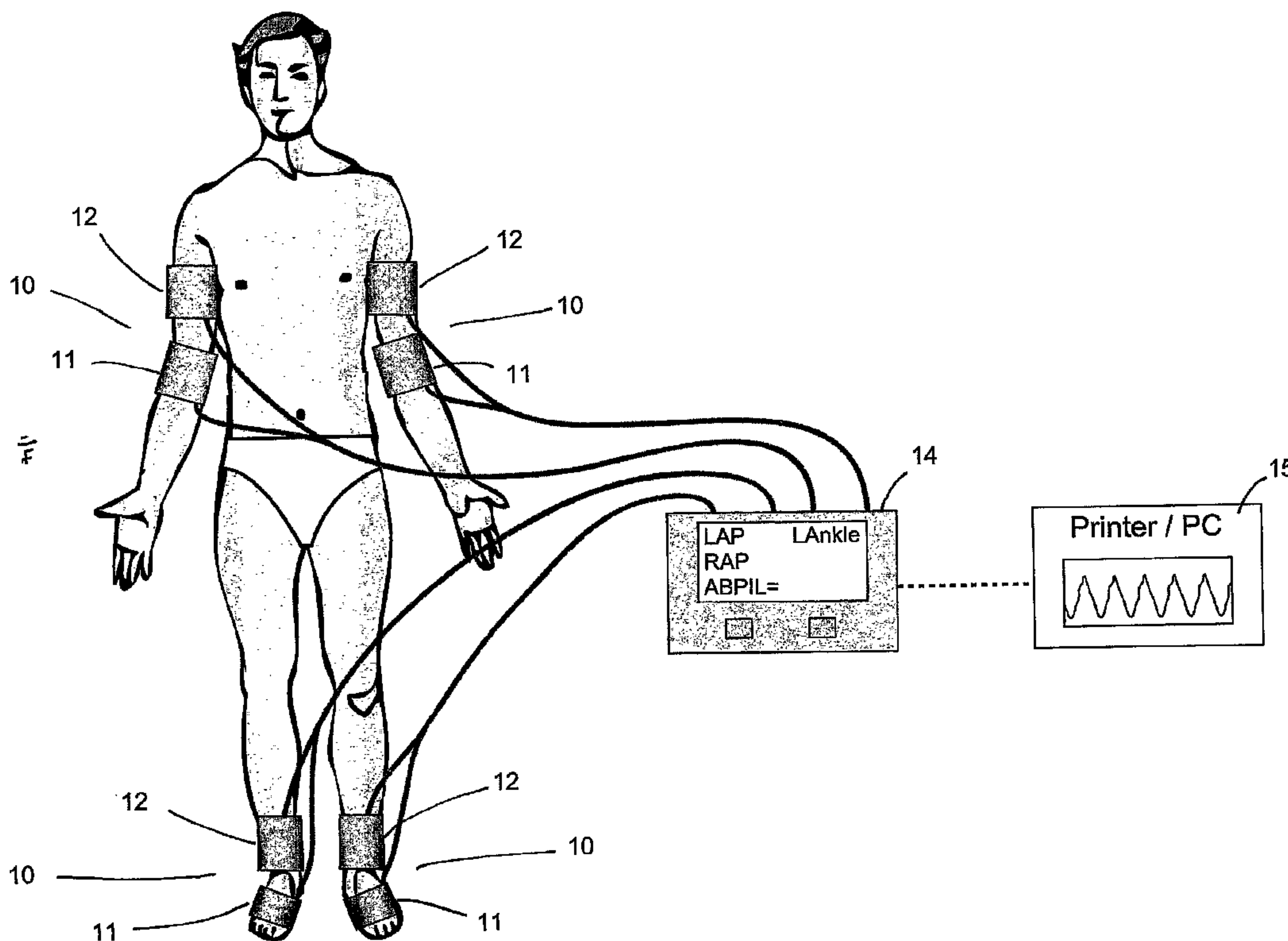




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(57) **Abrégé/Abstract:**

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 10mmHg 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.

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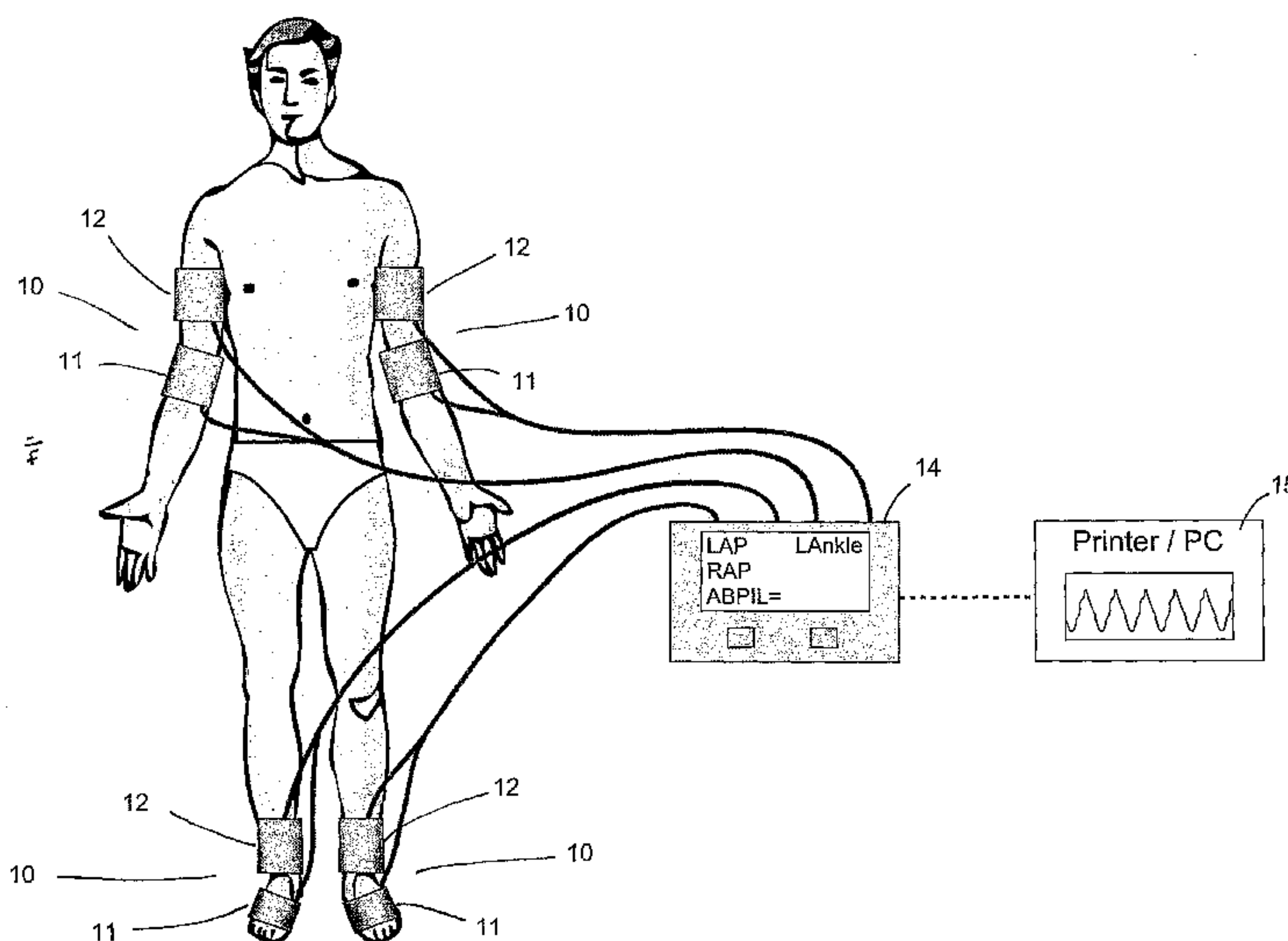
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WO 2007/096632 A1

WO 2007/096632 A1



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.

Automatic Ankle Brachial Pressure Index System

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..

5 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
10 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
15 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
20 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
25 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,
30 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
 5 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
 10 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
 15 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
 20 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
 25 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;

$$30 \quad ABPI_{left} = \frac{Ankle_pressure_{left}}{Highest_brachial_pressure}$$

$$ABPI_{right} = \frac{Ankle_pressure_{right}}{Highest_brachial_pressure}$$

$$TBPI_{left} = \frac{Toe_pressure_{left}}{Highest_brachial_pressure}$$

$$TBPI_{right} = \frac{Toe_pressure_{right}}{Highest_brachial_pressure}$$

5 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.

10 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. |
| 15 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. |
| 20 6) TBPI <0.64 | Abnormal indicating PAD |
| 7) TBPI 0.64-0.7 | Borderline |
| 8) TBPI >0.7 | Normal |

25 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.

30 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 TBPI measuring device comprises a plurality of inflatable cuffs (10), at least one first cuff (10) to be wrapped around an upper limb and at least one second cuff (10) to be wrapped around a lower limb, each of the cuffs having a first chamber (11) and a second chamber (12), means to inflate the chambers, control means to detect the pressure within the chambers (11, 12) and provide values of ABPI wherein the chambers (11, 12) are connected by a flexible material (13) such that during inflation, the first chamber (11) does not interfere with the action of the second chamber (12) but maintains a fixed distance between the chambers, means for inflating the first chambers (11) simultaneously to a first pressure until a PAPG signal relating to the arterial flow in the limb is detected, means for subsequently inflating the second chambers (12) simultaneously to a pressure until the PAPG signal is no longer detected and to inflate, the second chambers (12) subsequently simultaneously to a higher pressure and to slowly deflated simultaneously until the PAPG signal is again detected at the first chambers (11), the control means (14) recording the pressure value of the second chambers (12), and calculating an ABPI or TBPI value based on the pressures recorded.

2. An ABPI measuring device as claimed in claim 1 characterised in that the at least one cuff (10) is to be wrapped around a finger and the at least one cuff (10) is to be wrapped around a toe.

3. An ABPI measuring device as claimed in claim 1 characterised in that the device comprises four cuffs, each cuff to be wrapped around each limb or a toe or a finger from each limb.

4. A method for measuring the ABPI/TBPI comprising the steps of applying inflatable cuffs to at least an upper arm or finger and at least an ankle or toe of a patient, connecting the cuffs (10) to a fluid source and control, each cuff (10) having a first chamber (11) and a second chamber (12) connected by a flexible member (13) to maintain a fixed distance therebetween, inflating simultaneously each first chamber (11) of each cuff (10) to a first pressure until a PAPG signal relating to the arterial flow in the limb(s) is detected, then inflating simultaneously each second chamber (12) of each cuff (10) to a pressure until the PAPG signal is no longer detected, subsequently inflating simultaneously the second chambers (12) to a higher pressure, then slowly deflating simultaneously the second chambers (12) until the PAPG signal is again detected at each first chamber (11), the control (14) recording the pressure values in the second chambers (12), and calculating an ABPI or TBPI value based on the pressures recorded.

5. A method as claimed in claim 4 characterised in that the second chambers (12) are inflated and the waveforms related to the arterial flow in the limbs displayed.

6. A method as claimed in claim 5 characterised in that the waveforms from each chamber (11, 12) are used to provide qualitative and/or quantitative grading of arterial disease.

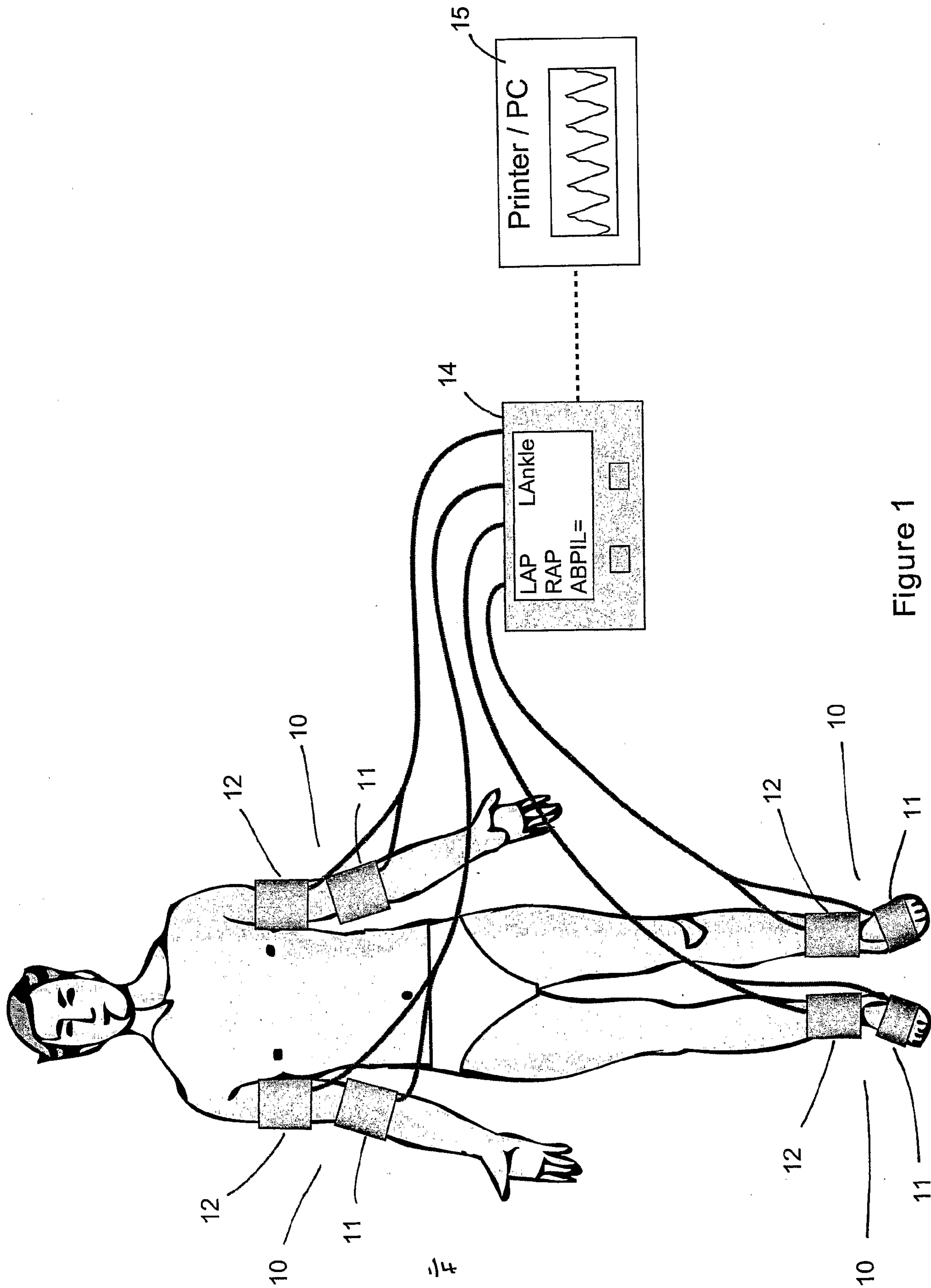


Figure 1

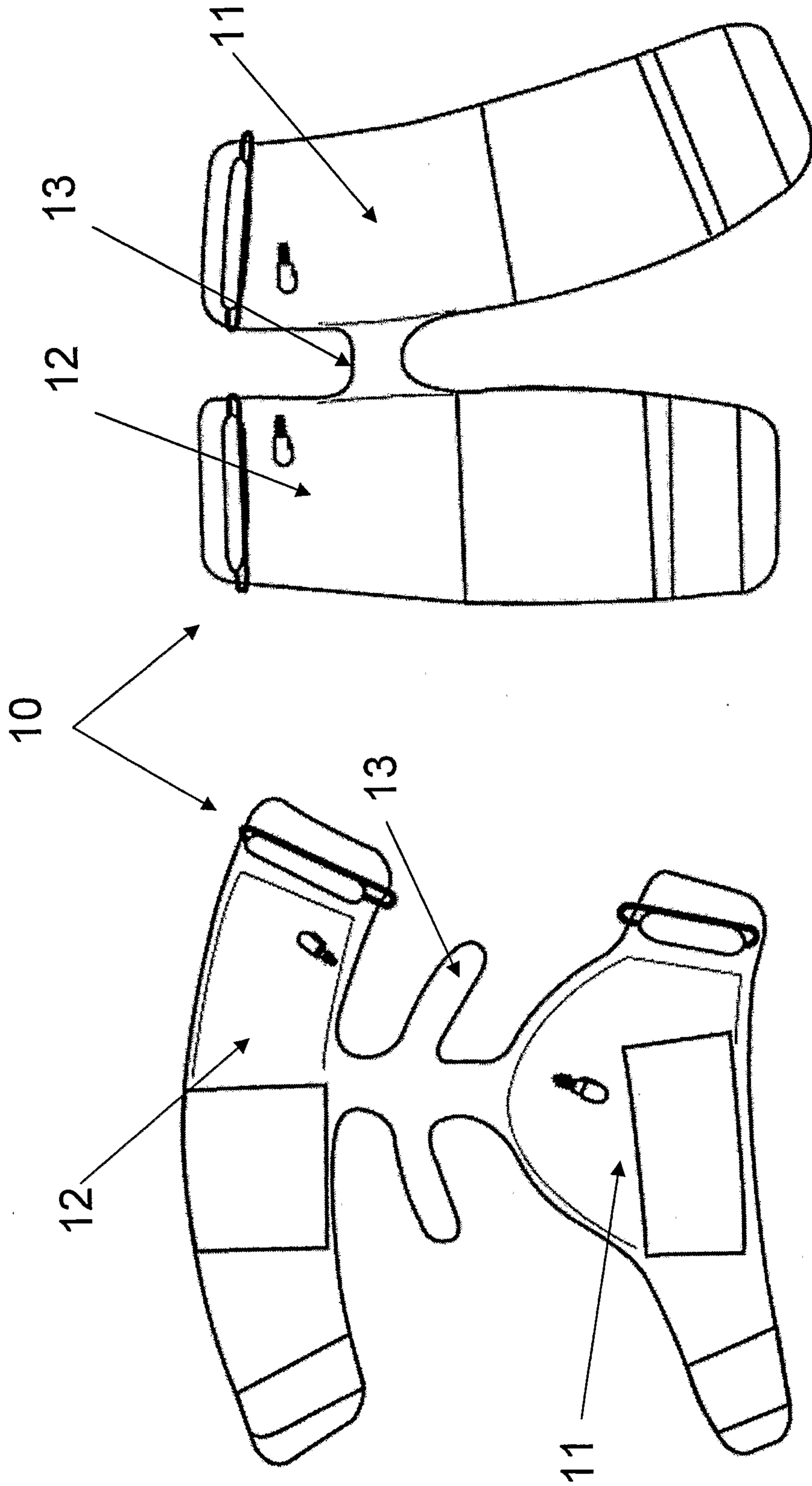


Figure 2b

Figure 2a

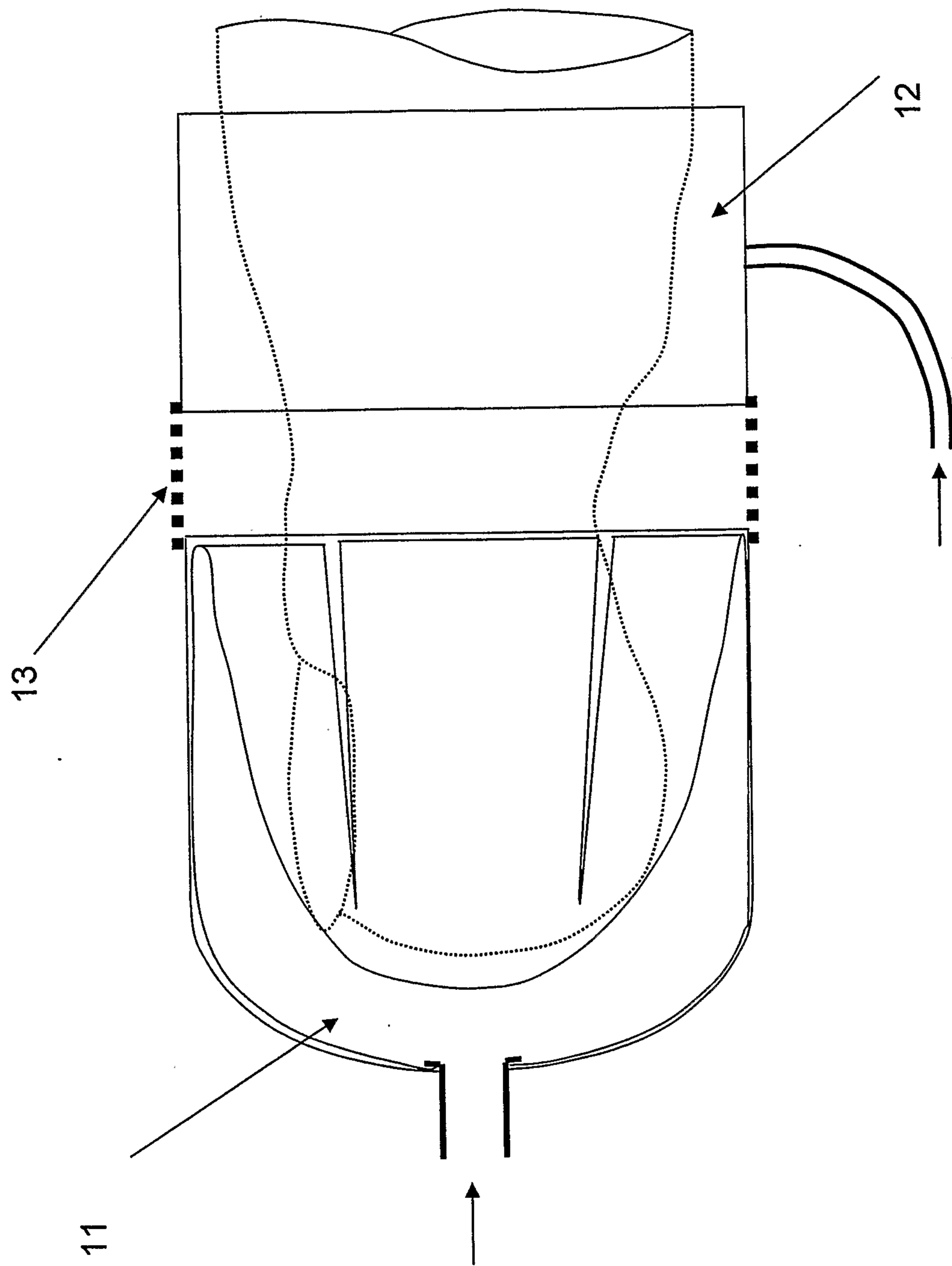


Figure 2c

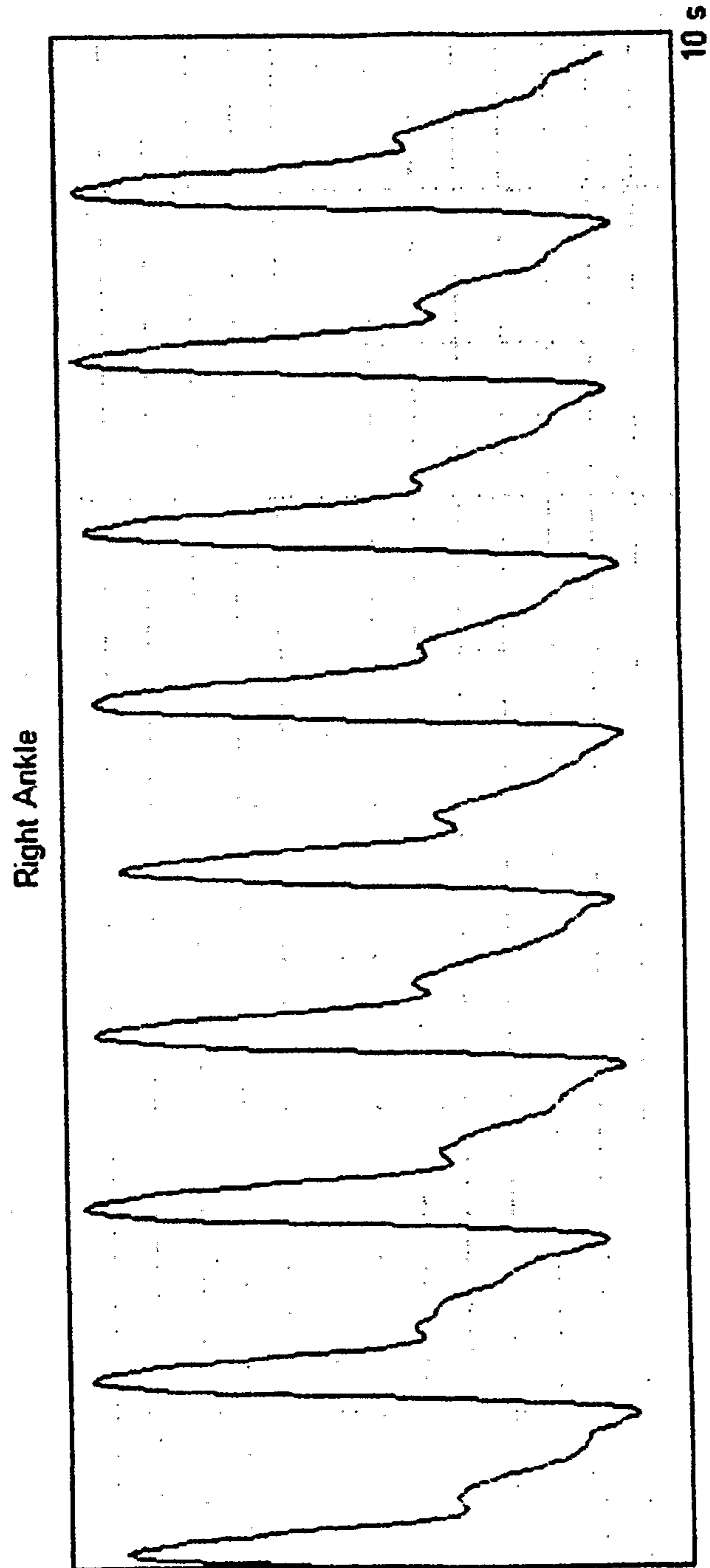


Figure 3

