Design and development of a new electronic sphygmomanometer

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Abstract—*The paper introduces a new technique for the indirect measurement of the systolic and diastolic blood pressure in humans. The technique is based upon a statistically consistent relationship between the amplitude of the pulsatile pressure waveform at the systolic and diastolic points and the amplitude of pulse signals detected when the artery is fully occluded. An adaptive measurement philosophy has been implemented in the design of an electronic sphygmomanometer which, in addition to a pressure transducer, contains suitable electronic instrumentation for processing and displaying the electronic signals. Verification of overall system accuracy is accomplished with direct comparison with manual auscultatory measurements. Clinical testing of a prototype indicates a satisfactory performance; measurement errors are maintained well within proposed standards for automated sphygmomanometers.*

Keywords—*Electronic design, Electronic sphygmomanometer, Noninvasive blood pressure measurement*

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1 Introduction

ACCURATE CLINICAL blood pressure readings have been a concern ever since the indirect method was developed at the turn of the century (HILL and FLACK, 1941, GEDDES, 1970). Conventional noninvasive methods for blood pressure measurement rely on the use of an inflatable occlusive cuff followed by analysis of the Korotkoff sounds by either stethoscopic or electronic auscultation methods (COLLINS and MAGORA, 1963; MCGOUCH and MCDONALD, 1981; SCHULTZE *et al.*, 1968). Other available techniques are based upon the oscillometric method (WALKER, 1982) or measure mean arterial pressure (RAMSEY, 1979) or long-term variations of blood pressure by peak-and-trough detection of the pressure waveform (MITCHELL *et al.*, 1979).

Analogue, digital and hybrid electronic techniques have been utilised for the detection and recording of the systolic and diastolic blood pressure in humans. Some automatic devices not using Korotkoff sounds, e.g. the 'Dinamap' machine, have reached the stage of commercial exploitation. Strain gauge or pressure transducing devices are usually coupled to signal-processing instrumentation and display equipment. Minimax peak-detecting electronic apparatus for identifying the systolic and diastolic pressure levels have been proposed (BIRNBAUM, 1975). Strain-gauge techniques (FIEGEL, 1965), analogue preprocessing (SANDMAN and HILL, 1974), appropriate blood-pressure amplifier means (ARNESON, 1975) and display devices (MONDSHINE *et al.*, 1969) have been developed and reported in the literature.

In principle, the auscultatory techniques are based upon the inclusion of a microphone in the cuff area for the direct detection of the Korotkoff sounds or via comparison methods with a reference signal or through identification of peak pressure amplitudes in an 'open loop' configuration. These basic design concepts require human intervention in recording the appropriate pressure levels. They are usually characterised by the need for medical supervision during measurement and a lack of performance reliability. The measurement complexity and lack of reliability have prevented the widespread nonprofessional use of these devices despite a growing awareness of hypertension as a serious health hazard and an increasing recognition of the importance of early detection and treatment of the disease.

This paper describes a new technique for the measurement of the systolic and diastolic blood pressure in humans. More specifically, it is concerned with the design, development and testing of a new electronic sphygmomanometer. The performance of a prototype device is collaborated with a series of clinical tests and statistical results validating the basic hypothesis of the proposed method.

2 Proposed approach

Fig. 1 shows a general block diagram of the proposed sphygmomanometric technique. A conventional occluding cuff and its associated relief valve are retained in this scheme. Cuff pressure is transferred to an appropriate pressure transducer whose electrical output is proportional to absolute pressure in the brachial area. The transducer output signal is processed accordingly so that the systolic and diastolic blood pressures are finally displayed or recorded.

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When the artery is completely occluded at some maximum pressure level, small-amplitude pulse signals are detected which are due to the ongoing pumping action of the heart. These pulse signals are superimposed on the cuff pressure and are called background pulses. With the artery fully occluded, their amplitude is a function of the physiological characteristics of the individual tested and the cuff pressure. Above a certain maximum cuff pressure, the amplitude of the background pulses B remains fairly constant for the individual tested.

Clinical evidence (VACHTSEVANOS *et al.*, 1984) indicates that a consistent and proportional relationship exists between the amplitude of the artery-occluded pressure pulses (background amplitude) and those resulting during deflation of the cuff and corresponding to the onset and termination of the Korotkoff sounds. This relationship is independent of the individual tested; i.e. when the cuff pressure corresponds to the systolic pressure SP, a relationship of the form

$$S = B \times SR \tag{1}$$

holds. Here, S is the pulse amplitude at the systolic level and SR a constant called the systolic ratio.

A similar relationship holds for the pulse amplitude D corresponding to a diastolic level DP of the cuff pressure, i.e.

$$D = B \times DR \tag{2}$$

where DR is the constant diastolic ratio.

The above-mentioned relationships are being exploited in the design of an electronic sphygmomanometer which, in addition to the pressure transducing device, contains suitable electronic instrumentation for processing and displaying the systolic and diastolic pressure signals.

A satisfactory number of recordings of cardiac pressure waveforms from various individuals has shown that the normal range of systolic pressure level is between 80 and 240 mm Hg (excluding a few pathological cases). Background pulses, therefore, should be measured at cuff pressure levels greater than 240 mm Hg. Such a situation, though, is not only unnecessary but also uncomfortable for individuals with a systolic level of less than 200 mm Hg. For this reason, the full range of possible cardiac pressure levels is subdivided into three regions. Table 1 shows the three regions and the maximum cuff pressure P_0, for each region, at which the amplitude of the background pulses is measured.

Statistical analysis of the clinical data has also shown that the values of the systolic (SR) and diastolic (DR) ratios for each region are functions of the background pulse amplitude B. This functional dependence may be approximated by a fifth-order polynomial of the form:

$$\begin{aligned} SR &= s_5 B^5 + s_4 B^4 + s_3 B^3 + s_2 B^2 + s_1 B + s_0 \\ DR &= d_5 B^5 + d_4 B^4 + d_3 B^3 + d_2 B^2 + d_1 B + d_0 \end{aligned} \tag{3}$$

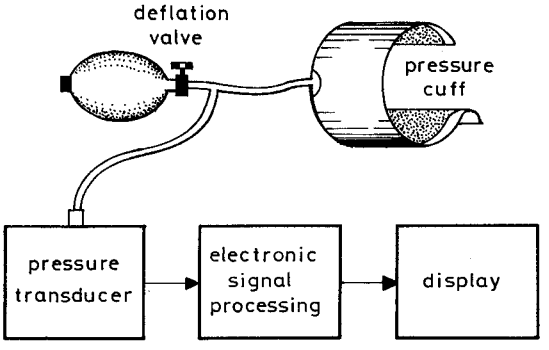

Fig. 1 *Simplified schematic of the sphygmomanometer*

It is sufficient, therefore, to measure the background pulse amplitude B of an individual to determine the cardiac pressure SP and DP. The procedure would use eqn. 3 to estimate the ratios SR and DR; next, eqns. 1 and 2 would be used to determine the systolic (S) and diastolic (D) pulse amplitudes, respectively; these last two quantities assist in determining, finally, the corresponding cardiac pressures SP and DP.

The approach outlined above requires a microprocessor-based device for its implementation. A much simpler realisation involves the assumption that the ratios SR and DR remain constant over each measurement region. These two values are set equal to the mean measured values for the ratios SR and DR and are listed in Table 1. The resulting instrument is characterised by a high degree of reliability and simplicity. Accuracy of performance is well within acceptable standards when compared with conventional means.

3 Instrument operation

Fig. 2 depicts the pressure transducer output signal during cuff deflation from the initial pressure P_0. The pulse signal superimposed on the absolute cardiac pressure is clearly indicated. Near the initial pressure P_0 the pulse amplitude is equal to B. When the cuff pressure reaches the systolic level SP the pulse amplitude becomes equal to S; the pulse amplitude corresponding to the diastolic level

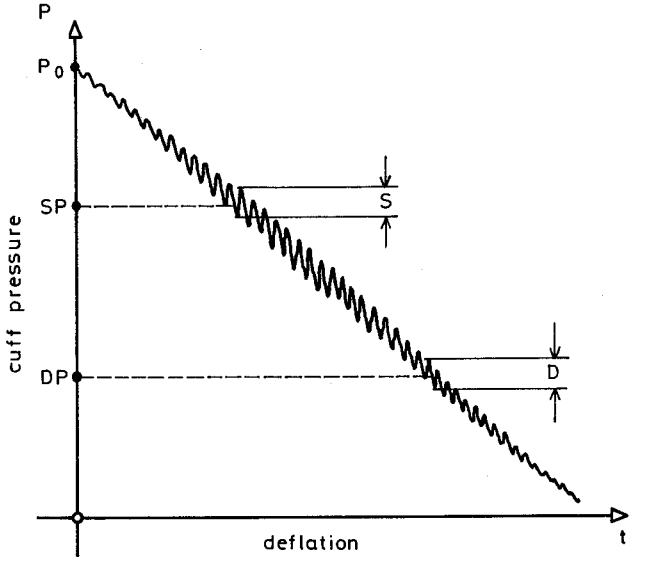

Fig. 2 *Schematic of combined output from the pressure transducer during cuff deflation*

Table 1 Statistical characteristics for phase I sample data

Phase I statistical characteristics	SR initial pressure		DR initial pressure	
	160 mm Hg	200 mm Hg	160 mm Hg	200 mm Hg
Mean value	3·561	4·42	3·3745	3·781
Standard deviation	0·6803	1·082	0·26	0·707
Summation of data	306·3099	380·130	74·24	83·19
Minimum value	2·25	2·85	1·74	2·59
Maximum value	6·8	3·780	7·470	4·96
Number of samples	86	86	22	22

DP is equal to D. For the quantities B, A and D, eqns. 1 and 2 are applicable in each measurement region. The pulse signal, separated from the absolute cardiac pressure, is shown in Fig. 3. The Figure clearly illustrates the background pulse region as well as the systolic and diastolic pulse levels.

The operation of the instrument will be explained with reference to Fig. 4. The upper part of the Figure shows the envelope of the rectified pulses of Fig. 2 (curve *a*). Curve (*b*) shows the same envelope waveform after multiplication consequently by factors of 1, $1/SR$ and $1/DR$. The middle part of the Figure depicts pictorially the procedure of inflating and deflating the pressure cuff; finally, the lower portion illustrates the milestone operations of the sphygmomanometer in conjunction with the previous two parts.

At the beginning, the cuff is inflated until a warning light indicates that the desired maximum pressure level P_0 has been exceeded. At this point cuff deflation is initiated. This indicator light is turned off when the pressure level passes through P_0 again. The measurement procedure begins at that particular moment with the time axis set arbitrarily at $t = 0$. During the first measurement phase the pulse envelope remains fixed while its amplitude (the background pulse amplitude B) is stored. In the next phase, the pulse envelope is amplified by $1/SR$ and is continuously compared with the stored value B of the background pulse amplitude. At the moment when the relationship $S = B \times SR$ is satisfied, the systolic cardiac pressure SP is stored and displayed. From that instant on, the pulse envelope is multiplied by a factor $1/DR$ and the resultant is continuously compared with B. When the second relationship, $D = B \times DR$, is satisfied, the instrument stores and records the diastolic pressure level DP. The measurement procedure is terminated with a simultaneous display of the individual's systolic and diastolic cardiac levels.

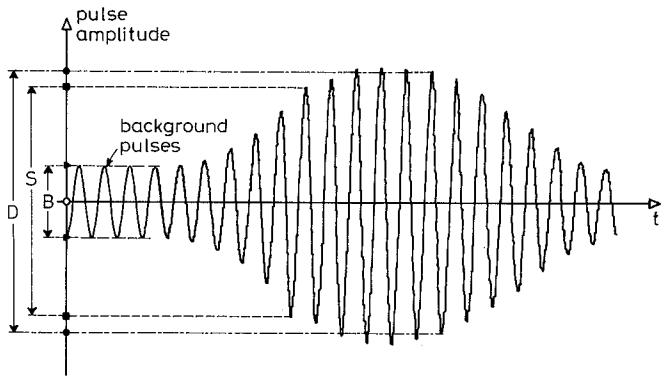

Fig. 3 *Cardiac pulses extracted from the combined signal of Fig. 2*

4 System description

Fig. 5 shows a simplified block diagram of the instrument realised on the basis of the procedure detailed in the previous paragraph. The following system description is based on the operational block configuration of this Figure.

Cardiac pressure is applied to the input of the pressure transducer and converted to an electrical signal of the form shown in Fig. 2. This signal drives the range-selecting initial pressure P_0 indicating unit. The indicator light comes on when, during cuff inflation, the pressure exceeds the value P_0. Indicator turnoff coincides again with P_0 (Fig. 4). At that same instant, the timing circuit is reset and controls, from that point on, the time sequence of the instrument's operations. The pressure transducer output is also directly connected to the display unit. The latter contains two parts: one used to display the systolic pressure and the other the diastolic. Freezing of the appropriate display indications is controlled by the rest of the circuitry.

The transducer output is finally used as an input to a bandpass filter. The filter output, shown in Fig. 3, contains only the cardiac pulses. This signal is applied next to a switchable amplifier whose amplification factor is controlled by an appropriate interface. This circuit is controlled by the range-selecting unit which sets the ratios SR and DR according to the pressure regions defined in Table 1. Also, the same circuit receives synchronisation signals from the timing unit and sets the amplifier's multiplying factor at the values of 1, $1/SR$ and $1/DR$, consequently. The amplifier output is applied to a rectifier-averaging circuit whose output is waveform (*b*) in Fig. 4. The rectified and smoothed signal is fed to a sampling network. Operation of the sampler is controlled by the timing circuits.

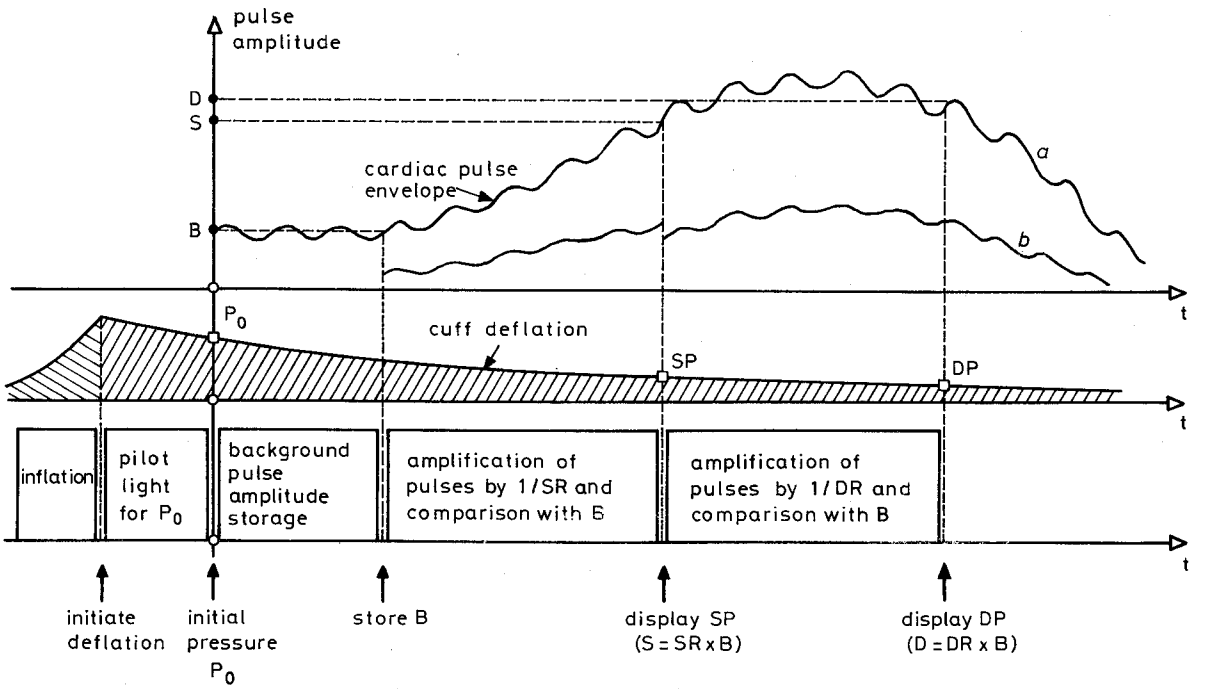

Fig. 4 *Pictorial description of sequencing and correlation of milestone events during the operation of the sphygmomanometer*

Thus, during this first procedural phase (amplification factor 1, pulse amplitude B), the amplitude of waveform (b) is sampled and stored. The stored value B together with the rectifier output signal are the two inputs to a comparator circuit. The comparator changes state each time the rectifier output signal goes through a level equal to the value B, i.e. when its amplitude becomes equal to $B \times SR$ and $B \times DR$. This change of state controls the display unit. As a result, two specific values of the cardiac pressure are applied each to the two separate parts of the display input port: the values SP and DP. The values of the systolic and diastolic pressure levels remain fixed on the display unit even after the measurement procedure is terminated.

5 Design details

A detailed diagram of the instrument is shown in Fig. 6. Functional circuits substitute for the operational blocks of Fig. 5. The pressure transducer is a linear hybrid integrated circuit (LX 1602 G) which incorporates a piezoresistive sensor as part of a balanced bridge arrangement. Cuff pressure, through plastic tubing, is transferred to the transducer input while an analogue voltage appears at the output port. A DC offset signal of $2{\cdot}5 + 0{\cdot}3$ V has been superposed on the transducer output voltage. Removal of the offset level results in the cardiac pulse shown in Fig. 2. The transducer calibrated pressure range is from 0 to 776 mm Hg. The conversion coefficient is 13 mV mm Hg^{-1}

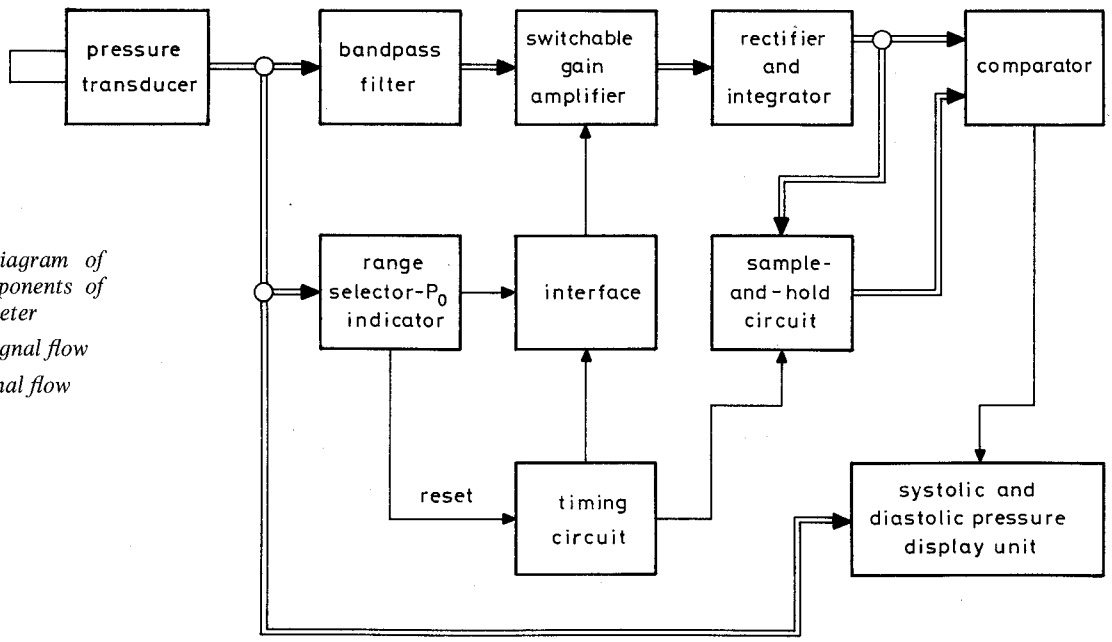

Fig. 5 *Simplified block diagram of the electronic components of the sphygmomanometer*
analogue signal flow
control signal flow

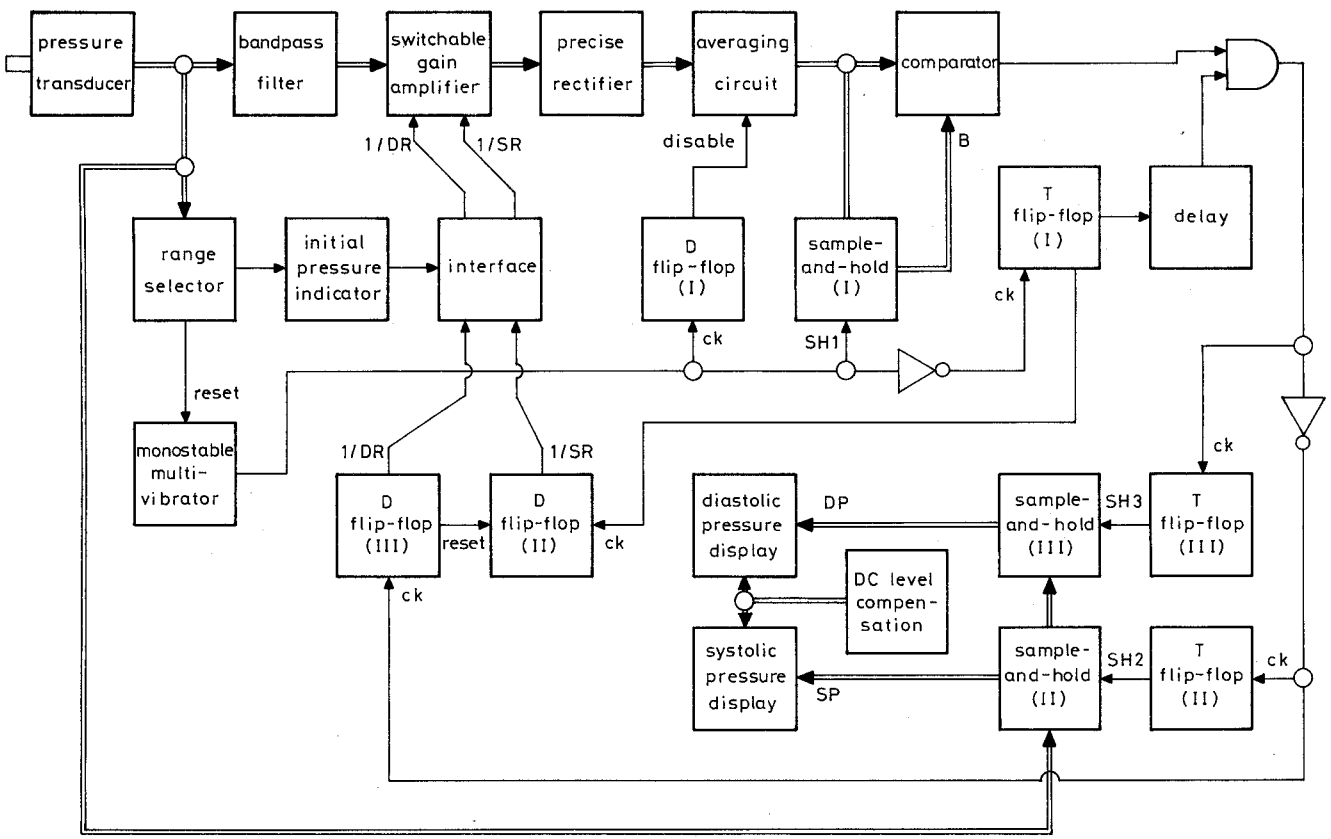

Fig. 6 *Detailed block diagram of the main components and functions of the sphygmomanometer*
analogue signal flow
digital signal flow

(accuracy = 0·25 mV mm Hg^{-1}) and the maximum calibration error is ±1·5 per cent of span.

The range selector is a circuit with a three-position switch which sets the initial pressure P_0. When the cuff pressure exceeds the value P_0, a light indicator comes on signalling that maximum pressure has been reached and cuff deflation may be initiated. The indicator is turned off at the moment cuff pressure reaches again the P_0 level (during deflation). Simultaneously, the monostable multivibrator, which is part of the timing circuit shown in the diagram of Fig. 5, is reset. The bandpass filter consists of two stages: a high-pass and a low-pass section. The high-pass filter is of second order with a cutoff frequency of $f_L = 0{\cdot}5$ Hz while the low-pass filter is of the first order with a cutoff frequency of $f_H = 2{\cdot}5$ Hz. This filtering action is intended to permit transmission of cardiac pulses only, eliminating any noise signals and improving the reliability of the instrument. Indeed, physiological constraints place the cardiac pulse rate between 40 and 120 pulses per minute corresponding to frequencies from 0·67 to 2 Hz. A two-pole (12 dB octave^{-1}) design was preferred for the high-pass section so that low-frequency signals due to random arm movement may be eliminated from further processing.

The amplification factors ($1/SR$, $1/DR$) of the switchable gain amplifier are set by the range selector switch. An appropriate interface circuit, consisting of booster sections and reed relays, undertakes to control these settings.

The rectifier design is based on a conventional full-wave circuit implemented with an operational amplifier. The integrator is a conventional averaging circuit with a 'disable' capability added on. The disable circuit disconnects the integrator during cuff inflation and brings it back to an operating state at the beginning of the measurement cycle (at time 0 in Fig. 4). This mode of operation is necessary to avoid storing, for the background pulse amplitude B, false signals of large amplitude originating during cuff inflation. The disable circuit is controlled via the 'disable' input of the D flip-flop (I).

The sampling circuit stores the input voltage level, corresponding to the maximum amplitude of the first four to five cardiac pulses (background pulses) when the control input SH1 is set to the proper logic state.

The comparator receives at one input the background pulse amplitude B; incoming cardiac pulses, amplified by $1/SR$ or $1/DR$ (depending on the measurement phase), are applied to its other input. The comparator output changes state when the input S/SR exceeds the value B or when the input D/DR falls below B. A high comparator state coincides with the systolic blood pressure while a low state is identified, subsequently, with the diastolic level. Synchronising signals for the display of the two pressure levels SP and DP are derived from these changes of the comparator output state. Two D flip-flops (II and III) are excited, each from the corresponding change of state, and provide the appropriate control signals SH2 and SH3. The latter control two identical sampling circuits (each at the appropriate time instant) so that the systolic (SP) and diastolic (DP) pressure levels are stored. Input to these samplers is provided directly from the pressure transducer output.

A zero offset circuit provides a stabilised and finely controlled DC voltage which is used to subtract the DC component from the transducer output signal. Two digital display circuits with appropriate analogue-to-digital convertors are displaying the difference between the sampler output and the reference signal. This difference is directly proportional to the cuff pressure.

The monostable multivibrator, as soon as it is reset, provides a signal at its output of 5 s duration which performs the following functions:

(*a*) It sets all instrument flip-flops at a reset state.
(*b*) It excites the D flip-flop (I) so that it may enable the operation of the integrator.
(*c*) At the end of the 5 s period, the sample-and-hold circuit (I) stores the value of the voltage amplitude.
(*d*) At the same time the T flip-flop is set into operation and performs the following two functions:

(i) A delay circuit is excited which provides an additional 2 s delay allowing the cardiac pulses to pass from the comparator output to the rest of the circuit through an AND gate. This mode of operation is necessary to prevent any transient pulse signals originating at the comparator output from disturbing the display circuit performance during switching of the gain amplifier.
(ii) It excites the D flip-flop (II) which, in turn, sets the gain unit amplification factor to $1/SR$ through the inerface circuit.

The first change in comparator state also excites a D flip-flop (III) so that the amplifier gain is set to its new value of $1/DR$. Simultaneously, the D flip-flop (II) is reset.

This completes the detailed circuit description, as outlined in the block diagram of Fig. 6.

6 Performance characteristics

A prototype sphygmomanometer was constructed and tested with a conventional mercury manometer taken as the standard. An attempt was made to use commercially available (of the inexpensive type) automatic devices in the evaluation process. The performance of these machines, however, was erratic and the attempt was abandoned in favour of the conventional mercury manometer as recommended by AAMI. A test population of 40 subjects was considered and the initial 'artery occluded' pressure was set at 200 mm Hg.

A statistical analysis of the collected data leads to a direct estimation of the probable measurement error. The probable error (i.e. the absolute error for a confidence level of 50 per cent) is found to be 2·1618 mm Hg and 1·66 mm Hg for the systolic and diastolic pressure levels, respectively. Under these conditions the instrument performs accurately, since the measurement error is well within the proposed ±5 mm Hg accuracy standard (AAMI, 1982). Possible error sources may be due to:

(*a*) the observer
(*b*) the equipment
(*c*) the subject tested
(*d*) the environmental conditions.

The proposed instrument is designed to operate with a minimum observer involvement, thus minimising the error contribution from this category. Errors due to equipment arise primarily from the nonlinear characteristics of the electronic pressure transducer (of the order of 1 per cent) and the other components (amounting to approximately 0·5 per cent of full scale). The subject tested may contribute a substantial part of the experimental error by allowing motion of the arm during measurement, abnormal breathing, etc. Finally, environmental conditions, such as vibrations, noise, etc., may affect the accuracy of the measurement.

Further improvement in performance may be achieved by selecting, for each measurement, an optimum systolic

and diastolic ratio value. The available test data are used in conjunction with a least squares algorithm to derive a functional relationship between the 'systolic to background' and 'diastolic to background' ratios, and the amplitude of the background pulses. Programming these relationships into the memory unit of an appropriately designed instrument and using the optimum ratio values for each testing situation will minimise the absolute measurement error, resulting in increased instrument accuracy.

7 Discussion and conclusions

A theoretical verification of the proposed technique's system efficacy is difficult to establish, if not impossible, owing to the character of the systolic and diastolic pressure levels, the inherent inaccuracies etc. It is generally accepted, therefore, that overall system accuracy may be verified by comparison with conventional (auscultatory and invasive) techniques (AAMI, 1982). Care must be exercised in organising and conducting the clinical testing and analysing the statistical data so that acceptable system accuracies are assured. The invasive method of verifying noninvasive blood pressure measurement devices is potentially the most precise means of verification. At the same time, it is practically more difficult to obtain subjects and conduct measurements. The AAMI standard for electronic or automated sphygmomanometers concludes that 'of the two methods, the first (auscultatory) is by far the easiest to implement and is generally acceptable'.

The proposed sphygmomanometer performs satisfactorily when compared with conventional standards. The design methodology adopted is based on a statistically consistent relationship between the pulse amplitude detected with the branchial artery fully occluded and the systolic and diastolic cardiac pressure points of an individual. The basic principle has been validated through extensive clinical testing.

The instrument design philosophy incorporates an all-analogue approach which leads to a reliable device realisation within acceptable accuracy limits and reasonable construction costs. Special attention has been given to the design of appropriate signal processing circuits so that errors due to environmental conditions or random arm movements are minimised and the desired signal is clearly distinguished from noise levels.

The approximations introduced in the design are supported with experimental performance data; further improvements in instrument accuracy are possible through storage, in digital form, and utilisation of the functional relationship, between the 'systolic to background' and 'diastolic to background' ratios on one hand, and the amplitude of the background pulses, on the other. Such an implementation would assign optimum values to these ratios and reduce further instrument errors.

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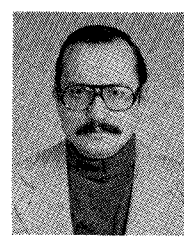

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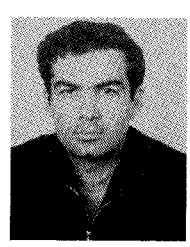

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