

[54] IDENTIFICATION SYSTEM

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[51] Int. Cl. G09f 3/14
[58] Field of Search 40/20, 21 C, 10,
40/129, 1.5

[56] References Cited

UNITED STATES PATENTS

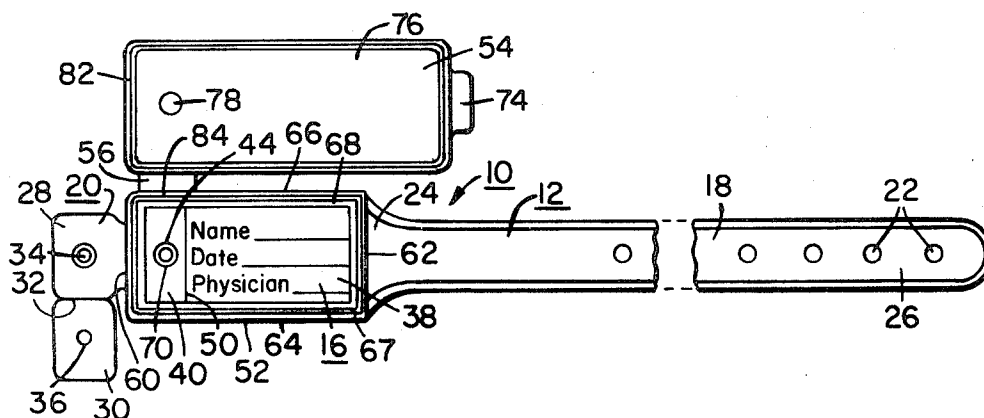
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[57] ABSTRACT

In an identification assembly of the type having an elongated flexible band with fastening means for locking to the limb of a patient wherein the improvement comprises the addition thereto of an identification label dispenser holding a plurality of patient identification labels, with the dispenser including means for holding the labels so that no label can be added without resultant indication thereof. All but one of the labels are removably held and removal thereof requires a pulling force which results in tearing of the label (in the vicinity of the holding means), with the securing of the pulling force insuring that no tampering has occurred. A method of correlating the identity between the patient and specimens taken therefrom sets forth the dispenser-attaching, specimen-drawing, label-removing and label-attaching steps required in carrying out this method.

7 Claims, 4 Drawing Figures



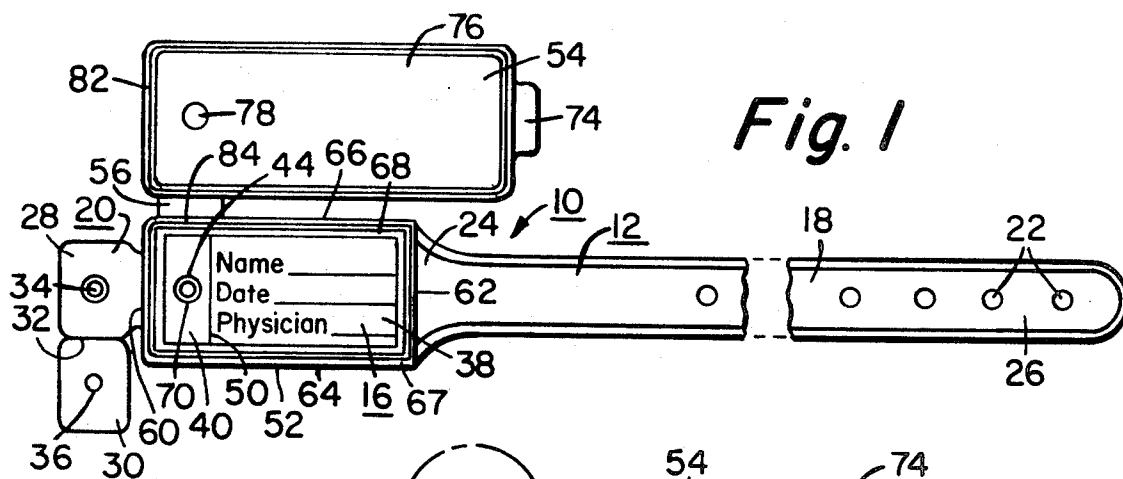


Fig. 1

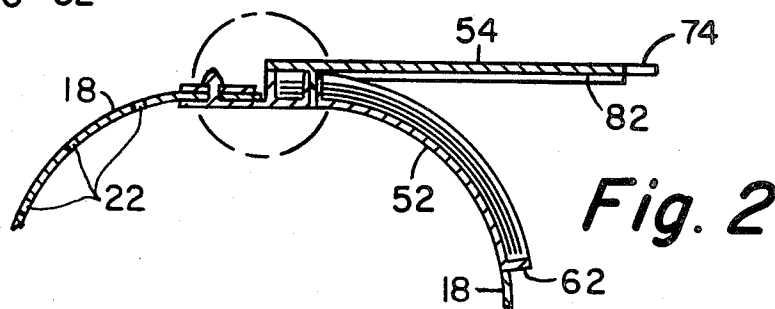


Fig. 2

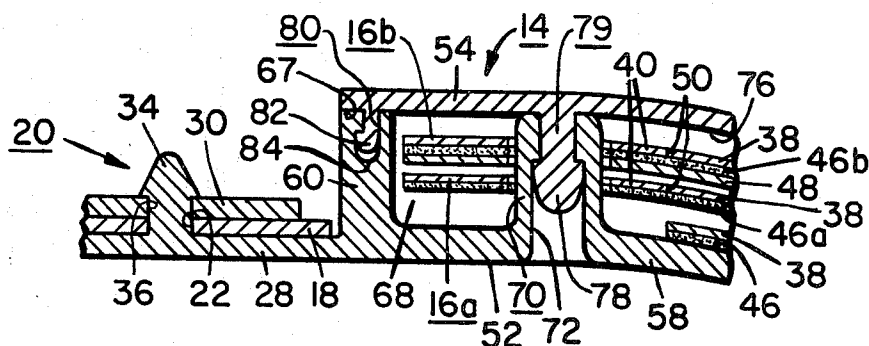


Fig. 3

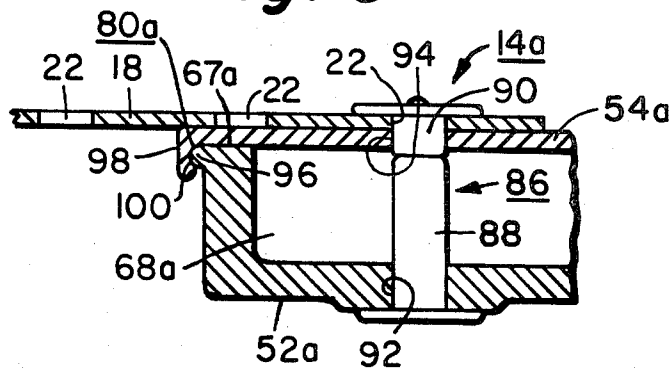


Fig. 4

IDENTIFICATION SYSTEM

BACKGROUND OF THE INVENTION

This invention pertains to an identification system, more specifically an identification assembly as well as a method for using same, particularly for hospital patients. This identification assembly includes a tamper-proof identification label dispenser and identification labels for use in patient specimen identification, wherein the dispenser is incorporated into the flexible band that is irreversibly locked to the limb of a patient.

In today's hospital routine, great emphasis is placed on the analyses of patients' body fluids. In some cases, a single value may be diagnostic for a given ailment, but in most cases it is an observable change in values which is significant. A single abnormal value is usually re-run. In addition to diagnosis, this testing is also used to evaluate the effect of a drug or specific treatment on the patient. Thus, testing may be of the profile type for general health checks where many tests are done once. It may be exploratory to find or confirm a specific ailment, or it may be done to evaluate treatment. The latter two testing objectives usually require repetitive testing involving periodic extraction of body fluids (from every few minutes in such tests as glucose up-take to every few days in some cases of treatment evaluation).

The hospital laboratory has several functional boundaries which create a need for the use of several containers of a given body fluid, rather than a single container. Often each container of sample differs in additives, or in the manner in which the sample is collected. In the case of blood, three tubes may be collected. One container, having no additives, will be used for blood chemistries. A second, similar container, will be collected for serological studies (a second department), while a third container with anticoagulant added, will be used for Hematology (a third dept. doing red and white cell counts, cell morphology, clotting time, etc.). A further tube could also be collected for bacterial culture, still another department. In the case of urine, physical and microscopic studies, some chemistries are done in the urinalysis dept. If a culture is to be done, a separate sterile container may be required along with a precise procedure for collecting. Throat swabs and other body fluids requiring culture are placed from the collection container into a broth which is incubated for several hours. The broth is then streaked onto one or several types of media and again incubated to obtain characteristics.

In addition to collection in conventional tubes and bottles, some samples are smeared on to microscope slides. Others are collected in micropipets less than one tenth of an inch in cross-section. Blood from a finger puncture may be aspirated into blood pipettes, then diluted and shaken before taken to the lab.

In summary, one to several body fluids may be collected in one to several containers having a diverse range of shapes and sizes. They are generally placed in a tray or rack with similar samples from many other patients during collection. When taken to the laboratory they are sorted and disseminated to several different laboratory departments for analysis. Different analyses require a variety of different additives and collecting procedures for a given patient fluid.

The technician who collects patient samples is given a list or stack of forms with patient name, ward, bed or room number and type and quantity of sample. Blood

is generally routinely collected first thing in the morning. The list usually contains 20 to 30 names and often there is more than one technician collecting at the same time. The collecting technicians are usually female and with relatively little schooling, training or experience in the laboratory. (This is due to the relatively high turn-over and the fact that the duties are more manual skill oriented than demanding of technical knowledge. As a result of this general job orientation one can expect a commensurate level of performance in sample handling and identification.)

Generally there are several procedures in use for patient identification. If a copy of the analysis check sheet for each department is sent with the technician, it may be wrapped around the sample and held with a rubber band. This may or may not be coupled with the use of a grease pencil or label tape. (Neither check sheet, nor grease pencil is effective for Microcapillaries.) Of more general purpose is the use of pressure sensitive tape, with the technician prelabeling the tubes or the surface of her cart with strips torn from a tape roll. She has the option of pre-writing the identification or writing it as she collects the samples.

Grease pencil rubs off in handling and multiple samples can get separated from check sheets. Pressure sensitive tape is a good choice for performance, but it does have problems, however. Frequently, a water soluble ink is used which gets wet and smears and since the writer of the label is not the end user, legibility of hand writing is a common problem. In addition, it does take time to tear strips of tape, transfer them to a cart, write the identification, and then transfer them to the sample. Clerical error can result in transposing from list to container.

One company does print form label sheets which accompany their blood sample tubes. However, they receive limited use as they require wetting to stick, which makes them awkward to use on the wards. A second company has begun adding pressure sensitive, form label sheets to their blood collection packs.

One problem that can arise in sample identification is collection from the wrong patient. For example, if the patient gets a room or bed shift without a change in lab records and if the technician does not check the patients wrist band, she may take the wrong patient's sample. Generally she will label the samples from her list, thus relating more to bed or room number rather than the patient, since this is easier to do.

There has been an attempt on the part of some computer companies and makers of automatic analysis equipment to develop blood container identification systems which would act as an actuator to program the analyzer or at least print out the patient's name with the corresponding test data. These systems however are oriented more toward avoiding clerical error between data and sample in the lab than toward insuring that the sample gets to the laboratory properly identified. Most of these systems rely on the technicians bringing a pre-written pressure sensitive label to the bedside from the lab or nurses' station, and depends on the technician to verify the labels with the patient's identification band. Thus, they remain vulnerable to mislabeling of the sample on collection.

One recent development, such as that set forth in U.S. Pat. No. 3,523,522, to Whitehead, strives for a "lock and key" system which requires no "mind transfer" or memory in the collection system. The original

identification is attached to the patient in the form of a code plate master which allows electronic or mechanical printing of each label as it is required. This system requires expensive printers and electronic readers and is directed strictly to blood collection tubes, thus having no application as a general purpose sample label.

SUMMARY OF THE INVENTION

This invention solves the previously-mentioned problems by utilizing a whole new concept of in the area of patient identification, namely the attachment of printed identification labels to the hospital patients in such a way that they are readily available for use by the hospital staff for patient sample marking while providing a permanent identification for the patient during his hospital stay.

This invention relates to the dispensing of identification labels, from an attachment to a hospital patient, to preserve the integrity of sample identification; where samples are removable from the patient; where the attachment is preferably made to the wrist; where the dispenser is a wrist band container of low profile; where the labels preferably are pressure-sensitive; and where the labels are pre-printed with the patient's identification information.

The attachment of an adequate supply of printed labels directly to the limb of a patient offers a unique solution to the problem of sample mis-identification. The present practice is to bring labels to the patient with this practice allowing room for the pick-up of wrong labels before approaching the patient. It also allows the technician in a post-labeling procedure to select the wrong labels from a group of labels. When labels are made at the nurses' station prior to use, the wrong printer plate can be picked from the rack. In addition, when the nurse or the physician is taking the sample, labels are not normally readily available and tubes of blood left unlabeled at the nurses' station are often mixed up. Furthermore, all labeling systems now using labels rely on the hospital personnel to check the patient's identification band for verification.

The use of a patient-attached supply of labels eliminates virtually all potential sources and conditions of patient sample mix-ups. Pre-printed labels save critical technician time and simplify the technician's procedure at a time when she is under the strain of patient contact. In addition, it forces attention to the identification band and verifies that the technician actually made patient contact. As a matter of fact, an additional label attached to the request form, after the samples have been drawn, would be verification that the samples were in fact taken.

In summary, the identification system of this invention includes an identification assembly of the type having an elongated flexible band with fastening means for irreversibly locking the band to the limb of a patient wherein the improvement comprises the addition thereto of means for receiving a plurality of identification labels, with this receiving means including means for holding the labels so that no label can be added without resultant indication thereof. This receiving means is a low profile, moisture-proof identification label dispenser (including a container and cover having an integral complementarily-mating closure means for detachably interlocking same) made of soft, flexible non-allergenic transparent plastic material of sufficient optical quality to allow easy reading of the labels there-

through. All but one of the labels are removably held by the holding means and removal of the labels requires a pulling force which results in tearing of the label in the vicinity of the holding means, with the sensing of the pulling force insuring that no tampering has occurred. The identification labels preferably are part of a label assembly further including a label holding portion, and preferably the label rear surface is coated with a pressure-sensitive adhesive.

The identification system of this invention also includes a method of correlating the identity between a patient and specimens taken from the patient wherein the steps comprise: attaching a label dispensing means to the limbs of a patient; drawing a specimen from the patient into a specimen container; removing a label from the label dispenser; and attaching the label to the container.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top plan view, partially broken away, of the identification system of this invention in a partially assembled, unattached condition.

FIG. 2 is a sectional view showing the identification system when it has been attached to and encompasses the limb of a patient and its cover has been opened to permit removal of an identification label.

FIG. 3, which is an enlargement of the circled area of FIG. 2, shows the relationship of the various parts of the identification system.

FIG. 4 is a modification of the enlargement of FIG. 3.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings in detail, FIGS. 1-3 show the identification system of this invention in the form of identification assembly 10 and a method for using same. Identification assembly 10 is basically comprised of a flexible band 12 having incorporated therein an identification label dispenser 14 adapted for receiving a plurality of identification label assemblies 16. While band 12 and dispenser 14, are made of a non-allergenic, flexible material, preferably polyethylene plastic, they are also readily made of other plastic materials such as polypropylene or polyvinylchloride.

Elongated, flexible band 12 includes a strap 18 and fastening means 20, with strap 18 being perforated to define a plurality of equally spaced openings 22 along the length of the strap. Strap 18, which has its one end portion 24 attached to one end of label dispenser 14, has its other end portion 26 free to be attached to fastening means 20. Flexible bands of the general type described herein are well known in the prior art, with examples thereof being set forth for instance in U.S. Pat. Nos. 2,641,075, 2,871,592 and 3,059,359.

Fastening means 20 includes lower tab portion 28, which is attached on its inner extremity to the other end of label dispenser 14, and upper tab portion 30, with portion 30 being attached to portion 28 at their common edge 32. As best seen in FIGS. 1 and 3, tab portion 28 has a raised central, flanged pin 34 and tab portion 30 has a central aperture 36.

In practice, for the installation of assembly 10 on the limb of a patient, it is merely necessary to encompass (see FIG. 2) for example the wrist and to size assembly 10 to the wrist in the most comfortable manner by engaging strap 18, through the intermediary of one of the

openings 22 therein, upon flanged pin 34 of tab portion 28. Thereupon, upper tab portion 30 is folded along edge 32 and superimposed over the engaged portion of strap 18, with aperture 36 also being engaged by pin 34. When this has been accomplished, the projecting portion 26 of the strap (not shown in FIGS. 2 and 3) is preferably cut with scissors. Both openings 22 and aperture 30 are smaller in diameter than the maximum diameter of flanged pin 34 and once they are press-fitted over pin 34 they are irreversibly attached thereto (as best seen in FIG. 3). This irreversible attachment prohibits the interchange of assemblies 10 between different patients. Removal of assembly 10 from the patient's limb requires the cutting of strap 18.

Each identification label assembly 16 (preferably of paper) is comprised at least of identification label 38 and holding portion 40, with portion 40 having a central aperture 44 and identification label 38 bearing at least the name of the patient on the front surface thereof. The rear surfaces of label 38 and portion 40 are coated with an adhesive means 46 which may either be of the dry type (46a), which is moisture-activated, or preferably of the pressure sensitive type (46b) which however requires a backing or slip 48 (such as paper) that overlies adhesive means 46. Thus, label assembly 16a (FIG. 3) is a two-layer assembly, (e.g., label 38 and portion 40 covered on their rear surface by adhesive means 46a), while label assembly 16b (FIG. 3) is a three-layer assembly (e.g., label 38 with portion 40 and backing 48, having adhesive means 46b interposed therebetween).

As best seen in FIGS. 1 and 3, identification label 38 and holding portion 40 abut at a common boundary 50 which, in the case of two-layer label assembly 16a, is preferably a perforation and in the case of three-layer label assembly is either also a perforation or preferably, a slit. If desired, backing 48 could also be perforated in the general area below boundary 50.

As previously noted, interposed between strap inner end 24 and fastening means 20 is identification label dispenser 14 which is basically comprised of label container 52 and cover 54, with cover 54 preferably being connected to container 52 by flexible connector portion 56. While connector portion 56 is not required its use does allow the unitary injection molding of band 12, container 52 and cover 54 as one piece, and due to the immediate availability of cover 54, permits ready assembly of container 52 and cover 54.

Label container 52 is comprised of curved or arcuate bottom portion 58, similar end portions 60, 62 and similar curved or arcuate side portions 64, 66, with bottom portion 58 preferably blending in with strap end portion 24 on one end and lower tab portion 28 on the other end. The upper surfaces of portions 60, 62, and 64, 66 define container peripheral rim 67. Bottom portion 58 together with portions 60, 62 and portions 64, 66 defines an arcuate compartment or cavity 68 which is adapted for receiving a plurality of stacked identification label assemblies 16 (or 16a, 16b). The arcuate shape (see FIG. 2) of dispenser 14 not only allows assembly 10 to be readily fitted to patients of all ages and sizes but also it can be worn in relative comfort.

Extending upwardly from container bottom portion 58, near end portion 60, is integral column upright 70 having a multiple diameter internal bore 72. One purpose of column 70 is to act as a holding means for label

assemblies 16 (or 16a, 16b), i.e., column 70 passes through the aligned apertures 44 in these assemblies.

Dispenser cover 54, which is generally rectangular in shape, has a pull tab portion 74 extending outwardly from one end thereof and a flanged pin 78 extending downwardly from cover inner surface 76 near the other end thereof. Since the minimum diameter of column internal bore 72 is smaller than the maximum diameter of flanged pin 78, once pin 78 is pressfitted into bore 72 they are irreversibly secured together, i.e., cover 54 if fixedly attached near one end to container 52 (as best seen in FIG. 3). Thus, another purpose of column 70, together with pin 78, is to act as a securing means 79 for irreversibly securing one end of cover 54 to container 52.

In order to make label dispenser 14 water tight, but yet allow the progressive opening (and subsequent closing) of cover 54 with reference to label container 52, cover 54 and container 52 are provided with integral complementarily-mating closure means 80. Closure means 80 preferably takes the form of a profiled, peripheral raised track 82, extending downwardly from cover inner surface 76, that detachably interlocks with a generally matching groove 84 in container peripheral rim 67.

Band 12 and dispenser 14, which are preferably injection molded as a unitary piece, are made of a transparent plastic of sufficient optical quality as to allow easy reading of identification label 38 through dispenser cover 54.

For maximum efficiency, label assemblies 16 preferably are printed, cut, hole punched, oriented and stacked by a stencil-type duplicating machine, with the label stencil preferably being generated as part of the hospital admittance form. In this manner, a plurality of label assemblies 16, for example 20 to 25 assemblies, may be rapidly assembled into dispenser compartment 68.

While one of the primary functions of the identification system of this invention is to provide multiple dispensable label assemblies, another primary function is to provide for the attachment of one label as a permanent identification means in the event that the dispensable labels are exhausted. This function preferably is accomplished by initially adhesively attaching a single label 38 on the inner surface of container bottom portion 58 as shown in FIG. 3.

Once the permanent label and the dispensable label assemblies are placed into compartment 68, cover 54 is irreversibly secured to container 52 by press-fitting flanged pin 78 into column bore 72. Compartment 68 is then fully closed by pressing profiled track 82 of cover 54 into profiled groove 84 of rim 67, with the flexibility of the plastic material permitting ready entry of track 82 into groove 84. Thereafter, identification assembly 10 is complete and it is then attached to the limb of the patient in the manner already described. It should be noted that if desired, assembly 10 can alternately be attached to the patient's chart or two identical assemblies may be prepared at the same time, with one being attached to the patient and the other to his chart.

It should further be noted that it is considered to be within the scope of this invention to combine label fastening means 20, column 70 (acting as a holding means for the label assemblies), and cover securing means 79 (column 70 and pin 78) into one unitary, irreversible

fastening means 86 for simultaneously performing these stated functions.

This embodiment is shown in FIG. 4 as container 14a and is substantially similar to container 14 previously described with reference to FIGS. 1-3, with like members having like numerals. Fastening means 86, which is a gripper type snap fastener of conventional design, is comprised of stud portion 88 and cap portion 90. Cap portion 90 is designed to be pressfitted or snapped over one end of portion 88 and thereafter is irreversibly attached thereto. As shown in FIG. 4, one end of stud portion 88, extends into compartment 68a through aperture 92 in label container 52a, while one end of cap portion 90 extends into compartment 68a through band aperture 22 and aperture 94 in cover 54a.

FIG. 4 further illustrates a further integral, complementarily-mating closure means 80a, in the form of a profiled peripheral raised track 96, on container peripheral rim 67a, that detachably interlocks with a generally matching groove 100 in downwardly extending peripheral cover lip 98.

It is also considered to be within the scope of this invention to utilize gripper-type snap fasteners (similar to fastening means 86) in place of locking means 20 and/or cover securing means 79 shown in FIGS. 1-3. Furthermore, the gripper-type snap fastener parts, i.e., stud portion 88 and cap portion 90, may be added to assembly 10 at the time assembly 10 is made up and attached to the patient's wrist, or they may be pre-assembled (e.g., portions 88 to lower tab portion 28 and/or compartment 68; and portions 90 to upper tab portion 30 and/or cover 54).

Since the method of use of assembly 10 is substantially identical regardless of the use of either container 14 or container 14a, the following description, while specifically referring to container 14, is also applicable to container 14a. For example, if a technician is requested to obtain a blood sample from patient "A," the technician, on approaching patient "A," first of all visually checks his irreversibly-attached identification assembly 10 to confirm that this patient is patient "A." Then, the technician extracts a specimen, such as a sample of blood, from patient "A" into a specimen container, such as a glass vacuum blood collection tube. Thereafter, upon grasping dispenser cover pull tab portion 74 between thumb and forefinger, the technician at least partially or progressively opens cover 54 by manually pulling thereon so as to at least disengage a portion of peripheral raised track 82 from peripheral groove 84 in container rim 67. Thereupon, the technician grasps the top of label assembly 16 and removes it from compartment 68 by the application of a pulling force which, in the case of 2 layer label assembly 16a, results in the tearing of label 38 from holding portion 40 at perforation 50, with portion 40 remaining in compartment 68. Then, label adhesive means 46a is moistened and label 38 is attached to the specimen container. In the case of preferred 3 layer assembly 16b, if backing or slip 48 is not perforated, tearing occurs in the narrow area of holding portion 40 between aperture 44 and the rear edge of assembly 16b. Upon the removal of label assembly 16b, label 38 is readily peeled from backing 48 (after bending assembly 16b at slit 50) and, since it has pressure sensitive adhesive backing 46b, it is merely pressed onto the specimen container. (If assembly 16b has a perforated backing 48, tearing will separate label 38 from holding portion

40.) Cover 54 is closed by pressing peripheral track 82 back into groove 67, with reclosure of cover 54 taking place either immediately after the removal of the label or after the application of the label to the specimen container.

The identification system of this invention guards against tampering in two ways, namely (1) it utilizes column 70 as a label assembly holding means and the combination of column 70 and pin 72 as an irreversible securing means 79 so that the label assemblies are not only held, but that no further or other label assemblies can be added to the container without visual indication thereof, and (2) a pulling force (which results in tearing of the label assembly in the vicinity of the label holding means) is required to effect label assembly removal, with the sensing of this pulling force insuring that no tampering has occurred. Thus, even if, for example, a label assembly 16b (with an unperforated backing 48) is removed from a first identification system and inserted into a second system (by pushing the torn area of holding portion 40 around column 70), this addition will readily be detected by the technician upon the subsequent removal of this added label assembly since this removal will not require any appreciable force and thus will indicate tampering. Since label assembly 16a, and label assembly 16b with a perforated backing, have holding portion 40 remaining in compartment 68 after the removal of label 38, these labels cannot be reinserted without visual and physical indications thereof.

With the identification system of this invention there remain two modes of system failure, namely: the extraction of a sample with no labeling of the sample and extracting a sample from the wrong patient, but with the wrong patient's own name attached thereto. Neither of these modes of failure represents a serious threat to the patient other than loss of the sample and loss of time. The other systems previously discussed leave room for mislabeling of the samples which is most serious since they can go through the system undetected and give false data.

The system of this invention in effect is a lock and key system as it definitely avoids misidentification. In addition, it reduces technician manipulation and label access is more rapid. When label making is done on hospital admittance there is less patient stress. Furthermore, the identification labels are applicable to any form of sample (or even personal effects or valuables) and are always available for emergency use. Full patient information may be recorded on the labels. If desired, the use of multiple labels on a specimen container allows later transfer of these labels to further sample containers — for example one label can be added to the specimen requisition form as verification that the sample was actually taken. Furthermore, due to its general low-profile, moisture-proof and tamper-proof form the identification system concept of this invention is useful and complementary at any hospital size.

While this invention has been described in connection with possible forms or embodiments thereof, it is to be understood that changes or modifications may be resorted to without departing from the spirit of the invention or scope of the claims which follow.

I claim:

1. In an identification assembly including an elongated flexible band with fastening means for irrevers-

ibly locking said band to a limb of a patient, the improvement comprising the addition thereto of an identification label dispenser, said identification label dispenser including a longitudinally arcuate container having a compartment formed therein; a flexible, transparent cover, said cover including means for irreversibly securing said cover in the vicinity of one of the ends thereof to said container for providing a moisture-proof closure for said compartment; a plurality of unconnected label assemblies within said identification label dispenser, each of said label assemblies including a label holding portion and an identification label positioned in said compartment in arcuate stacked relation; said dispenser further including means for holding said labels so that no label can be added without resultant indication thereof, said label holding means projecting through said label holding portion of each of said stacked label assemblies for releasably retaining said labels within said compartment; said label holding means being a part of said cover securing means; and said label holding means releasably retaining each of said labels so as to resistively tear said label assembly in the vicinity of said label holding means upon the application of a pulling force to each of said label assemblies, with the sensing of said resistive pulling force insuring that no tampering has occurred.

2. The identification assembly of claim 1 wherein said label holding means and cover securing means are part of said band fastening means.

3. The identification assembly of claim 1 wherein said label holding portion has an aperture, said label holding means extends through said aperture, said label

and label holding portion have a common transverse boundary, and said tearing of said label assembly occurs at the boundary between said label and label holding portion.

4. The identification assembly of claim 1 wherein said label holding portion has an aperture, said label assembly holding means extends through said aperture, and said tearing of said label assembly occurs in said label holding portion.

5. The identification assembly of claim 1 wherein all but one of said labels are dispensably held by said label holding means and said one label, which is the bottom-most of said stacked labels, is adhesively attached to said container to serve as a permanent identification means in the event that all of the dispensable labels are exhausted.

6. The identification assembly of claim 1 wherein said container and cover have integral complementarily-mating closure means for detachably interlocking the peripheral edges of said container and cover thus permitting progressive opening of the other of the ends of said cover by manually flexing said cover other end, thereby allowing access to said container compartment and permitting label removal, with said flexible cover allowing ready moisture-proof reclosure of said compartment.

7. The identification assembly of claim 6 wherein said closure means comprises a peripheral, raised, profiled track portion on one of said container and cover and a mating peripheral groove portion on the other of said container and cover.

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