(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
30 August 2007 (30.08.2007)

(10) International Publication Number
WO 2007/096632 A1

(51) International Patent Classification:
A61B 5/022 (2006.01)

(21) International Application Number:
PCT/GB2007/000629

(22) International Filing Date:
22 February 2007 (22.02.2007)

(25) Filing Language:
English

(26) Publication Language:
English

(30) Priority Data:
0603564.6 23 February 2006 (23.02.2006) GB

(71) Applicant (for all designated States except US):
HUNTELEIGH TECHNOLOGY LIMITED [GB/GB];
310-312 Dallow Road, Luton, Bedfordshire LU1 ITD (GB).

(72) Inventors:

(75) Inventors/Applicants (for US only):
GOUGH, Nigel [GB/GB]; Ty Twt, 15 Hensol Road, Miskin, Pontyclun CF72 8JT (GB).
EVANS, Jon [GB/GB]; Dingle Cottage, 87 Mill Road, Lisvane, Cardiff CF14 OVG (GB).

(74) Agent: THAKER, Shalini; Group IP Department,
Huntleigh Technology PLC; 310-312 Dallow Road, Luton,
Bedfordshire LU1 ITD (GB).

(74) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS,
JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS,
LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY,
MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS,
RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN,
TR, TT, TZ, UA, US, UZ, VC, VN, ZA, ZM, ZW

(74) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT,
RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA,
GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published: with international search report

[Continued on next page]

(54) Title: AUTOMATIC ANKLE BRACHIAL PRESSURE INDEX SYSTEM

(57) Abstract: An ABPI measurement system (1) includes two cuffs (10) for each ankle and two cuffs (10) for each arm of a patient. Each cuff (10) has chambers (11, 12). The four cuffs are applied to each limb (or finger or toe), each chamber (11) is inflated simultaneously to a pressure until a Pneumo Arterial Plethysmography (PAPG) signal related to the arterial flow in the limb is detected at the chambers (11). The chambers (12) are then simultaneously inflated until the PAPG signals are extinguished in each limb, the inflation of chambers (12) continuing for 30mmHg to 20mmHg above that pressure. The chambers (12) are then deflated and the pressure at which the PAPG signal returns in the first chamber (11) is recorded for each limb and this value of the pressure is used to calculate the ABPI. The ABPI is displayed or sent to a remote site.
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
The present invention relates to the identification and assessment of lower limb arterial disease based on an Ankle Brachial Pressure Index (ABPI).

ABPI is expressed as the ratio of the ankle blood pressure to the highest brachial (upper arm) blood pressure. Generally, systolic blood pressure values are measured to determine this index. When a certain portion of an artery is affected by occlusive disease, blood pressure downstream of the occlusion in the direction of flow is lower than upstream of the occlusion so that an abnormal ankle and brachial blood pressure index is obtained and arterial disease can be diagnosed.

A known technique to measure ABPI involves the patient being supine and having rested for 5 to 10 minutes. The systolic pressures are then measured sequentially in each of the four limbs by applying a cuff to the upper arms and at the ankles. Usually a hand held Doppler probe is used to listen to the blood flow either in the brachial artery for blood pressure in the arms or in the dorsalis pedis and posterior tibial arteries for ankle blood pressures. However, the technique has difficulties in identifying the arteries in the foot using the Doppler probe as well as maintaining the blood vessel contact with Doppler probe during inflation and deflation of cuff. Also, the blood pressure is continually changing and pressures measured at the beginning of the test may be disassociated with pressures taken at the end of the test.

The use of arterial photo-plethysmography (PPG) can overcome the disadvantages of Doppler. However, it is dependent on the presence of fingers or toes and adequate arterial flow which may be compromised either by
temperature or arterial disease. More recently, pulse oximeters have been used for the detection of arterial pulses when taking systolic pressures. However, their use is likely to introduce errors in the pressure readings during deflation of the barometric cuff due to the inherent averaging process within the instrument.

The present invention seeks to make improvements. Accordingly, the present invention provides an ABPI measuring device comprising a plurality of inflatable cuffs, at least one cuff to be wrapped around an upper limb and at least one cuff to be wrapped around a lower limb, each of the cuffs having a first and a second chamber, means to inflate the first chambers simultaneously to a pre-determined pressure, holding the first chambers at that pressure and inflating simultaneously the second chambers to a desired pressure, recording the pressure and deflating the first and second chambers.

In a preferred embodiment, at least one cuff is wrapped around a finger and at least one cuff is wrapped around a toe, when it is not possible to wrap a cuff around the ankle, for example with a diabetic foot. Preferably, the second chambers are inflated to a pressure greater than the desired pressure and then deflated slowly to the desired pressure.

Preferably, each first chamber is simultaneously inflated to a pressure until a signal related to the arterial flow in the limb is detected. Preferably, each second chamber is simultaneously inflated to a desired pressure until the signal from each first chamber is no longer detected, each second chamber then inflated to a greater pressure than the desired pressure and finally deflated until the signal from each first chamber is
detected again and this desired pressure in each second chamber recorded.

Preferably, the device comprises four cuffs, each cuff to be wrapped around each limb or toe or finger.

According to another aspect of the invention, there is provided a method of measuring the ABPI comprising the steps of applying inflatable cuffs to each upper arm or fingers and each ankle or toes of a patient, the cuffs connected to a fluid source and control, each cuff having a first chamber and a second chamber, inflating simultaneously each first chamber of each cuff to a first pressure until a signal relating to the arterial flow in the limb is detected, then simultaneously inflating each second chamber of each cuff to a pressure where the signal is no longer detected, and inflating further the second chambers to a higher pressure, deflating the second chambers slowly until the signal is again detected at the first chamber, the control recording the pressure value of the second chambers, and calculating an ABPI value based on the pressures recorded.

According to an embodiment of the invention, the method of measuring the ABPI comprises applying inflatable cuffs to each upper arm or finger and obtaining pressure values, and repeating the method for each ankle or toe to obtain a pressure value for each ankle and then providing a display of the ABPI. The device has the advantage over the conventional methods of measuring ABPI in that it can make simultaneous measurements of systolic pressures from pairs of limbs, for example, arms or legs or fingers or toes or all four limbs or fingers or toes together. Inflation of pairs of limbs or fingers or toes may be necessary for some patients who are not comfortable with simultaneous inflation of all the limbs or fingers or toes. Inflation
of all the limbs or fingers or toes simultaneously obviates the need for a resting period prior to the test.

Embodiments of the present invention are disclosed below, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 shows an embodiment of the ABPI measurement system according to the invention;

Figure 2a shows in schematic form the cuff for the arm of the ABPI measurement system according to the invention;

Figure 2b shows in schematic form the cuff for the ankle of the ABPI measurement system according to the invention;

Figure 2c shows in schematic form the cuff for the toe of the ABPI measurement system according to the invention;

Figure 3 shows an example of a graph that is displayed on a display device of the ABPI measurement system according to the invention.

Referring to the Figures, the ABPI measurement system 1 includes two ankle blood pressure measuring devices 10 for each left and right ankle (Figure 2b) and two arm blood pressure measuring devices 10 for each left and right arm (Figure 2a) of a patient. As shown in Figure 2c, it is also envisaged that instead of the two ankle blood pressure measuring devices 10 there could be two toe blood pressure measuring devices and instead of the two arm blood pressure measuring devices 10 there could be two finger blood pressure measuring devices.

Each device 10 comprises a cuff having two chambers 11, 12 connected together in a manner so that either chamber does not interfere with the other chamber. The cuff 10 is adapted to be wrapped around the ankle and foot (Figure 2b) or upper arm and forearm (Figure 2a) as appropriate.
The chambers 11, 12 are connected by a flexible material 13 such that the action of one chamber does not interfere with the action of the other while maintaining a fixed distance between the chambers and allowing for simple and convenient application to the patient. The chambers 11, 12 are connected to a conventional fluid source for inflation and control 14 having pressure sensors to control the inflation. The fluid source and control are conventional and known to the person skilled in the art and will not be further described herein.

In use, the four blood pressure measuring devices 10 are wrapped around the respective right and left upper and lower limbs of a patient and each chamber 11 is inflated simultaneously to a pressure appropriate for the limb, for example, 60 mmHg for the ankles and arms, and less than 30 mmHg for the toes and fingers, until a Pneumo Arterial Plethysmography (PAPG) signal related to the arterial flow in the limb is detected at the chambers 11. Once a PAPG signal is detected at all four chambers 11, chambers 12 are then inflated until the PAPG signals are extinguished in each limb, the inflation of chambers 12 continuing for a further 10mmHg to 20mmHg above that pressure. The chambers 12 are then deflated and the pressure at which the PAPG signal returns is noted for each limb and this value of the pressure is used to calculate the ABPIs according to the equation below, where the highest brachial pressure is the greater value of the left and right brachial pressures.

\[
ABPI_{\text{Ld}} = \frac{A_{\text{Ld}} \text{sure}_{\text{Ld}}}{\text{Highest_brachial_pressure}} \\
ABPI_{\text{Rd}} = \frac{A_{\text{Rd}} \text{sure}_{\text{Rd}}}{\text{Highest_brachial_pressure}}
\]
The system displays the measured systolic pressures and the calculated Left ABPI and Right ABPI. If toe blood pressures are measured then the Left TBPI and Right TBPI is displayed. The ABPI/TBPI value can also be printed as a waveform 15 or communicated to a remote site.

The ABPI/TBPI value is interpreted to give an indication of the status of the arterial system of the patient. Typical results are as shown below:

1) ABPI >= 1.00 Normal
2) ABPI >1.30 Suspect calcified arteries. Recommend toe pressures.
3) ABPI 0.8-1.0 mild PAD.
4) ABPI 0.5-0.8 Intermittent claudication. Do not compress.
5) ABPI <0.5 Refer to vascular specialist. Do not compress.
6) TBPI <0.64 Abnormal indicating PAD
7) TBPI 0.64-0.7 Borderline
8) TBPI >0.7 Normal

Inflation of the chambers 12 to a pressure of 60mmHg, either before or after the test, allows the system to display the waveforms 15 related to the arterial flow in the limbs as shown in Figure 3. The waveforms from each chamber 12, can be used for further waveform analysis for the grading of arterial disease.

The above describes a simultaneous four limb blood pressure measurement system. However, it is also
possible to stagger the limb pair pressure measurements by taking the arm or finger pressures first followed by the ankle or toe pressures. This may be desirable for patient comfort and clinical safety.
CLAIMS

1. An ABPI measuring device comprises a plurality of inflatable cuffs, at least one cuff to be wrapped around an upper limb and at least one cuff to be wrapped around a lower limb, each of the cuffs having a first and a second chamber, means to inflate the first chambers simultaneously to a pre-determined pressure, holding the first chambers at that pressure and inflating simultaneously the second chambers to a desired pressure, recording the pressure and deflating the first and second chambers.

2. An ABPI measuring device as claimed in claim 1 wherein at least one cuff is wrapped around a finger and at least one cuff is wrapped around a toe, each of the cuffs having a first and a second chamber, means to inflate the first chambers simultaneously to a pre-determined pressure, holding the first chambers at that pressure and inflating simultaneously the second chambers to a desired pressure, recording the pressure and deflating the first and second chambers.

3. An ABPI device as claimed in claims 1 or 2 wherein the second chambers are simultaneously inflated to a pressure greater than the desired pressure and then simultaneously deflated slowly to the desired pressure.

4. An ABPI device as claimed in claims 1, 2 or 3 wherein each first chamber is simultaneously inflated to a pressure until a signal related to the arterial flow in the limb or finger or toe is detected.
5. An ABPI device as claimed in claim 4 wherein each second chamber is simultaneously inflated to a desired pressure until the signal from each first chamber is no longer detected, each second chamber then simultaneously inflated to a pressure greater than the desired pressure and finally simultaneously deflated until the signal from each first chamber is detected again and this desired pressure in each second chamber recorded for calculation of the ABPI value or TBPI value.

6. The device as claimed in any preceding claim wherein four cuffs are provided, one to be wrapped around each limb or finger or toe.

7. A method for measuring the ABPI/TBPI comprising the steps of applying inflatable cuffs to each upper arm or finger and each ankle or toe of a patient, the cuffs connected to a fluid source and control, each cuff having a first chamber and a second chamber, inflating simultaneously each first chamber of each cuff to a first pressure until a signal relating to the arterial flow in the limb is detected, then simultaneously inflating each second chamber of each cuff to a pressure where the signal is no longer detected, and simultaneously inflating further the second chambers to a higher pressure, then simultaneously deflating the second chambers slowly until the signal is again detected at each first chamber, the control recording the pressure value of the second chambers, and calculating an ABPI or TBPI value based on the pressures recorded.

8. A method as claimed in claim 7 wherein the pressure values from each arm or finger are obtained initially, and the pressure values from each ankle or toe are
obtained next and finally calculating the ABPI or TBPI value from the pressures recorded.

9. A method as claimed in claims 7 or 8 wherein the second chambers are inflated and the waveforms related to the arterial flow in the limbs displayed.

10. A method as claimed in claim 9 wherein the waveforms from each chamber are used to provide qualitative and/or quantitative grading of arterial disease.
A. CLASSIFICATION OF SUBJECT MATTER

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>US 3 581 734 A (CROSLIN MICHAEL EMANUEL ET AL) 1 June 1971 (1971-06-01) column 2, line 1 - column 4, line 32</td>
<td>1,2,7</td>
</tr>
<tr>
<td>Y</td>
<td>US 5 050 613 A (NEWMAN DENNIS [US] ET AL) 24 September 1991 (1991-09-24) column 4, line 61 - column 5, line 21 column 7, line 42 - column 10, line 56</td>
<td>1,2,7</td>
</tr>
</tbody>
</table>

* Special categories of cited documents

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"Y" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

Further documents are listed in the continuation of Box C | See patent family annex

Date of the actual completion of the international search: 14 May 2007
Date of mailing of the international search report: 22/05/2007

Name and mailing address of the ISA/
European Patent Office, P B 5818 Patentlaan 2
NL - 2280 HV RUISWIJK
Tel (+31-70) 340-2040, Tx 31 651 epnl,
Fax (+31-70) 340-3016

Authorized officer
Manschot, Jan
### DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patent document cited in search report</td>
<td>Publication date</td>
<td>Patent family member(s)</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>-----------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2002272688 A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>KR 20020073374 A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TW 516951 B</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2002133082 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2004121806 A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>KR 20040014170 A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2004024325 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 924124 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CH 500706 A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DE 1811401 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FR 1602161 A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>GB 1224510 A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NL 6818176 A</td>
</tr>
<tr>
<td>US 5050613 A</td>
<td>24-09-1991</td>
<td>NONE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 3638907 B2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2003199720 A</td>
</tr>
</tbody>
</table>