A DEVICE FOR ASSESSING INTRACRANIAL PRESSURES

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ABSTRACT

An instrument has been designed to measure intracranial pressures in infants for the specific purpose of providing a clinical device to aid in the early detection of abnormal intracranial pressures. It is also useful in monitoring the intracranial pressure following surgery of the central nervous system or to determine whether shunting procedures are working adequately. The instrument provides a quick and reasonably accurate pressure measurement simply by placing a probe on the anterior fontanelle. Engineering design criteria and the operating principles of the instrument are fully discussed and alternative measuring devices and techniques are considered. Although clinical data is limited, a thorough analysis of the results to date is presented.

A transducer, an air pump, a pressure gage, an automatic control system, and memory with visual read-out, are the basic parts of the system. The transducer is a closed-end, fluid filled device which operates on a true applanation principle. The air supply for the pneumatically operated transducer is provided by the pump which is in turn, under the control of an automated logic circuit, thus simplifying operating procedure. Basically, the instrument makes twenty separate determinations of the intracranial pressure; the meter read-out is scaled to indicate the mean of these values.

Results obtained indicate that the intracranial pressure of infants with open fontanelles can be determined with an error of ±10%, and the time required to evaluate the pressure is minimal thereby facilitating clinical use.

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1.1 Outline of the Problem

1.1.1 Fluid pressures in the human body

In clinical situations, quantitative measurements of fluid pressures are obtained for several body fluids on a routine basis. For example, arterial blood pressure is very commonly measured because of its clinical significance and because of the ease with which it can be measured. A less familiar fluid pressure that is also easily measured, is the ocular fluid pressure. This fluid constitutes an important part of the refracting media of the eye and by virtue of its pressure preserves the corneal curvature. Another major fluid pressure is that of the cerebrospinal fluid (CSF), which bathes the brain and spinal cord. However, this important pressure is virtually ignored in the clinical routine of the hospital because of the relative difficulty of obtaining even a crude measurement.

1.1.2 The clinical significance of fluid pressure

The various fluids circulating throughout the body are important in the maintenance of life. If the fluid pressure gradients are of the correct magnitude, this circulation will result in a state of dynamic equilibrium (homeostasis) existing throughout the body. Diseases of the body destroy the dynamic equilibrium and as a result, organ functions if not attacked directly, are impaired indirectly. These events are in turn reflected in pressure changes, since fluid pressure forms an element of the many control loops which are disturbed by disease. For example, heart diseases are often accompanied by high blood pressure; eye diseases are sometimes associated with high intraocular pressures; and high intracranial pressures characterize a disease state called hydrocephalus.

1.1.3 The necessity of meassuring cerebrospinal fluid pressures

The brain and spinal cord making up the central nervous system (CNS), are two of the most important organs of the body. Control over virtually all other parts of the body is available to the brain and for this reason its' well being is especially important. Physical protection and support for the CNS is provided by the skull and bony vertebrae. However, it is a water solution, the CSF, which makes direct contact with the CNS. This fluid occupies the space between the soft brain tissues and the hard bony skull, and provides a hydraulic cushion for the CNS. Since the skull and vertebrae form a rigid closed structure, the intracranial pressure is extremely sensitive to any volume changes in either the CNS or the CSF. These volume changes may be caused by disease or injury. The sensitivity of pressure to disease states results in rapidly increasing pressures and may cause damage to the brain. Such rapid pressure increases if measured, can provide an indication of the presence of disease or injury to the CNS.

The clinical value of having a CSF pressure measurement is evident, but present methods of direct pressure measurement are not used in routine clinical work because an element of risk is involved. In some cases where disease of the CNS is partially established, the risk is warranted because the information to be obtained from direct pressure measurement has considerable value.

The routine blood and eye pressure measurements on the other hand, make available to the clinician some indication of fluid pressure and certainly the techniques make it possible to differentiate between abnormal and normal pressures without risk. If the routine measurements indicate an abnormality exists, more advanced tests, with their accompanying risk, are usually available. Unfortunately, a comparable routine technique for measuring intracranial pressure is not available. It is the development and evaluation of an instrument to provide this measuring capability which is covered in this thesis.

1.2 Introduction to a Possible Solution to the Problem

Several devices and techniques have been developed in the past to aid the clinician in estimating intracranial pressure. The advantages and disadvantages of these existing techniques are discussed and the need for an improved device is established. A comprehensive study of the influence of the medical aspects on instrumentation and measuring techniques is presented. Subject to these influences a suitable transducer was developed and the instrumentation necessary to provide virtually automatic operation of the system was constructed. The thesis contains a complete discussion of the design and testing of the device.

1.3 Outline of Clinical Evaluation

Extensive tests made on models with idealized fontanelle membranes are complimented by clinical studies. Clinical evaluation of the instrument, although limited, is included as a very necessary termination of a development project. For comparative purposes, infants with known abnormal and normal pressures were studied and the results evaluated. Test results obtained from some unique clinical cases are presented to show the full capabilities of the measuring device.

2. MEDICAL BACKGROUND

2.1 The Location and Purpose of Cerebrospinal Fluid

The CSF is a cavity-filling fluid found within the brain and spinal cord, and between the arachnoid and pia mater. The cavity formed by the arachnoid and pia mater is called the subarachnoid space. Fig. 1 illustrates the relationships between the subarachnoid space, the brain, the spinal cord and the CSF.

Chemically, the CSF is important in removing metabolic wastes from the brain and spinal cord, but the extent to which it also acts as a nutrient for the outer meninges is unknown(11).

The action of CSF as a hydraulic shock absorber for the brain is much better established(11)(31). The effect of a blow to the skull is decreased in intensity before it reaches the brain by a buffering action. This comes about because the fluid is contained in a rigid, fixed skull and the shock of the blow is therefore, distributed over the brain as a transient pressure. In this manner, the CSF gives good mechanical support and protection to the CNS.

2.2 Characteristics of the Cerebrospinal Fluid

Cerebrospinal fluid is produced as a secretion by specialized tissue called the choroid plexus. This is located in a series of fluid filled cavities within the brain called the ventricles. Fig. 2a shows a lateral view of the brain and the

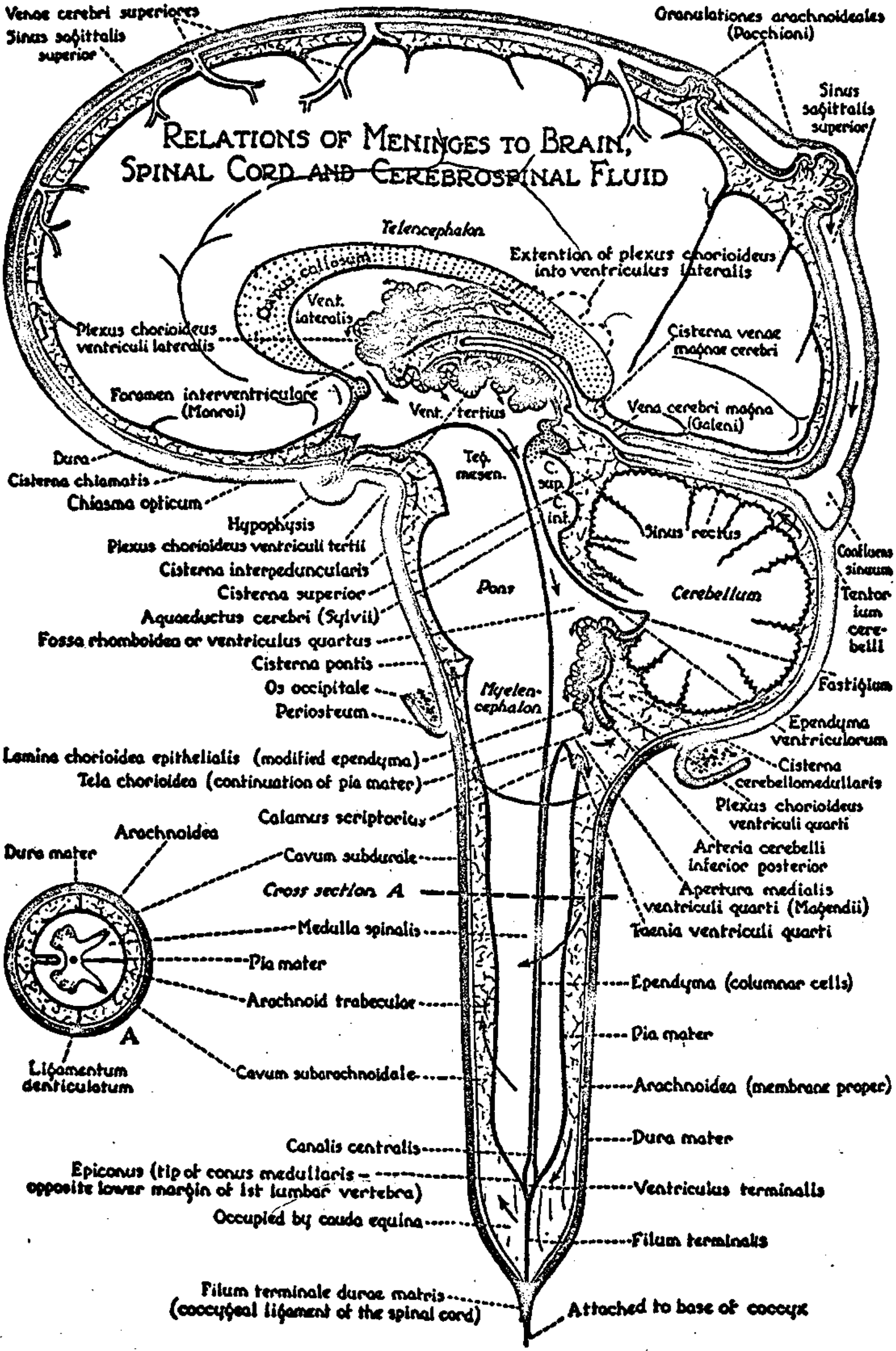
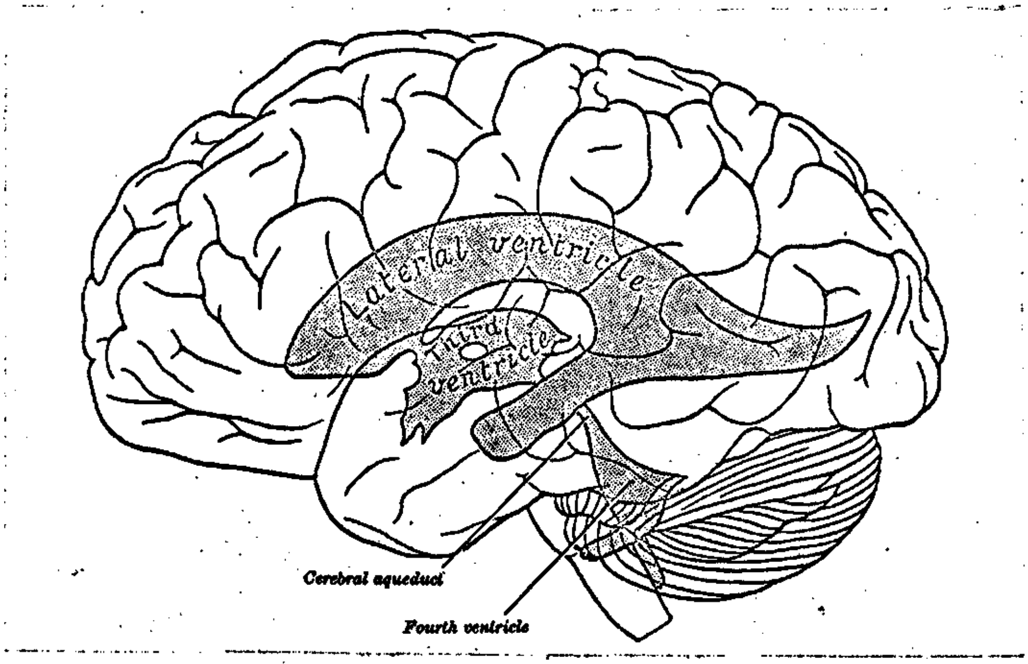
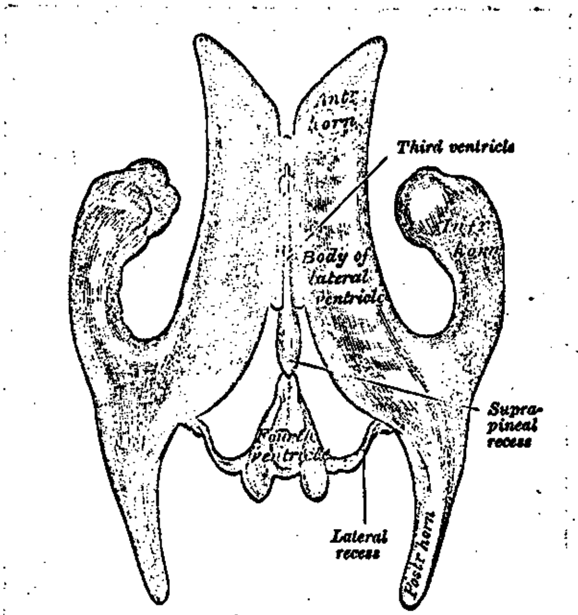


Fig. 1 Ventricles and Subarachnoid Space (After Ranson and Clarke (31)).



(a)



Note.—Where the lateral recess joins the fourth ventricle, the cast shows the curved lateral dorsal recesses of the roof of the ventricle ( ) projecting dorsally on each side beyond the posterior margin of the median dorsal recess.

The superior angle of the fourth ventricle and the aqueduct of the midbrain are hidden by the suprapineal recess.

(b)

Fig. 2 The Ventricles. (a) A scheme showing the relations of the ventricles to the surface of the brain. (b) A drawing of a cast of the ventricular cavities. Superior aspect. (After Davies and Davies(10)).

location of the ventricles. Fig. 2b shows the superior aspect of a body cast of the ventricles.

Circulation of the fluid produced in the ventricles has been established by Bering [4][5]. The fluid produced in the lateral ventricles moves into the third ventricle through the interventricular foramina. From the third ventricle the fluid passes through a small channel known as the aquaduct of sylvius into the fourth ventricle. At this point several openings allow the fluid to leave the cavities and circulate over the hemispheres of the brain in the subarachnoid space [10][31]. The fluid also flows down the spinal cord in a similar space. Several invaginations of the brain, called cisterni, give rise to pools of the fluid such as the cisterna magna. Removal of the fluid from the subarachnoid spaces takes place by absorption through small projections of the arachnoid mater into the venous sinus as shown in Fig. 1.

To account for the circulation of the CSF, some pressure gradient must be established. Bering [3] has shown that such a gradient exists and that it is a time varying pulsation due to the pumping action of the choroid plexus. It was also shown that this pumping is related to the arterial pulsations of the choroid plexus blood supply. Such pulsations can easily be observed in infants with open fontanelles.

The fluid pressures at various points in this system including the fluid in the spinal subarachnoid space are termed the intracranial or cerebrospinal fluid pressures. The pressure gradients established by the pulsations of the choroid plexus have been measured by Bering[3]. These results are summarized in Fig. 3. It is important to point out that the pressure at the ventricles can become negative with respect to the atmosphere under certain conditions[11].

2.3 Abnormalities Involving Cerebropsinal Fluid

To gain a fuller understanding of the CSF system, some mention must be made of the abnormalities which can occur.

Occasionally the actual production of CSF by the choroid plexus can be altered[6][19]. If this is in the form of an increase, then because of the fixed volume of the skull, an increase in intracranial pressure will result. In infants such an increase in pressure will cause the bones of the skull to separate resulting in an enlargement of the head.

A more common abnormality is the occurrence of a block in the circulation of the CSF. A total blockage in the adult can result in death within 24 hours[33]. In infants, the small diameter cerebral aqueduct is subject to congenital blockage. All the fluid produced in the ventricles (approximately) 4cc. per hr.)[33] must pass through this canal to the subarachnoid spaces, and any constriction results in a compression of the brain from within by the fluid pressure in the ventricles. A blockage can also occur at the interventricular foramena with a similar result[19].

Physical injuries to the skull are another cause of disturbances to the CSF system. Any deformity of the skull changes its volume and consequently the intracranial pressure[19][20]. Since bleeding from the meningeal arteries can occur in such situations, the volume may be further altered by the presence of a large blood clot.

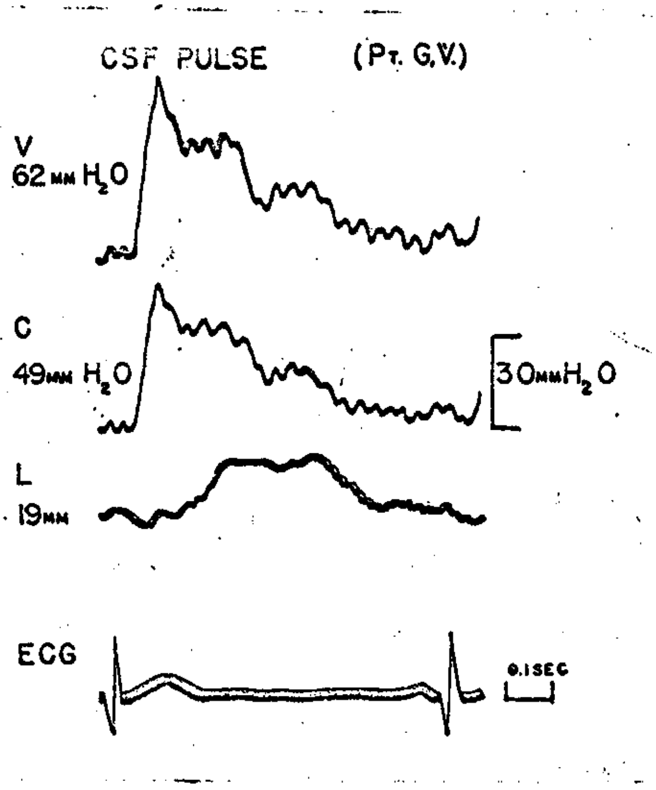


Fig. 3 Cerebrospinal fluid pressure pulsations. Simultaneous E.C.G. and pulse records from the cerebral ventricles, cisterna magna and lumbar subarachnoid space of an 11-year-old boy. The pulses in mmH_2O, are: ventricular, 62; cisternal, 49; lumbar 29. (After Bering(3)).

Some operative procedures to correct other defects associated with the CNS such as a myelomeningocele (open spinal meninges) may result in blockage of CSF circulation by scar tissue[19].

2.4 Pressure Reflections of Abnormalities

As pointed out above, many of the structural and functional abnormalities of the CNS and CSF result in pressure increases. These pressure increases if prolonged cause damage to the brain and in severe cases, death. Surgical techniques for re-establishing normal intracranial pressures are encouraging in their success, but the techniques for the early detection of chronic high intracranial pressures, are not. As a result, infants requiring corrective surgery remain undetected until extensive brain damage has occurred and manifested itself, and under such conditions, corrective surgery although functionally successful can only succeed in prolonging a difficult life[21].

3. EXISTING TECHNIQUES FOR MEASURING INTRACRANIAL PRESSURES

3.1 Clinical Methods

The present techniques used in the determination of intracranial pressures of infants fall into two categories: the indirect method, and the direct method.

The fact that the normal infant skull is free to expand to accommodate growth of the brain, has given rise to the indirect method. A measurement of the skull circumference is compared with a normal set of values[11], and an abnormal circumference or particularly abnormal rate of change in circumference is assumed to be due to high intracranial pressure. This method suffers greatly in the relative accuracy of the measurement since it is subject to the nurse's interpretation. Also it must be pointed out that a high pressure and an enlarged head are not entirely synonymous[8]. Palpitation of the fontanelle is a further aid in establishing qualitatively the presence of high pressure since the skin of the fontanelle will be tight and bulging under such conditions, even with the infant in the sitting position. At best, circumference measurements will only reveal the long term effects of high pressure.

A direct measurement of pressure is obtained by lumbar puncture when it is warranted. A needle is placed in the lumbar region of the spinal cord and the pressure measured directly. With the patient in the prone position[20], the lumbar subarachnoid pressure is assumed to be nearly the same as the intracranial pressure. There are three major disadvantages associated with this technique. The first is that the measuring technique will often cause an infant to cry and therefore a normal resting pressure can not be obtained. A second problem is that herniation of the cerebellum can occur causing death. This results if fluid is removed too rapidly during lumbar puncture causing the brain to impact on the base of the skull. The effect is analogous to a drain plug closing a sink drain. The third disadvantage is that lumbar puncture techniques could not be used in mass screening programs.

3.2 Review of the Literature

Recognizing the limitation of present techniques, several investigators have attempted to adapt equipment and methods from other fields to the measurement of intracranial pressure. The adaptation of various tonometric procedures accounts for the majority of these converted methods. A device called a Tympanometer, described by Keiber[23] provides the first suggestion on how an indirect pressure measurement on a membrane could be obtained. This involved correlating the displacement of a known force applied to a membrane with the pressure on the membrane. This same method applied to the measurement of eye pressures resulted in the development of the technique known as tonometry and one of the earliest such devices was called a Schiotz tonometer. A modification of the Schiotz device by Davidoff[8] was made to permit intracranial pressure measurements. Results presented by Davidoff however, indicate that only gross abnormalities could be detected.

A flatness or applanation tonometer was developed by Marg and MacKay[25] to overcome the theoretical objections to the indentation devices. Although this device has been moderately successful in measuring intraocular pressures, McKay's[24] suggestion that it could also be used to measure intracranial pressures appears not to have been followed up. The instrument is relatively expensive and difficult to operate and therefore, requires special personnel.

Another form of applanation tonometer employing air gaging developed by Durham[12] is still somewhat experimental and can not be evaluated.

The external arterial blood pressure measuring devices developed by Pressman[31] and later improved by Davis[9] offer only qualitative estimates of pressure and they can not be calibrated independent of the pressure to be measured.

The most promising adapted technique resulted from the ultrasonic studies of the brain. Jeppsom[21] has tried to correlate the amplitude of the midline-echo pulsations obtained from echoencephalographic studies on intracranial pressure. The results presented to date are inconclusive and open to question as is the origin of the midline-echo itself.

3.3 The Need for Improvement

In general, the present techniques employed by the clinician to evaluate the intracranial pressures of infants suffer greatly in accuracy, execution and interpretation. The proposed use of modified existing analagous devices apparently offers little in the way of improvement in the practical acquisition of accurate information. Certainly the development of a measuring technique comparable in simplicity and accuracy even to the sphygmomanometer used for blood pressure measurements has not yet occurred.

Future advanced and comprehensive studies of infant intracranial pressures will depend on the development of indirect, accurate methods and it is toward this end that a new instrument was developed.

4. THE TRANSDUCER

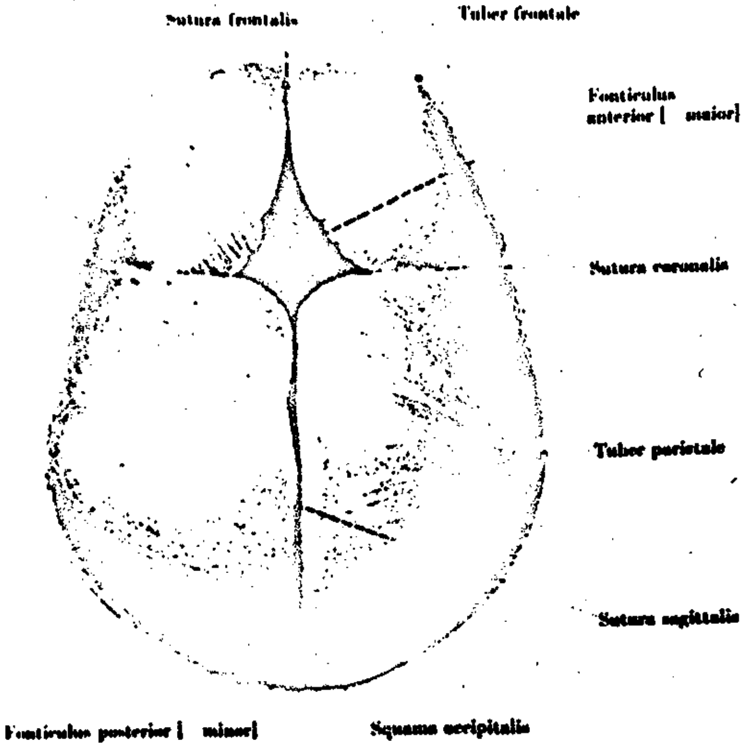
4.1 The Transducer - Subject Interface

The lack of an adequate transducer to transform intracranial pressures into a more readily measurable quantity, has prompted an investigation into the conditions under which it must operate so that a more suitable device might be built.

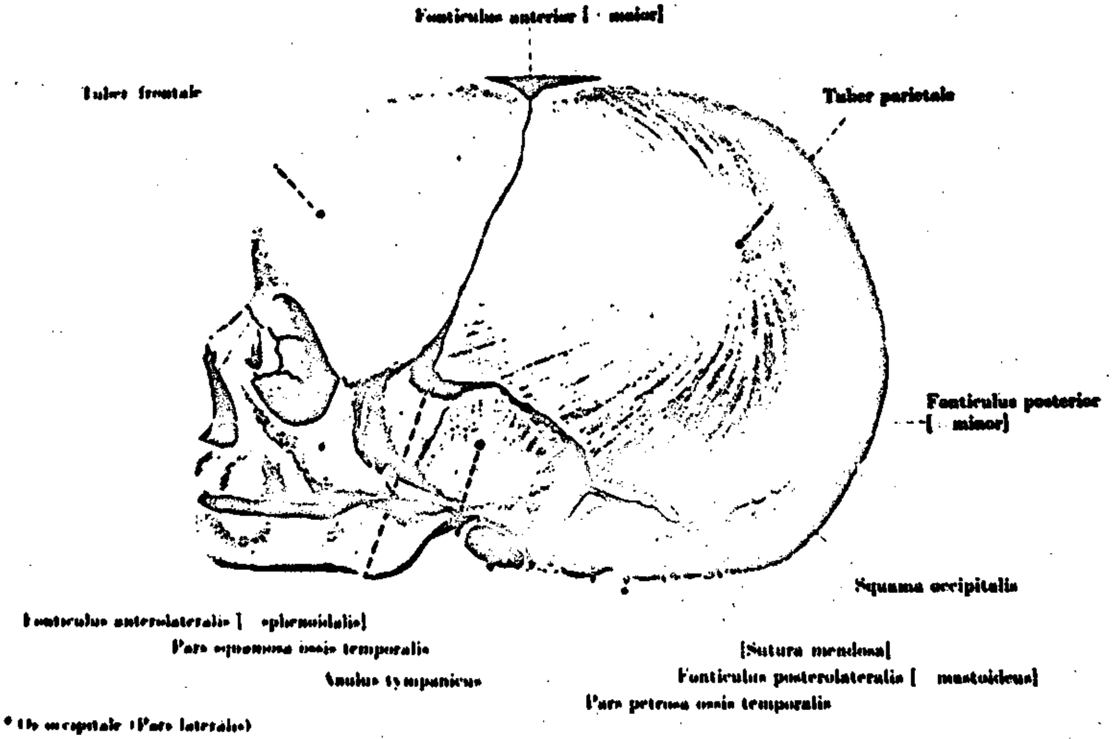
The risk element associated with a lumbar puncture to obtain a measure of pressure, dictates that a technique be developed which does not require direct contact with the CSF. The transducer therefore, must make available an external pressure of force which can be measured by conventional methods.

An infant's skull differs in several important aspects from that of the adult and this also influences the design of a transducer. Fig. 4a shows a lateral view of an infant's skull. Three large bones, the frontal, occipital, and temporal are separated by narrow regions of soft tissue forming sutures and by wide regions forming fontanelles. Fig. 4b shows a ventral view of the skull and in particular it shows two large areas of soft tissue, the anterior and posterior fontanelles.

An indirect measuring technique should make intimate contact with the CSF. The vertebrae of the spinal column almost completely shields this region. However, the soft tissue areas of the skull, particularly the fontanelles, are membrane-like and form only a thin covering above the CSF[10]. The anterior fontanelle, being the largest of these, then is the most logical point at which to apply a transducer. Unlike the remaining fontanelles the anterior one remains open for a considerable period of time, up to 12 months in the normal infant[10]. Furthermore, it is a consistant anatomical feature



(a)



(b)

Fig. 4 The Fontanelles. (a) Superior aspect of skull.
(b) Lateral aspect of skull. (After Wolf-Heidegger (39)).

of infants. Fig. 5 shows a crossectional view of the anterior fontanelle. A layer of skin overlays the meninges at this point. The subarachnoid space between the arachnoid and the pia mater containing the cerebrospinal fluid, is separated from the surface by a maximum of three mm. of tissue. Unfortunately, the great cerebral vein draining the cerebral hemispheres also underlies this region. Further complicating a measurement is the fact that CSF pressures are extremely low, normally being of the order of a cm. of mercury or a few hundred mm. of water [11].

4.2 Theoretical Consideration of the Transducer

4.2.1 Applanation principle and theory

At present most of the tonometric devices used to determine intraocular pressure, depend on the theory of applanation. This concept also offers a possible means of determining intracranial pressure.

The theory of applanation, illustrated in Fig. 6a, assumes that a thin elastic membrane is subject to some positive gage pressure P_2. If an external gage pressure P_1 is applied to the outside of this membrane, then depending upon its magnitude, three situations can occur. If P_1 is less than P_2, then the elastic membrane becomes concave or depressed. Between these two extremes a particularly useful situation can occur where $P_1=P_2$ and the elastic membrane is flat [26]. When this condition occurs, an equal external pressure P_1 is available which can be easily measured in a conventional manner. Some means must also be provided to determine when the membrane is flat.

The theory of deflection of an elastic membrane is discussed

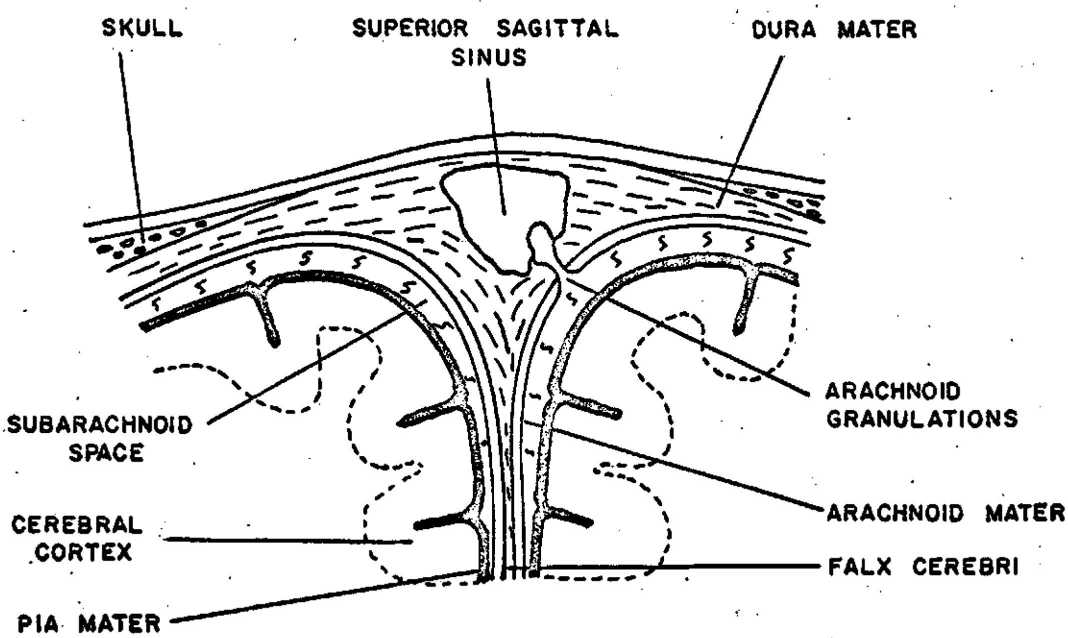


Fig. 5 Coronal section of anterior fontanelle. (After Wolf-Heidegger (39)).

in Appendix 10.1 along with the trivial solution for equal pressures.

4.2.2 The application of the theory to the fontanelle

A rigorous application of the theory of membranes is difficult. Quite obviously the fontanelle tissues are not homogeneous, and the outer meninx or dura mater itself exhibits few elastic properties. However, as was previously noted the fontanelle membrane pulsates considerably in response to the very small pumping pressures of the choroid plexus(3). Since the membrane does not suffer a permanent deformation, but recovers after each pulse, it must have some overall elastic properties. Added to the problem, is the presence of the cerebral vein imbedded within the dura and running the length of the fontanelle. In addition, the subarachnoid space containing the CSF, is not very deep beneath the fontanelle, since the folds or sulci or the cerebral cortex may rise to within a few milimeters of the dura. These sulci can interfere with the deflection of the fontanelle membrane when a transducer is applied, by exerting some force which would be related to the pressure of the CSF. This force could be called a tissue pressure. Only the building and testing of a transducer will determine how much effect these various factors will have on the application of the theory.

The fact that pressures to be encountered are very low, is an encouraging prospect from the point of view of the theory. In the prone position Bering(3) has shown that pressures taken by lumbar puncture are about 150 mmH_2O above atmosphere. Some investigators have found that negative intracranial gage pressures are present in the sitting position. Similar data for infants with open fontanelles is available only for the prone position and it indicates that a normal pressure is about 120 mmH_2O[19][20].

Pressing down on the fontanelle with a transducer could be expected to increase such small pressures and the act of measuring could disturb the system to be measured. However, Ryder[33] has indicated that any small transient changes in pressure are quickly compensated for, by the venous return volume[15].

4.3 Design Criteria

Transducer design is influenced in many ways by the fact that the measurement is to be carried out on an infant.

Although the presence of the fontanelle in the skull of an infant is consistant, its precise location and size is not. To determine the maximum size of the tranducer that can be used, a statistical study of the fontanelle size of newborns and infants was carried out. The results are summarized in Table 4.3 This study established that a transducer of 1 cm. in diameter would allow 95% of the newborns and infants to be examined.

TABLE 4.3

Distribution of Fontanelle Sizes

Subject Age	No. of Subjects	Average Size (cm.)	2 Std. Dev. (cm.)
1 day	141	1.9	.71
4 days	130	1.9	.68
1-36 wk.	56	2.3	1.21

The newborn infant also presents handling problems. The unpredictable movements of most babies makes it difficult to obtain pressure measurements. Restraining them only invites further protest which results in abnormal measuring conditions. Therefore, a premium is placed on a rapid measuring technique that does not disturb the child and does not require time consuming calibrations. Using fixed head gear to apply the transducer would not seem to be practical under these conditions. A hand held transducer applied in a manner similar to a stethoscope is preferable.

The measuring procedure must not involve risks to the patient in order that the infant's safety is assured and consents are not required. To protect against disease, the equipment, particularly the transducer, must be capable of withstanding repeated sterilization.

4.4 Transducer Design

4.4.1 Open-end transducer design

An open-end transducer design follows directly from a consideration of the theory of applanation. It simply consists of a hollow cylindrical probe with a center pin insulated from the cylinder to detect a condition of flatness. Fig. 6b shows such a device.

In operation the open-end of the probe is placed directly on the fontanelle which has been shaved to remove the hair and to which a conducting paste has been applied. On application, the center pin will be in contact with this paste. The pressure P_1, within the cylinder is now raised above that of the intra-

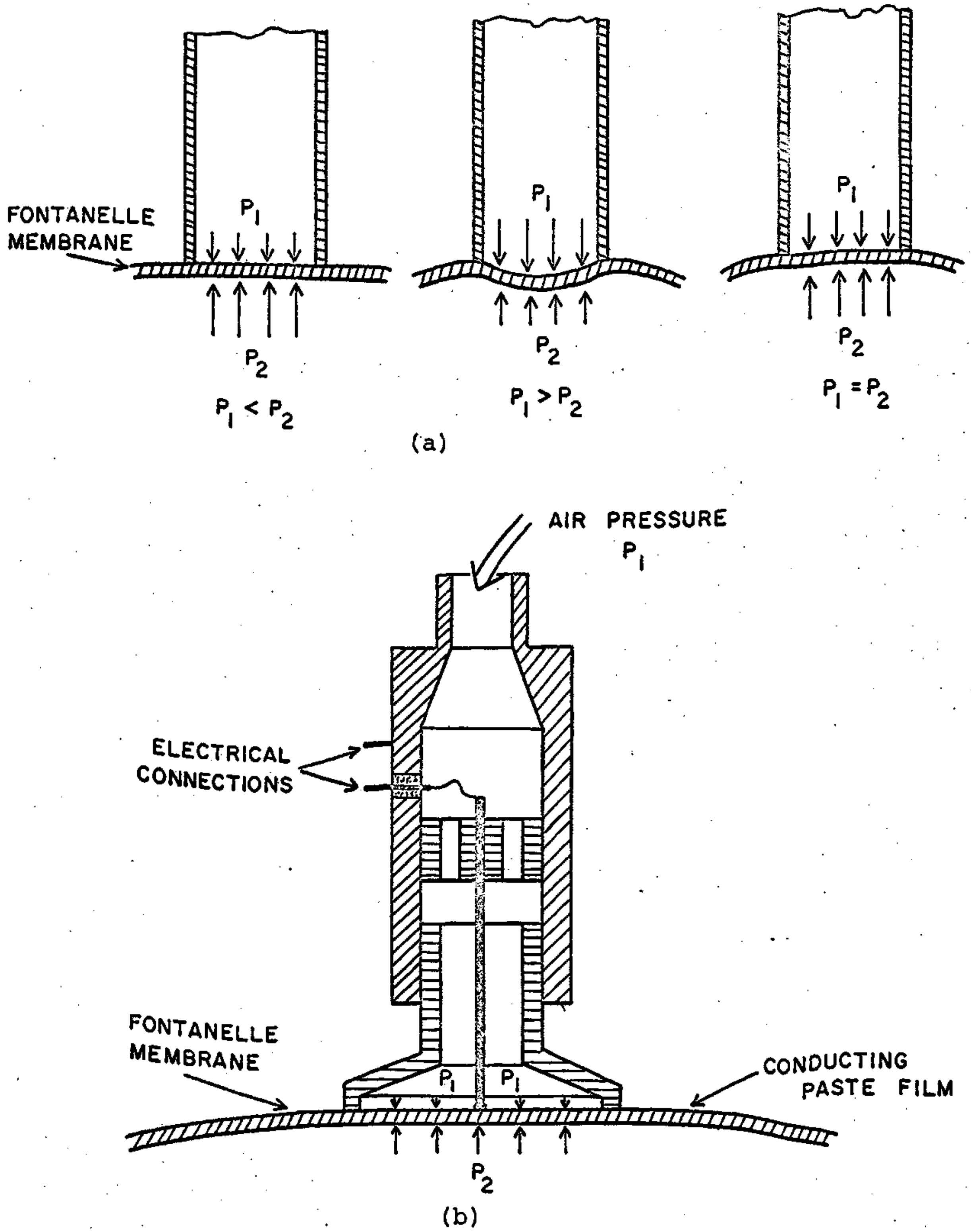


Fig. 6 The applanation principle. (a) Response of the fontanelle to various external pressures P_1. (b) Open-end transducer utilizing the applanation principle.

cranial pressure, causing a depression of the fontanelle beneath the probe. As P_1 is decreased, the skin and conducting film will move back toward the center pin and just make contact with it at flatness where the external pressure P_1, and the internal pressure are equal. The conducting film shorting the cylinder rim with the center pin, provides a switching action indicating flatness.

Unfortunately there are several disadvantages associated with this simple transducer. Calibration is difficult, since the end of the center pin must lie in the same plane as the concentric rim of the outer cylinder. Furthermore the skin of the fontanelle, even when shaved, does not present a smooth surface for detecting flatness. The conducting paste must also be harmless to the sensitive skin of an infant, but such pastes tend to evaporate quickly and lose their conducting properties. Attempts to flatten the hair with surgical plastic sprays proved inconvenient and unsatisfactory due to the difficulty experienced in removing the plastic after completing the measurement.

The transducer does however, have the advantage of being simple, easily cleaned and operation is possible in any position. It is also surprisingly accurate in determining pressures behind rubber membranes as can be seen from a typical series of measurements shown in Table 4.4

4.4.2 Closed-end transducer

The development of a closed-end transducer has provided a more suitable device for obtaining indirect measurements of pressure through membranes.

TABLE 4.4

RESULTS OF OPEN-END TRANSDUCER STATIC PRESSURE TESTS

READING NUMBER	MODEL PRESSURE	PRESSURE MEASURED BY TRANSDUCER	READING NUMBER	MODEL PRESSURE	PRESSURE MEASURED BY TRANSDUCER
1	140	180	13	140	145
2	140	155	14	140	140
3	140	145	15	140	140
4	140	145	16	140	140
5	140	145	17	140	140
6	140	145	18	140	145
7	140	140	19	140	150
8	140	140	20	140	150
9	140	140	21	140	140
10	140	140	22	140	155
11	140	140	23	140	145
12	140	140	24	140	140

The design again utilizes the applanation principle. Fig. 7 shows the construction of the device. To average any irregularities of the fontanelle surface including hair, the cylinder is closed off at the previously open end by a thin rubber diaphragm, and a liquid is placed above the diaphragm. Therefore, the major difficulty of determining when flatness has occurred, has been reduced to a problem of determining the level of the liquid at flatness. The liquid always presents a smooth surface for detection, and by using a center pin and a conducting fluid, an electrical switching action can be obtained. By decreasing the diameter of the cylinder around the center pin, some amplification in the transformation of deflection of the rubber membrane to the liquid level can be obtained. This gain is limited by meniscus effects.

Ethylene glycol is used as a fluid since its low vapor pressure at room temperature (10^{-3} mmHg)[17] helps eliminate evaporation problems. It is given conducting properties by the

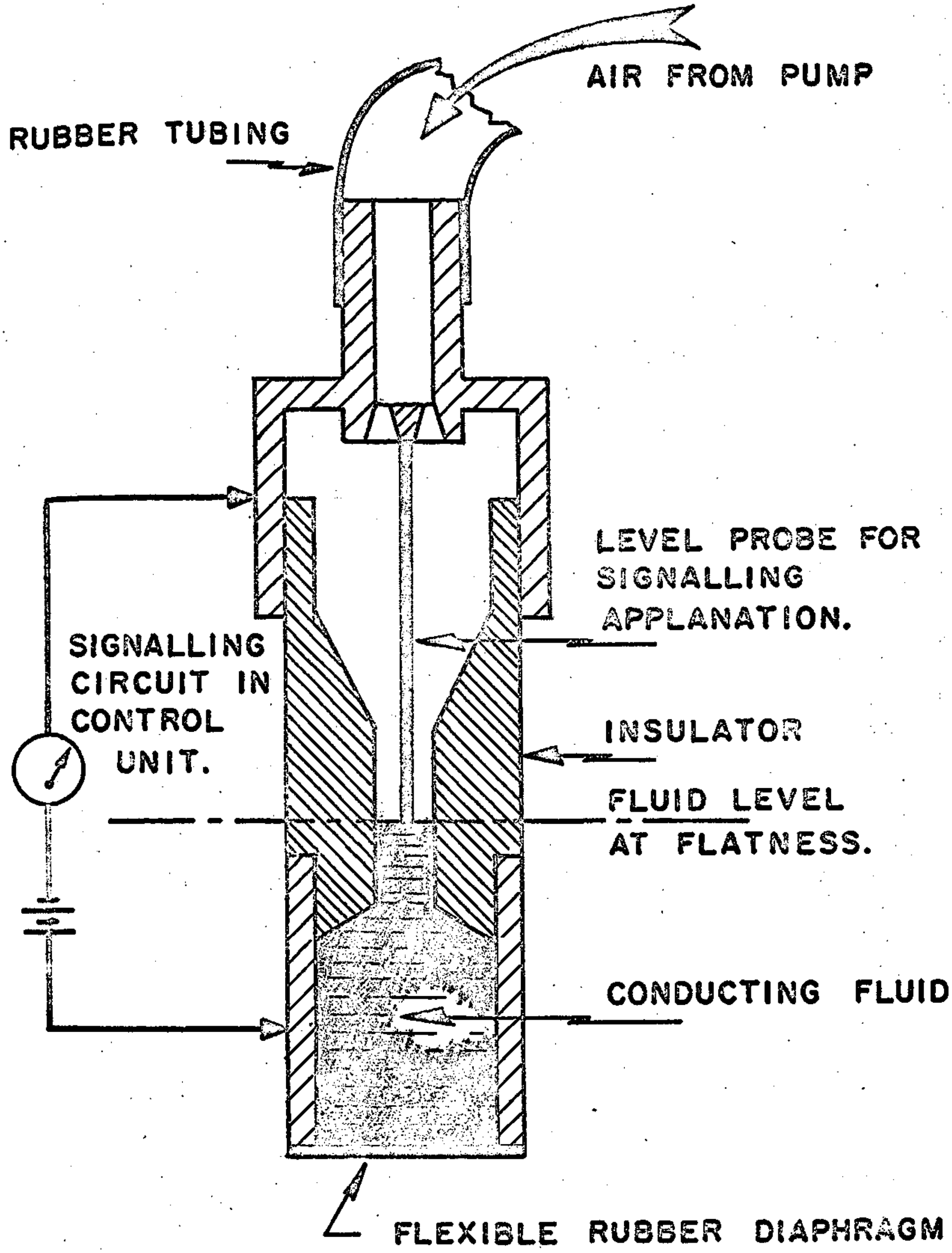


Fig. 7 Closed-end fluid filled pressure transducer.

addition of sodium chloride which further decreases the vapor pressure.

During operation, the center probe detects the liquid level best if the fluid approaches it to make contact. This requires that the external pressure be raised to a level well above the intracranial pressure so that the fontanelle is depressed and the liquid level is lower then the tip of the center probe. Then, if the transducer pressure is lowered, the liquid approaches the tip to provide a very well defined switching action at flatness.

This type of transducer offers an increase in accuracy over other devices and overcomes many of the problems of application to the fontanelle. The improvements are offset somewhat by the use of a liquid. Operation is only possible in the vertical position, and therefore, the infant can not be examined in the customary prone position. Also evaporation of the fluid, although slight, does not permit long term stability. Supplying air saturated with ethylene glycol vapor has increased the stability to the satisfactory period of several weeks. Fluid films, forming on the wall of the transducer also affect accuracy, but chemical agents such as stearic acid, decrease the contact angle of the fluid and thereby minimize both meniscus and fluid film effects[37].

The external pressure applied to the transducer must undergo a cycling process. This is necessary because the intracranial pressure may lie within a large range of values (70-200 mmHg)[3] and have a pulsating component of considerable magnitude (40 mmHg)[3]. An averaging of many measurements would therefore be required to obtain a meaningful pressure estimate. Repeated measurements to obtain this average will also give more confidence in the result then would a single measurement.

4.4.3 Testing the design

Comprehensive testing was carried out to evaluate the capabilities of the transducer. A simulated fontanelle was constructed using a thin sheet of rubber and this was subjected to a known static water or air pressure. The transducer, held in a rigid mechanical holder, was then applied to the model and the center pin moved to just make contact with the liquid when an equal external pressure was applied to the device. The external pressure was then varied repeatedly to determine at what pressure the center pin would indicate applanation. Fig. 8 shows the variation encountered for a given model pressure. The average external pressure, for a number of attempts, is also shown along with the two standard deviation limits. Fig. 9 shows the average pressure at which applanation occurred for different model pressures. This curve indicates the linearity of the transducer. If the transducer is hand held, and the tests repeated, similar results are obtained.

4.4.4 Test conclusions

These tests indicate that if the center probe is properly adjusted, the transducer is capable of accurately determining the pressure exerted on a rubber membrane. The adjustment of the center probe is very important however, since errors in calibration are reflected in the third power relationships

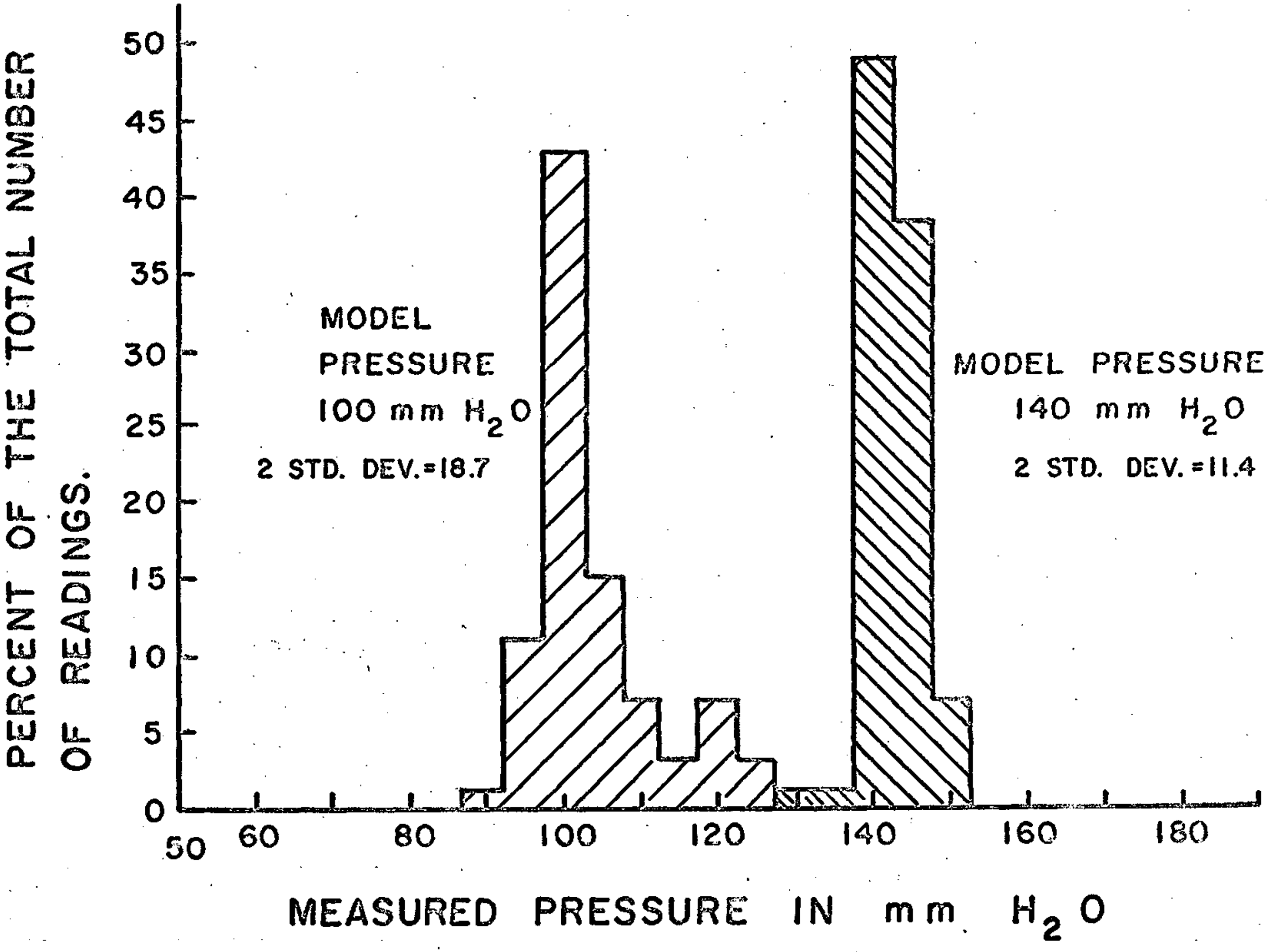


Fig. 8 Distribution histogram of model pressure as determined by transducer.

between pressure and deflections of the membrane from flatness[32]. Fortunately, calibration is a simple matter. If the transducer is applied to a smooth flat surface, such as a table top, the level of the liquid in the cylinder is fixed at the correct level representing flatness. It only remains to adjust the center probe such that a slight push on the transducer will cause the probe to make contact with the liquid. No difficulty has been experienced in calibrating the transducer in this manner to give errors of less than 10 mmH_2O at applanation.

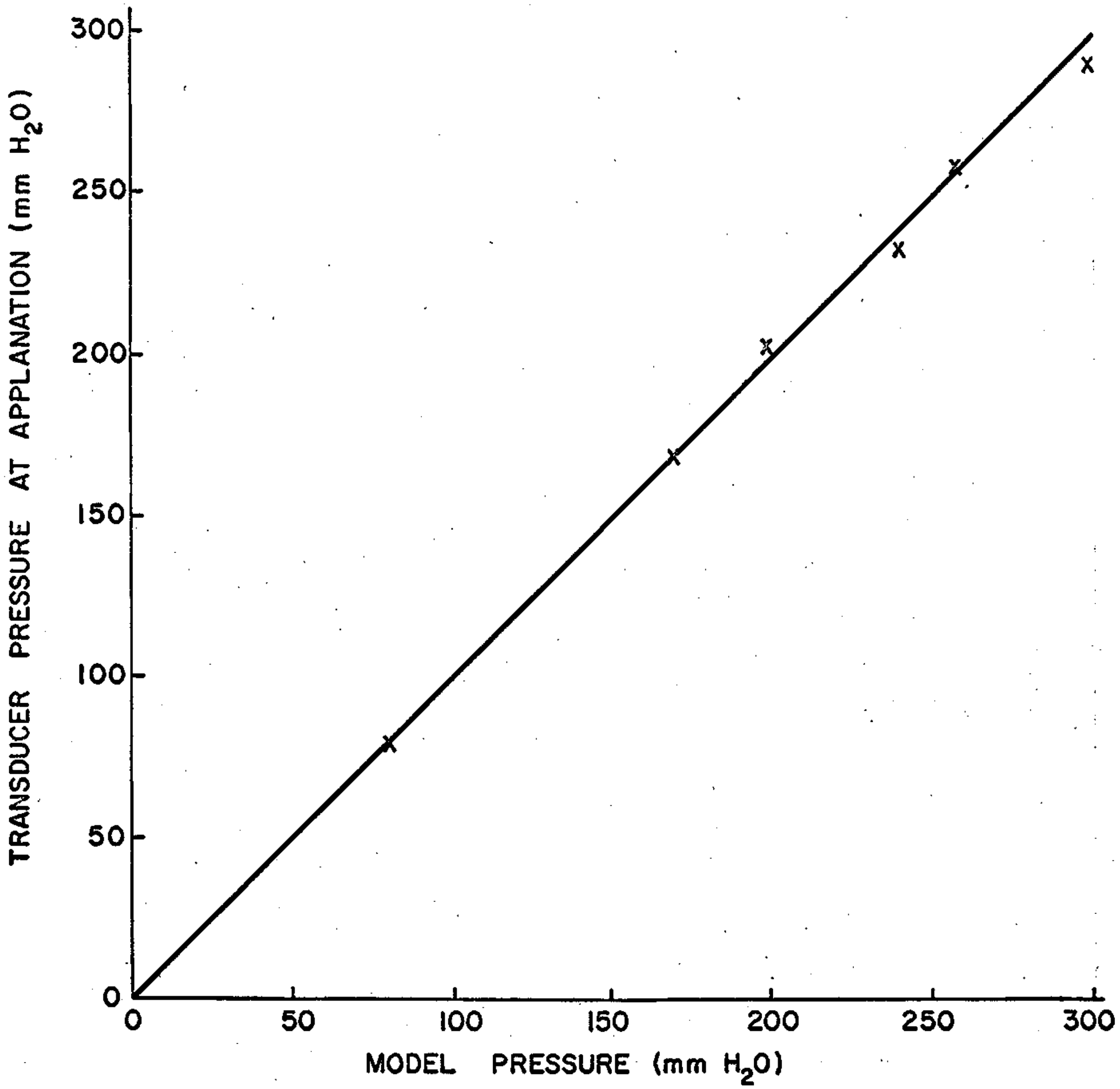


Fig. 9 Transducer linearity.

5. INSTRUMENTATION

5.1 Instrument-Hospital Staff Interface

Before proceeding with a description of the instrumentation necessary to support the operation of the transducer, the requirements of the hospital staff should be appreciated. Essentially the clinician desires to know what is a patient's intracranial pressure, how does it compare with others, and what changes have occurred since the last measurement. For routine clinical use, any pressure sensing device should be as simple and convenient to operate as possible. This means, minimization of calibrating procedures, manual operations, and data handling. The need for several measurements in one pressure determination necessitates an automated cycling procedure and a storage and a readout facility. Since random interruptions can occur, logic circuits are required. Some provision must also be made for control of an air supply for the transducer. The block diagram in Fig. 10 shows the general form of the resulting instrumentation.

5.2 The Prime Mover

5.2.1 Design of the pump

A controlled air supply is required to operate the transducer and it is convenient for the instrument to have a self-contained supply for greatest flexibility. The very low pressures required make it possible to use a small pump. Each measurement requires that an air pressure greater than the intracranial pressure be initially applied to the transducer and then decreased to zero. Such a pressure waveform is shown in Fig. 12.

The pump consists of two parts, a pumping chamber and a storage chamber as shown in Fig. 11. In operation, the solenoid is activated pulling in the rubber diaphragm. Air pressure then increases sharply in the pump and storage chamber and in the tubing leading to the transducer. When the solenoid is turned off, its spring return causes the air from the storage chamber to flow back into the pump chamber through a small hole. This gives the pressure waveform shown in Fig. 12. A slight ringing occurs due to the fast rise time of the pressure wave but it is of such short duration that it can be ignored. The spring return on the solenoid also aids in maintaining a large pressure difference between the two chambers causing nearly constant velocity flow through the small hole. This helps establish a more linear decrease in pressure, although, a non-linear pressure sweep does not influence the signal processing. (See Sec. 6.3).

5.2.2 Switching network

The solenoid requires 110 v at .3 amperes for its operation and since it operates in an intermittent mode, switching transients will be experienced. To eliminate these, an A.C. static switch[22] shown in Fig. 13 is used. A delay type static switch is used to allow firm positioning of the transducer on the fontanelle before the solenoid operates. When the transducer is placed on the fontanelle, the switching action of the center probe and the conducting fluid initiates the measuring sequence. This signal passes through a switching amplifier and then operates the relay of the A.C. static switch.

The contacts of relays #1, #2 and #3 (AND gate #1 see Fig. 13 and Appendix 10.4) upon closing initiate the time delay interval.

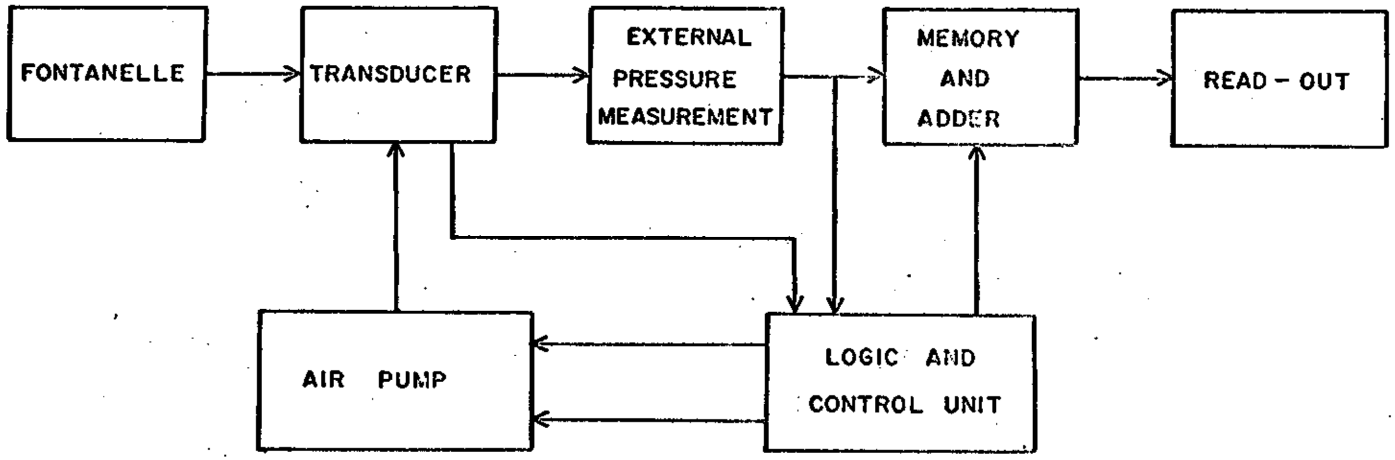


Fig. 10 Instrumentation for indirect pressure measurement.

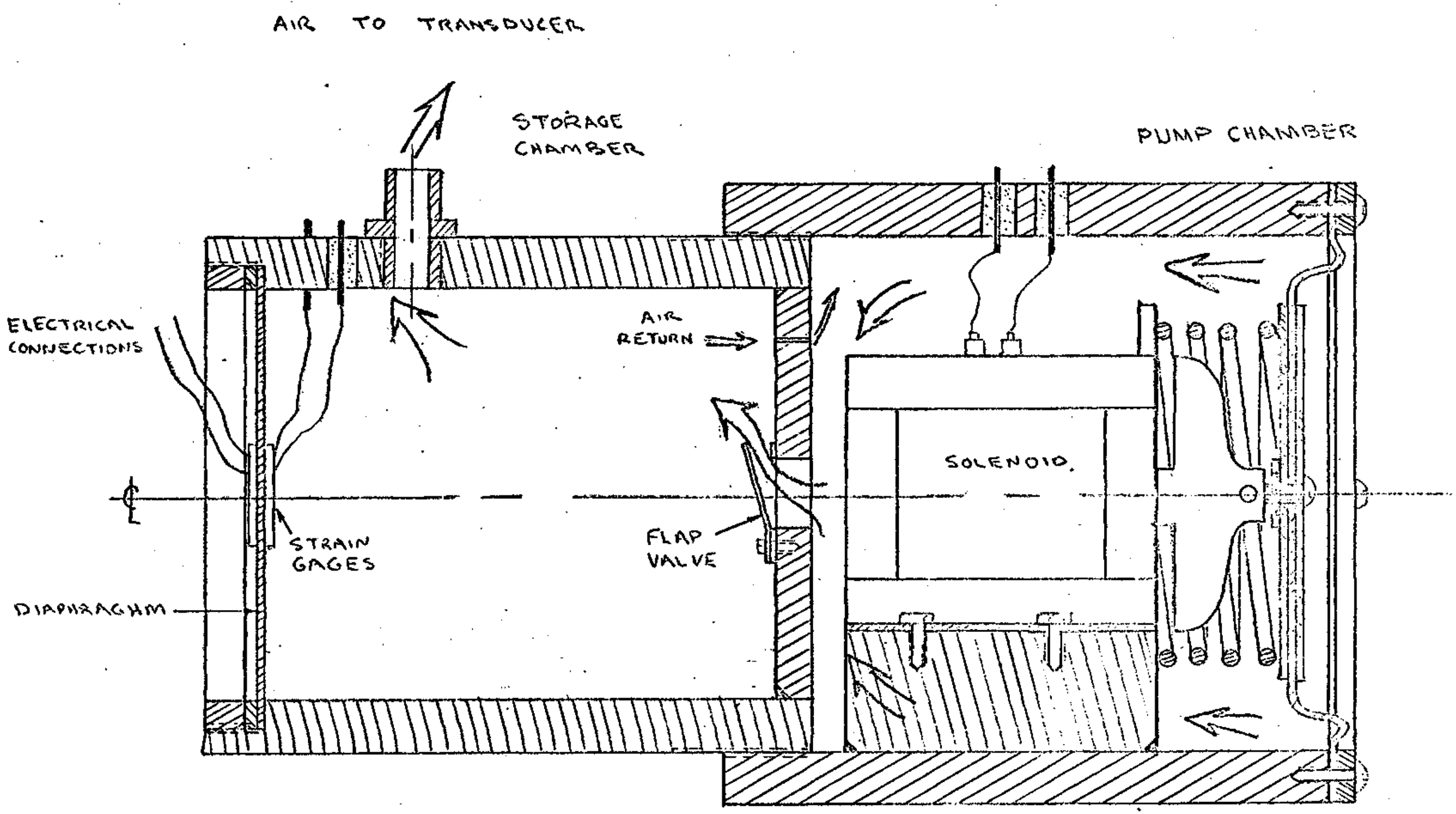


Fig. 11 A solenoid pump for obtaining a reverse saw-tooth pressure wave.

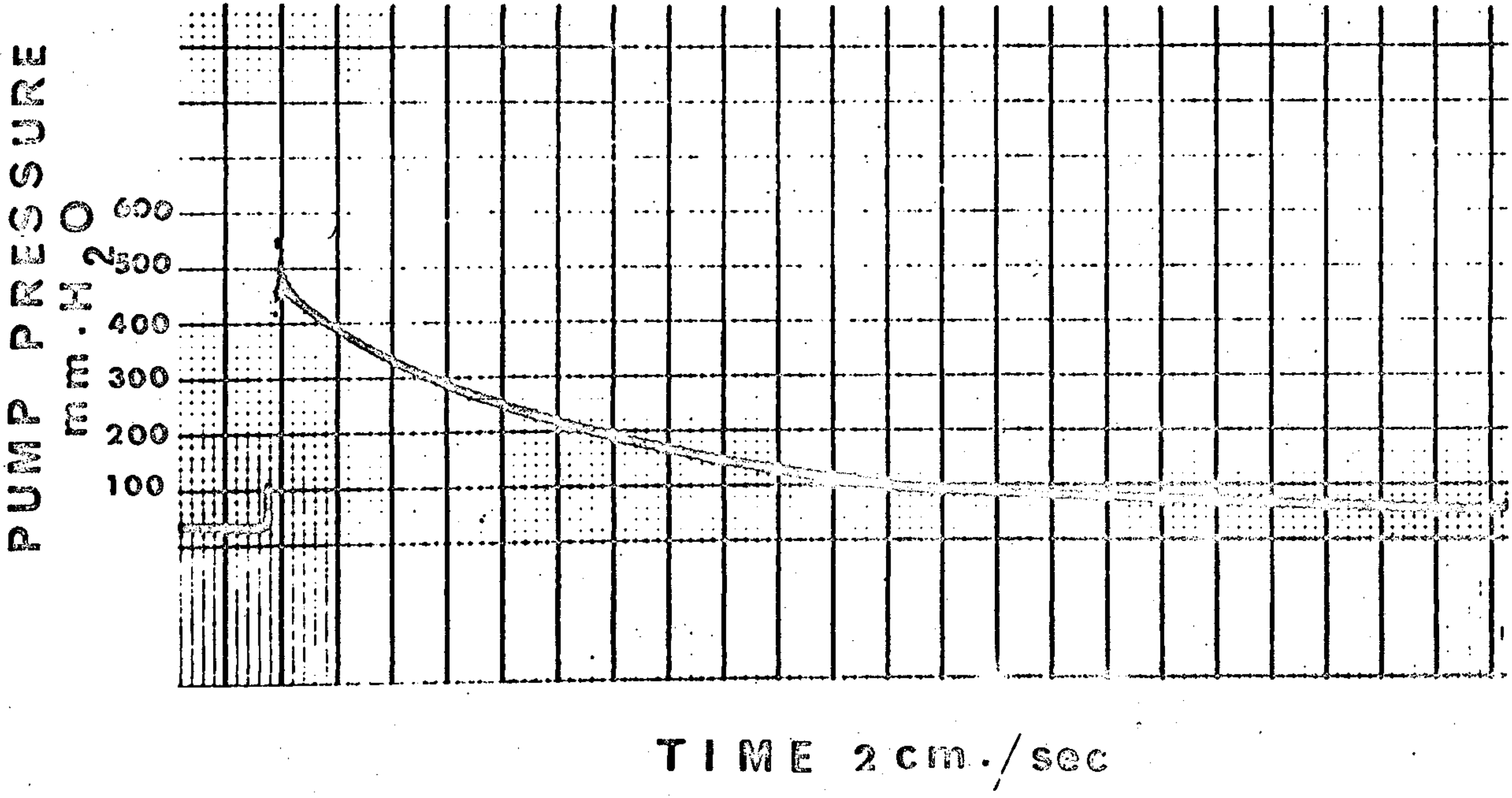


Fig. 12 Pressure wave produced by the solenoid pump.

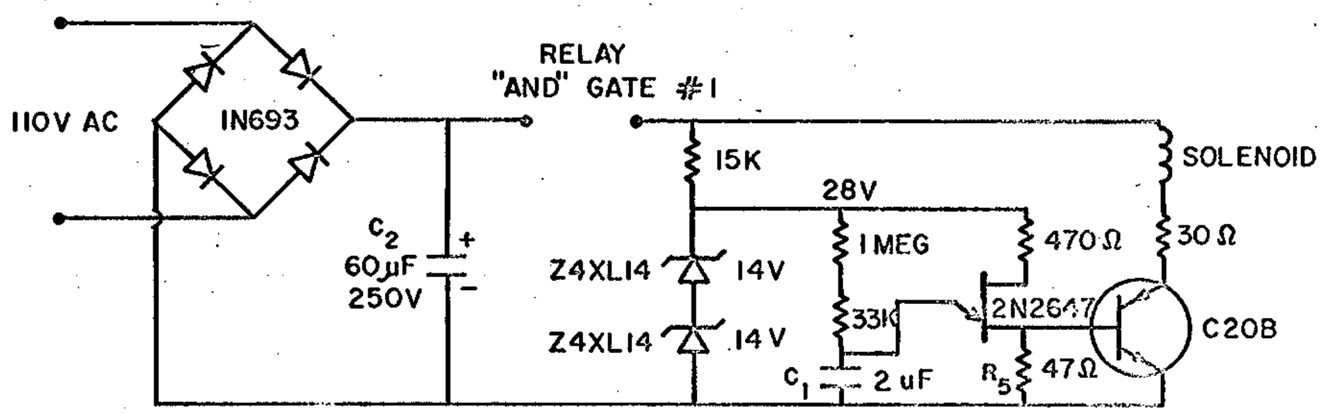


Fig. 13 An A.C. static switch with time delay. (After Jones (22))

A7 the end of the timing interval, the discharge of c_1 across resistor R_5 triggers the controlled rectifier. This places the full-wave rectified line voltage across the load. During the time interval, c_2 is able to maintain a d.c. potential of approximately 165 volts because of the low drain current. At the end of the timing interval, the higher bridge current supplied to the load causes the capacitor to discharge. Capacitor c_2 must be large enough to maintain the holding current requirements of the silicon controlled rectifiers

5.3 Signal Processing

5.3.1 Patient and staff influences

The manner in which signal processing is carried out is influenced by both the infant and the operating personnel. The restlessness of the infant necessitates that measurements be completed quickly, and that the signal processing circuits be immune to random interruption. The staff requires a visual readout of the average pressure upon completion of the measurement so a means of automatically adding all valid measurements to obtain this average is required. The block diagram in Fig. 14 shows the signal processing sequence.

5.3.2 External Pressure Measurements

A commercial pressure gage capable of measuring pressures of a few mm of H_2O is extremely expensive, but with the recent availability of semi-conductor strain gages[(7)(34)], a satisfactory pressure gage can readily be constructed.

A plastic circular diaphragm was chosen to form the primary transducer of such a gage. This diaphragm forms the end wall of the storage chamber of the air pump and therefore, it will

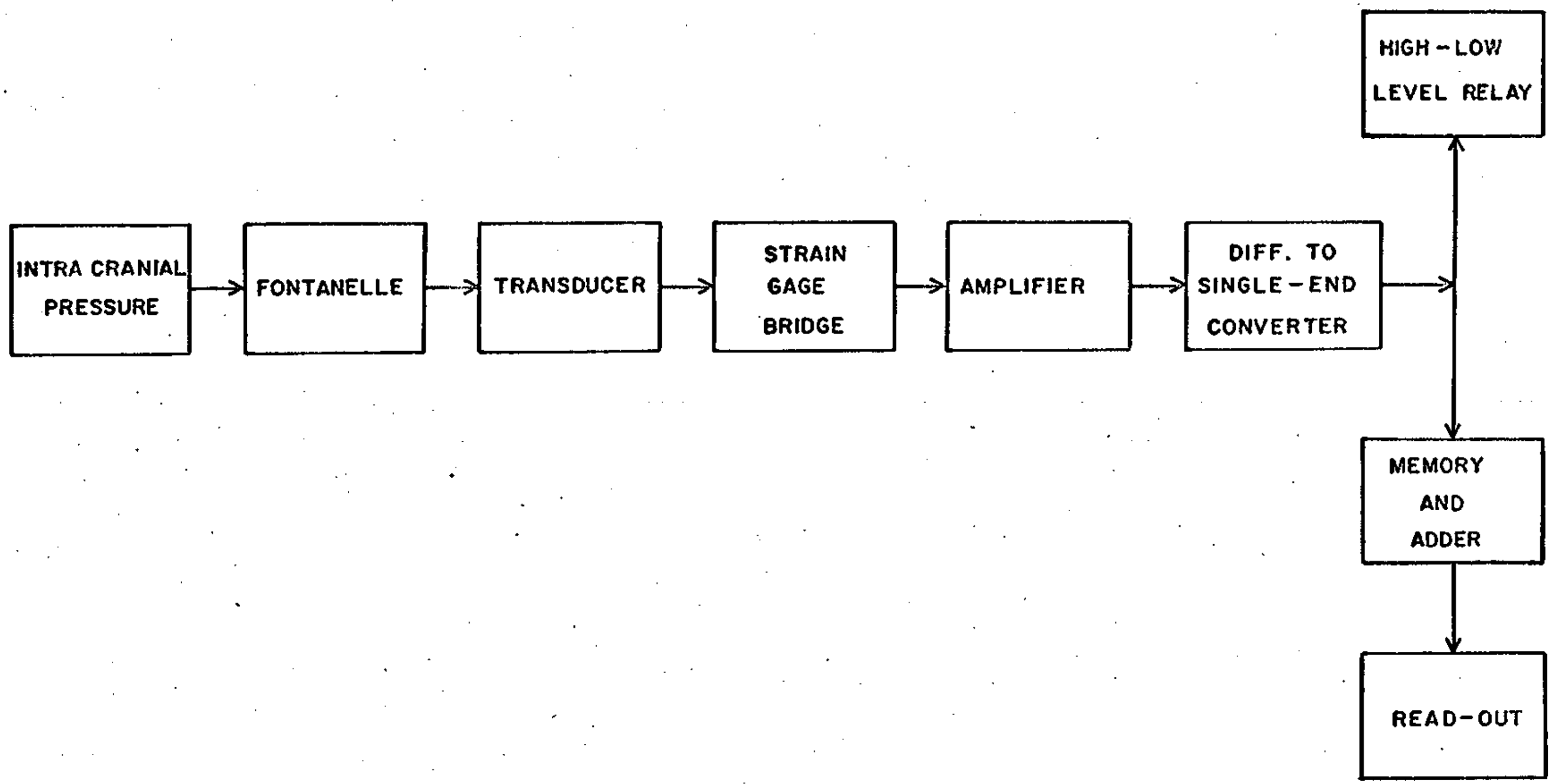


Fig. 14 Signal processing

allow measurement of the external pressure applied to the transducer. The small deflections of the diaphragm caused by the varying pressure, result in a stress on the diaphragm. Semiconductor strain gages cemented to the plastic are also subject to this stress and respond with a change in resistance [1][2][36]. The design considerations associated with the selection of a suitable diaphragm and strain gage are described in Appendix 10.2.

A bridge configuration coupling the strain gages is shown in Fig. 15. It is used to transform the resistance change into a suitable voltage change with minimum temperature distortions[28][35]. This voltage now represents the external pressure applied to the transducer. The accuracy of this representation is shown in Fig. 16, and it can be seen that over the expected pressure range, the transformation takes place in a sufficiently linear manner.

5.3.3 Amplification

Although the strain gages that are used have gage factors as high as 150, the output from the bridge will be a maximum of 20 mv. at a pressure of 500 mmH_2O. Therefore, the signal must be amplified before it can be used further.

The amplifier built for this purpose is a direct coupled, differential amplifier designed by Hilbiber[16]. The input and output characteristics are as follows:

Input - 20 mv. peak to peak.
- differential input.
- high input impedance.

Output - 20 volts peak to peak.

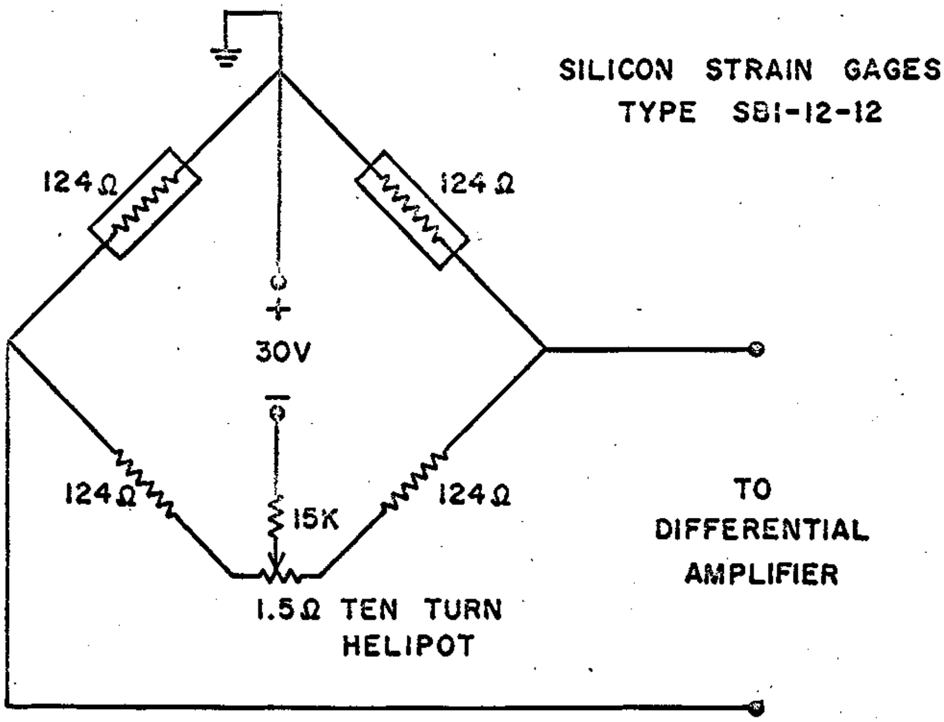


Fig. 15 Strain gage bridge configuration for measuring the external pressure P_1.

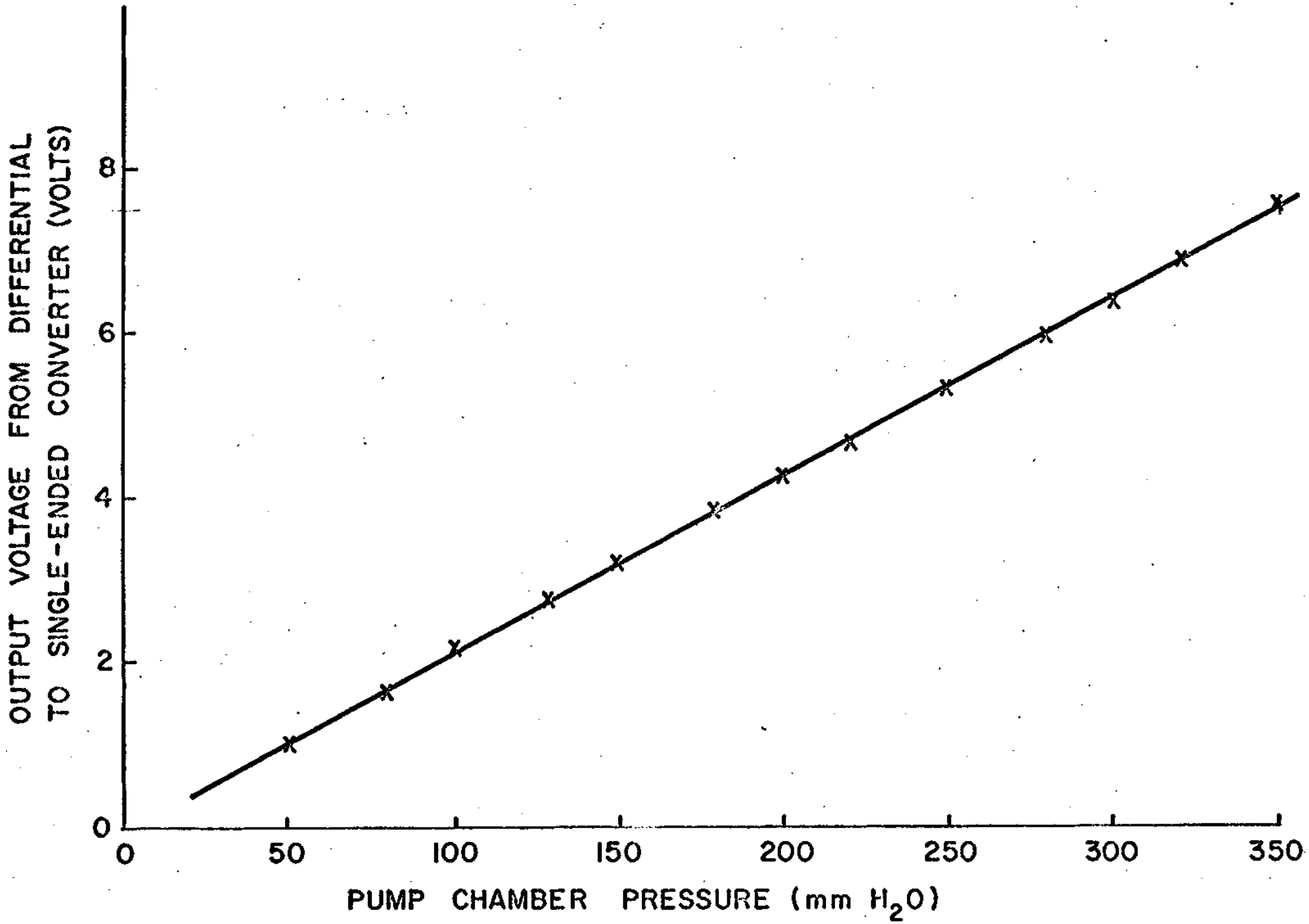


Fig. 16 Linearity of the external pressure measurement.

- dc to 5 kc response.
- zero offset.
- 2 ma. output current.

The modified circuit diagram is shown in Fig. 17. Standard transistors have been substituted for Q_1, Q_3, Q_4, Q_5 and Q_6. The current source formed by Q_2, was altered to increase the current to diode D_1. Adjustment of resistor R_2 permits a zero level to be set on each side of the amplifier output with respect to ground. Zener diodes D_3 and D_4 were chosen for extremely low holding currents to maintain zener action under all expected conditions.

The overall operating characteristics have been determined. The amplifier provides a voltage gain of 985 from D.C. to one kilocycle per second, and the output impedance is approximately 200 ohms. A test was also carried out to determine the long term stability of the amplifier[13]. The input was shorted to ground and the temperature was stabilized at 27°C. It was found that the output voltage remained within an envelope of 30 mv. for 8 hours. This compares favorably with the figure obtained by Hilbiber[16] of 25 mv. for 1200 hours. Changes of one volt in supply voltages result in .1% changes in the output levels.

Temperature compensation was accomplished by adjusting the collector currents of transistors Q_3 and Q_4. These currents control the temperature dependency of V_{be} of these transistors and therefore, the temperature stability of the amplifier. Fig. 18 shows the results of standard temperature tests for differential amplifiers[13] performed before and after compen-

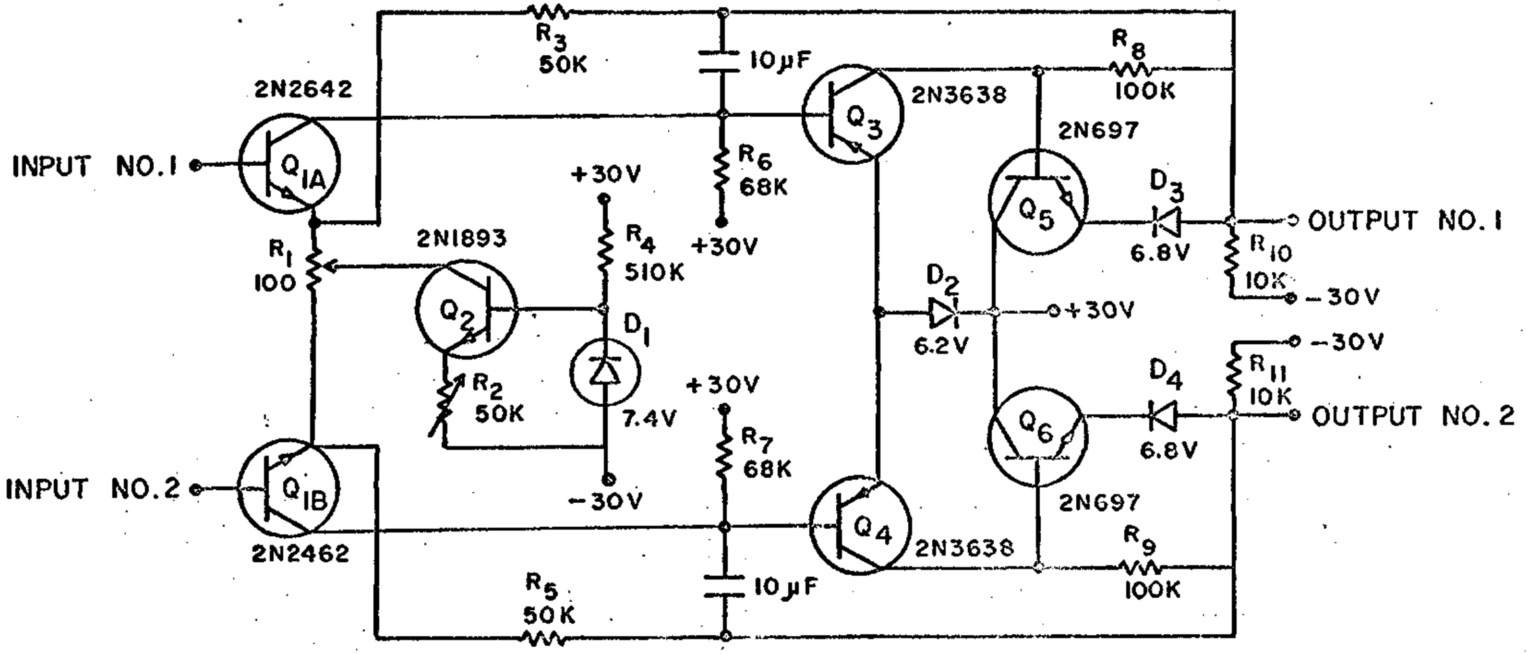


Fig. 17 D.C. differential amplifier. (After Hilbiber (16)).

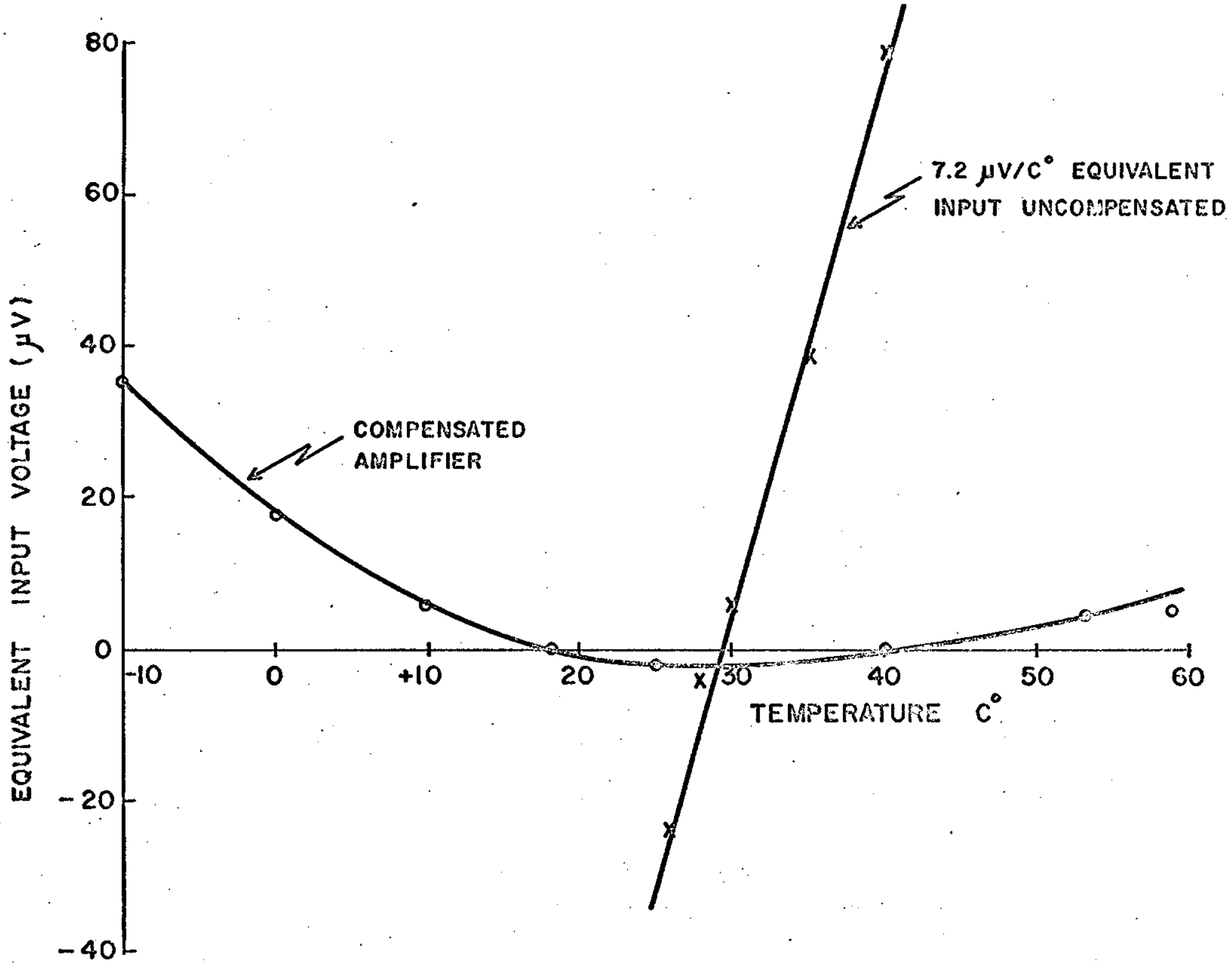


Fig. 18 Temperature compensation of the D.C. differential amplifier.

sation are contained in Appendix 10.3.

To obtain a single-ended output from the amplifier, a differential to single-ended converter was constructed. The circuit is shown in Fig. 19. The differential output voltage is applied to Q_1 across the emitter-base junction and a 10 kΩ resistor. Transistor Q_2 forms a current source to ensure forward biasing of the emitter base junction at all times. A 15 kΩ variable resistor and transistor Q_3 permit setting the output at zero volts for no input. The common emitter stage provides low impedances for coupling with the following stages. A gain of approximately 1.3 is provided by the converter.

5.3. Memory unit

The requirements of the memory unit are dictated by the form of the incoming signals, and the form in which they are to be presented to the operating staff.

As each measuring cycle is executed, a voltage representing the transducer pressure at the instant flatness occurs is to be added to the sum of all previous voltages of that measuring sequence. At the end of the procedure this sum will give an indication of the average intracranial pressure for a particular number of readings. Each input signal will be between zero and twelve volts in amplitude and each is to be added and stored for periods of time up to five minutes, without appreciable error. This is accomplished by using an analogue voltage adder.

The design is based on "ladle" and "bucket" technique, using a charge transfer for addition and a capacitive storage type of memory[29]. The principle of operation can be illustrated with the aid of Fig. 20a. If a small capacitor C_1, is charged

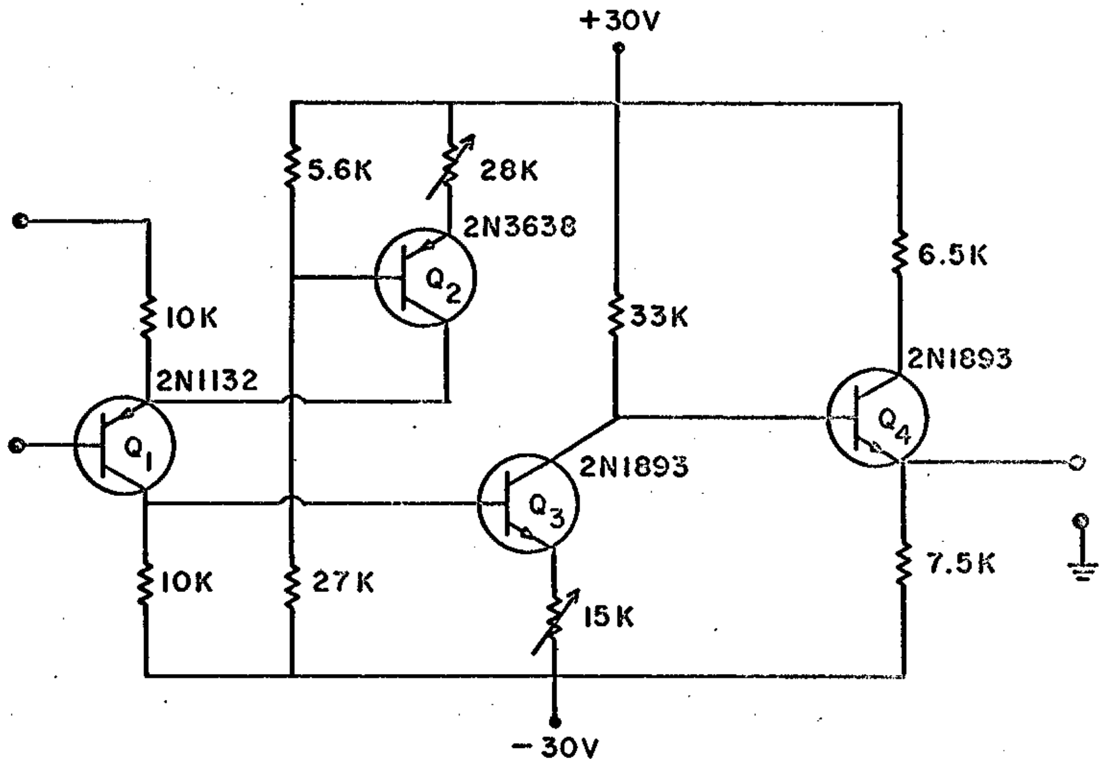


Fig. 19 Differential to single-ended converter.

to some voltage V_1, then charge can be transferred to the larger capacitor C_2. The resulting voltage will be given by equation

$$V_2 = \frac{C_1}{C_1+C_2} V_1 \qquad (1)$$

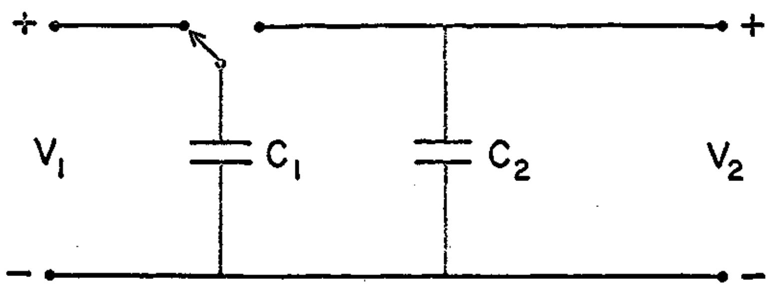
Repeating this operation of ladling small amounts of charge on C_1 into the large capacitor C_2, will result in V_2 approaching V_1 exponentially. If however, C_1 is bootstrapped[27] so that the total voltage applied to C_1 is (V_2+V_1) for each cycle, then after n cycles,

$$V_2 = nV_1\frac{C_1}{C_1+C_2} \qquad (2)$$

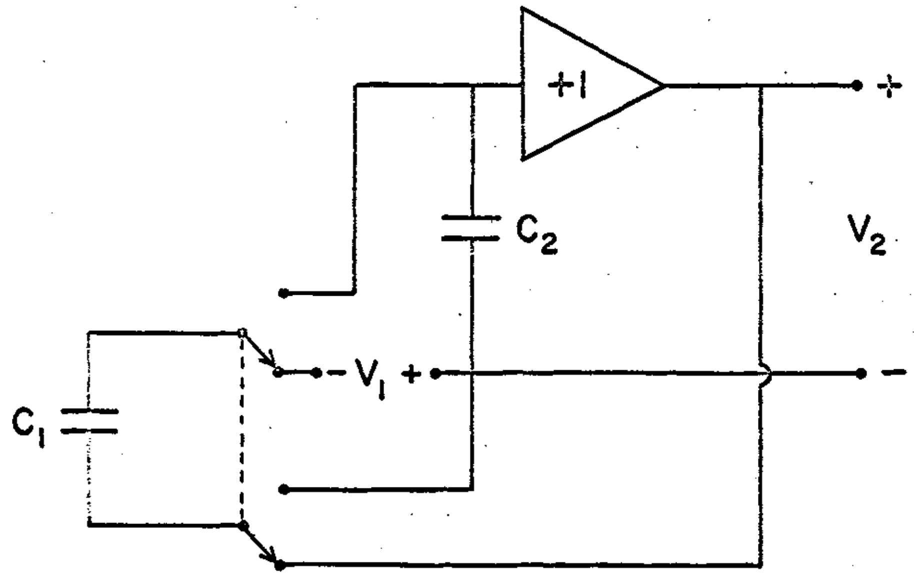
The bootstrapping technique is shown in Fig. 20b. A double pole double throw relay is required to alternately connect C_1 across the differential amplifier and then, as flatness occurs, across C_2. The unity gain amplifier is necessary to sample the voltage V_2 on the bucket capacitor C_2 for readout purposes, and to permit bootstrapping. Obviously a very high input impedance is required if the capacitor is to function as a memory.

The circuit details are shown in Fig. 21. A metal oxide, field effect transistor is used to obtain a high input impedance[31]. Such a device can provide input impedances of 10^{12} ohms which, when coupled ideally with C_2, would permit a time constant of about 24 hours. Mylar* capacitors are used to minimize leakage. Transistor Q_2 provides a low output

* Dupont Trademark.



(a)



(b)

Fig. 20 Analogue adder and memory unit. (a) Charge transfer using capacitors. (b) Linear charge transfer using bootstrapping techniques.

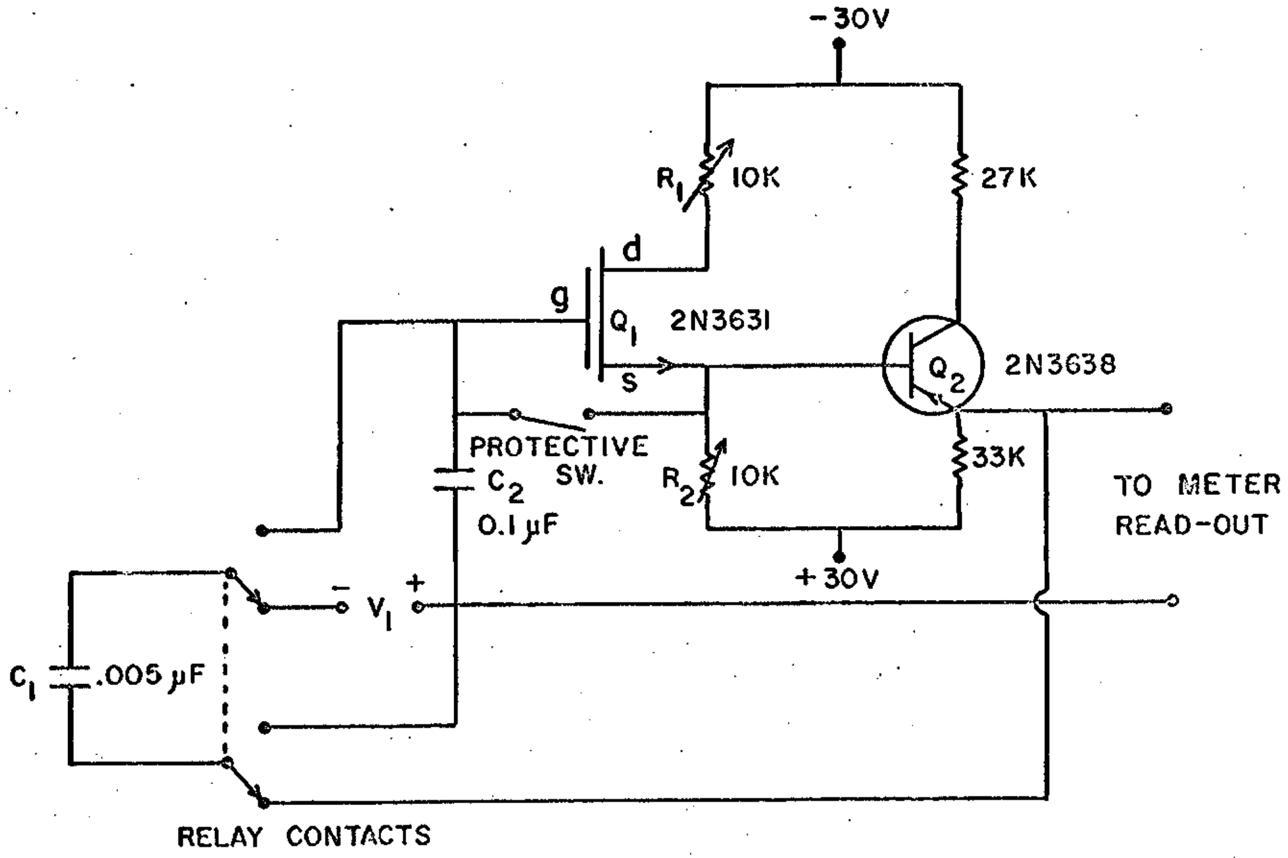


Fig. 21 High input impedance amplifier for analogue adder and memory unit.

impedance and acts as a buffer for the bootstrap connection.

In detailed operation, C_1 is placed across the output terminals of the differential amplifier. As the pressure decreases, the voltage V_1 decreases. At the instant flatness occurs C_1 is transferred by the relay to C_2, to form a parallel connection for approximately 400 msec. The voltage on C_1 is V_2 plus the new signal voltage of the second cycle.

The capabilities of this analogue adder and memory unit are demonstrated in Fig. 22. A fixed voltage representing the transducer pressure was used in place of V_1. The voltage decay is approximately 20 mv. per minute. Some errors in charge transfer occur due to the imperfections of the relay contacts but these are small and random in nature.

5.3.5 Read-out

The clinician desires an immediate presentation of the average intracranial pressure upon completion of the measuring sequence. For this reason a visual display in the form of a wide view meter is used.

The deflection of the meter movement depends on the summation of signal voltages on the storage capacitor, and by appropriate scaling of the meter face, an average pressure, for a specific number of pressure measurements, can be displayed.

An offset of 35 mmH_2O is required on the scale, since in addition to the air pressure supplied by the pump, a fluid pressure equal to the height of the column of liquid in the transducer also acts on the fontanelle.

5.4 Control and Logic Circuits

5.4.1 Controlling the pump

Automatic control of the measuring sequence under all

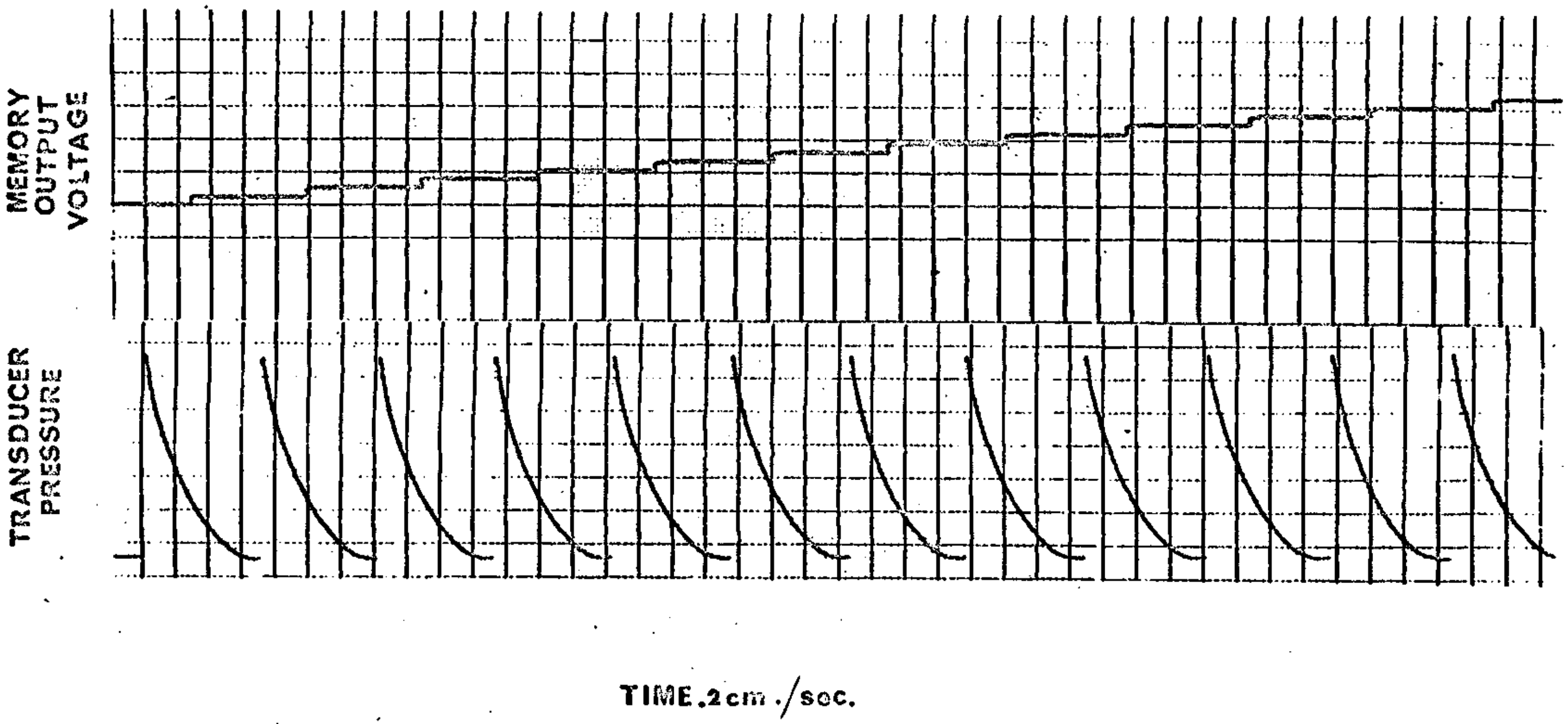


Fig. 22 Adding and storage capabilities of the analogue adder and memory unit. Pressure sweeps for each measurement are shown on lower trace.

possible situations is of considerable practical importance as pointed out in earlier chapters. To obtain this control, logic circuits determine the state of operation of the major operating systems.

Operation of the prime mover is subject to three logic conditions. First, the pump must operate only when the transducer is firmly placed on the fontanelle, and therefore, the switch, formed by the center probe and the conducting fluid, will be closed. This switch is not capable of directly forming part of the AND gate turning on the A.C. static switch supplying power to the pump, so its action must be amplified. A D.C. saturating amplifier shown in Fig. 23 does this. The small current available from the transducer (100 μa) is sufficient to saturate transistor Q_1 and therefore, Q_2. The current available from the collector Q_2 is now sufficient to operate a small relay #1, (connection normally off).

The second condition is determined by a counter. Some means of halting the measuring procedure after a predetermined number of cycles are completed, is required. A modified Veeder Root* mechanical counter is used. Each measurement causes the counter to be advanced one position until the required count is reached. A micro-switch is then activated, (operation normally closed) and since it is connected in series with the contacts of relay #1 to form the second part of the AND gate, the pump will no longer operate even though relay #1 may be closed. An A.C. static switch, similar to the one used to

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* Trade Name.

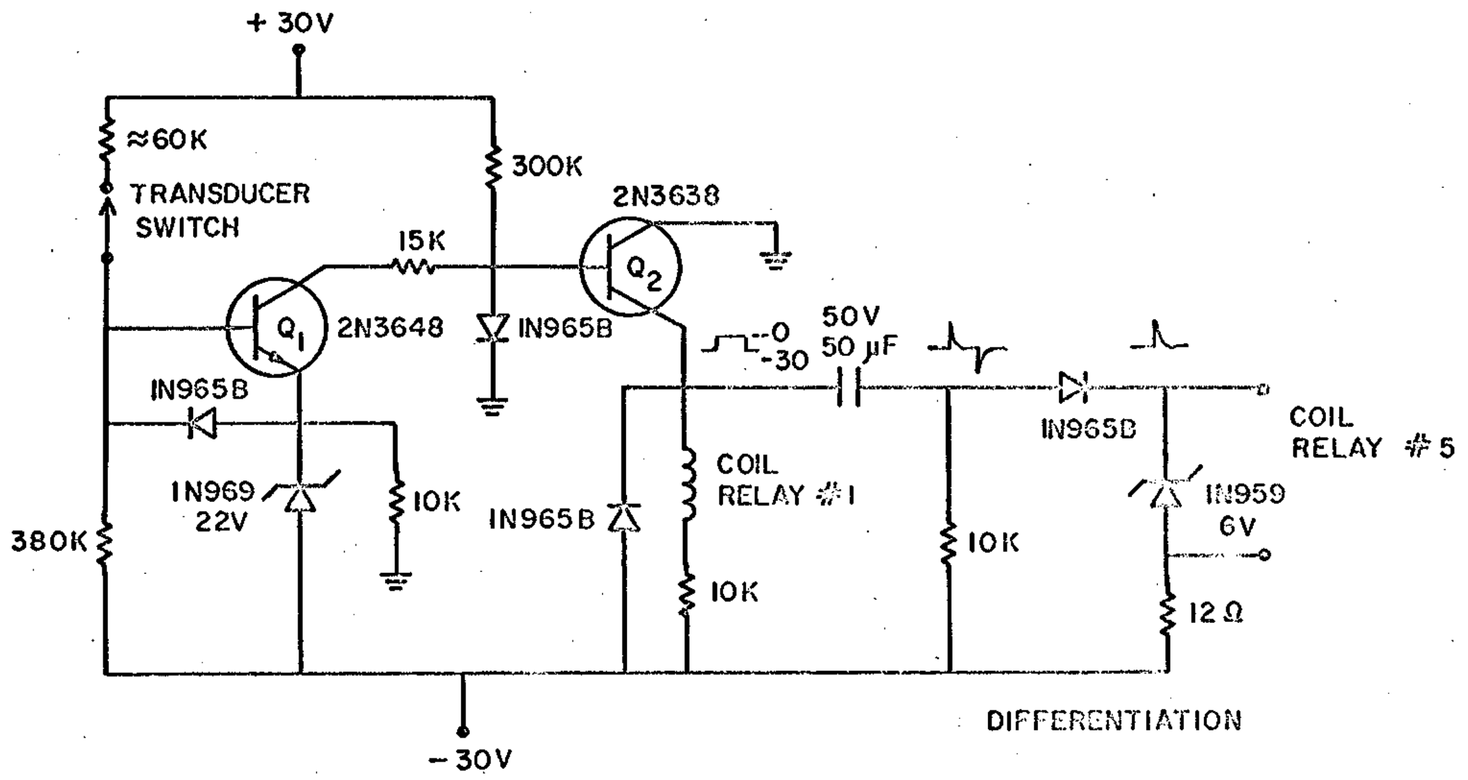


Fig. 23 D.C. saturating amplifier with differentiation.

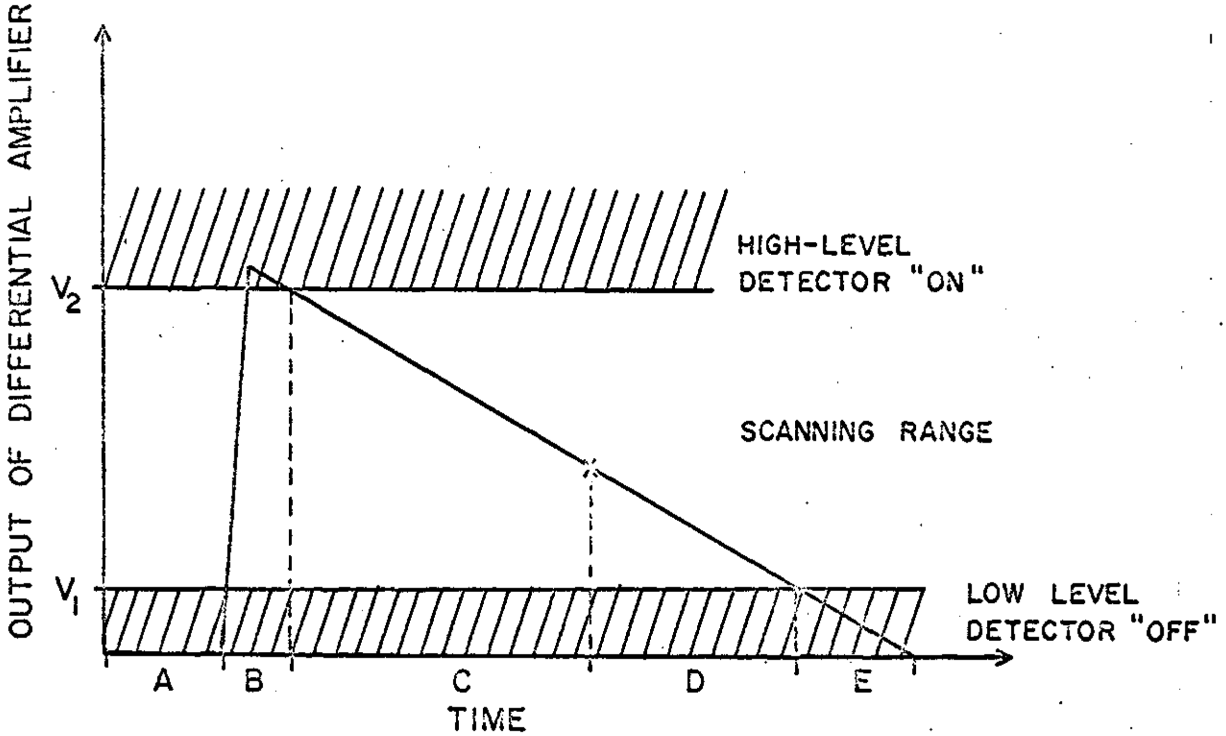
to operate the pump solenoid, supplies power to the counter.

An attempt was made to determine the number of cycles at which to halt the measuring procedure, from a study of the standard deviations of a series of measurements obtained from patients. It was found however, that the standard deviations of the readings were dependent upon the average intracranial pressure and for this reason it was arbitrarily decided to limit the number of cycles to twenty. Assuming a normal distribution, and if the average intracranial pressure is 150 mmH_2O, the two standard deviation value is approximately 25 mmH_2O for twenty readings. In other words, if the true average intracranial pressure is 150 mmH_2O and 20 attempts are made to measure this pressure, 19 of those attempts would indicate the pressure is between 125 mmH_2O and 175 mmH_2O[18].

The third condition that must be met before the pump is to be operated, is that the pressure is already at a low value. If the pressure is low, the output voltage of the differential amplifier is also low, and a switch must be available to sense this condition. As the pressure increases, the switch must open again at the higher levels. This requirement for a high-low level switch can best be met by a relay with high hysteresis characteristics. The double throw property of this relay can also be used in a control operation involving the transfer of charge in the adder and memory unit.

Fig. 24 shows the two levels at which operation must occur. A Sigma* relay with exceptional sensitivity and fully adjustable contacts, allows these two levels to be set very easily. The pull-in voltage of the relay was set at 10 volts and the drop-

* Trade Name.



	Low-Level Switch	High-Level Switch	Transducer Switch	Pump Solenoid	Memory Adder Switch
During A	ON	OFF	ON	ON	OFF
During B	OFF	ON	OFF	OFF	OFF
During C	OFF	ON	OFF - ON	OFF	ON at Applanatio
During D	OFF	ON	ON	OFF	OFF
During E	ON	OFF	ON	ON	OFF

Fig. 24 Operating levels of the high-low voltage relay and logic operations.

out was set at .5 volts. Adequate stability of these relay settings has been confirmed experimentally. Use of semiconductor circuits to carry out high-low level switching was considered but the required circuits are very complex and are inaccurate in operation at low levels.

Operation of the pump then, is dependent upon these conditions: the transducer must make contact with the fontanelle to operate relay #1, the counter must be set to some value less then 20 to close the micro-switch #2, and the pressure must be at a low level to allow the high-low level relay #4, to close in the low position energizing relay #3. Since the first three relays are connected in series with the A.C. static switch, they form the logic AND gate #1 necessary to maintain control of the pump. Appendix 10.4 contains a detailed diagram of the logic circuits and all the related connections.

5.4.2 Controlling the adder and memory unit

Pressure measurements are to be added and stored in memory only when a unique situation occurs. That is, the pressure in the transducer must be at an elevated level, and the condition of flatness must be occuring. These two situations are used to establish an AND gate to control the adder and memory unit.

The transducer switching action is once again incorporated in the AND gate action. This time however, a signal is desired only when the switch changes its state and therefore, A.C. coupling is required. The output signal from the switching amplifier is passed through a differentiating circuit as shown in Fig. 23. The relatively fast voltage transient generated by the opening and closing of the transducer switch is passed through a diode to remove the unwanted, negative pulses. Two transient voltages are then available to operate relay #5 forming part of AND gate #2. The first voltage pulse occurs when the transducer is placed on the fontanelle, and the second when flatness occurs.

The second contact of relay #4, the high level contact, is utilized to help control the adder and memory unit. As the transducer pressure is increased by the pump, relay #4 will switch from the low level state to the high level state. The contacts that have closed as a result of this switching, are placed in series with the contacts of relay #5, a power supply, and the coil of relay #6. This forms the second AND gate since relay #6 will only be energized if the transducer pressure is high and flatness has just occurred. Arc suppression techniques have been used on all logic relay contacts.

5.4.3 Adder input

Since the adder input consists of a Mylar capacitor and a field effect transistor, both with very high input impedances to ground, it is very important that the ladle capacitor be connected to this input in a similarly isolated manner to maintain the long time constant of the memory. This is best achieved by coupling C_1 to C_2 by a double throw, double pole relay. When this relay (#6) is inactivated, C_1 is placed across the output terminals of the differential amplifier. As the transducer pressure changes, so does the voltage across the capacitor. At the instant flatness occurs, the capacitor is transferred by relay #6 to form a parallel connection with C_2. The new pressure measurement is now added and stored on C_2 in the form of a charge. The relay apparently completes the transfer with little or no loss of charge as was shown in Section 5.3.3. The relay then returns capacitor C_1 to the differential amplifier terminals since the differentiating circuit provides a voltage pulse for only 400 msec.

5.4.4 System reset

Resetting the system in preparation for another set of pressure measurements consists of two operations. Firstly, the counter must be reset to zero which is accomplished by manually rotating the dials to zero. Secondly, the memory capacitor must also be discharged and this is done by simply returning the gate of the field effect transistor Q_1, to ground by a switch located on the front panel. These two operations prepare the system for another sequence of measurements. In addition, a check of the calibration of the transducer and the drift of the strain gage bridge, is recommended.

5.5 Power Supply

Relays and semiconductor circuits are operated from the same power supplies. An Acopian model (30D 40B) dual power supply rated at ±30 volts at 400 ma, was found to be adequate. The transient response of this supply was improved by placing 150 μf. capacitors across the output terminals. Without the capacitors, the loading effects of the relays caused transient voltage drops of as much as 3 volts, with time constants of approximately 30 msec. This was reduced to 30 mv. for 500 msec. using the buffering capacitors.

5.6 Packaging and Layouts

The entire instrument is housed in a metal chassis 20 x 11 x 8 inches. It weight spproximately 25 lbs. and is easily moved about by the nursing staff. Sterilization by gas techniques is possible but autoclaving will result in damage to the instrument. The transducer can be fully immersed in sterilizing solutions as desired. Printed circuit boards are used where possible and are easily removed for maintenance. Fig. 25 shows the completed instrument.

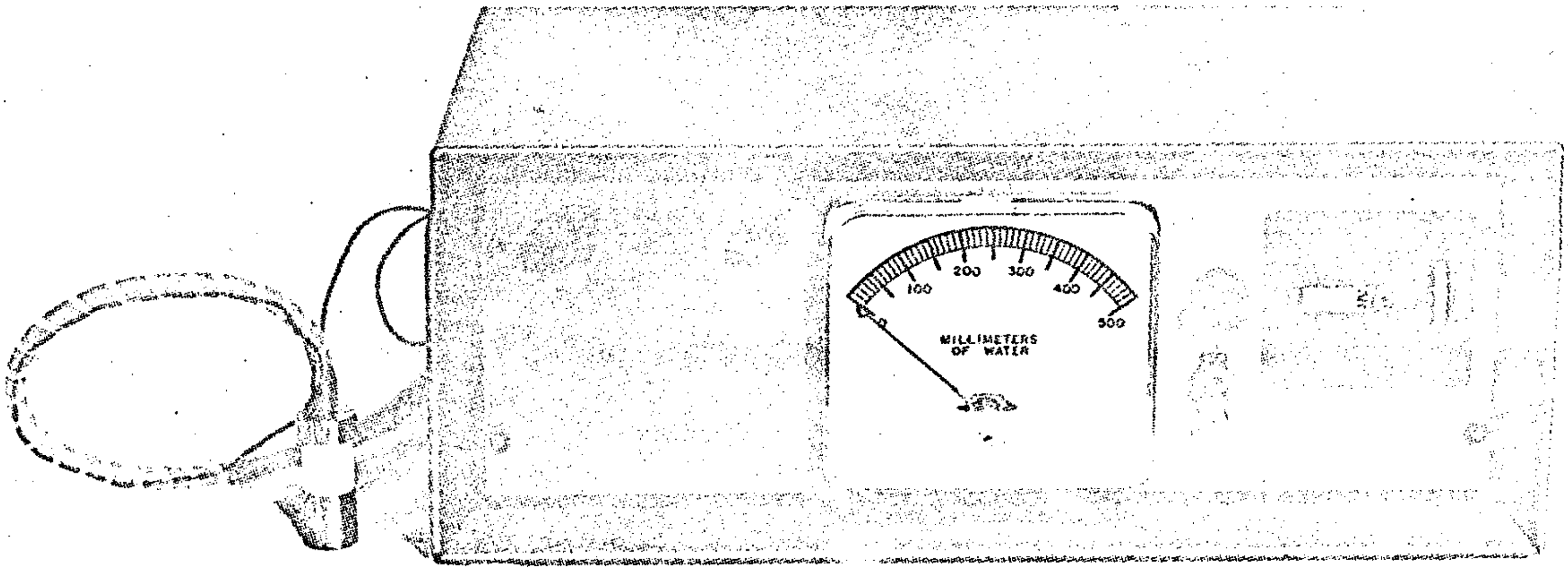


Fig. 25 The completed instrument.

6. TESTING THE INSTRUMENT ON A MODEL

6.1 Model Concept'

Tests of the entire insturment were performed on the model briefly described in Section 4.4.3. This rubber model is satisfactory for purposes of studying the instrument's capability of determining indirectly, pressures on membranes. The pressure within the model can be set at any desired level, to permit a complete check of the instrument's linearity. Since the intracranial pressure is a dynamically changing quantity, it was also necessary to provide a pulsating component to the model pressure. A small pump was used to cause pressure variations of 60 mmH_2O in the model.

6.2 Results of the Model Studies

The static pressure studies are shown in Fig. 26. The transducer was rigidly held by a clamp, and various pressures established in the model for each sequence of 20 readings. These readings illustrate the overall consistency and linearity of the pressure measurements. Tests were also made to determine if the force of application of the transducer influenced the pressure measurement. The model pressure was set at a low value under constant volume condition. The transducer was then applied with sufficient force to increase the model pressure by various amounts. Fig. 27 shows that the force of application has negligible effect on the measuring ability of the instrument. An inportant distinction must be made however, between the effect of the force of application on the transducer, and on the subject being measured. If the infant's skull acts as a constant volume container, then the force of application of

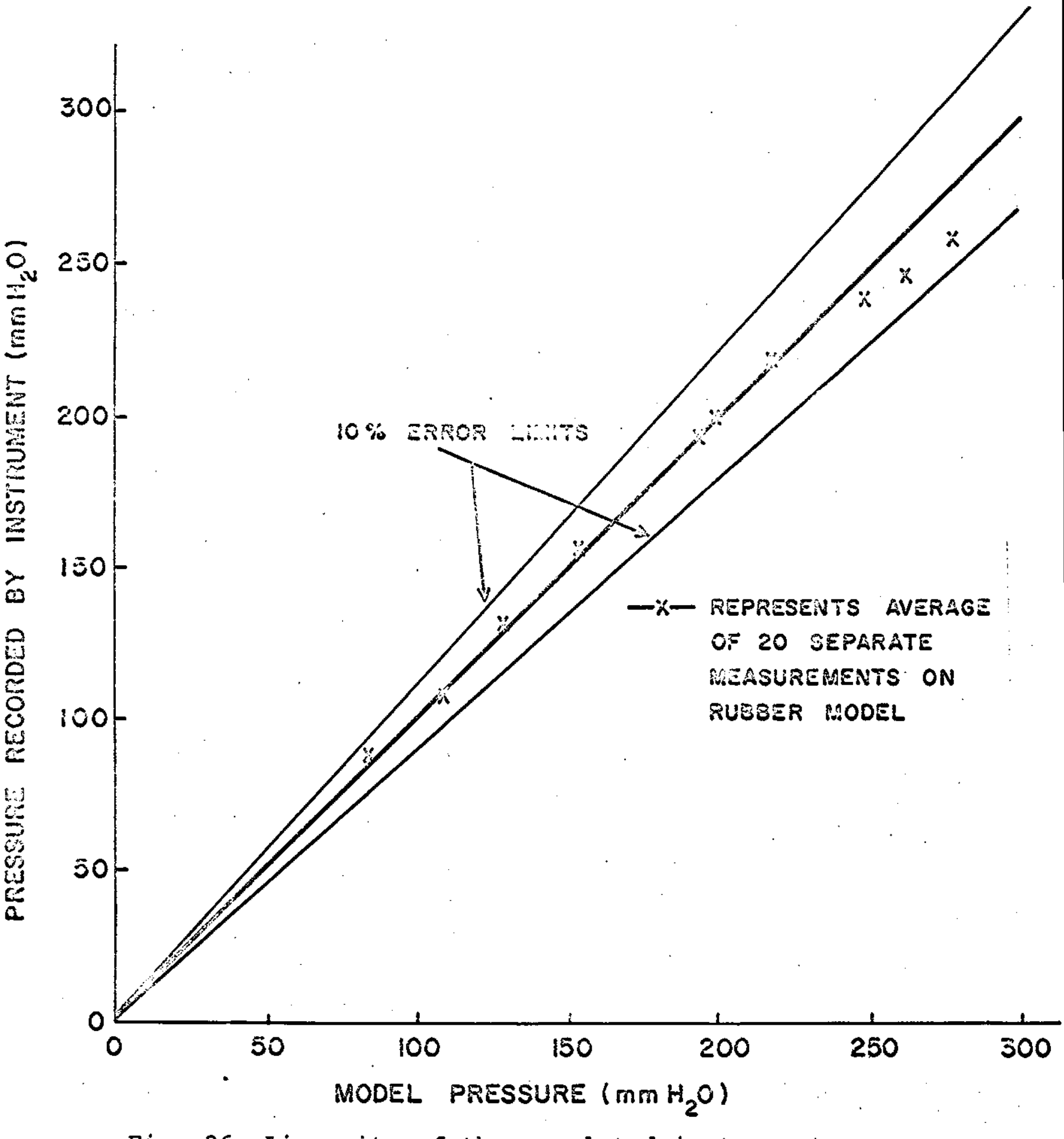


Fig. 26 Linearity of the completed instrument.

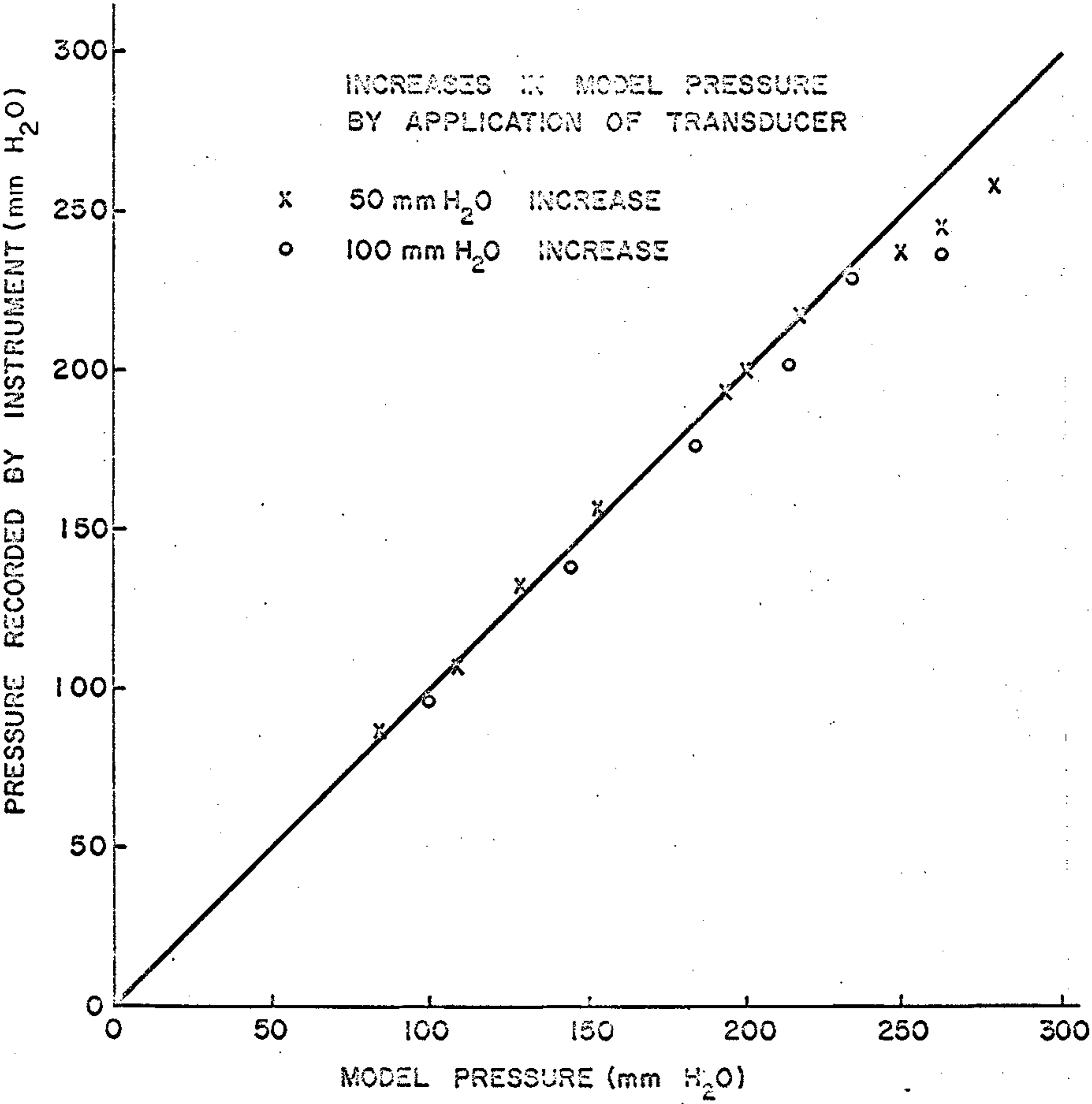


Fig. 27 Effects of force of transducer application on pressure measurement.

the transducer might have considerable effect on the intracranial pressure. However, the compensating mechanisms of the cerebral blood vessels outlined by Ryder[33], indicate this effect is unlikely to occur.

Because the transducer is a fluid filled device, tilting it can cause some inaccuracies in operation. Indications are, that operation at angles of up to 30° to the vertical, result in errors of 20% in the average pressure measured.

6.3 Dynamic Pressure Study

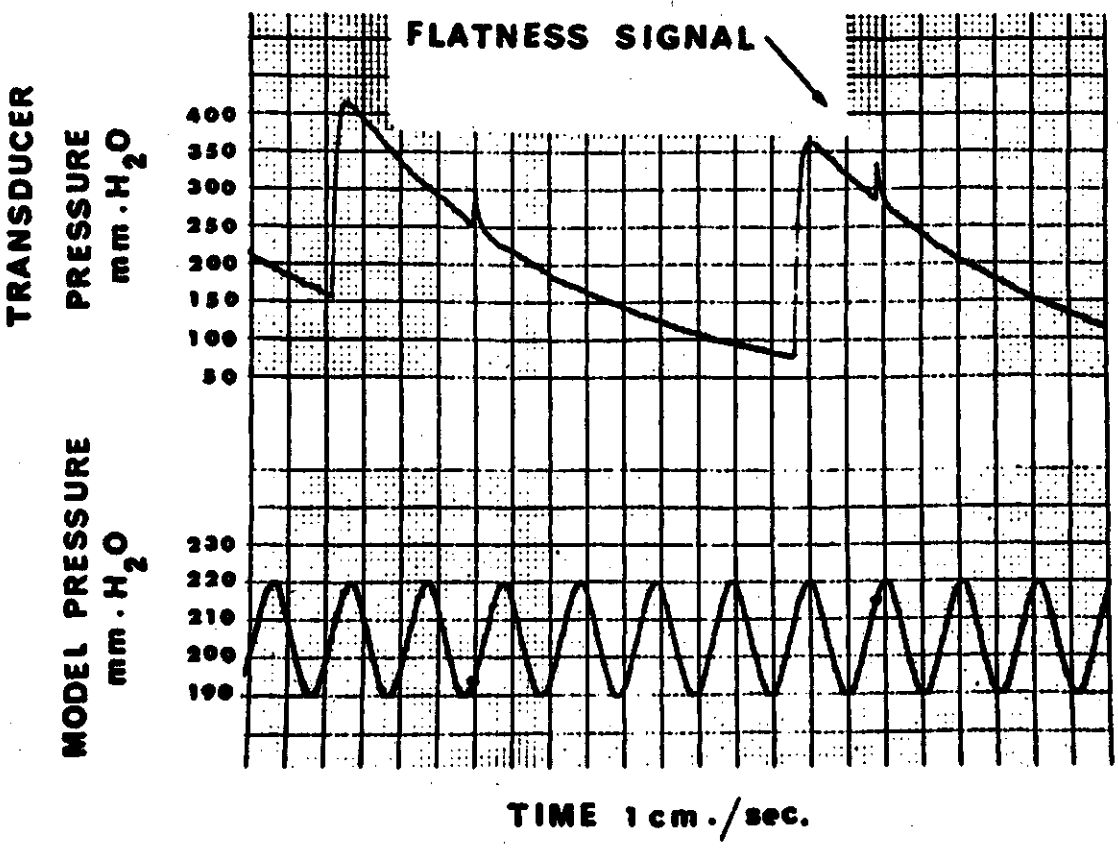
6.3.1 Relationship between transducer pressure rates of change, and model pulsation frequency

The pulsations of intracranial pressures are of considerable magnitude[3], and their effect on the averaging process must be considered. To study the effects, the pressure in the model was varied about a constant pressure level as shown in Fig. 28a. Since the external transducer pressure is also decreasing, some interesting interactions can result.

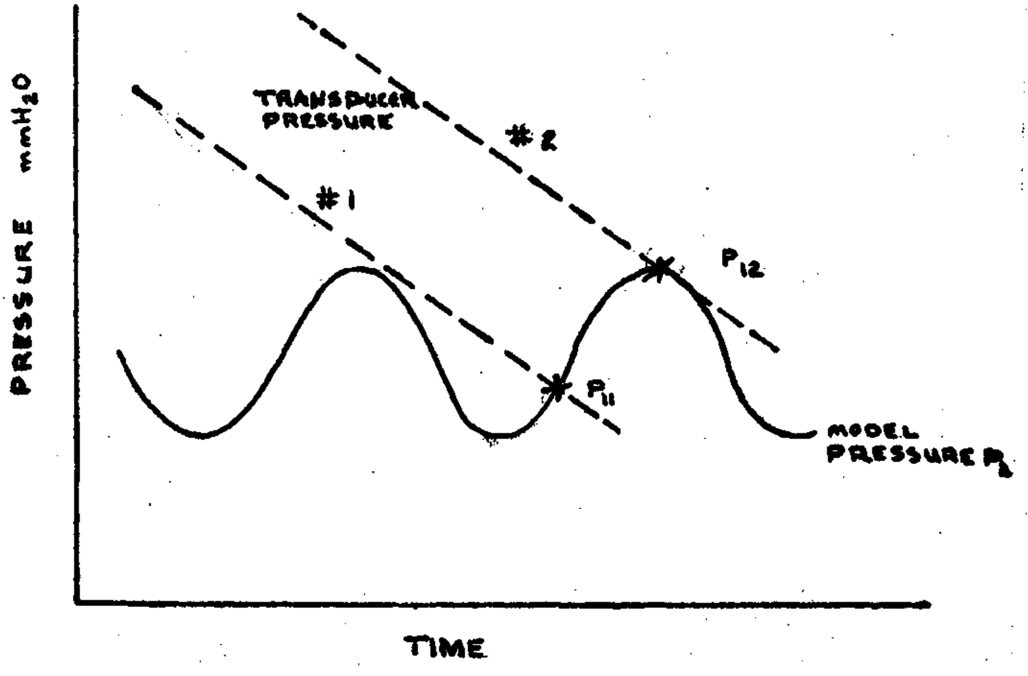
Consider Fig. 28b, where the transducer pressure P_1 is varying slowly with respect to the model pulsations P_2. If P_1 has the time position labelled #1, then the instrument will measure a pressure P_{11}. If P_1 follows line #2, then the pressure at flatness and therefore the one measured is P_{12}. Obviously, any value of pressure between these two extremes can be measured with equal probability, and if either the rate of decrease in transducer pressure or the frequency of pulsation is changed, so will the limits P_{11} and P_{12}.

6.3.2 Significance of intracranial pulsation

The interaction of rates of change and pulsation frequencies result in an average pressure being formed by the instrument



(a)



(b)

Fig. 28 Interactions between external pressure wave and intracranial pulsations. (a) Intracranial pulsations and external pressure measurement. (b) Possible interactions.

which is not the true average. The model tests indicate that the instrument will typically measure an average pressure of 150 mmH_2O when the actual average pressure is only 130 mmH_2O.

If strain gage recordings of the fontanelle deflections are made at the same time individual pressure recordings are made, then the amplitude of the intracranial pulsations could be found.

6.4 Model Test Conclusions

Certainly the rubber model used for tests is a poor representation of the complex fontanelle membrane. It does however, show that pressures can be measured accurately and simply by the indirect method outlined. The model also gives some indication as to what effects the actual intracranial pulsations will have on the measuring procedure. It remains though, for the actual clinical tests to validate the accuracy and usefulness of the device.

7. CLINICAL TESTS

7.1 Staff Operating Ability

Few members of the hospital staff have had the opportunity to operate the instrument. This is due in part, to the innovation of the device which requires that its operating characteristics and reliability be fully determined before uncontrolled use by the staff begins. In general though, the nursing staff of a pediatric ward has demonstrated that nurses can apply the transducer and operate the instrument with enough skill to obtain meaningful results. Further development of the transducer will permit full clinical usage and enable most hospital staff members to operate the device after only minimal training.

7.2 Case Studies

7.2.1 Normal children

A total of approximately 40 different normal individuals between the ages of a few days to ten months, have been examined with the instrument to give over 100 separate mesurements. These individuals are normal infants in the sense that abnormal intracranial pressures were not expected to be present. The tests were carried out to provide a basis from which to evaluate possible abnormal infants. All measurements were taken with the child kept as quiet as possible, while being held in a sitting position by an attendent nurse. Since the transducer was initially constructed with a diameter of 1.3 cm., only children with fontanelles larger than approximately 1.8 cm. in width, form this normal population. All readings were found to lie between 70 and 205 mmH_2O. This can be compared with the accepted normal range of 70 - 200 mmH_2O[11] established by direct lumbar puncture of children in the prone position.

Moderate variations in the average pressure of a single individual were observed when pressure measurements continued for several weeks. Fig. 29a shows a typical example of such variations.

Fig. 29b shows the onset of an elevated intracranial pressure coincident with the appearance of a skin rash on one normal subject studied. This perhaps indicates how dependent CSF pressures are on an infants general health.

7.2.2 Hydrocephalic infants

Pressure studies were carried out on clinically diagnosed hydrocephalic infants. In all cases the intracranial pressure, as measured by the instrument, was found to lie well above the upper pressure limit of the group of normal infants studied.

TABLE 7.2

Intracranial Pressures of Hydrocephalic Infants

Subject	Measured Pressure mmH_2O	Comment
CHI.	360	Prone position
F.L.	218	
TER.	209	Postoperative myelomeningocele
MON.	302	7 months old
SIN.	242	6 days old
SIN.	377	27 days old
WIT.	371	Has a shunt
DER.	233	
MAX.	210	
KAY.	215	
MUS.	230	
WIL.	263	7 days old
SMI.	325	

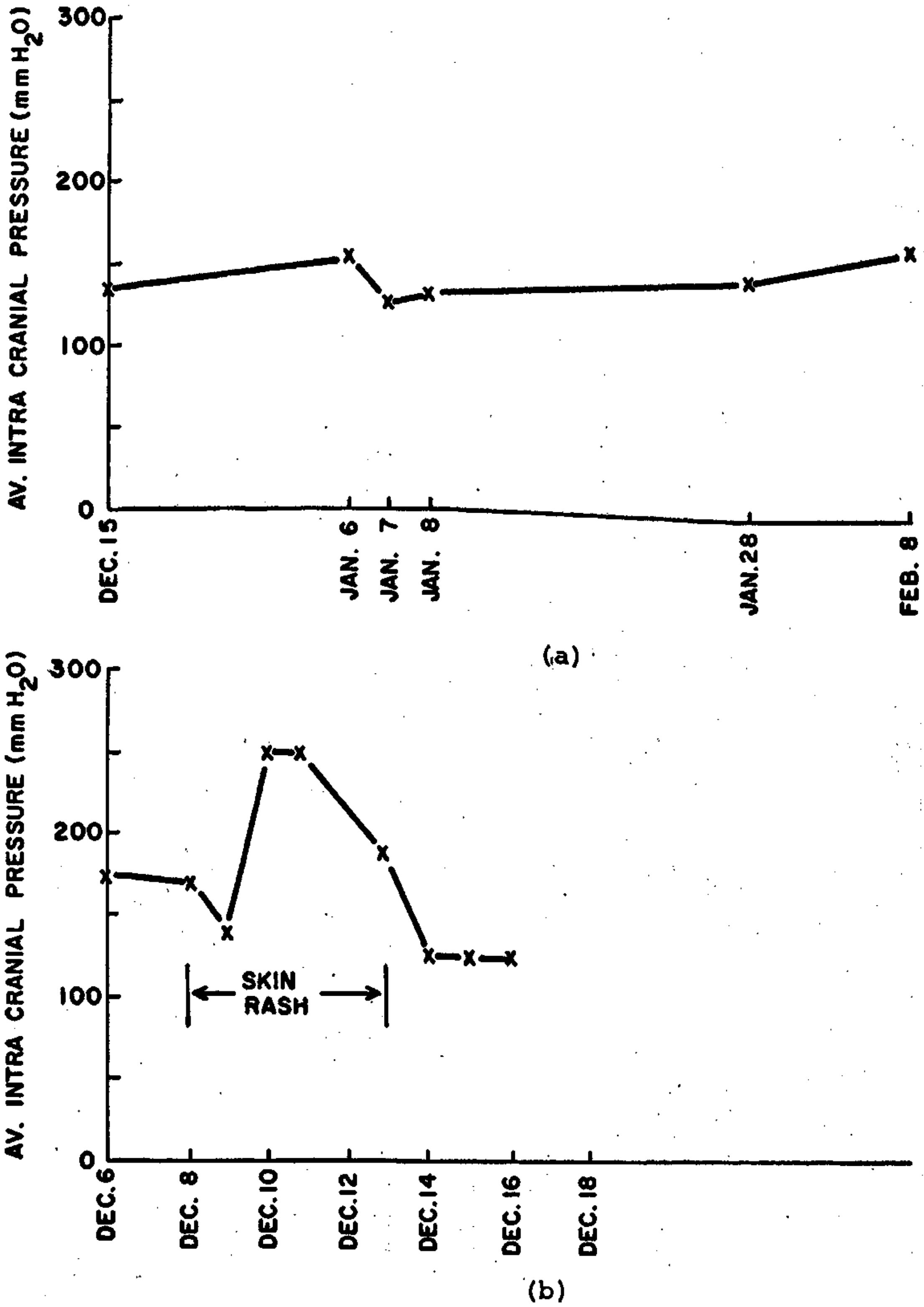


Fig. 29 Intracranial pressure measurements of normal children. (a) Typical normal infant. (b) Effect of a skin rash on a normal infant's intracranial pressure.

Table 7.2 shows the measured pressures of several of these infants. In cases where lumbar punctures were performed, the pressure was also found to be abnormally high.

Suspected, but not clinically confirmed hydrocephalics have also been measured. Five of these infants were studied, and all pressures were within normal ranges. Continued examination of these infants by clinicians confirmed the absence of hydrocephalus.

7.2.3 Myelomeningocele studies

The surgical repair of a myelomeningocele often results in the development of hydrocephalus. Pressure measurements in such instances were carried out to determine if changes in intracranial pressure could be detected before and particularly after the operation was performed. Fig. 30a illustrates the typical pressure changes accompanying an operation, and in this case, the onset of hydrocephalus is clearly evident. Fig. 30b again shows hydrocephalus developing after the operation. In this case, the pressure increased so quickly that the wound burst open releasing approximately 60 cc of CSF. The intracranial pressure dropped markedly as a result and then, as the wound began to heal once more, the pressure began to increase toward a hydrocephalic condition. The head circumference during this time, in no way reflected the marked pressure changes which occurred. Fig. 30c shows the pressures encountered after an uncomplicated operation

7.2.4 Shunt operation studies

Once a certain type of hydrocephalus has been diagnosed, the most common corrective procedure involves the installation

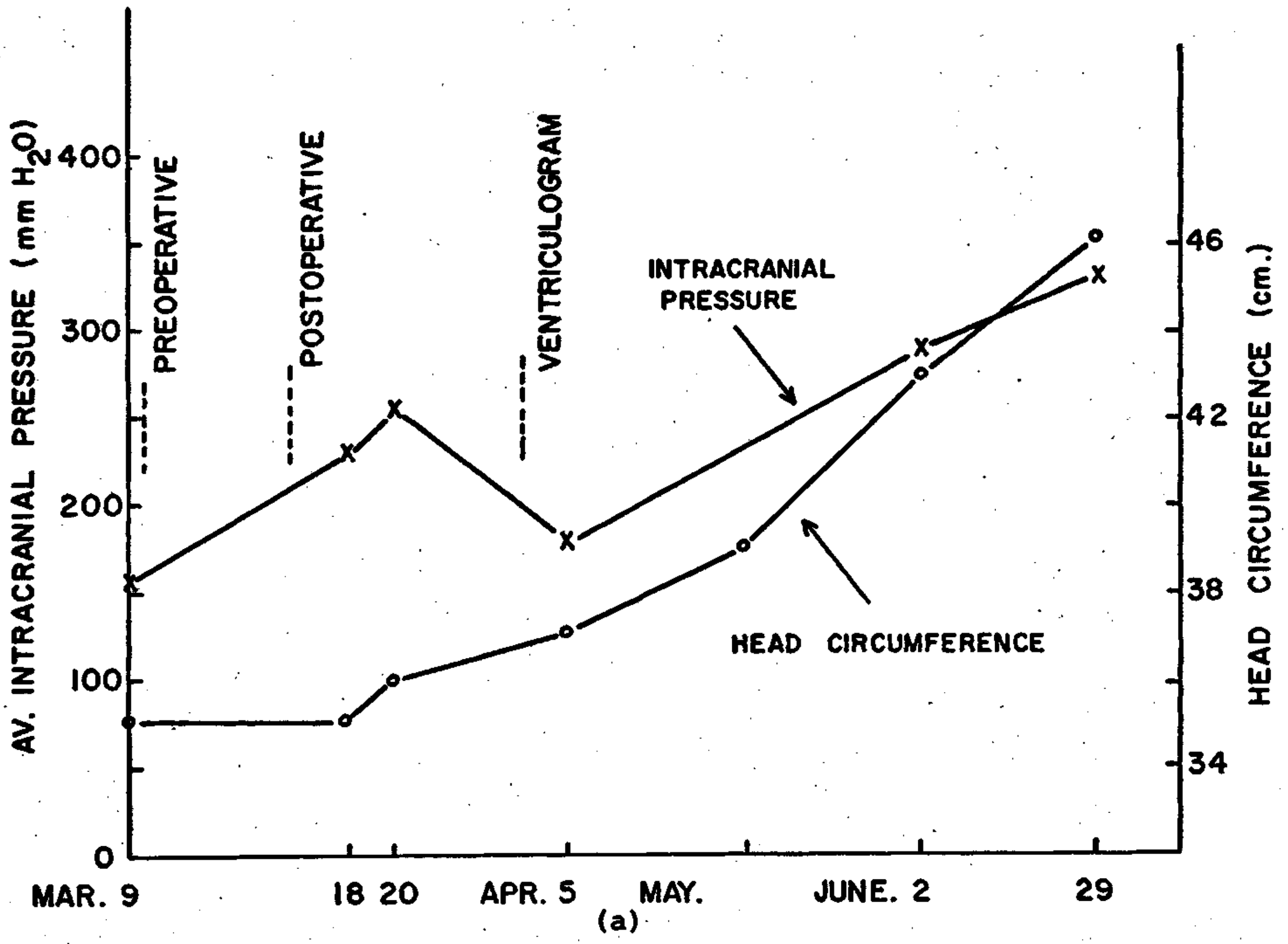


Fig. 30 Pressure variations in Myelomeningocele repair. (a) Hydrocephalus as a complication.

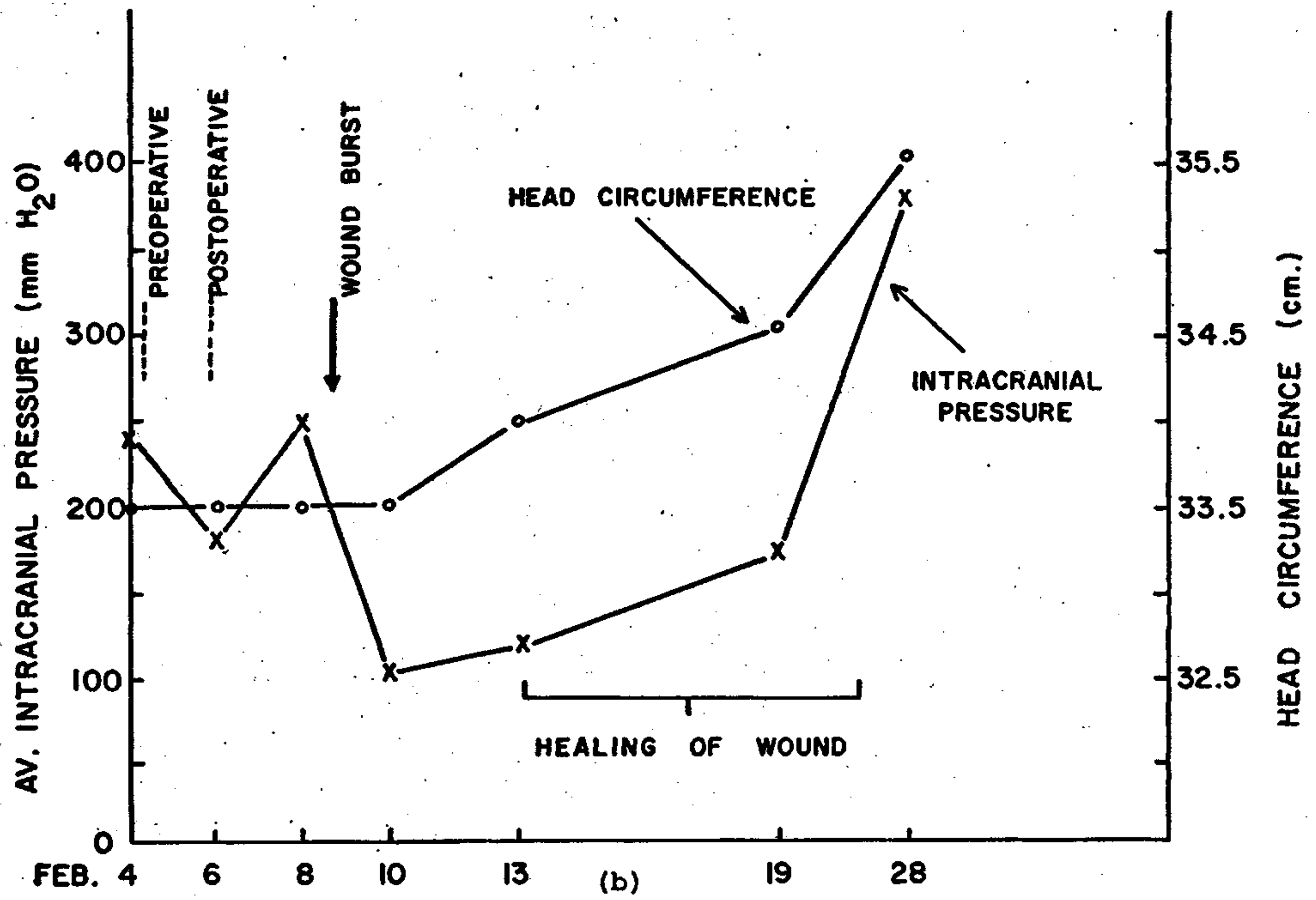


Fig. 30 Pressure variations in Myelomeningocele repair. (b) Burst wound and Hydrocephalus complications.

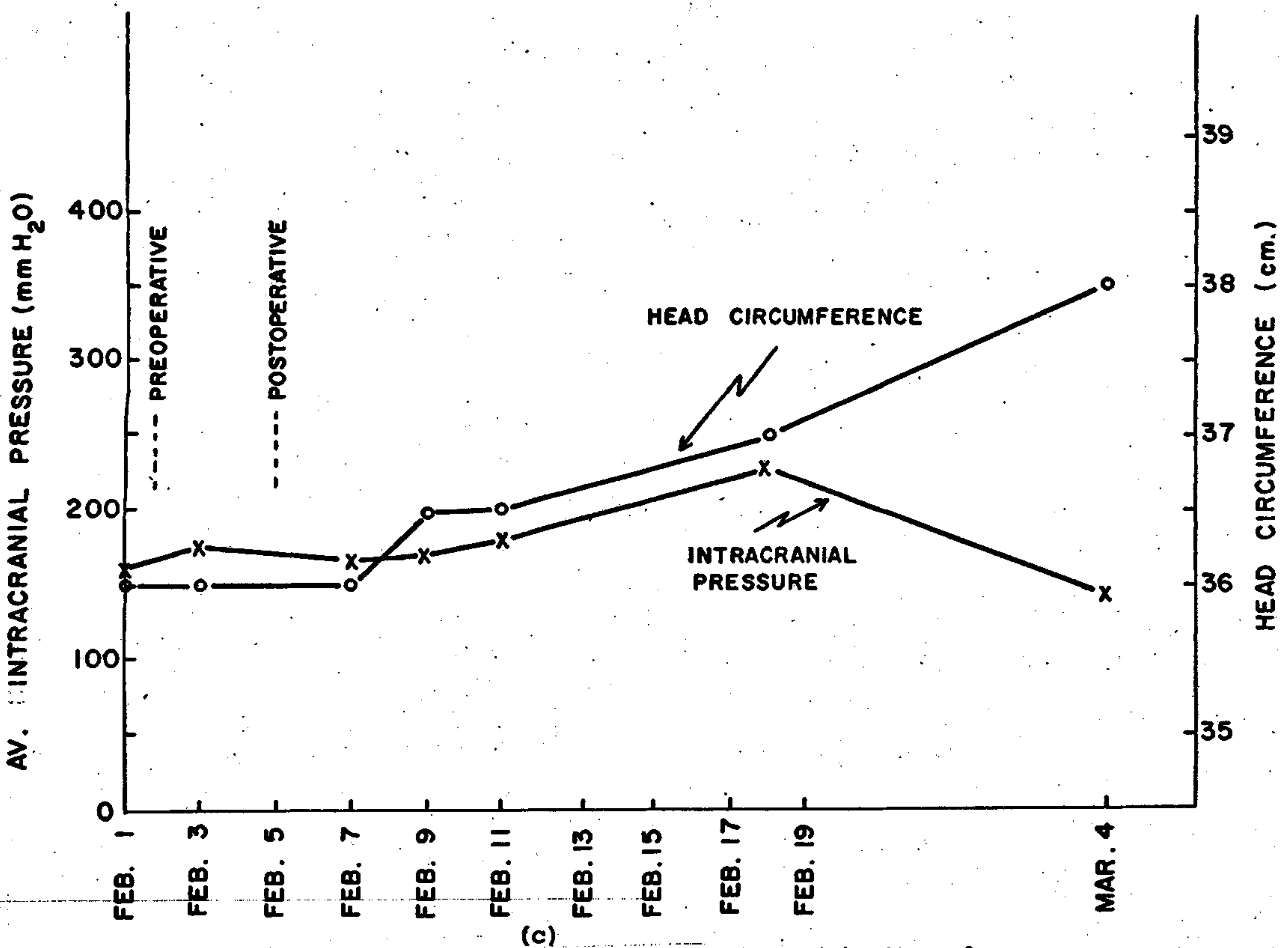


Fig. 30 Pressure variations in Myelomeningocele repair. (c) Normal recovery.

of an intraventriculo-canal shunt. This shunt permits the CSF to be artifically removed, by drainage into the internal jugular vein. The pressure can be maintained near normal by such a valve. However, it is not always possible to determine for some time if the valve is operating. Pressure measurements in such cases have permitted a demonstration of the in situ operation of the valve shortly after its installation. Fig. 31a and Fig. 31b show the effect on the intracranial pressure of manually pumping the valve. Measurements were taken before pumping and after each group of ten or twenty pumps. The initial compensating effect of the arteries described by Ryder[33], can be seen for the first series of pumps in each case. Pumping did not significantly lower the pressure. This is a common observation in such studies.

Obviously, once it is known how much the pressure will decrease with a given number of pumps, a better pumping schedule can be worked out until the automatic operation of the value is guaranteed.

7.2.5 Ventricular puncture study

One severe hydrocephalic infant was measured under quite unusual conditions. Fluid was removed directly from the ventricles, which had become extremely large under the prolonged influence of high intracranial pressure. Fig. 32 shows the pressure reductions accompanying removal of a series of discrete quantities of CSF. These measurements were obtained with the open-end transducer, and the child in the prone position. They demonstrate that a definite volume-pressure relationship exists within the skull.

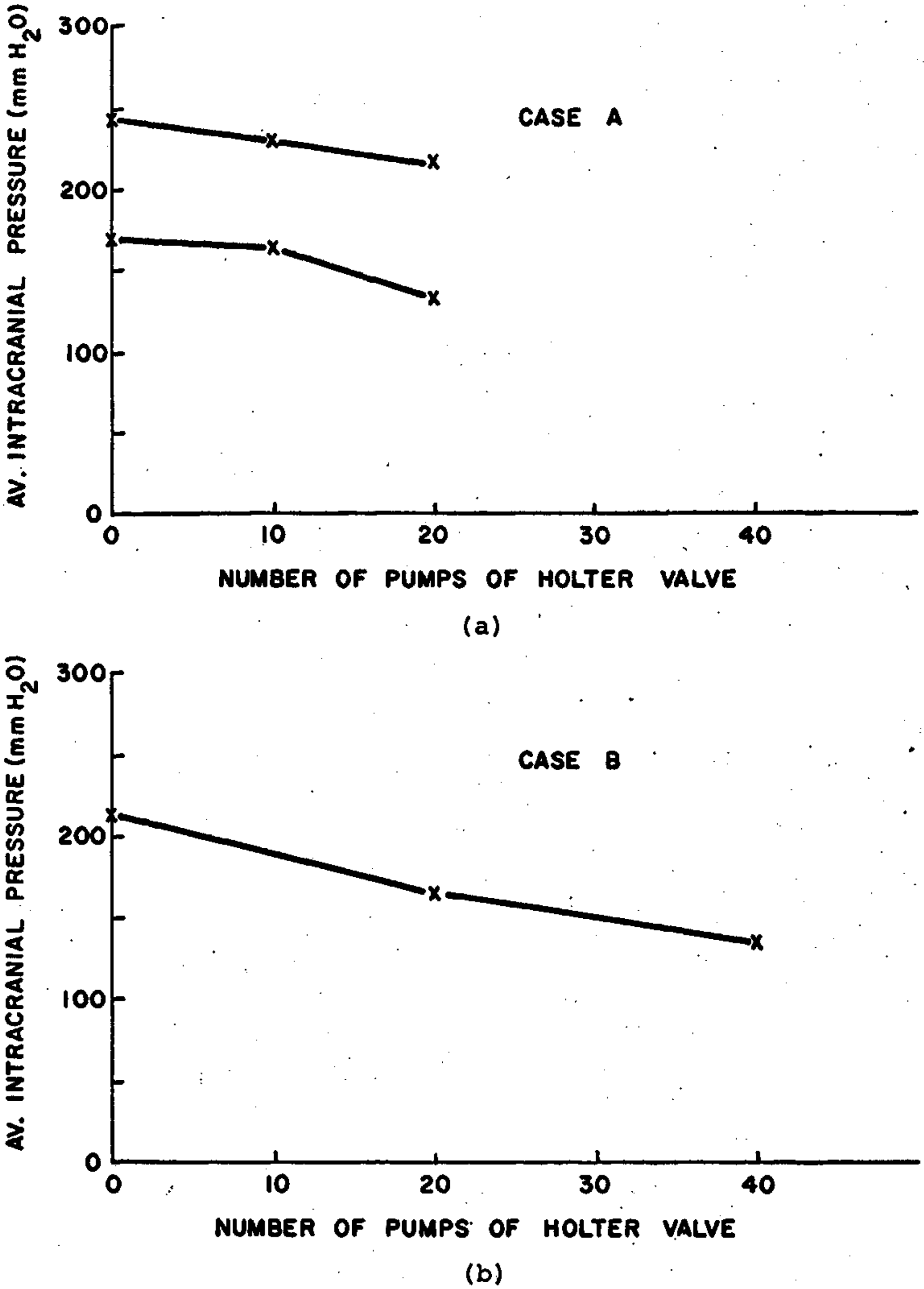


Fig. 31 Pressure reductions using ventricals-caval shunt valve.
(a) Light pumping. (b) Heavy pumping.

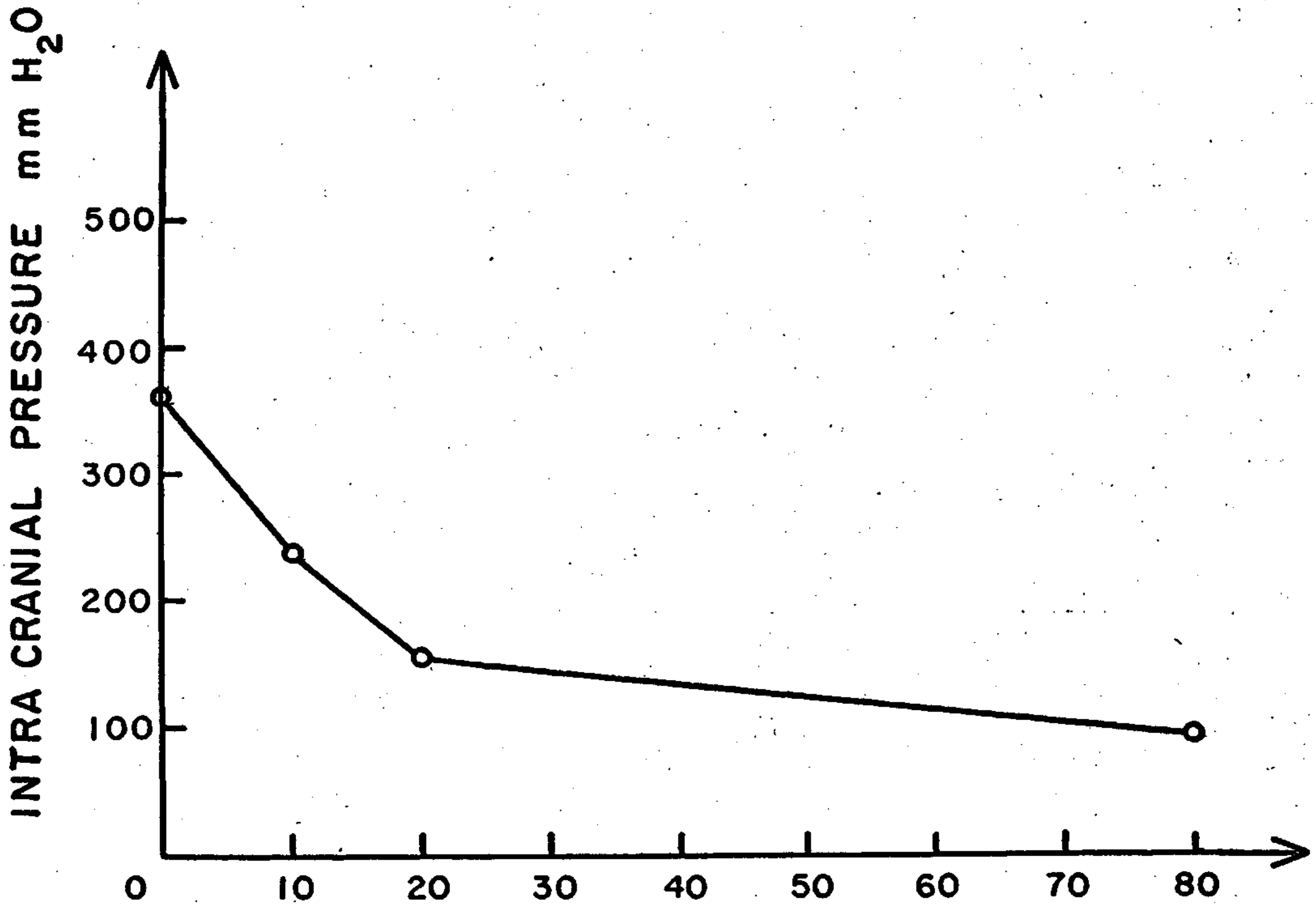


Fig. 32 Pressure changes accompanying CSF withdrawal by puncture.

7.2.6 Adult drug studies

Two adults with skin flaps devoid of underlying skull structures were also studied. These have bony defects forming an equivalent fontanelle through which pressure studies could be carried out. One such case is shown in Fig. 33. The pressure was measured while the patient was in the prone position, but the closed-end fluid transducer was used since the flap was located over the right ear. The effect of 80 gms of ureophil on lowering the intracranial pressure, is dramatically illustrated.

7.2.7 Pressure pulsations

A second adult patient with a similar flap, permitted a study of the relationships of pressure pulsations to the measured values. The pressure pulsations were assumed to be the cause of marked movement of the skin flap. These movements were recorded by the use of strain gage equipment. On the same recording each individual pressure measurement was also recorded. Fig. 34 shows a few deflection cycles of the flap, with marks indicating at what instant a pressure measurement was taken, and what pressure was recorded at that instant. It can be seen from this that if many cycles are similarly examined, then a nearly complete description of the pressures giving rise to the deflections of the fontanelle, can be obtained. The results indicate that the amplitude of the pulsations was about 60 mmH_2O. This compares favorably with published estimates of 50 mmH_2O[3].

7.3 Test Conclusions

The test carried out on the instrument were of two types. First, those that were performed on the model provided direct

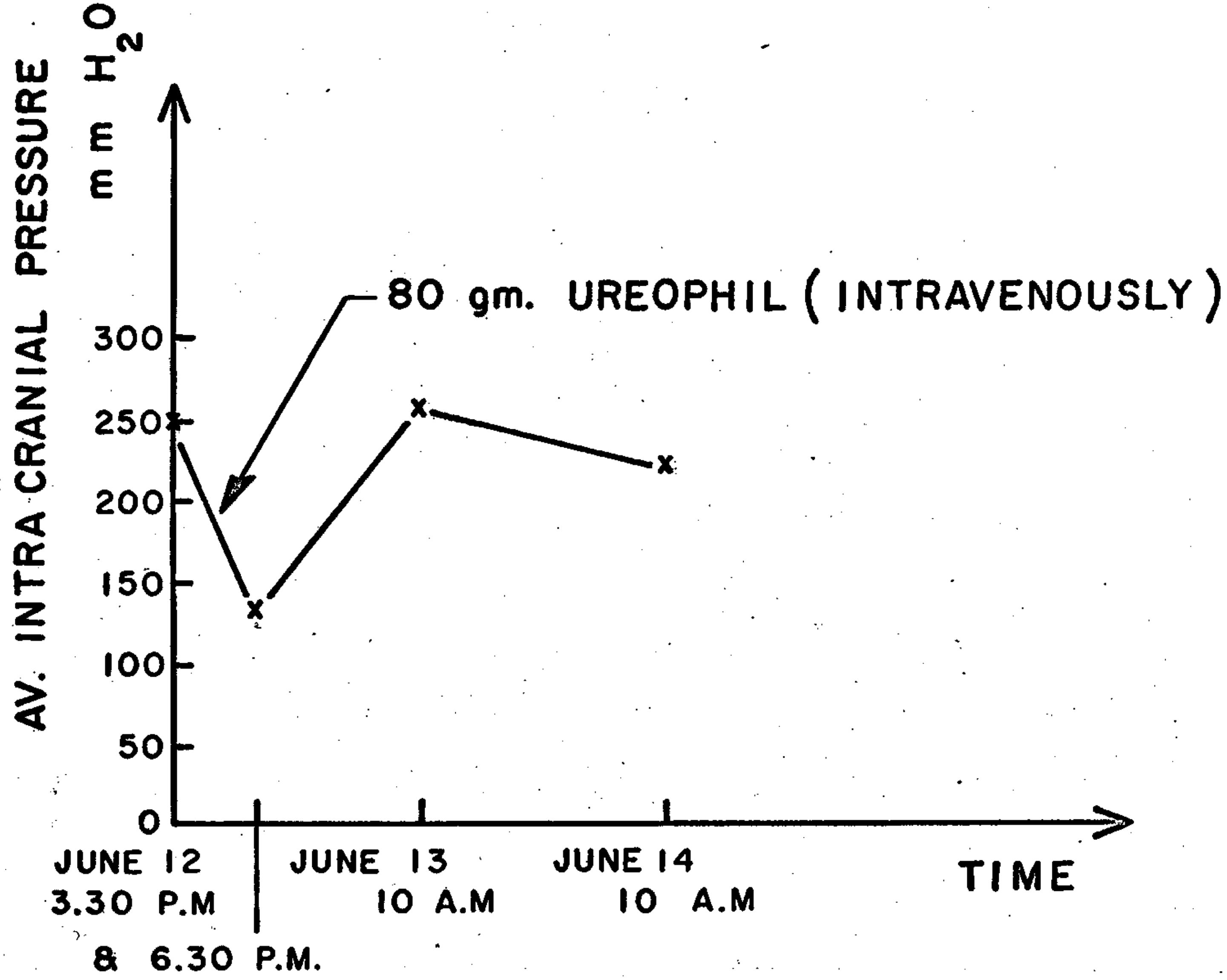


Fig. 33 Effects of Ureophil injection on intracranial pressure in an adult.

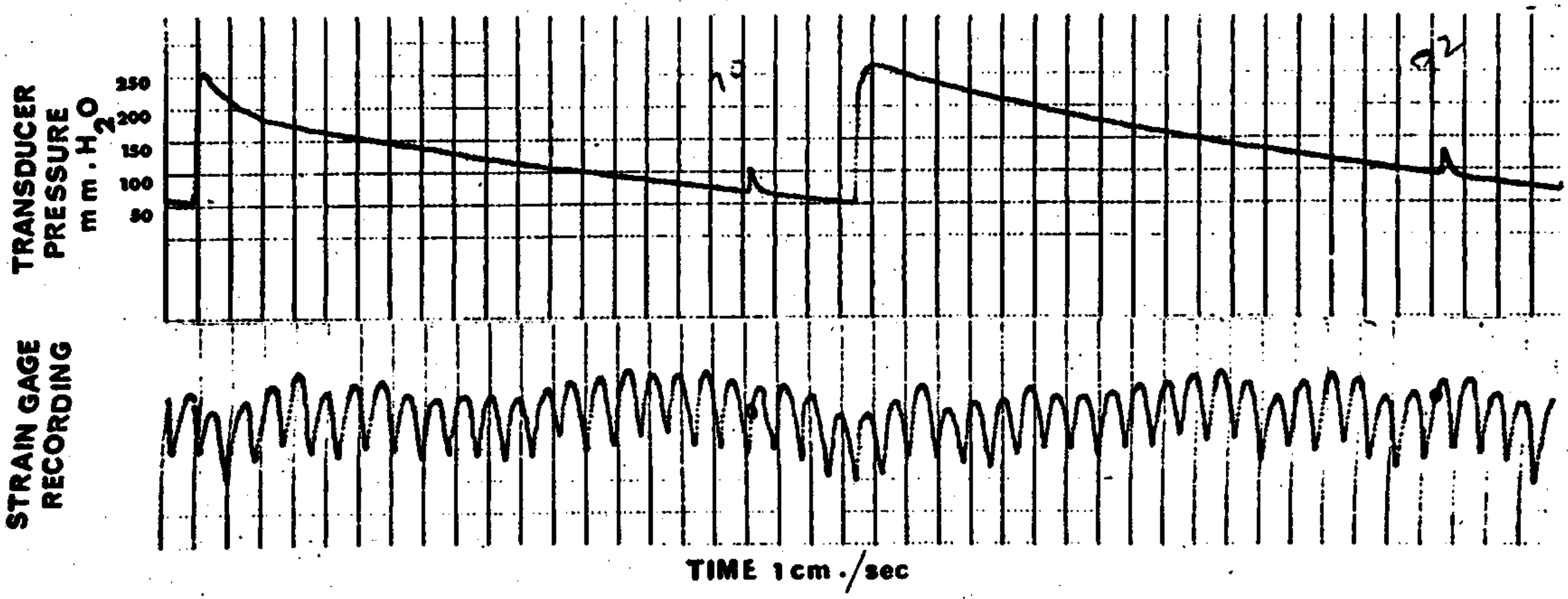


Fig. 34 Pressure pulsations and strain gage recording of the deflections of a skin flap in an adult.

evidence of the instrument's capability in determining pressures behind rubber membranes. The pressures applied to the rubber model were known at all times, and they could then be easily correlated with the pressures ascertained by the instrument. In this respect, ample evidence is provided to confirm that the transducer and related instrumentation, will accurately and simply measure pressure.

Second, are the tests performed on patients for which direct corroborating pressure measurements are not available. Corelations between measured and actual pressures can only be obtained in special circumstances, and virtually never for normal infants. Consequently, the clinical tests only provide circumstantial evidence. However, no test results yet obtained in the clinic conflict with the circumstantial evidence.

Measurements of CSF pressures by Bering[3][6] and Ryder[33], have shown that negative pressures with respect to atmosphere, can exist in the ventricle of standing adults. Since no comparable measurements were obtained apparently, for infants with open fontanelles, it can not be stated that a similar situation exists in infants. Indeed, when one considers the volume flexibility of an infants skull, the pressures and relative dimensions of the fontanelle structures, and the fact that a really definite depression of the fontanelle is rarely seen, then it is highly unlikely an average negative pressure exists beneath the fontanelle under any circumstance.

The success of the instrument as a clinical diagnostic aid is really the important consideration. The clinical tests indicate that for low order tests to help determine abnormal intracranial pressures, the instrument has a valid use. These tests also show that a reasonably quantitative relationship between CSF pressures of different individuals can be established. Certainly the valid extension of interpretation of results beyond this point, will be dependent on future, more definitive, tests being carried out.

8. CONCLUSIONS

8.1 Review of Present Techniques

The present techniques available to the clinician for the determination of intracranial pressures of infants are inadequate in several respects. The simplest and most widely used technique, that of measuring the head circumference does not measure pressure at all. Noticeable changes in circumference only reflect the long term effects of increased intracranial pressure.

Direct pressure measurements, obtained for lumbar puncture, are often unsatisfactory particularly in babies. Certainly a technique for obtaining CSF pressure measurements comparable in simplicity, accuracy, and safety, to that used in the routine determination of blood pressure, does not exist.

A new technique based on principles similar to those utilized in tonometry was developed. This technique makes use of the approximate membrane characteristics of the anterior fontanelle present in the skull of infants.

8.2 Review of Equipment Constructed

A transducer was constructed to convert the inaccessible intracranial pressure into a more readily measured equal external pressure. It operates on a true applanation principle.

The requirements of the infant and operating staff necessitated that the entire measuring procedure be made as automatic as possible. For this reason the signal processing circuits, an air pump, and the memory and read-out equipment that were built, are all placed under the control of logic circuits. The instrument controls are contained in a small portable cabinet.

8.3 Review of Equipment Tests

Tests of each functional unit were carried out and these have been described in detail. The linearity and accuracy of the measuring circuits was demonstrated. A rubber model was constructed to test both the transducer and the entire instrument. Tests on the model showed that it was possible to obtain indirect measurements of pressure, behind elastic diaphragms, with less then 10% error for pressures between 50 and 350 mmH_2O.

8.4 Clinical Test Results

Clinical tests were carried out to determine the usefulness of the instrument in determining infant intracranial pressures. Tests on normal infants revealed that the normal range of pressure is from 70 to 205 mmH_2O. Continued examination on a daily basis revealed small variation in the average pressure.

Abnormal children were examined when ever possible. The instrument was able to clearly demonstrate that abnormal intracranial pressures existed in hydrocephalic infants and that such infants could be differentiated from normals on this basis.

Many other tests were performed on young children. These tests also indicated that useful information could be obtained from indirect measurement.

8.5 General Conclusions and Recommendations

The development of the instrument has not fully suceeded in providing the clinician with an instrument of comparable accuracy and simplicity to the blood and eye pressure measuring equipment. However, it is now possible with the use of the instrument to obtain a reasonably accurate, quantitative measurement of intracranial pressures of infants, simply and with no risk. In its present form many useful tests can be carried out, particularly the evaluation of the ultrasonic techniques proposed for intracranial measurements. In particular, a study can be carried out to determine what effects changing atmospheric pressures might have on intracranial pressures, in both normal and abnormal infants. Further testing and modification of the device should confirm its operation and show if it will be possible to establish such an instrument as a standard clinical device.

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10. APPENDICES

10.1 Theory of Deflections of Elastic Membranes

Virtually all the theoretical studies which have been carried out on the deflections of uniformly loaded membranes and plates have resulted in only approximate solutions[37]. For this reason no attempt can be made here to propose relationships between loads and deflections for nonuniform, inhomogenous partially clamped membranes such as exists at the fontanelle of an infant. However, the relationships derived for clamped edge, ideal circular membranes, perhaps indicates what can be expected when the fontanelle is subject to uniform loading.

Timoshenko[37] provides an approximate solution in the case of very thin plates where the deflection w_o may be very large in comparison with the thickness of the membrane h. In such cases, the resistance of the membrane to bending can be neglected, and it can be examined as a flexible membrane.

Consider the equilibrium of a small element cut from the diaphragm as shown in Fig. 10.1.1 where N_r and N_t are the component forces in the radial and tangential directions, M_r and M_t the corresponding moments and Q_r the tangential shearing force. Suppose a uniform force q, acts on the plate. Denoting the radius as r, the radial displacement component at the center as E, then the following equations are derived by Timoshenko:

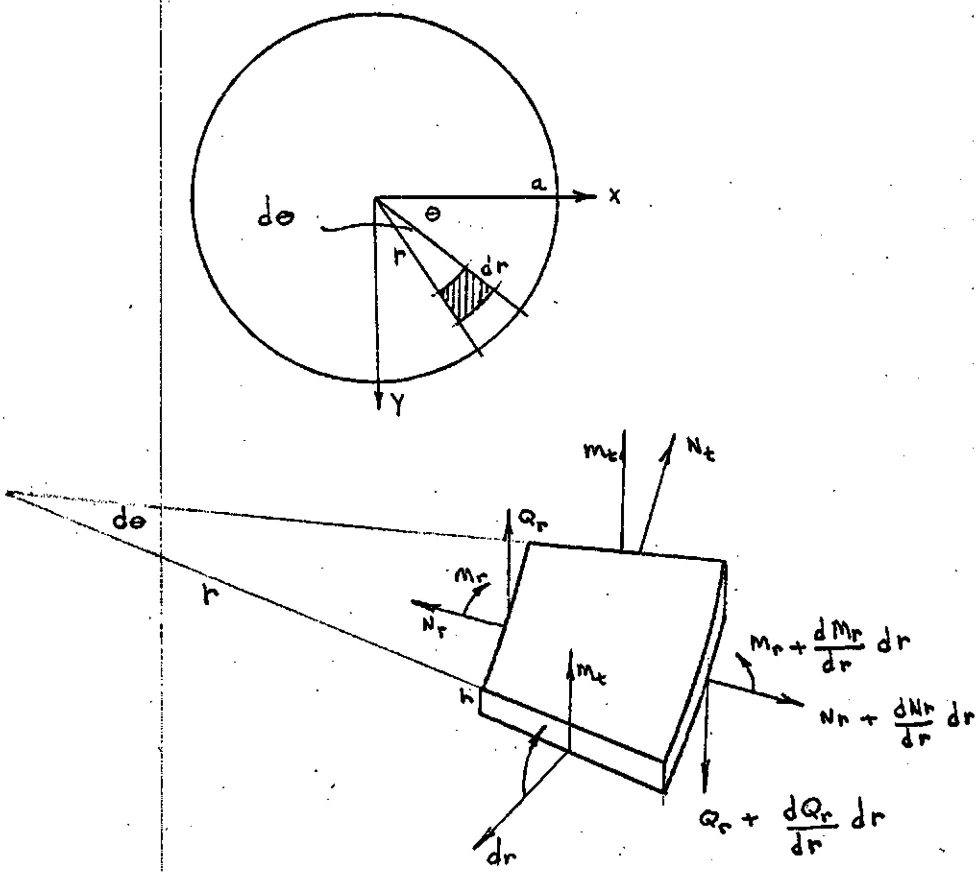

Fig.10.11 Forces acting on an element of a membrane

for the strain in the radial direction,

$$\varepsilon_r = \frac{du}{dr} + \frac{1}{2}\left(\frac{dw}{dr}\right)^2$$

for the strain in the tangential direction

$$\varepsilon_t = \frac{u}{r}$$

then from Hooke's law

$$N_r = \frac{Eh}{1-v^2}(\varepsilon_r + v\varepsilon_t)$$

$$= \frac{Eh}{1-v^2}\left[\frac{du}{dr} + \frac{1}{2}\left(\frac{dw}{dr}\right)^2 + v\frac{u}{r}\right]$$

$$N_t = \frac{Eh}{1-v^2}(\varepsilon_t + v\varepsilon_r)$$

$$= \frac{Eh}{1-v^2}\left[\frac{u}{r} + v\frac{du}{dr} + \frac{v}{2}\left(\frac{dw}{dr}\right)^2\right]$$

Taking the sum of the radial forces acting on the element then

$$r\frac{dN_r}{dr}\,dr d\theta + N_r dr d\theta - N_t dr d\theta = 0$$

or

$$N_r - N_t + r\frac{dN_r}{dr} = 0$$

Taking the sum of the perpendicular forces acting on the element then similarly,

$$Q_r = -D\left(\frac{d^3w}{dr^3} + \frac{1}{r}\frac{d^2w}{dr^2} - \frac{1}{r^2}\frac{dw}{dr}\right)$$

but Q_r becomes

$$Q_r = -N^r\frac{dw}{dr} - \frac{1}{r}\int_o^r q_r dr$$

if only the magnitude of the shearing force Q_r is considered. Substituting these expressions in the equations from Hooke's law gives the two non-linear equations

$$\frac{d^2u}{dr^2} = -\frac{1}{r}\frac{du}{dr} + \frac{u}{r^2} - \frac{1-v}{2r}\left(\frac{dw}{dr}\right)^2 + \frac{dw}{dr}\frac{d^2w}{dr^2}$$

$$\frac{d^3w}{dr^3} = -\frac{1}{r}\frac{d^2w}{dr^2} + \frac{1}{r}\frac{dw}{dr^2} + \frac{12}{h^2}\frac{dw}{dr}\left[\frac{du}{dr} + v\frac{u}{r} + \frac{1}{2}\left(\frac{dw}{dr}\right)^2\right]$$
$$+ \frac{1}{D_r}\int_o^r q_r dr$$

To obtain an approximate solution to the problem Timoshenko (39) writes the deflection w, as

$$\frac{dw}{dr} = C\left[\frac{r}{a} - \left(\frac{r}{a}\right)^n\right]$$

where C and n are constants to be determined. This expression vanishes for r = 0 and r = a, satisfying the boundary conditions. Substituting in the first Hooke's equation gives an approximation for u which can then be substituted into the second to obtain the constants C and n. For the deflection w_o at the center when v = .25 Timoshenko obtains the expression

$$\frac{w_o}{h} + .583\left(\frac{w_o}{h}\right)^3 = .176\frac{q}{E}\left(\frac{a}{h}\right)^4$$

For very thin plates $\frac{w_o}{h}$ can be neglected and the expression becomes

$$.583\left(\frac{w_o}{h}\right)^3 = .176\frac{q}{E}\left(\frac{a}{h}\right)^4$$

$$w_o = .665\ a\sqrt[3]{\frac{qa}{Eh}}$$

The deflection of the membrane then is dependent on the third root of the applied pressure q. However, if the pressure q is zero, the trivial solution results where the deflection w_o also equals zero. It is upon this relationship that all applanation tonometers depend. The difficulty in designing an indentation type of tonometer becomes evident when the third power relationship between load and deflection are appreciated.

To extrapolate this approximate solution for ideal membranes to the case of applanation in fontanelles will be difficlut. For the moment, the experimental evidence available gives the only indication of how the fontanelle membrane reacts under uniform loading.

10.2 Pressure Gages

Pressure is a measure of the unit force applied to a surface. It is usually measured, in the case of gas pressures, as the difference between the actual pressure and the atmospheric pressure, to give what is termed the gage pressure.

Numerous methods have been employed to measure gage pressure. A convenient approach is to measure the strain that a thin diaphragm is subjected to, if a pressure differential exists across it. Beckwith[2] gives the following relationships between strain and pressure for thin circular diaphragms clamped at the edge as shown in Fig. 10.2.1

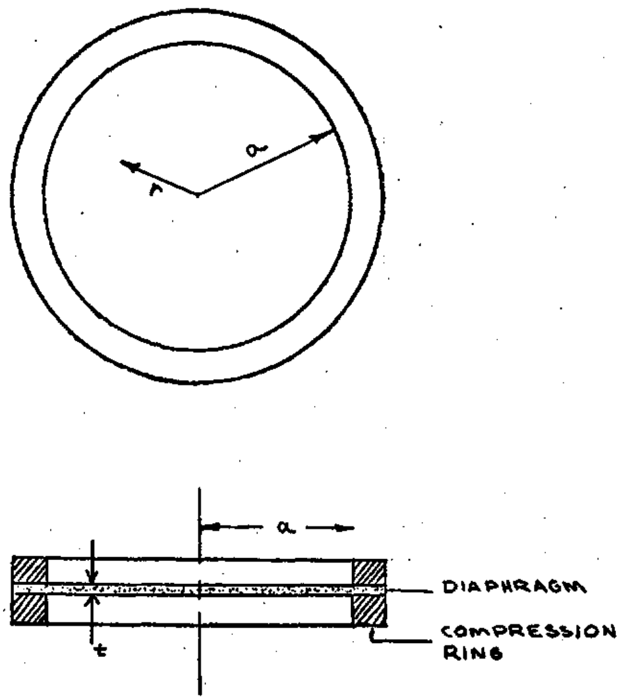

Fig. 10.2.1 Strain Gage Diaphragm

If P = applied gage pressure in psi.

δ_r = radial stress psi.

δ_t = tangential stress psi.

y = deflection in inches.

a = outer radius of diaphragm in inches.

r = radius in inches.

t = thickness of diaphragm in inches.

μ = poissons ratio.

E = Youngs modulus psi.

Then for radial stress

$$\delta_r = \frac{3}{8}\left(\frac{a}{t}\right)^2 P\left[(3+\mu)\left(\frac{r}{a}\right)^2 - (1+\mu)\right]$$

at $r = a$

$$\delta_r = \delta_{r\ max} = \frac{3}{4}\left(\frac{a}{t}\right)^2 P$$

For tangential stress

$$\delta_t = \frac{3}{8}\left(\frac{a}{t}\right)^2 P\left[(1+3\mu)\left(\frac{r}{a}\right)^2 - (1+\mu)\right]$$

at $r = 0$

$$\delta_t = \delta_{t\ max} = \frac{3}{8}\left(\frac{a}{t}\right)^2 P(1+\mu)$$

For deflection

$$y = -\frac{3}{16}\ \frac{P}{Et^3}\ (1-\mu^2)\left[(a^2-r^2)\right]^2$$

at $r = 0$

$$y = y_{max} = -\frac{3}{16}\left(\frac{P}{Et^3}\right)a^4(1-\mu^2)$$

These equations follow from Timoshenko's original equations shown in Appendix 10.1 Again, only approximate relationships result.

If a strain gage is placed at the center of the diaphragm where the tensile tangential strain is greatest and another on the opposite side, where the compressive tangential strain is greatest then a sensitive pressure gage can be constructed. Fig. 10.2.2 shows this arrangement

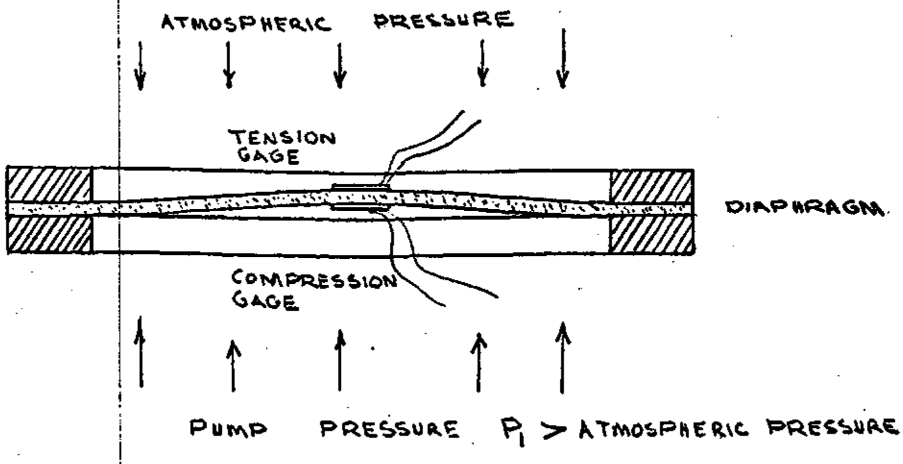

Fig. 10.2.2 Placement of Strain Gages

To remain within the linear stress region of the strain gages used, the strain at maximum pressure must not exceed 1000 μ in/in[7]. A further design limitation is imposed by the diaphragm if good linearity is desired. Beckwith[2] suggests choosing a diaphragm thickness such that the maximum deflection at the center will be one third of this thickness. At the low pressures encountered, the above two conditions can be best satisfied by a polystyrene diaphragm. Farkas[14] gives the following properties for polystyrene:

Poissons ratio 0.2x8

Young's modulus 300,000 psi.

For a diaphragm thickness of .050 inches, a pressure of 600 mmH_2O or .85 psi. and a diaphragm radius of 1.37 inches, the deflection at the center will be,

$$y_{max} = -\frac{3}{16}\left(\frac{P}{Et^3}\right)a^4(1-u^2)$$

$$= -\frac{3}{16}\left(\frac{.85}{3x10^5 \ x \ (50x10^{-3})^3}\right)(1.37)^4\left(1-(.28)^2\right)$$

$$= -.016 \text{ inches}$$

This is about $\frac{1}{3}$ of the thickness of the diaphragm.

The strain at the center will be

$$\varepsilon_t = \frac{\sigma_{t\ max}}{E} = \frac{3}{8}\left(\frac{a}{t}\right)^2 P(1+u)\frac{1}{E}$$

$$= \frac{3}{8}\left(\frac{1.37}{50x10^{-3}}\right)^2 .85(1+.28)\frac{1}{3x10^5}$$

$$= 1020 \times 10^{-6} \text{ in./in.}$$

Stein[36] gives the output voltage for the strain gage bridge shown in Fig. 15 as

$$V_{max} = \frac{I \ x \ R \ xK}{\mu\varepsilon} \text{ millivolts}$$

where I is the bridge current in ma., K is the gage factor and $u\varepsilon$ is the strain in micro-inches/inche . For a gage factor of 110 and a resistance of 124 Ω, the maximum output from the bridge will be

$$V_{max} = \frac{I \ x \ 124 \ x \ 110}{1020} = 12 \text{ millivolts/milliamp}$$

At 2 milliamps the output voltage is 24 millivolts.

The useful pressure sweep is from 50 to 350 mmH_2O which would yield output voltage of 2 and 14 millivolts respectively. Actual measurement showed that there voltages were .4 and 11.2 millivolts.

10.3 Temperature Compensation of Differential Amplifier*

The lowest output voltage from the differential amplifier is about 500 millivolts at 50 mmH_2O pressure. To maintain at least 10% accuracy in the pressure measuring system a stability of 50 millivolts or 50 microvolts equivalent input is required. This imposes restrictions on the temperature drift of the amplifier. A technique used by Hilbiber[16] provides the necessary temperature stability.

Base emitter voltages are uniquely related to collector current

$$I_c \approx I_s \left(e^{\frac{qV_{BE}}{KT}} - 1 \right)$$

where I_s is the base to emitter saturation current

V_{BE} is the voltage from base to emitter.

q is the electronic charge.

K is the Boltzman's constant.

T is the temperature in degrees K.

The saturation current is

$$I_s = CT^{\beta} e^{\frac{-E_g}{KT}}$$

where E_g is the semiconductor energy gap.

C and β are semiconductor parameters relating impurity concentrations and minority carrier mobility.

Combining these equations, and expanding as a Taylor series

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* Condensed from reference (16)

$$V_{BE} = \frac{kT_o}{q}\left(\ln\frac{I_C}{I_o} + A_o\right) + \frac{k}{q}\left[\ln\frac{I_C}{I_o} + (A_o-\beta) + \frac{E_{GO}}{kT_o}\right](T-T_o)$$
$$-\frac{\beta k}{qT_o}\frac{(T-T_o)^2}{2} \cdots$$

where I_o is the reference current level

$$A_o = \ln\frac{I_o}{I_sT_o}$$

and $I_s(T_o)$ is the saturation current at T_o.

The basic circuit of a differential amplifier is shown in Fig. 10.3.1

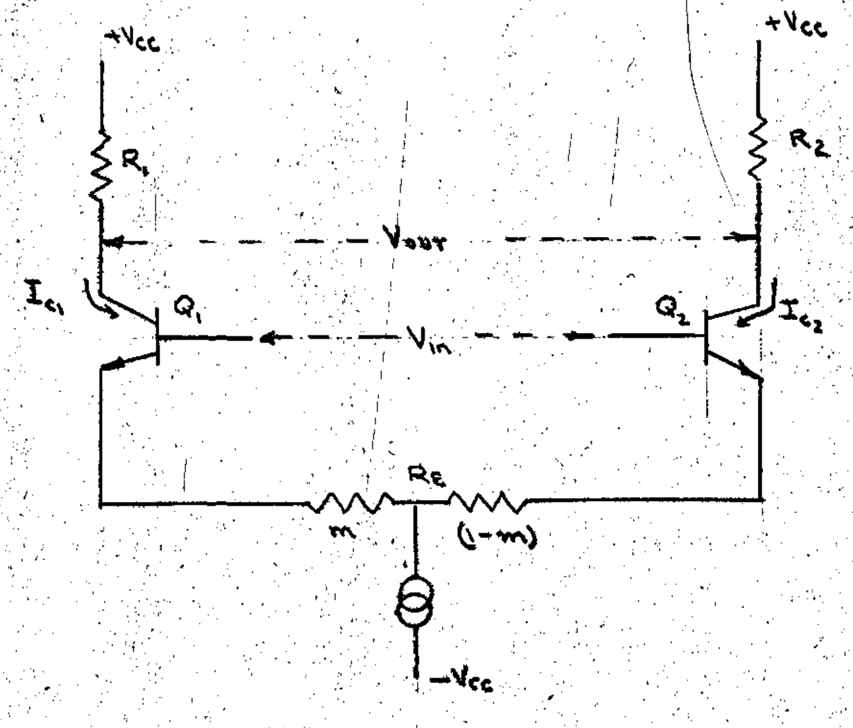


Fig.10.3.1 Basic Differential Input Differential Output Circuit.

Taking loop equations after balancing R_E so $V_{out} = 0$ at $V_{in} = 0$

$$(V_{BE1} - V_{BE2}) + RE(A_1 I_{c1} - A_2 I_{c2}) = 0$$

$$A_1 = m(1 + \frac{1}{h_{fe2}})$$

$$A_2 = (1-m)(1 + \frac{1}{h_{fe1}})$$

Substituting into the Taylor expansion

$$\frac{kT_o}{q} + (A_{o1} - A_{02}) + R_E(A_1 I_{c1} - A_2 I_{c2}) + \frac{k}{q}\left[\ln\frac{I_{c1}}{I_{c2}} + (A_{01} - A_{o2})\right] = 0$$

β is nearly constant and independent of operating levels so second order and higher terms are dropped.

Then the net differential temperature coefficient of base-to-emitter voltage is

$$\frac{k}{q}(A_{o1} - A_{02})$$

Circuit balance can be made independent of temperature by choosing

$$\frac{k}{q}\left[\ln\frac{I_{c1}}{I_{c2}} + (A_{o1} - A_{02})\right] = 0$$

But since $\frac{k}{q}(A_{o1} - A_{02}) = \frac{\Delta V}{\Delta T}$

then $\frac{I_{c2}}{I_{c1}} = e^{\frac{q}{h}\frac{\Delta V}{\Delta T}}$ for temperature compensation.

In Fig. 17 the voltage drops across resistors R_6 and R_7 are nearly equal. If I_{c1A} is the collector current of Q_{1A} and I_{c1B} is the collector current of Q_{1B}, then the voltages across R_6 and R_7 are nearly equal when the circuit is balanced.

Therefore, $I_{c1A}R_6 = I_{c1B}R_7$

or
$$\frac{I_{c1A}}{I_{c1B}} = \frac{R_7}{R_6}$$

This gives

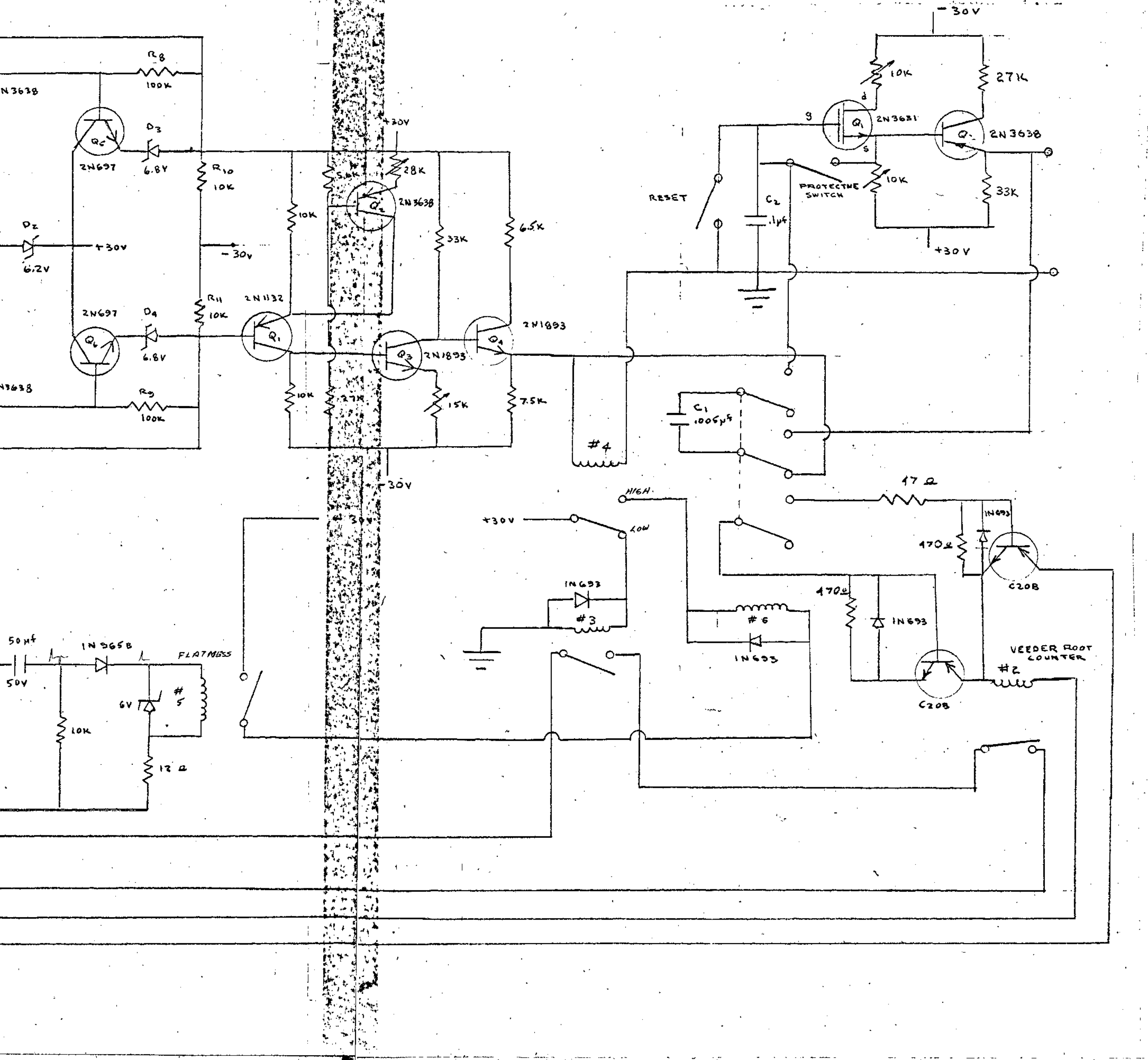
$$\frac{R_7}{R_6} = e^{\frac{q}{k}\frac{\Delta V}{\Delta T}}$$

A temperature cycling test revealed the initial value of $\frac{\Delta V}{\Delta T}$ = +7.2 microvolts/C° equivalent input. This requires a ratio between R_7 and R_6 of

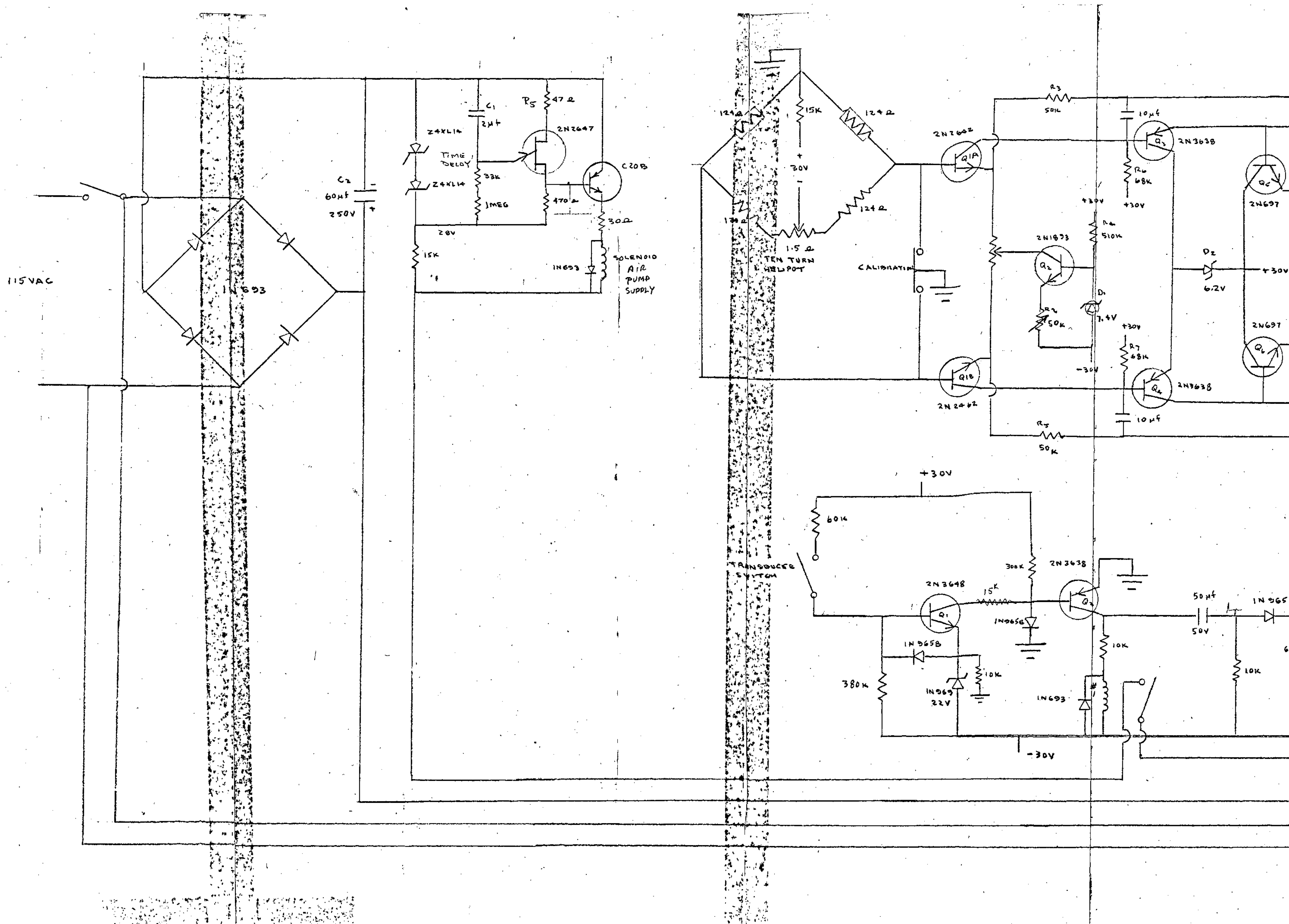
$$\frac{R_7}{R_6} = e^{\frac{1.602\times10^{-19}}{1.38\times10^{-23}} \times 7.2 \times 10^{-6}} = 1.091$$

Since R_7 = 68k and output number 2 was considered to be the common terminal R_6 must be increased by 6180 ohms. Repeating the temperature cycling, showed that the temperature drift is now about one microvolt/C° between 20 and 40°C.

10.4 INSTRUMENT CIRCUIT DIAGRAM



R8
100K
N3638
Q5
D3
2N697
6.8V
R10
10K
D2
6.2V
+30V
-30V
2N697
D4
Q6
6.8V
R11
10K
2N1132
Q1
N3638
R9
100K
+30V
5.6K
28K
Q2
2N3638
10K
33K
6.5K
2N1893
Q3
Q4
2N1893
10K
27K
15K
7.5K
30V
#4
+30V
-30V
10K
27K
d
g
Q1
2N3631
Q2
2N3638
s
10K
33K
+30V
RESET
C2
.1μf
PROTECTIVE SWITCH
C1
1005μf
47 Ω
HIGH
+30V
LOW
IN693
470Ω
C20B
IN693
#3
470Ω
IN693
#6
IN693
C20B
VEEDER ROOT COUNTER
#2
50μf
50V
IN965B
FLATNESS
#5
6V
10K
12 Ω



115VAC
IN693
C2
60μf
250V
Z4XL14
Z4XL14
TIME DELAY
C1
2μf
R5
47 Ω
2N2647
33K
1MEG
470 Ω
C20B
30 Ω
28V
15K
IN693
SOLENOID
AIR PUMP SUPPLY
124 Ω
15K
30V
124 Ω
124 Ω
124 Ω
1.5 Ω
TEN TURN HELIPOT
CALIBRATION
2N2462
Q1A
Q1B
2N2462
R3
50K
10μf
Q3
2N3638
R6
68K
+30V
2N1893
Q2
R4
510K
R2
50K
D1
7.4V
+30V
R7
68K
-30V
Q4
2N3638
10μf
R5
50K
Q5
2N697
D2
6.2V
+30V
2N697
Q6
+30V
60K
TRANSDUCER SWITCH
300K
2N3638
2N3648
Q1
15K
Q2
IN965B
IN965B
10K
380K
IN969
22V
10K
IN693
50μf
50V
IN965
10K
-30V