their delay time and phase. Muscle activity, ionic composition of saliva, or ionic composition of oral mucosa can be measured with near-field electrodes: changes in ionic composition change electrical impedance of the intervening fluid, and muscle activity generates electrical currents that can be detected with the electrodes.

FIG. **53** illustrates a method **5300** for monitoring a characteristic of a patient's intraoral cavity or airway using transmitter-receiver pairs disposed within an intraoral appliance.

In step **5310**, the appliance is positioned in the mouth of a patient. The appliance may comprise, for example, an appliance shell, or even a plurality of appliance shells, such as those disclosed herein. The appliance comprises a transmitter and a receiver disposed within the one or more shells. For example, the transmitter and the receiver may be positioned in place of the electrodes in appliances substantially as described in FIGS. **50**A-**50**F. The transmitter and receiver may also be disposed in a pair of shells with inductively coupled electronics, as disclosed in FIG. **50**G.

In step **5320**, the transmitter transmits a signal within the intraoral cavity. Examples of transmitters and respective transmitted signals include an electrode transmitting electrical pulses, a transducer transmitting acoustic waves, and an actuator transmitting mechanical force.

In step **5330**, a response signal is received and processed by a processor, then recorded to memory. The response signal can arise from an interaction between the transmitted signal and portions of the patient's intraoral cavity and/or airway, such as a scattering, reflection, or stimulation of tissue or fluids, for example. The response signal is received by a receiving sensor. Examples of receiving sensors and respective received signals include an electrode receiving piezoelectric pulses, a transducer receiving reflected acoustic waves, and an accelerometer detecting acceleration. The received signal contains information about the tissues and/or fluids it traveled through that can be analyzed to determine physiological characteristics; for example, modulations of the amplitude, frequency and phase of the received signals can correspond to corresponding changes in the transmission medium of the patient's intraoral cavity or airway.

In step **5340**, a physiological characteristic is determined based on the sensor measurement data recorded in memory. The determined physiological characteristic can be, for example, compression response of bone and collagen; temporomandibular joint articulation; grinding or clenching of teeth; decline in upper airway muscle activity; stiffness of tooth-PDL structure; tooth, root, and/or PDL health; root structures based on acoustic responses of surrounding tissue; oral cavity or upper airway shape and size; soft tissue crowding; opening or closing of the mouth; or mandibular protrusion or retrusion. These physiological characteristics may be respectively determined using the appropriate sensors and physiological relationships as described above regarding FIGS. **50**A-**50**G.

FIG. **54** illustrates a method of manufacturing an appliance comprising sensors and control electronics **5400**.

In step **5410**, the dental structure of the patient is obtained. This structure may be in the form of a physical mold or model, for example, or a 3D image of the patient's dentition.

In step **5420**, a first layer of appliance material is deposited. This deposition may be, for example, the application of a thermoformed layer of plastic over a mold. Alternatively, material may be deposited by direct fabrication, such as using a 3D printer, according to a 3D model of the appliance generated to fit the teeth of the patient, based on the 3D image of the patient's dentition in step **5410**. In some embodiments, steps **5420** and **5440** can be combined into a single step in which the appliance shell is directly fabricated around the control electronics and sensors of step **5430**.

In step **5430**, control electronics and sensors are placed over the first layer of appliance in appropriate locations. Wiring is provided as needed to connect each component of the sensing system. In this step, carbon fiber can be incorporated into the aligner to create an antenna for wireless communication to an external receiver. Multiple electrodes or other sensors can be provided to enhance signal acquisition; for example, in a manner similar to neuroelectrodes used for electroencephalogram measurements.

In step **5440**, a second layer of appliance material is deposited, as in step **5420**. The second layer, in combination with the first layer, envelops the control electronics and sensors.

In step **5450**, any material covering sensor leads can be removed, if necessary. For example, a robotic mill or laser cutter may be used to remove appliance material covering electrodes, transducers, actuators, accelerometers, etc., so as to provide a clear contact with the appropriate part of the patient's mouth when the appliance is worn.

In order to better isolate signals relevant to the physiological characteristics to be measured, multiple sensor systems can be combined using a sensor fusion technique. For example, as discussed above, airway width variation is correlated with patient breathing. Patient breathing rate can be determined using an accelerometer disposed within the intraoral appliance. FIG. **55** illustrates exemplary rotational velocity data collected with a gyroscopic accelerometer coupled to the maxilla of a patient. The grey spectra illustrate rotational velocity data a sensor loosely coupled to the body, near the hip. The black spectra illustrate corresponding data from a sensor coupled to the jaw of the patient via an appliance. The left spectra illustrate the raw data in each of the x, y, and z dimensions, while the right spectra illustrate the same data transformed into Fourier space and displayed as a power spectrum. The power spectrum of the black curve, measuring jaw movement, shows a maximum somewhat below 1 Hz, corresponding to the breathing rate of the patient. By contrast, the measurement at the patient's hip shows only a weak signal. Thus, intraoral measurement can be used to measure a signal sensitive to a patient's breathing rate. Using this measured breathing rate, it is possible to isolate the effect of airway width variation on impedance measurements from electrodes by detecting impedance variations with substantially matching frequencies. Since impedance measurements are also sensitive to the breathing of the patient, impedance and acceleration signal can be measured by an intraoral appliance and cross-validated to provide a breathing rate measurement with enhanced accuracy.

In some embodiments, an appliance comprising sensors as disclosed herein can be a treatment appliance, such as an orthodontic appliance or an appliance for the treatment of sleep apnea. In such an appliance, the monitoring of physiological conditions can comprise an assessment of treatment efficacy. For example, sleep apnea can be treated with the intraoral appliance, and the effectiveness can be monitored by tracking the resulting change in airway diameter or volume. The movement of teeth due to orthodontic forces can also be measured, such as by monitoring the stiffness of a tooth-PDL structure to which orthodontic forces are being applied by the appliance.

Appliances having teeth receiving cavities such as those disclosed herein include appliances that receive and reposition teeth, e.g., via application of force due to appliance resiliency. Examples of such appliances are generally illustrated with regard to FIG. **1**A. FIG. **1**A illustrates an exemplary tooth repositioning appliance or aligner **1000** that can be worn by a patient in order to achieve an incremental repositioning of individual teeth **1002** in the jaw. The appliance can include a shell having teeth-receiving cavities that receive and resiliently reposition the teeth. An appliance or portion(s) thereof may be indirectly fabricated using a physical model of teeth. For example, an appliance (e.g., polymeric appliance) can be formed using a physical model of teeth and a sheet of suitable layers of polymeric material. In some embodiments, a physical appliance is directly fabricated, e.g., using rapid prototyping fabrication techniques, from a digital model of an appliance.

Although reference is made to an appliance comprising a polymeric shell appliance, the embodiments disclosed herein are well suited for use with many appliances that receive teeth, for example appliances without one or more of polymers or shells. The appliance can be fabricated with one or more of many materials such as metal, glass, reinforced fibers, carbon fiber, composites, reinforced composites, aluminum, biological materials, and combinations thereof for example. The appliance can be shaped in many ways, such as with thermoforming or direct fabrication (e.g., 3D printing, additive manufacturing), for example. Alternatively or in combination, the appliance can be fabricated with machining such as an appliance fabricated from a block of material with computer numeric control machining.

An appliance can fit over all teeth present in an upper or lower jaw, or less than all of the teeth. The appliance can be designed specifically to accommodate the teeth of the patient (e.g., the topography of the tooth-receiving cavities matches the topography of the patient's teeth), and may be fabricated based on positive or negative models of the patient's teeth generated by impression, scanning, and the like. Alternatively, the appliance can be a generic appliance configured to receive the teeth, but not necessarily shaped to match the topography of the patient's teeth. In some cases, only certain teeth received by an appliance will be repositioned by the appliance while other teeth can provide a base or anchor region for holding the appliance in place as it applies force against the tooth or teeth targeted for repositioning. In some embodiments, some, most, or even all of the teeth will be repositioned at some point during treatment. Teeth that are moved can also serve as a base or anchor for holding the appliance as it is worn by the patient. Typically, no wires or other means will be provided for holding an appliance in place over the teeth. In some cases, however, it may be desirable or necessary to provide individual attachments or other anchoring elements **1004** on teeth **1002** with corresponding receptacles or apertures **1006** in the appliance **1000** so that the appliance can apply a selected force on the tooth. Exemplary appliances, including those utilized in the Invisalign® System, are described in numerous patents and patent applications assigned to Align Technology, Inc. including, for example, in U.S. Pat. Nos. 6,450,807, and 5,975,893, as well as on the company's website, which is accessible on the World Wide Web (see, e.g., the url "invisalign.com"). Examples of tooth-mounted attachments suitable for use with orthodontic appliances are also described

in patents and patent applications assigned to Align Technology, Inc., including, for example, U.S. Pat. Nos. 6,309,215 and 6,830,450.

FIG. **1**B illustrates a tooth repositioning system **1010** including a plurality of appliances **1012**, **1014**, **1016**. Any of the appliances described herein can be designed and/or provided as part of a set of a plurality of appliances used in a tooth repositioning system. Each appliance may be configured so a tooth-receiving cavity has a geometry corresponding to an intermediate or final tooth arrangement intended for the appliance. The patient's teeth can be progressively repositioned from an initial tooth arrangement to a target tooth arrangement by placing a series of incremental position adjustment appliances over the patient's teeth. For example, the tooth repositioning system **1010** can include a first appliance **1012** corresponding to an initial tooth arrangement, one or more intermediate appliances **1014** corresponding to one or more intermediate arrangements, and a final appliance **1016** corresponding to a target arrangement. A target tooth arrangement can be a planned final tooth arrangement selected for the patient's teeth at the end of all planned orthodontic treatment. Alternatively, a target arrangement can be one of some intermediate arrangements for the patient's teeth during the course of orthodontic treatment, which may include various different treatment scenarios, including, but not limited to, instances where surgery is recommended, where interproximal reduction (IPR) is appropriate, where a progress check is scheduled, where anchor placement is best, where palatal expansion is desirable, where restorative dentistry is involved (e.g., inlays, onlays, crowns, bridges, implants, veneers, and the like), etc. As such, it is understood that a target tooth arrangement can be any planned resulting arrangement for the patient's teeth that follows one or more incremental repositioning stages. Likewise, an initial tooth arrangement can be any initial arrangement for the patient's teeth that is followed by one or more incremental repositioning stages.

The various embodiments of the orthodontic appliances presented herein can be fabricated in a wide variety of ways. As an example, some embodiments of the appliances herein (or portions thereof) can be produced using indirect fabrication techniques, such as by thermoforming over a positive or negative mold. Indirect fabrication of an orthodontic appliance can involve producing a positive or negative mold of the patient's dentition in a target arrangement (e.g., by rapid prototyping, milling, etc.) and thermoforming one or more sheets of material over the mold in order to generate an appliance shell. Alternatively or in combination, some embodiments of the appliances herein may be directly fabricated, e.g., using rapid prototyping, stereolithography, 3D printing, and the like.

The configuration of the orthodontic appliances herein can be determined according to a treatment plan for a patient, e.g., a treatment plan involving successive administration of a plurality of appliances for incrementally repositioning teeth. Computer-based treatment planning and/or appliance manufacturing methods can be used in order to facilitate the design and fabrication of appliances. For instance, one or more of the appliance components described herein can be digitally designed and fabricated with the aid of computer-controlled manufacturing devices (e.g., computer numerical control (CNC) milling, computer-controlled rapid prototyping such as 3D printing, etc.). The computer-based methods presented herein can improve the accuracy, flexibility, and convenience of appliance fabrication.

In some embodiments, orthodontic appliances, such as the appliance illustrated in FIG. **1**A, impart forces to the crown of a tooth and/or an attachment positioned on the tooth at one or more points of contact between a tooth receiving cavity of the appliance and received tooth and/or attachment. The magnitude of each of these forces and/or their distribution on the surface of the tooth can determine the type of orthodontic tooth movement which results. Tooth movements may be in any direction in any plane of space, and may comprise one or more of rotation or translation along one or more axes. Types of tooth movements include extrusion, intrusion, rotation, tipping, translation, and root movement, and combinations thereof, as discussed further herein. Tooth movement of the crown greater than the movement of the root can be referred to as tipping. Equivalent movement of the crown and root can be referred to as translation. Movement of the root greater than the crown can be referred to as root movement.

When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative

descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term "comprising" will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

In general, any of the apparatuses and methods described herein should be understood to be inclusive, but all or a sub-set of the components and/or steps may alternatively be exclusive, and may be expressed as "consisting of" or alternatively "consisting essentially of" the various components, steps, sub-components or sub-steps.

As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about" or "approximately" may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/−0.1% of the stated value (or range of values), +/−1% of the stated value (or range of values), +/−2% of the stated value (or range of values), +/−5% of the stated value (or range of values), +/−10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For example, if the value "10" is disclosed, then "about 10" is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that "less than or equal to" the value, "greater than or equal to the value" and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value "X" is disclosed the "less than or equal to X" as well as "greater than or equal to X" (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point "10" and a particular data point "15" are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

What is claimed is:

1. A near field communication (NFC) signal coupler device for relaying monitoring data from an orthodontic monitoring apparatus (MA) to a handheld processor, the device comprising:

a housing;

a first antenna configured for NFC within the housing;

a second antenna within the housing;

a holder on or in the housing that is configured to hold a dental aligner to which the monitoring apparatus is coupled, so that the monitoring apparatus is in a fixed alignment with the first antenna; and

NFC coupling transmission circuitry configured to receive the monitoring data from the first antenna and to transmit the monitoring data from the second antenna.

2. The device of claim **1**, wherein the second antenna is configured for Bluetooth communication (BLE), further wherein the NFC coupling transmission circuitry is configured to receive data from the first antenna by NFC and to transmit data from the second antenna by BLE.

3. The device of claim **1**, wherein the monitoring apparatus is an electronic compliance indicator (ECI) apparatus.

4. The device of claim **1**, wherein the second antenna is larger than the first antenna and is configured for NFC with a phone placed on or in the housing.

5. The apparatus of claim **1**, wherein the holder comprises a case formed at least partially from the housing and configured to hold the monitoring apparatus within the case so that the monitoring apparatus is aligned with the first antenna.

6. The apparatus of claim **1**, wherein the holder comprises a case formed at least partially from the housing and configured to hold the dental aligner coupled to the moni-

toring apparatus within the case so that the monitoring apparatus is aligned with the first antenna.

7. The apparatus of claim **1**, further wherein the NFC coupling transmission circuitry comprises a power source within the housing.

8. The apparatus of claim **1**, wherein the holder comprises an indentation on the housing.

9. The apparatus of claim **1**, wherein the first antenna comprises a trace antenna or a coil antenna.

10. The apparatus of claim **1**, wherein the first antenna comprises a toroidal loop antenna having a ferrite core comprising a gap.

11. The apparatus of claim **1**, wherein the second antenna is 2× or more the size of the first antenna.

12. A near field communication (NFC) to Bluetooth communication (BLE) signal coupler device for relaying monitoring data from an orthodontic electronic compliance indicator (ECI) apparatus to a handheld processor, the device comprising:

a housing;

a first antenna configured for NFC within the housing;

a second antenna configured for BLE within the housing;

a holder on or in the housing configured to hold a dental aligner to which the ECI apparatus is coupled, so that the ECI apparatus is in a fixed alignment with the first antenna; and

NFC to BLE transmission circuitry configured to receive the monitoring data from the first antenna and to transmit the monitoring data from the second antenna.

13. The apparatus of claim **12**, wherein the holder comprises a case formed at least partially from the housing and configured to hold the ECI apparatus within the case so that the ECI is aligned with the first antenna.

14. The apparatus of claim **12**, wherein the holder comprises a case formed at least partially from the housing and configured to hold the dental aligner coupled to the ECI apparatus within the case so that the ECI is aligned with the first antenna.

15. The apparatus of claim **12**, further wherein the NFC to BLE transmission circuitry comprises a power source within the housing.

16. The apparatus of claim **12**, wherein the holder comprises an indentation on the housing.

17. The apparatus of claim **12**, wherein the first antenna comprises a trace antenna or a coil antenna.

18. The apparatus of claim **12**, wherein the first antenna comprises a toroidal loop antenna having a gap.

19. A method of relaying monitoring data from an orthodontic electronic compliance indicator (ECI) apparatus to a handheld processor, the method comprising:

aligning the ECI apparatus with a first antenna within a housing of a near field communication (NFC) signal coupler device, wherein the ECI apparatus is coupled to a dental aligner and the dental aligner is held by a holder on or in the housing so that the ECI apparatus is held in a fixed alignment;

transmitting the monitoring data from the ECI apparatus to the NFC signal coupler device by NFC; and

retransmitting the monitoring data from the NFC signal coupler device to a handheld electronics device.

20. The method of claim **19**, wherein retransmitting comprise retransmitting the monitoring data to the handheld electronics device by Bluetooth communication.

21. The method of claim **19**, further comprising inserting the ECI apparatus into the NFC signal coupler device, wherein the NFC signal coupler device is configured as a case configured to hold the ECI apparatus.

22. The method of claim **19**, further comprising inserting the ECI apparatus into the NFC signal coupler device, wherein the NFC signal coupler device is configured as a case configured to hold the ECI apparatus and a dental appliance to which the ECI apparatus is coupled.

23. The method of claim **19**, further comprising receiving the monitoring data in the handheld electronics device, wherein the handheld electronics device comprises a smartphone.

24. The method of claim **19**, further comprising modifying the monitoring data before retransmitting the data.

25. The method of claim **19**, wherein transmitting the monitoring data comprises receiving the NFC signal comprising the monitoring data on a first antenna of the NFC signal coupler device.

26. The method of claim **19**, wherein retransmitting the monitoring data comprises transmitting the monitoring data as a Bluetooth signal via a second antenna of the NFC signal coupler device that is configured for Bluetooth communication.

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摘要(译)

检测患者牙齿上牙齿对准器的位置，以指示佩戴的依从性。本文描述了用于通过将电子依从性信息有线或无线直接或间接通信到智能手机来检测包括依从性的穿戴以及用于可靠地传输数据的装置和方法。本文还描述了可以检测与呼吸和睡眠有关的生理参数的牙科用具。本文还描述了可与电子合规性指示器（ECI）设备进行NFC通信以及与智能手机进行蓝牙通信的Aligner外壳。