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Continuous non-invasive blood pressure monitoring using concentrically interlocking control loops

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Abstract

A new method and apparatus for non-disruptive blood pressure (BP) recording in the finger based on the vascular unloading technique is introduced. The instrument, in contrast to intermittent set point readjustments of the conventional vascular unloading technique, delivers BP without interruptions, thus refining the Peňáz' principle. The method is based on concentrically interlocking control loops for correct long-term tracing of finger BP, including automatic set point adaptation, light control and separate inlet and outlet valves for electro-pneumatic control. Examples of long-term BP recordings at rest and during autonomic function tests illustrate the potential of the new instrument.

Keywords: Non-invasive finger blood pressure; Vascular unloading technique; Intra-arterial pressure; Peňáz' principle

1. Introduction

For generations, researchers and scientists have been engaged with the non-invasive registration of beat-to-beat arterial blood pressure (BP). The basic principle of vascular unloading dates back to Marey in 1878 [1]. In 1942, Wagner introduced a mechanical system for the registration of BP at the A. radialis

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using this principle [2], and in 1973, a method for assessment of non-invasive BP by means of an electro-pneumatic control loop was introduced by Peňáz [3,4]. At that time the Peňáz' principle enabled the first, but only short, recording of non-invasive beat-to-beat BP using only a single control loop. This control loop is responsible for the fast tracking of BP changes as well as for the stability of the system. However, the changes in arterial diameter and wall tension due to vasoconstriction and vasodilatation render long-term measurements with this single control loop almost impossible, since the true unloading of the arterial wall (the so-called "set point") is easily lost. Therefore, the Peňáz' principle has been improved by several groups (see, e.g., [5–20]), but all of them still use one single control loop which necessitates regular interruptions of the BP tracings for set point recalibration purposes. This recalibration is achieved by opening the servo-control feedback loop and performing a pressure ramp in open-loop mode to recover the set point. This process is clearly a disadvantage of the vascular unloading principle because of data loss during the time of recalibration. Despite this short-coming, the vascular unloading technique has been used extensively and successfully for non-invasive measurement of beat-to-beat blood pressure (see, e.g., [21–25]).

The present paper describes a method for continuous non-invasive blood pressure measurement (contBP) which no longer needs "open-loop" recalibration of the set point. The contBP module is part of the Task Force® Monitor (TFM), a commercially available monitoring device combining contBP, beat-to-beat stroke volume measurement by impedance cardiography (ICG) and 4 lead ECG [26–28]. As explained below, contBP is measured on the proximal limb of the index or middle finger by an improved version of the vascular unloading principle using several concentrically interlocking control loops which enhance the accuracy and stability of BP measurement. Each control loop has its own well-defined part within the overall control mechanism: the inner control loops are responsible for fast adjustments and provide near-ideal conditions for the outer control loops which are responsible for the long-term stability of the system.

Due to this new multi-loop control system, truly continuous BP recordings (i.e., without interruptions for recalibration purposes) are possible for the first time. It not only ensures correct long-term BP measurements as will be shown in exemplary comparisons to the Finapres device and simultaneously recorded intra-arterial BP, but also allows the monitoring of beat-to-beat BP during marked rapid changes of blood pressure as observed, e.g., during autonomic function tests. The purpose of the present paper is, therefore, not a systematic comparison with other non-invasive BP recorders or intra-arterial recordings, which will be the content of a second paper, but a description of the technical details of the new method and a short overview of potential applications.

2. Methods

2.1. The Peňáz principle revisited

In principle, the Peňáz method with its single electro-pneumatic control loop (see Fig. 1) works as follows: an extremity of the human body containing an artery (e.g., finger, carpus, temple, etc.) is illuminated with infrared (IR) light. Part of the light is absorbed by the pulsatile blood volume so that the reflected light is an inverse measure of the pulsatile blood volume. Vendrik and Vierhout [29] concluded that a finger is the most suitable place for this method, but the accuracy would be limited due to tissue compressibility and as a consequence by arterial viscoelastic properties.

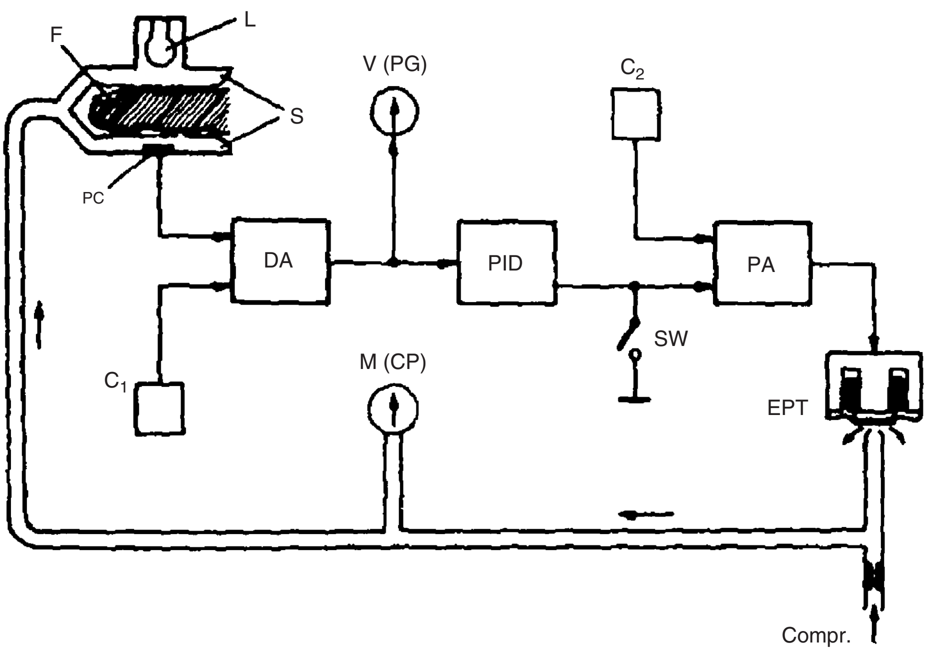

Fig. 1. Block diagram of the system: F, finger; L, lamp; PC, photo cell; S, segments of transparent pressure cuff; C_1, average of PC-signal; DA, difference amplifier; PG, plethysmographic signal; PID, correcting network; C_2, set point SP; SW, switch between open and closed loop; PA, power amplifier; EPT, electro-pneumatic transducer (original drawing from Peňáz, 1973).

As can be seen from Fig. 1, the more blood is contained in the finger arteries, the more IR-light is absorbed and the light to the photo cell (PC) is accordingly reduced. The instantaneous plethysmographic (PG) signal refers to the light signal PC compared to a constant C_1, which in turn represents the average of PC. Therefore, PG is reduced when the blood volume in the finger increases. Subtraction of C_1 from PC is performed by a difference amplifier (DA). PG is fed into a control unit having proportional-integral-differential characteristics (PID). The PID-signal is added to a constant set point (SP or C_2), amplified and fed to an electro-pneumatic transducer (EPT). EPT produces a pressure signal $p_C(t)$ in the cuff, which is applied to the finger illuminated by the IR-light.

The control condition is as follows: PG shall become zero over a period of time, especially over the cardiac cycle due to the pulsatile pressure $p_C(t)$ in the cuff. During systole, when pulsatile blood volume increases in the finger, the PID-controller increases the control point, thus $p_C(t)$ is increased until the excess of blood is removed by external pressure of the cuff. On the other hand, during diastole the blood volume in the finger is decreased, as a result PG increases and thus the PID-controller decreases the control point. Hence $p_C(t)$ is lowered and the overall blood volume remains constant. As blood volume and thus PG is held constant over time, the pressure difference between cuff pressure $p_C(t)$ and intra-arterial pressure $p_A(t)$—the transmural pressure $p_T(t)$—is zero (see Eq. (1)).

$$p_T(t) = p_C(t) - p_A(t) = 0 \Rightarrow p_C(t) = p_A(t). \tag{1}$$

Since intra-arterial pressure $p_A(t)$ is equal to cuff pressure $p_C(t)$, which can easily be measured by means of a manometer M, intra-arterial pressure $p_A(t)$ can be measured indirectly using the vascular unloading technique.

2.2. Difficulties of the Peňáz control loop

In the above description of the Peňáz principle, the electro-pneumatic control loop is in “closed-loop” operation; i.e., the switch SW does not ground the output of the PID-circuit. The control loop can be opened by closing SW and therefore grounding the control point of the PID-circuit, which is then not added to SP. The pressure in the cuff thus depends only on SP. In this “open-loop” operation, the optimal SP can be determined. According to Peňáz et al. [4], the optimal SP represents the mean arterial blood pressure, where the pulsations of PG are a maximum. Wesseling et al. regularly open the vascular unloading control loop in order to readjust SP from time to time in their Finapres, Portapres and Finometer devices (see e.g. [9,30]).

In closed-loop operation the vascular unloading technique represents a real challenge in terms of control engineering. The following independent systems, each with their own specific disturbance variables, can be identified:

- *Blood volume*: the pulsatile blood volume, caused by the cardiac cycle, is the typical disturbance variable of the Peňáz’ principle, which shall be controlled and set to zero by the cuff pressure.
- *Vessel tone*: the vessel tone of the finger artery changes permanently due to vasoconstriction and vasodilatation. This physiological function is controlled by the autonomic nervous system by means of the smooth muscle cells located in the wall of the arterial vessel. As a consequence, the diameter of the vessel and therefore the blood volume in the finger changes continuously, so that the initial vascular unloading condition is lost during physiological changes of autonomic control. This probably represents the greatest challenge to be solved by the vascular unloading control system.
- *Average of PC*: C_1, the average of the PC signal, is not constant over a long period of time as a consequence of the constant pressure applied to the finger which leads to fluid, volume and thus to reflectance changes; this also affects the mean PG signal and—via PID and EPT—the mean cuff pressure.
- *Cuff pump*: the pump pressure and the leakage of the valve are variable and depend on the current pressure in the system, thus making the system highly non-linear.
- *Cuff*: the transmission of the pressure from the cuff pressure chamber to the artery is also not—as commonly assumed—linear due to varying tissue properties at different pressure levels.
- *Light*: surrounding light might disturb the signal PC in an unpredictable way.
- *Instrument components*: influences due to aging, temperature and changing tolerances of mechanical and electronic components must be automatically eliminated.

These disturbances render it almost impossible, even with an optimal SP detected in open-loop operation, to establish stable long-term recordings (i.e., $t > 30$ s, especially in the beginning of measurement) of non-invasive BP with the original Peňáz principle (see also [7]).

2.3. Current improvements of the vascular unloading technique

2.3.1. Simultaneous use of several concentrically interlocking control loops

In contrast to other available devices based on vascular unloading, the basic principle of the TFM hardware and software is the simultaneous use of several interlocking control loops. Each loop is controlled separately by a fast operating micro-controller which allows the contBP module of the TFM to avoid

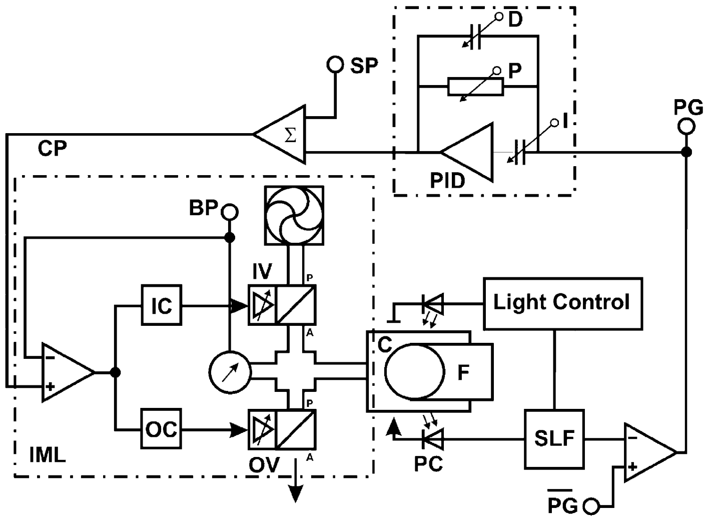

Fig. 2. Schematic overview of TFM's inner control loops. F, finger; C, cuff; PC, photo cell; SLF, surrounding light filter; PG, plethysmographic signal; $\overline{\text{PG}}$, average PG-signal; PID, proportional-integral-differential controller; P, proportional tuning; I, integral tuning; D, differential tuning; SP, set point; CP, control point; IC, inlet valve controller; IV, inlet valve; OC, outlet valve controller; OV, outlet valve; BP, blood pressure signal; IML, inner-most loop.

interruptions of the continuous BP recording even over prolonged periods of time. Each control loop is responsible for a well-defined characteristic of the overall control mechanism. The interlocking control loops are arranged concentrically: the inner-most control loops are designed to provide near-ideal conditions for the intermediate control loops which in turn provide near-ideal conditions for the outer-most control loops. The inner-most control loops are responsible for fast operations (i.e., fast pressure build-up, fast pressure release, pressure control, light control, surrounding light filter, fast vascular unloading control and high-frequency BP changes) whereas the outer loops control the long-term stability endangered, e.g., by low-frequency BP changes, changes of vascular tone, long-term drifts and changes of oxygen content in the finger induced by the constant pressure applied to the finger.

(Although the system thus allows continuous, uninterrupted measurement for an unlimited period, i.e., even for some hours, it is advisable to regularly change the site of measurement from one finger to another after approx. 30 min to avoid the venous congestion and numbness in the subject's finger known to be characteristic for the vascular unloading technique.)

In the following, details of the improvements of Peňáz' method as implemented in the TFM are given as far as patenting and disclosure regulations allow. As will then be shown in several examples, truly continuous as well as accurate BP recording without the need for interruptions can be achieved with this interlocking control loop system.

2.3.2. Digitally controlled pressure chamber with separate inlet and outlet valves

Fig. 2 shows the most important inner loops of the overall control system: the inner-most loop (IML) is the pressure control loop which is responsible for the fast adjustment of the cuff pressure (BP), with a given control point (CP, set by the outside PID controller) being compared to the electrical equivalent of BP. Subsequently, the loop branches off: (i) towards the inlet valve (IV) with its controller IC and (ii) towards the outlet valve (OV) with its controller OC.

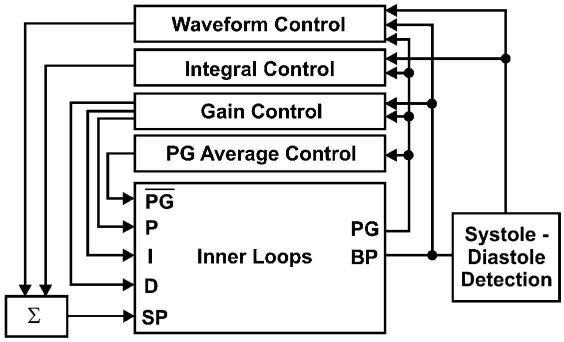

Fig. 3. Block Diagram of TFM's outer control loops. BP, blood pressure signal; PG, plethysmographic signal; $\overline{PG}$, average PG-signal; P, proportional tuning; I, integral tuning; D, differential tuning; SP, set point.

The IML works as follows: if BP is greater than CP then OC opens OV and BP is decreased until it equals CP. On the contrary, if BP is lower than CP then IC opens IV and BP is increased until BP and CP are equal. Because the response time of IML is faster than possible changes of CP, the outer control loop sees an ideal electro-pneumatic transducer where the input CP is equal to the output BP.

2.3.3. Light control

The second important inner control loop is the light control (LC) which produces pulsatile power for the IR-LED for optimal light utilization through the finger: depending on finger size and on how well the finger cuff fits the finger, the LC automatically provides more or less light to keep the reflected light within the desirable range for optimal blood volume detection in the finger. Furthermore, LC provides information to the surrounding light filter (SLF) which removes artifacts due to light changes not due to changes in blood volume, so an undisturbed PG is provided for the outer control loops.

2.3.4. PID controller

The PID control loop surrounds both light and pressure control loops and is implemented as a modified vascular unloading control loop according to the Peňáz principle. The schematic overview in Fig. 2 shows the advantages of the improved method as compared to the original Peňáz method: the inner light and pressure control loops provide ideal light and pressure conditions for the vascular unloading loop which is now exclusively responsible for adjusting PG to zero by changing CP and, therefore, cuff pressure BP.

2.3.5. Additional outer control loops

As can be seen in Fig. 3, the inner control loops provide two output signals to outer controllers: (i) the blood pressure signal BP and (ii) the plethysmographic signal PG. In turn, the proportional (P), integral (I) and differential (D) characteristics of the PID controller as well as the mean PG signal ($\overline{PG}$) and SP are tuned by the outer loops. While the inner loops are responsible for tracing fast changes in mean BP (i.e., $t < 30\,s$) and high-frequency BP changes ($> 0.03\,Hz$) as well as for simultaneously minimizing PG, the additional outer control loops are responsible for stable long-term recordings of BP without interruptions. The following additional loops have been implemented:

- *PG average control*: the next outer control loop is PG average control for monitoring and correcting $\overline{PG}$, which is one of the essential parts for correctly implementing the vascular unloading principle.

- *Gain control*: Gain control tunes P, I and D of the underlying vascular unloading loop by tracking the ratio of BP and PG to assure that the operating point of the PID controller is in the optimal range for reliable measurements. Please note that in contrast to the original work of Peňáz, there is no separation between open and closed-loop operation. Open-loop operation can be performed when P, I and D are set to zero while all other settings close the loop.
- *Systole–diastole detector*: For the outer-most control loops, a systole–diastole detector clips the BP-trace into single pulses and the systolic peak as well as diastolic trough are detected for each beat. Please note that this is performed without the need of an external ECG signal.
- *Integral control*: Integral control calculates the integral of PG from one diastolic trough to the next which, according to the overall control condition, must be zero. In the case of control deviations, integral control accordingly adapts SP and thus re-establishes the control condition. This control loop is an essential feature of the current method since it allows accurate BP measurement without the need for regular disruptive set point adjustments.
- *Waveform control*: Waveform control analyses the BP waveform using fuzzy logic and compares it with previous beats. Since the shape of a pulse depends on the compliance of large and small vessels [31], which is known to change with age but not noticeably in the course of a single BP recording, this shape can be used for the monitoring of changes in vessel tone. Changes in the shape of the pulse wave are caused by vasoconstriction or vasodilatation as well as by changes in cardiac output. BP as well as PG are analyzed by fuzzy rules to change the SP using the following parameters: amplitude of BP and PG, ratio between mean BP and diastolic BP, BP onset and decay, systolic and diastolic time intervals and ratios between these intervals in BP and PG. These subject-specific waveform control rules are automatically created at the beginning of the recording session on a single-beat basis and help ensure long-term stability of the BP recording.

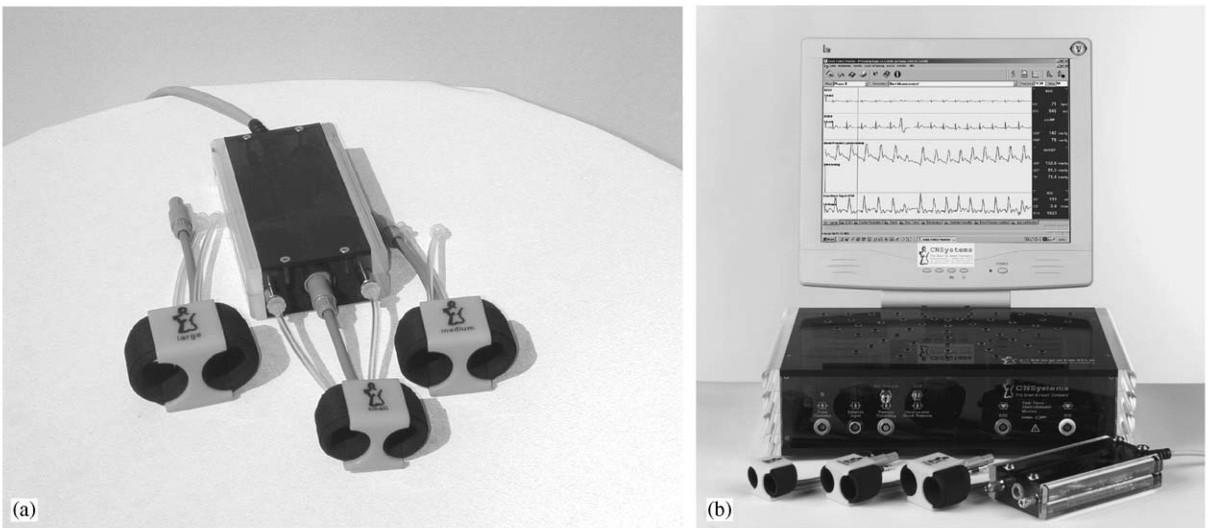

Fig. 4. Individual parts of the BP measurement device of the Task Force® Monitor: (a) finger cuffs (sizes S, M and L) connected to the contBP unit; and (b) finger cuffs (sizes S, M and L) as well as contBP unit in the front and the main device with the computer display in the back.

2.4. Implementation in the Task $Force^{®}$ Monitor

Fig. 4 shows the basic elements of the TFM necessary to measure non-invasive continuous BP: in Fig. 4 (a) one of the finger cuffs which encompass two fingers (usually index and middle finger) is connected to the contBP unit via two air pressure tubes (one controlling the pressure chamber around each finger) as well as one cable returning the sensor information to the contBP unit. This unit contains the fast BP control loops (i.e., control of the pressure chambers, light control and PID controller) implemented in fast hardware components and returns the measurement parameters to the main device seen in the background of Fig. 4(b) which also collects data from other sources (e.g., ECG and ICG). These are passed on to a PC (not shown) running the TFM software where the outer control loops are implemented and the results are displayed on screen (see Fig. 4 (b)).

3. Results

A systematic comparison of the new method with intra-arterial blood pressure is the subject of a separate paper. In the present paper, the high-quality performance of the new instrument for the vascular unloading technique is shown by demonstrating:

(a) Exemplary comparisons with the currently only other commercially available instrument for vascular unloading at the finger, the Finapres device.
(b) Examples of intra-arterial recordings as compared to the present technology of vascular unloading and
(c) the capabilities of the present technology in cases of extreme blood pressure variations during which other available continuous BP monitors usually failed.

3.1. Comparison of TFM's contBP with the Finapres device

The main difference between TFM's contBP and the Finapres device is the fact that contBP continuously delivers BP signals without any interruptions caused by intermittent readjustment of the set point. Beat-to-beat BP measurements of the contBP module were evaluated against the Finapres device in two normal subjects recorded during approx. 5 min rest in the sitting position. Both TFM's contBP and the Finapres device were recorded simultaneously on the same hand but on different fingers. To ensure time synchronization of measurements, TFM's external input was connected to the Finapres device and both signals were recorded simultaneously. Using maxima/minima search routines, systolic and diastolic BP were obtained for each heart beat in both signals.

As can be seen in Figs. 5(a) and (b), showing the systolic and diastolic BP trends for subjects A and B, the recording of the Finapres device was frequently interrupted by its automatic recalibration routine to recover the set point whereas TFM's contBP was able to supply values throughout the whole measurement period. Note the generally good agreement between contBP and Finapres, especially for the diastolic BP trend in subject B. In subject A, there is a marked offset between the two measurement devices.

3.2. Non-invasive finger BP versus intra-arterial BP measurements

The BP changes measured by TFM's non-invasive contBP module were compared with intra-arterial measurements (A-line) in three critically ill surgical patients. ContBP was measured simultaneously with

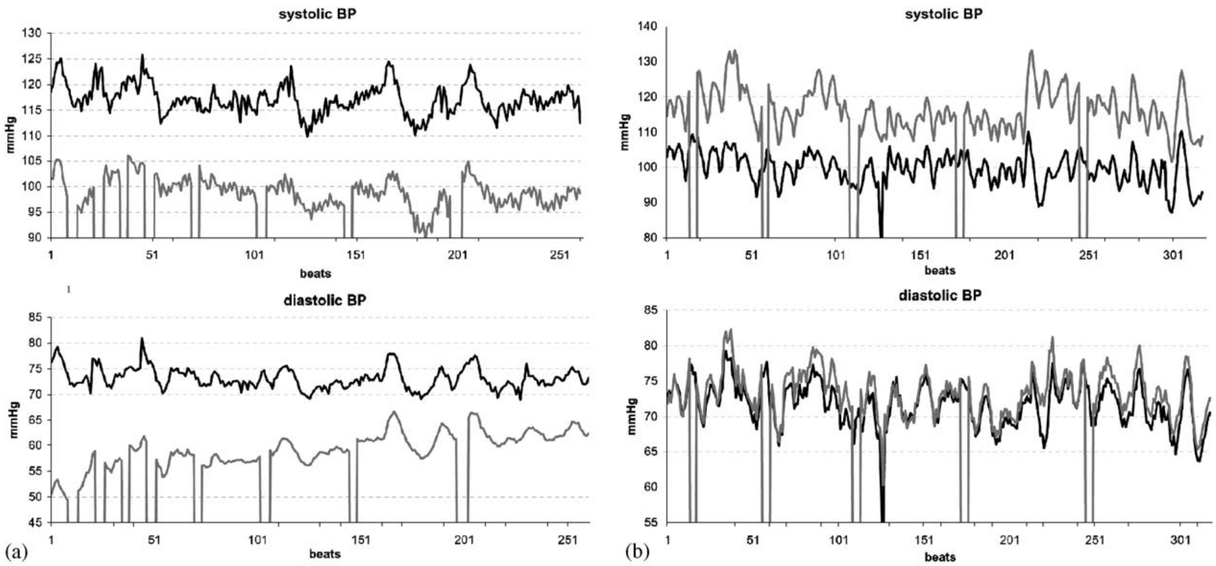

Fig. 5. (a): Beat-to-beat systolic and diastolic blood pressure signals for TFM's contBP module (black line) and the Finapres device (gray line) for (a) normal subject A and (b) for normal subject B. The missing values for the Finapres device indicate times when measurements were not available due to recalibration of the set point.

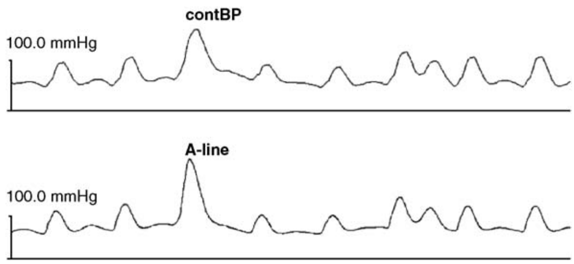

Fig. 6. Waveform comparison of BP changes in a patient with atrial fibrillation with large differences of individual beat-to-beat BP amplitude (contBP, top; A-line, bottom).

A-line (using standard arterial catheters in the A. radialis or A. femoralis, disposable pressure transducers and a standard Siemens Sirecust 1280 patient monitor). For this purpose, the analogue output of the patient monitor was connected to an external input of the TFM so that automatic time synchronization of A-line and contBP was ensured.

3.2.1. Short-term comparison

Fig. 6 shows continuous BP waveforms of a critically ill patient suffering from atrial fibrillation with large differences of individual beat-to-beat BP amplitude. Note the good agreement between the two curves (contBP—upper curve; A-line—lower curve).

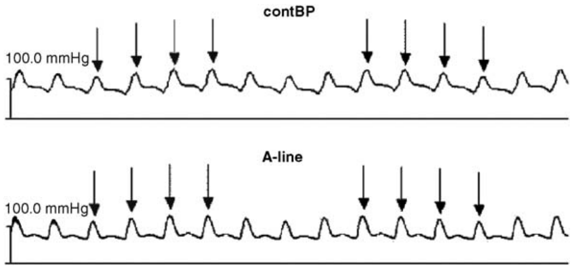

Fig. 7. Waveform comparison in the case of stable BP (contBP, top; A-line, bottom). Gray arrows indicate a rise in BP, black arrows indicate a drop in BP.

Fig. 7 shows an example of stable continuous BP waveforms where the minute physiological beat-to-beat variations of contBP (upper curve) and A-line (lower curve) are also in good agreement. Gray arrows indicate a rise in BP while black arrows indicate a drop in BP: these sequences provide the basis for the automatic analysis of baro-receptor sequences which is also implemented in the TFM [32].

3.2.2. Long-term comparison

Fig. 8 (a) shows a 30 min trend of contBP (upper curve) and A-line (lower curve) with Figs. 8(b) and (c) showing close-ups of data within the first 20 s. Note the good agreement of the encompassing trend in Fig. 8(a) and the subject's Mayer-waves which can be seen distinctly, especially in Fig. 8(b).

BP readings are known to depend on the site of pressure measurement since pressure pulsations are progressively distorted on their way towards the periphery. Therefore, differences between the contBP and A-line measurements are to be expected, especially level shifts and/or pulse amplification or damping [22,33]. Nevertheless, the close-up of Fig. 8(c) shows very satisfactory agreement of the two BP curves.

3.3. Autonomic function test maneuvers

Autonomic function tests such as the Ewing battery [34] are generally accepted for the bedside diagnosis of autonomic disturbances. They are usually evaluated based on the measurement of heart rate intervals as determined by ECG and on intermittent auscultatory or oscillometric BP measurements. In the following, the potential of the new methodology is demonstrated in exemplary fashion in a number of autonomic function tests.

3.3.1. Valsalva maneuver

In the Valsalva maneuver, the patient creates an intra-thoracal and intra-abdominal pressure by expiring against a hydrostatic pressure of 40 mmHg which causes characteristic changes of both blood pressure and heart rate. As can be seen in Fig. 9(a), four phases of the Valsalva maneuver (starting at 10 s and ending at 25 s) can be clearly identified. They are divided into phase (i), which usually lasts approx. 1–2 s, where blood pressure increases and the heart rate decreases due to the stimulation of the baroreceptor of the carotid sinus. In phase (ii) the blood pressure decreases due to reduced cardiac preload and stroke volume (early phase (ii)) before rising again to its initial value (late phase (ii)). Stroke volumes diminish because of a reduced venous return to the heart with a reflex increase in heart rate and in peripheral resistance. Phase (iii) is characterized by a fall in blood pressure and a rise in heart rate directly after the

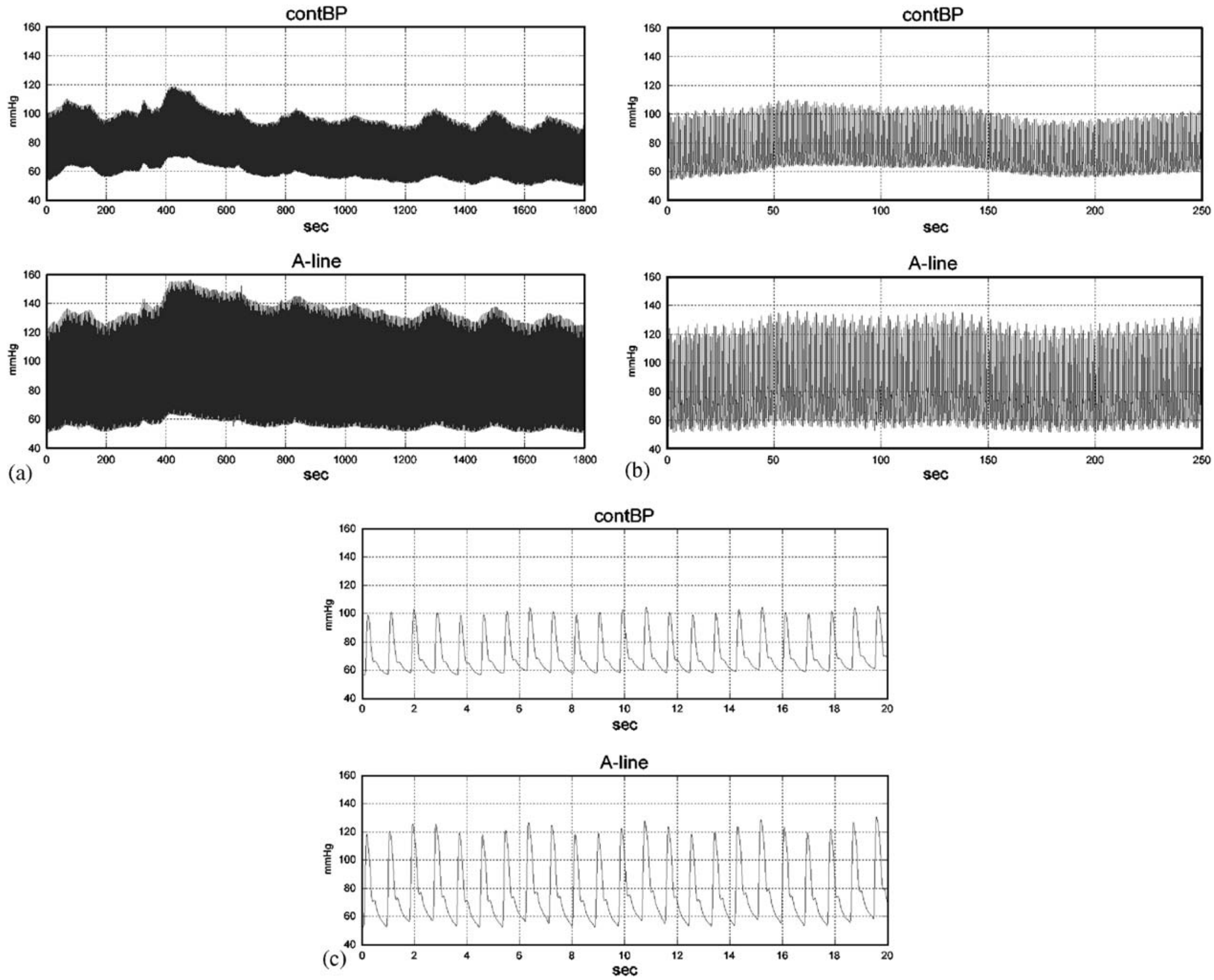

Fig. 8. (a): Waveform comparison of 30 min BP recording (contBP, top; A-line, bottom). (b): Waveform comparison of 4 min 10 s out of the 30 min BP recording shown in (a) (contBP, top; A-line, bottom). (c): Waveform comparison of 20 s out of the 30 min BP recording shown in (a) (contBP, top; A-line, bottom).

end of the Valsalva maneuver. In phase (iv) the blood pressure overshoots its initial value because the venous return to the heart as well as stroke volume normalize while the arterial vessels are still constricted due to sympathetic activation.

Fig. 9(a) shows a Valsalva maneuver in a normal subject where all the above phases can be clearly identified. In contrast, Fig. 9(b) shows a Valsalva maneuver in a patient with pure autonomic failure where the above described distinctive phases of the maneuver are clearly distorted or completely absent.

3.3.2. Deep breathing test

Normally, inspiration is characterized by an increase and expiration conversely by a decrease of heart rate which is mainly due to the changing parasympathetic activity during breathing and is called respiratory

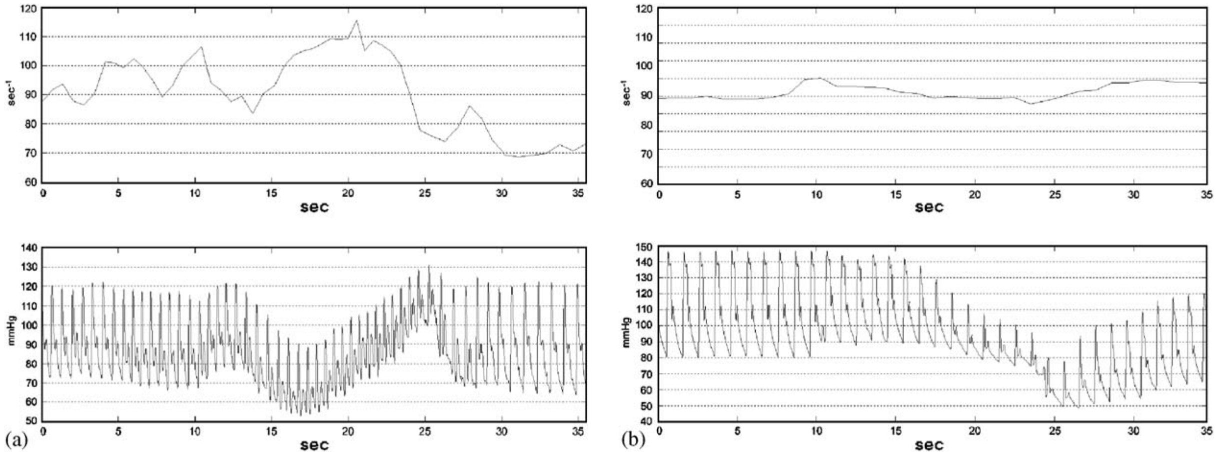

Fig. 9. Valsalva maneuver (starting at 10 and ending at 25 s) (a) of a normal subject and (b) of a patient with pure autonomic failure: the upper curve shows beat-to-beat heart rate while the lower curve depicts non-invasive BP.

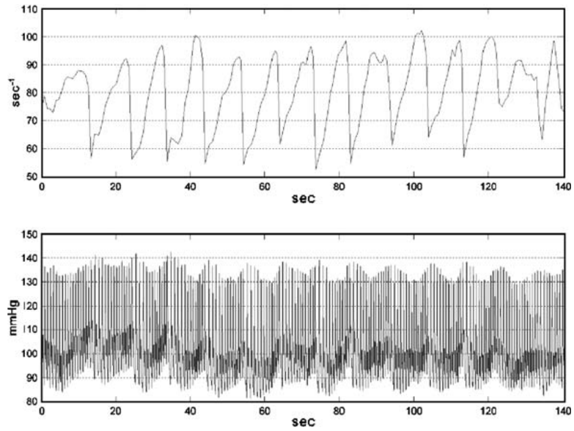

Fig. 10. Deep breathing test in a normal subject: the upper curve shows beat-to-beat heart rate while the lower curve depicts non-invasive BP.

sinus arrhythmia. This respiratory HRV can be maximized by a forced regular breathing synchronous to a metronome set such that both inspiration as well as expiration last for 5 s each, resulting in six deep breaths per minute. The ratio between the longest heart rate interval during expiration and the shortest interval during inspiration is the so-called E/I-ratio of the Ewing test battery [34].

Fig. 10 shows the recording of heart rate and continuous non-invasive blood pressure as measured with the present technology during forced deep breathing in a healthy subject demonstrating the marked rhythmic BP changes induced by the above maneuver.

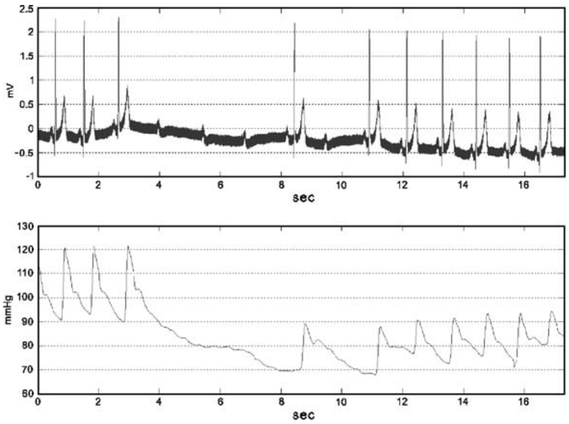

Fig. 11. Carotid sinus massage in a normal subject: the upper curve shows ECG while the lower curve depicts non-invasive BP. Complete AV block with an asystole over 5 s and a concomitant fall of blood pressure of 30 mmHg can be seen.

3.3.3. *Carotid sinus massage*

The massage of the carotid sinus is used to examine the sensitivity of the baroreceptors of the carotid sinus and the intactness of parasympathetic efferences of the corresponding reflex arc. The maneuver is intended to lead to a moderate decrease of heart rate and sometimes also of blood pressure. The following anomalies are considered pathological and characteristic for the diagnosis of carotid sinus syndrome: (i) an asystole of longer than 3 s refers to the cardioinhibitory subtype, (ii) a decrease of systolic blood pressure of greater than 50 mmHg is typed vasodepressor subtype while (iii) an incidence of both (i) and (ii) is called the mixed subtype of carotid sinus syndrome.

Fig. 11 shows an example of a patient where carotid sinus massage results in a total AV block over three heart beats and in a fall of systolic BP of about 30 mmHg.

4. Discussion

As described in the present paper, a number of major improvements of Peňáz's vascular unloading technique for long-term non-invasive BP recordings have been achieved. The use of several interlocking control loops arranged concentrically according to the necessity for speed (inner loops) or long-term optimization (outer loops) for the first time enables truly continuous non-interrupted non-invasive blood pressure measurement over long periods of time. The automatic detection and correction of dispersed light makes the new methodology nearly artifact-free even during motion of the finger (data not shown). The use of microcontroller-adjusted separate inlet and outlet valves allows the changing of the pressure chamber characteristics linearly or non-linearly, as requested, simply by changing the program parameters of the microcontroller. Therefore, a subject-specific optimum of system characteristics can be determined automatically at the start of the recording which allows best possible resolution of blood pressure in any given subject.

The comparisons with the Finapres device and intra-arterial blood pressure using the new method of vascular unloading during rest as well as in the course of autonomic function tests as presented in this paper are very satisfactory. A more detailed study to verify the fidelity of the BP measurements and the agreement with the standards of automated oscillometric sphygmomanometers (ANSI AAMI SP10-1992) is presented in a separate paper.

As can be seen in Figs. 9–11, continuous BP as recorded non-invasively on the finger can give good insight into the BP changes during the Valsalva maneuver, deep breathing test and carotid sinus massage. Up to now, diagnoses via autonomic function tests have been based on heart rate, RR-intervals and intermittent auscultatory or oscillometric blood pressure measurements. The availability of truly continuous non-invasive beat-to-beat BP may now lead to an enhanced sensitivity of these and other autonomic function tests.

As can be seen in Figs. 6 and 7 there is a slight time delay (approx. 20 ms) of contBP in relation to A-line, despite automatic synchronization of the time scale of continuous finger BP and intra-arterial BP recordings. To a large part, this time delay is due to the physiological time delay of the pulse wave between the two locations of BP measurement; to a small part, it is due to the time the contBP pressure controller needs to react to the change in arterial BP. As can be seen in Figs. 6 and 7 there are no marked level shifts, pulse amplification and/or dampening of the new vascular unloading device especially if the amplitude of the intra-arterial and the finger blood pressure curve are adjusted to the same height. Minor differences of the shapes of the blood pressure curves are certainly due to the different locations of measurement [22,33].

The finger arteries belong to the small arteries which are responsible for thermoregulation and therefore are subject to vasodilation and vasoconstriction according to environmental temperature and also according to the volume state of the subject. Therefore, absolute pressure in the finger arteries may or may not correspond exactly to the pressure in the large arteries. For clinical use of the new vascular unloading device it might thus be advantageous to adjust the measured finger blood pressure to the blood pressure measured in a large artery (e.g., measured by a reliable oscillometric BP measurement device on a contra-lateral brachial artery), thus resulting in true arterial BP values as opposed to finger arterial pressure. The potential and limitations of such a procedure will be presented in a second paper.

The presented continuous BP recorder has already been used extensively in clinical routine. Since there is no need for TFM's contBP module to regularly interrupt the recording for readjustment of the set point (as other devices do every minute), BP measurements are not lost when they might be most valuable: this is the case in time-critical situations like rapid BP changes, e.g., induced by the Valsalva maneuver, by vasovagal and other syncopes or after pharmacological interventions with rapidly acting vasoactive drugs.

5. Summary

The present paper describes improvements for continuous non-invasive blood pressure (BP) measurement based on the vascular unloading technique which no longer necessitate "open-loop" calibration readjustment of the set point and is therefore the first method to measure non-disruptive, truly continuous finger BP. The so-called contBP module is part of the Task Force® Monitor (TFM), a commercially available monitoring device combining contBP, beat-to-beat stroke volume measurement by impedance cardiography (ICG) and 4 lead ECG.

BP is measured on the proximal limb of the index or middle finger by an improved version of the vascular unloading principle using several concentrically interlocking control loops. These loops allow for highly accurate and stable BP measurement and include automatic set point adaptation, light

control and separate inlet and outlet valves for fast electro-pneumatic control. Each control loop has its own well-defined part within the overall control mechanism: the inner loops are responsible for faster changes and provide near-ideal conditions for the outer control loops which are responsible for the long-term stability of the overall system. Due to this new control system, truly continuous BP recordings (i.e., without interruptions for recalibration purposes) are possible for the first time.

The presented continuous BP recorder not only compares very well regarding the Finapres device and intra-arterial BP recordings but has also proved useful in clinical routine: since for the new vascular unloading device there is no need to regularly interrupt the recording for readjustment of the set point (as other devices do every minute), BP measurements are not lost when they might be most valuable: e.g., in critical situations like rapid BP changes such as induced by the Valsalva maneuver, by vasovagal and other syncopes or after pharmacological interventions with rapidly acting vasoactive drugs.

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