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Declaration of Equivalence Form

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2011

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

SECTION A - Please complete all items. Mark Beaton, a Director of Thermor Limited, Name of a Company Director hereby state that there are no differences that will affect blood pressure measuring accuracy between the Model **BIOS** Diagnostics BD204 Blood pressure measuring device for which validation is claimed. If alternative model names are used, include all blood pressure measuring device and the Manufacturer Honsun Model Honsun LD-578 Existing validated blood pressure measuring device. If alternative model names are used, include all blood pressure measuring device, which has previously passed the Internatio protocol, the results of which were published as follows: Yi Zhang, Jie Wang, Qi-Fang Huang, Chang-Sheng, Yan Li and Ji-Guang Wang Validation of Honsun LD-578 blood pressure monitor for home blood pressure monitoring according to the European Society of Hypertension International Protocol **Blood Pressure Monitoring** June 2009-Volume 14-Issue 3-pp 128-131. 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. It is necessary to provide details on each item ticked "Yes" in Section C or on a separate sheet. 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) Yes 🗌 No 🗌 5 Pressure Transducer Yes 🗌 No 🛛 6 Cuff or Bladder Yes 🗌 No 🖾 7 Inflation Mechanism No 🛛 Yes 🗌 8 **Deflation Mechanism** No 🖂 Yes 🗌 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 🗌 **Communication Facilities** 16 Yes 🔲 No 🗌 17 Power Supply Yes 🗌 No 🖂 Other Facilities Yes 🗌 No 🗆 An explanation of each item ticked "Yes" must be included in Section C on the next page **SECTION B** Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original to our address below. Please email a signed copy of this form together with manuals and images for both devices to info@dableducational.org. Signature of Director Company Stamp/Seal Name Mark Beaton October 25, 2011 Date

Name Joanna Binjek

Address 16975 Leslie Street, Newmorket, ON, Canada. © 2006-2011 dabl*Educational Trust Limited

Carraig Court, Georges Avenue, Blackrock, Co. Dublin, Ireland.

Signature of Witness

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SECTION C

An explanation for each item, 1 to 18, ticked "Yes" in Section A must be provided here or in an attached document. All differences between the devices must be described.

See Appendix A - Comparison of BIOS BD204 with Honsun LD-578

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Appendix A

| Devices | BIOS BD204 | Honsun LD-578 | | |
|-------------------|---|---|--|---|
| Pictures | BIOS Chargement of the Control of th | | 120 80 80 120 120 120 120 120 120 120 120 120 12 | |
| Validation | | | ESH | |
| Device 1 Criteria | Display/Symbols/Indicators Date and Time Date and Time Date and Time Date and Time (During memory recall) | 11 11 | | |
| | Buttons/Switches Measurement Records Memory (includes Date/Time set) | 10 | Buttons/Switches Measurement Records Memory | 10 |
| Same Criteria | Measurement Accuracy BP accuracy ± 3 mmHg Pulse accuracy ± 5% Method Oscillometric measurement method BP 40 mmHg – 260 mmHg Pulse 40 bpm – 160 bpm Manually initiated measurements Measurements are from single inflations Inflation Automatic Inflation Fuzzy Logic Four preset inflation pressures Deflation Automatic Deflation Cuffs Large (Arm circ. 32-43 cm) (Optional) Medium (Arm circ. 22-32 cm) Measurement Records Memory: 90 measurements | 1, 5 1, 5 1, 5 1, 5, 7, 8 1, 5, 8 13 13 7 7 7 8 6 6 | Measurement Accuracy BP accuracy ± 3 mmHg Pulse accuracy ± 5% Method Oscillometric measurement method BP 40 mmHg – 260 mmHg Pulse 40 bpm – 160 bpm Manually initiated measurements Measurements are from single inflations Inflation Automatic Inflation Fuzzy Logic Four preset inflation pressures Deflation Automatic Deflation Cuffs Large (Arm circ. 32-43 cm) (Optional) Medium (Arm circ. 22-32 cm) Measurement Records Memory: 90 measurements | 1, 5 1, 5 1, 5, 7, 8 1, 5, 8 13 13 7 7 7 8 6 6 |

| | Buttons/Switches | | Buttons/Switches | | |
|----------|--|----------------------------|--|--------|--|
| | Power On/Off with Start/Stop (O/I Label) | 10 | Power On/Off with Start/Stop (O/I Label) | 10 | |
| | Display/Symbols/Indicators | Display/Symbols/Indicators | | | |
| | Measurement Procedure | 40 | Measurement Procedure | 40 | |
| | Beeps before measurement | 18 | Beeps before measurement | 18 | |
| | During Measurement: BP Level & Heartbeat | 11 | During Measurement: BP Level & Heartbeat | 11 | |
| | Beeps after measurement Post Measurement | 18 | Beeps after measurement Post Measurement | 18 | |
| | SBP, DBP and Pulse | 11 | SBP, DBP and Pulse | 11 | |
| | Measurement error (no error numbers) | 11 | Measurement error (no error numbers) | 11 | |
| | Measurement Records | - '' | Measurement Records | 11 | |
| | Average "A" symbol | 11 | Average "A" symbol | 11 | |
| | Memory recall number (replaces pulse rate momen | | Memory recall number (replaces pulse rate moment | | |
| | Delete memory (Clr) | 11 | Delete memory (Clr) | 11 | |
| | Last 3 measurements mean | 11 | Last 3 measurements mean | 11 | |
| | Memory "M" symbol | 11 | Memory "M" symbol | 11 | |
| | Power | | Power | | |
| | Low battery | 11, 17 | Low battery | 11, 17 | |
| | Case | | Case | | |
| | Display | | Display | | |
| | Single screen display | 10 | Single screen display | 10 | |
| | Segment LCD | 10 | Segment LCD Power | 10 | |
| | 4 "AA" batteries (Optional) | 17 | 4 "AA" batteries | 17 | |
| | AC adapter | 17 | AC adapter (Optional) | 17 | |
| | Automatic switch-off when not used for 3 min | 17 | Automatic switch-off when not used for 3 min | 17 | |
| | Rechargeable batteries not permitted | 17 | Rechargeable batteries not permitted | 17 | |
| | Rechargeable batteries not permitted | 17 | Rechargeable batteries not permitted | 17 | |
| | Algorithms | | Algorithms | | |
| | Averages and Differences | | Averages and Differences | | |
| | Last 3 measurements mean | 13 | Last 3 measurements mean | 13 | |
| Comments | In addition to the above, both manuals provide detail BD204 appears identical from a measurement perspective. | | magnetic information which is the same in each case. To only addition being the date and time. | The | |
| | | • | | | |
| | Honsun is a manufacturer that distributes models under its own name (http://www.asian-medical.com). It is also an OEN | | | | |
| | company that distributes the same models to other distributers for sale under different brand names some of which use the same model number and some of which do not. The Canadian company Thermor uses BIOS as its brand name | | | | |
| | | | | | |
| | (http://biosexactly.com/) and supplies blood pressure monitors from, among others, Honsun. | | | | |
| | 17/10/2011 | | | | |



Device Equivalence Evaluation Form

Comparison of the BIOS BD204with the Honsun LD-578

| Devices | BIOS BD204 | | Honsun LD-578 | |
|-------------------|--|---|--|---|
| Pictures | BIOS Diagrandica: | HONSUN HOASUN | | |
| Display | 88.88 88.88° | | 88.8 88.8 mmHg 1 A 88. | |
| Validation | | | ESH | |
| Device 1 Criteria | Display/Symbols/Indicators Date and Time Date and Time Date and Time (During memory recall) | 11 11 | | |
| Same Criteria | Measurement Accuracy BP accuracy ± 3 mmHg Pulse accuracy ± 5% Method Oscillometric measurement method BP 40 mmHg - 260 mmHg Pulse 40 bpm -160 bpm Manually initiated measurements Measurements are from single inflations | 1, 5 1, 5 1, 5 1, 5, 7, 8 1, 5, 8 13 | Measurement Accuracy BP accuracy ± 3 mmHg Pulse accuracy ± 5% Method Oscillometric measurement method BP 40 mmHg - 260 mmHg Pulse 40 bpm -160 bpm Manually initiated measurements Measurements are from single inflations | 1, 5 1, 5 1, 5 1, 5, 7, 8 1, 5, 8 13 |

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Device Equivalence Evaluation Form

| Inflation | | Inflation | |
|--|------------|--|------------|
| 4 inflation levels (190, 230, 270, 300 mmHg) | 1, 5, 7 | 4 inflation levels (190, 230, 270, 300 mmHg) | 1, 5, 7 |
| Automatic Inflation | 7 | Automatic Inflation | 7 |
| Fuzzy Logic | 7 | Fuzzy Logic | 7 |
| Deflation | | Deflation | |
| Automatic Deflation | 8 | Automatic Deflation | 8 |
| Cuffs | _ | Cuffs | _ |
| Large (Arm circ. 32-43 cm) (Optional) | 6 | Large (Arm circ. 32-43 cm) (Optional) | 6 |
| Medium (Arm circ. 22 to 32 cm) | 6 | Medium (Arm circ. 22 to 32 cm) | 6 |
| Measurement Records Memory: 90 measurements | 14 | Measurement Records Memory: 90 measurements | 14 |
| Display/Symbols/Indicators | 14 | Display/Symbols/Indicators | 14 |
| Preparation Preparation | | Preparation | |
| Correct cuff wrapping indicator on cuff | 6 | Correct cuff wrapping indicator on cuff | 6 |
| Measurement Procedure | | Measurement Procedure | |
| Beeps before measurement | 18 | Beeps before measurement | 18 |
| During Measurement: BP Level & Heartbeat | 11 | During Measurement: BP Level & Heartbeat | 11 |
| Beeps after measurement | 18 | Beeps after measurement | 18 |
| Post Measurement | | Post Measurement | |
| SBP, DBP and Pulse | 11 | SBP, DBP and Pulse | 11 |
| Measurement error E_{rr} (no error numbers) | 11 | Measurement error Err (no error numbers) | 11 |
| Measurement Records | | Measurement Records | |
| Memory "M" symbol | 11 | Memory "M" symbol | 11 |
| Memory recall number (Replaces pulse rate momentarily) | 11 | Memory recall number (Replaces pulse rate momentarily) | 11 |
| Delete memory [Ir | 11 | Delete memory E Ir | 11 |
| Average "A" symbol | 11, 13, 14 | Average "A" symbol | 11, 13, 14 |
| Last 3 measurements mean | 13 | Last 3 measurements mean | 13 |
| Power | | Power | |
| Low battery | 11, 17 | Low battery | 11, 17 |
| Algorithms | | Algorithms | |
| Averages and Differences Last 3 measurements mean | 13 | Averages and Differences Last 3 measurements mean | 13 |
| Casing | 15 | Casing | 13 |
| Display | | Display | |
| Single screen display | 10 | Single screen display | 10 |
| Segment LCD | 10 | Segment LCD | 10 |
| Automatic switch-off when not used for 3 min | 17 | Automatic switch-off when not used for 3 min | 17 |
| Rechargeable batteries not permitted | 17 | Rechargeable batteries not permitted | 17 |

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Device Equivalence Evaluation Form

| Comparable Criteria | Buttons/Switches | Buttons/Switches | | |
|---------------------|--|------------------|------------------------------------|----|
| | Power | | Power | |
| | On/Off with Start/Stop and Enter (O/I Label) | 10 | On/Off with Start/Stop (O/I Label) | 10 |
| | Measurement Records/Settings | | Measurement Records/Settings | |
| | Memory with Date/Time Set | 10 | Memory | 10 |
| | Casing | | Casing | |
| | Power | | Power | |
| | 4 "AA" batteries (Optional) | 17 | 4 "AA" batteries | 17 |
| | AC adapter | 17 | AC adapter (Optional) | 17 |
| Device 2 Criteria | | | | |

| Comments | 1 | Response | In the manual for the BD204, the use of the two triangles is described as indicating insufficient inflation or deflation. The LD-578 screen contains up and down arrow symbols analogous to the triangles on the BD204. However, these are not mentioned in the manual. Are these symbols used in this device? After confirming the two arrows are not included as features in the BD204, we have removed this from our instructions. Explanation accepted | |
|----------------|---|----------|--|--|
| | Honsun, as well as supplying devices under its own brand name, is also an OEM supplier of devices. BIOS Diagnostics supplies OEM dev under its own brand. Honsun is one of the companies that it uses. Apart from the casing, the only difference is the BD204 allows for the date and time of measurements to be recorded. The memory and | | | |
| | buttons are given extra functionality to enable this. | | | |
| Recommendation | Equivalence is Recommended | | | |
| Date | 19/12/2011 | | | |

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