dabl® Educational Trust

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

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SECTION A - Please complete all items outline.

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

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

Braun Exact Fit BP4600
(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
(Authors(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 9 Model name and number are different than HL868BA.

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

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

d. Item13 BP4600 has not memory average function. HL868BA can calculate the average of last 3 memories.

e. Item14 BP4600 memory capacity 32 single user, HL868BA 3 user 80 memories each.

f. Item17 BP4600 power uses four AA batteries only. HL868BA can use battery or adaptor.

g. Item18 HL868BA has other facilities such as Irregular Heartbeat detector, Self-management, Temperature detect, and PC-Link. BP4600 has not foregoing facilities. Those other facilities don't affect the measurement algorithm.

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

Signature of Director _____ Company Stamp/Seal

Name ALBERT LEE

Date January 28, 2010

Signature of Witness _____ 2010-1-28

Name BILL HUANG

Address 9F., No. 186, Jian Yi Road, Chung He City 23553, Taipei, Taiwan

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Comparison of the Braun BP4600 with the Health and Life HL868BA

Devices	Braun BP4600	Health and Life HL868BA
Pictures		 **Image HL868BF** (Identical in appearance according to the manual))
Validation		ESH
Device 1 Criteria	***Buttons/Switches***	
	Settings	
	Set 10	
Same Criteria	***Measurement***	***Measurement***
	Accuracy	*Accuracy*
	BP accuracy ± 3 mmHg 1, 5	BP accuracy ± 3 mmHg 1, 5
	Pulse accuracy or ± 5% 1, 5	Pulse accuracy or ± 5% 1, 5
	Method	*Method*
	Oscillometric measurement method 1, 5	Oscillometric measurement method 1, 5
	BP 40 mmHg - 280 mmHg 1, 5, 7, 8	BP 40 mmHg - 280 mmHg 1, 5, 7, 8
	Pulse 40 bpm -199 bpm 1, 5	Pulse 40 bpm -199 bpm 1, 5
	Inflation	*Inflation*
	Inflation 0 mmHg - 300 mmHg 1, 5, 7	Inflation 0 mmHg - 300 mmHg 1, 5, 7
	Automatic Inflation 7	Automatic Inflation 7
	Deflation	*Deflation*
	Automatic Deflation 8	Automatic Deflation 8
	Automatic safety release valve 8	Automatic safety release valve 8
	Cuffs	*Cuffs*
	Medium (Arm circ. 22 to 33 cm) 6	Medium (Arm circ. 22 to 33 cm) 6
	Large (Arm circ. 33-43 cm) 6	Large (Arm circ. 33-43 cm) 6
	Sensors	*Sensors*
	Pressure sensor: semi conductor* 5	Pressure sensor: semi conductor* 5

Carraig Court, George's Avenue, Blackrock, Co. Dublin, Ireland Tel +353 1 278 0247 Fax +353 1 278 0882 Email info@dableducational.org Web www.dableducational.org

Devices	Braun BP4600		Health and Life HL868BA	
Same Criteria	***Buttons/Switches***		***Buttons/Switches***	
	Measurement Records		*Measurement Records*	
	Memory	10	Memory	10
	Mode	10	Mode	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Measurement Procedure		*Measurement Procedure*	
	Inflation symbol	11	Inflation symbol	11
	Deflation symbol	11	Deflation symbol	11
	Heartbeat symbol during deflation	11	Heartbeat symbol during deflation	11
	Post Measurement		*Post Measurement*	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Measurement error (no error numbers)	11	Measurement error (no error numbers)	11
	Measurement Records		*Measurement Records*	
	Memory	11	Memory	11
	Memory recall number	11	Memory recall number	11
	Date and Time		*Date and Time*	
	Date and Time	11	Date and Time	11
	Power		*Power*	
	Low battery	11, 17	Low battery	11, 17
	Algorithms		***Algorithms***	
	Case		***Case***	
	Display		*Display*	
	Single screen display	10	Single screen display	10
	Power		*Power*	
	4 “AA” batteries ~ 300 measurements	17	4 “AA” batteries ~ 300 measurements	17
	Rechargeable batteries permitted	17	Rechargeable batteries permitted	17
	Automatic switch-off when not used for 1 min	17	Automatic switch-off when not used for 1 min	17
Comparable Criteria	***Measurement***		***Measurement***	
	Measurement Records		*Measurement Records*	
	Memory: 32 measurements	14	Memory: 80 measurements × 3 zones	14
	Buttons/Switches		***Buttons/Switches***	
	Power		*Power*	
	Start/Stop (Start/Stop label)	10	Start/Stop (symbol label)	10

Devices	Braun BP4600	Health and Life HL868BA
Device 2 Criteria		***Measurement*** *Method* Optional repeated measurements (3 or 5) 13, 14 ***Buttons/Switches*** *Settings* Up and down 10 ***Display/Symbols/Indicators*** *Post Measurement* Irregular heartbeat 11, 13 BPs flash if HBP, ☺ symbol if BP OK 11, 13 *Features* Ambient temperature 11 ***Algorithms*** *Averages* Last 3 measurements mean 13 Three and five measurements median 13 *Diagnostic* Self diagnosis (Set thresholds) 10, 11, 13 Atrial fibrillation detection 13 ***Case*** *Power* AC adapter (Optional) 17
Web link		None available

Comments

* Not in the manual but supplied on data sheets

Though not in the manual, two cuff sizes for the HL868BA, for arm circumferences in the ranges 23-33 cm and 33-43 cm, are available.

Eight queries were sent to the initial application, which included extra information. These are shown below as Query 1 with corresponding Response 1 and Comment 1. The explanation was accepted in six of the cases but, for three (#3, #5 & #8), it meant that the application was incorrectly filled and a new application was required. Two of the answers (#1 & #2) conflicted with the manuals and they were queried further. A new application was returned and was fine for all but #2 and #5 which had minor errors. However neither of these have anything to do with measurement or validation. 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	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 BP4600.
		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 fully explain what is 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 "N/A" for the BP4600 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 also 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 describe this feature. Though the application indicates correctly that no "average display" is available in the BP4600, the generalised response to the query appears to suggest that there is. This must be described correctly in a fresh application.
		Comment 2	The response in the new application form states "BP7600 has not memory average function. 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 BP4600 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 24hr. 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. In the additional information provided, a single cuff, for arm circumferences in the range 9-17 inch, is declared for both devices. Such a cuff, covering a wider arm circumference range, is stated in the manual for the BP4900 and BP5900 devices but the HL868BA was not validated with this cuff. The difference in the Cuff or Bladder option (#6) is ticked as No in the application form.
		Response 1	The BP4600 is equipped with two cuffs just like the HL868BA; small cuff 9-13 inch and a larger cuff 13-17 inch. Please see attached ESH journal (page 2) for your reference.
		Comment 1	The explanation is accepted as being in accordance with the manuals and the publication. However, the row, in the additional information provided, labelled "Dimension of cuff" with "Arm cuff 9"~17"" for both devices is erroneous. This must be corrected in a fresh application.
		Comment 2	The new application form contains no references to cuff differences
Recommendation	Equivalence is recommended		
Date	12/03/2010		