CONTROL AND MONITORING OF AN INTRA-AORTIC BALLOON PUMP FOR CARDIAC ASSIST.

Submitted to the University of Cape Town by

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in fulfillment of the requirements for the degree of

M.Sc. (Electrical Engineering).

October, 1971.

ACKNOWLEDGEMENTS.

The author would like to express his gratitude to the following:-

Dr. Marius Barnard of the Surgical Research Department of the University of Cape Town, and THE CHRIS BARNARD FUND for initiating and financing the project.

Dr. J.L.N. Besseling, my supervisor, for his assistance and encouragement.

Messrs. J.N. Wright and D.J.B. Kenyon of the Electrical Engineering Department Workshop for their valuable assistance in the fabrication of the trolley.

Mr. J.L.B. Caryer, my co-worker, and Mr. R.M. Stegen, his supervisor, for undertaking and completing the mechanical aspect of the project.

Dr. D. Boonzaier for carrying out the clinical tests.

SUMMARY.

An anatomical and physiological background to the heart as a pump, followed by a description of the causes and results of cardiogenic shock is given.

A survey of the achievements of other researchers in this field is included.

The design of a system for controlling and monitoring the Intra-Aortic Balloon Pump is described. A narrow band-pass filter is used to reduce noise and limit the input to the detector to the spectrum within which the R-wave of an ECG signal lies. A safety circuit to prevent the heart pumping against an inflated balloon is incorporated. History of the 8 secs preceding any instant is available.

A description of the medical tests carried out so far is given.

CONTENTS.

1. INTRODUCTION.

The project, undertaken by the Engineering Faculty of the University of Cape Town, was to design and build an Intra-aortic Balloon Pumping Unit. This unit would be used to give cardiac assistance to patients who are in a state of terminal cardiogenic shock and would consist of a balloon inserted in the patient's aorta, via the femoral artery. The balloon to be inflated after every heart beat and deflated again prior to the next beat. Thus the blood pressure would be raised above normal during diastole and then reduced below normal just before systole. Consequently the work of the ailing heart would be reduced.

The project was divided into an electrical task and a mechanical task which combine to give the required system.

The author undertook the electrical side of the project. This entailed selecting a suitable and safe means of detecting the patient's Electrocardiogram and blood pressure, designing and building a detection system to detect when the patient's heart beats, a control system to control the pump and a monitor display system. A system was also incorporated to provide the history of the previous 8 secs at any instant.

The mechanical side involved the design and fabrication of the balloons, driver pump, fluidic controls and the air supply required by these items.

All the constituent components were to be mounted in a trolley. Thus making it a selfcontained unit requiring only an electric power source.

THE HEART

2.1. Anatomy of the Heart.[1]

The heart may be regarded as a pulsatile, four chambered pump composed of two atria and two ventricles (Fig. 1). The atria function principally as entry ways to the ventricles, but they also pump weakly to aid the flow of blood into the ventricles. The ventricles supply the main force that propells blood through the lungs and the body.

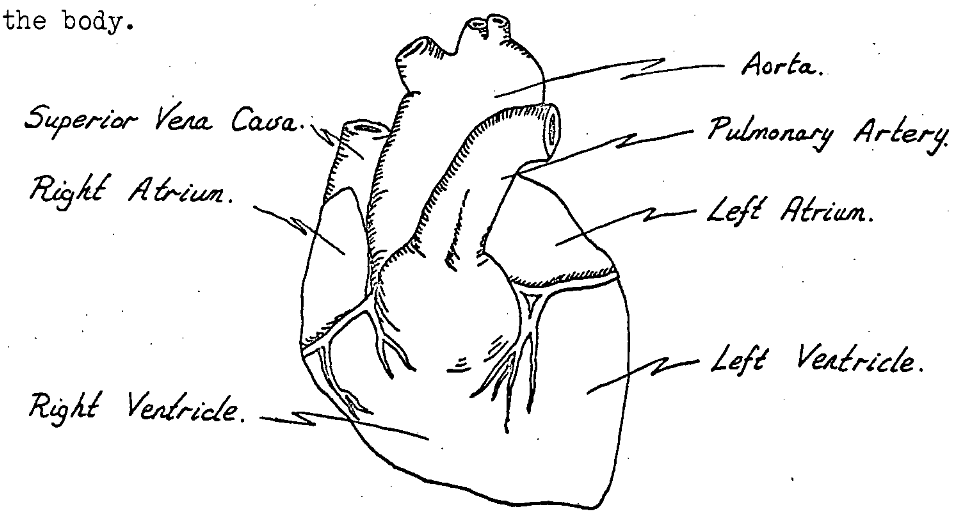


Fig. 1. The Heart.

The heart is divided into two halves, each comprising an atrium and a ventricle, named the left and right heart. There are one way valves between the atria and the ventricles, allowing flow from the atria to the ventricles, called A-V valves. There are also one way valves permitting blood to flow from the ventricles into the pulmonary artery and the aorta (Fig. 2).

Blood from the superior vena cava and the inferior vena cava enters the heart at the right atrium, it then flows through an A-V valve into the right ventricle from where it is pumped through the pulmonary valve into the pulmonary artery and thence to the lungs. The left atrium receives blood from the pulmonary vein which flows through an A-V valve into the left ventricle from where it is pumped through the aortic valve and thence

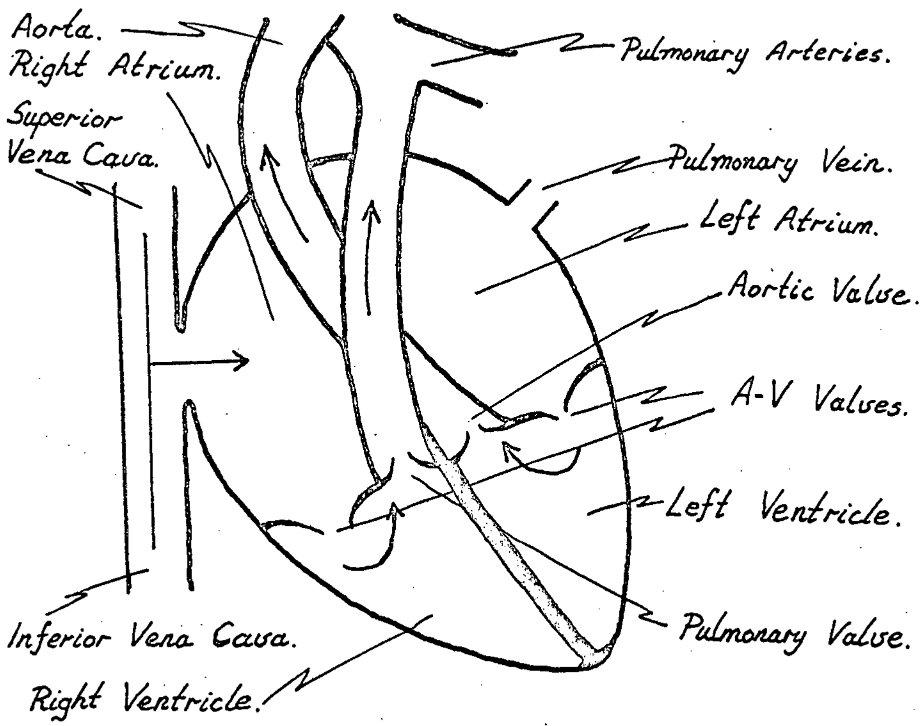


Fig. 2. Section of Heart.[2]

to the body.

2.2. <u>Function of Atria as Pumps.</u>

Blood normally flows continually from the great veins into the atria and approximately 70% of this flows directly into the ventricles before the atria contract. Then atrial contraction causes the additional 30% filling.

Observing the atrial pressure wave of Fig. 3, one notes three major pressure elevations called the 'a', 'c' and 'v' atrial pressure waves. The 'a' wave is caused by actual atrial contraction. Ordinarily, the right atrial pressure rises 4 - 6 mm. Hg during atrial contraction, while the left atrial pressure rises about 7 - 8 mm. Hg.

The 'c' wave is caused partly by reflux of blood out of the ventricles into the atria during ventricular contraction and partly because even after the A-V valves have closed, they bulge still further toward the atria because of increasing pressure in the ventricles.

The 'v' wave results from a slow build up of blood

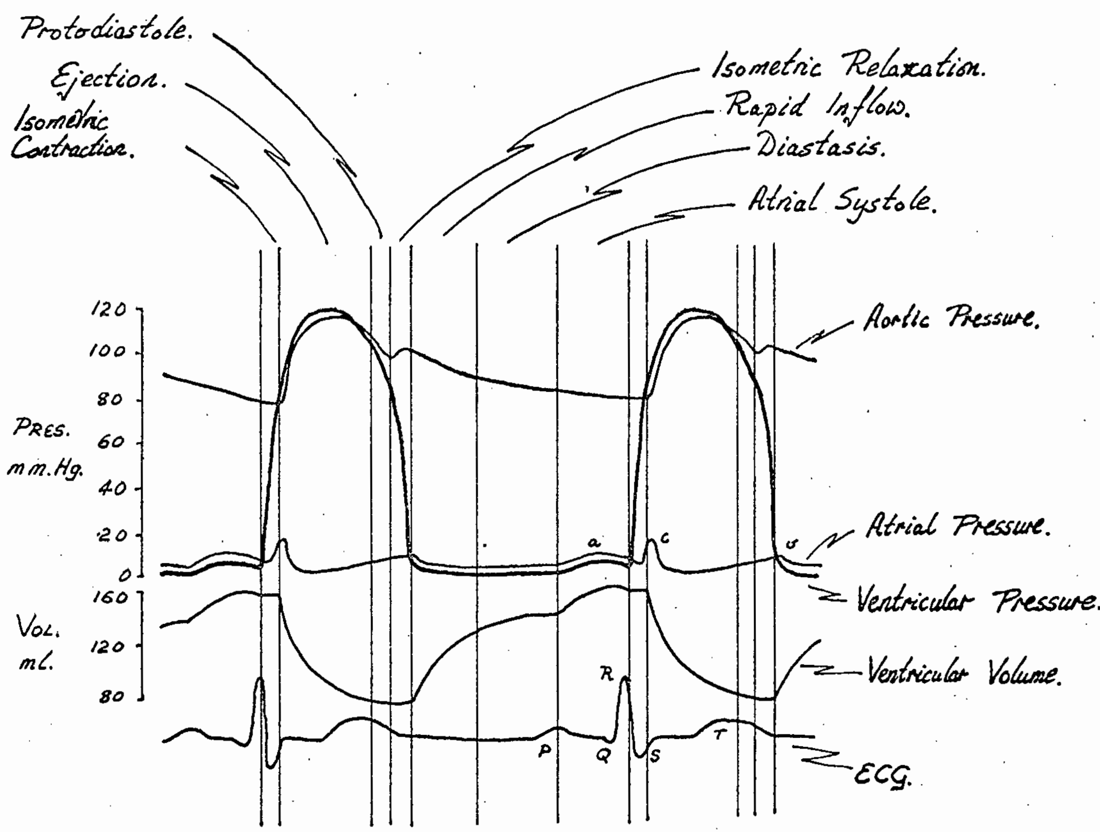


Fig. 3. Events of the cardiac cycle.

in the atria during ventricular systole. Because the A-V valves are closed during this time, the continual flow of blood into the atria from the veins, which does not stop for systole, causes the atrial pressure to rise until the end of systole. Then, when ventricular contraction is over, the A-V valves open, allowing blood to flow rapidly into the ventricles and causing the 'v' wave to disappear.

2.3. Function of the Ventricles as Pumps.

By the end of systole, large amounts of blood have accumulated in the atria; as a consequence the atrial pressures are elevated. Therefore, as soon as systole is over and the ventricular pressures fall again to their low diastolic values, the pressures in the atria push open the A-V valves and allow blood to flow rapidly into the ventricles, as shown in Fig. 3.

This period of rapid filling lasts approximately the first third of diastole. During the middle third of diastole only a small amount of blood normally flows into the ventricles; this is blood that continues to empty into the atria from the veins and passes directly into the ventricles. This middle third of diastole, when the inflow of blood into the ventricles is almost at a stand still, is called diastasis. During the latter third of diastole, the atria contract and give an additional thrust to the inflow of blood into the ventricles; this accounts for approximately 30% of the filling of the ventricle during each heart cycle.

Immediately after ventricular contraction begins, the ventricular pressure begins to rise, as also shown in Fig. 3. This rise in pressure causes the A-V valves to close, but is not initially sufficient to push the aortic and pulmonary valves open against the pressures in the aorta and pulmonary arteries. Therefore, during this time, contraction is occurring in the ventricles but there is no emptying. When the ventricular pressures rise above the diastolic pressures in the aorta and pulmonary artery the respective valves open. (Pressure 80mm. Hg and 8 mm. Hg normally). Blood now begins to pour out of the ventricles, about half of the emptying occurring during the first quarter of systole and most of the remaining half during the next two quarters.

During the last quarter of ventricular systole, almost no blood flows from the ventricles into the large arteries; yet ventricular musculature remains contracted. The arterial pressure falls during this period, because almost no blood is entering the arteries even though large quantities of blood are flowing from the arteries through the peripheral vessels. The ventricular pressure actually falls to a value below that in the aorta during this time, despite the fact that small quantities of blood are still emptying from the ventricles. This is due to the blood's momentum, the kinetic energy of momentum is converted into pressure in the large arteries, making the arterial pressure higher than that inside the ventricles.

At the end of systole, ventricular relaxation begins suddenly allowing the intraventricular pressures to fall rapidly. The elevated pressures in the large arteries immediately snap the aortic and pulmonary valves closed. The ventricular muscle continues to relax and the intraventricular pressures fall rapidly back toward their low diastolic levels. As the ventricular pressures fall below the atrial pressures the A-V valves open and a new cycle starts.

2.4. The Aortic Pressure Curve.

When the aortic valve opens and blood is ejected by the left ventricle, the aortic blood pressure rises, and in so doing causes the walls of the arteries to stretch and the pressure in the arterial system rises. Then, at the end of systole, even after the left ventricle stops ejecting blood, the elastic stretch of the arterial walls maintains high pressure in the arteries while the ventricular pressure falls. This creates a backward pressure differential across the aortic valve, and the aortic valve closes.

An incisura occurs in the aortic pressure curve when the aortic valve closes. This is because when the blood flows backward from the aorta into the left ventricle, some of the pressure in the artery is converted into kinetic energy; therefore, the aortic pressure falls slightly while the blood is flowing backward. When the aortic valve closes, this kinetic energy is converted back into pressure which again stretches the aortic walls.

After the aortic valve has closed, pressure in the aorta falls slowly throughout diastole because blood stored in the distended elastic arteries flows continually through the peripheral vessels back to the veins.

Obviously, the pressure curve in the pulmonary artery is similar to that in the aorta except that the pressures are much less.

2.5. Cardiac muscle.

The heart is composed of three major types of cardiac muscle; atrial muscle, ventricular muscle and specialised excitory and conductive muscle fibres. The atrial and ventricular types of muscle contract in much the same way as normal skeletal muscle fibres. The specialised excitory and conductive fibres contract only feebly; instead, they provide an excitory and transmission system for rapid conduction of impulses throughout the heart.

Across the outer membrane of all muscle cells potential differences exist due to differing concentrations of ions inside and outside the cells. A resting membrane potential is established by a resting muscle cell by blocking diffusion of sodium ions through its membrane and so maintaining the potential. If for some reason this block is removed, a rapid transfer of ions will take place causing the potential to change rapidly and usually to overshoot, producing a reversal of potential. This change in potential is known as an action potential. The reversal helps to reestablish the block, which is followed by a flight of potassium ions out of the cell reestablishing the resting membrane potential. The break down of the resting membrane potential is called depolarization, and the reestablishment of the resting membrane potential is called repolarization.

Figure 4 illustrates a typical section of cardiac muscle, showing the arrangement of muscle fibres in a latticework, the fibres dividing, then recombining and spreading in all directions. The dark areas are called intercollated discs; however, they are actually cell membranes that separate individual cardiac muscle cells from each other. Thus, cardiac muscle fibres are in reality a series of cardiac muscle cells connected in series. Electrical resistance through the intercollated discs is low. Therefore action potentials flow with relative ease along the axis of the cardiac muscle fibres. Cardiac muscle is thus a "functional syncytium", in which the cardiac muscle cells are so tightly bound that when one cell becomes excited the action potential spreads to them all through the lattice interconnections.

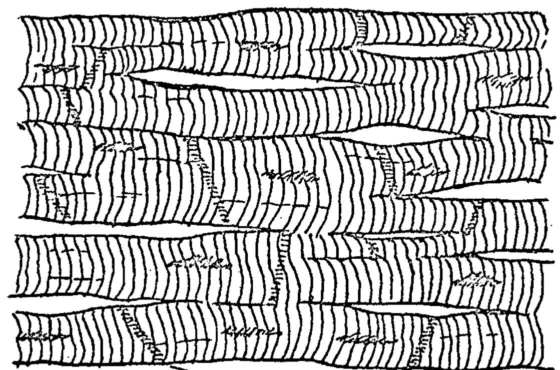


Fig. 4. The "syncytial" nature of cardiac muscle.

The heart is composed of two separate functional syncytiums. The atrial syncytium and the ventricular syncytium. These are normally only connected with each other by way of a specialized conductive system, the A-V bundle, which transmits impulses from the atrial muscle into the ventricular muscle. Other than this connection the two masses are separated from each other by fibrous tissue.

Because of the syncytial nature of the cardiac muscle stimulation of any single atrial muscle fibre causes the action potential to travel over the entire atrial muscle mass, and, similarly, stimulation of any single ventricular muscle fibre causes excitation of the entire ventricular muscle mass. And, if the A-V bundle is intact, the action potential passes from atria to ventricles or vice versa. This is the all or nothing principle.

2.6. Excitory and conductive system of the heart.

The adult human heart normally contracts at a rhythmic rate of about 72 beats per minute. Fig. 5 illustrates the special excitory and conductive system of the heart that controls these cardiac contractions.

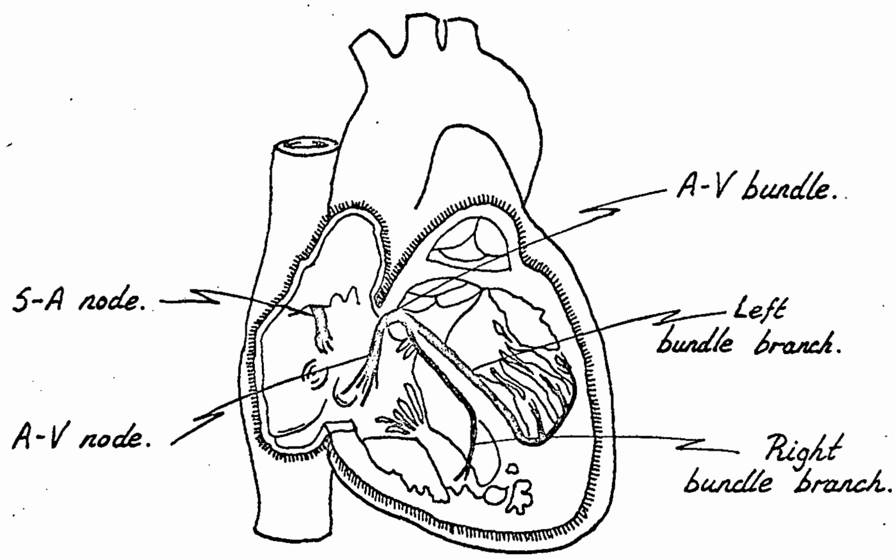


Fig. 5. Excitory and conductive system of the heart.

The Sino-Atrial Node is the region of the heart in which the normal rhythmic self-excitory impulse is generated. The resting membrane potential of the S-A fibres is quite low, only 55 - 60 mv. in comparison with 80 - 90 mv. in other cardiac muscle fibres. The cause of this low resting potential is the very high membrane conductance of these fibres for sodium, which allows rapid leakage of sodium through the membrane. This leakage of sodium also causes self-excitation of the S-A fibres. Fig. 6 illustrates the self-excitation process; each time the resting membrane potential is reestablished, it gradually decays until it reaches the threshold for self-excitation. At this point an action potential

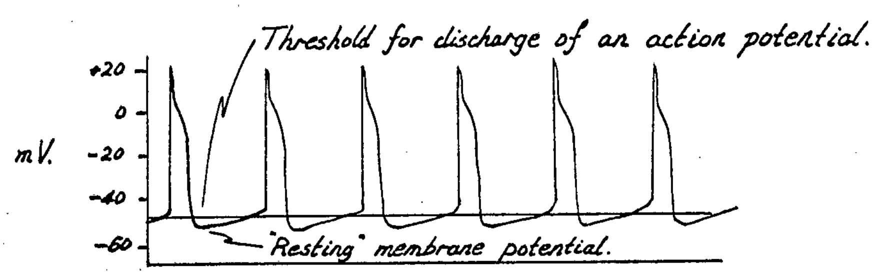


Fig. 6. Rhythmic discharge of an S-A nodal fibre.

suddenly appears. After the action potential is over, the conductance of the membrane for potassium becomes very high, and the rapid outward diffusion of potassium carries positive charges to the outside of the fibre, increasing the negativity inside the fibre to a level much greater than normal. As long as this increased potassium conductance persists, the membrane potential remains more negative than the threshold for self-excitation; but, gradually, the conductivity for potassium decreases, allowing the high sodium influx to excite the fibre again.

Each time a rhythmic impulse is generated in a fibre of the S-A node, it spreads into the surrounding atrial muscle. The atrial muscle in turn conducts the signal in all directions.

The Atrio ventricular (A-V) node picks up the signal from the atrial muscle and acts as a delay system to allow the atria to contract before ventricular contraction begins. Thus the impulse, after travelling through the atrial muscle reaches the A-V node approximately 0.04 sec. after its origin in the S-A node. However, between this time and the time that the impulse emerges in the A-V bundle, 0.11 sec. elapses.

The A-V bundle now transmits the signal rapidly throughout the ventricular system via the left and right bundle branches. Each of these branches spread downward toward the apex of the respective ventricle, then curves around the tip of the ventricular chamber and finally back toward the base of the heart along the lateral wall. All along the courses of the two bundle branches many small branches of fibres spread in all directions into the ventricular muscle.

In the above discussion of the origin and transmission of the cardiac impulse through the heart, it was stated that the impulse normally arises in the S-A node. However, under normal conditions, other parts of the heart can exhibit rhythmic contractions in the same way that the fibres of the S-A node can; this is particularly true of the A-V nodal and A-V bundle fibres.

The A-V nodal fibres, when not stimulated from some outside source, discharge at an intrinsic rhythmic rate of 40 - 60 beats per minute, and the A-V bundle fibres discharge at a rate of somewhere between 15 and 40 beats per minute. These rates are both slower than that of the S-A node. Each time the S-A node discharges, its impulse is conducted both into the A-V node and A-V bundle, discharging their excitable membranes. Then all these tissues begin their cycle of recovery. Buth the S-A node recovers more rapidly than either of the other two and emits another impulse before either of them can reach its own threshold of self-excitation. The new impulse again discharges both the A-V node and A-V bundle.

If, for some reason, another part of the heart develops a rhythmic discharge rate that is more rapid than that of the S-A node it will then take control of the heart beat.

2.7. The Electrocardiogram (ECG)

As the impulse described in Sec. 2.6. passes through the heart, electric currents spread into the tissues surrounding the heart, and a small proportion of these spread all the way to the surface of the body. If electrodes are placed on the body on opposite sides of the heart, the electric potential generated by the heart can be detected and recorded. The recording is known as an Electrocardiogram.

The normal ECG is composed of a P wave, a "QRS complex", and a T wave. (Fig. 7). The QRS complex is actually three separate waves, the Q wave, the R wave and the S wave, all of which are caused by the passage of the cardiac impulse through the ventricles. In the normal ECG, the Q and S waves are often much less prominent than the R wave and sometimes actually absent, but, even so, the wave is still known as the QRS complex.

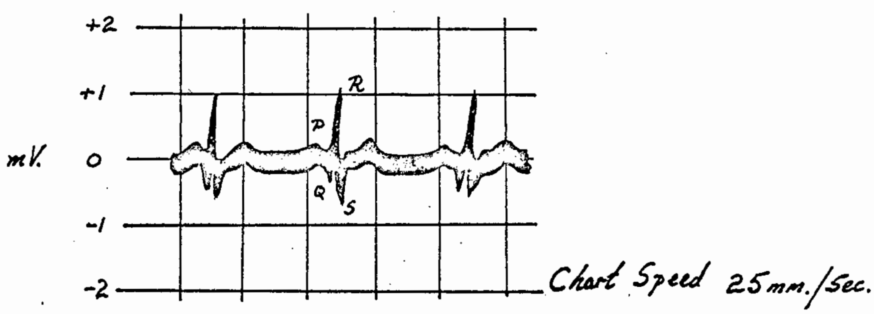


Fig. 7. A normal Electrocardiogram.

The P wave is caused by electric currents generated as the atria depolarise prior to contraction, and the QRS complex is caused by currents generated when the ventricles depolarise prior to contraction. The T wave is caused by currents generated as the ventricles recover from the state of depolarisation, this wave is, therefore, due to repolarisation.

Fig. 8 illustrates an action potential recorded from a microelectrode inserted into the inside of a single ventricular muscle fibre. The upsweep of this action potential is the depolarisation process and the return of the potential to the base line is the repolarisation process. Note below the simultaneous

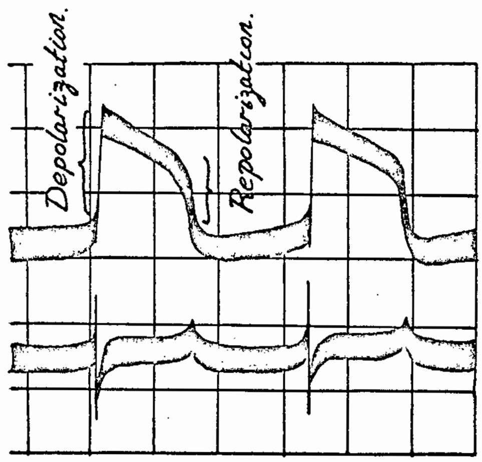


Fig. 8. Action potential from a ventricular muscle fibre.

recording of the ECG from this same ventricle, which shows the QRS wave appearing at the beginning of the action potential and the T wave appearing at the end. Actually, repolarisation begins immediately after depolarisation completes, however, during the plateau stage of repolarisation, the rate of repolarisation is too slow for a large amount of current to be generated around the heart. But, during the rapid phase of repolarisation at the end of the action potential, large amounts of current are again generated and the T wave appears.

The voltages of the waves in the normal ECG depend on the position in which the electrodes are placed on the surface of the body. When one electrode is placed directly over the heart and the second electrode is placed elsewhere on the body the voltage of the QRS complex may be as much as 4 mv. When ECG's are recorded from electrodes on the arms and legs, the voltage of the QRS complex is approximately 1 mv., and the P wave and the T wave are approximately 0.2 mv.

2.8. Cardiac blood supply.[3]

Nourishment of the heart muscle, valves and nerve supply comes from oxygenated blood carried through the coronary arteries and their branches to the abundant network of capillaries distributed throughout the heart. From this rich capillary bed the blood, partially desaturated of its oxygen content, is drained through numerous tributaries to the large and small coronary veins by which it returns to the general circulation. The orifices of the coronary arteries are, ordinarily, apertures in the wall of the aorta. These orifices are funnel shaped depressions, somewhat rounded in contour and are usually found in two of the three pockets lying behind the leaflets of the aortic valve. In the majority of hearts there is one orifice for the right coronary artery and one for the left. It is not unusual, however, to have two or more openings for either of these main arteries, or, to have both arteries originating in a single orifice.

The right main coronary artery (Fig. 9) leaves its orifice and runs from the aorta toward the right and anteriorly behind the base of the pulmonary artery and in front of and under the right atrium. This artery continues in the A-V groove toward the right until it coronary artery, and (2) the left circumflex coronary artery. These two vessels are so large and of such importance that they are frequently grouped with the right main coronary artery as the three main coronary arteries. The anterior interventricular coronary artery runs in the groove between the ventricles, on the heart's anterior surface, from its origin toward the apex of the heart and consequently supplies the anterior surface of the left ventricle. The left circumflex coronary artery runs around the left atrium and down the posterior surface of the left ventricle.

As the left ventricle does the majority of the work of the heart it needs more nutrition and oxygen, thus it has a far greater capillary bed than the right. (Fig. 10). Consequently, in the normal heart, the blood flow to the left coronary artery is approximately 85% of the total coronary blood flow.

The resting coronary blood flow in a human averages approximately 4% of the total cardiac output. In strenuous excercise the heart increases in cardiac output as much as six-fold, and it pumps this blood against a higher than normal arterial pressure. Consequently, the work output of the heart may increase as much as ten-fold. The coronary blood flow increases up to six-fold to supply the extra nutrient needed by the heart. This increase is not as much as the increase in work load, thus, the ratio of coronary blood flow to energy expenditure of the heart decreases. However, the "efficiency" of cardiac contraction increases to make up for this relative defficiency of blood supply.

In systole, due to the compression of the cardiac muscle around the intramuscular vessels, blood flow is low. During diastole the cardiac muscle relaxes completely and no longer obstructs blood flow through the

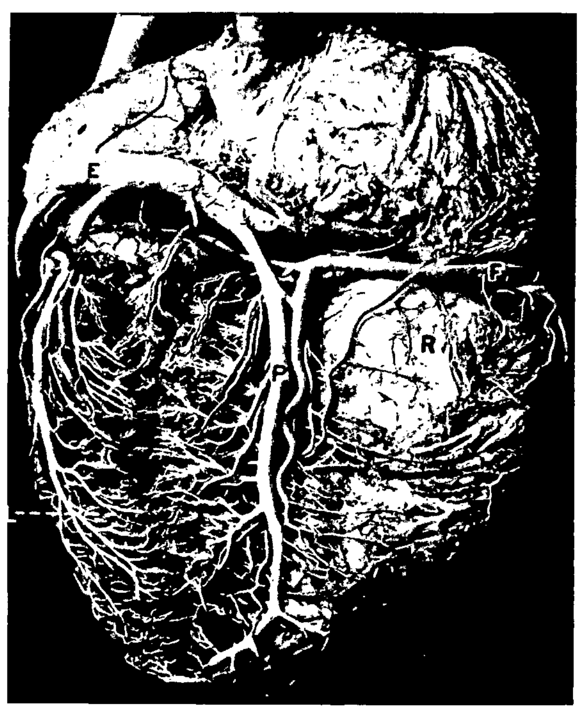


Fig. 10. Posterior view of the heart. R indicates the right ventricle; L, the left ventricle; E, the left coronary artery; F, the right coronary artery.

capillaries. Thus, blood flows rapidly throughout all diastole.

2.9. <u>Work done by the heart</u>.

The work output of the heart is the amount of energy that the heart transfers to the blood by pumping it to the arteries. By far the major proportion is used to move the blood from the low pressure veins to the high pressure arteries. A minor proportion of the energy is used to accelerate the blood to its velocity of ejection through the aortic and pulmonary valves.

The work performed by the ventricles to raise the pressure of the blood during each heart beat is equal to "stroke volume output" x "pressure rise from veins to arteries". Right ventricular output is usually about one-seventh the work output of the left ventricle because of the difference in systolic pressure against which the two ventricles must pump. The work output required to create the kinetic energy of blood flow is 2 - 4% of the total work output of the ventricles.

3. CARDIOGENIC SHOCK.

Cardiogenic shock is most frequently brought about by a portion of the cardiac muscle dying, called a Myocardial Infarction, due to lack of blood caused by a coronary artery becoming occluded.

The most frequent cause of coronary occlusion is thrombosis resulting from atherosclerosis.[4] Atherosclerosis results when cholestrol and cholestrol salts are deposited beneath the surface of the major arteries. These deposits become calcified over a period of years, and fibrous tissue invades the walls of the degenerated arteries, causing them to harden. Atherosclerotic growths occasionally break through the inner surface of the blood vessel and protrude into the lumen. The presence of such a rough surface inside a vessel initiates the clotting process. A small clot forms and develops until the vessel is plugged. This mechanism causes most coronary thromboses. The left coronary artery is far more prone to occlusion than the right coronary artery. Thus the left ventricle, the main pumping chamber of the heart, is most susceptible to myocardial infarction.

Occasionally the coronary arteries are not blocked suddenly but instead are slowly constricted by the atherosclerotic process. The deposits grow all the way around the artery, and this in turn causes progressive growth of fibrous tissue, which becomes thicker and thicker until it gradually constricts the artery.

When the coronary vessels are occluded slowly a collateral blood supply often develops to take over the function of the primary supply. Thus, an artery that becomes occluded under these conditions is less likely to cause acute heart failure, as a large portion of the muscle tissue it supplies will have an alternate blood supply. Unfortunately, this collateral blood supply does not become will developed until after the arteries are occluded. Therefore, if a sudden occlusion occurs, it may take several weeks to develop a new blood supply to the stricken muscle.

A common side effect of atherosclerosis is Hypertrophy. This means that the heart muscle grows in response to an imagined increase in demand due to the reduction in blood supply. Much as an athlete's heart grows in response to his genuine increase in demand. This is a short term solution as the increased heart muscle now needs increased blood supply. Once a certain size is reached the heart can no longer hypertrophy and thus cannot further increase the blood supply. The threatened reduction in blood supply now takes place, and the muscle becomes ischemic. This means that the muscle is on the brink of degenerating. Any sudden further reduction in blood supply will bring on myocardial infarction. Thus, a patient may incur a heart attack without an actual occlusion occurring by making too great a demand, like sudden unaccustomed exercise on a hypertrophied heart, portions of which have become ischemic.

After a heart becomes suddenly damaged, the natural reparative processes of the body begin immediately to restore normal cardiac function. Thus, a new collateral blood supply begins to penetrate the peripheral of the infarcted area, often completely restoring the muscle function. Also, the undamaged musculature hypertrophies, if possible, in this way off setting much of the cardiac damage.

Obviously, the degree of recovery depends on the type of cardiac damage, and it varies from no recovery at all to almost complete recovery.

4. A REVIEW OF MECHANICAL DEVICES TO ASSIST THE FAILING HEART.

Patients suffering myocardial failure from any cause should be benefited if the myocardial work and oxygen requirements are reduced while the peripheral and coronary circulation are supported until the heart regains its ability to perform pressure work.

Studies by Sarnoff et al.,[5] and Katz [6] demonstrate the dominant role of pressure work, specifically systolic pressure, in determining myocardial oxygen consumption. Since myocardial work is best related to myocardial oxygen consumption, the most effective system of reducing work would reduce systolic pressure. Any system for assisting the failing heart must also provide for adequate or increased coronary flow, since this determines the availability of oxygen to the heart. Although coronary flow occurs during both systole and diastole, more than two thirds of the total coronary flow occurs during diastole.[7] Thus, diastolic perfusion pressure and time must be maintained or, preferably increase to aid the failing myocardium. The ideal system for assisting the heart would combine:

1. A reduction of mean aortic systolic pressure.
2. A reduction of systolic time.

3. An increase in diastolic coronary perfusion pressure.

4. An increase in diastolic perfusion time.

Such a system may be life saving during the acute stage of myocardial infarction which is not responsive to medical measures.

The following methods of mechanical assistance have been used clinically and/or experimentally.

1. Veno-arterial pumping with or without an oxygenator.
2. Left heart bypass.
3. Counterpulsation.

A limitation inherent in all of these methods is the damage, to formed elements of the blood, produced by the pump, increasing with time and much more marked when an oxygenator is used; therefore great interest has been aroused by methods which do not require oxygenation of the blood.

4.1. Veno-arterial pumping.

Veno-arterial pumping involves taking blood from the right atrium, through a pump, and returning it to the arterial system, thus reducing the volume of blood that the heart has to pump. This may take place with or without an oxygenator. However, it usually involves major surgery, a condition best avoided in a patient in cardiogenic shock. This method of support to the failing myocardium has been tried extensively in a laboratory and in a limited way clinically.[8,9,10,11.]

The principal effects of this method are the relief of flow work and the maintainance of an adequate mean aortic root pressure for coronary perfusion. This has obvious advantages for the patient in circulatory shock but does very little to relieve the work of the heart, which is working against pressure produced by the arterial pump.

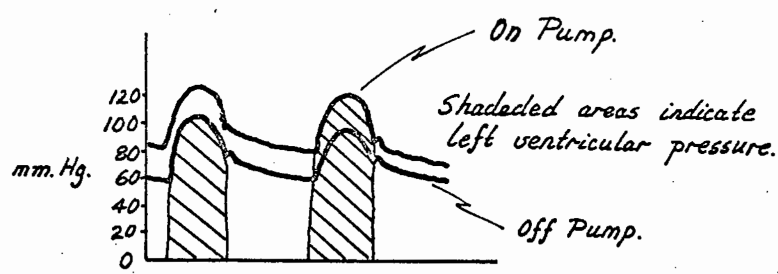


Fig. 11. A schematic diagram of the haemodynamic effects of veno-arterial assist.

Assuming in Fig. 11, that the output of the pump is a straight line, the cardiac pressure cycle is merely superimposed on pump pressure. Thus the pressure work of the heart is not being reduced and its myocardial oxygen requirements are not being reduced. This theory appears to have been supported by many who have investigated veno arterial assists.

4.2. Left Heart Bypass.

Left ventricular bypass involves removing blood from the left atrium and returning it through a pump to the arterial tree via a peripheral artery. It would seem a simple and straight forward concept that blood so routed would not have to be ejected by the left ventricle, and, in theory, left ventricular work should be reduced in proportion to the amount of blood removed from the left atrium. Synchronization with cardiac activity would not be essential to this technique, although it might be desirable to return blood to the arterial tree during diastole.

Liotta et al.,[12] Kusserow et al.,[13] and Akers [14] describe methods for partial left ventricular bypass involving opening the chest and showing apparent reduction of the left ventricular work. This apparent reduction is brought about by the fact that they consider the work of the heart to be a product of the intraventricular pressure and the ventricular output. However, even if the output is reduced the heart still does useless work against the intraventricular pressure, which is not reduced. The fact that the left ventricle is still "working" is borne out by Liotta[12] reporting no reduction in myocardial oxygen consumption.

Senning et al.,[15] demonstrated that the left atrium can be cannulated without thoracotomy via a cannula introduced through a jugular vein in the neck. Hall et al.,[16] and Dennis et al.,[17] have both conducted experiments using this technique. (Fig. 12). However, they do not report oxygen consumption. Although this technique reduces the amount of surgery required it still causes trauma to the heart, as the cannula has to pierce the atrial septum to enter the left atrium.

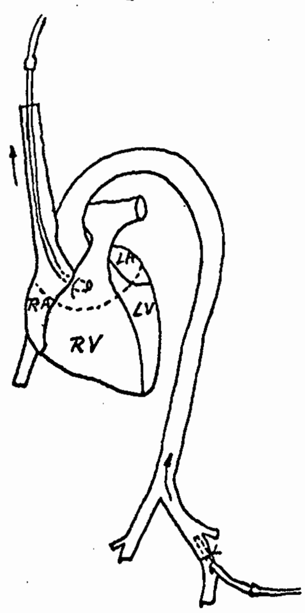


Fig. 12. Diagrammatic sketch of the bypass circuit showing the cannula placed in left atrium.

All the above researchers report good survival rates, however, Jacobson et al.,[18] raises doubt about its long term benefit on physiological grounds, as a result of detailed studies of early complications and late alterations in function, rather than on simple calculation of survival rates. He reports severe bleeding during the procedure despite careful haemostasis and minimal heparinization. (Hall[16] also noted this in prolonged left heart bypass.) He also notes small infarcts of the kidney and myocardial pathological changes.

Schenk et al.,[19] carried out a comparison between left ventricle bypass and counterpulsation and shows that the bypass had to be complete to be of assistance to the heart. When it was complete left ventricular pressure work and coronary flow were reduced. However, it was not possible to insure or maintain complete left ventricular bypass using the techniques and instrumentation described and it became apparent that partial bypass could be detrimental and increase coronary flow requirements. This is because the left ventricle is not empty, and at times is unable to eject against the peripheral arterial pressure built up by the pump. The trapping of blood in the left ventricle may result in a highly undesirable state since the left ventricle myocardium will continue to contract against the trapped blood. Although this leads to a marked reduction of the recorded external work of the heart, nevertheless, the energy requirements of the left heart are increased since the latter must expend considerable force to perform what is in fact "isometric exercise". The increase recorded in coronary flow under conditions of partial left heart bypass demonstrates clearly, that, under these conditions the load on the left ventricle is increased, in spite of the fact that the pump furnishes part of the cardiac output.

4.3. Counterpulsation.

The basic principle of counterpulsation was first described by Clauss et al.,[20] and is illustrated in Fig. 13. This technique requires only the cannulation of a single

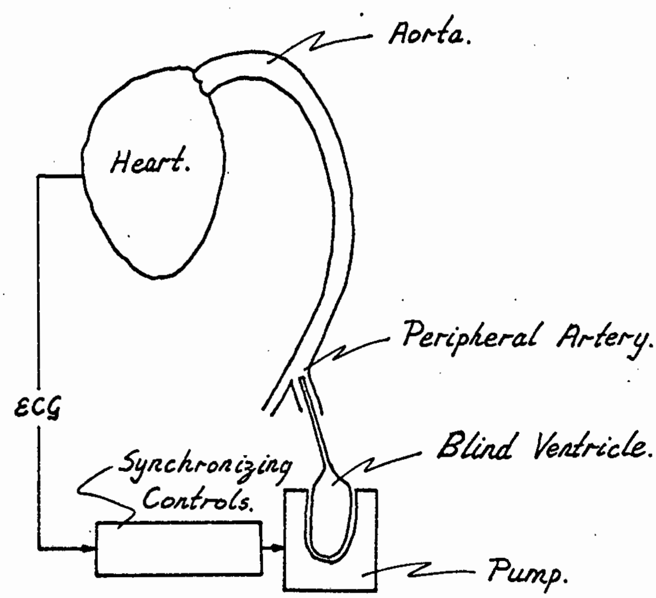


Fig. 13. Schematic representation of counterpulsation.

peripheral artery which is connected to a blind pump ventricle, and is a simple surgical procedure with minimal exposure of blood to an extracorporeal system. By synchronization with the ECG, the external ventricle is phased to remove blood rapidly from the arterial tree just prior to, and during, left ventricular ejection. This results in blood being ejected from the left ventricle against a lowered pressure, thus left ventricular work is reduced. After termination of systole, the volume of blood removed by the external ventricle is returned to the arterial tree, thus raising diastolic pressure. (Fig. 14). This should improve coronary driving pressure and

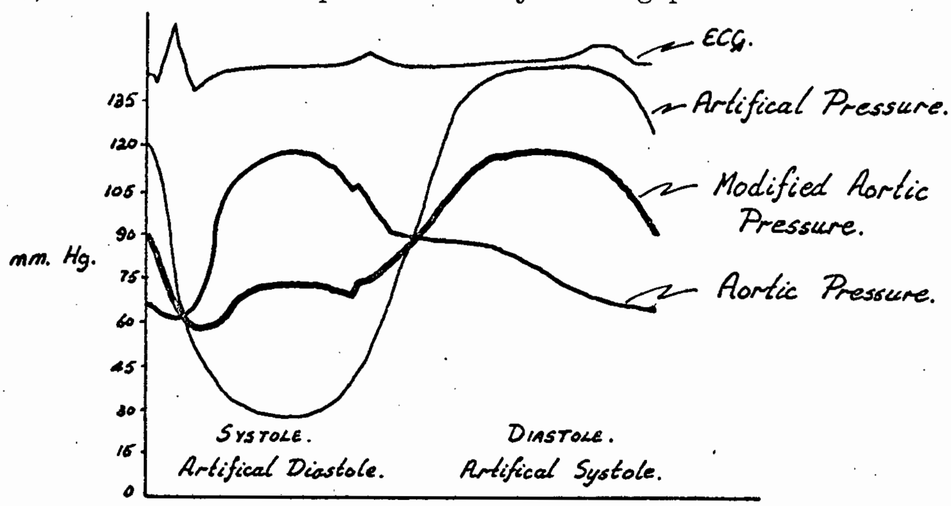
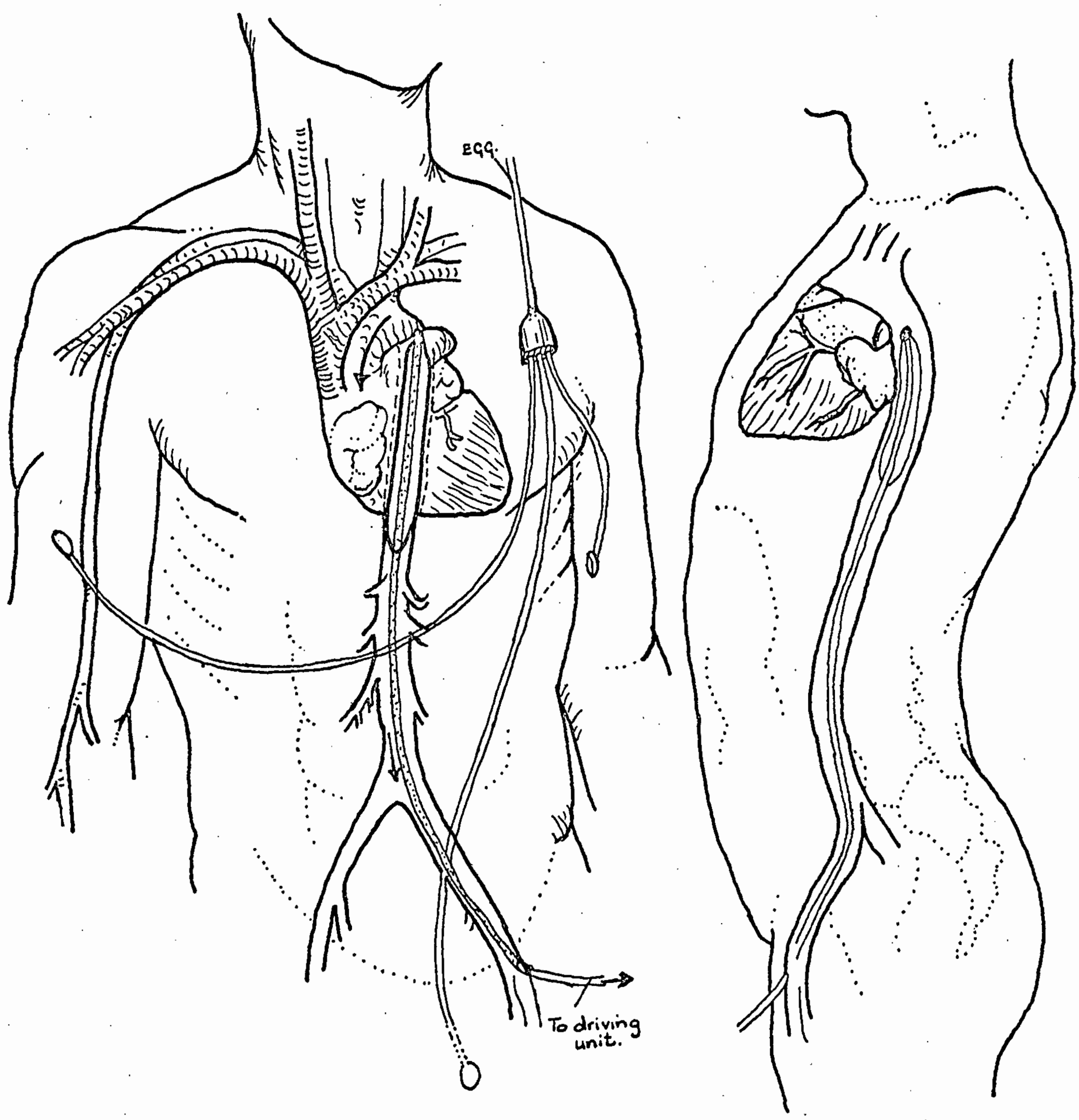


Fig. 14. Modification of the aortic pressure curve by the arterial counterpulsator.

might improve flow, since the latter occurs almost entirely during diastole.

Lefemine et al.,[21] initially obtained appropriate haemodynamic responses, but further experience demonstrated limitations imposed by the heart rate. Reduced efficiency was apparently due to the inertia of the extracorporeal fluid volume to rapid changes in the direction of flow. This volume is large in relation to the stroke change, and the elasticity of the system impedes effective alteration of systolic and diastolic pressures at higher heart rates. To correct this difficulty, they employed two alternative approaches. The



Position of balloon in aorta.

first circuit takes blood from one femoral artery, passes it through a ventricle with unidirectional valves, and delivers it to the opposite femoral artery. The second circuit involves cannulation of a single femoral artery with an extracorporeal circle circuit, returning to the same femoral artery. The latter system was preferred and studies of this circuit at heart rates from 80 - 190 beats per minute were conducted.

An early modification to the original counter-pulsation technique was proposed by Moulopoulos et al.[22] This consists of latex tubing tied around the end of a catheter with multiple side holes. The end of the catheter is closed so that the tubing can be inflated and deflated through the side holes. (Fig. 15). The balloon is

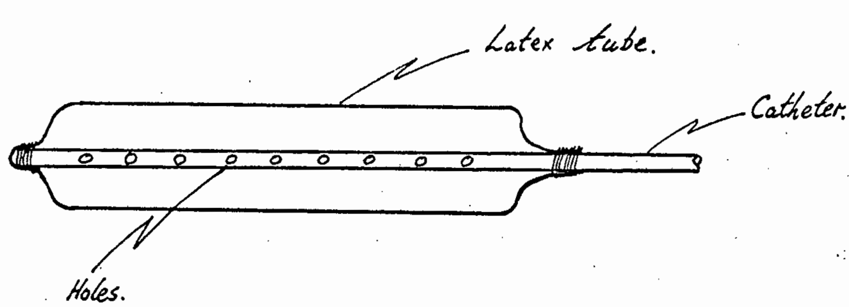


Fig. 15. A catheter balloon.

inserted into the aorta via the femoral artery, and is synchronised with the ECG to inflate during diastole and deflate immediately prior to systole. Initial tests on dogs showed that intra- aortic pumping with the balloon produced the same results as achieved with the original technique. However, the advantages of pumping by means of an intra-aortic balloon are these:

1. No blood is handled outside the body.
2. No blood is needed for priming the device.
3. The device is very simple.

Lefemine et al.,[23] showed that counterpulsation reduced mean systolic aortic pressure, systolic time, left ventricular pressure and left ventricular pressure work, as evidenced by the reduction in myocardial oxygen consumption and increased coronary flow. Schenk,[19] Brown et al.,[24] and Schilt et al.,[25] agree with these findings. Madras et al.,[26] investigated the effects of prolonged intra-aortic balloon pumping in pigs, and reported no significant physiological damage.

Kantrowitz et al., [27,28] has used this technique clinically and reported that 81% of their patients recovered from cardiogenic shock. However, only 44% went on to convalesce satisfactorily from their infarctions and were discharged from hospital. Because the balloon pumping procedure had not previously been attempted in patients, only those in terminal cardiogenic shock due to acute myocardial infarction were considered candidates for treatment. It must be remembered that cardiogenic shock as a complication of acute myocardial infarction accounts for a significant proportion of cardiac deaths, the mortality ranging between 85% and 95%.

4.4. Conclusion.

It would, therefore, appear from the research conducted that intra-aortic balloon counterpulsation best achieves the objectives expressed at the beginning of this review and has the added advantage of minimal surgical trauma. It is hoped that, as confidence in this technique increases, counterpulsation will be used in the initial phases of cardiogenic shock rather than as a last desperate resort.

5. THE U.C.T. INTRA-AORTIC COUNTERPULSATION BALLOON PUMP.

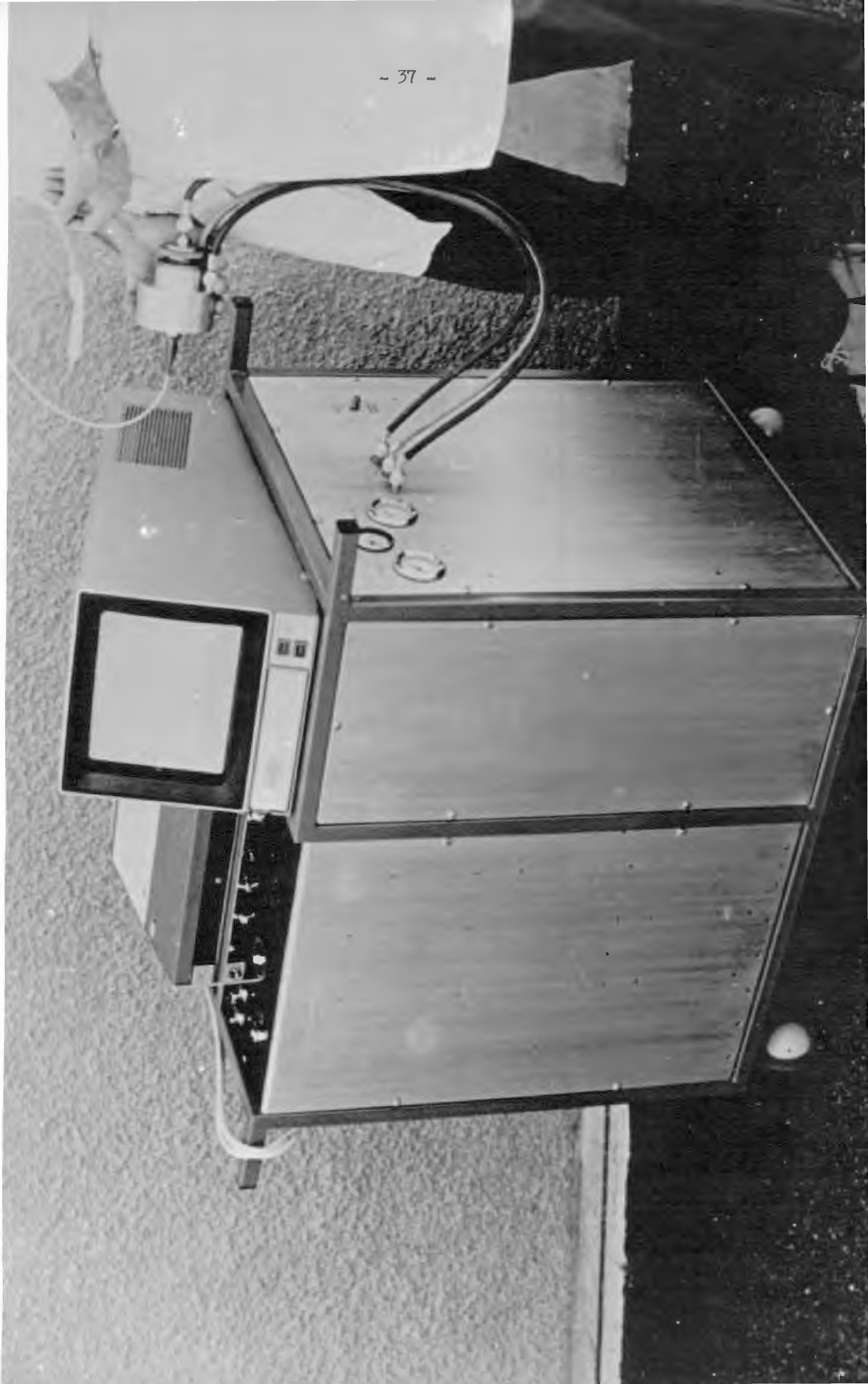
5.1. Introduction.

As Intra-aortic Counterpulsation has been shown to be a worthwhile means of assisting a patient in cardiogenic shock the objective was to build a portable and reliable system of this kind.

A number of previous researchers have encountered difficulty with their detection systems due to artifacts (i.e. noise) picked up with the ECG signal and spurious triggering from larger than normal P waves. Thus elimination of these became of prime importance in this design.

Most workers[21, 22, 23, 24, 25, 26, 27, 28], have used a solenoid valve to control the delivery of gas to the balloon but this tends to be rather noisy and relatively slow. Some have tried Helium[25,27,28] as the driver gas in an attempt to increase the response time of the system. We preferred to use fluidics coupled to a metered air pump.[29] Thus the electronics switches gas at low pressure.

We have also tried to strike a balance between a system so small that it is purely a control system, with no provision for monitoring, and one so large that it needs a number of trained operators and a room to itself. We aimed at a unit small enough to be wheeled around a hospital without difficulty, yet large



enough to be self sufficient once connected to a mains outlet. (Fig. 16). Thus a system was designed that can be operated by a doctor or nurse without any recourse to a technician. The operator controls the pump and monitors the patient's ECG and blood pressure from the same unit. (Fig. 17).

The electrical side of the system handles the monitoring of the patient and the control of the pump and was undertaken by the author.

It was required that the monitoring and control side to be able to:

1. Ensure patient safety from stray currents that could be introduced by the ECG electrodes or Blood Pressure probe.
2. Monitor the patient's ECG
3. Monitor the patient's Blood Pressure
4. Monitor the detector to enable any required change in sensitivity to be seen.

These traces to be displayed on an oscilloscope.

5. Detect the R wave in the QRS complex and deliver a signal to the control circuits.
6. Allow the operator to control the pump by varying the delay between detection and pump ON, and varying the time for which the balloon is inflated.
7. Detect a spurious signal and immediately deflate the balloon.
8. Give, at any instant, a record of the previous 8

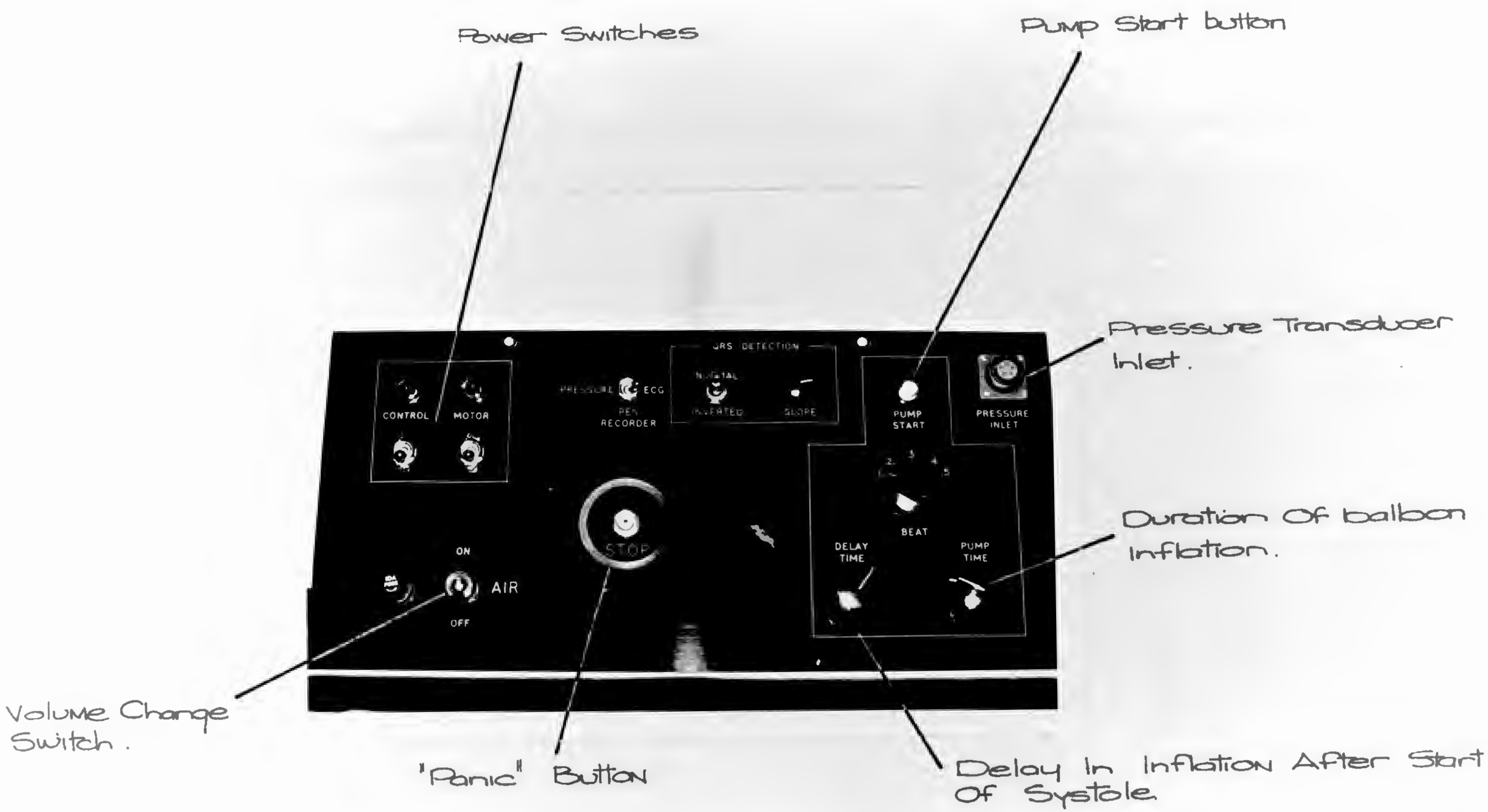


Fig. 17. Control Panel.

seconds of the ECG and Blood Pressure.

9. Be 'mastered' by a single push button. Operation of which would deflate the pump and automatically display the record of the previous 8 seconds.

10. Be reliable in service.

With these aims in mind the monitoring and control system was designed and built.

The design of the fluidic circuitry, the driver pump, balloons and the choice of the compressor used to power these items was undertaken by Mr. J.L.B. Caryer as an M.Sc. thesis that has been submitted to the Mechanical Engineering Department. Consequently the mechanical side of the system will only be described briefly with reference to Mr. Caryer's thesis.[32]

5.1. Functional Description.

The Block Diagram (Fig. 18) gives an overall picture of the system.

The patient's ECG is monitored by a HEWLETT PACKARD 1500A Electrocardiograph. As it is desired to use the Pen Recorder section of the unit for recording the Blood Pressure wave as well as the ECG, it was necessary to modify the unit. Thus the unit was altered to make the ECG signal available before it is fed into the recorder section and an input to the recorder was added.

The patient's Blood Pressure is monitored by a HEWLETT PACKARD 1280B Pressure Transducer. This is an AC excited, moving slug device. Signal detection, amplification and the

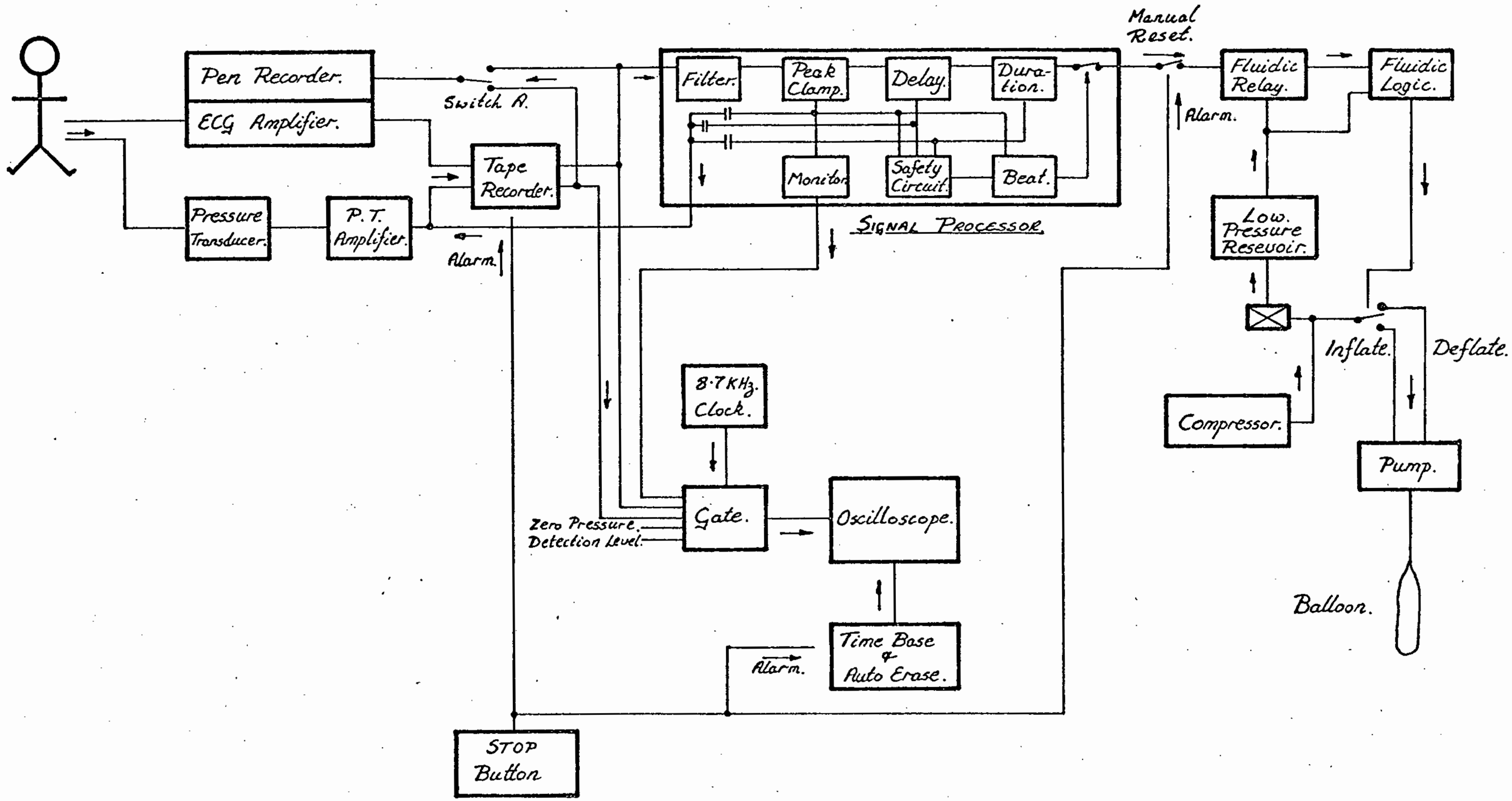


Fig. 18. The Block Diagram

AC excitation is provided by a complete printed circuit board normally contained in a HEWLETT PACKARD 780-9 Patient Monitor, Systolic, Diastolic Pressures.

These two signals are fed into a modified HEWLETT PACKARD 750B Signal Delay Unit. This unit is a twin channel, endless loop FM tape recorder, the tape loop running for 8 seconds to be compatible with the sweep rate of the oscilloscope. The recorder is designed to allow the signals being recorded to appear simultaneously at its output terminals, thus removing any need for a bridging circuit. The tape recorder is normally continuously recording, erasing and re-recording. On receipt of an alarm signal the modification switches it into its playback mode when the output terminals are connected to the playback head. The tape records are displayed on the oscilloscope and, as the loop continues to run they may be recorded on the Pen Recorder. At the end of the alarm the tape recorder is reset automatically.

Either the ECG, or the blood pressure signal can, at any time, be recorded, via switch A, on the Pen Recorder.

The ECG signal is fed into the Signal Processor where it passes through a 3-30Hz band-pass Filter to remove unwanted signals generated by muscular activity, thus eliminating the wandering of the ECG. From the Filter the signal is led, via a switch, to the Peak Clamp circuit used as a detector. This switch enables the operator to invert the ECG if necessary.

The R wave is detected by the Peak Clamp and the detection current spike is used to trigger the Delay monostable, a high noise immunity monostable with an astable state variable between 50 and 450 milleseconds. This Monostable is used to create a delay between the QRS complex and the inflation of the balloon, to allow the heart to contract, eject its blood and the aortic valve to close again. When this monostable returns to its stable state it triggers the Pump monostable, an identical monostable, that controls the time for which the balloon is inflated.

Spikes, corresponding to the detection of the R wave, the end of the delay period, and the end of the pump period, are superimposed on the Blood Pressure wave. This enables the operator to set the Delay and Pump monostables visually. (Fig. 19).

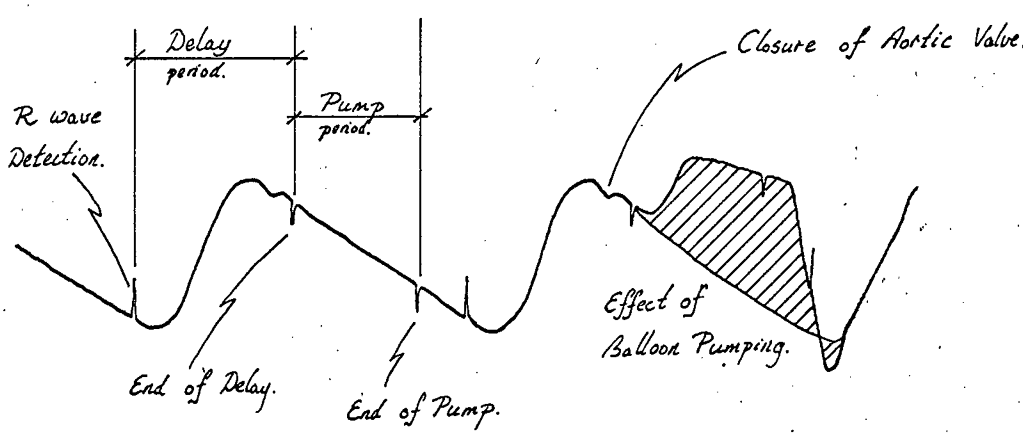


Fig. 19. Marker spikes on pressure wave.

The large positive spike corresponding to the R wave detection point and the two smaller negative spikes corresponding to the end of the delay and the end of the pump periods respectively.

To prevent the possibility of an extra systole causing the heart to pump against an inflated balloon a Safety Circuit was designed. This causes the balloon to deflate if another R wave is detected while either the Delay or Pump monostables are in their astable states. The output of the Safety Circuit is fed to the Beat Counter causing it to 'clear' and inhibit the output of the Pump monostable. The Beat Counter is also used to enable the operator to choose whether to inflate the balloon after every heart beat, or after every second, third, fourth or fifth heart beat.

The output of the Pump monostable is fed through the Manual Reset switch to the Fluidic Relay.

For monitoring purposes the ECG and Blood Pressure signals are fed into a 5-Input Gate together with a Zero Pressure line, a Detection Level line and a signal derived from the Peak Clamp. This signal is used together with the Detection Level line to determine whether the R wave of a particular QRS complex has been detected. Detection occurs if the R wave crosses the Detection Level line. (Fig. 20). If the R wave is not being detected, the sensitivity of the Peak Clamp can be increased by increasing the discharge rate of the Condensor. However as any crossing of the Detection Level line will be interpreted as an R wave care must be taken not to allow a P wave to cross the line

The 5-Input Gate is used to display the five signals on the Oscilloscope. The Gate is effectively five switches onto a common line to the Oscilloscope, the switches close sequentially. A8,720 Hz Clock is used to drive the 5-Input Gate, thus causing each trace to be sampled 1,544 times a second. The output from the Gate is fed to the Y-axis of the Oscilloscope.

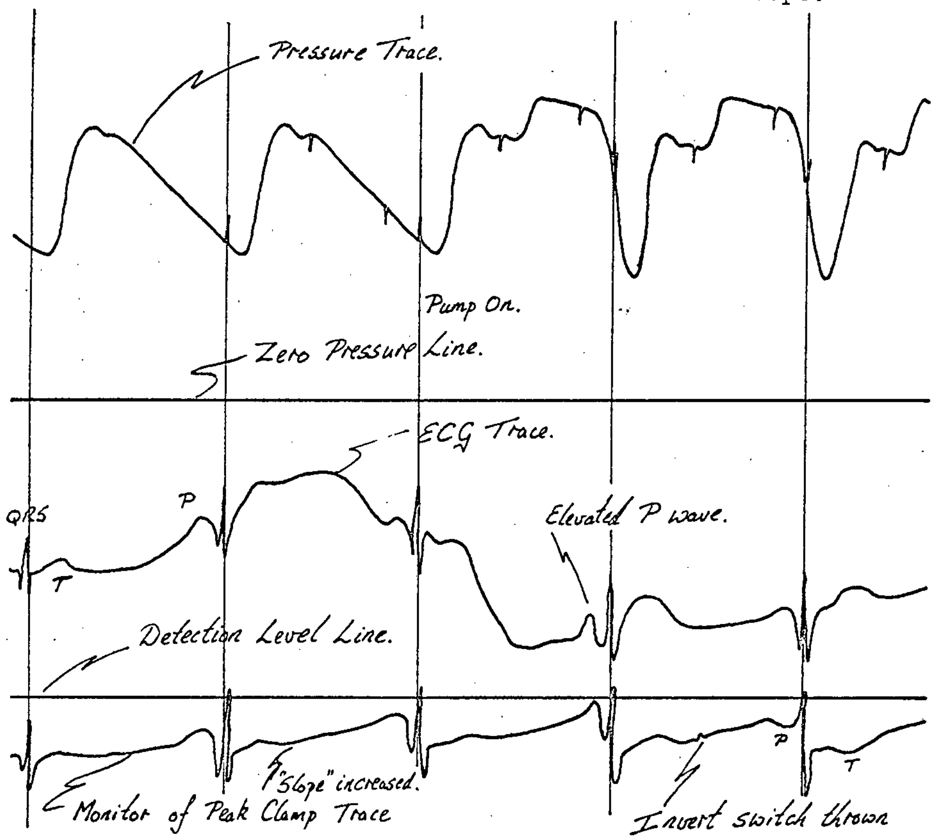


Fig. 20. Typical Oscilloscope Traces.

Note: (i) The Detection Point signal from the Peak Clamp does not wander with the ECG Signal due to the action of the Filter.

(ii) If the R wave is not detected, the Marker Spikes do not appear on the pressure wave.

(iii) With a greatly increased discharge rate the P wave is liable to cross the Detection line.

The display unit is a TEKTRONIX Type 611 Storage Oscilloscope. This unit is a cathode ray tube with buffer amplifiers allowing a 1 volt full scale deflection of the X and Y axes and a 1 volt (minimum) turn on for the Z-axis.

A Time Base and Auto Erase circuit were built to give a sweep rate of 8.4 seconds, this sweep being stored as it appears. At the end of each sweep the resultant trace is automatically erased and the next sweep starts.

The Fluidic Relay converts the electrical signals from the Signal Processor to low pressure (15" water gauge) air signals which are fed to the Fluidic Logic circuit. This circuit in turn controls the high pressure (40 p.s.i.) air that is used to drive the Pump which inflates and deflates the Balloon. The air required is supplied by a DEVILBLISS "TUFFY" diaphragm compressor.

The STOP button is used to "put" the system in an alarm mode by causing the following changes:

1. It causes the Pump to deflate the Balloon by tripping out the Manual Reset switch.
2. It puts the tape recorder into its playback mode.
3. It automatically erases the Oscilloscope screen, irrespective of the position of the sweep, and starts a new sweep with the input signals to the Gate being those previously recorded on the tape loop. At the end of this sweep the time base stops without erasing the data which is stored on the screen. The tape continues to run in the playback mode allowing the operator to make a paper recording of the ECG and/or aortic pressure during the last 8 seconds prior to the pressing of the STOP button.

When it is desired to restart the monitoring and control system the STOP button is pressed again. This has the effect of setting the machine back to normal:

1. It returns the tape recorder to the normal mode.
2. It erases the Oscilloscope screen and restarts the Time Base and Auto Erase System.

With the machine running in this mode, everything is functioning except the Fluidic Relay and consequently the Pump. To restart the Pump the Manual Reset switch is closed by pressing the Pump Start button.

For a complete description of the operating procedure refer to the copy of the INSTRUCTIONS TO OPERATORS contained in Appendix C.

5.2. Technical Description.

The circuit diagrams contained in the body of the text are, usually, part of larger diagrams. The complete circuit diagrams are contained in Appendix A and are identified by the letter A in front of the figure number, i.e. Fig. A4.

5.2.1. ECG Amplifier and Pen Recorder.

A HEWLETT-PACKARD 1500A Electrocardiograph is used to detect the patient's ECG. This unit was selected because of its good patient isolation and high common mode rejection, greater than 114 dB. in any lead. These are achieved by a floating input and a right leg driver amplifier both of which reduce common mode voltage susceptibility. The floating amplifier ensures a minimum of 30 Mohms isolation from power line connections.

As it is necessary to be able to record the patient's aortic pressure wave on the Pen Recorder of the instrument a modification was necessary. This entailed breaking the connection between Test Point 7 and the base of transistor Q103 (Fig. 21: Part of Fig. A1) and removing the lead to the Scope Output Jack. A screened lead was inserted between Test Point 7 and the Scope Output Jack thus giving an ECG signal output which is fed directly to the Tape Recorder. Another screened lead was inserted between the base of Q103 and an RCA jack,

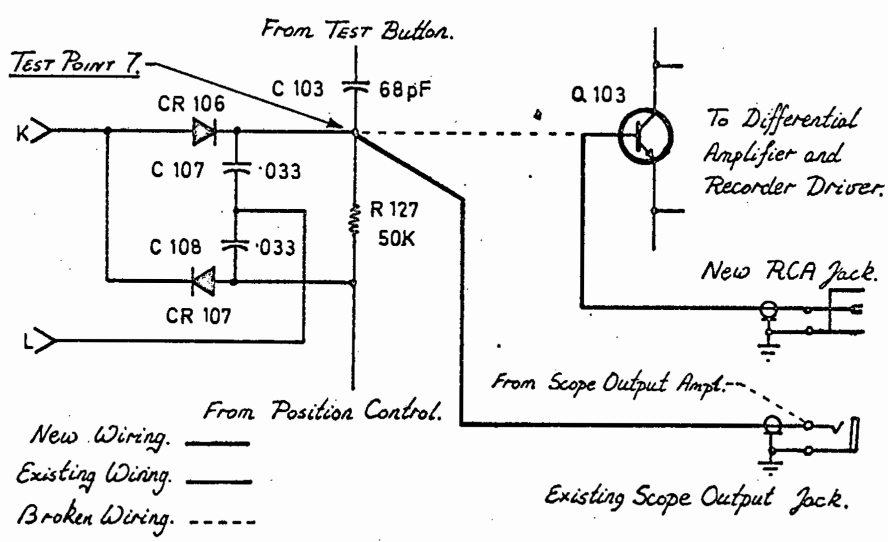


Fig. 21. Modification to Electrocardiograph.

which was mounted alongside the existing jack, thus giving an input to the Pen Recorder.

The 'Position' control of the ECG Amplifier controls the position of the ECG trace. A similar 'Position' control circuit was built to control the position of the blood pressure trace.

5.2.2. Pressure Transducer.

A HEWLETT-PACKARD 1280B Pressure Transducer is used to monitor the patient's blood pressure. The transducer is a moving slug device using a floating 2.4 KHz AC excitation provided by the Pressure Transducer Amplifier and provides high patient isolation. Leakage current is less than 1 μA at 800V. It also has the great advantage that all transducers of this design have identical characteristics. Therefore there is no calibration necessary.

5.2.3. Pressure Transducer Amplifier.

The Carrier card from a HEWLETT-PACKARD 780-9 Patient Monitor Systolic, Diastolic Pressures was used. This card provides the 2.4 kHz carrier frequency required to excite the Pressure Transducer. The output from the transducer is returned to the card where it is amplified and demodulated. (Fig. A2).

Normally the internal power supplies of the 780-9 provide the power to the card. As the complete unit was not being used the -22V full wave, rectified DC and the +12V and -12V regulated DC supplies were taken from the Tape Recorder.

The card was mounted in an edge connector and A3R1 the ZERO set, A3R3 the SENSITIVITY set and A3S3 the 200 MM CAL button were mounted on the Clock Board (Fig. A5) together with a 'Position' control circuit similar to that in the Electrocardiograph. When the transducer and amplifier were tested the performance was so good that we decided to mount these controls inside the machine in an effort to reduce the number of controls on the front panel. Switch S1 was set to the X1 position.

The output of the Pressure Transducer Amplifier was fed to the 'Position' control circuit through R531. (Fig. 22: Part of Fig. A5). The 'Position' control R536 biases the base of Q531 so that its emitter current will flow through R534. The marker spikes are also introduced at this point and the signal is then fed to the Tape Recorder.

5.2.4. Tape Recorder.

The Tape Recorder, a HEWLETT-PACKARD 7805B Signal Delay

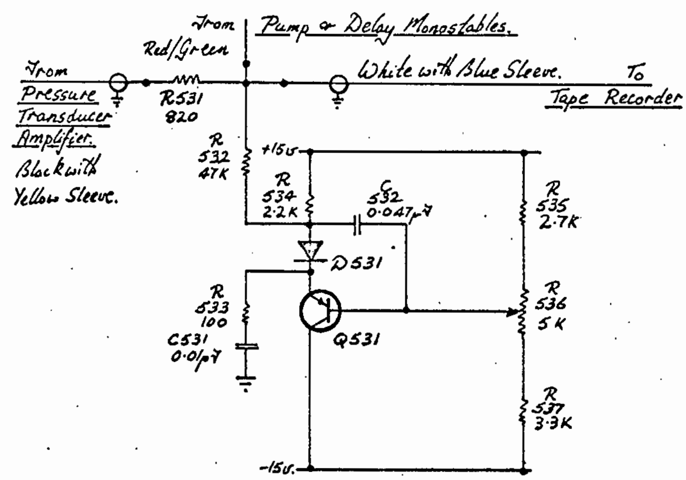


Fig. 22. Pressure 'Position' Circuit.

with the standard 01 option to convert it to a twin channel instrument, stores the received signals on an endless magnetic tape loop. The tape loop length was chosen to be 8 secs., thus when the system is in the Alarm Mode all the stored signals on the loop will appear in a single, 9 secs., sweep of the Oscilloscope screen.

The standard tape loop lengths are 3 secs, 40 secs, 5 mins and 15 mins. As none of these times were suitable for the system, loops of the correct length were made for the cassettes. Great care must be excercised in the handling of the tape to prevent noise due to creases or splicing. Early attempts to make our own cassettes were only partially successful as the background noise on the tapes tended to derate the recorded signals noticeably, especially the Marker Spikes on the pressure wave. Eventually we tried SCOTCH 404, a high quality, thin, mylar based tape and the background noise level was found to be of the same order as that on the tapes Hewlett-Packard supplied for demonstration purposes.

The unit is designed to have three operating modes; DELAY, AUTO and REPRO.

In the DELAY mode the instrument continuously records and erases the endless tape loop. An Alarm puts an Alarm signal on the tape and triggers, if connected, a suitable chart recorder to run for one tape loop cycle, plus ten secs after the alarm. However once this has occured, the information is lost as the tape will have been erased and re-recorded.

In the AUTO mode, the unit continuously records and erases until an Alarm occurs. If the Alarm persists for more than 10 secs, the unit automatically stops.

In the REPRO mode, information previously stored on the tape, such as a signal recorded in the AUTO mode after an Alarm, is reproduced. In the REPRO mode the erase/record head is disabled thus no data is erased.

We did not have a triggerable twin channel recorder available to take permanent records on, therefore none of these modes suited our purpose exactly and the unit was modified. We wanted a unit that would run in the AUTO mode and, on receipt of an Alarm signal, would automatically switch to the REPRO mode.

This was done by making minor alterations to the circuitry and inserting a relay with a mechanical latch holding it closed once it has been energised. Thus it is possible to pulse the

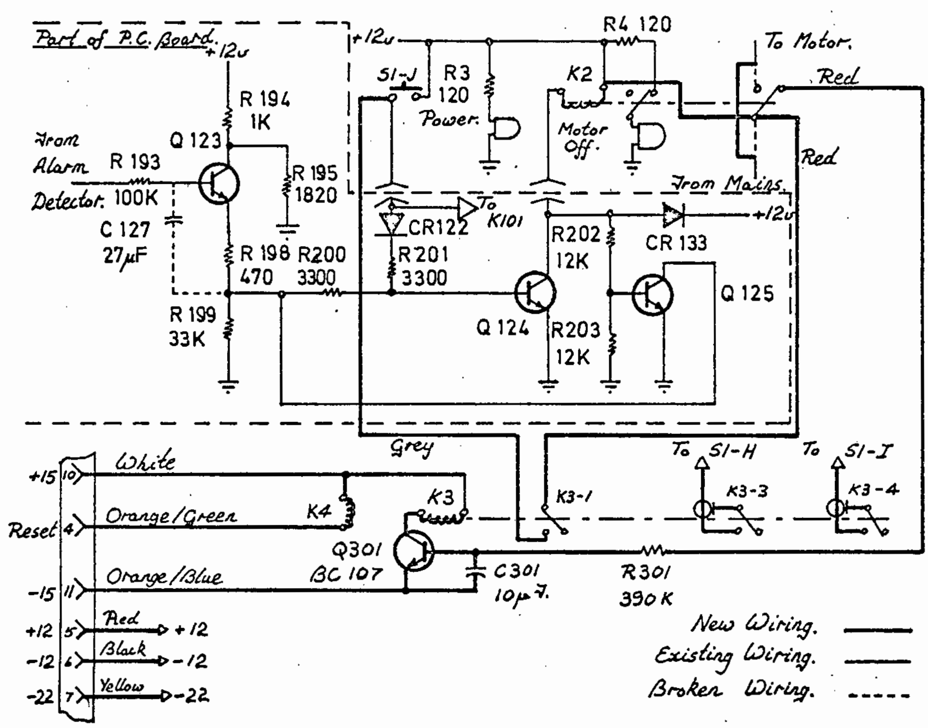


Fig. 23. Modifications to the Tape Recorder.

relay closed and it remains so until the latch is pulsed open.

Under normal circumstances when the unit is in the AUTO mode Q124 is biased On by the action of Q123. (Fig. 23: Part of Fig. A3). If an Alarm occurs and persists for longer than 10 secs, C127 charges and turns Q123 Off thus turning Q124 Off causing relay K2 to de-energise and stop the motor. Q125 acts as a latch to keep Q124 Off. The unit is restarted by pressing either the DELAY, or REPRO buttons. Either of these close S1-J and apply +12V through CR122 and R201 to turn Q124 On. Once the motor has restarted the AUTO button is pressed to return the unit to the AUTO mode.

To achieve our objective the AUTO mode was selected and C127 removed to allow the unit to respond immediately to an Alarm signal. The motor was not required to stop, as the unit was to switch straight into the REPRO mode, thus the motor wires disconnected from relay K2 and were joined. This set of contacts was then used to close relay K3, which latches closed. (Fig. 24).

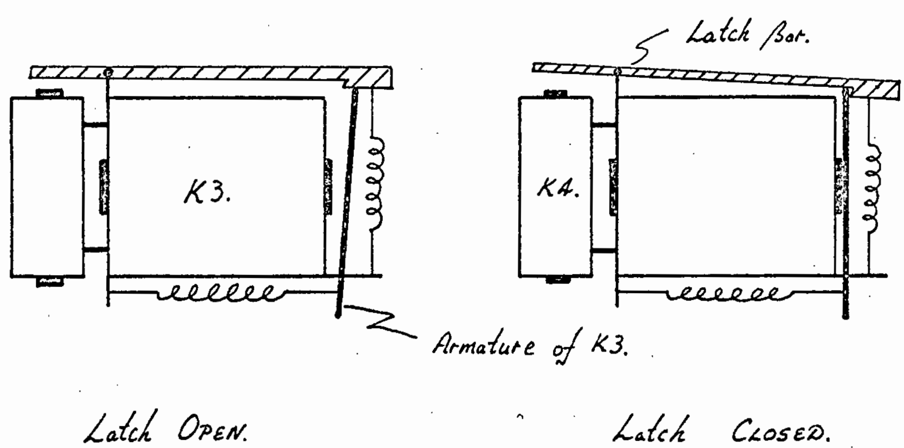


Fig. 24. Action of Mechanical Latch.

Contacts 1,3 and 4 of relay K3 are in parallel with S1-H, S1-I and S1-J. With K3 closed contacts A, B, C, D, F, G, H, I and J of S1 are closed and relay K101 is energised. This corresponds to the unit being in the REPRO mode. (See Table on Fig. A3).

K101 is the output change over relay. When it is de-energised the output terminals are connected directly to the input terminals. When it is energised they are connected to the playback heads. K101 is energised through K3-1 which also re-energises K2, by turning on Q124 as described above. When K2 closes Q301 is turned off. However K3 does not open due to the mechanical latch.

To revert to the AUTO mode K4 is pulsed to lift the mechanical latch and permit K3 to open, thus opening S1-H, S1-I, S1-J and de-energising K101. It was found that the whole circuit responded so quickly to an Alarm that an Alarm Marker signal was not recorded before the record heads were shorted. C301 was inserted to allow this signal to be recorded before K3 closes and shorts the record heads.

The outputs of +12V, -12V and -22V were required to power the Pressure Transducer Amplifier, as previously described.

5.2.5. Signal Processor.[30] (Fig. A4).

(a) Filter.

A Filter was incorporated to remove artifacts picked up with the ECG signal. These can be of both low and high frequency, compared to the R wave of the QRS complex. The low frequency artifacts are normally caused by muscular contractions, i.e. movement of a limb or stretching. The high frequency artifacts are normally caused by phenomena such as muscular spasms.

The R wave pulse is usually of approximately 70m secs duration. Corresponding to a frequency of approximately 15 Hz. To allow for variations in the duration of the R wave, with varying heart rate and stress, a band-pass filter with 3 Hz and 30 Hz as the

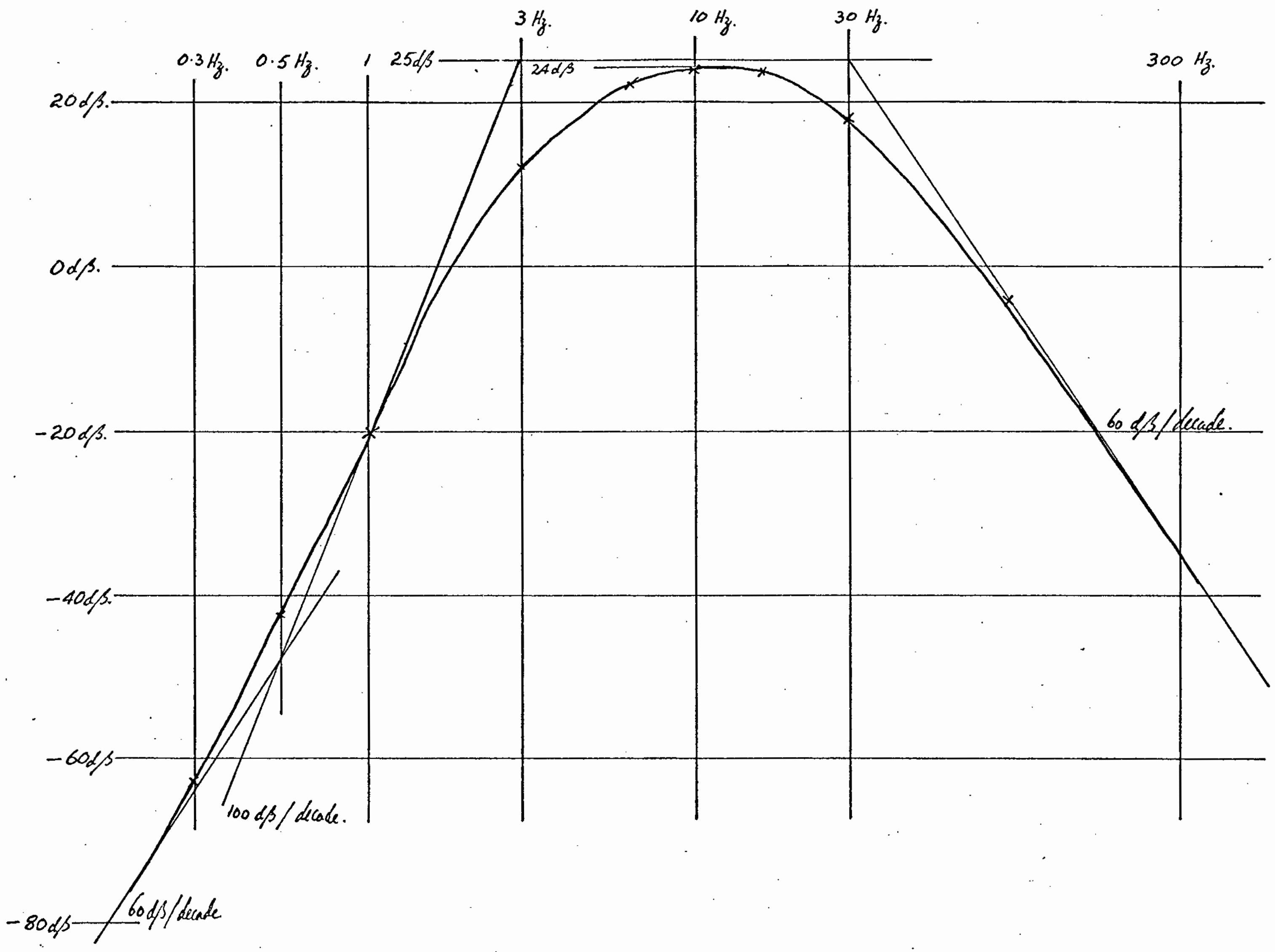


Fig. 26. Filter Frequency Response Curve.

approximate lower and upper break points, was designed. 31

The equation $f = \dfrac{1}{2\pi CR}$ gives the CR values necessary.

Low Frequency Break CR = 50m secs

High Frequency Break CR $\doteq$ ·5m secs

The filter was built with 5 Low Frequency Breaks and 3 High Frequency Breaks. (Fig. 25).

R401 and C401 make the first HF break: CR = 4.7m secs.

R402 and C402 make the first LF break: CR = 50m secs.

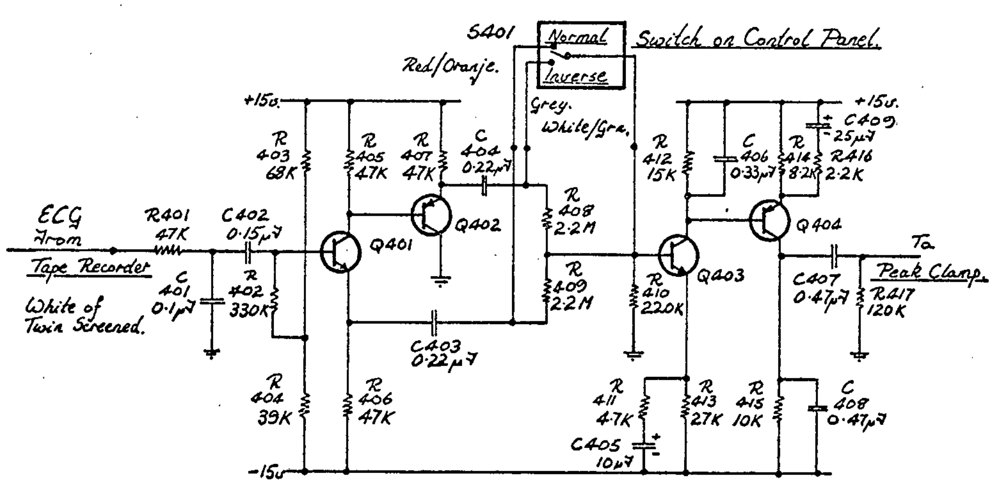


Fig. 26. Filter Circuit.

These breaks were inserted before any amplification occurs to prevent noise from overloading the amplifiers. (Fig. 26).

With S401 in the NORMAL position Q401 acts as an emitter follower and the signal passes through the second LF break, formed by R410 and C403, to Q403. With S401 in the INVERSE position Q401 acts as an inverter and the signal is passed through Q402 and the second LF break, formed by R410 and C404, to Q403: CR = 48m secs. R408 and R409 provide for quiet switching of

C403 and C404.

Q403 amplifies the signal and incorporates an HF break, formed by R412 and C406: CR = 5.0m secs, in its collector and a double LF break, formed by R411, R413 and C405, in its emitter. At low frequencies C405 is a high impedence and R413 acts as the emitter resistor. Thus the low frequency gain R_L/R_E is given by $\frac{R412}{R413} = 0.55$. As the frequency rises and the impedence of C405 approaches that of R413 a break occurs: CR = 270m secs. (0.6 Hz.) As the frequency rises further the gain of the stage rises until C405 breaks with R411: CR = 47m secs. The low frequency gain is now given by $\frac{R412}{R413//R411} = 3.7$. The signal is further amplified by Q404 which also incorporates an HF break, formed by R415 and C408: CR = 4.7m secs, in its collector and a double LF break, formed by R414, R416 and C409, in its emitter. At low frequencies C409 is a high impedence and R414 acts as the emitter resistor. Thus the low frequency gain is given by $\frac{R415}{R414} = 1.2$. As the frequency rises C409 breaks with R414: CR = 205m secs. (0.5 Hz). As the frequency rises further the gain of the stage rises until C409 breaks with R416: CR = 55m secs. The low frequency gain is now given by $\frac{R415}{R414//R416} = 5.8$. These double LF breaks account for the change in the slope of the low frequency side of the filter response curve (Fig. 25).

The signal is now fed to the Peak Clamp circuit through the final LF break formed by R417 and C407: CR = 56m secs.

(b) Peak Clamp. (Fig. 27).

Q405 acts as a buffer to the last stage of the Filter.

The signal is then fed to C410. D401 and the base-emitter junction of Q406 act as the clamping diode, D401 protects the base-emitter junction against reverse voltages. The current spikes through D401 and the base emitter junction saturate Q406, the collector of which makes a 15V to 0V excursion. This spike is fed to the Delay monostable. R420, R452 is the discharge resistor. R452 allows the rate of discharge of C401 to be varied and thus the sensitivity of the clamp to the input pulses.

Q412 and Q413 form a high input impedence, bootstrap, emitter

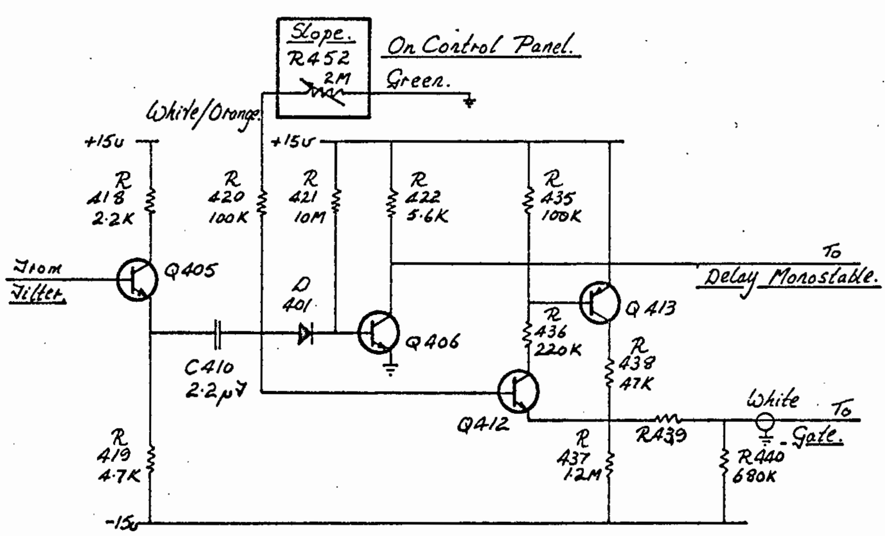


Fig. 27. Peak Clamp Circuit.

follower which monitors the clamp circuit. R439 acts as a dropper resistor to reduce the signal amplitude. R440 applies a negative bias voltage to position the trace of the screen.

A monitor is necessary to enable the operator to observe the action of the clamp and see whether a P wave is liable to be detected. P wave detection can be avoided either by reducing the discharge rate of C410 or by inverting the signal. This is accomplished with the NORMAL/INVERSE switch. (Fig. 26).

(c) Delay and Pump Monostable. (Fig. 28)

Q407 inverts the signal and C411 delays the arrival of the negative going edge, selected by D405 at the Delay Monostable. These actions are dictated by the requirements of the Safety Circuit Logic. (Section 5.2.5d.)

R425, R426, R427, R428, R453, C412, Q408 and Q409 comprise a high noise immunity monostable, the Delay period monostable. 5V noise immunity is provided by the common emitter configuration.

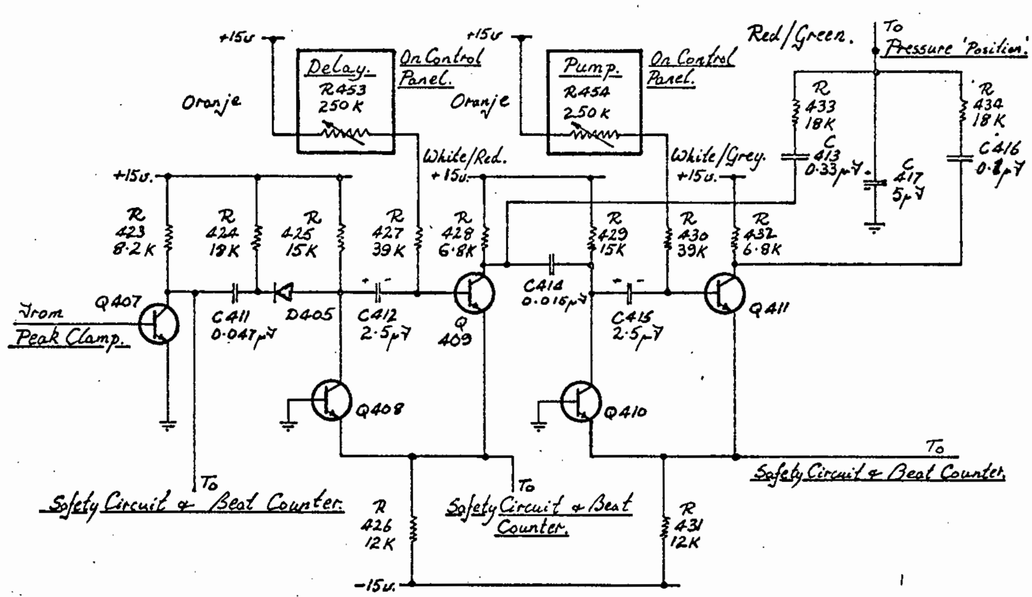


Fig. 28. Delay and Pump Monostables.

Normally Q409 is On and its emitter is at +4V. Before Q408 can turn On the emitter junction must fall below -0.7V. Consequently the monostable will not fire without a negative going pulse of at least 5V. R427 acts as a stopper resistor for R453 which is used to vary the length of the astable period between

50 and 450m secs. Before this design was adopted we experienced difficulties with our monostables firing on low, 0.7V, voltage noise spikes.

The collector of Q409 provides a 15-4V transition at the end of the astable period. This is coupled, through C414, to the Pump period monostable, comprised of R429, R430, R431, R432, R454, C415, Q410 and Q411, an identical monostable which also provides a variable astable period of 50-450m secs.

The collector outputs of the Delay and Pump monostables are coupled to the Pressure 'Position' circuit, through C413, R433 and C416, R434 respectively, to provide the Marker Spikes on the Pressure wave trace. These indicate the detection of the R wave, the end of the Delay period and the end of the Pump period. C417 slows and widens the spikes to allow them to be "written" on the Oscilloscope. When the Delay monostable is fired by the Peak Clamp a positive spike is provided via C413 and R433. This establishes the point of detection of the R wave. At the end of the Delay period a negative spike is provided. However the Pump monostable now fires and provides a positive spike via C416 and R434. This positive spike is smaller than, but coincident with, the negative spike from the Delay monostable. The result is a negative spike of approximately half the amplitude of the positive spike. This establishes the end of the Delay period. The end of the Pump period provides another negative spike of the same amplitude as the previous one.

(d) Safety Circuit and Beat Counter. (Fig. 29)

The input from the Pump monostable is taken from its emitter output, buffered by Q415 and fed through Q416, if it is conducting, to the Manual Restart circuit.

The input from the Peak Clamp is used to clock IC5, a 5-Bit Shift Register (See Appendix B) with the Serial Input, pin 9, held high. Consequently each detection pulse shifts a 1 into the first flip-flop. If S402, the BEAT switch, is set to 1 the output of the first flip-flop is applied to the base of Q416 removing the inhibit. The positive going edge at the end of the

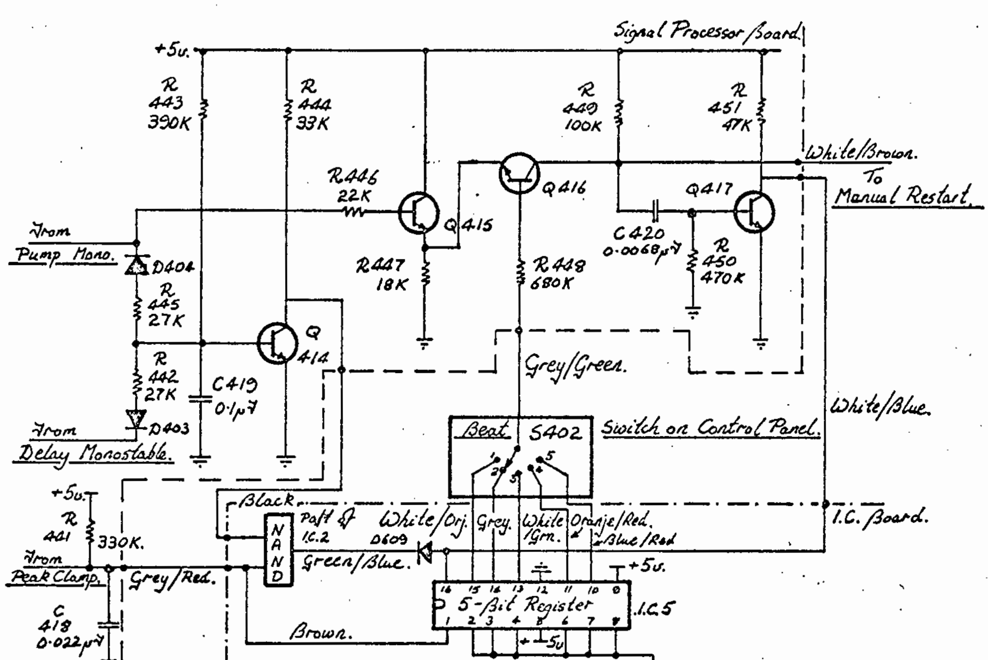


Fig. 29. Safety Circuit and Beat Counter.

Pump period is differentiated by C420, inverted by Q417 and used to clear IC5. If S402 is set to some other position, say 4, the output of the fourth flip-flop holds Q416 Off until the fourth beat. Q416 then opens, the Pump signal is allowed through and the 'end of Pump' edge again clears the register. C418 was inserted to increase the rise time of the pulse from the Peak Clamp as IC5 sometimes failed to clock satisfactorily.

D403 and D404 act as a negative logic OR gate, the inputs of which are taken from the emitter outputs of the Delay and Pump monostables. These normally are at +4V and fall to 0V when the appropriate monostable fires. Thus 0V at the base of Q414 indicates that one of the monostables is active. This is inverted by Q414 to provide 5V at one input of a dual NAND gate. (Part of IC2, see Appendix B). The other input is the positive R wave detection spike. Thus if either monostable is active and an R wave is detected the output of the NAND gate falls to 0V and clears IC5, through D609, which inhibits the output of the Pump monostable by turning Off Q416.

This circuit prevents the heart from beating against an inflated balloon, which could otherwise occur due to either an extra systole, or an increase in heart rate causing an incompatibility between the machine settings and patient demands.

Initially the circuit did not work because the Delay monostable was directly coupled to the junction of Q407 and R423 (Fig. 28) and it fired so quickly that the NAND gate "saw" the firing R wave as coincident with the Delay monostable being active and cleared IC5. This was cured by inserting C411 to delay the firing of the Delay monostable. (Fig. 30).

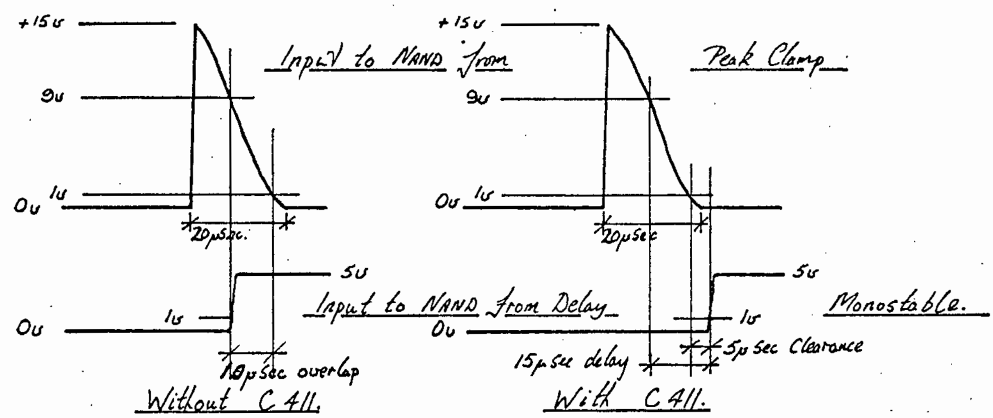


Fig. 30. Effect of C411

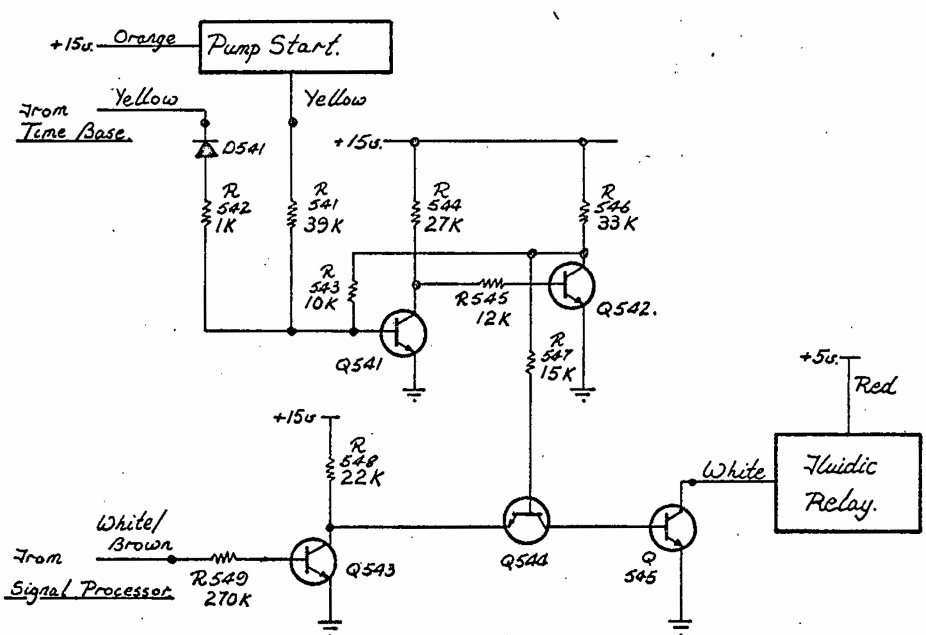


Fig. 31. Manual Restart Circuit.

5.2.6. Manual Restart (Fig. 31: Part of Fig. A5).

The signal from the Signal Processor is inverted by Q543 and is fed through Q544, if it is conducting, to Q545 which switches the fluidic relay.

The manual restart bistable inhibits Q544 until the PUMP

START button is pressed. This causes the bistable to change state and opens the signal path through Q544.

When the STOP button is pressed an Alarm is signalled by the appearance of OV at the cathode of D541, this reverses the bistable, returning the inhibit to Q544. When the STOP button is pressed again, to reset the system, the OV at the cathode of D541 is replaced by +5V and the bistable can be reset by the PUMP START button.

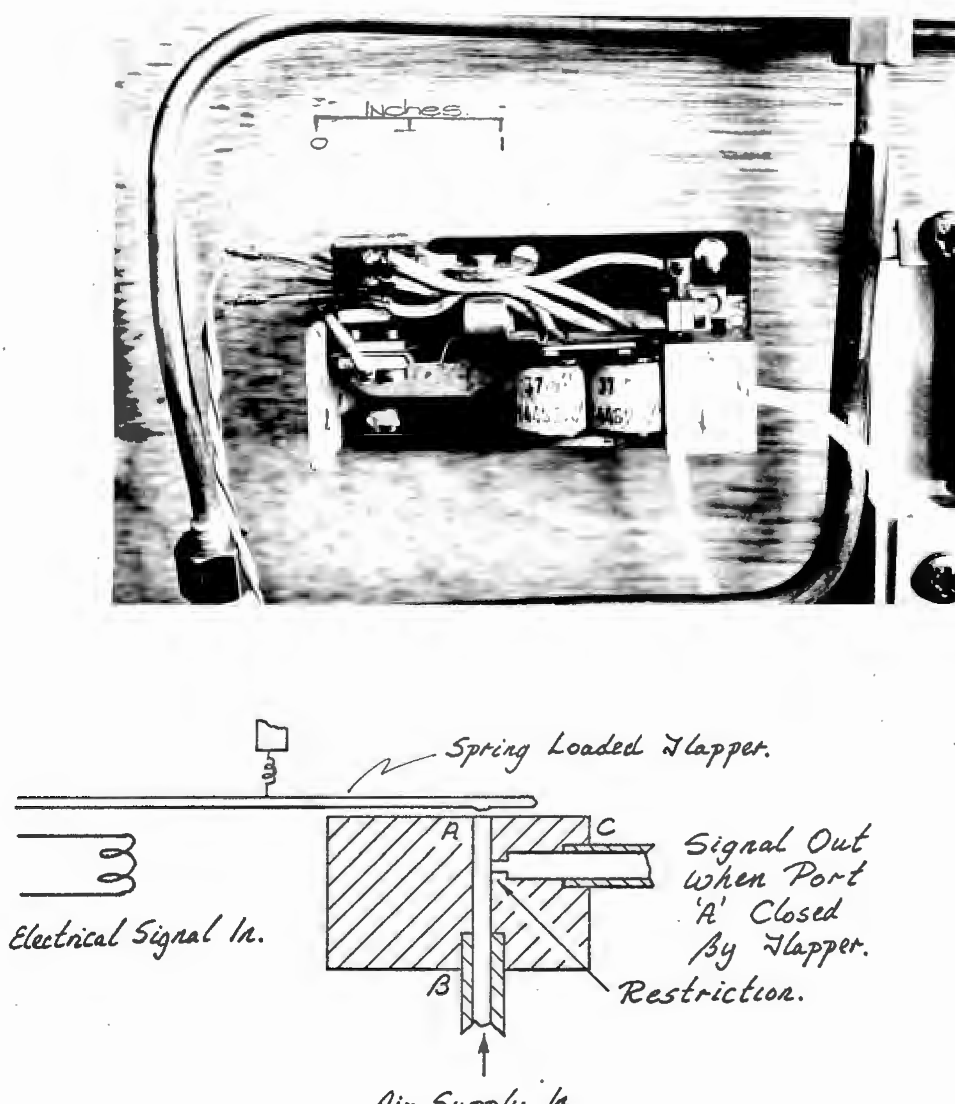


Fig. 32. Fluidic Air Switch.

5.2.7. Fluidic Air Switch.

The electronic/fluidic interface occurs at the Fluidic Air Switch, a 75 Ω Post Office Siemens High Speed relay. (Fig. 32). The normal armature and contacts were removed and replaced by an armature carrying a flapper and a specially machined block. When the armature is attracted to the coils the flapper closes Port 'A' and air issues from Port 'B' to switch the Fluidic Logic. This relay is mounted on the mechanical control board.

5.2.8. Clock and 5-Input Gate.

To provide the 5 traces required on the Oscilloscope screen a sampling technique was used. The 5 signals are fed to the signal inputs of a 5 Channel SILICONIX DG423L MOS FET Switch (See Appendix B) the output of which is fed to the Y-Axis of the Oscilloscope. The switches are closed sequentially by a 5-bit shift register driven by a 8,720 Hz multivibrator clock. Thus giving an individual trace sampling rate of 1,744 Hz.

Experimentation with sampling frequencies showed that to obtain an, apparently, continuous trace a signal should be sampled at above 400 Hz i.e. 2 kHz overall. However if the overall clocking rate was above 10 kHz the screen tended to flood between traces. 8.5 kHz was selected as suitable order of clock frequency. There is no tendency to flood the screen between traces, at normal writing intensities, and the individual sampling rate of 1.7 Hz allows faithful reproduction of the received signals.

A common emitter multivibrator was built to act as the Clock and runs at 8,720 Hz. (Fig. 33: Part of Fig A5). This drives Q512 through R514 to clock two 5-bit shift registers. IC4 and IC1 which drive the gate IC3.

IC4 acts as a starter for IC1 which drives the gate IC3. (Fig. 34: Part of A6). There is a permanent 1 on the Serial Input, pin 9, to IC4. Thus the register fills with each clock pulse until a 1 reaches the fifth flip-flop (E). The arrival of a 1 at the output of the fifth flip-flop injects a 1 into the first flip-flop (A) of IC1 via its Preset Enable, pin 8. Preset A being held at 1, pin 2. This 1 is also fed back via an inverter

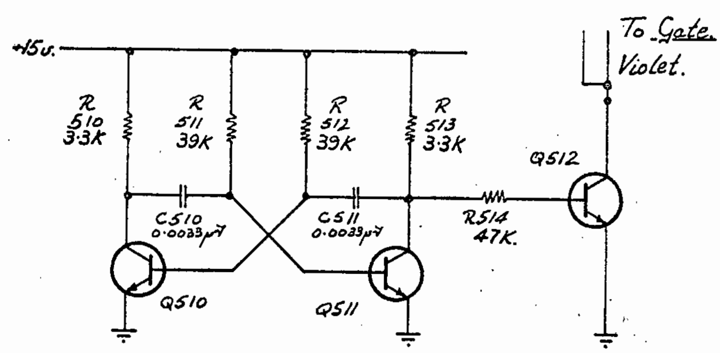
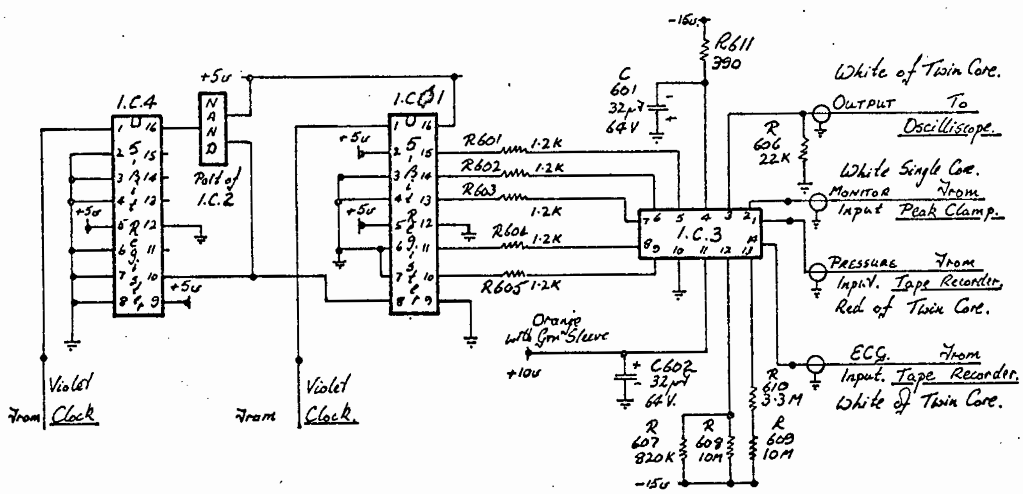


Fig. 33. Multivibrator Clock.

(1 gate of a Quad NAND: Part of IC2. See Appendix B) to the Clear of IC4. Successive clock pulses now fill IC4 again and shift the injected 1 along IC1. Every fifth pulse shifts the 1 out of IC1 while IC4 injects another 1. (See Table 1).

As this design is regenerative a spurious pulse cannot put the system into an inacceptable mode for longer than 5 clock pulses. Originally the system was designed to have one 5-bit shift register with Output E fed back to the Serial Input to to make it into a Ring Counter. (Fig. 35). When the system was switched on a Scmitt Trigger sensed the charging level of a capacitor. When the Schmitt Trigger changed state a bit was introduced and was shifted around the Ring. However, if a spurious pulse either cleared the Ring, or introduced another bit, an inacceptable situation occurred. The only means of rectifying this was to switch Off and On again.

The outputs of IC1 are connected to the switching inputs



Inputs 2, 12, 13, 14. have two IN914 Diodes back to back to Ground.

Fig. 34. 5-Input Gate.

Clock Pulse.	IC4 Outputs A	B	C	D	E	IC1 Outputs A	B	C	D	E
1	1	0	0	0	0	0	0	0	0	0
2	1	1	0	0	0	0	0	0	0	0
3	1	1	1	0	0	0	0	0	0	0
4	1	1	1	1	0	0	0	0	0	0
5	1	1	1	1	1	1	0	0	0	0
	0	0	0	0	0					
6	1	0	0	0	0	0	1	0	0	0
7	1	1	0	0	0	0	0	1	0	0
8	1	1	1	0	0	0	0	0	1	0
9	1	1	1	1	0	0	0	0	0	1
10	1	1	1	1	1	1	0	0	0	0
	0	0	0	0	0					
etc.										

Table 1.

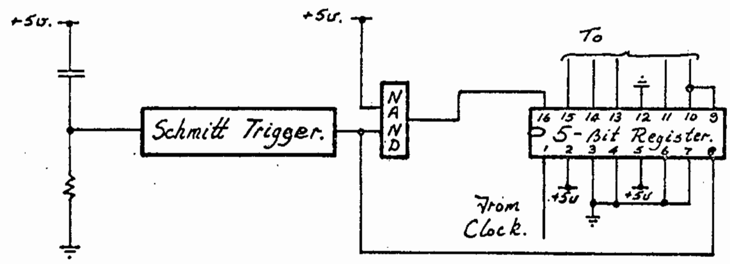


Fig. 35. Original Gate Drive Circuit.

of IC3 through R601-605 which act as switching current limiters. R606 acts as a load resistor for IC3. Diodes D601-608 prevent signals greater than $\pm$ 0.7V reaching the signal inputs to which they are connected. This signal limitation is sufficient as the Oscilloscope requires $\pm$ 0.5V full scale deflection. This was initially done at all the inputs and at the output to protect IC3 as we had experienced difficulties, apparently caused by overloading. However, these difficulties were due to incorrect usage and the diodes became redundant. They were removed from the Pressure input and the output leads because they were beginning to conduct and distort the higher portion of the Pressure trace. Because the other traces do not approach the limits of the diode blocking region, they were left in for added protection.

R607 and R608 provide the DC bias for the Detection Level line.

R609 and R610 provide the DC bias for the Zero Pressure line.

The +10V supply to IC3 is provided by a divider circuit on the Clock Board (Fig. A5) consisting of R501 and R503 and is decoupled by C602.

The -15V supply to IC3 is decoupled by R611 and C601.

5.2.9. Oscilloscope.

The Oscilloscope is a TECTRONIX 611 Storage Display Unit which uses an 11 inch storage cathode ray tube to present data. The X and Y axis deflection amplifiers require 1V for full scale deflection. The minimum Z axis turn on is 1V while practical turn on amplitudes lie between 1V and 9V.

Erasure of stored displays may be accomplished with either the front panel Erase switch or with a remote Erase signal by grounding the Erase pin of the Remote Program Connector J340. (Fig. 36). This is done at the end of every sweep by the Auto

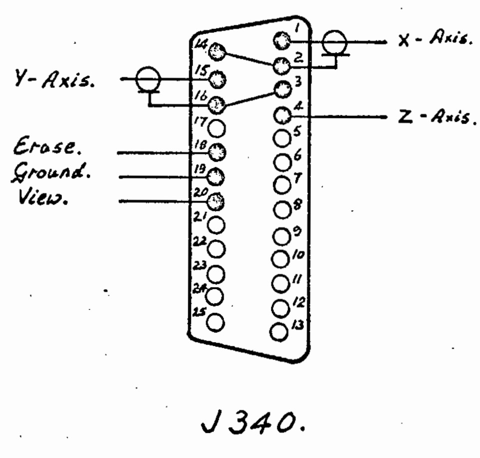


Fig. 36. Remote Program Connector.

Erase circuit (Section 5.2.10.)

When a display is stored it will remain at its normal viewing intensity for approximately 60 secs after the last Z axis turn on signal and then become very faint. At this point the unit would automatically shift to a holding mode. This is to preserve the life of the tube. To prevent this happening the View pin of J340 was grounded.

The Z axis is turned on by 5V applied to the Z axis pin of J340 through R502. The X and Y axis inputs are also fed in at J340.

When the trace is at rest it can be in one of nine positions;

Top Left Corner	Top Centre	Top Right Corner
Centre Left	Centre Screen	Centre Right
Bottom Left Corner	Bottom Centre	Bottom Right Corner.

These positions are selected on two 3 position switches inside the unit. We set the unit to be at rest in the Centre Left position. This means that full scale X axis deflection is 1V while full scale Y axis deflection is $\pm$ 0.5V.

5.2.10. <u>Time Base and Auto Erase</u>.

The sweep rate normally employed on the Pen Recorder is 25mm/sec. We decided to make the sweep rate of the Oscilloscope the same and, as the useful length of the Xaxis of the Oscilloscope is 21 cm., this meant an 8.4 sec. sweep.

When the circuit is switched on the UJT Q703 is fired by the positive voltage that appears at its emitter through the emitter-base junction of Q701 and C701. (Fig. 37). C701 is then charged through R715 and the UJT, until the emitter of the

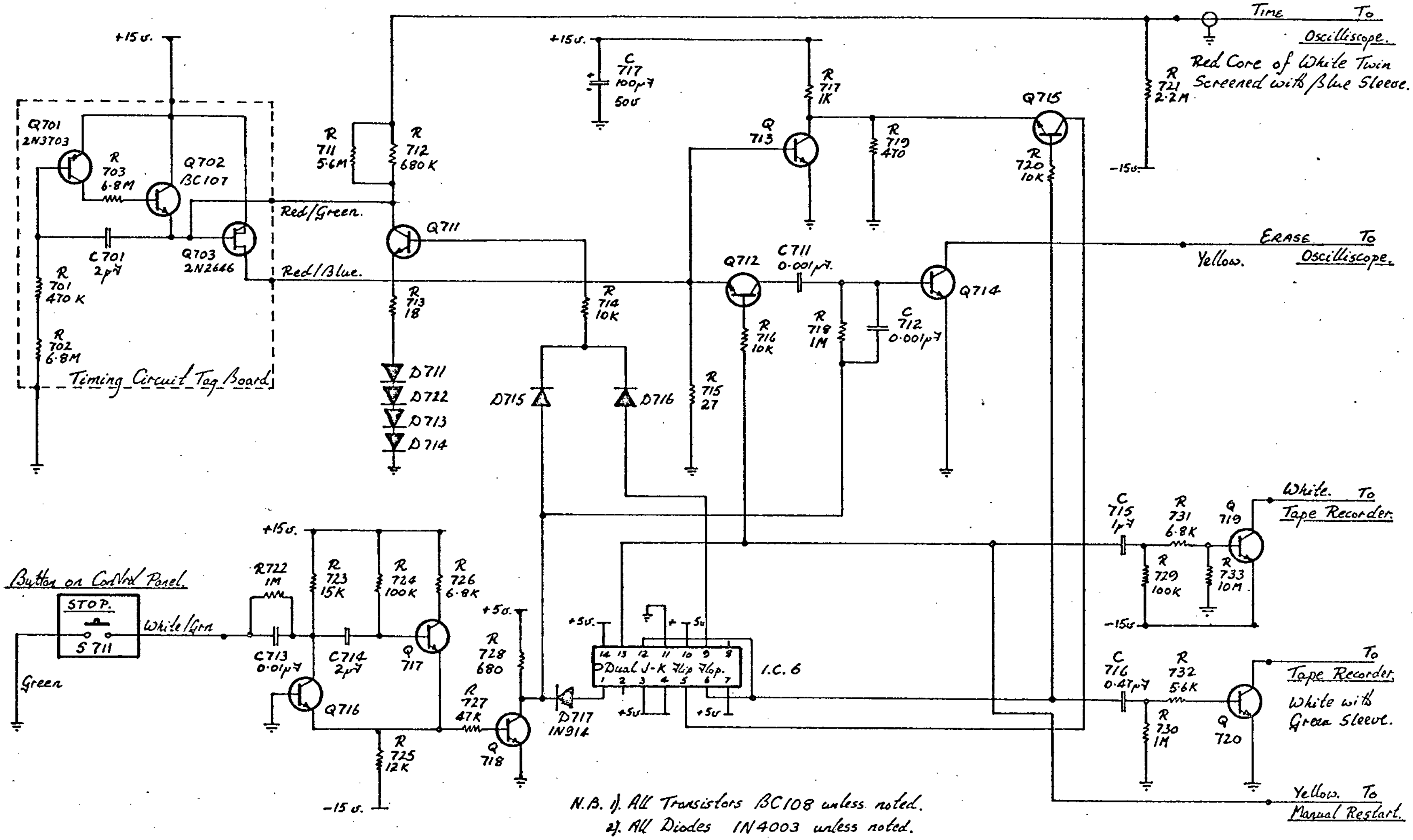


Fig. 37. Time Base and Auto Erase Circuit.

UJT falls below 1.9V, its valley voltage, when it turns Off. C701 now discharges through R701, R702 and Q702. Thus the voltage at the emitter of the UJT rises until its peak voltage, 8.2V, is exceeded, when it fires again and recharges C701. The emitter-base junction of Q701 clamps C701 and R701 to 14.3V. thus, as the base current of Q701 is negligible, R701 and R702 provide a constant discharge current of 2 uA. R703 protects Q702 by limiting its collector current when the UJT is On.

R711 and R712 act with the 100 KΩ input impedence of the X axis of the Oscilloscope to reduce the 6.3V sweep to the required level. A negative bias is applied through R721 to restore the beginning of the sweep to OV.

Our first sweep generator circuit is shown in Fig. 38.

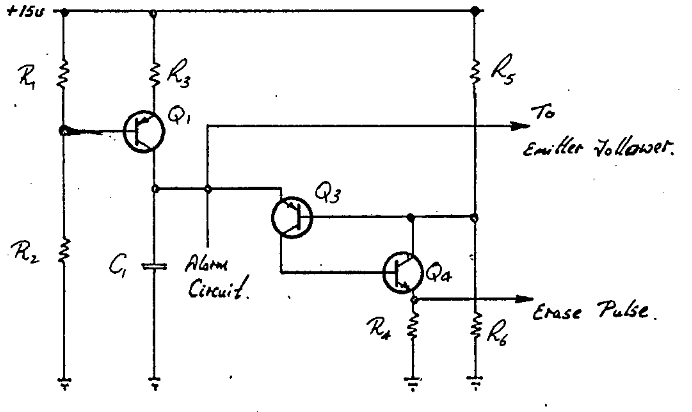


Fig. 38. Original Sweep Generator Circuit.

It appeared to work satisfactorily and was built into the system. However it became non-linear in service and eventually became thoroughly unreliable, causing us to discard it in favour of the existing circuit.

The base of Q1 was clamped by R1 and R2. Thus Q1, R3 acted as a constant current source to charge C1. When C1 charged to more than the voltage appearing at the junction of R5, R6, Q3 and Q4 fired to discharge it. R4 acted as the discharge resistor and the Erase pulse was derived from it. The sweep voltage was sensed by a high impedence emitter follower, as used in Section 5.2.5b. The rest of the circuit was identical to that being used now.

When the change to the present circuit was made the sweep generator was built on a small tag-board which was mounted on the main Veroboard.

When Q703 fires the charging current, through R715, creates a positive voltage spike which is coupled through Q712, normally held On by IC6, and C711 to the base of Q714 which is turned On. This grounds the Erase pin of J340 causing the screen to Erase.

5.2.11. Alarm Circuit.

When an Alarm is applied to the system via the STOP button the screen erases, one more sweep occurs and then the trace stops without erasing the screen.

The STOP command is received by the monostable Q716, Q717 which goes into its astable state for 100m secs (Fig. 37). Q718 acts as a buffer inverter for the monostable. When the monostable's emitter output goes low the collector of Q718 goes high turning Q711 On, through D715, and causing C701 to discharge. Diodes D711-714 prevents C701 from discharging below 1.9V, the level to which Q703 discharges it. Q718 also turns Q714 On, through C712 and erases the Oscilloscope screen. R718 acts as a discharge resistor for C712.

When the monostable returns to its stable state the collector of Q718 falls to OV and triggers bistable 1 of IC6. (See Appendix B). This causes the states of pins 12 and 13 (Fig. 39b) to reverse thus Q712 is now turned Off while Q715 is turned On. When the next discharge spike arrives from R715 it cannot

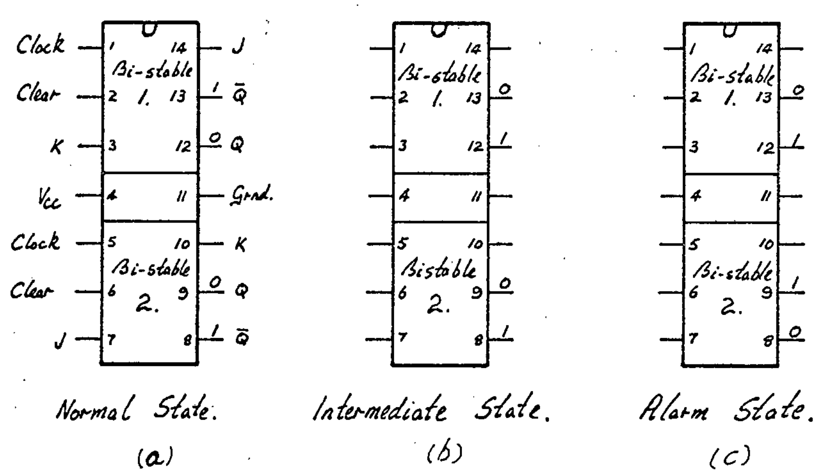


Fig. 39. States of IC6.

erase the Oscilloscope screen but is inverted by Q713 and fed via Q715, now On, to the trigger input of bistable 2 of IC6. This causes the state of pin 9 to change (Fig. 39c) this holds Q711 On, via D716, and prevents the sweep generator from recycling.

The positive going edge at pin 12 is differentiated by C716 and turns Q720 On. This sends an Alarm signal to the Tape Recorder (Section 5.2.4.) The OV now appearing at pin 13 is fed to the Manual Restart switch to trigger the latch bistable. (Section 5.2.6.)

A second pulse from the STOP button causes the monostable to go into its astable state again. This erases the Oscilloscope screen via C712 and triggers bistable 1, as before. Thus pin 12 returns to OV and pin 13 to 5V. Pin 12's return to OV is used to clear bistable 2. This returns pin 9 to OV.

The positive going edge at pin 13 is differentiated by C715 and turns Q719 On. This pulses coil K4 which lifts the mechanical latch on relay K3 in the Tape Recorder. (Section 5.2.4.) C717 acts as a storage capacitor to provide the current required to pulse relay K3 and coil K4.

5.2.12. DC Power Supplies.

A PHILBRICK/NEXUS Model 2204 Dual Regulated Power Supply was used to provide the +15V and -15V required by the system. The entire power supply is complete in one unit with no external transformer or filter required. Input voltage can be either 115 or 230V. Output voltages are accurate within $\pm$ 0.15V and each output can supply 50mA. "Fold back" overload protection is provided which reduces short circuit currents to 30mA.

A PHILBRICK/NEXUS Model 2206 Regulated Power Supply was used to provide the +5V required. As with the Model 2204 the power supply is complete. Input voltage is 210-250V. Output regulation over the whole, 0-100%, load range is 0.15%. Maximum output current is 500 mA. Both current, and overvoltage protection are provided.

5.2.13. AC Power Supply.

The Mains Input is brought to a terminal block on the trolley frame. (Fig. A8). From here the supply is taken through a 10A fuse to the MOTOR and CONTROL switches on the Control Panel. The MOTOR switch operates the Compressor and Fan. The CONTROL switch operates the monitoring and control system. These supplies return to the terminal block. The Compressor and Fan are directly connected to the terminal block. The electrical circuits are fed through two Isolation Transformers. The 250 watt Transformer feeds the Oscilloscope. The output of the 100 watt Transformer is returned to the terminal block, from where it feeds the Electrocardiograph, the Tape Recorder and the DC Power Supplies. To cut down on earth loop currents one leg of the secondaries of the Isolation Transformers were earthed. A 6.75 μF capacitor was inserted across their primaries to reduce interference from transients in the mains.

5.3.14. Mechanical aspect.

The balloon pump, which is a latex chamber on the end of a Teflon Catheter, is inflated and deflated by a double piston displacement pump driven by high pressure air supplied by a small diaphragm type compressor. The air supply is controlled by a Fluidic Logic circuit which receives its input from the Fluidic Air Switch.

There are two sizes of balloons; one having a maximum inflated volume of 18 cc, and the other a maximum inflated volume of 28 cc. The smaller balloon was intended for trials on dogs and the larger, for humans. (Fig. 40).

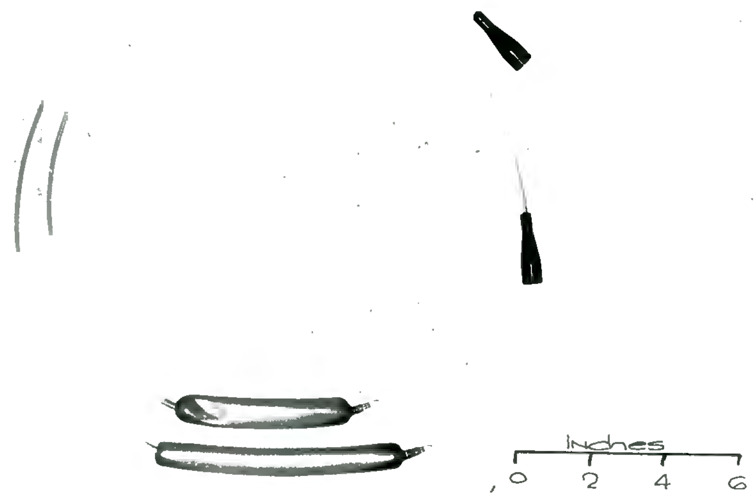


Fig. 40. Balloon sizes.

The design of the displacement pump which has two connected pistons operating in separate chambers is shown in Fig. 41. The driver pump consists of a double acting power piston (A), connected to the balloon piston (B) and a volume control piston (C). The position of this piston is hand adjusted by the volume adjustor (D). In the 'Deflate' position air is supplied via the Deflate port (H) to force the piston against the volume control piston (C). Operation of the Fluidic Air Switch causes air to be fed via the Inflate port (F) so that the pistons are driven forward to force gas into the feed line to the balloon, attached to G.

A "make-up" valve, actuated by the driving pressure momentarily connects a pressure regulated gas supply (7" water guage) through port E thus allowing the pressure to reach the same level

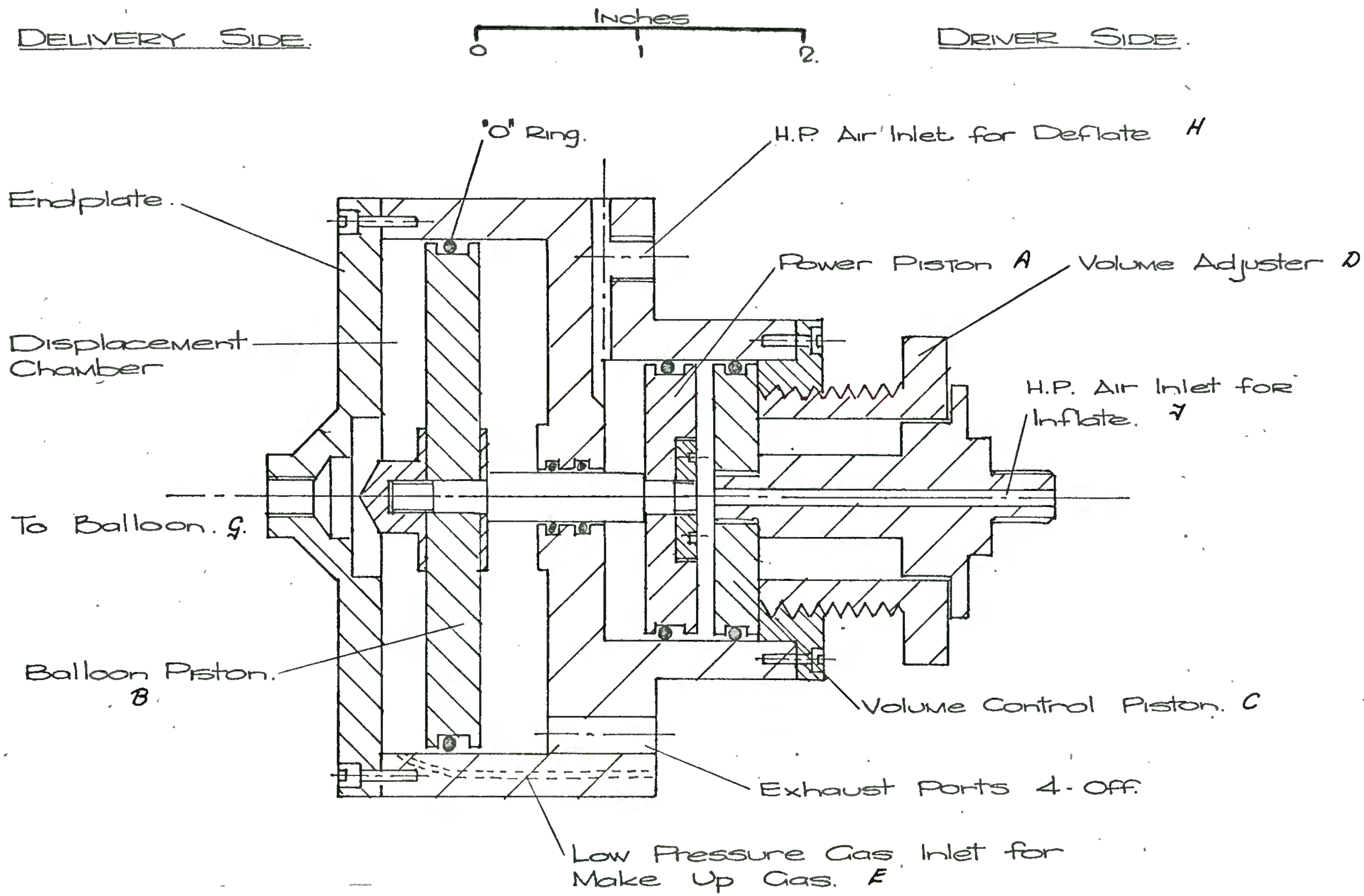


Fig. 41. Driver Pump

at the commencement of each stroke. This arrangement compensates for temperature effects and leakage of gas past the balloon piston (B) '0' ring. It also allows the amount of gas in the balloon to increase or decrease with the adjustment of the piston stroke.

Fig. 42 illustrates the pump with a balloon attached.

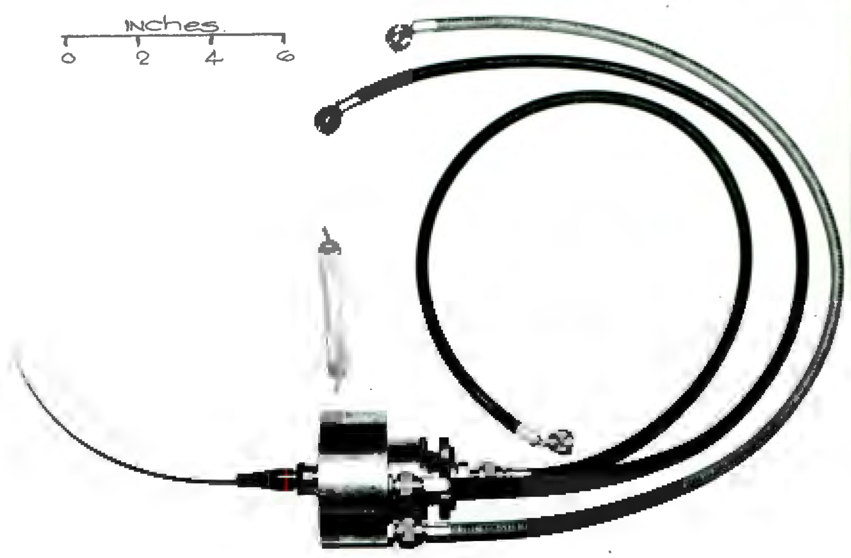


Fig. 42. Driver Pump and Balloon.

The compressed air needed for driving the pump is supplied by a DEVILBLISS "Tuffy" diaphragm type compressor. The air from the compressor is passed through a coil of copper tubing which is cooled by a draught induced by a fan. This is done to remove the moisture from the air which would otherwise condense in the connecting tubes and interfere with the operation of the components of the fluidic circuit. An automatic drain filter was put in the line between the cooling coil and the high pressure manifold, to collect any water that might have condensed out of the air during its passage through the cooling coil.

The drain of this filter is connected to a small, removable glass container, which is easily accessible through a hole in the back panel of the trolley. Thus it can be removed and emptied of its contents while the pump is in operation.

Two step-up relays regulate the supply of high pressure air to the driver pump. These step-up relays are in fact just pneumatic switches which are controlled by low pressure air signals from the logic circuitry.

5.3. The Trolley.

We decided to mount all the components, electrical and mechanical (with the exception of the driver pump), into a closed-in trolley on wheels. The electrical and mechanical control circuits were built onto two separate panels that can fold out for easy access. (Fig. 43).

Fig. 43. Demonstration of Folding Panels.

The trolley frame is an all welded structure fabricated out of 1" square tubing. The Oscilloscope supports were made out of $\frac{7}{8}$" square tubing. The overall dimensions of the trolley are 36" wide, 23" deep and 32" high. The handles on the end of the trolley (actually part of the frame) were included to allow the trolley to be moved easily and to protect the gauges and air outlets protruding from the right hand panel. A working drawing is included in Appendix A. (Fig. A9).

The front and the two side panels were made of $\frac{1}{8}$" annealed aluminium sheeting while the back panel was cut from a perforated $\frac{1}{8}$" aluminium sheet. This was necessary to allow ample air circulation. The panels were attached to the trolley frame with $\frac{1}{8}$" self tapping screws ($\frac{1}{2}$" long). These self-tappers screw into mounting lugs that had been fabricated out of 16 gauge mild steel sheeting and welded in place along the length of the appropriate frame members. These lugs can be seen in Fig. 44.

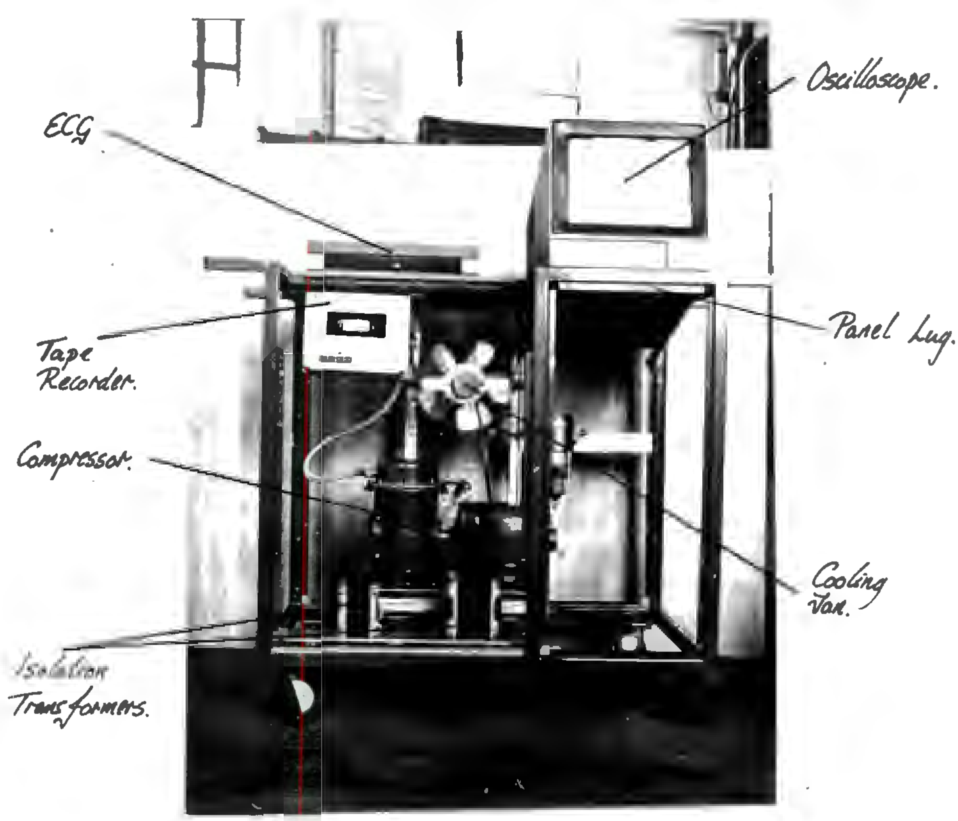


Fig. 44. Major components mounted in trolley frame.

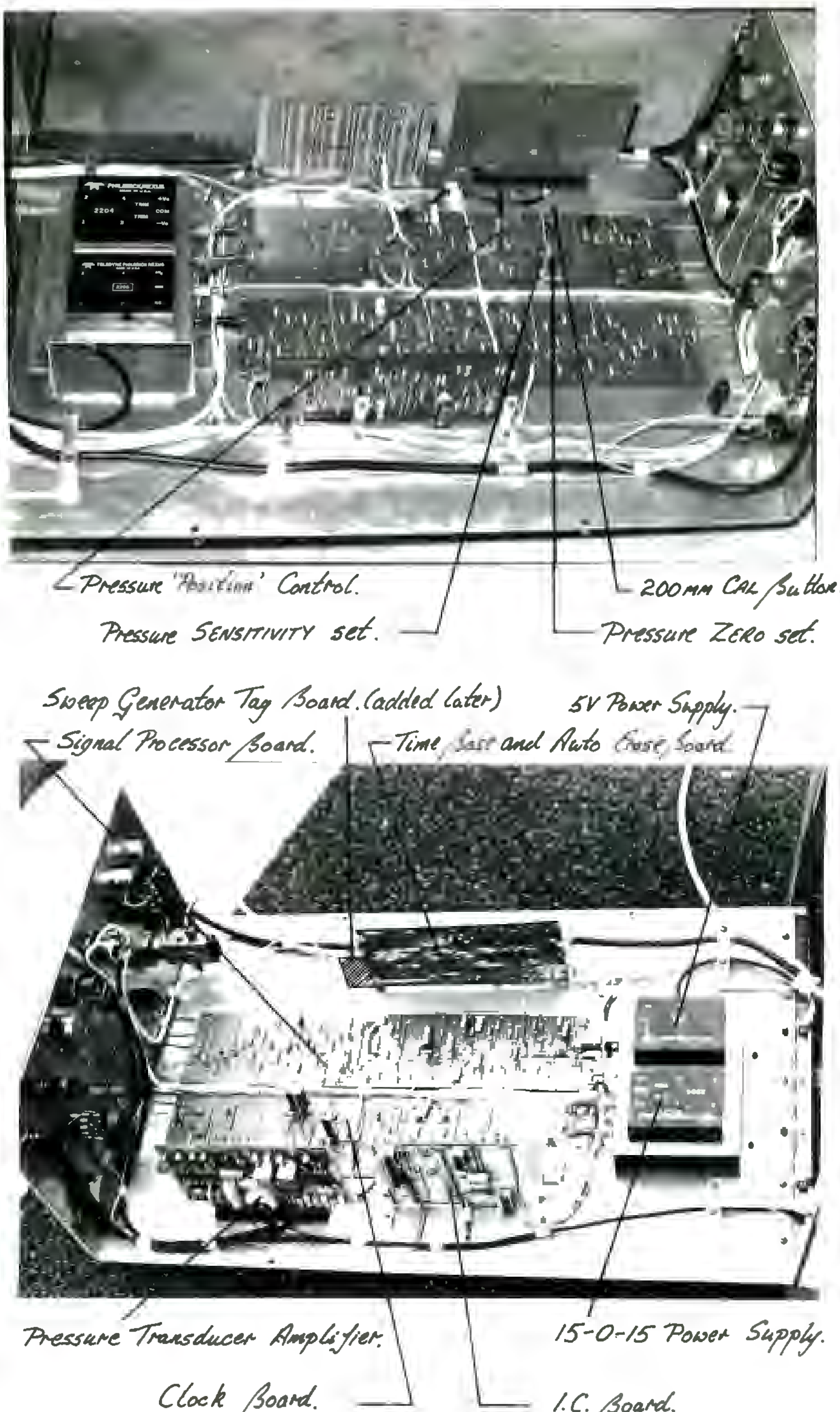


Fig. 45. Layout of Electronic Circuits on folding panel.

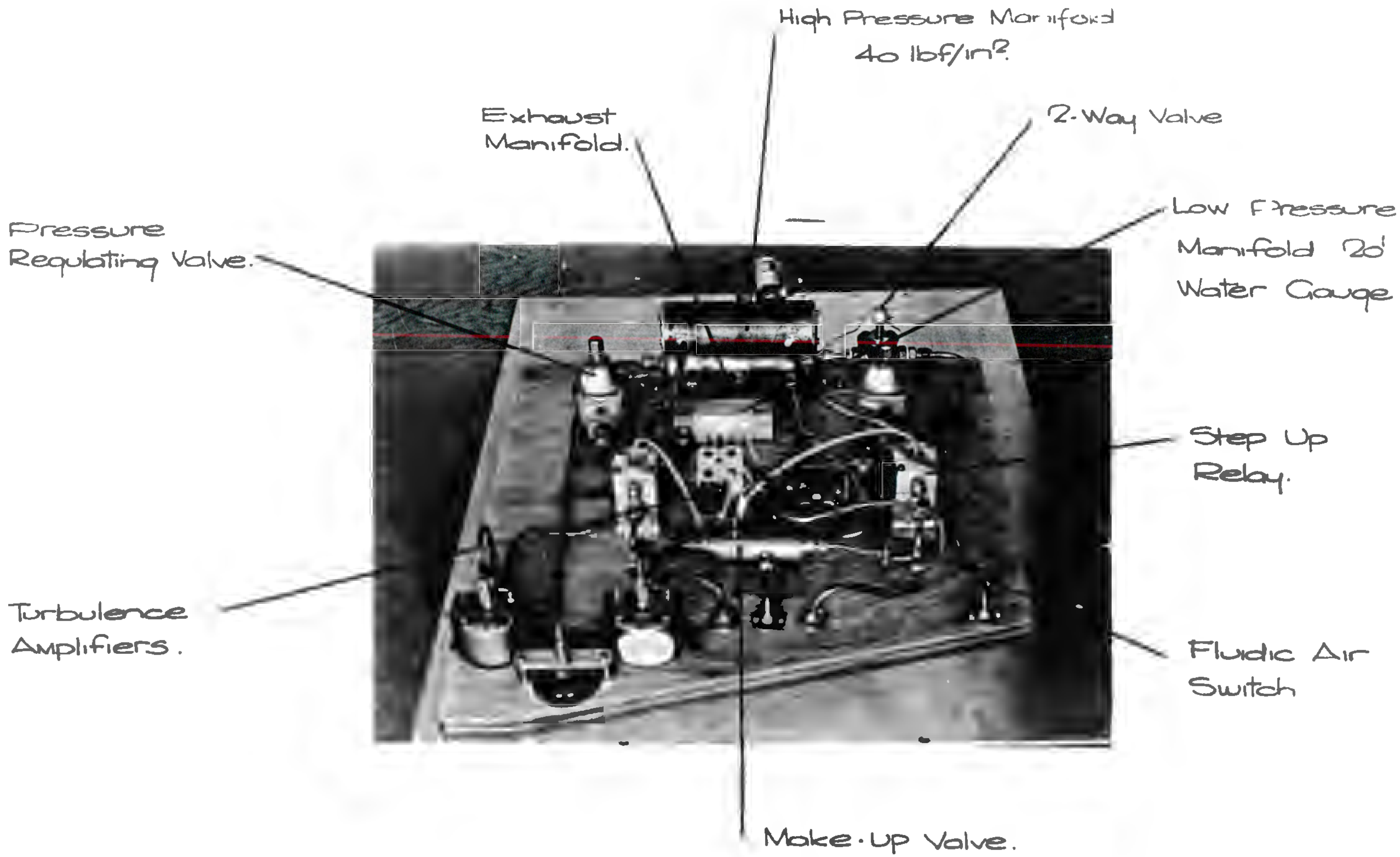


Fig. 46. Lay-out of Mechanical Control Circuit.

The Oscilloscope, Electrocardiograph, Tape Recorder, Isolation Transformers, Compressor and Cooling Fan were all mounted on the trolley frame. (Fig. 44). All the electronic circuitry was built on boards and mounted on a hinged, L-shaped panel that also carries the DC power supply and the control panel. (Fig. 45.) The lay-out of the mechanical control circuit is illustrated in Fig. 46.

5.4. Laboratory Tests.

During the construction of the heart assist pump it was necessary to have a simple apparatus with which to test the system. For this purpose a test rig consisting of a balloon pump within a pressurised glass cylinder was built.

The test rig used is shown in Fig. 47 and consists of a glass tube $2\frac{1}{4}$" in diameter and 30" long. The tube was sealed at both ends by means of two rubber bungs. The pressure within the air space can be varied by raising or lowering the reservoir 'A', and the volume of the air space can be altered via vent 'B'. The static pressure within the air space was determined by means of the mercury manometer. The balloon pump within the air space had an inflated volume of 28 cc. The variation in the pressure of the air space due to the pumping action of the balloon was monitored by the Pressure Transducer.

Normally the pressure within the air space was set at 100 mm. Hg., and the volume of air within the air space was adjusted to be such that when the balloon pump was inflated, the pressure within the air space increased to approximately 130 mm Hg.

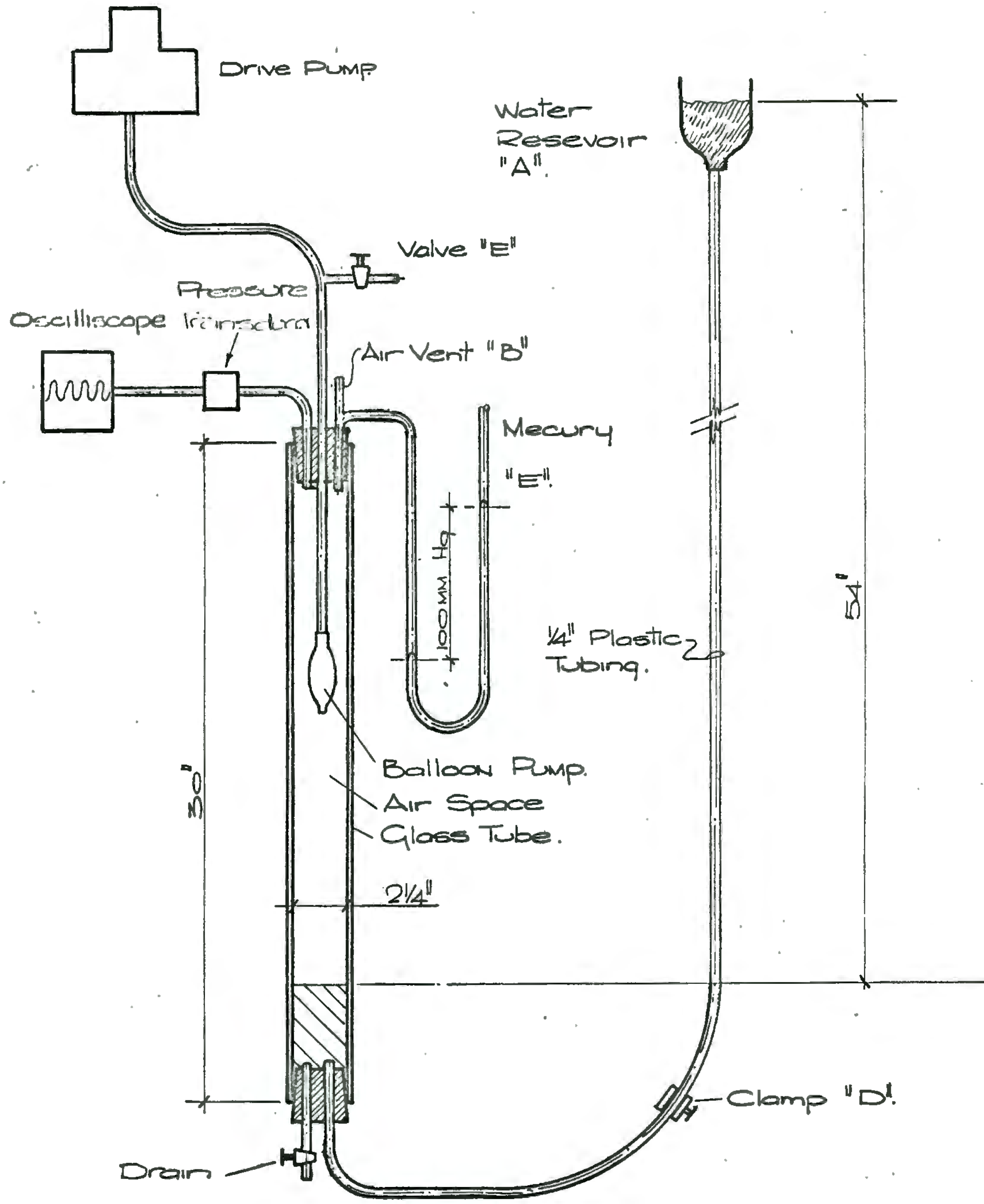


Fig.47. Test Rig

Once the pressure and volume of the air space had been adjusted to the desired values, clamp D on the plastic tube leading from the glass tube to the water reservoir was closed. This was done to stop the water level within the glass tube from oscillating during pumping. If the water level is allowed to oscillate during pumping the pressure readings are erroneous and do not give the true pressure rise due to the balloon inflating.

Once the apparatus had been adjusted the driver pump was connected to the balloon and was started by switching on an ECG simulator. (Set to deliver 60 pulses per minute). Its displaced volume was adjusted so that the balloon pump was completely filled on the inflate stroke. An example of the trace of the resultant pressure fluctuation is shown in Fig. 48.

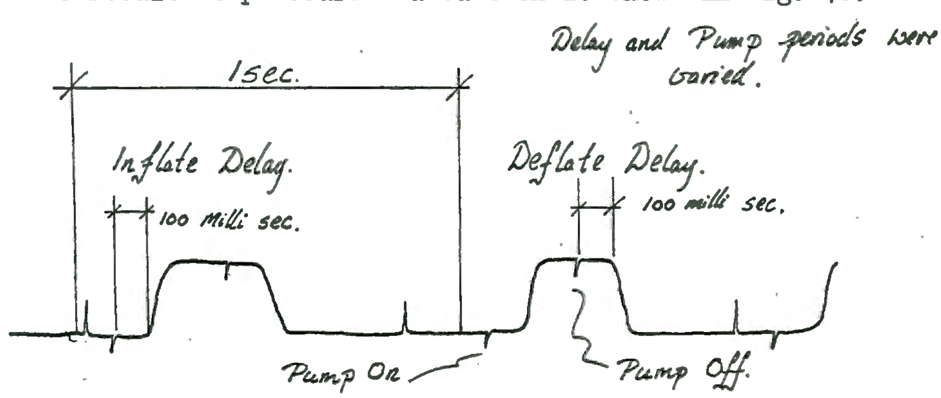


Fig. 48. Pressure Trace obtained in Test Rig.

The apparatus was also used to determine the time delay of the mechanical control circuit, driver pump and balloon pump, i.e. the time that elapses from the time that the electrical Pump signal enters the Fluidic Air Switch to when the balloon pump starts to inflate, and the corresponding deflate delay. These delay times were determined from the Marker

Spikes on the Pressure trace.

From the trace it can be seen that both these delays are approximately 100 m secs. These delays in the pumping system do not change appreciably with an increase in pump rate.

The system was left to run for periods of up to eight hours and, basically, was found to be reliable. It was during these test runs that the original sweep generator in the Time Base (Section 5.2.10.) failed and the need for C418 became apparent. (Section 5.2.5d, Fig. 29). Certain faults in the mechanics were also discovered and eradicated.

Once the author and his co-worker were satisfied with the performance and reliability of the system the unit was handed over to the Cardiac Research Department of the University of Cape Town for medical testing and evaluation.

5.5. Medical Tests.

The medical test program envisaged, was to prove the system using dogs, before proceeding to any clinical application.

The first problem we encountered was that the balloons intended for the dogs were too big for insertion in a femoral artery. Even when sucked flat and rolled tightly around the catheter they bunched and were unable to be inserted. Alternative balloons are in the process of being made. In the mean time smaller makeshift balloons were made out of fingers of surgical gloves. These balloons have a serious limitation in that they have little inherent volume and are very easy to overfill, leading to rupture.

The doctor in charge of the testing program used two dogs to familiarise himself with the unit and its controls. These dogs both survived and were operated on a number of times until they were killed by rupture of our make-shift balloons.

Once the familiarisation program was complete attempts were made at inducing cardiogenic shock. An electromagnetic blood flowmeter was available for one of these cases and was used to monitor the blood flow in the sub-clavian artery. Cardiogenic shock was induced in a healthy dog (mean blood pressure 100 mm Hg; flow rate 340 ml/sec), by bleeding the dog of approximately one pint of blood and then returning the blood quickly.

When the blood pressure had dropped to 60mm Hg., and the blood flow had dropped to 110 ml/sec. Pumping was commenced in an effort to avoid the impending crisis. Within 3 mins the blood pressure had risen to 95 mm Hg. while the blood flow had risen to 410 ml/sec. Indicating beneficial action by the pump. Unfortunately the balloon was an old one and ruptured a few minutes later. (It is not normally intended that balloons be re-used).

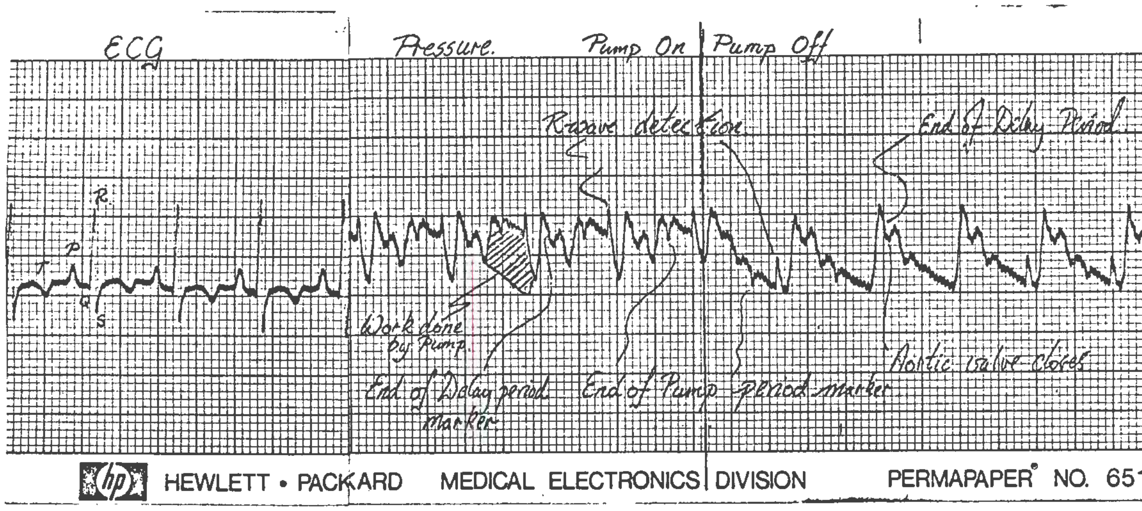
There then followed a long series of tests in an artificial system, similar to that described in Section 5.4., during which an attempt was made to make one of the latex balloons supplied, fail. The unit ran non-stop for 48 hours when the test was abandoned as a success. The balloon had not ruptured and no system malfunction had occurred. As a result of these tests the medical researchers became convinced of the system's reliability.

When tests on dogs were resumed a control group of four dogs had their coronary arteries tied at various points. This induced cardiogenic shock leading to fatal ventricular fibrillation, i.e. mechanical cardiac standstill. The mean time taken to fibrillate was 4.5 mins. (Fig. 49).

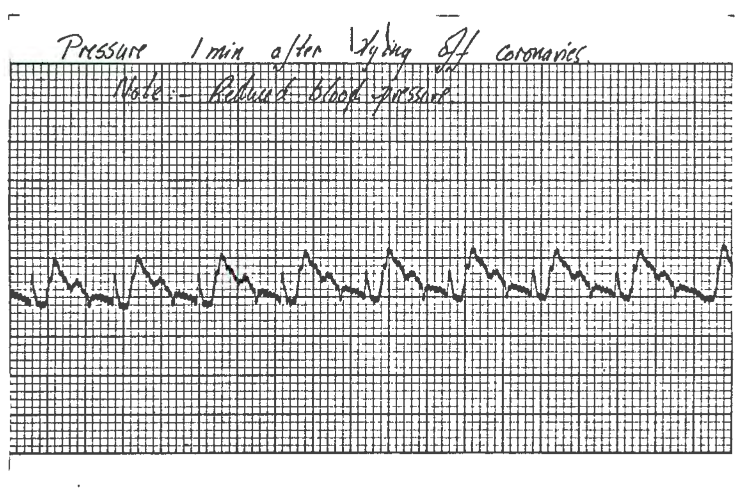
Fig. 49. ECG showing Ventricular Fibrillation.

Two other dogs were treated similarly but were pumped at the time of the assault. One dog lasted 8 mins before fatal ventricular fibrillation. The other dog was already in ventricular tachycardia (the stage before fibrillation) when pumping was commenced. Within 4 mins the blood pressure rose from 65 mm Hg. to 100 mm Hg. All signs of cardiac ischemia, as judged by the ECG parameters, disappeared in the course of 3 hours pumping. After 4½ hours the dog was weaned from the pump, using the Beat switch, and managed to maintain his blood pressure without further assistance. The ECG and blood pressure traces shown in Fig. 50 refer to this case. The shaded area in Fig. 50a illustrates the work done by the pump. Note:- As the dog was still healthy at this stage there is no rise in

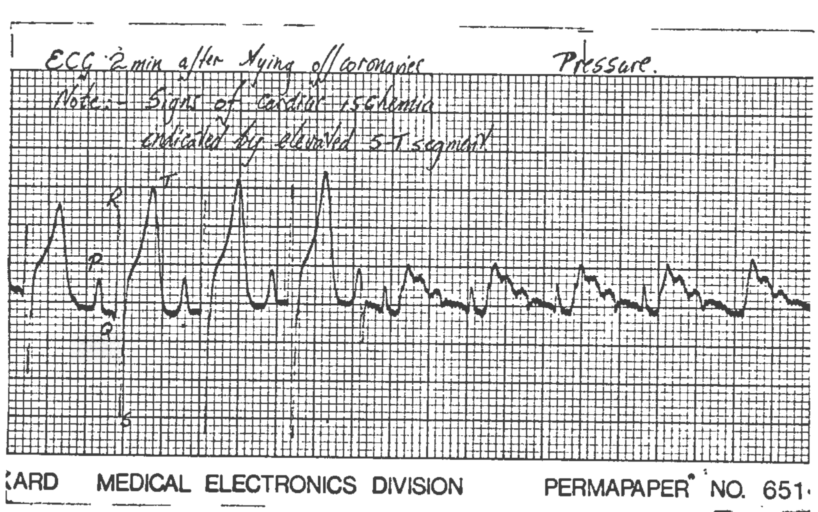
FIG. 50 EXPERIMENTAL TRACES.



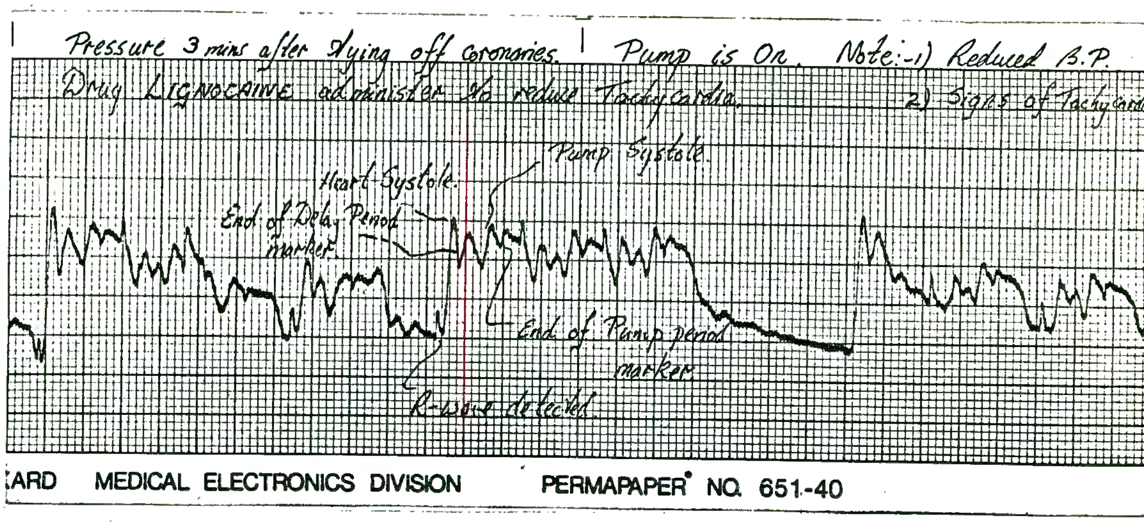
(a)



(b)



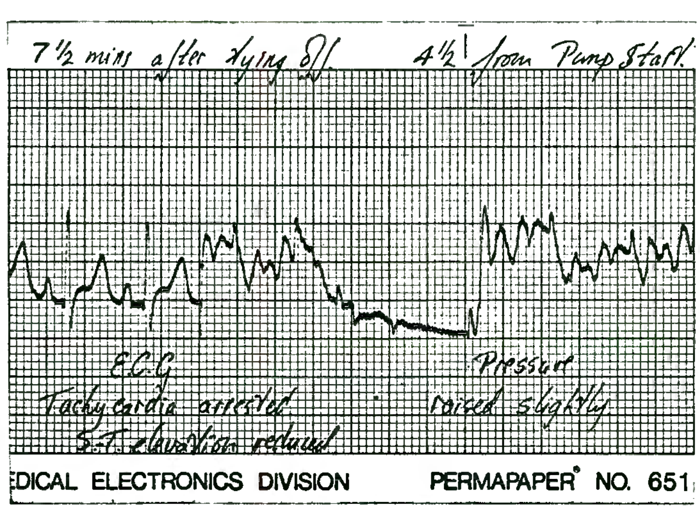
(c)


Pressure 3 mins after tying off coronaries. Pump is On. Note:-1) Reduced B.P.
Drug LIGNOCAINE administer to reduce Tachycardia.
2) Signs of Tachycardia
Pump Systole
Heart Systole
End of Delay Period marker
End of Pump period marker
R-wave detected
ARD MEDICAL ELECTRONICS DIVISION PERMAPAPER® NO. 651-40

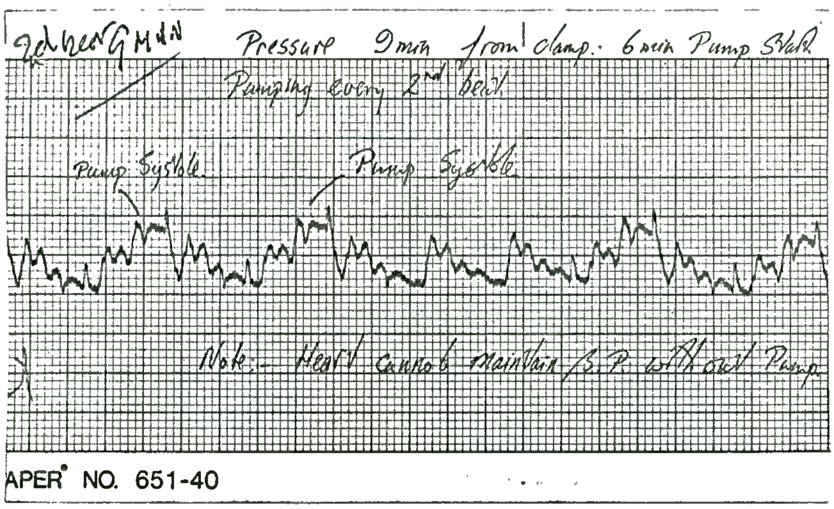
(d)


4½ mins from tying off. 1½ from Pump Start.
Extra Systoles
ECG
Tachycardia still present
S-T elevation .. large
Pressure still reduced

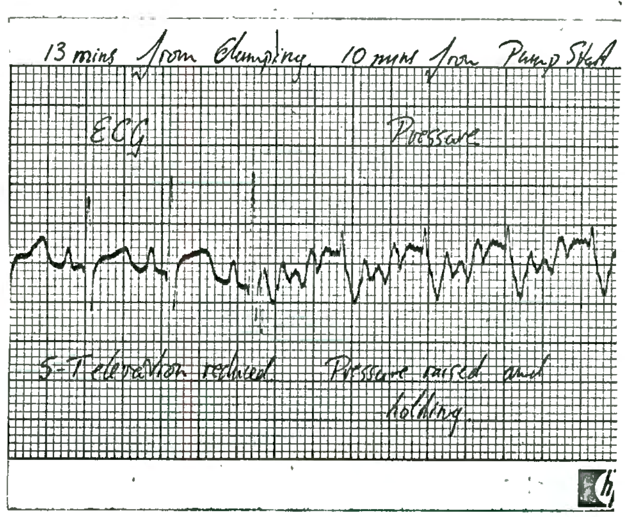
(e)


7½ mins after tying off. 4½ from Pump Start.
ECG
Tachycardia arrested
S.T. elevation reduced
Pressure raised slightly
DICAL ELECTRONICS DIVISION PERMAPAPER® NO. 651

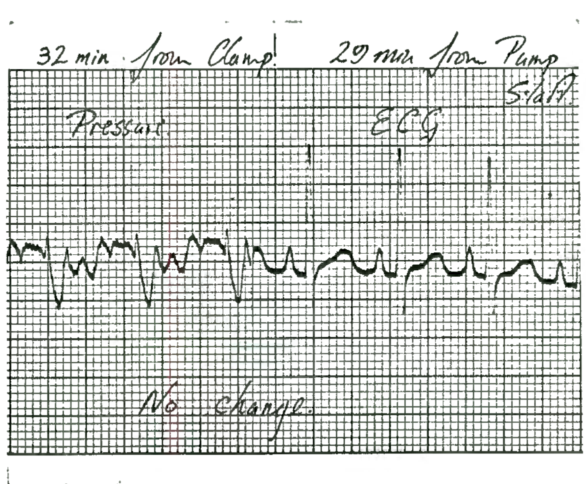
(f)


Pressure 9 min from clamp. 6 min Pump Start
Pumping every 2nd beat
Pump Systole
Pump Systole
Note:- Heart cannot maintain B.P. without Pump
APER NO. 651-40

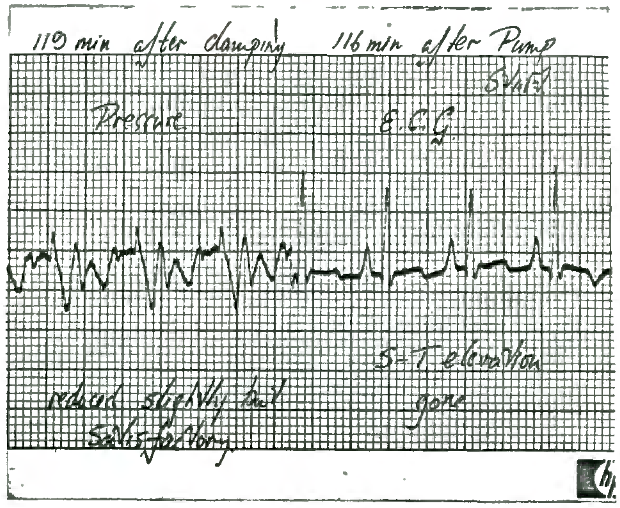
(g)


13 mins from Clamping 10 mins from Pump Start
ECG
Pressure
S-T elevation reduced. Pressure raised and holding.

(h)

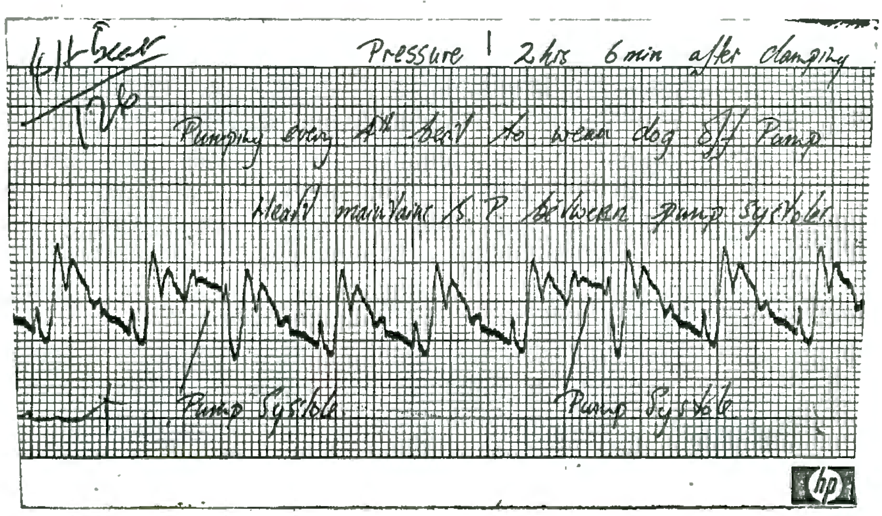

32 min from Clamp 29 min from Pump Start
Pressure
ECG
No change.

(i)



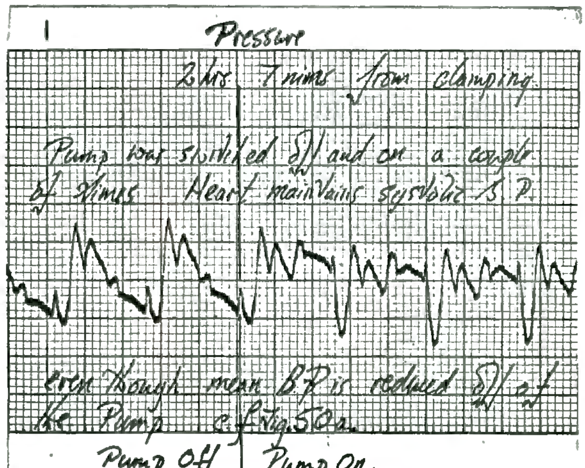
119 min after clamping
116 min after Pump Start
Pressure
E.C.G.
S-T elevation gone
reduced slightly but satisfactory

(j)



Pressure
2 hrs 6 min after clamping
Pumping every 4th beat to wean dog off Pump
Heart maintains S.P. between pump systoles
Pump Systole
Pump Systole

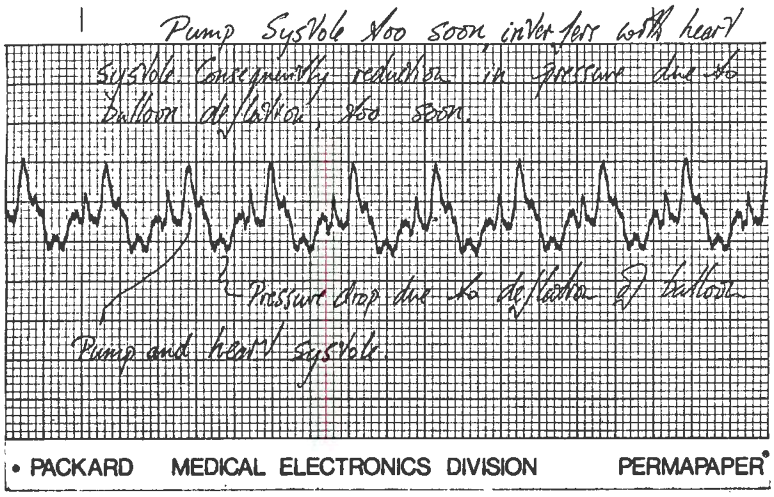
(k)



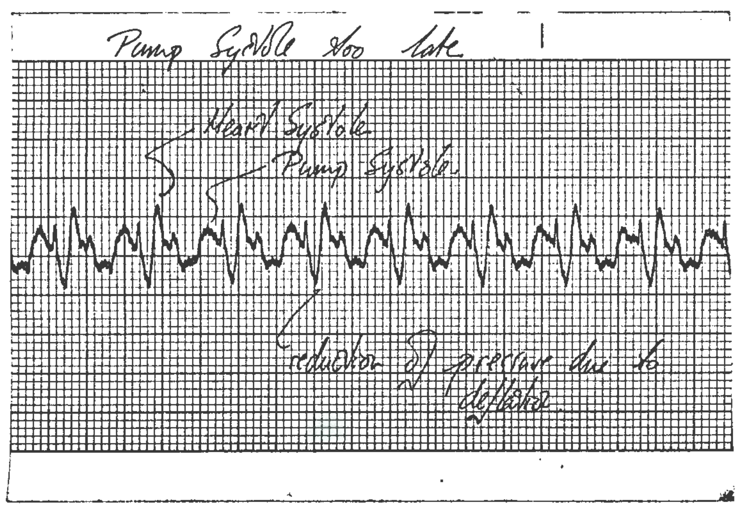
Pressure
2 hrs 7 mins from clamping
Pump was switched off and on a couple of times. Heart maintains systolic S.P.
even though mean BP is reduced off of the Pump c.f. Fig 50 a.
Pump Off
Pump On.

(l)

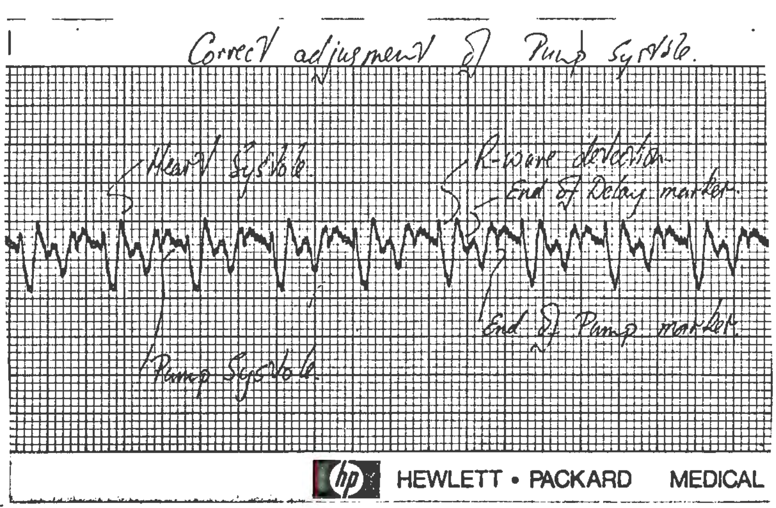
Pump adjustment traces. Dog still healthy.



(m)



(n)



(o)

systolic blood pressure but there is a rise in mean blood pressure.

In all the above tests the heart rate lay between 120 and 150 beats/min. and the system experienced no difficulty in coping with these rates.

5.6. Conclusion.

At the time of writing this thesis the medical tests had only been carried out on dogs. The results appear to be favourable, both from a medical and an engineering point of view and the medical researchers are willing to proceed to a human application when a suitable patient presents himself. Medical opinion indicates that when the unit is used on a patient a balloon could be inserted, and pumping commenced, within 20 mins of the unit's arrival at the patient's bedside. Once the insertion has taken place it would only require the attention of a doctor and nurse to keep the unit running.

A request has been made for a modification to enable a larger scale twin channel recorder to be plugged in to record the ECG and pressure trace simultaneously. This is required for research purposes and to enable more detailed traces to be taken for analysis. It is anticipated that this will be done by inserting two Op-Amp follower stages before the signal levels are reduced for display, i.e. before R522 (ECG) and R521 (Pressure). (Fig. A5). Fig. 51 illustrates the anticipated circuit.

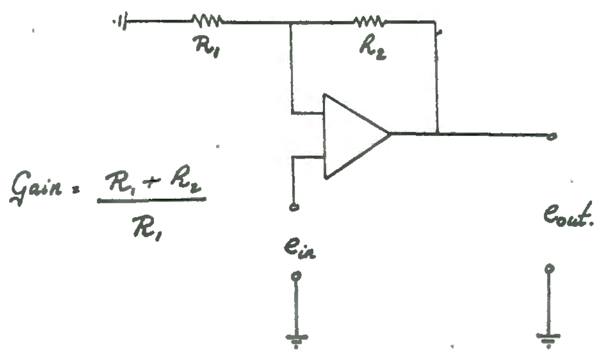


Fig. 51. Anticipated Modification.

APPENDIX A.

CIRCUIT DIAGRAMS.

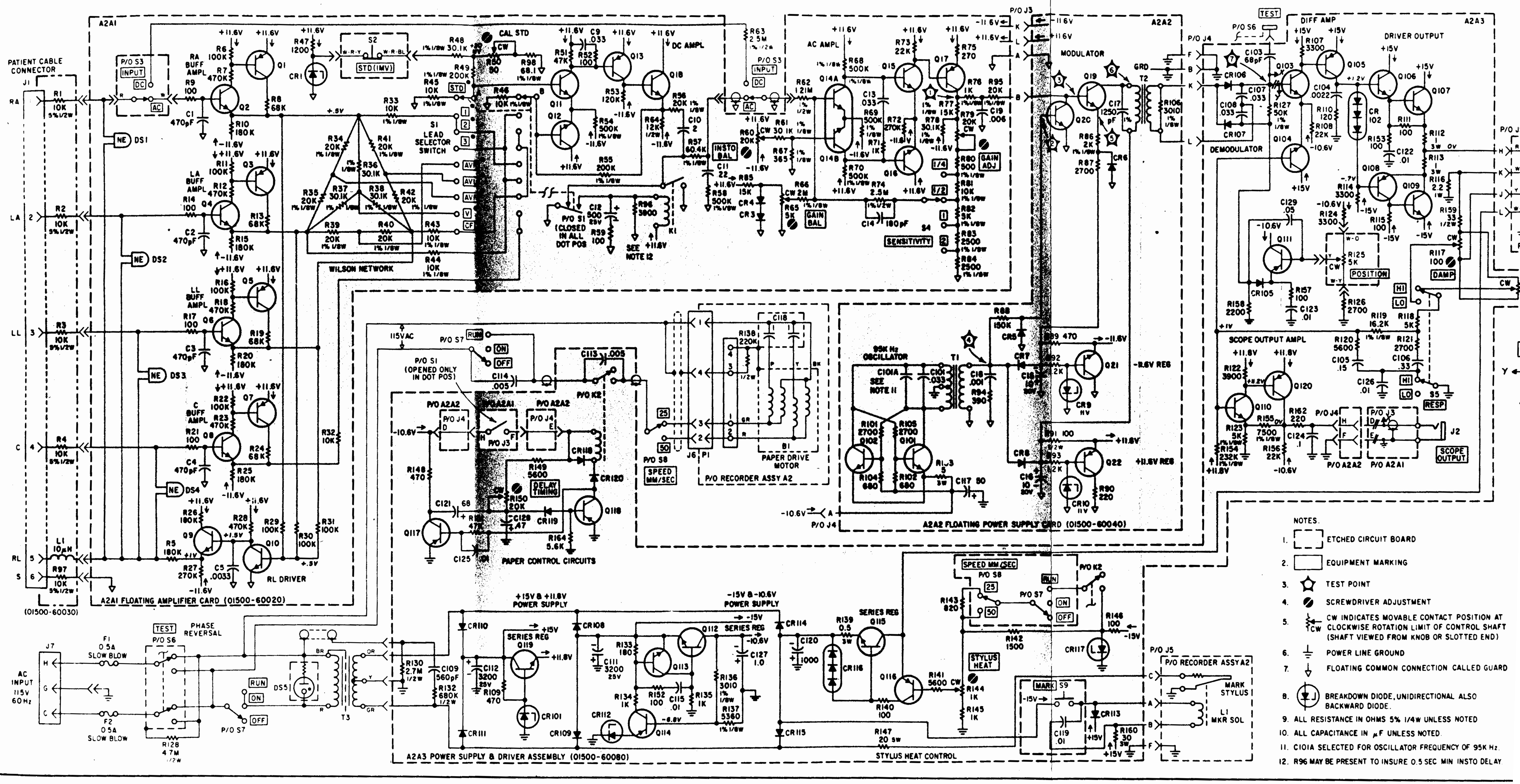

PATIENT CABLE CONNECTOR
A2A1
A2A1 FLOATING AMPLIFIER CARD (01500-60020)
(01500-60030)
WILSON NETWORK
S1 LEAD SELECTOR SWITCH
CAL STD
DC AMPL
AC AMPL
INSTO BAL
GAIN BAL
GAIN ADJ
SENSITIVITY
RL DRIVER
PAPER CONTROL CIRCUITS
DELAY TIMING
P/O RECORDER ASSY A2
PAPER DRIVE MOTOR
SPEED MM/SEC
A2A2
MODULATOR
DEMODULATOR
95K Hz OSCILLATOR
A2A2 FLOATING POWER SUPPLY CARD (01500-60040)
A2A3
DIFF AMP
DRIVER OUTPUT
POSITION
DAMP
SCOPE OUTPUT AMPL
SCOPE OUTPUT
RESP
AC INPUT 115V 60Hz
SLOW BLOW
PHASE REVERSAL
+15V & +11.6V POWER SUPPLY
-15V & -10.6V POWER SUPPLY
SERIES REG
STYLUS HEAT
STYLUS HEAT CONTROL
MARK STYLUS
MKR SOL
A2A3 POWER SUPPLY & DRIVER ASSEMBLY (01500-60080)
NOTES.
1. ETCHED CIRCUIT BOARD
2. EQUIPMENT MARKING
3. TEST POINT
4. SCREWDRIVER ADJUSTMENT
5. CW INDICATES MOVABLE CONTACT POSITION AT CLOCKWISE ROTATION LIMIT OF CONTROL SHAFT (SHAFT VIEWED FROM KNOB OR SLOTTED END)
6. POWER LINE GROUND
7. FLOATING COMMON CONNECTION CALLED GUARD
8. BREAKDOWN DIODE, UNIDIRECTIONAL ALSO BACKWARD DIODE.
9. ALL RESISTANCE IN OHMS 5% 1/4W UNLESS NOTED
10. ALL CAPACITANCE IN μF UNLESS NOTED.
11. C101A SELECTED FOR OSCILLATOR FREQUENCY OF 95K Hz.
12. R96 MAY BE PRESENT TO INSURE 0.5 SEC MIN INSTO DELAY

Fig A

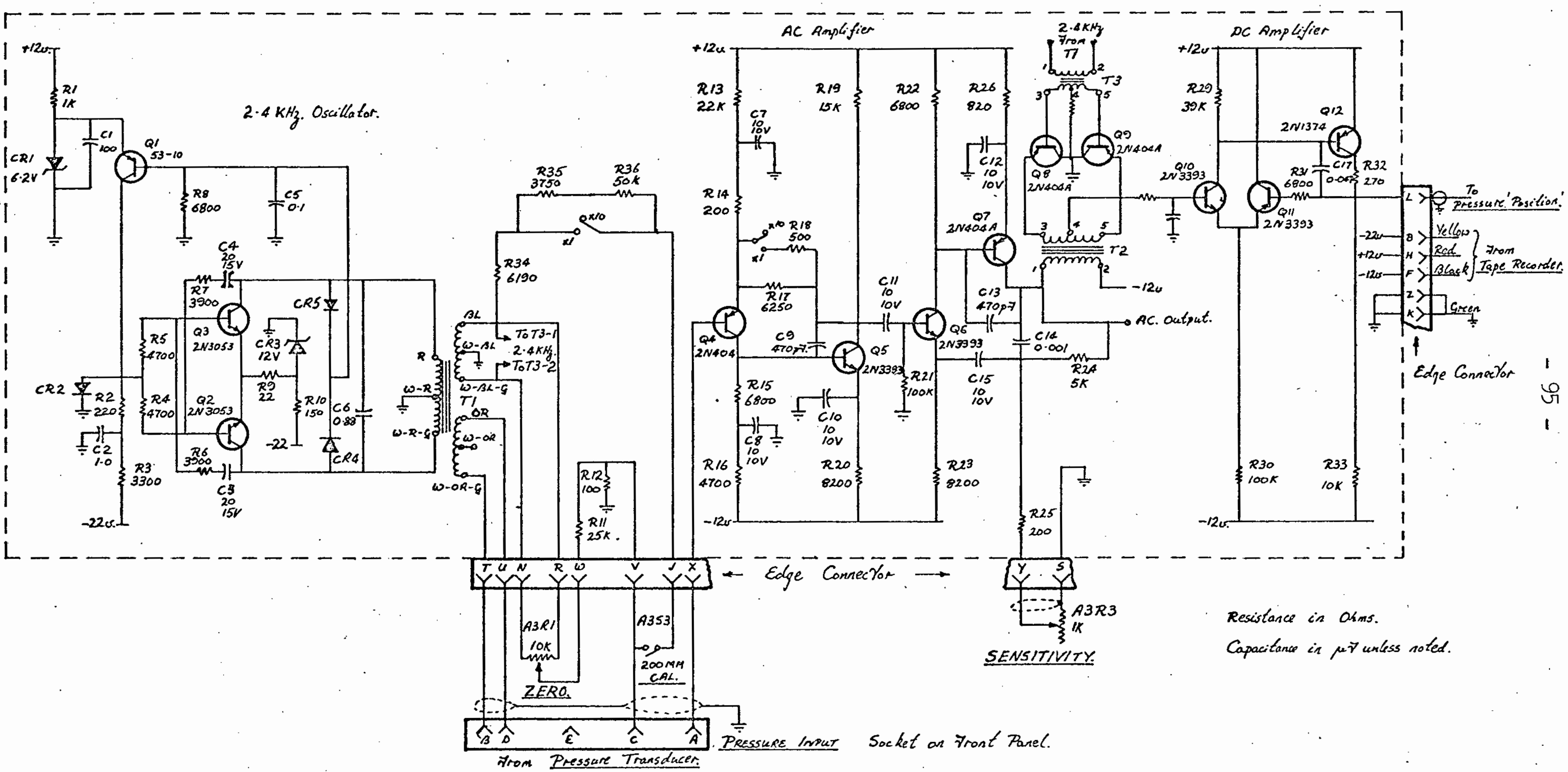


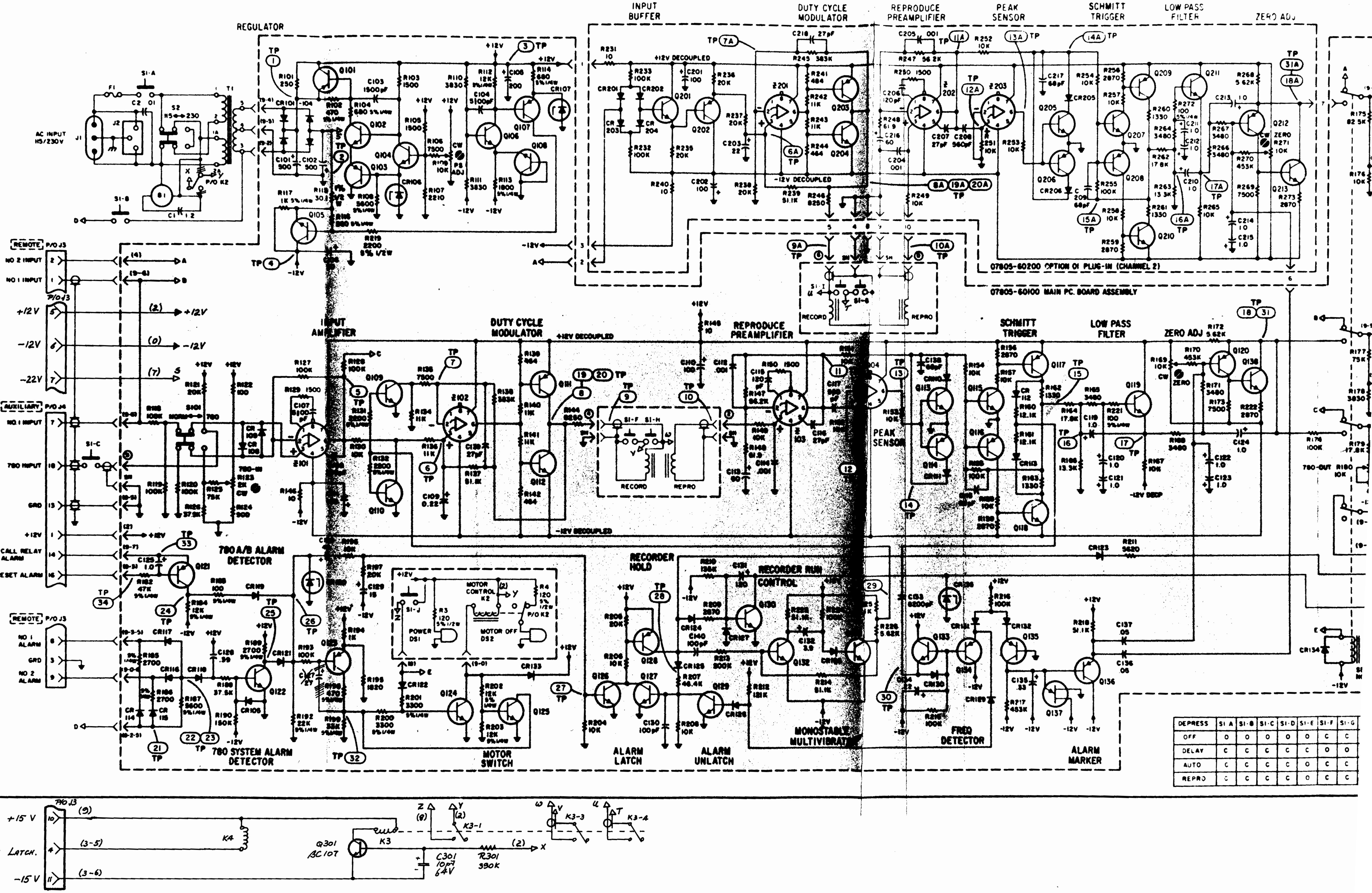
Fig. A2. Pressure Transducer Amplifier Card.

OTES

1. LOCATED ON FRONT PANEL
2. LOCATED ON REAR PANEL
3. ETCHED CIRCUIT BOARD
4. SCREWDRIVER ADJUSTMENT
5. CW INDICATES MOVABLE CONTACT POSITION AT CLOCKWISE ROTATION LIMIT OF CONTROL SHAFT (SHAFT VIEWED FROM KNOB OR SLOTTED END)
6. BREAKDOWN DIODE, UNIDIRECTIONAL. ALSO BACKWARD DIODE
7. COMMON CONNECTION (WITH LETTER)
8. SIGNAL COMMON
9. CHASSIS GROUND (POWER GROUND)
10. TP TEST POINT
11. P/O PART OF
12. ALL RESISTANCE IN OHMS, 1% 1/8W UNLESS NOTED
13. ALL CAPACITANCE IN µF UNLESS NOTED
14. WIRE COLOR IS GIVEN, USING STD CODE EX (9-5-6) = WHITE, GREEN, BLUE
    - 0 - BLACK
    - 1 - BROWN
    - 2 - RED
    - 3 - ORANGE
    - 4 - YELLOW
    - 5 - GREEN
    - 6 - BLUE
    - 7 - VIOLET
    - 8 - GRAY
    - 9 - WHITE

14A. (WITH NUMBER) DENOTES COLOR OF BAND ON SHIELDED WIRE. SH DENOTES SHIELD

15. TAB — I C LEAD LOCATION (TOP VIEW)
16. K101 SHOWN IN DEENERGIZED STATE.
17. SWITCH S1, SECTIONS A THROUGH J ARE ALL SHOWN IN THE OPEN POSITION. THE TABLE BELOW SHOWS WHICH SECTIONS ARE OPEN (O) OR CLOSED (C) IN THE DIFFERENT MODES OF OPERATION



DEPRESS	S1 A	S1-B	S1-C	S1-D	S1-E	S1-F	S1-G
OFF	O	O	O	O	O	C	C
DELAY	C	C	C	C	C	O	O
AUTO	C	C	C	C	O	C	C
REPRO	C	C	C	C	O	C	C

07805-52

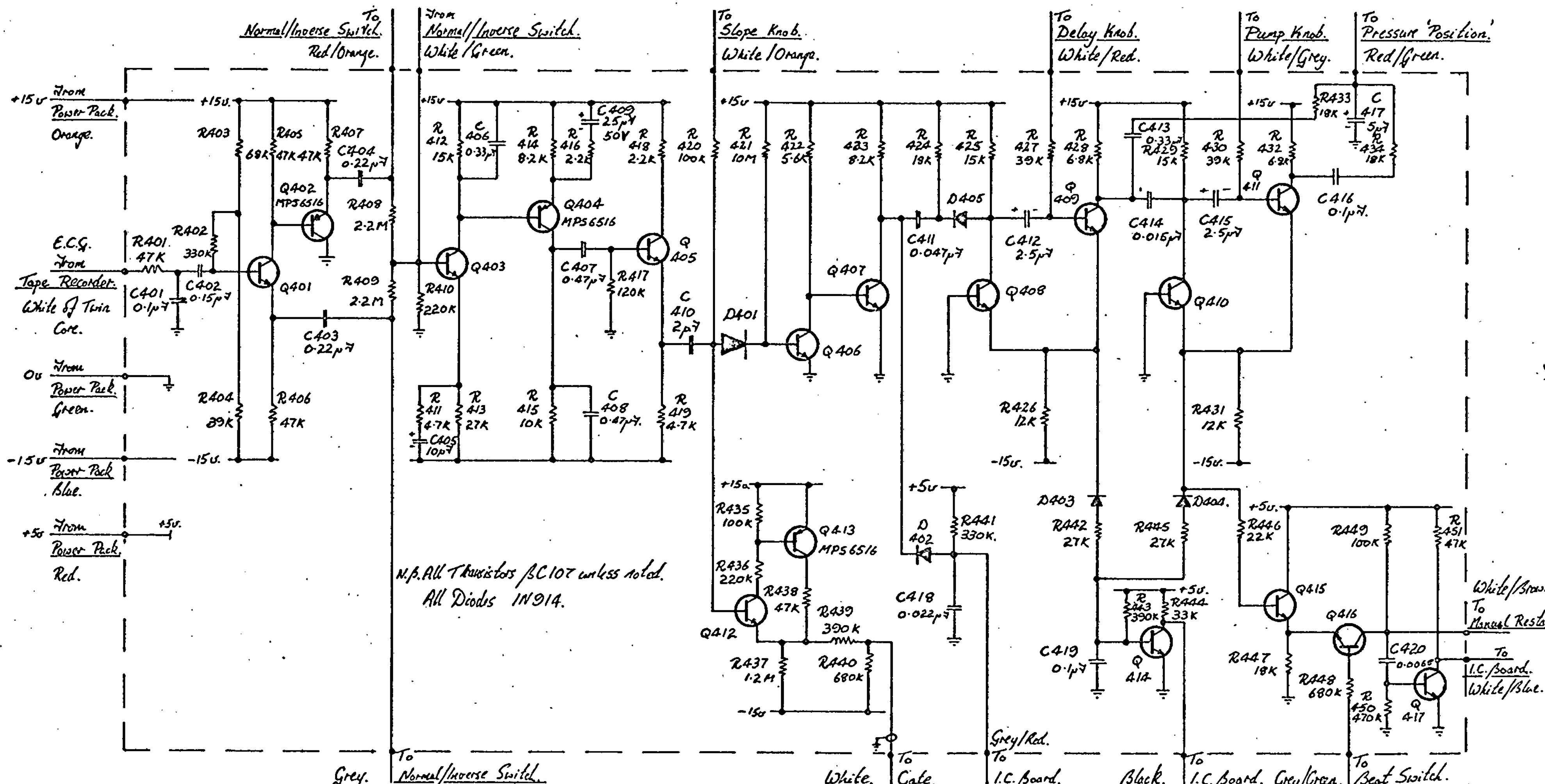


Fig. A4. Signal Processor Board.

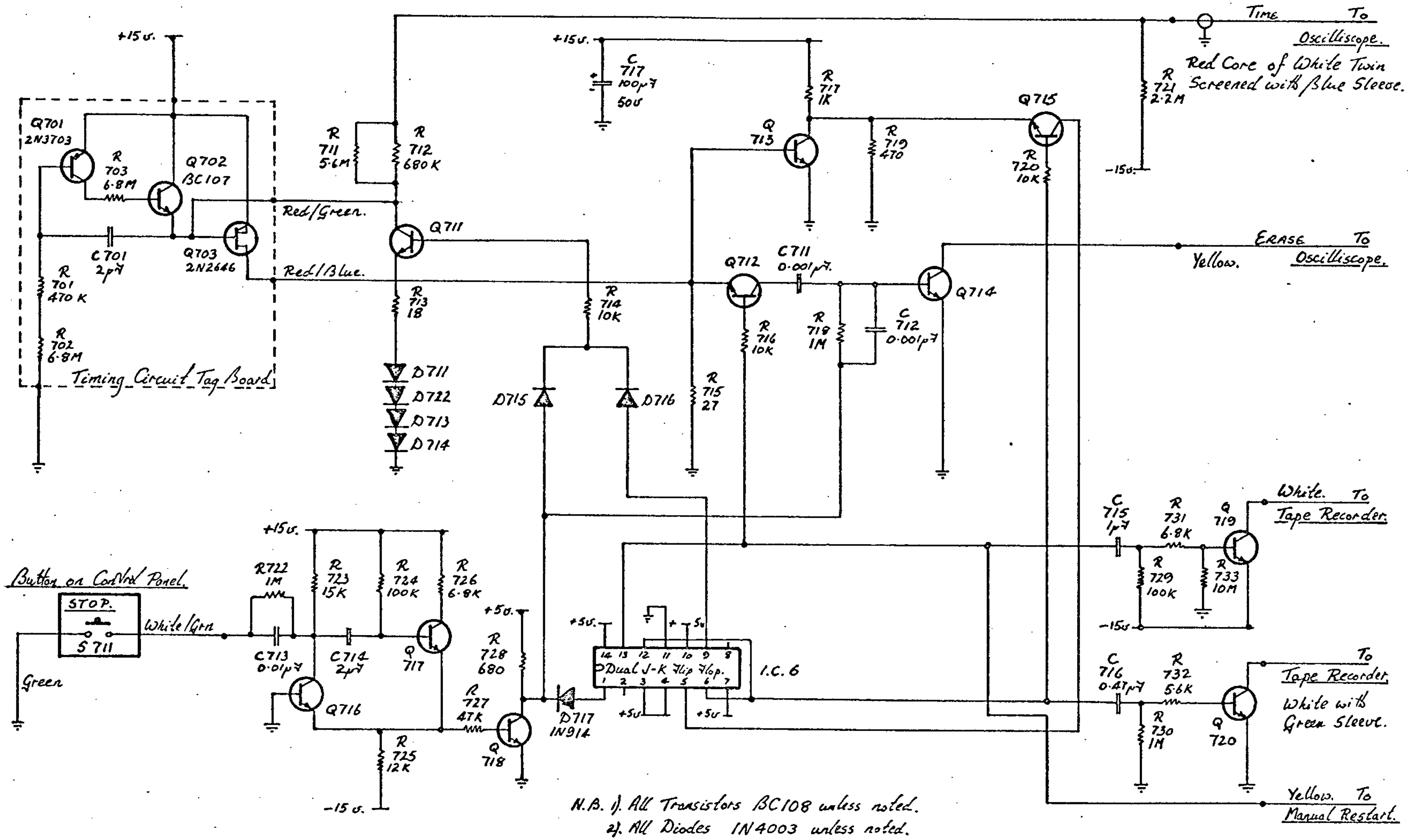


Fig. A7 Time Base Board

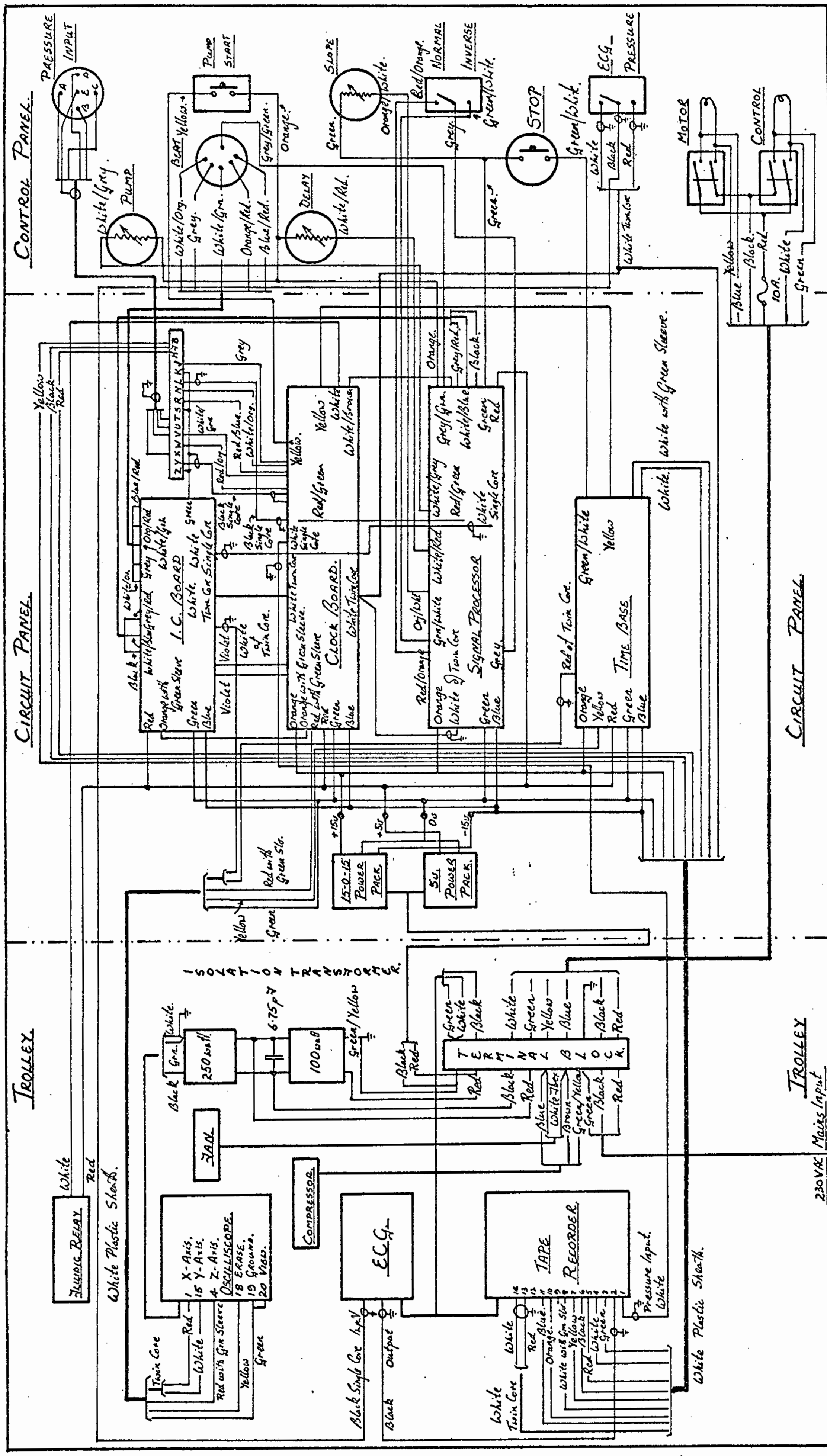
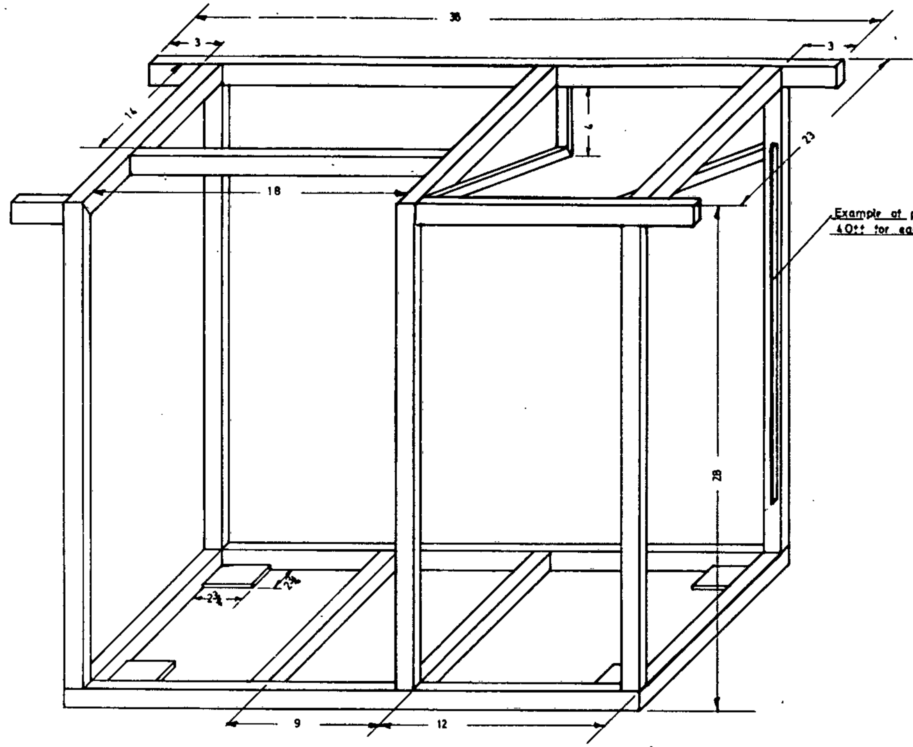
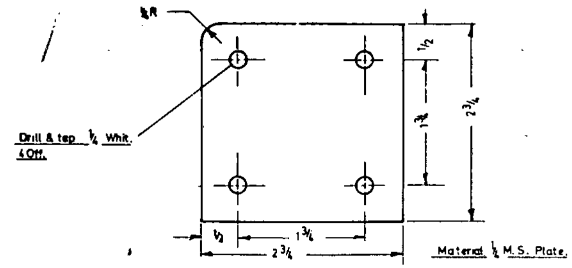


Fig. A8. Interconnection Diagram.



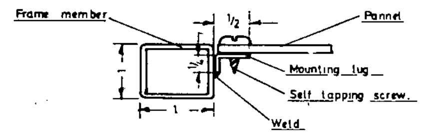
—FRAME—

(All welded structure, material 1" square tubing.)



—WHEEL MOUNT—

Scale Full size



—PANNEL MOUNTINGS—

Scale Full size

UNIVERSITY OF CAPE TOWN DEPT. OF MECHANICAL ENGINEERING	
—TROLLEY FRAME—	
SCALE 1"=4"	DATE Febuary 1971
DRAWN BY J.J.S.	Nº BP4
CHECKED BY	

Fig. A9.

APPENDIX B

INTEGRATED CIRCUITS.

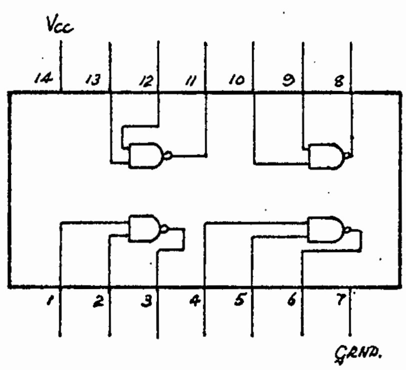
All the Integrated Circuits used in the system utilised Positive Logic.

Logical 1	5V nominal
Logical 0	0V nominal

1. SN7400N Quad 2-Input NAND Gate.

Manufacturer:- Texas Instruments.

The SN7400N consists of four 2-Input NAND gates in a 14-pin Dual-In-Line package.



$V_{cc} = 5v.$

TRUTH TABLE.

Input.	Input.	Output
0	0	1
1	0	1
0	1	1
1	1	0

Fig. B1. SN7400N Quad 2-Input NAND Gate.

Connection Diagram and Truth Table are illustrated in Fig. B1.

2. <u>SN7496N 5-bit Shift Register.</u>

Manufacturer:- Texas Instruments.

The SN7496N consists of five R-S master-slave flip-flops connected as a shift register, with the input and output to each flip-flop accessible, in a 16-pin Dual-In-Line package.

Transfer of information occurs when the Clock input rises from logical 0 to logical 1. Since the flip-flops are R-S master-slave circuits the proper information must appear at the R-S inputs prior to clocking. The Serial Input provides information for the first flip-flop, while the outputs of the subsequent flip-flops provide information for the remaining R-S inputs.

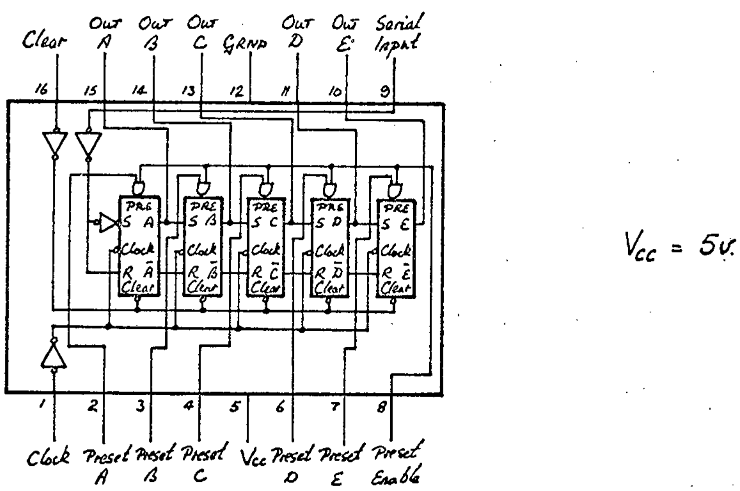


Fig. B2. SN7496N 5-bit Shift Register.

All flip-flops are simultaneously set to logical 0 by applying logical 0 to the Clear input and may be so set independant of the Clock.

Flip-flops may be independantly set to logical 1 by applying logical 1 to both the Preset input of the specific flip-flop and to the Preset Enable. Preset is independant of the Clock and Clear inputs.

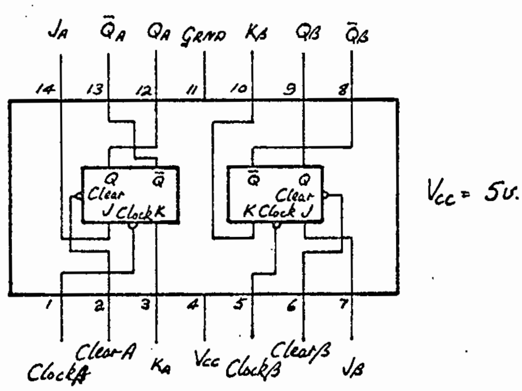
Connection Diagram illustrated in Fig. B2.

3. <u>SN7473N Dual J-K Master-slave Flip-flop.</u>

Manufacturer:- Texas Instruments.

The SN7473 consists of two J-K Master-slave flip-flops in a 14-pin Dual-In-Line package.

Fig. B3 illustrates the Connection Diagram and Truth Table. It can be seen from the Truth Table that by applying logical 1 to the J and K inputs one achieves a Trigger flip-flop.



TRUTH TABLE.

t_n		t_{n+1}
J	K	Q
0	0	Q_n
0	1	0
1	0	1
1	1	$\bar{Q}_n$

Fig. B3. SN7473N Dual J-K Master-slave Flip-flop.

4. <u>DG423L 5-Channel Drivers with FET Switches.</u>

Manufacturer:- Siliconix.

The DG423L consists of five driver-switches providing five channels in one TO-86 Flatpac. Each channel consists of a driver circuit controlling one MOS FET switch. Inputs are compatible with most 5V,DTL, TTL, and RTL logic outputs. A current-limiter pull-up FET is used for the driver collector load to provide minimum propagation delay for a given power dissipation.

For Positive Logic a logical 1 at the driver input turns the MOS FET switch ON and logical 0 turns the switch OFF.

Fig. A4 illustrates the Connection Diagram and the Circuit Diagram, for one channel.

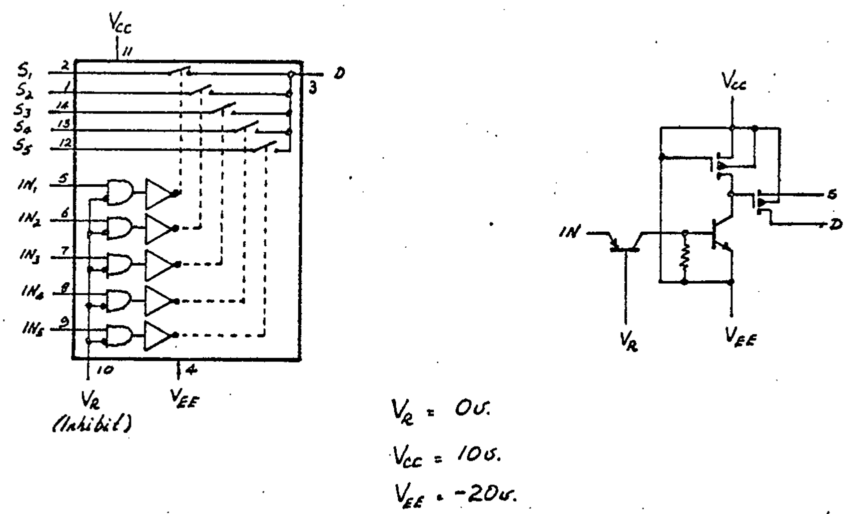


Fig. B4. DG423L 5-Channel Drivers with FET Switches.

APPENDIX C.

INSTRUCTIONS TO OPERATORS.

HEART ASSIST PUMP

INSTRUCTIONS

To Start the System

Connect the pump to the trolley, following the colour code on the air hoses and outlet points.

Switch *ON* the *CONTROL* and *MOTOR* switches. The tape/recorder always switches on in its playback mode, therefore depress the *STOP* button twice to bring the system on to the normal Monitor mode.

Once the Osscilliscope has warmed up, five traces will be visible. From the top they are:

1) A pressure wave.

2) A zero line. (N.B. If there is a zero pressure input these two will be coincident)

3) An ECG trace. (N.B. The position of this trace is controlled by the *POSITION* knob of the ECG unit)

4) A reference line for the peak detector.

5) A filtered ECG at the peak detector.

If the QRS complex of the ECG pattern is positive the *QRS DETECTION* switch should be in the *NORMAL* position. If the complex is negative the switch should be in the *INVERSE* position.

If the spikes on the filtered ECG trace do not cut the reference line above them adjust the *SLOPE* knob until they do (N.B. Any spike that cuts this line will act as an ECG signal and will trigger the system. Therefore if the P wave signal is large and appears on the filtered trace, care should be taken that it is not cutting the line. To prevent this happening adjust the *SLOPE* knob or reverse the switch).

Once the spikes are cutting the reference line a positive blip, followed by two negative blips, will appear on the pressure trace. The positive blip indicates the detection of the QRS complex. The first negative blip indicates the pump *TURN ON* signal, the second negative blip indicates the pump *TURN OFF* signal.

Turn the *DELAY* knob. The positive blip remains stationary, while the negative blips move together relative to the positive blip. Showing the changing delay between the initiation of heart beat and the pump *TURN ON* signal.

Turn the *PUMP* knob. The first negative blip remains stationary relative to the positive blip, while the second negative blip moves relative to these two. Showing the changing pump on time.

(N.B. If the total delay and pump times exceed the beat to beat time, the second negative blip disappears and the system will lock out until the incompatibility is rectified)

The *DELAY* and *PUMP* times should now be set, taking into account the fact that the effects of the *TURN ON* and *OFF* signals are not seen for approximately one tenth of a second.

Select on which beat the pump should pump by setting the *BEAT* knob (1 pumps every beat; 2 pumps every second; 3 pumps every third; 4 pumps every fourth; 5 pumps every fifth).

Set the balloon inflation volume by switching the *AIR* switch *OFF* and turning the volume adjusting knob on the pump. Clockwise rotation reduces the volume, anticlockwise rotation increases it. Once the volume is set, switch the *AIR* switch *ON*.

The system is now ready to run.

To Start Pumping

Press the *PUMP START* button. The pump will start and continue to run, unless the patient's heart rate changes and becomes incompatible with the delay and pump times or the system is stopped.

To Stop Pumping

(a) If the operator wants to stop the pump without a break in the monitoring, switch the *AIR* switch to *OFF*. This deflates the balloon and stops the pumping.

(b) In the event of an EMERGENCY of which the operator would like a record, press the *STOP* button. The screen will fill once more with recorded data of the 8 seconds prior to the emergency. This will remain on the screen until the operator wishes to resume monitoring the patient.

To Resume Pumping

After stopping as in (a) above, switch the *AIR* switch *ON*.

After stopping as in (b) above, press the *STOP* button again. This puts the system back to the Monitor mode. Readjust the system as required, then press the *PUMP START* button.

To Obtain a Permanent Record on the Pen Recorder

A permanent record of either the pressure or ECG traces may be obtained at any time by switching the *PEN RECORDER* switch to the desired trace and setting the ECG unit to *RUN*. This also applies when the system is in the Alarm mode after the *STOP* button has been depressed, for, although the

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screen fills and stops, the tape continues to run and therefore a record can be taken.

N.B. AS THE *STOP* BUTTON ALSO ACTS AS A RESET BUTTON, CARE SHOULD BE EXERCISED

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