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# FINAL REPORT
# ADVANCED LIFE SYSTEMS HARDWARE DEVELOPMENT FOR FUTURE MISSIONS

Contract NAS 9-13603

Submitted to

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
Lyndon B. Johnson Space Center
Houston, Texas

By


TELECARE, INC.
8575 Mosley Road
Houston, Texas 77034



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## PREFACE

This final report covers the period of performance of Contract NAS 9-13603 from September 27, 1973 to January 24, 1975. Three major tasks were accomplished under this contract. The results achieved in each of these tasks are summarized in separate sections of this report. The three tasks were:

1. Arterial Pulse Wave Analysis
2. Blood Pressure Under High Noise Environments
3. Miniature Battery or 28-VDC Line-operated Defibrillator/Scope

Breadboards of each of these items have been delivered.

# TECHNICAL REPORT

## ARTERIAL PULSE WAVE ANALYSIS

# ARTERIAL PULSE WAVE ANALYSIS

## TABLE OF CONTENTS

# A REVIEW OF PULSE PRESSURE WAVEFORM MEASUREMENT

## DISCUSSION

### The Pulse and Processes Contributing to It

The palpable pulse is a consequence of a regional volume and pressure changing process within the vascular system. The two processes are not in phase with the volume pulse generally leading the pressure pulse in the order of 0.005 seconds.[1] An examination of the pulse formation in an externalized vessel suggests that the vessel does not behave as a simple visco-elastic tube.[1] These findings show that a regional increase in pressure is preceded by a regional increase in volume. Concomitant with the radial motion of the vessel wall, there is a longitudinal motion which may be quite large in relation to the radial motion.[1,2] It is usually this longitudinal motion that results in a straightening of the vessel: a motion that contributes in a major fashion to the palpable pulse in the radial artery.[2] While a shortening of the vessel with pulse propagation is the usual observation, a lengthening of a vessel with pulse propagation may also occur.[1]

As the pulse wave (volume and pressure) propagates along the vascular system, the wave changes shape.[3-5] As a consequence of this change in shape, peripheral pulse waveforms may not always reflect what is occurring in the central vascular system. For example, during periods of vascular stenosis in a peripheral artery, a flow into limb segments distal to the stenosis may be adequate although a palpable pulse may not be present.

### The Processes of Transduction

Pressure-pulse waveform transducers are sensitive either to the pressure present at the vessel wall or to the volume of blood filling a region of tissue.

The pressure determination requires the transducer to contact the vessel wall through the intervening tissue. Some deformation of the vessel wall is required for such a measurement which can, in turn, change how the wall responds to the pressure.[1] Regardless of how the pressure is transduced, the transducer must be in intimate contact with the vessel wall in order to sense the intra-vascular pressures exerted on the wall. Since the transducer is responding to a hydraulic process, it is often optimally coupled to the vessel in order to obtain the best reproduction of intra-vascular pressures as possible.[6,7] In other words, it must successfully communicate with the vessel wall through the intervening tissue and "float" on the vessel without distorting the waveform. This approach obviously necessitates a transducer designed specifically for each size of vessel to be examined. Further, the transducer must then be placed correctly on the vessel.

Correlation Between Intra- and Extra-Vascular Pulse Waveforms

When discussing the pulse waveform, it is important to specify where in the vascular system the pulses are taken. This is a consequence of the change in shape that occurs as the pulse is propagated through the arterial system.[3-5] A further complication occurs with the application of the sensing transducer which has the potential to distort the measured waveform when the transducer is in intimate contact with the vessel.

The most uncomplicated method of obtaining pulse waveforms is using a pressure cuff as a sensing device. Dontas used such a device to examine some of the properties of the cuff in sensing the pulse pressure waveform.[10] Simultaneously, an intra-arterial catheter was placed under the region of measurement for the cuff. Several sites on the arm and the carotid artery were examined in this fashion.

The pressure waveform was found to increase in amplitude when the counter pressure exerted by the cuff increased.[10] The optimum intra-cuff pressure for the best correlation between intra- and extra-arterial pressures was determined to be 40 mm Hg. Cuff pressures exceeding diastolic pressure were observed to transform carotid and upper brachial artery waveforms to more peripheral-vessel-looking waveforms. With the use of vasoactive agents, Dontas observed that external pulses do not reflect intra-arterial pressures when the vessel wall tension changes.[10] However, the extra-arterial pulses best resembled intra-arterial pulses when the cuff pressure was kept slightly below the diastolic pressure.

Robinson examined the relationship between the carotid extra-vascular waveform sensed with a pressure cuff and its intra-vascular shape in patients with cardiac abnormalities.[11] While the extra- and intra-vascular recordings were not identical and suffered considerable variation from case to case, the way the waveforms differed was almost always the same. High-frequency components of the intra-vascular recording were attenuated in the extra-vascular recordings, but not lost entirely. Robinson further observed that the brachial artery often showed intra-vascular pressure differences from the carotid internal and external recordings that would preclude some diagnoses from the radial artery waveform; and he concluded that carotid artery pulse waveforms contain information on aortic pressures that is lost in brachial artery measurements.[11]

Impedance plethysmography has received a great deal of attention concerning the relationship between extra-vascular impedance and intra-vascular pressure recordings.[5, 12, 13] The changes in pulse wave contour associated with segments of the human lower limb have been closely examined.[5] These changes in shape follow the kinds of changes observed for intra-vascular pressure waveform mappings.[3, 4] The primary premise is that impedance plethysmographic techniques are measuring the tissue volume-impedance changes between sensing electrodes due to blood flow into the sensed region. In spite of this supposition, the impedance waveform is observed to be highly correlated with the intra-vascular pressure waveform.[12, 13] Indeed, Mohammad and Coulter have determined by Fourier analysis that the harmonic content for intra-vascular pressure waveforms and extra-vascular impedance waveforms is nearly the same.[12] However, a critical analysis of impedance plethysmographic techniques suggests that the entity sensed by the impedance plethysmograph may not be tissue volume impedance at all.[14] Rather, Hill et al. have stated that skin-electrode interface, straingauge-type transduction may be occurring.[14] This type of transduction would explain the close correspondence observed between intra- and extra-vascular recordings. Since mechanical straingauges are manufactured that can be calibrated better than impedance plethysmographs, Hill et al suggested that a standard straingauge would be a better choice than the impedence plethysmograph for extra-vascular recordings.[14]

Heyman has carefully examined intra- and extra-vascular recordings of the pulse pressure with an externally positioned piezoelectric crystal.[15] Heyman observed in both man and dog that extra-vascular pressure waveforms occurred before the intra-vascular pressure recordings in the majority (66%) of the observed subjects. The remaining subjects (34%) produced intra- and extra-vascular recordings close in shape, phase, and amplitude.[15] With the occurrence of vasoactivity, the observed differences in the two recordings increased with intra- and extra-vascular waveforms changing simultaneously but in opposite directions.[15] These kinds of changes were noted in both humans and dogs. These changes in the extra-arterial waveform with vaso-activity observed by Heyman are similar to those observed by Dontas using the pressure cuff.[10]

While Heyman's crystal pickup device was rather elaborate, a simple crystal system has been reported by Abbott and Hemsley which was produced from a phonograph crystal pickup and showed an excellent correspondence between extra- and intra-vascular waveforms.[16] However, Abbott and Hemsley did not examine waveform changes with variations in vasomotor tone.

Chlebus has reported on the relationship between several extra-arterial pulse measurement devices and intra-arterial pressure waveforms.[17] One of the devices functions in an unknown manner but the remaining were crystal microphones and photoelectric receivers. Chlebus found the best correspondence between intra- and extra-vascular recordings with the so called "resonance electrosphygmometer," the operation of which is unknown at this time. Reasons for this ignorance will be explained later. However, sequential readings with piezoelectric crystals and photoelectric systems showed a large variation in reading to reading for both devices.[17] In many instances, these variations were statistically significant and had little relation to intra-vascular pressure recordings. Simultaneous photoelectric and piezoelectric recordings were shown to differ significantly not only between one another but with intra-arterial pressure recordings.[17] The variations were found to be strongly influenced by the "loading" of the device to the vessel wall, that is, the pressure applied to the vessel by the crystal or photoelectric receivers.[17] The resonance electrosphygmograph, however, is reported to measure vessel wall displacement some four millimeters from the vessel and, thus, does not "load" the vessel wall.[17]

It is evident from these studies that considerable differences between intra- and extra-vascular recordings can arise from changes in vasomotor tone and transducer application.[9] Such changes may preclude definitive diagnoses in some individuals and may further specify some of the measurement strategy.

Selected Transducer Systems

Of the many systems available to determine the pulse waveform, only a few show real promise for development into specifically useful devices. Most of these devices are presently used clinically for evaluation of pulse waveforms obtained from various sites on the body. All are subject to the problems inherent to any attempt to transduce waveforms by contact with vessels and surrounding tissue. Except for mechanical straingauges, none of the devices allow for an absolute measurement. Thus, the measurements remain largely qualitative in nature.

A primary system is simply a straingauge placed in contact with a vessel wall or with a digit and held in place with a circumferential strapping system.[6-8, 18] Reported experience with such devices show some potential for calibration to absolute values.[6-8, 18] One could calibrate by taking systolic and diastolic pressures with a sphygmomanometer before using the device to obtain waveforms. Some difficulties associated with straingauges include positioning of the transducer on the vessel and coupling the signal over to the transducer.[6,7] This later problem has produced a number of experimental devices that use a water chamber to couple to the vessel wall and carefully designed "platens" that reliably transduce the pressure exerted on the vascular wall.[6-8] While the transducer may be successfully coupled to the vessel wall, that coupling has a good potential for changing the entity being measured.[9] This is not an easy problem to overcome and several good engineering attempts have been made to compensate for these deficiencies.[6-8, 19, 20] The successes have not been excitingly great.

Positioning the transducer will not be an easy problem to solve because a "large" transducer does not couple well to the vessel wall and a small one requires an exact positioning over the vessel wall. Deep lying vessels and those with a poorly palpable pulse will make this kind of transduction difficult at best.

Piezoelectric microphones, like straingauges, can be obtained with considerable "flatness" in the passband of measurement. Further, they can be cut to many sizes, loaded, damped, shaped, and are very sensitive when coupled into modern high-gain, high-impedance amplifiers. Unfortunately, piezoelectric devices lack any possibility of being calibrated in absolute values. There is the further problem of loading the vessel being measured with the microphone and distorting the measured waveform.[17] However, in spite of these limitations, the piezoelectric, contact microphone is commonly used to obtain carotid artery pulses for diagnosis in cardiology. Along with the pressure waveform, and ECG and heart sounds are also recorded.[24] Two major manufactured devices used clinically are the Hewlett-Packard Pulse Wave Pickup microphone system (Model 21051D) and the Electronics for Medicine contact microphone system (Models A161 and PS-1B). There are numerous articles showing a developing analytical base for qualitative analysis of the waveforms obtained with these crystal microphones.[21-24, 29]

Interestingly, there has not developed a common or successful "loading" technique for the use of these devices; and, since all are hand-held in position, they are subject to the vibration and pressure judgements of the person holding the device. Hand-held devices can be a source of noise, for example, experience in ultrasound shows that a hand-held ultrasound transducer becomes a major source of noise in many ultrasound techniques.

While the clinical use of a sensing cuff for carotid pressures is uncommon in the U.S., the British have approached the cuff constructively and use it for qualitative evaluation of pulse waveforms.[11,25] Sensing of pulse waveforms in the upper limbs with a cuff has been experimented with in our laboratory in order to understand some of its limitations.

Another technique worthy of exploration is ultrasound ranging. The basic concept is simply one of ranging on a vessel wall to follow its motion.[26] It could be argued that this may be more a volume sensing process than a pressure sensing process. The results of some experimentation with ultrasound will be presented in more detail later in the report.

Along with the more obvious techniques listed above is what may be called a "mystery transducer."[17] Chlebus has presented a quantitative evaluation of this device versus intra-vascular-pressure waveforms in a Western publication.[17] However, the technical aspects of the device including its means of transduction are still published only in Polish. The device is called a "resonance electrosphymograph" and is purported to transduce the pulse waveform at a distance of four millimeters from the vessel wall. The published correlative study suggested a good correspondence between the transduced waveform and the intra-vascular waveform. The device is worthy of some further investigation to determine the means of transduction and its potential application to clinical measurements in the U.S. Evidently, the device was designed and manufactured in Poland and knowledge of this device has extended little beyond. Reports in Western journals suggest a rather widespread clinical use of this device in Poland.[17,27] Copies of the Polish papers concerning the basis of operation for this device have been ordered and an interpreter located. While this will be of little value to the present program, the potential applicability of such a device warrants some scrutiny.

## Experimental Results

A large number of experiments were conducted by Telecare, Inc. in order to better understand some of the parameters associated with obtaining pulse waveforms. Since many of these techniques are well established, the main thrust of the experimentation was directed at the quality of the waveforms and what variables are present in obtaining the waveform.

All the microphone and cuff displays and recordings were made with an Electronics for Medicine, Model DR-8 recorder. Ultrasound techniques were examined using an SKI Ekoline 20 and a Physionics Engineering, Inc. Somascope, Model TMA-2 in conjunction with the Electronics for Medicine Model DR-8 recorder.

Since the pressure cuff was the most simple approach, an adult size cuff (15 cm wide) was used to detect pressure waveforms in the arms of three subjects. The results were generally the same as reported by Dontas.[10] There is a direct relationship between the intra-cuff pressures and the magnitude of the recorded pressure waveform. The optimum waveforms were consistently obtained with cuff pressures of 40 to 60 mm Hg. A combination of the pressure cuff and the Hewlett-Packard microphone, which was connected to the intra-cuff air volume, produced a system that was sensitive to the cuff pressure for waveform amplitudes, but, unlike a pressure straingauge, did not require re-zeroing for changes in intra-cuff static pressures. The microphone proved to be quite sensitive when coupled to the pressure cuff and pressure waveforms were obtainable in subjects in whom pressure waveforms were difficult to obtain by other means.

The digit plethysmograph was also briefly examined in terms of its position dependence and temperature dependent vasoactivity. Results indicated that a cold subject simply did not produce a pulse waveform much larger than muscle tremor signals. While the weightlessness of space takes away the digit-heart level relationship as a variable, normal vasoactivity in the digits produces wide variability in the size and shape of the transduced waveforms.

Several microphones were examined which were of the piezoelectric type. The Hewlett-Packard and Electronics for Medicine microphones are routinely used in cardiology for carotid artery waveforms and apexcardiography. Thus, a rather broad experience background is available for microphones and their application to cardiology. Included in the microphone examination was the NASA type with a contact face 3.9 centimeters in diameter. Some experimentation with these devices showed them to be pressure sensitive, with some waveform amplitude variations occurring with variation in applied pressure. Clinically these devices are seldom held in position with anything but the hand. There has not developed a standardized approach to minimizing these observed variations. This fact may help explain the relegation of pulse waveform analysis to a minor role in cardiovascular diagnosis.

While ultrasound ranging is considered one of the techniques worthy of exploration, it does not represent an "off-the-shelf" technology. Ultrasound has been included because of the technological explosion presently occurring in ultrasound and its potential for utilization.

The signal is obtained by echo ranging off the vessel wall that is in motion as a consequence of the volume and pressure changes within the vessel. The signal presentation was amplitude versus time: an "A mode" presentation.

The resulting signal was an amplitude varying signal rather than a time displaced signal. This was a somewhat unexpected result but after some consideration of the arterial motion amplitude involved and the resolving ability of ultrasound, the result is quite in line with the facts.[28]

Measurements of radial and longitudinal vessel motion during pulse wave propagation support the notion that radial movement is very small in peripheral arteries. If the equipment being used has a resolution of 1-2 millimeters, then vessel motion less than this value will not be detected.[28] However, a varying amplitude is detectable by two means: 1) some variation in the acoustical impedances at the interface between the vessel wall and either the intra-or extra-vascular fluids, and 2) a change in vessel position that increases the amount of acoustical energy scattered back to the transducer.

A problem assuming major proportions in this technique is transducer noise. The major source of noise is a consequence of using a hand-held device. The vessel signal is further masked by signals coming from the transducer-skin interface, and ringing of the crystal. Most of the vessels of interest are close to the surface and standard clinical transducers focused at 10 and 15 centimeters are not optimal for this technique. One method of moving the signal out of the noise is an "extension" made of water or Lucite which would change the absolute positioning between the transducer and the vessel wall. The results can be summarized as follows. The technique: 1) does show a pulse related signal change, 2) does require a modification of transducer configuration to shorter focal lengths and movement of the signal out of the noise, 3) does require a coupling material consistent with contemporary ultrasonic techniques, 4) does have a potential worth exploring, and 5) does require the development of new ultrasound technology or the reapplication of existing technology to display the pulse events as a waveform.

Assuming some improved technique for displaying the information, the question of what pulse events are being transduced still needs to be answered.

In order to provide a means of evaluating different techniques of transduction, an analytical circuit was constructed. This device was developed with the concept of examining waveforms for comparison as well as diagnostic parameters. Mason, <u>et al.</u> have presented good empirical data to support the use of the first and second derivatives of pulse pressure waveforms in diagnosis.[30] Thus, the bread-board circuit was designed as a two channel input and derivatives of these inputs as outputs from the circuit. Dontas and Cottas have demonstrated the analytical advantages of using a differential amplifier as a comparator.[13] In order to provide a scalar comparison technique between two waveforms, a comparator was also incorporated into the bread board permitting a comparison of the two input channels. Because of severe time limitations, the circuit has not yet been fully evaluated but will be delivered as a part of this contract for potential use in any follow-on activity.

## CONCLUSIONS

### Methods of Transduction

Of the many devices and techniques available to obtain pulse waveforms, none fall into a category of optimum. All have drawbacks that prevent definitive evaluations of pulse waveforms. Indeed, the system being measured can present a number of changes that will defeat the measuring technique being used. Results of comparisons between intra- and extra-vascular pressure recordings suggest that changes in vasomotor tone and transducer-vessel pressures may be the greatest contributors to the divergence of extra-vascular waveforms from intra-vascular waveforms. Fortunately, many of the changes can be understood and contingency alternatives could possibly be included into the analysis.[11] However, changes in the transducer-vessel relationship can vary subtly and there is always a doubt about the measurements being made and what conclusions can be safely drawn from them. It is evident from the literature and experimentation in this laboratory that no single recommended transducer can be chosen. Although the capabilities of some transduction techniques do not overlap with other techniques, the requirement for intimate communication between the vessel and the transducer establishes a common set of problems for each of the transducers. Just how common these problems are can be seen in the way transduced waveforms change in a like manner for different measurement techniques when vasomotor tone changes.

It is with these common problems and deficiencies in mind that a different proposal for research effort is made. While an improvement in technology is possible for all the devices that were examined, none of these improvements would, in all probability, drastically change the results obtainable with the device. Thus, it may be more profitable to develop a strategy or approach with multiple instrumentation rather than a single device capable of "doing it all."

Incorporated into this overall strategy might be a computer system capable of analyses.[32-34] Indeed, the correlative analysis between data from multiple instruments could be handled by a small special-purpose computer.[34] With the combination of volume and pressure pulses, a consideration of vascular perfusion is also possible. Transduction could be made with any of the devices listed in the selected transducer section. However, a technology that would permit the integration of information from several transducers at different sites would be required. This technology might involve improvement of several devices for compatibility within a multiple transducer measurement strategy.

A summary of the devices considered worth further investigation is shown in Table I. For each of the devices a brief list of advantages and disadvantages is provided.

Sites of Transduction

The brachial artery has been the more common site to determine blood pressure. This preference for the brachial artery may stem largely from its closeness to the surface and ease of placing cuffs around the limb. However, other sites are available where arteries are palpable. Beyond the availability of the pulse, the amount of diagnostic information within the pulse becomes important. It has been asserted that the brachial and radial artery pulses contain less information about central pressure events than the carotid artery.[11] No comparison between the temporal artery and aortic pressures was readily found in the literature. However, the temporal artery is an attractive site for measurements since it is close to central arteries and has little overlying tissue to make coupling to a transducer difficult. However, it is a small artery and may present waveforms consistent with its size.

Other sites deserving consideration include the carotid artery, brachial and radial arteries, and the femoral artery. The carotid artery and perhaps the temporal artery provide a good source of pulse pressure waveforms that are closely correlated with central pulse pressures. The

LIST OF TRANSDUCER TYPES WITH
ASSOCIATED ADVANTAGES AND DISADVANTAGES

TABLE 1

| Transducer Type | Advantages | Disadvantages |
|---|---|---|
| Photoplethysmography | Low position dependence; requires no vascular occlussion; provides a distinct waveform; can be quite small using solid state techniques. | Volume-pulse measurement; requires an energy input; with high light intensity, a possibility for burns; requires a light seal; calibration to absolute values difficult or impossible; moderate dependence on underlying tissue. |
| Straingauge - fluid and nonfluid coupled | Pulse pressure measurement; very small solid state devices possible; produces a distinct waveform; can measure static loads; useable in either volume or pressure measurements; fluid coupling to vessel-tissue complex possible. | Very position dependent; very dependent on amount and composition of underlying tissue; only relative pressure changes with current techniques; coupling to vessel wall difficult with specific coupling techniques (i.e., platens and fluid filling). |
| Piezoelectric crystal, fluid and nonfluid coupled | Pressure waveform measurement; passive device; not dependent on static load over a wide range of values; possible shapes and characteristics desired are available in great variety; can be very sensitive. | Relative pressures only--no absolute values possible; very position dependent; loading pressure dependent; very dependent on amount and composition of underlying tissue; requires stable high impedence amplifiers. |

TABLE 1 CONTINUED

| Transducer Type | Advantages | Disadvantages |
|---|---|---|
| Ultrasound (echo ranging) | Able to detect pulse related events through a variety of intervening tissues and thicknesses; deep-lying as well as superficial vessels can be used; | Standard transducers do not fulfill transduction requirements (i.e., too large, focused too deep, frequency too low); very position dependent; sophisticated signal shaping required; coupling material required; very limited use experience in this technique. |
| Impedence Plethysmography | Large user experience; moderate position dependence; a distinct waveform obtainable; low dependence on underlying tissue. | Serious questions of what is being measured; no way to calibrate the technique; good devices require elaborate and sophisticated electronics to control the many variables present. |
| Pressure Cuff Sensor | Established application techniques; microphone or strainguage can be used with cuff; applicable over large part of limbs and neck; low position dependence; | Waveform dependent on intra cuff pressure; wave shaping can occur with tubing between cuff and transducer; large deviations between intra-vascular and cuff waveforms possible; system may be too "soft" for good analysis of derivatives of pressure waveforms. |

TABLE 1 CONTINUED

| Transducer Type | Advantages | Disadvantages |
| --- | --- | --- |
| Resonance Electrosphygmograph | Non-contact with vessel or surrounding tissue; reported high correspondence between intra- and extra-vascular records; no reported secondary tissue changes from its use. | No knowledge of its operation; photos suggest a bulky transducer and processor; do not know if the device is active or passive. |

more distal the artery, the less it can be related to central pressures, but the more it can provide information on the pressures and flow into the limb being examined.

Important too is what diagnostic information the measurement is being used to detect. One does not examine for peripheral vascular disease in the carotid artery. However, while central pressures may give little information on atherosclerotic disease, the blood flow into the pinna of the ear may.[35] These considerations lead to a conclusion that a combinational measurement at more than one site with more than just pressure measurements may provide the needed level of reliability for diagnosis. Supporting such a multiple measurement idea is the fact that the cardiovascular system is attempting to preserve tissue perfusion and regulates this perfusion by baroreceptors centrally and peripherally as well as tissue-vessel responses to low oxygen tensions in self-regulating vascular beds. The great questions diagnostically are: whether tissue perfusion is adequate and whether blood-pressure is being controlled within normal ranges.

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# APPENDIX A

## Review of Two Additional Papers

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## APPENDIX A -- Review of Two Additional Papers

Two additional papers of importance are:

Abbott, J. A., "The Fidelity of the Externally Recorded Human Pulse," American Journal of the Medical Sciences 258:40-51, 1969.

Martin, G. E., M. L. Brown, R. H. Barnes, "Carotid Pulse Contour Patterns in Normal Subjects," Cardiologia 44:1-16, 1964.

Abbott reports on a careful examination of the fidelity of external pulse records, and provides some experimental evidence supporting some of the conclusions stated in the final report. Abbott used a crystal microphone made from a phonograph pickup, a photo-cell, and intra-vascular recordings to obtain pulse pressure waveforms. A frequency analysis was performed on arterial and venous recordings. Abbott found little information about 10 Hz for arterial and venous external recordings. In addition, he found an increasing phase lag as frequencies increased. The attenuation of frequency components noted in external recordings was found to increase in obese patients. The major contribution to external waveform distortion was found to be an increase in information in the 6 to 10 Hz passband. Such changes have been also seen in waveforms obtained with fluid-filled transducers.

Abbott concluded from his work that:

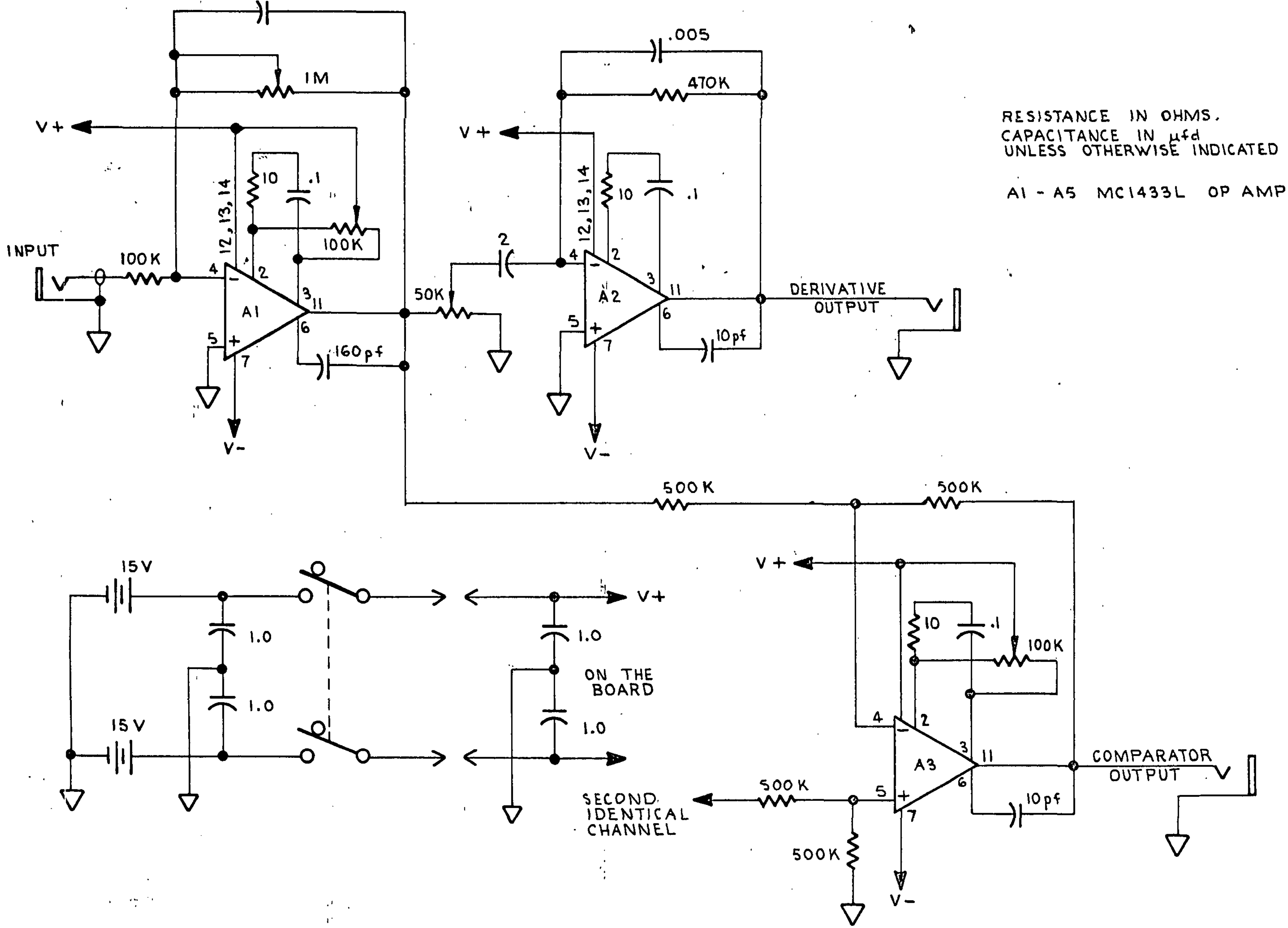
1. Phase and amplitude distortions observed in external recordings resulted in large measure from the over and under damping of perivascular tissue;
2. Distortions were the same for all transducers regardless of the amount of vessel loading;
3. Changes in vasomotor tone enhanced the attenuation of frequencies observed as attenuated in control extra-vascular measurements; and
4. When pulse amplitudes are small, attenutation occurs in a linear fashion but rapidly becomes non-linear with large pulse amplitudes.

These data confirm the conclusion stated in the final report that the distortion in external recordings is more a consequence of properties attributable to the system being measured than the transducer used.

The second report by Martin et al provides a basis for evaluating carotid pulse morphology in normal subjects. The transducer was an electromechanical device called an "Infraton" carotid pickup made by Beckman Corporation. The closeness between these recordings and recordings obtained with a crystal microphone in this laboratory is remarkable.

APPENDIX B

Schematic of Pulse Wave Analysis Breadboard




BREADBOARD SCHEMATIC

# APPENDIX C

## Waveforms from Pulse Wave Analysis Breadboard

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Carotid Waveform and Derivative

Blood Pressure Under High Noise Environments

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## Blood Pressure Under High Noise Environments

### Literature Study

In accordance with the Statement of Work, it is the purpose of the first part of this effort to search current literature in order to establish what the "state of the art" is in blood pressure microphones and to recommend future efforts at improving the noise rejection characteristics of a blood pressure microphone. Specifically, a "best" choice technique for optimum detection of blood pressure "Korotkoff" sounds in high ambient noise environments must be determined. In order to assist in determining what a best technique might be, a list of desirable properties has been established.

1. Maximum signal-plus-noise-to-noise ratio
2. Inherent artifact rejection characteristics
3. Small enough for use with a cuff and thin enough to prevent pressure amplification under cuff
4. Rugged
5. Lighweight
6. Noise cancelling and directional
7. Inexpensive
8. A constant amplitude sensitivity to dynamic pressures in a large static pressure field.

All of the above criteria are based on the premise that the device is compatible with existing Skylab blood pressure system design.

In addition to the above general overview of the problem, specific topics are of particular interest including investigation of geo-phone type transducers and special noise-cancelling type microphones.

Of primary importance are sources of artifact and noise which may mask signals of interest. Ambient noise, of course, could consist of any frequency, amplitude, and duty cycle making a generalized definition impossible. Artifact sources, however, generally consist of erratic sensor-patient motion and external forces causing vibration of the microphone directly or indirectly. Artifact disturbances sometimes can be controlled by soliciting user cooperation during critical measurement cycles. However, efforts to design against artifact not be disregarded since artifacts may be beyond the control of the user such as in environmental vibration.

The literature search has uncovered several interesting approaches to the solution of problems of detecting blood pressure sounds. Methods for the detection of blood pressure sounds can be identified by the transduction technique and are listed below:

1. Strain Gauge Transducers
2. Variable Capacitance
3. Variable Inductance and Reluctance
4. Piezoresistive
5. Piezoelectric
6. Anemometer
7. Ultrasonic

A detailed discussion of each approach with conclusions as to the effectiveness, practicality, and applicability to overall system requirements is given below.

1. Strain Gauge Transducers

This type of transducer usually consists of a rigid housing with a movable diaphram or beam which has strain gauges connected to it.[11] A plunger connected to the beam carries surface variations caused by pulsing blood flow to the strain-sensing beam. Since this type of mechanical system is well defined, it serves as a model for similar types of transducers even though the detecting mechanisms may not be the same. In that this is a mechanoelectric displacement type transducer it suffers from severe artifact problems and is referenced here only because this type of transducer forms the foundation for many other types.

Advantages: Rugged
Lightweight
Ambient Noise Free

Disadvantages: Very artifact prone
Difficult to stabilize
Sensitive to position and temperature

2. Variable Capacitance Techniques

Several investigators have used the variable capacitance-type pressure transducer which is usually comprised of movable plates attached to a diaphram which in turn is displaced by a contact-type plunger. These types of transducers can be fabricated using silicon integrated circuit technology[4] with gauge factors over 500, a 10-to-1 improvement over strain-gauge type displacement transducers. These transducers exhibit temperature independence and linear operation. Some researchers use the basic variable capacitive element in an RF bridge arrangement thereby improving system resolution. These microphones are basically an extension of the displacement transducer principal in that variations in distention of arteries under the blood pressure cuff are detected. Artifact can be a severe problem unless special application procedures are employed. Development to date has not addressed the fundamental noise artifact problems associated with these types of microphones.

Advantages: Linear
Good low frequency response
Temperature insensitive
Small
Lightweight

Disadvantages: Artifact prone
Non-compatible with Skylab equipment
Difficult to handle and use

3. Variable Inductance and Reluctance Techniques

Two types of variable inductance contact microphones dominate the field, those being the heavy mass type and the lightweight (accelerometer) type. Operation is based on displacement of a core within a magnetic field. Output response is proportional to the displacement of the movable electrode. This system as a derivative of the displacement transducer suffers from extreme artifact problems due to the minute magnitude of the forces acting on the surfaces of the plunger during the measurement of blood pressure. The capacitance and inductance type microphones are so similar that both can be considered to have similar advantages and disadvantages. Within this category is the geophone, a reluctance-type displacement transducer. This device features a spring-loaded moveable core placed in a strong magnetic field which when displaced results in a biphasic signal the magnitude of which can be related to the producing force by known transducer spring constants and sensitivity factors. Transducers of this type suffer from artifact and placement problems.

4. Piezoresistive

Piezoresistive transducers are fabricated from materials which exhibit resistance variation as a function of pressure. Investigators[9] have reported successful design of miniature piezoresistive bridges using integrated circuit techniques resulting in stable, repeatable results. Temperature drifting can be minimized by the use of special transducer design techniques. These transducers rely on displacement of a metal diaphram. Extremely small transducers can be fabricated which demonstrate rugged, lightweight characteristics with good sensitivities. While literature concerning this technique is oriented toward "in vivo" transducer applications, the capabilities of the transducer could be effective for external use.

Advantages: Extremely small size
Very lightweight

Disadvantages: Fragile
Artifact sensitive

## 5.0 Piezoelectric

This type of microphone is perhaps the most common type used for indirect blood pressure measurements, since it is small, rugged, simple, and dependable. The transducer produces a small electrical potential proportional to displacement forces, with some influence from first and second derivatives. While the trasnducer does operate on the displacement principle, the excellent signal plus noise-to-noise ratio which is acquired when it is placed under a blood pressure cuff makes the piezoelectric microphone a better choice than other types of displacement types in high ambient noise environments. SCI has been particularly active in the development of low-noise rugged microphones of this type. These microphones generally consist of piezoelectric crystals mounted inside a plastic or metal case which when deflected on the active face transmits bending forces to the crystal. Techniques for mounting and properly supporting the crystals are of utmost importance in achieving a good signal-producing device which has minimum ambient noise and artifact effects. Skylab microphone design activities were concentrated on making the microphone rugged and insensitive to static loads such as those seen by any microphone located under a cuff.

Advantages: Small
Lightweight
Rugged
Ambient noise suppresive
Inexpensive

Disadvantages: Sensitive to artifacts

6. Anemometer

This approach consists of using two fine hot wire thermistor probes mounted inside a cup which is placed over the signal source area.[10] As the air column inside the cup is modulated by arterial displacement, a biphasic signal is produced. This technique features low sensitivity to environmental noise. Investigators recommend attaching the cup with skin adhesive in order to minimize movement artifact. Impact tests indicated the rugged nature of these assemblies. Application of this device has been limited to heart sounds, however, application to blood pressure sounds seems feasible. The main disadvantages are the use of hot wire probes close to the skin surface and complications with handling and attaching the device to the subject being monitored.

Advantages: Ambient noise free
Lightweight

Disadvantages: Hot wire proximity to skin
Compatibility problems on interface to Skylab blood pressure device
Difficult to apply and maintain
Artifact prone when not properly applied

7.0 Ultrasonic Techniques

Application of ultrasound techniques to blood pressure measurements has been investigated by many researchers.[15] Such transducers depend upon the detection of doppler shifts associated with the motion of reflective tissue. Electrically-excited, piezoelectric crystals provide the source of ultrasound which is then coupled via a water-based jelly to the patient's body. A focussed beam can be produced which is bounced off the surface of the area of interest. Mortan, et.al.[5], report that the ultrasound signals resulting from arterial wall motion must be properly processed to reject blood flow sounds and to "pull out" blood pulse sounds associated with blood pressure measurements. The resultant signals using this technique are somewhat similar to the Korotkoff sounds heard during auscultation.

Advantages: Rugged
Lightweight
Ambient Noise free

Disadvantages: Coupling jelly must be used
Artifact noise susceptable
Expensive
Additional circuitry required to interface to Skylab Blood Pressure Device

## Conclusions

Based on this literature search, "state-of-the-art" blood pressure microphone appear not to have changed radically, nor is there evidence of new types that solve old problems. The most promising improvements so far appear in reports made by Geddes and Moore[7] whereby placement of piezoelectric crystals inside the blood pressure cuff instead of below the distal end or inside a pocket under the inflatable bladder improves signal amplitude resulting in an overall improvement of signal-to-noise ratio. Intrinsic noise may or may not be an important factor in this respect. If the signal + noise-to-noise ratio is high, then processing the signal for accurate determination of systolic and diastolic blood pressure can be accomplished. This implies that intrinsic noise levels are not extremely important as long as their ratio-to-signal is low.

The problem of developing a microphone system which demonstrates improved rejection of artifact and ambient noise is best approached by considering (1) multiple crystal systems which may display common mode signal rejecting characteristics, (2) microphones within the bladder of the blood pressure cuff to determine the effects of such placement and improvements, if any, on the rejection of ambient noise and artifact, (3) improved packaging of our existing single crystal type, such as lead encasement on the back side with increased mass and possible reduction of artifact effects, and (4) modifications to the cuff assembly for improvement of the system. Directivity and its relationship to position sensitivity will be studied. Compafison analysis to the Littman Stethoscope and why this technique is so effective will be made in an effort to develop a microphone with much improved artifact and ambient noise rejection effects.

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3. Peter Strong, Biophysical Measurements. Oregon:Tketronix, Inc., 1971.

4. W.D. Frobenius, A.C. Sanderson, H.C. Nathanson, "A Microminiature Solid-State Capacitive Blood Pressure Transducer with Improved Sensitivity," IEEE Transactions on Biomedical Engineering, pp. 312-314, July 1973.

5. A.R. Soffel, "A New Low-Noise Condenser Microphone," Journal of the Audio Engineering Society, vol. 14, pp. 240-243, July 1966.

6. E. Van Vollenhoven, "Calibration of Contact Microphones Applied to the Human Chest Wall," Medical & Biological Engineering, vol. 9, pp. 365-373, 1971.

7. K.Ikegaya, N. Suzumura, and T. Funada, "Absolute Calibration of Phonocardiographic Microphones and Measurements of Chest Wall Vibration," Medical and Biological Engineering, vol. 9, pp. 683-692, 1971.

8. Harry F. Olson, "Calibration of Microphones by the Principles of Similarity and Reciprocity," Journal of the Audio Engineering Society, vol. 17, number 6, pp. 654-656, December 1969.

9. Samaun, Kensall D. Wise, and James B. Angell, "An IC Piezoresistive Pressure Sensor for Biomedical Instrumentation," IEEE Transactions on Biomedical Engineering, vol. BME-20, no. 2, pp-101-109, March 1973.

10. D.E. Laughlin and R.P. Mahoney, "New Phonocardiographic Transducers Utilizing the Hot-Wire Anemometer Principle," Medical and Biological Engineering, vol. 10, pp. 43-55, 1972.

11. G.L. Pressman and P.M. Newgard, "A Transducer for the Continuous External Measurement of Arterial Blood Pressure, IEEE Transactions on Bio-Medical Electronics, pp. 73-81, April 1963.

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13. L.A. Geddes and A.G. Moore, "The Efficient Detection of Korotkoff Sounds," Medical & Biological Engineering, vol. 6, pp. 603-609, 1968.

14. John M. Lagerwerff and Robert S. Luce, "Artifact Suppression in Indirect Blood Pressure Measurements," Aerospace Medicine, pp. 1157-1161, October 1970.

15. J.L. Morgan, "Doppler Shifted Ultrasound," Advance, pp. 503-506, March 1969.

## Experimental Results

Experiments were undertaken to investigate the possibility of improving the performance of microphones presently used in blood pressure measurement instruments. Our efforts were broken into three categories: (1) investigation of other sensor types, (2) hypothetical improvement of existing sensors, and (3) experimental evaluation. Testing was performed on a dummy arm which simulated an arterial pulse wave. Artifacts were simulated in a repeatable manner to evaluate the artifact rejection performance of each sample. Each microphone was also evaluated during actual blood pressure measurements using a standard blood pressure measuring system.

The microphone found most successful at this time is manufactured by Telecare for several commercial applications. Simple in concept, it is fundamentally a piezoelectric crystal bonded to a thin sheet of brass for strengthening. This crystal assembly is potted in a protective case using soft silicone rubber. The crystal is edge-supported in such a manner that forces on the surface of the potting product flexure charges on the crystal. A transconductance amplifier converts these dynamic charge currents to a voltage signal. In practice, there is no clear distinction between the response of the crystal when loaded with a force and the response when subjected to acceleration normal to the surface of the crystal. Although the physical phenomena of these stimuli are greatly different, flexure charges are generated in either case. Since pressure loading and unloading is always present during a useful measurement cycle, it appears desirable to investigate any sensor type which would respond to acceleration only. Several geophones were acquired in order to assess their performance. These transducers were found to be extremely sensitive to forces tangential to the axis of orientation and required extreme overdamping such that they could not be considered useful in this application. The geophones having a frequency response low enough to pick up Korotkoff sound frequencies necessary for determining systolic pressure could only be used when positioned parallel to the earth's gravity axis due to the low spring constant of the core support springs in the device. Also, due to the bulky size of commercially available geophones, application of these devices to this study was abandoned.

Earlier, the response of the crystal microphone had been described as flexure response caused either by force loading or acceleration. Artifacts, then, must be classifiable as either force or acceleration, or both. Considering the physical placement of the microphone under the distal edge of the cuff, it appears that force loading, but not acceleration, could be caused by any added force on the exterior of the inflated cuff. We have referred to this force loading as a "cuff bump." Similarly, lateral translation, but not force loading, could be caused by movement of the arm other than muscle flexing. We have called this translation effect an "elbow bump."

The small physical size of the crystals normally used in these microphones suggested the possibility that additional crystals might be incorporated into the microphone housing and arranged in a manner such as to aid artifact rejection. Two arrangements, shown in Figures 1b and 1c, appeared possible. Microphone "A" was built with two crystals mounted back-to-back with material separating the two brass discs only at the edges. The crystals were electrically connected in parallel. This unit would appear to reduce the effect of acceleration as acceleration would deform the crystals equal amounts in opposite directions. Charges produced from each crystal in opposite phase would thus cancel. However, the sensitivity of the top crystal to localized forces, such as arterial pulses, should be essentially unchanged. (Neglecting the increased capacitance.)

Microphone "B" was built with two crystals mounted back-to-back, but the crystals were electrically connected in reverse phase; i.e., the opposite of Microphone "A", the concept being that incremental pressure loading deforms the crystals in the same direction with the reverse-phase wiring allowing the charges to cancel. Similarly, the presence of localized forces, such as

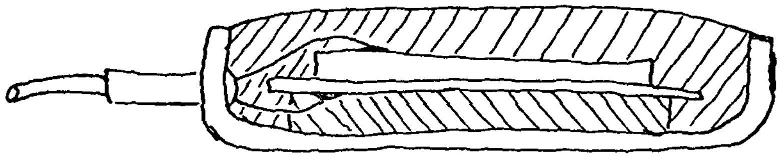


FIG 1a

SINGLE CRYSTAL MICROPHONE

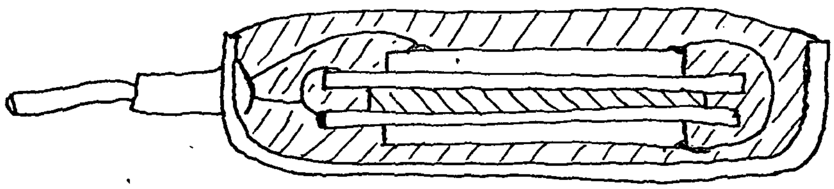


FIG 1b

DUAL CRYSTAL MICROPHONE
"A"

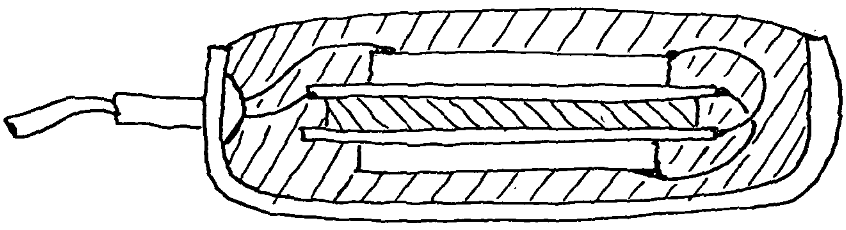


FIG 1c



DUAL CRYSTAL MICROPHONE

"B"

arterial pulses, would primarily stilumate the top most crystal. It was recognized from the start that these connections, while designed to reject certain artifacts, would possibly enhance others; nevertheless, microphones "A" and "B" were fabricated for evaluation.

In order to test the new microphone configurations, a model "arm" was fabricated from common materials representing the various parts of a normal human limb. Construction consisted of a solid plexiglass rod about 1.5 inches in diameter slipped inside a roll of tissue paper. In addition, a soft plastic tube was passed between the layers of tissue paper about .15 inches from the surface. The tubing was tied closed at one end with the other end connected to a three-way valve and regulated air supply. A control circuit was designed to pulse the control valve resulting in air impulses alternately expanding the plastic tubing and then releasing the pressure to atmosphere, resulting in simulated arterial wall motion. Drawings and pictures of the test fixture are shown in Figures 2 and 3. In order to stimulate the test are with "translation" and "elbow bump" artifacts two mechanisms were used. Translation artifact was created by attaching a doorbell buzzer to the plexiglass rod. As power was applied to the buzzer vibration of the rod was carried throughout the system. "Cuff bump" effects were created by a simple pendulum supported weight impacting the surface of the cuff. Force calculations for this system are derived in Appendix A.

Testing began with the standard single crystal microphone being subjected to three tests. These tests consisted of measuring the pulse waveform amplitude received by the microphone with and without translation effects and the sensitivity of the microphone to "cuff bump" effects without pulsing the artery. In all cases the cuff was pumped to a constant 130 mmHg. After these tests were completed, the two new microphones were subjected to the same routine. Data were taken using the same sensitivities as used during the standard single crystal microphone testing and all results were normalized to the sensitivity of the standard microphone. Photographs of the results and a table of normalized sensitivities of the two test microphones are shown in figures 4 through 7.

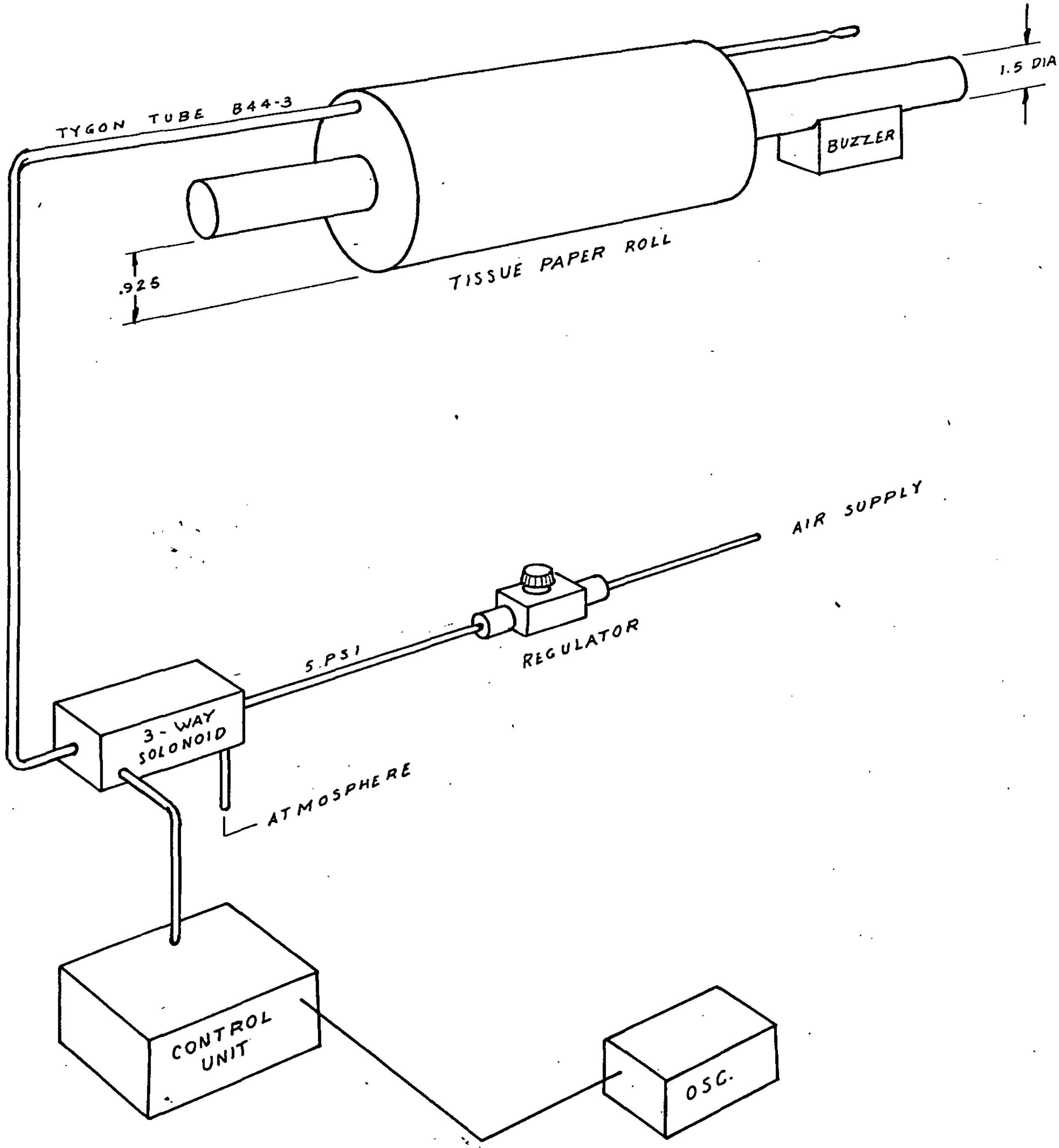
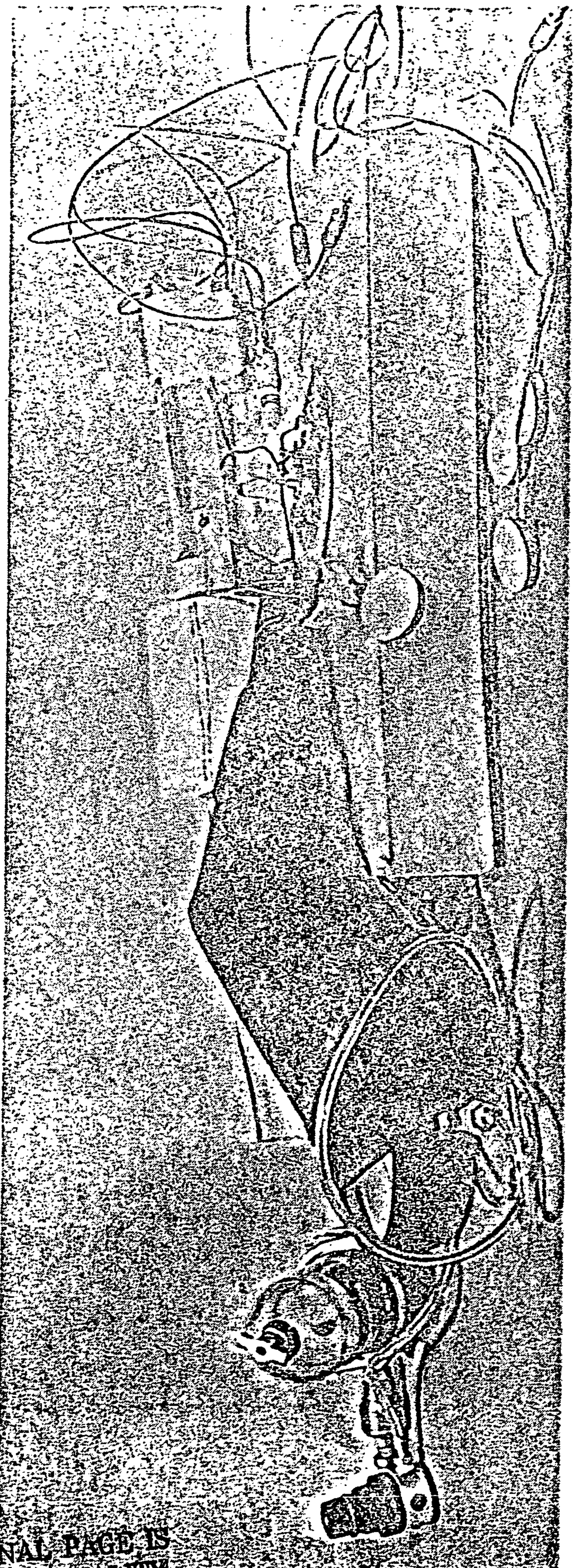
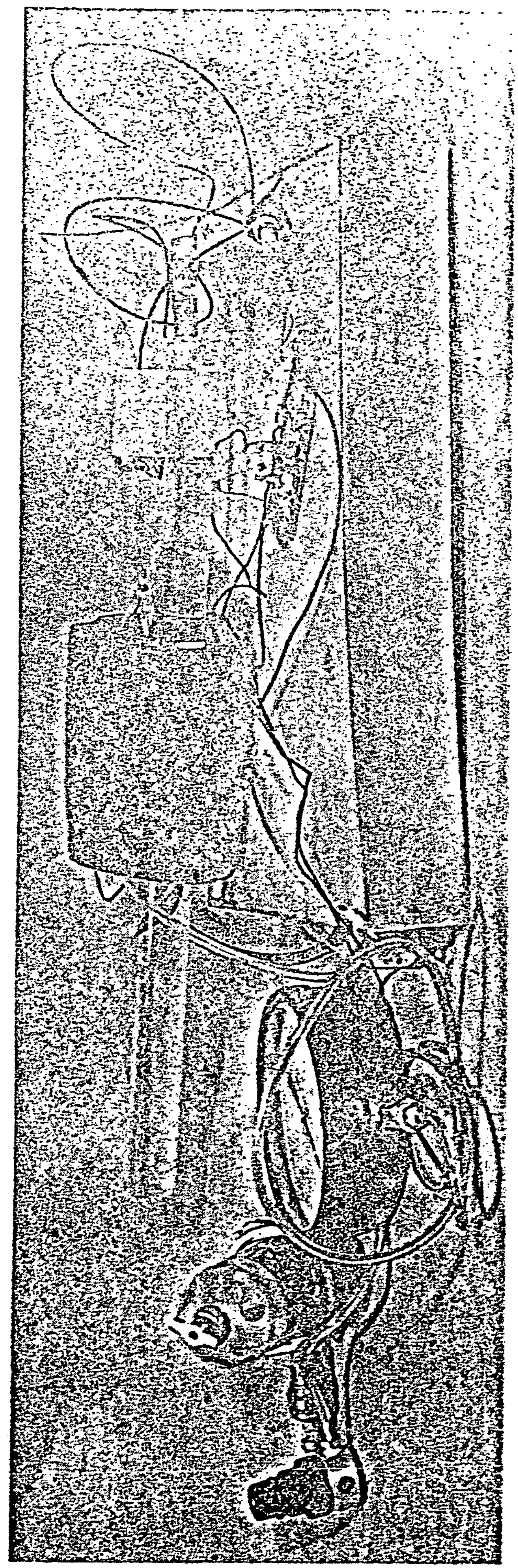





FIG. 2 MODEL ARM





<u>SINGLE CRYSTAL MICROPHONE</u>

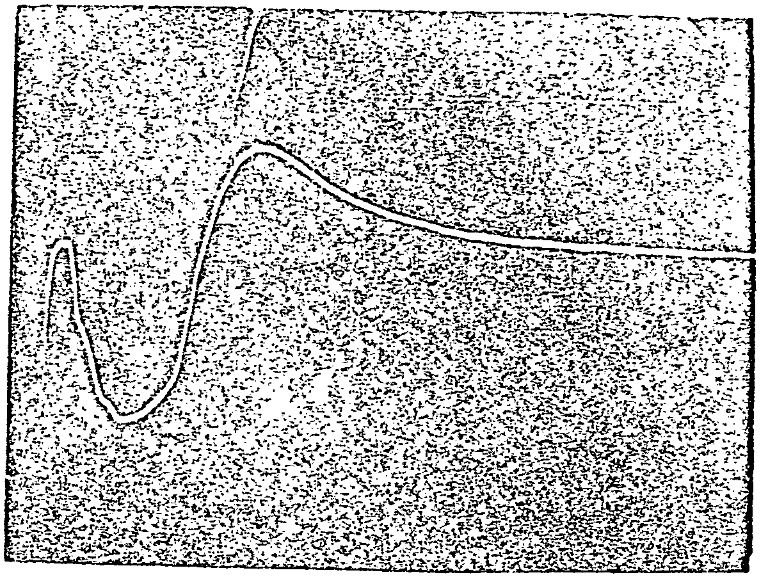


Figure 4a

Simulated arterial wall
Deflection detection
Horizontal = 20 msec/div
Vertical = 5 v/div
$P_{air}$ = 5 psi

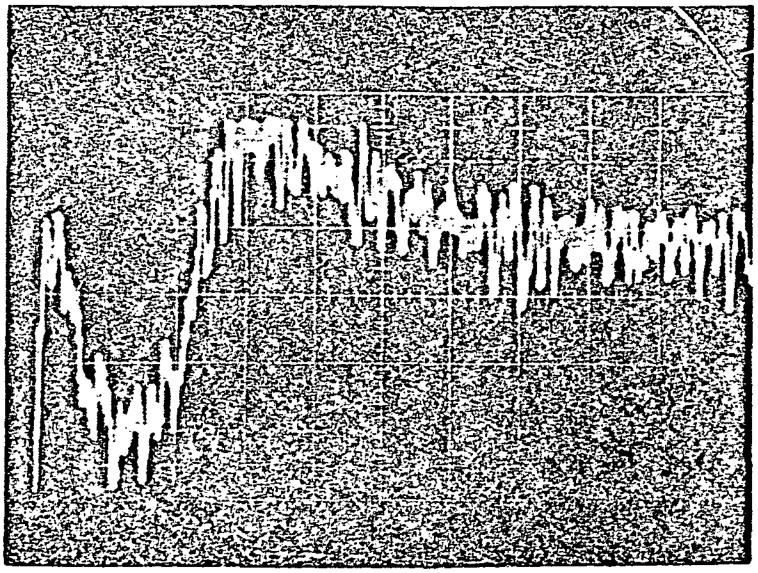


Figure 4b

Arterial wall detection with translation artifact
Horizontal = 20 msec/div
Vertical = 5 v/div
$P_{air}$ = 5 psi

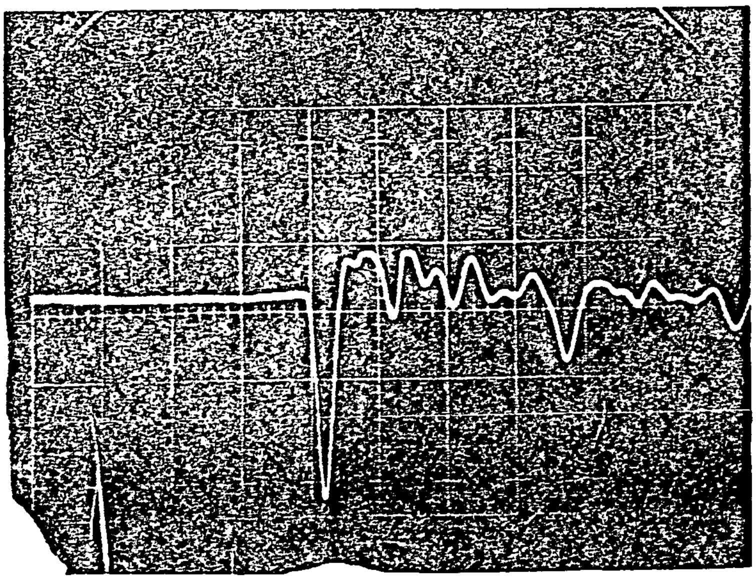


Figure 4c

Cuff bump artifact detection
Horizontal = 10 msec/div
Vertical = 5 v/div

DUAL CRYSTAL, MICROPHONE A

Figure 5a

Simulated arterial wall

Deflection Detection

Horizontal = 20 msec/div

Vertical = 5 v/div

$P_{air}$ = 5 psi

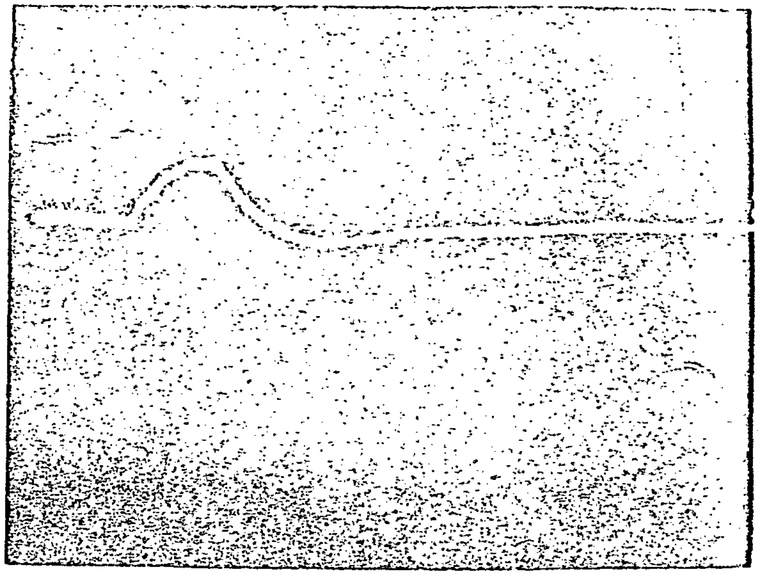


Figure 5b

Arterial wall detection

with Translation Artifact

Horizontal = 20 msec/div

Vertical = 5 v/div

$P_{air}$ = 5 psi

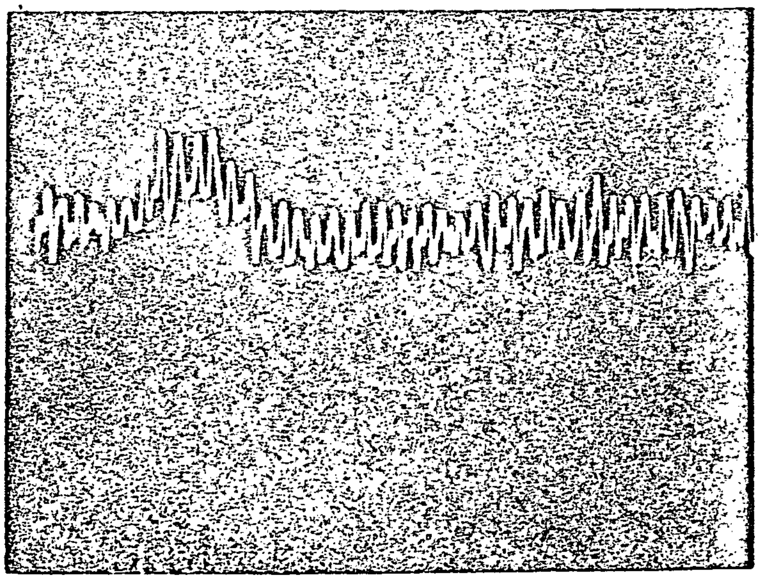


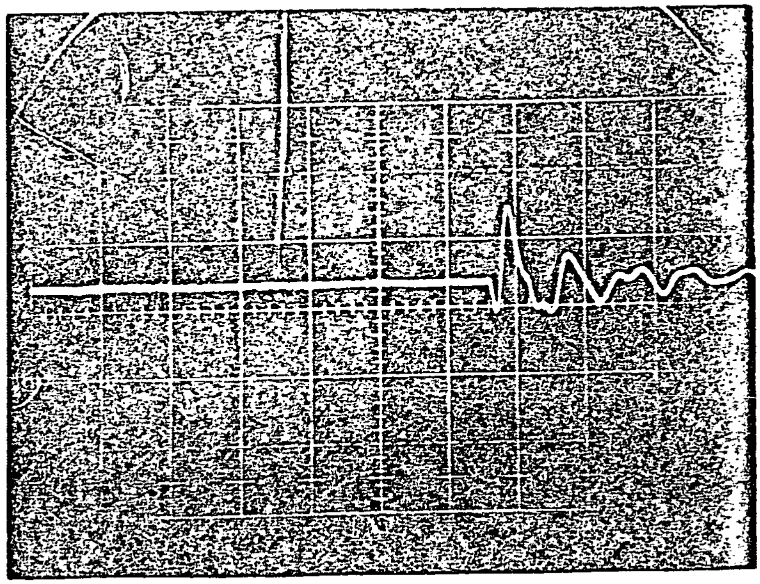


Figure 5c

Cuff bump artifact detection

Horizontal = 10 msec/div

Vertical = 5 v/div



NORMALIZED SENSITIVITIES

| | Single Crystal | Microphone A | Microphone B |
|---|---|---|---|
| Arterial Wall Motion | 1 | .35 | .425 |
| Translation | 1 | 2.57 | 1.41 |
| Cuff Bump | 1 | 1.26 | 10.8 |

FIGURE 7

In addition to the previous tests each of the three microphones were used on a standard SCI blood pressure measuring system in order to determine their overall sensitivity to Korotkoff sounds during actual measurement cycles. A subjective evaluation of the rejection of normal artifacts associated with taking blood pressure was also made. Strip chart recordings were made on each of the three microphones evaluating unfiltered Korotkoff sound sensitivity as well as sensitivity to sounds in the frequency bands of interest for optimum detection of systolic and diastolic blood pressure. It is, of course, imperative that any transducer used be capable of responding to these frequencies for accurate detection of these events. These recordings are shown in Figures 8 through 10.

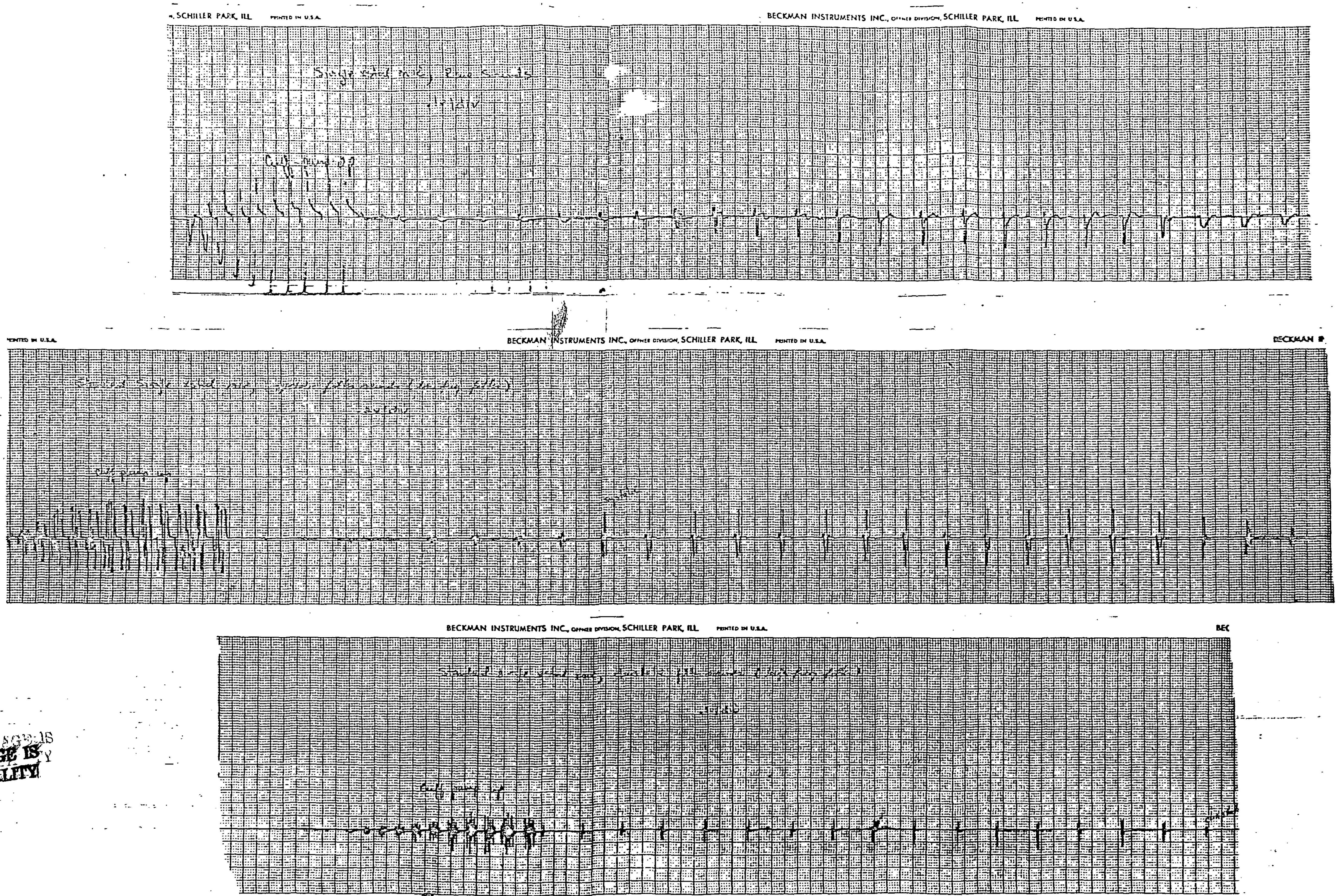
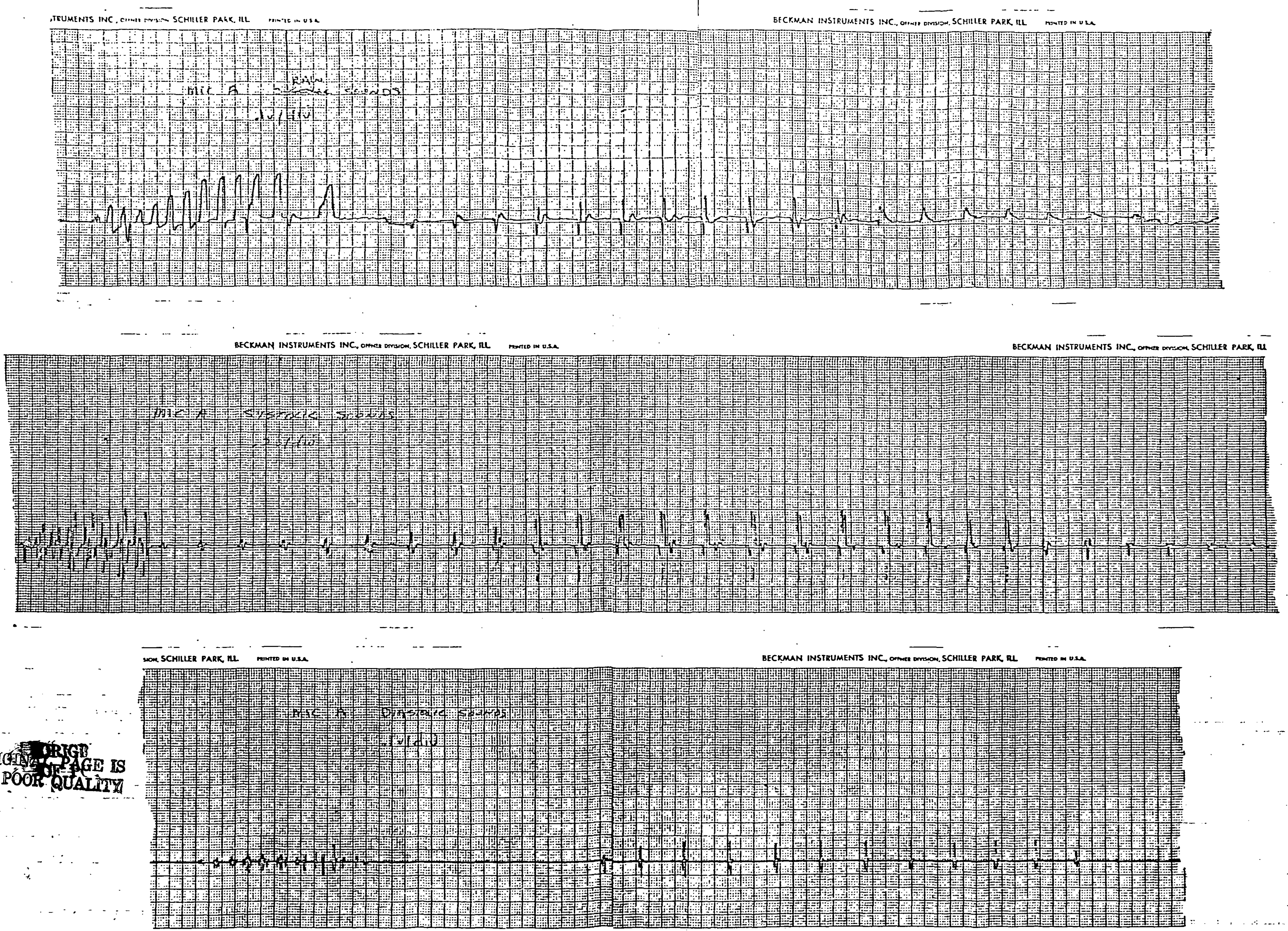







FIG. 8 STANDARD SINGLE
CRYSTAL MIC.




FOLDOUT FRAME 1

FIG. 9 MICROPHONE A

FOLDOUT FRAME 2

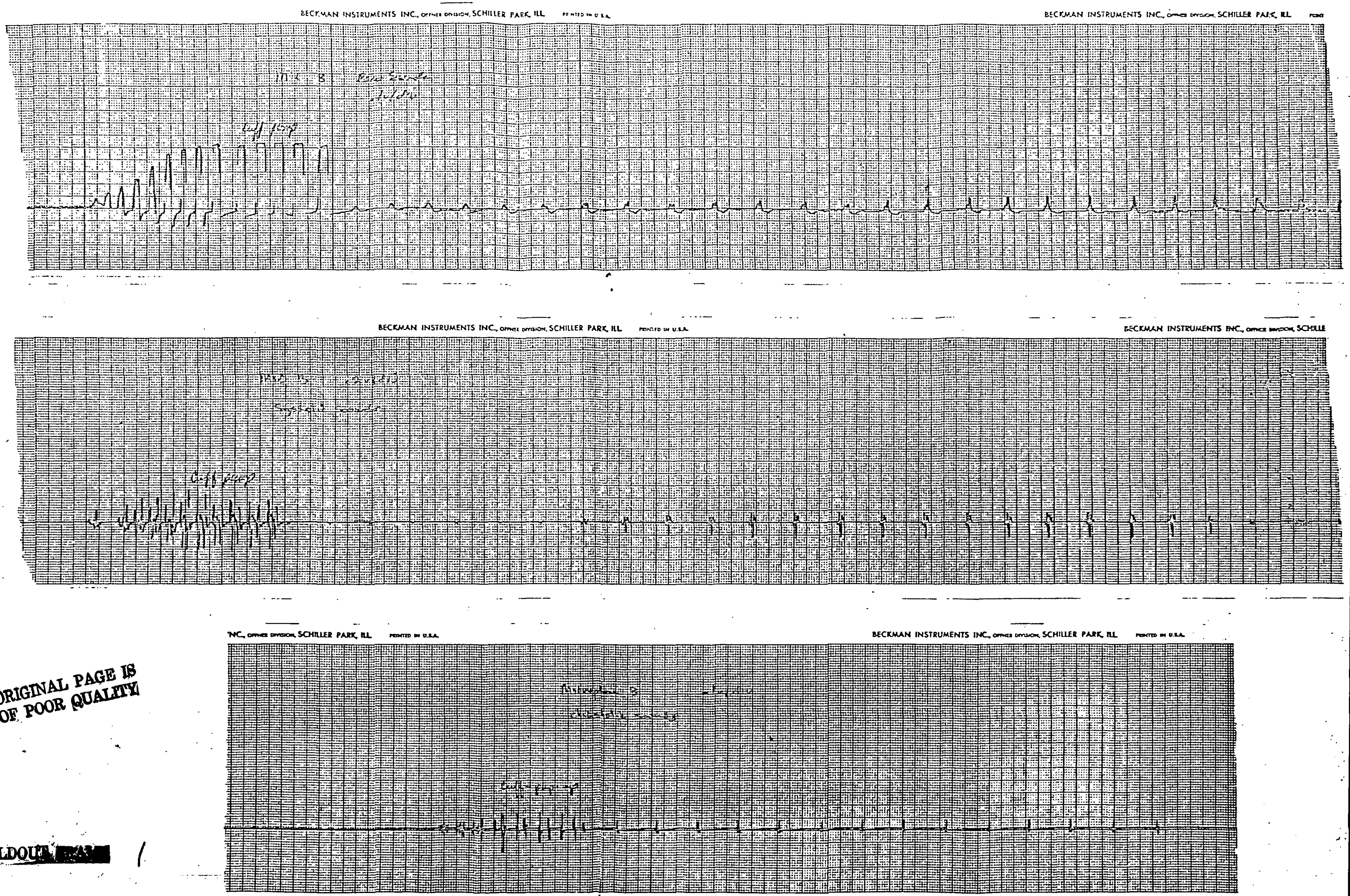
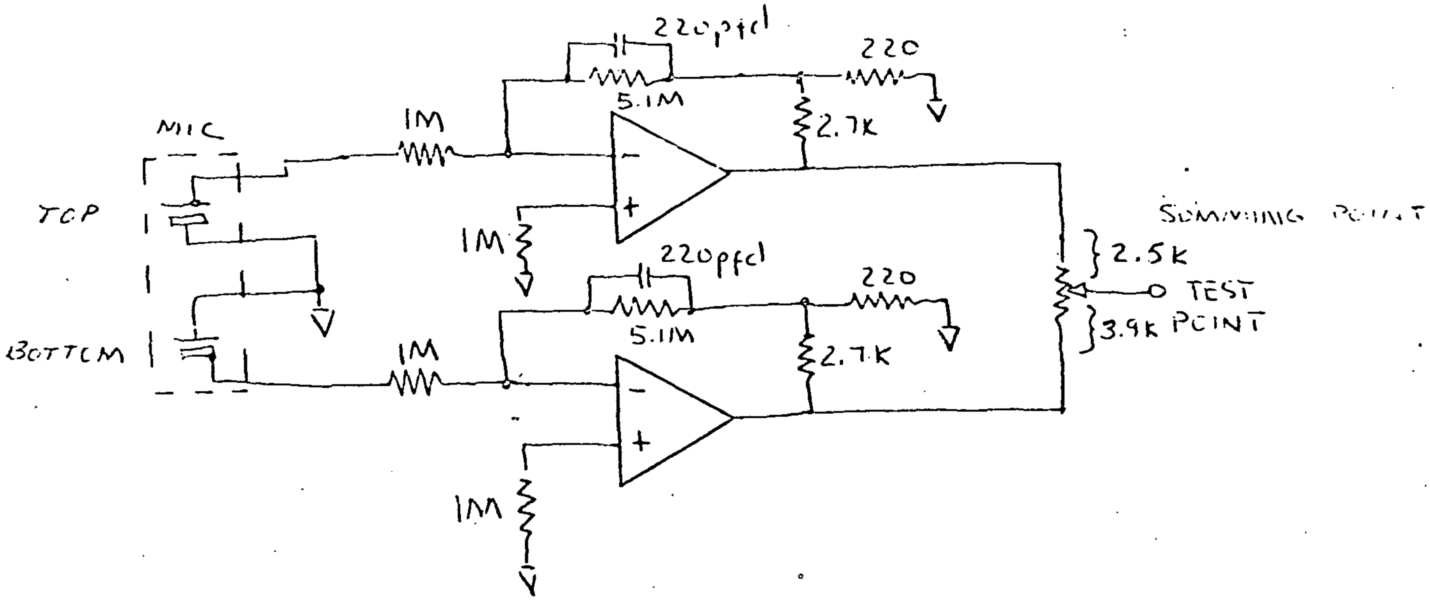
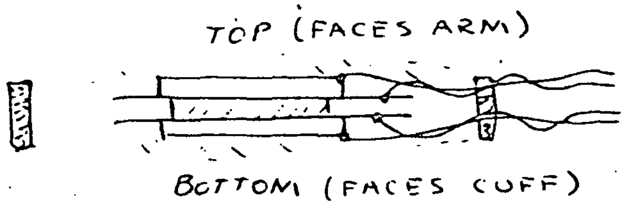





FIG. 10 MICROPHONE B




MICROPHONE CONSTRUCTION

FIGURE 11

## CONCLUSIONS AND RECOMMENDATIONS

Regrettably, the obvious conclusion to be drawn from the test data is that the performance of each of the experimental microphones was inferior to the standard microphone. Further, each microphone appeared to be particularly sensitive to the type of artifact it was intended to reject. In the forlorn hope that the microphones had been assembled improperly, both were carefully disassembled and examined. There were no apparent defects, and both microphones were rebuilt and the testing repeated. However, the data were repeatable in spite of being irrefutably opposite to the theory. The obvious conclusions being that the standard single crystal microphone was still the best choice (for the three configurations tested) for general use.

After making additional analysis of the inter-crystal connection system used, it was decided that perhaps using direct coupling of the basically capacitive microphone crystals for cancellation of artifacts was not the optimum approach, therefore, a third microphone was built, electrically bringing out each crystal separately and terminating each into its own preamplifier. The output of the preamplifiers was then terminated into one side of a potentiometer permitting adjustment of the summing ratio (see Figure 11). The previously described tests were conducted on this new configuration, with results as indicated in Figures 12, 13, and 14.

Figure 12

Simulated Arterial Wall Motion Detection

Horizontal: 20 msec/div

Vertical = 1 v/div

$P_{air}$ = 5 psi

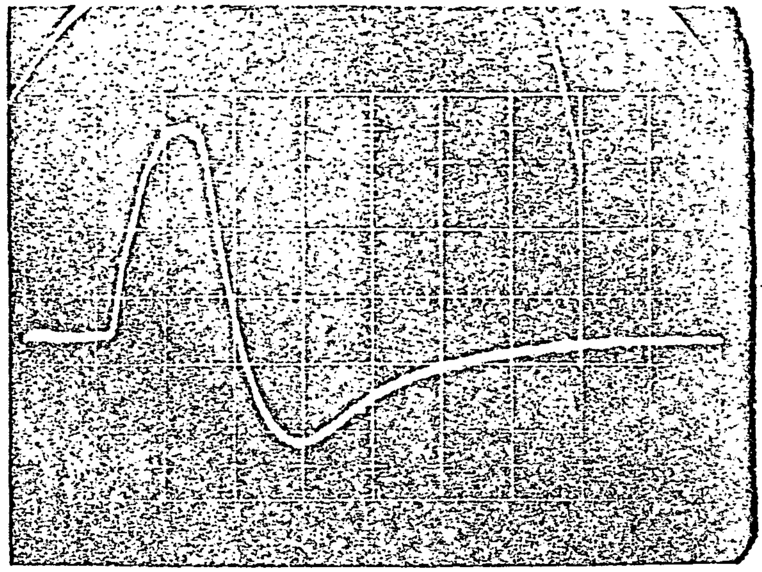


Figure 13

Arterial Wall Detection with translation artifact

Horizontal = 20 msec/div

Vertical = 1 v/div

$P_{air}$ = 5 psi



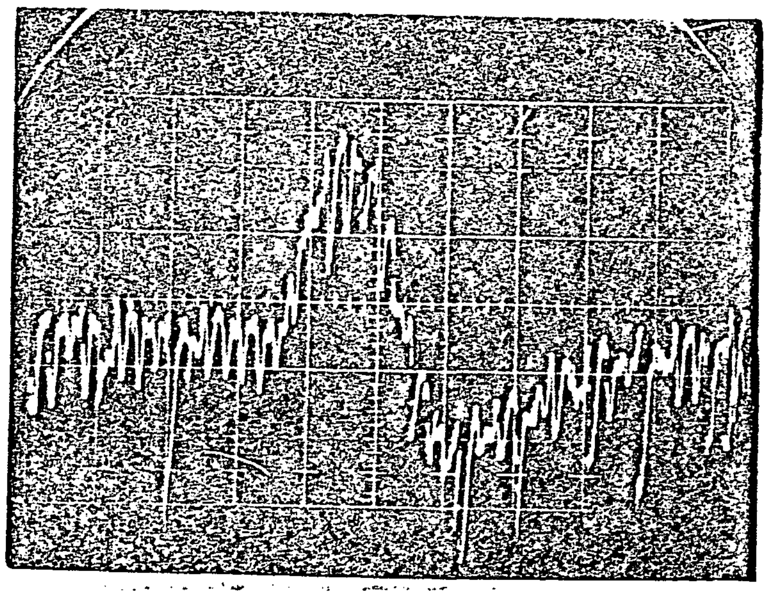
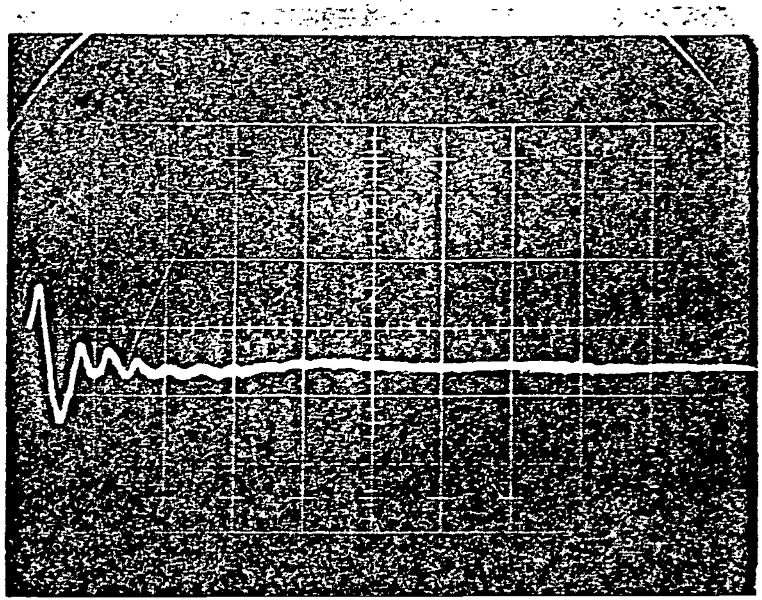


Figure 14

Cuff Bump Artifact Detection

Horizontal = 20 msec/div

Vertical = 1 v/div



The summing potentiometer was adjusted for minimum rejection of signal with maximum rejection of translation artifact. Resultingly the signal amplitude in the test configuration was five times less than the standard single crystal microphone. After scaling all resulting data by a factor of 5 normalized sensitivity ratios were calculated as shown below.

| | Single Crystal | Dual Crystal |
|---|---|---|
| Arterial Wall Motion | 1 | 1.125 |
| Translation | 1 | 2 |
| Cuff Bump | 1 | .555 |

As indicated significant reduction of cuff bump was achieved with the new microphone. Further adjustment of the summing potentiometer resulted in further rejection of cuff bump artifact as well as signal amplitude. The best overall summing ratio for this microphone was attained when adjustment for minimum translation artifact was made.

## FINAL CONCLUSIONS

Although the final microphone does afford a means for minimization of certain artifacts signal levels, desired sounds signals are also affected, in addition, choosing a minimization adjustment for some artifact results in the enhancement of others as predicted at the outset of this investigation. It is our opinion that due to the difficulty in making a best choice for summing the two microphone signals, the Telecare single crystal microphone is still a best choice for detection of Korotkoss sounds with good rejection of artifact.

# APPENDIX A

## PENDULUM CALCULATIONS

$$F = Ma = mgl \sin \theta$$

$$M = \frac{\text{Weight}}{g} \quad \therefore \quad F = Wl \sin \theta$$

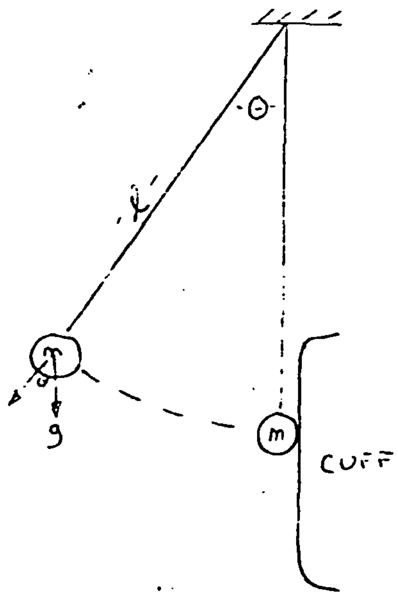
In cuff bump experiments:

$W_m = 5$ gm

$\theta = 30°$  $l = 12''$

$F = (5 \text{ gm})\ (12'')\ (\sin 30°)\ (2.54 \text{ cm/in})$

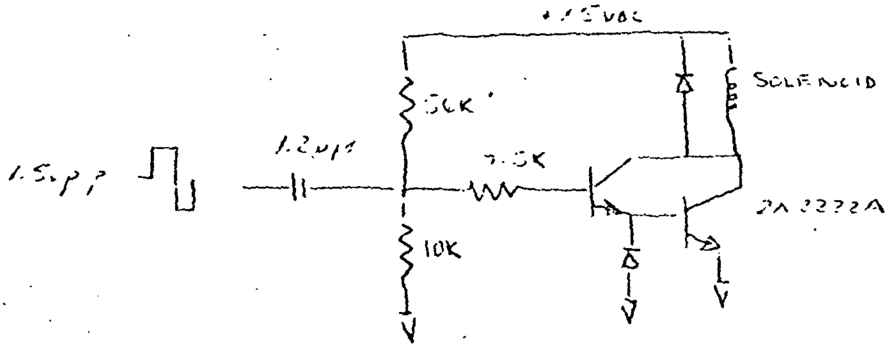
$F = 76.2$ gm/cm



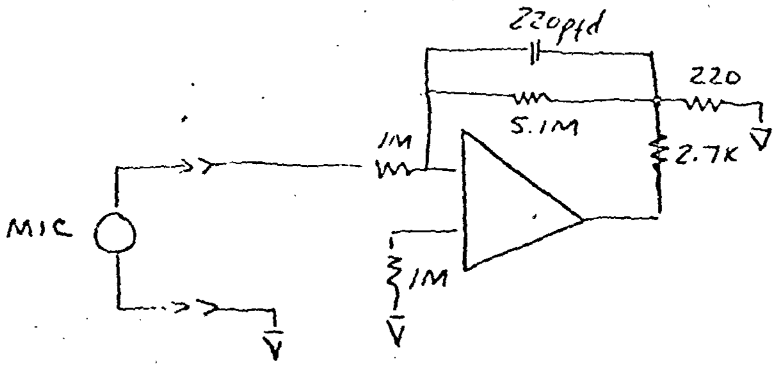
# APPENDIX B

## CIRCUIT DIAGRAMS

1. Simulated arterial pulse control valve circuitry




2. Front end signal amplifier




Break Points

$$\text{Gain} = \frac{(5.1M)}{(1M)} \quad \frac{(2.7K)}{(220)} = 62.5$$

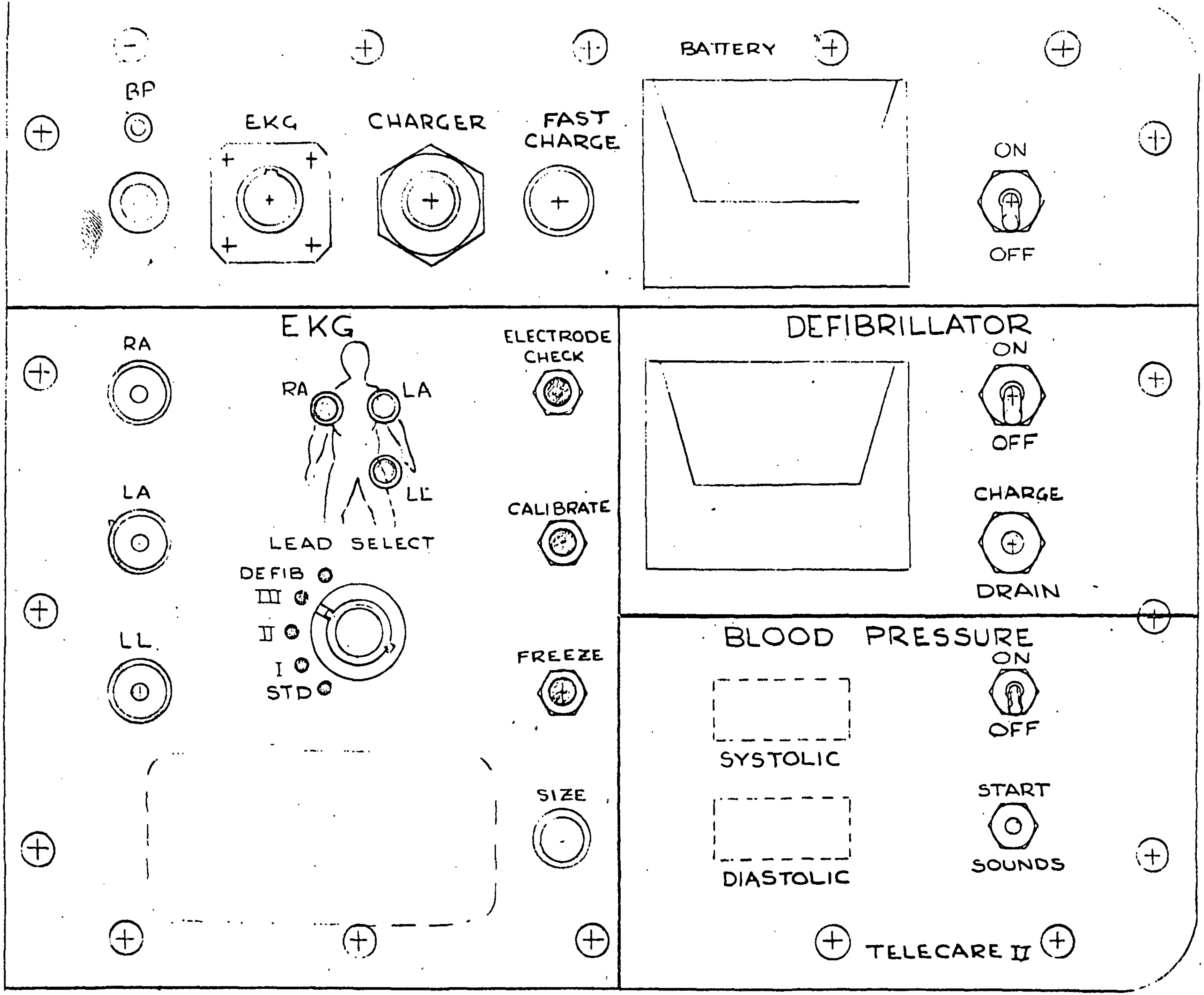
$$f_{high} = 135 \text{ Hz}$$

$$f_{low} = 5.8 \text{ Hz @ } C_{mic} = .027 \text{ pfd}$$

Miniature Battery or 28 VDC
Line-operated Defibrillator/Scope

## Miniature Battery or 28 VDC Line-operated Defibrillator/Scope

Major effort was expended on the Defibrillator/Scope. Several meetings on the subject were held with the Technical Monitor. The results of the configuration decisions are shown by the front panel drawing on the next page. The unit was delivered and has been found to function well.


BATTERY
BP
EKG
CHARGER
FAST CHARGE
ON
OFF
EKG
RA
LA
LL
RA
LA
LL
LEAD SELECT
DEFIB
III
II
I
STD
ELECTRODE CHECK
CALIBRATE
FREEZE
SIZE
DEFIBRILLATOR
ON
OFF
CHARGE
DRAIN
BLOOD PRESSURE
ON
OFF
SYSTOLIC
DIASTOLIC
START
SOUNDS
TELECARE II