Quintal Research Group, Inc.
1905-D Palmetto Avenue
Pacifica, CA 94044
650-557-5708

May 14, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments on FDA proposal for Barcodes on Drug packaging and Labels

Dear FDA Representative:

Quintal Research Group, Inc. is a technology development corporation and is in the process of evaluating and implementing the Nellhaus Universal Pill Identification System. The Nellhaus Universal Pill Identification System was devised by the late, Dr. Gerhard Nellhaus to reduce medication errors, primarily in "out-patent" situations. Described in three issued U.S. Patents, the system:

1. Utilizes an image or picture-stamp of the actual pill, capsule or tablet for creating medication schedules for patients. This system also includes the use of a pictorial image on the label of the pill bottle or container for visual comparison. (Patent No. 5,031,937)

2. Proposes printing a barcode directly on the medication, including direct marking of pills, capsules, tablets and other solid-form drugs. (Patent No. 5,845,264)

3. Proposes the use of a two-dimensional barcode, similar to a data-matrix barcode printed or embossed on the pill, together with a human recognizable icon or symbol that identifies the general type of pill. This barcode and icon should also be printed on the container or label as well for visual and machine-read comparison. (Patent No. 6,543,692)

In commenting on the proposed regulations it must be understood that Quintal Research Group generally supports the proposed regulations, but is concerned that the regulations may inhibit implementation of technologies for direct machine-identification of solid form oral drugs that comply with the marking requirements of 21 CFR §§ 206, 207, 314 and 330. By a combination of image recognition, character recognition and barcode recognition technologies, the machine-identification of solid form drugs that are marked to comply with FDA marking requirements is a near reality.

The focus of the proposed FDA barcode regulations is reduction in the number of medication errors occurring in hospitals. This goal should not be inconsistent with reduction of medication errors in other settings, including self medication by individuals.

Therefore, consistent with the primary FDA objective and the complement objective to enhance informational databases Quintal Research Group offers the following comments and suggestions:

1. The drug establishment and listing rule should require a quality digital image of side 1 and side 2 of solid oral dosage forms of drugs, now required to be described in writing on a supplemental form under 21 CFR § 207.30.

2. The container or label on which the NDC linear barcode is imprinted should include an image of the solid form drug or at least the imprint marking that distinguishes one drug from another under the drug marking regulations.

3. The FDA should adopt a set of universal symbols to identify the type or class of drugs. The symbols should be easily recognizable by the user to distinguish one type of drug from another and should at least be printed on the label as a last barrier to medication errors.

Quintal Research Group is not unmindful that it is researching a proprietary system for drug identification and therefore has a special interest. However, because of the technical realities in devising a barcode that can be printed on the limited real estate of a typical pill, certain compromises must be made that are inconsistent with the preference of the FDA to use linear barcodes that incorporate the NDC identifying number:

1. In order to identify at least twenty thousand different pills, by directly marking on a pill, a two dimensional barcode symbol is required.

2. To present cells of a two-dimensional barcode symbol large enough to be read by existing two-dimensional barcode readers, a modified data-matrix symbol must be used and software changes in the readers are required.

3. While the machine readable code can directly translate into alphanumeric characters, a translation table is required to relate the alphanumeric code to the National Drug Code number.

Finally, in devising a system of symbolic images to identify different drug classes, symbols recognized by their outline or silhouette alone were found to be more important than an attempt to emulate symptoms or treatment procedures by pictograms as suggested by U.S. Pharmaceutical. If the goal is to eliminate or reduce all medication errors without limitation, then aids to identification by the ultimate user should be considered. Our company agrees that the FDA should be the central repository for an informational database, and if bar coding is extended to the pill itself, the FDA should control the issuance of the code system.

Very truly yours,

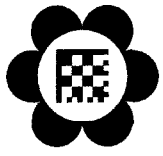
Richard Esty Peterson
President

REP/taz

encs: Copy of Suggested Symbols
Copies of Patent Nos. 5,031,937
5,845,264
6,543,692

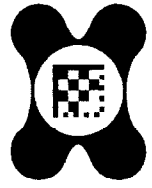
P. Familiar Primitives, N. Recognizable Glyphs

N
FLOWER



Smell

P
BONE



Bones & Toxics

P
DROP

Lymph & Liquids

P
EYE

Sight

N
BELL

Ears Nose
& Throat

N
CUP

Hydration /
Stomach

N
FOOT

Endurance

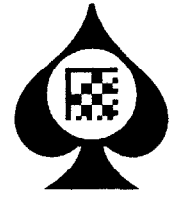
P
HEART

Heart & Blood

P
DIAMOND

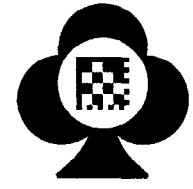
Well-Being

P
SPADE



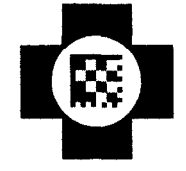
Sex Organs

P
CLUB



Stomach

P
CROSS



Emergency

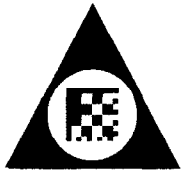
N
BALLOON

Respiratory

P
ARROWS

Psyche

P
TRIANGLE

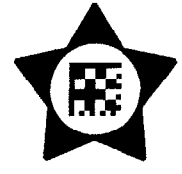


Nutrition

P
SQUARE

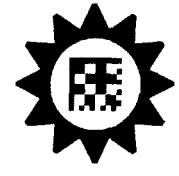
Blocker

P
STAR



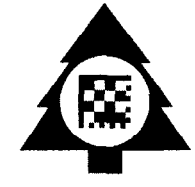
Pain

N
SUN



Health &
Well-Being

N
TREE

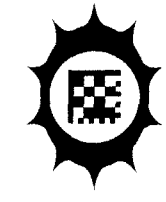


Hair & Limbs

N
MOON

Sleep

N
BURR



Itch / Skin

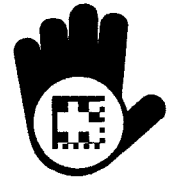
N
FISH

Skin & Eye

N
CROWN

Brain / Head

N
HAND



Joints &
Extremities

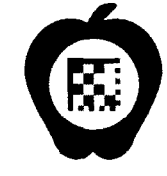
N
CASTLE

Strength /
Bones

P
CIRCLE

Target

N
APPLE



Nutrition

P
HEXAGON

Genetic/
Imune-System

United States Patent [19]

Nellhaus

[11] Patent Number: 5,031,937

[45] Date of Patent: Jul. 16, 1991

[54] PICTORIAL GUIDANCE/REMINDER SYSTEM FOR MEDICATION

[76] Inventor: Gerhard Nellhaus, 670 Vernon St. #106, Oakland, Calif. 94610

[21] Appl. No.: 516,685

[22] Filed: Apr. 30, 1990

[51] Int. Cl.[5] B42D 15/00

[52] U.S. Cl. 283/52.1; 283/48.1; 283/900

[58] Field of Search 283/52.1, 48.1, 900; 206/534, 532, 538, 459

[56] References Cited

U.S. PATENT DOCUMENTS

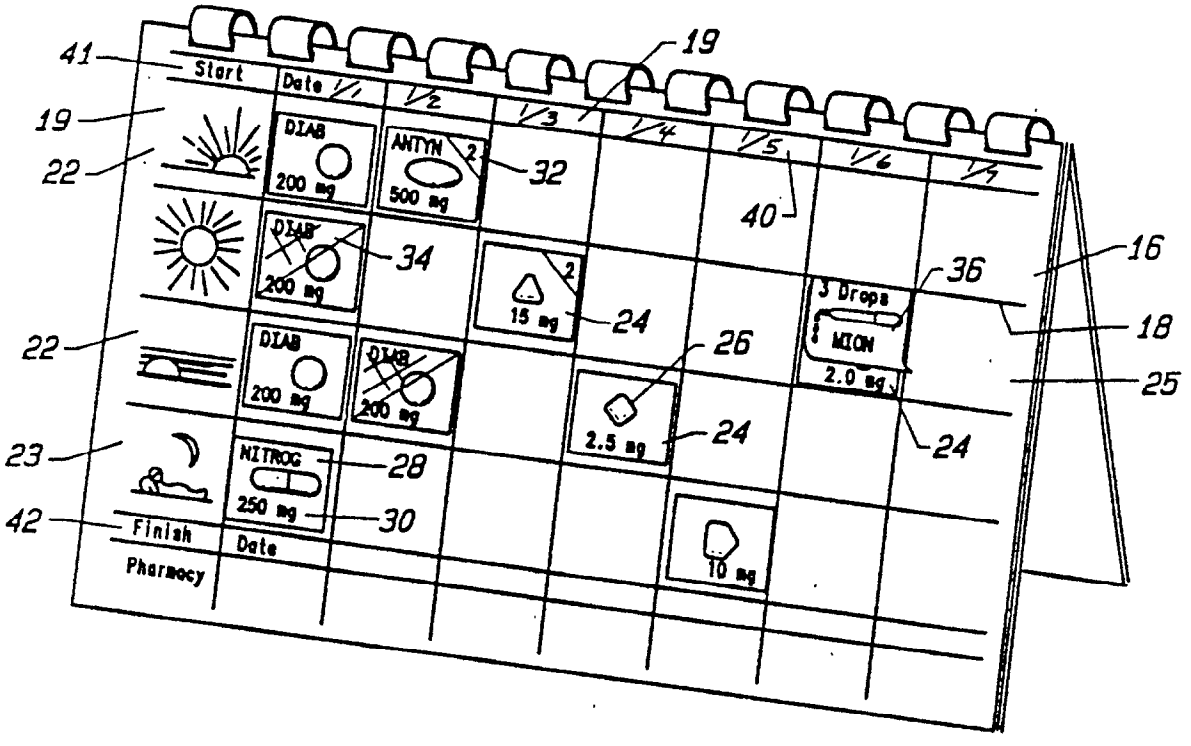
3,675,620	7/1972	Baustin	206/534
4,441,739	4/1984	Cluff et al.	283/900
4,556,390	12/1985	Rahn et al.	283/48.1
4,815,767	3/1989	Lambert	283/900

Primary Examiner—Douglas D. Watts
Assistant Examiner—Hwei-Siu Payer
Attorney, Agent, or Firm—Bielen, Peterson & Lampe

[57] ABSTRACT

A pictorial system is devised to assist in the administration of medication, either to self or to another, based on picture stamps of a particulate medication to be taken by or given to a patient at a specified time either over a specified period of time or over an extended and unspecified calendar period. The picture stamps, each reflecting a unit of a medication, are to be pasted into discrete spaces of a sheet, card, label or box cover divided into columns and rows identified by icons for the time of day one or more units of the medication or of the medications are to be taken or given.

10 Claims, 2 Drawing Sheets



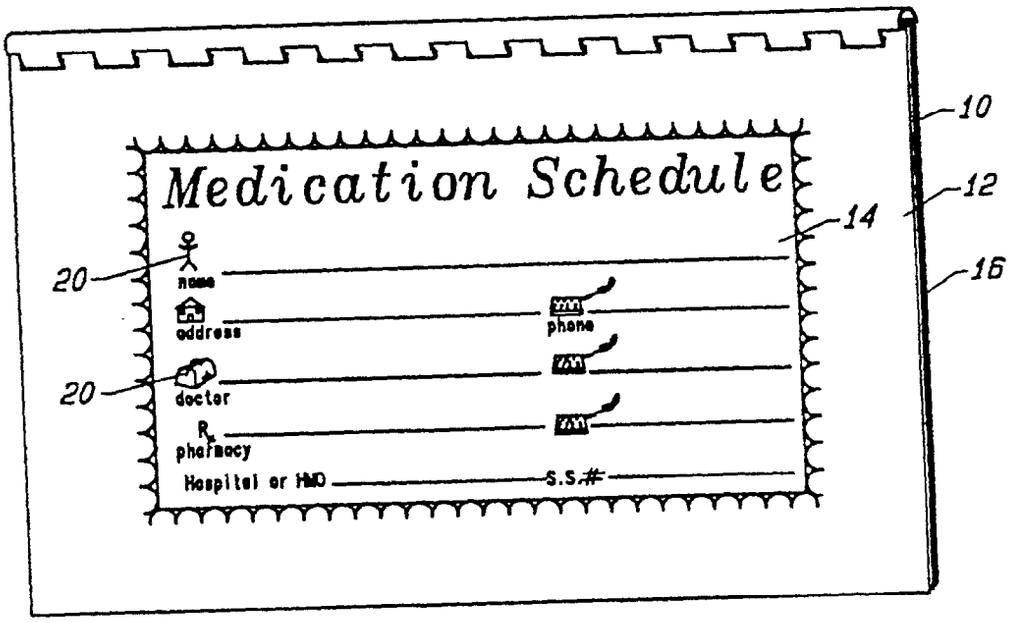

Medication Schedule
name
address
phone
doctor
Rx
pharmacy
Hospital or HMO
S.S.#
10
12
14
16
20
20

FIG. 1

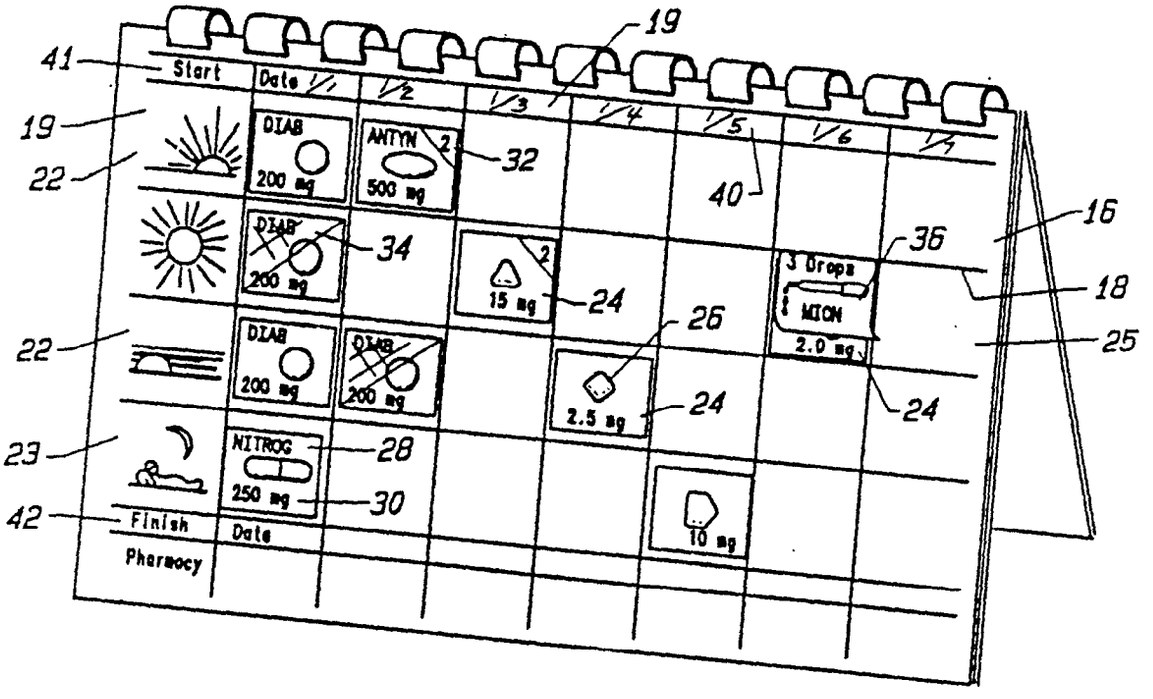

Start
Date
DIAB
200 mg
AMTYN
500 mg
15 mg
3 Drops
MION
2.0 mg
2.5 mg
NITROG
250 mg
10 mg
Finish
Date
Pharmacy
19
22
23
24
25
26
28
30
32
34
36
40
41
42

FIG. 2

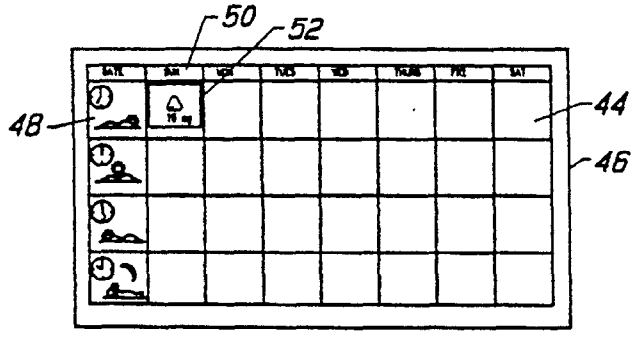


FIG. 3

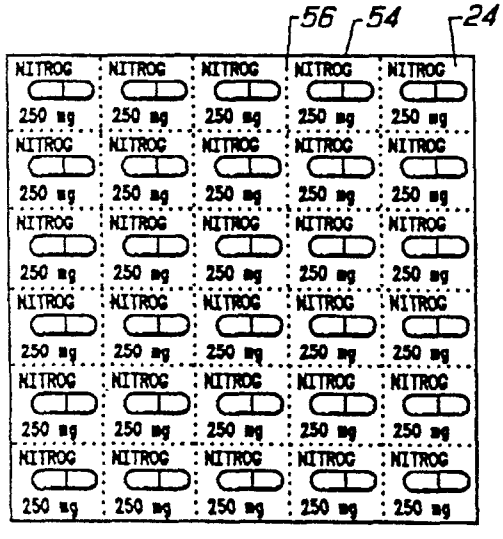


FIG. 4

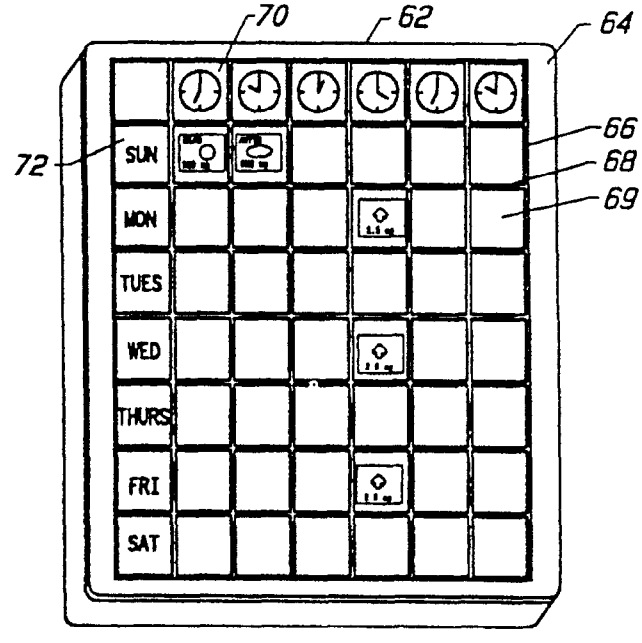


FIG. 7

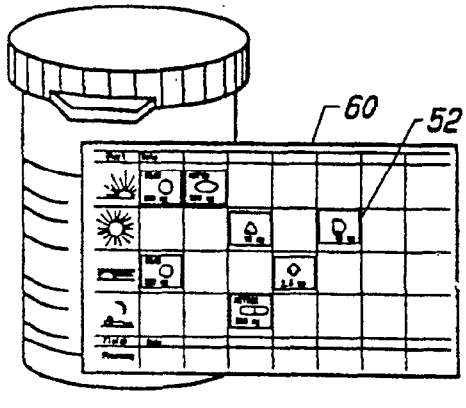


FIG. 6

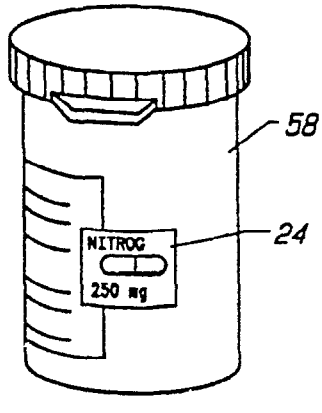


FIG. 5

PICTORIAL GUIDANCE/REMINDER SYSTEM FOR MEDICATION

BACKGROUND OF THE INVENTION

This invention relates to a visual guidance or reminder system to assist in the administration of medications, whether taken by oneself or given by a caregiver. The pictorial medication system is desirable since many patients must take multiple medications, often at different times of the day. The taking or giving of medications often becomes confusing because of the complex identifying names of the medications, similarities of the containers for the medications, and the circumstance of the patient who may be ill, infirm, or limited in ability to read or to grasp pharmacologic or medical terminology.

The NATIONAL COUNCIL ON PATIENT INFORMATION AND EDUCATION, Washington, D.C. published the following data for the U.S.A. for 1987: (1) Nearly 2.3 billion inpatient and outpatient prescriptions were dispensed; (2) An estimated $23 billion was spent on prescription drugs; (3) The average pharmacy dispensed nearly 27,500 prescriptions that year; (4) In 1986, the Food and Drug Administration received almost 54,000 reports of adverse drug reactions, including 1,347 deaths and 4,1481 hospitalizations; (5) Sales of nonprescription drugs were rising by 6% a year, as two-thirds of Americans self-medicate; (6) Almost 100% of over-the-counter (OTC) medication purchasers used self-selected regimens, and even those taking prescription drugs complied only about 50% of time with the regimens advised.

Among the many problems and complications that arise from the improper timing of medication are ineffectiveness, as with antibiotics or anticonvulsants when doses are missed, or oversedation when doses are taken too close together as with antihistamines. Often, there may be failure to identify the correct medication to be taken or the correct dosage to be administered. Frequently, the very infirmity that requires a patient to take medication, may debilitate judgment and memory.

The interval between doses of a drug, or how frequently during the day a drug must be taken, is determined by its pharmacokinetics, i.e. the rate of absorption, peak blood or tissue level, and rate of degradation and elimination. Thus while the administration of medications is not always critical as to the precise time of the day, it is necessary to take most drugs within readily identifiable periods or at fairly regular intervals. While various dispensers have been devised for periodic dispensing of preselected pills and the like, such devises require preloading by the patient, a caregiver or the pharmacist, and are usually expensive. The visual reminder system of this invention is cost effective, is comprised solely of paper goods, and enables the pharmacist (or less frequently the physician) to quickly and easily select the pictorial representation of the medication to be taken, and to paste such representation on a sheet, in a booklet, on a card, the top of a box, or as a part or tag of a label that can then guide the patient or caregiver in the administration of the medication. Further significant advantages of this pictorial reminder system are that such filled-in sheets may be kept posted in several places about a home such as on the refrigerator door and by the bedside, or kept in a booklet or a card which can be readily carried on one's person as in a purse or wallet. This latter application of the visual guide to medication also permits ready identification of the medication an individual may be taking, which may be of crucial importance to the treating and prescribing physician in the recognition and prevention of polypharmacy and drug-drug interaction, and determination of a suitable regimen for the client. Finally, the ready identification of drugs being taken by a person may be of critical importance in life-threatening situations.

Preferably, the visual depictions of the medications can be directly reproduced on picture stamps from the *Physicians Desk Reference* (PDR) published by Medical Economics Company, from the *Compendium of Drug Therapy*, published by McGraw-Hill Book Company, or from their equivalents in other countries. The icon or stamp of a particular medication preferably includes the name and strength of the drug as additional reminders to the patient or caregiver, providing a learning experience in associating the appearance of the drug with its name and strength.

The principal object of this invention is to provide a convenient and inexpensive means of identifying particular medication and the time of day and period that the medication is to be taken to assist in self-administration or the giving of medications while reducing the risks of improper medication that could result in serious consequences.

SUMMARY OF THE INVENTION

The pictorial guidance or reminder system for administration of medications of this invention is a convenient means to visually identify the medication to be taken, and the dosage, time, and period of administration. This visual reminder system is based on paste-on picture stamps depicting a specific medication in a specific strength, and can be used with a sheet, card, or label having a matrix format with rows and columns that divide the sheet, card, or label into discrete spaces to receive the stamps. The stamps can also be mounted directly on the covers of plastic medication boxes that have a preformed matrix format.

Preferably, the number of rows are selected to conveniently indicate the times of day in which the medication is to be taken. The columns preferably indicate the number of units that make up the total dose at the indicated time as well as the starting and stopping dates of the medication, or alternately, indicate consecutive calendar days of the medication period, or that the medication is to be taken continuously without restriction as to time, or even on a prn—"as necessary" basis. Of course, the format can be reversed with the columns representing the periods during a day in which the medications are to be taken, and the rows dedicated to the dates or days on which the medications are to be administered. The former arrangement has been found to be preferable for a pictorial display that can be arranged in a booklet form of convenient size. While the four icons or ideograms for times of day cover by far most of the commonly prescribed regimens, pictures of a clock showing three or four hour intervals can be used to head the columns when such regimens are desired, as with certain anti-parkinsonian drugs. Thus, while different formats can be selected and the format shown in the detailed description of this invention may be modified by the physician, the essential concept will be the same. This holds true also for application of this visual reminder system in cultures where reading is from right to left, or is vertical rather than horizontal.

The main purpose of this invention is to improve the administration, or the taking or giving of medication by a system that does not require literacy and which can be quickly and easily understood by almost all patients or caregivers because of its intuitive and visual foundation.

Frequently, a patient must self-administer a number of medications that are all dispensed in similar appearing bottles or boxes. The name and strength of the medication and the dose and frequency of administration are often typed on small labels adhered to the cylindrical pill containers or to boxes making accurate reading difficult even for those with unimpaired vision and with medical literacy. Using the visual guidance system of this invention, which is based on picture stamps, enables not only the patient booklet to be filled with picture stamps that visually represent the medication to be taken but also permits a stamp to be applied to the pill container for the medication, to assist in the selection of the proper pill container when taking medications. Furthermore, once the container has been selected and the correct number of pills removed, the visual system which utilizes an accurate pictorial representation of the medication and dosage at a specified time, will provide a final check before the medication is taken by or given to the patient. As described, a sheet or sheets depicting the medication regimen can also be posted at convenient spots around a home, such as on a refrigerator door or by a bedstand, or in nursing/convalescent homes and even in hospitals by a patient's bedside.

As a collateral benefit, the likelihood of misprescribing drugs will be diminished by the visual check that is required by the pharmacist or the physician pasting the medication stamp to the container and to the appropriate locations in the booklet.

In addition, the pictorial system of medication regimen can be applied to a card easily carried on one's person, and even to the printed containers of over-the-counter nonprescription drugs.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the pictorial guidance system in the form of a booklet.

FIG. 2 is a perspective view of the system of FIG. 1 with the booklet opened to a schedule page showing the matrix format and pictorial stamps.

FIG. 3 is a front view of the pictorial guidance system in the form of a wallet-size card.

FIG. 4 is a front view of a sheet of identical picture stamps.

FIG. 5 is a perspective view of a medication container having an identifying picture stamp.

FIG. 6 is a perspective view of a medication container having a matrix format tab with picture stamps pasted thereon.

FIG. 7 is a perspective view of a medication box with an integral matrix format having picture stamps and icon stamps pasted thereon.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The pictorial system of this invention relates to a means to assist in the administration of medication to self or to another based on picture stamps of particular medications to be taken by or given to a patient at a specified time over a day or a number of days. Several embodiments of the system are shown and described to present the system in various forms such that the general concept is readily understood.

Referring to FIG. 1 and 2, one preferred embodiment of the visual guidance system is shown as a booklet **10** having a cover **12** with a form **14** for conventional patient information, and a number of pages **16** having a matrix format **18** with identification spaces **19** into which information is placed to indicate the time or time of day medication is to be taken. In both the cover form **14** and in the matrix format **18** the use of icons and other pictorial representations is preferred to enable the patient to self-administer or be administered medication by a visual guidance or reminder system. For example, in the cover form **14** are various icon identifiers **20** that represent the patient, his/her address, his/her doctor, etc. Similarly, in the matrix format **18** are icon identifiers **22** to identifying rows to represent the four periods of the day during which particular medications are to be taken by or administered to the patient. The matrix format **18** divides a surface **23** into discrete spaces **25** where identifiers for medications are inserted. The medications are identified by picture stamps **24** which at least include a pictorial representation **26** of the particular drug or other medication to be taken. In addition to the pictorial representation **26** the stamp may preferably include the name **28** of the drug and the strength **30** of the drug printed thereon. Additionally, the stamp can include printed or hand written representations alternately **32** indicating the number of the pill or capsule to be taken, or by cross hatch **34** whether only a half of a unit is to be taken. Furthermore, it is understood that more than a single picture stamp **24** maybe pasted into a single space **25** formed by the matrix format **18** by wetting only a portion of the back of the added stamp or stamps when inserting, such that the stamp can be lifted up to determine one or more other stamps underneath as shown for the eye drop icon stamp **36** in FIG. **2**.

In the embodiment of FIG. **2**, the matrix format **18** is divided into rows and columns with the icon identifiers **22** representing rows and date markers indicating columns, which may be broken either into days of the week or calendar days as shown by the hand written identifiers **40** along the top of each column. Other information such as a start date marker **41** and a finish date marker **42** may be applied and utilized, particularly where the top column markers are merely days of the week, such as Monday, Tuesday, Wednesday, etc.

Referring now to FIG. **3** an alternate embodiment of the pictorial medication system is shown. A matrix format **44** is printed on a card **46** that includes icon identifiers **48** to represent periods during the day, and printed markers **50** representing the days of the week. The icon markers **48** include both a pictorial representation of periods in a day and a pictorial representation of an analog clock. As in the former embodiment, the matrix format is broken into columns and rows with the icon markings for the periods of the day segregating rows and the print markings for the days of the week, identifying the columns. Miniature picture stamps **52** identify the particular medication or medications that are to be taken or administered.

The picture stamps **24**, **36** and **52** preferably come from a source of sheets, one of which is shown in FIG. **4**. Alternately, the stamps can come in rolls or other convenient means for grouping stamps of identical kind. The representative stamp sheet **54** of FIG. **4** includes a plurality of identical stamps which are separated by perforation **56** allowing individual stamps to be easily separated from the sheet and pasted on the surface of

one of the various alternative devices for exemplifying the system.

As shown in FIG. 5 a stamp from the stamp sheet 54 can be used on a conventional pharmacy container 58 used to dispense drugs to identify the contents of the container. Alternately, the system can be applied as a tab 60 attached to the container label with the miniature stamps 52 pasted into appropriate boxes of the matrix format to visually represent a medication schedule for the patient for whom the prescription is filled as shown in FIG. 6.

Although the primary embodiments of this invention have shown the pictorial medication system utilizing one or more printed sheets, it is to be understood that the invention can be embodied in the physical structure of a surface medium such as the top on a medication-containing container 62 as shown in FIG. 7. In the container 62 of FIG. 7, the plastic top 64 is molded with a unitary grid matrix 66 of raised ribs 68 which define a series of boxes 69. If desired, the interior of the container can be similarly divided into separate compartments by dividers (not visible). The top 64 of the container 62 has pasted in certain of the divider icon stamps 70 depicting an analog clock with the clock hands representing certain periods of the day, and, word markers 72 depicting the days of the week. In the particular embodiment shown in FIG. 7 the analog clock stamps 70 designate six columns for six periods during the day in which selected medications should be taken or administered. The word markers 72 indicate the seven days during the week which are available for the taking of the medications. As is evident from the various embodiments shown the concept of this invention can be incorporated in various types of devices to effectively achieve the results desired. Variations in the format can also be made without departing from the concepts disclosed.

While in the foregoing, embodiments of the present invention have been set forth in considerable detail for the purposes of making a complete disclosure of the invention, it may be apparent to those of skill in the art that numerous changes may be made in such detail without departing from the spirit and principles of the invention.

What is claimed is:

1. A pictorial guidance or reminder system to assist a patient in self-administration of medications or to assist a caregiver in the administration of medications to a patient, comprising:

a surface with a matrix format having rows and columns dividing the surface into discrete spaces adapted to receive paste-on stamps with a first plurality of identification spaces for identifying discrete rows and a second plurality of identification spaces for identifying discrete columns, the first plurality of identification spaces being adapted to identify specified days or dates or even continuous open-ended series of days (with cut-off to be determined by the physician during the course of treatment) and the other plurality of identifying spaces being adapted to identify specific times in a day for taking or giving of medication, and a plurality of different groups of pasteable stamps, each group having a plurality of individual, identical picture stamps visually identifying a select medication, wherein each stamp has depicted thereon an accurate picture of the actual medication visually identified, and wherein each group consists of a different medication, visually identified in each of its stamps, the plurality of groups comprising a source from which selected stamps are removed and pasted in discrete spaces on the surface representing the time and date the pictorially identified medication is to be taken wherein when pasted on such surface, the filled-in surface provides a visual guide or reminder to the patient or caregiver of the type of medication and total dose to be taken or given at a particular time during the day and on a particular date or during a specified or open-ended calendar period.

2. The medication system of claim 1 wherein one of the two pluralities of identification spaces has icon markings identifying discrete periods in the day.

3. The medication system of claim 2 wherein the icon markings include an icon marking visually depicting morning, an icon marking visually depicting mid-day, an icon marking visually depicting evening, and an icon marking visually depicting bed time.

4. The medication system of claim 1 wherein the surface comprises a sheet, sized to a wallet-size card.

5. The medication system of claim 1 wherein the surface comprises a sheet, sized to a calendar-size wall poster.

6. The medication system of claim 1 wherein the surface comprises a plurality of like sheets formed into a booklet for extended medication periods.

7. The medication system of claim 1 wherein the surface comprises the cover of a pill box.

8. The medication system of claim 1, wherein the surface comprises a label sheet attached to a medication container.

9. The medication system of claim 1 wherein the picture stamp groups are perforated sheets with individual pasteable stamps separable by perforations, wherein individual stamps are separated from the sheets by tearing along the perforations.

10. The medication system of claim 1 wherein the pictorial representation of the actual medication is reproduced from one of the authoritative references, *Physician's Desk Reference* and *Compendium of Drug Therapy*.

* * * * *

US005845264A

United States Patent [19]

Nellhaus

[11] Patent Number: 5,845,264

[45] Date of Patent: Dec. 1, 1998

[54] **BAR CODE IDENTIFICATION OF DRUGS**

[76] Inventor: **Gerhard Nellhaus**, 670 Vernon St. #207, Oakland, Calif. 94610

[21] Appl. No.: **612,372**

[22] Filed: **Mar. 7, 1996**

[51] **Int. Cl.**[6] **G06F 17/60**

[52] **U.S. Cl.** **705/28**; 705/2; 235/375

[58] **Field of Search** 705/2, 3, 22, 28, 705/29; 715/3; 235/375

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Primary Examiner—Gail O. Hayes

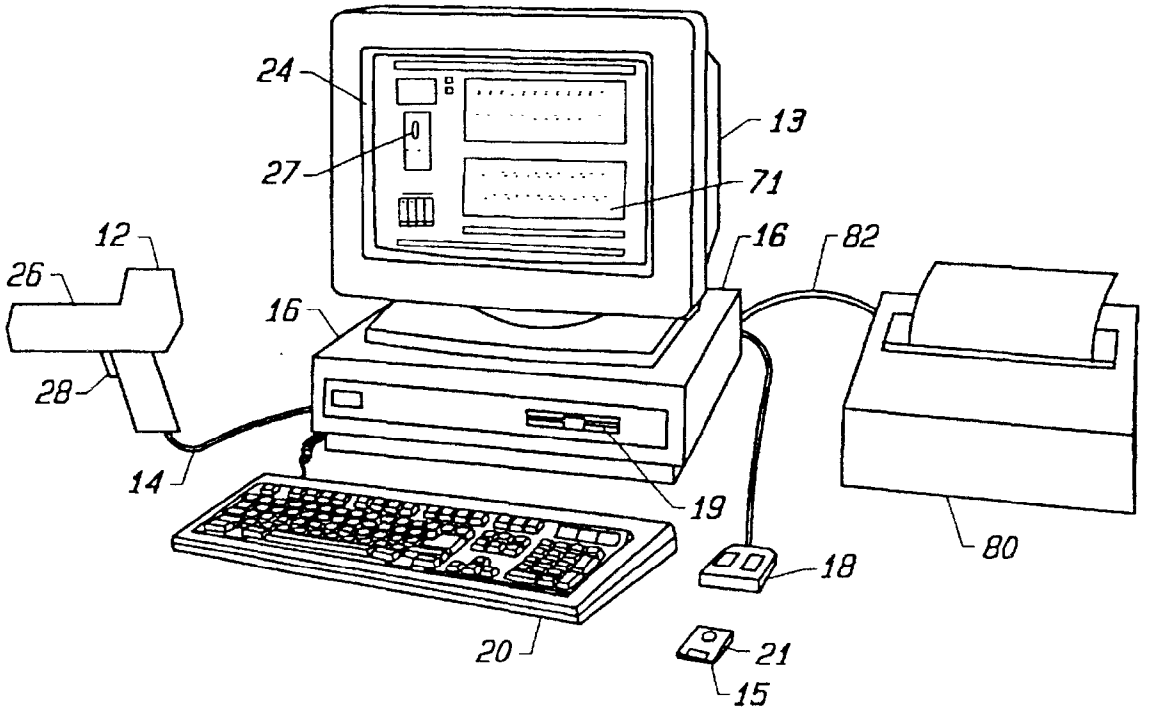
Assistant Examiner—Alexander Kalinowski

Attorney, Agent, or Firm—Bielen, Peterson & Lampe

[57] **ABSTRACT**

A system for the identification of medications in pill, capsule, tablet, and caplet for the system including the placement of machine scannable bar code symbols on the surface of the medication and the identification of the medication by use of the bar code. The resulting identification information can be analyzed by a computer program, permitting both a drug identification and verification method for use by a doctor, pharmacist, emergency room or other medical staff, paramedics, law enforcement personnel, patient and/or family members, or indeed anyone who may need to know a drug's identity, and a tracking system by inclusion of the identification data into an appropriate information database to monitor an individual's prescription drug consumption and to alert of potential harmful drug interactions.

5 Claims, 3 Drawing Sheets



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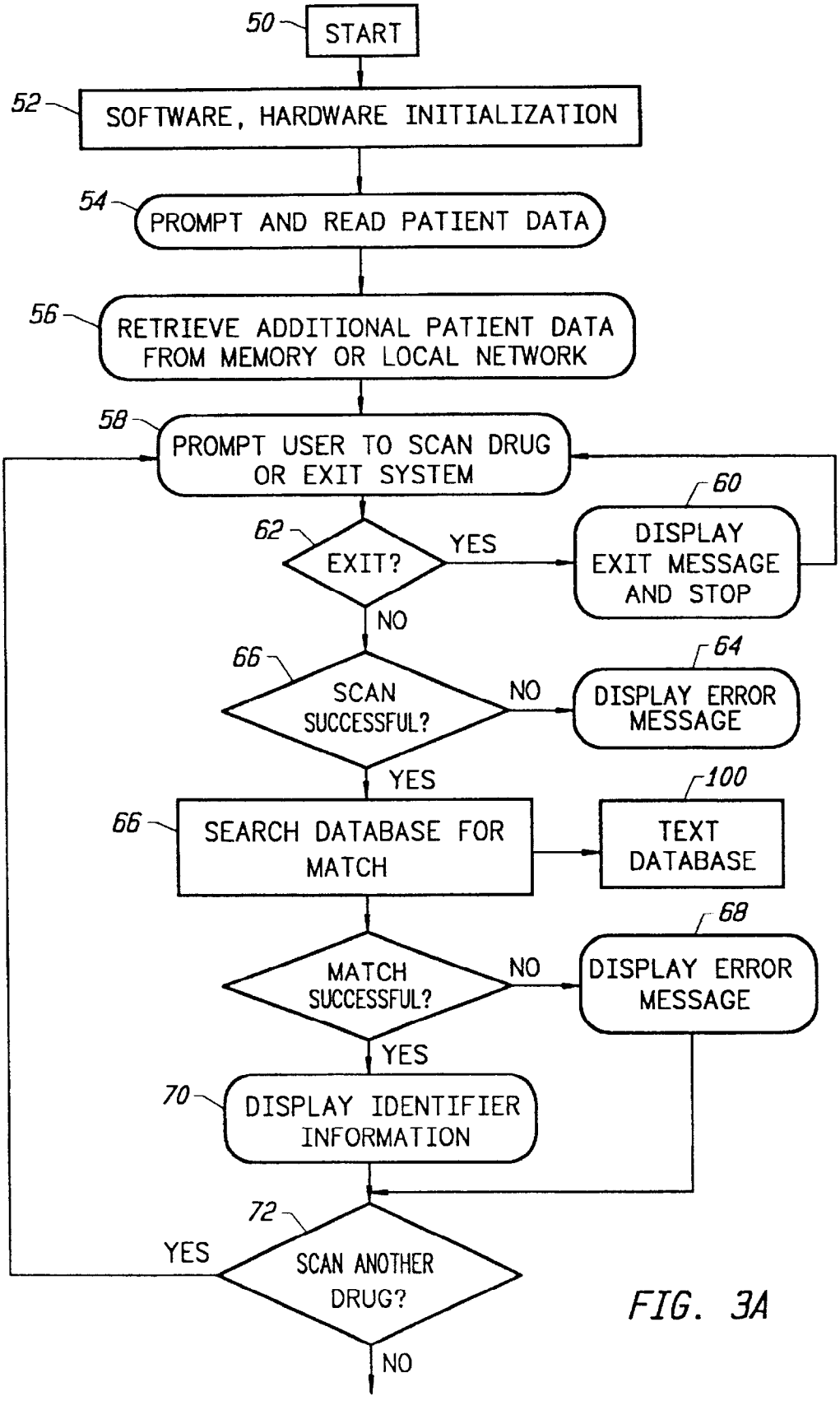
50
START
52
SOFTWARE, HARDWARE INITIALIZATION
54
PROMPT AND READ PATIENT DATA
56
RETRIEVE ADDITIONAL PATIENT DATA FROM MEMORY OR LOCAL NETWORK
58
PROMPT USER TO SCAN DRUG OR EXIT SYSTEM
60
62
EXIT?
YES
DISPLAY EXIT MESSAGE AND STOP
NO
66
64
SCAN SUCCESSFUL?
NO
DISPLAY ERROR MESSAGE
YES
100
66
SEARCH DATABASE FOR MATCH
TEXT DATABASE
68
MATCH SUCCESSFUL?
NO
DISPLAY ERROR MESSAGE
YES
70
DISPLAY IDENTIFIER INFORMATION
72
YES
SCAN ANOTHER DRUG?
NO

FIG. 3A

BAR CODE IDENTIFICATION OF DRUGS

BACKGROUND OF THE INVENTION

This invention relates generally to a system for identification of prescription medications that has a primary feature the placement of identification markers on the outside of the medication. Specifically, this invention relates to a system for prescription medication identification using bar code symbols placed on the outside of the medication.

The proliferation of new prescription medications created by advances in pharmacology and the steady increase of generics unfortunately has unintentionally created health problems when: (1) patents misidentify and thereby misuse their prescribed drugs; (2) patients suffer adverse drug interactions when two or more prescribed drugs taken concurrently combine in a harmful manner; or (3) doctors misprescribe medications based on a lack of information regarding the patient's history. Health problems based on these scenarios are likely to grow over time because the introduction of every new medication increases the number of potential interactions with the prior existing set of medications.

Several related problems occurring most frequently in the elderly population are beginning to receive attention in research publications such as *The Journal of the American Medical Association* (JAMA), as well as the popular press. A recent JAMA study based on review of nursing home subjects concluded that roughly 23% of Americans ages 65 and over are using at least one of twenty medications that are notorious for triggering insomnia, fainting spells, or amnesia among the elderly. The study also stated broader educational and regulatory initiatives are needed, and a companion JAMA editorial referred to this study as illuminating "the tip of the iceberg".

This widespread problem prevails despite the well-known medical technique doctors often employ, called the "brown-bag" test. The brown-bag test consists of a patient, typically elderly, being instructed to empty the contents of their medicine chest into a bag and then to bring the bag into the physician's office or to a pharmacist for analysis.

Additionally, physicians are beginning to trace health problems in the elderly to the overprescription of medications in amount or duration. This phenomena has been explained as the result of the human body's changing reaction to medications as part of the aging process.

Currently, patients and doctors who cannot readily identify a prescribed medication can attempt to consult a guide such as *The Physician's Desk Reference* (PDR) that contains a pictorial index of commonly prescribed drugs. However, the elderly patients most at risk for these problems probably fail to possess the visual or mental acuity necessary to complete these tasks, and even the professionals who can consult the PDR may fail to locate their medication because it is a generic equivalent not shown. For the physician to consult the PDR each time the identity of a drug is in question, is an imposition that is time consuming and hence an added cost of service.

The patient's recourse is to visit a physician, physician's assistant or pharmacist who will conduct a brown-bag test. A physician, health provider, or law enforcement agent who cannot identify a medication using the PDR may be forced to conduct expensive laboratory tests on the unknown medication.

This inventor has devised a graphical system to assist in the identification of drugs. This system is described in U.S. Pat. No. 5,031,937, issued 16 Jul. 1991, entitled, "Pictorial Guidance/Reminder System for Medication." The system includes a pictorial graphic representation showing the drug and providing for the use of such graphic representations for a medication table for scheduled taking of medications. Because of the many similarly appearing generic and proprietary drugs, visual identification is frequently difficult.

Recent trends in health care also indicate that patients are being placed at risk because of the increased workload on pharmacists. Several national pharmacy associations have identified the problems caused by increased cost-cutting pressures on pharmacists. Examples cited include patients receiving the wrong medication dosage or even the wrong medication. Pharmacists are often cited for failing to comply with state laws requiring patient notification and counseling upon receipt of prescribed medications.

The identification problems described above are solved when medications are individually labeled with bar code symbols that uniquely identify the medication, or class of medications, when the medication is scanned through a common bar code reader. The bar code reader is connected to a computer containing the appropriate software to translate the output provided by the bar code reader into a data identifier that can be referenced to a database table that operates as an index of bar code-medication pairs. The computer could then display the medication name plus additional information desired.

This identification system could be utilized both by the patient at home and by the dispensing pharmacist, and would increase patient safety while decreasing health care costs.

As early as 1989, individuals in the bar code community generally suggested that bar codes could be used by health care providers in areas such as patient billing, pharmacy, and bedside medication verification. However, there was no suggestion that this should extend to actually placing a bar code on the drug item itself.

This system can operate using at least one of the many commercially available bar code symbologies that meet desired requirements based on: (1) the number of unique codes available; (2) medication size constraints; and (3) error detection and correction tolerances. Once implemented, this system will eliminate nearly all human error in confirming medication identification and will serve as a low-cost medication verification system.

Additionally, this system could be incorporated into an extended system that includes a database containing individual patient medication histories, and a database of known harmful drug interactions. Through this system, a patient would then receive a brown-bag test at a pharmacy or medical office that would reveal potentially dangerous medication interactions that no individual pharmacist or physician could have discovered, because of incomplete medical records.

SUMMARY OF THE INVENTION

The bar code drug identification system is accomplished by: (1) the application of a bar code identifier to the outside surface of the medication; and (2) the programming of a central processing unit (CPU) that is connected to a bar code reader and able to convert the electrical signals input by the bar code reader into the appropriate computer output identifier corresponding to the medication scanned by the bar code reader.

1. Application of the Bar Code Identifier

Several bar code symbologies have been commercially developed that permit numbers or alphanumeric characters

Once all necessary input patient information is complete, the video display screen **24** indicates that the user may begin to issue read commands from the bar code scanner **12**, as indicated in item step **58** in FIG. **3**. The user then points the face **26** of the bar code scanner **12** at the bar code symbol **42** marked on the outer surface of an exemplar medication item **40**, as shown in FIG. **2**. Alternatively, to stop the procedure the user issues an exit system command from the mouse **18** or keyboard **20**, as indicated in item step **58** in FIG. **3**.

The location of the face **26** of the bar code scanner **12** relative to the medication item **40** necessary to achieve an optimal scan will vary due to the physical specification of the bar code scanner **12**, the choice of bar code symbology, and the physical dimensions of the medication **40**.

Once the user has positioned the face **26** of the bar code scanner **12** relative to the medication item **40**, the user issues a read command typically by pressing a trigger button **28** on the bar code scanner **12**. The bar code scanner **12** analyzes the bar code symbol **42** and sends data corresponding to the bar code symbol **42** through the communications cable **14**.

If the user issues an exit system command, the computer software program **15**, displays an appropriate exit message and stops operation, as indicated in item step **60** in FIG. **3**.

Once the user attempts a scan operation using the bar code scanner **12**, the computer software program **15** first analyzes the data received from the bar code scanner **12** to check that the scan operation did not yield an error corresponding to events such as the mispositioning of the bar code scanner **12** relative to the medication item **40**, as indicated in item step **60** in FIG. **3**. If a scan error is detected, the computer software program **15** displays an error message and graphics on the video display screen **24** of the monitor **13** to direct the user to attempt another scan, as indicated in item step **64** in FIG. **3**.

If no scan error is detected, the computer software program **15** searches through a drug identification database **100** carried within the software program **15** that typically contains a list of matching medication numeric drug identifiers and an ASCII character string that contains the name of the medication plus additional ASCII character strings and graphical images, as indicated in item step **66** in FIG. **3**.

For example, a record from the drug identification database **100** might appear as:

667, 50 mg, Zoloft (sertraline HCl), Pfizer, Roerig Division

meaning that the computer software program **15** would interpret a bar code symbol **42** that was decoded into the medication identifier integer value 667 as 50 milligrams of the medication "Zoloft".

The result of the database search will indicate whether a successful match was found. If the match was unsuccessful, an error message is shown on the display screen **24**, as indicated in item step **68** in FIG. **3**. If the match is successful, information corresponding to the medication item **40** is shown on the display screen **24**, as indicated in item step **70** in FIG. **3**. The display screen **24** then prompts the user to scan another medication or to create an informational summary report **71** on the display screen **24**, as indicated in item step **72** in FIG. **3**.

Once the user requests an information report **71**, the computer software program **15** first performs a comparison of the set of medications scanned with reference to an extended database **102** containing known harmful medication side effects and interactions, as indicated in item step **74** in FIG. **3**. The information report **71** includes information regarding possible harmful medication interactions, is then shown as a report on the display screen **24**, as indicated in item step **76** in FIG. **3**. The computer software program **15** then displays a request for the user to indicate if a printed record is requested at the step **78**. If yes, then a printed record is generated at item step **79** by a printer **80** in communication with the computer **16** by a communication link, here a cable **82**.

As noted, the system may be used with a portable unit that because of memory limitations only identifies the drug using the text database **100** and does not include the extended database **102** that contains data related to specific patients, to graphical images or to adverse side effects and harmful interactions. Once the report is printed, the computer software program **15** then stops. If after the inquiry at step **84** no report is requested, then the software program stops at step **84** after display of the report at item step **76**.

While, in the foregoing, embodiments of the present invention have been set forth in considerable detail for the purposes of making a complete disclosure of the invention, it may be apparent to those of skill in the art that numerous changes may be made in such detail without departing from the spirit and principles of the invention.

What is claimed is:

1. A computerized drug identification system for the identification of medication items in pill, capsule, tablet, and caplet form, comprising:

a plurality of medication items, each medication item having an outer surface marked with a machine scannable bar code symbol identifying the medication item;

scanner means for electronically scanning the bar code symbol and decoding the bar code symbol into binary data;

a general purpose computer having a random access memory and a database of medication identifier codes;

means for transmitting the binary data from the scanner means to the random access memory of the computer;

means for processing the binary data in the random access memory of the computer and comparing the processed binary data to the database of medication identifier codes to match the processed binary data with a medication identifier code; and

means for display of the medication identification data associated with the matched medication identifier code.

2. The computerized drug identification system of claim **1** wherein the system contains means for computer input of patient identifier information.

3. The computerized drug identification system of claim **2** wherein the database of medication identifier codes contains patient identifier information supplied by the user.

4. The computerized drug identification system of claim **1** wherein the system displays a pictorial graphic of the medication item.

5. The computerized drug identification system of claim **4** wherein the system contains a database of harmful medication interaction identifiers, wherein the system displays an information report indicating the set of scanned medication items that includes a combination appearing in the database of harmful medication interaction identifiers.

* * * * *

US005845264A

United States Patent [19]

Nellhaus

[11] Patent Number: 5,845,264

[45] Date of Patent: Dec. 1, 1998

[54] **BAR CODE IDENTIFICATION OF DRUGS**

[76] Inventor: **Gerhard Nellhaus**, 670 Vernon St. #207, Oakland, Calif. 94610

[21] Appl. No.: **612,372**

[22] Filed: **Mar. 7, 1996**

[51] **Int. Cl.**[6] **G06F 17/60**

[52] **U.S. Cl.** **705/28**; 705/2; 235/375

[58] **Field of Search** 705/2, 3, 22, 28, 705/29; 715/3; 235/375

[56] **References Cited**

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4,967,928	11/1990	Carter	221/2
5,129,974	7/1992	Aurenius	156/64
5,237,157	8/1993	Kaplan	235/375
5,463,209	10/1995	Figh et al.	235/383
5,542,420	8/1996	Goldman et al.	600/301
5,597,995	1/1997	Williams et al	235/375

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Primary Examiner—Gail O. Hayes

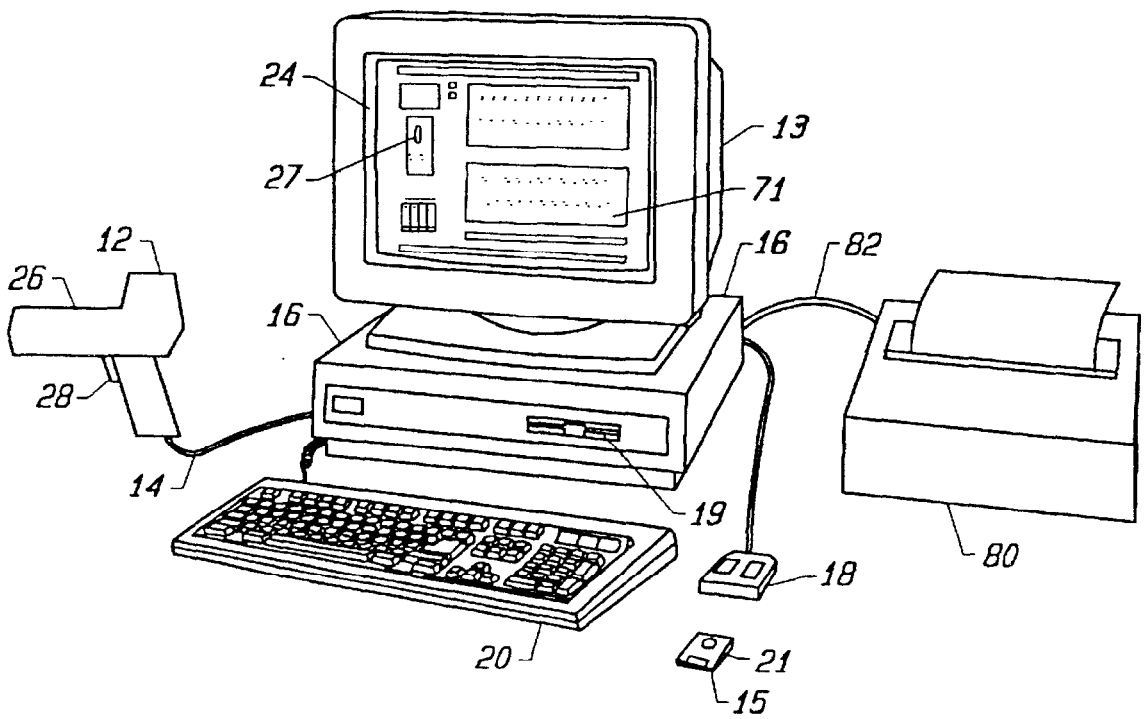
Assistant Examiner—Alexander Kalinowski

Attorney, Agent, or Firm—Bielen, Peterson & Lampe

[57] **ABSTRACT**

A system for the identification of medications in pill, capsule, tablet, and caplet for the system including the placement of machine scannable bar code symbols on the surface of the medication and the identification of the medication by use of the bar code. The resulting identification information can be analyzed by a computer program, permitting both a drug identification and verification method for use by a doctor, pharmacist, emergency room or other medical staff, paramedics, law enforcement personnel, patient and/or family members, or indeed anyone who may need to know a drug's identity, and a tracking system by inclusion of the identification data into an appropriate information database to monitor an individual's prescription drug consumption and to alert of potential harmful drug interactions.

5 Claims, 3 Drawing Sheets



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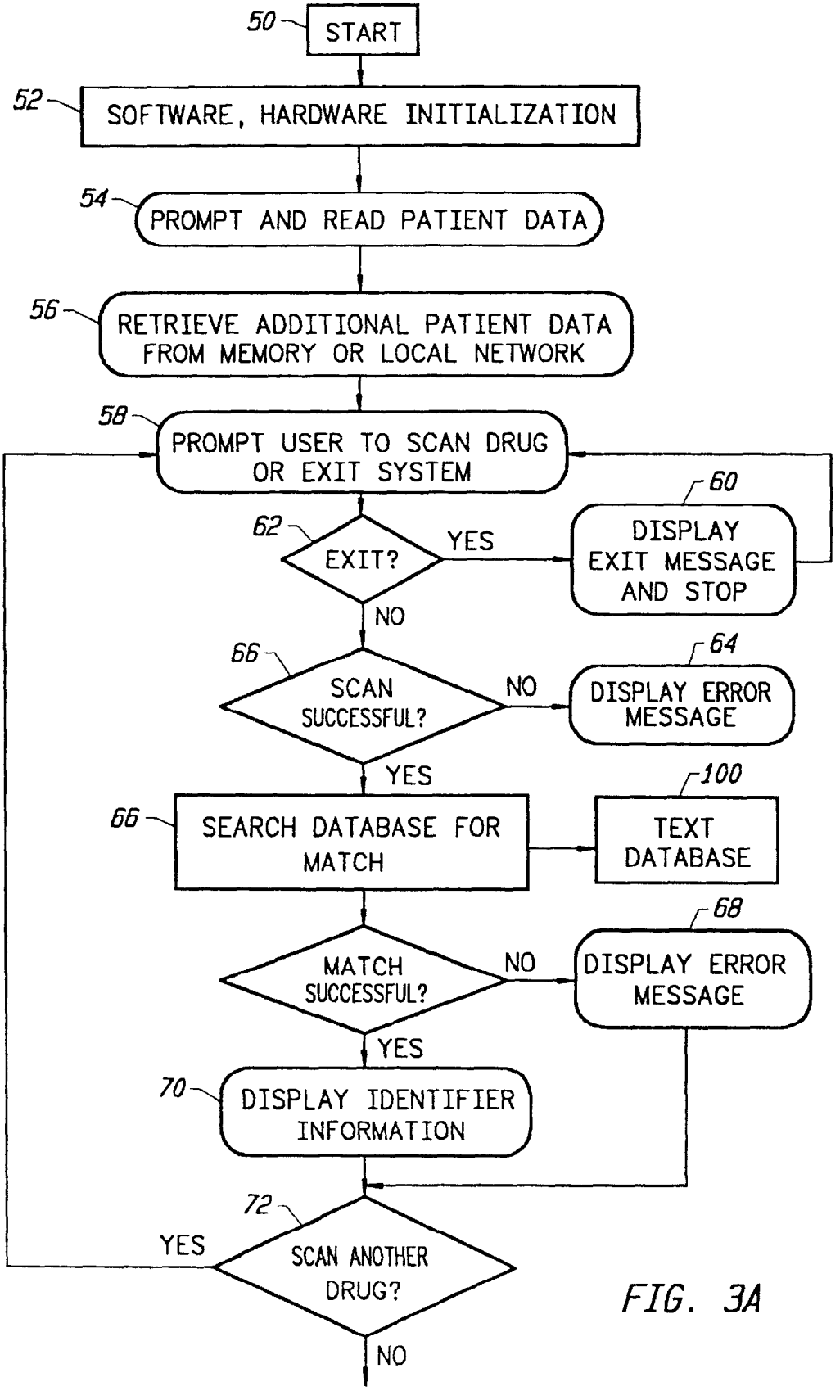
50
START
52
SOFTWARE, HARDWARE INITIALIZATION
54
PROMPT AND READ PATIENT DATA
56
RETRIEVE ADDITIONAL PATIENT DATA FROM MEMORY OR LOCAL NETWORK
58
PROMPT USER TO SCAN DRUG OR EXIT SYSTEM
62
EXIT?
YES
60
DISPLAY EXIT MESSAGE AND STOP
NO
66
SCAN SUCCESSFUL?
NO
64
DISPLAY ERROR MESSAGE
YES
66
SEARCH DATABASE FOR MATCH
100
TEXT DATABASE
MATCH SUCCESSFUL?
NO
68
DISPLAY ERROR MESSAGE
YES
70
DISPLAY IDENTIFIER INFORMATION
72
SCAN ANOTHER DRUG?
YES
NO

FIG. 3A

BAR CODE IDENTIFICATION OF DRUGS

BACKGROUND OF THE INVENTION

This invention relates generally to a system for identification of prescription medications that has a primary feature the placement of identification markers on the outside of the medication. Specifically, this invention relates to a system for prescription medication identification using bar code symbols placed on the outside of the medication.

The proliferation of new prescription medications created by advances in pharmacology and the steady increase of generics unfortunately has unintentionally created health problems when: (1) patents misidentify and thereby misuse their prescribed drugs; (2) patients suffer adverse drug interactions when two or more prescribed drugs taken concurrently combine in a harmful manner; or (3) doctors misprescribe medications based on a lack of information regarding the patient's history. Health problems based on these scenarios are likely to grow over time because the introduction of every new medication increases the number of potential interactions with the prior existing set of medications.

Several related problems occurring most frequently in the elderly population are beginning to receive attention in research publications such as *The Journal of the American Medical Association* (JAMA), as well as the popular press. A recent JAMA study based on review of nursing home subjects concluded that roughly 23% of Americans ages 65 and over are using at least one of twenty medications that are notorious for triggering insomnia, fainting spells, or amnesia among the elderly. The study also stated broader educational and regulatory initiatives are needed, and a companion JAMA editorial referred to this study as illuminating "the tip of the iceberg".

This widespread problem prevails despite the well-known medical technique doctors often employ, called the "brown-bag" test. The brown-bag test consists of a patient, typically elderly, being instructed to empty the contents of their medicine chest into a bag and then to bring the bag into the physician's office or to a pharmacist for analysis.

Additionally, physicians are beginning to trace health problems in the elderly to the overprescription of medications in amount or duration. This phenomena has been explained as the result of the human body's changing reaction to medications as part of the aging process.

Currently, patients and doctors who cannot readily identify a prescribed medication can attempt to consult a guide such as *The Physician's Desk Reference* (PDR) that contains a pictorial index of commonly prescribed drugs. However, the elderly patients most at risk for these problems probably fail to possess the visual or mental acuity necessary to complete these tasks, and even the professionals who can consult the PDR may fail to locate their medication because it is a generic equivalent not shown. For the physician to consult the PDR each time the identity of a drug is in question, is an imposition that is time consuming and hence an added cost of service.

The patient's recourse is to visit a physician, physician's assistant or pharmacist who will conduct a brown-bag test. A physician, health provider, or law enforcement agent who cannot identify a medication using the PDR may be forced to conduct expensive laboratory tests on the unknown medication.

This inventor has devised a graphical system to assist in the identification of drugs. This system is described in U.S. Pat. No. 5,031,937, issued 16 Jul. 1991, entitled, "Pictorial Guidance/Reminder System for Medication." The system includes a pictorial graphic representation showing the drug and providing for the use of such graphic representations for a medication table for scheduled taking of medications. Because of the many similarly appearing generic and proprietary drugs, visual identification is frequently difficult.

Recent trends in health care also indicate that patients are being placed at risk because of the increased workload on pharmacists. Several national pharmacy associations have identified the problems caused by increased cost-cutting pressures on pharmacists. Examples cited include patients receiving the wrong medication dosage or even the wrong medication. Pharmacists are often cited for failing to comply with state laws requiring patient notification and counseling upon receipt of prescribed medications.

The identification problems described above are solved when medications are individually labeled with bar code symbols that uniquely identify the medication, or class of medications, when the medication is scanned through a common bar code reader. The bar code reader is connected to a computer containing the appropriate software to translate the output provided by the bar code reader into a data identifier that can be referenced to a database table that operates as an index of bar code-medication pairs. The computer could then display the medication name plus additional information desired.

This identification system could be utilized both by the patient at home and by the dispensing pharmacist, and would increase patient safety while decreasing health care costs.

As early as 1989, individuals in the bar code community generally suggested that bar codes could be used by health care providers in areas such as patient billing, pharmacy, and bedside medication verification. However, there was no suggestion that this should extend to actually placing a bar code on the drug item itself.

This system can operate using at least one of the many commercially available bar code symbologies that meet desired requirements based on: (1) the number of unique codes available; (2) medication size constraints; and (3) error detection and correction tolerances. Once implemented, this system will eliminate nearly all human error in confirming medication identification and will serve as a low-cost medication verification system.

Additionally, this system could be incorporated into an extended system that includes a database containing individual patient medication histories, and a database of known harmful drug interactions. Through this system, a patient would then receive a brown-bag test at a pharmacy or medical office that would reveal potentially dangerous medication interactions that no individual pharmacist or physician could have discovered, because of incomplete medical records.

SUMMARY OF THE INVENTION

The bar code drug identification system is accomplished by: (1) the application of a bar code identifier to the outside surface of the medication; and (2) the programming of a central processing unit (CPU) that is connected to a bar code reader and able to convert the electrical signals input by the bar code reader into the appropriate computer output identifier corresponding to the medication scanned by the bar code reader.

1. Application of the Bar Code Identifier

Several bar code symbologies have been commercially developed that permit numbers or alphanumeric characters

Once all necessary input patient information is complete, the video display screen **24** indicates that the user may begin to issue read commands from the bar code scanner **12**, as indicated in item step **58** in FIG. **3**. The user then points the face **26** of the bar code scanner **12** at the bar code symbol **42** marked on the outer surface of an exemplar medication item **40**, as shown in FIG. **2**. Alternatively, to stop the procedure the user issues an exit system command from the mouse **18** or keyboard **20**, as indicated in item step **58** in FIG. **3**.

The location of the face **26** of the bar code scanner **12** relative to the medication item **40** necessary to achieve an optimal scan will vary due to the physical specification of the bar code scanner **12**, the choice of bar code symbology, and the physical dimensions of the medication **40**.

Once the user has positioned the face **26** of the bar code scanner **12** relative to the medication item **40**, the user issues a read command typically by pressing a trigger button **28** on the bar code scanner **12**. The bar code scanner **12** analyzes the bar code symbol **42** and sends data corresponding to the bar code symbol **42** through the communications cable **14**.

If the user issues an exit system command, the computer software program **15**, displays an appropriate exit message and stops operation, as indicated in item step **60** in FIG. **3**.

Once the user attempts a scan operation using the bar code scanner **12**, the computer software program **15** first analyzes the data received from the bar code scanner **12** to check that the scan operation did not yield an error corresponding to events such as the mispositioning of the bar code scanner **12** relative to the medication item **40**, as indicated in item step **60** in FIG. **3**. If a scan error is detected, the computer software program **15** displays an error message and graphics on the video display screen **24** of the monitor **13** to direct the user to attempt another scan, as indicated in item step **64** in FIG. **3**.

If no scan error is detected, the computer software program **15** searches through a drug identification database **100** carried within the software program **15** that typically contains a list of matching medication numeric drug identifiers and an ASCII character string that contains the name of the medication plus additional ASCII character strings and graphical images, as indicated in item step **66** in FIG. **3**.

For example, a record from the drug identification database **100** might appear as:

667, 50 mg, Zoloft (sertraline HCl), Pfizer, Roerig Division

meaning that the computer software program **15** would interpret a bar code symbol **42** that was decoded into the medication identifier integer value 667 as 50 milligrams of the medication "Zoloft".

The result of the database search will indicate whether a successful match was found. If the match was unsuccessful, an error message is shown on the display screen **24**, as indicated in item step **68** in FIG. **3**. If the match is successful, information corresponding to the medication item **40** is shown on the display screen **24**, as indicated in item step **70** in FIG. **3**. The display screen **24** then prompts the user to scan another medication or to create an informational summary report **71** on the display screen **24**, as indicated in item step **72** in FIG. **3**.

Once the user requests an information report **71**, the computer software program **15** first performs a comparison of the set of medications scanned with reference to an extended database **102** containing known harmful medication side effects and interactions, as indicated in item step **74** in FIG. **3**. The information report **71** includes information regarding possible harmful medication interactions, is then shown as a report on the display screen **24**, as indicated in item step **76** in FIG. **3**. The computer software program **15** then displays a request for the user to indicate if a printed record is requested at the step **78**. If yes, then a printed record is generated at item step **79** by a printer **80** in communication with the computer **16** by a communication link, here a cable **82**.

As noted, the system may be used with a portable unit that because of memory limitations only identifies the drug using the text database **100** and does not include the extended database **102** that contains data related to specific patients, to graphical images or to adverse side effects and harmful interactions. Once the report is printed, the computer software program **15** then stops. If after the inquiry at step **84** no report is requested, then the software program stops at step **84** after display of the report at item step **76**.

While, in the foregoing, embodiments of the present invention have been set forth in considerable detail for the purposes of making a complete disclosure of the invention, it may be apparent to those of skill in the art that numerous changes may be made in such detail without departing from the spirit and principles of the invention.

What is claimed is:

1. A computerized drug identification system for the identification of medication items in pill, capsule, tablet, and caplet form, comprising:

a plurality of medication items, each medication item having an outer surface marked with a machine scannable bar code symbol identifying the medication item;

scanner means for electronically scanning the bar code symbol and decoding the bar code symbol into binary data;

a general purpose computer having a random access memory and a database of medication identifier codes;

means for transmitting the binary data from the scanner means to the random access memory of the computer;

means for processing the binary data in the random access memory of the computer and comparing the processed binary data to the database of medication identifier codes to match the processed binary data with a medication identifier code; and

means for display of the medication identification data associated with the matched medication identifier code.

2. The computerized drug identification system of claim **1** wherein the system contains means for computer input of patient identifier information.

3. The computerized drug identification system of claim **2** wherein the database of medication identifier codes contains patient identifier information supplied by the user.

4. The computerized drug identification system of claim **1** wherein the system displays a pictorial graphic of the medication item.

5. The computerized drug identification system of claim **4** wherein the system contains a database of harmful medication interaction identifiers, wherein the system displays an information report indicating the set of scanned medication items that includes a combination appearing in the database of harmful medication interaction identifiers.

* * * * *

US006543692B1

(12) **United States Patent**
Nellhaus et al.

(10) **Patent No.: US 6,543,692 B1**
(45) **Date of Patent: Apr. 8, 2003**

(54) **SCHEMA FOR IDENTIFICATION OF SOLID FORM DRUGS**

(76) Inventors: **Gerhard Nellhaus**, Kursana Residenzen Rabenkopfstrasse 2, Freiburg (DE), 79102, **Richard E. Peterson**, 537 Valley St., San Francisco, CA (US) 94131

( ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 71 days.

(21) Appl. No.: **09/652,528**

(22) Filed: **Aug. 31, 2000**

Related U.S. Application Data

(60) Provisional application No. 60/152,288, filed on Sep. 3, 1999

(51) **Int. Cl.**[7] **G06K 7/10**

(52) **U.S. Cl.** **235/462.01**; 235/375

(58) **Field of Search** 235/375, 462.01–462.49, 235/472.01–472.03, 494, 383, 454; 53/55, 168, 498

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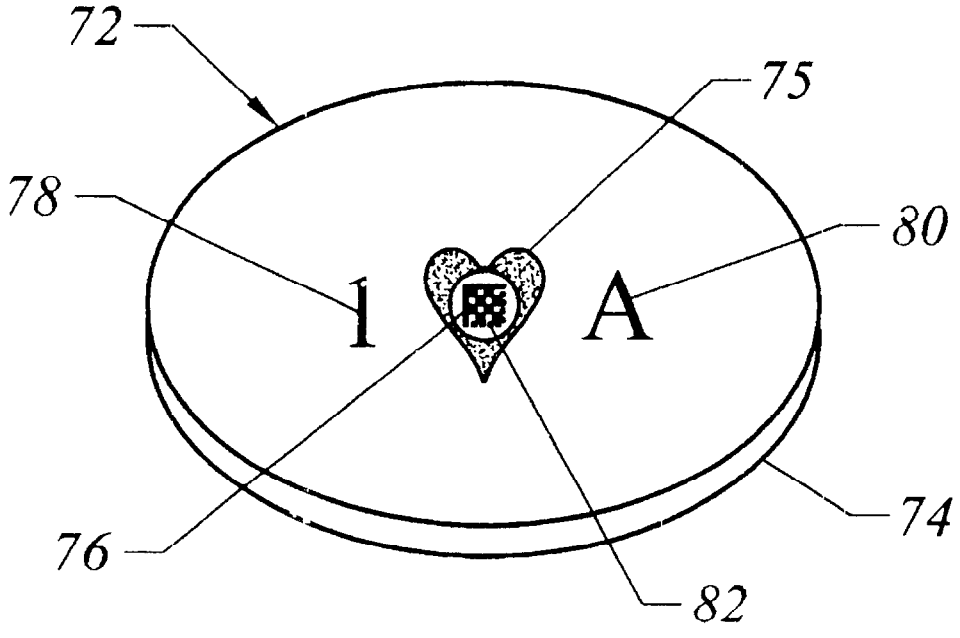
Primary Examiner—Thien M. Le
(74) *Attorney, Agent, or Firm*—Richard Esty Peterson

(57) **ABSTRACT**

A bar code schema for identification of solid form drugs, such as pills, tablets, capsules and the like using a data matrix type symbology for compact coding that is easily deciphered in combination with a common visual symbol that is easily recognized, the schema incorporating a portable code reading pen.

11 Claims, 4 Drawing Sheets



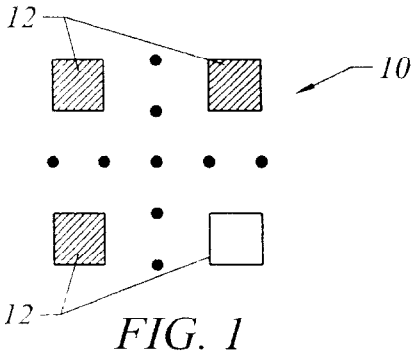


FIG. 1

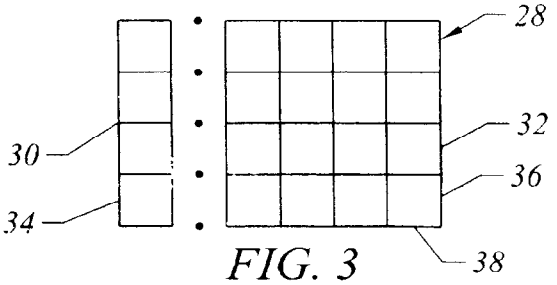


FIG. 3

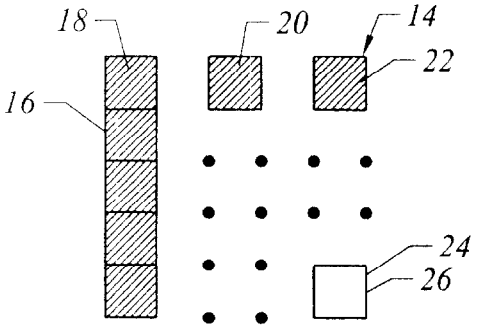


FIG. 2

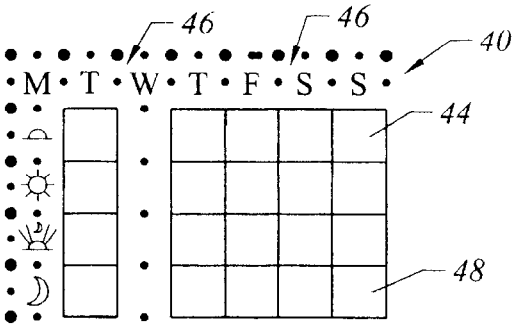


FIG. 4

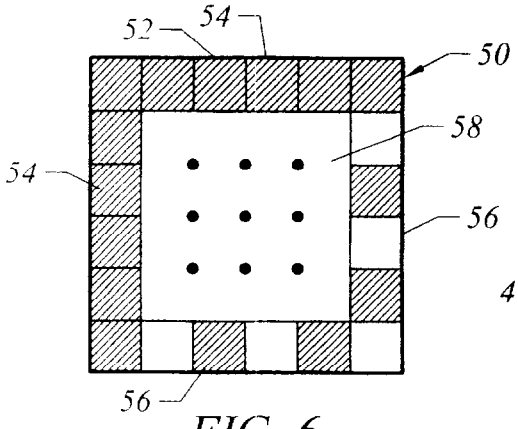


FIG. 6

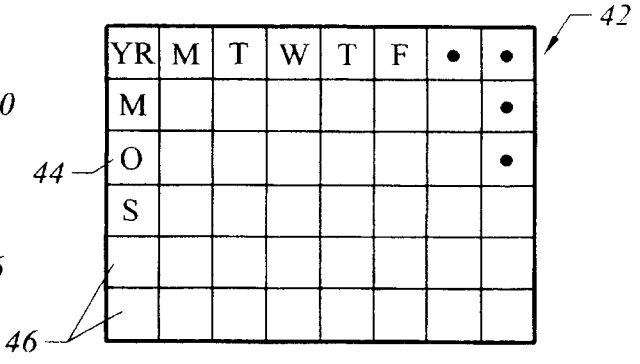


FIG. 5

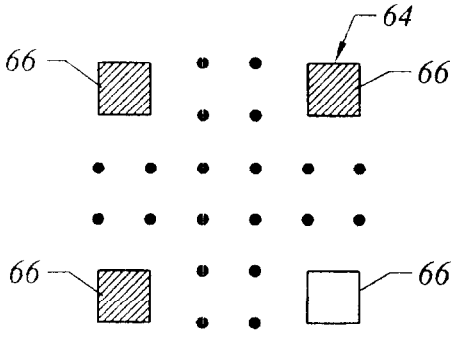


FIG. 8

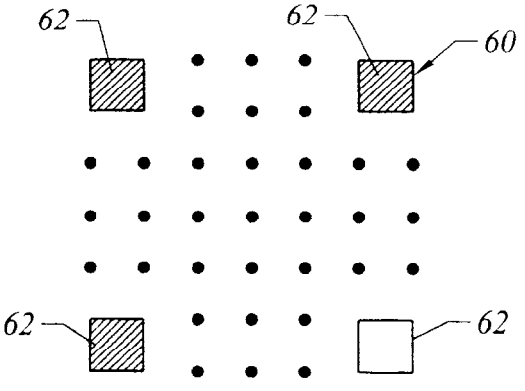


FIG. 7

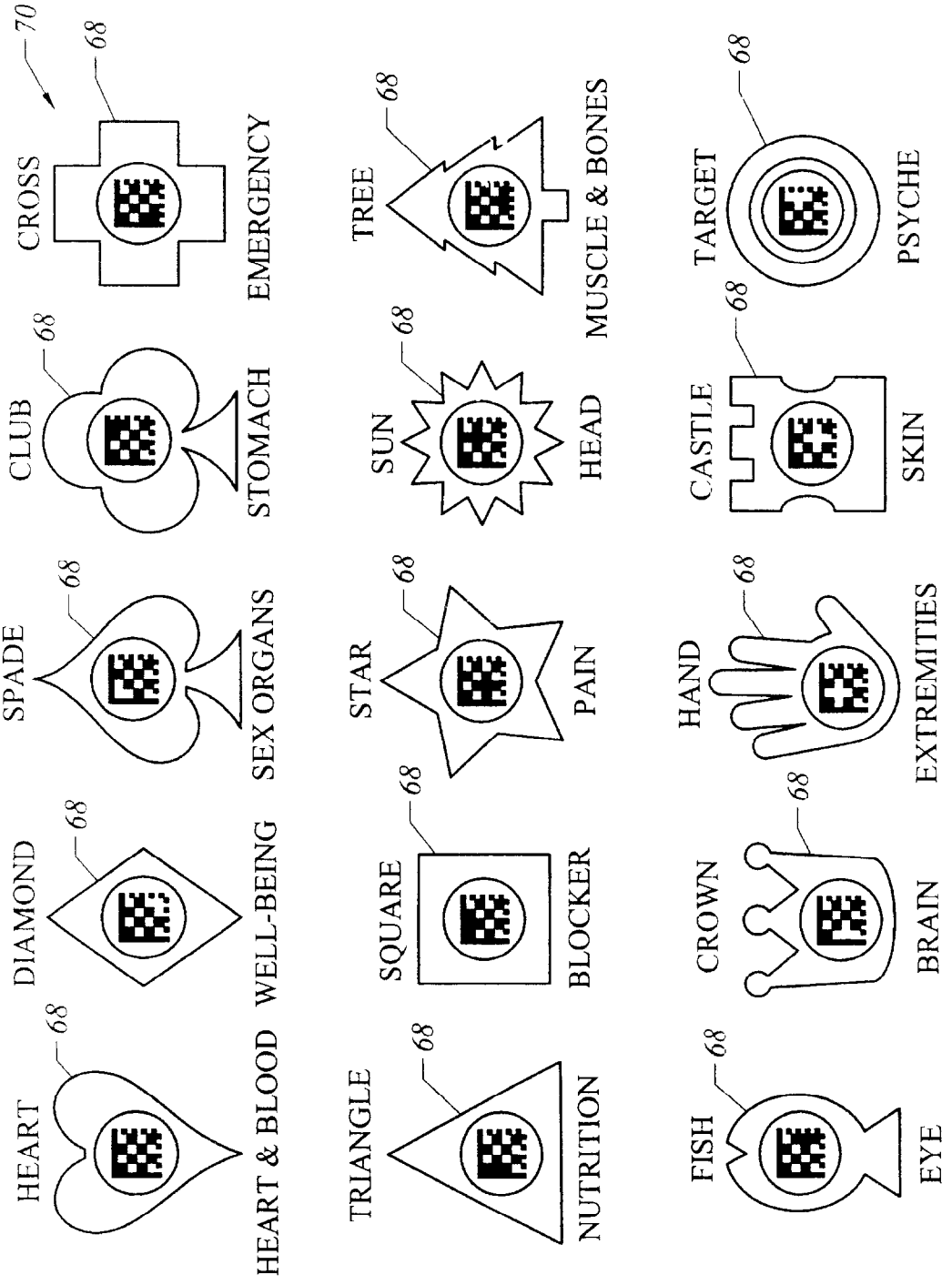

70
HEART
68
HEART & BLOOD
DIAMOND
68
WELL-BEING
SPADE
68
SEX ORGANS
CLUB
68
STOMACH
CROSS
68
EMERGENCY
TRIANGLE
68
NUTRITION
SQUARE
68
BLOCKER
STAR
68
PAIN
SUN
68
HEAD
TREE
68
MUSCLE & BONES
FISH
68
EYE
CROWN
68
BRAIN
HAND
68
EXTREMITIES
CASTLE
68
SKIN
TARGET
68
PSYCHE

FIG. 9

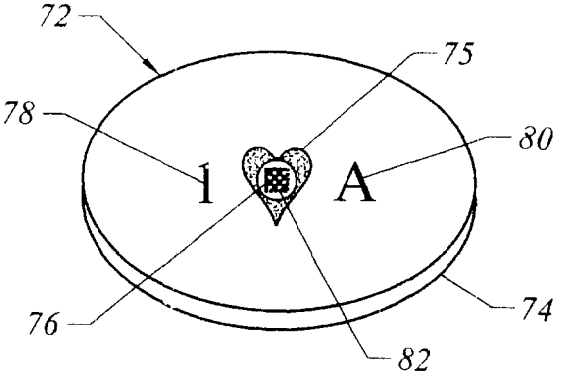
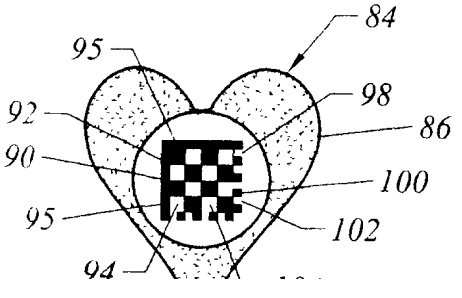
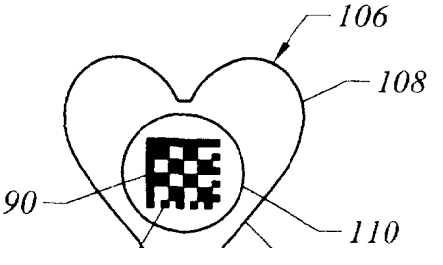


FIG. 10





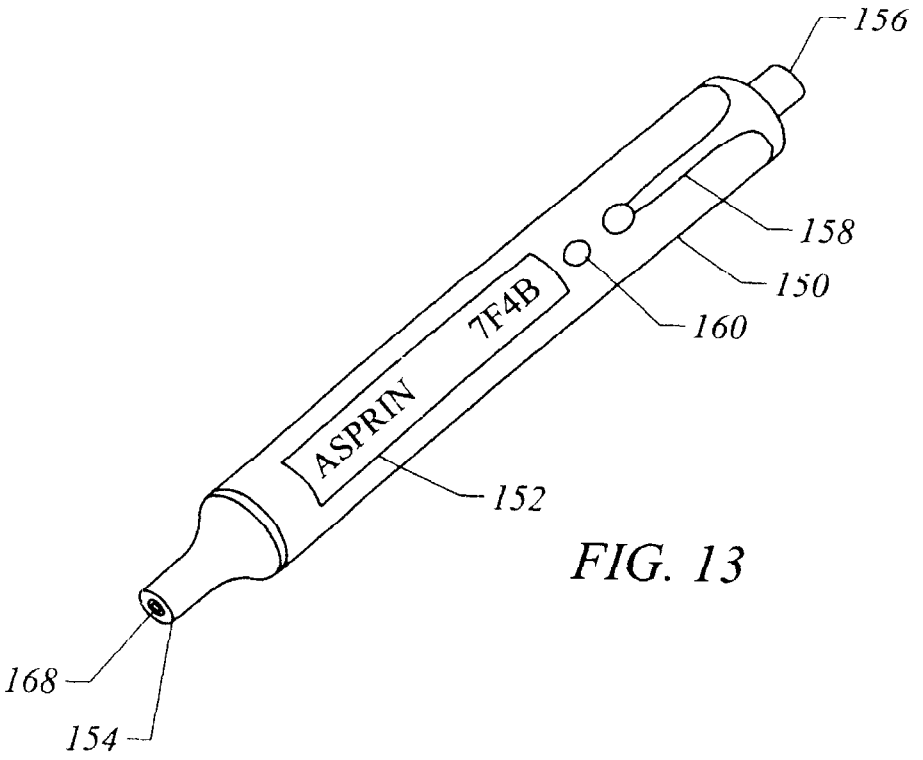
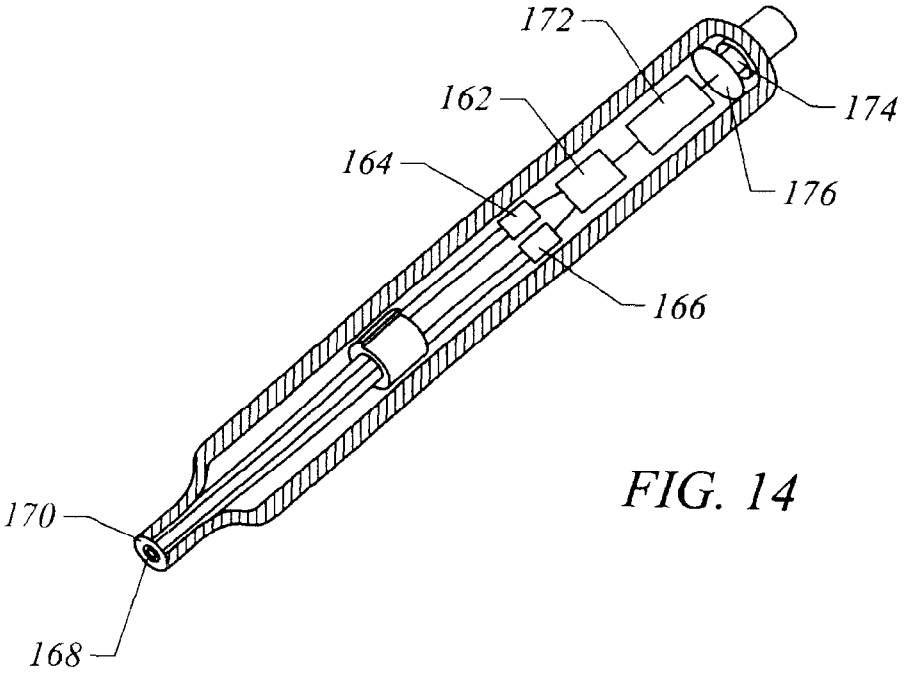

156
158
150
160
ASPRIN
7F4B
152
168
154

FIG. 13


172
162
174
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176
166
170
168

FIG. 14

SCHEMA FOR IDENTIFICATION OF SOLID FORM DRUGS

This application claims the benefit of provisional application Ser. No. 60/152,288, filed Sep. 3, 1999.

BACKGROUND OF THE INVENTION

The identification schema for drugs proposed by this invention extends the concepts described in U.S. Pat. Nos. 5,031,937 and 5,845,264 of Dr. Gerhard Nellhaus and in particular the system for bar coding drug tablets, capsules, pills and the like for identification.

In selecting a bar code scheme for drugs, ease of reading both by machine and by visual inspection is an important criterion. A two dimensional bar code of the data matrix type is compact and can be easily scanned by an image capture device. Certain sweep scanners can read primitive data matrix type codes. However, the use of charged, coupled devices (CCD's) for images capture and software for image rotation and decoding makes the matrix pattern more practical for small objects.

SUMMARY OF THE INVENTION

For the application of identifying drugs, simplicity is desired. A 4×4 matrix is compact and lends itself to code in hexadecimal. Any standard reference can decode the hexadecimal to obtain alphanumeric characters. Theoretically, a 4×4 matrix can code 65,536 items using a binary half-bite system.

However, orientation is a problem for a correct read of a matrix symbol, which may be a square mark at the center of a round pill. For most applications in drug marking, a 5×5 "adapted" matrix or a 6×6 matrix using Data Matrix™ alignment protocol is appropriate. For the very small pills a 4×4 matrix can be used with three of the corner squares having a common marking, i.e. black with the remaining square unmarked. This allows a definition of orientation, but reduces the date bits to 12 for itemizing only 4,096 objects.

Therefore, in the preferred bar code schema for imprinted drugs, that minimally satisfies the current FDA requirement for imprinting solid form drugs, a modified 4×4 matrix data field is used. To accommodate more than 4,096 objects, except for the reserve code for ultra small drugs, a 5×5 matrix is the preferred minimum.

Alternately, a matrix outline and a header bar for orientation can be used.

This results in a 6×4 matrix, since a space column should be incorporated between the data matrix and the header bar. Notably, the header bar could constitute the alphanumeric, advised, but not required by the FDA with little useful purpose other than orientation.

The 5×5 matrix, however, advantageously allows a solid header bar to be combined with an alternating checkerboard square pattern to both define the matrix size and allow for determination of granularity, which is an aid in reading. The granularity allows the size of the data bits to be determined.

As a last resort, the full protocol of the Data Matrix™ system can be implemented with a 6×6 matrix, although ironically this is too small to comply with the current ANSI Data Matrix™ standards which start with a 12×12 matrix.

Larger matrices are not required unless larger numbers of drugs are to be marked. Since marked information is desired to be informative, encryption codes are not required, thereby maximizing the data content in drug identification applications using a data matrix type protocol.

One solution to the competing interests of maximizing the visibility of the data squares within a data matrix orientation and granularity frame, and minimizing the overall size of the matrix is provided by doubling the size of the data squares in comparison with the squares forming the frame. In this manner, a 4×4 matrix of double size data squares in a frame of unitary size squares forms an effective 10×10 matrix. A 5×5 matrix of double size data squares with an orientation and granularity frame of unitary size squares effectively forms a 12×12 matrix, coincidentally the minimum matrix for an ANSI Data Matrix™ symbol. It is to be understood, however, that the error correction and validation coding within the matrix of a Data Matrix™ symbol are not employed. In the hybrid Data Matrix™ system disclosed, the increased size of the data squares substantially improves the likelihood of an accurate reading, and, more than off-sets the loss of error correction coding within the data field.

It is preferred that the matrix of the data matrix imprint be contained within a perimeter graphic that is useful for visual determination or differentiation of the drug by the patient. This graphic may be used in combination with other alphanumeric or symbolic marks, or with the pill shape or color for visual identification. The preferred graphic ideograph or icon should be easily recognizable for categorical identification. Additionally, the ideograph or icon should be of a type that can be easily communicated orally, for example, from one person to another by telephone, to aid in determining the pill's identity.

Upon implementation of the coding schema, a code reader pen is used for automatic identification of the drug item without resorting to tables and directories. The code reader pen is a self contained instrument similar in operation to a push-top, ball point pen with a light source, and a data retrieval lens that focuses the code imprint on a charged, coupled device (CCD) to capture a readable image. The pen includes a small processor and memory to decode the pattern, for example, by rotation and pattern matching against a set of stored templates or patterns. A database listing of drug names, for example, is displayed in an elongated display along the side of the pen which the user reads, like a thermometer, when making an identification using the code reader pen.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a bar code in the form or a 4×4 matrix with the corner square marked for orientation.

FIG. **2** is a bar code in the form of a 5×5 matrix with an alignment column and granularity row.

FIG. **3** is a bar code in the form of a 6×4 rectangular matrix with a header bar for alignment.

FIG. **4** is a 5×7 field, incidentally used for drug image display.

FIG. **5** is a 6×8 field, incidentally used for calendars, including drug image display.

FIG. **6** is a bar code in the form or a 6×6 Data Matrix™ format with a 4×4 data field.

FIG. **7** is a bar code in the form of a 6×6 matrix using corner squares for orientation.

FIG. **8** is a bar code in the form of a 5×5 matrix using corner squares for orientation.

FIG. **9** is a set of icons, or ideographs, that are suitable for easy recognition in outline form.

FIG. **10** is a top view of a typical pill in the form of an oval tablet.

FIG. **11** is an enlarged view of a typical combination marking of an icon and matrix from FIG. **9**.

FIG 12 is an enlarged view of an alternate style of icon in the combination marking of the type shown in FIG. 11.

FIG. 13 is a perspective view of a code reading pen.

FIG 14 is a cross-sectional view of the code reading pen of FIG. 13

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings, a preferred bar code system for the application as a solid form drug identifier is shown in FIG 1 as a 4×4 matrix **10**. It is to be understood that in the following disclosure the code matrix is printed on the drug using standard drug imprinting machinery, for example, an inkjet or roll type printer It is to be understood that alternate means of imprinting the drug code on the drug can be accomplished For example, the pill, capsule or tablet can be scored, embossed or pitted in a manner that can be read by a reading device using reflected and/or diffracted light or other means such as ultrasonic waves. However, the use of a simple printing system that prints black ink in a "checker board" type matrix is expedient for implementing this invention.

In the 4×4 matrix **10** of FIG. **1**, the four corner squares **12** must be reserved to indicate the orientation of the matrix **10** since the matrix may be placed on the center of a circular pill. By utilizing the four corner squares **12** the data content is reduced to identifying 4,096 items, which is insufficient for the number of available drugs. However, this small matrix can be reserved for those very small pills in which a larger matrix would be inappropriate.

Referring to FIG. **2**, a 5×5 matrix **14** is shown that complies in principal with Data Matrix™ symbology in that an orientation bar **16**, indicated as the first column **18** in the matrix, and a granularity bar **20**, indicated as the first row **22** in the matrix, can provide for information about both the orientation of the matrix and the granularity of the data bits that are indicated as discrete squares **24** that are either black or white (or background color). Because the fourth corner square **26** should remain uncolored to allow for orientation, the data content is sufficient for coding 32,768 items.

FIG. **3** is an alternate rectangular arrangement **28** in which an alignment bar **30** or header is provided proximate to a data field **32** In this embodiment it is expected that both the squares **34** of the alignment bar **30** and the squares **36** of the data field **34** delineated with lines **38** by the printing process. In this manner, the code outline can be identified and the fields can be supplied with printed squares for coding. Preferably, the header bar **30** is oriented under the data field when reading or interpreting the code as in the convention for underlining "6" and "9" for defining orientation.

FIGS. **4** and **5** are ancillary to this invention and disclose the manner in which displays for calendaring or scheduling the taking of drugs can be divided into a matrix **44** that can also serve as a coded device for carrying coding of the data field that is implemented by a printer when printing the encoded data field on a drug item. For example, these scheduling templates can be designed with reserved fields for one or more embedded data matrices in the headings **46** in the form of small, barely visible, graphics that identify and link to tablet or capsule images for pictorial display of the actual pill images in scheduling squares **48** of the matrix. These graphics can be read with the reader pen as a cross check for pill identification, since the pictorial pill image that is printed on the schedule will likely be of a quality that the data matrix marking on the pill image cannot be accurately read when using an ordinary color ink jet printer or the like to print the schedule.

FIG **6** is a 6×6 matrix **50** that has a frame **52** with two contiguous solid orientation bars **54** and two contiguous granularity bars **56** of alternating squares of different contrast, for example, black and white squares. The frame **52** forms a perimeter around a data matrix **58** and permits full use of the 65,536 item identifications available in a 4×4 matrix.

FIG. **7** is a 6×6 matrix **60** with the corner squares **62** reserved for marking the orientation of the matrix when read. Since the 6×6 matrix has available thirty two remaining squares for data encoding, over 4 billion items can be encoded.

FIG. **8** is a 5×5 matrix **64** with the 4 corner squares **66** reserved for orientation of the matrix with twenty one remaining squares for data content allowing for over 2 million items to be identified.

Since it is expected that generic drugs will be the first drugs marked with an imprint code that is machine readable, it is preferred that the imprint code be accompanied by a standard graphic symbol that is human readable without regard to language, such as one of the symbols or icons **68** depicted in the emblem chart **70** of FIG. **9**. In the emblem examples of FIG 9, the preferred hybrid Data Matrix™ symbology described with reference to FIGS 11 and **12** is utilized.

Referring to FIG. **10**, a typical drug item **72**, such as the oval pill **74** on which is marked with a heart icon **75**, would advantageously include the matrix code **76** within the center of the outline of the well recognized symbol. In addition, a number **78** and/or a letter **80** can accompany the graphic symbol **75** and the data matrix **82** to enable a patient or handler of the pill to readily identify the pill using easily described symbology. For example, in an emergency a patient can by telephone indicate that the pill in question is an oval pill of pale orange color with a heart and the alphanumeric indicia of "1 and A" marked on the pill. Notably, this additional symbology and alphanumeric marking is not required by the FDA to comply with the FDA imprinting regulations. The symbology in the form of a readily recognizable icon is preferably suggestive of the category or drug or type of ailment treated. Even without the addition of an alphanumeric marking, it is believed that such common, easily identified symbology, would be a great aid and a useful addition to bar coding for the purpose of drug identification. Where possible, it is desired that the data matrix **82** be centered in the ideograph or icon **75** wherein the icon forms a target for locating the matrix code. Where printing degenerates, for example, on imprinting a very small matrix on very small pills, the data matrix **82** can be printed on one side of the pill and the icon **75** on the other.

In adopting a particular bar code arrangement, a conventional bar code can be utilized. However, for economy of size and readability, a data matrix type of bar coding system is preferred. While a number of different alternatives for encoding have been proposed, the actual system that is considered best for adoption is disclosed with reference to FIGS. **11** and **12**. Ultimately, the bar code format adopted should be decided with the involvement of both the drug manufacturers and distributors, and the standards organizations. It is to be understood that the ANSI standards for bar code symbology do not include the smaller matrices that are here proposed. However, since readability is desired and the ability to decode a marking, even without a machine reading device is preferred, the simplest system with the fewest squares is considered the best.

In a preferred embodiment, a hybrid code symbology that approximates the standard Data Matrix™ symbology is

described with reference to FIGS. **11** and **12**. This would allow use of devices that have been designed for recognition of standard ANSI Data Matrix™ symbologies with little modification. The hybrid Data Matrix™ system devised, incorporates an alignment and granularity frame that complies with the ANSI standards, but incorporates a data field using squares that are twice as large as the granularity squares in the symbol.

Referring to FIG. **11**, the result is shown for a combination symbol **84** including a graphic symbol **86** in the form of a heart that forms a border around a quiet zone **88** in the form of a circle around the hybrid Data Matrix™ symbol **90**. The Data Matrix™ symbol **90** includes a frame **92** around a data field **95**. The frame **92** comprises a perimeter alignment pattern that comprises two contiguous solid bars **94** of dark squares **96** and two granularity bars **98** formed of alternating patterns of dark squares **100** and light squares **102**. In this manner, the orientation of the symbol to be decoded can be determined, and the granularity of the data in the data field is defined. However, in the hybrid system the data field **94** includes double sized squares **104** for ease of printability and readability. Effective error correction can be accomplished by determining whether any of the squares in the granularity portions of the frame are missing. If a correct read of the granularity squares cannot be obtained, then great caution should be used in reading the double sized squares of the data field. It is highly unlikely the double sized squares of the data field will be damaged beyond recognition give the comparative size of the squares which can be visually examined for damage and visually decoded if necessary.

If the size of the data field is maintained at a 4×4 matrix, then added protection can be obtained by following the rules for a data field without a frame or perimeter pattern. If this is done as a safety measure for the most critical of solid form drugs, then the remaining pharmaceuticals can be identified using a data field having a 5×5 matrix. Notably, when using a 5×5 matrix, the effective size of the hybrid data matrix symbol is a 12×12 matrix. Furthermore, where the identification of the solid form capsule or tablet is not critical, as in the unregulated area of dietary supplements, then a 6×6 matrix resulting in a hybrid Data Matrix™ symbol with an effective 14×14 matrix can be utilized.

In FIG. **11** the graphic symbol **86** in the composite marking is shown in a solid form. In general, this minimizes the size of the symbol and maximizes the readability of the encompassed hybrid Data Matrix™ symbol **90**. However, if it is desired, the graphic symbol can be in line form as shown in FIG. **12**.

In FIG. **12**, the combination visual readable and machine readable symbol **106** includes the visual symbol **108** in outline form, a target circle **110** that encompasses the hybrid Data Matrix™ symbol **90** at the center of the circle **110**. Notably the thickness of the printed line **112** in the combination symbol **106** of FIG. **12** is equivalent to the dimension of a granularity square **100** in the hybrid Data Matrix™ symbol **90**.

It is to be understood that the emblems shown in FIG. **9** are merely examples of readily identifiable ideographs that can be used for categorizing drugs. More traditional icons that are used in medicine for identifying categories of drug substances can be employed. These icons are often pictographs such as the outline of a head, stomach, or other anatomical part affected by the drug. The "hand" icon in the emblem chart of FIG. **9** would be of this type.

In order to conveniently read the imprint code, a code reading device **148** is provided for use by the physician, pharmacist, patient or other user. The device **148** is preferably in the form of a pen as shown in FIG. **13** with a body or housing **150** and a side display **152** with a reading tip **154** and an activating button **156**. The pen can include a clip **158** for the convenience of the user and preferably has a light **160** to indicate whether a correct read has been made. In use, the physician simply points the tip **154** at the code matrix on the drug item and presses the button **156** at the end of the code reading pen. If a correct read is effected, the light **160** lights and the display **152** displays the item identification, here ASPIRIN, and preferably the interpreted bar code read, which is shown as the hexadecimal reference 7F4B.

As shown in FIG. **14**, the pen operates by having an internal processor **162** that controls a light source **164** and a read device such as a charged, coupled device (CCD) **166** that receives an image of the matrix through an optic rod **168** in the end of the pen **154**. Around the optic rod **168** is a concentric light tube **170** that provides an illumination to assist in the reading process. The end of the combined rod and tube may be machined in the form of a suitable lens. Depressing the button **156** activates a switch **174** connected to a power source such as a battery **176** to initiate the read procedure. The matrix image received by the charged, coupled device **166** is processed by the processor **162**. Customarily, the processed image is rotated, using software algorithms, to match one of the template images in memory which is interpreted as a hexadecimal code that is compared with a record listing of drug item identifications in a memory **172**. The processor **162** causes the matched drug item identification to be displayed in the display **152**. It is to be understood that the code reading pen **148** can be connected to a conventional personal computer with a cable or wirelessly for further processing of the data received, for example by accessing a data base for further description of the identified drug, including a pictorial image of the drug.

It is understood that other conventional 1D and 2D bar coding symbologies can be used to implement the imprinting of drugs with a bar code and an icon that are useful for identification and for the other procedures in manufacturing and distributing drugs that are assisted by bar code systems. The imprint system is implemented by means of a drug registry where manufacturers and/or distributors can apply for a unique imprint mark for the identification of their solid form drug.

While, in the foregoing, embodiments of the present invention have been set a forth in considerable detail for the purposes of making a complete disclosure of the invention, it may be apparent to those of skill in the art that numerous changes may be made in such detail without departing from the spirit and principles of the invention.

What is claimed is:

1. A drug identification system for marking solid form drugs comprising a pill imprint having a first marking in the form of a human recognizable symbolic icon and a second marking in the form of a machine readable bar code,

wherein the human recognizable symbolic icon provides a general identification suitable for categorical identification and communication, and the machine readable bar code provides an item identification.

2. The drug identification system of claim **1** wherein the marking is a composite marking that combines the first icon marking and the second bar code marking into a composite symbol.

3. The drug identification system of claim **2** wherein the symbolic icon marking provides a target for the bar code marking.

4. The drug identification system of claim **3** wherein the bar code is a 2D bar code.

5. The drug identification system of claim **4** wherein the 2D bar code is a data matrix type bar code.

6. The drug identification system of claim **4** wherein the 2D bar code is a matrix of squares with corner orientation squares and remaining data squares.

7. The drug identification system of claim **4** wherein the 2D bar code is a hybrid data matrix code with a data field and an orientation and granularity frame around the perimeter of the data field, wherein the frame and field are comprised of squares having a dimension and the squares of the data field have a dimension twice the dimension of the squares of the frame.

8. The drug identification system of claim **1** in combination with a portable bar code reader pen having a drug identification display for displaying drug item identifications responsive to a bar code read.

9. The portable bar code reader of claim **8** wherein the reader is in the form of a pen and the bar code is in the form of a 2D bar code.

10. The drug identification system of claim **1** in combination with a database with pictorial images of drugs wherein a select bar code identifies a particular drug and is linked to the pictorial image of the identified drug.

11. The drug identification system of claim **1** wherein the 2D bar code is a hybrid data matrix code with a data field and two contiguous orientation bars around two sides of the perimeter of the data field, wherein the orientation bars are comprised of like kind squares having a dimension and the squares of the data field have a dimension twice the dimension of the squares of the frame.

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