A POSSIBLE ADVANCE IN MEDICAL MANOMETRY

BY


SUMMARY

An integrated circuit pressure transducer is described which has an inherent stability such that it requires only electrical calibration. Furthermore the output of the gauge is so high that inexpensive amplifiers can be used without drift appearing in the output to the final display.

It is a surprising fact that little progress has been made in the development of patient monitoring over the last few years. Possibly this is due to the lack of simple, sensitive, stable, cheap, electrical manometers. Although the most frequent application of such manometers is in the measurement of intravascular pressure, there are numerous other situations in which the measurement of pressure will give much valuable information. A good example is the monitoring of oesophageal pressures, which with certain reservations may be taken as an index of intrapleural pressure and therefore, during the treatment of respiratory failure, can yield considerable information otherwise unobtainable. Dornhorst and Leathart (1952) have shown the value of such manometry in the treatment of status asthmaticus. Robinson (1967) has shown the futility of monitoring airway pressure during artificial ventilation when airway resistance is high and has suggested that the oesophageal pressure is the real guide to the mode of use of mechanical ventilators. Unfortunately such applications of manometry are seldom used because of the disadvantages of available instrumentation.

Commercially available strain gauge transducers in common use have several disadvantages, namely high cost, fragility and a low output. This last leads to the necessity for high gain amplifiers with their attendant troubles of zero and span drift. It was thought that the development of semiconductor strain gauges (Higson, 1964) might obviate many of these difficulties because the gauges themselves would be cheaper and the voltage output could easily be one hundred times that of the conventional wire gauge. This would dispense with the need for expensive and trouble-some high gain amplifiers. This did not prove to be the case because such experimental gauges showed large variations in output with temperature. In these gauges the conventional wire sensing elements were replaced with a single fine crystal filament of silicon which was attached to the load bearing member of the diaphragm by epoxy-type adhesives and it was from this bonding of the sensing elements that most of the temperature difficulties arose. It is now possible to eliminate the use of adhesives by using semiconductor diffusion techniques, in which a wafer of silicon is used as the diaphragm or load-bearing member of the strain gauge, and into this are placed, by semiconductor diffusion techniques, impurity resistors. Due to the piezo-resistive effect in silicon these resistors change their value when any load is applied to the silicon diaphragm and therefore are used as the sensing elements of the gauge.

In 1966, Ferranti Ltd. produced such a micro circuit pressure transducer and it is the development of this, for medical use, that we report here. The transducer has a pressure-sensitive diaphragm which is designed in accordance with the Timoshenko clamped edge, thick, circular, flat, plate formula (Timoshenko and Woinowsky-Krieger, 1959). In these circumstances the surface of the diaphragm behaves under load in such a way that at its centre it is stretched and outside a certain radius (the minimum stress radius) the surface is compressed. Therefore if strain sensitive resistors are diffused into the crystal...
diaphragm at its centre plane and outside the radius of minimum stress the resistors will be deformed by opposite strain so that their resistance changes will be of opposite sign. A fully active four-arm bridge can be formed which will respond to uniform pressure with a large change in resistance and consequent increase in output. Figure 1 shows the diaphragm layout and figure 2 is a schematic representation of the behaviour of the diaphragm.

**Fig. 1**
Silicon diaphragm layout.

**Fig. 2**
Schematic diaphragm deflections.
The silicon diaphragm has a diameter of 4.5 mm and a thickness of 0.1 mm and is welded to the thermally matched ring, a construction which prevents creep and hysteresis and ensures electrical output stability. It can withstand pressures of 5,000 mm Hg and gives a linear response from 0 to 2,600 mm Hg. The transducer has also withstood shocks up to 1,000 g without change in its output characteristics. It seemed likely that the fragility of conventional wire strain gauges or of other solid state strain-sensitive elements has been overcome without loss of sensitivity because the Ferranti gauge still has an output of 16 mV per 100 mm Hg in spite of the thickness of the diaphragm.

The natural frequency response of this gauge was found to be 75 kHz (kc/s) so that the expected frequency response of a medical transducer would be well within that required for blood pressure or respiratory manometers which require a maximum response of 30 Hz.

The compressibility of air is many times that of fluids and any air in the liquid system acts as a cushion, causing distortion and decreased frequency response. The transducer described had an operating range of —20 to +120°C, so that it would be possible to follow the recommendation of Crul (1962) that the transducer and its pressure chamber should be boiled to expel air bubbles. These factors were considered in designing the pressure chamber for the transducer to the configuration and size seen in figure 3. The transducer in its titanium case is inserted into a transparent pressure dome of clear plastic TPX (ICI Ltd.) which is screwed into a titanium housing through which the electrical cable is led. The pressure seal between the transducer module and the manometer housing is by a sealing ring in the cuvette clamped down on to a shoulder on the transducer module. The TPX pressure dome (which will withstand a temperature of 179°C) has two Luer taper drillings to accept disposable nylon three-way taps. No attempt was made to put Luer lock fittings on this head because experience has shown that metal-to-metal or metal-to-plastic fittings eventually leak and they are tiresome to use. The nylon-to-TPX fitting proved to be excellent; it could not be parted by pressures in excess of 1,000 mm Hg and there was no loss of pressure as judged from lack of change in the output of the gauge when a pressure of 200 mm Hg was applied to the diaphragm and left for 48 hours.

There is no doubt that conventional hydraulic...
A possible advance in medical manometry

Calibration of pressure transducers is time-consuming and sometimes dangerous in that it is possible to inject air or the calibrating column fluid into the patient. Such calibration methods are necessary because temperature change and other factors cause zero and span drift of the output of conventional pressure transducers. This requires frequent recalibration which is the reason for the complex calibration apparatus, and procedures which have been outlined from time to time, e.g. Hepburn (1967). A stable pressure transducer which had a constant electrical output for each pressure applied would have distinct advantages in minimizing the complexity of the manometry equipment and in its speed of operation. That such a device was feasible was shown when a Ferranti strain gauge was cycled from atmospheric pressure to 1,500 mm Hg 10,000,000 times over several months by means of a hydraulic pressure generator. The maximum changes in output which were recorded were 0.3 per cent at zero and 1 per cent of span. Such changes when applied to conventional blood pressure manometry are beyond the accuracy of the recording or display equipment. Finally with this pressure transducer a temperature change of 50°C was found to change the total output at 2,500 mm Hg by only 1 per cent and the large output could be used to reduce amplifier drift.

The attraction of an electrical transducer which required no further calibration after its initial assessment was very great and attention was, therefore, directed to this aspect of its development. The electrical apparatus used consisted of the transducer which was given an excitation of 6 V from a Leclanché dry cell, and the output from the resistance bridge of the transducer was fed to a very cheap solid-state amplifier. The amplifier was a Fairchild 702C high-gain wide-band d.c. linear integrated circuit amplifier (cost £3). As the output of this with an input from the transducer is of the order of 1 V/100 mm Hg, any oscilloscope with a sensitivity of 0.1 V/cm and a slow time base will give a good display (e.g. Dartronic 381, cost approximately £39 10s. 0d.). Alternatively, if a dynamic fast transient display is not required a 1 mA FSD milliammeter can be used.

The complete circuit is shown in figure 4. The decouplers, capacitors, C1, C2, remove all interference above 100 Hz and enable readings to be taken during the use of diathermy with a meter output.

Calibration is altered by changes in the supply voltage to the bridge of the transducer but the zero and span adjustments efficiently overcome such changes and are so simple and rapid to perform that both can be checked each time a read-

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**Fig. 4**

Circuit diagram.

* Value determines gain; must not be less than 50 K. High-stability resistors throughout.
ing is required. However, the use of mercury cells such as TR146 (8.4 V) and TR153 (4.2 V) lessen the need for such adjustment as they have a continuously rated output of some 60 hours.

The 702C is rated for a maximum supply of 21 V, and to exceed this would destroy the amplifier. A total potential of 13 V should not be exceeded, as above this thermal instability of the amplifier occurs. Using this circuit, initially the transducer must be matched to the amplifier in the following manner:

1. Switch on and leave for 15 minutes for circuit to stabilize completely.
2. Press \( S_i \) and adjust \( P_z \) to zero output.
3. Release \( S_i \) and adjust \( TP_{12} \) to zero output.
4. Attach calibration column and adjust \( P_3 \) to scale calibration (e.g. 100 mm Hg).
5. Press \( S_i \) and \( S_2 \); adjust \( TP_2 \) to scale calibration.

The unit is now ready for use. A battery change requires only \( P_2 \) (zero) and \( P_3 \) (span) to be adjusted.

If the transducer is changed the whole procedure must be repeated.

Once set up, the clinical use is as follows:
1. Switch on.
2. Attach catheter to transducer via threeway tap and flush with a syringe.
3. After 10–15 minutes, the circuit is stable enough to set zero and span using \( S_1 \), \( P_2 \) and \( S_2 \) and \( P_3 \) respectively. Measurements can then be made.

During use, checks on calibration can be made electrically for:
- zero-press \( S_1 \);
- span-press \( S_1 \) and \( S_2 \).

Various ranges of amplification of the transducer output were required (for example, oesophageal pressure 0–30 cm H\(_2\)O) and this was done by simultaneously changing the values of resistance across AB and CD, but this has not been shown in the circuit diagram for reasons of clarity. Using such a system we were unable to detect any change in output over a period of twelve months, although the electrical calibration was checked frequently against mercury and water columns.

While investigating this aspect of the behaviour of the semiconductor electrical manometer it was noticed that earthing of the cuvette via a saline column caused either a large signal error or complete loss of signal. It was then realized that the diaphragm being of semiconductor material was the equivalent of an infinite number of diodes radiating from the strain element resistors to the opposite face of the diaphragm which is presented to the fluid column or to the metal housing. This is the same as a single diode holding the face of the diaphragm at a potential several volts above that of the strain elements. If an intracardiac saline-filled catheter were connected to the transducer it is very likely that this potential would be harmful, and certainly earthing of the column with loss of signal is annoying to the user. Two methods of overcoming this problem were tried successfully:

1. an amplifier was built having a balanced input independent of earth and having an unbalanced output, one side of which was at earth potential;
2. by oxidizing the obverse face of the diaphragm thus insulating it from the saline column and insulating the mounting of the diaphragm to the metal housing.

The second of the two solutions is the more desirable because it is cheaper, balance-to-unbalance amplifiers being of some complexity and expense. Furthermore the patient's electrical safety is assured even if the transducer should be connected to the wrong type of equipment.

This alarming diode effect has not been reported previously in the medical literature nor do the manufacturers of other semiconductor pressure transducers appear aware of it, because it is not referred to in their literature and all other available semiconductor transducers examined had this effect.

If constant and absolute calibration accuracy of this manometer is to be assured then consideration must be given to the volume of air behind the diaphragm. If this were not open to atmosphere then the static load on the diaphragm would alter with temperature and ambient atmospheric pressure. This would result in a change in the electrical zero of the manometer but no change in its output characteristics. Although this can be easily corrected electrically, it was felt that because the transducer was so stable and required no amplifier adjustments it should not be sealed from atmosphere so that its stable zero characteristics could be retained. It
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is for this reason that a "breather" pipe is placed in the electrical cable terminating in the plug; this prohibits the plug being boiled although the transducer body can be boiled, and it is also suitable for chemical sterilization.

The facility for accurate electrical calibration has led us to discard all the complex plumbing consisting of pressurized fluid reservoirs (with safety valves to prevent air entering the patient's vessels) and mercury or water calibration columns. The transducer diaphragm is robust, withstanding pressures of 5,000 mm Hg, so that the system can be flushed with a small-bore syringe via one of the taps. The hydraulic coupling from the intravascular catheter or needle to the conventional pressure transducer by narrow-bore manometer tubing is a great potential source of error in frequency and phase response, as well as sampling of the pressure wave. For example, an appreciation of the frequency response of a transducer can be examined by placing a thin rubber balloon over one of the taps in the pressure dome, and filling it with air-free water at a pressure of 150 mm Hg. The balloon can then be burst with a needle and the pressure decay recorded on a UV chart recorder at a paper speed of 200 mm/sec. The frequency response of this silicon pressure transducer alone proved to be better than 10 kHz when assessed by this method but fell to 30 Hz when a Portex 6-ft. manometer tube of 1.5 mm internal diameter was interposed between the transducer and the balloon.

Although, the critical sizes for hydraulic coupling tubes have been established by Fry, Noble and Mallos (1957), Sutter and Wood (1960) and Shirer (1962), these criteria are often ignored as shown by numerous unsuitable, commercially available, coupling tubes. Pressure transducers which require no calibration when in use can, if small enough, be placed near to the site of measurement with a very short coupling tube. The transducer described can be coupled to the radial artery by a 15-cm tube and then strapped to the arm; thus changes in the height of the operating table do not cause zero shift due to gravitational effects in the hydraulic coupling.

A recurring dream in medical manometry is the appearance of a cheap intravascular pressure transducer. Such a transducer, apart from its miniature size, would require to have very stable characteristics and an ability to be calibrated electrically, because there would be no means of calibrating such a transducer dynamically once it was within the vascular system of the patient. The work reported here may make the dream nearer to reality because the strain gauge described has such stable characteristics and it is technically feasible to make the crystal small enough to enter blood vessels.

A development of the transducer described is commercially available: Ferranti ZPT 6 GMC.

REFERENCES


UN PROGRES POSSIBLE DANS LA MANOMETRIE MEDICALE

SOMMAIRE

Un transducteur de pression de circuit integre est decrit, qui possede une telle stabilité inherente, qu'il suffit de le calibrer electrique. Le debit est en outre si grand que des amplificateurs peu onereux peuvent être utilise, sans troubler le resultat final.

EIN MÖGLICHER FORTSCHRITT IN DER MEDIZINISCHEN DRUCKMESSUNG

ZUSAMMENFASSUNG

Es wird ein Manometer mit integrierten Schaltkreisen beschrieben, daß aufgrund seiner Stabilität nur elektrisch kalibriert werden muß. Da das ausgehende Signal so groß ist, können billig Verstärker benutzt werden, ohne daß es zu Drifterscheinungen bei der Endaufzeichnung kommt.