Clinical evaluation report of Automatic Pulsewave Blood Pressure Monitor

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Contents

1. Product summary

Product name: Automatic Pulsewave Blood Pressure Monitor

Product model: RBP-7000、RBP-7000B、RBP-7000G

Supplier: iDoctorCloud Technology Co., Ltd

2. Description of the product and its intended applications

2.1 Intended applications

Automatic Pulsewave Blood Pressure Monitors is suitable for measuring blood pressure and pulse rate of people above 12 years older in hospital, social medical organizations and etc, not suitable for infants or young children. Pregnant women and mental disorder patients should be used under the guidance of a doctor or a healthcare provider.

2.2 Product description

Automatic Pulsewave Blood Pressure Monitor is classified to class IIa according to Annex IX of directive 93/42/EEC for Medical Device. It belongs to class II, AC power supply, and type B, continuous operation equipment classified by safety standards.

The monitor consists of mainframe and the cuffs. The cuffs direct contact human body with short time, usually a few minutes. The material of the cuffs has passed the biocompatibility test, harmless to human body. The basic functions of all models are measuring blood pressure and pulse rate; All models have a manual shutdown, 30 seconds automatically shutdown, manual pressure, low-voltage prompts and error prompts.

It utilizes upper arm cuff plus the downstream pulse wave detection method, which can accurately measure human systolic and diastolic blood pressure with measurement accuracy of ± 2 mmHg, much higher accuracy than other similar electronic blood pressure monitors on the market, their accuracy generally of ± 4mmHg.

The monitor has obtained the national invention patents, and has applied for invention patents of the overseas' major markets such as the United States, Russia, the United Kingdom, Germany, Canada, Japan, South Korea, and etc.

3. Evaluation background and choice of clinical data types

3.1 Evaluation background

Blood pressure is one of the major medical parameters of human beings. Non-invasive blood pressure measurement is the most commonly used method of blood pressure check, including Korotkoff sound

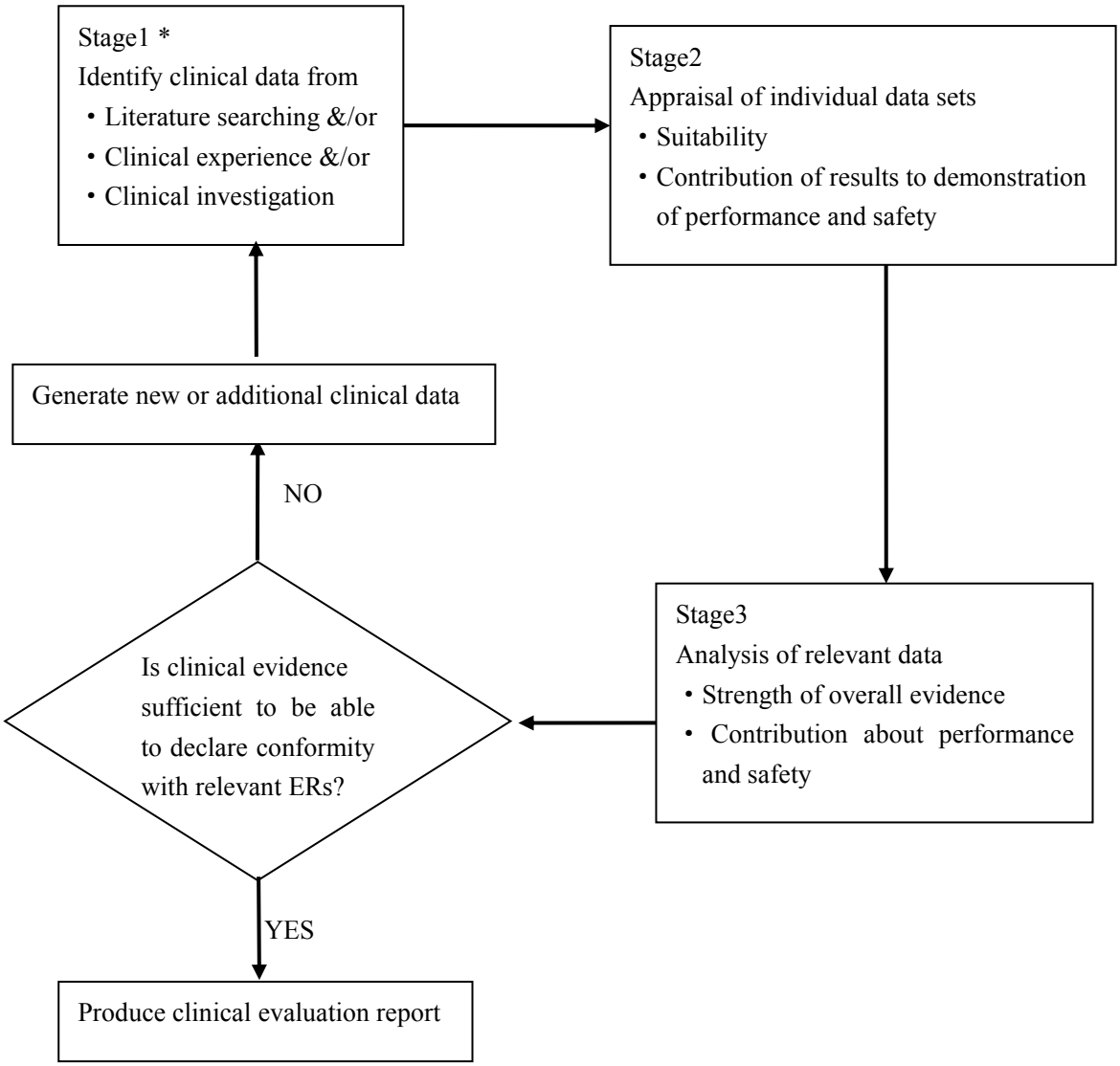
stethoscope applied in a mercury sphygmomanometer and oscillometric method applied in most of electronic sphygmomanometers. Korotkoff sound stethoscope is a simple method, and the disadvantage is that different people may get different measurement results, sometimes the difference is very significant, and the main reasons are: 1) the discontinuity of heartbeat can cause a mercury drop height to have an unavoidable error between two consecutive heartbeats; 2) when the blood flow is merely a trickle of flow, Korotkoff sound is not necessarily produced so that a user is unable to determine an emergence time of the characteristic sound while listening; 3) observing a mercury manometer often have an visual error while listening; 4) Identification of an emergence time of the characteristic sound while listening is relative to skill and proficiency; 5) pressure relief speed is likely to deviate from international standards for about 3~5mmHg/sec to produce an error. Oscillometric method is a state-of-the-art electronic measurement method, the systolic and diastolic blood pressure are estimated based on the average pressure and the empirical coefficient to cause relatively large individual differences; the discontinuity of heartbeat also leads gasbag pressure drop between two consecutive heartbeats to produce an error; body movement, cuff vibration, gas tube vibration, gas tube rigidity and pressure release speed will affect the correctness of the measurement results.

Automatic Pulsewave Blood Pressure Monitor compensates for the defects of the above-mentioned disadvantages, utilizes the upper arm cuff plus downstream pulse wave detection methods, changes the non-continuous blood pressure check into a continuous measurement. On the one hand, based on the substantially linear variation of the amplitude of measured pulse wave near the systolic blood pressure; to alternate analyzing the Korotkoff sound process from scratch and to avoid the possible errors caused by the non-continuity and inevitable heart beat, this new method can accurately measure the systolic blood pressure; On the other hand, based on the time characteristic of the delay time between the measured pulse wave and its correspondent air pressure AC signal near the diastolic blood pressure, to alternate the Korotkoff sound processing, and to avoid the non-contiguous inevitable error by the heart beats, this innovative method can accurately detect the diastolic blood pressure.

Research and evaluation literatures concerned sphygmomanometer. RG-BPⅡ8000、RG-BPⅡ5800、RG-BPⅡ3800、RG-BPⅡ2800、RG-BPⅡ1800 Pulsewave Blood Pressure Monitors have gotten positive feedbacks from users, without the occurrence of any adverse events, which can prove the efficiency and safety of RBP-7000、RBP-7000B、RBP-7000G Automatic Pulsewave Blood Pressure Monitor.

3.2 Clinical appraisal stage

Divide the clinical stages and carry out the clinical evaluation according to the following process.



*Conformity to harmonized performance standard may be sufficient go demonstrate compliance to relevant Essential Requirements (ERs)

3.3 Literature search

3.3.1 Literature search range

Literature covered security, performance, and adverse event information of Sphygmomanometer.

3.3.2 Literature search methods

(1) literature sources:

a） Academic literature general stores, namely, network of Chinese academic literature publishing general stores on China National Knowledge Infrastructure (http://www.cnki.net/)

b） http://journals.lww.com/bpmonitoring/pages/default.aspx

c） Adverse event report databases(e.g. MAUDE,IRIS)

d） America FDA website

e） China SFDA website

(2) Retrieve details:

- Keywords retrieved are as follows:
  1） “pulse wave” or “pulsewave”
  2） “blood pressure”
  3） “continuous”
  4） “adverse event”
- Medium: Computer and network

(3) Literature selection standards

According to its relativities to clinic evaluation literature to conduct the primary screening

3.3.3 Literature search outputs

1) Literatures highly related to items to be assessed, reference literature index 9

2) Information about no adverse event occurred anywhere

4. The clinical data of equivalent products

RG-BP Ⅱ8000、RG-BP Ⅱ5800、RG-BP Ⅱ3800、RG-BP Ⅱ2800、RG-BP Ⅱ1800 have got the CE certificate at 2014 years. Comparing with RBP-7000、RBP-7000B、RBP-7000G，they have the same principle. So using RG-BP Ⅱ8000 series to make substantial equivalence assessment of RBP-7000、RBP-7000B、RBP-7000G Automatic Pulsewave Blood Pressure Monitor, the detail Comparative information for below table:

product name	Pulsewave Blood Pressure Monitor	Automatic Pulsewave Blood Pressure Monitor	/
model	RG-BP Ⅱ8000、RG-BP Ⅱ5800、RG-BP Ⅱ3800、RG-BP Ⅱ2800、RG-BP Ⅱ1800	RBP-7000、RBP-7000B、RBP-7000G	/
certificate	CE certificate	New products	/
manufacture	Shenzhen iDoctorCloud Technology Co., Ltd	Shenzhen iDoctorCloud Technology Co., Ltd	same
principle	The Automatic Pulsewave Blood Pressure Monitor adopts the pulse wave detection method, uses multi-point measurement instead of single point measurement, and makes use of the intrinsic relationship and	The Automatic Pulsewave Blood Pressure Monitor adopts the pulse wave detection method, uses multi-point measurement instead of single point measurement, and makes use of the intrinsic relationship and	same

	change rules of the points near the systolic and diastolic pressure to calculate the real systolic and diastolic pressure with the method of approximation and fitting. It realizes continuous measurement of the discontinuous events, that is to say, blood pressure value between two consecutive beats can be measured.	change rules of the points near the systolic and diastolic pressure to calculate the real systolic and diastolic pressure with the method of approximation and fitting. It realizes continuous measurement of the discontinuous events, that is to say, blood pressure value between two consecutive beats can be measured.	
Product Picture	 		The more pictures please see user manual
intended use	The Pulsewave Blood Pressure Monitor is suitable for people who are older than 12 years old in family, hospital, social medical organizations etc, not suitable for infants.	The Automatic Pulsewave Blood Pressure Monitor is suitable for people who are older than 12 years old in hospital, social medical organizations etc, not suitable for infants.	new products don't use in the family
Measurement Range	Pressure: 0-270(mmHg) (0-36[kPa]) Pulse Rate: 40/min-180/min	Pressure: 0-300(mmHg) (0-40[kPa]) Pulse Rate: 30/min-200/min	same
Accuracy	Pressure: ±3mmHg (±0.4kPa) Pulse Rate: ±5%	Pressure: ±2mmHg (±0.26kPa) Pulse Rate: ±2%	same
Power Supply	DC 6V（ 4 X AA batteries）and power adaptor DC 6V（Input：AC 100-240V，0.25A，50/60Hz,Output：DC6V，1A）	AC 100-240V，50-60Hz，1.6-0.8A	New products have passed safety and EMC test

Applicable Arm Circumference	S: (15cm – 22cm) M: (23cm – 32cm) L: (33cm – 42cm)	17-42 cm	/
Operating Temperature	5℃～40℃	5℃～40℃	same
Relative Humidity	15%RH～80%RH	15%RH～80%RH	same
Storage and Transportation Temperature	-20℃～+55℃	-20℃～+55℃	same
Relative Humidity	≤93%RH	≤93%RH	same
Air Pressure	80kPa～106kPa	80kPa～106kPa	same
Storage and Transportation Air Pressure	50kPa～106kPa	50kPa～106kPa	same
Shock Protection: Internal power source	BF TYPE	B TYPE	New products have passed safety and EMC test
Materials	Machine casing and external connectors are made by medical insulated rubber and non-toxic side effects of PC + ABS plastic, cuff materials are passed the biocompatibility tests.	Machine casing and external connectors are made by medical insulated rubber and non-toxic side effects of PC + ABS plastic, cuff materials are passed the biocompatibility tests.	same

Note: The comparison table involved in the details of the content see product user manual: Model: RBP-7000、RBP-7000B、RBP-7000G, , RG-ME-BPII8000, RG-ME-BPII5800, RG-ME-BPII3800, RG-ME-BPII2800, RG-ME-BPII1800

From the above table, compare with the model RBP-7000、RBP-7000B、RBP-7000G and RG-BPⅡ5800, RG-BPⅡ3800, RG-BPⅡ2800, RG-BPⅡ1800, RG-BPⅡ8000 Pulsewave Blood Pressure Monitor, it is clear that the product principle, intended use, key performance indicators, the main structure, basic functions, the software key algorithm are basically the same, the differences only exist on the power, the individual auxiliary functions and appearances. Therefore, we can determine they belong to the equivalent equipments, so the RBP-7000、RBP-7000B、RBP-7000G Automatic Pulsewave Blood Pressure Monitor have the same effectiveness and safety with RG-BPⅡ5800, RG-BPII-3800, RG-BPII 2800, RG-BP II1800 and RG-BP II8000.

5. Equipment test report

a) The safety test report of the RBP-7000、RBP-7000B、RBP-7000G, Automatic Pulsewave Blood Pressure Monitors（report No.: EED33K00019901）.

b) The EMC test report of the, RBP-7000、RBP-7000B、RBP-7000G, Automatic Pulsewave Blood Pressure Monitors (reports No.: EED32K00069901).

c) The cuff biocompatibility test report (reports No.: DY18050038、 DY18050039、DY18050040).

6. Appraisal of literature documents

6.1 Appraisal of literature applicability

Appraise initially the literature applicability according to the flow form 1 and chart 1

Form 1 Appraisal Criteria of Suitability

Suitability Criteria	Description	Grading System
Appropriate device	Was the data generated from the device in question	D1 Actual device D2 Equivalent device D3 Other device
Appropriate device application	Was the device used for the same intended use (e.g. methods of deployment, application, etc.)?	A1 Same use A2 Minor deviation A3 Major deviation
Appropriate patient group	Where the data generated from a patient group that is representative of the intended treatment population (e.g. age, sex, etc)and clinical condition(e.g. disease, including state and severity)?	P1 applicable P2 Limited P3 Different
Acceptable report/data	Do the reports or data contain sufficient information to be able to undertake rationale and object assessment?	R1 High quality R2 Minor deficiencies R3 insufficient information

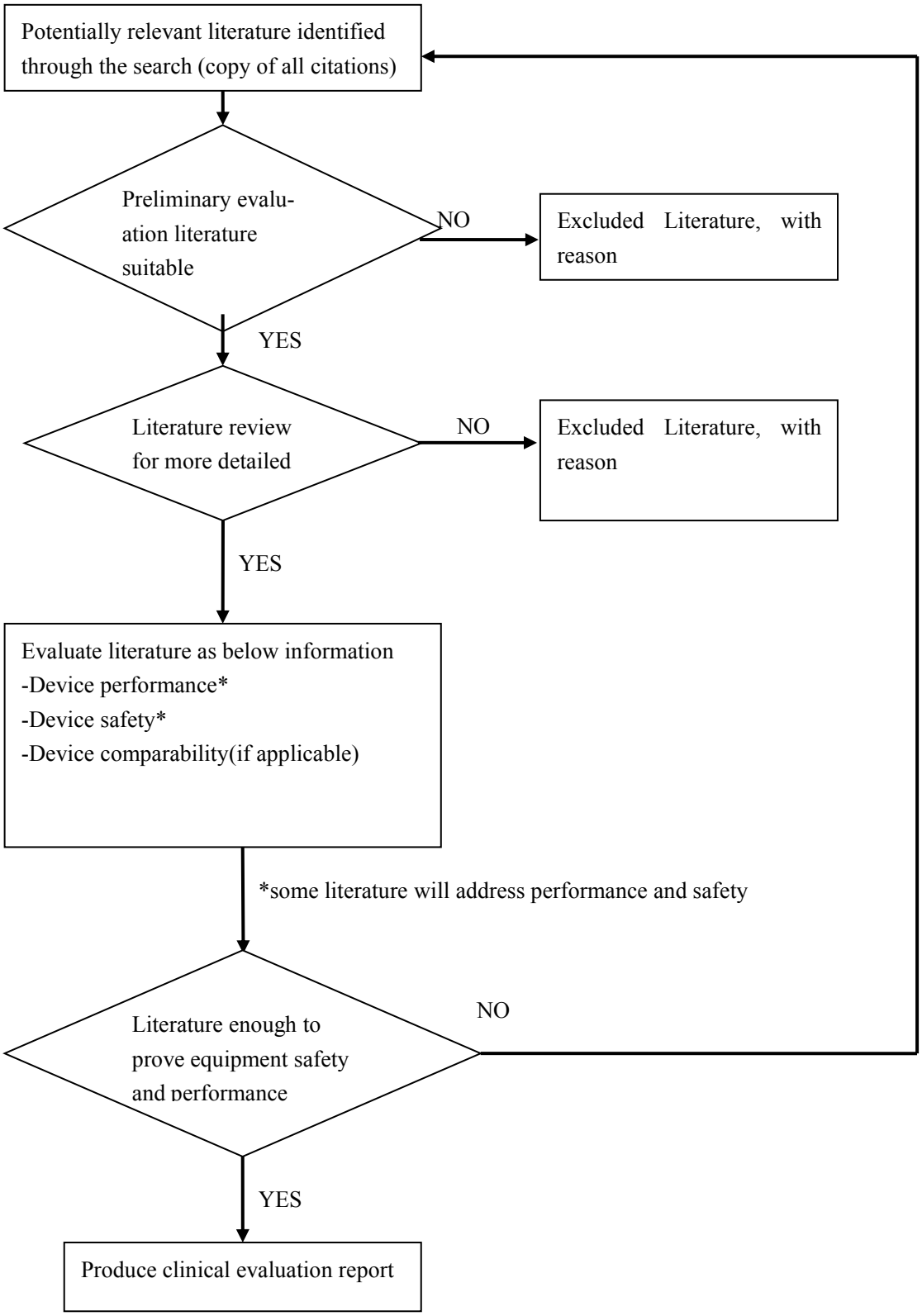


chart. 1

6.2 Literature summaries

(1) The Techniques of Non-invasive blood pressure measurement and Development

The Literature briefly introduced the history of the development of non-invasive blood pressure measurement technology, focusing on the principles and characteristics of today's non-invasive blood pressure measurements, including Korotkoff sound auscultation, oscillometric method and constant volume method. Moreover, it concluded the status of the blood pressure measurements in China and abroad, and the prospect of non-invasive blood pressure measurement technology trends.

Provided the relation between pulse wave and the discipline of cardiovascular blood flow is well understood and solved, the pulse wave method could be the best way to detect the vessel hemodynamics parameter; it could also provide the necessary basis for inventing a new medical device.

(2) A Noninvasive and Continuous Method for Blood Pressure Measurement Using the Characteristic Parameter of Pulse Wave

The method is realized by extracting the characteristic parameters of human brachial artery pulse wave and developing the stepwise regression equation. The experiment results showed that blood pressure measured by this method was well correlated with which measured by mercury sphygmomanometer. The mean difference of blood pressure was smaller than 3mmHg, and the standard deviation was smaller than 5mmHg.

(3) The development and clinical evaluation of blood pressure measuring instrument using the characteristic parameter of pulse wave

The blood pressure is an important medical parameter of human body. The pumping function of the heart, heart rate, peripheral vascular resistance, the aorta and the aorta elastic, systemic blood of the physical state and other factors are reflected in the indicators of the blood pressure, the correct detection of the blood pressure in clinical has great significance. How to use non-invasive, economical way to get accurate and reliable blood pressure parameters have constantly been an issue in biomedical engineering field. In this thesis, they upgraded the blood pressure measuring instrument from the points of hardware circuitry and software algorithms, and have made the following improvements:

1, using high resolution analog-to-digital converter as a signal detection circuit, and use the module for the core processor of the blood pressure measuring apparatus. It has integrated high-precision analog-to-digital converter and powerful analog part, also advanced on-chip digital peripherals, thus it becomes a powerful, simple structure, low power consumption, anti-interference ability system.

2, the complete hardware deflated protection circuit, from the hardware design to enhance human safety.

3, It has improved and accomplished the blood pressure software algorithms design by utilize pulse wave signal analysis, digital filtering algorithm, pulse detection algorithm, blood pressure fitting algorithm.

4, From the clinical assessment, the use of mercury sphygmomanometer carry out an assessment of this program by the interpretation of the algorithm systolic blood pressure and diastolic blood pressure values, and compare with the results of the mercury sphygmomanometer used, and adhere to the American sphygmomanometer standard SP10 experiment programs and statistical criteria, validated the availability of clinically of the design of this blood pressure measurement system.

(4) The experimental study of non-invasive continuous blood pressure measurement using characteristic parameters of pulse wave

Continuous blood pressure measurement can measure beat-to-beat blood pressure and continuous wave form of arterial blood pressure at a certain period of time. Therefore, this method can provide sufficient evidence for clinical diagnosis and it has important practical significance, especially in clinical monitoring and observing continuous change of blood pressure in some special conditions.

The blood pressure measurement using characteristic parameters of pulse wave is a rising method, which based on the theory that amplitude and form of pulse wave contain a great deal of important physiological information of

cardiovascular system. The measurement system designed with this method can get rid of the bondage of gasbag thoroughly and measure beat-to-beat blood pressure continuously and monitor the change of blood pressure wave for a long time. In order to analyze the correlation between blood pressure and characteristic parameters of pulse wave accurately, we choose the blood pressure values measured by intra-arterial catheter method as comparing standard in this study and provide experimental foundation for the noninvasive continuous blood pressure measurement using pulse wave.

Compared the difference between real blood pressure values and calculated blood pressure values, the conclusion indicates that the accuracy of this measurement is excellent in normal anesthetized condition.

（5）Continuous and Noninvasive Blood Pressure Measurement: A Novel Modeling Methodology of the Relationship between Blood Pressure and Pulse Wave Velocity

In this paper, we aim to establish a new mathematical model that relates pulse wave velocity (PWV) to blood pressure (BP) for continuous and noninvasive BP measurement. For the first time, we derive an ordinary differential equation (ODE) expressing the fundamental relation between BP, elastic modulus G and PWV. The general solution of this ODE is the mathematical BP-PWV model. In our model, the elastic modulus G is included in model parameters, unlike the existing theoretical models. This enables us to express the BP-PWV relationship for subjects of different ages and genders. A family of BP-PWV functions for specific age and gender groups can be obtained using statistical methods based on clinical trial data, which serve as the calibrated benchmark models for continuous and noninvasive BP measurement. To illustrate the modeling methodology, we construct benchmark models for people aged 19 and 60 and apply them to continuous diastolic blood pressure (DBP) measurement without individual calibration. The results of clinical tests meet the test standard in ANSI/AAMI SP10, which attests the feasibility of the modeling methodology.

7. Literature analysis

7.1 Analysis of literature contribution

Criteria	References	Data source	Description	Grading System
1.Electrical safety assessment	Safety test report	The safety test reports of the RBP-7000、RBP-7000B 、RBP-7000G Automatic Pulsewave Blood Pressure Monitors	Was the data generated from the device in question?	■D1 Actual device ☐D2 Equivalent device ☐D3 Other device
2.EMC assessment	EMC test report	The EMC test reports of the RBP-7000、RBP-7000B、RBP-7000G Automatic Pulsewave Blood Pressure Monitors	Was the data generated from the device in question?	■D1 Actual device ☐D2 Equivalent device ☐D3 Other device
3.Biological compatibility assessment	Biological compatibility test report	Biocompatibility test of the Arm type blood pressure monitor cuff manufactured by HUI ZHOU YING YI MOTOR Co., Ltd	Was the data generated from the device in question?	■A1 Same use ☐A2 Minor deviation ☐A3 Major deviation
4. Residual risk & potential risk assessment	Risk management report	The risk management report of the RBP-7000、RBP-7000B、RBP-7000G Automatic Pulsewave Blood Pressure Monitors	Was the data generated from the device in question?	■D1 Actual device ☐D2 Equivalent device ☐D3 Other
5.The applicability evaluation and clinical evaluation	Substantial equivalence comparison	Compare with the RG-BP Ⅱ 8000、RG-BP Ⅱ 5800、RG-BP Ⅱ 3800、RG-BP Ⅱ 2800、RG-BP Ⅱ 1800 Automatic Pulsewave Blood Pressure Monitor which have got CE certificate.	Was the data generated from the device in question?	☐D1 Actual device ■D2 Equivalent device ☐D3 Other device
			Was the device used for the same intended use?	■A1 Same intended use ☐A2 Minor deviation ☐A3 Major deviation

5.The applicability evaluation and clinical evaluation	Oscillo metric estimation of aortic pulse wave velocity: comparison with intra-aortic catheter measurements	Foreign literature	Was the device used for the same intended use?	■A1 Same intended use ☐A2 Minor deviation ☐A3 Major deviation
	Accuracy of the HoMedics Walgreens Deluxe Arm Blood Pressure device (WGNBPA-540) compared with auscultation in 85 individuals	Foreign literature	Was the device used for the same intended use?	■A1 Same intended use ☐A2 Minor deviation ☐A3 Major deviation
	Comparison of blood pressure measurements between an automated oscillometric device and a Hawksley random-zero sphygmomanometer in the northern Sweden MONICA study	Foreign literature	Was the device used for the same intended use?	■A1 Same intended use ☐A2 Minor deviation ☐A3 Major deviation
	Home blood pressure measurement in elderly patients with cognitive impairment: comparison of agreement between relative-measured blood pressure and automated blood pressure measurement	Foreign literature	Was the device used for the same intended use?	■A1 Same use ☐A2 Minor deviation ☐A3 Major deviation
	Validation of home blood pressure-monitoring devices, Omron HEM-1020 and Omron i-Q132 (HEM-1010-E), according to the European Society of Hypertension International Protocol	Foreign literature	Was the device used for the same intended use?	■A1 Same use ☐A2 Minor deviation ☐A3 Major deviation

5.The applicability evaluation and clinical evaluation	Validation of the A&D BP UA-651 device for home blood pressure measurement according to the European Society of Hypertension International Protocol revision 2010	Foreign literature	Was the device used for the same intended use?	■A1 Same use ☐A2 Minor deviation ☐A3 Major deviation
	Stephan Lu¨ dersa,b, Ralf Kru¨ gerb,c, Claudia Zemmrichc, Klaus Forstnerd, Claus-Dieter Sturmb,* and Peter Bramlageb,c. Validation of the Beurer BM 44 upper arm blood pressure monitor for home measurement, according to the European Society of Hypertension International Protocol 2002	Foreign literature	Was the device used for the same intended use?	■A1 Same use ☐A2 Minor deviation ☐A3 Major deviation
	alidation of the iHealth BP5 wireless upper arm blood pressure monitor for self-measurement according to the European Society of Hypertension International Protocol revision 2010	Foreign literature	Was the device used for the same intended use?	■A1 Same use ☐A2 Minor deviation ☐A3 Major deviation
	Validation of the Medipro MediCare 100f upper arm blood pressure monitor, for self-measurement, according to the European Society of Hypertension International Protocol revision 2010	Foreign literature	Was the device used for the same intended use?	■A1 Same use ☐A2 Minor deviation ☐A3 Major deviation

5.The applicability evaluation and clinical evaluation	Validation of the Medisana MTP Plus upper arm blood pressure monitor, for self-measurement, according to the European Society of Hypertension International Protocol revision 2010	Foreign literature	Was the device used for the same intended use?	■A1 Same use ☐A2 Minor deviation ☐A3 Major deviation
	Validation of the Nihon Kohden PVM-2701/Impulse-1 automated device by both AAMI (2002) and ISO standards testing	Foreign literature	Was the device used for the same intended use?	■A1 Same use ☐A2 Minor deviation ☐A3 Major deviation
	Validation of the UEBE Visomat Double Comfort upper arm blood pressure monitor, in auscultation mode, for clinic use and self-measurement in a general population, according to the European Society of Hypertension International Protocol revision 2010	Foreign literature	Was the device used for the same intended use?	■A1 Same use ☐A2 Minor deviation ☐A3 Major deviation
	Validation of the Welch Allyn SureBP (inflation) and StepBP (deflation) algorithms by AAMI standard testing and BHS data analysis	Foreign literature	Was the device used for the same intended use?	■A1 Same use ☐A2 Minor deviation ☐A3 Major deviation
	Correlations between different measures of clinic, home, and ambulatory blood pressure in hypertensive patients	Foreign literature	Was the device used for the same intended use?	■A1 Same use ☐A2 Minor deviation ☐A3 Major deviation
	Disagreement of the two oscillometric blood pressure measurement devices, Datascope Accutorr Plus and Omron HEM-705CP II, and bidirectional conversion of blood pressure values	Foreign literature	Was the device used for the same intended use?	■A1 Same use ☐A2 Minor deviation ☐A3 Major deviation

5.The applicability evaluation and clinical evaluation	Measurement with an automated oscillometric wrist device with position sensor leads to lower values than measurements obtained with an automated oscillometric arm device from the same manufacturer in elderly persons	Foreign literature	Was the device used for the same intended use?	■A1 Same use ☐A2 Minor deviation ☐A3 Major deviation
	Oscillometric sphygmomanometers: a critical appraisal of current technology	Foreign literature	Was the device used for the same intended use?	■A1 Same use ☐A2 Minor deviation ☐A3 Major deviation

7.2 Function

The analysis of the information above has showed that the blood pressure measurement based on the parameter of pulse wave became the most advanced technology of non-invasive blood pressure measurement. It has proved the advantages of the parameter of pulse wave method to replace the traditional mercury sphygmomanometer trend, based on a variety of research and clinical validation.

The related literatures and substantial equivalence comparison data identify that the new products RBP-7000、RBP-7000B、RBP-7000G are safety and effective

7.3 Safety

1) RG-BP Ⅱ5800, RG-BP Ⅱ3800, RG-BP Ⅱ2800, RG-BP Ⅱ1800 and RG-BP Ⅱ8000 Automatic Pulsewave Blood Pressure Monitor does not appear any adverse event in the domestic market so far, and model RBP-7000、RBP-7000B、RBP-7000G、Automatic Pulsewave Blood Pressure Monitor do not received any adverse feedback recently in China.

2) RBP-7000、RBP-7000B、RBP-7000G Automatic Pulsewave Blood Pressure Monitor strictly complied with the medical device electrical safety standard (IEC 60601-1:2006 / AC2010), blood pressure monitor security designed standard (EN 80601 - 2-30:2010), home medical equipment standar, electrical safety professional standards (IEC 60601-1-11:2010), EMC standard (IEC 60601-2-22:2007/ AC: 2010) and other standards for the design and verification, and have passed the standard test (reports No.: EED33K00019901) and the cuff contacted with the body is made from the same material which has passed the biocompatibility test (reports No.: DY180100004、DY18010005、DY18010006).All that has greatly reduced the risk of electric shock and biological hazards, see risk Management Report (No.: RG-CE-009-004).

7.4 Product literature and instructions for use

Automatic Pulsewave Blood Pressure Monitor complied with the requirements of the relevant standards，laws and regulations, the safety information has appropriately identified on the user manual and label, and analysis and evaluate in the risk management, to ensure that the safety risks have been reduced to the minimum.

8．Conclusions

Based on the above information, the performance and security of RBP-7000、RBP-7000B、RBP-7000G Automatic Pulsewave Blood Pressure Monitor have meet the intended use and safety of the product we claimed. It utilizes non-invasive blood pressure measurement, harmless to the human body, and no significant risk. When balancing the benefits and the risks of this monitor to clients, the benefits outweigh the risks and the risks have been effectively controlled. Moreover, the moderate size, conveniences operation and easy to carry, suitable to use in clinical applications and home use.

9. Literature index

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