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Tirinato et al.

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(54) **POINT-OF-CARE INVENTORY MANAGEMENT SYSTEM AND METHOD**

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(65) **Prior Publication Data**

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CPC ***G01K 13/00*** (2013.01); ***G01K 1/02*** (2013.01); ***G01K 3/04*** (2013.01); ***G06Q 10/087*** (2013.01);
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(58) **Field of Classification Search**
None
See application file for complete search history.

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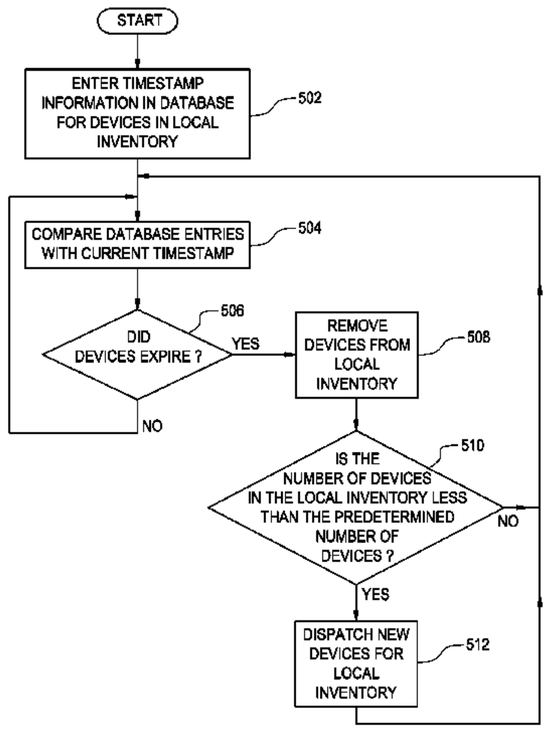
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(57) **ABSTRACT**

A system and method are disclosed for controlling an inventory of point-of-care diagnostic devices. The inventory includes a main inventory and at least one subinventory. Each device has an ambient temperature shelf life. Data associated with the devices is entered, including: the current quantity and predetermined minimum quantity of devices in the main inventory; and the current quantity and predetermined minimum quantity of devices in the subinventory. A first timestamp is associated with each device when the device is transferred from the main inventory to the ambient temperature subinventory. The first timestamp is compared to a second timestamp prior to use of the device to determine whether the device's ambient temperature shelf life is exceeded. The current quantity of devices in the subinven-
(Continued)



tory is updated in response to an event that causes a change in the current quantity of devices in the subinventory.

6 Claims, 9 Drawing Sheets

Related U.S. Application Data

continuation of application No. 12/428,969, filed on Apr. 23, 2009, now Pat. No. 7,912,754, and a division of application No. 11/761,142, filed on Jun. 11, 2007, now Pat. No. 7,552,071, and a continuation of application No. 10/384,820, filed on Mar. 11, 2003, now Pat. No. 7,263,501.

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G06Q 30/06	(2012.01)
G01K 1/02	(2006.01)
G01K 3/04	(2006.01)

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FIG. 1

Location/Cartridge	ER	CCU	PICU	ICU	RDU	OR	CVOR	GW
Type 1	200	100	100	200		100	100	
Type 2	250	250	250	250		500	500	
Type 3	50	50	50	50		100	100	
Type 4	50	50	50	50		100	100	
Type 5	100	200	200	400	100			
Type 6	100	100	100	100				
Type 7	500	500	500	500		500	500	
Type 8		100	100	200				
Type 9	200	100	100	100		100		200

FIG. 2

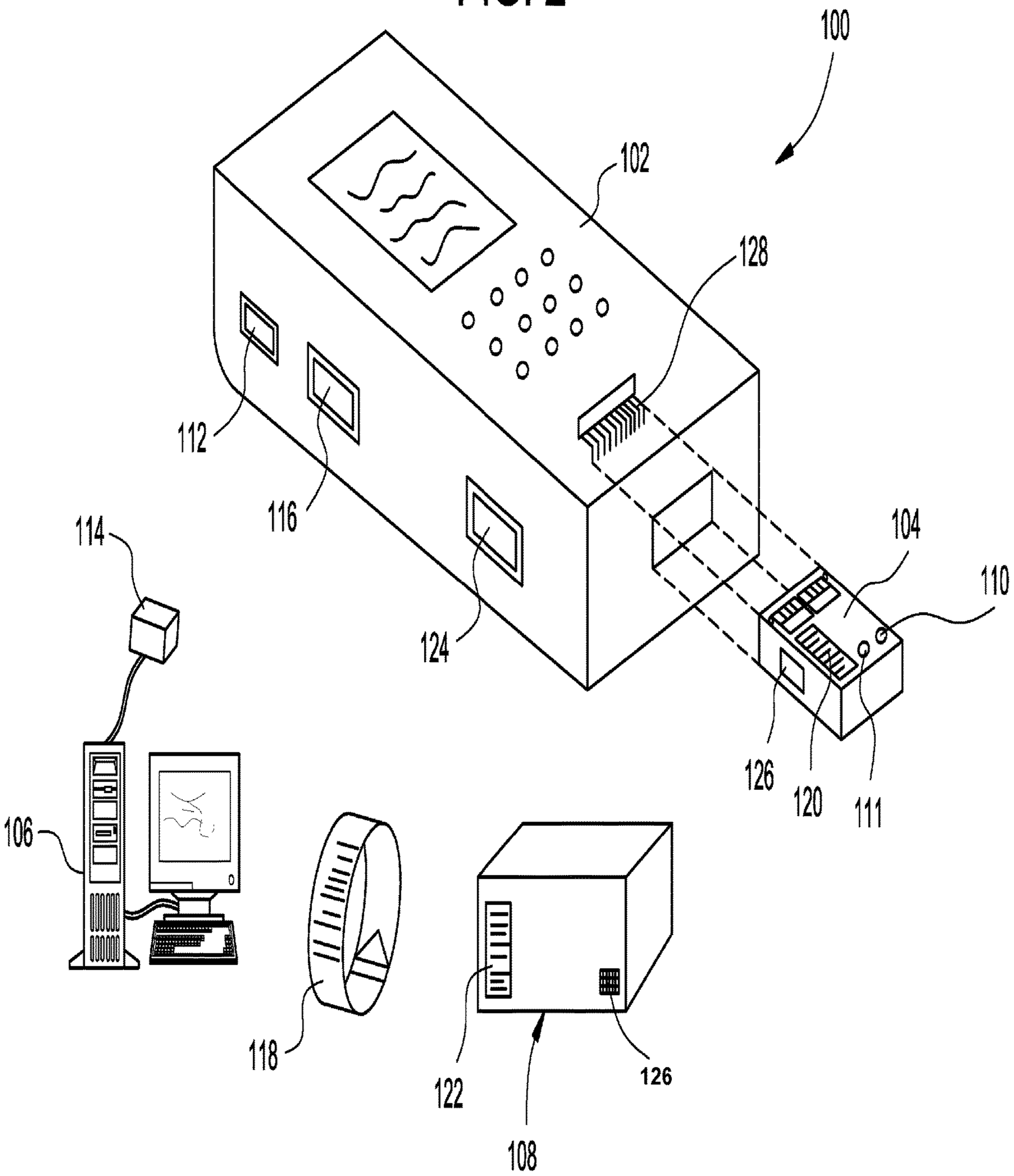

100
102
128
112
116
124
114
104
110
106
126
120
111
118
122
126
108

FIG. 3

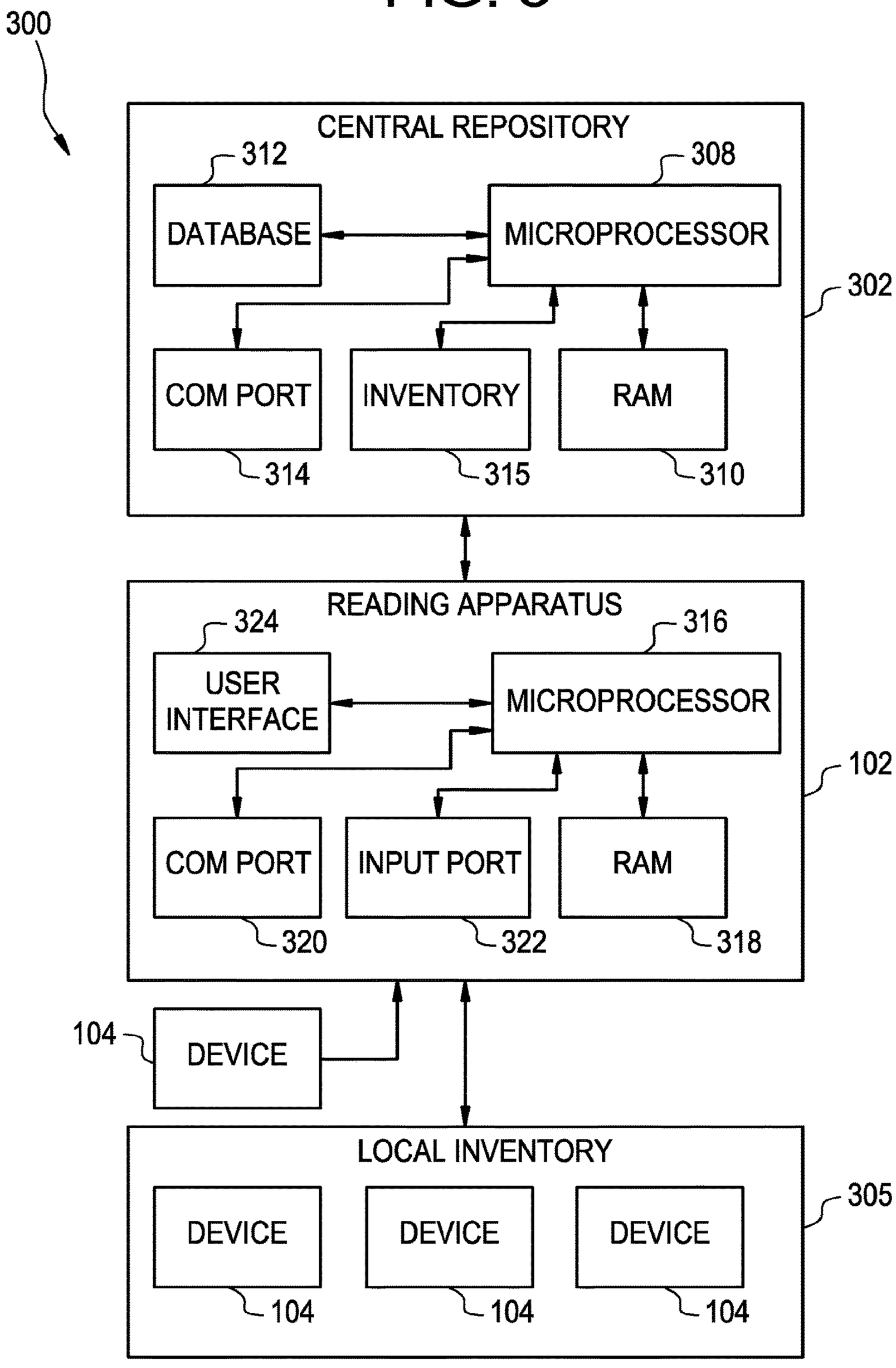

300
CENTRAL REPOSITORY
312
DATABASE
308
MICROPROCESSOR
302
COM PORT
INVENTORY
RAM
314
315
310
READING APPARATUS
324
USER INTERFACE
316
MICROPROCESSOR
102
COM PORT
INPUT PORT
RAM
320
322
318
104
DEVICE
LOCAL INVENTORY
305
DEVICE
DEVICE
DEVICE
104
104
104

FIG. 4

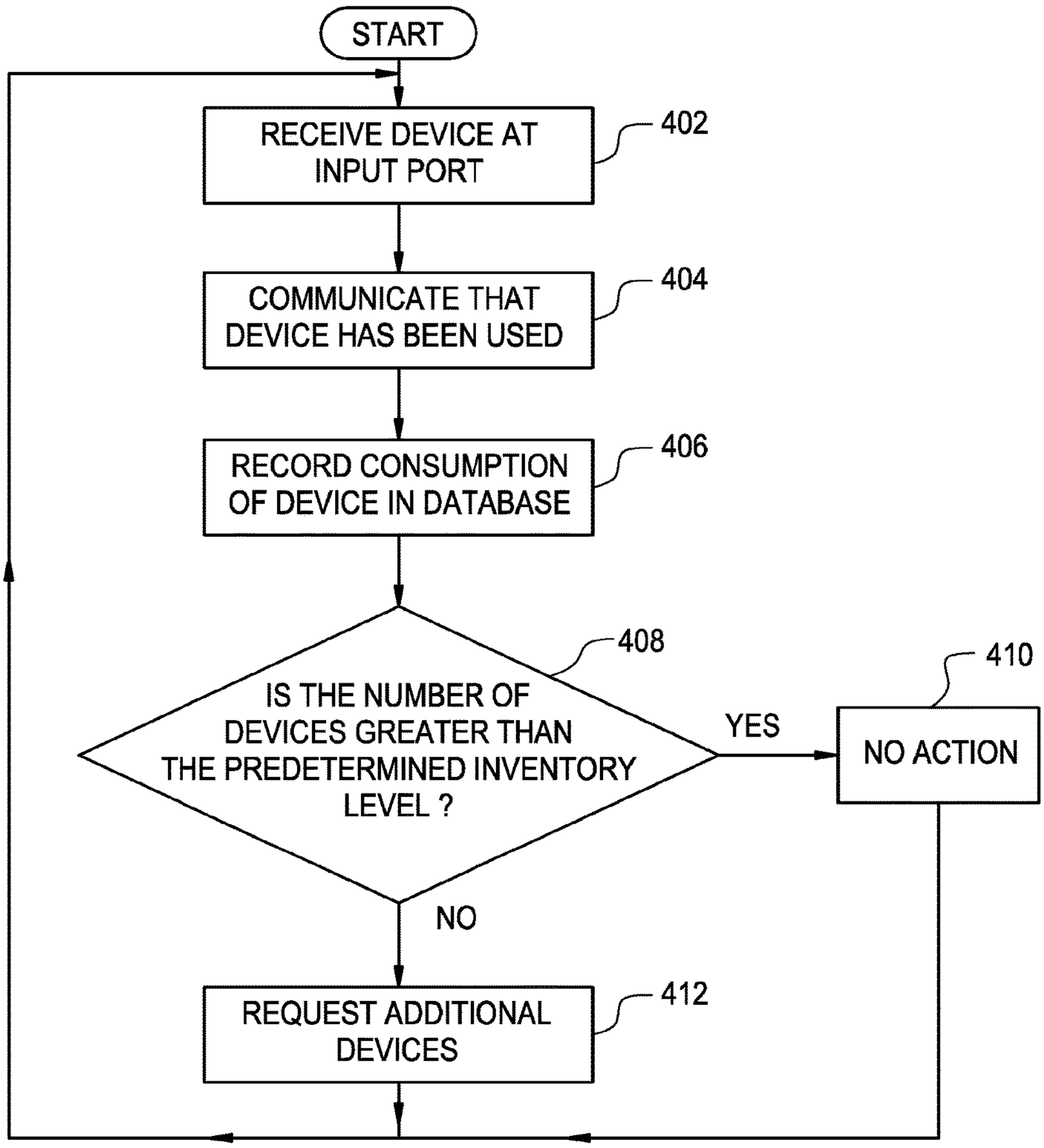

START
RECEIVE DEVICE AT INPUT PORT
402
COMMUNICATE THAT DEVICE HAS BEEN USED
404
RECORD CONSUMPTION OF DEVICE IN DATABASE
406
IS THE NUMBER OF DEVICES GREATER THAN THE PREDETERMINED INVENTORY LEVEL ?
408
YES
NO ACTION
410
NO
REQUEST ADDITIONAL DEVICES
412

FIG. 5

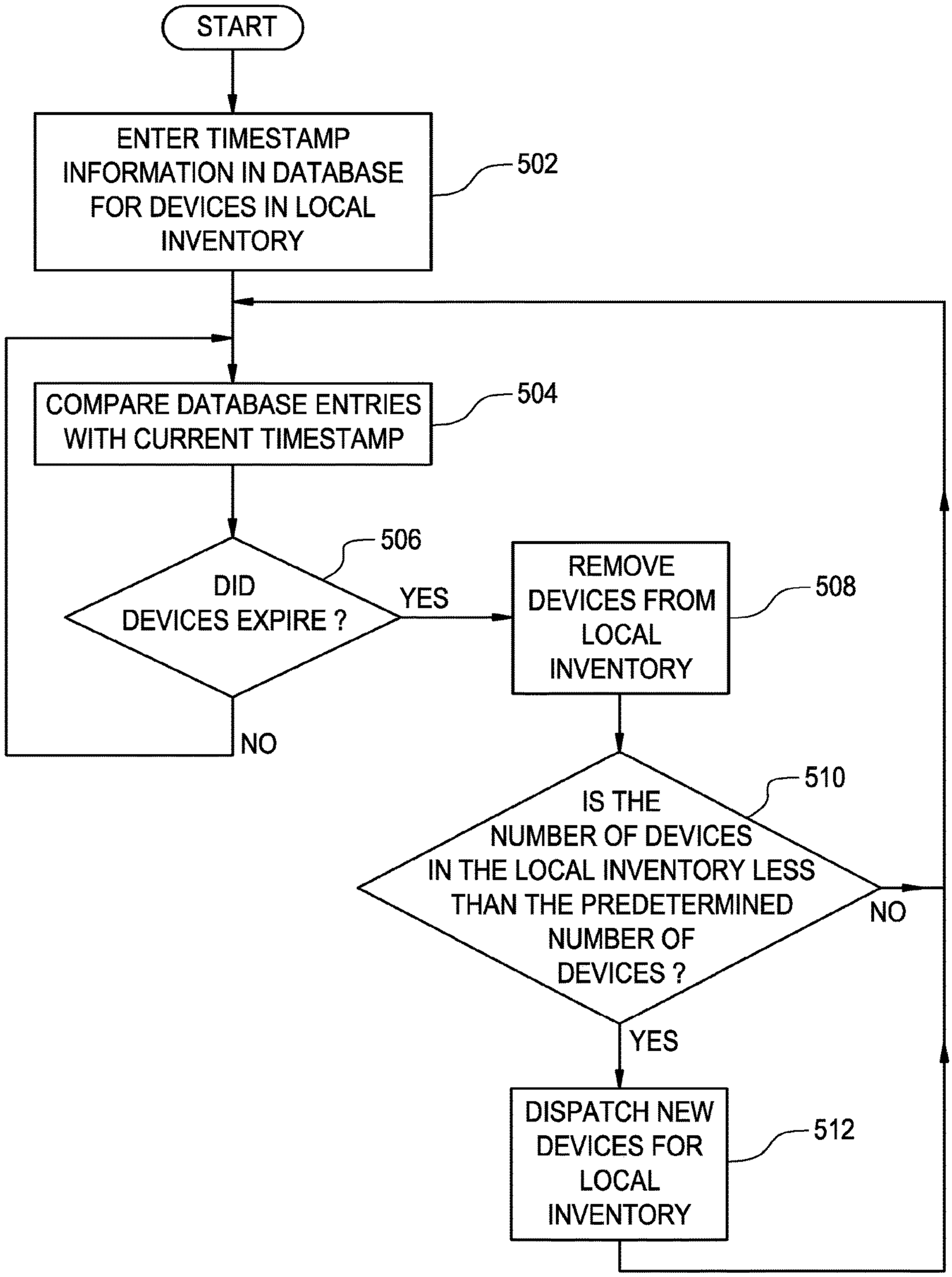

START
ENTER TIMESTAMP INFORMATION IN DATABASE FOR DEVICES IN LOCAL INVENTORY
502
COMPARE DATABASE ENTRIES WITH CURRENT TIMESTAMP
504
DID DEVICES EXPIRE ?
506
YES
NO
REMOVE DEVICES FROM LOCAL INVENTORY
508
IS THE NUMBER OF DEVICES IN THE LOCAL INVENTORY LESS THAN THE PREDETERMINED NUMBER OF DEVICES ?
510
NO
YES
DISPATCH NEW DEVICES FOR LOCAL INVENTORY
512

FIG. 6

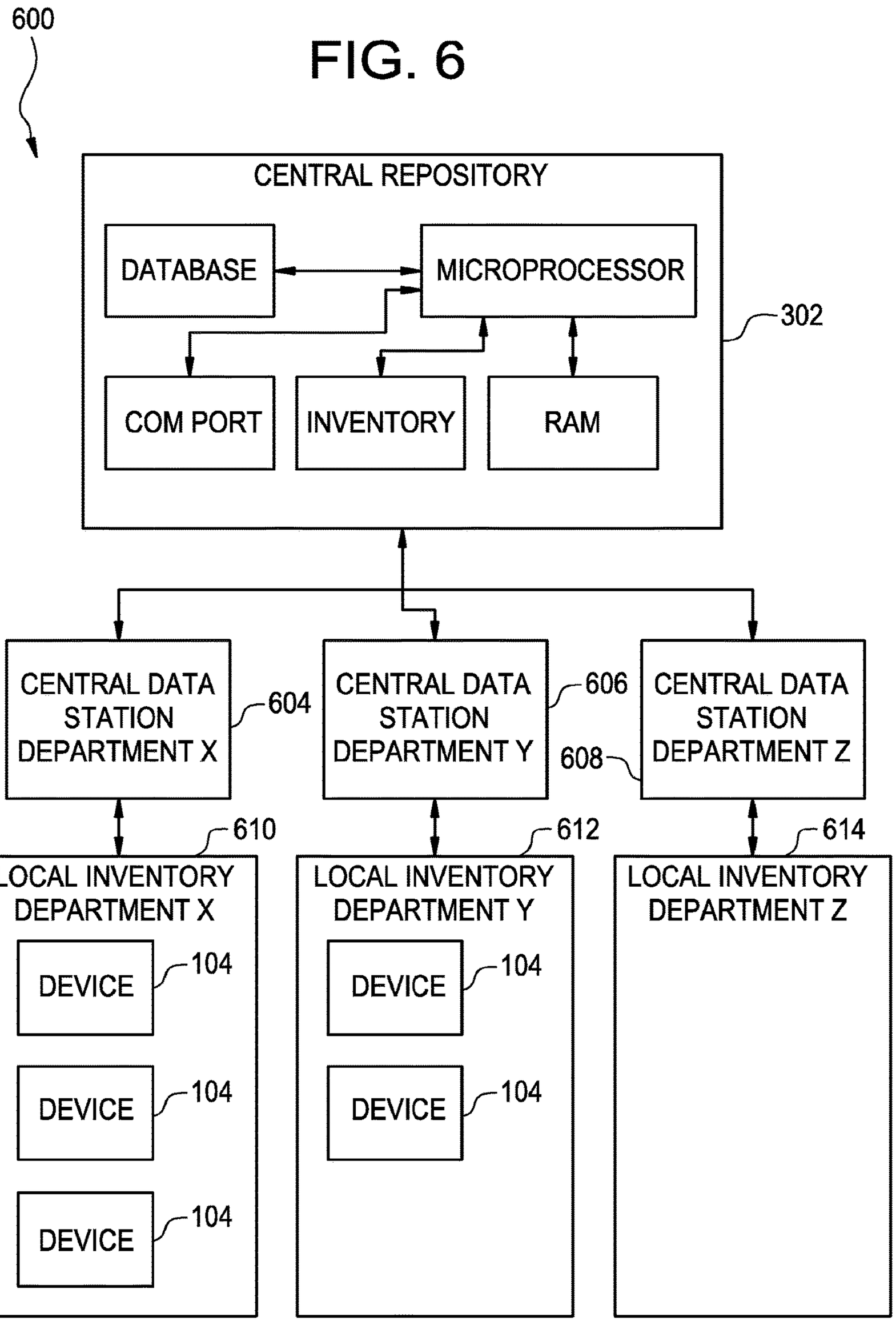

600
CENTRAL REPOSITORY
DATABASE
MICROPROCESSOR
302
COM PORT
INVENTORY
RAM
CENTRAL DATA STATION DEPARTMENT X
604
CENTRAL DATA STATION DEPARTMENT Y
606
CENTRAL DATA STATION DEPARTMENT Z
608
610
612
614
LOCAL INVENTORY DEPARTMENT X
LOCAL INVENTORY DEPARTMENT Y
LOCAL INVENTORY DEPARTMENT Z
DEVICE
104
DEVICE
104
DEVICE
104
DEVICE
104
DEVICE
104

FIG. 7

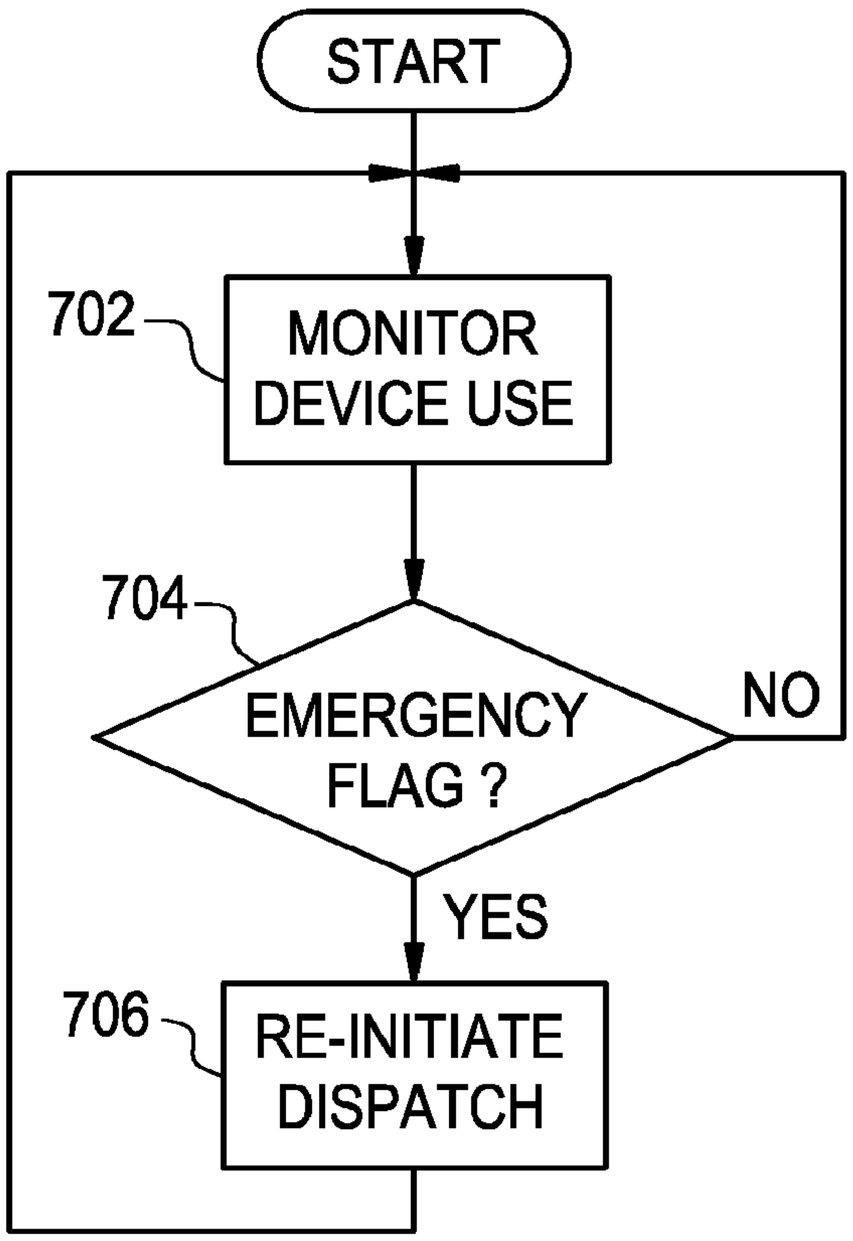

START
702
MONITOR DEVICE USE
704
EMERGENCY FLAG ?
NO
YES
706
RE-INITIATE DISPATCH

FIG. 8

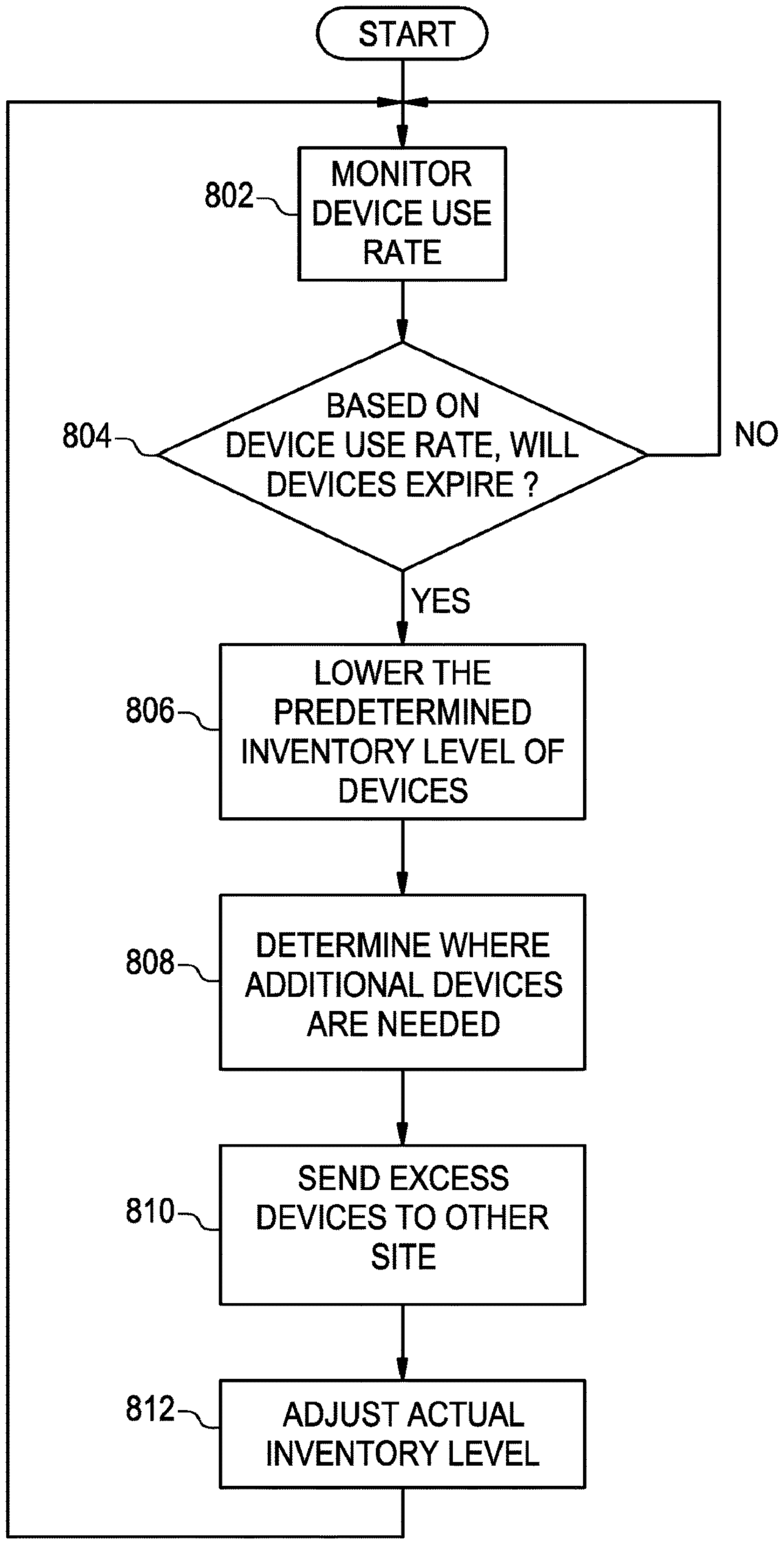
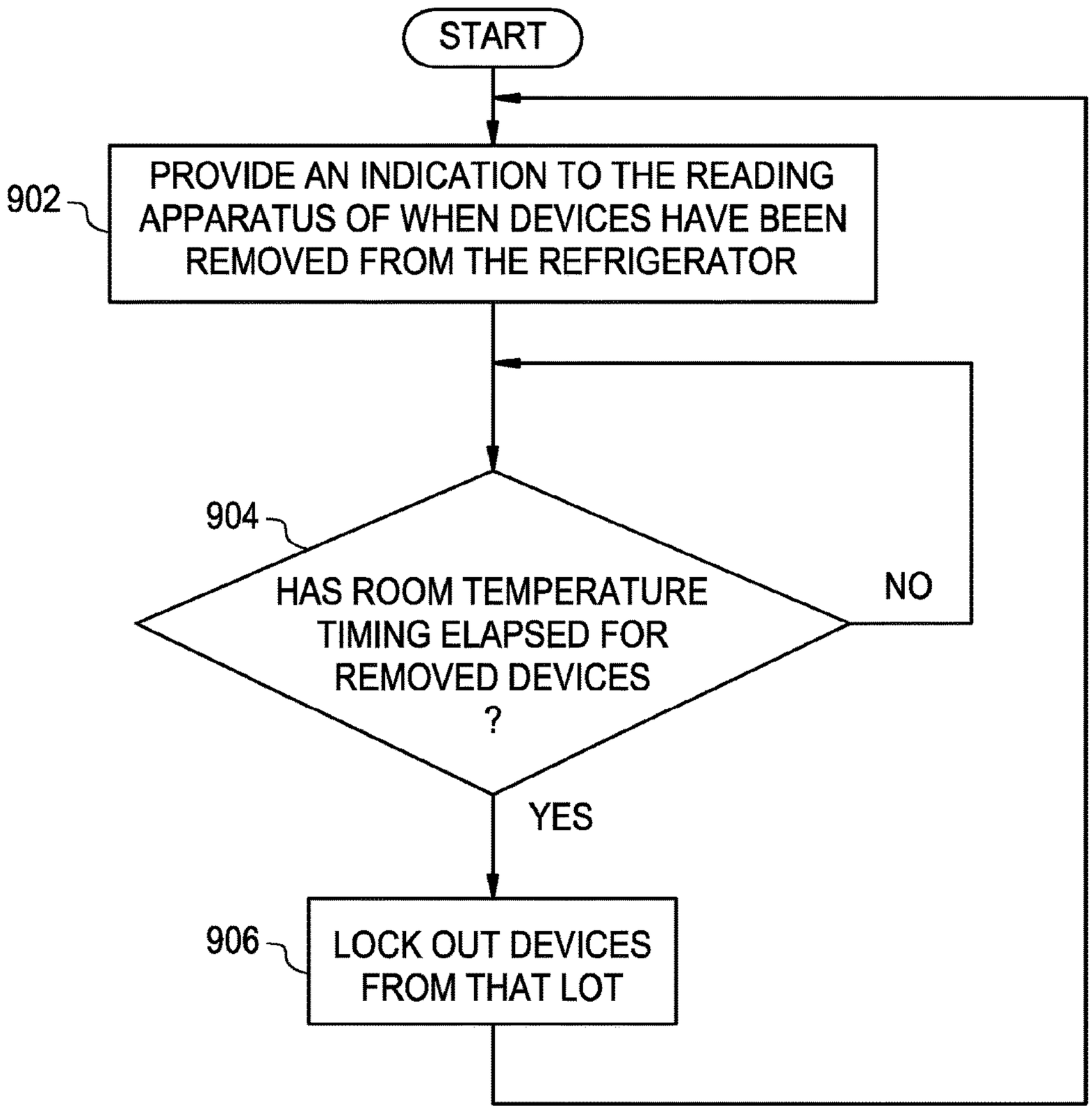

START
802
MONITOR DEVICE USE RATE
804
BASED ON DEVICE USE RATE, WILL DEVICES EXPIRE ?
NO
YES
806
LOWER THE PREDETERMINED INVENTORY LEVEL OF DEVICES
808
DETERMINE WHERE ADDITIONAL DEVICES ARE NEEDED
810
SEND EXCESS DEVICES TO OTHER SITE
812
ADJUST ACTUAL INVENTORY LEVEL

FIG. 9


START
902
PROVIDE AN INDICATION TO THE READING APPARATUS OF WHEN DEVICES HAVE BEEN REMOVED FROM THE REFRIGERATOR
904
HAS ROOM TEMPERATURE TIMING ELAPSED FOR REMOVED DEVICES ?
NO
YES
906
LOCK OUT DEVICES FROM THAT LOT

POINT-OF-CARE INVENTORY MANAGEMENT SYSTEM AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation of U.S. patent application Ser. No. 13/051,520, filed Mar. 18, 2011, which is a continuation of U.S. Pat. No. 7,912,754, issued on Mar. 22, 2011, which is a division of U.S. Pat. No. 7,552,071, issued on Jun. 23, 2009, which is a continuation of U.S. Pat. No. 7,263,501, issued on Aug. 28, 2007. Each of these applications is incorporated herein by reference in its entirety.

BACKGROUND

Field of the Invention

The present invention relates to a method and apparatus for inventory control, specifically to disposable elements and general consumable items that are used in a hospital or medical facility, and more specifically to point-of-care sample analysis systems that use different types of disposable devices.

Background Information

For hospitals, the recent introduction of point-of-care testing capabilities has created unique requirements for inventory control. The inventory control requirements arise from the use of multiple types of disposable sample testing devices at various locations within a hospital. The hospital must provide an adequate supply of each type of device at each site of use. However, the hospital tries to be mindful of the cost of carrying excess inventory at each site. This is also true for other locations where point-of-care testing occurs, such as military combat sites, cruise ships and nursing homes.

Certain sample testing devices have a finite shelf-life, in which the shelf-life may depend upon whether the sample testing device is refrigerated or maintained at ambient or room temperature, e.g., room temperature for a hospital. For example, a blood testing device may have a shelf-life of six to nine months when refrigerated, or a limited shelf-life of two weeks at ambient temperature. Because of the differences in shelf-life, a hospital will generally store devices at a central refrigerated location, and deliver devices to specific departments as demand requires. These departments may or may not have available refrigerated storage, which consequently affects the inventory they will maintain. In certain departments, general storage may be limited, which will also affect what level of inventory they maintain.

Point-of-care sample analysis systems are generally based on a re-usable reading apparatus that performs sample tests using a disposable device, e.g., a cartridge or strip, that contains analytical elements, e.g., electrodes or optics for sensing analytes such as, for example, pH, oxygen and glucose. The disposable device can optionally include fluidic elements (e.g., conduits for receiving and delivering the sample to the electrodes or optics), calibrant elements (e.g., aqueous fluids for standardizing the electrodes with a known concentration of the analyte), and dyes with known extinction coefficients for standardizing optics. The reading apparatus contains the electrical circuitry and other components for operating the electrodes or optics, making measurements, and doing computations. The reading apparatus also has the ability to display results and communicate those results to laboratory and hospital information systems (LIS and HIS, respectively), for example, via a computer workstation. Communication between the reading apparatus and a workstation, and between the workstation and a LIS, can be via, for example, an infrared link, a wired connection, wireless communication, or any other form of data communication that is capable of transmitting and receiving electrical information, or any combination thereof.

One benefit of point-of-care sample testing systems is the elimination of the time consuming need to send a sample to a central laboratory for testing. Point-of-care sample testing systems allow a nurse, at the bedside of a patient, to obtain a reliable, quantitative, analytical result, comparable in quality to that which would be obtained in a laboratory. In operation, the nurse selects a device with the required panel of tests, draws a sample, dispenses it into the device, optionally seals the device with, for example, a snap-closure, and inserts the device into the reading apparatus. While the particular order in which the steps occur may vary between different point-of-care systems and providers, the intent of providing rapid sample test results close to the location of the patient remains. The reading apparatus then performs a test cycle, i.e., all the other analytical steps required to perform the tests. Such simplicity gives the physician quicker insight into a patient's physiological status and, by reducing the time for diagnosis, enables a quicker decision by the physician on the appropriate treatment, thus enhancing the likelihood of a successful patient treatment.

In the emergency room and other acute-care locations within a hospital, the types of sample tests required for individual patients tend to vary. Thus, point-of-care systems generally offer a range of disposable devices with different sample tests, or combinations of sample tests. For example, for blood analysis devices, in addition to traditional blood tests, including oxygen, carbon dioxide, pH, potassium, sodium, chloride, hematocrit, glucose, urea, creatinine and calcium, other tests can include, for example, prothrombin time (PT), activated clotting time (ACT), activated partial thromboplastin time (APTT), troponin, creatine kinase MB (CKMB) and lactate. While devices typically contain between one and ten tests, it will be appreciated by persons of ordinary skill in the art that any number of test may be contained on a device. For example, a device for genetic screening may include numerous tests. To illustrate the need for different devices, a patient suspected of arrhythmia may require a device with a test combination that includes a potassium test, whereas a patient suspected of a diabetic coma may require a device with a test combination that includes a glucose test. An emergency room will need to have sufficient inventory of both types of device to ensure the supply meets the anticipated workload, while seeking to limit the economic cost associated with carrying an unnecessarily high inventory.

A given hospital may use numerous different types of devices and accordingly needs to maintain a combination of some or all of these at each point-of-care testing location within the hospital. These locations can include, for example, an emergency room (ER), a critical care unit (CCU), a pediatric intensive care unit (PICU), an intensive care unit (ICU), a renal dialysis unit (RDU), an operating room (OR), a cardiovascular operating room (CVOR), general wards (GW) and the like. Other hospital locations can be used to deliver point-of-care testing, as can other non-hospital-based locations where medical care is delivered, including, for example, MASH units, nursing homes, and cruise, commercial and military ships, and the like. FIG. **1** depicts an example of monthly device consumption rates at different locations in a hospital versus the=different available device types. It will be appreciated by persons of

ordinary skill in the art that the demand for particular devices may vary significantly between locations within, for example, a hospital.

Previously, inventory control of devices at the point-of-care relied on direct human intervention. Typically, personnel in the emergency room and/or other locations would call the hospital laboratory, where disposable devices are usually centrally stored to place an order. Alternatively, the hospital laboratory can control the disposable device storage at a central repository. The hospital laboratory would then request additional devices of specific types to be delivered to the requesting department. The central repository would then arrange for the devices to be delivered. Alternatively, a person from the laboratory, e.g., a designated point-of-care testing coordinator, would be responsible for regularly visiting point-of-care testing locations, checking device inventory needs and ensuring that those needs are met. Because of the manual nature of this inventory control scheme, there are several opportunities for delay and possible human error.

Once devices are delivered from the central repository, the devices can be stored at a convenient location, e.g., somewhere close to the patient. The convenient location will vary by department, but can include, for example, at the patient bedside (e.g., when the reading apparatus is part of a patient monitoring system), at a nursing station, in an auxiliary room attached to a ward, in a satellite laboratory attached to a critical care unit, and the like. One skilled in the art will recognize that where devices are stored at the bedside, the devices are unlikely to be refrigerated, whereas devices stored in a satellite laboratory may be refrigerated.

Typically, devices are supplied by the manufacture to the hospital in boxes with a given number of units, e.g., 25 or 50 units, or any number of units. The central repository in the hospital can supply these devices to the different departments in boxes or individually. Thus, the minimum inventory level for a department can be set in terms of the number of available unopened boxes of devices or on an absolute number of available individual devices.

Current inventory control systems and methods for handling point-of-care device inventory place the end-user, usually a nurse, at the center of the process. Essentially, the end user had to log or visually monitor the number of boxes of each type of device at their location and call the central repository to order more, as they see fit. Alternatively, a person from the laboratory was responsible for coordinating point-of-care testing by making regular visits to each site and ensuring devices are delivered when needed.

Thus, in creating the new environment of point-of-care sample testing, where a nurse performs sample tests at or close to the bedside of the patient, many of the previous problems associated with delay due to sample transportation to a hospital laboratory for analysis have been solved. The following patents relating to point-of-care sample testing are assigned to the same assignee as the present application: DISPOSABLE SENSING DEVICE FOR REAL TIME FLUID ANALYSIS, Lauks et al., U.S. Pat. No. 5,096,669; WHOLLY MICROFABRICATED BIOSENSORS AND PROCESS FOR THE MANUFACTURE AND USE THEREOF, Cozzette et al., U.S. Pat. No. 5,200,051; METHOD FOR ANALYTICALLY UTILIZING MICROFABRICATED SENSORS DURING WET-UP, Cozzette et al., U.S. Pat. No. 5,112,455; SYSTEM, METHOD AND COMPUTER IMPLEMENTED PROCESS FOR ASSAYING COAGULATION IN FLUID SAMPLES, Opalsky et al., U.S. Pat. No. 6,438,498; MICROFABRICATED APERTURE-BASED SENSOR, Davis et al., U.S. Pat. No. 6,379,883; APPARATUS FOR ASSAYING VISCOSITY CHANGES IN FLUID SAMPLES AND METHOD OF CONDUCTING SAME, Davis et al., U.S. Pat. No. 5,447,440; REUSABLE TEST UNIT FOR SIMULATING ELECTROCHEMICAL SENSOR SIGNALS FOR QUALITY ASSURANCE OF PORTABLE BLOOD ANALYZER INSTRUMENTS, Zelin et al., U.S. Pat. No. 5,124,661; STATIC-FREE INTERROGATING CONNECTOR FOR ELECTRICAL COMPONENTS, Lauks, U.S. Pat. No. 4,954,087; and REFERENCE ELECTRODE, METHOD OF MAKING AND METHOD OF USING SAME, Lauks, U.S. Pat. No. 4,933,048.

However, new inventory management issues were created as a consequence of the transition to point-of-care sample analysis.

SUMMARY OF THE INVENTION

A system and method are disclosed for controlling an inventory of a plurality of point-of-care diagnostic devices. The plurality of devices includes at least one type of device. Each device is configured to perform at least one sample analysis, and each device has a usable lifetime. The inventory includes a main inventory and at least one subinventory. Each subinventory is associated with a point-of-care location. According to a first aspect of the present invention, the inventory control system comprises a data input interface for entering data associated with the devices and a data output interface for displaying data associated with the devices. The data can include a current number of at least one type of device in the main inventory and a predetermined minimum number of devices of that type in the main inventory, and can include a current number of at least one type of device in the at least one subinventory and a predetermined minimum number of devices of that type in the at least one subinventory. A memory stores data associated with the devices and stores steps of a computer program to automatically update the current number of devices in the at least one subinventory in response to an occurrence of an event that causes a change in the current number of devices in the at least one subinventory. For example, the event can include at least one of (i.) a device from the at least one subinventory is used to perform at least one sample analysis, (ii.) a device from the at least one subinventory is transferred to another subinventory, and (iii.) a device from the at least one subinventory exceeds the usable lifetime of the device. The inventory control system also includes a processor for accessing the memory to execute the computer program.

According to a second aspect of the present invention, a method for controlling an inventory of a plurality of point-of-care sample analysis devices, wherein the inventory includes a main inventory and at least one subinventory, wherein the plurality of devices includes at least one type of device, wherein each device is configured to perform at least one sample analysis, and wherein each device has a usable lifetime, comprises the steps of: (i.) entering data associated with the devices, wherein the data includes a current number of at least one type of device in the main inventory and a predetermined minimum number of devices of that type in the main inventory, and includes a current number of at least one type of device in the at least one subinventory and a predetermined minimum number of devices of that type in the at least one subinventory, wherein each of the at least one subinventory is associated with a point-of-care location; and (ii.) automatically updating the current number of devices in the at least one subinventory in response to an occurrence of an event that causes a change in the current number of devices in the at least one subinventory.

According to a third aspect of the present invention, a method for distributing devices having a finite usable lifetime, the devices being contained within an inventory of devices, comprises the steps of: (i.) determining an inventory level of devices in the inventory of a first location, in response to an occurrence of an event that causes a change in a current number of devices in the inventory; (ii.) computing a device usage rate for the first location; (iii.) determining an excess device differential based on the device usage rate and the inventory level, wherein the excess device differential represents the devices that will remain in the inventory at the expiration of the usable lifetime; and (iv.) transferring the excess device differential to a second location. According to the alternative exemplary embodiment, a predetermined inventory level represents a minimum number of devices contained in the inventory. The method can further comprise the steps of (v.) adjusting the predetermined inventory level based on the device usage rate, and (vi.) adjusting the predetermined inventory level based on the excess device differential, thereby providing a dynamic and flexible approach to managing the inventory of devices having a finite usable lifetime.

According to a fourth aspect of the present invention, an inventory control system for controlling an inventory of a plurality of point-of-care diagnostic devices comprises means for entering data associated with the devices. The inventory includes a main inventory and at least one subinventory. The plurality of devices includes at least one type of device. Each device is configured to perform at least one sample analysis, and each device has a usable lifetime. The data includes a current number of at least one type of device in the main inventory and a predetermined minimum number of devices of that type in the main inventory, and includes a current number of at least one type of device in the at least one subinventory and a predetermined minimum number of devices of that type in the at least one subinventory, wherein each of the at least one subinventory is associated with a point-of-care location. The inventory control system comprises means for displaying data associated with the devices and means for storing data associated with the devices. The inventory control system also comprises means for automatically updating the current number of devices in the at least one subinventory in response to an occurrence of an event that causes a change in the current number of devices in the at least one subinventory.

According to a fifth aspect of the present invention, an inventory control system for controlling the use of a plurality of point-of-care diagnostic devices in an inventory includes a data input interface for entering data associated with the devices. The data includes an indicator associated with at least one device. The plurality of devices includes at least one type of device, wherein each device is configured to perform at least one sample analysis. The inventory includes a refrigerated inventory and an ambient temperature subinventory. The devices are stored in the refrigerated inventory and transferred to the ambient temperature subinventory prior to use. Each device has an ambient temperature usable lifetime. The inventory control system includes a memory for storing data associated with the devices and for storing steps of a computer program to: (i.) receive an indication from the indicator associated with the at least one device, prior to performing sample analysis using the at least one device; (ii.) determine, using the indication, whether the ambient temperature usable lifetime of the at least one device has been exceeded; and (iii.) prevent the at least one device from being used when a determination is made that the ambient temperature usable lifetime of the at least one device has been exceeded. The inventory control system also includes a processor for accessing the memory to execute the computer program.

According to the fifth aspect, the indicator comprises a code associated with the at least one device. The memory stores steps of a computer program to: receive a first instance of the code associated with the at least one device, when the at least one device is transferred from the refrigerated inventory to the ambient temperature subinventory; and associate a first time indication with the first instance of the code associated with the at least one device. For the step of receiving an indication, the memory stores steps of a computer program to: receive a second instance of the code associated with the at least one device, prior to performing sample analysis using the at least one device; and associate a second time indication with the second instance of the code associated with the at least one device. For the step of determining, the memory stores steps of a computer program to compare the first and second time indications with the ambient temperature usable lifetime of the at least one device. According to another alternative exemplary embodiment, the indicator is a time-temperature indicator.

According to a sixth aspect of the present invention, a method for controlling the use of a plurality of point-of-care diagnostic devices in an inventory comprises the steps of: (i.) entering data associated with the devices, wherein the data includes an indicator associated with at least one device, wherein the plurality of devices includes at least one type of device, wherein each device is configured to perform at least one sample analysis, wherein the inventory includes a refrigerated inventory and an ambient temperature subinventory, wherein the devices are stored in the refrigerated inventory and transferred to the ambient temperature subinventory prior to use, and wherein each device has an ambient temperature usable lifetime; (ii.) receiving an indication from the indicator associated with the at least one device, prior to performing sample analysis using the at least one device; (iii.) determining, using the indication, whether the ambient temperature usable lifetime of the at least one device has been exceeded; and (iv.) preventing the at least one device from being used when a determination is made that the ambient temperature usable lifetime of the at least one device has been exceeded.

According to the sixth aspect, the indicator is a code associated with the at least one device, and the method comprises the steps of: receiving a first instance of the code associated with the at least one device, when the at least one device is transferred from the refrigerated inventory to the ambient temperature subinventory; and associating a first time indication with the first instance of the code associated with the at least one device. The step of receiving an indication comprises the steps of: receiving a second instance of the code associated with the at least one device, prior to performing sample analysis using the at least one device; and associating a second time indication with the second instance of the code associated with the at least one device. The step of determining comprises the step of comparing the first and second time indications with the ambient temperature usable lifetime of the at least one device. According to another alternative exemplary embodiment, the indicator is a time-temperature indicator.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and advantages of the present invention will become apparent to those skilled in the art upon reading the following detailed description of preferred embodiments, in

conjunction with the accompanying drawings, wherein like reference numerals have been used to designate like elements, and wherein:

FIG. **1** illustrates an exemplary table comparing monthly demand for different devices at various hospital locations.

FIG. **2** is a block diagram illustrating an inventory control system for controlling an inventory of a plurality of point-of-care diagnostic devices, in accordance with an exemplary embodiment of the present invention.

FIG. **3** is a block diagram illustrating an inventory control system for controlling an inventory of a plurality of point-of-care diagnostic devices, in accordance with an exemplary embodiment of the present invention.

FIG. **4** is a flow chart illustrating the steps for maintaining an adequate supply of point-of-care diagnostic devices, in accordance with an exemplary embodiment of the present invention.

FIG. **5** is a flow chart illustrating the steps for monitoring the shelf-life of point-of-care diagnostic devices and replenishing a local inventory, in accordance with an exemplary embodiment of the present invention.

FIG. **6** is a block diagram illustrating a system, including multiple central data stations, wherein the point-of-care diagnostic devices are distributed between departments that are controlled by the central data stations, in accordance with exemplary embodiments of the present invention.

FIG. **7** is a flow chart illustrating steps for determining whether to initiate point-of-care diagnostic device re-dispatch, in accordance with an exemplary embodiment of the present invention.

FIG. **8** is a flow chart illustrating the steps for re-dispatching the point-of-care diagnostic devices between local inventories to reduce excess devices, in accordance with exemplary embodiments of the present invention.

FIG. **9** is a flow chart illustrating steps for locking out point-of-care diagnostic devices, in accordance with an exemplary embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A system and method are disclosed for controlling an inventory of a plurality of point-of-care diagnostic devices. The plurality of devices includes at least one type of device. Each device is configured to perform at least one sample analysis, and each device has a usable lifetime. The inventory includes a main inventory and at least one subinventory. Each subinventory is associated with a point-of-care location. The inventory control system comprises a data input interface for entering data associated with the devices and a data output interface for displaying data associated with the devices. The data can include a current number of at least one type of device in the main inventory and a predetermined minimum number of devices of that type in the main inventory, and can include a current number of at least one type of device in the at least one subinventory and a predetermined minimum number of devices of that type in the at least one subinventory. A memory stores data associated with the devices and stores steps of a computer program to automatically update the current number of devices in the at least one subinventory in response to an occurrence of an event that causes a change in the current number of devices in the at least one subinventory. For example, the event can include, but is not limited to, at least one of (i.) a device from the at least one subinventory is used to perform at least one sample analysis, (ii.) a device from the at least one subinventory is transferred to another subinventory, and (iii.) a device from the at least one subinventory exceeds the usable lifetime of the device. However, the event can be any type of event that can cause a change in the current number of devices. The inventory control system also includes a processor for accessing the memory to execute the computer program.

Exemplary embodiments of the present invention provide an automated system that ensures the maintenance of an adequate inventory of different types of disposable devices at multiple locations within a hospital. The disposable diagnostic devices can include, for example, blood analysis devices, urine analysis devices, serum analysis devices, plasma analysis devices, saliva analysis devices, cheek swab analysis devices, or any other type of disposable diagnostic device that can be used for point-of-care sample testing. Other consumable items that are used in conjunction with the sample testing device or a reading apparatus can also be inventory items in the automated system, and the system is capable of providing an adequate inventory of those items, as well. These consumable items can include, for example, syringes, vacutainers, swabs, needles, capillary tubes and collection devices, control fluids of different types, printer paper, batteries, and the like. The automated system according to exemplary embodiments is capable of initiating automatic reordering of devices of various types from the supplier, in relation to the consumption of devices at a given institution. The automated system can redistribute devices between locations within a hospital when a temporarily inadequate inventory exists at a central location within a hospital, for instance where there is an emergency medical situation causing a spike in demand for devices in one particular department, or where supplies of new devices to the hospital from the supplier have been delayed by a transportation emergency.

Additionally, where devices have a fixed shelf life, the automated system of the present invention ensures that inventory is supplied from the central inventory to ensure a high remaining shelf life in the central inventory, for example, using a first in, first out (FIFO) mode of operation. The automated system can be controlled by a computer and optionally integrated into an existing laboratory information system and a hospital information system. The automated system of the present invention provides a user-friendly, and optionally substantially real-time, display of inventory levels of each device type at each location where devices are used or stored. Exemplary embodiments of the present invention can also provide a user-friendly tracking means for following the different types of device consumption occurring in a hospital for the purpose of assisting the hospital in the analysis of operations, making forecasts, planning and the like.

Exemplary embodiments of the present invention can control the use of a plurality of point-of-care diagnostic devices in an inventory. Devices can be stored in a refrigerated inventory and transferred to an ambient temperature subinventory prior to use. Each device has an ambient temperature usable lifetime. A device or a collection of devices can be prevented from being used when a determination is made that the ambient temperature usable lifetime of the device or devices has been exceeded. The determination can be made, for example, by using a time-temperature indicator associated with each device that indicates when the ambient temperature usable lifetime of the device has been exceeded. Alternatively, a code, such as, for example, a bar code, RF tag or the like, can be associated with a device or collection of devices. When the device or devices are transferred from the refrigerated inventory to the

ambient temperature subinventory, a first timestamp can be associated with the code. Prior to the use of the device or devices, a second timestamp can be associated with the code and can be compared to the first timestamp. The device or devices can be prevented from being used if the time difference between the two timestamps exceeds the ambient temperature usable lifetime of the device or devices.

These and other aspects of the present invention will now be described in greater detail. FIG. **2** is a block diagram illustrating an inventory control system for controlling an inventory of a plurality of point-of-care diagnostic devices, in accordance with an exemplary embodiment of the present invention. The system **100** includes a reading apparatus **102**, a disposable device **104**, a central data station **106** and a box of devices **108**. The reading apparatus **102** can include, for example, a display, electronic memory and a keypad for manual data entry. The disposable device **104** can include, for example, a port for receiving a patient sample **110**. The reading apparatus **102** can communicate with the central data station **106** using, for example, a wire, a wireless connection, an infrared link, an optical link, a network connection **112**, **114**, or any other form of communication link that uses any form of communication protocol to transfer information electronically.

The reading apparatus **102** can include a barcode reader **116** for reading information from a patient's bar-coded wristband **118**, from a barcode **120** on a device **104** or from any other item **122** (e.g., the box of devices **108**) used in conjunction with the reading apparatus **102**. Other such encoding arrangements can be used. For example, the reading apparatus **102** can also include (either alternatively or in addition to the barcode reader **116**) a radio-frequency (RF) identification device **124** that is capable of identifying a RF tag **126** that is contained on or in each individual device or each box of devices **108**.

According to another exemplary embodiment of the present invention, one or more of the encoding arrangements can be based upon a binary coding pin array **128** of the type disclosed in, for example, jointly-owned U.S. Pat. No. 4,954,087.

The various encoding arrangements can convey relevant information such as, for example, the identity of a specific device type, date and location of manufacture, manufacturing lot number, expiration date, a unique number associated with a device, coefficients for use by the reading apparatus **102** associated with the calculation of blood or other sample parameters and the like. The devices can be used for measurements selected from groups such as, for example, amperometric, potentiometric, conductimetric, optical and the like. Other relevant information of this general type is well known in the medical manufacturing art, as is the technology for bar coding and barcode recognition.

For encoding on the basis of radio-frequency (RF) communication, the device **104** can include a tag on which one or more indications of, for example, the refrigerator shelf life of the device **104**, the ambient temperature shelf life of the device **104**, the age of the device **104**, and the like is located. Alternatively, rather than including numerous elements of relevant information on the tag, a single piece of information, e.g., a lot number, can be included on the tag. The lot number can be any alphanumeric sequence or unique identifier that can be used to identify the device **104** and associate relevant information with that device. For example, the lot number can be applied to a lookup table or any other type of computer database located within or connected to the reading apparatus **102** or any other computing system. Using the lookup table or computer database, relevant shelf life or other such information can be associated with the lot number such that, based on the lot number, the refrigerator shelf life, the ambient temperature shelf life, the age of the device **104** and the like can be determined.

The technology for RF encoding and RF code recognition using RF identification coded tags are known to those skilled in the art. A RF identification device **124**, **126** can comprise, for example, a self-contained, passively powered device with, for example, an antenna, memory, transmitter and the like in a package with dimensions of, for example, a few millimeters. The RF identification device **124** can be implemented on, for example, a printed circuit board with a serial port with dimensions of, for example, about one square centimeter or more. Alternatively, the RF identification device **124** can be in the form of, for example, an application specific integrated circuit (ASIC) for integration into an established system. However, the RF identification device **124** can be implemented using hardware, firmware, or any combination thereof, with the size of the device dependent upon the means of implementation. The electronic components for RF encoding can be selected to determine the proximity of the encoding element to the receiving component for reliable transmission to occur. Such proximity can range from, for example, a few millimeters up to a few meters, although the actual proximity will depend upon the choice of electronic components. Optionally, the proximity can be set such that the exchange of information occurs when the device **104** is inserted into the reading apparatus **102**.

The aforementioned encoding arrangements differ in the amount of information that can be conveniently transferred to the reading apparatus **102** and the required proximity between the reading apparatus **102** and source of the information. For the binary pin array of U.S. Pat. No. 4,954,087, there is physical contact between the device **104** and the reading apparatus **102** and the data is limited by the number of available pins, generally in the range of, for example, two to about twenty pins. For bar-coding, the user brings the barcode and reading apparatus **102** into close proximity and at a specific orientation relative to each other. However, the data contained in the barcode can be significantly greater than the binary pin array. The RF encoding approach offers even greater data capabilities without requiring the user to bring the device **104** into a specific orientation with the reading apparatus **102** for successful transmission.

The devices **104** can have a finite refrigerator and ambient temperature shelf life. For example, the devices **104** can have a refrigerated usable lifetime in the range of, for example, about three months to three years, although the devices **104** could have any range of refrigerated usable lifetime. The devices **104** can have an ambient temperature usable lifetime in the range of, for example, about three days to three months, although the devices **104** can have any range of ambient temperature usable lifetime. Given that the devices **104** can have a finite refrigerator and ambient temperature shelf life, there is a need to ensure that expired devices **104** (i.e., the devices **104** that have exceeded the refrigerated or ambient temperature shelf life) are not used.

In accordance with exemplary embodiments, the device **104** can include an indicator **111**, such as, for example, a time-temperature indicator that provides an indication of whether the device **104** has expired. For indicator **111**, the device **104** can include temperature-sensing circuitry (e.g., hardware, firmware, or any combination thereof) for monitoring the temperature of the device **104**. When the temperature-sensing circuitry included in device **104** determines that the temperature of the device **104** has remained within

a certain range (e.g., ambient temperature) for a period of time that is greater than a predetermined threshold (e.g., the ambient temperature shelf life), the circuitry can provide an electrical signal to indicator **111** that causes the indicator **111** to emit an indication (e.g., a flashing, blinking or steady light, a change in color, a sound, and the like) that the device **104** is expired. Alternatively, the temperature monitoring component can be based on a physical or chemical change that is temperature dependant. This can result in, for example, a physical or color change that is registered by the reading apparatus **102**. The temperature monitoring component can be, for example, a liquid crystal or mechanical device, for example, a threshold device with a wax seal that, when melted at a certain temperature, releases a spring, or any other type of liquid crystal or mechanical device that is temperature sensitive and can register or otherwise indicate that the device **104** has expired based on temperature.

The temperature monitoring component can alternatively be a device that acts as a time-temperature monitor with a threshold that equates to a safe, but variable, lifetime. In other words, the time-temperature monitor can either increase or decrease the lifetime of the device **104** depending upon the temperature in which the device **104** is kept. For example, a device **104** that has been removed from a refrigerator and has been maintained at a low ambient temperature (e.g., at or near the refrigerator temperature), for example, a military MASH unit during a winter deployment, can have a time-temperature indicator that permits, for example, one extra week of post-refrigerator shelf-life because of the low ambient temperature. Alternatively, the same MASH unit in a desert deployment in which the ambient temperature is high (e.g., well above the refrigerator temperature), can have a time-temperature indicator that expires before one where the ambient temperature is lower. However, those of ordinary skill in the art will recognize that the amount of increase or decrease in the lifetime of the device **104** will depend upon the actual ambient temperature of the post-refrigerator environment into which the device **104** is removed, and will thus vary accordingly. As used herein, "refrigerated storage" generally refers to storage in the range of about 36 to about 46 degrees Fahrenheit (about 2 to about 8 degrees Celsius), and "room temperature storage" generally refers to storage in the range of about 64 to about 86 degrees Fahrenheit (about 18 to about 30 degrees Celsius). Ambient storage conditions can be similar to room temperature storage, but can be in the range of about 36 to about 104 degrees Fahrenheit (about 2 to about 40 degrees Celsius).

According to an alternative exemplary embodiment of the present invention, the device **104** or a collection of devices **104** (e.g., a box of devices **108**) can be prevented from being used by comparing, for example, time indicators associated with the device **104** with the ambient temperature usable lifetime of the device or devices **104**. For example, each device or devices **104** can have a code, such as for example, a bar code, RF tag or the like, associated with the device or devices **104**. When the device or devices **104** are transferred from a refrigerated inventory to an ambient temperature subinventory, a first instance of the code associated with the device or devices **104** can be entered into the reading apparatus **102** via the identification device associated with the reading apparatus **102** (e.g., via barcode reader **116** or the like). A first time indication, such as, for example, a first timestamp, can be associated with this first instance of the code by the reading apparatus **102**. Prior to performing sample analysis using the device or devices **104**, a second instance of the code associated with the device or devices **104** can be entered into the reading apparatus **102** via the identification device associated with the reading apparatus **102**. A second time indication, such as, for example, a second timestamp, can be associated with the second instance of the code by the reading apparatus **102**. The time difference between the two timestamps can then be determined, and this time difference can be compared to the ambient temperature usable lifetime of the device or devices **104**. If the time difference exceeds the ambient temperature usable lifetime of the device or devices **104**, the device or devices **104** can be prevented from being used. For example, the operator can be notified that the device or devices **104** have expired through visual means (e.g., a warning message is displayed on the display of the reading apparatus **102**, an warning light or indicator blinks or otherwise flashes on the reading apparatus **102**, or the like), audible means (e.g., a warning sound is played by the reading apparatus **102**), an electronic message relayed to the operator, central repository, or other entities through a computer or other network connection, or the like.

Referring to the disposable device **104** and the patient sample entry port **110**, the device **104** can perform analyses on a range of sample types. These sample types can include, for example, arterial, capillary and venous blood, plasma, serum, interstitial and spinal fluid, urine, bodily secretions and the like. Appropriate consumable items for use in conjunction with the device **104** are well known in the art. These include, for example, vacutainers, needles, capillary tubes and collection devices, control fluids of different types, syringes, swabs, printer paper, batteries and any other consumable item that can be used in conjunction with the device **104**. The consumable items can also be used to facilitate introduction of the sample into the sample entry port **110**.

FIG. **3** is a block diagram illustrating an inventory control system for controlling an inventory of a plurality of point-of-care diagnostic devices, in accordance with an exemplary embodiment of the present invention. The system **300** can include a central repository **302**, a reading apparatus **102**, a local inventory of devices **305**, and a device **104**. The central repository **302** can include a microprocessor **308**. The microprocessor **308** can be any type of processor, such as, for example, any type of general purpose microprocessor or microcontroller, a digital signal processing (DSP) processor, an application-specific integrated circuit (ASIC), a programmable read-only memory (PROM), an erasable programmable read-only memory (EPROM), an electrically-erasable programmable read-only memory (EEPROM), a computer-readable medium, or the like.

The central repository **302** can also include computer memory, such as, for example, RAM **310**. However, the computer memory of central repository **302** can be any type of computer memory or any other type of electronic storage medium that is located either internally or externally to the central repository **302**, such as, for example, read-only memory (ROM), random access memory (RAM), compact disc read-only memory (CDROM), electro-optical memory, magneto-optical memory, or the like. According to exemplary embodiments, RAM **310** can contain, for example, the operating program for the central repository **308**. As will be appreciated based on the following description, the RAM **310** can, for example, be programmed using conventional techniques known to those having ordinary skill in the art of computer programming. The actual source code or object code for carrying out the steps of, for example, a computer program can be stored in the RAM **310**.

The central repository **308** can also include a database **312**. The database **312** can be any type of computer database

for storing, maintaining, and allowing access to electronic information stored therein. For example, the database **312** can contain information relating to threshold requirements of the device **104** for each reading apparatus **102**, e.g., the minimum desired number of devices **104** to be maintained in local inventory **305**. The central repository **308** can also include a communications port **314** with which the central repository **302** can communicate with the reading apparatus **102**. The communications port **314** can be any type of communications port through which electronic information can be communicated over a communications connection, whether locally or remotely, such as, for example, an Ethernet port, an RS-232 port, or the like. The central repository **302** can also include an inventory **315**, which can be a physical repository of devices **104**, other consumable items that can be used in conjunction with the devices **104**, or the like.

The reading apparatus **102** can include a microprocessor **316** (e.g., any type of processor). The reading apparatus can also include any type of computer memory or any other type of electronic storage medium that is located either internally or externally to the reading apparatus **102**, such as, for example, RAM **318**. According to exemplary embodiments, the RAM **318** can contain, for example, the operating program for the reading apparatus **102**. As will be appreciated based on the following description, the RAM **318** can, for example, be programmed using conventional techniques known to those having ordinary skill in the art of computer programming. The actual source code or object code for carrying out the steps of, for example, a computer program can be stored in the RAM **318**.

The reading apparatus **102** can include a communications port **320** (e.g., any type of communications port through which electronic information can be communicated over a communications connection, whether locally or remotely) with which the reading apparatus **102** can communicate with, for example, the central repository **302**. The reading apparatus **102** can also include an input port **322** that, for example, allows insertion of the device **104** and is appropriately configured to receive the device **104**. The reading apparatus **102** can also include a user interface **324**. The user interface **324** can be any type of computer monitor or display device on which graphical and/or textual information can be displayed to a user (e.g., through a graphical user interface) and which allows a user to enter information (e.g., commands and the like) through, for example, a keyboard, a touch-screen, any type of pointing device, electronic pen, and the like. For example, the user interface **324** can be configured to receive instructions from the operator of the reading apparatus **102**.

According to exemplary embodiments, the local inventory **305** is a repository of physical items that can include, for example, the actual devices **104** of one or more types of devices that are available to the reading apparatus **102**. However, the local inventory **305** can also include any other consumable item that can be used in conjunction with the devices **104**.

According to an exemplary embodiment, the number of devices **104** that are associated with the local inventory **305** can be entered electronically, for example, through a scanning arrangement using a barcode reader, data transmission from the central repository **302**, or other electronic means. According to an alternative exemplary embodiment, the number of devices **104** can be entered manually. The initial stock level can be set through, for example, an electronic notification, manual entry, application summing notifications, and the like. With respect to an electronic notification, the initial stock level can be set electronically by, for example, a message from the supplier with an indication of the quantity and type of devices **104**. With respect to application summing notifications, when inputting the initial stock level, the number of devices **104** in each box **108** can be allocated based on a single scan of the box. For example, where each box **108** of devices **104** can have a barcode **122** (see FIG. **2**) that identifies the type of the devices **104** and number of devices **104** in the box **108**, the user can swipe the box **108** past the barcode reader **116** located on the reading apparatus **102**. The number of devices **104** in the box **108** may be in the range of, for example, 1 to 100. However, it should be appreciated that the number of devices **104** in the box **108** can vary, for example, with the size of the box **108**. Alternatively, the barcode reader **116** can be located on a departmental central data station (CDS). If multiple boxes **108** of the same device **104** type are being added to the department's local inventory **305**, then the user can swipe all the boxes, swipe the first box and manually input the total number of boxes, or some combination in between. It should be appreciated by persons of ordinary skill in the art that application summing notifications can be manual or automatic, based on, for example, electronic notifications, as described above.

Alternatively, when the devices **104** arrive at a given department from the central repository **302**, the boxes **108** can be scanned by, for example, bar-code or RF means, thereby updating the departmental local inventory **305**. The inventory information can be recorded in the CDS and a message can be optionally sent back to the central repository **302** confirming that the correct devices **104** have arrived. The central repository **302**, or a second location, can be, for example, a hospital central laboratory store, or a general hospital store. In some circumstances where the hospital is small, or there are supply constraints, the central repository **302** can be off-site, such as, for example, a hospital supply company store or a device **104** and consumables store at a remote vendor location.

When a device **104** is consumed by the reading apparatus **102**, it is desirable to maintain an adequate supply of devices **104** available for further consumption by the reading apparatus **102**. FIG. **4** is a flow chart illustrating the steps for operating the system **300** to maintain an adequate supply of devices **104**, in accordance with an exemplary embodiment of the present invention. First, the reading apparatus **102** receives the device **104** at the input port **322** (block **402**). The device **104** can be received by any of the arrangements that have been described, including physical interface, barcoding, RF interface, infrared interface, and the like. Upon receipt of the device **104**, the reading apparatus **102** can communicate via COM port **320** to the central repository **302** that the device **104** has been used (block **404**). The central repository **302** can record the consumption of device **104** in the database **312** (block **406**). The central repository **302** can compare the number of devices **104** that are available in local inventory **305** to the reading apparatus **102** with a predetermined minimum inventory level for the reading apparatus **102** (block **408**). Based on, for example, the consumption rate for a device at a given point-of-care location, the predetermined minimum inventory level for that location can be set. For purposes of illustration and not limitation, if the ambient shelf-life of the device is two weeks, the predetermined minimum inventory level can be set to one week. However, those of ordinary skill in the art will recognize that the predetermined minimum inventory level can be set based on any one or combination of additional or alternative factors that are associated with the

given point-of-care location, such as, for example, a location's needs, device usage rate, the rate at which devices are wasted, the rate at which devices are transferred to other locations, and the like.

If it is determined that the number of devices **104** that are available to the reading apparatus **102** is above the predetermined minimum inventory level, then no action is required (block **410**). If it is determined that the number of devices **104** that are available to the reading apparatus **102** is below the predetermined minimum inventory level, then the central repository **302** can request that additional devices **104** be dispatched so that they can be made available to the reading apparatus **102** (block **412**). The additional devices **104** can be dispatched from within the hospital or from outside of the hospital. It may be desirable, as a matter of economy, that a first in, first out (FIFO) method be adopted, as this preserves the devices **104** with the longest remaining refrigerated shelf-life in the central repository **302**. Thus, according to exemplary embodiments, the consumption of devices **104** by the reading apparatus **102** can be monitored to ensure an adequate supply of devices **104** for each reading apparatus **102**.

According to an exemplary embodiment of the present invention, a unique identification code can be associated with each reading apparatus **102**. The unique identification code can be contained in each communication to the central repository **302**. The central repository **302** can contain information in its database **312** that allows the central repository **302** to identify the location of a specific reading apparatus **102**. For example, the central repository **302** can recognize, based on identifying information (e.g., Internet Protocol (IP) address) contained within the database **312**, the specific infrared link, network port, or other communication connection that is used by the reading apparatus **102**, thereby identifying the location of the reading apparatus **102**. Thus, the central repository **302** can track the inventory levels in each department's local inventory **305**. When devices **104** are dispatched to a given department, one or more of the reading apparatus **102** in that department can be used to scan the new inventory.

According to exemplary embodiments of the present invention, initiation of the dispatch of the devices **104** and other consumable items from the central repository **302** to the individual departments can be prompted by sending an instruction for dispatch by a hospital's consumables management system. This can be, for example, an e-mail communication to personnel in the central repository **302**, an automated dispatch instruction where inventory management at the central repository **302** is automated and under computer control, a display message on the computer screen of the management system, or any other form of communication of an instruction typical of a hospital's consumables management system. It will be apparent to one skilled in the art that the degree of automation and computer control will vary between these institutions. Thus, the exact embodiment of the dispatch initiation is dependent upon the needs, budget, existing management system infrastructure, and the like of the hospital.

According to exemplary embodiments, the central depository **302** determines whether the number of devices **104** in local inventory **305** is adequate for reading apparatus **102**. However, it should be appreciated that such a determination can be made by other computing systems, such as by reading apparatus **102**. It should also be appreciated that, while a single reading apparatus **102** is shown in FIG. **3**, multiple reading apparatus **102** can be included within the system **300**, and specifically within a department sharing the local inventory **305** within the hospital. According to exemplary embodiments, the number of devices **104** that are available in the local inventory **305** for use by any of the reading apparatus **102** is monitored so that an adequate supply of devices **104** are available for use with each of the reading apparatus **102**.

It should further be appreciated by persons of ordinary skill in the art that the method of FIG. **4** is applicable to a variety of types of devices **104**, each of which is capable of being used for a different test. The devices **104** can include, for example, blood analysis devices, urine analysis devices, serum analysis devices, plasma analysis devices, saliva analysis devices, cheek swab analysis devices, or any other type of disposable diagnostic device that can be used for point-of-care sample testing. The central repository **302** can monitor the use of particular types of devices **104** and can dispatch further inventories of those particular devices **104**. The method of FIG. **4** is also applicable to other types of consumable items as herein described. For example, in a neonatal intensive care unit (NICU), each device **104** may be used with a heel-stick device, a capillary collection device, a swab to clean the collection site, a pair of latex gloves, and the like. In an emergency room, a device **104** for electrolytes may be used in conjunction with a swab, latex gloves, a needle-stick device, a vacutainer, a syringe, and the like. Other combinations of consumable items would be evident to those performing point-of-care testing. The inventory for the consumable items can thus be effectively monitored according to exemplary methods of the present invention. For example, when dispatching a given number of devices **104** to the NICU, the system can also dispatch a given number of heel-stick devices. Such a determination can be based on, for example, a simple one-to-one relationship or a more complicated algorithmic function that accounts for wastage or alternative uses for the consumable item. For example, an algorithm can be created for the inventory control system by tracking the utilization history of these consumable items versus a device **104**.

It should further be appreciated by persons of ordinary skill in the art that the local inventory **305** can contain devices **104** that are refrigerated and that are maintained at ambient temperature. The devices **104** can be identified as being refrigerated or ambient temperature devices (e.g., using their associated identifying information) so that the central repository **302** can maintain proper inventory control of each type of device **104**.

Once the local inventory **305** has been inputted into the database **312** (FIG. **3**), the system **300** can provide a real-time or near real-time estimate of remaining inventory in the local inventory **305**, based on recognizing a consumption of a device **104** or consumable item by receiving an electronic notification from the reading apparatus **102** of the consumption, as described with reference to FIG. **4**. While effectively instantaneous communication and real-time estimates are desirable, the high degree of portability of certain types of point-of-care reading apparatus **102** means that the reading apparatus **102** may be temporarily left at a location in which communication is not enabled. Furthermore, the reading apparatus **102** can run several devices **104** while at a location. Accordingly, the RAM **318** or other computer memory of reading apparatus **102** is of sufficient size to allow storage of the device **104** results until a time that the use can be communicated. According to an exemplary embodiment, the RAM **318** can accommodate up to 100 sets of results, although any number of sets of results can be stored in RAM **318**, depending on the amount of memory used. Thus, exemplary embodiments of the present inven-

tion provide for real-time updates to inventory usage, as well as allow the storage of the usage information in the reading apparatus **102** until such time that this information can be communicated or otherwise downloaded to, for example, the central repository **302**.

The system **300** can also provide an on-demand estimate of remaining inventory, based on analyzing data that has been compiled into the database **312**. These results can be displayed, for example, on the central data station, at the LIS, at the central repository **102** and on the user interface **324** of each individual reading apparatus **102**. The results display can also include a visual or audible flag or warning when estimated inventory falls to, near or below a minimum defined, or predetermined, level. The predetermined level can be set by individual departments or centrally within a hospital to provide for a more efficient overall inventory control based on economic and clinical considerations. These considerations are known in hospital management.

As was discussed previously, the devices **104** can have a finite shelf-life. Accordingly, it is desirable to maintain an adequate supply of devices **104** that have remaining shelf-life and replenish the local inventory **305** as the shelf-life of the devices **104** expire. FIG. **5** is a flow chart illustrating the steps for monitoring the shelf-life of devices **104** and replenishing the local inventory **305**, in accordance with an exemplary embodiment of the present invention. Initially, timestamp information can be entered into the database **312** for the devices **104** that are associated with the local inventory **305** (block **502**). The timestamp information can be entered either manually by an operator or electronically, for example, through bar-code reading at the time the devices **104** are entered into the local inventory **305** and communicated to the central repository **302**. The timestamp information can be maintained in the database **312** of the central repository **302**. The timestamp information can indicate when the devices **104** were added to the local inventory **305** (i.e., creation date) or when the shelf-life of the devices **104** will expire (i.e., expiration date). The central repository **302** can compare the timestamp database entries with the current timestamp (i.e., the current time) (block **504**). If it is determined that the devices **104** have not expired (block **506**), i.e., the current timestamp is before the expiration date of the devices **104**, then the central repository **302** can continue to monitor the timestamp database entries and control is returned to step **504**. If it is determined that the devices **104** have expired (block **506**), i.e., the current timestamp is after the expiration date of the devices **104**, then the devices **104** can be removed from the local inventory **305** (block **508**), both physically and from the computer record of their inventory.

It is then determined if the number of devices **104** in the local inventory **305**, after the expired devices **104** have been removed, is less than the predetermined number of devices **104** for the local inventory **305** (block **510**). If it is determined that the number of devices **104** in the local inventory **305** is above the predetermined number of devices **104**, then control is returned to step **504**. If it is determined that the number of devices **104** in the local inventory **305** is below the predetermined number of devices **104**, then the central repository **302** can dispatch additional devices **104** to replenish the local inventory **305** so that the number of devices **104** exceeds the predetermined minimum number of devices **104** (block **512**). Control is then returned to step **504**, where the monitoring of the timestamp database entries continues. To provide for economically-efficient consumption of the devices **104**, the local inventories **305** can be set to an adequate level to meet demand, but also at a level in which the number of devices **104** that reach their expiration date is reduced or minimized. The number of devices **104** contained within the local inventories **305** can be monitored based on usage so as to dynamically reallocate the number of devices **104** among the local inventories **305** based on trends in usage.

As discussed previously, FIG. **4** illustrates how the devices **104** are dispatched to the local inventory **305** from the central repository **302**. FIG. **6** is a block diagram illustrating a system **600**, including multiple central data stations **604**, **606** and **608**, wherein the devices **104** are distributed between the departments that are controlled by the central data stations **604**, **606** and **608**, in accordance with exemplary embodiments of the present invention. The system **600** includes a central repository **302**, a central data station **604** for department X, a central data station **606** for department Y and a central data station **608** for department Z. However, the system **600** can include any number of central data stations. A local inventory **610** is associated with central data station **604**, a local inventory **612** is associated with central data station **606** and a local inventory **614** is associated with central data station **606**, although any number of local inventories can be associated with each central data station. Local inventories **610**, **612** and **614** can contain any number of devices **104**. For purposes of illustration and not limitation, in the system **600** depicted in FIG. **6**, local inventory **610** includes three devices **104**, local inventory **612** includes two devices **104**, and local inventory **614** does not include any devices **104**.

The central data stations **604**, **606** and **608** can provide connectivity between individual reading apparatus **102** and central locations, such as, for example, a LIS or HIS, and device **104** and central repositories **302**. The central data stations **604**, **606**, and **608** can be connected with the various system constituents using any type of communications connection that is capable of transmitting and receiving electronic information, such as, for example, an Ethernet connection or other computer network connection. The central data stations **604**, **606** and **608** can optionally provide a direct link back to a vendor's information system, for example via the Internet, a dial-up connection or other direct or indirect communication link, or through the LIS, HIS, or central repository **302**. Such an exemplary embodiment can provide for automated re-ordering of devices **104** to maintain the predetermined levels of inventory at the hospital's central repository **302**, and allow the vendor to forecast demand and adequately plan the manufacture of the devices **104**.

In an emergency situation, the inventory level at the central repository **302** or individual locations can fall below that necessary to meet the normal demand based on the predetermined levels for each department. Thus, the system according to exemplary embodiments of the present invention can automatically adjust the predetermined inventory levels in each department based on various criteria. One exemplary criterion would be, for example, to distribute devices **104** preferentially to the departments that treat patients with highest acuity. Other similar such criteria can be used.

In certain emergency circumstances, the system **600** can initiate transfer of devices **104** from one department or local inventory to another, despite these devices **104** having already been moved out of the central repository **302**. For example, where a hospital ER is dealing with a major accident, the devices **104** useful for the triage of patients can be redistributed to the emergency room. In such a situation, a flagged message can be sent from the central repository

302 to the central data stations of departments other than the ER to initiate re-dispatch. The method of redistribution of devices **104** can also be extended to other consumable items used in connection with the devices **104**, such that the consumable items can be transferred between departments when necessity arises. Such redistribution of inventory enables the hospital to manage these resources in an efficient manner.

FIG. **7** is a flow chart illustrating the steps for determining whether to re-dispatch devices **104**, in accordance with an exemplary embodiment of the present invention. The central repository **302** can monitor device **104** use and/or expiration (block **702**). Thus, the central repository **302** attempts to maintain the local inventory levels above the predetermined inventory level. The central repository **302** can receive messages from, for example, central data stations **604**, **606** and **608**. If a message is received, the central repository **302** can determine if the message contains an emergency flag (block **704**). If the message does not contain an emergency flag, the control returns to block **702**. If the message does contain an emergency flag, then the central repository **302** initiates a re-dispatch from amongst the local inventories (block **706**), thus maintaining the local inventory level above the predetermined inventory levels.

According to another exemplary embodiment of the present invention, the central repository **302** can be used to control and dynamically modify the predetermined level of inventories **610**, **612** and **614** for each department. The central repository **302** can be in direct or indirect communication with a vendor information system (not shown), in which the vendor information system is responsible for providing devices **104** and, optionally, other consumables to the hospital. The central repository **302** can be connected to the vendor information system through human intervention, i.e., verbal communication, but preferably is connected via automated computer-controlled processes, such as, for example, a computer connection (e.g., a dial-up connection, an Internet or other direct or indirect network connection using hard-wired, infrared, optical, wireless or any other form of communication medium that allows for the transfer of electronic information).

The initial predetermined levels of inventory and subsequent modifications can be based on variations in demand between department, the acuity of the patients in the departments, or even an emergency situation, such as, for example, a hospital power failure emergency, a transportation emergency affecting the supply of devices **104** to the hospital, and the like.

Because devices **104** expire within a time period after being placed in an ambient temperature setting, it is desirable to maintain the predetermined inventory level based on actual usage. For example, if a department is not using its allocated devices **104** within the ambient or room temperature storage period, then remaining devices **104** will be wasted. FIG. **8** is a flow chart illustrating the steps for re-dispatching the devices **104** between local inventories **610** to reduce excess devices **104**, in accordance with exemplary embodiments of the present invention. The device **104** usage rate is monitored (block **802**). The monitoring can be performed by the central repository **302**, the reading apparatus **102**, or any other computing system. Based on the monitored device **104** usage rate, it can be determined whether any devices **104** will expire, i.e., will not be used before the room temperature or ambient storage time has elapsed (block **804**). If devices **104** will not expire, then the device **104** usage rate is again monitored, and control returns to block **802**. If devices **104** will expire, then the predetermined inventory level for the department can be lowered to reflect a level that is more appropriate based on the actual usage (block **806**). Then, it can be determined where additional devices **104** (i.e., the devices **104** that will expire) can be used prior to their expiration (block **808**). The excess devices **104** can be sent to another department where they can be used prior to their expiration (block **810**). Finally, the actual inventory level of the initial department is adjusted to reflect that the sent devices **104** are no longer available for consumption within the initial department (block **812**). Thus, according to exemplary embodiments of the present invention, rather than sending new devices **104** to a department and allowing other devices **104** to expire, devices **104** that are to expire are used and waste is reduced.

According to an alternative exemplary embodiment, by recognizing that devices **104** in the local inventory (e.g., local inventory **610**) have expired, a waste rate can be computed. Specifically, because some devices **104** were contained within the local inventory **610** and were not used because they expired, they were thus wasted. By comparing the number of devices **104** that were dispatched to the local inventory **610** and the number of devices **104** that were used, the number of devices **104** that were wasted (i.e., not used and expired) can be determined. Based on the waste rate calculation, the predetermined local inventory level can be recalculated to reduce or otherwise modify the waste rate. The new predetermined local inventory level can then be updated in, for example, the database **312** of the central repository **302**.

According to another exemplary embodiment of the present invention, it is desirable to make certain devices **104** unavailable for use. For example, if a device **104** has expired due to having exceeded the room temperature or ambient storage time, the device **104** should not be used. FIG. **9** illustrates a flow chart for "locking out" devices **104**, in accordance with exemplary embodiments of the present invention. Initially, an indication of when certain devices **104** have been removed from the refrigerator is provided to the reading apparatus **102** (block **902**). Based on the indication, the reading apparatus **102** can determine when the removed devices **104** will expire due to exposure to ambient or room temperature. Such a determination can be based on direct information (e.g., the removed devices **104** will expire on a particular date), or computed information (e.g., the removed devices **104** will expire a certain amount of time from the date that they were removed from the refrigerator, depending on factors such as, for example, the actual ambient or room temperature). It can then be determined whether the ambient or room temperature timing for the removed devices **104** has elapsed (block **904**). If the ambient or room temperature timing has not elapsed, then control returns to block **904** and the reading apparatus **102** continues to monitor whether the ambient or room temperature timing has elapsed. If the ambient or room temperature timing has elapsed, then the reading apparatus **102** locks out the expired devices **104** (block **906**). Because the expired devices **104** are locked out, the expired devices **104** are not used. Thus, exemplary embodiments of the present invention can prevent devices **104** from being used that have expired.

The steps of a computer program as illustrated in FIGS. **4**, **5** and **7-9** for controlling an inventory of a plurality of point-of-care diagnostic devices can be embodied in any computer-readable medium for use by or in connection with an instruction execution system, apparatus, or device, such as a computer-based system, processor-containing system, or other system that can fetch the instructions from the instruction execution system, apparatus, or device and

execute the instructions. As used herein, a "computer-readable medium" can be any means that can contain, store, communicate, propagate, or transport the program for use by or in connection with the instruction execution system, apparatus, or device. The computer-readable medium can be, for example but not limited to, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, device, or propagation medium. More specific examples (a non-exhaustive list) of the computer-readable medium can include the following: an electrical connection having one or more wires, a portable computer diskette, a random access memory (RAM), a read-only memory (ROM), an erasable programmable read-only memory (EPROM or Flash memory), an optical fiber, and a portable compact disc read-only memory (CDROM).

It will be appreciated by those of ordinary skill in the art that the present invention can be embodied in various specific forms without departing from the spirit or essential characteristics thereof. The presently disclosed embodiments are considered in all respects to be illustrative and not restrictive. For example, it is to be understood that the present invention is applicable to other methods and apparatus for inventory management in a point-of-care system beyond sample testing devices. The scope of the invention is indicated by the appended claims, rather than the foregoing description, and all changes that come within the meaning and range of equivalence thereof are intended to be embraced.

All United States patents and patent applications, foreign patents and patent applications, and publications discussed above are hereby incorporated by reference herein in their entireties to the same extent as if each individual patent, patent application, or publication was specifically and individually indicated to be incorporated by reference in its entirety.

What is claimed is:

1. A point of care testing system, comprising:

a disposable device comprising:

a port configured to receive a patient sample;

analytical elements including electrodes or optics for sensing analytes within said patient sample; and

a time and temperature sensor comprising temperature-sensing circuitry configured to:

provide a code or signal associated with the disposable device that indicates a first time at which the disposable device has been moved from a refrigerated storage condition to an ambient storage condition;

monitor a temperature of the device at the ambient storage condition prior to the disposable device receiving the patient sample;

determine whether the temperature has remained below, above, or within a predetermined temperature range; and

in response to determining that the temperature has remained below or above the predetermined temperature range, increase or decrease, respectively, a predetermined shelf life of the device by a predetermined amount of time that is dependent upon the temperature to generate a modified shelf life;

an analyzer comprising:

a port configure to receive the disposable device; and

a processor and a memory storing program instructions, wherein the program instructions when operated on by the processor, cause the processor to perform operations comprising:

obtain the code and the modified shelf life from the disposable device;

determine a second time when the disposable device will expire due to the temperature of the device at the ambient storage condition based on the code and the modified shelf life;

determine whether the second time has elapsed prior to use of the disposable device to determine whether the modified shelf life of the disposable device is exceeded; and

when the second time has elapsed, lock out the disposable device such that the disposable device is prevented from being used.

2. The device of claim **1**, wherein the predetermined shelf life is a finite ambient temperature shelf life that is dependent upon an ambient temperature in which the disposable device is stored.

3. The device of claim **2**, wherein said finite ambient temperature shelf life is from about 3 days to 3 months.

4. The device of claim **1**, wherein the time and temperature sensor further comprises a chemical component, a liquid crystal, a mechanical device, a threshold device, or combinations thereof.

5. The device of claim **1**, wherein the patient sample comprises blood, plasma, serum, interstitial fluid, spinal fluid, urine, bodily secretions or combinations thereof.

6. The device of claim **1**, wherein the disposable device is a blood analysis device, a urine analysis device, a serum analysis device, a plasma analysis device, a saliva analysis device, a cheek swab analysis device, or a diagnostic device.

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