

Non-Invasive Blood Pressure Monitor: Beat to Beat

Vineet Sinha, R.K. Jain, G.D. Jindal and C.K. Pithawa

Electronics Division

and

C.D. Kapse

Watumull Institute of Electronics Engineering & Computer Technology

and

Bhagyashree Sarade

Senior Research Fellow, BRNS Project

Abstract

Non-Invasive Blood Pressure Monitor has been developed at Electronics Division, BARC. It comprises of an Oscillometric, Impedance Plethysmographic (IPG), Photo Plethysmographic (PPG) and Electrocardiographic (ECG) modules. Oscillometric module facilitates spot or periodic measurement of blood pressure whereas other modules yield various hemodynamic parameters to obtain beat to beat blood pressure. Linear multivariate equations have been used for this purpose, which have been derived from IPG, PPG and ECG data in 137 subjects aging 10-80 years. Revalidation of these equations has been done in another group of 136 subjects and has yielded a correlation of 82.6% for Systolic Blood Pressure (SBP) and 73.1% for Mean Arterial Pressure (MAP).

Introduction

Blood Pressure (BP) monitoring is important for the management of cardiovascular diseases. The BP of an individual can vary by tens of millimeters of mercury during 24 hours depending on number of factors that include subject's physical activity, mental state, use of medications and condition of internal BP regulatory system.

Continuous and non-invasive arterial BP measurement is desirable for patient monitoring in Intensive Care Units (ICU). It is also desirable for 24 hour ambulatory monitoring; telemedicine; and study on blood pressure variability. Continuous arterial pressure along with ECG has been used in Intensive Cardiac Care Units (ICCU) to improve the automatic diagnosis of cardiac arrhythmias.

IPG and PPG signals have been used in the past to derive Systolic Blood Pressure (SBP), Mean Arterial Pressure (MAP) and Diastolic Blood Pressure (DBP). However the studies have not been consistent and for most of the time the correlation values reported are not in the acceptable range. Most of these

investigations have been centered on one or two hemodynamic parameters and few control subjects. Therefore a systematic study was carried out to identify different IPG and PPG parameters that are sensitive to blood pressure values. Subsequently an instrument named "Non-Invasive Blood Pressure Monitor – Beat to Beat" has been developed at ED, BARC, which is discussed here.

The Instrument

The instrument is a versatile hemodynamic monitor comprising a PPG module, an IPG module, an ECG amplifier and an Oscillometric BP module, as shown in Fig. 1. All the signals can be simultaneously acquired and saved in the personal computer.

PPG module comprises a pulse oximeter transducer, current amplifier, photo detector amplifier, sample & hold circuits and amplifier for IR signals. The oximeter transducer has a red light emitter, an infrared (IR) light emitter and a photo sensor, mounted along with the cushion on the inner side. It is energized by the microcontroller through current amplifier. The transmitted photo current is amplified

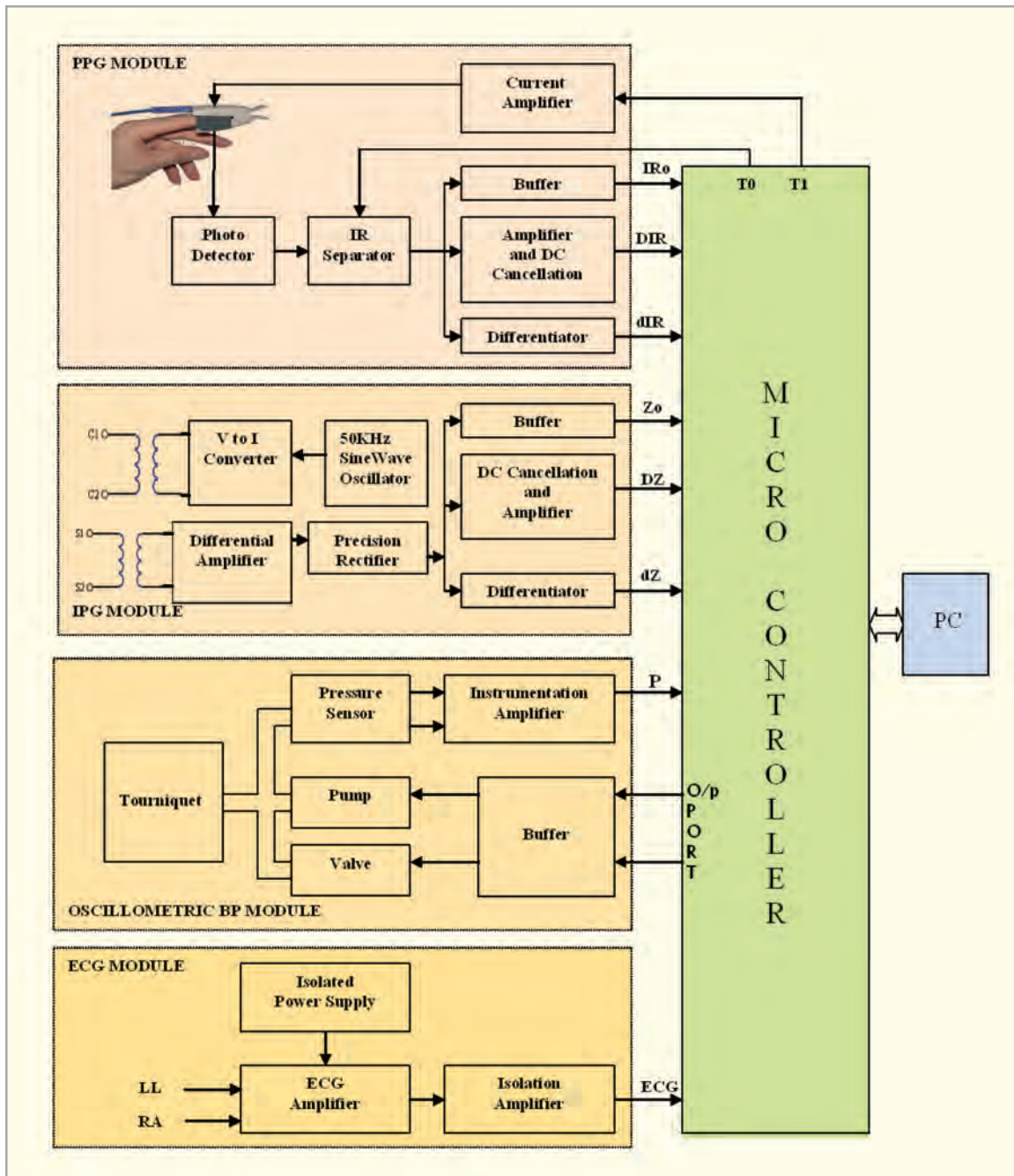


Fig. 1: Schematic block diagram of Non-Invasive Blood Pressure Monitor – Beat to Beat.

and IR signal is separated with the help of timer pulse T_0 . This signal is further processed to obtain average transmitted IR intensity (IR_0), change in transmitted IR intensity as function of time (DIR) and rate of change of transmitted IR intensity (dIR).

IPG module comprises a 50 kHz sine-wave generator followed by voltage to current converter.

This converter outputs sinusoidal current of constant amplitude 2mA at 50 kHz. This current is passed through the body with the help of two silver plated band electrodes called carrier electrodes (C_1, C_2), placed at neck and left palm. Voltage signal developed along the current path is sensed with the help of another pair of electrodes called sensing electrodes (S_1, S_2), placed 4-5 cm apart on left arm

near axillae. This sensed signal is amplified, filtered and rectified to yield an output signal which is proportional to instantaneous impedance (Z) of the left upper arm segment. The initial value of the impedance (Z_0), also known as basal impedance, is obtained from sample and hold circuit. Small changes in the impedance of the upper arm segment caused by blood circulation are obtained by subtracting the initial value of the impedance from the instantaneous impedance and is called the DZ waveform. Z also differentiated with respect to time to get rate of change of impedance waveform called as dZ waveform.

ECG is recorded in Lead II configuration. For this, the electrical potentials generated by the heart muscle are sensed with the help of two silver/silver chloride electrodes; positive electrode on the left leg (LL) and the negative electrode on right arm (RA). These signals are connected to pre-amplifier (powered by isolated supply) through protection circuit. The pre-amplifier output is connected to base line restoration circuit in feedback loop. This output

is isolated and further amplified to obtain ECG waveform in lead II.

Z_0 , IR_0 , DIR , dIR , DZ , dZ and ECG signals are interfaced to personal computer using a microcontroller (MSP430 FG4618). Each signal is sampled at 500 Hz frequency. Graphical user interface (GUI) has been developed to save, load and display all waveforms on a single panel as shown in Figure 2. This GUI also has cursor positioning facility to display sample number and its corresponding amplitude in every waveform.

Working Methodology

With the subject in supine, after a rest of 10-15 minutes, Oscillometric BP and Plethysmographic signals were recorded with the help of developed instrument. SBP, MAP and DBP values were measured with help of Oscillometric module. Three sets of readings were taken and two having minimum difference were averaged to yield the reference SBP, MAP and DBP values. Subsequently ECG electrodes were applied at left leg and right

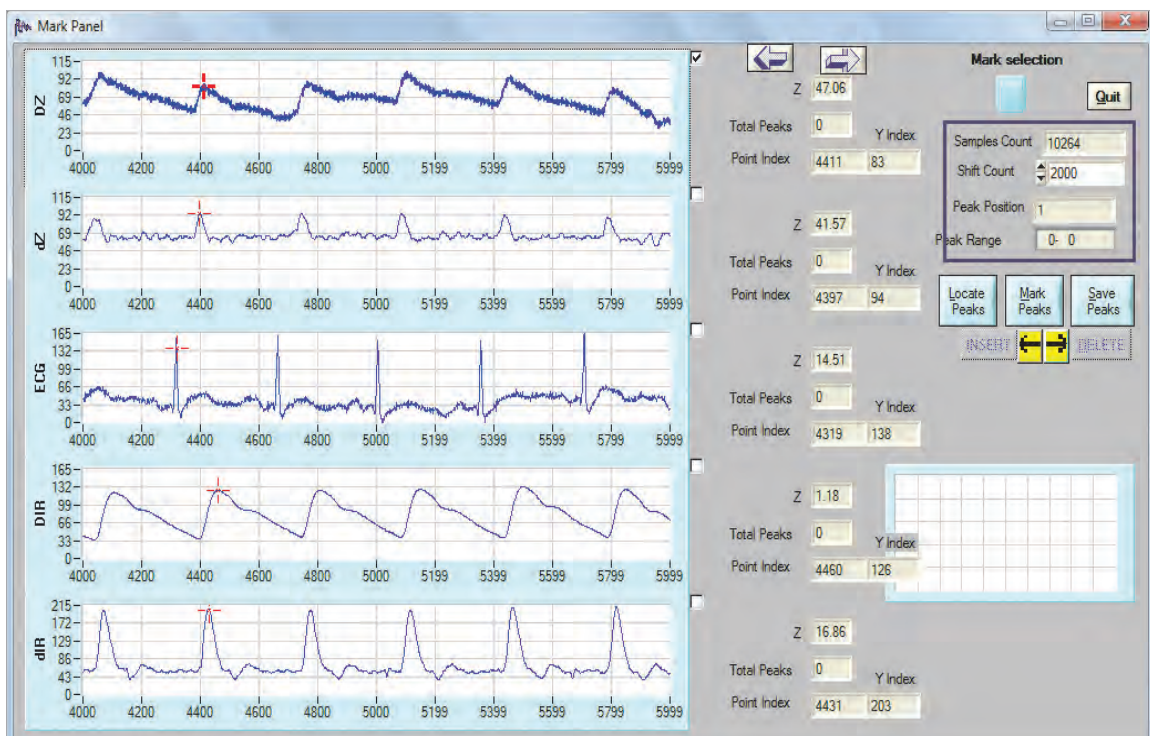


Fig. 2: Display showing simultaneously acquired signals using the developed instrument.

arm; carrier electrodes (C_1, C_2) for IPG were applied at neck and left palm; sensing electrodes (S_1, S_2) for IPG were applied 4-5 cm apart at the left upper arm segment near the axillae; the PPG probe (in the form



Fig. 3: Data acquisition using Beat-to-Beat NIBP Monitor

of clip) was put on the left index finger, as shown in Fig. 3.

PPG, IPG and ECG were acquired simultaneously at a sampling rate of 500sps for a period of 50-60 seconds and saved. The study has been carried out in two phases: -

- Phase-I: 137 Indian subjects (94 men and 43 women), in the age group of 10-80 years, including those with hypertension, were randomly selected and were referred as Group-I subjects. Data obtained from IPG, PPG and ECG in Group-I subjects were used for development of prediction equations for SBP and MAP
- Phase-II: 136 Indian subjects (84 men and 52 women) were randomly selected and were referred as Group-II subjects. Observations were used to validate the prediction equations developed during Phase-I study in Group-II subjects.

Since, the study has been exploratory, large number of parameters (given in Table 1) have been derived from PPG, IPG and ECG data of four consecutive cardiac cycles and averaged. This data along with reference blood pressure values in Group-I subjects have been used to obtain the prediction equations.

Statistical analysis has been carried out to obtain descriptive statistics regarding weight (W), age, gender, SBP and MAP in all subjects. The values of 27 predictors (given in Table 1) in Group-I subjects were used to obtain prediction equations.

Stepwise multiple regression analysis has been adopted to develop subject insensitive prediction equations for SBP and

MAP from various predictors in recorded waveforms and individual information of Group-I subjects. W, T, G and AG20 (age ≥ 20) have been kept compulsory predictors in each model for the following reasons: -

- a) BP is gender and weight sensitive [London et al. 1995] and
- b) Subjects under antihypertensive treatment and those aging < 20 years record different morphology of PPG/IPG waveforms.

Optimum model was selected on the basis of minimum value of root mean square errors (RMSE, indicator of SD of error), higher overall correlation coefficient (r) and physiological relevance. The prediction equations obtained for SBP and MAP as above have subsequently been validated on Group-II subjects. Results in Group-II subjects are expressed in terms of correlation coefficient between reference and estimated BP; mean error \pm standard deviation of error; agreement between reference and estimated BP with the help of Bland and Altman plots [Bland and Altman, 1986].

Table 1: Predictors used for stepwise multiple regression analysis on Group-I subjects.

Signals	Predictor	Description
PPG	DIR(t_1)	Rise time of DIR
	DIR(t_2)	Fall time of DIR
	A	Amplitude of DIR pulse
	A/IR_0	Normalized amplitude
	DIR_dIR(p-p)	Time interval between peak of DIR and peak of dIR
	dIR_DIR(p-f)	Time interval between peak of dIR and foot of DIR
	$1/DIR(t_1 + t_2)$	Inverse of total time duration of DIR
IPG	DZ(t_1)	Rise time of DZ
	DZ(t_2)	Fall time of DZ
	AZ	Amplitude of DZ pulse
	AZ/Z_0	Normalized amplitude
PPG-IPG	DIR_DZ (p-p)	Time interval between peak of DIR and peak of DZ
	$L/DIR_DZ(p-p)$	Pulse Wave Velocity (m/s) measured from peak to peak
	DIR_DZ(f-f)	Time interval between foot of DIR and foot of DZ
	$L/DIR_DZ(f-f)$	Pulse Wave Velocity (m/s) measured from foot to foot
	dIR_dZ	Time interval between peak of dIR and peak of dZ
L/dIR_dZ	Pulse Wave Velocity (m/s) measured from dIR and dz	
PPG-ECG	DIR(p)_R _{ecg}	Time interval between peak of DIR and R of ECG
	DIR(f)_R _{ecg}	Time interval between foot of DIR and R of ECG
	dIR(p)_R _{ecg}	Time interval between peak of dIR and R of ECG
IPG-ECG	DZ(p)_R _{ecg}	Time interval between peak of DZ and R of ECG
	DZ(f)_R _{ecg}	Time interval between foot of DZ and R of ECG
	dZ(p)_R _{ecg}	Time interval between peak of dZ and R of ECG
Others	T	Under hypertensive treatment
	G	Gender
	W	Weight (kg)
	AG20	Age \geq 20 years

Results

Descriptive statistics of all the subjects employed in phase-I and phase-II are shown in table 2, SBP and MAP indicated in Table 2 are reference readings obtained by oscillometric method. Prediction equations developed in phase-I for SBP and MAP from Group-I subjects are presented in Table 3.

Predicted SBP and MAP have shown satisfactory correlations with reference measurements ($r = 0.88$, $RMSE = 6.98$, $mean\ error \pm standard\ deviation\ of\ error = 0 \pm 6.77$ mm Hg for SBP; and $r = 0.797$, $RMSE = 7.09$, $mean\ error \pm standard\ deviation\ of\ error = 0 \pm 6.88$ mm Hg for MAP).

Table 2: Descriptive statistics of all subjects included in the study for developing prediction equations (Phase-I, n= 137) and revalidation (Phase-II, n = 136)

	n	age(years)	W(kg)	SBP(mm Hg)	MAP(mm Hg)
Group-I					
Male	94	36.81 ± 13.74	65.36 ± 16.89	122.9 ± 15.62	90.04 ± 12.4
Female	43	33.44 ± 11.77	57.37 ± 8.66	116.0 ± 9.38	83.70 ± 7.25
Combined	137	35.75 ± 13.2	62.85 ± 15.23	120.7 ± 14.3	88.05 ± 11.41
Range	137	10-80	27-110*	85-158	63-126
Group-II					
Male	84	36.98 ± 13.39	66.98 ± 12.97	125.3 ± 13.46	90.68 ± 10.47
Female	52	34.12 ± 13.76	55.40 ± 11.10	112.7 ± 11.04	81.29 ± 8.14
Combined	136	35.88 ± 13.55	62.02 ± 13.22	120.5 ± 13.98	87.09 ± 10.65
Range	136	10-80	22-90	88-160	65-113

n = number of subjects; W = weight; SBP = systolic blood pressure; MAP = mean arterial pressure SBP and MAP measured by reference oscillometric method. Groups used for developing the equations (Group-I) and revalidation (Group-II) are totally different; * one of the subject was having weight of 150 kg.

Table 3: Prediction equations for SBP and MAP (Phase-I, n = 137)

<p>SBP = 116 + (17.3 × 'T' ; = 1 subject on antihypertensive treatment, else = 0) + (1.4 × 'G' ; male = 1, female = 0) + (0.497 × 'W') - (130 × 'DIR(t₁)') + (8 × 'DIR_DZ(f-f)') - (365 × 'dir_DIR(p-f)') + (10.8 × 'AG20' ; = 1 age ≥ 20 , = 0 age < 20) + (1.03 × ('L' / 'DIR_DZ(f-f)'))</p> <p>SBP measured by oscillometric system = 120.7 ± 14.3 mm Hg.</p> <p>SBP predicted = 120.7 ± 12.59 mm Hg (r = 0.88, RMSE = 6.98, mean error ± standard deviation of error = 0 ± 6.77 mm Hg).</p>
<p>MAP = 37.9 + (8.62 × 'T') + (3.83 × 'G') + (0.411 × 'W') - (237 × 'dir_dZ(p-p)') + (14.1 × 1/ 'DIR(t₁ + t₂)') + (8.33 × 'AG20') - (0.445 × ('L' / 'dir_dZ(p-p)')) + (133 × 'DIR(f)R_{ecg}')</p> <p>MAP measured by oscillometric system = 88.05 ± 11.41 mm Hg.</p> <p>MAP predicted = 88.05 ± 9.095 mm Hg (r = 0.797, RMSE = 7.09, mean error ± standard deviation of error = 0 ± 6.88 mm Hg).</p>

Phase-I is development of prediction equations.

Table 4: Comparison of SBP/MAP measured by reference method and estimated by developed equations in Group-II (Phase-II, n= 136)

	Measured by oscillometric method	Predicted by developed equation	r	Mean error ± SD of error(mm Hg)
SBP (mm Hg)	120.50 ± 13.98	120.03 ± 12.44	0.826 P < 0.001	-0.47 ± 7.93
MAP (mm Hg)	87.09 ± 10.65	87.28 ± 8.578	0.731 P < 0.001	0.1946 ± 7.3

Phase-II is revalidation of developed equations in phase-I.

These prediction equations have been used to estimate SBP and MAP in Group-II subjects. Table 4 shows the descriptive statistics for these measurements. As can be seen from the Table 4 that estimated SBP and MAP have moderately correlated with reference measurements ($r=0.826$, *mean error \pm standard deviation of error* = -0.47 ± 7.93 mm Hg for SBP; and $r=0.731$, *mean error \pm standard deviation of error* = 0.19 ± 7.3 mm Hg for MAP).

Discussions

The studies carried out hitherto have been centered around single parameter derived from ECG and plethysmographic signals on limited number of subjects. The present study is aimed at improving the correlation by including additional parameters on a wider population. In the study of Ye et al., 2010, though the number of subjects is not specified, the correlation of systolic pressure is shown to be 0.8126 in the range of 100-137 mm Hg [Ye et al., 2010]. In comparison present study gives a correlation of 0.826 for systolic pressure ranging between 88-160 mm Hg on 136 subjects aging 10 to 80 years, which is certainly better than the previous attempts.

Thus it appears that plethysmographic parameters that are complementing pulse wave velocity increase the accuracy of SBP and MAP measurement. The predicted results are within the error limits prescribed by Association for the Advancement of Medical Instruments (AAMI) [O'Brien et al., 2002]. According to the AAMI standard, mean error i.e. bias should be $\leq \pm 5$ mm Hg with $SD \leq 8$ mm Hg [37]. The results of this study show that predicted SBP and MAP during validation phase satisfy the AAMI recommendations [SBP (-0.47 ± 7.93) and MAP (0.19 ± 7.3)]. Efforts are being made to obtain better DBP estimation.

Acknowledgements

The authors are thankful to Shri G. P. Srivastava, Director, E & I Group, BARC and Shri R. K. Patil,

Associate Director (C), E & I Group, BARC; for inspiring us to undertake this development work. The authors also acknowledge the help provided by Smt Gouri V. Sawant and Shri. Ashok D. Kamble during the development and data acquisition.

References

1. Allen J. and Murray A. (2002), "Age- related Changes in Peripheral Pulse Timing Characteristics at the Ears, Fingers and Toes", *Journal of Human Hypertension*, vol. 16, pp. 711-717.
2. London G.M., Gurein A.P., Pannier A., Marchais S.J., Stimpel M. (1995), "Influence of Sex on arterial Hemodynamics and Blood Pressure, Role of Body Height", *Hypertension, American Heart Association, Inc.* vol. 26, pp. 514-519.
3. O'Brien E., Pickering T., Asmar R., Myers M., Parati G., Staessen J., Mengden T., Imai Y., Waeber B. and Palatini P. (2002), "Working Group on Blood Pressure Monitoring of the European Society of Hypertension International Protocol for validation of blood pressure measuring devices in adults", *Blood Pressure Monitoring*, vol. 7, no.1, pp. 3-17.
4. Park M., Kang H., Huh Y., Kim K.C. (2006), "Cuffless and Noninvasive Tonometry Mean Arterial pressure Measurement by Physiological Characteristics and Applied Pressure" *28th IEEE EMBS Annual International Conference, USA*, Aug 30- Sep 3, pp. 6418-6421.
5. Webster J. G., Editor (2008), "Medical Instrumentation, Applications and Design" 3rd Edition, *Wiley India*, pp. 317-328.
6. Ye S.Y., Kim G.R., Jung D.K., Baik S W, and Jeon G.R. (2010), "Estimation of Systolic and Diastolic Pressure using the Pulse Transit Time" *World Academy of Science, Engineering and Technology*, vol. 67, pp. 726-731.