## dable Educational Trustanana

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

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

Takefumi Nakanishi Nakanis	SECTION	A - Plea	se complete all items online.					
Omron i-C10 (HEM-7070-E)	I				Omron Healt	hcare Europe B.V.		
Blood pressure measuring device and the Omno Mc Comfort (HEM-7000-E)   Childing validated blood pressure measuring device, which has previously passed the International protocol, the results of which were published as follows   Jalii Belghazi,Ramzi N El Feghali,Thérèse Moussalem,Maya Rejdych,Roland G Asmar Authorste)   Validation of four automatic devices for self-measurement of blood pressure   according to the International Protocol of the European Society of Hypertension   Tule   Vascular Health and Risk Management   2007;3(4) 1–12   Veer Volume Pages   Validation of Four automatic devices for self-measurement of blood pressure   according to the International Protocol of the European Society of Hypertension   Tule   Vascular Health and Risk Management   2007;3(4) 1–12   Veer Volume Pages   Validation in the relevant, both Yea and two should be left blank. Pleases provide details on any differences below.)  Part I	hereby state	that the	ere are no differences that will affect blood	i pressure measu	ring accuracy bet	tween the		
Omron M6 Comfort (HEM-7000-E)   Editing validated blood pressure measuring device   Dood pressure   Dood   Do			Omron i-C10 (HEM-7070-E) Blood pressure measuring device for which validation is claim	ned				
Omron M6 Comfort (HEM-7000-E)   Editing validated blood pressure measuring device   Dood pressure   Dood   Do	blood press	ure mea	suring device and the					
Part I	•		Omron M6 Comfort (HEM-7000-E)					
Falil Belghazi, Ramzi N El Feghali, Thérèse Moussalem, Maya Rejdych, Roland G Asmar Authorate)   Validation of four automatic devices for self-measurement of blood pressure   according to the International Protocol of the European Society of Hypertension   The Vascular Health and Risk Management   2007;3(4) 1—12   Vear Volumin Pagas   Vear Volumin Vear Vear Vear Vear Vear Vear Vear Vear			suring device, which has previously passed	d the Internation	nal protocol, the	results of which were		
Authors(s)  Validation of four automatic devices for self-measurement of blood pressure  according to the International Protocol of the European Society of Hypertension Titles  Vascular Health and Risk Management  Vascular Health and Risk Management  2007;3(4) 1–12  Publication  Performance between the devices involve the following components:  **None 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)  5 Pressure Transducer Yes  No   6 Cuff or Bladder Yes  No   7 Inflation Mechanism Yes  No   8 Deflation Mechanism Yes  No   8 Deflation Mechanism 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   18 Other Facilities Yes No   19 No   3 Rief explanation of differences and further relevant details:  10) includes I memory button (to see the individual readings) instead of 2 memory button, includes memory button for Morning time and Evening, includes 2 user button, includes Cuff compartment the foundation of weekly average in Morning and Evening, includes Symbol for Auto-mode (3 continuous measurements)  13) includes the function of weekly average in Morning and Evening, includes Auto-mode (3 continuous measurements)  14) includes the function of weekly average in Morning and Evening, includes Auto-mode (3 continuous measurements)	<b>T</b>			haa Mangaalam N	Aarra Daidreah Da	land C. Asman		
According to the International Protocol of the European Society of Hypertension Title   Vascular Health and Risk Management   Yascular Health and Risk Management   Yes   No			<u>Jalil Belghazi, Ramzi N El Feghali, Thérèse Moussalem, Maya Rejdych, Roland G Asmar</u> Authors(s)					
The Vascular Health and Risk Management			Validation of four automatic devices for	self-measureme	nt of blood press	ure		
Vascular Health and Risk Management   2007;3(4) 1—12   Year Volume Pages				of the European S	Society of Hypert	ension		
Part I			Vascular Health and Risk Management					
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 9 Yes   No   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 18 Other Facilities 19 No   10 Casing 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 18 Other Facilities 19 No   19 Other Facilities 10 includes 1 memory button (to see the individual readings) instead of 2 memory button, includes memory button for Morning time and Evening time, includes 2 user button, includes cuff compartment 19 includes symbol for 2 user, includes symbol for the high blood pressure in morning, includes symbol for the weekly average readings in Moring and Evening, includes Auto-mode (3 continuous measurements) 10 includes the function of weekly average in Morning and Evening, includes Auto-mode (3 continuous measurements)					pelow.)			
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3		2	_		Yes □			
5 Pressure Transducer Yes  No   No   No   No   No   No   No   N		3	Artefact/Error Detection		Yes □	No ⊠		
6 Cuff or Bladder 7 Inflation Mechanism 8 Deflation Mechanism 9 Wood 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 18 Other Facilities 19 Wood Nood 10 Casing 10 Casing 11 Display 11 Display 12 Carrying/Mounting Facilities 19 Wood 10 Casing 10 Casing 11 Nood 12 Carrying/Mounting Facilities 10 Nood 11 Memory Capacity/Number of stored measurements 11 Nood 12 Carrying/Mounting Facilities 19 Nood 10 Casing 10 Nood 11 Display 11 Display 12 Carrying/Mounting Facilities 14 Memory Capacity/Number of stored measurements 15 Printing Facilities 16 Communication Facilities 17 Power Supply 18 Other Facilities 18 Other Facilities 19 Nood 10 Other Facilities 10 Includes 1 memory button (to see the individual readings) instead of 2 memory button, includes memory button for Morning time and Evening time, includes 2 user button, includes cuff compartment 10 Includes symbol for 2 user, includes symbol for the high blood pressure in morning, includes symbol for the weekly average readings in Moring and Evening, includes symbol for Auto-mode (3 continuous measurements) 13 includes the function of weekly average in Morning and Evening, includes Auto-mode (3 continuous measurements)		4	Microphone(s)		Yes □	No 🗆		
7 Inflation Mechanism		5	Pressure Transducer		Yes □	No ⊠		
Restriction		6	Cuff or Bladder		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 □ 18 Other Facilities Yes □ No □ 19 Orief explanation of differences and further relevant details: 10) includes 1 memory button (to see the individual readings) instead of 2 memory button, includes memory button for Morning time and Evening time, includes 2 user button, includes cuff compartment 11) includes symbol for 2 user, includes symbol for the high blood pressure in morning, includes symbol for the weekly average readings in Moring and Evening, includes symbol for Auto-mode (3 continuous measurements) 13) includes the function of weekly average in Morning and Evening, includes Auto-mode (3 continuous measurements)		7	Inflation Mechanism		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 □ 18 Other Facilities Yes □ No □ 19 No □ No □ 110 includes 1 memory button (to see the individual readings) instead of 2 memory button, includes memory button for Morning time and Evening time, includes 2 user button, includes cuff compartment (1) includes symbol for 2 user, includes symbol for the high blood pressure in morning, includes symbol for the weekly average readings in Moring and Evening, includes symbol for Auto-mode (3 continuous measurements) 18 includes the function of weekly average in Morning and Evening, includes Auto-mode (3 continuous measurements)		8	Deflation Mechanism		Yes □	No 🖂		
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15 Printing Facilities  16 Communication Facilities  17 Power Supply  18 Other Facilities  19 No □  18 Other Facilities  10 includes 1 memory button (to see the individual readings) instead of 2 memory button, includes memory button for Morning time and Evening time, includes 2 user button, includes cuff compartment  11) includes symbol for 2 user, includes symbol for the high blood pressure in morning, includes symbol for the weekly average readings in Moring and Evening, includes symbol for Auto-mode (3 continuous measurements)  13) includes the function of weekly average in Morning and Evening, includes Auto-mode (3 continuous measurements)			5		<del></del>			
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measurements)								
,	•		nction of weekly average in Morning and E	Evening, include	s Auto-mode (3 c	continuous		
		•	dings in memory instead of 90 readings					
	,		<u> </u>					

Tel +353 1 278 0247 Fax + 353 1 278 3835

## 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 \_

Takefumi Nakanishi Name

Address

Date 30 July. 2008

Signature of Witness

Name

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

Omron Healthcare Europe B.V., Kruisweg 577, 2132NA Hoofddorp, The Netherlands

Tel +353 1 278 0247

Fax +353 1 278 3835

## Comparison of the Omron i-C10 with the Omron M6 Comfort

Devices	Omron i-C10 (HEM-7070-E)		Omron M6 Comfort (HEM-7000-E)	
Pictures		TIB STORY		
Validation			ESH	
Device 1 Criteria	Cuff Compartment User ID switch, symbol Auto mode (3 continuous measurements - button, symbol) Morning/Evening weekly Average buttons and algorithms Morning hypertension symbol	10 10, 11 10, 11, 13 10, 11, 13 11, 13		
Same Criteria	Accuracy ± 3 mmHg BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm Body movement error indicator Pressure detection by "capacitive" pressure sensor Cuff: 152 mm × 600 mm (Arm circ. 22 to 42 cm) O/I Start button Single screen display Date/Time Display During Measurement: Deflation & Heartbeat Symbols Hypertension indicator Irregular heartbeat detection Last 3 measurements averages Power: Optional AC adapter	1, 5 1, 5, 7, 8 3, 11, 13 5 6 10 10 11 11 11, 13 11, 13 13 17	Accuracy ± 3 mmHg BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm Body movement error indicator Pressure detection by "capacitive" pressure sensor Cuff: 152 mm × 600 mm (Arm circ. 22 to 42 cm) O/I Start button Single screen display Date/Time Display During Measurement: Deflation & Heartbeat Symbols Hypertension indicator Irregular heartbeat detection Last 3 measurements averages Power: Optional AC adapter	1, 5 1, 5, 7, 8 3, 11, 13 5 6 10 10 11 11, 13 11, 13 13, 13
Comparable Criteria	Set Button Memory button, memory symbol Memory: 84 measurements × 2 users Power: 4 "AA" batteries ~ 1400 measurements	10 10, 11 11, 14 17	Date/Time setting button 2 memory buttons, memory symbol Memory: 90 measurements Power: 4 "AA" batteries ~ 1500 measurements	10 10, 11 11, 14 17
Device 2 Criteria				

Web link	http://www.omron-healthcare.com/sitepreview.php?SiteID=537

Comments	The i-C10 essentially has extra averaging facilities not available on the M6 Comfort. Weekly morning and evening averages are included with a special symbol if the morning average is elevated. While both devices provide averages for the last three readings, the i-C10 has a facility for automatically taking three readings in sequence. Readings can be stored separately for 2 people. Date and time settings on the i-C10 are provided using the set (auto mode) and memory buttons.
	Bar the removal of the USB facility, the i-C10 appears to be almost identical to the M-10IT with the casing extended to be a built-in carry case, including the cuff compartment and cover.
	All of the additions are calculated extras There appears to be no differences in any aspects concerned with BP detection.  The i-C10 is not yet listed on the Omron website.
Recommendation	Equivalence is recommended
Date	06/10/2008