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Investigation of blood pressure measurement using a hydraulic occlusive cuff

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This thesis presents an improved oscillotonometric system for the measurement of human blood pressure. The study included:

1. The design of a hydraulic occlusive cuff,
2. The investigation of the wave forms taken from the blood pressure measurements, and
3. The design of a mechanism for the simulation of human blood pressure pulse.

In this study, an experimental system consisting of a rigid shell occlusive cuff, a constant volume displacement pump, a transducer, and a chart recorder was designed and used for data

collection.

Data from more than sixty human subjects were collected and analyzed in this study. Criteria were established to determine the diastolic and systolic pressures. The data obtained by the hydraulic scheme were compared to that achieved from the conventional auscultatory method with remarkable agreements.

The hydraulic occlusive cuff was further used in the mechanical pressure pulse simulation system. This study was done with the intention of studying the physical properties of blood vessel.

Since the pressure can be transmitted hydrostatically almost without loss of amplitude and without change of frequency, it is believed that this system would be a more accurate instrument to measure human blood pressure. Furthermore, the possibility of extrapolating more information of diagnostic significance becomes available by studying the recorded wave forms.

INVESTIGATION OF BLOOD PRESSURE MEASUREMENT USING A HYDRAULIC OCCLUSIVE CUFF

by
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TO THE OFFICE OF GRADUATE STUDIES AND RESEARCH:

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INTRODUCTION

A non-invasive technique, known as oscillometry, for measuring the human arterial pressure pulse was introduced just around the turn of the century (2,4). The method consisted of applying a pneumatic occlusive cuff around a limb and observing the dynamic pressure variations within the cuff caused by the pulsating blood flow in arteries passing through the region subject to occlusion. Criteria were established to correlate oscillographic events with the cuff pressures that matched diastolic and systolic blood pressure (i.e., the pressure corresponding to the lowest and highest values, respectively, of the pulsatile blood pressure). The oscillatory phenomenon was first detected when the diastolic pressure is exceeded due to the increasing static pressure in the cuff. The oscillation then ceases when the systolic pressure is exceeded. This technique is distinctly different from that presently used clinically. Although the clinical method (auscultatory) also employs a pneumatic occlusive cuff, it uses as criteria for systolic and diastolic pressure levels the changes in the different phases of sound pattern detected with a stethoscope while deflating the pressure in the cuff.

The method of oscillography has essentially been abandoned as a means of measuring blood pressure. The abandonment was forced by technical problems but the method merits further investigation, since as yet unresolved controversy surrounds the auscultatory technique (7).

This project presents a variation on principle involved in oscillometry which is believed to be conceptually and fundamentally advanced. A rigid volume container was used to convert the measurement from a pneumatic (compressible) scheme to a hydraulic (incompressible) scheme. Thus, a positive fluid displacement entering the cuff will result in an increase in pressure inside the cuff. Since the system would be theoretically incompressible, vascular pressure would be transmitted directly (minus compliance effects) to the hydraulic cuff. This enables us to plot accurately the volume displacement against the arterial pressure. In addition, a great deal more data, possibly of diagnostic significance, are available from a record of the pressure pulsations in a hydraulic occlusive system than that provided by the auscultatory pulse pressure measurement technique.

HISTORICAL REVIEW

The concept of measuring blood pressure in living beings was first recorded in 1733 when S. Hales measured direct blood pressure in an unanesthetized horse (1). He noticed that there were small oscillations synchronous with the heart beat while he was using a U-tube Hg-manometer for the observation. The investigations were further noted by many researchers, since then, to ascertain an accurate and reliable instrumentations for measuring blood pressure on both men and animals by direct and indirect techniques. Much of the research were focused on indirect techniques because of the invasive risk in direct methods. However, the direct readings give more accurate results.

On the pace of investigation, Von Basch was the first to introduce in 1876 (1) a non-invasive technique for measuring blood pressure by applying the water filled bag to the skin over a superficial artery. Counter pressure was applied by pressing down on the water filled bag. By palpating the distal artery, the force on the water bag is increased until the radial pulse disappears. The force was lessened until pulse reappears. The pressure indicator was noted when pulse reappeared and then disappeared. The average of the two was taken as systolic pressure. In the meantime, von Basch and Potain (1) carried out the same procedure by using air-filled instruments. The method served some clinical purposes. French physiologist, E. J. Marey, in 1876 (1), attempted to investigate hydraulic counter pressure to the forearm. The bare arm was placed inside a closed cylinder fitted with a window for viewing the arm. The pressure in the system was increased by raising a water reservoir. The pulsatile oscillations were observed in a recording manometer as the reservoir was elevated. The applied counter pressure for maximum oscillation was considered as diastolic pressure and the point when oscillation ceased was taken as systolic pressure. The use of water as an occluding medium caused a serious problem in sealing. The leaking problem encountered by Marey were later overcome by Hürthle, who in 1886 used a U-shaped bladder in a glass cylinder to apply hydraulic counter pressure to vessels in an extremity. Several other occluding devices such as Marey's single digit occluding instrument, Mosso's four finger occluding instrument, etc., were tried at that time. The oscillations were easily detectable with these devices but none of the methods received clinical acceptances and the use of oscillatory method was diminishing due to lacking of sensitive pressure recording devices.

METHODS FOR MONITORING AND RECORDING BLOOD PRESSURE

The investigations of von Basch, Potain and Marey brought up two important facts: (1) the application of counter-pressure could occlude an artery with the indication of visible oscillations, and (2) with the application of adequate pressure, the skin blanches and the color only returns to normal when the pressure is reduced below the systolic pressure level.

The above observations led to the method of arterial occlusion for the measurement of blood pressure in the human subjects and experimental animals. There are five basic methods which employ an externally applied arterial-occluding device: (1) the palpatory method, (2) the flush method, (3) the oscillometric method, (4) the auscultatory method, and (5) the ultrasound method. A brief summary of the development, complexity, validation and accuracy of each of these methods are reviewed here.

PALPATORY METHOD

The palpatory method introduced by Noris (9) is applied to measure blood pressure, routinely, when the other indirect methods fail. In this technique, the stethoscope can be replaced by electronic, mechanical or manual tactile sensing of the arterial pulse. This technique has been standardized by the American Heart Association in 1951.

In this method, the pressure in the cuff is raised, as used in the auscultatory technique, to a level about 30 mm Hg above the point where the radial pulse disappears. The pressure is then released gradually (2 to 3 mm Hg per beat) and the systolic pressure is read at the time the distal pulse first reappears regularly. The distal pulse may be manually palpated by placing the finger over the radial artery during cuff deflation.

A reinvestigation of palpatory method carried out by Van Bergen (14) in relation to direct method shows that the systolic (palpatory) pressure was found to be below intra-arterial systolic pressure by about 30 mm Hg. Another study performed by Segall in 1940 (10) reported that diastolic pressure can be determined with this palpatory technique using the thumb and the results agreed within the accuracy of 2-10 mm Hg. Rogge and Meyer re-examined the Segall's method using auscultatory method and found the correlation coefficients of 0.91 for systolic pressure and 0.96 for diastolic pressures. Geddes (3) investigated that the transition described by Segall is inconsistent because the transition is so small and hence difficult to detect. However, this phenomenon of palpatory method is still in existence and cannot be condemned without further careful investigation.

FLUSH METHOD

The flush method was introduced by Gaertner in 1899 (3). He used a small occlusive cuff placing over the finger where pressure is to be measured. With no pressure applied in the cuff, the finger was pushed into a cylinder with a rubber membrane stretched across the top. The tip of the finger will be compressed because of the elasticity of the rubber and the blood will be expelled, in the meantime out of the finger. The cuff is then inflated to above suspected systolic pressure and the finger is removed from the rubber. The cuff pressure is now slowly decreased until the blanched finger starts to return to the normal color. At this point, the occluding pressure is recorded as systolic pressure.

The flush method did not receive the clinical acceptance because of the discomfort (as pain) with the patient and difficulty of detecting the color change needed for recording pressure. The major disadvantage of this technique is that vaso-constriction of the digital arteries and, accordingly, the finger color are directly affected by a variety of extraneous factors such as pain, temperature and "emotion"(7). However, this method appears to have been most effectively applied in clinical pediatric practices when other indirect methods were not practical for new-born infants.

OSCILLOMETRIC METHOD

The oscillometric method was initially investigated by Howell and Brush in 1901 (4) who observed the relation between the arterial pressure and the amplitude of the oscillation as the counter pressure was reduced in the cuff. Von Recklinghausen found that with decreasing counter pressure, the amplitude of the oscillations were increased just below systolic pressure; slightly below the point of maximum oscilations the occluding pressure was equal to diastolic pressure(1,3). Martin in 1903 showed that the point of maximum oscillation was not coinciding with the diastolic pressure(1,3). In 1903, a detailed experimental study based on the same principle performed by Erlanger (2) brought much to encourage the use of this oscillometric method. All the studies performed above consisted of an arm occluding cuff which is used to apply a counter pressure to the radial artery. When the counter pressure in the cuff is reduced from above systolic pressure to below diastolic pressure, the oscillations in the cuff reflect amplitude changes which increase to a maximum and then rapidly fall to a minimum during the dropping of the cuff pressure below the diastolic level. A sensitive pressure gage or calibrated recording chart-devices were used in conjunction with the cuff for recording the oscillatory pulsations. Even though the oscillations were clearly observed, the diastolic pressure indication became conflicting observation and could not easily be identified. The oscillometric method could not achieve acceptance as an experimental or clinical tool without further verifications. The measuring instruments and devices available during the early investigations were also inadequate. In the meantime, the investigation was hampered because of the advancement of the auscultatory technique due to its portability and accuracy.

Recently, in connection with the research of Uzman and Wood (13), Kraudsman (7) compiled NASA investigation on an advanced technique based on using infrared photoelectric detector cells, coupled with an illuminating infrared light source and a miniature pressure capsule that is clamped to the pinna of the human ear. By using this technique, a good correlation was found between direct and indirect blood pressure. But it is yet to be recognized that this method is another version of the oscillometric method. The pressure measured is that in the ear vessels, not aortic. Nonetheless, because the photoelectric oscillometric method is easy to apply and works well, it will probably experience further growth.

AUSCULTATORY METHOD

The auscultatory method of measurement was first introduced by Korotkoff in 1905 (5) and became a universally adopted tool in clincial practices for measuring human blood pressures. The methods for inflating, deflating, pulse detection and reading of cuff pressure is thoroughly verified by several investigators and has been standardized by the American Heart Association since then.

In this auscultatory technique, an external force is applied to produce deformation of the brachial artery. The largely laminar flow in the major arteries can be changed to turbulent as a result of the vascular deformation due to this applied force. In clinic application, a pneumatic occlusive cuff is placed around the upper-arm that can be inflated to a pressure above systolic pressure which results in a flow stopage where no sound can be detected by a stethoscope. As the cuff pressure is reduced gradually, the systolic pressure is identified as the first sound is detected. Further reducing the pressure, diastolic pressure is detected when the Korotkoff sounds become dull and muffled. Thus, the noises due to turbulent flow in the human arteries are considered as the Korotkoff sounds for detecting the systolic and diastolic pressures.

Steele (11) verified the accuracy between auscultatory and direct blood pressure measurements and found out that auscultatory systolic was on average 10 mm Hg too low and diastolic pressure was on average 8.8 mm Hg too high. In 1944 Kotte, Iglauer, and McGuier (6) also investigated and verified that systolic and diastolic levels were 2 mm Hg below and 7 mm Hg above direct arterial pressures, respectively.

The different phases of sound characteristics described by Korotkoff requires a trained observer using the auscultatory technique to achieve readings of systolic and diastolic levels. The pressure recorded varies by only a few percent from those simultaneously recorded by an invasive arterial catheter connected to a pressure transducer. Such technique records only two data; the values of systolic and diastolic pressures occurring during the brief period of observation. However, such technique cannot be used by a person who has a hearing problem. Also, the arm size of the subjects plays an important role and requires correction factor to adjust the readings. The coin operated blood pressure machines, currently available for public use, have an automatic recording and display system. These machines utilize the auscultatory technique with a pneumatic cuff and the readouts display very large errors in blood pressures.

ULTRASOUND METHOD

The ultrasound method, described by Ware and Laenger, is an advanced auscultatory technique (3) in which an ultrasonic transducer and receiver are used to detect the pulsatile movement of the brachial artery wall when the pressure is decreased in the pneumatic occluding cuff. The changes in wall movement correspond to changes in occluding pressure. At systolic occluding pressure, the vessel first begins to move. Movements become larger as pressure drops, then gradually diminish. At diastolic occluding pressure, movement ceases. A small flat transducer assembly, mounted on the inside of the cuff, which transmits and receives ultrasonic energy, is used instead of stethoscope or microphone. With this method, vessel wall position and velocity of movement were obtained and it was found that velocity (Doppler) signals that clearly identifies the closing (systolic) and opening (diastolic) of the artery as the cuff pressure is gradually reduced. This ultrasonic detector provides reliable monitoring of the opening and closing vessel sounds during cuff deflation and accordingly, valid detection of both systolic and diastolic pressures. Several investigators validated the studies (7) by using the Doppler ultrasound method and compared the results with direct intra-arterial cannulation and reported the average error in systolic pressure +0.1 ±2.2 mm Hg, and -0.3 ±2.1 mm Hg for diastolic pressure. These pressure levels can be significantly identified even in an extremely noisy environment.

Reviewing the foregoing methods of blood pressure measurements, they all provide an unambiguous indication of systolic pressure. But, only the auscultatory method provides an indication of diastolic pressure with acceptable accuracy. However, none has completely overcome all of the basic deficiencies such as varying degree of accuracy and reliability. The palpatory method served some clinical purposes but the indication of pressure pulse was unstable and the transition was very small. The flush method was applied in pediatric practice but it was difficult to detect the appropriate color change in the skin for reading the needed pressures. In the oscillometric technique the instrumentation involved during the early research period were not sufficient to indicate the pressure reading sensitively. During the period of testing, the oscillations were clearly observed but due to the conflicting observation of detecting diastolic pressure, this method could not obtain clinical acceptance and it was abandoned in favor of auscultatory technique.

The auscultatory technique, which identifies both the systolic and diastolic pressures, has dominated the daily clinical practices. The correlation of the pressure readings has been found in good agreement with the intra-arterial methods. However, the successful recording of pulse pressure by this technique depends on the auditory acuity of the observer, the lack of interfering acoustic noise of certain frequencies during the observation period, and the adequacy of the auditory pickup system with respect to frequency response characteristics. Also, the cuff size used plays an important factor when applied to children with small arms or adult subjects with larger arms. With a standard cuff applied to subjects with arm circumference ranging from about 15 to 50 cm, the correction factor extending from as much as -25 mm Hg to +15 mm Hg are typically required for agreement with true arterial pressure.

Thus among the two distinct methods of measuring human arterial blood pressure, (1) direct or invasive, and (2) indirect or non-invasive, the indirect method has become universally used in both clinical and experimental environments. However, because of the complexity of the instrumentation and methodology of indirect techniques which leads to inaccuracies and certain unreliabilities, more careful examination into this area is required.

COMPONENTS AND SYSTEM DESIGN

The overall system design in this project is described in three phases.

1. Design of a hydraulic occlusive cuff
2. Design of instrumentation system
3. Design of a mechanism to simulate human arterial pressure pulse

DESIGN OF THE HYDRAULIC OCCLUSIVE CUFF

First of all, a specially designed hydraulic cuff is developed and constructed. The unit consists of an enclosed cuff using water to transmit pressure. The cuff is designed to allow the insertion of a human forearm. Several alternate designs were investigated before the final system was chosen. Major problems encountered during the construction of the cuff were due to the unavailability of proper bladder material as well as proper bonding glue to withstand the fluid pressure applied.

The design of the hydraulic cuff system is developed by considering the following important requirements:

1. The hydraulic system should be completely leak proof.
2. The shell of the cuff should be rigid.
3. It should be convenient to use by clinical personnel while comfortable for patients.
4. The pressure transducer used should respond sensitively to small pressure changes.
5. There is a need of an accurate recording system.

Figure 1 shows the detail of the cross-sectional view of the hydraulic occlusive cuff. The photograph of the cuff is shown in Figure 2. A rigid transparent circular tube (3.5" i.d. and 5.0" long) made of plexiglas is used as the outer shell of the pressure cuff. The applied hydraulic pressure will be transmitted over the length of 2.7" only. The transparency facilitates the detection of air bubbles in the system. The inner diameter of the tube is selected in such a way that it fits to an average human forearm. Two holes opposite each other are drilled on the cuff as shown, one for connecting the system from the pump and the other to a pressure transducer. A domed shape arrangement with a hole on the top of the tube is provided to remove the air bubbles easily.

A thin membrane tube of highly flexible rubber material is placed around the compression rings at both ends of the rigid cuff (as shown). This helps to seal the torus of both ends. The compression plugs are tightened against the compression rings with nuts and bolts to seal the rubber bladder tight. Thus the entire system can become leak proof.

Since the human arm varries, special attachments were used to prevent side thrust due to those rather tapered shaped forearms. Rubber plugs of constant outside diameter which is equal to the inner diameter of compression plug and rings are used for this purpose. Different sizes of rubber plugs were prepared in order to fit various sizes of forearms. A plug is placed at each end of the cuff to seal the gaps between the forearm and the cuff. The rubber plugs were made

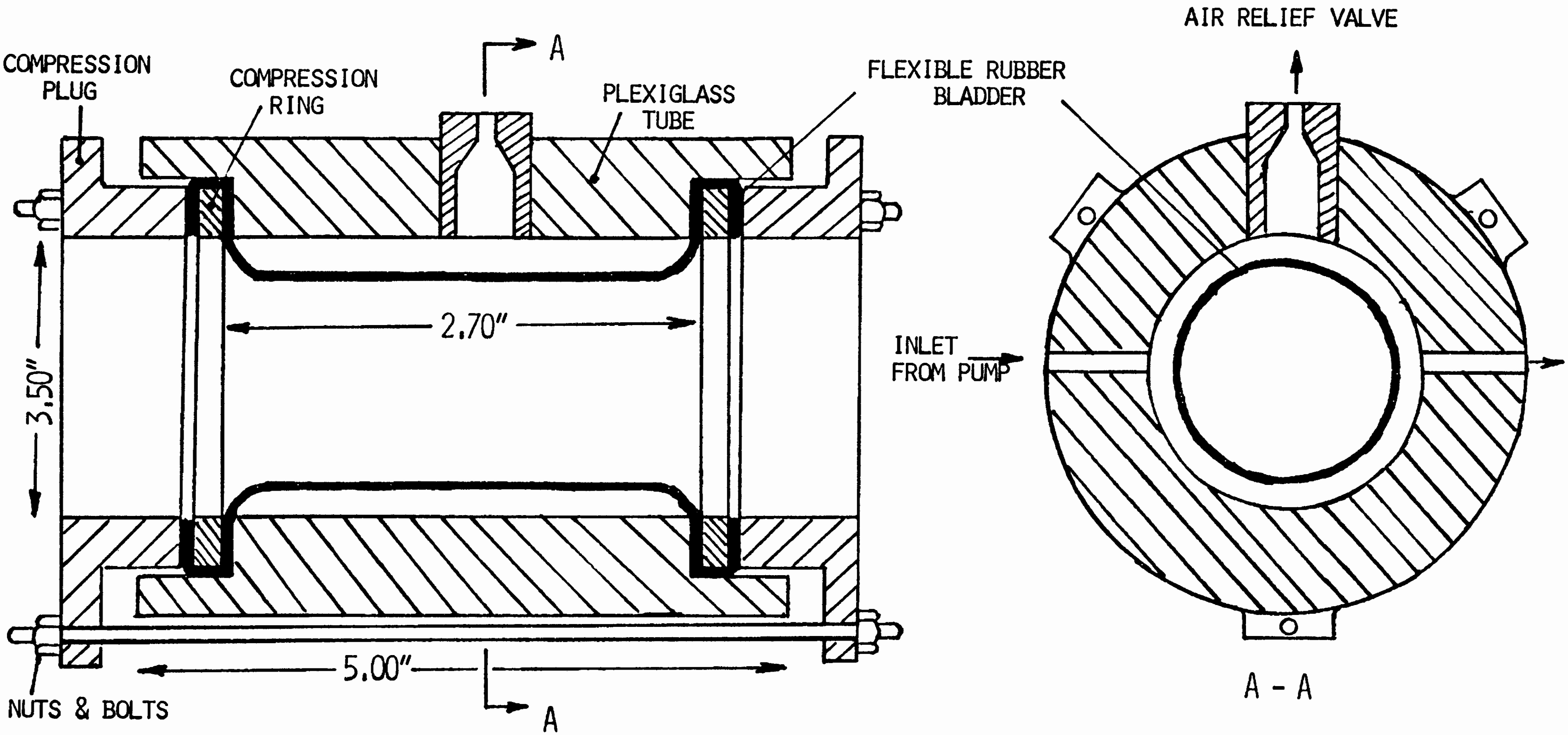

FIGURE 1. HYDRAULIC OCCLUSIVE CUFF

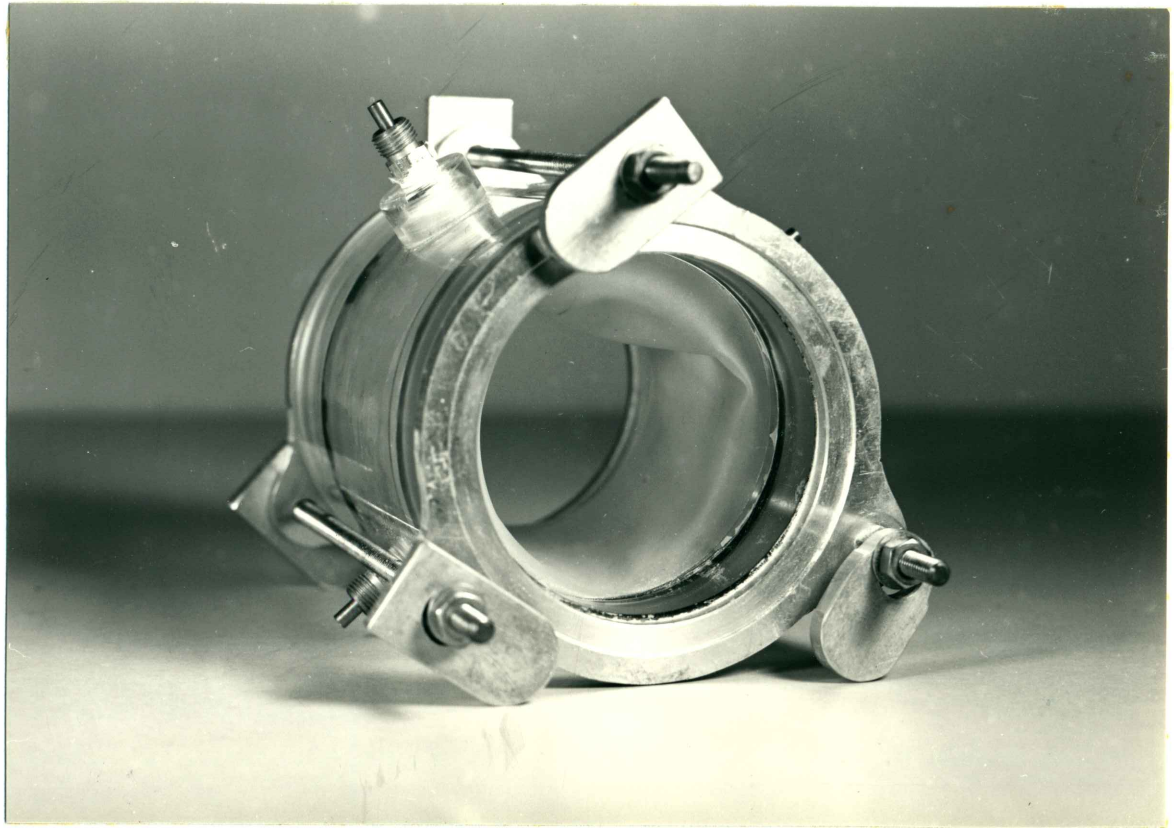

FIGURE 2. PHOTOGRAPH OF THE HYDRAULIC OCCLUSIVE CUFF

from liquid rubber. Figure 3 shows the detail of the forearm and cuff using the side thrust attachments (rubber plugs).

DESIGN OF A MECHANISM TO SIMULATE PRESSURE PULSE

Secondly, a mechanical working model for simulating human arterial pressure pulse was designed and constructed. The mechanism was designed according to the standard human arterial pulse contour. Figure 4 shows the installation diagram for complete experimental set up. Simulated arterial pressure pulse is created in the latex tubing. Static pressure head is maintained by the water level in the reservoir. Oscillations and pressures are caused by the movement of the piston in the cylinder. The piston is actuated by the lever arm which is driven about the fulcrum by the action of the cam. The design of each individual mechanical component is presented as follows:

1. CAM

   With reference to the standard human pulse contour (12), an enlarged cam profile is drawn and designed (8) for each rise and return of 2" stroke. To simulate the best pressure wave form as in Figure 5 a rise of 128°, return of 36°, constant of 52°, and return of 144° is established. Figure 6 shows the configuration of the cam. It was done by hand filing, later polished with sand paper to achieve smooth surface finish and close accuracy. The polishing work was needed to exclude any vibration during the operation. This cam is mounted on the shaft of a dc motor.

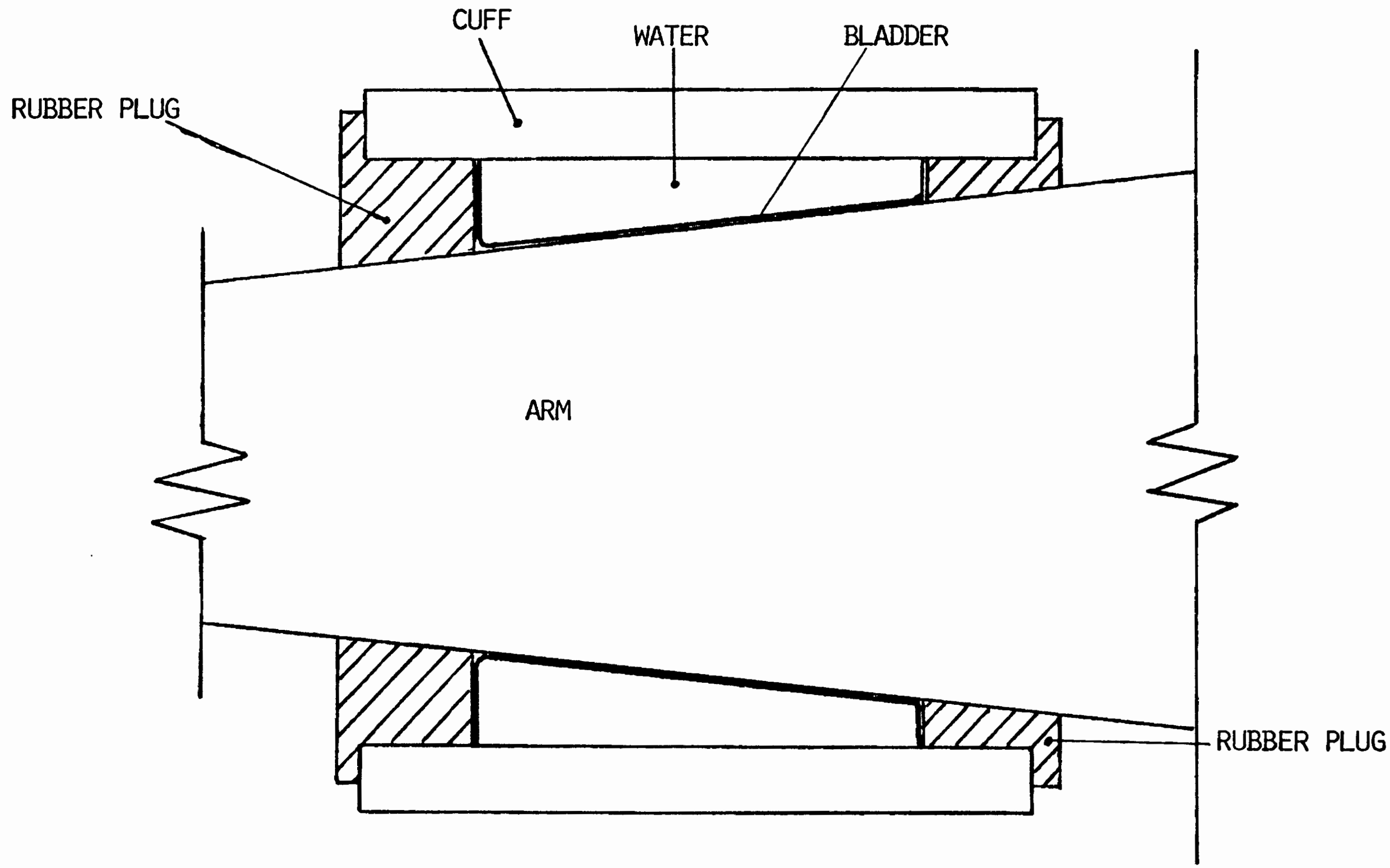

FIGURE 3. DETAIL OF FOREARM WITH RUBBER PLUG ATTACHMENTS

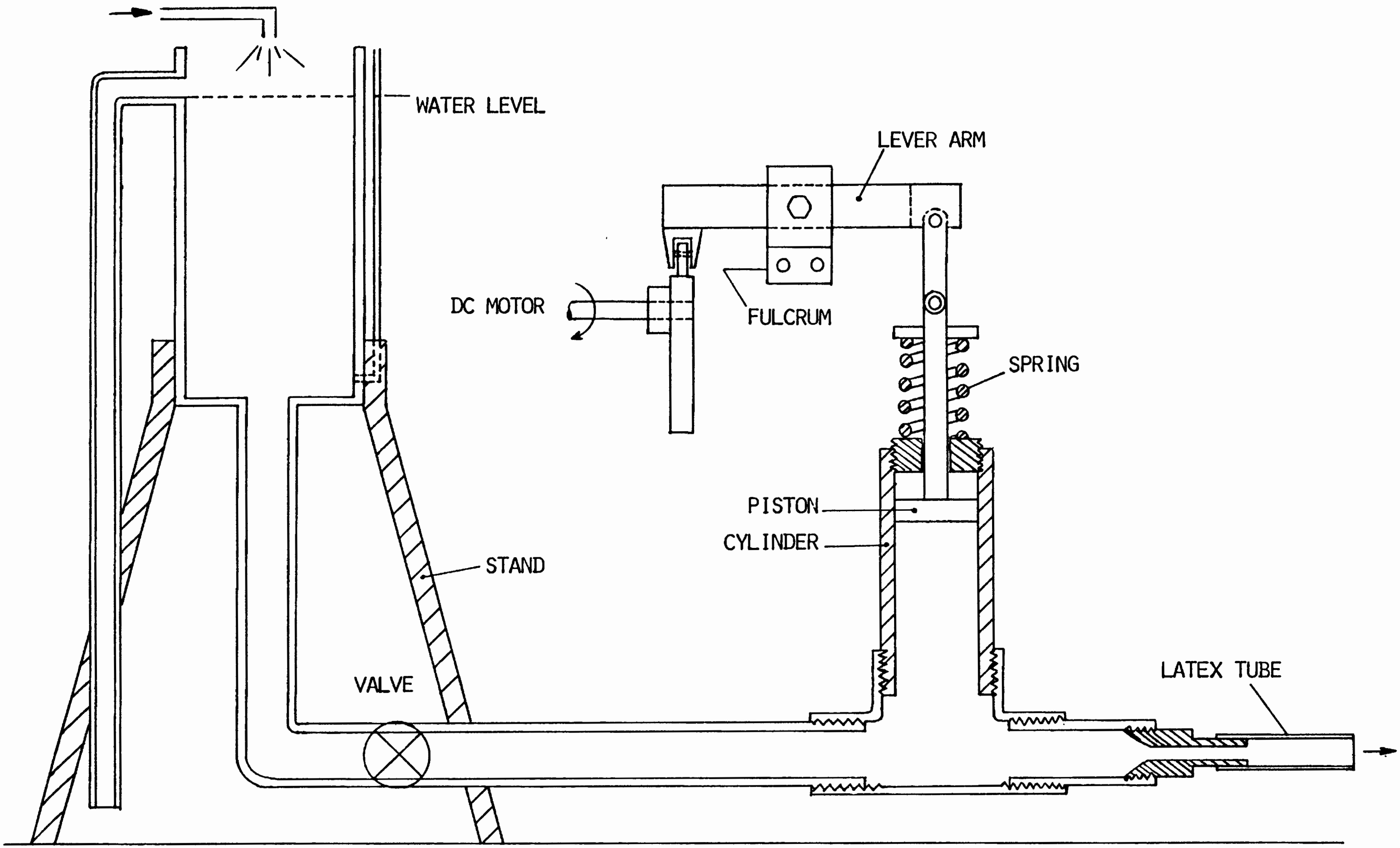

FIGURE 4. EXPERIMENTAL SET-UP TO SIMULATE BLOOD PRESSURE WAVE FORM

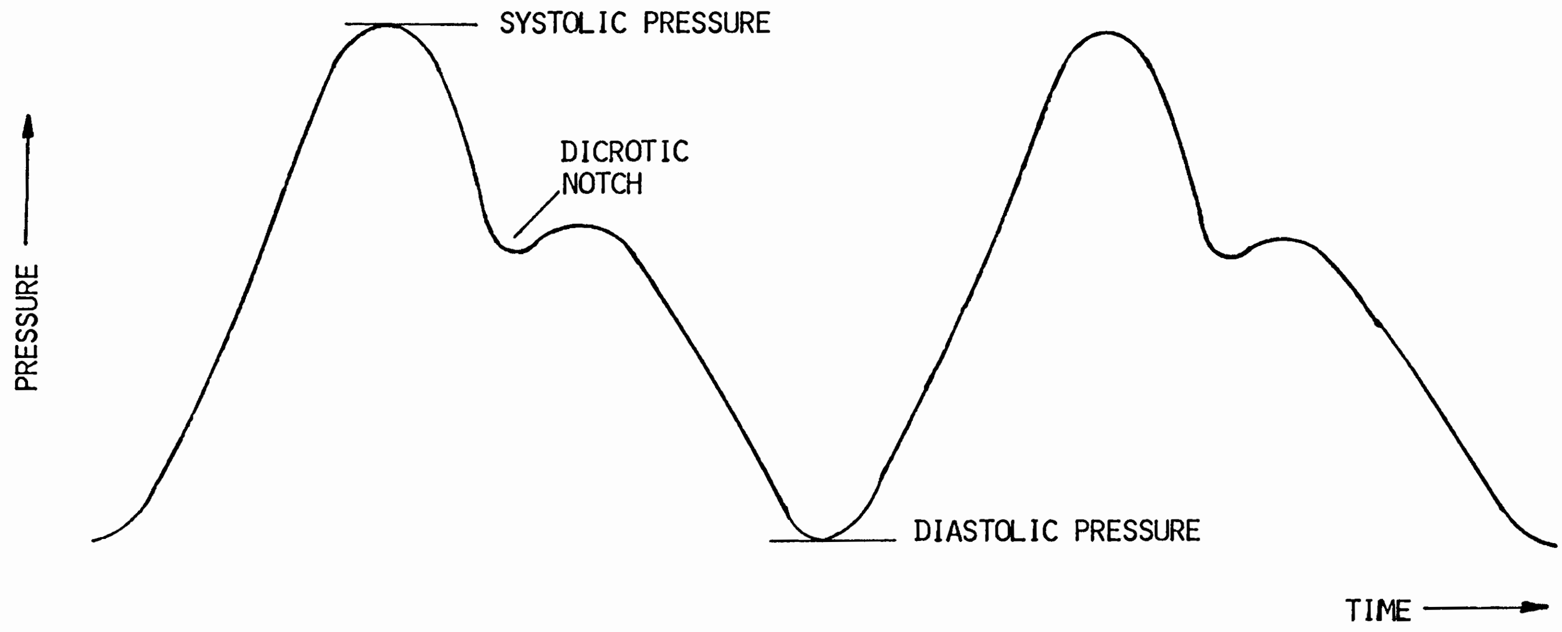

FIGURE 5. HUMAN BLOOD PRESSURE WAVE FORM

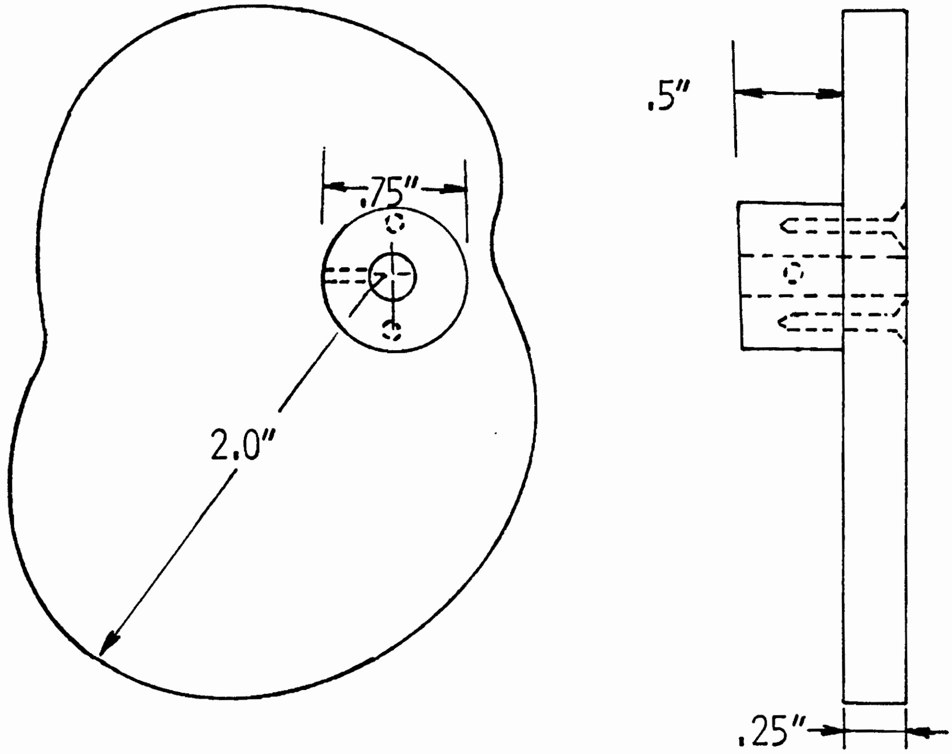

FIGURE 6. CAM CONFIGURATION

2. LEVER ARM

Figure 7 shows a lever arm of length 8" with a cam follower attached at one end and a linkage joint at the other end. This lever arm is supported by a fulcrum with frictionless pivotal mechanism. A small roller bearing is mounted in the follower to serve the function of a roller. During the rotation of cam, the motion is transmitted to the linkage via the lever arm resulting a reciprocating motion. The piston rod and the linkage is connected by a pin. The rotation of cam has direct control on the movement of the piston to obtain desired pulse contour.

3. FULCRUM

Figure 8 is the detail plan and cross-sectional view of the fulcrum. The lever arm can be held tightly by two screws to protect it from sliding during the operation. The stroke of the piston can be readjusted by changing the arm length on either side of the lever arm. Two side plates with shielded bearings hold the rectangular hollow piece tightly with the help of two bolts on each side (as shown). The shielded bearing provides smooth operation. The overall fulcrum assembly is mounted on a metal base plate for stability.

4. PISTON & CYLINDER

A steel hollow cylinder of 1" internal diameter with 1/16" wall thickness was selected. The cylinder has a maximum stroke of 3.5". The hollow plug attached to the top of the cylinder helps to guide the piston rod. The plug also

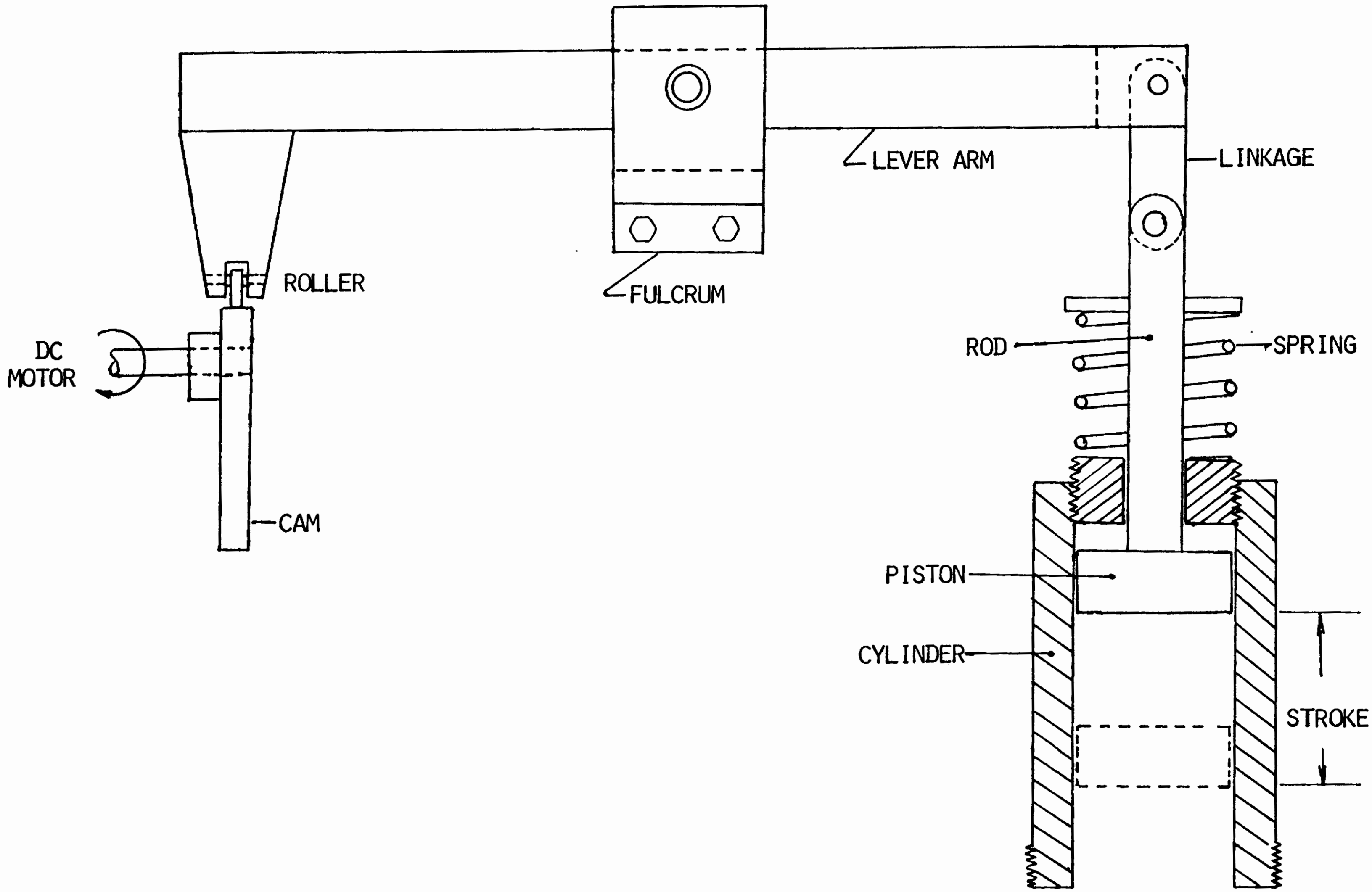

Figure 7. Pressure pulse mechanism and pump detail

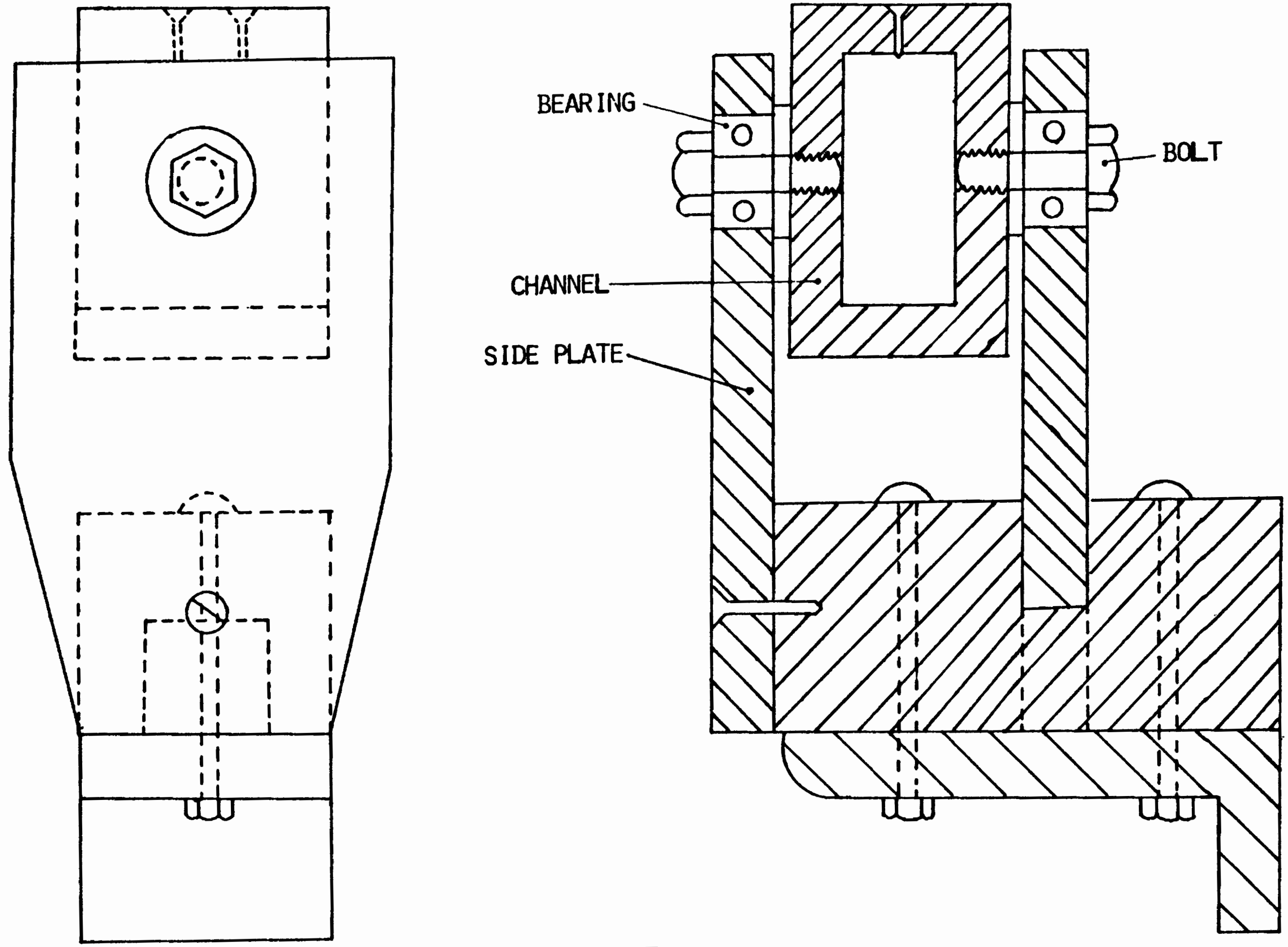

FIGURE 8. FULCRUM DETAIL

functions as a seal to prevent the water from leaking. A T-joint is also attached at the bottom of the cylinder to connect the pipe coming from the reservoir and flowing towards the latex tube. A 1" diameter self lubricating piston (Teflon material) inside the hollow cylinder reciprocates according to the motion of the cam. A spring is also used as a return mechanism for the piston.

5. RESERVOIR & PIPINGS

A reservoir of constant head (150 mm Hg) is installed. The water inlet to the reservoir is connected to a regular water tap. The outlet connects to a 2" internal diameter galvanized pipe. It further connects to a T-joint attached at the bottom of the cylinder. The other end of the T-joint connects to a 2" pipe that reduces to a 1/4" diameter fitting. Lastly, the latex tube is connected to the fitting as a simulated blood vessel. A manometer is also installed at the end of the latex tube as a visual aid for identifying the head loss and the pressure oscillation in the system.

EXPERIMENTAL SET UP AND TEST PROCEDURES

The experimental set up and test procedure for recording the human blood pressure and the testing using the mechanical pressure pulse pump are described as follows:

RECORDING HUMAN BLOOD PRESSURE

The experimental system for measuring human blood pressure consists of a hydraulic occlusive cuff, a constant volume displacement syringe pump, a pressure transducer, and a chart recorder. This experimental system block diagram is shown in Fig. 9. A photograph of the experimental setup is also shown in Figure 10. The "heart" of the system is the occlusive cuff which is connected to the pressure transducer and the syringe pump. The chart recorder provides a record for subsequent derivation of pulse pressure. An air relief valve is attached on the top of the cuff in order to remove the air bubbles from the system.

The test procedures for a human subject are as follows:

1. Fill water (from a reservoir) in the syringes by reversing the pump (thus providing adequate water for operation).
2. Remove any air bubbles contained in the system.
3. Carefully insert the subject's forearm into the cuff.
4. Insert a suitable side thrust attachment (rubber plug) at both ends, if needed, to seal the gaps between the arm and the cuff as shown in Fig. 3.
5. Introduce sufficient water to bring the elastic tube into contact with the forearm.

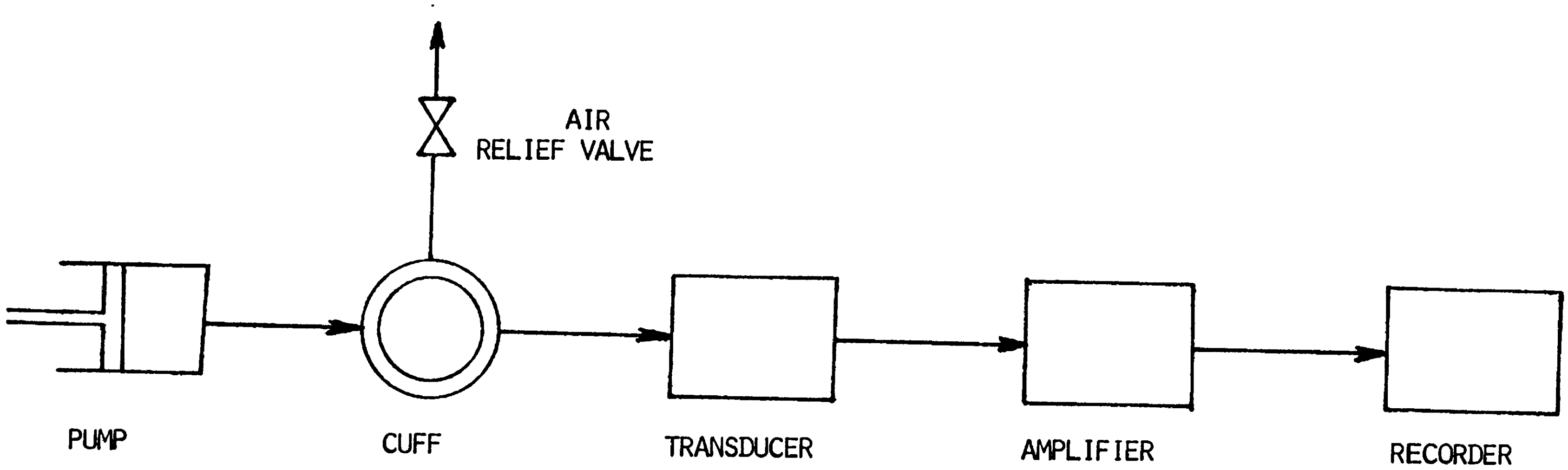

Figure 9. Recording system block diagram

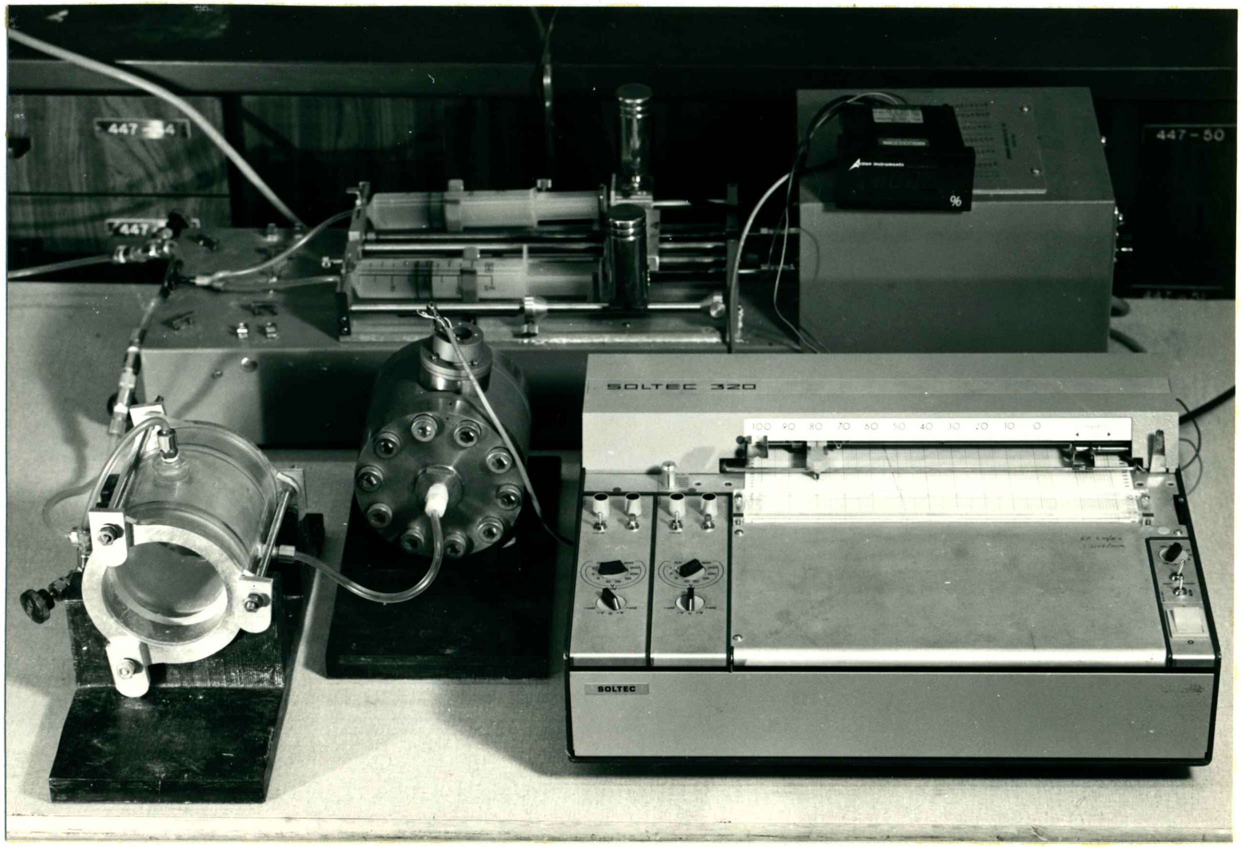

FIGURE 10. EXPERIMENTAL SETUP

6. Close the valve through which the water is flowing from the reservoir. At this time, the forearm experiences a pressure equal to the head in the reservoir.
7. Inflate the bladder by actuating the pump while the subject is at rest. Start the chart recorder simultaneously.
8. Watch carefully the hydraulic pressure to a point judged to be well above systolic pressure and reverse the pump in order to bring the pressure in the cuff back to ambient.
9. Perform a second subsequent trial immediately in an identical fashion.
10. Turn off the pump and the chart recorder, then withdraw the forearm.
11. Record the subject's blood pressure by the conventional method (auscultatory) immediately after the measurement by the hydraulic scheme.

During the period of pressurization, the pressure pulse is picked up by a pressure transducer. The amplified voltage depicting blood pressure wave forms are recorded on the strip chart recorder. The voltage recorded on the chart is calibrated to read in mm of Hg as shown in Fig. 11.

TESTINGS USING MECHANICAL PRESSURE PULSE PUMP

The experimental set-up for recording blood pressure is also used for monitoring the simulated arterial pressure pulse. The set-up system is shown in Fig. 4. A schematic diagram of the test set up is shown in Fig. 12. An oscilloscope was used to check the frequency and amplitude of the mechanical pulse during the experiment. Beef kidney

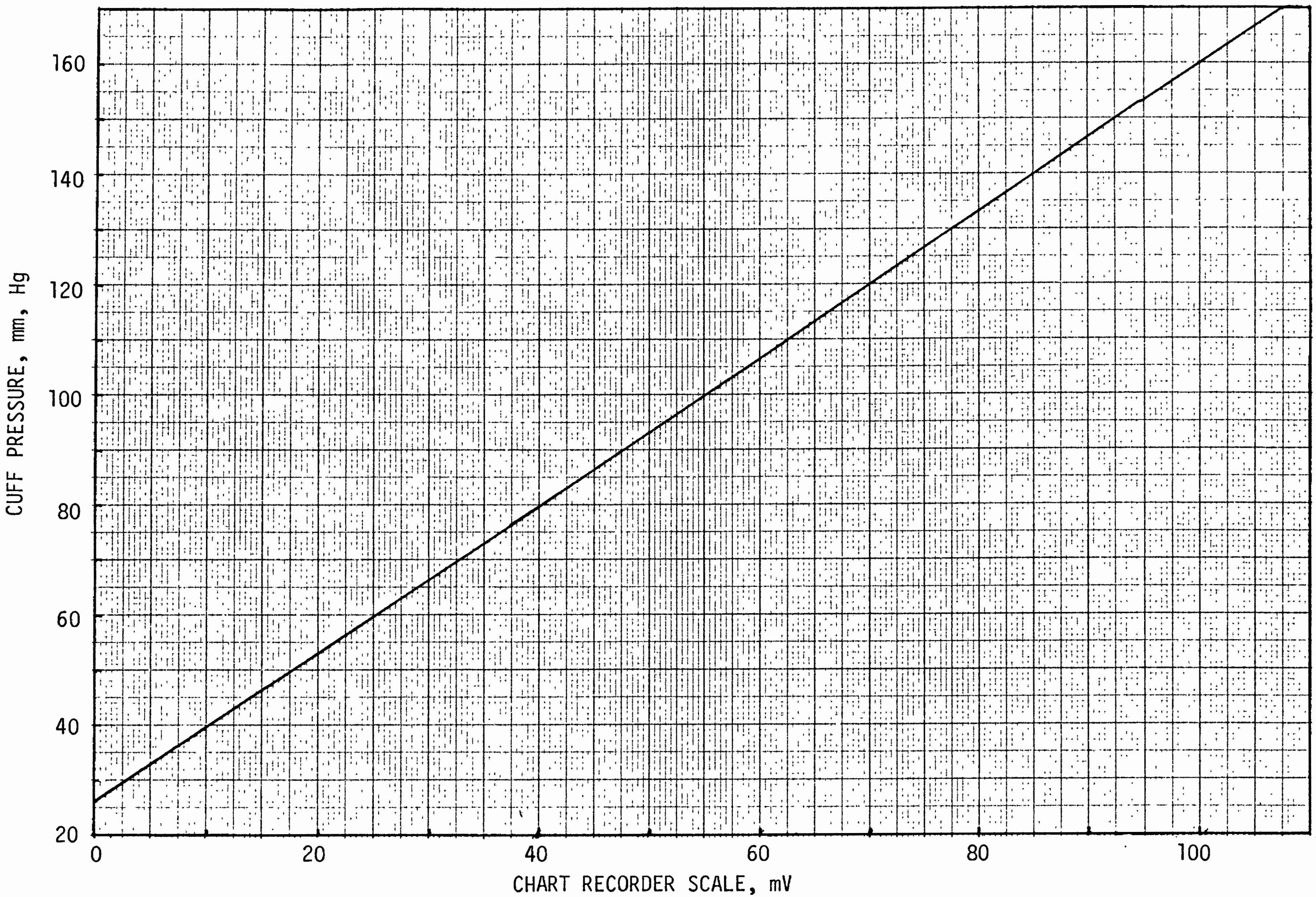

FIGURE 11. CALIBRATION CHART

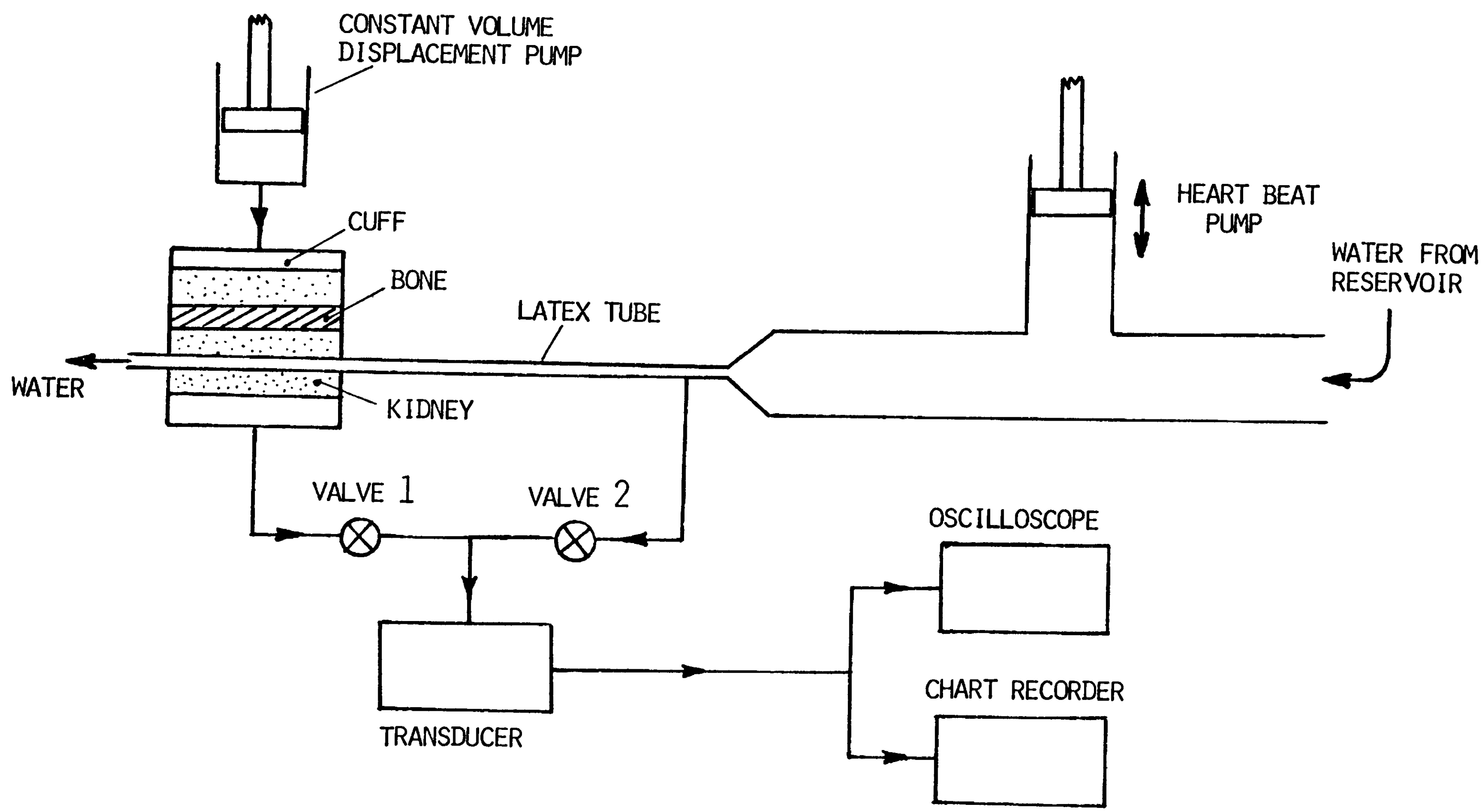

FIGURE 12. SCHEMATIC TEST PROCEDURE FOR SIMULATED ARM

is found to have sufficient elastic behavior which somewhat resembles human arm muscles under the test arrangement. The blood vessel is a latex tube implanted in the beef kidney (as arm muscle). There is a 1" diameter wooden rod inserted in the middle of the kidney to simulate the arm bone.

A constant head reservoir is filled with water during the operation of the mechanical pump. The water from the reservoir flowing through the latex tube simulates the blood flow.

The experiment is performed by operating two pumps, one to provide arterial pressure waves and the other to inflate the hydraulic cuff. To simulate the condition of arteriosclerosis (which causes vessels to become restricted), the water flow in the latex tube was restricted by clamping the tube upstream from the cuff. The results are recorded in the chart. Comparisons have been made on restricted vs. unrestricted latex tubes.

EQUIPMENT USED

The following equipment was used for the experiments involving blood pressure measurement:

1. HARVARD SYRINGE PUMP

   A constant volume displacement pump equipped with multi-speed forward and reverse transmission arrangement (by a gear reduction mechanism) is used for supplying water thus pressure to inflate the rubber bladder. Figure 13 shows the photograph of the pump.

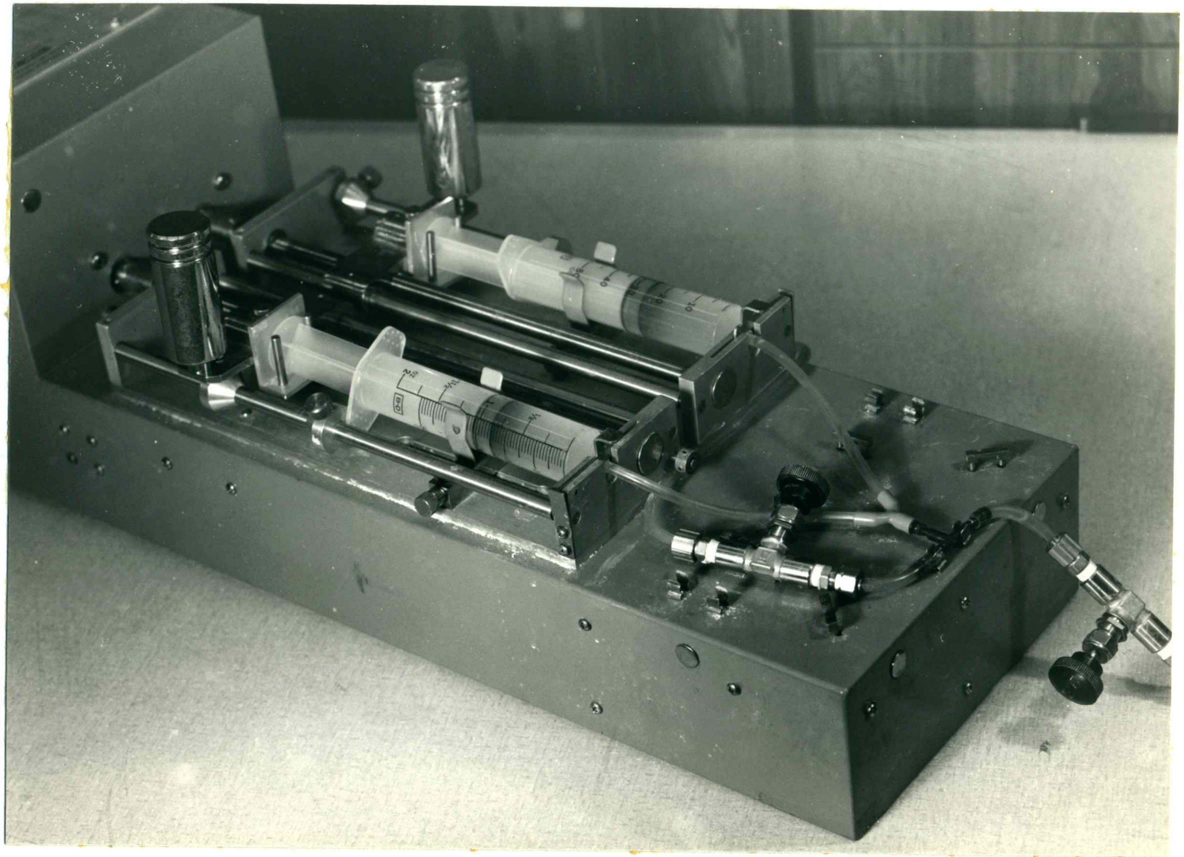

FIGURE 13. SYRINGE PUMP

Specifications: Constant volume displacement pump

Manufacturer: Harvard Apparatus Co.

Volume Displacement Rate: 0.43-2178 ml/hr

Syringe Size: 2/50 cc

The pump is modified to supply 4356 ml/hr of water during the blood pressure measurements. Both plungers of the syringes are arranged to move together in the same direction in the experiment in order to provide a sufficient amount of water for compressing the forearm such that the artery can be occluded.

The delivery end of the syringes is connected to the inlet of the hydraulic cuff via a Y-junction tube. The experiments were performed with a constant volume displacement rate of 3480 ml/hr on human forearm and 1744 ml/hr on simulated (beef kidney) arm.

2. PRESSURE TRANSDUCER

A Statham Pressure Transducer which converts pressure input signal to voltage output signal was used for measuring static and dynamic pressures.

Specifications: Differential Pressure Transducer

Manufacturer: Gould Statham, CA

Model: PL 280 TC

Pressure Ranges: ±0-50 psi differential

Excitation: 5 volt DC

The transduction of this device is through a resistive, balanced and fully active strain gage bridge of resistance

350 ohms. The combined nonlinearity and hysteresis is less than ±1% of full scale.

The outlet of the hydraulic cuff is connected to the inlet pressure port of the transducer. A strip chart recorder and/or oscilloscope is connected to the transducer via a digital signal conditioner for recording the corresponding responses.

3. DIGITAL PROCESS INDICATOR

A Digital Process Indicator is used to supply power to the transducer.

Specifications: Digital Process Indicator

Manufacturer: VISIPAK Action Instrument

Model: VIP 504

Excitation: 5 volt to 15 volts

This indicator serves as a dual function direct process indicator and a signal conditioner for driving recorder or controls. Figure 14 consists of a 4-arm bridge conditioner

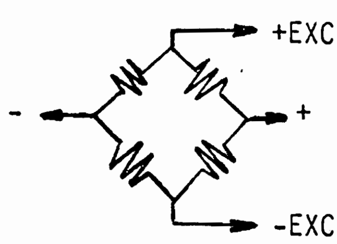

Figure 14. Bridge conditioner circuit

for direct display of strain gage process. Excitation is field adjustable from 5-15 volts dc. The display is specified to read directly in % of voltage change.

4. STRIP CHART RECORDER

A SOLTEC Strip Chart Recorder is used for the entire experiment. The pressure response in the transducer is monitored in the recorder.

Specifications: SOLTEC Chart Recorder

Manufacturer: SOLTEC Corporation, CA

Chart Speed: 1.5 cm/hr to 120 cm/min

Scale: ±0.5mV to 200V

Response Time: 0.25 sec

For best experimental results, a 30 cm/min of chart speed and 200mV scale were selected during the blood pressure measurement in human subjects. Next, a 60 cm/min of chart speed and 500 mV scale were used for testing on the mechanical heart system. The input signal to the chart recorder is directly connected from output of digital display indicator.

5. OSCILLOSCOPE

A Tektronix Storage Oscilloscope is used to display the pressure pulse when mechanical heart simulation system is in operation.

Specifications: 5111 Storage Oscilloscope

Manufacturer: Tektronix, Inc., OR

Plug-in Unit: 5A22N Differential Amplifier

Type 3C66 Carrier Amplifier

A vertical scale of 50mV and a horizontal scale of 0.2 sec/div were used to receive the best pulse contour.

6. GEAR MOTOR

The Dayton Gear Motor is used to drive the mechanical heart pump.

Specifications: Model 2Z802

Manufacturer: Dayton Electric Manuf. Co., IL

Full Load Torque: 45 in-lb

Powered By: 1/15 hp, 5000 rpm, full load series wound motor

The speed of the motor is variable according to the load applied. The unit is equipped with triple reduction gears (ratio 100:1) wound motor. The cam is mounted on the shaft of the motor. The speed of the motor is set approximately at 105 rpm. At that speed the form of pressure pulse as observed in the oscilloscope is quite similar to a normal arterial pulse.

EXPERIMENTAL RESULTS AND ANALYSIS

According to the concept hypothesized previously on the development of the hydraulic occlusive cuff blood pressure measurement technique, more than sixty data had been collected from different subjects. Immediately after each measurement by the hydraulic scheme, the subject's blood pressure was taken by the conventional pneumatic (auscultatory) method. The data obtained by two methods were compared.

The main differences between the two blood pressure measurement schemes are as follows:

	Hydraulic	Pneumatic (auscultatory)
1.	Identification of diastolic and systolic levels by pressure pattern on the compression curve.	Identification on diastolic and systolic levels by turbulence sound on the decompression side.
2.	Curve contains more than just diastolic and systolic points, e.g., display of pulse contour as well as pressure-volume displacement recording for vascular properties.	Only diastolic and systolic points are obtainable.
3.	Imcompressible fluid (water) is used as medium for transmitting hydraulic pressure.	Compressible fluid (air) is used for transmitting acoustic sound.

4.	Readings sensitive to small movement in arm, hand, and finger, even talking.	Readings rather insensitive to all these, but room noise may impair good reading, acoustically.
5.	More instrumentation is involved.	Device is simple and portable.
6.	Readings are taken on the forearm.	Reading are taken on the upper arm.

Regardless of these differences in concept and in measurement, the results obtained by both methods are in remarkable agreement. Table I shows the list of subjects whose systolic and diastolic pressures are recorded by both hydraulic and pneumatic systems and its percent of deviation between the two. A bar chart has been prepared in Fig. 15 to display the results shown in Table I. Table II shows a summary for number of cases, in percent, which agree within various confidence limits measured by the individual methods. It can be observed that, for a $\pm$5% comparative differences, both systolic and diastolic values are over 80% in agreement. There is no consistent difference, however, existing between these readings. Most subjects were young males, aged 20-30. Seven young females as well as a few males up to ages 58 participated. Only two were hypertensive, and of the normotensive subjects, none reported any known cardiovascular abnormality.

The pressure records on the chart demonstrated a similar pattern, regardless of slope and pulse frequency, for all the subjects. The first phase of the record began with the increasing static pressure up to a certain point. The second phase shows the

TABLE I

COMPARISON OF BLOOD PRESSURE RECORDS MEASURED BY PNEUMATIC AND HYDRAULIC SCHEMES

Test No.	Pneumatic mm Hg Sys/Dias	Hydraulic mm Hg Sys/Dias	% Deviation Sys/Dias
1	114/82	115/84	-1.0/-2.4
2	124/85	123/84	+0.8/+1.1
3	130/90	131/86	-0.7/+4.4
4	115/88	120/88	-4.3/ 0.0
5	125/88	125/88	0.0/ 0.0
6	108/76	107/70	+0.9/+7.8
7	116/76	117/85	-0.9/-11.8
8	96/70	98/73	-2.0/-4.2
9	100/70	104/71	-4.0/-1.4
10	106/71	106/72	0.0/+2.7
11	118/78	115/80	+2.5/-2.5
12	114/88	117/85	-2.6/+3.4
13	104/75	106/74	-1.9/+1.3
14	125/82	119/80	+4.8/+2.4
15	145/92	133/88	+8.3/+4.3
16	160/100	160/98	0.0/+2.0
17	145/98	144/98	+0.7/ 0.0
18	125/85	124/90	+0.8/-5.8
19	122/82	122/82	0.0/ 0.0
20	118/90	122/72	-3.4/+18.8
21	118/82	122/81	-3.4/+1.2
22	118/84	120/80	-1.7/+4.7
23	110/64	120/66	-9.0/-3.0
24	130/76	117/75	+10.0/+1.3
25	118/75	118/72	0.0/ 0.0
26	130/86	138/90	-6.2/-4.6
27	118/75	120/75	-1.7/ 0.0
28	100/65	104/66	-4.0/-1.5
29	115/82	135/81	-17.4/+1.2
30	130/80	128/82	+1.5/-2.5
31	123/75	120/75	+2.4/ 0.0
32	95/62	95/61	0.0/+1.6
33	148/92	143/93	+3.4/-1.0
34	108/72	112/56	-3.7/+22.2
35	118/72	117/74	+0.8/-2.7
36	110/75	120/88	-9.1/-17.3
37	110/74	111/76	-0.9/-2.7
38	115/74	115/76	0.0/-2.7
39	105/74	106/78	-0.9/-5.4
40	126/86	128/88	-1.6/-2.2
41	115/72	112/74	+2.6/-2.7
42	115/82	115/80	0.0/+2.4
43	120/72	120/77	0.0/-6.9
44	125/84	123/85	+1.6/-1.2
45	128/78	115/75	+10.0/+3.8
46	120/76	109/75	+9.2/-1.3
47	120/68	125/72	-4.2/-5.8
48	122/72	120/69	+1.6/+1.4
49	122/74	122/74	0.0/ C.0
50	115/80	120/80	-4.3/ 0.0
51	112/80	111/82	+0.9/ 0.0
52	110/78	109/77	+0.9/+1.2
53	112/70	109/71	+2.6/-1.4
54	145/102	149/101	-2.8/+1.0
55	106/68	122/67	-13.2/+1.4
56	135/72	131/72	+3.0/ 0.0

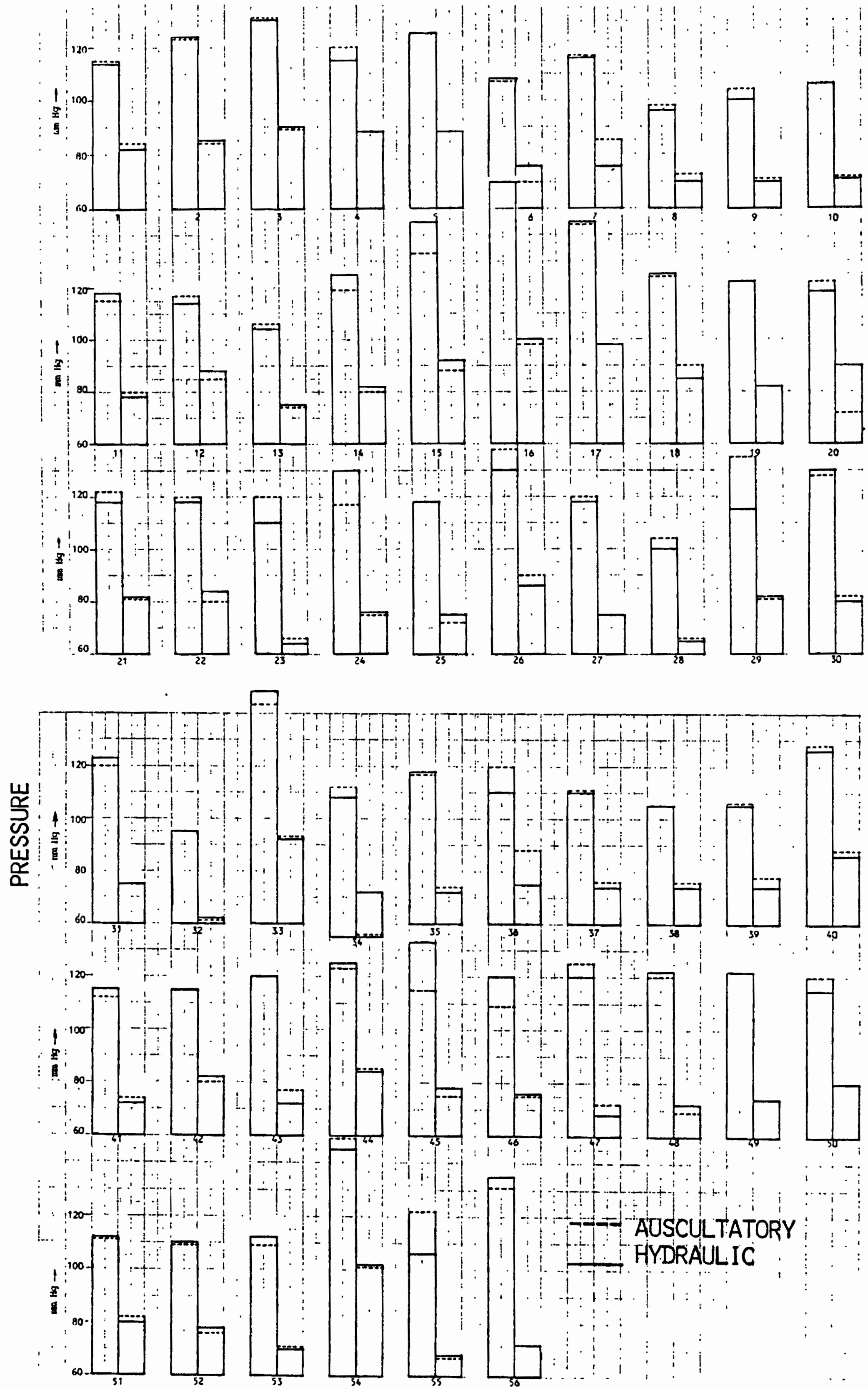

FIGURE 15. BAR CHART TO DISPLAY THE RECORDS SHOWN IN TABLE I

TABLE II

PERCENT OF INDEPENDENT HYDRAULIC CUFF
VS. AUSCULTATORY PRESSURE MEASUREMENTS
FALLING WITHIN SELECTED DIFFERENCE LIMITS

Difference limit percent	Cases falling within difference limit percent	
	Systolic	Diastolic
1	32	18
2	53	46
3	61	70
4	75	77
5	82	84
6	82	89
7	84	91
8	84	93
9	86	93
10	94	93

oscillations due to the dynamic pressure caused by the pulsatile flow in the blood vessel during collapsing. Finally, in the third phase, the oscillations almost ceased after the blood vessel collapsed completely. Due to the extreme sensitive experimental set up, low amplitude oscillations still exist as heart pulses continue to be transmitted to the upstream side of the cuff.

CRITERIA FOR PULSE PRESSURE

The records obtained during the rising pressure phase were more useful than the records obtained during the pressure dropping phase on the chart. In many cases, features of actual intra-arterial pressure including the presence of a dicrotic notch were observed. Pressure fell in a non-linear fashion on the decompression curve as the fluid was withdrawn from the cuff, yielding oscillatory records whose shape was difficult to analyze. A typical record is shown in Fig. 16.

Upon examination of preliminary results, some unique features of the oscillatory records were found which correspond closely with auscultatory diastolic/systolic pressure values. These are indicated in the expanded view of Fig. 17. The diastolic value corresponds closely to the low amplitude pulsations where a rather flat (zero slope) inter-pulse profile first appears as pressure rises.

The pressure oscillations continue after the diastolic point during the rising pressure period. The pulse amplitudes generally rise to a peak, then diminish. Concurrently, the inter-pulse profile goes through changes in slope. The pulse just prior to the point where inter-pulse profiles seem to passively follow the rising cuff

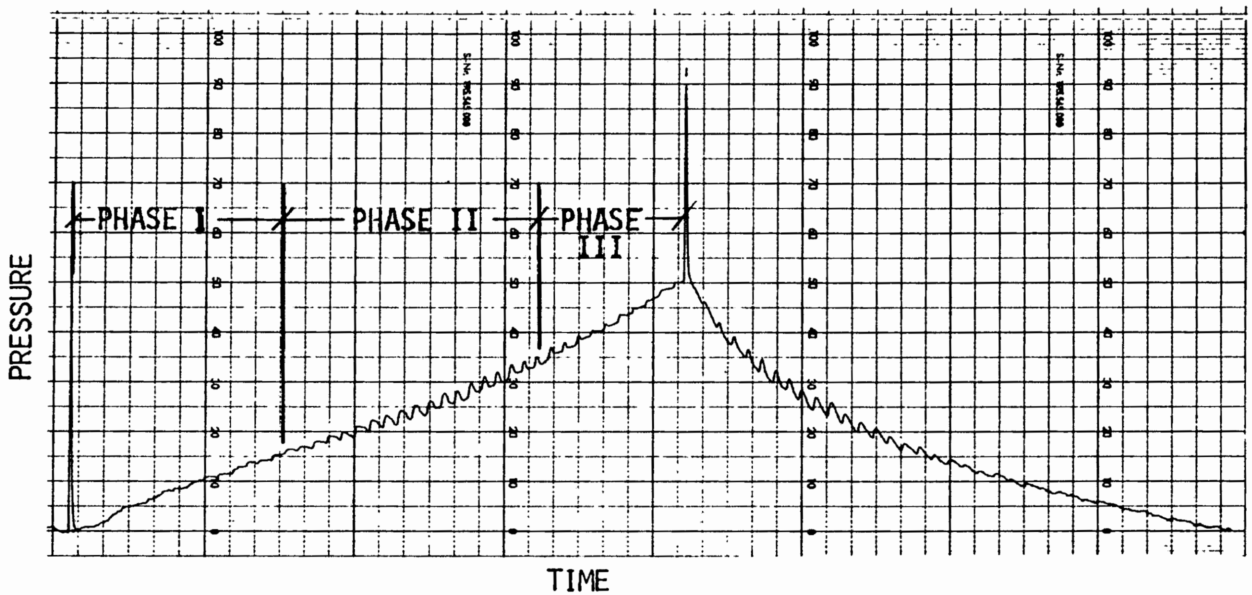

FIGURE 16. TYPICAL ONE-CYCLE RECORD GENERATED DURING A RECORDING SESSION; EACH SUBJECT SAT FOR TWO CONSECUTIVE CYCLES

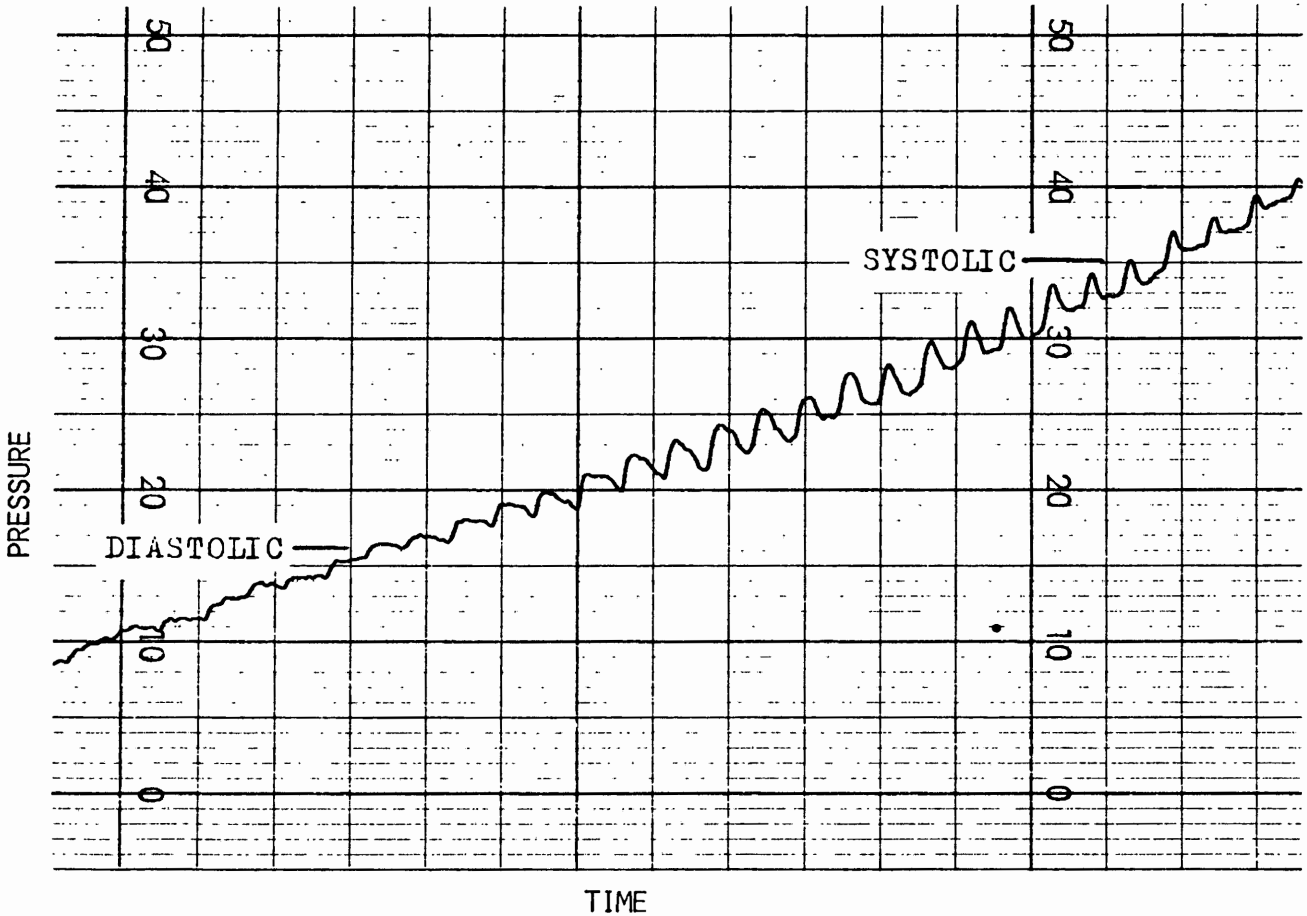

Figure 17. Enlarge view of rising phase of figure 15, with the diastolic and systolic pressures indicated according to the criteria described in text

pressure corresponds quite closely to systolic pressure. From there on, the oscillatory pulse profile reduces significantly as the vessel becomes fully collapse. From here and beyond, small amplitude oscillations, due to the arterial pulse at the upstream side of the occluded vessel, are observed. It is likely that the changes of pulse profile are closely related to the sound producing events which are detectable with a stethoscope.

The above description forms the criteria used in obtaining the diastolic and systolic pressures for purpose of comparison.

No two records were exactly alike and we attribute the difference to size of forearms, relative volume of muscle/vascular tissue and possibly other factors. The slope of the rising pressure curve, with constant pump displacement, varied considerably between subjects. Figure 18 shows the sample of selected records for comparing pressure gradient for different subjects (regardless of oscillations). It can be observed that curve I has the largest gradient, while curve VI has the smallest pressure gradient. About 80% of the records fell between the curve III and V in which 60% (approx.) fell between III and IV. The curve pattern between diastolic and systolic point is also different for different subjects. Greater nonlinearity (as concave behavior) appears as curve approaches near or beyond the systolic level.

In addition to the difference in slope of rising pressure, amplitude and waveform of pulsatile pressure oscillations also varied markedly. Among the various types of oscillations observed, Fig. 19 shows the typical form of oscillation. The pulse pressure waves, as

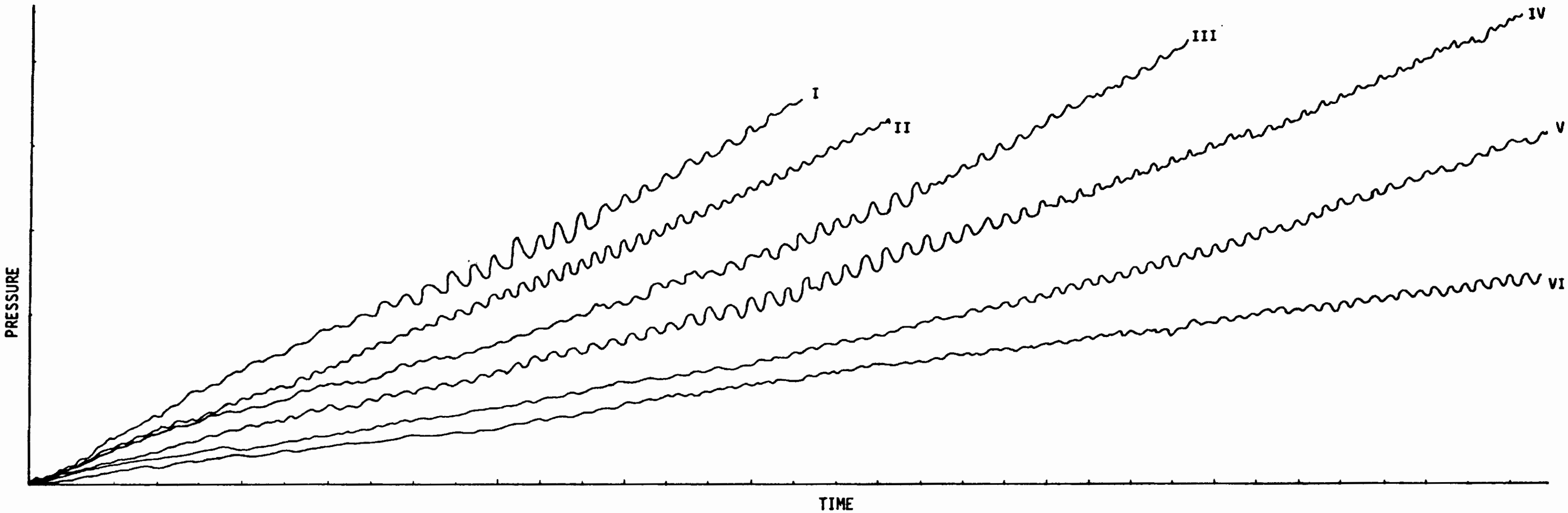

Figure 18. Comparison of various types of pressure gradient for human subjects

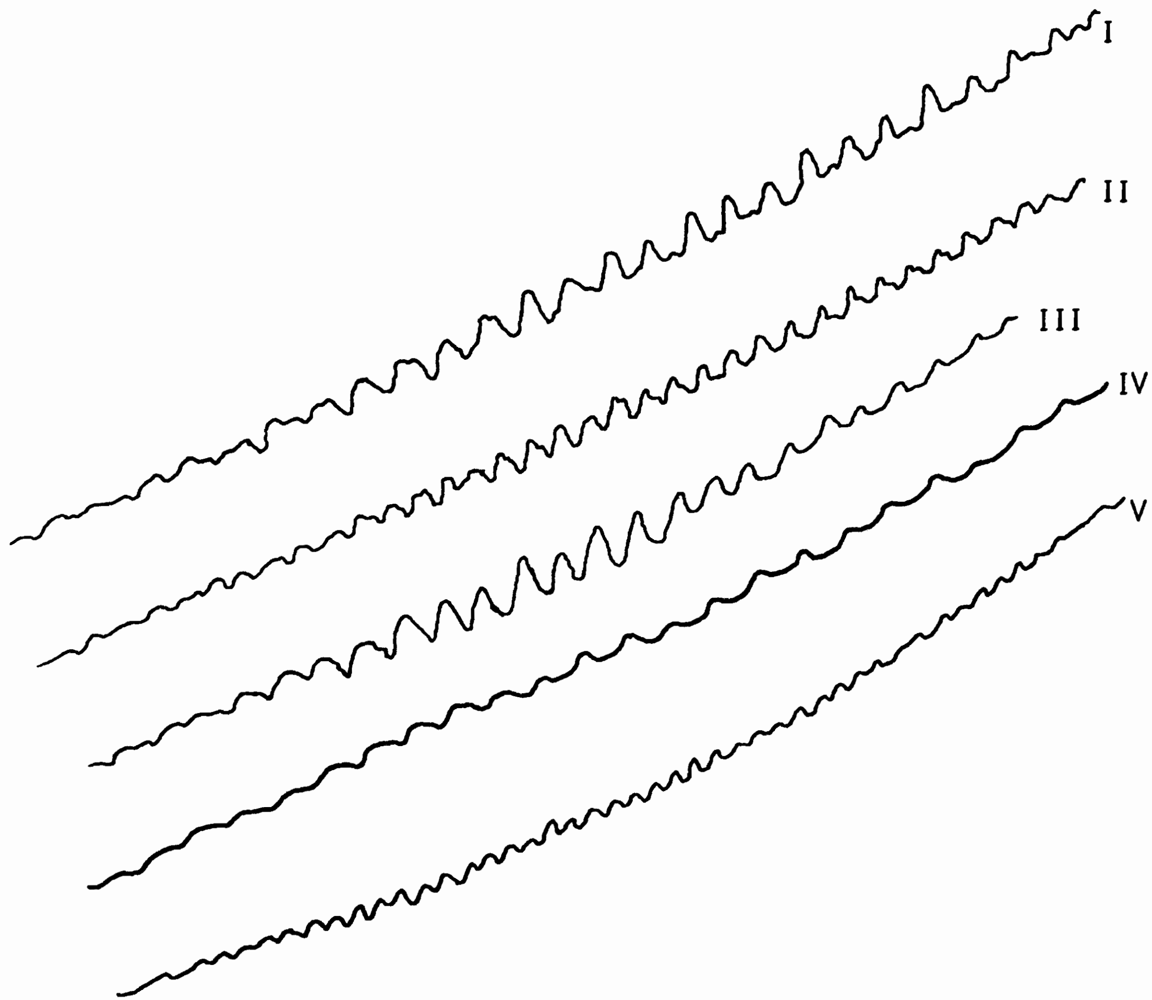

Figure 19. Various types of oscillations

those measured by direct intra-arterial pressures, can be observed in each record. The dicrotic notch exists if the amplitudes of oscillation are bigger. Curve I is an example which shows big oscillation with dicrotic notch clearly visible. Curve II and III are the most common types of oscillation observed while curve IV and V are the examples of small oscillations. The latter are distinguished by low and high pulse rate.

The readings are further recorded as the pressure was decreased by reversing the speed of the constant volume displacement pump. This process is similar to that used in the pneumatic occlusive technique. However, no distinct criteria have been found which yield a good correlation with the pneumatic auscultatory data. Data curves in this portion are more nonlinear than those on the increasing side. Sharp "saw-tooth" forms are superimposed on rather steep curve. The time taken to return to zero pressure level is also shorter than on the increasing side. It is also observed that between every two trials the first record always took a little longer than the second reading. This may be caused by the muscle relaxation properties.

The hydraulic occlusive cuff, designed for measuring blood pressure, is further used in the mechanical pressure pulse simulation system. Figure 20 shows a photograph of the pressure pulse recorded when the mechanical pressure pulse pump is operating. The pulse is similar to those measured by direct invasive method in which the systolic and diastolic levels as well as dicrotic notch can be observed clearly. To observe the pulse contour, the inlet port of the transducer is directly connected to a T-connection at the rubber

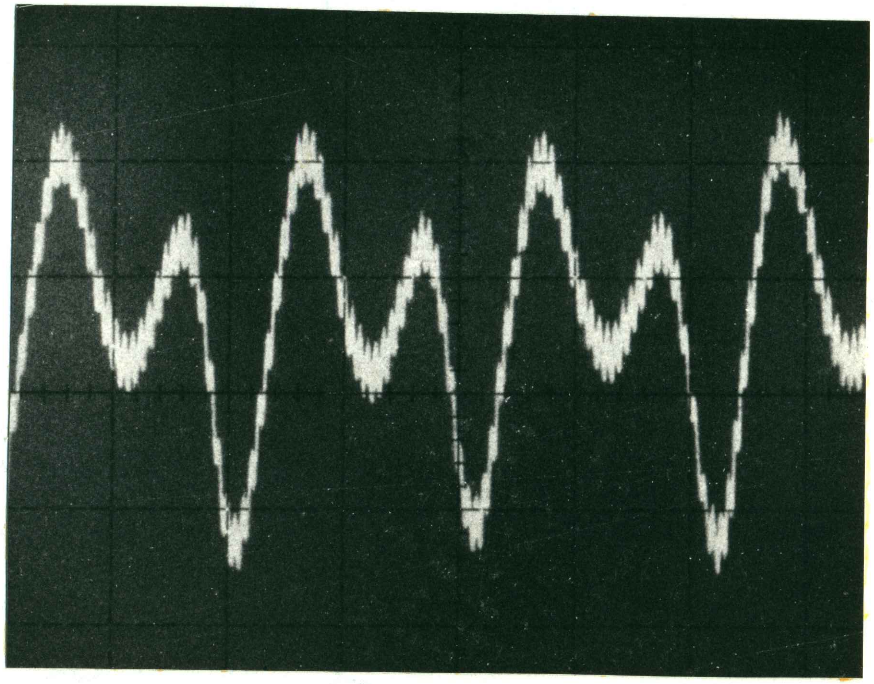

FIGURE 20. PULSE CONTOUR OBTAINED DURING THE OPERATION OF MECHANICAL PRESSURE PULSE PUMP

tubing through which the water is flowing. The changes in pressure levels during the pump operation were received by transducer and displayed on the storage oscilloscope.

The experimental setup as shown in Fig. 9 is utilized again to demonstrate the use of mechanical heart beat pump. Beef kidney was found to be the best material that can simulate the muscle properties of the human arm. However, the kidney used was not living tissue which also lost its elastic properties with time. The simulated arm is inserted inside the hydraulic cuff and accordingly the pressure is increased by operating the constant volume displacement pump. The date is recorded during both pressure increasing and decreasing periods.

Figure 21 is the complete record measured when the latex rubber tube, which simulates blood vessel, is fully open and in kinked (low) position. This is also similar to the pattern obtained in the indirect blood pressure measurement in humans by using the hydraulic occlusive cuff. Oscillation begins when the rubber tube starts collapsing and finally ceased after the tube is completely collapsed. The record as shown for the fully open and kinked positions did not follow the same pattern as differences were found in various aspects. The most significant difference is observed at point 37 of the chart on each experimental operation.

The oscillation begins at point 37 in the fully open position and again diminishes at point 40 of the recorded chart. Some small oscillations still exist beyond point 40. This oscillation is growing bigger slowly and approaches maximum amplitudes up to point 67.

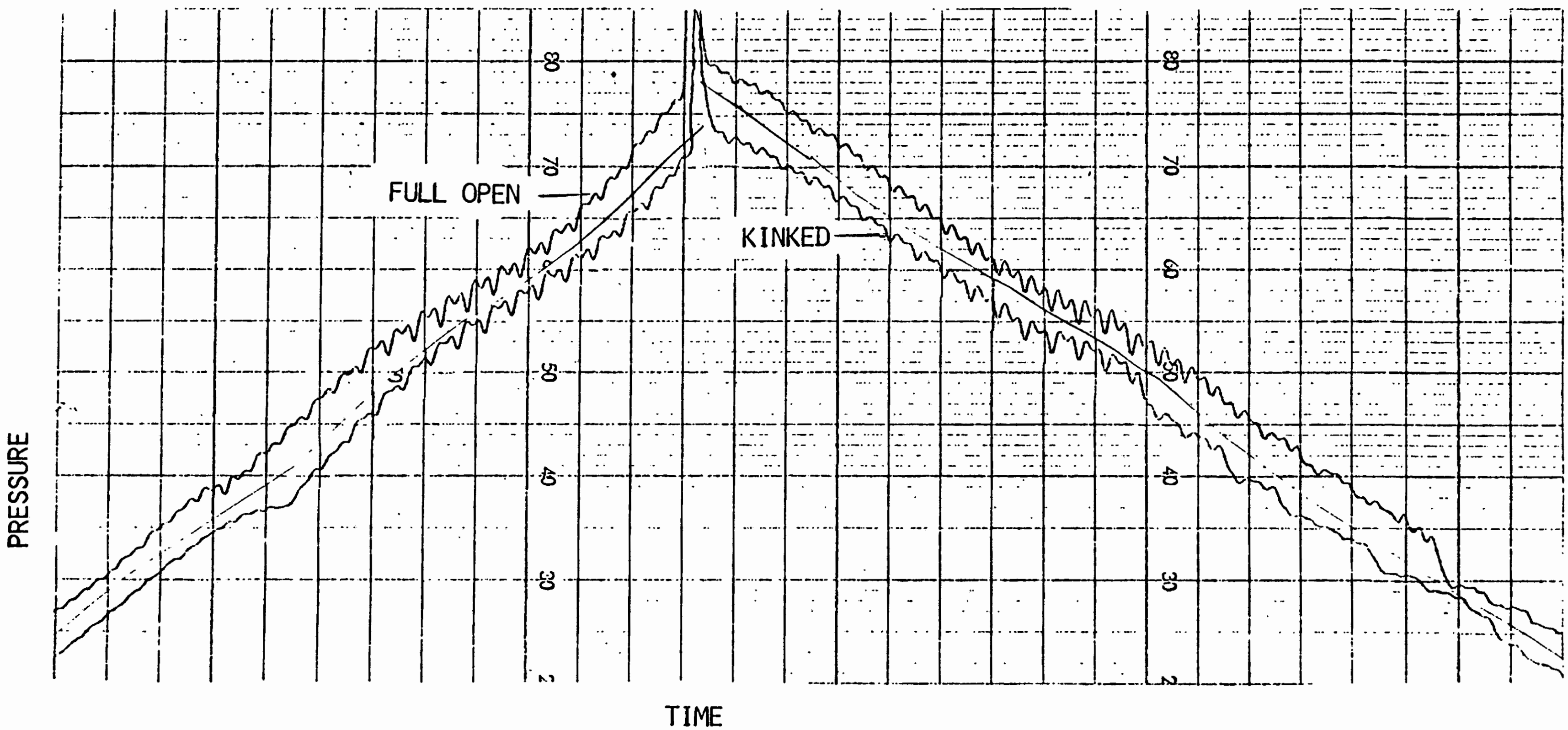

Figure 21. Records obtained from simulated arm with latex tube full open and kinked position

Similarly, it followed the same pattern in the kinked position except there are fewer activities in terms of oscillations. At point 37 the pressure gradient decreases in contrast to the fully open position. The pressure gradient picks up again and follows the same as in fully open later. Oscillations also began after point 50 only. However, fewer oscillations are observed in the kinked position as compared to the bigger oscillations and more distinctive dicrotic notches in the fully open position. During the period of pressure drop, there are more irregularities in the kinked position, such as sudden change in the uniform pressure gradient. The results are caused by the restriction in the flow from which the pressure wave does not travel freely, and, the effect of compliance (beef kidney) and rubber tube properties.

CONCLUSIONS AND RECOMMENDATIONS

An oscillometric arterial pulse-pressure measurement system has been developed and tested. The design and the construction of a rigid occlusive cuff were presented. An instrumentation and a testing procedure were described. Criteria were established as how to determine the systolic and diastolic pressure levels.

A mechanical model for simulating human blood pressure pulse was also studied. The records taken on the simulated arm by operating the mechanical model resembled those measured from the human subjects. Doe to the difference in muscle properties between the human arm and simulated arm, these records showed different frequency and amplitude. Based on the limited number of test runs, in connection with the demonstration of arteriosclerosis properties, it was speculated that the changes in the pulse profile were due to the constriction of the latex rubber tubing used as blood vessel. A detailed study would be required to verify this behavior by testing directly on either human subjects or using experimental animals.

The results obtained from the oscillometric method using the hydraulic occlusive cuff have shown close correlation with respect to the current auscultatory technique. Additionally, it is believed that the data obtained would be suitable to convert automatically to digital display system. This will allow independence from human observer error in determining the systolic/diastolic pressure values.

The improved oscillometric system may overcome the problems associated with auscultatory blood pressure measurements. Electronic pressure transducers as well as the monitoring equipment are available now with high frequency response to accurately signal the pressure oscillations. A further advantage of the hydraulic cuff-oscillometric system is that much more data can be generated in a single pulse pressure determination, potentially of diagnostic utility, than results from auscultatory pressure measurements. In addition, it is speculated that features of the pulsatile pressure records might be detected that correspond to the various Korotkoff sound phases identified by a stethoscope. It is believed that this system could be useful not only for determining the usual pulse pressure reading (systolic/diastolic), but it would also be useful in evaluating vascular compliance, vascular volume, and changes in vascular resistance.

Much further work remains to be done, specifically, including:

1) build a more compact and convenient unit; ideally the unit should be housed in a compact enclosure with only a "power" switch and an "operate" button on the front panel,
2) establish adequacy of pulse pressure criteria,
3) develop a satisfactory algorithmn for automatic pulse pressure determination from an oscillometric record, and
4) establish potential diagnostic criteria that corresponds to quantifiabale features of a standard oscillometric pressure record.

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