dabl® Educational Trust

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

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SECTION A - Please complete all items online.

I Albert Lee (Name of a Company Director) Director of Health & Life Co., Ltd. (Company name)

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Braun Exact Fit Plus BP5900
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

HL868BA
Existing validated blood pressure measuring device

blood pressure measuring device, which has previously passed the ESH protocol, the results of which were published as follows

Han-E Chen, Yan Cui, Chang-Sheng Sheng, Li-Hua Li, Yan Li, Ji-Guang Wang
Author(s)

Validation of the Healthy & Life HL868BA blood pressure monitor for home blood pressure monitoring according to the European Society of Hypertension International Protocol
Title

Wolters Kluwer Health/Lippincott Williams & Wilkins (Publication) 2008, Vol 13 No 5, Page 305-308 (Year Volume Pages)

The only differences between the devices involve the following components:
(When a component is not relevant, both Yes and No should be left blank. Please provide details on any differences below.)

Part I	1	Algorithm for Oscillometric Measurements	Yes ☐	No ■
	2	Algorithm for Auscultatory Measurements	Yes ☐	No ☐
	3	Artefact/Error Detection	Yes ☐	No ■
	4	Microphone(s)	Yes ☐	No ☐
	5	Pressure Transducer	Yes ☐	No ■
	6	Cuff or Bladder	Yes ■	No ☐
	7	Inflation Mechanism	Yes ☐	No ■
	8	Deflation Mechanism	Yes ☐	No ■
Part II	9	Model Name or Number	Yes ■	No ☐
	10	Casing	Yes ■	No ☐
	11	Display	Yes ■	No ☐
	12	Carrying/Mounting Facilities	Yes ☐	No ☐
	13	Software other than Algorithm	Yes ■	No ☐
	14	Memory Capacity/Number of stored measurements	Yes ■	No ☐
	15	Printing Facilities	Yes ☐	No ■
	16	Communication Facilities	Yes ☐	No ■
	17	Power Supply	Yes ■	No ☐
	18	Other Facilities	Yes ■	No ☐

Brief explanation of differences and further relevant details:

a. Item 6 BP5900 use universal cuff (9"~17"). HL868BA use normal cuff (9"~13") and large cuff (13"~17"). Base on the test result from our Internal Clinical Report in the attached file, we think and confirm that our universal cuff does not impact the device accuracy.

b. Item 9 Model name and number are different than HL868BA.

c. Item10 The device external and dimension are different than HL868BA.

d. Item11 LCD size and symbols are different than HL868BA.

e. Item13 BP5900 can calculate the full day, morning, or evening average during last 7 days. HL868BA can calculate the average of last 3 memories.

f. Item14 BP5900 memory capacity 99 single user. HL868BA 3 user 80 memories each.

g. Item17 BP5900 power uses four AA batteries only. HL868BA can use battery or adaptor.

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h. Item18 HL868BA has other facilities such as Irregular Heartbeat detector, Self-management, Temperature detect, and PC-Link. BP5900 has Irregular Heartbeat detector. This facility and HL868BA's facility are the same. Those other facilities don't affect the measurement algorithm.

SECTION B - Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original along with manuals for both devices to our address below.

Signature of Director _____ Company Stamp/Seal

Name ALBERT LEE

Date January 28, 2010

Signature of Witness _____ 2010.1.28

Name BILL HUANG

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Comparison of the Braun BP5900 with the Health and Life HL868BA

Devices	Braun BP5900		Health and Life HL868BA	
Pictures				
Validation			ESH	
Device 1 Criteria			Up and down buttons Self diagnosis (Set thresholds, BPs flash if HBP, ☺ if OK) Multi-measurements (3 or 5 continuous measurements) Time and temperature display in standby mode 3-measurement or 5-measurement median Power: Optional AC adapter	10 10, 11, 13 10, 11, 13 11, 13 13 17
Same Criteria	Accuracy ± 3 mmHg Oscillometric measurement method BP 0 mmHg to 300 mmHg, Pulse 40-199 bpm Semiconductor pressure sensor* Automatic Inflation and Deflation Deflation: Automatic exhaust valve Mode button Single screen LCD display Start/Stop button Memory button, memory symbol Date/Time Display During Measurement: Inflation, Deflation & Heartbeat Symbols Measurement error symbol Irregular heartbeat detection & symbol Low battery symbol Power: Automatic switch-off when not used for 1 min	1, 5 1, 5 1, 5, 7, 8 5 7, 8 8 10 10 10 10, 11 11 11 11 11, 13 11, 17 17	Accuracy ± 3 mmHg Oscillometric measurement method BP 0 mmHg to 300 mmHg, Pulse 40-199 bpm Semiconductor pressure sensor* Automatic Inflation and Deflation Deflation: Automatic exhaust valve Mode button Single screen LCD display Start/Stop button Memory button, memory symbol Date/Time Display During Measurement: Inflation, Deflation & Heartbeat Symbols Measurement error symbol Irregular heartbeat detection & symbol Low battery symbol Power: Automatic switch-off when not used for 1 min	1, 5 1, 5 1, 5, 7, 8 5 7, 8 8 10 10 10 10, 11 11 11 11 11, 13 11, 17 17
Comparable Criteria	Cuff: (Arm circ. 23 to 43 cm) Memory: 99 measurements Power: 4 “AA” batteries ~ 250 measurements	6 11, 14 17	Cuff: (Arm circ. 23 to 33 cm) Memory: 80 measurements × 3 users (zones) Power: 4 “AA” batteries ~ 300 measurements	6 11, 14 17

Devices	Braun BP5900		Health and Life HL868BA
Device 2 Criteria	Average Button	10	
	Set Button	10	
	Morning hypertension symbol (set thresholds)	10, 11, 13	
	Evening average and symbol	11, 13	
	Morning average and symbol	11, 13	
	7-day average	13	
Web link			

Comments

* Not in the manual but supplied on data sheets

Eight queries were sent to the initial application, which included extra information. These are shown below with each Query, Response and Comment numbered according to the communication number. In three cases (#4, #6 & #7), the explanation was accepted. Two of the responses (#1 & #2) conflicted with the manuals and they were queried further. For the remaining three (#3, #5 & #8), a new corrected application was required. A new application was returned and was fine for all but for some minor errors.

The company "Kaz", mentioned in some responses, is the OEM manufacturer of both devices.

1	Query 1	The difference in the *Printing Facilities* option (#15) is ticked as *Yes* in the application form. There do not appear to be printing facilities on either device.
	Response 1	*Printing facilities option (#15) was ticked off as "yes" because the printer which makes the owner's manual and other packaging items is different than the HL868BA.*
	Query 2	Can you please point out where the printing facilities are described in the manuals?
	Comment 2	The *Printing Facilities* option (#15) is ticked as *No* in the new application form.
2	Query 1	The difference in the *Communication Facilities* option (#16) is ticked as *Yes* in the application form. Furthermore, a USB cable to link the HL868BA to a PC is stated in the additional information provided. Yet there is no information available in the manual.
	Response 1	*The USB cable or PC link feature is only available on H&L model HL868BA not available for Kaz models. This is why we do not mention it in the owner's manual.*
	Query 2	Where is the USB port in the HL868BA? It is not mentioned in the manual and there is no information available in the Health and Life or other websites.
	Comment 2	The *Communication Facilities* option (#16) is ticked as *No* in the new application form. However, "PC-Link" is erroneously included in as a difference under the *Other Facilities* option (#18). However, it is not a measurement or validation matter.
3	Query 1	The difference in the *Power Supply* option (#17) is ticked as *No* in the application form. Yet there is an optional power supply with the HL868BA that is not provided with the BP5900.
	Response 1	*The Kaz models do not have an optional power supply. The power source for HL868BA and Kaz models are the same; both use 4 AA 1.5V alkaline batteries.*

		Comment 1	Explanation accepted. However, this should have been ticked as “Yes” with the explanation that an optional AC adaptor is available only with the HL868BA. This must be corrected in a fresh application form.
		Comment 2	The *Power Supply* option (#17) is ticked as *Yes* in the new application form and the explanation is provided.
	4	Query 1	The measurement range for blood pressure, for both devices is 0-300 mmHg in the manuals but 40-280 mmHg in the additional information provided.
		Response 1	*These devices are designed to measure blood pressure values ranging 0-300 mmHg (range of inflation), and 40-280 mmHg is range of measurement.*
		Comment 1	Explanation accepted
	5	Query 1	The "Average display" claimed, in the additional information provided, as a feature of the HL868BA, does not appear to be in the manual. A facility for measuring 3 or 5 measurements and returning the "middle one" (presumably the median) is described in the manual.
		Response 1	*The “Average display” for Kaz models is different than H&L’s model as indicated in the application (#13 & #14). Kaz’s “Average display” feature specifications are explained in the owner’s manuals.*
		Comment 1	Items #13 and #14 are ticked as “Yes” but the application does not provide a paragraph for each “Yes” clearly stating what the differences are. Instead, a matrix is provided from which one has to try and work out what which differences match which “Yes”. In this case, there is a row in the matrix labelled “Average display” which is marked as “Last 7 days (Morning / Evening) data average” for the BP5900 and “Last 3 memories” for the HL868BA. Although “average” can mean any type of “typical” measurement, it is usually taken to mean the “mean value”. The manual for the HL868BA describes a “multi-measurement option in which 3 or 5 measurements can be taken automatically in succession and “after all measurements have been taken, the middle reading of each Systolic, Diastolic and Pulse reading will be displayed on the screen.”. These “middle readings” presumably refer to the medians. Though medians are, indeed, averages, “Average display – last 3 memories” does not accurately describe this feature. On the other hand, the “correct 7-Day Average result”, available in the BP5900, presumably means the arithmetic mean of the “full day averages” (also presumably the arithmetic means of the BPs during each day) taken during the preceding 7 days. Similarly, though no definitions of “morning” and “evening” are provided, the “morning average” and “evening average”, presumably mean the arithmetic mean of the daily am readings (themselves the arithmetic means of the BPs taken from 00:00 to 11:59) during the preceding 7 days and the arithmetic mean of the daily pm readings (themselves the arithmetic means of the BPs taken from 12:00 to 23:59) during the preceding 7 days. The devices provide very different averages both in kind and scope. This must be described correctly in a fresh application.
		Comment 2	The response in the new application form states “BP5900 can calculate the full day, morning or evening average during last 7 days. HL868BA can calculate the average of last 3 memories”. The median facility is not added. However, it is not a measurement or validation matter.
	6	Query 1	The 12hr or 24hr option for the BP5900 clock claimed, in the additional information provided, does not appear to be in the manual.
		Response 1	*12hr or 24hr option is not mentioned in the owner’s manual as this is pre-set at the factory (H&L). The user does not have the option to set 12hr or 24 hr. This option is for internal use only and is set at the factory pending the region the device will be sold. So all units*

			shipping to USA will be pre-set to 12hr and all units shipping to Europe will be set at 24hrs.
		Comment 1	Explanation accepted
	7	Query 1	The *Deflation time*, *Deflation rate of air leakage*, and *Specification of pressure* do not appear to be in the manuals. From where does this information come?
		Response 1	*Our products were designed per EN1060-1 & EN1060-3 protocols, which are engineering specifications and aren't printed in the user's manual.*
		Comment 1	Explanation accepted
	8	Query 1	The cuff size, in the HL868BA manual, is suitable for arm circumferences in the range 23-33 cm/9-13 inch, and a warning to this effect is included. However, the paper validating the HL868BA and the manual for the BP4600 state that a larger cuff, for arm circumferences 33-43 cm, is also available. The manual for the BP4900 and BP5900 states that a single 23-43 cm/9-17 inch cuff is provided. In the additional information provided, this cuff is declared for both devices. The HL868BA was not validated with this new cuff covering a wider arm circumference range. The difference in the Cuff or Bladder option (#6) is ticked as *No* in the application form.
		Response 1	*I confirm the BP4900 and BP5900 are equipped with a single 9-17 inch cuff. Aside from the arm circumference, the cuff is equal to two approved cuffs in the ESH journal. Cuff/bladder option may have been ticked off incorrectly.*
		Comment 1	The application must be corrected. The "No" in the application form is incorrect. This is an important difference. The large cuff was only used in one patient in the study. Furthermore, a single cuff covering a wide range of arm circumferences is not necessarily the same as separate cuffs each covering narrower ranges.
		Comment 2	A separate internal validation was carried out by Health and Life to validate the HL868BA with the universal cuff.
Recommendation	Equivalence is approved		
Date	25/06/2010		