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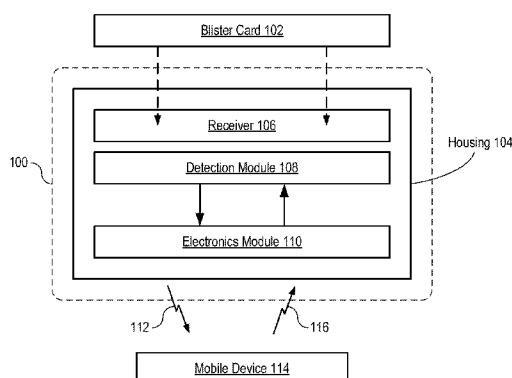
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(54) **Title:** APPARATUS AND METHOD FOR IMPROVED DRUG REGIMEN COMPLIANCE

(57) **Abstract:** A method and apparatus for monitoring drug-regimen compliance is disclosed. Systems in accordance with the present invention enable automatic monitoring of the state of medicine content of a blister card. Each tablet location on the blister card is operatively coupled with a different sensor that detects whether the tablet location is occupied and/or a dispensing event at a tablet location. In some embodiments, capacitive sensing is employed, where the capacitance of each sensor is based on the physical state of a dispensing region of the lidding film of the blister pack, which is located at the tablet location being monitored. Alternative sensing approaches are based on optical, acoustic, and tactile sensors that interrogate either the dispensing region at each tablet location or the tablets themselves to determine whether tablets have been dispensed. The sensors interface with a mobile app that provides the user instructions to help improve drug-regimen compliance.

**WO 2017/176571 A1**

## **Apparatus and Method for Improved Drug Regimen Compliance**

### **Statement of Related Cases**

[0001] This case claims priority to U.S. Provisional Patent Application Serial Number 62/320,234 filed on April 8, 2016 (Attorney Docket: 3005-004PR1), which is incorporated herein by reference.

### **Background of the Invention**

[0002] Medication noncompliance is a costly problem in many ways, from driving up health care costs to financial losses to the pharmaceutical industry to serious negative human impacts:

- 125,000 people die in the US each year as a result of failure to adhere to drug regimens;
- Studies reflect \$290 billion per year of healthcare implications of medication non-adherence;
- The global pharmaceutical market loses an estimated \$564 billion annually, or 59% of the \$956 billion in total global pharmaceutical revenue in 2011 due to non-adherence;
- In developed countries, adherence to long-term therapies in the general population is around 50%, and much lower in developing countries; and
- Nearly three out of four Americans are not taking their medications as directed—which results in serious health consequences, especially for people with chronic diseases.

[0003] The need to follow a drug regimen properly is particularly acute for oral contraceptive pills (OCP). For example, in addition to the above issues, failure to follow the proper regimen for OCP has already led to countless unwanted pregnancies and could lead to many more. OCP is one of the most popular forms of contraception, particularly among young women. A government report published October 18, 2012 provides the following statistics for the U.S.:

*Sixty-two percent of women of reproductive age are currently using contraception. Of women using a contraceptive method in the month of the interview, the most common methods used are the pill (28%, or 10.6 million women) and female sterilization (27%, or 10.2 million women). Use of intrauterine devices as a current method has increased since 1995 (from 0.8% in 1995 to 5.6% in 2006–2010), whereas fewer women report that their partners are using condoms as their current, most effective contraceptive method. Of women at risk of an unintended pregnancy, 11% report not currently using a method of contraception.*

[0004] A United Nations report published in 2011 provides the follow statistics worldwide:

*In developed countries as a whole, the most commonly used methods are the pill (used by 18 per cent of women of reproductive age who are married or in a union) and the male condom (with 18 per cent prevalence). Those two methods accounted for half of all contraceptive use in the developed countries. By contrast, in developing countries the methods with the highest prevalence were female sterilization (21 per cent) and the IUD (15 per cent), accounting together for 58 per cent of overall contraceptive use.*

[0005] Failure to take a pill is one of the main reasons for seeking emergency contraception (e.g., the morning after pill) in women relying on OCP. A primary cause of unintended pregnancy in these women may therefore be poor adherence. Studies suggest that as much as 47% of women worldwide show poor adherence, missing two or more pills per cycle. (A menstrual cycle is on average 28 days.) Britain's largest manufacturer of OCP, Schering Health Care Ltd, reports that on average women forget to take their pill eight times a year. Most know they have to take remedial steps when they miss a pill, but few know what. Only 10% know missing just one pill places them at risk of pregnancy.

[0006] The success of OCP is tightly coupled to adherence to the prescribed daily regimen, i.e., taking the right pill on the right day during a woman's menstrual cycle. For this reason, birth control pills are packaged in blister cards on which a calendar is printed to guide the patient on which pill to take on which day. Furthermore, the recommended intake

interval, from day to day, is 24 hours. For this reason, many use daily reminders (e.g., on mobile devices) to help stay compliant. When a patient becomes non-compliant, the manufacturer recommends specific steps to regain compliance and reduce chances of unintended pregnancy in the interim. Unfortunately, the recommended mediation approaches are not always followed correctly, leading to higher risk of unwanted pregnancy.

[0007] A packaging approach that provides one or more of improved patient adherence/compliance, treatment results, authentication, and packaging and distribution approaches would be a welcome advance for the pharmaceutical industry and have particular benefit in the realm of OCP regimen compliance, as well as other drug regimens.

### **Summary of the Invention**

[0008] The present invention enables tracking of adherence to drug regimens, such as medicinal prescription regimens, through connected, smart packaging. Embodiments of the present invention are particularly well suited for improving adherence of oral contraceptive pills regimens.

[0009] Embodiments of the present invention enable the state of a blister card to be automatically monitored, which enables adherence to a drug regimen to be tracked and/or improved. In some embodiments, the state of the blister card is automatically assessed periodically and compared to its previous state to determine whether a tablet has been dispensed during the intervening period. In some embodiments, the action of dispensing a tablet gives rise to an output signal that enables the dispensing event to be automatically recorded. The history of dispensing events is then compared to a prescribed regiment for the medication contained in the blister card to assess whether the dispensing events have been as prescribed. If an error (*i.e.*, noncompliance) in the dispensing history is detected, an alert is issued to the user, and/or one or more designated persons in the care circle of the user (e.g., caregiver, nurse, doctor, clinic/hospital, parent, partner, relatives, friends, etc.).

[0010] Embodiments of the present invention include a package comprising a housing that accepts and locates a blister card containing a plurality of medicine tablets. The package includes a detection module comprising a plurality of sensors that is arranged to match the arrangement of the tablets on the blister card. As a result, each tablet location is operatively coupled with a different sensor. When a tablet is dispensed, its

respective sensor is operative for providing an output signal indicating the dispensing event, which enables the dispensing history of the blister card to be compared to the prescribed regimen.

**[0011]** An illustrative embodiment of the present invention is a package comprising a housing that includes a detection module comprising a plurality of capacitive sensors, each of which includes a sense electrode. When the blister card is located in the housing, the blister card and the detection module are operatively coupled such that the lidding foil in the dispensing region of each tablet location and the electrode of its respective sensor collectively define a capacitor whose capacitance is based on the physical state of the dispensing region. A change in this capacitance is indicative that the tablet at that sensor location has been dispensed.

**[0012]** In some embodiments, the detection module includes a plurality of capacitive sensors that are shielded from external noise and interference. In some of these embodiments, the sense electrode is shielded from stray capacitance and electrical noise arising from the other side of the blister card by a drive electrode located between the sense electrode and the dispensing region. The drive and sense electrode are characterized by a mutual capacitance that is affected by fringing fields based on the physical state of their respective dispensing region. In some embodiments, the sense electrode is between a pair of drive electrodes. The drive electrodes shield the sense electrode from stray capacitance and electrical noise received from the top and bottom sides of the blister card/detection module arrangement. In some embodiments, the sense electrode is substantially surrounded, in-plane, by grounded shield lines. As a result, the sense electrode is also shielded from stray capacitance and electrical noise directed at it from the side.

**[0013]** In some embodiments, the package includes a detection module that employs a sensing technique other than capacitive sensing. In some embodiments, the detection module includes optical sensors. In some embodiments, the detection module includes acoustic sensors. In some embodiments, the detection module includes tactile sensors.

**[0014]** In some embodiments, the package is operatively coupled with an accompanying mobile app to help women relying on OCP with good adherence to the prescribed regimen and better management of the efficacy requirements.

[0015] An embodiment of the present invention is a system for monitoring the state of a blister card that includes a forming film, a lidding film, and a first tablet contained in a first reservoir defined by the forming film and the lidding film, wherein the system comprises: a housing that is operative for locating the blister card in a first position; a detection module comprising a first sensor, wherein the first sensor is operative for providing a first electrical signal that is based on at least one of (a) the presence of the first tablet in the first reservoir and (b) the physical state of a first dispensing region of the lidding film; and an electronics module that is operative for providing a first output signal based on the first electrical signal.

[0016] Another embodiment of the present invention is a system for monitoring the state of a blister card that includes a forming film, a lidding film, and a plurality of tablets that are arranged in a first arrangement, wherein the system comprises: a detection module comprising a plurality of sensors arranged in the first arrangement, wherein each sensor is operative for providing an electrical signal based on the physical state of a different dispensing region of the lidding film; and an electronics module operative for providing an output signal based on the plurality of electrical signals.

[0017] Yet another embodiment of the present invention is a method for monitoring the state of a blister card that includes a forming film, a lidding film, and a plurality of tablets that are arranged in a first arrangement, wherein the method comprises: providing a detection module comprising a plurality of sensors that is arranged in the first arrangement; operatively coupling the plurality of sensors and the blister card such that each sensor of the plurality thereof is operative for providing an electrical signal based on the presence of a different tablet of the plurality thereof in the blister card; determining a physical state of the blister card based on the plurality of electrical signals; comparing the physical state of the blister card with an expected state of the blister card, wherein the expected state is based on a predetermined prescription regimen for the plurality of tablets; and providing an output signal based on the physical state of the blister card relative to the expected state.

[0018]

### **Brief Description of the Drawings**

[0019] FIG. 1 depicts a block diagram of a package in accordance with an illustrative embodiment of the present invention.

[0020] FIGS. 2A-B depict schematic drawings of perspective and cross-sectional views, respectively, of blister card **102**.

[0021] FIG. 3 depicts operations of a method for monitoring a drug regimen in accordance with the illustrative embodiment.

[0022] FIG. 4 depicts a schematic drawing of a perspective view of package **100** including inserted blister card **102**.

[0023] FIG. 5 depicts an enlarged cross-sectional view of a portion of an alternative receiver **106**.

[0024] FIGS. 6A-B depict schematic drawings of top and cross-sectional views, respectively, of a capacitive-sensing-based detection module in accordance with the illustrative embodiment of the present invention.

[0025] FIG. 7 depicts a cross-sectional view of an alternative capacitive sensor having improved noise immunity in accordance with the present invention.

[0026] FIG. 8 depicts a schematic drawing of the electrical connectivity of sensor **700**.

[0027] FIG. 9 depicts a cross-sectional view of another alternative capacitive sensor having improved noise immunity in accordance with the present invention.

[0028] FIG. 10 depicts a schematic drawing of the electrical connectivity of sensor **900**.

[0029] FIG. 11 depicts a plan view of a detection module having improved noise immunity by virtue of shield lines formed around each of its sense electrodes.

[0030] FIGS. 12A-B depict measurement results for two individual sensors **900** in response to the sequential dispensing of two tablets from blister card **102**.

[0031] FIG. 13A depicts a schematic drawing of a cross-sectional view of package **100** having an alternative capacitive-sensing-based detection module.

[0032] FIGS. 13B-C depict cross-sectional views a portion of detection module **1300** before and after dispensing of a tablet, respectively, in accordance with the present invention.

[0033] FIGS. 13D-E depict cross-sectional views of a portion of yet another alternative capacitive-sensing-based detection module, before and after dispensing of a tablet, respectively, in accordance with the present invention.

[0034] FIGS. 14A-B depict cross-sectional views of a portion an alternative acoustic-sensing-based detection module, before and after dispensing of a tablet, respectively, in accordance with the present invention.

[0035] FIG. 15 depicts a schematic drawing of a perspective view of a blister card comprising a plurality of microphones in accordance with another acoustic-sensing-based embodiment of the present invention.

[0036] FIGS. 16A-B depict cross-sectional views of a portion a tactile-sensing-based detection module, before and after dispensing of a tablet, respectively, in accordance with the present invention.

[0037] FIGS. 17A-B depict cross-sectional views of a portion an optical-sensing-based detection module, before and after dispensing of a tablet, respectively, in accordance with the present invention.

[0038] FIGS. 18A-B depict cross-sectional views of a portion an optical-sensing-based detection module, before and after dispensing of a tablet, respectively, in accordance with the present invention.

[0039] FIG. 19 depicts a schematic drawing of a perspective view of a multi-blister-card package in accordance with an alternative embodiment of the present invention.

### **Detailed Description**

[0040] The present invention is directed, in part, to connected-packaging solutions for pharmaceutical products, with a focus on medicine containers comprising blister cards. It should be noted that, although the focus of the instant Specification is on OCP, the present invention can be directed to any blister-card-based packaged product. For the purposes of this Specification, including the appended claims, the term “**tablet**” is defined to mean any and all variety of medication, which includes, without limitation, pills, capsules,

powder, gel-caps, and the like. Some of the embodiments described herein draw on concepts developed for connected packaging solutions directed to "blister cards," which are described in U.S. Patent Application No. 14/879,874 (Attorney Docket: 3005-002US1), entitled "Connected Packaging," which was filed October 9, 2015, and which is incorporated herein by reference.

[0041] FIG. 1 depicts a block diagram of a package in accordance with an illustrative embodiment of the present invention. Package **100** is an oral-contraceptive protective case that includes smart-packaging capability, which enables it to monitor the state of OCP blister card **102** and enable tracking of the drug regimen for the tablets it contains, initiate messages to the user and/or caregivers, and the like. Package **100** includes housing **104**, receiver **106**, detection module **108**, and electronics module **110**. Package **100** is dimensioned and arranged to accept a conventional "push-through-pack" blister card comprising a twenty-eight-day dosage of oral contraceptive tablets and locate the blister card such that it is operatively coupled with the detection module.

[0042] FIGS. 2A-B depict schematic drawings of perspective and cross-sectional views, respectively, of blister card **102**. Blister card **102** is a conventional blister card that includes forming film **202**, lidding film **204**, reservoirs **206**, and tablets **210**.

[0043] Forming film **202** is a layer of thermoformed plastic in which cavities **208** are formed.

[0044] Lidding film **204** is a thin sheet of aluminum foil. In some embodiments, lidding film **204** is a sheet of another electrically conductive material. In some embodiments, lidding film **204** includes a sheet of conductive material and a sheet of electrically insulating material, such as a paper sheet (with a printed calendar or instructions), polymer, etc. After tablets **210** are dispensed into cavities **208**, lidding film **204** is joined with forming film **202** to seal the cavities, thereby forming reservoirs **206**. Typically, a calendar that describes the drug regimen is printed on the card and/or otherwise provided as part of the blister card.

[0045] The region of lidding film **204** located under each cavity defines a dispensing region **212**, through which its respective tablet **210** is dispensed by pushing the tablet through the lidding foil.

[0046] FIG. 3 depicts operations of a method for monitoring a drug regimen in accordance with the illustrative embodiment. Method **300** begins with operation **301**, wherein blister card **102** is located in package **100**. Method **300** is described with continuing reference to FIGS. 1 and 2A-B.

[0047] FIG. 4 depicts a schematic drawing of a perspective view of package **100** including inserted blister card **102**.

[0048] When mounted in package **100**, blister card **102** is protected from damage and inadvertent tablet dispensing by housing **104**. Housing **104** is an injection-molded plastic case having sufficient strength to protect blister card **102** from damage during normal handling and storage, such as might happen, for example, if blister card **102** were kept in a purse or a pocket without such protection.

[0049] The location of blister card **102** within package **100** is determined by receiver **106** (*i.e.*, receiver **106** locates blister card **102**). Receiver **106** is a rigid frame containing openings for exposing reservoirs **206** of blister card **102**. To locate blister card **102** in housing **104**, the blister card is positioned within a seat formed in the bottom of housing **104** (not shown) and receiver **106** is closed over the blister card to trap it in place. Receiver **106** is dimensioned and arranged to provide distributed pressure over the surface of the blister card to ensure that it is operatively coupled with detection module **108**.

[0050] In some embodiments, blister card **102** includes printed information on its forming-film side (*e.g.*, instructions for the user, advertising, logos, *etc.*). In such embodiments, those package components (*e.g.*, receiver **106**) that overlay such printed information would be made of optically transparent material.

[0051] In some embodiments, receiver **106** comprises a different conventional latching system for locating a blister card in housing **104** such that it is operably coupled with detection module **108**.

[0052] FIG. 5 depicts an enlarged cross-sectional view of a portion of an alternative receiver **106**. The cross-sectional view depicted in FIG. 5 is taken through region **406** of FIG. 4. Receiver **106** includes a plurality of latches **502** and shoulder **504**, which are formed as part of the outer wall of housing **104**. Latch **502** is a deformable tab that can be depressed to enable blister card **102** to seat against shoulder **504**. The tab is resilient such that once the blister card is located in its proper position against the shoulder, it springs

outward to lock the blister card in this position. In the illustrative embodiment, the desired position of blister card **102** is abutting the top surface of detection module **108**, as discussed below. Typically, latches **502** and shoulder **504** are formed as part of the sidewalls of housing **104** in accordance with conventional injection molding techniques. One skilled in the art will recognize that there are myriad conventional ways to form receiver **106** and that the receiver designs depicted in FIGS. 4 and 5 are merely examples of receivers suitable for use with the present invention.

[0053] Detection module **108** is a two-dimensional arrangement of sensors that substantially matches the arrangement of tablets **210** in blister card **102**. In some embodiments, detection module **108** includes a mechanically robust plate comprising a plurality of holes through which tablets **210** are dispensed. As discussed below, detection module **108** employs capacitive sensing technology to monitor the state of blister card **102**. It will be clear to one skilled in the art, after reading this Specification, however, that many alternative sensing technologies can be employed in detection module **108** without departing from the scope of the present invention. Sensing technologies suitable for use in embodiments of the present invention include, without limitation, optical sensing, acoustic sensing, and tactile sensing, among others. Detection module **108** is described in more detail below.

[0054] Electronics module **110** is an electronics package that is operatively coupled with detection module **108**. Electronics module **110** comprises electronic circuitry suitable for interfacing with the sensors of the detection module, signal-conditioning electronics (*e.g.*, pre-amplifiers, comparators, *etc.*) for receiving the output signals of each sensor, output electronics for providing output signal **112**, and the like. In some embodiments, electronics module **110** includes, without limitation:

- i. communications electronics (wired and/or wireless, such as Bluetooth, cellular, *etc.*); or
- ii. processing capability; or
- iii. memory; or
- iv. onboard clock circuitry; or
- v. power (*e.g.*, batteries, *etc.*) and/or energy scavenging electronics, or

- vi. sensor interface circuitry; or
- vii. wake-up detection circuitry; or
- viii. on-case alerts (e.g., light-emitting diodes, buzzers, etc.); or
- ix. environmental (e.g., temperature, humidity, shock, geolocation, etc.) sensors; or
- x. any combination of i, ii, iii, iv, v, vi, vii, viii, and ix.

[0055] In the depicted example, electronics module **110** communicates with mobile device **114** wirelessly via output signal **112** and input signal **116**.

[0056] Mobile device **114** is a cell phone that runs a software application (*i.e.*, a mobile app) that provides assistance to the patient and/or caregiver to achieve and maintain good adherence to the prescribed drug regimen. In some embodiments, electronics module **110** communicates with a different device, such as a computer and/or base station. Further, in some embodiments, electronics module **110** is integrated with detection module **108** on the same substrate.

[0057] In some embodiments, electronics module **110** includes sleep-mode circuitry to facilitate long battery life between charges. In such embodiments, sensing is activated only when desired and the instrument is in sleep mode most of the time. Examples of sleep-mode circuitry suitable for use in embodiments of the present invention include, without limitation, low-power accelerometers, touch/proximity sensors, and the like.

[0058] One skilled in the art will recognize, after reading this Specification, that the design features of housing **100** are based on the particular arrangement of blister card **102**, as well as the sensing technology used to monitor its state. As a result, the design details provided herein are merely exemplary and that myriad alternative designs are possible without departing from the scope of the present invention.

[0059] In the package configuration depicted in FIG. 4, detection module **108** and electronics module **110** are embedded into the bottom surface of housing **104**. It should be noted, however, that there are numerous ways to integrate detection module **108** and/or electronics module **110** into housing **104** without departing from the scope of the present invention. In some embodiments of the present invention, for example, detection module **108** is embedded into the bottom of housing **104**, while electronics module **110** is

mounted on lid **402**. Interconnects (not shown) embedded in housing **104** run through hinge **404** to electrically couple the detection and electronics modules. In another embodiment, housing **104** includes an extra compartment to house electronics module **110**. In some embodiments, detection module **108** and electronics module **110** are disposed in or on one or more printed circuit boards (PCBs) that are mounted in housing **104** (*i.e.*, a hybrid implementation).

[0060] In some embodiments, electronics module **110** includes a touch display disposed on housing **104** to enable direct interaction with the user via displayed text, graphics, user input, and the like.

[0061] It should be noted that, although this disclosure provides electronics/sensing/display functionality by locating appropriate electronics, *etc.*, in or on the case, some or all of such functionality can be provided via integration into the blister card itself without departing from the scope of the present invention.

[0062] At operation **302**, electronics module **110** monitors the time and date via an onboard clock. In some embodiments, mobile device **114** monitors the time and date. In some embodiments, electronics module **110** requests time and date information from mobile device **114**. In some embodiments, the time and date is tracked in another conventional manner.

[0063] At operation **303**, the state of blister card **102** is monitored. One skilled in the art will recognize that the manner in which the state of blister card **102** is determined is based on the sensing technology employed. As mentioned briefly above, many sensing technologies can be used to sense the state of a blister card and examples of several sensing approaches are discussed in detail below.

[0064] At operation **304**, the state of blister card **102** is compared with the dosing regimen for the prescription it contains (*i.e.*, tablets **210**). In the illustrative embodiment, this comparison occurs periodically each day (*e.g.*, every minute, hour, several hours, *etc.*) throughout the anticipated dosing period of 28 days. In the depicted example, the prescribed dosing regimen is maintained in the mobile app running on mobile device **114**, which provides regimen data to electronics module **110** via input signal **116**. In some embodiments, the dosing regimen is downloaded into a memory module included in

electronics module **110**. In some embodiments, output signal **112** provides blister-card-state information to mobile device **114**, which compares it to the dosing regimen.

[0065] It is an aspect of the present invention that the ability to automatically record dispensing events for a blister card enables improved software, such as mobile apps, for assisting the user to adhere to a prescribed drug regimen. There currently exist numerous cell-phone- and computer-based apps to help OCP adherence through automatic calendar reminders. These apps typically provide features for tracking adherence and some level of management of the efficacy requirements, as well as outline the basic methodology for helping achieve and maintain good adherence and manage the efficacy requirements.

[0066] Conventional OCP apps typically begin with a setup stage when the app is first downloaded. The setup step normally requires a user to input several bits of personal information, such as:

- Log-in credentials;
- Privacy agreement (Agree or Do Not Agree);
- Cycle Length (only the first time the user launches app);
- First day of last period (only the first time user launches app);
- Number of days since the current card was started (only the first time the user launches); and
- Daily Reminder settings:
  - Time or time window to take a pill;
  - Reminder type: alarm, text or email;
  - Customized reminder message (e.g., "Take your Pill");
  - Snooze activation; and
  - Alarm type (e.g., sound).

[0067] Once the app is set up, the routine use methodology includes providing reminder alerts to take the correct pill at the correct time (or within the proper time window). After taking a pill, the user then manually enters the time, date, and the pill taken into the app. The time-date-pill data is stored and is accessible to the user to analyze

for adherence. The adherence data and trend can also be forwarded to one or more designated persons in the care circle of the user.

[0068] The basic limitation of these mobile apps is that the need to manually input all of the necessary data falls to the user, since presently available apps do not have a capability to automatically capture actual adherence data. As a result, prior-art OCP apps are tedious to use, are often incorrectly used, and are most effective only for very motivated patients.

[0069] Automated systems for tracking medication adherence via mobile apps are known; however, these are typically directed toward medication packaged in bottles. These conventional systems incorporate wireless connectivity and sensors to monitor and communicate adherence data in an accompanying mobile app and/or network servers. If a dose is missed, the system provides a reminder alert automatically, either by an indicator on the system itself or sent to the care circle of the user via an automated call or text message. The ability to automatically generate a reminder message represents an important step in supporting good adherence.

[0070] Embodiments of the present invention include apparatus and methods that enable further improvements to the conventional methodology described above, however. It should be noted that, although these improvements are particularly well suited for OCP compliance, they are also suited for use in many other medication compliance applications as well – particularly those that are significantly affected by the quality of adherence. Specifically, the present invention enables improvements to the prior art due to the fact that it enables:

- monitoring of the distance between the instrument and the mobile device via Bluetooth radio signal range (e.g., up to approximately 20 meters);
- comparisons of actual adherence data from the instruments with OCP manufacturer's instructions stored in a mobile app on the mobile device; and
- provision of adherence-status feedback on the instrument itself, as well as through a mobile app.

[0071] As a result, the present invention affords several significant advantages over automated tracking systems of the prior art. For example, the present invention enables an ability to monitor the distance between blister card **102** and a mobile device. This provides

monitoring capability that can determine whether the blister card and the mobile device are within the same general space (e.g., a home). As a result, if, for example, the user were leaving her home without her pills, an alert could be sent to the user. The stridency of the reminder could be weighted in importance depending on whether the next dose were due shortly (e.g., in the next hour or the same day) or not until the following day. In some embodiments, information on an electronic calendar kept on the mobile device is accessed to determine the risk in leaving the pills behind, e.g., does she have an overnight trip scheduled, etc.

[0072] The ability to compare actual adherence information acquired by package **100** to OCP the regimen for blister card **102** enables embodiments of the present invention to provide a user with next recommended steps. This is particularly advantageous when adherence is interrupted, such as when a pill is missed and the user is unsure of how to best mitigate the risk of an unintended pregnancy.

[0073] Further, the present invention enables adherence-status feedback, thereby helping the user to adjust her behavior accordingly. Such feedback also can be provided to the user's care circle for needed intervention toward improving adherence. Still further, in some embodiments, the adherence-status feedback can be stored in long-term memory at a monitoring site for use in long-term care treatment planning, to enable its use as evidence in legal proceedings, civil proceedings (e.g., paternity suits, etc.), and the like.

[0074] In some embodiments, the status of the blister card (e.g., number of pills dispensed, which pills have been dispensed, etc.) is saved at case closure. Upon the next opening of the case, the status of the blister card is again examined and compared to the last saved state. This ensures that untimely change of a blister card is detected and the user is asked related questions through the mobile app. Further, the blister-pack state upon opening provides a baseline against which a state change can be measured. In some embodiments, detection of an unanticipated difference between the blister-pack states at closing and opening gives rise to an alarm, error flag, or transmission to the user and/or third party to alert one or both of the possibility of an error.

[0075] Returning now to method **300**, if operation **304** reveals an improper event, method **300** continues with operation **305A**, wherein an error signal is initiated by electronics module **110**. Improper events that would initiate an error signal to the user or user's care circle include, without limitation:

- i. the dosing-time window has passed and the anticipated tablet **210** has not been dispensed; or
- ii. an incorrect tablet **210** has been dispensed during the dosing-time window; or
- iii. a tablet **210** has been dispensed at a time other than its proper dosing-time window; or
- iv. more than one tablet **210** has been dispensed; or
- v. any combination of i, ii, iii, and iv.

[0076] In addition, in some embodiments, if it has been determined that the time for dispensing a tablet is approaching but the tablet has not been dispensed, a reminder can be sent to the user to encourage her to take the proper pill.

[0077] If operation **304** reveals that the correct tablet **210** has been dispensed within its allotted dosing-time window, at operation **305B**, the time at which the tablet was dispensed is logged into memory by electronics module **110**. In addition, if the tablet dispensed was the last tablet in blister card **102**, method **300** continues with operation **306**, wherein a warning to the user or user's care circle is initiated to alert them that blister card **102** is now empty. In some embodiments, this warning is generated when the number of tablets in the blister card **102** has dropped to a threshold level so as to initiate a refill reminder to the user or user's care circle, or generate a refill request directly to the pharmacy.

[0078] If blister card **102** is not depleted, method **300** continues with the repetition of operations **302** through **306**.

[0079] The mobile app may incorporate additional features to help the user to better manage her health. For example, at operation **305B**, the user may be provided a reward through the mobile and/or an opportunity to input notes into the mobile app, *e.g.*, recording experiencing side effects, having intercourse in the last 24 hours, *etc.* At operation **305A**, the mobile app may provide the user with counseling and education information. Since the point of the cycle for the user is known, the mobile app may provide contextual health and wellness information to the user.

[0080] One skilled in the art will recognize, after reading this Specification, that method **300** is merely one non-limiting, exemplary method for improving a drug regimen and that myriad alternative methods can be employed without departing from the scope of the present invention.

*Sensing Approaches for Monitoring the State of a Blister Card*

[0081] As discussed above, many sensing technologies can be exploited for monitoring the state of a blister card, including capacitive sensing, acoustic sensing, optical sensing, thermal, and tactile sensing. Capacitive-sensing technology is particularly attractive for use with the present invention, however. As a result, in the illustrative embodiment, detection module **108** includes a plurality of capacitive sensors, as described herein.

*Capacitive Sensing*

[0082] FIGS. 6A-B depict schematic drawings of top and cross-sectional views, respectively, of a capacitive-sensing-based detection module in accordance with the illustrative embodiment of the present invention. Detection module **108** comprises substrate **602**, holes **604**, and sensors **606-1** through **606-28** (referred to, collectively, as sensors **606**).

[0083] Substrate **602** is a conventional PCB substrate. Substrate **602** is sized to fit into housing **104** such that it forms the bottom of package **100**. Typically substrate **602** is held in housing **104** via a receiver that is analogous to receiver **106** described above. In some embodiments, substrate **602** is another substrate, such as a semiconductor wafer suitable for planar processing, and the like. In some embodiments, instead of a rigid substrate (e.g., substrate **602**), detection module **108** comprises a substrate that is flexible and optionally visually transparent, as discussed below and with respect to FIGS. 13A-B.

[0084] Holes **604** extend through substrate **602** to allow for the passage of each of tablets **210** through detection module **108** when they are dispensed from the blister card.

[0085] Each of sensors **606** includes an electrode **608** and its respective dispensing region **212** of lidding film **204**. Electrode **608** is a planar, circular metal electrode that completely surrounds hole **604**. Electrode **608** is formed within the body of substrate **602** such that, when blister card **102** is in contact with detection module **108**, the electrode and lidding film **204** form a capacitive sensor **606**, whose capacitance is based on the state of

the lidding film in its respective dispensing region **212**, as depicted in FIG. 6B. In some embodiments, sensors **606** (as well as other sensors described herein) are formed directly on a surface of the bottom of housing **104**, thereby obviating substrate **602**.

[0086] Each of sensors **606** is electrically connected to sensing circuitry in electronics module **110** via electrical traces (not shown for clarity). As a result, each sensor can be monitored individually to enable specificity of the dispensing of each tablet **210** of blister card **102**. In some embodiments, sensors **606** are electrically connected and interrogated using a row/column addressing scheme.

[0087] OCP represents one of many application wherein it is critical to be able to identify when tablet has been dispensed during a dispensing event. One skilled in the art will recognize, however, after reading this Specification, that not all medication requires the ability to uniquely identify the identity of a tablet that has been dispensed and, as a result, the sensing approach used to detect tablet dispensing can be greatly simplified. For example, in some cases, all of the tablets of a blister card are substantially identical. In some embodiments of the present invention, therefore, all of sensors **606** are electrically connected in parallel or serially and specificity for which tablet **210** is dispensed is not enabled. In some such embodiments, a single sensor is used to detect dispensing events, such as an accelerometer operatively coupled with the blister card, a single capacitive sensor that spans all the tablet sites such that each dispensing event is indicated by a change in the capacitance of this solitary capacitor.

[0088] Alternatively, in some embodiments, row/column sensing is simplified to row or column sensing wherein, for example, one electrode of a capacitive sensor is common to an entire row or column of tablet locations, while the other electrode is divided into site-specific individual electrodes.

[0089] In such embodiments, exhaustion of a blister card (which denotes a refill is due) can be detected in numerous ways, such as simply tracking the dispensing events and comparing their count to the total count of the tablets on the blister card as provided or monitoring of the total magnitude of the sensor output signal change with dispensing events and comparing the result with a reference magnitude change determined, for example, by prior calibration operation.

[0090] In each sensor **606**, the conductive material (*i.e.*, lidding film **204**) of its dispensing region **212** forms fringing fields with its electrode **608**. These fringing fields impact the capacitance of the capacitive sensor giving it a first value when the dispensing region is intact. When tablet **210** is dispensed, however, the breakage of dispensing region **212** changes the physical configuration between the lidding film material and electrode **608**, which affects the fringing fields and, therefore, the capacitance of sensor **606**. It should be noted that the capacitance of sensor **606** changes whether or not the material of dispensing region **212** breaks away entirely or pieces of it remain hanging in hole **604** thereafter.

[0091] To sense the capacitance of each sensor **606**, lidding film **204** is electrically grounded, while each electrode **608** is connected to a high-impedance sense circuit. In some embodiments, lidding film **204** is left electrically "floating;" however, grounding the lidding film is preferable because it provides improved sense-signal stability and noise immunity. Unfortunately, sensor **606** can be sensitive to external noise and interference, such as stray or parasitic capacitances, electromagnetic interference (EMI), and the like.

[0092] In some embodiments, in order to mitigate the effects of noise and interference, electrode **608** is segmented into a pair of half-rings. In some embodiments, electrode **608** is segmented into more than two circumferential sections. Using such electrode configurations, capacitive sensing is implemented by monitoring the change in the capacitance between the electrode segments, which is still affected by fringing fields between the electrode segments and the aluminum foil over the hole. Unfortunately, while segmenting electrode **608** provides some measure of noise immunity, noise and interferences can still be a problem.

[0093] FIG. 7 depicts a cross-sectional view of an alternative capacitive sensor having improved noise immunity in accordance with the present invention. Sensor **700** is suitable for use in detection module **108** and comprises substrate **602**, electrode **608**, and electrode **702**. Sensor **700** has significantly improved noise immunity as compared to sensor **606**.

[0094] Electrode **702** is analogous to electrode **608**; however, electrode **702** is formed within substrate **602** such that it is parallel with electrode **608** and located distal to lidding film **204** when blister card **102** is located in package **100**. Electrodes **608** and **702** collectively define a parallel-plate capacitor within substrate **602**.

[0095] Sensor **700** operates in accordance with projected capacitive sensing techniques, such as those described in Microchip Application Note TB3064 entitled, "mTouch™ Projected Capacitive Touch Screen Sensing Theory of Operation," published January 5, 2010, which is incorporated herein by reference.

[0096] FIG. 8 depicts a schematic drawing of the electrical connectivity of sensor **700**.

[0097] In circuit **800**, electrodes **608** and **702** collectively define capacitor **C1**, whose value is determined by the mutual capacitance between the electrodes.

[0098] Electrode **608** and lidding film **204** collectively define capacitor **C2**, whose capacitance is determined by the fringing fields between electrode **608** and the lidding film. These fringing fields are based on the state of detection region **212**.

[0099] Capacitance **C3** is the touch capacitance between electrode **608** and the finger of the user, which develops only while the user is pressing on forming film **202** to push tablet **210** through lidding film **204** and after the lidding film has broken in dispensing region **212**, as discussed below.

[00100] Electrode **608** is also characterized by substantially fixed electrode capacitance **C4**.

[00101] In similar fashion, electrode **702** is characterized by its own substantially fixed electrode capacitance **C5**.

[00102] In operation, electrode **608** is driven as a transmitter and receives drive signal **802** from electronics module **110**. Electrode **702** operates as a receiver and provides output signal **804** to sensing circuitry in electronics module **110**, where the output signal is based on mutual capacitance **C1**.

[00103] Prior to the dispensing of tablet **210**, detection region **212** is whole and fringing capacitance **C2** and mutual capacitance **C1** are substantially unchanging since the physical configuration of their respective elements remains fixed. In addition, the value of capacitor **C3** is substantially zero, since the intact lidding film **204** in the detection region **212** shields electrode **608** from stray capacitance and electrical noise from regions opposite lidding film **204** from the electrodes. In other words, the intact lidding film **204** in the detection region **212** acts as an "electrical shield" for electrode **608**. For

the purposes of this Specification, including the appended claims, an “**electrical shield**” is defined as an element that mitigates the effects of stray capacitance, electrical noise, and electrical interference on an electrical parameter measured at another element.

[00104] When tablet **210** is dispensed, however, detection region **212** is broken, which changes the physical configuration between the conductive material of lidding film **204** and electrode **608** and, therefore, the fringing capacitance of capacitor **C2**. It also enables the capacitance of capacitor **C3** to develop. The change in the configuration of the elements of **C2** affects mutual capacitance **C1**. Since the shielding capability of lidding film **204** is compromised by its breakage in dispensing region **212**, the value of **C1** is further affected by the development of touch capacitance **C3**. The resultant change in **C1** is then detected by the sensing circuitry of electronics module **110**.

[00105] Unfortunately, while an improvement over the noise immunity of sensor **606**, in sensor **700**, high-impedance electrode **702** remains unshielded for noise and interference received from directions other than from the top of housing **104**.

[00106] FIG. 9 depicts a cross-sectional view of another alternative capacitive sensor having improved noise immunity in accordance with the present invention. Sensor **900** is suitable for use in detection module **108** and comprises substrate **602**, electrodes **608** and **702**, and electrode **902**. Sensor **900** has significantly improved noise immunity as compared to sensors **606** and **700**.

[00107] Electrode **902** is analogous to electrode **702**; however, electrode **902** is formed within substrate **602** such that it is parallel with electrodes **608** and electrode **702** but located such that electrode **702** is between electrodes **608** and **902**. Electrodes **608** and **702** collectively define a first parallel-plate capacitor within substrate **602** and electrodes **702** and **902** collectively define a second parallel-plate capacitor with the substrate.

[00108] FIG. 10 depicts a schematic drawing of the electrical connectivity of sensor **900**. In circuit **1000**, electrode **702** operates as a sense electrode that is sandwiched between driving electrodes **608** and **902**, which shield the sense electrode from noise and interference emanating from above blister card **102** and below housing **104**.

[00109] Electrodes **702** and **902** collectively define capacitor **C6**, whose value is determined by the mutual capacitance between these electrodes.

[00110] Electrode **902** and lidding film **204** collectively define capacitor **C7**, whose capacitance is determined by the physical configuration between electrode **902** and lidding film **204**. Like capacitor **C2**, the value of this capacitance is based on the state of detection region **212**.

[00111] Electrode **902** is also characterized by capacitor **C8**, which is analogous to capacitor **C3**, described above.

[00112] Electrode **902** is also characterized by substantially fixed electrode capacitance **C9**.

[00113] The operation of sensor **900** is analogous to that of sensor **700**; however, the fringing-field capacitances of sensor **900** additionally include **C7** and **C8**, whose capacitances are determined by the fringing fields between electrode **902** and lidding film **204**, as well as touch capacitances **C3** and **C8**. As in sensor **700**, the values of fringing-field capacitances **C7** and **C8** are based on the state of detection region **212**, although the value of **C7** can also be influenced by the touch of the user on the back of housing **104**.

[00114] In some embodiments, additional shielding is provided for sense electrodes **702** by adding shielding lines that surround each sense electrode in its plane within substrate **602**.

[00115] FIG. 11 depicts a plan view of a detection module having improved noise immunity by virtue of shield lines formed around each of its sense electrodes. Detection module **1100** is analogous to detection module **108**; however, detection module **1100** includes a plurality of sensors **900** and shield lines **1102**. FIG. 11 depicts a section of detection module **1100** as taken through the plane of electrodes **702**.

[00116] Shield lines **1102** are electrically conductive traces formed such that they nearly completely encircle sense electrodes **702** in the plane of the electrodes. Shield lines **1102** are electrically grounded as depicted in the figure.

[00117] By virtue of the shielding provided by electrodes **608** and **902** and shield lines **1102**, each of sense electrodes **702** is virtually completely shielded from interference from all external noise and EMI sources. It should be noted that shield lines **1102** can also be incorporated into sensors **606** and **700**, described above.

[00118] It should be noted that, in the depicted example, electrodes **702** are optionally electrically connected together in each column of the 7x4 array of sensors **900**. Even though they are electrically connected as shown, each sensor **900** can be individually detected by employing a row-column addressing scheme in which each row of drive electrodes **608** and **902** are driven in either a time-division-multiplexed fashion, or with different drive frequencies. In some embodiments, each of electrodes **702** is individually electrically connected with electronics module **110**.

[00119] FIGS. 12A-B depict measurement results for two individual sensors **900** in response to the sequential dispensing of two tablets from blister card **102**. Plots **1200** and **1202** show the capacitance of mutual capacitor **C6** versus time for two sensors **900** in detection module **1100**. In plot **1200**, tablet **210** is dispensed at a time of 34 seconds. In plot **1202**, tablet **210** is dispensed at a time of 45 seconds. As plots **1200** and **1202** show, for each sensor, the corresponding mutual capacitance changes significantly, enabling detection of each dispensing event. It should be noted that the presence or absence of a tablet **210** in each reservoir **206** can also be determined by the absolute magnitude of these sense capacitances, using a previously calibrated threshold value to indicate presence or absence of a tablet in each reservoir **206**.

[00120] It should be further noted that the sensing principle might also be changed in the implementation of the instrument. In previously filed U.S. Patent Application Serial Number 14/879,874, filed on 10/09/2015 (Attorney Docket: 3005-002US1), and U.S. Patent Application Serial Number 15/170,121, filed 6/1/2016 (Attorney Docket: 3005-002US2), each of which is incorporated herein by reference, the use of electrical impedance tomography (EIT) and electrical capacitance tomography (ECT) to image the state of a blister card (*i.e.*, which pill locations are dispensed and which are intact) and detect dispensing events are disclosed. In some embodiments, the apparatus and methods described therein are employed in the present invention to enable imaging of the state of the OCP card and detect dispensing events.

[00121] Still further, in some embodiments, predictive models/algorithms based on modeling and experimentation are used to relate specific sensor output signatures with dispensing events. The model is then used for tablet identification during a dispensing event based on the sensor output. For example, the output signatures of a motion sensor

in a detection module would enable the location at which a dispensing event occurred to be determined by utilizing a respective predictive model/algorithm.

[00122] FIG. 13A depicts a schematic drawing of a cross-sectional view of package **100** having an alternative capacitive-sensing-based detection module. Package **100** is depicted in its open state and with blister card **102** located in the package by receiver **106** (not shown for clarity). The package cross-section depicted in FIG. 13A is taken through a plane along line b-b depicted in FIG. 4.

[00123] Detection module **1300** includes sensor substrate **602** and sensors **1302-1** through **1302-28** (referred to, collectively, as sensors **1302**), which are arranged on the substrate in an arrangement that matches that of tablets **210** on blister card **102**.

[00124] Detection module **1300** is analogous to detection module **108** described above; however, detection module **1300** is located in lid **402** by a receiver that is analogous to receiver **106** described above (not shown for clarity). The closure of lid **402** brings detection module **1300** into close proximity with blister card **102**, thereby operatively coupling each of sensors **1302** with its respective tablet **210**.

[00125] FIGS. 13B-C depict cross-sectional views a portion of detection module **1300** before and after dispensing of a tablet, respectively, in accordance with the present invention.

[00126] Each of sensors **1302** includes electrodes **1304** and **1306** and shield **1308**.

[00127] Electrodes **1304** and **1306** are electrically conductive electrodes disposed on a first surface of substrate **602**.

[00128] Shield **1308** is an electrically conductive electrode disposed on a second surface of substrate **602**. Shield **1308** is grounded such that it is operative for shielding electrodes **1304** and **1306** from electrical noise and interference emanating from the top side of detection module **1300**. Lidding film **204** is also typically grounded, thereby enabling it to act as a shield from the bottom side for electrodes **1304** and **1306**.

[00129] When lid **402** is closed and tablet **210** is located in reservoir **206**, electrodes **1304** and **1306** are capacitively coupled with tablet **210** via fringing fields

**1310.** As a result, the capacitance between electrodes **1304** and **1306** is based on these fringing fields.

[00130] When lid **402** is closed and reservoir **206** is empty of its tablet, however, fringing fields **1310** are coupled with only the remnants of reservoir **206** (*i.e.*, deformed forming film **202**), which gives rise to a difference in the capacitance between electrodes **1304** and **1306** from that of a filled reservoir because of the different manner in which fringing fields **1310** couple with the empty reservoir.

[00131] In operation, typically, detection module **1300** interrogates blister card **102** each time lid **402** is closed. The output signal from the detection module is then compared to the most recent previous blister-pack state to determine whether a tablet has been dispensed and, if so, which tablet. In some embodiments, the presence or absence of a tablet **210** in each reservoir **206** is determined by a change in the absolute magnitude of sense capacitances between lid closures, using a previously calibrated threshold value to indicate presence or absence of a tablet in each reservoir **206**.

[00132] FIGS. 13D-E depict cross-sectional views of a portion of yet another alternative capacitive-sensing-based detection module, before and after dispensing of a tablet, respectively, in accordance with the present invention. Detection module **1312** is analogous to detection module **1300** described above; however, detection module **1312** is a flexible detection module that is dimensioned and arranged to be placed in contact with blister card **102** during operation.

[00133] Detection module **1312** includes substrate **1314** and the plurality of capacitive sensors **1302**, as described above.

[00134] Substrate **1314** is a flexible substrate comprising polyimide. In some embodiments, substrate **1314** is formed of another material suitable for flexible electronics, such as a polymer, such as poly(methylacrylate) (PMMA), polyimide, polyurethane, polyester, polyether ether ketone (PEEK), and the like. Preferably, substrate **1314** is sufficiently flexible to enable a force applied to it to deform forming film **202** and push tablet **210** through lidding film **204**.

[00135] When detection module **1312** is in contact with blister card **102**, electrodes **1304** and **1306** are capacitively coupled with tablet **210** via fringing fields **1310**. As discussed above, the capacitance between electrodes **1304** and **1306** is based on

fringing fields **1310** such that the capacitance of each sensor **1302** is based on the presence of its respective tablet **210**.

[00136] The use of a flexible substrate also enables integration of detection module **1312** in or on forming film **202**.

[00137] In some embodiments of the present invention, detection module **1312** is formed such that it includes an interior volume for receiving blister card **102** (*i.e.*, detection module has the form analogous to a flexible pouch). The interior volume is dimensioned and arranged such that, when blister card **102** is located in the pouch, the pouch holds the blister card in intimate contact on the top (forming-film side) and bottom surfaces (lidding-film side). The top and bottom surfaces of the pouch incorporate holes to enable access to reservoirs **206** and dispensing regions **212**. Alternatively, as described in some embodiments above, the detection module may include a substrate that is sufficiently flexible to partially or fully cover the topside holes. It should be noted that such embodiments of the present invention can be implemented using more than one of the different sensing approaches described herein. These embodiments are particularly well suited for use with capacitive sensing and tactile sensing techniques.

#### Acoustic Sensing

[00138] FIGS. 14A-B depict cross-sectional views of a portion an alternative acoustic-sensing-based detection module, before and after dispensing of a tablet, respectively, in accordance with the present invention. Detection module **1400** is analogous to detection module **108** described above; however, detection module **1400** includes substrate **602** and a plurality of acoustic sensors **1402**, each of which is operative for detecting the presence of a tablet in a blister-card reservoir when the detection module is operatively coupled with a blister card from its forming-film side.

[00139] Each of acoustic sensors **1402** comprises transmitter **1404** and acoustic detector **1406**.

[00140] Transmitter **1404** is a piezoelectric transducer operative as a conventional acoustic transmitter. Transmitter **1404** is arranged to direct acoustic energy (*e.g.*, ultrasonic waves, *etc.*) toward tablet **210** when detection module **1400** is aligned with blister card **102**.

[00141] Acoustic detector **1406** is a piezoelectric transducer operative as a conventional acoustic receiver. Acoustic detector **1406** is arranged to receive acoustic energy from the direction of tablet **210** when detection module **1400** is aligned with blister card **102**.

[00142] In the depicted example, detection module **1400** is mounted on the inside surface of lid **402** of housing **104**. Sensors **1402** are arranged on substrate **602** such that, when lid **402** is closed, the sensors are brought into contact with reservoirs **206** of blister card **102** to operatively couple each sensor with a different reservoir. In some embodiments, sensors **1402** and reservoirs **206** are separated by a small air gap when lid **402** is closed. In some embodiments, detection module **1400** is located within housing **104** via a receiver, as discussed above.

[00143] One skilled in the art will recognize, after reading this Specification, that the acoustic impedance of reservoir **206** is different when it is occupied with a tablet **210** versus when the reservoir is empty. In operation, each time lid **402** is closed, each of sensors **1402** provides an electrical signal whose magnitude is indicative of whether its respective reservoir contains a tablet. When a change in the acoustic impedance from the previous interrogation of blister card **102** is sensed, electronics module **110** can determine that a tablet-dispensing event has occurred, as well as identify which tablet has been dispensed. In some embodiments, the presence or absence of a tablet **210** in each reservoir **206** determined based on the absolute magnitude of acoustic signatures, using previously calibrated threshold values to indicate presence or absence of a tablet in each reservoir **206**.

[00144] In some embodiments, detection module **1400** comprises a flexible substrate that is analogous to substrate **1312** described above. In such embodiments, sensors **1402** are formed in such substrate using flexible piezoelectric films (*e.g.*, polyvinylidene fluoride or polyvinylidene difluoride, also known as PVDF, *etc.*) in accordance with conventional flexible-electronics fabrication technology. As discussed above, the use of a flexible substrate in detection module **1400** enables a force applied to the detection module to deform forming film **202** and push tablet **210** through lidding film **204**. It also enables integration of detection module **1400** in or on forming film **202**. Further, in some embodiments, a flexible substrate enables the use of the piezoelectric materials of sensors

**1402** to harvest mechanical energy (e.g., such as that generated while a tablet is being dispensed) and convert it into electrical energy usable for powering detection module **1400**.

[00145] One skilled in the art will recognize that detection module **1400** can be dimensioned and arranged for operation from the lidding film side of blister card **102** without departing from the scope of the present invention.

[00146] In some embodiments, transmitter-free acoustic sensing is achieved by disposing three or more microphones on blister card **102**.

[00147] FIG. 15 depicts a schematic drawing of a perspective view of a blister card comprising a plurality of microphones in accordance with another acoustic-sensing-based embodiment of the present invention. Blister card **1500** is analogous to blister card **102**; however, blister card **1500** includes six microphones **1502**, which are disposed on forming film **202** and distributed across its area.

[00148] In operation, each microphone detects the sound of a tablet being dispensed. Signal processing capability included in electronics module **110** and/or mobile device **114** processes the outputs of the microphones to triangulate the sound and identify the specific tablet location at which it originates.

[00149] In some embodiments, detection module **1500** comprises a flexible substrate, which is placed in contact with blister card **102** within housing **104**.

[00150] In some embodiments, detection module **1500** comprises a conventional PCB substrate that is mounted on the inside surface of lid **402** of housing **104**.

[00151] In some embodiments, microphones **1502** are disposed on a PCB substrate having holes that enable force to be applied to reservoirs **206**. For example, the PCB substrate would be in the shape of a frame, running along one or more of the inside sidewalls of the housing **104** adjacent to the blister card **102**. In some embodiments, detection module **1500** is mounted therein. In some embodiments, detection module **1500** is located therein via a receiver.

#### Tactile Sensing

[00152] FIGS. 16A-B depict cross-sectional views of a portion of a tactile-sensing-based detection module, before and after dispensing of a tablet, respectively, in accordance with the present invention. Detection module **1600** is analogous to detection

module **108** described above; however, detection module **1600** includes substrate **602** and a plurality of tactile sensors **1602**, each of which is operative for detecting the presence of a tablet in a blister-card reservoir when detection module **1600** is operatively coupled with blister card **102** from its forming-film side. Sensors **1602** are disposed on substrate **602** in an arrangement that substantially matches the arrangement of tablets in blister card **102**.

[00153] In the depicted example, detection module **1600** is mounted on the inside surface of the lid **402** of housing **104**. In some embodiments, detection module **1600** is located within housing **104** via a receiver, as discussed above.

[00154] In the depicted example, each of tactile sensors **1602** includes electrodes **1604** and **1606** and optional shield **1308**.

[00155] Each of tactile sensors **1602** is a parallel plate capacitor comprising conventional planar electrodes **1604** and **1606** and projection **1608**, which is a projection of soft dielectric material (*e.g.*, PMMA, *etc.*) disposed between and around electrodes **1604** and **1606**. The capacitance of sensor **1602** is based on the spacing between its electrodes.

[00156] In operation, when lid **402** is closed, sensors **1602** are put into contact with reservoirs **206**. When a tablet is contained in a reservoir, a pressure/force is generated between sensor **1602** and the reservoir, which is sufficient to depress the forming film **202** of the reservoir **206** but not large enough to break the lidding film **204** in the dispensing region **212**. This force causes compression of the material between electrodes **1604** and **1606**, giving rise to a relatively large capacitance for sensor **1602**. When a sensor is placed in contact with a reservoir that does not contain a tablet, however, little, if any, force is generated between the sensor and the reservoir. As a result, the amount of compression of the material between electrodes **1604** and **1606** is minimal, giving rise to a relatively lower capacitance for the sensor.

[00157] At each closure of lid **402**, therefore, electronics module **110** reads the capacitance of each sensor **1602** and determines which tablets have been dispensed from blister card **102**.

[00158] In some embodiments, the region between electrodes **1604** and **1606** is occupied by a piezoelectric material, which provides an electrical output based on the force applied to tactile sensor **1602**. Such embodiments allow for harvesting energy from

the piezoelectric material to detect the state of the blister card **102** and power the detection module **1600**.

[00159] In some embodiments, substrate **602** is replaced with a flexible substrate, such as substrate **1314**. Typically, sensors **1602** are formed in such a substrate using flexible electronics fabrication technology. In such embodiments, detection module **1600** is sufficiently flexible to enable a force applied to it to deform forming film **202** to push tablet **210** through lidding film **204**. Such embodiments enable integration of detection module **1600** in or on the forming film of the blister card.

[00160] In some embodiments, the detection module **1600** is operatively coupled with the blister card from its lidding-film side. Sensors **1602** are arranged between dispensing regions **212**, such that they are operative for sensing forces imparted to blister card **104** during each dispensing operation.

[00161] It would be obvious to one skilled in the art, after reading this Specification, that there are a variety of ways to implement tactile sensing. For example, sensors **1602** can be realized based on any principle that generates a detectable signal, electrical or other, as a result of a tactile stimulus. A broader interpretation of tactile sensing would for example include measurement of deformations of the blister card **102** or surfaces of the housing **104** by utilizing strain sensors on/in flexible substrates directly printed on such surfaces.

#### Optical Sensing

[00162] FIGS. 17A-B depict cross-sectional views of a portion of an optical-sensing-based detection module, before and after dispensing of a tablet, respectively, in accordance with the present invention. Detection module **1700** is analogous to detection module **108** described above; however, detection module **1700** includes substrate **602** and a plurality of optical sensors **1702**, each of which is operative for detecting the presence of a tablet in a blister-card reservoir when the detection module is operatively coupled with a blister card from its forming-film side. In the depicted example, detection module **1700** is located on the inside surface of lid **402**.

[00163] Each of sensors **1702** comprises photodetector **1704**, which is operative for detecting light **1706**. The plurality of photodetectors are disposed on

substrate **602** in an arrangement that substantially matches that of tablets **210** of blister card **102**.

[00164] In the depicted example, light **1706** is ambient light that originates outside housing **104**. In some embodiments, light **1706** is provided by a light source included within package **100**, typically mounted underneath detection module **108**. Light sources in accordance with the present invention include, without limitation, diffuse light sources, arrays of light emitters (*e.g.*, LEDs, lasers, *etc.*) aligned with photodetectors **1704**, *etc.*

[00165] In operation, when a tablet **210** is dispensed, opaque lidding film **204** is fractured, thereby enabling light to pass through detection region **212** of that tablet site to reach photodetector **1704**. As a result, detection of light by a photodetector signals that a tablet has been dispensed from its respective sensor location. In some embodiments, the state of blister card **102** is interrogated after each time lid **402** is closed.

[00166] Although detection module **1700** is disposed on the top side (*i.e.*, forming-film side) of blister card **102** in the depicted example, it will be clear to one skilled in the art, after reading this Specification, how to make and use alternative embodiments of the present invention wherein detection module **1700** is disposed on the bottom side (*i.e.*, lidding-film side) of blister card **102** such that light signal **1706** passes through the blister card from the top side to the bottom side. In some of these embodiments, the state of blister card **102** is determined at the opening of lid **402**.

[00167] In some embodiments, the substrate of detection module **1700** is formed of a transparent, flexible substrate comprising a substantially transparent polymer, such as PMMA, polyimide, polyurethane, polyester, PEEK, and the like. In such embodiments, detection module **1700** can be located in contact with blister card **102**. Preferably in such embodiments, the substrate is made of a material suitable for the formation of flexible electronics and is sufficiently flexible to enable a force applied to it to deform forming film **202** to push tablet **210** through lidding film **204**. The use of a flexible substrate also enables integration of detection module **1700** in or on forming film **202**.

[00168] In some embodiments, detection module **1700** includes planar-lightwave circuits (PLCs) whose surface waveguides convey light generated from a source remote to sensors **1702** to each sensor and collect light transmitted through the sensor

region and convey it to a remote detector. Preferably, in such embodiments, the PLCs are substantially parallel with blister card **102** and light is coupled from the PLCs into and out of the sensor region via vertical grating couplers.

[00169] FIGS. 18A-B depict cross-sectional views of a portion of an optical-sensing-based detection module, before and after dispensing of a tablet, respectively, in accordance with the present invention. Detection module **1800** is analogous to detection module **1700** described above; however, detection module **1800** is located on the inside bottom surface of housing **104** and operates in reflection mode. Detection module **1800** includes a plurality of sensors **1802**, which is arranged to match the arrangement of tablets in blister card **104**.

[00170] Each sensor **1802** includes a photodiode **1704**, which is dimensioned and arranged to detect light reflected from lidding film **204** only when its respective dispensing region **212** is intact. In the depicted example, sensors **1802** detect ambient light. In some embodiments, each of sensors **1802** also includes a light source for illuminating dispensing region **212**. In some embodiments, a single light source is included in detection module **1800** to illuminate the entire lidding film with diffused light.

#### Thermal Sensing

[00171] As mentioned briefly above, thermal sensing can also be used to detect a tablet dispensing event in accordance with the present invention. By monitoring heat conduction across each dispensing region **212** of blister card **102**, detection of the breaking of the lidding film in the dispensing region can be detected. In some embodiments, a first resistor disposed on lidding film **204** at one side of dispensing region **212** is driven to generate heat into the lidding film. The heat is then detected by a temperature sensor disposed on the lidding film **204** on the other side of the dispensing region. When the temperature of the heater is increased by an incremental amount, if the lidding film is intact in the dispensing region, a temperature rise is detected by the temperature sensor. When the lidding film is broken, however, heat conduction through dispensing region **212** is impeded and the detected temperature rise at the temperature sensor is significantly smaller.

[00172] It should be noted that the concepts of the present invention are applicable to smart packages suitable for monitoring the state of multiple blister packs.

[00173] FIG. 19 depicts a schematic drawing of a perspective view of a multi-blister-card package in accordance with an alternative embodiment of the present invention. Package **1900** is a metapackage that is operative for monitoring the state of multiple blister cards **102**, where each blister card can have a different prescription or multiple copies of the same prescription.

[00174] Package **1900** includes housing **1902**, electronics module **110**, receivers **1904-1** through **1904-N** and detection modules **1906-1** through **1906-N**. Package **1900** is dimensioned and arranged to receive and locate blister cards **102-1** through **102-N**.

[00175] Housing **1902** is analogous to housing **104**; however, housing **1902** is dimensioned and arranged to contain multiple receivers, detection modules, and blister cards.

[00176] Each of receivers **1904-1** through **1904-N** (referred to, collectively, as receivers **1904**) is analogous to receiver **106**; however, each receiver **1904** includes a hinge that enables it to be rotated out to expose a different blister card.

[00177] Each of detection modules **1906-1** through **1906-N** (referred to, collectively, as detection modules **1906**) is analogous to detection module **108**; however, each detection module **1906** is dimensioned and arranged to monitor the status of a different blister card. In some embodiments, detection modules **108** employ multiple sensor technologies.

[00178] Each of detection modules **1906** is electrically coupled with electronics module **110** as described above, which enables operation of package **408** as described above and with respect to package **100**.

[00179] It is to be understood that the disclosure teaches just some examples of embodiments of the present invention and that many variations of the invention can easily be devised by those skilled in the art after reading this disclosure and that the scope of the present invention is to be determined by the following claims.

What is claimed is:

**1.** A system for monitoring the state of at least one blister card (102) that includes a forming film (202), a lidding film (204), and a first tablet (210) contained in a first reservoir (206) defined by the forming film and the lidding film, wherein the system comprises:

a housing (104) that is operative for locating the blister card in a first position;  
a first detection module (108) comprising a first sensor (606-1), wherein the first sensor is operative for providing a first electrical signal (804) that is based on at least one of (a) the presence of the first tablet in the first reservoir and (b) the physical state of a first dispensing region (212) of the lidding film; and  
an electronics module (110) that is operative for providing a first output signal (112) based on the first electrical signal.

**2.** The system of claim 1 wherein the first sensor includes a first capacitor (C2) having a first capacitance that is based on the physical state of the first dispensing region, and wherein the first electrical signal is based on the first capacitance.

**3.** The system of claim 2 wherein a first electrode (608) and the first dispensing region collectively define the first capacitor, and wherein the first capacitance has a first magnitude when the first dispensing region is intact and a second magnitude when the first dispensing region is broken, and wherein the first electrical signal is based on the first capacitance.

**4.** The system of claim 2 wherein the first sensor includes a first electrode (608) and a second electrode (702), the first and second electrodes collectively defining the first capacitor (C1), and wherein the capacitance of the first capacitor is based on a fringing field between the dispensing region and the first electrode.

**5.** The system of claim 2 wherein the first sensor includes a first electrode (608), a second electrode (702), and a third electrode (902), the second and third electrodes collectively defining the first capacitor (C6), and the first and second electrodes collectively defining a second capacitor (C1) having a second capacitance that is based on a fringing field between the dispensing region and the first electrode, and wherein the first capacitance is based on the second capacitance.

**6.** The system of claim 5 wherein the second electrode is between the first electrode and third electrode, and wherein the first electrode and third electrode collectively define an electrical shield for the second electrode.

**7.** The system of claim 6 further comprising a shielding line (1102) that substantially surrounds the second electrode in a first plane, wherein the first electrode, third electrode, and shielding line collectively define an electrical shield for the second electrode.

**8.** The system of claim 1 wherein the electronics module is operative for providing the first output signal as a wireless signal.

**9.** The system of claim 1 wherein the first sensor includes:  
an acoustic transmitter (1404) that transmits a first acoustic signal; and  
an acoustic receiver (1406) operative for providing the first electrical signal based on the magnitude of a second acoustic signal;

wherein the acoustic transmitter and acoustic receiver are arranged such that the acoustic transmitter transmits the first acoustic signal toward the first reservoir and the acoustic receiver receives the second acoustic signal as a reflection of the first acoustic signal from the first reservoir; and

wherein the second acoustic signal has a first magnitude when first reservoir contains the first tablet and a second magnitude when the first reservoir does not contain the first tablet.

**10.** The system of claim 1 wherein the first sensor (1602) is operative for detecting a force applied to the first reservoir.

**11.** The system of claim 1 wherein the first sensor includes a photodetector (1704) that is dimensioned and arranged to provide the first electrical signal based on a first light signal (1706) received from the first reservoir.

**12.** The system of claim 11 wherein the first light signal comprises ambient light.

**13.** The system of claim 11 wherein the first sensor further includes a light source that is operative for transmitting a second light signal toward the first reservoir, and wherein the first light signal is based on the second light signal.

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**14.** A system that is operative for monitoring the state of a first blister card (102-1), the first blister card including a first forming film (202), a first lidding film (204), and a first plurality of tablets (210) that are arranged in a first arrangement, wherein the system comprises:

a first detection module (1906-1) comprising a first plurality of sensors (606) arranged in the first arrangement, wherein each sensor of the first plurality thereof is operative for providing an electrical signal (804) of a first plurality thereof such that each electrical signal of the first plurality thereof is based on the physical state of a different dispensing region (212) of the first lidding film; and

an electronics module (110) operative for providing a first output signal (112) based on the first plurality of electrical signals.

**15.** The system of claim 14, wherein the system is further operative for monitoring the state of a second blister card (102-2), the second blister card including a second forming film, a second lidding film, and a second plurality of tablets that are arranged in a second arrangement, wherein the system further comprises:

a second detection module (1906-2) comprising a second plurality of sensors arranged in the second arrangement, wherein each sensor of the second plurality thereof is operative for providing an electrical signal of a second plurality thereof such that each electrical signal of the second plurality thereof is based on the physical state of a different dispensing region of the second lidding film;

wherein the electronics module is further operative for providing a second output signal based on the second plurality of electrical signals.

**16.** The system of claim 14 wherein at least one sensor of the first plurality thereof is operative for interrogating its respective dispensing region optically.

**17.** The system of claim 14 further comprising a tactile sensor (1602) that is operative for detecting a force applied to the blister card.

**18.** The system of claim 14 wherein the at least one sensor (1602) of the first plurality thereof is operative for detecting a force applied to a first tablet of the plurality thereof.

**19.** The system of claim 14 wherein a first sensor of the first plurality thereof includes a first capacitor (C2) having a first capacitance that is based on the physical state of the first sensor's respective dispensing region, and wherein a first electrical signal of the plurality thereof is based on the first capacitance.

**20.** The system of claim 19 wherein the first sensor includes a first electrode (608) that is capacitively coupled with the first sensor's respective dispensing region to define the first capacitor.

**21.** The system of claim 19 wherein the first sensor includes a first electrode (702) and a second electrode (608) that collectively define the first capacitor (C1), and wherein the first capacitance is based on a fringing field between the first sensor's respective dispensing region and the first electrode.

**22.** The system of claim 21 wherein the first electrode is operative as an electrical shield for the second electrode.

**23.** The system of claim 19 wherein the first sensor includes a first electrode (608), a second electrode (702), and a third electrode (902), the first electrode and second electrode collectively defining a second capacitor (C1), and the second electrode and the third electrode collectively defining the first capacitor (C6), and wherein the first capacitance is based on a fringing field between the first sensor's respective dispensing region and the first electrode.

**24.** The system of claim 23 wherein the second electrode is between the first electrode and third electrode, and wherein the first electrode and third electrode are operative as an electrical shield for the second electrode.

**25.** The system of claim 24 further comprising a shielding line (1102) that substantially surrounds the second electrode in a first plane, wherein the first electrode, third electrode, and shielding line collectively define an electrical shield for the second electrode.

**26.** The system of claim 14 wherein the electronic module is operative for providing the first output signal as a wireless signal.

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**27.** A method for monitoring the state of a blister card (102) that includes a forming film (202), a lidding film (204), and a plurality of tablets (210) that are arranged in a first arrangement, wherein the method comprises:

providing a detection module (108) comprising a plurality of sensors (606) that is arranged in the first arrangement;

operatively coupling the plurality of sensors and the blister card such that each sensor of the plurality thereof is operative for providing an electrical signal (804) based on the presence of a different tablet of the plurality thereof in the blister card;

determining a physical state of the blister card based on the plurality of electrical signals;

comparing the physical state of the blister card with an expected state of the blister card, wherein the expected state is based on a predetermined prescription regimen for the plurality of tablets; and

providing an output signal (112) based on the physical state of the blister card relative to the expected state.

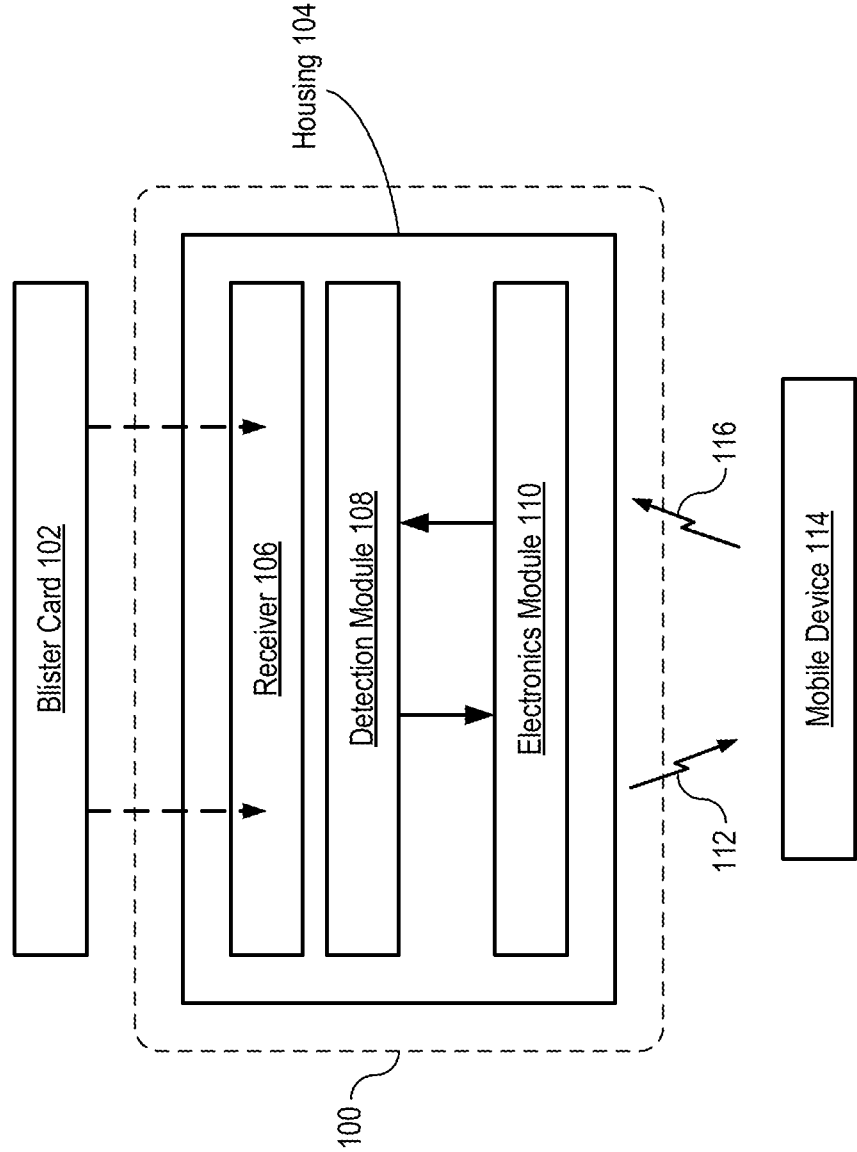
**28.** The method of claim 27 wherein the output signal is provided as a wireless signal.

**29.** The method of claim 27 further comprising monitoring the time and date, wherein the expected state is based on the monitored time and date.

**30.** The method of claim 27 further comprising initiating an error signal if the physical state and expected state are different.

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FIG. 1



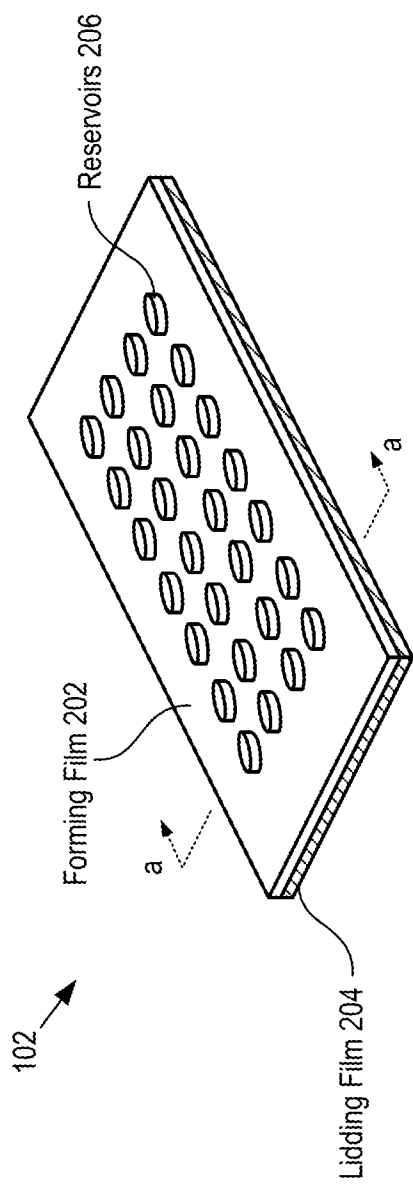


FIG. 2A

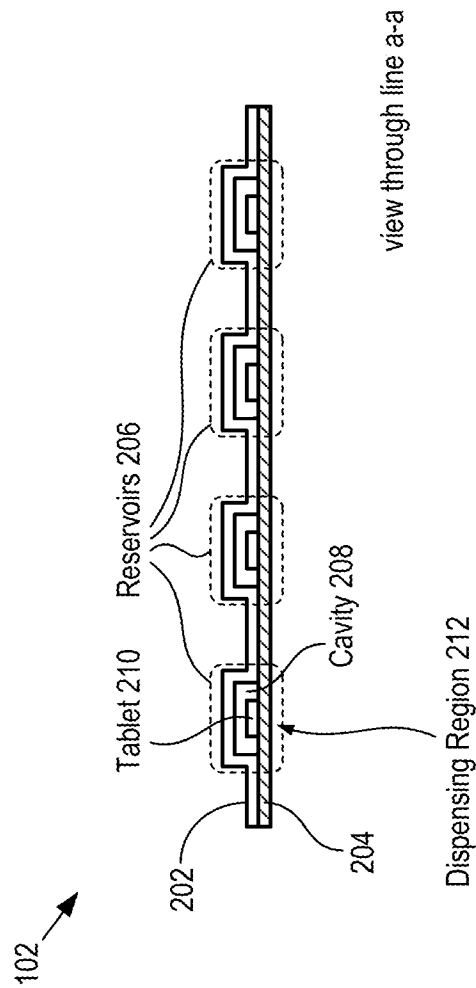


FIG. 2B

FIG. 3

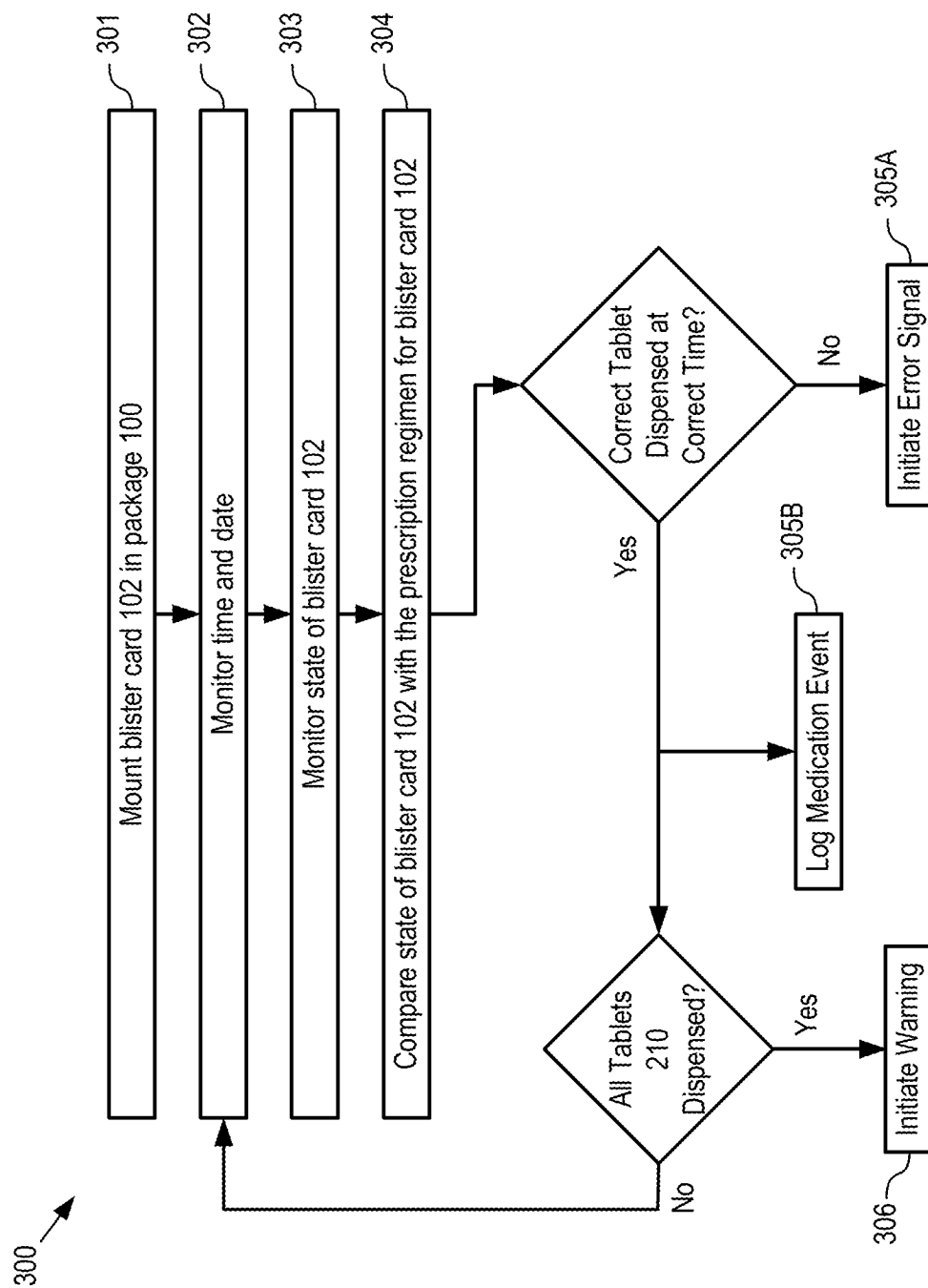


FIG. 4

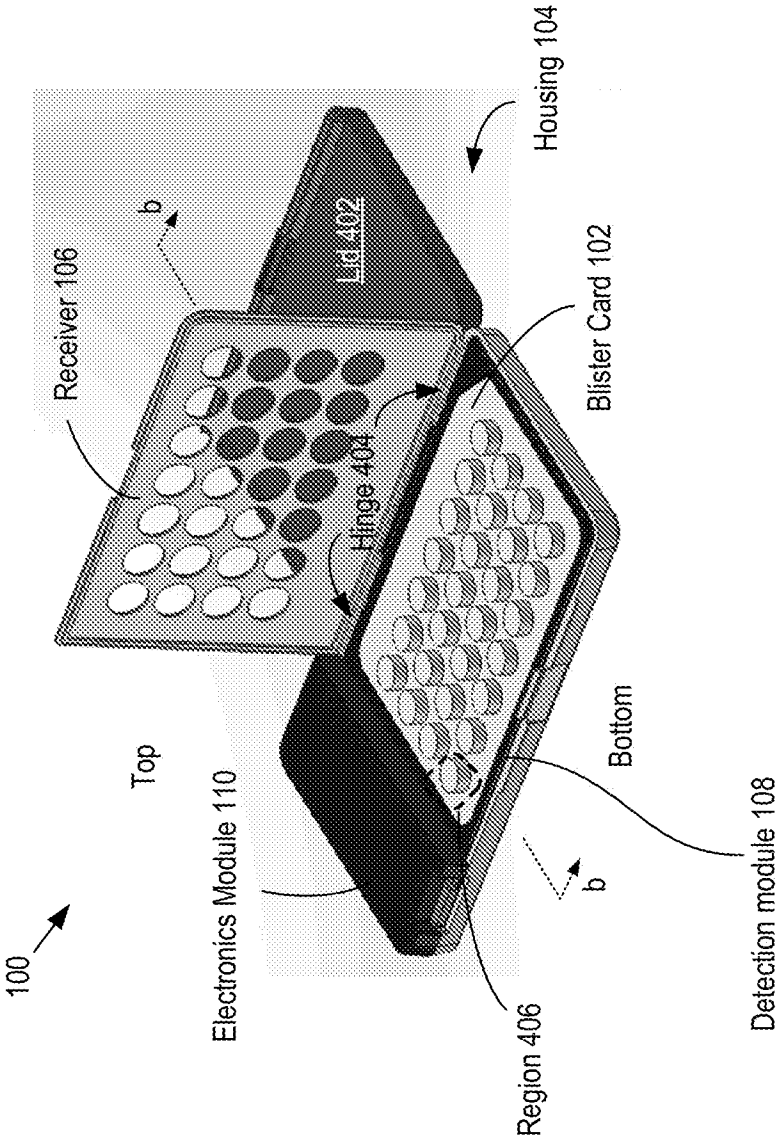
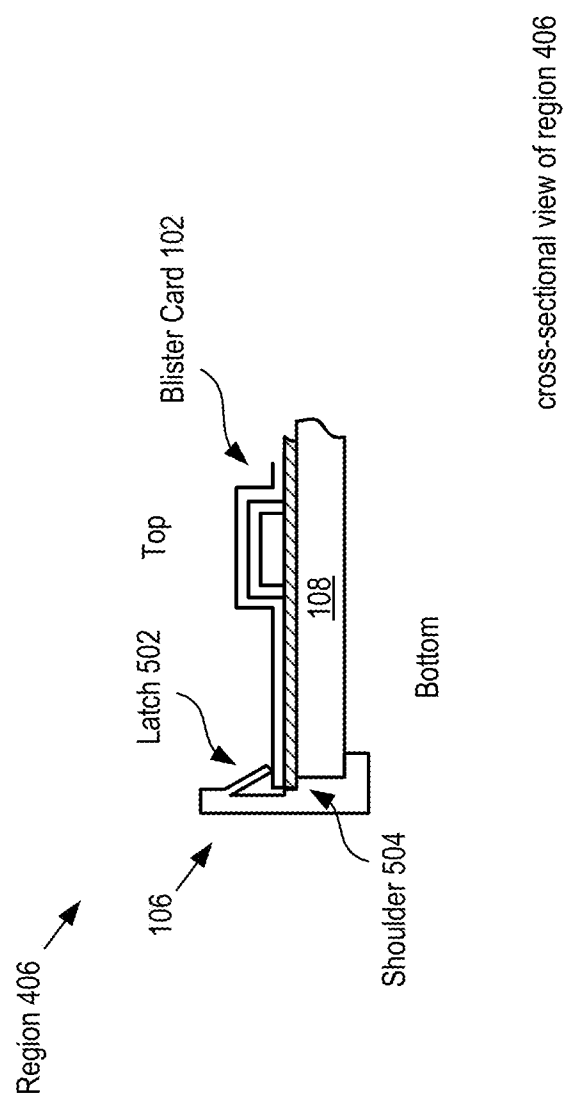


FIG. 5



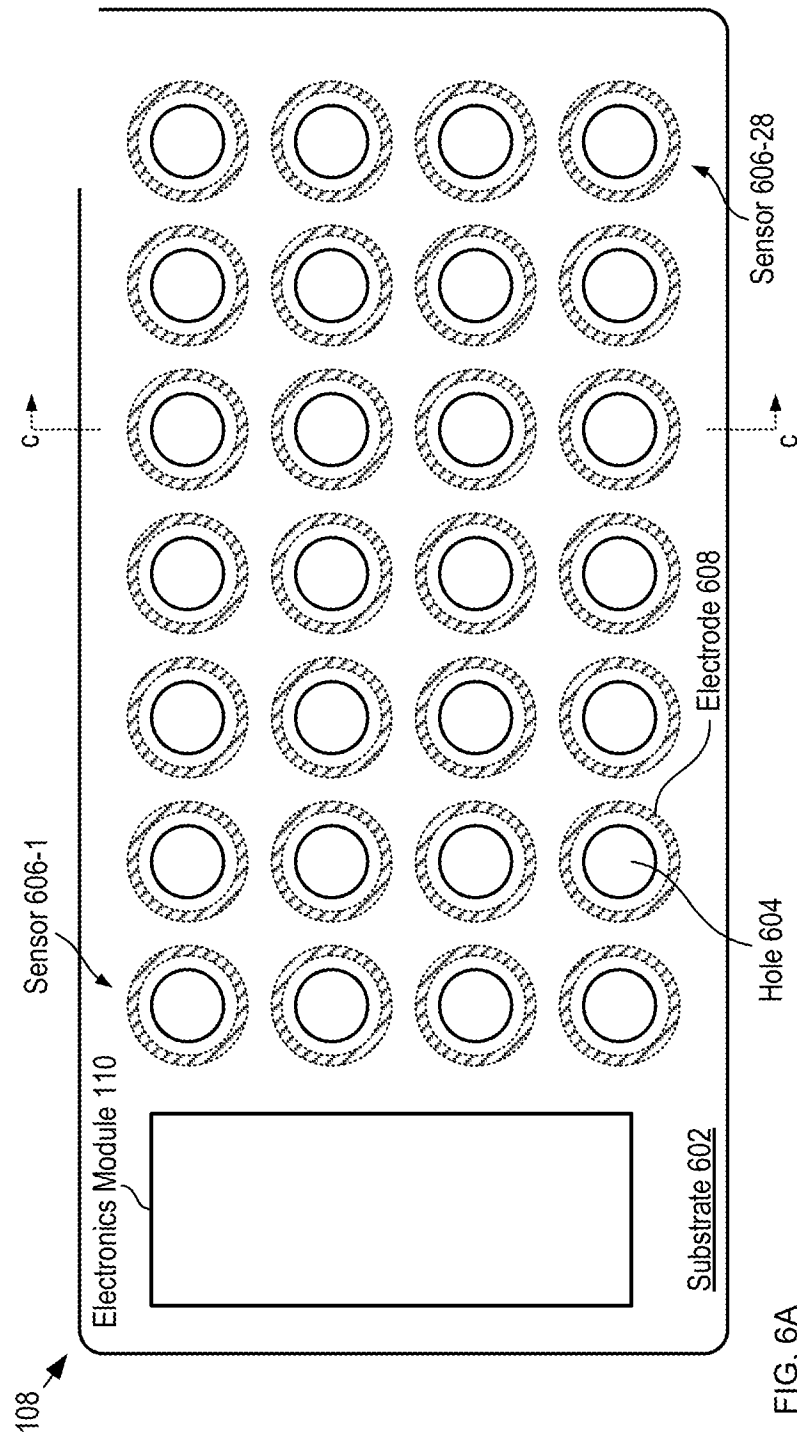


FIG. 6A

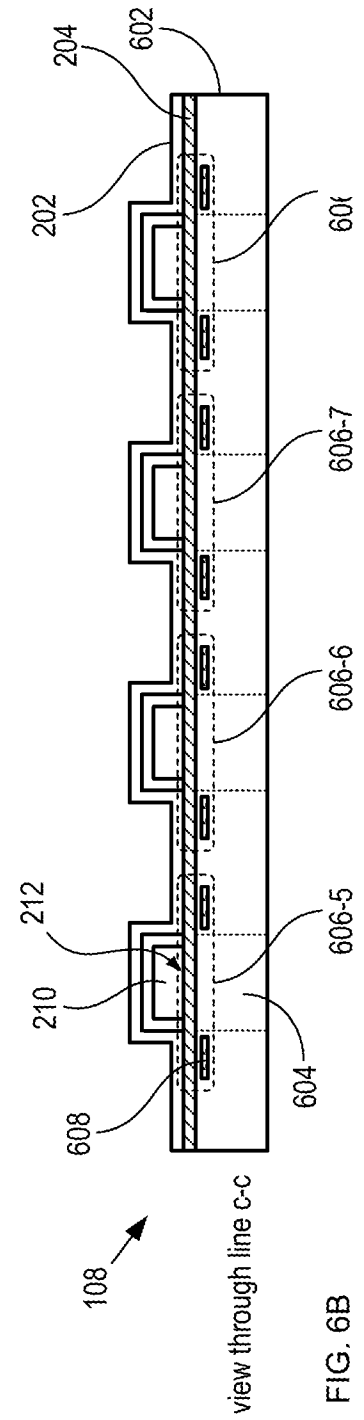


FIG. 6B

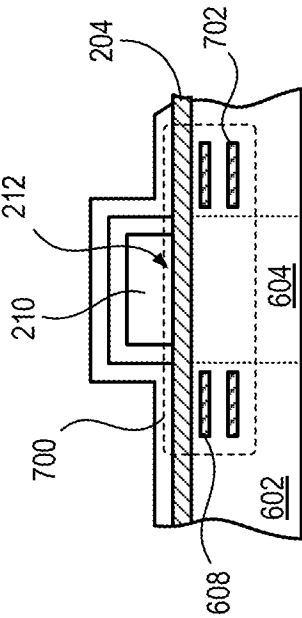


FIG. 7

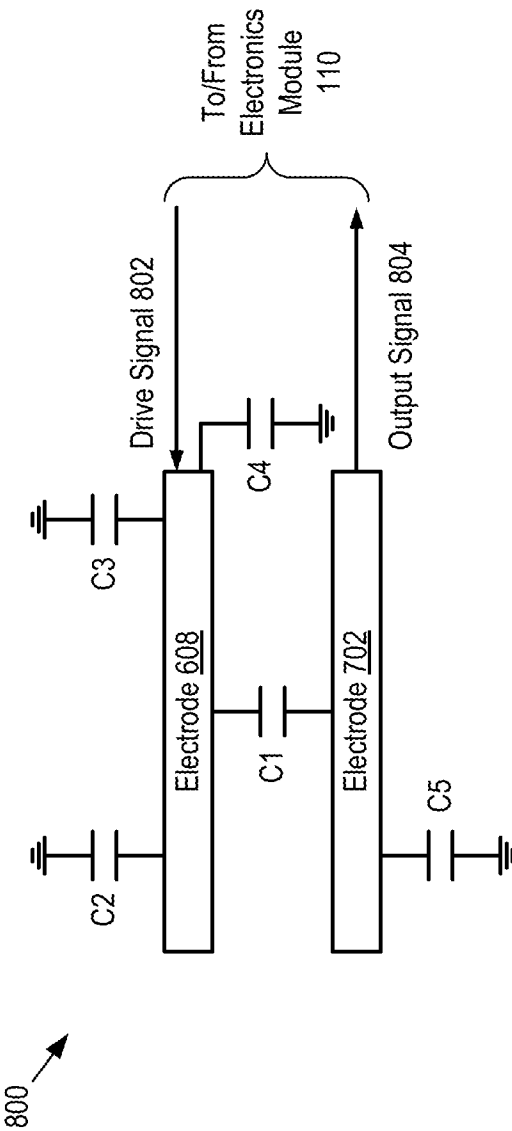


FIG. 8

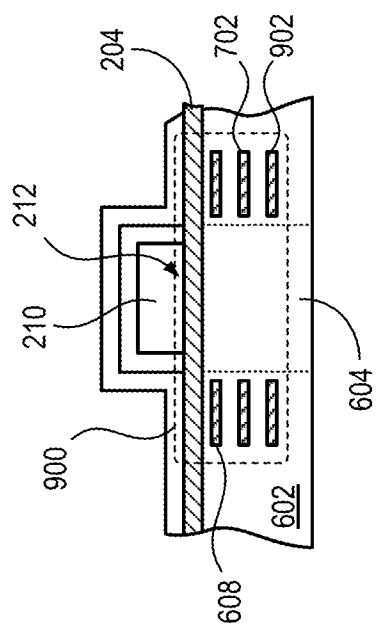


FIG. 9

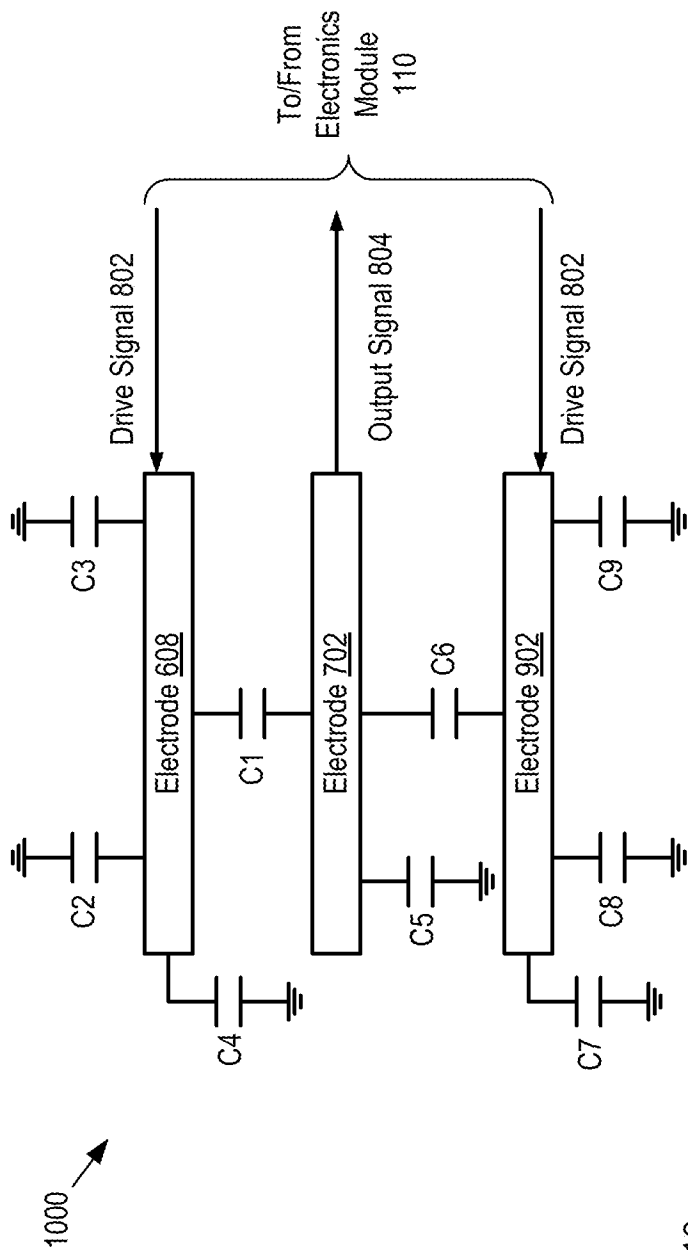
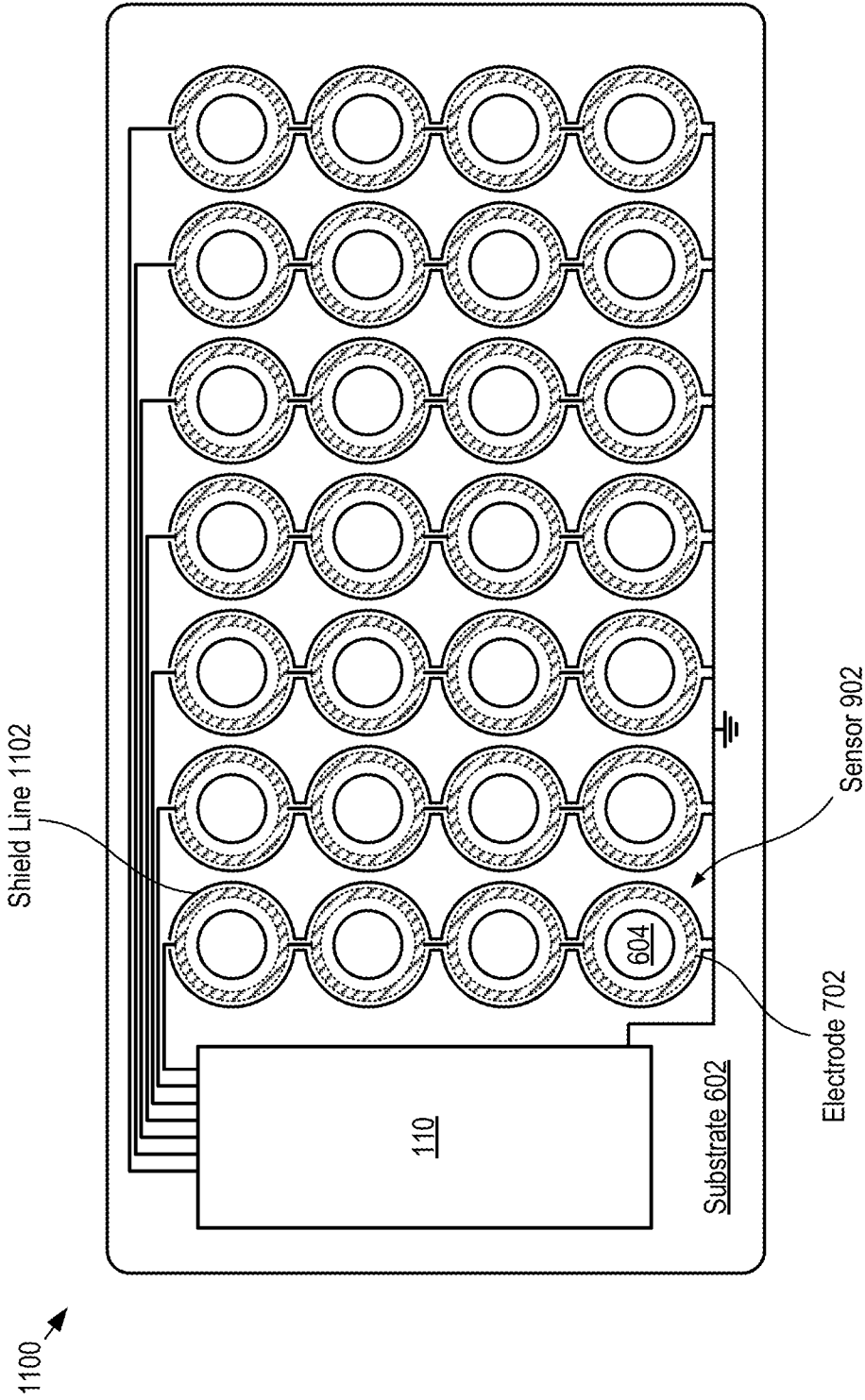
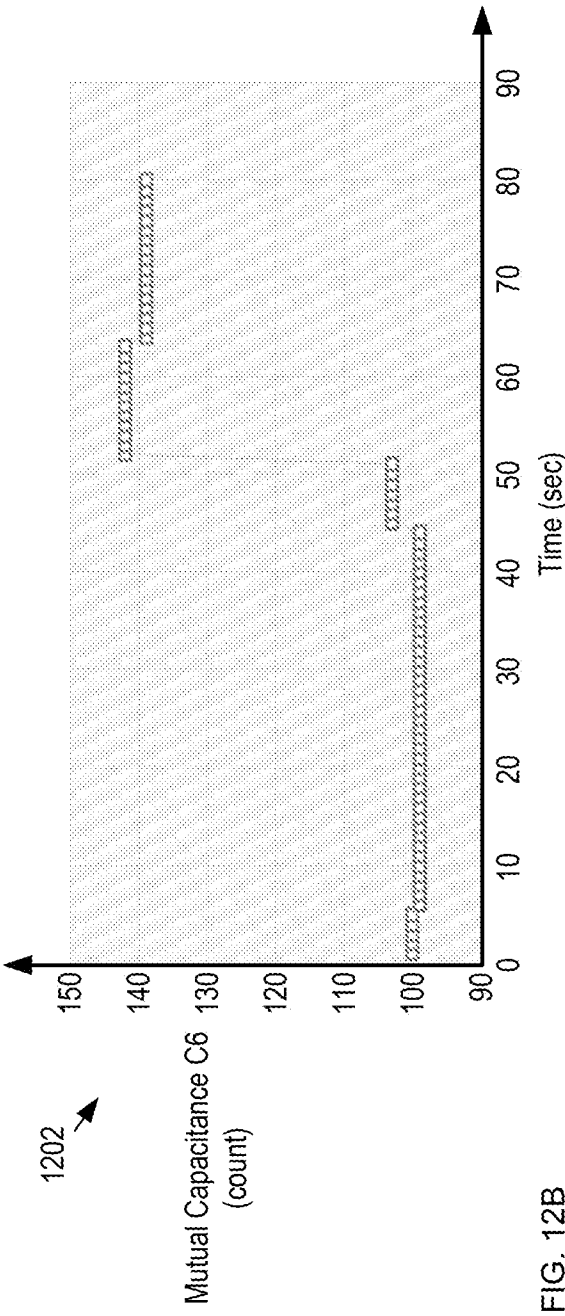
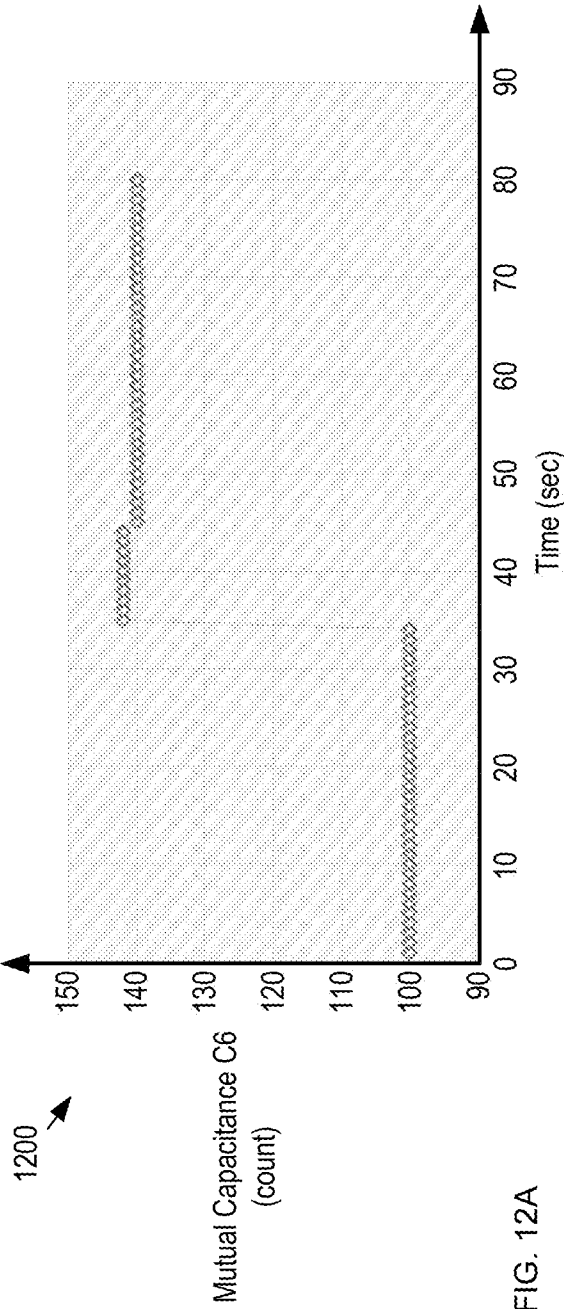


FIG. 10

FIG. 11





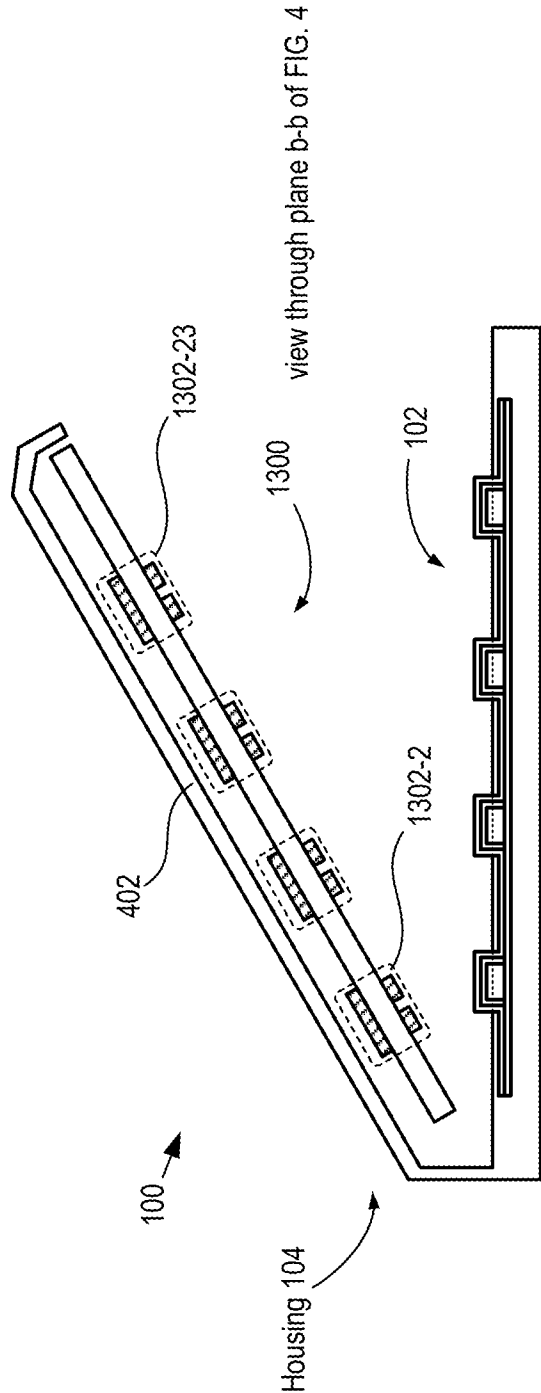


FIG. 13A

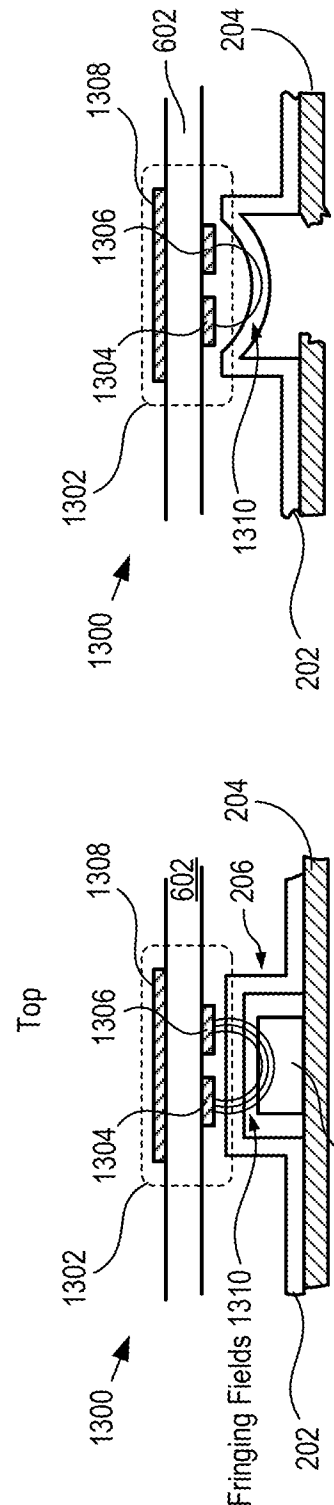


FIG. 13B

FIG. 13C

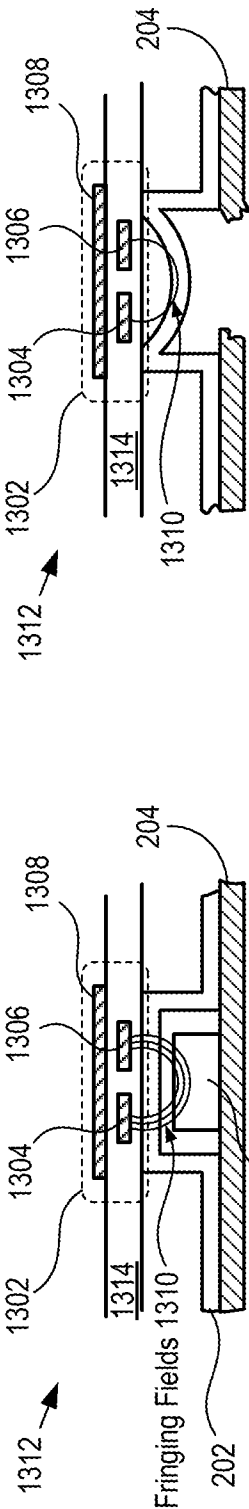


FIG. 13E

FIG. 13D

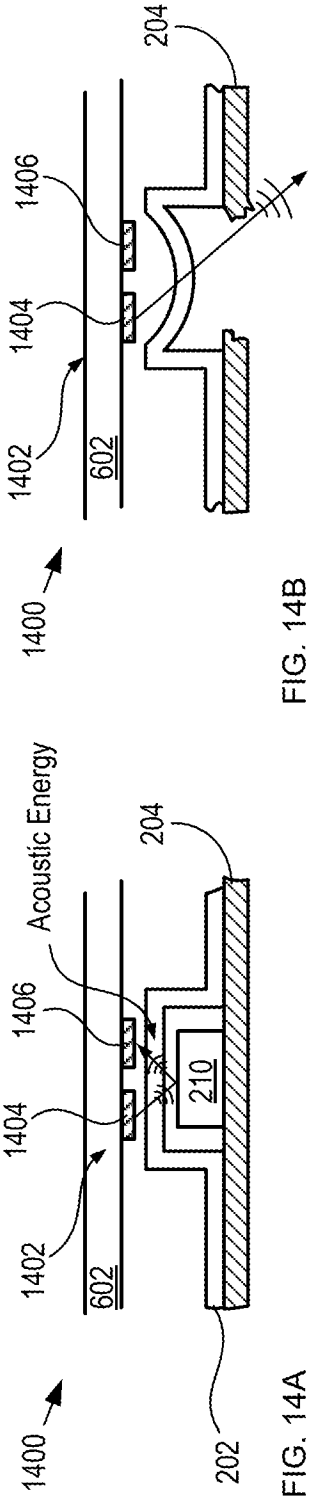


FIG. 14B

FIG. 14A

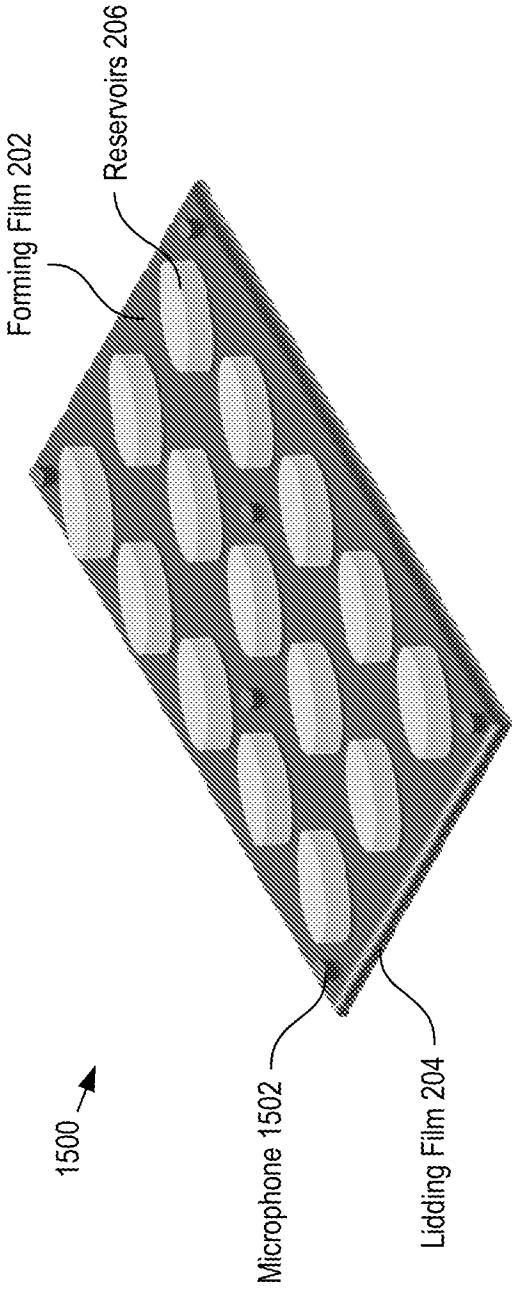


FIG. 15

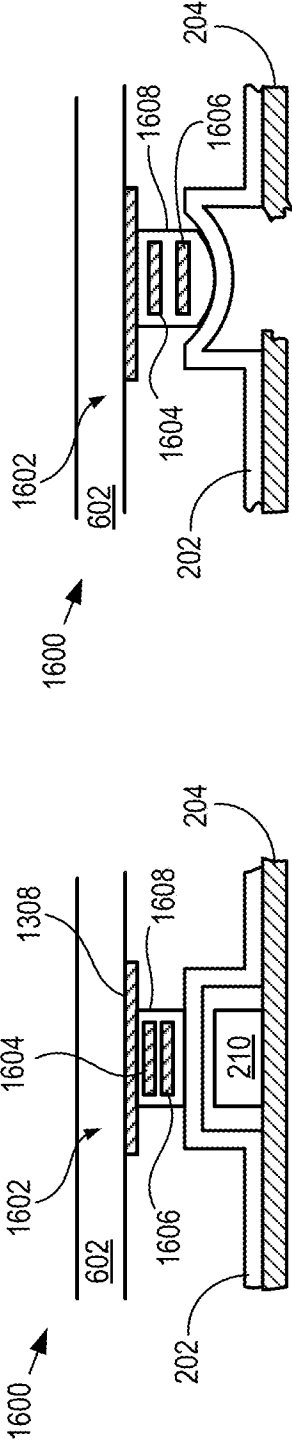


FIG. 16A

FIG. 16B

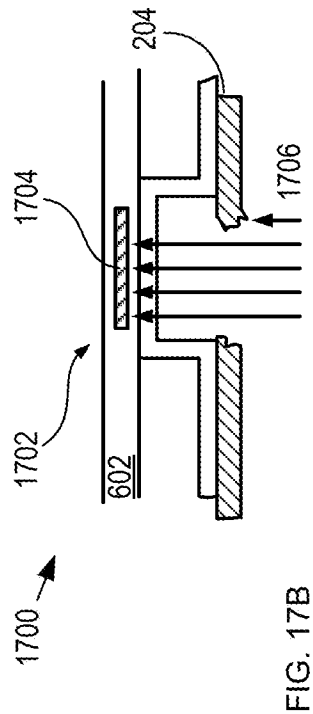


FIG. 17A

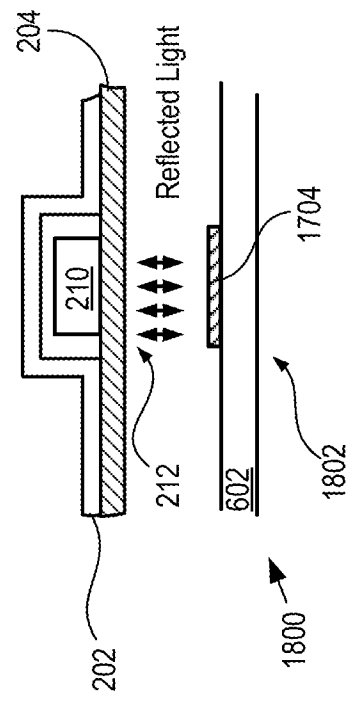


FIG. 18A

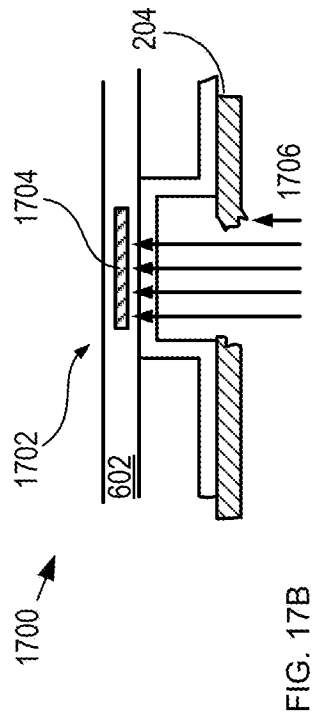


FIG. 17B

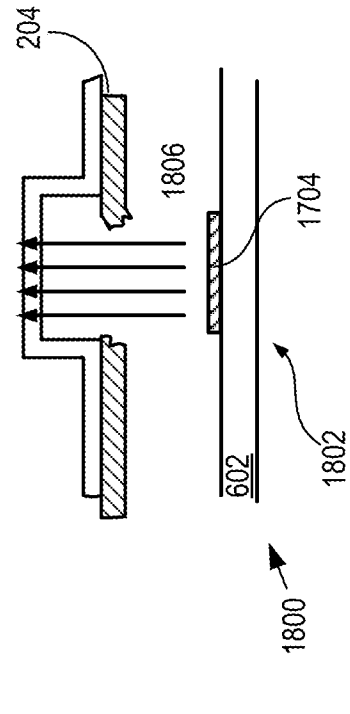
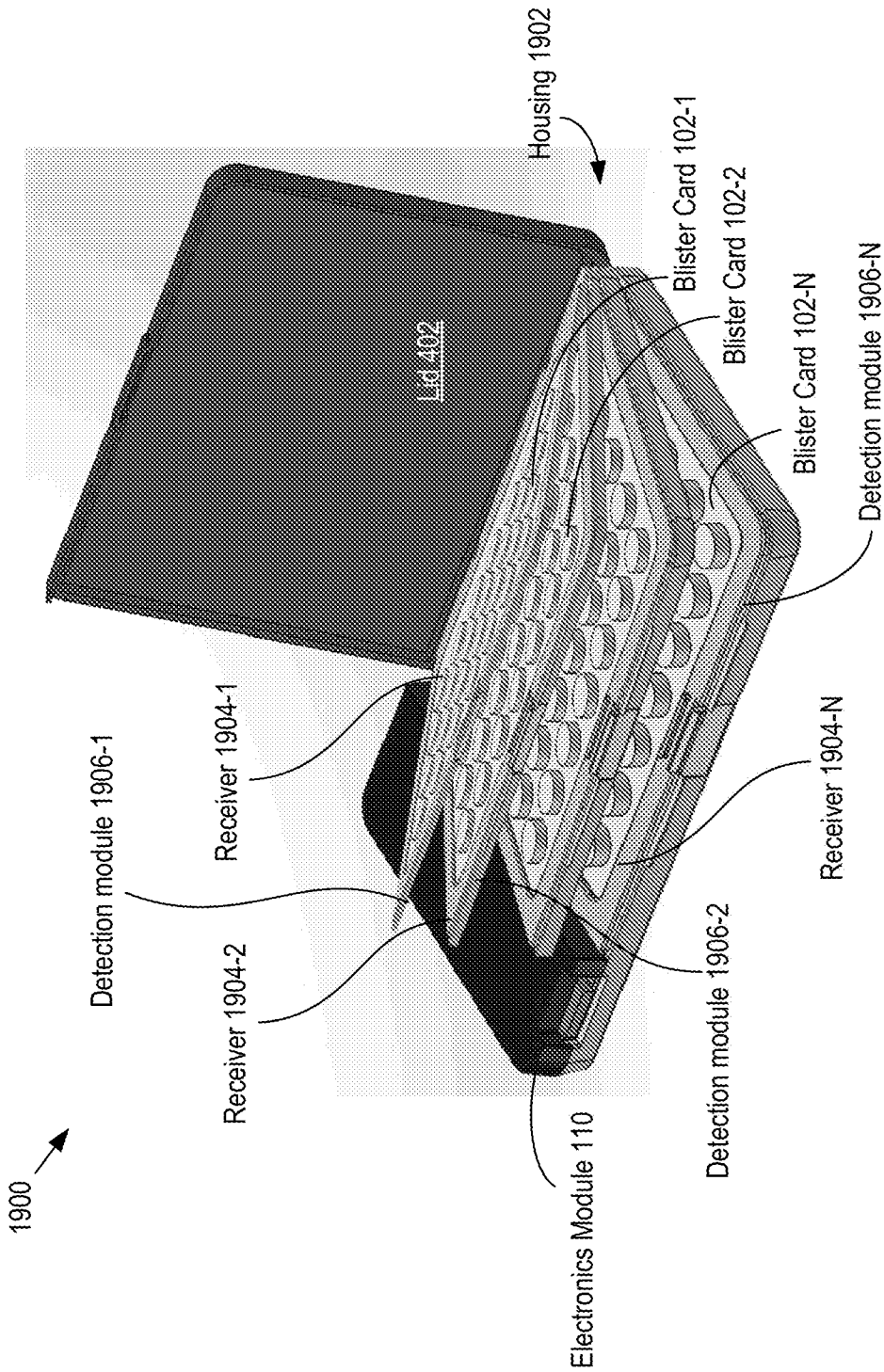


FIG. 18B

FIG. 19



## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2017/025302

A. CLASSIFICATION OF SUBJECT MATTER  
 INV. A61J7/04 A61J1/03  
 ADD.

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

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
 A61J

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2012/111034 A1 (TUFU OSVALDO [IT]) 23 August 2012 (2012-08-23)	1-3,8, 11,13, 14,16, 19-21, 26-30
A	page 9, line 12 - page 10, line 24 page 11, line 5 - page 12, line 6 page 12, line 25 - page 13, line 9 page 13, line 23 - page 14, line 7 page 16, line 14 - page 17, line 19 page 17, line 20 - page 19, line 7 page 20, line 17 - line 21 figures 1-15  -----  -/--	4-7,9, 10,12, 15,17, 18,22-25



Further documents are listed in the continuation of Box C.



See patent family annex.

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

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

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Date of the actual completion of the international search

8 June 2017

Date of mailing of the international search report

16/06/2017

Name and mailing address of the ISA/

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Authorized officer

Ong, Hong Djien

## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2017/025302

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X A	WO 2013/159198 A1 (INTELLIGENT DEVICES INC [BB]; WILSON ALLAN [CA]; PETERSEN MICHAEL [CA]) 31 October 2013 (2013-10-31) page 10, line 24 - page 12, line 26 page 17, line 5 - page 23, line 11 figures 1-31B -----	1-4,8, 14, 19-21, 26-30 5-7, 9-13, 15-18, 22-25

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Information on patent family members

International application No

PCT/US2017/025302

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