VALIDATION AND VERIFICATION OF THE *TASK FORCE® MONITOR*

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I. INTRODUCTION

The Task Force® Monitor (TFM) is a newly developed, commercially available monitoring device for the continuous measurement of blood pressure (contBP) by use of the vascular unloading technique [1, 2, 3] and beat-to-beat stroke volume (SV) measurement with impedance cardiography [2, 3, 4, 5] (ICG). ContBP is automatically corrected to oscillometric BP (oscBP) values obtained at the contralateral arm. In addition, a 2-channel ECG is included for R-R interval determination. Furthermore these beat-to-beat values are used for a real-time calculation of heart rate (HR) and BP variability (HRV, BPV) by an autoregressive model [2, 6, 7], which are displayed as 3-dimensional sliding power spectra. Additionally, an automatic evaluation of baroreceptor reflex sensitivity (BRRS) by the sequence method [8] is performed and also displayed on-line. The TFM has passed the tests for the CE-quality mark (CE 0408, TUeV Austria, Vienna)

For FDA 510(k), several test procedures and clinical studies were necessary. In the present paper the methods and protocols of the clinical studies are described and the results are presented. The ICG-unit of the Task Force® Monitor is considered to be substantially equivalent to the BioZ-PC (CardioDynamics, San Diego, CA, USA,) and the contBP of the TFM is considered to be substantially equivalent to the Finapres (Ohmeda, Luiseville CO, USA). Therefore the TFM was compared to the above mentioned devices (Bio Z model No.BZ-410-04 11/98 SNr.: 000581001) and Finapres BP Monitor (Stock no: 6050-0000-130, SNr: FAM 000032).

II. METHODS

ECG - QRS-detection

One core part of the system is the online QRS-detector. Several published [9, 10] detection algorithms were combined and the decision rules were adapted. The resulting algorithm is tested with the MIT-BIH arrhythmia database, which contains "real world" signals with the broadest possible range of waveforms, including ambiguous cases [11]. 42 Short term recordings (½ hour MITDB 101-234) and 7 long term Holter recordings (12-24 hour LTDB 14046-15814) were evaluated. The goal was to achieve an overall failure rate (FR) of less than 2% for QRS-detection (± 30 ms to annotated MIT-beat) and FR < 1.5% for beat-detection (± 200 ms to annotated MIT-beat) .

Impedance Cardiography

In order to obtain the ICG-signals $^{dZ}/_{dt}(t)$ and $Z_0(t)$ new electrodes have been designed. The reproducibility of stroke volume measurements using these electrodes was tested against standard band electrodes and spot electrodes. (N=42, 22 normal subjects (NT) and 20 hypertensive subjects, (HT)). For the reproducibility measurements the patients were in the supine position for at least 15 minutes before and during the measurements. The electrodes were placed exactly as described for the different methodes [4, 12, 13]. All electrodes were removed after the location was marked with ink and new electrodes were placed exactly on the same spot a second time.

The ICG-signals $^{dZ}/_{dt}(t)$ and $Z_0(t)$ are used for the detection of stroke volume [3, 4]. A newly developed signal processing tool is eliminating the electrical influence of breathing and is detecting the maxima of the $^{dZ}/_{dt}$ -signal (C-point), the aortic opening point (B-point) and the aortic closing point (X-point). SV and cardiac output (CO) are calculated by a new mathematical formula.

The results were compared with the BioZ device. (N=45; 21 healthy subjects without heart diseases (NHD), 6 patients with coronary heart diseases without heart failure (CHD), 5 patients with diastolic heart failure (DHF), 13 patients with systolic congestive heart failure (CHF). The SV measurements were performed with the BioZ and Task Force® Monitor consecutively in randomized order. The patients were in supine position during the measurement and for at least 15 minutes before the measurement was started. Additionally, the measurements were performed also during passive head up tilt with 16 subjects. The measurement period with each device was 5 minutes, so that the stroke volume measurements of at least 300 heart beats could be averaged. Therefore, in total, 61 measurements with both devices could be compared.

Apart from that, the CO measurements were also compared with thermodilution (TD) (Baxter Explorer 650359/2049, Edwards Critical Care, Irvine, CA, USA) (N=16, all with CHF). For this comparison the ICG was recorded over a period of 20 minutes in hemodynamically stable patients in supine position; during this period in each single patient five TD bolus injections were performed. The mean CO as measured by ICG was compared to the mean value of CO as calculated from the 5 TD measurements.

In previous studies the correlation coefficients (r) between CO measurements of various other impedance devices versus TD was reported to be between 0.35 and 0.95, whereby the correlation was best in normal subjects and worst in patients with CHF [14, 15]. In order to be clinically useful the mean difference between the non-invasive measurement by ICG and the invasive gold standard of TD should be less than 10ml (SV) and 0.5L/min (CO), SD should be less than 20 ml (SV) and 1.0 L/min (CO), respectively [14].

Continuous Blood Pressure

The patented contBP instrument of the TFM delivers the blood pressure wave p(t) continuously without any interruptions caused by intermittent readjustment of the set point. This makes the main difference compared to the other commercially available devices such as Finapres or Portapres. With maxima/minima search routines systolic and diastolic blood pressure (sBP, dBP) values are obtained. Since the contBP is measured on the small artery of the fingers which is not representative for the systemic blood pressure in the large arteries, in the TFM contBP values are automatically and continuously corrected to the oscBP measured on the brachial artery.
The beat-to-beat changes of the contBP measured by the TFM were validated against the Finapres device, which should be substantially equivalent. Since the Finapres has no automatic correction to the oscillometric values obtained from the contralateral upper arm, the absolute BP values cannot be expected to be identical. Therefore, the relative changes of beat-to-beat sBP and dBP were investigated (N=22, 10 NT, 12HT)

Oscillometric Blood Pressure

The oscBP measurements were evaluated by referring to the protocol of the American national standard for electronic or automated sphygmomanometers (ANSI AAMI SP10-1992). Additionally, the oscBP of the Task Force® Monitor was evaluated using the protocol for the "Quality Mark" (Gütesiegel) of the German Hypertension League. 255 auscultatory and oscBP measurements in 85 subjects (51 NT and 34 HT) were performed. Furthermore, the oscBP was tested against the Dinamap® Blood Pressure Monitor 1846SX (Critikon, Tampa, FL, USA, SNr.: 8263H1244) and the Spacelabs® Medical Blood Pressure Monitor Mod. 90309 (SpaceLabs, Redmond, WA, USA, SNr.: 309-01187). (N=40, 23NT, 17HT). Correlation coefficients (r) between Dinamap versus TFM and SpaceLabs versus TFM should lie in the same range as Dinamap versus SpaceLabs.

Power Spectral Analysis

For the online monitoring of the frequency content of the biological signals "Recursive Least Squares Algorithm (RLS)" [2, 6, 7] were used. Time-variant AR coefficients are determined by adaptive parametric identification which obtains weighted values of a sliding exponential window. The time-varying power spectrum is calculated from the adaptive AR coefficients derived from each hemodynamic parameter (RR, sBP).

The RLS-algorithm was evaluated with the following testsignal: *t<250 sec: HF s(t) = 3*cos(2*pi*t/3) + u(t)*
*t>=250 sec: LF s(t) = 3*cos(2*pi*t/10) + u(t)*
with *u(t)*: white noise SNR = 10dB
Apart from testing a synthetic signal, a physiological test of the algorithm during controlled breathing was performed. The breathing frequency of the subject should be detected in the power spectra of the impedance signal since breathing influences cardiac filling and therefore stroke volume .

III. RESULTS

ECG - QRS-detection

The QRS-algorithm was evaluated with the MIT/BIH database. The total QRS-detection rate (± 30 ms to annotated MIT-beat) of all included data was 98,873% and the total beat-detection rate (± 200 ms to annotated MIT-beat) was 99.324%.

Records	Beats	PVCs	Paced	FP Beat	FN Beat	FR % Beat	FR % QRS
MITDB	97.403	8.103	7.981	315	881	1,1868	1,5544
LTDB	667.867	62.699	0	589	3.438	0,6021	1,0649
Sum	**765.270**	**70.802**	**7.981**	**904**	**4.319**	**0,6765**	**1,1272**

Table 1: QRS-detection algorithm evaluated with MIT/BIH database

Impedance Cardiography

Reproducibility

The reproducibility of two consecutive measurements with the new Task Force® Monitor-electrodes is compared with the reproducibility of conventional double band electrodes [4] and spot elecetrodes [12].

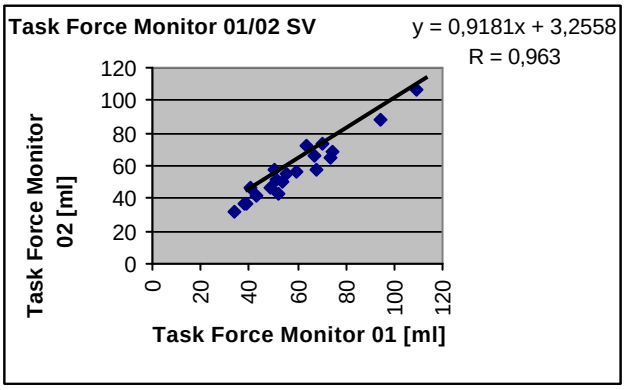

Figure 1: Reproducibilty of SV using the TFM-electrodes

As can be seen the correlation coefficient (r=0.963, N=42, p<0.001) was higher with the TFM electrodes as compared to circular band electrodes (r=0.731, N=42, p<0.001) and spot electrodes (r=0.814, N=42, p<0.001). Spot electrodes show better reproducibility than circular band electrodes, but less reproducibility than Task Force® Monitor electrodes.

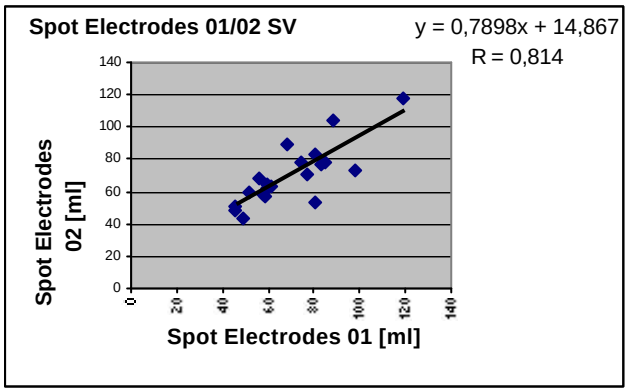

Figure 2: Reproducibilty of SV using circular band electrodes

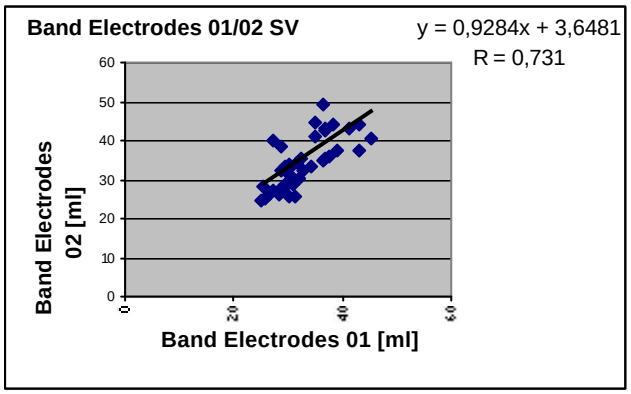

Figure 3: Reproducibilty of SV using spot electrodes

Comparison of TFM with BioZ

The comparison of SV and CO values as obtained by the BioZ device and the TFM is shown in Fig. 4 and 5.
A correlation coefficient r=0.861 (N=61, p<0.001) for SV measurements and r=0,837 (p<0.001) for CO measurements were observed. This appears to be a remarkably good conformity, especially if one considers that the measurements had to be performed consecutively and not simultaneously (due to interference of the BioZ and TFM device when the two AC-currents were applied simultaenously). The relevance of consecutive measurements for the interpretation of the shown results is emphasized by the fact that even for heart rate a correlation coefficient close to 1 could not be obtained due to the consecutive measurement procedure r=0.945 (p<0.001).

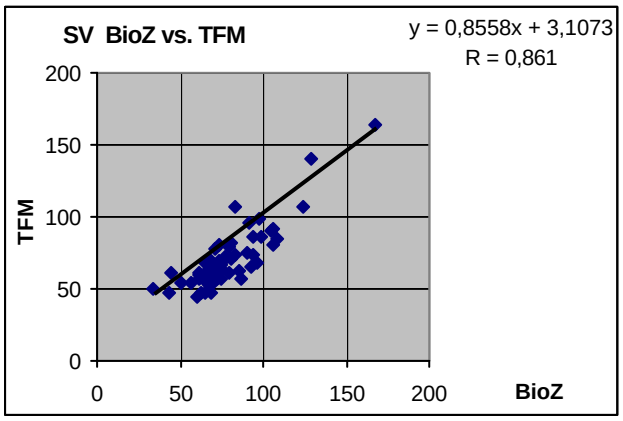

Figure 4: Regression of SV as obtained by the BioZ and TFM

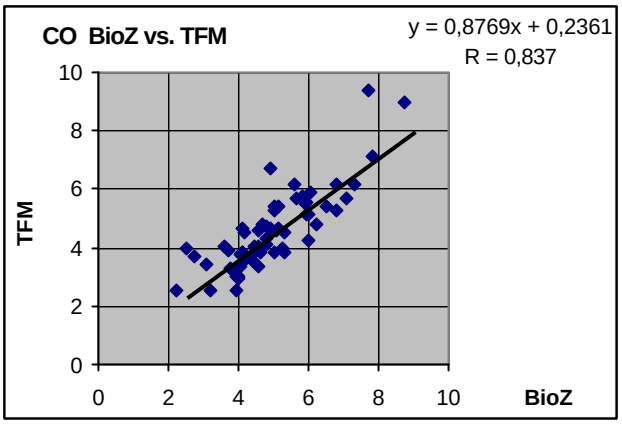

Figure 5: Regression of CO as obtained by the BioZ and TFM

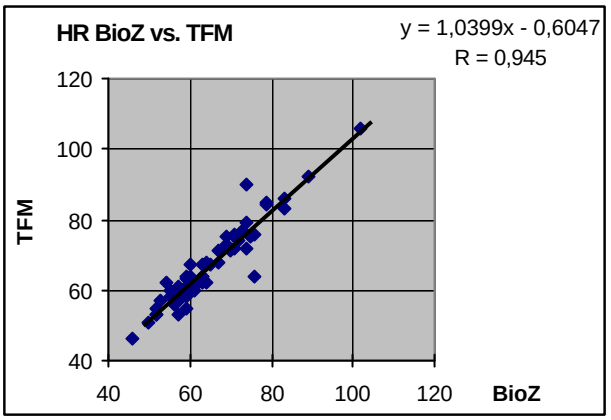

Figure 6: Regression of HR as obtained by the BioZ and TFM

The comparison of the two devices with the Bland Altmann method shows no significant difference (TFM-BioZ SV = -8.18 ± 11.15 ml, TFM-BioZ CO = -0.37 ± 0.76 L/min.) (Fig 7 and 8).

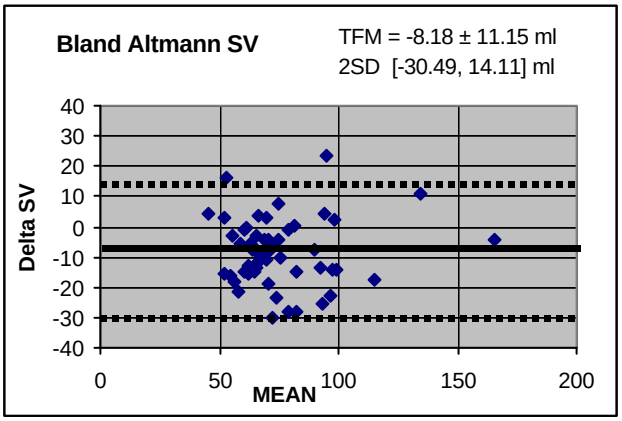

Figure 7: Bland Altmann of SV as obtained by the BioZ and TFM

Delta	*HR [bpm]*	*SV [ml]*	*CO [L/min]*	*PEP [ms]*	*LVET [ms]*
Mean	1.97	-8.19	-0.38	-4.48	9.84
SD	3.57	11.15	0.76	18.94	28.05
SD [%]	5.46	15.03	15.84	17.55	8.80

Table 2: Mean and standard deviation of the differences

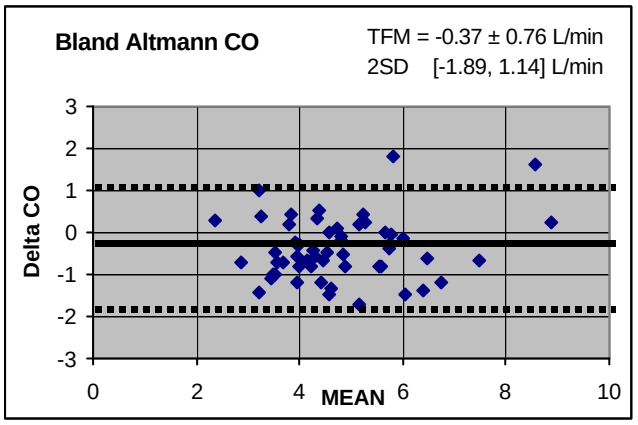

Figure 8: Bland Altmann of CO as obtained by the BioZ and TFM

Further comparisons of the two devices are shown in Table 2. As can be seen, Pre Ejection Period (PEP) and Left Ventricular Ejection Time (LVET), which are determined by the aortic valve opening point (B-point) and by the aortic valve closing point (X-point) are detected in a very comparable way in both instruments.

Comparison of TFM with thermodilution

The comparison of cardiac output measurements as obtained by the TFM and by TD is shown in Fig. 9 to 11.

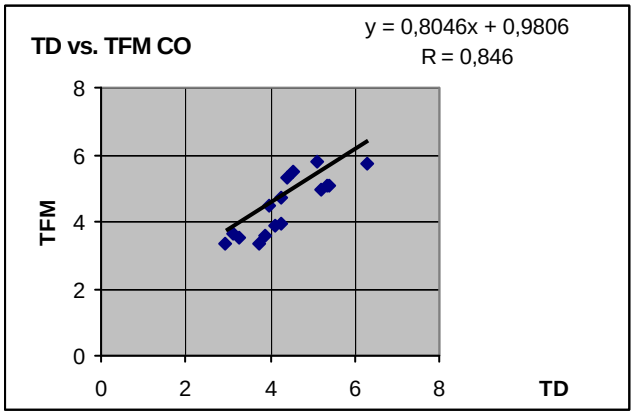

Figure 9: Regression of CO as obtained by TD and TFM

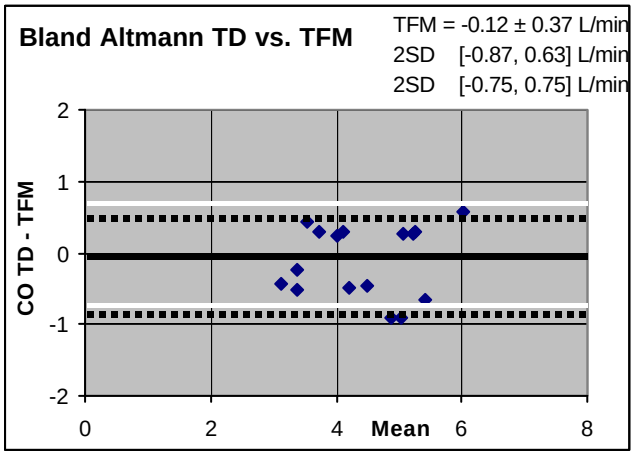

Figure 10: Bland Altmann of CO as obtained by TD vs. TFM

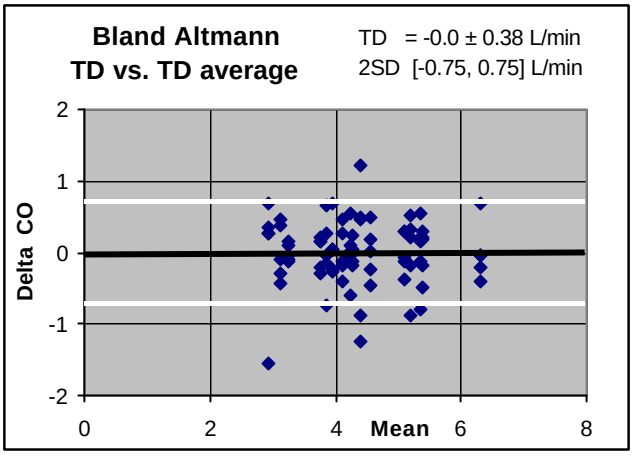

Figure 11: Bland Altmann of Single TD-measurements to their mean

As can be seen in Fig 9 the correlation coefficient between CO measurements by TD and the TFM is even higher than that obtained by comparing the TFM and the BioZ device ($r= 0.846$,$N=16$, $p<0.01$). Fig. 10 shows that the mean difference between TFM-CO and TD-CO was -0.12 ± 0.37 L/min. All of the TFM values lie within the 95% confidential interval of the TD CO[-1.13, 0.87] L/min.

We consider this excellent result as a consequence of the fact that TD-measurements could be performed simultaneously with the impedance measurements. Furthermore we consider this also as a consequence of the new patented double short band electrodes of the TFM, which show better reproducibility of CO measurements than previously used circular band or spot electrodes. This also matches favourably with the published comparison of BioZ to TD [14], especially if it is considered that in the present study only patients with severe heart failure were included. As mentioned above the results of historical ICG measurements were usually notoriously bad in chronic heart failure [14, 15]. In light of the here presented comparison of the TFM with the established BioZ device and of the comparison of the TFM with the gold standard of TD the TFM device appears at least as suitable for monitoring the patient with heart disease on the intensive care unit as the BioZ device.

The standard deviation (SD) of the 5 TD-measurements was 0.43 L/min (9.79% of mean), in contrast, the SD of TFM-CO was only 0.18 L/min (4.26% of mean). The high SD of the TD-CO of 9.79% obtained in hemodynamically stable resting patients with heart failure reemphasizes also the limitations of TD [14].

The doted black lines in figure 10 show the 95% confidential interval (2SD) of the differences between TD and TFM. The white lines (figure 10 and 11) show the 95% confidential interval (2SD) between the 5 consecutive TD-measurements and their average. These figures also demonstrate the broad variation of a single TD-measurement.

CO-comparison during pharmacological intervention

Fig 12a-d show the effect of Alprostatil® in 4 patients with primary pulmonary hypertension. CO-measurements (TD and TFM) were obtained consecutively every hour. The gray bars show the effects of pharmacological intervention on CO

measured with TD, the dark bars show the simultaenously recorded CO-TFM measurements. As can be seen, not only the absolute values of CO between TD and TFM correspond closely but there are also identical changes in the trend of both CO-measurements after pharmacological intervention.

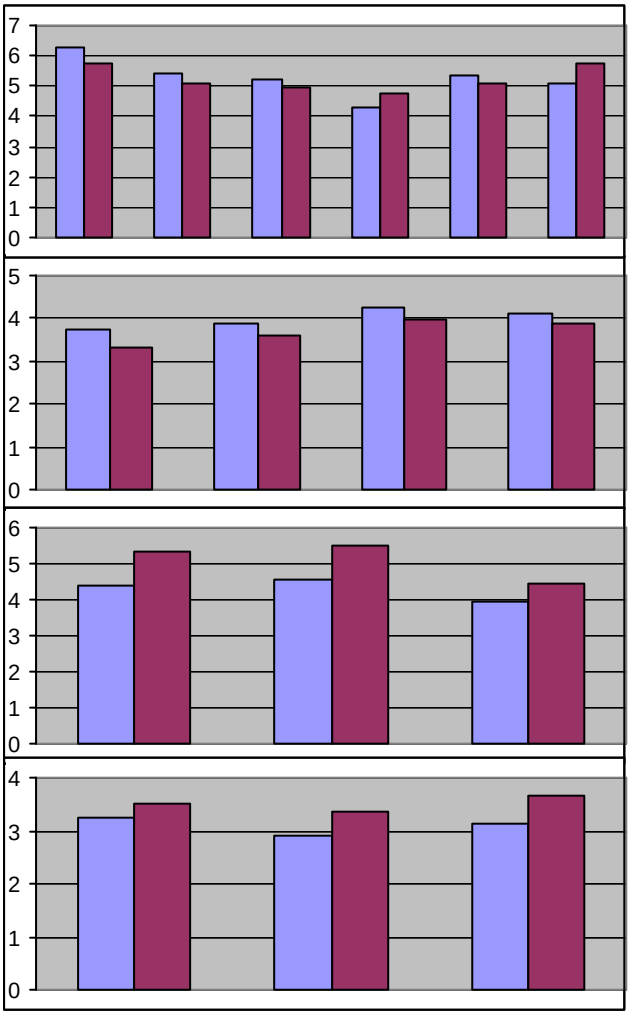

Figure 12a-d: Trend plots comparing CO-TD (gray bars) vs. CO-TFM (dark bars) during pharmacological intervention with Alprostatil®

Continuous Blood Pressure

Fig 13 show 6 trend plots comparing the continuous blood pressure measurements as obtained with the Finapres and the Task Force® Monitor in a representative sample of subjects. (The comparisons of the other 16 subjects are on file). As can be seen, both devices show remarkably comparable blood pressure trends. The Finapres device however, interrupts the "continuous" measurements every minute for readjustment of the set point [16], whereas the Task Force® Monitor never interrupts the measurement because of continuous re-adjustment of the setpoint.

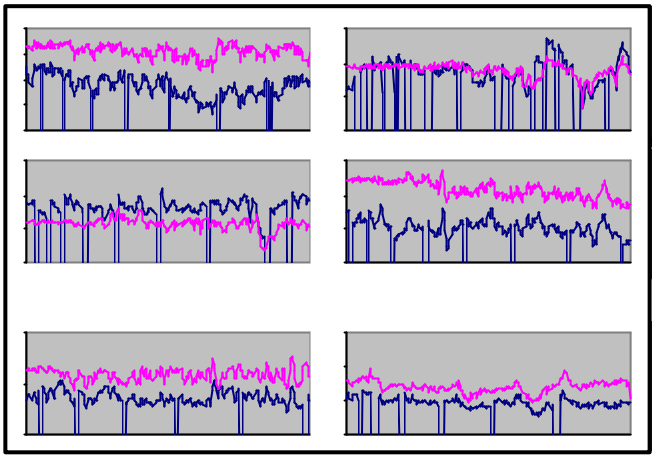

Figure 13: Trend plots comparing continuous blood pressure trends using the Finapres (dark blue lines) and the TFM (pink lines).

Oscillometric Blood Pressure

The oscBP of the Task Force® Monitor fulfils the protocol of the American national standard for electronic or automated sphygmomanometers (ANSI AAMI SP10-1992). In addition, the oscBP of the TFM achieves the criteria for the "Quality Mark" (Gütesiegel) of the German Hypertension League. The difference in sBP was -1.82±7.64 mmHg and in dBP = -1.76±6.36 mmHg.

The comparison (table 3) between oscBP, Dinamap and SpaceLabs shows, that the differences in obtained sBP and dBP values and the correlation coefficients between the three devices are comparable.

N=40; p<0.001	TFM vs. SpaceLabs		TFM vs. Dinamap		Dinamap vs. SpaceLabs	
	r [%]	mean ± SD [mmHg]	r [%]	mean ± SD [mmHg]	r [%]	mean ± SD [mmHg]
sBP	94,6	-2,98±11,66	95,1	-0,11±7,65	98,5	2,87±8,00
dBP	87,7	9,30±6,81	88,7	7,48±6,75	89,3	-1,81±4,85

Table 3: Differences in BP between Dinamap, SpaceLabs and TFM

Adjustment of contBP to oscBP

Fig 14 and 15 show 2 representative examples of the raw signals of cont BP as compared to the intermittently obtained oscillometric BP values in patients who show great changes of BP on the tilt table (upper panel). The lower panel shows the final adjustment of cont BP to osc BP as performed by the TFM. In the upper panel it can be seen that changes of contBP closely mirror changes of oscBP but the absolute values of cont BP may be higher or lower than oscBP (obtained in a large artery) depending on the vasodilative or vasoconstrictive state of the finger arteries of a particular subject. After read-justment a perfect fit of both recordings is achieved.

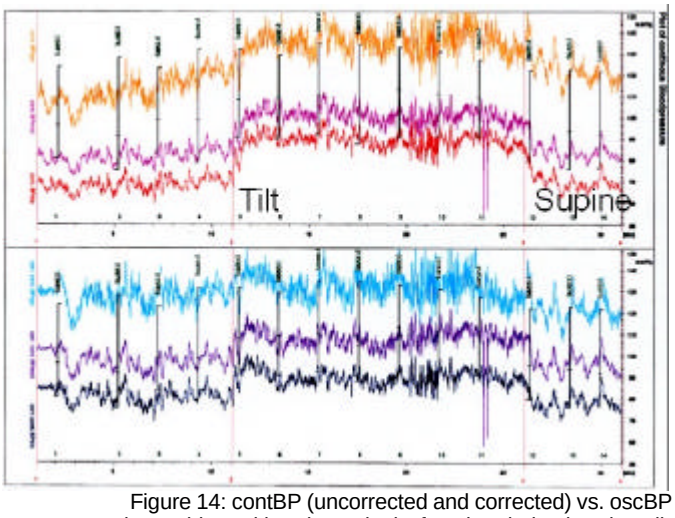

Figure 14: contBP (uncorrected and corrected) vs. oscBP in a subject with orthostatic dysfunction during head up tilt

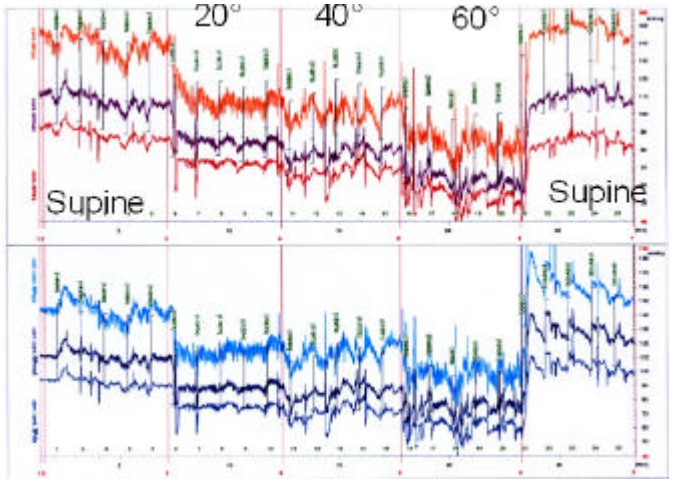

Figure 15: contBP (uncorrected and corrected) vs. oscBP in a subject with orthostatic hypotension on the tilt table

Power Spectral Analysis

Fig. 16 shows the 3-D sliding spectra of the synthetic test signal. It can be seen that even the fast change between HF to LF at *t= 250 sec* is captured accurately by the algorithm used in the TFM.

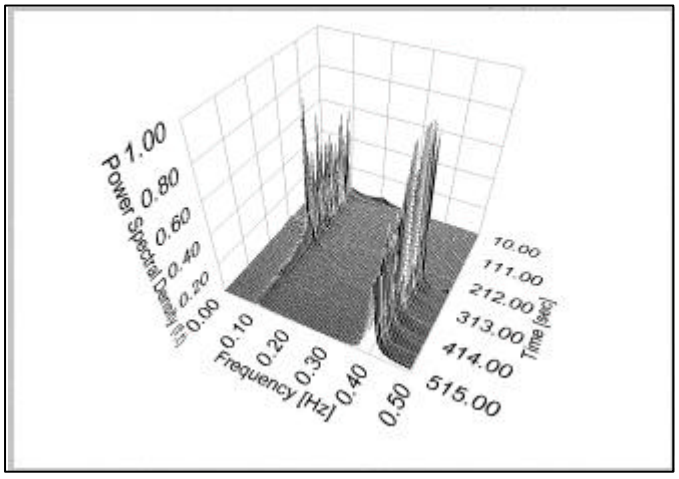

Figure 16: 3-D sliding power spectra of the test signal

The reliability of the TFM-Power Spectra Analysis can also be seen in Figure 17. This figure shows the frequency content of contractility ($^{dZ}/_{dt}$) from a subject during controlled breathing at different rates of 2 to 10 tides/minute. As can be seen the breathing frequency is clearly identified by the TFM which proves not only the accuracy of the TFM power spectra analysis algorithm but also the quality of the analysis of the ICG signal.

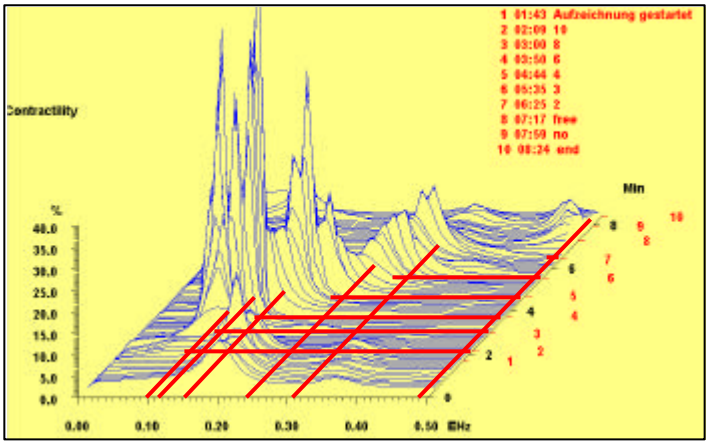

Figure 17: 3-D sliding power spectra of the dz/dt signal during controlled breathing frequencies of 0.1, 0.125, 0.183, 0.25, 0.33, 0.5 Hz.

IV. CONCLUSION

The present paper proves evidence that the TFM, already certified in Europe by its CE mark (CE 0408, TUeV Austria, Vienna), provides correct and reliable hemodynamic data.

The ICG component appears at least as reliable as the BioZ, which is certified by FDA. A big advantage appears to be not only the close correlation with the gold standard of TD even for patients with severe heart failure but also the comparatively better reproducibility of repeated measurements of SV using the newly designed double short band electrodes instead of the spot electrodes.

The oscillometric blood pressure device of the TFM does not only fulfill the very strict criteria of the ANSI AAMI SP10-1992 and of the ”Gütesiegel” of the “German Hypertension league” but also bears comparison with 2 devices, namely the Dinamap and the SpaceLabs, both registered in the USA for patient monitoring in the intensive care unit.

The continuous blood pressure device compares very well to the Finapres device which is also registered in the USA for investigative human use. In addition, there is no need for contBP component of the TFM to interrupt the recording for readjustment of the set point as the Finapres device does every minute. Therefore the TFM is the first true continuous blood pressure measurement device. Furthermore the continuous adjustment of the changes of blood pressure measured on the finger to the blood pressure in a large artery (measured with a reliable oscillometric BP measurement device) ensures the possibility of tracing accurately blood pressure in the circulation on a beat to beat basis.

All hemodynamic parameters, are detected on a beat-to-beat basis and visualized in real-time.

Also the clinical importance of power spectral analysis of cardiovascular signals has been growing in the past few years. Heart rate and blood pressure variability have become substantial diagnostic tools for the detection of autonomic diseases [17]. The increasing interest in the analysis of short-term heart and blood pressure variability for the detection of sympathico-vagal tone demands for an online system of beat to beat hemodynamic parameters as provided in the TFM. The TFM does not only facilitate the diagnosis of all kind of haemodynamic disturbances, it has also proved to be a valuable device for the investigation of pharmacological interventions. New insights into genetically determined differences to vasoactive drugs[18] may be obtained. Likewise, the consequences of metabolic disturbances to the function of the autonomic nervous system can be assessed[19].

Over and above, the TFM has proved across Europe to be a valuable tool for teaching the medical student the function of the circulation in the lecture theatre on-line per video beamer during all varieties of physiological and pharmacological maneuvers.

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