A FAIL-SAFE, THREE WAY, VARIABLE FLOW CONTROL VALVE FOR A COMMERCIALLY AVAILABLE, IMPLANTABLE INSULIN INFUSION PUMP

by

JOSEPH PETER FEEHAN

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Abstract

A three way, fail safe control valve was designed for the modification of a commercially available drug delivery system. The implantable infusion pump required a very small, energy efficient actuator, which requlates the flow of insulin solutions to the body.

The design utilizes a permanent magnet armature, a series of bellows and linkages for mechanical advantage, and a castellated valve stop. A special three way mechanical linkage is used to increase safety. To check on the energy requirement, a prototype armature setup wasused. The coil generated over 12 grams of force, which is close to the theoretical value of 15 grams of force. A comparison of a magnetic armature with a steel rod gives magnetic armature at least 7 times as much as force. Finally, an endurance load of 2.4 million cycles was applied to the magnet. There was no discernable damage to the samarium cobalt source.

Thesis Supervisor: Professor Ernesto E. Blanco

Title: Adjunct Professor of Mechanical Engineering

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III ACKNOWLEDGEMENTS

Foremost, I wish to thank my thesis advisor, Professor Blanco. He introduced me to the engineering group at Infusaid, and this problem. His enthusiasm, support, insight and patience made this project not only challenging but enjoyable. Having worked with an outstanding engineer and true gentleman on a fascinating problem, I wish to further explore design. Without Professor Blanco, this project simply would not have been.

I also wish to thank Infusaid Corporation for the chance to work on this project. The enthusiasm and suppport I received was excellent. At Infusaid, my immediate supervisor was Samir Idriss, who spent many hours poring over the work and the direction it was taking. His enthusiasm added to this whole experience. This project is as much the work and enthusiasm of Professor Blanco and Samir as can be said. It would be hard indeed to do justice to the time, effort and concern they put forth.

Many other provided invaluable assistance in getting to this point. My two academic advisors, Professors Woodie Flowers and Dave Hardt put things in perspective. So many friends gave so much support throughout, I cannot thank them all. But Charlie, Don, Paris and Panos, thanks a million. And to my parents, I dedicate this thesis. They made it possible for me to come here. My words are not nearly enough to express what I feel for all those who've helped along the way.

IV INTRODUCTION

The problems associated with diabetes include heart disease, kidney failure, blindness and shock. These conditions are all aggravated by large fluctuations in sugar levels. To prevent such damage, a number of artificial means have been tried. The oldest method of diabetes control is to inject insulin several times each day. The major problem with injections is that they do not follow the bodies needs closely enough. Also infection, scarring and low acceptance pose problems.

Another way of delivering insulin is via an external pump. These are usually belt mounted units, and meet the bodies needs very closely. However, the units are bulky, uncomfortable and in danger of being dislodged. Besides disconnecting at the body interface, the present interfaces are also very good sites for infection to enter the body. At the present time, a strong case can be made that the unit is not worth the discomfort and danger it creates.

Infusaid produces another alternative, the steady flow infusion pumps. By sterilizing and implanting the pump, the danger of infection and open interfaces is dramatically reduced. This particular design does not quite match the bodies needs as well as the external pumps, but does better than injections.

The ideal situation would have an implantable pump which would vary in output so as to meet the bodies needs, which leads into this thesis. This project is aimed at making progress in that direction.

V. DESIGN - BACKGROUND

In the previous section, it was shown that there exists a definite need for better time varying methods of insulin delivery. Problems with the most common form of delivery, subcutaneous injection, were discussed. In this section, other methods are discussed, especially with regards to the thesis work, and its design emphasis.

As was discussed earlier, a number of external pumps are commercially available. Some good results have been obtained, but also serious liabilities are associated with that particular design. These shortcomings were also previously discussed. In this context, an alternative approach to needle therapy or external pumps is discussed. Namely, the Infusaid steady flow infusion pumps are examined. Modifications to that system are then considered.

5.1 IMPLANTABLE PUMP - STEADY STATE FLOW

Infusaid corporation of Norwood, Massachussetts has been producing and implanting a large number [~8000] of drug delivery systems. These are self contained units, surgically implanted under the skin in the upper chest area. The small disk shaped unit delivers the insulin to the body via a small tube known as a catheter. This catheter, constructed of flexible, medical quality stainless steel, is generally placed in a vein. The insulin then drips in at a slow steady rate, as was shown earlier

in Figure 5-

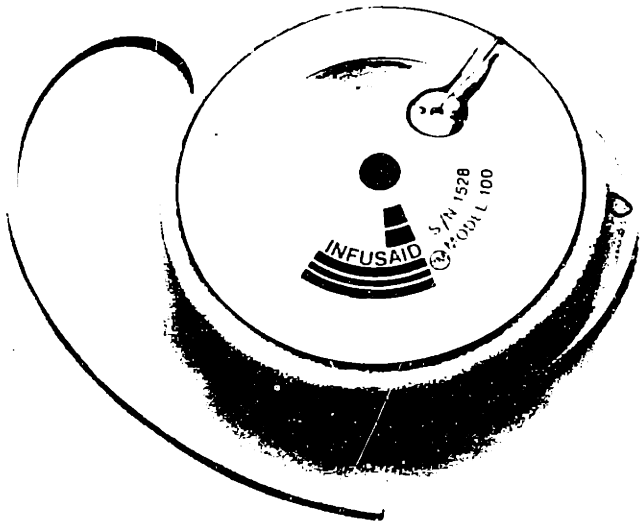
The pump is shown in Figure 5-1, a reproduction from an Infusaid technical brochure. Several important engineering features are present in the pump. Its small size, light weight and biologically compatible shape allow it to be worn without discomfort to the patient. A normal lifestyle can be maintained, and there is generally no outward presence of the pump. Hence the embarassment of having a pump attached to a belt or strap is removed. More importantly, the problems of infection and disengagement at the catheter-body interface are eliminated.

Second, the pump is constructed so that only biologically inert materials are in open contact with the body. Three materials are widely used: titanium, stainless steel, and various inert polymers. Titanium provides the main structure of the pump. It was chosen for a number of reasons. Foremost, it is biologically inactive, more so than stainless steel, which is active but protected by a passive oxide layer. Titanium's neutrality to the affects of the body matches closely with surgical steel. However, titanium is a little less active, and weighs considerably less for a given volume. Since it will be carried permanently, weight is a prime concern. Other good qualities include ease of machining, ability to weld, and widespread availability.

Stainless steel and polymers perform secondary roles in the system. The catheters are of flexible stainless steel, with a polymer coating. The device is also coated with a smooth plastic, to further reduce the chance of interaction.

INFUSAID ®

Technical Bulletin: Models 100, 200, 500



INFUSAID Pumps are totally implantable drug delivery systems for long-term term therapy in the ambulatory patient. All Models deliver a precise, continuous drug flow to a selected organ or site via a soft, non-traumatic, non-thrombogenic, silicone rubber catheter. The pump is powered by a self-contained, permanent, inexhaustible energy supply.

Total Implantability

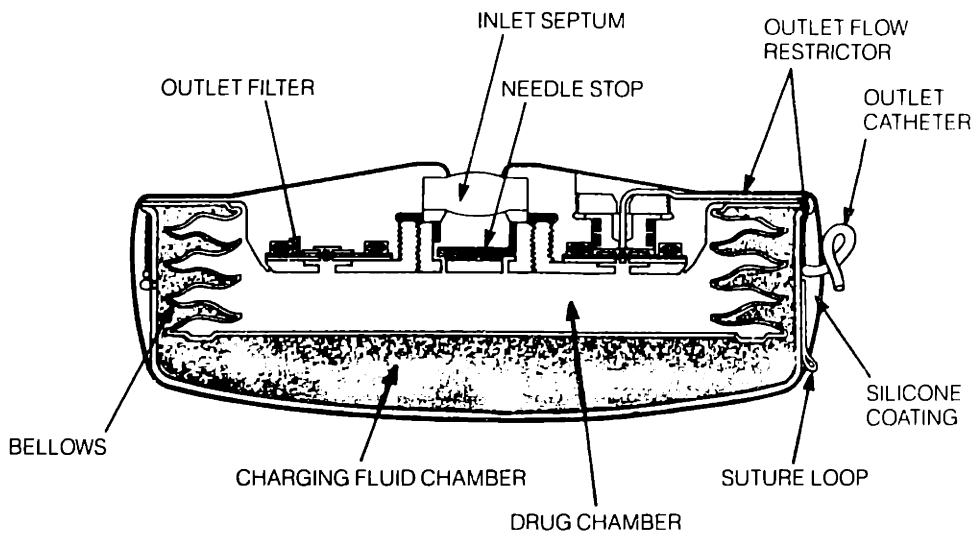
Arterial or venous perforation, hemorrhage, sepsis, and catheter-tip thrombosis are all serious complications with external pumping devices. These problems are rarely encountered in patients with the INFUSAID pump and present minimal threat to extended, continuous, out-patient treatment.

Permanent Power Supply

The intrinsic energy source is the inexhaustible charging fluid permanently sealed in the pump. During each refill procedure, the act of forcing a drug into the pump's reservoir simultaneously re-energizes the charging fluid and refills the drug chamber. The constant pressure of the charging fluid exerted on the reservoir expels the drug causing it to flow through the bacterial filter, through the flow restrictor, and out the outlet catheter.

Out-Patient Benefits

Following a short hospital stay for implantation, the patient is ambulatory with few restrictions. Drug refills are accomplished percutaneously and are generally required every two weeks on an out-patient basis. The INFUSAID Pump allows the patient to receive continued therapy while enjoying normal freedom of movement.



CROSS SECTION MODEL 100

Figure 5-1 Infusaid Pump

Specifications

Flow rate	Calibrated and pre-set to a specified value, typically between 1.0 and 6.0 ml/day.
Bacteria filter	0.22 micron membrane filter
Output pressure	450 mmHg at 37°C
Materials	The drug is only in contact with inert materials: titanium, polypropylene, stainless steel, silicone rubber, teflon, and a membrane filter.
Catheter	30 inches long, radiopaque, silicone rubber with suture bead. Outer diameter is 2.3 mm. Inner diameter is 0.4 mm.

Dimensions and capacities

Model	**100**	**200**	**500**
Useable volume	47ml	32ml	22ml
Diameter	87mm	87mm	87mm
Thickness	28mm	23mm	20mm
Empty weight	187gm	172gm	165gm

Caution. Federal law requires that this device be used in strict accordance with FDA-approved labeling, noting the indications, contraindications, warnings, precautions, and adverse effects of this device. Federal (USA) law also restricts this device to sale by or on the order of a physician.

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The pump provides insulin to the body in the following manner. The section marked bellows in Figure 5-1 is the heart of the whole system. Made of inert, welded titanium, the bellows acts as a sealed, linear spring. The springlike nature allows freon to act as the passive energy source [pressure] for the pump. This is due to the very low spring rate of the pump, compared with the pressure of the freon. By filling the pump with insulin once every refill period, [~2 weeks to 1 month], the bellows is forced to expand, and thus keeps the insulin under pressure. Further pressure control comes from the freon pressure reservoir. A specific concentration of freon stays in two-phase equilibrium at the body temperature of 98.6 F, ensuring constant pressure. Combined, these sources ensure a constant pressure reservoir of insulin.

Metering the insulin in the constant flow system is straightforward. A thin diameter capillary serves as a fluid resistance element, limiting the flow to the desired rate. The particular rate chosen is controlled by selecting proper length, and wrapping it around the outside of the pump. The whole assembly is then coated in plastic, and implanted.

Steady state pumps are presently on the market, and a large number have been successfully implanted. They provide excellent treatment in many cases, and use is spreading. However, as earlier discussed, a variable flow pump would have many benefits in insulin therapy.

5.2 FIRST GENERATION VARIABLE FLOW PUMP

Infusaid Corporation has produced several pre-production models with the features necessary for controllable flow. They will collectively be known as the first generation variable flow pumps. These pumps, soon to be commercially available, form the next level of diabetes control. Based on the steady flow models, this generation provides a number of advances in an implantable pump:

* Variable Flow
* Control by Patient [Under Physician Supervision]
* Programmable

These pump can alter their output digitally, by varying the rate of release of small doses of insulin. The flow rate is controlled by the patient, with supervision by a physician. The patient controls the device through a radio transmitter based telemetry system. Overall, it is similar to a model airplane radio control unit. The box is placed in close proximity to the pump's location in the body. A specific code for each box signals the pump, and then the pump receives the pre-programmed message from the box. The pump receives the electromagnetic signal via an antenna wrapped around the outside of the device. This is possible since flesh is reasonably permeable to low frequency waves. The pump's electronics then take over, giving the proper messages to the control mechanisms. These control

mechanisms then release the insulin.

Figure 5.2 shows the new system. The pump is drawn laid out linearly, while in fact batteries, electronics and actuating mechanisms all fit within the pump body. Several changes determine the new method of delivery. Foremost, the passive nature has been eliminated. The resistance to flow offered by the long capillary tube has been removed. In its place is a digital actuation system. Instead of the slow, passive trickle effect, bursts of small amounts of the insulin are delivered. This is accomplished using several complex mechanisms. Important is the capacitive accumulator. A small, microchip, controlled titanium mechanism, the accumulator stores and then delivers precise amounts of insulin, namely 1.0 microliter. This amount flows from the accumulator upon each actuation.

Each actuator consists of a thin diaphragm of titanium, 0.001" thick, which flexes between an open and closed position, with no intermediate states. Powered by pressure reserves and electronics, it is presently well tested and reliable. The presence of the accumulator allows this undertaking to be possible.

At each end of the accumulators are the actuator-valve combinations. These actuator setups are manufactured by Wilson Greatbatch Corporation, and are also important for the pumps variable operation. By opening one valve while keeping the other closed, the capacitor is either filled or discharged. An electromagnet pulls either valve open upon an electrical signal determined by the circuitry. These valves are reliability

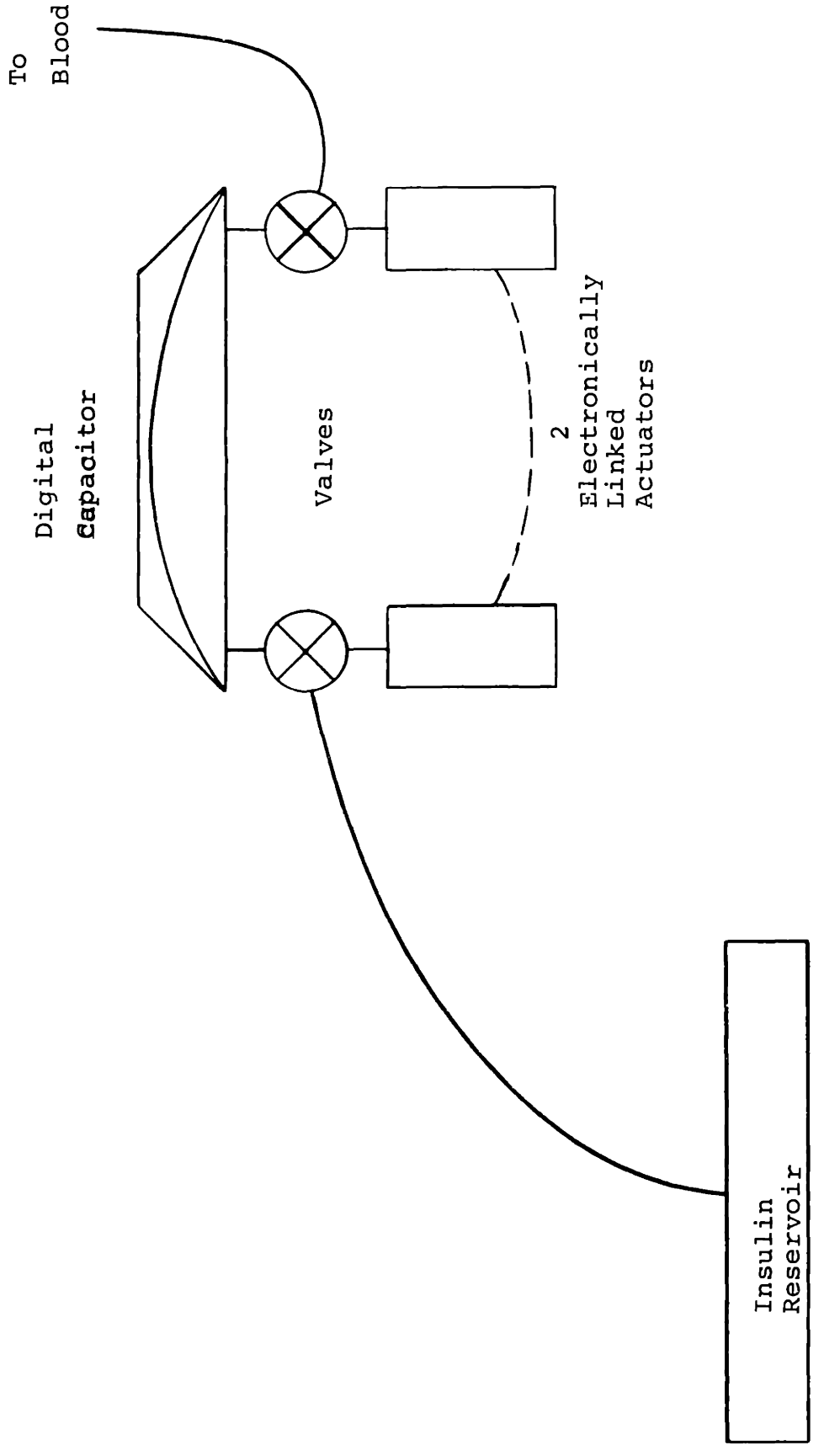


Figure 5-2 Digital Actuator Schematic

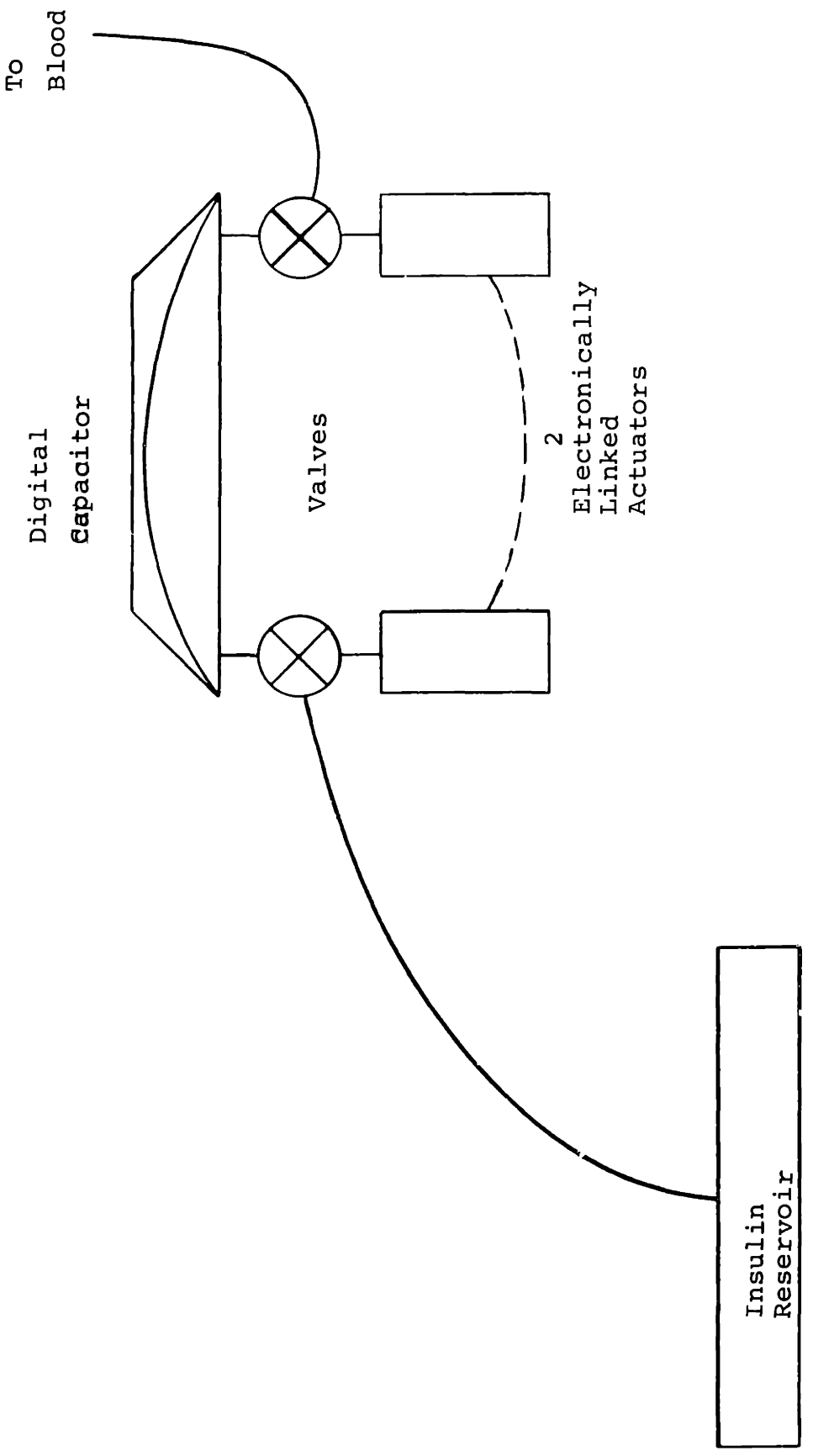


Figure 5-2 Digital Actuator Schematic

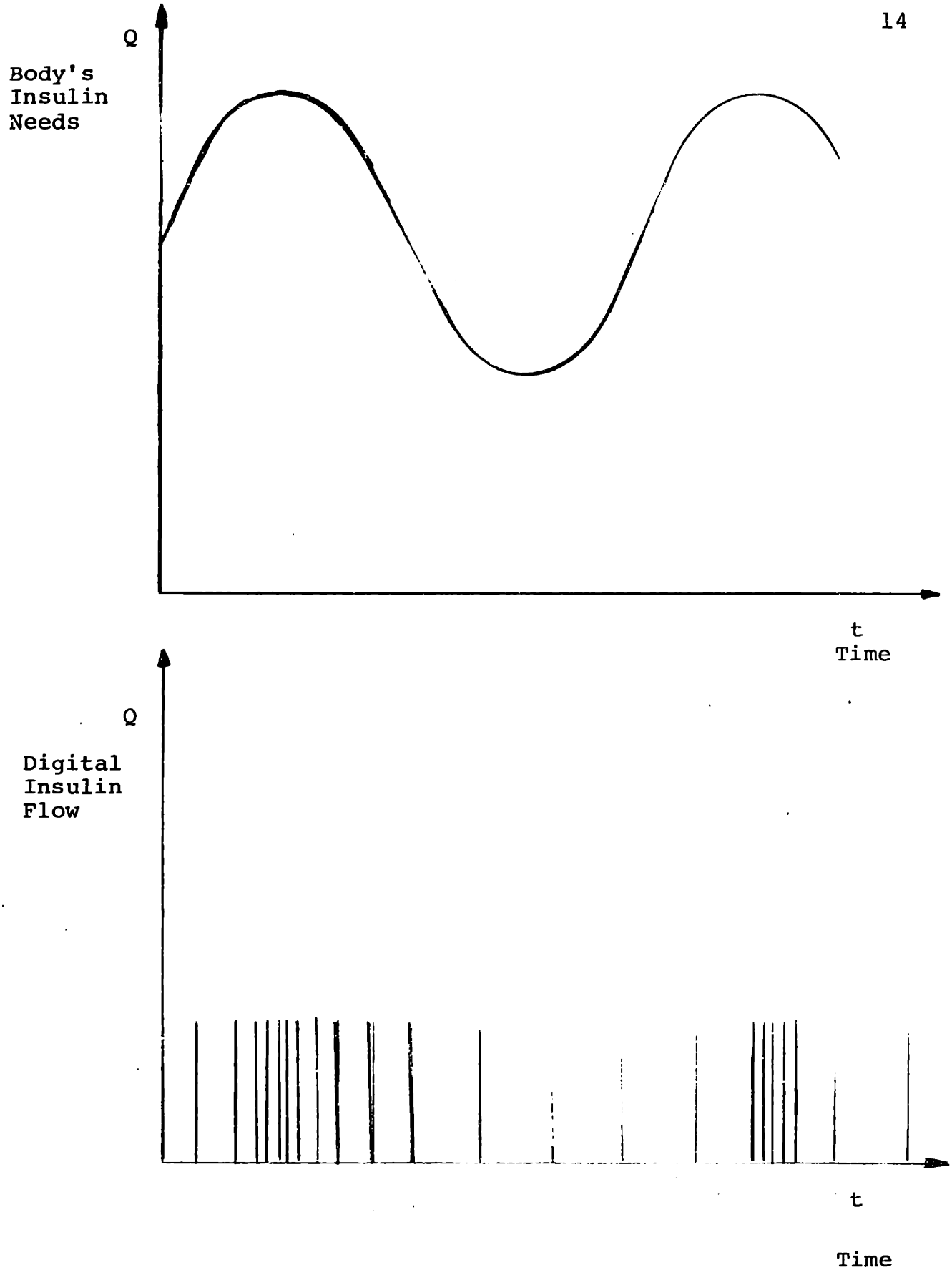


Figure 5-3 Digitized Operation

valves, consisting of a compliant material, spring loaded on a small nozzle tip. It is the spring force on the compliant plastic which holds the valve closed, stopping flow. The actuator must overcome this force.

The system delivers varying flow in the following manner. Each digital actuation causes a small amount of insulin to be released, 1.0 microliters. The capacitor is then refilled, and then another actuation can occur. By increasing the number of digital actuations, the total volume released can be controlled very precisely. This is shown graphically in Figure 5-3.

5.3 PROBLEMS WITH PRESENT PROTOTYPE

As noted in Figure 5-4, there are two valve-actuator assemblies. These are operated electronically, and follow the instructions of an integrated chip. This leaves us with the major danger of such a system. Namely, both valves could possibly be open at the same time. This would give an open path for the high pressure insulin to flow into the body. Insulin flowing in such amounts causes rapid shock followed by death. Such an occurence must be avoided at all possible costs. However, the only safeguards are in the electronic circuitry, and not in the design of the valves themselves. Thus the valves have no built in protection. It is because of this severe danger, however unlikely, that the work was undertaken and a more failsafe design with built in safeguards was produced.

Two possible modes of failure for the present prototype

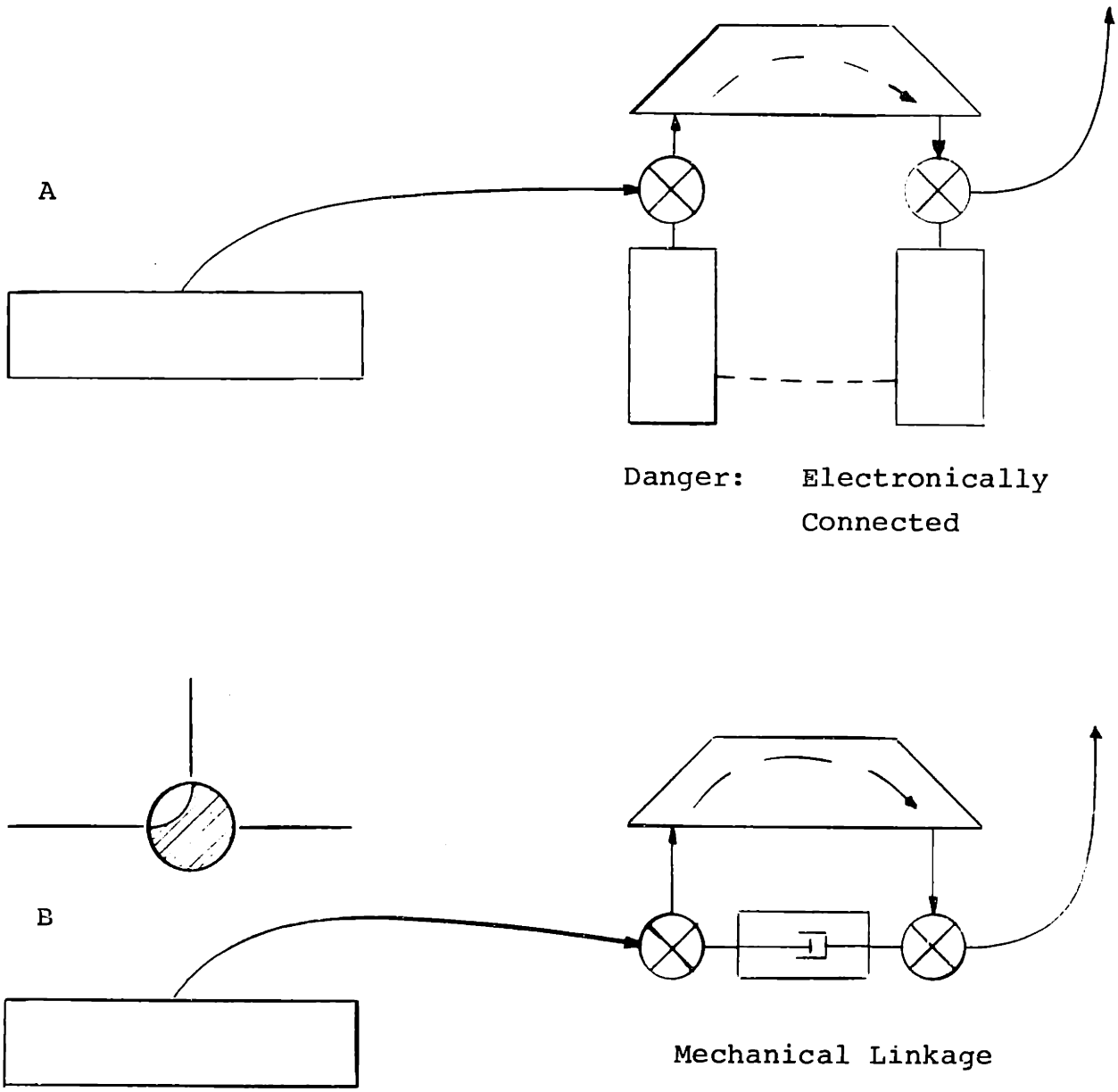


Figure 5-4 Linkages Compared

valves come to mind. A mechanical sticking of one of the valves would then create an open path once the other valve opened. Even for a short time of actuation, a dangerous amount of insulin would be released. The effect would be cumulative. This information is based on prior studies by Infusaid Corporation. The second mode of failure would be electrical. Rather than opening sequentially, both could be actuated simultaneously by a malfunction of the circuitry. Both potential failure modes seem remote indeed, but could be induced in a number of ways. It should be emphasized again that failure, the threat of failure, and the perception of risk must all be reduced if the pump is to be successful. Marketability, psychological acceptance and safety are all connected issues. These factors all weigh for a device with built in safety features. This study was conducted with that hope.

5.4 COMPLICATING FACTORS

Before the new design could begin, a number of interrelated problems had to be considered. Besides safety, these include constraints on materials, size, geometry, and perhaps most importantly, energy. Of major concern, all these factors pulled the design in its own direction, causing many conflicting goals. The result comes from juggling many requirements, which are strongly at odds by their very nature.

Beyond the need for high reliability and built in safety, the first constraint to be met is size. The actuator must fit in

the pump. It has to fit in a small space in a small pump inside the human body. The requirements initially given by Infusaid demanded dimensions less than or equal to 1.0" by 0.4" by 0.7". Such a small package eliminates many common possibilties. Another demand was the need for antiseptic isolation of the insulin. The valve seating area and the metal isolating it from the environment were to be titanium and a few special plastics. Stainless steel and spring steel could not be used, as the insulin caused corrosion, and the steel caused the insulin to clot on its surface.

Further complicating the situation beyond the previous problems was the problem of energy dynamics. This problem can be stated in the following manner. Could the mechanisms have enough force to pull the valves open in a reasonable time [power requirement], and still not use too much energy? This question on dynamic performance proved most difficult. Energy was a limiting factor. A tiny battery had to power the valves, without any chance of failure for the expected lifetime of the pump, 5 years. Five years of activation comes to almost five million activations. Thus the energy allowed is quite small, $3*10^{-3}$ joules per activation. The magnitude can be appreciated when one considers a small household lightbulb of 30 watts. Such a bulb uses 30 joules per second. The bulb burns ten thousand activations worth of energy in just one second. This strict requirement was further constrained by the form of the energy delivery. High voltage is not available, and the battery provides 3.6 volts of electricity. This can be considered as an

almost pure voltage source. However, it can be doubled by a capacitive circuit to 7.2 volts, which is the design goal.

5.5 DESIGN APPROACH

This section leads into the next section, VI - Design, and the proposed solution to the problem. A quick overview of the problem seems in order. Foremost, this project on valve design is not the creation of a whole new drug delivery system. Rather, it is a small part of a larger problem. In this and previous sections, the problem has been further defined. A fail safe valve actuation system needs to be produced to fit specific criteria.

The present prototype method uses two valves linked electronically. Figure 5-5A shows this and the potential dangers. In Figure 5-5B, a schematic of the proposed solution is shown. Rather than have two separate actuators electronically linked, a single mechanical method of opening the valves is sought. The design philosophy was to find a way of mechanically linking the valves such that only one valve would open at a time, under any circumstances.

VI DESIGN OF VALVE ACTUATION SYSTEM

Introduction

As stated earlier, the goal of our valve design is to increase reliability and eliminate or reduce the chance of catastrophic failure. A single mechanical actuator operating both valves is proposed to meet the design criteria.

Before describing the design further, several terms and conditions should be defined. Failsafe is the first such term. By the term fail safe, it is meant that should a mishap occur to the system, the system would shut down in a safe manner. In this particular case, if the actuator malfunctions, flow of insulin would stop. This is exactly opposite of the present situation, where a malfunction will cause an open passageway and a large release of insulin. The second concept in need of definition is three way. In this particular context, three-way implies that the valve operates in the following manner:

* Both valves closed - No flow
* Inlet valve open, outlet valve closed - Accumulator fills
* Outlet valve open, inlet valve closed - Accumulator empties

These concepts are an integral part of the valve design.

A schematic of the overall valve design is shown in Figure 6-1. Shown here are the two valves, with a solenoid activated mechanical linkage operating the valves. The details of the design are presented in the following subsections. It should be noted that the system was not designed as a collection of

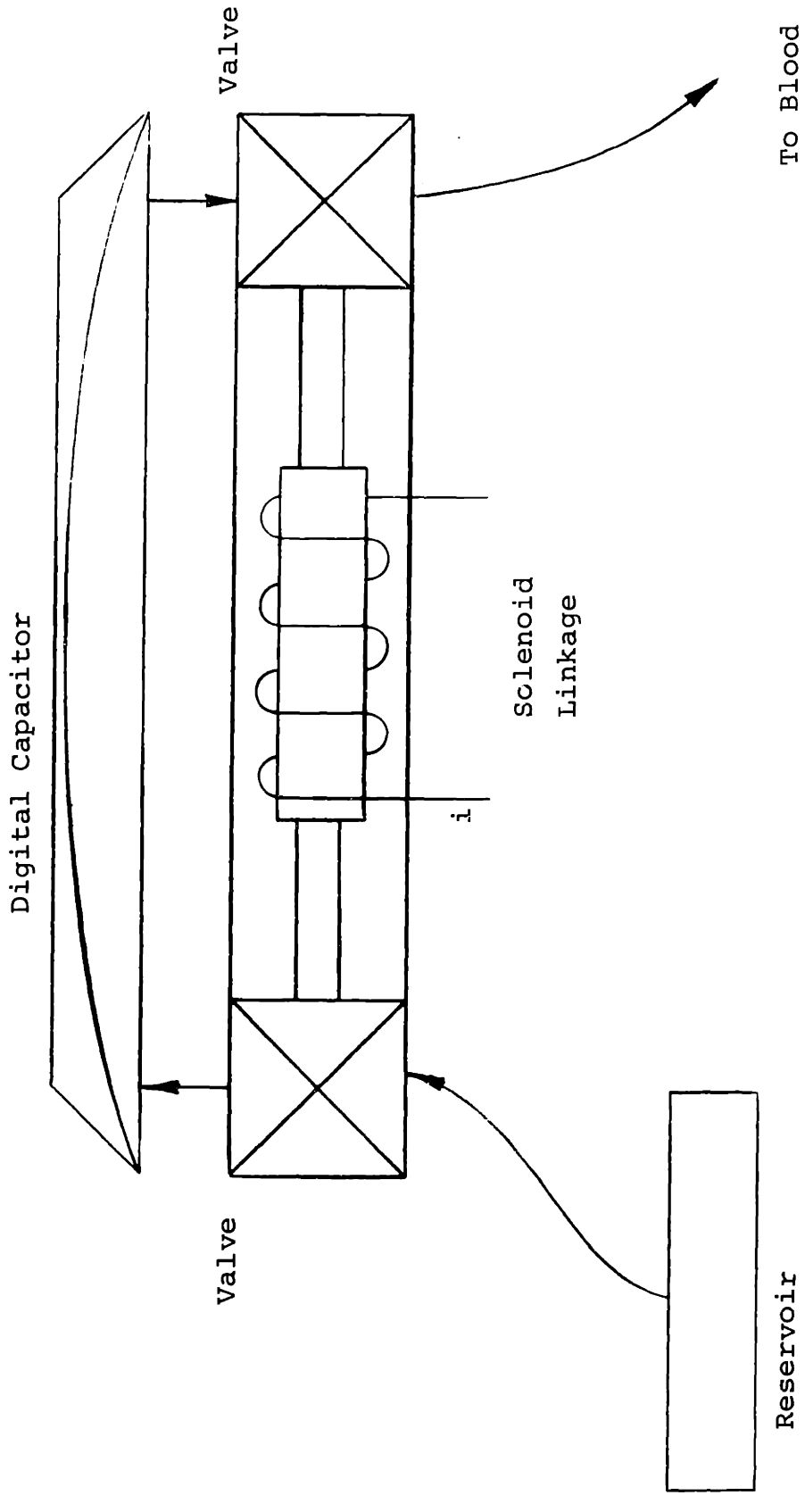


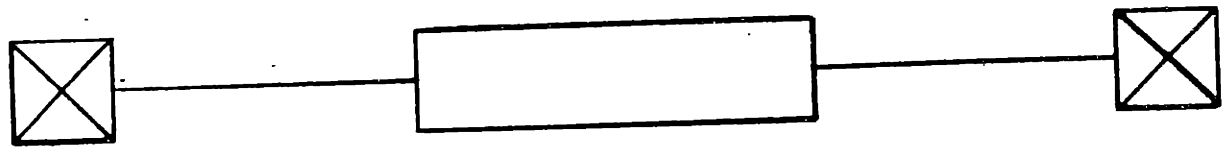
Figure 6-1 System Schematic

piecemeal parts. Rather, it was designed to fit well within the concept of safety, meet all the physical constraints, and fulfill the energy requirements. Also, the actual path taken to the design is not totally shown here, as many wrong turns were taken. What is presented are the key features of the project, put forth so as to explain the design, rather than describe the route taken to get there.

6.1 Schematic of Mechanism Operation

In this section, the method of valve operation is discussed. The valves are plastic seals, both normally closed. The modes of activation are shown in Figure 6-2. As mentioned before, the actuator is a three-way mechanism. In Figure 6-2A the actuator is in the neutral position, and both valves are shut. Power is off. To open the valves, the actuator must move away from the particular valve to be opened. A pulling motion by the actuator opens the valve. This is shown in Figure 6-2B. It is very important to note that when the right valve is pulled open in 6-2B, the left valve is compressed and more sealing pressure is applied. The non-intended valve [left] is physically prevented from opening. Only one valve can be open at one time. In Figure 6-2C, the other valve is shown open with its partner pushed closed. The actuator cannot pull both valves open at the same time. Further subsections will give the mechanical details of the actuator.

A



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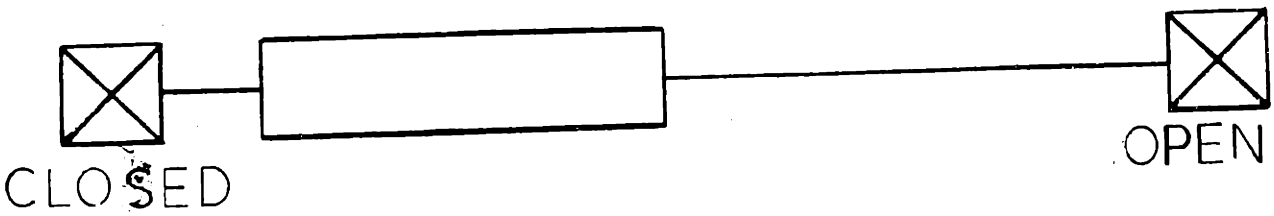

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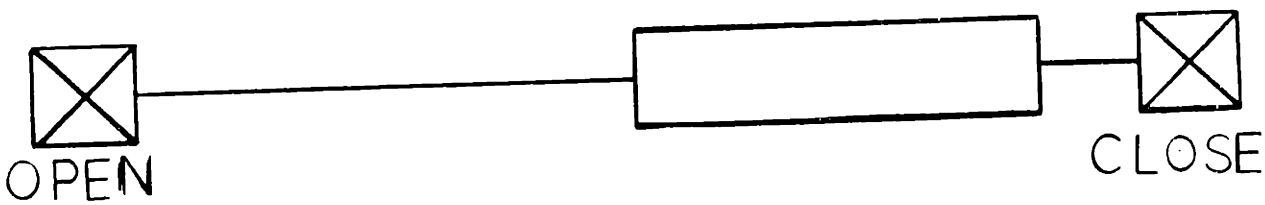


Figure 6-2 Seal Activation Modes

6.2 Valve Seat - "Castellated" Ring Stop

A vital part of the system is to impede improper flow of insulin. To accomplish this, two valves are used. The valve itself is constructed of titanium, and forms a 'needle' or thin cylinder, with a flat landing area. The inner diameter of the valve is 0.014" and the outer diameter at the tip is 0.020". The valve itself stays stationary, and a large compliant plastic seal moves to block the flow. The spring loaded seal provides enough pressure so as to shut off all flow, sealing the valve. So far this layout resembles the present setup, made by Wilson Greatbatch, which has been well tested. The seals do a good job of blocking the flow. However, a number of problems are encountered with the present design. The first is leakage and wear on the soft plastic seal due to creep fatigue and the high stress concentration formed by the valve tip. Due to the high pressure, the stationary valve bites further into the seal over time, causing permanent deformation and eventual cutting of the plastic. Thus the valve operates less efficiently, and may either so indent as to cause blockage, or slice the plastic which can cause leakage.

The second problem relates to and compounds the first. Due to the redesign, larger forces have been displaced into the seating valves, causing faster wear and even higher stress concentrations. Not only are these forces larger, they vary as well, increasing wear and tear on the seat. Previously, the load was limited to 7 grams on the valve seats. With the new design,

upwards of 50 grams can be applied to the seat.

To solve this problem of high stress, induced creep, and eventual seat displacement, a valve seat stop was designed. Called the "castellated" ring valve stop, it both lowers stress on the plastic, as well as physically limiting motion of creep. It is set at the back end of the desired travel of the valve. Once the plastic valve seat reaches the stop, it no longer can move forward, thus preventing creep. Also, due to the large area of the castellated ring, the loading pressures per area are markedly reduced. Thus the driving force behind creep is further reduced, and higher forces can be handled with lower stress levels.

Figure 6-3 shows a cross section of the castellated ring stop, the needle tip nozzle and the moving plastic seal. The nozzle remains fixed, and the castellated ring stop is pressed or welded onto a shoulder of the valve seat. The two form one unit, which remains stationary. The plastic valve seat, however, moves on a sealed spring known as a bellows. The valve seat moves with the bellows. In the normal position the seat rests against the nozzle. The plastic yields elastically, and forms a good seal against the nozzle tip. In the first generation valves, the plastic would further move forward over the seat, and deform even more. It is this extra displacement which the stop prevents. The castellated ring provides a physical barrier to the excess advancement of the plastic seat. Also, due to the larger area, the pressures on the seat are much lower, reducing creep.

To give a better three-dimensional view of the geometry of

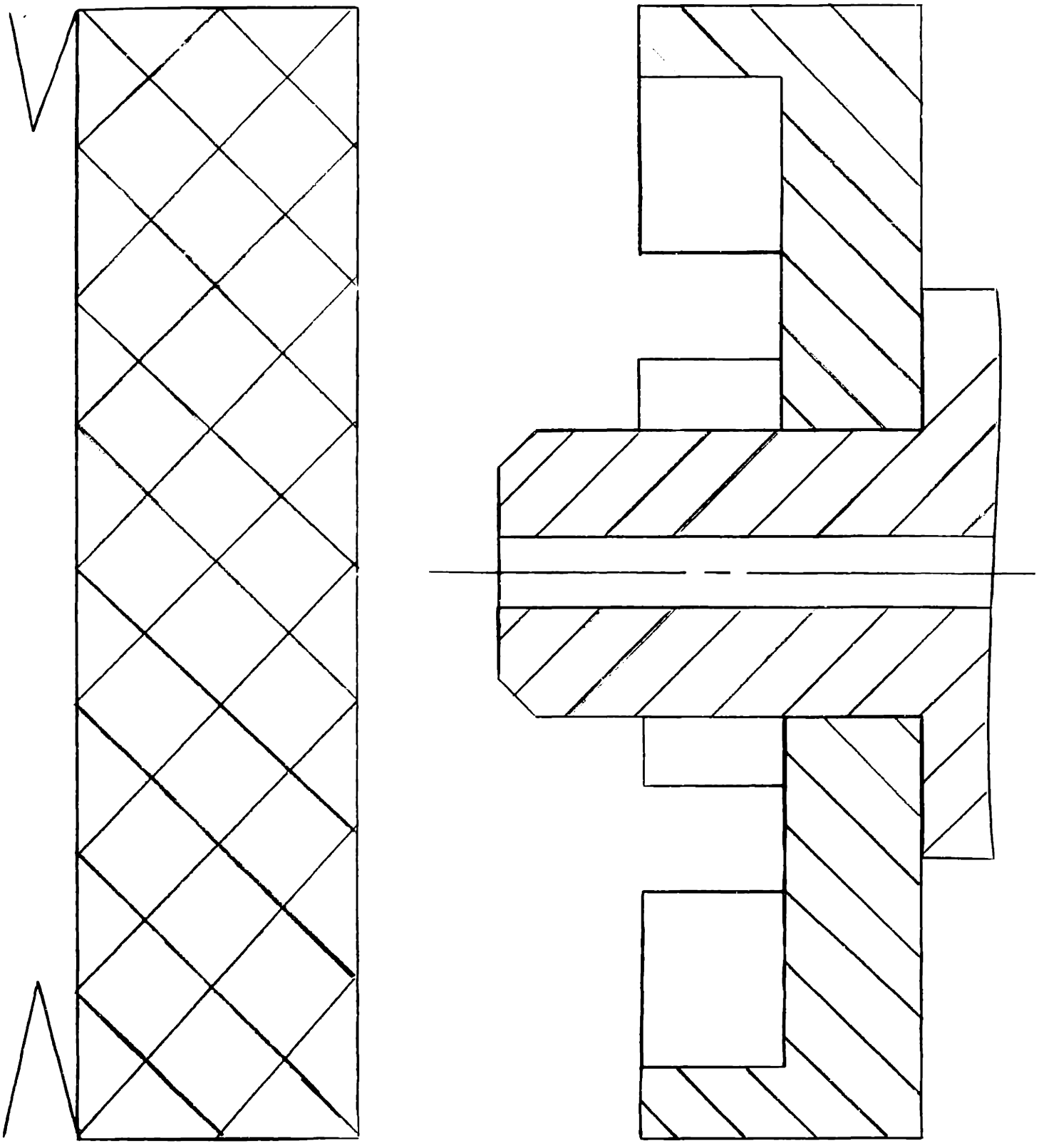


Figure 6-3 Castellated Ring
Cross Section

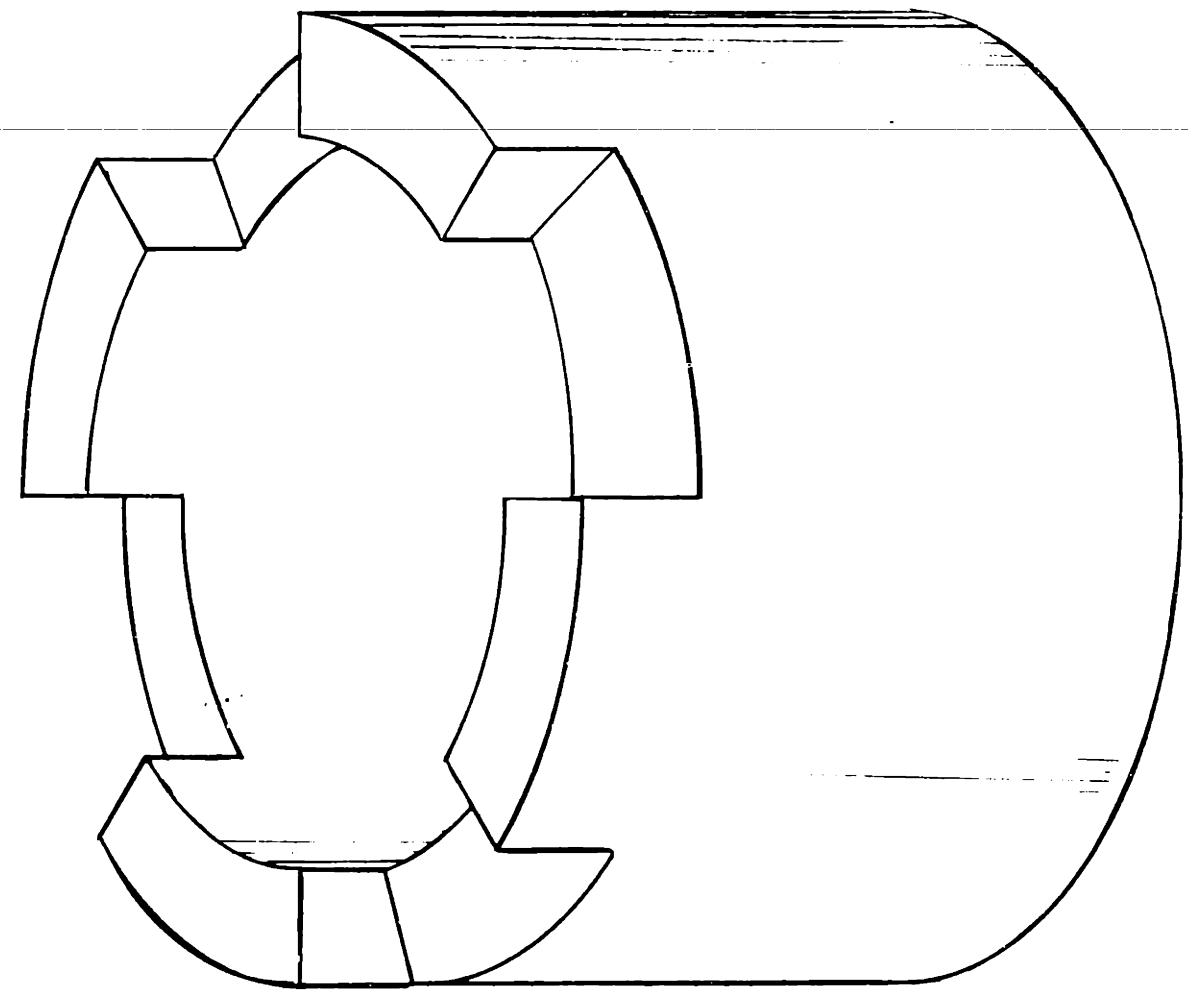


Figure 6-4 Castellated Ring

Isometric

the castellated seat, Figure 6-4 provides an isometric sketch of the castellated ring. Several design features become clearer from the isometric sketch. There are large numbers of open flow areas next to upright, teethlike sections. Due to the geometry looking similar to that of a Norman castle, it was called the castellated ring stop. Large openings provide for free flow of insulin into the nozzle area. A flat shoulder, set 0.001" behind the nozzle tip was originally considered, but rejected due to its large restriction area. Flow would be severely slowed, and the boundary layer effects would have detrimental, non-linear effects on the flow of insulin.

The second major feature is the large size compared to the small nozzle tip size. By suddenly increasing the contact area at the desired depth of nozzle penetration, the system will behave much differently. The stiffness will increase dramatically at the point of contact with the castellated stop. This can be shown in the following equation, Equation 6-1.

Eq. 6-1

A $F = K X$ (Hookes Law)

B $F = P A$

C $pA = K X$

D $\frac{P \cdot A}{X} = K$

E $\frac{K_2}{K_1} = \frac{A_2}{A_1}$

It follows that the spring rate goes as the area. The larger the area, the larger the spring rate, K.

This dependence of spring rate on area is graphically illustrated in Figure 6-5. The sketch shows spring rate before and after the contact with the valve seat stop. This is based on the theoretical calculation of differential areas and corresponding spring rates. A number of underlying assumptions are needed form this model to be accurate. It is assumed that the whole plastic to metal interface acts as a linear spring. This seems a reasonable assumption for small deflections [< 0.001"] and small forces of less than 75 grams.

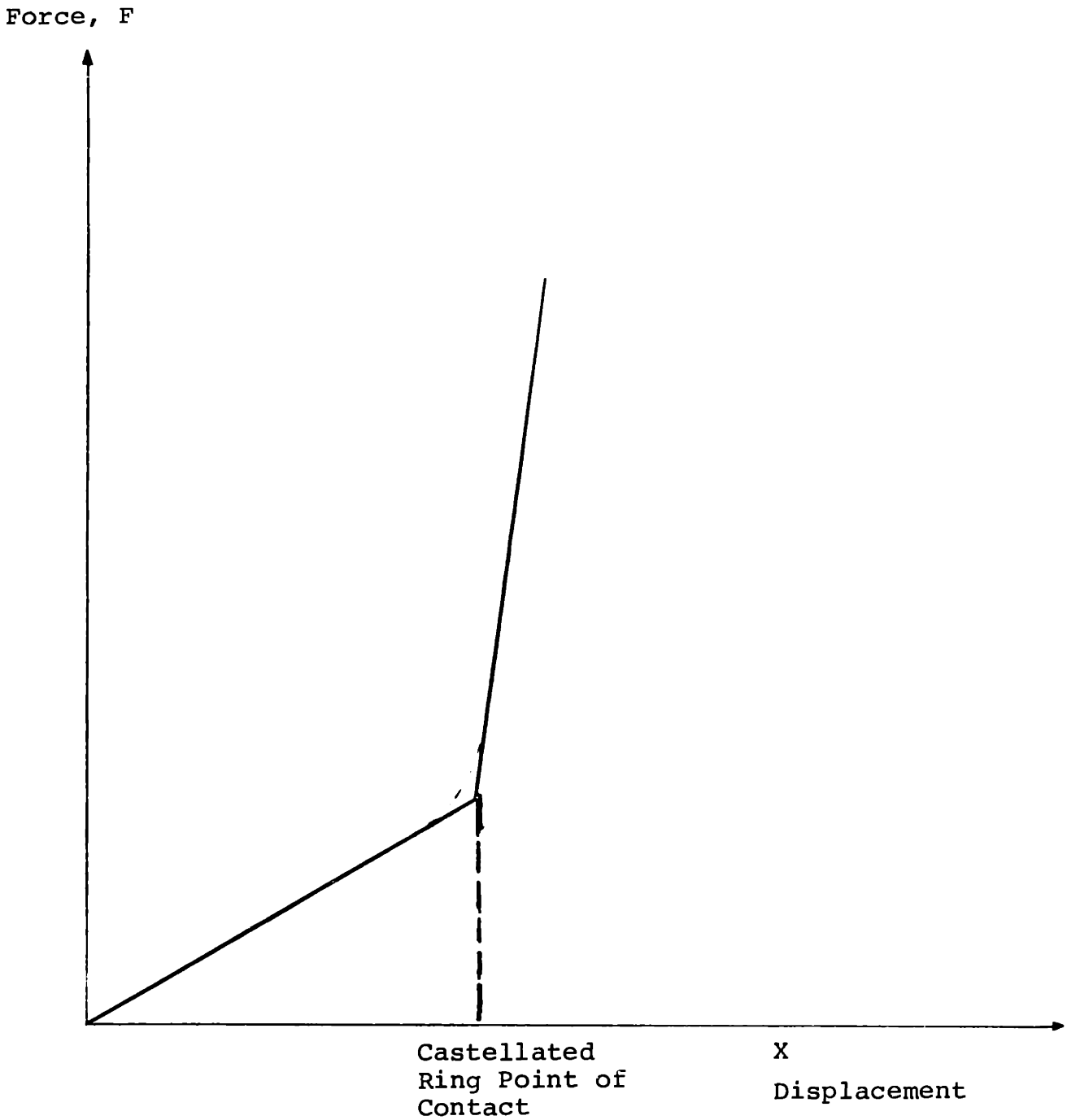


Figure 6-5

Spring Rates

6.3 BELLOWS WITHIN BELLOWS

In the last section, it was stated that the plastic valve seat was activated by a moving spring. This spring serves both as a linear elastic element [F=kx] and as a flexible seal. These spring seals are known as bellows, and form an important part of the design. Bellows consist of series of convolutions of metal joined together. They can flex in either a rotational or linear direction, though linear is usually preferred. Bellows are manufactured by a number of means, including welding, chemical deposition and electrical deposition. In the earlier sections, it was mentioned that a large bellows forms the main drive element of the pump itself. In section 6.2, the plastic seat was mentioned as being connected to a movable bellows.

Several important factors went into the design of the bellows sealing linkage mechanism. Going back to the problem of the body and its environment, one realizes that the body does not remain static, but is dynamic, and subject to variation. Thus a range of values can be expected for most parameters of interest including blood pressure and insulin delivery need. The body delivery side has a range of 10-15 psi in absolute units. This is the pressure at the site of drug delivery, at the catheter. On the other end of the actuator, the values range from 21 to 27 psi absolute. These values are acted upon by a number of forces, including the need to keep the flow at a proper rate in the proper direction. Altitude, flying, age, and personal variables all spread the range of the numbers.

Also, the seals are marked as bellows at the interface. It is these bellows which do the actual linking of valve to actuator and thus move the seals for proper flow. Due to the pressures involved, a certain amount of force is going to be generated along the seal, in the direction of the pressure gradient.

Besides the considerations of movement with pressure, the problem of sealing and materials arose. As discussed before, the two sealed sections can only be of titanium, small amounts of stainless steel and certain polymers. This is due to the need for absolute non-corrosiveness and non-reactivity in a sterile insulin environment. Besides the attack of insulin on the materials, there is the question of the materials effect on the insulin. Infusaid, among others, has noted a problem of coagulation of insulin in certain mechanisms. Part of the problem seems to be the material and nature of its surface. Titanium has been shown to be one of the few materials practically free from the effect, and was determined to be the best material for the seal from that standpoint.

The structural seal areas such as the walls, the bellows which connects to the plastic seat are constructed of titanium. Besides the primary biological constraints, titanium can be used because it can be easily formed. Other inert materials were considered for the sealing bellows, such as gold or platinum. However, due to the problems of joining two dissimilar metals in a corrossive environment. Titanium also has a much better high and low cycle fatigue strength, an important factor when the pump is designed to operate five million times over an expected

lifetime of five years.

Bellows Within Bellows

A cross section of the seating section is shown at the end of section six. Shown are the valve, castellated stop, flow path and the plastic sealing pad. Also included are the mechanism areas and the theoretical isolation areas. Separating and connecting the areas are two bellows, the bellows-within-a-bellows linkage and sealing mechanism.

This particular concept evolved for a number of reasons. The present, first generation valve uses springs rather than bellows for moving the plastic seal. However, the first design allows no mechanical linkage, only an electromagnetic connection. Thus for a direct mechanical connection, a flexible seal was needed. As bellows technology is commercially available and well tested, bellows provide an excellent solution

The first, large bellows is welded out of titanium, and serves as the seal to keep the necessary areas isolated. It also serves as the location and spring for the plastic seal. The second bellows is constructed out of nickle, and has no direct physical contact with the fluid. The second bellows connects to the first via an incompressible hydraulic fluid. The two bellows form a hydraulic lift such that the forces applied to the linkage are multiplied by the area ratio. Therefore larger forces can be generated at the large spring site, and the seal seats better. This is derived in the following equations, Equation 6-1.

$P_L = P_S$ [incompressible]

$$\frac{F_L}{A_L} = \frac{F_S}{A_S}$$

$$\therefore F_L = \left[\frac{A_L}{A_S}\right] F_S$$

↳ mechanical advantage ≈ 10

The bellows system was designed for the worst case mode of operation. The most extreme conditions, least favorable to operation, were used as operating conditions. The bellows was then designed to then meet these specifications. Besides meeting the applied design constraints, the bellows system was designed to use the minimum force at the site where energy would be put in, the solenoid area. Low forces would allow a smaller solenoid, saving energy and space. The second bellows, small and nickle, serves to multiply the applied forces to a useful range at the large bellows.

Safety and freedom from accidental release of insulin were

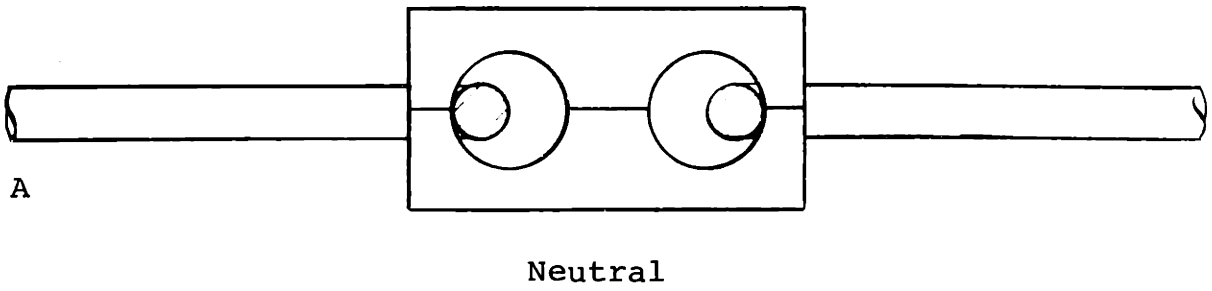
primary concerns. The whole seal-linkage is designed so that at the worst pressure situation [27 psi, load chamber] the bellows is shut. As the pressure becomes smaller, the preset spring forces apply even more force to close the seat, sealing it tighter. The extra force is then absorbed by the castellated ring stop.

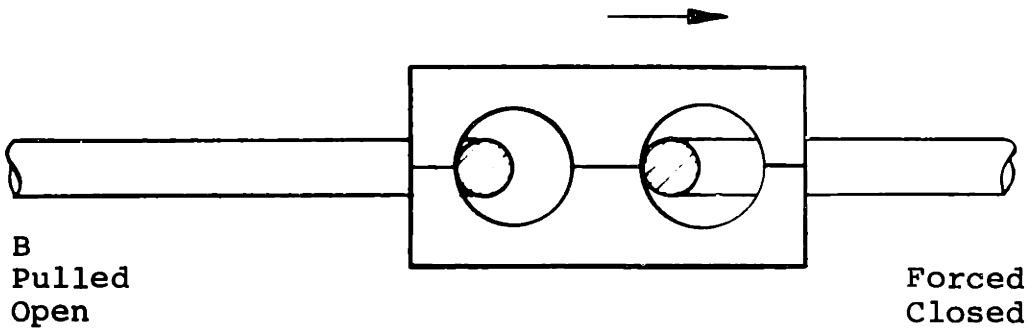
Several design features are important. The mechanical linking rod shown is an integral part of the small nickle bellows. Formed by electroplating nickle to aluminum and then dissolving the aluminum, the bellows is commercially available from Servometer Corporation in the proper specifications. It can be brazed to the back of the titanium, provided the titanium is coated with a special ceramic metal interface. The problem of corrosion of dissimilar metal provides no threat in a dry environment, and all the technology is commercially available.

6.4 LINKAGE MECHANISM

The last section showed how the valve seats were connected to the interior of the mechanism. In this section, the connections between the linkages and actuators will be presented.

In the interior of the mechanism, a force actuator is desired to pull one valve open and force the other shut, preventing any mishaps. Such a three way linkage is shown in Figures 6-6 and 6-7. Figure 6-7 gives an isometric view of the geometry of the linkage, while 6-6 gives the sequences of operation.





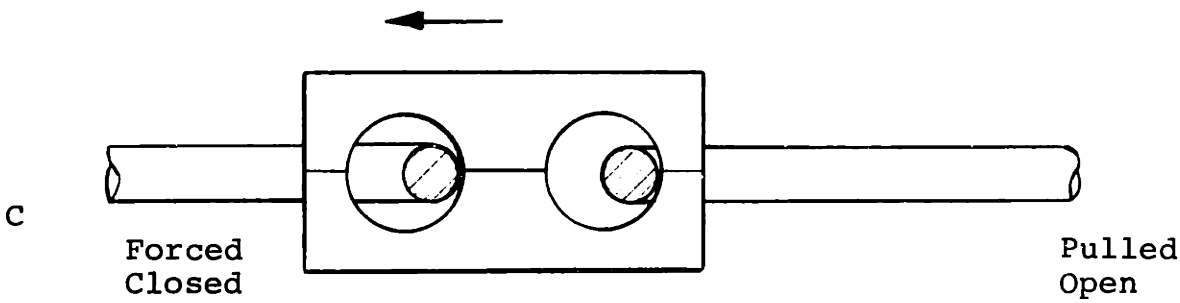


Figure 6-6 Linkage Operation Schematic

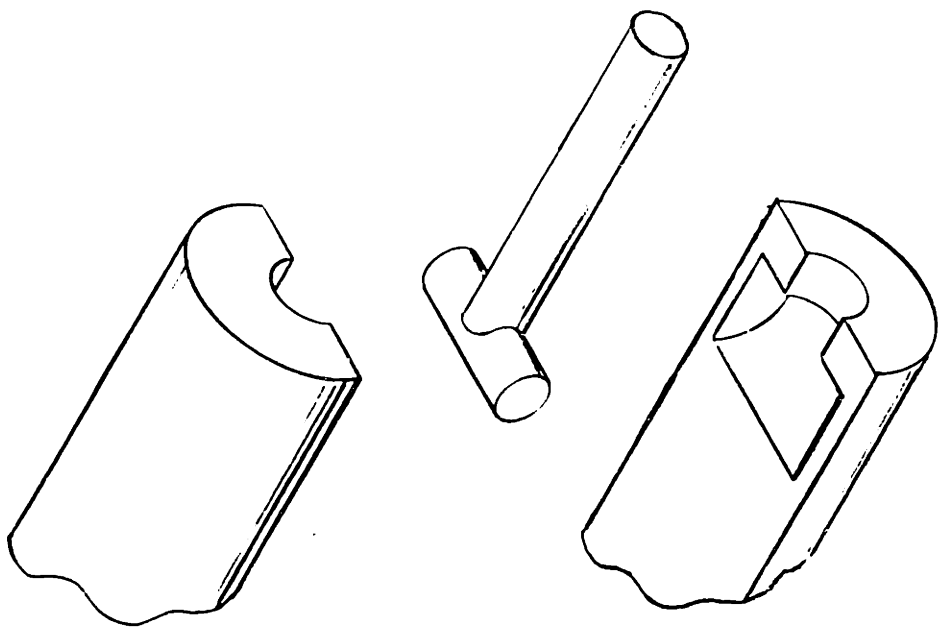


Figure 6-7 Linkage Isometric

In Figure 6-6B, the two rods connected to the bellows are shown. Connecting them will be a precision connector, which is drawn just prior to assembly. A number of materials could be used but most probably titanium, since it will not be affected one way or another by the solenoid magnetic field.

In Figure 6-6, the three way nature of the linkage is shown. Neutral, with both valves closed, and no flow, is shown in 6-6A. The inlet valve is open, and the outlet valve closed, in 6-6B. This corresponds to the accumulator filling. The outflow condition is shown in 6-6C. Here the inlet valve is closed, while the outlet valve is open. It should carefully be noted that the design is intended to have the opening of one valve force the shutting of the second.

Connected to the linkage will be the armature of the solenoid. However, it was not drawn in, and will be shown in the following sections.

6.5 Solenoid Magnet Actuation

Shown in the last section was the linkage mechanism opening the seating valves. It was assumed in the design of the linkage that there would be a means of providing a linear force in either direction. To provide the needed amounts of force from an electrical source, a solenoid was chosen. The configuration of the solenoid allows it to fit the physical constraints such as length and width, the force requirement opening the correct valve, and still meet the energy constraint on the voltage provided.

Due to the very strict energy requirements, a bistable, or two position, valve was originally considered. Bistable means that the system is at rest only at two end conditions. Everywhere else it is unstable. In this particular situation, bistable implies that a small amount of energy would switch the valve one way, say for example, closed. The valve would remain in that state, closed, until a small impact activates it to the other state, open. This bistable valve had several problems which caused its elimination. First, the intermediate time of transition in any mechanical system requires a finite timespan, though small. Such an intermediate open time was considered unacceptable, due to the insulin flowing during that time. The effect would have been cumulative, non-linear and very hard to measure and control. The second reason for rejection was that the constant open position would have been little better than the present situation. Namely, if one valve stuck open and the other opened even temporarily, there would be an unacceptable insulin free flow. The only advantage would be small, efficient energy bursts, requiring no holding open time. Energy would have been saved.

A failsafe concept was next considered after bistability. Besides having the linear mechanical linkage with its built in levels of safety, it was decided that the electrical system would operate in a similar manner. Such an electrical mechanism would provide force only as long as the input voltage was maintained. When the voltage was no longer applied, the mechanism would

provide no more force, and thus the valves would go back to the neutral position. Flow would cease. The only problem is that such a system uses power continuously while holding the valve open. If it was not efficient enough, the energy constraint would be violated.

The first idea for providing linear motion through electric power was to use a solenoid. Solenoids consist of a series of coils of wire wrapped in a cylindrical pattern. These wires generate a magnetic field when a voltage induced current is applied to the wire. Placed into this cylindrical center is the armature. Responding to the magnetic field of the coil, the armature becomes magnetized and responds to the magnetic field by moving into the field. This movement of the armature is what actuates the linkage. A more detailed treatment will be given below.

The most important feature of the solenoid relates to the direction of motion of the armature. In a normal solenoid, the armature consists of a rod of the nonmagnetized but highly magnetizable ferromagnetic substance. Common armatures include soft iron, various steels, and exotic alloys such as mu-metal. These materials respond to the solenoid by being attracted to the center of the solenoid, where the magnetic field is the strongest. Since the magnetic field stops when the power is disconnected, the armature no longer has any force on it, and remains stationary. Thus a standard solenoid operates as a one way mechanism and can only pull the armature into the coil. Since the solenoid operates as a one way device, modifications

must be made to allow two way operation. To overcome this, a two coil, one armature arrangement was considered. The armature would be connected to the linear linkages described in the last section. There would be two separate coils wrapped around the armature, each one extending to the midpoint of the armature. When one of the solenoids was activated, the coil would then pull the armature into the center, opening one of the valves and forcing shut another. When the power was disconnected no force would act on the solenoid and then the spring forces on the valve would seal the seat, pulling the armature to the neutral center position. When it was desired to open the other valve, the second coil would be activated and the armature would move in the opposite direction. By using an electrical circuit to alternate which coil had power, true two way motion would be achieved.

This two way motion of the solenoid, accompanied by the neutral center position, allowed the valve to act in a three way manner. Such a system would be failsafe for two reasons. First, the single armature itself could only be in one of two ends of its travel at the same time. It could not be pulled in both directions simultaneously. Only one of the two valves could be open at a time. The second safety feature built into the system was the power-off, no force condition. Since a loss-of-electrical-power mishap would result in no force on the activation, the system would shut itself off in case of a power failure or circuitry problems.

Two problems arose from that design, namely the overall size of the coils and the total amount of force capable of being

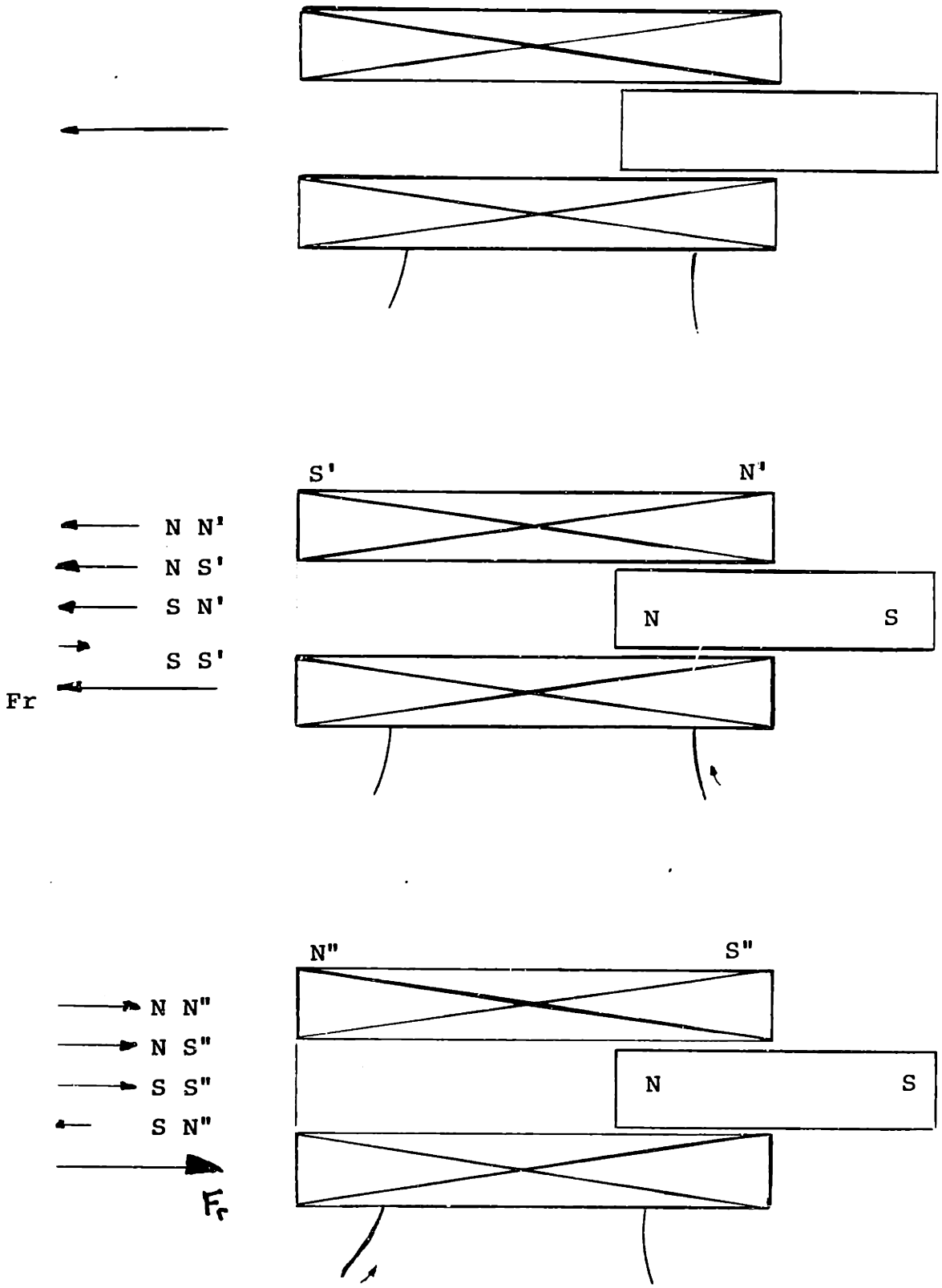


Figure 6-8 Solenoid Motion

generated. The size problem comes from the pump having to be implanted. A first approximation for coil size came from both calculations and an examination of the Wilson Greatbatch solenoid. The first rough estimation placed the coil with an outer diameter of a little less than half an inch, and length very near a half inch. Two such half inch long solenoids would alone fill up the space requirement given for the solenoid. Just as unnerving was the consideration that each solenoid would be sitting inert half the time , providing no real useful output for the system. The whole arrangement seemed too bulky and inefficient for use in such a tightly constrained package.

Force output proved to be just as limiting a boundary condition as the size requirement. To understand the generation of forces, and the problems associated with it, a mathematical discussion is given.

In figure 6-8A, a soft iron core armature is shown wrapped by a solenoid coil. A current [i] flows into the wires, generating a magnetic field similar to that produced by a permanent magnet. This magnetic field then induces a force on the non-magnetized core, pulling it towards the center. Equations 6-2 give the derivation:

6-2 (A) $B_o = \mu_o i n$

B_o = magnetic field strength
μ_o = constant
i = applied current
n = $\frac{\#\ \text{turns}}{\text{unit length}}$

(B) $B = B_o + B_m$

B = total Field Strength
B_o = coil field strength
B_m = magnetization field strength

(C) $F = \oint B \cdot d\ell = BL$ F = force generated

6.2 (D) $F = L[B_o + B_m]L$

(E) $F = L[\mu_o i A + B_m]$

Force, as described in Equation 6-2E, depends on a number of parameters, including length, number of turns per unit length [wrap density], the current supplied i, and especially the magnetization, Bm.

From equation 6-2D, the total magnetic field which then generates the force is broken up into two parts, Bo and Bm. The electrically induced field Bo, is generated by the solenoid. The solenoid's particular geometry, its current input and output, and wire wrapping efficiency, all come into play in determining Bo. Many of these parameters can be varied by the designer to good effect. This emphasis on solenoid induced magnetization results in changes in the produced magnetic field. Going back to Figure 6-8A, changes in Bo, would change the shape and density of the indicated magnetic field lines. The denser the lines, the more magnetic force is generated. Also, the lines must not only be dense, but they should be dense at the correct locations. Such channeling of the field increases efficiency.

Actual mechanical force capable of being put to good use,

derives from the motion of the armature. Combining equation 6-2D with Figure 6-8A, we see the force on the armature depends on both the generated field and magnetization Bm. This resultant force, Fr, is directed towards the center of the solenoid, and is the result of the armature being made of a ferromagnetic substance such as iron. When non-magnetized ferromagnetic substances such as iron are placed in a magnetic field, the magnetic field attracts them to the strongest portion of the field. In this case, it is the center of the solenoid to which the armature is attracted. It must be remembered that Bm is a materials property, depending on the nature of the substance chosen for the armature.

By looking at equation 6-2D, one sees that there are two ways of increasing solenoid force output. Solenoid geometry and parameters can be changed so that Bo is as large as possible. Or Bm can be made as large as possible. A conflict of routes arises. Even though the physical parameters used for solenoid alterations of Bo are more easily accessible to the engineer, there is a drawback to that approach. Bo is often much smaller than the materials effect, Bm [Bm >> Bo , Halliday & Resnick]. But materials available to the designer are limited in number, costly, and not under direct control of the engineer. They are taken as given.

The present design for the first generation of pump valves made by Wilson Greatbatch Corporation emphasizes improving the solenoid magnetic efficiency, Bo. Exact details of the design cannot be released due to the commercial nature of the work.

However, it can be said that various material and geometric modifications are used to channel the magnetic field most efficiently.

The first approximation of the present design using two solenoids, concerned itself with the basic use of a solenoid. One reason that it was inefficient was due to the lack of improvements on both the magnetization effect and the coil induced effect.

The second level of solenoid design is shown in Figures 6-8B and 6-8C Here, the two solenoid concept has been abandoned for a single solenoid with a permanent magnet armature. Using such a system results in controlled bidirectionality in a much more efficient way. First, the method of operation for controlled bidirectionality is described. Rather than looking at the solenoid as a source of magnet flux lines, it is treated as a temporarily existing dipole magnet, with properties similar to that of permanent magnet. Though a solenoid is both non-linear and full of edge effects, it can approximate a dipole [Halliday & Resnick]. This is illustrated in the diagram by N' and S' for 6-8B, and N'', S'' for 6-8C. By comparing 6-8C with 6-9B, one sees that the magnet's north to south orientation has been inverted. This is entirely controlled by the direction of the current going into the coil. By reversing current flow direction, one reverses the north to south orientation. Also included in Figures 6-8B and 6-8C is the permanent magnet armature. This armature consists of a very high strength samarium-cobalt permanent magnet. The permanent magnet is also

considered as a dipole for the discussion on directionality.

Looking at Figure 6-8A, one sees that a set of continuous effects was charged into four distinct poles, N', Samarium-Cobalt, N and S. By doing so, the presentation of directionality is clarified. However, such a presentation, though useful for conveying the idea, oversimplifies the situation. A more rigorous approach is given in Equation 6-3.

6-3 (A) $F = (\mathcal{M} \cdot \nabla)\vec{B}$

+X, +B directions to right
S to N is +B
$\mathcal{M}$ = bar magnetization

6-3 (B) $\mathcal{M} \cdot \nabla = +$

$B = +$

$F = (\mathcal{M} \cdot \nabla)(B) = (+)\cdot(+) = +$ direction $\rightarrow$

6-3 (C) $\mathcal{M} \cdot \nabla = -$ [magnet & field in opposite direction $\therefore -$]

$B = +$

$F = (\mathcal{M} \cdot \nabla)(B) = (-)(+) = -$ to left

Having an already oriented magnet with directional Uo, along with changeable B-field solenoid, one can get bidirectionality out of one solenoid. Therefore the packaging and space requirements have been taken care of, and one solenoid is eliminated. Efficiency is increased.

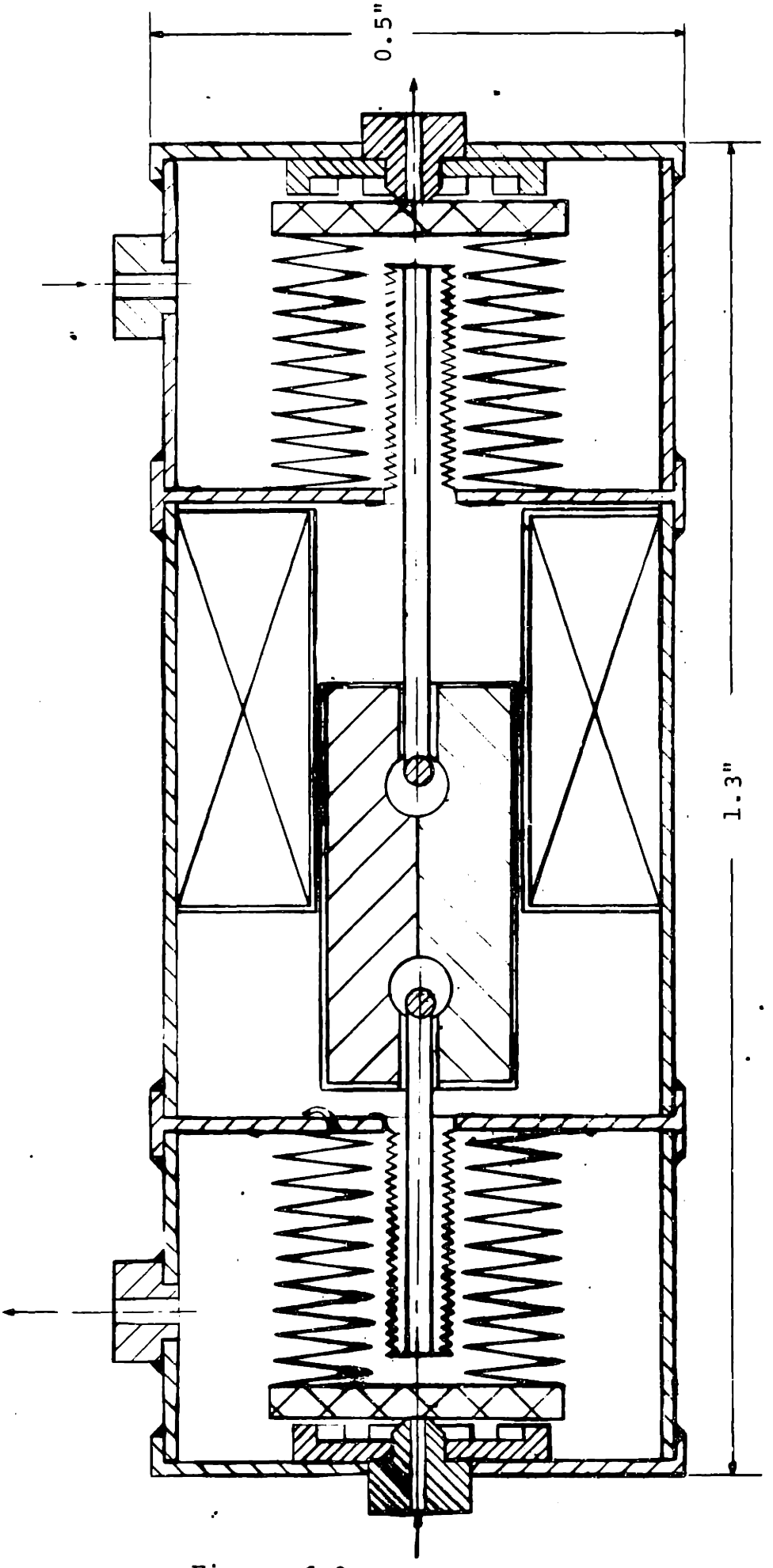


Figure 6-9 Actuator Cross Section

VII EXPERIMENT - SETUP AND PROCEDURE

7.1 Introduction

In the last section, the proposed design was described in some detail. In this section, several experiments are discussed to validate a number of points of interest. Each particular set of experiments had its own purpose, and that purpose is described just prior to the presentation of the procedure used.

The driving philosophy behind these tests was not to make a total prototype and analyze the results. Rather, each of the three types of experiments tests some important aspect of the design which would cause severe problems if it failed. Serious problems with the test section would have resulted in major redesign.

Testing concentrates on three prime areas of concern, and they are as follows:

* Force generated by magnetic armature,
* Comparison of force made by nonmagnetic armature,
* Endurance of magnetization.

However, before these sections are studied, there is a discussion the setup, which describes construction and arrangement of the testing apparatus. This setup is commonly used in much of the testing, and is thus described first.

7.2 Setup

The major parts of the solenoid studied were the armature and the coil for the solenoid. This is due to having little reliable information on the performance of this crucial part.

This section concentrates on the parts used. Such a discussion on hardware is broken into a number of subsections.

For the study to begin, the parts themselves had to be acquired or custom made. Of the solenoid pieces, only the samarium cobalt magnet was immediately available. The magnets come in a number of sizes and shapes, and are commercially available. A size and shape were chosen so as to match with the desired actuator specifications, with the magnet being 0.6" long and 0.2" wide. The particular magnet chosen has a strength of about 3 standard alnico magnets, but still stronger versions are available.

To match the magnet, two coil holding spools were machined of aluminum, due to the ease of machining and non magnetic properties of aluminum. Around these spools were wrapped two coils, with resistances of ~1000 ohms and ~340 ohms. The coils were both 0.6" long and a little over half an inch wide. The wire for the coils determined the resistance, with the 340 ohm coil using wire six one-thousandths of an inch thick [0.006"]. Two thousand five hundred turns were used for the 340 ohm coil. The other coil had 2500 turns of 0.003" diameter copper wire, giving a resistance of 1000 ohms.

Wrapping the spools was accomplished via a jewler's lathe connected to a potentiometer controlled variable power source. This source allowed the speed of the wrapping to be carefully monitored. Along with the speed of the wrapping, the tension on the wire was maintained via a network of linkages and sponges, so as to be as uniform as possible. Thin copper wire wrapped the

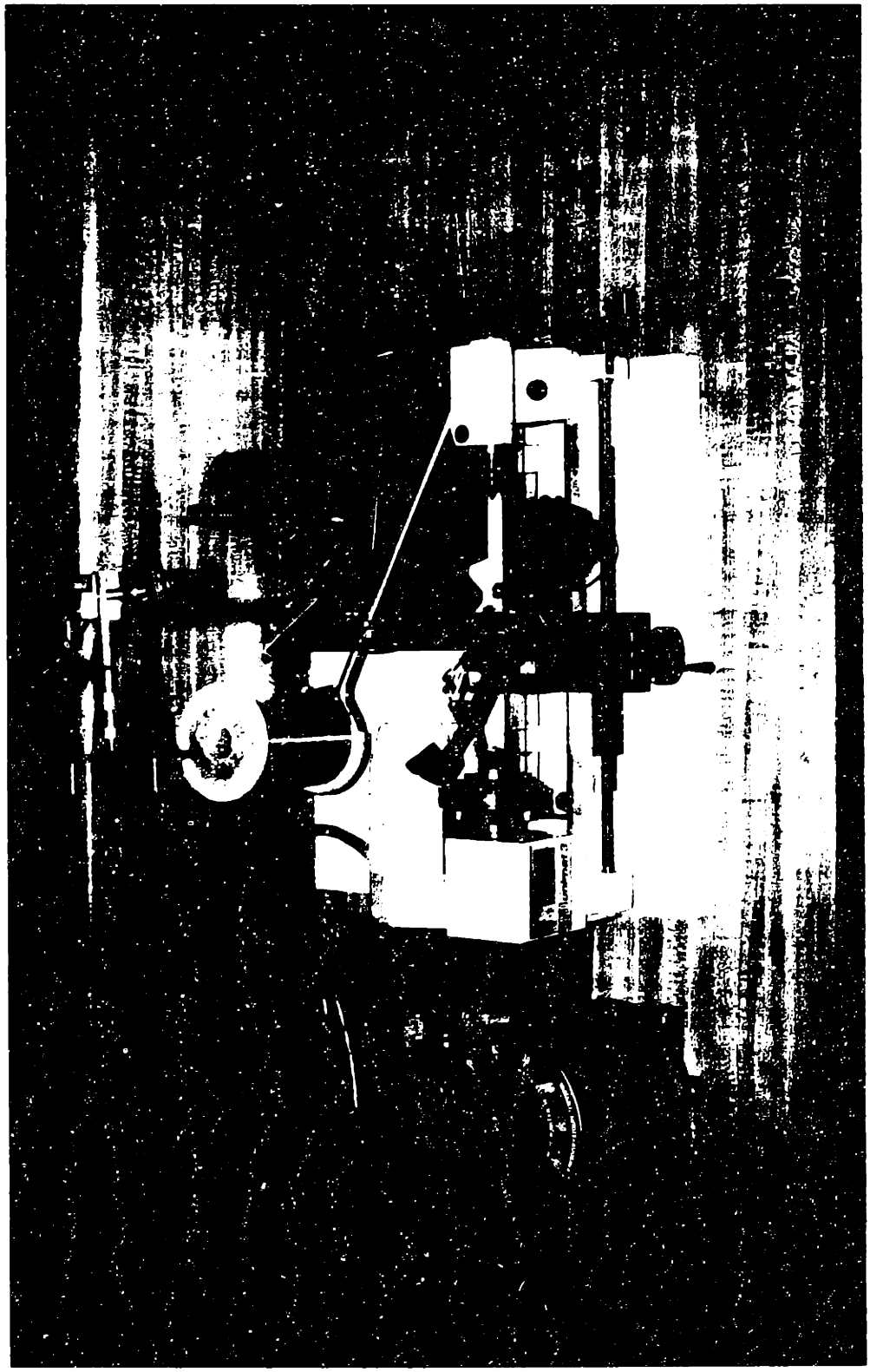


Figure 7-1 Wrapping Setup

coils with the number of turns being counted on a digital recorder. This whole wrapping setup is shown in Figure 7-1, a photograph. Right at the very center of the jaws is the aluminum coil, about to be rotated.

A separate picture of the coil and the armature are shown in Figure 7-2. alongside the coil are the teeth of the XYZ holder. This mechanism holds the coil securely, with very precise allowances for motion only in the z direction. A plastic dish, less than an inch thick, is used as a rest for the magnet, as well as an insulator, to keep the magnet away from the metal in the scale.

Data acquisition was carried out by a number of devices. First, a scale was used to record forces generated. Digitally operated, very easy to control, the scale would zero with the plastic dish, and then read forces in both the positive and negative directions. Powering the coil was a regulated DC power supply, which operated in the 0--~8 volt for our test. To measure both the resistances of the coils, as well as the real voltage output, a digital multiprobe was used during the test.

Holding the coil over the magnet was the specialized XYZ table, which was set up so as to allow motion only in the Z axis. The device allowed smooth motion of the armature within the coil. The complete setup is shown in Figure 7-3.

7.3 Force vs. Voltage, Magnetic Armature

Actual force derived from the armature depends on a large number of factors, including voltage, current, the number of windings and many other parameters. However, direct calculations

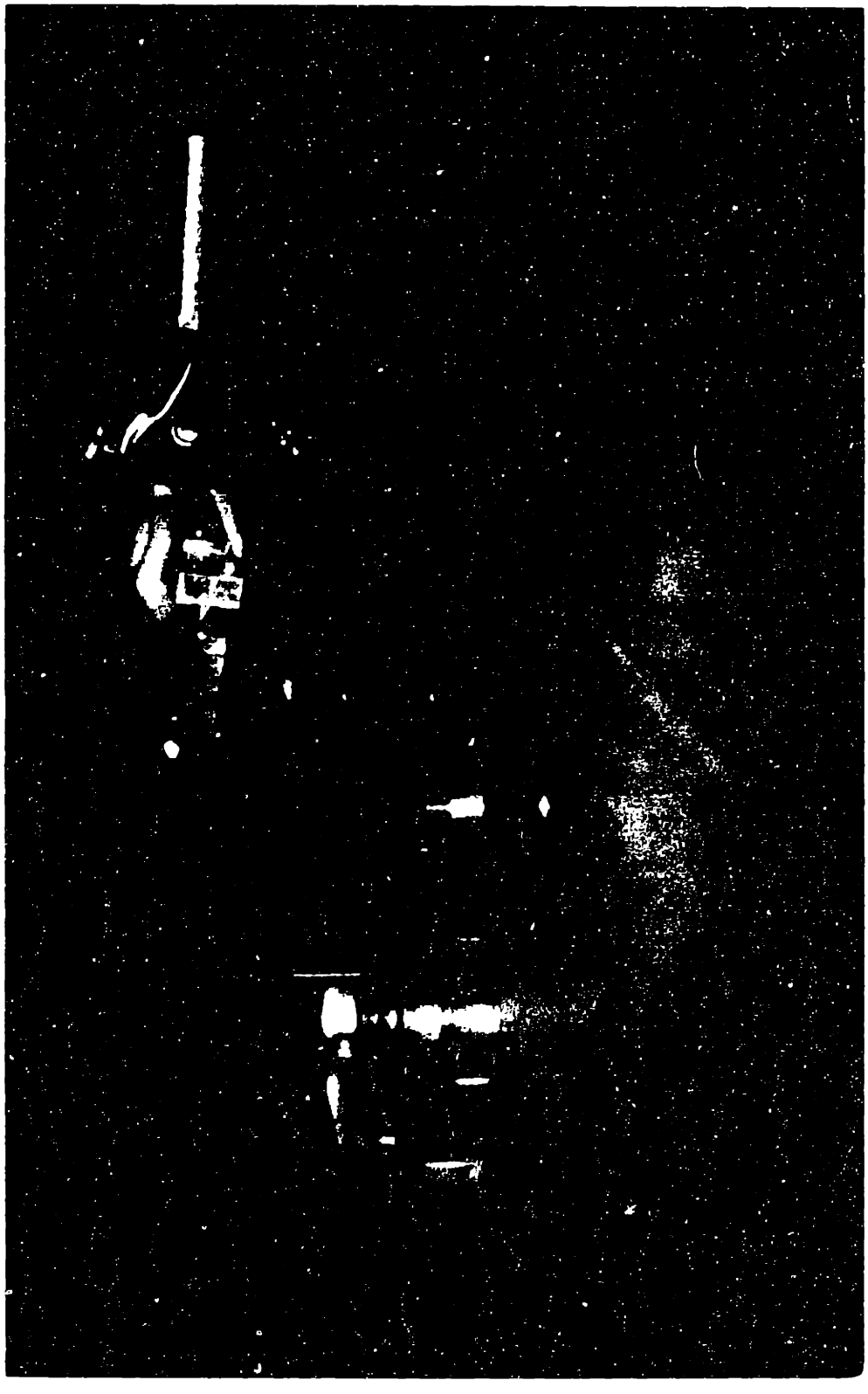


Figure 7-2 Armature, Coil, XYZ Arm

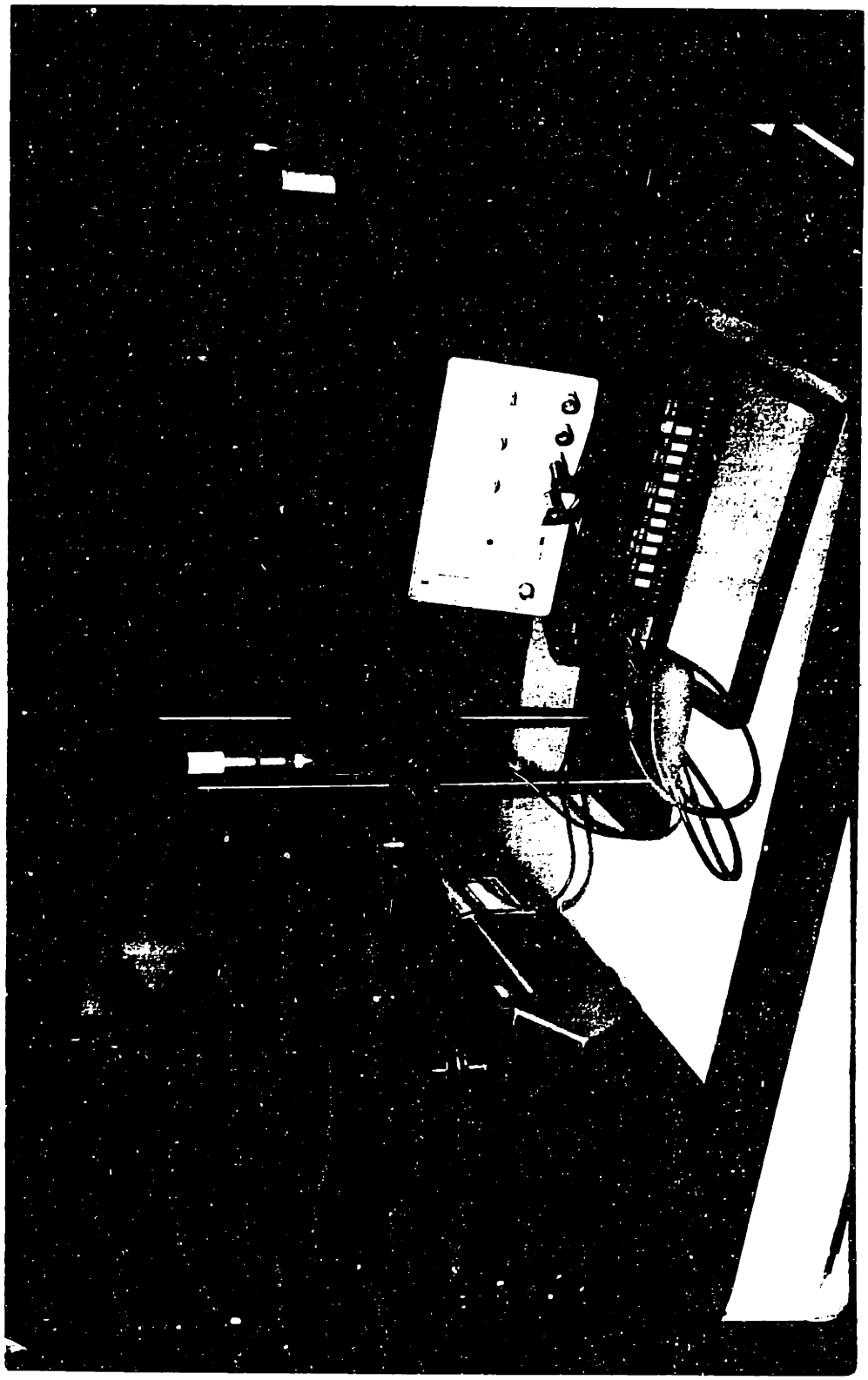


Figure 7-3 Experimental Setup

on the power generated from a permanent magnet armature were difficult to locate, and proved unpromising. Therefore the actual power and force specified by the design were not readily available from calculations, and far from concrete. It was this lack of good calculations which prompted an investigation of the forces generated.

Beyond the lack of well established equations, an even larger factor came into play. In the last section, on design, the arrangements of the actuator were given. To open the valves would require a force of ~14-15 grams, given the worst possible conditions. The 7.2 volt doubling circuit would be used. Wilson Greatbatch Corporation, the makers of the present actuator, generate 7 grams of force with 7.2 volts. Much of the design depended upon the actuator generating a force of 14 grams, which would open the valves.

Procedure

To test the capacity of the magnet, the coil was hooked into the arm of the XYZ table. Connected to the coil was both the digital multimeter in voltage reading format, as well as the DC power source. At any given time, the position of the coil as well as the voltage supplied were under experimental control. The magnet was glued to the insulating plastic base, and the pair was placed on the digital scale, which was then zeroed. Following the zeroing, the coil would be placed just over the magnet, with none of the magnet inserted. This was zero position, and no current flowed.

Distance was increased at 0.10" increments until the magnet

was entirely within the coil. At each increment, the voltage was varied at one volt increments, both positive and negative. Also the voltage was allowed to go as high as the sources range would allow, usually less than 8 volts. The distance went from 0.0" to 0.6", the magnets length. Voltages were changed in sign to test the true bipolar motion of the armature.

Various combinations of arrangements were made. The two coils with different resistances and wire diameters were used. Also, two different diameters of magnets were used, so as to test the volume and width effects of the magnet. Length on the small diameter magnet depended upon the number of segments used, so the length was varied as well. These varied results are shown in section VIII, Results.

7.4 Nonmagnetized Comparison

Our theoretical considerations led us to believe a magnetic armature would generate more force than a non magnetic armature. To check this experimentally, a slug of mild steel, approximately in the 1080 range, was machined. It was made in the same dimensions as the small diameter magnet, and compared by using the exact same procedure to generate force output. This test served more as a check on magnet efficiency and our ideas, rather than an independent study.

7.5 Endurance Test

Many times an alnico magnet will eventually lose its magnetization after a long exposure to an externally applied field. Such a loss of magnetization in our design would render it useless, as the magnetization force Bm generates much of the

force to open the valves. Samarium Cobalt magnets are less well studied than alnico magnets, and especially with regards to demagnetization. It was felt that a test was necessary. A samarium cobalt magnet was checked for force before the test, and the 340 ohm coil was used. The magnet was placed fully within the coil, and a square wave alternating between 0 and 6 volts was applied at a frequency of 10 hertz. This was carried out over the span of 36 hours, and gave 2.4 million cycles. This is almost half of the life of a pump, which is expected to the last 5 years and actuate 5 million times. After the high cycle fatiguing, the magnet was placed in the same setup, and was tested for for force. The results are compared in section VIII, Results.

VIII EXPERIMENTAL RESULTS

Generating the force to activate the system's valves was considered the greatest unknown in the design. To gather the appropriate force, three types of tests were performed, and their setups and procedures were discussed in the last section. In this section, the results from those tests are presented in graphical form, as well as a short comment on the running of the tests. The types of tests are:

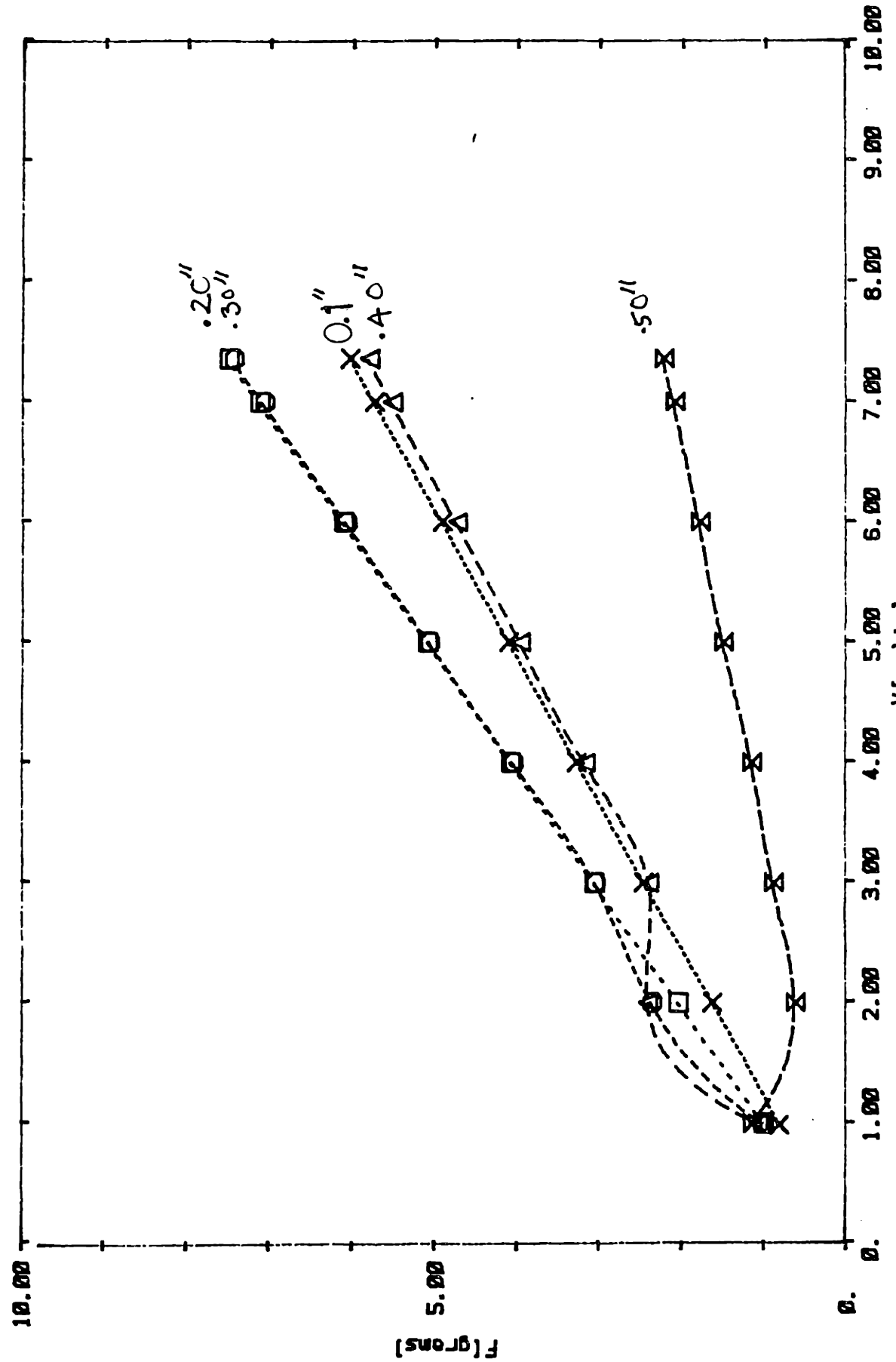
* Force as a function of voltage, magnetic armature
* Force comparisons, Magnetic vs. Non-magnetic armature

* Endurence tests

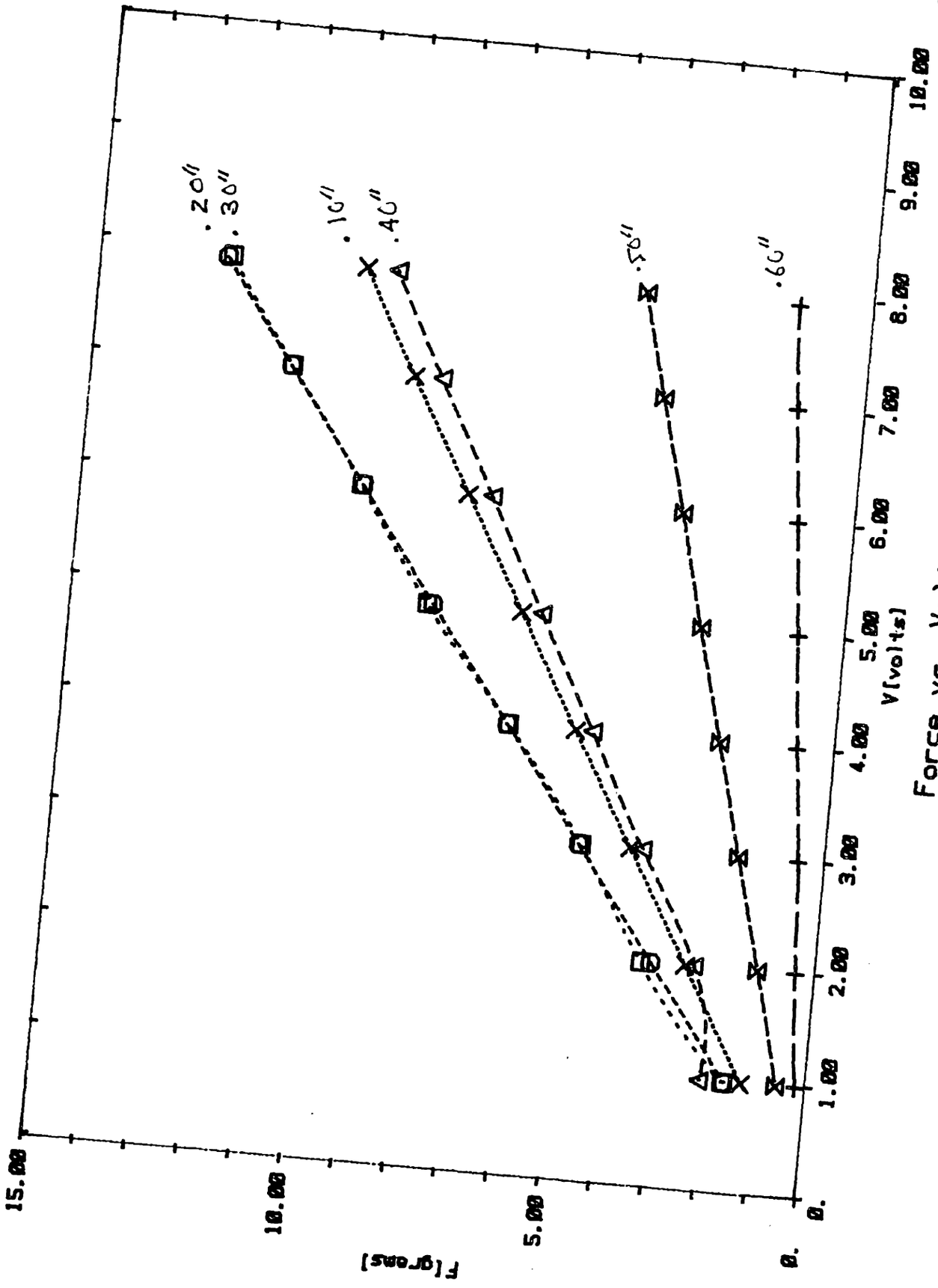
8.1 Force vs. Voltage Results.

Of primary concern to the design was whether or not the solenoid would produce enough force output as a function of a capacitor circuit input. A number of different factors were examined in determining the force output of the magnetic armature powered solenoid: the diameter of the wire used to wrap the coil [and thus the resistance of the solenoid] , the dimensions of the magnet in question, the voltage, and the insertion distance of the magnet into the coil.

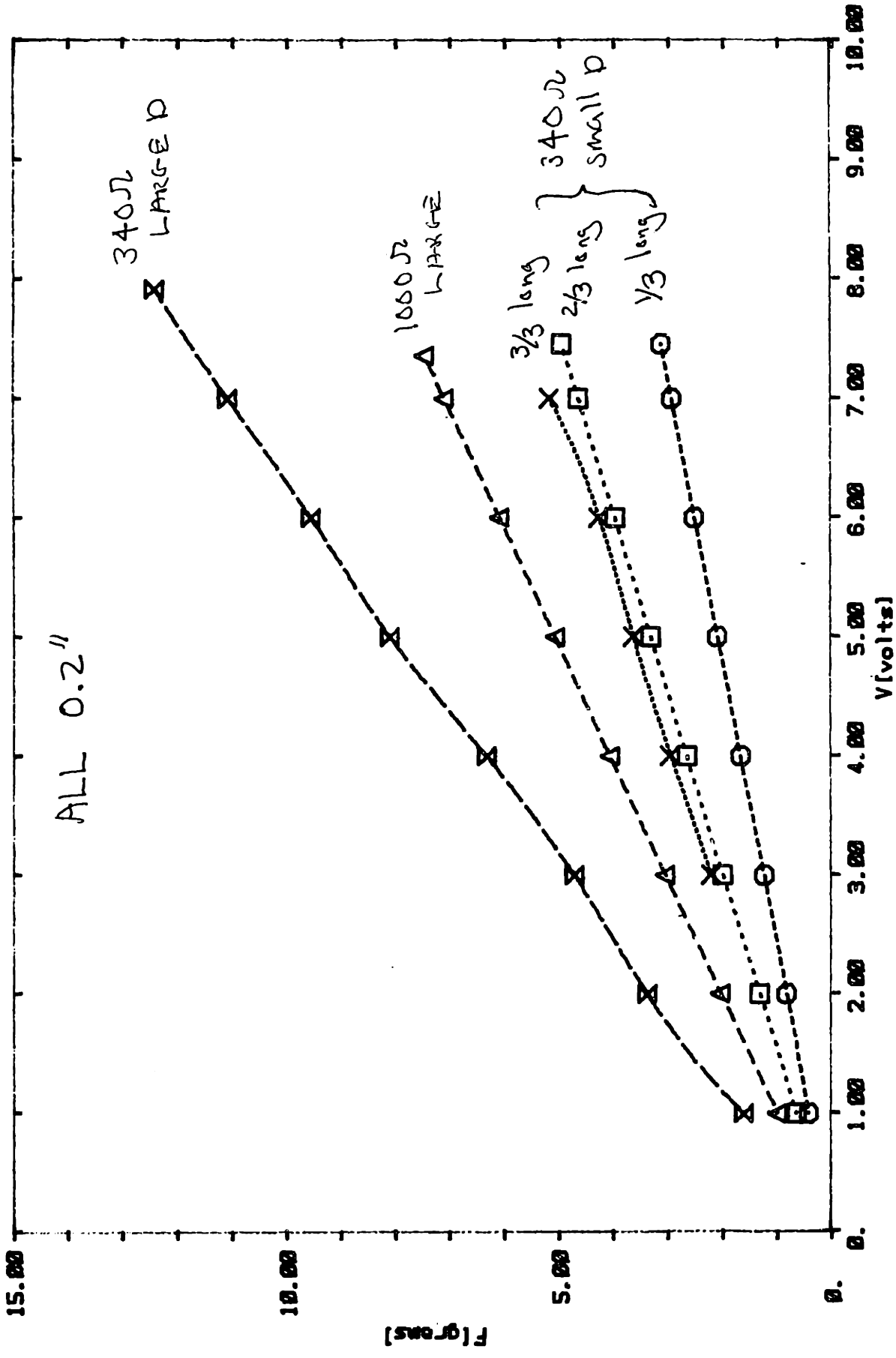
The curves were generated in the following manner: first, each of the two coils, 340 ohm and 1000 ohm, would go with the large diameter magnet. The large diameter magnet was approximately the size originally suggested; thus our emphasis was placed on experimentation concerning the large magnet. The voltage was the input, whereas the force generated was the output. With each coil and magnet combination the insertion distance was fixed. Therefore, one insertion distance generates one force-voltage curve. The collection of the insertion curves for one coil, generates the family of curves for that coil. Two families of curves come from the primary, large diameter magnet. These results are shown in Figures 8-1 and 8-2. Figure 8-1 shows the results of the resistance, 1000 ohm coil. The symbols for the insertion distances are given as are the forces. The curve between the points represents a third order fitting of the



Force vs. Voltage-1000 Coil



Force vs. Voltage, 340 Ohms



Comparisons of Force vs. Voltage

points. With the large diameter magnet in the high ohm coil, the maximum force at the required 7 volts is 7.2 grams.

In the second coil of 340 ohms a very similar curve is shown. Again, a family of curves is generated from Figure 8-2, and the results are more promising. This time, 12.5 grams of force were generated at the insertion distances of 0.20'' and 0.30''. Both insertion distances less than 0.20'' and greater than 0.30'' generated much less force per voltage.

Small Diameter Magnet

The small diameter magnet was used primarily to gauge the magnetic field strength of the system, due to the magnet. By keeping the voltage, coil and insertion constant, one focuses on the magnet. These comparisons show a number of interesting features. The data is presented in Figure 8-3, and in a different manner, even though the curves seem similar.

The first difference is that a number of factors were varied for different curves. Included are the large diameter magnet powered by both the large and small resistance coils. Also present are several curves showing the importance of magnet volume. Figure 9-3 shows the forces generated on the small diameter magnet. The small diameter magnet is used in the 340 ohm coil, at a constant distance of 0.20''. Consisting of magnetically connected segments of the samarium cobalt magnet, the magnet's length is subject to change. All these parameters are used to gauge varying effectiveness of altering each particular design parameter.

8.2 Magnet vs. Non-magnet Force Comparison.

To check the added efficiency of the magnet powered system, another armature was produced to compare with the magnet. A small steel slug of low carbon alloy, approximately 1080 steel, was made of identical dimensions to the small diameter magnet. The slug was mounted and put into the coil with the same varying voltage schedule. However, no curve could be reasonably fitted. This was due to the extremely poor force readings generated. Forces of less than 0.1 grams were generated, and no force greater than 1.0 grams was produced. Many hovered just under 1.0 grams. These forces were very hard for the scale to calculate efficiently, due to one major complicating reason. With the magnetic armature, the scale would have a dynamic response, and then reach a steady state, which was recorded. But the steel armature had a very small force which fluctuated. No steady state could be held. Thus no accurate force voltage point was generated. But for the sake of comparison, the output at 7 volts was reasonably close to 1.0 grams, so that will be used to calculate efficiency.

8.3 Endurance Test

As was described earlier, the magnet was placed in a coil, and 2.4 million cycles of 0 to 6 volts were applied. Just prior to this, the force generated by the magnet was measured, and the following results were obtained:

* 12.5 grams 10.0 grams 9.5 grams

After the test, the same setup was reproduced, and 11.0 grams were produced. The range in the first three numbers seemed

to be due to friction and sticking of the experimental setup. When the magnet was tried a second time, several resettings gave the same result.

IX CONCLUSIONS AND RECOMMENDATIONS

From the overall viewpoint of the project, a number of accomplishments were made. A valve which has a mechanical linkage preventing dangerous insulin flow was designed, thus promoting a failsafe operation. The need for a two coil actuator has been eliminated, with the result of saving much needed space. Also, the corresponding circuitry with its potential hazards has been eliminated, simplifying the design. By utilizing a magnetic armature solenoid, the efficiency of the whole system has been increased, along with simplifying the method of bidirectionality.

From the set of experimental results, it was found that the system used would generate a maximum of 12.5 grams of force. This compares well with a needed 15 grams of force on the linkage. To increase the output of the solenoid, a number of improvements can be made. First, the large advantage of the magnetized armature implies an even stronger magnet would increase the output. This can easily be accomplished by selecting a higher strength rare earth magnet. A number of compounds exceed the magnetic force of the magnets which were investigated. The tests showed that the maximum force occurs when the magnet is nearly halfway inserted, a feature which is utilized in the design. The coil itself can be altered so as to increase efficiency. Using a much tighter wrapping pattern, thinner bobin walls and overall better dimensioning would strengthen the magnetic force generated.

The system is so designed to meet the original criteria, and makes strong progress in that direction. With further

engineering refinement, the device seems quite capable of becoming operational. The system is being considered for further development, and it is the author's hope that this work will be part of the progress towards the relief of those who suffer from diabetes.