

APPARATUS AND METHOD FOR NON-INVASIVE MONITORING OF BLOOD FLOW IN FISTULA

Field of the Invention

5 This invention relates to an apparatus and method of monitoring of blood flow in a fistula. This invention further relates to an apparatus that accurately measure blood flow in a fistula using non-invasive sensors via a two-point measurement method on a single-handed operated device.

Prior Art

10 Many vascular procedures such as central venous catheter insertion, dialysis catheter insertion, arterial angiograms, etc. are conducted on a daily basis across the globe. Such vascular procedures require a skilled medical person to complete the task. Even so, there would be times where a skilled medical person may accidentally insert the needle too
15 deep and puncturing through the vessel.

 There are various approaches for monitoring blood flow in a fistula. One approach is to insert a sensor directly into a suitable artery of a subject. The sensor can then be connected to a monitoring device to translate the signal and display the results on a monitor. This approach provides accurate and instantaneous blood flow measurements.
20 However, this approach is invasive and requires surgical procedure to insert the sensor to the fistula. Furthermore, the pathway for the sensor into the fistula presents a possibility for infection.

 A common approach to measuring blood flow or blood pressure is via a sphygmomanometer or more commonly known as a blood-pressure monitor. A typical
25 sphygmomanometer has an inflatable cuff adapted to be wrapped around an arm to collapse and release the artery by inflating and deflating the inflatable cuff in a controlled manner and an aneroid or mercury gravity sphygmomanometer to measure pressure in the

cuff. A stethoscope or other system is also required when using the sphygmomanometer. These apparatus and devices are widely used in hospitals and clinics for routine blood pressure measurements. However, skilled medical person is required to use the apparatus and devices.

5 Therefore, those skilled in the art are striving to provide an improved apparatus or method for monitoring blood flow in a fistula in a simple non-invasive manner.

Summary of the Invention

10 The above and other problems are solved and an advance in the art is made by a apparatus in accordance with this invention. An advantage of the apparatus in accordance with this invention is that the apparatus uses non-invasive sensing that can be used by non-clinical staff at dialysis centres for regular monitoring of fistula for stenosis. As dialysis patients usually undergo dialysis thrice a week, monitoring can take place as frequent as three times a week. There is much less need for additional visit to the healthcare facilities
15 such as a hospital for regular monitoring. For patients who are on home hemodialysis, they can also use the apparatus at home, as the system does not require specialist expertise and can be operated by caregiver or patient himself. Another advantage of the apparatus in accordance with this invention is that the apparatus allows remote monitoring. Hence, an alert could be raised when stenosis is suspected thus prompting a downstream review
20 process, allowing early intervention/ treatment.

 A first aspect of the disclosure describes a non-invasive apparatus for measuring blood flow from a fistula. The non-invasive apparatus comprises a main body, an adjustable handle pivotally coupled to the main body, a first sensor coupled to the main body, and a second sensor movably coupled to the main body and apart from the first sensor.

25 In accordance with an embodiment of the first aspect, the non-invasive apparatus further comprises a pivot connecting the adjustable handle to the main body such that the

adjustable handle is adjustable about the pivot forming an angle Θ to allow a balanced pressure to be applied to a subject.

In accordance with an embodiment of the first aspect, the main body comprises a horizontal bar and a vertical bar with one end extending from the center of the horizontal bar and forming an inverted T shaped main body and the pivot is arranged proximate
5 another end of the vertical bar.

In accordance with an embodiment of the first aspect, the non-invasive apparatus further comprises a button extending out from the other end of the vertical bar, the button is a record switch provided to activate and deactivate the first and second sensors from
10 recording of signals.

In accordance with an embodiment of the first aspect, the angle Θ is preferably about 140degrees away from the vertical bar.

In accordance with an embodiment of the first aspect, the first sensor is fixedly coupled to one end of the horizontal bar of the main body and the second sensor comprises
15 an adjustable mechanism coupled to the horizontal bar to allow the second sensor to move along the horizontal bar.

In accordance with an embodiment of the first aspect, the adjustable mechanism comprises a push spring mechanism for locking and unlocking the slide mechanism.

In accordance with an embodiment of the first aspect, each of the first and second
20 sensors comprises: two magnets, each of diameter of about 6mm, thickness of about 1 mm and are placed side by side; a magnetic sensor arranged apart from the two magnets in the range of between 2.5 to 3.5 mm; and a housing to house the two magnets and the magnetic sensor.

A second aspect of the disclosure describes a system comprising the non-invasive
25 apparatus according the first aspect of the disclosure, a conditioning hardware adapted to condition the signals from the first and second sensors to a suitable level before translating the signal from analogue signals to digital signals to obtain position 1 signal for the first

sensor and position 2 signal for the second sensor; and a processing unit comprising a processor, a memory and instructions stored on the memory and executable by the processor to: receive the digital signals from the conditioning hardware; store the digital signals in the memory; and execute an algorithm to process the digital signals.

5 In accordance with an embodiment of the second aspect, the instruction to execute the algorithm to process the digital signals comprises instructions to: determine a plurality of peaks from each of position 1 signal and position 2 signal; calculate time differences from respective peaks in each of position 1 signal and position 2 signal; determine a median of the time differences; determine a fistula flow index (FFI) classification; in response to the
10 median being more than FFI classification, determine the fistula is good and in response to the median being less than FFI classification, determine the fistula is mild-moderate.

 In accordance with an embodiment of the second aspect, the instruction to execute the instruction to determine the FFI classification comprises instructions to: determine a standard deviation and a mean from each of the position 1 signal and position 2 signal;
15 determine function p1 from a ratio of standard deviation and mean of the position 1 signal; determine function p2 from a ratio of standard deviation and mean of the position 2 signal; and calculate a ratio of p1 and p2 to determine the FFI classification.

 In accordance with an embodiment of the second aspect, the instruction to execute the instruction to determine the FFI classification further comprises instructions to: in
20 response to the FFI being outside the range of between 0.5 and 1.9, trigger an alert and transmit a notification to a physician for immediate review.

Brief Description of the Drawings

 The above and other features and advantages in accordance with this invention are
25 described in the following detailed description and are shown in the following drawings:

 Figure 1 illustrating an overview of a system of the non-invasive apparatus in accordance with an embodiment of this invention;

Figure 2.1 illustrating a front side view of the non-invasive apparatus in accordance with an embodiment of this invention;

Figure 2.2 illustrating a perspective view of the non-invasive apparatus in accordance with an embodiment of this invention;

5 Figure 2.3 illustrating a top view, a bottom view and a side view of the non-invasive apparatus in accordance with an embodiment of this invention;

Figure 3.1 illustrating an exploded view of the non-invasive apparatus in accordance with an embodiment of this invention;

Figure 3.2 illustrating a partial view of the non-invasive apparatus showing the adjustable mechanism in accordance with an embodiment of this invention;

Figure 4 illustrating an arrangement of the first and second sensors in accordance with an embodiment of this invention;

Figure 5 illustrating the placement of the first and second sensors on a subject in accordance with an embodiment of this invention;

15 Figure 6 illustrating the types of blood flow in a fistula and respective amplitudes measured from the first and second sensors in accordance with an embodiment of this invention;

Figure 7 illustrating an example of a waveform of a dialysis fistula with stenosis where there is high variation of waveform amplitudes due to turbulence blood flow in dialysis;

Figure 8 illustrating an overview of the network architecture of the system in accordance with an embodiment of this invention;

Figure 9 illustrating process executable by the processor of the computing device to perform the algorithm to process the blood flow signals in accordance with an embodiment of this invention;

Figure 10 illustrating the peaks and time difference from the position 1 signal and position 2 signal in accordance with an embodiment of this invention;

Figure 11 illustrating an exemplary design of non-invasive apparatus; and
Figure 12 illustrating an exemplary design of non-invasive apparatus
communicative connected to the conditioning hardware for blood flow acquisition.

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Detailed Description

This invention relates to an apparatus and method of monitoring of blood flow in a fistula. This invention further relates to an apparatus that accurately measure blood flow in a fistula using non-invasive sensors via a two-point measurement method on a single-handed operated device.

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It is envisioned that a non-invasive apparatus in accordance with embodiments of this invention enables a user to regularly measure blood flow in a dialysis fistula using non-invasive sensors via a two-point measurement.

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Figure 1 illustrates an overview of a system 100 of the non-invasive apparatus 110 in accordance with an embodiment of this invention. The system 100 comprises the non-invasive apparatus 110 that is capable of regular measurement of blood flow in a dialysis fistula using non-invasive sensors via a two-point measurement method, a signal conditioning hardware 120 adapted to condition the signals from the non-invasive sensors and a computing device 130 to process the signal received from the conditioning hardware 120. The system 100 is simple to use and can be operated even by non-clinical staff at dialysis centres or patient / caregiver at home for regular monitoring of blood flow.

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The non-invasive apparatus 110 is a single-handed operated device that supports self-administered assessment. The non-invasive apparatus 110 uses non-invasive sensors to acquire signals concurrently at two positions of the fistula, at inflow and outflow. Specifically, the non-invasive apparatus 110 comprises a fixed sensor and an adjustable sensor mounted on the body of the apparatus 110 to acquire signals from two ends of the fistula, achieving direct measurement of blood flow rate in the fistula. More details on the non-invasive apparatus 110 will be described below.

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The computing device 130 executes a software application to analyse and display the data based on signals acquired from the sensors. The fixed sensor and an adjustable sensor would be marked with outflow and inflow so that a user knows where to place the sensors on a subject. Alternatively, the software application may include an algorithm that identifies the position 1 and position 2 signals, detects the baseline and peaks of the signals for effective processing. In addition, the algorithm can eliminate the false peaks for post-processing of the signals to determine the presence of stenosis. For example, if the time difference between the position 1 and position 2 peaks is greater than a predefined time, then peaks are considered as false peaks which would be removed from the readings. If stenosis is suspected, the patient is referred to see a nephrologist for confirmation and early treatment.

Figure 2.1 illustrates a front side view of the non-invasive apparatus 110, figure 2.2 illustrates a perspective view of the non-invasive apparatus 110 and figure 2.3 illustrates a top view 310, a bottom view 320 and a side view 330 of the non-invasive apparatus 110. Figure 3.1 illustrates an exploded view of the non-invasive apparatus 110 and figure 3.2 illustrates the adjustable mechanism 235 being arranged in the horizontal bar 211 of the main body 210. The non-invasive apparatus 110 comprises a main body 210, an adjustable handle 221, a first sensor 230 and a second sensor 240. The main body 210 comprises a horizontal bar 211 and a vertical bar 212 with one end extending from the center of the horizontal bar 211 and forming an inverted T shaped main body 210. A button 215 extends out from the other end of the vertical bar 212. The button 215 is a record switch provided to activate and deactivate recording of signals. Proximate this other end of the vertical bar 212 includes a pivot 222 connecting the adjustable handle 221 to the main body 210. The adjustable handle 221 is adjustable about the pivot 222 forming an angle θ to allow a balanced pressure to be applied to the main body 210. As the adjustable handle 221 and button 215 are arranged in proximity to each other, a user can easily activate and deactivate the record switch with ease when using the non-invasive apparatus 110. The button 215

also eliminates the use of foot switch or operator assistant. As the non-invasive apparatus 110 allows a single-handed operation, it minimises the difference in pressure applied to the first and second sensors 230 and 240 as both sensors are housed in one device. It is observed that an angled handle of about 140 degrees away from the vertical bar (as shown in Figure 2) is able to achieve minimum difference in pressure applied to the first and second sensors 230 and 240 for the non-invasive apparatus 110.

The first sensor 230 and second sensor 240 are coupled to the horizontal bar 211 of the main body 210. The first sensor 230 and second sensor 240 are coupled apart from each other on the horizontal bar 211 of the main body 210. Specifically, the first sensor 230 is fixedly coupled to one end of the horizontal bar 211 of the main body 210 while the second sensor 240 comprises an adjustable mechanism 235 that is coupled to the horizontal bar 211 to allow the second sensor 240 to move along the horizontal bar 211 of the main body 210 in order to vary the distance between the first sensor 230 and second sensor 240. The adjustable mechanism 235 is based on the slide-and-lock mechanism as shown in figure 3.2. Specifically, the adjustable mechanism 235 comprises a push spring mechanism 2351 for locking and unlocking the slide mechanism. For example, pressing the push spring mechanism would unlock the slide mechanism allowing the second sensor 240 to move along the horizontal bar 211 of the main body 210 and releasing the push spring mechanism would lock the slide mechanism preventing the second sensor 240 from moving along the horizontal bar 211 of the main body 210. The adjustable mechanism 235 allows for easy adjustment of second sensor 240 to the desired position providing fast and secure positioning. The adjustable mechanism 235 allows varying of the distance between the first sensor 230 and second sensor 240 to cater to the distance between 2 needle points on a fistula which can range from 30mm to 100mm. This enables the non-invasive apparatus 110 to be one size fits all, a universal non-invasive apparatus 110 for autogenous arteriovenous fistula.

To use the non-invasive apparatus 110, measurement is done from 2 needle points on the fistula which length varies from 30mm to 100mm. Pressure applied to the 2 points of measurement should be the same for best results. To achieve balanced pressure applied to the 2 points of measurement, the non-invasive apparatus 110 with the first and second
5 sensors is provided as illustrated above and shown in figure 2. The angle of handle, Θ can be adjusted to achieve balanced pressure applied to the fistula. As mentioned above, it is observed that an angle of 140 degrees is able to achieve minimum difference in pressure applied to the first and second sensors 230 and 240 for most cases.

Figure 4 illustrates an arrangement of the first and second sensors. Each of the first
10 and second sensors comprises a housing 410, two magnets 421 and 422 and a magnetic sensor 430. The magnetic sensor 430 is a giant magnetoresistance (GMR) based magnetic sensor to provide unidirectional magnetic field. Each of the two magnets 421 and 422 is of diameter of about 6mm, thickness of about 1 mm and are placed side by side to increase the coverage for easier magnetic coupling. The distance between two magnets 421 and
15 422 and the GMR based magnetic sensor 430 is set between 2.5 to 3.5 mm to achieve a magnetic field of 1000-1500 Gauss. The housing 410 is made of silicone and houses the two magnets 421 and 422 and the magnetic sensor 430.

To use the non-invasive apparatus 110, measurements can be recorded with a subject seated or lying on the dialysis bed with arm rested for static measurement. The
20 magnetic sensors 430 of the first and second sensors 230 and 240 are placed in the vicinity of the inflow and outflow of blood to dialysis machine. Specifically, the first sensor 230 is placed in the vicinity of the outflow of blood to dialysis machine and the second sensor is placed in the vicinity of the inflow of cleaned blood from the dialysis machine as illustrated in Figure 5. This two-position measurement enables direct estimation of blood flow rate in
25 fistula. Blood flow rate is estimated directly by evaluating the relationship of the distance between the two measuring points and the time difference in signal acquired. The distance between the two measuring points can be determined based on the position of the final

position of the adjustable mechanism 235. Further details on the measurement will be described below.

An algorithm is provided to determine the difference in the signals at the two positions to detect early formation of stenosis in the fistula. If there is no significant stenosis in the dialysis fistula, the blood flow measured from the first sensor (i.e. position 1) where
5 needle access point of blood to the dialysis machine to blood flow measured from the second sensor (i.e. position 2) where blood flows back from dialysis machine to the patient will be laminar as shown at top of figure 6. Specifically, the difference in amplitude of signal from both positions will not have significant difference. If a significant stenosis is present in
10 the dialysis fistula, the flow at position 1 and position 2 will be very different as shown at bottom of figure 6. In such cases, the flow will be more turbulent with elevated amplitude signal at position 1 due to the luminal narrowing in the dialysis fistula. The luminal narrowing would result in increased pressure, leading to increased amplitude of signal at position 1. At position 2, the signal amplitude will be variable as a result of the turbulence. Comparing
15 the relative difference in amplitude variation in magnetic sensors between the two positions would allow one to suspect an underlying stenotic lesion. Figure 7 shows an example of a waveform of a dialysis fistula with stenosis where there is high variation of waveform amplitudes due to turbulence blood flow in dialysis.

The algorithm is based on the measurement protocol. If the fistula has no stenosis,
20 the signals measured from both ends of the fistula will be very similar, where else for a stenosed fistula, signals measured from both ends will be very different. The algorithm is executable by the processing unit of the computing device 130. Figure 8 illustrates an overview of the network architecture of the system 100. On the non-invasive apparatus 110, the button 215 is connected to the first and second sensors to activate and deactivate
25 the first and second sensors. If the button 215 activates the first and second sensors, the first and second sensors commence measurement and transmit signals to the conditioning hardware 120. The conditioning hardware 120 comprises first and second amplifier 123

and 124 to receive signals from first and second sensors respectively. The signals are conditioned to a suitable level before the analogue digital converter (ADC) 121 translates the signal from analogue signal to digital signal to obtain position 1 signal for the first sensor and position 2 signal for the second sensor. Specifically, the signals from the first and second sensors are amplified before the ADC 121 translates the signal from analogue signal to digital signal to obtain position 1 signal for the first sensor and position 2 signal for the second sensor. The digital signal comprising position 1 signal and position 2 signal is then transmitted to an input/output port of the computing device 130.

The computing device 130 can receive and transmit data, execute software applications. The computing device 130 comprises a processor 131, memory 132, transceiver 137, input/output ports 136, display 135 and power unit (not shown). The processor 131 is a processor, microprocessor, microcontroller, application specific integrated circuit, digital signal processor (DSP), programmable logic circuit, or other data processing device that executes instructions to perform the processes in accordance with the present invention. The processor 131 has the capability to execute various applications that are stored in the memory 132.

The memory 132 may include read-only memory (ROM), random-access memory (RAM), electrically erasable programmable ROM (EEPROM), flash cards, or any memory commonly used for computers. The algorithm 133 is a set of instructions that is executable by the processor. The data includes raw digital signals received from the conditioning hardware 120 and data obtained from the algorithm 133.

Transceiver 137 connects processor 131 to a network for transmission of data to and from other processing systems such as a server to allow remote access to the data 134.

One or more input/output (I/O) ports 136 can be configured to allow the processor 131 to communicate with and control from various I/O devices such as the ADC 121. Some peripheral devices that may be connected to computing device 130 via the I/O ports 136

include the image capturing device, a USB storage device, an SD card or other storage device for transmitting information to or receiving information from the computing device 130.

Display 135 receives display data from processor 131 and display images on a
5 screen for a user to see. Display 135 may be a low power liquid crystal display (LCD) showing a variety of information for ease of identification and trouble shooting. The computing device 130 is powered by a power unit which may be battery operated or direct feed from the power grid. One skilled in the art will recognize that other features may be included in the computing device 130. Further, the components in computing device 130
10 may be replaced by other components that perform similar functions. In brief, the computing device 130 as shown in figure 8 is considered merely illustrative and non-limiting.

Figure 9 illustrates a process 900 executable by the processor of the computing device 130 to perform the algorithm to process the blood flow signals. The digital signals from the ADC 121 are automatically stored in the data 134. The digital signals contain the
15 direct measurement from fistula at two points. The digital signals from the data 134 are read into the algorithm. Process 900 begins with step 910 to determine the peaks of position 1 signal (i.e. peak 1) and position 2 signal (i.e. peak 2) as shown on top of figure 10 where the peaks of signals from positions 1 and 2 are circled in white.

In step 920, process 900 calculates the time differences from respective peaks in
20 peak 1 and peak 2. Specifically, the time difference is calculated between the first peak from position 1 signal and the first peak from position 2 signal. The time difference is then calculated between the second peak from position 1 signal and the second peak from position 2 signal. This step is repeated until all peaks are considered.

In step 930, process 900 determines the median of the time differences. In short,
25 the time differences in step 920 are sorted in ascending or descending order and the middle time difference is selected.

In step 940, process 900 determines the fistula flow index (FFI) classification. This classification index will identify if stenosis is present in the fistula. The FFI can be determined in the following manner. The steps involved include the creation of function p1 and p2 to deliver the marker FFI. Function p1 is derived from the ratio of standard deviation and mean of the signal samples obtained from position 1 signal. Likewise, function p2 is derived from the ratio of standard deviation and mean of the signal from position 2 signal. The marker FFI is calculated from the ratio of p1 and p2. For fistula with good flow rate, showing no sign of stenosis, p1 and p2 should have very similar values, and thus the ratio of p1 and p2 will result in close to unity value. FFI value for good flow fistula was determined to be between 0.5 and 1.9, with reference to clinical gold standard (i.e. ultrasound assessment by experienced physician). The FFI can be elaborated using the following expressions.

Position 1 signal	Position 2 signal
$mean(\tilde{x}_1) = \frac{\sum x}{N}$	$mean(\tilde{x}_2) = \frac{\sum x}{N}$
$standard\ deviation(s_1) = \sqrt{\frac{\sum(x_1 - \tilde{x}_1)^2}{N - 1}}$	$standard\ deviation(s_2) = \sqrt{\frac{\sum(x_2 - \tilde{x}_2)^2}{N - 1}}$
$p1 = \frac{s1}{\tilde{x}_1}$	$p2 = \frac{s2}{\tilde{x}_2}$

$$FFI = \frac{p1}{p2}$$

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After determining the FFI, process 900 compares the median from step 930 against the FFI. If the median is more than FFI, process 900 determines the fistula is good in step 950. If the median is less than FFI, process 900 determines the fistula is mild-moderate in step 955.

In step 940, if the FFI is outside the range of between 0.5 and 1.9, an alert may be triggered and notification may be sent to a physician for immediate review. This is applied especially for patients who are on home hemodialysis where an alert could be raised when stenosis is suspected thus prompting a downstream review process, allowing early
5 intervention/ treatment.

Potential application for this invention is in regular monitoring of fistula flow in dialysis centers or at home, just like daily monitoring of blood pressure for early detection of high blood pressure. With regular monitoring of fistula health, early stenosis can be detected for early intervention to take place. It can also be used for monitoring and
10 surveillance of other vascular structures such as arteries, arterial or other vascular grafts for patients with vascular diseases, diabetes, stroke, etc.

Figure 11 shows an exemplary design of non-invasive apparatus and figure 12 show an exemplary design of non-invasive apparatus 110 communicative connected to the conditioning hardware 120 for blood flow acquisition.

15 The above is a description of exemplary embodiments of an apparatus, system and method in accordance with this disclosure. It is foreseeable that those skilled in the art can and will design alternative devices based on this disclosure.

Claims

1. A non-invasive apparatus for measuring blood flow from a fistula comprising:
5 a main body;
an adjustable handle pivotally coupled to the main body;
a first sensor coupled to the main body; and
a second sensor movably coupled to the main body and apart from the first sensor.
- 10 2. The non-invasive apparatus of claim 1 further comprising a pivot connecting the adjustable handle to the main body such that the adjustable handle is adjustable about the pivot forming an angle Θ to allow a balanced pressure to be applied to a subject.
3. The non-invasive apparatus of claim 2 wherein the main body comprises a
15 horizontal bar and a vertical bar with one end extending from the center of the horizontal bar and forming an inverted T shaped main body and the pivot is arranged proximate another end of the vertical bar.
4. The non-invasive apparatus of claim 3 further comprising a button extending out
20 from the other end of the vertical bar, the button is a record switch provided to activate and deactivate the recording of signals from first and second sensors.
5. The non-invasive apparatus of claim 3 wherein the angle Θ is preferably about 140 degrees away from the vertical bar.
- 25 6. The non-invasive apparatus of claim 3 wherein the first sensor is fixedly coupled to one end of the horizontal bar of the main body and the second sensor comprises an

adjustable mechanism coupled to the horizontal bar to allow the second sensor to move along the horizontal bar.

7. The non-invasive apparatus of claim 6 wherein the adjustable mechanism
5 comprises a push spring mechanism for locking and unlocking the slide mechanism.

8. The non-invasive apparatus of claim 6 wherein each of the first and second sensors comprises

two magnets, each of diameter of about 6mm, thickness of about 1 mm and are
10 placed side by side;

a magnetic sensor arranged apart from the two magnets in the range of between 2.5 to 3.5 mm; and

a housing to house the two magnets and the magnetic sensor.

15 9. A system comprising:

the non-invasive apparatus according to anyone of claims 1-8;

a conditioning hardware adapted to condition the signals from the first and second sensors to a suitable level before translating the signal from analogue signals to digital signals to obtain position 1 signal for the first sensor and position 2 signal for the second

20 sensor; and

a processing unit comprising a processor, a memory and instructions stored on the memory and executable by the processor to:

receive the digital signals from the conditioning hardware;

store the digital signals in the memory; and

25 execute an algorithm to process the digital signals.

10. The system according to claim 9 wherein the instruction to execute the algorithm to process the digital signals comprises instructions to:
- determine a plurality of peaks from each of position 1 signal and position 2 signal;
 - calculate time differences from respective peaks in each of position 1 signal and
 - 5 position 2 signal;
 - determine a median of the time differences;
 - determine a fistula flow index (FFI) classification;
 - in response to the median being more than FFI classification, determine the fistula is good and in response to the median being less than FFI classification, determine the
 - 10 fistula is mild-moderate.
11. The system according to claim 10 wherein the instruction to execute the instruction to determine the FFI classification comprises instructions to:
- determine a standard deviation and a mean from each of the position 1 signal and
 - 15 position 2 signal;
 - determine function p1 from a ratio of standard deviation and mean of the position 1 signal;
 - determine function p2 from a ratio of standard deviation and mean of the position 2 signal; and
 - 20 calculate a ratio of p1 and p2 to determine the FFI classification.
12. The system according to claim 11 wherein the instruction to execute the instruction to determine the FFI classification further comprises instructions to:
- in response to the FFI being outside the range of between 0.5 and 1.9, trigger an
 - 25 alert and transmit a notification to a physician for immediate review.