International Journal on Obstetrics and Gynecology

Investigation of the Measurement Accuracy of Different Cuff Types and Measurement Modes According to ISO 81060-2 in Pregnant and Pre-Eclamptic Women

Research Article
Volume 4 Issue 2- 2024

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Article History

Received: August 02, 2024 Accepted: August 06, 2024 Published: August 07, 2024

Abstract

This clinical study shall confirm the blood pressure measurement accuracy according to the standard ISO 81060-2 for the different measurement modes deflation measurement technique (DMT) and inflation measurement technique (IMT) as well as the usage of different cuff types. The systolic (SBP) and diastolic blood pressures (DBP) of 93 pregnant and pre-eclamptic women were measured and compared with reference measurements obtained by two observers using a standard aneroid sphygmomanometer.

The test device showed for the measurement modes and cuff types the following accuracy for SBP (DBP):

a. Mean deviation of 2.9mmHg (-2.3mmHg) and standard deviation of 5.7mmHg (5.5mmHg) compared to the observer measurements when using the DMT with rectangular cuff.

b. Mean deviation of -0.8mmHg (-0.4mmHg) and standard deviation of 5.4mmHg (5.2mmHg) compared to the observer measurements when using the IMT with rectangular cuff.

c. Mean deviation of 2.1mmHg (-2.1mmHg) and standard deviation of 5.2mmHg (5.4mmHg) compared to the observer measurements when using the DMT with conical cuff.

Mean deviation of -0.3mmHg (-1.7mmHg) and standard deviation of 5.1mmHg (5.4mmHg) compared to the observer measurements when using the IMT with conical cuff.

All configurations passed the accuracy requirements of the standard ISO 81060-2.

In summary, DMT and IMT algorithm and measurement hardware from PAR that is used in all of PAR's blood pressure measurement devices meet the accuracy requirements of the ISO 81060-2 standard for pregnant and pre-eclamptic women when using PAR's different cuff types.

Keywords: Automatic, Noninvasive Blood Pressure, ISO 81060-2, ISO 14155, Regulation (EU) 2017/745, Oscillometric, Upper Arm, Validation, NIBP2020 UP, Deflation Measurement Technique, DMT, Inflation Measurement Technique, IMT, Algorithm, Accuracy, Safety, Performance

Abbreviations: DMT: Deflation Measurement Technique; IMT: Inflation Measurement Technique; DBP: Diastolic Blood Pressures; BP: Blood Pressure; ABPM: Automatic Non-Invasive Blood Pressure Measurement; MV: Mean Deviation

Introduction

The non-invasive measured upper arm blood pressure (BP) is a standard diagnostic tool in medical practice today. The upper arm BP is used to identify the patient specific cardiovascular risk or health status according to the measured BP values. The diagnostic value depends on the one hand side on the device accuracy and on the other hand side on combination with other investigations. A correct blood pressure measurement reading is a prerequisite for making the necessary blood pressure adjustments to ensure patient safety and reduce the likelihood of cardiovascular events. Patient groups with special vascular characteristics such as pregnant and pre-eclamptic women pose a particular challenge for blood pressure measurement devices.

The standard ISO 81060-2 [1] is an accepted standard for validation of automatic non-invasive blood pressure measurement (ABPM) devices, enabling comparison and providing profound information on measurement performance under varying pressure levels and patients including special patient groups like pregnant and pre-eclamptic women. The constant technical progress in ABPM devices leads in combination with the standards ISO 81060-2 and ISO 14155 [2] to a standardized data presentation with strict pass and fail criteria to characterize the accuracy of these devices.

Contact

The clinical study was monitored by PAR Medizintechnik GmbH & Co. KG, Rigistr. 11, 12277 Berlin, Germany. Contact person for study conduction and product support was Mr. Thomas Fischer. The location where the data collection was conducted is described in the section 5.4.

Materials and Methods

Device Details

The Sonicaid Team3 fetal monitor from Huntleigh Healthcare Ltd. contains a blood pressure measurement module NIBP2020 UP [3] developed and offered by PAR Medizintechnik GmbH & Co. KG (PAR). The module itself bears a CE mark in accordance with Regulation (EU) 2017/745 on medical devices [4]. All blood pressure measurement modules like NIBP2020 UP and ambulatory blood pressure measurement devices like PHYSIO-PORT or TONOPORT from PAR use the same blood pressure measurement algorithm and measurement hardware.

The module can determine blood pressure using the deflation measurement technique (DMT) or inflation measurement technique (IMT) from PAR to measure upper arm blood pressure with a blood pressure cuff. Used cuffs are rectangular (non D-Ring) or conical (with D-Ring) cuff type and are made for upper arm circumferences between 17 and 46cm (see Table 1). The cuffs are class I medical devices according to the Regulation (EU) 2017/745 (MDR) on medical devices and are developed and offered by PAR. In addition, an extension hose with a length of 3.0m was used.

Table 1: Cuff information.

Cuff Size	Abbreviation	Upper Arm Circumference
Small	S	17 - 26cm (6.7 - 10.2″)
Medium	M	24 - 32cm (9.4 - 12.6″)
Large	L	32 - 42cm (12.6 - 16.5″)
Extra-large	XL	38 - 46cm (15.0 - 18.1″)

Study Objective

The clinical study was designed to confirm the performance and safety of the DMT and IMT algorithm when rectangular or conical cuffs from PAR are used in the special patient group pregnant and pre-eclamptic women in accordance with the standard ISO 81060-2 and to confirm the compliance of the clinical data with this standard.

Therefore, the BP accuracy of the test device was compared to the blood pressure values obtained by two trained observers. The used clinical investigation method was "sequential measurement on the same arm" according to the standard ISO 81060-2. The primary endpoint was to confirm a mean deviation (MV) in the range of -5.0 ≤ MV ≤ 5.0mmHg and a standard deviation less than or equal to 8.0mmHg compared to the reference values of the observer in at least 45 pregnant women for each configuration of measurement mode and cuff type. The primary hypothesis was that the test device meets the accuracy demanded by the standard ISO 81060-2. The secondary endpoint was the identification of risks for patient, user or third parties that have not been (adequately) considered so far. The secondary hypothesis was that the test device does not pose any unknown risks.

Familiarization

All study physicians are licensed physicians experienced in blood pressure measurement. A familiarization procedure was executed before the validation measurements. Several test measurements were taken using the test device to gain experience with it and the measuring procedure. The study physicians were trained in all safety regulations regarding the test device, with the measurement sequence, the used software tool as well as in the validation rules like needed patient population, blood pressure distribution, and exclusion criteria (see section 5.5).

Recruitment

In accordance with the German MPDG, an approval by the local ethics committee was not necessary because the product is CE marked and is used within the scope of its intended purpose. In addition, no stressful or risky measurements are carried out on the patients, but data from everyday clinical practice is collected and analyzed.

Patient recruitment was conducted among patients of the Department of Gynecology and Obstetrics at St. Joseph Hospital (Germany) from July to December 2023. Different patients were recruited for the two cuff types (see Table 3 and Table 4), but the two measurement methods per cuff type were conducted on the same patient (see Figure 1).

In general, arrhythmias, poor oscillations that lead to erroneous measurements and cuffs that are unsuitable for the patient's upper arm circumference are exclusion criteria for patients according to standard ISO 81060-2. Pregnant women must also be at least in their second trimester and before giving birth to be included in the analysis.

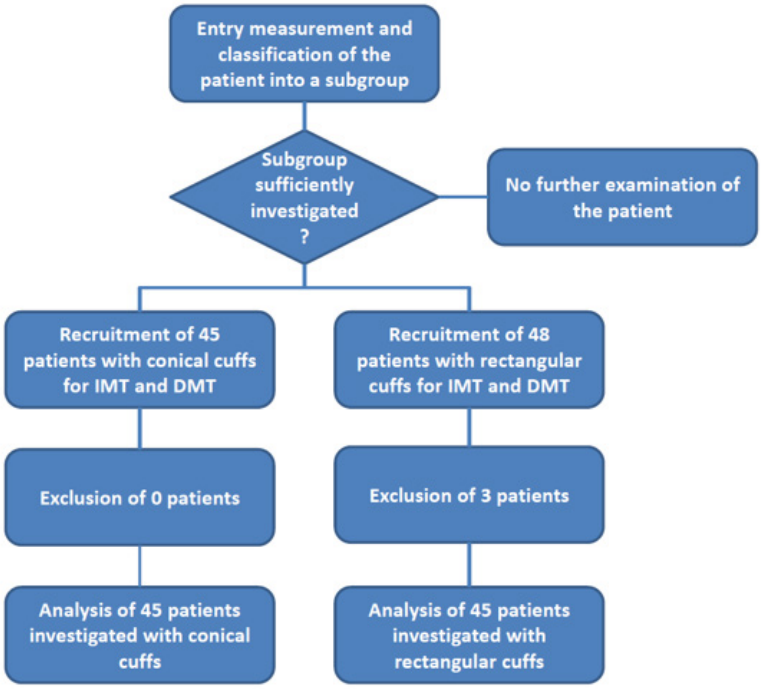

Figure 1: Recruitment flow chart.

Procedure

The standards ISO 81060-2 for the validation of ABPM devices and ISO 14155 for good clinical practice were followed precisely. After written consent was obtained from all participants, the upper arm circumference was measured with a measuring tape at the middle of the relaxed uninjured upper arm. The study physicians applied a suitable cuff to the upper arm without clothing between cuff and upper arm. The cuff was placed on the upper arm at a distance of two fingers from the bend of the elbow, at heart level and was wrapped around the upper arm so tightly that one finger can still be slid between the cuff and the upper arm. The patient sits relaxed on a chair (legs uncrossed, arm supported next to the body, and back supported) without speaking during the validation sequence. The validation sequence was performed after a resting time of 5 to 10min.

Each validation measurement per patient started with two entry measurements followed by seven validation measurements. All these measurements were sequentially performed on the same arm in a 60-second interval. The two observers, blinded from each other, took their reference measurement using a calibrated standard aneroid sphygmomanometer (K I, boso, Jungingen, Germany) and a dual-earpiece stethoscope (KaWe Colorscop-Plano training stethoscope, KaWe, Asperg, Germany). The observer readings were checked immediately by the supervisor and repeated, if they differed by more than ± 4mmHg from each other. Subsequently, a measurement with the test device was performed. In the following, 7 alternating observer and device readings were executed. The sequence started and ended with an observer reference measurement. Hence, each device reading was adjacent to two observer measurements. The observers and the device used the same blood pressure cuff for the measurements; therefore, the cuff position did not change.

Processing

Microsoft Excel was used for the data processing to analyze patient details, measured SBP and DBP readings. All statistical requirements (hypotheses, sample size, analysis method etc.) are defined by the standard ISO 81060-2. According to this standard, the two entry measurements have been ignored for the calculation of the accuracy of the test device. Each pair of observer measurement that differs by 4mmHg or less from each other was averaged. The mean value of the previous and the subsequent averaged observer measurement to a device measurement is used as reference value to calculate the accuracy of the device. The validation data of each patient was documented on a separate test protocol and additionally digitized using a software tool.

Results

Patients

90 of the 93 patients recruited were included in the final analysis. A summary of the exclusions can be found in Table 2 and these are further discussed in section 7. Table 3 demonstrates that the recruited special patient group pregnant and pre-eclamptic woman fulfils the requirements of the standard ISO 81060-2 regarding BP ranges and status (normotensive, hypotensive and hypotensive with Preeclampsia).

The XL cuff was less frequently used, because upper arm circumferences of more than 38cm are difficult to recruit in the examined patient collective. The standard ISO 81060-2 requires equal recruitment of pregnant patients from three subgroups. These subgroups are defined as follows:

i. Group 1: Normotensive pregnant patients (SBP < 140mmHg / DBP < 90mmHg)

ii. Group 2: Hypertensive pregnant patient (SBP ≥ 140mmHg / DBP ≥ 90mmHg, proteinuria ≤ 300mg in 24h)

iii. Group 3: Pre-eclamptic patient (SBP ≥ 140mmHg / DBP ≥ 90mmHg, proteinuria > 300mg in 24h)

The patients were assigned to the subgroups after the two entry measurements. Patients who fell into a subgroup that had already been sufficiently examined were not examined further and are not mentioned in Table 2.

Reference Measurements

Table 4 lists the blood pressure distribution of the observer measurements that were used as reference values for comparison with the device readings, respectively for SBP and DBP. The distribution requirements of the ISO 81060-2 were met. All 45 included patients have up to three valid pairs of reference readings.

Table 2: Recruitment and exclusion. Data without square brackets apply to recruitment with rectangular cuffs and data with square brackets apply to recruitment with conical cuffs.

Total Recruited	**48 [45]**
Total Excluded	**3 [0]**
Arrhythmias	0 [0]
No device measurement	0 [0]
Poor quality sounds	0 [0]
Cuff size unavailable	0 [0]
Observer disagreement	1 [0]
High blood pressure variation	2 [0]
Other reasons	0 [0]
Total included	45 [45]

Table 3: Patient details. Data without square brackets apply to recruitment with rectangular cuffs and data with square brackets apply to recruitment with conical cuffs.

Age (years)	Range (low : high)	24:44 [19:43]	
	Mean (SD)	33.7 (4.7) [32.6 (6.3)]	
Cuff For Test Device	S	15 [11]	
	M	21 [24]	
	L	8 [10]	
	XL	1 [0]	
Upper Arm Circumference (cm)	Range (low : high)	24:40 [21 : 37]	
	Mean (SD)	28.6 (3.3) [27.2 (4.1)]	
Validation BP (mmHg)		**SBP**	**DBP**
	Range (low : high)	92 : 168 [98 : 177]	56 : 105 [47 : 112]
	Mean (SD)	135.6 (16.8) [133.9 (19.8)]	80 (14.4) [81.8 (15.2)]
Pregnancy State WOP + Day	Range (low : high)	23 + 0 : 41 + 4 [21 + 0 : 41 + 0]	
	Group 1	16 [16]	
	Group 2	14 [15]	
	Group 3	15 [14]	

Abbreviations: SD: Standard Deviation, WOP: Week of Pregnancy

Table 4: Blood pressure distribution. Data without square brackets apply to recruitment with rectangular cuffs and data with square brackets apply to recruitment with conical cuffs.

SBP [mmHg]		DBP [mmHg]	
SBP	7	DBP	15
≤ 100mmHg	[8]	≤ 60mmHg	[21]
SBP	51	DBP	57
≤ 140mmHg	[67]	≥ 85mmHg	[72]
SBP	8	DBP	8
≥ 160mmHg	[9]	≥ 100mmHg	[11]

Validation Results

Table 5 and Table 6 show the validation results according to the standard ISO 81060-2. The standard requires that the mean deviation of BP has to be in the range of -5.0 ≤ MV ≤ 5.0mmHg and the standard deviation is less than or equal to 8.0mmHg.

Figure 2 and Figure 3 visualize the measurement deviation of the systolic as well as diastolic test device readings compared with auscultatory reference measurements. The vertical solid line in Figure 2 and Figure 3 mark the mean value of the reference blood pressure values (blue - rectangular cuffs / red - conical cuffs). These values are in in accordance with Table 3 "Validation BP". The horizontal line in Figure 2 and Figure 3 mark the mean value of the measurement accuracy of the test device. These values are in accordance with Table 5 and Table 6.

The SBP Bland-Altman plots (see Figure 2) and the DBP Bland-Altman plots (see Figure 3) show the nearly even distribution of the blood pressure values. Table 7 and Table 8 are showing the measurement accuracy for SBP (DBP) that was obtained for the individual subgroups.

The distribution of the blood pressure values fulfills the requirements of the validation standard. All activities within the clinical study were done according to the clinical investigation plan without any deviation and in accordance with the declaration of Helsinki. The usage of the test device was in accordance with intended purpose and intended use of the test device. All participants were informed and in writing consented to the measurements.

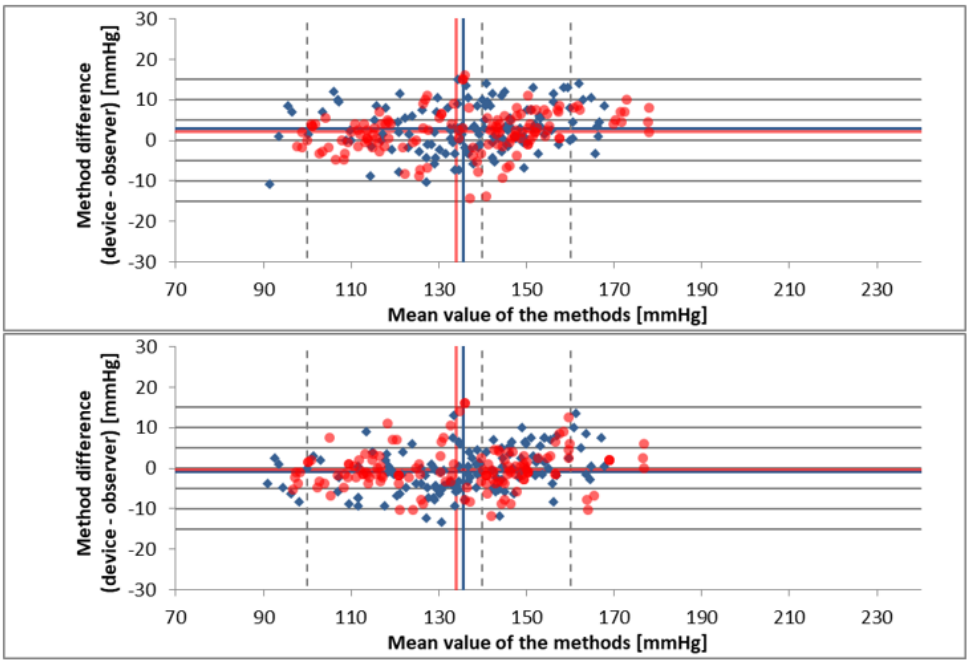

Figure 2: Bland-Altman plots of the SBP readings of Sonicaid Team3 fetal monitor compared with auscultatory reference measurements. Upper plot is for DMT algorithm and lower plot is for IMT algorithm. The blue squares represent measurements with rectangular cuffs and the red circles represent measurements with conical cuffs.

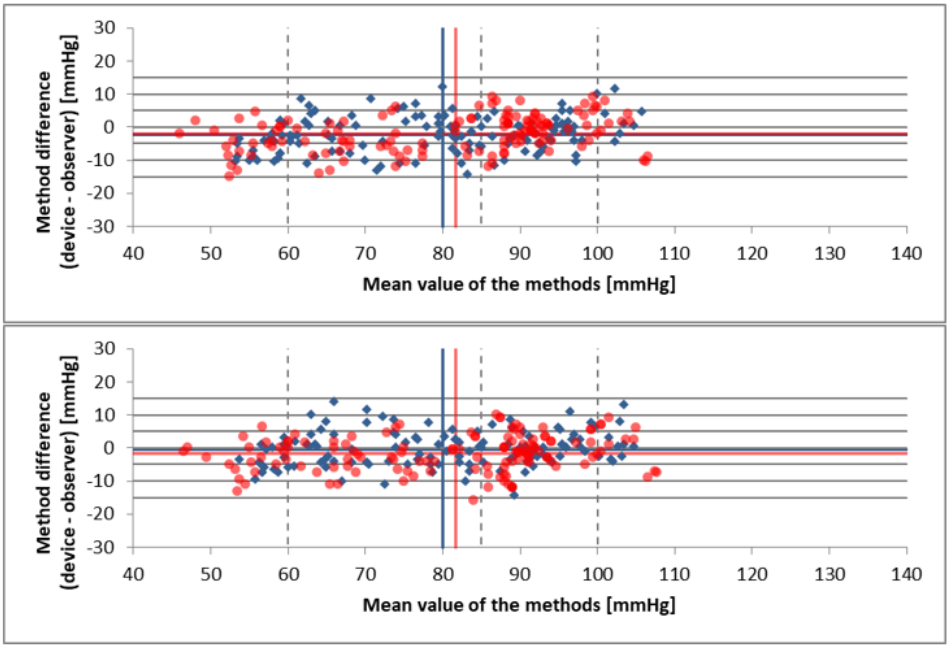

Figure 3: Bland-Altman plot of the DBP readings of Sonicaid Team3 fetal monitor compared with auscultatory reference measurement. Upper plot is for DMT algorithm and lower plot is for IMT algorithm. The blue squares represent measurements with rectangular cuffs and the red circles represent measurements with conical cuffs.

Table 5: Validation results for DMT algorithm. Data without square brackets apply to recruitment with rectangular cuffs and data with square brackets apply to recruitment with conical cuffs.

Parameter			Requirement
SBP	MV	2.9 [2.1]	-5.0 ≤ MV ≤ 5.0
	SD	5.7 [5.2]	≤ 8.0
DBP	MV	-2.3 [-2.1]	5.0 ≤ MV ≤ 5.0
	SD	5.5 [5.4]	≤ 8.0

Abbreviations: MV: Mean Value

Table 6: Validation results for IMT algorithm. Data without square brackets apply to recruitment with rectangular cuffs and data with square brackets apply to recruitment with conical cuffs.

Parameter			Requirement
SBP	MV	-0.8 [-0.3]	-5.0 ≤ MV ≤ 5.0
	SD	5.4 [5.1]	≤ 8.0
DBP	MV	-0.4 [-1.7]	5.0 ≤ MV ≤ 5.0
	SD	5.2 [5.4]	≤ 8.0

Abbreviations: MV: Mean Value

Table 7: Validation results for IMT algorithm. Data without square brackets apply to recruitment with rectangular cuffs and data with square brackets apply to recruitment with conical cuffs.

Conical Cuffs		DMT	IMT
Group 1	SBP	0.7 ± 3.2	-0.7 ± 3.9
	DBP	-4.0 ± 4.7	-3.2 ± 4.5
Group 2	SBP	2.1 ± 6.5	-1.0 ± 6.1
	DBP	0.1 ± 4.0	-0.3 ± 4.7
Group 3	SBP	3.5 ± 5.1	0.7 ± 5.1
	DBP	-1.0 ± 6.1	-1.6 ± 6.6

Table 8: Measurement accuracy of the conical cuffs for the different subgroups of the patient population and measurement methods.

Rectangular Cuffs		DMT	IMT
Group 1	SBP	3.3 ± 6.0	-2.0 ± 4.6
	DBP	-1.3 ± 5.8	0.0 ± 5.8
Group 2	SBP	3.7 ± 5.4	0.3 ± 5.7
	DBP	-0.8 ± 3.9	0.9 ± 4.6
Group 3	SBP	1.6 ± 5.5	-0.5 ± 5.7
	DBP	-4.6 ± 5.7	-1.9 ± 4.7

Discussion

The presented data confirmed the safety and performance of NIBP2020 UP blood pressure measurement technology according to standard ISO 81060-2 requirements. The primary and secondary endpoint for all configurations was reached. The test device fulfills the accuracy requirements of the standard ISO 81060-2 for the special patient group pregnant and pre-eclamptic women and during the clinical study no new risks for patient, user or third parties were identified. No adverse events happened during the clinical study. Consequently, no corrective or preventive actions were necessary. The benefit-risk analysis is still valid and no further risk control measurements have to be implemented into the test device.

No device defects happened during the study. The test device was all the time available for the study physicians. Three patients had to be excluded from the study, one because of observer disagreement and two because of high blood pressure variation. Nevertheless, a sufficient number of patients were available to meet the requirements of the standard. The clinical data illustrate a good agreement between observer reference and test device. The measuring accuracy is not significantly influenced by the type of cuff. For all subgroups the accuracy requirements are met. The data for the different cuff types were collected from different patients, but the two patient populations were very similar, as shown in Table 3 and Table 4 in Section 6. The mean age differed by only 1.1 years in a range of 19-44 years, the mean upper arm circumference differed by only 1.4cm in a range of 21- 40cm, the mean systolic blood pressure differed by 1.7mmHg and the mean diastolic blood pressure differed by 1.8mmHg. The blood pressure distribution was also comparable in both collectives. Thus, a comparison of the data sets of the two cuff types can be made. Rectangular and conical cuffs provide similar results if they are applied correctly. The conical cuffs are easier to apply correctly due to the D-ring, as this allows the cuff to be applied evenly over the entire upper arm area. In addition, women have a slightly more pronounced conical shape of the upper arm [5], which is why conical cuffs are easier to apply to female patients.

Conclusion

NIBP2020 UP that uses DMT and IMT algorithm from PAR passed all applicable requirements of the standard ISO 81060-2. Therefore, the module is recommendable for the measurement of blood pressure in the special patient group pregnant and pre-eclamptic woman, if the provided cuffs fit for the patient's upper arm.

Clinical Study Management Structure

The clinical study was conducted under the supervision of Prof. Dr. med. Michael Abou-Dakn (Medical Director and Head Physician of the Clinic for Gynecology and Obstetrics) [6] at St. Joseph hospital (Germany).

Declaration of Conflicts of Interest

The manufacturer provided the test device including accessories and technical assistance in the use of the test device. The manufacturer did not offer any financial incentives for the conduct of the study, neither for the validation team nor for the patients studied. All activities were done for scientific motives with patients voluntarily participating.

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