



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 Istvan Szollosi 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 card(X)plore ambulatory ECG, BP and actigraphy monitor

Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Meditech ABPM-04 ambulatory blood pressure monitor

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 I, Keszei A, Dunai A

Authors(s)

Evaluation of Meditech ABPM-04 ambulatory blood pressure measuring device

according to the British Hypertension Society protocol

Title

Blood Press Monit.

Publication

1998;3:363-368

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 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 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 type="checkbox"/>	No <input checked="" 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 type="checkbox"/>	No <input checked="" type="checkbox"/>

Brief explanations of differences and further relevant details: same ABP unit combined with holter ECG

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

Company Stamp/Seal

Name Istvan Szollosi

Date 23 Feb 2010



Signature of Witness

Name Laszlo Meleg

Address 200 Ulloi ut, Budapest, H-1191 Hungary



Comparison of the Meditech card(X)plore with the Meditech ABPM-04

Devices	Meditech card(X)plore	Meditech ABPM-04
Pictures		
Validation		BHS, AAMI
Device 1 Criteria	<p>Measurement</p> <p><i>Method</i></p> <p>Automatic ABPM measurements at ECG triggered events 13, 14</p> <p><i>Measurements other than Blood Pressure</i></p> <p>Holter ECG 10, 3, 14, 18</p> <p>Actigraphy monitor 13, 14, 18</p> <p>Display/Symbols/Indicators</p> <p><i>Communication</i></p> <p>Bluetooth connection PC -- (Optional) 11, 16</p> <p>Case</p> <p><i>Ports</i></p> <p>Bluetooth receiver (Optional) 16, 18</p> <p>Memory card slot + Memory Card 16, 18</p> <p>ECG socket and cable 16, 18</p>	
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg or $\pm 2\%$ 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>BP 30 mmHg - 260 mmHg 1, 5, 7, 8</p> <p>Pulse 40 bpm -200 bpm 1, 5</p> <p>Automatic ABPM measurements at programmed times 13, 14</p> <p>Manually initiated measurements 13, 14</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg - 300 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg or $\pm 2\%$ 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>BP 30 mmHg - 260 mmHg 1, 5, 7, 8</p> <p>Pulse 40 bpm -200 bpm 1, 5</p> <p>Automatic ABPM measurements at programmed times 13, 14</p> <p>Manually initiated measurements 13, 14</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg - 300 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p>

Devices	Meditech card(X)plore	Meditech ABPM-04
Same Criteria	Measurement	Measurement
	<i>Deflation</i>	<i>Deflation</i>
	Automatic Deflation 8	Automatic Deflation 8
	Automatic safety release valve 8	Automatic safety release valve 8
	<i>Cuffs</i>	<i>Cuffs</i>
	Medium 150 mm × 560 mm (Arm circ. 24 to 32 cm) 6	Medium 150 mm × 560 mm (Arm circ. 24 to 32 cm) 6
	Small 110 mm × 320 mm (Arm circ. < 24 cm) (Optional) 6	Small 110 mm × 320 mm (Arm circ. < 24 cm) (Optional) 6
	Large 170 mm × 770 mm (Arm circ. 32-42 cm) (Optional) 6	Large 170 mm × 770 mm (Arm circ. 32-42 cm) (Optional) 6
	<i>Sensors</i>	<i>Sensors</i>
	Pressure sensor: piezo-resistive 5	Pressure sensor: piezo-resistive 5
	Buttons/Switches	Buttons/Switches
	<i>Power</i>	<i>Power</i>
	Start/Stop (plain button) 10	Start/Stop (plain button) 10
	<i>Event Marking</i>	<i>Event Marking</i>
	Event Marker (indented circle mark - also includes Stop) 10	Event Marker (indented circle mark - also includes Stop) 10
	Display/Symbols/Indicators	Display/Symbols/Indicators
	<i>Measurement Procedure</i>	<i>Measurement Procedure</i>
	Inflation symbol □ 11	Inflation symbol □ 11
	During Measurement: BP Level 11	During Measurement: BP Level 11
	<i>Post Measurement</i>	<i>Post Measurement</i>
	SBP, DBP and Pulse 11	SBP, DBP and Pulse 11
	Measurement error 11	Measurement error 11
	<i>Date and Time</i>	<i>Date and Time</i>
	Time 11	Time 11
<i>Power</i>	<i>Power</i>	
Voltage Check 11, 17	Voltage Check 11, 17	
Low battery (3 dots) 11, 17	Low battery (3 dots) 11, 17	
<i>Communication</i>	<i>Communication</i>	
PC connection PC 11, 16	PC connection PC 11, 16	
Case	Case	
<i>Display</i>	<i>Display</i>	
Single screen display 10	Single screen display 10	
<i>Ports</i>	<i>Ports</i>	
Optical data port (USB or RS232 cable and PC software) 16, 18	Optical data port (USB or RS232 cable and PC software) 16, 18	
<i>Power</i>	<i>Power</i>	
Rechargeable batteries and charger 17	Rechargeable batteries and charger 17	
<i>Features</i>	<i>Features</i>	
Pouch, belt and shoulder straps 10	Pouch, belt and shoulder straps 10	

Devices	Meditech card(X)plore	Meditech ABPM-04
Comparable Criteria	<p>Measurement Measurement Records Memory Card: > 400 measurements, 12-51 hour ECG 12-51 hour actigraphy) 14</p> <p>Case Power 4 “AA” batteries (200-300 measurements, ECG & actigraphy) 17</p>	<p>Measurement Measurement Records Memory: > 400 measurements 14</p> <p>Case Power 4 “AA” batteries (200-300 measurements) 17</p>
Device 2 Criteria		<p>Measurement Method Suspension of automatic ABPM measurements 13, 14</p>
Web link	http://www.meditech.hu/main.php?lang=en&page=features&device=cardxplore	http://www.meditech.hu/main.php?lang=en&page=features&device=abpm04
Comments	<p>Meditech provide a number of ABPM, ECG and combined devices. The combined devices are based on the ABPM-04 ABPM monitor for blood pressure monitoring. All use the same manual in which it states that the algorithms for blood pressure are the same.</p> <p>The card(X)plore has holter ECG and actigraphy features.</p> <p>The main difference is that measurements in the ABPM-04 are stored in internal memory but, as this is insufficient to store the ECG and actigraphy measurements, they are stored in a memory card in the card(X)plore. A card reader is required to upload the measurements. The optical cable is used in the card(X)plore to check the placement of the ECG leads.</p> <p>In the ABPM-04, there is a facility for turning off and on the automatic recording that is not available in the card(X)plore. The card(X)plore can be programmed to take extra BP measurements should particular ECG events occur.</p>	
Recommendation	Equivalence is recommended	
Date	12/03/2010	