Abstract

In order to determine the accuracy of the PAR NIBP2010 module, a clinical trial in compliance with the standards DIN EN 1060-4:2004, ANSI/AAMI SP10:2002/A1:2003 and the requirements of the BHS (British Hypertension Society) was performed.
The module measurements were compared with the mean of the reference measurements of two observers. A total of 85 patients (47 male, 38 female) provided 255 measurements for comparison. Patient age ranged between 28 and 96 years and the circumference of the arm was between 22 and 47 cm. The NIBP module showed a mean (standard) deviation from observer measurements of 0.39 (2.57) mmHg for systolic and 0.43 (1.73) mmHg for diastolic blood pressure. For the heart rate measurements, the values were 0.59 (2.21) bpm. According to DIN EN 1060-3:2006, a mean deviation of ±5 mmHg and a standard deviation of 8 mmHg would be permissible.

Introduction

The NIBP module is designed for noninvasive automatic measurement of blood pressure (systole, diastole, mean) of adult patients according to the oscillometric principle. In addition, it measures the patient's heart rate, using the oscillations. The NIBP module measures the systole in the range from 45 to 280 mmHg and the diastole in the range from 15 to 220 mmHg, as well as the heart rate between 30 and 240 bpm.

The oscillometric principle requires blood pressure cuffs which are placed on the upper arm of the patient on the same level of the heart. The cuffs must have the correct size for the arm circumference; the module can measure with 3 cuff sizes:

- Standard adult cuff for arm circumferences from 25 to 35 cm
- Small adult cuff for arm circumferences from 18 to 26 cm
- Large adult cuff for arm circumferences from 33 to 47 cm

If the cuff used for the blood pressure measurement is too small, the measured values are too high; if the cuff is too large, the measured values are too low. The cuff must be placed on the upper arm at a distance of two fingers from the bend of the elbow and must not be moved during the measurement series.

The NIBP module is not a finished medical device but is an electronic PCB designed to be integrated in a host system. The NIBP module is connected to the power supply and the serial interface in the host system. Control of the NIBP module is accomplished by commands via this serial interface. The results of the measurements are also transferred via this interface.

Clinical study procedure

To determine the measurement accuracy of the NIBP module, a clinical trial with 92 patients was performed. The clinical trial took place from June 2008 until October 2008 in the Jüdisches Krankenhaus in Berlin-Mitte under the supervision of Dr. Brauner and at St. Joseph Krankenhaus in Berlin-Tempelhof under the supervision of senior physician Dr. Anngret Mallick.

Since heart rate is an important parameter, it was recorded in addition to the standards DIN EN 1060-4:2004, ANSI/AAMI SP10:2002/A1:2003 and to the requirements of the BHS (British Hypertension Society), and the heart rate of the NIBP module was compared to the heart rate of an SpO2 measurement as a reference.

The NIBP module was powered from an external supply; control of the module was performed with a laptop by commands via the serial interface. The results of the blood pressure measurement and further information were also transferred via the serial interface to the laptop and saved there.

The three cuff sizes were used for the clinical trial. The cuff appropriate for the circumference of the arm was selected. The reference measurements were taken with a calibrated reference manometer and a double stethoscope (dual head stethoscope) from BOSO. The reference measurement is a mean of two single reference measurements performed by two trained observers.

The test series was performed as follows:

1. Pre-measurements – observer
2. Pre-measurement – NIBP module
3. Reference measurement
4. NIBP module
5. Reference measurement
6. NIBP module
7. Reference measurement
8. NIBP module
9. Reference measurement

The cuff is placed once and used for the module measurement as well as the reference measurement without changing its position. The stethoscope is also put in place once prior to the test series and remains under the cuff for the entire time. The measurements are performed at 60-second intervals. The entire time for a test series is approx. 15 to 20 minutes.
All measurements made with the reference instrument must agree among themselves, i.e., the 4 reference systoles must not deviate from one another by more than 12 mmHg and the reference diastoles by more than 8 mmHg. If this is the case, the patient must be excluded

from the analysis according to DIN EN 1060-4:2004. To achieve better measurement reliability, additional control measurements were performed with an automatic sphygmomanometer in some patients who were difficult to measure. These control measurements were not taken into account in the analysis; these served to assure the observers that they were measuring correctly.

The pre-measurements served for the classification of the patients; measurements 4 through 9 are included in the analysis. The comparative measurements are the differences between measurements 4 and 5, 6 and 7, 8 and 9.

Results

A total of 92 patients participated in the clinical trial. In two of the patients, a reference measurement was not possible at all because the Korotkoff sounds could not be heard. In another 5 patients, blood pressure variations were too big and the values from these patients were not included in the analysis (in accordance with DIN EN 1060-4:2004, all measurements with the reference instrument must be consistent with each other).

The analysis of the test series was performed according to the recommendations of the British Hypertension Society (BHS) [1]. This protocol is based on important points from the ANSI/AAMI SP10:2002/A1:2003 and is presently the most comprehensive test protocol that allows a differentiated evaluation of measurement accuracy. The BHS validation procedure results in grades A, B, C and D (Table 2). The grade of A, for example, means that 85% of the module measurements deviate from the auscultatory reference measurements by less than 10 mmHg. For each of the 3 module measurements, the difference between the reference measurements is calculated and subsequently the mean of all differences is calculated. A total of 255 comparative measurements were performed in 85 patients; this corresponds to 100%.

A classification for both, the systolic and diastolic blood pressure values can be performed in the three categories, ≤ 5, ≤ 10 und ≤ 15 mmHg, by percentual distribution. For a better understanding, the same principle is also used for the heart rate.

Table 1 shows a distribution of patients by gender, age, arm circumference, blood pressure and heart rate.

Group	Mean	Range
Sex (M/F)	Male: 47 / Female: 38	
Age (years)	65	28 to 96
Arm circumference (cm)	29	22 to 47
SBP (mmHg)	121 (SD: 29)	48 to 212
DBP (mmHg)	66 (SD: 15)	32 to 109
Heart rate (bpm)	74 (SD: 15)	49 to 120

Table 1: Patient distribution
SBP (systolic blood pressure), DBP (diastolic blood pressure), SD (standard deviation)

Summary

The NIBP module receives a BHS grade A, this is the highest level, both for systolic and diastolic blood pressure measurements and for the determination of heart rate. The criteria required by the BHS (Table 2) were greatly exceeded (see Table 3, Figures 1, 2 and 3).

In order to be classified as a grade A by the BHS, at least 60% of the module measurements must have a deviation of ≤ 5mmHg with regard to the reference measurements. The NIBP module fulfills this requirement with no problem. The systolic values fulfills the requirement in 91% of module measurements, the diastolic values in 92.6%, and the heart rate in 94.5%.

	Required percentage of differences between observer and device		
Grade	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
A	60	85	95
B	50	75	90
C	40	65	85
D	Below a C		

Table 2: Grading criteria of blood pressure device by percentage of differences according to BHS protocol

	Percentage of differences between observer and module		
	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
SBP	91	98.4	100
DBP	92.6	99.6	100
HR	94.5	100	100

Table 3: Percentage of differences between observer and NIBP module

The mean deviation and the standard deviations for the systolic and diastolic blood pressure and the heart rate measurements were extraordinarily good (Table 4). According to DIN EN 1060-3:2006 and ANSI/AAMI SP10:2002/A1:2003 a mean deviation of ±5 mmHg and a standard deviation of 8 mmHg is permissible for the blood pressure values.

	Mean deviation	**Standard deviation**
SBP	**0.39 mmHg**	**2.57 mmHg**
DBP	**0.43 mmHg**	**1.73 mmHg**
HR	**0.59 bpm**	**2.21 bpm**

Table 4: Overall results of the clinical trial NIBP module

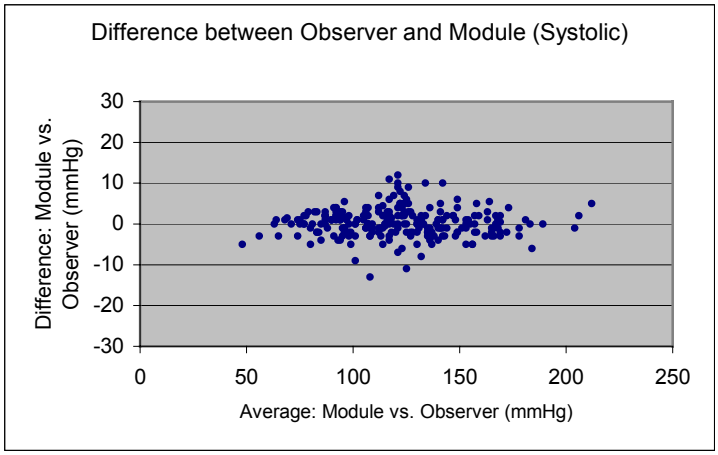

Figure 1. Systolic pressure: Difference between observer und NIBP module
85 patients, 255 measurements

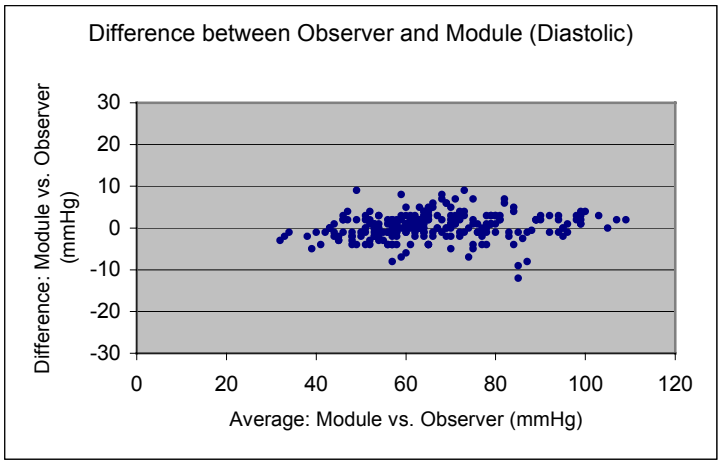

Figure 2. Diastolic pressure:
Difference between observer and NIBP module
85 patients, 255 measurements

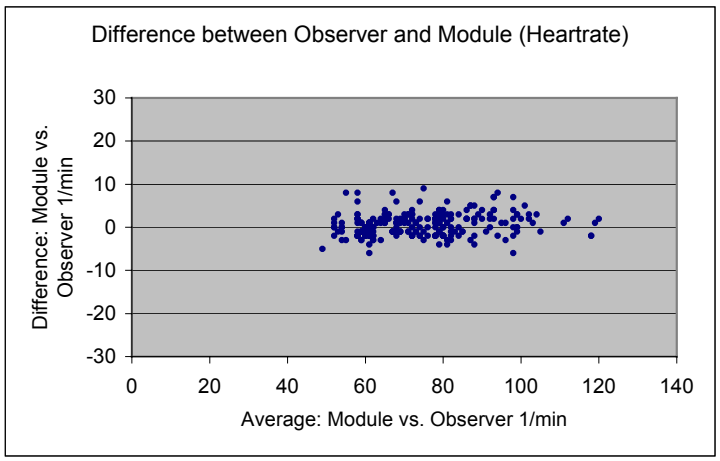

Figure 3. Heart rate:
Difference between observer and NIBP module
85 patients, 255 measurements

[1] **British Hypertension Society Protocol**: O'Brien E, Petrie J, Littler W et al. (1993) The British Hypertension Society protocol for the evaluation of blood pressure measuring devices. J Hypertension. 11(suppl 2) : S43-S62