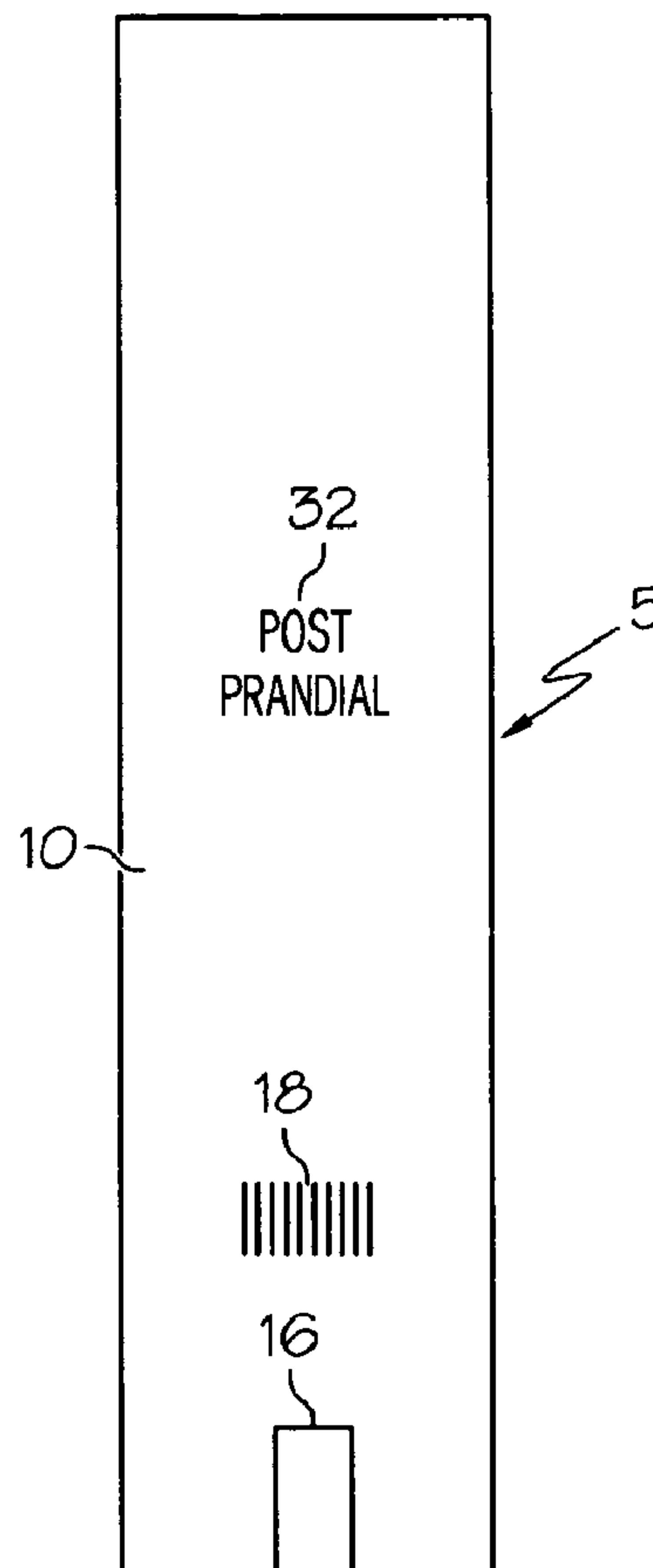




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(54) **Titre : KIT D'ESSAI STRUCTURE SOUS GUIDAGE**
(54) **Title: A GUIDED STRUCTURED TESTING KIT**



(57) **Abrégé/Abstract:**

A guided structured testing kit comprising a test strip container, a test strip meter, a testing protocol advisor, and at least one of diagnostic test strip is presented. The diagnostic test strip comprising a support element, a glucose reagent provided on the



(57) Abrégé(suite)/Abstract(continued):

support element, and a glycemic context code provided on the support element. The glycemic context code can be machine-readable. The glycemic context code signals a glycemic context to a test strip meter, either upon insertion of the diagnostic test strip or by a user manually inputting the glycemic context into the test strip meter. A method for performing a guided structured test is also provided.

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[Continued on next page]

(54) Title: A GUIDED STRUCTURED TESTING KIT

(57) Abstract: A guided structured testing kit comprising a test strip container, a test strip meter, a testing protocol advisor, and at least one of diagnostic test strip is presented. The diagnostic test strip comprising a support element, a glucose reagent provided on the support element, and a glycemic context code provided on the support element. The glycemic context code can be machine-readable. The glycemic context code signals a glycemic context to a test strip meter, either upon insertion of the diagnostic test strip or by a user manually inputting the glycemic context into the test strip meter. A method for performing a guided structured test is also provided.

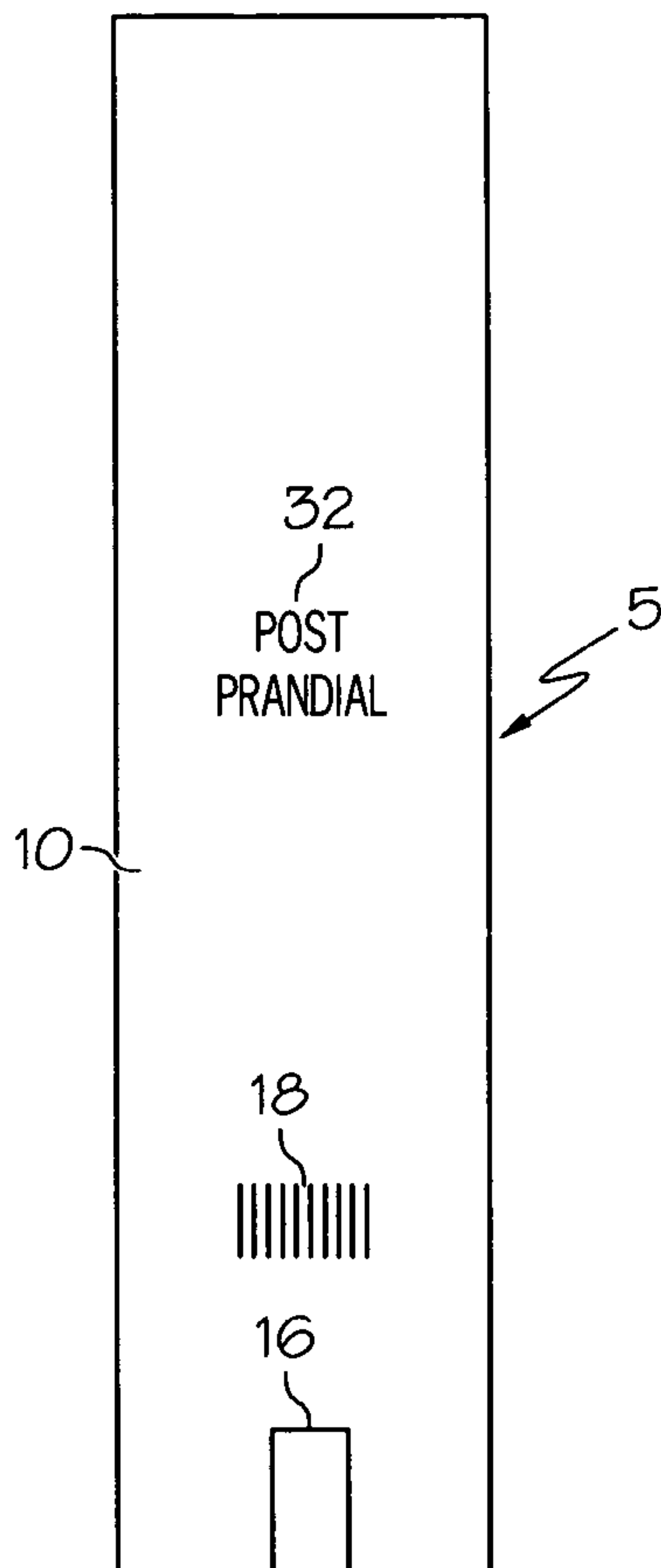


FIG. 1B

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HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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A GUIDED STRUCTURED TESTING KIT

TECHNICAL FIELD

[0001] This application generally relates to a guided structured testing kit, and more particularly relates to a guided structured testing kit comprising at least one diagnostic test strip that signals a glycemic context to a test strip meter.

BACKGROUND OF INVENTION

[0002] In order to support glucose pattern testing, it is necessary to know the glycemic context of a blood glucose test. Devices that require a user to manually input or select the glycemic context of a particular blood glucose test often result in problems. Users may mistakenly select or input the wrong glycemic context associated with a particular test. Other users may fail to select or input a glycemic context altogether. Furthermore, many compact, easy-to-use test strip meters are not compatible with a user interface that would support the input of a glycemic context associated with a blood glucose test. The glycemic context for one or more tests may be forgotten if a user has to wait to input the glycemic context until they reach a computer or other data-input device.

[0003] Accordingly, there remains a need for a glucose testing system that provides an improved way to associate the glycemic context with a blood glucose test result.

SUMMARY OF INVENTION

[0004] In accordance with one embodiment of the present disclosure, a diagnostic test strip comprises a support element, a glucose reagent provided on the support element, and a glycemic context code provided on the support element. The glycemic context code may signal a glycemic context to a test strip meter upon insertion of the diagnostic test strip.

[0005] In accordance with another embodiment of the present disclosure, a guided structured testing kit is presented. The guided structured testing kit comprises a test strip container, a test strip meter, a testing protocol advisor, and at least one of a diagnostic test strip. The at least one of the diagnostic test strip comprises a support element, a reagent provided on the support element, and a glycemic context code provided on the support

element. The glycemic context code signals a glycemic context to the test strip meter upon insertion of the at least one diagnostic test strip. The test strip container defines an internal volume to hold the at least one diagnostic test strip and the testing protocol advisor notifies a user of an at least one glycemic testing protocol.

[0006] In accordance with another embodiment of the present disclosure, a method for performing a guided structured test is presented. The method comprises providing a diagnostic test strip having a glycemic context code and a test strip meter. The method may also comprise signaling a glycemic context to a test strip meter from the glycemic context code and associating the signaled glycemic context with a blood glucose test result provided by the diagnostic test strip.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0007] The following detailed description of specific embodiments of the present disclosure can be best understood when read in conjunction with the following drawings, where like structure is indicated with like reference numerals and in which:

[0008] Figs. 1A-D show front views of diagnostic test strips in accordance with one or more embodiments of the present invention;

[0009] Fig. 2 shows a structured testing kit in accordance with another embodiment of the present invention;

[0010] Fig. 3 shows a schematic view of a test strip meter in combination with a diagnostic test strip of Figs. 1A-D in accordance with yet another embodiment of the present invention;

[0011] Fig. 4 shows a front perspective view of test strip container in accordance with one embodiment of the present invention;

[0012] Fig. 5 shows an alternative test strip container in accordance with one embodiment of the present invention;

[0013] Fig. 6 shows a glycemic testing protocol in accordance with yet another embodiment of the present invention; and

[0014] Fig. 7 shows an exterior view of a structured pattern testing kit in accordance with one embodiment of the present invention.

DETAILED DESCRIPTION

[0015] Referring initially to Fig. 1A, in one embodiment, a diagnostic test strip 5 is provided. The diagnostic test strip may comprise a support element 10, a glucose reagent 16 provided on the support element, and a glycemic context code 12 provided on the support element. In one exemplary embodiment, the glycemic context code 12 can be machine-readable by, for example, a medical device meter such as a blood glucose meter or the like. The glycemic context code signals a glycemic context to a test strip meter 14 (as shown in Fig. 2) upon insertion of the diagnostic test strip.

[0016] In further describing the embodiments of the present disclosure, a conventional test strip may be referenced. Examples of such test strips suitable for use with the subject disclosure include those described in U.S. Patent Nos. 6,193,873; 6,475,372; 6,716,577; 6,620,310; and 6,558,528. The length of the test strip 5 generally ranges from about 3 mm to about 1000 mm, or from about 10 mm to about 100 mm, or from about 20 mm to about 60 mm. The support element may comprise a flexible plastic, or similar material suitable to provide a machine-readable glycemic context code to a test strip meter. The reagent 16 may comprise a material or device suitable to indicate the levels of glucose provided in an assay of blood, as will be appreciated by one of ordinary skill.

[0017] Referring further to Fig. 1A, the diagnostic test strip 5 may also comprise a glycemic context code 12. In one example embodiment, the glycemic context code 12 can be machine-readable. The glycemic context code 12 may be provided on any portion of the support element 10. In one embodiment, the glycemic context code 12 is provided on one end of the test strip 5. However, it is also contemplated that the glycemic context code 12 may be provided at any location along the strip 5, suitable to signal the glycemic context to a test strip meter. The glycemic context code 12 may be provided on the same end of the diagnostic test strip 5 as the reagent 16. The glycemic context code 12 may be oriented on the support element 10 such that it does not interfere with the blood glucose testing functionality of the reagent 16.

[0018] In one embodiment, the glycemic context code 12 allows the glycemic context 26 of a performed blood glucose test to be signaled to a test strip meter 14 by simply inserting a diagnostic test strip 5 into the test strip meter 14 (as shown in Fig. 2). Once the glycemic context code 12 is inserted into the test strip meter 14, the test strip reader may read the glycemic context code 12, and receive the glycemic context 26 associated with the diagnostic

test strip 5. In another embodiment, the test strip meter 14 could have an external reader that can, for example, optically scan the glycemic context from the diagnostic test strip 5 to receive the glycemic context 26 associated with the diagnostic test strip 5. In yet another embodiment, the glycemic context 26 of a performed blood glucose test associated with the diagnostic test strip 5 can be manually inputted into a test strip meter 14 by the user. In one embodiment, the user can simply type-in the glycemic context 26 using an input device, such as a keyboard, touch screen or the like. In another embodiment, the user can select the glycemic context 26 by a user interface, such as, a graphical user interface 34, on the test strip meter 14. The graphical user interface 34 may comprise a series of drop down text boxes, radio buttons or combinations of any suitable known user interface. Once the glycemic context code 12 associated with the diagnostic test strip 5 is inputted into the test strip meter 14, the test strip meter 14 may then assign the glycemic context 26 to the blood glucose test result of that particular diagnostic strip 5.

[0019] Each diagnostic test strip 5 may include a glycemic context code 12 designed to signal the intended glycemic context 26 to the test strip meter 14. By changing the glycemic context code 12, the glycemic context 26 signaled to the test strip meter 14 changes. Therefore, by modifying the glycemic context code 12 embedded on each test strip 5, a comprehensive glycemic testing procedure may be provided, such that a variety of test strips 5 may be provided in a kit suitable to signal all possible glycemic contexts 26 to the test strip meter 14.

[0020] Referring generally to Figs. 1A-1D, the glycemic context code 12 may comprise a range of signaling indicia that may be read by, scanned into or inputted into the test strip meter 14 (as shown in Fig. 2) to communicate the intended glycemic context 26. The glycemic context 26 may be defined as any event that may have a significant impact on blood glucose levels of an individual. In other words, the glycemic context 26 defines the conditions under which a blood glucose measurement needs to be taken. These conditions can be based directly on a blood glucose measurement itself and/or on actions which are chronologically related to the measurements that may impact the blood glucose measurement. For example, the time, or the time windows, for taking the blood glucose measurement can be determined by the conditions that have to be executed before or after that measurement, e.g., fasting or pre and post-prandial. The glycemic context code 12 may be selected from the group including, but not limited to, an optical signaling indicia 18, an electrical signaling indicia 20,

a mechanical signaling indicia 22, and combinations thereof. Alternatively, other signaling indicia may be used suitable to convey a glycemic context 26 to a test strip meter 14 by, for example, upon insertion of a diagnostic test strip 5, manual input into the test strip meter 14, or scanning a diagnostic test strip 5.

[0021] Referring to Fig. 1B, in one embodiment, the glycemic context code 12 may comprise optical signaling indicia 18. The optical signaling indicia 18 may be selected from the group, but not limited to, a bar code, a hole pattern, and combinations thereof. The test strip meter 14 may sense the optical signaling indicia 18, and recognize the particular glycemic context associated therewith, as will be appreciated by one of ordinary skill.

[0022] Referring to Fig. 1C, in one embodiment, the glycemic context code 12 may comprise electrical signaling indicia 20. The electrical signaling indicia 20 may be selected from the group, but not limited to, a distinctive resistance, capacitance, break pattern, and combinations thereof. Other types of electrical signaling indicia 20 are also contemplated, as will be appreciated by one of ordinary skill.

[0023] Referring to Fig. 1D, in one embodiment, the glycemic context code 12 may comprise mechanical signaling indicia 22. The mechanical signaling indicia 22 may be selected from the group, but not limited to, an indent pattern, a hole pattern, strip width or combinations thereof. It is also contemplated that other forms of mechanical, optical, and electrical signaling indicia may be used in conjunction with the methods and devices disclosed herein, as will be appreciated by one of ordinary skill, such as RFID, wireless adapters, dyes, magnetic encoding, and similar communication interfaces.

[0024] Referring to Fig. 2, in one embodiment, a structured patterned testing kit 24 is provided. The structured pattern testing kit 24 may comprise a test strip meter 14. The test strip meter 14 may be configured and designed to interact with the type of signaling indicia provided on the diagnostic test strips 5 as described above. The test strip meter 14 may be suitable to detect the blood glucose levels present in the blood sample provided on the inserted diagnostic test strip 5. The test strip meter 14 may comprise a code reader 52 (Fig. 3), configured and designed to read the signals provided by the glycemic context codes 12. In one embodiment, the code reader 52 can be internal to the test strip meter 14. In another embodiment, the code reader 52 can be external to the test strip meter 14. Alternatively, the test strip meter 14 may have the glycemic context codes 12 manually inputted into the test strip meter 14.

[0025] The code reader 52 may be an optical code reader, a mechanical code reader, or an electrical code reader. More generally, the code reader 52 may be selected to correspond to the type of signaling indicia provided on the diagnostic test strips 5 that will be used in conjunction with the test strip meter 14. Accordingly, in one embodiment, if there is an internal code reader 52, when a test strip 5 is inserted into the test strip meter 14 having a glycemic context code 12, a processor 54 of the test strip meter 14 may read the glycemic context 26 associated with the particular glycemic context code 12, and associate that glycemic context 26 with the blood glucose test result. In another embodiment, if there is an external code reader 52, the processor 54 of test strip meter 14 may optically scan the glycemic context code 12 via the code reader and read the glycemic context 26 associated with that particular glycemic context code 12 on the diagnostic test strip 5 and associate that glycemic context 26 with the blood glucose test result. Alternatively, a user can input via the input device or graphical user interface 34 the glycemic context 26 associated with the particular glycemic context code 12 on the test strip 5 into the test strip meter 14, and the processor 54 of test strip meter 14 can then associate that glycemic context 26 with the blood glucose test result.

[0026] The processor 54 of test strip meter 14 may be designed to store the glycemic context 26 communicated by the diagnostic test strip 5 in a local memory system 56. The processor 54 of test strip meter 14 may associate the glycemic context 26 with the blood glucose test result 28, and assign a date and time stamp 31 for the test for subsequent download to a program to aid in the analysis of blood glucose trends and patterns. The memory system 56 and processor 54 may be configured to store and analyze a plurality of blood glucose test results, and their corresponding glycemic contexts 26 for later upload and assessment.

[0027] The glycemic context 26 represents the intended usage of the diagnostic test strip 5 in terms of the glycemic events that a user of a diagnostic test strip 5 would experience. As was described previously, the glycemic context 26 may be defined as any event or condition that may have a significant impact on blood glucose levels of an individual. The glycemic context 26 may be selected from the group including, but not limited to, pre-prandial, post-prandial, fasting, bedtime, and combinations thereof. Other glycemic events may include pre-, or post-exercise, pre- or post- nap, pre- or post- snack, and other similar glycemic events as will be appreciated by one of ordinary skill. By supplying

the glycemic context 26 in conjunction with the blood glucose test result, more information may be obtained for a particular test subject.

[0028] It is contemplated that a plurality of diagnostic test strips 5 may be provided to a user. The diagnostic test strips 5 may be provided to a user in groups, pertaining to their encoded glycemic contexts 26. Each group of diagnostic test strips 5 may be configured to signal a different glycemic context 26. For example, the groups may include approximately ten diagnostic test strips 5 having glycemic context codes 12 configured to signal a pre-prandial glycemic context 26; approximately ten diagnostic test strips 5 configured to signal a post-prandial glycemic context 26; and approximately ten diagnostic test strips 5 configured to signal a fasting glycemic contexts 26. Other group sizes and groupings may also be provided, as will be appreciated by one of ordinary skill. Therefore, a user may select from the plurality of test strips 5, a diagnostic test strip 5 having a glycemic context code 12 appropriate to signal the proper glycemic context 26 pertaining to the user's glycemic state.

[0029] Referring again to Fig. 1A, in another embodiment, the diagnostic strip 5 may comprise a glycemic context identifier 30 corresponding to the glycemic context 26 of the test strip 5. The glycemic context identifier 30 may comprise an identifier suitable to convey the glycemic context 26 associated with a particular diagnostic test strip's glycemic context code 12. For example, a diagnostic test strip 5 having a glycemic context code 12 configured to signal a pre-prandial glycemic context 26, it may have a glycemic context identifier 30 comprising a blue color strip. Each glycemic context 26 may have a distinct glycemic context identifier 30, so a user can quickly identify which diagnostic test strip 5 is configured to signal the appropriate glycemic context 26.

[0030] Referring to Fig. 2, in one configuration, the glycemic context code 12 may be readable by the test strip meter 14 and may communicate to a test strip user the intended glycemic context 26 of the strip 5. Accordingly, in one embodiment, the glycemic context code 12 is both machine readable and identifiable by a user. For example, the glycemic context code 12 may comprise a particular color. The test strip meter 14 may comprise a code reader 52 configured to associate a particular color with a particular glycemic context 26. Similarly, a user of the test strip 5 may be instructed to associate a particular test strip color with the intended glycemic context 26. It is also contemplated that the glycemic context code 12 may signal to a test strip meter 14, the glycemic context code 12, and act as a glycemic

context identifier 30 through color coding, textual signals, patterns, and other forms as will be appreciated by one of ordinary skill.

[0031] The glyceemic context identifier 30 may be selected from the group, including, but not limited to, a color code; a tactile code, a label 32 (Fig. 3); and/or combinations thereof. For example, the glyceemic context identifier 30 may comprise a band of color or the entire strip 5 may be colored to correspond to the particular glyceemic context 26.

[0032] In one configuration, the glyceemic context identifier 30 may comprise a color coded strip identifier, where each color is associated with a particular glyceemic context 26. The color code may be located along the support element 10 in a range of configurations, such as a strip of colored material, or the entire strip may be colored, to correspond to a particular glyceemic context 26. For example, a black strip identifier may indicate the glyceemic context 26 of fasting. Therefore, a user should select a black strip identifier after they have been fasting for a certain period of time and wish to perform a blood glucose test. Similarly, a red glyceemic context identifier 30 may be associated with diagnostic test strips 5 intended for a post-prandial glyceemic context 26. In this case, the user should select a red glyceemic context identifier after a predetermined period of time after a meal to perform a blood glucose test.

[0033] Referring to Fig. 3, in one embodiment, the glyceemic context identifier 30 may comprise a label 32. The label 32 may textually or symbolically indicate the intended glyceemic context 26 of a particular test strip 5. The glyceemic context identifier 30 may also comprise a particular strip shape, texture, or other distinctive marking suitable to indicate to a user the intended glyceemic context 26 of the diagnostic test strip 5. The glyceemic context identifier 30 may also comprise a distinctive wrapper (not shown) for each targeted glyceemic context 26. For example, each wrapper color may be associated with a particular glyceemic context 26. The wrapper may comprise a distinctive label 32 which indicates its targeted glyceemic context 26 in addition to a particular color.

[0034] Referring again to Fig. 2, the guided structured test kit 24 may comprise a test strip container 36, a test strip meter 14, a testing protocol advisor (not shown), and at least one of the diagnostic test strips 5 described above. In one embodiment, the test strip container 36 may define an internal volume 38 configured to contain at least one of the diagnostic test strips 5. The test strip container 36 may comprise a range of shapes and configurations, such as rectangular, elliptical, rounded, and other shapes. The test strip container 36 may be sealed

to prevent the ingress of moisture through cooperation with a lid 42. In addition, in one example embodiment, the test strip container 36 may be integrated in combination with the test strip meter 14 as a single device.

[0035] In another embodiment, the test strip container 36 can have a plurality of compartments 60, within each of the plurality of compartments, a plurality of diagnostic test strips 5 having related glycemic context code 12 can be housed. For example, as illustrated in Fig. 5, a three compartment test strip container 36 could be configured so that in the first compartment 62, the fasting diagnostic test strips 5 are housed; in the second compartment 64, the pre-prandial diagnostic test strips 5 are housed; and in the third compartment 66, the post-prandial diagnostic test strips 5 are housed. In addition, the plurality of compartments 60 can have particular lids 70 to prevent the ingress of moisture and can be labeled such that the user can easily identify the glycemic context code 12 for each diagnostic test strip 5 by, for example, labeling the top of the compartments 60 with the type of diagnostic strip 5 contained within. This labeling can be realized by text, colour or tangible identifier such as a tangible form or texture. In contrast to having the glycemic context code 12 directly on the diagnostic test strip 5, the glycemic context code 12 can be also somewhere on/or in the test strip container 36 so that the glycemic context code 12 for the related test strip 5 is assigned to the associated compartment 60 of the test strip container 36. For example, different glycemic context codes 12 can be labeled on the particular lids 70 of the compartments 60 so that different compartments 60 can be assigned to different glycemic context codes 12. By labeling the compartments 60, the glycemic context code 12 can be related to the diagnostic test strips 5 within the compartment 60 of the test strip container 36 so that a diagnostic test strip 5 can be assigned a glycemic context code 12 even if the glycemic context code 12 is not directly on the diagnostic test strip 5 itself.

[0036] Although a three compartment test strip container 36 is described, it can be envisioned that other plurality of compartments 60 could be used without deviating from the scope of the present invention such as, for example, a seven compartment test strip container 36, wherein each compartment 60 represents a day of the week and houses the diagnostic test strips 5 that need to be used for that particular day; a two compartment test strip container 36, wherein one compartment 60 contains a pre-event diagnostic test strips 5 the other compartment 60 contains post-event diagnostic test strips 5, such as, for example, pre- and post-exercise; or any other suitable plurality of compartment test strip container 36.

[0037] The guided structure testing kit 24 may comprise a context identifier legend 40. The context identifier legend 40 may comprise instructions that indicate which glycemic context identifier 30 is associated with each glycemic context 26 to prevent the use of an improper diagnostic test strip 5 with a different glycemic context 26. The context identifier legend 40 may be provided as a separate document or instruction manual, or may be integrated into the kit 24, the container 36 or the meter 14, or may be digitally displayed.

[0038] Referring to Fig. 7, in another embodiment, the guided structured test kit 24 can comprise a lid 42. The lid 42 may comprise a display 44. The display 44 may be configured to provide a visual notification to a user of at least one glycemic testing protocol 46. Alternatively, the display 44 may be provided on the test strip meter 14 (Fig. 3).

[0039] The visual notification may comprise a calendar comprising appointments organized by dates. The visual notification may also be a signal indicative of the time of the testing, and type of context. The display 44 may comprise an e-paper display, LED, OLED, or other display system as will be appreciated by one of ordinary skill. The visual notification may comprise an icon, or textual message to the user to perform a blood glucose test, and may indicate which glycemic context identifier 30 or what glycemic context 26 is being targeted.

[0040] Referring to Fig. 6, a testing protocol advisor 50 may notify a user of at least one glycemic testing protocol 46. In one example embodiment, the testing protocol advisor 50 may be implemented as a paper tool. The paper tool may be provided to the user, for example, as a hardcopy or it may be downloaded and printed. In one embodiment, the paper tool testing protocol advisor can be attached to the guided structured test kit 24 by, for example, adhesive or the like. The paper tool testing protocol advisor can be attached to the guided structured test kit 24 in such a way that the paper tool can be easily visible to the user. In one example embodiment, as illustrated in Fig. 7, the testing protocol advisor 50 can be displayed on the outside top of the lid 42 of the guided structured test kit 24. In another embodiment, the testing protocol advisor can be displayed on the inside of the lid 42 of the guided structured test kit 24. In yet another embodiment, the testing protocol advisor can be displayed on a side of the guided structured test kit 24 or any other foreseeable location.

[0041] In another example embodiment, the testing protocol advisor 50 may comprise a programmed functionality embodied on a processor and memory system device 58 (Figs. 3 and 7). The testing protocol advisor may be integrated into the guided structured test kit 24,

or the test strip meter 14. The testing protocol advisor 50 may comprise a processor and memory system device 58, programmed to perform the functions described throughout the application, integrated into the memory system 56 and processor 52 of the test strip meter 14 (Fig. 3), or may comprise a stand alone processor and memory system device 58 associated with a display 44 (Fig. 7).

[0042] The glycemic testing protocol 46 may comprise a plurality of scheduled tests 48. Each schedule test 48 may comprise a date/time stamp, and a glycemic context 26. The plurality of scheduled tests 48 may be pre-arranged according to the patient's recommended testing routine, with a certain number of blood glucose tests performed each day, at certain times and glycemic contexts 26.

[0043] In one configuration, the testing protocol advisor 50 may associate at least one of the scheduled tests 48 with a glycemic context 26 as described above. Accordingly, when a blood glucose test is conducted near the date/time and glycemic context 26 of a scheduled test 48, the testing protocol advisor may automatically associate the test result with the scheduled test 48. Alternatively, a user may manually associate a blood glucose test 28 with at least one scheduled test 48, and at least one glycemic context 26. Additional testing protocols 46 may be programmed and selected, as may be desired by a user.

[0044] Referring again to Fig. 2, in another embodiment, if a diagnostic test strip 5 is inserted into, or scanned by, the test strip meter 14, or alternatively, if the user manually enters a glycemic context of the diagnostic test strip 5 into the test strip meter 14, that indicates a glycemic context incompatible with the glycemic context 26 associated with the scheduled test 48, the processor 54 of the test strip meter 14 may be configured to present a signal to the user that the diagnostic test strip 5 has a glycemic context code 12 programmed for a different glycemic context 26 than prescribed. The testing protocol advisor 50 may be configured to notify the user what glycemic context 26 is targeted, and the glycemic context code 12 of the mistakenly inserted test strip 5. The signal may comprise a visual, audible, or mechanical signal, such as a vibration, flashing light, or beep. Referring to Fig. 6, in another configuration, if at least one scheduled test 48 is missed, the test strip meter 14 may signal to a user that a test should be performed.

[0045] In one embodiment, the glycemic testing protocol 46 may be programmable by a user to suit their own needs or schedule. The testing protocol advisor 50 may interact with a computer or similar textual input device to view and/or modify the testing protocol 46 and at

least one scheduled test 48. The testing protocol 46 may be viewed using a calendar, with at least one scheduled test 48. The testing protocol 46 may be printed in a hard-copy format, or may be downloaded into guided structured test kit 24 mentioned above. A variety of connection types are contemplated, as will be appreciated by one of ordinary skill.

[0046] Referring again to Fig. 2, in another embodiment, the processor 54 of the test strip meter 14 can override the glycemic context 26 indicated by the glycemic context code 12 of the diagnostic test strip 5. For example, if a user selects a "pre-fasting strip," and inserts it into the test strip meter 14, the processor 54 of the test strip meter 14 may display on display 44 a message to the user asking "Is this a pre-fasting test?" At this point, the processor 54 of the test strip meter 14 may query the user to confirm the test, or pick an alternative glycemic context 26 from a presented list.

[0047] In another embodiment, the testing protocol advisor 50 running on the test strip meter 14 can query the user if the blood glucose measure value is not reasonable and/or plausible for the glycemic content code 12 of the used diagnostic test strip 5. For example, if a "pre-fasting" strip is selected and processor 54 of the test strip meter 14 measures an unreasonable high blood glucose value, the processor 54 of the test strip meter 14 may display on display 44 a message to user asking "Are you sure you fasted?" At this point, the processor 54 of the test strip meter 14 may query the user to repeat the test, confirm the test, or pick an alternative glycemic context 26 from a presented list or any other foreseeable alternative. In another example, the processor 54 of the test strip meter 14 can calculate the time stamps between an indicated pre-prandial test and an indicated post-prandial test. If the time difference between the two tests is outside an allowable predefined time window, the processor 54 of the test strip meter 14 may display on display 44 a message to user asking "Are you sure this is a post-prandial measurement?" The processor 54 of the test strip meter 14 then may ask the user, in this example, to select another diagnostic test strip 5 and/or answer additional questions regarding potentially missing tests.

[0048] In yet another embodiment, the testing protocol advisor 50 may comprise at least one strip sensor configured to detect when at least one of the scheduled tests 48 has been performed. The testing protocol advisor 50 may review the results of the at least one scheduled tests 48 in the at least one glycemic test protocols 46 and determine which scheduled tests 48 have been performed. The testing protocol advisor 50 may assign a 'status'

to each of the scheduled tests 46, corresponding to whether the processor 54 of the test strip meter 14 has recorded a blood glucose test result for that scheduled tests 48.

[0049] The status of the at least one scheduled test strip 5 may comprise "completed," "missed," "late," and other indicators as will be appreciated by one of ordinary skill. The testing protocol advisor 50 may be programmed to inform a user of a recommended action based on the status of the at least one scheduled glycemic test 48. For example, if the status of the at least one scheduled glycemic test 48 is "missed," the testing protocol advisor 50 may be programmed to inform a user that another blood glucose test should be performed at the next glycemic context. Alternatively, if the status is "missed," the testing protocol advisor 50 may be programmed to inform a user to perform a blood glucose test immediately. It is also contemplated that the testing protocol advisor may advise a user to perform other actions compatible with the glycemic testing protocol, such as exercise, eat, take insulin, or perform the next scheduled test.

[0050] In an exemplary embodiment, the glycemic testing protocol 46 may be a structured testing protocol such as those structured testing protocols described in U.S. Patent Application 11/424,757 filed June 16, 2006 entitled "System and method for collecting patient information from which diabetes therapy may be determined;" U.S. Patent Application 12/643,338 filed December 21, 2009 entitled "Structured Testing Method for Diagnostic or Therapy Support of a Patient with a Chronic Disease and Devices thereof;" and U.S. Patent Application 12/643,415 filed December 21, 2009 entitled "Management Method and System for Implementation, Execution, Data Collection, and Data Analysis of a Structured Collection procedure which runs on a Collection Device," all of which are assigned to Roche Diagnostics Operations, Inc. The structured testing parameters may be preprogrammed into testing protocol advisor or may be manually programmed by the user or the user's health care provider. The structured testing parameters may reside in the test strip meter 14 or may be implemented as a paper tool or may be a combination of both.

[0051] In one example embodiment of a programmed testing protocol advisor, it is to be appreciated that the processor 54 of the testing protocol advisor can implement one or more structured glycemic testing protocol 46 provided in the memory device 56. Each structured glycemic testing protocol 46, in one example embodiment, can be stand-alone software, thereby providing the necessary program instructions which when executed by the

processor 54 causes the processor to perform the structured glycemic testing protocol 46 as well as other prescribed functions. In other embodiments, each structured glycemic testing protocol 46 can be part of the software, and can be then be selectively executed by the processor 54 either via receiving a selection from a menu list provided in the display 44 in the lid 42. In another embodiment, the glycemic testing protocol 46 can be implemented as a paper tool. It is to be appreciated that the software, likewise, provides the necessary program instructions which when executed by the processor 54 causes the processor to perform the structured glycemic testing protocol 46 as well as other prescribed functions of the software. One suitable example of having a selectable structured collection procedure provided as a selectable mode of a collection meter is disclosed by in U.S. Pat. Application No. 12/491,523, filed June 25, 2009, titled “Episodic Blood Glucose Monitoring System With An Interactive Graphical Diabetic person Interface And Methods Thereof,” assigned to Roche Diagnostics Operations, Inc.

[0052] In still another embodiment, a command instruction can be sent from a health care provider’s computer and received by the processor 54 via a communication module (not shown), which runs automatically the structured glycemic testing protocol 46. Such a command instruction may specify which of the one or more structured collection procedures to run and/or provide a structured collection procedure to run. In still another embodiment, a list of defined medical use cases or medical questions can be presented on the display 44 by the processor 54, and a particular structured glycemic testing protocol 46 can be automatically chosen by the processor from a plurality of structured collection procedures depending on the selection of the defined medical use cases or medical questions received by the processor or can be manually selected by the user or the user’s health care provider.

[0053] In still yet another embodiment, after selection, the structured glycemic testing protocol 46 can be provided through computer readable medium and loaded by the guided structured test kit 24, or the test strip meter 14, downloaded from a computer, or a server. The server, for example, may be a healthcare provider or company providing such pre-defined structured glycemic testing protocol 46 for downloading according to a selected defined medical use case or question. It is to be appreciated that the structured glycemic testing protocol 46 may be developed by a healthcare company and implemented via a public network through a webpage and/or made available for downloading on the server. In still other embodiments, the processor 54 may notice that a new structured glycemic testing

protocol 46 is available for use on the guided structured test kit 24 or the test strip meter 14 to help address a particular use case/medical question that a diabetic person (e.g., healthcare provider and patient) which can then be provided in any standard fashion, such for via postal letters/cards, email, text messaging, tweets, and the likes.

[0054] In some embodiments, as mentioned above previously, a paper tool can perform some of the functions provided by the diabetes software. An example of some of the functions which may be incorporated into the diabetes software and which is configured as a paper tool is the Accu-Chek® 360 View Blood Glucose Analysis System paper form available from Roche Diagnostics also disclosed in U.S. Patent Application No. 12/040,458 filed February 29, 2007 entitled “Device and method for assessing blood glucose control,” assigned to Roche Diagnostic Operations, Inc.

[0055] In this structured testing embodiment, the glycemic testing protocol 46 may have structured testing parameters defining entry, exit and adherence criteria as defined in a structured testing protocol. The entry criteria can include criteria used to determine whether to begin data collection for the structured testing protocol. The entry criterion for this exemplary embodiment may be, for example, that the user has indicated a willingness to perform the structured testing protocol or that the user has maintained his/her blood glucose level for a predetermined period of time. However, any other suitable entry criteria is foreseeable.

[0056] The adherence criteria can include criteria used in accepting or rejecting a glycemic context 26 for a diagnostic test strip 5. For example, the adherence criteria can include criteria used in determining whether the indicated glycemic context 26 of the diagnostic test strip 5 closely enough adheres to expected glycemic context 26 of that diagnostic test strip 5 associated with a properly executed structured testing protocol 46. The adherence criteria in this example embodiment can be to check, for example, if the user insert the correct diagnostic test strip 5 into the test strip meter 14 with the glycemic context 26 associated with the scheduled test 48, or if the user completed all the scheduled tests 48 within a predetermined time period, or any other suitable adherence criteria. If the user does not adhere to the structured testing glycemic testing protocol 46, the user may be notified by the testing protocol advisor 50 and/or test strip meter 14 and may be given the opportunity to test, or to re-test, depending on the adherence violation, using the correct diagnostic test strip 5 in a manner as described above for the non-structured testing protocol.

[0057] Further, the exit criteria can include criteria used to determine whether the structured testing protocol should end. In this example structured testing embodiment, the exit criterion may be, for example, that the user has successfully completed the structured testing glycemic testing protocol 46, that the user has not sufficiently adhered to the structured testing glycemic testing protocol 46 (i.e., a wrong diagnostic test strip 5 was used, a scheduled test 48 was missed), that the results of the scheduled test 48 are too high or too low for a predetermined number of times, or any other foreseeable exit criteria.

[0058] In another embodiment, a test strip meter 14 and a set of diagnostic test strips 5 with imprinted glycemic context codes 12 are provided to a user. In one embodiment, the diagnostic test strips 5 may be provided to a user in groups, pertaining to their encoded glycemic contexts 26 as described above. For example, each group of diagnostic test strips 5 may be configured to signal a different glycemic context 26. For example, the groups may include approximately ten diagnostic test strips 5 having glycemic context codes twelve configured to signal a pre-prandial glycemic context 26; approximately ten diagnostic test strips 5 configured to signal a post-prandial glycemic context 26; and approximately ten diagnostic test strips 5 configured to signal a fasting glycemic contexts 26, etc. Other group sizes and groupings may also be provided, as will be appreciated by one of ordinary skill.

[0059] The user may select from the plurality of test strips 5, a diagnostic test strip 5 having a glycemic context code 12 appropriate to signal the proper glycemic context 26 pertaining to the user's glycemic state. The glycemic context identifier 30 may comprise an identifier suitable to convey the glycemic context 26 associated with a particular diagnostic test strip's glycemic context code 12. For example, a diagnostic test strip 5 having a glycemic context code 12 configured to signal a pre-prandial glycemic context 26, it may have a glycemic context identifier 30 comprising a blue color strip. Each glycemic context 26 may have a distinct glycemic context identifier 30, so a user can quickly identify which diagnostic test strip 5 is configured to signal the appropriate glycemic context 26. The glycemic context identifier 30 may be selected from the group, including, but not limited to, a color code (not shown); a label 32 (Fig. 3); and combinations thereof. A context identifier legend 40 may also be provided to the user.

[0060] In this embodiment, the user can simply be instructed to use the set of diagnostic test strips 5 as indicated by the glycemic context identifier 30 with the test strip meter 14. Therefore, in this embodiment, a protocol advisor may not be needed. The user can

simply be guided by the glycemic context code 12 itself. In other words, the user can be taught by the glycemic context code 12 under which conditions blood glucose tests should be taken. It also may be helpful to use a glycemic context code 12 which is readily identified to the user by, for example, look or feel, to quickly identify under which the conditions the blood glucose test should be taken. The taken blood glucose test can then be stored together with the glycemic context 26 either automatically, e.g., by being read by the test strip meter 14, or manually, e.g., via a data input by the user. Therefore, it may be possible to establish a testing protocol without having a protocol advisor. The data can then be evaluated and reported taking into account the established structured measurement procedure. Moreover, a testing protocol can be established by storing the information of the glycemic context code 12 and automatically generating a reminder system based on the stored information. For example, if it is determined that the user typically takes a blood glucose measurement within specific time windows and/or under specific conditions such that a pattern might be detected, an alarm can be generated if that specific time window and/or conditions are detected.

[0061] For example, in one embodiment, the user can use the diagnostic test strip 5 marked with the fasting glycemic context identifier 30 after waking up, or after fasting for a predetermined amount of time; the diagnostic test strip 5 marked with the pre-prandial glycemic context identifier 30 before every meal; and the diagnostic test strip 5 marked with the post-prandial glycemic context identifier 30 after a predetermined time after every meal. In one embodiment, after a predetermined amount of time, the user and health care provider can review the blood glucose measurement results as they are typically stored in the test strip meter 14. If the user correctly adheres to using the right diagnostic test strip 5 with the right associated glycemic context of the event, e.g., fasting or meals, the user can create simply and cheaply a structured test protocol by reviewing these blood glucose values.

[0062] For the purposes of describing and defining the present invention, it is noted that reference herein to a variable being a “function” of a parameter or another variable is not intended to denote that the variable is exclusively a function of the listed parameter or variable. Rather, reference herein to a variable that is a “function” of a listed parameter is intended to be open ended such that the variable may be a function of a single parameter or a plurality of parameters.

[0063] It is also noted that recitations herein of “at least one” component, element, etc., should not be used to create an inference that the alternative use of the articles “a” or “an” should be limited to a single component, element, etc.

[0064] It is noted that recitations herein of a component of the present disclosure being “programmed” in a particular way, “configured” or “programmed” to embody a particular property, or function in a particular manner, are structural recitations, as opposed to recitations of intended use. More specifically, the references herein to the manner in which a component is “programmed” or “configured” denotes an existing physical condition of the component and, as such, is to be taken as a definite recitation of the structural characteristics of the component.

[0065] It is noted that terms like “preferably,” “commonly,” and “typically,” when utilized herein, are not utilized to limit the scope of the claimed invention or to imply that certain features are critical, essential, or even important to the structure or function of the claimed invention. Rather, these terms are merely intended to identify particular aspects of an embodiment of the present disclosure or to emphasize alternative or additional features that may or may not be utilized in a particular embodiment of the present disclosure.

[0066] For the purposes of describing and defining the present invention it is noted that the terms “substantially” and “approximately” are utilized herein to represent the inherent degree of uncertainty that may be attributed to any quantitative comparison, value, measurement, or other representation. The terms “substantially” and “approximately” are also utilized herein to represent the degree by which a quantitative representation may vary from a stated reference without resulting in a change in the basic function of the subject matter at issue.

[0067] Having described the subject matter of the present disclosure in detail and by reference to specific embodiments thereof, it is noted that the various details disclosed herein should not be taken to imply that these details relate to elements that are essential components of the various embodiments described herein, even in cases where a particular element is illustrated in each of the drawings that accompany the present description. Rather, the claims appended hereto should be taken as the sole representation of the breadth of the present disclosure and the corresponding scope of the various inventions described herein. Further, it will be apparent that modifications and variations are possible without departing from the scope of the invention defined in the appended claims. More specifically, although some

aspects of the present disclosure are identified herein as preferred or particularly advantageous, it is contemplated that the present disclosure is not necessarily limited to these aspects.

[0068] It is noted that one or more of the following claims utilize the term “wherein” as a transitional phrase. For the purposes of defining the present invention, it is noted that this term is introduced in the claims as an open-ended transitional phrase that is used to introduce a recitation of a series of characteristics of the structure and should be interpreted in like manner as the more commonly used open-ended preamble term “comprising.”

[0069] In the following some embodiments of the invention are described:

1. A diagnostic test strip, the diagnostic test strip comprising: a support element; a glucose reagent provided on the support element; and a glycemic context code provided on the support element, wherein the glycemic context code indicates a glycemic context for the diagnostic test strip.
2. The diagnostic test strip of embodiment 1, wherein a user inputs the glycemic context code into a test strip meter, wherein the glycemic context code indicates the glycemic context of the diagnostic test strip to a test strip meter.
3. The diagnostic test strip of embodiment 2, wherein the glycemic context code is an optical signaling indicia, a mechanical signaling indicia, or combinations thereof.
4. The diagnostic test strip of embodiment 1, wherein the glycemic context code is machine-readable.
5. The diagnostic test strip of embodiment 4, wherein the glycemic context code indicates a glycemic context to a test strip meter upon insertion of the diagnostic test strip.
6. The diagnostic test strip of embodiment 4, wherein the machine-readable glycemic context code is an optical signaling indicia, an electrical signaling indicia, a mechanical signaling indicia, or combinations thereof.
7. The diagnostic test strip of embodiment 6, wherein the optical signaling indicia is a bar code, a hole pattern, a color, or combinations thereof.
8. The diagnostic test strip of embodiment 6, wherein the mechanical signaling indicia is an indent pattern, a hole pattern, strip width or combinations thereof.
9. The diagnostic test strip of embodiment 6, wherein the electrical signal indicia is a resistance pattern, capacitance pattern, break pattern, or combinations thereof.

10. The diagnostic test strip of embodiment 1, wherein the glycemic context sets the condition under which the measurement is taken as pre-prandial, post-prandial, pre-event; post-event, fasting, bedtime, or combinations thereof.
11. The diagnostic test strip of embodiment 1, wherein a plausibility check is executed with respect to the glycemic context and a signal is provided if an incorrect glycemic context is provided.
12. The diagnostic test strip of embodiment 12, wherein the plausibility check is based on the time, the current measured blood glucose value, historical data or combinations thereof.
13. The diagnostic test strip of embodiment 1, wherein a signal is provided if a scheduled test is missed.
14. The diagnostic test strip of embodiment 13, wherein the scheduled test is determined to be missed based on information about the time, the current measured blood glucose value, historical data or combinations thereof.
15. A guided structured testing kit comprising a test strip container, a test strip meter, a testing protocol advisor, and at least one of diagnostic test strip, wherein the at least one of the diagnostic test strip comprises a support element, a glucose reagent provided on the support element, and a glycemic context code provided on the support element, wherein the glycemic context code provides a glycemic context of the at least one diagnostic test strip, wherein the test strip container defines an internal volume to hold the at least one diagnostic test strip, and wherein the testing protocol advisor notifies a user of an at least one glycemic testing protocol.
16. The guided structured testing kit of embodiment 15, wherein the test strip meter comprises a memory system to store the signaled glycemic context of the at least one diagnostic test strip, and associate the signaled glycemic context with a blood glucose test result provided by the at least one diagnostic test strip, and wherein the testing protocol advisor is provided on the guided structured testing kit.
17. The guided structured testing kit of embodiment 15, wherein the test strip meter comprises a memory system to store the signaled glycemic context of the at least one diagnostic test strip, and associate the signaled glycemic context with a blood glucose test result provided by the at least one diagnostic test strip, and wherein the testing protocol advisor is integrated into the test strip meter.

18. The guided structured testing kit of embodiment 15, wherein the guided structured testing kit further comprises a lid, wherein the lid comprises at least one display, wherein the at least one display provides a visual notification of the at least one glycemic testing protocol.
19. The guided structured testing kit of embodiment 18, wherein the visual notification comprises a calendar comprising a plurality of scheduled tests.
20. The guided structured testing kit of embodiment 15, wherein the at least one glycemic testing protocol comprises at least one scheduled glycemic test.
21. The guided structured testing kit of embodiment 20, wherein the testing protocol advisor detects the status of the at least one of scheduled glycemic test.
22. The guided structured testing kit of embodiment 21, wherein the testing protocol advisor comprises a device to inform a user of a recommended action based on the status of the at least one scheduled glycemic test.
23. The guided structured testing kit of embodiment 15, wherein the glycemic testing protocol is programmable by a user.
24. The guided structured testing kit of embodiment 15, wherein the at least one diagnostic test strip comprises a glycemic context identifier corresponding to the indicated glycemic context of the at least one diagnostic test strip.
25. A method for performing a guided structured test, the method comprising: providing a diagnostic test strip having a glycemic context code associated with the diagnostic test strip and a test strip meter; executing a blood glucose measurement by the diagnostic test strip and the test strip meter before or after signaling a glycemic context to the test strip meter from the glycemic context code associated with the diagnostic test strip and storing the glycemic context into a memory of the test strip meter; and associating the signaled glycemic context with a blood glucose test result provided by the diagnostic test strip and storing the blood glucose test result with the glycemic context.
26. The method of embodiment 25, further comprising, evaluating the blood glucose test result in conjugation with the glycemic context associated with that blood glucose test result.
27. The method of embodiment 25, further comprising, generating a report with respect to the blood glucose test result and the glycemic context associated with that blood glucose test result.
28. The method of embodiment 25, further comprising, establishing a reminder system based on historically stored glycemic context to remind the user to execute an action.

29. The method of embodiment 25, wherein the glycemic context is pre-prandial, post-prandial, pre-event, post-event, fasting, bedtime, or combinations thereof.
30. The method of embodiment 25, wherein the glycemic context code is machine-readable.
31. The method of embodiment 30, wherein the machine-readable glycemic context code is an optical signaling indicia, an electrical signaling indicia, a mechanical signaling indicia, or combinations thereof.
32. A guided structured testing kit comprising a lid, a test strip container, a test strip meter, a testing protocol advisor, and at least one of diagnostic test strip, wherein the test strip container defines at least one internal volume to hold the at least one diagnostic test strip, wherein the testing protocol advisor notifies a user of an at least one glycemic testing protocol, and wherein the lid comprises at least one display, wherein the at least one display provides a visual notification of the at least one glycemic testing protocol comprising a plurality of scheduled tests.
33. The guided structured testing kit of embodiment 32, wherein the testing protocol advisor is programmed with structured testing parameters.
34. A test strip container, the test strip container comprising: at least one internal volume to hold at least one diagnostic test strip; a plurality of a compartments, wherein each compartment houses at least one diagnostic test strip, wherein each diagnostic test strip comprises, a support element, a glucose reagent provided on the support element, and at least one glycemic context code provided on the test strip container and associated with each compartment in the plurality, wherein the glycemic context code indicates a glycemic context for the diagnostic test strip housed within each compartment.

CLAIMS:

1. A diagnostic test strip for assaying blood, the diagnostic test strip comprising:
 - a support element;
 - a glucose reagent, which reacts with glucose in the blood, provided on the support element; and
 - a machine-readable glycemic context code provided on the support element, wherein the glycemic context code indicates a glycemic context of a blood glucose test for the diagnostic test strip.
2. The diagnostic test strip of claim 1, wherein the glycemic context code indicates the glycemic context of the diagnostic test strip to a test strip meter.
3. The diagnostic test strip of claim 1 or 2, wherein the glycemic context code is an optical signaling indicia, an electrical signaling indicia, a mechanical signaling indicia, or combinations thereof.
4. The diagnostic test strip of claim 2 or 3, wherein the glycemic context code indicates the glycemic context to the test strip meter upon insertion of the diagnostic test strip into the test strip meter.
5. The diagnostic test strip of claim 3, wherein the optical signaling indicia is a bar code, a hole pattern, a color, or combinations thereof.
6. The diagnostic test strip of claim 3, wherein the mechanical signaling indicia is an indent pattern, a hole pattern, strip width or combinations thereof.
7. The diagnostic test strip of claim 3, wherein the electrical signal indicia is a resistance pattern, capacitance pattern, break pattern, or combinations thereof.

8. The diagnostic test strip of any one of claims 1-7, wherein the glycemic context sets the condition under which a measurement of the blood is taken as pre-prandial, post-prandial, pre-event, post-event, fasting, bedtime, or combinations thereof.
9. A guided structured testing kit for assaying blood comprising a test strip container, a test strip meter, a testing protocol advisor, and at least one diagnostic test strip, wherein the at least one diagnostic test strip comprises a support element, a reagent which reacts with glucose in the blood provided on the support element, and a machine-readable glycemic context code provided on the support element, wherein the glycemic context code provides a glycemic context of a blood glucose test of the at least one diagnostic test strip, wherein the test strip container defines an internal volume to hold the at least one diagnostic test strip, and wherein the testing protocol advisor notifies a user of an at least one glycemic testing protocol and is provided in the testing kit as a paper tool, on the testing kit as a paper tool, in the testing kit as a stand-alone electronic device or electronically by the test strip meter.
10. The guided structured testing kit of claim 9, wherein the test strip meter comprises a memory system configured to store the glycemic context of the at least one diagnostic test strip when inputted into the test strip meter, and associate the inputted glycemic context with a blood glucose test result provided by the at least one diagnostic test strip.
11. The guided structured testing kit of claim 9 or 10, wherein the test strip container of the guided structured testing kit further comprises a lid, wherein the lid comprises at least one display, wherein the at least one display provides a visual notification of the at least one glycemic testing protocol.
12. The guided structured testing kit of claim 11, wherein the visual notification comprises a calendar comprising a plurality of scheduled tests.

13. The guided structured testing kit of any one of claims 9-12, wherein the at least one glycemic testing protocol comprises at least one scheduled glycemic test.
14. The guided structured testing kit of claim 13, wherein the testing protocol advisor detects the status of the at least one of scheduled glycemic test.
15. The guided structured testing kit of claim 14, wherein the testing protocol advisor comprises a device to inform the user of a recommended action based on the status of the at least one scheduled glycemic test.
16. The guided structured testing kit of any one of claims 9-15, wherein the glycemic testing protocol is programmable by the user.
17. A method for performing a guided structured test for assaying blood, the method comprising:
 - providing a diagnostic test strip having a machine-readable glycemic context code indicating a glycemic context of a blood glucose test for the diagnostic test strip and a glucose reagent which reacts with glucose in blood associated with the diagnostic test strip and a test strip meter; applying blood to the diagnostic test strip;
 - executing a blood glucose measurement on the blood by inserting the diagnostic test strip into the test strip meter; and
 - signaling a glycemic context to the test strip meter by inputting the glycemic context code associated with the diagnostic test strip into the test strip meter, wherein the test strip meter associates the signaled glycemic context with a blood glucose test result provided by the diagnostic test strip and stores the blood glucose test result with the glycemic context in a memory of the test strip meter.
18. The method of claim 17, further comprising, evaluating the blood glucose test result in conjugation with the glycemic context associated with that blood glucose test result.

19. The method of claim 17 or 18, further comprising, generating a report with respect to the blood glucose test result and the glycemic context associated with that blood glucose test result.
20. The method of any one of claims 17-19, further comprising, establishing a reminder system based on historically stored glycemic context from the memory of the test strip meter which reminds a user to execute a blood glucose measurement within a specific time window and/or under specific conditions that have been determined from the historically stored glycemic context.
21. The method of any one of claims 17-20, wherein the glycemic context is pre-prandial, post-prandial, pre-event, post-event, fasting, bedtime, or combinations thereof.
22. The method of claim 17, wherein the machine-readable glycemic context code is an optical signaling indicia, an electrical signaling indicia, a mechanical signaling indicia, or combinations thereof.
23. The method of claim 17, wherein a plausibility check is executed automatically by the test strip meter with respect to the glycemic context inputted via the glycemic context code and a signal is provided by the test strip meter if an incorrect glycemic context is provided.
24. The method of claim 23, wherein the plausibility check is based on a time, a current measured blood glucose value, historical data or combinations thereof.
25. The method of claim 17, wherein a signal is provided if a scheduled test is missed.
26. The method of claim 25, wherein the scheduled test is determined to be missed based on information about a time, a current measured blood glucose value, historical data or combinations thereof.

27. A guided structured testing kit for assaying blood comprising a test strip container, a test strip meter, a testing protocol advisor, and at least one diagnostic test strip, wherein the at least one diagnostic test strip comprises a support element, a reagent which reacts with glucose in the blood provided on the support element, and a machine-readable glycemic context code provided on the support element, wherein the glycemic context code provides a glycemic context of a blood glucose test of the at least one diagnostic test strip,

wherein the test strip container defines at least one internal volume to hold the at least one diagnostic test strip and comprises a lid,

wherein the testing protocol advisor notifies a user of an at least one glycemic testing protocol, and is provided in the testing kit as a paper tool, on the testing kit as a paper tool, in the testing kit as a stand-alone electronic device or electronically by the test strip meter, and

wherein the lid comprises at least one display, wherein the at least one display provides a visual notification of the at least one glycemic testing protocol comprising a plurality of scheduled tests.

28. The guided structured testing kit of claim 27, wherein the testing protocol advisor is programmed with structured testing parameters.

29. A test strip container, the test strip container comprising:

at least one internal volume to hold at least one diagnostic test strip;

a plurality of a compartments, wherein each compartment houses at least one diagnostic test strip, wherein each diagnostic test strip comprises,

a support element,

a glucose reagent, which reacts with glucose in blood, provided on the support element, and

at least one machine-readable glycemic context code provided on the test strip container and associated with each compartment in the plurality, wherein the glycemic context code indicates a glycemic context of a blood glucose test for the diagnostic test strip housed within each compartment.

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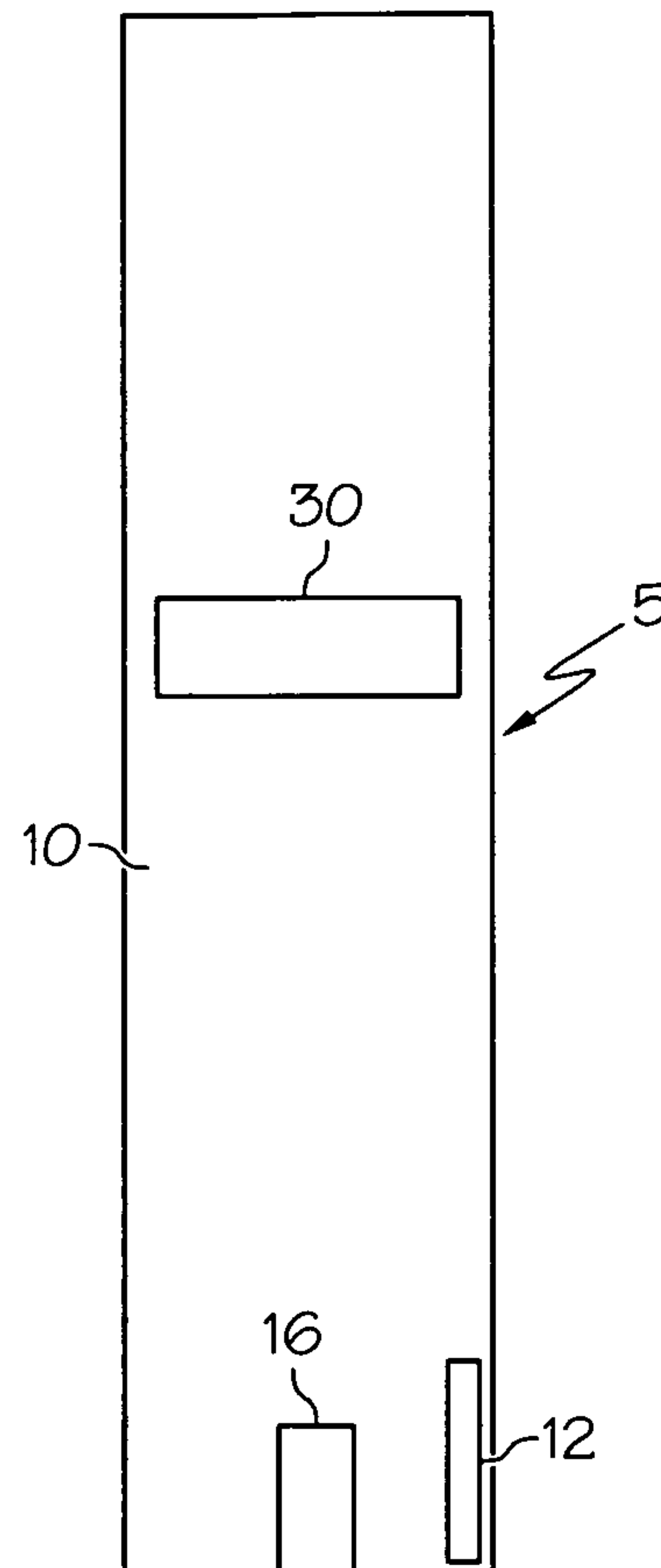


FIG. 1A

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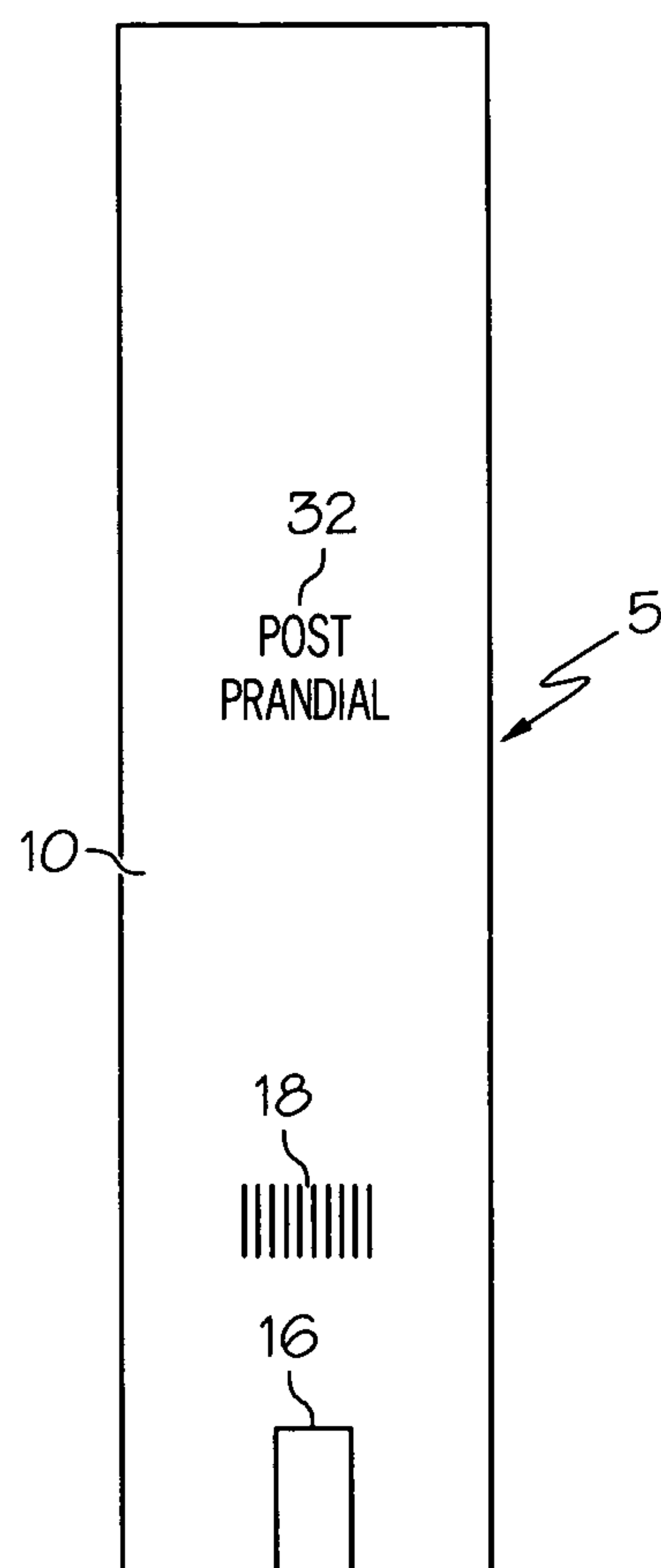


FIG. 1B

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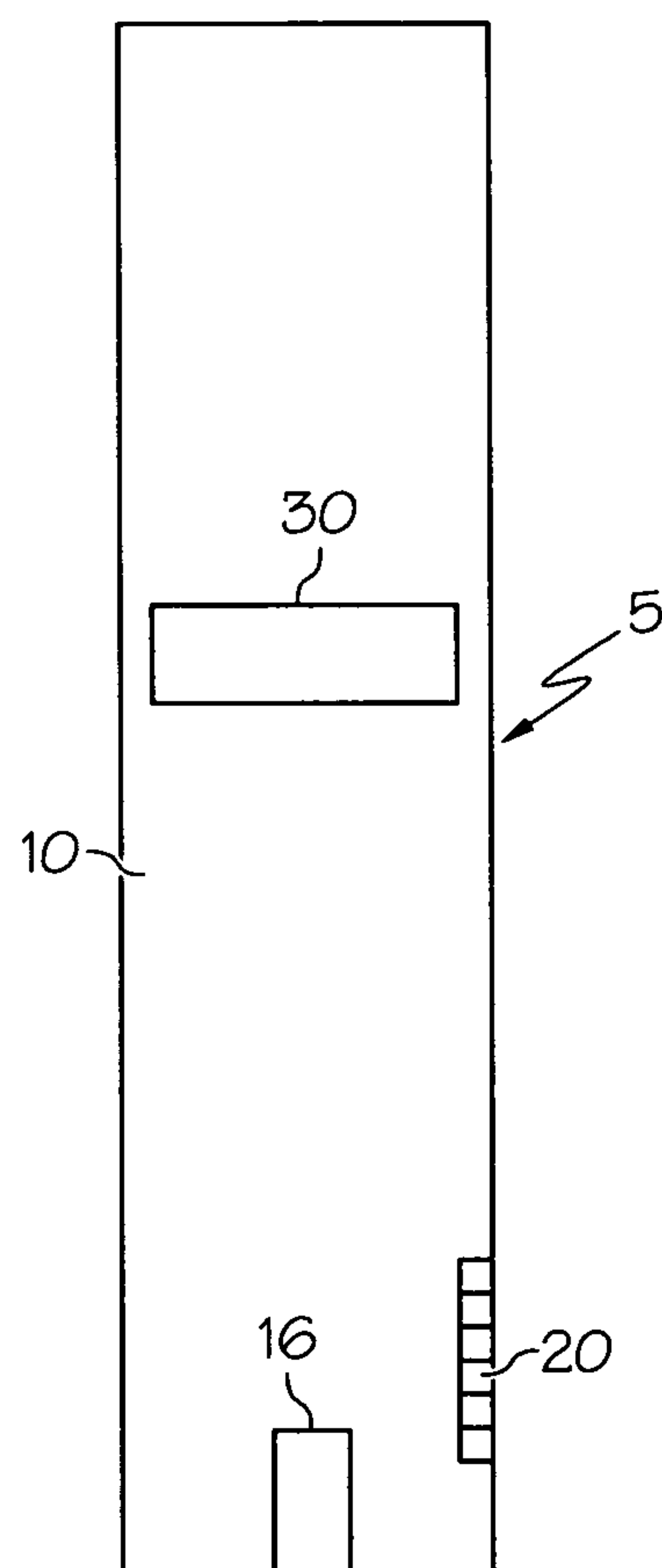


FIG. 1C

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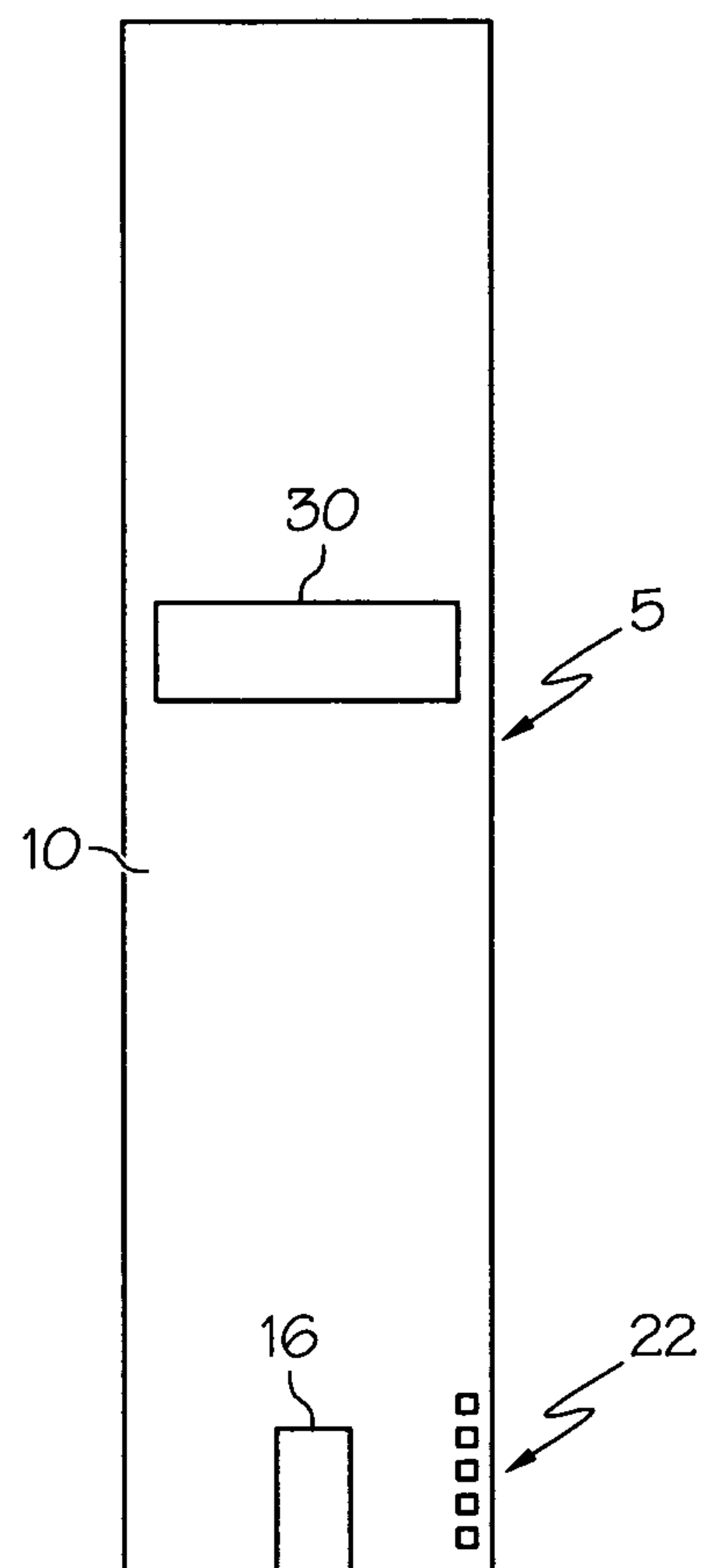


FIG. 1D

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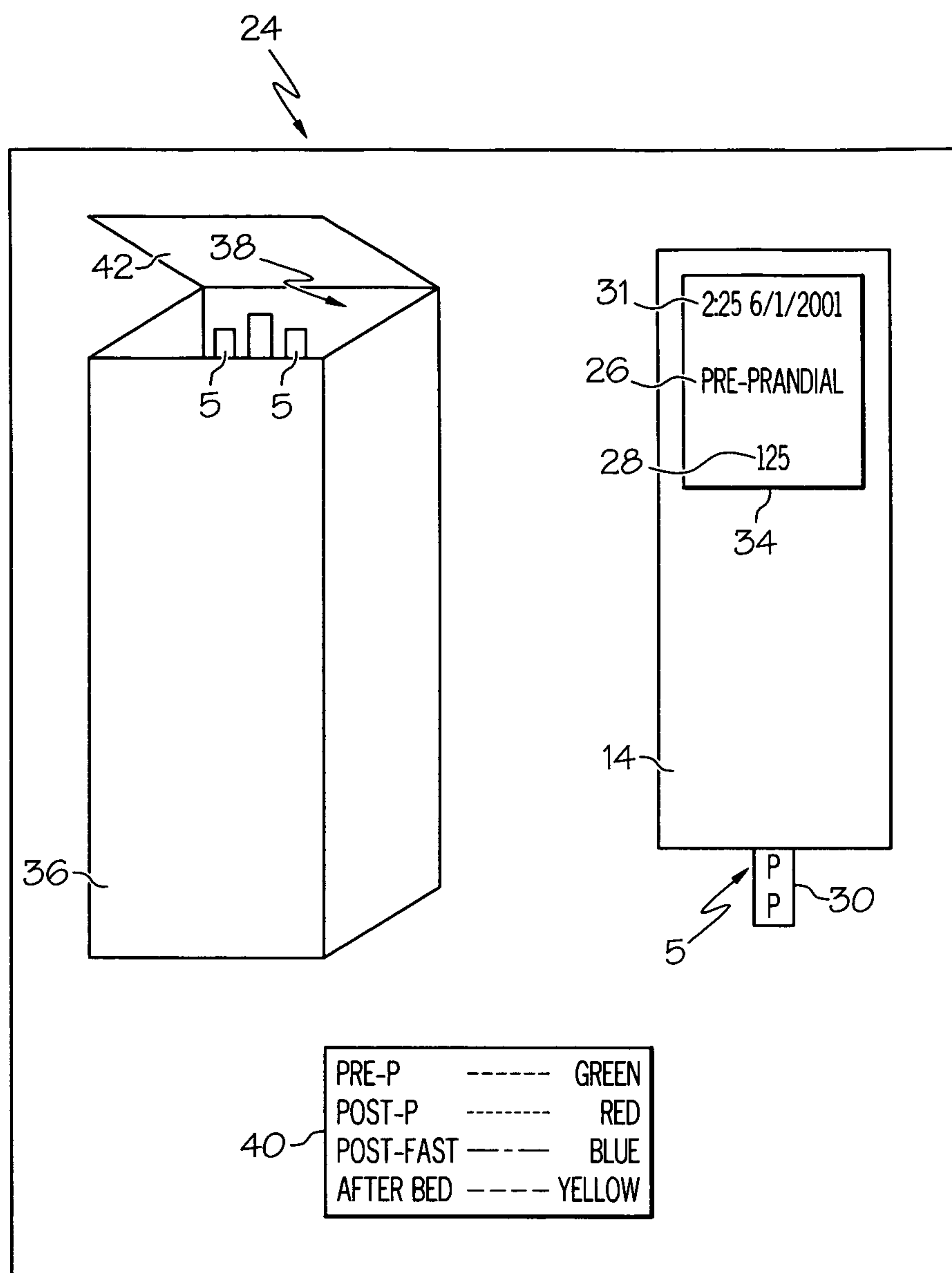


FIG. 2

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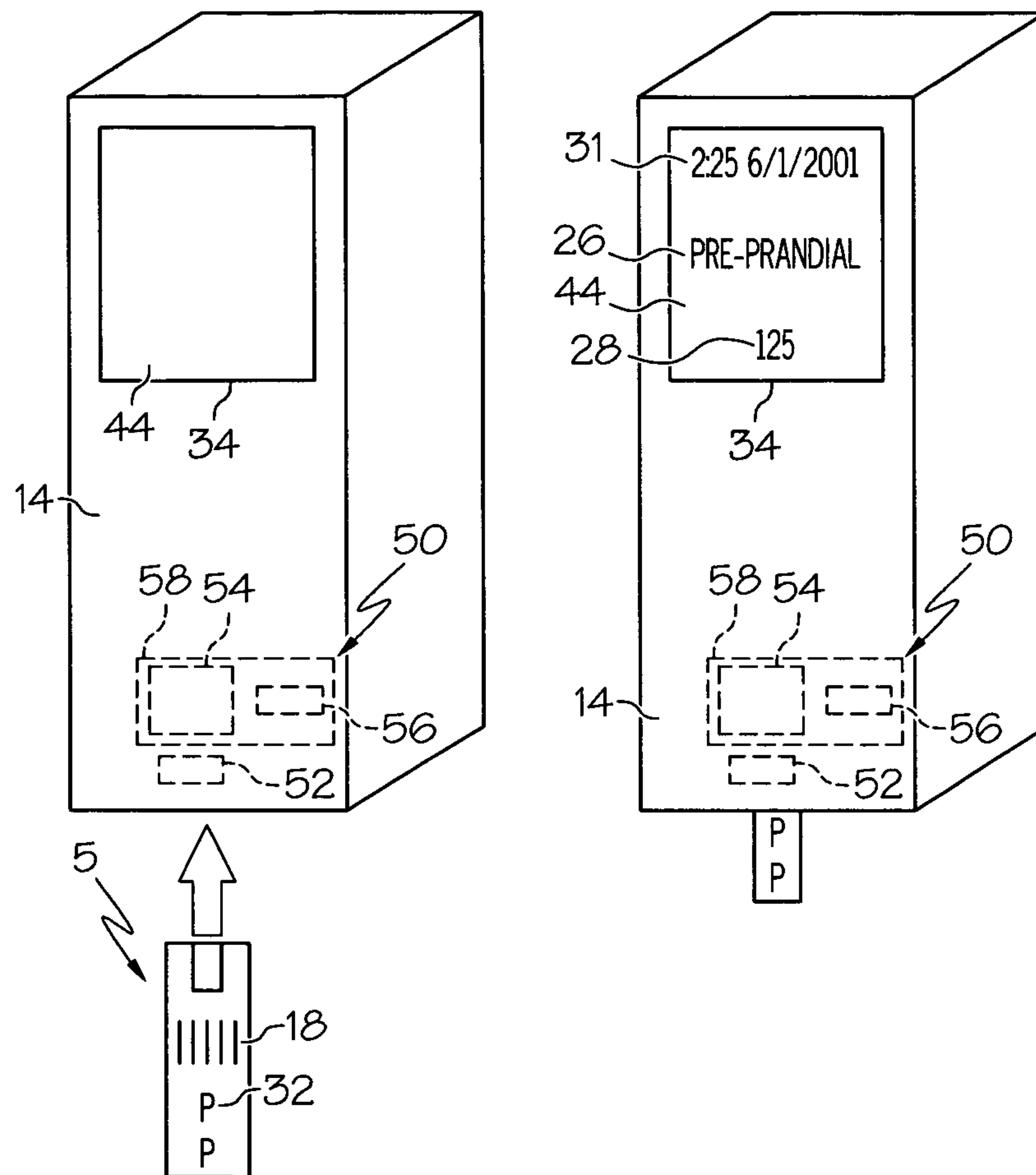


FIG. 3

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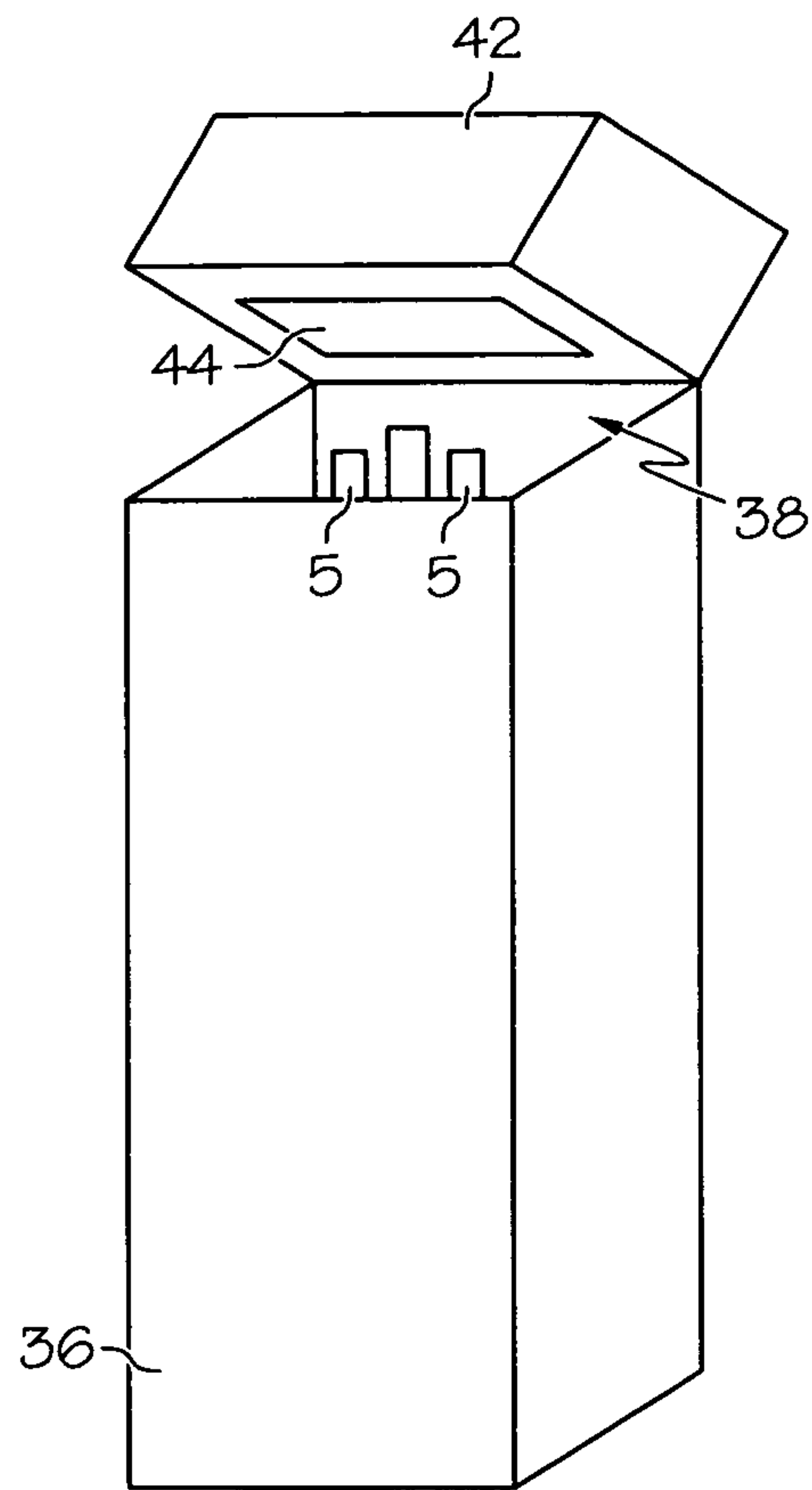


FIG. 4

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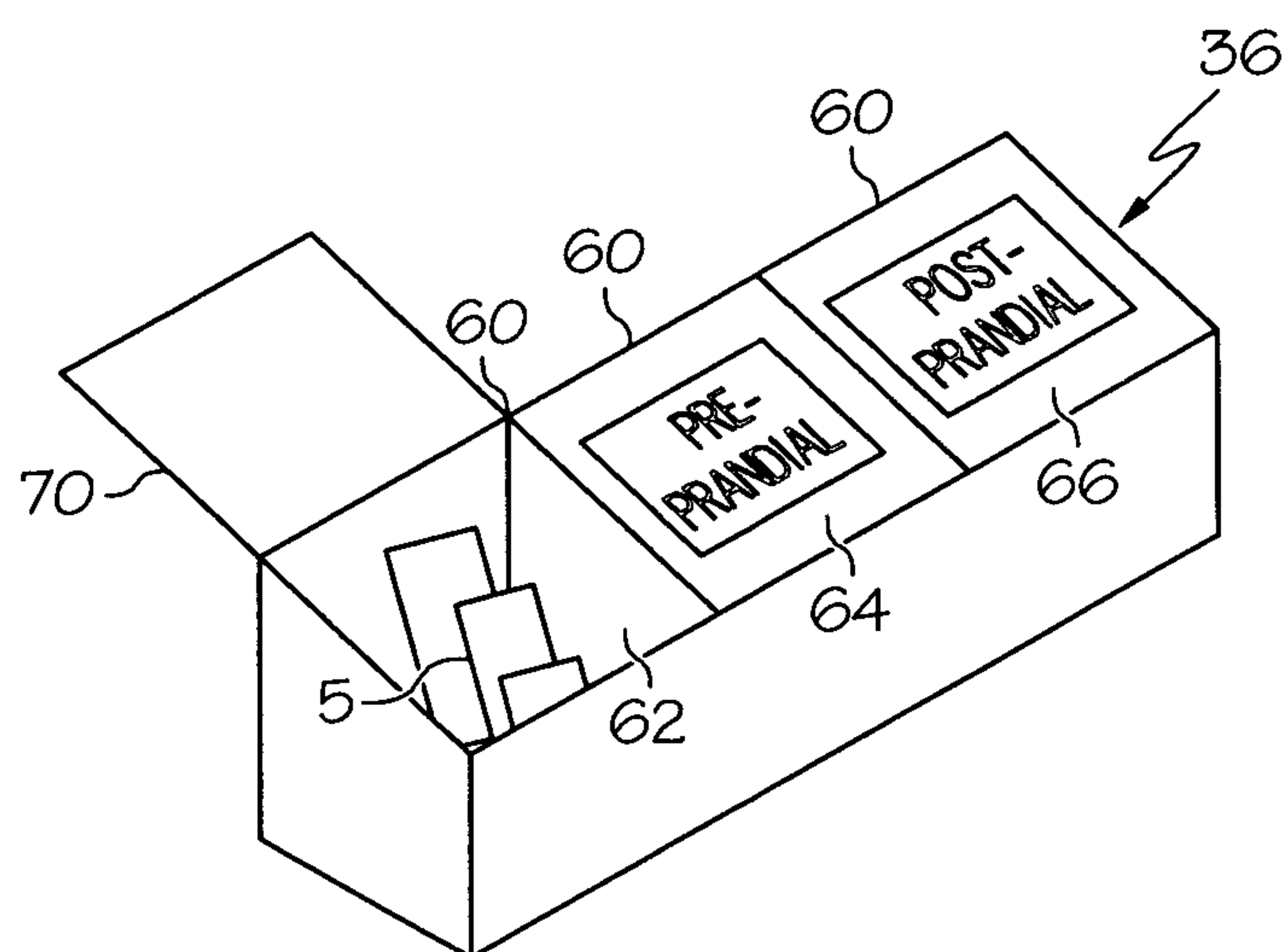


FIG. 5

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The diagram shows a 6x7 grid of cells. The first four rows (rows 1-4) contain the text 'PP' and 'PB' stacked vertically. The first three columns (columns 1-3) are labeled with numbers 1 through 30, with some numbers appearing twice (e.g., 30 in columns 3 and 4 of row 5). The grid is labeled with 46, 48, and 50. Label 46 points to the top-left corner. Label 48 points to the top-right corner. Label 50 points to the bottom-right corner.

1 PP PB	2 PP PB	3 PP PB	4 PP PB	5 PP PB	6 PP PB	7 PP PB
8 PP PB	9 PP PB	10 PP PB	11 PP PB	12 PP PB	13 PP PB	14 PP PB
15 PP PB	16 PP PB	17 PP PB	18 PP PB	19 PP PB	20 PP PB	21 PP PB
22 PP PB	23 PP PB	24 PP PB	25 PP PB	26 PP PB	27 PP PB	28 PP PB
29 PP PB	30 PP PB	30 PP PB				

FIG. 6

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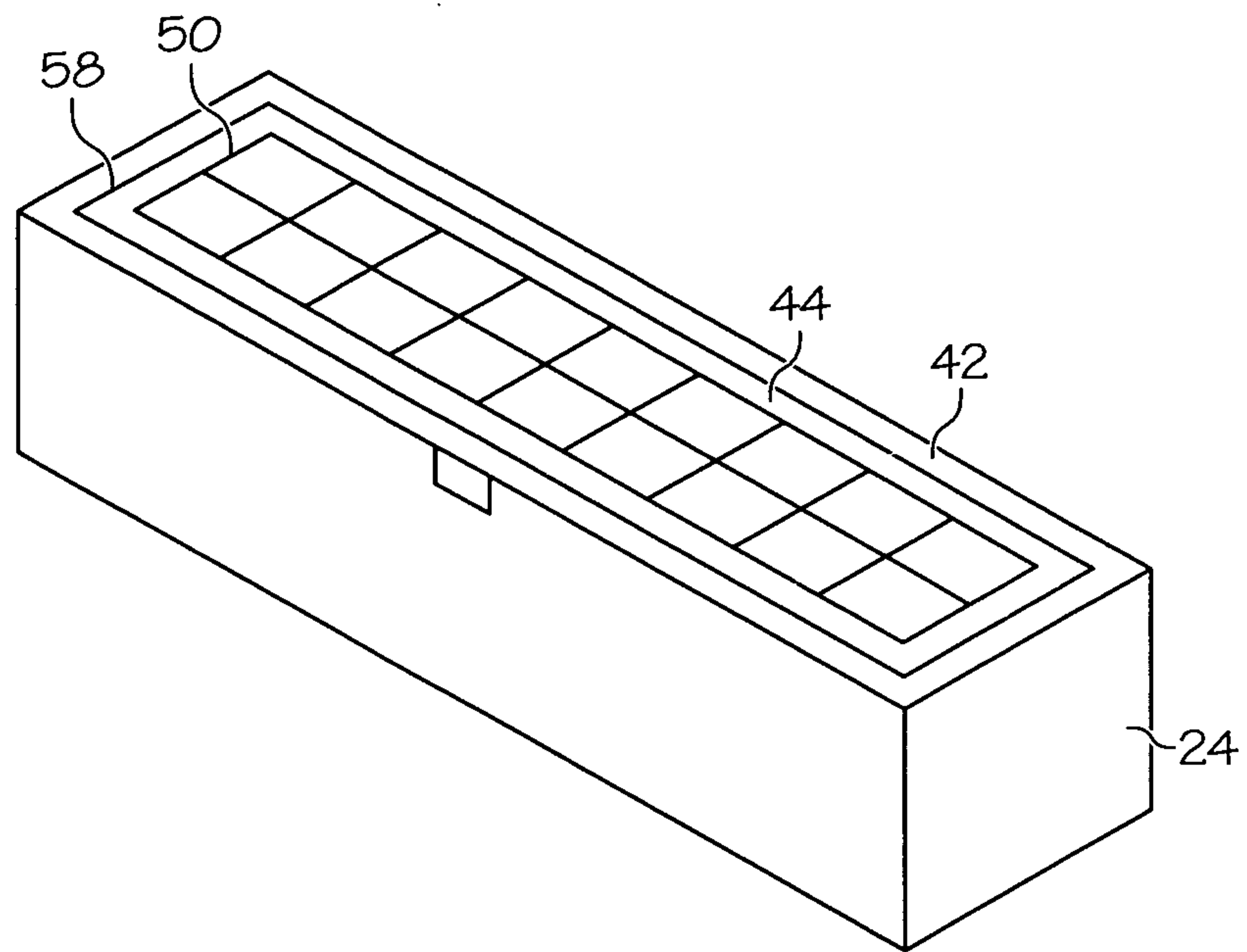


FIG. 7

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PRANDIAL

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