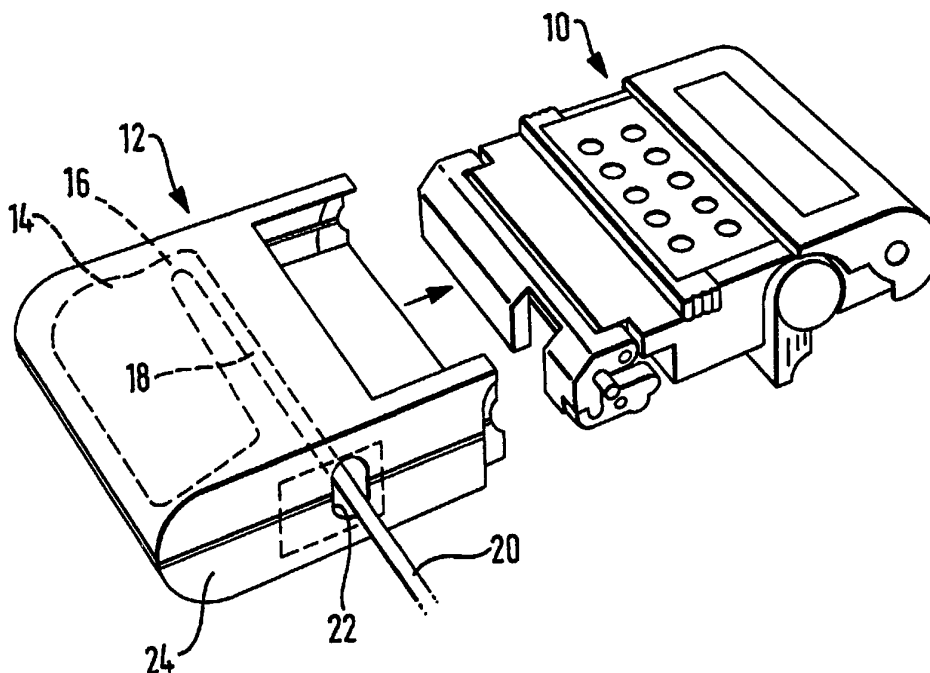




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: INFUSION SET INCLUDING A CLOSURE MEANS



## (57) Abstract

An infusion set (10, 12) comprises a first part (10) housing a pump and control means and a second part (12) housing a replaceable infusate reservoir (14) with an integral infusion line (16). An anti-freeflow sliding member (26) has an opening (28) through which the infusion line (16) passes, and is slidable between a first open position and a second closed position by detaching the parts.

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**INFUSION SET INCLUDING A CLOSURE MEANS**

The present invention relates to an infusion set including a closure means for closing an infusion line, for example in a medical apparatus.

Such closure means are often provided with or incorporated in medical infusion sets and similar equipment, to prevent the free flow of infusate which may otherwise occur, for example, when an empty infusate reservoir or cassette is replaced with a full one, or when, in a pumped system, an infusion line is removed from engagement with the pump.

According to the present invention there is provided an infusion set comprising a first part, a second part for containing an infusate reservoir and infusion line, the parts been releasably attachable together, and means for closing the infusion line, the closure means being operable, by detachment of the parts, to close the infusion line. The invention therefore provides a simple and reliable anti-freeflow mechanism.

The closure means may be slidably mounted on the second part between a first, open infusion line position and a second, closed infusion line position. The infusion line may pass through an opening in the closure means and the closure means may be mounted such that in the first position the infusion line passes through a portion of the opening of dimension great enough to allow flow of infusate through the infusion line and in the second position the infusion line passes through a portion of the opening having a dimension sufficiently less than the diameter of the infusion line to occlude the infusion line. In the first position, therefore, infusate can flow freely, whereas in the second position, the infusion line is constricted at the point at which it

passes through the opening, preventing the flow of infusate. The opening may be bounded by the closure member or may be unbounded at at least one end.

5 The closure means may have a tongue with a detent arranged to engage a projection on the first part to slide the closure means from the first to the second position as the parts are pulled apart and further arranged to release the closure means when the parts are fully detached. The tongue and detent may be arranged to  
10 engage the projection on the first part to slide the closure means from the second position to the first position when the parts are re-attached.

The infusion set may further include a tool adapted for manual operation of the closure means.

15 The first part may house a pump for pumping infusate from the infusate reservoir.

Accordingly, a two-part infusion set consists, for example, of a pump unit comprised within one part, and an infusate reservoir and flexible infusion line comprised  
20 within the other part, the two parts being adapted to fit together in use. In operation, the flexible infusion line in the second part is engaged by the pump in the first part to permit the infusate to be pumped from the infusate reservoir out through the infusion line to a  
25 patient. To prevent free flow of infusate to the patient, as might otherwise occur when the first, pump, part is detached from the second, reservoir, part, means are provided operative upon detachment of the two parts, to close the infusion line and to retain it in a closed  
30 condition. In addition to preventing unwanted infusion, the infusion line can then be detached from the patient without the need to manually close off the line to prevent infusate spillage.

The invention will be described by way of example

with reference to the embodiment illustrated in the accompanying drawings of which:

Figure 1 is a perspective view of a two-part portable infusion pump;

5           Figure 2 shows the operating elements of the anti-freeflow device applied to the pump of Figure 1; and

Figure 3 shows a view of the device of Figure 2 from the other direction.

Referring to the drawings, the two-part infusion pump comprises a first part 10, housing a pump and control means, together with an associated battery for powering both; and a second part 12, consisting of an upper and a lower half assembled together, attachable to and detachable from the first part 10, the second part 12 housing a replaceable infusate reservoir 14, with an integral infusion line 16.

10           The infusion line 16 has an aligned portion 18 which is engaged by the pump mechanism of the pump of part 10, and a portion 20 leading through exit port 22 in wall 24 of part 12. Portion 20 of infusion line 16 may be terminated by means of a luer coupling (not shown) or other attachment to permit ready access to an infusion site.

20           In operation, the two parts 10 and 12 are attached together, in which position the aligned portion 18 of the infusion line 16 is engaged from one side by a platen carried by the first part 10, and from the other by the pump fingers of the pump carried within part 10, such that progressive operation of the pump fingers upon portion 18 produces a peristaltic pumping action, pumping infusate from the reservoir 14 through portion 20 of infusion line 16 to the patient.

30           Referring to Figure 2, which shows a partial view of parts 10 and 12, on a larger scale than Figure 1, to

illustrate the operation of the anti-freeflow device in accordance with the invention, portion 20 of line 16 is shown passing through port 22 in wall 24 of part 12.

5 Sliding member 26 has a shaped aperture 28 of varying cross-sectional shape through which portion 20 of line 16 passes.

10 In the position shown in Figure 2 the portion 20 of the infusion line 16 passes through a part of the aperture having a width substantially the same as the diameter of the portion 20 of the line 16 so that the line 16 is not constricted by the aperture 28 and is a loose fit within it.

15 A tongue 30 having a detent 31 is provided on sliding member 26 and is engaged by projection 32 formed in the body of part 10 when part 10 and part 12 are in full engagement. In this condition portion 18 of infusion line 16 is engaged between platen and pump fingers, and when the pump motor is not operating, portion 18 of line 16 is occluded by pressure applied to it by at least one of the pump fingers, preventing any  
20 inadvertent flow of infusate to the patient.

When part 10 is removed from part 12 however, portion 18 of infusion line 16 will be disengaged from the pump, and will no longer be occluded, and free flow  
25 of infusate to the patient might occur.

However this is prevented by the operation of the anti-freeflow device as follows.

30 As part 10 is withdrawn from part 12, projection 32 moves leftwardly as shown in Figure 2 and draws the sliding member 26 leftwardly within its mounting slide in wall 24, by virtue of the engagement between the projection 32, and the tongue 30 and detent 31. This causes the narrower end of aperture 28 to engage with and constrict portion 20 of infusion line 16, prior to

disengagement of portion 18 from the pump, thereby occluding portion 20 and preventing free flow of infusate to the patient from reservoir 14, which could otherwise occur once the part 10 had been fully withdrawn from part 12.

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Tongue 30, moulded in one piece with sliding member 26, is free to flex in a direction at right angles to the direction of travel of member 26, such that once member 26 has reached the limit of its leftward travel, (that limit being provided, for example, by a projection on the member 26 abutting a stop on the second part 12) tongue 30 flexes outwardly to permit release of the projection 32 by the detent 31 and continued leftward movement as part 10 is fully disengaged from part 12.

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Figure 3 shows the view of the anti-freeflow device from the rear, with part 10 removed from part 12, and portion 20 of infusion line 16 fully occluded by the narrower part of aperture 28.

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If parts 10 and 12 are subsequently re-attached, projection 32 engages tongue 30 and detent 31, causing sliding member 26 to move rightwardly in Figure 2 (leftwardly in Figure 3), so that portion 20 of infusion line 16 passes once again through the larger part of aperture 28, opening the line to flow of infusate to patient under control of the pump within part 10.

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With part 12 removed from part 10, the sliding member 26 may be displaced manually by means of a tool which engages the recess in tongue 30 normally engaged by projection 32, if it is required either to remove and replace the infusate reservoir 14 and integral infusion line 16, or to recharge the reservoir with infusate through line 16.

Although sliding member 26 is shown with aperture 28 open at one end, in order to simplify the fitting and

removal of the disposable infusate reservoir 14 and  
infusion line 16 in part 12, sliding member 28 may  
alternatively be provided with aperture 28 closed at both  
ends, completely encircling portion 20 of line 16, to  
5 ensure that portion 20 cannot become dislodged from  
aperture 28 in operation.

In the latter case sliding member 26 may also be a  
disposable element, provided upon the infusion line 16 of  
each replacement infusate reservoir 14 for fitment into  
10 the wall of part 12 when infusate reservoir 14 is  
changed.

It will be appreciated that use of an anti-freeflow  
device in accordance with the invention prevents  
inadvertent and possibly dangerous free flow of infusate  
15 from the infusate reservoir of a two-part infusion pump  
of the type described, when the two parts are separated.

As will be apparent various modifications may be  
made to the device described without exceeding the scope  
of the invention.

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## CLAIMS

1. An infusion set comprising a first part, a second part for containing an infusate reservoir and infusion line, the parts been releasably attachable together, and means for closing the infusion line, the closure means being operable, by detachment of the parts, to close the infusion line.  
5
2. An infusion set as claimed in claim 1 in which the closure means is slidably mounted on the second part between a first, open infusion line position and a second, closed infusion line position.  
10
3. An infusion set as claimed in claim 2 in which the infusion line passes through an opening in the closure means and the closure means is mounted such that in the first position the infusion line passes through a portion of the opening of dimension great enough to allow flow of infusate through the infusion line and in the second position the infusion line passes through a portion of the opening having a dimension sufficiently less than the diameter of the infusion line to occlude the infusion line.  
15  
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4. An infusion set as claimed in claim 3 in which the opening is bounded by the closure member.  
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5. An infusion set as claimed in claim 3 in which the opening is unbounded at at least one end.  
30
6. An infusion set as claimed in any of claims 2 to 5 in which the closure means has a tongue with a detent arranged to engage a projection on the first part to

slide the closure means from the first to the second position as the parts are pulled apart and further arranged to release the closure means when the parts are fully detached.

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7. A closure means as claimed in claim 6 in which the tongue and detent are arranged to engage the projection on the first part to slide the closure means from the second position to the first position when the parts are re-attached.

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8. An infusion set as claimed in any preceding claim further including a tool adapted for manual operation of the closure means.

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9. An infusion set as claimed in any preceding claim in which the first part houses a pump for pumping infusate from the infusate reservoir.

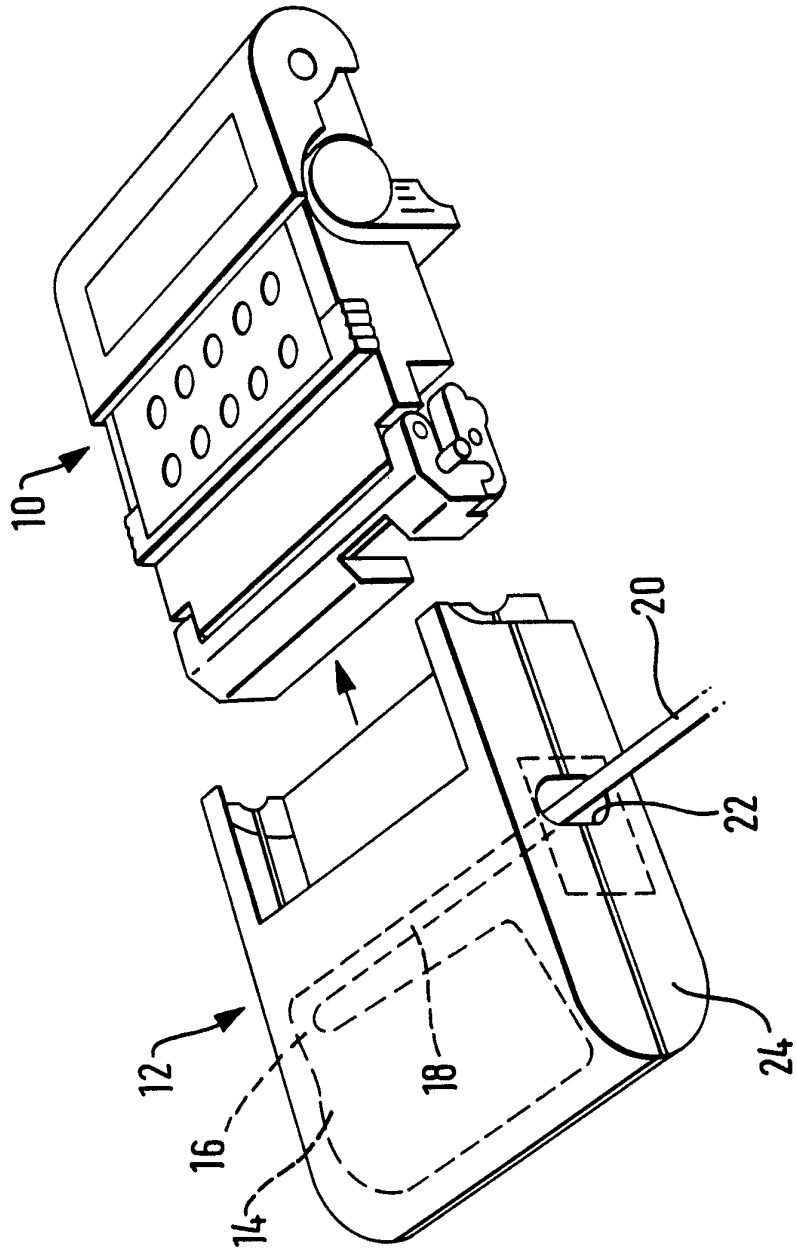
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10. An infusion substantially as herein described and as illustrated by Figures 1 to 3 of the drawings.

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11. A closure means for an infusion set, the closure means being substantially as herein described and as illustrated by Figures 2 and 3 of the drawings.

FIG. 1



2/2

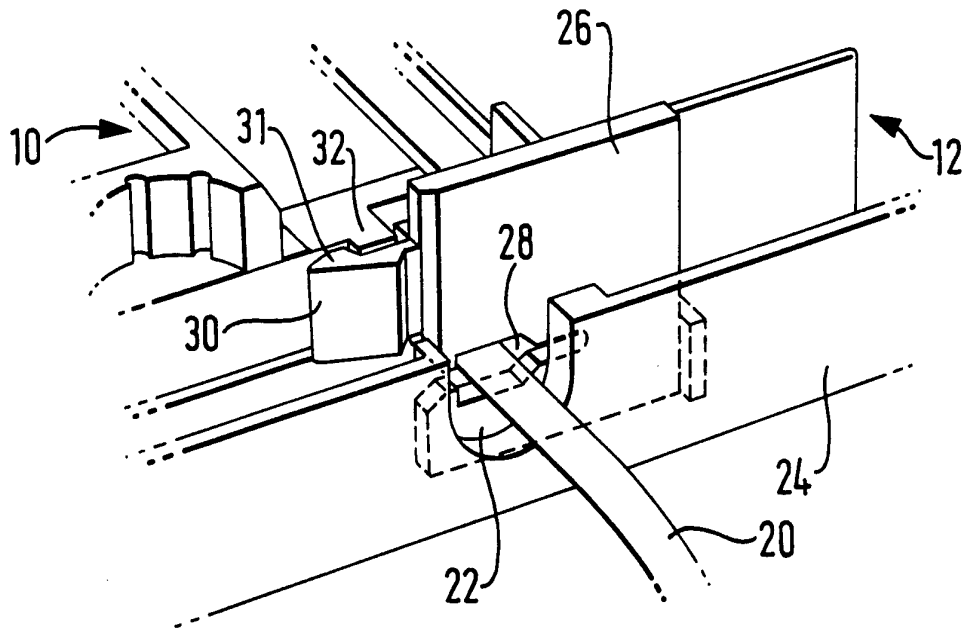


FIG. 2

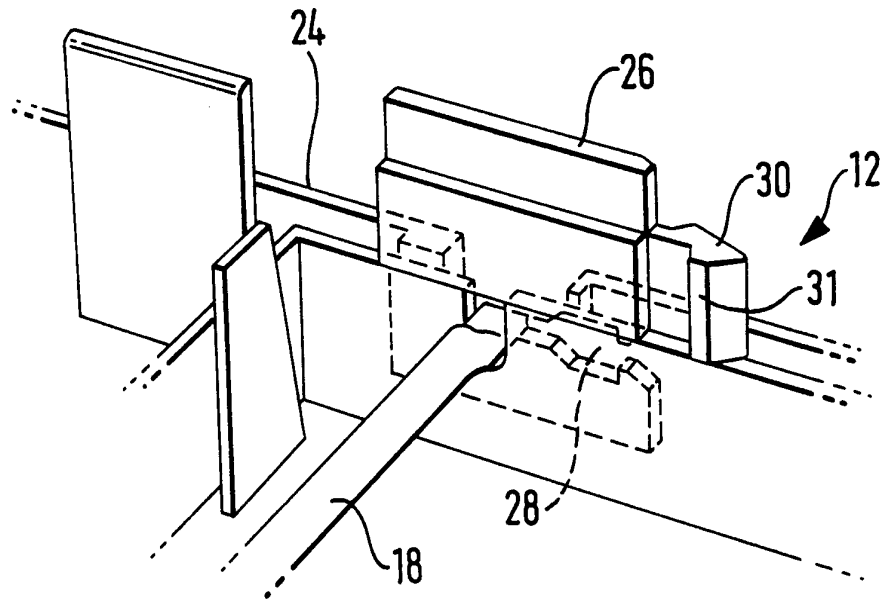


FIG. 3

# INTERNATIONAL SEARCH REPORT

International Application No

**PCT/GB 95/01545**

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC 6 A61M39/28				
According to International Patent Classification (IPC) or to both national classification and IPC				
<b>B. FIELDS SEARCHED</b>				
Minimum documentation searched (classification system followed by classification symbols) IPC 6 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)				
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>				
Category <sup>*</sup>	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
A	EP,A,0 319 279 (PACESETTER INFUSION LTD.) 7 June 1989 see abstract; claims 1-4; figures 1,27-32 ---	1-9		
A	EP,A,0 510 881 (MINNESOTA MINING & MANUFACTURING COMPANY) 28 October 1992 see abstract see column 7, line 40 - column 8, line 32; figures 3-7 ---	1-9		
A	EP,A,0 569 030 (IVAC CORPORATION) 10 November 1993 see abstract; figures 2,3,5 -----	1-9		
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Date of the actual completion of the international search  <p style="text-align: center; font-size: 1.2em;">21 September 1995</p>	Date of mailing of the international search report  <p style="text-align: center; font-size: 1.2em;">13.10.95</p>			
Name and mailing address of the ISA 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	Authorized officer  <p style="text-align: center; font-size: 1.2em;">Michels, N</p>			

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern:    d Application No

**PCT/GB 95/01545**

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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