providing the system that enables lay persons or paramedics to record ECGs at home, ambulance or even in remote inaccessible areas and that allows doctors to remotely monitor, interpret and provide medication to the patient in real-time thus saving precious time and lives in ACS and other cardiac disorders, and also avoiding unnecessary hospital visits.

OBJECTS

It is an object of the present invention to provide a system for 12-lead ECG recording and wireless remote monitoring.

It is another object of the present invention to provide a method for 12-lead ECG recording and wireless remote monitoring.

It is another object of the present invention to provide a wearable ECG assembly (or unit) and system and method that is light weight, portable, cost effective, user friendly and reliable for recording of standard 12-lead ECG and wireless remote monitoring thereof of a patient.

It is still another object of the present invention to provide a wearable ECG assembly and system and method which integrates therewithin communication means to allow automatic or manual and remote communication capabilities between said wearable ECG assembly and healthcare personnel, hospital or any other monitoring facility in real-time.

It is yet another object of the present invention to provide a wearable ECG assembly and system and method which is universal, and requires no alteration of electrode positions irrespective of the type of ECG to be recorded, thereby eliminating dependency upon the skilled personnel and avoiding unnecessary hospital visits of the patient for each instance the 12-lead ECG is to be recorded.

SUMMARY ~~OF THE INVENTION~~

The present ~~invention~~ disclosure provides a system and method for12-lead ECG recording and wireless remote monitoring. The system and the method records the 12-lead ECG that

is equivalent to a standard 12-lead ECG which is recorded using a conventional 12-lead ECG system and from conventionally advocated placement positions of 10 electrode sensors thereof. Accordingly, the system of the present ~~invention~~ disclosure comprises of a wearable ECG acquisition unit, a plurality of communication device and a communication module. The afore-mentioned components are operably connected with each other to facilitate recording and wireless remote monitoring of cardiac activity of a user/ patient.

The wearable ECG acquisition unit facilitates acquisition of 12-lead ECG signals and thereafter generation of the 12-lead ECG therefrom subsequent to wearing of the wearable ECG acquisition unit by the user on torso region thereof. The wearable ECG acquisition unit comprises of a support substrate, a first component preconfigured on the support substrate and a second component electrically coupled to the first component. The support substrate forms body of the wearable ECG acquisition unit to facilitate mounting/ configuration of the first component thereacross. The first component is an electrode sensor assembly being preconfigured and fixedly positioned across the support substrate for adhering at positions specifically on the torso region of the user to collectively acquire 12-lead ECG signals therefrom when the wearable ECG acquisition unit is worn by the user. The electrode sensor assembly comprises of 10 electrode sensors including, six precordial electrode sensors (V1- V6) and four limb electrode sensors (RA, LA, RL, LL). The six precordial electrode sensors (V1- V6) adhere to their conventionally advocated placement positions on chest region of the user to acquire precordial ECG signals therefrom when the wearable ECG acquisition unit is worn. That is, to elaborate, the six precordial electrode sensors (V1- V6) are preconfigured across the support substrate for adhering to skin of the user at said positions in a manner such that when the wearable ECG acquisition unit is worn, amongst the six precordial electrode sensors (V1- V6), V1 and V2 gets disposed to lie on fourth intercostal space on opposite side of sternum and equidistant therefrom, V4 gets disposed to lie on fifth intercostal space at mid-clavicular line of the user, V3 gets disposed to lie midway between placement position

of V2 and V4, whereas V5 and V6 gets disposed to lie on the fifth intercostal space at anterior-axillary line and mid-axillary line respectively to acquire the precordial ECG

and telemetry. Thus, the wearable ECG acquisition unit provides for a cheaper and a user friendly alternative to the conventional 12-lead ECG system, without compromising on accuracy achieved therefrom i.e. the wearable ECG acquisition unit provided by the system of the present ~~invention~~ disclosure facilitates recording of the 12-lead ECG that is equivalent to the standard 12-lead ECG (i.e. ECG recorded from the conventionally advocated placement positions of the electrode sensors on the chest and limbs) and thus aids in diagnosis of cardiovascular disorders and heart attacks. In addition, the wearable ECG acquisition unit permits unconstrained free movement during monitoring and the wearer is unaware of the presence of the electrode assembly thereby facilitating a long term wear and versatility and with ease and comfort.

In an aspect, the present disclosure provides A system for 12-lead ECG recording and wireless remote monitoring, the system being capable of recording a 12-lead ECG that is equivalent to a standard 12-lead ECG recorded using a conventional 12-lead ECG system, the system comprising: a wearable ECG acquisition unit being adapted to acquire the 12-lead ECG when worn by a user around torso region thereof, the wearable ECG acquisition unit comprising of: a support substrate, a first component being an electrode sensor assembly preconfigured and fixedly positioned across the support substrate for being adhered at positions on the torso region of the user to collectively acquire 12-lead ECG signals therefrom when the wearable ECG acquisition unit is worn by the user, the electrode sensor assembly comprising, six precordial electrode sensors (V1- V6) provided for being adhered to chest region of the user for acquiring precordial ECG signals therefrom, the six precordial electrode sensors (V1- V6) preconfigured at fixed predetermined positions across the support substrate for adhering to the chest region of the user at positions such that V1 and V2 gets disposed to lie on fourth intercostal space on opposite side of sternum and equidistant therefrom, V4 gets disposed to lie on fifth intercostal space at mid-clavicular line of the user, V3 gets disposed to lie midway between placement position of V2 and V4 whereas V5 and V6 gets disposed to lie on the fifth intercostal space at anterior-axillary line and mid-axillary line respectively upon wearing of the wearable ECG acquisition unit by the user, wherein, positions of the V4, V5 and V6 generally

define a horizontal plane, and four limb electrode sensors (RA, LA, RL, LL) provided for being adhered to the chest and abdominal region of the user for acquiring ECG signals therefrom, the four limb electrode sensors (RA, LA, RL, LL) preconfigured at fixed predetermined positions across the support substrate for adhering to the chest and abdominal region of the user at positions such that RA and LA gets disposed to lie exactly in or adjacent to right and left delto-pectoral groove of the user below lateral end of clavicle respectively whereas RL and LL gets disposed to lie at a distance ranging from 1- 3 inches above and left-lateral to umbilicus of the user at 12 o'clock and 3 o'clock position respectively upon wearing of the wearable ECG acquisition unit by the user, and a second component being a signal processing unit electrically coupled to the first component for receiving the 12-lead ECG signals therefrom, the signal processing unit being capable of performing processing and digitization of the 12-lead ECG signals to generate the 12-lead ECG therefrom indicative of cardiovascular health of the user, wherein the signal processing unit being adapted with capability of wireless transmission of the 12-lead ECG of the user to facilitate wireless remote monitoring cardiac condition thereof; a plurality of communication device coupled over a communication network to the second component of the wearable ECG acquisition unit for receiving the 12-lead ECG generated and transmitted wirelessly therefrom, each of the plurality of communication device represents a computing device configured with a web application for enabling real-time interaction and remote exchange of information therebetween over the communication network thereby facilitating wireless remote monitoring of the cardiovascular health of the user by a healthcare provider, wherein, the user and the healthcare provider interacts using the web application executing on the communication device independently coupled thereto; and a communication module operatively coupled to the second component and to each of the plurality of communication device for establishing the communication network therebetween and therewithin to enable effective real-time monitoring and management of the cardiovascular health of the user by the healthcare provider, wherein, adherence of the four limb electrode sensors (RA, LA, RL, LL) at said positions on the chest and the abdominal region of the user imparts portability and wearability whilst facilitating

acquisition of the 12-lead ECG across ECG modalities without alteration in placement/adherence positions of the electrode sensor assembly thereby imparting universality with respect thereto and enabling uniform acquisition of the 12-lead ECG across ECG modalities allowing extrapolation of ECG changes thereacross, wherein, the ECG modalities includes recording of resting, ambulatory and stress ECG and continuous monitoring of ECG during ongoing surgical procedures in ICU and telemetry.

The present ~~invention~~disclosure, in another ~~aspect~~embodiment, provides the method for 12-lead ECG recording and wireless remote monitoring. The method involves the user wearing the wearable ECG acquisition unit provided by the system of the present ~~invention~~ disclosure subsequent to which the electrode sensor assembly gets placed at respective positions only on the torso region of the user to capture the 12-lead ECG signals therefrom. Thereafter, the method involves processing of the 12-lead ECG signals by the signal processing unit to generate the 12-lead ECG further to which it is wirelessly transmitted therefrom to the communication device of the user, and thereafter which the web application executing on the communication device automatically allocates and sends the data to the communication device of the healthcare provider located remote for interpretation and receiving medication therefrom in real-time over the communication network. The user and the healthcare provider interacts in real-time using the web application executing on the communication device independently coupled thereto thereby facilitating wireless remote monitoring of the cardiovascular health of the user by the healthcare provider.

Hence, the system is a cost effective, portable and versatile alternative to the conventional bulky 12-lead ECG systems deployed in hospitals without compromising on the accuracy when compared therewith. The system and the method facilitates remote monitoring of the patient by the doctor and ensures that the patient receives immediate medical assistance when demanded without any delay when the

patient is sitting at comfort of their home. The present ~~invention~~ disclosure thus enables rapid diagnosis of the cardiovascular condition in remote areas in underdeveloped countries and also reduces symptom to door time in developed countries thus saving many lives.

BRIEF DESCRIPTION OF DRAWINGS

The objectives and advantages of the present invention will be more clearly understood from the following description of the invention taken in conjunction with the accompanying non-limiting drawings, wherein:

Figure 1 is a schematic front view of human showing conventional electrode sensor placement positions used for obtaining a standard 12-lead ECG (resting 10 electrode 12-lead ECG);

Figure 2 shows an overall representation (block diagram) of components of the system for 12-lead ECG recording and wireless remote monitoring, in accordance with the present invention;

Figure 3 and 4 is a schematic front view of human torso showing the proposed torso only electrode sensor placement positions used for obtaining the 12-lead ECG, wherein six precordial electrode sensors are seen conventionally placed whereas four limb electrode sensors are placed at proposed torso positions according to the present invention;

Figure 5 and 6 illustrates some example implementations of the wearable ECG acquisition unit of the system embodying the invention, in accordance with the present invention;

Figure 7 shows a flow-chart of the method for 12-lead ECG recording and wireless remote monitoring, in accordance with the present invention;

Figures 8 -10 shows graphical representations of comparison between the conventional ECG (c-ECG) and the torso ECG (t-ECG) in different subsets of ACS,

in accordance with a sample case study run for validating the proposed torso only electrode positions of the present invention for accurate diagnosis of ACS; and

I CLAIM:

1. A system (100) for 12-lead ECG recording and wireless remote monitoring, the system (100) being capable of recording a 12-lead ECG that is equivalent to a standard 12-lead ECG recorded using a conventional 12-lead ECG system, the system (100) comprising:

a wearable ECG acquisition unit (40) being adapted to acquire the 12-lead ECG when worn by a user around torso region thereof, the wearable ECG acquisition unit (40) comprising of:

- a support substrate,
- a first component being an electrode sensor assembly (10) preconfigured and fixedly positioned across the support substrate for being adhered at positions on the torso region of the user to collectively acquire 12-lead ECG signals therefrom when the wearable ECG acquisition unit (40) is worn by the user, the electrode sensor assembly (10) comprising,
    a) six precordial electrode sensors (V1- V6) provided for being adhered to chest region of the user for acquiring precordial ECG signals therefrom, the six precordial electrode sensors (V1- V6) preconfigured at fixed predetermined positions across the support substrate for adhering to the chest region of the user at positions such that V1 and V2 gets disposed to lie on fourth intercostal space on opposite side of sternum and equidistant therefrom, V4 gets disposed to lie on fifth intercostal space at mid-clavicular line of the user, V3 gets disposed to lie midway between placement position of V2 and V4 whereas V5 and V6 gets disposed to lie on the fifth intercostal space at anterior-axillary line and mid-axillary line respectively upon wearing of the wearable ECG acquisition unit (40) by the user,

wherein, positions of the V4, V5 and V6 generally define a horizontal plane, and

b) four limb electrode sensors (RA, LA, RL, LL) provided for being adhered to the chest and abdominal region of the user for acquiring ECG signals therefrom, the four limb electrode sensors (RA, LA, RL, LL) preconfigured at fixed predetermined positions across the support substrate for adhering to the chest and abdominal region of the user at positions such that RA and LA gets disposed to lie exactly in or adjacent to right and left delto-pectoral groove of the user below lateral end of clavicle respectively whereas RL and LL gets disposed to lie at a distance ranging from 1- 3 inches above and left-lateral to umbilicus of the user at 12 o'clock and 3 o'clock position respectively upon wearing of the wearable ECG acquisition unit (40) by the user, and

- a second component being a signal processing unit (20) electrically coupled to the first component for receiving the 12-lead ECG signals therefrom, the signal processing unit (20) being capable of performing processing and digitization of the 12-lead ECG signals to generate the 12-lead ECG therefrom indicative of cardiovascular health of the user, wherein the signal processing unit (20) being adapted with capability of wireless transmission of the 12-lead ECG of the user to facilitate wireless remote monitoring cardiac condition thereof;

a plurality of communication device (80) coupled over a communication network (60) to the second component of the wearable ECG acquisition unit (40) for receiving the 12-lead ECG generated and transmitted wirelessly therefrom, each of the plurality of communication device (80) represents a computing device configured with a web application for enabling real-time interaction

and remote exchange of information therebetween over the communication network (60) thereby facilitating wireless remote monitoring of the cardiovascular health of the user by a healthcare provider, wherein, the user and the healthcare provider interacts using the web application executing on the communication device (80) independently coupled thereto; and

a communication module operatively coupled to the second component and to each of the plurality of communication device (80) for establishing the communication network (60) therebetween and therewithin to enable effective real-time monitoring and management of the cardiovascular health of the user by the healthcare provider,

wherein, adherence of the four limb electrode sensors (RA, LA, RL, LL) at said positions on the chest and the abdominal region of the user imparts portability and wearability whilst facilitating acquisition of the 12-lead ECG across ECG modalities without alteration in placement/adherence positions of the electrode sensor assembly (10) thereby imparting universality with respect thereto and enabling uniform acquisition of the 12-lead ECG across ECG modalities allowing extrapolation of ECG changes thereacross, wherein, the ECG modalities includes recording of resting, ambulatory and stress ECG and continuous monitoring of ECG during ongoing surgical procedures in ICU and telemetry.

2. The system (100) as claimed in claim 1, wherein the wearable ECG acquisition unit (40) is fabricated in at least one form selected from a group consisting of a vest, a jacket, a pad, a garment, a pador band, a shirt, a strip, a strap, a band, a belt, a plate, a patch, a mask, a harness and combinations thereof.

3. The system (100) as claimed in claim 1, wherein the wearable ECG acquisition unit (40) further comprises of a GPS module to provide location information of the user to the healthcare provider.

4. The system (100) as claimed in claim 1, wherein the communication module comprises of anyone of a wired and a wireless communication network module, and preferably includes a wireless communication network module for establishing a wireless communication network within the system (100).

~~5. A method (200) for 12-lead ECG recording and wireless remote monitoring, the method (200) being capable of recording a 12-lead ECG that is equivalent to a standard 12-lead ECG recorded using a conventional 12-lead ECG system, the method (200) comprising the steps of:~~

~~**providing a system for 12-lead ECG recording** and wireless remote monitoring, the system (100) comprising:~~

~~**a wearable ECG acquisition unit (40)** comprising of a support substrate, a first component being an electrode sensor assembly (10) including six precordial electrode sensors (V1–V6) and four limb electrode sensors (RA, LA, RL, LL) preconfigured and fixedly positioned across the support substrate for adhering at positions on torso region of user to collectively acquire 12-lead ECG signals therefrom, and a second component being a signal processing unit (20) electrically coupled to the first component for receiving the 12-lead ECG signals to generate the 12-lead ECG therefrom when the wearable ECG acquisition unit (40) is worn by the user, **a plurality of communication device (80)** coupled to the second component over a communication network (60) for receiving the 12-lead ECG transmitted wirelessly therefrom, wherein each of the plurality of communication device (80) represents a computing device configured with a web application to facilitate interaction and real-time exchange of data therebetween, and **a communication module** operatively coupled to the system (100) for establishing the communication network (60) within components/parts of the system (100) thereby~~

facilitating wireless remote monitoring and management of cardiovascular health of the user by a healthcare provider;

wearing of the wearable ECG acquisition unit (40) by the user around torso region thereof facilitating torsional placement of the electrode sensor assembly (10) such that amongst the six precordial electrode sensors (V1- V6), V1 and V2 gets disposed to lie on opposite side of sternum equidistant therefrom and on fourth intercostal space, V4 gets disposed to lie on fifth intercostal space at mid-clavicular line, V3 gets disposed to lie midway between V2 and V4, V5 and V6 gets disposed to lie on the fifth intercostal space at anterior axillary line and mid-axillary line respectively, whereas amongst the four limb electrode sensors (RA, LA, RL, LL), RA and LA gets disposed to lie within or adjacent to right and left delto-pectoral groove respectively below lateral end of clavicle, and RL and LL gets disposed to lie at a distance ranging from 1-3 inches above and left lateral to umbilicus of the user at 12 o'clock and 3 o'clock position respectively to acquire ECG signals therefrom;

sensing and acquisition of precordial ECG signals and ECG signals by the six precordial electrode sensors (V1-V6) and the four limb electrode sensors (RA, LA, RL, LL) respectively thereby collectively facilitating acquisition of 12-lead ECG signals from corresponding positions on chest and abdominal region of the user;

transmission of the 12-lead ECG signals by the electrode sensor assembly (10) to the signal processing unit (20) electrically coupled thereto;

processing of the 12-lead ECG signals to generate the 12-lead ECG therefrom by the signal processing unit (20), wherein the 12-lead ECG indicates cardiovascular health of the user;

transmission of generated 12-lead ECG to a user communication device by the signal processing unit (20) coupled thereto over a communication network (60), and preferably a wireless communication network (60);

routing of the 12-lead ECG to a healthcare provider communication device located remote to the user by the web application executing on the user communication device over the communication network (60), wherein the healthcare provider remotely views and analyzes user's data via a healthcare provider interface

~~of the web application executing on the healthcare provider communication device to provide expert comments to the user; and~~

~~**receiving remote medical assistance** and medication by the user via the web application executing on the user communication device from the healthcare provider communication device coupled thereto over the communication network (60) thereby facilitating effective real time monitoring and management of the cardiovascular health of the user by the healthcare provider,~~

~~**wherein,** acquisition of the 12 lead ECG across ECG modalities is facilitated without alteration in placement/adherence positions of the electrode sensor assembly (10) thereby imparting universality with respect thereto and enabling uniform acquisition of the 12 lead ECG across the ECG modalities allowing extrapolation of ECG changes thereacross, wherein, the ECG modalities includes recording of resting, ambulatory and stress ECG and continuous monitoring of ECG during ongoing surgical procedures in ICU and telemetry.~~

~~6. The method (200) as claimed in claim 5, comprising a step of acquisition of location signals of the user by a GPS module operatively coupled to the wearable ECG acquisition unit (40) to additionally provide location information of the user to the healthcare provider thereby facilitating reception of immediate medical assistance in an unforeseen event.~~