A STUDY INTO DESIGN AND DEVELOPMENT OF NONINVASIVE BLOOD PRESSURE MONITORING DEVICE

MAGED N. CHOUCAIR

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A STUDY INTO DESIGN AND DEVELOPMENT OF NONINVASIVE BLOOD PRESSURE MONITORING DEVICE

By

MAGED N. CHOUCAIR

Presented in Partial Fulfillment of the Requirements
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Approved By

DR. E. KORDYBAN,PROF. OF MECHANICAL ENGINEERING, (ADVISOR)

DR. Y.S. CHADDA, CHAIRMAN, DEPARTMENT OF MECHANICAL ENGINEERING,(CO-ADVISOR)

DR. D. OLOWOKERE, ASSOCIATE PROF. (CIVIL ENGINEERING)

DR. M. J. OTTENBREIT, ASSOCIATE PROF. (BIOLOGY)

DR. H. SABBAH, HENRY FORD HOSPITAL, DETROIT

UNIVERSITY OF DETROIT

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PRESENTED BY MAGED N. CHOUCAIR

ACCEPTED BY THE DEPARTMENT OF MECHANICAL ENGINEERING

Eugene Kordyban
PROF. EUGENE KORDYBAN
MAJOR PROFESSOR — 8-9-91 DATE

Yogendra
Dr. YOGENDRA S. CHADDA
DEPARTMENT CHAIRMAN — Aug 9, 1991 DATE

APPROVED BY THE GRADUATE COUNCIL
PROF. A. HAMAN, ACTING DEAN
CHAIRMAN — AUGUST 13, 1991 DATE

TO MY PARENTS

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ABSTRACT

This work describes the design, development and testing of an instrument for continuous, noninvasive measurement of blood pressure in humans. While there is a great need in medical fields for such an instrument, it is not available at present.

Tonometry principle is used in this work. This method has the difficulty in locating the tonometer over the artery. However, this difficulty was overcome by locating the tonometer where major arteries are absent, such as fingertips or ear lobes. Linear relationship between the blood pressure variations in the arterioles, capillaries and the main arteries, is shown by mathematical analysis and simulation tests.

While it is shown that it is possible to obtain the measurements in various locations, the present work concentrates to develop a device suitable for the finger. Such device is built and tested successfully on a number of individuals as well as in a hospital. Also, a calibration procedure using a standard cuff method has been worked for this device. However, one difficulty has been still remains to be solved, namely, long-term zero shift of the measuring system. This is due to the convection currents and the deterioration of the adhesive presently in use.

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CHAPTER I

INTRODUCTION

The rapid development of modern technology has made great advances in medical field in recent years. Some of those are the introduction of artificial intelligence technique to diagnose some diseases, the microsurgery or the continuous monitoring of a patient in ICU (intensive care unit). These advances require a parallel progress in the field of blood pressure measurements, but only little progress has been made in the noninvasive method of continuous blood pressure monitoring over the last sixty years. Even in ICU and CCU (coronary care unit) the blood pressure is monitored by the use of the cuff method which, although automated , provides only intermittent measurements.

The blood carries nutrition and many enzymes to the cells of the body and therefore, the blood pressure can tell the physician quite a bit about the patient's condition. Furthermore, many medications are injected into blood stream and, if the physician can have continuous monitoring of certain medications in the patient's body through the monitoring of the patient's blood pressure ,then she or he can decide on the amount and duration of given medication to be given in a particular case . Another factor that has an even greater need of continuous blood pressure monitoring is the possibility of early detection of a heart attack or a stroke.

Continuous , noninvasive blood pressure measuring device can be designed to be portable and be equipped with an alarm system . The alarm system would be very helpful in the following cases: First, it can be used to detect some early disturbances in the human body. This would permit early treatment of some diseases which are very easy to cure at an early stage and very difficult to deal with if discovered late. Second , the alarm system would be useful in daily physical exercises. Finally the alarm system could be used to maintain the pressure on the artery walls within acceptable range.

A continuous record of not only the blood pressure magnitude but also the wave shape will aid greatly in basic blood pressure research as well as providing a better understanding of hemodynamic condition ,cardiovascular diseases, hypertension or arteriosclerosis . It could also be used to study the relation between life span and blood pressure, or the relationship between any kind of life style and the blood pressure variations. In other words, the relation between any variable in human body and the blood pressure could be studied for both the short and long time studies. This last idea appears to be going too far but the huge development in the computer sciences should be taken into consideration, especially the development of a supercomputer which has a great ability to store and analyze large amounts of data . Also one should not forget the fast development of the artificial intelligence field which has, in fact, invaded the medical field in the recent years. Finally, it should be added that nowadays records of medical history are kept for people in many fields. Therefore, it would be useful to keep a record of blood pressure variation for a person during his life .

In summary, medical science at present is greatly hampered by the lack of a means to monitor and record the blood pressure continuously and an invention of such an instrument would be welcomed by practicing physicians and medical researchers.

It may be concluded from above that there is great need to develop reliable method for blood pressure monitoring. A number of scientists have exerted considerable effort to find a solution to this problem , but thus far, their efforts have not yielded fruitful results. One field where a degree of success has been achieved is in the development of a direct method where a cannula is inserted into the artery. This , however, requires a surgical procedure which the physicians prefer not to use unless they have no other choice , (i.e. It is used only in emergency cases in CCU and ICU). In most cases the physicians prefer to use the cuff method which is not very accurate (scientists agree that it has about 10% to 20% error) to estimate the blood pressure variation in non-emergency cases . The cuff method is not only not accurate, but also the application of high and repetitive pressure on the arm of the patient may injure the vessels in the patient's arm and may also affect patient's heart. In a discussion of this research objective with Dr. Sabbah of Henry Ford hospital he pointed out an urgent need for such an instrument, because it would do the job of the direct method of blood pressure monitoring in a less risky way, especially, if the indirect method could approach the accuracy and the goal of the direct method. He expressed his opinion that the absolute values of blood pressure are not as important as the ability to detect changes in blood pressure with time .

Based on the study of previous methods which have not been successfully developed, and on the preliminary experiments conducted in this field, a method for continuous blood pressure measurement has been developed which will be hopefully accepted by the medical profession.

CHAPTER II

BACKGROUND

II-1 Medical Needs

Throughout the medical history there has been an urgent need to measure the blood pressure, especially the blood pressure variations, for a better treatment of patients. Not only blood pressure measurement is needed for clinical needs, but also the measurement of blood pressure plays an important role in the medical research. This can be explained as follows:

First, the human body has a great capability to cope with stable conditions. That is, the problem is not how high the blood pressure of a person is (of course within a certain range), but how much it varies during a given time period. Hence, the blood variations are more important than the initial readings of the blood pressure. The blood pressure variations would create stress variations in the artery walls, which will be followed by fatigue and sometimes failure in the arteries.

Second, a noninvasive blood pressure monitoring is very important during the time before a serious illness happens to a patient. This is due to the fact that the direct method is very risky in this case. However, once a serious failure in the patient condition occurs, the direct method should be used to save the patient's life.

Finally, in the absence of an accurate noninvasive blood pressure monitoring method, there is justification for development of a noninvasive method which might not be as accurate as the direct one. This would better than risking the use of difficult, unsafe and painful direct blood pressure monitoring method.

Therefore, there is an urgent need to develop an instrument to measure the blood pressure variations in a noninvasive way. This need was answered about sixty years ago when the cuff method was introduced, after the discovery of Korotkoff sounds. Although the cuff method has about 10% to 20 % error, it was accepted by physicians on a large scale.

A great number of papers have appeared over the years describing the automation of the cuff method, analysis and interpretation of Korotkoff sounds and suggesting various procedures to standardize this method and to improve its accuracy. The relative accuracy and the ease of application of the auscultatory method will undoubtedly continue to improve, but it will remain a method which produces only periodic measurements. For certain situations such as blood pressure research, ICU and CCU, continuous beat-by-beat recording of the blood pressure would be preferable.

The introduction of the cuff method answered some of the medical needs. However, the rapid development of medical sciences requires not only blood pressure measurement but also a continuous blood pressure monitoring, especially in the ICU and CCU units. Based on that need, the scientists developed many solutions. Unfortunately, each of these solutions possesses disadvantages which prevent it from being used in practice.

Without question, the most accurate and foolproof method of blood pressure measurement is the direct method where a cannula is inserted into an artery. This method has been employed in some situations and, apart from some minor problems with blood coagulation, there appear to be no major obstacles in its use. It will remain a standard to which all other methods must ultimately be compared, but because its use requires a surgical procedure it will always be limited in its applications.

Several principles of blood pressure measurement such as tonometry, ultrasonic measurement of artery distension and the movement of skin over the artery have been considered for this application. All these methods have certain problems associated with them and none have been developed to the point of practical use.

The method of tonometry has attracted probably the most investigators. It is based on the principle that, when a curved surface of a pressure vessel is flattened by a rigid plane, the force on the plane is equal to the pressure multiplied by the area of the contact. It has been used successfully in the measurement of intraocular pressure.

In conclusion, physicians are looking for an instrument that measures the blood pressure in an accurate and continuous way. It is preferred for the instrument to be portable, easy to install and not to have deleterious effects on the patient's health or comfort.

Based on the literature search in the medical and engineering fields and, on the preliminary experiments conducted, a method which satisfies the medical profession in the noninvasive continuous blood pressure measurement areas needs to be developed.

Chapter II presents a historical background for the noninvasive blood pressure measurements.

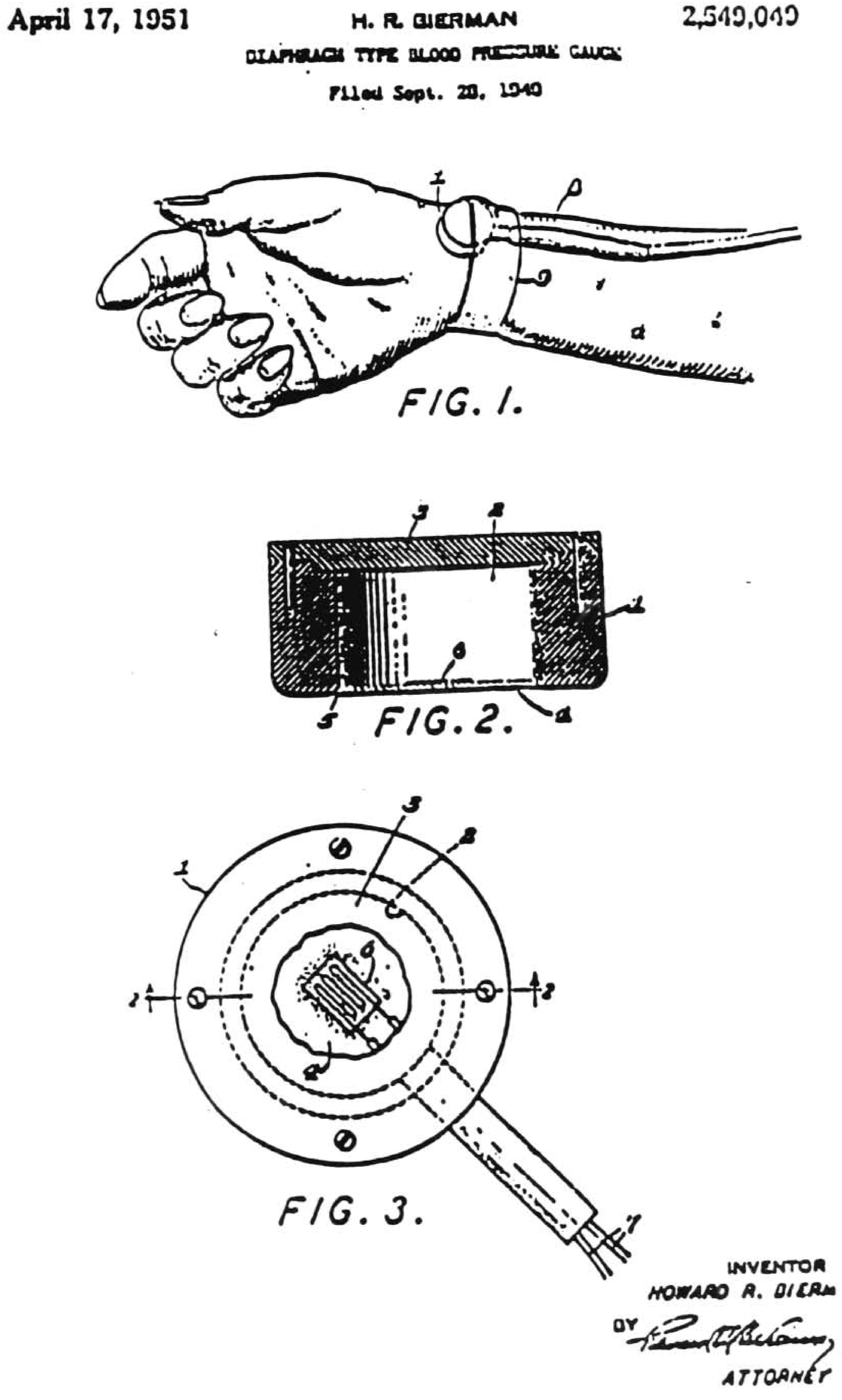
II-2 Historical Background on Indirect Blood Pressure Measurements

One of the primitive methods to measure the blood pressure was the method in which the physician uses his right thumb to feel the pressure (in fact the pulse) on the patient's wrist. Of course, this method is not scientific because the measurements are dependent on the physician's experience and his physical condition. However, some physicians became experts in telling the relative blood pressure of patients. Such physicians were able to monitor the blood pressure of a patient, especially the variations in the pulse. This method does not give objective results and there is no way to keep a record of the variations of blood pressure versus time. This method is still used in some primitive countries. However, it is very difficult to determine where, when and who first used this method.

The first scientific instrument to measure the blood pressure was introduced after the discovery of Korotkoff sounds. Korotkoff[31] discovered that, whenever the blood flow is shut off on the patient's arm a certain sound can be detected at first flow of blood in the artery. The outside pressure applied on the arm at the " first hearing of that sound ", is approximately equal to the systolic pressure in the artery. Korotkoff's sound disappears when the outside applied pressure is approximately equal to the diastolic pressure in the arm. In this method , the systolic and diastolic pressure are determined once for every shut off and gradual release of the blood flow. For successive readings the procedure of applying high pressure (enough to shut off the blood flow) on the arm should be repeated. Note that the systolic and the diastolic readings are not read for the same beat of the heart, because a certain elapse of time is needed to release the outside pressure gradually. Therefore, if certain variations of blood pressure take place between the systolic reading and diastolic one, they cannot be detected by this method. The studies of this method indicate an estimated error of about 10% to 20 % in the measurement of blood pressure. Despite that error in the basic auscultatory method, it has been widely accepted and used in the medical field for over sixty years. During the last sixty years, the scientists have come up with a great number of ideas which describe the automation of the cuff method, analyze and interpret the Korotkoff sounds and suggest different procedures to standardize this method. Undoubtedly, the relative accuracy and the ease of application of the cuff method will continue to improve, but whatever effort is spent in this area the auscultatory method will remain a method which produces only periodic measurements.

In 1951 a U.S. patent describing a diaphragm type blood pressure gage was issued to H. R. Bierman, the first page of which is shown in FIG.1. It consists of a flexible membrane in contact with the skin directly over the artery; the membrane is equipped with a strain gage whose output is related to blood pressure. The patent does not mention a method of positioning the membrane directly over the artery, calibration, nor the effect of tissue elasticity; these were undoubtedly among the problems which prevented this invention from gaining practical use.

Correl [13] in his M. S. thesis at MIT in 1959 has analyzed the distension due to variation of blood pressure



April 17, 1951 H. R. BIERMAN 2,549,049

DIAPHRAGM TYPE BLOOD PRESSURE GAUGE

Filed Sept. 20, 1948

INVENTOR

HOWARD R. BIERM

BY

ATTORNEY

FIG. 1: BIERMAN'S DIAPHRAGM TYPE BLOOD PRESSURE GAGE

and has studied various methods of measuring the motion of the skin above the artery. The main problem with this method, as pointed out by Pressman and Newgard [40], is the fact that the skin displacement is not uniquely related to blood pressure. For example, studies show that there are some drugs which reduce the blood pressure, while increasing the arterial distension.

Because of this limitation, Pressman and Newgard [40] undertook to work on a direct method of force measurement which falls in the general category of tonometry. Its operation is based on the fact that, when a cylinder or a sphere under internal pressure is flattened by a rod, usually called a rider, the wall, being perpendicular to the axis of the rider, does not contribute to the force component in the direction of axis and, consequently, the internal pressure is equal to the force on the rider divided by the area of contact. Using this principle Pressman and Newgard [40] have developed a transducer which permits continuous measurement and recording of blood pressure. The results compare favorably with other methods of blood pressure measurement.

There are several difficulties with this method which prevented it from becoming practically useful. Probably the most serious problem is with the proper positioning directly over the artery. The authors suggest moving the instrument around until the maximum output is obtained, but then a slight motion of the body will shift the instrument sufficiently to prevent proper pressure measurement. There is also evidence that the artery, when subjected to pressure, will attempt to move to an unpressurized location.

Although the measurements are based on a sound theoretical principle and a single calibration should be sufficient for the instrument, the authors thought the in situ calibration desirable and have described some methods to accomplish this.

Bahr and Petzke [6] pointed out that, for the Pressman-Newgard transducer, blood pressure changes of more than 30 % result in excessive errors; they proceeded to develop tonometry which utilizes electronic feedback to correct the variances in mean blood pressure by changing the force with which the plate presses against the skin. However, this method did not succeed because of some practical difficulties.

In 1978, Weaver et al [55] have introduced further significant improvements to the Pressman-Newgard transducer. They published a paper under the title " Study of Noninvasive Blood Pressure Measurement Techniques". They addressed themselves to solve two problems (the above paper discusses only the second problem). The first problem is the difficulty of detecting Korotkov sounds with a small probability of errors, and classifying it. The second problem is the difficulty of identifying false Korotkov detections and to determine which sound corresponds to systolic or diastolic blood pressure. Still, they based their work on the theory of arterial tonometry.

To solve the second problem mentioned above, they developed an array of transducer elements. Each transducer in the array is similar to the one used by Pressman and Newgard. Weaver et al claimed that the use of an 8-mm linear array of 16 transducers, each of which is 0.5 mm long, when placed transversely over radial artery with a small tolerance, then one or more of the arterial riders in the array will be correctly positioned over the artery (FIG.2). Thus, even if the transducer shifts its position during the monitoring of blood pressure, some rider will find itself positioned over the artery and its output will be selected. A computer algorithm is developed for the purpose of selecting the right output. This computer algorithm uses a recorded data base contains approximately 30,000 Korotkov sounds. The data base which was acquired from a protocol which was developed for that purpose whereby Korotkov sounds, ECGs, cuff pressures and outputs from a wave detector were used during the following activities for a statistically selected number of human beings :

1- person is lying flat on the back,
2- person is sitting at a desk and writing,
3- person is walking in place with a predetermined step frequency,

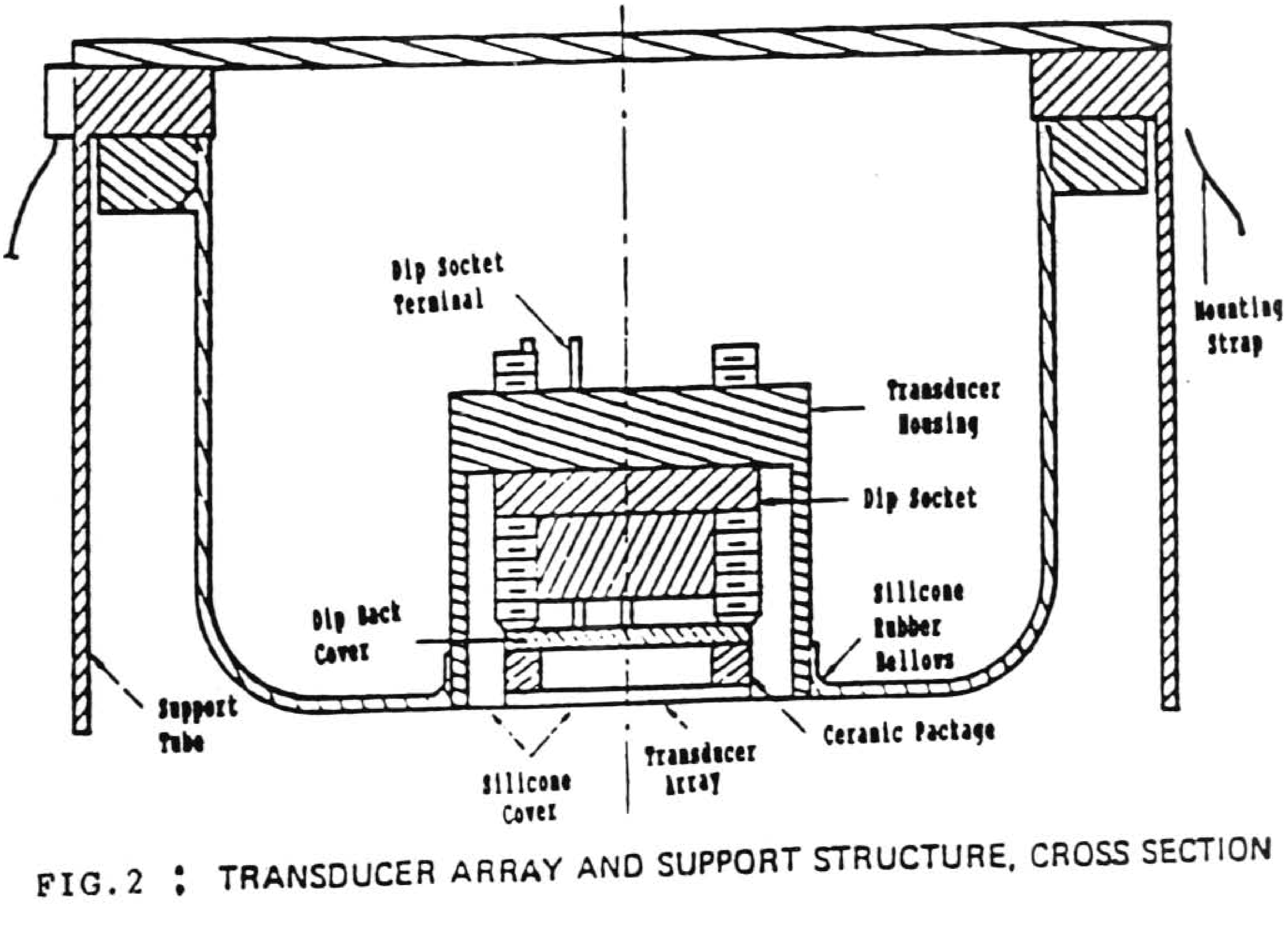


FIG.2 : TRANSDUCER ARRAY AND SUPPORT STRUCTURE, CROSS SECTION

4- person is walking on a treadmill at two feet per second.

This system appears to have reasonable chances of success, but it has been over twelve years since the publication of their paper and the transducer is as yet to be put to practical use; it is likely that the authors have encountered some additional difficulties.

Based on preliminary laboratory work, Weaver et al's method could have failed for the following reasons : First, artifact motions are very close in frequency (and sometimes in amplitude) to the those of blood pressure waves, therefore it is very difficult to use a computer algorithm to distinguish between the two. Second, some artifact motions add to the amplitude of the blood pressure reading when they are both in the same direction and subtract from it when they are in opposite direction. Third, an artifact motion usually changes the flexiblity of artery wall by moving the artery to a new position, then even if the rider transducer is still on the artery its reading will change due to the change in flexibility of artery wall. Fourth , the data base used in Weaver et al computer algorithm is not large enough to cover all the cases, because it is difficult to generalize in the case of human body. It is much better theoretically to use a data base for the same patient in different activities. Fifth, the artery walls relax and tense in a consecutive manner whenever they are subjected to external pressure; this will change the artery wall flexibility and therefore the blood pressure readings. Finally, the natural frequency of the transducer used in operation will play a role in destabilizing the blood pressure reading. Due to this last fact, the base line of blood pressure output moves up and down periodically giving the appearance of a sine-wave.

To overcome the difficulties mentioned in the above paragraph, researchers could write a computer algorithm to correct for all the above problems, knowing that some of those problems are not easy to correct for, or they should try to use the transducer away from the artery if it is possible.

In 1979, a paper by Ramsey et al [42] was published. This paper describes a method for the determination of mean arterial pressure. Although, this method is noninvasive and automated, it cannot determine the systolic and diastolic pressure.

In 1983 Stein et al published [50] a paper about a method which automates the known cuff method to give about forty readings per hour. However, a study showed later that the successive application of pressure on the patient's arm might have side effects on the patient's health. Another study showed also that the successive use of cuff device within a short time period makes the blood pressure reading less accurate.

In 1986, Shimazy et al [47] used volume oscillometric method to determine the systolic, mean and diastolic arterial blood pressure in human fingers. This method is based on the principle of pressure-volume relation in the artery. They claim that the auscultation method using cuff-sphygmomanometric technique originally developed by Korotkoff has two problems, the first being the inaccurate measurement of diastolic pressure. This is due to the fact that it is very difficult to tell the exact time of the disappearance of Korotkoff sound unless a sophisticated computer is used for this purpose; there are also some other biological difficulties in the determination of the diastolic blood pressure. The second problem is an inaccurate determination of systolic and diastolic pressure in hypotensive patients, and in newborn babies and infants. Shimazy et al claimed that their method provides a solution for the above mentioned problem in the cuff method. Although, their method is based on sound theory and they developed some formulas for the determination of systolic, mean and diastolic pressures, the authors did not mention if this method can be used for a continuous monitoring of blood pressure variations.

In 1986, H. Nakane et al [35] designed a device for noninvasive blood pressure measurement. This device which is based on volume compensation, can be used on the finger or on the concha auricle (external ear). However, they admitted that the readings of their device are different from the corresponding readings of a conventional auscultatory method. This problem may be due to the fact the pressure-volume relation is not a linear one.

In 1987, Yamakoshi et al [60] introduced more improvement in the volume compensation method for noninvasive blood pressure measurement. They came up with a method that takes into consideration the nonlinear behavior of pressure-volume relation. They developed an automated portable device for longterm ambulatory monitoring of indirect arterial pressure in human finger. Their device was tested in some clinical work on human fingers, on rat tails and on rabbit forelegs. This method which uses a photoelectric plethysmography, is capable of measuring the arterial elastic properties also.

It seems that this method has a good chance of success, and a device was designed for the market use in this field; however, as the authors mentioned, this method requires a thirty seconds time period between successive readings, and the device can be preset for measurement interval at 1, 2, 5 or 10 minutes. Therefore, the method does not give continuous readings which are required in ICU and CCU units. Another disadvantage of this method is that it cannot solve for artifact motions.

In 1989, Shimazu et al [46] published another paper where they introduced more improvement on the volume compensation method. They designed a new plethysmography called the electric impedance cuff in which the cuff chamber was filled with electrolyte solution instead of water. They mentioned some advantages for this improved method over the past one, however, this method still gives discrete readings for the systolic and diastolic measurements.

The remaining part of this chapter presents a short review for the patents issued for the last thirty years in the field of noninvasive blood pressure measurements.

II-3 Patents Issued For Noninvasive Blood Pressure Measurements

More than a hundred patents were issued in the field of noninvasive blood pressure measurements since 1969. We can group these patents under the followings groups.

First, some of these patents are for non-continuous blood pressure measurements, for example the sphygmomanometer where a cuff apparatus is wrapped around the arm or around the finger. Although, some of these apparatus are automated for repetitive readings, they give discontinuous readings that do not fully answer the medical field's requirements for a continuous blood pressure monitoring. Some of these automated apparatus are used in clinical work due to the lack of fully continuous monitoring of blood pressure machines and due to the difficulties accompanying the direct blood pressure monitoring.

Second, some patents [4,8,10] study different aspects of blood pressure curves and the effects of certain drugs and / or disease on these curves. Although, these studies were developed to an advanced stage of studies, no device was developed to the point of practical use in monitoring the blood pressure. For example, the pressure-volume relation was studied in depth, but all the apparatus recommended in this area fall short of practical uses due to the non-linear relation between pressure and volume of the blood flow.

In the third group of patents doppler and other sound-waves are used to determine some variables in the blood pressure area (for example velocity of blood flow, viscosity,etc). Once some of these parameters are determined, there are formulas available relating these parameters and blood pressure. Unfortunately, these approaches were not successful thus far in the design of a device for blood pressure monitoring. These methods failed because there are many parameters in the blood flow and most of those parameters are interlaced in very complicated ways so that it is almost impossible to come up with a simple relation between them and the blood pressure.

Finally, this group of patents uses tonometry principle to measure the variation of blood pressure in a continuous monitoring. This method is based on a sound principle since it was shown that whenever two flexible tubes are in direct contact (crossing each other) any variation in pressure in lower tube is faithfully transmitted to the upper tube. Many attempts were tried to monitor the blood pressure variations, as for example in patent number D284508 and patent number 3,704,708. In the latest patent, which was issued 1972, the authors used the tonometry principle to design a device for blood pressure monitoring. They put the device over the temporal artery. The problems associated with this device are the difficulty in positioning the device above the artery, since any skin movements will move the device from place,which will lead to errors in readings (although this displacement of the device is very small in most cases), and the calibration of the device. The authors did not address these two problems in a clear cut way.

The use of tonometry device over an artery has little or no chance of success for many reasons:

a- The artery will attempt to escape the outside pressure by moving to a less pressurized position.

b- Any skin movement will shift the device from above the artery, consequently a large error is introduced due to that movement.

c- Since the artery system is interconnected in the human body, then any attempt to block partially (or fully) the blood flow in an artery will cause a change in the blood flow in such a way that less blood will flow in the pressurized artery. This fact will be accompanied by some change in the blood pressure measurements.

d- From the conservation of momentum principle, the determination of the energy left for a particle after a collision with another particle (in this case the artery wall) depends on the direction of the movement of that particle after that collision. Therefore, it is important to know the particle direction after collision to better estimate the momentum transferred to the artery wall. Consequently, the use of tonometry device on capillary blood duct (instead of the artery), gives a better estimation of the blood particles' movements after collision with the artery's wall. Hence, a more accurate linear relation could exist between the blood pressure and the device readings.

See appendix A for a list of patents issued for noninvasive blood pressure measurements for the last twenty years.

CHAPTER III

BACKGROUND ON THE INSTRUMENT IN THIS WORK

III-1 Introduction

Chapters I and II clarify the existence of an urgent need in the medical field for a noninvasive blood pressure monitoring. Such a device is needed to keep this medical field in pace with the advances in the other medical fields and to give more momentum for other discoveries in the medical research areas. Many attempts have been made over the years to design such a device for blood pressure monitoring, however, little improvement has been made in that direction, except for the direct method of continuous blood pressure monitoring. Although no device until now has reached the practical clinical use for noninvasive blood pressure monitoring, the previous attempts and studies in that field help in narrowing the studies to the discovery of a certain solution.

One can combine more than one method with the great advances in technology lately to come up with a new device that will answer the medical needs and will be accepted by physicians. This would be very helpful because some methods were tried about ten to fifteen years ago for the last time. Consequently, the tonometry method has been forgotten by researchers for many years, since many scientists believe that this method has come to a dead end.

The cuff method, regardless of improvement, will never serve well to monitor the blood pressure correctly for the following reasons : First, it will always give periodic readings for blood pressure measurements. Secondly, scientists have applied much of high technology for that purpose, and any further improvement would add much cost to the device, which will prevent the device from being widely used in practice. Finally, as was mentioned in previous chapters, the repetitive applications of high pressure on the human limbs (arm or finger) will affect the patients' health and comfort in a negative way and will introduce errors in the automated cuff method readings.

Similar things can be said about the volume - compensation method. This method cannot overcome the fact that it gives discontinuous readings for the blood pressure. Therefore, it is not worthwhile to invest more efforts in this area.

Another method for measuring blood pressure is the use of ultrasonic principle. However, this method does not give a direct determination of blood pressure; instead it determine other parameters like the mean velocity of the blood and arterial flexibility, etc, and then uses these parameters to calculate the blood pressure. This method has little chance of success, if any, because many parameters are needed for the pressure calculation and most of these variables are related in non-linear manner. Furthermore, some of the required parameters for pressure determination cannot be determined accurately.

Studies of the Korotkoff's sound in the laboratory lead to the discovery that it is possible to record the pulse sound directly using sound detector instrument. It was surprising to find that the wave-form recorded from this method had the same shape as the one recorded from the tonometry. Unfortunately, that wave-form using a "sound" phone was insensitive to the blood pressure variation produced by valsalva manoeuver. This is a physiological effort which increases and decreases the mean blood pressure and thus serves as the test of the sensitivity of the instrument. This fact caused the abandonment of this method, but it might be worthwhile to study it further, especially if all other noninvasive blood pressure monitoring methods fail.

Semi-invasive method for blood pressure monitoring can be studied also. This method might have a better chance for success than the above mentioned ones. However, it is better to develop a noninvasive blood pressure monitoring method, which will be safer to use and which will have a broader practical use once it is developed.

Therefore, tonometry has the best chance of success for the following reasons : First, tonometry is based on a very sound principle. Second, this method was left out of the research area for many years now. Third, it could be used for monitoring transient or rapid changes of blood pressure such as would occur in ICU and CCU. Fourth, a portable device could be designed. Finally, the device could be designed for comfortable, uncomplicated and inexpensive use.

Now, the problems that keep the tonometry method away from practical use area will be specified. Later, this chapter will discuss a preliminary work in designing a new device for blood pressure monitoring.

III-2 Tonometry Method and its Problems

The concept of arterial tonometry was known in 19th century with the kymographion (1847) and the sphygmograph (1854) [51]. The basic principle stated that if two tubes are placed one perpendicular over the other (FIG.3), their mutual reaction is the same. Then any motion in the bottom tube (which is flattened at the point of contact with the upper tube) will be transmitted to the upper tube faithfully but with smaller amplitudes. The amplitude of the motion in the upper tube will be directly proportional to that of the bottom tube.

This principle was tested and studied in the laboratory using two rubber tubes placed as described above.

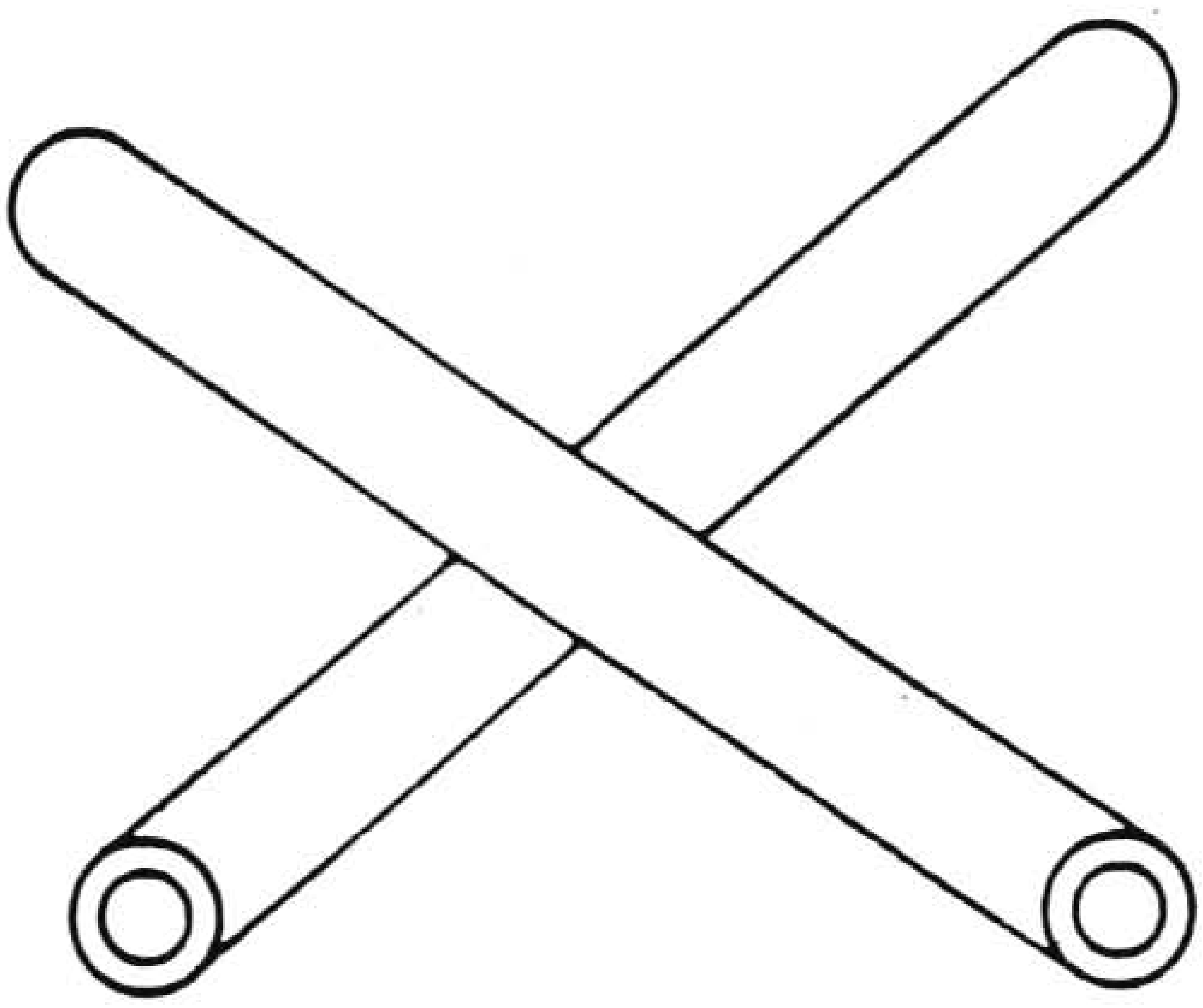


FIG. 3: CROSSED TUBES, WHERE THE MUTUAL REACTIONS ARE INDEPENDENT OF EXACT POSITION OF CONTACT

The lower tube was connected to an air pump at one end (that pump could be hand or machine operated) and to a pressure transducer on the other end. The upper tube was closed at one end and connected to another pressure transducer at the other end. FIG.4 and FIG.5 which are taken from a report by Dr. Kordyban [30], show a direct relation between pressure signal and the reading of the tonometry method. In other words, FIG.4 shows the records of the readings of the two transducers and FIG.5 shows the direct proportionality between the signal magnitude and the pressure.

To construct a mathematical model for the tonometry principle applied on human wrist, the notation in FIG.6 is used, where :

D : difference between transducer displacement and skin displacement

Fb : force due to blood pressure

Ft : force exerted on the transducer

Ka : spring constant of adjacent tissue to the artery

Ks : spring constant of the skin

Kt : spring constant of transducer

Kw : spring constant of artery wall

Xs : the displacement of the skin

Xt : the displacement of the transducer

Xw : the displacement of the artery wall

Let $D = Xt - Xs$ ....(Eq.1)

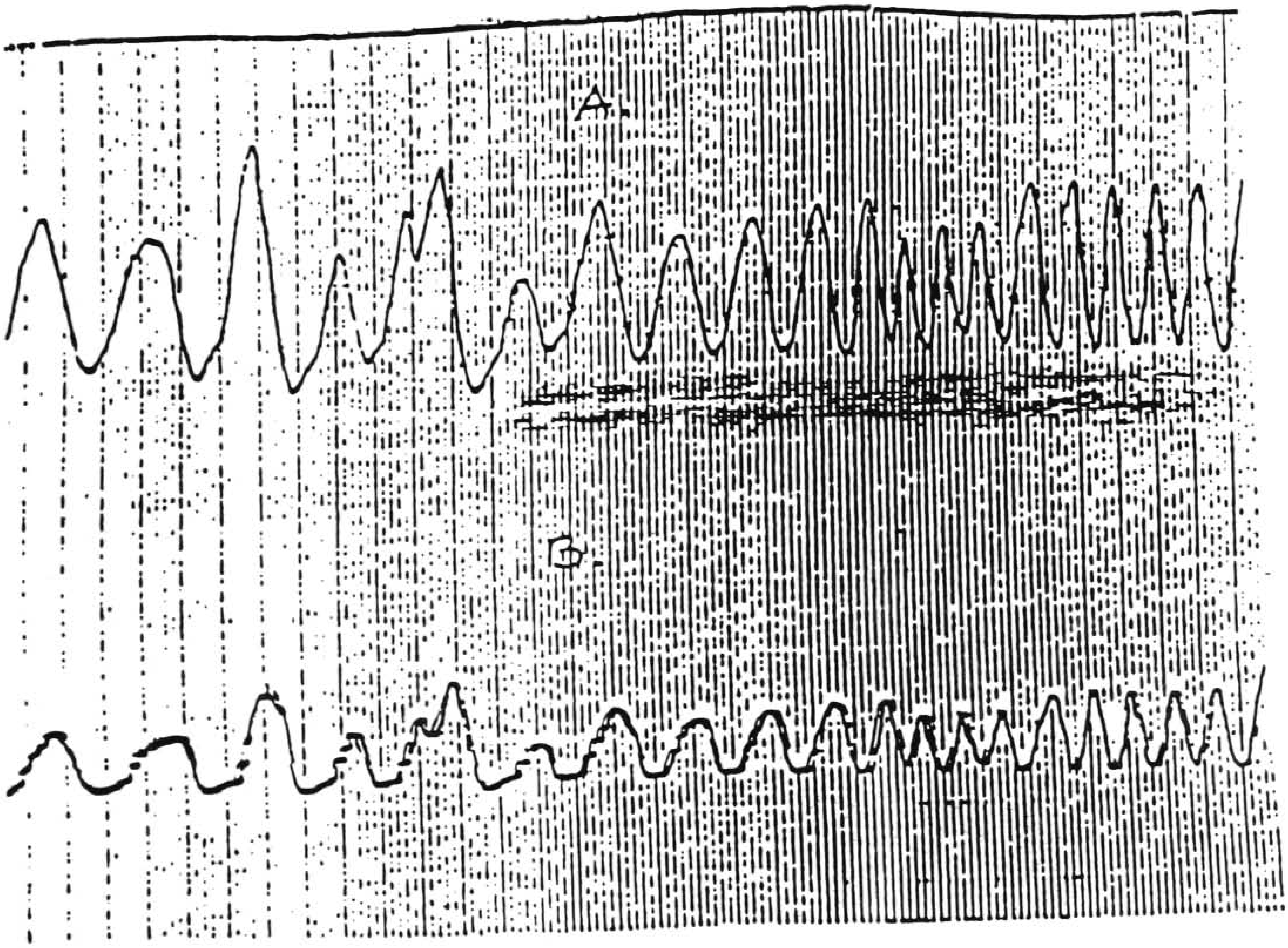


FIG. 4 : RESPONSE OF THE TOP TUBE TO PRESSURE FLUCTUATIONS IN THE BOTTOM TUBE; A. SIGNAL, B. ACTUAL PRESSURE VARIATION.

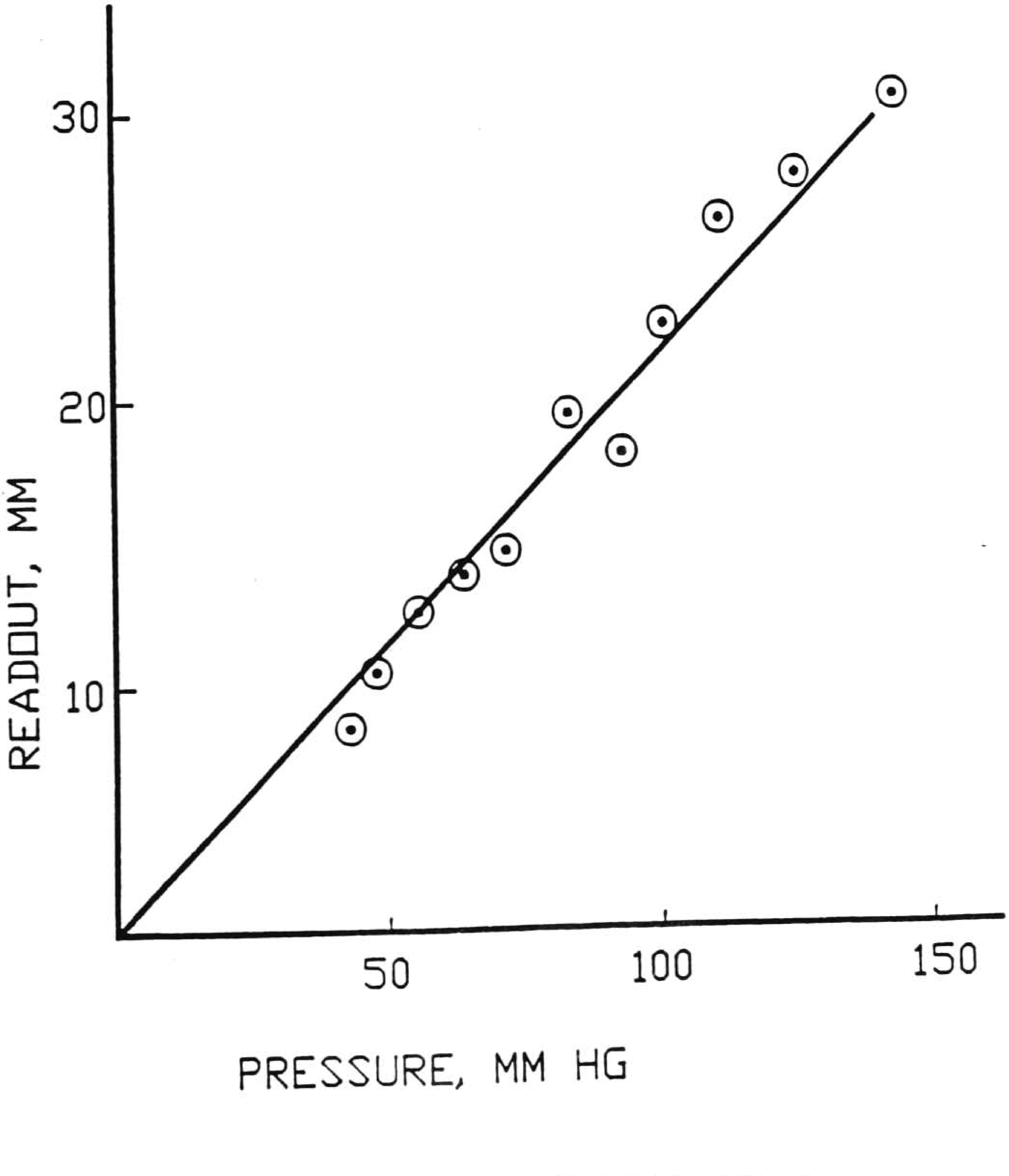


FIG. 5: SIGNAL MAGNITUDE AS A FUNCTION OF PRESSURE.

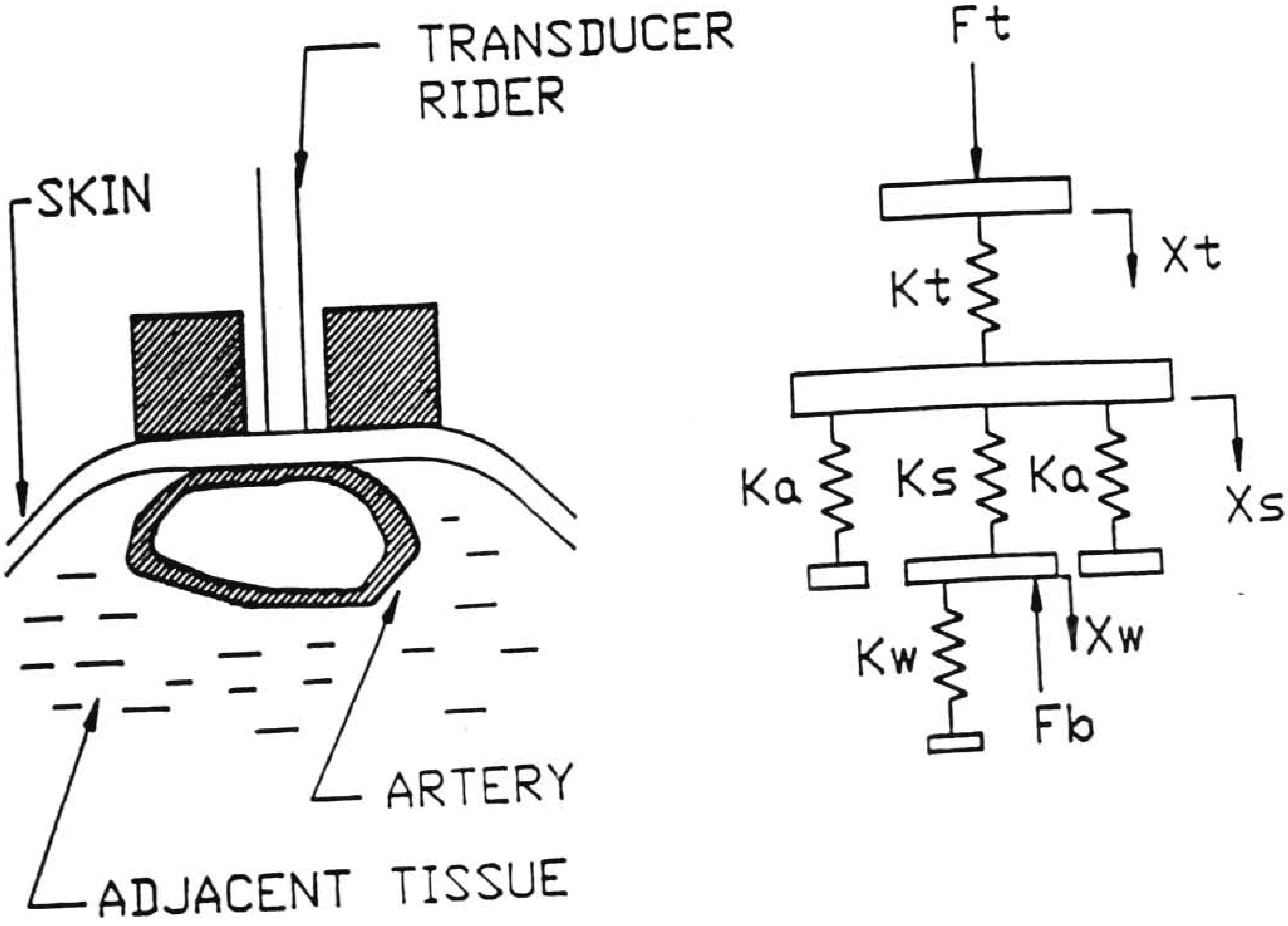


FIG. 6: MATHEMATICAL MODELING OF THE TRANSDUCER OVER THE ARTERY

Balancing forces at Xs :

$Kt (Xt - Xs) = Ka\ Xs + Ks (Xs - Xw)$ .....(Eq.2)

and at Xw :

$Ks (Xs - Xw) = Kw\ Xw + Fb$ ....(Eq.3)

then using Eq.2 and Eq.3 in Eq.1 gives :

$D=(Ka/Kt)Xs+(Ks/Kt)[Xs-(KsXs-Fb)/(Ks+Kw)]$

$D=(Ka/Kt)Xs+(Ks/Kt)[Kw\ Xs+Fb]/(Ks+Kw)$ .....(Eq.4)

If $Ks>>Kw$ (for thin and rigid skin), replace $(Ks+Kw)$ by Ks in Eq.4 and simplify :

$D = Xs\ (Ka + Kw)/Kt + Fb/Kt$ ....(Eq.5)

But the output of transducer is proportional to D , therefore, from Eq.5 the transducer output is proportional to the skin movement (Xs) and to the force due to blood pressure (Fb).

Studying the above mathematical model, it is easy to note the following:

a) To get the reading of the transducer directly proportional to the blood pressure, the factor $Xs(Ka +Kw)/Kt$ should approach zero.

b) The goal in (a) can be achieved by making the skin motion very small (theoretically equal to zero).

This can be done by using the transducer over the finger nail if this possible practically.

c) If the idea in (b) above fails, then the other option is to make $(Ka+Kw) << Kt$. This can be accomplished by using the transducer away from arteries for example on the finger tip or on the ear lobe. In this case Xs is close to zero.

d) Notice that Xs can be caused by two motions:
First, by external motion of the skin, moving the hand or fingers while the transducer is on the wrist of that hand. The other cause is the motion of skin due to the artery motion while that artery is trying to escape the outside applied pressure to a less pressurized position.

Consequently, the tonometry method is suitable for use in monitoring the blood pressure variations. However, the following problems remain to be overcome :

First, the signal produced by the transducer is quite weak and needs to be greatly amplified without reaching the threshold of the device amplification effectiveness. This problem can be solved by using very sensitive transducers like the semi-conductor strain gage, if needed. This strain gage can be connected to an appropriate bridge amplifier meter and a filter. By this way the signal could be amplified about hundred times.

Probably the biggest problem is the positioning of the rider exactly over the artery and keeping it fixed. This may be accomplished by a number of ways. For example, one may use two protrusions on each side of the artery. Those protrusions will press higher pressure in the vicinity of the artery than the pressure on the artery, so that the artery will find nowhere to escape. Another solution is to try to use the transducer away from the artery on relatively stable parts of the human body. A good place for the transducer is on any of the following: the finger tip, the ear lobe, the nose, or the fingernail if those locations have no other problems.

Finally, the calibration problem should be solved. This problem is not too serious because physicians do not require an absolute blood pressure measurement, but rather they are looking for exact variations of that pressure. So, if a device can be developed which can measure the blood pressure variations in an accurate and faithful way, then physicians will tolerate from 10% to 20 % error in the absolute readings of blood pressure. After all, this magnitude of error is tolerated with the cuff method. An in-situ calibration for the device is recommended. One way to do this, is to use an automated cuff device for a periodical check (many of them are already in the market), for example, every hour, and to correct the tonometer in case of errors. Another method to solve the calibration problem is to study further the relationship between the closing of the blood flow and the amplitude of the transducer readings when that transducer is used on the finger. It was observed in preliminary work in the laboratory that when the transducer was used on the finger and a cuff was used on the same arm, during the application of high external pressure on the arm the reading of the transducer was zero (at the same time no Korotkoff's sound could be heard). After releasing the outside pressure gradually, at certain pressure a small amplitude of transducer readings began to appear at the time of the appearance of Korotkoff's sound. Note also that the amplitude of the readings of the transducer continued to increase as the outside pressure slowly decreased until Korotkoff's sound disappeared, whereafter the amplitude of the transducer readings was independent of the outside applied pressure. Consequently, when using this procedure, the systolic and diastolic pressures correspond respectively to the outside pressures at the first appearance of the transducer readings and to the first point when the readings become constant. More study could be done in this area, for example, the record of both Korotkoff's sounds and the transducer reading should be taken at the same time using a two-channel recorder.

III-3 Preliminary work

Preliminary studies led to more than one possible solution for the main two problems in the tonometry method, that is, the problem of finding the artery and of keeping the transducer in the right position above the artery and the second problem which is the calibration of the device to get accurate and faithful readings.

More than one type of instrument was tried on a preliminary basis, taking into consideration the followings

: First, the device should give output which is acceptable in the medical fields. Second, the device should be of portable size. Third, that instrument should be easy to install on the patient's body and this should be done in relatively short time, while keeping in mind the comfort of the patient, especially if the device is to be used for a long period of time. Finally, the device should not be expensive, that is,that price should not exceed the cost of the direct method.

More than four types of transducers and more than six locations on the human body were examined carefully.

The laboratory work introduced some modifications to the transducers used. This was done to get a better solution for the problems of monitoring the blood pressure. The rest of this chapter describes these devices in chronological order of design.

III-3-1 Design one

This design uses a mechanical transducer that has a needle (rider) which rests on the artery. The contact area between the rider and the artery is about one millimeter in diameter. The transducer transfers the force due to the blood pressure variation to a variable transformer; the voltage signal, after passing through a bridge amplifier meter, is fed through a filter to cut off all the high frequency noise, and then the signal is shown on a recorder or oscilloscope. FIG.7 shows device one and its connections.

The problems associated with the use of device one on the wrist are as follows:

1. The difficulty in locating the artery.
2. The difficulty in keeping the rider of the transducer above the artery after the motion of the hand or of the fingers.
3. A good and easy procedure for calibrating the device must be found, since an absolute calibration gives large errors.

The first problem can be solved by designing the system shown in FIG.8. In that design, the wrist should be confined into a channel type seat filled with plaster of paris for a comfortable resting of the wrist in the channel and to render the wrist immobile. The channel is covered by a cover plate and a mount for the transducer has been built in the cover in such a way that the transducer can move in two perpendicular directions using screws and sliding nuts, that is, nuts that will hold the screw and slide in a perpendicular direction to the axis of the screw. This device should be made out of light weight material such as aluminum.

Since the transducer can fall freely to touch the wrist, its weight will apply a constant force on the artery.

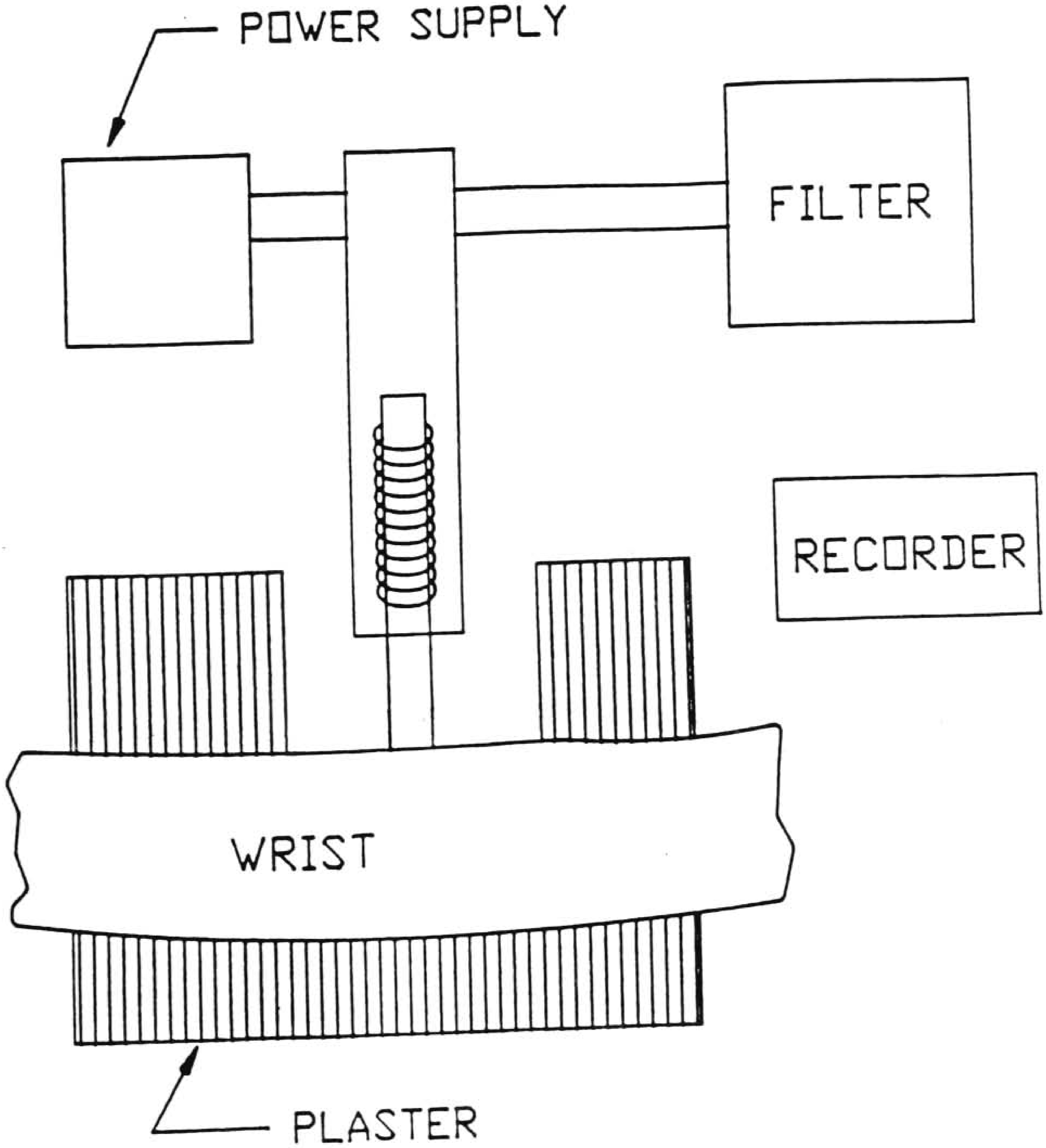


FIG. 7: APPLICATION OF TONOMETRY DESIGN #1

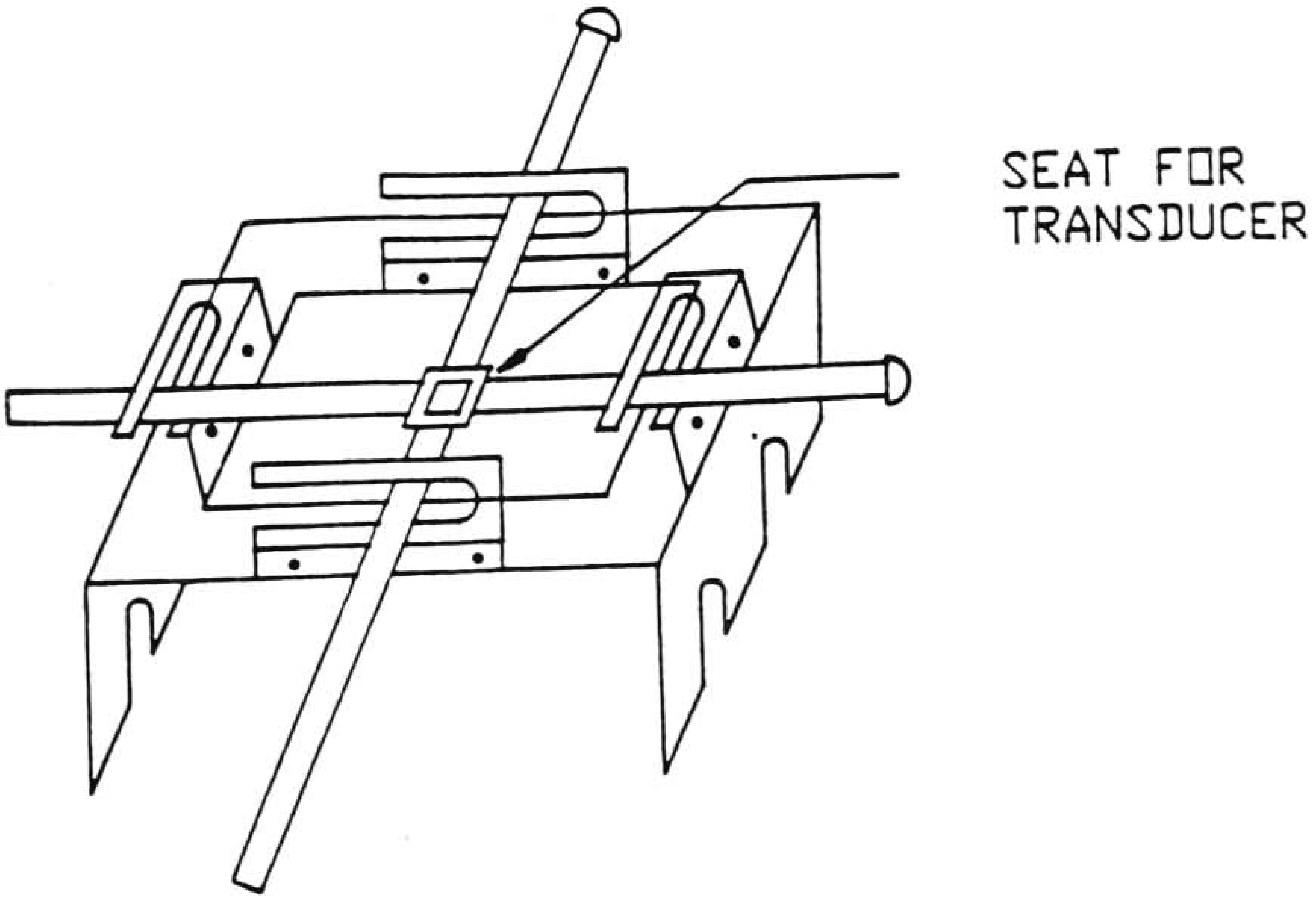


FIG. A. UPPER PART

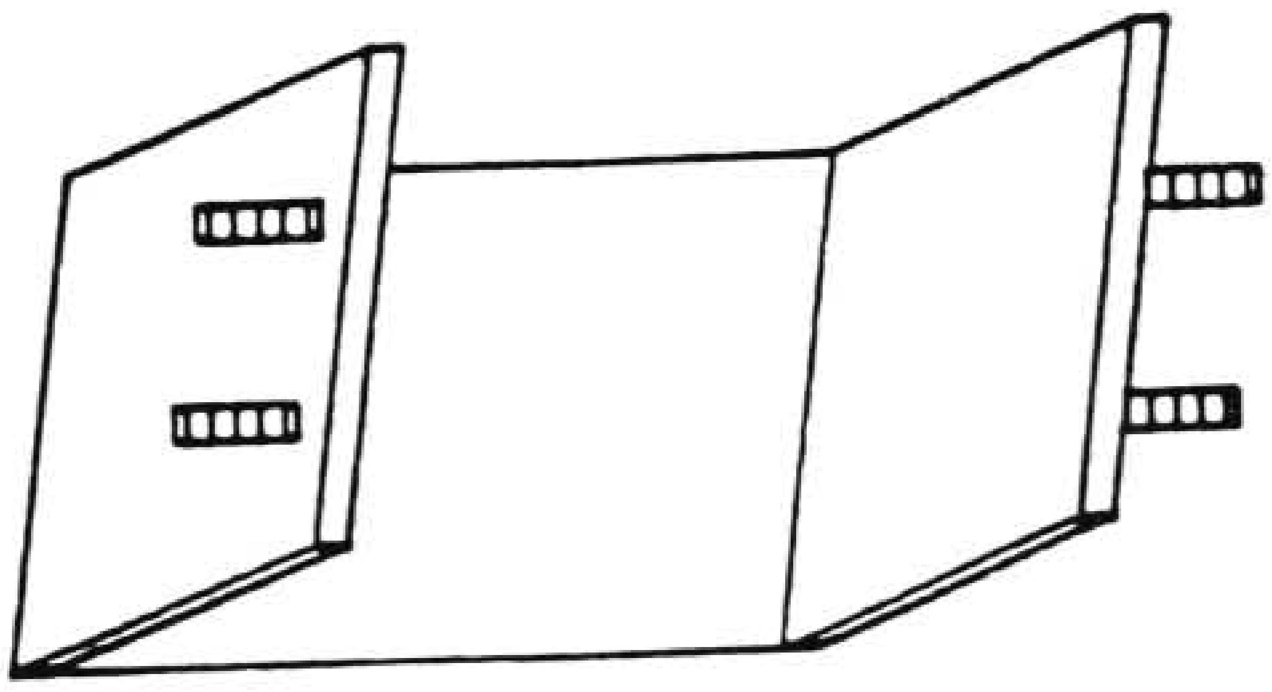


FIG. B. LOWER PART

FIG. 8 : TWO DIRECTIONAL
SLIDING TRANSDUCER

The cover and its attachments can be held fixed by four screws and wing nuts to the outside of the channel seat.

Hopefully, this system will eliminate a great deal of the wrist motions, but it might not be able to cut off all the skin motion, especially the one due to the fingers motions. It may be necessary to hold the fingers fixed by using stiff gloves which could be attached to the channel seat.

This system might not be able to eliminate the motion of the artery, which will try to escape the high pressure due to the transducer's rider application. Therefore, the use of ridges on sides the artery could stop its escape.

Hopefully, this device will give some solution for the problem of finding the artery by moving the transducer in two perpendicular directions until we reach the point with the highest amplitude of the recorder readings. Also, a great deal of the skin motion could be eliminated. Notice that theoretically this device should provide us with a good solution for the tonometry problems. However, the probability of success for this device is doubtful, because it is used on the artery. The use of transducer away from the artery will enhance its chances of success. One reason for this is the fact that the velocity of blood flow in the capillaries is much less than the velocity of the blood in the artery. This will guarantee more time for force transfer between the blood particles and the transducer. Another reason is that the area under the transducer rider in the field of capillaries is much more of uniform than the one over the artery. Further investigation should show whether the transducer should be placed on the artery or away from it.

For the calibration of the device, procedure should be tried where the patient can elevate the arm a known distance; and difference in pressure due to the elevation changes can be computed using the hydrostatic pressure principle. In this manner the calculated pressure changes can be used to calibrate the device, knowing that the changes in the device readings are directly proportional to the changes in the blood pressure. This procedure may fail due to the correction that the human body does to react to the blood pressure changes.

This device may be used not only on the wrist, but also on the finger.

III-3-2 Design Two

In this method the efforts were oriented to apply the principle of tonometry by pressing a piece of rubber tube around the finger. The rubber tube was connected on one end to a pressure transducer while the other end was closed. The output of the pressure transducer was connected to a recorder after passing through a low-pass filter. (FIG.9).

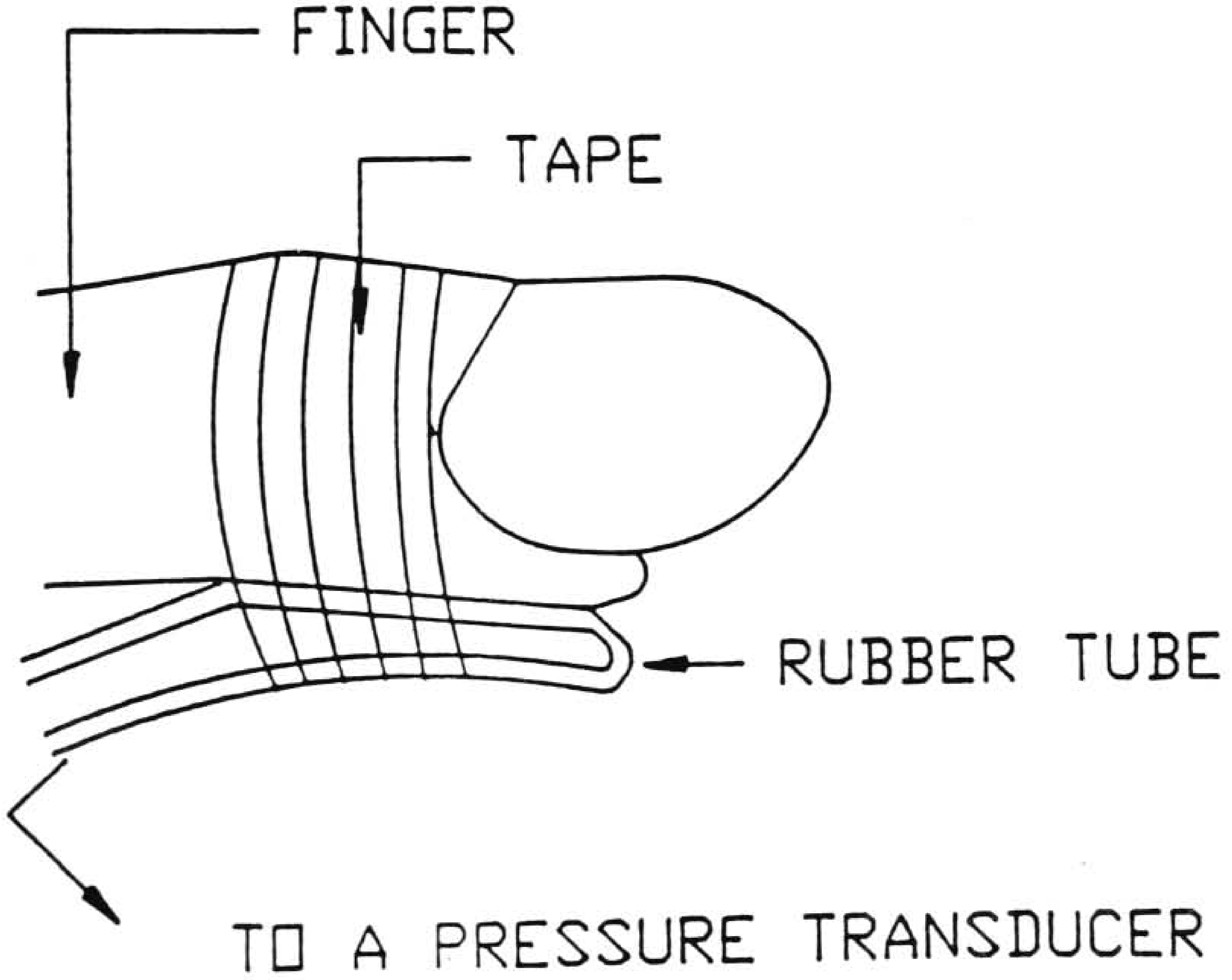


FIG. 9: APPLICATION OF TONOMETRY DESIGN #2

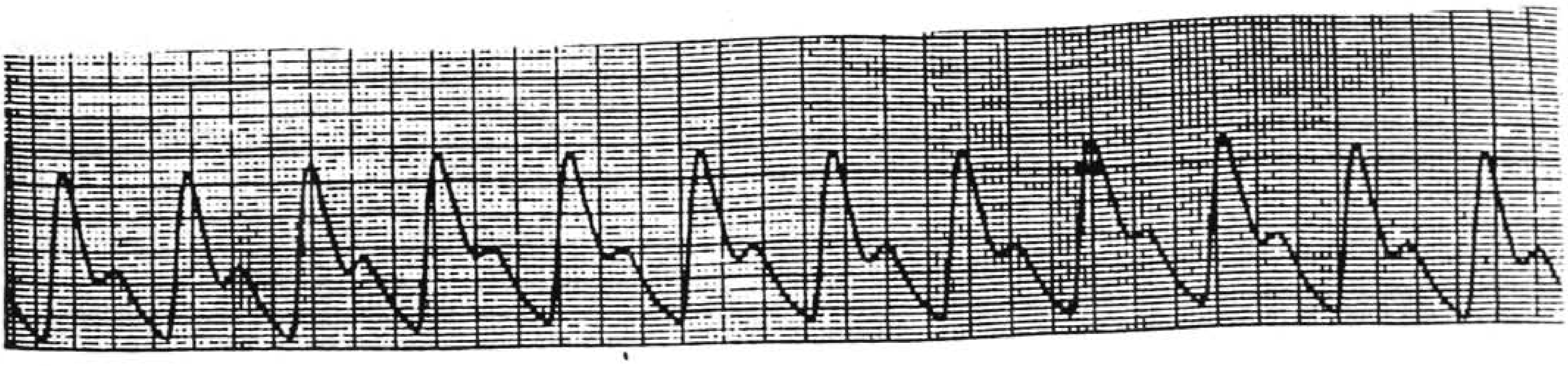
Studies of the data of many experiments on this device, clarify the following points :

The output wave was quite stable for long period of use. This may be due to the fact that the transducer is used away from the artery.

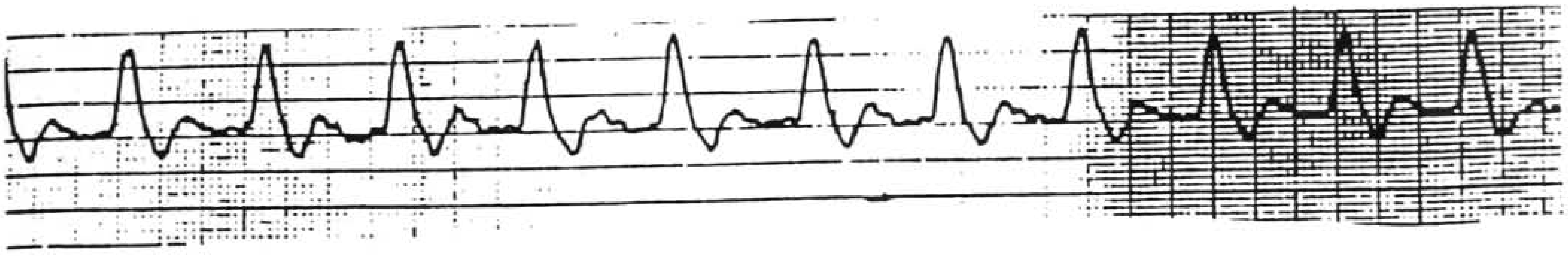
The shape of the pressure signal, however, was not of the right shape. FIG.10 shows the right shape of blood pressure variations and the different shape given by design two.

This device should be studied more closely to discover why the shape of the blood pressure has deviated from the expected one, although the same principle of tonometry could be applied to design two.

To correct the shape of the signal from design two, the following procedures could be used : First, the length of the rubber tube should be varied to see the effect on the signal shape; the signal from the blood pressure will propagate in the rubber tube in both directions (toward and away from the pressure transducer), then the wave will strike the closed end of the rubber tube and get reflected with opposite sign. The reflected wave will interfere with subsequent waves. Consequently, the two wave subtract one from the other in such a way the resultant signal is modified to a new amplitude and therefore a new shape. Second, the diameter of the tube should vary to determine if that will make any difference. The reason for this



A. SIGNAL FROM DESIGN #1
(CORRECT SHAPE)



B. SIGNAL FROM DESIGN #2
(INCORRECT SHAPE)

FIG.10: BLOOD PRESSURE SIGNALS FROM DESIGN #1 AND DESIGN #2

recommendation is that, the size of the rubber tube used in that experiment (about 1/4 inch in diameter) is very large compared the diameter of a capillary blood vessel, so the wave might be transformed and dissipated before reaching the pressure transducer. Notice here that when the principle of tonometry was tested on two rubber tubes, two identical rubber tubes (except for the length) were used. Finally, for the reasons mentioned above, it is advisable to try different flexibility of the rubber tube by using different materials.

The calibration problem for design two can be solved in the same way it was suggested for design one.

Note that in case of failure of the above mentioned calibration procedures, the cuff device can be for an initial calibration. Moreover, since new automated cuff devices have been developed lately, they can be used for periodical check on the calibration of our device using a computer program to handle this task. Another method of calibration is to use the other procedure described before in this chapter. The outside pressure is applied by a cuff on the arm until the transducer reading is zero, then the outside pressure is released slowly, until the reading starts to appear at which point the outside pressure will be equal to the systolic pressure and, when the reading becomes constant (independent of outside pressure) then the corresponding outside pressure will be equal to diastolic pressure. Notice the last procedure of calibration can be used for any device (design one, design two, etc..), when that device is used on the finger, fingernail, or on the wrist.

III-3-3 Design Three

The laboratory work showed also the possiblity of applying the principle of tonometry using strain gages. In fact, the design was to place two strain gages (gage type : WK-13-125AD-350) on a piece of plastic (one gage on each side of the plastic), then form it in a wristband fitting over the radial artery. The strain gages were connected to a wheatstone bridge, the bridge power and signal amplification means. The signal from the bridge amplifier was fed to a low-pass filter which allows the passage of low frequency signals (less than 20 hertz) and amplifies the signal about 100 times. Then the signals were displayed on a recorder (or an oscilloscope). See FIG.11 for the schematic of the electronic circuit used. The above setup gave good signals, but it was found, as in the previous investigations, that their magnitudes depend on the proximity to the artery.(See chapter IV Recommeded Device).

The setup for design three has many advantages over design one and two, but this device requires work to eliminate some problems like the proper positioning problem

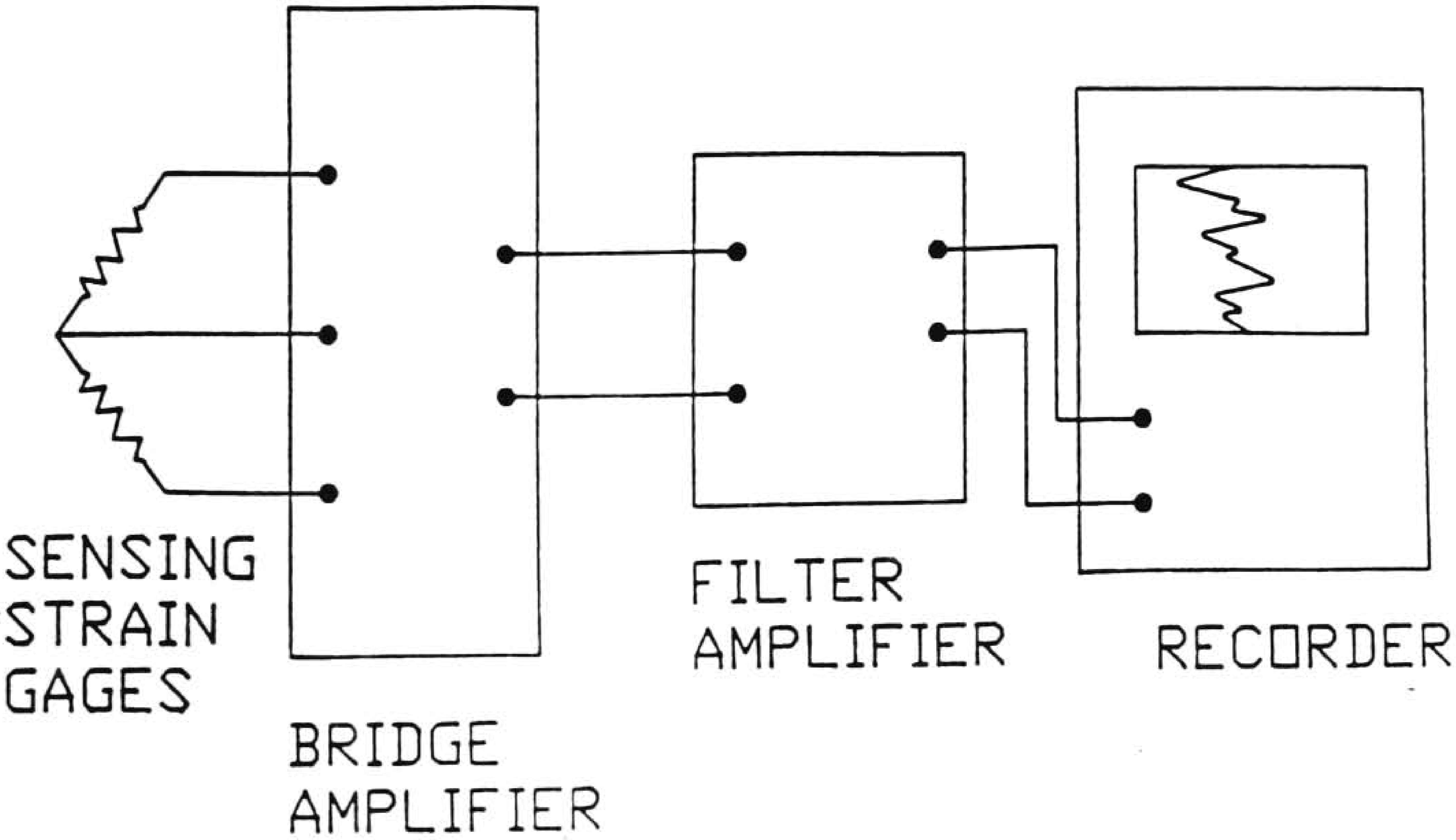


FIG. 11: ELECTRONIC CIRCUIT FOR DESIGN #3

and the problem of calibration. In fact, this device has the following advantages:

First, the system used in design three can be made of portable size. This is because the strain gage has a very small size and a very light weight compared to other devices.

Second, design three can be used on many places on the human body. For example, patients can use this device on the finger tip, on the ear lobe, on the nose, or on the fingernail. It is expected to get the best results when the device is placed on the fingernail, because the nail is the most stable part of the human body where that device can placed and the area of contact between the device and the nail can be kept constant.

Third, the outside applied pressure on the human flesh could be kept very small, therefore, it is possible to measure the blood pressure with little disturbance for the blood flow. This fact will give more accurate and faithful measurements.

Fourth, we can use semi-conductor strain gages to measure very small signal like the one on the fingernail with acceptable precision. This type of measurements seems impossible for design one or two.

Fifth, to guarantee a better stability for the readings, device three should be designed in such a way that one directional motion is allowed for the system. To do so, the strain gages should be placed on a flexible piece of plastic, then the plastic is attached to a clamp in the form of a clothes pin. The pressure on the clamp should be sufficient to keep it at the attachment point. This clamp can be used on the ear lobe, or for other parts of the body and for each the form should be modified to fit the particular shape.

Sixth, the one-directional motion of the device mentioned above (which is usually perpendicular to the flesh surface) will eliminate a great amount of the body motion, because usually the skin motion starts at some muscle movement away from the device, then the skin movement will propagate along the skin surface and in its direction until that wave reaches the flesh below the device. In this case, since the direction of that skin motion is perpendicular to the direction of the motion of the device, the skin motion has little or no effect on the readings of the device.

Seventh, patients should use design three away from the artery, even though the device has one-directional motion, because of the reasons mentioned above for other devices. Another reason for that is the fact that the flow of the blood in the artery adds a tangential component, in the direction of the flow, to the force generated by the blood pressure. This fact will prevent the force in the blood from being perpendicular to the artery wall. In this case the device will keep oscillating back and forth in a continuous motion. This oscillation depends on the amplitude of the blood pressure and on the velocity of the blood flow. This fact causes instability in the output of the device. On the other hand, for the case of using the device on capillary vessels, the blood flow is in all directions. This and the fact that the blood velocity in capillaries is very small compared to the one in the artery, will give more stability to the output of the device when the latter is used away from arteries.

Finally, the cost of design three is low, compared to the direct method expenses. This will give the device a broader application in case of success.

One problem with design three is the selection of the best material as substrate for the strain gages. Some specialists recommend the use of special type of material to increase the stability of the device output.

For the calibration of design three, the same procedures are recommended as for the other devices above.

Now, chapter IV has the recommendation for the best procedure to develop an acceptable device for blood pressure monitoring in the medical field.

CHAPTER IV

RECOMMENDED DEVICE

IV-1 Introduction

Chapter III describes three different devices to be developed for blood pressure monitoring. All these devices are based on tonometry principle for measuring the blood pressure. Note that each of these devices requires more development to reach the stage of practical and clinical use.

It is clear from chapter III that design three is more promising than design two, which in turn is more promising than design one. Some of the advantages of design three over the other two designs are : First, design three could be made very small in size, in such a way that it fits on the ear lobe, finger, fingernail, or on the nose. Second, design three has very light weight, which is very helpful for designing a portable device. Third, this device is easy to install, it takes just few seconds for installation and the calibration can be performed during the recording of the blood pressure. Fourth, this device is not complicated and, therefore, any malfunctioning can be detected easily. Fifth, this device can be designed to be very comfortable in such a way that it can be worn by the patient for a long time.

Sixth, this device has no allergic effect on any patient, so that it can be used in all cases. Seventh, design three can be used on more than three places on the human body and this will give the device a broader application. If it is not possible to use the device on the finger for some medical reasons, then it could be used on the ear lobe or on the nose. Finally, this device is not expensive, so it would have a very broad practical use and it can be replaced in case of damage.

Notice that the other two devices (i.e. designs one and two) and direct recording of the pulse sound mentioned in previous chapters, are all promising too. However, the development of those devices will be for other researchers.

Finally, a calibration method for design three has been worked out.

IV-2 Principle for Design Three

Design three is somewhat related to tonometry method. The method of tonometry has attracted probably the most investigators. It is based on the principle that, when a curved surface of a pressure vessel is flattened by a rigid plane, the force on the plane is equal to the pressure multiplied by the area of the contact. It has been used successfully in the measurement of intraocular pressure.

Many investigators have attempted to apply the tonometry principle in monitoring blood pressure. Unfortunately, the work thus far has been unsuccessful in using this method directly on the artery. Previous chapters state some possible reasons for this failure. Therefore, it would be better to use the tonometry method away from the artery, that is, the design should be used on the arterioles and capillary vessels.

Furthermore, recommendations point towards the use of a device which picks up one directional movement. That movement should be perpendicular to the flesh surface. In this manner the effect of flesh movement on the blood pressure reading will be minimized.

In conclusion, design three is based on the principle of tonometry. However, that device should be used on arterioles and capillaries vessels of the human body. Moreover, design three has been designed to pick up one directional movements.

IV-3 Problems and Solutions

As mentioned before, the tonometry method is based on a sound principle. However, many attempts to use this method to monitor blood pressure have failed. One problem encountered in applying this method to blood pressure measurements, was the problem of finding the artery. Design three offers a easy solution for this problem, namely, it is not necessary to locate the artery when using this device, since design three should be used away from artery. Furthermore, it is very easy to use the device on arterioles and capillaries.

The second problem with the application of tonometry method, is to keep the device rider on the artery (remember that the artery usually tries to escape from pressurized positions to a less pressurized ones). Also, the use of this device away from the artery will offer a good solution for this problem because arterioles and capillaries have very few muscles in their walls compared to arteries and this fact will minimize their movement when pressurized. In addition, the size of the arteriole or capillary is much less than that of the artery, then the movement of the former (i.e. arteriole or capillary) is much smaller than the artery when pressurized. Moreover, the force due to pulse in arterioles and capillaries is much smaller than the force in the arteries. Adding to this the fact that the force per unit area exerted by the device on arterioles or capillaries is much less than the one exerted on the arteries, then it may be concluded that the movement of arterioles and capillaries to escape high outside pressure is much smaller than the one for arteries. Furthermore, while the readings of blood pressure depend on the vicinity of the device rider to the artery (any flesh movement will shift the rider and affect the readings of blood pressure)

, this problem is absent when the device is used away from the artery.

The third problem with tonometry method is the instability of the base line of the device reading (the base line of the readings oscillates in sine wave form). This problem has been corrected by designing the device to have one-directional movement.

The final problem consists of calibrating the device. This is an inherent step in the blood pressure measurement procedure and must be performed in each case the transducer is used. The known cuff method will be used for the purpose of getting an initial reading for the calibration, and thus the accuracy of this transducer cannot be better than that of the cuff method. The accuracy of the cuff method has been studied by a number of investigators and there is a general agreement that it is no better than 10 to 20 % [48, 51], but it has been used for many years by a great number of practicing physicians and there is a feeling of confidence among the professions. Furthermore, physicians [44]pointed out that the absolute values are not as important as the changes in blood pressure. It is felt, therefore, that the use of the cuff method in the calibration procedure is justified and will be accepted by the medical profession.

When the transducer is used on the ear lobe, or on the nose, the cuff measurement will have no effect on the reading, hence the calibration procedure can be quite simple. The transducer is attached to the ear lobe (or on the nose) and the standard auscultatory pressure reading is taken. The amplitude of the signal is then adjusted so the top of the curve shows the systolic and the bottom the diastolic value of the blood pressure. It is recommended that the transducer be checked periodically thereafter to assure its continued proper operation.

Note here that it is possible to make use of any future improvement in the accuracy in the cuff method because any variation in the blood pressure is faithfully picked up by design three device with high accuracy and scientists [51] prove that tonometry method has a good accuracy level; therefore any improvement to the calibration, which is determined by the cuff method in this case, will introduce a better accuracy to design three.

For the transducer positioned on the finger or on the fingernail, the procedure must be modified since the applications of pressure in the cuff will stop the blood flow to the finger and the signal will disappear. This was studied during tests in which a sound meter measured Korotkoff sounds and the output was displayed on the recorder alongside the blood pressure curve. The results are shown in FIG.12. This showed that the first appearance of the blood pressure peaks corresponds accurately to the initiation of Korotkoff sounds, while their disappearances corresponds to the end of the signal growth. Thus, the

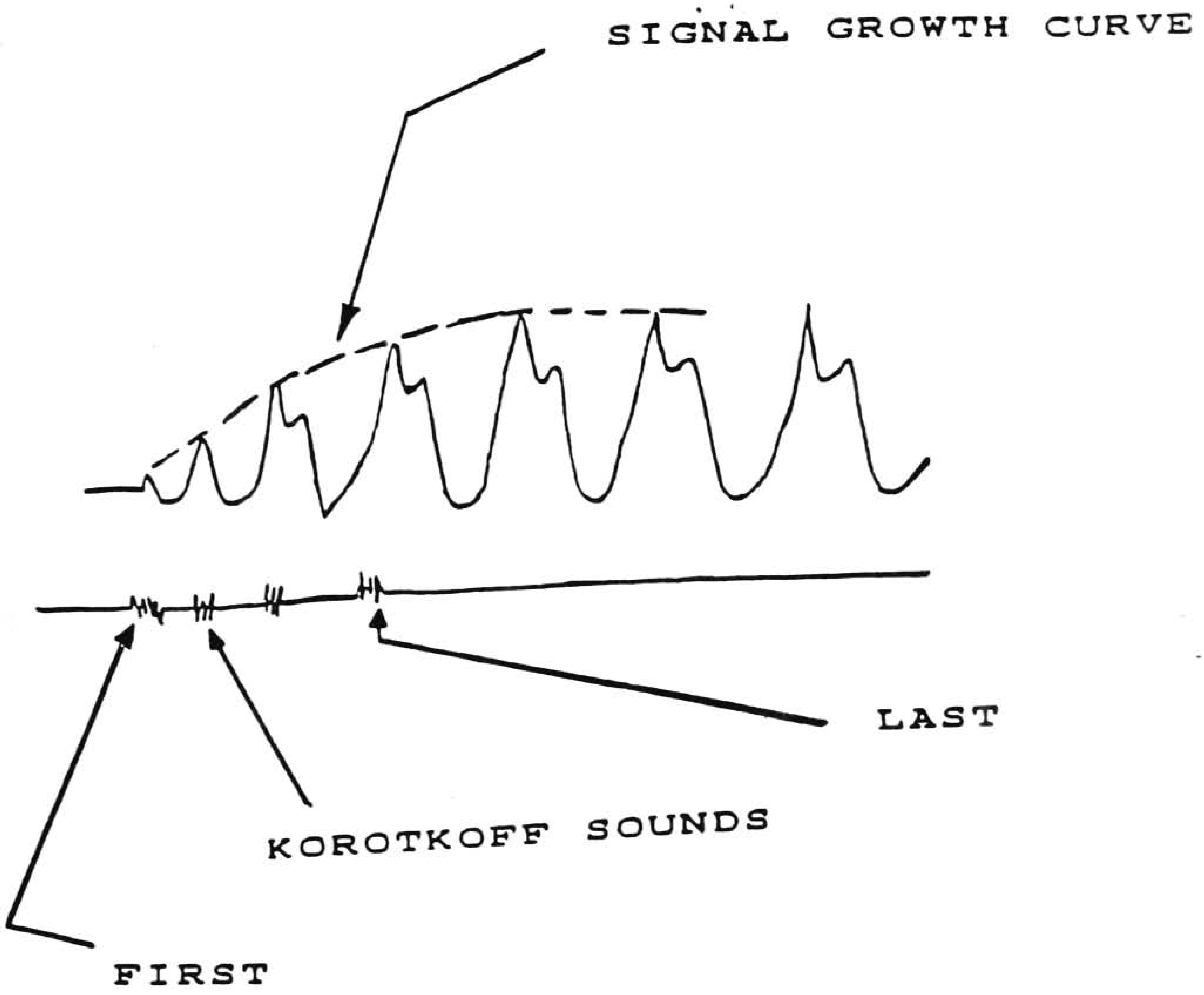


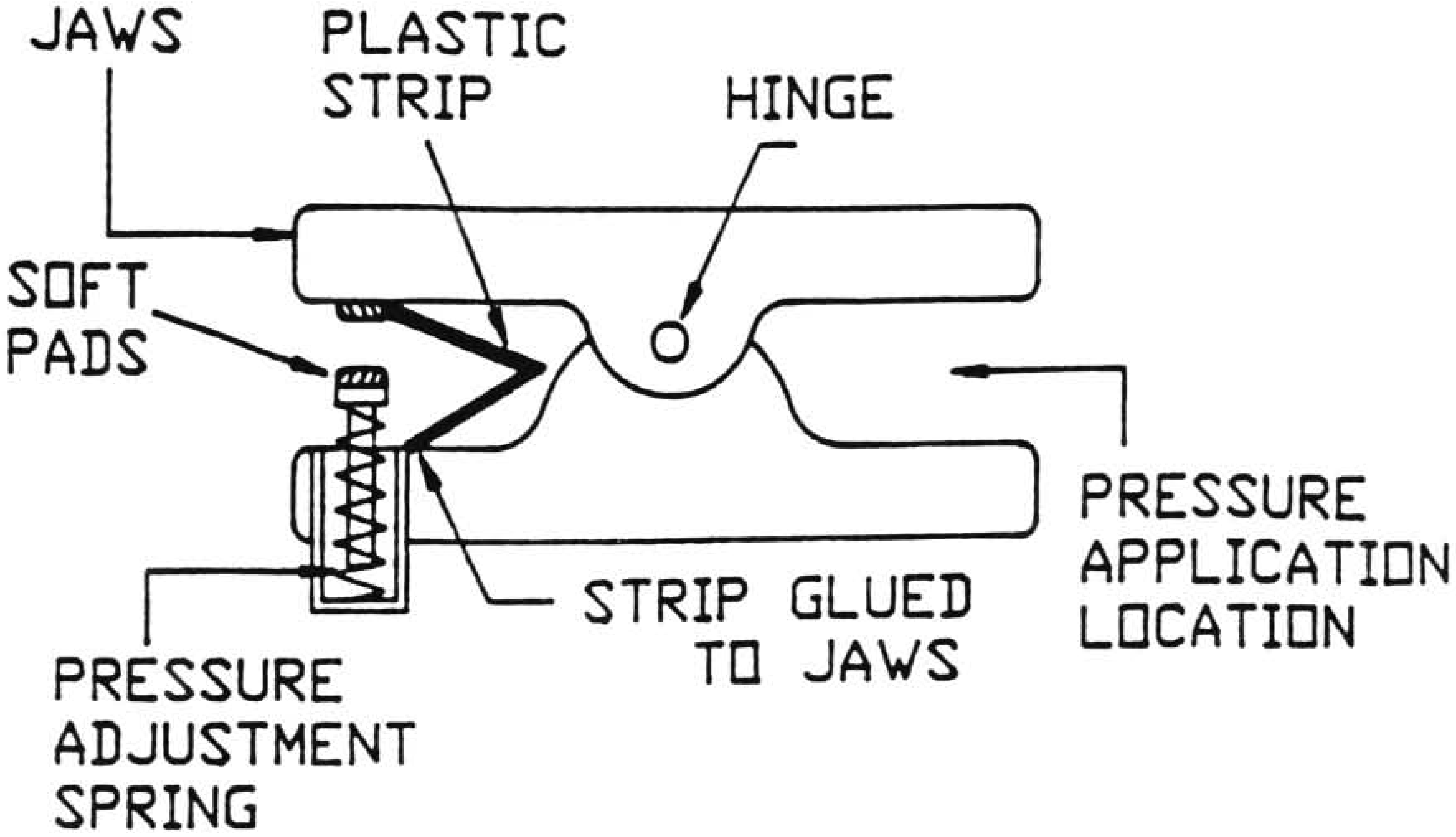
FIG. 12: EFFECT OF EXTERNAL PRESSURE ON BLOOD PRESSURE SIGNAL

systolic and diastolic pressure can again be determined and the amplitude of signal set.

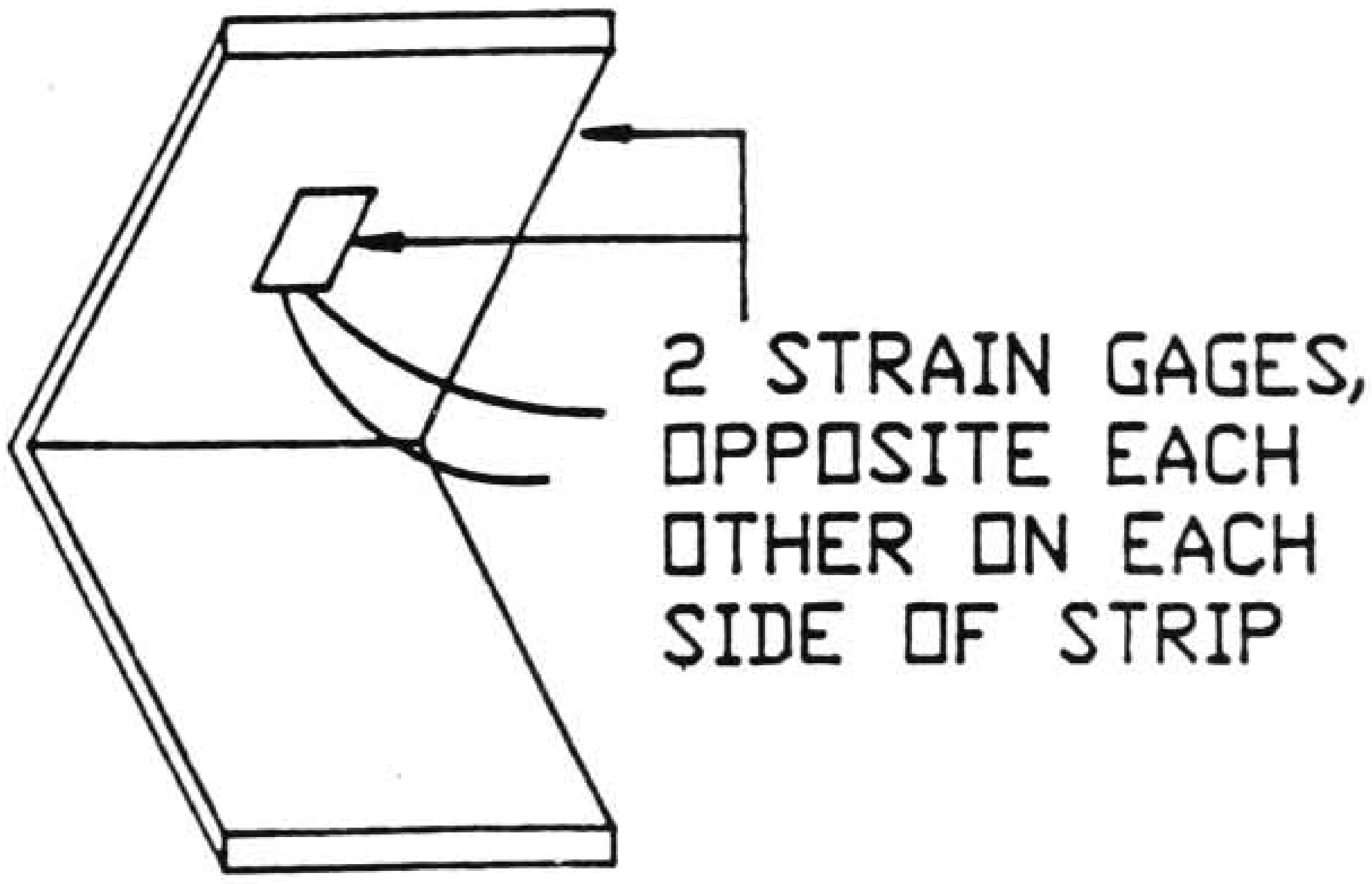
Also, for the transducer positioned on the finger, or fingernail, the procedure where the patient elevates the hand (on which the transducer is positioned) a known distance with respect to the heart, permits the calculation of the difference in pressure due to change in elevation and relates it to the difference in the signal amplitude change. This method seems highly promising because it gives a very accurate calibration. However, applying this method on design one device failed to give satisfactory results. Hence, more investigation of this method could point out the reasons for its failure.

IV-4 Some Versions of Design Three for the Transducer

One design of blood pressure measuring device is shown in FIG.13.a. Basically it consists of jaws, connected by a hinge pin which permits the motion in one direction only. The jaws should be rigid, but preferably made of light weight material such as plastic. The jaws are equipped with soft pads on one side of the hinge, where the device is clamped onto the body. The pads are made of some flexible material such as foamed plastic and their purpose is to minimize the discomfort of attachment. One of the pads is attached directly to the jaw, while the other is positioned



A. ASSEMBLY



B. THIN PLASTIC STRIP

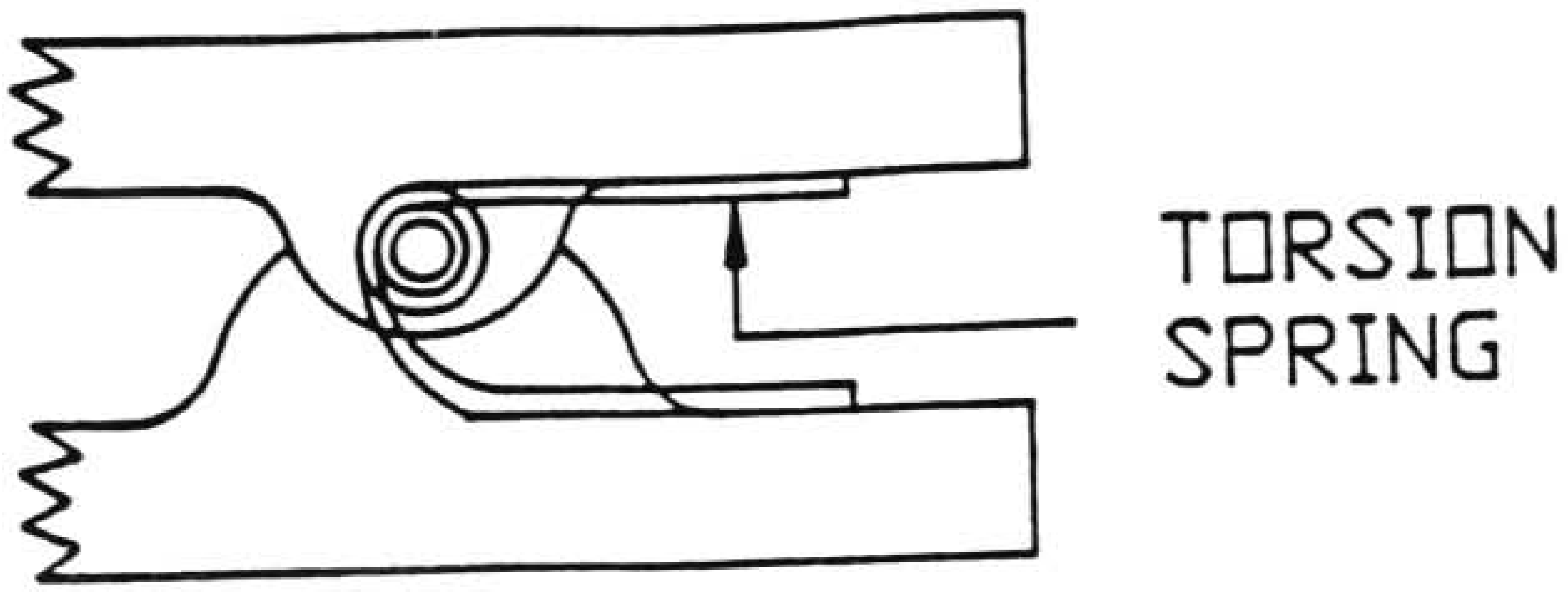
FIG. 13: BLOOD PRESSURE PICK UP

on a spring (built on the second jaw) which has the role to adjust the attachment pressure in case of change in volume of the body part to which the device is attached. Alternatively, the spring could be replaced by flexible bellows to which a controlled air pressure is applied. The same side of the jaws contains also a thin plastic strip; its details are shown in FIG.13.b. Two strain gages, one on each side, are glued to the strip. As the jaws move under the pulses of blood pressure, the strip

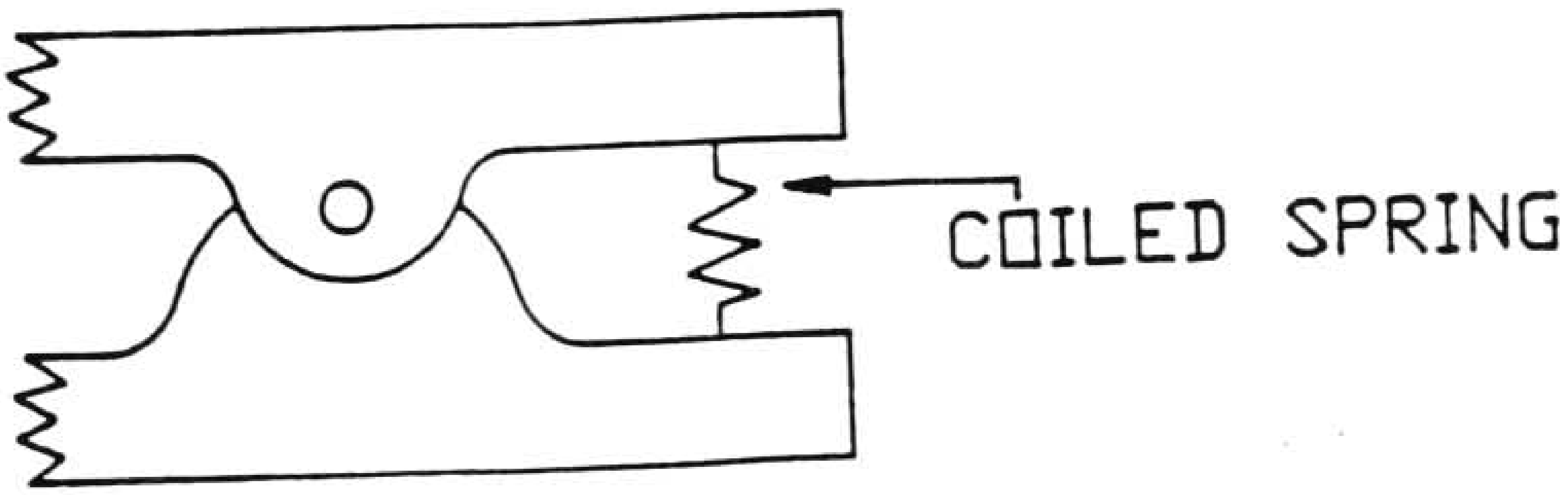
bends causing the changes in the electrical resistance of the strain gages which then can be used to produce a continuous record of blood pressure curve. The other side of the jaws contains means for applying the clamping pressure which is shown in detail in FIG.14. These may consist of a simple torsion spring shown in Fig.14.a, or a coiled spring shown in Fig.14.b. These have the advantage of simplicity and portability. The flexible bellows shown in FIG.12.c has the advantage of precise adjustment, but it would require a source of air supply.

The device can be applied to many parts of the human body, some of which are shown in FIG.15. For ear lobe, shown in FIG.15.a and nose bridge, shown in FIG.15.b the shape of the jaws should be flat, but for the use on the finger tip the jaws should be semicircular, as shown in FIG.15.c.

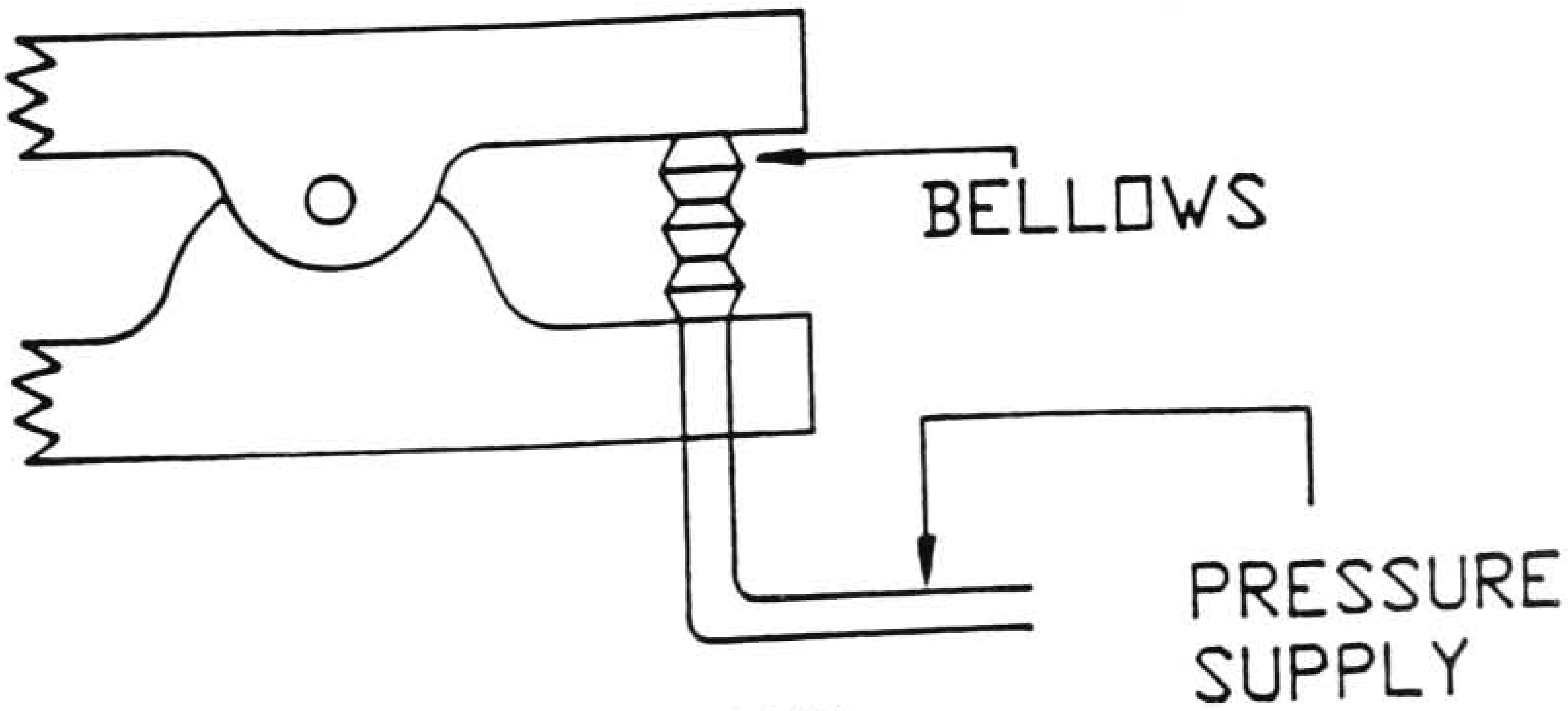
The device has been tested extensively in the laboratory and has given some good results, but required



A. TORSION SPRING AT HINGE

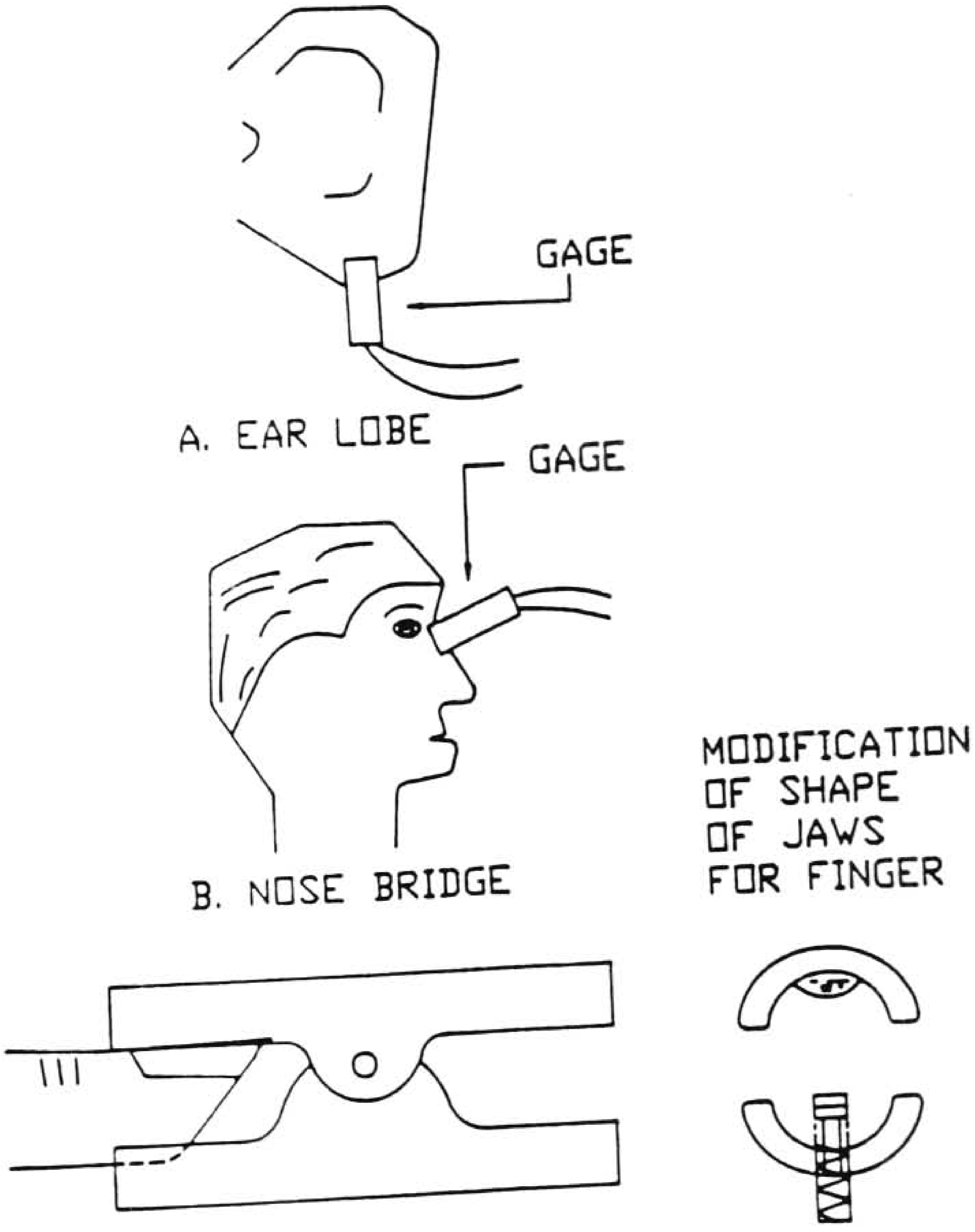


B. COILED SPRING



C. PNEUMATIC MEANS

FIG. 14: ALTERNATE MEANS OF PRESSURE APPLICATION



A. EAR LOBE

B. NOSE BRIDGE

C. FINGER TIP

FIG. 15: ALTERNATE LOCATIONS OF GAGE ON HUMAN BODY

stability has not been achieved. This is thought to be due to temperature variations and deterioration of adhesive with use as described in more details in chapter VI. Further study of adhesives or other methods of attaching the strain gages as well as insulating the strain gages to remove effects of convection currents should solve these problems.

It has been discovered recently in the laboratory that with the help of semi-conductor strain gages, the new device can be applied to the fingernail for blood pressure monitoring. This procedure is very promising because the fingernail is stable and the device when glued to the nail should give a very stable reading, namely, the base line is a straight line rather than sinusoidal.

It is recommended to use polyimide film to glue the semi-conductor strain gages on it for a better stability. The semi-conductor strain gage is very small, so that it is very tedious to build the circuit for the transducer without special equipment. Realizing this fact, firms specializing in such work have been engaged to produce printed circuit on polyimide film and to attach the semiconductor strain gages to the strips (FIG.16).

The best and easiest procedure is to glue the above mentioned strip (with the strain gages on it) to the nail directly using suitable type of glue. However, this procedure makes the reuse of the same transducer more than

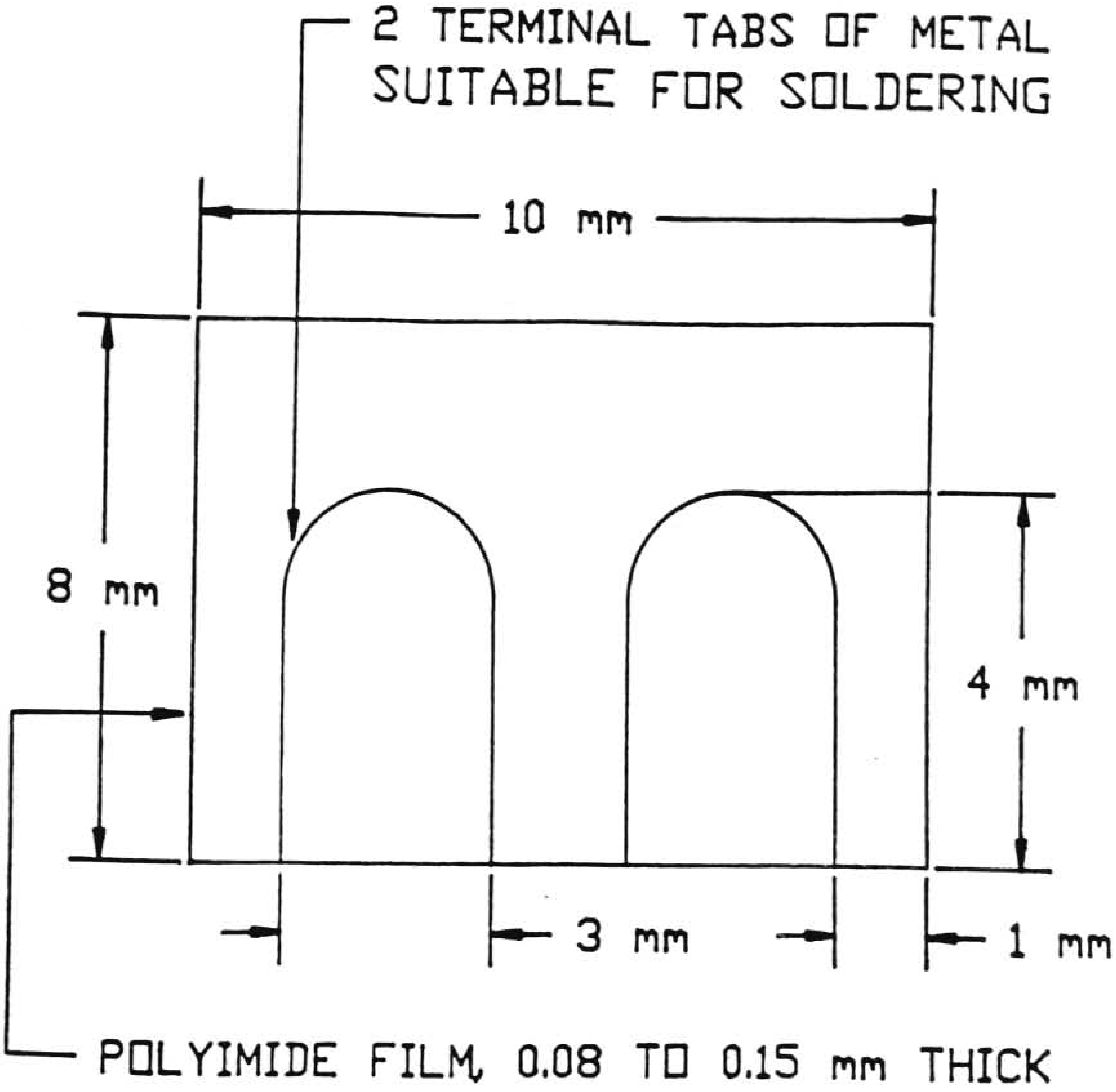


FIG. 16: FLEXIBLE CIRCUIT BOARD FOR SEMICONDUCTOR STRAIN GAGES

once very difficult, because the transducer would likely be destroyed when taken off the nail. This fact will make the device more expensive.

Alternatively, the device shown in FIG.17 makes the reuse of the above device on the nail more practical. This design consists of a plastic bell shape with a spring to press the strain gage to the nail. The plastic bell can be attached to the nail using vacuum through a special orifice on the side of the bell. The bell can be of small, medium and large sizes, to fit all sizes of the nail. Note here that the bell should not be of exact size of the nail.

After the semiconductor strain gages on polyimide film were obtained, they were tested on the finger nail, but, contrary to expectation, the signal was found to be very sensitive to body motions and further development of this method was abandoned for the present. This method, however, still looks promising and futher studies are recommended.

The electrical circuit shown in FIG.11 can be used to provide proper readout, whether the transducer is used on the finger, fingernail, ear lobe, or the nose. This electrical circuit explains how the changes in the resistance of the strain gages could be converted to a voltage signal which is used in the recorder to produce a blood pressure curve. The sensing strain gages constitute one half of a wheatstone bridge. The bridge is shown only schematically in FIG.11, because there are a number of

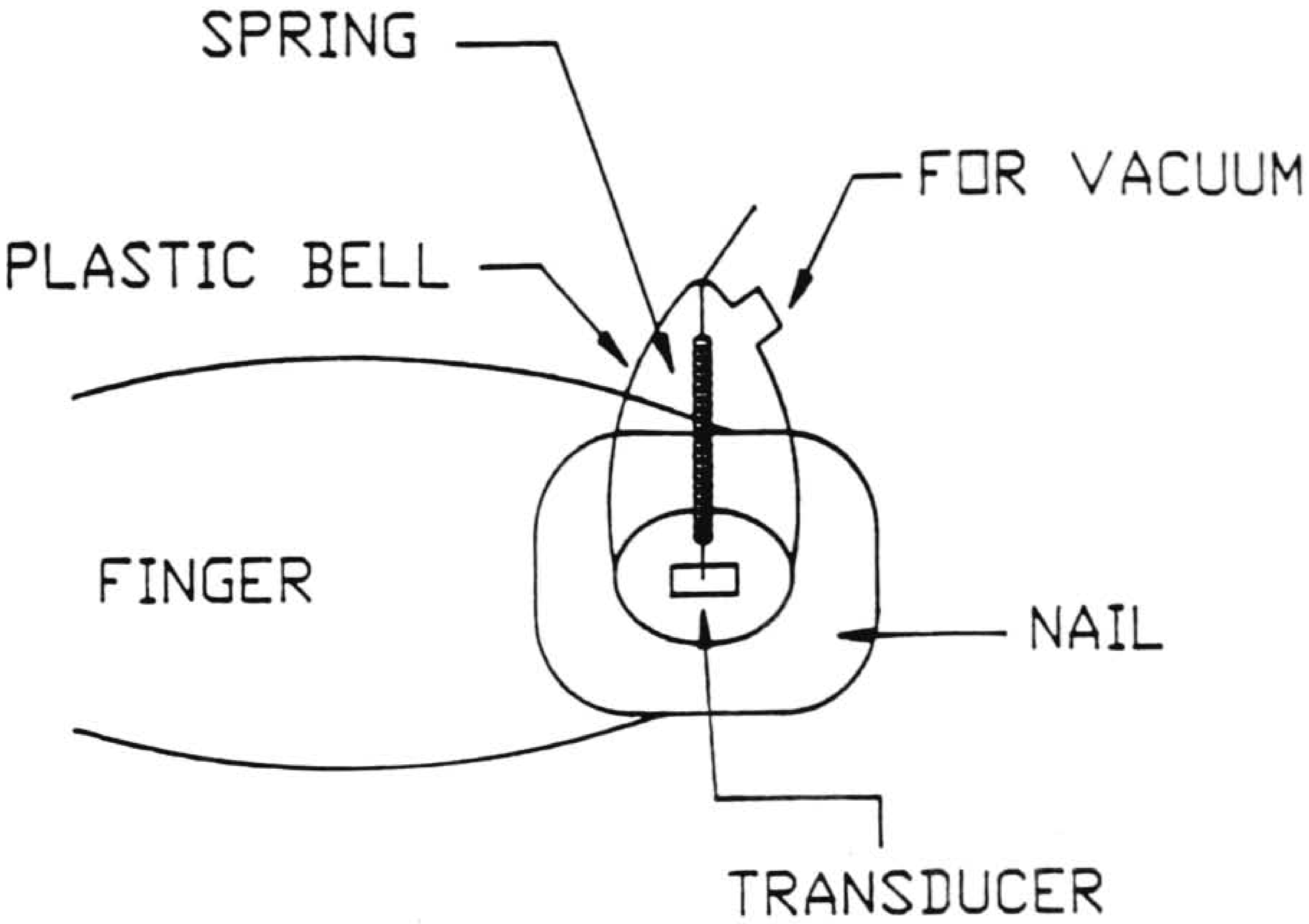


FIG. 17: TRANSDUCER ON THE FINGER NAIL

adjustments not shown in the figure. The bridge is powered by about 4 V dc although ac power supply could also be used. The output of the bridge is in the millivolt range and may be amplified if desired. A low pass filter with a cutoff frequency of about 20 hertz should be used before the recorder, since the human body appears to be a source of various higher frequency potentials and those tend to obscure the blood pressure curve. The output from the filter may be connected to a recorder to obtain a continuous blood pressure curve, or to digital readout which would show the values of systolic and diastolic blood pressure. It may also be used to trigger an alarm once certain pressure values of blood pressure are reached.

CHAPTER V

ANALYSIS OF RELATIONSHIP BETWEEN BLOOD PRESSURE IN ARTERIES, ARTERIOLES, AND CAPILLARIES

V-1 Introduction

This chapter discusses the linear relation between the blood pressure variations in the arterioles, capillaries and the in the main arteries. Note the design used for this study is design four discussed in previous chapters.

V-2 Linearlity of Blood Pressure Variations in Blood Vessels

Two different approaches were conducted to validate the linearlity assumption for blood pressure variations in different blood vessels.

V-2-1 Mathematical Analysis

Let w be the axial velocity, u be the radial velocity, μ the dynamic viscosity, ν the kinematic viscosity and ρ the density of blood.

Assume further that the motions in the radial direction are small, so that $u \approx 0$ and w is not a function of z. (See FIG.18 for coordinate system for blood vessel).

The equation of motion can then be written as follows:

$$\rho\left[\frac{\partial w}{\partial t}+u\frac{\partial w}{\partial r}+w\frac{\partial w}{\partial z}\right]=-\frac{\partial P}{\partial z}+\mu\left[\frac{\partial^2 W}{\partial r^2}+\frac{1}{r}\frac{\partial w}{\partial z}+\frac{\partial^2 w}{\partial z^2}\right]\ldots\ldots eq.6$$

Using the above assumptions eq.6 may be simplified to:

$$\frac{\partial w}{\partial t}=-\frac{1}{\rho}\frac{\partial P}{\partial z}+\nu\left[\frac{\partial^2 w}{\partial r^2}+\frac{1}{r}\frac{\partial w}{\partial r}\right]\ldots\ldots eq.7$$

or

$$-\frac{1}{\rho}\frac{\partial P}{\partial z}=\frac{\partial w}{\partial t}-\nu\left[\frac{\partial^2 w}{\partial r^2}+\frac{1}{r}\frac{\partial w}{\partial r}\right]\ldots\ldots eq.8$$

now, let

$y = r/R$ and $\alpha = R\sqrt{(n/\nu)}$ eq.9

where n is pulse frequency in radians/second.

Eq.8 is then rewritten :

$$\frac{1}{\rho}\frac{\partial P}{\partial z}=\frac{\partial w}{\partial t}-\frac{\nu}{R^2}\left[\frac{\partial^2 w}{\partial y^2}+\frac{1}{y}\frac{\partial w}{\partial y}\right]\ldots\ldots eq.10$$

Womersley [56] solved eq.8 and found that :

$$w=\frac{A_1}{\rho c}\left[1+\eta\frac{J_0(\alpha i^{3/2}\,y)}{J_0(\alpha i^{3/2})}\right]\sum_{k=0}^{\infty}C_n\exp(\,i\,k\,n\,(t-\frac{z}{c}))\ldots\ldots eq.11$$

Various symbols are defined in his paper, but of particular interest here is the wave speed C which he showed to be a function of α. This will be discussed more fully later.

It is possible to obtain the needed derivatives of w, namely :

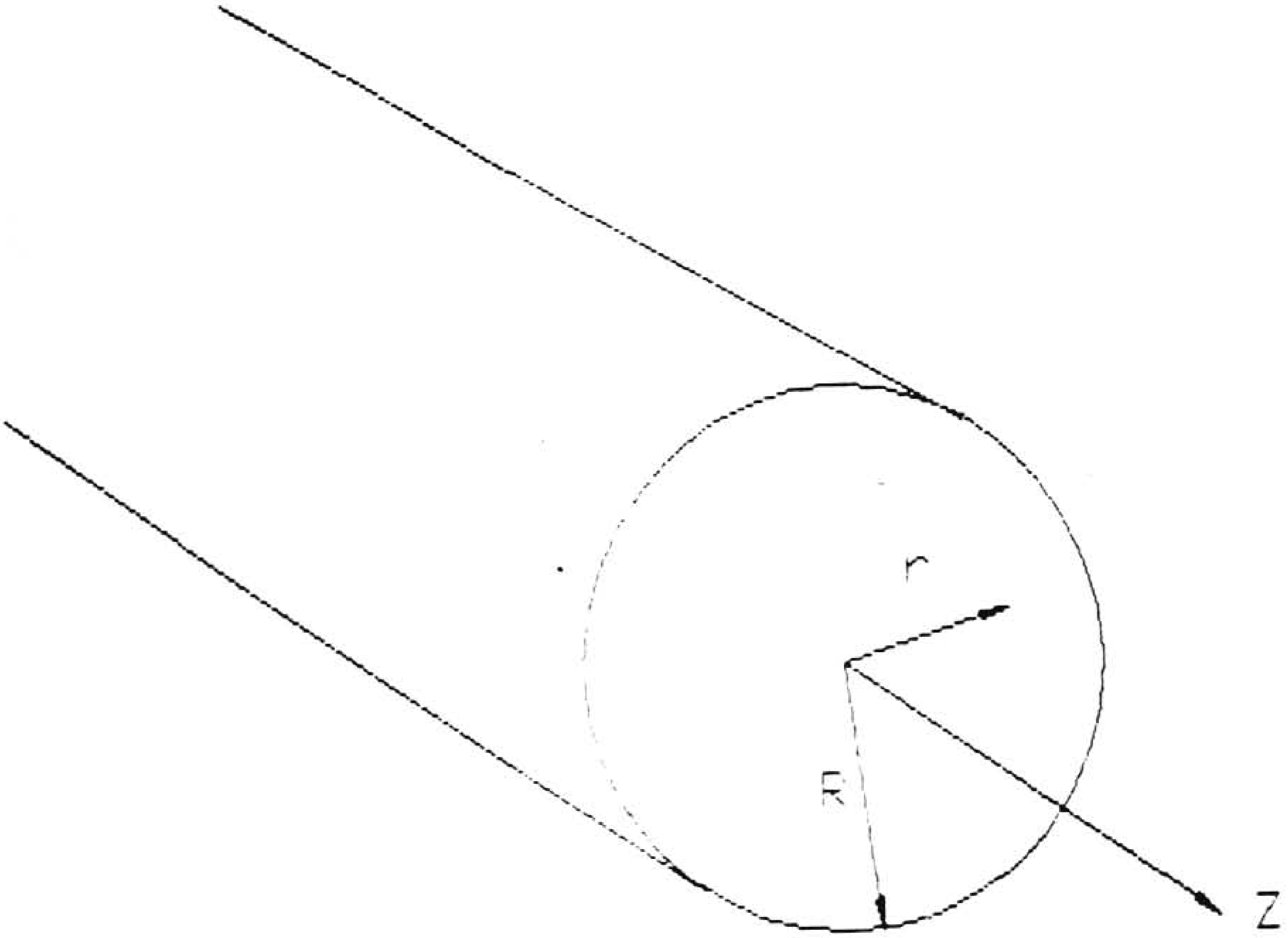


FIG.18 Coordinates System For Blood Vessel

$$\frac{\partial w}{\partial t}=\frac{A_1}{\rho C}[1+\eta\frac{J_0(\alpha i^{3/2}\ y)}{J_0(\alpha i^{3/2})}]\sum_{k=0}^{\infty}C_n\ i\ k\ n\ \exp[i\ k\ n(t-\frac{z}{C})]\ldots eq.12$$

$$\frac{\partial w}{\partial y}=\frac{A_1}{\rho C}[\frac{\eta}{J_0(\alpha i^{3/2})}\frac{d}{dy}(J_0(\alpha i^{3/2}y)]\sum_{k=0}^{\infty}C_n\exp[ikn(t-\frac{z}{C})]\ldots.eq.13$$

$$\frac{\partial^2 w}{\partial y^2}=\frac{A_1}{\rho C}[\frac{\eta}{J_0(\alpha i^{3/2})}d\frac{{}^2}{dy^2}(J_0(\alpha i^{3/2}y)]\sum_{k=0}^{\infty}C_n\exp[ikn(t-\frac{z}{C})]..eq.14$$

Substituting these in eq.10 gives :

$$\frac{1}{\rho}\frac{\partial P}{\partial z}=\frac{A_1}{\rho C}[(1+\eta\frac{J_0(\alpha i^{3/2}y)}{J_0(\alpha i^{3/2})})\sum_{k=0}^{\infty}C_n ikn\exp(ikn(t-\frac{z}{C}))-\frac{\eta}{R^2 J_0(\alpha i^{3/2})}$$

$$\times(\frac{d^2}{dy^2}(J_0(\alpha i^{3/2}y))+\frac{1}{y}\frac{d}{dy}(J_0(\alpha i^{3/2}y))\sum_{k=0}^{\infty}C_n\exp(ikn(t-\frac{z}{C}))].eq.15$$

Note that the pressure is evaluated at the wall so y= 1. Also, all quantities except for those under summation sign are either constant or functions of α only. Then, the pressure gradient can be expressed in the following short form :

$$\frac{1}{\rho}\frac{\partial P}{\partial z}=P_1\sum_{k=0}^{\infty}C_n ikn\ \exp(ikn(t-\frac{z}{C}))-P_2\sum_{k=0}^{\infty}C_n\exp(ikn(t-\frac{z}{C}))..eq.16$$

Womersley shows that an actual velocity curve can be represented well by the first five terms of the series, and

$$\frac{1}{\rho}\frac{\partial p}{\partial z}=P_1(\alpha)(nC_1 i\exp(in(t-\frac{z}{C})+2nC_2 i\exp(2in(t-\frac{z}{C})+$$

$$+3nC_3\exp(3\epsilon(t-\frac{z}{C})+4nC_4 i\exp(4\epsilon(t-\frac{z}{C})))-P_2(\alpha)[C_0+$$

$$+C_4\exp(4in(t-\frac{z}{C}))] \dots\dots\dots\dots\dots\dots\dots\dots eq.17$$

Rewriting gives :

$$\frac{1}{\rho}\frac{\partial P}{\partial z}=C_0+(P_1nC_1i-P_2C_1)\exp(\epsilon(t-\frac{z}{C}))+(2P_1nC_2i-P_2C_2)\times$$

$$\exp(2\epsilon(t-\frac{z}{C}))+(3P_1(\alpha)nC_3i-P_2C_3)\exp(3in(t-\frac{z}{C}))+$$

$$+(4P_1(\alpha)nC_4i-P_2(\alpha)C_4)\exp(4\epsilon(t-\frac{z}{C})) \dots\dots\dots\dots\dots eq.18$$

Any exponential term may be expressed by its expansion as follows :

$\exp[in(t-z/C)] = \exp(int)(1 + inz/C - n^2z^2/(2C^2) + \dots)$...eq.19

Substituting this in eq.18, gives :

$$\frac{1}{\rho}\frac{\partial P}{\partial z}=C_0+C_1[P_1(\alpha)ni-P_2(\alpha)]\exp(int)(1+\frac{inz}{C}-\frac{n^2z^2}{2C^2}+\dots)+$$

$$+C_2[2P-1(\alpha)ni-2P_2(\alpha)]\exp(2int)(1+\frac{2inz}{C}-\frac{4n^2z^2}{2C^2}+\dots)$$

$$+3C_3[P_1(\alpha)ni-P_2(\alpha)]\exp(3int)(1+\frac{3inz}{C}-\frac{9n^2z^2}{2C^2}+\dots)+$$

$$+4C_4[P_1(\alpha)ni-P_2(\alpha)]\exp(4int)(1+\frac{4inz}{C}-\frac{16n^2z^2}{4C^2}+\dots)\dots eq.20$$

Integrating, gives :

$$\frac{1}{\rho}P=A+C_0z+[P_1(\alpha)ni-P_2(\alpha)][C_1\exp(int)(z+\frac{inz^2}{2C}-\frac{n^2z^3}{6C^2}+\dots)+$$

$$+2C_2\exp(2int)\left(z+\frac{2inz^2}{2C}-\frac{4n^2z^3}{6C^2}+\ldots\right)+$$

$$+3C_3\exp(3int)\left(z+\frac{3inz^2}{2C}-\frac{9n^2z^3}{6C^2}+\ldots\right)+$$

$$+4C_4\exp(4\epsilon t)\left(z+\frac{4inz^2}{2C}-\frac{16n^2z^3}{6C}+\ldots\right)]\,\ldots\ldots\ldots eq.21$$

It will be observed then from the above equation that the pressure is not a linear function of z. Furthermore, since C is a function of α and α in turn is the function of the frequency, then the pressure signal is expected to be distorted along the blood vessel.

To examine the amount of distortion the wave speed C needs to be determined. Womersley provides the following procedure for this purpose:

$$C = \frac{C_0}{X} \quad \ldots\ldots\ldots\ldots eq.22$$

Where C_o is the velocity for perfect fluid found by him to be approximately 1000 cm/sec. X is the real part of

$$\sqrt{\,}[(1-\sigma^2)\,x/2] \quad \ldots\ldots\ldots\ldots eq.23$$

and x can be found from:

$$(1-\sigma^2)\,x = G \pm \sqrt{\,}[G^2-(1-\sigma^2)H] \quad \ldots\ldots\ldots\ldots eq.24$$

$$G = (1.25-\sigma)\,/\,(1-F_{10}) + (k\,/\,2+\sigma-0.25) \quad \ldots eq.25$$

$$H = (1+2k)\,/\,(1-F_{10}) - 1 \quad \ldots\ldots\ldots\ldots\ldots\ldots\ldots eq.26$$

where : σ is the Poisson's ratio for blood vessels (varies between 0 and 0.5); k is the ratio of wall thickness to radius, (taken as 0.1) and,

$F_{10} = [2 J_1 (\alpha i^{3/2})] / [\alpha i^{3/2} J_0 (\alpha i^{3/2})]$..eq.27

Assuming, for a human artery with a diameter of 3 mm, $\alpha = 3.34$. For this value of α, C = 914 cm/sec.

Turning now to eq.21, evaluate the second term in the series and compare it with the first one :

$z + (i n z^2) / (2 C^2) = [1 + (i n z)/(2 C)] z$

Now, for a rough calculations, take z =10 cm and n for a one beat /sec is approximately 6.28. The above term is:

$1 + 6.28(10)/ [2(914)] = 1 + 0.0344 i$

the modulus of the above vector is $[(1)^2 + (0.0344)^2]^{0.5}$ =1.0006. The theoretical answer should be 1.0 in order to ignore the non-linear term in eq.21. Therefore, the error is 0.06 %. Consequently, it is possible to assume linearity in this case.

For the arterioles and capillaries the diameters are much smaller producing a much smaller wave celerity, but their lengths are also much smaller. To check the linearity in this case the following work was done :

1. A computer program was written in " Turbo Pascal" language to generate a table for α versus C for different values of k and σ. Note here that it was found that

$C = 525.49\ \alpha$, for α between 0 and 0.040 .(See appendix A).

2. α was calculated for arterioles and capillaries, based on average values for their diameters, wall thickness and

Poisson's ratio for vessel walls.

3. Then, the percent errors in magnitude and angle distortion angle for pulse signals were calculated.

The following results were found : all non-linear terms in eq.21 can be neglected (error is less than 0.5 %), then eq.21 becomes :

$$P/\rho = A + z\ [P_1(\alpha)\ n\ i - P_2(\alpha)]\{\ C_0 + C_1\ \exp(int) +$$

$$+ 2\ C_2\ \exp(2int) + 3C_3\ \exp(3int) + 4\ C_4\ \exp(4int)] \ldots \text{eq.28}$$

and, while there is a decrease in the amplitude, it is linear and the wave shape is not distorted.

Furthermore, the entrance conditions on pulse wave shape showed no significant effect on the linearlity, for the following reasons :

If the device discussed in this work is placed away from the artery, it will be positioned over terminal arteries, arterioles and capillaries. It has been shown previously that, for vessel of constant diameter there is a linear variation of pressure and the wave shape will be distorted only slightly.

It is also necessary to investigate the effect of the flow from vessel of one diameter to another. It should be noted that, upon entering a vessel there will be certain distortion of velocity profile over a length known as the entrance length and, since this distortion may be different for various Fourier components of pressure wave, it may lead to distortion of the pressure wave.

The entrance length in laminar flow has been calculated for steady flow in the following manner [36]:

The entrance length L_e is obtained from Bernoulli equation written along the vessel axis:

$P_1 - P_e = (\rho u_o^2 /2)-\rho V^2/2$

or

$P_1 - P_e = [(u_o^2/V)^2 -1]\rho V^2/2$

where P_1 is the entrance pressure, P_e is the pressure at the end of entrance length, u_o is the velocity on the centerline and V is the average velocity.

Note also that the customary way to express the pressure drop in the entrance length is :

$$\frac{P_1-P_e}{\rho V^2/2}=\frac{fL_e}{D}+k_L$$

Combining the above two equations

$$\frac{L_e}{D}=\frac{1}{f}[(\frac{u_0}{V})^2-1-k_L]$$

The values of k_L for steady flow has been determined [36] to be about 1.30 while $f=64/R_e$ in laminar flow where R_e is the Reynolds number. For steady laminar flow the value of $u_o/V=2$ and the equation becomes :

$L_e/D = 0.0265\ R_e$

In pulsating flow u/V is a variable, but its maximum value should not exceed 2, so the maximum value of L_e/D will remain as above.

It is now possible to calculate the entrance length for the terminal arteries, arterioles and capillaries and the values are shown below :

Vessel	Diameter mm	R_e	L_e mm
Terminal artery	0.6	9	0.143
Arteriole	0.02	0.03	1.59×10^{-5}
Capillary	0.008	0.003	6.36×10^{-7}

The calculation of $\alpha = R\ (n/\nu)^{0.5}$, wave speed C and time to traverse the entrance length gives :

Vessel	α	C cm/s	time sec
Terminal artery	0.334	174	8.22×10^{-4}
Arteriole	1.11×10^{-2}	5.78	2.75×10^{-6}
Capillary	4.45×10^{-3}	2.31	2.75×10^{-7}

Note that the above wave speeds are for the basic Fourier component. Higher frequency components will travel at higher speeds, but the delay time between the components is not likely to exceed 1.0×10^{-3} sec. Since the pulse beat has a frequency of about 1 per second the distortion should not exceed 0.36° which would be negligible.

V-2-2 Finger Simulation

In a finger simulation model the following set up was used:

A hand-operated air pump, which could produce different type of pressure variations, was connected to a tee. Two rubber tubes were connected to the free ends of the tee, one tube at each free end of the tee. Each of the rubber tubes were of two feet length, 0.351 inches of outside diameter and 0.080 inches of wall thickness. One of the above mentioned rubber tubes was connected at one end to the tee and at the other end to a pressure transducer. Meanwhile, the second rubber tube, which was connected at one end to the tee, had the other end packed with glass wool for 1.5 inches of its free end. The glass wool packed end of the rubber tube would simulate the arterioles/ capillaries vessel in human finger. Then the design four device, which was described in chapter IV, was clamped to the end of that rubber tube at a distance of 0.5 inch from the free end of that tube. Note that since design four was clamped over the area packed with glass wool, then that device would sense the pressure in the packed area simulating the arterioles/ capillaries of the human finger, (FIG.19).

The output signals of the pressure transducer were fed to one channel of a two-channel recorder, while the output signals from design four device were fed to the second channel of that recorder.

Various types of pressure variations were produced by the air pump of that set up. The results showed a linear relation between the pressure signals produced by the design

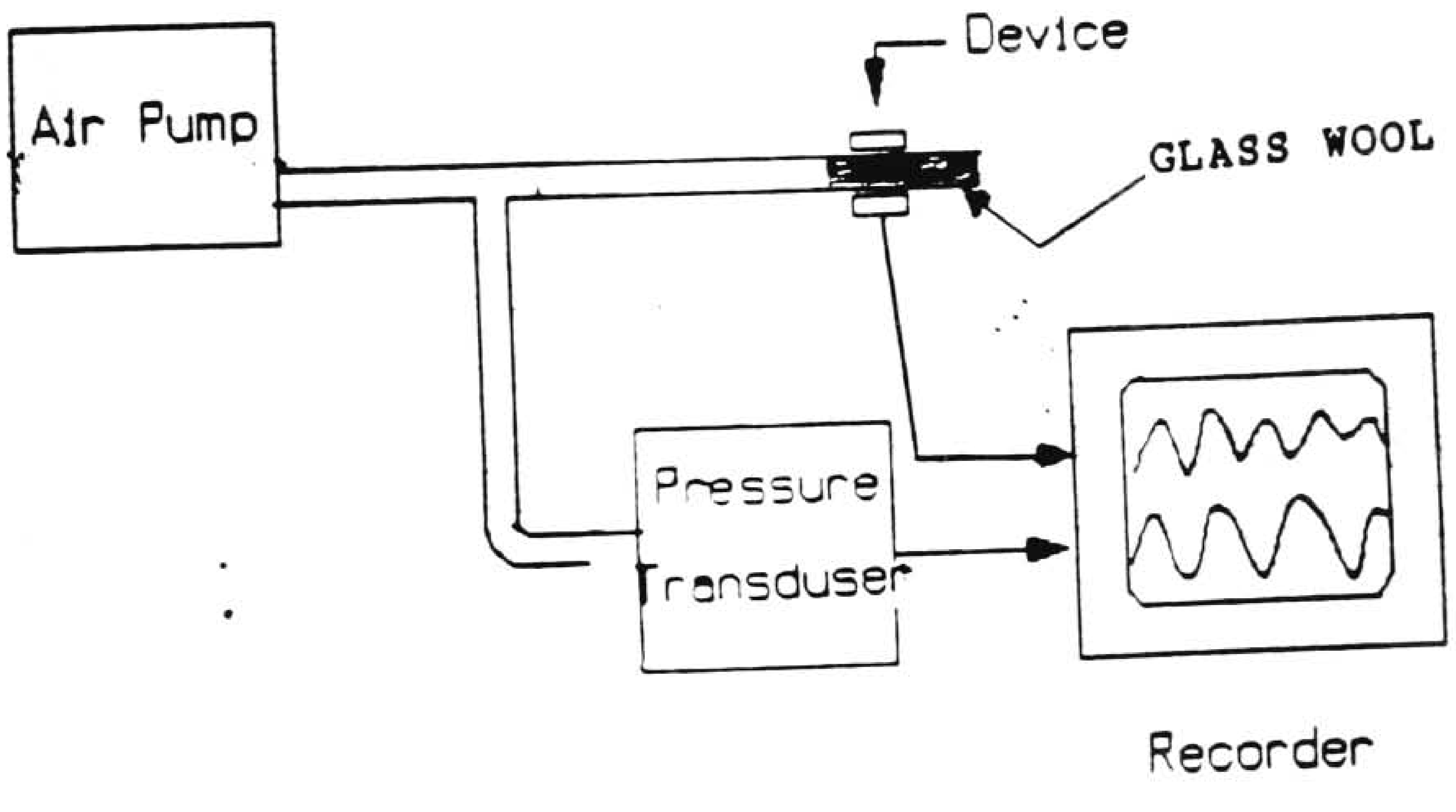


FIG.19 :Air Pump Set Up

four device and the ones recorded by the pressure transducer. Since design four device was recording the pressure variations in simulated arterioles/ capillaries while the pressure transducer was sensing the pressure variations in the simulated large vessels, this verified the linear relation between the pressure signals in large vessels and arterioles/capillaries.(FIG.20).

It is easy to notice the time delay between the pressure variations in the arterioles/capillaries and the large arteries in FIG.21.

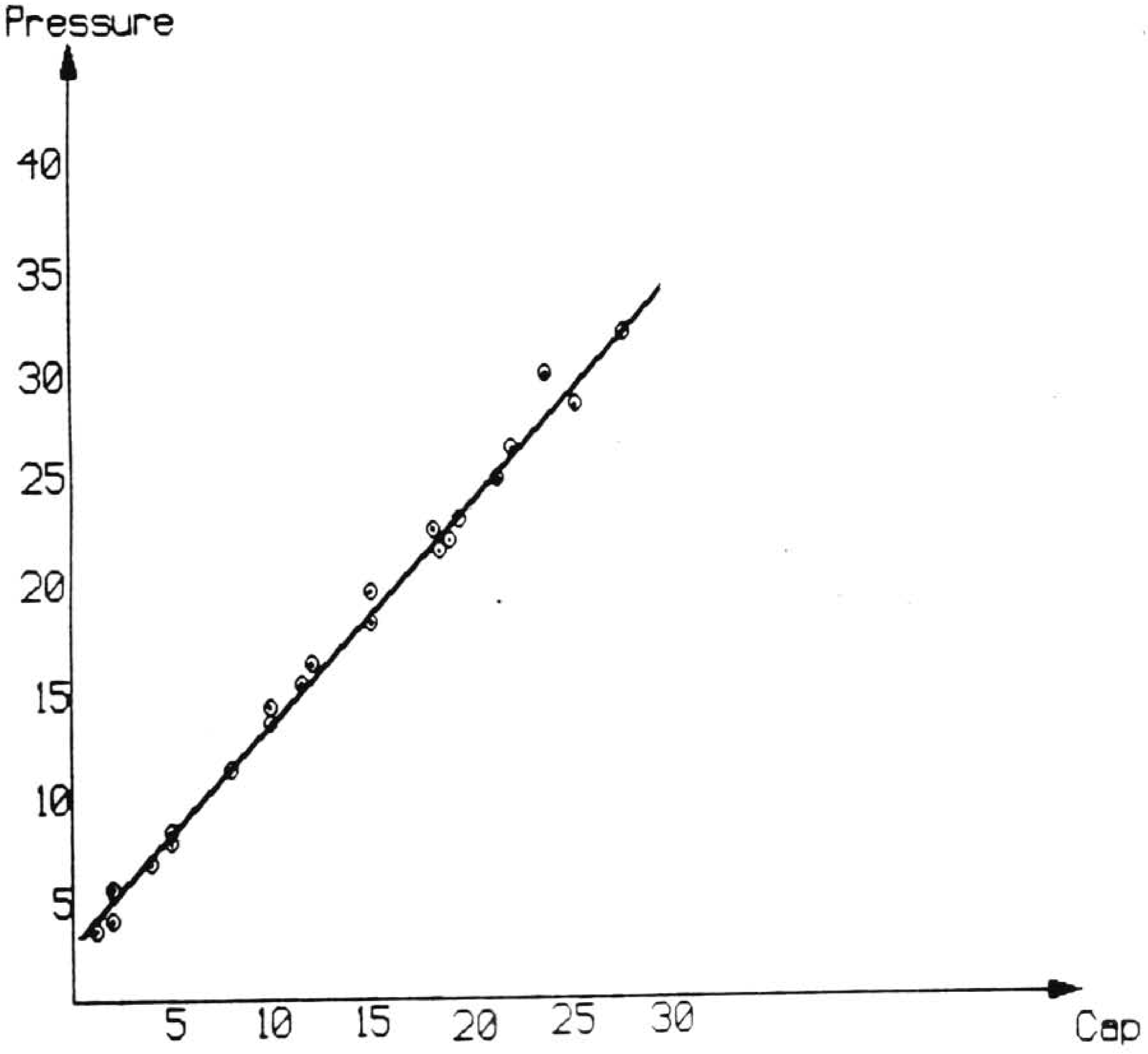
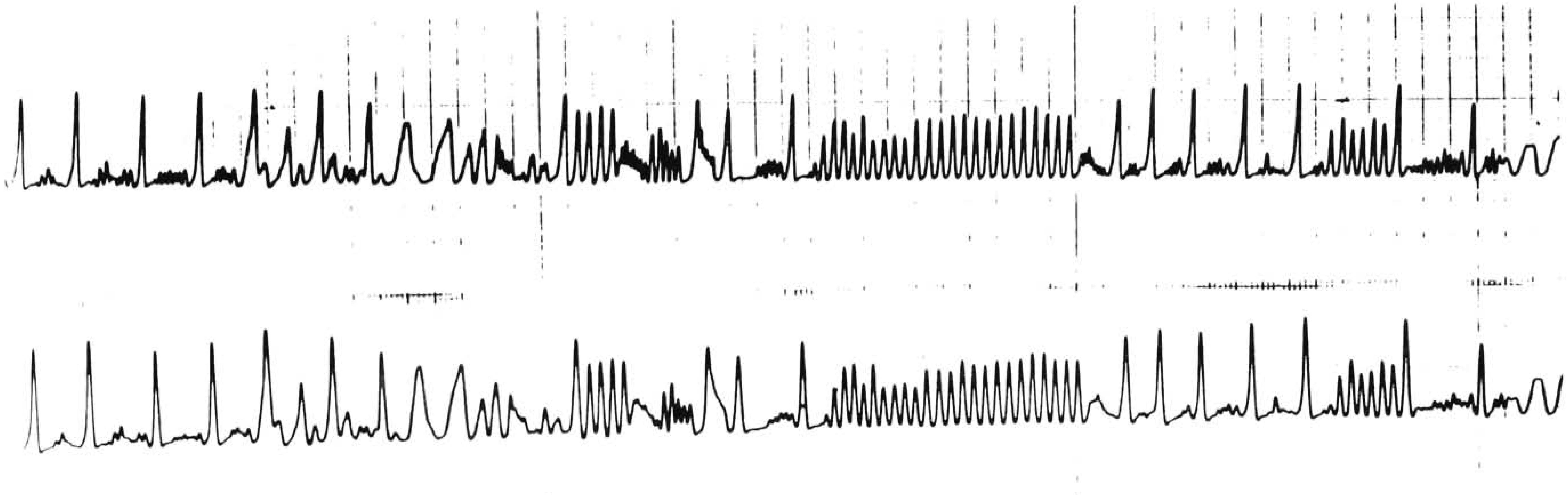


FIG.20 Straight Line Relation Between Pressure in Different Blood Vessels. (Simulated)



A. THE UPPER SIGNAL FROM THE DEVICE

B. THE LOWER SIGNAL FROM THE PRESSURE TRANSDUCER

FIG.21 Signals From Air Pump

CHAPTER VI

TESTS AND RESULTS

VI-1 Introduction

This chapter contains the results of two types of tests on the blood pressure device described in this work :

1. The laboratory tests on various individuals
2. The hospital tests on four patients

The prototype design which resulted from the experience gained in above tests and its testing are also discussed.

VI-2 The Laboratory Tests

On June 2nd, 3rd and 4th 1991, the device was tested on the thumbs of twenty different individuals. Subjects were selected at random with different age, sex, race, weight and height. The summary of results of these tests are shown in table 1 while detailed records are shown in appendix B. The individuals to be tested were seated and the blood pressure taken by standard cuff method. The transducer was then placed on the thumb and taped. The record of the blood pressure was then produced and samples are shown in appendix B.

In these tests the device responded well to the variation in blood pressure whenever the tested person was told to produce valsalva manoeuver or take deep breath.

Moreover, the device detected the blood pressure variation due to heart skipping beats (it showed a bigger and longer beats) in the case of one subject during the test. (FIG.22).

It was also noted that the dicrotic notch was practically non-existent for older subjects. This was explained by Dr. Sabbah as being due to lack of blood vessels elasticity in such cases.

VI-3 The Hospital Tests

On June 24th and July 2nd, 1991, the device was tested on four patients at Henry Ford Hospital. These patients were undergoing the procedure of heart cauterization during which the caterer is inserted into the blood stream to investigate possible blockages in the arteries. This was an ideal situation to test our device, since the caterer produces direct readings which could be recorded. Unfortunately, it was not practical to record both traces on the same recorder, but we synchronized the two recorders. It was found that the patients' blood pressure remained relatively constant during the addition of various medications, but valsalva maneuver proved to be very advantageous for our

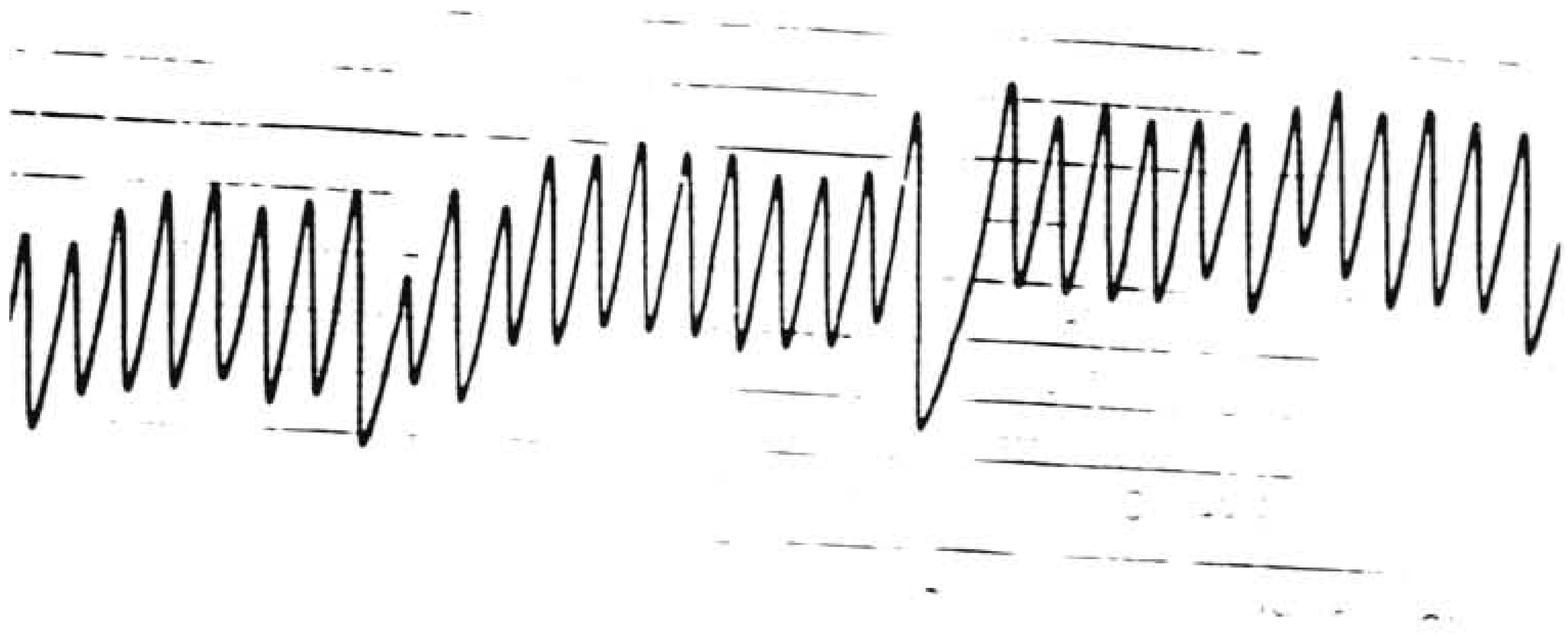


FIG.22 :HEART SKIPPING BEAT

Table 1: Laboratory tests results

Subject No	Age (yr)	Weight (lb)	Height (ft,inch)	Systolic/Diastolic pressure (mmHg)
1	63	168	5' 10"	150 / 88
2	22	160	6' 0"	172 / 110
3	29	148	5' 10"	120 / 78
4	40	130	5' 9"	118 / 76
5	56	170	5' 5"	168 / 88
6	27	147	5' 7"	168 / 78
7	22	130	5' 7"	110 / 72
8	40	160	5' 7"	140 / 88
9	22	120	5' 7"	104 / 64
10	25	165	5' 9"	110 / 60
11	21	120	5' 7"	104 / 68
12	27	175	6' 0"	140 / 95
13	30	220	5' 7"	118 / 80
14	28	190	5' 6"	128 / 80
15	59	135	5' 1"	112 / 80
16	40	147	5' 4"	108 / 72
17	26	140	5' 10"	108 / 66
18	29	100	5' 2"	108 / 78
19	59	238	6' 0"	150 / 108
20	31	120	5' 7"	140 / 80

comparison, since during this procedure the blood pressure increases and drops significantly.

Comparing the output of our device (device #4) with the output of the direct method, it was found that there is a direct linear relationship between the amplitude (difference between systolic and diastolic pressure) of the two outputs. (FIG.23).

Appendix B shows portions of the record of our device and the corresponding one from direct blood pressure measurement.

During the hospital tests two problems were uncovered, namely, long term instability of our signal and abnormally high shift during valsava manoeuver, both of which required further work. It is of interest to note that the devices were tested prior to the hospital tests and were found to be quite stable for extended periods of time.

VI-4 Problems and Solutions

Four factors were found to be behind the problem of deterioration of the device response with time and usage. This deterioration caused the instability and the exaggerated response of this device during the hospital tests. These factors are :

1. Temperature variation
2. The hinge instability

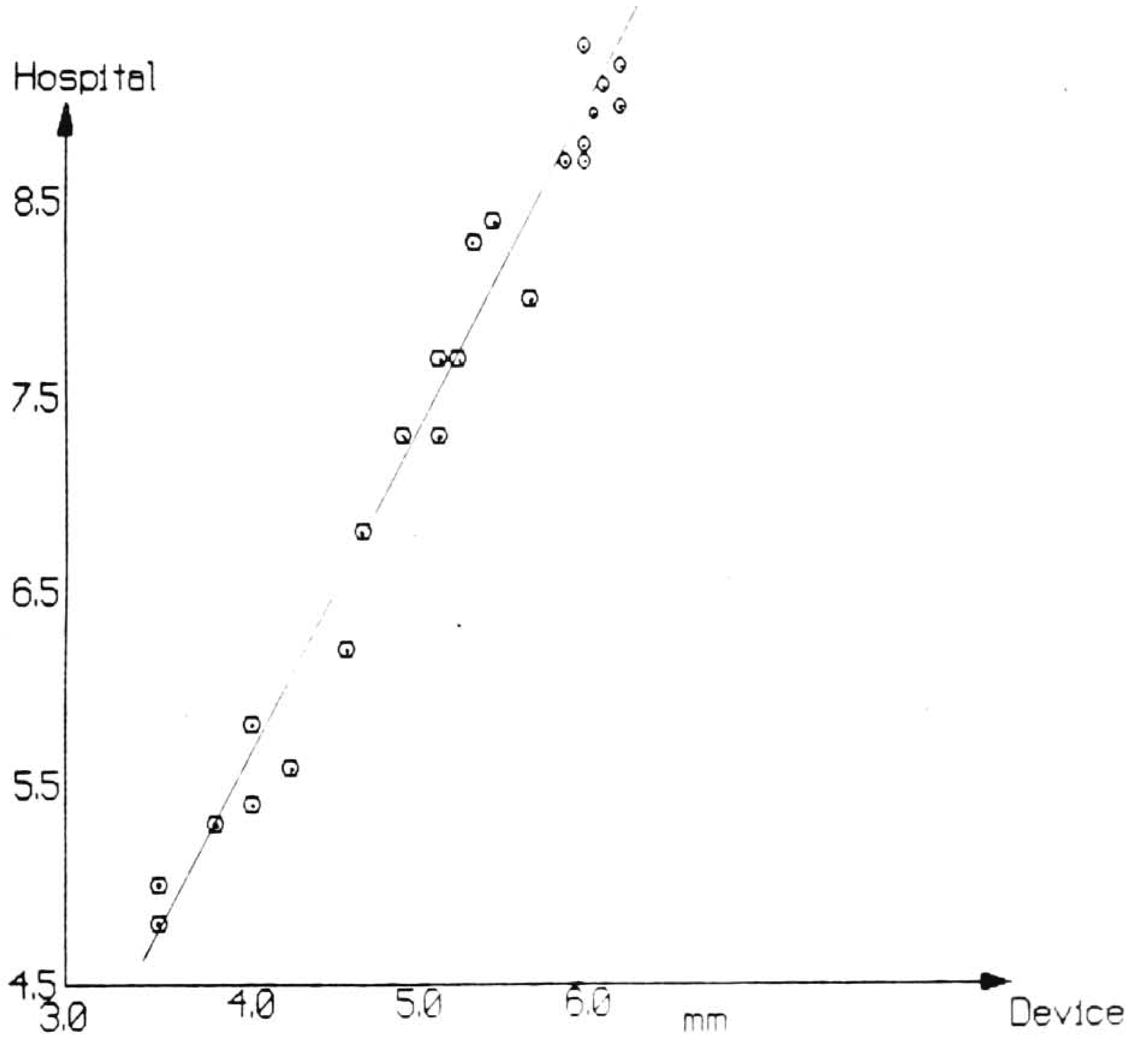


FIG.23 : LINEAR RELATIONSHIP BETWEEN HOSPITAL READINGS AND DEVICE READINGS FOR CASE #1 6-24-91

3. Glue deterioration under heat and stress alternation
4. Humidity factor

VI-4-1 Temperature Variation

While we were aware of the sensitivity of strain gages to temperature changes, we sought to compensate for this effect by using two strain gages in the opposite arms of the wheatstone bridge. In this case, however, there seems to be sufficient temperature changes between the two strain gages to produce the instability of readings in the presence of even mild convection current, such as must have been present during the hospital testing. This was well proven during subsequent laboratory experiments in which light blowing impinging on the strain gage or briging a warm body into its proximity caused drastic shifts in the output.

It was thought at first that placing the strain gages on metal would produce a better temperature distribution, but from the tests it was found that metals carry the new temperature more rapidly to the strain gages. Consequently, it was decided to place the strain gages on hard plastic, such as acrylic and to insulate them thermally from the surroundings.

VI-4-2 The Hinge

The configuration of the device which was used for hospital tests is somewhat different from that originally envisioned and tried in initial tests. It is shown in FIG.24. The device consists of a strip of brass 1/2 inch wide, 1/16 inch thick and bent into the shape shown in the figure. The device is secured on the finger by means of a velcro strip and a spring is used to control the compression of the finger. Configurations with and without a hinge were tried in the laboratory and the main difference was found to be the response to a valsalva manoeuver. The difference between the responses is shown in FIG.25. From this figure it may be seen that the presence of the hinge produces a rather large shift of the base and this was presumed to be the more correct form and the hinged devices were used in the hospital testing.

The comparison with the direct blood pressure readings indicated that the hingeless version of the device produces a more correct trace of the valsalva manoeuver and thus the hinge will be eliminated from the final design, as described in the following chapter.

VI-4-3 Glue Deterioration

The indication from the tests on a great number of

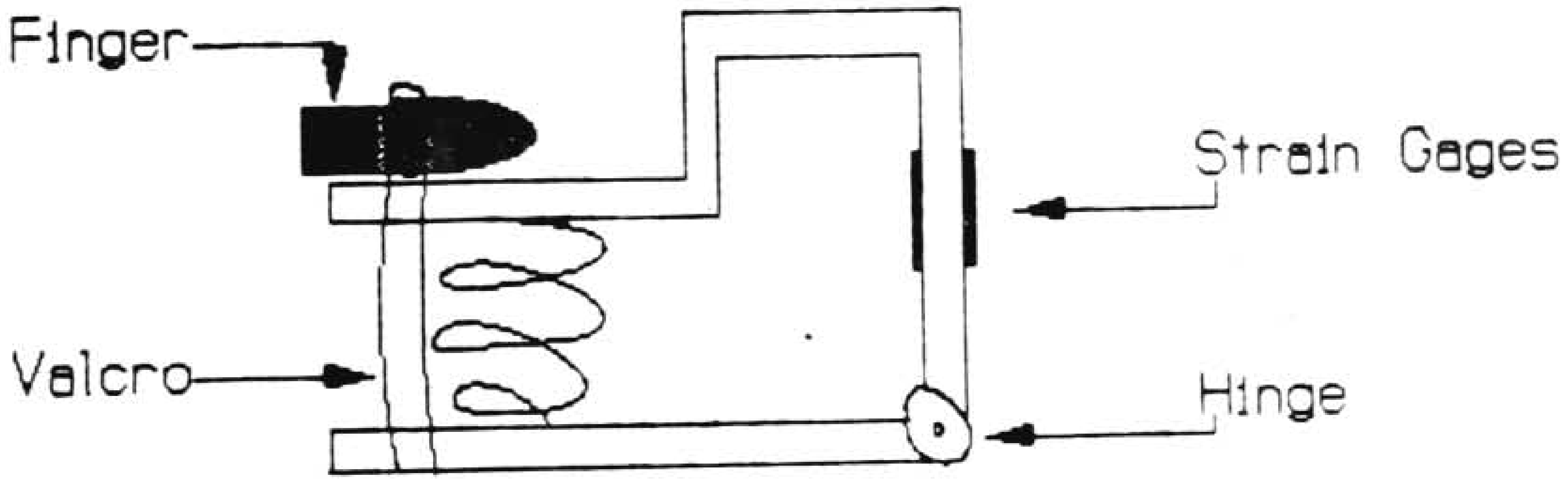
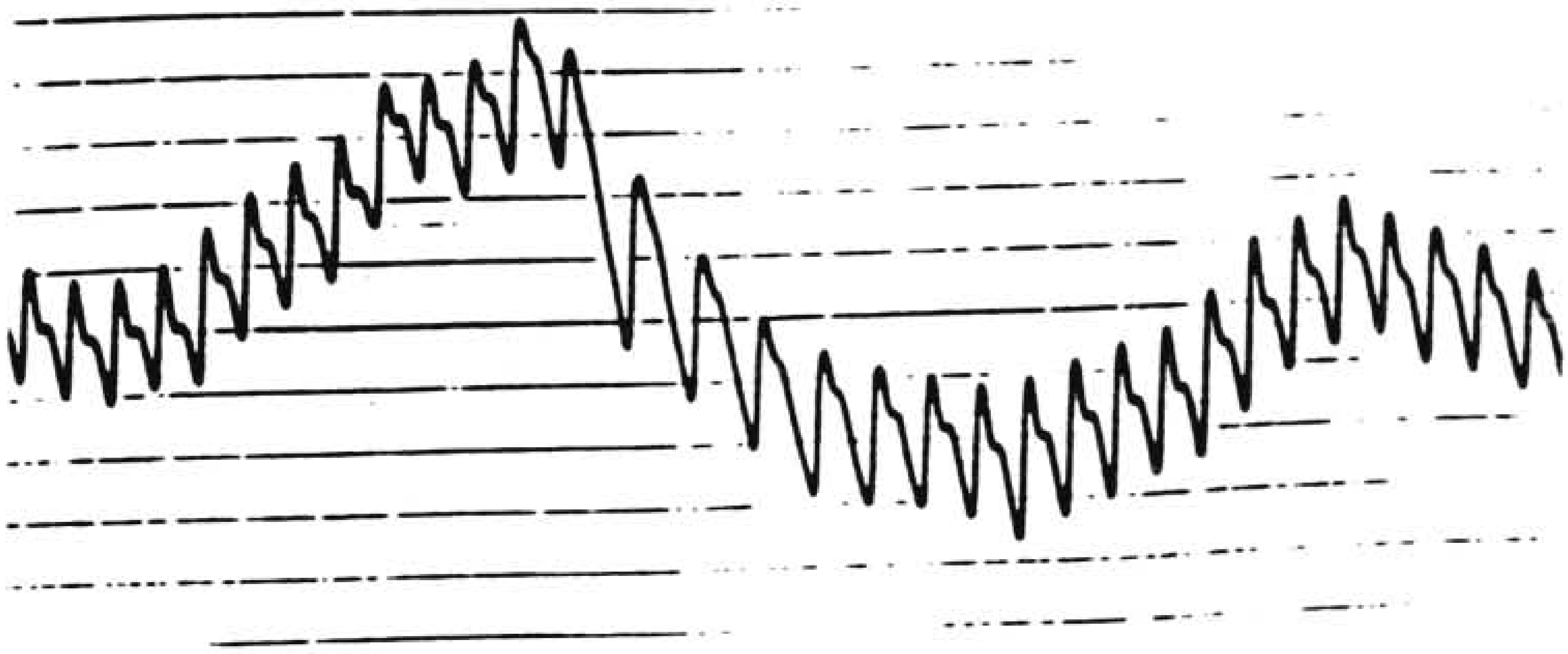
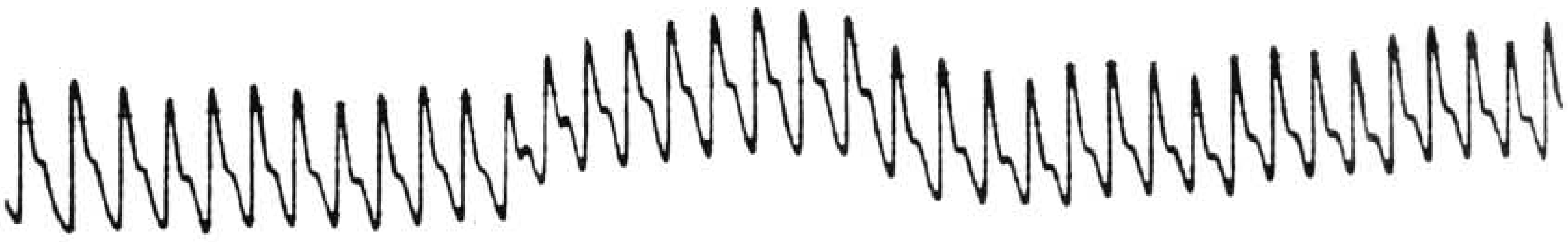


FIG.24 Design Device Used in The Hospital (metal)



A. VALSALVA MANEUVER FROM A DEVICE WITH A HINGE



B. VALSALVA MANEUVER FROM A DEVICE WITHOUT A HINGE

FIG.25 :SIGNALS FROM DEVICES WITH / WITHOUT A HINGE

devices are that the performance deteriotates with time. The deterioration is exhibited by erratic behavior of the instrument and the suspicion is strong that the adhesive used does not perform as expected. It appears that the bonding characteristics of the adhesive deteriorate after a few days' exposure to oscillations, probably enhanced by the elevated temperature of the gages.

Initially, standard adhesive for the strain gages was used and , when this was found unsatisfactory, epoxy adhesive was tried, but this worked no better. Finally, contact cement was tried. It has the advantage of remaining flexible and, while this no doubt reduces the signal amplitude, it has been performing properly for two weeks.

This problem no doubt requires further study. One possible solution is to embed the strain gages in plastic.

VI-4-4 Humidity

Moisture coming in contact with the strain gages will produce some limited shorting of the wires and will interfere with the proper operation of the device. This problem can be easily overcome by the use of waterproof coatings.

VI-5 Prototype of the Final Design

Based on the experience with previous analyses and tests the prototype of the final design was built and tested. It may be seen in FIG.26. It consists of a split ring one inch in diameter and 1/8 inches thick made of acrylic plastic. Two strain gages are attached on opposite sides of the ring by the use of contact cement. The gages are insulated by silicone rubber and plastic foam. At the split of the ring the plastic is bent outward permitting the insertion of the finger between the resulting tabs. The ring itself acts as a spring, so that additional coil springs are not required.

Several tests have been performed on this prototype and the results are shown in FIGs.27, 28, 29 and 30.

In the first test the device was attached to a rubber tube in parallel with a pressure transducer. The other end of the tube was attached to a hand pump which allowed production of oscillations of various shapes, amplitudes and frequencies. The output of both the pressure transducer and of the design device were displayed on two channels of an oscilloscope. Fig.27 shows relatively uniform oscillations, while fig.28 shows a variety of irregular shapes. Fig.29 contains a relatively longer record of oscillations. As may be seen from this figure, a faithful reproduction of the shape of the curves and a good stability have been demonstrated.

In the second test the hand pump has been attached to an oscillating platform, so that uniform oscillations could be produced for a long period of time. The output of the device was displayed on a recorder. Fig.30 shows the record of the readings for 15 minutes indicating good stability.

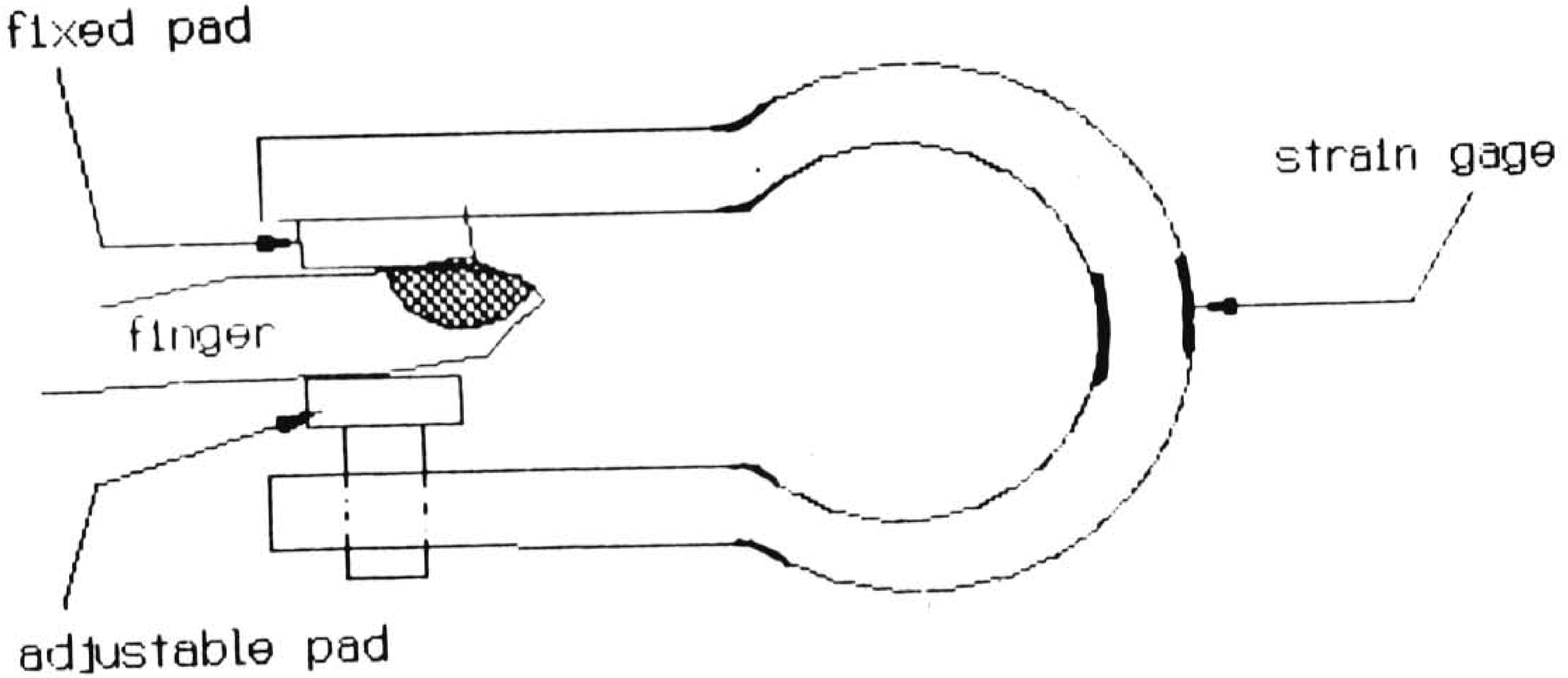
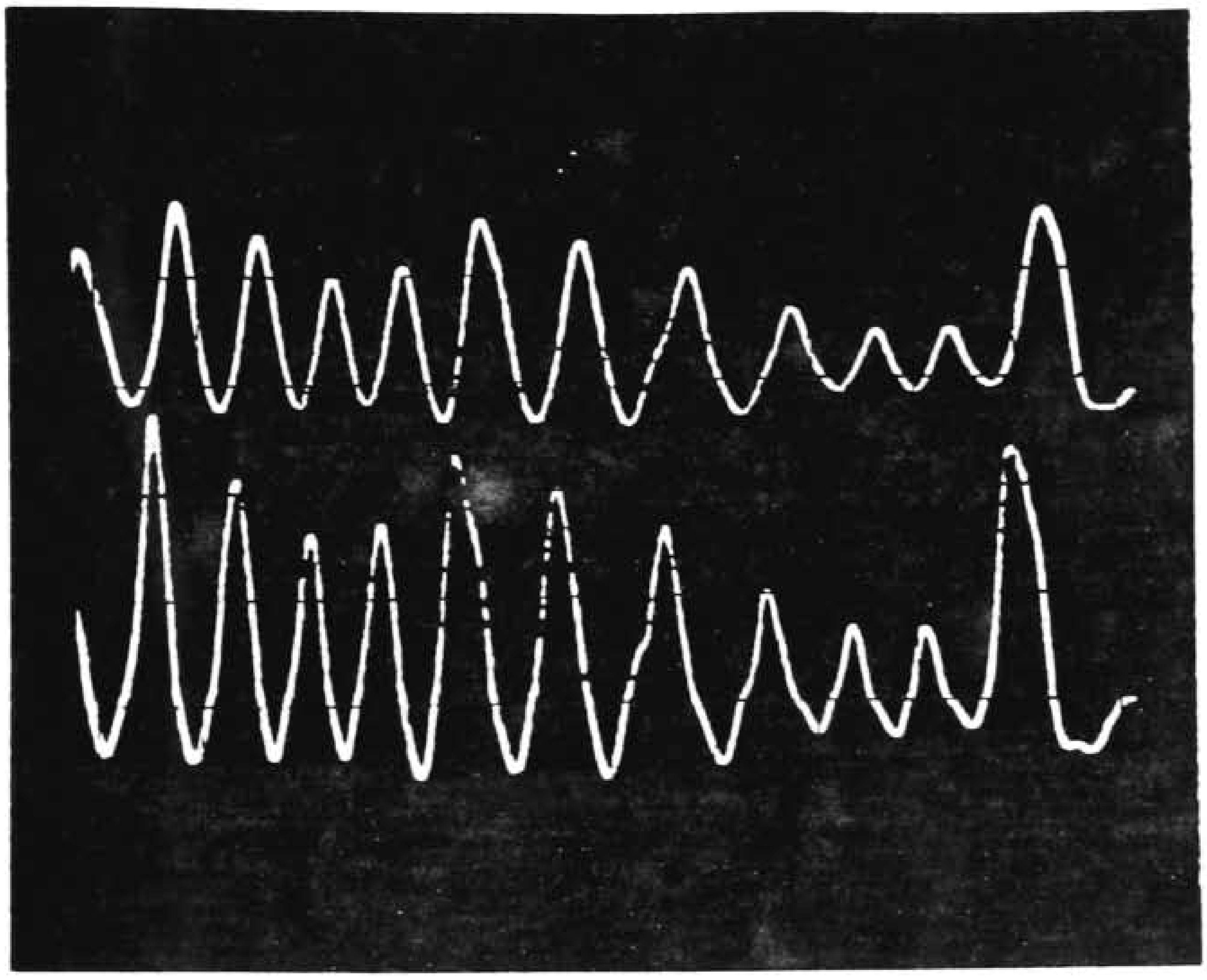


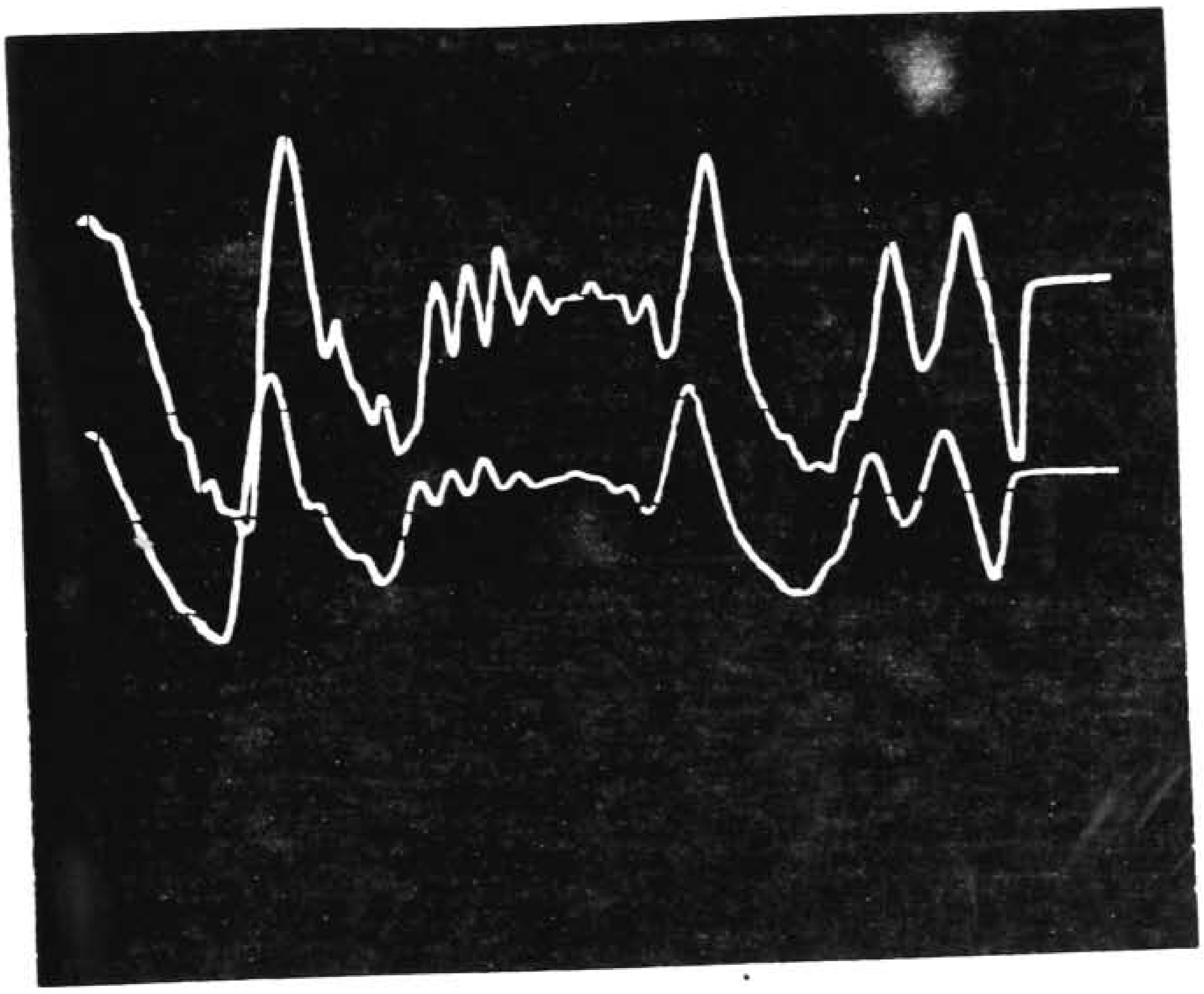
FIG.26 , PROTOTYPE DESIGN



A. THE UPPER SIGNAL FROM THE DEVICE

B. THE LOWER SIGNAL FROM THE PRESSURE TRANSDUCER

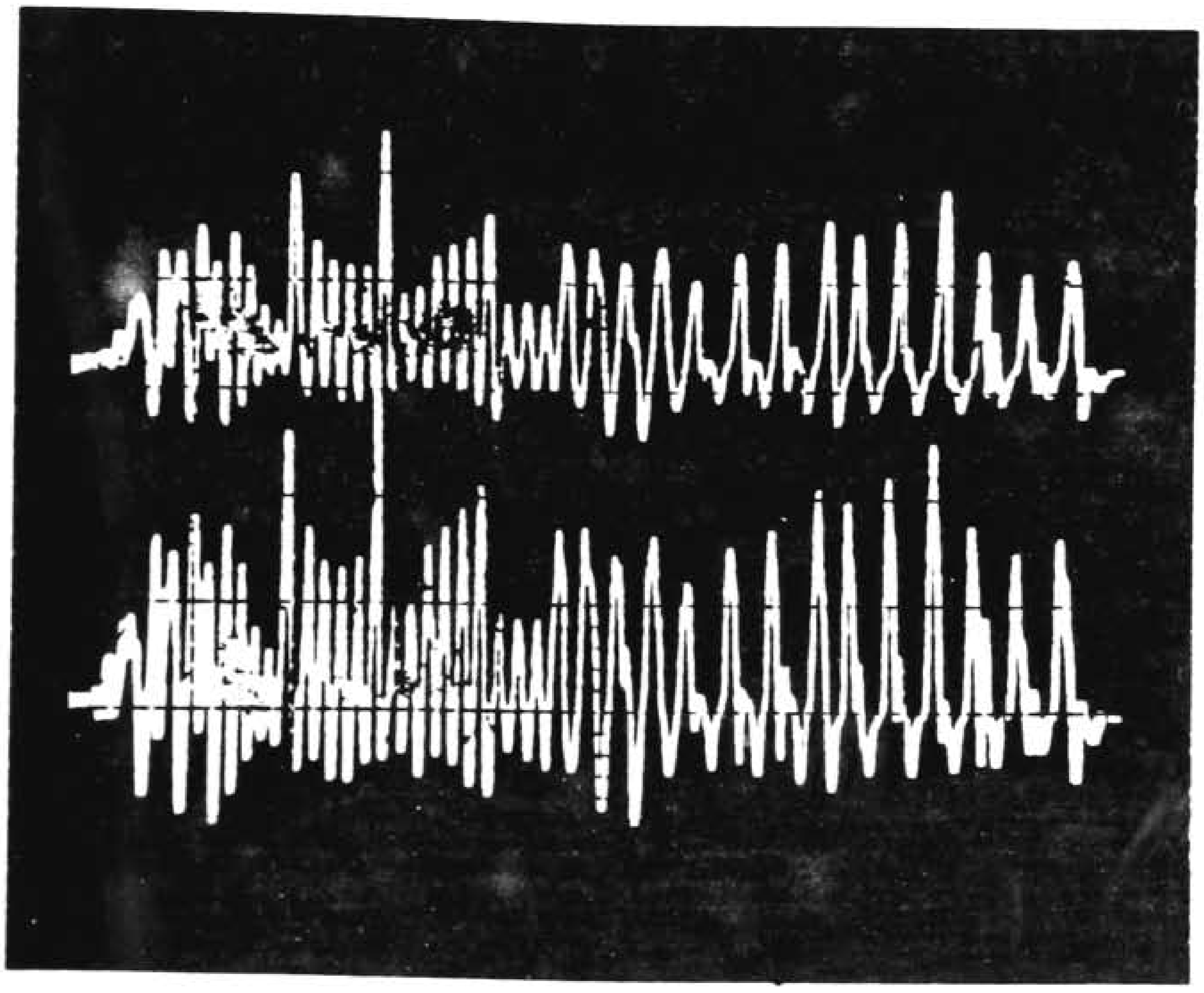
FIG.27: SIGNALS FROM AIR PUMP SET UP
(relatively uniform oscillations)



A. THE UPPER SIGNAL FROM THE DEVICE

B. THE LOWER SIGNAL FROM THE PRESSURE TRANSDUCER

FIG.28: SIGNALS FROM AIR PUMP SET UP
(a varity of irregular shapes)

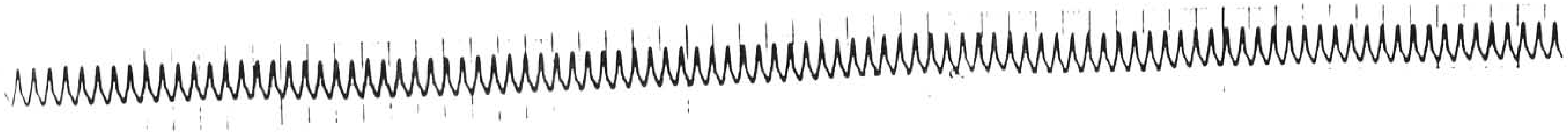


A. THE UPPER SIGNAL FROM THE DEVICE

B. THE LOWER SIGNAL FROM THE PRESSURE TRANSDUCER

FIG.29: SIGNALS FROM AIR PUMP SET UP
(a relatively longer record of oscillations)

A. RECORDING AT LOW SPEED (5 mm per minute)



B. RECORDING AT RELATIVELY HIGH SPEED (5 mm per second)

FIG.30 : LONG TIME STABILITY OF THE SIGNAL
(air pump operated mechanically)

CHAPTER VII

FINAL DESIGN AND ITS OPERATION

VII-1 Introduction

This chapter describes the final design for the noninvasive continuous blood pressure monitoring device which is attached to the thumb (or any finger/toe) of the patient. Also, it describes the instruments that accompany that device. Finally, it proposes a calibration and a self check method for that device.

VII-2 Final Design

It is recommended to make the final device out of hard plastic, half inch wide and 1/ 8 inch in thick, with a smoothly curved outline as shown in FIG.31. Two strain gages should be cast inside the plastic in the location shown in the figure. The portion of the plastic that contains the strain gages should be covered by thin elastic, heat-insulating material (like rubber) in such a way that the heat transfer between gages and outside surrounding is very small.

The finger can be inserted between the jaws of the device and should rest on soft pads as the figure shows; one

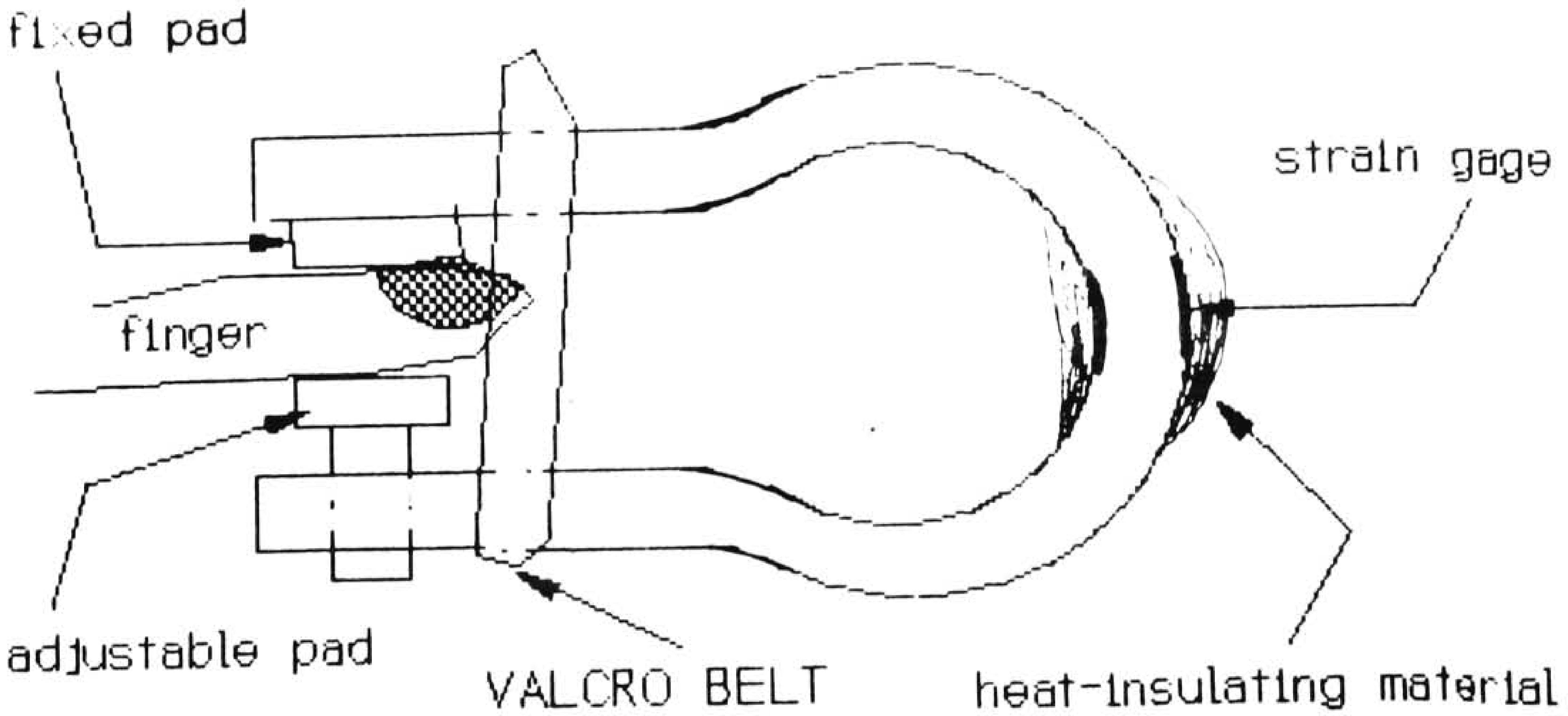


FIG.31 : FINAL DESIGN

of the pads can be adjusted by rotating a screw on which the adjustable padding rests. The finger can be held stable inside the jaws of the device by buckling the outside belt made for that purpose. The finger itself should be inserted inside a rubber glove in such a way the device will see the finger as a rubber tube.

The procedure for monitoring the blood pressure is :

1. insert the patient's finger inside the rubber glove
2. insert the finger between the jaws of the device
3. tighten the outside belt
4. adjust the pressure on the finger by rotating the knob to produce firm but comfortable attachment for the patient's finger.

VII-3 Instrumentation

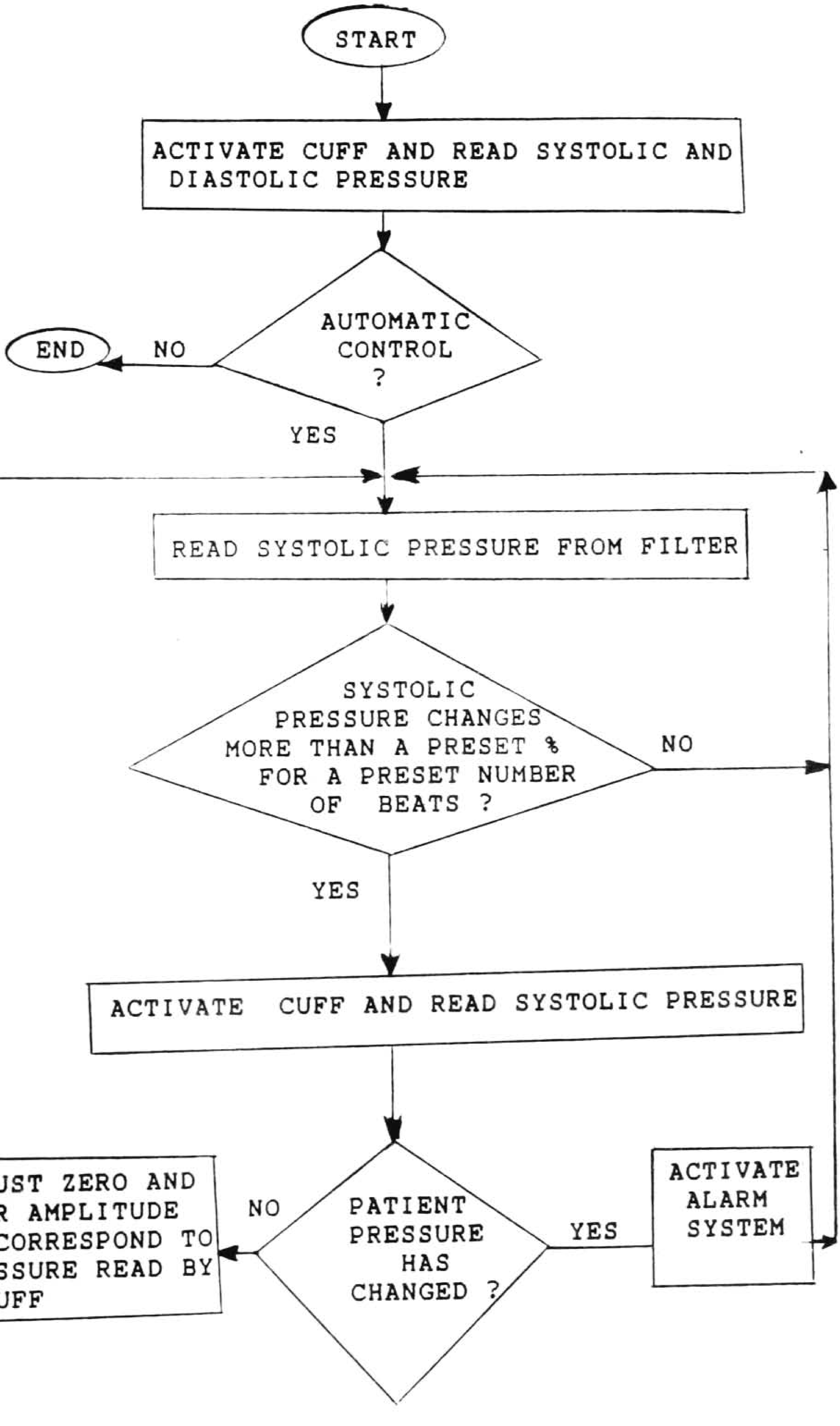
The following instruments are needed for the operation of this device :

1. good stable bridge amplifier
2. active filter (non-adjustable) with low pass up to 25 Herz
3. good stable D.C. amplifier
4. recorder and/or oscilloscope
5. automatic cuff sphygmomanometer
6. small central process unit (cpu)
7. alarm system

The setup of these instruments is shown in FIG.32.

VII-4 Calibration

The following flow chart should be implemented inside the central process unit :


START
ACTIVATE CUFF AND READ SYSTOLIC AND DIASTOLIC PRESSURE
AUTOMATIC CONTROL ?
NO
END
YES
READ SYSTOLIC PRESSURE FROM FILTER
SYSTOLIC PRESSURE CHANGES MORE THAN A PRESET % FOR A PRESET NUMBER OF BEATS ?
NO
YES
ACTIVATE CUFF AND READ SYSTOLIC PRESSURE
PATIENT PRESSURE HAS CHANGED ?
NO
ADJUST ZERO AND / OR AMPLITUDE TO CORRESPOND TO PRESSURE READ BY CUFF
YES
ACTIVATE ALARM SYSTEM

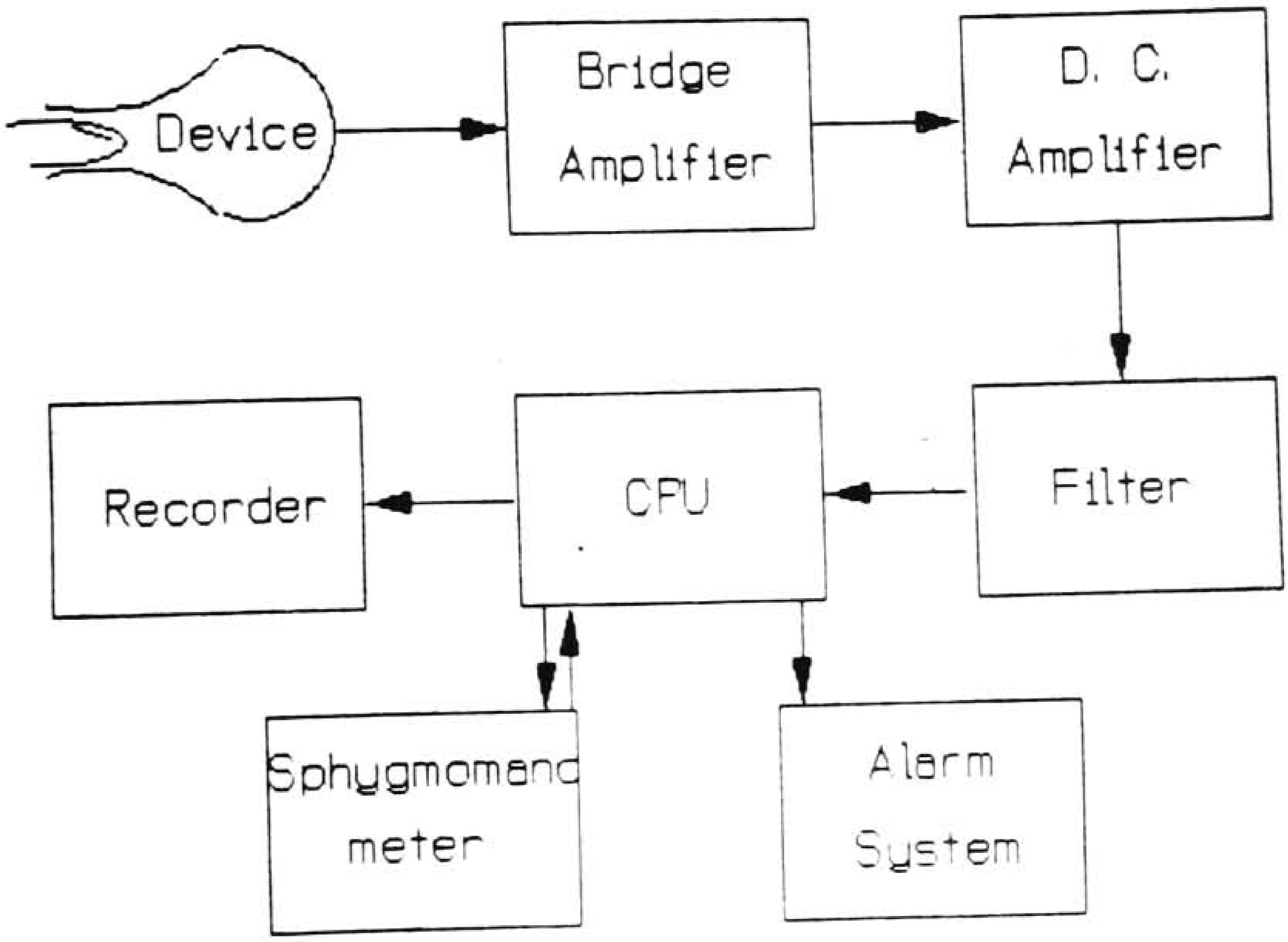


FIG. 32 : INSTRUMENTATION

CONCLUSION AND RECOMMENDATION

Conclusions

In this work a method and a device is developed for a continuous, noninvasive blood pressure monitoring. The method is based on tonometry principle, which has been studied previously without success due to the difficulty of positioning the device over the artery. It was decided to modify this method by placing the device away from major arteries, such as a fingertip or an ear lobe. Theoretical work and simulation tests were carried out which show the validity of the assumption of linear relationship between blood pressure in arteries, arterioles and capillaries. In this case, the error does not exceed 0.06 %.

The amplitude of the blood pressure, however, is smaller than that in the major arteries and it is necessary to calibrate the present device. A calibration method using a standard cuff method has been worked out and tested. Due to this, the accuracy of this method cannot be greater than that of the cuff, but this should be satisfactory, since the physicians are mainly looking for changes in the blood pressure.

The development work concentrated on a device which is applied to the finger tip. Such devices were built and tested as follows :

1. Long term stability tests on one individual
2. Tests on twenty individuals
3. Simulation tests in which the device was placed on a rubber tube attached to a hand pump and a pressure transducer.
4. Hospital tests on four individuals undergoing heart catherization in which the readings of our device were compared to direct blood pressure readings.

It was found from simulation tests that this device faithfully reproduces the pressure curves of various shapes, amplitudes and frequency.

Hospital tests indicate a linear relationship between the readings of this device and those of direct blood pressure measurement.

Based on these experiences the final version of the blood pressure measurement device is proposed. A computer-aided method to use this method for long term blood pressure monitoring has been developed.

One problem which still plagues this design is long-term shift of the zero position in our measuring system and it will be necessary to overcome this before the device can be put to practical use. It has been found that the device, completely stable immediately after manufacture, becomes less so with time and use and there are strong indications that this is due to the adhesive presently used to attach the strain gages. Several adhesives were tried, but problem is still not completely solved.

Recommendation

1. It is recommended that further work be done to refine the design for commercial use.
2. The various adhesives should be studied to find the ones that produce stable results over long periods of time.
3. The use of semiconductor should be investigated, because they have a much greater sensitivity.
4. The placing of the sensor on the fingernail shows promise, but it is plagued by a number of problems. It should be investigated further.
5. It is recommended, finally, to integrate any future development on the cuff method into this work, because the cuff method is needed in the calibration of this work device.

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Issue year :1990
Title :No title available

2. Patent number :4890625
Issue year :1990
Title :Blood Pressure Cuff with Integral Acoustic Pickup Cup

3. Patent number :4889132
Issue year :1989
Title :Portable Automated Blood Pressure Monitoring Apparatus and Method

4. Patent number :4878501
Issue year :1989
Title :Electronic Stethoscopic Apparatus

5. Patent number :4870973
Issue year :1989
Title :Electonic Blood Pressure Meter Having Means for Detecting Artifacts

7. Patent number :4867171
Issue year :1989
Title :Blood Pressure Measurement Apparatus

8. Patent number :4862895
Issue year :1989
Title :Electronic Blood Pressure Meter

9. Patent number :4860760
Issue year :1989
Title :Electronic Blood Pressure Meter Incorporating Compensation Function for Systolic and Diastolic Blood Pressure Determinations

10. Patent number :4858616
Issue year :1989
Title :Blood Pressure Measurement System for Filtering Low-frequency, High-amplitude Noise

11. Patent number :4850368
Issue year :1989
Title :Electronic Blood Pressure Measurement Device and its Method of Operation, Performing Minimal Squeezing of Patient's Arm

12. Patent number :4840181

Issue year :1989
Title :Sphygmomanometer Adopting Recognition of Korotkoff Sounds

13. Patent number :4832039
Issue year :1989
Title :Linear, Low Noise Inflation System for Blood Pressure Monitor

14. Patent number :4830019
Issue year :1989
Title :Electronic Blood Pressure Meter

15. Patent number :4821734
Issue year :1989
Title :Sphygmomanometer

16. Patent number :4819654
Issue year :1989
Title :Method and Apparatus for Diagnosis of Coronary Artery Disease

17. Patent number :4777959
Issue year :1989
Title :Artifact Detection Based on Heart Rate in a Method and Apparatus

18. Patent number :4768519
Issue year :1988
Title :Blood Pressure Measurement Apparatus

19. Patent number :4747412
Issue year :1988
Title :Electronic Sphygmomanometer with Graphical Output

20. Patent number :4730621
Issue year :1988
Title :Blood Pressure Measurement

21. Patent number :4729383
Issue year :1988
Title :Method and Apparatus for Automatically Determinig Blood pressure Measurements

22. Patent number :4723555
Issue year :1988
Title :Multi-functional Radio/wire Stethoscopic Apparatus

23. Patent number :4677983

Issue year :1987
Title :Method and Apparatus for Measuring Circulatory Function

24. Patent number :44664126
Issue year :1987
Title :Technique for Obtaining Information Associated with an Individual's Blood Pressure Including Specifically a Stat Mode Technique

25. Patent number :4660567
Issue year :1987
Title :Method of Automatically Measuring Blood Pressure, and Apparatus Therefor

26. Patent number :4651748
Issue year :1987
Title :Method and Device for Determing State of Cardiovascular System

27. Patent number :4649929
Issue year :1987
Title :Method and Apparatus for Diagnosis of Coranary Artery Disease

28. Patent number :4635645
Issue year :1987
Title :Electronic Sphygmomanometer

29. Patent number :4625277
Issue year :1986
Title :Blood Pressure Measurement Device Having Adaptive Cuff Deflation Rate

30. Patent number :4617937
Issue year :1986
Title :Blood Pressure Monitoring System

31. Patent number :4607641
Issue year :1986
Title :Electronic Sphygmomanometer

32. Patent number :4592366
Issue year :1986
Title :Automated Blood Pressure Monitoring Instrument

33. Patent number :4592365
Issue year :1986
Title :Electronic Sphygmomanometer

34. Patent number :4567899
Issue year :1986
Title :Cuff Pressure controller for Blood Pressure Measurement Apparatus

35. Patent number :4559953
Issue year :1985
Title :Apparatus for Detecting Changes in Shape of a Body

36. Patent number :4558707
Issue year :1985
Title :Electronic Sphygmomanometer with Voice Synthesizer

38. Patent number :4549549
Issue year :1985
Title :Electronic Sphygmomanometer

39. Patent number :4546775
Issue year :1985
Title :Detection of Blood Pressure Complexes in Automated Vital Signs Monitors

40. Patent number :4553962
Issue year :1985
Title :Method of Automated Blood Pressure Detection

41. Patent number :4534361
Issue year :1985
Title :Method and Apparatus for Measuring Blood Pressure by Instantaneous Comparison of Multiple Frequency range Components of Korotkoff Noise

42. Patent number :4517986
Issue year :1985
Status :E
Title :Four Function Vital Sign Monitor

43. Patent number :4510943
Issue year :1985
Title :Display Inhibition in an Electronic Sphymomanometer

44. Patent number :4510942
Issue year :1985
Title :Electronic Sphygmomanometer

45. Patent number :4501281
Issue year :1985
Title :Electronic Sphygmomanometer

46. Patent number :4493326
Issue year :1985
Title :Automated Blood Pressure System with Servo Controlled Inflation and Deflation

47. Patent number :4484584
Issue year :1984
Title :Method and Apparatus For Blood Pressure Measurement

48. Patent number :4475557
Issue year :1984
Title :Method and Apparatus for Performing Blood Pressure Measurements

49. Patent number :4461266
Issue year :1984
Title :Adaptive incremental Blood Pressure Monitor

50. Patent number :4458690
Issue year :1984
Status : E
Title :Blood Pressure Monitor

51. Patent number :4432373
Issue year :1984
Title :Electronic Blood Pressure Measuring Apparatus

52. Patent number :4417586
Issue year :1983
Title :Blood Pressure Measuring Device

53. Patent number :4408614
Issue year :1983
Title :Blood Pressure Measurement with Korotkov Sound Artifact Information Detection and Rejection

54. Patent number :4397317
Issue year :1983
Title :Electronic Blood Pressure and Pulse Rate Calculator with Optional Temperature Indicator, Timer and Memory

55. Patent number :4396018

Issue year :1983
Title :Apparatus and Method for Detecting Korotkoff Sounds

56. Patent number :4378807
Issue year :1983
Title :Blood Pressure Measurement Apparatus

57. Patent number :4356827
Issue year :1982
Title :Method of Arrhythmia Detection with Detecting Mechanism

58. Patent number :4343314
Issue year :1982
Title :Non-invasive Real Time Blood Pressure Measurement System

59. Patent number :4337778
Issue year :1982
Title :Blood Pressure Measuring Apparatus

60. Patent number :4328810
Issue year :1982
Title :Automatic Blood Pressure System

61. Patent number :4321929
Issue year :1982
Title :Tourniquet

62. Patent number :4320767
Issue year :1982
Title :Pocket-size Electronic cuffless blood pressure and Pulse rate Calculator with Optional Temperature Indicator, Timer and Memory

63. Patent number :4313445
Issue year :1982
Title :Electronic Sphygmomanometer

64. Patent number :4312359
Issue year :1982
Title :Noninvasive Blood Pressure Measuring System

65. Patent number :4300573
Issue year :1981
Title :Sphygmomanometer

66. Patent number :4290434

Issue year :1981
Title :Blood Pressure Measuring Device

67. Patent number :4273136
Issue year :1981
Title :Electronic Sphygmomanometer

68. Patent number :4262675
Issue year :1981
Title :Blood Pressure Measuring Instrument Having Compensation Circuit

69. Patent number :4262674
Issue year :1981
Title :Sphygmomanometer with an Arrhythmia Detection Mechanism

70. Patent number :4261368
Issue year :1981
Title :Electronic Blood Pressure Recorder

71. Patent number :4248242
Issue year :1981
Title :Occlusive Sphygmomanometer for the Measuring of the Arterial Blood pressure

72. Patent number :4245648
Issue year :1981
Title :Method and Apparatus for Measuring Blood Pressure and Pulse Rate

73. Patent number :4214589
Issue year :1980
Title :Method and Apparatus for Blood Pressure Measurement Including a True Korotkov Sound Detector

74. Patent number :4204545
Issue year :1980
Title :Limb Blood Flowmeter

75. Patent number :4202348
Issue year :1980
Title :Korotkov Sound Sensor

76. Patent number :4188955
Issue year :1980
Title :Blood Pressure Measuring Process and Apparatus

78. Patent number :4181122
Issue year :1980

Title :Device for Measuring Blood Pressure

79. Patent number :4175547
Issue year :1979
Title :Sphygmomanometer Aid

80. Patent number :4162674
Issue year :1979
Title :Instrument for Recording Blood Pressure

81. Patent number :4144879
Issue year :1979
Title :Blood Pressure Measuring Instrument

82. Patent number :4141350
Issue year :1979
Title :Vascular Sound Detector

83. Patent number :4112929
Issue year :1978
Title :Method for Measuring the Blood Pressure of a Patient

84. Patent number :4111057
Issue year :1978
Title :Dual-indicator Manometer for an electromedical Device

85. Patent number :4026277
Issue year :1977
Title :Blood Pressure Measuring Apparatus

86. Patent number :4012604
Issue year :1977
Title :Microphone for the Transmission of Body Sounds

87. Patent number :4005701
Issue year :1977
Title :Noise Rejecting Eletronic Sphygmomanometer and Method for Measuring Blood Pressure

88. Patent number :3920004
Issue year :1975
Title :Device and Method for Noninvasive Measurement of Blood Pressure, Resistance Inertance, Compliance, Impedance, Blood Flow Rate, Kinetic Energy, Flow VE

89. Patent number :3906939
Issue year :1975
Title :Blood Pressure Measuring Means

90. Patent number :3906937
Issue year :1975
Title :Blood Pressure Cuff and Bladder and Apparatus Embodying the Same

91. Patent number :3896791
Issue year :1975
Title :Electronic Blood Pressure Meters

92. Patent number :3878834
Issue year :1975
Title :Blood Pressure Recorder

93. Patent number :3771515
Issue year :1973
Title :Automatic Recording Sphygmomanometer

94. Patent number :3730172
Issue year :1973
Title :Sphygmomanometer

95. Patent number :3712297
Issue year :1973
Title :Blood Pressure Measuring Device with Variable Frequency Recorder and Linearized Leak Means

96. Patent number :3704708
Issue year :1972
Title :Blood Pressure Measuring Mechanism

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Issue year :1972
Title :Blood Pressure Indicator and Noise

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Issue year :1971
Title :Recording Sphygmomanometer

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Issue year :1971
Title :Blood Pressure Measurement Apparatus

100. Patent number :3552385
Issue year :1971
Title :Device for Measuring Blood Pressure

101. Patent number :3480005

Issue year :1969
Title :Apparatus for Measuring Blood Pressure with Plural BRake Controlled Indicators

102. Patent number :3480004
Issue year :1969
Title :Apparatus for Measuring Blood Pressure with an In-cuff Microphone and Preamplifier

103. Patent number :3467837
Issue year :1969
Title :Blood Pressure Measuring System for Separating and Separately Recording D.C. Signal and an A.C. Signal

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Issue year :1969
Title :Blood Pressure Monitor

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Title :Tonometer

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APPENDIX A: COMPUTER PROGRAM

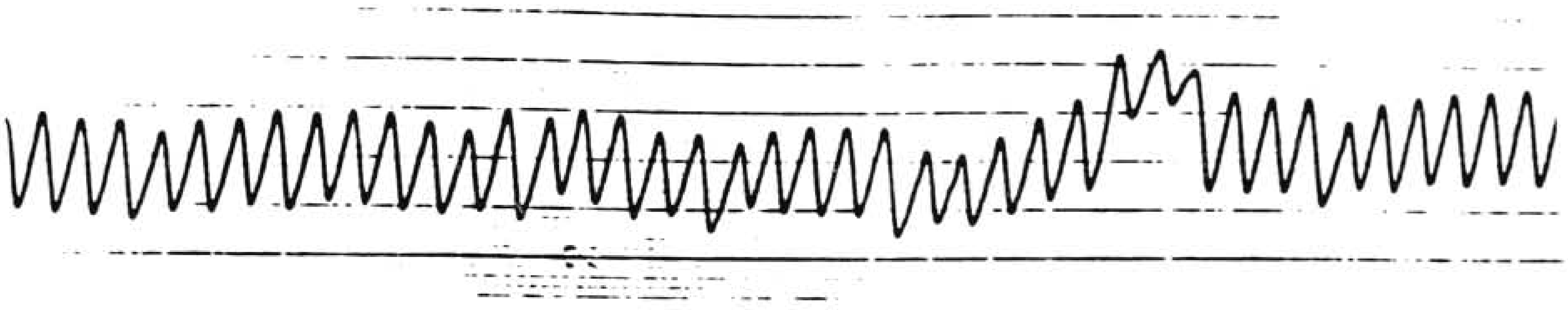
```
program blood;
{
 *************************************************

 THIS PROGRAM  GENERATES  A TABLE OF  WAVE SPEED ( C)
 VERSUS    α ( α = √(n/ Nu)).

 *************************************************}

 uses printer;
 const
 S=0.5;
 R=0.0003;
 CO=1000;
 L=0.10 ;
 SKIP='  ';
 TYPE
 ARRAY2=ARRAY[1..2] OF REAL;
 VAR
 I:INTEGER;
 A,A2,K,T,C,F:REAL;
 F10,J0,J1,JTI,G,G1,H,X,X1,BX:ARRAY2;
 {
 ...............................................

 THIS FUCTION CALCULATES  X TO THE POWER N

 ...............................................}

 FUNCTION POWER(X:REAL;N:INTEGER):REAL;
 BEGIN
 IF N=0 THEN POWER:=1;
 IF N=1 THEN
 POWER:=X
 ELSE
 BEGIN
 N:=N-1;
 POWER:= X*POWER(X,N);
 END;
 END;
 {
 ...............................................

 THIS PROCEDURE CALCULATES  THE COMPLEX SQUARE ROOT
 OF A COMPLEX VARIABLE.

 ...............................................}
```

```
PROCEDURE CSQRT (VAR ZI,ZO:ARRAY2);
VAR
TA,AN,RO,SRO:REAL;
BEGIN
RO:=SQRT(ZI[1]*ZI[1]+ZI[2]*ZI[2]);
SRO:=SQRT(RO);
TA:=ZI[2]/ZI[1];
AN:=ARCTAN(TA);
ZO[1]:=SRO*COS(AN/2);
ZO[2]:=SRO*SIN(AN/2);
END;
{
..............................................

MAIN PROGRAM STARTS HERE.

..............................................}

BEGIN
T:=0.000015;

WRITELN (LST,SKIP:10,'TABLE 2 : C VERSUS α  '
,'(  σ = ',S:5:4,', L = ',L:4:3);
WRITELN(LST,SKIP:10,'R = ',R:5:4,', T = ',T:8:7,')');

WRITELN(LST,SKIP:10,'__________________________________________',
'______________________');WRITELN(LST);
A:=0.0;
FOR I:=1 TO 40 DO
BEGIN
T:=0.00015;
A:=0.001 +A;
A2:=A/2;
JO[1]:= 1-POWER(A2,4)/4 +POWER(A2,8)/576;
JO[2]:= POWER(A2,2)-POWER(A2,6)/36;
J1[1]:=-1-POWER(A2,2)/2+ POWER(A2,4)/12   ;
J1[1]:=J1[1]*(A/2)/SQRT(2);
J1[2]:=1 - POWER(A/2,2)/2 -POWER(A/2,4)/12;
J1[2]:=J1[2]*(A/2)/SQRT(2);
```

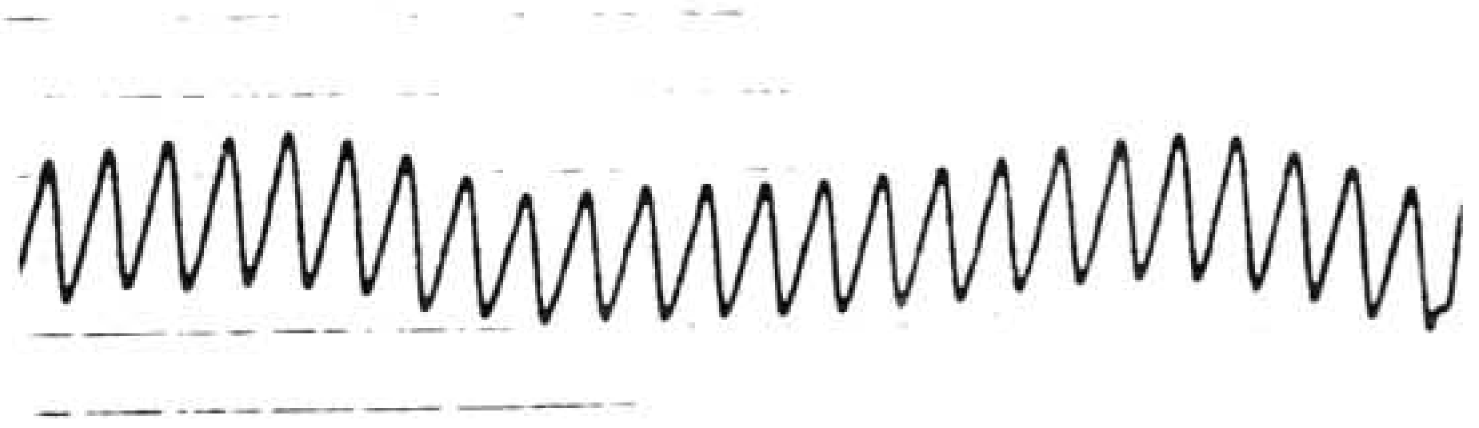
```
JTI[1]:= -JO[1]-JO[2];
JTI[2]:= JO[1]-JO[2];
F:= 2*SQRT(2)/(A*(SQR(JTI[1])+SQR(JTI[2])));
F1O[1]:=F*(JTI[1]*J1[1]+JTI[2]*J1[2]);
F1O[2]:=F*(JTI[1]*J1[2]-JTI[2]*J1[1]);
K:=T/R;
G1[1]:=1-F1O[1];
G1[2]:=-F1O[2];
G[1]:=G1[1]/(SQR(G1[1])+SQR(G1[2]));
H[1]:=G[1];
G[1]:=(1.25-S)*G[1]+(K/2+S-0.25);
H[1]:=(1+2*K)*H[1]-1;
G[2]:=-G1[2]/(SQR(G1[1])+SQR(G1[2]));
H[2]:=G[2];
G[2]:=G[2]*(1.25-S);
H[2]:=H[2]*(1+2*K);
X[1]:= G[1]*G[1]-G[2]*G[2]-(1-S*S)*H[1];
X[2]:=2*G[1]*G[2]-(1-S*S)*H[2];
CSQRT(X,X);
X[1]:=(X[1]+G[1])/(1-S*S);
X[2]:=(X[2]+G[2])/(1-S*S);
X1[1]:=(1-S*S)*X[1]/2;
X1[2]:=(1-S*S)*X[2]/2;
CSQRT(X1,BX);
C:=CO/BX[1];
WRITELN(LST,SKIP:10,'α = ',A:5:3,SKIP:5,'C = ',C:6:5);
END;
END.
```

```
TABLE 2 : C VERSUS α  (  σ = 0.5000, L = 0.100
R = 0.0003, T = 0.0000150)
--------------------------------------------------------------------

            α = 0.001        C = 0.52549
            α = 0.002        C = 1.05098
            α = 0.003        C = 1.57648
            α = 0.004        C = 2.10197
            α = 0.005        C = 2.62746
            α = 0.006        C = 3.15295
            α = 0.007        C = 3.67843
            α = 0.008        C = 4.20392
            α = 0.009        C = 4.72940
            α = 0.010        C = 5.25489
            α = 0.011        C = 5.78036
            α = 0.012        C = 6.30584
            α = 0.013        C = 6.83131
            α = 0.014        C = 7.35679
            α = 0.015        C = 7.88225
            α = 0.016        C = 8.40772
            α = 0.017        C = 8.93318
            α = 0.018        C = 9.45863
            α = 0.019        C = 9.98408
            α = 0.020        C = 10.50953
            α = 0.021        C = 11.03497
            α = 0.022        C = 11.56041
            α = 0.023        C = 12.08584
            α = 0.024        C = 12.61127
            α = 0.025        C = 13.13669
            α = 0.026        C = 13.66210
            α = 0.027        C = 14.18751
            α = 0.028        C = 14.71291
            α = 0.029        C = 15.23831
            α = 0.030        C = 15.76369
            α = 0.031        C = 16.28908
            α = 0.032        C = 16.81445
            α = 0.033        C = 17.33981
            α = 0.034        C = 17.86517
            α = 0.035        C = 18.39052
            α = 0.036        C = 18.91586
            α = 0.037        C = 19.44120
            α = 0.038        C = 19.96652
            α = 0.039        C = 20.49183
            α = 0.040        C = 21.01714
```

APPENDIX B : TESTS DATA

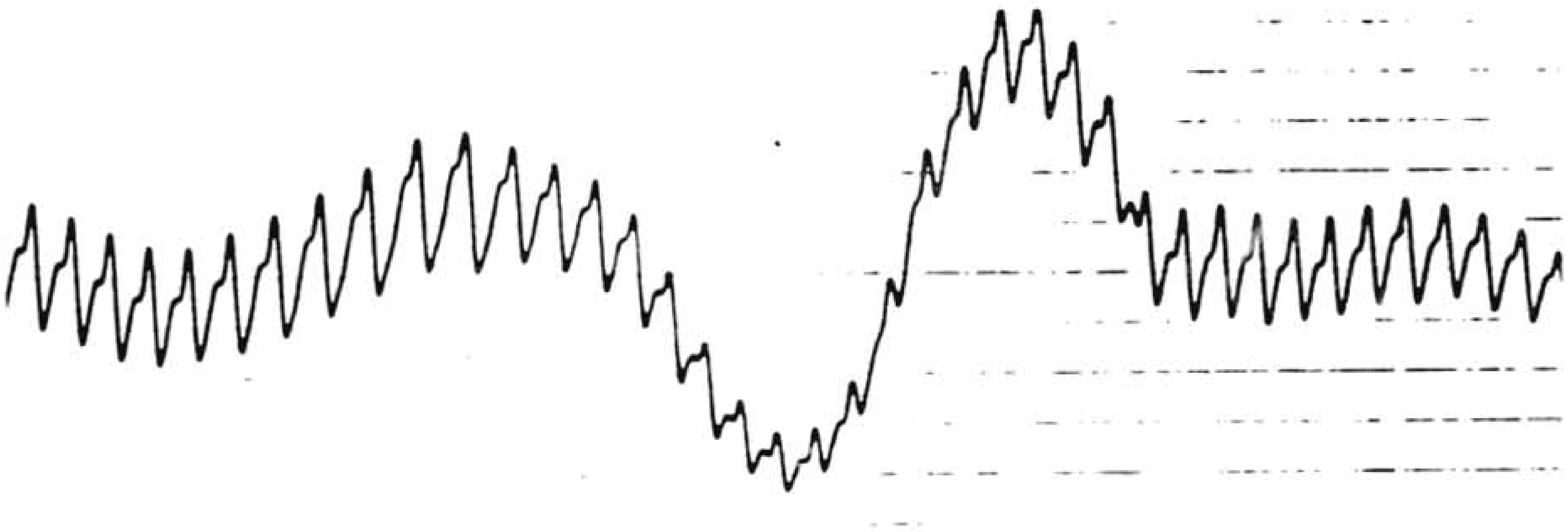


A. VALSALVA MANEUVER



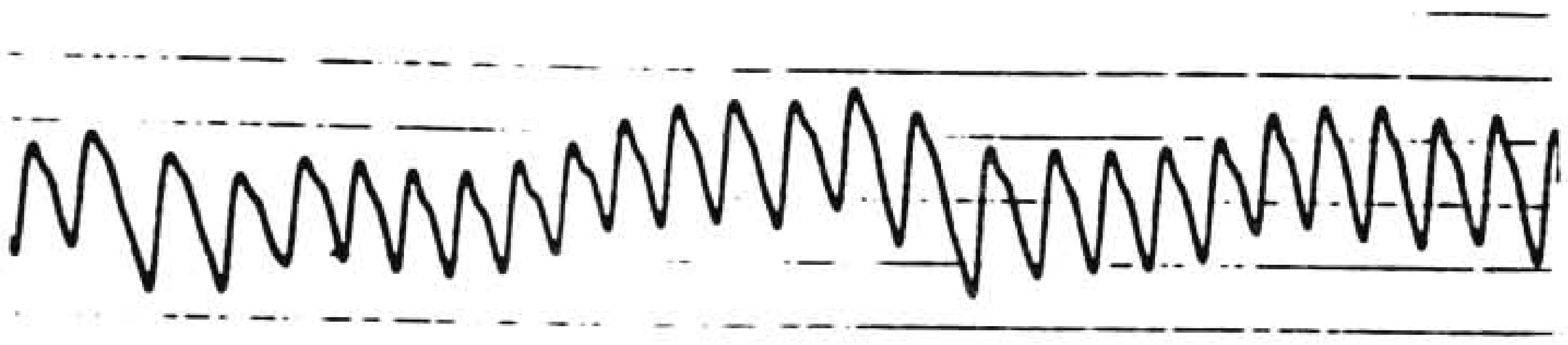
B. DEEP BREATH

SUBJECT # 1



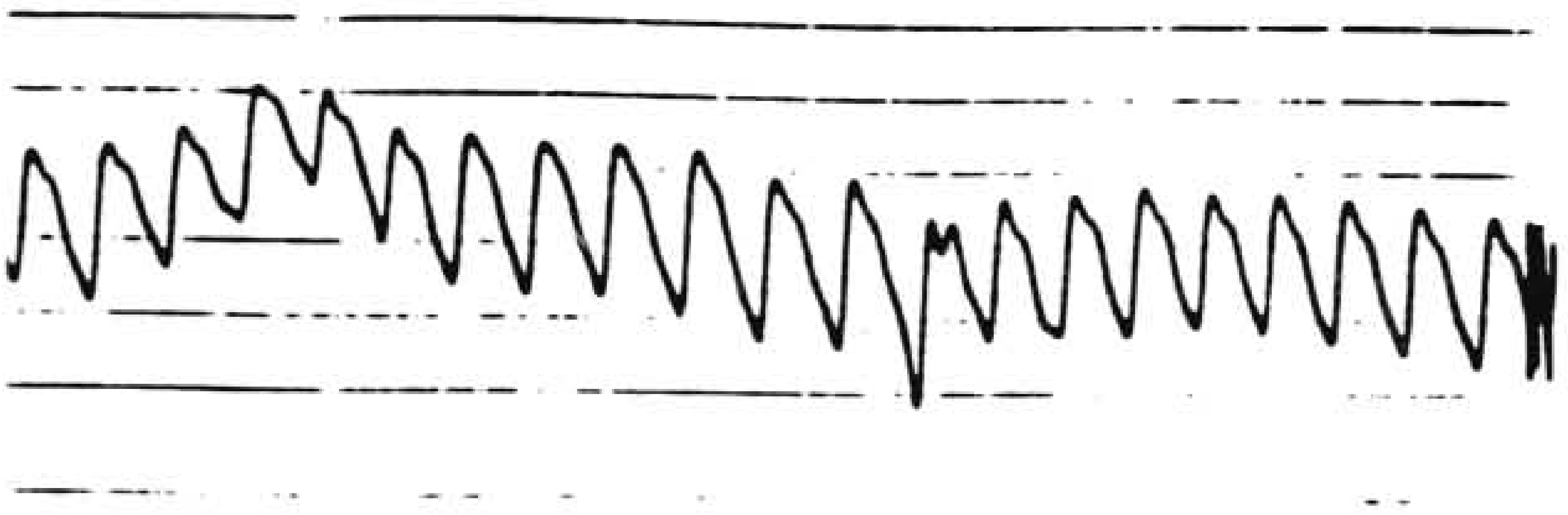
VALSALVA MANEUVER

SUBJECT # 2

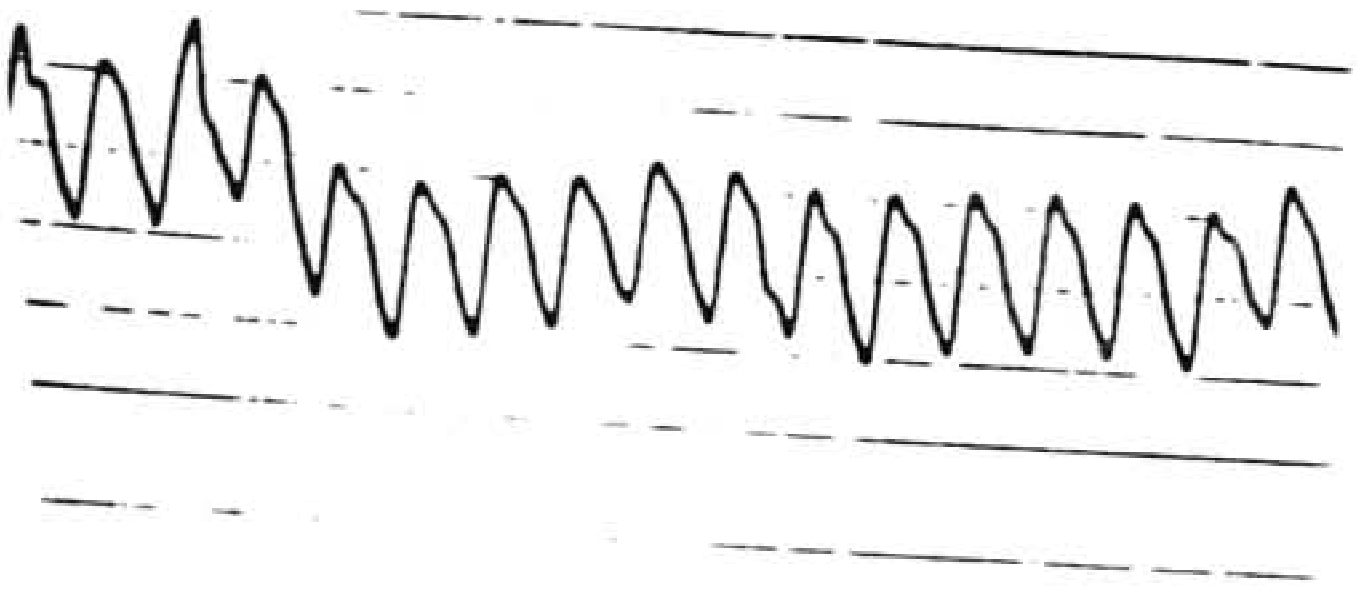


VALSALVA MANEUVER

SUBJECT # 3



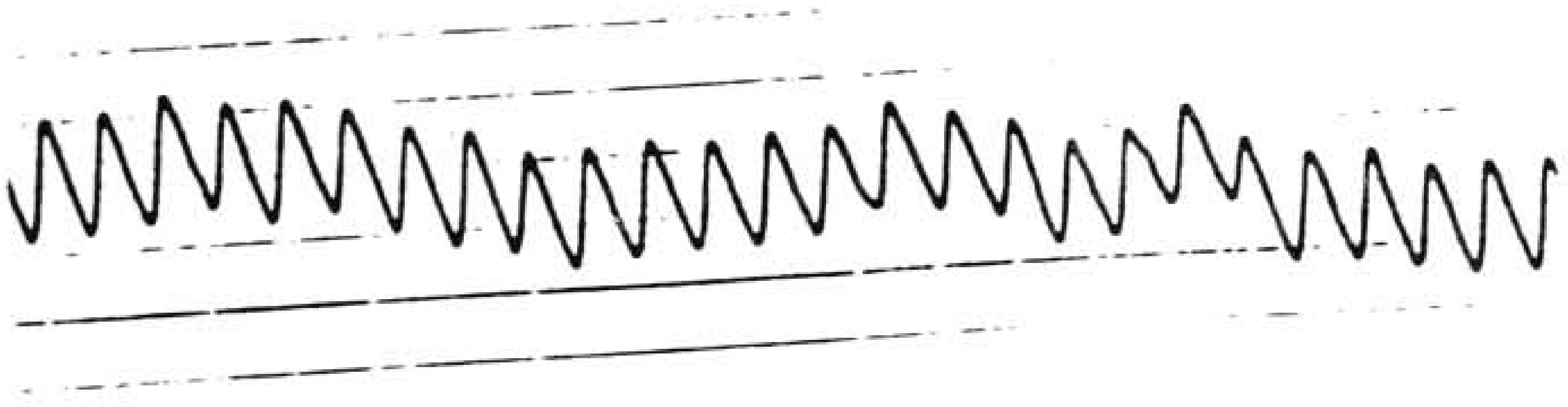
A. VALSALVA MANEUVER



B. DEEP BREATH

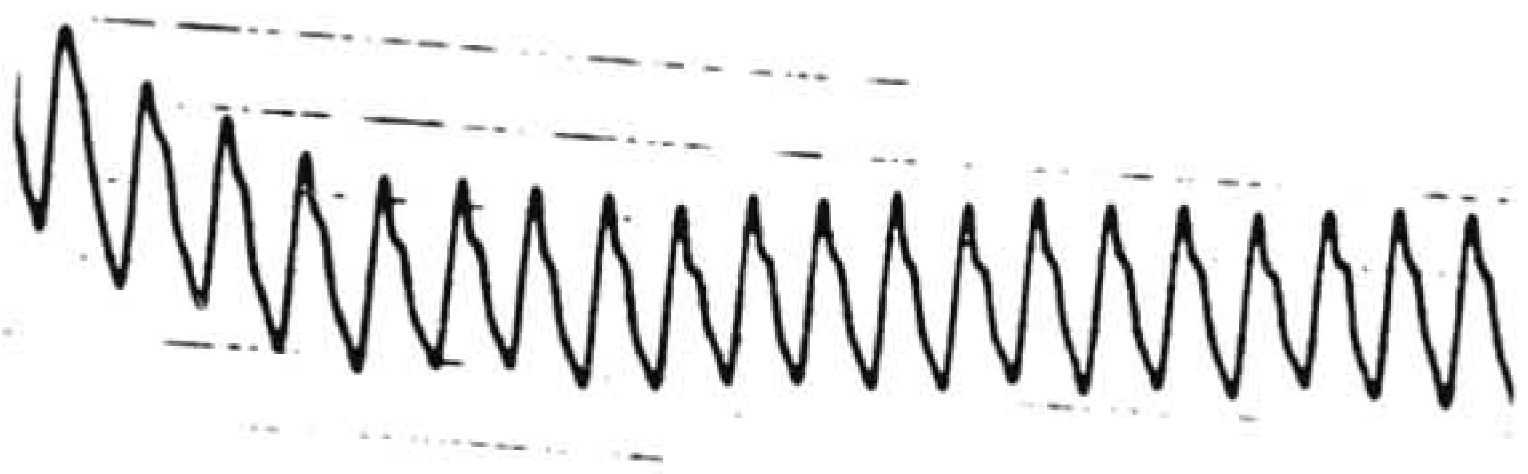
SUBJECT # 4

A. VALSALVA MANEUVER

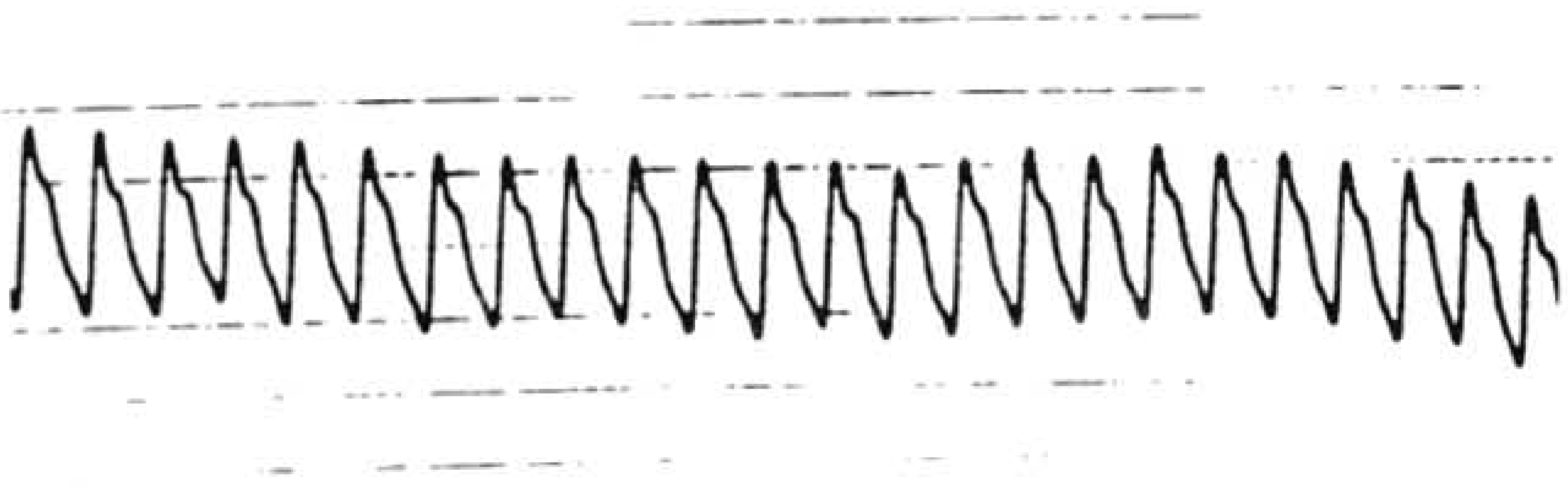


B. DEEP BREATH

SUBJECT # 5

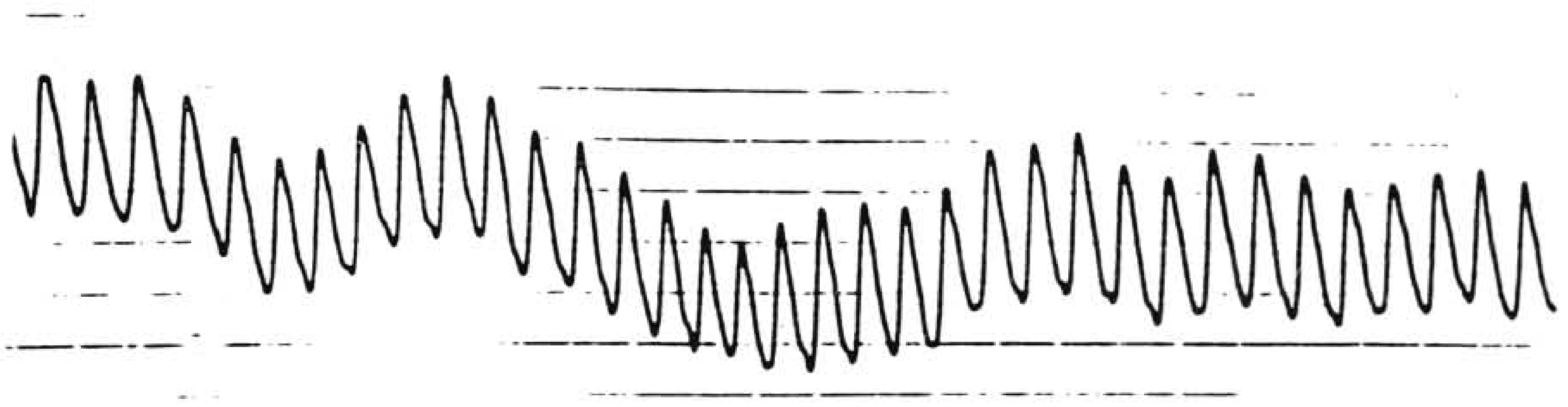


A. VALSALVA MANEUVER

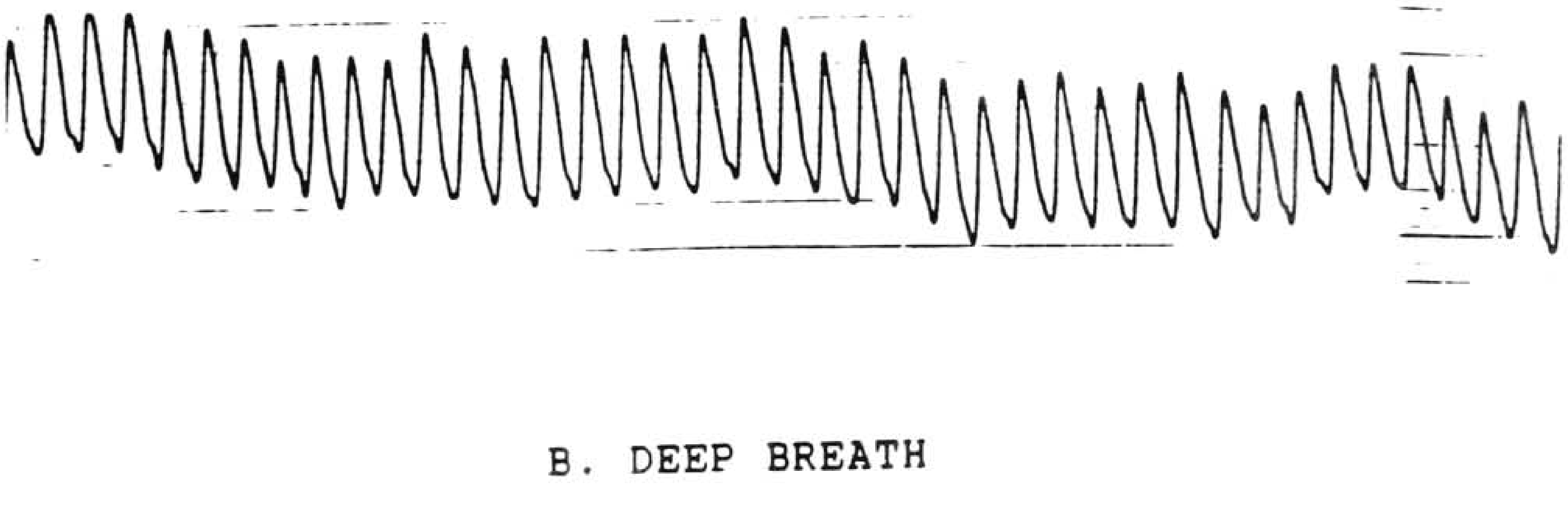


B. DEEP BREATH

SUBJECT # 6

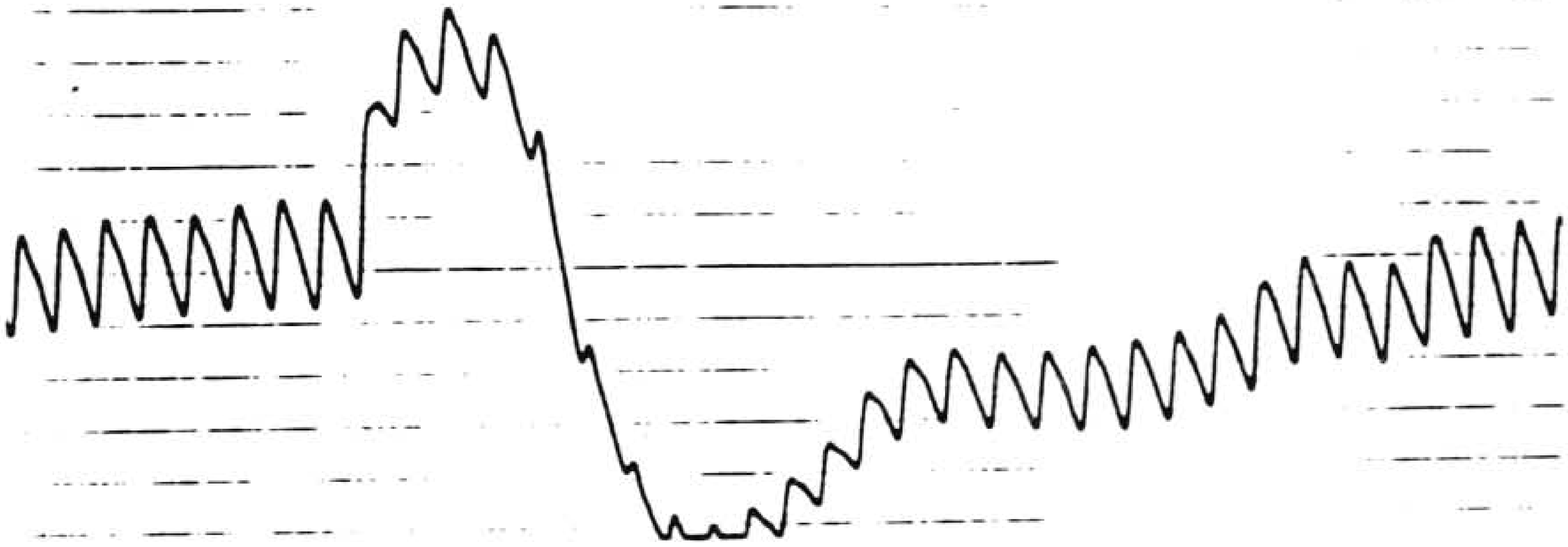


A. VALSALVA MANEUVER

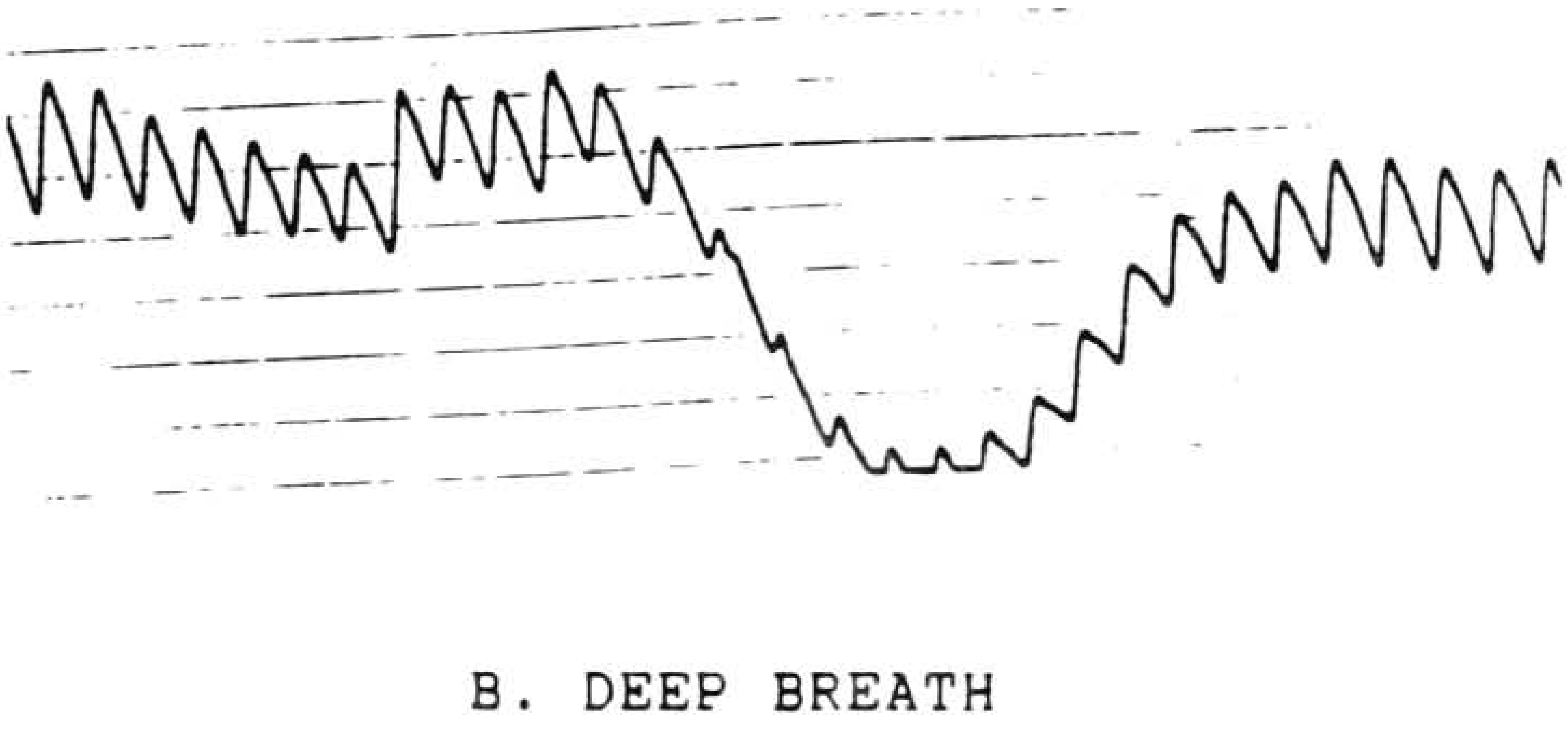


B. DEEP BREATH

SUBJECT # 7

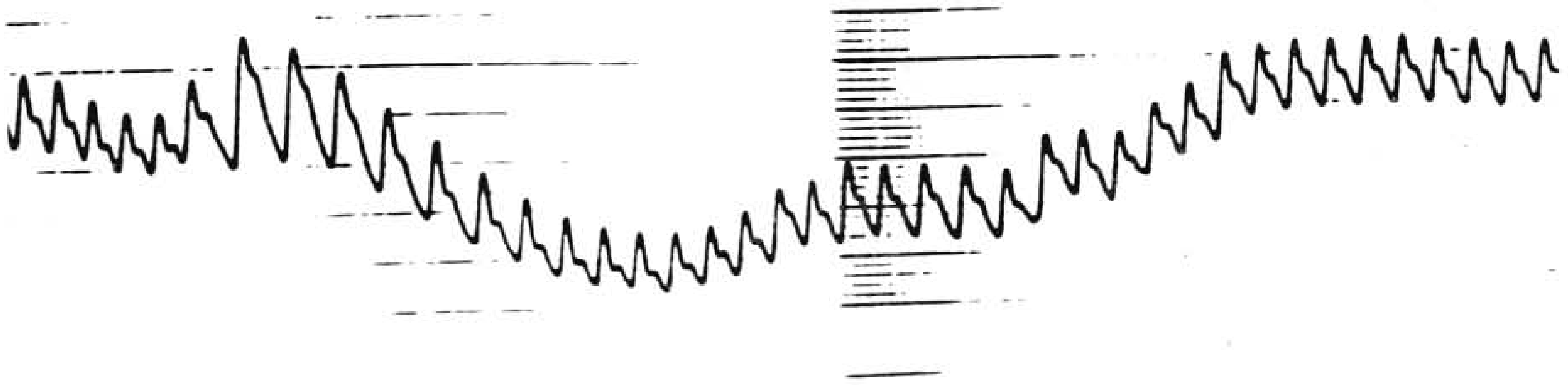


A. VALSALVA MANEUVER



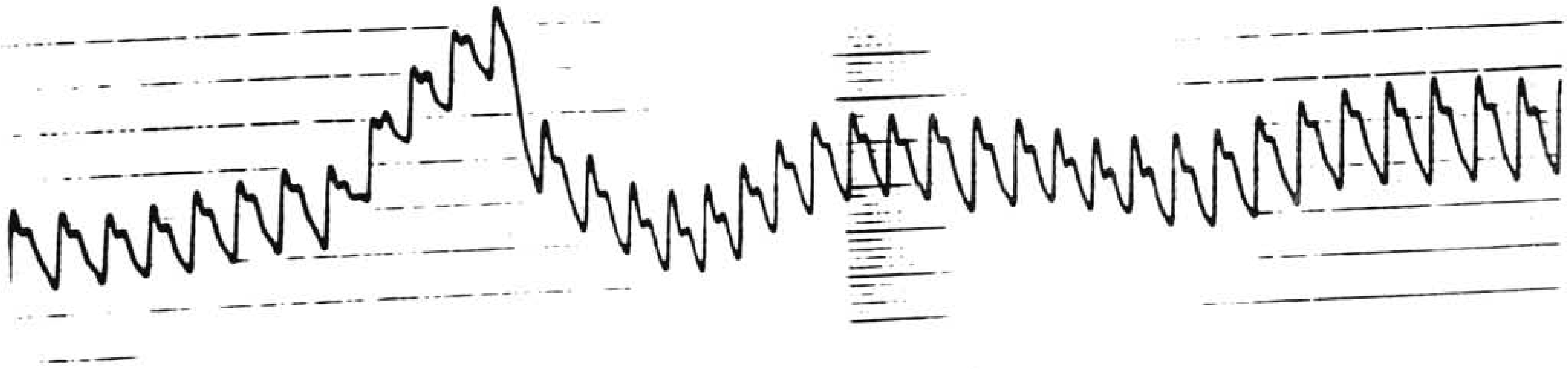
B. DEEP BREATH

SUBJECT # 8



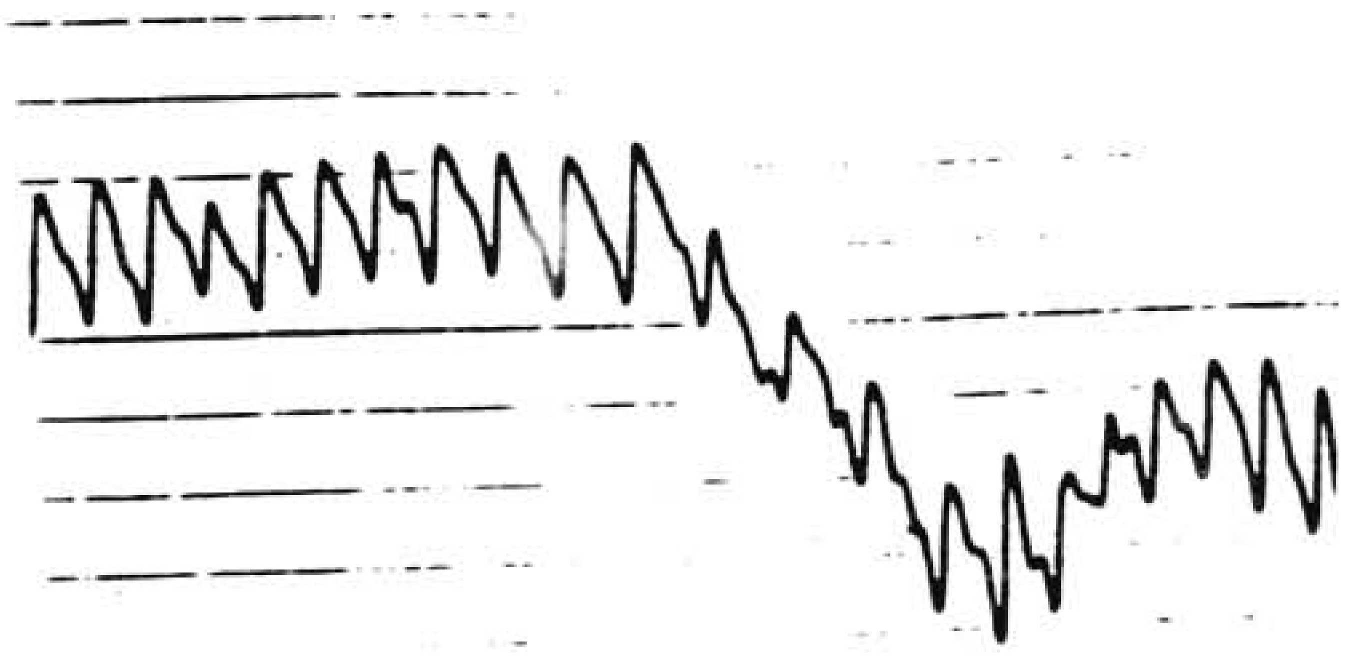
VALSALVA MANEUVER

SUBJECT # 9

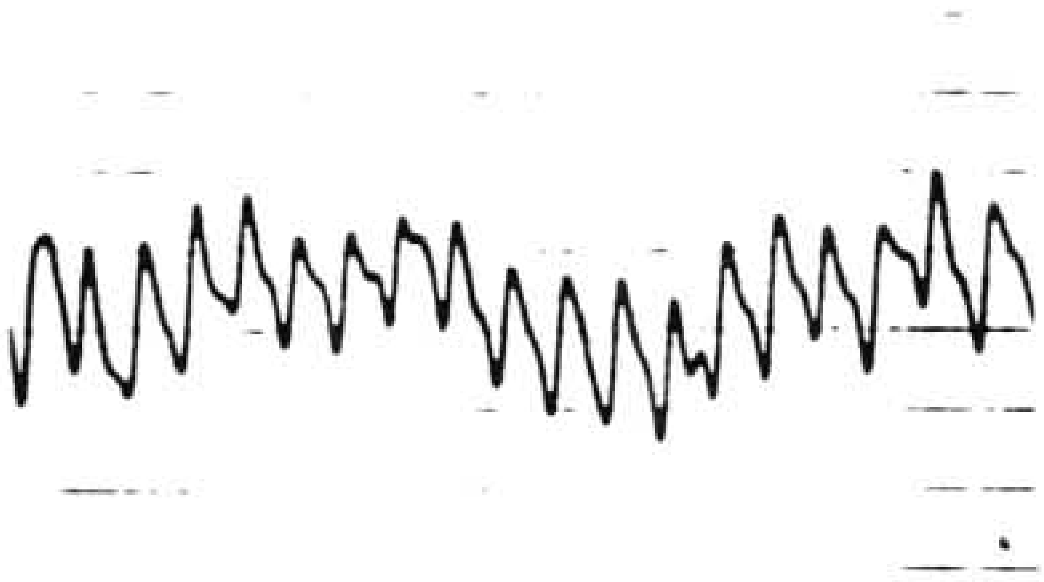


VALSALVA MANEUVER

SUBJECT # 10

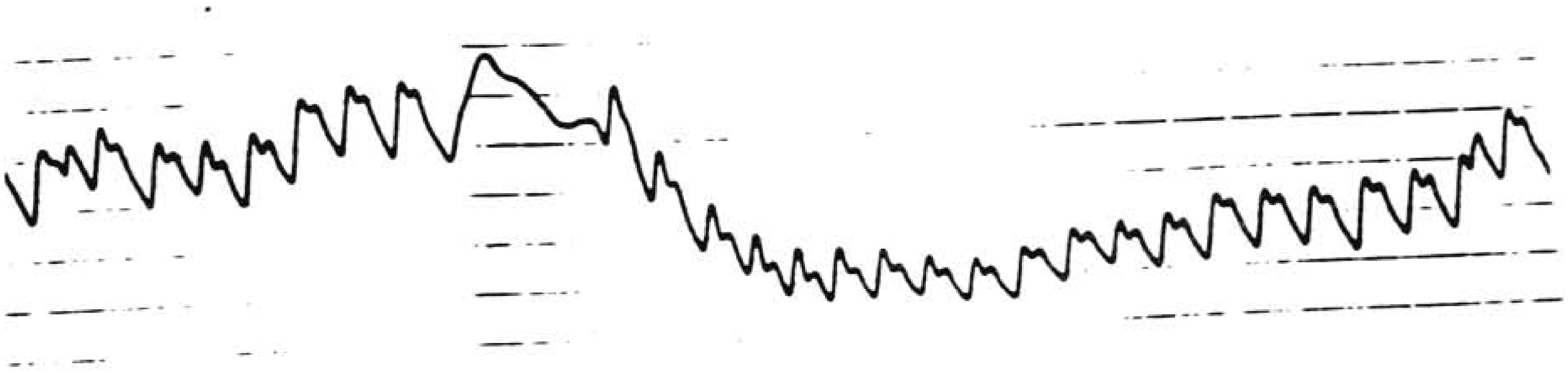


A. VALSALVA MANEUVER

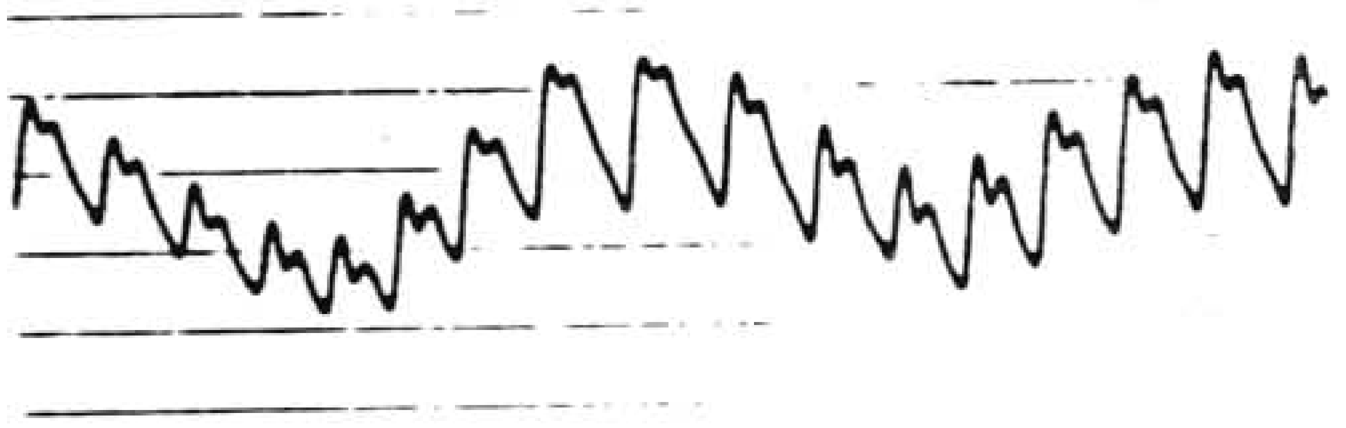


B. DEEP BREATH

SUBJECT # 11

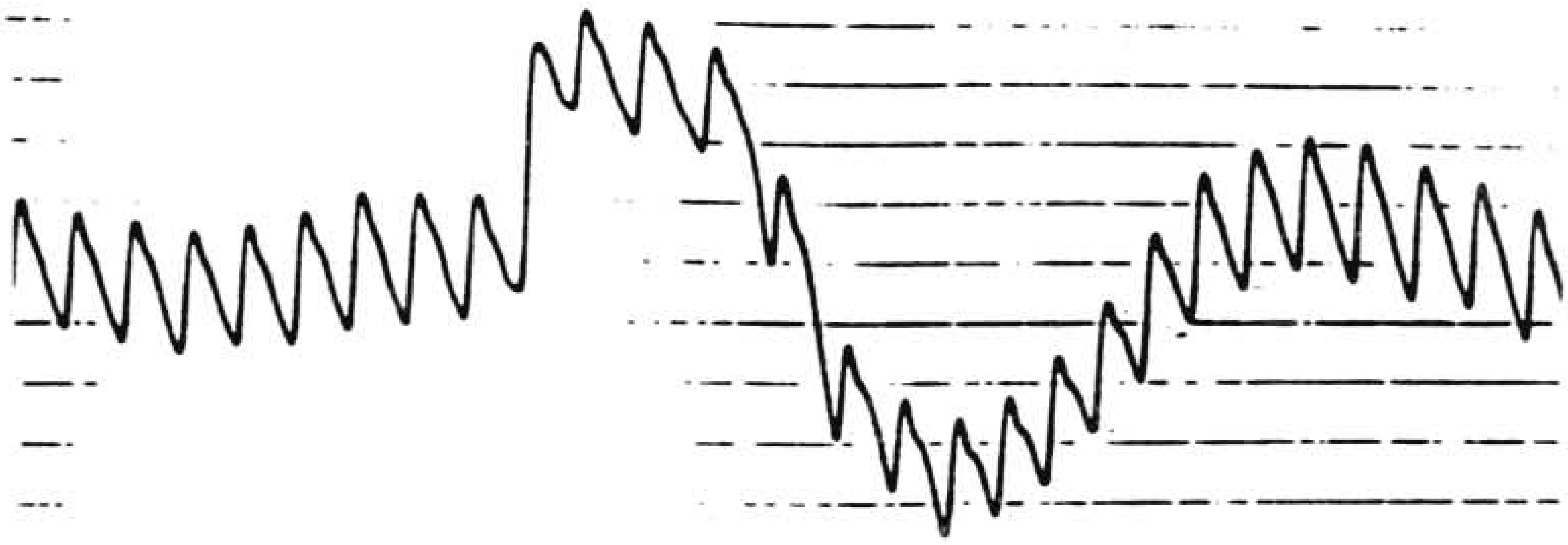


A. VALSALVA MANEUVER



B. DEEP BREATH

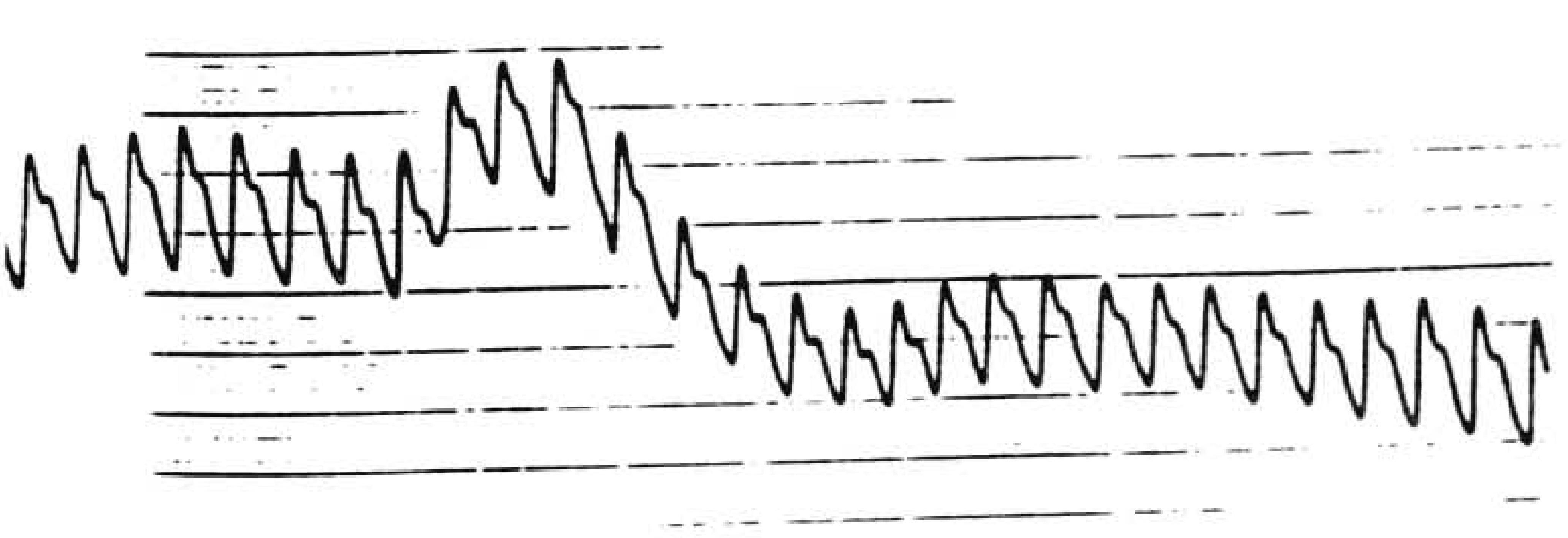
SUBJECT # 12



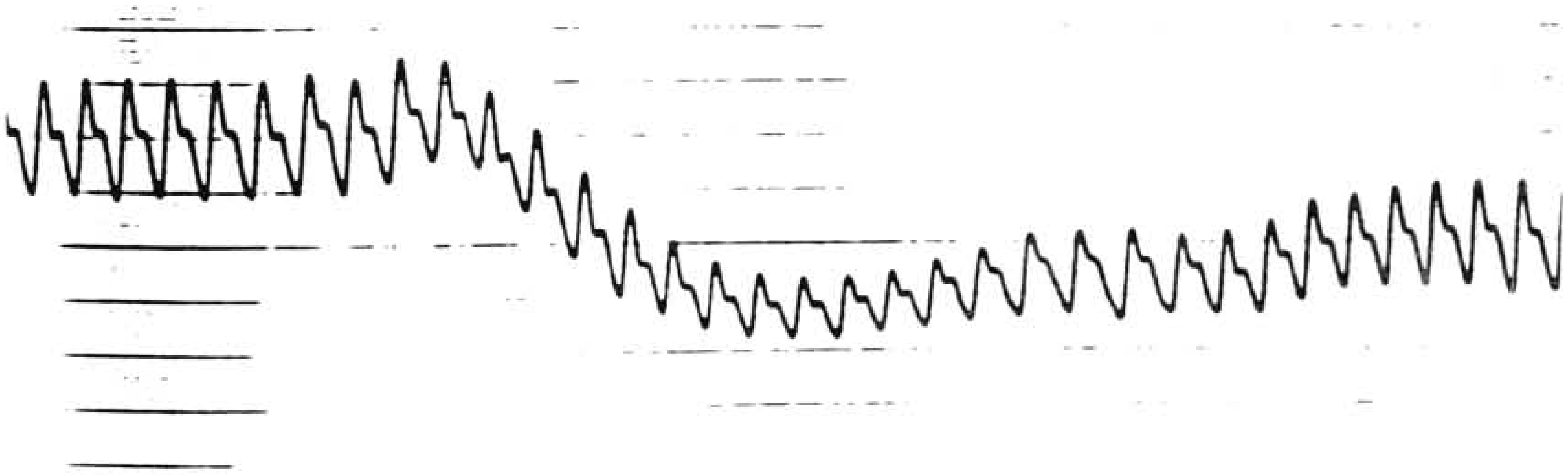
A. VALSALVA MANEUVER

B. DEEP BREATH

SUBJECT # 13

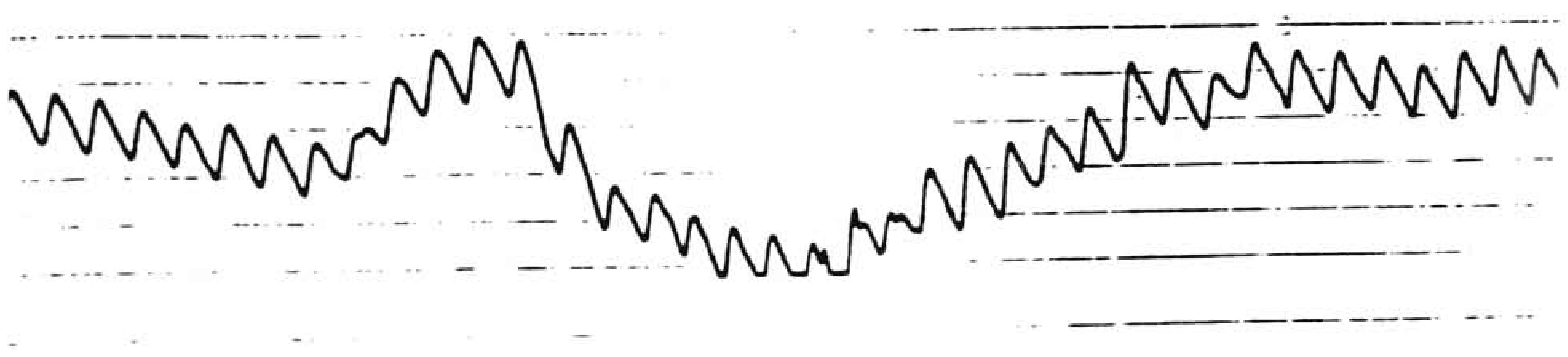


A. VALSALVA MANEUVER

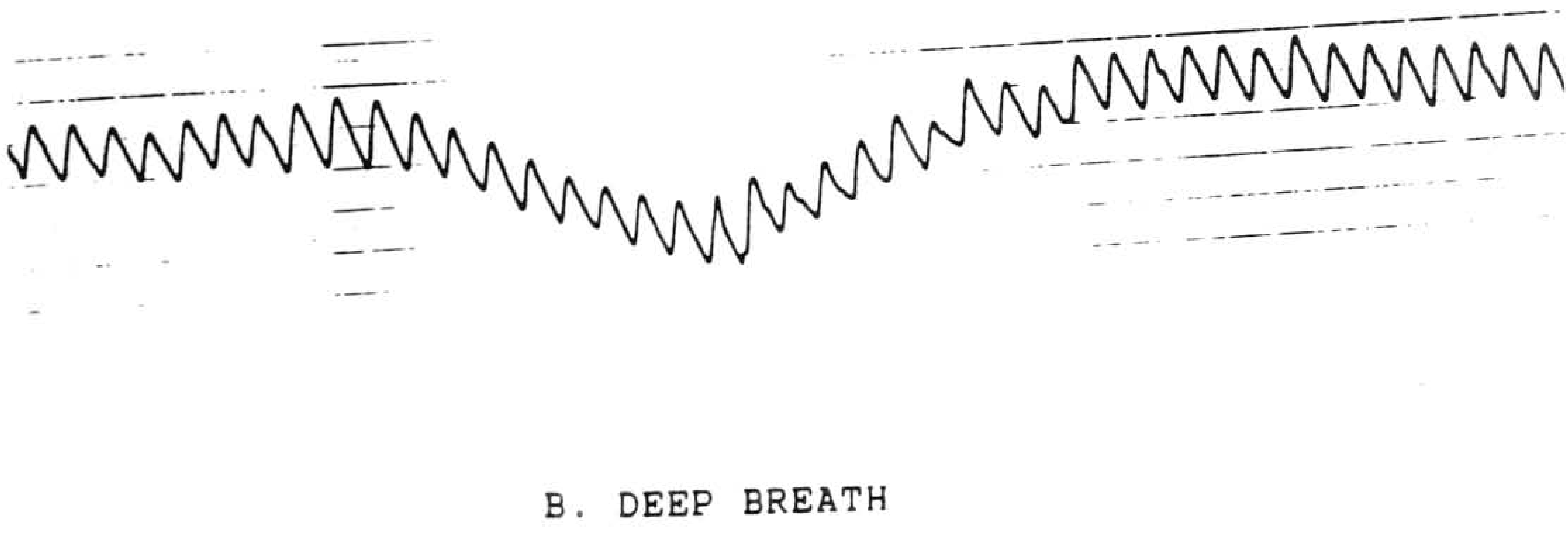


B. DEEP BREATHSUBJECT

SUBJECT # 14



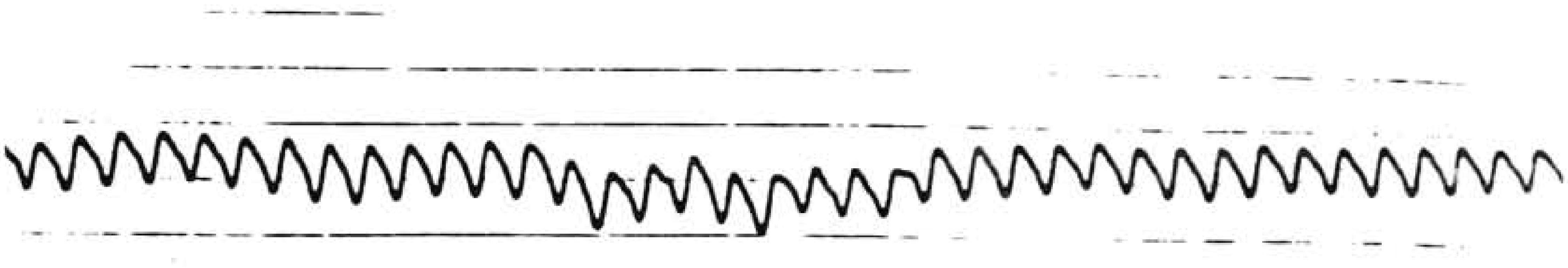
A. VALSALVA MANEUVER



B. DEEP BREATH

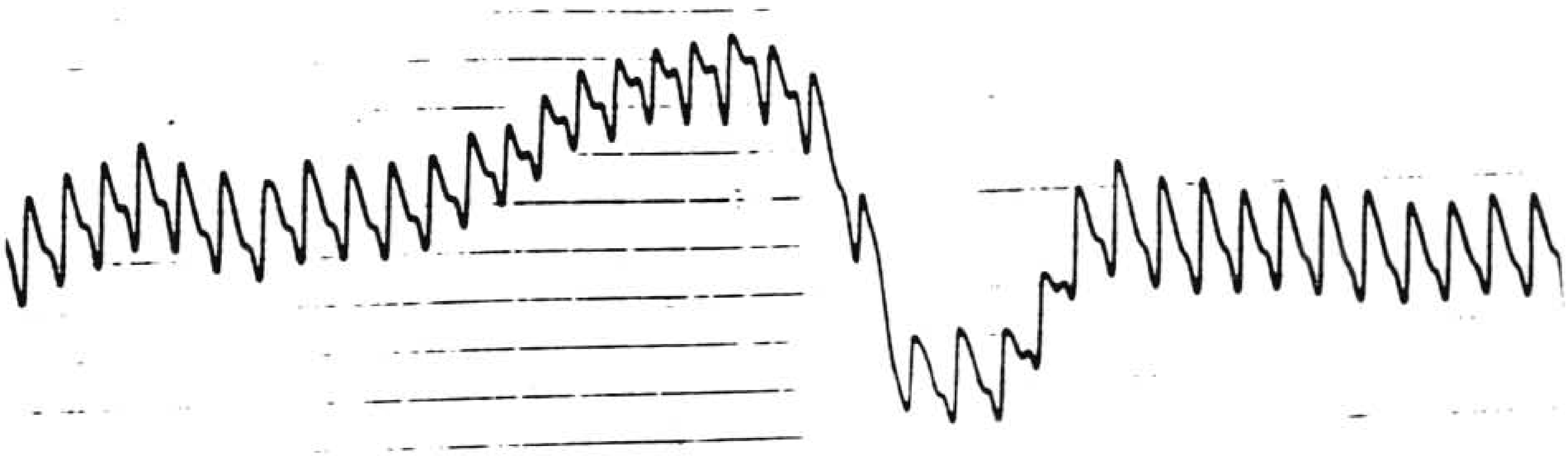
SUBJECT # 15

A. VALSALVA MANEUVER

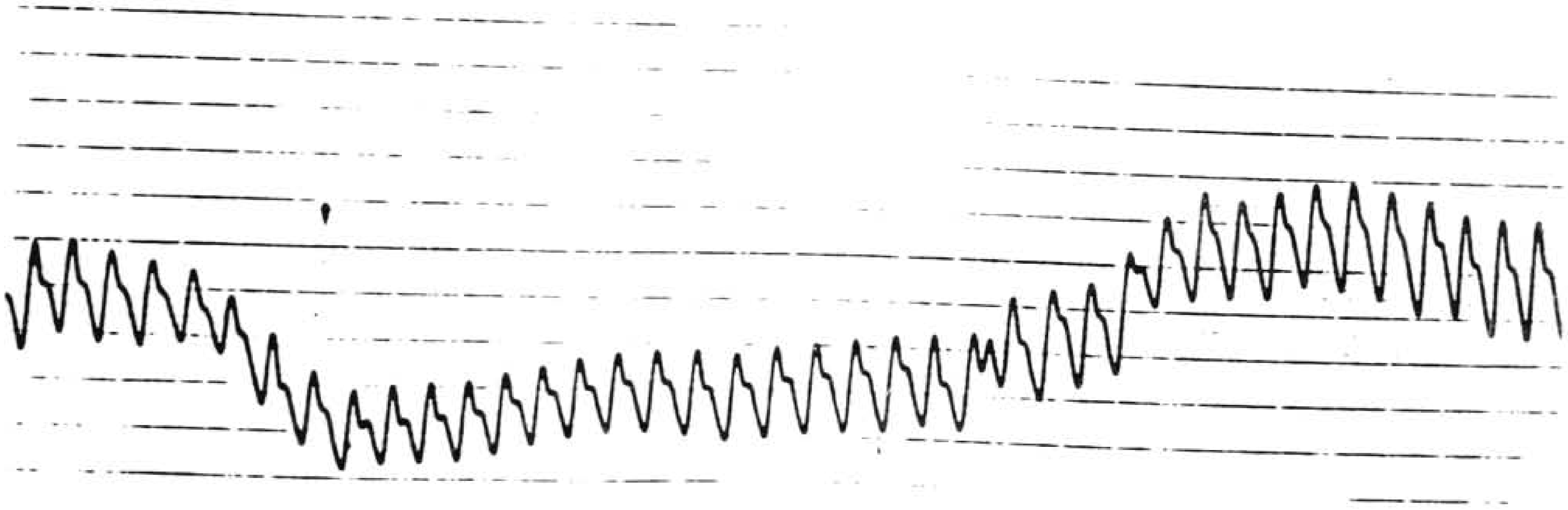


B. DEEP BREATH

SUBJECT # 16

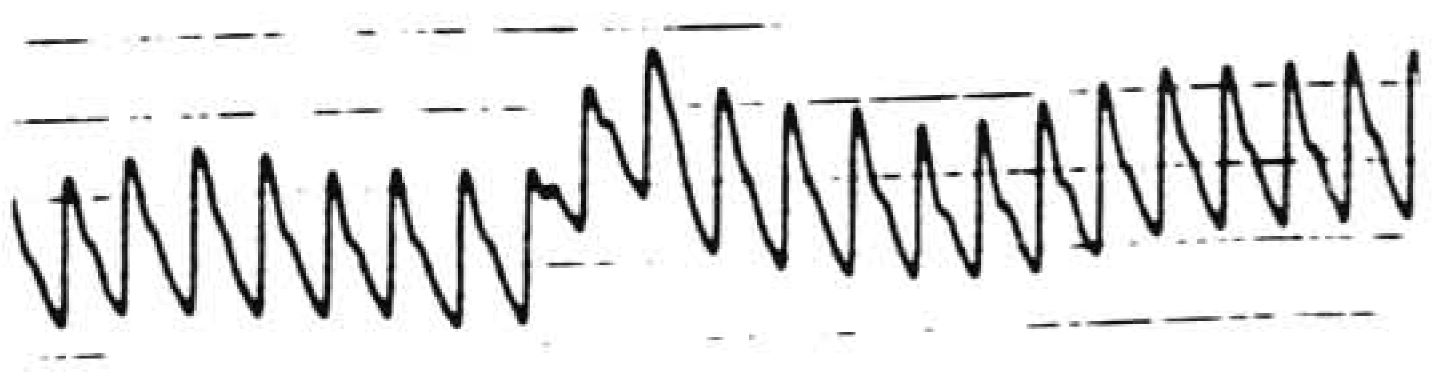


A. VALSALVA MANEUVER

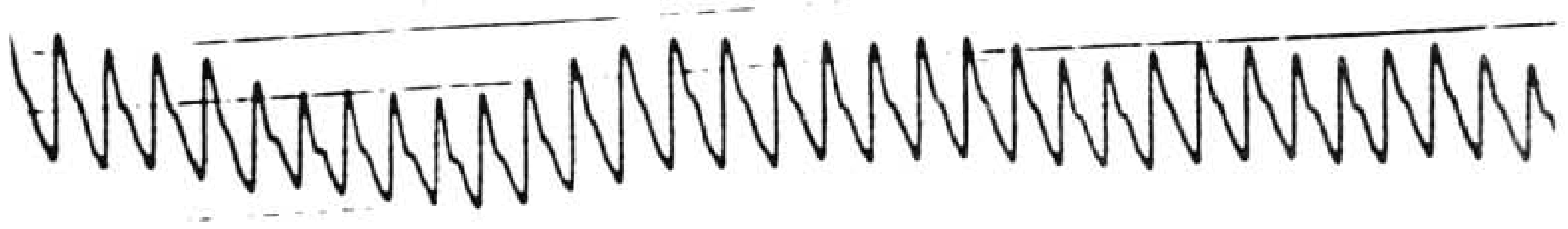


B. DEEP BREATH

SUBJECT # 17

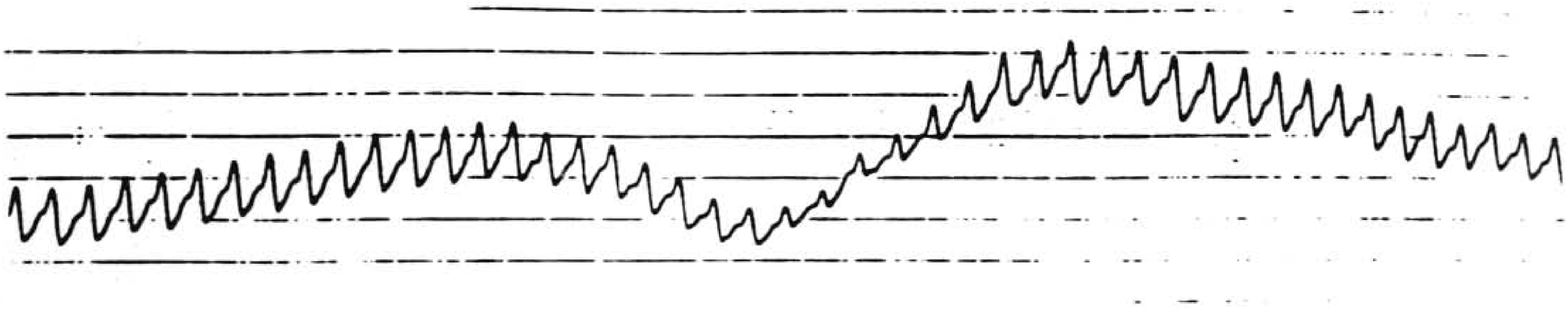


A. VALSALVA MANEUVER



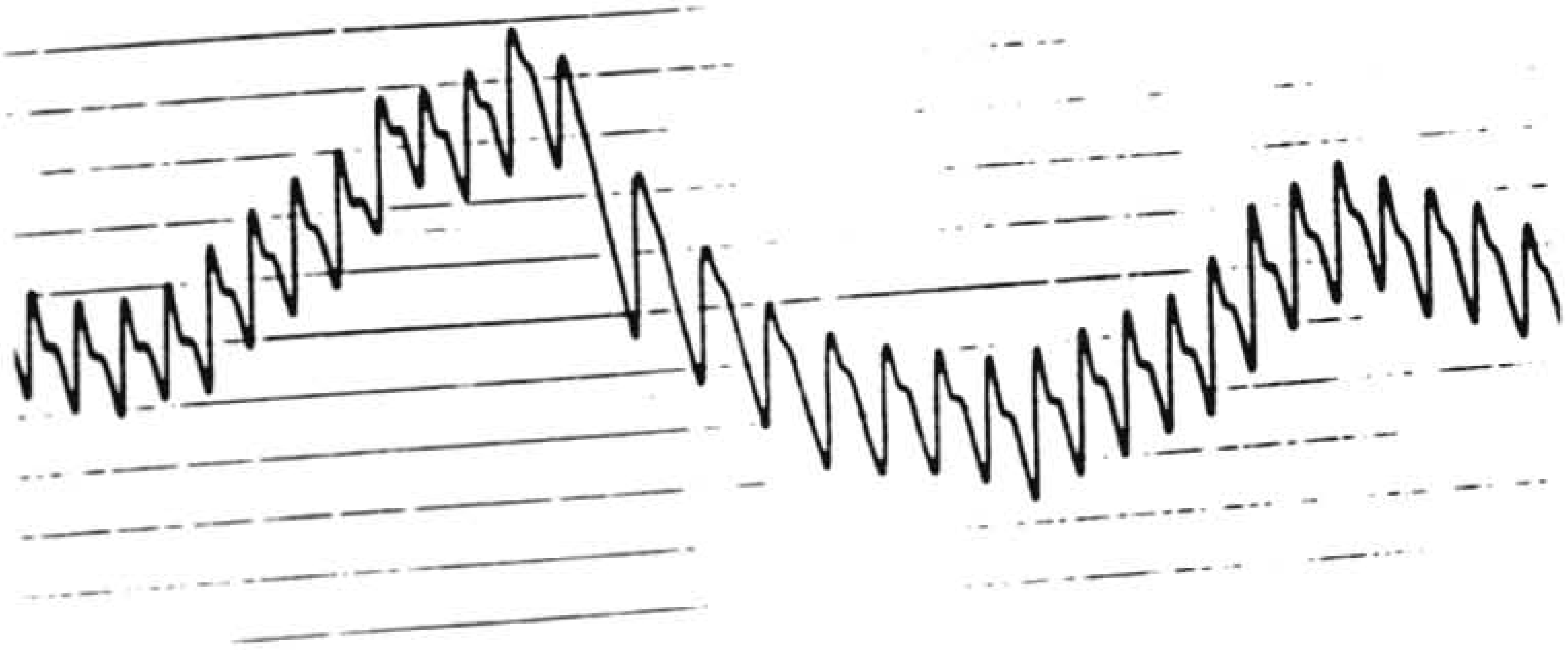
B. DEEP BREATHSUBJECT

SUBJECT # 18

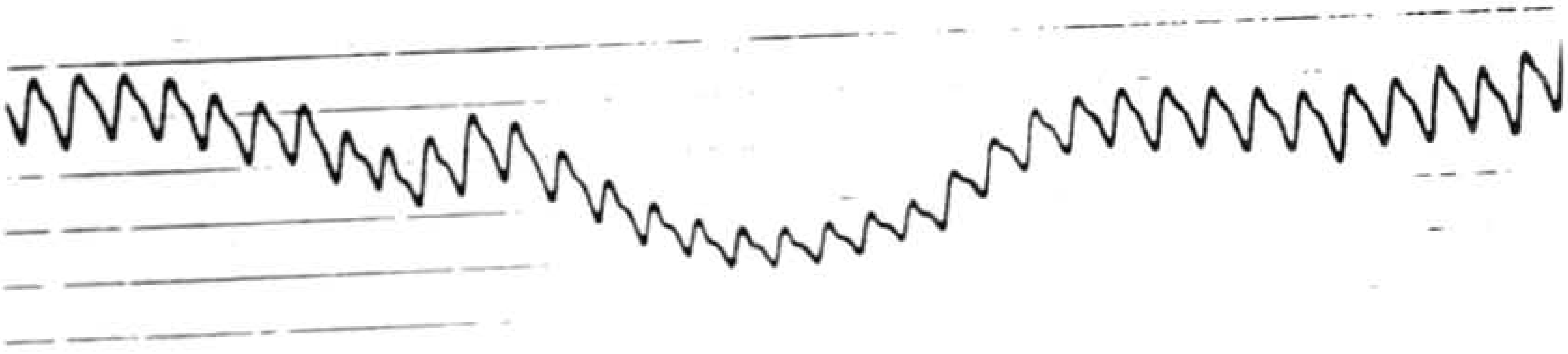


VALSALVA MANEUVER

SUBJECT # 19

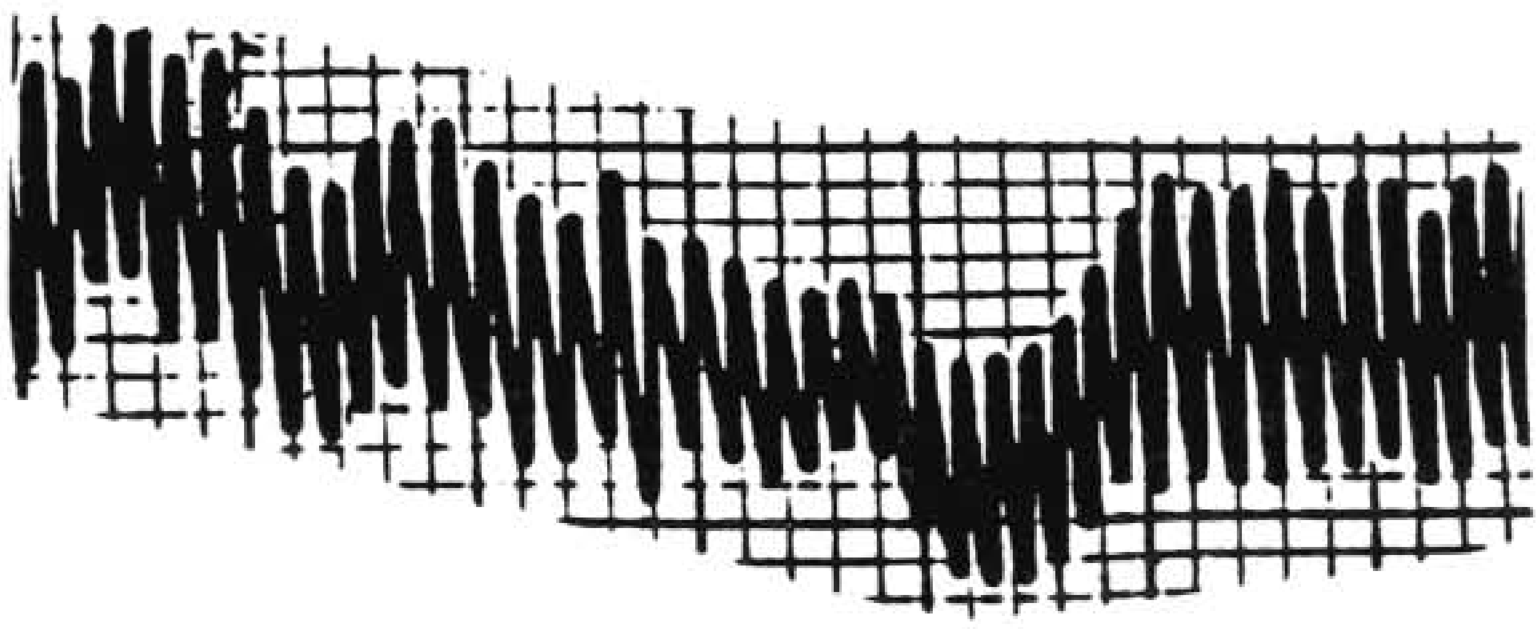


A. VALSALVA MANEUVER

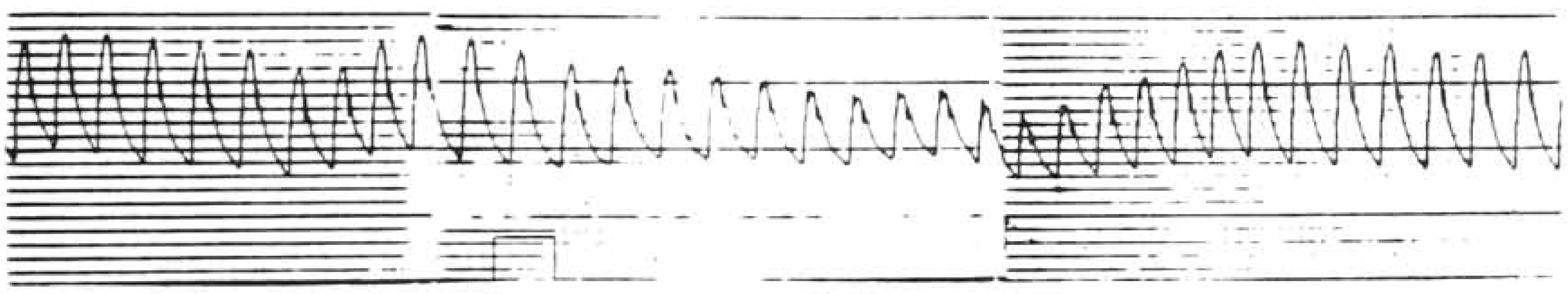


B. DEEP BREATH

SUBJECT # 20



A. VALSALVA MANEUVER FROM THE DEVICE



B. CORRESPONDING ONE FROM DIRECT METHOD (hospital)

CASE #1 , 6 / 24 / 91 (HENRY FORD HOSPITAL)