Office de la Propriété Intellectuelle du Canada
Un organisme d'Industrie Canada

Canadian Intellectual Property Office
An agency of Industry Canada

CA 2618976 C 2017/01/03

(11)(21) **2 618 976**

(12) **BREVET CANADIEN**
CANADIAN PATENT

(13) **C**

(86) **Date de dépôt PCT/PCT Filing Date:** 2006/08/11
(87) **Date publication PCT/PCT Publication Date:** 2007/02/22
(45) **Date de délivrance/Issue Date:** 2017/01/03
(85) **Entrée phase nationale/National Entry:** 2008/02/12
(86) **N° demande PCT/PCT Application No.:** US 2006/031519
(87) **N° publication PCT/PCT Publication No.:** 2007/022017
(30) **Priorité/Priority:** 2005/08/12 (US60/708,125)

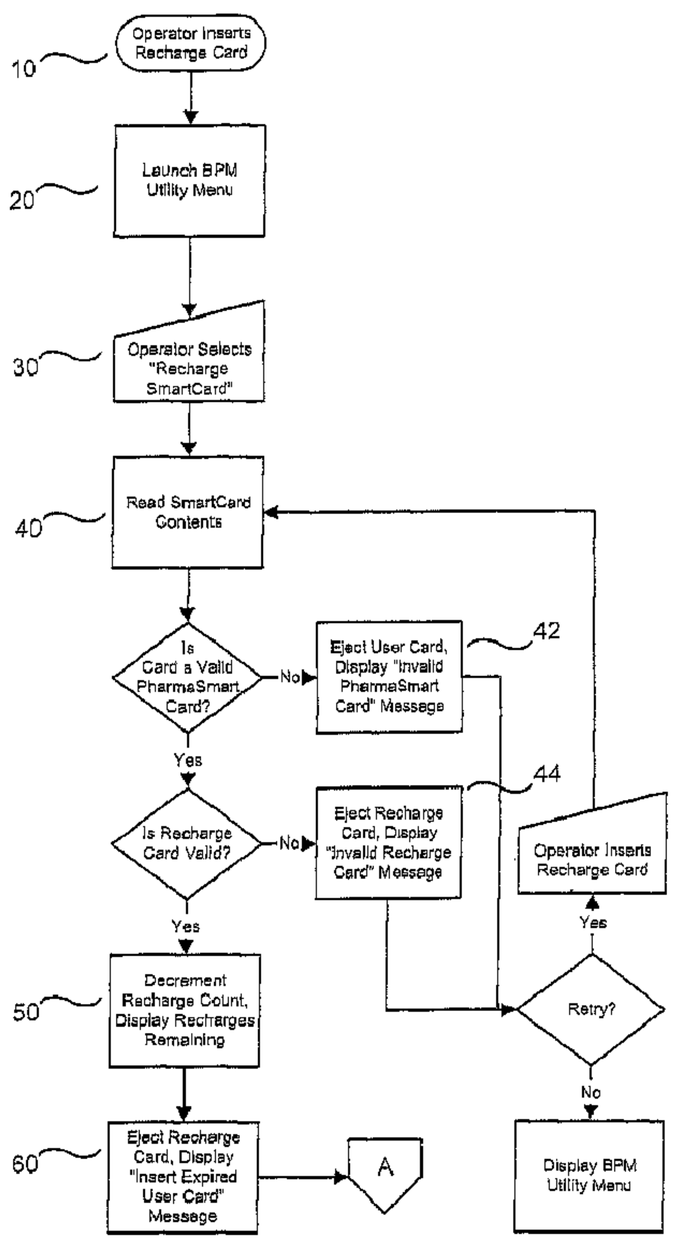
(51) **Cl.Int./Int.Cl.** ***G06K 5/00*** (2006.01),
A61B 5/00 (2006.01), ***G06F 19/00*** (2011.01),
G06K 19/07 (2006.01)

(72) **Inventeurs/Inventors:**
SARKIS, FREDERICK W., JR., US;
SARKIS, JOSEPH O., CA;
GOODWIN, LISA, US

(73) **Propriétaire/Owner:**
PHARMA-SMART INTERNATIONAL, INC., US

(74) **Agent:** RIDOUT & MAYBEE LLP

(54) **Titre : PROCEDE ET APPAREIL D'ENREGISTREMENT DE LA PRESSION ARTERIELLE SUR CARTE INTELLIGENTE RECHARGEABLE**
(54) **Title: RECHARGEABLE SMART CARD BLOOD PRESSURE RECORDING METHOD AND APPARATUS**



(57) **Abrégé/Abstract:**
Enabling the providers of automated blood pressure readings, such as pharmacies, corporate work sites, health clubs and other customers, to charge a fee for the long-term use of a memory card to record non-invasive physiological test data and make the

CA 2618976 C 2017/01/03

(11)(21) **2 618 976**

(13) **C**

(57) **Abrégé(suite)/Abstract(continued):**
data available for health consultations. In an automated blood pressure system with one or more memory-card interface devices, a custom- formatted end-user memory card keeps track of the user's non-invasive physiological test data, and a recharge memory card controls the provider's recharging of the end-user memory card after the end-user memory card expires. The contents of the recharge memory card are updated in order to track its use by the provider of the readings.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 February 2007 (22.02.2007)

PCT

(10) International Publication Number
WO 2007/022017 A3

(51) International Patent Classification:
G06K 5/00 (2006.01) *G06F 19/00* (2006.01)
G06K 19/00 (2006.01) *A61B 5/00* (2006.01)

(21) International Application Number:
PCT/US2006/031519

(22) International Filing Date: 11 August 2006 (11.08.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/708,125 12 August 2005 (12.08.2005) US

(71) Applicant *(for all designated States except US)*: **PHARMA SMART LLC** [US/US]; 3495 Winton Place, Bldg. A, Ste. 1, Rochester, NY 14623 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **SARKIS, Frederick, W., Jr.** [US/US]; 65 Landing Road, S., Rochester, NY 14610 (US). **SARKIS, Joseph, O.** [US/CA]; Suite 505, 4438 W. 10th Avenue, Vancouver, B.C. V6R4R8 (CA). **GOODWIN, Lisa** [US/US]; 21 Woodlyn Way, Penfield, NY 14526 (US).

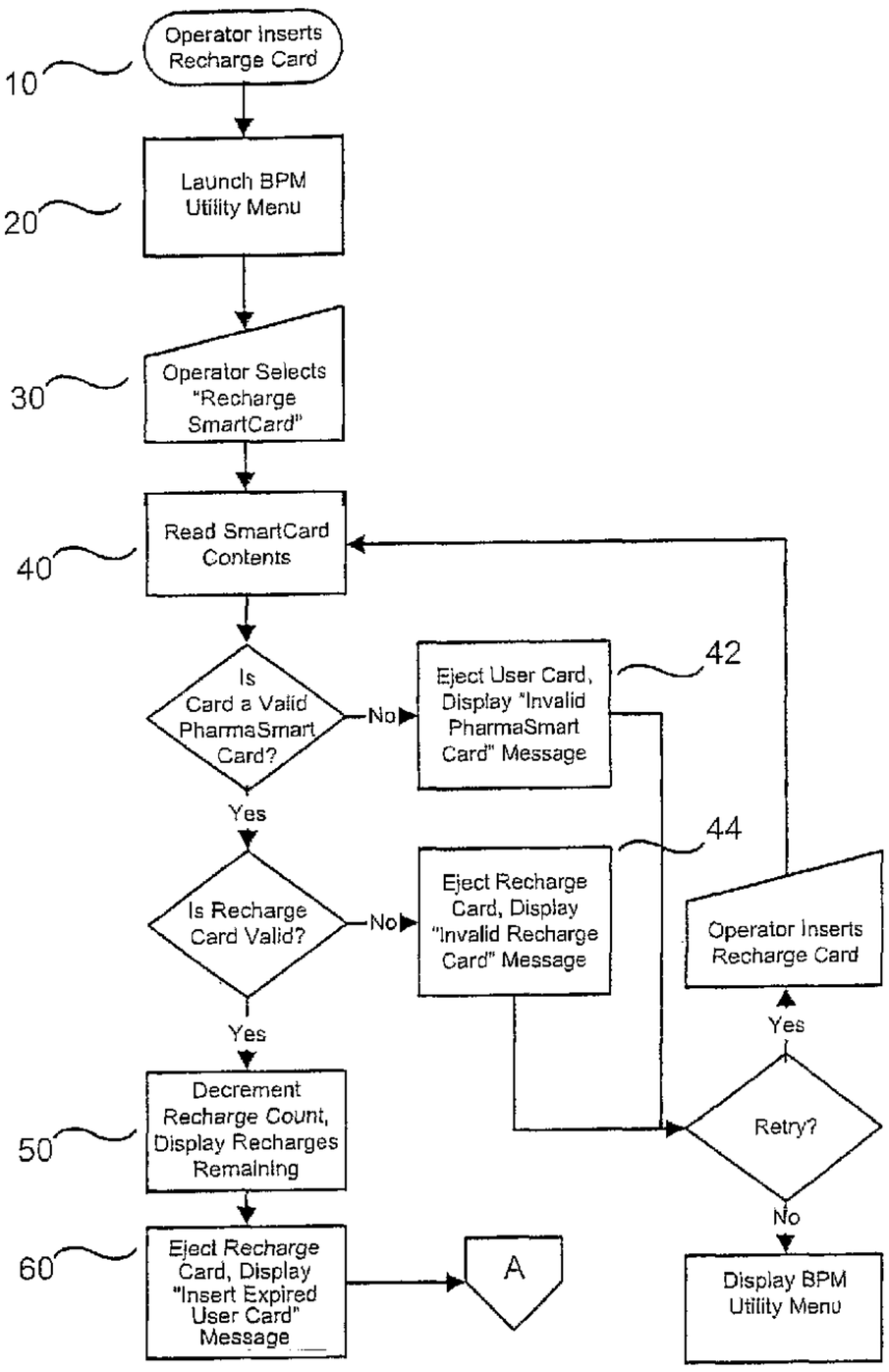
(74) Agent: **FITZGERALD, Thomas, R.**; HISCOCK & BARCLAY, LLP, 2000 HSBC Plaza, Rochester, NY 14604-2404 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,

[Continued on next page]

(54) Title: RECHARGEABLE SMART CARD BLOOD PRESSURE RECORDING METHOD AND APPARATUS



(57) Abstract: Enabling the providers of automated blood pressure readings, such as pharmacies, corporate work sites, health clubs and other customers, to charge a fee for the long-term use of a memory card to record non-invasive physiological test data and make the data available for health consultations. In an automated blood pressure system with one or more memory-card interface devices, a custom- formatted end-user memory card keeps track of the user's non-invasive physiological test data, and a recharge memory card controls the provider's recharging of the end-user memory card after the end-user memory card expires. The contents of the recharge memory card are updated in order to track its use by the provider of the readings.

WO 2007/022017 A3

WO 2007/022017 A3

FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) Date of publication of the international search report:
7 June 2007

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

RECHARGEABLE SMART CARD BLOOD PRESSURE RECORDING METHOD AND APPARATUS

BACKGROUND AND FIELD OF THE INVENTION

The invention relates to the use of "smart card" storage of data, and more specifically to the use of "smart cards" to store medical test result information.

SUMMARY

Automated blood pressure (ABP) machines and other types of non-invasive medical self-monitoring equipment, e.g., automated glucose monitors, cholesterol monitors, blood oxygen monitors are either purchased or leased by pharmacies, corporate work sites, health clubs and other customers. For the purpose of this discussion, these customers will be referred to as "Locations".

The Locations provide ABP and other medical self-monitoring machines as a service to their customers, employees, members, etc. For the purpose of this discussion, we will refer to these customers, employees, and members using the ABP or other medical self-monitoring machines as the "End Uscr". Such Locations often offer the End User the option to use a memory card or a Smart Card to record and track their blood pressure history over time.

As used in this patent specification, the term "memory card" includes any device that is generally the size of a credit card (2" x 3.25") with power, ground, input and output ports or terminals and an array of memory cells arranged in rows and columns. Such memory cells are typically made of flash memory which are static memory devices that retain their information when electrical energy to the card is removed. Smart Cards include memory arrays of flash memory cells and have a microprocessor or other control or logic circuitry. One purpose of the microprocessor or other circuitry is to provide security for the data on the card. Such Smart Cards have encryption and decryption keys or stored programs that secure the card from unwanted access.

Each time the End User uses the memory card or Smart Card in the machine, the blood pressure reading, pulse rate, and the date of the measurement are recorded on the card. The ABP machine then prints out a history of the End User's most recent results (as many as 10 results), and provides a calculated average blood pressure and pulse rate for the

End User.

Similar monitoring, data collection, data compilation, and data presentation opportunities exist for other forms of medical self-monitoring equipment. A printed history of the End User's most recent results for any such monitoring process is important as it provides the End User with information to share with physicians, pharmacists, and other health care professionals. Recorded ABP information assists the health care professional in evaluating the End User's blood pressure history and the effectiveness of any End User hypertension control program. Recorded glucose levels, cholesterol levels, blood oxygen levels, and other records of medical monitoring for the End User can likewise assist health care professionals in their care of that End User.

Embodiments of the present invention enable the providers of automated blood pressure readings and other non-invasive physiological test data, such as pharmacies, corporate work sites, health clubs and other customers, to charge an annual fee for the use of a memory card or Smart Card to record the non-invasive physiological test data and make the data available for health consultations. Software embodying the invention installed in an automated blood pressure system or other medical self-monitoring system with one or more memory card or Smart Card interface devices, uses a custom-formatted end-user memory card for keeping track of the user's noninvasive physiological test data and the dates these readings were taken. The software also uses a recharge memory card for controlling the provider's recharging of the end-user memory card. The embodiment's processing reactivates the end-user memory card or Smart Card after it expires, and updates the contents of the recharge memory card in order to track the number of recharges provided.

Thus, according to one aspect of the invention, there is provided an apparatus for recording and tracking non-invasive physiological test data comprising:

a machine for automatically detecting non-invasive physiological test data of an individual;

means for recording the detected non-invasive physiological test data on a first transportable device adapted to receive and hold non-invasive physiological test data;

means for recording the date of each recording of non-invasive physiological test data on the first transportable device;

means for deactivating the first transportable device after a first predetermined

number of readings, after a first predetermined duration, or both; and

means for reactivating the first transportable device to store a second predetermined number of readings, a second predetermined duration, or both.

According to another aspect of the invention, there is provided an apparatus for recording and tracking non-invasive physiological test data comprising:

a machine for automatically detecting non-invasive physiological test data of an individual, said machine comprising a computer having software stored on a computer readable medium including instructions for execution by the computer;

means for recording the detected non-invasive physiological test data on a first transportable device adapted to receive and hold non-invasive physiological test data;

means for recording the date of each recording of non-invasive physiological test data on the first transportable device;

means for deactivating the first transportable device after a first predetermined number of readings, after a first predetermined duration, or both; and

means for reactivating the first transportable device to store a second predetermined number of readings, a second predetermined duration, or both;

wherein the means for limiting the duration and number of recordings made on the first transportable device to a first period of time further comprises:

means for reading the expiration date information, stored on the first transportable device and specifying the end of the first period of time;

means for reading a source of current date information;

said software program on said computer of said machine for comparing the current date information with the expiration date information;

means for taking and recording non-invasive physiological test data on the first transportable device when the results of said comparison is a date between the expiration date information and the current date information.

According to yet another aspect of the invention, there is provided an apparatus for recording and tracking non-invasive physiological test data comprising:

a machine for automatically detecting non-invasive physiological test data of an individual, said machine comprising a computer having software stored on a computer readable medium including instructions for execution by the computer;

means for recording the detected non-invasive physiological test data on a first transportable device adapted to receive and hold non-invasive physiological test data;

means for recording the date of each recording of non-invasive physiological test data on the first transportable device;

means for deactivating the first transportable device after a first predetermined number of readings, after a first predetermined duration, or both; and

means for reactivating the first transportable device to store a second predetermined number of readings, a second predetermined duration, or both;

wherein the means for recharging the first transportable device to extend the fixed period of time to a second period of time further comprises:

a second transportable device for limiting the number of recharge operations performed on one or more first transportable devices;

a machine-readable and machine-writable recording of the number of recharge operations, stored on the second transportable device and specifying the number of recharge operations remaining to be performed;

said software program on said computer of said machine for decrementing the number of recharge operations remaining to be performed until no further recharge operations remain on the second transportable device; and

said software program on said computer of said machine for resetting the expiration date information stored on the first transportable device.

According to still another aspect of the invention, there is provided a process for recording and tracking non-invasive physiological test data comprising the steps of:

detecting the non-invasive physiological test data of an individual;

recording the detected non-invasive physiological test data on a first transportable device adapted to receive and hold non-invasive physiological test data;

recording the date of each recording of non-invasive physiological test data on the first transportable device;

limiting the duration, number of recordings made, or both on the first transportable device to a first period of time;

deactivating the first transportable device after the first period of time; and

reactivating the first transportable device to store a second period of time comprising

a duration, number of recordings made, or both.

According to a further aspect of the invention, there is provided a process for recording and tracking non-invasive physiological test data comprising the steps of:

detecting the non-invasive physiological test data of an individual;

recording the detected non-invasive physiological test data on a first transportable device adapted to receive and hold non-invasive physiological test data;

recording the date of each recording of non-invasive physiological test data on the first transportable device;

deactivating the first transportable device after a first predetermined number of readings, after a first predetermined duration, or both; and

reactivating the first transportable device to store a second predetermined number of readings, a second predetermined duration, or both;

wherein the step of recording the detected non-invasive physiological test data on a first transportable device further comprises the steps of:

at the time of routine use by a user, reading the expiration date of the first period of time stored on the first transportable device;

at the time of routine use by a user, comparing the expiration date to the current date; and

when the expiration date has not been passed at the time of routine use by a user, recording the detected non-invasive physiological test data on the first transportable device.

According to yet a further aspect of the invention, there is provided a process for recording and tracking non-invasive physiological test data comprising the steps of:

detecting the non-invasive physiological test data of an individual;

recording the detected non-invasive physiological test data on a first transportable device adapted to receive and hold non-invasive physiological test data;

recording the date of each recording of non-invasive physiological test data on the first transportable device;

deactivating the first transportable device after a first predetermined number of readings, after a first predetermined duration, or both; and

reactivating the first transportable device to store a second predetermined number of readings, a second predetermined duration, or both;

wherein the step of reactivating the first transportable device further comprises the steps of:

at the time of authorization of additional reactivation operations for one or more first transportable devices, writing a count of reactivation operations available onto a second transportable device;

at the time of reactivation of the first transportable device, reading a count of recharge operations available from the second transportable device;

at the time of reactivation of the first transportable device, decrementing the count of recharge operations available;

when the count of recharge operations available has reached zero, notifying the operator that the second transportable device requires authorization of further recharge operations; and

when the count of recharge operations available has not reached zero, writing the expiration date of the second period of time onto the first transportable device.

According to a still further aspect of the invention, there is provided an apparatus for recording and tracking usage information comprising:

a machine for automatically detecting parameters of usage of a service, resource or object;

means for recording parameters of the detected usage on a first transportable device adapted to receive and hold usage data;

means for limiting the duration, number of recordings made, or both on the first transportable device to a first period of time, wherein the first transportable device ceases to record non-invasive physiological test data once a predetermined limit for the first period of time is exceeded;

means for reactivating the first transportable device to extend the first period of time to a second period of time;

means for limiting the duration, number of recordings made on the first transportable device, or combination thereof to a second period of time;

means for preventing access to or alteration of any component of the records of usage information;

wherein reactivating the first transportable device to extend the first period of time to a second period of time permits continued recording of non-invasive physiological test data until a predetermined limit for the second period of time is reached.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. IA shows the processing flow of steps for updating a Recharge Card using a single-port card reader.

Fig. 1B shows the processing flow of steps for recharging a User Smart Card using a single-port card reader.

Fig. 1C shows the processing flow of steps for correcting the Recharge Count on a Recharge Card using a single-port card reader.

Fig. 2A shows the processing flow of steps for updating a Recharge Card using a dual-port card reader.

Fig. 2B shows the processing flow of steps for recharging a User Smart Card and correcting the Recharge Count on a Recharge Card using a dual-port card reader.

Fig. 3A shows the format of the data stored on the User Smart Card prior to encryption. A memory map of the encrypted card is not shown as the encryption techniques are well known in the art.

Fig. 3B shows the format of the data stored on the Recharge Card.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

Basic embodiments of the invention comprise both an apparatus and a process, developed initially for the PharmaSmart Model PS-2000 blood pressure machine and similar machines made by others. The PS-2000 is equipped to use blood pressure Smart Cards to store blood pressure readings for the End User. It is likely that millions of these blood pressure Smart Cards will eventually be in circulation in North America and in other parts of the world. Embodiments of the invention provide the option for Locations to: 1) generate additional revenues by charging the End User an annual fee for use of the Smart Card, and 2) provide End User with at least one annual blood pressure consultation.

The use of the basic embodiments of the invention is as follows. The Location issues a Smart Card to the End User. The first time the End User uses the Smart Card in the ABP

machine, it electronically "stamps" a recharge date onto the Smart Card. The recharge date is a fixed or variable date, but preferably is one (1) year from the date of first use in the machine. This means the End User has a full year of use of the Smart Card before it will require a recharge. If the card is not recharged by the recharge date, it will no longer work in the ABP machine.

At any time, the Location may purchase recharge credits directly from manufacturer of the ABP machine. These credits are loaded onto a unique "Recharge Smart Card", and shipped directly to the Location. Upon the End User's request, the Location personnel can use the Recharge Smart Card to recharge the End User's card for an additional year. In order to do this the Location personnel must have both the Recharge Smart Card and the End User Smart Card in hand. They then simply insert the Recharge Smart Card into the ABP machine and follow the instructions provided on the machine's display. Once completed, an updated recharge date is electronically "stamped" onto the End User Smart Card providing another full year of use of the Smart Card. Each time the Location personnel recharges an End User Smart Card, the Recharge Smart Card is debited one (1) recharge credit. Once all of the recharge credits are used, the Location personnel discards the Recharge Smart Card and, as required, may order an additional Recharge Smart Card from the ABP machine manufacturer.

The ABP machine manufacturer may charge Locations a fee for each recharge credit they order, and the Location, in turn, can charge the End User an annual fee for the User Smart Card.

Figs. 1A through 1C show a combined flow chart presenting specific software design and operational details of the Smart Card recharge process as performed using a single-port card reader. There are three overall parts of the recharge process: 1) updating the Recharge Card, 2) updating the User Smart Card, and 3) restoring the Recharge Card to an earlier state when a User Smart Card update has not been completed. Fig. 1A shows the basic steps of the updating of a Recharge Card. Refer to Fig. 3 A for the data memory map for the data fields stored on the User Smart Card (User Type '00') and to Fig. 3B for the data fields stored on the Recharge Card (User Type 'E0').

1. The operator inserts (10) the Recharge Card in the card reader.
2. The system presents (20) the BPM utility menu to the operator.
3. The operator selects (30) the "Recharge Smart Card" option from the menu.

4. The system reads (40) the Recharge Card contents. If the card is not a valid PharmaSmart card of any type, the system displays (42) a message to that effect and prompts the user to use a PharmaSmart Recharge card.
5. If the card is a valid PharmaSmart card but not a Recharge Card, the system displays (44) a message to that effect and prompts the user to use a PharmaSmart Recharge card.
6. If the card is a valid PharmaSmart Recharge Card, the system decrements (50) the card's Recharge Count, and displays the number of recharges remaining on the card.
7. The system ejects the Recharge Card and prompts (60) the operator to insert the User Smart Card.

Once the Recharge Smart Card is decremented one credit, the User Smart Card updating process begins. See Fig. IB for the steps:

1. The operator inserts (70) the User Smart Card.
2. If the card is not a valid PharmaSmart card of any type, the system displays (72) a message to that effect and prompts the user to use a PharmaSmart user Smart Card.
3. If the card is a valid PharmaSmart card but not a User Smart Card, the system displays (74) a message to that effect and prompts the user to use a PharmaSmart User Smart Card.
4. If the card is a valid PharmaSmart User Smart Card, the system advances (80) the card's Expiration Date by 365 days, or if the Expiration Date has passed, sets a new Expiration Date 365 days from the User Smart Card's update.
5. The system notifies (90) the operator of the successful update and displays the total number of days until the User Smart Card will require another recharge.
6. The system ejects (100) the User Smart Card.
7. The system updates (110) its management report data.
8. The system displays (120) the BPM Utility Menu.

During the User Smart Card update, the operator may decide that the recharge process cannot be completed. If the process is not completed, the Recharge Card and the User Smart Card are left in states that are mutually inconsistent. The Recharge Card indicates that a

recharge has been done, while the User Smart Card has not been recharged. Consequently, the inconsistency should be corrected. The Recharge Card should be incremented one Recharge Credit.

See Fig. 1C. The steps:

1. The system prompts (130) the operator to insert the Recharge Card.
2. The system reads the Recharge Card contents. If the card is not a valid PharmaSmart card of any type, the system displays (142) a message to that effect and prompts the operator to use a PharmaSmart Recharge card.
3. If the card is a valid PharmaSmart card but not a Recharge Card, the system displays (144) a message to that effect and prompts the operator to use a PharmaSmart Recharge card.
4. If the card is a valid PharmaSmart Recharge Card, the system increments (150) the card's Recharge Credits by one credit, and displays the number of Recharge Credits remaining on the card.
5. The system updates (160) its management report data.
6. The system displays (170) the BPM Utility Menu.

In an alternative embodiment of the system, a dual-port card reader allows the Recharge Card to remain accessible to the system while the User Smart Card is being updated. In this alternative dual-port embodiment, Step 4 of Fig. 1C is done as part of the process of Fig. 1A after the operator has interrupted the User Smart Card update, and the entire process is simplified as shown in Figs. 2A and 2B. This alternative dual-port embodiment, while more expensive in hardware terms, has the advantage of eliminating all manual steps for correcting the inconsistency between the Recharge Card and the User Smart Card.

Fig. 2A shows the basic steps of the updating of a Recharge Card:

1. The operator inserts (10) the Recharge Card in the Recharge card reader slot.
2. The system presents (20) the BPM utility menu to the operator.
3. The operator selects (30) the "Recharge Smart Card" option from the menu.
4. The system reads (40) the Recharge Card contents. If the card is not a valid PharmaSmart card of any type, the system displays (42) a message to that effect and prompts the user to use a PharmaSmart Recharge card.

8. If the card is a valid PharmaSmart card but not a Recharge Card, the system displays (44) a message to that effect and prompts the user to use a PharmaSmart Recharge card.
9. If the card is a valid PharmaSmart Recharge Card, the system decrements (50) the card's Recharge Count, and displays the number of recharges remaining on the card.
10. The system prompts (60) the operator to insert the expired User Smart Card in the User Smart Card card reader slot.

Once the Recharge Smart Card is updated, the User Smart Card updating process begins. See Fig. 2B for the steps:

1. The operator inserts (70) the User Smart Card in the User Smart Card reader slot.
2. If the card is not a valid PharmaSmart card of any type, the system displays (72) a message to that effect and prompts the user to use a PharmaSmart user card.
3. If the card is a valid PharmaSmart card but not a User Smart Card, the system displays (74) a message to that effect and prompts the user to use a PharmaSmart User Smartcard.
4. If the card is a valid PharmaSmart User Smart Card, the system advances (80) the card's Expiration Date by 365 days, or if the Expiration Date has passed, sets a new Expiration date 365 days from the User Smart Card's update.
5. If the operator has interrupted the User Smart Card update process without change to the User Smart Card's Expiration Date, the system increments (150) the Recharge Card's Recharge Count, and displays the number of recharges remaining on the card.
6. If the operator has completed the User Smart Card update process successfully, the system notifies (90) the operator of the successful update and displays the new expiration date placed on the card.
7. The system ejects (100) the User Smart Card.
8. The system ejects (100) the Recharge Card
9. The system updates (110) its management report data.

10. The system displays (120) the BPM Utility Menu.

Regarding Step 2, identifying a valid PharmaSmart card, the format defined in Fig. 3 contains values in 'Security Code', 'Smart Card Version Number', 'User Type', 'Pharmacy Code', and 'Expiration Date' that may be used in combination in ways well-known in the art to identify the card as a valid PharmaSmart card.

Regarding Step 3, distinguishing between the Recharge Card and the User Smart Card, the formats of the Recharge Card and the User Smart Card are the same, as shown in Fig. 3, except that the Recharge Card contains an 'E0' code in the User Type field, while the User Smart Card contains a '00' in the User Type field. Also, since the Recharge Card is not used for storing readings, the 'Number of Readings on Card', 'Next Reading Inserted Here', and the '30 Latest Readings' on the Recharge Card will not contain valid data unless such data is added by another application.

See Figs. 3A and 3B. The User Type field may contain codes that identify other special-purpose card formats as needed for conventional technical and developmental purposes. Fig. 3A shows a map of the memory card. Such cards may be used in embodiments of the invention but they do not provide security for the data on the card. But they are less expensive than the more secure Smart Cards and can store the same user data that is stored on a Smart Card.

In a general embodiment providing for storage and analysis of noninvasive physiological test data and other medical monitoring information, the embodiment's User Smart Card records values from automated equipment for reading blood glucose level, blood cholesterol level, or other testable medical parameter values. The range of testable medical parameter values expands constantly as new technologies enable rapid, reliable, low-powered monitoring techniques to be packaged and made available to an End User.

The User Smart Card records the non-invasive physiological test data that the user took over the course of a year. The user can use the User Smart Card to access this entire history at any Location, and print out the most recent 10 entries or all of them. The average of the printed entries is given with the printout. The date of each reading is also recorded on the User Smart Card and printed alongside each entry, allowing the user or a physician to identify trends in the data. Additionally, at the user's request, the data from the User Smart Card can

be loaded into the computer system of a pharmacy or doctor's office, allowing health care workers quick access to the user's non-invasive physiological test data.

At a Location, the user can print out the entire history of non-invasive physiological test data stored on the user Smart Card. Additionally, at a pharmacy or physician's office this data can be submitted for a consultation on the patient's condition. When the User Smart Card is recharged, an option is given to allow the user to submit his data to a pharmacy for a consultation.

Tests now performed in a laboratory, such as blood enzyme levels for such critical markers as creatine phosphokinase (CPK), will eventually be capable of being performed properly and inexpensively in a manner similar to that now used for blood pressure monitoring. Furthermore, evaluations requiring significant analysis and processing of data, such as the classification of cardiac arrhythmias requiring medical attention, may become capable of being performed in a consumer setting as well.

Finally, numerous drugs, such as the COX-2 inhibitors, can produce varied deleterious effects on small subsets of their users. The monitoring of blood markers for adverse or allergic reactions to such drugs presents another field of application for the present invention.

To record the values captured, embodiments of the invention substitute different value sets and ranges for different types of reading and different sensitivity requirements. For example, readings of blood glucose levels when fasting range from the 60-100 range (excellent) to above 180 (poor), but after a meal the range rises so that the 110-140 range represents an excellent level, while above 220 represents a poor level of blood glucose (source of values: University of Massachusetts Medical School Web page concerning self-monitoring of blood glucose levels using the lancet). Ranges for different classes of monitored values are represented in the invention using range classifications, biasing of values, elimination of nonsignificant digits of precision, and other techniques well-known in the art for compressing data values for storage in limited memory space.

In a secure embodiment of the invention, conventional anti-tampering hardware and software components is incorporated in the User Smart Card and the Recharge Card to prevent an End User, a Location employee, or a thief from using a conventional standalone card reader to alter the contents of the User Smart Card or the Recharge Card.

In the secure embodiment, encryption is applied to the contents of the card, rendering the contents of the card unreadable by any process except the decryption of the encrypted values. The Location employee (for the Recharge Card) or the End User (for the User Smart Card) reads and updates the card's contents by furnishing the decryption key for the card. The specific encryption techniques used are well-known in the art and so are not described here.

Any attempt to read the card's contents using a conventional standalone card reader triggers the execution of software which breaks open one or more fuses on the card, rendering the card useless. While such measures do not prevent fraudulent misuse of the card, they make such misuse considerably more difficult.

The operation, contents, encryption, and decryptions of the invention's Recharge Card are the same for all classes of data to be collected.

The invention embraces additional embodiments usable in non-medical contexts for any application that gathers, stores, and recalls a limited number of data values on a rechargeable basis as described hereinabove. Two such applications are:

1. Transit systems, wherein the invention charges a User Smart Card with travel credit increments deductible by the user at entry into each stage of a journey on a transit system using embodiments of the invention. At each stage of the journey, the embodiment notes the time and location of the user's entry for travel, and deducts one or more credit increments as appropriate for the stage on which the user is embarking. The user may afterwards obtain from the Smart Card a record of travel for business or evidentiary reasons.
2. Libraries and lending systems, wherein embodiments of the invention charge a User Smart Card with lending credit increments deductible by the user when borrowing a book, film, music score, or other item of rental or lease goods or equipment. Different items borrowed may result in different numbers of credit increments being deducted. The invention stores the time and date of lending or rental and the time and date of return of the item on the User Smart Card.

The invention is not limited to the embodiments described hereinbefore but embraces apparatus and methods which apply to non-medical systems for recording readings and verifying usability.

WHAT IS CLAIMED IS

1. An apparatus for recording and tracking non-invasive physiological test data comprising:

a machine for automatically detecting non-invasive physiological test data of an individual;

means for recording the detected non-invasive physiological test data on a first transportable device adapted to receive and hold non-invasive physiological test data;

means for recording the date of each recording of non-invasive physiological test data on the first transportable device;

means for deactivating the first transportable device after a first predetermined number of readings, after a first predetermined duration, or both; and

means for reactivating the first transportable device to store a second predetermined number of readings, a second predetermined duration, or both.

2. The apparatus of claim 1 further comprising:

means for preventing access to or alteration of any component of the records of non-invasive physiological test data.

3. The apparatus of claim 1 further comprising:

means for accessing and printing a hard copy of the data contained on the first transportable device.

4. The apparatus of claim 1 wherein the means for recording the detected non-invasive physiological test data and the date of each recording on a first transportable device further comprises a first reading and writing device.

5. The apparatus of claim 1 wherein the first reading and writing device further comprises a first electronic smart card reading and writing device.

6. The apparatus of claim 1 wherein the first reading and writing device further comprises a first flash memory reading and writing device.

7. The apparatus of claim 1 wherein the first reading and writing device further comprises a first optical memory reading and writing device.

8. The apparatus of claim 1 wherein the first reading and writing device further comprises a first magneto-optical memory reading and writing device.

9. The apparatus of claim 1 wherein the means for accessing and printing a hard copy of the data contained on the first transportable device further comprises:

a means for accessing data entries contained on the first transportable device alongside the dates the data entries were recorded;

means for selecting a set of data entries, taking an average of the set of data entries, and displaying or printing the set of data entries including the date the entries were made and their average.

10. The apparatus of claim 9 wherein the selected data entries comprise the last ten entries.

11. The apparatus of claim 9 wherein the selected data entries comprise all the data entries on the card.

12. The apparatus of claim 9 further comprising:

a means for uploading the data entries onto a computer.

13. An apparatus for recording and tracking non-invasive physiological test data comprising:

a machine for automatically detecting non-invasive physiological test data of an individual, said machine comprising a computer having software stored on a computer readable medium including instructions for execution by the computer;

means for recording the detected non-invasive physiological test data on a first transportable device adapted to receive and hold non-invasive physiological test data;

means for recording the date of each recording of non-invasive physiological test data on the first transportable device;

means for deactivating the first transportable device after a first predetermined number of readings, after a first predetermined duration, or both; and

means for reactivating the first transportable device to store a second predetermined number of readings, a second predetermined duration, or both;

wherein the means means for deactivating the first transportable device after a first predetermined number of readings, after a first predetermined duration, or both further comprises:

means for reading expiration date information, stored on the first transportable device and specifying the end of the first period of time;

means for reading a source of current date information;

said software program on said computer of said machine for comparing the current date information with the expiration date information;

means for taking and recording non-invasive physiological test data on the first transportable device when the results of said comparison is a date between the expiration date information and the current date information.

14. The apparatus of claim 13 wherein the first transportable device comprises an electronic smart card.

15. The apparatus of claim 13 wherein the first transportable device comprises a flash memory card.

16. The apparatus of claim 13 wherein the first transportable device comprises an optical memory device.

17. The apparatus of claim 13 wherein the first transportable device comprises a magneto-optical memory device.

18. An apparatus for recording and tracking non-invasive physiological test data comprising:

a machine for automatically detecting non-invasive physiological test data of an individual, said machine comprising a computer having software stored on a computer readable medium including instructions for execution by the computer;

means for recording the detected non-invasive physiological test data on a first transportable device adapted to receive and hold non-invasive physiological test data;

means for recording the date of each recording of non-invasive physiological test data on the first transportable device;

means for deactivating the first transportable device after a first predetermined number of readings, after a first predetermined duration, or both; and

means for reactivating the first transportable device to store a second predetermined number of readings, a second predetermined duration, or both;

wherein the means for reactivating the first transportable device to extend a fixed period of time to a second period of time further comprises:

a second transportable device for limiting the number of reactivation operations performed on one or more first transportable devices;

a machine-readable and machine-writable recording of the number of reactivation operations, stored on the second transportable device and specifying the number of reactivation operations remaining to be performed;

said software program on said computer of said machine for decrementing the number of reactivation operations remaining to be performed until no further reactivation operations remain on the second transportable device; and

said software program on said computer of said machine for resetting expiration date information stored on the first transportable device.

19. The apparatus of claim 18 wherein the second transportable device comprises an electronic smart card.

20. The apparatus of claim 18 wherein the second transportable device comprises a flash memory card.

21. The apparatus of claim 18 wherein the second transportable device comprises an optical memory device.

22. The apparatus of claim 18 wherein the second transportable device comprises a magneto-optical memory device.

23. The apparatus of claim 18 wherein the means for means for recharging the first transportable device further comprises a second reading and writing device.

24. The apparatus of claim 23 wherein the first reading and writing device further comprises a second electronic smart card reading and writing device.

25. The apparatus of claim 23 wherein the first reading and writing device further comprises a second flash memory reading and writing device.

26. The apparatus of claim 23 wherein the first reading and writing device further comprises a second optical memory reading and writing device.

27. The apparatus of claim 23 wherein the first reading and writing device further comprises a magneto-optical memory reading and writing device.

28. The apparatus of claim 1 wherein the detected non-invasive physiological test data further comprise one or more of the group consisting of:

the systolic blood pressure of the individual;

the diastolic blood pressure of the individual;

the pulse rate of the individual;

the respiration rate of the individual;

the blood oxygen level of the individual;

the blood glucose level of the individual;

the blood cholesterol level of the individual;

one or more blood enzyme levels of the individual;

indications and a log of one or more classes of cardiac arrythmias of the individual;

the weight of the individual;

the percent body fat of the individual; and

the bone density of the individual.

29. The apparatus of claim 1 wherein the means for preventing access to or alteration of any component of the records of non-invasive physiological test data further comprises a means for encryption of the records of non-invasive physiological test data.

30. The apparatus of claim 1 wherein the means for preventing access to or alteration of any component of the records of non-invasive physiological test data further comprises a means for decryption of the records of non-invasive physiological test data.

31. The apparatus of claim 1 wherein the means for preventing access to or alteration of any component of the records of non-invasive physiological test data further comprises a means for destroying the records of non-invasive physiological test data.

32. A process for recording and tracking non-invasive physiological test data comprising the steps of:

automatically detecting the non-invasive physiological test data of an individual;

recording the detected non-invasive physiological test data on a first transportable device adapted to receive and hold non-invasive physiological test data;

recording the date of each recording of non-invasive physiological test data on the first transportable device;

limiting the duration, number of recordings made, or both on the first transportable device to a first period of time;

deactivating the first transportable device after the first period of time; and

reactivating the first transportable device to store a second period of time comprising a duration, number of recordings made, or both.

33. The process of claim 32, wherein the step of detecting the non-invasive physiological test data of an individual further comprises the steps of:

the systolic blood pressure of the individual;

the diastolic blood pressure of the individual;

the pulse rate of the individual;

the respiration rate of the individual;

the blood oxygen level of the individual;

the blood glucose level of the individual;

the blood cholesterol level of the individual;

one or more blood enzyme levels of the individual;

indications and a log of one or more classes of cardiac arrythmias of the individual;

the weight of the individual;

the percent body fat of the individual; and

the bone density of the individual.

34. A process for recording and tracking non-invasive physiological test data comprising the steps of:

automatically detecting the non-invasive physiological test data of a user;

recording the detected non-invasive physiological test data on a first transportable device adapted to receive and hold non-invasive physiological test data;

recording the date of each recording of non-invasive physiological test data on the first transportable device;

deactivating the first transportable device after a first predetermined number of readings, after a first predetermined duration, or both; and

reactivating the first transportable device to store a second predetermined number of readings, a second predetermined duration, or both;

wherein the step of recording the detected non-invasive physiological test data on the first transportable device further comprises the steps of:

at the time of routine use by the user, reading an expiration date of the first period of time stored on the first transportable device;

at the time of routine use by the user, comparing the expiration date to the current date; and

when the expiration date has not been passed at the time of routine use by the user, recording the detected non-invasive physiological test data on the first transportable device.

35. The process of claim 32, wherein the step of limiting the duration and number of recordings made on the first transportable device to a first period of time further comprises the steps of:

at the time of recharging of the first transportable device, writing an expiration date of the first period of time onto the first transportable device;

at the time of routine use by a user, reading the expiration date of the first period of time stored on the first transportable device;

at the time of routine use by a user, comparing the expiration date to the current date;

when the expiration date has been passed at the time of routine use by a user, notifying the user of the first transportable device that said device requires recharging.

36. A process for recording and tracking non-invasive physiological test data comprising the steps of:

automatically detecting the non-invasive physiological test data of an individual;

recording the detected non-invasive physiological test data on a first transportable device adapted to receive and hold non-invasive physiological test data;

recording the date of each recording of non-invasive physiological test data on the first transportable device;

deactivating the first transportable device after a first predetermined number of readings, after a first predetermined duration, or both; and

reactivating the first transportable device to store a second predetermined number of readings, a second predetermined duration, or both;

wherein the step of reactivating the first transportable device further comprises the steps of:

at the time of authorization of additional reactivation operations for one or more first transportable devices, writing a count of reactivation operations available onto a second transportable device;

at the time of reactivation of the first transportable device, reading a count of reactivation operations available from the second transportable device;

at the time of reactivation of the first transportable device, decrementing the count of reactivation operations available;

when the count of reactivation operations available has reached zero, notifying an operator that the second transportable device requires authorization of further reactivation operations; and

when the count of reactivation operations available has not reached zero, writing an expiration date of the second period of time onto the first transportable device.

37. An apparatus for recording and tracking usage information comprising:

a machine for automatically detecting parameters of usage of a service, resource or object;

means for recording parameters of the detected usage on a first transportable device adapted to receive and hold usage data;

means for limiting the duration, number of recordings made, or both on the first transportable device to a first period of time, wherein the first transportable device ceases to record non-invasive physiological test data once a predetermined limit for the first period of time is exceeded;

means for reactivating the first transportable device to extend the first period of time to a second period of time;

means for limiting the duration, number of recordings made on the first transportable device, or combination thereof to the second period of time;

means for preventing access to or alteration of any component of the records of usage information;

wherein reactivating the first transportable device to extend the first period of time to the second period of time permits continued recording of non-invasive physiological test data until a predetermined limit for the second period of time is reached.

38. The apparatus of claim 37 wherein the parameters of usage comprise the time, date, and location of the usage.

39. The apparatus of claim 37 wherein the service, resource, or object is selected from the list consisting of:

passage on a transit conveyance;

borrowing of a book, recording, or other document; and

rental of a piece of equipment.

40. The apparatus of claim 37 wherein the means for preventing access to or alteration of any component of the records of non-invasive physiological test data further comprises a means for encryption of the records of usage information.

41. The apparatus of claim 37 wherein the means for preventing access to or alteration of any component of the records of non-invasive physiological test data further comprises a means for decryption of the records of usage information.

42. The apparatus of claim 37 wherein the means for preventing access to or alteration of any component of the records of non-invasive physiological test data further comprises a means for destroying the records of usage information.

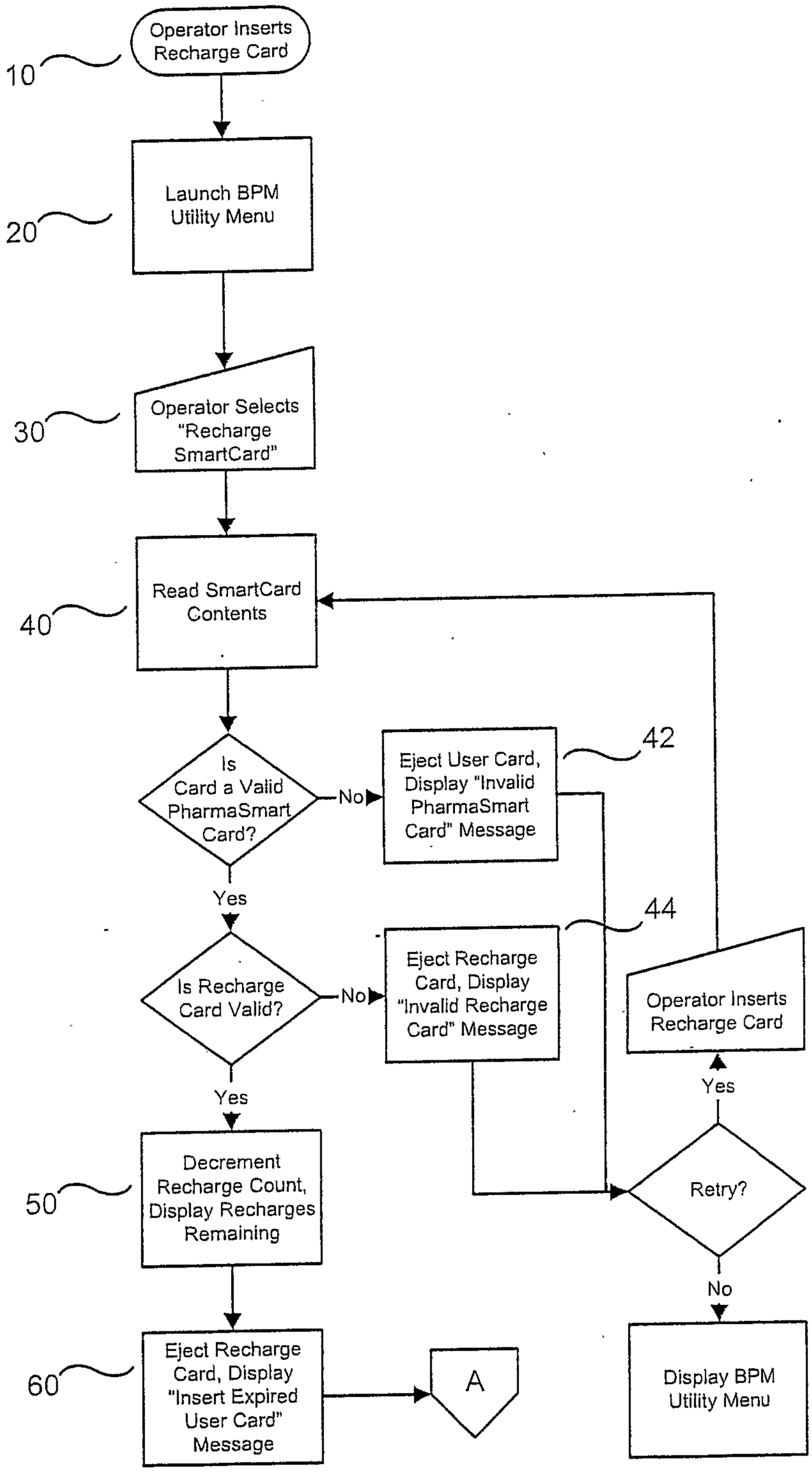

Operator Inserts Recharge Card
10
Launch BPM Utility Menu
20
Operator Selects "Recharge SmartCard"
30
Read SmartCard Contents
40
Is Card a Valid PharmaSmart Card?
No
Eject User Card, Display "Invalid PharmaSmart Card" Message
42
Yes
Is Recharge Card Valid?
No
Eject Recharge Card, Display "Invalid Recharge Card" Message
44
Yes
Decrement Recharge Count, Display Recharges Remaining
50
Eject Recharge Card, Display "Insert Expired User Card" Message
60
A
Operator Inserts Recharge Card
Yes
Retry?
No
Display BPM Utility Menu

FIG. 1A

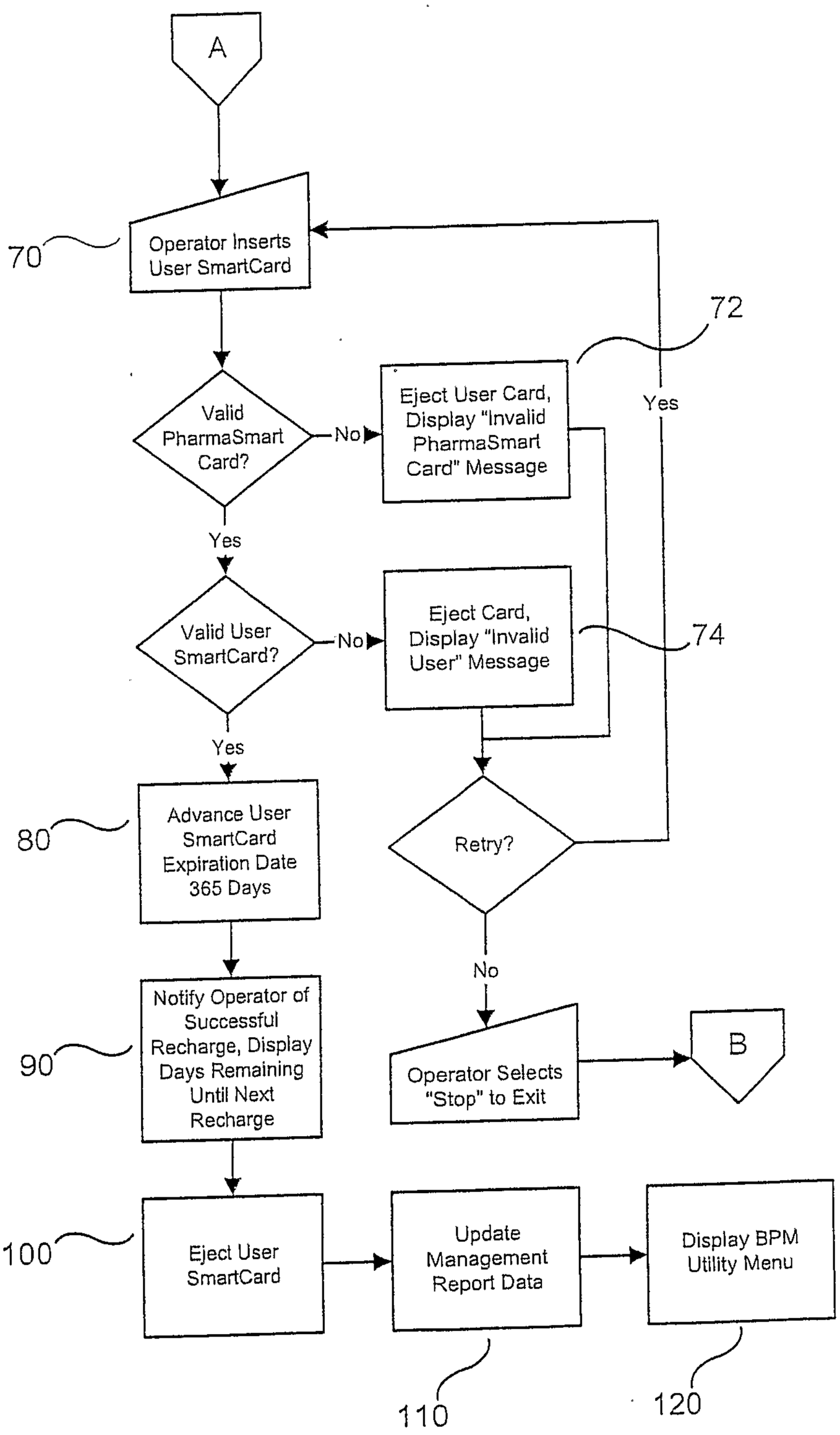

A
70
Operator Inserts User SmartCard
Valid PharmaSmart Card?
No
Eject User Card, Display "Invalid PharmaSmart Card" Message
72
Yes
Yes
Valid User SmartCard?
No
Eject Card, Display "Invalid User" Message
74
Yes
Retry?
Yes
No
80
Advance User SmartCard Expiration Date 365 Days
90
Notify Operator of Successful Recharge, Display Days Remaining Until Next Recharge
Operator Selects "Stop" to Exit
B
100
Eject User SmartCard
Update Management Report Data
Display BPM Utility Menu
110
120

FIG. 1B

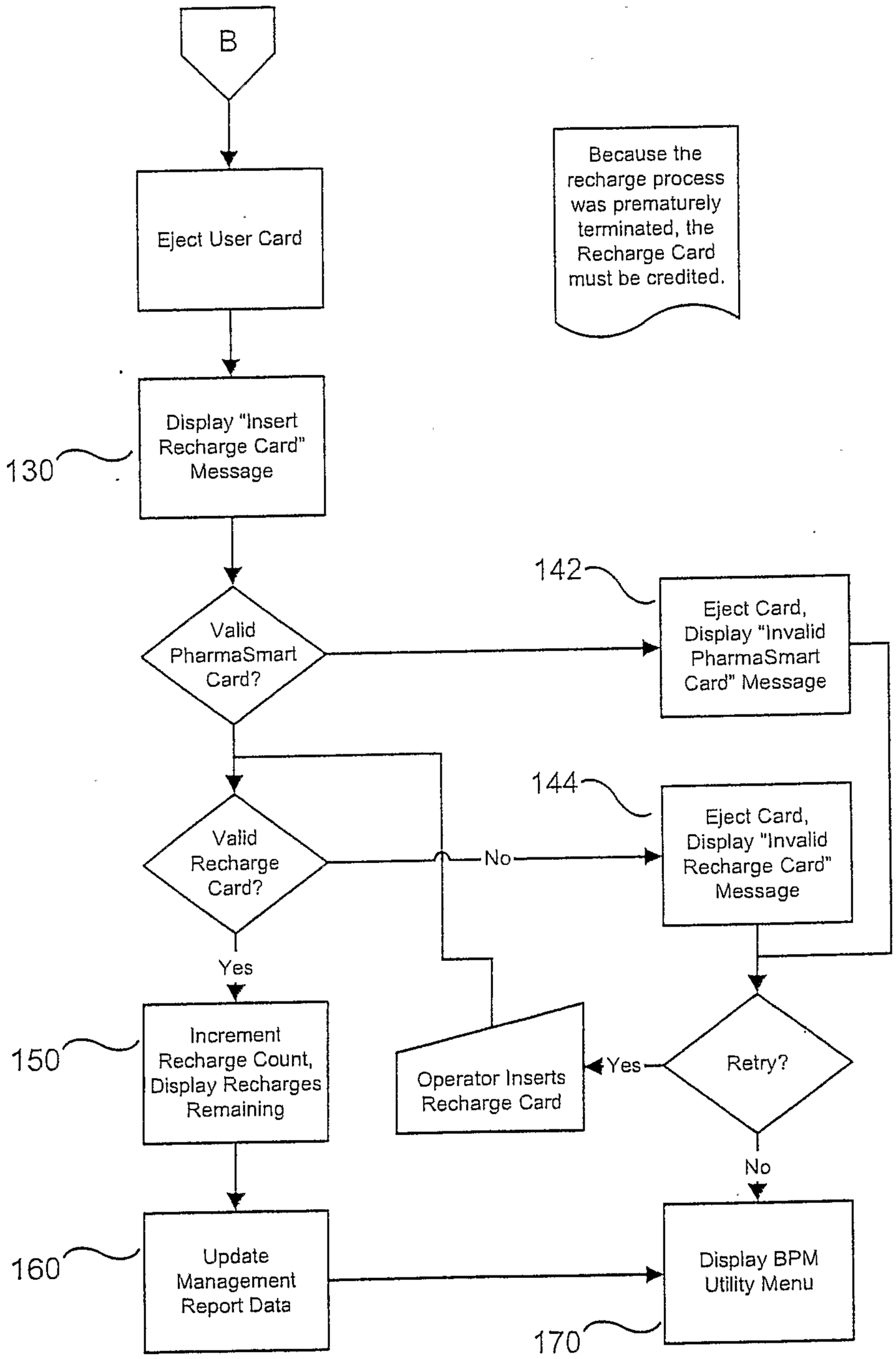

B
Eject User Card
Because the recharge process was prematurely terminated, the Recharge Card must be credited.
Display "Insert Recharge Card" Message
130
142
Valid PharmaSmart Card?
Eject Card, Display "Invalid PharmaSmart Card" Message
144
Valid Recharge Card?
No
Eject Card, Display "Invalid Recharge Card" Message
Yes
Increment Recharge Count, Display Recharges Remaining
150
Operator Inserts Recharge Card
Yes
Retry?
No
160
Update Management Report Data
Display BPM Utility Menu
170

FIG. 1C

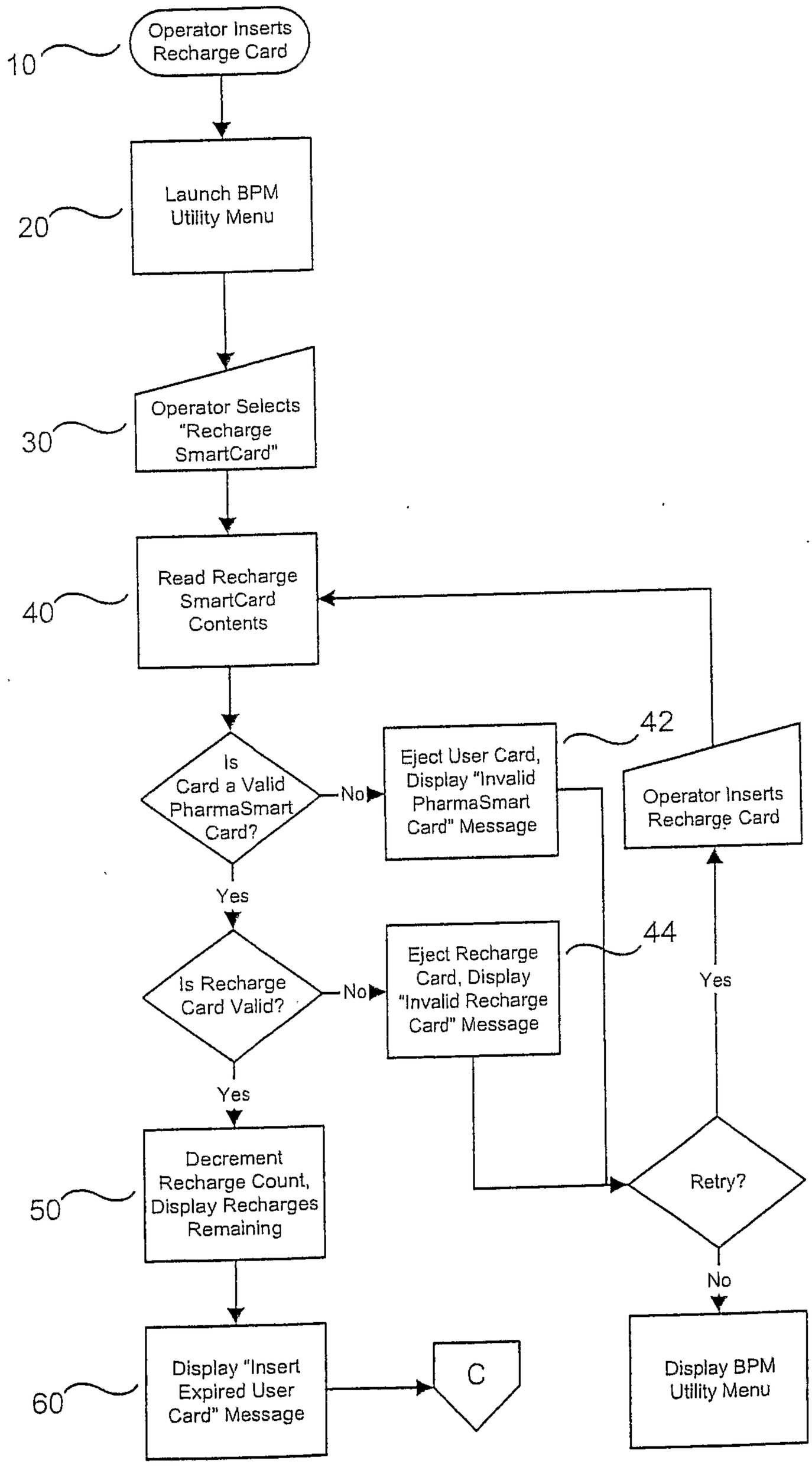

Operator Inserts Recharge Card
10
Launch BPM Utility Menu
20
Operator Selects "Recharge SmartCard"
30
Read Recharge SmartCard Contents
40
Is Card a Valid PharmaSmart Card?
No
Eject User Card, Display "Invalid PharmaSmart Card" Message
42
Operator Inserts Recharge Card
Yes
Is Recharge Card Valid?
No
Eject Recharge Card, Display "Invalid Recharge Card" Message
44
Yes
Retry?
Yes
No
Decrement Recharge Count, Display Recharges Remaining
50
Display "Insert Expired User Card" Message
60
C
Display BPM Utility Menu

FIG. 2A

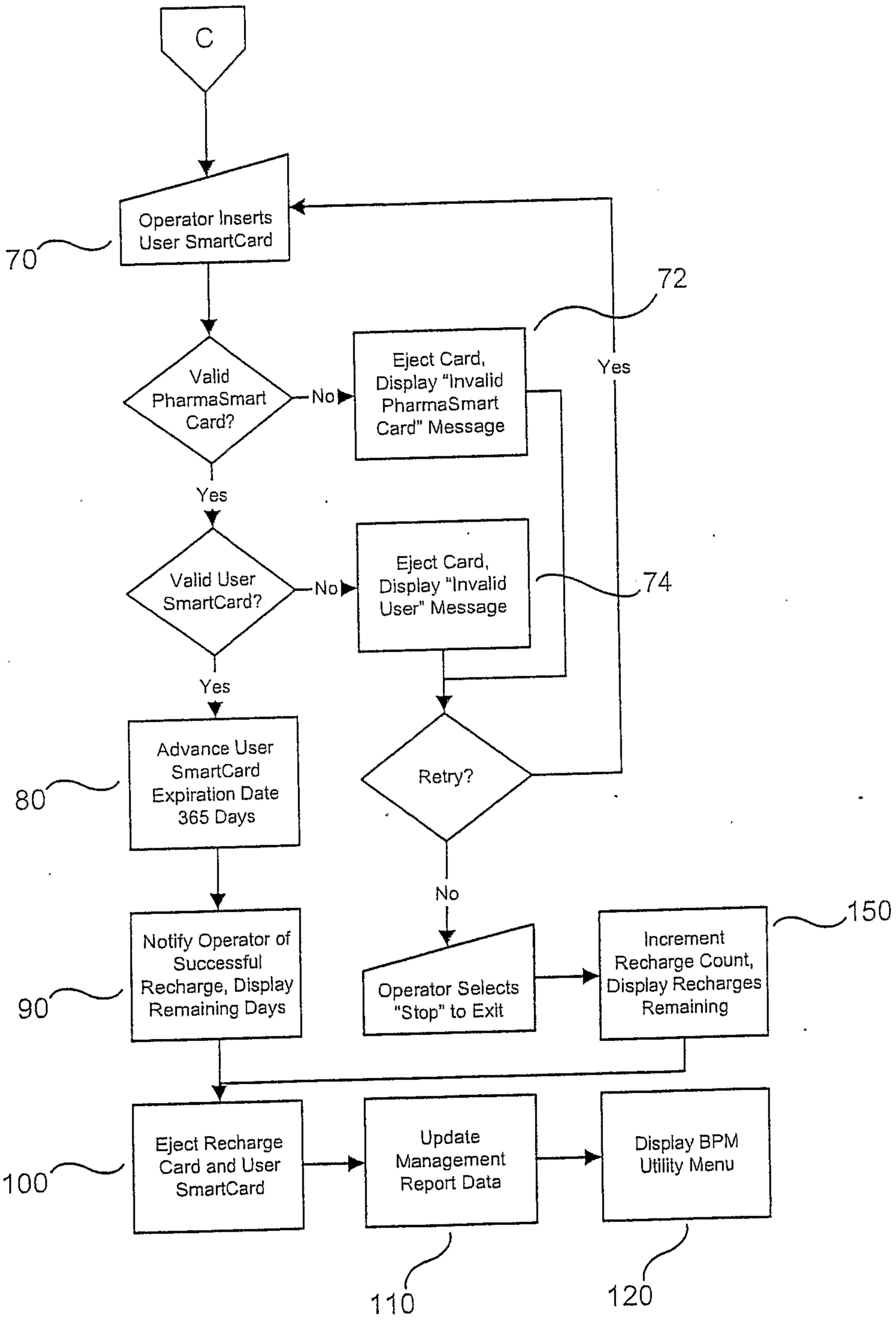

C
Operator Inserts User SmartCard
70
Valid PharmaSmart Card?
No
Eject Card, Display "Invalid PharmaSmart Card" Message
72
Yes
Valid User SmartCard?
No
Eject Card, Display "Invalid User" Message
74
Yes
Retry?
Yes
No
Advance User SmartCard Expiration Date 365 Days
80
Notify Operator of Successful Recharge, Display Remaining Days
90
Operator Selects "Stop" to Exit
Increment Recharge Count, Display Recharges Remaining
150
Eject Recharge Card and User SmartCard
100
Update Management Report Data
110
Display BPM Utility Menu
120

FIG. 2B

	0	1	2	3	4	5	6	7	8	9	A	B	C	D	E	F
00	S1	Ver	00	Phar	dd	mm	yy	#	Next			Lang				
10																
20	dd	mm	yy	D	S	P	dd	mm	yy	D	S	P	dd	mm	yy	D
30	S	P	dd	mm	yy	D	S	P	dd	mm	yy	D	S	P	dd	mm
40	yy	D	S	P	dd	mm	yy	D	S	P	dd	mm	yy	D	S	P
50	dd	mm	yy	D	S	P	dd	mm	yy	D	S	P	dd	mm	yy	D
60	S	P	dd	mm	yy	D	S	P	dd	mm	yy	D	S	P	dd	mm
70	yy	D	S	P	dd	mm	yy	D	S	P	dd	mm	yy	D	S	P
80	dd	mm	yy	D	S	P	dd	mm	yy	D	S	P	dd	mm	yy	D
90	S	P	dd	mm	yy	D	S	P	dd	mm	yy	D	S	P	dd	mm
A0	yy	D	S	P	dd	mm	yy	D	S	P	dd	mm	yy	D	S	P
B0	dd	mm	yy	D	S	P	dd	mm	yy	D	S	P	dd	mm	yy	D
C0	S	P	dd	mm	yy	D	S	P	dd	mm	yy	D	S	P	dd	mm
D0	yy	D	S	P												
E0																
F0												S2	S3	S4	S5	S6

Sn	Security Code n (1-6)	
Ver	Smart Card Version Number	Start at 1, incremented as format changes
User	User Type 00	00 - User; E0 - Recharge; FD - Technician; FE - OEM; FF - Developer
Phar	Pharmacy Code	Issuing pharmacy's code
	Expiration Date	1 year from initial use, dd/mm/yy date format
#	Number of Readings on Card	0 - 30
Next	Next Reading Inserted Here	
	Number of Recharges Remaining	
Lang	Language	0x00 - English, 0x01 - French, 0x02 - Spanish
	30 Latest Readings	Last 10 printed, all 30 used for graph. dd/mm/yy - date of reading, D - diastolic pressure, S - systolic pressure, P - pulse rate
	Unused Control Data	Future expansion
	Unused Data	Future expansion

FIG. 3A

WO 2007/022017 PCT/US2006/031519 CA 02618976 2008-02-12

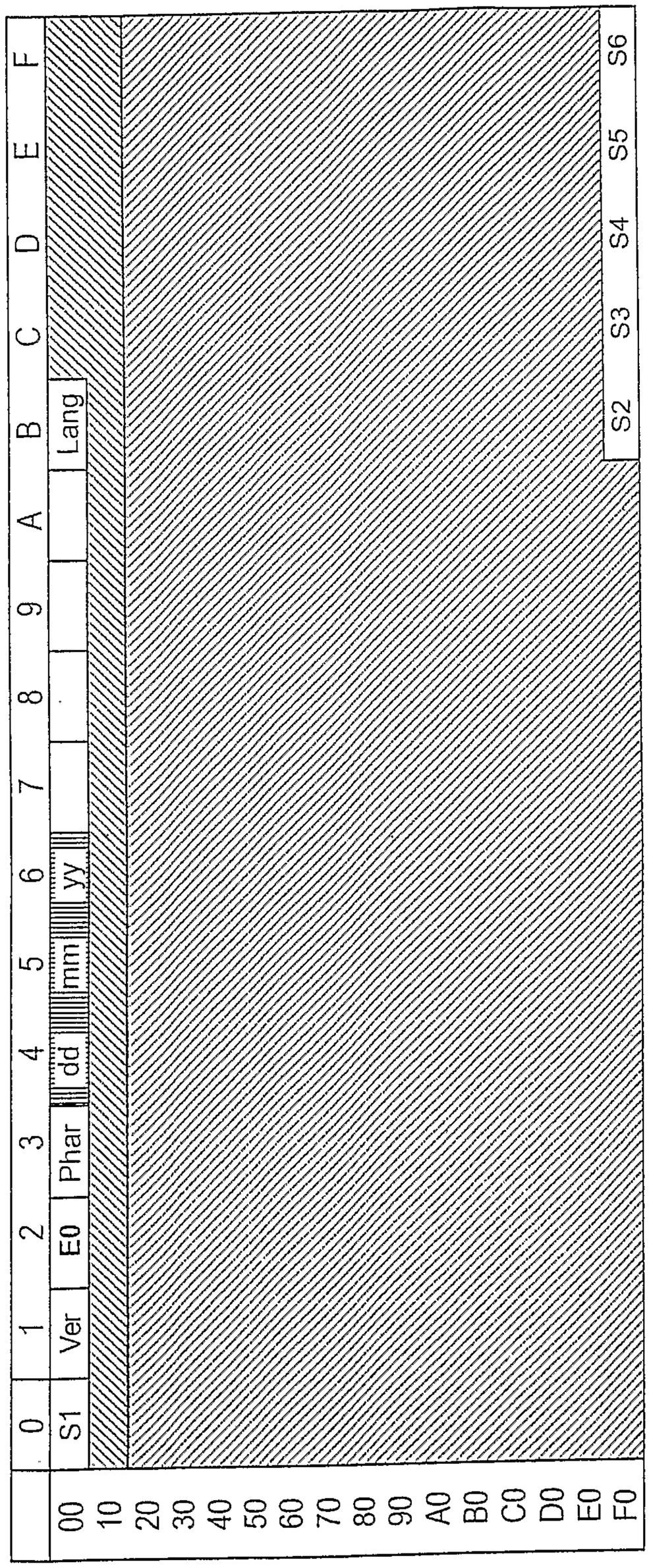
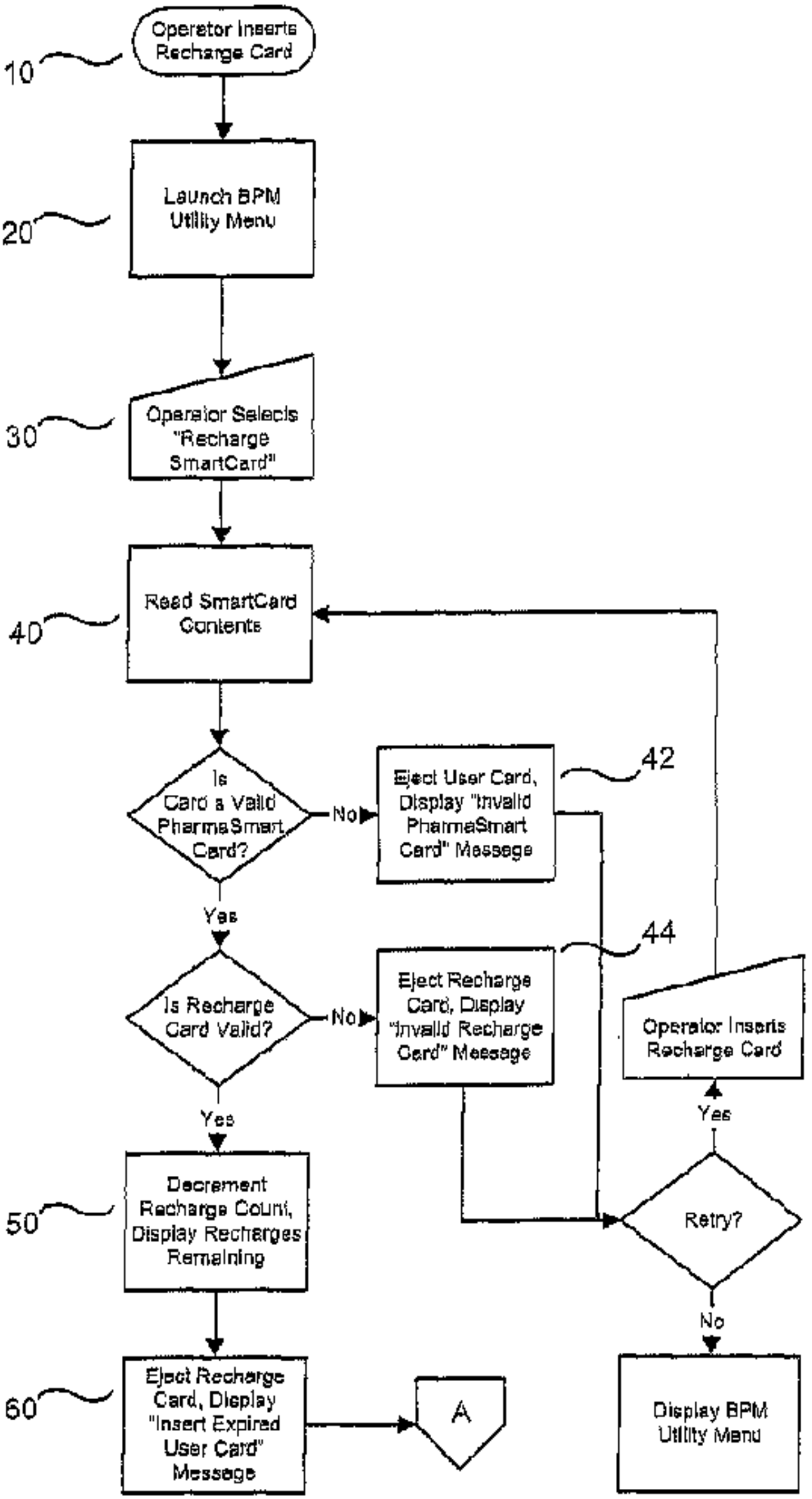

1 2 3 4 5 6 7 8 9 A B C D E F
Ver E0 Phar dd mm yy Lang
0 S1 S2 S3 S4 S5 S6
00 10 20 30 40 50 60 70 80 90 A0 B0 C0 D0 E0 F0
Security Code n (1-6)
Smart Card Version Number
User Type E0
Pharmacy Code
Expiration Date
Number of Readings on Card
Next Reading Inserted Here
Number of Recharges Remaining
Language
30 Latest Readings
Unused Control Data
Unused Data
Start at 1, incremented as format changes
00 - User; E0 - Recharge; FD - Technician; FE - OEM; FF - Developer
Issuing pharmacy's code
1 year from initial use, dd/mm/yy date format
0 - 30
0x00 - English, 0x01 - French, 0x02 - Spanish
Last 10 printed, all 30 used for graph. dd/mm/yy - date of reading,
D - diastolic pressure, S - systolic pressure, P - pulse rate
Future expansion
Future expansion
Sn
Ver
User
Phar
#
Next
Lang

FIG. 3B


Operator Inserts Recharge Card
10
Launch BPM Utility Menu
20
Operator Selects "Recharge SmartCard"
30
Read SmartCard Contents
40
Is Card a Valid PharmaSmart Card?
No
Eject User Card, Display "Invalid PharmaSmart Card" Message
42
Yes
Is Recharge Card Valid?
No
Eject Recharge Card, Display "Invalid Recharge Card" Message
44
Yes
Decrement Recharge Count, Display Recharges Remaining
50
Eject Recharge Card, Display "Insert Expired User Card" Message
60
A
Operator Inserts Recharge Card
Yes
Retry?
No
Display BPM Utility Menu