DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

SECTION A - Please complete all items online.

I   <u>Takefumi Nakanishi</u>   Director of   <u>Omron Healthcare Europe B.V.</u>
Name of a Company Director   Company name

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

<u>HEM-7051 (HEM-7051-SH)</u>
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

<u>Omron M3 Intellisense (HEM-7051-E)</u>
Existing validated blood pressure measuring device

blood pressure measuring device, which has previously passed the <u>International</u> protocol, the results of which were published as follows

<u>Asmar R, Khabouth J, Topouchian J, El Feghali R, Mattar J</u>
Authors(s)
<u>Validation of three automatic devices for self-measurement of blood pressure according</u>

<u>to the International Protocol: The Omron M3 Intellisense (HEM-7051-E), the Omron M2</u>

<u>Compact (HEM 7102-E), and the Omron R3-I Plus (HEM 6022-E)</u>
Title
<u>Blood Pressure Monitoring</u>   <u>2010; 15:49-54</u>
Publication   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.)

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

Brief explanation of differences and further relevant details:

10) No clock setting button.

11) The symbols for irregular heartbeat detection and hypertension indicator are removed. Clock function is removed. The symbol for mmHg/kPa is added.

13) The functions of irregular heartbeat detection and hypertension indicator are removed. Beeper is removed. Clock function is removed. The function of switching mmHg/kPa is added.
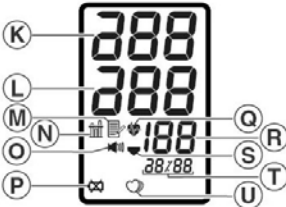
14) Stores 21 readings instead of 42, without time stamp.

dabl®Educational Trust

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 _T. Nakanishi_

Name _Takefumi Nakanishi_

Date _08 Feb 2010_

Signature of Witness _J Meijer_

Name _Janet Meijer_

Address _Omron Healthcare Europe B.V., Kruisweg 577, 2132NA Hoofddorp, The Netherlands_

Company Stamp/Seal

OMRON HEALTHCARE EUROPE B.V.
Kruisweg 577
NL-2132 NA Hoofddorp
P.O. Box 2150 NL- 2130 GL Hoofddorp
Tel. +31 - 20 354 82 00
Fax +31 - 20 354 82 01

dabl®Educational Trust

Comparison of the Omron HEM-7051 (HEM-7051-SH) with the Omron M3 Intellisense (HEM-7051-E)

Devices	HEM-7051 (HEM-7051-SH)	M3 Intellisense (HEM-7051-E)
Pictures		
Display		K. Systolic blood pressure Q. Heartbeat symbol L. Diastolic blood pressure R. Pulse display M. Memory symbol S. Deflation symbol N. Average value symbol T. Date/Time display O. Buzzer symbol U. Irregular heartbeat P. Battery low symbol symbol
Validation		ESH

Device 1 Criteria	**Display/Symbols/Indicators**
	  Settings
	    Current unit (kPa / mmHg) marker　　11
	Algorithms
	  Parameter Settings
	    Unit conversion (kPa / mmHg)　　13	

Same Criteria	**Measurement**
	  Accuracy
	    Pulse accuracy ± 5%　　1, 5
	  Method
	    Oscillometric measurement method　　1, 5
	    Pulse 40 bpm -180 bpm　　1, 5
	    Measurements are from single inflations　　13
	    Manually initiated measurements　　13, 14
	  Inflation
	    Inflation 0 mmHg - 299 mmHg　　1, 5, 7
	    Automatic Inflation　　7
	    Fuzzy Logic　　7
		Measurement
		  Accuracy
		    Pulse accuracy ± 5%　　1, 5
		  Method
		    Oscillometric measurement method　　1, 5
		    Pulse 40 bpm -180 bpm　　1, 5
		    Measurements are from single inflations　　13
		    Manually initiated measurements　　13, 14
		  Inflation
		    Inflation 0 mmHg - 299 mmHg　　1, 5, 7
		    Automatic Inflation　　7
		    Fuzzy Logic　　7

	Press button if BP > 220 mmHg	7	Press button if BP > 220 mmHg	7
	Manually adjustable inflation pressure	7	Manually adjustable inflation pressure	7
	Deflation		*Deflation*	
	Automatic Deflation	8	Automatic Deflation	8
	Automatic safety release valve	8	Automatic safety release valve ^{Query 1}	8
	Cuffs		*Cuffs*	
	Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) ^{Query 2}	6	Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) ^{Query 2}	6
	Sensors		*Sensors*	
	Pressure sensor: capacitive	5	Pressure sensor: capacitive	5
	Buttons/Switches		***Buttons/Switches***	
	Measurement Records		*Measurement Records*	
	Memory	10	Memory	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Measurement Procedure		*Measurement Procedure*	
	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 *EE*, *E*, *E/E* and *Eo25* ^{Query 3}	11	Measurement error *EE*, *E*, *E/E* and *Eo25* ^{Query 3}	11
	Measurement Records		*Measurement Records*	
	Memory icon	11	Memory icon	11
	Power		*Power*	
	Low battery	11, 17	Low battery	11, 17
	Case		***Case***	
	Display		*Display*	
	Single screen display	10	Single screen display	10
	Segment LCD	10	Segment LCD	10
	Power		*Power*	
	AC adapter (Optional)	17	AC adapter (Optional)	17
	Automatic switch-off when not used for 5 min	17	Automatic switch-off when not used for 5 min	17
Comparable Criteria	**Measurement**		***Measurement***	
	Accuracy		*Accuracy*	
	BP accuracy ± 4 mmHg	1, 5	BP accuracy ± 3 mmHg	1, 5
	Measurement Records		*Measurement Records*	
	Memory: 21 measurements	14	Memory: 42 measurements	14
	Buttons/Switches		***Buttons/Switches***	
	Power		*Power*	
	On/Off with Start/Stop (Start/Stop Label)	10	On/Off with Start/Stop (O/I Start Label)	10

	Display/Symbols/Indicators
	  Measurement Records
	    Memory recall number (Replaces pulse rate momentarily)
		11	**Display/Symbols/Indicators**
			  Date and Time
			    Date and Time (During memory recall)
				11

	Case
	  Power
	    4 "AAA" batteries ~ 300 measurements
		17	**Case**
			  Power
			    4 "AA" batteries ~ 1500 measurements
				17

Device 2 Criteria			**Measurement**
			  Cuffs
			    Large (Arm circ. 32-42 cm) (Optional)
				6

			Buttons/Switches
			  Settings
			    Set
				10

			Display/Symbols/Indicators
			  Measurement Procedure
			    Audible pulse indicator during deflation (Optional)
				18

			Beeps after measurement (Optional)	18
			Post Measurement Hypertension (Blinking heartbeat)	11, 13
			Irregular heartbeat	11, 13
			Average symbol	11, 13
			Date and Time Date and Time	11
			Settings Audible pulse indicator mode active	11, 18

			Algorithms
			  Averages
			    Last 3 measurements (within 10 min of each other) mean
				13

			Diagnostic Normotension/Hypertension	13
			135 / 85 mmHg thresholds	13
			Irregular heartbeat detection	13
Web link			http://www.omron-healthcare.com/sitepreview.php?SiteID=227

Comments	Query 1	Rapid pressure release: The manual, for the HEM-7051, include two deflation entries. In addition to the regular deflation, there is an automatic exhaust valve for rapid pressure release. This is understood to be a safety feature. It appears not to be available for the M3 Intellisense. There is no reference to this difference in the declaration. Please explain.

	Response 1	*The fact we have is that the M3 Intellisense (HEM-7051-E) and the HEM-7051 (HEM-7051-SH) have same deflation mechanism. They have same valves for deflation system, as you mentioned, which are the regular deflation valve (slow deflation during measurement) and the rapid exhaust valve (release pressure rapidly from air system in the device after measurement to make comfortable and safe patients). Also these 2 valves are operated by automatic. In some device's manual e.g. M3 Intellisense (HEM-7051-E), we mention only "Deflation: Automatic pressure release valve" as one function of automatic deflation so that we could provide easy explanation to end users.*
	Query 2	There appear to be some differences in the cuffs supplied with the monitors.
		There are different part numbers between those listed for the devices. No part numbers are provided for the HEM-7051 and no difference is made in the declaration. It is taken that there are no changes.
	Response 2	*These cuffs have no differences except cloth covers. The parts number difference comes from different cloth covers.*
	Query 3	There appear to be some differences in the error codes (apart from the extra features) which would not be expected if there were no algorithm changes. In the list, a slash indicates a line break where the error code is on two lines. Please explain.
	Response 3	*Regarding to Chart 1, when error appears in the device, the number in 2nd line indicates current air pressure. Therefore, EE and EE/0 indicates same error "cuff is under inflated" and also E and E/38 for measurement error. The number "0" and "38" means for "0mmHg" and "38mmHg". These are no more than example description for manual. However, in order not to confuse users, we are not using this description in manual any more.*

Chart 1 Error Codes

Model	Error codes			
M3 Intellisense	EE	E	E/E	Eo25
HEM-7051	EE/0	E/38	E/E	Eo25

Recommendation	The queries were adequately answered. A further query needs to be made regarding the accuracy ranges. Equivalence is recommended subject to an adequate response.
Date	26/08/2010