ARTICLE

Validation of combiomed hipermax-BF model A7101 automatic oscillometric upper-arm sphygmomanometer in general population: AAMI/ESH/ISO universal standard (ISO 81060-2:2018/Amd 1:2020)

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This study evaluates the accuracy of the Hipermax-BF model A7101 (Combiomed, Havana, Cuba) automatic oscillometric upper-arm sphygmomanometer for office and home use in general population as part of the HEARTS in the Americas initiative. The research was developed according to the Universal Standard AAMI/ESH/ISO ISO 81060-2:2018/Amd 1:2020. The subjects were recruited according to the requirements of age, gender, blood pressure values and upper-arm circumference. The same upper-arm sequential blood pressure measurement method was used. For measurements with the device under test, the 2-piece cuff from 22–44 cm limb circumference range was used. 92 subjects were recruited and 85 were analyzed. Mean age was 44.8 ± 14.7 years, mean upper-arm circumference was 32.3 ± 6.2, and 56.5% were female. For Validation Criterion 1, the mean value ± standard deviation of the differences in readings between the device under test and the reference device was 1.2 ± 4.9/0.8 ± 4.9 mmHg (systolic/diastolic). For both pressures, in criterion 1 the standard requires a mean value of the differences ≤ ± 5 mmHg and a standard deviation ≤ ± 8 mmHg. For Validation Criterion 2, the standard deviation of the mean blood pressure differences per subject was 4.2/4.2 mmHg (systolic/diastolic). According to Table 1 of criterion 2, for the mean values of 1.2/0.8 mmHg (systolic/diastolic), the maximum allowable standard deviation had to be < 6.84 for systolic and < 6.89 for diastolic pressure. The Combiomed Hipermax-BF A7101 automatic sphygmomanometer meets the requirements of the AAMI/ESH/ISO Universal Standard (ISO 81060-2:2018/Amd 1:2020) in the general population.

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INTRODUCTION

Hypertension is the leading modifiable single risk for death [1]. The accuracy of blood pressure assessment, including the use of validated blood pressure devices, is the cornerstone, both for the diagnosis of hypertension and for monitoring the control of diagnosed patients [2]. One of the main problems facing clinicians in clinical practice, as well as patients, is the widespread use of non-validated devices to measure blood pressure and the general lack of knowledge about the availability of accurately validated devices [3, 4]. Moreover, the widespread sales of non-validated blood pressure monitors globally, typically at a lower price relative to validated devices [5, 6], adds to the difficulties that developing countries face. Consequently, they need to strengthen the capacity to conduct clinical validation tests using internationally accepted protocols and to promote a transparent and rigorous regulatory environment to use, market, and distribute validated accurate blood pressure devices. Related to this is the importance of having the local devices potentially included on international lists of validated devices [4].

The HEARTS initiative in the Americas, led by the Ministries of Health with the technical support of the Pan American Health Organization (PAHO) [7, 8] was initiated to enhance the capacity and capability of countries of the Americas to develop hypertension and cardiovascular diseases control programs using global best practices. PAHO/WHO and the World Hypertension League have emphasized the need for accurate validated BP devices. The magnitude of misdiagnosis when blood pressure is not properly assessed is large [9, 10].

This study evaluated the accuracy of blood pressure (BP) measurement with the Hipermax-BF A7101 automatic oscillometric upper-arm sphygmomanometer (Combiomed, Havana, Cuba) in the general population, developed for the measurement of BP in the office and in home. The methodology of the Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) Universal Standard (ISO 81060-2:2018/Amd 1:2020) [11–14].

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Table 1. Participants recruited and excluded from the analysis.

Inclusion and exclusion of	Number of participants
Recruited	92
Excluded	7
Reasons for exclusion:	
a) Reference BP variability >12/8 mmHg (systolic/diastolic)	2
b) Anxiety attack[a]	1
c) Frequent arm movements during measurement[a]	4
Analyzed	85
Characteristic (n = 85)	Mean ± SD (Range)
Age (years)	44.8 ± 14.7 (13–71)
Gender (male/female)	37/48 (43.5%/56.5%)
Arm circumference (cm)	32.3 ± 6.2 (22–44)
Initial SBP R0 (mmHg)	120.9 ± 19.2 (90–173)
Initial DBP R0 (mmHg)	78.1 ± 11.5 (58–110)
HR (l/m)	75.6 ± 11.2 (44–15)

Characteristics of the participants.
[a]Measurements were made during the pandemic period. Despite the informed consent of the participants was obtained and the previous preparation for the tests was done, in some of them manifestations of fear of getting sick with Covid or behavioral consequences of isolation were detected, unrelated to the purpose of the study.

METHODS AND MATERIALS

Expertise

For the development of the research, the Cuban Ministry of Public Health (MINSAP) designated the Institute of Cardiology and Cardiovascular Surgery (ICCCV) as the authorized academic institution and research site. Specialists with experience in the use of automatic devices from the ICCCV, the "General Calixto García" University Hospital and the "América Arias" Gynecobstetric Hospital were selected. The acting professionals were certified in relation to the Universal Standard (ISO 81060-2:2018/Amd 1:2020) in an international training for the clinical validation of automatic sphygmomanometers, led by experts from the University of Alberta, Canada (WHO-PAHO Technical Cooperation); and they are part of the Group for the conduct of clinical validation studies of automatic sphygmomanometers approved by the National Technical Advisory Commission for Arterial Hypertension of MINSAP.

Approval of the study

Ethics approval was obtained from the Advisory Committee and the Research Ethics Committee of the ICCCV. The study was registered on February 4, 2022 in the Cuban Public Registry of Clinical Trials (RPCEC) under registration number RPCEC00000400. Its execution was authorized by the National Center for Clinical Trials (CENCEC) of the Ministry of Public Health of Cuba. Regarding compliance with Good Clinical Practices, the clinical research plan [15] and current regulatory requirements were verified by the Cuban regulatory authority, the State Center for the Control of Medicines, Equipment and Devices (CECMED), a WHO collaborating center. This institution approved the protocol presented for the execution of the trial in humans and audited the documentation and development of the trial, to verify its validity and quality. In all cases, the ethical principles of the Declaration of Helsinki were respected and the informed consent of the participants was obtained.

Device under test

The Hipermax-BF is an automatic oscillometric upper-arm device for blood pressure measurement developed, according to its accompanying documentation, for the measurement of blood pressure of adults at home or by qualified medical personnel in the hospital. The device has a 2-piece, wide-range cuff for an upper-arm circumference of 22–44 cm, which was used in the validation study according to the manufacturer's instructions It is capable of maintaining 2 sets of memory data, with 60 measurements each. The device does not have built-in Bluetooth connectivity. Two identical devices were provided by the manufacturer for the validation study, along with a written statement that they were standard production models. One of them was randomly selected for the validation procedure.

Participants

As per the AAMI/ESH/ISO Universal Standard ISO 81060-2:2018/Amd 1:2020 for a general population validation study of a blood pressure monitor requires, 85 subjects older than 12 years, with 30% representation of each gender were enrolled. Subjects were recruited from patients attending the outpatient clinic and research site staff.

As inclusion criteria, subjects over 12 years of age were selected, with blood pressure values in the range of SBP 80–220 mmHg and DBP 50–120 mmHg. Pregnancy, the presence of arrhythmias and subjects with non-audible Korotkoff K5 sound were considered exclusion criteria. The universal standard also defines the criteria in terms of: distribution by sex, blood pressure ranges and sample distribution according to the upper-arm circumference of the participants.

Validation team

The study was conducted by a supervisor and 2 trained observers experienced in blood pressure measurement research and were standardized for agreement on BP measurement before the start of the study.

Reference blood pressure

Rubber tubes and a Y-connector were used to connect to a single mercury sphygmomanometer, so both observers shared the same inflation system. The mercury sphygmomanometer used as the reference standard has a measurement range between 0–300 mmHg. Before the start of the study the mercury sphygmomanometer was verified in the Pressure Laboratory of the Metrology Research Institute (INIMET) by direct measurement according to the Cuban Standard NC-599 Verification of Sphygmomanometers. Two examiners simultaneously used a double-headed stethoscope (3 M Littmann TM Classic II) and the mercury sphygmomanometer for the determination of reference pressures. Three reference cuffs (WelchAllyn) of 2 pieces with neoprene bladder of a tube in the measurements: Small Adult (20–29) cm, Adult (29–42) cm and Large Adult (34–52) cm were selected according to the upper-arm circumference of the participating subjects (2,3). These bracelet measurements brought with them an overlap between the reference bracelet sizes. In the case of patients with upper-arm sizes where it was possible to use two of the cuff measurements purchased for the study, the cuff in which the patient's upper-arm size occupied the central region of its range was selected.

Process

The sequential method was applied in the same upper-arm, which includes 2 initial blood pressure measurements (reference R0 and device under test T0) followed by 4 reference measurements (R1, R2, R3, R4) taken alternately with 3 measurements of the test device (T1, T2, T3). All measurements were taken on the right upper-arm with an interval of 60 s A screen was used that allowed the separation between observers, the individual and the supervisor and prevented the visualization of the results between them, as well as visual contact with the subject. The supervisor recorded the test device measurements and verified the observer measurement data. In case of disagreement between the observers, additional pairs of measurements were made. A maximum of 8 pairs of blood pressure measurements were allowed after which the subject was excluded.

Analysis

The requirements of the AAMI/ESH/ISO Universal Standard (ISO 81060-2:2018/Amd 1:2020) were strictly followed.

RESULTS

Ninety-two subjects were evaluated, 85 were analyzed and 7 were excluded.

The causes of exclusion and the characteristics of the participants are shown in Table 1. The requirements for age, sex, BP values and upper-arm diameter distribution were met.

The mean difference ± standard deviation of BP from simultaneous measurements by both observers was 0.1 ± 1.3/−0.1 ± 1.4 mmHg

Table 2. Distribution of baseline blood pressure measurements (n = 255).

Reference pressures (n = 255)							
SBP requirement		**Achieved**		**DBP requirement**		**Achieved**	
5%	SBP ≤ 100 mmHg	13.7%	Pass	5%	DBP ≤ 60 mmHg	5.1%	Pass
5%	SBP ≥ 160 mmHg	5.1%	Pass	5%	DBP ≥ 100 mmHg	5.5%	Pass
20%	SBP ≥ 140 mmHg	20%	Pass	20%	DBP ≥ 85 mmHg	25.1%	Pass

Table 3. Compliance with the amendment of the standard on the distribution of arm diameters.

Arm circumference (mínimum % per Amendment 1)						
Arm circumference requirement			**Achieved**		**Arm circumference requirement**	**Achieved**
Lower octile	0.10	22–24.75	14.1%	Pass	1/4 Total range 20%	29.4%
	0.10	24.76–27.5	15.3%		22–27.5	Pass
	0.20	27.6–32.9	24.7%	Pass	1/4 Total range	
	0.20	33–38.4	21.2%	Pass	1/4 Total range	
	0.10	38.5–41.24	12.9%		1/4 Total range 20%	24.7%
Upper octile	0.10	41.25–44	11.8%	Pass	38.5–44	Pass

(systolic/diastolic) with a range of (−3.5 to 4)/(−3 to 3) mmHg (systolic/diastolic). There were 54 readings with differences between observers >4 mmHg, which were repeated until agreement was achieved, without exceeding 8 pairs per subject.

The distribution of reference BP measurements is presented in Table 2. The criteria of Amendment 1 of the standard on the distribution of upper-arm diameters are met as shown in Table 3. The analysis of the validation results is summarized in Table 4. Validation criteria 1 and 2 established by the standard were met, both for systolic and diastolic pressure.

Standardized scatter plots of the differences in measurement and upper-arm circumference are shown in Figs. 1, 2. Standardized Bland-Altman scatter plots of the differences in BP measurement methods against their average are shown in Figs. 3, 4.

Table 4. Results of the validation study.

Standard criteria	Requirement to meet	Obtained	
		SBP	**DBP**
Criterion 1 (n = 255 measurements)			
Mean value of BP differences (mmHg)	≤ ± 5	1.2	0.8
SD (mmHg)	≤8	4.9	4.9
		Pass	Pass
Criterion 2 (n = 85 subjects)			
SD (mmHg, SBP/DBP)	≤6.84/6.89	4.2	4.2
		Pass	Pass
Overall result	Pass		

DISCUSSION

This study shows that the Combiomed Hipermax-BF A7101 automatic upper-arm sphygmomanometer met the accuracy criteria of the AAMI/ESH/ISO Universal Standard (ISO 81060-2:2018/Amd 1:2020) in the general population and can be recommended for clinical use. The device was validated in the general population and additional validation is necessary for its use in special populations.

Hipermax-BF A7101 could be used by patients at home. Health professionals also use them in-office blood pressure measurements based on its reliability and compliance with the repeatability of the measurements, that is guaranteed with the verification carried out on the equipment, according to the requirements of the National Standardization Office. The device is classified as a simple type [16], because to use it must be activated by an individual, either the healthcare professional or the patient. It does not have the delay mechanism before starting the measurement that allows its sequential programming to facilitate unattended evaluations [17, 18].

Currently, in many countries of the Americas, the use of aneroid devices prevail despite recommendations to adopt accurate validated devices since 2004 [19, 20]. HEARTS in the Americas promotes the transition to best practices in the technique of measuring blood pressure and the use of automated measurements [7, 21]. At the same time, some countries have been identified that have the capacity for production of automated blood pressure devices, which would allow expanding their own national coverage and of other countries in the region.

Cuba, one of the initial HEARTS implementing countries has developed a medical technology industry that produces automated blood pressure devices for use in the office and at home, as well as devices for ambulatory blood pressure monitoring. This validation expertise can also be applied to automated devices produced or imported by developing countries of the Americas, for the wider benefit of the region, and have the devices placed on internationally recognized lists of validated devices [4]. That´s why Cuba's contribution, both in providing training and in conducting validation studies, is so relevant.

As an additional comment, in 2024 a new amendment to ISO 81060:2 was published [22]. This Clinical Trial was executed on a previous date and the manuscript was under review at the time of publication of amendment 2. However, after analyzing its content, the authors consider that there are no major methodological differences, mainly because the device under test uses a single bracelet. The new established parameters

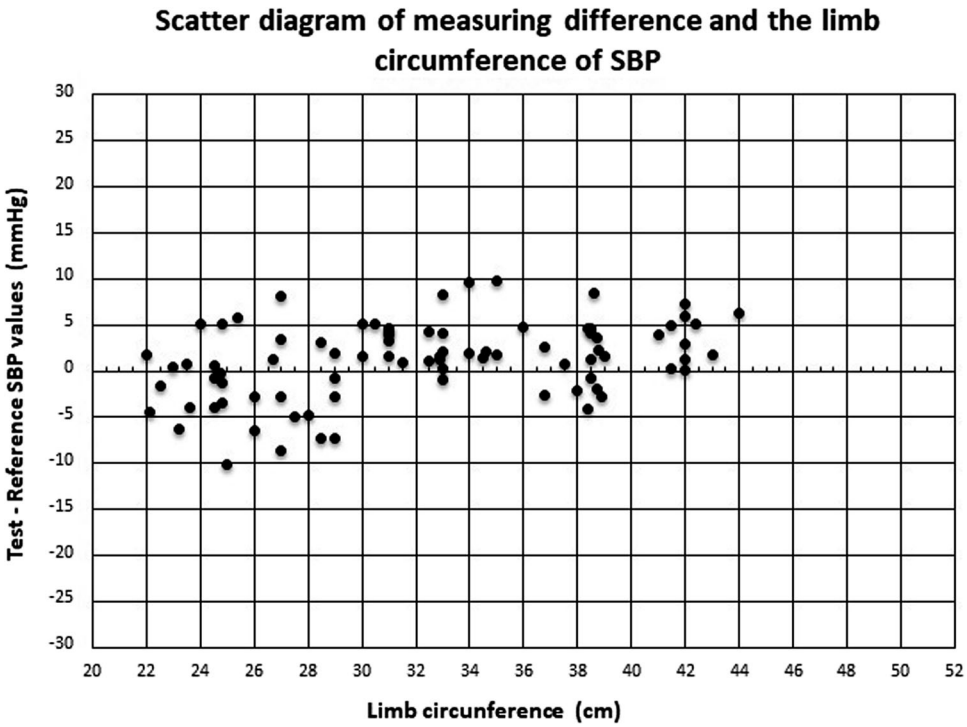

Fig. 1 Standardized scatter plots of the differences in measurement and the limb circumference for Systolic Pressure.

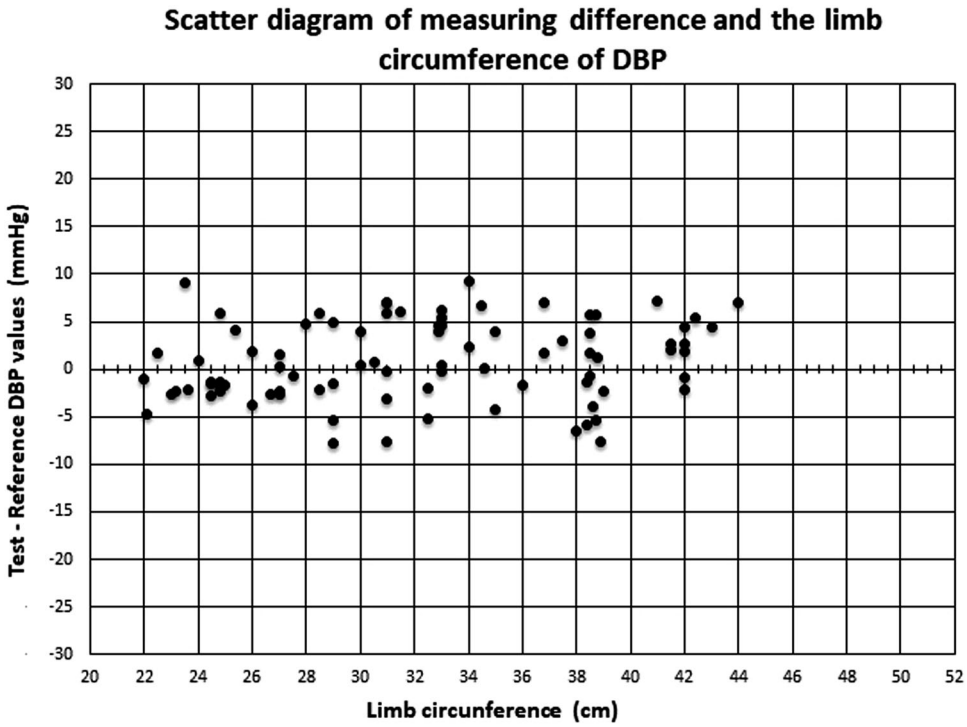

Fig. 2 Standardized scatter plots of the differences in measurement and the limb circumference for Diastolic Pressure.

will be taken into account in the design of the new planned studies.

Considering that most of the devices marketed today worldwide and those used in health services are not validated, it would be essential to ensure that the devices used are accurate. Countries would be aided by procurement policies that only allow the purchase of validated devices and regulations restricting the marketing and sales of non-validated devices [23, 24]. The creation of a Latin American and Caribbean list of validated devices could be advantageous. It is critical to enhancing

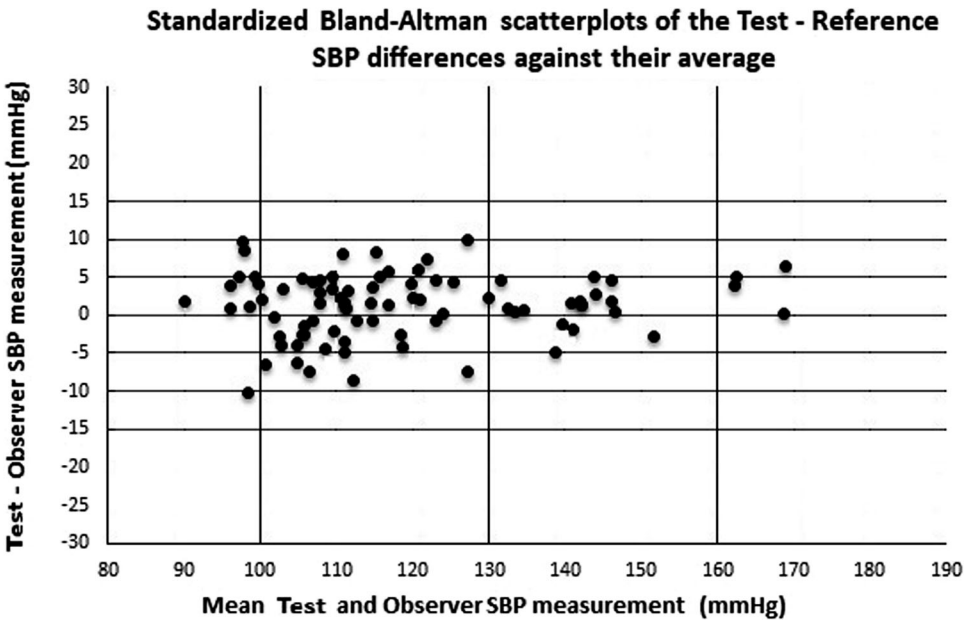

Fig. 3 Standardized Bland-Altman scatterplots of the Test—Reference Systolic BP differences against their average.

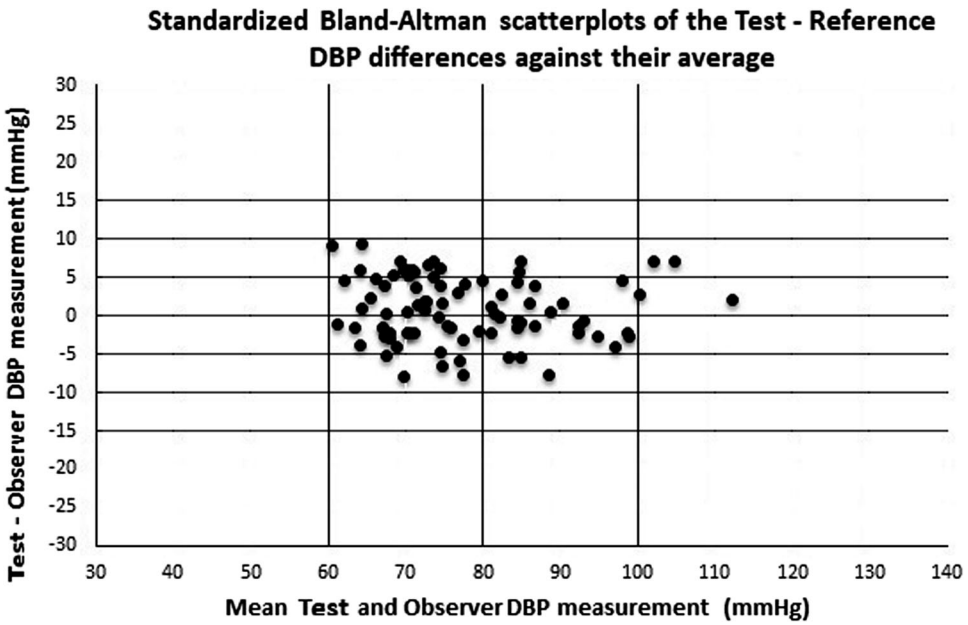

Fig. 4 Standardized Bland-Altman scatterplots of the Test—Reference Diastolic BP differences against their average.

consumer and healthcare professional awareness of this issue to ensure accurate blood pressure measurement.

SUMMARY

What is known about topic

- For proper diagnosis and control of high blood pressure, it is necessary to have accurate measuring devices.
- Automatic sphygmomanometers facilitate records in health institutions and at home, but few models have been subjected to clinical validation studies.
- There is a Universal Standard that systematizes the procedures of clinical validation studies of automatic sphygmomanometers.

What this study adds

- The results of the first validation study of automatic sphygmomanometers in Cuba, carried out as part of the HEARTS initiative in the Americas, are shown.
- The design, execution and reporting of a Clinical Trial is put into practice in accordance with the AAMI/ESH/ISO Universal Standard (ISO 81060-2:2018).

DATA AVAILABILITY

The data analyzed during this study are available in the Cuban Public Registry of Clinical Trials. https://rpcec.sld.cu/.

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AUTHOR CONTRIBUTIONS

DHV conceived the original idea, designed the procedures according to the standard, collected data, helped write the manuscript. YVG conceived the original idea, designed the procedures according to the standard, collected data, helped write the manuscript. NAR designed the procedures according to the standard, participated in data extraction and processing, provided comments on the report. RDLNG designed the procedures according to the standard, collected data, helped write the manuscript. JR provided comments on the Clinical Investigation Plan design and experimental issues according to the standard, advised data collection/processing and provided comments on the report. RP provided comments on the Clinical Investigation Plan design and experimental issues according to the standard, advised data collection/processing and provided comments on the report.

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COMPETING INTERESTS

The authors declare no competing interests.

ETHICAL APPROVAL

In all cases, the ethical principles of the Declaration of Helsinki were respected and the informed consent of the participants was obtained.

ADDITIONAL INFORMATION

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