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GENERAL BIOPHYSICAL INVESTIGATION AND INSTRUMENTATION 405819

REPORT

GENERAL BIOPHYSICAL INVESTIGATION AND INSTRUMENTATION

FINAL REPORT

ON

TASK III: "Intracardiac and Intravascular Blood Pressure Measurement Utilizing a Transducer Effective at the Focus of Measurement"

TASK VI: Intracardiac Blood Pressure Transducer

For

OFFICE OF NAVAL RESEARCH
Washington 25, D.C.

Principal Investigators

Dr. Alvin Singer
Charles Reinhardt

Contract NOnr 2912(00)

American Biophysics Research Laboratory

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CONTENTS

I. INTRODUCTION

The present standard cardiac catheterization instrumentation consists of a hollow catheter inserted at one end into the blood stream and connected to an electrical strain gauge at the other end.[1] The strain gauge output then is amplified and recorded on a moving strip chart.

The catheter is filled with physiologic saline containing heparin, an anti-coagulant.

This hydraulic system has several attendant problems:

(1) Coagulation of the blood within the catheter lumen.[2] To avoid clotting within the lumen, periodic flushing of the catheter with the heparinized saline is necessary.

(2) Low frequency distortion. Movement of the catheter tip by the contracting heart walls imparts a pressure to the fluid within the lumen resulting in low frequency distortion (.6-4 cycles per second) synchronous with the heart beat.[3]

(3) High frequency distortion. Resonance peaking in a high frequency range (12-65 cycles per second) of the hydraulic catheter-external strain gauge system results in high frequency distortion because of the greater sensitivity in the area of resonance.[4]

In order to avoid the problem of the hollow catheter in the blood stream with the external strain gauge, several non-hydraulic catheterization systems with a miniature transducer on the distal catheter tip have been designed.[5,6,7]

The catheter system described here is most unique in that the system is primarily optical rather than electrical. The catheter tip transducer is an optical transducer. The catheter contains two fiber optics bundles with one bundle conveying constant amplitude light to the transducer from a light source and the other bundle returning to a photocell light of amplitude proportional to the pressure exerted on the transducer.[8] The photocell output is subsequently amplified and displayed.

The utlilization of cardio-vascular catheterization for measurement of pulsatile pressure within the cardio-vascular system has demanded physical information of the catheterization system in use. It is necessary to know at least (1) sensitivity (i.e., electrical output amplitude vs. static pressure input) (2) frequency response (electrical output amplitude vs. frequency of pressure input at constant magnitude) (3) phase shift in order that the output data be interpretable in terms of intravascular pressure.[9] (Phase shift vs. frequency of pressure input at constant magnitude)

This paper describes such information with respect to the catheterization system herein described.

II. DESCRIPTION OF THE MICROMINIATURE OPTICAL PRESSURE TRANSDUCER

The function of the optical pressure transducer is to vary light intensity in accordance with variations in pressure impinging on the transducer. The values of light intensity can then be converted to values of pressure. The light beam whose intensity is varied is passed sequentially through a polarizer, photostress material which actually varies the elliptical polarization of the light and an analyzer.[10] The photostress material is deformed by the pressure which is exerted perpendicularly to the direction of light propagation. This may be best explained by inspection of Figure 1, where:

"A" is a small disk of polaroid material.

"B" is a small disk of a quarter-wave plate.

"C" is a small cylinder of a photostress material.

"D" is a reflecting surface.

Unpolarized parallel light is directed through polaroid "A" from which the light emerges as plane-polarized parallel light. The plane-polarized parallel light in passing through the quarter-wave plate "B" undergoes a 90° phase shift and emerges from "B" as circularly polarized light. The optic axis of the quarter-wave plate "B" is at 45° to the optic axis of the polaroid "A". The circularly polarized parallel light emerging from "B" enters the photostress material "C". "C" is a photostress material[11] by virtue of fact that light which is elliptically polarized (of which circularly and plane-polarized light are special cases) will have the degree of elliptical polarization changed to an extent depending upon: (1) the stress which is exerted on the photostress material perpendicular to the direction of light propagation; (2) the length of the stressed

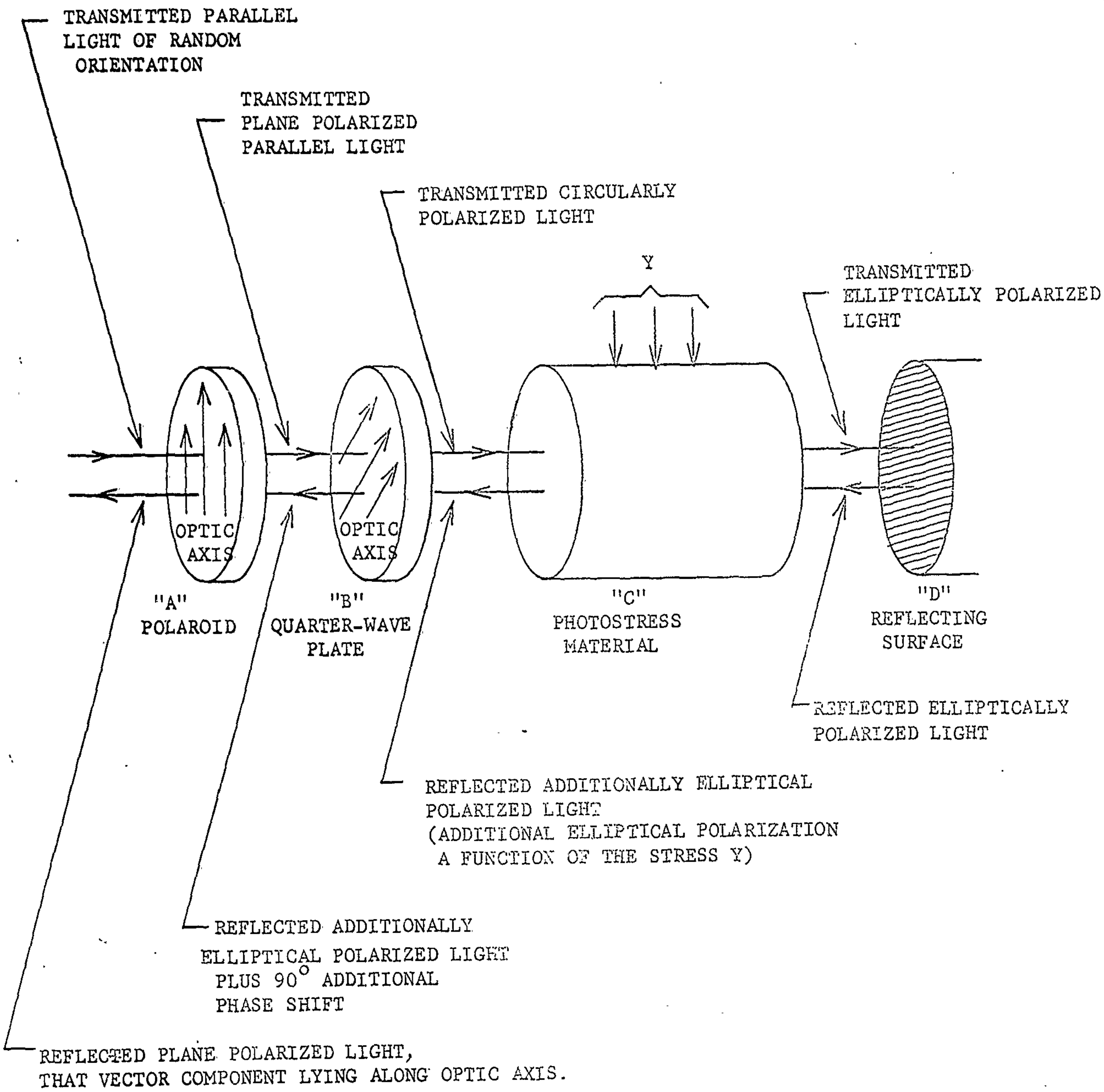

Figure 1. General Outline of Transducer

photostress material; and, (3) a constant of the photostress material - this is the ratio of the amount of elliptical polarization change per unit stress. (Brewster's number). If stress is exerted on "C", the circularly polarized light which enters "C" will emerge from "C" with a degree of elliptical polarization different from that circular polarization which existed when the light entered into "C". The polarized light will then be reflected from "D" and back to "C".

The light now passes through "C" to "B". On passage through "C", the light experiences an additional change from "D" in elliptical polarization equal to that which originally was secured in passage from "B" to "D" through "C". Light now passes from "C" into "B". On passage through "B", the quarter-wave plate, the elliptically polarized light emerges from "B" and passes through "A". The component of the elliptically polarized light which lies along the optic axis of "A" will now emerge as a plane-polarized beam. When a stress Y occurs, the amount of light which emerges will be a function of the amount of stress exerted in the Y direction.

In optical vector terms (Figure 2), unpolarized light (two perpendicular vectors) enters polaroid "A" and emerges as plane polarized light (single vector along optic axis). The plane polarized light passes through quarter-wave plate "B" undergoes a 90° phase shift and emerges as circularly polarized light. On passing through photostress material "C", a phase shift occurs which is a function of the stress exerted perpendicularly to the direction of the optical path. This is shown as some arbitrary phase shift Δ°. Reflection occurs at surface "D" where a 180° phase shift occurs. This, however, is not consequential and will be eliminated from further consideration since both vectors rotate

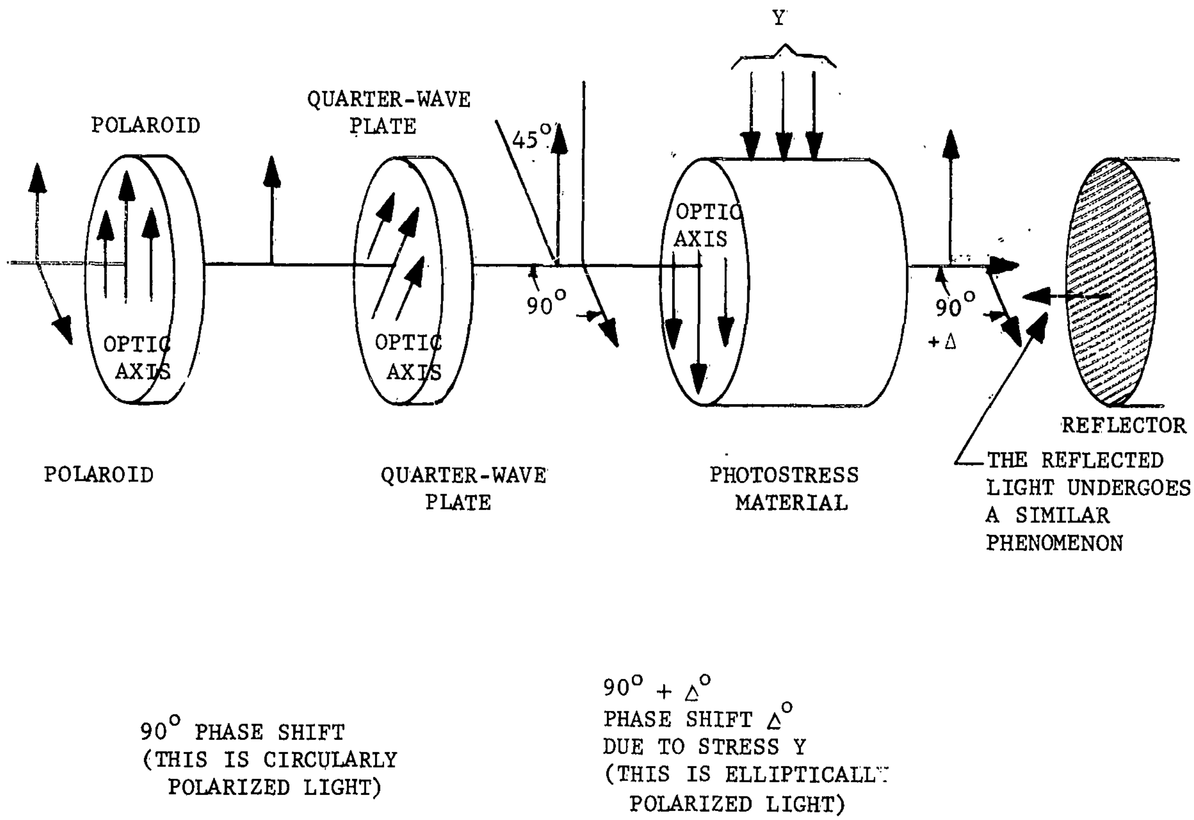

Figure 2. Optical Vectors Utilized to Explain Phase Shift

180^o. On repassage through "C", the additional phase shift, which occurs in equal to the original phase . Repassage through "B" now introduces another shift of 90^o, one-quarter-wave.

The vector sum of the elliptically polarized light which lies along the optical axis of the polaroid disk "A" will now emerge from "A". Thus, the amount of light which will emerge from "A" is a function of the stress Y exerted on the photostress material. If no stress Y occurs, the amplitude of emerging light will be zero, since the reflecting light has undergone only the two 90^o phase shifts. The resulting phase shift total of 180^o renders the vector sum along the optical axis of "A" to be zero. The effect, therefore, is that no light emerges. However, if photostress occurs, then some light will emerge, the intensity of which is a function of the stress Y.

This transducer has been developed in the configuration shown in Figure 3. The transducer is a cylinder, 2 centimeters in length and 3 millimeters in diameter. A thin rubber sleeve separates the transducer from the blood stream. This transducer operates in conjunction with a flexible fiber optics catheter. The fiber optics have been encased in a #9 French catheter for convenience in intracardiac and intravascular catheterization. The complete catheter is shown in Figure 4. Photographs of the catheters are seen in Figures 5 and 6.

The fiber optics catheter consists of a double bundle of glass fibers of small diameter, so that the catheter is easily flexed (Figure 7). Light is applied to the distal end of one bundle. This light is then conveyed up the fiber optics bundle to the pressure transducer. The reflected light which has completed the two-way passage through the transducer is then applied to

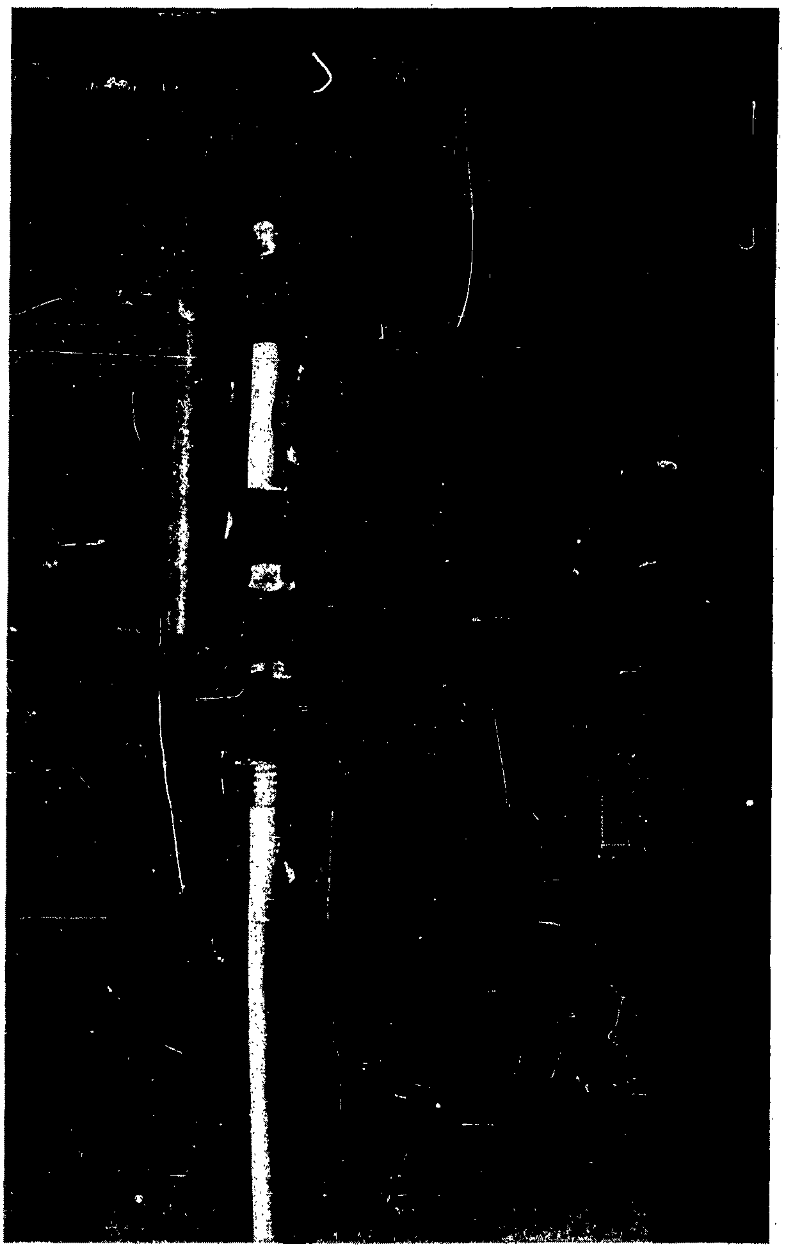

Figure 3. Photograph of Transducer Assemblage

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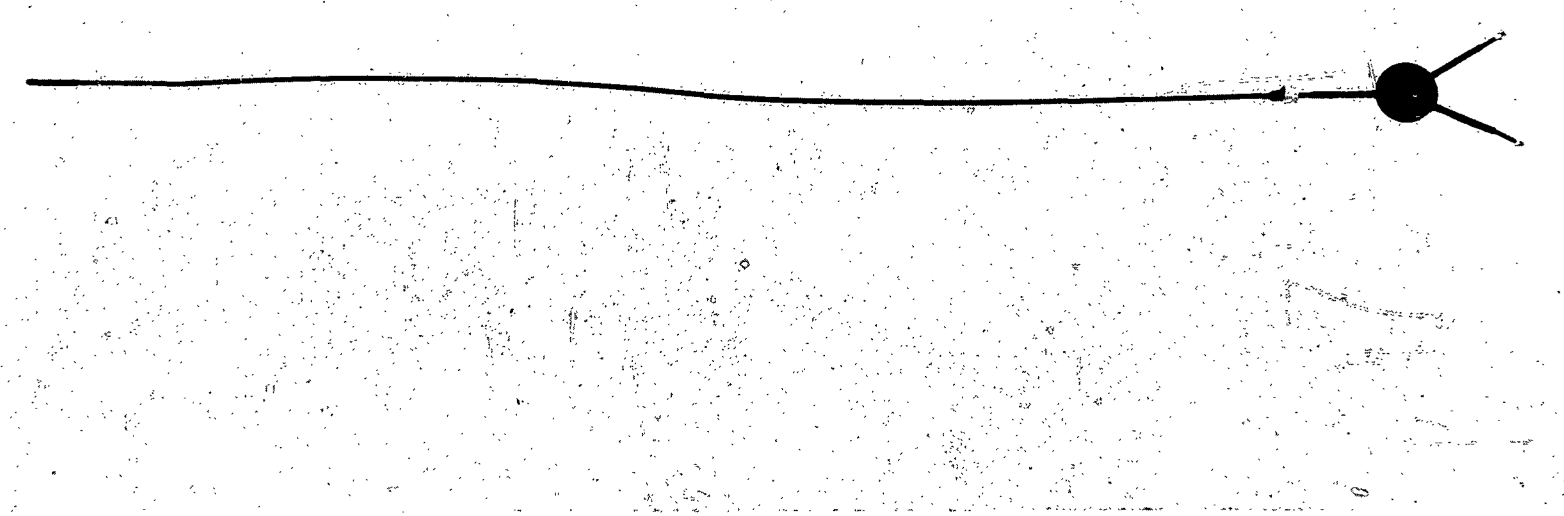

Figure 4. Entire Catheter

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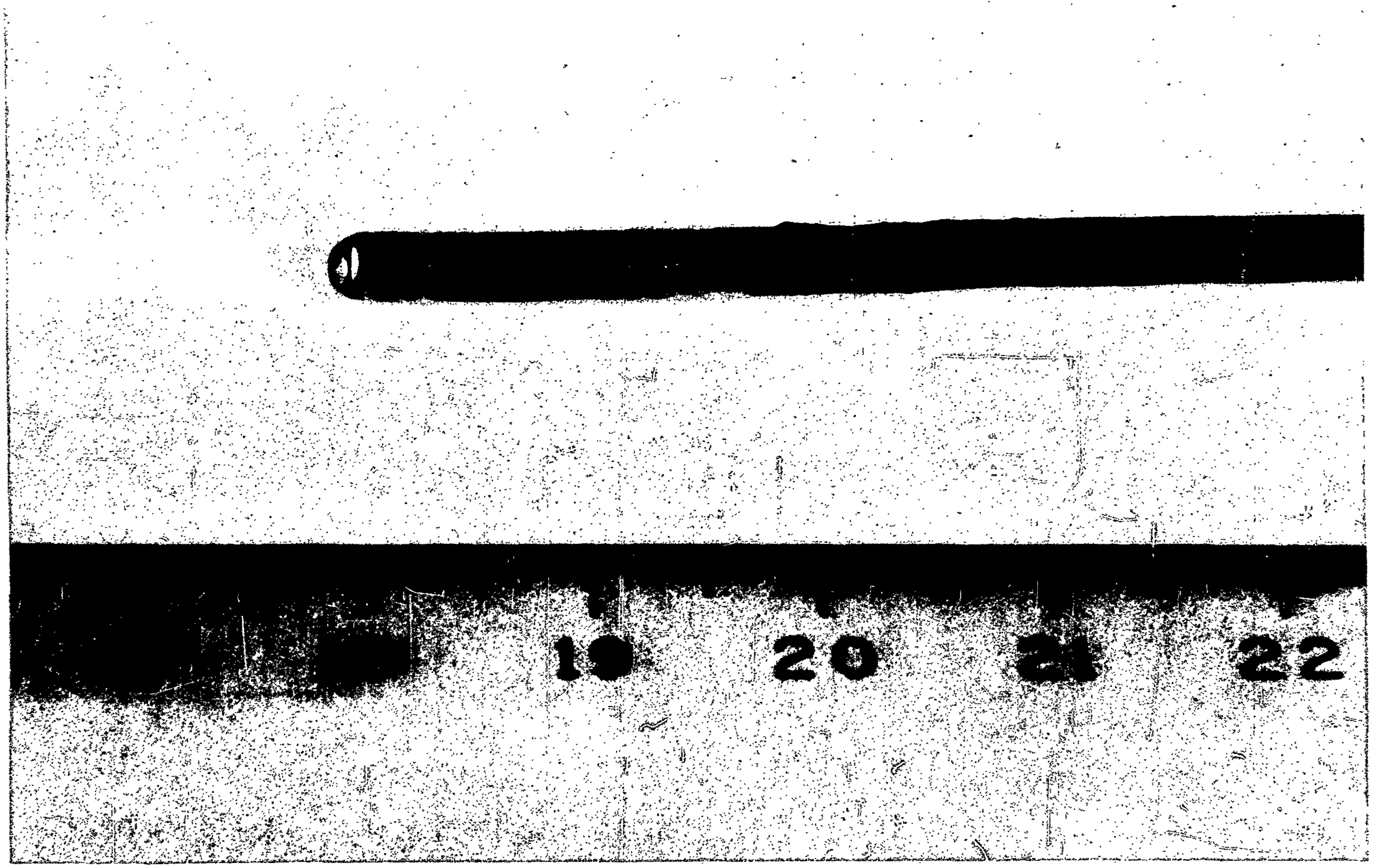

Figure 5. Catheter Tip with Internal Elements Exposed

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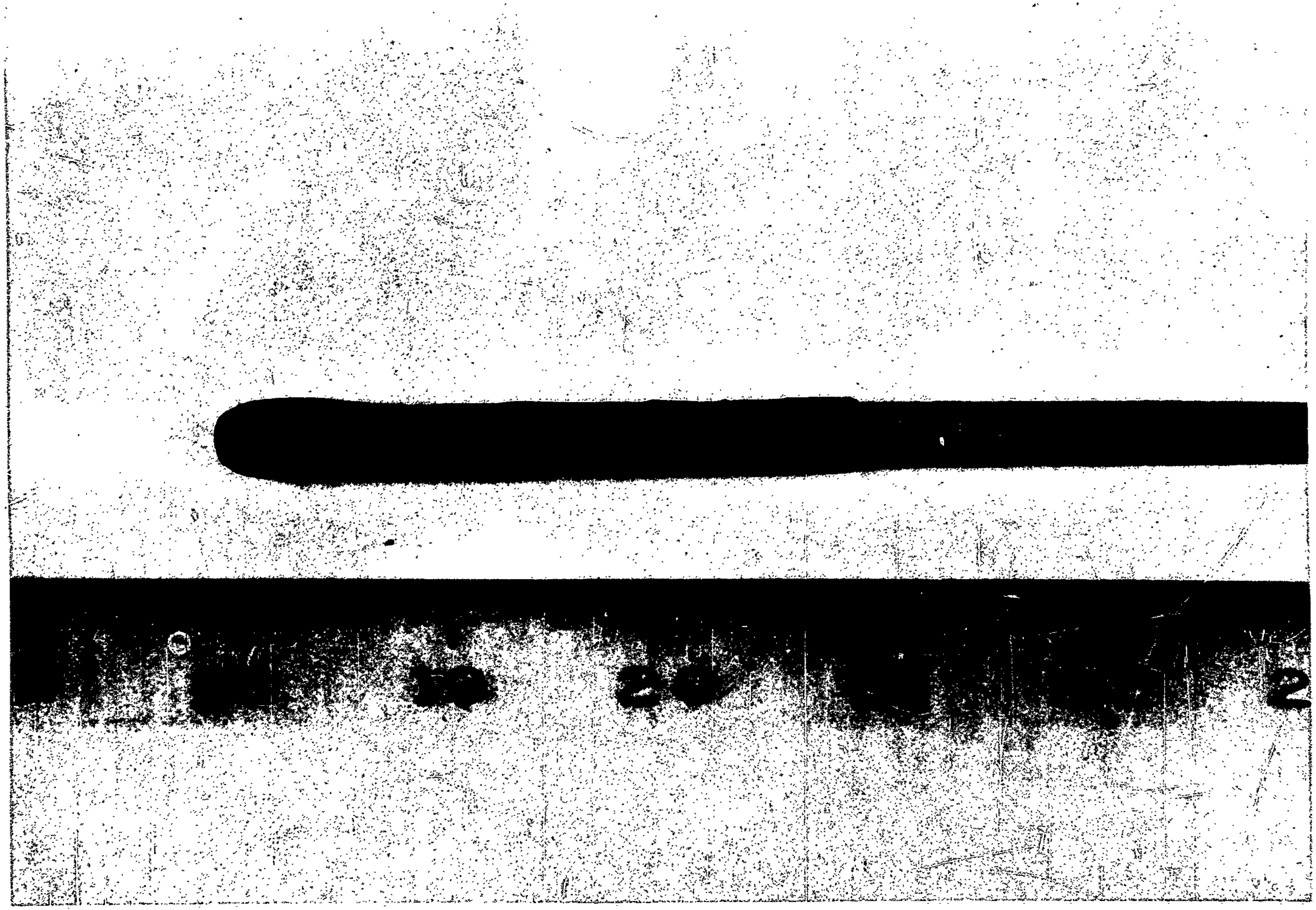


Figure 6. Catheter Tip with Internal Elements Covered by Rubber Sleeve

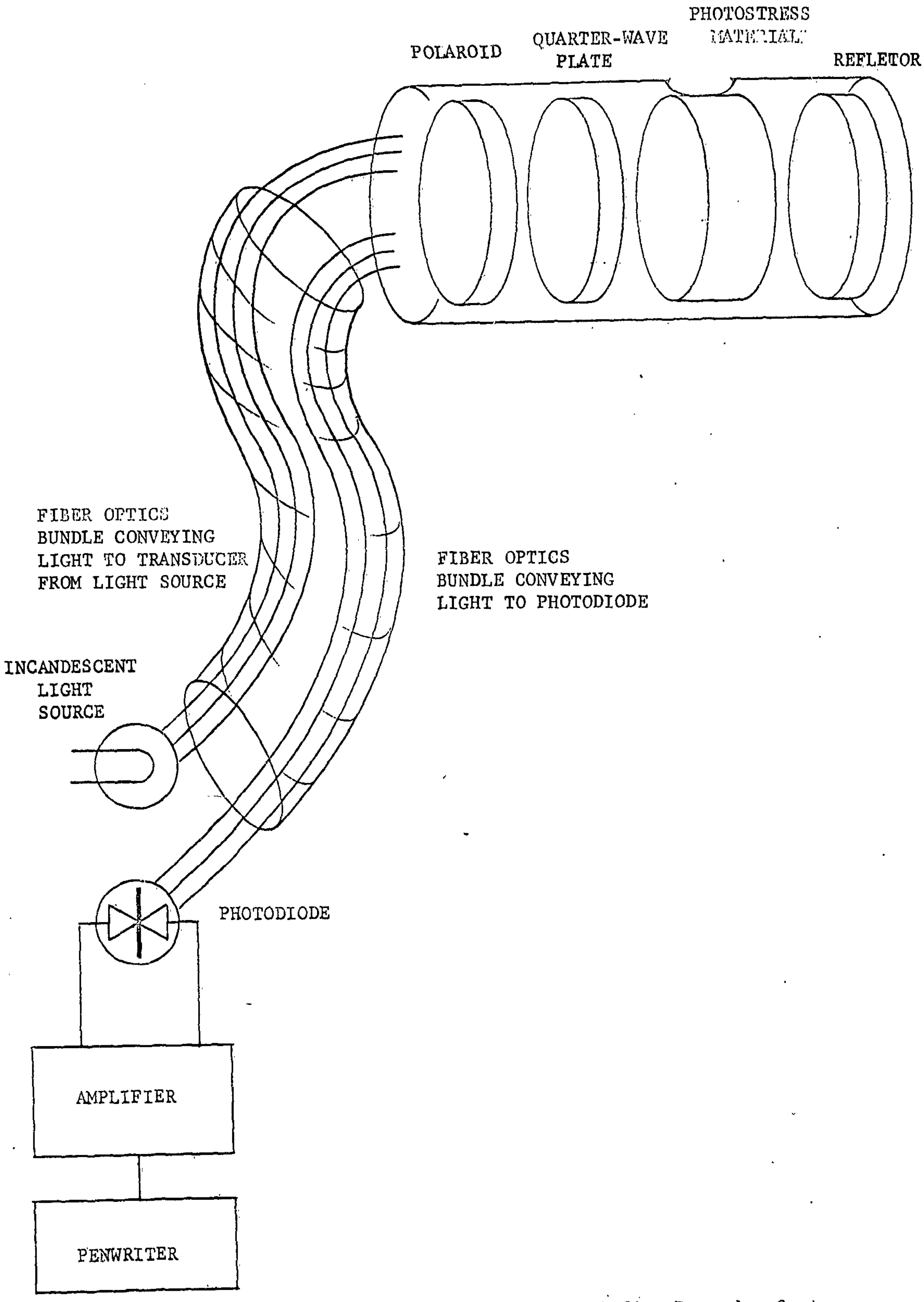


Figure 7. Optical Transducer Catheter - Amplifier-Recorder System

the second bundle and conveyed down the catheter to emerge at its distal end. At the distal end a sensitive photocell receives the light. The photocell output voltage is amplified and then applied to a standard pen writer. Thus, the variation in pressure becomes recorded graphically.

III. RESULTS OF PHYSICAL EVALUATION

The physical results of the evaluation of the optical transducer and fiber optics catheter are described.

A table of the properties of the optical transducer are enumerated as follows:

Sensitivity	100 millivolts per millimeters Hg pressure
Pressure Range (mm/mHg)	0-300
Lower Frequency Limit (Maximum Output)	0 cps
Upper Frequency Limit (Down 30 db from Static Pressure Output)	800 cps
Noise Level	less than three microvolts
SIZE	
Diameter	3 mm (#9 French) (= .117 inch)
Length	20 mm (= .78 inch)
Phase Shift at 800 cps.	80°
Output in Specified Ranges	linear stepless compatible with standard recorders

Safety	inherently safe sterilizable tissue inert non-traumatic non-fragmentable X-ray opaque non-clot supporting or initiating

The properties of the optical transducer are based on actual sinusoidal pressures being applied to the transducer.[12, 13, 14]

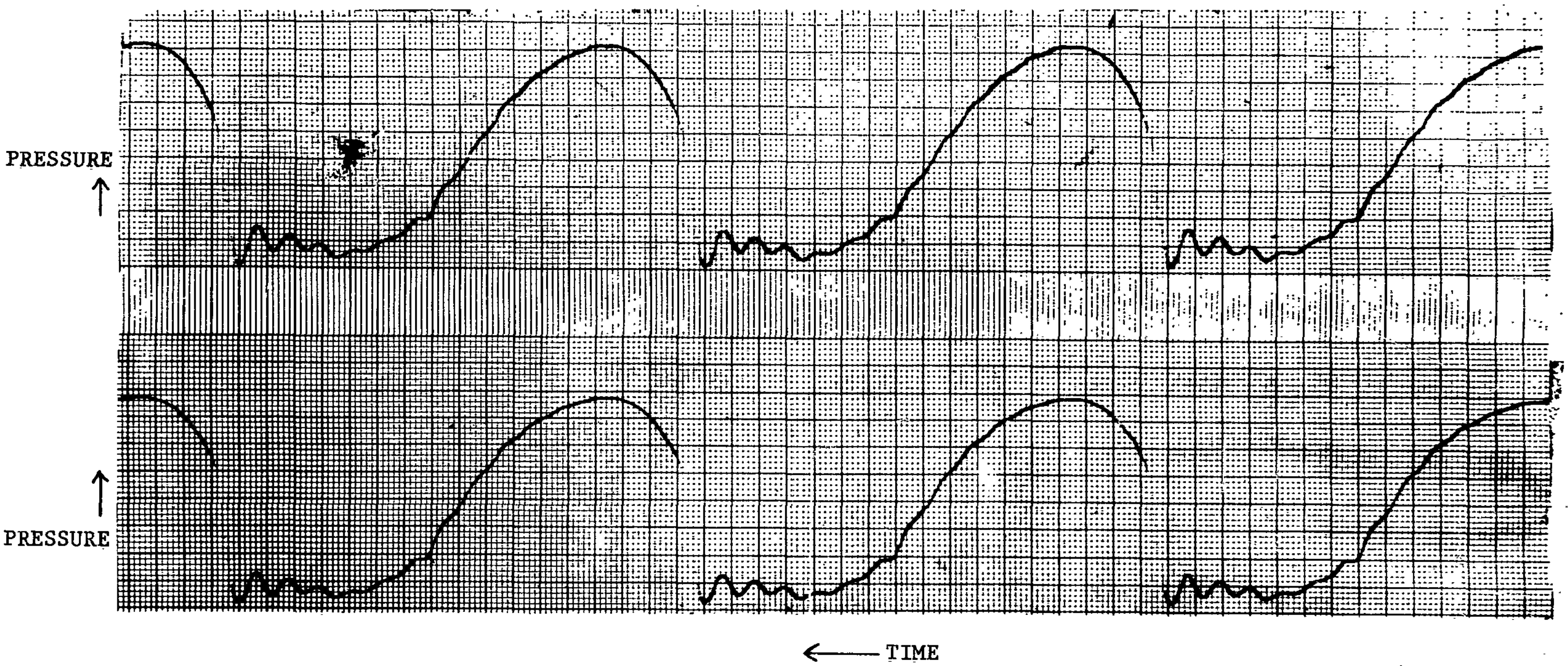
From static pressure to 33 c.p.s. the characteristics were determined utilizing a hydraulic pump driven by a varying speed motor. Comparison is shown against a Statham strain gauge known to pass the frequencies investigated without attenuation or phase shift. See Figures 8 and 9. From 20 c.p.s. to 1000 c.p.s. the characteristics were determined by an electromechanical vibrator driven at various frequencies by a varying frequency oscillator (Figures 10, 11, 12, 13, 14). Comparison is made against the oscillator output where the electromechanical vibrator is known to pass the frequencies investigated without attenuation or phase shift.

Noise level was established by using increasing gain until noise was first noted.

It should be noted that the response to the step function (Figure 15) is non-oscillatory. In this circumstance the transducer may be described as overdamped [15]. There is no resonant frequency for this system.

Curves of the frequency response and phase shift are shown in Figure 16.

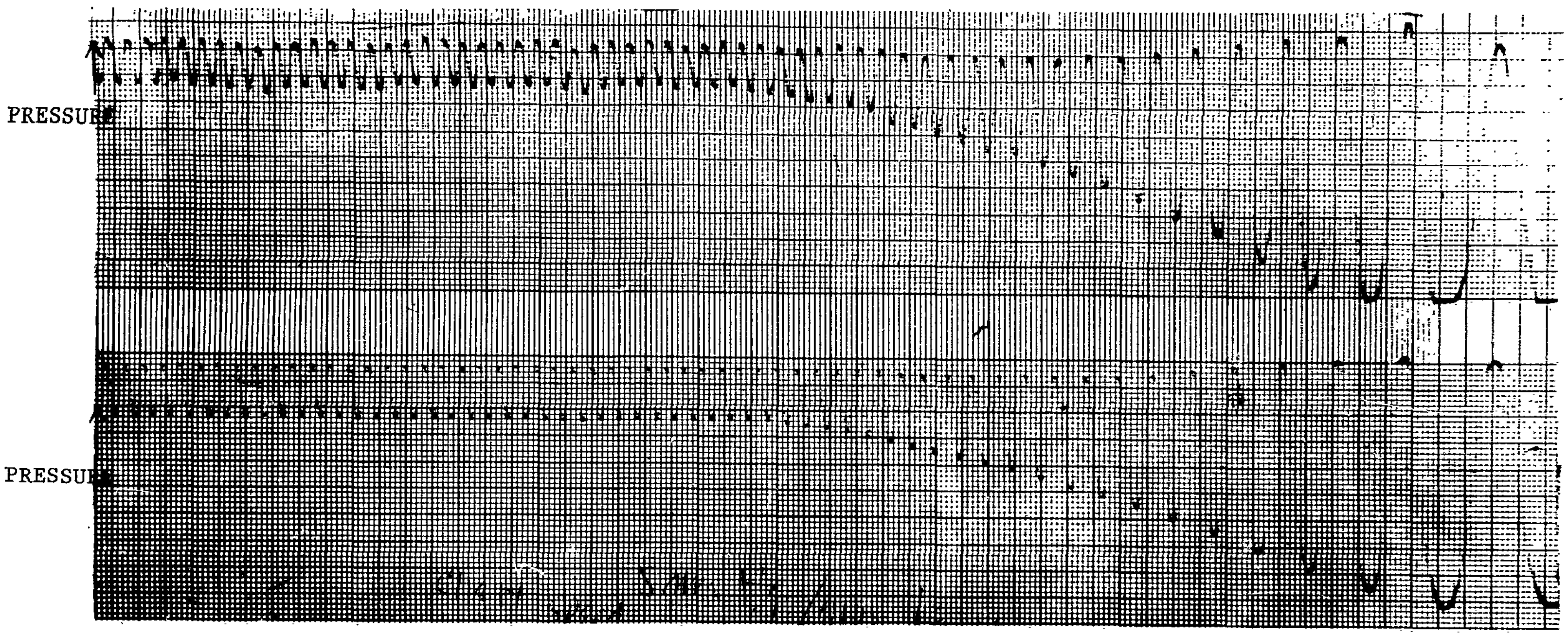
For comparison purposes, it may be noted that the highest frequency response from any commercially available cardiac catheter-external strain gauge system has a peak frequency at 70 cycles per second, falling off to near zero at 100 cycles per second. For this system, the sensitivity is 1.5 millivolts per millimeters of mercury pressure. The sensitivity from any commercially available cardiac catheter-external strain gauge system is 6.7 millivolts per 100 millimeters of



Note: Using hydraulic Pump .7 cycles/sec.
Upper Tracing AEL optical transducer
Lower Tracing Statham strain gauge without catheter

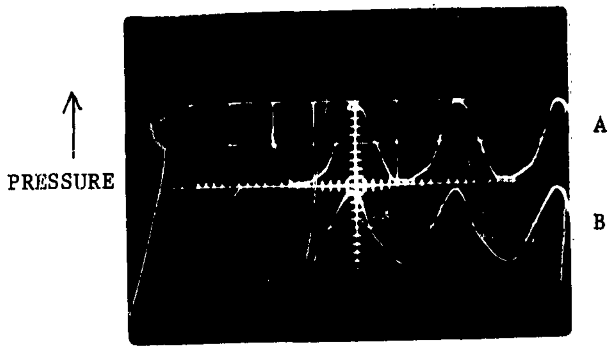
Calibration: 5mm Hg/mm height
Chart Speed: 100 mm/sec.
Phase Shift = 0°
Output/Input Ratio = 1
Distortion: Imperceptable

Figure 8



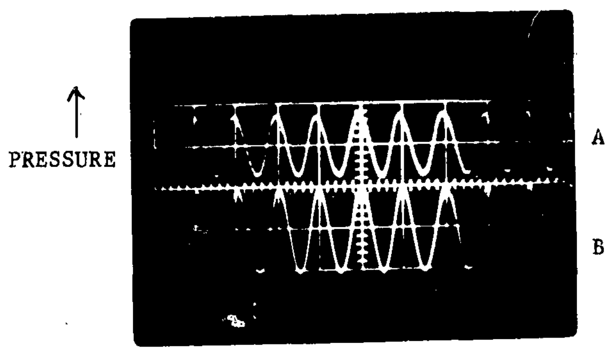
Using hydraulic pump, speed from right to left starting 6 cps to 33 cps.
Lower tracing AEL transducer - catheter
Upper tracing Statham strain gauge without catheter
Calibration: 5 mm Hg/mm height
Chart Speed: 100 mm/sec.
Phase Shift: 0°
Output/Input Ratio = 1
Distortion: Imperceptable.

Figure 9



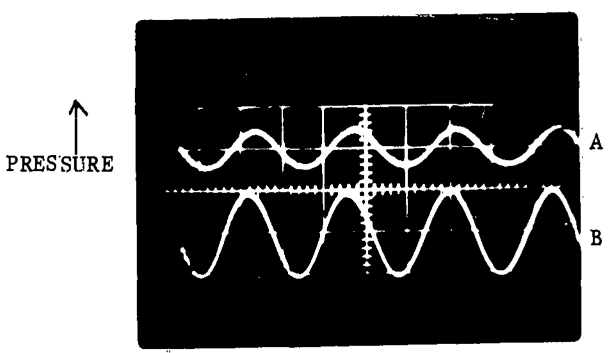
20 Cycles/Sec.
Upper Tracing
A: AEL Transducer Output
B: Electromagnetic Input
Lower Tracing
Phase Shift = 0°
Output/Input Ratio = 1.
Distortion: Imperceptable

Figure 10.



50 Cycles/Sec.
A: A: AEL Transducer Output
B: B: Electromagnetic Input
Phase Shift = 0
Output/Input Ratio = .9
Distortion: Imperceptable

Figure 11.



100 Cycles/Sec.
A: A: AEL Transducer Output
B: B: Electromagnetic Input
Phase Shift = 5°
Output/Input Ratio = .5
Distortion: Imperceptable.

Figure 12.

Calibration Using Electromagnetic Driver Directly
Mechanically Coupled to AEL Transducer

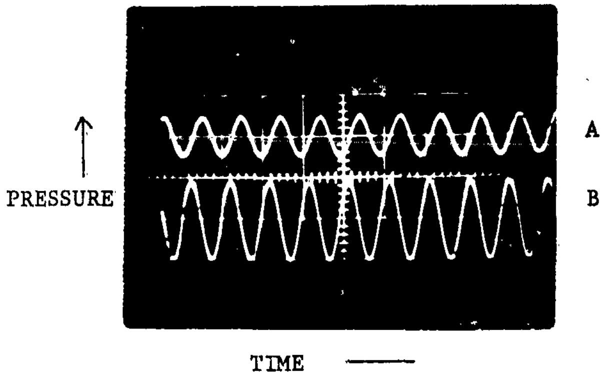


Figure 13

500 Cycles/Sec

A: AEL Transducer Output

B: Electromagnetic Input

Phase Shift = 30°

Output/Input Ratio = .5

Distortion: Imperceptable

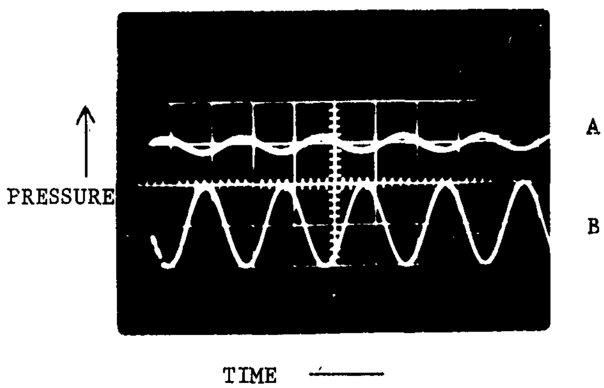


Figure 14

1000 Cycles/Sec

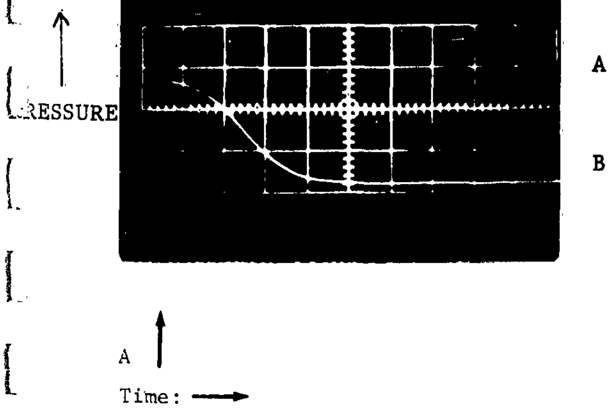
A: AEL Transducer Output

B: Electromagnetic Input

Phase Shift = 180°

Output Input Ratio = .3

Distortion: Imperceptable



Step Function Response Starting at Point A

300 mm Hg to 0.

Large Division = 2 millisecond.

Transducer is Inherently Overdamped by Nature of Photostress Material Without Resonance Peak.

Figure 15

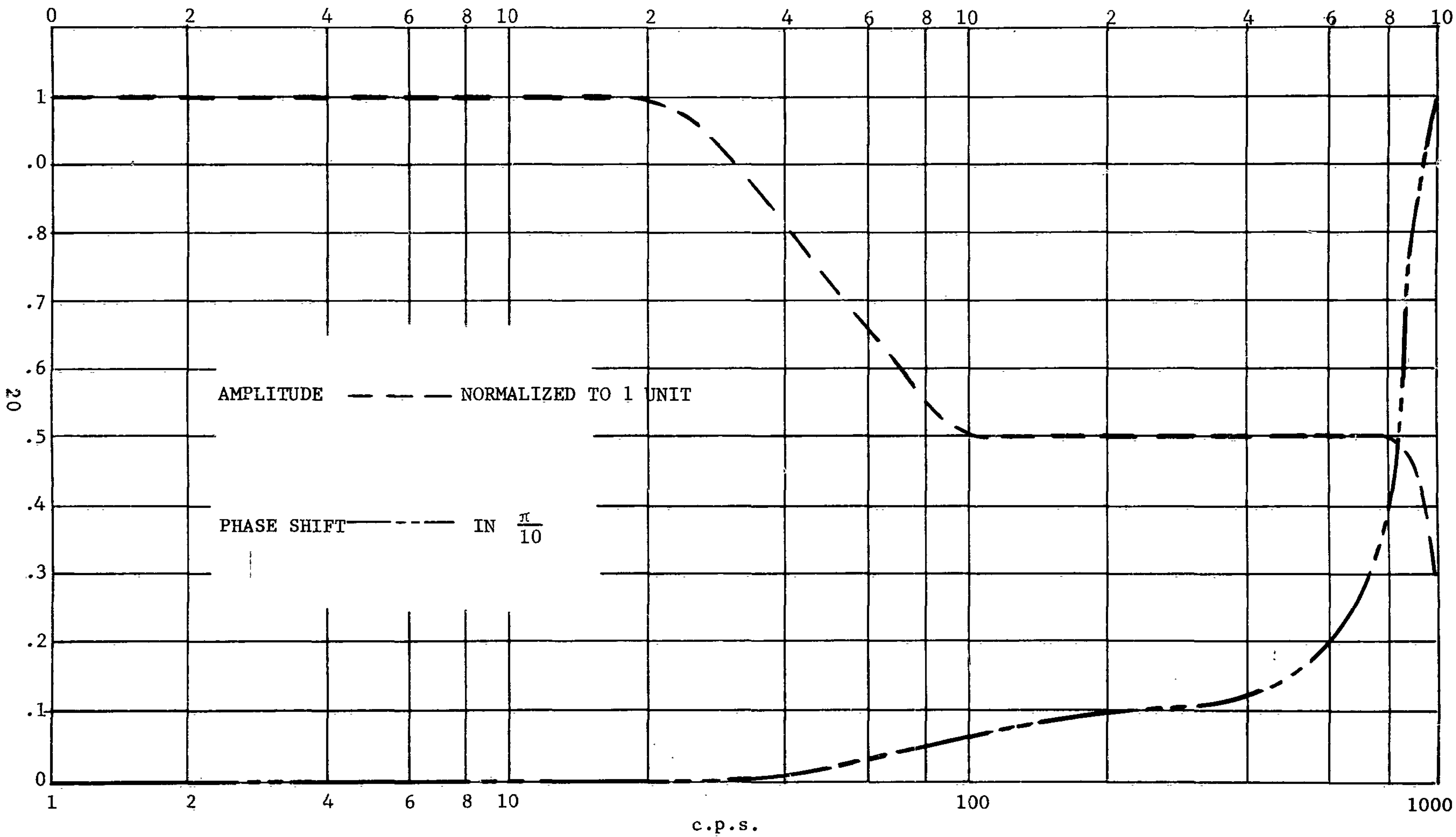


Figure 16. Approximate Frequency Response and Phase Shift.

of mercury pressure. For this system, the peak frequency is 40 cycles per second, falling off to near zero at 70 cycles per second.

Since the usual catheter-external strain gauge systems have peak resonance somewhere between 12 and 65 cycles, depending upon the exact model strain gauge, it is necessary to limit high frequency response to avoid the high frequency distortion introduced by the greater sensitivity in the area of peak resonance. Frequently, hydraulic and/or electromagnetic damping are used to obtain a sharp cut-off around 10 cycles. With the optical catheter system here described however, the full high frequency band may be used since there is no peak resonance.

Also, low frequency artifacts of the same frequency as cardiac rate are introduced in the usual hydraulic catheter-external strain gauge system as a consequence of fluid movement in the catheter resulting from catheter tip displacement from the periodically contracting heart walls. With the optical transducer described here however, there is no such low frequency artifact since there is no hydraulic column.

IV. RESULTS OF PHYSIOLOGIC EVALUATION

Evaluation of the optical transducer has been performed in comparison with the standard Statham strain gauge. The optical stress transducer was inserted into one femoral artery of a dog and the #9 cardiac catheter was inserted into the opposite femoral artery. The output of the optical stress transducer with accompanying amplifier was applied to the Sanborn 150 amplifier. The output of the #9 French Cardiac Catheter was applied to the Statham strain gauge, which in turn was fed into another channel of the Sanborn 150 recorder. Both catheters were then advanced into the aorta and positioned side by side within that vessel. The readings were then taken for comparison purposes.

A long strip of the results of this evaluation is given in Figure 17. One may observe that the recordings are very similar.

The values of the pressures are not identical. Which catheter system is more accurate is a subject of continuing investigation.

CONCLUSION

A new and unique cardiac catheterization instrumentation system has been designed and evaluated both physically and physiologically.

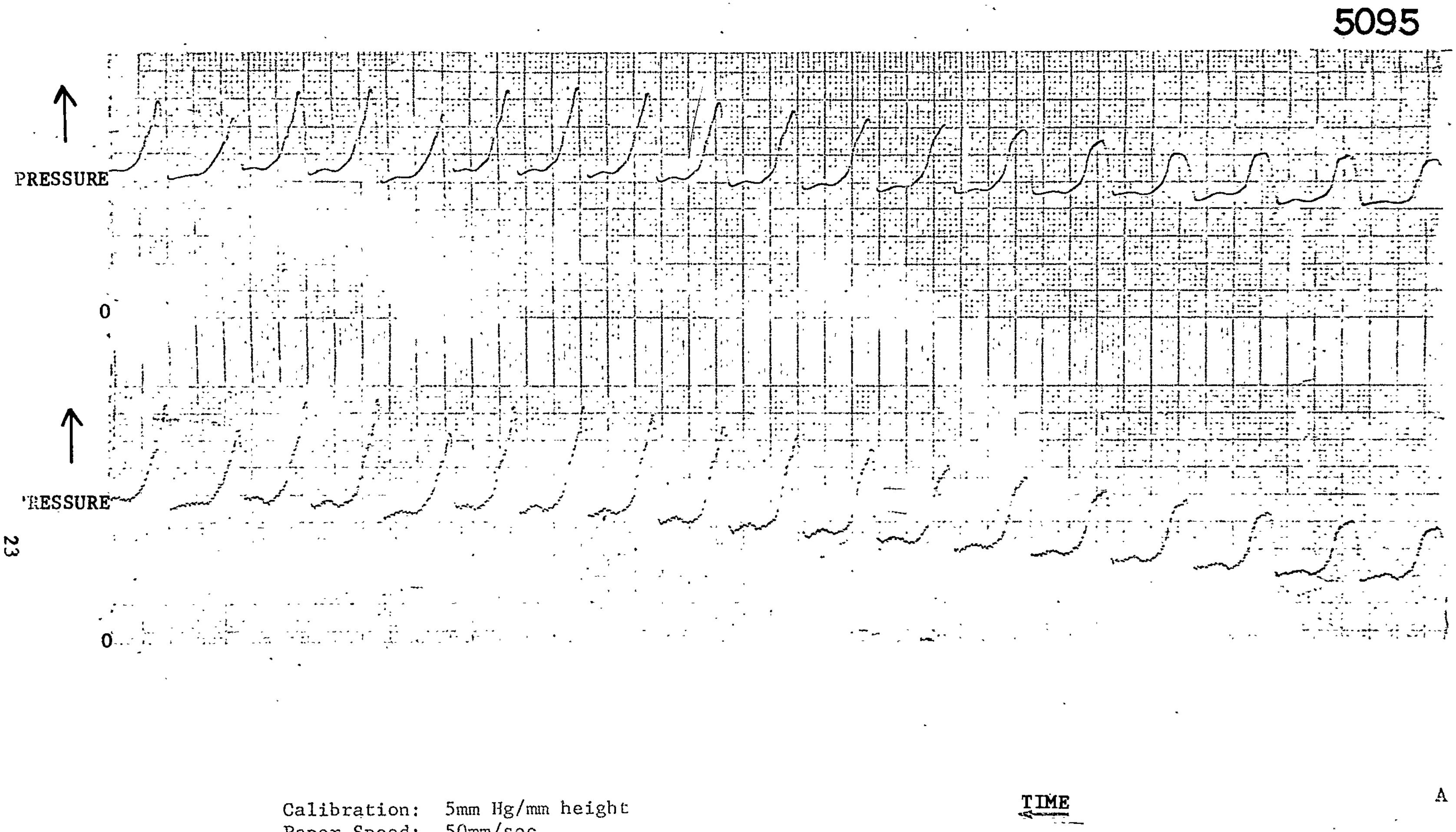
The system has been shown to function in a fashion superior to present available instrumentation since the new system possesses:

(a) higher frequency response

(b) greater sensitivity

(c) avoids blood clotting problems

(d) avoids motion artifacts



Calibration: 5mm Hg/mm height
Paper Speed: 50mm/sec.
Upper Tracing: Right Femoral Artery: #9 French Catheter connected to Statham strain gauge.
Lower Tracing: Left Femoral Artery: AEL transducer - catheter, epinephrine administered at point A. Change in configuration of pulse and increased pressure and rate noted. Explanation for different pressure levels not determined.

Figure 17.

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