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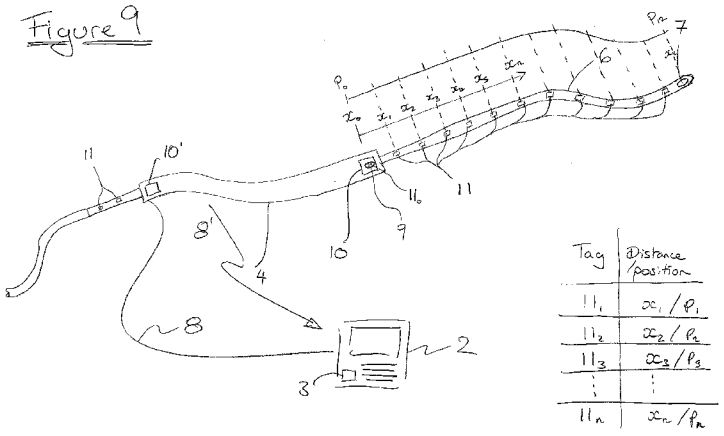
(54) Title: APPARATUS AND METHOD OF CHARACTERISING A NARROWING IN A FLUID FILLED TUBE



(57) Abstract: A system and method for characterising a narrowing in a fluid filled tube, the system comprising: a probe having a first measurement sensor to take an instantaneous measurement at different locations along the tube; a mechanism to draw the probe through the tube; a position measure to provide location data relating to the location at which a respective instantaneous measurement is taken by the first measurement sensor; a processor to calculate, from the instantaneous measurements, a characteristic of the tube at different locations along the tube.

Title: Apparatus and method of characterising a narrowing in a fluid filled tube

Field of the invention

This invention relates to an apparatus and method of characterising a narrowing in a fluid filled tube.

Background to the invention

An example of a fluid filled tube or vessel formed with a constriction or narrowing is a blood vessel having a stenosis. Assessment or measurement of the constriction is helpful to review the extent and location of the constriction.

A methodology for assessment of a constriction in a fluid filled tube such as a coronary stenosis is fractional flow reserve (FFR). This technique measures the drop in pressure at two points along a vessel; see Figure 1 of the accompanying drawings where example points P1 and P4 identify where measurements of pressure and flow rate can be taken, under conditions of maximal achievable hyperemia in a coronary environment. The Pd measurement comes from a pressure sensor on the wire and the Pa measurement comes from the catheter. A comparison is then made by expressing the mean distal pressure (*Pd*), as a proportion of mean proximal pressure (*Pa*), wherein the values are mean Pa and Pd over the entire cardiac cycle, taken over at least one complete cardiac cycle (but usually an average of 3 or more beats):

$$Fractional\ Flow\ Reserve\ (FFR) = \frac{P_d}{P_a}$$

It is an object of the invention to provide an apparatus and method of profiling or characterising a narrowing in a fluid filled tube.

One aspect of the present invention provides system for characterising a narrowing in a fluid filled tube, the system comprising: a probe having a first measurement sensor to take an instantaneous measurement at different locations along the tube; a mechanism to draw the probe through the tube; a position measure to provide location data relating to the location at which a respective instantaneous measurement is taken by the first measurement sensor; a processor to calculate, from the instantaneous measurements, a characteristic of the tube at different locations along the tube.

Another aspect of the present invention provides a probe for assessing a characteristic of a fluid filled tube comprising two measurement sensors spaced apart by a known distance and a line between the two sensors, the line being drawable through the tube to alter the known distance between the first sensor and the second sensor.

A further aspect of the present invention provides a method of characterising a narrowing in a fluid filled tube using a probe having a sensor, comprising: drawing the probe within the tube along the tube; recording probe sensor readings at different locations along the tube; and calculating, from the instantaneous measurements, a characteristic of the tube at different locations along the tube.

A yet further aspect of the present invention provides a probe for assessing a characteristic of a fluid filled tube comprising two measurement sensors and a line between the two sensors, the line being drawable through the tube to alter the distance between the first sensor and the second sensor.

Brief description of the drawings

In order that the present invention may be more readily understood, embodiments of the invention will now be described with reference to the accompanying drawings, in which:

FIGURE 1 is a schematic diagram of a series of constrictions in a fluid filled tube, where *P* is pressure, *R* is a ratio of the pressures and *D* is the distance between measurements;

FIGURE 2 is a schematic diagram of a system embodying the present invention;

FIGURE 3 is a schematic diagram of part of the system of figure 2 located in a fluid filled tube;

FIGURE 4 is a plot created using a method embodying the present invention illustrating the IPR for a length of artery;

FIGURE 5 is a point-by-point constriction intensity map generated following one embodiment of the present invention and based on the Figure 4 data, in this example, the point-by-point assessment is of a stenosis in an artery, where D_0 is the start of a recording, D_1 is a point at the start of high stenosis intensity, D_2 is a point at the end of high stenosis intensity and D_3 is the end of the recording;

FIGURE 6 is a plot created using a method embodying the present invention illustrating the IPR for a length of artery and a likely site for a stent along the tube between locations D1 and D2;

FIGURE 7 is a plot illustrating the likely effect on the same characteristic, IPR, on the artery after a hypothetical angioplasty procedure of locating a stent along the tube between locations D1 and D2 together with a plot of the measured values of IPR obtained using a method embodying the present invention; and

FIGURE 8 is a flowchart showing operation of a system embodying the present invention incorporating a feedback procedure.

FIGURE 9 is a schematic diagram of another system embodying the present invention.

Description

This invention provides an apparatus and method of profiling or characterising a narrowing in a fluid filled tube. The apparatus and method of profiling or characterising is also useful to characterise or profile a series of narrowings in a fluid filled tube.

Referring to Figure 2, a system 1 embodying the invention for characterising a narrowing in a fluid filled tube comprises haemodynamic equipment 2 including a processor 3, a catheter 4, a motor drive 5 and an intra-arterial probe 6 such as an intra-arterial pressure wire (WaveWire or Combowire (Volcano Corp.) or Radi pressure wire (St Jude Medical) with a pressure measurement transducer or sensor 7 – i.e. a device measuring pressure (*P*). Preferably, the probe 6 comprises the wire and the sensor 7 integrated in the wire. The sensor 7 is shown in situ in Figure 3.

The processor 3 analyses and operates on the measurements taken by the sensor 7. A signal line 8 relays the pressure measurement signal from the sensor 7 to the processor 3. The signal line 8 is illustrated both as a wired connection 8 and as a wireless connection 8' from either the motor drive 5, the catheter 4 or direct from the transducer 7 – any configuration is available.

The processor 3 operates on the measurements received from the transducer 7 in accordance with a number of algorithms which are discussed in greater detail below.

The sensor 7 is a pressure measurement sensor but other forms of sensor are envisaged; flow sensors, for example. Additionally, a capacitive sensor for measuring or calculating a thickness of an arterial wall is within the scope of the invention.

The system 1 may be provided in the following configurations or combination of configurations, but these are not an exhaustive list of configurations:

i. a stand-alone device incorporating a probe with pressure measurement capacity in wired connection with a processor to provide on-device analysis;

ii. a device incorporating a probe with pressure measurement capacity in wireless connection with a processor to provide analysis at the processor;

iii. a stand-alone device incorporating a probe with pressure measurement capacity and a data storage device operable to record measurement data for real time or subsequent communication to a processor to provide analysis at the processor (real time and/or off-line); and

iv. a device incorporating a probe with pressure measurement capacity in wireless connection with a data storage device

operable to record measurement data for real time or subsequent communication to a processor to provide analysis at the processor (real time and/or off-line).

In the cardiac environment where the system 1 is configured as part of haemodynamic equipment, the system is configured using the processor 3 in the haemodynamic equipment, such as in McKesson equipment - Horizon Cardiology™, a cardiovascular information system (CVIS). The processor can be configured as supplemental to the haemodynamic equipment. Such configurations are particularly effective for the equipment processor to perform off-line analysis of the pressure data.

The system 1 can be used in combination with other haemodynamic equipment, medical imaging equipment and/or in-patient marker location equipment.

The system is used for profiling or characterising a narrowing in a fluid filled tube. An example of the use of such a system is in the cardiac environment when the tube is an artery and the narrowing/restriction/constriction in the tube is a stenosis.

The basic system components are: the probe 6 having a measurement sensor 7 to take an instantaneous measurement at different locations along the tube; the motor drive 5 to draw the probe 6 at a predetermined rate through the tube; and the processor 3 to calculate, from the instantaneous measurements, a characteristic of the tube at different locations along the tube. In this example a particularly useful measurement to sense is that of pressure as a pressure drop results following the fluid passing through a restriction.

A profile or assessment of a restriction to flow is made by expressing the ratio of distal to proximal pressures within the tube. This measures the total

restriction to flow across all stenoses along the length of the tube from position D1 to D3 where the respective pressure measurements are taken and expressed as a ratio (P_4 / P_1) either with or without conditions of maximal hyperaemia.

In addition to calculation of the total restriction to flow along a vessel, it is possible to calculate the instantaneous pressure drop across an individual stenosis from the ratios of pressure in segments *D* distance apart. For example the ratio of fall in pressure over distance D_3 is:

$$Instantaneous\ Pressure\ ratio\ (R_3) = \frac{P_4}{P_3}$$

which is approximately identical to the normalised instantaneous pressure ratio (nIPR):

$$Normalised\ Instanteous\ Pressure\ Ratio\ (R_3) = \frac{\frac{P_4}{P_1}}{\frac{P_3}{P_1}}$$

In one example, there are two measurement sensors displaced from one another - see Figure 3. This system 1 has a further sensor 9 so that two instantaneous measurements are taken, one by the further sensor 9 at a substantially constant location along the tube and another by the first sensor 7 at different locations along the tube. The line or wire between the two sensors is drawable through the tube to alter the distance between the first sensor and the second sensor. One sensor (9 in this example) is fixed at the substantially constant location. The other sensor (7 in this example) moves relative to the one sensor 9. The “fixed” sensor 9 is located at the end of the catheter 4 from which the wire 6 carrying the other sensor 7 emanates. The probe sensor 7 therefore moves relative to the fixed sensor 9. The measurements are normalised with respect to the measurements taken at the substantially

constant or fixed location.

The normalised instantaneous pressure ratio is more robust, as each distal value is normalised to the proximal aortic pressure, thus making comparisons along the length of the vessel more reliable as perturbations in absolute pressure are minimised.

Systematically moving back along the vessel, at velocity *U*, and logging the instantaneous measurements alongside the draw distance for the probe create a pressure ratio (R_1, R_2, and $R_{3\ etc.}$) for each position (D1, D2, and D3 etc.) as shown in figure 5. The profiling or assessment of stenosis can be performed using either the normalised instantaneous pressure ratio or the instantaneous pressure ratio.

In one example, the predetermined rate of draw through the tube of the probe is a known and preferably constant speed. The draw is a known velocity draw to allow instantaneous pressure measurements to be taken as the probe is being drawn along the tube, for those measurements to be recorded as pressure measurements and for a pressure ratio to be calculated for each position of the probe along the tube.

The motor drive 5 is controlled, preferably by the processor 3, to draw the probe 6 back toward the catheter 4. The control may involve use of a feedback loop.

The systematic assessment of pressure along a vessel is performed by withdrawing the pressure sensor, at velocity *U*. Pressure is recorded at each location. It is possible to minimise error and to speed up the acquisition phase by using a feedback loop. In this feedback loop, the sensor is positioned in the tube, and then attached to the variable speed motor drive, or stepper motor. After sampling for a period of *x* seconds to establish a baseline for the

measurements being taken and characteristics calculated, in this case NIPR or IPR mean and standard deviation moving averages, the motor drive commences pullback of the probe at velocity *U*. Sampling can also be over a fraction or specific time point of a beat.

Using high sampling frequencies and an appropriate sensor with a suitable frequency response, the pullback velocity *U* can be made faster by looking at a partial cardiac cycle in a single beat over a known distance.

Pressure measurements are fed to the processor in the control console, and IFR or nIFR is calculated. This live pressure is compared against the moving average mean and standard deviation for the proceeding *n* beats, in a cardiac environment. If the live pressure data falls within the tolerance threshold, the motor continue with the pullback. If however the live pressure data falls outside of the tolerance threshold, the motor is paused and further measurements of pressure are made. Once pressure measurement falls within the tolerance threshold the motor continues with the pullback. A serial assessment or profile is created by this method. The feedback loop example is illustrated in Figure 6.

In another example, the draw is stepped through the tube with at least one instantaneous measurement being taken at each location along the tube. The probe is then drawn through the tube for a predetermined distance, stopped and then another at least one instantaneous measurement is taken at the next location and so on. Preferably but not necessarily, the predetermined distance is a constant distance.

Each instantaneous measurement is logged as being at a respective location or with respect to a draw distance.

An alternative system embodying the invention has a position sensor fitted

which monitors the position of the pressure sensor wire whilst being pulled back through the tube. In this way, each distance point/position/location would be linked or cross-referenced to a specific pressure measurement. Specifically, the position sensor monitors the guide wire holding the pressure sensor.

Referring now to figure 9 another embodiment of the system is described which may operate with or without a motor drive 5. In the embodiments shown in figure 2, the system relies upon the motor to operate in a known way to determine the distance x along the line 6 to the sensor 7. Other mechanisms for determining the distance x to the sensor from a known point, usually on the catheter, may be used to take measurements at different known positions of x. In a purely manual version of the system, the line 6 may be drawn back through the catheter 4 manually and markings on the line 6 in the form of physical indicia can convey the distance x to the user. The system takes the position measure by reading the markings or marker on the probe. The marker may be a visible indicator read by a laser position indicator.

A semi-automatic version of the system can use a manually drawn line 6 through the catheter 4 and a combination of i) an RF reader 10 positioned preferably at the head of the catheter 4 from which the line 6 projects a distance x out of the catheter 4 and ii) multiple RF tags 11 positioned along the line 6. The line 6 is provided with a series of equispaced passive RF tags 11 each having an individual identifier which is read when in close (if not only immediate) proximity to the reader 10. In one embodiment, the RF tag reader 10 is in a coincident position with the second sensor 9 mounted at the head of the catheter 4. Coincidence of these two elements is not essential. More than one RF tag reader 10 can be used on the catheter.

A lookup table stored locally or in the processor 3 takes the read information from the reader 10 and identifies the tag adjacent the reader 10 for example

as tag 11_0 and identifies from the lookup table that tag 11_0 which is positioned at the reader 10 is a distance x away from the sensor 7 along the line 6 meaning that the sensor 7 is at known position P_{12} The line is then drawn through until another RF tag 11 is read by the reader 10 at which point that tag is identified, its position is known as being at the reader 10 and the distance from that tag to the sensor 7 is also known so the position of the sensor 7 is known. This process is repeated and tags 11 are identified, the sensor 7 position is identified as known and at least one measurement is taken at the known position.

Preferably, the RF tags 11 are equispaced along the line 6 but they need not be equispaced as their positions along the line 6 relative to the sensor 7 is the only essential data to be associated with each tag. This essential data need not be present at the time the measurements are taken. Measurements can be taken and logged against each RF tag identifier and then subsequently the line can be measured to provide the relative position information for each tag and then that position information is associated with the measurement taken at each tag.

Preferably, the RF tags 11 are passive RF tags. The RF tags 11 could be active RF tags powered by a conductor in the line 6.

Examples of the invention allow a serial assessment of pressure ratio along a vessel. A rate of change of pressure or a rate of change of pressure ratio is further calculated to provide a measure of stenosis intensity. The rate of change in pressure or stenosis intensity at any position is calculated as which can be plotted as a point-by-point stenosis intensity map as shown in Figure 4.

$$stenosis\ intensity = \frac{dIPR}{dt}$$

A systematic assessment is made at rate *U* over time *t*, (known velocity example) so it is possible to calculate the withdrawal distance and thus the physiological stenosis length. In this example, this is the length (D_2-D_1) a segment which has the greatest physiological impact. The characteristic of the tube or further characteristics derived from the characteristic of the tube can be assessed and thresholded. This process can be automated using a search algorithm which looks for points at which the IPR or nIPR exceeds a given threshold (in this example D1 and D2).

$$physiological\ stenosis\ length = D_2 - D_1$$

The characteristics and/or derived characteristics are used to assess or profile the tube to identify the length and/or location of a narrowing of the tube along the tube length. The use of thresholding techniques for the various characteristics and/or derived characteristics identifies regions of the tube where the thresholds are exceeded allowing identification and locating of stenosis and their length.

An example of a derived characteristic of the tube is the cumulative burden on the tube caused by a narrowing in the tube. It is possible to calculate the individual stenosis burden or stenosis occlusive value (with time points D_1 start of a stenosis, and D_2 end of a stenosis):

$$instantaneous\ stenosis\ burden = \int_{D_1}^{D_2} IPR$$

Or,

$$normalised\ instantaneous\ stenosis\ burden = \int_{D_1}^{D_2} nIPR$$

and total stenosis burden (over time points D_0 to D_3) for the entire vessel,

$$total\ stenosis\ burder = \int_{D_0}^{D_3} IPR$$

Or

$$normalised\ total\ stenosis\ burder = \int_{D_0}^{D_3} nIPR$$

Virtual angioplasty assessment is enabled by examples of the present invention. Referring to Figure 6, a systematic assessment approach is applied and the measured profile is displayed. The segment of tube to which a stent or other angioplasty is to be applied (having a high stenosis grade (D_1-D_2)) has its profile characteristic estimated with the stent applied and then subtracted away on an individual segment basis to give a compensated profile as shown in Figure 7. It is therefore possible to assess the effects of angioplasty on IPR of nIPR prior to treatment.

$$Virtual\ iPR_{D_0-D_1} = iPR_{D_0-D_1} + \Delta iPR_{D_2-D_1}$$

OR

$$Virtual\ niPR_{D_0-D_1} = niPR_{D_0-D_1} + \Delta niPR_{D_2-D_1}$$

Where D_0 is distance=0, D_1 the distance at the start of the high stenosis grade, and D_2 the distance at the end of the high stenosis grade.

Such virtual assessment or profiling of a tube or stenosis in a tube using

either IPR or nIPR allows the effects of removing a stenosis to be assessed prior to performing the procedure itself.

There are particular needs in the cardiac environment for simplified equipment having the smallest possible footprint (or being the least invasive requiring the smallest possible entry site) so the provision of a known position probe to assess or profile stenoses along the length of the tube represents a significant technical advance in that field.

When used in this specification and claims, the terms "comprises" and "comprising" and variations thereof mean that the specified features, steps or integers are included. The terms are not to be interpreted to exclude the presence of other features, steps or components.

The features disclosed in the foregoing description, or the following claims, or the accompanying drawings, expressed in their specific forms or in terms of a means for performing the disclosed function, or a method or process for attaining the disclosed result, as appropriate, may, separately, or in any combination of such features, be utilised for realising the invention in diverse forms thereof.

CLAIMS:

1. A system for characterising a narrowing in a fluid filled tube, the system comprising:

a probe having a first measurement sensor to take an instantaneous measurement at different locations along the tube;

a mechanism to draw the probe through the tube;

a position measure to provide location data relating to the location at which a respective instantaneous measurement is taken by the first measurement sensor;

a processor to calculate, from the instantaneous measurements, a characteristic of the tube at different locations along the tube.

2. A system according to claim 1, wherein the mechanism is a motorized mechanism.

3. A system according to claim 1, wherein the mechanism is a manual mechanism to draw the probe through the tube.

4. A system according to any preceding claim, wherein the position measure is a reader to read a marker on the probe.

5. A system according to claim 4, wherein the marker on the probe is an RF tag.

6. A system according to claim 4 or 5, wherein the marker is read by an RF reader.

7. A system according to any preceding claim, wherein the position measure provides a relative location of the first measurement sensor with respect to a known datum.

8. A system according to any preceding claim, wherein the position measure provides an absolute location of the first measurement sensor.

9. A system according to any preceding claim, wherein the instantaneous measurements are pressure measurements.

10. A system according to any preceding claim, wherein the characteristic of the tube is a ratio of instantaneous measurements taken at different locations along the tube, the characteristic of the tube being variable along the tube.

11. The system of any preceding claim, wherein a further sensor is provided so two instantaneous measurements are taken, one by the further sensor at a substantially constant location along the tube and another by the first sensor at different locations along the tube.

12. The system of claim 11, wherein the calculated characteristic is normalised with respect to the substantially constant location.

13. The system of any preceding claim, wherein the probe is drawn at a predetermined rate of draw through the tube of the probe is a constant speed.

14. The system of claim 13, wherein the predetermined rate is a constant speed.

15. The system of claim 13 or 14, wherein the predetermined rate is a stepped draw through the tube with instantaneous measurements being taken at one location along the tube and the probe is then drawn through the tube for a predetermined distance for the next set of instantaneous measurements to be taken at the next location and so on.

16. The system according to claim 15, wherein the predetermined distance is a constant distance.

17. The system of any preceding claim, wherein each instantaneous measurement is logged at a respective location or with respect to a draw distance.

18. The system of any preceding claim, wherein the characteristic represents a restriction to flow along the tube in terms of a pressure drop.

19. The system according to any preceding claim, wherein the draw is a known velocity draw.

20. The system according to any preceding claim, wherein a rate of change of pressure or a rate of change of pressure ratio is further calculated to provide a measure of stenosis intensity.

21. The system of any preceding claim, wherein the characteristic of the tube or further characteristics derived from the characteristic of the tube can be assessed and thresholded.

22. The system of any preceding claim, wherein a length and location of a narrowing of the tube beyond a predetermined threshold is identified.

23. The system of any preceding claim, wherein a derived characteristic of the tube is a cumulative burden on the tube caused by a narrowing in the tube.

24. The system of any preceding claim, wherein instantaneous pressure measurements are recorded and a pressure ratio calculated for each position of the probe along the tube.

25. A probe for assessing a characteristic of a fluid filled tube comprising two measurement sensors spaced apart by a known distance and a line between the two sensors, the line being drawable through the tube to alter the known distance between the first sensor and the second sensor.

26. A probe according to claim 25, wherein the first sensor is fixed and the second sensor moved relative to the first sensor.

27. The probe according to claim 26, wherein the first sensor is at a substantially constant location in the tube and the second sensor moves along the tube at varying distances from the first sensor

28. A method of characterising a narrowing in a fluid filled tube using a probe having a sensor, comprising:

drawing the probe within the tube along the tube;

recording probe sensor readings at different locations along the tube; and

calculating, from the instantaneous measurements, a characteristic of the tube at different locations along the tube.

29. The method according to claim 28, wherein the instantaneous measurements are pressure measurements.

30. The method according to claim 28 or 29, wherein the characteristic of the tube is a ratio of instantaneous measurements taken at different locations along the tube, the characteristic of the tube being variable along the tube.

31. The method of any one of claims 28 to 30, wherein a further sensor is provided and the method further comprises taking two instantaneous measurements, one by a further sensor at a substantially constant location along the tube and another by a first sensor.

32. The method of claim 31, comprising normalising the calculated characteristic with respect to the substantially constant location.

33. The method of any one of claims 28 to 32, comprising drawing the probe at a constant speed through the tube of the probe.

34. The method of any one of claims 28 to 33, comprising drawing the probe at a stepped draw through the tube with instantaneous measurements being taken at one location along the tube and drawing the probe for a predetermined distance to a next location for a next set of instantaneous measurements to be taken at the next location and so on.

35. The method of claim 34, wherein the predetermined distance is a constant distance.

36. The method of any one of claims 28 to 35, comprising logging the draw distance between measurements and associating the draw distance or location of the probe with each instantaneous measurement taken at that location.

37. The method of any one of claims 28 to 36, comprising drawing the probe and taking instantaneous pressure measurements as the probe is being drawn along the tube, recording those measurements as pressure measurements and calculating a pressure ratio for each position of the probe along the tube.

38. The method of any one of claims 28 to 37, comprising calculating a rate of change of pressure or a rate of change of pressure ratio to provide a measure of stenosis intensity.

39. The method of any one of claims 28 to 38, comprising thresholding the characteristic of the tube or further characteristics derived from the characteristic of the tube to provide a measure of stenosis intensity.

40. Use of an apparatus according to any one of claims 1 to 27 to carry out the method of any one of claims 28 to 39.

41. A probe for assessing a characteristic of a fluid filled tube comprising two measurement sensors and a line between the two sensors, the line being drawable through the tube to alter the distance between the first sensor and the second sensor.

42. A probe according to claim 41, wherein the first sensor is fixed and the second sensor moved relative to the first sensor.

43. A data storage medium operable to carry out the method steps of any one of claims 28 to 39.

44. A processor operable to carry out the processing steps of any one of claims 28 to 39.

45. An apparatus, method, processor or data storage medium substantially as described herein and/or as shown in Figures 2 to 6 and 9.

38. Any novel feature or combination of features disclosed herein.

Figure 1

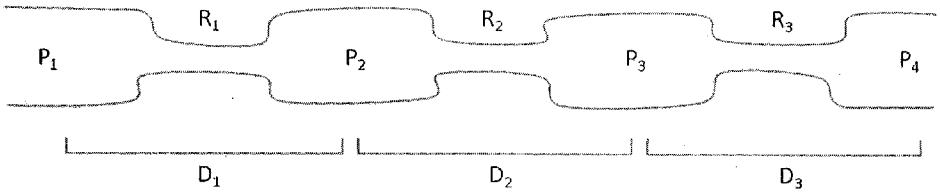


Figure 2

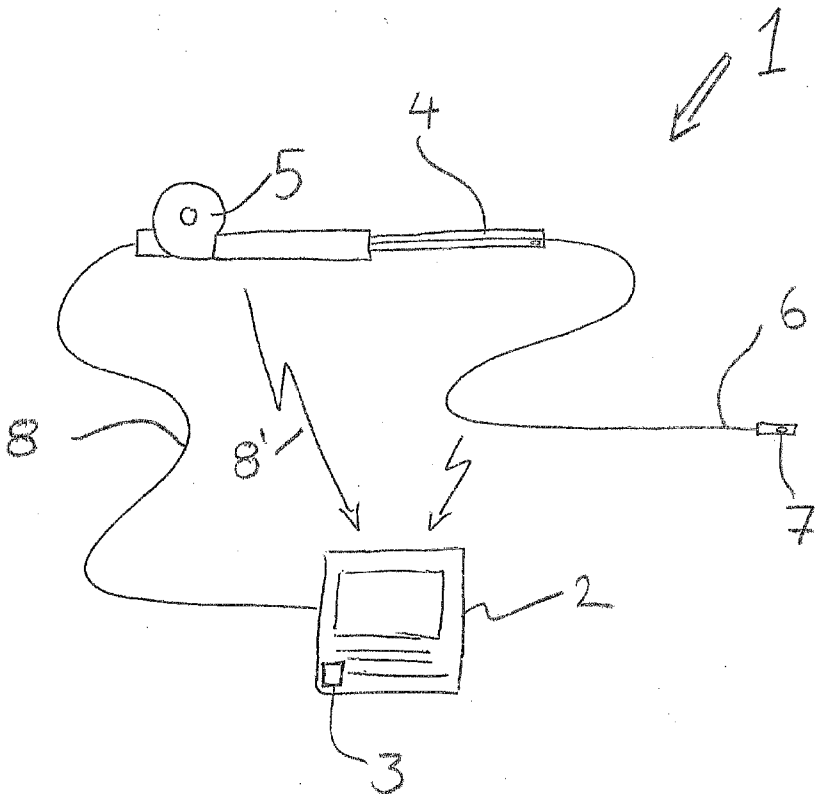


Figure 3

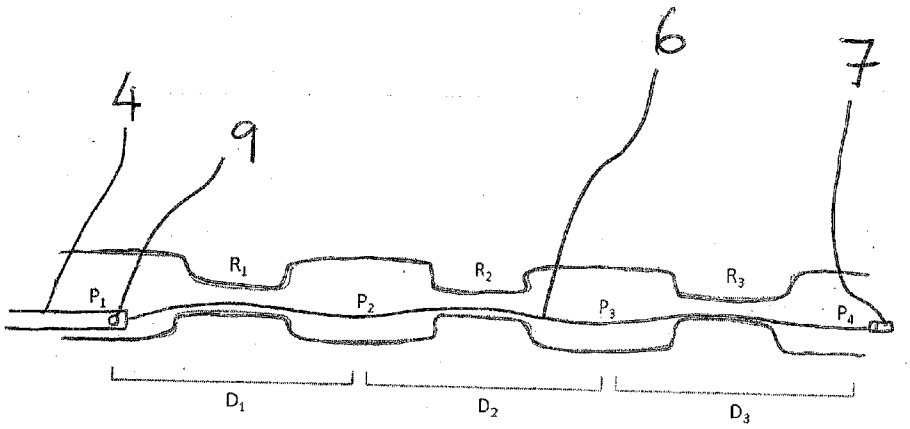
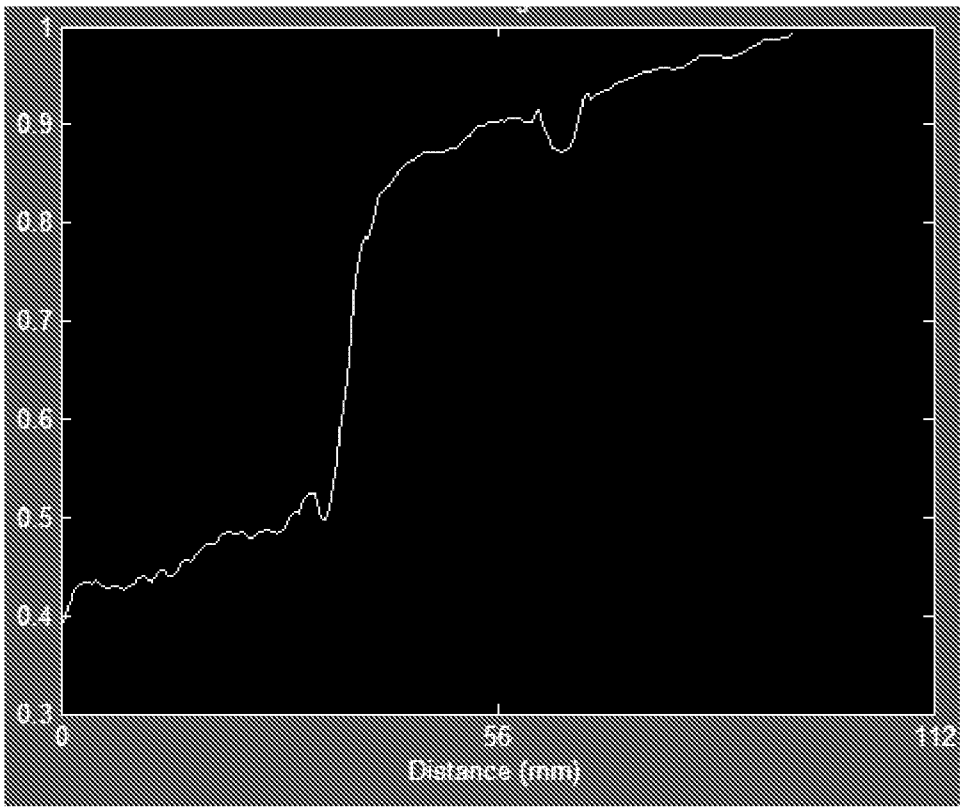


Figure 4



Cumulative change in iPR

Figure 5

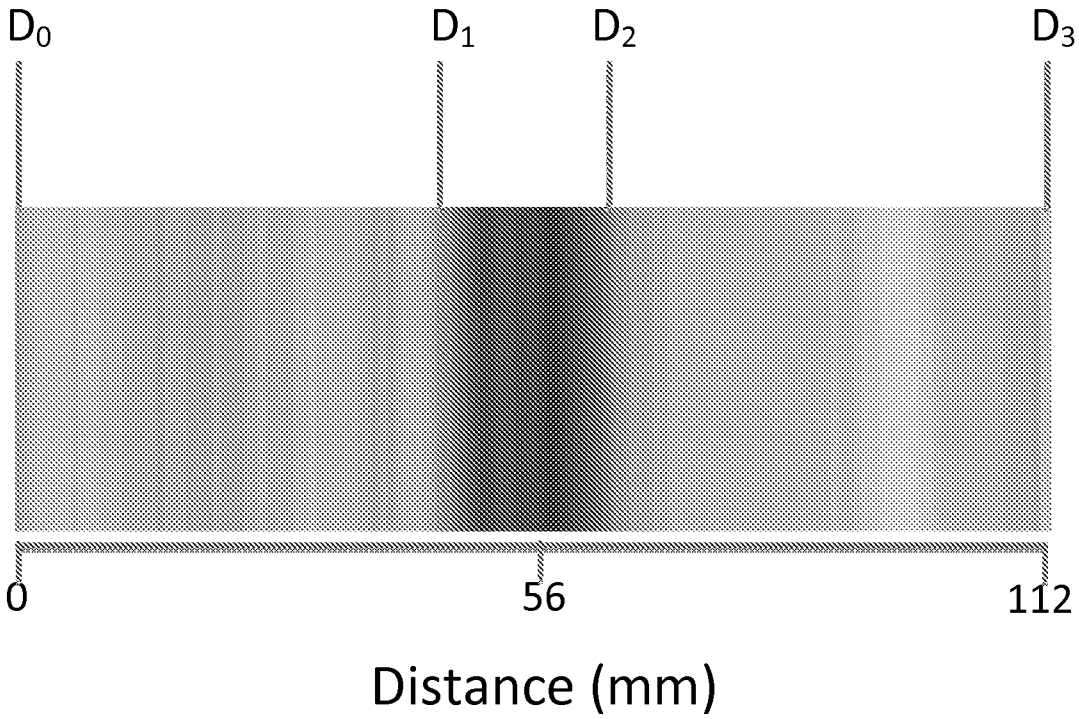


Figure 6

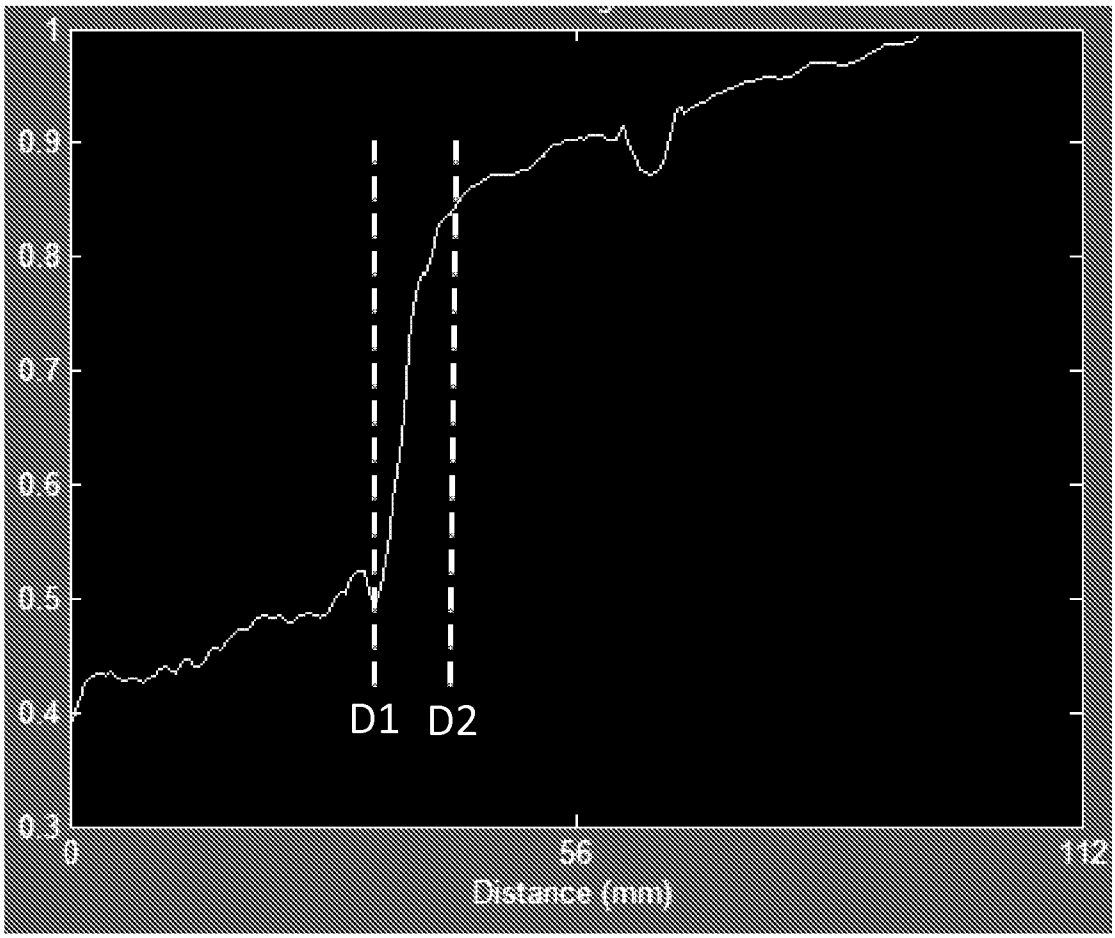


Figure 7

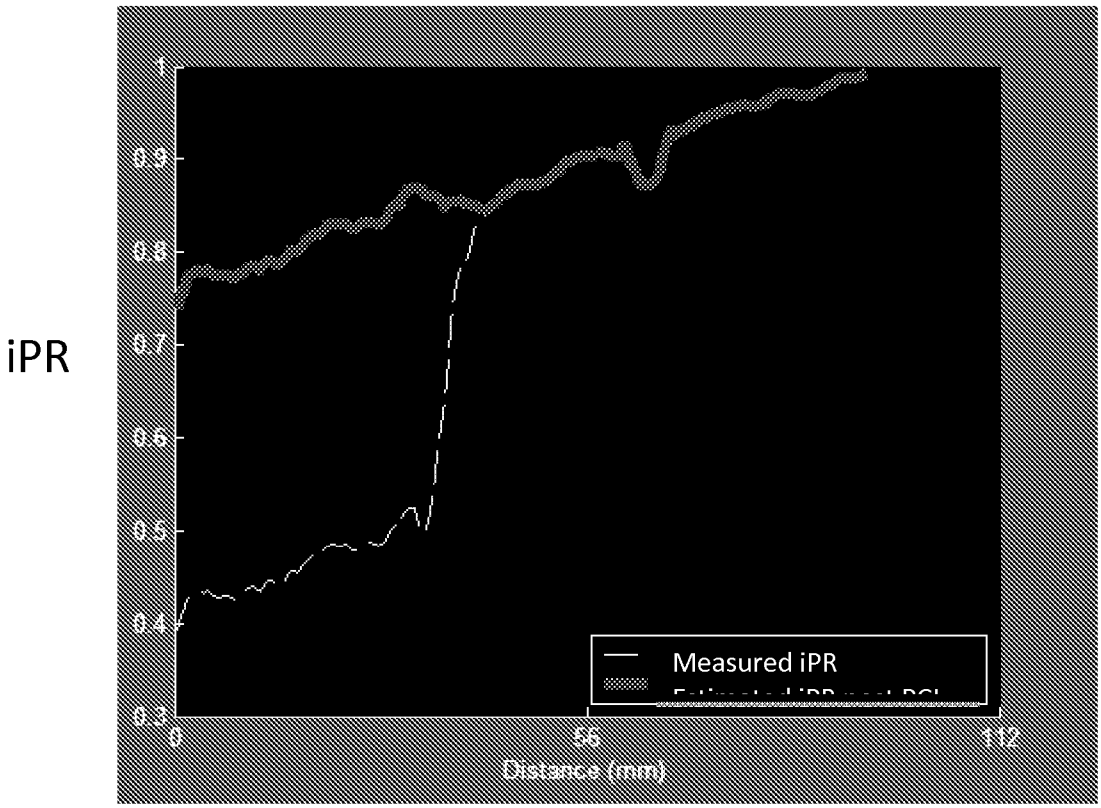
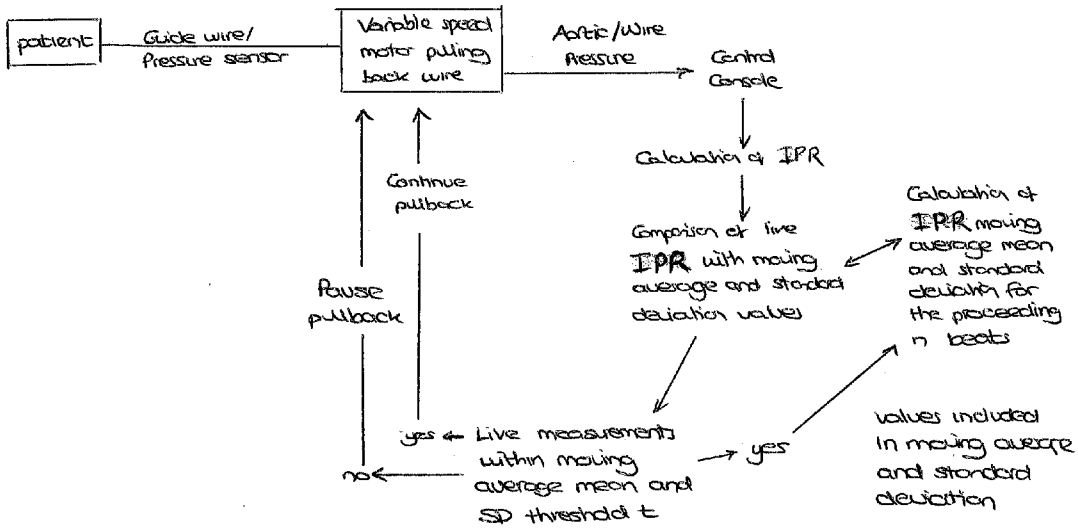


Figure 8


patient
Guide wire/ Pressure sensor
Variable speed motor pulling back wire
Aortic/Wire Pressure
Control Console
Calculation of IPR
Comparison of live IPR with moving average and standard deviation values
Calculation of IPR moving average mean and standard deviation for the preceeding n beats
Continue pullback
Pause pullback
yes
Live measurements within moving average mean and SD threshold t
yes
values included in moving average and standard deviation
no

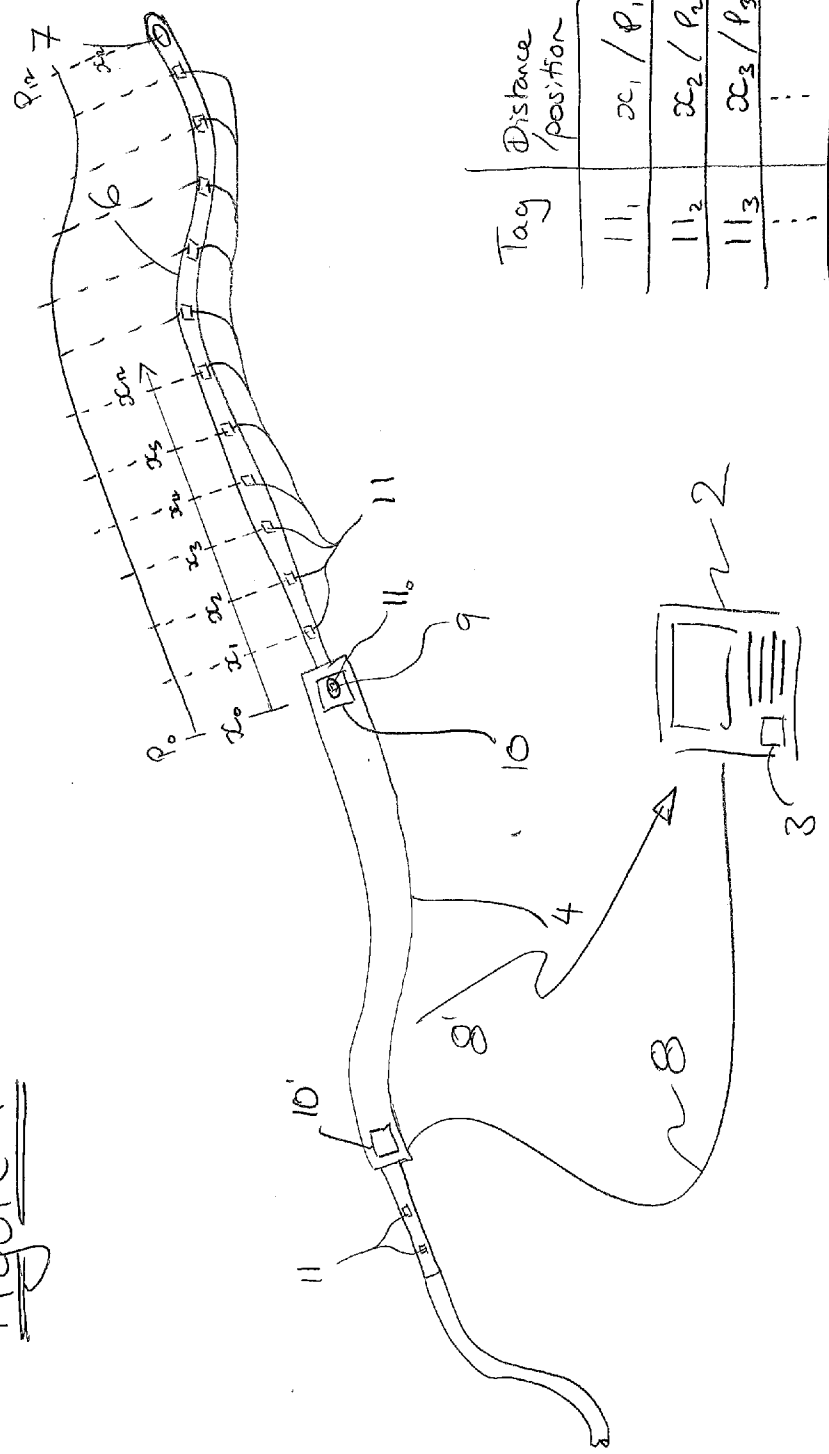

Tag
Distance /position
11_1
x_1 / p_1
11_2
x_2 / p_2
11_3
x_3 / p_3
11_n
x_n / p_n
Pn 7
16
x_n
x_5
x_4
x_3
x_2
x_1
x_0
P0
11
11'
9
10
2
3
4
8'
8
10'
11

Figure 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2012/050015

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/0215 A61B5/103 A61B5/02
ADD.

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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/234698 A1 (MANSTROM DALE R [US] ET AL) 16 September 2010 (2010-09-16) paragraphs [0035] - [0053], [0062], [0070] - [0072], [0079] - [0086], [0119]; figures 1-8	1,2,4, 8-12,15, 16,18, 20-27, 41-44
X	WO 01/13779 A2 (FLORENCE MEDICAL LTD [IL]; NOSKOWICZ SIMON HENRI [IL]; DGANY ELHANAN []) 1 March 2001 (2001-03-01) page 8, line 5 - page 16, line 8; claims 1-8; figures 1-7	1-3, 8-27, 41-44

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* 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

"T" 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.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 April 2012	20/04/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Apostol, Simona

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2012/050015

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/176683 A1 (WHITIN KATHERINE [US] ET AL) 9 September 2004 (2004-09-09) paragraphs [0001] - [0009], [0012], [0059] - [0071], [0078] - [0079], [0127] - [0131]; claims 1-8; figures 1-12	1,3,5-7, 17
X	US 2007/100239 A1 (NAIR ANUJA [US] ET AL) 3 May 2007 (2007-05-03) paragraphs [0033] - [0034], [0055] - [0059], [0064] - [0068]; figures 1-6	1,3,13, 14,17,19
X	US 4 691 709 A (COHEN DONALD M [US]) 8 September 1987 (1987-09-08) column 4, line 45 - column 8, line 19; claim 1; figures 1-5	25,26, 41,42

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2012/050015

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 28-40
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [X] Claims Nos.: 45, 46
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 28-40

Claims 28-40 relate to methods of assessing a narrowing in a fluid filled tube using a probe, comprising the step of drawing the probe within the tube. From the description, the tube appears to be a blood vessel (of a living patient) having stenosis (p.1, li.7-10) and the method being oriented mainly to clinical applications in the field of coronary stenosis, as resulted from the description (page 4, para.6, Fig.2, see also p.6, para.2-5, p.14, li.3-7). This step is performed in view of the description (p.4, para.6) by using an intra-arterial pressure wire draw through the vessel (p.6, para.4-5) and is considered a substantial intervention performed by specialized surgeon and involving a substantial health risk, by means of which the method as a whole is considered to be a method for treatment of a human or an animal body by surgery according to the Rule 39.1(iv) PCT.

Continuation of Box II.2

Claims Nos.: 45, 46

The definition of Claim 45 and following claim 46 (numbered erroneously claim 38) are not specifying the technical features of the invention and are not allowing to derive clearly and unambiguously which of the possible combination of features disclosed in the description and/or Figures is claimed.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2012/050015

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010234698 A1	16-09-2010	AU 2009291623 A1	18-03-2010
		CA 2734698 A1	18-03-2010
		CA 2762123 A1	18-03-2010
		CN 102202562 A	28-09-2011
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		WO 0113779 A2	01-03-2001
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		JP 2012005857 A	12-01-2012
		US 2004176683 A1	09-09-2004
		WO 2004084702 A2	07-10-2004
US 2007100239 A1	03-05-2007	NONE	
US 4691709 A	08-09-1987	NONE	