

## 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, István Szöllősi Director of Meditech Ltd.  
Name of a Company Director Company name

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

Meditech ABPM-05  
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Meditech ABPM-04  
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

Barna L., Keszei A., Dunai A.  
Author(s)  
Evaluation of Meditech ABPM-04 ambulatory blood pressure measuring device

according to the British Hypertension Society protocol.  
Title  
Blood Press Monit. 1998;3:363-368  
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.)

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 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"/>
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 checked="" type="checkbox"/>	No <input type="checkbox"/>
	13	Software other than Algorithm	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	14	Memory Capacity/Number of stored measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	18	Other Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

Brief explanation of differences and further relevant details: Smaller casing; larger display; 2 instead of 4 AA batteries; an additional day/night button.

### 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 István Szöllősi

Company Stamp/Seal

Name István Szöllősi

Date 20 May 2008

Signature of Witness László Meleg

Name László Meleg

Address Vasvári u. 17/b, Budapest, Hungary



Meditech Kft. - Orvosi Elektronika  
 1191 Budapest, Üllői út 200.  
 Adószám: 10397680-2-43

### Comparison of the Meditech ABPM-05 with the Meditech ABPM-04

Devices	ABPM-05	ABPM-04
Pictures		
Validation		BHS
Device 1 Criteria	Day/Night button 10 Bed-time and Rising recording (using Day/Night button) 10 Heart symbol shows pulse during deflation 11 Moon symbol shows night mode 11 Patient can switch to next period frequency 13	
Same Criteria	BP 30-260 mmHg, Pulse 40-200 bpm 1, 5, 7, 8 Accuracy $\pm 3$ mmHg or $\pm 2\%$ (2 years) 1, 5 Oscillometric, Piezo-resistive sensor 5 Cuff (Med Bladder 125×225mm, Sleeve 16×52cm, Arm 24-32cm) 6 Automatic Inflation & Deflation, Safety release 7, 8 Start and Event Buttons 10	BP 30-260 mmHg, Pulse 40-200 bpm 1, 5, 7, 8 Accuracy $\pm 3$ mmHg or $\pm 2\%$ (2 years) 1, 5 Oscillometric, Piezo-resistive sensor 5 Cuff (Med Bladder 125×225mm, Sleeve 16×52cm, Arm 24-32cm) 6 Automatic Inflation & Deflation, Safety release 7, 8 Start and Event Buttons 10
Comparable Criteria	Dimensions 70 × 99 × 30 mm, 240 g inc batteries 10 Larger LCD screen display with symbols 10 Crossed battery symbol shows low battery 11 Arrow symbol and PC shows communication with PC 11 Memory: > 600 measurements 14 2 AA rechargeable or alkaline batteries (250 measurements) 17	Dimensions 82 × 124 × 33.5 mm, 330 g inc batteries 10 Small LCD screen display 10 Three dots shows low battery 11 PC shows communication with PC 11 Memory: > 400 measurements 14 4 AA rechargeable or alkaline batteries (250-300 measurements) 17
Device 2 Criteria		
Web link	<a href="http://www.meditech.hu/main.php?lang=en&amp;page=features&amp;device=abpm05">http://www.meditech.hu/main.php?lang=en&amp;page=features&amp;device=abpm05</a>	<a href="http://www.meditech.hu/main.php?lang=en&amp;page=features&amp;device=abpm04">http://www.meditech.hu/main.php?lang=en&amp;page=features&amp;device=abpm04</a>

<p><b>Comments</b></p>	<p>The main differences in the ABPM-05 are</p> <ul style="list-style-type: none"> <li>a) It is smaller and lighter than the ABPM-04.</li> <li>b) The display is larger and has symbols to supplement statuses shown on the numeric display.</li> <li>c) Special bed-time and rising events are easily recorded.</li> <li>d) If a patient goes to bed or rises prior to the programmed night and day frequency settings, the option to bring forward those settings (within 2 hours) is provided.</li> </ul> <p>There appears to be no change to any of the aspects dealing with blood pressure detection. The range of cuffs are identical and the pressure sensor appears to be unchanged. Apart from a feature to enable/disable the feature allowing the patient to bring forward the frequency of the next period, the software for both systems is the same. There is nothing to suggest a change in the algorithm.</p> <p>Query from Advisory Board member:</p> <p>Does the reduced power consumption suggest a different pumping mechanism and a consequent difference in inflation or deflation cuff rate that may affect the measurements?</p> <p>Reply:</p> <p>As a matter of fact, it is only the number of batteries that has been reduced (from 4 to 2 AA size batteries). Some simple electronic components - NOT in connection with the measuring process itself - ensure that the motor pump gets the same voltage in ABPM-05 as it did in ABPM-04, so there is no difference in the actual pumping mechanism.</p> <p>Therefore, there is no (consequent) difference in inflation rates. The operating as well as the safety release valves work in the same manner, getting an up-converted voltage from two batteries in ABPM-05, where they used to get a down-converted voltage in ABPM-04. So there is no difference in the cuff deflation mechanism, either. Therefore, measurements are not affected by any means due to the reduced number of batteries.</p> <p>On a side note, it is true that 2 batteries of the same size normally offer a lower total power capacity than 4 batteries. However, AA batteries have improved so much since the release of ABPM-04 that even 2 batteries in ABPM-05 will provide enough energy for all practical ABPM sessions (2 pieces of properly charged AA NiMH rechargeables will provide energy for a minimum of 250 measurements).</p> <p>In summary, the operation of the pump and valves (inflation and deflation mechanisms) are not affected by the change in the number of batteries due to a correct voltage conversion.</p>
<p><b>Recommendation</b></p>	<p>Equivalence is recommended.</p>
<p><b>Date</b></p>	<p>29/05/2008</p>