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# FLUID INFUSION SYSTEM

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FLUID INFUSION SYSTEM



PREPARED FOR: National Aeronautics and Space Administration
Lyndon B. Johnson Space Center
R&T Procurement Branch
Houston, Texas 77058



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## 1.0 SUMMARY

Development of the subject Fluid Infusion System was undertaken by Beckman ATO in response to a need for an intravenous infusion device operable under conditions of zero-g. A system offering variable flow rates, as well as a flowmeter for monitoring flow rate, was required. The ability to infuse two 500 ml fluid packs in sequence was required, with automatic triggering from the first to the second bag. An alarm was required to indicate a no-flow condition or the presence of bubbles in the liquid line. Sterility of the infused liquid obviously was also a requirement.

It is necessary to pressurize a fluid to produce flow; so the problem, simply stated, is to pressurize the fluid using some means other than gravity (static head). Since the infusion solutions are contained in flexible vinyl bags, a squeezing action can be used to produce fluid pressure inside the bags, and this was the approach taken. The infusion solution bags are squeezed between two rigid flat plates, with regulated pressurized gas used to produce a controlled force. The resulting liquid flows from the infusion bags are controlled and directed by means of pinch valves; and flow readout is provided by a clinical flowmeter which is modified and made part of the system.

The initial design approach, pursued in the construction of the first breadboard instrument, was simply to regulate the pressure of the motive gas--$CO_2$--and thereby produce a similar regulated pressure in the infusion liquid itself. This scheme did not prove workable because of the varying bag contact area, and a major design iteration was made. A floating sensor plate in the center of the bag pressure plate was made to operate a pressure regulator built into the bellows assembly, effectively making liquid pressure the directly controlled variable. Other design changes were made as experience was gained with the breadboard.

Extensive testing was performed on both the breadboard and the prototype device to ensure adequate performance. Accurately regulated flows from 6 ml/min to 100 ml/min can be achieved, and all system functions operate satisfactorily. The system was subjected to acceptance tests before delivery.

The Fluid Infusion System represents a successful development that meets all program objectives. A design concept has been evolved and consummated in working hardware. Some areas in which further gains may be made are evident; and other potentially fruitful avenues may unfold as additional experience with the prototype system is gained.

## 2.0 SYSTEM DESCRIPTION

### 2.1 General

The Fluid Infusion System is a self-contained, portable benchtop unit. Motive power for expressing infusion solutions from the bags is provided by high-pressure $CO_2$ gas cartridges. Control functions are all accomplished mechanically, so that the only electrical power needed by the device is that required for the electronic flowmeter. The entire system including the electronic flowmeter is shown in Figure 1.

Two rectangular pockets are provided in the infusion device for receiving the fluid bags--in the front and in the rear of the unit (see Figure 2). The outside faces of the chambers consist of acrylic plastic windows, so that proper loading of the bags into the chambers may be verified visually. The pneumatic bellows that provide the bag squeezing force are centrally located, as are the pushbutton exhaust valves for retracting the pressure plates. One side of the unit is devoted to the pneumatic system, and the other side houses the liquid plumbing components. Design of the liquid side is such that a complete tubing set can be laid into the unit without violating its sterility.

The probe for the Carolina Medical Electronics electromagnetic flowmeter is a part of the pre-sterilized tubing set. The remainder of the flowmeter is a

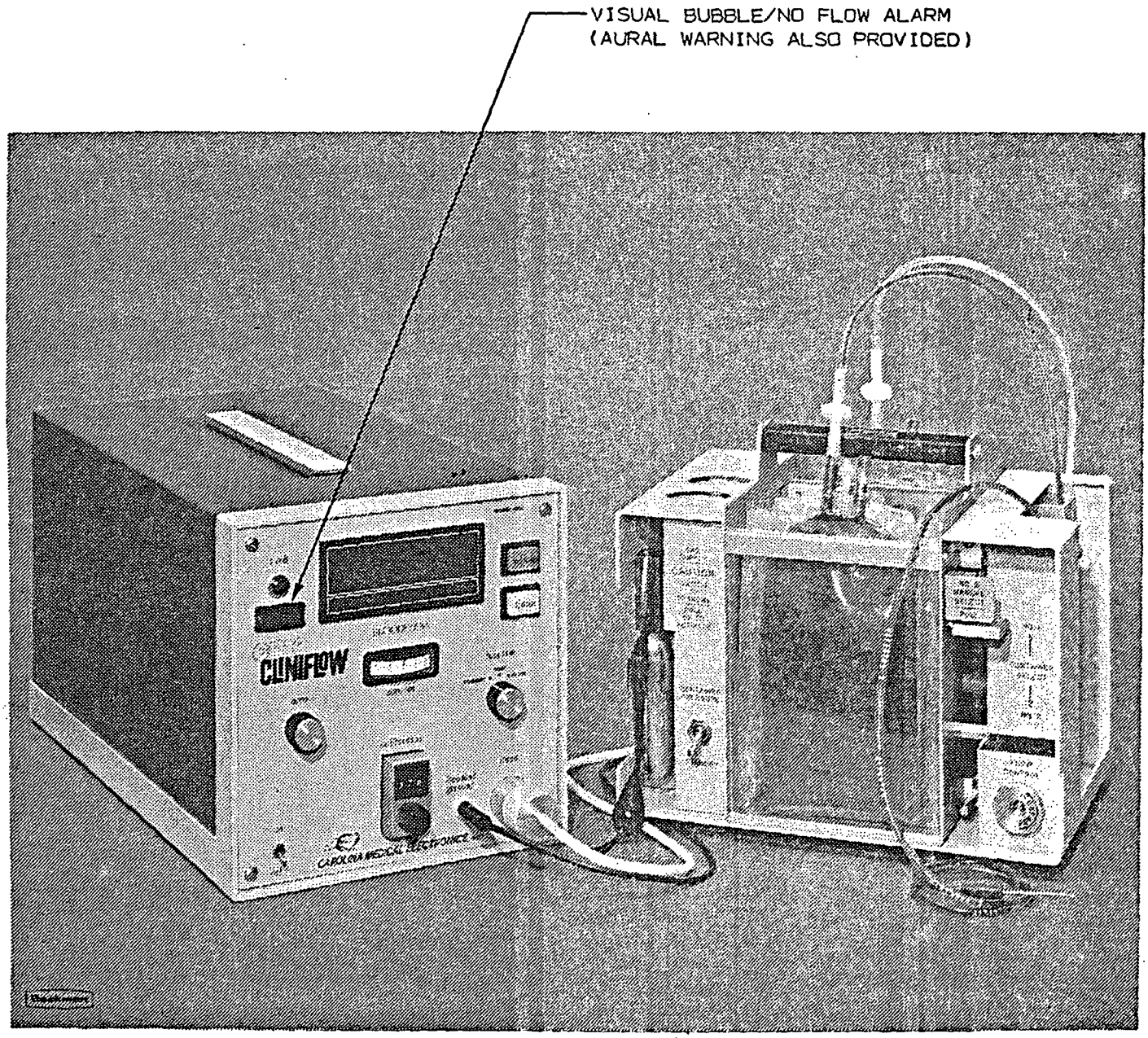


Figure 1. Fluid Infusion System with Electronic Flowmeter

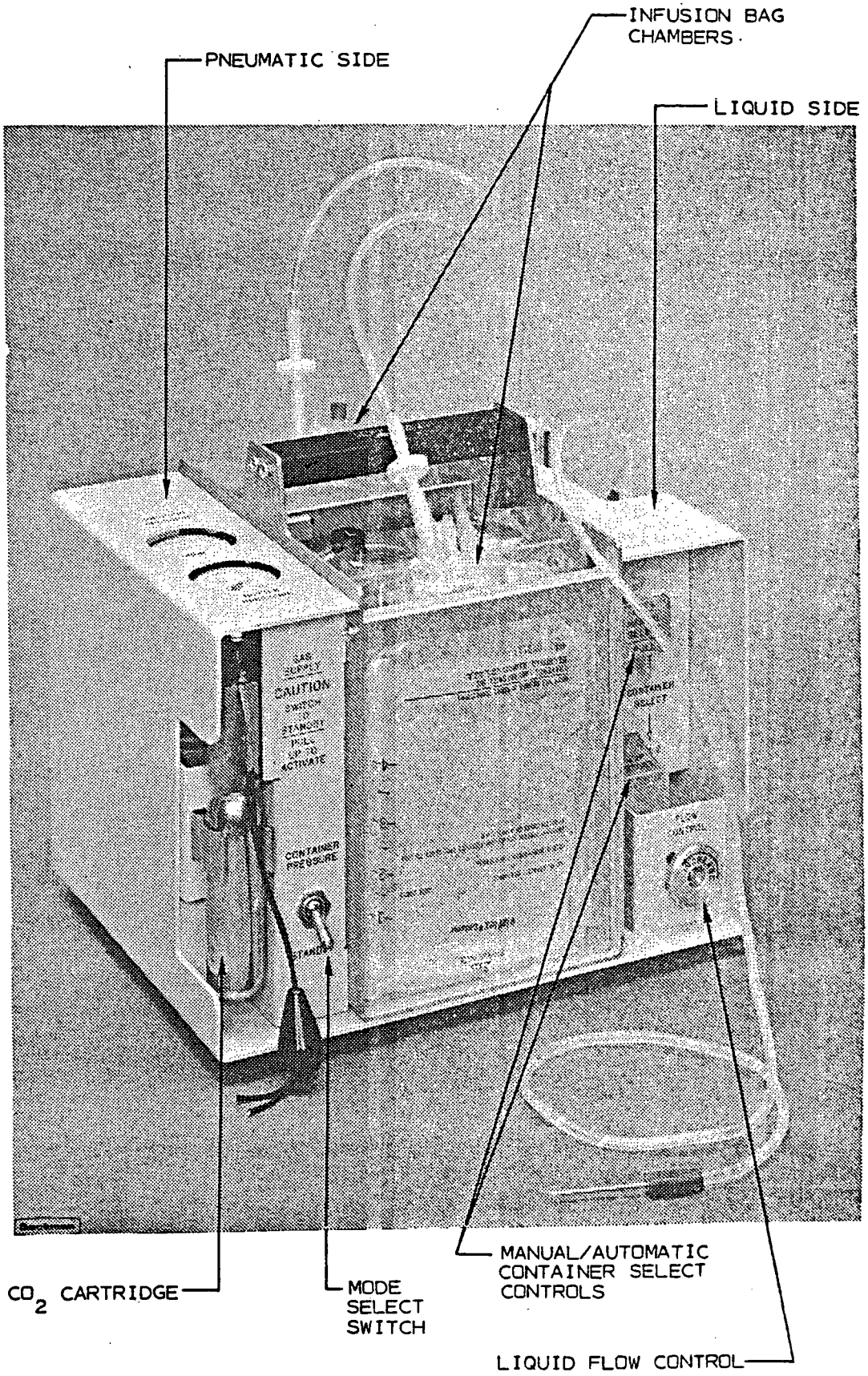




Figure 2. Infusion Unit

separate bench-mounted unit, containing electronics, readout, and the ATO-designed no-flow/bubble alarm circuit.

## 2.2 Pneumatic System

The pneumatic system consists of the $CO_2$ cartridge, pressure regulator, mode switch, bellows pressure control valves, bellows, and exhaust valves. The function of the pneumatic system is to store motive gas, and apply regulated pressure to the infusion bags under control of the mode switch.

There is no high-pressure plumbing per se, since the $CO_2$ bottle is mounted directly to the high-pressure inlet of the regulator. There is a swivel fitting for convenience in changing bottles, but no piping or tubing. The maximum pressure in a fresh $CO_2$ bottle is about 1100 psi, and the regulator is rated for much more. The regulator output pressure is set at 15 psi, which is sufficiently low that flexible tubing and push-on barbed fittings can be used on the output side.

The mode switch is a toggle-actuated Clippard miniature three-way valve. It admits regulated pressure to the bellows pressure control valves in one state (Pressurize), and dead-ends the regulator output in the other state (Standby).

The bellows pressure control valves are a unique development evolved to overcome the nonsteady flow characteristics of the original breadboard. The sensed variable is the actual liquid pressure in the infusion bags, and it is used to control pressure in the bellows. $CO_2$ can enter the bellows only as metered through the bellows pressure control valves. The action of this control system is to produce a constant pressure in the liquid bags. Movement of the bellows and pressure plates occurs as necessary when liquid is allowed to flow from the bags.

The bellows themselves are made from a convoluted tubular reinforced elastomeric material. Pressure relief valves are installed in both bellows spaces to guard against bellows damage in the event of regulator or pressure control valve failure. The two manual pushbutton exhaust valves allow pressure to

be bled from the bellows spaces when desired, so that the pressure plates may be pushed back from the extended position.

## 2.3 Liquid Handling System

The liquid handling system consists of the bag selector valve, flow control valve, drug injection port, and flowmeter cell (see Figure 3). Its function is to select flow from one or the other bag, control that flow, and provide for injection of drugs and measurement of the flow rate.

The bag selector valve is located at the Y in the tubing set, where it branches to run to either bag. One or the other tube is pinched shut depending on the position of the valve handle. The valve may be moved manually to either Bag No. 1 or Bag No. 2, and is tripped automatically from 1 to 2 by movement of the No. 1 pressure plate.

The flow control valve is located downstream from the bag selector valve, and can be used to close off all flow, or to regulate the liquid flow. Like the bag selector valve, it operates by pinching the vinyl tubing.

The flow cell is necessarily a part of the tubing set, since its electrodes must be wetted by the fluid. The flow cell must be installed in the tube set as received from the vendor, and the entire assembly sterilized. The Y-type drug injection port is standard tubing-set hardware. All these components, including the flow cell, are mounted by slipping them laterally into clips or channels in the "liquid side" of the instrument. Thus the sterility of a pre-stabilized flow cell/tubing set assembly need not be violated at assembly.

## 2.4 Flowmeter

A flowmeter is needed in the system to allow initial setting of flow rate and monitoring. Additionally, it was possible to modify the Carolina Medical Electronics device to give an alarm when flow is interrupted or stopped. The flow is through the flow cell only, so that the only connections between the flowmeter electronics chassis and the rest of the system are electrical.

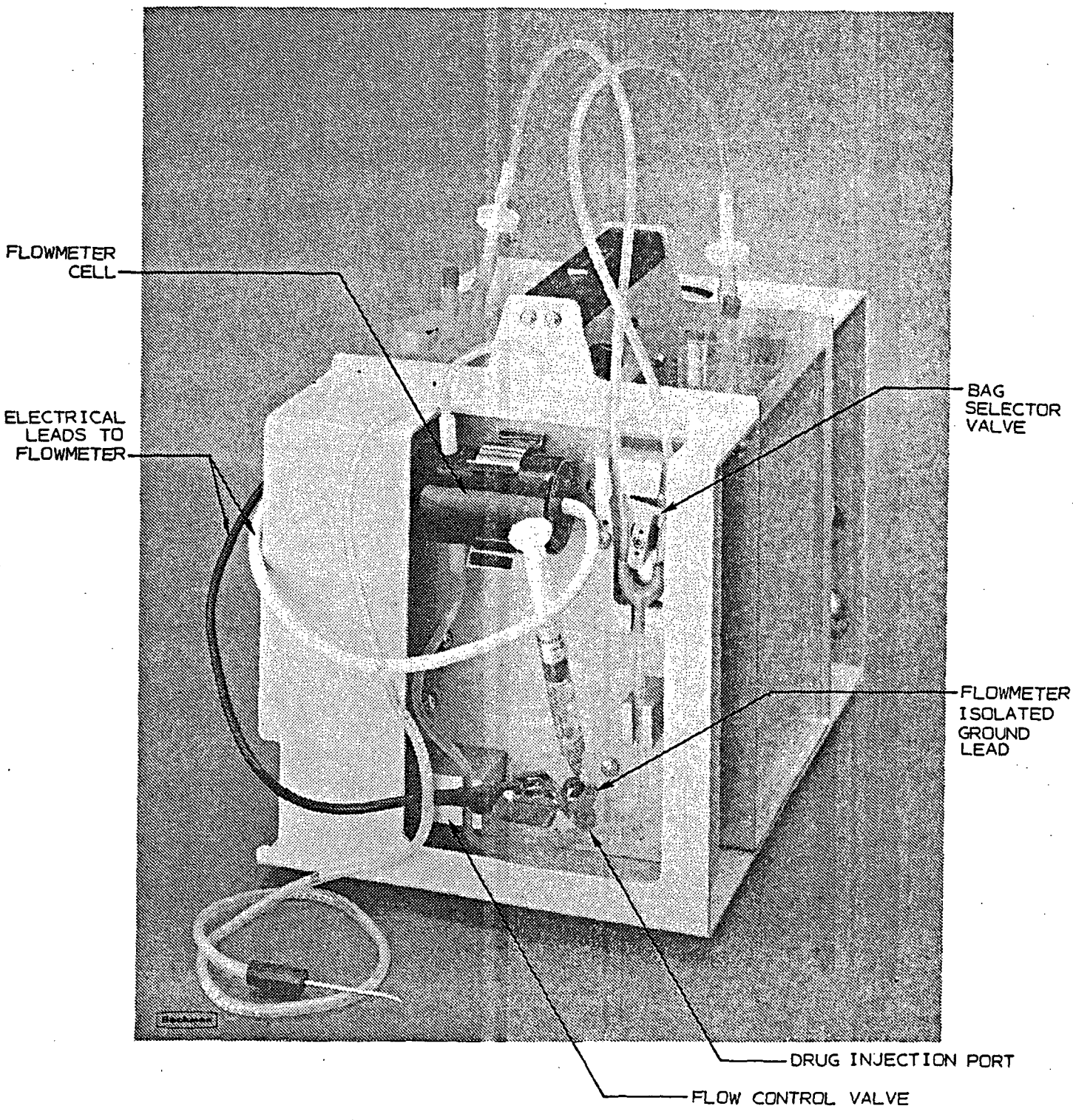


Figure 3. Detail of Liquid Side of Unit

## 3.0 TESTING

Engineering and Acceptance tests and results are discussed in the test report, ATP-1185-501.

## 4.0 PERFORMANCE

Performance characteristics of the prototype Fluid Infusion System are discussed in Sections 4.1 through 4.6.

### 4.1 Flow Rate

Usable flow rates are in the range of 6 to 100 ml/minute. The upper limitation is simply the capacity of the system; i.e., a certain maximum flow is achieved when the flow control valve is wide open. The lower limit is imposed by the characteristics of the flexible tubing system. It was observed in testing that lower flows (less than about 6 ml/minute) would slowly decline--sometimes by as much as 50% over 500 ml. This was ascribed to relaxation effects in the vinyl tubing at the flow control valve. The flow control pinch valve is almost closed for the lower flows, and any change in geometry of the tubing bore would have a noticeable effect.

It was possible to establish quite low flows; and the flow decay was predictable and very gradual so this effect could possibly be tolerated. However, until the phenomenon is investigated further, it is felt that the lower flow should simply be stated as the lowest flow offering adequate unattended flow regulation.

### 4.2 Flow Accuracy

Flow regulation accuracy of the system represents a substantial improvement over current practice (approximately ±20% for the decreasing hydrostatic head method). The flow accuracy achieved with the unit during testing was ±5% at the higher flow rates (50 and 100 ml/minute), and ±8% at the low flow rate (5 ml/minute). This advance was made possible by the incorporation of the bag pressure control valves in the bellows assemblies of the prototype unit.

These control valves regulate the liquid pressure in the bags directly--a technique that has proved very desirable since pressure perturbations due to bag elasticity, wrinkling, and bag contact friction are not, in fact, negligible.

## 4.3 Pneumatic System Performance

Viability of the $CO_2$ cartridges as a simple, lightweight, and inexpensive method of powering the system and making it completely self-contained was demonstrated. One 25-gram $CO_2$ cartridge contains sufficient gas for eight complete cycles of the unit. If this capacity is not needed, smaller cartridges are available and are usable in the unit. Leakage from a pierced bottle, with the mode switch in STANDBY, is virtually nil, with no supply pressure drop being discernible over a period of many days.

## 4.4 Automatic Bag Switching

Flow is automatically switched from Bag No. 1 to Bag No. 2 at a preset point. This is accomplished entirely mechanically, without the need for solenoids or other active components. The trip point is wrench-adjustable; manual selection can be performed at any time. This feature has consistently performed well.

## 4.5 Bubble Detection

The Carolina Medical Electronics blood flowmeter is modified to give a visual and aural alarm when liquid flow ceases or is interrupted by bubbles. This feature of the device works consistently, with some variability at the threshold of bubble detection. Its performance is presented in quantitative terms in the aforementioned test report.

## 4.6 Flowmeter Performance

Flow indication accuracy of the Carolina Medical Electronics flowmeter is well within the manufacturer's stated tolerance; i.e., ±5% of full scale. The type of flow cell furnished as part of the system is their most accurate type, and the manufacturer stated verbally that ±1% of full scale accuracy may be expected of it (full scale is 1999 ml/minute). During all testing to date, the device has, in fact, indicated flow to an accuracy of better than ±1% full scale. In

some cases erratic indications were noted, but this was invariably an indication that the manufacturer's probe cleaning routine needed to be done. A device for accomplishing this, and instructions, are included with the flowmeter.

## 5.0 RECOMMENDATIONS

The Prototype Fluid Infusion System developed under this contract meets all established performance goals, and has proven easy and convenient to use. Examination and use of the completed prototype system reveal several areas where further effort should be considered. This is not surprising, of course, as this is one of the primary reasons for constructing a prototype.

Examination of the complete system on the bench immediately reveals that a disproportionately large share of the total volume, weight, and cost is taken up by the flowmeter. Its technique is also inherently invasive when used on plastic tubing, and thus it complicates sterilization procedures. Replacement of the electromagnetic unit with a cheaper, simpler, inherently noninvasive device is highly desirable, and should be pursued. An ultrasonic device similar to flowmeters currently under development at Beckman ATO would meet these criteria, and additionally would not depend on ionic conductivity in the solution for its operation.

Accuracy of flow regulation is good over the flow range of the device, 6 to 100 ml/minute. Below the range, an unexpected phenomenon was encountered--the flow would very slowly decrease even though the bag liquid pressure control valve was holding constant pressure in the bag. This effect is thought to be caused by relaxation effects in the plastic tubing where it is most highly stressed; i.e., the flow control valve. That it is due to the flexible tubing and not the valve itself is suggested by the fact that substitution of a commercial pinch valve has no effect.

The phenomenon only appears at these very low flow rates; however, if fine regulation is desired at extremely low flows for metering medications, etc., the problem is probably amenable to solution. A different technique for

restricting the plastic tubing to produce lower stresses and/or a different stress distribution in the plastic material may provide a solution. This would require redesign of the flow control valve, and regardless of other changes, more sensitivity would certainly be built into the device. The present knob is somewhat "touchy" at the low end of the flow range. Incorporation of a differential screw thread in the device would yield any desired degree of sensitivity, and could be easily implemented. There is also the possibility that a suitably designed flow control valve, with much greater sensitivity and detenting or indicating capabilities, could be used to set the flow rate in an open loop manner. A simple calibration to match its indication to the characteristics of the particular plastic tubing in use would probably be necessary.