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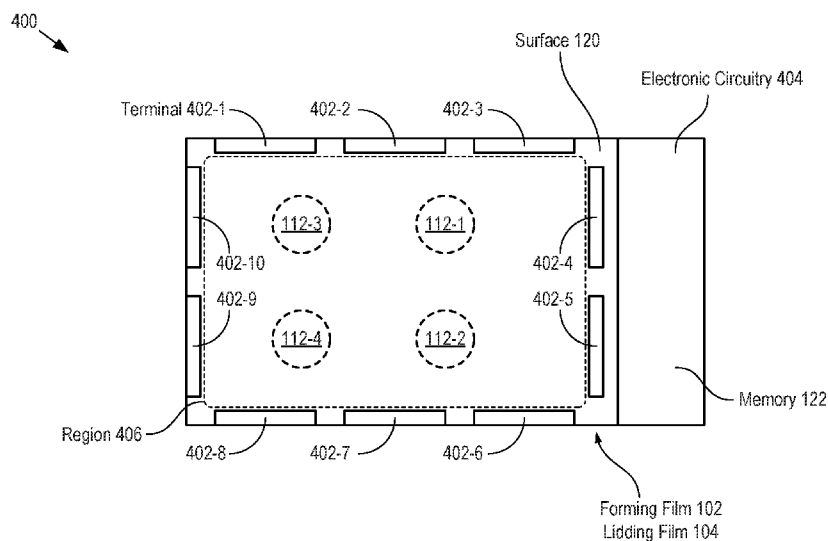
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(54) Title: CONNECTED PACKAGING

FIG. 4



(57) Abstract: A method and apparatus for determining when a tablet (112) has been removed from a container, such as a blister pack (400), are disclosed. The method includes measuring an electrical characteristic, such as electrical resistance or impedance, between at least two terminals (402) that are in electrical communication with an unpatterned lidding film (104) included in the blister pack (400), wherein the removal of a tablet (112) from the blister pack (400) results in an opening in the lidding film (104), thereby giving rise to a finite change in the electrical characteristic.

Connected Packaging

Field of the Invention

[0001] The present invention relates to packaging in general, and, more particularly, to smart packaging.

Background of the Invention

[0002] The term “packaging” refers to the collection of different components that surround a product from the time of its production until its use. It typically serves many purposes, often simultaneously, such as providing protection from physical damage during shipping and handling, theft deterrence, inhibiting contamination, providing protection from electrical damage due to electrostatic discharge, *etc.*, preventing tampering, inhibiting product degradation, and the like.

[0003] In recent years, blister packaging has become a primary form of packaging for many products, such as toys, hardware, electronics, and medications. The primary component of a blister pack is a cavity made in a formable layer, which usually is made of a type of thermoformed plastic. In some cases, the formable layer is folded back onto itself, thereby sealing the cavity and forming a “clamshell” package. More typically, a lidding seal of metal foil is joined to the formable layer as a backing layer to seal the cavities thereby forming one or more enclosed reservoirs.

[0004] As blister packaging has become rather ubiquitous, there has been increasing interest in improving its utility by adding intelligence. Referred to as “smart,” “active,” or “connected” packaging, such packages include sensors and monitoring circuitry that can be used to provide product status, monitor freshness, track temperature exposure, record shocks imparted to the package, send an alert when one or more product units have been removed from a package, and the like. Further, it is possible to include complex product codes that are very difficult to copy, thereby frustrating counterfeit attempts. As a result, such added intelligence can enhance theft deterrence, inhibit product counterfeiting, enable tracking of product end-to-end (*i.e.*, from production to the consumer), *etc.*

[0005] Unfortunately, conventional approaches for providing intelligent packaging are typically complex, expensive and often easily damaged.

[0006] The simplest prior-art approach relies on patterned electrical traces that are arranged such that they are broken during the removal of a unit from the package. For multi-unit blister packs, a separate trace is normally disposed over each reservoir. Electronic circuitry monitors the resistance of each trace and generates a signal when infinite resistance for one of the traces is detected. Unfortunately, incorporating patterned traces into a blister pack requires a significant modification of conventional packaging approaches. As a result, it adds significant complexity and cost. Further, narrow conductive traces are subject to corrosion and physical damage that can give rise to false indications of unit removal.

[0007] Another prior-art smart-packaging approach relies on optical monitoring of product units contained in a package. The need to include active optical sources, as well as detectors, significantly increases packaging costs, however. Further, such devices are notoriously power hungry, which shortens the life of a battery used to power them.

[0008] Yet another conventional smart-packaging approach employs radio-frequency identification (RFID) tags that are associated with each unit contained in a package. Although this enables highly reliable tracking of the products packaged, these approaches require specialized base stations capable of energizing and reading the RFID tags. Further, the range over which the RFID tags are operable is fairly short. Still further, most RFID-based approaches require patterning of the metal-foil lidding-seal layer to form the requisite antenna that enables RF communication with the tag.

[0009] The need for a simple, lower-cost smart-packaging approach that enables end-to-end tracking of a packaged product remains, as yet, unmet.

Summary of the Invention

[0010] The present invention enables tracking of a product, such as drugs, medication, foodstuffs, consumer electronics products, batteries, *etc.*, from production to consumption through connected packaging. Embodiments of the present invention are operative for wirelessly reporting medication adherence, environmental exposure (*e.g.*, temperature, shock, chemical exposure, *etc.*), tampering, and theft.

[0011] An illustrative embodiment of the present invention is a smart package for pharmaceutical products. The package includes a first layer that is electrically conductive and unpatterned, first and second terminals that are electrically connected to the first layer

such that they are in electrical communication through the first layer, a second layer having a plurality of cavities, and electronic circuitry for monitoring the electrical resistance between the first and second terminals and providing an output signal indicative of the formation of openings in the first layer. The first and second layers are joined such that the first layer and the cavities collectively define a plurality of reservoirs, each reservoir being operative for locating a medicinal tablet. In some embodiments, the reservoirs are operative for holding another medicinal product unit, such as a pill, capsule, lozenge, and the like. In some embodiments, the reservoirs are operative for holding another production unit, such as a toy, a foodstuff, an electronic product, *etc.*

[0012] In some embodiments, the first layer includes an electrically non-conductive film and an electrically conductive film, where the non-conductive film is between the conductive film and at least one of a plurality of terminals. In such embodiments, the terminals are capacitively coupled to the conductive film using an alternating current signal and are therefore, electrically coupled through the first layer. In such embodiments, the electronic circuitry is operative for providing the alternating current signal to the terminals and monitoring electrical impedance between them.

[0013] In some embodiments, a plurality of terminals are arranged around the perimeter of an area of the first layer and electrically coupled through the first layer such that an electrical parameter (*e.g.*, electrical resistance or impedance) can be measured between each terminal and each other terminal of the plurality of terminals. In some embodiments, the electrical parameter between each terminal and each other terminal is used to develop a map of the electrical parameter over an area of the first layer. In some embodiments, the map is generated by a processor using electrical resistance tomography or electrical impedance tomography techniques. In some embodiments, the processor is included in the electronic circuitry of the package. In some embodiments, the processor is an external processor that is in communication with the electronic circuitry.

[0014] In some embodiments, the electronic circuitry includes a wireless communications device that enables wireless communications from and/or to the package.

[0015] An embodiment of the present invention is an apparatus for containing one or more product units (112), the apparatus comprising: a first layer (104) that is substantially continuous throughout a first region (406); a first plurality of terminals (402) that is arranged such that each terminal is in electrical communication with each other terminal of

the first plurality thereof through the first layer before and after formation of an opening in the first layer; and electronic circuitry (404) that is operative for (1) providing an electrical stimulus between a first terminal and second terminal of the first plurality thereof and (2) measuring an electrical parameter at each of a second plurality of terminals, wherein the first plurality of terminals includes the first terminal, second terminal, and the second plurality of terminals, and wherein the second plurality of terminals excludes the first terminal and second terminal, and wherein the electrical parameter is based on the electrical stimulus.

[0016] Another embodiment of the present invention is an apparatus for containing one or more product units (112), the apparatus comprising: a first layer (104) that is substantially continuous throughout a first region (406); a first plurality of terminals (402) that is arranged such that each terminal is in electrical communication with each other terminal of the first plurality thereof through the first layer before and after formation of an opening in the first layer; and electronic circuitry (404) that is operative for (1) providing an electrical stimulus between a first terminal and second terminal of the first plurality thereof and (2) measuring an electrical parameter at each of a second plurality of terminals, wherein the first plurality of terminals includes the first terminal, second terminal, and the second plurality of terminals, and wherein the second plurality of terminals excludes the first terminal and second terminal, and wherein the electrical parameter is based on the electrical stimulus.

[0017] Another embodiment of the present invention is a method for monitoring the state of a package (400), the method comprising: providing the package such that it includes: a first layer (104) that is substantially continuous throughout a first region (406); and a second layer (102) including one or more cavities (116), wherein the first layer and second layer are joined such that each of the one or more cavities and the first layer collectively defines a reservoir (106) that is operative for holding a product unit (112); providing a first plurality of terminals (402) that is arranged such that each terminal is in electrical communication with each other terminal of the first plurality thereof through the first layer before and after formation of an opening in the first layer; providing a first stimulus between first and second terminals (402-1 and 402-6) of the first plurality thereof; and measuring an electrical parameter at each of a second plurality of terminals (402-2 through 402-6 and 402-7 through 402-10), wherein the first plurality of terminals includes

the second plurality of terminals, and wherein the second plurality of terminals excludes the first and second terminals, and further wherein the electrical parameter is based on the first stimulus.

Brief Description of the Drawings

[0018] FIG. 1A depicts a schematic drawing of an exploded view of a blister pack in accordance with an illustrative embodiment of the present invention.

[0019] FIG. 1B depicts a schematic drawing of a cross-sectional view of blister pack **100** after its assembly.

[0020] FIG. 2 depicts operations of a method suitable for monitoring the state of a blister pack in accordance with the illustrative embodiment.

[0021] FIG. 3 depicts a schematic drawing a perspective view of blister pack **100** after the removal of tablets from the package.

[0022] FIG. 4 depicts a schematic drawing of a plan view of a blister pack in accordance with a first alternative embodiment of the present invention.

[0023] FIG. 5 depicts operations of an exemplary method suitable for monitoring the state of a blister pack in accordance with the first alternative embodiment.

[0024] FIGS. 6A-D depict EIT models of region **406** for different possible configurations of openings at known tablet locations in an exemplary lidding film having four terminals arranged about its perimeter.

[0025] FIG. 7 depicts a sub-method suitable for determining the location of one or more openings in a blister pack in accordance with the first alternative embodiment.

Detailed Description

[0026] The present invention is directed toward smart blister packaging for use across a variety of packaging applications, including consumer electronics, toys, healthcare products (*e.g.*, razor blades, *etc.*), foodstuffs, toner cartridges, and the like. It should be noted, however, that it is particularly well suited for use in pharmaceutical packaging.

[0027] For many medicinal products, blister packaging has become the dominant form of packaging; however, it is a broad, encompassing, and multi-faceted task. It is

responsible for providing life-saving drugs, medical devices, medical treatments, and new products like medical nutritionals (nutraceuticals) in every imaginable dosage form to deliver every type of supplement, poultice, liquid, solid, powder, suspension, or drop to people the world over.

[0028] Although some medicinal packaging efforts to frustrate “tampering” of medicinal products have been made (*e.g.*, non-resealable tamper indicators, such as tapes, foil seals, *etc.*), on the whole, most drugs and medicines are still packaged in a manner that primarily addresses only environmental concerns, such as humidity, oxidation, light, contamination, *etc.* It is an aspect of the present invention, however, that smart packaging can add value and provide solutions to many issues plaguing the healthcare industry – in particular, improving patient compliance with self-dosing regimens. Smart packaging in accordance with the present invention, for example, enables certain events, such as a dosing event, to be prompted and/or logged, and/or communicated with a care provider.

[0029] It should be noted that patient compliance is one of the most vexing problems facing the health care industry today. Nearly three out of four Americans do not take their medications as directed, which results in serious health consequences - especially for people with chronic diseases. In developed countries, adherence to long-term therapies in the general population is around 50% on average, but is much lower in developing countries. The failure of patients to adhere to prescribed medication regimens directly contributes to poor drug efficacy, higher medical care costs due to an increased need for acute care, and financial losses to the pharmaceutical industry. The impact of poor patient compliance is blamed for:

- 125,000 patient deaths per year in just the United States;
- up to \$290 billion per year of additional healthcare costs; and
- losses for the global pharmaceutical market of an estimated \$564 billion annually, which corresponds to 59% of the \$956 billion in total global pharmaceutical revenue in 2011.

[0030] In addition, the theft and counterfeiting of drugs has become a critical issue with worldwide health ramifications. Counterfeiting is estimated to be in the range of 2% worldwide; however, it is concentrated in developing countries, where it is estimated to be as high as 60% in some regions. The consequences of counterfeit drugs can be dire,

including negative side effects, poor or non-existent efficacy, and death in many cases. Further, while medication theft makes up only 5% of all cargo theft by volume, the average value of stolen medication is \$3.78 million per robbery. The direct economic impact on drug producers can be significant, hitting some companies extremely hard in recent years. Even beyond the significant loss of money and trial delays due to lost product, pharmaceutical theft also carries hidden consequences, such as damage to a company's reputation and the need to recall products not yet released to market. Further, stolen medicines can end up in the legitimate supply chain and pose a severe risk to patients that receive it.

[0031] Connected packaging in accordance with the present invention has positive implications for the complete life cycle of a drug - from production to consumption.

Embodiments of the present invention enable:

- i. improved patient adherence/compliance; or
- ii. increased efficacy; or
- iii. abiding by prescribed timing, dosage, refills, *etc.*; or
- iv. improved treatment outcome through improved results enabled by;
 - a. better engagement with patients; or
 - b. improved ability to measure and provide feedback on therapies/efficacy, thereby providing opportunities for caregivers to improve treatment outcomes, pharmaceutical companies to improve revenue control and cost management; or
 - c. improved ability to collect and analyze user data; or
- v. new distribution models (*e.g.*, direct sales from supplier to customer); or
- vi. improved drug control (*e.g.*, theft prevention, anti-counterfeiting, *etc.*); or
- vii. expedited clinical trials; or
- viii. opportunities for new diagnostic capabilities;
- ix. any combination of i, ii, iii, iv, v, vi, vii, and viii.

[0032] FIG. 1A depicts a schematic drawing of an exploded view of a blister pack in accordance with an illustrative embodiment of the present invention.

[0033] FIG. 1B depicts a schematic drawing of a cross-sectional view of blister pack **100** after its assembly. FIG. 1B depicts a cross-section of blister pack **100** taken through line a-a, as shown in FIG. 1A.

[0034] Blister pack **100** comprises forming film **102**, lidding film **104**, reservoirs **106**, terminals **108** and **110**, tablets **112**, and electronic circuitry **114**. Blister pack **100** is often referred to as a "push-through pack," because lidding film **104** is designed to allow each tablet **112** to be removed by pushing it through the lidding film by forcibly collapsing any of the semi-rigid formed cavities in the forming film. One skilled in the art will recognize, however, that the present invention is suitable for use with other types of packaging as well, such as medical blister trays, peel-open blister packs, and the like. Further, although the embodiments described herein are substantially rectangular blister packs, in some embodiments, blister pack **100** has a shape other than rectangular, such as circular, elliptical, polygonal, square, or irregular. In some embodiments, one or more terminals are located in the interior of blister card **100**.

[0035] Blister pack **100** is a single, unfolded blister card. In some embodiments, blister pack **100** includes multiple blister cards, each of which holds one or more tablets, where the blister cards are physically and electrically connected but perforated along "fold lines" that facilitate fanning them into an easily packaged unit. For the purposes of this Specification, including the appended claims, a region of a layer that is unpatterned but includes perforated fold lines is considered to be substantially continuous.

[0036] One skilled in the art will recognize that many types of medication are offered in a form suitable for packaging in a blister package, such as pills, capsules, lozenges, etc. For the purposes of this Specification, including the appended claims, the term "tablet" is used as a general term that encompasses all such medicinal forms.

[0037] Forming film **102** is a layer of thermoformed plastic comprising cavities **116** (*i.e.*, blisters). Cavities **116** are typically formed via a conventional thermoforming process, wherein the forming film is heated and pressed into features of a forming tool. One skilled in the art will recognize that there are myriad suitable alternative methods for making forming film **102** without departing from the scope of the present invention.

[0038] Each of cavities **116** is filled with one of tablets **112-1** through **112-M**, where M is the total number of medicinal doses included in blister pack **100** (in the illustrative embodiment, each dose includes a single tablet **112** and M=6). Tablets **112-1** through **112-M** are loaded into their respective cavities in conventional fashion. The loading process is normally monitored using an automated vision system to ensure that no cavities are empty, contain multiple tablets, or have damaged tablets. In some embodiments, at least one of cavities **116** includes a plurality of tablets **112**.

[0039] Lidding film **104** is a layer of metal foil, such as aluminum foil, suitable for pharmaceutical applications. Lidding film **104** is joined with forming film **102** in conventional fashion, using localized heat and pressure to seal the lidding film against the edges of the cavities. Once forming film **102** and lidding film **104** are joined, the lidding film and cavities **116** collectively define reservoirs **106**. Reservoirs **106** are located within region **118**, which is an area of the blister pack that is clear of additional structure so as to facilitate the removal and capture of tablets **112** when they are dispensed by pushing them through the lidding film.

[0040] In some embodiments, surface **120** of lidding film **104** includes printed information, such as dosage schedule, emergency procedures, and the like. In some embodiments, lidding film **104** is a multi-layer film including a metal layer and a thin electrically non-conductive layer (e.g., a paper layer on which information is printed, etc.). In some embodiments, a conductive layer is added to a non-conductive lidding film as part of the fabrication process for blister pack **100**.

[0041] In some embodiments, blister pack **100** is perforated along lines to define individual, easily separated blister cards, each containing at least one reservoir **116**.

[0042] Terminals **108** and **110** are electrical contacts disposed on surface **120** at either end of region **118**. Terminals **108** and **110** enable electrical connection to electronic circuitry **114**. Terminals **108** and **110** are disposed on surface **120** such that the terminals are in electrical communication through lidding film **104**.

[0043] In some embodiments, terminals **108** and **110** are formed directly on surface **120** using an electrically conductive printing ink. In some of these embodiments, the terminals are formed during the printing of user information on the film, as discussed above. In some embodiments, electrical traces suitable for interconnecting terminals **108**

and **110** with electronic circuitry **114** are also formed on the blister pack using electrically conductive ink.

[0044] Electronic circuitry **114** includes sensor circuitry for monitoring the resistance of region **118**, memory module **122** for logging date and time, a wireless device for communicating with the user and/or a medical services provider, and a module for tracking the chain of custody of blister pack **100**. Electronic circuitry **114** is mounted on surface **120** via conventional hybrid bonding techniques such that it is electrically coupled with terminals **108** and **110**. In some embodiments, electronic circuitry **114** is formed directly on lidding film **104** using, for example, thin-film transistor technology, such as is used in the fabrication of active-matrix liquid-crystal displays, *etc.* In some embodiments, electronic circuitry **114** includes additional sensors for monitoring, for example, environmental factors (*e.g.*, humidity, temperature, *etc.*), storage duration, light exposure, and the like. In some embodiments, electronic circuitry **114** includes visual and/or audible status indicators for providing user information such as dosage reminders, expiration date warnings, tamper alerts, *etc.* In some embodiments, electronic circuitry **114** communicates information to and/or from blister pack **100** via a wired communications link. In some embodiments, electronic circuitry **114** includes additional functionality, such as signal processing/computation, and a power module (*e.g.*, inductive energy-coupling system, battery pack, an energy scavenging system, *etc.*).

[0045] Preferably, embodiments of the present invention are substantially compatible with conventional blister packaging user experience and manufacturing. It is desirable, therefore, that blister packs in accordance with the present invention be untethered and, further, that medication dispensing should not place an added burden on the user. As a result, electronic circuitry **114** typically includes a wireless communication device that enables information to be wirelessly transmitted to and/or from blister pack **100**. In addition, in some embodiments, the electronics module enables the blister pack to be "self-reporting." The choice of wireless protocol is generally dominated by power and cost requirements. Broadband/cellular communication is most desirable since it does not require a local/short-range gateway to reach the network; however, it is also the most taxing in power and cost. Attractive alternatives include short-range wireless protocols (*e.g.*, Blue Tooth Low Power, Near Field Communication, Inductive Coupling, *etc.*) to communicate with a local gateway (*e.g.*, user's cell phone, custom transmission system, docking station, *etc.*).

One skilled in the art will recognize that such approaches require that the blister pack be near the local gateway when the data is to be retrieved (e.g., during dispensing or subsequent downloading of dispensing history).

[0046] In some embodiments, electronic circuitry **114** is located, at least in part, in a module external to blister pack **100**. In some embodiments, electronic circuitry **114** is included, at least in part, in a docking station that accepts and locates blister pack **100** and establishes electrical connectivity with terminals **108** and **110**.

[0047] FIG. 2 depicts operations of a method suitable for monitoring the state of a blister pack in accordance with the illustrative embodiment. Method **200** begins with operation **201**, wherein an electrical parameter measured between terminals **108** and **110** is monitored. In the illustrative embodiment, the electrical parameter measured between terminals **108** and **110** (i.e., of region **118**) is electrical resistance.

[0048] In some embodiments, lidding film **104** includes an electrically non-conductive film and an electrically conductive film, wherein the non-conductive film is between the electrically conductive film and terminals **108** and **110** (or between the electrically conductive film and at least one of the terminals). As a result, the terminals are not electrically connected with the first layer and electrical resistance between the terminals cannot be effectively measured. By driving the terminals with an alternating current (AC) signal, however, the terminals are still electrically coupled through the first layer by virtue of capacitive coupling between each terminal and the conductive film. In such embodiments, electronic circuitry **114** is operative for providing an alternating current (AC) signal to the terminals and measuring electrical impedance between the them (i.e., the measured electrical parameter is electrical impedance).

[0049] In some embodiments, lidding film **104** includes an electrically non-conductive film and an electrically conductive film, as described above; however, the non-conductive film includes openings that enable each of the terminals to be in direct electrical contact with the conductive film. In such embodiments, therefore, the measured electrical parameter can be electrical resistivity.

[0050] The magnitude of the electrical resistance, **R**, of region **118** is given by $R = \rho \frac{L}{wt}$, where ρ and t are the resistivity and thickness, respectively, of the metal that

composes the lidding film, L is the distance between terminals **108** and **110**, and W is the width of the terminals, which defines the width of region **118**.

[0051] At operation **202**, electronic circuitry **112** monitors date and time.

[0052] It is an aspect of the present invention that each time a tablet is dispensed from blister pack **100**, a corresponding finite change in the magnitude of the electrical resistance of region **118** occurs.

[0053] At operation **203**, a finite change in the measured electrical parameter is detected at date $D(j)$ and time $T(j)$, where j is an integer within the range of 1 through M . As discussed above, M is the number of doses included in blister pack **100**. For the purposes of this Specification, including the appended claims, a “finite change” in an electrical parameter is defined as a change from a first non-infinite value to a second non-infinite value. This definition explicitly excludes a change from a first non-infinite value to infinity, such as, for example, a change in the resistance of a conductive trace upon to its breakage.

[0054] FIG. 3 depicts a schematic drawing a perspective view of blister pack **100** after the removal of tablets from the package. The view of blister pack **100** shown in FIG. 3 is that of view b-b, as shown in FIG. 1B. The removal of a tablet **112** gives rise to an opening **302** in lidding film **104**, since a tablet is dispensed from the package by pressing against a cavity **116** to push it through the lidding film. It should be noted that, for illustrative purposes, openings **302** are depicted as identical rectangular holes. In practice, however, openings **302** are typically neither rectangular nor identical. Further, it is common for one or more holes to include metal foil that is merely broken out of, but not removed completely from, lidding film **104**.

[0055] Each opening in lidding film **104** removes some conductive material from the electrical path between terminals **108** and **110** (*i.e.*, region **118**). The removal of this conductive material gives rise to a discernable, finite change in the magnitude of the resistance measured between terminals **108** and **110**. For an illustrative example wherein identical rectangular holes **202** that have width ΔW and length ΔL , are formed in lidding film **104**, the change in resistance, ΔR , that occurs due to the formation of a hole **202** is given by: $\Delta R = R \left(\frac{\Delta L}{L} - \frac{\Delta W}{W} \right)$. For an exemplary circular hole shape, (*i.e.*, $\Delta L = \Delta W$) and a ratio of L/W of 2, ΔR is given by: $\Delta R = R \left(\frac{\Delta W}{2W} \right)$.

[0056] By monitoring the change in the electrical resistance between terminals **108** and **110**, therefore, the present invention detects the removal of a tablet, how many tablets are dispensed per event, and a record of dispensing events.

[0057] At operation **204**, electronic circuitry **114** generates output signal **124(j)**, which indicates that a tablet **112** has been dispensed from blister pack **100**, as well as the date $D(j)$ and time $T(j)$ at which the tablet was dispensed. In some embodiments, output signal **122** includes additional information, such as how many tablets **112** were dispensed, and the like.

[0058] At operation **205**, electronic circuitry **114** creates a log entry in memory **122** that includes the number of tablets dispensed at date $D(j)$ and time $T(j)$.

[0059] Further, by extending the foregoing approach and adding additional terminals arranged around region **118**, it is possible to determine the location within region **118** from which each tablet is dispensed, as well as improving the robustness of determining dispensing events and numbers.

[0060] FIG. 4 depicts a schematic drawing of a plan view of a blister pack in accordance with a first alternative embodiment of the present invention. Blister pack **400** comprises forming film **102**, lidding film **104**, reservoirs **106**, terminals **402-1** through **402-N**, tablets **112**, and electronic circuitry **404**. Blister pack **400** is analogous to blister pack **100** described above and with respect to FIGS. 1-3; however, blister pack **400** includes a greater number of terminals, which are distributed around the perimeter of region **118**. It should be noted that, although the embodiment depicted in FIG. 4 includes ten terminals **402** (*i.e.*, $N=10$), it will be clear to one skilled in the art, after reading this Specification, how to specify, make, and use embodiments of the present invention comprising any practical number of terminals **402** (*i.e.*, wherein N is any practical number).

[0061] The addition of eight additional terminals around the perimeter of lidding film **104** improves the sensing resolution of blister pack **400** beyond that of blister pack **100**, such that the identity of which individual tablet has been dispensed can be determined. The configuration of terminals **402-1** through **402-10** (referred to, collectively, as terminals **402**) enables forty five pair-wise measurements of the electrical resistance between the ten terminals. This enables sufficient resolution for sensing the location of each dispensed tablet—both per dispensing event and historically. One skilled in the art will recognize that

the sensing resolution achievable is based upon the number and location of the dispensed tablets on the blister pack, as well as the size and density of the blisters, the relative distance of the blisters from the terminals, and the size, shape, number and location of the terminals.

[0062] Electrical resistance tomography (ERT) imaging (a.k.a., electrical resistance imaging (ERI)) and electrical impedance tomography (EIT) are well-known techniques used for imaging tissue in medical applications. An exemplary method for determining the location of one or more openings formed in region **406** in accordance with the present invention is based on analogous electromagnetic and mathematical modeling techniques, such as those described in U.S. Patent 8,733,432, and by Duraiswami, *et al.*, in "Efficient 2D and 3D EIT using dual reciprocity boundary element techniques," *Engineering Analysis with Boundary Elements*, Vol. 22, pp. 13-31 (1998), each of which is incorporated herein by reference. In such approaches, a forward model of a system is first developed by modeling the system for a plurality of potential configurations of a parameter of interest. These modeled configurations are then stored in a look-up table. An unknown parameter configuration is then reconstructed by making measurements of the system, whose results are then compared to those predicted by the stored models. Typically, an iterative algorithm is used in doing so, identifying features of interest in the measured system.

[0063] One skilled in the art will recognize that, in embodiments wherein at least one of terminals **402** is capacitively coupled with lidding film **104**, using ERI to generate a map of electrical conductivity in region **406** would be difficult, if not impossible; however, EIT can be used to generating a map of electrical impedance within the region.

[0064] FIG. 5 depicts operations of an exemplary method suitable for monitoring the state of a blister pack in accordance with the first alternative embodiment. Method **500** begins with operation **501**, wherein an EIT model of region **406** is created by processor **126**, which is a conventional data processing system external to system **100**. In some embodiments, processor **126** is included in electronic circuitry **114**. In some embodiments, the processor is an external processor that is in communication with the electronic circuitry, such as a mobile device (e.g., cell phone, tablet, laptop computer, etc.), or base station. The EIT model comprises a plurality of computed maps of the current density distribution throughout the region based on assumed electrical stimuli. Each map is based on a

different anticipated configuration of openings in lidding film **104**. Generating this plurality of computed maps is often referred to as “solving the forward problem.”

[0065] FIGS. 6A-D depict EIT models of region **406** for different possible configurations of openings at known tablet locations in an exemplary lidding film having four terminals arranged about its perimeter. Each of plots **600-606** is based on a finite-element 2-D electrical model of current density distribution for a four-tablet blister card and assumed electrical stimuli.

[0066] Plot **600** depicts the current density distribution in lidding film **104** while in its original state (*i.e.*, without any openings within region **118**).

[0067] Plot **602** depicts the current density distribution in lidding film **104** after formation of an opening **302-1** at the location of tablet **112-1**.

[0068] Plot **604** depicts the current density distribution in lidding film **104** after the additional formation of openings **302-2** and **303-3** at the locations of tablets **112-2** and **112-3**.

[0069] Plot **606** depicts the current density distribution in lidding film **104** after the additional formation of opening **302-4** at the location of tablets **112-4**.

[0070] It can be readily seen from plots **600-606** that the conductivity of each tablet-area changes each time a tablet **112** is dispensed. This change in the conductivity results in a significant change in the current density distribution in region **406** and the corresponding output voltages measured at terminals **402**.

[0071] At operation **502**, the EIT model of region **406** is stored as a look-up table in memory **122**.

[0072] At operation **503**, electronic circuitry **404** monitors date and time.

[0073] At operation **504**, a finite change in the electrical parameter measured between at least one pair of terminals **402** is detected at date $D(j)$ and time $T(j)$, where j is an integer within the range of 1 through M , as discussed above and with respect to blister pack **100**. This finite change equates to a perturbation in the conductivity map of region **406**, which indicates a tablet-dispensing event at the location of one of tablets **112** has occurred.

[0074] At operation **505**, the location of the perturbation within region **406** is identified. In some embodiments, the location of the perturbation is identified by comparing the measured EIT map to the modeling results stored in operation **502**.

[0075] FIG. 7 depicts a sub-method suitable for determining the location of one or more openings in a blister pack in accordance with the first alternative embodiment. Operation **505** begins with sub-operation **701**, wherein pair-wise measurements of electrical resistance are made between each terminal **402-*i*** and each other terminal **402-1** through **402-(*i*-1)** and **402-(*i*+1)** through **402-N**, where *i* is an integer within the range of 1 through N. Typically, the electrical resistance is determined by applying a plurality of currents to terminals **402** and measuring the resultant voltages at the same terminals. In some embodiments, at operation **501**, pair-wise measurements of electrical impedance are made between each terminal **402-*i*** and each other terminal **402-1** through **402-(*i*-1)** and **402-(*i*+1)** through **402-N**, where *i* is an integer within the range of 1 through N. These pair-wise measurements include, in the depicted example, the electrical resistance between terminal **402-1** and each of terminals **402-2** through **402-10**, the electrical resistance between terminal **402-2** and each of terminals **402-3** through **402-10**, the electrical resistance between terminal **402-3** and each of terminals **402-4** through **402-10**, and so on.

[0076] At sub-operation **702**, a map of conductivity distribution within region **406** is reconstructed from the measured electrical resistances.

[0077] In some embodiments, each pair-wise measurement made in sub-operation **701** includes the generation of an electric current between a first pair of terminals, which serve as the current source and sink, and the measurement of a potential difference between a second pair of terminals to determine the potential difference between their respective locations. In such embodiments, for a system with N terminals there are approximately N^4 different terminal configurations. Such pair-wise measurements are analogous to ERT methods described by LaBrecque in U.S. Patent 8,733,432 and EIT measurements described by Duraiswami, *et al.*, in "Efficient 2D and 3D EIT using dual reciprocity boundary element techniques."

[0078] For example, LaBrecque discloses, "...in ERT, each measurement uses four electrodes; one pair of electrodes serves as the current source and sink and a second pair measures the potential difference between two points. For a system with N electrodes there

are approximately N^4 different configurations referred to as arrays.” In similar fashion, Duraiswami discloses, “In electrical impedance tomography (EIT) the distribution of impedances inside an object (‘image’) is sought by applying specified currents at some electrodes, and performing measurements of the voltage at other electrodes. The equations for the electric field then provide a relationship between the impedance distribution inside the medium and the measured voltages and applied currents. Different kinds of materials have different impedances, and the availability of an impedance map provides an image of the material Distribution.” One skilled in the art will recognize that ERT and EIT measurements, such as those described by LeBrecque and Duraiswami, are suitable for use in embodiments of the present invention.

[0079] At sub-operation **703**, the reconstructed map is compared to those stored in memory **122**.

[0080] At sub-operation **704**, the error between the measured values of electrical resistance and the predicted values of electrical resistance between the terminals based on the EIT model of region **406**.

[0081] At sub-operation **705A**, if the error meets a specified threshold (*i.e.*, is within a specified tolerance), a location of the perturbation in the conductivity map is identified as the site of a new opening **302** based on the reconstructed map of region **406**.

[0082] At sub-operation **705B**, if the error exceeds the specified threshold, a new conductivity distribution is reconstructed using an error minimization procedure and sub-operations **703-704** are repeated until the error meets the threshold.

[0083] Returning now to method **500**, at operation **506**, the identity of the tablet **112** dispensed by the formation of the new opening **302** is determined. Typically, a pharmaceutical blister pack contains multiple tablets of the same medication. In some embodiments, however, different types of tablets, or product units in non-pharmaceutical applications, are located at different locations within a single blister pack. For example, in some cases, a blister pack might contain different components of a “drug cocktail” that are intended to be taken together. Or, in an exemplary non-pharmaceutical application, a blister pack might include a printer ink cartridge for each of several different ink colors. In such embodiments, memory **122** typically includes a map or lookup table that corresponds to product type and location within the blister pack.

[0084] At operation **507**, electronic circuitry **404** generates output signal **408(j)**. Output signal **408(j)** is analogous to output signal **124(j)** described above and with respect to blister pack **100**; however, output signal **408(j)** also includes information about the specific tablet **112** that was dispensed at date $D(j)$ and time $T(j)$.

[0085] At operation **508**, electronic circuitry **404** creates a log entry in memory **122** that indicates that a dispensing event occurred at date $D(j)$ and time $T(j)$, and which also includes information about which tablet **112** or tablets were dispensed.

[0086] In some embodiments, placement of the terminals **402** on the periphery of region **406** is augmented or replaced with terminals **402** placed within the interior of the region. In some embodiments, the terminals may have more or less than four sides or may include non-rectilinear shapes.

[0087] It is to be understood that the disclosure teaches just one example of the illustrative embodiment 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.** An apparatus for containing one or more product units (112), the apparatus comprising:

 - a first layer (104) that is substantially continuous throughout a first region (406);
 - a first plurality of terminals (402) that is arranged such that each terminal is in electrical communication with each other terminal of the first plurality thereof through the first layer before and after formation of an opening in the first layer; and
 - electronic circuitry (404) that is operative for (1) providing an electrical stimulus between a first terminal and second terminal of the first plurality thereof and (2) measuring an electrical parameter at each of a second plurality of terminals, wherein the first plurality of terminals includes the first terminal, second terminal, and the second plurality of terminals, and wherein the second plurality of terminals excludes the first terminal and second terminal, and wherein the electrical parameter is based on the electrical stimulus.
- 2.** The apparatus of claim 1 wherein the electronic circuitry is further operative for (3) providing a first signal based on a first finite change in the magnitude of the electrical parameter at at least one terminal of the second plurality thereof.
- 3.** The apparatus of claim 2 wherein the electronic circuitry is further operative for determining the first location based on the first finite change.
- 4.** The apparatus of claim 2 wherein the electronic circuitry is further operative for determining a first time at which the first finite change is detected.
- 5.** The apparatus of claim 1 wherein the electrical stimulus is selected from the group consisting of voltage and current.
- 6.** The apparatus of claim 1 wherein the apparatus further includes a second layer (102) comprising a first cavity (116), the first layer and second layer being joined such that the first cavity and the first layer collectively define a first reservoir (106) for locating the a first unit.
- 7.** The apparatus of claim 1 wherein the first layer is electrically conductive.
- 8.** The apparatus of claim 1 wherein the electronic circuitry includes a wireless communications device.

9. The apparatus of claim 1 wherein the first layer is an unpatterned layer.

10. An apparatus for containing one or more product units (112), the apparatus comprising:

a first layer (104) that is substantially continuous throughout a first region (406);

a second layer (102) including one or more cavities (116), wherein the first layer and second layer are joined such that each of the one or more cavities and the first layer collectively defines a reservoir (106) that is operative for holding a product unit;

a first plurality of terminals (402) that is arranged such that each terminal is in electrical communication with each other terminal of the first plurality thereof through the first layer before and after formation of an opening in the first layer; and

electronic circuitry (404) that is operative for providing (1) a first signal based on a first finite change in the magnitude of an electrical parameter measured at at least one terminal of the first plurality thereof and (2) a second signal based on the time at which the first finite change in the magnitude of the electrical parameter is detected, wherein the electrical parameter is based on an electrical stimulus provided between first and second terminals of the first plurality thereof.

11. The apparatus of claim 10 wherein the electronic circuitry is further operative for determining a first location within the first region at which a first opening in the first layer is formed, and wherein the first location is determined based on the magnitude of the electrical parameter measured at the at least one terminal of a second plurality of terminals, wherein the first plurality of terminals includes the second plurality of terminals, and wherein the second plurality of terminals excludes the first and second terminals of the first plurality thereof.

12. The apparatus of claim 11 wherein the electronic circuitry is further operative for determining a second location within the first region at which a second opening in the first layer is formed, and wherein the second location is determined based on the magnitude of the electrical parameter measured at at least one terminal of the second plurality thereof.

13. The apparatus of claim 10 wherein the electronic circuitry is operative for wireless communication.

14. The apparatus of claim 10 wherein the electrical parameter is selected from the group consisting of electrical resistance, electrical impedance, and voltage.

15. The apparatus of claim 10 wherein the electronic circuitry is further operative for (3) providing a second electrical signal between third and fourth terminals of the first plurality thereof, wherein the electrical parameter measured is based on the second electrical signal.

16. The apparatus of claim 15 wherein the second electrical signal is an electric current and the electrical parameter is a voltage difference.

17. (New): A method for monitoring the state of a package (400), the method comprising:

providing the package such that it includes:

a first layer (104) that is substantially continuous throughout a first region (406); and

a second layer (102) including one or more cavities (116), wherein the first layer and second layer are joined such that each of the one or more cavities and the first layer collectively defines a reservoir (106) that is operative for holding a product unit (112);

providing a first plurality of terminals (402) that is arranged such that each terminal is in electrical communication with each other terminal of the first plurality thereof through the first layer before and after formation of an opening in the first layer;

providing a first stimulus between first and second terminals (402-1 and 402-6) of the first plurality thereof; and

measuring an electrical parameter at each of a second plurality of terminals (402-2 through 402-6 and 402-7 through 402-10), wherein the first plurality of terminals includes the second plurality of terminals, and wherein the second plurality of terminals excludes the first and second terminals, and further wherein the electrical parameter is based on the first stimulus.

18. The method of claim 17 further comprising estimating a first location of the first opening, wherein the estimate of the first location is based on the magnitude of the electrical parameter measured at at least one terminal of the second plurality thereof.

19. The method of claim 17 wherein the electrical parameter is selected from the group consisting of electrical resistance, electrical impedance, and voltage.

20. The method of claim 17 further comprising providing a first signal (124) that indicates (1) the formation of a first opening in the first region when a first finite change in the magnitude of the electrical parameter at at least one terminal of the second plurality thereof is detected, and (2) a first time at which the first finite change in the magnitude of the electrical parameter is detected.

21. The method of claim 20 further comprising providing a second signal (124) that indicates (1) the formation of a second opening in the first region of the first layer when a second finite change in the magnitude of the electrical parameter at at least one terminal of the second plurality thereof is detected, and (2) a second time at which the second finite change in the magnitude of the electrical parameter is detected.

22. The method of claim 21 further comprising estimating a second location of the second opening, wherein the estimate of the second location is based on the magnitude of the electrical parameter measured at the at least one terminal of the second plurality thereof.

23. The method of claim 20 wherein the first signal is provided as a wireless signal.

24. The apparatus of claim 17 wherein the first stimulus is provided as an electric current and the electrical parameter is voltage.

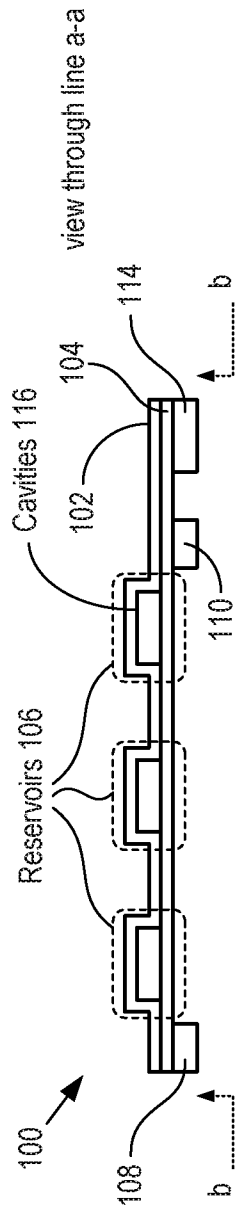
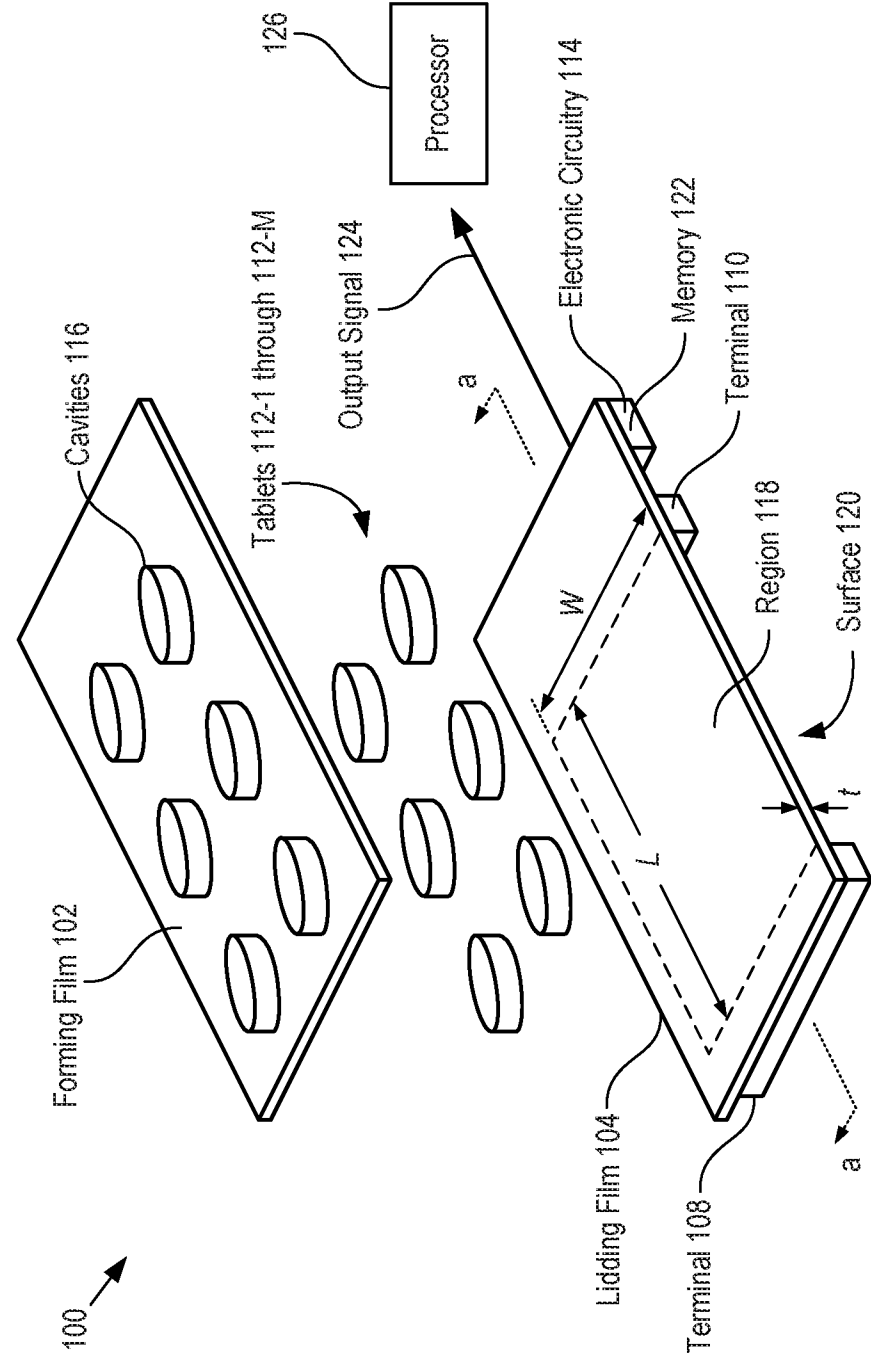


FIG. 2

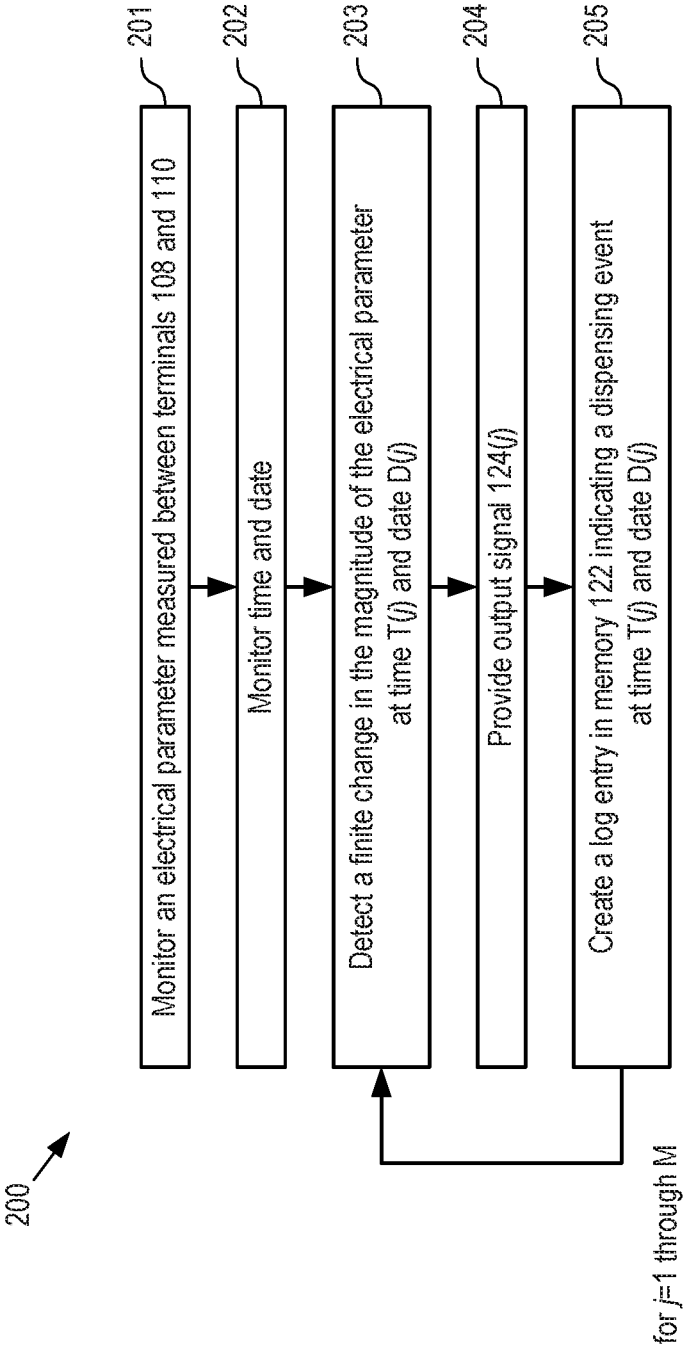


FIG. 3

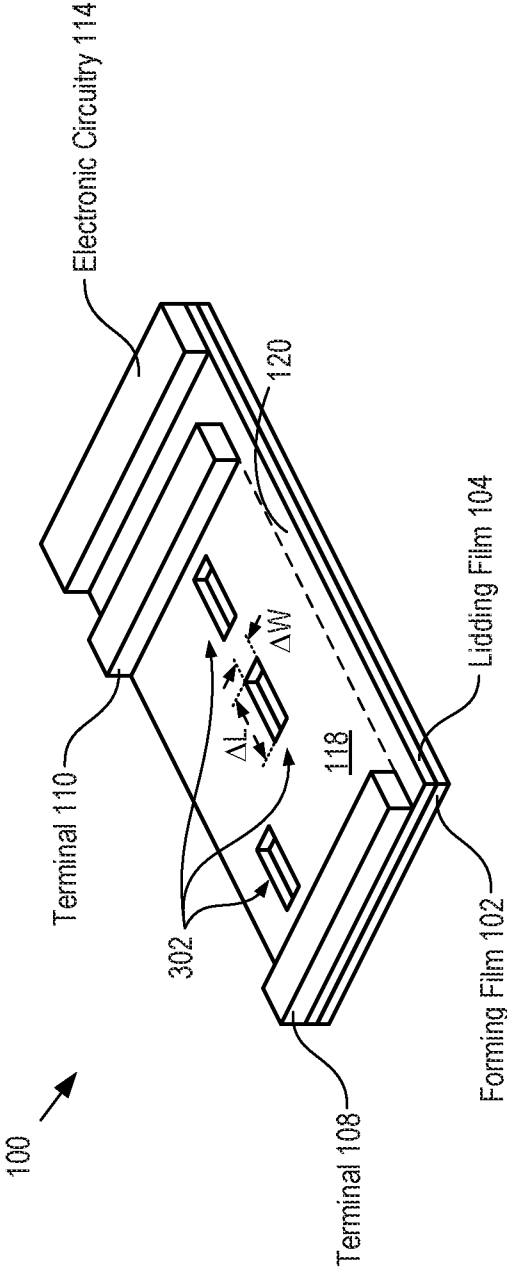


FIG. 4

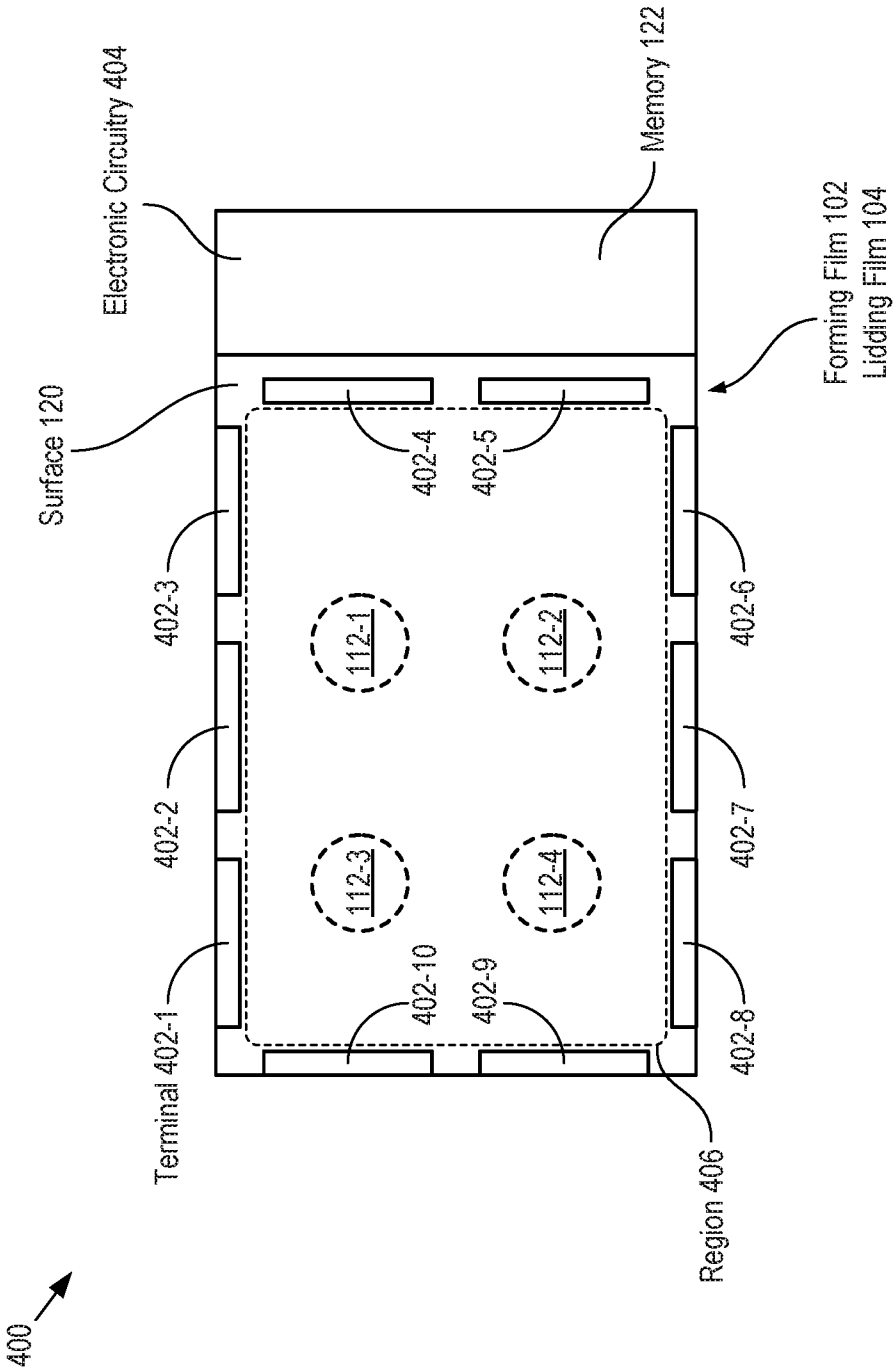
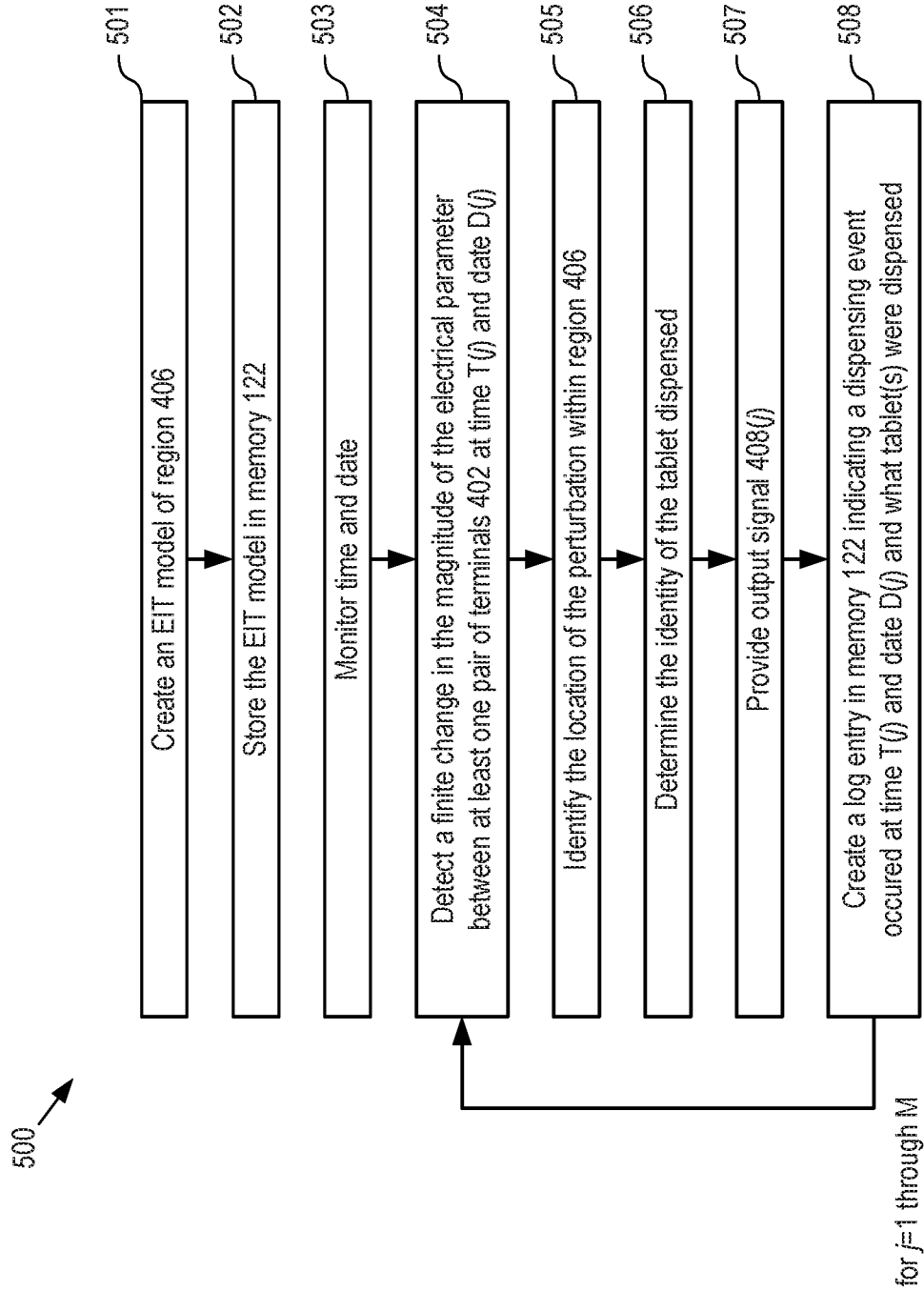


FIG. 5



3005-002WO1

Replacement Sheet

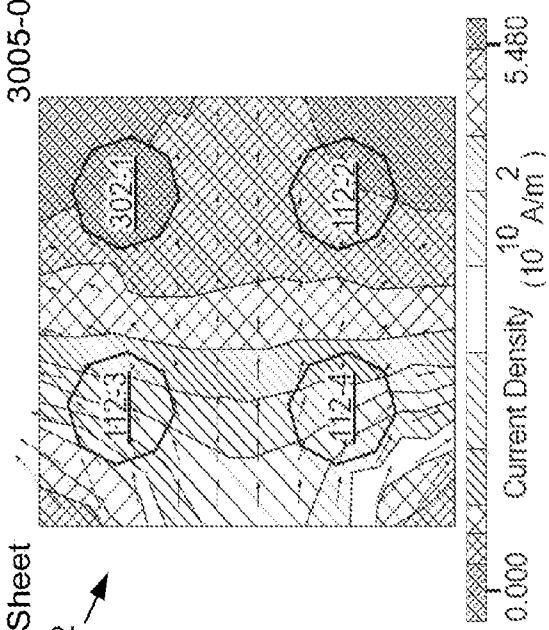


FIG. 6B

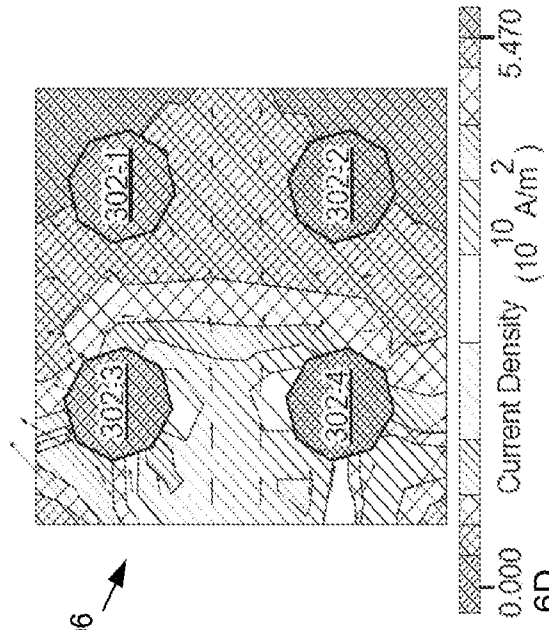


FIG. 6D

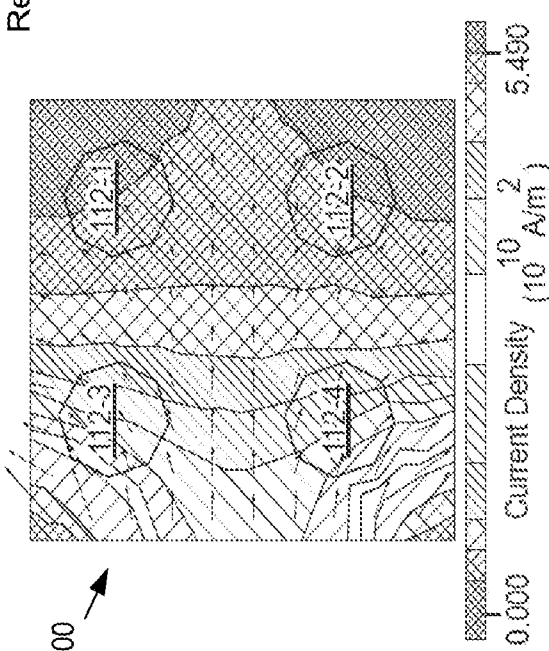


FIG. 6A

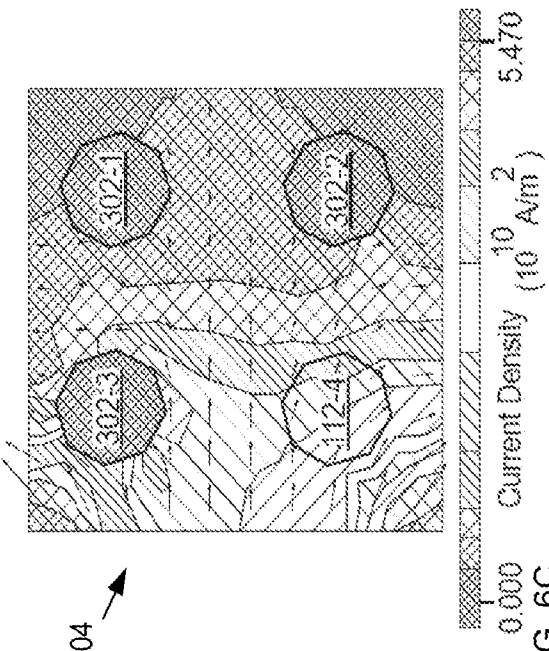
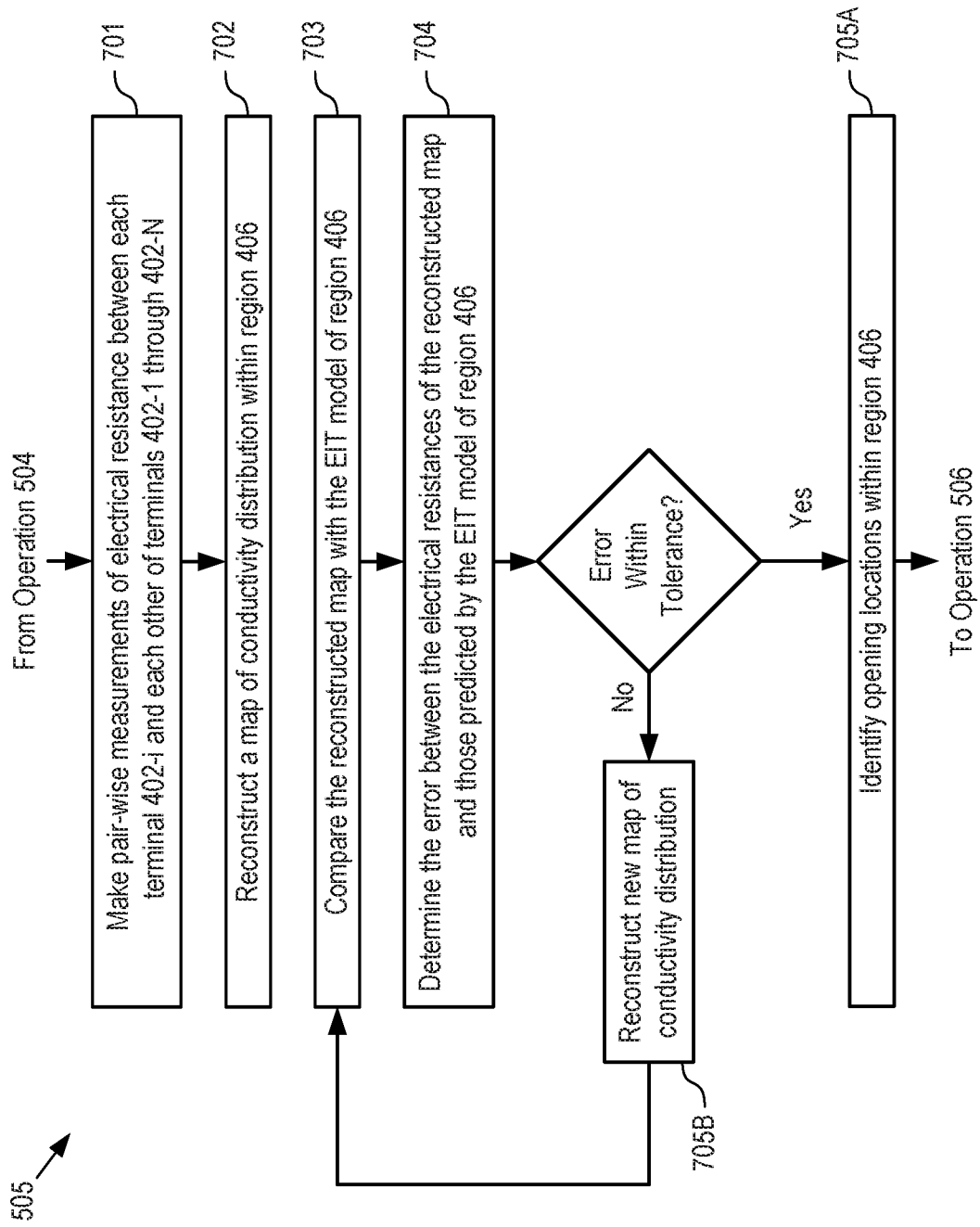


FIG. 6C

FIG. 7



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/055516

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61J1/03 B65D75/36 B65D75/32
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 B65D

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 | US 2010/089789 A1 (ROSENBAUM RONALD [US] ET AL) 15 April 2010 (2010-04-15) | 1-8, 17-24 |
| Y | paragraph [0021] - paragraph [0043]; figures 1-9 | 11-13 |
| X | US 8 960 440 B1 (KRONBERG JAMES W [US]) 24 February 2015 (2015-02-24) | 10,14-16 |
| Y | column 16, line 36 - column 24, line 24; figures 7, 8 | 11-13 |
| A | WO 2010/108838 A1 (CYPAK AB [SE]; LINDMAN VILHELM [SE]; ERIKSSON LEIF HENRIK [SE]) 30 September 2010 (2010-09-30) page 2, line 18 - page 5, line 10; figures 1, 2 page 8, line 4 - line 34; figure 7 | 1-7,10, 17-19,24 |



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

5 January 2017

Date of mailing of the international search report

13/01/2017

Name and mailing address of the ISA/

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Sommer, Jean

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2016/055516

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---------------------|----------------------------|---------------------|
| US 2010089789 | A1 | 15-04-2010 | NONE |
| US 8960440 | B1 | 24-02-2015 | NONE |
| WO 2010108838 | A1 | 30-09-2010 | NONE |