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(54) Title: METHODS AND SYSTEMS FOR TRACKING OBJECTS IN A VALIDATION PROCESS

(57) Abstract: The subject invention relates to methods and systems for tracking objects in a validation process. The subject invention can achieve the benefit of managing an inventory of objects without using a manual log-book entry system using a web-based application in order to automate a method for tracking objects through a validation process. The subject invention further enables a user to audit, recall and report the status of an object or a batch load of objects without the costly storage and errors associated with manual inventory management.

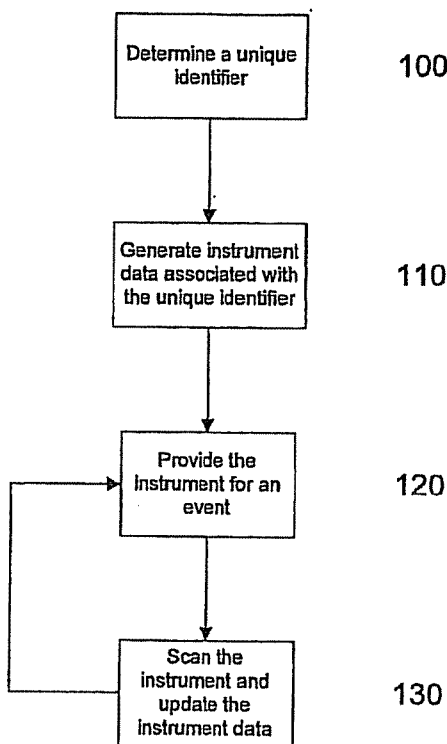


Fig. 1



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METHODS AND SYSTEMS FOR TRACKING OBJECTS IN A VALIDATION PROCESS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional Application Serial Nos. 61/188,853 filed on August 12, 2008 and 61/200,563 filed on December 1, 2008. The entire contents of these applications are incorporated herein by this reference.

FIELD OF INVENTION

The present invention relates to a method and system for tracking objects, and more particularly to tracking the use of objects such as assets in a medical environment.

BACKGROUND OF THE INVENTION

The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

There is a need within the medical industry to be able to track medical instruments throughout their life to thereby monitor the procedures in which the medical instruments have been used, together with details of their cleaning operations and the like. This is important for situations in which the instruments have either been used in a procedure where there is a risk of instrument contamination, or when problems are discovered with the sterilization process, and there is a consequent risk of contamination or infection of patients. In these situations it is useful to be able to identify those patients on which the instruments have been used, thereby allowing the patients to be examined to check there has not been any contamination or infection.

However, it is difficult to reliably mark medical instruments. Existing techniques generally use laser engraving or the like. However, medical instruments are typically formed from a range of different alloys, depending on factors such as the quality and source of the instrument, and each of the alloys will have different properties. As laser engraving is dependent upon the properties of

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the material being engraved, this means that any laser used in such a process must be configured and subsequently calibrated for each instrument to be marked. Thus, for example, instruments made with different materials would require different laser configurations for successful engraving to be achieved. This results in significant expenditure when arranging to encode a number of instruments.

In addition to this, the engrave process creates surface relief structures which can in turn cause difficulties in suitable cleaning of the instrument, as well as effecting the strength of the instrument in some cases.

Accordingly, instrument tracking is generally performed on a per tray basis. In this case, when medical instruments are used in procedures the medical instruments are provided as part of a tray. The use of the tray can be monitored allowing instruments to be tracked. However this suffers from a number of disadvantages.

In particular, as instruments cannot be distinguished, this requires that instruments are always used with the same tray. As a result, if any one instrument is unavailable for use, for example due to the problems with sterilization in the cleaning process, the entire tray cannot be used until the instrument is replaced. This results in significant problems in tray supply.

Secondly, it is possible for instruments on different trays to be mixed up, which in turn leads to inaccuracies in the tracking procedure.

In addition to this, irrespective of the marking procedures used, it is often difficult to track the use of assets, such as medical instruments, and other items such as consumables, within a hospital. In this instance, this is important not only from the point of view of ensuring that sufficient stock is maintained, but also to make sure that it is possible to subsequently identify what assets have been used on a patient, or during procedures undergone by a patient. This can be important both from the perspective of inventory management, and subsequently identifying used assets in the case in which an investigation is required.

It is therefore desired to provide systems and methods to ameliorate one or more of the above mentioned problems.

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SUMMARY OF THE INVENTION

The present invention relates to methods and systems for tracking objects in a validation process. The present invention can achieve the benefit of managing an inventory of objects without using a manual logbook entry system. The present invention further enables a user to audit, recall and report the status of an object or a batch load of objects without the costly storage and errors associated with manual inventory management.

The present invention provides a user with a method of tracking objects within a validation process. A validation process may be, for example, a sterilization process, a maintenance procedure, a stock transfer, an inventory update, a consumption of goods, or a repair process. The method consists of first providing the user with one or more tags, adhesive labels, flags or other known labeling mechanisms for labeling one or more objects. The labeling means are supplied to the user with one or more pre-printed serial indicators such as a bar code or serial number. After the labeling means have been supplied, the user is then able to associate the labeling means with the inventory objects by wither affixing the label, tag etc. directly to the object. Groups, batches or kits of objects may also be assigned together in this way.

After the labeling means have been serialized and supplied to the user, the user then creates and assigns one or more indicia to the labeling means of each object. The indicia, or categories of identification, can be personalized by the user so as to be relevant indicators of the validation process for which the objects are being used. Once an object are subjected to the validation process, the associated label may be scanned by a user at one more checkpoints during the process. After scanning, a database is updated which keeps track of a status of the at least one checkpoint in the process, and based on the updates in the database, the one or more objects can be tracked.

The method of the present invention may also include the step of creating a report of a history of database updates in order to recall a record of the status over time of one or more of the objects. In addition, the validation process may be managed at one or more check point using a go forward or stop process action or command.

The present invention also provides for a web-based system for tracking objects in a

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validation process. The system includes one or more means for labeling at least one object. The labeling means, such as a tag, adhesive label or the like are provided having pre-printed serialized indicators such as a bar code and/or serial number. The system also includes a scanner for scanning the labeling means during at least one checkpoint during a validation process and providing information to a web-based application.

The web based application or software enables a user to do a variety of functions including: assigning at least one indicia to a labeling means after the serialized labeling means have been provided to the user or after the labeling means has been associated with the object. The web-based application also enables a user to update a database within the application with a status entry of one or more checkpoints within the validation process based on information received from the scanner indicating a status of the object within the validation process. In so doing, the web-based application enables a user to track one or more objects based on the status entries in the database.

The system of the present invention may also include a scanner which is further associated with a sensor attached/identified with or connected to the scanner for providing scanner information to the web based application. The scanner may be a radio frequency, sonar, or global positioning type sensor. By doing so, the system of the present invention can track objects by wirelessly pairing a scanner with the objects to be tracked such that a scanner information, such as a validation process checkpoint, scanner location, user identification information, or other similar information, may resolve where a scanned object associated with the scanner is being scanned and thus provide information as to the status of one or more objects within the validation process.

In one exemplary embodiment, the web-based system of the present invention is used for tracking a plurality of medical assets in a validation process. In this embodiment, one or more pre-printed labeling means are pre-allocated to a user or delivery point and validated as unique to that user locations for allocation and association to the asset. The asset may be, for example, a reusable asset (e.g. surgical instrument; medical instrument trays, sheets, etc.); a disposable asset (e.g. gauze, syringes, etc.), a patient specific or single use object (e.g. prosthetic, artificial organ, etc.), or a consumable asset (e.g. food, medication, saline).

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After the serialized labeling means are provided, and/or after the user associates the labeling means with the asset, the user can then assign at least one indicia to each object or a group of objects. The indicia, may be, for example, a patient information, a validation process information, a location information, a quarantine indicator, or a user information.

The labeling means may further includes one or more electronic, biological, environmental process indicator. The process indicator is another means for tracking and recalling data regarding a status of the validation process, with respect to a particular object or group of objects. For example, the tag or label may have a chemical indicator painted on which changes color or chemically reveals a status of the object after being exposed to a temperature or humidity level, or other environmental signal during the process to alert the user to such an exposure.

The present invention has a number of advantages over manual labeling systems including, but not limited to: the ability to provide better validation process status reports with less time and decreased cost; legible reports with accurate description of individual objects and batch loads; consistent capture of time, temperature, pressure, load and sterilizer validation; decreased time spent on manual data entry; audit, recall and reporting capabilities; elimination of manual record storage; the ability to immediately verify validation process parameters; as well as the ability to track objects individually or batch loads of objects between facilities.

Other aspects and embodiments of the invention are discussed below.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the nature and desired objects of the present invention, reference is made to the following detailed description taken in conjunction with the accompanying drawing figures wherein like reference character denote corresponding parts throughout the several views and wherein:

Figure 1 is a flow chart outlining an example of a process of tracking medical instruments;

Figure 2A is a schematic side view of an example of a mounting rig for use in marking medical instruments;

Figure 2B is a cross sectional view of the mounting rig of Figure 2A;

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Figure 2C is a schematic plan view of the mounting rig of Figure 2A;

Figure 2D is a schematic side view of an example of a support member;

Figure 2E is a schematic end view of the support member of Figure 2D;

Figure 3 is a schematic plan view of an example of a system for marking medical instruments;

Figure 4A is a schematic side view of an example of a scanner;

Figure 4B is a schematic end view of the scanner of Figure 4A;

Figure 4C is a schematic side view of the scanner of Figure 4A with an attached shroud;

Figure 4D is a schematic perspective view of the shroud of Figure 4C;

Figure 5 is a schematic diagram of an example of a distributed architecture for use in marking medical instruments;

Figure 6 is a schematic diagram of an example of the base station of Figure 5;

Figure 7 is a schematic diagram of an example of one of the end stations of Figure 5;

Figures 8A and 8B are a flow chart of an example of the process for marking medical instruments;

Figures 9A and 9B are examples of a user interface used in the process of marking medical instruments;

Figure 9C is an example of a 2-D bar code used in marking medical instruments;

Figures 10A to 10D are a flow chart of an example of the process of using marked medical instruments;

Figure 11 is an examples of a user interface used in the process of using marked medical instruments; Figures 12A and 12B are a flow chart of an example of a stock management process;

Figure 13 is a flowchart of an example of the process of maintaining patient data;

Figure 14 is a flowchart of an example of the stages involved in a patient procedure;

Figure 15 is a flow chart of an example of the process of scheduling procedures;

Figures 16A and 16B are schematic examples of a GUI used in scheduling procedures;

Figure 17 is a flow chart of an example of the process of item tracking during a procedure;

Figures 18A and 18B are a flow chart of an example of the process of monitoring a

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procedure;

Figure 19 is a flow chart of a method of tracking an object according to an embodiment of the present invention;

Figure 20 is a flow chart of a workflow program according to one embodiment of a system of the present invention;

Figure 21A is an example of a serialized tag for labeling an object in a validation process according to the present invention;

Figure 21B is an example of a serialized adhesive label for labeling an object in a validation process according to the present invention;

Figure 22A is an example of a first type of process indicator according to the present invention; and

Figure 22B is an example of a second type of process indicator according to the present invention.

DEFINITIONS

The instant invention is most clearly understood with reference to the following definitions:

As used in the specification and claims, the singular form "a", "an" and "the" include plural references unless the context clearly dictates otherwise.

DETAILED DESCRIPTION OF THE INVENTION

Although preferred embodiments of the invention have been described using specific terms, such description is for illustrative purposes only, and it is to be understood that changes and variations may be made without departing from the spirit or scope of the following claims.

INSTRUMENT IDENTIFICATION

An example of a process for identifying medical instruments will now be described with reference to Figure 1. In particular, at step 100 a unique identifier is determined. This can be achieved in a number of ways as will be outlined in more detail below. For example, this can be

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achieved by generating a unique identifier which is then encoded as a machine readable code, which may be of any form such as a 2-D barcode, or the like. The machine readable code can then be applied to the medical instrument, which again may be achieved in a number of ways, as described in more detail below.

Alternatively, the identifier can be determined by imaging the instrument, for example using an infra-red imaging device, and then using the resulting image to generate the unique identifier. Thus, for example, the infra-red image may be representative of the particle structure of all or part of the instrument. As this structure is unique to the instrument, this effectively acts as a fingerprint, so that when a predetermined algorithm is applied to the image, this results in the generation of a unique number that then forms the unique identifier.

At step 110 instrument data is associated with the unique identifier and stored in a database or the like. At step 120 the instrument is provided for an event which may include for example use in a procedure, sterilization, reconditioning, repair or the like. At step 130 the instrument data associated with the instrument is updated to reflect the event that has occurred. The process may then be returned to step 120 allowing the instrument to be reused as required. These steps may alternatively be interchanged, so that the instrument data is updated either prior to or as part of the event.

By maintaining instrument data associated with the unique identifier, this allows the use of each instrument to be uniquely tracked, thereby allowing the use history to be subsequently reviewed as required. This therefore effectively establishes an audit trail of use for each instrument. Thus, by including suitable information within the instrument data, such as details of the procedure performed, the date on which the procedure was performed and the details of any medical personnel involved therein, it will be appreciated that this allows for subsequent and rapid identification of any events in which the instrument has been used.

In this case, each time the instrument is used, it can be scanned to determine the unique identifier, either from the applied machine readable code, or by rescanning the instrument with an infra-red scanner to recreate the image, derive the structure fingerprint and regenerate the unique identifier using the same predetermined algorithm.

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For situations in which a machine readable code is applied to the instrument, it is typical to use specific apparatus to ensure correct marking is achieved. An example of such apparatus will now be described with reference to Figures 2A to 2E. In particular, as shown the apparatus used in marking the instrument includes a mounting rig 50 formed from a frame 51 provided on a base 52. The frame 51 includes a number of apertures 53, which are generally aligned with corresponding support members 54. Thus, as shown a respective support member 54 is associated with each aperture 53.

Each support member 54 is formed from a shaft 55, mounted to the base 52, and a housing 56. The housing 56 is in the form of a cylinder that sits over the shaft 55, with a spring 59 being provided between the shaft 55 and the housing 57, as shown. The housing 56 includes a skirt 57 and is coupled to a mounting pad 58.

The mounting pad 58, which is shown in more detail in Figure 2D and 2E, includes two arms 61 connected to an upper portion 56A of the housing 56, via an axle 62. In use, the mounting pad 58 is pivotally mounted to allow the mounting pad 58 to rotate between the extreme positions shown by the dotted lines in Figure 2D. In use, the housing 56 can be urged in a downward direction towards the base 52 by exertion of appropriate pressure on the skirt 57. An instrument 60 can then be placed on the mounting pad and the pressure on the skirt 57 released, thereby causing the instrument 60 to be urged against the underside of the frame 51, aligned with one of the apertures 53, as shown. It will be appreciated that as the mounting pad 58 is pivotally mounted to the housing 56, the mounting pad will rotate to accommodate the shape of the instrument as shown in Figure 2D. This ensures that the instrument 60 is securely mounted and is unable to move, allowing it to be accurately marked.

Marking is achieved by laser marking a material applied to the instrument 60, in a process known as laser bonding. Laser bonding is an additive process in which a material is bonded to the instrument using an Nd: YAG, YVO₄, or CO₂ laser. This can be achieved using proprietary materials, which generally consist of a glass frit powder or ground metal, oxides mixed with inorganic pigment, and a liquid carrier (usually water). Such bonding materials are available from companies such as Cerdec CorporationTM. The material can be applied to the instruments using a

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number of different techniques depending on the preferred implementation, and this many include for example painting, spraying or printing the material directly onto the instrument surface. Adhesive backed tapes coated with an additive can also be used in this process.

In order to ensure correct marking it is important to ensure that the bonding material is provided at the focal point of the laser beam. This is achieved through the use of the mounting rig 50, with the bonding material being positioned aligned with the aperture 53, so that this ensures correct exposure of the bonding material to the laser beam, and in turn ensures accurate marking of the instrument. Furthermore, by providing an adhesive backed dot as the bonding material, this provides a target on which the laser may align, using a suitable tracking system, thereby further enhancing the accuracy of the encoding procedure.

In general, laser bonding is preferably achieved using a YAG laser as this generally has improved optical characteristics and can therefore achieve an improved resolution compared to other laser systems. However, in this instance, the accurate alignment of the bonding material with the laser focal point, as well as the use of a consistent bonding material, allows suitable resolution to be achieved using a cheaper CO₂ laser, combined with an HPDFO (High Power Density Focusing Optics) lens system.

An example of a laser based marking system is shown in Figure 3. As shown the apparatus includes a number of mounting rigs 50 generally aligned in an array. Although any number may be used, eight mounting rigs 50 are shown in this example for clarity purposes only. In addition to the array, a laser system 70 is provided on a movable frame shown generally at 71, 72. Whilst this may be achieved in any one of a number of manners, in this example the laser system 70 moves relative to the frame 71, in the direction shown by the arrow 73, whilst the frame 71 moves relative to the frame 72, as shown by the arrow 74. This allows the position of the laser system 70, with respect to the mounting rigs 50, to be controlled, thereby allowing the focal spot of the laser beam to be aligned with the apertures 53.

It will therefore be appreciated that motion of the laser system is typically achieved through the use of suitable control motors such as stepper or servo motors. This allows the position of the laser system 70 to be accurately controlled by a suitable control system, such as a

computer system or the like as will be described in more detail below. This in turn allows a number of instruments 60 to be provided in the mounting rig array, and then marked in a substantially automated process under computer control.

The laser system includes a CO₂ laser with HPDFO focusing system, and as such systems are 25 proprietary, this will not be described in further detail. The laser system may also incorporate a number of additional elements, such as a printer system for applying the bonding material to the instrument, a dryer for drying the bonding material, and a scanner for scanning the machine readable code, as will be described below. Utilizing a laser bonding process has a number of advantages over traditional marking techniques such as engraving. In particular, during the laser exposure process the bonding material bonds to the surface of the instrument, and is selectively coloured as it is exposed to the laser beam, thereby allowing 2-D markings to be applied to the surface. The bonding material is substantially level relative to the surface of the instrument, and therefore does not provide any surface relief structure which can allow material to become trapped on the surface of the instrument. The use of a bonding material ensures that the properties of the instrument, such as the strength of the instrument, are unaffected. Furthermore, by using the same bonding material on each instrument, and accurately aligning the bonding material with the laser, this allows a cheaper CO₂ based laser system to be used as opposed to a more expensive YAG laser. In order to detect the 2-D code applied to the instrument surface, a laser based scanning system can be used. However, laser scanning of medical instruments is generally hampered by the fact that the instrument surface is highly reflective.

An example of a scanner utilized to scan barcodes is shown for example in Figures 4A and 4B. As shown the scanner 80 includes a body 81 having a laser emitter/detector element 82 and a number of illumination sources 83. In use, the laser emitter/detector element 82 generates a laser beam shown generally at 84, which exposes an area of the surface of the instrument 60, typically using a raster pattern or the like. The laser emitter/detector element 82 detects reflected radiation, and uses this to sense the barcode or other 2-D code applied to the instrument. The barcode will typically be interpreted by suitable processing provided in the housing 81, allowing an output indicative of the barcode (or the information encoded therein) to be output, as will be

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appreciated by persons skilled in the art. In addition to this, a number of illumination sources 83 are arranged surrounding the laser 20 emitter/detector element 82 to allow the surface of the instrument to be illuminated. This helps to ensure even illumination over the surface of the instrument 60, which in turn aids with the scanning process.

Such instruments are known in the art and an example of one is Code CorpTM's Code Reader 2.0 (CR2) device. However, such instruments suffer from a number of drawbacks. In particular, stray reflections from the surface of the instrument 60, as shown at 86 can impinge upon the laser emitter/detector element 82, and interfere with the detection of the reflected laser beam 84. This problem is exacerbated in many cases by the presence of glass shield (not shown) provided over the scanning element, with reflections onto the glass shield causing flaring and internal reflections. This, in turn, affects the results of the scanning. Similarly, radiation from the illumination sources, as shown generally at 85, can also be reflected from the instrument surface to thereby cause similar problems. Accordingly, the scanner is preferably modified by the utilization of a shroud shown in Figures 4C and 4D. The shroud includes an outer housing 90 having a reflective inner surface, and a diffuser cone 91, having an opening 92 therein.

In use, when the housing 90 is coupled to the scanner 80, the opening 92 is aligned with the laser emitter/detector element 82, allowing the laser beam 84 to pass through the opening 92 unimpeded. This allows the laser beam 84 to expose the surface of the instrument 60 in the normal way. However, the presence of the housing 90 prevents stray reflections 86 from impinging on the scanning element 81 as shown. In addition to this, the diffuser cone 91 diffuses radiation from the LEDs 82, as shown by the arrows 93. The diffused radiation is reflected from the inner surface of the housing 90 and impinges on the surface of the instrument 60. By diffusing the radiation and reflecting it from the inner surface of the housing 90, this ensures that the radiation is incident on the instrument 60 at a range of angles substantially over the entire region surrounding the 2-D code being detected.

This helps reduce the chance of stray reflections impinging on the laser emitter/detector element 82, and provides a constant intensity of background radiation reflected from the entire instrument surface 60. This in turn allows the laser emitter/detector element 82 to distinguish the

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reflected radiation beam from the background radiation thereby ensuring accurate scanning of the code provided on the instrument 60. It will be appreciated that a similar scanning device incorporating an infra-red laser may be used to generate the infra-red image outlined above.

Apparatus suitable for administering instrument marking will now be described with respect to Figures 5 to 7. As shown the apparatus includes a base station 1 coupled to a number of end stations 3 via suitable communications networks 2, 4, such as the Internet and/or one or more Local Area Networks (LANs), Wide Area Networks (WANs), or the like. The base station 1 typically includes a processing system coupled to a database 11 as shown.

In one example, the base station 1 operates to control the creation and distribution of unique identifiers, thereby allowing instruments to be uniquely marked on a global basis. The unique identifiers can be obtained by users of the end stations 3, and then applied to instruments allowing the instruments to be tracked. It will therefore be appreciated from this that the end stations 3 are adapted to communicate with the base station 1, utilizing appropriate communications techniques, thereby allowing unique identifiers to be generated and assigned by the base station 1 and then returned the end station 3. It will therefore be appreciated that a wide range of architectures may be used, and that the current example is for the purpose of illustration only.

An example of a suitable processing system 10 is shown in Figure 6. As shown the processing system 10 includes a processor 20, a memory 21, an input/output device 22, such as a keyboard and display or the like, and an external interface 23, coupled together via a bus 24. In use the external interface 23 may be coupled to the database 11, as well as providing connections to the communications networks 2, 4. Accordingly, the processing system 10 may be any form of processing system, such as a computer server, a network server, a web server, a desktop computer, a lap-top or the like. Alternative specialized hardware may be used.

Similarly, the end station 3 may be formed from a processor 30, a memory 31, an input/output device 32 and an external interface 33, coupled together via a bus 34. Again the external interface 33 may be used to provide a connection to the communications networks 2, 4 as well as allowing the processing system 3 to be coupled to either the laser system 70 and/or one or more scanners

80, as shown. Accordingly the end station 3 may be any form of computer system such as a desktop computer, laptop, specialized hardware or the like.

In one example, the base station 1 and the end stations 3 communicate via the Internet to allow one or more unique identifiers to be requested by the end station 3, and then delivered via the communications networks 2, 4. This may therefore be achieved through the use of a suitable web-pages hosted by the base station 1. In this case, a user of the end station 3 will access a web-page presented by the base station 1, and select an appropriate option to request one or more unique identifiers. Typically identifiers are only supplied to authorized users of the system, and the user of the end station 3 therefore typically has to undergo an authentication procedure. This may be achieved using any one of a number of techniques, such as the use of certificates or the like, but will typically involve having the user submit a username and password, or the like, which is then authenticated by the base station 1, in the normal way. Thus, it will be appreciated from this that the user will typically have to undergo a registration procedure before being able to obtain identifiers, and hence use the tracking system.

In any event, once the user has been authorized, the base station 1 generates one or more identifiers as required. The base station 1 may generate the unique identifier based on certain information, depending on the implementation, and this may therefore require the user to provide the information when requesting the identifiers, or may use information stored in the memory 21 and/or the database 11 during a registration procedure. Additionally, the identifiers are to be unique, and accordingly, the base station 1 will typically use details of previous assigned identifiers to ensure that identifier duplication does not occur.

The identifiers may then be downloaded to the end station 3, for example, via the Internet, or supplied to the user of the end station 3 on physical media, such as a CD, DVD or the like. In either case, the identifiers are typically provided in a predetermined format, such as in a text file, CSV file or the like. As an alternative, the base station 1 may provide software to allow a user to generate their own identifiers using the end station 3. In this instance, the software may be provided via download, or on physical media, such as a CD, DVD or the like. The software is typically adapted to generate identifiers which are specific to the respective user. To achieve this,

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the software can incorporate information relating to the user, so that the identifiers generated by the software are globally unique.

An example of a suitable identifier will now be described. In particular, a number of factors need to be considered when producing the identifiers, including the maximum and minimum code sizes. The code size will in turn affect the size of the resulting 2-D code and it is therefore necessary to ensure a maximum length is set to ensure that the resulting 2-D code can be read accurately. In particular, if the code becomes too large, then this will require either a high code density, or alternatively a code extending over a large area. In the first case, the laser encoding system and the scanner both require a high degree of accuracy that in turn requires more expensive optical and laser equipment. In the second case, the laser system and the scanner must be able to encode or read codes over a larger area, which again increases the complexity and cost. Additionally, there can be problems in providing large codes on some pieces of equipment, which may have only a small enclosable surface area.

However, this must be counterbalanced by a minimum code size required to ensure that the generated identifier is globally unique. To achieve this, in one example, the unique identifier is formed from three portions, namely:

- Country code - typically derived from the ISO 3166 country codes and reflecting the location of the entity marking the instrument;
- Prefix - reflecting the identity of the entity marking the instrument; and,
- Unique number - a sequence of alphanumeric characters that is unique for instruments marked by the respective entity.

Thus, an example could be in the form AU BT8 JK4WT, where:

- AU - country code;
- BT8 - prefix; and,
- JK4WT - unique number.

In general, at least the country code and prefix will be scrambled or otherwise disguised so that it is not possible for the country code or prefix to be determined by third parties. Thus, whilst the country code and prefix will generally be the same for a given encoding entity, the alpha

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numeric characters will be effectively meaningless if the resulting code is scanned and the unique identifier decoded. This helps reduce the chance of entities fraudulently generating their own codes, as well as preventing third parties being able to determine the entity and the location in which the encoding was performed.

Similarly, it is typical for the unique numbers to be generated non-sequentially, again thereby preventing entities obtaining a single identifier, and then generating further identifiers by incrementing the provided unique number. In this instance, if the entity than also obtained further identifiers from the base station 1 they may duplicate the identifiers already generated. Additionally, mixing the unique number with the prefix and country code, effectively scrambling the entire identifier, helps further prevent fraudulent identifier use.

It will be appreciated from this, that the marking of instruments may be performed by any one of a number of entities, depending at which stage the instrument is marked. Thus, for example, instruments in hospitals or other medical facilities may be marked, to allow the process to be applied to existing instruments, in which case the prefix will reflect the identity of the hospital. Alternatively, a manufacturer or supplier may mark the instruments when the instruments are first created or sold.

It will be appreciated that as each entity uses it's own unique numbers, then these numbers can be generated internally using suitable applications software executed by the end station 3. In this case, the user of the end station 3 will therefore obtain the one or more identifiers by downloading the software from the base station 1. In this case, the user (or the marking entity with which the user is associated) is assigned the country code and prefix, and this can be supplied together with, or as part of the software, thereby allowing the software to generate the identifiers for the respective entity. In this case, the entity need only contact the base station a single time during initial set-up of the end station 3, allowing the end station 3 to generate the identifiers in future. However, any unique code can be used as the unique identifier. Accordingly, in the event that the infra-red image is used to derive a unique "fingerprint" based on the infra-red image of the instrument structure, then this can simply be translated to a suitable alpha-numeric code using a suitable algorithm.

It will also be appreciated that as long as the resulting identifiers are unique then the different techniques for identifier generation can be used in conjunction within the same tracking system. Thus for example, some instruments can be marked with a machine readable code, whilst others have the unique identifier derived from the structure of the instrument via the infra-red image. The end station 3 can then use the generated identifiers to mark instruments as will now be described with respect to Figures 8A and 8B.

Initially, at step 200, a user will utilize the end station 3 to obtain a set of unique identifiers as described above. At step 210 the user applies bonding material to the instruments to be marked, and then places the instruments in the mounting rigs 50, at step 220. The user then executes appropriate application software provided on the end station 3 to control the marking of the instruments. The application software will provide the user with a representation of an array of mounting rigs 50 as shown for example in Figure 9A. In this example, twelve encoding positions are shown, although it will be appreciated that this is for the purpose of example only. The user selects positions in the representation corresponding to the location of instruments to be marked in the physical array of rigs 50, thereby selecting the rig positions for encoding, at step 230.

At step 240 the end station 3 generates a barcode for each encoding position based on a selected unique identifier. The barcode may be encoded using any one of a number of techniques and will typically utilize standard encoding algorithms available in the art. This will not therefore be described in any detail, although a representation of a typical 2-D barcode is shown in Figure 9C. In any event, once the end station 3 has generated the barcode, the end station 3 operates to control the laser system to cause marking of each instrument. This is achieved by having the end station 3 activate the stepper motors to control the positioning of the laser system 70 relative to the array of rigs 50, thereby aligning the exposing laser beam with the bonding material applied to the instrument mounted in a respective one of the apertures 53, at step 250.

In use, this can be achieved using any one of a number of suitable control systems. Thus, for example, the laser system 70 can be moved to a predetermined position which is aligned with the aperture. However, as an alternative, the laser system can include a suitable imaging system

which is adapted to image the array, allowing the end station 3, or other control processing system, to detect the position of the bonding material. In the example in which the bonding material is applied in the form of an adhesive dot, the end station 3 will operate to locate the dot in the image, and then control the position of the laser system 70, to thereby align the laser beam with the dot.

It will be appreciated that a combination of the two techniques can also be used, to allow initial gross alignment with the array to be performed by moving the laser system 70 to a predetermined location, and then using an imaging process to perform more accurate alignment. The end station 3 will then operate to activate the laser beam, with the beam being modulated so as to encode the corresponding barcode in the bonding material, at step 260. The modulated laser beam impinges on the bonding material and thereby operates to bond the material to the instrument surface, as well as to encode a visible representation of the barcode therein.

Once each barcode is encoded, the end station 3 controls the relative position of the laser system 70, thereby moving the laser system 70 to the next aperture 53 in which an instrument is located, thereby allowing each instrument in the array to be encoded in turn. Once each instrument has been encoded the operator optionally scans each instrument using a scanning device 80, at step 270. The scanner 80 will generate indicating data indicative of the barcode, or the encoded unique identifier, and transfers this to the end station 3 to allow the clarity of the resulting code to be confirmed. Thus, this process ensures that the barcode can be read to determine the unique identifier.

At step 280, the instrument is then provided to allow a suitable database entry to be created. To achieve this, at step 290, the user provides instrument details for each instrument to be marked using an appropriate input screen, as shown for example in Figure 9B. The instrument details will typically include some or all of the following information:

- an instrument description;
- an item code indicative of a type of the instrument;
- manufacturer details;
- date of purchase;

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- warranty details or requirements;
- instrument cost;
- replacement information or requirements;
- instrument cleaning instructions or requirements;
- processing or maintenance information or requirements;
- a risk level associated with the instrument;
- status information, such as whether the instrument is available for use;
- equivalent instruments;
- instrument use instructions or requirements; and,
- a photo.

Additional information may also be provided depending on the implementation.

In any event, at step 300, the user scans the instrument, using the scanner 80, to allow the end station 3 to decode the unique identifier at step 310. At step 320, the end station 3 records an association between the unique identifier and the instrument data, such that the instrument data can then be subsequently retrieved when the instrument is scanned.

It will be appreciated that the instruments may be marked either by a manufacturer or supplier, or by an end user, depending on the respective implementation. In the former case, the instrument may be provided with no associated instrument data, thereby allowing the instrument data to be defined by the end user. However, additionally, or alternatively, the manufacturer/supplier may create instrument data to allow the instrument to be tracked through the supply chain. In this instance, the end user may create new instrument data, or use some or all of the manufacturer's instrument data, modifying this to suit their own purpose, as required. The instrument data is typically stored in a centralized repository, which may be administered by a central server or base station, such as the base station 1, as will be described in more detail below.

It will also be appreciated that in the event that the unique identifier is derived from an infra-red image of the instrument, then the marking steps 200 to 270 can be effectively omitted. In this example, steps 280 and 290 are performed to generate the database entry. At step 300 the instrument is scanned with an infra-red scanner to generate the image, which is then used to

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generate the unique identifier at step 310. The end station then proceeds to create the association as in the example above at step 320.

An example of the tracking of an instrument will now be described with reference to Figures 10A to 10D. In particular, after an instrument has been marked, or after use, the instrument is sent for cleaning, which may include sterilization and other appropriate cleaning techniques, at step 400. When a user is to perform cleaning, the user will typically perform this as a batch process, with a number of instruments being cleaned at the same time. Accordingly, the end station 3 is used to define batch data at step 410. The batch data includes details of the cleaning procedure, such as:

- the cleaning technique used;
- the time and date on which the cleaning occurred; and,
- details of the individual performing the cleaning operation.

The user will then scan the next instrument for inclusion in the batch at step 420. The end station determines the unique identifier associated with the scanned instrument at step 430, using this to determine and display the instrument data at step 440. At step 450 the user confirms the instrument data is correct before associating the batch data and the instrument data to thereby add the instrument to the assigned batch at step 460.

Associating instrument and batch data may be achieved in a number of manners depending on how the instrument data and batch data are stored. For example, the instrument and batch data may be stored in respective database tables, with each instrument or batch being provided a table row. In this case, a link can be defined between corresponding rows in the batch and instrument tables to thereby associate the instrument with the corresponding batch.

Alternatively, the batch data may include an identifier which is stored as part of the instrument data, or vice versa. At step 470 it is determined if the batch is complete, and if not, the process returns to step 420 allowing the user to scan the next instrument. Once the batch is complete, the process moves on to step 480 to allow the batch to be cleaned. During or following this, the batch data can be updated with information regarding the cleaning process at step 490. This information can be obtained from the machine used in performing the cleaning, which is

typically able to provide cycle data including details such as:

- a cleaning time;
- a cleaning temperature;
- a cleaning pressure;
- machine maintenance information;
- a machine operator identifier; and,
- other cleaning details.

Accordingly, subsequently scanning an instrument will allow an end station to determine the unique identifier, and consequently the instrument data associated with the instrument. From this, the corresponding batch data can be accessed, thereby allowing details of the cleaning procedure for the respective instrument to be determined.

It will be appreciated that the above described process can be performed in a number of ways, and the above is for the purpose of example only. Thus, the batch data could be created prior to, after or during the cleaning procedure. Similarly, a batch may include only a single instrument, depending on the cleaning performed, and the term batch should therefore be understood to be for the purpose of example only.

At step 500 the instrument is sent for packing or other further processing. This may include placing the instrument in packs or the like, as well as adding instruments to a tray, as will be described below. At step 510, the end station 3 updates the status of the instrument stored as part of the instrument data to indicate that that the instrument is now available for packing. An example of the process of adding an instrument to a tray will now be described, although it will be appreciated that the general steps outlined could also apply to other parts of the packing process.

At step 520 the user uses the end station 3 to select a tray for creation. This can be achieved using a suitable graphical user interface, so that, for example, the user of the end station 3 can be presented with a drop down list of different tray types available. The user will select a tray type to be created, causing the end station 3, causing the GUI to display details of required instruments at 1000, a photo of the completed tray 1001, and a tray ID, as shown in Figure 11.

At step 530, the end station 3 generates tray data, which is typically achieved by adding an entry to a tray table in the database. The tray data typically includes details of the tray creation process including:

- the tray ID;
- the time and date on which the tray was created; and,
- details of the individual creating the tray.

In the example of Figure 11A, the tray ED, shown at 1002, includes a prefix (000017 in this example) indicative of the type of tray being created, and a suffix (-2 in this example), which is indicative of the number of trays of that type being created.

The tray data also typically includes an identifier which is determined by scanning an appropriate barcode. Accordingly, the tray may be marked using the process described above, in a similar way to other instruments. Alternatively, the tray may be identified by a tag applied to the tray, or provided on the tray for example, using a suitable label or the like. The list of the instruments to be provided in the tray, typically includes:

- an item code indicative of the instrument type; and
- a description of the instrument.

If the user then selects a respective one of the instruments from the list, additional details can be displayed, including for example, a photo of the instrument, a more detailed description of the instrument and any associated requirements or restrictions on its use.

This aids the user in selecting a suitable instrument from the available instruments. In particular, the user can request an instrument based on the required item code, which is used to obtain an instrument of the correct type from stores. The item code may also be provided on any packaging or the like, to further aid instrument identification. The instrument is then scanned using the scanner 80 at step 540, allowing the end station 3 to determine the unique identifier at step 550, and uses this to determine corresponding instrument data at step 560.

The instrument data is used to confirm a suitable instrument has been selected. This can be achieved in a number of manners. For example, this can cause the end station 3 to display the instrument data to the user, to allow the user to view any associated restrictions on use, as well as

to view the item code, to ensure the correct instrument is displayed. Additionally, or alternatively, the instrument data can be compared to the tray data, using predetermined business rules, to determine if the instrument is suitable for use.

This is required, for example, to take account risk levels associated with instruments. For example, when an instrument is used in a high risk procedure, this is indicated within the instrument data. In this instance, this may indicate that the instrument can only be used in certain procedures. Accordingly, the intended use of the tray is determined, based on the tray type indicated by the tray ID, allowing the end station to determine if the instrument is suitable for use on the corresponding tray.

The use of such a technique helps reduce the chance of instruments being incorrectly provided on certain trays, which in turn can help reduce the chance of the instruments being used incorrectly. At step 590, the end station 3 associates the instrument data with the tray data, and updates the status provided in the instrument data and the tray data at step 600. In this example, the end station achieves this by generating a suffix to be included on the item code, to thereby create a unique item code for each instrument of that type of the tray. The unique item code for that tray is then stored in the tray data, with an association being recorded between the unique item code and the instrument data of the corresponding instrument. This allows each instrument within a given tray to be uniquely identified, thereby allowing the use of instruments on different trays to be tracked. If the tray is not complete, the process returns to step 550 allowing the next instrument to be selected at step 610.

Otherwise, at step, at step 620 the tray is provided for use in a procedure. The manner in which this is performed is typically in accordance with standard procedures, which are typically specific to the medical institution performing the procedure. At step 630, the procedure is performed, with the end station 3 being used to create procedure data reflecting the details of the procedure. Typically the details of the procedure will include information such as:

- the nature of the procedure;
- the medical practitioners involved in performing the procedure;
- the time and date of the procedure; and,

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- information indicative of the patient.

Due to security reasons it is typical that the patient identity is not included directly in the procedure information, but rather an identifier can be used which is associated with the identity of the patient for example by way of an appropriate mapping through the hospitals and internal secure records.

The end station 3 then operates to associate the procedure data and the instrument data. This may be achieved for example by directly associating the procedure data with the instrument data for each instrument, or by associating the procedure data with the tray data of the tray, which is in turn linked to the instrument data of the instruments provided thereon. Once the tray has been used, the instruments thereon can be returned for cleaning at step 660, with the instrument data being updated to reflect the status of the instrument.

Thus, the above-described process allows instruments to be uniquely identified and consequently tracked throughout their life. This allows a history of events in which the instrument has been involved to be retrieved by scanning the barcode, determining the unique identifier, and accessing the instrument data. Whilst only limited events of cleaning, adding to a tray and use in a procedure are shown, it will be appreciated that the technique can be used to track any event. Thus each time an instrument undergoes an event, a data entry is made in a suitable database table, so if no appropriate table exists, a new one can be created. In this instance, each event instance of a respective type is provided in a suitable table row, with the rows of each table being linked to corresponding rows in the instrument data table. This allows the instrument data to be used to retrieve details of those events in which the instrument is involved. This can be used for a number of purposes, such as identifying patients that have undergone procedures with respective instruments, or the like. Additionally, as the instrument data is linked to patient data, this also allows patient details to be used to access information regarding the instruments used on the patient.

This technique provides a number of advantages over existing tray tracking techniques that rely on an instrument being associated with a respective tray throughout their life. For example, in such techniques, if any one instrument in the tray is unavailable, such as if the

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instrument it requires cleaning, repair or replacement, then this means all of the instruments in the tray cannot be used, which can in turn cause tray supply restrictions. Additionally, if instruments become incorrectly used on a tray, this prevents the history of the procedures in which the instrument is used to be determined definitively. As a result it is difficult to determine on which patients the instrument has been used.

However, in the above-described system, as each instrument is uniquely tracked, it does not matter if instruments are used on different trays in different procedures. In particular, the tray identifier is uniquely associated with the instrument each time the instrument is used. The tray identifier can then be used to determine what procedure the tray was used in at the time the instrument was assigned to the respective tray.

Thus, if an instrument is found to be used in a procedure where there is a resulting risk of contamination to other patients, or is found to be incorrectly washed, this allows the corresponding procedure and/or the cleaning batch to be identified from the instrument data. This in turn allows all other instruments used in the respective procedure, or in the respective batch to be identified and checked for contamination. Additionally, each patient that has undergone a procedure with the respective instruments can also be determined and checked to ensure that no patient contamination of infection has occurred.

STOCK MONITORING

In addition to the above functionality the system described can also provide supply chain to allow ordering, payment for, and use of stock to be monitored in real time or near real time. An example of the manner in which this is achieved will now be described with reference to Figures 12A and 12B. This can be applied to any form of stock, such as any items, consumables, disposable instruments, other instruments, or the like, which will generically be referred to as items for clarity.

At step 700, items required are determined. This may be achieved in any one of a number of ways, and may be based for example on the needs associated with a procedure being performed on a patient. As will be described in more detail below, this can therefore involve determining a

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procedure to be performed on a patient, and then using preference cards or the like, to determine the items required. In the case of a scheduled procedure, the stock is typically checked in advance to ensure that required items are ordered before the procedure is commenced. However, in the case of an emergency, items will typically be provided from existing stock, with replacement items being after the stock is used.

To check the available stock, it is typical to utilize stock data, which is indicative of items available for use, and optionally of suppliers for each respective item. The stock data is typically stored in an appropriate repository, such as the inventory management repository, which is stored centrally, for example by the base station 1, as will be described in more detail below. Thus, a user of one of the end stations 3 will access the stock data using a suitable interface, such as an inventory management module, allowing the user to check available stock and determine if further stock is to be ordered.

If it is determined that further stock is required, for example, if items are unavailable or will require replacement, then at step 710 order data representing the required items is provided to the supplier. The order data may be created in any one of a number of manners, such as by having the end station 3 create the order data using the stock data. Thus, the user can use the end station 3 to view the stock data representing live information of available stock, and where stock is running low, the user can select an associated order option.

The end station 3 then determines the preferred supplier from the stock data, if this information is available, together with any other required information, such as delivery protocols, order codes, an ETA for delivery, or the like. It will be appreciated that this information may be stored or otherwise linked to the stock data and can be based on historical data collected during previous deliveries, and/or suppliers contractual arrangements for supply. The order data is transferred to the supplier as an electronic request, in a suitable form, such as a CDA document, secure certificates, xml document or the like.

At step 720, the supplier receives the order data, and checks to see if the required items are available for supply. This is typically a substantially automated process achieved by having the supplier implement their own supplier stock data, which can be accessed via a supplier end station

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3. Thus, in this instance, the supplier end station 3 can receive the electronically transferred order data from the user end station 3, and parse this to determine the items identified therein. The items will then be compared to supplier stock data to see if the supplier has the items in stock.

If it is determined that items are not available at step 730, then the process moves on to step 740 to generate details of optional equivalent items that may be provided. Following this, or if all items are available, at step 750, the supplier generates supply data and transfers this to the medical institution that provided the order data. The supply data includes details of the items that are available, which are also concurrently or subsequently dispatched for delivery as indicated in the supply data, together with details of any unavailable instruments. The details will typically include information regarding the items to be supplied, and can for example include one or more of:

- an item description;
- an item code indicative of an item type;
- an item identifier, such as a barcode;
- manufacturer details;
- date of purchase;
- warranty details or requirements;
- item cost;
- replacement information or requirements;
- item cleaning instructions or requirements;
- processing or maintenance information or requirements;
- a risk level associated with the instrument;
- status information, such as whether the instrument is available for use;
- equivalent instruments;
- item use instructions or requirements;
- an indication of whether the item is provided on consignment; and,
- a photo.

The supply data forwarded to the user end station 3 may also typically include all up-to-

date product documentation relevant to the supplied or proposed equivalent items, such as rebate codes, catalogue numbers, descriptions, and even pictures, instructions and possibly material safety data sheets. This may also contain the invoice information for electronic invoicing. Thus, it will be appreciated that the supplier end station 3 can automatically process received order data, determine item availability for supply, and then generate supply data. To allow the supply data to be received by the user end station 3 at the medical institution, the supply data will typically be in the form of a CDA type communication similar to the format described above. At step 760 a user of the end station 3 receives supply data and typically uses this to update the stock data. To ensure that this is handled correctly, the user typically ensures that the items are received before the stock data is updated, although this is not essential.

Ensuring that the ordered items are correctly received can be achieved using the item identifier. Thus, in some cases, the item identifier may need to uniquely identify the item, for example, if the item is an instrument. Alternatively, however, the identifier may simply be indicative of the item type, for example, if items can be used interchangeably, or do not need to be uniquely tracked. This may occur for example, if the item is a consumable or the like. Accordingly, in one example, such as if the item is an instrument, the item identifier may be in the form of a barcode generated and applied using the techniques described above with respect to Figures 8 to 10. However, in situations where the items are not required to be uniquely marked, then the item identifier may be a standard EAN product barcode, or the like.

It will also be noted that the supply data can include similar details to the instrument data described above, and as such can be used as a basis for the instrument data, thereby avoiding the need for a user to manually define the instrument data. At step 760 the items are received and subsequently scanned, at step 770, to thereby determine the item identifier. The scanning procedure is typically achieved using a scanner that is suitable for the respective type of identifier. Thus, the scanner may be similar to the scanner 80 described above with respect to Figure 4A to 4D, and/or may be a standard barcode scanner, depending on the respective implementation.

At step 780, the end station 3 uses the determined item identifiers to determine if all items have been received. This will be achieved by removing each scanned item from the supply data

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and then 15 determining if any items remain defined in the supply data when all received items have been scanned. If the item identifiers are not unique to each item, for example, if the item identifier is merely indicative of a specific type of item, then the supply data will typically also include a number of items ordered, thereby allowing a similar check to be performed.

In the event that certain items have not been received, for example if they are missing, or if they were unavailable, then at step 790 the process operates to contact the supplier to arrange delivery of unreceived items. This can include, for example, generating supply data corresponding to equivalent items described in the supply data, or providing an indication of missing items. Alternatively, this may include contacting an alternative supplier to source the items from a different location. The process then returns to step 710 to allow order data corresponding to unreceived items to be provided to the supplier.

This is particularly important in the case of organizations such as medical institutions, as these will typically be invoiced for all ordered items, and typically include little or no mechanism for checking if the items have been received. This is exacerbated by the fact that items may be ordered by a number of different individuals within the organization. As a result, this can make it difficult to track which items have been ordered and consequently means that a large amount of revenue is wasted on paying for unreceived items.

For received items, the process can in any event move on to step 800, at which point, the end station 3 operates to determine whether the items are on consignment. This will typically be indicated in the supply data, although alternatively a separate of consignment items may be stored locally by the end station 3. Consignment items are generally expensive items that the organization would be unable to pay for up front, such as prosthesis, or the like. In this case, payment for such items is only made when the item is used. However, for all other items, such as consumables, instruments, or the like, payment is generally made on receipt, and accordingly, if it is determined that an item is not on consignment, then the end station 3 will operate to arrange for payment to be made at step 810.

Payment may be achieved in a number of manners, such as by raising a purchase order and transferring this to suitable accounting entity to thereby cause the invoice to be paid. This may be

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achieved automatically utilizing a suitable processing system, or alternatively may be performed manually as will be appreciated by a person skilled in the art. Typically however, arranging for the payment to be made will involve validation of supply data against purchase orders or requisition orders, and then validating the items against billing and invoicing requirements for automation of payments.

In any event, at step 820 the end station updates the stock data to include details of the now available items. The stock data may be formed in a number of ways. For example, in the case of instruments marked in accordance with the above described procedure, the stock data may simply include a link or other association to the instrument data. For other items, particularly if the item identifier is only indicative of the item type, the stock data usually includes details of the item together with an indication of the number of available items in stock. In this case, the item details are typically based on the details provided in the supply data, although this is not essential.

The process of steps 700 to 820 will typically be an ongoing process that is repeated as required, and is therefore used to process all incoming stock. When it is determined that an item is required at step 830, a user will select an appropriate item from stores and then scan the item at step 840 to thereby determine the item identifier. The manner in which an item is requested will depend on the nature of the item and the respective implementation, as will be described in more detail below. At step 850 the end station 3 utilizes the item identifier to update the stock data to thereby reflect that the item is to be used, and therefore no longer forms part of available stock. The manner in which this is achieved will depend on the stock data, and may therefore include reducing a count of the number of items of a certain type available, if the item is not uniquely identified, or removing the item from the stock data entirely.

At step 860 the end station further determines if the items are on consignment. In this particular instance if the items are on consignment, then the end station 3 arranges for payment of the items at step 870. This would typically be achieved using a process similar to that performed at step 810. In addition to paying the supplier, the end station 3 will also typically generate an invoice to pass the charges onto another entity, such as a health insurance company or the like.

This is particularly important in the case of expensive items that are on consignment, such as prosthesis, as it is important to ensure not only that sufficient prosthesis are available for use, but also that the costs for the prostheses are recovered.

At step 880 the end station 3 may optionally determine if stock levels are low and if so contact a supplier to arrange delivery of additional items by returning to step 700. This may be achieved, for example, by comparing the number of stock items for a particular item type to a predetermined threshold and arranging to order more items in the event that the stock level is below the threshold. However, any suitable mechanism may be used.

At step 890 the item is then provided for use.

It will be appreciated that this therefore provides a mechanism for automatically tracking items in the supply chain from the supplier to their ultimate use, as well as allowing for automated payment and re-ordering to be achieved. This significantly simplifies the monitoring of stock, and allows integration with the above-described marking techniques.

It will be appreciated that as a development on the above, the system can be used to return delivered items if there is an overstock.

Additionally, the process can be used to coordinate the allocation of items to different procedures. In this case, each delivery can be associated with a booking number that associates the item as being for use by a particular surgeon and in a certain procedure. This can be achieved based on the use of preference cards, as will be described below.

The above described process can be achieved by allowing the supplier access to the repositories described in more detail below. The supplier may also implement similar applications software to that used within the medical institution, to allow stock management, and the like, albeit in a reduced form as attributes of the system such as procedure scheduling or the like may not be required. The process can also be extended, to allow feedback of item usage to be provided to the supplier. In this example, the supplier can track received orders, thereby allowing the supplier to determine medical institutions that use certain items, to allow advertising or the like to be appropriately targeted.

Additionally, further information can be collected by, for example, storing information

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regarding an items intended usage at step 890. In this instance, details may be stored as item data, or the like, which can then be accessed and reviewed by suppliers. This allows suppliers to collect further information regarding the usage of items, to assist further with marketing, sales or the like. This can also extend to other entities within the medical, or other business environments.

Thus, for example, when a GP or hospital issues a prescription and then the prescription is filled at a pharmacy, the supplier can identify all the information available legally to them regarding the GP or other facility actually prescribing the product, as well as if the patient has actually used the prescription. With appropriate configuration of data within the repository, this can be made available to the supplier without the supplier being provided with access to any patient specific (private/confidential) information. Similarly, this could be used by purchasers to find out which products are provided by which suppliers.

Searching could be achieved via a “Google” type search interface, which allows details of a product to be entered, for example in the form of product codes, item types, or the like, with the results providing information regarding product requirements, suppliers that have product, product end usage and other vital supply chain information dynamically across many suppliers and purchasers.

The presented information may be connected to or independent of patient information, for example, depending on the circumstances in which the information is provided. Thus for example, medical personnel may be required to undergo authentication to allow patient information to be reviewed. This can therefore be used as both a powerful business and possibly public safety tool, for example to allow the government to determine the extent of dissemination of a certain drug, over a certain time period and/or in a certain demographic area, alerting the government to an outbreak, or the like.

ITEM REQUIREMENT DETERMINATION

In the example processes discussed above, such as at step 700, it is necessary to determine if an item or instrument is required for use. The manner in which this is achieved will depend on the type of instrument or item being used, and the nature of the corresponding event.

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In the case of events, such as cleaning, an indication that items are required may be generated automatically by the end station 3 based on the batch data. Thus, the end station 3 can use the stock data to determine when an item was last provided, and also use the batch data to determine the number of specific types of cleaning events that have occurred since that time. This, in turn allows the end station 3 to calculate when a replacement item is required. Thus, for example, if the item is a consumable such as cleaning fluid, the batch data can indicate a typically number of cleaning events that can be performed before the fluid is used up. In this case, when the end station 3 generates the batch data at step 410, the end station 3 will check when the item was last replaced, and in the event that this exceeds a predetermined number of cleaning events, additional cleaning fluid will be requested from stores.

Alternatively, the requests may be provided manually. Thus, for example, cleaning fluid may be wasted during the cleaning process, for example, if some of the fluid is spilled. Accordingly, replacement cleaning fluid may be required before the predetermined number of cleaning events have occurred, in which case a user of the end station 3 can submit a request to stores manually via an appropriate mechanism. In the case of items used in a medical procedure, the items used will generally depend not only on the procedure involved, but also on the preferences of the medical personnel involved in the procedure. For example, each surgeon may use a different combination of instruments for performing the same procedure.

To account for this, the system is adapted to store preference card data. The preference card data indicates, for each medical practitioner, and for each type of procedure they are to perform (which is typically determined based on an association to the procedure data), the instruments and other items required. In this case, when a procedure is scheduled, and the practitioner involved determined, a user of the end station 3 can access the preference card, which indicates each of the items and instruments required. This information is then used at step 700, to ensure the correct items are made available. It will be appreciated from the above, that when the preference card is used to obtain items for use in the procedure, this can be used to automatically trigger the ordering of replacement items.

PATIENT INFORMATION COLLECTION

In addition to the above-described processes, the current system can also operate to collect and collate information regarding a patient and their progress through a procedure, as will now be described with reference to Figures 13 and 14. As will be described in more detail below, this allows information regarding use of assets or stock, such as items and instruments, to be associated with the patient, thereby allowing subsequent identification of assets, such as instruments, used on the patient.

The manner in which data collection occurs will first be described with reference to Figure 13. At step 1000 the patient is to be involved in the procedure. Accordingly, the end station 3 is used to generate patient data including patient details at step 1010. The patient details will include information allowing the patient to be identified, as well as any information relevant to the procedure, and may therefore typically include information such as:

- name;
- address;
- phone number;
- other contact details;
- details of prior medical conditions;
- details of allergies;
- current medication taken;
- a current patient status, including for example:
 - blood pressure;
 - temperature;
 - location;
 - procedure stage; and,
- other relevant information.

As an alternative to generating patient data, patient data may be received from another source. Thus, for example, if the patient is referred from another medical institution, the patient data may be received from multiple other sources, such as one or more other medical institutions

and/or other internal facility systems, thereby avoiding the need to create patient data already in existence.

In any event, the end station 3 will generate a patient tag associated with a corresponding patient identifier. The patient tag is typically in the form of a wristband or other wearable device that can be fixed to the patient to allow the patient to be identified by medical personnel. In one example, the patient identifier is a linear barcode, such as a barcode defined in accordance with EAN protocols or the like. In any event, irrespective of the nature of the patient identifier, the patient identifier is used to uniquely identify the patient within the medical institution, and therefore is unique for the respective institution. The patient identifier is associated with the patient data, allowing it to be retrieved by the end station 3.

Thus, at step 1030, when a stage in the procedure is to be performed, or when the status of the patient is updated or checked, the patient tag is scanned using a suitable scanner, such as a barcode scanner, with details of the scanned identifier being transferred to the end station 3. At step 1040, the end station 3 will determine the access the corresponding patient data and display this, thereby allowing the patient details to be reviewed by medical personnel.

At step 1050 it is assessed if the patient data needs to be updated and if so the process moves on to step 1060, allowing the medical personnel to update the patient data using the end station 3. Once this is completed or in the event that no update is required, the returns to step 1030 allowing the patient data to be further reviewed as required. Thus, it will be appreciated that utilization of the barcode associated with the patient allows the patient tag to be scanned and the corresponding patient data displayed on a suitable end station 3. In the event that an end station 3 is a portable device, such as a PDA, Tablet PC, Lap-top or the like, this allows medical personnel to move around the medical institution and view and update information regarding patients as required.

In this particular instance each time details of the patient are measured, such as blood pressure, temperature or the like this can be added to the patient data together with a corresponding time indication so that a complete record of the patient's history is displayed. An example of the circumstances when this may be used is shown in Figure 14, which shows the

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general stages involved in performing a procedure on a patient. Thus, as shown at step 1100 the patient undergoes pre-admission. Such a pre-admission stage is generally used to prepare the patient for the operation by allowing tests, such as blood pressure checks, or the like to be performed, to allow the patient data to be generated, as well as to ensure the patient does not eat or drink prior to surgery or the like being performed. Whilst the pre-admission may be performed in a hospital, it is also possible for the pre-admission process to be undergone at a different environment, such as a hotel or the like.

At step 1110 the patient is admitted to hospital during an admission stage. At this point, it is typical for the patient details to be checked, and the patient assigned to a bed or the like. Following this, and once the procedure is ready to be performed, the patient is transferred to holding area at step 1120 to allow the patient to await surgery. At this point, the patient's identifier will typically be scanned and the patient data compared to a schedule indicative of the procedure to be performed, to thereby ensure that the correct patient is provided for the procedure.

At step 1130 the procedure is performed. During this process, the patient data may again be checked and updated as required, for example to allow the status of the patient during the procedure to be recorded. This also allows details of the procedure to be recorded, although alternatively this can be achieved by generating procedure data, which is then associated with the patient data, for example by utilizing suitable linking within a database.

At step 1140, the patient enters the recovery stage with details of the patient's recovery been recorded in the patient data, before the patient is discharged at step 1150. Thus, it will be appreciated from the above, that this provides a mechanism for maintaining a detailed record of the patient, and in particular, their health status at each stage during a procedure. This can include, for example, details of health status indicators, such as temperature, blood pressure, or the like.

Thus, this technique can provide an audit trail of the patient's health status, with the results of each monitoring step being recorded together with information such as the time and date, to allow the progress of the patient through the procedure to be subsequently reviewed.

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It will be appreciated that the information collected during this process may be used in any one of a number of environments, such as post discharge care 1160, pathology 1170, by a general practitioner or other medical personnel at 1180, in recall of patients, equipment or the like at step 1190, and for a number of other uses at step 1200.

PROCEDURE SCHEDULING

In order to allow a number of procedures to be performed in a number of different theatres, or other appropriate rooms, it is necessary to schedule the procedures and the use of the rooms. This is a complex task particularly when it must be taken into account that procedures can overrun if complications occur. Accordingly, the above described system can also be used to maintain and update a theatre schedule which sets out details of the times and locations in which respective procedures are to be performed.

In order to achieve this at step 1300 it is necessary to determine procedures to be performed. This will typically be in the form of a list of procedures, together with additional information such as the preferred ordering, or relative importance of the procedures, together with an indication of additional requirements, such as requirements for the room facilities or the like. This information may be derived from requirements data as will be described in more detail below.

At step 1310, the end station 3 generates a theatre schedule. In this instance, the end station 3 will utilize a scheduling algorithm to assign procedures from the list to respective ones of a number of different available operating theatres. This will take into account requirements for the procedure, thereby ensuring the theatre to which the procedure is assigned is suitable for such use. This will typically utilize generic scheduling algorithms, or may be performed manually, depending on the preferred implementation, and this will not therefore be described in any further detail.

Once the schedule is defined, it is important to ensure that this is maintained in as an efficient manner as possible to allow the maximum number of procedures to be performed. Accordingly, at step 1320 the end station 3 is used to determine the current status of procedures,

using this to generate a GUI showing the current procedure status. An example of a suitable GUI is shown in Figure 16.

As shown the GUI 2000 includes a list 2001 associated with each of the available rooms, as shown at 2001A, 2001H. In this example, and for the purpose of clarity, the explanation will focus on the use of two theatres only, represented by the lists 2001A, 2001B, although it will be appreciated that the techniques are equally applicable to any number of theatres. In any event, in this example, each of theatres utilizes six time slots, shown generally at 2010, 2011, 2012, 2013, 2014, 2015. Each slot is therefore typically of a predetermined time length, such as one hour, or the like.

In use, each time slot is used to represent whether a procedure is scheduled to performed within the theatre during the respective time slot. This allows, an operator is presented with the GUI and can therefore view the procedures scheduled for different theatres at different times. When the end station 3 presents the GUI the end station 3 utilizes the current status of procedures to generate an appropriate status indication on the schedule. The status indication is based on a comparison of the current status of the procedure with a predicted status.

Thus, for example if the procedure is running behind time the current time slot for the corresponding theatre 2000 will be highlighted in a different colour, such as red, whereas if the procedure is running on time a green status indicator colour will be provided. Scheduled procedures not yet in progress are then indicated in a further colour. In this example, the time slots indicate the status as follows:

- time slots 2010A, 2011A - procedure in progress and on schedule;
- time slots 2012A, 2013A, 2014A, 2012B, 2013B, 2014B, 2015B - procedure scheduled to be performed;
- time slots 2010B, 2011B - procedure in progress and behind schedule;
- time slots 2015A - no procedure scheduled;

Accordingly, an operator will examine the available theatre rooms and in the event that any one of the procedures is behind schedule can operate to update the schedules. Thus, at step 1320 if the operator determines that the current status does not effect the schedule the process will return to

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1310, allowing the GUI 2000 to be updated as the procedures progress, as required. However, if the operator determines that the current status will effect the schedule, for example if a procedure is likely to overrun, then the operator will determine other available rooms at 1330.

Thus in this example, the procedure being formed in the theatre 2000B is currently overrunning, and accordingly, the operator must make additional time available, by moving one of the procedures subsequently scheduled for the respective operating theatre 2001B to another room. Accordingly, the operator can determine if the schedule can be revised at step 1340 by determining if the procedure can be moved to a different theatre. In this example, the theatre 20021A includes an available time slot, and accordingly, this is achieved by moving the procedure scheduled for the time slot 2012B, to the time slot 2015A, as shown in Figure 16B. This is achieved by having the user drag and drop the procedure from the representation 2001B to the representation 2001A.

It will be appreciated that the manner in which the operator reschedules procedures will depend on a number of factors, such as the relative importance of the procedure. Thus, for example, if the procedure at 2012B is urgent, each of the procedures at 2012A, 2013A, 2014A may be delayed to allow the procedure shown at 2012B to be performed at the originally allotted time, albeit in a different theatre.

To assist with this, the GUI will typically allow the operator to view details of the scheduled procedures, for example, by allowing the operator to click on one of the time slots and view procedure details in a separate window or dialogue box. Additionally, the GUI can include a list of as yet unscheduled procedures. This allows the operator to add procedures to the schedule, and it will be appreciated that this technique can be used to define the initial schedule at step 1310.

In any event, when the GUI is manipulated, the end station 3 will update the schedule based on the revisions made by the operator and then return to step 1310 to allow monitoring to continue. Alternatively if it is determined that the schedule cannot be updated, for example if no other rooms are available, then the user can simply delay a procedure by canceling it as required. At this point, the procedure will be returned to the list of as yet unscheduled procedures, allowing

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the procedure to be reallocated to a theatre as time slots become available.

ELECTRONIC COUNT SHEET

During procedures, it is important that all medical items and instruments are accounted for. In particular, this is important to ensure that instruments and/or items such as swabs or the like, are not left within the patient. This is typically achieved using a count sheet, and an example of utilizing the above described system for providing an electronic count sheet will now be described with respect to Figure 16. In this example, at step 1400 a doctor or other medical personnel defines requirements data for a respective procedure.

The requirements data will be generated on a case by case basis as each doctor will generally have respective requirements for each procedure. In any event, the requirements data typically includes a list of the items or instruments used during the procedure, and can therefore be formed from the preference card data discussed above. Accordingly, the requirements data can be used to order items for use in the procedure, at step 1410, as has previously been described.

At step 1420 the procedure is commenced, with any items used being recorded at step 1430. Periodically at step 1440 medical personnel will determine if used items are accounted for. If not the process can move on to step 1450 to allow the missing items to be investigated. Otherwise the procedure can be continued by confirming the items are accounted for and then returning to step 1430 to allow use of additional items to be recorded. It will be appreciated that this provides a mechanism for continually updating a list of used items with this being periodically checked to ensure the used items are accounted for and not left within the patient or the like.

To achieve this, the medical personnel may be presented with a GUI by an end station 3 during the procedure, with the GUI displaying a list of each item available for use. As each item is used, it is selected on the list, with the list being modified to indicate the item has been used. When an item has been accounted for, the item can be selected a second time, allowing its status to be further updated to reflect that it has been used.

DATA MANAGEMENT

It will be appreciated that the techniques described above can be combined to provide for an integrated hospital management system that allows tracking of item use, procedure scheduling, patient monitoring and stock monitoring.

In one example, this is achieved by using an association between patient data indicative of a patient involved in a medical procedure and asset indicating data indicative of assets used within the medical environment. This allows information regarding assets associated with the patient during the performance of the procedure, to be subsequently retrieved and reviewed. Additionally or alternatively, this allows inventory control and ordering, billing and the like to be achieved. The indicating data can take any one of a number of forms such as instrument data regarding instruments used, as well as inventory data, stock data or asset data regarding the assets used. To achieve this, the system utilizes a number of repositories for storing data including:

- an asset repository;
- an instrument repository;
- corporate data repository; and,
- inventory management repository.

ASSET REPOSITORY

The asset repository is used to store asset data, which provides details of any asset used within the medical institution, including all assets, such as medical instruments, items, consumables, other stock, or the like. Entries in the asset repository are provided so that they contain information that is common to each instance of the particular asset, thereby allowing details of an asset, to be provided by referencing the asset repository. This can include information such as an asset product code, the manufacturer/supplier of the asset, the manner in which the asset should be used, maintenance information, cost, or the like.

INSTRUMENT REPOSITORY

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The instrument repository is used to store details of each instance of a physical instrument within the medical institution, such as the instrument data outlined above. This is achieved by providing information that is specific to the respective instrument instance, and then linking this to an appropriate entry in the asset repository. Thus, the asset repository will include information that is common to each instrument of a specific type, with each physical instance of an instrument within the medical institution being identified by an entry within the instrument repository.

When a user is required provide instrument details for a new instrument at step 290 above, the user can simply access the asset repository and determine if details of that type of instrument already exist. If so, the instrument details are provided in the instrument repository by providing specific information such as the date of purchase of the instrument, and the associated unique identifier, and then linking this information to the appropriate entry in the asset repository.

So, for instance, if the user is entering details of a scalpel that has just been assigned a unique identifier, the user can achieve this by accessing the asset repository to determine if a record for a scalpel asset of the same type exists. In this case, the user can then simply create a new scalpel instance in the instrument repository, which includes the unique identifier and therefore distinguishes the scalpel from each other scalpel, and then link this to the scalpel asset entry in the asset repository, to thereby provide the necessary details of the instrument. If no suitable entry is present in the asset repository, then this will need to be created.

INVENTORY MANAGEMENT REPOSITORY

This is used to store information, such as stock data, regarding the inventory within the medical institution, as described in the stock monitoring procedure above with respect to Figures 12A and 12B. Thus, stock data is typically formed by entries in the inventory management repository, which reflect numbers of specific asset instances, such as items, and consumables in stock within the medical institution.

Thus, entries within the inventory management database reflect specific item instances, with a link being provided to information common to the each item of a specific type being provided in the asset repository. Thus, for example, bandages of a given type may have a

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description and product code, which is stored in the asset repository, with each bandage within the medical institution being identified by a unique entry in the inventory management repository, allowing current stock levels to be easily determined.

CORPORATE DATA REPOSITORY

This is used to facilitate the management and/or compilation of data for patient related and/or influenced activities. This allows integration between existing systems and the above described processes and their corresponding implementing applications, as well as to provide data management pathways.

To achieve this, the corporate data repository stores, or provides references to data which forms the patient data, electronic count sheet data, preference card data, or the like.

Thus, the data collected by systems utilized in the above described processes, as well as other systems within the medical institutions may either be stored in the corporate data repository or in the case where the data is stored in other databases, simply addressed by the corporate data repository. This then enables the applications to manage this data for process management and/or control/manipulation and then ultimately updating other systems with the data compilation.

The corporate data repository is generally built from HL7 messaging or ODBC connection to such other databases or information sources, could be from triggering an event that in turn provides a simple XML string for the corporate data repository to interact/be populated with. An example of the databases connected to and information managed by the corporate data repository are as follows:

- Purchasing
- Sterilization department processing
- Maintenance
- Accounting
- Asset repository
- Pharmacy
- Theatre list or theatre management systems

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- Billing
- PAS (Patient Administration System)

Accordingly, data such as patient data can be formed from a combination of patient information held in the corporate data repository and/or information created in specific applications and/or stored in specific databases used for implementing the above described processes. The patient data is appropriately linked to each of the other repositories to reflect interactions with the patient. This is performed in advance of procedures being performed on the patient, thereby allowing inventory for the procedure to be ordered and prepared. Additionally, once the procedure has been completed, this provides an effective audit trail of interaction with the patient, allowing identification of procedures performed on the patient, and the respective assets used during this process. This makes the data model patient centric, so that once a patient has been identified, all information relevant to patient may be retrieved. Medical staff preference cards, electronic count sheets and scheduling information may also be formed from a combination of data from the corporate data repository, asset, instrument and inventory repositories and information created in specific applications, and/or stored in specific local or centralized databases.

DATA COLLECTION

In addition to manual creation of the entries in the repositories, data may also be collected automatically from existing hospital systems. This can include for example, the following systems:

- Purchasing
- Sterilization department processing
- Maintenance
- Accounting
- Asset repository
- Pharmacy
- Theatre list or theatre management systems

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- Billing
- PAS (Patient Administration System)

The collected information will relate not only to surgical instruments but all inventory, from a consumable, fixed asset used or replaced, consignment asset, drug allocations, pathology requests and results, blood types and usages, loan items or impress asset of actions taken by a clinician or healthcare worker enhancing the data set for these other systems. This information can even be expanded to bed or chart locations, remotely accessed by specialists and GPs.

DATA ACCESS

To provide for centralized access to the data by different medical institutions, the data is typically stored in databases hosted by a central server or base station, such as the base station 1 shown in Figure 5. This allows the repositories to be made available to medical institutions via a web based, or another similar portal, using for example, the end stations 3. Alternatively, this can be dynamically presented e.g. to a GP via a connection integrated to the GP practice management solution for viewing and updating the core system with such information as patient related and/or inventory management such as drug usage or referrals requirements or patient historical clinical information. The repositories can be implemented and accessed at any one of a number of different levels, such as:

- GP (general practitioner)
- Hospital
- Area health service or hub
- State or nation level

Thus, for example, a separate base station 1 may be implemented at each of these levels, so effectively separate repositories are provided. In the case, for example, of an area health service or hub, the base station 1 will therefore collect data from each of the medical institutions, such as hospitals, GPs, or the like, and store this centrally. Each medical institution within the area is then able to access the information via an end station 3 provided within (and/or externally to) the institution. As mentioned above, this can be achieved via a patient centric model, so this

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can be performed on the basis of patient details alone.

Thus, for example, if a patient is received within the emergency department of a hospital, the hospital can use the patient's details to access the repositories and determine the patient's medical history. This includes details of previous procedures performed on the patient within the area health service or remote health service presenting as a hub or state level data repositories as in the above, even if these are performed by other medical institutions. Furthermore, this includes details not only of the procedures themselves, but also of the assets involved in the procedure, such as the medical staff, the instruments used, drugs and the like. This allows a rapid check to be made to determine if any of these assets could have had an impact on the patient's current health status.

Accordingly, the corporate data repository, asset repository, inventory and instrument repositories can all be accessed dynamically from suitable system, such as suitable applications software implemented on a processing system, or via other projects, databases or the like. This means that any above described process and/or process management solution can access directly, or from a local source database, information required to manage such processes, as well as to retrieve such data for its own use and/or that of the other systems from the core system. It will be appreciated that the entity administering the repositories may administer the identifiers used in marking instruments, but this is not essential and entirely separate systems may be used. The reference to the base station 1 is therefore for the purpose of example only, and particularly to illustrate a suitable apparatus configuration, and is not therefore intended to be limiting.

SPECIFIC EXAMPLE

A specific example of the manner in which the above described processes may be integrated for the purpose of performing a procedure on a patient will now be described with respect to Figures 18A and 18B.

At step 1500 the doctor defines requirements data for a respective procedure. This will be a one of process that is performed each time the doctor defines a new procedure, and is not performed for each patient is admitted. This information may be stored either in a central

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repository, or locally within a medical institutes own database system, and is typically based on, or formed from any preference cards, procedure data, or the like, that has previously been defined. The requirements data will typically include information such as the items and instruments required to perform the process, and will therefore typically include links back to the asset, inventory, instrument repositories and billing systems. Additional information may also be included, such as:

- an estimated procedure duration;
- theatre requirements;
- medical personnel required for the procedure;
- the actions involved in the procedure;
- items required for the procedure;
- instruments required for the procedure;
- restrictions on patient health status indicators;
- admission procedures; and,
- other relevant information
- Procedure costs

At step 1510, once a patient has been diagnosed, a procedure and a doctor for performing the procedure are selected. This may be done in any manner and will depend on whether the patient has been referred, is admitted as an emergency, or the like.

At step 1520 procedure data is created. As described previously, the procedure data is data corresponding to details of the respective procedure to be performed on the respective patient and is therefore unique to each procedure/patient combination. The procedure data allow a concordance between the patient and details of the procedure performed to be subsequently determined. In simple terms this may be no more than an association between appropriate the patient data described above in Figure 13 and the requirements data for the associated procedure. The patient data may be generated either by accessing a suitable repository, by receiving details from a referrer, or by interviewing the patient, depending on the particular circumstances.

In any event, once this has been created, it is possible to subsequently access the

requirements data and confirm what procedure is to be performed, and what assets are required. This can be used for the purpose of subsequently tracking asset usage, as well as billing, scheduling or the like.

Accordingly, at step 1530 the requirements data is used to access the inventory repository and check whether sufficient inventory is available for performing the procedure. This will also trigger the ordering of replacement inventory, such as disposable instruments, consumables, or other items that are to be used in the procedure. This ensures that minimum stock levels are maintained at all times and increase income via accurate automated billing or items used.

At step 1540, the requirements data is used to schedule a time at which the procedure can be performed. This will involve determining when an appropriate theatre is available, for example based on the scheduling process described above. This may also be based on other information, such as an assessment of the required urgency of the procedure, which may be assessed by other medical personnel, for example, as part of a referral process.

The end station 3 will then monitor the schedule and then use the requirements data to trigger the admission process at step 1550. Thus, the end station 3 will monitor a schedule and at a predetermined time before the procedure is scheduled to be performed, operate to arrange for the patient to undergo the steps of pre-admission, admission and holding, as described in Figure 13 above.

At step 1560 a procedure outline is generated using the procedure data. The procedure outline includes a list of actions that will be performed during the procedure together with the corresponding items used for that action. At step 1570, when the procedure is being performed, the next procedure action is displayed on an end station 3 provided in the corresponding theatre.

At step 1580 as the corresponding actions are performed, any items used will be recorded by having one of the medical personnel enter information utilizing a suitable GUI. Thus in general, the action displayed will include a list of typical items used. In this instance as an item is used by the doctor or other medical personnel an operator can simply select this on the action list for example by touching a suitable touch screen or the like.

It is determined that if the action is completed at step 1590 and if not the process returns

to 1580 to allow any additional items used to be recorded. Once the action is completed at step 1600, it is determined if all used items are accounted for. This is achieved for example by having the medical personnel review the list of items and ensure that each one of the items is either disposed of, still available for use, or used.

If any items are determined to be missing at step 1600 these are investigated at 1610 with the process returning to 1590 if further action is required, for example to recover the item from the patient. Once all used items are accounted for the procedure moves on to step 1620 to update the procedure data.

This will typically be achieved by having one of the medical personnel select an action option on the GUI which indicates the action is completed, which will in turn automatically update the procedure data. This typically involves updating the procedure data with instrument data reflecting the actual instruments used during the procedure, as set above for example at step 650. Thus, an association is created between the patient and the instruments, so the instruments used on the patient can be subsequently determined. In one example, whilst the use of procedure data is described, this could be as simple as creating an association, such as appropriate links between the patient data and the entries for the respective instruments in the instrument repository.

Once completed, the process moves on to step 1630 to determine if the procedure is complete. If not the process moves back to step 1570 allowing the next procedure action to be displayed and this process is then repeated until the procedure is completed at step 1640. It will be appreciated from this that the procedure data for a respective procedure is updated in real time, allowing this to be used in scheduling other procedures at step 1320.

Furthermore, at the end of the process, the procedure data, which as mentioned above may be no more than a mapping between the patient data, core systems and entries in other ones of the repositories, will reflect what the items and specific instruments used in the procedure, allowing the information to be subsequently retrieved based on patient information.

USAGE

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Accordingly, the process provides a physical control system that operates to scan and validate items used in medical institutions. This information, together with details of procedures, item and instrument usage are then stored against patient information allowing the system to provide control management based on the patient information.

This allows a range of different functions to be performed, including those outlined above, and including:

- Purchasing - updating of asset levels
- Sterilization department processing - validation of items for process and patient safety
- Maintenance - allocation of use and maintenance cost - whole of life cost - purchasing requirements - business requirements
- Accounting - business intelligence reporting on billable items, rebateable items, asset usage against costs based upon a patient episode - other KPI and business reporting and modeling
- Asset handling - ensuring the accounting and purchasing and other systems in the facility use and recognize the same base item information across all systems even if the users call or identify the item under a different description.
- Pharmacy - allocation, stock control and usage - combine with patient and procedure giving a total consolidated view of the cost, time and materials against a patient centric view.

In addition to this, patient information can be retrieved from the system and returned to internal systems within the medical institution, for use in, for example:

- Theatre list or theatre management systems,
- Billing - allocation of stock against the patient for billing against a patient episode - increased revenue by accurate management of cost and items used.
- PAS (Patient Administration System) - updating of patient information if more current from other systems.

This service can update, view and pass information about a patient from the data repositories to

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the different levels for enabling these systems.

Such an example would be a GP wants to know what drugs have been used on a patient and therefore can see this or add this info on their own patient system - add the new drugs they prescribe and then update the repository and or keep the information in their own GP system. Or an area health service may wish to use the system for central purchasing solutions, or national cost reporting and/or the same for any level, where the requirement is for a consolidated view from an intelligent system that allows either the storage of or knowledge of where the data is and which core systems require it, to then supply this information as managed to these systems for data processing based on an action of the user to update the repository either with the new data or a reference of what systems hold what data based upon a patient centric data repository module. Thus, this allows for an audit trail to be provided relating to procedures a patient has previously undergone, or is to undergo, together with details of all consumable items and the like used therein. This not only allows this information to be subsequently retrieved and reviewed, but also allows the information to be used in ancillary services, such as billing the patient for the procedures and items used, as well as ordering replacement stock.

FURTHER FEATURES

A number of variations and additional features of the above described process will now be described. The bonding material can be applied to the instrument surface using any one of a number of techniques. This can include for example manually painting the bonding material onto the instrument surface, or manually applying an adhesive dot of material. However, as an alternative a suitable printing system can be integrated into the laser system 70.

In this instance, when the laser system 70 is to be used to expose the bonding material, the end station 3 first controls the laser system 70 to selectively position a print head over the aperture 53. The print head is used to print bonding material onto the instrument surface thereby ensuring that the bonding material is provided aligned with the aperture 53. The laser system 70 can then be moved or otherwise controlled to allow the laser beam to expose the bonding material.

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Similarly, it is possible for the laser system 70 to incorporate a suitable detection system, such as a scanner 80, to allow the barcode provided on the instrument to be detected. This allows the laser system 70 to automatically scan the encoded instruments to allow checking of the clarity of the barcode to be performed. This obviates the need for an operator to manually handle the instruments to perform the scanning and subsequent check of the instruments.

It will be appreciated that in the event that the laser system 70 includes an imaging system to allow detection of the position of the aperture 53, or the bonding material, that this can also be used to provide appropriate scanning of the barcode to allow barcode clarity to be checked. The trays can be identified in the same way as the instruments utilizing an appropriate barcode which encodes a unique identifier corresponding to the tray identifier. This allows trays to be uniquely tracked by scanning the barcode in a manner similar to that described above with respect to the instruments.

The system also allows costing information to be determined. In this instance, a cost can be defined for each of the events performed. The cost can either be predefined, for example, with a set cost for each event, or may alternatively be defined as part of the event data, each time the event is performed. This allows a cost total to be determined for various events, as well as for each instrument. Additionally, the process can be used to monitor stock levels, for example, by tracking the number of instruments in circulation, thereby allowing replacement instruments to be automatically ordered when required. The use of appropriate rules in monitoring the number of events occurring can be used in order consumables used in different events, such as cleaning materials, as well as monitoring maintenance of machines used in cleaning.

As mentioned above, appropriate business rules can be used to restrict the use of instruments, thereby ensuring instruments are only used in procedures falling into appropriate risk categories, as well as to ensure instruments of different risk levels are not used together. The system can also be used to ensure that correct maintenance is performed on instruments, for example, by monitoring the number of times the instrument has been used, and generating an alert if scheduled maintenance is due.

Whilst the above process has been described with respect to an end station 3, it will be

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appreciated that medical institutions, such as hospitals, general practitioners, private clinics, and the like will typically use a number of different end stations 3, depending on the implementation. Typically, this is achieved by having each of the end stations 3 access a central repository which stores the instrument and other event data, typically via a suitable LAN, WAN, or the like. Thus a single database may be provided for all of the instruments used within an organization. Access can be via wired or wireless connections, and it will therefore be appreciated that the end stations may be formed from portable devices which include a suitable scanner 80, thereby allowing instruments to be scanned, and the corresponding instrument data displayed. Interaction with the instrument data can then be performed as required.

By having access to the data restricted in an appropriate manner, this allows any authorized user of the system to access the instrument data. Additionally, the actions that can be performed with both the data and the instruments may be associated with respective authorization levels. Thus a user with only limited access rights may be able to view data but not modify the data in any way. In this case, when the user scans the instrument, an alert can be generated indicating to the device user that they are unauthorized to perform certain actions with the instrument or associated data.

In the above described examples, when instruments and/or trays are provided for use in procedures, it is typically for the instruments and/or tray to be provided in a sterilized package that is only opened upon use in the procedure. In this instance, it is difficult to scan and correctly identify instruments through the packaging. Accordingly, it is typical to include an identifier on the packaging.

The identifier used on the packaging may be similar in nature to the instrument identifier, and in the case of a single instrument being wrapped, could be the same as the identifier of the packaged instrument. However, typically it is far easier to encode information on, and read information from the packaging, due to the inherent different properties of packaging material compared to the instruments. Accordingly, it is typical to use a standard barcode, such as an EAN barcode.

In this instance, the identifier provided on the packaging is uniquely associated with each

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instrument contained therein, with subsequent tracking of the tray and/or the instruments being achieved by tracking the barcode associated with the packaging. Thus, for example, when a tray is received for use in a procedure, the tray packaging is scanned and the barcode determined. The end station 3 can then access the instrument data for each instrument provided in the packaging, allowing the instrument data to be associated with the corresponding procedure data as previously described.

The term instrument is not intended to be limiting and the techniques could be applied to any item used in medical procedures. The terms item and instrument have therefore been used only for clarity purposes, and the processes involved could be applied equally to instruments or items as appropriate.

Additionally, whilst the above described techniques are focused on the treatment of patients in medical environments, such as medical institutions, private clinics, GPs offices, or the like, this can be extended to any environment in which either humans or animals are treated or otherwise provided with services.

METHOD FOR TRACKING AN OBJECT

The subject invention also relates to methods and systems for tracking objects in a validation process. While the description herein discusses an exemplary embodiment relating to tracking medical assets, the systems and methods described herein are not limited to medical type validation processes only, and can be applied to any process in which an inventory of one or more objects requires validation, management and tracking.

The following exemplary method outlines the management of assets and inventory (hereinafter also referred to as objects) through a pre-validated process by the use of unique serialized labels. In particular, an inventory of objects can be managed by associating the objects with unique serialized labels to create a database of the objects. These serialized objects are then scanned at various points during specific events or checkpoints during a validation process and this data is captured and transmitted to the database in order to track the objects. It is noted that the present methods can further be used in the management and tracking of patients, staff, and other entities in an environment such as a hospital setting. For example, the methods can be

used to create and keep track of surgeon preference cards, scheduling and tracking of patient procedures, clinical chart information, and the like.

Figure 19 is a flow chart of a method of tracking an object according to an embodiment of the present invention. In step 1900, a serialized label is provided to a user or facility. For purposes of example only, the method of Figure 19 is described herein in terms of providing a label, however, the serialized label may be an adhesive label having a piggyback or smaller duplicate label having the barcode and/or serial number that can be placed in a patient's chart, or other record. The label may also be a tag or any other known labelling means.

In step 1910, the serialized labels are then associated with one or more objects to be tracked, for example, a reusable asset (e.g. surgical instrument; medical instrument trays, sheets, etc.); a disposable asset (e.g. gauze, syringes, etc.), a patient specific or single use asset (e.g. prosthetic, artificial organ, etc.), or a consumable asset (e.g. food, medication, saline). The association step 1910 may include physically placing the label on the object itself, or on the object's packaging, holder, trolley, or tray on which the object is placed.

The next step of assigning a number of indicia to a label in connection with an object is shown in step 1920. These indicia may include any number of categories of identifying information such as: a patient information (e.g. name, date of birth, weight, etc.), validation process information (e.g. time, pressure, temperature, process parameters etc.), a location information (e.g. geographic location within the process, floor, facility name etc.), a quarantine indicator (e.g. whether an instrument needs to be quarantined through all or a portion of the validation process, etc.), or a user information (the name, identification number, title of the user etc.), or process action commands (e.g. alarm, go forward, or stop process action commands etc.). The indicia can be created by an end user to correspond to relevant portions of a given validation process. In addition, as illustrated by the dashed lines, step 1920 may occur, prior to associating a label with a respective object in step 1910. For example, in one embodiment, the method of the subject invention first assigns one or more indicia relating to the object's validation process in step 1920 prior to the association step 1910. This feature is particularly beneficial because it eliminates the need to reprint individual labels as indicia associated with a particular

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object may change. The indicia may be modified at any time by the user without the need to create and associate a new label.

After the objects are associated with the labels and the indicia have been assigned to the labels in steps 1910-1920, the objects are subjected to the desired validation process as shown in step 1930. In a medical environment, for example, a validation process may include, for example, the sterilization of medical instruments, maintenance of surgical devices, stock transfer of various medicines and other consumable items, inventory, ordering, updating and tracking, consumption of food and/or medicine by patients, or repair procedures for various medical assets etc. Next in step 1940, at one or more checkpoints during the validation process, the objects are scanned. A database is then updated in step 1950 with a status of the object at each of the checkpoints. Over time, a history or log of the database updates are created, as shown in step 1960, thereby tracking the object through the validation process. The history may then be recalled by the user to create reports, audit the process, ship objects between facilities, create invoices etc.

SYSTEM FOR TRACKING AN OBJECT

The system of the present invention performs the method of tracking the one or more objects in conjunction with a web-based application. The system includes one or more means for labeling at least one object. The labeling means, such as a tag or adhesive label may be provided in a roll with a label applicator for efficient association of the label with a large number of objects. The system also includes a scanner, or any other known scanning/reading devices for capturing the serialized information and supplying it to the web-based application. The scanner communicates with the web-based application and can be used during both steps 1920 and 1940 in order to assign various indicia and scan the labeling means during one or more checkpoints during the validation process.

The web-based application may be embedded in a computer readable medium or launched from the internet on a computer. The web-based application enables a user perform a variety of functions without having to rely on paper or handwritten entries. The system of the subject invention also allows users to immediately create reports, and track items transported to and from

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patients. In addition the web based application of the system of the subject invention provides standardization and compliance capabilities throughout a facility, and can be secured through a username and password protected security feature.

The web-based application also enables a user to update a database within the application with a status entry of one or more checkpoints within the validation process based on information received from the scanner indicating a status of the object within the validation process. In so doing, the web-based application enables a user to track one or more objects based on the status entries in the database.

The system of the subject invention may also include a scanner which is optionally associated with a sensor. The sensor may be attached, embedded, or in some other way identified with or connected to the scanner for providing scanner information to the web based application. The sensor may be a radio frequency (e.g. bluetooth, radar, RFID tag), a sonar, or global positioning type sensor device that enables the system of the subject invention to wirelessly locate a scanner and associate the objects being scanned with a number of scanner information. The scanner information, for example, may include information about a specific validation process checkpoint, the geographic location of the scanner, user identification information etc.

In one embodiment, if the scanner passes through a wireless access data zone or entry point, the sensor enables location tracking of the scanner or input device such that the system may then deduct stock, for example, or update stock subject to stock being scanned by the scanner or input device within a known location. Alternatively, if passing through multiple Bluetooth or wireless access data entry points, the system will auto pair the scanning device with such pairing requirement to enable other items to be tracked and associated to such location by simple scanning of an item, person, trolley, medical record into the scanner thus resolving where such item/patient/record is currently located.

The system therefore is capable of resolving where a scanned object associated with the scanner is being scanned and thus provide information as to the status of one or more objects within the validation process. The benefit not only tracks allocation of objects but enables efficient tracking of stock movement, stock level updating, automated reordering. In addition, in

a medical environment, for example, the system of the subject invention enables real time graphical statistical data capture, reporting and displaying (dash boards, graphs and KPI's) capabilities on work flow, staff management, and patient throughput (e.g. satisfaction length of stay benchmarking of clinical pathways).

Figure 20 is a flow chart of one specific embodiment of a system 3000 according to the subject invention. A detailed description of the system 3000 illustrated in Figure 20 is as follows. The system setup 3010 establishes a number of parameters including: security; facility /locations; Kit definitions; bill of materials; inventory; materials management; item serialization protocol; doctor/surgeons preference cards; patient systems interfacing and/or information; and patient and /or clinical chart location. After a purchase order is requested through a central web-based database, a purchase order (PO) is created as shown in element 3012 from a user or facility. The labels are then supplied by a supplier (e.g. Surgidat) as shown in element 3014.

In some embodiments, a validation process is carried out on a grouping of several objects (e.g. a batch load, kit, tray, pack, or container of objects). In accordance with this embodiment, the supplier can update a label serial range against a client facility as shown in element 3016. As shown in element 3018, a plurality of objects are packed using the serialized labels. The packing process can include a number of steps such as: associating and affixing a serialized label to a kit or other suitable container (e.g. pack, tray, etc.) which holds a plurality of objects as shown in element 3020; scanning and entering individual objects (which may be assigned a serial code using the present labelling means or using other permanent serial code labelling means such as, for example, laser printing or the like) into the kit or other suitable container thereby defining the kit/container contents 3022; and scanning the serialised label on the kit/container to thereby associate the kit/container with the kit/container definition (i.e. kit contents).

Using the user-interface of the web-application, the user packs the kit/container on screen. This can be achieved by choosing the appropriate category/row and selecting the plus/add to button to thereby add each scanned object individually. The user can alternatively add/scan multiple items grouped together in a pack or scan all objects (entire kit/container content) of the kit/container to achieve a record of actual items packed. This updates the kit record so as to

reflect the quantity level of objects in the kit/container. If desired, individual objects within a kit/container can further be serialized for additional individual object tracking in addition to tracking the entire kit/container contents.

In some embodiments, objects are packaged in, for example, peel packs, rather than containers/bins. Grouping and tracking of such objects can also be accomplished, for example, as follows: a user can scan/type in the objects/object information from a book (e.g. medical supply book) or the like into the pack so as to create the pack definition (listing/quantity of items contained within the pack), and a label is then applied to the pack as in element 3020. The serialised label of the pack can then be scanned and the pack can proceed to one or more validation processes as described herein.

In accordance with another method for calling up a kit definition is to display onscreen an array of buttons with can be drilled into (i.e., “drilled down”) subject to their object type to refine the search to a level such that the user may choose the specific object to be processed. In addition, the user may scan or type the individual serial number of an item to resolve what it was last packed as or what kit it is uniquely associated with and display the data on screen for the user to then associate the serialized label with. Once these steps have been accomplished, the serialized label to be scanned in step 3022 can then be associated with a specific kit and an accurate bill of materials within the kit can be provided either by virtue of the serialized labelling of individual items or by user packing within the web-application.

It is noted that in embodiments of the above-described methods, labels and count sheets will not necessarily be required or generated by the system. Rather, the label can be supplied to the system externally through a purchase order receipt (see, for example, Serenity workflow Visio diagram – Fig. 19).

Because workflow may change between the components, an additional interface can be added to capture the electronic cycle or process data. For example, a 3M company ETS (electronic cycle parameter testing device) may be interface with the web application of the subject invention which allows the passing of data from the ETS to populate cycle parameters and draw onscreen graph with pass or fail attributes from the ETS being attributed to the load and

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items /against each serialize label of the load Information sourced from 3M.

In accordance with some methods, a user can be supplied with a card scanner for electronically reading via optical character recognition (OCR) the printout/parameters of the sterilizer, machine, validation process cycle parameters. These can be added to a file saved as an image as well as extracted text. A sterilizer process parameters may also be acquired electronically, e.g., over a network and/or the Internet, and added to the database. Using the ePrint capability of the subject invention, the user is able to create a data capture point within the scanned document to extract specific data based upon data position and machine ID as shown in element 3024-3026. This data is then added to the database and displayed onscreen as validated data for a specific validation process for the user to pass or fail, as shown in element 3028. This can further be enhanced by setting pass or fail parameters within the system to auto fail if outside these parameters. The user may scan the machine printout and then browse and save against the load as a picture. Alternatively, the user may also interface directly with the machine interface by electronic connection attributing this information as above to the serialized label / load/ and cycle parameters.

The distribution and release of objects can also be automated by the system of the subject invention, as shown for example in element 3028. For example, in order to distribute and release a product which has passed the validation process, the following occurs: Items may be distributed by scanning any serialised label to resolve the batch and then the user may subsequently elect to distribute the complete batch or an individual pack/object. The system, however, will not allow any item with a status of quarantine or fail to be distributed and will warn the operator or user of such quarantine/fail status. Any item that does not pass this point will not be allowed to be processed by any other part of the system moving forward including stock transfer and/or allocation to patient or case or other action. Packs may have an associated auto distribute to location, which upon a batch being distributed, the item will be automatically added to such a location as stock. Items may then be released for any one of the following purposes: stock transfer between one or more locations/customers/other entity; allocation to a case cart, trolley or surgeons preference card; or allocation to patient.

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If an item is allocated to a patient, the system and method of the subject invention enables automation of scanning a patient wrist band or look up or pre-populated list for location to resolve various parameters such as patient procedures, cases, surgeon data etc. Alternatively, the patient information and case details can be entered manually/or interfaced with a hospital information system and displayed on a human hardware interface.

In accordance with another embodiment - which may, for example, be used for multiple item types, interfaced with multiple systems for data capture, and updated based upon workflow and data capture - a scanner having an embedded sensor as described above may be used to resolve whether an item should be associated with a specific patient.

In accordance with further embodiments, the methods allow for creation and counting into and out of cases as well as closing cases. In order to count into a case, the case is displayed on the user interface of the web application and objects and packs allocated to the case can be viewed at the object content level. Objects may also be grouped within packs for ease of counting on screen (or using electronic pen/pad or other data capture device), for example, by grouping into item type (e.g. forcep / scissor/drill etc.) In order to count out of a case, the same method is used as that used to count into a case. One advantage of this system is that actions performed by any user will require such user to log in to the system, thereby creating an audit log of users actions making the user accountable for actions applied. This provides statistical graphical/reporting on user production by time and uses weighting values applied against each item type subject to such items as difficulty to reprocess. In addition, a case may be closed by time/case closed, which may be derived by interfacing into the clinical system for the time the case was closed (or other such time as may be deemed appropriate for the workflow requirement) as entered or by entering/touching the screen or other such input device to validate the case closed time/action. If there are any discrepancies between objects packed and/or items counted into the case and/or items counted out of the case, a warning and automated email can be displayed and sent to alert user(s) of missing unaccounted for items.

The system of the present invention enables automatic indication of unused items that need to be return to stock; updating of surgeon preference cards; return of used stock to SPD. These

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features can be implemented by scanning/typing any individual serialised item to resolve the serial label and then disassembling the items of that pack back into stock as items thus, validating individual instruments return, resolving individually scanning tracked items back to serial label; and locking a serialized label record.

Another added benefit of the system of the subject invention is the ability to recall any and/or all, item(s) used on a patient (within a case/procedure) and subsequently by date range, retrospectively recall any patient case /procedure method that these items where used on within this search criteria throughout the item lifecycle.

As noted above, the labeling means is not limited to a label, and can be a tag, an adhesive label, a piggyback label having a duplicate serial indicator for placing in an alternate paper record or any other known labeling means in the art. Figures 21A and 21B show two exemplary embodiments of labeling means according to the subject invention.

Figure 21A illustrates a unique pre-printed label 2130 according to the present invention. Typically, the label contains a barcode 2110 or a unique serial number 2120, but may also include both as shown. In one embodiment, labels 2130 for more than one object may share the same barcode 2110, which may be one or two dimensional, however, each label 2130 has a unique serial number 2120. One benefit of this unique serial number 2120 is that a central database may track it without ambiguity. This can be important, for example, when the central database tracks several objects such medical assets that share the same identifying barcode. If the central database tracks such assets from several health care facilities, the unique serial number 2120 can associate each instrument with a specific facility.

Consider one embodiment of the invention where a central database is maintained that several health care facilities use to manage their respective assets. Each facility will acquire, typically by purchase order, a quantity of labels that bear barcodes and unique serial numbers. Thus, labels that facility "A" acquires will include one or barcodes (typically one barcode per label) and each label will have a unique serial number. Facility "B" may acquire labels with same and/or different barcodes, but the serial numbers on these labels will be different from those on the labels acquired by facility "A" or any other facility. In this embodiment, the central database

associates the first group of serial numbers with facility "A" and the second group of serial numbers with facility "B." Personnel at each facility can then access the central database to load in and obtain additional information about their respective instruments or products, as described herein. The unique serial numbers ensure that even if assets at facility "A" and facility "B" share the same barcode there is no chance that information regarding one facility's asset is inadvertently associated with another facility's asset that has the same barcode. In another embodiment, the unique serial label need not be printed label made from paper or some other material. The unique serial label may be a RFID device that includes information regarding the identity of the assets or group of assets on a tray as well as a unique serial number or other unique code to ensure traceability as described above. In other embodiments, devices that are readable using an ultrasonic signal or readable using a laser, may be used in conjunction with, or as an alternative to, printed labels and/or RFID devices. In some embodiments the devices may receive information from a Global Positioning System ("GPS") and provide their geographic location when read. This information may be included in the central database as well.

Figure 21B illustrates an exemplary tag 2100 for labeling an object according to the subject invention. This tag 2100 is made of a material that will be suitable for the environment of the validation process in which it is used in and or it is intended to be used in. For example the tag 2100 may be manufactured to withstand low temperature, high temperatures, wet or high humidity, dry heat or steam, or chemical or Ozone, hydrogen peroxide gas plasma, or per acetic acid immersion, or ozone environments, depending on the nature of a sterilization process. The tag 2100 also includes a barcode 2110 and/or a serial number (not shown) as similarly discussed with respect to the label 2130.

The labelling means of the present invention may also be made to incorporate various forms of information relevant to a user and a process. For example, as shown in Figures 21A and 21B, a space can be provided on the label where one could write Month/day/year or have a date label gun (or other date identification method) add the date either to or associated with a tag. A date gun may also be incorporated that would work with the label of the subject invention or, a date label or date identifier can be added to the tag.

OPERATION OF THE PROCESS INDICATOR

A process indicator may also be added by way of printing on, or attaching an indicator device to a tag/labeling means of the subject invention. The purpose of the process indicator is to capture and/or show a user whether, for example, an object has been through all or a portion of a validation process, or been exposed to a chemical or environmental condition (e.g. temperature pressure). A process indicator may or may not be part of the labeling means described above, and may simply stand alone as an individual component to be associated by use of bar-coding or other identification as described herein. The process indicator may also serve as one of the indicia associated with a label or tag in step 1920.

Once the tag is placed through or around or affixed or associated to by way of manual or electronic or other reporting or information capture of an item, (e.g. medical asset), the tag may be scanned and attached to an asset, directly or indirectly.

Two exemplary embodiments of process indicators according to the subject invention are illustrated in Figures 22A and 22B. In Figure 22A, a chemical indicator painted on a tag, for example is described. For example, a chemically treated portion of the tag may change to three different shades (or other suitable number of shades) as illustrated by elements 2210, 2220 and 2230. The chemically treated portion of the tag changes color light to medium to dark for example should the tagged object be exposed to a certain temperature after 30 days, 178 days or 356 days. This change alerts the user to the temperature exposure and signals the user as to a status in the validation process.

Figure 22B illustrates another embodiment of a process indicator which may be placed on a labeling means according to the present invention. For example, a grey or invisible indicator may change to red (or other suitable color) and become visible after exposure to ultra violet light (or other specified condition), and/or may deepen in hue after removal of a protective layer or exposure for, e.g. 30, 178 or 365 days. Once the indicator becomes visible, a user would be alerted by the now colored portion or changed hue of the tag not to use a device and return it to maintenance.

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Process indicators described herein may be incorporated or embedded in the access bar code of individual items or trays (or identifier of an asset or group or bill of materials). This helps to prevent other companies from utilizing the tag.

The subject invention has the added benefit of reflecting data capture of a group of assets or bill of materials such as manufacturer; model; serial number; lot number. It further enables a user to select repair templates, set descriptions date, sent out method of shipment, tracking number or on-site status, date and time of select repair templates, etc.

In addition the subject invention adds value to quoting needs by tracking: quote received date and time; quote approved date; received from vendor information; vendor quote number; vendor work order number; vendor invoice number; repair description; and warranty period. It also gives a user the ability to apply information to arrive at fee per procedure, such as life of repair, warranty flags, and lifetime warranty if model and serial number are loaded. In addition, the subject invention enables a user to preset price or price templates; receive notification if price exceeds a given price; associate instrument to a department, tray or kit; and allows for multiple users to access system by department or administrative view. It further enhances the ability to enter pricing for repair or replacement, from multiple vendors and quickly compare price, turn around time, warranty time period, and repair descriptions.

The subject invention also has added efficiencies for a user to create a work order; monitor budgets per department, facility or IDN; compare turn around time, up time, down time, longevity and price of manufacturers, models, and repair vendors; create standard or specialized repair request forms and sign off forms whereby a vendor states completion of work; note reason for repair and note exclusions to contract pricing.

Although the subject invention has been described with respect to preferred embodiments, those skilled in the art will readily appreciate that changes or modifications thereto may be made without departing from the spirit or scope of the subject invention as defined by the appended claims.

INCORPORATION BY REFERENCE

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The entire contents of all patents, published patent applications and other references cited herein are hereby expressly incorporated herein in their entireties by reference.

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What is claimed is:

1. A method for tracking objects in a validation process comprising the steps of:
 - a) providing at least one means for labeling at least one object, said means for labeling having a serialized indicator;
 - b) associating the at least one means for labeling with at least one object;
 - c) assigning at least one indicia to the at least one means for labeling, after the at least one means for labeling has been serialized or after the at least one means for labeling has been associated with the at least one object;
 - d) scanning the at least one means for labeling during at least one checkpoint during the validation process;
 - e) updating a database with a status of the at least one checkpoint; and
 - f) tracking the at least one object based on updates of the database.
2. The method of claim 1, wherein step a) further comprises providing at least one pre-printed serial indicator having at least a barcode and/or a reference number on the at least one means for labeling.
3. The method of claim 1, wherein said means for labeling comprises one or more tags, adhesive labels, or combinations thereof.
4. The method of claim 1, further comprising the step of:
 - g) creating a history of database updates in order to recall a record of the status over time of the at least one object.
5. The method of claim 1 further comprising the step of :
 - h) managing the validation process at the at least one check point using a go forward or stop process action.

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6. A web-based system for tracking objects in a validation process comprising:
 - at least means for labeling at least one object having serialized indicators provided thereon;
 - a scanner for scanning said at least one means for labeling during at least one checkpoint during a validation process and providing information to a web-based application, the web based application being adapted and configured to enable a user to:
 - assign at least one indicia to at least one means for labeling after said at least one tag has been serialized or after the at least one means for labeling has been associated with the at least one object;
 - update a database with a status entry of said at least one checkpoint of said validation process based on information received from said scanner;
 - track the at least one object based on the status entries in said database.
7. The system of claim 6, wherein the scanner further comprises a sensor associated with the scanner for providing scanner information to the web based application.
8. The system of claim 7, wherein the scanner information includes at least one of a validation process checkpoint, scanner location and user identification information.
9. The system of claim 7, wherein the sensor is one of a radio frequency, sonar, or global positioning type sensor.
10. The system of claim 6, wherein the validation process is one of a sterilization, maintenance, stock transfer, inventory tracking, consumption, or repair procedure.
11. The system of claim 6, wherein the at least one object is an asset.
12. The system of claim 6, wherein the means for labeling is an adhesive label.

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13. The system of claim 6, wherein the means for labeling further includes at least one of an electronic, biological, environmental process indicator or any combination thereof.

14. The system of claim 6, wherein the serialized indicators includes one of a barcode, a reference number or any combination thereof.

15. The system of claim 6, wherein the at least one indicia is one of a patient information, a validation process information, a location information, a quarantine indicator, or a user information.

16. The system of claim 6, wherein the means for labeling is pre-allocated to the user or delivery point and validated as unique to that user locations for allocation and association to an object.

17. A web-based system for tracking a plurality of medical assets in a validation process comprising:

at least one means for labeling a plurality of medical assets, the means for labeling having serial indicators printed thereon;

a scanner for scanning the at least one means for labeling during at least one checkpoint during the validation process and providing information to a web-based application,

wherein the web based application is adapted and configured to enable a user to:

assign at least one indicia to the at least one means for labeling for each of the plurality of medical assets, after the at least one means for labeling has been distributed to a user, the at least one indicia comprising at least one of: a patient information, a validation process information, a location information, a quarantine indicator, and a user information;

update a database with a status entry of the at least one checkpoint of the validation process based on information received from said scanner;

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track each of the plurality of medical assets based on status entries in said database;

and;

create a history of the database updates in order to recall a record of the status entries over time of each of the plurality of medical assets.

18. The system of claim 17, wherein said means for labeling comprises one or more tags, adhesive labels or combinations thereof.

19. The system of claim 17, wherein the web based application is further adapted and configured to manage the validation process at the at least one check point using a go forward or stop process action.

20. The system of claim 17, wherein the web based application is further adapted and configured to group, track and manage a batch of medical assets.

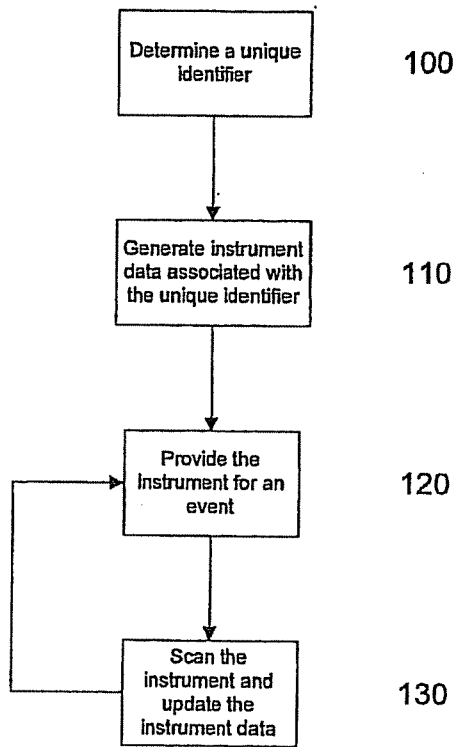


Fig. 1

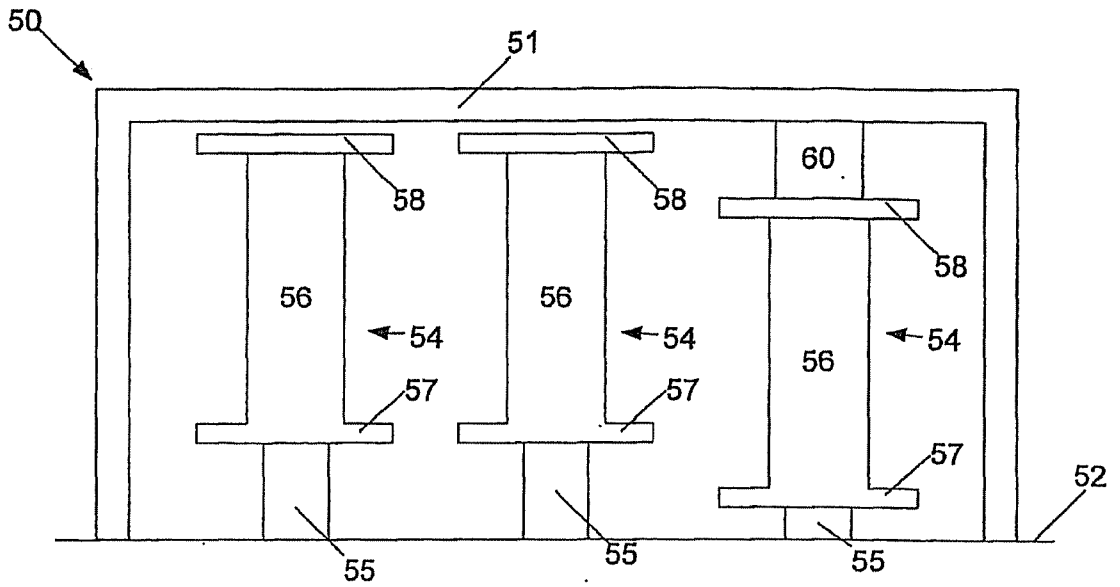


Fig. 2A

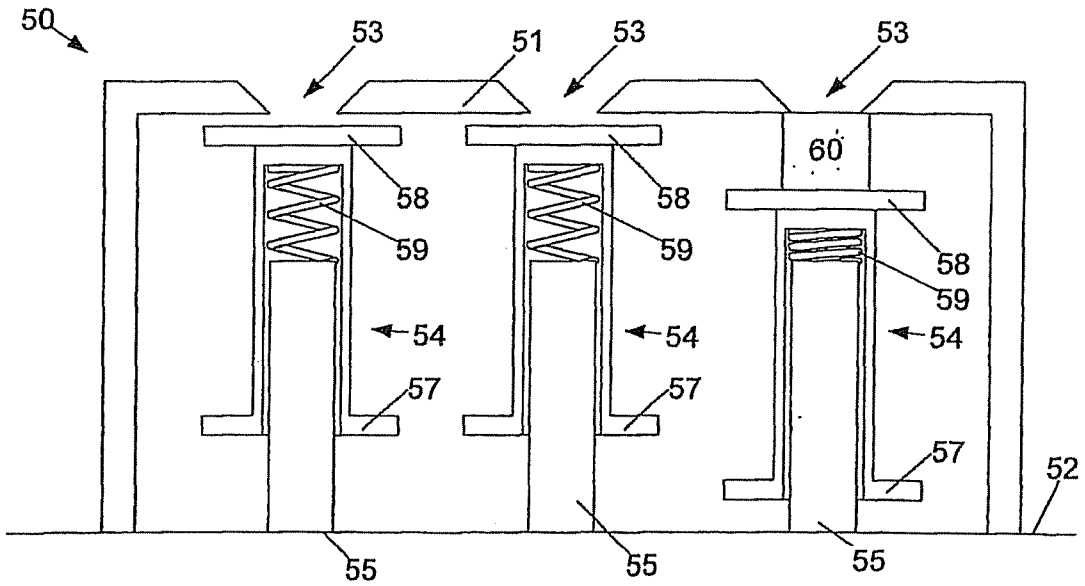


Fig. 2B

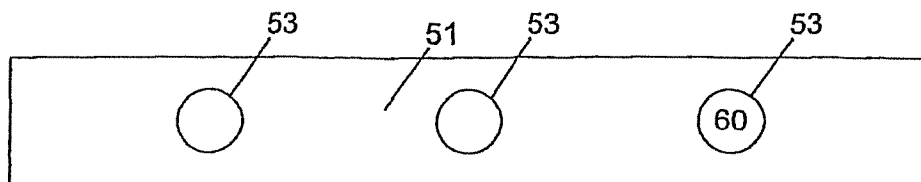


Fig. 2C

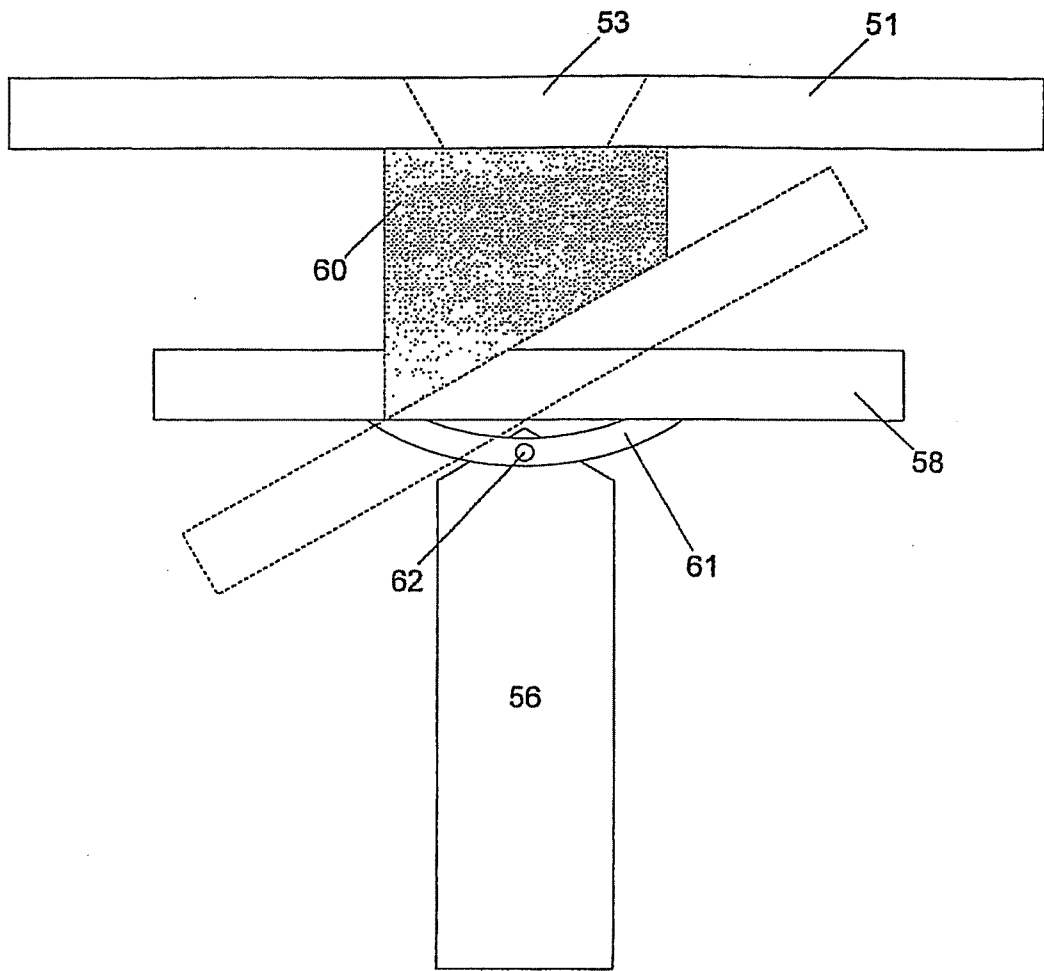


Fig. 2D

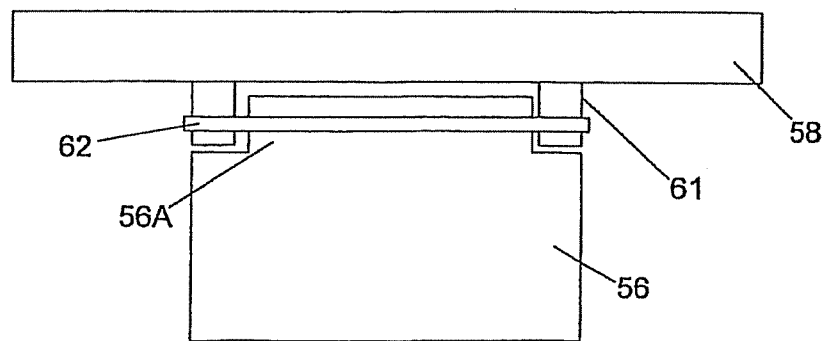


Fig. 2E

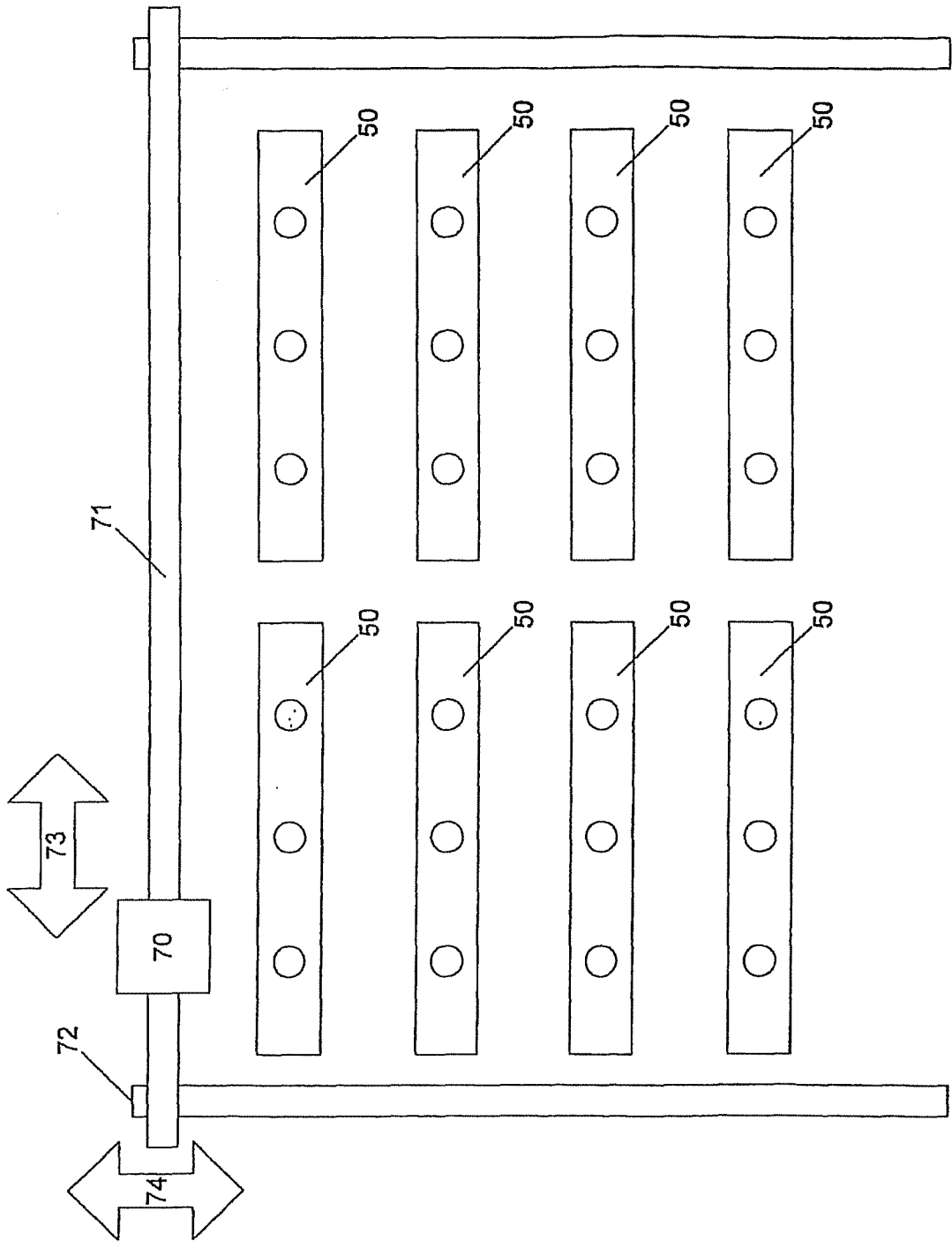


Fig. 3

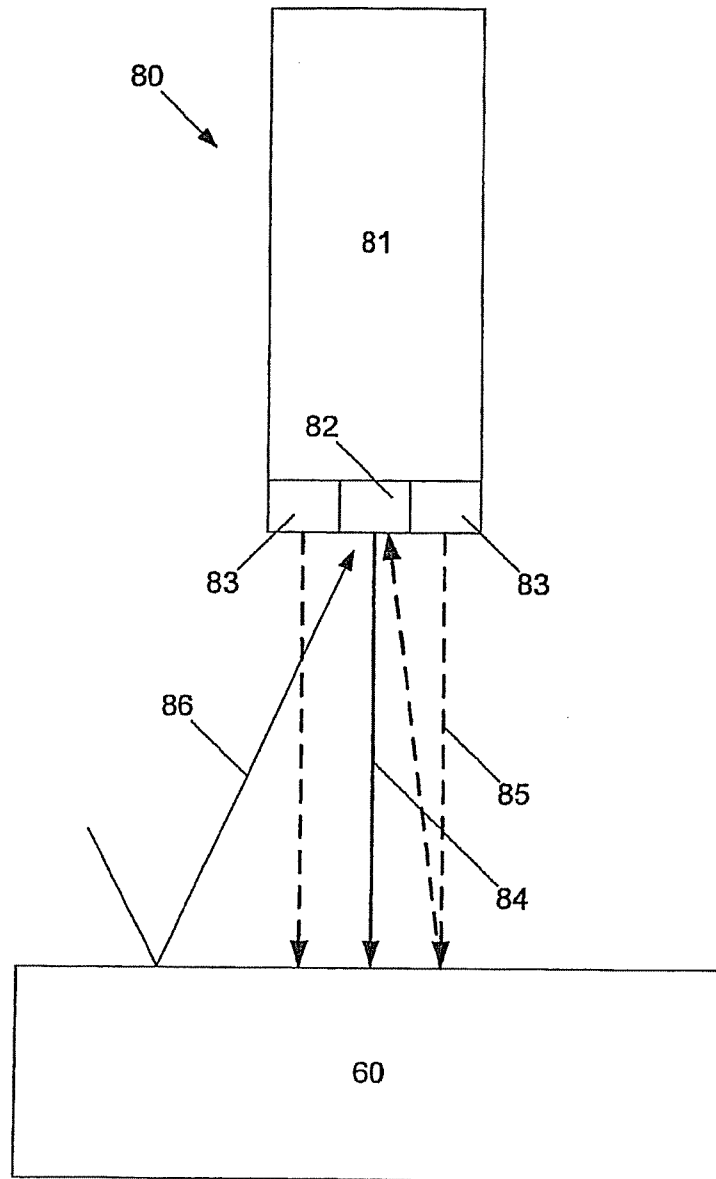


Fig.4A

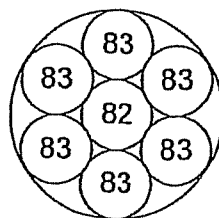


Fig. 4B

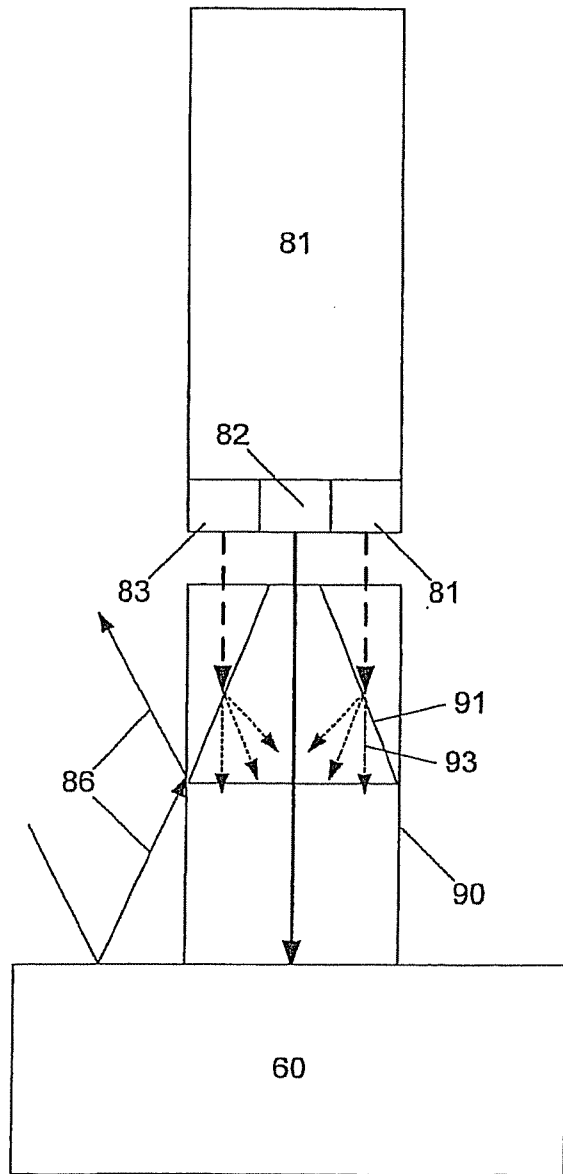


Fig. 4C

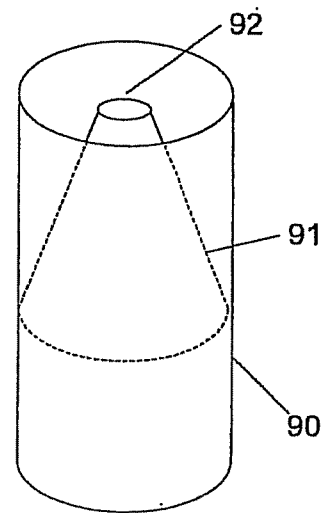


Fig. 4D

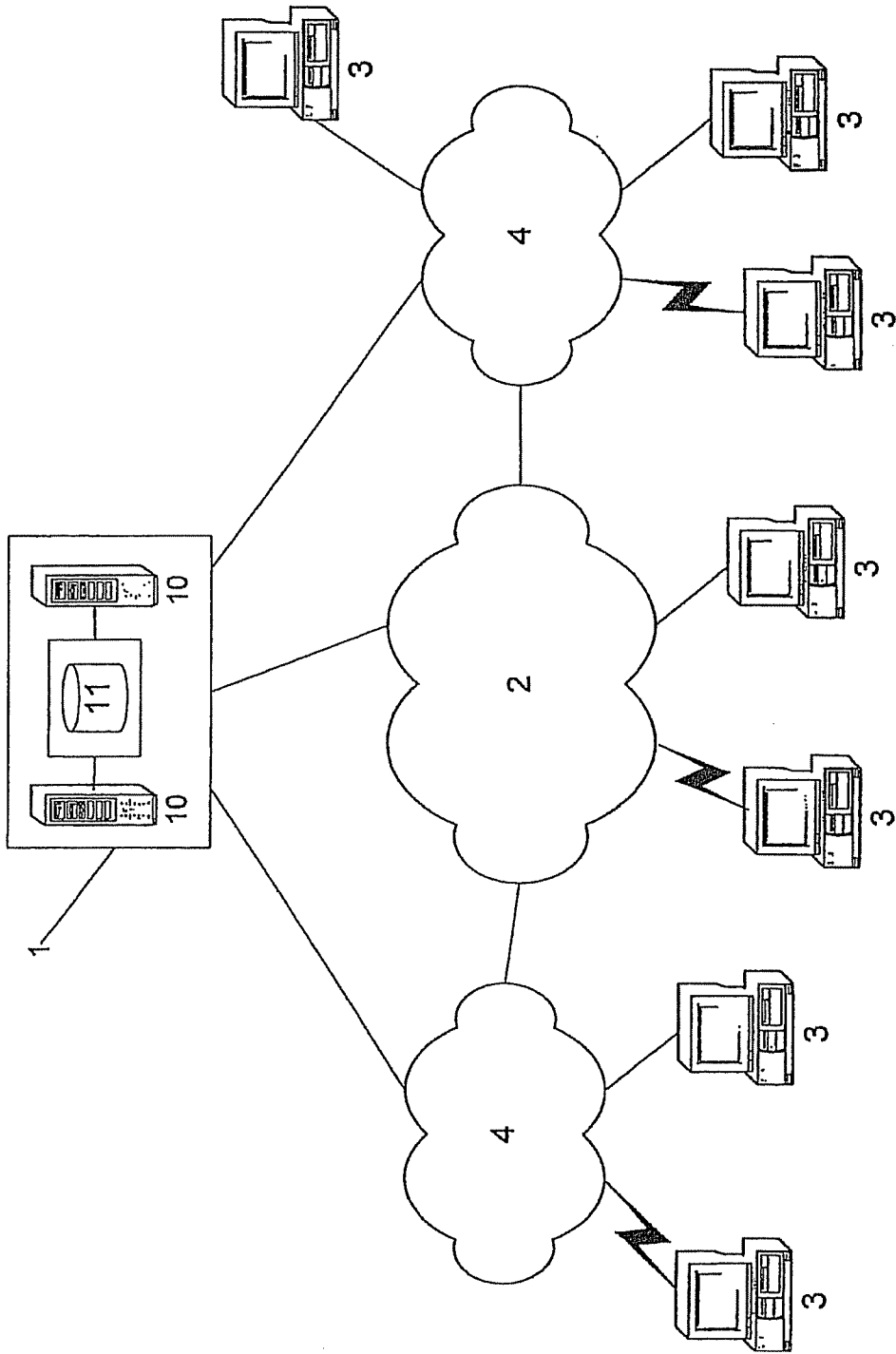
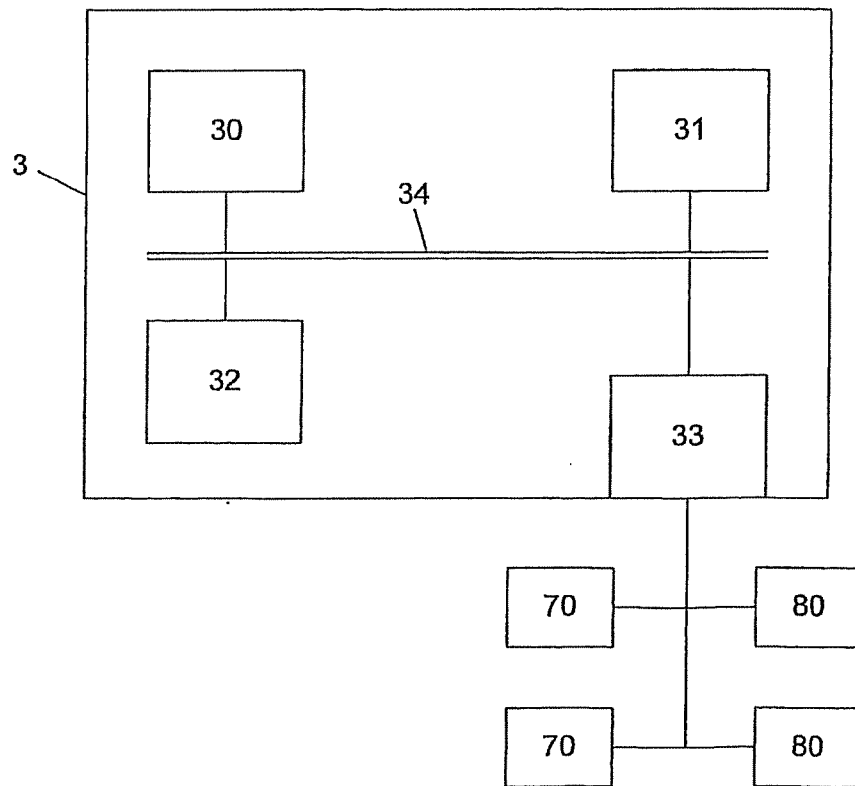
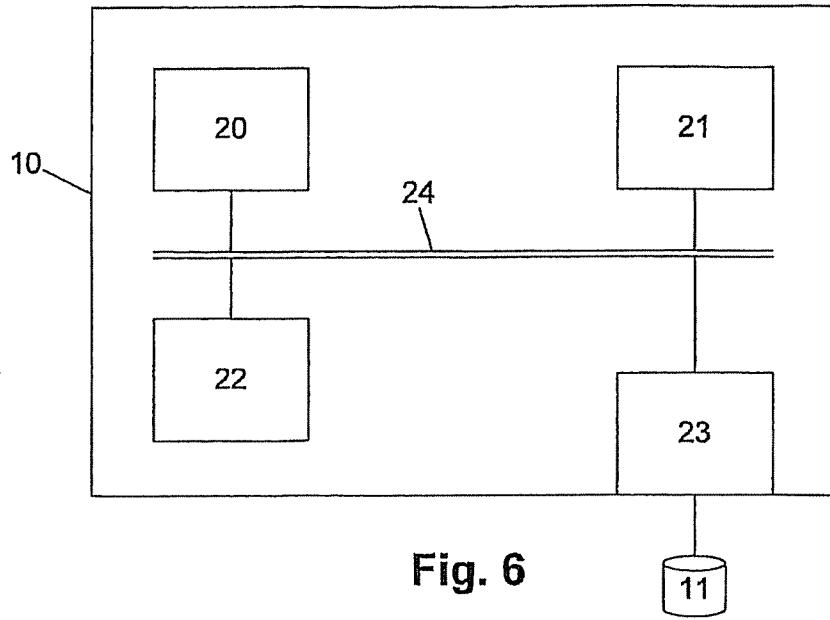


Fig. 5



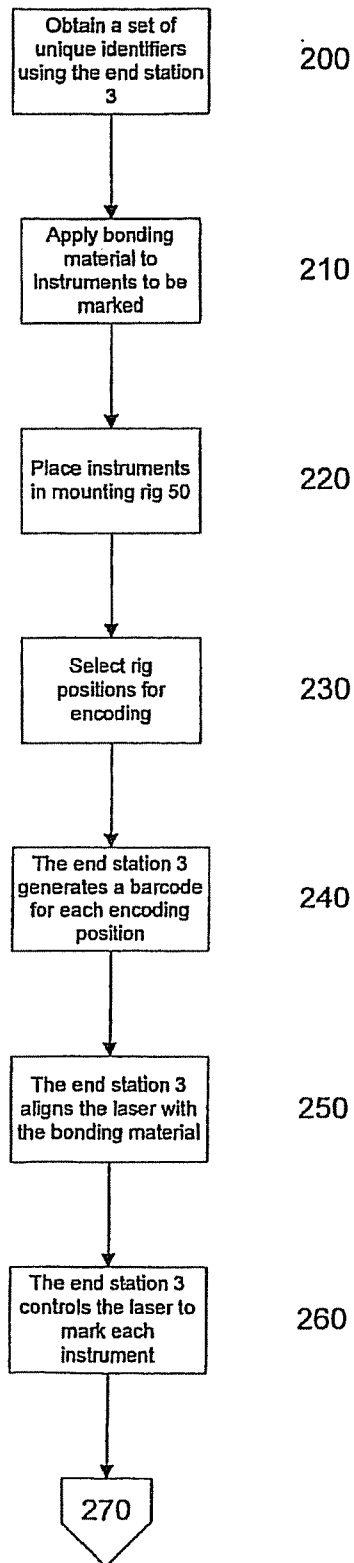


Fig. 8A

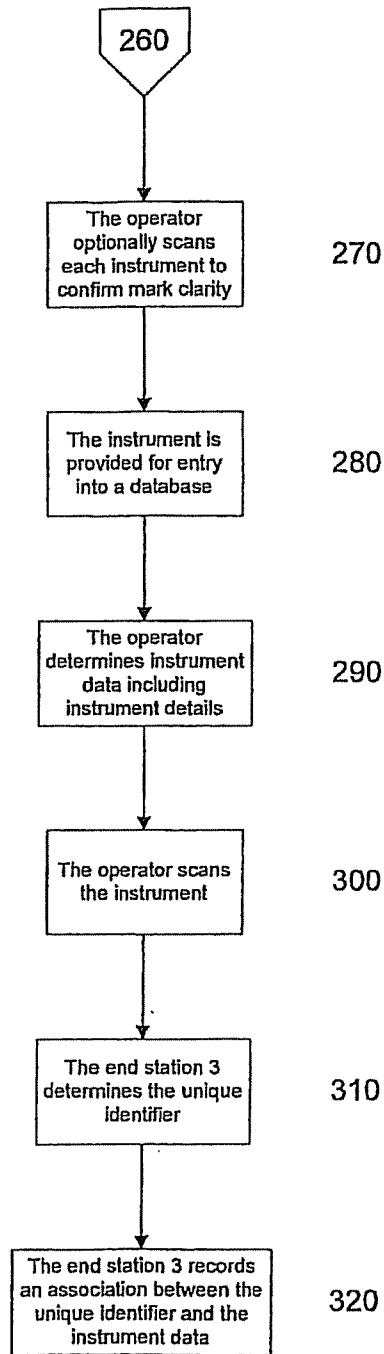


Fig. 8B

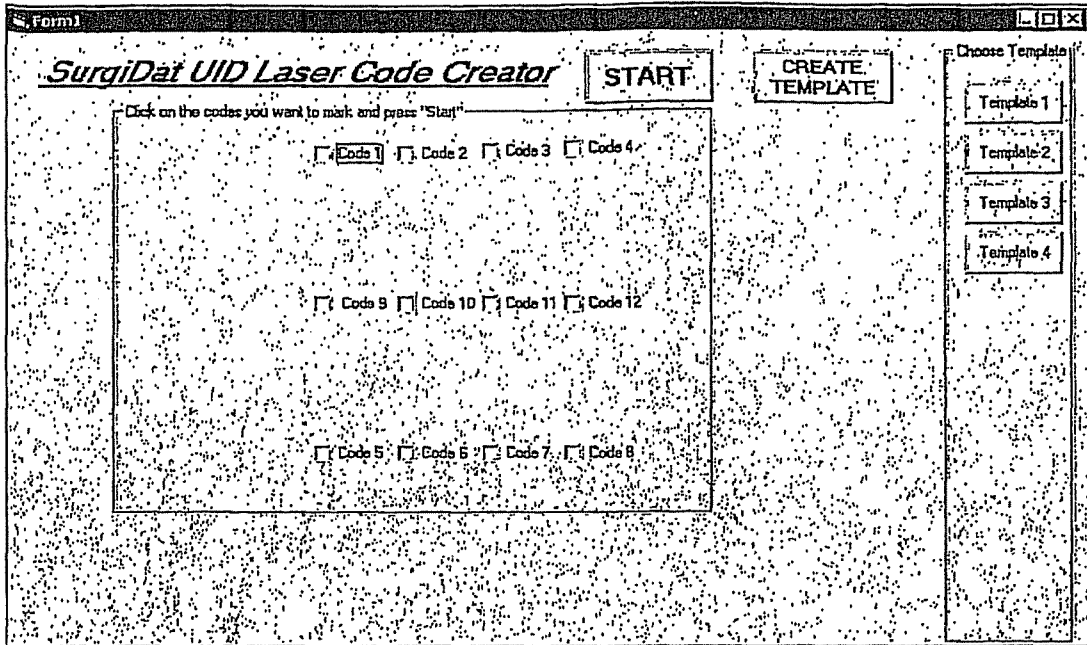


Fig. 9A

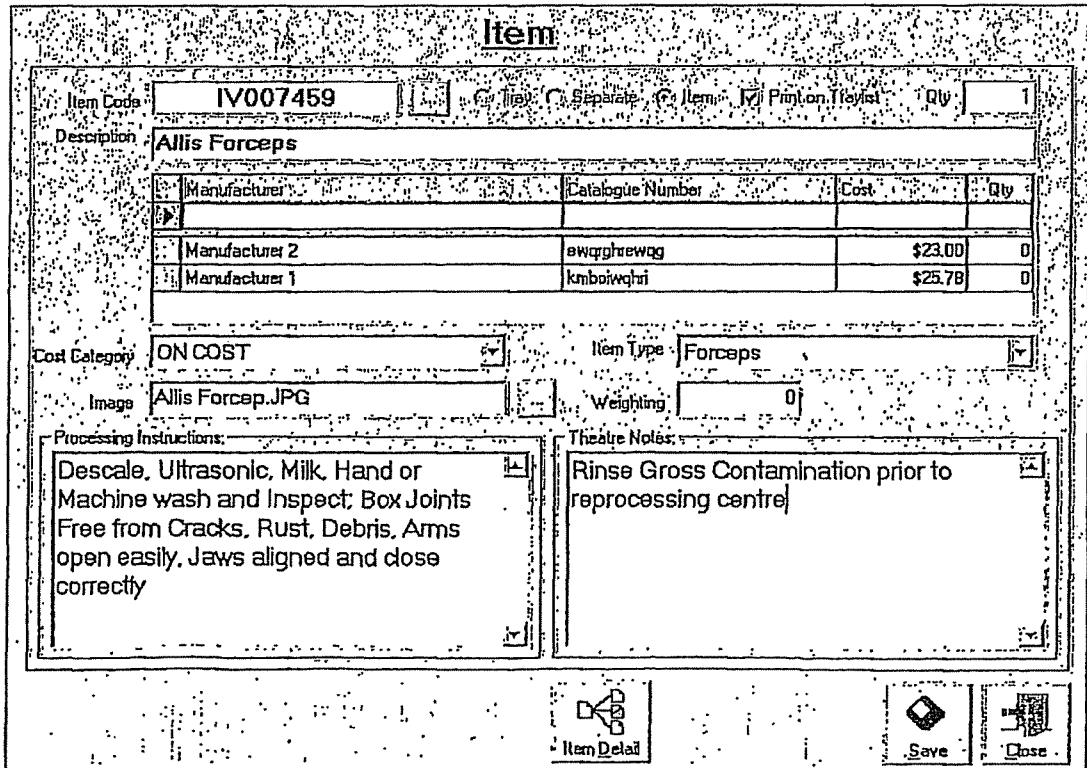


Fig. 9B

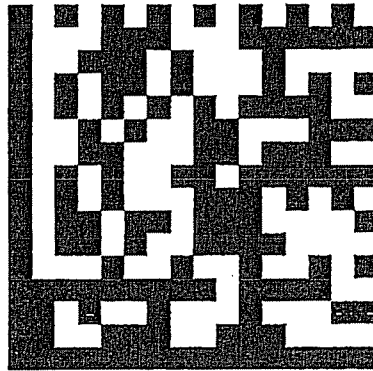


Fig. 9C

1002

Tray ID: 000017-2 Tag ID: 000017-2

Find Track Items Remove Item

General Tray

Item Code	Description	Qty
IV007449	SMALL NEEDLE HOLDER	1
000198	Pppp	1
IV001327	STRAIGHT BLACKS	2
IV004896	ARTERY CLIPS	5
IV004908	BONE CUTTERS	1
000200	Rm	5
IV001349	DIATHERMY FORCEPS	1
IV004913	NO. 3 B.P. HANDLE	1
IV004912	NO. 4 B.P. HANDLES	1
IV007444	SUTURE SCISSORS	1
IV004901	TODTHED ADSON FORCEPS	1
IV007452	TODTHED GILLES FORCEPS	1

Next

1000

1001

CSSD notes Theatre notes Item Images Tray Images Manufacturer Barcodes List Close

Fig. 11

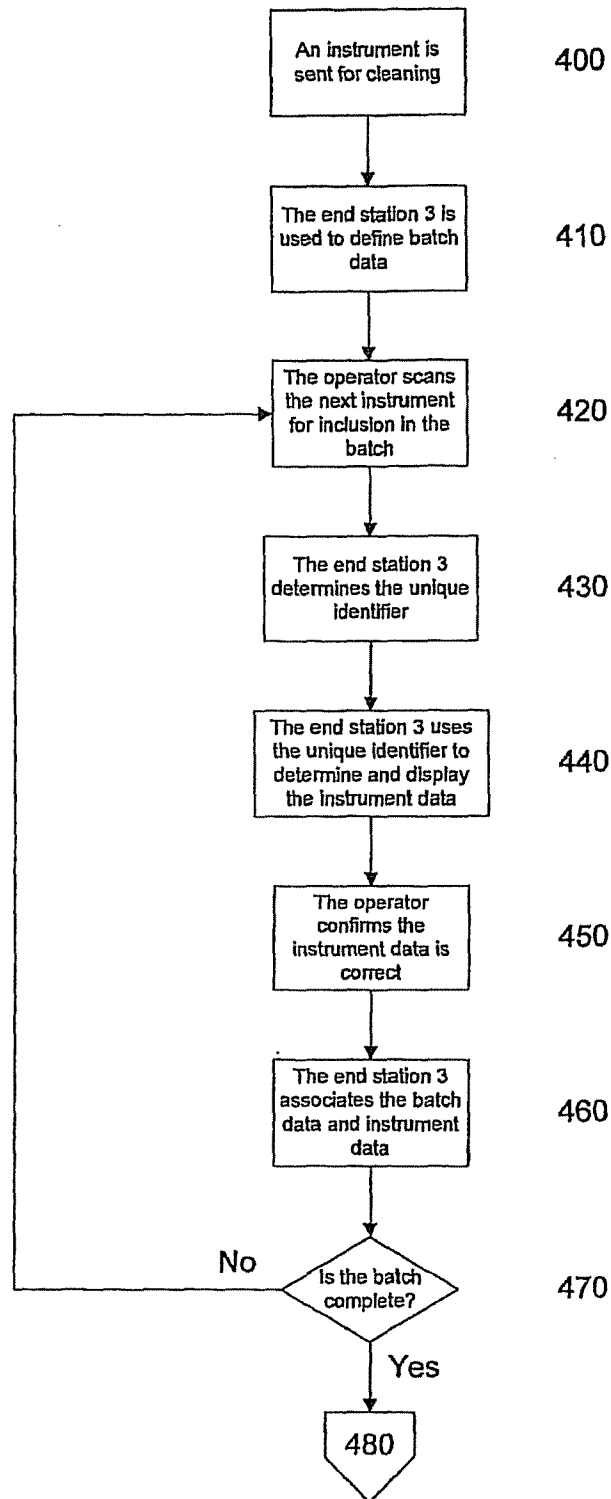


Fig. 10A

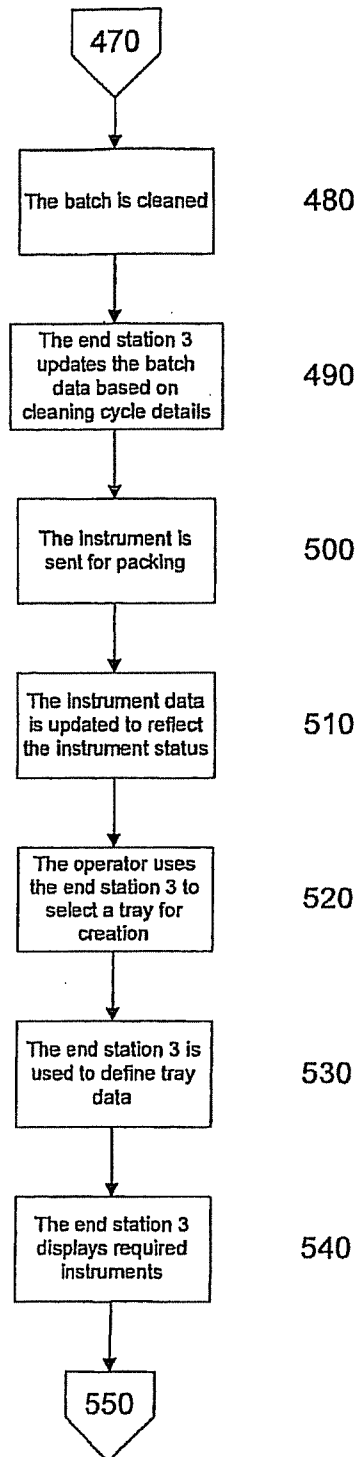


Fig. 10B

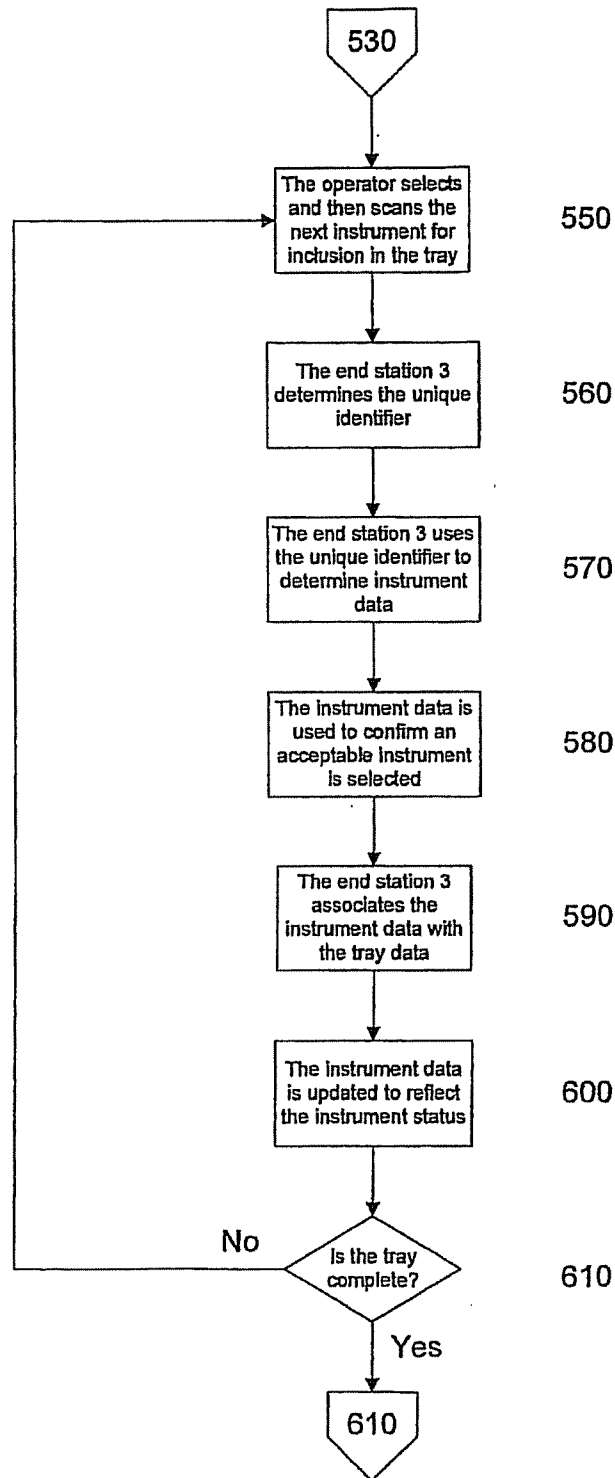


Fig. 10C

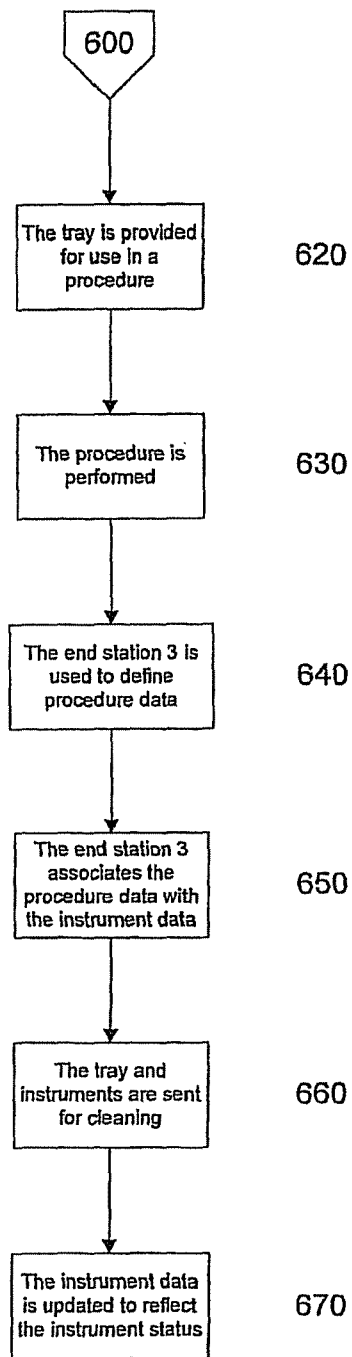


Fig. 10D

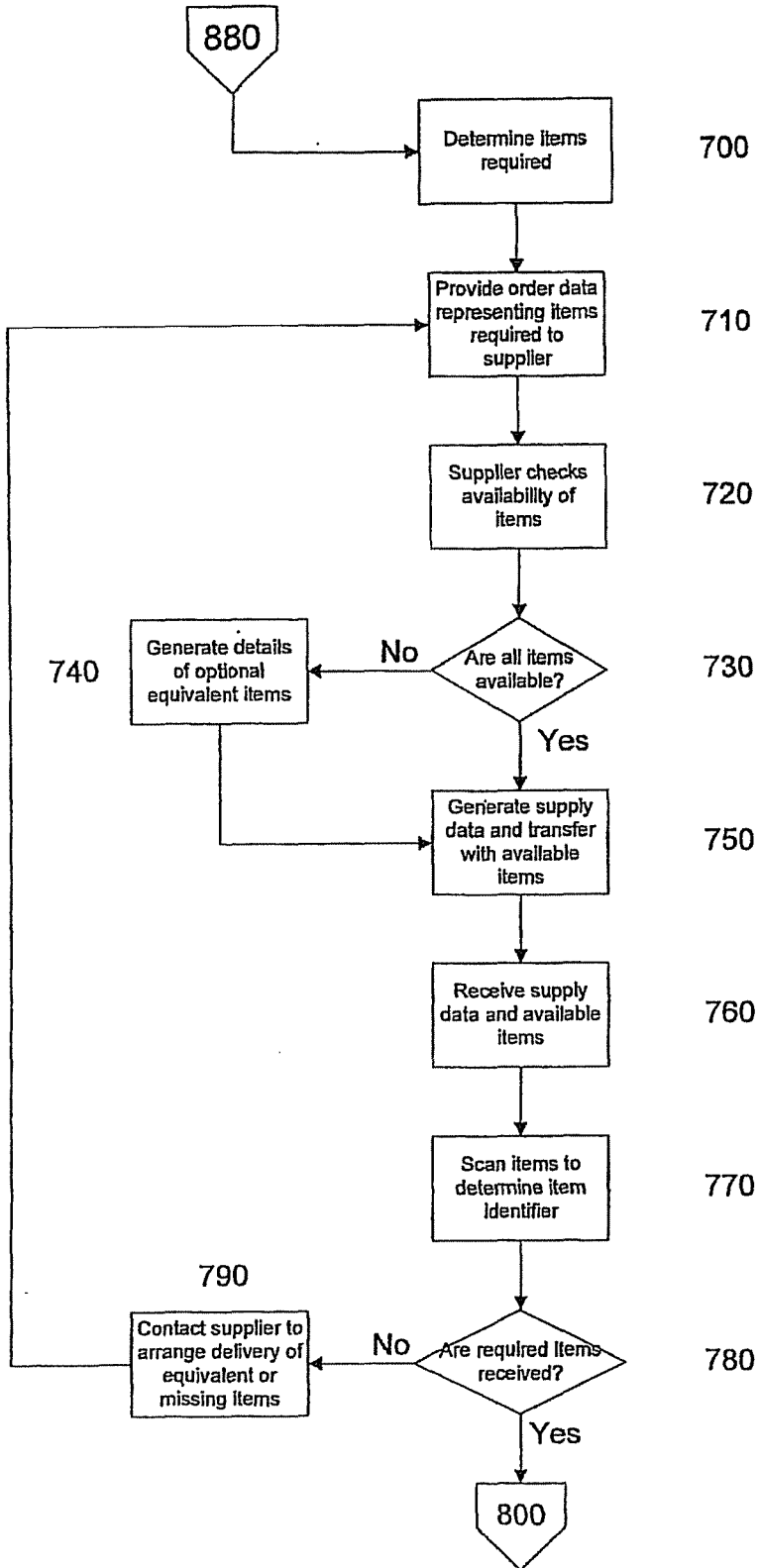


Fig. 12A

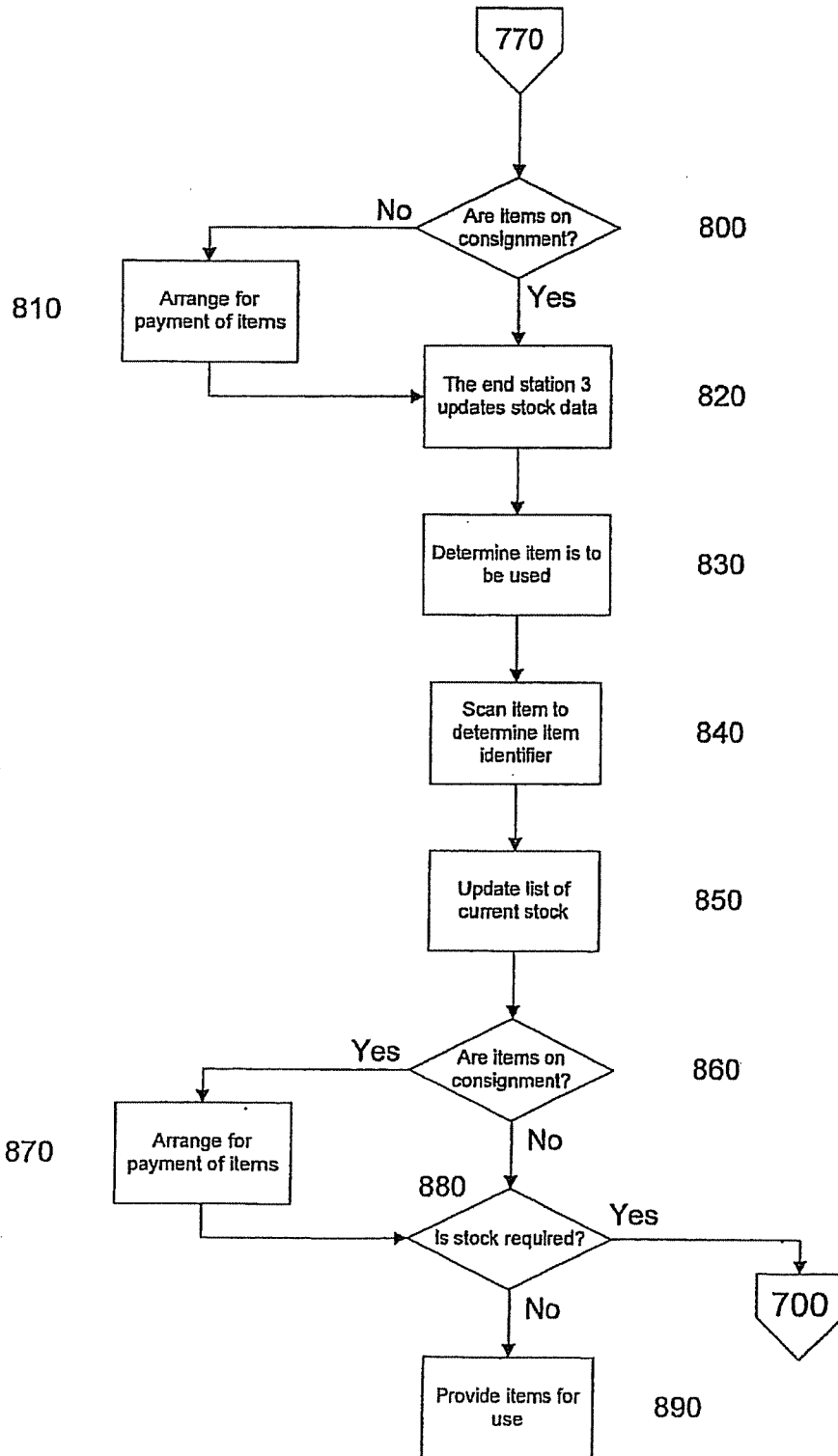


Fig. 12B

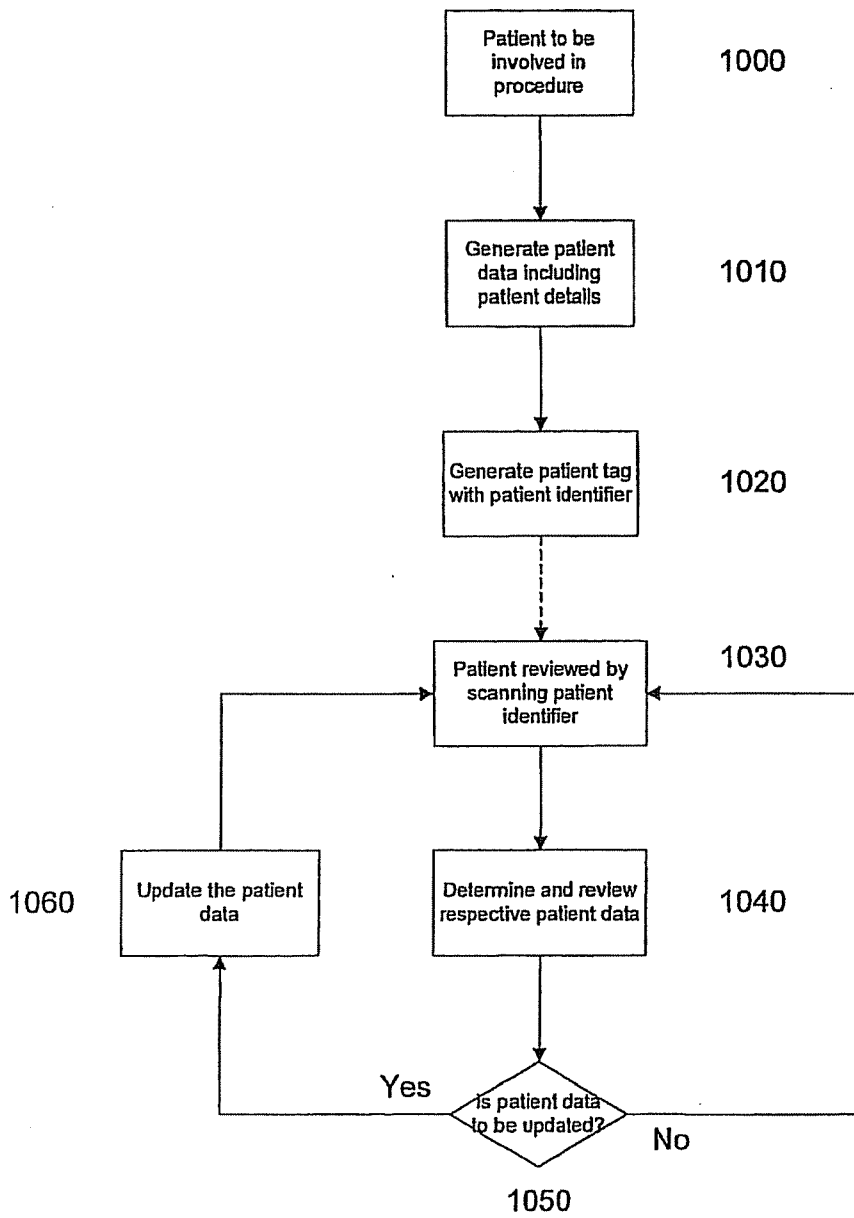


Fig. 13

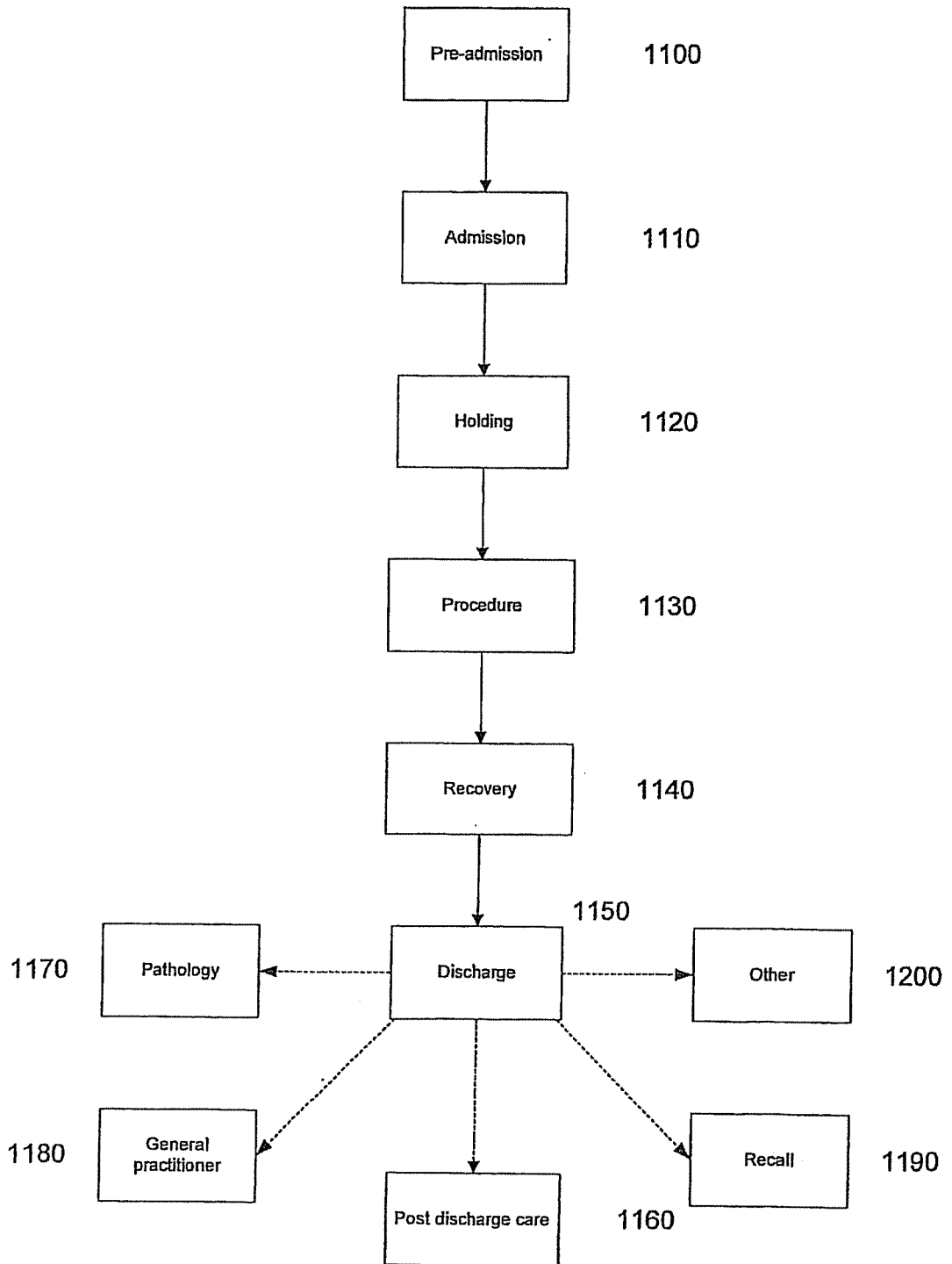


Fig. 14

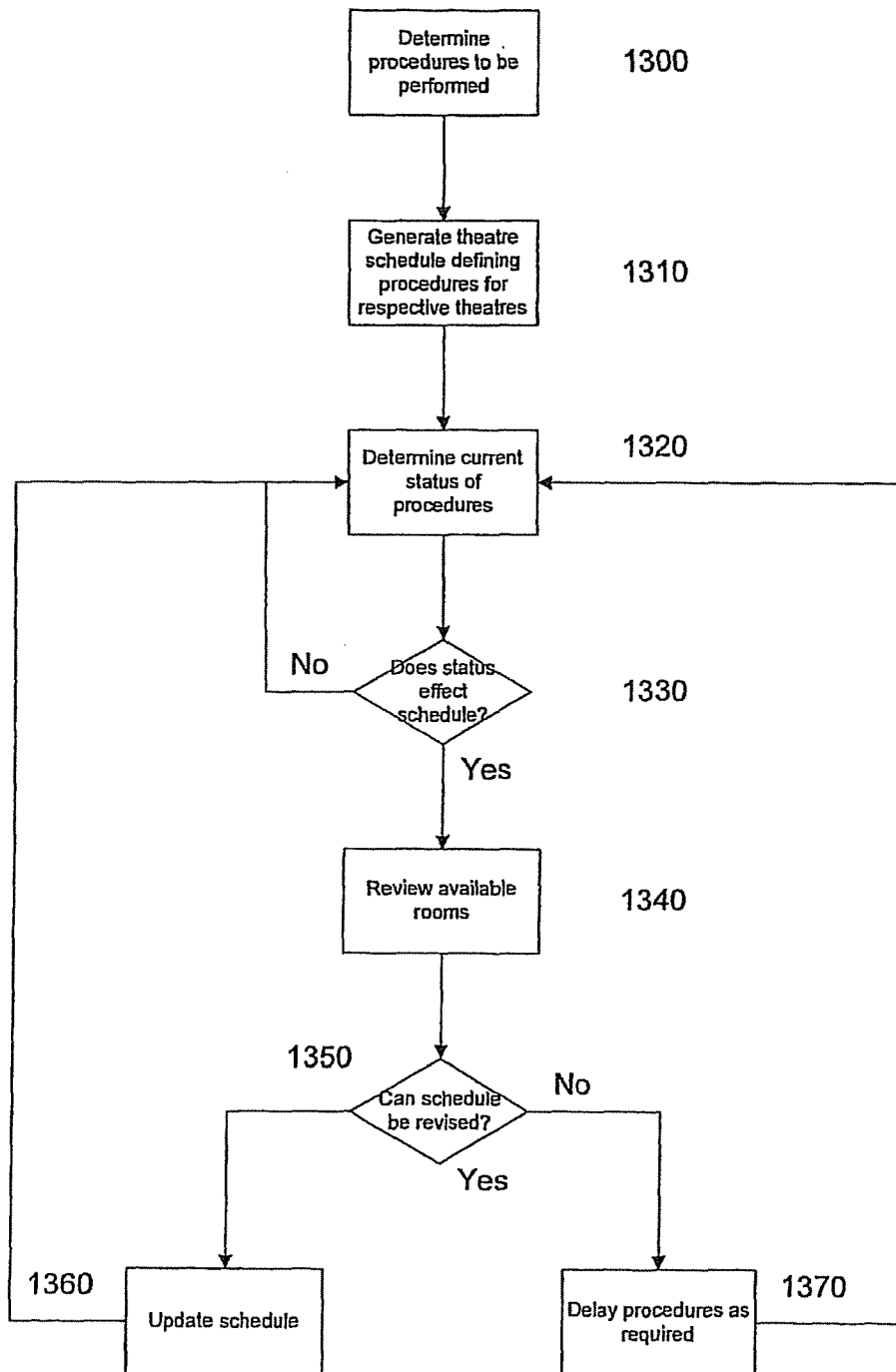


Fig. 15

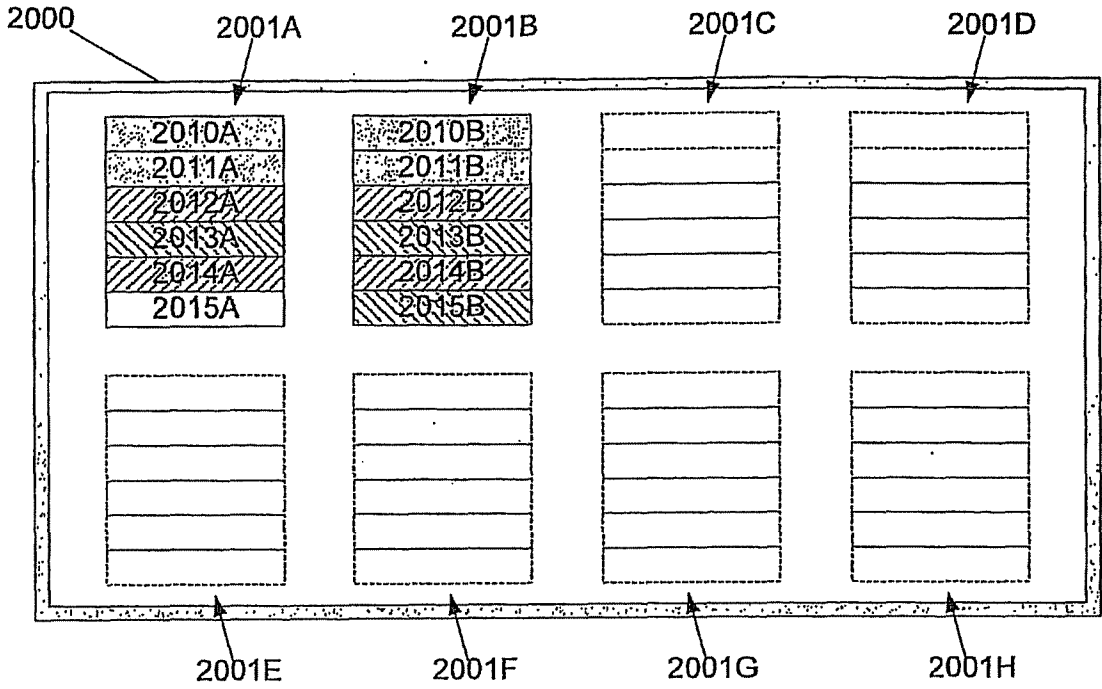


Fig. 16A

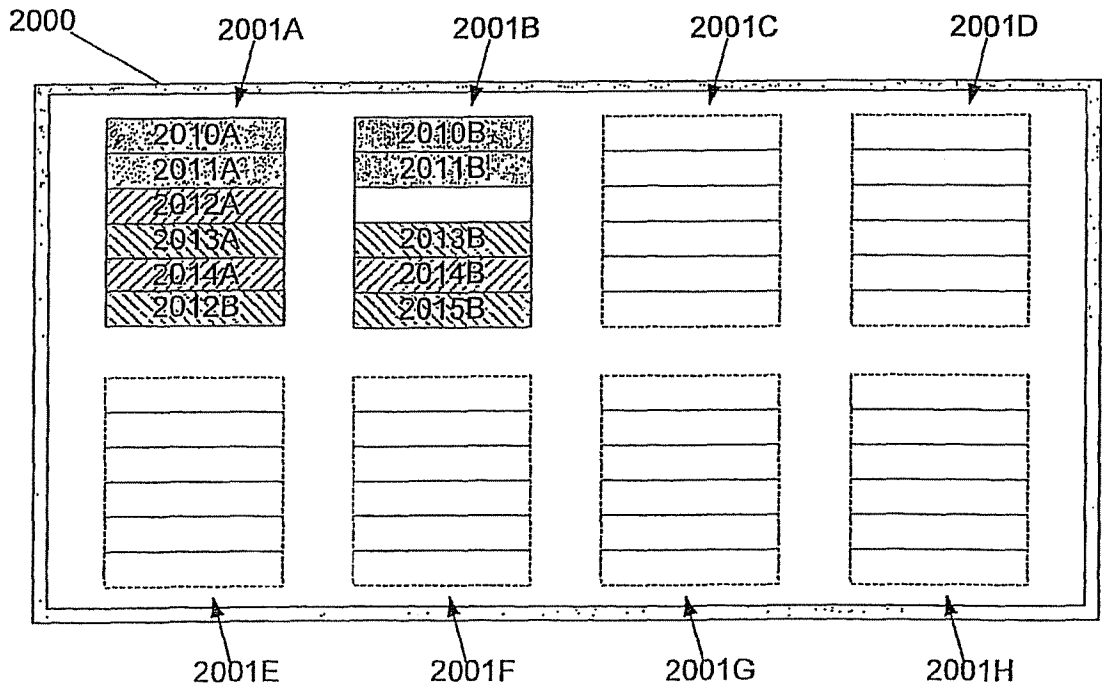


Fig. 16B

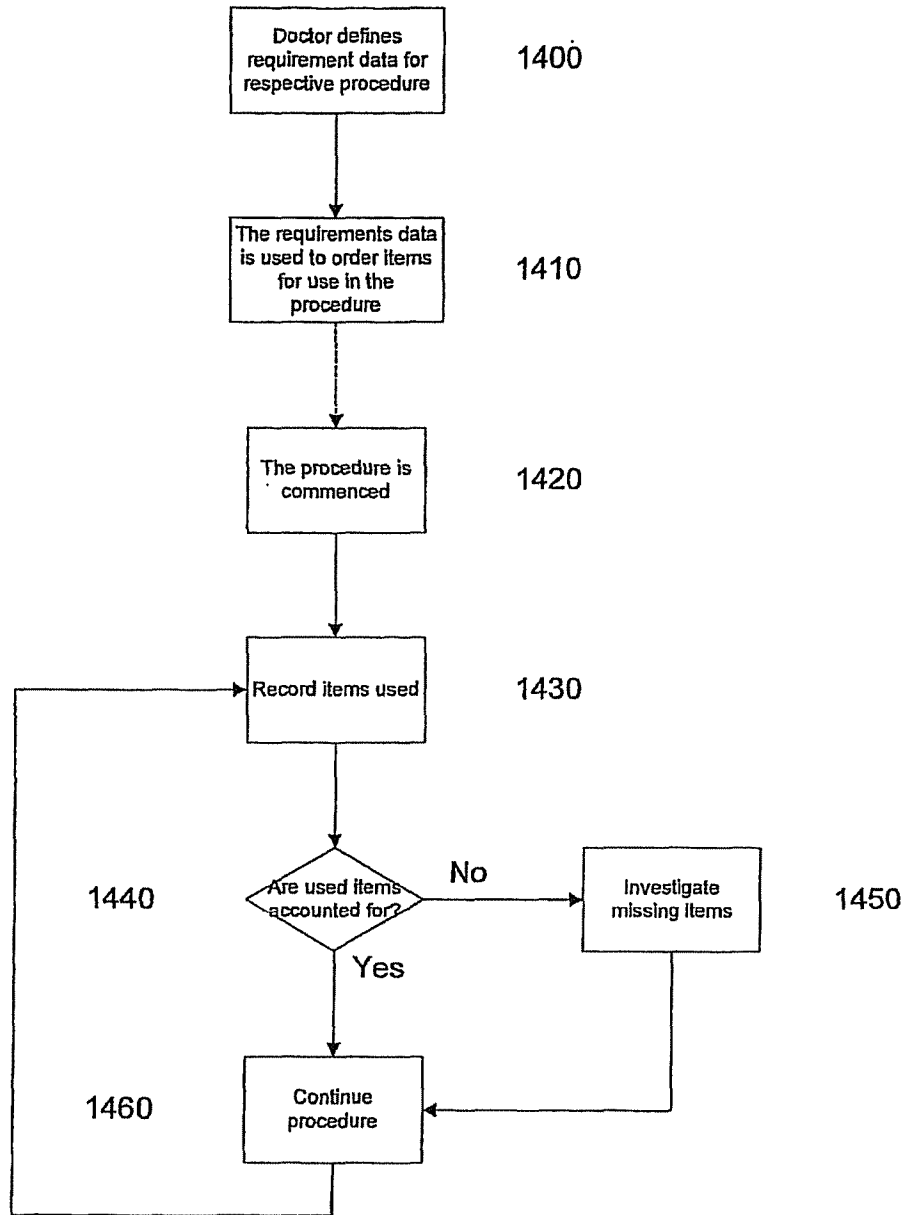


Fig. 17

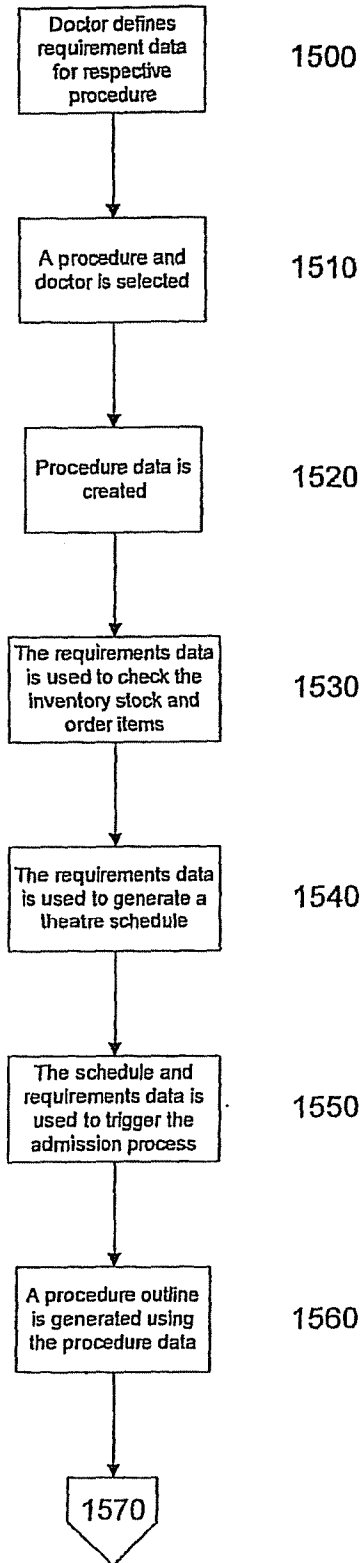


Fig. 18A

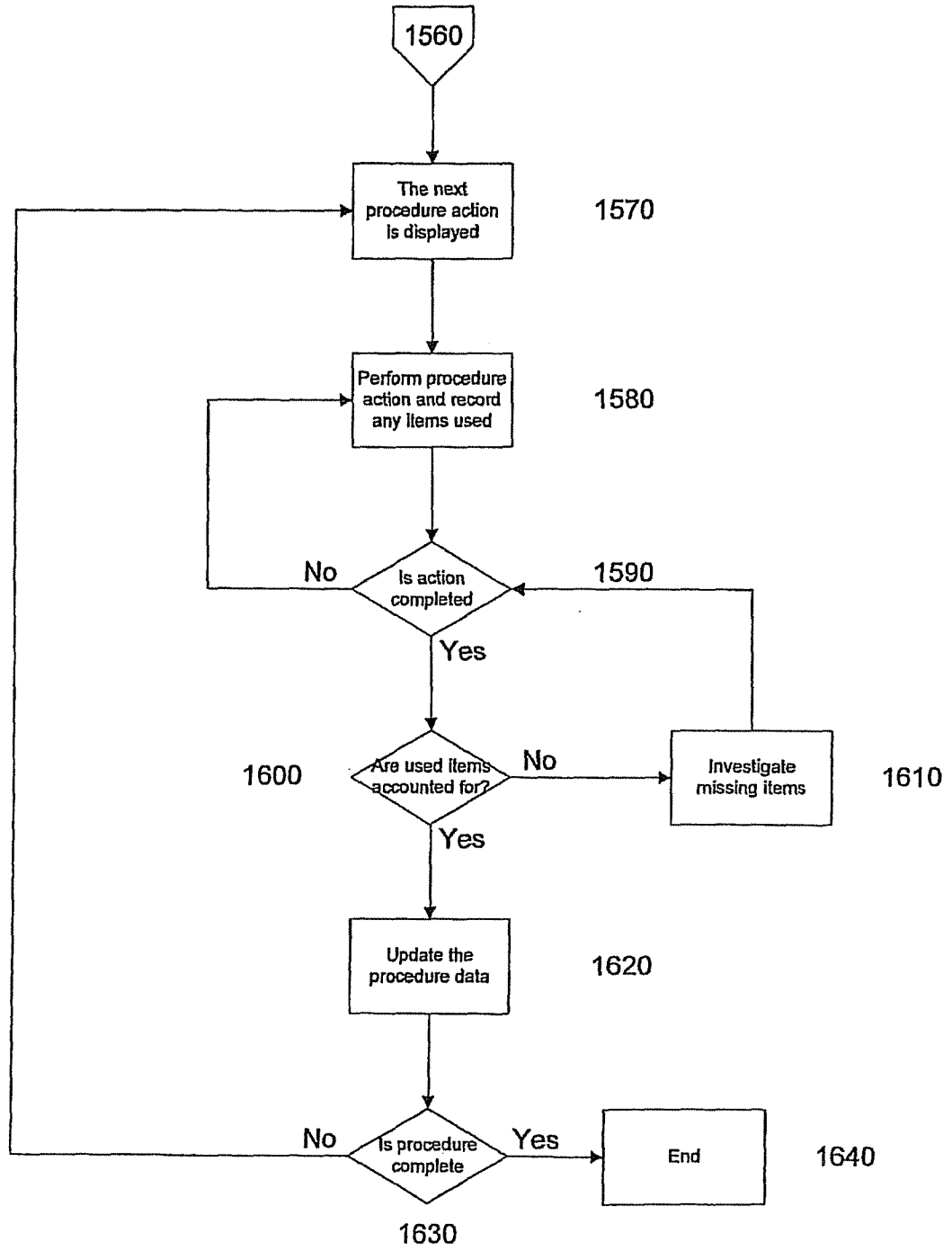
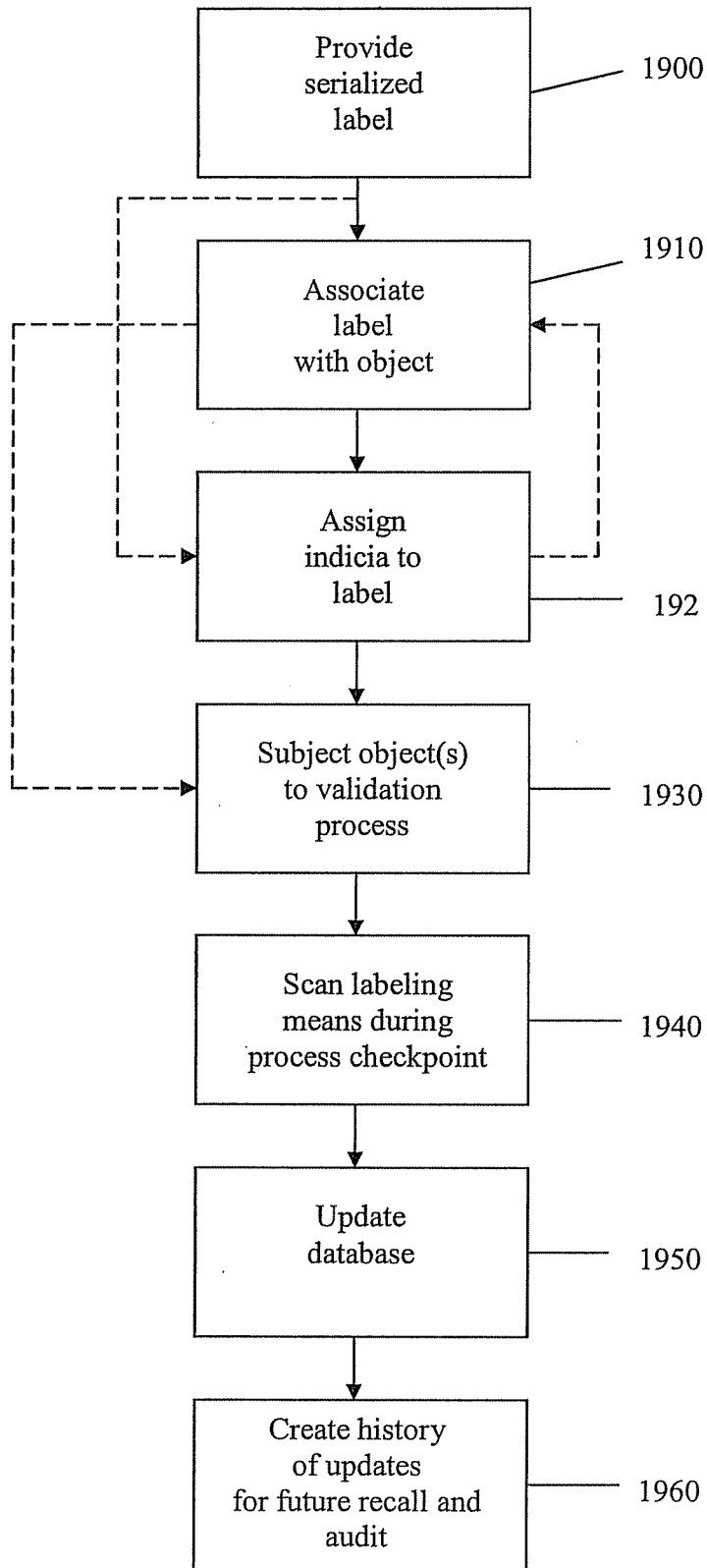


Fig. 18B

Figure 19



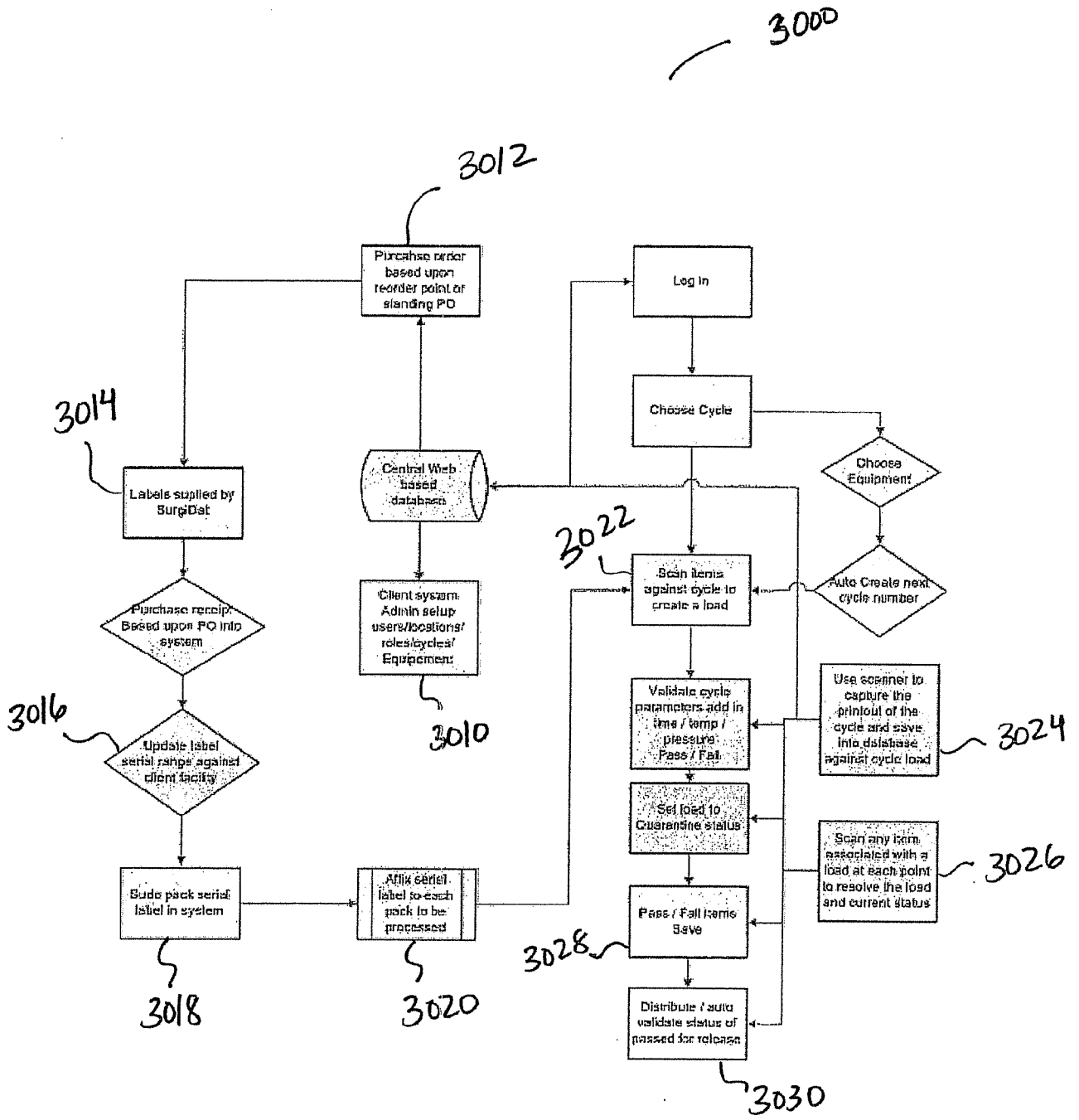
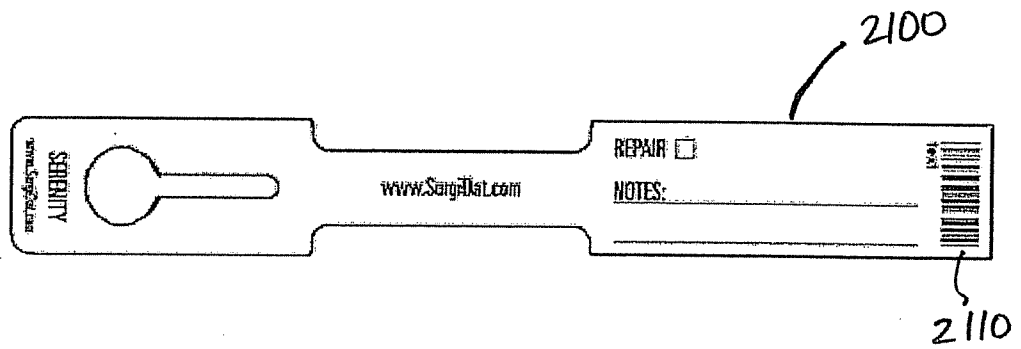


Figure 20

Figure 21A



Figure 21B



Green upon reaching a
temperature of 134c Or 207f

Red upon set number of days after
reaching a Temperature of the above
Make for

- 1. 30 days
- 2. 178 day
- 3. 356 dyas

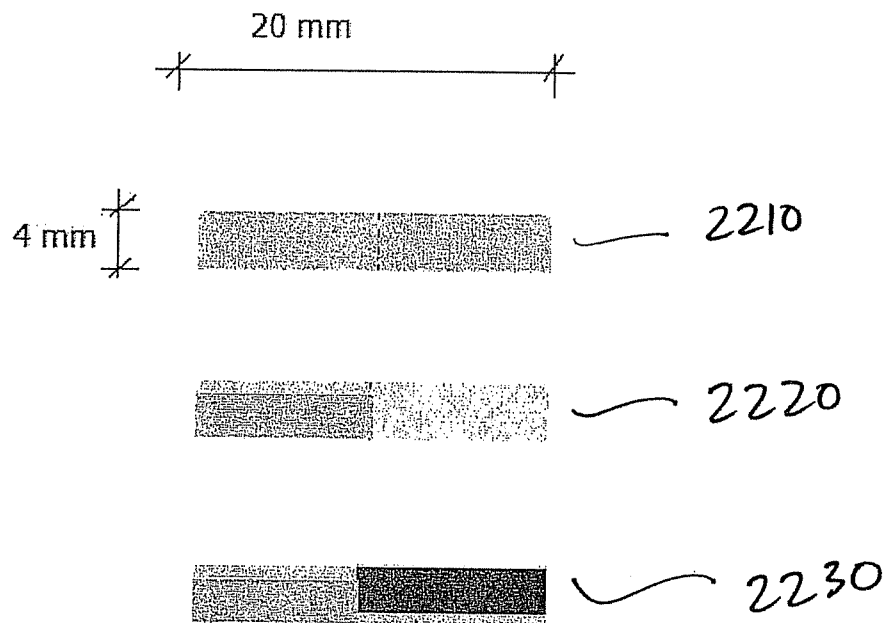
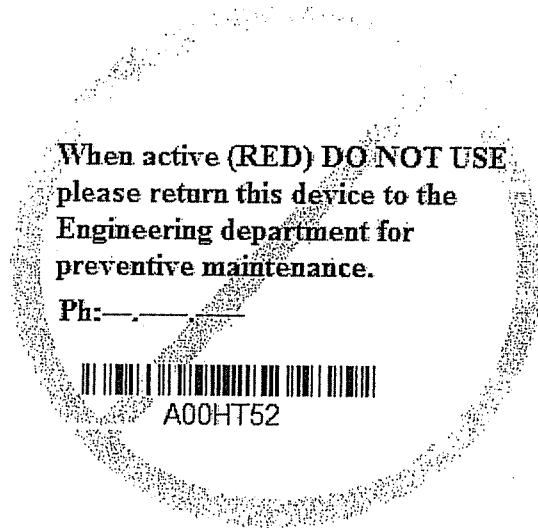


Figure 22A



- Color Change to RED
after Ultra Violet Light Activation
1. 30 days
 2. 178 day
 3. 356 das

Or by removal of protective
layer

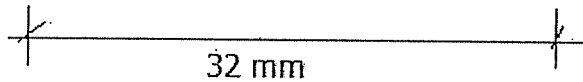


Figure 22B