CLINICAL EVALUATION REPORT

DIGITAL BLOOD PRESSURE MONITOR

Document No. : NTLD- CE-BPM-A-08

Version : B

Compile by :

Approved by :

Date : 2017-8-3

HONSUN（NANTONG） CO., LTD

1. Summary

LD series Digital Blood Pressure Monitor is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm or the wrist. Some type of the device can detect the appearance of irregular heartbeat during measurement and gives a warning signal once IHB is detected.

2. Scope of the clinical evaluation

2.1 General information:

Product name: Digital Blood Pressure Monitor

Product model: LD series

Manufacturer: Honsun (Nantong) Co., Ltd

Software versions: V1.1

Device status: CE-marked devices

This clinical evaluation is submitted to the MDD as amended by directive 2007/47/EC

2.2 Device description: LD series digital BMP is mainly made up of cuff, silicon pressure transducer, electronic inflation pump, mechanical deflation valve, PCB board, LCD screen, and adaptor (selectively). The BMP can be classified as wrist type and upper arm type based on the cuff location, and can be classified as fully automatic and semi automatic based on inflation method.

Basic parameters: Cuff pressure range: 0-300mmHg

Pressure accuracy: ±3mmHg (±0.4kPa)

Pulse accuracy: ±5% of reading

Cuff air tightness: less than 4mmHg/min

Rapid exhaust time: ≤10s (from 260 to 15mmHg)

Some of the device own the function of time display, temperature display, memory, IHB detection, WHO guide, etc.

2.3 Intended use: LD series digital Blood Pressure Monitor is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm or the wrist.

2.4 Components and accessories: The devices include the main unit and the cuff unit. ABS and PP are used for the outer housing of the main unit and the lenticular image is printed as the positioning guide to remind the user to take correct posture for blood pressure measurement. The preformed cuff unit, which is applicable to arm circumference approximately between 220 and 320mm, includes the inflatable bladder and the nylon shell.

2.5 New technologies used

Fuzzy Algorithm is the processing algorithm taking into account of the specialty of individual heartbeats, which provides higher accuracy of measurement.

2.6 Principles of operation

This device adopts the oscillometric technology with Fuzzy Algorithm measuring the arterial blood pressure and pulse rate. The cuff is wrapped around the arm and automatically inflated by the air pump. The sensor of the device catches weak fluctuation of the pressure in the cuff produced by extension and contraction of the artery of the arm in response to each heartbeat. The amplitude of the pressure waves is measured, converted in millimeters of the mercury column, and is displayed by digital value.

2.7 Clinical evaluation plan

For scientific comprehensive evaluation, we conduct the evaluation from three aspects: Clinical literature, equivalence and Clinical investigation.

a) Clinical literature: the digital blood pressure monitor is diagnostic equipment, the objectives of clinical literature evaluation are:

--demonstrate the general standards international for digital blood pressure monitor

--the accuracy compare between mercury sphygmomanometer with digital blood pressure

For more details refers to 4.2 Clinical data from literature

b) Equivalence: the objective of demonstration of equivalence is to justify the equivalence of clinical, biological and technical characteristics of the equivalent device, demonstrate the equivalence in three aspects.

c) Clinical investigation: The clinical investigation weights highest in clinical evaluation since its high clinical significance.

The clinical investigation is conducted to determine the clinical study results of automatic blood pressure monitor meet the standard: ESH&SP10 & ISO81060-2 &EN1060-4.

For more details refers to 4.4.1 Pre-market clinical investigation

3. Clinical background, current knowledge, state of the art

3.1 Clinical scope: The Scian Automatic Digital Blood Pressure Monitor is device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.

As the technology develops, the device contains additional function such as voice function, date &time display, memory function and others. These functions don't affect accuracy and security of device. Therefore the clinical evaluation evaluates the device from accuracy and security two aspects.

3.2 Clinical research background

The blood pressure can be measured directly and indirectly. The directly measurement is invasive measurement, which has high accuracy of measurement result. The invasive measurement is not applied wildly because it causes pain during measurement. And the measurement process is not simple for common user. The indirect measurement is non-invasive measurement, which has a history of more than 100 years, and is the most common in clinical diagnose and treatment.

The indirectly measurement is non-invasive measurement. At present, the indirect method contains auscultatory method and oscillometric method. The mercury sphygmomanometer use auscultatory method and was wildly applied in the past. In recent years, the use of mercury sphygmomanometer is trend to be prohibited, because the mercury material is not friendly to environment. In recent years most BMP use oscillometric method to measure blood pressure. It distinguishes blood pressure by establish wave relationship of systolic, diastolic and cuff pressure. The blood pressure measured by oscillometric method is accurate because pulse pressure wave and blood pressure is relatively stable. Therefore, the oscillometric measurement technology of LD series BPM is mature. And the measurement is easy for common user. There should be plenty of document for oscillometric method research, evaluation and analysis, and materials for adverse events, which can declare the safety and efficiency of oscillometric method in clinical use.

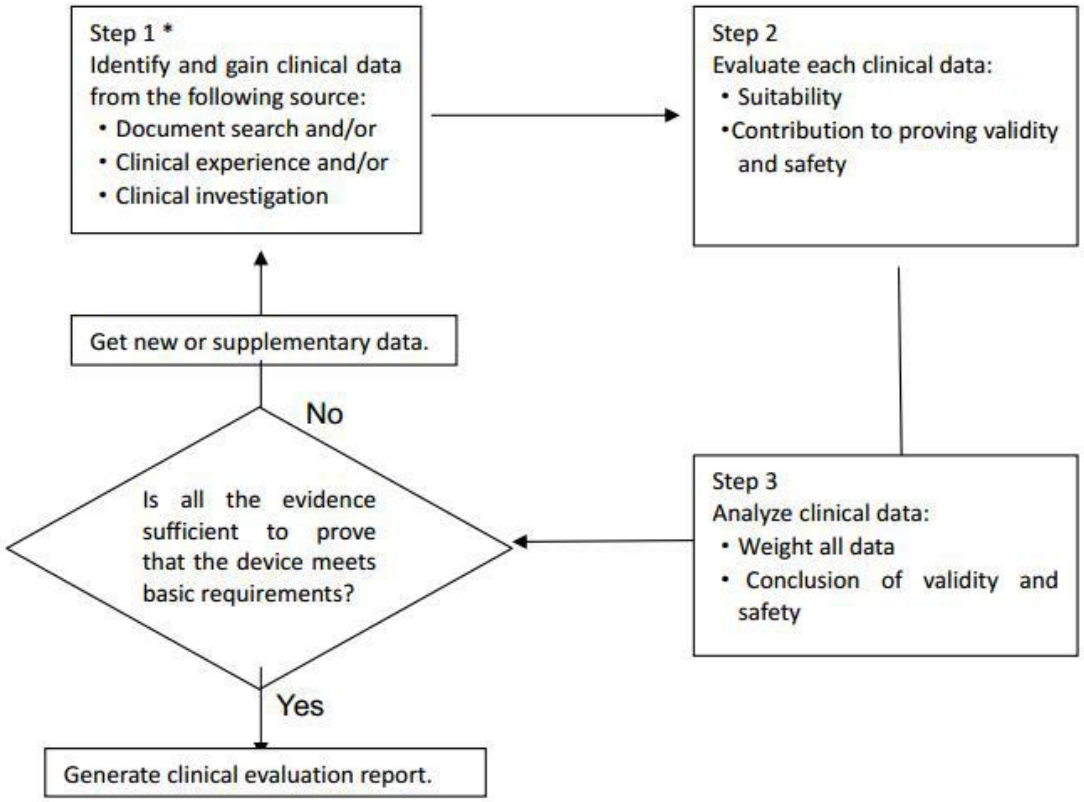
3.3 Hazards of device under evaluation

The hazards relevant to the device under evaluation have been evaluated. See Risk Management Report.

3.4 Literature search strategy

See chapter 4.4 Clinical data from literature

Overview of clinical evaluation



*Meeting with regulatory standards can be considered as sufficiently meeting with related basic requirements.

3.5 Applicable standards & documents

Standards No	Standard' s Title	Documents
IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Safety and essential performance;	IEC 60601-1 Test Report
IEC 60601-1-2	General requirements for basic safety and essential performance Collateral standard: Electromagnetic compatibility-Requirements and tests	IEC 60601-1-2 Test Report
IEC 60601-1-6	Medical electrical equipment -Part1-6 :General requirements for basic safety and essential performance	IEC 60601-1-6 Test Report
ISO 81060-2	Non-invasive sphygmomanometers — Part 2:Clinical investigation of automated measurement type	Clinical report
EN1060-4	Non-invasive sphygmomanometers— Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers	Clinical report

IEC 80601-2-30	Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	Performance Testing (Bench) Testing Report
ISO 10993-5	Biological Evaluation of Medical Devices-Part 5: Tests for in vitro Cytotoxicity	Biocompatibility Test Report
ISO 10993-10	Biological Evaluation of Medical Devices-Part 10: Tests for irritation and skin sensitization	Biocompatibility Test Report

4. Device under evaluation

4.1 Type of evaluation

The clinical evaluation is based on scientific literature and clinical investigations. The demonstration of conformity with essential requirements is based on appropriate clinical data.

4.2 Clinical data from literature

The evaluation of clinical literature is conducted according to clinical evaluation plan.

4.2.1Document search is conducted based on the following protocol:

a) Document search objective: Documents covered reliability of oscillometric method, intended performance of device, clinical performance, clinical safety, performance of BMP and information about adverse events.

b) Source of the documents:

--- Science Direct website

--- Pubmed website

--- FDA official website

--- OA Library

- --IEC report

c) Search questions: oscillometric method, safety and performance of BMP and information about adverse events.

d) Key words: digital blood pressure monitor, oscillometric method; digital blood pressure monitor, performance; digital blood pressure monitor, adverse events

Note: if the above key word is not effective, then take “blood pressure monitor” as the main key word, and select the documents according to the clinical evaluation range.

e) Selection criteria: preliminary select according to the document content and clinical evaluation range.

f) Output:

---Enclosing the copies of documents

---Data selection process

The documents related with the evaluation content in question are as follows:

a) Validation of the Omron 705IT (HEM-759-E) oscillometric blood pressure monitoring device according to the British Hypertension Society protocol ---Mohamed A. El Assaad, Jirar A. Topouchian and Roland G. Asmar

b) Validity of a Wrist Digital Monitor for Blood Pressure Measurement in Comparison to a Mercury Sphygmomanometer---Ana M. B. Menezes, Samuel C. Dumith, Ricardo B. Noal, Ana Paula Nunes, Fernanda I. Mendonça, Cora L. P. Araújo, Marta A. Duval, Paulo E. Caruso, Pedro C. Hallal

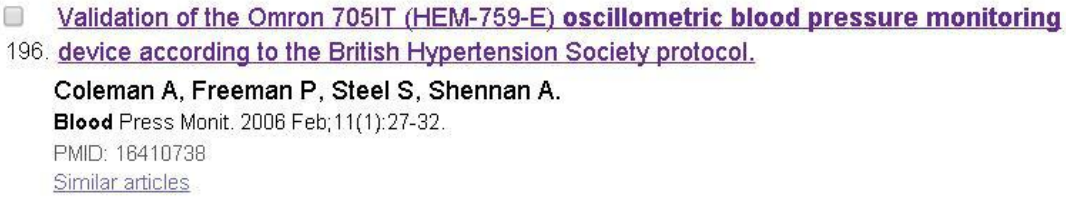
c) Validation of the OMRON M3500 Blood Pressure Measuring Device Using Normal- and High-Speed Modes in Adult and Specific Populations (Obese and Children) According to AAMI Protocol---Mirna N. Chahine, PhD; Nathalie Assemaani, MSc; Ghada Sayed Hassan, MD; Mariam Cham, MD; Pascale Salameh, PharmD, MPH, PhD; Roland Asmar, MD

d) Evaluation of two devices for self-measurement of blood pressure according to the international protocol: the Omron M5-I and the Omron 705IT---Andrew Colemana, Paul Freemana, Stephen Steela and Andrew Shennanb

4.2.2 Clinical data from literature and evaluation abstract

Entering /www.pubmed.com/, inputting key word oscillometric blood pressure monitoring, 786 matches were found.

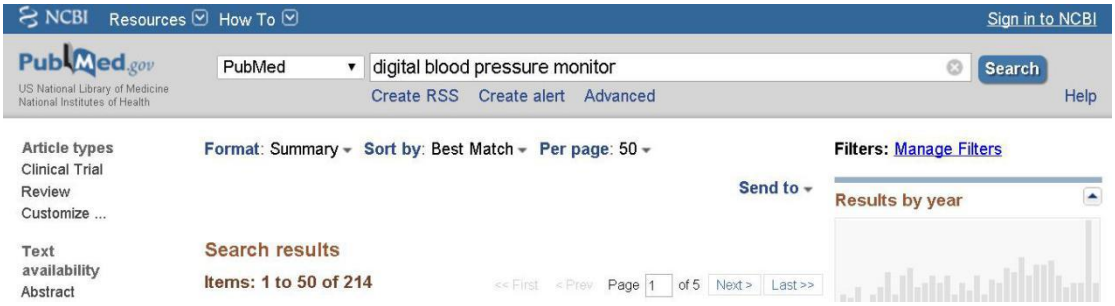
Read the titles one by one, and several paper titles were relevant to this evaluation report. Click to read the abstract to judge if it is relevant to the requirements, if yes, download and read to check if the paper meets the requirement. After screening, we choose 1 pieces of paper to be adopted.



The paper of *Validation of the Omron 705IT (HEM-759-E) oscillometric blood pressure monitoring device according to the British Hypertension Society protocol* shows that the accuracy of digital blood pressure monitor OMRON 705IT (HEM-759-E) satisfy the requirements of British Hypertension Society and the Association for the Advancement of Medical Instrumentation SP10 validation criteria. It can be recommended for professional and home-use in an adult population. Therefore, it can be adopted as it meets the requirements of the evaluation.

4.2.2.2

Entering /www.pubmed.com/, inputting key word digital blood pressure monitor, 214 matches were found.



Read the titles one by one, and several paper titles were relevant to this evaluation report. Click to read the abstract to judge if it is relevant to the requirements, if yes, download and read to check if the paper meets the requirement. After screening, we choose 2 pieces of paper to be adopted.

3. Validity of a wrist **digital monitor** for **blood pressure** measurement in comparison to a mercury sphygmomanometer.

Menezes AM, Dumith SC, Noal RB, Nunes AP, Mendonça FI, Araújo CL, Duval MA, Caruso PE, Hallal PC.

Arq Bras Cardiol. 2010 Mar;94(3):345-9, 365-70. English, Portuguese.

PMID: 20730264 **Free Article**

Similar articles

Validation of the OMRON M3500 Blood Pressure Measuring Device Using Normal- and High-Speed Modes in Adult and Specific Populations (Obese and Children) According to AAMI Protocol.

Chahine MN[1,2], Assemaani N[1], Sayed Hassan G[1], Cham M[1], Salameh P[1,3], Asmar R[1,2].

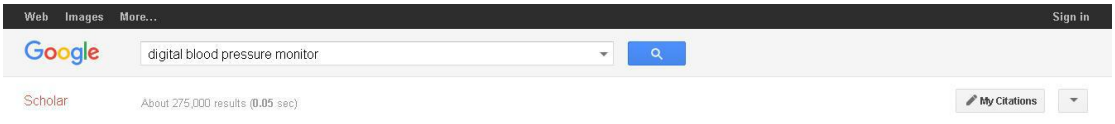
Author information

The paper of *Validity of a Wrist Digital Monitor for Blood Pressure Measurement in Comparison to a Mercury Sphygmomanometer* shows that to evaluate the validity of a wrist digital monitor for measuring blood pressure among adolescents in comparison to a mercury sphygmomanometer, The digital device showed a high level of agreement with the mercury manometer when measuring systolic blood pressure. The level of agreement was lower for diastolic blood pressure. Therefore, this paper can be adopted as it shows the accuracy of wrist digital monitor.

The paper of *Validation of the OMRON M3500 Blood Pressure Measuring Device Using Normal- and High-Speed Modes in Adult and Specific Populations (Obese and Children) According to AAMI Protocol* shows that show that the OMRON 3500 device using the normal- and high-speed mode for BP determinations in adult and specific populations(children and obese) fulfills the recommendations of the ISO 81060-2 protocol. Therefore, it can be adopted as it meets the requirements of the evaluation.

4.2.2.3

Entering /www.scholar.google.co.jp /, inputting key word digital blood pressure monitor, about 275,000 results matches were found.



Read the titles and judge if it is relevant to the requirements, if yes, download and read to check if the paper meets the requirement. After screening, we choose 1 piece of paper to be adopted.

Evaluation of two devices for self-measurement of **blood pressure** according to the international protocol: the Omron M5-I and the Omron 705IT [PDF] cmcv.org

MA El Assaad, JA Topouchian... - **Blood pressure** ..., 2003 - journals.lww.com

... Collapse Box Abstract. Background: Two devices for self-measurement of **blood pressure** at the brachial artery—the Omron M5-I and the Omron 705IT—were evaluated according to the international protocol of the European Society of **Hypertension**. ...

Cited by 203 Related articles All 10 versions Cite Save

The paper of *Evaluation of two devices for self-measurement of blood pressure according to the international protocol: the Omron M5-I and the Omron 705IT* shows that Readings for the two devices differing by less than 5, 10 and 15 mmHg for systolic and diastolic values fulfill the recommendation criteria of the international protocol as well as the individual analysis. Thus it can

be adopted.

After analyzing the data we found, we chose 2 aspects to evaluate the digital blood pressure monitor.

Firstly we compare accuracy of digital blood pressure monitor with mercury sphygmomanometer. It shows that the digital device showed a high level of agreement with the mercury manometer when measuring systolic blood pressure. The level of agreement was lower for diastolic blood pressure. Thus the paper can be adopted as it shows the performance and accuracy of the device.

Secondly, we chose 3 clinical studies to evaluate the performance of the device satisfy the international protocol. Which also prove that the digital blood pressure monitor is effective.

4.3 Demonstration of equivalence

Clinical, biological and technical characteristics taken are taken into consideration for the demonstration of equivalence.

4.3.1 General information of equivalent device

Device name	OMRON Fully automatic blood pressure monitor
Model	OMRON 705IT
Size	115mm(L) x 117mm(W) x 71mm(H)
Accessories	Medium cuff, CD-ROM, USB cable, instruction manual, storage case, battery set
Manufacturer	OMRON HEALTHCARE, INC
Relationship to the device under evaluation	Equivalent device, not predecessor, not successor.

4.3.2 Comparison of clinical characteristics to equivalent device

Items	Honsun BPM	OMRON 705IT	Comparison
Use clinical condition	Blood pressure & pulse rate measurement	Blood pressure & pulse rate measurement	equivalent
Indented use	The Digital Blood Pressure Monitor is device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.	OMRON devices are especially designed for regular blood pressure measurement. And it can detect pulse rate.	equivalent
Target use site in body	Upper arm	Upper arm	equivalent
Target population	Adult	Adult, not suitable in cases of serious arteriosclerosis, not suitable for monitoring the frequency of cardiac	different

		pacemakers. The pregnant women and arrhythmia should use the device under the consultation of doctor.	

Discussion of differences:

Difference of Target population: The OMRON device have described the special patient that not suitable for using device. We didn't describe it the instruction manual, but our device is applicable as OMRON 705IT, which causes no effect to the function and safety of the product.

4.3.3 Comparison of technical characteristics to equivalent device

Items	Honsun BPM	OMRON 705IT	Comparison
Measuring method	Oscillometry	Oscillometry	equivalent
Blood pressure	300mmHg	0 mmHg -299 mmHg	equivalent
Pulse rate	40-160 beats/minute	40-180 bests/minute	equivalent
Measuring accuracy	±3mmHg for static pressure ±5% of the reading for the pulse rate	±3mmHg for static pressure ±5% of the reading for the pulse rate	equivalent
Inflation	Automatic by the pump	Fuzzy-Logic controlled by electric pump	equivalent
Deflation	Automatic electronic valve	Automatic pressure release valve	equivalent
Batteries	4 "AA"x1.5V	4 alkaline batteries 1.5V (Type LR6)	equivalent
Adapter	6V,600mA optional component	6V,600mA optional component	equivalent
Operation temperature and humidity	10℃ to 40℃ 90% RH and below	10℃ to 40℃ 15 to 90% RH maximum	different
Storage temperature and humidity	-20℃ to 55℃ 90% RH and below	-20℃ to 60℃ 15 to 95% RH maximum	different
Cuff size	Arm circumference 22-32cm	Arm circumference 22-32cm	equivalent

Discussion of differences

Difference of operation/ storage temperature and humidity: The difference of operation/ storage temperature and humidity belongs to outer environment, which cause no effect to the use and function of the device.

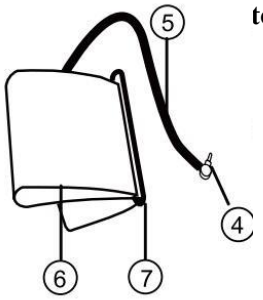
4.3.4 Comparison of biological characteristics to equivalent device

The element in contact with the body is cuff.

The use site of body is upper arm. The material of cuff is same. And the cuff of Honsun blood pressure monitor has passed the ISO 10993-5 and ISO 10993-10.

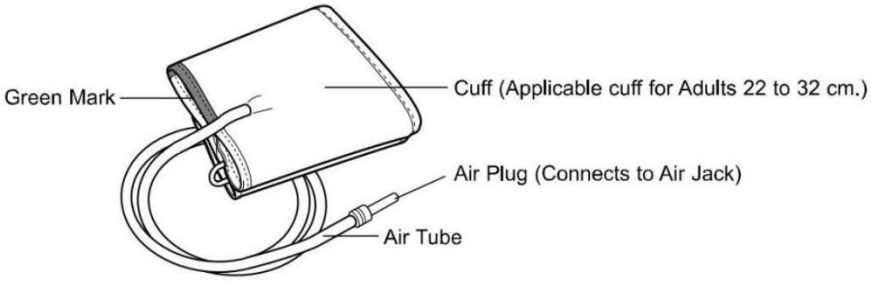
The following pictures show the cuff of two devices.

Honsun digital blood pressure monitor:



4: Tube Plug
5: Air House
6: Cuff
7: D-ring

OMRON Fully automatic blood pressure monitor 705IT:



Conclusion: After comparison and evaluation, we demonstrated our device is equivalent to OMRON 705IT in clinical, technical and biological characteristics. Thus the OMRON 705IT blood pressure monitor can be choose to be the equivalent device. The difference not affects the clinical performance and clinical safety of the device under evaluation.

Evaluation and analysis of clinical literature:

1. The purpose of clinical literature analysis is to demonstrate the applicability and effectiveness in clinical use of digital blood pressure monitor. And it is demonstrated by clinical literature.
2. The comparison between Honsun products with clinical use products testified that two products are equivalent in performance, specification and material, which demonstrated the product applicability in clinical aspects.
3. Accuracy in clinical aspect: The clinical investigation of equivalent device is conducted in conformity with ESH and SP10 standards. And is in conformity with standards. Therefore we considered if our products accord the same standards with clinical use products, the accuracy in clinical aspects can be demonstrated.
4. For accuracy verification in clinical aspects please refers to chapter 4.4 for details.

4.4 Clinical data generated and held by the manufacturer

Content of clinical data:

4.4.1	Pre-market clinical investigation	
4.4.2	clinical data generated from risk management activities and the PMS programmers	4.4.2.1 post market clinical investigation
		4.4.2.2 PMS reports
		4.4.2.3 Incident reports sent to the manufacturer (including the manufacturer's own evaluation and report)

4.4.3	Pre-clinical studies	

4.4.1 Pre-market clinical investigation

The digital blood pressure monitor is diagnostic equipment, the accuracy of device need to be demonstrated by clinical investigation data.

Digital blood pressure monitor standards in clinical accuracy evaluation includes following:

ESH (European Society of Hypertension), USA SP10,(replaced by ISO 81060-2), EU standards EN1060-4. Except ESH choose 33 people as subjects there is no big difference in testing method of several standards. The differences are in gender, blood pressure and cuff.

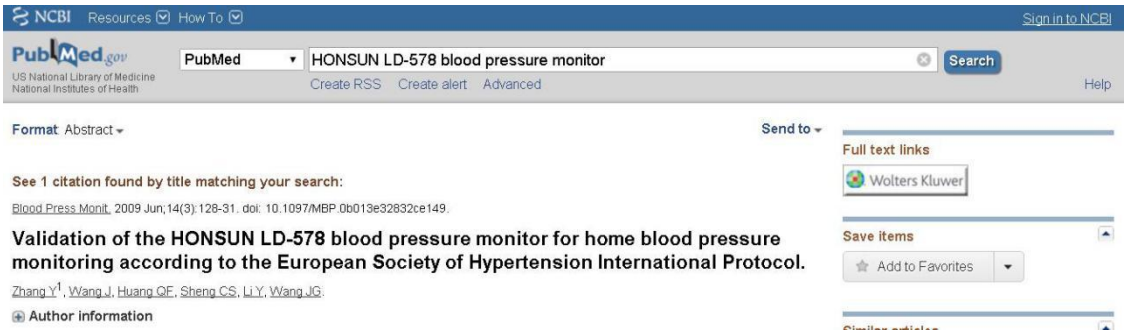
	SP10	81060-2	1060-4
gender	unlimited	At least 30% male, at least 30% female	At least 40% female, at least 40% male
Blood pressure distribution	≥10% subjects SYS＜100mmHg; ≥10% subjects SYS＞160mmHg; ≥10% subjects DIA＜60mmHg; ≥10% subjects DIA＞100mmHg.	At least 5% subjects: systolic pressure ≤ 100mmHg. At least 5% subjects: systolic pressure ≥ 160mmHg. At least 20% subjects: systolic pressure ≥ 140mmHg. At least 5% subjects: diastolic≤60mmHg. At least 5% subjects: diastolic≥100mmHg. At least 20% subjects: diastolic≥85mmHg.	At least 10% high pressure <100 mmHg. At least 10% high pressure >160 mmHg. At least 10% low pressure <70 mmHg. At least 10% low pressure >100 mmHg.
Limb size distribution	10% subjects have a limb circumference smaller than 25cm. 10% subjects have a limb circumference bigger than 35cm. Single-size cuff: at least 40% subjects have a limb circumference bigger than 1/2 of cuff size. 40% subjects have a limb circumference smaller than 1/2 of cuff size.	For blood pressure monitor with various cuff size, each kind of cuff size should be used on at least 1/（2×n） subjects, n is quantity of kind of cuff size. For blood pressure monitor with s single-size cuff, at least 40% subjects limb size ＞1/2 of cuff size. At least 40% subjects have a limb circumference smaller than 1/2 of cuff size. At least 20% subjects have a limb circumference bigger than 1/4 of cuff size,	50%~75% subjects have a limb circumference bigger than 1/2 of cuff size. 50%~75% subjects have a wrist circumference bigger than 1/2 of cuff size.

		and at least 20% subjects have a limb circumference smaller than 1/4 of cuff size.	

In 2009 Honsun LD-578 passed the certification of European Society of Hypertension, demonstrated the accuracy of products.

Entering /www.pubmed.com/, inputting key word blood pressure monitoring, 568247 matches were found.

Read the titles one by one, and several paper titles were relevant to this evaluation report. Click to read the abstract to judge if it is relevant to the requirements, if yes, download and read to check if the paper meets the requirement. After screening, we choose 1 pieces of paper to be adopted.



The paper of *Validation of the HONSUN LD-578 blood pressure monitor for home blood pressure monitoring according to the European Society of Hypertension International Protocol* shows that The Honsun LD-578 product satisfied the requirements of European Society of Hypertension International Protocol. Therefore, this paper can be adopted as it shows the accuracy of wrist digital monitor.

In 2010, LD-587 (inflation measuring technology) Products was conducted clinical investigation in People's Liberation Army 411 Hospital according to EN1060-4 standard. The testing result satisfied the standard requirements of average value 5mmHg, variance 8mmHg. This demonstrated the conformity of products.

In 2016, LD-537&LD533U (universal cuff) was conducted clinical investigation in Dean People Hospital according to ISO81060-2:2013 standard. The testing result satisfied the standard requirements of average value 5mmHg, variance 8mmHg. This demonstrated the conformity of products.

Because the congeneric products uses same software algorithm, we didn't conduct clinical investigation for each products. We only conduct investigation for changing characters, such as inflation measuring technology and universal cuff.

For the tested products, the design of measurement scope and precision for blood pressure of the human body is reasonable, the work is reasonable, the measured values are reliable, and with alert of error and indication of low voltage, the operation is easy. The device may be used safely without adverse reaction observed. And the requirements of clinical application are met.

For more details refers to Clinical Investigation Plan and Clinical Investigation Report.（see clinica test report）

Through clinical investigation data the device accuracy clinical aspects can be demonstrated.

4.4.2 Risk management activities and the PMS programmers

4.3.2.1 Post market clinical investigation

Objective: To confirm clinical performance and safety throughout the expected lifetime of the medical device. To collect clinical data based on the use of a CE-marked device of adverse effect, complaints from customers.

Device market time: 2009

Source of investigation:--FDA Website

--Customer complaints sent to manufacturer

Frequency of post market clinical investigation: half-year

4.4.2.2 PMS reports

We set up the VIGILANCE SYSTEM according to GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM MEDDEV 2.12-1 rev 7. No adverse event which triggers the vigilance system since the product launching . Therefore there is no official vigilance system report.

4.4.2.3 PMS literature search and evaluation

After searching in the MDR database through FDA, The adverse event of digital blood pressure monitor mainly contains following issues:

1) Measurement is not accurate. Proportion: 80%
2) Self-medication according to measurement result: 5%
3) Machinery breakdown (eg. cannot start up, no display): 15%

Because of the difference of human body, measurement environment and condition, although the digital blood pressure monitor satisfied requirements of the clinical investigation, there are still problems in practical using (the clinical standard permits error for special proportion). And some users take medication arbitrarily according to measurement result, which causes harm to body. These are residual risk of digital blood pressure monitor risk analysis. In the risk management report, through comparison of risk and benefit, the digital blood pressure monitor is used for daily blood pressure monitoring, and to know body condition through change trend of blood pressure. We have stated in instruction manual that don't take medication arbitrarily according to measurement result, which reduce the potential risk. Therefore the benefit is greater than risk.

4.4.3 Pre-clinical studies

The following tests have been conducted as pre-clinical studies. The device accords with the standards in the following table.

Standards No	Standard s Title	Verification and Validation Data
IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Safety and essential performance;	IEC 60601-1 Test Report
IEC 60601-1-2	General requirements for basic safety and	IEC 60601-1-2 Test Report

	essential performance Collateral standard: Electromagnetic compatibility-Requirements and tests	
IEC 60601-1-6	Medical electrical equipment -Part1-6 :General requirements for basic safety and essential performance	IEC 60601-1-6 Test Report
IEC 80601-2-30	Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	Performance Testing (Bench) Testing Report
ISO 10993-5	Biological Evaluation of Medical Devices-Part 5: Tests for in vitro Cytotoxicity	Biocompatibility Test Report
ISO 10993-10	Biological Evaluation of Medical Devices-Part 10: Tests for irritation and skin sensitization	Biocompatibility Test Report

4.5 Appraisal of clinical data

4.5.1 Appraisal plan

To ensure systematic and unbiased appraisal of the data, an appraisal plan was been set up:

a) Methodological quality and scientific validity

b) The relevance to the clinical evaluation

c) Data contribution

4.5.2 Appraisal of clinical data

a) Methodological quality and scientific validity

Clinical investigation: The clinical investigation meets the clinical standard, the investigation includes adequate number of observations to guarantee the scientific validity of the conclusions.

Clinical data from literature: The equivalent device satisfied the international protocol British Hypertension Society and the Association for the Advancement of Medical Instrumentation SP10 validation criteria which The Honsun digital blood pressure monitor satisfied either.

b) The relevance to the clinical evaluation

Relevance determination criteria:

Description	Examples
To what extent are the data generated representatives of the device under evaluation?	-device under evaluation -equivalent device -benchmark device -other devices and medical alternatives -data concerning the medical conditions that are managed with the device
What aspects are covered?	-pivotal performance data -pivotal safety data -claims -identification of hazards -estimation and management of risks -establishment of current knowledge/ the state of the art

	-determination and justification of criteria for the evaluation of the risk/benefit relationship -determination and justification of criteria for the evaluation of acceptability of undesirable side-effects -determination of equivalence -justification of the validity of surrogate endpoints
Are the data relevant to the intended purpose of the device or to claims about the device?	-representative of the entire intended purpose with all patient populations and all claims foreseen for the device under evaluation -concerns specific models/ sizes/ settings, or concerns specific aspects of the intended purpose or of claims -does not concern the intended purpose or claims
If the data are relevant to specific aspects of the intended purpose or claims, are they relevant to a specific -model, size, or setting of the device?	-smallest / intermediate / largest size -lowest / intermediate / highest dose -etc.
-user group?	-specialists -general practitioners -nurses -adult healthy lay persons -disabled persons -children -etc.
-medical indication (if applicable)?	-migraine prophylaxis -treatment of acute migraine -rehabilitation after stroke -etc.
-age group?	- pre-term infants / neonates / children /adolescents / adults / old age
-gender?	- female/ male
-type and severity of the medical condition?	-early / late stage -mild / intermediate / serious form -acute / chronic phase -etc.
-range of time?	-duration of application or use -number of repeat exposures

	-duration of follow-up

c) Data contribution

Based on their scientific validity and relevance, the data is weighted according to their relative contributions.

Appraisal Criteria for data contribution:

Data contribution criteria	Description	Grading system
Data source type	Was the design of the study appropriate?	T1 Yes T2 No
Outcome measures	Do the outcome measures reported reflect the intend of performance of the device?	O1 Yes O2 No
Statistical significance	Has a statistical analysis of the data been provided and is it appropriate?	S1 Yes S2 No
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	C1 Yes C2 No

We identify the data contribution criteria as follows:

Items	Contribution
Clinical investigation	60%
Clinical data from literature	20%
Clinical data generated and held by the manufacturer	20%

4.6 Analysis of the clinical data

4.6.1 Requirement on safety (MDD ER1/ AIMDD ER1)

Summary of conformity assessment with requirement on safety.

The risk on safety of digital blood pressure monitor mainly contains electrical safety, structure safety, reliability, biocompatibility and information safety

As for electrical safety, the risk on clinical is current leakage caused by equipment. The external radiated interference cause device error, which effect the measurement. To avoid this risk, we take measures via design; control the risk with the standard, which cannot cause harm to human body and equipment abnormal.

As for structure safety, the main risk is equipment abnormal, and the equipment cannot work normally. In clinical aspect it won't cause any unacceptable risk.

As for reliability, the equipment used under wrong temperature may cause measurement result deviation, which causes the deviation on clinical effect. We stipulate the storage and use environment in instruction manual. Use the equipment within standard temperature will not cause wrong measurement result.

As for material, the element in contact with the body is cuff. The cuff material in market is same material, we tested the cuff material in biocompatibility, confirmed the material won't cause the harm of sensitivity, irritation and toxicity. To avoid cross infection, we stipulate disinfection method in instruction manual, which minimize security risks in this area. 。

In the clinical use aspect, the measurement posture, measurement interval, notices before and during measurement are all effect the accuracy of measurement results. We stipulate and warning relevant information in instruction manual, which can decrease the safety risk in this aspect.

Patient's misjudgment caused by results caused by safety risks above, evaluation of residual risk is described in benefit/risk profile.

4.6.2 Requirement on acceptable benefit/risk profile (MDD ER1 / AIMDDER1)

Summary of conformity assessment with requirement on acceptable benefit/risk profile.

The digital blood pressure monitor provides a simple and convenient method to measuring blood pressure, which is suitable for non-professional operating in home. The user can use the equipment to get blood pressure value, know the condition of blood pressure, and determine the physical condition effectively. This is the benefit of the equipment.

In the risk aspect, risk measures have been taken on the digital blood pressure monitor, the residual risk is the risk cause by user, such measurement posture, condition of human body during measurement, these all cause measurement result deviation. If user adjusted the medication according to measurement result, it can be harm to your body. Therefore we emphasize attention during measurement in the instruction manual, and warning that don't adjust medication according to result without doctor's advice.

Overall, the digital blood pressure is convenient and simple for user to measure blood pressure at home, knowing condition of blood pressure. Providing abundant information for doctor to judge body condition, and adjust therapy. The user who take medicine without doctor's authorization is tiny minority and be ignored. Therefore the benefit is greater than risk.

4.6.3 Requirement on Performance (MDD ER3 / AIMDDER2)

Summary of conformity assessment with requirement on performance

As for clinical performance, digital blood pressure monitor evaluate the clinical accuracy. The clinical investigation conducted according to EN1060-4. The standard specifies the sample quantity (85 people), sample range (blood pressure range, cuff range) and contrastive testing method. The standard also specifies the unsuitable condition in testing process, providing the judge criterion. We conducted clinical investigation according to the standard, the equipment satisfies the standard, which proved the product is accord with standard in clinical accuracy.

4.6.4 Requirement on acceptability of side-effects (MDDER6 / AIMDD ER5)

Summary of conformity assessment with requirement on acceptability of undesirable side-effects

The digital blood pressure monitor is diagnosis product, which doesn't have side-effects in clinical aspects.

5. Conclusion

Based on the above analysis and evaluation, we state our evaluation compliance to Essential requirements. The benefit/risk profile according to current knowledge/ the state of the art in the medical fields concerned and according to available medical alternatives is acceptable. Safety and performance of our digital blood pressure monitor are met with the declared intended use. Through risk evaluation and clinical evaluation, the risk of using the device is acceptable.

6. Clinical evaluation reports update frequency

Date of the next clinical evaluation: The clinical evaluation is actively updated every 5 years. The next evaluation date is 2022, or the evaluation reports will update if the guide version updates.

7. Revision table of the clinical evaluation report

Revision	Version number	Initiation date	Completion date	Major change
First draft	Version A	July 17, 2017	Aug,1,2017	

Statement

I certify that, as evaluators of this clinical evaluation report, I agree with the contents of report.

(Signature)

Qian Fang

(Typed Name)

2017-7-3

(Dated)

8. Qualification of the responsible evaluators

Fan Yifeng

Position: Associate chief physician

No.411 Hospital of PLA of the people's Republic of China, vice director of Department of Cardiology.

He is skilled at pacemaker placement, arrhythmia radiofrequency ablation therapy, heart failure,, coronary heart disease.

He graduated from Second Military Medical University. He has worked on Department of Cardiology for over 18 years. He now started to carry out the interventional diagnosis and treatment of coronary artery. More than 40 medical papers were published. He won the 8 military scientific and technological progress and medical achievement award. He participated in compiling the *practical technique of interventional cardiology.*

He is member of Shanghai Biomedical Engineering Society, member of Shanghai cardiac pacing and electrophysiology group. He was selected as county leaders of Shanghai health system in 1999.

Qian Fang

QA Manager, editor of clinical literature with experience in medical equipment industry for fifteen years. Compiling of clinical literature and reviewing of clinical application for multiple times. Participate in design and development, manufacture and operation and practical application process of product in digital blood pressure monitor field. Cooperate with scientific research institutions for deep study in application of digital blood pressure monitor, and has rich experience in product application.

9. References

a) Validation of the Omron 705IT (HEM-759-E) oscillometric blood pressure monitoring device according to the British Hypertension Society protocol ---Mohamed A. El Assaad, Jirar A. Topouchian and Roland G. Asmar

b) Validity of a Wrist Digital Monitor for Blood Pressure Measurement in Comparison to a Mercury Sphygmomanometer---Ana M. B. Menezes, Samuel C. Dumith, Ricardo B. Noal, Ana Paula Nunes, Fernanda I. Mendonça, Cora L. P. Araújo, Marta A. Duval, Paulo E. Caruso, Pedro C. Hallal

c) Validation of the OMRON M3500 Blood Pressure Measuring Device Using Normal- and High-Speed Modes in Adult and Specific Populations (Obese and Children) According to AAMI Protocol---Mirna N. Chahine, PhD; Nathalie Assemaani, MSc; Ghada Sayed Hassan, MD; Mariam Cham, MD; Pascale Salameh, PharmD, MPH, PhD; Roland Asmar, MD

d) Evaluation of two devices for self-measurement of blood pressure according to the international protocol: the Omron M5-I and the Omron 705IT---Andrew Colemana, Paul Freemana, Stephen Steela and Andrew Shennanb