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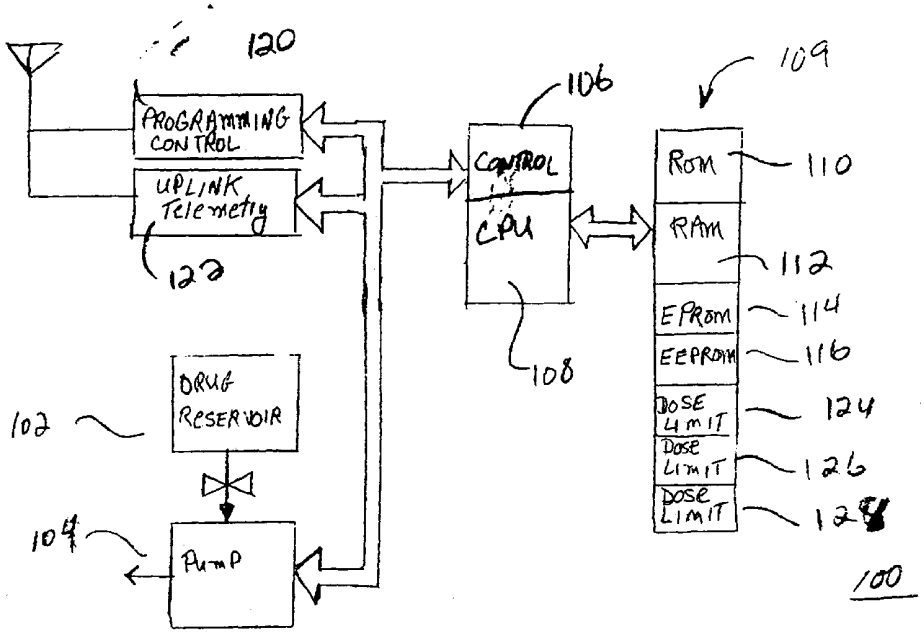

(57) Abstract: An implantable drug infusion pump for delivering drug therapy to a patient and which also permits a patient to deliver or self-administer an additional bolus, reduces the likelihood of over dosage or under dosage by drug dosage characteristic limitations programmed into a microprocessor memory. The dose limits define the maximum and minimum amount of drug to be delivered per unit time or otherwise, reducing the likelihood that a patient may inadvertently or deliberately interfere with a treatment regimen.

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METHOD AND APPARATUS TO CONTROL DRUG THERAPY DOSAGES IN AN IMPLANTABLE PUMP

FIELD OF THE INVENTION

This invention relates to implantable drug infusion pumps. In particular, this invention relates to a method and apparatus for controlling drug dosages that can be delivered by an implantable drug infusion pump.

BACKGROUND OF THE INVENTION

Implanted infusion pumps deliver therapeutic drugs to a patient according to a computer program executed by a processor that is programmed with drug dosing parameters. A microprocessor controls a small, positive displacement pump according to programming instructions delivered to the microprocessor through an RF programming link so as to permit the implantable pump to be remotely programmed and operated. In the course of executing its program, the processor controls a mechanical pump according to programmed dosage parameters.

A problem with prior art drug infusion pumps are that they run open-loop, i.e. there is no feedback mechanism controlling drug dosing. Moreover when used for treating many disorders, implantable infusion pumps need to permit the patient to self-administer a bolus of medication on demand. For example, many diabetics need to administer a bolus of insulin either just prior to or just after a meal. The changing of drug infusion rates is important as the insulin requirements of diabetic patients' change during the course of a day. Therefore, it is important that any drug treatment system be able to accommodate a predetermined constant delivery rate as well as any adjustments that may be required during the course of a day. However, this frequent changing of dosage rates can lead to potential underdosing or overdosing situations.

While prior art implantable and programmable infusion pumps permit a patient to administer additional drug dosages on demand, these prior art devices do not adequately control the amount of patient-administered dosages increasing the likelihood that a patient may overdose or underdose himself, adversely affecting the patient's physician-prescribed therapy.

A remotely programmable and implantable tissue stimulator is disclosed in U.S. Patent No. 5,443,486 to Hrdicka et al., for a "Method and Apparatus to Limit Control of Perimeters of Electrical Tissue Stimulators." While the '486 Patent discloses a remotely programmable tissue *stimulator* and permits the patient to control the administration of tissue stimuli, the device disclosed in the '486 patent does not provide for programmable drug infusion therapy. Nor does the '486 provide for software-based drug infusion limits.

Programmable infusion limits in implantable infusion pumps might lessen the likelihood that a patient will overdose or underdose himself. Moreover, a software-defined limit might also lessen the likelihood that certain drug regimens will be used improperly – even by health-care providers. By using a software-defined drug dosage limit, pump manufacturers might specify certain maximum and minimum dosages for certain disorders by pre-programming their own infusion pumps with the drug dosage limitations.

In order to lessen or prevent inadvertent infused drug overdoses or underdoses, implanted drug infusion pumps require limits to be placed upon the drug delivery amount and/or frequency by health care professionals. An internal limit on the amount by which a patient can self-dose a drug, would be an improvement over the prior art implantable infusion pumps. Similar limits might prevent health care providers from inadvertently overdosing, or even underdosing treatments.

SUMMARY OF THE INVENTION

A fully implantable drug infusion pump, which includes an RF programming link, an implantable drug reservoir wherein a therapeutic drug is stored and a small, microprocessor-controlled positive displacement pump is entirely software controlled using an embedded and implantable microprocessor and power supply. Programming instructions and data delivered to the microprocessor through an RF programming link are used to limit infused drug dosage. The dosage limit data is stored in programmable memory within the microprocessor or in separate memory devices. The microprocessor controlling drug administration compares the amount of drug administered over time according to the data parameters defining the treatment regimen's dosage limits.

In the preferred embodiment of the invention, the programmable infusion pump also permits the patient to self-administer additional doses on demand. The patient-requested additional dosage limits are specified by the patient's health care provider and these limits can be programmed into the implantable pump by the health care provider using the RF programming link. Thereafter, access to the dosage limits is not available to the patient. RF programming, data encryption or other security software could limit access to the drug dosage limit data. Within the therapy program limits, patients would have the flexibility to adjust the delivery of dosages to account for meals or needed bolus flow rates during the course of the day. These changes to the base flow would be tracked by a therapy program and compared to the dosage limits. Patient notification, for example through an alarm, may be utilized if the actual dosage would fall above or below the programmed dosage limits. Patient-controlled drug dosage is limited by the health care provider-specified limit value.

In another embodiment, drug manufacturers, as well as health-care providers, might offer implantable infusion pumps for use with certain drugs that have precise treatment regimens. Over-dosing or under-dosing might be precluded by way of dosing definitions programmed into secure data storage locations.

In yet another embodiment, underdosage by the patient could be avoided if the pump is programmed to a minimum dosage or by warning the patient. The warning could be an audio alarm from the pump or an indicator on the patient's controller to which the patient could respond by increasing the dosage.

The same underdosage alarm could be implemented to alert the patient of a requested overdosage, thereby alerting the patient when a dosage request amounts to an overdosage not allowed by the pump.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 discloses a simplified block diagram of an implantable, software controlled infusion pump providing software dosage limits.

Figure 2 shows a full system implementation of a pump including, the pump, a catheter, two external controllers, one patient use and one medical person use.

Figure 3 shows a diagrammatic view illustrating a patient controller and a physician programmer and their communication with an implantable drug pump.

Figure 4 illustrates a method of decreasing drug use in accordance with an embodiment of the invention.

Figure 5 illustrates a method of preventing drug underdosage in accordance with an embodiment of the invention.

Figure 6 illustrates a method of reducing the number of episodes requiring dose activations in accordance with an embodiment of the invention.

Figure 7 illustrates a method of preventing a drug overdose in accordance with an embodiment of the invention.

DETAIL DESCRIPTION OF THE PREFERRED EMBODIMENT

Figure 1 shows a simplified block diagram of the functional elements of an implantable and programmable drug infusion pump 100 having re-programmable (i.e. software-specified) dosage limits. The functional elements of the infusion pump 100 shown in Figure 1 are small, such that the pump can be readily implanted into the abdomen of a patient for purposes of controlling chronic diseases, such as diabetes. An implanted infusion pump might also be used for acute treatment regimens, e.g. to administer chemotherapy drugs or morphine to treat cancer or treat pain respectively.

Referring to Figure 1, a reservoir 102 contains some appropriate volume of drug to be administered to the patient by a pump 104, preferably a precision positive displacement pump drawing drug material from the reservoir 102. While Figure 1 shows only a single reservoir and a single pump, the invention disclosed herein is readily adapted for use with multiple reservoirs for administering several different drugs or for increasing the volume of a single drug that might be implanted into the patient. Multiple pumps might be also used with multiple reservoirs to administering different drugs at different rates and times. Multiple pumps might be used with a single reservoir for increased reliability.

The pump 104 is operatively coupled to and responsive to electrical signals delivered to it from a control unit 106. Electrical signals from the control unit 106 would, for example, start and stop the pump 104 and including its delivery rate so as to modulate the delivery of drugs from the reservoir 102 to the patient. The control circuitry within the control unit 106 would typically include appropriate electronic drive circuits, the essential function of which is to couple a central processor 108 to the pump 104 through appropriate interface circuitry well know to those skilled in the art.

Alternate embodiments of the invention would of course include implementing any required pump/CPU interface directly into the microprocessor, or selecting and/or designing the pump 104 to eliminate the need for an interface between it and the low power circuits of the microprocessor. Many commercial grade microprocessors include a plethora of ancillary circuitry on a single substrate including analog-to-digital converters, digital-to-analog converters, counters, timers, clocks and so forth.

The central processor unit 108 controls the amount of drug treatment administered to the patient according to the therapy program instructions stored in a program memory 110. The program memory, which could be resident on the same semiconductor substrate as the CPU, typically requires the ability to temporarily store and retrieve data. Random access memory 112 shown in Figure 1 and well known to those skilled in the art, is available for use by the program executed by the CPU 108.

Those skilled in the art will recognize that while the program executed by the CPU 108 might be most economically implement in read-only-memory (ROM) structure equivalent to the ROM could include electrically programmable read only memory (EPROM) 114 as well as electrically erasable programmable read-only memory (EEPROM) 116. Both of these alternate structures are capable of retaining executable instructions required by the central processing unit 108 to operate and control the pump 100.

The EPROM 114 and the EEPROM 116 are re-programmable semi-conductor memories as those skilled in the art will recognize. EEPROM 116 is particularly useful in the invention as it readily lends itself as a repository for drug therapy dosage characteristics and is safer than RAM (random access memory) because RAM is volatile and susceptible to errors caused by power source interruption. EEPROM retains data for long periods of time yet is readily re-programmed by the CPU. Many commercially available microprocessors include addressable EEPROM directly on the substrate comprising the CPU further simplifying the implementation of a software-limited dosage implantable drug infusion device. Figure 2 shows the pump system embodiment including a drug infusion pump 200 and a drug infusion catheter 204, suitable to deliver drugs to a distal sight in the body. Two external controllers are shown, one for patient use 210 and one for medical person use 220. The pump 200 with the connected catheter

204 is implanted in the patient's body 216 under the skin 214. For remote programming purposes, RF energy 212 flows bi-directionally between the pump 200 and the patient use external controller 210. Similarly, the health care provider uses an external controller 220 to independently program the implanted pump to the desire infusion parameters as is commonly done in the art. The manufacturer of the controller 220 sets the range of controller 220. A piezoelectric transducer or other suitable audio enunciator 202 on the pump body or otherwise electrically coupled to the pump and its internal controller might be used to provide an audible alarm to the patient in the case of under or overdosing.

A health care provider programs the implantable infusion pump 100 using a remote programming device 210, such as the programming device disclosed in U.S. Patent No. 5,443,486 and U.S Patent No. 4,676,248, "Circuit for Controlling a Receiver in an Implanted Device" by Berntson. The program executed by the CPU 108 regularly scans the RF link (embodied by the programming control 120 and the uplink telemetry 122) for commands. Alternate embodiments would of course include RF communication link circuits that assert an interrupt control line on so-equipped processors. At least one command recognizable by the CPU 108 is a patient-initiated request to the pump 100 to administer a bolus of drug from the reservoir 102. Such a request would be sent to the pump 100 by the patient being provided with a transponder specifically designed to transmit a bolus-request command. The functionality of the patient-operated device 210 is limited and incapable of altering key data programmed by a health care provider.

Both the health-care provided instructions and the patient requested doses are delivered to the CPU 108 through an input port on the CPU. Such an input port of the CPU 108 would include a memory mapped input/output device or other parallel or appropriate buffered serial input port, all of which are commonly found on many commercially available micro controllers.

In the course of programming, the infusion pump, the health care professional can specify a dose infusion characteristic parameter to be stored into one or more of the memory locations 124, 126 and 128 of the memory device 109 depicting Figure 1. The dose infusion characteristic stored in memory may be one or more bytes of data (recognizable by the program instructions) to limit the amount, frequency, or other

characteristic(s) of a dose of the drug to be administered to the patient by the pump 100. The dose infusion characteristics could also prescribe dosage minimum dosage amounts as well.

For example, the dose infusion characteristic stored in one of the memory locations (124, 126, 128) in Figure 1 could be used by the program stored in ROM 110 to limit the number of drug bolus deliveries that a patient may initiate in a twenty-four hour period. Alternatively, the drug dose infusion characteristic might control the volume of drug to be delivered upon the request of the patient over a given period of time. The bolus frequency, bolus dosage size per unit time, bolus size, or other dose information might also be stored.

Similarly, a drug dose infusion characteristic might be programmed into one of the memory locations 124, 126 and 128 as fail-safe limits to prevent overdosing or underdosing a patient by a health care professional. Such an upper-limit of a drug dose might be used by the program in ROM 110 or EPROM 114, 116 as a fail safe to prevent a health care professional from accidentally overdosing or underdosing the patient. When the health care professional programs the infusion pump via the RF programming link.

In an alternate embodiment, the CPU 108 might scan or poll sensors (not shown) providing data on the efficacy of the treatment. Alternate dosages might be indicated by input from one or more sensors. Dose limits would still provide a means by which maximum or minimum treatments would not be exceeded.

Those skilled in the art will recognize that the controller 108 is preferably a programmable microcontroller or microprocessor. Such devices are well known in the electronics art and many include read-only memory, random access memory, EPROM and EEPROM on board the device. Such devices also routinely include a/d converters, d/a converters, counters, timers, and other circuits usable in a real time control application including an implantable infusion pump.

Altering embodiments might include combinational as well as sequential logic although those skilled in the art will recognize the inherent advantages of using a microprocessor or micro controller. Still other embodiments would contemplate using analog devices, such as an analog computer to control the pump 104 in response to bodily conditions.

Program instructions for the controller 108 are stored an appropriate memory device. Program instructions might also be stored in ROM, RAM, EPROM or EEPROM as set forth above. Infusion limits or dose characteristics are preferably stored in a programmable memory location, such as EPROM or EEPROM because of their ability to retain data over long periods of time, even if power is lost. In the case of random access memory (RAM) power may have to be continuously applied to the memory device and any ancillary circuitry to avoid data loss.

In operation, a health care professional would preferably download programming and/or data into the memory device 109 through the RF interlink circuitry 120 and 122. As shown in Figure 1, these programming instructions and/or data have passed through the central processing unit 108. Depiction of this data path in Figure 1 should not be construed as limiting. Sufficient intelligence might be built into the RF link circuitry to directly load random access memory or other memory devices 109 directly through the programming link.

Figure 3 represents an alternative embodiment to the configuration of the patient controller 310 and the physician programmer 320. In this embodiment, the patient controller 310 contains a therapy program 306 for possible drug infusion rate adjustments. The patient controller 310 also contains a microprocessor 318 and memory 326 that would store treatment information such as base rate drug flows, the maximum and minimum daily allowable doses, patient activation requests, and drug delivery monitoring data. The health care provider would use the physician programmer 320 to specify the drug infusion characteristics that may include the maximum and minimum daily allowance dosages, 24 hour rolling average rate limits, nominal dosage rates, and a minimum time interval between bolus requests. In particular, the health care provider may program two or more different base infusion rates that would be acceptable in reaching the daily dosages. The nominal dosage rates would be the default rates and a patient could then select a different base rate using the patient controller 310 depending on the needed amount of therapy at any given time of the day. The patient controller 310 through the therapy program 306 would only allow a base rate change to those rates already approved by the health care professional.

Optionally, the patient controller 310 may also contain a notification mechanism to provide feedback to the patient. For example and without limitation, the patient controller 310 may contain an audio speaker 302 and a LCD display 304 to provide the patient with alarm, status and task information. The alarm information would be generated from the changes in the patient controller therapy program output. A brief overview of some of the steps that the therapy program would perform in determining whether the proper amount of drugs are being administered are shown in Figures 4, 5, 6, and 7. These steps generally track drug infusion characteristics and allows the patient to adjust the therapy to provide a more efficient and effective drug treatment.

Figure 4 illustrates the steps that may be performed by the therapy program to determine whether the amount of drug being administered should be decreased. This may occur, for example, when the patient is not administering any additional bolus of drug, thereby suggesting that the base rate could possibly be reduced. In step 402, the therapy program determines whether the patient has requested a dose of medication in a specified period of time. This dose request by the patient could be either a bolus dose or an increase in the base rate. The specified period of time would depend on the type of drug being administered and may be, for example, based one or more days or one or more hours. If the patient has requested dose activation within the specified period of time, then the program does not make any changes, at step 404. If, on the other hand, the patient has not requested a dose indication within the specified time, at step 406, then the drug therapy could be reduced. Either the patient would be prompted, by the notification mechanism, to use the patient controller to select the next lowest base rate to reduce drug usage, or the therapy program could activate the smallest programmed dose when the patient makes an activation request. These steps ensure that a patient is not being over medicated by a base infusion rate flow that is larger than the patient's current medication requirements.

Figure 5 illustrates the steps that may be performed by the therapy program to prevent drug underdosage. In step 502, the therapy program determines whether a patient is nearing an underdosage condition. The program tracks the patient drug therapy and therefore, knows the actual total dosage being delivered to the patient. The actual total dosage delivered to the patient is the combination of the base rate and the number of

bolus activations over the specified time period. The program also knows the minimum allowed dosage that is desired for a particular drug. The program compares the actual dosage and the minimum allowed dosage. If the actual dosage is within a predetermined percentage of the minimum allowed dosage then the patient is nearing an underdosage condition. This tracking of the total dosage allows flexibility in the administering of the drug therapy. For example, the physician may prescribe a base rate over the course of a period of time below the minimum dosage with the knowledge that the patient will be administering a number of bolus dosages during that period of time. The combination of the base rate and the bolus dosage activations over the course of that time period would together reach the minimum allowed dosage. If the patient is not nearing an underdosage condition then the therapy program does not make any changes at step 504. If, however, the therapy program determines that a patient is nearing an underdosage condition then the therapy program may prompt the patient, through the client notification system, to use the patient controller to either activate a bolus dose of medication or to use the next highest base rate as depicted in step 506. This reminds the patient to make sure that they administer their bolus dosages. This type of notification is important, as preventing underdosing is important in many drug therapy plans. For example, in the case of Baclofen for spasticity, drug withdrawal has serious side effects and is a major concern.

Figure 6 illustrates the steps that may be performed by the therapy program to determine whether the patient has requested too many bolus activations over a specified period of time. In step 602, the therapy program determines whether the patient has requested more bolus activations than allowed by the health care provider. Because the program tracks the patient drug therapy, the program knows the number of bolus activations and bolus activation requests over a specified time period. If the number of bolus activations is below the allowable amount, then the therapy program continues in its normal fashion at step 604. If, however, the patient has had more than the allowed number of drug bolus activations then the patient would be prompted by the notification mechanism to use the patient controller to select a higher base rate in an attempt to reduce the amount of future bolus activation requests.

Figure 7 illustrates the steps that may be performed by the therapy program to prevent a drug overdosage. In step 702, it is determined whether the patient is currently utilizing the highest base rate allowed by the health care provider. Because the program tracks the patient drug therapy, the program knows the current base rate and the highest base rate programmed by the physician. If the patient is not at the highest base rate then the therapy program continues as normal at step 704. However, if the base rate is at the highest allowable setting then the therapy program determines whether the patient is nearing his or her maximum daily dose at step 706. If the patient is not nearing his or her maximum daily dose then the therapy program stops the inquiry and continues as normal at step 708. However, if the patient is nearing the maximum daily dose then the therapy program could deny further activation requests, activate the smallest programmed dose when an activation request is made by the patient or prompt the patient to select the next lowest base rate.

By use of the invention disclosed herein, the likelihood of overdosing a patient with a drug from an implanted and therefore an inaccessible diffusion pump is reduced. Software based limits programmed into a microcomputer increased the flexibility of the implanted pump for a wider range of therapies compared to prior art, hard-wired devices. The software-based limits add an increased level of safety not found in prior art implantable drug infusion pumps devices.

The description of the apparatus of this invention is not intended to be limiting but is merely illustrative of the preferred embodiment of this invention. Those of ordinary skill in the art will recognize that modifications can be made without departure from the true spirit and scope of the invention.

The true spirit and scope of the inventions of this specification are best defined by the appended claims, to be interpreted in light of the foregoing specification. Other apparatus which incorporate modifications or changes to that which has been described herein are equally included within the scope of the following claims and equivalents thereof. Therefore, to particularly point out and distinctly claim the subject matter regarded as the invention, the following claims conclude this specification.

What is claimed is:

1. An automatic drug therapy delivery system, capable of being implanted into a patient comprised of:

a) at least one implantable reservoir of a drug to be administered to the patient;

b) an implantable, programmable pump coupled to the implantable reservoir, for delivering from the implantable reservoir at least one drug from the reservoir to the patient;

c) a programmable first memory module for storing a dose infusion characteristic;

d) a first input port receiving a first input signal from a patient so as to cause the pump to administer a bolus of drug, the bolus limited by the dose infusion characteristic;

e) a programmable microprocessor coupled to the programmable first memory module and to the first input port, the programmable microprocessor monitoring the amount of drug therapy administered to the patient according to instructions stored in the programmable first memory module and ensuring against overdosage or underdosage of the drug therapy; and

a programming link coupled to the implanted programmable pump for receiving instructions for the implantable programmable pump from outside the patient's body and for programming the dose infusion characteristic.

2. The system of claim 1 wherein the microprocessor performs the step selected from the group consisting of denying further activation requests, activating the smallest programmed dose when an activation request is made and prompting the patient to select the next lowest base rate, when an overdosage condition is detected.)

3. The system of claim 1 wherein the programmable first memory module is a memory device storing data controlling bolus dosage frequency.

4. The system of claim 1 wherein the programmable first memory module is a memory device storing data controlling bolus dosage size per unit time.

5. The system of claim 1 wherein the programmable first memory module is a memory device storing data for a dosage bolus size.

6. The system of claim 1 wherein the programmable first memory module is a memory device capable of receiving data received from the programming link.

7. The system of claim 1 further including an enunciator coupled to the pump.

8. The system of claim 1 further including a piezoelectric enunciator coupled to the pump.

9. An automatic drug therapy delivery apparatus, capable of being implanted into a patient comprised of:

a) an implantable reservoir of a drug to be administered to the patient;

b) an implantable, programmable pump coupled to the implanted reservoir, for delivering from the implantable reservoir a programmable amount of drug from the reservoir to a patient;

c) at least one programmable memory location, storing a dose infusion characteristic;

d) a first input port receiving a first input signal from a patient so as to administer a bolus of drug, the bolus limited by the dose infusion characteristic;

e) a positive displacement pump coupled to and drawing drug material from the implantable reservoir;

f) a programmable microprocessor coupled to the at least one programmable memory location, the first input port and to the positive displacement pump, the programmable microprocessor monitoring the amount of drug therapy administered to the patient according to instructions stored in the programmable first memory module and ensuring against overdosage or underdosage of the drug therapy; and

g) a programming link coupled to the implantable programmable pump for receiving signals for the implanted programmable pump and for programming the dose infusion characteristic into the programmable memory location;

whereby the system based on historical drug usage by the patient notifies the patient of any underdosage or overdosage conditions.

10. The apparatus of claim 9 wherein the remotely programmable pump includes a programmable microcontroller.

11. The apparatus of claim 9 wherein the programmable controller includes at least one programmable memory device.

12. The apparatus of claim 9 wherein the programmable controller includes at least one electrically erasable programmable read only memory.

13. The apparatus of claim 9 wherein the at least one programmable memory location is a programmable memory device storing data controlling bolus dosage frequency.

14. The apparatus of claim 9 wherein the at least one programmable memory location is a memory device storing data controlling bolus dosage size per unit time.

15. The apparatus of claim 9 wherein the at least one programmable memory location is a memory device storing data for a dosage bolus size.

16. The apparatus of claim 9 further including an enunciator coupled to the pump.

17. The apparatus of claim 9 further including a piezoelectric enunciator coupled to the pump.

18. In an automatic drug therapy delivery system capable of being implanted into a patient, the system capable of being remotely programmed by radio frequency signals, the drug therapy system for delivering a bolus of drug to the patient in

response to a patient-originated stimulus, the automatic drug therapy delivery system including a programmable controller having at least one input port through which signals from the patient are received by the controller and having at least one programmable memory location, a method of limiting the amount of patient-requested drug delivered to the patient comprised of the steps of:

a) programming at least one dose infusion characteristic value into the programmable memory location using a radio frequency signal;

b) delivering a bolus of a drug to the patient in response to an input signal received by the programmable controller upon the determination of the programmable controller that the bolus is compliant with the dose infusion characteristic;

c) determining the amount of drug delivered to a patient;

d) determining whether there exists a risk of overdosage or underdosage of the drug therapy; and

e) if a risk of overdosage or underdosage is determined, notifying the patient.

19. The method of claim 18 wherein the dose infusion characteristic limits the drug bolus frequency.

20. The method of claim 18 wherein the dose infusion characteristic limits the drug bolus size.

21. The method of claim 18 wherein the dose infusion characteristic limits the drug bolus frequency and size.

22. The method of claim 18 wherein the dose infusion characteristic is programmed into the programmable controller by a patient care provider.

23. The method of claim 18 wherein the programmable controller is programmable using a radio frequency programming link.

24. A computer-readable medium having computer-executable instructions for performing steps comprising of:

a) storing historical base rates and bolus drug infusion rates for an implantable drug delivery device;

b) comparing the stored historical base rates and bolus drug infusion rates with prescribed dosage rate limits; and

c) if the compared rates indicate an overdosage or underdosage situation, then notifying the patient of the underdosage or overdosage conditions.

25. A method of providing controlled treatment therapy to a patient using an implantable pump, comprising the steps of:

(a) receiving from a health care provider a set of drug dosage limit information describing at least one drug therapy dosage limit;

(b) receiving from the patient drug delivery instructions describing an amount of drug to be delivered;

(c) storing in memory historical information relating to the amount of drug delivered to the patient; and

(d) displaying feedback in the form of a notification mechanism if the drug delivery approaches the drug therapy dosage limit.

26. The method of providing a controlled treatment therapy of claim 25, wherein the notification mechanism is a LCD display.

27. The method of providing a controlled treatment therapy of claim 25, wherein the notification mechanism is an enunciator.

28. The method of providing a controlled treatment therapy of claim 25, wherein the drug dosage limit information is selected from the group consisting of maximum daily dosage, minimum daily dosage, and bolus dosage.

29. A controller in communication with an implantable drug delivery device for delivering at least one drug to a patient, the controller comprising in combination:

(a) an input for receiving drug usage information and drug dosage limit information;

(b) a memory for storing therein the drug usage information and the drug dosage limit information; and

(c) a drug therapy program determining whether the drug information has reached the drug dosage limit information, and if so, notifying the patient of the condition.

30. The controller of claim 29, wherein the controller is part of the implantable drug delivery device and the pump further comprises telemetry providing bi-directional communication between the controller and an external device.

31. The controller of claim 29, wherein the controller part of an external programmer and the pump further comprises telemetry providing bi-directional communication between the external programmer and the pump.

32. The controller of claim 29, wherein the external programmer is a patient programmer.

33. The controller of claim 29, wherein the drug therapy program determines whether a drug delivery rate may be adjusted based on the drug usage information and the drug dosage limit information, and if so, notifying the patient of the condition.

34. A controller in communication with an implantable drug delivery device for delivering at least one drug to a patient, the controller comprising in combination:

(a) an input for receiving drug usage information and drug dosage limit information;

(b) a memory for storing therein the drug usage information and the drug dosage limit information; and

(c) a drug therapy program determining whether a drug delivery rate may be adjusted based on the drug usage information and the drug dosage limit information, and if so, notifying the patient of the condition.

35. The controller of claim 34, wherein the controller is part of the implantable drug delivery device and the pump further comprises telemetry providing bi-directional communication between the controller and an external device.

36. The controller of claim 34, wherein the controller part of an external programmer and the pump further comprises telemetry providing bi-directional communication between the external programmer and the pump.

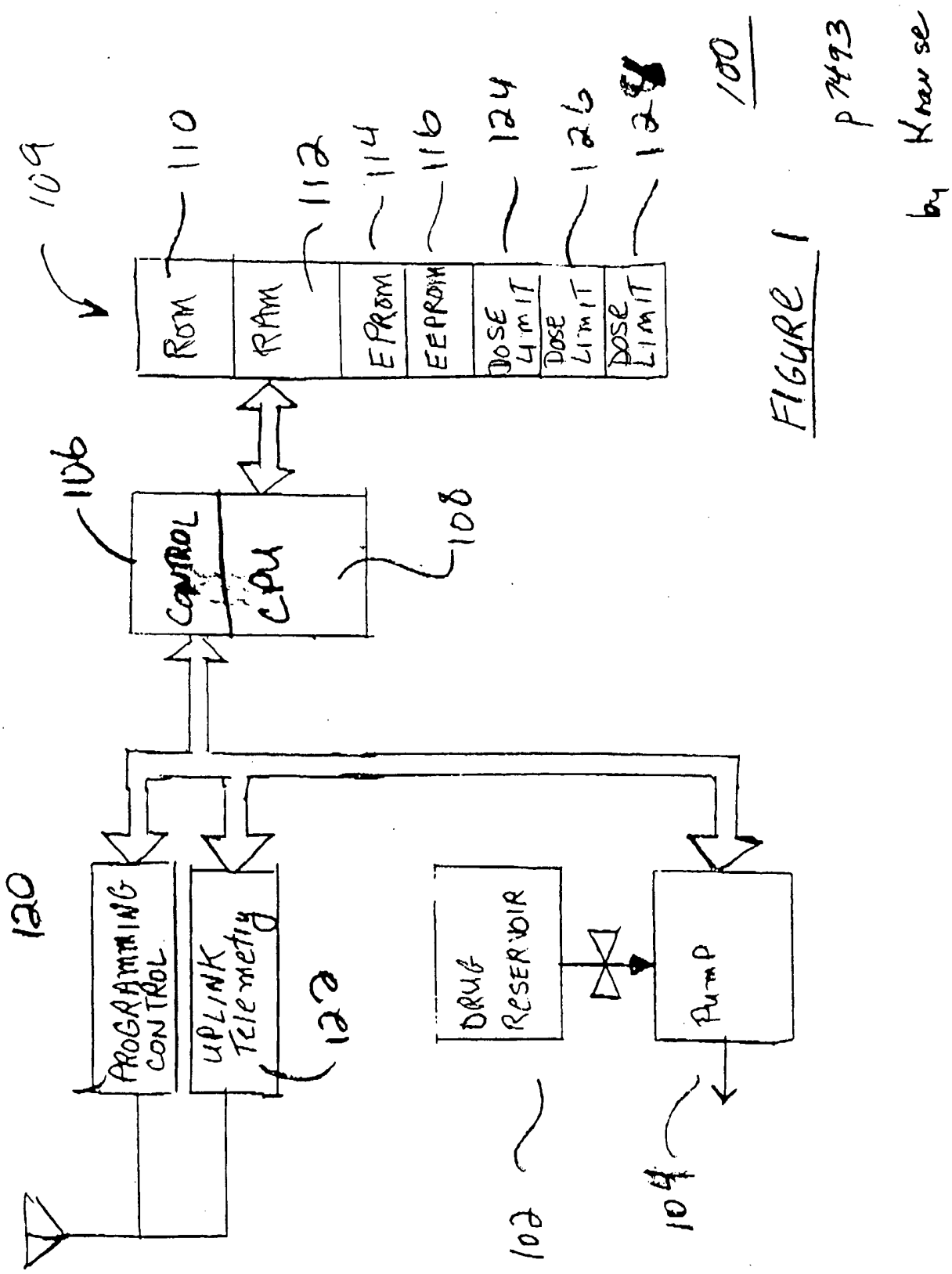
37. The controller of claim 34, wherein the external programmer is a patient programmer.

38. A computer-readable medium having computer-executable instructions for performing steps comprising of:

a) storing historical base rates and bolus drug infusion rates for an implantable drug delivery device;

b) comparing the stored historical base rates and bolus drug infusion rates with prescribed dosage rate limits; and

c) if the compared rates indicate that drug delivery rate may be adjusted notifying the patient of the condition.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DOSE LIMIT
DOSE LIMIT
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CONTROL
CPU
108
120
PROGRAMMING CONTROL
UPLINK Telemetry
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DRUG RESERVOIR
PUMP
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104
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by Krause

FIGURE 1

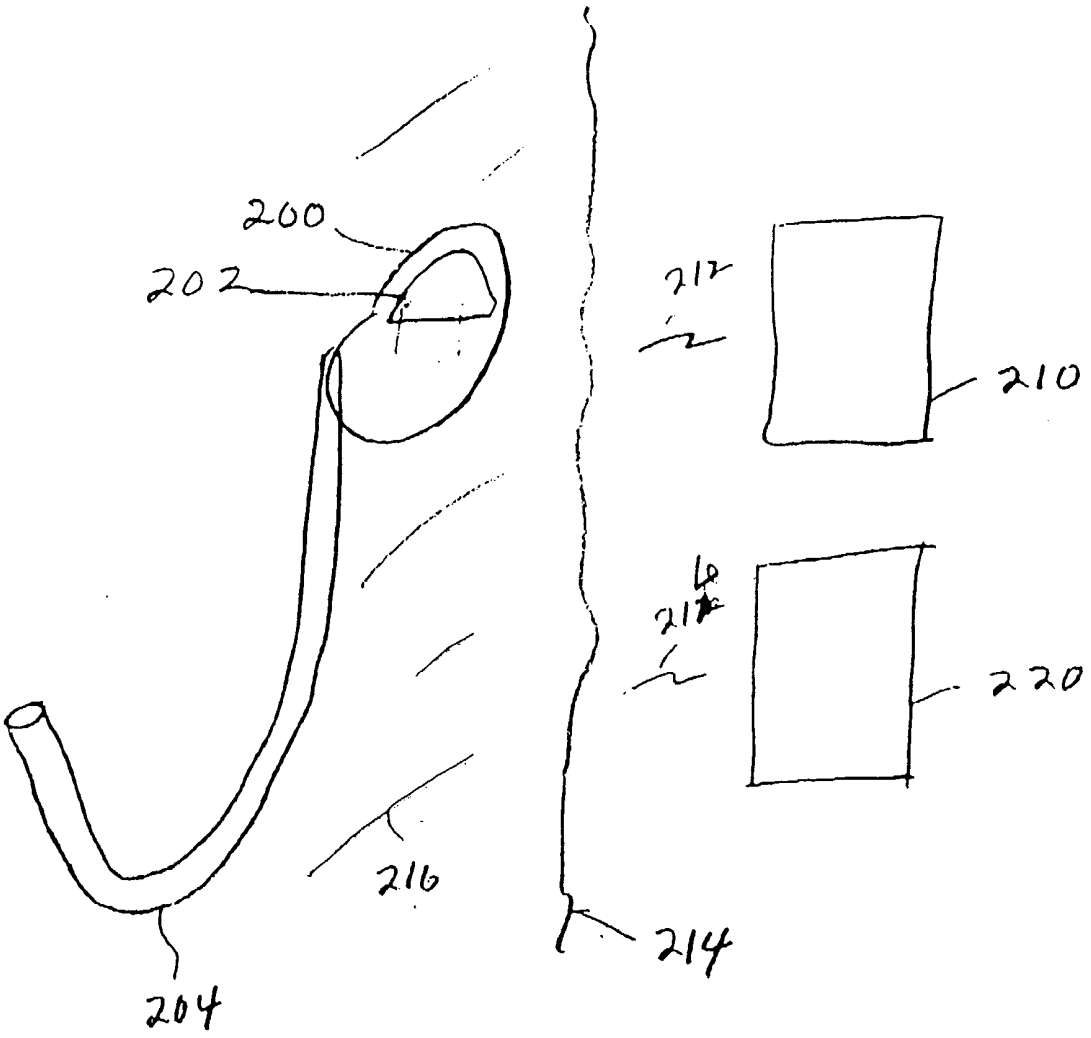

Figure 2
(by Hamilton)
p 7493

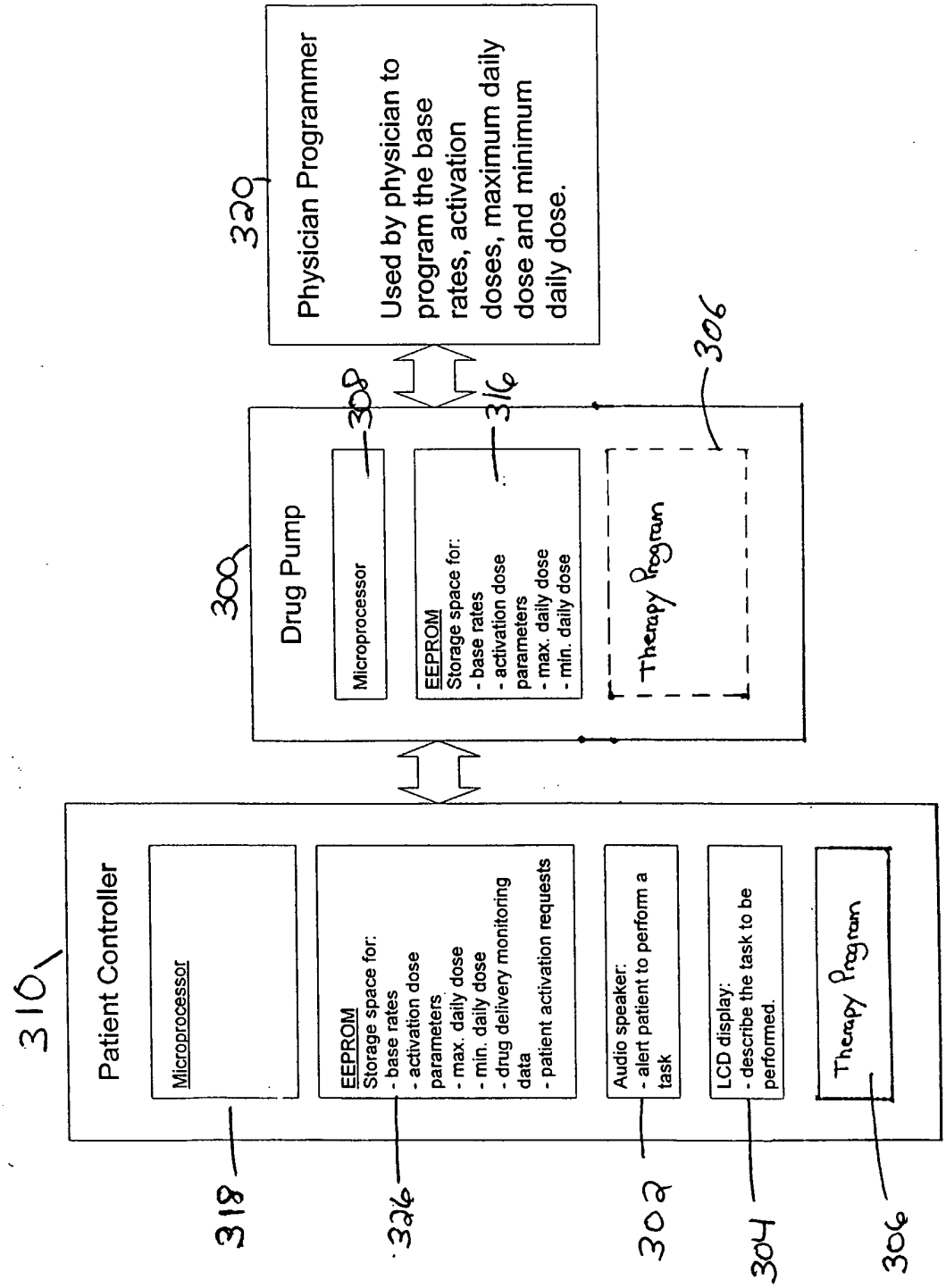
Physician Programmer
Used by physician to program the base rates, activation doses, maximum daily dose and minimum daily dose.
320
Drug Pump
300
Microprocessor
308
EEPROM
Storage space for:
- base rates
- activation dose parameters
- max. daily dose
- min. daily dose
316
Therapy Program
306
Patient Controller
310
Microprocessor
318
EEPROM
Storage space for:
- base rates
- activation dose parameters
- max. daily dose
- min. daily dose
- drug delivery monitoring data
- patient activation requests
326
Audio speaker:
- alert patient to perform a task
302
LCD display:
- describe the task to be performed.
304
Therapy Program
306

Figure 3

Decrease Drug Use:

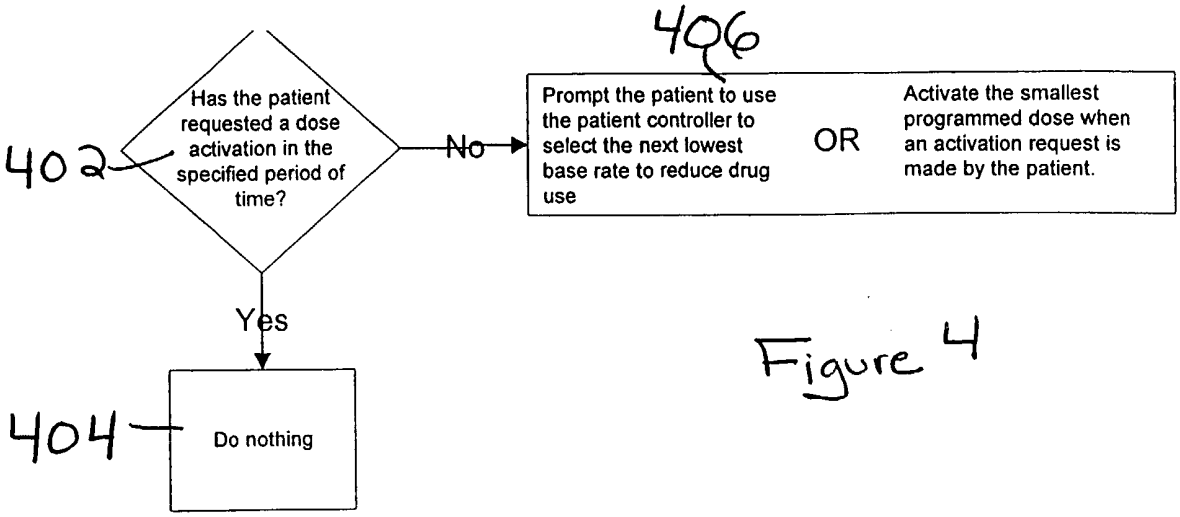

Figure 4

Prevent Underdose:

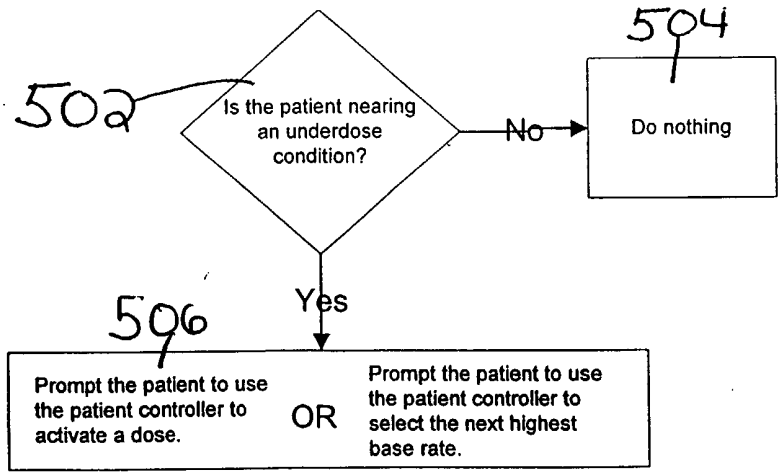

Figure 5

Reduce Number of Episodes Requiring Dose Activations:

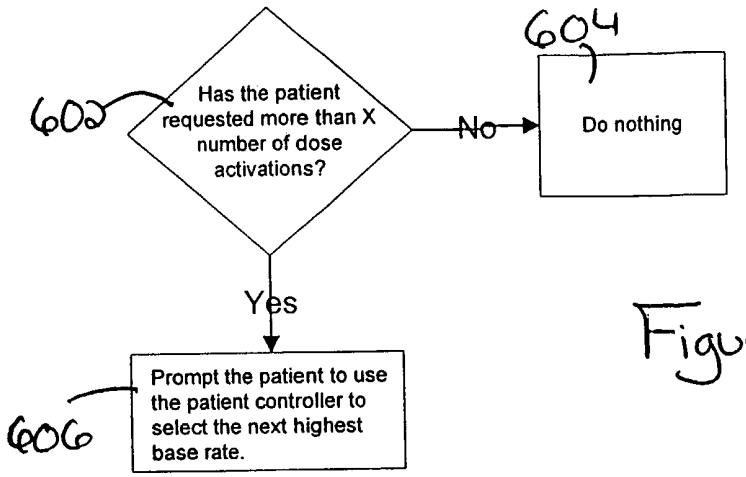

Figure 6

Prevent Overdose:

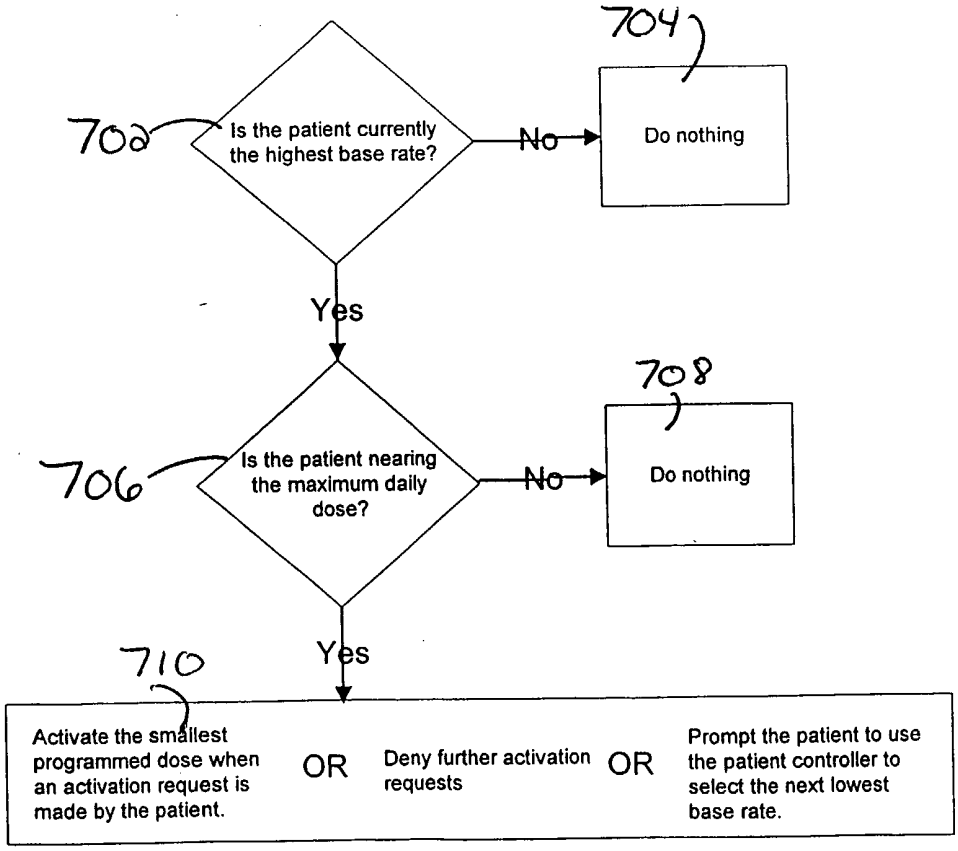

Figure 7

INTERNATIONAL SEARCH REPORT

Int ional Application No
PCT/US 02/06720

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/142

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 100 20 494 A (MEDTRONIC INC) 2 November 2000 (2000-11-02) the whole document	1-17,24, 29-38
X	US 4 731 051 A (FISCHELL ROBERT E) 15 March 1988 (1988-03-15) the whole document	1-11, 13-16, 24,29-38
P,X	WO 01 52935 A (MEDICAL RES GROUP INC) 26 July 2001 (2001-07-26)	1,6,7, 9-11,16, 29-38
A	page 11, line 19 -page 14, line 4; figures 1-3 page 15, line 14 -page 18, line 32	12

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 August 2002	26/08/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Jameson, P

INTERNATIONAL SEARCH REPORT

...ernational application No.
PCT/US 02/06720

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 18-23, 25-28
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

In ional Application No
PCT/US 02/06720

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 10020494 A	02-11-2000	DE 10020494 A1	02-11-2000
		FR 2792839 A1	03-11-2000
		US 2001037083 A1	01-11-2001
US 4731051 A	15-03-1988	US 4373527 A	15-02-1983
		CA 1207871 A1	15-07-1986
		DE 3390462 C2	29-07-1993
		DE 3390462 T	24-01-1985
		EP 0137789 A1	24-04-1985
		GB 2146460 A ,B	17-04-1985
		IT 1219342 B	03-05-1990
		JP 6059315 B	10-08-1994
		JP 60501293 T	15-08-1985
		WO 8403218 A1	30-08-1984
		DE 3247232 A1	05-07-1984
		FR 2537873 A1	22-06-1984
		GB 2132090 A ,B	04-07-1984
		GB 2174218 A ,B	29-10-1986
		US 4573994 A	04-03-1986
		US 4525165 A	25-06-1985
		US 4619653 A	28-10-1986
WO 0152935 A	26-07-2001	WO 0154753 A2	02-08-2001
		WO 0152935 A1	26-07-2001
		US 2002058906 A1	16-05-2002
		US 2001041831 A1	15-11-2001
		US 2002065509 A1	30-05-2002
		US 2002065454 A1	30-05-2002
		US 2002016568 A1	07-02-2002
		US 2002019606 A1	14-02-2002
		US 2001041920 A1	15-11-2001
		US 6427088 B1	30-07-2002
		US 2002065540 A1	30-05-2002
		US 2002049480 A1	25-04-2002