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SURGICAL FORCE DETECTION PROBE

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ABSTRACT

This paper reports the development progress of a precision electro-mechanical instrument which allows the detection and documentation of the forces and moment applied to human tissue during surgery under actual operating room conditions. The pen-shaped prototype probe which measures 1/2 inch in diameter and 7 inches in length was fabricated using an aerodynamic balance. The aerodynamic balance, a standard wind tunnel force and moment sensing transducer, measures the forces and the moments transmitted through the surgeon's hand to the human tissue during surgery. The prototype probe which was fabricated as a development tool was tested successfully. The final version of the surgical force detection probe will be designed based on additional laboratory tests in order to establish the full scale loads. It is expected that the final product will require a simplified aerodynamic balance with two or three force components and one moment component with lighter full scale loads. A signal conditioner has been fabricated to process and display the outputs from the prototype probe. This unit will be interfaced with a PC-based data system to provide automatic data acquisition, data processing and graphics display. The expected overall accuracy of the probe is better than one percent full scale.

INTRODUCTION

The objective of this Technology Utilization Office funded project is to develop a surgical force detection probe suitable for medical applications at the request of Dr. Richard Prass of the Eastern Virginia Medical School in Norfolk, Virginia. Based on Dr. Prass's microsurgical experiences and requirements it was decided that a multi-component strain gaged aerodynamic balance can be modified to meet the objective of the surgical force detection probe. The use of a force detection device provides the ability to monitor the forces applied to human tissue during surgery under actual operating room conditions. Dr. Prass cited the following advantages:

(1) It allows documentation of the usual forces applied during routine surgical procedures. Such documentation has never been reported.

(2) It allows comparison among experienced surgeons and those in training. Such data may provide feedback that may be effectively used during residency training.

(3) When used in conjunction with interoperative neurological monitoring, it will allow correlation of specifically applied forces to monitored nerves that are responsible for nerve injury. These data may lead to new concepts in nerve dissection that improve surgical outcome.

The aerodynamic balance, a standard precision wind tunnel force and moment detection transducer, is used to measure the forces and the moments applied to the test model. Most of the balances used at Langley Research Center (LaRC) are designed to measure three forces and three moments. The prototype surgical force detection probe, shown in Fig. 1, consists of three components: an external housing or a cover shield, an aerodynamic balance and a clamp adapter for holding interchangeable probe tips. It will measure the forces and moments transmitted through the surgeon's hand to the human tissue during surgery. The prototype unit utilizes an existing six-component aerodynamic balance as a development tool.

MECHANICAL DESIGN

The prototype surgical force detection probe incorporates LaRC's 747 strain-gage balance, a six component aerodynamic balance which measures three forces and three moments. Balance 747 is oversized in loads as it has the following full scale design loads: 30 lbs in normal, 10 lbs in axial, 20 lbs in side, 40 in-lbs in pitch, 10 in-lbs in roll and 20 in-lbs in yaw. It is used only for proof of concepts and for laboratory evaluation to establish the load requirements of the final production version of the surgical force detection probe.

The prototype probe measures 0.5 inch in diameter and 7.0 inches in length, excluding the probe tips. Shown in Fig. 2, the actual probe will have the same diameter as the prototype, however, it will be approximately one inch shorter in length. The prototype probe as well as the final probe consists of the same three main components. An assembly view depicting these three components can be seen in Fig. 3. The clamp adapter is metric and is used to hold various microsurgery probe tips. The cover shield serves as the mechanical ground and is held in the surgeons hand. The transducer contains three strain-gaged measuring beam sections which yield output signals proportional to the loads transmitted from surgeon's hand to the probe tips. This compact probe will allow accurate monitoring of the forces and moments that the surgeon is applying to the patient during microsurgery.

In order to produce a multi-component transducer, such as the surgical force detection probe, many steps must be taken. The design specifications and constraints must be established first before actual mechanical design. Following design, the transducer must be fabricated, strain gaged and calibrated. This series of steps will be discussed in the following.

<u>Design Specifications and Constraints</u> Design specifications and constraints for the surgical force detection probe are listed below:

(1) Design loads: The full scale design loads for the probe have not been firmly established. It is expected that the design loads will be fairly light. One pound in normal and side forces and two inch-pound in rolling moment or torque are the tentative design loads for the actual probe. The exact values will be determined by experimenting with the prototype probe.

(2) Probe size: The size and weight of the probe should be minimized in order not to impede surgeon's operation.

(3) Overload protection: Mechanical protection should be included in the design to prevent accidental overloading of the probe.

(4) Sterilization: The probe must withstand the sterilization process.

(5) Tip insertion method: Interchangeable probe tips must be incorporated in the design.

The first two specifications are met by choosing aluminum as the transducer material and sizing the measuring beams as small as possible. However, the measuring beams must be large enough for strain-gage installation and they must yield sufficient outputs to maintain measurement accuracy. A photograph of the prototype transducer measuring beams is shown in Fig. 4. Two of the measuring beam sections are used to measure normal force, side force, and the rolling moment. The center beam section measures axial force. All of the measuring sections contain parallel beam configurations. Spring constants are calculated for each beam set to determine the system stiffness relative to the magnitude of the measured loads. This procedure is discussed in more detail in reference 1. The beams are designed to have a relatively low spring constant to measured forces and moments while having higher spring constants to unmeasured forces and moments. This ensures that the transducer will be sensitive to the measured loads and insensitive to the unwanted loads. In order to obtain acceptable sensitivities the measuring beams will be highly stressed during operation. For this reason, the actual probe will be manufactured out of 7075-T6, a lightweight, high strength aluminum which has a 2% yield strength of 72,000 psi [2].

To avoid damaging and to improve the durability of the probe, it was decided that overload protection should be provided. This is difficult to incorporate into the design since the full scale deflection of the measuring beam systems is typically on the order of 0.001 inch. It is difficult to maintain clearance with such a small gap between the metric end of the balance and the cover shield. The method of providing mechanical stops has not yet been determined. To date, the most feasible idea is to provide set screws around the circumference of the cover shield which can be adjusted, prior to probe use, to set the clearance. This process may prove to be impractical to the medical staff. If providing mechanical stops is not feasible, then an electronic alarm will be included into the electronics control box. The alarm will alert the surgeon of potential overload conditions.

To incorporate interchangeable probe tips, a clamp adapter is attached to the front end of the prototype probe using a close diameter fit and a threaded dowel to secure the position. A dowel knocker is used to remove the positioning dowel, allowing disassembly of the adapter from the transducer. The clamp adapter and some examples of probe tips are shown in Fig. 5. However, in most cases, the adapter need not be removed from the transducer to change probe tips. The tapered clamp on the end of the adapter is designed such that probe tips can be quickly interchanged during an operation. To change a probe tip, the adapter is held and the tapered clamp rotated, counterclockwise. By holding the adapter, all of the loads induced during tip replacement are grounded and can not overload the measuring beams. The probe tip is removed and replaced after the tapered clamp is loosened. The clamp is rotated clockwise to tighten against the new tip. When clamped, the surgical force detection probe is ready for use.

The final design requirement on sterilization is currently being investigated. The main question to be answered is the effect of the sterilization process on the service life of the adhesive and gage coating used on the transducer. A strain-gaged test beam will be subjected to prolonged sterilization in ethylene chloride gas. Also, to increase the life of the strain-gages on the actual probe, a thin sheath over the metric to nonmetric joint will be used to shield the gages from debris during an operation. A mandrel has been designed to manufacture a .003 in. walled sheath out of Dow Corning Silastic #Q7-4840 which is a medical grade liquid silicon. As shown in Fig. 2, the sheath will be anchored in the grooves on the forward end of the transducer. The effects of the sheath bridging the metric and nonmetric ends of the probe will be taken into account during calibration.

<u>Fabrication</u> Fabrication of a one-piece multi-component force transducer is a very complicated process. There are many difficult cuts and critical dimensions that must be held to tight tolerances of ± 0.0005 inch during fabrication. The actual transducer will be manufactured from a single piece of aluminum to eliminate as many joints as possible. One-piece transducers yield smaller zero shifts than multiple piece transducers and are therefore inherently more accurate. A large portion of the machining is performed by Electrical Discharge Machining (EDM) [3]. EDM allows the multiple beam measuring sections to be precisely machined using a single piece of material. Basically, EDM removes metal from the work piece by vaporizing the top surface through an electric spark. A dielectric fluid flushes away the molten metal. This process slowly erodes the metal until the desired dimension is obtained. It would be impossible to fabricate this compact transducer without the EDM process.

<u>Strain-gaging</u> Mounting strain-gages on the measuring beams of the transducer is the next step in production. 5,000 ohm foil strain-gages will be bonded to the measuring beams and interconnected in Wheatstone bridge forms [4]. The 5000 ohm gages will allow larger input voltages to be applied to the bridge, yielding larger signal outputs without heat build up on the measuring beams. The measuring beams are therefore not required to be stressed as highly as beams with lower resistance strain-gages, consequently providing a larger safety factor to the design. The strain-gages are placed such that they are sensitive to the measured component while electrically canceling the unwanted components. This method greatly reduces the interactions between different

components. By carefully selecting the strain-gages and their locations, real time correction of nonlinear interaction errors is unnecessary.

Calibration The final step of production, calibration of the transducer, is one of the most important. Calibrations are most accurate when performed by methods which closely simulate the actual use of the transducer. Calibration hardware is designed to apply dead weight loads similar to those which will be applied to the metric probe tips. Care was taken to make the calibration hardware as light as possible to minimize the initial or tare loads applied to the transducer. The arms can be adjusted for variable load point distances. This allows calibration for various length probe tips. To begin calibration, the probe outputs will be connected to a data acquisition system which consists of a power supply, a scanner, a voltmeter, and a personal computer. The cover shield is positioned such that dead weight loads are applied in line with a force and the moment center. Incremental loads are applied to the calibration arms which are inserted into the tapered clamp. The electrical output signals are recorded and reduced using a short arm calibration method. This is repeated for each force and moment component. First and second order interaction terms are calculated to determine whether they have significant or negligible effects on the accuracy of the probe [5]. If the effects are negligible, then the data can be reduced using only the sensitivities of each component. However, if the effects are significant, then interaction terms must be accounted for, thus making the data reduction more complex. Due to the equal force magnitudes and the calibration procedure, it is expected that the interaction effects will be negligible.

ELECTRONICS DESIGN

Figs. 6 & 7 are two photographs depicting a separate control box which houses the signal conditioning circuits, the front panel controls and the back panel. The control box provides two modes of operation: the manual and CPU modes. This operation will be briefly described in the following.

Modes of Operation

Manual Mode: In this mode, the CPU or a personal computer is not required and the control box will operate as a stand alone unit to process and display the probe outputs. Here, the control box amplifies and filters the probe outputs and displays the signals on bar graphs located on the front panel of the control box. Manual nulling and gain setting will be required for this mode of operation.

CPU Mode In the CPU mode, bridge outputs are routed through a different path in the control box for amplification and filtering. The processed signals are simultaneously transmitted to the CPU and displayed on the same front panel bar graphs. Under software control, the CPU will control offset nulling and gain setting on the programmable amplifier. Additional signal processing and graphic displays by the CPU are planned.

The processed signals are also available for retransmission and recording through the BNC connectors on the back panel for either manual or CPU mode.

The electronics hardware will next be described in the following.

Signal Conditioner The block diagram for a typical channel of the signal conditioner is shown in Fig. 8. It comprises seven major blocks: an isolation amplifier, a null/span adjust, a control switch, a low pass filter, a bar graph display, a multiplying DAC, and a programmable amplifier. As shown, the signal conditioner communicates with a data acquisition system. This interface box remains to be defined. The hardware contained in each block and its function are briefly described in the following using a more detailed schematic diagram shown in Fig. 9.

(1) Isolation Amplifier - An isolation amplifier is commonly used in medical equipment where safe and accurate measurement of a voltage signal is required. The isolation amplifier used employs transformer

coupling and an amplitude modulation technique to provide a complete isolation between input and output signals. The amplification is set at 100. A voltage follower was added behind this isolation amplifier to remove any loading problem from the null/span adjust circuit.

(2) Null/Span Adjust - An operational amplifier is used to provide the null and span capabilities. Null adjust is used to remove output offset which may be caused by tare weight while span adjust allows the operator to increase the output to the full scale value of the output stage. Note that Null/Span Adjust is active only in the manual mode.

(3) Control Switch - A SPDT toggle switch is used to select either the manual or CPU mode. In the manual mode, the output from the Null/Span Adjust is sent to the low-pass filter. In the CPU mode, the output from the programmable amplifier is sent to the low-pass filter.

(4) Low Pass Filter - An active two-pole low-pass Butter-worth filter is used for conditioning the signal coming from the control switch. The corner frequency of the filter is set at 1 Hz.

(5) Bar Graph Display - For visual display two 10-segment LED bar graphs are used to form a 20-segment LED zero center bar graph. Each bar graph is driven by an operational amplifier and by a bar display driver. The driver senses the analog input voltage levels from the low-pass filter and provides a linear analog display on the 10 LEDs. A red LED bar graph is used to display positive output while a green one is for negative output. The bar graph display is on for both manual and CPU modes.

(6) Multiplying DAC - An 8-bit multiplying digital to analog converter is used to generate the offset required to null the programmable amplifier in the CPU mode. It provides an output equal to the product of a fixed reference signal at 1.2 volt and the fractional equivalent of the 8-bit digital word which will be supplied by the CPU. The multiplying DAC block includes two operational amplifiers needed for bipolar operation. The entire block is calibrated to provide a full scale voltage of ± 2 volts.

(7) Programmable Amplifier - This is a precision instrumentation amplifier with selectable gains of 1, 10, 100 and 500. Two CMOS compatible gain control lines selected by the CPU are used to pick the required gain. The programmable amplifier takes its input from the isolation amplifier, subtracts the output from the multiplying DAC and amplifies the difference by the gain selected.

Front Panel Control As shown in Fig. 6, the front panel of the prototype control box contains the potentiometers for the null/span adjust and the 20-segment LED displays for three probe channels. A ten-turn precision potentiometer is used for span adjustment and a one-turn potentiometer is used for null or zero adjustment. The front panel also contains a power switch, the manual/CPU switch and an auto zero LED display. The LED display is on when the foot switch is depressed.

Foot Switch External to the control box, a foot operated switch is provided to generate a timing pulse. This pulse will signal the CPU to mark the current signal levels and/or null out the programmable amplifiers in the control box. This feature is necessary for the two following reasons: it allows the surgeon to synchronize his surgical operation with external video taping, and it gives the surgeon a record to begin a sequence of steps, when the orientation of the probe is changed. Ideally, this switch should be installed on the cover shield of the force probe for better access by the surgeon.

CONCLUDING REMARKS

In an effort to advance the state of art of surgical instrumentation, the feasibility of using a small aerodynamic balance as a surgical force detection probe which monitors and documents the forces and moments applied to human tissue during surgery under actual operating room conditions has been demonstrated. The pen-shaped prototype probe, approximately 1/2 inch in diameter and 7 inches in length, measures the forces and the moments transmitted through the surgeon's hand to the human tissue during surgery. A prototype probe using an existing aerodynamic balance as a development tool, as well as the signal conditioner, were fabricated and tested successfully.

The final version of the surgical force detection probe will be designed and fabricated based on laboratory test results using the prototype probe. A fully automated PC-based data system will also be developed for data acquisition and graphics display.

The probe tip can easily be replaced by a pen to convert this device into an instrumented writing tool. Such a tool can be used to monitor the steadiness of handwriting which may be useful to check for soberness in the law enforcement field.

REFERENCES

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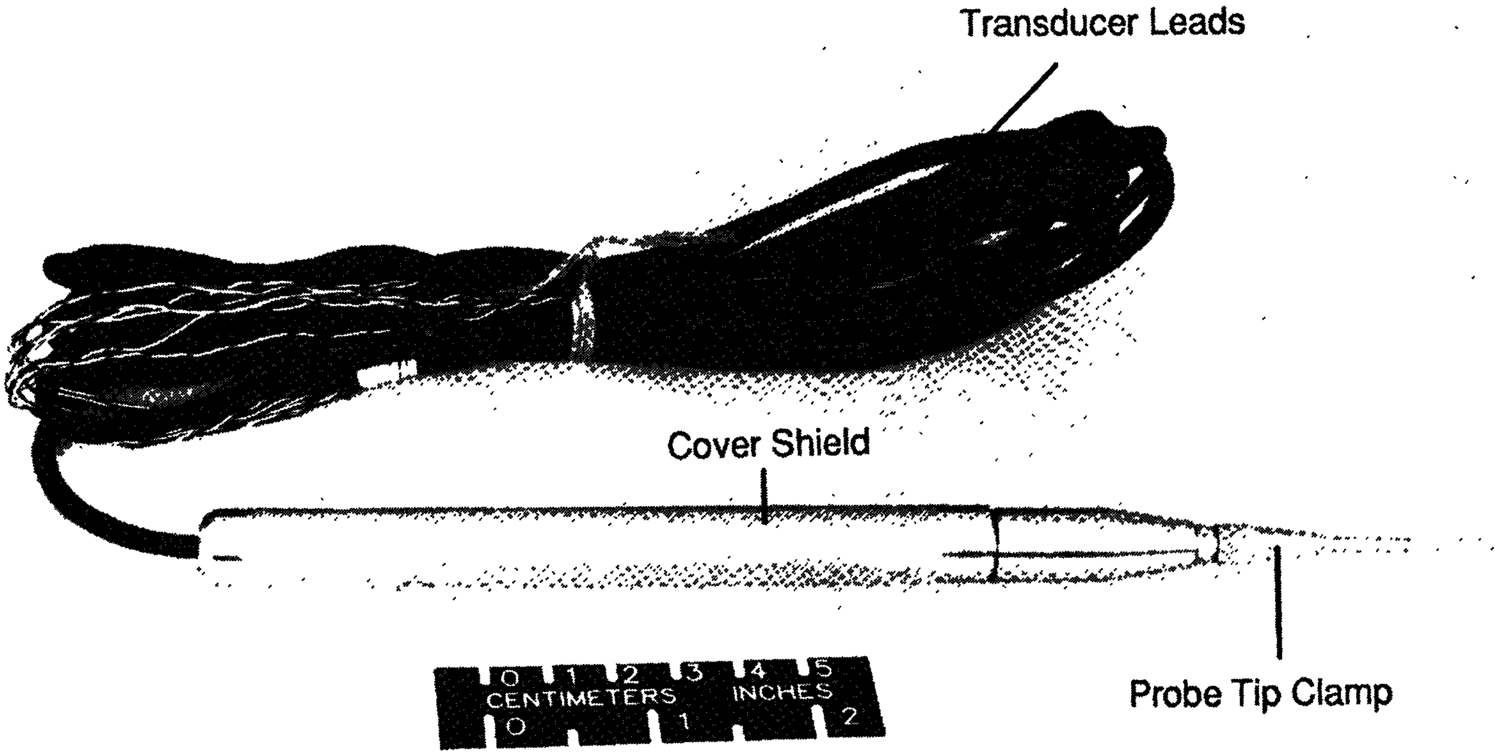

Fig. 1. The Prototype Probe

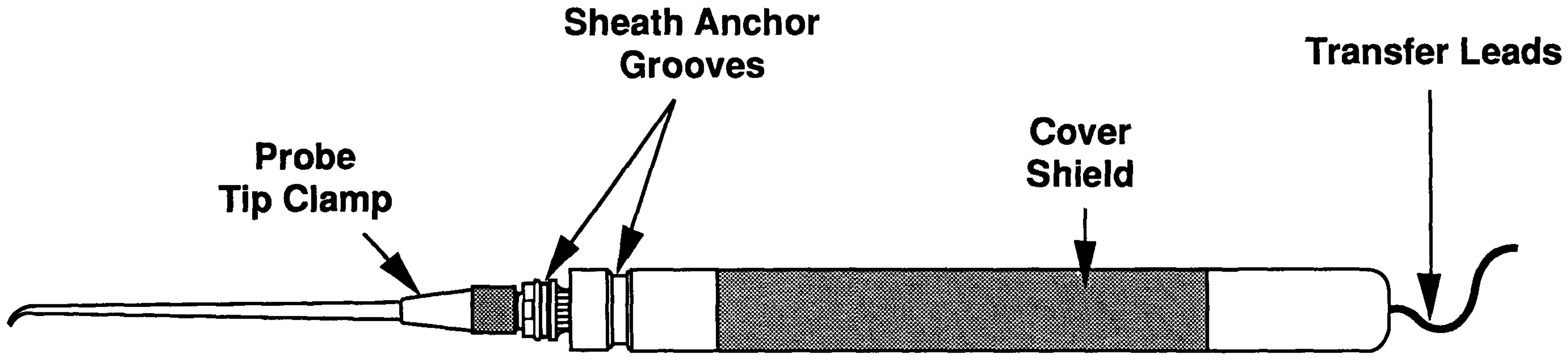

Fig. 2. An Assembley View of the Production Probe

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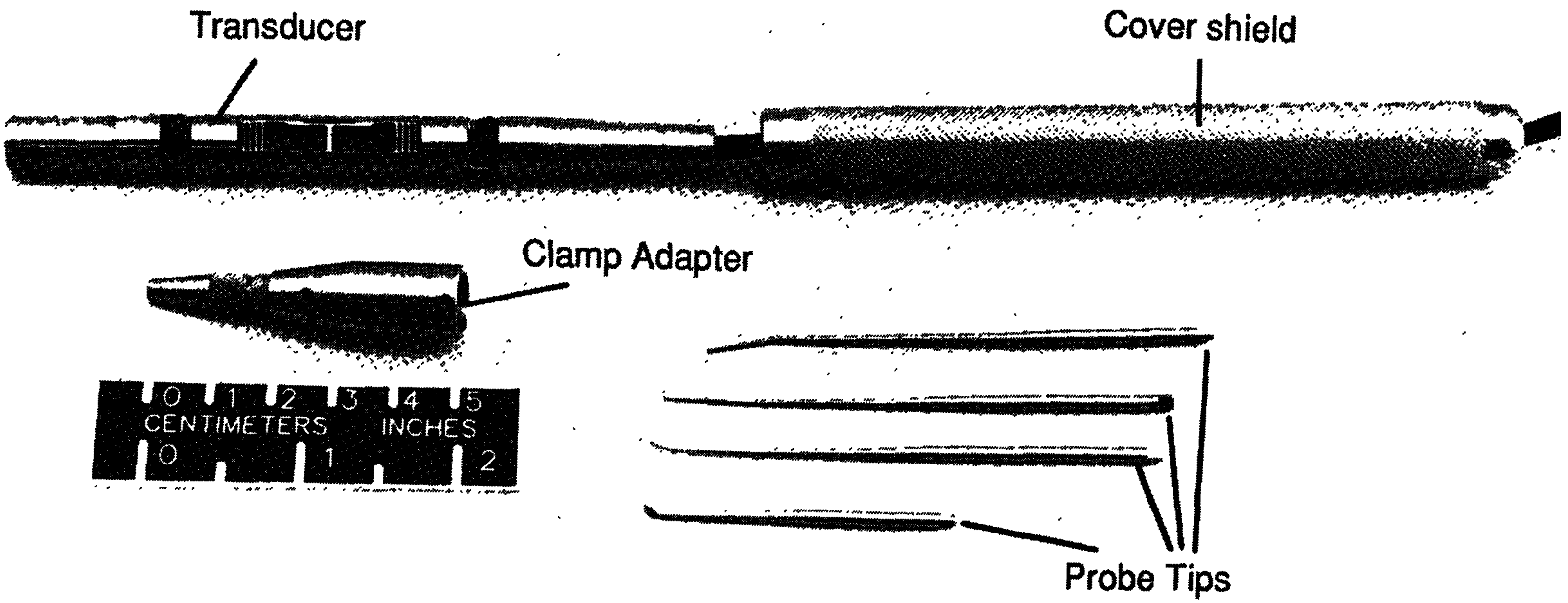

Fig. 3. The Disassembled Prototype Probe

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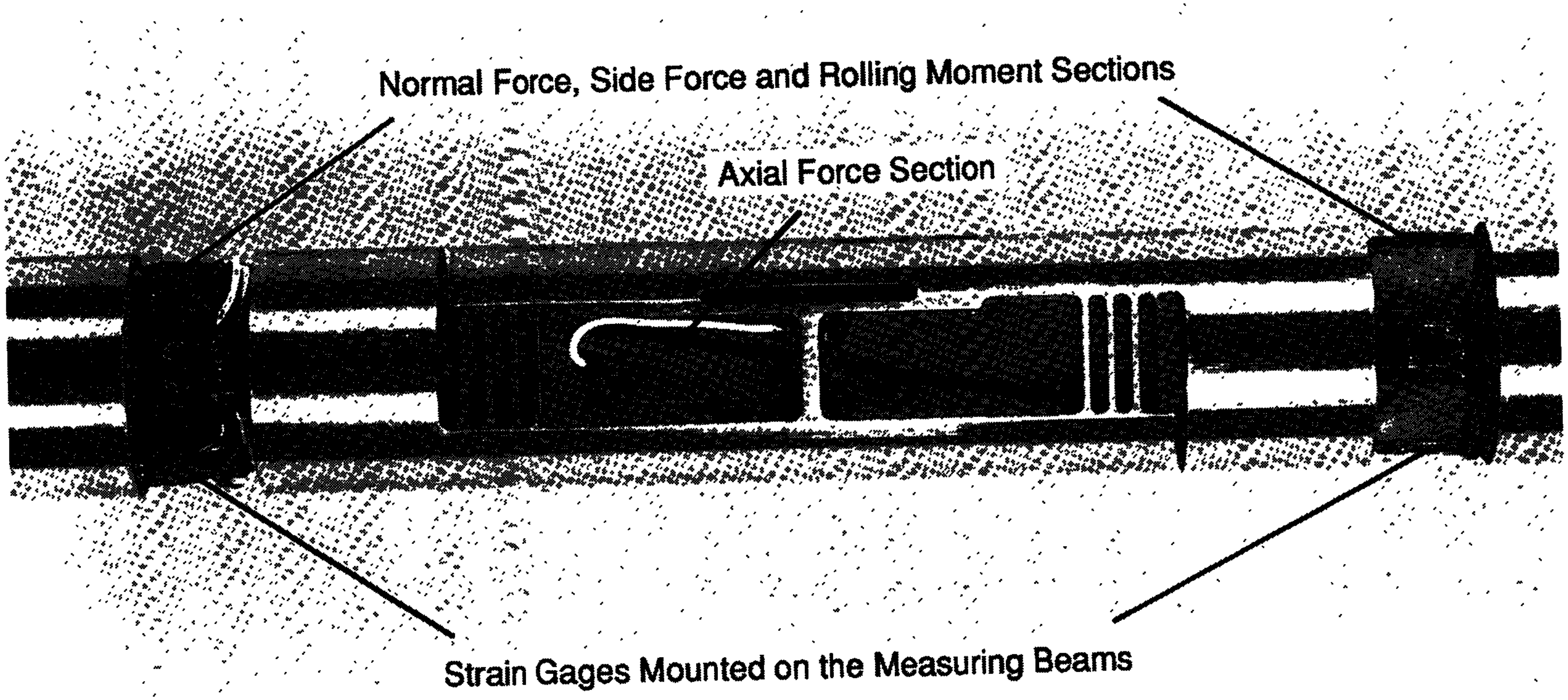

Fig. 4. Measuring Beam Sections of Balance 747

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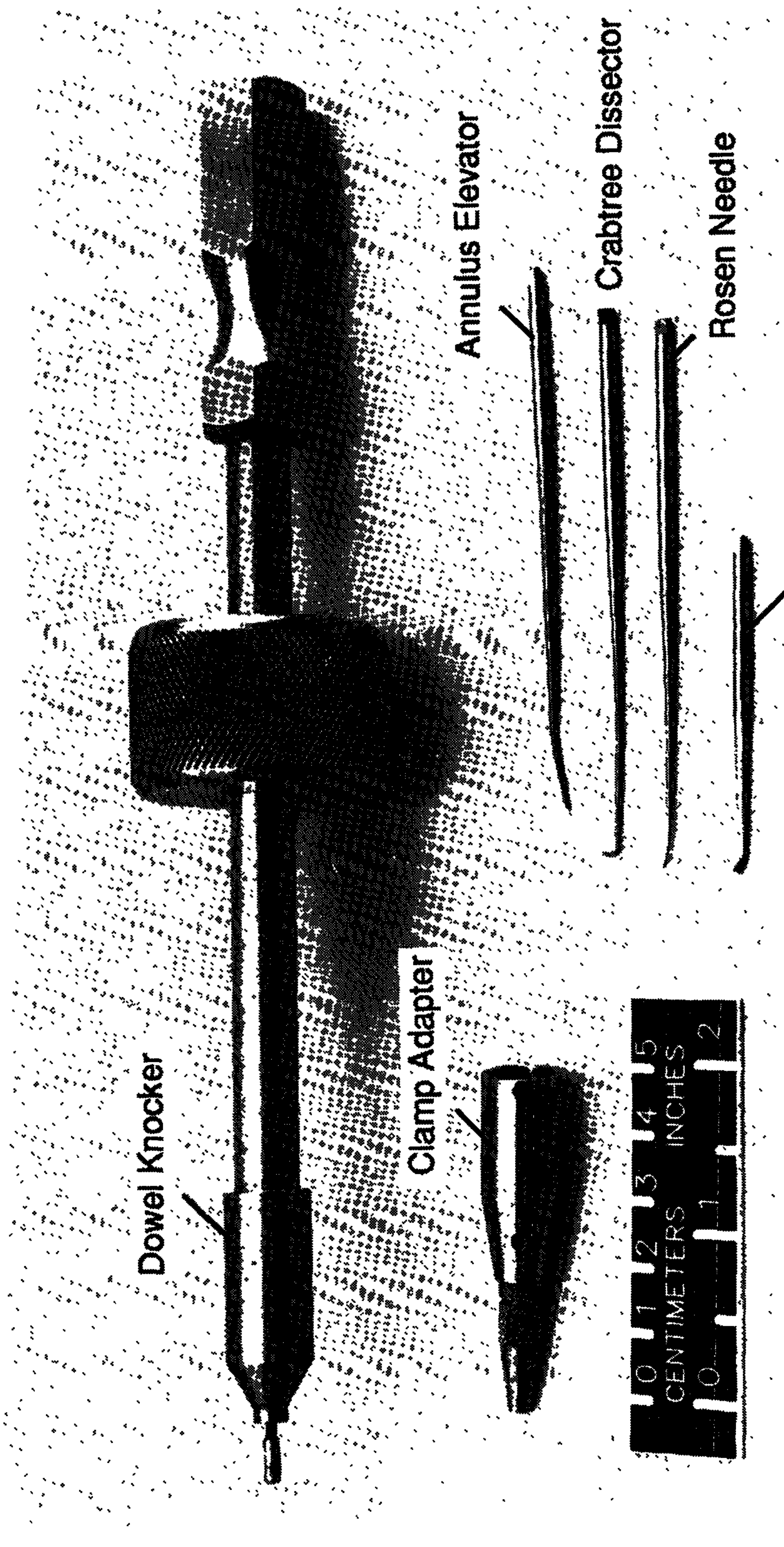

Fig. 5. The Clamp Adapter, dowel Knocker,and Probe Tips

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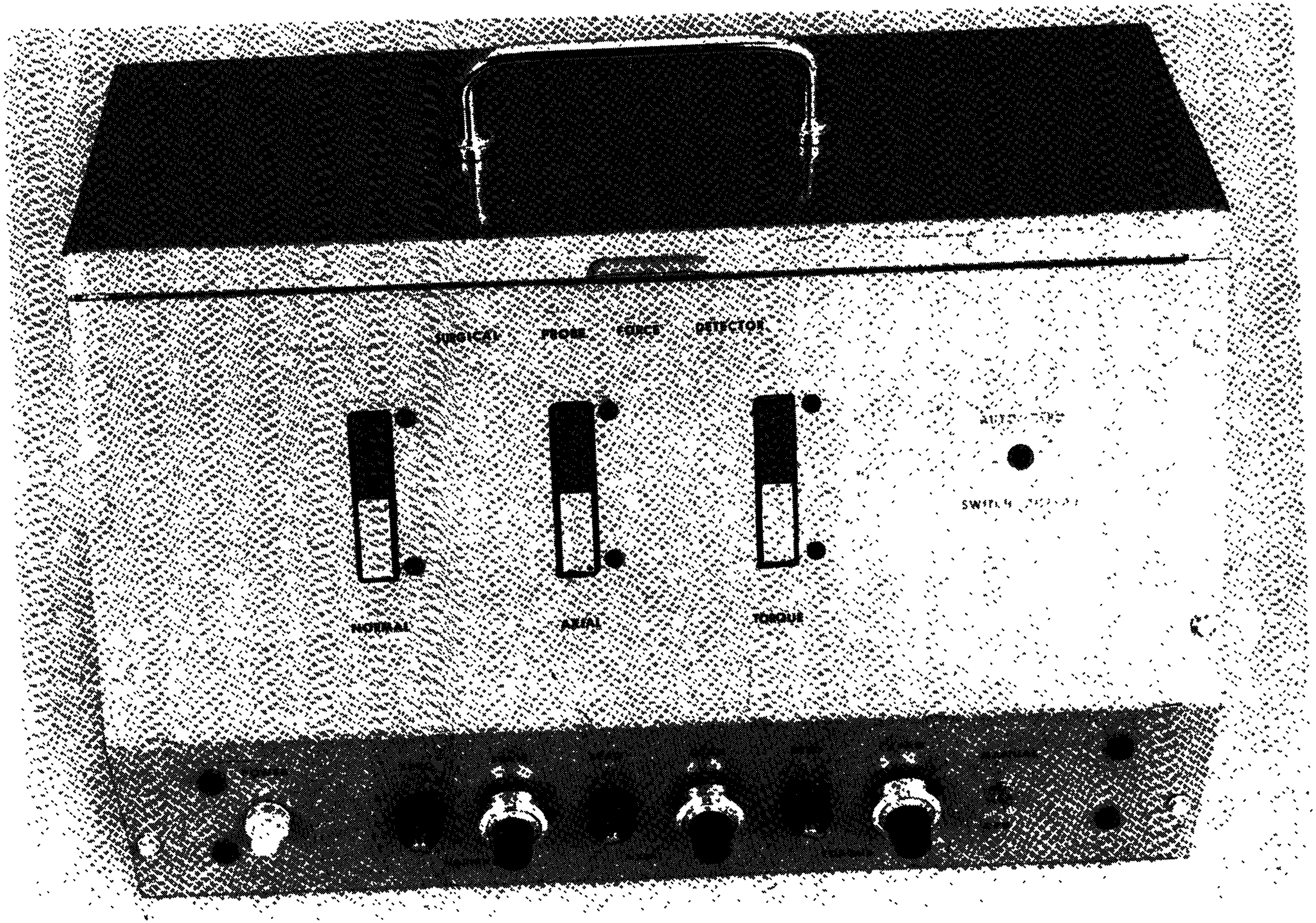

Fig. 6. The Control Box Front Panel

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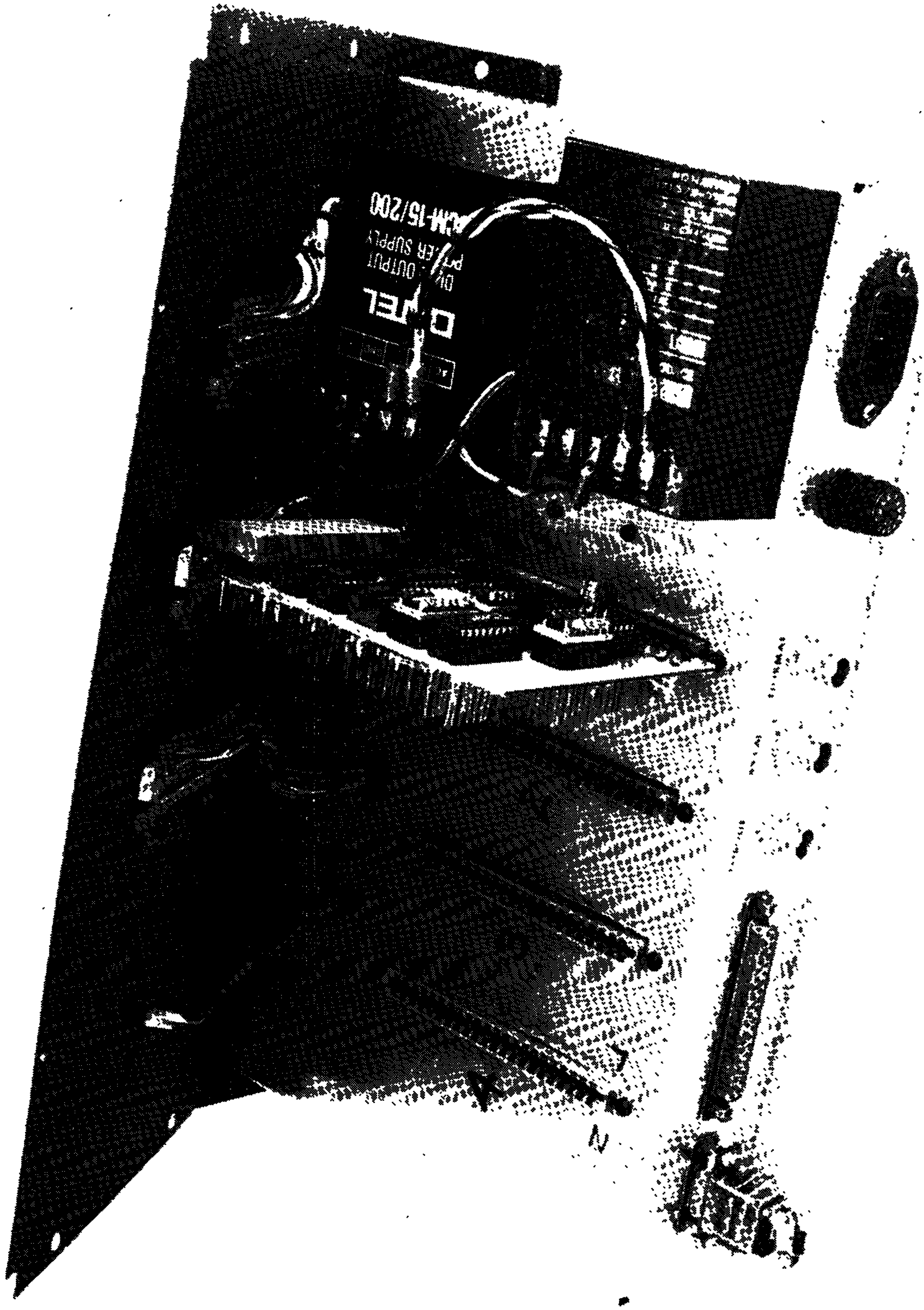

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Fig. 7. The Back Panel and Internal Circuitry of the Control Box

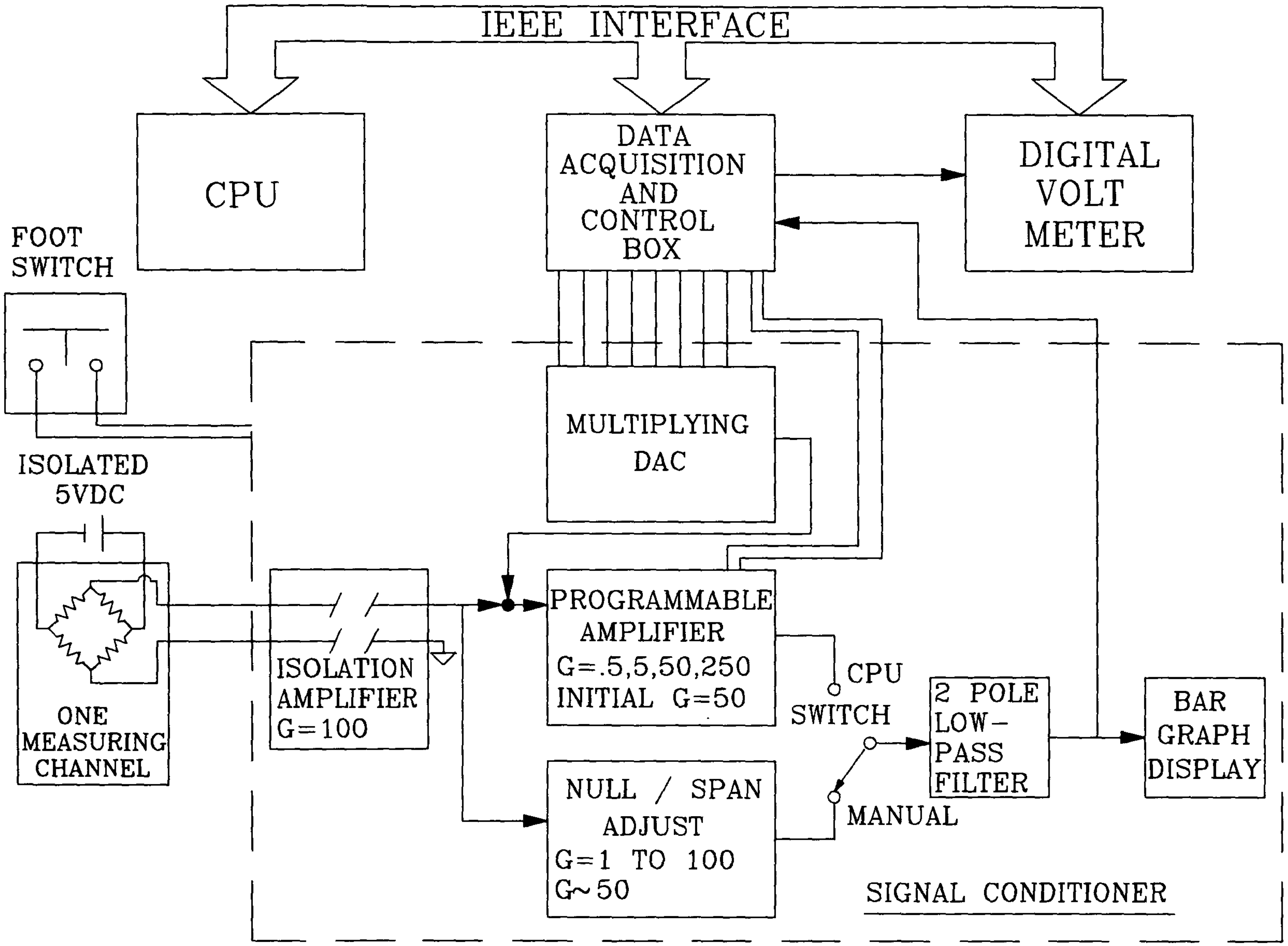

Fig. 8. The Signal Conditioner Block Diagram

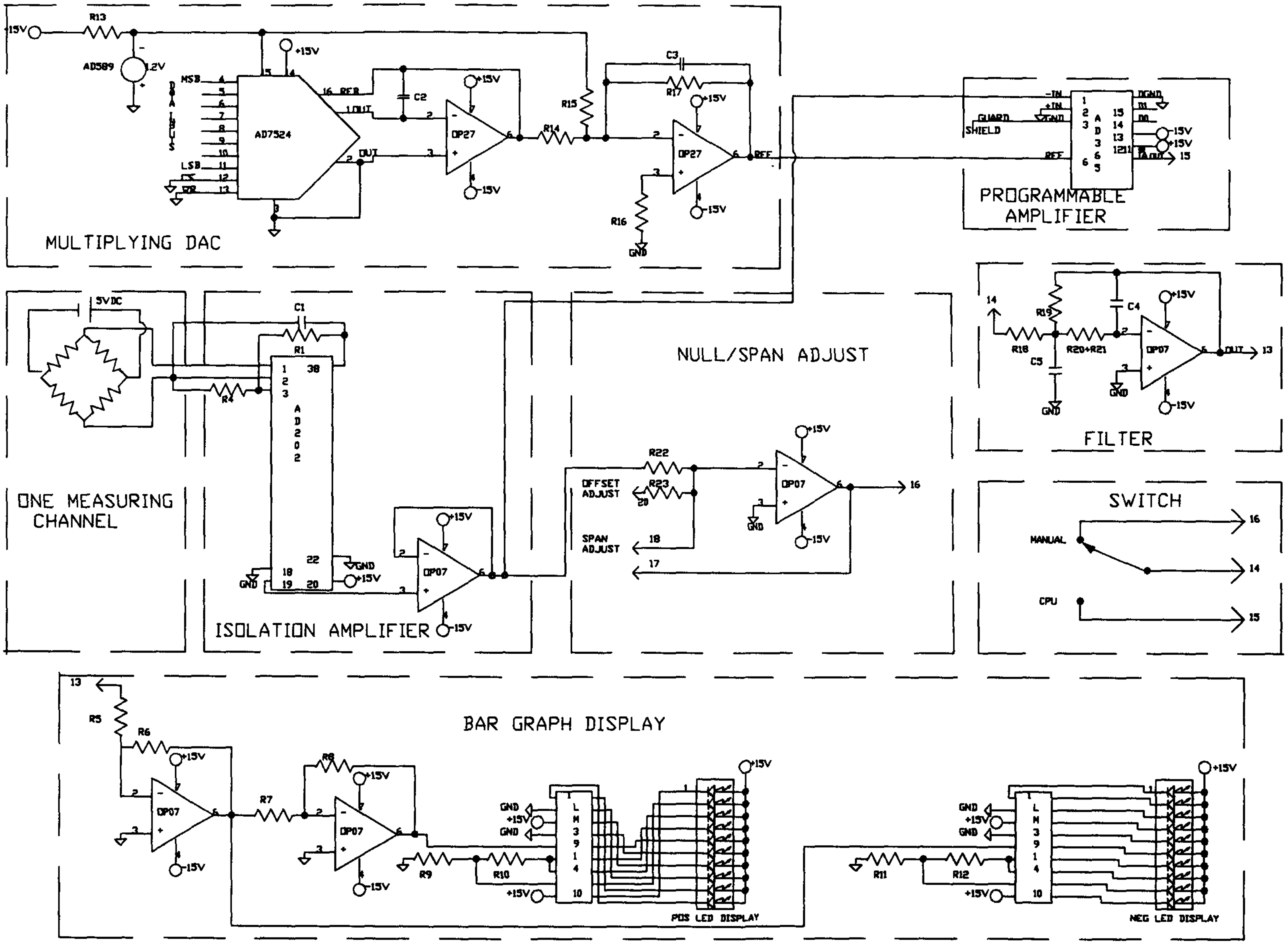

Fig. 9. A Schematic Diagram for the Signal Conditioner