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TECHNOLOGY INCORPORATED
LIFE SCIENCES DIVISION

BREADBOARD DEVELOPMENT

OF A

FLUID INFUSION SYSTEM

CONTRACT NAS 9-14081

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SAN ANTONIO, TEXAS

FINAL REPORT

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FLUID INFUSION SYSTEM

CONTRACT NUMBER NAS 9-14081

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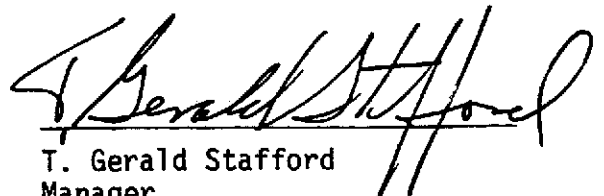

SUBMITTED TO:

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TABLE OF CONTENTS

i

LIST OF FIGURES

I. INTRODUCTION

A functional breadboard of a Zero Gravity Intravenous Infusion System (IVI) was shipped to Lyndon B. Johnson Space Center on December 31, 1974. This unit was the result of efforts by Technology Incorporated under Contract Number NAS9-14081.

The IVI delivered is designed to meet the following objectives:

(1) to demonstrate the feasibility of a positive displacement pump delivery system for the emergency infusion of various liquids in a zero G environment,

(2) to accept two standard Travenol^{TM} or equal infusion packs containing any suitable IV fluid,

(3) to deliver those fluids to a patient at a continuously adjustable flow rate between 0.5 ml/min and 10.0 ml/min,

(4) to furnish an indication of flow and an integral "no flow" alarm system,

(5) to allow for the injection of drugs through the IVI venipuncture,

(6) to provide selection of the infusate source and automatic switching between sources,

(7) to furnish a concept for the intravenous infusion of liquids in a zero G environment that is adaptable to manned space flight qualifications, and

(8) to deliver a unit suitable for experimental testing on non-human subjects.

The IVI system delivered meets or exceeds each of these objectives.

II. OPERATING INSTRUCTIONS

1. Insert prefilled infusion set in pump section. Infusion set includes blood filters and 20 ga. needle.

2. Insert infusate packs in both pack pressurizers and connect to infusion set. Be sure infusion set connectors correspond to pack pressurizers.

3. Set Mode Select Switch to "A".

4. Set Power Switch to "ON".

5. Set Reset Switch to "UP" position (not spring loaded).

6. Operate both Cover Interlock Switches (lever microswitches on pack pressurizers).

7. Allow pump flow to stabilize. Alarm will sound on a regular basis.

8. Set rate control for the desired frequency indication on the counter.

9. Set Reset Switch to "CENTER" position.

10. If alarm occurs, (a) momentarily operate Reset Switch down (spring loaded position); (b) check depletion warning lamps (if both are illuminated, the alarm is valid); (c) check for obstructions in the flow path.

III. DESIGN DESCRIPTION

The IVI system consists of five major components, two infusate pack pressurizers, the pump module, the infusion set and the electronic control package.

A.   Infusate Pack Pressurizers

Each of the two infusate pack pressurizers is designed to accept one pliable 500 ml liquid container equivalent to the Travenol^{TM} pack. These units consist of a fixed plate, mounted between two channels, a movable plate attached to two coil springs and three switches with appropriate interconnecting wiring. The infusate pack is placed between the two plates with the tubing connections protruding through a slot in the fixed plate. The two springs force the movable plate against the pack with 11.2 lbs. of force. These springs are manufactured by Hunter Springs Division of Ametek and are designed to exert a constant force over the usable travel of the movable plate. This constant force results in a constant infusate source pressure which eliminates changes in system flow rate due to the elasticity of the infusion set. Two of the three switches are mounted on the fixed plate to sense the depletion of that infusate pack. These switches are connected in series and are normally open. Therefore, the movable plate must be within the set proximity and nearly parallel to the fixed plate before the circuit is closed to indicate depletion of the infusate pack. The third switch senses the elevation of the movable plate for the insertion of a new infusate pack.

A flight model of the IVI conceptually uses a closed box for each of the infusate packs, enclosing the pack on four sides. The operating principal of the flight unit concept and the breadboard are identical except that

the third switch might detect the opening of the box lid rather than the extension of the movable plate.

B. Pump

The pump section consists of a plate with milled channels to accept the infusate set, a cover plate to hold the infusate set in place, the source selection solenoids, two parallel pump sections and the flow sensor. The two source selection solenoids normally occlude the infusate set tubing, preventing flow from the adjacent source and are opened on command from the control electronics.

The two parallel pump sections are also subject to the command of the control electronics and provide mutually exclusive flow through two parallel paths. The two pump approach was selected to increase the dynamic range (i.e., flow rate range) of the system and to provide redundancy in case of a failure. Each pump section consists of three solenoids, an upstream solenoid (for convenience identified as N and S), an expression solenoid (O and T) and a downstream solenoid (P and U). These solenoids are sequenced as shown below:

Cycle	N	O	P	S	T	U
0	U	U	D	D	D	U
1	U	U	D	D	D	U
2	D	U	D	D	D	D
3	D	D	U	U	U	D
4	D	D	U	U	U	D
5	D	D	D	D	U	D

U = Solenoid up tubing open
D = Solenoid down tubing closed

Solenoids N, P, S and U occlude the tubing, preventing flow in either direction. Solenoids O and T compress a section of tubing (not occluding) to express the infusate down stream. Solenoids N and O (S and T) are raised allowing the infusate to fill the tubing down to solenoid P(U). Solenoid N(S) is then closed trapping a fixed volume of fluid between the two occluding solenoids N and P (S and U). Solenoid P (U) is then raised and O (T) is closed, expressing the fluid downstream. The cycle is completed by closing P (U), leaving all solenoids in the down position. These pump sections are described as mutually exclusive as the upstream solenoids (N and S) are never open at the same time. Likewise, the downstream solenoids (P and U) are never open simultaneously, preventing the cycling of fluid from one pump section to the other.

Each solenoid is spring loaded such that the power off or failure condition is with the tubing occluded (no flow). The adjustment of this spring tension and the alignment of the pump elements is critical to the proper performance of the system. The spring tension should be just high enough to cause the section to "snap" closed, occluding the tubing. Too much spring tension will overpower the solenoids while too little will result in sluggish operation and/or uncontrolled fluid leakage through the section.

The system flow rate is controlled by adjusting the pump cycle time. In addition, the rate may be changed by varying the length of the contacting bar on the expression solenoids (O and T) and by adjusting the stroke length of these elements. On the breadboard unit, the stroke length was adjusted by inserting shims under the collar on the pump shaft.

A least squares fit was performed on the final flow rate data taken on the IVI breadboard resulting in

$$R = .84861 \ F - .04641$$

where R is the flow rate in ml and F is the VFO frequency (monitored by the counter) in kHz. Figure 1 is a graphic representation of this transfer function. Breadboard testing also indicates that the flow rate is affected by the backpressure at the needle at the rate of 0.13% per mm Hg.

The flow sensor is mounted on the downstream side of the parallel pumps and detects the pressure surge through the tubing on each pump stroke. The element consists of a strain gage laid on a small plastic block and monitored by the flow detection circuitry discussed in Section III.D.3.

C.   Infusion Set

The IVI infusion set is made up of standard infusion set blood filters and needle adapters, an experimental silicone rubber tubing and hand blown glass "T"s. The blood filters were taken from Cutter model 866-01 tandum blood sets while the needle adapters were taken from Travenol^{TM} model 2C0002 infusion sets. This needle adapter is designed to provide a drug injection site in addition to the standard drug injection port on Travenol^{TM} infusion pack. The tubing was selected after an extensive market search and has not been approved for use on human subjects. Standard tubing materials do not exhibit sufficient resilience to operate at pump cycle periods shorter than one second. As a result, the pump cycle period must be very slow (on the order of 20 seconds) in order to provide the dynamic range required. Three hand blown glass "T"s are
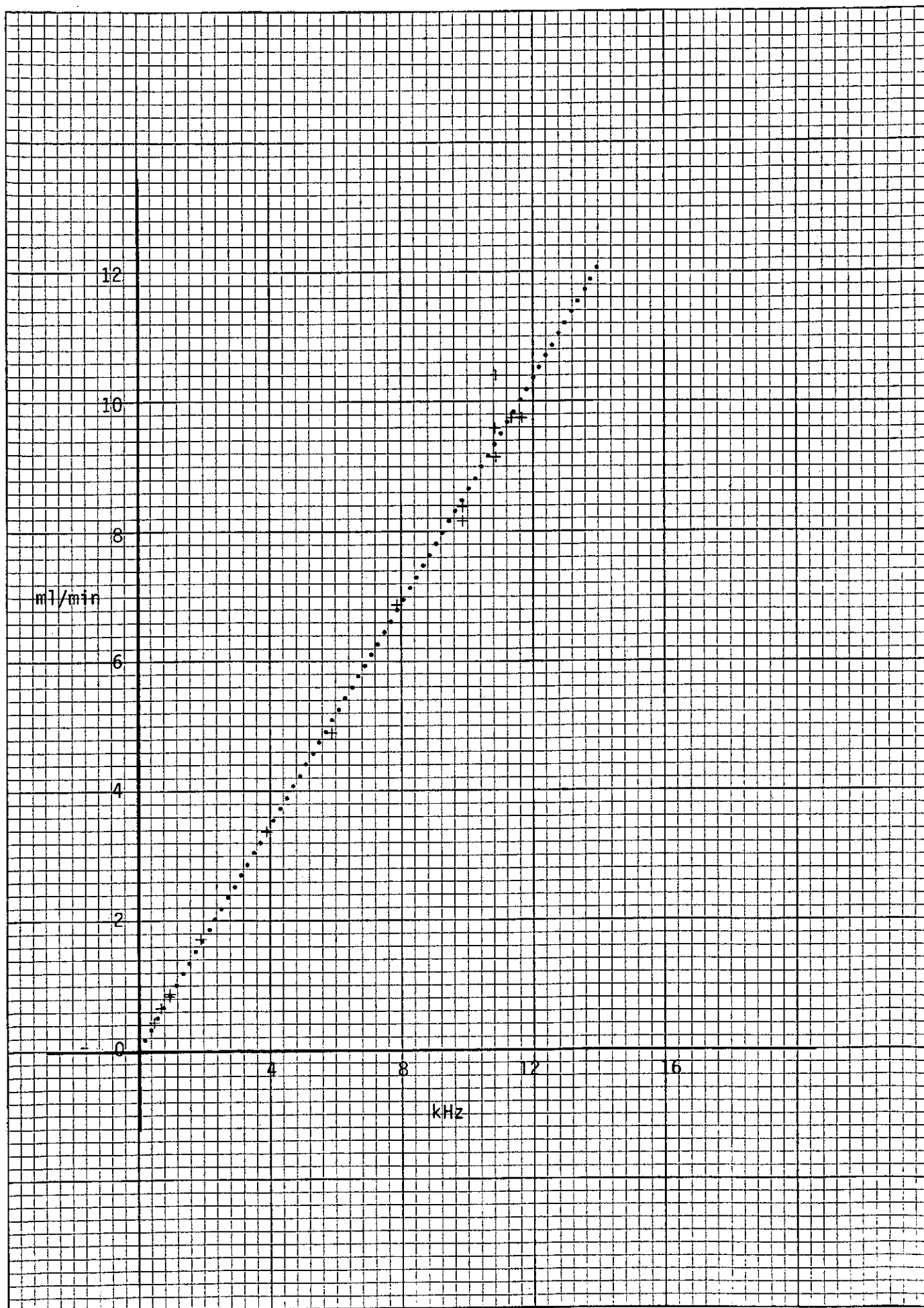
Figure 1.   Flow vs. VCO Frequency

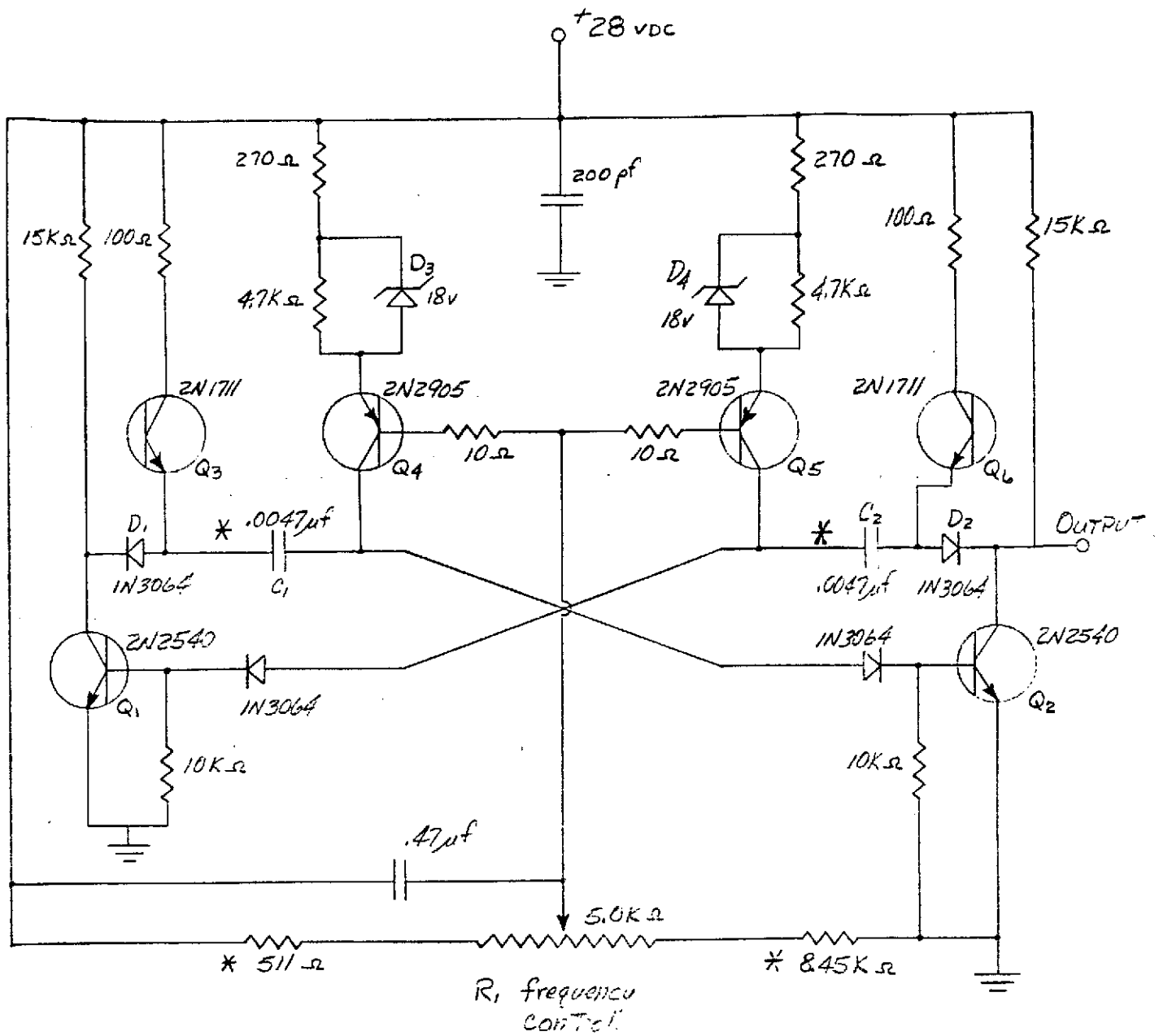required for each infusion set and were purchased locally for one dollar each.

D. **Electronic Control Package**

The electronic control package consists of four sections: (1) the voltage controlled oscillator, (2) the digital control electronics, (3) the flow detection circuitry and (4) the power distribution circuitry. The voltage controlled oscillator (VCO) provides front panel control of the pump speed and is directly monitored by the external counter. The digital control electronics divides the output of the VCO to the proper pump frequency, controls the operation of the pump solenoids and makes the source selection, switching and alarm decisions. The flow detection circuitry senses flow stoppages in the infusion set and the power distribution circuitry generates the 24 VDC and 5 VDC required by the solenoids and logic circuitry respectively.

1. **Voltage Controlled Oscillator**

The voltage controlled oscillator (VCO) is an astable multivibrator with a voltage controlled charging rate. Figure 2 is a schematic of the VCO. The principal active elements of the multivibrator are Q1 and Q2. The frequency of oscillation is controlled, classically, by the charging time of capacitors C1 and C2 from the collector voltages of these active elements.

In this circuit, the collector voltages are blocked from the charging circuit by diodes D1 and D2. In this case, the charging rate is controlled by the constant current generators Q4 and Q5 which are in turn controlled by the front panel control R1. The timing

Figure 2. VCO Schematic

*28 VDC

270 Ω   200 pf   270 Ω

15KΩ   100Ω   4.7KΩ   D₃ 18v   D₄ 18v   4.7KΩ   100Ω   15KΩ

2N1711   2N2905   2N2905   2N1711

Q₃   Q₄   10Ω   10Ω   Q₅   Q₆

D₁   * .0047μf   C₁   IN3064   C₂   D₂   OUTPUT

IN3064   .0047μf   IN3064

2N2540   2N2540

Q₁   IN3064   IN3064   Q₂

10KΩ   10KΩ

.47μf

5.0KΩ

* 511 Ω   * 845KΩ

R, frequency control

* Selected Components

III-7

capacitors (C1 and C2) alternately assume control of the circuit timing during the off cycle, they are quickly recharged by Q3 and Q6. This approach assures that the recharging time constant is at least an order of magnitude shorter than the off period which in turn improves the stability of the circuit. The breadboard unit is designed to operate from 470 Hz to 12,000 Hz. The output is directly monitored by the external frequency counter and drives the frequency divider in the digital control electronics.

2. Digital Control Circuitry

Drawing number TS313100 is a schematic of the digital control circuitry (DCC). The output of the VCO is buffered into the DCC by Q1. This saturating amplifier serves the tri-fold purpose of (1) furnishing impedance matching between the VCO and the DCC, (2) effecting a voltage level conversion and (3) providing a current sinking source to drive the TTL logic in the DCC. The output frequency of the VCO is digitally divided by 12,000 by the decade counters 1-1, 1-2 and 1-3, one of the flip flops in 1-4 and the synchronous counter 1-5. The dual input nand gate 1-6-2 provides the count feedback enable that limits the count of 1-5 to 6. The synchronous counter is used in the last stage of the frequency divider to prevent transient false outputs during the counting sequence. Gates 1-6-2 and 1-6-4 sense the presence of cycles 5 and 2 respectively and through 1-6-3, 2-5-1 and 1-6-1 inhibit the flip flop and synchronous counter during these cycles anytime an alarm condition is sensed on 2-5-1 pin 2. This arrangement assures that the pump stops after each alarm with both downstream solenoids (P and U) closed.

The output of 1-5 is decoded by 2-4-1, 2-4-2, 2-4-3, 2-2-1, 2-2-2, 2-2-3, 2-2-4, 2-3-1, 2-3-2, 2-4-4 and 2-4-5 which in turn drive the saturating darlington solenoid drivers Q13-Q14(P), Q15-Q16(S), Q17-Q18(N), Q19-Q20(U), Q21-Q22(T) and Q27-Q28(O). The unused transistors Q7 through Q12 were used to drive LED indicators to troubleshoot the circuit during the early development stages. Initial selection of the infusate source occurs when the start switch is actuated. A low level is imposed on the input of 4-4-5, enabling 3-6-3 and 3-6-4. When the mode selection switch is set to A, a high level is impressed on 3-6-4 pin 9 resulting in a low level to 4-2-1, a high to 4-4-4 and a low to set the flip flop 4-2-3 and 4-2-4. This in turn results in a low level to 4-6-4, a high to 4-6-2, a low to 4-4-3 and a high to drive the A source indicator (E) and the A source solenoid driver Q23-Q24. A similar sequence occurs when the mode selection switch is set to B, resulting in the activation of the B source indicator (D) and the B source solenoid driver Q25-Q26. When the mode switch is in the A & B position, both inputs to 3-4-4 are enabled, resulting in a low to both 4-6-3 and 4-6-4, highs to 4-6-1 and 4-6-2, lows to 4-4-2 and 4-4-3 enabling both source indicators and solenoid drivers. Passage of these signals through 4-6-1 and 4-6-2 is dependent upon a high at the output of 3-2-3. When both sources are depleted, this line goes low, disabling both source indicators and solenoid drivers.

When source A is selected and that source is depleted, both inputs to 3-2-4 are high, resulting in a low to 4-2-2, a high to 4-4-1 and a low to flip flop 4-2-4 and 4-2-3 resulting in the switching of

that flip flop and the ensuing circuitry to the B source. A similar sequence occurs when the B source is selected and depleted through 3-4-3, 4-2-1 and 4-4-4 to the flip flop.

Under normal operating conditions, the depletion detection switches (A and B) are open and the lid interlock switches (C and D) are closed. When the A source is depleted, both detection switches (A) are closed impressing a low level on 3-1-2 pin 5 resulting in a high to 3-3-4 and a low to 3-2-1 pin 1, setting the depletion flip flop and illuminating the A depletion warning lamp (B). When the pressurizing unit is opened to replace the infusate pack, both the depletion detection switches (A) and lid interlock switch (C) are open enabling 3-5-1. As a result the recharge flip flop (3-5-3 and 3-5-4) is set which in turn impresses a high on 3-4-1 pin 3. After the pressurizing unit has been reloaded and the lid is closed resulting on low to 3-3-3, a high to 3-1-2, a low to 3-3-4, a high to 3-4-1 and a low to 3-2-2 pin 5 resetting the depletion flip flop. The resulting low at 3-2-1 pin 3 extinguishes the depletion warning lamp and resets the recharge flip flop through 3-1-4 pin 9. This sequence returns the circuit to the original condition. The B source depletion circuit operates in a similar manner. The capacitors on the outputs of 3-4-1 and 3-4-2 assure that the depletion detection flip flops initialize in the reset condition during the power up process.

When both sources are depleted, 3-2-3 is enabled impressing a low on 2-6-3, a high on 3-3-2 and a low on 2-6-4 pin 10, setting the

alarm flip flop and enabling the visual and audible alarms, and disabling the frequency divider through 3-3-1 and 2-5-1. The alarm flip flop is reset by operating the reset switch, impressing a low on 2-5-2 pin 4.

The alarm flip flop may also be set by the flow detection circuitry. When either of the downstream solenoids (P and U) are open, lows are impressed on the input of 2-3-3 resulting in the initiation of one of the one shots in 2-1. The output of that one shot puts a low on 2-3-4 pin 10, setting that flip flop. Under normal conditions, low level pulse from the positive pulse detection (PPD) output of the flow detection circuit initiates the other one shot in 2-1, resulting in a low to 2-6-1 pin 1 resetting the flip flop and the alarm is inhibited. Should the PPD output not occur, the flip flop (2-3-4 and 2-6-1) will not be reset and a high from 2-3-4 pin 8 will enable 2-6-2. When both downstream solenoids are closed (cycles 2 and 5) both inputs to 2-3-3 will be high, providing a low to 2-5-3, a high to the other input of 2-6-2, a low to 2-6-3, a high to 3-3-2 and a low setting the alarm flip flop (2-6-4 and 2-5-2). The alarm may also be initiated if the negative pulse detection output (NPD) of the flow detection circuit produces a low level pulse before the PPD output. The NPD output results in a high pulse from 2-5-3 and sets the alarm through 2-6-2 in the same manner as the closing of the downstream solenoids. In summary, the alarm is set if either of two conditions occur. Either the PPD output does not occur during the period that one of the downstream solenoids is open or an NPD output occurs before the PPD output. The logic of this arrangement will

III-11

be explained in the description of the flow detection circuit.

3.   Flow Detection Circuitry

When the expression solenoid closes, a pressure surge occurs down-
stream, forcing the infusate through the needle. This pressure surge
is sensed by a strain gage mounted on a thin plastic block which
presses against the infusion set wall. Figure 3 is a schematic of
the strain gage bridge - amplifier circuit. R1, R2 and R3 along
with the strain gage form a bridge which is balanced by R4. The
output of the bridge through points A and B into the differential
inputs of A1. This amplifier provides a gain of approximately 470
and high frequency noise attenuation. R5 compensates for the offset
voltage of the amplifier. C1 blocks the dc component of the output
of A1, avoiding saturation of the output amplifier A2. The second
amplifier also provides a gain of approximately 470 and high frequency
noise filtering. R6 compensates for the offset voltage of A2. D1 and
D2 provide the voltage reference required by the positive input bias
circuitry of both amplifiers. The circuit output (0) drives the
signature recognition circuit. Each pressure surge in the infusion
set results in a minimum pulse of 2 volts at 0.

When an occlusion occurs in the infusion set upstream from the pump,
an apparent void is created when the expressing solenoid is raised.
When the downstream solenoid is opened, the downstream infusate is
drawn into this apparent void resulting in a negative pressure pulse
(with respect to ambient) at the strain gage detector and produces
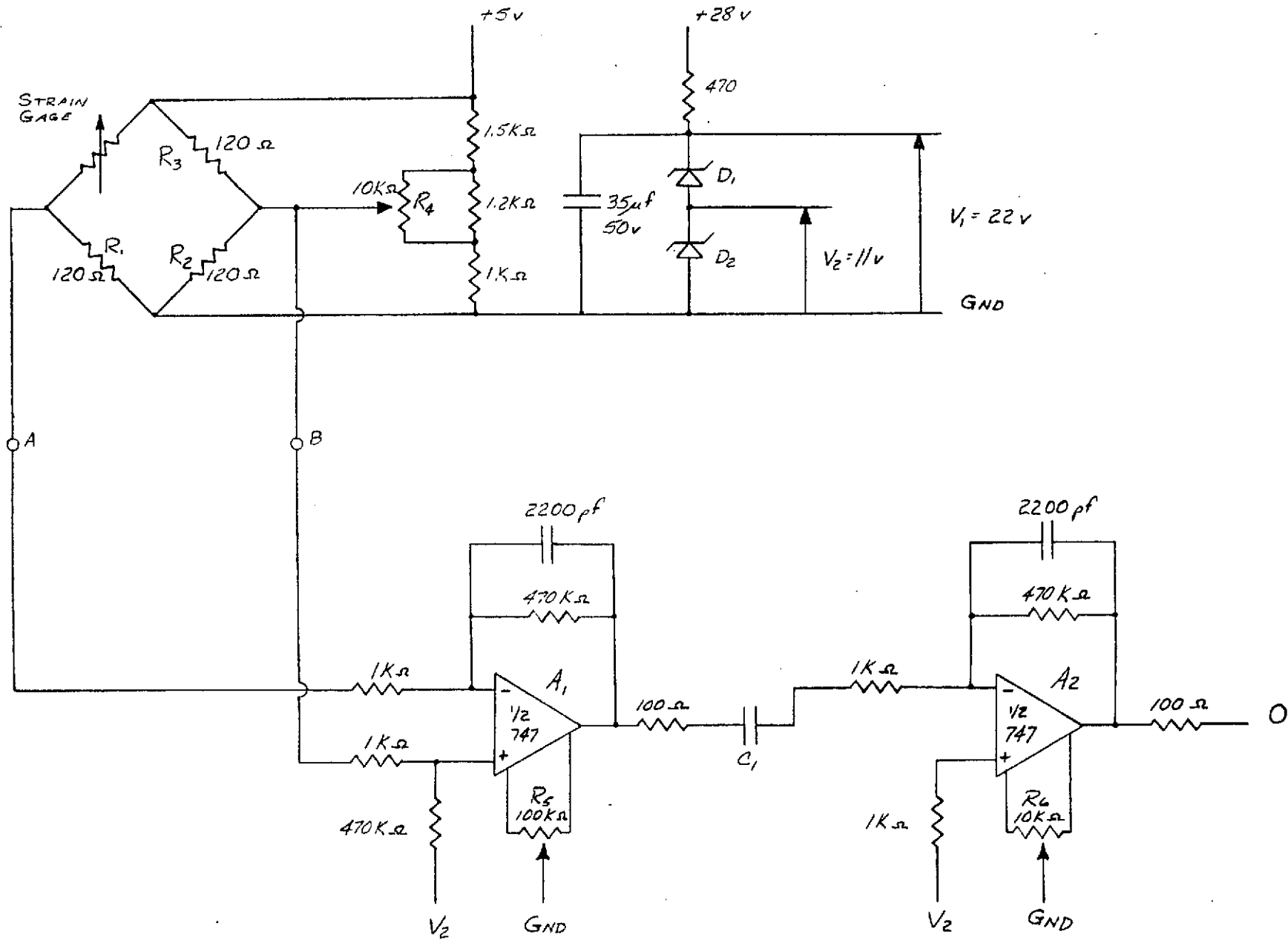a negative pulse at 0. When the expressing solenoid closes, the

III-12

Figure 3. Strain Gage Bridge - Amplifier

normal positive pulse occurs. Summarizing, when an upstream occlusion occurs, a negative pulse followed by positive pulse appears at 0.

When a downstream occlusion occurs, the same output is seen at 0. Under these conditions, the pump continues to build the pressure in the infusion set downstream until it exceeds the pressure supplied by the infusate pack pressurizers. When the downstream pressure significantly exceeds the supply pressure, fluid cycling occurs similar to the upstream occlusion case.

When any element of the pumps fails, an occlusion occurs between the pump and the flow detector or the flow detector fails, the positive pressure pulse is not indicated at 0.

Figure 4 is a schematic of the signature recognition circuit. T1 provides impedance matching between the strain gage amplifier and the rest of the detection circuitry. When a positive pulse occurs at 0, T2 saturates resulting in a low level (ground) pulse at the positive pulse detection output (PPD). When a negative pulse occurs at 0, T3 is turned off, saturating T4 and providing a low level pulse at the negative pulse detection output (NPD). The significance of the PPD and NPD outputs was previously explained in the alarm circuit description.

4. Power Distribution Circuitry

Figure 5 is a schematic of the 5 NDC power supply which supplies the digital circuitry and other miscellaneous circuits. The IN5232 provides a voltage reference for the series regulator 2N4921. This
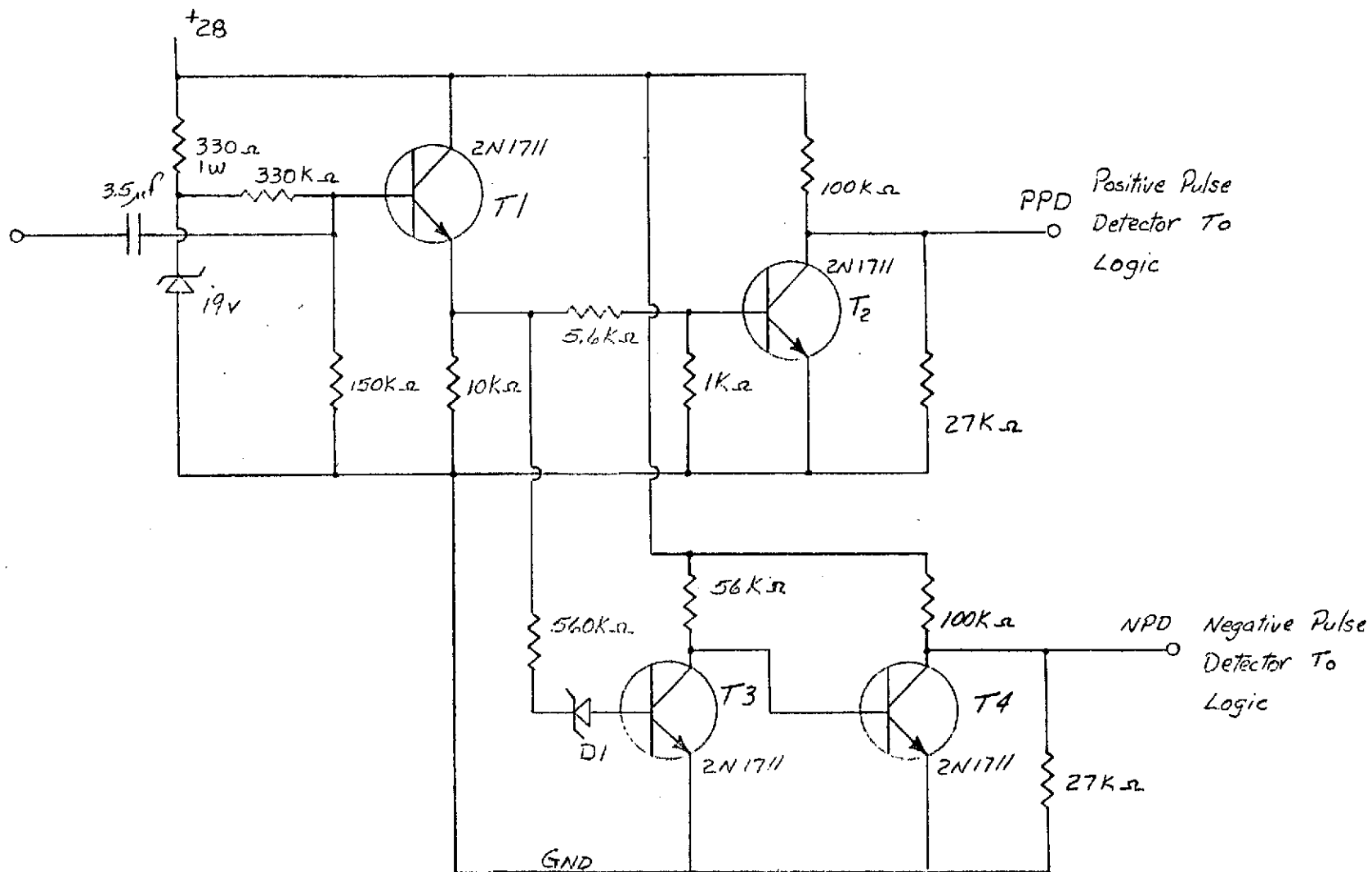
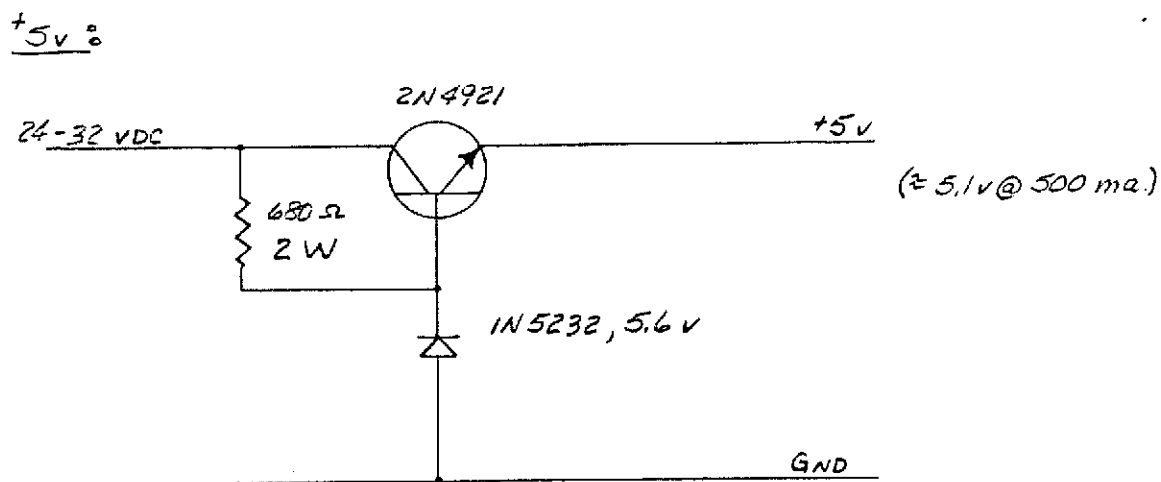Figure 4. Signature Recognition Circuit

+5v :

2N4921

24-32 VDC ————————————————— +5v

680 Ω
2 W

(≈ 5.1v @ 500 ma.)

1N5232, 5.6v

GND

Figure 5.   5 VDC Power Supply

+24v :

T₁

25v - 32 VDC ————————————— 24 VDC @ 2a

D₂

T₂   T₃

$T_1 = 2N5986$
$T_2 = 2N1711$
$T_3 = 2N1711$
$D_1 = 1N5249, 19v$
$D_2 = 1N5231, 5.1v$
$R_1 = 1.2K Ω, ½ W$
$R_2 = 330 Ω, 2 w$
$R_3 = 910 Ω, 1 w$
$C_1 = 56 μf, 20 v$
$C_2 = 56 μf, 20 v$
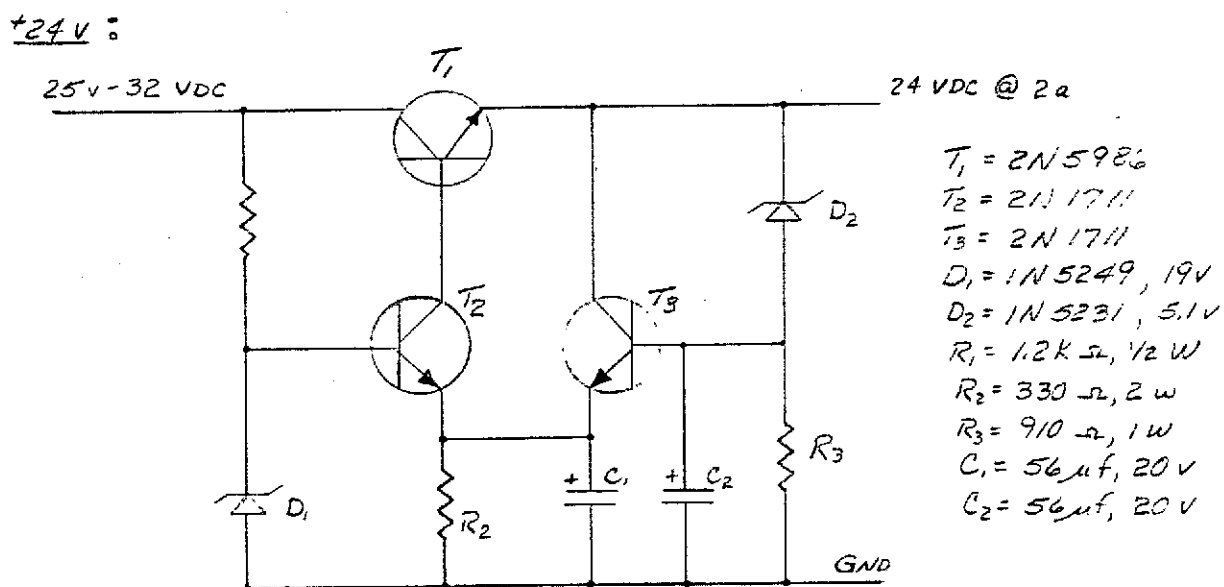
+ C₁   + C₂   R₃

D₁   R₂

GND

Figure 6.   24 VDC Power Supply

simple circuit is capable of providing 500 ma.

Figure 6 is a schematic of the 24 VDC power supply which supplies the solenoids. This approach was selected because it minimizes the voltage drop across the series regulator (T1), and is self starting. Drive for the T1 is supplied by a regulator driver (T2), which is in turn supplied by the unregulated voltage. D1 provides a voltage reference for T2. Regulation is affected through D2 and T3 which control the voltage across R2 and the bias across the base-emitter junction of T2. C1 and C2 provide high frequency noise suppression fed back into the supply by the solenoids.

IV. PERFORMANCE

The IVI breadboard designed by Technology Incorporated demonstrates the feasibility of using the parallel solenoid pump and spring powered infusate source pressurizers for the emergency infusion of various liquids in a zero G environment. All of the components used are available in manned space flight qualified versions. The unit accpets two Travenol^{TM} or equal infusion packs and provides continuously variable flow rates ranging from 0.5 ml/min to 10 ml/min. Front panel controls allow selection of either pressurized infusate pack as an initial source while the control circuitry automatically switches to the second source when the first is depleted. Two ports are available for the injection of drugs. The needle adapter on the infusion set is designed to accept an injection and a standard Travenol^{TM} pack also has an injection port. The pumping action of the solenoids is visible through the clear pump section cover for verification of operation. The visual and audible alarm circuitry in turn confirms the proper flow of fluid through the infusion set.

The IVI was tested for flow rate resulting in the data presented in Figure 1. The transfer function for flow rate is given in Section III-B of this report. The IVI was also tested for sensitivity to back pressure at the needle. For a back pressure change from 0 mm Hg to 150 mm Hg, the flow rate variation averaged 0.13% per mm Hg. When a 500 ml infusate pack is allowed to pump to depletion, approximately 25 ml of fluid is left unused in the pack.

For the final test for the breadboard IVI, a 6½ lb male rhesus monkey was anesthetized. Approximately 6.5 ml of 5% dextrose were infused into the animal through a #19 catheter. The test was terminated as soon as the presence of flow was verified because of the small size of the animal.

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