

# DEVICE FOR DETERMINING ATRIAL FIBRILLATION RISK AND METHOD THEREOF

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## TECHNICAL FIELD

The present disclosure relates broadly to a device for determining atrial fibrillation risk and a method of determining atrial fibrillation risk.

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## BACKGROUND

Atrial fibrillation (AF) is an important type of cardiac arrhythmia that is associated with a 5-fold increased risk of ischemic stroke. Atrial fibrillation occurs as a result of disorganized and chaotic firing of electrical impulses that leads to irregular heart contractions and formation of blood clots within the different heart chambers. Blood clots that are associated with AF are typically larger and tend to occlude larger blood vessels in the brain, potentially causing severe ischemic stroke that are associated with a more debilitating outcome.

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FIG. 20A provides an exemplary display of an ECG signal obtained from a healthy individual showing sinus rhythm which indicate normal electrical conduction in the heart. FIG. 20B provides an exemplary display of an ECG signal obtained from an individual suffering from atrial fibrillation showing the presence of an irregular R-R interval and absent P wave.

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AF is diagnosed based on an electrocardiogram (ECG) recording of an irregular R-R interval and absent P wave. An important AF subtype is paroxysmal AF that results in brief AF runs, with each run lasting seconds and minutes. The detection of paroxysmal AF is often elusive to standard methods of acquiring cardiac rhythm such as a 12-lead ECG. For a correct diagnosis of AF to be made, an individual will require continuous and prolonged monitoring of ECG to detect brief AF runs that are associated with increased stroke risks. An accurate diagnosis of AF is important as there are specific medications (anticoagulants) that have been shown to significantly reduce the likelihood of stroke among high-risk individuals.

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Existing methods used to continuously monitor the ECG rhythm for prolonged periods include Holter monitors, cardiac event recorders and implantable loop recorders.

These devices entail the use of multiple electrodes and wirings to be worn that are strapped or attached to the body (e.g. sensor patches). Some methods (e.g. implantable loop recorder) require a minor operation to insert cardiac monitoring devices adjacent to the heart. As these devices are placed on the body continuously for extended periods of time, many patients find them uncomfortable as it could interfere with their daily activities. Patients are required to avoid contacting the electrodes with water and to refrain from shower or excessive sweating. Skin irritations also often arise in patients from the prolonged contact with the electrodes. In addition, because the patient is continuously moving about throughout the day, the obtained ECG signal contains many artefacts and may not be an accurate representation of the actual ECG of the patient. Given the intermittent nature of AF runs, most patients require a prolonged period of ECG monitoring (in most cases, weeks and months) to improve the detection of AF.

There is therefore a need for a method and device for detecting atrial fibrillation risk that seek to address or ameliorate at least one of the above problems.

## SUMMARY

In accordance with a first aspect, there is provided a method of determining atrial fibrillation risk, the method comprising obtaining a hemodynamic signal with a hemodynamic sensor; obtaining an electrocardiographic signal (ECG signal) with an electrocardiogram (ECG) sensor; and determining atrial fibrillation risk based on the ECG signal and hemodynamic signal with a processor.

The method may further comprise detecting high risk patterns within the hemodynamic signal with the processor; and triggering the obtaining of the ECG signal when high risk patterns are detected with the processor.

Detecting high risk patterns may comprise monitoring the area under the curve of pulses within the hemodynamic signal by the processor.

High risk patterns may be determined to be detected by the processor when the area under the curve of one or more pulses within the hemodynamic signal is less than a first pre-determined threshold.

The method may further comprise determining pulse transit times (PTTs) between pulses of the ECG signal and the hemodynamic signal, by the processor.

Atrial fibrillation risk may be determined when the variability of the PTT exceeds a pre-determined PTT threshold, by the processor.

5           The method may further comprise storing or transmitting the ECG signal for further analysis when the variability of the PTT exceeds a pre-determined PTT threshold by a data storage unit or transceiver.

10           The hemodynamic signal may be obtained using a capillary sensor, an arterial sensor, or both.

The capillary sensor may be an optical pulse oximeter and the arterial sensor may be a modulated magnetic signature of blood (MMSB) sensor.

15           The ECG signal may be obtained using a finger-based ECG sensor.

In accordance with another aspect, there is provided a device for determining atrial fibrillation risk, the device comprising a hemodynamic sensor for obtaining a hemodynamic signal; an electrocardiogram (ECG) sensor for obtaining an electrocardiographic signal  
20           (ECG signal); and a processor configured for determining atrial fibrillation risk based on the ECG signal and hemodynamic signal.

The processor may be further configured for detecting high risk patterns within the hemodynamic signal; and triggering the obtaining of the ECG signal when high risk patterns  
25           are detected.

The processor may be further configured for detecting high risk patterns based on monitoring the area under the curve of pulses within the hemodynamic signal.

30           The processor may be further configured to detect high risk patterns when the area under the curve of one or more pulses of the hemodynamic signal is less than a first pre-determined threshold.

The processor may be further configured to determine pulse transit times (PTTs)  
35           between pulses of the ECG signal and the hemodynamic signal.

Atrial fibrillation risk may be determined by the processor when the variability of the PTT exceeds a pre-determined PTT threshold.

5 The device may further comprise a data storage unit for storing the ECG signal for further analysis when the variability of the PTT exceeds a pre-determined PTT threshold.

The device may further comprise a transceiver for transmitting the ECG signal for further analysis when the variability of the PTT exceeds a pre-determined PTT threshold.

10 The hemodynamic sensor may comprise one or both of a capillary sensor and an arterial sensor.

The capillary sensor may an optical pulse oximeter and the arterial sensor may be a modulated magnetic signature of blood (MMSB) sensor.

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The ECG sensor may comprise a finger-based ECG sensor.

The device may be housed within a brace-housing capable of being worn on a limb of a user.

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The ECG sensor may comprise a first lead positioned on the back surface of the strap; and a second lead positioned on the front surface of the strap, such that when the device is worn on the limb of the user, the ECG sensor is capable of obtaining ECG signals of a user, when the first lead is in physical contact with the limb of the user; and the second lead receives a digit on an opposing limb of the user.

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The hemodynamic sensor may be capable of obtaining hemodynamic signal from a wrist area of a person, when the device is worn on the wrist area.

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The hemodynamic sensor may comprise a photoplethysmographic (PPG) sensor, said PPG sensor positioned in close proximity to the second lead, such that the PPG sensor is capable of obtaining a capillary signal simultaneously with the ECG signals, when the digit is received at the second lead.

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In accordance with another aspect, there is provided a non-transitory computer readable storage medium, having stored thereon computer code for instructing a processing unit to execute a method of determining atrial fibrillation risk, the method comprising,

obtaining a hemodynamic signal with a hemodynamic sensor; obtaining an electrocardiographic signal (ECG signal) with an ECG sensor; and, determining atrial fibrillation risk based on the ECG signal and hemodynamic signal with a processor.

5 In the non-transitory computer readable storage medium, the method may further comprise, detecting high risk patterns within the hemodynamic signal with the processor; and triggering the obtaining of the ECG signal when high risk patterns are detected with the processor.

10 In the non-transitory computer readable storage medium, detecting high risk patterns may comprise monitoring the area under the curve of pulses within the hemodynamic signal by the processor, and high risk patterns are determined to be detected by the processor when the area under the curve of one or more pulses is less than a first pre-determined threshold.

15 In the non-transitory computer readable storage medium, the method may further comprise determining pulse transit times (PTTs) between pulses of the ECG signal and the hemodynamic signal by the processor, and determining atrial fibrillation risk when the variability of the PTT exceeds a pre-determined PTT threshold by the processor.

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## **BRIEF DESCRIPTION OF THE DRAWINGS**

Example embodiments of the invention will be better understood and readily apparent to one of ordinary skill in the art from the following written description, by way of example only, and in conjunction with the drawings, in which:

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FIG. 1 is a schematic block diagram of a device for determining atrial fibrillation risk in an exemplary embodiment.

30 FIG. 2 is a schematic block diagram of a device for determining atrial fibrillation risk in another exemplary embodiment.

FIG. 3 is a schematic flowchart illustrating a method of determining atrial fibrillation risk in an exemplary embodiment.

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FIG. 4A shows an exemplary display of synchronously acquired ECG, arterial and capillary (hemodynamic) signals in a healthy individual.

FIG. 4B shows an exemplary display of synchronously acquired ECG, artery and capillary (hemodynamic) signals in an individual with atrial fibrillation.

5           Fig. 5A shows the exemplary waveforms of hemodynamic and ECG signals.

FIG. 5B shows the measurement of pulse transit times, in an exemplary embodiment.

FIG. 6A is a chart showing arterial Pulse Transit Time (PTT) variability in individuals, in an exemplary embodiment.

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FIG. 6B is a chart showing capillary Pulse Transit Time (PTT) variability in individuals, in an exemplary embodiment.

FIG. 7 shows a position of an ECG sensor on a user during the collection of ECG  
15   signals, in an exemplary embodiment.

FIG. 8 shows a position of a capillary sensor on a user during the collection of capillary signals, in an exemplary embodiment.

20           FIG. 9 shows a position of an arterial sensor on a user during the collection of artery signals, in an exemplary embodiment.

FIG. 10 shows a position of a capillary sensor on an upper arm of a user, in an exemplary embodiment.

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FIG. 11 shows a position of an arterial sensor on a user during the collection of artery signals, in an exemplary embodiment.

FIG. 12A shows an exemplary device comprising three physiological sensors.

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FIG. 12B shows a device comprising three physiological sensors, when wrapped around the left arm of a user, in an exemplary embodiment.

FIG. 13 is a schematic perspective view of a device for determining atrial fibrillation  
35   risk, in an exemplary embodiment.

FIG. 14 shows a schematic flowchart for illustrating a method of determining atrial fibrillation risk, in an exemplary embodiment.

5 FIG. 15 shows a schematic flowchart for illustrating a method of determining atrial fibrillation risk, in an example embodiment.

FIG. 16A is a graph showing an arterial pulse waveform of a healthy volunteer.

10 FIG. 16B is a graph showing an arterial pulse waveform of a patient with high blood pressure, diabetes mellitus, high cholesterol, stroke or irregular heart rate.

FIG. 17A is schematic block diagram of a device comprising two physiological sensors for determining atrial fibrillation risk in another exemplary embodiment.

15 FIG. 17B is schematic block diagram of a device for determining atrial fibrillation risk in an exemplary embodiment.

Figure 18 is a schematic drawing of a computer system suitable for implementing an example embodiment.

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Figure 19 is a schematic drawing of a wireless communication device suitable for implementing an example embodiment.

25 FIG. 20A shows an exemplary display of an ECG signal obtained from a healthy individual.

FIG. 20B shows an exemplary display of an ECG signal obtained from an individual suffering from atrial fibrillation.

## 30 DETAILED DESCRIPTION

Exemplary, non-limiting, embodiments may provide a device for determining atrial fibrillation risk. The device comprises a hemodynamic sensor for obtaining a hemodynamic signal; an electrocardiogram (ECG) sensor for obtaining an electrocardiographic signal  
35 (ECG signal); and a processor configured for determining atrial fibrillation risk based on the ECG signal and hemodynamic signal.

Example embodiments described herein may also provide a method of determining atrial fibrillation risk. The method comprises, obtaining a hemodynamic signal with a hemodynamic sensor, obtaining an electrocardiographic signal (ECG signal) with an electrocardiogram (ECG) sensor; and determining atrial fibrillation risk based on the ECG signal and hemodynamic signal with a processor.

Example embodiments described herein may further provide a non-transitory computer readable storage medium, having stored thereon computer code for instructing a processing unit to execute a method of determining atrial fibrillation risk. A method comprises, obtaining a hemodynamic signal with a hemodynamic sensor, obtaining an electrocardiographic signal (ECG signal) with an electrocardiogram (ECG) sensor; and determining atrial fibrillation risk based on the ECG signal and hemodynamic signal with a processor.

The terms "coupled" or "connected" as used in this description are intended to cover both directly connected or connected through one or more intermediate means, unless otherwise stated.

The description herein may be, in certain portions, explicitly or implicitly described as algorithms and/or functional operations that operate on data within a computer memory or an electronic circuit. These algorithmic descriptions and/or functional operations are usually used by those skilled in the information/data processing arts for efficient description. An algorithm is generally relating to a self-consistent sequence of steps leading to a desired result. The algorithmic steps can include physical manipulations of physical quantities, such as electrical, magnetic or optical signals capable of being stored, transmitted, transferred, combined, compared, and otherwise manipulated.

Further, unless specifically stated otherwise, and would ordinarily be apparent from the following, a person skilled in the art will appreciate that throughout the present specification, discussions utilizing terms such as "obtaining", "configuring", "determining", "detecting", "generating", "monitoring", "transmitting", and the like, refer to action and processes of an instructing processor/computer system, or similar electronic circuit/device/component, that manipulates/processes and transforms data represented as physical quantities within the described system into other data similarly represented as physical quantities within the system or other information storage, transmission or display devices etc.

The description also discloses relevant device/apparatus for performing the steps of the described methods. Such apparatus may be specifically constructed for the purposes of the methods, or may comprise a general purpose computer/processor or other device selectively activated or reconfigured by a computer program stored in a storage member. The algorithms and displays described herein are not inherently related to any particular computer or other apparatus. It is understood that general purpose devices/machines may be used in accordance with the teachings herein. Alternatively, the construction of a specialized device/apparatus to perform the method steps may be desired.

In addition, it is submitted that the description also implicitly covers a computer program, in that it would be clear that the steps of the methods described herein may be put into effect by computer code. It will be appreciated that a large variety of programming languages and coding can be used to implement the teachings of the description herein. Moreover, the computer program if applicable is not limited to any particular control flow and can use different control flows without departing from the scope of the invention.

Furthermore, one or more of the steps of the computer program if applicable may be performed in parallel and/or sequentially. Such a computer program if applicable may be stored on any computer readable medium. The computer readable medium may include storage devices such as magnetic or optical disks, memory chips, or other storage devices suitable for interfacing with a suitable reader/general purpose computer. In such instances, the computer readable storage medium is non-transitory. Such storage medium also covers all computer-readable media e.g. medium that stores data only for short periods of time and/or only in the presence of power, such as register memory, processor cache and Random Access Memory (RAM) and the like. The computer readable medium may even include a wired medium such as exemplified in the Internet system, or wireless medium such as exemplified in bluetooth technology. The computer program when loaded and executed on a suitable reader effectively results in an apparatus that can implement the steps of the described methods.

The example embodiments may also be implemented as hardware modules. A module is a functional hardware unit designed for use with other components or modules. For example, a module may be implemented using digital or discrete electronic components, or it can form a portion of an entire electronic circuit such as an Application Specific Integrated Circuit (ASIC). A person skilled in the art will understand that the example

embodiments can also be implemented as a combination of hardware and software modules.

Additionally, when describing some embodiments, the disclosure may have disclosed a method and/or process as a particular sequence of steps. However, unless otherwise required, it will be appreciated the method or process should not be limited to the particular sequence of steps disclosed. Other sequences of steps may be possible. The particular order of the steps disclosed herein should not be construed as undue limitations. Unless otherwise required, a method and/or process disclosed herein should not be limited to the steps being carried out in the order written. The sequence of steps may be varied and still remain within the scope of the disclosure.

Further, in the description herein, the word "substantially" whenever used is understood to include, but not restricted to, "entirely" or "completely" and the like. In addition, terms such as "comprising", "comprise", and the like whenever used, are intended to be non-restricting descriptive language in that they broadly include elements/components recited after such terms, in addition to other components not explicitly recited. Further, terms such as "about", "approximately" and the like whenever used, typically means a reasonable variation, for example a variation of +/- 5% of the disclosed value, or a variance of 4% of the disclosed value, or a variance of 3% of the disclosed value, a variance of 2% of the disclosed value or a variance of 1% of the disclosed value.

Furthermore, in the description herein, certain values may be disclosed in a range. The values showing the end points of a range are intended to illustrate a preferred range. Whenever a range has been described, it is intended that the range covers and teaches all possible sub-ranges as well as individual numerical values within that range. That is, the end points of a range should not be interpreted as inflexible limitations. For example, a description of a range of 1% to 5% is intended to have specifically disclosed sub-ranges 1% to 2%, 1% to 3%, 1% to 4%, 2% to 3% etc., as well as individually, values within that range such as 1%, 2%, 3%, 4% and 5%. The intention of the above specific disclosure is applicable to any depth/breadth of a range.

FIG. 1 is a schematic block diagram of a device 100 for determining atrial fibrillation risk in an exemplary embodiment. The device 100 comprises a hemodynamic sensor 102 for obtaining a hemodynamic signal, an electrocardiogram (ECG) sensor 104 for obtaining an ECG signal, and a processor 106. The processor 106 is specially configured for determining atrial fibrillation risk based on the ECG signal and hemodynamic signal.

In the exemplary embodiment, the hemodynamic sensor 102 comprises a capillary sensor in the form of a pulse oximeter for acquiring hemodynamic signals (e.g., blood flow characteristics in the capillary of an individual). In an alternative embodiment, the hemodynamic sensor 102 may comprise an arterial sensor in the form of a modulated magnetic signature of blood (MMSB) sensor. An example of an MMSB sensor is disclosed in United States Patent No. 8180427B, which is incorporated herein in its entirety by reference.

A hemodynamic signal provides an indication of the functional status of the cardiovascular system in an individual, which relates to the blood flow and blood pressure exerted in the veins, arteries and chambers of the heart. The hemodynamic signal comprises a hemodynamic waveform, from which important arterial or capillary-related parameters such as, but not limited to, systolic pressure, diastolic pressure, pulse pressure, heart rate, temperature, respiratory rate and blood oxygen saturation ( $SpO_2$ ), may be obtained.

In the exemplary embodiment, the device 100 may further comprise a data storage unit 108. The data storage unit is provided for storing the ECG signal for further analysis when atrial fibrillation risk is determined by the processor 106.

In the exemplary embodiment, the device 100 may further comprise a transceiver 110. The transceiver is provided for transmitting the stored ECG signal for further analysis e.g., a central processor located in a different location as the device 100, when atrial fibrillation risk is determined by the processor 106.

In the exemplary embodiment, the device 100 may be housed within a brace-housing (not shown) capable of being worn on a limb of a user.

FIG. 2 is a schematic block diagram of a device 200 for determining atrial fibrillation risk in another exemplary embodiment. The device 200 comprises a hemodynamic sensor 202 for obtaining one or more hemodynamic signals, an electrocardiogram (ECG) sensor 208 for obtaining an ECG signal and a processor 210. The processor 210 is specially configured for determining atrial fibrillation risk based on the ECG signal and one or more hemodynamic signals. The hemodynamic sensor 202 comprises a capillary sensor 204 and an arterial sensor 206.

In the exemplary embodiment, the capillary sensor 204 may comprise an optical pulse oximeter and the arterial sensor 206 may comprise a modulated magnetic signature of

blood (MMSB) sensor. An example of an MMSB sensor is disclosed in United States Patent No. 8180427B, which is incorporated herein in its entirety by reference. The capillary sensor 204 and the arterial sensor 206 acquire hemodynamic signals of the arteries and capillaries (i.e. blood flow activities).

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In the exemplary embodiment, the ECG sensor 208 may comprise two or more leads which when placed in contact and in specific locations of an individual, allow ECG signals representative of electrical activities of the heart, to be acquired.

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In the exemplary embodiment, the device 200 may further comprise a data storage unit 212. The data storage unit is provided for storing the ECG signal for further analysis when atrial fibrillation risk is determined by the processor 210.

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In the exemplary embodiment, the device 200 may further comprise a transceiver 214. The transceiver is provided for transmitting the stored ECG signal for further analysis by e.g., a central processor located in a different location as the device 200, when atrial fibrillation risk is determined by the processor 214.

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FIG. 3 shows a schematic flowchart illustrating a method 300 of determining atrial fibrillation risk in an exemplary embodiment. The method may be implemented on the exemplary devices 100 or 200 as illustrated in FIG. 1 and FIG. 2 respectively.

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At step 302, one or more hemodynamic signals are obtained using e.g., a PPG (photoplethysmographic) sensor and/or a MMSB sensor (e.g., sensors 102, 202 in FIG. 1 and FIG. 2 respectively). At the same time, an ECG signal is obtained from an ECG sensor (e.g., sensor 104, 208 in FIG. 1 and FIG. 2 respectively). At step 304, the one or more hemodynamic signals and ECG signal are processed to extract useful parameters for determining AF risk, by the processor (e.g., processor 106, 210 in FIG. 1 and FIG. 2 respectively). At step 306, the processor determines the AF risk based on these parameters.

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In the example embodiment, the useful parameters may include, but are not limited to, pulse transit time, amplitude of one or more waves in the arterial and/or capillary waveforms, area under the curve of the arterial and/or capillary waveforms, and slope of the rising edge of the pulses within the arterial and/or capillary waveforms.

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FIG. 4A provides an exemplary display of synchronously acquired ECG, arterial and capillary (hemodynamic) signals in a healthy individual using ECG, MMSB and Pulse

Oximeter sensors respectively. It was observed that the size, shape and amplitude of arterial and capillary waveforms are relatively consistent and predictable following each ECG QRS complex.

FIG. 4B provides an exemplary display of synchronously acquired ECG, artery and capillary (hemodynamic) signals in an individual with atrial fibrillation using ECG, MMSB and Pulse Oximeter sensors respectively. In contrast to the graphs obtained for healthy individuals as shown in FIG. 4A, arterial and capillary waveforms in individuals with atrial fibrillation are highly variable in terms of size, shape and amplitude. Missing and/or degraded pulses are observed in both the artery and capillary signals with respect to the ECG signal.

FIG. 5A and 5B show exemplary waveforms 500a and 500b, representative of the hemodynamic and ECG signals obtained from the hemodynamic and ECG sensors, in the example embodiments. FIG. 5A and 5B illustrate the parameters from which the determination of atrial fibrillation risk are obtained or extracted from the respective hemodynamic and/or ECG signals. The waveforms shown in FIG. 5A and 5B may also be displayed on a display unit, and the display unit may be comprised within the exemplary devices (e.g., reference numerals 100 or 200 of FIG. 1 and 2).

Fig. 5A shows the exemplary waveforms 500a of hemodynamic and ECG signals, with output parameters which may be extracted therefrom. The output parameters are pulse transit time 502, amplitude 504, area under the curve 506 and the slope ( $dP/dT$ ) 508 of the arterial/capillary waveforms. The pulse transit time 502 (PTT) is defined as the time it takes the blood pressure wave to propagate from the heart to a specified point in the body and is measured as the period from the peak of the ECG waveform to the peak of the immediately following arterial and/or capillary waveform. The amplitude 504 is defined as the amplitude of a pulse within the arterial and/or capillary waveform. The area under the curve 506 is defined as the area under the curve of a pulse within the arterial and/or capillary waveform and is measured or obtained by performing a definite integral between the 2 points, as shown by the shaded area in 506. The slope ( $dP/dT$ ) 508 is determined as gradient of a rising edge of a pulse within the arterial and/or capillary waveform.

FIG. 5B shows the measurement of pulse transit times, in an exemplary embodiment. As shown in FIG. 5B, arterial PTT 508 is measured as the period from the peak of a pulse in the ECG waveform to the peak of the immediately following pulse in the arterial waveform (e.g., see T1). The capillary PTT 510 is measured as the period from the peak of a pulse in

the ECG waveform to the peak of the immediately following pulse in the capillary waveform (e.g., see T2).

In an exemplary embodiment, the processor (e.g., 106, 210 in FIG. 1 and 2 respectively), determines AF risk by monitoring the area under the curve of pulses within the hemodynamic signal(s) of the cardiovascular system, as well as the PTTs. The processor determines high AF risk if one or more pulses of the hemodynamic signal is less than a first pre-determined threshold level, and/or if a PTT variability is high. In another exemplary embodiment, the processor (e.g., 106, 210 in FIG. 1 and 2 respectively), may simply determine AF risk based on PTT variability alone.

Tables 1 and 2 illustrate the effectiveness of an exemplary method of determining the risk of atrial fibrillation based on the parameters of area under the curve and PTT, in the example embodiment. In particular, the diagnostic performance of the exemplary methods disclosed herein to discriminate between users with AF and users without AF is evaluated. Uncertainty in the measured values of the output variables (i.e. Area under curve and variability in pulse transit time) have been taken into account and the values shown in Tables 1 and 2 are derived based on standardised experimental data values (i.e., where standard deviation and standard error of mean of the experimental data set are used).

[Table 1]

| Upper cut-off<br>for AUC | Sensitivity<br>(%) | Specificity<br>(%) |
|--------------------------|--------------------|--------------------|
| 1.9305                   | 21.4               | 94.0               |
| 1.9455                   | 42.9               | 90.8               |
| 1.9905                   | 42.9               | 87.1               |
| 1.9965                   | 57.1               | 69.1               |
| 2.0015                   | 71.4               | 32.4               |
| 2.0105                   | 85.7               | 18.6               |
| 2.0375                   | 100.0              | 9.2                |

Table 1 shows the performance of using different AUC thresholds to screen high risk arterial waveform patterns for the risk of atrial fibrillation. In the present application, it was found that waveforms with a lower area under the curve (AUC) are predictive of atrial fibrillation. Based on the results of Table 1, it is observed that the device is capable of

screening out normal waveforms during arterial/capillary monitoring by using the AUC variable.

[Table 2]

| <b>Lower cut-off<br/>for PTT<br/>variability</b> | <b>Sensitivity<br/>(%)</b> | <b>Specificity<br/>(%)</b> |
|--------------------------------------------------|----------------------------|----------------------------|
| 0.0000305                                        | 14.3                       | 98.4                       |
| 0.0000905                                        | 28.6                       | 94.3                       |
| 0.0002405                                        | 50.0                       | 91.5                       |
| 0.0007300                                        | 64.3                       | 82.3                       |
| 0.0018070                                        | 85.7                       | 73.5                       |
| 0.0051850                                        | 92.9                       | 57.7                       |
| 0.0131150                                        | 100.0                      | 39.7                       |

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Table 2 shows the performance of using PTT variability to screen high risk ECG rhythm signals for atrial fibrillation. Based on the information shown in Table 2, a lower variability in PTT is predictive of atrial fibrillation. Thus, normal ECG signals may be filtered out during cardiac ECG monitoring by using PTT variability.

FIG. 6A and 6B are charts showing the PTT variability, i.e., the arterial pulse transit time (T1) and/or capillary pulse transit time (T2). In particular, FIG. 6A shows T1 acquired for individuals diagnosed with atrial fibrillation (i.e., P1-T1, P2-T1 and P3-T1), individuals diagnosed as previously having suffered a heart attack (myocardial infarction) (i.e. P4-T1), and individuals of generally good health (i.e. H1-T1). It is observed that the PTT variability is much higher for individuals diagnosed with AF.

Similarly, FIG. 6B shows T2 (the capillary pulse transit time) acquired for individuals diagnosed with atrial fibrillation (i.e., P1-T2, P2-T2 and P3-T2), individuals diagnosed as previously having suffered a heart attack (myocardial infarction) (i.e. P4-T2), and individuals of generally good health (i.e. H1-T2). It is observed that the PTT variability is higher for individuals diagnosed with AF.

The graphs shown in FIG. 4A and 4B are obtained from three physiological sensors (i.e., the ECG sensor, capillary sensor, and artery sensor) as shown in FIG. 7, 8 and 9.

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FIG. 7 shows an exemplary positioning of an ECG sensor 700 on a user during the collection of ECG signals. In the exemplary embodiment, the mounting location for the ECG sensor, comprising a pair of ECG leads 700, is on the inner arm close to the biceps at around 4cm below the axilla (i.e. armpit). The distance separating the ECG sensor leads (ECGx) is designed to be  $3\text{cm} < \text{ECGx} < 5\text{cm}$  as illustrated in FIG. 7.

FIG. 8 shows an exemplary positioning of a capillary sensor (pulse oximeter sensor) 800 on a user during the collection of capillary signals. In the exemplary embodiment, the mounting locality for the pulse oximeter sensor is on the finger 800 as illustrated in FIG. 8.

FIG. 9 shows an exemplary positioning of an artery sensor (MMSB sensor) 902 and 904 on a user during the collection of artery signals. In the exemplary embodiment, the mounting locality for the MMSB sensors is on the wrist area 900, more particularly along the radial artery on the wrist as illustrated in FIG. 9. The MMSB sensor further comprises a magnet 904 spaced between 1.3cm to 1.8cm apart from the sensor 902, for optimal sensor biasing and magnetic coupling.

In the above embodiment (illustrated in FIG. 7, 8 and 9), the ECG sensor 700 is positioned on the upper arm, close to the biceps of the user, the capillary sensor 800 is positioned at the finger tip of the user, and the arterial sensor 902 is positioned around a wrist of the user. It will be appreciated that the three sensors are positioned along the entire arm of the user.

In an alternative embodiment, it has been recognised that the ECG sensor, arterial sensor and capillary sensor may be positioned in closer proximity, resulting in a more advantageously compact and smaller device, and which may be more easily worn by a user. In particular, the capillary sensor may be positioned on an outer part of the upper arm of the user, around the triceps area. FIG. 10 shows the position of the capillary sensor 1000 on an upper arm of a user when in use.

In addition, the arterial sensor may be positioned near the upper forearm of the user such that it is near the antecubital space and vicinity of the triceps. FIG. 11 shows an exemplary positioning of an arterial sensor (MMSB sensor) 1102 and 1104 on a user during the collection of artery signals. In the exemplary embodiment, the mounting locality for the MMSB sensors 1102 is near or about the antecubital space 1100 of the user. The MMSB

sensor further comprises a magnet 1104 is spaced between 1.3cm to 1.8cm apart from the sensor 1102 for optimal sensor biasing and magnetic coupling.

FIG. 12A shows an exemplary device 1200 comprising three physiological sensors.

The device 1200 comprises a brace or cuff 1202 capable of being wrapped around a limb of a user. Within the brace or cuff 1202, the device 1200 further comprises a pair of ECG sensor leads 1204, a capillary (pulse oximeter) sensor 1206 and an arterial sensor (MMSB sensor) 1208.

When the brace or cuff 1202 is wrapped around a limb e.g., left arm of the user, the three physiological sensors 1204, 1206 and 1208 are positioned such that they are able to acquire the ECG and hemodynamic signals (i.e., activities of the cardiovascular system) on the limb (e.g., left arm) of the user. FIG. 12B shows the brace or cuff 1202 when wrapped around the left arm of a user, in an exemplary embodiment. When wrapped around the left arm of the user, the sensors 1204, 1206 and 1208 (not shown) are positioned on the left arm of the user, as disclosed in e.g., FIG. 7, 10 and 11 above. It will be appreciated that the sensors 1202, 1204 and 1206 are coupled to a processor (not shown) in order for the obtained signals to be processed.

FIG. 13 is a schematic perspective view of a device 1300 for determining atrial fibrillation risk in an exemplary embodiment. The device 1300 comprises a strap 1302 capable of being wrapped around a limb of a user. The device further comprises an ECG sensor 1304, the ECG sensor comprising a first lead 1306 and a second lead 1308, with each lead 1306, 1308 positioned on opposing surfaces of the strap 1302. The first lead 1306 is positioned on a back surface 1314 of the strap 1302 and a second lead 1308 positioned on a front surface 1316 of the strap 1302. When worn on the limb of the user, the first lead is in physical contact with the limb of the user and the second lead is exposed and capable of receiving a digit on an opposing limb of the user.

The device 1300 may be in the form of a watch comprising a finger-based ECG sensor, which may be worn on the wrist of the user, such that the first lead 1306 is in physical contact with the wrist of the user. When the user is prompted to obtain his/her ECG, the user's finger from an opposing arm (on which the watch is not worn), is placed in physical contact with the second lead 1308. This allows for the ECG of the user to be obtained. The device 1300 further comprises an arterial sensor 1310 and a capillary sensor 1312 positioned on the back surface 1314 of the strap. A processor 1320 is also housed within a main housing of the device 1300.

FIG. 14 shows a schematic flowchart for illustrating a method 1400 of determining atrial fibrillation risk in an exemplary embodiment. The method 1400 may be implemented on the exemplary devices e.g., 100, 200, 1200 or 1300 as illustrated in FIG. 1, 2, 12 and 13 respectively. In the exemplary embodiment, the processor is specially configured to detect high risk patterns within the hemodynamic signal and triggering the obtaining of the ECG signal when high risk patterns are detected.

When in use, the device continuously and autonomously acquires and monitors the hemodynamic (i.e., arterial and/or capillary) signals of the user. When a high risk pattern is detected within the hemodynamic signal(s), ECG signals are triggered to be obtained. Thereafter, the acquired ECG signals are monitored for abnormal ECG rhythms that may be indicative of atrial fibrillation.

In the exemplary embodiment, at step 1402, the hemodynamic sensor (e.g., 102, 202, 1310, 1312 in FIG. 1, FIG. 2 and FIG. 13) obtains the hemodynamic signals of the user. The processor (e.g., 106, 210 or 1320 in FIG. 1, 2 or 13) receives the hemodynamic signals collected from the user by hemodynamic sensor 102 (e.g., 102, 202, 1310, 1312 in FIG. 1, FIG. 2 and FIG. 13) and processes the hemodynamic signals to detect for high risk waveform patterns in the hemodynamic signals of the user, at step 1404.

In the exemplary embodiment, the processor (e.g., 106, 210 or 1320 in FIG. 1, 2 or 13) is specially configured to detect high risk patterns based on monitoring the area under the curve of the arterial and/or capillary pulses within the hemodynamic signal. The processor (e.g., 106, 210 or 1320 in FIG. 1, 2 or 13) extracts the area under the curve parameter from the hemodynamic signal and considers high risk patterns detected when the area under the curve of one or more arterial and/or capillary pulses of the hemodynamic signal is less than a pre-determined AUC threshold.

If the presence of high risk patterns within the hemodynamic signals is detected at step 1404, the processor (e.g., 106, 210 or 1320 in FIG. 1, 2 or 13) triggers an alert signal to activate the ECG sensor (e.g., 104, 208, 1306/1308 in FIG. 1, 2, 13) to obtain an ECG signal of the user, as shown in step 1406. If the high risk pattern is not detected at step 1404, i.e., a low risk pattern is detected instead, no further action is taken.

Upon the triggering to obtain ECG signals at step 1406, the ECG sensor (e.g., 104, 208, 1304 in FIG. 1, 2, 13) of the device (e.g., 100, 200, 1300 in FIG. 1, 2, 13) proceeds to

acquire the ECG signals of the user over a predetermined time interval at step 1408. The ECG signals of the user are then processed by the processor (e.g., 106, 210 or 1320 in FIG. 1, 2 or 13) and monitored for high risk ECG rhythms that indicate atrial fibrillation risk at step 1410.

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In the exemplary embodiment, the ECG sensor (e.g., 104, 208, 1304 in FIG. 1, 2, 13) responds to the alert signal triggered by processor (e.g., 106, 210 or 1320 in FIG. 1, 2 or 13) and obtains the ECG signal of the user at step 1408. The processor (e.g., 106, 210 or 1320 in FIG. 1, 2 or 13) receives the ECG signal collected from the user by ECG sensor (e.g., 104, 208, 1304 in FIG. 1, 2, 13) and processes the ECG signals together with the hemodynamic signals to determine atrial fibrillation risk of the user.

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In the exemplary embodiment, when the trigger is activated at step 1406, the device 100 (FIG. 1) sends an alert to prompt the user to establish a point of contact with the ECG sensor 104 (FIG. 1) so that ECG collection can take place. The alert to the user may be in the form of an output sound, a vibration or a light up display.

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As an illustration, for the example embodiment 1300 illustrated in FIG. 13, a user wearing the device 1300 on his left wrist would have his/her left upper wrist is in contact with the first lead 1306. When alerted on the need to allow ECG to be collected (i.e., by a ringing sound or vibration of the device), the user would place his right e.g., index finger on the second lead 1308 such that a complete cycle is formed via the ECG leads 1306 and 1308, from his left wrist through the heart to his right index finger.

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In the exemplary embodiment, at step 1410, the processor (e.g., 106, 210 or 1320 in FIG. 1, 2 or 13) is specially configured to determine high risk ECG rhythms as an indicator for atrial fibrillation risk based on monitoring the pulse transit times (PTTs) between pulses of the ECG signal and the hemodynamic signal, each said PTT is representative of the time interval between a cardiac contraction and the flow or pulse of blood through an artery, vein or capillary. Atrial fibrillation risk is determined when the variability of the PTT exceeds a pre-determined PTT threshold.

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In the event that the processor (e.g., 106, 210 or 1320 in FIG. 1, 2 or 13) determines a risk of atrial fibrillation at step 1410, the device (e.g., 100, 200 or 1300 in FIG. 1, 2 or 13) proceeds to store the ECG signals in a data storage unit (e.g., 108, 212 in FIG. 1 or 2), and/or transmits the ECG signals to a remote analysis unit using transceiver (e.g., 110, 214 in FIG. 1 or 2) for further analysis, as shown in step 1412 and/or 1414.

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In the exemplary embodiment, the parameter used for detecting high risk waveform patterns at step 1404 is the area under the curve of pulses within the hemodynamic signal of the cardiovascular system. At step 1404, the processor receives the hemodynamic signals collected from the user and processes the hemodynamic signals. For example, if the area under the curve of one or more pulses of the hemodynamic signal is less than a pre-determined AUC threshold level, the processor triggers an alert signal to indicate the presence of high risk patterns at step 1406 and activates the ECG sensor for obtaining an ECG signal at step 1408.

In the exemplary embodiment, the parameter used for determining atrial fibrillation risk at step 1410 is the PTTs between the pulses of the ECG signal and the hemodynamic signal, each said PTT is representative of the time interval between a cardiac contraction and the flow or pulse of blood through an artery, vein or capillary. At step 1410, the processor receives the ECG signals collected from the user by ECG sensor and processes the ECG signals together with the hemodynamic signals. For example, if the variability of the PTT exceeds a pre-determined PTT threshold, the processor determines presence of atrial fibrillation risk at step 1410 and proceeds to store the ECG signals in the data storage unit in step 1412. The processor then transmits the ECG signals using the transceiver for further analysis at step 1414.

According to the exemplary method 1400, an ECG signal is obtained only when a high risk hemodynamic signal pattern is observed by the processor and no ECG signal is collected if a low risk hemodynamic signal pattern is observed by the processor, as shown at step 1404. This significantly reduces the amount of data storage space required in the device. The storage space is only reserved for data that has been determined to contain a risk of AF, and this in turn reduces the battery drain of the device and increases the operating life of the battery.

More advantageously, the exemplary method 1400 performs a two-level screening process (i.e. steps 1404 and 1410) to filter normal hemodynamic and ECG signals during continuous monitoring. In the first level 1404 of the screening process, the processor is configured to go through a careful filtering such that it is triggered only if a high risk hemodynamic signal pattern is observed. The method then proceeds to the second level 1410 of the screening process if it is determined by the processor that the signals contain a risk of AF. In this way, this improves the accuracy and efficiency of the data collection and allows a detailed analysis of the stored data for the determination of AF.

In addition, the exemplary method 1400 of determining atrial fibrillation risk using device 100, 200 or 1300 (FIG. 1, FIG. 2 and FIG. 13) is capable of detecting and preventing the storage of artefact signals. Hemodynamic and ECG signals are commonly subjected to artefacts (i.e. falsification of the signals), which can be caused by an external electrical interference nearby or electrical interference arising from somewhere within the body, poor skin contact with the electrode or machine malfunction. During the recording of hemodynamic and ECG signals, a simple movement made by the patient can create a significant artefact (motion-induced artefact), therefore producing noisy measurements corrupted by outliers. In exemplary methods, in utilising both hemodynamic and ECG signals, the processor is specially configured to differentiate high risk patterns from artefacts signals, picking out only data that is useful for storage and further analysis.

As mentioned in the background section, it is often difficult to obtain ECG signals continuously due to the cumbersome nature of obtaining ECG with multiple electrodes and wiring strapped or attached to the body. The exemplary device 100, 200 or 1300 (FIG. 1, FIG. 2 and FIG. 13) shows a design that combines all components of the device into a single locality, for eg. wrist, arm, neck, leg of the body. The device 100, 200 or 1300 (FIG. 1, FIG. 2 and FIG. 13) does not require complex wiring or multiple electrodes attached to the chest of an individual. The device is easily transported and does not affect with one's daily activities.

The exemplary device 100, 200 or 1300 (FIG. 1, FIG. 2 and FIG. 13) is also resistant to water or sweat and is designed to endure prolonged periods of wearing. As such, contrary to conventional methods, this device does not overly restrict the patient's daily activities.

FIG. 15 shows a schematic flowchart for illustrating a method 1500 of determining atrial fibrillation risk in an example embodiment. At step 1502, a hemodynamic signal is obtained. At step 1504, an electrocardiographic signal (ECG signal) is obtained. At step 1506, atrial fibrillation risk is determined based on the ECG signal and hemodynamic signal.

In the exemplary method 1500, the hemodynamic signal may be obtained by a hemodynamic sensor. The exemplary method 1500 may further comprise detecting high risk patterns within the hemodynamic signal by a processor specially configured to do so. Subsequently, the processor may trigger the obtaining of the ECG signal by an ECG sensor when high risk patterns are detected. The ECG sensor may comprise two or more leads.

In an exemplary embodiment, the processor may further be specially configured to extract parameters from the hemodynamic signal. In the exemplary method, the parameter is the area under the curve of pulses within the hemodynamic signals, and the processor detects high risk patterns by monitoring the area under the curve of pulses within the hemodynamic signal, such that high risk patterns are determined to be detected when the area under the curve of one or more pulses in the hemodynamic signal is less than a first pre-determined threshold. It will be appreciated that high risk patterns may be determined based solely on the area under the curve of one or more pulses of the arterial signal. Alternatively, high risk patterns may be determined based solely on the area under the curve of one or more pulses of the capillary signal. In a further alternative, high risk patterns may be determined based on the area under the curve of one or more pulses of both the arterial signal and capillary signal.

Exemplary arterial waveforms obtained from a patient and a healthy volunteer are illustrated in FIG. 16A and FIG. 16B respectively. Typically, as shown in FIG. 16A, the arterial waveform for a healthy volunteer is regular and has well defined peaks and equal heights.

In comparison to the waveforms obtained from healthy volunteers, the arterial pulse waveform obtained from a patient with high blood pressure, diabetes mellitus, high cholesterol, stroke or irregular heart rate, as shown in FIG. 16B, is irregular and tends to be rounded and has uneven heights.

One exemplary method used to determine area under the curve comprises a first step of removing noise/artefacts and baseline wandering, and a second step of integrating the waveform over the measurement period (8 minutes or 500 pulses) and normalising the result based on average heart rate.

In an exemplary embodiment, the processor may further be specially configured to extract the pulse transit time (PTT) parameter. The pulse transit times (PTTs) is the period from a peak of an ECG pulse in the ECG signal to a peak of an immediately following pulse in the arterial and/or capillary signal. Each said PTT representative of the time interval between a cardiac contraction and the flow or pulse of blood through an artery, vein or capillary.

In an exemplary embodiment, the processor may be configured to determine atrial fibrillation risk when the variability of the PTT exceeds a pre-determined PTT threshold. It will

be appreciated that the AF risk may be determined based solely on the variability of the PTT between an ECG pulse and the immediately following arterial pulse. Alternatively, the AF risk may be determined based solely on the variability of the PTT between an ECG pulse and the immediately following capillary pulse. In a further alternative, the AF risk may be determined based on the variability of the PTT between an ECG pulse and the immediately following arterial pulse, as well as the variability of the PTT between the ECG pulse and the immediately following capillary pulse.

In an exemplary embodiment, the processor may further be specially configured to store and/or transmit the ECG signal for further analysis when the variability of the PTT exceeds a pre-determined PTT threshold.

In the example embodiments, the hemodynamic signal may be obtained using a capillary sensor, an arterial sensor, or both.

The capillary sensor may be an optical pulse oximeter and the arterial sensor may be a modulated magnetic signature of blood (MMSB) sensor. In an example embodiment, the ECG signal may be obtained using a finger-based ECG sensor.

It may be appreciated that the embodiments of the device described above may also be in a touch-based form as shown in FIG. 17A and FIG. 17B.

FIG. 17A shows an exemplary embodiment of a device 1700 comprising two physiological sensors (i.e., the ECG sensor 1702 and the PPG (photoplethysmographic) sensor 1704) for determining atrial fibrillation risk. When the user is prompted to obtain his/her ECG and/or hemodynamic signals, the user's finger 1706 is placed in physical contact with the device as shown in FIG. 17B. The device 1700 may be in the form of a watch comprising the finger-based ECG sensor as described in FIG. 13, wherein the device of FIG. 13 is modified to incorporate the PPG sensor as shown in 1704, as a touch based PPG sensor which is positioned to capture capillary signals from the user's finger 1706.

In the exemplary embodiment, the ECG sensor 1702 comprises a first lead positioned on the back surface of the strap (not shown), and a second lead (reference numeral 1702 shows the second lead only) positioned on the front surface of the strap, such that when worn on the limb of the user, the ECG sensor is capable of obtaining ECG signals of a user, when the first lead is in physical contact with the limb of the user (e.g., the wrist of the user); and the second lead 1702 receives a digit on an opposing limb of the user (e.g., in

this case the finger 1706 on the opposing hand on which the strap is worn). The PPG sensor 1704 is positioned in close proximity to the second lead of the ECG sensor 1702, such that the PPG sensor is capable of obtaining a capillary signal simultaneously with the ECG signals, when the digit is received at the second lead of the ECG sensor 1702.

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One or more example embodiments may be implemented as software, such as a computer program being executed within a computer system 1800, and instructing the computer system 1800 to conduct a method of an example embodiment.

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The computer system 1800 comprises a computer module 1802, input modules such as a keyboard 1804 and a pointing device 1806 and a plurality of output devices such as a display 1808, and printer 1810. A user can interact with the computer module 1802 using the above devices. The pointing device can be implemented with a mouse, track ball, pen device or any similar device. One or more other input devices (not shown) such as a joystick, game

15 pad, satellite dish, scanner, touch sensitive screen or the like can also be connected to the computer module 1802. The display 1808 may include a cathode ray tube (CRT), liquid crystal display (LCD), field emission display (FED), plasma display or any other device that produces an image that is viewable by the user.

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The computer module 1802 can be connected to a computer network 1812 via a suitable transceiver device 1814, to enable access to e.g. the Internet or other network systems such as Local Area Network (LAN) or Wide Area Network (WAN) or a personal network. The network 1812 can comprise a server, a router, a network personal computer, a peer device or other common network node, a wireless telephone or wireless personal digital

25 assistant. Networking environments may be found in offices, enterprise-wide computer networks and home computer systems etc. The transceiver device 1814 can be a modem/router module located within or external to the computer module 1802, and may be any type of modem/router such as a cable modem or a satellite modem.

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It will be appreciated that network connections shown are exemplary and other ways of establishing a communications link between computers can be used. The existence of any of various protocols, such as TCP/IP, Frame Button, Ethernet, FTP, HTTP and the like, is presumed, and the computer module 1802 can be operated in a client-server configuration to permit a user to retrieve web pages from a web-based server. Furthermore, any of various

35 web browsers can be used to display and manipulate data on web pages.

The computer module 1802 in the example comprises a processor 1818, a Random Access Memory (RAM) 1820 and a Read Only Memory (ROM) 1822. The ROM 1822 can be a system memory storing basic input/ output system (BIOS) information. The RAM 1820 can store one or more program modules such as operating systems, application programs and program data.

The computer module 1802 further comprises a number of Input/Output (I/O) interface modules, for example I/O interface module 1824 to the display 1808, and I/O interface module 1826 to the keyboard 1804. The components of the computer module 1802 typically communicate and interface/couple connectedly via an interconnected system bus 1828 and in a manner known to the person skilled in the relevant art. The bus 1828 can be any of several types of bus structures including a memory bus or memory controller, a peripheral bus, and a local bus using any of a variety of bus architectures.

It will be appreciated that other devices can also be connected to the system bus 1828. For example, a universal serial bus (USB) interface can be used for coupling a video or digital camera to the system bus 1828. For example, a device for determining atrial fibrillation risk may be coupled to the bus 1828 for transmitting and receiving data to the tester. Data such as detected transmittances may be received at the computer module 1802. An IEEE 1394 interface may be used to couple additional devices to the computer module 1802. Other manufacturer interfaces are also possible such as FireWire developed by Apple Computer and i.Link developed by Sony. Coupling of devices to the system bus 1828 can also be via a parallel port, a game port, a PCI board or any other interface used to couple an input device to a computer. It will also be appreciated that, while the components are not shown in the figure, sound/audio can be recorded and reproduced with a microphone and a speaker. A sound card may be used to couple a microphone and a speaker to the system bus 1828. It will be appreciated that several peripheral devices can be coupled to the system bus 1828 via alternative interfaces simultaneously.

An application program can be supplied to the user of the computer system 1800 being encoded/stored on a data storage medium such as a CD-ROM or flash memory carrier. The application program can be read using a corresponding data storage medium drive of a data storage device 1830. The data storage medium is not limited to being portable and can include instances of being embedded in the computer module 1802. The data storage device 1830 can comprise a hard disk interface module and/or a removable memory interface module (both not shown in detail) respectively coupling a hard disk drive and/or a removable memory drive to the system bus 1828. This can enable reading/writing

of data. Examples of removable memory drives include magnetic disk drives and optical disk drives. The drives and their associated computer-readable media, such as a floppy disk provide nonvolatile storage of computer readable instructions, data structures, program modules and other data for the computer module 1802. It will be appreciated that the computer module 1802 may include several of such drives. Furthermore, the computer module 1802 may include drives for interfacing with other types of computer readable media.

The application program is read and controlled in its execution by the processor 1818. Intermediate storage of program data may be accomplished using RAM 1820. The method(s) of the example embodiments can be implemented as computer readable instructions, computer executable components, or software modules. One or more software modules may alternatively be used. These can include an executable program, a data link library, a configuration file, a database, a graphical image, a binary data file, a text data file, an object file, a source code file, or the like. When one or more computer processors execute one or more of the software modules, the software modules interact to cause one or more computer systems to perform according to the teachings herein.

The operation of the computer module 1802 can be controlled by a variety of different program modules. Examples of program modules are routines, programs, objects, components, data structures, libraries, etc. that perform particular tasks or implement particular abstract data types. The example embodiments may also be practiced with other computer system configurations, including handheld devices, multiprocessor systems, microprocessor-based or programmable consumer electronics, network PCs, minicomputers, mainframe computers, personal digital assistants, mobile telephones and the like. Furthermore, the example embodiments may also be practiced in distributed computing environments where tasks are performed by remote processing devices that are linked through a wireless or wired communications network. In a distributed computing environment, program modules may be located in both local and remote memory storage devices.

Different example embodiments may also be implemented in the context of data structure, program modules, program and computer instructions executed in a communication device. For example, the device for determining atrial fibrillation risk may be in the form of a wireless communication device. An exemplary communication device is briefly disclosed herein. One or more example embodiments may be embodied in one or more communication devices e.g. 1900, such as is schematically illustrated in FIG. 19.

One or more example embodiments may be implemented as software, such as a computer program being executed within a communication device 1900, and instructing the communication device 1900 to conduct a method of an example embodiment.

5           The communication device 1900 comprises a processor module 1902, an input module such as a touchscreen interface or a keypad 1904 and an output module such as a display 1906 on a touchscreen.

10           The processor module 1902 is coupled to a first communication module 1908 for communication with a cellular network 1910. The first communication module 1908 can include, but is not limited to, a subscriber identity module (SIM) card loading bay. The cellular network 1910 can, for example, be a 3G or 4G network.

15           The processor module 1902 is further coupled to a second communication module 1912 for connection to a network 1914. For example, the second communication module 1912 can enable access to e.g. the Internet or other network systems such as Local Area Network (LAN) or Wide Area Network (WAN) or a personal network. The network 1914 can comprise a server, a router, a network personal computer, a peer device or other common network node, a wireless telephone or wireless personal digital assistant. Networking  
20 environments may be found in offices, enterprise-wide computer networks and home computer systems etc. The second communication module 1912 can include, but is not limited to, a wireless network card or an ethernet network cable port. The second communication module 1912 can also be a modem/router module and may be any type of modem/router such as a cable-type modem or a satellite-type modem.

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          It will be appreciated that network connections shown are exemplary and other ways of establishing a communications link between computers can be used. The existence of any of various protocols, such as TCP/IP, Frame Button, Ethernet, FTP, HTTP and the like, is presumed, and the communication device 1900 can be operated in a client-server  
30 configuration to permit a user to retrieve web pages from a web-based server. Furthermore, any of various web browsers can be used to display and manipulate data on web pages.

          The processor module 1902 in the example includes a processor 1916, a Random Access Memory (RAM) 1918 and a Read Only Memory (ROM) 1920. The ROM 1920 can  
35 be a system memory storing basic input/ output system (BIOS) information. The RAM 1918 can store one or more program modules such as operating systems, application programs and program data.

The processor module 1902 also includes a number of Input/Output (I/O) interfaces, for example I/O interface 1922 to the display 1906, and I/O interface 1924 to the keypad 1904.

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The components of the processor module 1902 typically communicate and interface/couple connectedly via an interconnected bus 1926 and in a manner known to the person skilled in the relevant art. The bus 1926 can be any of several types of bus structures including a memory bus or memory controller, a peripheral bus, and a local bus using any of a variety of bus architectures.

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The processor module 1902 may perform the functions of e.g. determining atrial fibrillation risk based on the ECG signal and hemodynamic signal etc.

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It will be appreciated that other devices can also be connected to the system bus 1926. For example, a universal serial bus (USB) interface can be used for coupling an accessory of the communication device, such as a card reader, to the system bus 1926.

20

The application program is typically supplied to the user of the communication device 1900 encoded on a data storage medium such as a flash memory module or memory card/stick and read utilising a corresponding memory reader-writer of a data storage device 1928. The data storage medium is not limited to being portable and can include instances of being embedded in the communication device 1900.

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The application program is read and controlled in its execution by the processor 1916. Intermediate storage of program data may be accomplished using RAM 1918. The method(s) of the example embodiments can be implemented as computer readable instructions, computer executable components, or software modules. One or more software modules may alternatively be used. These can include an executable program, a data link library, a configuration file, a database, a graphical image, a binary data file, a text data file, an object file, a source code file, or the like. When one or more processor modules execute one or more of the software modules, the software modules interact to cause one or more processor modules to perform according to the teachings herein.

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The operation of the communication device 1900 can be controlled by a variety of different program modules. Examples of program modules are routines, programs, objects,

components, data structures, libraries, etc. that perform particular tasks or implement particular abstract data types.

5       The example embodiments may also be practiced with other computer system configurations, including handheld devices, multiprocessor systems/servers, microprocessor-based or programmable consumer electronics, network PCs, minicomputers, mainframe computers, personal digital assistants, mobile telephones and the like. Furthermore, the example embodiments may also be practiced in distributed computing environments where tasks are performed by remote processing devices that are linked  
10       through a wireless or wired communications network. In a distributed computing environment, program modules may be located in both local and remote memory storage devices.

15       It will be appreciated by a person skilled in the art that other variations and/or modifications may be made to the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects to be illustrative and not restrictive.

**CLAIMS**

1. A method of determining atrial fibrillation risk, the method comprising  
 obtaining a hemodynamic signal with a hemodynamic sensor;  
 5 obtaining an electrocardiographic signal (ECG signal) with an electrocardiogram  
 (ECG) sensor; and  
 determining atrial fibrillation risk based on the ECG signal and hemodynamic signal  
 with a processor.
- 10 2. The method as claimed in claim 1, further comprising  
 detecting high risk patterns within the hemodynamic signal with the processor; and  
 triggering the obtaining of the ECG signal when high risk patterns are detected with  
 the processor.
- 15 3. The method as claimed in claim 2, wherein detecting high risk patterns comprises  
 monitoring the area under the curve of pulses within the hemodynamic signal by the  
 processor.
4. The method as claimed in claim 3, wherein high risk patterns are determined to be  
 20 detected by the processor when the area under the curve of one or more pulses within the  
 hemodynamic signal is less than a first pre-determined threshold.
5. The method as claimed in any one of claims 2 to 4, further comprising determining  
 pulse transit times (PTTs) between pulses of the ECG signal and the hemodynamic signal,  
 25 by the processor.
6. The method as claimed in claim 5, wherein atrial fibrillation risk is determined when  
 the variability of the PTT exceeds a pre-determined PTT threshold, by the processor.
- 30 7. The method as claimed in claim 5 or 6, further comprising storing or transmitting the  
 ECG signal for further analysis when the variability of the PTT exceeds a pre-determined  
 PTT threshold by a data storage unit or transceiver.
8. The method as claimed in any one of the preceding claims, wherein the  
 35 hemodynamic signal is obtained using a capillary sensor, an arterial sensor, or both.

9. The method as claimed in claim 8, wherein the capillary sensor is an optical pulse oximeter and the arterial sensor is a modulated magnetic signature of blood (MMSB) sensor.

10. The method as claimed in any one of the preceding claims, wherein the ECG signal  
5 is obtained using a finger-based ECG sensor.

11. A device for determining atrial fibrillation risk, the device comprising  
a hemodynamic sensor for obtaining a hemodynamic signal;  
an electrocardiogram (ECG) sensor for obtaining an electrocardiographic signal  
10 (ECG signal); and  
a processor configured for determining atrial fibrillation risk based on the ECG signal  
and hemodynamic signal.

12. The device as claimed in claim 11, wherein the processor is further configured for  
15 detecting high risk patterns within the hemodynamic signal; and  
triggering the obtaining of the ECG signal when high risk patterns are detected.

13. The device as claimed in claim 12, wherein the processor is further configured for  
detecting high risk patterns based on monitoring the area under the curve of pulses within  
20 the hemodynamic signal.

14. The device as claimed in claim 13, wherein the processor is further configured to  
detect high risk patterns when the area under the curve of one or more pulses of the  
hemodynamic signal is less than a first pre-determined threshold.

25 15. The device as claimed in any one of claims 12 to 14, wherein the processor is further  
configured to determine pulse transit times (PTTs) between pulses of the ECG signal and  
the hemodynamic signal.

30 16. The device as claimed in claim 15, wherein atrial fibrillation risk is determined by the  
processor when the variability of the PTT exceeds a pre-determined PTT threshold.

17. The device as claimed in claim 15 or 16, further comprising a data storage unit for  
storing the ECG signal for further analysis when the variability of the PTT exceeds a pre-  
35 determined PTT threshold.

18. The device as claimed in claim 15 or 16, further comprising a transceiver for transmitting the ECG signal for further analysis when the variability of the PTT exceeds a pre-determined PTT threshold.

5 19. The device as claimed in any one of the preceding claims, wherein the hemodynamic sensor comprises one or both of a capillary sensor and an arterial sensor.

20. The device as claimed in claim 19, wherein the capillary sensor is an optical pulse oximeter and the arterial sensor is a modulated magnetic signature of blood (MMSB) sensor.

10

21. The device as claimed in any one of the preceding claims, wherein the ECG sensor comprises a finger-based ECG sensor.

22. The device as claimed in any one of the preceding claims, wherein the device is  
15 housed within a brace-housing capable of being worn on a limb of a user.

23. The device as claimed in claim 22, wherein the ECG sensor comprises a first lead positioned on the back surface of the strap; and a second lead positioned on the front surface of the strap, such that when worn on the limb of the user, the ECG sensor is capable  
20 of obtaining ECG signals of a user, when

the first lead is in physical contact with the limb of the user; and  
the second lead receives a digit on an opposing limb of the user.

24. The device as claimed in claim 23, wherein the hemodynamic sensor is capable of  
25 obtaining hemodynamic signal from a wrist area of a person, when the device is worn on the wrist area.

25. The device as claimed in claim 23, wherein the hemodynamic sensor comprises a PPG sensor, said PPG sensor positioned in close proximity to the second lead, such that the  
30 PPG sensor is capable of obtaining a capillary signal simultaneously with the ECG signals, when the digit is received at the second lead.

26. A non-transitory computer readable storage medium, having stored thereon computer code for instructing a processing unit to execute a method of determining atrial  
35 fibrillation risk, the method comprising,

obtaining a hemodynamic signal with a hemodynamic sensor;  
obtaining an electrocardiographic signal (ECG signal) with an ECG sensor; and,

determining atrial fibrillation risk based on the ECG signal and hemodynamic signal with a processor.

27. The non-transitory computer readable storage medium as claimed in claim 26, the method further comprising,

detecting high risk patterns within the hemodynamic signal with the processor; and triggering the obtaining of the ECG signal when high risk patterns are detected with the processor.

28. The non-transitory computer readable storage medium as claimed in claim 27, wherein detecting high risk patterns comprises

monitoring the area under the curve of pulses within the hemodynamic signal by the processor, and high risk patterns are determined to be detected by the processor when the area under the curve of one or more pulses is less than a first pre-determined threshold.

29. The non-transitory computer readable storage medium as claimed in any one of claims 26 to 28, the method further comprising determining pulse transit times (PTTs) between pulses of the ECG signal and the hemodynamic signal by the processor, and

determining atrial fibrillation risk when the variability of the PTT exceeds a pre-determined PTT threshold by the processor.