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(19) **United States**(12) **Patent Application Publication****Snyder et al.**(10) **Pub. No.: US 2005/0241983 A1**(43) **Pub. Date: Nov. 3, 2005**(54) **MONITORED MEDICATION PACKAGE**

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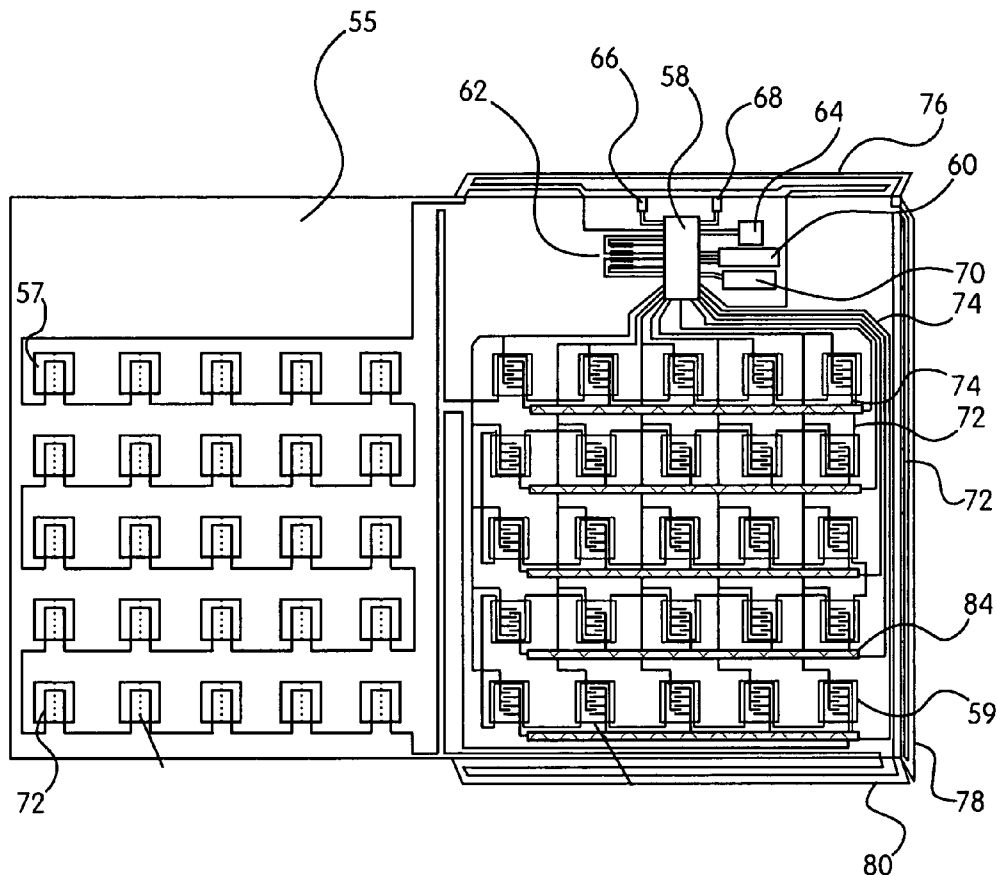
Publication Classification(51) **Int. Cl.⁷** **B65D 83/04**(52) **U.S. Cl.** **206/539**(57) **ABSTRACT**

A child resistant medication package and associated system can enable compliance and anti-diversion features. The medication package can include a timing reminder, can detect and record a compliance history of each dose of medication, and can include anti-tamper capabilities to ensure doses are removed in the intended fashion. The medication package can have the capability to exchange data with other devices, including personal computers. The associated system can include a central database that receives data from the medication package, and provides for the transmission of data between various system locations, including not only the individual medication package, but also, for example, drug manufacturers, pharmacies, physician offices, law enforcement agencies, and a database managing agency.

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BUCHANAN INGERSOLL, P.C.**ONE OXFORD CENTRE, 301 GRANT****STREET****20TH FLOOR****PITTSBURGH, PA 15219 (US)**(21) Appl. No.: **11/096,994**(22) Filed: **Apr. 1, 2005****Related U.S. Application Data**

(63) Continuation-in-part of application No. 10/796,224, filed on Mar. 9, 2004.



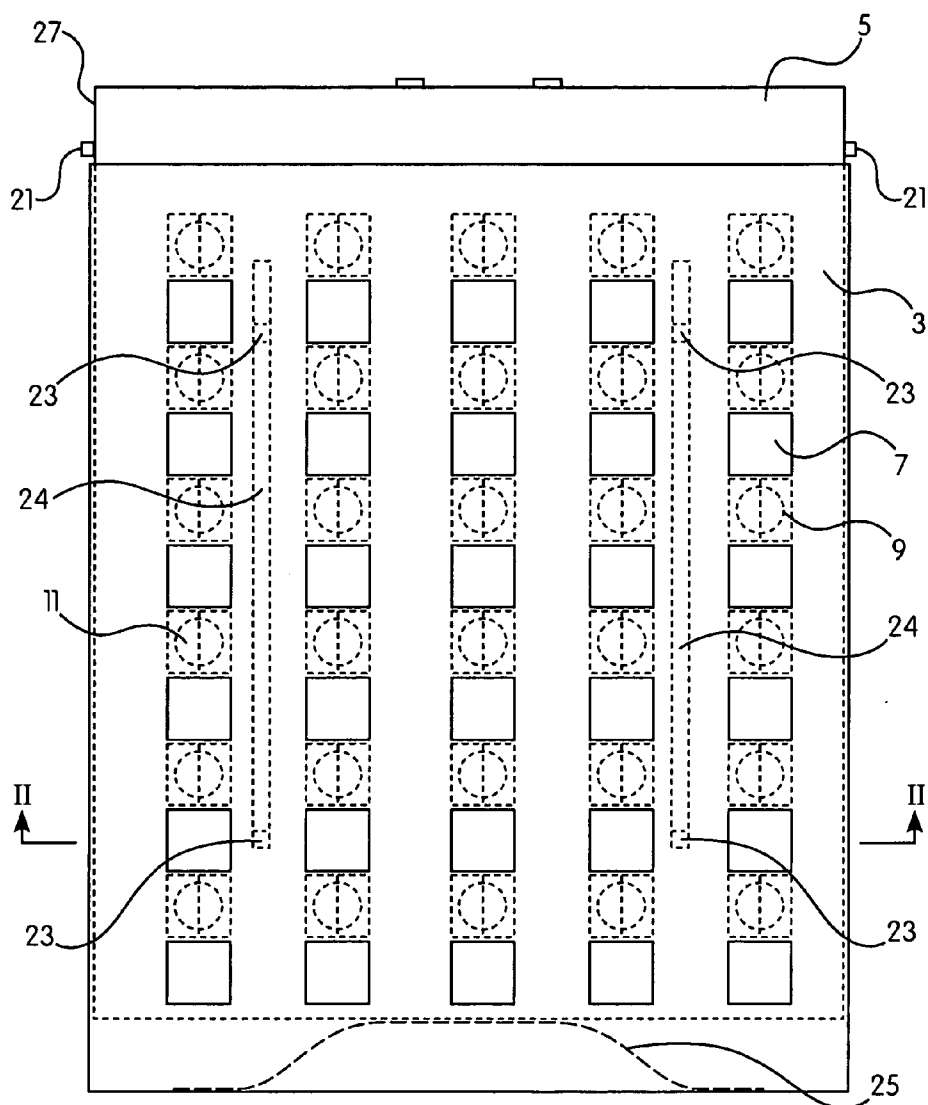


FIG. 1

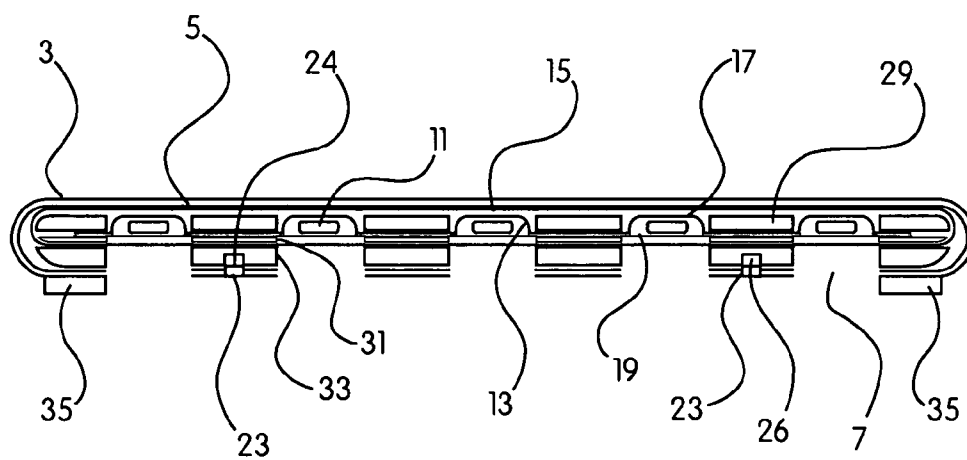


FIG. 2

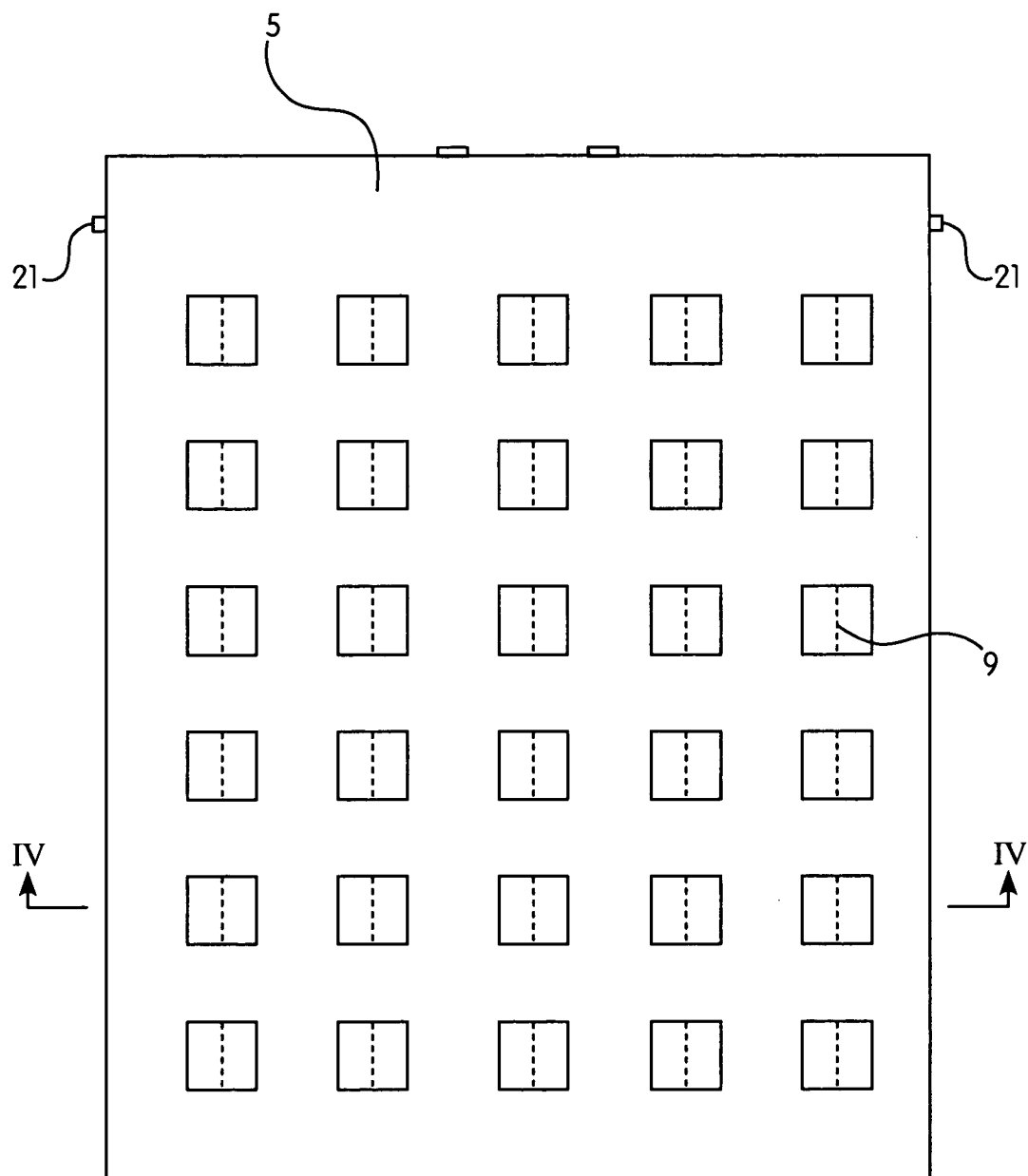


FIG. 3A

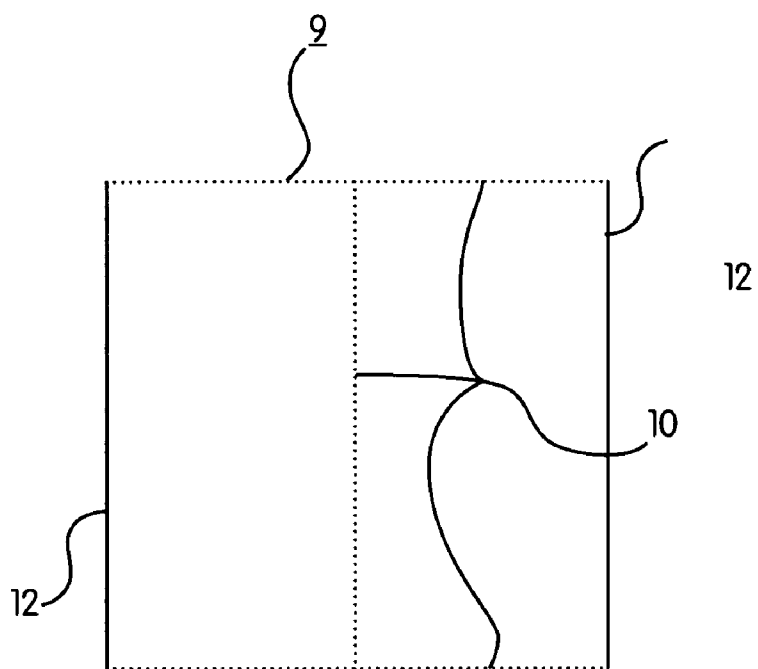


FIG. 3B

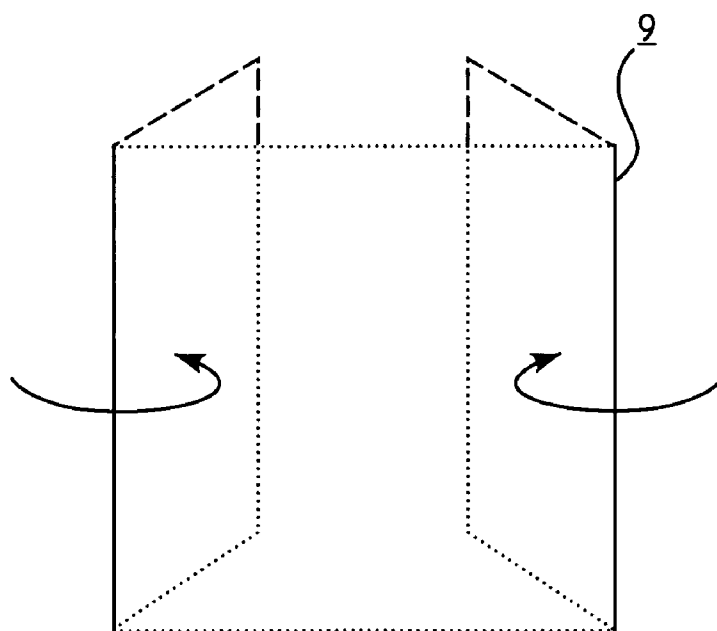


FIG. 3C

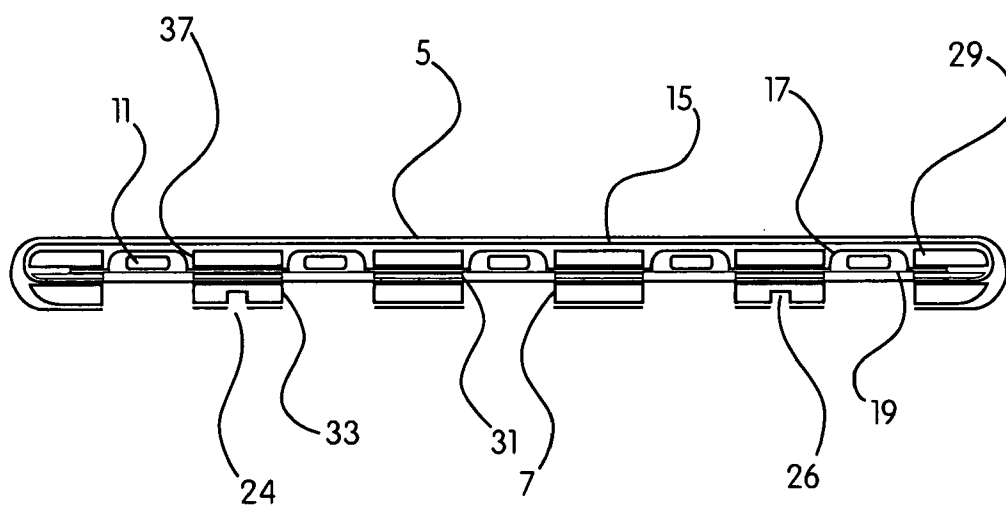


FIG. 4

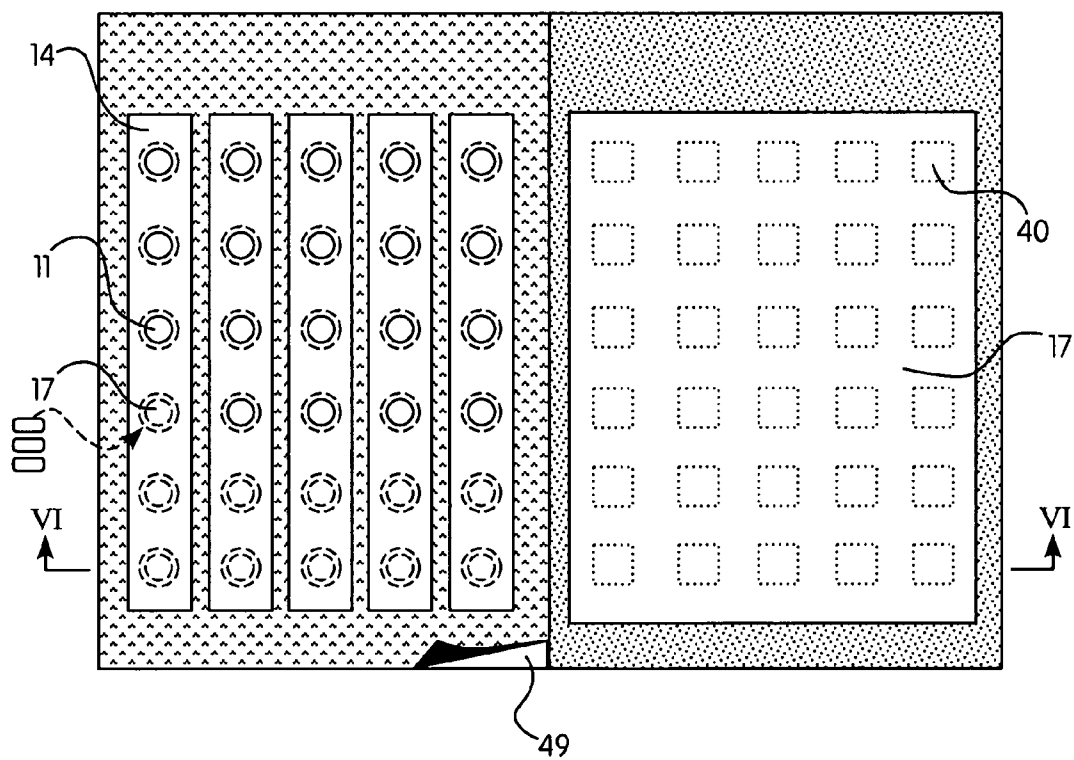


FIG. 5

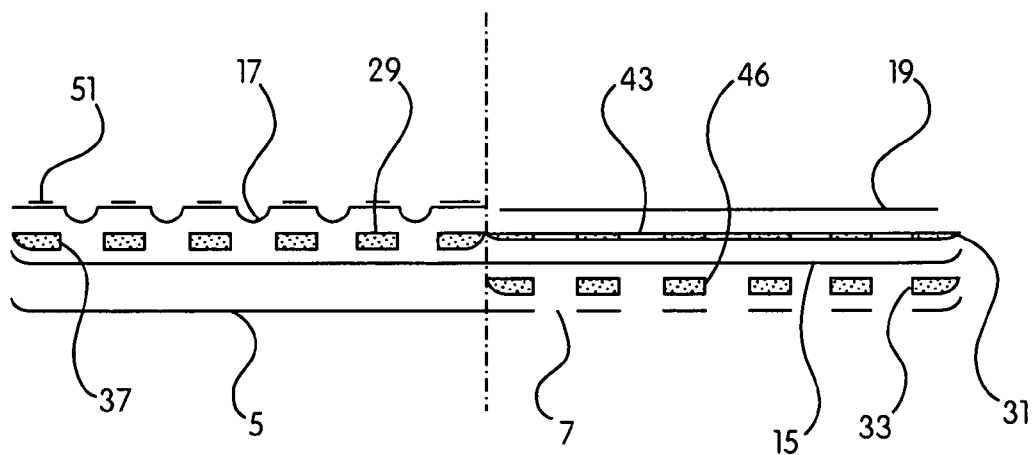


FIG. 6

FIG. 7A

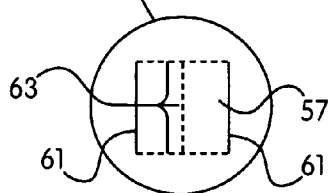
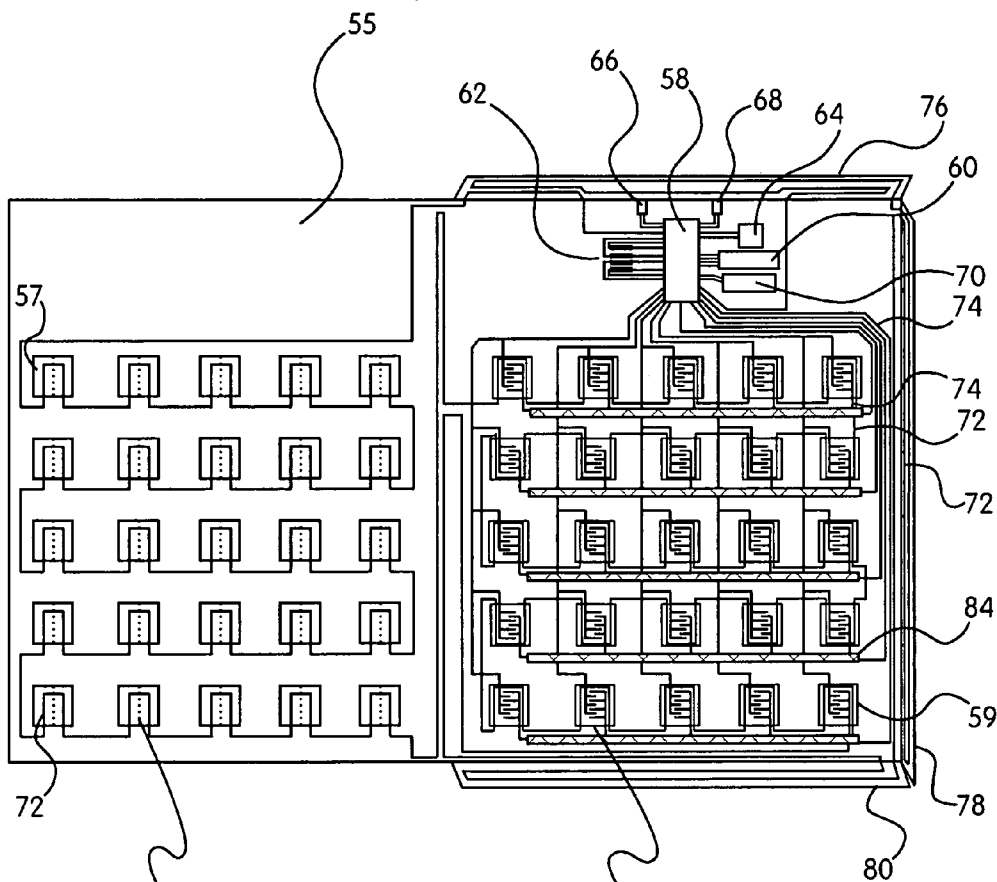


FIG. 7B

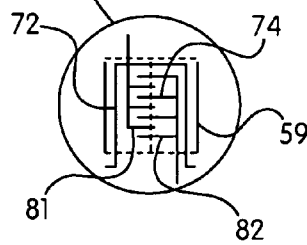


FIG. 7C

FIG. 8A

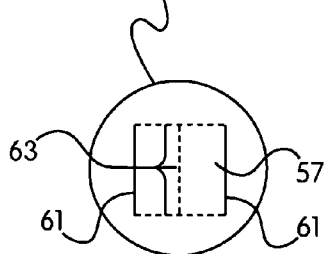
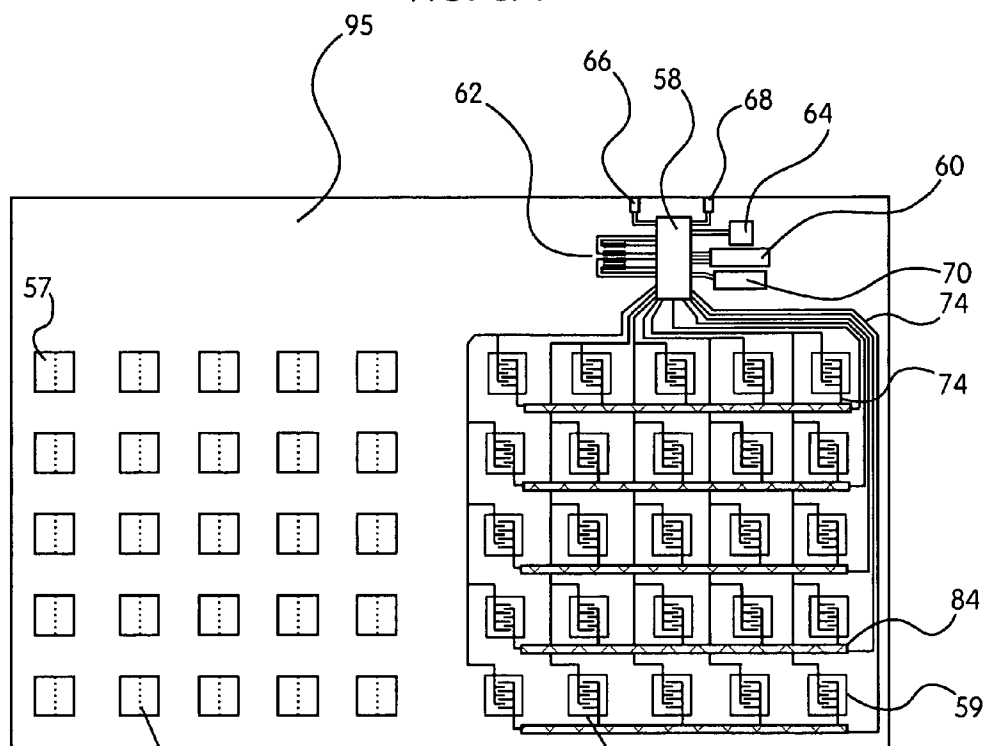


FIG. 8B

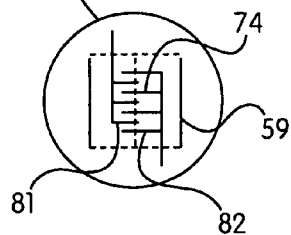
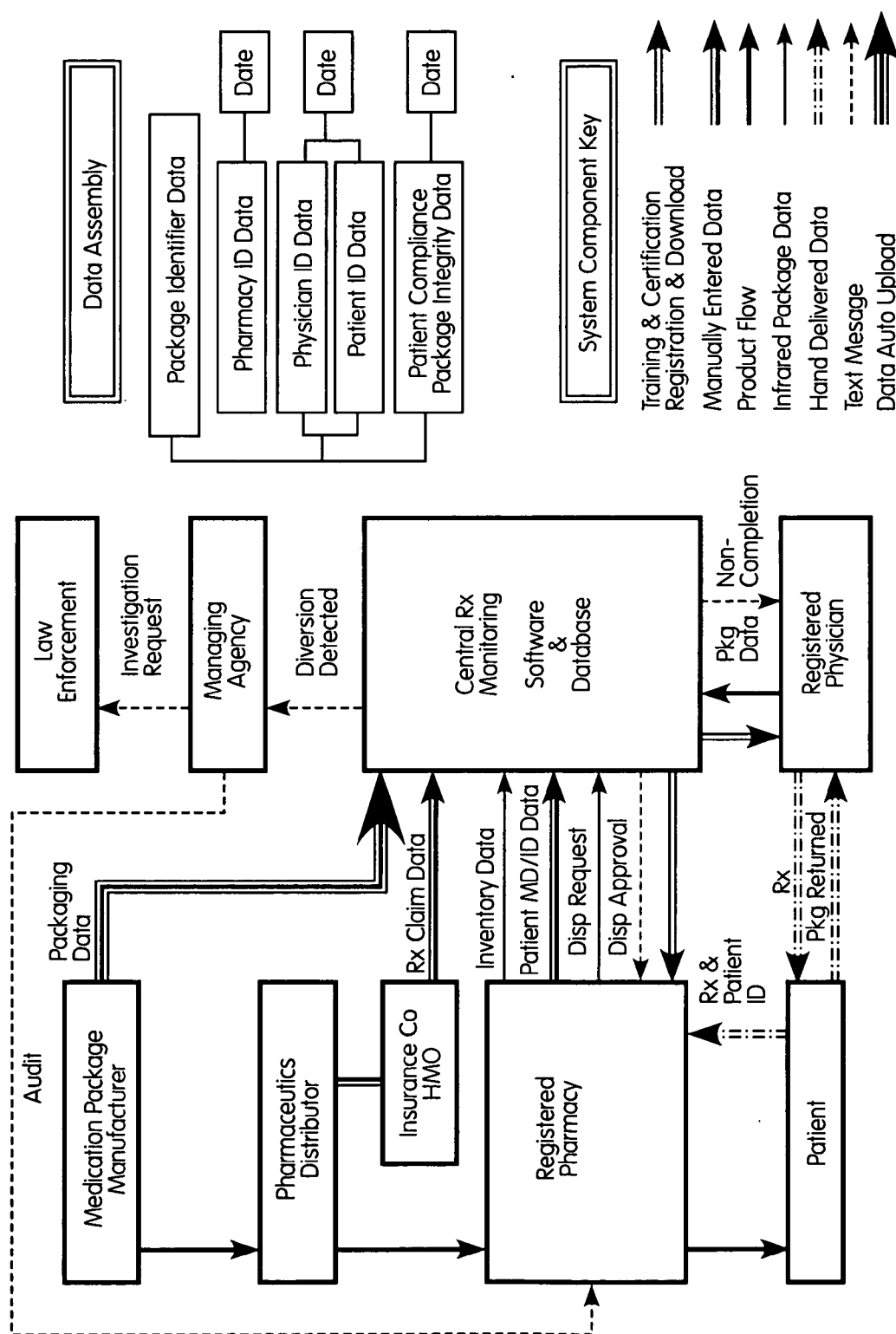
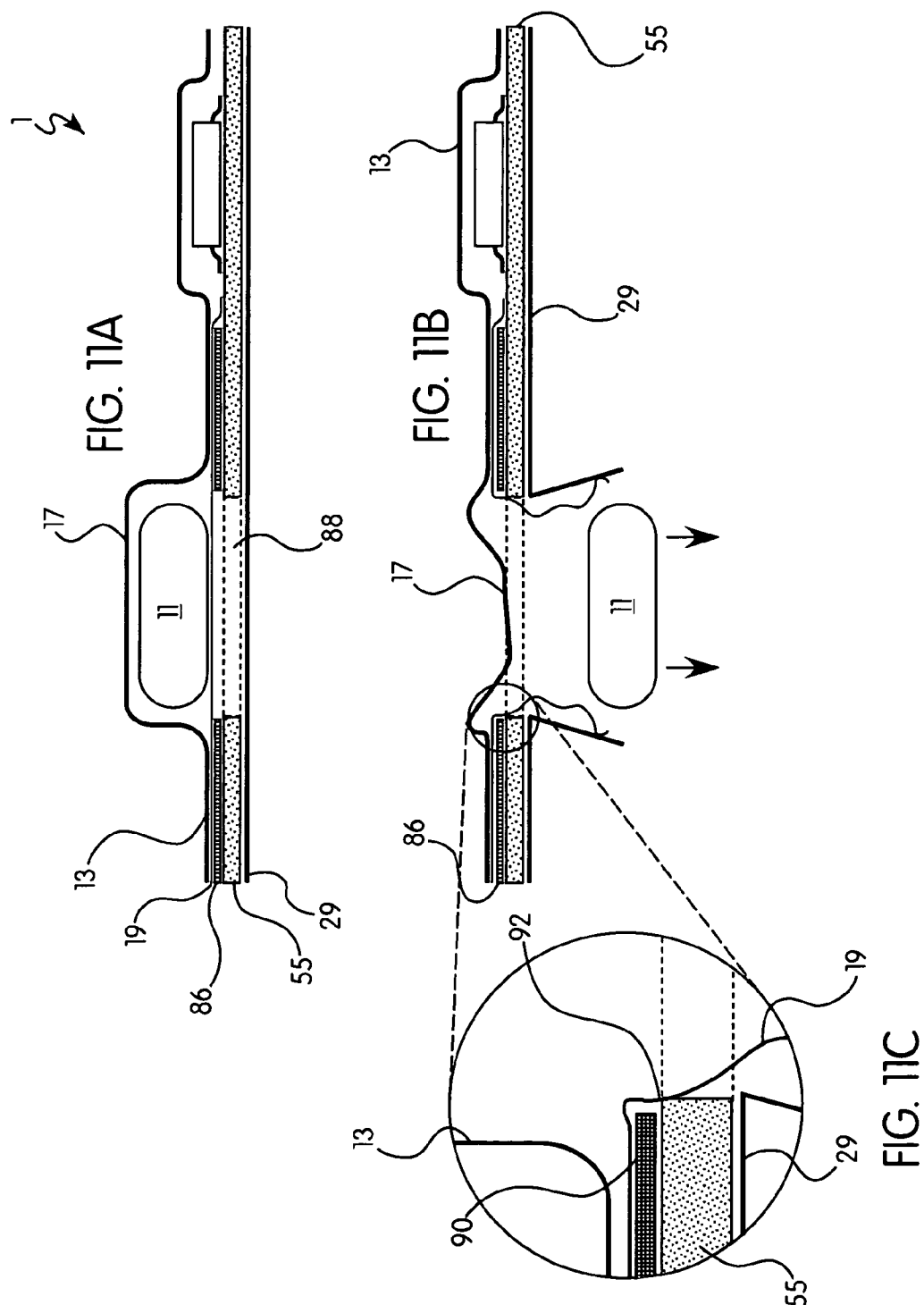
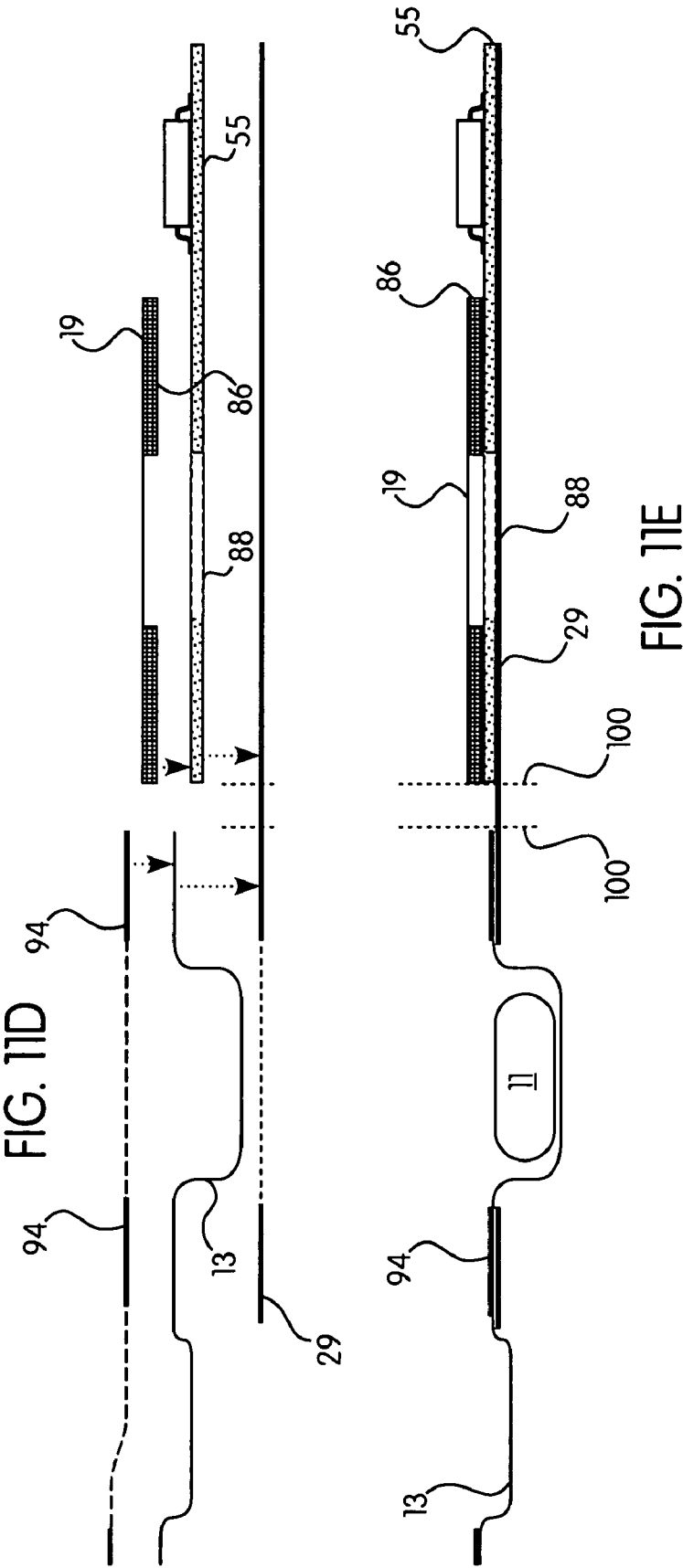
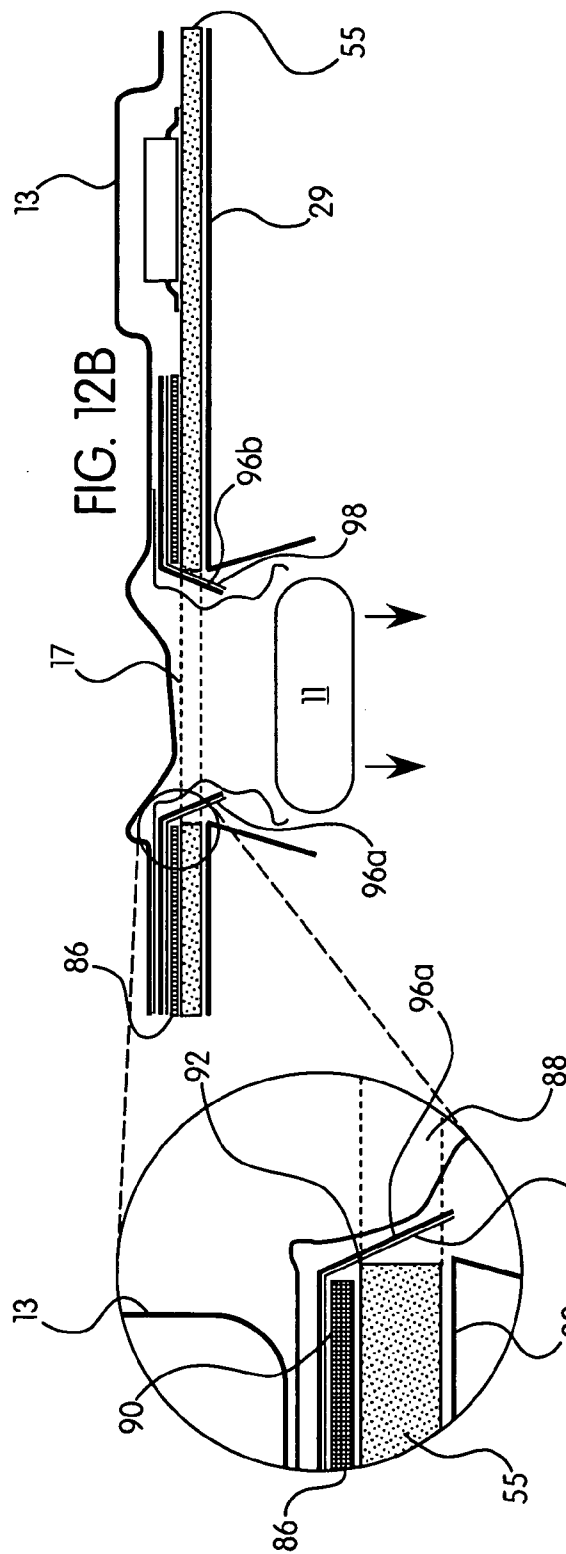
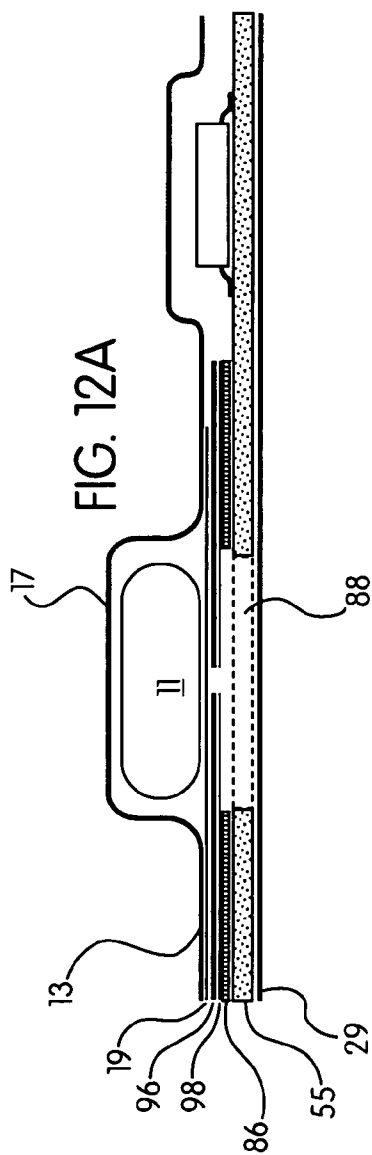


FIG. 8C









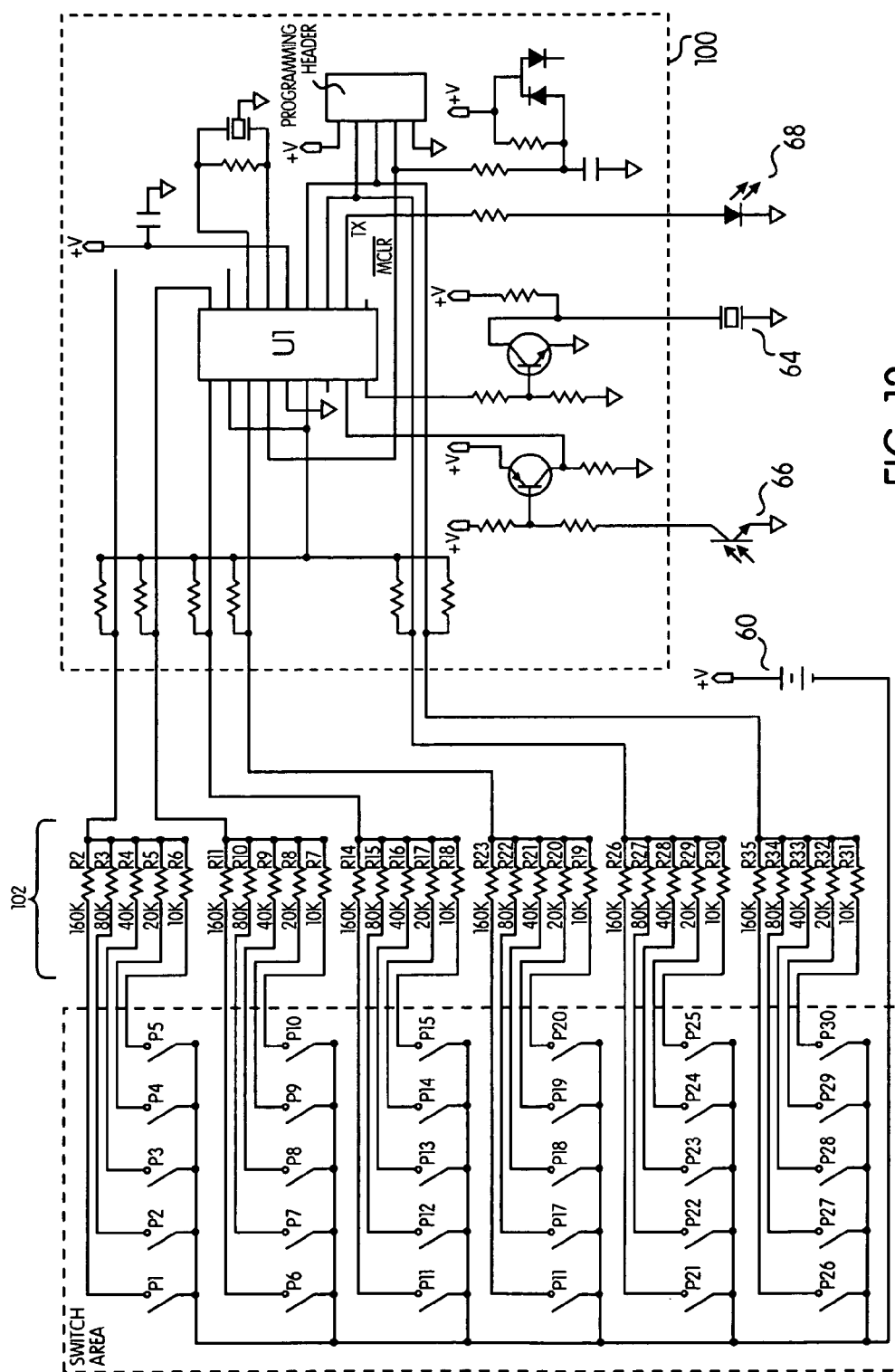
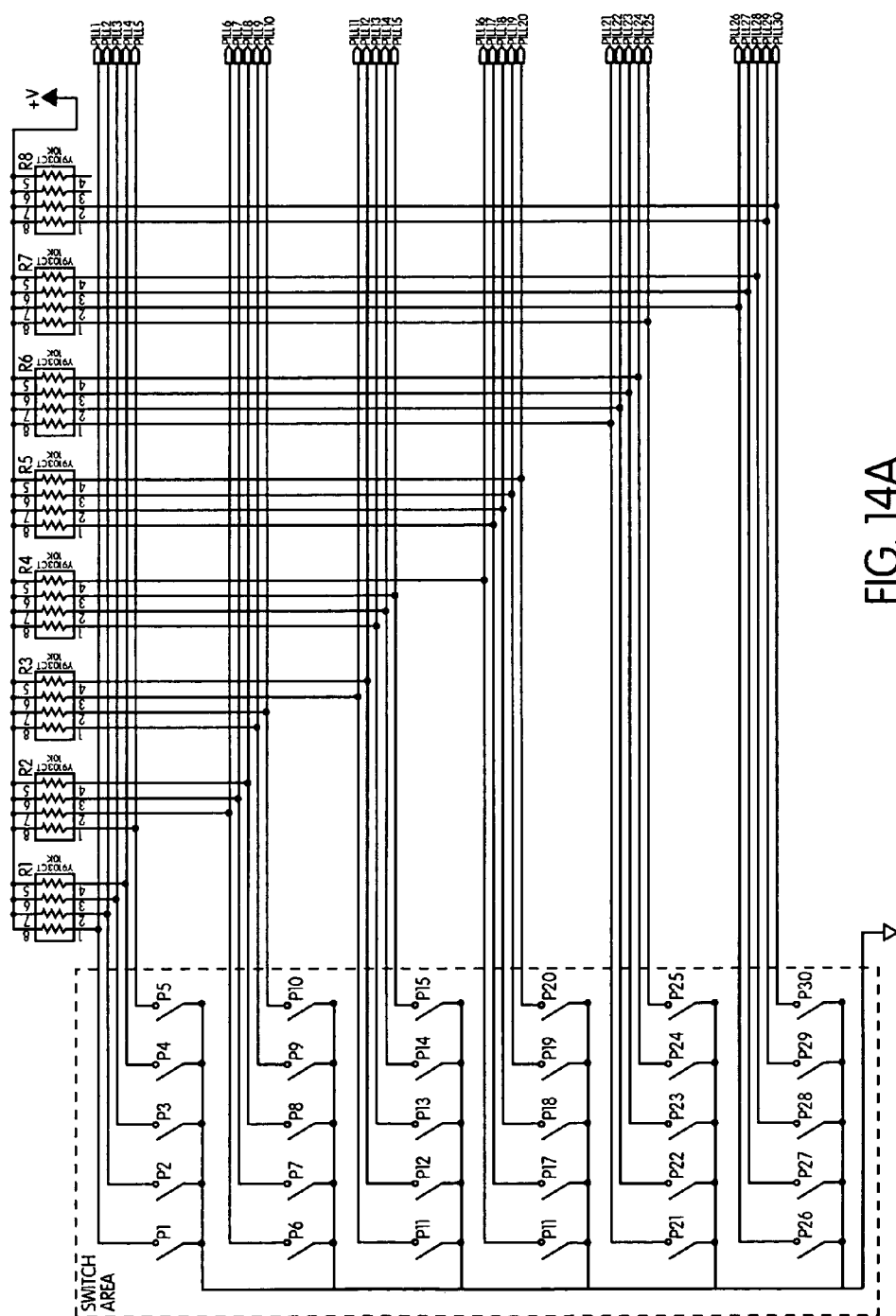


FIG. 13



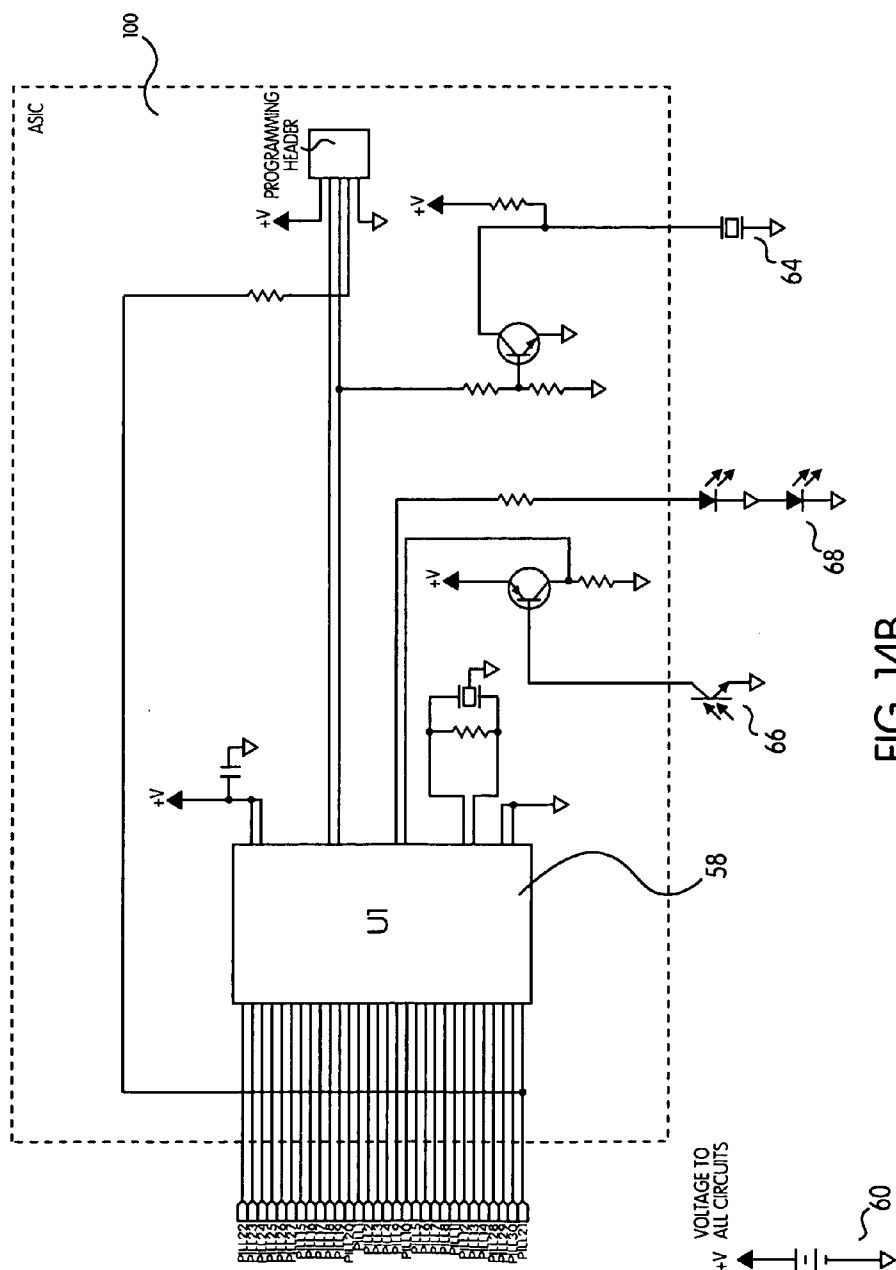


FIG. 14B

MONITORED MEDICATION PACKAGE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. patent application Ser. No. 10/796,224, filed Mar. 9, 2004, which application in turn claims the benefit of U.S. Provisional Patent Application Ser. No. 60/453,297, filed Mar. 10, 2003.

BACKGROUND OF THE INVENTION

[0002] The invention generally relates to packages and containers for medication, and more particularly, to a medication package and associated method for anti-diversion detection and compliance monitoring.

[0003] Adherence to prescription medication dosing schedules is often problematic for both the patient and the physician. Forgetting to take medications, or non-compliance, results in poor patient outcome and often is not reported to the prescribing physician by the patient. This can result in the physician increasing the dosage or changing to a different class of medication because of apparent ineffectiveness. Conversely, the taking of medications too frequently, or abuse, can have dangerous consequences for the patient. There is also a problem with diversion of the medication. Hereinafter, "diversion" will be used to refer to the diversion of a medication with abuse potential from the intended legitimate patient population to an illicit market. The non-medical use and diversion of prescription drugs such as opioids, stimulants and central nervous system depressants can lead to abuse, addiction, and even death. While doctors and pharmacists often attempt to assure medications are being dispensed and used as prescribed, diversion of medications to the illicit market has risen to unprecedented levels. Currently, there are no, or inadequate, effective measures in place to counteract the problems that allow diversion of medications with abuse potential.

[0004] It is well known that prescription drugs relieve symptoms for millions of people and allow those who suffer from chronic syndromes to lead productive lives. Unfortunately, noncompliance is common in many disease syndromes such as schizophrenia, depression and dementia. It is intuitive that non-compliance translates into additional cost to our health care system. Additionally, most people who use medications do so responsibly; however, the non-medical use of prescription drugs, especially pain medications, has become a serious public health concern. Non-medical use of drugs such as opioids, stimulants and central nervous system depressants can lead to abuse, addiction, and even death. Consequently, communities are finding their limited social and financial resources overwhelmed by the high cost of rehabilitating those who become addicted to one of these medications. In addition, crime rates have risen dramatically in those geographic areas endemic with abuse of these medications. According to the "National Household Survey on Drug Abuse," 1999, there were an estimated 4,000,000 people were using prescription drugs non-medically in that year. That survey found that, of these, 2.6 million misused pain relievers, 1.3 million misused sedatives and tranquilizers, and 0.9 million misused stimulants. Furthermore, this illicit diversion of medications has resulted in unnecessary expense to medical insurance carriers, a significant factor in

our cost driven health care system. As provided in a 1999 report by the "Substance Abuse and Mental Health Services Administration" (SAMHSA), visits to hospital emergency departments due to abuse of one particular pain medication, hydrocodone, increased 37% from 1997 to 1999. Aside from the obvious problem addiction causes the patient, many of these cases also result in expensive litigation costs to the drug manufacturer, physician and the malpractice liability insurance carriers. While doctors and pharmacists currently attempt to assure medications are being dispensed and used as prescribed, diversion of medications to the illicit market has risen to unprecedented levels. The total cost to the U.S. economy associated with diversion of prescription medications is estimated to be 1.77 billion dollars annually.

[0005] Prescribing physicians and pharmacists have little at their disposal to prevent non-compliance, abuse, and diversion, other than the word of the patient that the medications are being sought and taken in a legitimate fashion and as prescribed. Patients, for example, who receive prescription drugs legitimately may inadvertently or intentionally take them too frequently, which may result in abuse or addiction. Additionally, a patient may obtain prescriptions for a pain reliever from multiple doctors simultaneously in an attempt to abuse the medication or sell it illegally. Known as "doctor-shopping," this practice continues because current prescription monitoring programs are inefficient and ineffective. At follow-up office visits the prescribing physician has no way of monitoring whether any doses were removed from the package ahead of time, which could suggest abuse or diversion is occurring. There are also reported cases of unscrupulous doctors financially motivated to wantonly write prescriptions or directly supply pain relievers to patients for cash. Other examples of diversion are theft of pain relievers by pharmacy employees, falsification of medication inventory by pharmacy employees and theft of prescription pads from doctors' offices.

[0006] According to a March 2001 report by "Alliance of States with Prescription Monitoring Programs," there are currently 17 states that have central prescription-monitoring (PM) programs. However these programs established to counteract diversion can be ineffectual due to multiple factors, such as, for example, the following:

[0007] The transfer of patient and prescription information from the pharmacy to the PM database at the time the medication is dispensed is manually entered by the pharmacist. This process is slow, inefficient, allows for human error with regard to data entry and is not in real-time.

[0008] The current PM programs require months to process the data received from the pharmacies. The lack of a real-time database allows diversion to continue because the dispensing pharmacy has no way of communicating with other pharmacies to determine, for example, if the patient had filled similar prescriptions obtained from different doctors that day.

[0009] Pharmacies are mandated by law to perform monthly inventories of all medications with abuse potential and report this data to the managing agency overseeing the PM program. This depends on the pharmacist entering truthful and valid inventory data, which is unlikely to occur if the pharmacists themselves are diverting the medications for profit.

[0010] Patients by law can only be prescribed one-month supplies, with no refills, of medications with abuse potential such as pain relievers or stimulants. This requires the patient to return to their doctor monthly for subsequent prescription renewals. The physician has no way of knowing at these follow-up office visits if the pills were taken as prescribed during the previous month. Currently, for example, a patient can remove all the pills from the bottle on the day the prescription is filled and sell them, or take them too frequently and become addicted.

[0011] There have been numerous examples of unscrupulous doctors prescribing medications with abuse potential in a profit-seeking manner. The current PM programs have allowed this illegal activity to continue, often for years before the trend is detected, due to the slow dissemination of information to the central database.

[0012] Patients currently steal prescription pads or forge legitimately obtained prescriptions. Current PM programs are unable to detect this illegal activity.

[0013] It is known in the art to provide packages, containers, dispensers, and the like which have provisions for dispensing individual doses of medication and have audible reminders of dosing times. Such a device is described in, for example, U.S. Pat. No. 4,617,557. It is also known to obtain and provide compliance data to prescribing physicians for review, as described in, for example, U.S. Pat. No. 6,198,383. However, it is not known to address the aforementioned issues that allow abuse, addiction and diversion of prescription medications to illicit use. Additionally, such medication packages may not sufficient incorporate child-resistant features. Furthermore, in regard to the patent referenced above which addresses compliance issues, the device described therein employs conductive traces that must be broken to detect removal of the medication from the package. This can result in decreased battery life of the medication package, and an increased number of required inputs to the central processing unit (CPU) in the medication package, thereby increasing the packaging cost.

[0014] Accordingly, there is a need for a medication packaging system which has improved packaging, including child-resistant features and longer battery life, and which further incorporates both anti-diversion capabilities and compliance monitoring functions.

SUMMARY OF THE INVENTION

[0015] According to the invention, a medication package and associated system are provided to enable compliance monitoring and anti-diversion features. The medication package can also be provided with child-resistant features. An electronic circuit board, integrated with the medication package, has low power requirements, which enables the compliance monitoring and anti-diversion capabilities. The CPU can identify and record dose removal events and the medication package can further include components for conveying the record of such events to other devices electronically via various mediums, including wired or wireless data transfer. Thereby, the data can be transferred to other computers or printed out. The data can also be provided to various personnel involved in addressing the compliance and/or anti-diversion issues.

[0016] The medication package can comprise a plurality of doses disposed in any arrangement, for example, a rectangular-shaped package containing rows and columns of doses or a circular package containing doses arranged in concentric circles. The doses are contained in a blister pack of a type well known in the art, for example, a plastic bubble film defining a plurality of bubble chambers and a frangible layer covering the bubble chambers to retain the doses therein. The improvement to the well known blister pack of the present invention incorporates a circuit having a conductive trace associated with each bubble chamber in the blister pack. Additionally, the frangible layer is composed of a conductive material and is also connected to the circuit via a conductive trace. The breaking of the frangible layer to remove a dose cannot occur without the frangible layer contacting one of the conductive traces associated with an individual bubble chamber, thus causing a detectable event. The CPU detects removal events when a dose is removed, and records the relative time of each removal.

[0017] In a second embodiment of the invention, a flexible plastic layer is disposed under the frangible foil layer, the plastic layer having a conductive foil adhered to the underside thereof. When a dose is pushed through the frangible foil layer, its passage causes a portion of the flexible plastic layer to bend toward the electronic circuit board, thereby causing the conductive foil on the underside thereof to contact conductive traces on the electronic circuit board, closing a circuit and causing a dosage removal event to be recorded. The resilient nature of the plastic layer then causes the conductive foil to be retracted from the electronic circuit board.

[0018] The medication package can include a child-resistant cover, i.e., a cover resistant to access by children, and a heavy backing material and/or circuit board spacers on either side of the blister pack. The openings on the child-resistant cover do not align with the openings in the thicker backing material until the child-resistant cover is moved to a second, aligned position. The child-resistant cover cannot be moved to the aligned position without negotiating cooperating engagement features associated with the child-resistant cover, and at least the outer packaging material. In addition, the child-resistant cover is spring loaded, such that it must be held in its aligned position during the dosage removal event, and then automatically snaps back to its original, locked position.

[0019] Initially, the blister pack can be loaded with medication by a licensed pharmacist and then assembled together with the thicker backing material, electronic circuit board portion, and other parts of the medication package, which are within the child-resistant cover. The medication package can be manufactured in such a fashion that allows a pharmacist to "load" the blister pack with any combination or doses of pills, thereby providing dosing flexibility to the prescribing physician. The dose time interval can be preset when the dose package is assembled by the pharmacist.

[0020] The anti-diversion capability can further include providing a conductive trace incorporated into the periphery of the package such that removing a dose cannot be done without disturbing one of the breakaway conductive traces and causing a detectable event. Attempts to remove doses in an unconventional manner, to avoid breaking the frangible layer directly adjacent a bubble chamber, are thereby

deterred. Also, the heavy backing material can be designed to cooperate with the blister pack in such a fashion that each dose must be removed from it in the prescribed manner, i.e., by pushing it through the frangible backing layer, or the removal of the dose will be detected and recorded by the CPU as a "tamper" event. The CPU can periodically check the status of the conductive traces to detect dose removal and tamper events.

[0021] The removal of the first dose can initiate the countdown timer sequence which in turn can trigger a visual or audible alarm when the next dose is to be taken by the patient. When each subsequent dose is removed from the package, the CPU can record the time elapsed from the previous dose, and can reset the timer to count down to the next dose. In another embodiment, a pharmacist may activate the circuitry and start the countdown timers at the time when the doses are loaded into the package at a local pharmacy. The CPU can also contain a unique and sequentially programmed package identifier code.

[0022] The CPU can transfer stored data to other devices, including a central database, via wired or wireless communication, including via the Internet, where the information can be processed and analyzed. This data may include information identifying the individual dose package code, patient compliance data and data reflecting the integrity of the medication package, as well as manually entered data, such as via a connected computer, reflecting the unique prescribing physician identifier data and unique patient identifier data. The collected data can be accessed and processed by various entities involved in implementing compliance and anti-diversion objectives.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] FIG. 1 is a front view of an embodiment of a medication package according to the invention.

[0024] FIG. 2 is a view partially in section of the of the medication package in FIG. 1.

[0025] FIG. 3a is a front view the medication package shown in FIG. 1 with a child-resistant cover portion removed.

[0026] FIGS. 3b and 3c show the mechanical details of the perforated opening of FIG. 3a.

[0027] FIG. 4 is a section view of the medication package in FIG. 3a.

[0028] FIG. 5 is a laid open view of a medication package as shown in FIG. 1.

[0029] FIG. 6 is an exploded partial section view of FIG. 5.

[0030] FIG. 7a is a laid open front view of an embodiment of a circuit board configuration having both tamper-proof traces and dose removal traces.

[0031] FIG. 7b is a mechanical detail of a perforated opening in FIG. 7a.

[0032] FIG. 7c is an electronic detail of a perforated opening in FIG. 7a.

[0033] FIG. 8a is a laid open front view of an embodiment of a circuit board configuration having only dose removal traces.

[0034] FIG. 8b is a mechanical detail of a perforated opening in FIG. 8a.

[0035] FIG. 8c is an electronic detail of a perforated opening in FIG. 8a.

[0036] FIG. 9 is a detail view of FIG. 4a illustrating removal of a dose of medication.

[0037] FIG. 10 is a logic diagram illustrating transmission, collection, and processing of data obtained by a medication package according to the invention.

[0038] FIG. 11a is a cross-sectional view of an additional embodiment of the invention.

[0039] FIG. 11b is a cross sectional view of the embodiment of FIG. 11a showing a dosage unit being pushed out of the packaging.

[0040] FIG. 11c is an expanded view of a portion of FIG. 11b.

[0041] FIG. 11d is a cross sectional view of the embodiment of FIG. 11a. prior to the packaging being sealed.

[0042] FIG. 11e is an exploded version of the cross sectional view of FIG. 11d.

[0043] FIG. 12a is a cross sectional view of an additional embodiment of the invention.

[0044] FIG. 12b is a cross sectional view of the embodiment of FIG. 12a showing a dosage unit being pushed out of the packaging.

[0045] FIG. 12c is an expanded view of a portion of FIG. 12b.

[0046] FIG. 13 is a schematic of the electronic portion of the packaging, showing one possible embodiment of the circuit.

[0047] FIGS. 14a and 14b show an alternative embodiment of the invention having switches directly connected to the logic detection circuitry.

DETAILED DESCRIPTION OF THE INVENTION

[0048] Referring now to FIGS. 1 and 2, there is shown a frontal view of an embodiment of a complete medication package 1 according to the invention, as configured for a 30-dose prescription, including a child-resistant cover 3 enveloping the outer packaging material 5 of the medication package 1. The child-resistant cover 3 can include multiple openings 7 arranged in rows and columns. When the child-resistant cover 3 is moved to a second position, these openings 7 are arranged to align with multiple perforated and/or scored regions 9, referred to hereinafter as perforated openings 9, in the outer packaging material 5 which are likewise arranged in rows and columns. Ultimately, these rows and columns of openings 7 and perforated openings 9 align with individual doses 11 of medication contained in a blister pack 13 (FIG. 2) enclosed within the outer packaging material 5. However, child-resistant cover 3 cannot be moved to the second, aligned position unless multiple child-resistant safety features are first negotiated.

[0049] As shown best in FIG. 2, the outer packaging material 5 encloses an electronic circuit board portion 15, and that the electronic circuit board portion 15 further

surrounds the blister pack 13 formed of a plastic layer having formed therein a plurality of individually formed blisters 17, hereinafter referred to as bubble chambers 17, in which can be contained the individual doses 11 of medication. The other side of the blister pack can be covered by a frangible layer 19. Between the blister pack 13 and an upper side of the electronic circuit board portion 15 can be provided a layer of heavy backing material 29, and the lower side of the electronic circuit board portion 15 can be sandwiched between thin and thick circuit board spacers 33. The thin spacer 31 can be intermediate the blister pack 13 and the lower side of the electronic circuit board portion 15, whereas the thick spacer 33 can be opposite the thin spacer 31, but beneath the lower side of the electronic circuit board portion 15, such that the electronic circuit board portion 15 is sandwiched between the thin 31 and thick 33 spacers.

[0050] The rear face (not shown) of child-resistant cover 3 can also have multiple openings, which can also be denoted by reference number 7, and which are also aligned with the openings 7 in the front face. Feet 35 can be provided on child-resistant cover 3, which extend downwards from the rear face of the cover 3, and which can support the medication package 1 up off of an underlying surface (not shown), such as a table or counter top. As implied by the name, child-resistant cover 3 can be provided with the aforementioned safety features that make the cover resistant to being manipulated by children. These safety features can include a pair of locking portions, such as safety push buttons 21, which can project from opposite the sides, or edges, of the outer packaging material 5, a cover closure spring 25, and slide tabs 23, which could also be rails, on child-resistant cover 3 that cooperate with slots 24 in the outer packaging material 5. The safety pushbuttons 21 can prevent movement of child-resistant cover 3 relative to the outer packaging material 5 unless the push buttons 21 are depressed to unlock child-resistant cover 3 and permit movement to a position where the openings 7 are aligned with the doses 11 in the blister pack 13. The cover closure spring 25 urges child-resistant cover 3 in a closed position in which the openings 7 are not aligned with the doses 11 in the blister pack 13. Child-resistant cover 3 must be pushed in against the closure spring 25 to compress the closure spring 25, and the closure spring 25 must be held in the compressed state in order to maintain child-resistant cover 3 in the aligned position until the dose 11 is removed from the blister pack 13.

[0051] The slide tabs 23 are slidably received in the slots 24, and a cover closure spring 25 can be provided to urge child-resistant cover 3 in a normally unaligned position. In cooperation with child-resistant cover 3 safety features, a portion of the enclosed medication package 1 extends from within surrounding child-resistant cover 3, i.e., child-resistant cover 3 can have a length somewhat shorter than the enclosed portion of medication package 1. The portion 27 of the outer packaging material 5 of the medication package 1 which extends out beyond child-resistant cover 3 can have the aforesaid safety pushbuttons 21 which must be negotiated in order to permit child-resistant cover 3 to slide relative to the enclosed medication package 1, via the cooperating slide tabs 23 and slots 24, in order to move child-resistant cover 3 to the second position with the openings 7 aligned with the doses 11 contained in the enclosed blister pack 13. The safety push buttons 21 can retractably project outwards from the sides of the outer packaging material 5 such that the

openings 7 in child-resistant cover 3 cannot align with the perforated openings 9 in the outer packaging material 5, and thus the individual doses 11 in the enclosed blister pack 13.

[0052] Child-resistant cover 3 and closure spring 25 can be designed such that depressing the safety push buttons 21 permits the enclosed portion of the medication package 1 to be pressed into child-resistant cover 3, by compressing the closure spring 25, to align the openings 7 in child-resistant cover 3 with the perforated openings 9 in the outer packaging material 5 and the individual doses 11 contained in the enclosed blister pack 13. As shown, the slide tabs 23 on the inside of the rear face of child-resistant cover 3 can project inwardly toward the outer packaging material 5, and the slots 24 can be provided in the lower face of the outer packaging material 5 for slidably receiving the slide tabs 23. The slide tabs 23 and slots 24 can help position and maintain child-resistant cover 3 in a properly aligned sliding relationship to ensure alignment of the openings 7 in child-resistant cover 3 with the doses 11 stored in the enclosed blister pack 13 when child-resistant cover 3 is negotiated.

[0053] Child-resistant cover 3 must be moved to a position at which the openings therein align with the perforated openings 9 in the outer packaging material 5 and thus the individual doses 11 of medication contained in the blister pack 13, before it is possible to remove any doses 11. Generally, opening the fully assembled medication package 1 and removing a dose 11 of medication can be accomplished by a three step sequence: depressing each safety push button 21; sliding the medication package 1 relative to child-resistant cover 3 to align the openings 7 therein with the perforated openings 9 in the outer packaging material 5; and pressing through the openings 7 and perforated openings 9 to dislodge a dose 11 from the enclosed blister pack 13 and out from the package 1. Removal of a dose 11 can most easily be done by placing the medication package 1 on a flat surface prior to pressing through the openings 7 to dislodge the dose 11 from the blister pack 13. Additional details of the pill removal procedure will be described hereinafter, and especially in connection FIG. 9.

[0054] Referring now to FIGS. 3a through 4, further details of the portions of the medication package 1 surrounded by child-resistant cover 3 and the outer packaging material 5 can be viewed. As shown with child-resistant cover 3 removed, the outer packaging material 5 can have the plurality of perforated openings 9 referred to above. A detail view of a perforated opening 9 is shown in FIGS. 3b and 3c, which show that the region can have scoring 12 at opposite sides and perforations 10 along the top, bottom, and centerline of the region. It is to be understood that these, or any other similar perforated openings of other portions of the medication package 1 as described hereinafter, could instead be true "openings." As shown in FIG. 3c, applying pressure, particularly against the perforated center line, will result in pushing through the opening 9 by tearing along the perforations 10 and folding, or hinging, about the scoring 12. The perforated openings 9 in the outer packaging material 5 are located for alignment with each of the individual doses 11 contained in the bubble chambers 17 in the enclosed blister pack 13.

[0055] The cross section view in FIG. 4 provides a more detailed look at the inner arrangement of the components of the medication package 1, showing that the outer packaging

material **5** surrounds the electronic circuit board portion **15**, and that the electronic circuit board portion **15** encloses the blister pack **13** containing the individual doses **11** of medication. Other layers of the assembly can also be provided, including a heavy (e.g., thicker or more rigid) backing material **29** adjacent the bubble chamber **17** side of the blister pack **13**, intermediate the blister pack **13** and an upper side of the electronic circuit board portion **15**. The heavy backing material **29** can have a plurality of openings **40** which are aligned with the raised bubble chambers **17** of the blister pack **13**, such that the bubble chambers **17** project through the openings **40** in the heavy backing material **29**, thus permitting the heavy backing material **29** to lie generally flat adjacent the blister pack **13**. The thickness of the heavy backing material **29** can be generally equal to the depth of the bubble chambers **17**, which accounts for the thickness of the raised bubble chambers **17**, thus creating a generally flat surface to facilitate closely adjacent positioning of the upper side of the electronic circuit board portion **15** against the bubble chambers **17**. The heavy backing material **29** can also be designed to cooperate with the blister pack **13** to prevent removal of a dose **11** of medication in an unconventional manner, i.e., in some manner other than forcing the dose **11** through the frangible layer **19** of the blister pack **13**. Providing a generally flat surface can be desirable because the upper side of the electronic circuit board portion **15** has perforated openings with associated conductive traces provided thereon (described in connection with FIGS. 7a and 8a) adjacent each of the bubble chambers **17**, which contain the individual doses **11** of medication. It can be desirable that the perforated openings and conductive traces be closely adjacent the bubble chambers **17** to facilitate both removal of a dose **11** and the detection of such a removal.

[0056] The blister pack **13**, which is generally the innermost portion of the medication package **1**, can comprise two layers. The first can be the blistered plastic layer **14** having formed therein the bubble chambers **17**, in which are disposed the individual doses **11** of medication. The second layer is the frangible backing **19**, which covers the open side of the bubble chambers **17**. The frangible layer **19** can be a thin sheet of frangible material, which can also be made from a conductive material, such as a thin foil layer. The frangible foil layer **19** can have perforated openings **40** adjacent each of the bubble chambers **17** to facilitate removal of the doses **11** of medication therethrough. Adjacent the frangible layer **19** of the blister pack **13**, intermediate the frangible layer **19** and the upper side of the electronic circuit board portion **15**, can be provided a further layer of material, referred to previously as the thin circuit board spacer **31**, or simply a thin spacer **31**. The thin circuit board spacer **31** can, like the heavy backing material **29**, also be provided with a plurality of openings **43** therethrough, each of which can be located to align with all of the following: the perforated openings **40** in the adjacent frangible layer **19** of the blister pack **13**; the bubble chambers **17** covered thereby; the openings in the heavy backing material **29**; and perforated openings in the upper side of the electronic circuit board portion **15**. A second spacer, referred to previously as the thick circuit board spacer **33**, or simply a thick spacer **33**, can also be provided, and can be positioned beneath of the lower side of the electronic circuit board portion **15**. Thus, the lower side of the electronic circuit board portion **15** is sandwiched between the thin **31** and

thick **33** circuit board spacers. As with the upper side of the electronic circuit board portion **15**, the lower side thereof can likewise have a plurality of perforated openings, which are positioned in alignment with the perforated openings in the upper side thereof. Similarly to the thin spacer **31**, the thick spacer **33** can have a plurality of openings **46**, which can be located to align with each of the perforated openings in both sides of the electronic circuit board portion **15**, the openings **43** in the thin spacer **31**, the perforated openings **40** in the frangible layer, and the bubble chambers **17**. As shown, the thick circuit board spacer **33** is intermediate the lower side of the electronic circuit board portion **15** and the rear face of the outer packaging material **5**. The thick spacer **33** can also have slots **26** in the underside thereof which align with the slots **24** (see FIGS. 2 and 4) in the rear face of the outer packaging material **5**, such that the slide tabs **23** on the lower face of child-resistant cover **3** can extend through the outer packaging material **5** and be slidably received in the slots **24** in the thick spacer **33**.

[0057] Referring to FIG. 5, prior to assembly the medication package **1** is initially open, much like an open book, such that the doses **11** can be loaded into the blister pack **13** by the pharmacist. The various layers are best viewed in FIG. 6. The blister pack **13** is initially open, i.e., the frangible layer **19** has not yet been adhered to the plastic blister layer **14** so that the medication can be inserted into each bubble chamber **17** prior to assembly of the filled blister pack **13**. The doses **11** are loaded into the individual bubble chambers **17**, as shown on the left side of the figure. The plastic blister layer **14** can also include an adhesive backing **49** with a protective cover **51** on the flat surfaces of the bubble layer intermediate the bubble chambers **17**. After the doses **11** of medication are loaded into the bubble chambers **17**, the protective layer **51** is removed, exposing the adhesive layer **49**. The right side of the blister pack **13** can then be folded over onto the left side and, by applying pressure thereto, adhered together via the adhesive layer **51** thus forming a completed, sealed blister pack **13**.

[0058] The left side of the blister pack **13** shows the frangible backing **19** material that covers the openings into the bubble chambers **17**. The frangible backing material **19** can have the aforementioned perforated openings **43** where it covers each of the bubble chambers **17**. However, if the layer **19** is sufficiently frangible, perforations or scoring would not be necessarily required. Preferably, the frangible material is a conductive foil layer. As best shown in FIG. 6, the left side of the blister pack **13** (i.e., the upper half of the completed, "folded over" medication package **1**) will be associated with the thicker heavy backing material **29** and the right side (i.e., the lower half of the completed medication package **1**) will include the thin circuit board spacer **31** and a thick circuit board spacer **33**. The electronic circuit board portion is thus sandwiched between the thin **31** and thick **33** spacers. When the doses **11** of medication are loaded into the blister pack **13**, and the entire assembly of layers is "folded over" by closing the halves against each other, the structure obtained will be as just described in FIG. 4.

[0059] Generally, the upper and lower (or left and right) halves or portions can be brought over adjacent each other by folding along a centerline. However, such as in the case of the electronic circuit board portion **15** in particular, the two halves, or sides, of some layers, particularly the elec-

tronic circuit board portion **15**, can be radiused to bring the two side into a folded over relationship. This can be done to avoid potential damage to the conductive traces on the electronic circuit board portion **15** which could be caused by simply folding the electronic circuit board portion **15** about a centerline. Alternatively, the left and right side portions of the laid open medication package can be entirely separate halves which are secured over against each other in a manner to hold the layers together as depicted, for example, in **FIG. 4**.

[0060] Referring now to **FIG. 7a**, a flat, laid open, view of a particular embodiment of an electronic circuit board portion **55** is shown. As described previously, when folded over, the electronic circuit board portion **55** will enclose the blister pack **13**, in a manner wherein the left (upper) side of the electronic circuit board portion **55** will be adjacent the bubble chambers **17**, and the right (lower) side thereof will be separated from the frangible layer **19** of the blister pack **13** only by the thin circuit board spacer **31**. Both the upper and lower sides of the electronic circuit board portion **15** have a plurality of perforated openings **57** and **59**, respectively, with each perforated opening **57**, **59** located to align with the bubble chambers **17**, and thus also with the perforated openings **40** on the frangible layer **19**, as well as each of the openings **37**, **43**, **46** in each of the heavy backing material **29** and thin **31** and thick **33** circuit board spacers.

[0061] The electronic circuit board portion **55** can have appropriate electronic components mounted thereon, as shown at the top right side thereof, which can include, for example, the CPU **58** (assumed to include memory elements), a battery **60**, a clock generator, or timer **62**, a sound generator **64** (for providing an audible alarm), a data output/input port **66**, an LED **68** (for providing a visual alarm), and an EPROM **70**. Additional components can also be included, as may be found useful in carrying out the electronic functions of the medication package **1**.

[0062] The perforated openings **57**, **59** on each side of the electronic circuit board portion **55** can be as shown in the mechanical opening detail view in **FIG. 7b**, which can have scoring at opposite sides and perforations along the top, bottom and center thereof. The perforated openings **57**, **59** can thus open in the same manner as shown in **FIG. 3c**. This embodiment of the electronic circuit board portion **55** can be provided with two types of conductive traces and the requisite electronic components for effecting both anti-diversion and compliance functions. As shown, the left side of the electronic circuit board portion **55** includes the perforated openings **57** which positioned to lie adjacently above each bubble chamber **17** of the blister pack **13**. Conductive anti-tamper traces **72** can be provided associated with each of the perforated openings **57**, **59** on each side of the electronic circuit board **55** to effect the anti-diversion function. The right side of the electronic circuit board **55** includes the perforated openings **59** which are positioned to lie below the bubble chambers **17**, adjacent the perforated openings **40** on the frangible conductive foil layer **19**. Conductive dose removal traces **74** are provided associated with each of these perforated openings **59** to detect dose removals. The embodiment shown includes both types of conductive traces for a 25-dose blister pack **13**. As shown, tamper-proof traces **72** can be provided on each of the perforated openings **57** and **59** on both left and right sides of the electronic circuit board portion **55**. Additionally, the tamper-proof traces **72**

can be provided on peripheral side portions **76**, **78**, **80** which are designed to fold over the three otherwise exposed sides of the blister pack **13** when the medication package **1** is assembled by bringing the two halves together. The anti-tamper traces **72** can further be provided around the entire periphery of the medication package, i.e., side portion **75** in addition to side portions **76**, **78** and **80** to detect any attempts to remove doses **11** in an unconventional manner.

[0063] The circuit board can be made of a flexible substrate and, as illustrated, exhibits one possible arrangement of electronic components and conductive traces **72**, **74**. In the embodiment of the electronic circuit board **55** shown, the tamper-proof traces **72** (shown in lighter lines) could be provided on the back surface of the electronic circuit board portion **55**, and the dose removal traces **74** (shown in darker lines) could be provided on the front surface thereof, closely adjacent the conductive foil layer **19** of the blister pack **13**. Insulating strips **84** can be provided where necessary to prevent short circuits between overlapping portions of the conductive dose removal traces **74**. Alternatively, if both the tamper-proof **72** and dose removal **74** traces are placed on the same surface of the electronic circuit board portion **55**, additional insulating strips, such as insulating strips **84**, can be utilized to prevent short circuits between overlapping portions of the traces. Detailed mechanical and electronic views of the perforated openings **57**, **59** are shown in **FIGS. 7b** and **7c**.

[0064] The embodiment of the electronic circuit board portion **55** contemplates a circuit design with overlapping conductive dose removal traces **74**, using the aforesaid strips of insulating material **84** interposed at overlapping locations. As shown, five horizontal traces (underneath the insulating strips **84**) between rows of perforated openings **59** can be used in sequence to supply a voltage, and five vertical traces between the columns of perforated openings **59**, can be used synchronously to sense voltage. In this manner, a momentary continuity between dose removal traces **74**, as will result from a dose **11** removal, can be checked individually for every one of the **25** positions using only ten lines. For example, if "N" lines are used to supply voltage and "M" lines are used to sense voltage, then N×M positions can be tested using only N+M lines. This arrangement can require that voltage and sense traces cross each other. Therefore, an appropriate manufacturing sequence would be to first print all the voltage traces (or sense traces), print the insulating strips **84** to cover all expected crossing points, then lastly print all the sense traces (or voltage traces).

[0065] The anti-diversion, or tamper-proof conductive traces **74** can be designed such that pushing on the bubble chamber **17** to remove a dose **11**, via the various openings and perforated openings in the medication package **1**, will break the perforated opening **57** above the dose **11**, and the associated tamper-proof trace **72** thereon, which event will be detected by the CPU **58**. Similarly, when a dose **11** is forced from the bubble chamber by such pushing action, the conductive foil layer **19** will be ruptured, and will contact an associated dose removal trace **74** on the perforated opening **59**, resulting in a continuity event which will be detected by the CPU **58**.

[0066] In the case of the tamper-proof traces **74**, a voltage is normally applied to the traces, and thus breaking the trace **72** on any particular perforated opening **57** will thus result

in an open circuit that is sensed by the CPU 58. In contrast, as best understood from the electronic detail view in FIG. 7c, the dose removal traces 74 can actually be a pair of two separate traces 81 and 82. The pair of traces 81, 82 can be electrically discontinuous, i.e., not normally in contact with each other. However, when the conductive foil layer 19 is ruptured by a dose 11 removal, the conductive foil 19 will contact the perforated opening 59, and concurrently contact each of the pair of traces 81, 82, thereby creating a continuity therebetween which will be sensed by the CPU 58 and identified with the specific perforated opening 59, and associated dose 11 of medication.

[0067] As discussed above, two types of events are designed to be detected utilizing the two types of conductive traces. One event is a broken trace and the other is a continuity.

[0068] The tamper-proof traces 72 can be one continuous trace associated with each perforated opening 57, 59 and can further surround a periphery of the medication package 1. If an attempt is made to cut through the sides of the package 1 to remove a dose 11 from the blister pack 13 unconventionally, a break in the tamper-proof trace 74 will be detected by the CPU 58 as a tamper event. As a power savings consideration, the tamper-proof trace 72 is not designed as normally open due to its length and extensive coverage of the entire package 1. The battery 60 drain from this one trace is negligible. Since the tamper-proof trace 72 one continuous trace, the only the initial break will be detected by the CPU 58. The tamper-proof trace 72 can be particularly useful for detecting, and inhibiting, diversion of medication at a pharmacy.

[0069] In contrast, the dose removal traces 74 are normally open traces provided on the perforated opening of the electronic circuit board portion 15 which underlie the individual dose locations in the blister pack 13. As described above in connection with FIG. 7c, there is no continuity between the pair of separate traces 81, 82 until a dose 11 is removed and the conductive foil 19 causes a brief connection therebetween. An advantage of this design is that the battery 60 will be not drained by having the CPU 58 continuously interrogating dose 11 locations before the first dose 11 is even removed. Instead, the removal of the first dose of medication can be the signal to initiate the timer 62.

[0070] The portion of the CPU 58, i.e., the particular pin, which monitors the tamper-proof trace 72 will read a voltage (i.e., a '1') in the normal state, and no voltage (i.e., a '0') when the package 1 is physically tampered with as to result in a broken tamper-proof trace 72. A continuity detection by the CPU 58 signals the removal of a dose 11 in the prescribed manner. In contrast to the tamper-proof traces 72, the dose removal conductive traces 74 associated with each of the perforated openings 59 have no continuity in the normal state. Thusly, before a first dose 11 is removed from the blister pack 13, the individual CPU 58 pins monitoring the respective perforated openings 59 will register no voltage. However, when a dose 11 of medication is pushed through frangible conductive foil layer 19, the foil 19 will cause a continuity between the pair of separate traces 81, 82. This continuity results in a voltage spike at the associated pin of the CPU 58. After the dose 11 is entirely removed from the package 1, the dose removal trace 74 associated

with the particular perforated opening 59 is designed to be sheared off in order to prevent an erroneous repeat signal at that location.

[0071] At such time as the CPU 58 detects a continuity, the preceding break in the tamper-proof trace 72 will not be recorded as a tamper event. However, this can be conditional upon removal of the dose 11 being recorded by the CPU 58 within a predetermined time frame. The detection of the broken tamper-proof trace 72 will not be recorded as a tamper event so long as the dose 11 is removed within the predetermined time frame. If the dose 11 is not removed within the preset time frame, the event will then be recorded as a tamper event. As explained above, only the initial break of the tamper-proof trace 72 will be detected. Thus, the preceding condition will only exist in regard to the initial break of a tamper-proof trace 72.

[0072] Each time a subsequent dose 11 is removed from the package 1 by the patient, the CPU 58 records the time elapsed from the previous dose 11, and resets the timer 62 to count down to the removal time for the next dose 11. Removal of the first dose 11 of medication, i.e., the voltage spike created thereby, can be used as the initiating event for the CPU 58 to activate the timer to begin recording time/counting down. After sensing this voltage spike, the CPU 58 will define the event as "time zero," the timer 62 will begin accumulating time. The elapsed time between dose removals can continually be compared with the preset dosing schedule. In this manner the CPU 58 can detect when the patient should take the next dose 11. The CPU 58 can, at the set time to remove the next dose 11, activate a visual alarm (via the LED 78) and/or audible alarm (via the sound generator 64) when the next dose 11 is due to be taken by the patient. When each subsequent dose 11 is removed from the package, the CPU 58 can record the time elapsed from the previous dose 11, and can reset the timer 62 to count down to the next dose 11. When the CPU 58 detects the next dose 11 should be removed, the LED 78 can be illuminated, or caused to blink, and/or the audible alarm can also be sounded. The visual and/or audible alarm can continue for a preset time if the dose 11 is not removed. The proper removal of the subsequent dose 11 causes the aforesaid voltage spike, that is sensed by the CPU 58, which can respond by silencing and the alarms and resetting the countdown timer 62.

[0073] The CPU 58 accumulates relative time from when the first dose 11 was removed, and not the actual time of day. This allows the preset dosing schedule to be automatically adjusted to the patient's daily schedule, for example, patients who work night shift will be taking doses at different times than ones who work during the day shift. The dose schedule can be set by the pharmacist when the medication package 1 is assembled by writing the pertinent data to EEPROM 70, for example via a modem associated with a personal computer used by the pharmacist. The package 1 can be designed such that without the necessary software, the dose schedule cannot be altered once established by the pharmacist.

[0074] The medication package 1 can include a battery 60, which can be part of the electronic circuit board portion 55. The battery 60 can be installed at the time the medication package is assembled. Since the CPU 58 remains essentially inactive, except for monitoring the tamper-proof traces 72,

the shelf life of the battery **60** can be about 5 years, well exceeding the shelf life of the medication.

[0075] Among other information, the CPU **58** can store a unique and sequentially programmed package identifier code. The CPU **58** can transfer stored data to other devices, including a central database, via wired or wireless communication, including via the Internet, where the information can be processed and analyzed. This data may contain information identifying the individual dose package code, patient compliance data, and data reflecting the integrity of the medication package **1**, as well as manually entered data, such as via a connected computer, reflecting the unique prescribing physician identifier data and unique patient identifier data. The collected data can be accessed and processed by various entities involved in implementing the compliance and anti-diversion objectives.

[0076] The CPU **58** can control all the logic of the medication package **1**, including using a clock generator to track elapsed time between doses, giving alarms via the LED **68** and/or sound generator **66**, and responding to temporarily closed circuits, i.e., continuities, detected via the dose removal traces **74** as doses are removed.

[0077] According to the invention, CPU **58** logic could follow, for example, rules such as these:

[0078] 1. If no dose **11** has yet been removed, monitor the tamper-proof traces **72** continuously to ensure the package was not tampered with in an attempt to remove pills unconventionally.

[0079] 2. When the first dose **11** is removed, the CPU **58** captures that event as time zero and activates the timer **62** to begin counting down time until the next preset scheduled dose removal.

[0080] 3. If a dose **11** is removed before the countdown timer **62** reaches zero, the actual elapsed time since the last dose will be recorded, and the timer **62** will begin a new countdown.

[0081] 4. If the actual time was no less than 80%, for example, of the prescribed time, the timer **62** will start at the prescribed delay plus the "leftover" time. In other words, the new target time will be the same as if the dose **11** had been removed exactly on schedule.

[0082] 5. If the actual time was no more than 120%, for example, of the prescribed time, the timer **62** will start at the prescribed delay minus the "extra" time. In other words, the new target time will be the same as if the dose **11** had been removed exactly on schedule.

[0083] 6. Otherwise, a "noncompliance" event will be recorded, and the timer will reset to the prescribed delay between doses, which probably will change the time of day when doses are scheduled.

[0084] Each CPU **58** in a medication package **1** can be programmed with a unique identifier code to enable its identification when the medication packaging is coupled with a central database collection site via its specified form of data transmission, such as an infrared data output port. When coupled with the compliance data collected as previously described, this data string will represent a unique set

of information specific to each individual medication package **1**. CPU **58** is connected to all of the components on the circuit board the tamper-proof **72** and dose removal **74** conductive traces.

[0085] Referring to FIG. **8a**, there is shown a laid open view of another embodiment of an electronic circuit board portion **95**, which can be like the electronic circuit board portion **55** in FIG. **7a**, including all of the electronic components and perforated openings **57**, **59**, and the only exception can be the omission of the tamper-proof traces **72**. Only dose removal conductive traces **74** are provided in this embodiment of the electronic circuit board **95**, and the CPU **58** function is generally directed to a compliance mode, in regard to detecting the removal of each dose **11** of medication in a conventional manner, and as regards the proper time of each removal. In this "compliance only" embodiment, no tamper-proof traces **74** are provided associated with the perforated openings **57** overlying the bubble chamber side of the blister pack **13**. Only the perforated openings **59** on the right side (in the laid open view) of the electronic circuit board portion **95** have associated conductive traces, i.e., the dose removal traces **74**.

[0086] The tamper-proof traces **72** can be eliminated to make the electronic circuit board portion **95** less expensive to produce than the electronic circuit board portion **55** having the additional tamper-proof traces **74**. As stated above, this configuration otherwise retains all of the capabilities described previously, except for the lack of anti-diversion related functions. Thus, electronic circuit board portion **95** can be suitable for use where the medication contained in the package **1** is not of a type with which there is a concern regarding abuse or diversion of the medication; the electronic circuit board portion **55** in FIG. **7a** would instead be used for medications with abuse potential such as analgesics, stimulants, and sedatives.

[0087] Mechanical and electronic details of the perforated openings on the electronic circuit board portion **95** are shown in FIGS. **8b** and **8c**, respectively. With the exception of the omission of the tamper-proof traces **74**, the perforated openings **57**, **59** can be the same as shown in FIGS. **7b** and **7c**.

[0088] Referring now to FIGS. **9a** and **9b**, a dose removal is illustrated. The dose **11** removal procedure and path, is as heretofore described, i.e., via each of the aligned openings and perforated openings in each of the layers of the completed and assembled medication package **1**. To remove a dose **11** of medication, the openings **7** in child-resistant cover **3** must first be aligned with the perforated openings **9** in the front face of the outer packaging material **5**, which can only be done by negotiating child-resistant cover **3** and associated safety features. Once the openings **5** and perforated openings **9** are aligned, sufficient pressure must be applied to the perforated opening **9** to break through the perforated opening **9** and also break through the underlying perforated opening **57** in the upper side of the electronic circuit board portion **55** (or **95**) which lies above the bubble chamber **17** containing a dose **11** of medication. This pressure drives the dose **11** of medication contained in the bubble chamber **17** through the perforated opening **40** in the frangible layer **19**, on the opposite side of the blister pack **13**, and also through the perforated opening **59** in the lower side of the electronic circuit board portion **55** (or **95**). Once

through the perforated opening 59, the dose 11 of medication can fall freely from the medication package 1 onto an underlying support surface, such as a table or counter top, via openings 43 and 46 in each of the thin 31 and thick 33 circuit board spacers, and openings in the underside of the outer packaging material 5 and the rear surface of child-resistant cover 3. Additional space can be created between the bottom of child-resistant cover 3 and the underlying support surface by the feet 35 on the rear face of child-resistant cover 3. The feet 35 provide added space between the support surface and the bottom of child-resistant cover 3 for the dose 11 to drop completely through the medication package 1 onto the underlying support surface. In this way, the medication package 1 does not need to be lifted from the underlying support surface to fully remove a dose 11 of medication.

[0089] It should be noted that the heavy backing material 29 can provide added mechanical integrity, which can be a significant improvement over conventional blister packs with regard to dose removal. The heavy backing material 29 results in easier dose removal by eliminating package twisting and the misdirection of force as can commonly occur with conventional blister packs. This can be particularly important for that segment of the patient population with, for example, tremors or arthritic hands.

[0090] Referring now to FIG. 11a, an additional embodiment of the invention is shown in cross-sectional form. Note that this embodiment of the invention performs only the compliance monitoring function and not the function of detecting attempted diversions of the doses indicated by removal of the doses from the package in an unconventional manner, such as by breaching the bubble chamber through the plastic blister package. In addition, this embodiment is shown illustrated without a child proof cover, however, the child-resistant cover as described above could easily be added to the embodiment of this invention as well. Dose 11 is disposed within bubble chamber 17 of blister packet 13 and is held in place therein by frangible aluminum foil layer 19. Frangible aluminum foil layer 19 may be situated with perforated openings underneath the pills or may be composed of a material which is fragile enough such that dose 11 may be pushed directly through frangible aluminum layer 19 just by breaking through the area directly beneath dose 11. Directly beneath frangible aluminum foil layer 19 is a layer of insulation 86 which has holes 89 defined therein corresponding to each individual bubble chamber 17.

[0091] Disposed on insulation layer 86 is printed circuit board 55. Printed circuit board 55 defines holes 88 which directly correspond to holes 89 defined in insulation layer 86 and which correspond to each individual bubble chamber 17. Holes 88 in circuit board 55 may be of varying sizes depending upon the type of medication being dispensed in package one. As can be seen in the expanded view of FIG. 11c, electronic circuit board 55 is provided with conductive circuit board traces 90 which encircle each of openings 88 in circuit board 55. Note also that holes 89 in insulation layer 86 do not exactly correspond in size with holes 88 in circuit board 55, but are slightly larger to allow a portion of conductive circuit board trace 90 to be exposed.

[0092] Disposed on the bottom of circuit board 55 is stiff paper backing layer 29 which may have holes or perforated openings corresponding to openings 88 in circuit board 55.

Backing layer 29 serves two purposes. First, as discussed above, it provides structural integrity to overall package 1. Second, it may act as a hinge, as shown in FIG. 11e on a package 1 which has not yet been filled with a plurality of doses 11.

[0093] The removal of dose 11 is shown in FIG. 11b. As the individual bubble chamber 17 is compressed, driving dose 11 through frangible aluminum foil layer 19, through holes 89 and 88 defined in insulation layer 86 and in printed circuit board 55 respectively, and the perforated opening in paper backing layer 29. The broken portion of frangible aluminum foil layer 19 contacts conductive PC board trace 90 which encircles opening 88 in circuit board 55, thereby completing a circuit. It should be noted that frangible aluminum foil layer 19, in this embodiment, is a part of the detection circuit. As shown in FIG. 11a, conductive frangible aluminum foil layer 19 is electronically connected to PC board 55. Circuit board traces 90 surrounding holes 88 in circuit board 55, in conjunction with electrically conductive frangible foil layer 19, form individual open switches that are closed as individual doses 11 are forced from their respective bubble chambers 17. As a result, the removal of dose 11 from an individual bubble chamber 17 will cause an open circuit to be closed and can be detected by the logic circuit mounted on circuit board 55, which will be discussed in further detail later.

[0094] FIG. 11d shows an exploded view of package 1 prior to doses 11 being placed therein. Note that frangible aluminum foil layer 19 is wrapped around insulation layer 86 such that aluminum foil layer 19 contacts traces on circuit board 55 when the device is assembled. Frangible aluminum foil layer 19 may either be wrapped around in this manner or otherwise electronically connected directly to circuit board 55 as shown in FIGS. 11a and 11b. FIGS. 11d and 11e also show adhesive 94 with peel-off cover which is situated on the surface of vacuum form blister pack 13 in areas in between individual bubble chambers 17.

[0095] In practice, doses 11 are placed in the individual bubble chambers 17 and the peel-off cover is removed from is removed adhesive layer 94 on blister pack 13, thus exposing the adhesive areas in between individual bubble chambers 17. The two sides side of the package, as shown in FIG. 11e, are then folded together at hinge points 100 defined in paper backing layer 29 and adhesive layer 94 is adhered to frangible foil layer 19 when the pack is folded over, thereby sealing individual bubble chambers 17.

[0096] Referring to FIGS. 12a through 12c, another embodiment of the invention is shown. This embodiment is substantially similar to the embodiment of FIG. 11a through 11e with the exception that plastic spring board layer 96 is disposed between insulating spacer 86 and frangible layer 19, which, in this embodiment, need not necessarily be composed of aluminum or any other electrically conductive material, but may, for example, be composed of paper. On the underside of plastic spring board layer 96, a contact layer 98 is adhered thereto, and can be composed of any electrically conductive material, for example, aluminum foil. In this embodiment, frangible layer 19 is not a part of the circuit and is, therefore, not connected electrically to circuit board 55. Instead, contact layer 98, adhered to the underside of plastic springboard layer 96 becomes part of the circuit and is electrically connect to circuit board 55 by folding

around insulating layer **86** or by otherwise being directly electrically connected to circuit board **55**. This embodiment is similar to the embodiment of **FIG. 11** in that the plurality of switches formed by circuit board traces **90** surrounding holes **88**, in conjunction with contact layer **98** are originally in an open state and become closed, momentarily, when dose **11** is removed from bubble chamber **17**.

[0097] Plastic layer **96** is preferably composed of a resilient plastic with “springboards” defined under each bubble chamber **17** in blister pack **13**. In operation, as shown in **FIG. 12b** and in the expanded view of **FIG. 12c**, as bubble chamber **17** is depressed, dose **11** is forced through frangible layer **19** and, as dose **11** passes through opening **88** in circuit board **55**, springboards **96a** and **96b** defined in plastic layer **96** are forced downward such that contact layer **98** is forced into an engaged relationship with circuit board trace **90** situated around each opening **88** in circuit board **55**. Note that we mention “springboards” in an exemplary manner herein; the shape of the openings in plastic layer **96** and number of “leafs” (**96a** and **96b**) that fold down when dose **11** is removed from bubble chamber **17** can be of any design and number.

[0098] As in the previous embodiment, dose **11** is then forced through a perforated opening in stiff paper backing layer **29**. Plastic layer **96** is provided to ensure that the contact between contact layer **98** and circuit board trace **90** is momentary in nature. As soon as dose **11** passes through opening **88** in circuit board **55**, and clears the plastic springboards **96a** and **96b** defined in plastic layer **96**, plastic springboards **96a** and **96b** are designed to spring back toward bubble chamber **17** such that contact layer **98** is disengaged from circuit board trace **90**, thereby opening the detection circuit. Thus, this embodiment is necessary that the circuitry be able to detect the momentary contact of either of springboards **96a** or **96b** defined in plastic layer **96** which are disposed under each bubble chamber **17**.

[0099] **FIG. 13** shows one possible embodiment of circuitry that can be used with the embodiment shown in **FIGS. 11a-11e** and **12a-12c**. Switches **P1** through **P30** represent open circuits present under each of bubble chamber **17**, which are closed when contact layer **98** electrically contacts with circuit board traces **90** surrounding each of openings **88** in circuit board **55**. In the embodiment in **FIG. 13** each row of switches (i.e., **P1** through **P5**, **P6** through **P10**, etc.) is connected to a particular input on the central processing unit **58**. Additionally, each open switch in any particular row is connected to a resistor of unique value within that row. For instance in the first row shown in **FIG. 13**, **P1** is connected to the input via a 160 k Ω resistor, **P2** via an 80 k Ω resistor, **P3** via a 40 k Ω resistor, **P4** via a 20 k Ω resistor, and **P5** via a 10 k Ω resistor. Thus, central processing unit **58** is able to determine which switch has been activated by a change in the voltage present on one of inputs **AN1** through **AN6**. Central processing unit **58** preferably includes a logic circuit capable of distinguishing the particular switch **P1** through **P30** which has been closed, using the resistor array shown in **FIG. 13** recording the event to an EEPROM or other form of non-volatile memory. **FIGS. 14a** and **14b** shows an alternative embodiment of the circuitry. In this embodiment, switches **P1** through **P30** are connected directly to central processing unit **58**. Note that CPU **58** and its associated circuitry may be embodied in a custom chip **100**. The advantage of with this embodiment is that it is possible to

identify the exact dose that has been removed from the package in a more reliable manner. This may be important if it is necessary, for example, to monitor which dose is take first, second, etc. In addition, this circuitry may be more appropriate for use in embodiments which do not utilize the “springboard” feature previously described because of its increased reliability.

[0100] Other embodiments are also possible, as there are many other designs which may be well known by those of skill in the art of circuit design, all of which are contemplated to be within the scope of this invention. For example, in an additional embodiment, multiple central processing units **58** or ASICs **100** may be provided to accommodate a larger number of doses in each package, mainly due to the cost in producing chips with a large number of pins. In particular, one embodiment of the invention contemplates utilizing an electronic circuit board having room and traces for multiple central processing units **58** or ASICs **100**, which may or may not be used depending upon the number of doses contemplated to be dispensed in the package. Thus, the board may be populated with the appropriate number of chips or left unpopulated to save costs.

[0101] Components within block **100** in **FIG. 13** may be provided on a custom ASIC chip and may include outputs for IR receiver **66**, alarm **64**, and IR LED **68**, the purposes of which have been discussed above with respect to other embodiments of the invention. Alarm **64** may be a piezoelectric beeper, vibration unit, LED or any other device capable of getting the end user’s attention.

[0102] Prior to the closing of the package **1**, CPU **58** is not active for the purpose of prolonging the self life of battery **60**. In operation, when package **1** is filled and closed by a pharmacist, central processing unit **58** will begin polling switches **P1** through **P30** at a predetermined interval, which in a preferred embodiment, is approximately once every 40 ms. After activation, the shelf life of battery **60** is expected to exceed the number of days during which doses **11** within the package **1** will be consumed by the end user. Additionally, to preserve battery life, the CPU **58** is in a hibernating mode only waking up once every polling interval to poll the switches and then returning to a sleeping state.

[0103] When a closed switch is detected during the routine polling of the switches, the switch is immediately polled an additional consecutive predetermined number of times, which in the preferred embodiment is 8 times. To record an actual closed switch event, it will be necessary that the switch be recognized as being closed a plurality times during the number of predetermined consecutive polls. This method is useful in filtering out noise which may cause spurious closed circuit events not related to a dosage removal event. When it is determined that an actual dosage removal event has occurred, the time of the event will be recorded in EPROM **70** on board ASIC chip **100**. This record can be transferred to an external computer at a later time by a pharmacist to detect consumption of doses **11** that are non-compliant with the instructions for the prescription, and, in addition, is also useful in determining when to again alert the end user that another dose **11** should be removed.

[0104] Referring now to **FIG. 10**, there is diagrammatically illustrated an overview data flow, according to an embodiment of the invention, between the medication package **1** and various other locations/entities for implementing

anti-diversion and compliance functions. This data flow can be employed to accomplish the objectives explained in more detail hereinafter. As shown, information flow can be configured between the medication package 1 and other sites, such as a central database, a database managing agency, a prescribing physician, a pharmacist, insurance providers, and law enforcement agencies. As shown, a system contemplated according to the invention can comprise, for example, the following features:

[0105] A central database, supervised by either a community, statewide or national agency, is established to receive, process and transmit data throughout the various system locations including pharmacies, physician offices, insurance companies, health maintenance organizations, and law enforcement agencies.

[0106] Each dispensing site (pharmacy) and each prescribing physician must, via the Internet, be trained, certified by, and register with the managing agency supervising the central database in order to download the software that will allow communication between the dispensing site or the physician, the central database and the dose 11 packages. This is especially important with the dispensing of medications with abuse potential, as these are commonly diverted to the illicit market. Each registered dispensing site will be assigned its own unique pharmacy registration number. Each registered physician can also be assigned a unique physician registration number, if so required.

[0107] One possible example of data flow assumes the drug manufacturer will utilize the proposed medication package 1 in the production process and load the pills at the manufacturing site and seal the packages for shipment to pharmaceutical distributors nationally. In this example, the central database will initially receive distribution data from the drug manufacturer in some automated fashion regarding the number of dose 11 packages manufactured and their unique sequential identifier information contained in the CPU 58, and the dates they were shipped.

[0108] When a registered dispensing site receives a certain number of the dose 11 packages, the unique data identifying each individual dose 11 package is sent via a specified form of data transmission, such as an infrared data output port on the dose 11 package to a personal computer or other such transmission device maintained by the dispensing site. This data is immediately and automatically transmitted via the Internet to the central database. Thus, inventory is established regarding the location of the unit and the current integrity of the dose 11 package.

[0109] In another possible application of this invention, the manufacturer will not use the package internally, and will ship its medication in bulk to pharmaceutical distributors and pharmacists. In this case the medication package 1 will be supplied to the pharmacists and loaded with doses 11 at the pharmacy. Therefore the flow of information in this example will begin at the local pharmacy. In either case the following description of events will occur.

[0110] When a patient presents a prescription to a registered dispensing site, the dispensing site relays encrypted information to the central database via the Internet. This encrypted information includes, automatically, the unique pharmacy identifier data, date and time, as well as manually entered data containing a unique patient identifier (e.g. social security number), and the prescribing physician's identifier data. The unique data identifying the individual dose 11 package to be dispensed is also entered into the central database via a specified form of data transmission, such as an infrared data output port, on the dose 11 package. The totality of this information represents a dispensing request.

[0111] The central database immediately compares the dispensing request data with current stored pharmacy and physician status data and any existing patient prescription or patient non-compliance history. Based on the outcome of a review by the central database of this current stored information, the central database will immediately transmit back to the requesting dispensing site, via the Internet, either a dispensing approval or denial, and such action will be recorded in the central database.

[0112] If approval is granted, the pharmacy will dispense the aforementioned dose 11 package to the patient. If dispensing is denied, the central database will categorize the reason(s) for the denial and this information will be automatically transmitted to the managing agency. If the reason for the denial is based on the condition of the dose 11 package, the ineligibility of the prescribing physician or the patient history, the pharmacy will automatically receive instructions from the central database.

[0113] If the patient who receives the medication presents insurance information to the pharmacy, a claim is submitted by the pharmacy to the patient's insurer according to their normal procedure. Periodically, when insurance company claims data is compared to central database information, diversion may be detected.

[0114] Each patient contracts with the prescribing physician to return the empty dose 11 package to the physician in order to receive a subsequent prescription renewal. This will allow the physician to determine if the doses 11 were removed from the dose 11 package according to the prescribed schedule.

[0115] Upon receiving the empty dose 11 package from the patient, the physician examines the package for indications of tampering and reviews the package compliance data. Thus, the physician will be able to identify possible diversion and also document those at risk for abuse if, for example, they removed the doses 11 more frequently than prescribed. The physician then sends the data containing the unique package identifier and the compliance data via a specified form of data transmission, such as an infrared data output port, to the central database via the Internet using a PC or similar device, and the central database records this information (hereafter referred to as completion data), as well as the time and date of said transmission.

[0116] The physician also will be provided with the capability to print a 'hard copy' of the patient's compliance data to place in the patient's permanent medical records.

[0117] If the central database does not receive the completion data from the prescribing physician within a predetermined time frame after the package dispensing date, this fact is recorded and a non-completion notice is automatically sent via the Internet to the physician.

[0118] If non-compliance or tampering has occurred and is therefore detected by the central database, or if patterns of non-completion develop, the managing agency may be automatically notified of possible abuse or diversion.

[0119] At all times the central database has an immediate record of how frequently any of its registered physicians are writing prescriptions for a particular medication, the physician's current registration status, how often and at which dispensing site each individual patient is obtaining prescriptions for the medication, the dispensing site's current registration status, and an accurate inventory of where all of the medications are located.

[0120] As prescribing, dispensing, compliance and completion data accumulates in the central database, over-prescribing physicians, patients who engage in "doctor-shopping" and those at risk for abuse can be quickly identified and investigative procedures can be initiated, as indicated.

[0121] Monthly inventory at dispensing sites is quickly accomplished by transferring data from each dose 11 package via a specified form of data transmission, such as an infrared data output port, to a PC or other transmission device, and then to the central database via the Internet.

[0122] The central database and associated software also allows for the random auditing of each registered dispensing site to determine whether the correct number of dose 11 packages is present and what the integrity of each dose 11 package is.

[0123] Therefore, according to the invention, and in accord with the foregoing description, a cooperative system of a medication package 1 having sensing, communication, data storage and data analysis features can be provided to help detect and deter non-compliance and diversion of medications. The medication package 1 described herein can provide audible and/or visual reminders of the prescribed dosing times to assure patient compliance with the prescribed dosing regimen. The medication package 1 can be a disposable package that is capable of transmitting data collected by or stored in system memory to other devices, such as remote computers, via wired or wireless transmission methods. The data can include, but need not be limited to, a unique medication package 1 identifier, individual dose removal history, which can include tamper events, and package integrity status. The medication package 1 can help ensure that doses cannot be removed in any fashion without the event being recorded, or the intrusion made obvious. The medication packaging system can also be inexpensively

made, and can employ an electronic design that ensures the cost of the packaging relative to the cost of the medication is not prohibitive.

[0124] Personal computer based software can be provided to collect data from the medication package 1 and to facilitate communications with a central "Prescription Monitoring" (PM) database. An overall central database can utilize the software necessary to collect, process and transmit data between the various remote locations and the medication package 1. Information can be received and downloaded, for example via the internet, to and from a variety of locations, including physician offices, pharmacies, drug manufacturers, a managing agency, insurance companies, health maintenance organizations, and law enforcement agencies.

[0125] Additionally, software can be provided for the training, certification, and registration of pharmacies and physicians. Such training, certification, and registration can be made a prerequisite to the downloading of software to these sites to permit the transfer of data between these locations. The transmission of data via a specified form of data transmission can also be provided, for example via an infrared LED port, to transfer the data to a central data collection location, via a PC or similar device, to document and process pertinent information, including unique prescribing physician identifier data, unique patient identifier data, unique pharmacy identifier data, unique package identifier data, dose 11 removal history, and package integrity status. The central database can document the arrival date and integrity of each medication package 1 at each dispensing site when that data is transmitted to the dispensing site PC from each medication package 1, such as via a specified data transmission port, for example, an infrared output port. The central database can also contain drug manufacturer data reflecting the number of medication package 1s shipped to the pharmacy dispensing sites and the associated unique package identifier data. The central database software can compare the manufacturer data reflecting the number of medication package 1s shipped to the pharmacy dispensing sites, and the associated unique package identifier data, to the arrival date and integrity of each medication package 1 at the dispensing sites. In this manner, the inventory and status of each unique medication package 1 at the dispensing sites can be documented.

[0126] Preferably, the central database managing agency can have auditing capabilities, and can request, such as via the internet, any dispensing site to transmit the unique package identifier data and package integrity status contained in the inventory of a dispensing site, such as a pharmacy. Such data can be transmitted from the medication package 1 to a PC at the dispensing site (in the manner described above), and thence from the PC back to the central database, via the internet, for processing. The central database can further be programmed to perform a variety of functions, including, but not limited to, automatically notifying an overseeing, managing agency when a suspected diversion event occurs, allowing a dispensing pharmacy to manually enter, via a PC, unique prescribing physician identifier data and unique patient identifier data to the central database for processing, allowing this unique prescribing physician identifier data and unique patient identifier data to be combined with the associated unique package identifier information.

[0127] The central database, as well as associated dispensing sites and physician sites, can have software that provides for the encryption of all data transmission and storage, with the de-encryption of said data possible only by a managing agency in order to ensure confidentiality. A physician, such as at follow up office visits, can also be enabled to review exactly when each dose was removed from the medication package 1 by displaying compliance data, such as obtained from the medication package 1, on an office PC.

[0128] The medication package 1 can also be designed to enable immediate transmission of data in real-time (reflecting the location and integrity of each specific medication package 1) between various system locations (pharmacies, physician offices, central database, a managing agency, drug manufacturer, and law enforcement agency), and can provide for the organization of a central PM database to receive and process the data. The medication package 1 can thus make it possible to:

[0129] Identify patients who are taking their legitimately obtained medications with abuse potential too frequently, thereby deterring addiction and/or diversion;

[0130] Identify those who simultaneously obtain multiple prescriptions for medications with abuse potential from various physicians, thereby detecting and deterring doctor shopping;

[0131] Identify physicians who over-prescribe medications with abuse potential, thereby identifying improper or illegal prescribing practices;

[0132] Provide for a tamper-proof electronic inventory system at all dispensing sites, thereby detecting and deterring pharmacy theft in a timely fashion;

[0133] Provide for the immediate transmission of prescription data from pharmacies to a central database. This data, when processed, would quickly reveal any discrepancies that may represent abuse and/or diversion and facilitate early investigative intervention;

[0134] Provide for the prerequisite training, certification and registration of all physicians and pharmacies with regard to accepted prescribing protocol; and

[0135] Provide for auditing capabilities in order to detect illegal trends at all registered dispensing sites.

[0136] Ensure compliance of medications in that patient population who are predisposed to forget to take their medications as prescribed.

[0137] Data from the medication package 1 could be used at an individual physician's office solely to monitor compliance. The data could also be utilized at a community, state, or national level with the associated database to thwart the diversion of prescription medications. There are currently proposals by Congress and the Federal Drug Enforcement Agency (DEA) to establish a national PM program. The proposed database can readily be adapted to existing state prescription monitoring programs, and ones established in the future, if a form of data transmission is utilized that is compatible with the medication packaging system, such as, for example, infrared data transmission. The central

database can contain software provisions for the interconnection of various community-based databases with each other and a statewide central database. Similarly, states using the proposed database at a statewide level can readily be adapted to communicate with a national PM program.

[0138] Although certain embodiments of the invention have been described in detail hereinabove, it will be appreciated by those skilled in the art that various modifications to those details could be developed in light of the overall teaching of the disclosure. Accordingly, the particular embodiments disclosed herein are intended to be illustrative only and not limiting to the scope of the invention which should be awarded the full breadth of the following claims and any and all embodiments thereof.

We claim:

1. A medication package comprising:

a blister pack defining a plurality of bubble chambers therein, each adapted to receive a dose of medication;

a layer composed of a frangible material covering said plurality of bubble chambers;

a insulating layer of an electrically non-conductive material disposed on said layer of frangible material, said insulating layer defining a plurality of holes therein corresponding to said plurality of bubble chambers; and

a circuit board disposed on said insulating layer opposite said frangible layer, said circuit board defining a plurality of holes therein corresponding to said plurality of holes defined in said insulating layer and said bubble chambers, wherein each of said plurality of holes in said circuit board is surrounded by an electrically conductive trace;

wherein said holes in said insulating layer are slightly larger than said holes in said circuit board, such that said electrically conductive traces surrounding said holes in said circuit board are exposed when said circuit board and said insulating layer are in contact with each other.

2. The medication package of claim 1 wherein said layer of frangible material is electrically conductive and is electrically coupled to said circuit board, said frangible layer and said conductive traces surrounding said plurality of holes on said circuit board forming a plurality of open switches.

3. The medication package of claim 2 wherein removal of a dose of medication from a particular bubble chamber causes the portion of said frangible layer covering said bubble chamber to engage the conductive trace surrounding said corresponding hole in said circuit board, thereby closing said switch.

4. The medication package of claim 3 further comprising:

a logic circuit capable of determining which of said plurality of switches has been closed by a dosage removal event; and

non-volatile memory, for recording said dosage removal event.

5. The medication package of claim 4 wherein said logic circuit includes one or more central processing units and further wherein each of said conductive traces surrounding said holes in said circuit board is directly connected to one of said central processing units.

6. The medication package of claim 4 further comprising:
data transfer circuitry, enabling the transfer of data regarding dosage removal events from said non-volatile memory and the transfer of information into said non-volatile memory regarding the timing of dosage removal events
7. The medication package of claim 6 further wherein said data transfer circuitry includes an infrared LED for transferring data out of said package and an infrared detector for transferring data into said package
8. The medication package of claim 4 further comprising alarm circuitry, for alerting a user of said package to remove one or more of said doses from said package.
9. The medication package of claim 8 wherein said alarm circuitry includes an alarm mechanism selected from a group comprising an LED, a beeper and a vibrator.
10. The medication package of claim 4 further comprising:
a battery, for powering said logic circuit; and
a means for activating said logic circuit.
11. The medication package of claim 4 further comprising:
a sheet of backing material disposed on said circuit board opposite said insulating layer, said backing material having perforated openings defined therein corresponding to said openings defined in said circuit board, said perforated openings tearing open when a dose of medication is forced from a bubble chamber.
12. The medication package of claim 11 wherein said sheet of backing material is composed of stiff paper.
13. A medication package comprising:
a first side comprising:
a blister pack defining a plurality of bubble chambers therein, each adapted to receive a dose of medication; and
a layer of adhesive having a peel-off cover, said adhesive layer being disposed on the surface of said blister pack between said plurality of bubble chambers; and
a second side comprising:
a circuit board, said circuit board defining a plurality of holes therein corresponding to said plurality of bubble chambers defined in said blister pack, wherein each of said plurality of holes in said circuit board is surrounded by an electrically conductive trace;
a insulating layer of an electrically non-conductive material disposed on said circuit board, said insulating layer defining a plurality of holes therein corresponding to said plurality of holes defined in said circuit board, bubble chambers, wherein said holes in said insulating layer are slightly larger than said holes in said circuit board, such that said electrically conductive traces surrounding said holes in said circuit board are exposed when said insulating layer is placed on said circuit board; and
a layer composed of a frangible material disposed on said insulating layer;
wherein said first side and said second side are connected via a hinge mechanism that can be closed to bring said frangible layer into contact with said adhesive layer after said peel-off cover has been removed, thereby sealing said bubble chambers.
14. The medication package of claim 13 wherein said layer of frangible material is electrically conductive and is electrically coupled to said circuit board, said frangible layer and said conductive traces surrounding said plurality of holes on said circuit board forming a plurality of open switches.
15. The medication package of claim 14 wherein removal of a dose of medication from a particular bubble chamber causes the portion of said frangible layer covering said bubble chamber to engage the conductive trace surrounding said hole in said circuit board corresponding to said bubble chamber, thereby closing said switch.
16. The medication package of claim 15 further comprising:
a logic circuit, capable of determining which of said plurality of switches has been closed by a dosage removal event; and
non-volatile memory, for recording said dosage removal event.
17. The medication package of claim 16 wherein said logic circuit includes one or more central processing units and further wherein each of said conductive traces surrounding said holes in said circuit board is directly connected to one of said central processing units.
18. The medication package of claim 16 further comprising:
data transfer circuitry, enabling the transfer of data regarding dosage removal events from said non-volatile memory and the transfer of information into said non-volatile memory regarding the timing of dosage removal events
19. The medication package of claim 18 further wherein said data transfer circuitry includes an infrared LED for transferring data out of said package and an infrared detector for transferring data into said package
20. The medication package of claim 16 further comprising alarm circuitry, for alerting a user of said package to remove one or more of said doses from said package.
21. The medication package of claim 20 wherein said alarm circuitry includes an alarm mechanism selected from a group comprising an LED, a beeper and a vibrator.
22. The medication package of claim 16 further comprising:
a battery, for powering said logic circuitry; and
a means for activating said logic circuitry.
23. The medication package of claim 16 further comprising:
a sheet of backing material disposed on said circuit board opposite said insulating layer, said backing material having perforated openings defined therein corresponding to said openings defined in said circuit board.
24. The medication package of claim 23 wherein said sheet of backing material is coupled to said first side of said package and acts as said hinge between said first and said second sides.

25. The medication package of claim 24 wherein said sheet of backing material is composed of stiff paper.

26. A medication package comprising:

a blister pack defining a plurality of bubble chambers therein, each adapted to receive

a dose of medication;

a layer composed of a frangible material covering said bubble chambers;

a layer of plastic disposed on said frangible layer such that one or more portions of said layer of plastic are obstructing the opening of each of said bubble chambers such that said obstructing portion(s) of said plastic layer are displaced from the plane of the plastic layer when a dose of medication is pushed through said frangible layer;

an electrically conductive layer disposed on said plastic layer opposite said frangible layer;

a insulating layer of an electrically non-conductive material disposed on said electrically conductive layer, said insulating layer defining a plurality of holes therein corresponding to said plurality of bubble chambers; and

a circuit board disposed on said insulating layer opposite said frangible layer, said circuit board defining a plurality of holes therein corresponding to said plurality of holes defined in said insulating layer and said bubble chambers, wherein each of said plurality of holes in said circuit board is surrounded by an electrically conductive trace;

wherein said holes in said insulating layer are slightly larger than said holes in said circuit board, such that said electrically conductive traces surrounding said holes in said circuit board are exposed when said circuit board and said insulating layer are in contact with each other.

27. The medication package of claim 26 wherein said electrically conductive layer is electrically coupled to said circuit board, said electrically conductive layer and said conductive traces surrounding said plurality of holes on said circuit board forming a plurality of open switches.

28. The medication package of claim 27 wherein said electrically conductive layer is composed of aluminum foil.

29. The medication package of claim 27 wherein removal of a dose of medication from a particular bubble chamber causes said portion(s) of said plastic layer obstructing the opening of said bubble chamber to be displaced toward said circuit board.

30. The medication package of claim 29 wherein the displacement of said portion(s) of said plastic layer obstructing the opening of said bubble chamber causes said electrically conductive layer to engage said conductive trace surrounding said hole in said circuit board corresponding to said bubble chamber, thereby closing said switch.

31. The medication package of claim 30 wherein said portion(s) of said plastic layer obstructing the opening of said bubble chamber are resilient and further wherein said portion(s) of said plastic layer obstructing the opening of said bubble chamber cause said electrically conductive layer to disengage from said conductive trace surrounding said hole in said circuit board corresponding to said bubble

chamber when said dose of medication has been completely removed from said medication package, thereby opening said switch.

32. The medication package of claim 31 further comprising:

a logic circuit capable of determining which of said plurality of switches has been closed by a dosage removal event; and

non-volatile memory, for recording said dosage removal event.

33. The medication package of claim 32 wherein said logic circuit includes one or more central processing units and further wherein each of said conductive traces surrounding said holes in said circuit board is directly connected to one of said central processing units.

34. The medication package of claim 32 further comprising:

data transfer circuitry, enabling the transfer of data regarding dosage removal events from said non-volatile memory and the transfer of information into said non-volatile memory regarding the timing of dosage removal events

35. The medication package of claim 34 further wherein said data transfer circuitry includes an infrared LED for transferring data out of said package and an infrared detector for transferring data into said package

36. The medication package of claim 32 further comprising alarm circuitry, for alerting a user of said package to remove one or more of said doses from said package.

37. The medication package of claim 36 wherein said alarm circuitry includes an alarm mechanism selected from a group comprising an LED, a beeper and a vibrator.

38. The medication package of claim 32 further comprising:

a battery, for powering said logic circuitry; and

a means for activating said logic circuitry.

39. The medication package of claim 32 further comprising:

a sheet of backing material disposed on said circuit board opposite said insulating layer, said backing material having perforated openings defined therein corresponding to said openings defined in said circuit board, said perforated openings tearing open when a dose of medication is forced from a bubble chamber.

40. The medication package of claim 39 wherein said sheet of backing material is composed of stiff paper.

41. A medication package comprising:

a first side comprising:

a blister pack defining a plurality of bubble chambers therein, each adapted to receive a dose of medication; and

a layer of adhesive having a peel-off cover, said adhesive disposed on the surface of said blister pack between said plurality of bubble chambers; and

a second side comprising:

a circuit board, said circuit board defining a plurality of holes therein corresponding to said plurality of bubble chambers defined in said blister pack,

wherein each of said plurality of holes in said circuit board is surrounded by an electrically conductive trace;

an insulating layer of an electrically non-conductive material disposed on said circuit board, said insulating layer defining a plurality of holes therein corresponding to said plurality of holes defined in said circuit board, wherein said holes in said insulating layer are slightly larger than said holes in said circuit board, such that said electrically conductive traces surrounding said holes in said circuit board are exposed when said insulating layer is placed on said circuit board;

an electrically conductive layer disposed on said insulating layer;

a layer of resilient plastic disposed on said electrically conductive layer such that one or more portions of said layer of plastic are obstructing the holes defined in said insulating layer and said circuit board, such that said obstructing portion(s) of said plastic layer can be displaced from the plane of the plastic layer toward said circuit board; and

a layer composed of a frangible material disposed on said plastic layer opposite said electrically conductive layer;

wherein said first side and said second side are connected via a hinge mechanism that can be closed to bring said frangible layer into contact with said adhesive layer after said peel-off cover has been removed, thereby sealing said bubble chambers.

42. The medication package of claim 41 wherein said electrically conductive layer is electrically coupled to said circuit board, said electrically conductive layer and said conductive traces surrounding said plurality of holes on said circuit board forming a plurality of open switches.

43. The medication package of claim 41 wherein said electrically conductive layer is composed of aluminum foil.

44. The medication package of claim 41 wherein removal of a dose of medication from a particular bubble chamber causes said portion(s) of said plastic layer obstructing the hole defined in said insulating layer and a said circuit board to be displaced toward said circuit board.

45. The medication package of claim 44 wherein the displacement of said portion(s) of said plastic layer obstructing the opening of said bubble chamber causes said electrically conductive layer to engage the conductive trace surrounding said hole in said circuit board corresponding to said bubble chamber, thereby closing said switch.

46. The medication package of claim 45 wherein said portion(s) of said plastic layer obstructing the opening of said bubble chamber are resilient and further wherein said portion(s) of said plastic layer obstructing the opening of said bubble chamber causes said electrically conductive layer to disengage from said conductive trace surrounding said hole in said circuit board corresponding to said bubble chamber when said dose of medication has been completely removed from said medication package, thereby opening said switch.

47. The medication package of claim 46 further comprising:

a logic circuit capable of determining which of said plurality of switches has been closed by a dosage removal event; and

non-volatile memory, for recording said dosage removal event.

48. The medication package of claim 47 wherein said logic circuit includes one or more central processing units and further wherein each of said conductive traces surrounding said holes in said circuit board is directly connected to one of said central processing units.

49. The medication package of claim 47 further comprising:

data transfer circuitry, enabling the transfer of data regarding dosage removal events from said non-volatile memory and the transfer of information into said non-volatile memory regarding the timing of dosage removal events

50. The medication package of claim 49 further wherein said data transfer circuitry includes an infrared LED for transferring data out of said package and an infrared detector for transferring data into said package

51. The medication package of claim 47 further comprising alarm circuitry, for alerting a user of said package to remove one or more of said doses from said package.

52. The medication package of claim 51 wherein said alarm circuitry includes an alarm mechanism selected from a group comprising an LED, a beeper and a vibrator.

53. The medication package of claim 47 further comprising:

a battery, for powering said logic circuit; and

a means for activating said logic circuit.

54. The medication package of claim 47 further comprising:

a sheet of backing material disposed on said circuit board opposite said insulating layer, said backing material having perforated openings defined therein corresponding to said openings defined in said circuit board, said perforated openings tearing open when a dose of medication is forced from a bubble chamber.

55. The medication package of claim 54 wherein said sheet of backing material is coupled to said first side of said package and acts as said hinge between said first and said second sides.

56. The medication package of claim 55 wherein said sheet of backing material is composed of stiff paper.

57. A medication package comprising:

a plurality of bubble chambers defined in a blister pack; and

a plurality of switches corresponding to each of said bubble chambers;

wherein a unique one of said plurality of switches is closed when a dose of medication is removed from a bubble chamber.

58. The medication package of claim 53 wherein said plurality of switches are of the momentary contact type.

59. The medication package of claim 58 further comprising:

a logic circuit capable of determining which of said plurality of switches has been closed by a dosage removal event; and

non-volatile memory, for recording said dosage removal event.