Apparatus for automatic profiled infusion in cyclic total parenteral nutrition.

Priority: 08.08.85 US 763922

Date of publication of application: 24.06.87 Bulletin 87/26

Publication of the grant of the patent: 26.02.92 Bulletin 92/09

Designated Contracting States: DE FR GB

References cited:
EP-A- 0 192 786
US-A- 4 066 736
US-A- 4 299 218
WO-A- 84/00493
US-A- 4 282 872
US-A- 4 475 901

Proprietor: BAXTER INTERNATIONAL INC. (a Delaware corporation)
One Baxter Parkway
Deerfield Illinois 60015(US)

Inventor: Schoon, Joanna
981 Presidio Drive
Costa Mesa California 92626(US)
Inventor: Weyant, Robert Russell
880 Marymount Lane
Claremont California 91711(US)
Inventor: Zobel, Gregory Brian
25201 Spindletwood
Laguna Niguel California 92677(US)

Representative: Day, Jeremy John et al
REDDIE & GROSE 16 Theobalds Road
London, WC1X 8PL(GB)

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European patent convention).
Description

This invention relates to cyclic total parenteral nutrition, and more particularly to a method and apparatus for administering the same.

Background of the Invention

Certain diseases in which the body becomes unable to extract nutrition from food in the natural manner require the intravenous administration of large daily quantities of hypertonic dextrose in order to keep the patient alive. Continuous long-term administration of dextrose in this manner makes it necessary to hospitalize the patient for extended periods of time and causes health problems such as fatty infiltration of the liver, hyperinsulism, lipogenesis, and essential fatty acid deficiency, among others.

Most of the foregoing problems can be prevented or treated by administering total parenteral nutrition (TPN) in a cyclic manner in which the infusion of hypertonic dextrose is discontinued each day for a period of eight to twelve hours. In addition to the direct medical benefits of cyclic TPN administration, considerable psychological benefits are gained by allowing the patient free movement for most of the waking day and making it possible for the TPN to be administered in a home environment.

Cyclic TPN has one disadvantage: sudden starting of TPN at the full steady-state infusion rate is prone to cause clinical symptoms of hyperglycemia and rapid electrolyte influx into the cells because of the inability of the pancreas to suddenly adjust to the high glucose load of the TPN volume. Likewise, sudden cessation of TPN without a tapering-off procedure can cause reactive hypoglycemia.

It has been proposed that patients be instructed to use half the maximum infusion rate for an hour or two at the start of each cycle and to do likewise at the end of each cycle. However, this regimen is only a partial solution to the problem, and is also somewhat impractical in a home environment because the patient may be inattentive or asleep at a time when the infusion rate should be changed.

To overcome the disadvantages described above and to make it possible for a home care patient to self-administer cyclic TPN with a minimum possibility of error, it is desirable to provide an infusion pump which can be programmed to automatically provide tapering-on and tapering-off of the hypertonic dextrose solution during each cycle of administration.

One such infusion pump, infusing fluids into the human body at rates which are at least partially tapered in accordance with a predetermined regimen is described in US-A-4282872 (Franetzki et al). On the basis of input cycle parameters, the Franetzki pump computes and controls an at least partially tapered infusion profile, in spaced identical cycles of given length, which results in administration of the total required fluid volume during the total duration of the cycle.

In accordance with the present invention there is provided an infusion pump for infusing fluids into the human body at rates which are at least partially tapered in accordance with a predetermined regimen administered in spaced identical cycles, comprising: input means for receiving data representing the total required fluid volume and the total duration of the cycle; computing means for computing, on the basis of said data, an at least partially tapered infusion profile in response to pre-established profile criteria, said profile resulting in the administration of the total required fluid volume during the total duration of said cycle; and control means for controlling the infusion rate of the pump in accordance with said tapered infusion profile; characterised in that said pre-established profile criteria include the percentages of a cycle parameter allocated to specific tapered and/or steady-state rates.

The invention provides for the pump to set and regulate itself in accordance with certain criteria which may either be preset within the apparatus or pre-established by the physician. These criteria may typically involve clinically acceptable starting and ending rates and the proportions of the total cycle time ideally devoted to the taper-on and taper-off procedures, respectively. Although one would normally use a single steady-state infusion rate between two tapers, the invention in its broad sense could also be used with appropriate tapers connected by several or no steady-state levels.

With the above-mentioned criteria being pre-established in one form or another, the only daily cycle information which needs to be programmed into the pump is the total volume of dextrose to be administered and the total cycle time over which it is to be administered. In accordance with the invention, the pump uses this information to calculate the appropriate tapers and, where applicable, steady-state infusion rate or rates which, in the light of the pre-established criteria, will produce the desired administration cycle.

It is therefore the object of the invention to automatically provide a tapered administration of an infusion in accordance with medically determined criteria.

Brief Description of the Drawings

Fig. 1 is an elevational view of an infusion
pump adapted to carry out the invention.

Fig. 2 is a time-rate diagram representative of a preferred tapered administration regimen of the invention.

Fig. 3 is a general flow chart of the program carrying out the invention.

Fig. 4 is a detailed time-rate diagram illustrating the manner in which an appropriate taper is established.

Fig. 5 is a time-rate diagram showing an example of a multi-steady-state level infusion regimen which could be used with the pump of this invention.

**Description of the Preferred Embodiment**

Fig. 1 shows an infusion pump adapted for use in connection with this invention. The pump 10 has a conventional keyboard 12 using a set of programming keys 14 as well as time, volume and rate parameter selection keys 16, 18, 20, and start and stop keys 21, 22. In addition, the pump 10 has a special TPN TAPER key 24 with an indicator light 25. The TPN TAPER key 24, when pressed, disables the rate entry and sets the pump 10 into the TPN taper mode of this invention as indicated by illumination of the indicator light 25. Because of the need for the pump to be able to function temporarily in the absence of commercial power, it is provided with a rechargeable battery pack (not shown) whose condition may be indicated by a battery indicator 26. Information relating to the operation of the pump may be shown on a display 28.

A conventional pumping mechanism (not shown) located behind the door 30 pumps fluid from an inlet cannula 32 into an outlet cannula 34 at a rate determined precisely by the internal program of the pump 10.

Fig. 2 shows a preferred tapered time-rate profile of the regimen of this invention. In a typical preferred embodiment, the infusion rate begins at 60 ml/hr and then gradually increases to the steady-state infusion rate R at 38. In the preferred embodiment, the interval within which the infusion rate increases from 60 ml/hr to R ml/hr, as shown at 40, is set at 8% of the total administration time T. After that period, the infusion rate remains at R until 92% of the total delivery time T have elapsed. In the final 8% of T, the rate tapers down, as shown at 42, from R ml/hr to a preferred ending rate of 40 ml/hr. When the ending rate has been reached, the pump uses an audible signal that the cycle is complete. It then continues to run at the keep-vein-open rate of 3 ml/hr, shown at 44, until it is shut off either manually, or automatically by the exhaustion of the dextrose solution.

The flow chart of Fig. 3 illustrates the operation of the pump 10. When the power to the pump is turned on and the TPN TAPER key 24 is pressed, the pump's memory is clear, and it is ready to accept an input of total cycle time and total volume of solution to be administered per cycle. When these entries have been made, the criteria entered in the criteria registers of the memory, or stored in a permanent read-only memory of the pump, are combined with the time and volume entries to compute the TPN profile parameters in accordance with the formulas set out below.

In the preferred embodiment of the invention in which the infusion rate is tapered up from a predetermined starting rate to a calculated steady-state rate over a predetermined percentage of the total cycle, and tapered down from the steady-state rate to a predetermined ending rate over a predetermined portion of the total cycle time, it will be found that the steady-state rate R in ml/hr is determined by the following formula:

$$R = \frac{2V - T \left( F_u R_s + F_d R_e \right)}{T \left( 2 - \left( F_u + F_d \right) \right)}$$

in which the keyboard inputs are:

- V = total volume to be infused (ml)
- T = total infusion time (hrs)

and the criteria are:

- $F_u =$ fraction of T devoted to upward taper
- $F_d =$ fraction of T devoted to downward taper
- $R_s =$ starting rate (ml/hr)
- $R_e =$ ending rate (ml/hr)

In the preferred embodiment using the specific parameters of Fig. 2, it will be seen that the steady-state rate R in ml/hr can be expressed as:

$$R = \frac{1500V - 100t}{23t}$$

where t = total infusion time in minutes.

Once the steady-state rate R has been calculated in accordance with the foregoing formulas, the program checks whether the rate R is within the allowable limits of, e.g., 65 ml/hr and 350 ml/hr, which represent the physiologically acceptable range of steady-state rates for most TPN patients. If the calculated steady-state rate is outside these limits, the program returns to the data input step for selection of another combination of time and volume.

If the steady-state rate is within the allowable limits, an infusion profile such as the profile of Fig. 2 is entered into the pump's memory, and an
indicator light 45 on start key 21 is caused to flash to show that the pump 10 is ready for operation. If the pump is not immediately started, a one-hour timer 46 (Fig. 3) is initiated to maintain the pump 10 in the ready mode until it is manually started. During this time an audible walk-away signal may be generated to alert the patient that the pump 10 should be started.

When the start button 21 is pushed, the indicator light 45 changes from flashing to steady, and the pump 10 begins to infuse nutrients in accordance with the calculated infusion profile of Fig. 2, as described in more detail hereafter in connection with Fig. 4. When the cycle has been completed and the volume remaining to be administered is zero, the pump continues to operate at the KVO rate and produces an audible signal to alert the patient that the infusion has been completed.

When the patient thereupon stops the pump by pushing the stop button 22, the indicator light 47 comes on, and the pump remains in an active mode for a short period under the control of a five-minute timer 48 and then enters a sleep mode in which the display 28 is shut off. The pump remains in the sleep mode until the patient pushes any key on the keyboard. At that time, the program retrieves the stored TPN profile information from memory and recalculates the profile parameters in Fig. 2 for another day’s cycle.

If the pump 10 is stopped before the remaining volume to be administered is zero, the pump begins to produce the walk-away two minutes after it is stopped, and awaits a restart at the point in the profile where the STOP command occurred. If the pump 10 is not restarted within an hour, the timer 50 causes the pump to go to the sleep mode from which it can only be restarted by performing the profile of Fig. 2 from the beginning. If this presents a clinical problem, the pump 10 can be taken out of the tapered mode by pressing the TPN TAPER key followed by the STOP key 22. The pump 10 may then be operated manually through the keyboard. Patient control over the keyboard may be prevented by entering a keyboard lockout code in a conventional manner after the time and volume settings have been entered.

As is conventional in infusion pumps, several alarm conditions (e.g. air in line, door open, or pump malfunction) may create an alarm condition in which a STOP command is automatically executed by the pump 10. Upon the correction of the alarm condition, the pump restarts at the point in the cycle where it left off, provided the remedial action is taken within the one-hour window set by timer 50.

In the event of a low battery condition (which may interfere with the pump’s memory), however, the pump 10 is switched to the KVO rate and is returned to the beginning of the Fig. 2 profile when the low battery condition has been corrected.

Fig. 4 illustrates the operation of the tapers. Inasmuch as continuous adjustment of the pumping rate is impractical due to hardware constraints and the digital nature of the conventional peristaltic pump control mechanism, the transition to or from the steady-state rate R is preferably accomplished in a series of steps which, in the preferred embodiment, are arbitrarily chosen to be increments of 5 ml/hr. As illustrated in Fig. 4, the number of steps depends on the difference between the predetermined starting rate and the calculated steady-state rate. The steepness of the taper is determined by the length of the intervals t₁ or t₂. The shorter these intervals, the steeper the taper. In the illustrative example of Fig. 4 using the chosen increments, if T is 18 hours and V = 2722 ml, t₁ would be 4.32 minutes and t₂ would be 3.6 minutes. The step time t₁ or t₂ can, of course, be calculated by the formulas:

\[
t₁ = \frac{5}{R - R_S} \left(60 \frac{T}{T}ight)
\]

\[
t₂ = \frac{5}{R - R_E} \left(60 \frac{T}{T}ight)
\]

It will be understood that the tapered infusion method of this invention is not limited to a single steady-state rate. It is equally applicable to programs which provide for no steady-state rate or for a plurality of steady-state rates 60, 62, 64, interconnected by varying kinds of tapers such as 66, 68, 69, 70, 71, 72 (Fig. 5). Likewise the parameters defining the tapers and the relative steady-state rates may be preset in a read-only memory or may be made changeably presettable at the physician’s direction through the keyboard.

Claims

1. An infusion pump (10) for infusing fluids into the human body at rates which are at least partially tapered in accordance with a predetermined regimen administered in spaced identical cycles, comprising:
   - input means (12) for receiving data representing the total required fluid volume (V) and the total duration (T) of the cycle;
   - computing means for computing, on the basis of said data, an at least partially tapered
infusion profile (38, 40, 42, 44) in response to pre-established profile criteria, said profile resulting in the administration of the total required fluid volume (V) during the total duration (T) of said cycle; and

control means for controlling the infusion rate of the pump in accordance with said tapered infusion profile;

characterised in that said pre-established profile criteria include the percentages (F_u, F_d) of a cycle parameter allocated to specific tapered and/or steady-state (R) rates.

2. A pump according to Claim 1, further comprising sleep-mode means (48, 48, 50) for partially shutting down said pump (10) after a predetermined period of non-operation.

3. A pump according to Claim 1, wherein the pump (10) can be partially shut down and further comprising memory means for retaining, when said pump (10) is partially shut down, sufficient information for the repeated execution of said profile (38, 40, 42, 44).

4. A pump according to Claim 2 or Claim 3, further comprising reinitiating means for reinitiating said cycle following a partial shutdown of said pump (10).

5. A pump according to any of Claims 1 to 3, wherein said criteria include the allocation of a predetermined percentage (F_u, F_d) of the total cycle duration (T) to said tapered portion (40, 42).

6. A pump according to any preceding claim, in which a tapered portion (40, 42) of said profile begins and/or ends at a predetermined rate (R_u, R_d) greater than zero.

7. A pump according to any preceding claim, in which said pump (10) continues to infuse at a keep-vein-open (KVO) rate (44) after reaching the end of said cycle.

8. A pump according to any preceding claim, in which said profile tapers upwardly (40) to a steady state level (38) and then tapers downwardly (42).

Revidendications

1. Pompe d’injection (10) pour injecter des fluides dans le corps humain à des débits qui sont au moins en partie progressivement variables conformément à un régime prédéterminé administré en cycles identiques espacés, com-

prenant :

- des moyens d’entrée (12) pour recevoir des données représentant le volume de fluide requis total (V) et la durée totale (T) du cycle ;

- des moyens de calcul pour calculer, sur la base desdites données, un profil d’injection au moins en partie progressivement variable (38,40,42,44) en réponse à des critères de profil prédéterminé, ledit profil ayant pour résultat l’administration du volume de fluide requis total (V) pendant la durée totale (T) dudit cycle ; et

- des moyens de commande pour commander le débit d’injection de la pompe conformément audit profil d’injection à variation progressive ;

caractérisée en ce que lesdits critères de profil prédéterminé comprennent les pourcentages (F_u, F_d ) d’un paramètre de cycle alloués à des débits spécifiques progressivement variables et/ou de régime établi (R).

2. Pompe suivant la revendication 1, comprenant en outre des moyens de mode de sommeil (46,48, 50) pour fermer partiellement ladite pompe (10) après une période prédéterminée de non fonctionnement.

3. Pompe suivant la revendication 1, dans laquelle la pompe (10) peut être partiellement fermée, et comprenant en outre des moyens de mémoire pour conserver, lorsque ladite pompe (10) est partiellement fermée, des informations suffisantes pour l'exécution répétée du dit profil (38,40,42,44).

4. Pompe suivant la revendication 2 ou la revendication 3, comprenant en outre des moyens de redémarrage pour reprendre ledit cycle après une fermeture partielle de ladite pompe (10).

5. Pompe suivant l’une quelconque des revendications 1 à 3, dans laquelle lesdits critères comprennent l’affectation d’un pourcentage prédéterminé(F_u, F_d) de la durée de cycle totale (T) à ladite partie de variation progressive (40, 42).

6. Pompe suivant l’une quelconque des revendications précédentes, dans laquelle une partie de variation progressive (40,42) dudit profil commence et/ou se termine à un débit prédéterminé (R_u, R_d) plus grand que zéro.

7. Pompe suivant l’une quelconque des revendications précédentes, dans laquelle ladite pompe (10) continue à injecter à un débit de maintien d’ouverture de veine (44) après avoir
atteint la fin du dit cycle.

8. Pompe suivant l’une quelconque des revendications précédentes, dans laquelle le dit profil monte progressivement (40) jusqu’à un niveau de régime établi (38) puis descend progressivement (42).

Patentansprüche

1. Infusionspumpe (10) zur Infusion von Fluiden in den menschlichen Körper in Mengen, die wenigstens teilweise nach Maßgabe eines vorbestimmten Schemas steigen/fallen, verarbeitet in beobachteten identischen Zyklen, wobei die Infusionspumpe aufweist:
   eine Eingabeinrichtung (12), die dem erforderlichen Gesamtfliudvolumen (V) und der Gesamtdauer (T) des Zyklus entsprechende Daten erhält;
   eine Recheneinrichtung, die auf der Basis dieser Daten ein wenigstens teilweise steigendes/fallendes Infusionsprofil (38, 40, 42, 44) aufgrund von vorbestimmten Profilkriterien berechnet, das in der Verabreichung des erforderlichen Gesamtfliudvolumens (V) während der Gesamtdauer (T) des Zyklus resultiert; und
   eine Steueeinrichtung, die die Infusionsrate der Pumpe nach Maßgabe des steigenden/fallenden Infusionsprofils steuert;
   dadurch gekennzeichnet, daß die vorbestimmten Profilkriterien die Prozentsätze (F_m, F_d) eines Zyklusparameters enthalten, der spezifischen steigenden/fallenden und/oder stabilen (R) Mengen zugeordnet ist.

2. Pumpe nach Anspruch 1, die ferner eine Ruhe-
   moduseinrichtung (46, 48, 50) aufweist, die die Pumpe (10) nach einer vorbestimmten Betriebsunterbrechungsperiode teilweise abschal-
   tet.

3. Pumpe nach Anspruch 1, wobei die Pumpe (10) teilweise abschaltbar ist und ferner eine Speichertiefeinrichtung aufweist, die ausreichende Information für die wiederholte Ausführung des Profils (38, 40, 42, 44) zurückhält, wenn die Pumpe (10) teilweise abgeschaltet ist.

4. Pumpe nach Anspruch 2 oder 3, die ferner eine Wiederauslösung einrichtung aufweist, die den Zyklus nach einem teilweisen Abschalten der Pumpe (10) wieder auslöst.

5. Pumpe nach einem der Ansprüche 1 bis 3, wobei die Kriterien die Zuordnung eines vorbestimmten Prozentsatzes (F_m, F_d) der Gesamtzy-
   klusdauer (T) zu dem steigenden/fallenden Teil

(40, 42) enthalten.

6. Pumpe nach einem der vorhergehenden An-
   sprüche, wobei ein steigender/fallender Teil
   (40, 42) des Profils bei einer vorbestimmten Menge (R_p, R_d) von mehr als Null beginnt und/oder endet.

7. Pumpe nach einem der vorhergehenden An-
   sprüche, wobei die Pumpe (10) nach Erreichen des Endes des Zyklus mit einer Menge (44) zum Offenhalten der Vene (KVO) die Infusion fortsetzt.

8. Pumpe nach einem der vorhergehenden An-
   sprüche, wobei das Profil auf einen stabilen Pegel (38) steigt (40) und dann fällt (42).
**Fig. 4**

- (160) S/S Rate
- (60) Starting Rate
- (40) Ending Rate
- (3) KUD Rate

**Fig. 5**

- 60, 68, 69, 70, 71, 64, 72

**Time**