Increasing observer objectivity with audio-visual technology: the Sphygmocorder

Neil Atkins, Eoin O'Brien, Karel H. Wesseling* and Ilja Guelen*

The most fallible component of blood pressure measurement is the human observer. The traditional technique of measuring blood pressure does not allow the result of the measurement to be checked by independent observers, thereby leaving the method open to bias. In the Sphygmocorder, several components used to measure blood pressure have been combined innovatively with audio-visual recording technology to produce a system consisting of a mercury sphygmomanometer, an occluding cuff, an automatic inflation–deflation source, a stethoscope, a microphone capable of detecting Korotkoff sounds, a camcorder and a display screen. The accuracy of the Sphygmocorder against the trained human observer has been confirmed previously using the protocol of the British Hypertension Society and in this article the updated system incorporating a number of innovations is described.

Blood Pressure Monitoring 1997, 2:269–272

Keywords: Sphygmocorder, blood pressure measurement, observers, validation, British Hypertension Society protocol

From the Blood Pressure Unit, Beaumont Hospital, Dublin 9, Ireland and *TNO Biomedical Instrumentation, Academic Medical Centre, Suite K2-228, Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands.

Sponsorship: Support from the Charitable Infirmary Charitable Trust, the Royal College of Surgeons in Ireland and Beaumont Hospital is acknowledged with gratitude.

Requests for reprints to Professor E. O'Brien, The Blood Pressure Unit, Beaumont Hospital, Dublin 9, Ireland.

Received 18 September 1997 **Accepted** 23 September 1997

Introduction

Developments in engineering and computer technology have led to the manufacture of an array of automated blood pressure measuring devices [1,2]. The British Hypertension Society (BHS) [3] and the Association for the Advancement of Medical Instrumentation (AAMI) [4] have clearly stipulated that such devices must be subjected to independent validation. Several automated devices have been subjected to the testing requirements of the BHS and Association for the Advancement of Medical Instrumentation (AAMI) protocols [5]. One of the major difficulties with such validation procedures has been training observers to achieve a high degree of accuracy and then to maintain that accuracy throughout the study [6]. A need has been recognised, therefore, for a technique to measure blood pressure in validation studies that would not be dependent on observers, but which would, nonetheless, retain the traditional auscultatory methodology with the mercury sphygmomanometer. The Sphygmocorder was developed for this purpose and, since it was first described in 1995 [7], a number of improvements to the system have been made. These are described in this article.

Component description

The Sphygmocorder consists of the components listed in Table 1 and shown diagramatically in Figure 1.

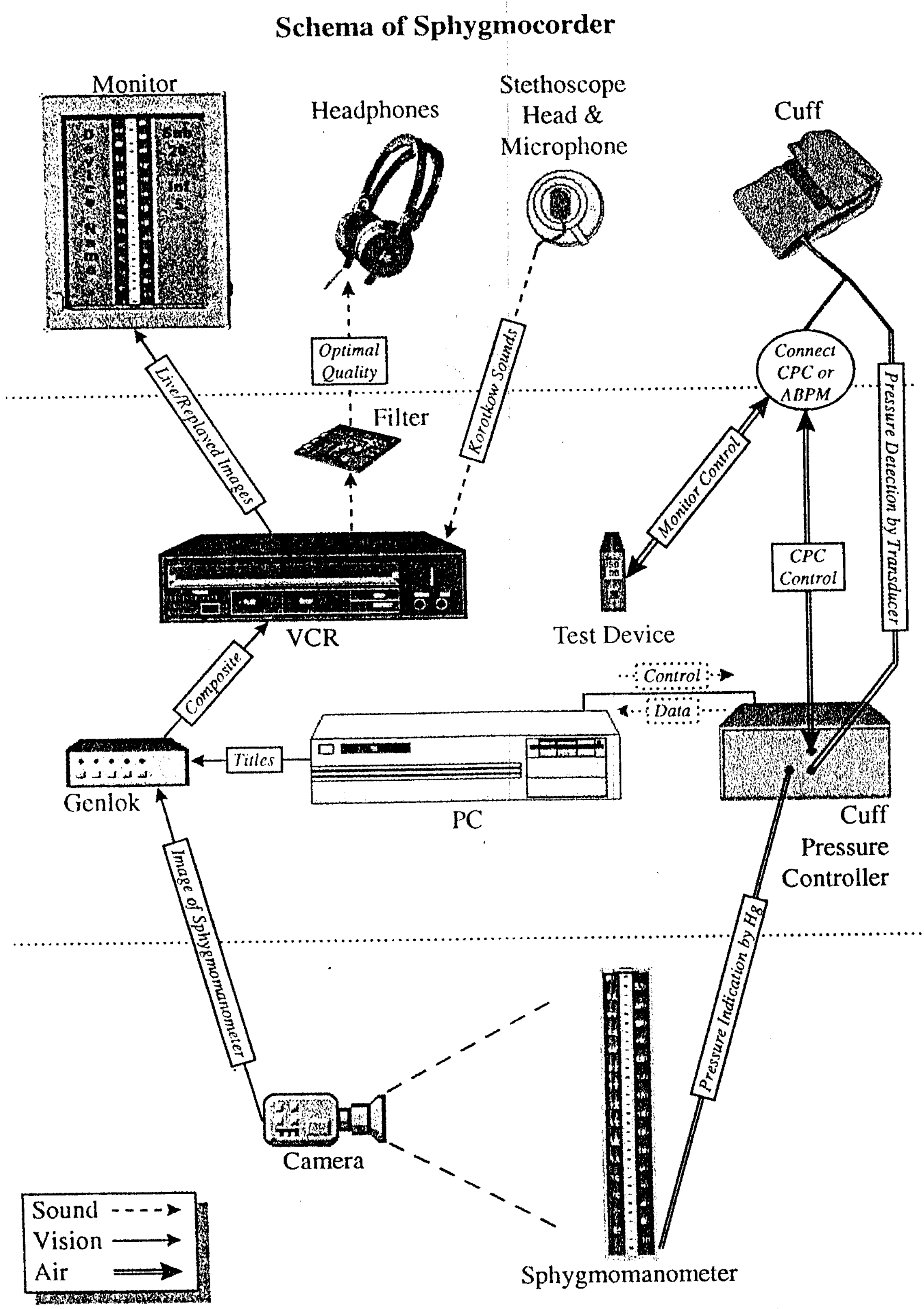
Automated inflation–deflation system

The incorporation of an automated inflation–deflation system is one of the unique features of the modified Sphygmocorder. This system automates upper-arm cuff inflation and deflation. Inflation can be pre-set to a selected pressure level and deflation can be pre-set to a selected deflation rate. The system is controlled by software running on a PC. Manual interruption is possible at all times. Each measurement cycle is stored on computer hard disc. Cuff pressure is read by a semiconductor pressure gauge that is automatically zeroed before each inflation–deflation cycle. An air outlet is available for connection to a standard manometer to calibrate the sensitivity of the built-in pressure gauge.

Inflation

Cuff inflation from a pressurized air chamber is always completed within 5 s, even at the maximum inflation pressure of 330 mmHg with the largest (thigh) cuff. Inflation is computer controlled to be to a pre-set pressure level. At a pre-set inflation pressure of 200 mmHg, overshoot is less than 5 mmHg for cuffs of the largest to the smallest

Fig. 1



The Sphygmocorder.

Table 1 Components of the Sphygmocorder

Item	Type	Brand	Model
Sphygmomanometer	Mercury	PyMaH	Trimline
Inflation pump	Cuff-pressure controller	TNO Biomedical Instrumentation	
Headphone	Full size	Wharfedale	WH303
Stethoscope head	Diaphragm only	Littman	
Microphone (power supply)	miniature	Schure (Schure)	WL93T (PS1A)
Camera	High-resolution colour CCD with F1.4 12 mm television lens	Sanyo	VCC-2972
Television	Colour video monitor	Sanyo	VMC 7514P
VCR	S-VHS	Mitsubishi	HS-M1000(B)

CCD, charge-coupled device; VCR, videocassette recorder.

adult size; overshoot remains within 15 mmHg even with the smallest infant cuff. After inflation it is possible to program a period of controlled steady pressure for 0–10 s at the pre-set inflation pressure.

Deflation

A primary deflation rate can be pre-set at a value in the range 1–10 mmHg/s, a range wider than that recommended by any standards committee. A secondary deflation rate can be pre-set in the range 1–20 mmHg/s, thereby facilitating more rapid deflation between systolic and diastolic end-points. Deflation rates are activated by depressing and holding a key. Cuff deflation is controlled by a servo system and occurs according to an ideal pressure down-ramp to within 2 mmHg to a cuff pressure of 30 mmHg. Cuff pressure is sampled at 200 Hz with a resolution of 0.125 mmHg.

Final rapid deflation

Rapid deflation at the end of an inflation–deflation cycle is initiated by key depression by an operator, after which rapid deflation can be programmed to occur according to one of three pre-selectable courses: immediate deflation, deflation to begin when cuff pressure has been deflated a further pre-set amount and deflation to begin when a certain pre-set time has elapsed from the instant of key depression.

Hardware

The system contains the following components: an air pump and chamber, various electromechanical on/off valves, a proportional air pressure control valve, an electronic power supply, driver electronics and interfaces, an embedded microcomputer, a connector to the air supply, a connector to the pressure transducer, a connector to an external manometer, two BNC input connectors to display and store externally applied signals and an RS232 serial interface connector to a personal computer.

Human interface

The inflation pump is controlled by a special graphics based DOS program. It allows pre-selection of the various levels and rates from menus, the reading of the device and process status, the monitoring of cuff pressure and the display of another signal such as that from a peripheral pulsation sensor. Cuff pressure can be read from an on-screen simulated parallax-free mercury manometer. The simulated mercury column also displays the oscillations in cuff pressure which occur predominantly when cuff pressure is between systolic and diastolic blood pressures. In a small screen box beside the simulated mercury meniscus, moving simultaneously with it, actual cuff pressure is displayed in mmHg. This facility can be linked to a stethoscope, thus allowing measurement of the Riva Rocci/Korotkoff blood pressure in the usual manner, but further testing and validation of this modality is required.

Programmable protocols

Fixed inflation–deflation protocols can be programmed to be run fully automatically.

Validation of the Sphygmocorder

The Sphygmocorder was validated in three separate experiments in which three devices were being validated against two trained observers with 85 subjects with a wide range of blood pressure according to the BHS protocol [7]. The Sphygmocorder was as accurate as at least one of the two observers used in each of these experiments.

Discussion

In previous validation studies various strategies have been employed to overcome observer error. By using the BHS video combined with direct instruction we have been able to bring all paired nurse observer measurements within 5 mmHg of each other for both systolic and diastolic blood pressures [7]. However, whereas it is possible to bring observers to a high degree of accuracy for research work, the procedure of training is time consuming and expensive. Moreover, observers may lose accuracy with time and require re-training [8].

Semi-automated and automated devices have the potential advantage of eliminating errors of interpretation together with observer bias and terminal digit preference. However, this apparent advance has to be balanced against the considerable inaccuracy of most such devices

[9,10], especially at higher blood pressure levels [11,12]. It will be some time, therefore, before automated devices can be substituted for the traditional standard, namely, an accurate observer using a standard mercury sphygmomanometer and stethoscope.

The Sphygmocorder, in its original form [7], innovatively combined technology that had been available for some time by providing the facility for storing recorded data while preserving the time-honoured technique of blood pressure measurement with the mercury sphygmomanometer by an auscultating observer. Other advantages of the Sphygmocorder were the ability to review stored data at leisure; the facility for a number of expert observers to observe the recorded data, thereby eliminating bias and terminal digit preference from the measurement process; the removal of unsatisfactory recordings, such as those with weak Korotkoff sounds, which are so often a source of doubt and error in purely live auscultation; and the elimination of observer inattention or loss of concentration, which so often had necessitated the unnecessary recruitment of additional subjects.

Several improvements to the Sphygmocorder have been made, the most important of which has been the incorporation of an automatic inflation–deflation system that guarantees a constant inflation and deflation rate. This system, developed at TNO Biomedical Instrumentation in Amsterdam, allows the computer-controlled inflation and deflation of upper-arm cuffs of various dimensions. The deflation rate can be set within wide limits and the entire process can be controlled and monitored by a computer in the Sphygmocorder. By eliminating manual deflation, human variability and bias in the deflation are removed and the reference standard has been made even more objective.

References

1 Ng K-G, Small CF: **Survey of automated noninvasive blood pressure monitors.** *J Clin Engineering* 1994, **19**:452–475.

2 O'Brien E, Atkins N, Staessen J: **State of the market: a review of ambulatory blood pressure monitoring devices.** *Hypertension* 1995, **26**:835–842.

3 O'Brien E, Petrie J, Littler WA, de Swiet M, Padfield ML, Altman D, *et al.*: **The British Hypertension Society Protocol for the evaluation of blood pressure measuring devices.** *J Hypertens* 1993, **11** (suppl 2):S43–S63.

4 *American National Standard: Electronic or Automated Sphygmomanometers.* Arlington, VA: Association for the Advancement of Medical Instrumentation; 1993.

5 O'Brien E, O'Malley K, Atkins N, Mee F: **A review of validation procedures for blood pressure measuring devices.** In *Ambulatory Blood Pressure.* Edited by Waeber B, O'Brien E, O'Malley K, Brunner HR. New York: Raven Press; 1994:1–32.

6 O'Brien E, Mee F, Tan KS, Atkins N, O'Malley K: **Training and assessment of observers for blood pressure measurement.** *J Hum Hypertens* 1991, **5**:7–10.

7 O'Brien E, Atkins N, Mee F, Coyle D, Syed S: **A new audio-visual technique for recording blood pressure in research: the Sphygmocorder.** *J Hypertens* 1995, **13**:1734–1737.

8 Mee F, Atkins N, O'Brien E: **Problems associated with observer training in blood pressure measurement.** *J Hum Hypertens* 1994, **8**:293.

9 Labarthe DR, Hawkins CM, Remington RD: **Evaluation of performance of selected devices for measuring blood pressure [abstract].** *Am J Cardiol* 1973, **32**:546–553.

10 O'Brien E, Atkins N, Mee F, O'Malley K: **Inaccuracy of seven population sphygmomanometers for home-measurement of blood pressure.** *J Hypertens* 1990, **8**:621–634.

11 O'Brien E, Mee F, Atkins N, O'Malley K: **Technical aspects of 24-hour ambulatory blood pressure monitoring: comparative accuracy of six ambulatory systems determined by the BHS protocol.** *High Blood Press* 1993, **2** (suppl 1):76–79.

12 O'Brien E, Atkins N, Mee F, O'Malley K: **Comparative accuracy of six ambulatory devices according to blood pressure levels.** *J Hypertens* 1993, **11**:673–675.