

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE

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SECTION A - Please complete all items online.

I Stephen MacAleese
Name of a Company Director

Director of Omron Healthcare (UK) limited
Company name

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

Omron 705CP-II (HEM-759P-E)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron 705-IT (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 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 705-IT

Title
Blood Pressure Monitoring
Publication

2003, Vol 8, No 3
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)

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 checked="" type="checkbox"/>
3	Artefact/Error Detection	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
4	Microphone(s)	Yes <input type="checkbox"/>	No <input checked="" 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"/>
9	Model Name or Number	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
10	Casing	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
11	Display	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
12	Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
13	Software other than Algorithm	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
14	Printing Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
15	Communication Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
16	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
17	Other Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>

Further relevant details:


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

Signature of Director 

Company Stamp/Seal

Name Mr Stephen MacAleese

Date 10/10/2005



Signature of Witness 

Name Ms J Mills

Address Omron Healthcare, Fox Milne, Milton Keynes, MK15 0DG

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Table 11: Comparison of the Omron 705CP-II with the Omron 705IT

Devices	Omron 705CP-II (HEM-759P-E or HEM-759P-E2)	Omron 705IT (HEM-759E or HEM-759P-E)
Pictures		
Validation	ESH and BHS	ESH and BHS
Device 1 Criteria		
Same Criteria	“Intellisense” technology (Fuzzy logic on inflation) Memory: 28 measurements Large 2-fold display Medium cuff with optional large and small cuffs Bio Information Link (BI) functionality	“Intellisense” technology (Fuzzy logic on inflation) Memory: 28 measurements Large 2-fold display Medium cuff with optional large and small cuffs Bio Information Link (BI) functionality
Comparable Criteria	USB cable and software optionally available Includes printer for hard copies	Includes USB cable and software Optional Printer for hard copies
Device 2 Criteria		
Web link	http://www.mortonmedical.co.uk/omron_705CPII.htm	http://www.omron-healthcare.com/site/index.cfm?BID=3&SID=1&TID=29&MID=32&ART=218&LG=2&back=1
Comments	These are essentially the same model; one comes with a printer and the other a USB cable. The HEM names in bold were those supplied but they differ from those advertised as shown in italics. Omron links both monitors to the information page. “Bio Information Link (BI) functionality” is claimed on site but no explanation is provided in the manual.	
Recommendation	Recommend this device using the supplied HEM numbers.	