

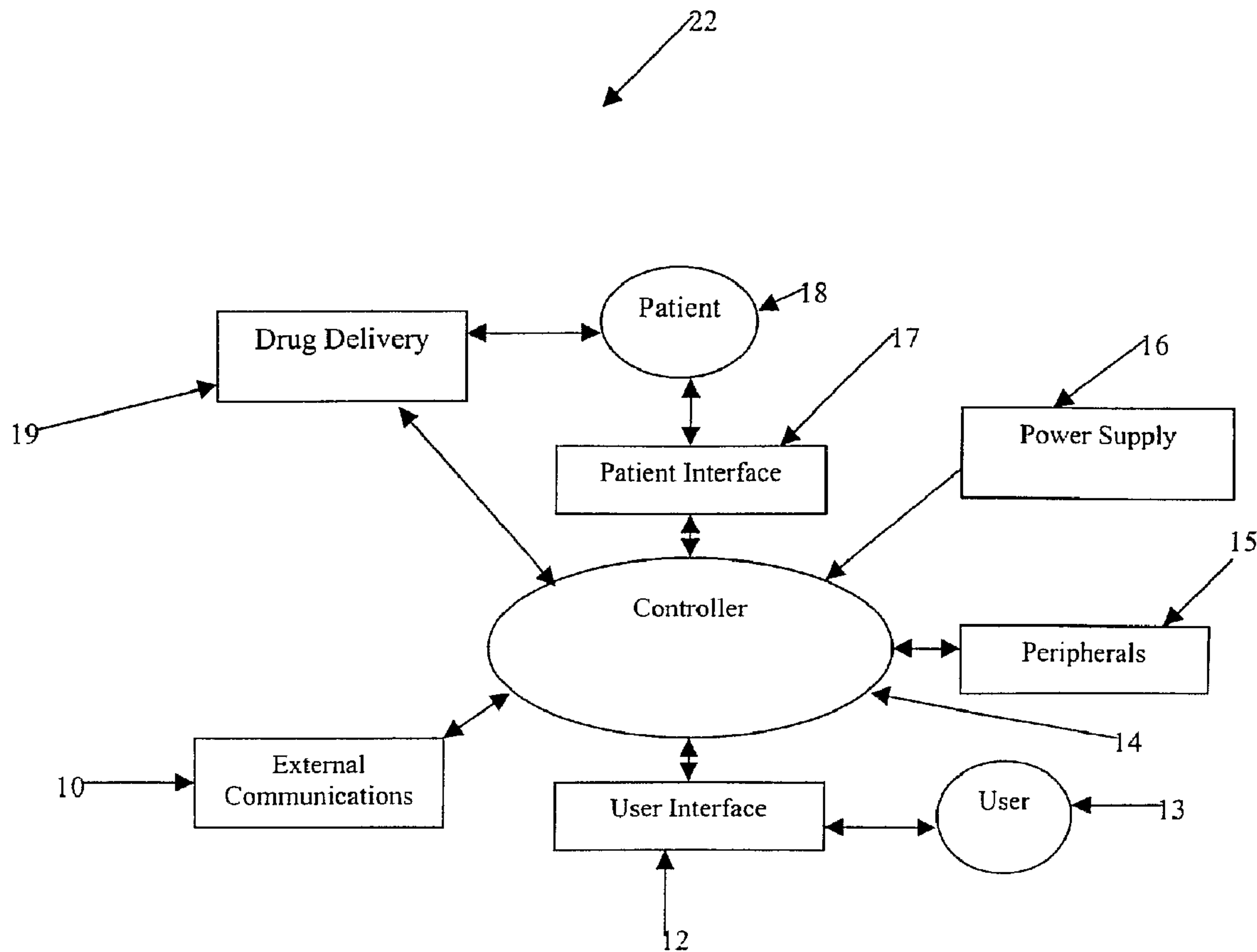


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(54) Titre : SYSTEME ET PROCEDE D'AUTORISATION D'UTILISATEUR POUR SYSTEME DE SEDATION ET D'ANALGESIE

(54) Title: USER AUTHORIZATION SYSTEM AND METHOD FOR A SEDATION AND ANALGESIA SYSTEM



(57) Abrégé/Abstract:

The present invention (22) comprises a security system integral with a sedation and analgesia system. The invention (22) includes a computer assisted IV drug infusion administration device coupled with a secure user interface (12), or other security means, that

(57) **Abrégé(suite)/Abstract(continued):**

can restrict and monitor user access to prevent unauthorized or improper use of the device. The system can also provide varying levels of access to the device so that different users (13) may have different levels of access to system operations. The variety of access levels may prevent accidental or intentional misuse of the system., while still permitting access to the required functionality. Data, such as usage statistics and procedural events associated with drug delivery, may be recorded in association with a user's personal identification information to help identify training needs and to identify possible misuse of access information.

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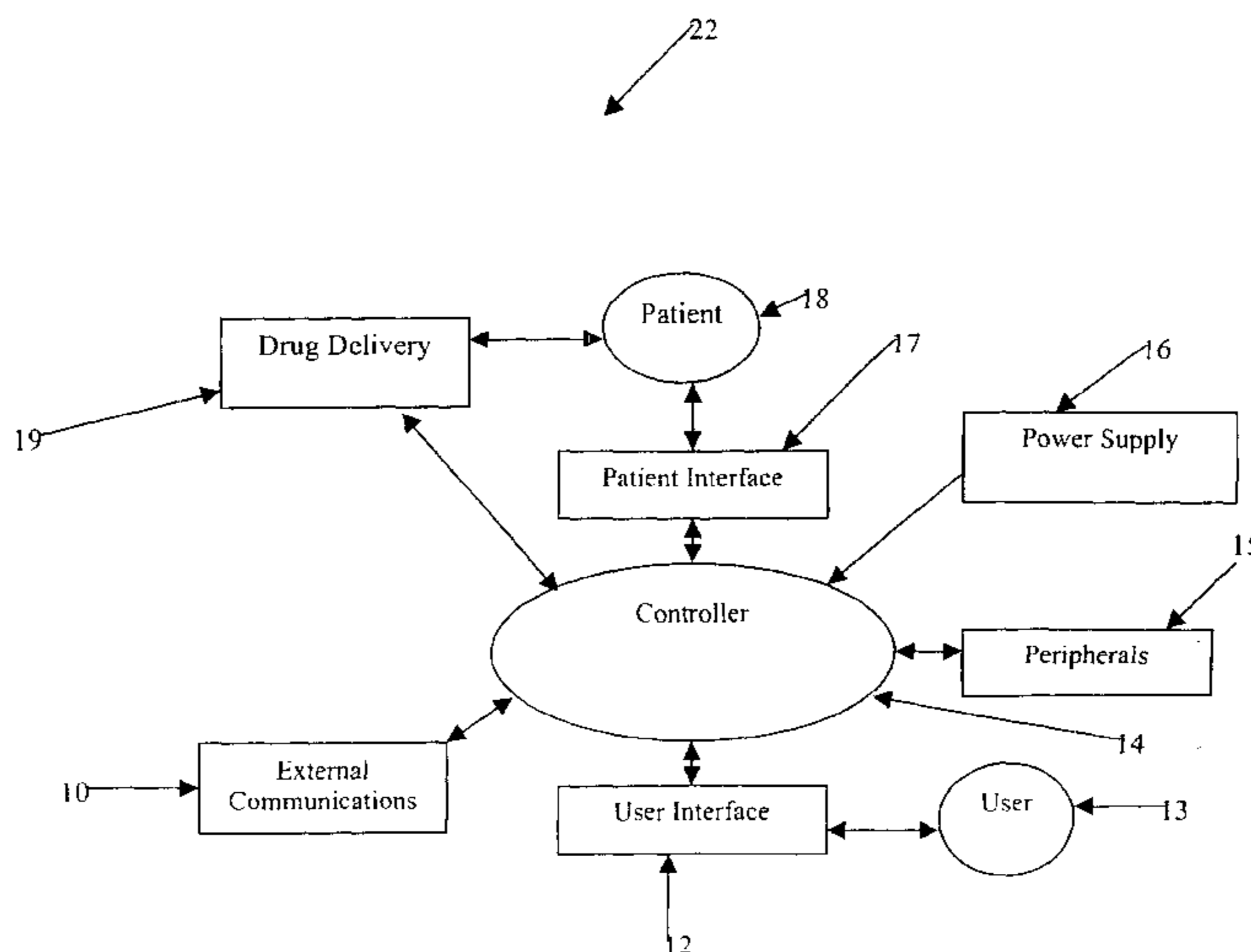
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(54) Title: USER AUTHORIZATION SYSTEM AND METHOD FOR A SEDATION AND ANALGESIA SYSTEM



(57) Abstract: The present invention (22) comprises a security system integral with a sedation and analgesia system. The invention (22) includes a computer assisted IV drug infusion administration device coupled with a secure user interface (12), or other security means, that can restrict and monitor user access to prevent unauthorized or improper use of the device. The system can also provide varying levels of access to the device so that different users (13) may have different levels of access to system operations. The variety of access levels may prevent accidental or intentional misuse of the system., while still permitting access to the required functionality. Data, such as usage statistics and procedural events associated with drug delivery, may be recorded in association with a user's personal identification information to help identify training needs and to identify possible misuse of access information.

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USER AUTHORIZATION SYSTEM AND METHOD FOR A SEDATION AND ANALGESIA SYSTEM

BACKGROUND OF THE INVENTION

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Field of the Invention

The present invention relates, in general, to security systems and, more particularly, to security systems associated with the operation of medical devices.

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Description of the Related Art

A sedation and analgesia system was developed to provide patients undergoing painful, uncomfortable or otherwise frightening (anxiety inspiring) medical or surgical procedures with a means for receiving sedative, analgesic, and/or amnestic drugs safely in a way that reduces the risk of overmedication with or without the presence of a licensed
15 anesthesia provider. By reducing the number of potential failure modes potentially associated with anesthesia machines, a sedation and analgesia systems has been rendered safer for use in hospital and ambulatory environments and may be operated by individuals other than trained anesthesiologists such as, for example, certified registered nurse anesthetists, trained physicians, or other licensed operators. The sedation and analgesia
20 system has gone far to meet the anesthesia needs of office based practitioners who are unable to afford or schedule anesthesia providers for every procedure where sedation and analgesia would be beneficial. The advent of a sedation and analgesia system devoted to these purposes provides these individuals with a drug delivery system integrated into a patient monitoring system that decreases the manual tasks and cognitive load that may be
25 required by anesthesia machines, yet gives the clinician ultimate decision making responsibility following a “clinician knows best” philosophy. The reduction of many manual activities associated with anesthesia machines allows for a sedation and analgesia

system to be operated without an anesthesia provider in ambulatory settings providing the patient with a cost-effective and readily available means of sedation.

However, the relatively easy operation of the sedation and analgesia system may lead to its inappropriate use by clinicians who have not been properly trained. Though the sedation and analgesia system has been designed for efficient and easy use by non-anesthetist practitioners, such systems remain sufficiently complex to require appropriate training before being used on patients. Because the sedation and analgesia system is designed to be an efficient, easily operable system, untrained clinicians may be tempted to use such systems on patients without having received formal training. If sedation and analgesia systems are used in such a manner by uncertified persons, patients may be put at considerable risk.

The potential for abuse of sedation and analgesia systems is also present in recreational drug users with access to such systems. Designed to prevent an overdose of medication to a patient during authorized medical procedures, recreational drug users may feel that they can use sedation and analgesia systems to self-administer narcotics and/or other illicit drugs safely. Use of the system for such purposes may result in severe adverse consequences due to the addiction to illicit drugs or overdose resulting from the use of drugs whose effects and concentrations may not be accounted for by the pharmacokinetic model of the sedation and analgesia system. The need has therefore arisen for a sedation and analgesia system that permits only authorized and properly trained clinicians to operate the system.

Chronic misuse of sedation and analgesia systems, even by trained individuals, may also result in severe patient complications. Such users may have access to sedation and analgesia systems, yet have insufficient training or experience to ensure patient safety during procedures involving sedation and analgesia. The need has therefore arisen for a sedation and analgesia system that records the personal information of a user as well as the presence or absence of critical system or patient episodes in order to ascertain whether users may require additional training in order to be allowed access to sedation and analgesia systems.

BRIEF SUMMARY OF THE INVENTION

The present invention solves the aforementioned drawbacks of automated drug infusion devices by providing security devices and methods for sedation and analgesia systems. The invention includes a computer assisted IV drug infusion administration device coupled with a

secure user interface, or other security means, that can restrict and monitor user access to prevent unauthorized or improper use of the device.

It is an object of the present invention to provide a computer assisted IV drug infusion administration device that permits only authorized and properly trained clinicians to operate the system. Providing varying levels of access to the device so that different users may have different levels of access to system operations can further control access.

It is a further object of the present invention to provide a sedation and analgesia system that records the personal information of a user as well as the presence or absence of critical system or patient episodes or critical incidents in order to ascertain whether users may require additional training in order to be allowed, or to retain, access to sedation and analgesia systems.

In one embodiment, the present invention uses a security prompt incorporated into the user interface of the delivery device that requires a user to provide a personal identification number (PIN), fingerprint, voice command, data card, or other identification means such as biometric data prior to operating the system. Data relating to authorized identification entries is stored in a memory device included in the delivery device. In the case where unrecognized personal access information is provided to the system, the system's drug delivery functionality may remain disabled.

The present invention may also incorporate a plurality of security levels associated with different types of users. For example, one level of access can be granted to the extent required for maintenance only, while a greater level of access can be granted for clinician use. Access for administrative purposes is also feasible. The variety of access levels may prevent accidental or intentional misuse of the drug delivery system, while tailoring access to the required functionality.

Data, such as usage statistics and procedural events associated with drug delivery, may be recorded in association with a user's personal identification information. Such recorded data may be used to help identify training needs, for quality assurance purposes and to identify possible misuse of access information.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates an overview block diagram of one embodiment of a sedation and analgesia system in accordance with the present invention;

FIG. 2 illustrates one embodiment of a security prompt in accordance with the present invention; and

FIG. 3 illustrates one embodiment of a method of using a security system integrated with a sedation and analgesia system in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 illustrates a block diagram depicting one embodiment of the present invention comprising sedation and analgesia system **22** having user interface **12**, software controlled controller **14**, peripherals **15**, power supply **16**; external communications **10**, patient interface **17**, and drug delivery **19**, where sedation and analgesia system **22** is operated by user **13** in order to provide sedation and/or analgesia to patient **18**. A sedation and analgesia system **22** is disclosed and enabled in commonly assigned U.S. Patent No. 6,807,965 issued October 26, 2004. Embodiments of user interface **12** are disclosed and enabled in commonly assigned U.S. Patent Application Publication No. 2003/0135087 published July 17, 2003.

The sedation and analgesia system of above-mentioned U.S. Patent No. 6,807,965 includes a patient health monitor device adapted so as to be coupled to a patient and generate a signal reflecting at least one physiological condition of the patient, a drug delivery controller supplying one or more drugs to the patient, a memory device storing a safety data set reflecting safe and undesirable parameters of at least one monitored patient physiological condition, and an electronic controller interconnected between the patient health monitor, the drug delivery controller, and the memory device storing the safety data set; wherein said electronic controller receives said signals and in response manages the application of the drugs in accord with the safety data set.

FIG. 2 illustrates one embodiment of security prompt **30**, where security prompt **30** may be incorporated into user interface **12**. User interface **12** may be any suitable means for allowing user **13** to interface with sedation and analgesia system **22** such as, for example, a touch-sensitive screen, soft buttons, hard buttons, and/or a partially or completely voice activated system. Security prompt **30** may comprise text box **31**, where text box **31** comprises any textual and/or iconic information capable of indicating to user **13** that he must input suitable

authorized identification information in order to be allowed access to sedation and analgesia system **22**. For example, if a personal identification number (PIN) security system is implemented into sedation and analgesia system **22**, text box **31** may read "Enter PIN." Security prompt **30** further may comprise data display **32**, where data display **32** may be any textual and/or iconic information indicative of the authorized identification information entered by user **13**. For example, in the case of a PIN security system, data display **32** may indicate an asterisk (*) for every numeral entered by user **13** in order to indicate to user **13** that a character has been entered, while at the same time maintaining the privacy of the identification information of user **13** towards other individuals in sight of prompt **30**. Data display **32** may further comprise a textual display, such as the phrase "data entered," or any other suitable text and/or icon such as, for example, a display of actual data entered, a symbolic representation of data entered, and/or displays relating to completed data entry if data has been entered into security prompt **30**. Data display **32** may further comprise an audio component, where audio signals may be initiated at the press of input buttons **33**, successful entry of authorized user information, or for any other suitable reason. Buttons **33** may also provide tactile feedback to a user when pressed so that the user knows a button has been pressed.

Input buttons **33** of security prompt **30** may be touch buttons, soft buttons, hard buttons, or any other suitable means of inputting secure data. In one embodiment of the present invention, security prompt **30** comprises a plurality of input buttons **33**, having integers from 0-9 listed sequentially on 10 input buttons **33**, where user **13** is required to input a personal identification number that is any suitable combination of any number of input buttons **33**. Input buttons **33** may further comprise text, case specific text, icons, and/or and suitable combination of numerals. Security prompt **30** further comprises enter button **35**, where enter button **35** may be depressed or otherwise initiated by user **13** to confirm a PIN entry. Security prompt **30** further comprises cancel button **34**, where cancel button **34** may be depressed or otherwise initiated by user **13** if user **13** makes an error in inputting his/her PIN number. Requiring user **13** to input authorized user identification such as, for example, a personal identification number, diminishes the possibility that untrained clinicians, recreational drug users, or other unauthorized individuals will be able to gain access and misuse the system. Other embodiments of the system

of the present invention may include alphanumeric buttons **33** so that the security information entered by user **13** can be more complex than a PIN or more easily remembered by the user.

The present invention further may provide an error prompt (not shown) in the event that an invalid PIN is entered into security prompt **30**, where user **13** may be required to reenter
5 their PIN or other suitable personal identification information. Authorized PIN entries for each user may be pre-programmed into the system, with each user having the ability to change the user's PIN once access to the system has been granted. Data relating to authorized PIN entries may be stored in controller **14** in a hard drive, flash disk, super disk, or other suitable data storage device. Authorized PIN entries may be transmitted to sedation and analgesia system **22**
10 via wireless communications such as, for example, by incorporated wireless Ethernet into sedation and analgesia system **22**. Authorized PIN entries may also be transmitted to sedation and analgesia system **22** over hardwired lines such as, for example, RS-232 or Ethernet connections.

In one embodiment of the present invention, sedation and analgesia system **22** comprises
15 a plurality of security levels, where individuals may be authorized for maintenance access, clinician access, administration access, or other suitable levels of access to sedation and analgesia system **22**. For example, a PIN entry corresponding to maintenance access may allow user **13** access to basic system features in order to ensure sedation and analgesia system **22** functionality, yet disallow the insertion of a drug vial into drug delivery **19** or other function.
20 Providing only limited access to maintenance personnel or other groups further diminishes the probability of misuse of the system by unauthorized individuals. Clinicians may, for example, be allowed access to drug delivery capabilities of sedation and analgesia system **22**, yet may not be given access to functionalities such as PIN authorization or other administrative features. Denying clinicians access to, and the ability to enter and/or change authorization codes, may
25 prevent the accidental or intentional misuse of sedation and analgesia system **22**.

Administrators may be given access to authorization codes, yet may not be given access to the features of sedation and analgesia system **22** related to drug delivery and/or patient **18** care.

The present invention further comprises storing general data relating to the use of sedation and analgesia system **22**, where the data may be stored in connection with the personal
30 identification number of user **13**. Data may be stored in a flash disk, super disk, hard drive, transmitted to a server for storage, or stored in any other suitable manner. Data stored may be

related to duration of use by user **13**, number of times user **13** has accessed sedation and analgesia system **22**, at what time during the day user **13** accessed sedation and analgesia system **22**, information related to administration of drugs, information related to negative procedural events, or any other suitable data for ascertaining whether misuse of sedation and analgesia system **22** has occurred. Recording data related to sedation and analgesia system **22** use may also help identify a user who may need additional training if a number of system failures or critical incidents are attributable to that user.

The present invention may further comprise incorporating any suitable security device into sedation and analgesia system **22** such as, for example, a retinal scanner, fingerprint scanner, biometric scanner, voice recognition system, or a magnetic strip identification card system for the verification of the authority of a user to perform a functionality of the system **22**. Any suitable combination of a plurality of security devices is further consistent with the present invention.

FIG. 3 illustrates one embodiment of method **100** in accordance with the present invention, where method **100** comprises start step **101**. In one embodiment of the present invention, start step **101** comprises providing a sedation and analgesia system integrated with a user authorization security system and delivering power to the integrated sedation and analgesia system **22**. The user authorization security system may be a PIN authorization system, retinal scanner, fingerprint scanner, magnetic strip identification card system, and/or any other suitable user authorization system. Following start step **101**, method **100** may proceed to step **103**.

In one embodiment of the present invention, step **103** comprises initiating security prompt **30**, where security prompt **30** may be displayed on user interface **12**. Further embodiments of security prompt **30** may request user **13** to participate in a retinal scan, fingerprint scan, enter their PIN, and/or request user **13** to scan their identification card in an identification card scanner. Security prompt **30** may further indicate whether user **13** has gained access and what level of access to sedation and analgesia system **22** they have received. Following step **103**, method **100** may proceed to step **104**.

In one embodiment of the present invention, step **104** comprises user **13** inputting their user identification into sedation and analgesia system **22**. User **13** input comprises user **13** subjecting themselves to a retinal scan, fingerprint scan, entering their PIN, swiping their identification card, and/or any other suitable means of inputting personal identification for

authorization. Once user **13** has input their personal identification information, method **100** may proceed to query **105**.

Query **105** comprises controller **14** determining whether the personal identification information input by user **13** matches the personal information of those individuals who are
5 allowed access to sedation and analgesia system **22**. Controller **14** may further determine what level of access user **13** is granted such as, for example, maintenance access, clinician access, or administrative access. Authorized personal identification information may be stored in controller **14** in the form of a flash disk, super disk, hard drive, or other suitable storage means. In one embodiment of the present invention, sedation and analgesia system **22** is connected to
10 an intranet and/or extranet, where user identification may be authorized from a remote location. User **13** input may also be used for billing purposes, where user **13** may be charged per use of sedation and analgesia system **22**. For example, if user **13** is an authorized clinician licensed to operate sedation and analgesia system **22**, but maintenance, use, software, or other fees have not been paid, user **13** may be denied access to sedation and analgesia system **22** and/or
15 provided an explanation as to the reason why access was denied.

If the personal identification of user **13** does not correspond to the data stored in sedation and analgesia system **22**, method **100** may proceed to finish step **107**. In one embodiment of the present invention, finish step **107** comprises placing or retaining sedation and analgesia system **22** in a powered state where patient monitoring and drug delivery **19**
20 functionality are disabled. Finish step **107** may disable sedation and analgesia system **22** functionality and prevent user **13** from monitoring or delivering drugs to patient **18**. Finish step **107** further comprises fully powering down sedation and analgesia system **22**.

If the personal identification of user **13** corresponds to the data stored in sedation and analgesia system **22**, method **100** may proceed to step **106**. Step **106**, in one embodiment of the
25 present invention, comprises providing user **13** access to the features of sedation and analgesia system **22** consistent with their authorization level as indicated by their personal identification. For example, user **13** may enter a PIN, and controller **14** will determine that user **13** is authorized for maintenance access only. Sedation and analgesia system **22** will then limit the functionality of sedation and analgesia system **22** to only those features that pertain to the needs

of maintenance personnel. Once user **13** has accessed sedation and analgesia system **22** and completed their work, method **100** may proceed to finish step **107**.

While exemplary embodiments of the invention have been shown and described herein, it will be obvious to those skilled in the art such embodiments are provided by way of example
5 only. Numerous insubstantial variations, changes, and substitutions will now be apparent to those skilled in the art without departing from the scope of the invention disclosed herein by the Applicants. Accordingly, it is intended that the invention be limited only by the spirit and scope by the claims as they will be allowed.

10

CLAIMS:

1. A sedation and analgesia system comprising:
 - 5 a patient health monitor device adapted so as to be coupled to a patient and generate a signal reflecting at least one physiological condition of the patient;
 - a user interface allowing a user to enter inputs;
 - a drug delivery controller supplying one or more drugs to the patient;
 - an electronic controller operably connected to the patient health monitor, and the drug delivery controller, wherein said electronic controller receives said signal and in response manages
 - 10 the application of the drugs in accord with stored parameters of at least one monitored patient physiological condition; and
 - a security system incorporated into said user interface that requires said user to input authorized personal identification information so as to restrict unauthorized use of said sedation and analgesia system, wherein information related to negative procedural events during the use of
 - 15 said sedation and analgesia system is recorded in association with said authorized personal identification information of said user and said information related to negative procedural events is used to determine future authorization of said user, and wherein administrative access to the sedation and analgesia system is separable from access to features of the sedation and analgesia system related to drug delivery and/or patient care.
 - 20
2. The sedation and analgesia system according to claim 1, wherein said security system comprises a security prompt that requires said user to input said authorized personal identification information before said sedation and analgesia system is enabled for operation.
- 25 3. The sedation and analgesia system according to claim 2, wherein data relating to said authorized personal identification information is stored in a memory device associated with said sedation and analgesia system.
4. The sedation and analgesia system according to claim 3, wherein said authorized personal
- 30 identification information is at least one of a personal identification number, a retinal scan, a fingerprint, a biometric scan, a voice recognition command, and a magnetic strip identification card.
5. The sedation and analgesia system according to claim 3, wherein said authorized personal
- 35 identification information is transmitted to said sedation and analgesia system via wireless communications.

6. The sedation and analgesia system according to claim 3, wherein said security system comprises a plurality of security levels that permits access to varying functionalities of said sedation and analgesia system.

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7. The sedation and analgesia system according to claim 6, wherein said plurality of security levels includes a maintenance access level, an administration access level, and a clinician access level.

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8. The sedation and analgesia system according to claim 3, wherein general data relating to the use of said sedation and analgesia system is recorded in association with said authorized personal identification information of said user.

15

9. The sedation and analgesia system according to claim 8, wherein said general data comprises at least one of a duration of use by said user, a number of times said user has accessed said sedation and analgesia system, a time of day said user accessed said sedation and analgesia system, and information related to administration of drugs.

20

10. The sedation and analgesia system according to claim 8, wherein said general data comprises system failures, such that training needs can be identified for said user associated with said data.

25

11. A method of operating a sedation and analgesia system comprising the steps of:
connecting to a patient a drug delivery device having a drug delivery controller supplying one or more drugs, said drug delivery controller being coupled to an electronic controller which controls the delivery of the drugs to the patient;

30

attaching at least one patient health monitor device to a patient, which health monitor device generates a value reflecting at least one physiological condition of a patient and is coupled to said electronic controller;

inputting into a security system identification information of an authorized user to enable operation of said sedation and analgesia system;

accessing a safety data set reflecting parameters of at least one patient physiological condition;

35

delivering the drugs to the patient in accord with the safety data set, and
recording information related to negative procedural events during the use of said sedation and analgesia system in association with said security system identification information, wherein said information related to negative procedural events is used to determine future authorization of

said user, and wherein administrative access to said information is separable from access to features of the sedation and analgesia system related to drug delivery and/or patient care.

12. The method of operating a sedation and analgesia system according to claim 11, further comprising the step of pre-programming said security system to accept particular authorized identification information.

13. The method of operating a sedation and analgesia system according to claim 12, wherein data relating to said authorized identification information is stored in a memory device associated with said sedation and analgesia system.

14. The method of operating a sedation and analgesia system according to claim 13, wherein said authorized identification information is at least one of a personal identification number, a retinal scan, a fingerprint, a biometric scan, a voice recognition command, and a magnetic strip identification card.

15. The method of operating a sedation and analgesia system according to claim 13, wherein said authorized identification information is transmitted to said sedation and analgesia system via wireless communications.

16. The method of operating a sedation and analgesia system according to claim 13, wherein said security system comprises a plurality of security levels that permits access to varying functionalities of said sedation and analgesia system.

17. The method of operating a sedation and analgesia system according to claim 16, wherein said plurality of security levels includes a maintenance access level, an administration access level, and a clinician access level.

18. The method of operating a sedation and analgesia system according to claim 13, wherein general data relating to the use of said sedation and analgesia system is recorded in association with said authorized identification information of said user.

19. The method of operating a sedation and analgesia system according to claim 18, wherein said general data comprises at least one of a duration of use by said user, a number of times said user has accessed said sedation and analgesia system, a time of day said user accessed said sedation and analgesia system, and information related to administration of drugs.

20. The method of operating a sedation and analgesia system according to claim 18, wherein said general data comprises system failures, such that training needs can be identified for said user associated with said data.

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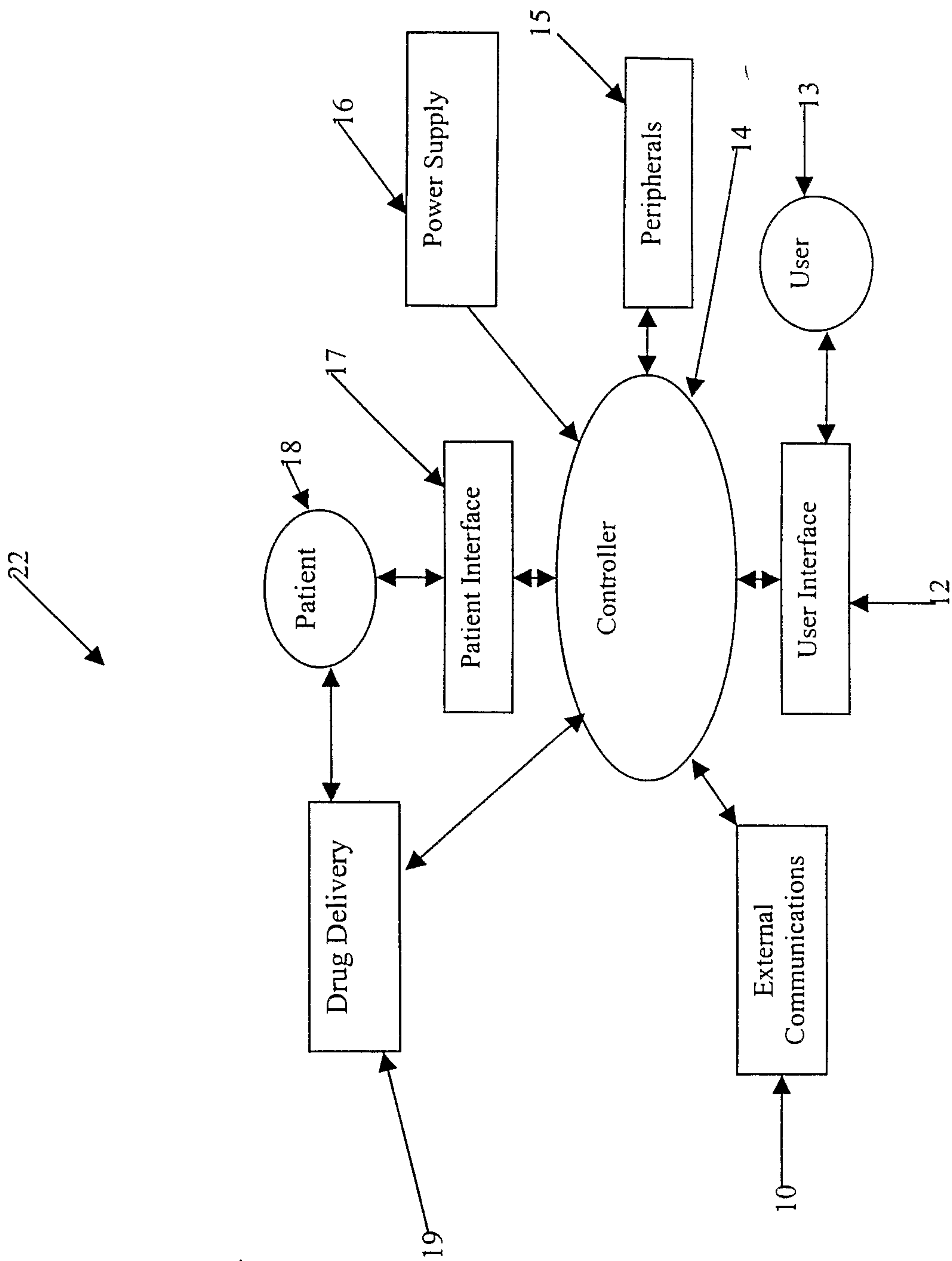


Fig. 1

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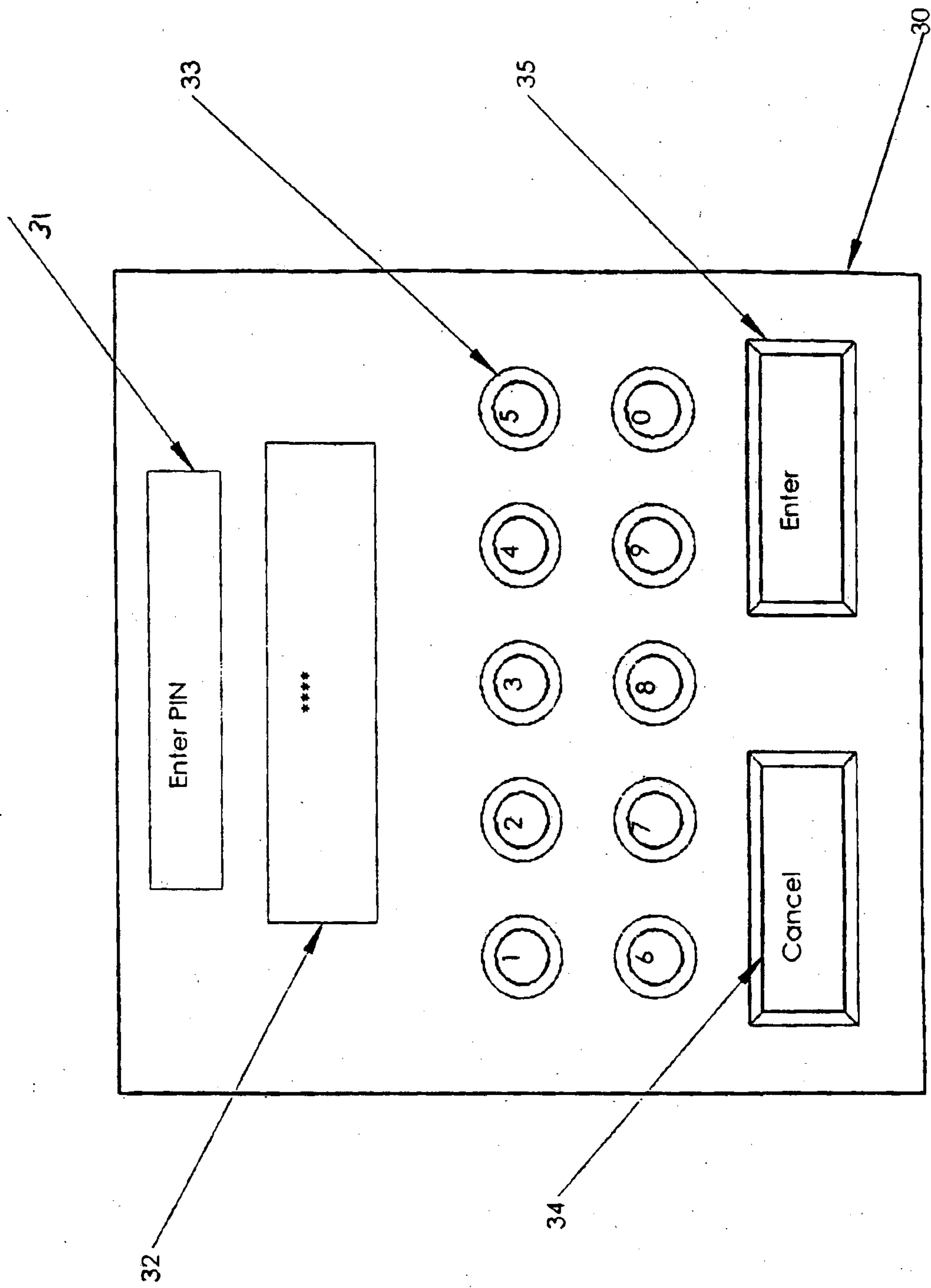


Fig. 2

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