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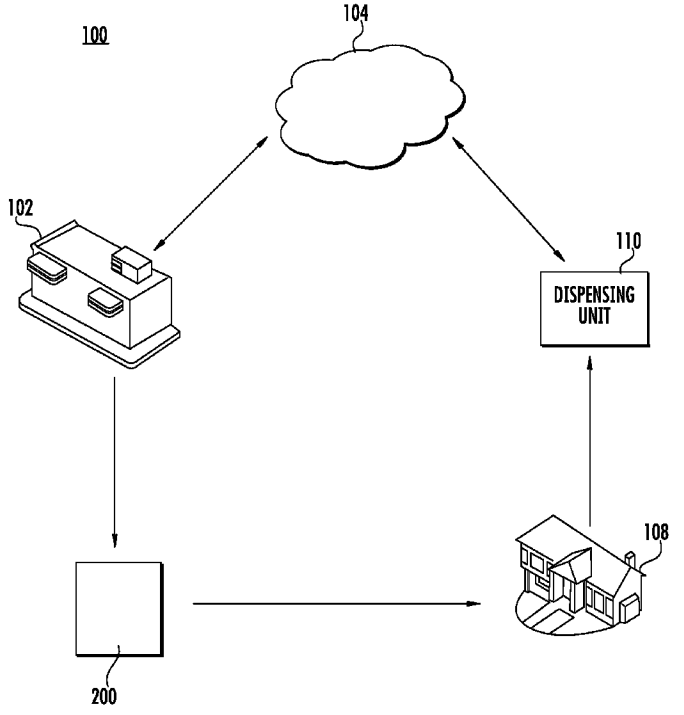

(57) Abrégé/Abstract:
The present specification describes a medicine dispensing system for automatically dispensing medication at a predetermined time. The system includes a cartridge that carries a strip of medicine pouches. When the cartridge is dropped into a dispensing unit, it automatically aligns with the dispensing unit without requiring any installation work from the user. The automatic alignment is enabled because of self-aligning features manufactured in the cartridge housing.

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(54) Title: SYSTEM AND METHOD FOR RELIABLY DISPENSING PRE-PACKAGED PHARMACEUTICALS

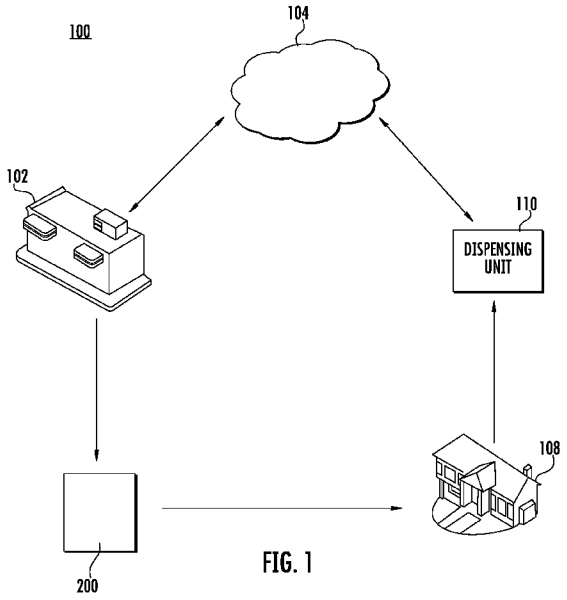

FIG. 1

(57) Abstract: The present specification describes a medicine dispensing system for automatically dispensing medication at a predetermined time. The system includes a cartridge that carries a strip of medicine pouches. When the cartridge is dropped into a dispensing unit, it automatically aligns with the dispensing unit without requiring any installation work from the user. The automatic alignment is enabled because of self-aligning features manufactured in the cartridge housing.

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SYSTEM AND METHOD FOR RELIABLY DISPENSING PRE-PACKAGED PHARMACEUTICALS

RELATED APPLICATIONS

[0001] The present application claims priority from and the benefit of U.S. Provisional Patent Application Nos. 62/171,646, filed June 5, 2015; 62/263,345, filed December 4, 2015; and 62/292,713, filed February 8, 2016.

FIELD

[0002] The present invention relates generally to devices for dispensing items, and more specifically, to systems and methods for assisting patients in taking prescription medication, in accordance with a desired regimen prescribed by a physician.

BACKGROUND

[0003] Even with the present day advances in medicines and healthcare, people, especially senior citizens and disabled persons, face a number of challenges in taking care of their health at home. Typically there is little assistance for the `home patient` in managing multiple prescriptions and inventories of medicines. According to some estimates, the average senior person is prescribed up to thirteen different oral medications that must be taken correctly at different times each day. These medications are typically delivered in bulk supply and must be sorted, managed, and then taken correctly by the individual, leading to numerous errors and omissions, including failing to take the medications at the prescribed time, taking the medications at the wrong time and/or in the incorrect amount, misusing the medications, fatally combining the medications with other medications, under-using the medications, or over-using the medications, collectively referred to "non-compliance."

[0004] The costs associated with such non-compliance are higher than the costs associated with a number of major illnesses. Studies have shown that 10% of admissions to regular hospitals in the United States are due to non-compliance, at a cost of $15 billion a year, and 30% of hospital admissions for people over the age of 65 are directly caused by non-compliance. Non-compliance causes 125,000 deaths per year--twice as many as are

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caused by auto accidents. Twenty-three percent to forty percent of nursing home admissions are due to noncompliance and inability to take medications at home unsupervised. According to estimates, nearly half of all prescriptions are taken incorrectly, contributing to prolonged or additional illness. People who miss doses need 3 times as many doctor visits as others and face an average of $2,000 more in medical costs per year.

[0005] The fact that the aging population continues to grow, combined with the steady increase in the average number of medications prescribed per person, indicates that these issues will continue to compound along with the associated costs.

[0006] In order to ensure that medications are taken at the proper time, a variety of devices, such as the ones disclosed in U.S. Pat. Nos. 4,361,408 and 7,944,342, have been devised to generate audible and/or visible prompting or alarm signals that remind a patient or his caretaker to administer the correct dosages at the correct time. Various dispensing devices have also been developed to help patients adhere to their medication protocols or regimens. Examples of such devices are provided in U.S. Patent Nos. 8,060,246 and 8,196,774.

[0007] There may be a need for a simple yet efficient system that not only reminds a patient to take medication according to their prescribed schedule, but also provides the required medicines to the patient in a simple, convenient and reliable manner.

SUMMARY

[0008] As a first aspect, embodiments of the invention are directed to a cartridge for a pharmaceutical dispensing system, comprising: a frame with opposed sidewalls and having a floor and a base, the floor positioned above the base and including a routing hole; and a plurality of individually sealed pouches of pharmaceuticals to be dispensed, the packets formed as an elongate strip, the strip of pouches being wound into a roll over an axle member that extends between the sidewalls of the frame, wherein a free end of the strip extends through the routing hole in the floor and between the floor and the base. A brake member is mounted between the floor and the base floor and is configured to press the strip against the floor or the base to apply a braking force thereto.

[0009] As a second aspect, embodiments of the invention are directed to a pharmaceutical dispensing system, comprising: a housing with an opening, the housing having an internal compartment and a delivery outlet; a drive unit mounted in the housing; and a cartridge as described above. The cartridge and the housing include alignment features that enable the cartridge to be inserted through the opening in the housing and into the compartment of the

housing such that the free end of the strip is positioned adjacent the drive unit so that operation of the drive unit conveys the free end of the strip toward the delivery outlet.

[0010] As a third aspect, embodiments of the invention are directed to a method of loading a pharmaceutical dispensing system, comprising the steps of:

(a) providing a cartridge comprising:

a frame with opposed sidewalls and having a floor and a base, the floor positioned above the base and including a routing hole;

a plurality of individually sealed packets of pharmaceuticals to be dispensed, the pouches formed as an elongate strip, the strip of pouches being wound into a roll over an axle member that extends between the sidewalls of the frame, wherein a free end of the strip extends through the routing hole in the floor and between the floor and the base;

wherein a brake member is mounted between the floor and the base floor and is configured to press the strip against the floor or the base to apply a braking force thereto;

(b) providing a pharmaceutical dispensing system comprising:

a housing with an opening, the housing having an internal compartment and a delivery outlet; and

a drive unit mounted in the housing; and

(c) inserting the cartridge into the housing through the opening in the housing and into the compartment of the housing such that the free end of the strip is positioned adjacent the drive unit so that operation of the drive unit conveys the free end of the strip toward the delivery outlet.

[0010a] The present invention as claimed relates to a pharmaceutical dispensing system, comprising: a housing having a plurality of walls, one of the walls having an opening, the housing having an internal compartment defined by a plurality of walls and a delivery outlet separate and spaced apart from the opening; a drive unit mounted in the housing; and a cartridge comprising a frame, a cover and a plurality of pouches containing pharmaceuticals, the pouches formed as an elongate strip; wherein the cartridge and the housing include alignment features that enable the cartridge to be inserted through the opening in the housing and into the compartment of the housing such that the free end of the strip is positioned adjacent the drive unit so that operation of the drive unit conveys the free end of the strip toward the delivery outlet.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0011] These and other features and advantages of the present invention will be appreciated, as they become better understood by reference to the following detailed description when considered in connection with the accompanying drawings, wherein:

[0012] **Figure 1** is a schematic diagram that illustrates an overall arrangement that is utilized by the present system for dispensing medicines;

[0013] **Figure 2** is a top view of an exemplary pouch of medication, attached to a strip of pouches in a roll, to be dispensed by a dispensing system according to embodiments of the invention;

[0014] **Figure 3A** is a front perspective view of an exemplary cartridge;

[0015] **Figure 3B** is a rear perspective view of the cartridge of **Figure 3A;**

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[0016] **Figure 4** is a perspective view of a dispensing unit according to embodiments of the invention;

[0017] **Figure 5A** is a front perspective view of the cover of a cartridge for use with the dispensing unit of **Figure 4**;

[0018] **Figure 5B** is a rear perspective view of the cover of the cartridge of **Figure 5A**;

[0019] **Figure 6** is a perspective view of a cartridge frame loaded with a strip of medication pouches for use with the cartridge of **Figure 3A**;

[0020] **Figure 7** is a front perspective view of a cartridge frame of **Figure 6** without the cylinder;

[0021] **Figure 8** is a perspective view of two modular halves of the cylinder portion of the cartridge of **Figure 3A**;

[0022] **Figure 9** is a perspective view of the halves of **Figure 8** in an assembled condition;

[0023] **Figure 10** is a front perspective view of the cartridge frame and cylinder of the cartridge of **Figure 3A**;

[0024] **Figure 11A** is a rear perspective view of the cartridge frame of **Figure 7**;

[0025] **Figure 11B** is a top view of the cartridge frame of **Figure 11A** showing the floor of the cartridge;

[0026] **Figure 12A** is a section view of the cartridge frame of **Figure 10**;

[0027] **Figure 12B** is a section view of the cartridge frame of **Figure 10** with a medication strip loaded on the cylinder and following its path through the frame;

[0028] **Figure 13** is a top view of the base of the cartridge of **Figure 3A**;

[0029] **Figure 14** is a bottom view of the base of the cartridge of **Figure 3A**;

[0030] **Figure 15** is perspective view of the flattened form of the cartridge frame of **Figure 3A**;

[0031] **Figure 16** is a perspective view of the opposite side of the flattened form of the cartridge frame of **Figure 15**;

[0032] **Figure 17A** is a top perspective view of the dispensing unit of **Figure 4** with the top door removed to show the compartment into which the cartridge fits;

[0033] **Figure 17B** is a top perspective view of the dispensing unit of **Figure 17A**, showing the other side of the compartment;

[0034] **Figure 17C** is a top view of the dispensing unit of **Figure 17A** showing the bottom of the compartment;

[0035] **Figure 18** is a perspective section view of the dispenser of **Figure 17A** with a cartridge loaded in it;

[0036] **Figure 19A** is a side section view of the dispenser of **Figure 17A** with a cartridge loaded in it, showing the dispensing path of the medication strip;

[0037] **Figure 19B** is a side section view of the dispenser of **Figure 17A** with a cartridge loaded in it, showing the exception path of a medication pouch;

[0038] **Figure 20** is a flow chart of the operational flow of the dispensing unit of **Figure 4**;

[0039] **Figure 21** is a chart of the mechanical flow of the dispensing unit of **Figure 4**;

[0040] **Figure 22** is a chart of the manual dispense flow of the dispensing unit of **Figure 4**;

[0041] **Figure 23** is a flow chart of the validation of cartridge data during the cartridge load process of the dispensing unit of **Figure 4**;

[0042] **Figures 24A, 24B** and **25** are a flow chart of the validation of pouch data during the pouch dispensing process of the dispensing unit of **Figure 4**;

[0043] **Figure 26** is a top view of an exemplary pouch of medication to be dispensed by a dispensing system according to embodiments of the invention;

[0044] **Figure 27A** is a perspective view of a cartridge according to alternative embodiments of the invention;

[0045] **Figure 27B** is a perspective view of one half of the cartridge of **Figure 27A** with the free-spinning hub shown therein;

[0046] **Figure 27C** is an enlarged reverse partial perspective view of the cartridge of **Figure 27A** installed in a dispenser, with a spring for maintaining the pouches in position;

[0047] **Figure 27D** is an enlarged partial perspective view of the cartridge of **Figure 27A** in a dispenser with a spring release mechanism for releasing the spring shown in **Figure 27C**;

[0048] **Figure 28** is a perspective view of a portion of the dispenser of **Figure 27C** with a cartridge of **Figure 27A** loaded therein, showing an embodiment for placement of cameras to read the barcodes on the cartridge and pouches;

[0049] **Figure 29A** is a perspective view of the door locking mechanism of the dispenser of **Figure 32** shown in the unlocked position;

[0050] **Figure 29B** is a perspective view of the door locking mechanism of **Figure 29A** shown in the locked position;

[0051] **Figure 29C** is a perspective view of the cam of the door locking mechanism of **Figure 29A** shown in the locked position;

[0052] **Figure 29D** is a perspective view of the cam of the door locking mechanism of **Figure 29A** shown in the unlocked position;

[0053] **Figure 29E** is a perspective view of the door sensor of the door locking mechanism of **Figure 29A**;

[0054] **Figure 30A** is a partial perspective view of the inside of the dispenser door, loaded with a cartridge and the door closed, showing a spring-loaded bracket located on the inside of the door;

[0055] **Figure 30B** is a partial perspective view of the spring loaded bracket of **Figure 30A** without a cartridge;

[0056] **Figure 31** is a perspective view of a cartridge according to additional embodiments of the invention;

[0057] **Figure 32** is a perspective view of a dispenser according to additional embodiments of the invention;

[0058] **Figure 33** is a perspective view of a cartridge cover of the cartridge of **Figure 31**;

[0059] **Figure 34** is a perspective view of a cartridge frame of the cartridge of **Figure 31** with a pouch strip mounted therein;

[0060] **Figure 35** is a perspective view of the cartridge frame of **Figure 34** without the hub/axle and pouch strip;

[0061] **Figure 36** is a perspective view of the free-spinning hub/axle of the cartridge frame of **Figure 34**;

[0062] **Figure 37** is a perspective view of the cartridge frame of **Figure 34** without the pouch strip;

[0063] **Figure 38** is a top view of the cartridge frame of **Figure 34**;

[0064] **Figure 39** is a section view of the cartridge frame of **Figure 34**, including the pouch strip and hub;

[0065] **Figure 40** is a bottom section view of the cartridge frame of **Figure 34**; and

[0066] **Figure 41** is a section view of the dispenser of **Figure 32**, without a cartridge loaded therein.

DETAILED DESCRIPTION

[0067] The present specification discloses a method and system that assists people at home in taking medication according their prescribed regimen. In one embodiment, the present system reminds a patient to take their medication at the scheduled time, and also provides all the required medicines to be taken at that time in one or more convenient pouches. The system may be useful for patients taking medication on a daily schedule, patients participating in a clinical study, or anyone needing to take medications, supplements, etc. on a regular, consistent basis.

[0068] In one embodiment, the present system allows a user to simply drop a cartridge into a receptacle and have the medicine pouches with the appropriate medication dosages dispensed at the requisite times, without the need for any programming, installation, aligning, fitting or other work. In one embodiment, the cartridge contains pouches of medicines spooled around a cartridge cylinder, which is used to dispense pouches as and when required. The cartridge is typically mailed or otherwise delivered to or received by the person on a regular basis.

[0069] The present invention will now be described more fully hereinafter, in which preferred embodiments of the invention are shown. This invention may, however, be embodied in different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. In the drawings, like numbers refer to like elements throughout. Thicknesses and dimensions of some components may be exaggerated for clarity.

[0070] Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the relevant art and will not be interpreted in an idealized or overly formal sense unless expressly so defined herein.

[0071] The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or

addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof. As used herein the expression "and/or" includes any and all combinations of one or more of the associated listed items.

[0072] In addition, spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if the device in the figures is turned over, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly.

[0073] Well-known functions or constructions may not be described in detail for brevity and/or clarity.

[0074] As described above, the invention relates generally to a system and process for dispensing pharmaceuticals. A high level process incorporating the invention is described generally with reference to **Figure 1**. The process begins with a medicine supplier **102**, such as a pharmacy, that receives and processes prescriptions for a patient in any suitable manner. In one embodiment, the prescriptions are sent to the medicine supplier **102** through a network, computer system, a cloud or any other communication mechanism **104**, or they may originate through a paper prescription provided to the medicine supplier by the patient, as received from their physician or via a phone call or fax from a physician. Such prescriptions also may be refills of previously filled prescriptions for the patient. The medicine supplier packages the medications in pouches, according to the time that the medication is to be taken by the patient. Exemplary systems for the packaging of medications in pouches are described in U.S. Patent Nos. 5,671,592 and 6,202,385. Medications that are to be taken at the same time are packaged in the same pouch and each pouch is assigned a time of administration, in accordance with the prescription(s). It should be noted that more than one pouch may be required to package all the medications for a given administration time. For the sake of simplicity, a single pouch will be referred to herein, but should be understood to include one or more pouches, as necessary to accommodate a patient's medication regimen. U.S. Patent No. 8,311,853 describes an

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exemplary system that can be used to assign administration times for groups of medications and align the refills for the prescriptions to facilitate the refill process for all medications packaged in the pouches for a single patient. In one embodiment, a series of pouches are connected together to form a strip, such that a pouch may be removed from the strip, one at a time, through a cutting, tearing, or other removal mechanism. Pouches are ordered in the strip in chronological order, based on the date and time of administration. In one embodiment, a strip of medication pouches is loaded in a cartridge **200** (as shown in **Figure 6**), and sent to the user's home **108**. In one embodiment, the cartridge **200** is sent periodically to the patient, and the periodicity is based on the patient's preference – such as every week, every ten days, or once per month. The cartridge **200** contains medicines sufficient to last the predetermined period of time.

[0075] At the patient's home, the cartridge of packaged prescription medication is loaded by the patient into a dispensing unit **110**. In one embodiment, the cartridge **200** is designed to automatically self-align with the dispensing unit **110**, without the need for any installation work on the user's part. Therefore, the user may simply drop the cartridge **200** into the housing of dispensing unit **110** and apply sufficient pressure (either manually or via a mechanism in the dispenser) to cause the cartridge to seat in place (some embodiments employ a snapping action). Once the cartridge **200** seats in place, it is automatically aligned with the dispensing mechanisms and capable of dispensing medicines without further work, adjustment, or installation by the user as described in more detail below.

[0076] **Figure 2** illustrates exemplary pouches of medication, with each pouch containing the medicines to be taken by the patient at a particular time of administration, in accordance with their prescription(s). Individual pouches of medicine **112** are connected together to form a medication strip **114**, which is loaded into a cartridge **200**. In one embodiment, the number of pouches **112** in the strip **114** depends on the number of days for which the patient has ordered the medicines. Thus, for example, a patient may order prescription medicines for one week; then the number of pouches **112** in the strip **114** corresponds to the number of times the patient has to take medicines each day times seven days. In one embodiment the patient may have a schedule established with the medicine supplier to automatically receive a new strip of pouches on a regular basis (i.e., every two weeks, once per month, etc.)

[0077] Thus, one or more single or multi-medicine pouches **112** are prepared for each medication administration time for a predetermined period of time, and connected in the correct sequence to form a strip **114**. The medication administration time may be time based

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or event based. For example, the administration time may be "9.00 a.m." or "Breakfast". **Figure 26** illustrates another exemplary pouch in which the administration time is indicated as "7:00 AM, Monday, Aug 01". Individual pouches may be separated along the strip **114** by a transverse perforation or seam **116** that allows for easy separation of the pouches from the strip one at a time. Individual medicine pouches may be labeled with information **118**, such as the name of the patient, date of packaging or manufacturing, expiry date(s) of the medications, date and time of administration, instructions for taking the medication (i.e., take with food), warnings (i.e., do not operate heavy machinery when taking this medication, do not drink alcohol when taking this medication), and pouch contents, including the name, dosage, and number of pills of each medication; such information may be modified as necessary to comply with state and/or federal regulations. The medicine pouches **112** may each include a bar code **120** for identifying the individual pouch **112**. The bar code **120** may also contain some or all of the information **118.** In some embodiments, the bar code **120** may contain a unique pouch ID. The bar code **120** also may include an encoded index which determines its order within the strip **114** and may be used to determine the dispense time for that pouch **112**. Each bar code **120** also may contain information about the prior pouch **112** and/or the subsequent pouch **112**. This information can be used in processes for error recovery when the data collected from a bar code **120** is incomplete or determined to be invalid, as discussed below. Pouches **112** may include duplicate bar codes **120** located in separate areas of the pouch **112** (for example, in either corner). Identification of pouches **112** may additionally or alternatively be accomplished by RFID tag, colors, symbols, etc. Pouches **112** may include one or more registration symbols **122** that may be used to facilitate pouch **112** detection, particularly when using computer vision applications. Registration symbols **122** may be of any appropriate shape or size suitable for detection such as, for example, T-shaped, a vertical line, horizontal line, bar, dot, etc. and may be located in any appropriate area of the pouch **112**. In one embodiment, the pouches **112** are made from any suitable material that meets federal requirements for medication packaging and is of any size suitable to properly accommodate medications and the dispensing unit **110**.

[0078] It may be noted that the medicine supplier **102** that packages the medication into the pouches **112** /strip **114** may be a pharmacy themselves, or may be a third party with which the pharmacy has contracted for packaging/distributing the medications.

[0079] After the medications are packaged into pouches **112** corresponding to the appropriate doses for each time of administration for a single patient, the strip **114** of pouches

for that patient is loaded into a dispensing cartridge **200**. Each cartridge **200** is loaded with medicine pouches **112** sufficient to last a predetermined time frame specified by the patient, as explained above. The cartridge **200** with loaded medicines may be mailed, or otherwise delivered, to the patient on a regular basis. The cartridge **200** then can be loaded into a dispensing unit **110** for the patient and the individual pouches **112** can be dispensed at the appropriate times of administration. When the medication pouches **112** have all been dispensed, the used cartridge **200** may be disposed of, recycled, or may be returned to the medicine supplier **102**, or other designated facility, for reuse.

[0080] **Figures 3A** and **3B** illustrate an exemplary cartridge **200** which comprises a cartridge cover **202** and a cartridge frame **204**. Cartridge **200** also comprises a cylinder **206** about which the medication strip **114** is wound (see, e.g., **Figure 6**). Any discussion herein that references the loading of a cartridge **200** into a dispensing unit **110**, includes the medication strip **114** loaded in the cartridge **200**.

[0081] **Figure 4** illustrates an exemplary dispensing unit **110**. As can be seen in **Figure 4**, dispensing unit **110** comprises a housing **300** with a front **302**, back **304**, sides **306**, **308**, top **310** and bottom **312**. Top **310** includes a door **314** which is openable to expose an opening **316** in the housing **300**; the opening **316** provides access to the compartment **322** for receiving a cartridge **200** as described above. In the given example, an opening **316** is defined on the top **310** of the dispenser housing **300** such that the cartridge **200** may be dropped into the compartment **322** of the dispensing unit **110**. It may be appreciated however, that an opening may also be defined in any portion of the dispensing unit **110**, as long as it serves the purpose of conveniently inserting a cartridge **200** in the compartment **322**. The door **314** may include a lock **315** to restrict access to the components of the dispensing unit **110** and, in particular, to the contents of the cartridge **200**. The lock may be of a standard type requiring a key or combination, and/or may require radio frequency or biometric identification or other suitable security feature to unlock and provide access to the opening **316** and the contents of the dispensing unit **110**. This locking feature may be desirable for both security and child-safety considerations. Further, screen functions also may be locked and require a user-defined PIN, biometrics or other security mechanism to unlock. The patient may choose whether or not to enable the various locking functions of the dispensing unit.

[0082] The dispensing unit **110** comprises a delivery slot **318** to dispense a medication pouch **112** at the requisite time of administration. In one embodiment, delivery slot **318** may be covered by a door. In one embodiment, the dispensing unit **110** further comprises a

display screen **320** suitable for communicating with the patient and providing buttons and menus for the patient to interact with the dispensing unit **110** and make selections. Information communicated to the patient may include dosage information, notification that a pouch is ready to be dispensed, alerts for missed medication, refill requirement, errors, etc. as needed. In one embodiment, the dispensing unit **110** further includes a local or remote audible, visual, and/or tactile alarm or other device for notifying the patient that a medication pouch **112** is ready to be dispensed, has been missed or that a message is on the display screen. In one embodiment, the screen **320** may be used to allow the patient to enter information, answer questions, confirm his/her identity, etc. In one embodiment, the screen **320** of the dispensing unit **110** may be used as a digital photo frame when communications on the display are not required.

[0083] In one embodiment, dispensing unit **110** also is equipped with a radio receiver, which allows a user to tune into radio stations when a medicine pouch **112** is not being dispensed.

[0084] In one embodiment, dispensing unit **110** is equipped for networking with a secured wireless network such as a home Wi-fi or cellular broadband service. In one embodiment, dispensing unit **110** is additionally or alternately equipped with a secured Ethernet connection as well as an RJ-45 jack (i.e., a telephone jack) as means of communication. A network connection enables the dispensing unit **110** to communicate with the cloud **104**, as necessary, to receive information such as updates, electronic medication administration records (eMARs), schedules, and alerts provided to the cloud **104** by the patient's medicine supplier **102**, physician, clinical study coordinator, etc. The dispensing unit **110** also may provide information to the cloud **104** such as adherence data, verification information, answers to questions, etc.. The dispensing unit **110** may further use this communication path to send out requests for replenishment or help, or to communicate discrepancies in data (i.e., downloaded eMAR does not match patient identification) or a change in medications or schedules. In one embodiment, all data is sent and received via the cloud **104.**

[0085] In one embodiment, dispensing unit **110** comprises a suitable controller or microprocessor to control the operation of various components of the dispensing unit **110** and to communicate with the medicine supplier **102**, caregiver, or other appropriate individual or organization (i.e., study teams, insurance providers, etc.). Dispensing unit **110** further

comprises an internal memory, such as RAM, for storing the controller's instructions and an internal or external memory for downloading and uploading required data to the cloud **104.**

[0086] In one embodiment, the dispenser unit **110** has a graphical user interface (GUI), which is displayed on the screen **320** and helps a user to navigate through and select various options from the functions of the dispensing unit **110**.

[0087] The structure and features of the cartridge components will now be described. Referring to **Figures 3A, 3B, 5A** and **5B**, cartridge cover **202** comprises a top **220**, sides **222**, **224**, front **226**, and back **228**. The top **220** may include a handle **230** to facilitate handling and loading of the cartridge **200** into the compartment **322** of the dispensing unit **110**. In the embodiment illustrated herein, on each side **222**, **224** of cover **202** are holes **232**, slots **234** and recesses **236** to accommodate features of the cartridge frame **204** and will be discussed in detail later with regard to frame **204**. Side **224** also includes recess **238** which accommodates a feature of the cartridge frame **204** and also will be discussed further with regard to frame **204**. Other embodiments may employ different alignment/guide/retention features.

[0088] **Figure 6** illustrates an exemplary cartridge **200** with the cover **202** removed. The frame **204** is loaded with a strip **114** of medication pouches that have been rolled around the cylinder **206**. In one embodiment, the cartridge frame **204** is sized and configured to fit into a dispenser unit **110** located in the patient's home.

[0089] The structure of the cartridge frame **204** will now be described with reference to **Figure 7**. **Figure 7** is a perspective view of the cartridge frame **204**. In one embodiment, the cartridge frame **204** comprises sidewalls **208**, **210**, a floor **216**, and a base **218** with a bottom surface **227**, top surface **229**, front section **217** and a back section **219**, base side walls **221**, **223** and base rear wall **225**. In one embodiment, the frame may be made of injection moldable plastic, such polypropylene, ABS or polyethylene, for example, metal, such as steel or aluminum, for example, or a composite material, such as fiberglass or a heavy-duty cardboard, for example.

[0090] In one embodiment, the cartridge sidewalls **208, 210** are substantially pentagonal in shape, with the rectangular portion **209** of the pentagon forming the lower portion of each sidewall, below the triangular portion **211**. As can be seen in **Figure 7**, the rectangular portion **209** of each sidewall **208**, **210** includes a variety of features which will be described now. Sidewall **208** includes a wedge **244**, which is a hollow, outward protrusion from the sidewall **208**. Wedge **244** is located substantially in the center of the rectangular portion of sidewall **208**. Two latches **242** are present on each sidewall **208**, **210** of the frame **204**.

Latches **242** are each a substantially square-shaped member that is separated from the sidewall on three sides, such that it protrudes slightly out of the plane of the sidewall while connected to the sidewall at the bottom of the latches **242** by an angled portion **250** (**Figure 10**) of the sidewall, forming an upward-facing, flat, hook-like portion of the sidewall. Latches **242** are located near the lower edge of the rectangular portion **209** of each sidewall **208, 210**. Within the face of the latch **242** is a protrusion **248** that faces back toward the sidewall **208, 210**, creating a bump in the latch **242**. Additionally, sidewalls **208, 210** each include two tabs **240**. Tabs **240** are wedge-shaped, outward protrusions of the sidewall **208, 210**, each located at the end of a strip of the sidewall **208, 210** that is disconnected laterally along its length; this allows for freedom of movement of the tabs **240** into and out of the plane of the sidewall **208, 210**. Tabs **240** are located approximately in an equatorial plane of the rectangular portion **209** of the sidewall **208, 210** and are spaced equidistantly from a horizontal line in the center of the rectangular portion **209** of the sidewall **208, 210**. On sidewall **208**, tabs **240** are located far enough apart as to flank wedge **244**. One of skill in the art will recognize that latches **242**, tabs **240**, and wedge **244** could be located elsewhere on the sidewalls **208, 210**, provided that other features of the system with which each feature interacts are likewise relocated.

[0091] Referring back to **Figures 5A** and **5B**, the cartridge cover **202** includes holes **232**, slots **234** and recesses **236** and **238**, which are designed to accommodate the previously discussed features of the sidewalls **208, 210**. As can be seen in **Figures 3A** and **3B**, and with reference to **Figures 5A** and **5B**, when the cartridge cover **202** is placed over the cartridge frame **204**, side **224** of cover **202** is aligned with sidewall **208** of cartridge frame **204** so that recess **238** can receive wedge **244**; this allows wedge **244** to be accessible for alignment of the cartridge **200** when inserted in the dispensing unit **110**, as will be discussed later. When the cover **202** and cartridge frame **204** are aligned, tabs **240** fit into holes **232** and extend outward from the cartridge **200**. Slots **234** and recesses **236** accommodate latches **242**: recesses **236** receive the angled portion **250** of the sidewall **208, 210** that makes up the lower portion of each latch **242**, and the protrusion **248** of each latch **242** is received by its respective slot **234**. The fit of the cover **202** of the frame **204** is tight enough such that the protrusions **248** "snap" into place in the slots **234** which allows the cover **202** of the cartridge **200** to fit removably but securely in place on the frame **204**.

[0092] Again referring to **Figure 7**, each of the triangular portions **211** of sidewalls **208, 210** includes a hole **212, 214**, respectively, into which a central cylinder **206** is inserted to

serve as an axle (see **Figure 8**). The cylinder **206** may be made of injection-moldable plastic, such polypropylene or polyethylene, for example, metal, such as steel or aluminum, for example, or composite material, such as fiberglass or a heavy-duty cardboard, for example. **Figure 8** and **Figure 9** show that, in one embodiment, the cylinder **206** may be created by assembling two identical halves **252**. Located substantially in the center at each end of each cylinder half **252** is a longitudinal tab **260**. Each longitudinal tab **260** is separated from the adjacent portion of the cylinder **206** along the length of the longitudinal tab **260** and has an upturned lip **262** at its end. Extending perpendicularly to the cylinder **206** near each end and circumferentially in all regions except for the longitudinal tabs **260** is a radial ridge **254**. On one longitudinal edge of the cylinder half **252,** each ridge **254** extends from the cylinder **206** and ends in a small hook tab **256**. On the other longitudinal edge of the cylinder half **252**, aligned with the radial ridge **254** and opposite each hook tab **256**, is a small receiver tab **258**.

[0093] When the two halves **252** are assembled to make the complete cylinder **206** (**Figure 9**), each hook tab **256** snaps onto its respective receiver tab **258** on the other half **252** to secure the halves **252** together. When the cylinder **206** is assembled, the halves are separated slightly along their length between the radial ridges **254**, creating a longitudinal slot **264** along the cylinder **206**. The halves **252** may be assembled around the edge of the first pouch **112** of a medication strip **114**; the plates **266** secure the edge of the first pouch **112**, which then extends through the slot **264**, thus anchoring the strip **114** and facilitating the process of winding the strip **114** on the cylinder **206**. In this instance, the "first" pouch **112,** is the first pouch to be wound around the cylinder **206**, as opposed to the first pouch **112** to be dispensed, which would be at the opposite end of the strip **114** and will be referenced later. The first pouch **112** to be wound around the cylinder **206** may be the last pouch **112** to be dispensed from the strip **114** or may be an empty pouch **112** or one of a series of empty pouches **112**. Alternatively, a strip of paper or plastic or other suitable material may be attached to the end of the strip **114** and used for attachment of the strip **114** to the cylinder **206**. The paper/plastic strip or empty pouch or pouches **112** may include notifications to the patient that the cartridge **200** is empty, refill information, pharmacy contact information, the next scheduled time for medication administration, and/or other information helpful to the patient. The medication strip **114** may then be wound around the cylinder **206** prior to insertion of the cylinder **206** into the frame holes **212**, **214**. U.S. Patent Publication No. 2013/0264376 describes an exemplary system that can be used to wind a strip of medication pouches into a roll.

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[0094] Loading of the strip **114** of pouches onto the cylinder **206** may be performed as the strip of pouches is produced and its contents verified for accuracy. When inserting the cylinder **206** into the holes **212**, **214** of the cartridge frame **204**, the cylinder tabs **260** can be displaced inwardly to facilitate the insertion process. One end of the cylinder **206** is inserted through each hole **212**, **214** on the inner side of the cartridge frame **204**, thereby connecting the two sidewalls **208**, **210** via the cylinder **206** (**Figure 10**). As the cylinder end is inserted into the holes **212**, **214**, the radial ridge **254** limits the distance that the cylinder **206** can pass through the holes **212**, **214**. Once inserted to the furthest extent allowable by the radial ridges **254**, the lips **262** of the tabs **260** latch on the outer side of the respective sidewall **208**, **210**, thereby preventing, in concert with the radial ridges **254**, lateral movement of the cylinder **206** within the cartridge frame **204**. When inserted into the frame **204**, the cylinder **206** acts as an independently rotating hub within the cartridge such that the medication strip **114** can be unwound as necessary during dispensing of the medication pouches **112** from the dispensing unit **110**.

[0095] Turning now to **Figures 11A** and **11B**, viewing the cartridge frame **204** from the rear, further features of the cartridge frame **204** will now be described. The floor **216** of the frame **204** contains a routing hole **270** located in the rear-most quarter of the floor **216**. The hole **270** is substantially rectangular with its longer side (width) extending across most of the width of the floor **216**. The width of the hole **270** is at least wide enough to accommodate the width of the medication strip **114**. Along the forward-most edge of the hole **270** is a series of loops **268**. In one embodiment, there are four loops **268**. The outer diameter of the loops **268** may range from 0mm to 40 mm. In one embodiment the outer diameter of the loops is in the range of 20mm-30mm. In one embodiment, the outer diameter of the loops is approximately 20mm. One of skill in the art will recognize that the number and size of the loops may be varied while still maintaining functionality. A second, substantially rectangular hole **272** is located in the front **217** quadrant of the floor **216** closest to sidewall **208**, with its longer edge parallel with the sidewall **208**. As can be seen clearly in the cross-section view of the cartridge frame **204** shown in **Figure 12A**, extending forward from the rear edge of the hole **272**, adjacent the longer edge of hole **272** parallel with sidewall **208**, is an arm **274** that serves as a brake member. Where the arm **274** attaches to the floor **216**, the arm **274** slopes downward toward the cartridge base **218** and includes a hollow rib **275** on the top surface of arm **274** to provide more stiffness and stability to arm **274**. The free end of arm **274** is arched and is positioned over a notch **284** on the upper surface **229** of base **218** (see **Figure 13**).

Turning back to **Figures 11A** and **11B**, extending from sidewall **208** is arm **276** with hollow rib **277** on the top edge of arm **276** to stabilize arm **276**. Arm **276** is positioned above the center of arm **274** and extends downwardly toward and near arm **274**. The length and angle of arm **276** are such that arm **274** resides at a height approximately 12mm or less above the upper surface **229** of base **218** when the cartridge **200** is inserted in the dispensing unit **110**. **Figure 12B** shows the location of a medication strip **114** when loaded on the cartridge frame **204**. The medication strip **114** is loaded on the cylinder **206** so that its free end exits the roll in the direction of the rear of the cartridge frame **204** (defined by the rear section **219** of the cartridge base **218**). The free end of the strip **114** is then fed through the hole **270** in the floor **216**. The loops **268** provide a rounded surface past which the strip **114** can more easily move. The strip **114** is now in the space between the base **218** and the floor **216**. The strip then passes under arm **274**, moving toward the front of the cartridge (defined by the front section **217** of the cartridge base **218**). The strip **114** remains between the base **218** and floor **216** such that it passes between notch **284** and the arch **279** of arm 274. This positioning of the strip between the notch **284** and arch **279** of arm **274** allows the strip to be held securely in place, particularly during transport. As the strip **114** follows this path it passes over hole **280**.

[0096] Turning now to **Figures 13** and **14**, features of the base **218** of cartridge frame **204** are illustrated. In **Figure 13**, the notch **284**, discussed above, on the upper surface **229** of the base **218** is illustrated. This notch **284** is positioned directly below the arch **279** in the free end of arm 274. A rectangular recess **281** in the front quadrant of base **218** adjacent sidewall **208** forms hole **280** and is positioned below hole **272** in the floor **216.** Notch **284** is adjacent the forward edge of hole **280**. A laterally adjacent recess in base wall **221** creates window **283** (see **Figures 10** and **15**). Viewing the base **218** from below in **Figure 14**, feet **278** are positioned in each corner on the bottom surface **227** of base **218**. The bottom surface **227** of base **218** may also include identifying information **282** for the cartridge **200**. In one embodiment, identifying information may be provided in the form of an RFID tag. One of skill in the art will recognize that the identifying information may be provided in other suitable formats (such as bar code, for example), or in other locations on the cartridge. Identifying information that may be included in the RFID tag may include, but not be limited to, cartridge identification number, patient name, patient identification number, patient address, physician name, pharmacist name, pharmacy name, pharmacy address, prescription number(s), refill information, medical record number, cartridge fill date, cartridge expiration

date, time zone information, and/or other information specific to the patient, the medication regimen, including medication administration times. In some embodiments, the identifying information may include administration times for some or all pouches **112** in the medication strip **114**.

[0097] Provision of the cylinder **206** as two halves **252** can be advantageous with respect to helping to secure the medication strip **114** with the cylinder **206** for loading, as discussed elsewhere. Providing two halves **252** also may be desirable for ease of packing and shipping as the two halves **252** may be stackable and thus take up less room than the full cylinder **206**. Cartridge frame **204** also may be provided to the medicine supplier in a flat, stackable form as shown in **Figures 15** and **16**. In order to accommodate this, some features of the cartridge frame **204** are made hollow, such as the ribs **275** and **277**, tabs **240**, and wedge **244**, as well as latches **285** and stops **289**, described below. Loops **268** also facilitate stacking of the flat frame; forming this region as a solid tube or cylinder would not as easily accommodate stacking. This structure provides for ease of packing and shipping of the cartridge frame **204**; this form can then be folded into the final arrangement (**Figure 7**) in conjunction with loading the cartridge frame **204** with the cylinder **206** containing the medication strip **114**. Referring to **Figure 15**, viewing the flat cartridge **204** from the perspective of the top of the floor **216**, each side **208**, **210** would be folded up at 90 degree angles to the floor **216** (out of the plane of the page) and secured in place with wedge-shaped latches **285** which interlock with slots **287** in sidewall **208**, **210**. Similarly, base **218** folds 180 degrees underneath (into the plane of the page for **Figure 15**) floor **216** by bending 90 degrees at each edge of base rear wall **225**. Wedge-shaped stops **289** prevent base rear wall **225** from folding further than 90 degrees on either edge. Base **218** is secured in place by interaction of latches **286** at the bottom edges of sidewalls **208**, **210** (see **Figure 16**) with receiver slots **288** in each of the base side walls **221**, **223**.

[0098] **Figures 17A** and **17B** illustrate a dispensing unit **110** with the door **314** removed to reveal the opening **316** and the compartment **322** into which the cartridge **200** is inserted for dispensing of medication pouches **112** from the cartridge **200**. Compartment **322** includes channel **326** (**Figure 17A**) to accommodate wedge **244** of the cartridge frame **204**. The singular location of channel **326** ensures that the cartridge can be loaded in one direction only and will be properly aligned within the compartment **322**, with the front of the cartridge (front **217** of the cartridge base **218**) facing toward the front **302** of the dispensing unit **110**. Feet or pegs **278** on the bottom of cartridge frame **204** are another alignment feature; feet **278**

help to properly seat the cartridge **200** in compartment **322**. As can be seen in **Figure 17C**, a channel **332** or receiving hole runs across the width of the front of the floor of the compartment **322**. The two feet **278** located in the front **217** of the base **218** of the cartridge **204** are seated into the channel **332**. Thus, the alignment features, feet **278** and wedge **244**, ensure that the cartridge **200** is positioned correctly within the compartment **322** so that the medication pouches can be properly dispensed, as will be discussed further below. As can be seen in both **Figures 17A** and **17B**, compartment **322** also includes slots **324** on both sides of the compartment **322**. Tabs **240** on the frame **204**, which protrude through holes **232** of the cover **202**, are received in slots **324** and removably snap into place to secure the cartridge **200** in position for dispensing. Two channels **328** on each side of compartment **322** also are provided to accommodate the protrusion of latches **242** of the cartridge **200**. As discussed above, in other embodiments the cartridge and compartment may include other features that retain the cartridge in place.

[0099] Additionally, the dispensing unit **110** contains a roller **330** or other drive unit that extends into the compartment **322**. When a cartridge **200** is properly loaded into the compartment **322**, roller **330** is positioned in line with hole **280**, along its lateral edge adjacent sidewall **208**, directly opposed to arm **274** (in other embodiments, a hard stop may be employed instead – see **Figure 27C** at **1220**). **Figure 18** shows a cross-section of the dispensing unit **110** with a cartridge **200** loaded in compartment **322**. Roller **330** extends through hole **280**, contacting the strip **114** along its side seam and pressing it against arm **274** such that, when it is time to dispense a pouch **112**, roller **330** is able to move strip **114** forward through frictional interaction with the pouch **112** against arm **274**. Arm **276** provides resistance to the pressure of roller **330** against arm **274** by limiting the ability of arm **274** to move away from the roller **330**.

[00100] **Figures 19A** and **19B** illustrate further detail of the dispensing unit **110** relative to movement of the medication strip **114** and pouches **112**; some components, not relevant to this discussion, have been removed for clarity. As can be seen in **Figure 19A**, the forward (dispensing) path **F** of the medication strip **114** continues past a cutting mechanism **334** (i.e., scissors, blade, etc.) and sensor **340**. The sensor **340** detects a perforation or seam **116** between pouches so that cutting mechanism **334** can cut and separate the forward-most pouch **112** at the appropriate time, as will be detailed later. Sensor **340** may be a redundant sensor (more than one sensor closely spaced) to ensure detection of the seam **116** and cutting of the pouches **112** in the correct location. As the medication strip **114** moves forward, it moves

along ramp **350** and is engaged by roller **336** which helps to pull the strip **114** forward. Roller **336**, as well as roller **330**, may be made of a type of foam, such as urethane, for example, or other sufficiently soft material so that the medications within the pouches **112** are not crushed or otherwise damaged as the pouches are moved by the rollers **330**, **336** in the dispensing process. When positioned on the edge of hole **280** and only contacting the pouch **112** side seam, roller **330** may be made of a harder material such as rubber or plastic, since it does not come in contact with the medication. When a pouch **112** is paused in the forward path **F** such that the following perforation or seam **116** is placed in position to be cut by the cutting mechanism **334,** sensor **342** may view the bar code **120** on the medication pouch **112** to confirm that the correct pouch **112** is in position to be dispensed. Once pouch **112** is confirmed and the perforation or seam **116** has been cut, the released pouch **112** is moved forward by roller **336** onto staging platform **337**. Sensor **344** is positioned to detect if a pouch is present on the platform **337**. When dispensing of the pouch **112** is requested by the patient, roller **336** can move the pouch **112** through the slot **318** to be retrieved by the patient. One of skill in the art will recognize that sensors, **340**, **342**, and **344** may be LED, camera or any other type of sensor appropriate for detecting the events and for the environment. The dispensing unit **110** may also include door lock sensor **348** and cartridge identifier **282** sensor **346** (i.e., RFID reader, bar coder reader, camera, etc., as appropriate for identifier **282** on cartridge **204**).

[00101] **Figure 19B** illustrates the path **R** of the pouch **112** under certain circumstances, such as when the wrong pouch **112** is in position for dispensing or the patient does not retrieve the pouch **112** during the allowed administration window. Under these circumstances, roller **336** may operate in reverse and move pouch **112** along path **R**. Due to the upwardly sloping geometry of ramp **350**, when the pouch **112** is moved rearwardly by the reverse movement of roller **336**, the pouch **112** slides under the ramp **350** and falls into exception tray **338**. Tray **338** may include a locking mechanism (not shown) for security and child-safety purposes, but may be opened by appropriate individuals to access medication pouches **112** contained therein. Some embodiments may lack an exception tray altogether.

[00102] **Figure 20** is a flowchart illustrating the operation of the dispensing unit to automatically dispense a medicine pouch at a requisite and predetermined time. Referring to **Figure 20**, firstly in step **401** a cartridge frame is loaded with a strip of medicine pouches covered with the cartridge cover and delivered to the patient/customer. The customer opens the door of the dispensing unit in **step 402**, drops the cartridge into the dispensing unit and

closes the door in **step 403**. The controller in the dispensing unit senses the cartridge by means of a suitable sensor and initiates a startup sequence. The startup sequence, in one embodiment, comprises validation of the patient, medicine strip and the cartridge, as shown in **step 404**. Through appropriate sensors in the dispensing unit, information about the cartridge and medications contained therein is read from the identifier on the cartridge (i.e., bar code, RFID, etc.). The dispensing unit itself may be patient agnostic; that is, the dispensing unit may not be assigned to a particular patient or waiting for a certain cartridge. The specifics of the medication regimen for that patient may be determined when the cartridge is inserted into the dispensing unit. When the information of the identifier on the cartridge is read, the controller of the dispensing unit may require validation of the patient's identity in **step 404** to confirm that the correct medications have been received for the correct patient. The controller may employ a user-specific PIN, RFID identification, biometric or other appropriate identifying data for patient validation. The controller may communicate information about the patient and cartridge to the cloud and patient-specific information retained by the cloud may then be downloaded to the dispensing unit. The electronic medication administration record (eMAR) for that patient, which includes medication administration times (hour of administration, or HOA), is created by the pharmacist and maintained in the cloud for access by the dispensing unit. When the eMAR is downloaded in **step 405**, the controller of the dispensing unit contains the schedule for dispensing the mediation pouches to the patient. Access to the cloud also provides a means of data recovery if the data collected from the identifier is determined to be incomplete or invalid.

[00103] When the dispensing unit is inactive (in terms of dispensing medication) other features may be used such as the radio or digital photo frame features of the dispensing unit, as in **step 406**. Other options include webcams, Bluetooth devices, and the like.

[00104] When the time for administration of the first medication pouch arrives, the dispensing unit issues an alert to the patient in **step 407**. Alerts may consist of any appropriate means of notifying the patient of availability of the medication and may include, but not be limited to, audible alerts such as bells, buzzers, chimes, etc.; tactile alerts such as vibration; visual alerts such as flashing lights which may be on the unit, on a device carried by the patient, including cell phone, smart phone, MP3 player or other mobile device, or may be through control of the room lighting; text alerts; email alerts, phone calls or the like. The eMAR may include information defining a time period within which each medication dose may be administered (the HOA window). During the HOA window, the patient is able to

dispense the appropriate medication pouch; once the HOA window expires (the time period for administration of that medication dose has been exceeded) the patient will no longer be able to dispense the pouch through the usual path. With the opening of the HOA window, the medication pouch is made accessible within the dispensing unit in **step 408**. When the patient is ready to dispense the medication pouch and if the time is still within the HOA window, the patient selects the dispense button on the dispensing unit screen in **step 409**. In **step 410**, the medication pouch is dispensed to the patient and adherence data is transmitted to the cloud in real time, reporting that the patient's medication was taken. In one embodiment, the dispensing unit may display achievements or provide a game (i.e., health-related game, game related to adherence progress, etc.) to the patient in **step 411**. In one embodiment, in **step 412** the dispensing unit may display promotional or informational messages, such as information about the drug or a message for the patient, which has been configured in the cloud by the pharmacy, physician, clinical study coordinators, etc. In one embodiment, a series of questions for the patient may be configured in and delivered from the cloud, with the patient's answers being delivered back to the cloud in **step 413**. This may be particularly useful for clinical studies or questions from the patient's physician relative to side effects of the medications and/or the patient's general health. **Steps 411, 412,** and **413** are not all required and are not mutually exclusive; any or all of these steps may be utilized with the dispensing unit.

[00105] Alternatively, if the patient does not dispense the medication pouch when the HOA window opens, the dispensing unit may provide additional alerts of escalating frequency and urgency to remind the patient that the pouch is ready to dispense, as in **step 419**. Escalating alerts may include, but not be limited to, louder audible alerts, changes in the sound or pattern of audible alerts, increased strength and length of tactile alerts, brighter or faster flashing lights, increased frequency of texts, emails, phone calls, etc. If the patient does not select the dispense button before the HOA window expires, information may be sent to the cloud in **step 415** indicating that the patient has missed the medication administration event and an alert may be sent to an appropriate individual such as a caregiver, pharmacist, physician, family member, etc. In **step 416**, if an exception tray is included, the missed pouch is moved to the exception tray to remove it from the dispensing path. The pouches in the exception tray can still be accessed. In one embodiment, access to the exception tray may be limited to a caregiver in cases where it is not advisable to allow the patient access to the medications. A sensor in the dispensing unit may monitor contents of the exception tray and

notify the patient or other individual when the tray is full. If the tray becomes full, the dispensing unit may stop dispensing until the tray has been emptied or at least enough pouches have been removed so that it is no longer full.

[00106] At decision point **417**, sensors of conventional construction determine if the end of the medication strip has been reached. If sensors determine that the end of the medication strip has not been reached, then a new HOA window will open at the appropriate time and the process will move back to **step 407.** If the end of the medication strip is sensed, the dispensing unit will not open an HOA window and flow will move to **step 418** where a message is delivered to the patient that the end of the strip has been reached and prompting the patient to remove the empty cartridge and load a new one. The system may also ask the patient if they would like to order another refill cartridge to have on hand and may submit refill requests automatically through the cloud to the medicine supplier. In one embodiment, the status of all the events generated at the dispensing unit, such as alarms, refill requests, and dispensing activity indicators may be uploaded to the cloud.

[00107] **Figure 21** illustrates an exemplary mechanical flow of the dispensing unit during the operation of the unit. At **step 501**, the HOA window opens and the patient is alerted to dispense a medication pouch, as in **step 407** of **Figure 20**. At decision point **502**, the unit determines if the user has selected the button to dispense the medication pouch. If the user selects the dispense button during the HOA window, at **step 503** a sensor confirms the identification of the first pouch in the strip by reading the bar code, RFID tag, etc. If the data collected at this step is determined to be invalid or incomplete, the system may access the cloud to retrieve the relevant information (see **Figure 23**, dashed lines). Alternatively, the system may attempt error recovery using approaches discussed below. At **step 504** the pouch is then advanced past a sensor that identifies the location across which to cut the pouch strip in order to separate the first pouch from the remainder of the strip. A perforation may be provided within the seam between the pouches and the cut may occur at or near the perforation, but at least within the seam. The strip is cut at **step 505** and the pouch is advanced to a platform within the dispensing unit at **step 506** and moved forward through the dispensing slot to be dispensed to the patient at **step 507**. The system then waits for the next HOA window at **step 519**.

[00108] In one embodiment, one or more cameras are used for the sensors and a computer vison subsystem may use one or more pouch features (including but not limited to the registration symbols, barcode regions, pouch seams, physical material characteristics) in the

pouch detection and evaluation process. This process can identify various aspects of the pouch and enable system functionality, including but not limited to seam detection discussed above, reading of bar code information, and counting and indexing of pouches as they are removed from the cartridge.

[00109] If the patient does not select the dispense button during the HOA window at **step 502**, if an exception tray is present, the process moves to decision point **508** and the sensor monitoring the status of the exception tray (also called the exception bin) determines if the tray is full. If the sensor determines that the bin is not full, at **step 509** a sensor confirms the identification of the first pouch in the strip by reading the bar code, RFID tag, etc. At **step 510**, the pouch is advanced past a sensor that identifies the location across which to cut the pouch strip in order to separate the first pouch from the remainder of the strip. The strip is cut at **step 511** and the pouch is then advanced to a platform within the dispensing unit at **step 512**. At this point, the pouch is rerouted at **step 513** to move it to the exception tray. A missed dispense alert may be shown on the display screen of the dispensing unit at **step 514** and an alert may be sent to an appropriate individual such as a caregiver, physician, family member, etc. The system then waits for the next HOA window at **step 519**.

[00110] At decision point **508**, if the sensor determines that the exception tray is full, the pouch remains attached to the medication strip at **step 515**. An alert is provided at **step 516** notifying the user that the tray must be emptied and dispensing is halted until further action is taken to empty the tray. The alert may take any form, as described above for other alerts of the system, as appropriate to notify the user, and may be made distinguishable from other types of alerts of the system. At **step 517**, the bin is emptied and at **step 518** the system progresses to the exception routine (**steps 509** through **514**). After completion of the exception routine, the system resumes normal operation and waits for the next HOA window at **step 519**. Alternatively, a "full" determination at **step 508** may trigger a visual alert that a medication was missed.

[00111] **Figures 23-25** illustrate steps in the cartridge loading and pouch dispensing processes of the dispensing unit. With the exception of steps specific to online mode operation (which are shown with dashed arrows in **Figure 23**), the steps described here can be used in an offline mode, which may be used when there is not access to the cloud to obtain the necessary information for dispensing. Referring to **Figure 23**, at **step 601**, the cartridge is loaded in the dispensing unit and at **step 602** the unit may scan and collect data from the cartridge barcode (or RFID tag, as appropriate). The data collected may include, but may not

be limited to, schedule information pertaining to administration times for the pouches in the strip; patient name; patient ID; cartridge ID; prescription numbers; the date the cartridge was filled with the medication strip; time zone information; any other information required and/or desirable to identify the patient, the medications in the cartridge, and the dispensing schedule, and any information required and/or desirable to properly dispense medication from the cartridge to the patient at the appropriate time without requiring access to the cloud. At **step 603**, the system may evaluate if all cartridge data is valid. If the barcode or RFID information is damaged or otherwise unreadable making the data invalid, the system may attempt error recovery at **step 604**. It is well known in the art that 2D Data Matrix barcodes incorporate duplicated data encoded in and distributed throughout the barcode image. This duplication of data provides the potential for data to be reconstructed from one part of the barcode if the data in another part of the barcode is damaged. The system may make a determination at **step 605** as to whether the data has been recovered --depending upon the level of damage done to the code, the data may or may not be recoverable. If the data cannot be recovered, the cartridge load process fails (**step 606**); in this case the unit may display a message to the user indicating that the medication cannot be dispensed. The unit also may provide additional guidance such as: a recommendation to the user to contact their pharmacist or another individual who can address the issue; a notification that the medication can be dispensed manually until the dispensing issues are addressed; notification of the time to manually dispense a pouch; the appropriate pouch identification number for each administration time for manual dispensing; instructions on how to manually dispense the pouches; contact information for the pharmacist or other individual to contact; an option for the patient to request a call-back from the pharmacy; etc. The unit also may still provide alerts to the user at the appropriate medication administration times.

[00112] Turning briefly to the online mode (dashed lines in **Figure 23**), if the data is not recovered at **step 605** and the system is online, the system may access the cloud at **step 607** to recover the necessary information. At **step 608**, the system again evaluates whether the data has been recovered. If the data has not been recovered from the cloud, the cartridge load process fails (**step 606**) and the unit may provide messages, guidance, alerts, etc., as described above. If the data has been recovered, the system may move to the steps identified in **Figures 24A** and **24B**, as described below.

[00113] If the cartridge data is determined to be valid at **step 603**, or if the system determines at **step 605** or **step 608** that the data has been recovered, the system may move to

the steps identified in **Figures 24A** and **24B**. At **step 701** (**Figure 24A**), the system may scan and read the data from the barcode (or RFID or other identifier, as applicable) on the first pouch in the strip. At **step 702**, the system may evaluate if all pouch data is valid. If the information obtained from the scan is damaged or otherwise unreadable, the system may attempt error recovery at **step 703** (**Figure 24B**). The system may attempt to utilize the built-in error correction of the barcode, as discussed above with respect to the cartridge identifier/barcode. Alternatively or in addition, the system may read a second, duplicate bar code located in another area of the pouch to determine if the data contained there is valid. At **step 704**, the system may evaluate if the pouch data has been recovered as a result of the local error recovery process. If all data has not been recovered, the system may attempt data recovery using data obtained from the next pouch, at **step 705**. If the data can be more easily read from the neighboring pouch, the information can be extrapolated to the first pouch—the system can determine the number of the first pouch as well as the administration time (using information obtained about the schedule from the cartridge barcode). The system may again determine at **step 706** if the data for the first pouch has been recovered. If the data has not been recovered, the system may check the pouch index at **step 707** and, by identifying the pouch number, may retrieve schedule information from the cartridge data. By keeping an accurate count of the pouches, the system always knows the sequence of the pouches in the administration schedule. The system may again determine at **step 708** if the data has been recovered. If the data cannot be recovered, the pouch read process fails at **step 709**. The unit may display a message to the user indicating that the medication cannot be dispensed. The unit also may provide additional guidance such as: a recommendation to the user to contact their pharmacist or another individual who can address the issue; contact information for the pharmacist or other individual to contact; an option for the patient to request a call-back from the pharmacy; etc.

[00114] If the pouch barcode scan is successful at **step 702**, or if the data can be successfully recovered at any of **steps 704**, **706**, or **708**, the system may proceed to **step 710** where it evaluates if the data acquired from the pouch matches the data acquired from the cartridge. Some of the information provided in the pouch barcode (such as, for example, patient identification, cartridge identification, prescription numbers, etc.) can be redundant to the information provided in the cartridge barcode, allowing for this validation step. This verification process ensures that the correct cartridge was used to load the correct strip of medications and does not allow the dispensing to proceed based only on the cartridge

information. If the matching is successful at **step 710**, the system may proceed to **step 711** where it makes a determination as to whether the cartridge is empty. If the cartridge is determined to be empty, the load process fails at **step 712** and the system may provide one or more messages to the user such as, for example: notification that a new cartridge must be loaded; instructions on how to load a cartridge; identification of the next cartridge to be loaded; instruction to contact the pharmacy to order a new cartridge; contact information for the pharmacy; an option for the patient to request a call-back from the pharmacy; etc. If the cartridge is not empty, the system may proceed to **step 713** and make a determination as to whether the cartridge has expired. If the cartridge has expired, the load process fails at **step 714**. The user may be notified of the failure and instructed to load a new cartridge or contact the pharmacy to obtain a new cartridge. The system also may provide additional information to the user such as, for example: instructions on how to load a cartridge; identification of the next cartridge to be loaded; contact information for the pharmacy; an option for the patient to request a call-back from the pharmacy; etc. Referring back to **step 710**, if the pouch data and cartridge data do not match, the load process fails at **step 715**. The system may display a message to the user such as, for example: instruction to contact the pharmacy; contact information for the pharmacy; an option for the patient to request a call-back from the pharmacy.

[00115] If the system determines that the cartridge is not expired at **step 713**, the process moves to **Figure 25**. At **step 801**, the system may display the patient name for the loaded cartridge and request verification from the user. When the user verifies that he/she is the correct patient for that cartridge, the system may determine at **step 802** if the loaded cartridge has been previously loaded in that unit. Some circumstances, for example, regarding when a cartridge may have previously been used in the unit may include: 1) a patient uses multiple units to dispense their medication; for example, the patient might use one unit at home and another unit at a family member's house, thereby moving the cartridge back and forth between units when they travel; 2) one unit may serve several patients in the same household; in this case there may be situations where patient #1 removes their cartridge and patient #2 inserts theirs, and vice versa; 3) some patients may remove their cartridge from the unit in order to manually dispense one or more pouches from the cartridge to take with them if they will be away from the unit for the day or for an extended period of time. Under circumstances where a cartridge is reinserted in a unit in which it has previously been used, the system knows which pouches have been dispensed and which pouch to expect next. If

the system determines at **step 802**, that the cartridge has been previously used in that unit, the system may proceed to **step 803** to retrieve information regarding the last medication pouch that was dispensed from that cartridge. Once the system retrieves this information, or if it determines at **step 802** that it is a new cartridge, the system may evaluate if the first pouch in the strip is the pouch that it expects, at **step 804**; this expectation may be based on the retrieved data regarding the last pouch dispensed, if the cartridge is a previously used cartridge, or it may be the expected first pouch in a strip, if it is a new cartridge. In either situation, the system may use the data acquired from the cartridge barcode and pouch barcode to make this determination. If the system determines that the first pouch is not the expected pouch, it may then assess, at **step 805,** whether the first available pouch appears later in the dispensing schedule for that cartridge. If the pouch does not appear later in the schedule, the load process fails at **step 806**. The system may display a message to the user such as, for example: instruction to contact the pharmacy; contact information for the pharmacy; an option for the patient to request a call-back from the pharmacy. If the system determines, at **step 805**, that the first pouch is to be dispensed later in the schedule, the system may notify the user, at **step 807**, that some pouches have been removed from the cartridge. If the first pouch is the expected pouch (**step 804**) or appears later on the dispensing schedule (**step 807**), the system may then move to **step 808**, retrieving the schedule and dispensing data. This information may be used to display to the user the scheduled administration time for the first pouch in the strip (**step 809**), which will then be dispensed at the scheduled time (**step 810**).

[00116] One of skill in the art will recognize that not all of the steps enumerated above need necessarily occur in the order in which they are described here. As nonlimiting examples, the system may first collect data from the first pouch and then from the cartridge, or it may collect the data from each source simultaneously; the system may make a determination on whether the cartridge is new or has been previously loaded in the unit prior to determining whether the cartridge is empty or expired. One of skill in the art will also recognize that many of the same steps may be performed in the cartridge loading and dispensing process regardless of whether the information is obtained from the cloud or offline but that the collection of data from the barcodes, in particular, provides the local information to enable offline dispensing. Additionally, one of skill in the art will recognize that, while these steps are discussed with respect to the "first" pouch, this process occurs for each pouch in the strip as it becomes the first pouch in the roll (i.e., next pouch to be dispensed), not only

for the first pouch in a new cartridge. In one embodiment, the dispensing unit of the present specification also provides a user with an option of "Manual dispense". When this option is selected, medicine pouches can be dispensed outside the designated HOA; this may be desirable if the patient is traveling or has other reason to be away from the dispensing unit during one or more HOA events. **Figure 22** is a flowchart illustrating an exemplary process flow to carry out the manual dispense option. Referring to **Figure 22**, **steps 651** to **656** are identical to **steps 401** to **406** of **Figure 20**. At **step 657** the patient selects a manual dispense option provided in a menu on the display screen of the dispensing unit. When choosing the manual dispense option, the patient is able to select the time period for which he wishes to manually dispense medication pouches. In one embodiment, the user may select a time period – such as 1 day or 2 days - for which they want the medication. The user may instead select a number of pouches, such as 2 or 3. The user may select as few or as many pouches as needed within a certain range; a limit may be set on the total number of pouches to be dispensed manually without consultation with the patient's physician, pharmacist, etc. The GUI of the dispensing unit prompts the user for a confirmation of the manual dispense and time period or number of pouches selected, as shown in **step 658**. On receiving a confirmation from the patient, the dispensing unit dispenses a cut or uncut strip (as desired) consisting of the appropriate pouches for the selected timeframe and an update about the manual dispense is then submitted to the cloud, as shown in **step 659**. At step **660**, normal dispensing flow continues, accounting the for the appropriate HOA events covered by the manual dispensing activity.

[00117] Referring now to **Figures 31-41**, another dispenser unit, designated broadly at **1110**, is illustrated therein (and shown in full in **Figure 32**). Many of the components of the dispenser unit **1110** and the cartridge **1200** residing therein are the same as or similar to those of the dispenser unit **110** in operation and function. Some of the differences in the dispenser units **110**, **1110** and the cartridges **200**, **1200** are discussed below.

[00118] Referring first to **Figure 33**, a cartridge cover **1202** of the cartridge **1200** is illustrated therein. The cover **1202** includes is generally rectangular, and includes a dispensing window **1202a** in its lower front edge. A handle **1230** projects from the center of the top **1220** of the cover **1202**. The cover **1202** also includes a hole **1202b** in the floor **1202c**. In some embodiments, the cover **1202** is formed of cardboard, and is typically constructed by folding a single flat blank of cardboard into a rectangular box. As can be seen in **Figure 31**, the cover **1202** overlies a cartridge frame **1204** (discussed in more detail

below); the combination of the cover **1202** and the cartridge frame **1204** comprise the cartridge **1200** that is loaded into the dispenser **1110**.

[00119] Referring now to **Figures 34-40,** the cartridge frame **1204** includes rectangular side walls **1208, 1210** rising from a floor **1216.** Two support braces **1209** extend from side wall **1208** and interlock with corresponding support braces **1211** that extend from side wall **1210.** Each side wall also includes a corresponding tabs **1212, 1214** on which a free spinning hub **1206** (see **Figures 36** and **37**) is rotatably mounted. The tabs **1212, 1214** are deflectable to enable the hub **1206** to be easily installed and removed. As shown in **Figure 39**, a rolled strip **1114** is mounted on the hub **1206.**

[00120] As can be seen in **Figure 39**, the floor **1216** has an open-celled configuration, with an upper surface **1216a** and a lower surface **1216b** separated by ribs **1216c.** The upper surface **1216**a is sloped at its rear end. An idle roller **1216d** is located below the rear end of the floor **1216** and provides a movable arcuate surface to facilitate advancement of the strip **1114.** A base **1218** (also curved at its rear end) is positioned below the lower surface **1216b** and forms a gap **1218a** through which the strip **1114** can travel. A window **1218b** is present in the base **1218** (see also **Figure 40**) and receives a drive roller **1330** mounted to the dispenser that drives the pouch strip through the gap **1218a** and out of the dispensing window **1202a** in the cover **1202.** It can also be seen that an elongate, rigid stop member **1220** depends from the lower surface **1216b** of the floor **1216** to provide purchase against the drive roller **1330**; in some embodiments, the lower surface of the stop member **1220** is treated to have low friction.

[00121] A spring **1221** extends transversely across the gap **1218a** and can replace the arm **274** discussed above (see **Figure 27C**). A spring release mechanism **1223** (**Figure 27D**) can deflect the spring **1221** upwardly when the cartridge **1200** is inserted in the dispenser **1110** to enable the strip **1114** to more freely if desired.

[00122] A guide **1222** also projects from the lower surface **1216b** near the dispensing window **1202a.** Guide posts **1224** extend downwardly from the base **1218**; these seat in holes in the cutter/exit assembly of the dispenser **1110** to align the cartridge **1200** and the dispenser **1110.** A notch **1229** is present between the stop member **1220** and guide **1222** (**Figure 39**).

[00123] As can be seen in **Figure 28** and envisioned from **Figure 41**, the cartridge **1200** fits within a cavity in the dispenser **1110** located above the drive roller **1330.** The guide posts **1224** are received in receptacles in the dispenser **1110.** The drive roller **1330** protrudes through the window **1218b** (see **Figure 27C**) and engages the stop member **1220** to form a

nip through which the strip **1114** travels. The upper surface of the cartridge **1200** is held in place by a spring-loaded bracket **1231** that is pivotally attached to the door **1314** of the dispenser **1100** at a pivot **1233** and biased away from the door **1314** by a spring **1234** (see **Figures 30A** and **30B**). A depending edge **1236** contacts the top surface of the cartridge **1200** and helps to maintain the cartridge **1200** in position by providing downward pressure on the cartridge **1200**.

[00124] Referring now to **Figures 29A-29E**, a door locking mechanism **1240** is illustrated. The door locking mechanism **1240** includes a slide bar **1242** and a cam **1244**. The slide bar **1242** has two slots **1246**, **1248** in its main portion; the forward slot **1246** is tripartite, with its middle segment sloping downwardly and rearwardly. Posts **1245**, **1247** mounted on the side wall of the dispenser **1110** are received in the slots **1246**, **1248**, respectively. The slide bar **1242** also includes a vertical slot **1250** at its rear end. A tab **1252** extends upwardly from the main portion of the slide bar **1242**; a rim that follows the periphery of the tab **1252** forms a pocket **1254** that is open to the rear. A tab **1256** is mounted on the underside of the door **1314**.

[00125] The cam **1244** (best seen in **Figures 29C** and **29D**) is pivotally mounted onto the shaft **1258** of a motor mounted to the side wall of the dispenser **1110**. A post **1260** is mounted on one end of the body **1262** of the cam **1244**. The post **1260** is received in the vertical slot **1250** of the slide bar **1242**.

[00126] As can be seen in **Figures 29A** and **29D**, in the unlocked position, the cam **1244** is oriented so that the post **1260** is forward of the shaft **1258**. In this position, the slide bar **1242** is forced forwardly, such that the posts **1245**, **1247** are in the rear ends of the slots **1244**, **1246**. When a sensor **1261** mounted to the wall of the dispenser (**Figure 29E**) detects that the door **1314** is closed, the system activates the motor to rotate the shaft **1258** (clockwise from the vantage point of **Figure 29D**), which draws the slide bar **1242** rearwardly (guided by the posts **1245**, **1247** in the slots **1244**, **1246**). As it moves rearwardly, the slide bar **1242** tilts so that its rear end rises and its front end descends. The rearwardly and angular movement of the slide bar **1242** positions the pocket **1254** to capture the tab **1256** on the door **1314**, thereby locking the door **1314** in place (see **Figures 29B** and **29C**). Sensors **1265** and **1267** are positioned to verify the position of the cam **1244** (see **Figures 29C** and **29D**).

[00127] Referring now to **Figures 28** and **41**, the dispenser **1110** also includes two cameras **1400**, **1402** mounted therein. The camera **1400** is mounted facing downwardly to take a "vertical" image of the pouch barcodes. The camera **1400** can also determine the

position of the pouch strip for cutting of a pouch from the strip **1114** with the cutting assembly (thus, the camera **1400** can replace the sensor **340** discussed above). The camera **1402** is mounted to face downwardly and rearwardly in order to read both the pouch barcodes and the cartridge barcodes; the cartridge barcodes are affixed to the cover of the cartridge and are visible through a window **1406** in the compartment/cavity of the dispenser.

[00128] It should also be noted that **Figures 27A** and **27B** illustrate a slightly different configuration of a cartridge frame **1204'**. The cartridge frame **1204'** includes only one brace **1209'**, **1211'** rather than two of each.

[00129] The present invention has been described herein with reference to flowchart and/or block diagram illustrations of methods, systems, and devices in accordance with exemplary embodiments of the invention. It will be understood that each block of the flowchart and/or block diagram illustrations, and combinations of blocks in the flowchart and/or block diagram illustrations, may be implemented by computer program instructions and/or hardware operations. These computer program instructions may be provided to a processor of a general purpose computer, a special purpose computer, or other programmable data processing apparatus to produce a machine, such that the instructions, which execute via the processor of the computer or other programmable data processing apparatus, create means for implementing the functions specified in the flowchart and/or block diagram block or blocks.

[00130] These computer program instructions may also be stored in a computer usable or computer-readable memory that may direct a computer or other programmable data processing apparatus to function in a particular manner, such that the instructions stored in the computer usable or computer-readable memory produce an article of manufacture including instructions that implement the function specified in the flowchart and/or block diagram block or blocks.

[00131] The computer program instructions may also be loaded onto a computer or other programmable data processing apparatus to cause a series of operational steps to be performed on the computer or other programmable apparatus to produce a computer implemented process such that the instructions that execute on the computer or other programmable apparatus provide steps for implementing the functions specified in the flowchart and/or block diagram block or blocks.

[00132] It will be further appreciated that the functionality of any or all of the program modules may also be implemented using discrete hardware components, one or more

application specific integrated circuits (ASICs), or a programmed digital signal processor or microcontroller. The program code may execute entirely on a single processor and/or across multiple processors, as a stand-alone software package or as part of another software package. The program code may execute entirely on an electronic device or only partly on the electronic device and partly on another device. In the latter scenario, the other device may be connected to the electronic device through a wired and/or wireless local area network (LAN) and/or wide area network (WAN), or the connection may be made to an external computer (for example, through the Internet using an Internet Service Provider).

[00133] The above examples are merely illustrative of the many applications of the system of present invention. Although only a few embodiments of the present invention have been described herein, it should be understood that the present invention might be embodied in many other specific forms without departing from the spirit or scope of the invention. Therefore, the present examples and embodiments are to be considered as illustrative and not restrictive, and the invention may be modified within the scope of the appended claims.

CLAIMS:

1. A pharmaceutical dispensing system, comprising:

a housing having a plurality of walls, one of the walls having an opening, the housing having an internal compartment defined by a plurality of walls and a delivery outlet separate and spaced apart from the opening;

a drive unit mounted in the housing; and

a cartridge comprising a frame, a cover and a plurality of pouches containing pharmaceuticals, the pouches formed as an elongate strip;

wherein the cartridge and the housing include alignment features that enable the cartridge to be inserted through the opening in the housing and into the compartment of the housing such that the free end of the strip is positioned adjacent the drive unit so that operation of the drive unit conveys the free end of the strip toward the delivery outlet.

2. The system defined in Claim 1, wherein the housing further comprises a door covering the opening, the door movable between an open position, in which the compartment is accessible for installation and removal of the cartridge, and a closed position, in which the compartment is inaccessible.

3. The system defined in Claim 2, wherein the housing further comprises a mechanism mounted therein that is configured to exert downward pressure on the cartridge when the door is in the closed position.

4. The system defined in Claim 2, wherein the housing further comprises a locking mechanism that locks the door in the closed position.

5. The system defined in Claim 1, wherein the cartridge further comprises a brake configured to press the strip against the cartridge to apply a braking force thereto and the housing comprises a mechanism associated with the brake that selectively releases the brake.

Date Reçue/Date Received 2020-06-01

6. The system defined in Claim 1, wherein the housing includes an alarm that alerts a user to the dispensing of a pouch and/or the passing of a preselected time for dispensing of a pouch.

7. The system defined in Claim 1, wherein the housing is configured to receive instructions from a remote location and to send signals regarding dispensing to a remote location.

8. The system defined in Claim 1, further comprising an indicia reader positioned to read indicia on a pouch within the housing.

9. The system defined in Claim 1, further comprising an indicia reader positioned to read indicia on a cartridge within the housing.

Date Reçue/Date Received 2020-06-01

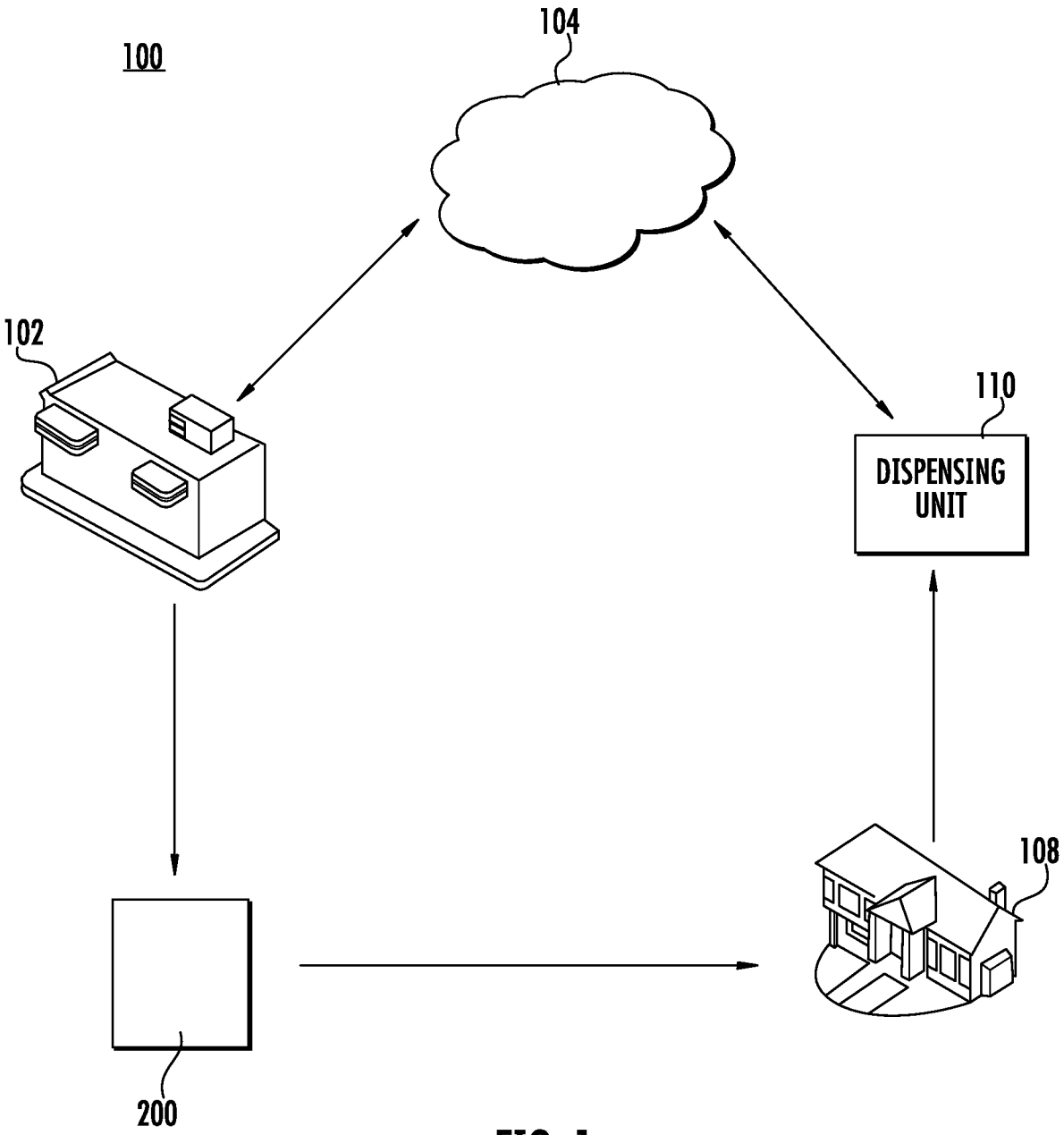


FIG. 1

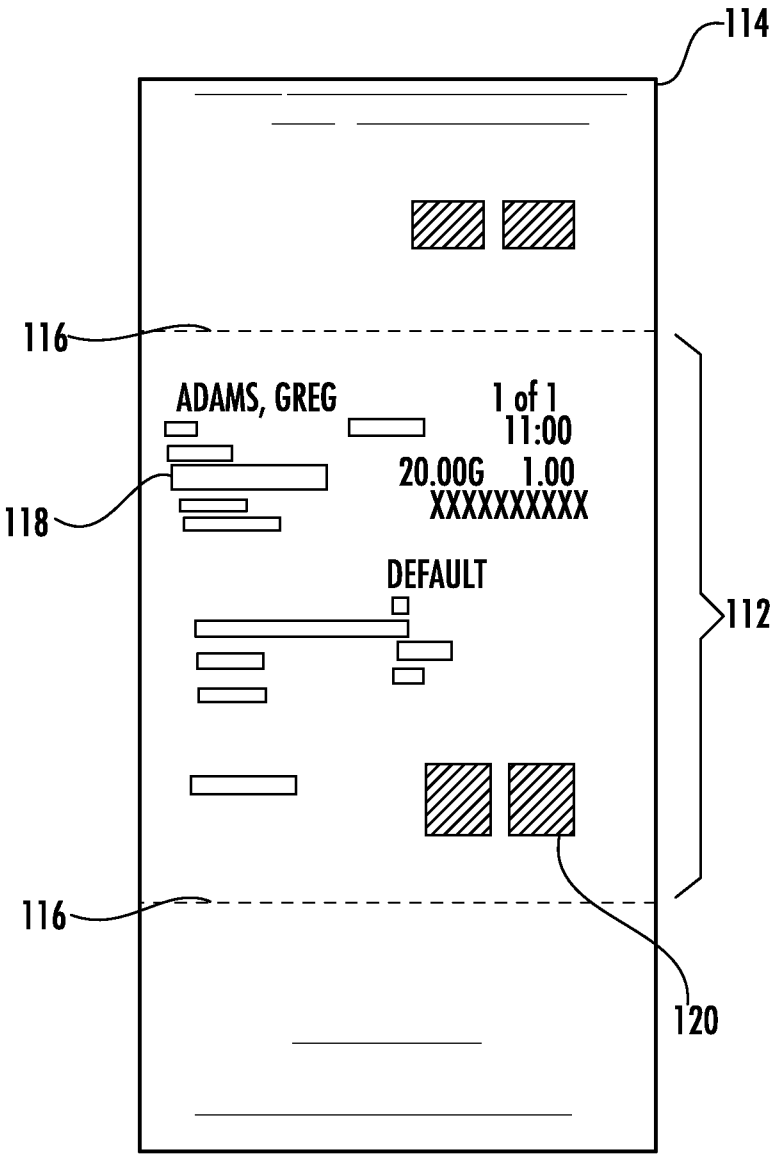

114
116
ADAMS, GREG
1 of 1
11:00
20.00G 1.00
XXXXXXXXX
118
DEFAULT
112
116
120

FIG. 2

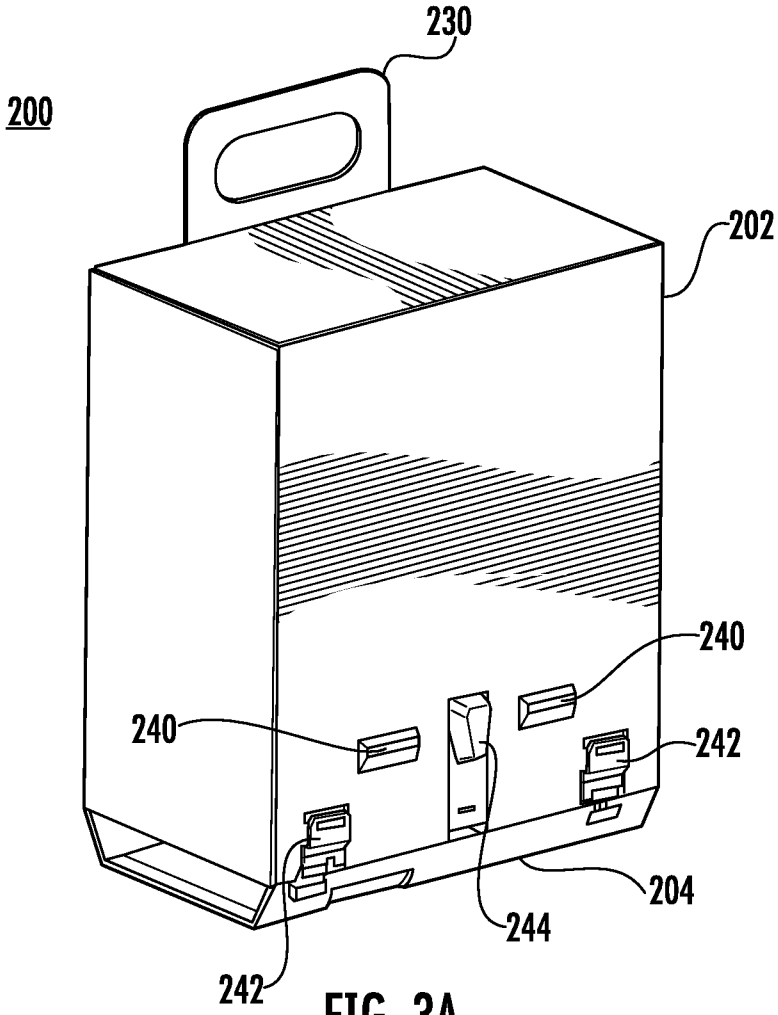


FIG. 3A

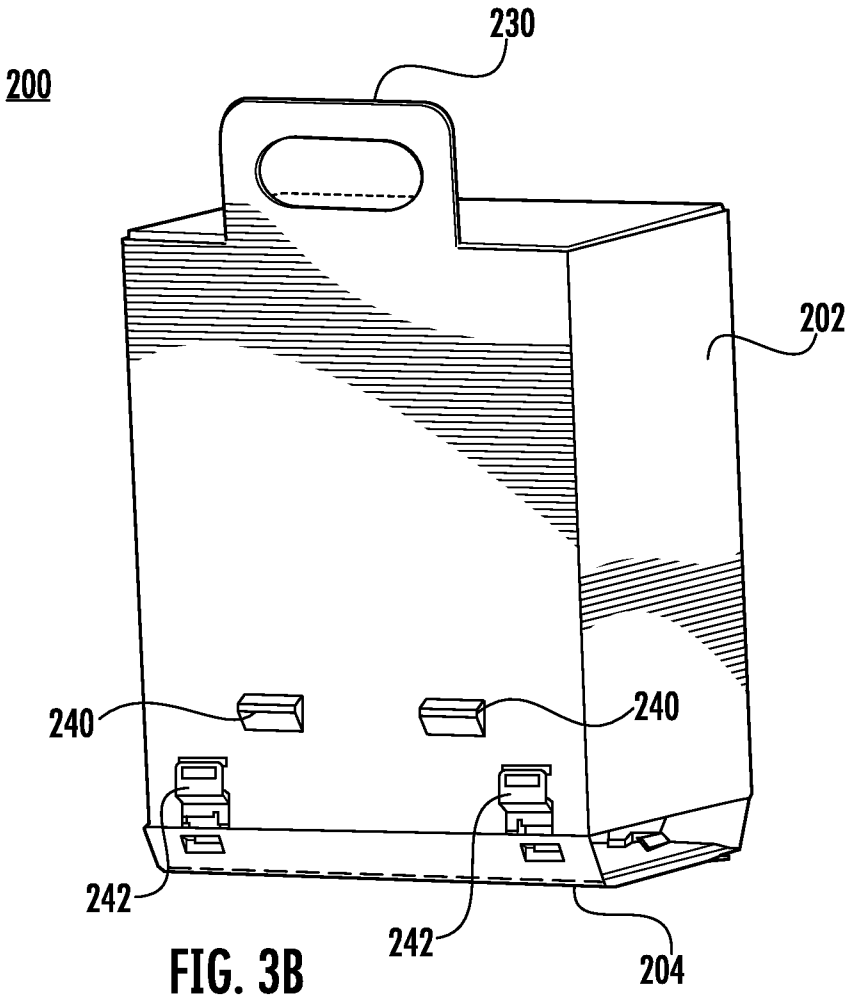


FIG. 3B

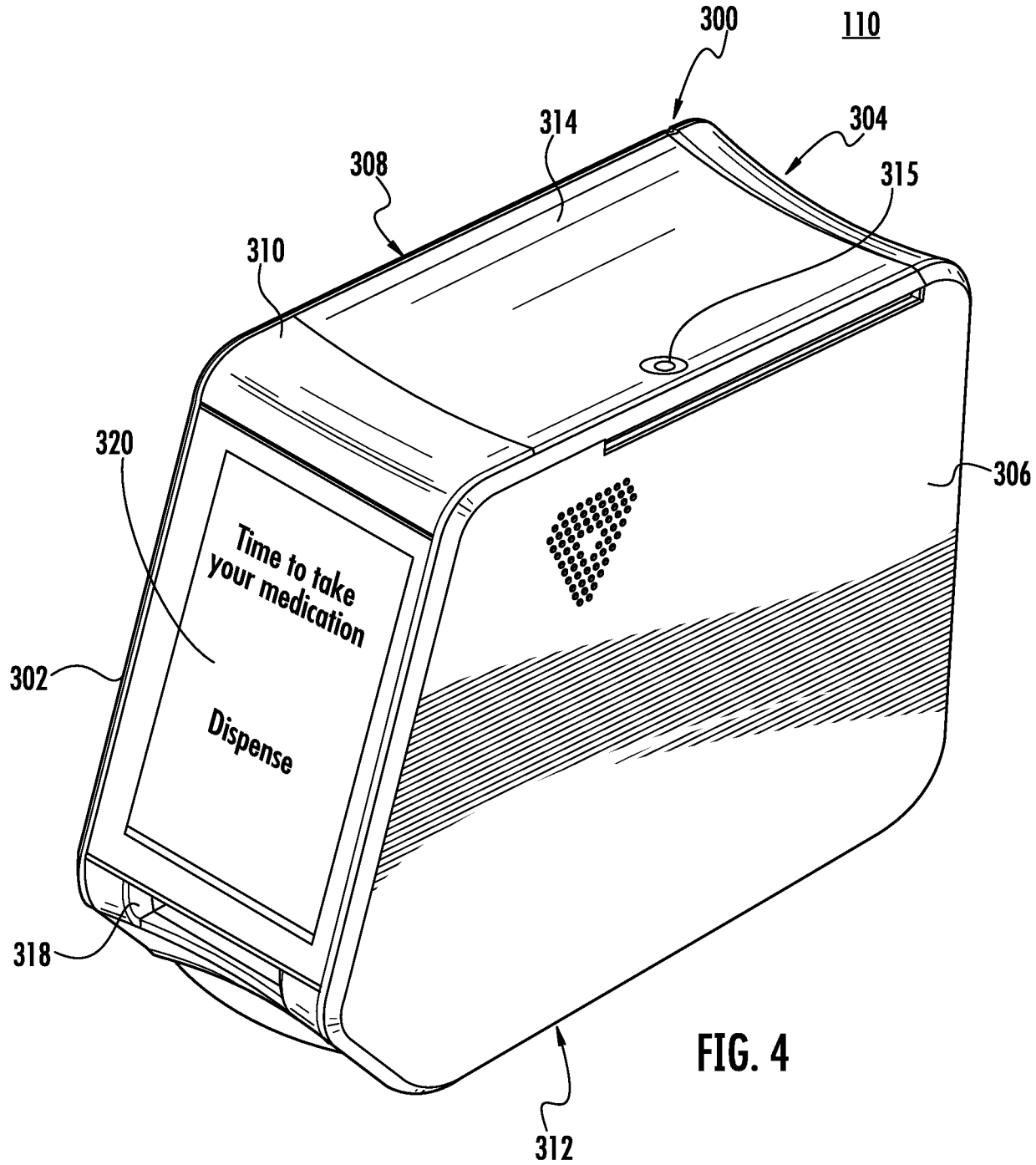

300
110
314
304
308
315
310
320
306
Time to take your medication
Dispense
302
318
312

FIG. 4

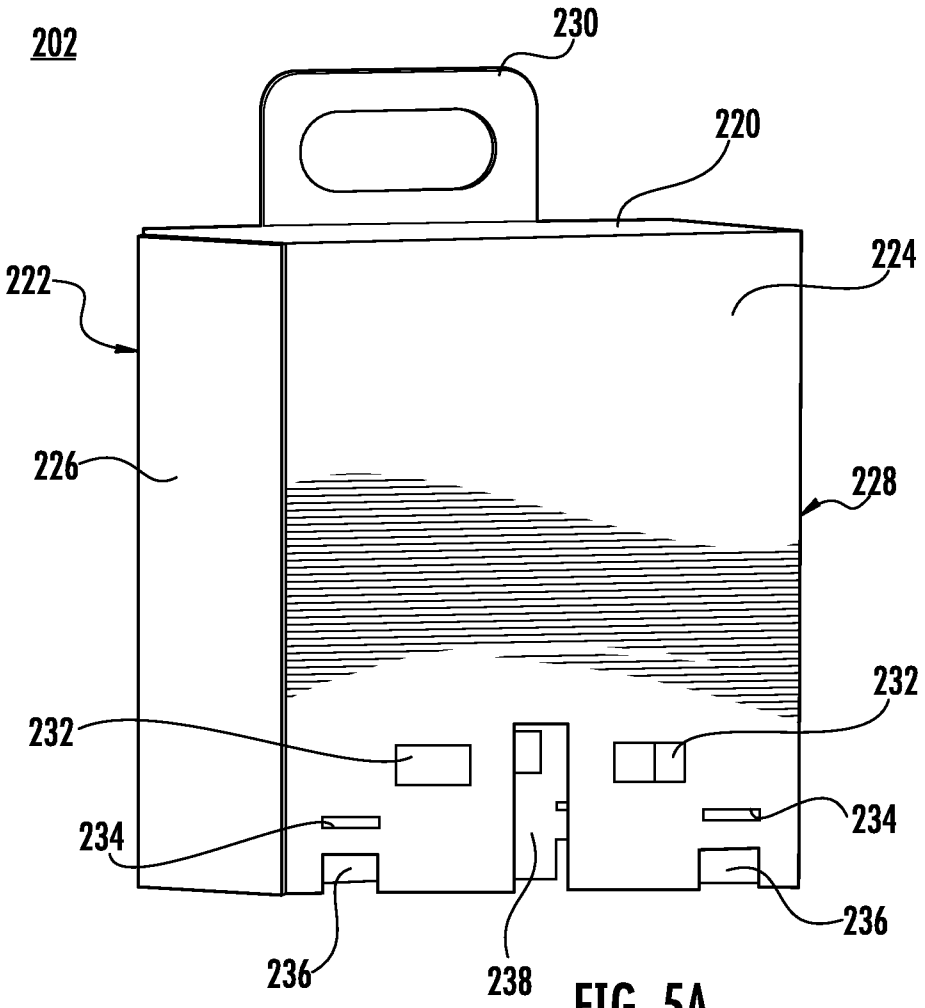


FIG. 5A

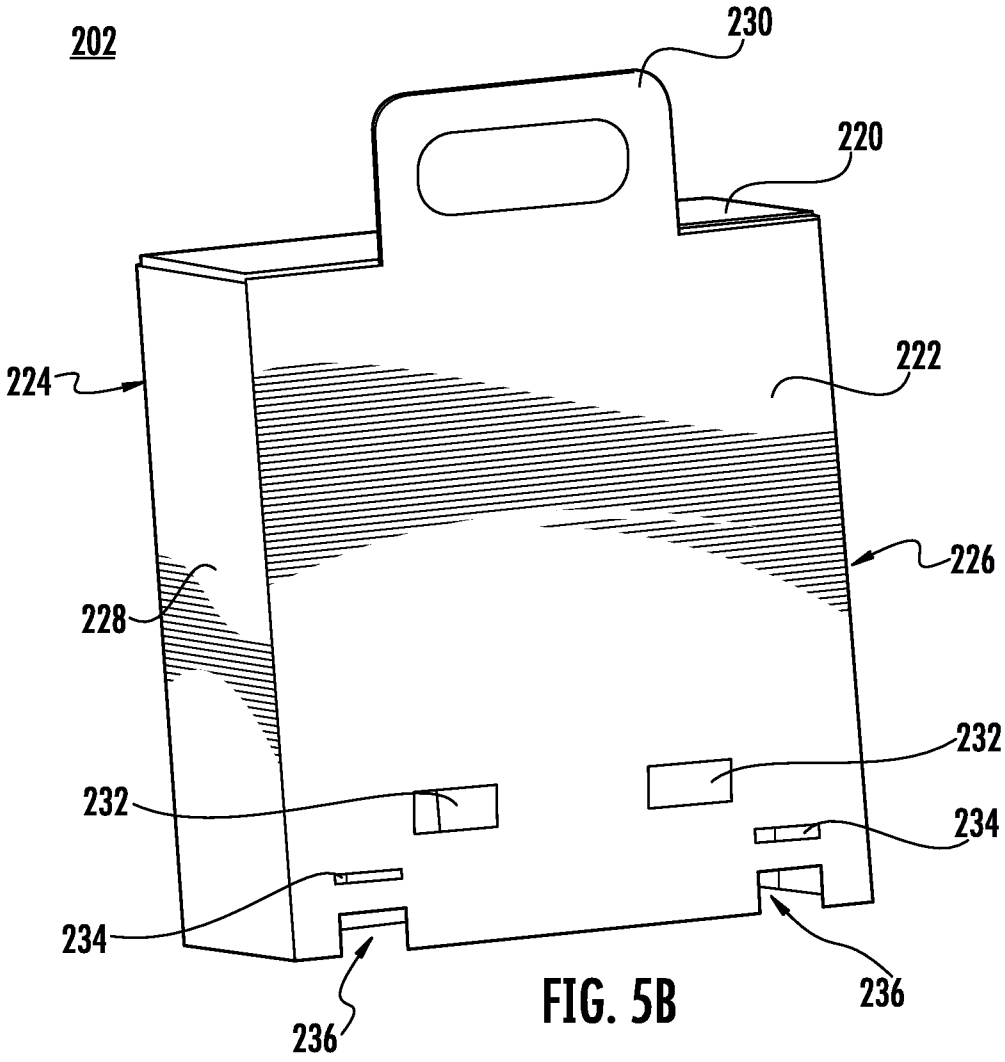


FIG. 5B

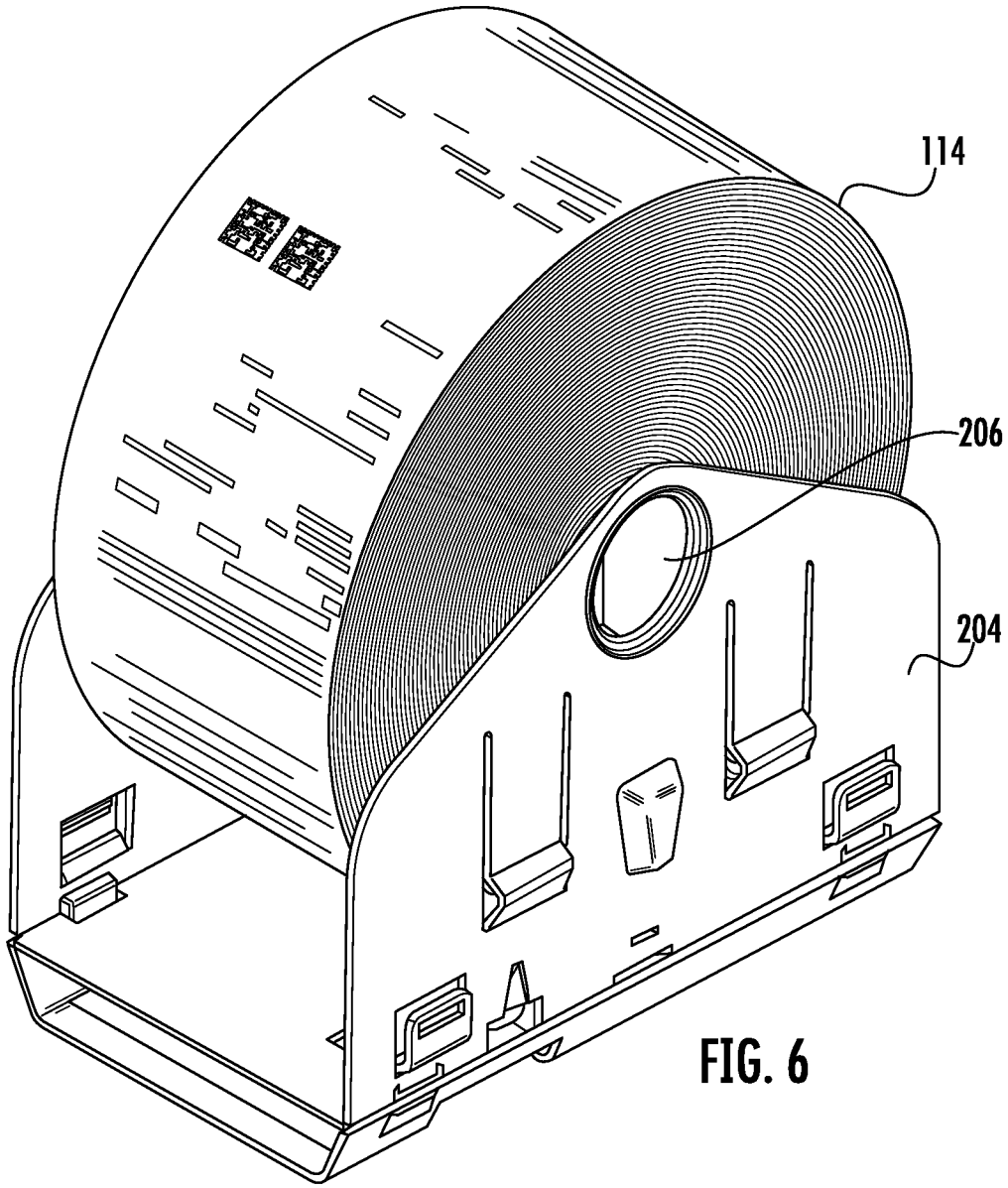
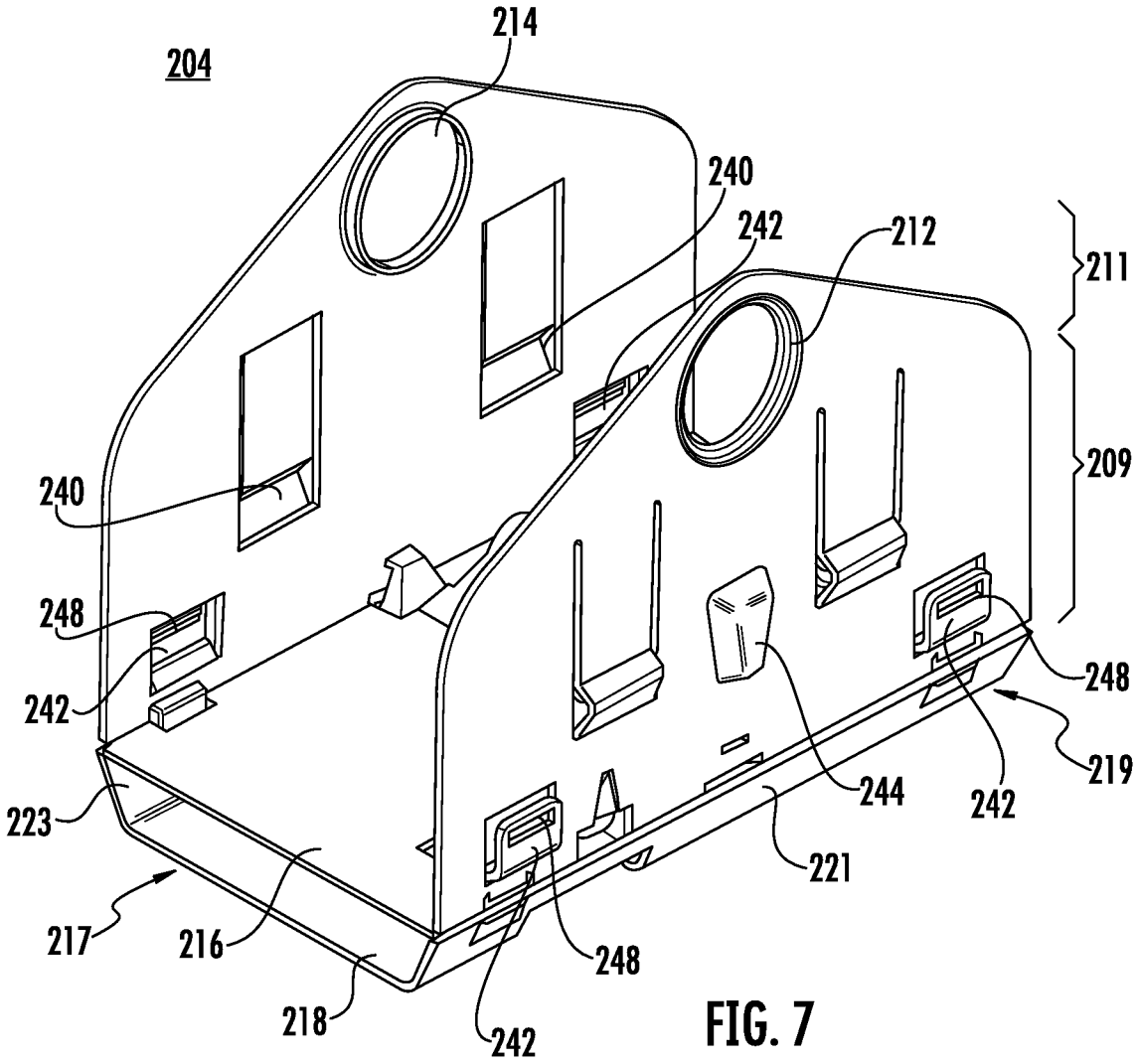


FIG. 6


204
214
240
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209
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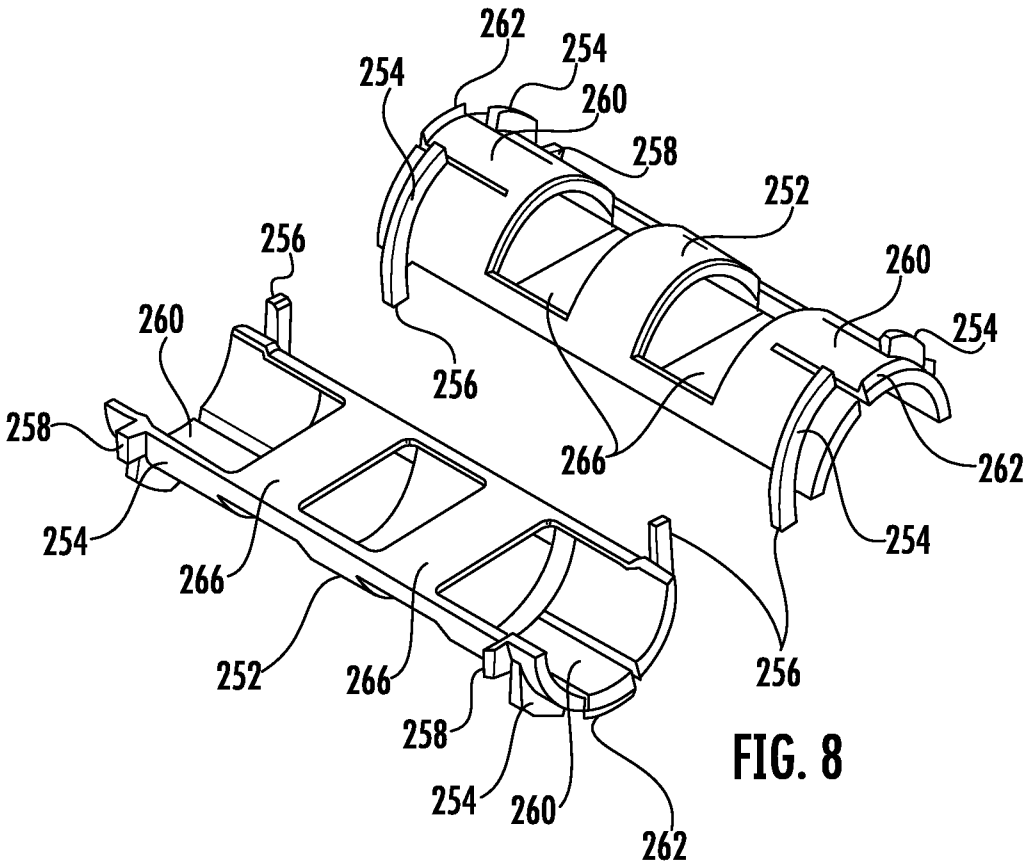
218
242

FIG. 7


262
254
254
260
258
252
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266
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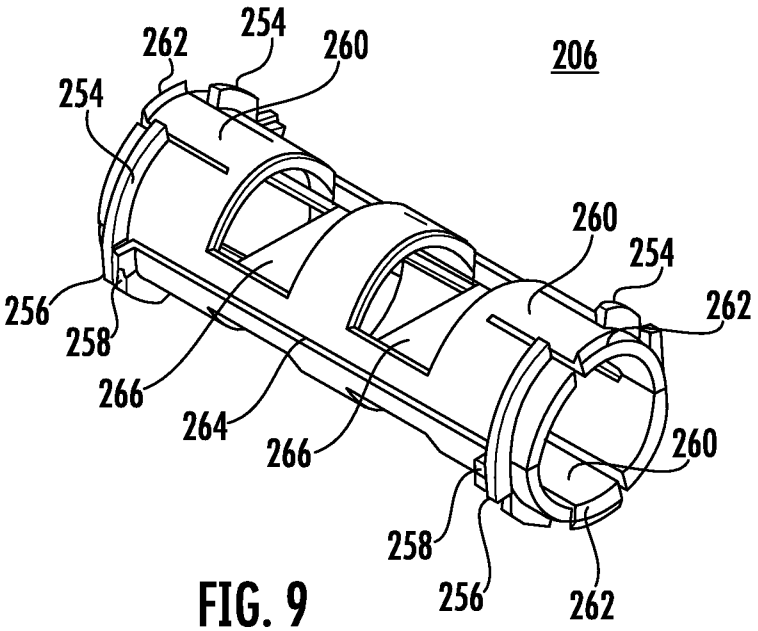
260
262

FIG. 8


262
254
260
206
254
260
254
262
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258
266
264
266
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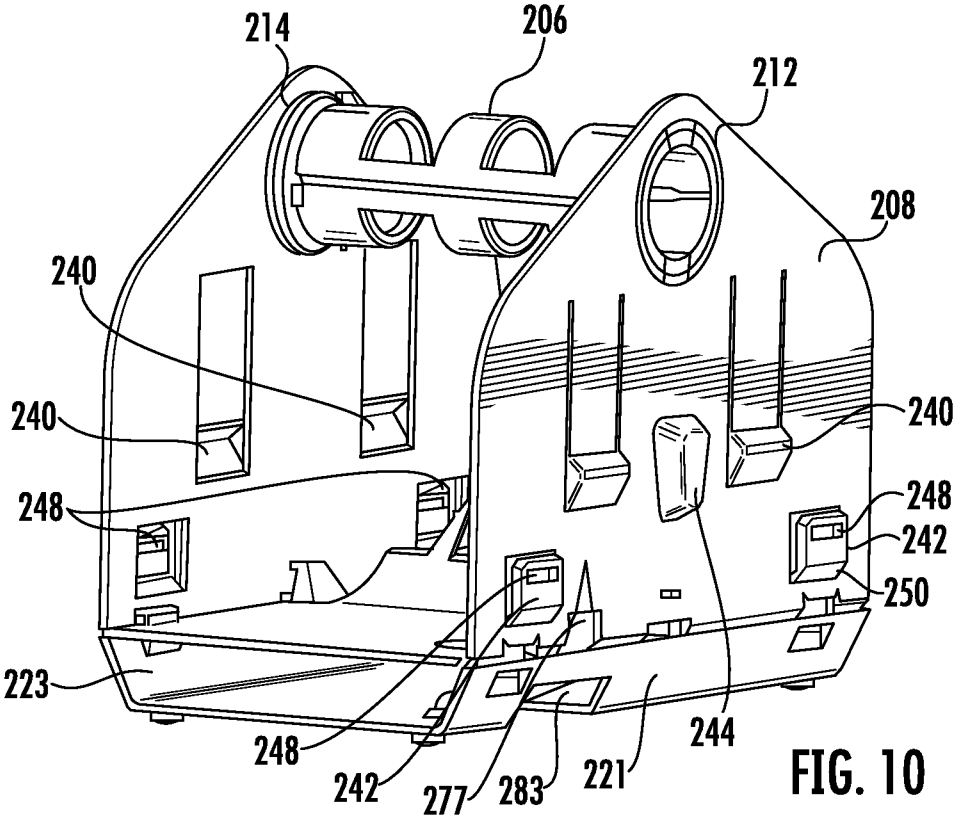
258
256
262

FIG. 9


214
206
212
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248
248
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250
223
248
242
277
283
221
244

FIG. 10

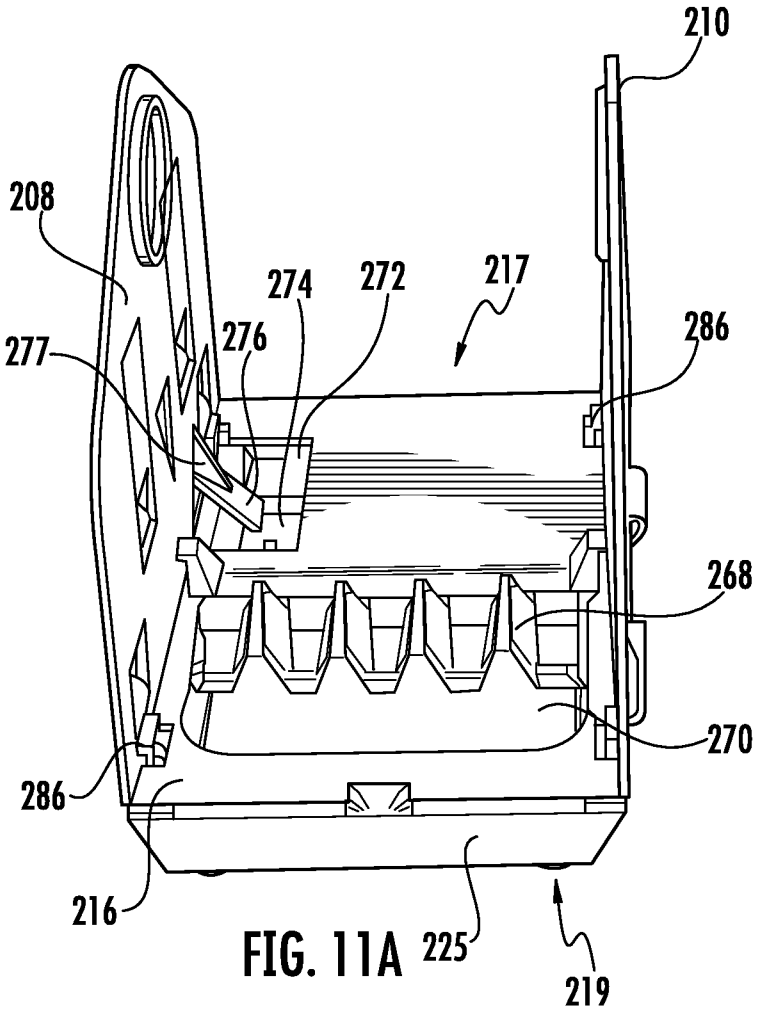

FIG. 11A

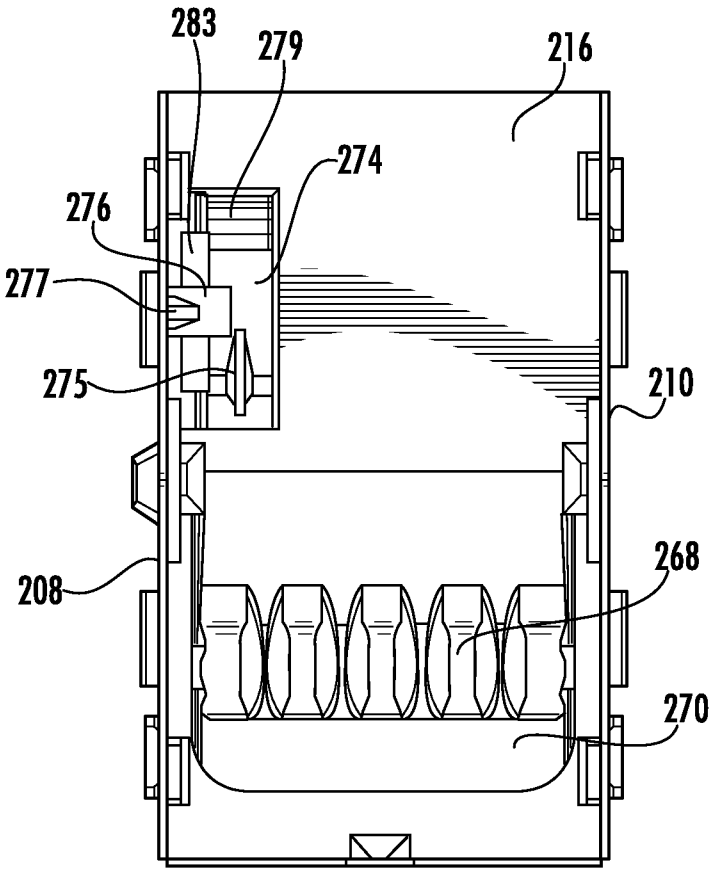

FIG. 11B

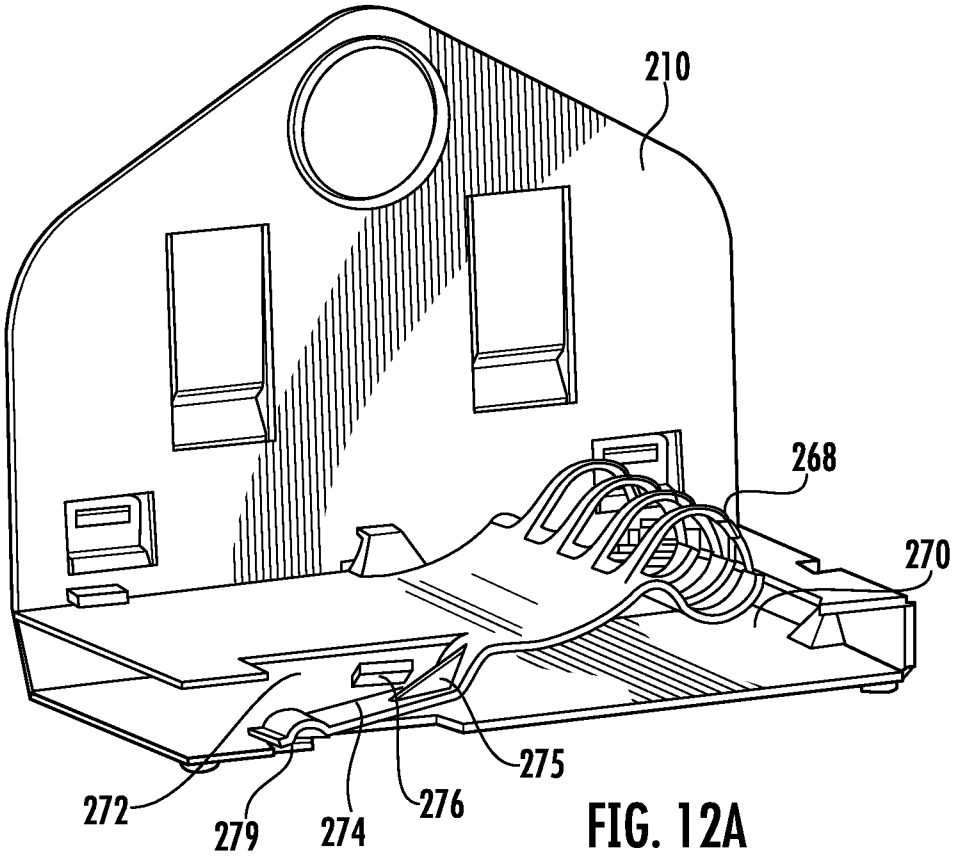

FIG. 12A

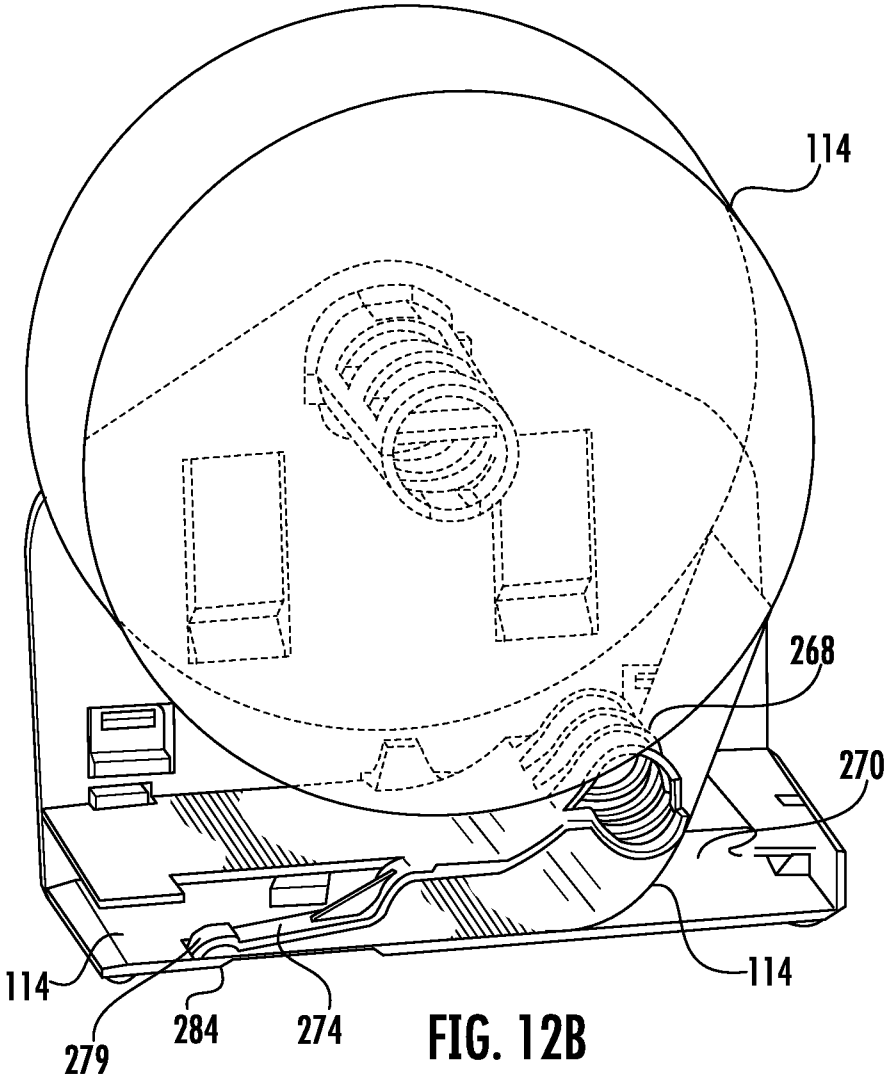

FIG. 12B

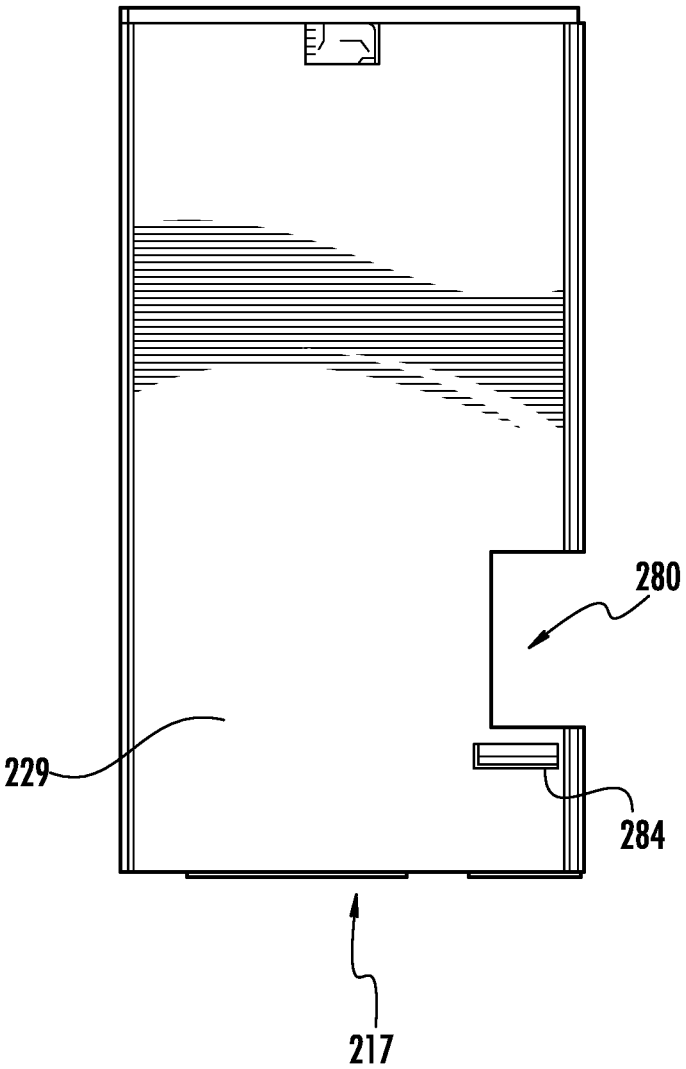

FIG. 13

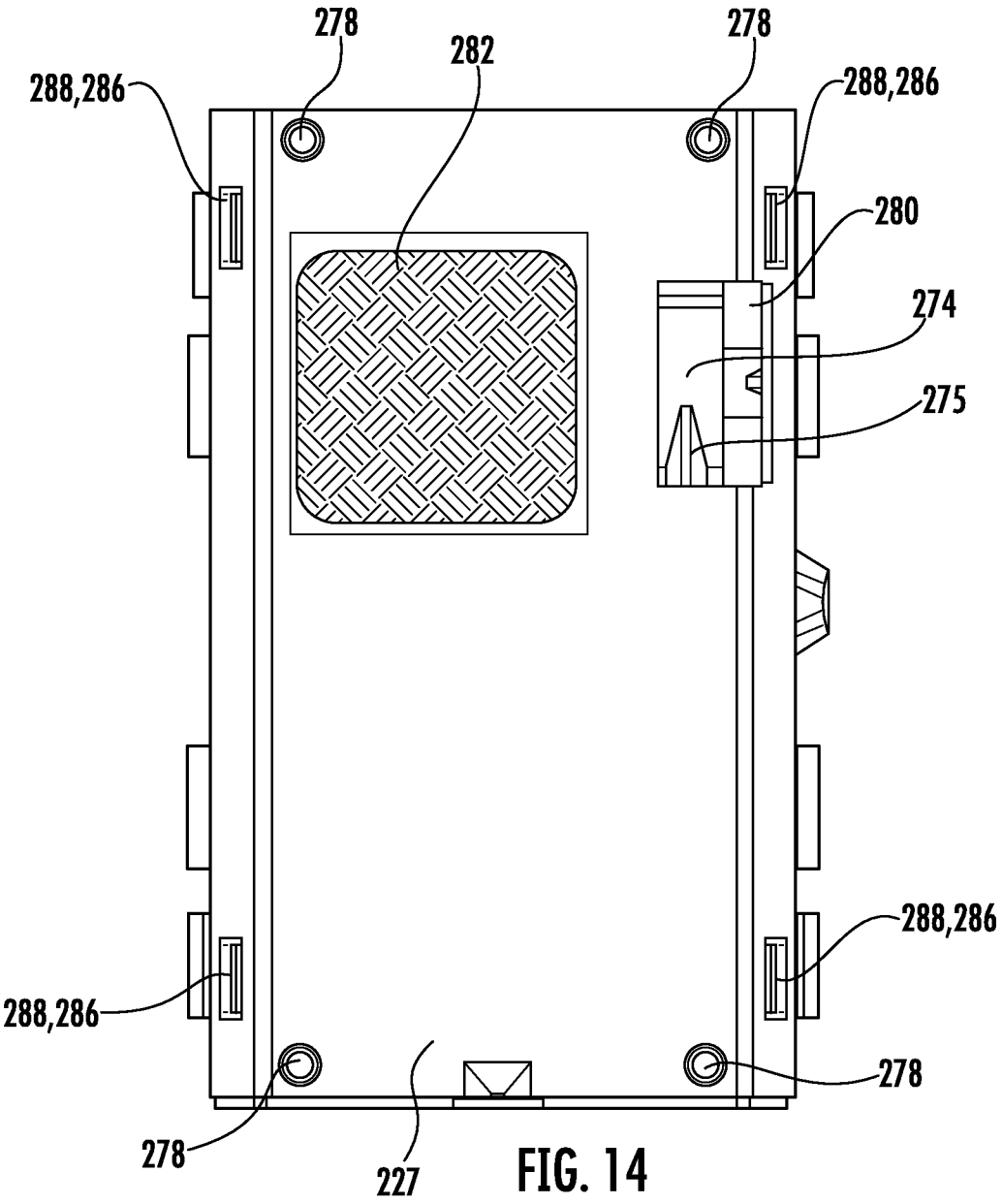
278
282
278
288,286
288,286
280
274
275
288,286
288,286
278
278
227

FIG. 14

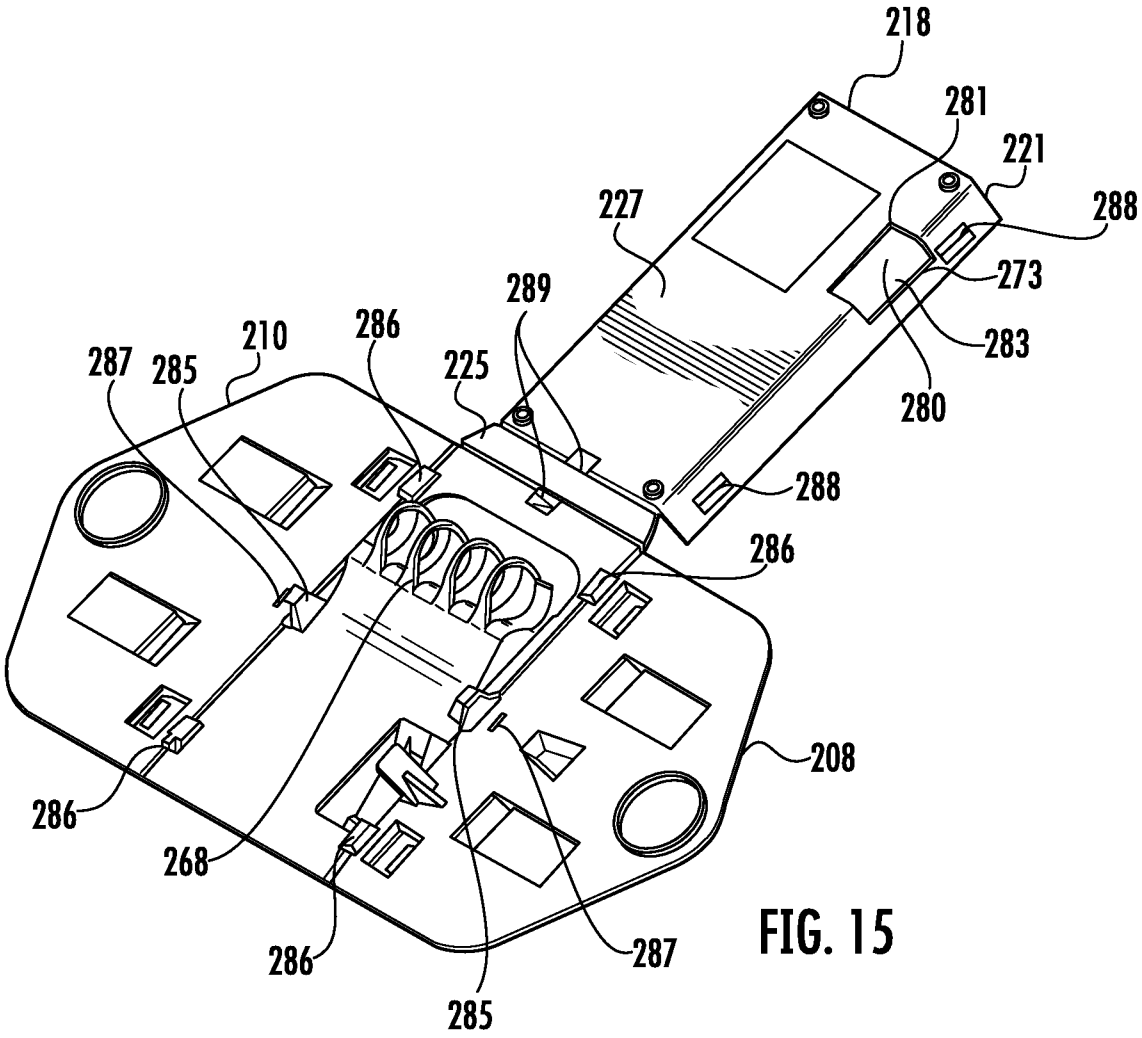
218
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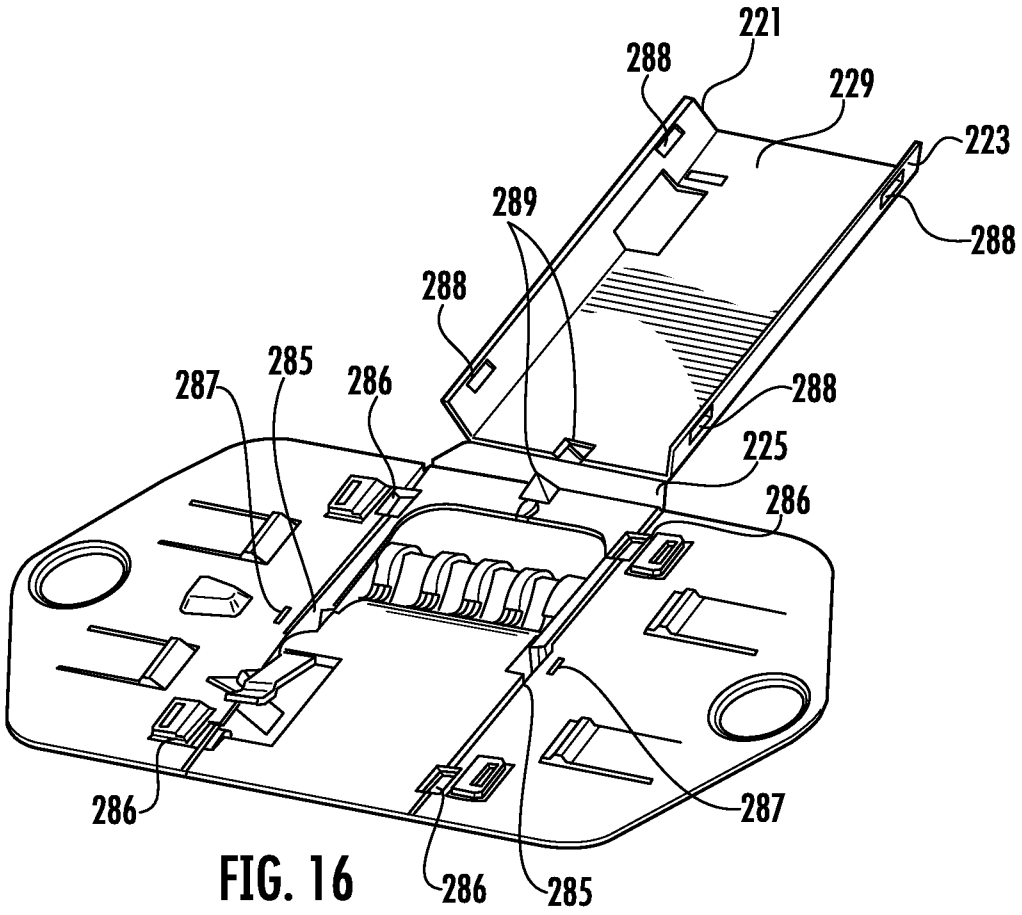
FIG. 15


221
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288
225
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286
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286
285

FIG. 16

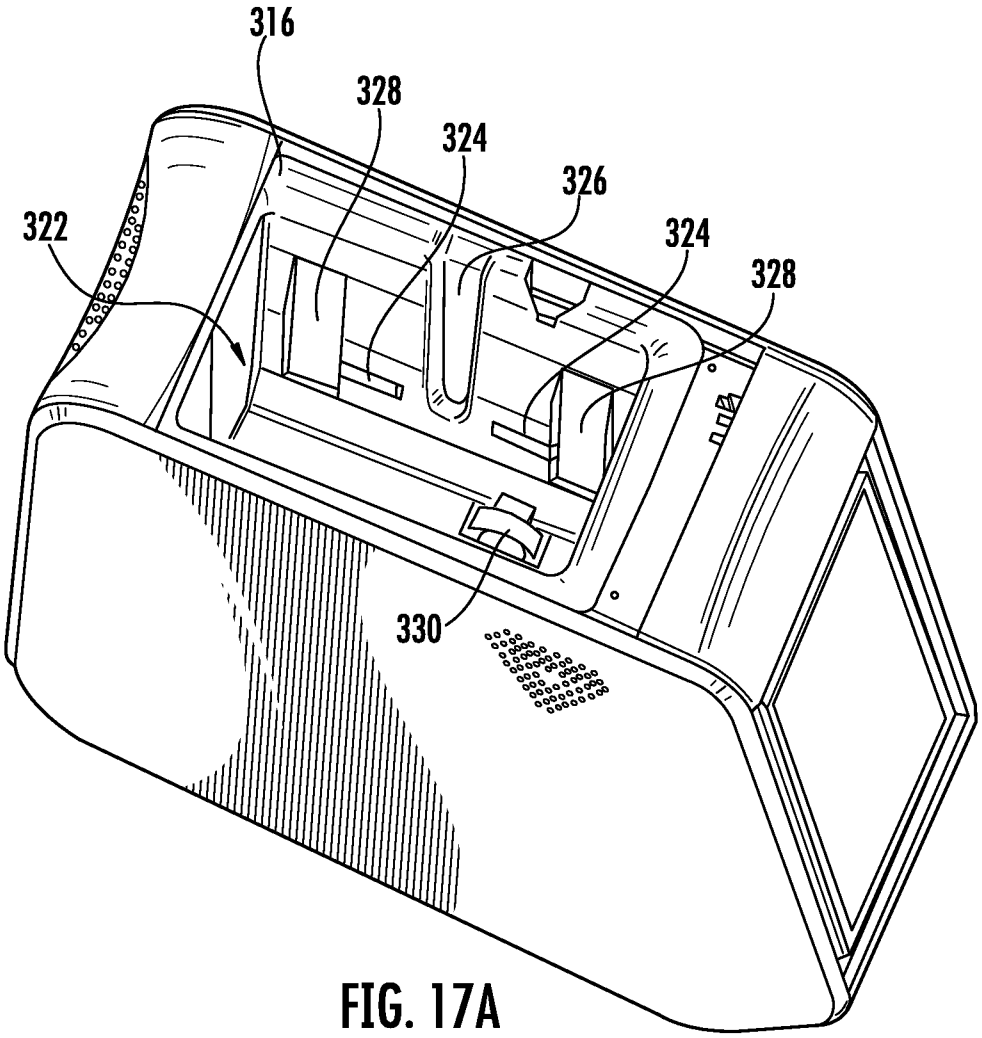

FIG. 17A

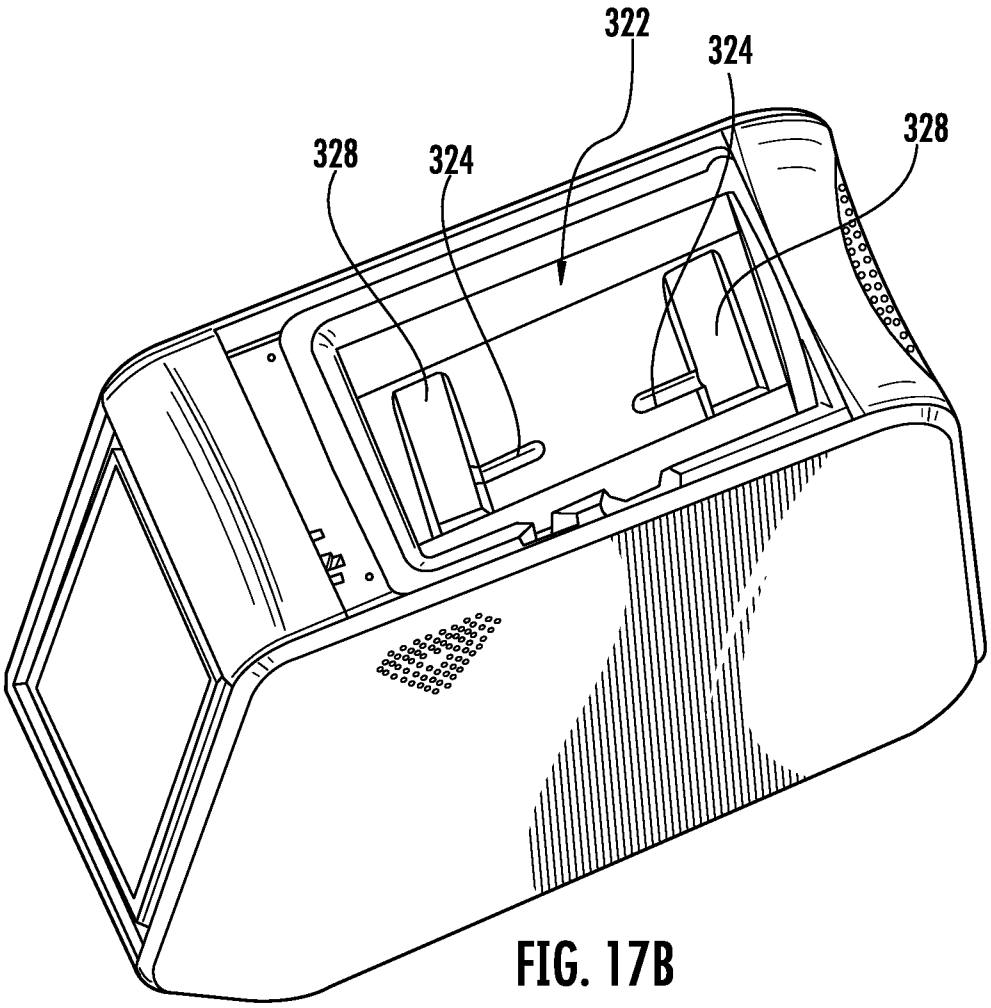

FIG. 17B

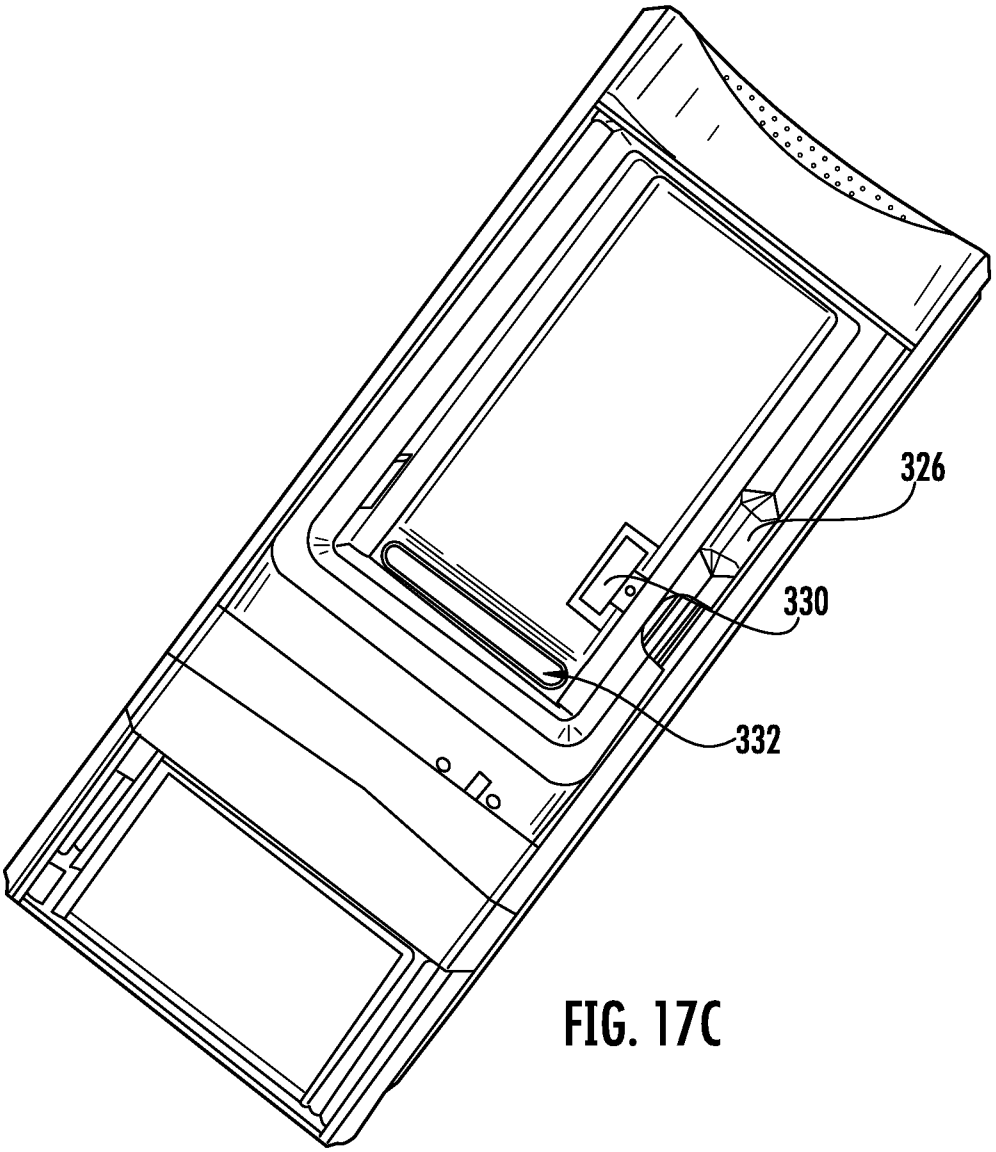

FIG. 17C

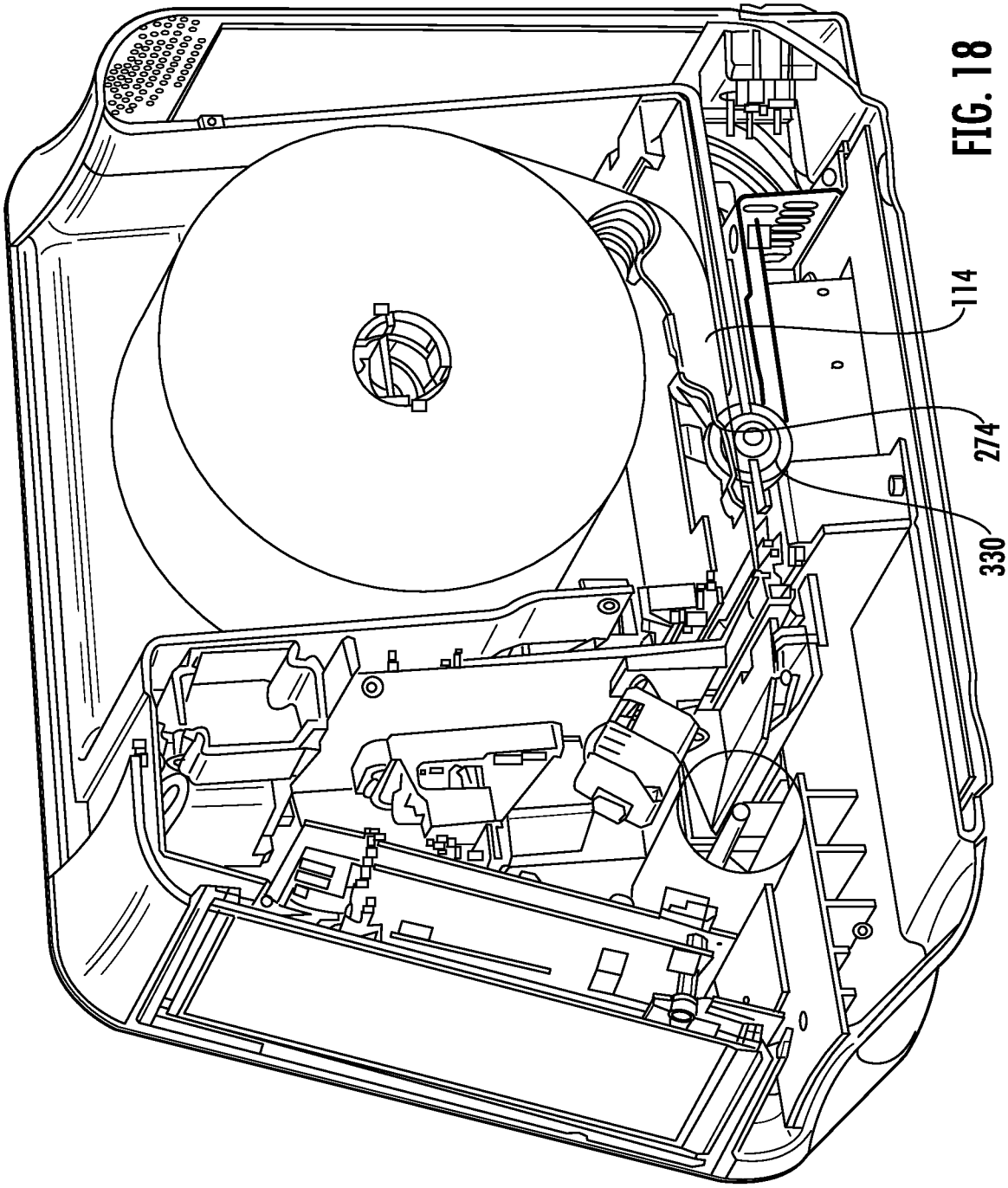

FIG. 18

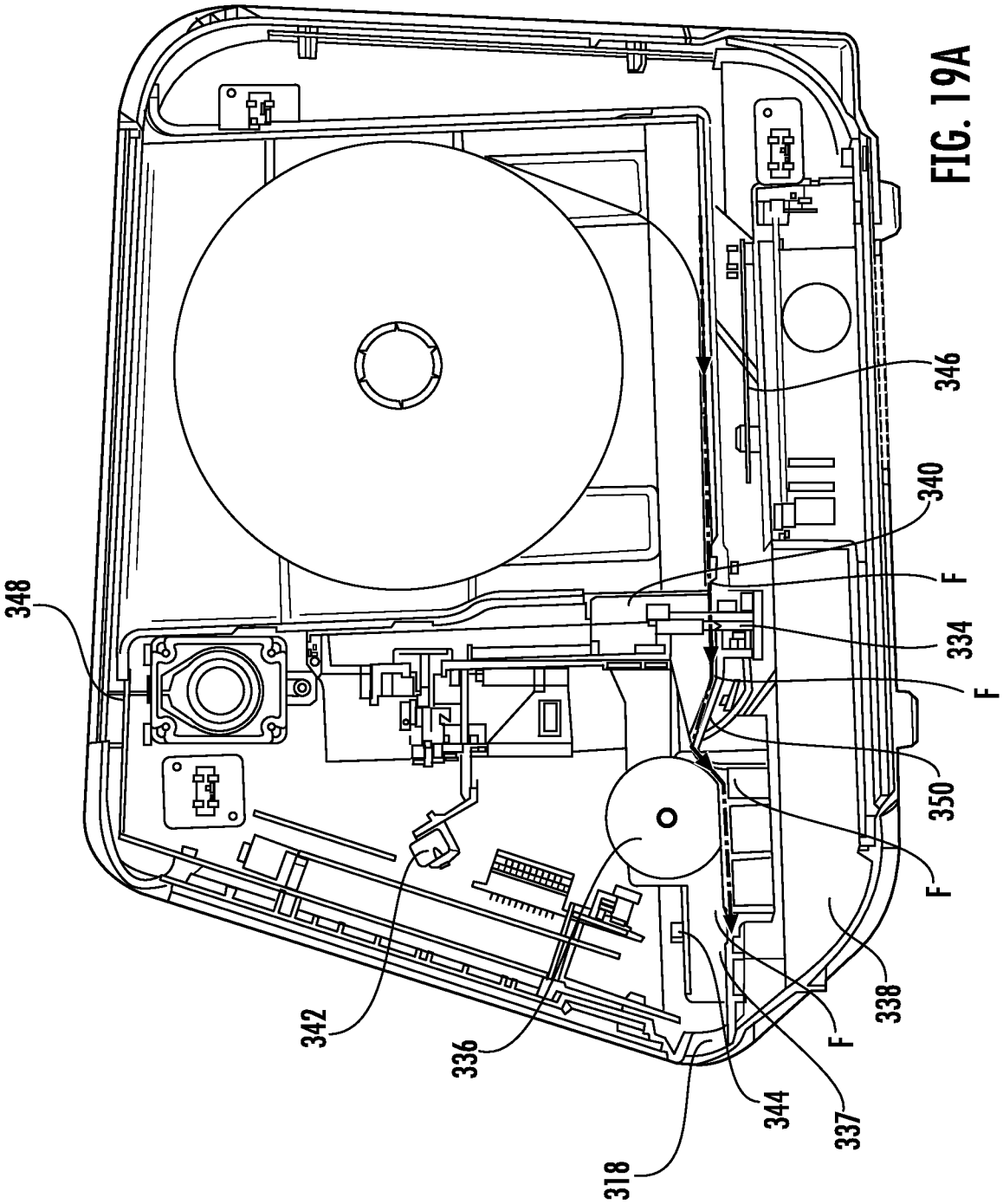

FIG. 19A

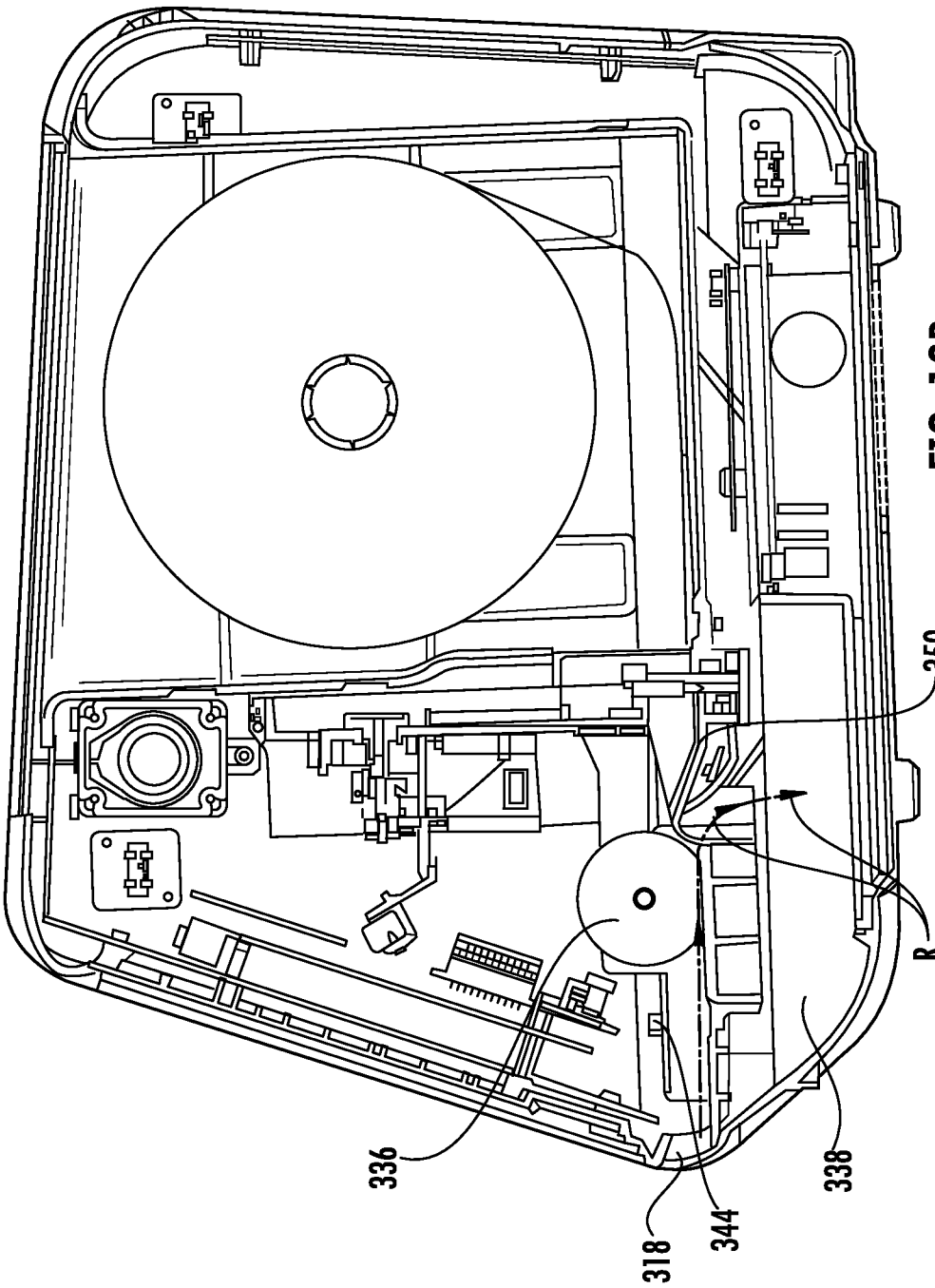

FIG. 19B

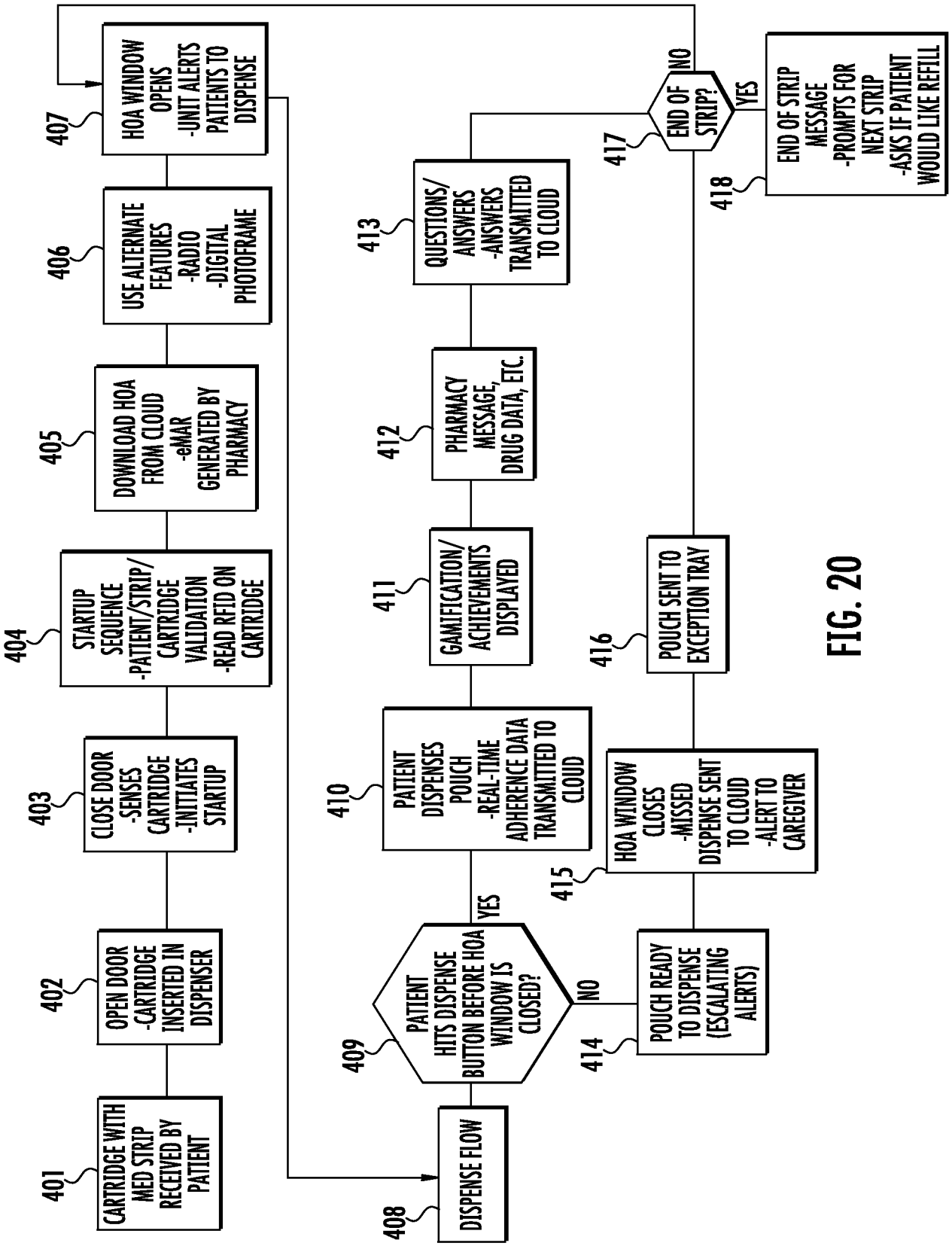
401
CARTRIDGE WITH MED STRIP RECEIVED BY PATIENT
402
OPEN DOOR -CARTRIDGE INSERTED IN DISPENSER
403
CLOSE DOOR -SENSES CARTRIDGE -INITIATES STARTUP
404
STARTUP SEQUENCE -PATIENT/STRIP/ CARTRIDGE VALIDATION -READ RFID ON CARTRIDGE
405
DOWNLOAD HOA FROM CLOUD -eMAR GENERATED BY PHARMACY
406
USE ALTERNATE FEATURES -RADIO -DIGITAL PHOTOFRAME
407
HOA WINDOW OPENS -UNIT ALERTS PATIENTS TO DISPENSE
408
DISPENSE FLOW
409
PATIENT HITS DISPENSE BUTTON BEFORE HOA WINDOW IS CLOSED?
YES
NO
410
PATIENT DISPENSES POUCH -REAL-TIME ADHERENCE DATA TRANSMITTED TO CLOUD
411
GAMIFICATION/ ACHIEVEMENTS DISPLAYED
412
PHARMACY MESSAGE, DRUG DATA, ETC.
413
QUESTIONS/ ANSWERS -ANSWERS TRANSMITTED TO CLOUD
414
POUCH READY TO DISPENSE (ESCALATING ALERTS)
415
HOA WINDOW CLOSES -MISSED DISPENSE SENT TO CLOUD -ALERT TO CAREGIVER
416
POUCH SENT TO EXCEPTION TRAY
417
END OF STRIP?
YES
NO
418
END OF STRIP MESSAGE -PROMPTS FOR NEXT STRIP -ASKS IF PATIENT WOULD LIKE REFILL

FIG. 20

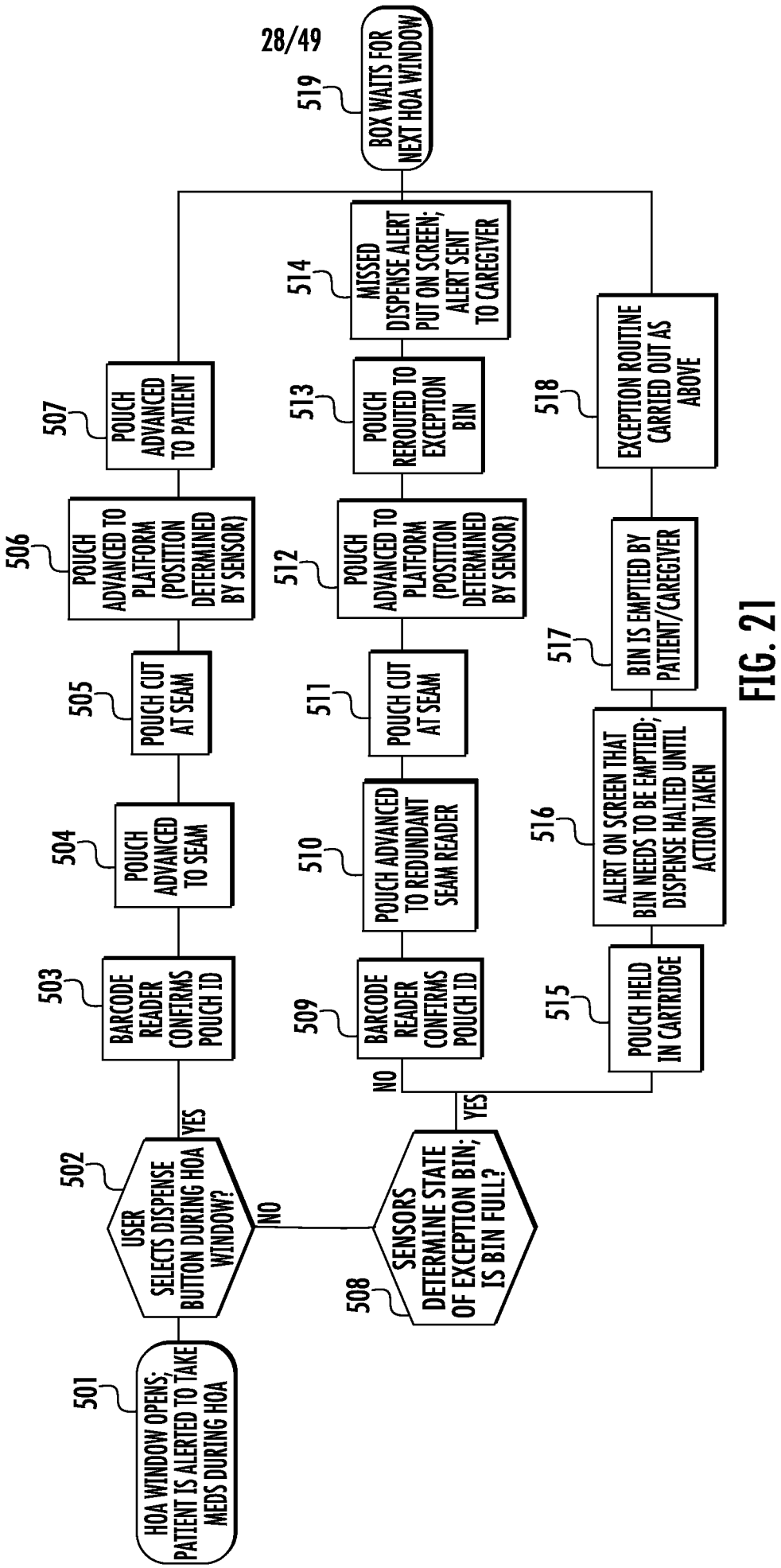
501 HOA WINDOW OPENS; PATIENT IS ALERTED TO TAKE MEDS DURING HOA
502 USER SELECTS DISPENSE BUTTON DURING HOA WINDOW?
YES
NO
503 BARCODE READER CONFIRMS POUCH ID
504 POUCH ADVANCED TO SEAM
505 POUCH CUT AT SEAM
506 POUCH ADVANCED TO PLATFORM (POSITION DETERMINED BY SENSOR)
507 POUCH ADVANCED TO PATIENT
508 SENSORS DETERMINE STATE OF EXCEPTION BIN; IS BIN FULL?
NO
YES
509 BARCODE READER CONFIRMS POUCH ID
510 POUCH ADVANCED TO REDUNDANT SEAM READER
511 POUCH CUT AT SEAM
512 POUCH ADVANCED TO PLATFORM (POSITION DETERMINED BY SENSOR)
513 POUCH REROUTED TO EXCEPTION BIN
514 MISSED DISPENSE ALERT PUT ON SCREEN; ALERT SENT TO CAREGIVER
515 POUCH HELD IN CARTRIDGE
516 ALERT ON SCREEN THAT BIN NEEDS TO BE EMPTIED; DISPENSE HALTED UNTIL ACTION TAKEN
517 BIN IS EMPTIED BY PATIENT/CAREGIVER
518 EXCEPTION ROUTINE CARRIED OUT AS ABOVE
519 BOX WAITS FOR NEXT HOA WINDOW

FIG. 21

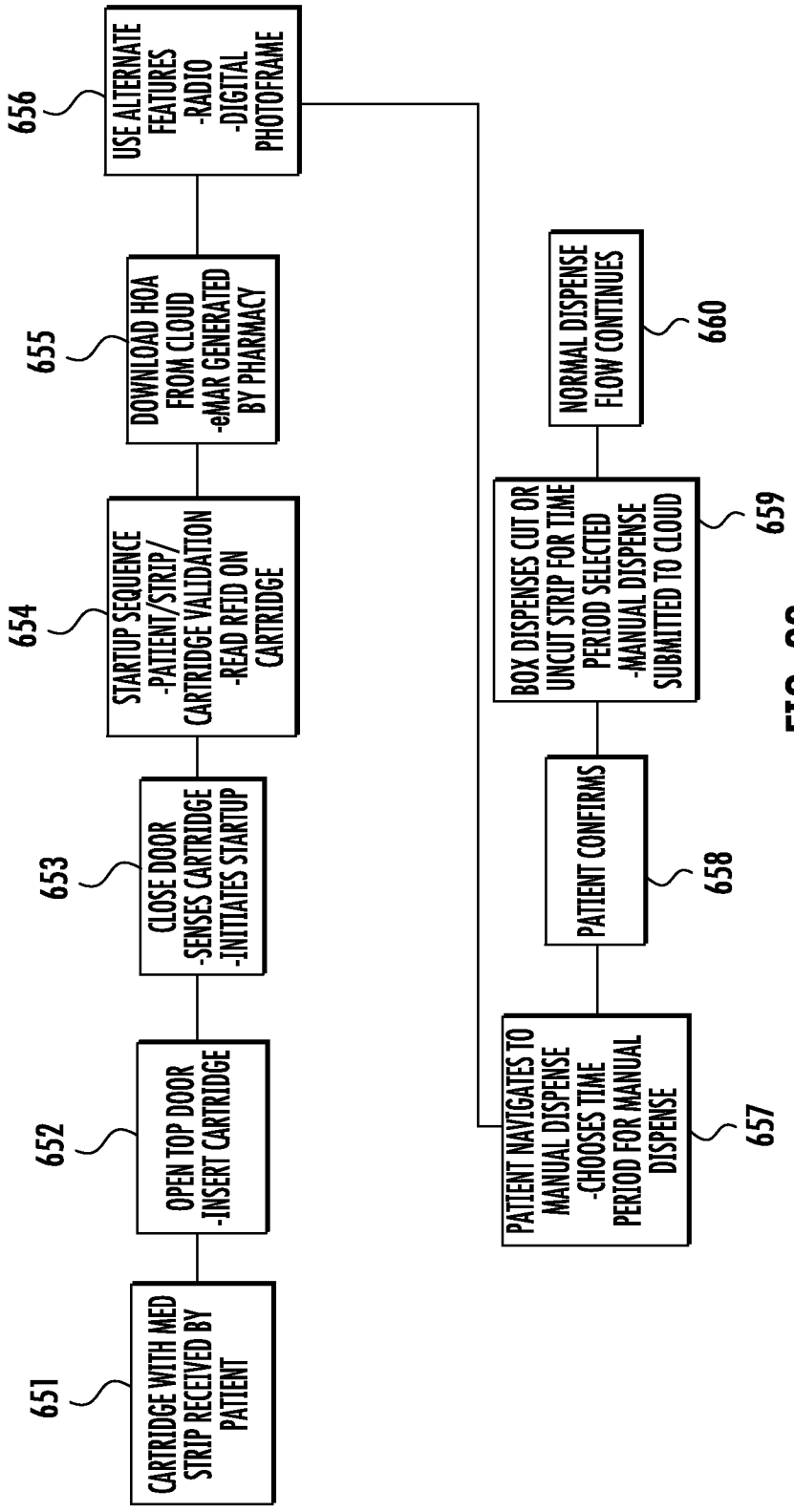
651
CARTRIDGE WITH MED STRIP RECEIVED BY PATIENT
652
OPEN TOP DOOR -INSERT CARTRIDGE
653
CLOSE DOOR -SENSES CARTRIDGE -INITIATES STARTUP
654
STARTUP SEQUENCE -PATIENT/STRIP/ CARTRIDGE VALIDATION -READ RFID ON CARTRIDGE
655
DOWNLOAD HOA FROM CLOUD -eMAR GENERATED BY PHARMACY
656
USE ALTERNATE FEATURES -RADIO -DIGITAL PHOTOFRAME
657
PATIENT NAVIGATES TO MANUAL DISPENSE -CHOOSES TIME PERIOD FOR MANUAL DISPENSE
658
PATIENT CONFIRMS
659
BOX DISPENSES CUT OR UNCUT STRIP FOR TIME PERIOD SELECTED -MANUAL DISPENSE SUBMITTED TO CLOUD
660
NORMAL DISPENSE FLOW CONTINUES

FIG. 22

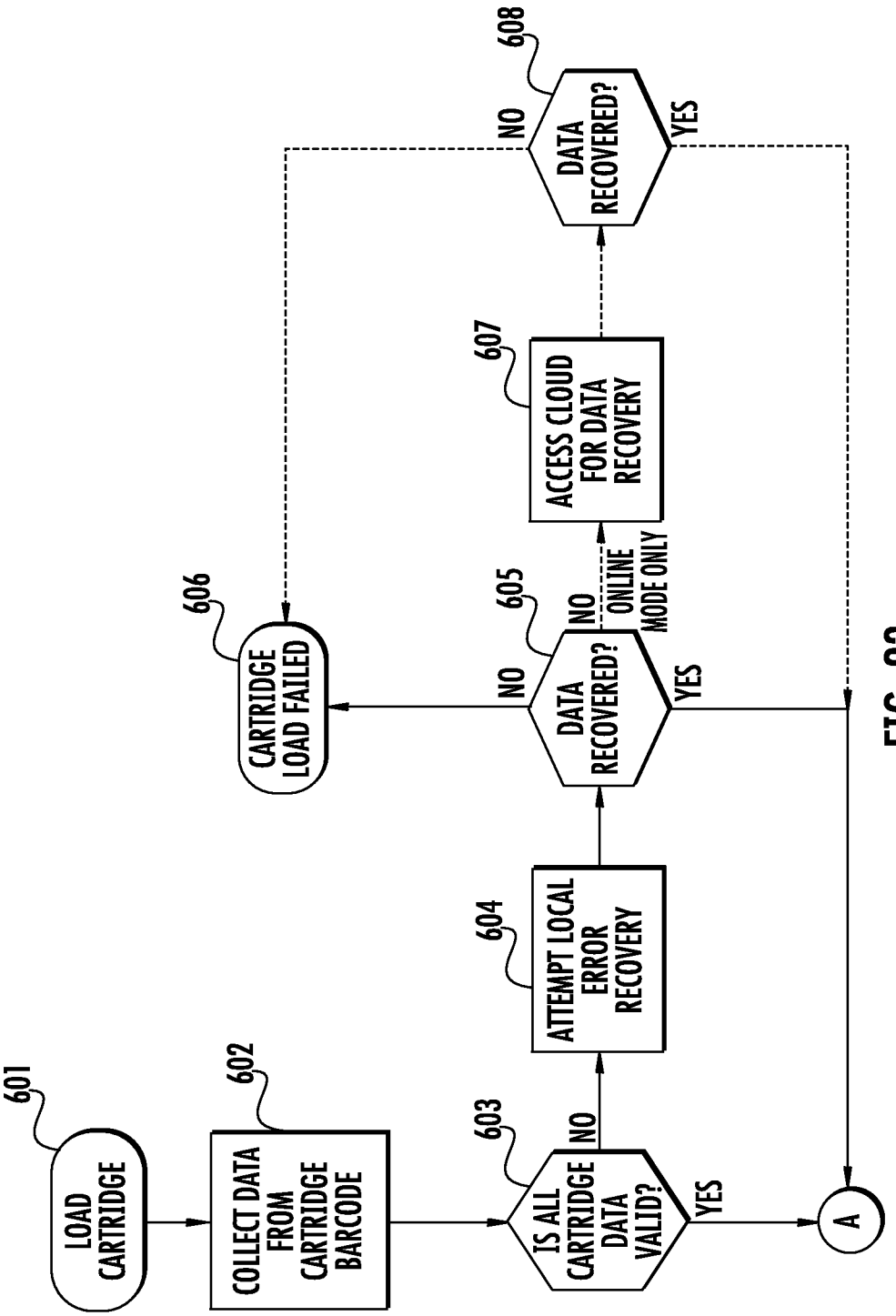
601
LOAD CARTRIDGE
602
COLLECT DATA FROM CARTRIDGE BARCODE
603
IS ALL CARTRIDGE DATA VALID?
NO
YES
A
604
ATTEMPT LOCAL ERROR RECOVERY
605
DATA RECOVERED?
NO
YES
606
CARTRIDGE LOAD FAILED
607
ACCESS CLOUD FOR DATA RECOVERY
ONLINE MODE ONLY
608
DATA RECOVERED?
NO
YES

FIG. 23

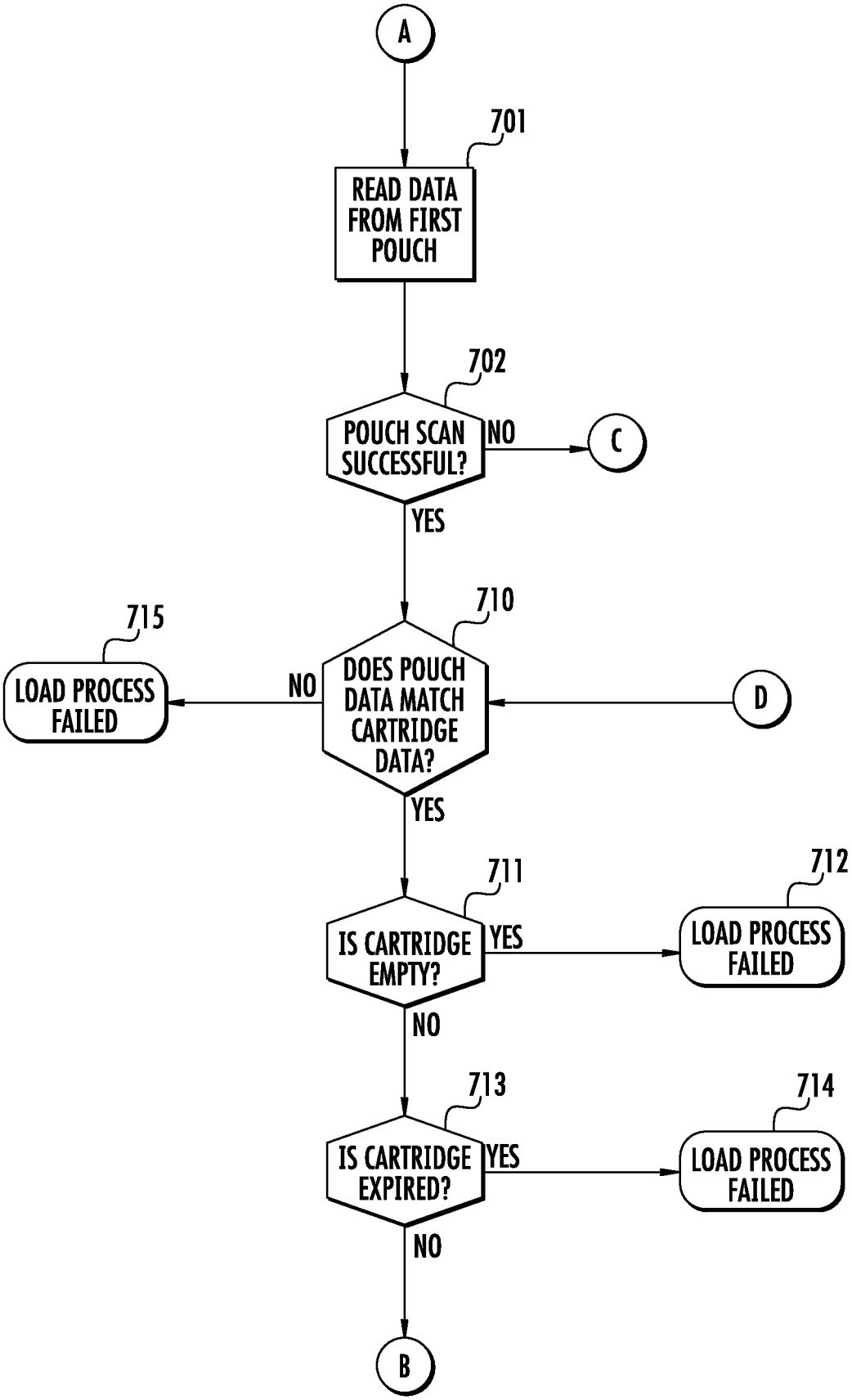
A
701
READ DATA FROM FIRST POUCH
702
POUCH SCAN SUCCESSFUL?
NO
C
YES
710
715
LOAD PROCESS FAILED
NO
DOES POUCH DATA MATCH CARTRIDGE DATA?
D
YES
711
712
IS CARTRIDGE EMPTY?
YES
LOAD PROCESS FAILED
NO
713
714
IS CARTRIDGE EXPIRED?
YES
LOAD PROCESS FAILED
NO
B

FIG. 24A

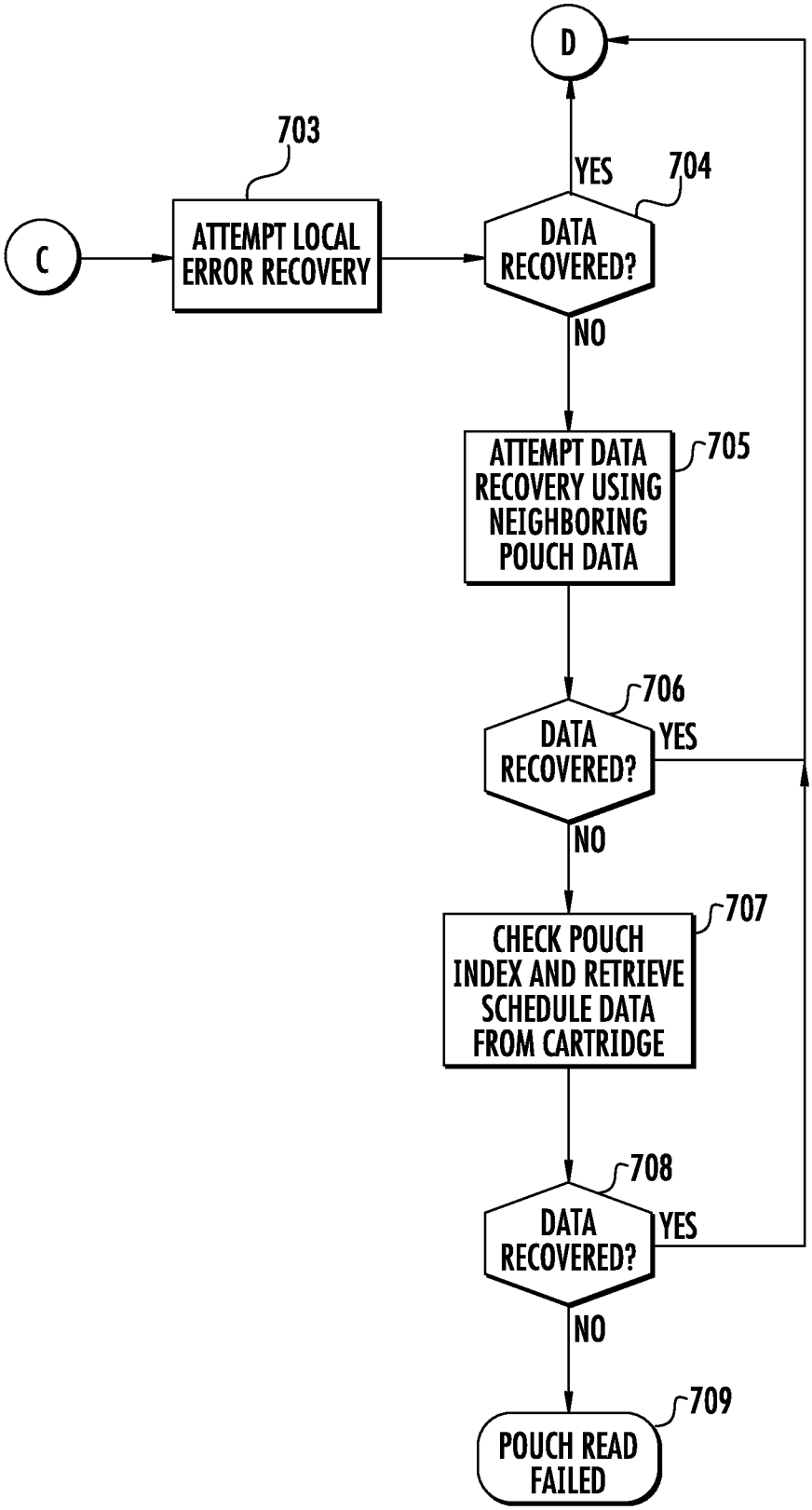
D
703
YES
704
C
ATTEMPT LOCAL ERROR RECOVERY
DATA RECOVERED?
NO
ATTEMPT DATA RECOVERY USING NEIGHBORING POUCH DATA
705
706
DATA RECOVERED?
YES
NO
707
CHECK POUCH INDEX AND RETRIEVE SCHEDULE DATA FROM CARTRIDGE
708
DATA RECOVERED?
YES
NO
709
POUCH READ FAILED

FIG. 24B

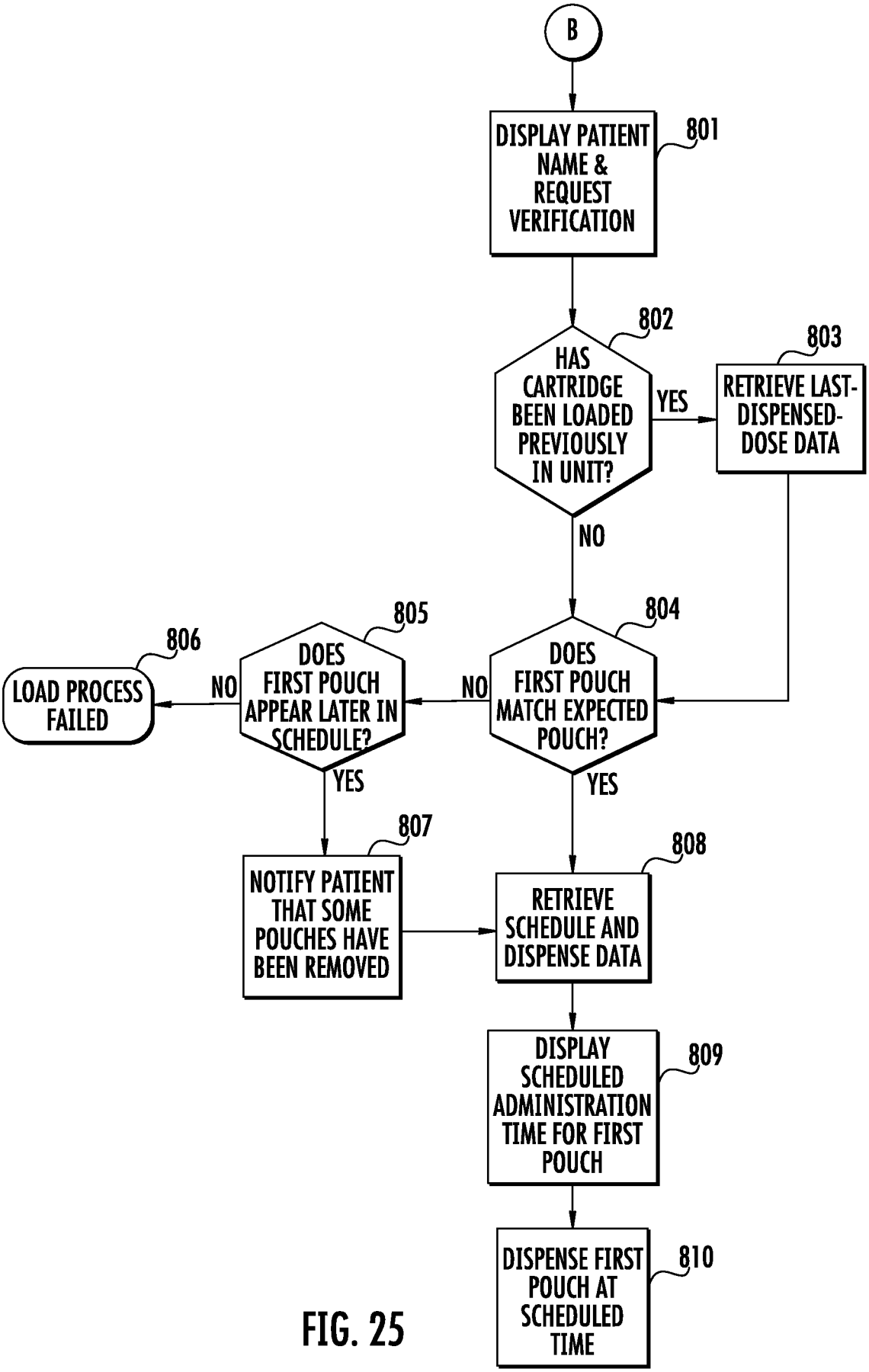
B
DISPLAY PATIENT NAME & REQUEST VERIFICATION
801
HAS CARTRIDGE BEEN LOADED PREVIOUSLY IN UNIT?
802
YES
RETRIEVE LAST-DISPENSED-DOSE DATA
803
NO
DOES FIRST POUCH MATCH EXPECTED POUCH?
804
NO
DOES FIRST POUCH APPEAR LATER IN SCHEDULE?
805
NO
LOAD PROCESS FAILED
806
YES
NOTIFY PATIENT THAT SOME POUCHES HAVE BEEN REMOVED
807
YES
RETRIEVE SCHEDULE AND DISPENSE DATA
808
DISPLAY SCHEDULED ADMINISTRATION TIME FOR FIRST POUCH
809
DISPENSE FIRST POUCH AT SCHEDULED TIME
810

FIG. 25

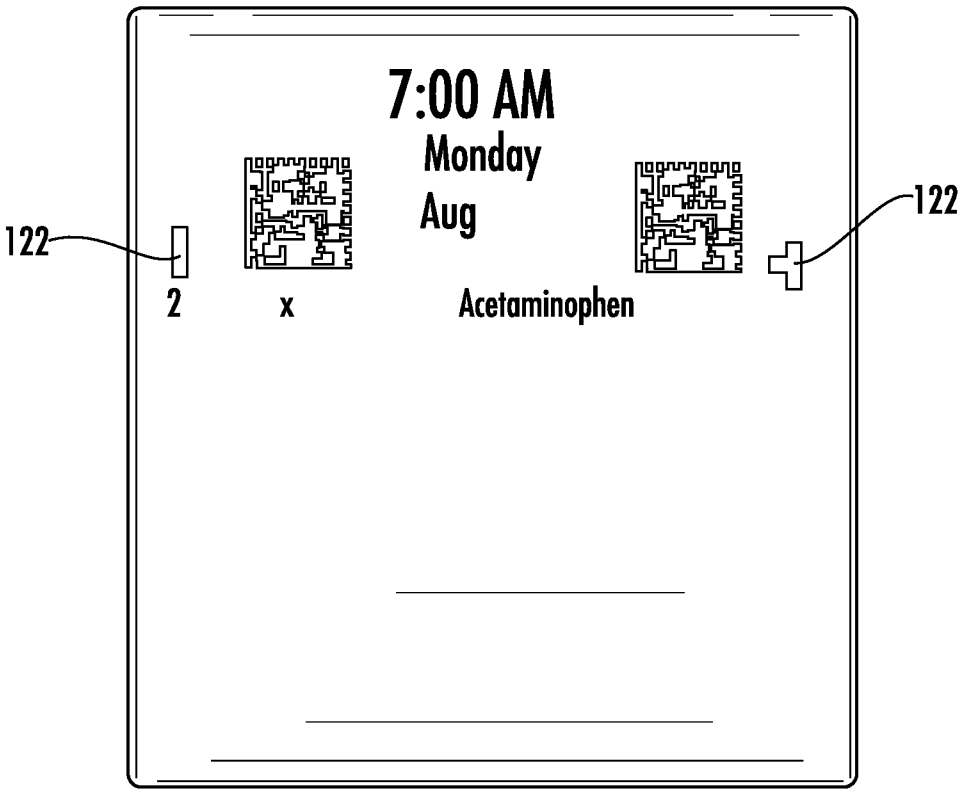

FIG. 26

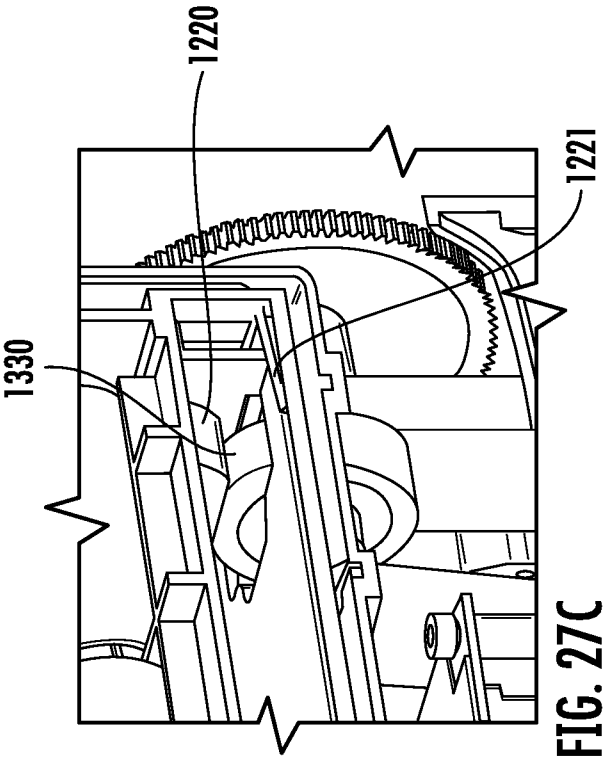

FIG. 27C

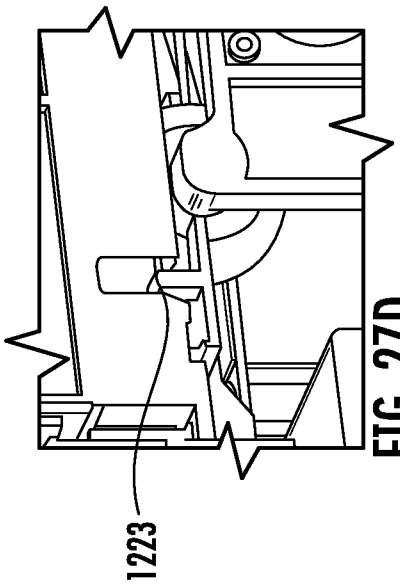

FIG. 27D

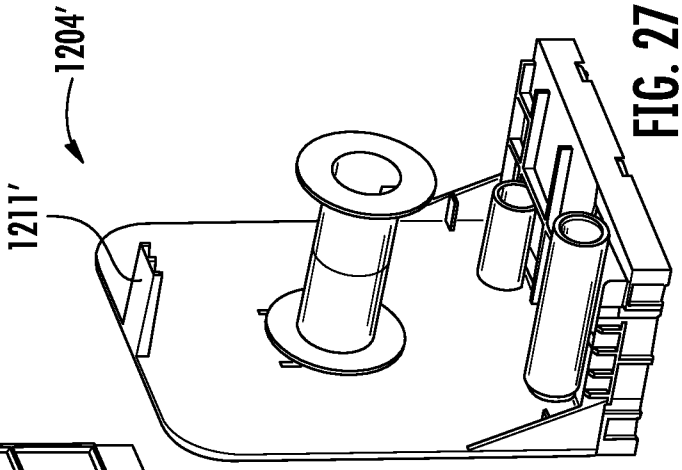

FIG. 27B

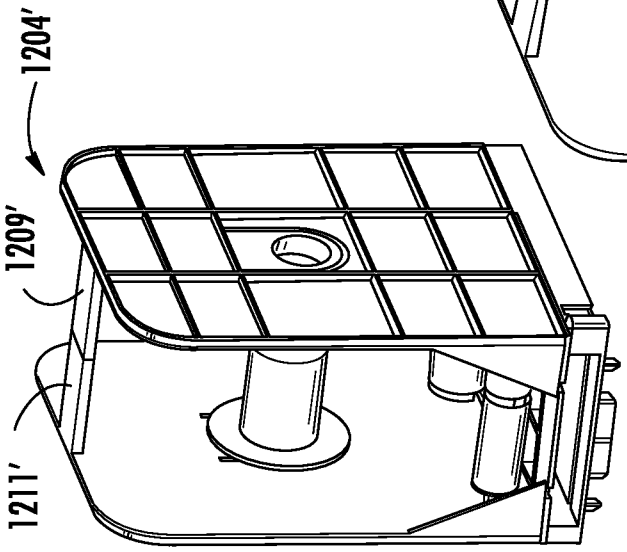

FIG. 27A

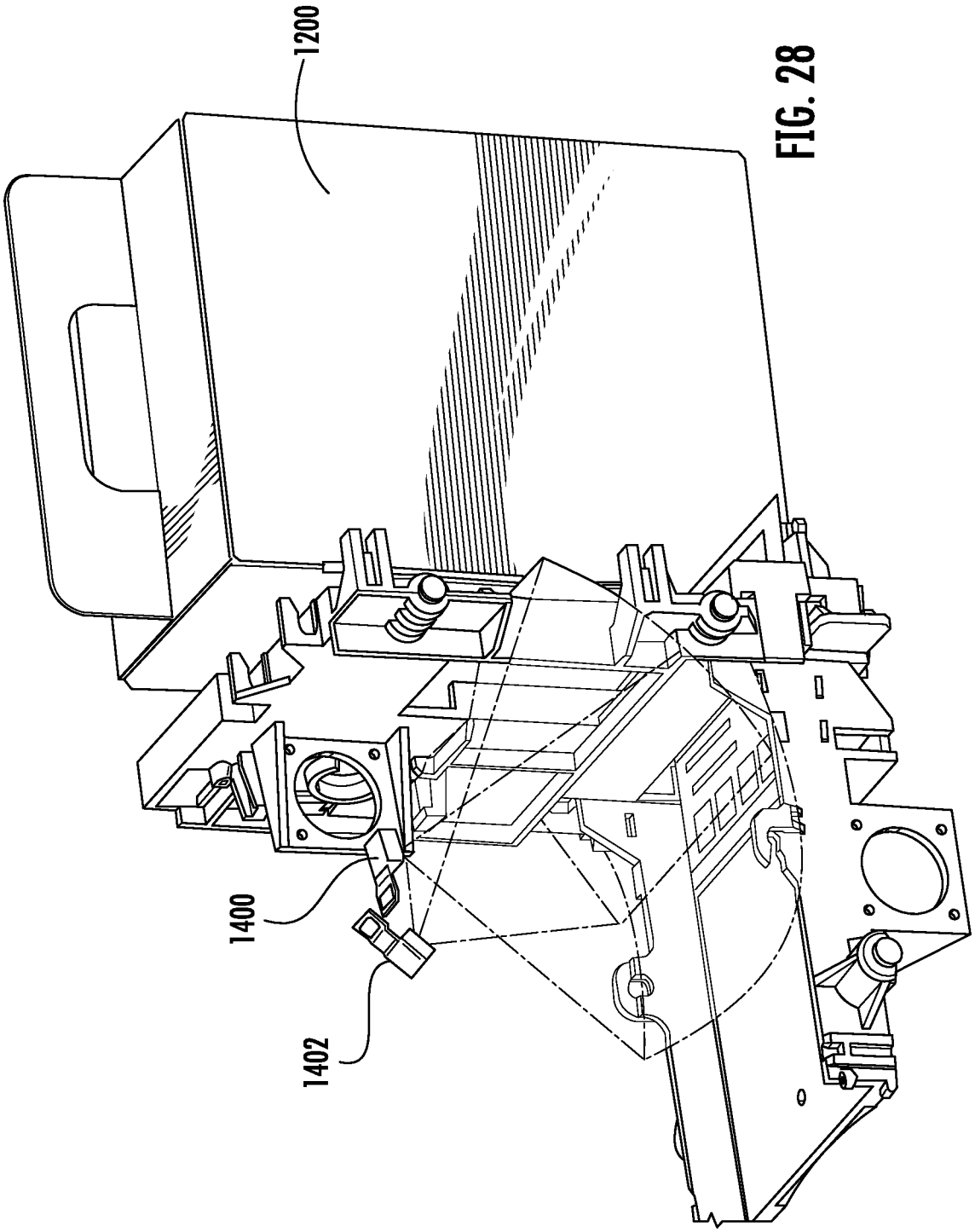

FIG. 28

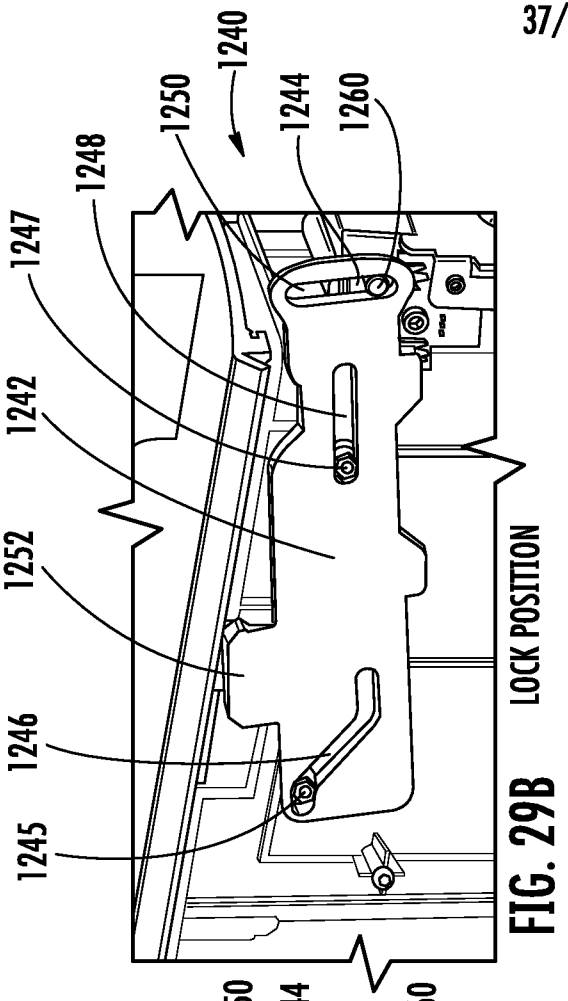

FIG. 29B

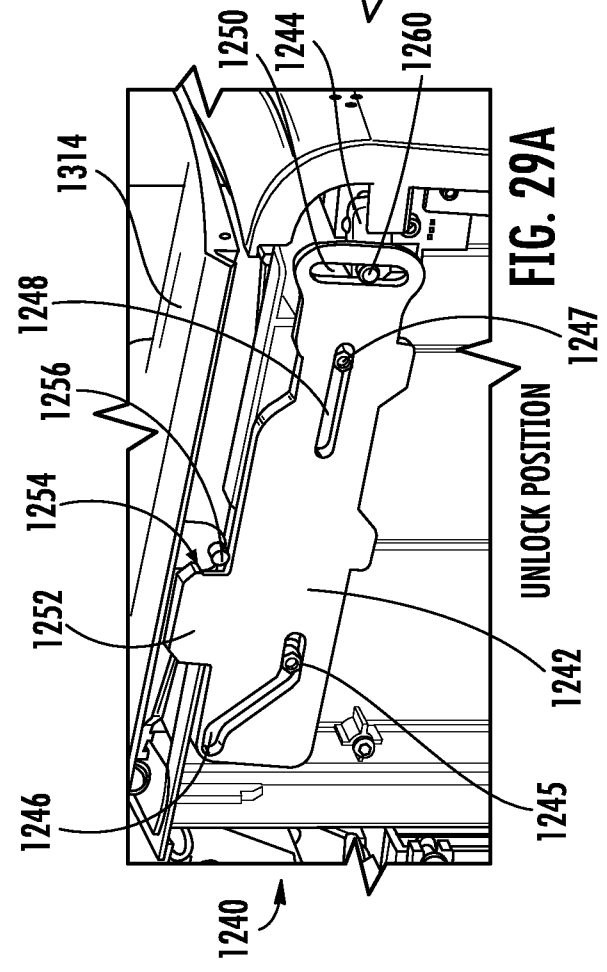

FIG. 29A

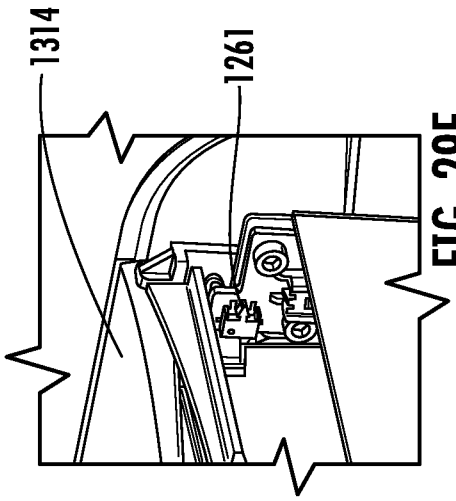

FIG. 29E

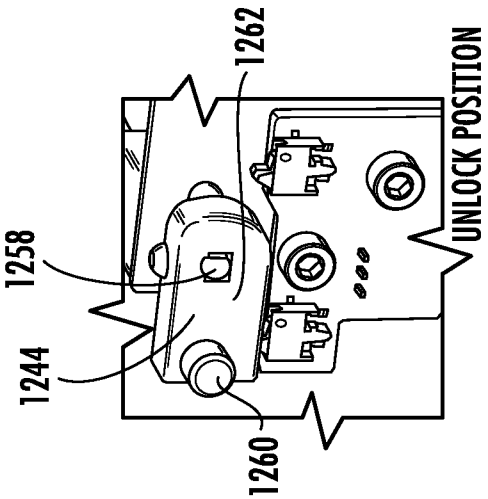

FIG. 29D

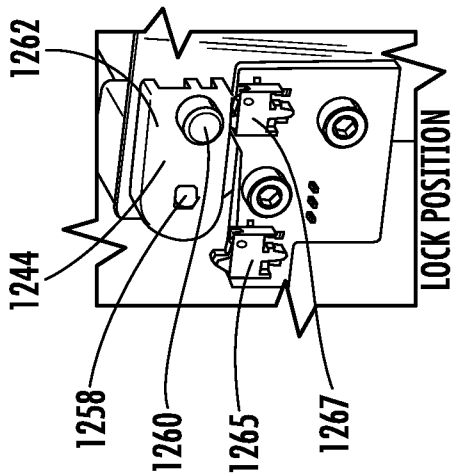

FIG. 29C

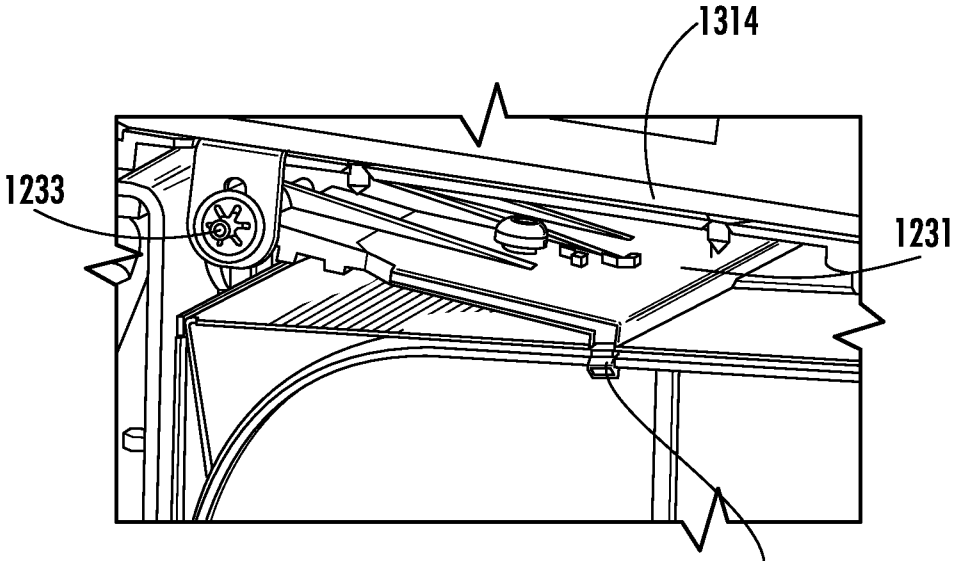

FIG. 30A

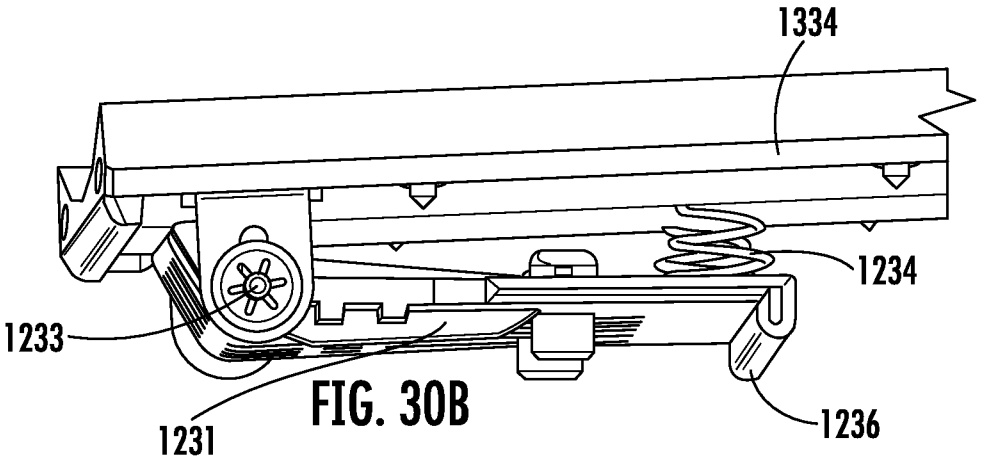

FIG. 30B

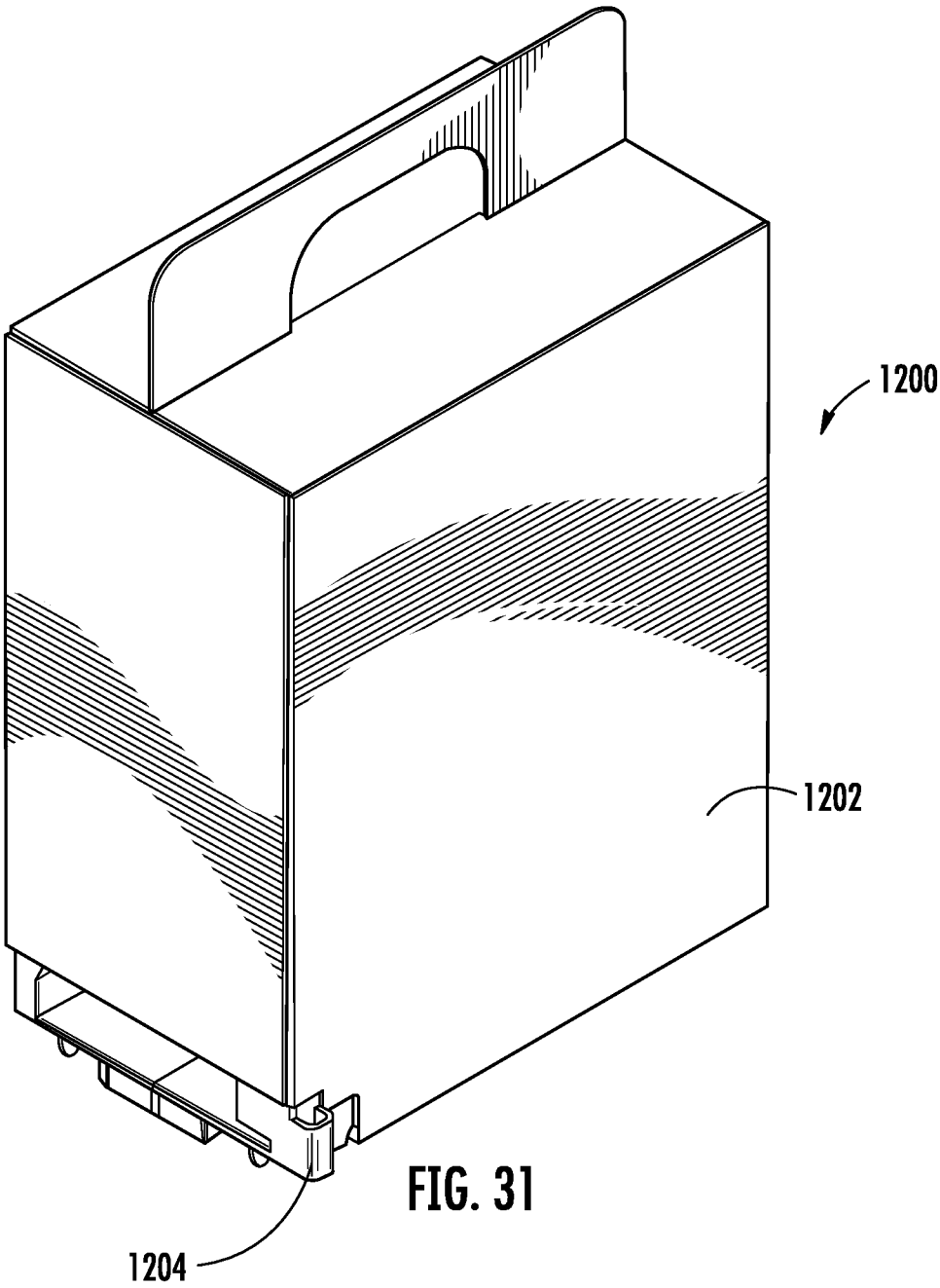

FIG. 31

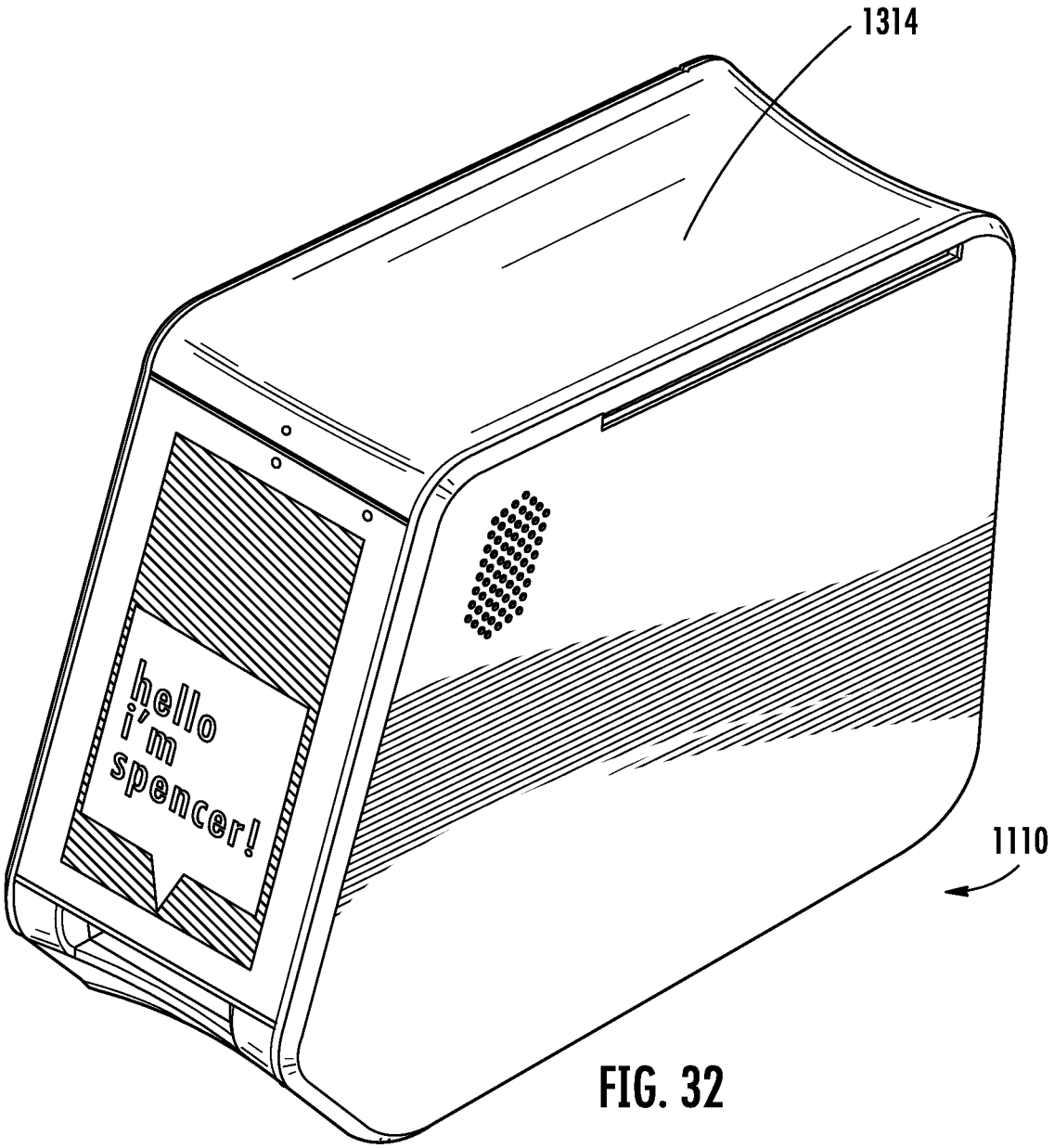

FIG. 32

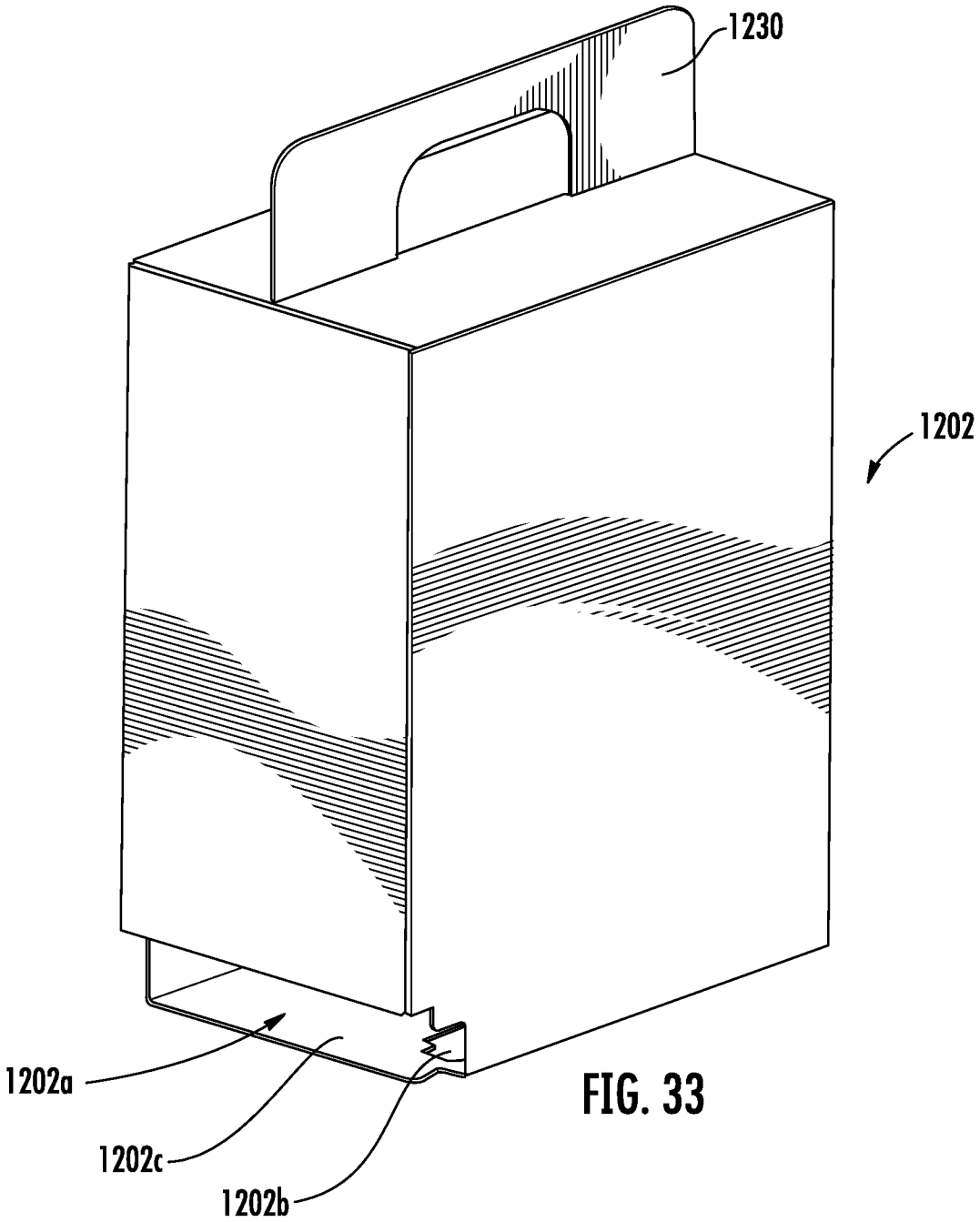

FIG. 33

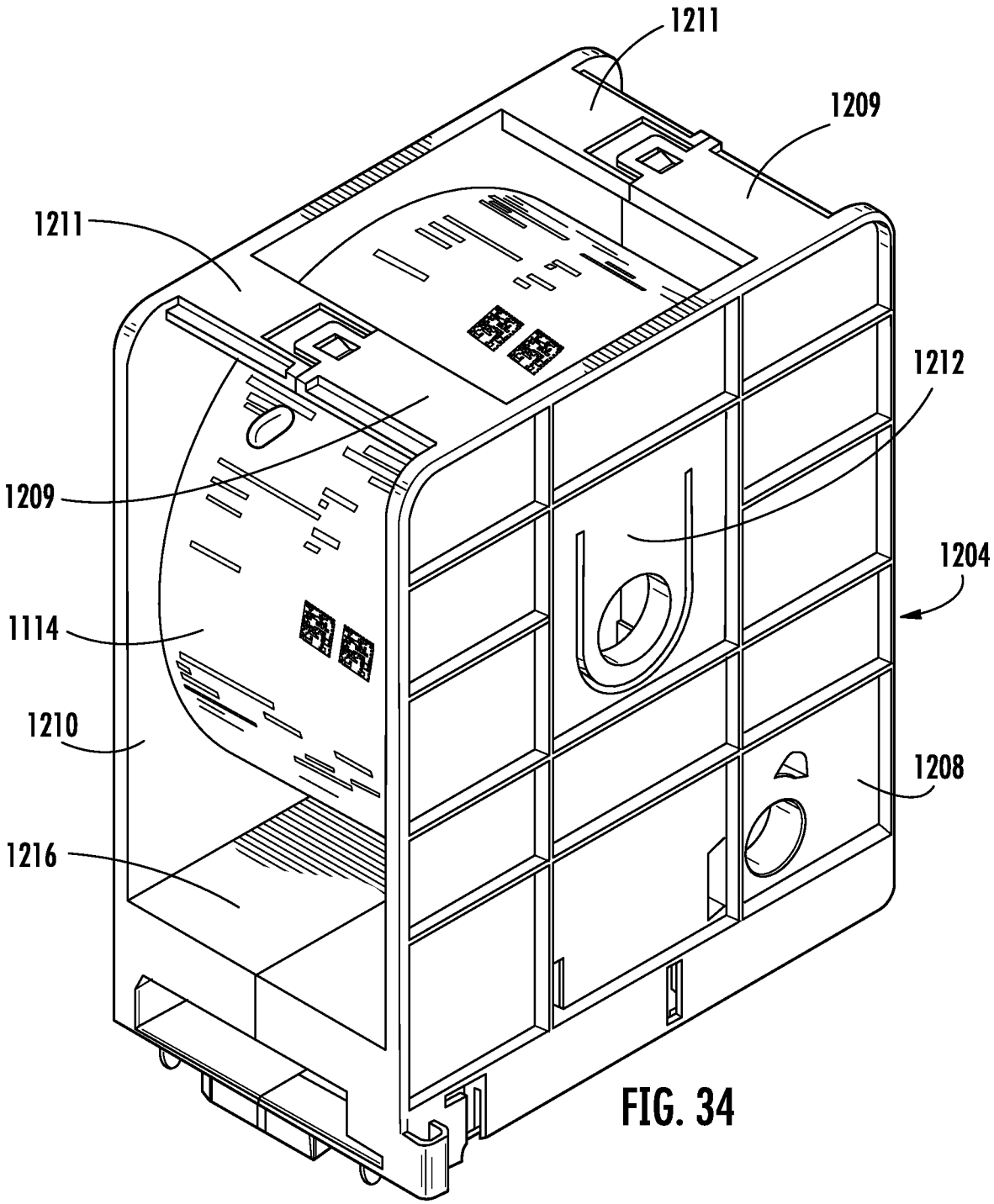

FIG. 34

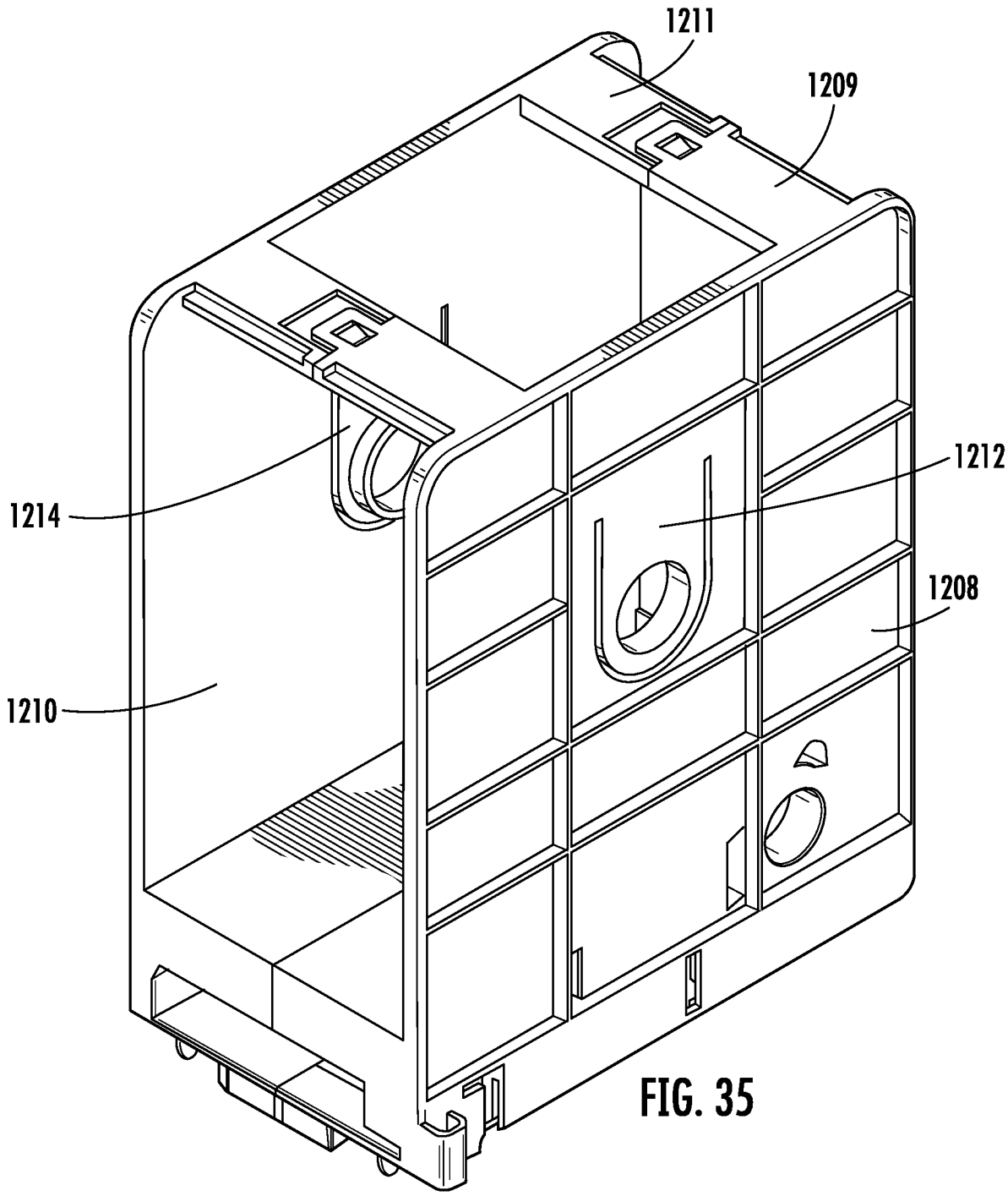

FIG. 35

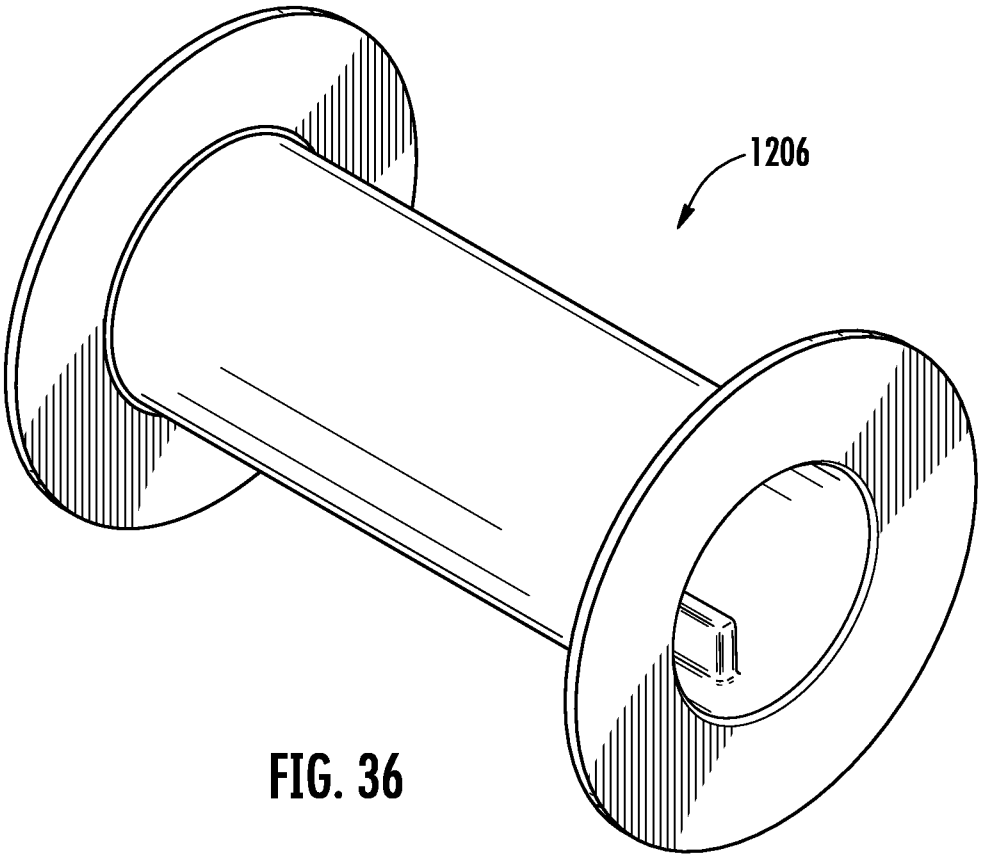

FIG. 36

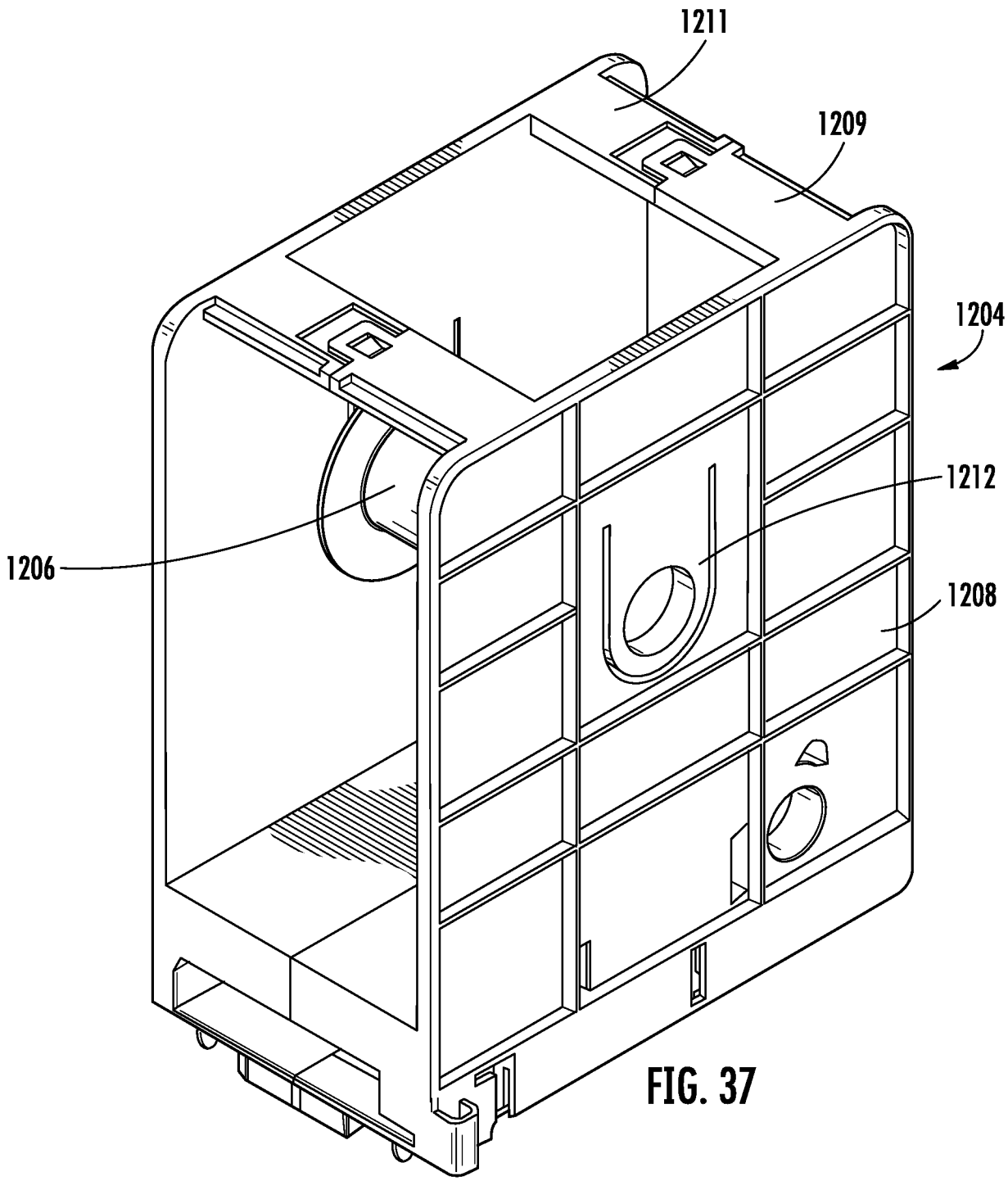

FIG. 37

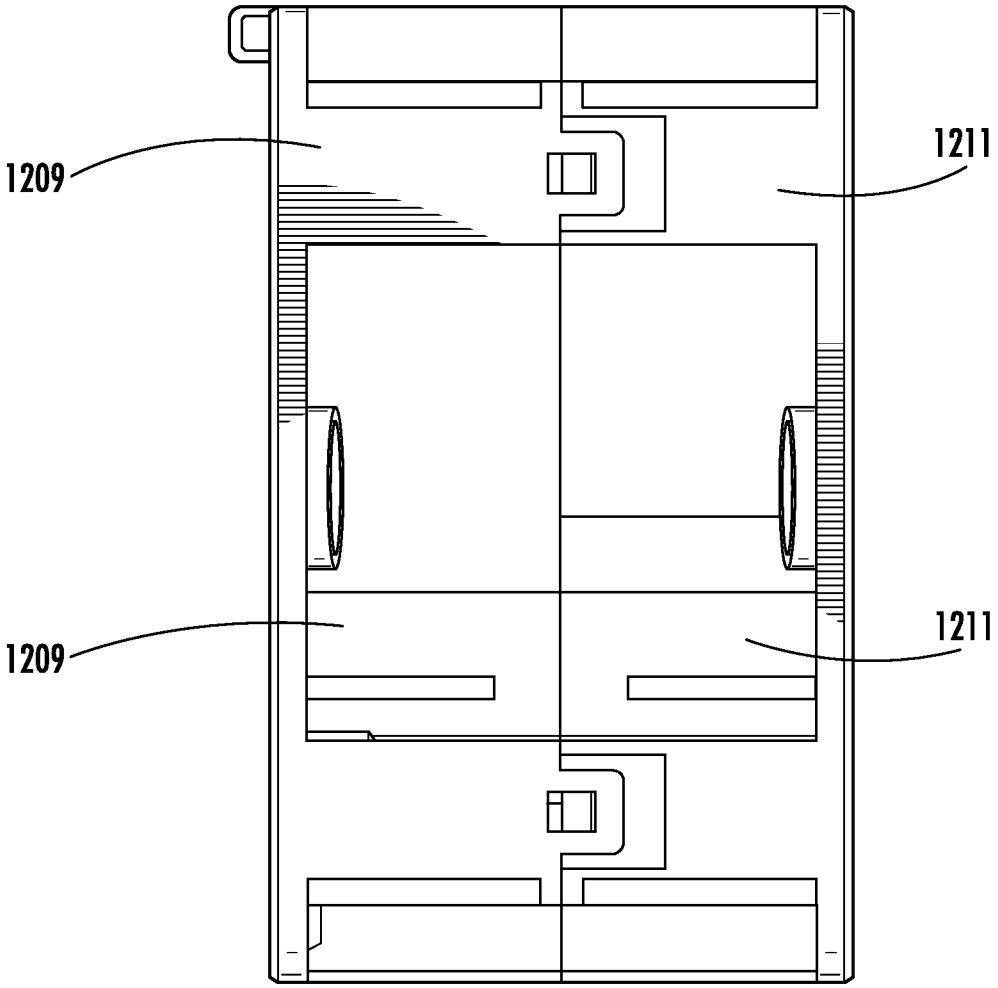

FIG. 38

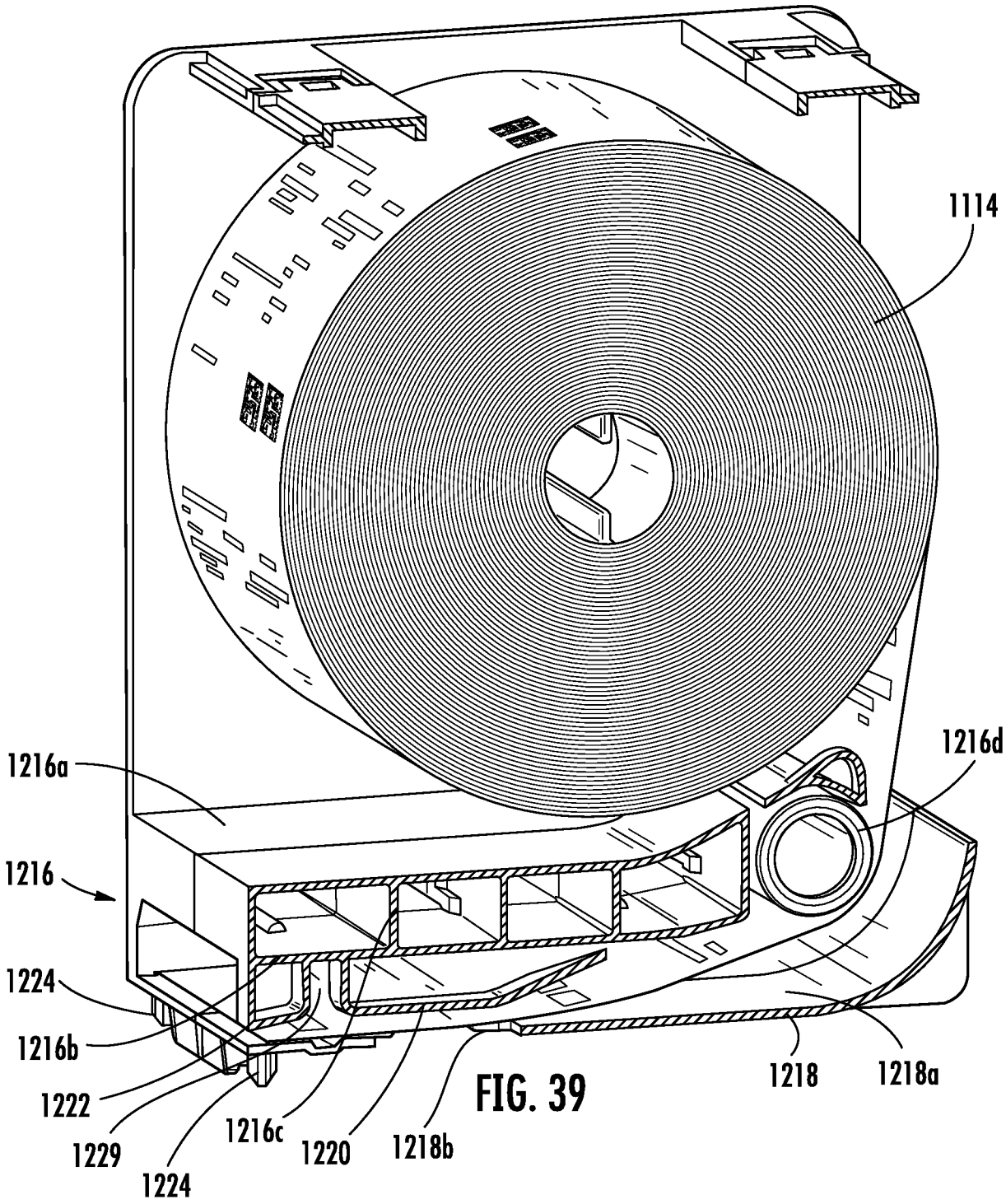
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FIG. 39

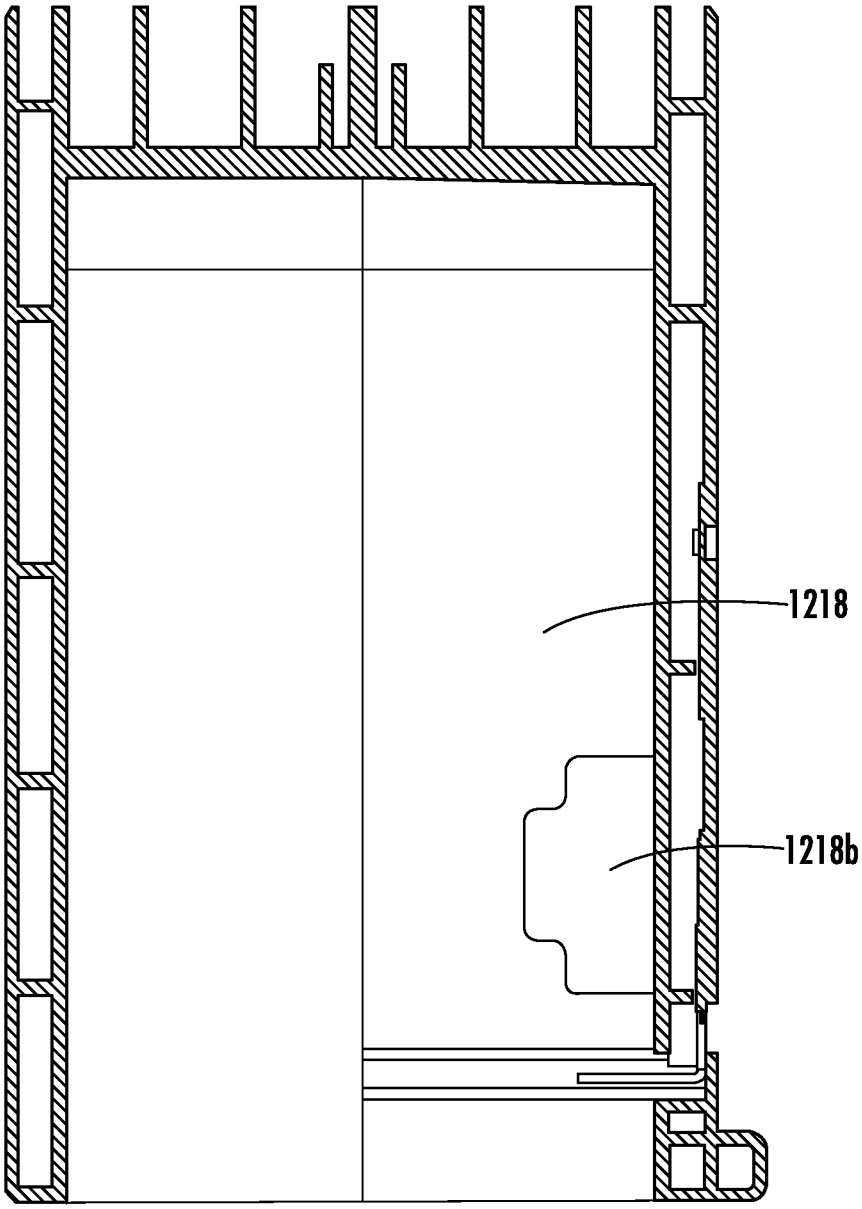


FIG. 40

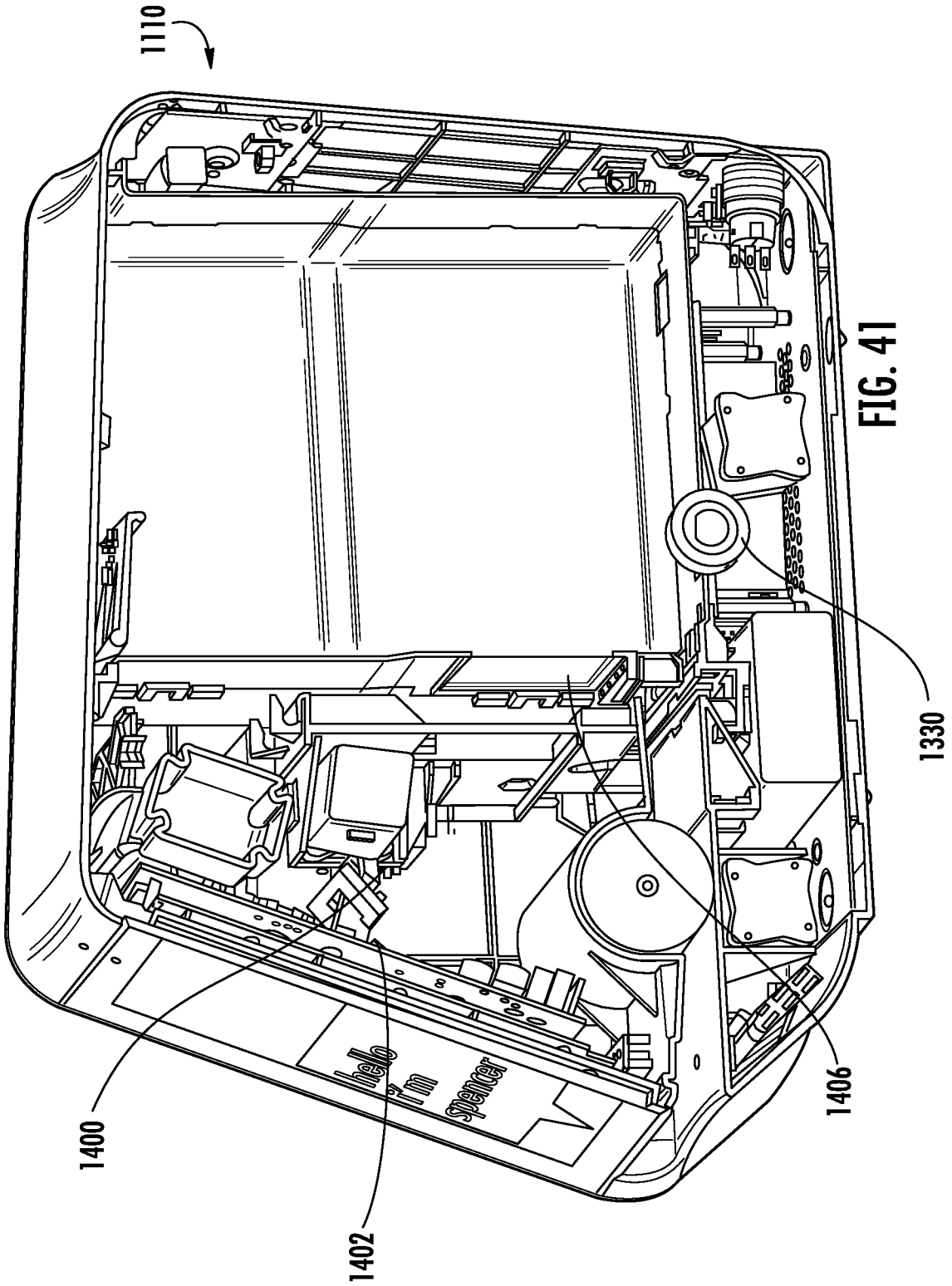
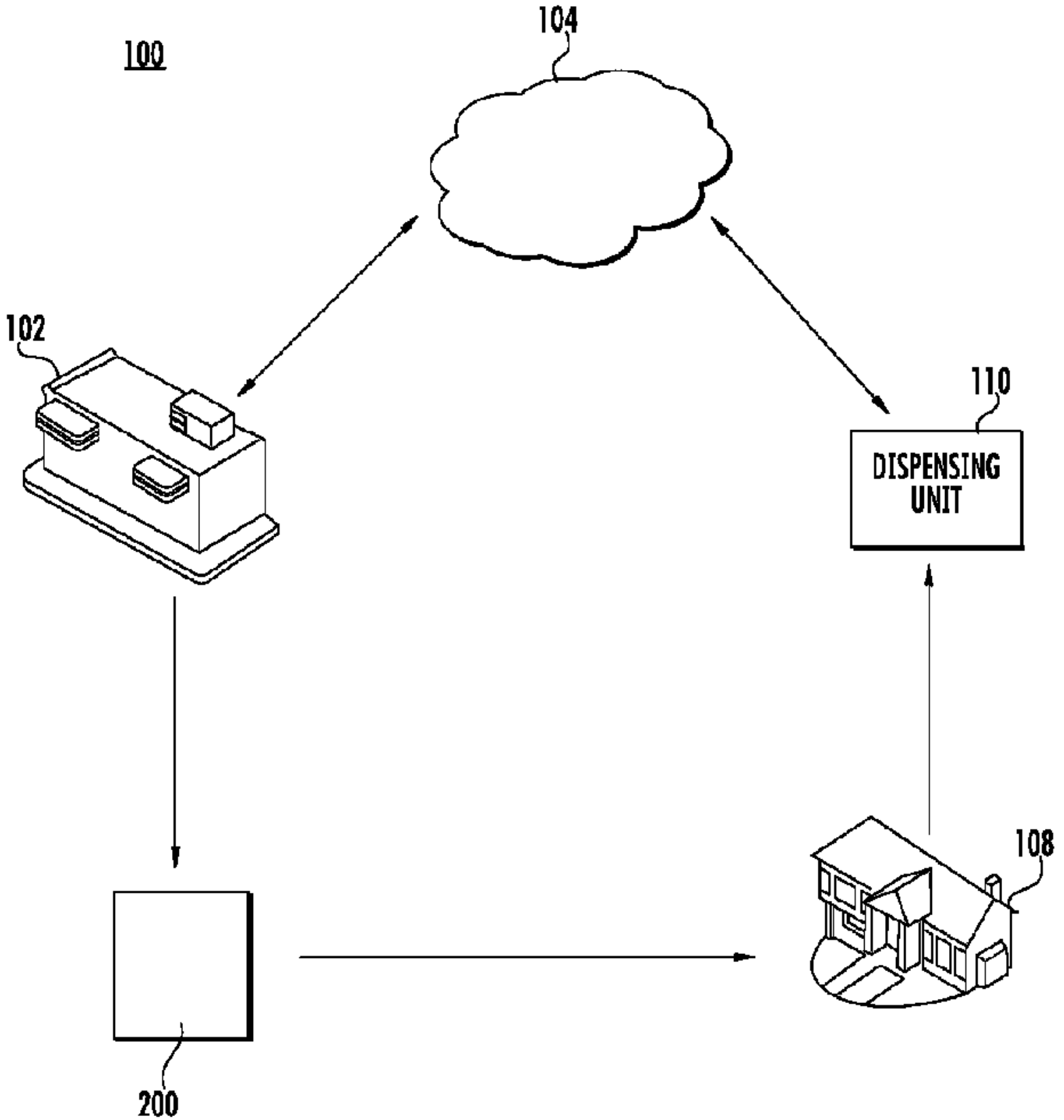


FIG. 41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