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GB 2183014 A **GB 1519558 A** **GB 1511367 A**
DE 3209721 A1 **US 4613325 A**

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UK CL (Edition J) **A5R RCK, F2V VA4 VV12 VV13**
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(54) Infusion apparatus

(57) Infusion apparatus in which fluid is delivered via a catheter from an infusion line supplied by a pump 21 includes a pressure limiting valve 12 limiting pressure at the infusion site to protect against tissue damage due to high line pressure. In response to a pressure increase in chamber 11a, diaphragm 14 is displaced against bias of spring 16, valve 12 approaches its seat 12a, and an alarm 26 is activated via micro-switch 25. The pump may include an integral pressure limiter 22 which will stop the pump in response to a continued increase of pressure in the input line 19a to port 10 when the valve 12 has closed.

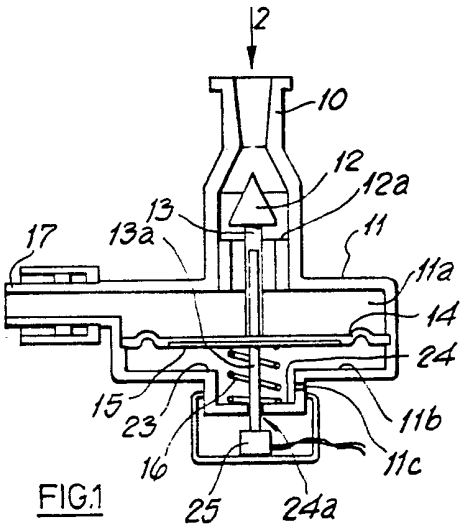

FIG.1

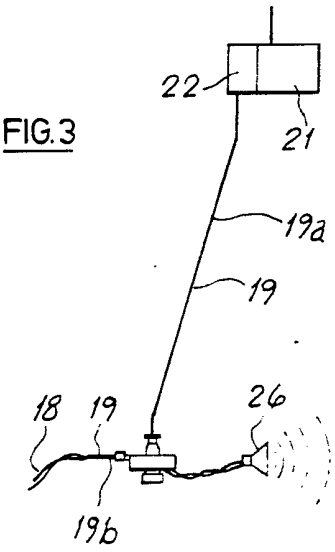

FIG.3

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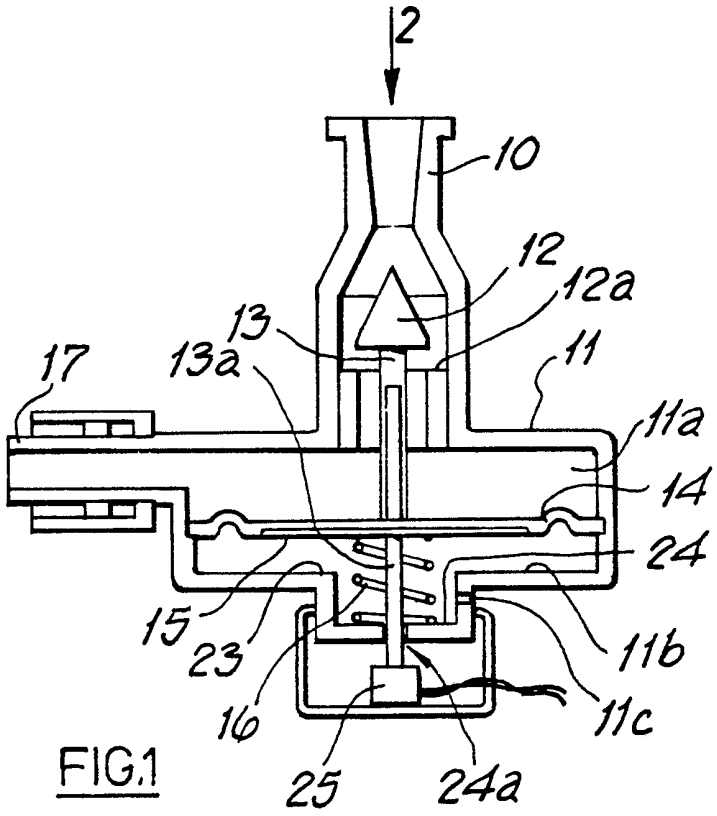


FIG.1

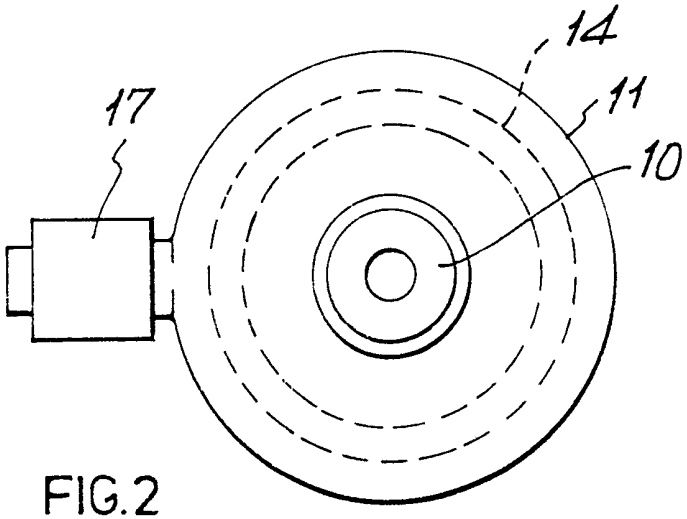


FIG.2

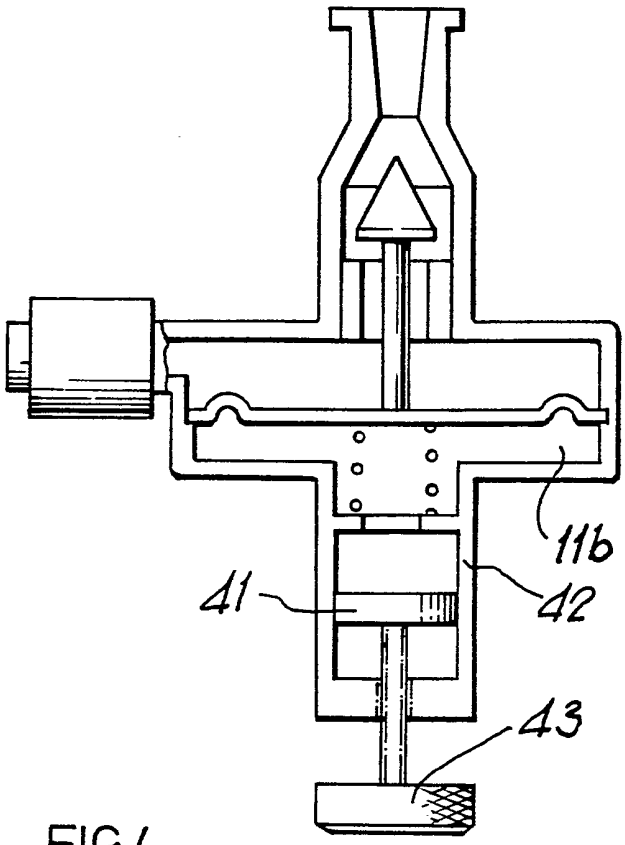
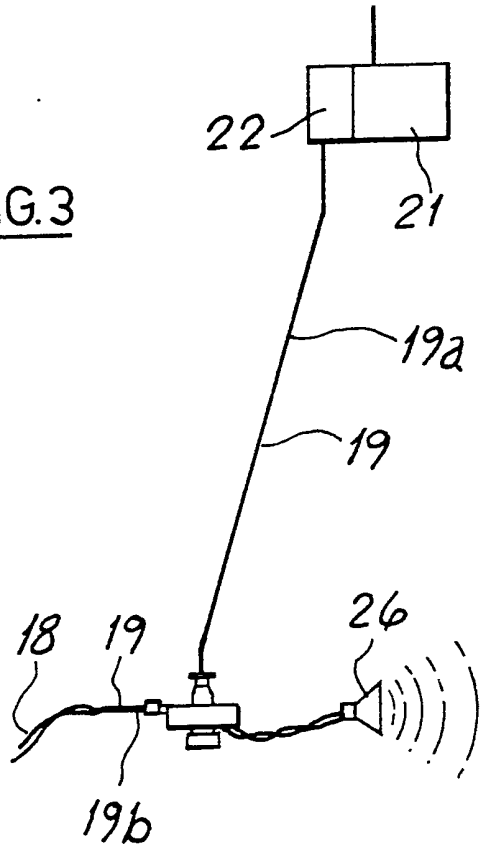


FIG.4

FIG.3



INFUSION APPARATUS

This invention relates to infusion apparatus used to administer drugs or other liquids to a patient directly into a vein or artery.

When mechanical pumps are used to administer liquid directly into the blood flow of a patient, a serious hazard exists in the event of the infusion site becoming blocked or occluded. Most modern mechanical pumps used include means for detecting excessive pressures in the infusion line. The problem with this approach is that in order to achieve high flow rates or pump viscous liquids, the pump must develop relatively high pressure due to the small diameter and long length of the infusion line.

This in turn means that if there is any obstruction internally of the transfusion site, a considerable pressure can build up there which can give rise to serious tissue damage due to pressure itself or due to over-infusion of fluid if the blockage clears spontaneously.

The present invention overcomes this problem.

The invention comprises infusion apparatus comprising pressure limiting means limiting pressure in the infusion line at the infusion site.

The apparatus may be adapted to limit pressure at the infusion site to a value only just above peak venous or arterial pressure.

The pressure limiting means may comprise valve means located in the infusion line at the infusion site. Said valve means may be sensitive to pressure in the infusion line and operative to restrict the infusion line against flow to the infusion site, and may indeed be operative to close and to latch closed the infusion line against flow to the infusion site.

The valve means may be adjustable to set the limiting pressure.

The apparatus may comprise a valve controlled by a diaphragm exposed to infusion line pressure and connected to move a valve member against a valve seat. The diaphragm may be in a valve body having an inlet for connection to an infusion source and an outlet for connection to the infusion site, and divide the valve body into line pressure and reference pressure chambers. The latter may be open to atmosphere.

The valve member may comprise a valve head on a valve stem attached to the diaphragm, the stem being directed towards the inlet and the valve seat being intermediate the head and the diaphragm, the stem projecting through it. The valve head may be designed to spread under the influence of pressure forcing it against the valve seat so as to confirm its sealing action against the valve seat. The valve head, however, may also be such that it can be resiliently inserted through the valve seat, either by resilient compression of the head or resilient expansion of the seat, for example, for assembly of the valve.

The diaphragm may be stiffened, and may have a restricted travel to reinforce the valve against excess pressure forcing the valve head through the valve seat.

The valve may comprise indicator means indicating actuation of the pressure limiting means, which may comprise an indicator rod attached to the diaphragm which on displacement of the diaphragm projects out of the valve body, and may comprise an integral electric switch for operating an alarm circuit.

The invention also comprises infusion apparatus comprising a pump supplying an infusion line, infusion site pressure limiting means in the infusion line

limiting pressure at the infusion site, and pump pressure limiting means operative at the pump to prevent excess build up of pressure in the line when the infusion site pressure limiting means operates to limit pressure at the infusion site. Said pump pressure limiting means may operate to stop or by-pass the pump, and may be integrally contained in the pump.

Embodiments of the infusion apparatus according to the invention will now be described with reference to the accompanying drawings, in which :-

Figure 1 is a cross-section through a pressure limiting valve in an infusion line;

Figure 2 is a view on Arrow 2 of Figure 1;

Figure 3 is an illustration of an infusion system incorporating the valve of Figures 1 and 2;

and Figure 4 is a cross-section through a second embodiment of the valve.

The valve illustrated in Figures 1, 2 and 4 comprises an input port 10 fitted with a leur lock or similar connector for connection of the infusion line, a

valve body 11 housing a valve head 12 which is attached by a stem 13 to a diaphragm 14 which consists of a flexible outer portion which is attached to the walls of the body 11 around its perimeter to provide a pressure-tight seal, and which has a more rigid centre portion from which the valve stem protrudes. The centre portion is provided with a stiffening member 15 and is supported by a spring 16 or similar resilient structure. The output port 17 is fitted with a leur lock or similar connector to allow connection with the infusion catheter 18 of Figure 3.

When the valve is included in the infusion line 19, liquid will pass through the body 11 unhindered, providing the pressure at the valve, which is located in the line 19 at the infusion site end thereof is below the designed cut-off pressure. If a blockage or partial blockage occurs, causing the pressure in the line to rise, the diaphragm 14 will be deflected against the restraint of the spring 16. The higher the pressure rise, the greater the deflection until the valve closes by the head 12 seating on the valve seat 12a. Assuming attempted delivery of liquid continues, i.e. the pump 21 (Figure 3) continues to operate, the pressure in the input line 19a will continue to rise until detected by the integral pressure limiter arrangement 22 normally supplied with infusion pumps. The output pressure, in

the output line 19b, will not increase, and any leakage of liquid to the patient, as in the case of a partial blockage, will cause the outlet pressure to fall, allowing the valve to open slightly until just enough liquid has entered the valve to replace the liquid leaving it.

Because, once closed, the pressure upstream of the valve head is greater than the pressure in the valve body 11 - and also because the area of the valve head exposed to line pressure is greater than the area beneath the valve head exposed to the lower, valve body pressure, the valve will latch closed, provided the spring 16 is not too strong.

If the pressure at the input becomes excessive, the valve will be unable to open, and the output pressure may then drop substantially below that required to initiate the cut-off action. In this condition, there is the danger that the valve head 12 could be forced through the valve seat 12a, allowing high pressure liquid access to the patient. This is prevented in this embodiment in two ways. Firstly, the shape of the valve head 12, whilst allowing insertion through the valve seat 12a during manufacture, will result in a spreading action of the head 12 under load confirming the seal. Secondly the design of the diaphragm 14 and body 11 is

such that excessive deflection is prevented regardless of the potential compressability of the spring 16, by the shoulders 23 around the spring seat 24. The clearance between these shoulders 23 and the diaghragm 14 is such as to allow the valve head 12 to fully close, but not to be pushed through the valve seat 13.

The valve stem 13 has an extension rod 13a which is on the other side of the diaphragm 14 and which, when the diaphragm 14 is displaced under pressure to cut off the supply of fluid, projects from an aperture 24a in the spring seat 24. This could itself constitute an indicator that the valve has been actuated and has latched closed, and constitutes a means by which a latched valve may be reset, simply by pushing the extension 13a back into the valve body - though in practice this should not be done until the cause of the actuation has been investigated and excess line pressure relieved.

However, the extension rod 13a can also, as illustrated, operate a microswitch 25 which in turn operates an alarm 26 (Figure 3) to indicate that the valve has been actuated by excess pressure.

It may be desirable to produce a range of valves set, as by selecting the rate of spring 16, to operate

at different pressures, or an adjustment may be provided on the valve to preset the limiting pressure. As illustrated in Figure 1, the diaphragm 14 divides the valve body into a line pressure chamber 11a and a reference chamber 11b, which is open to atmosphere through a vent 11c.

However, the reference chamber 11b could be sealed, as illustrated in Figure 4, and the pressure in it changed by a plunger 41 adjusted in a cylinder 42 by a graduated knob 43.

All materials used in the construction of the valve should be of a kind approved for use in drug delivery systems if the apparatus is going to be used clinically. The body 11 is desirably of clear plastic to allow visual confirmation that all air bubbles have been purged from the valve chamber before clinical use.

When a problem occurs in infusion, the build up of pressure in between the pump and the valve will not normally be dissipated. The pressure may be relieved by disconnecting the line from the valve inlet 10, when the contents of the line will, of course, tend to spray out. The valve could, of course, be provided with a manual vent to release the pressure without dismantling, but it may be preferred not to provide this facility in

case it is used as a palliative to relieve the problem symton - namely build up of pressure in the infusion line - without fully investigating the cause of the problem.

CLAIMS

1. Infusion apparatus comprising pressure limiting means limiting pressure in the infusion line at the infusion site.

2. Apparatus according to claim 1, adapted to limit pressure at the infusion site to a value only just above peak venous or arterial pressure.

3. Apparatus according to claim 1, said pressure limiting means comprising valve means located in the infusion line at the infusion site.

4. Apparatus according to claim 3, said valve means being sensitive to pressure in the infusion line and operative to restrict the infusion line against flow to the infusion site.

5. Apparatus according to claim 4, said valve means being operative to close the infusion line against flow to the infusion site.

6. Apparatus according to claim 5, adapted to latch closed against pressure in the infusion line.

7. Apparatus according to claim 3, in which said valve means are adjustable to set the limiting pressure.

8. Apparatus according to claim 1, comprising a valve controlled by a diaphragm exposed to infusion line pressure and connected to move a valve member against a valve seat.

9. Apparatus according to claim 8, in which the diaphragm is in a valve body having an inlet for connection to an infusion source and an outlet for connection to the infusion site and divides the valve body into line pressure and reference pressure chambers.

10. Apparatus according to claim 9, in which the reference pressure chamber is open to atmosphere.

11. Apparatus according to claim 9, in which the valve member comprises a valve head on a stem attached to the diaphragm, the stem being directed towards the inlet and the valve seat being intermediate the head and the diaphragm, the stem projecting through it.

12. Apparatus according to claim 9, in which the valve head is designed to spread under the influence of pressure forcing it against the valve seat so as to confirm its sealing action against the valve seat.

13. Apparatus according to claim 11, in which the valve head can be resiliently inserted through the valve seat for assembly of the valve.

14. Apparatus according to claim 7, in which the diaphragm is stiffened.

15. Apparatus according to claim 7, in which the diaphragm has a restricted travel to reinforce the valve against excess pressure forcing the valve member through the valve seat.

16. Apparatus according to claim 1, comprising indicator means indicating actuation of the pressure limiting means.

17. Apparatus according to claim 16, comprising an integral electric switch for operating an alarm circuit.

18. Infusion apparatus comprising a pump supplying an infusion line, infusion site pressure limiting means in the infusion line limiting pressure at the infusion site, and pump pressure limiting means operative at the pump to prevent excess build up of pressure in the line when the infusion site pressure limiting means operates to limit pressure at the infusion site.

19. Apparatus according to claim 18, said pump pressure limiting means operating to stop or bypass the pump.

20. Apparatus according to claim 19, said pump pressure limiting means being integrally contained in the pump.

21. Apparatus substantially as hereinbefore described with reference to the accompanying drawings.

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