

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

A SIGNED COPY WILL BE POSTED ON THE [www.dableducational.org](http://www.dableducational.org) WEBSITE

### SECTION A - Please complete all items online.

I Takefumi Nakanishi Director of Omron Healthcare Europe B.V.  
Name of a Company Director Company name

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

HEM-7080IC (HEM-7080-IC)  
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron 705IT (HEM-759-E)  
Existing validated blood pressure measuring device

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

Mohamed A. El Assaad, Jirar A. Topouchian and Roland G. Asmar  
Authors(s)

Evaluation of two devices for self-measurement of blood pressure

according to the international protocol: the Omron M5-I and the Omron 705IT

Title

Blood Pressure Monitoring

Publication

2003, 8:127-133

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

Brief explanation of differences and further relevant details:

10) 1 button for both Power ON and START instead of 2 respective buttons. No buttons for clock setting. 2 buttons for nocturnal measurements are added. 2 buttons to call the readings in the memory instead of 1 button. The button to store and call the events in the memory is added.

11) The symbols for body movement detection is added. Clock displays AM/PM instead of 24 hours.

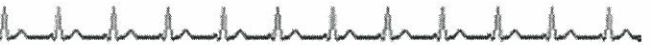
13) The functions to detect body movement, measure nocturnal blood pressure, and store events in the memory are added.

14) Stores 350 readings instead of 28 readings.

15) No printer connection.

18) USB cable and PC software in CD-ROM are available. (not included, to be supplied separately)

# 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	<u>T. Nakanishi</u>	Company Stamp/Seal
Name	<u>Takefumi Nakanishi</u>	OMRON HEALTHCARE EUROPE B.V.
Date	<u>29 Jan. 2008</u>	Kruisweg 577
Signature of Witness	<u>Helen Demeny</u>	NL-2132 NA Hoofddorp
Name	<u>Helen Demeny</u>	P.O. Box 2150 NL- 2130 GL Hoofddorp
Address	<u>Omron Healthcare Europe B.V., Kruisweg 577, 2132NA Hoofddorp, The Netherlands</u>	Tel. +31 - 20 354 82 00
		Fax +31 - 20 354 82 01

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

A SIGNED COPY WILL BE POSTED ON THE [www.dableducational.org](http://www.dableducational.org) WEBSITE

### SECTION A - Please complete all items online.

I Takefumi Nakanishi Director of Omron Healthcare Europe B.V.  
Name of a Company Director Company name

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

HEM-7080IC (HEM-7080-IC)

Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron 705IT (HEM-759-E)

Existing validated blood pressure measuring device

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

Andrew Coleman, Paul Freeman, Stephen Steel and Andrew Shennan

Authors(s)

Validation of the Omron 705IT (HEM-759-E) oscillometric blood pressure monitoring

device according to the British Hypertension Society protocol

Title

Blood Pressure Monitoring

Publication

2006;11:27-32

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

Brief explanation of differences and further relevant details:

10) 1 button for both Power ON and START instead of 2 respective buttons. No buttons for clock setting. 2 buttons for nocturnal measurements are added. 2 buttons to call the readings in the memory instead of 1 button. The button to store and call the events in the memory is added.

11) The symbols for body movement detection is added. Clock displays AM/PM instead of 24 hours.

13) The functions to detect body movement, measure nocturnal blood pressure, and store events in the memory are added.

14) Stores 350 readings instead of 28 readings.

15) No printer connection.

18) USB cable and PC software in CD-ROM are available. (not included, to be supplied separately)

# dabl<sup>®</sup> 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 29 Jan. 2008



Signature of Witness Helen Demeny

Name Helen Demeny

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

### Comparison of the Omron HEM-7080IC with the Omron 705IT

Devices	Omron HEM-7080IC (HEM-7080-IC)	Omron 705IT (HEM-759-E)
Pictures		
Validation		ESH and BHS
Device 1 Criteria	Body movement error indicator 3, 11, 13 Nocturnal pressure 10, 11, 13 Event Recording 10, 11, 13	
Same Criteria	BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Accuracy $\pm 3$ mmHg 1, 5 Pressure detection by “capacitive” pressure sensor 5 Cuff (140 mm $\times$ 480 mm) 6 Fuzzy logic inflation; automatic deflation 7, 8 4 $\times$ 1.5 V “AA” (LR6) Batteries (300 measurements) 17 AC adapter jack and AC Adapter 17	BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Accuracy $\pm 3$ mmHg 1, 5 Pressure detection by “capacitive” pressure sensor 5 Cuff (140 mm $\times$ 480 mm) 6 Fuzzy logic inflation; automatic deflation 7, 8 4 $\times$ 1.5 V “LR6” (AA) Batteries (300 measurements) 17 AC adapter jack (Adapter available as accessory) 17
Comparable Criteria	Single screen display 10 Two memory buttons (previous and next) 10 On/Off button 10, 13 No Date/Time Setting button but 12-hour clock? 10, 13 12-hour Clock 11 Memory: 350 measurements 14 USB Port 15, 16 USB Cable and PC Software available as accessory 16, 18	Two screen display 10 Memory button (cycle) 10 On/Off (inc Stop) and Start buttons 10, 13 Date/Time Set and Adjust buttons 10, 13 24-hour Clock 11 Memory: 28 measurements 14 USB/Printer Port 15, 16 USB Cable and PC Software 16, 18
Device 2 Criteria		
Web link	<i>Only available in Chinese and Japanese sites.</i>	<a href="http://www.omron-healthcare.com/sitepreview.php?SiteID=222">http://www.omron-healthcare.com/sitepreview.php?SiteID=222</a>

<b>Comments</b>	<p>The manual for this device is only available in Chinese. A translation of the technical specifications was supplied by the manufacturer. The elements affecting accuracy appear to be the same. A query, mainly due to features stated in the declaration of equivalence but which could not be checked in the Chinese manual was sent and the reply was satisfactory.</p> <p>Query Sent 11/03/2008:  For completeness, however, could a translation be provided regarding the elements on the display, the meaning of “Nocturnal pressure” and “Event Recording” and the location where it states that it records 350 measurements so that they can be verified? If there are no buttons for setting the clock, how are it and the date set?</p> <p>Reply Sent 27/10/2008:  Regarding your question of "For completeness, however, could a translation be provided regarding the elements on the display, the meaning of “Nocturnal pressure” and “Event Recording” and the location where it states that it records 350 measurements so that they can be verified? If there are no buttons for setting the clock, how are it and the date set?", please find the following feedback from Omron.</p> <ul style="list-style-type: none"> <li>- “Nocturnal pressure” means BP readings obtained by a function of the device which automatically performs BP measurement based on timer during sleep.</li> <li>- “Event recording” means the device’s function which records time and date when the “event button” was pressed by operator. This function is usually used to record time of patient’s activity, such as medication, meals, physical exercise, etc.</li> <li>- The statements about 350 reading recording appear on page 2 and 27 but not in the technical information; see attached copy of the pages the statements are included.</li> <li>- The setting the clock is done at the factory level before the product is shipped out from our factory.</li> </ul>
<b>Recommendation</b>	Equivalence is recommended.
<b>Date</b>	12/11/2008

HEM-7080ICは、このような流れで使います。

## 測定する

### ② 測定



- 1 腕帯を巻く  
(☞ 15ページ)
- 2 正しい姿勢の確認  
(☞ 17ページ)
- 3 血圧の測定  
(☞ 19ページ)

毎日同じ時間帯に測定して、  
血圧管理に役立ててください。

### ③ 記録を見る



この血圧計は、350回分の測定記録を見ることができます。

(☞ 27ページ)

## 測定記録を呼び出す

この血圧計は、血圧と脈拍を日時とともに自動的に記録し、350回分の測定記録やメモスイッチによる記録を呼び出すことができます。

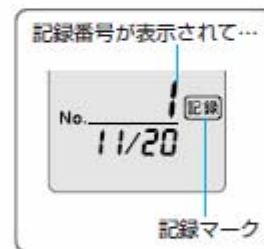
◎測定記録やメモスイッチによる記録が350回を超えると、古い記録から消去されます。

- 1 記録呼出 ◀ スイッチを押して、  
最も新しい測定記録を表示する

最も新しい測定記録が表示されます。



使い方



最も新しい  
測定記録  
表示例

午後 10:08 日付と時刻が交互に表示されます

