(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
2 March 2017 (02.03.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/033140 A1

(51) International Patent Classification:
A61B 5/0402 (2006.01) *A61B 5/04* (2006.01)
A61B 5/00 (2006.01) *A61B 5/044* (2006.01)

(21) International Application Number:
PCT/IB2016/055061

(22) International Filing Date:
25 August 2016 (25.08.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/209,394 25 August 2015 (25.08.2015) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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(54) Title: HIGH/LOW FREQUENCY SIGNAL QUALITY EVALUATIONS OF ECG LEAD SIGNALS

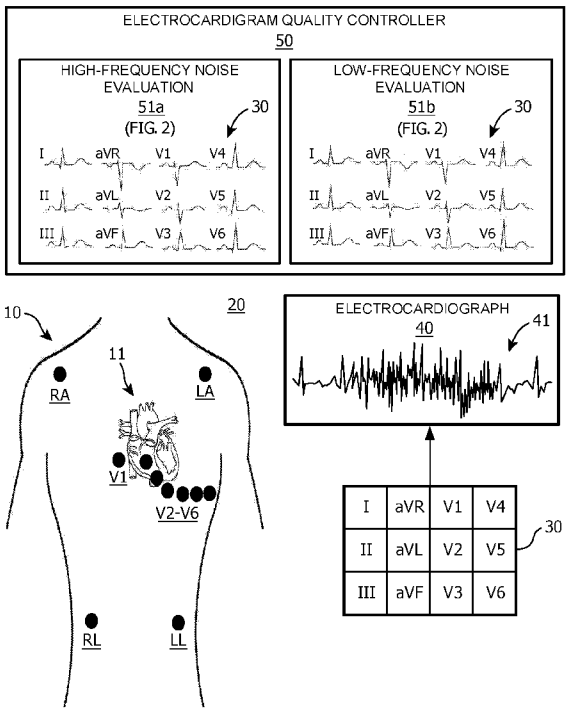

FIG. 1A

(57) Abstract: A monitoring device (e.g., a ECG monitor or a Holter monitor) employing an electrocardiograph (40), and an ECG quality controller (50). In operation, the electrocardiograph (40) derives an electrocardiogram from one or more ECG leads (30) upon a connection of the electrocardiograph (40) to the ECG lead(s) 30 (e.g., electrode based or pad/paddle based). In response to the connection of the electrocardiograph (40) to the ECG lead(s) (30), the ECG quality controller (50) controls separate evaluations of a high-frequency noise level (e.g., a degree of muscle artifact and/or a degree of electrode motion artefact within the electrocardiogram) and a low-frequency noise level (e.g., a degree of baseline wander by the electrocardiogram) of an individual ECG lead (30) on an electrocardiogram segmentation basis (e.g., a continual ECG recording divided into segments of a specified duration).

WO 2017/033140 A1

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

High/Low Frequency Signal Quality Evaluations of ECG Lead Signals

FIELD OF THE INVENTION

The present disclosure generally relates to signal quality of each electrocardiogram ("ECG") lead in an ECG recording during continuous ECG monitoring of a patient. The present disclosure more particularly relates an evaluation and visually display of high-frequency and low-frequency noise levels within electrocardiogram segments of each ECG lead in an ECG recording during continuous ECG monitoring of a patient.

BACKGROUND OF THE INVENTION

Electrocardiography is a non-invasive procedure for recording a multi-lead electrocardiogram ("ECG") (e.g., a standard 12-lead ECG or a non-standard EASI lead ECG) as a representation of an electrical cardiac activity of a patient conducted to vector cardiogram or other ECG lead system electrodes on the body surface of the patient. Electrocardiography is utilized in a wide variety of clinical settings ranging from physical examinations for regular checkups and emergencies to monitoring for the preparation, operative and recovery phases of surgical/diagnostic procedures. The purpose of the electrocardiography for these setting is a detection and evaluation of cardiac problems including, but not limited to, arrhythmias (commonly known as an irregular heartbeat), tachycardia (commonly known as a fast heartbeat), bradycardia (commonly known as a a slow heartbeat), and myocardial infarction (commonly known as a heart attack). Thus, a high-quality ECG in terms of accuracy is imperative to a reliable cardiac diagnosis and monitoring.

More particularly, various sources of noise induced on an ECG recording may mask diagnostic features of the ECG, which may result in an inaccurate interpretation of the ECG recordings and resulting diagnosis by a monitoring device and/or operator of the monitoring device. In an extreme case, a high level of noise on the ECG recording makes it impossible to interpret the ECG at all. Clearly, a low-quality ECG may cause a high number of false alarms generated by monitoring devices, particularly in critical care units (CCU) and intensive care units (ICU), which in turn may cause alarm in medical personnel.

One beneficial method known in the art for evaluating a signal quality of an ECG recording involves a determination of an average level of all types of noise in all leads as a single noise score for long term ECG signals and further involves a display of a compressed time-scale color-bar as the signal quality indicator. This method is very useful in rapid selection of high-quality ECG signal as representative segments to review for detailed analysis of rhythm and morphology. The present disclosure is directed to complementing the known method by determining and displaying a quality of real-time multi-lead short segments shown on a monitor screen and a reliability of each plot based on the level of noise categories including high-frequency noise and flow-frequency noise.

SUMMARY OF THE INVENTION

The present disclosure provides inventions providing an evaluation and visual display of high-frequency and low-frequency noise levels within electrocardiogram segments of each ECG lead in an ECG recording during a continuous ECG monitoring of a patient.

For purposes of the present invention, the term "high-frequency" broadly encompasses high-frequency noise of a ECG lead as known in the art including, but not limited to, muscle artifact and electrode motion artifact of ECG leads, and the term "low-frequency" broadly encompasses low-frequency noise of a ECG lead as known in the art including, but not limited to, baseline wander.

One form of the inventions of the present disclosure is a monitoring device (e.g., a ECG monitor or a Holter monitor) employing an electrocardiograph, and an ECG quality controller. In operation, the electrocardiograph derives an electrocardiogram from one or more ECG leads upon a connection of the electrocardiograph to the ECG lead(s) (e.g., electrode based or pad/paddle based). In response to the connection of the electrocardiograph to the ECG lead(s), the ECG quality controller controls separate evaluations of a high-frequency noise level (e.g., a degree of muscle artifact and/or a degree of electrode motion artefact within the electrocardiogram) and a low-frequency noise level (e.g., a degree of baseline wander by the electrocardiogram) of an individual ECG lead on an electrocardiogram segmentation basis (e.g., a continual ECG recording divided into segments of a specified duration).

For purposes of the inventions of the present disclosure, terms of the art including, but not limited to, "electrocardiograph", "electrocardiogram", "ECG lead", and "electrocardiogram segmentation" are to be interpreted as understood in the art of the present disclosure and as exemplary described herein.

For purposes of the inventions of the present disclosure, the term "controller" broadly encompasses all structural configurations of an application specific main board or an application specific integrated circuit housed within or linked to a monitoring device for controlling an application of various inventive principles of the present disclosure as subsequently described herein. The structural configuration of the controller may include, but is not limited to, processor(s), computer-usable/computer readable storage medium(s), an operating system, application module(s), peripheral device controller(s), slot(s) and port(s).

Examples of the monitoring device include, but are not limited to, diagnostic ECG monitoring devices (e.g., PageWriter TC cardiographs, Efficia series of cardiograph), exercise ECG monitoring devices (e.g., ST80i stress testing system), ambulatory ECG devices (Holter monitor), bed-side monitoring ECG devices (e.g., IntelliVue monitors, SureSigns monitors, and Goldway monitors), telemetry ECG monitoring devices (e.g., IntelliVue MX40 monitor); advanced life support products (e.g., HeartStart MRx and HeartStart XL defibrillators, and Efficia DFM100 defibrillator/monitor), and ECG management system (e.g., IntelliSpace ECG management system).

For purposes of the inventions of the present disclosure, the descriptive labeling "ECG quality" for a controller herein serves to identify the controller as described and claimed herein without specifying or implying any additional limitation to the term "controller".

For purposes of the inventions of the present disclosure, the term "application module" broadly encompasses a component of the controller consisting of an electronic circuit and/or an executable program (e.g., executable software and/firmware) for executing a specific application.

For purposes of the inventions of the present disclosure, any descriptive labeling of an application module herein (e.g., a "activity monitor" module, a "noise estimator" module, a "noise scorer" module, a "noise comparator" module and a "noise indicator"

module) serves to identify a particular application module as described and claimed herein without specifying or implying any additional limitation to the term "application module".

The foregoing forms and other forms of the present disclosure as well as various features and advantages of the present disclosure will become further apparent from the following detailed description of various embodiments of the present disclosure read in conjunction with the accompanying drawings. The detailed description and drawings are merely illustrative of the present disclosure rather than limiting, the scope of the present disclosure being defined by the appended claims and equivalents thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1A and 1B illustrate exemplary embodiments of a monitoring device in accordance with the inventive principles of the present disclosure.

FIG. 2 illustrates a flowchart representative of an exemplary embodiment of an a monitoring method in accordance with the inventive principles of the present disclosure.

FIG. 3 illustrates an exemplary ECG segment for ECG leads in accordance with the inventive principles of the present disclosure.

FIG. 4 illustrates an exemplary activity of an electrocardiogram in accordance with the inventive principles of the present disclosure.

FIG. 5 illustrates exemplary signal quality zones in accordance with the inventive principles of the present disclosure.

FIGS. 6-9 illustrates exemplary quality indications of the ECG leads in accordance with the inventive principles of the present disclosure.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

To facilitate an understanding of the present disclosure, the following description of FIGS. 1A and 1B, teaches basic inventive principles of evaluating and visually displaying a high-frequency noise level (e.g., muscle artifact and electrode motion artifact) and a low-frequency noise level (e.g., baseline wander) within electrocardiogram segments of each ECG lead in an ECG recording during a continuous ECG monitoring of a patient. From this description, those having ordinary skill in the art will appreciate how to apply the inventive principles of the present disclosure to a variety of monitoring devices displaying segments of a single lead or

multi-lead continuous physiological waveform, which is often disturbed by noise or artifact that limits the interpretation and analysis of the physiological waveform, whereby the inventions of the present disclosure provides an evaluation and display of a level of noise from different sources in each individual lead.

Referring to FIG. 1A, a monitoring device 20 employs an electrocardiograph 40 and an ECG quality controller 50. In practice, ECG quality controller 50 may be segregated or integrated with electrocardiograph 40.

In operation, a strategic placement of ten (10) electrodes on a body surface of a patient 10 relative to a heart 11 of patient 10 as known in the art for establishing ECG leads 30 listed as follows:

1. Lead I: electrode RA (-) to electrode LA (+);
2. Lead II: electrode RA (-) to electrode LL (+);
3. Lead III: electrode LA (-) to electrode LL (+);
4. Lead aVR: electrode RA (+) to electrodes LA & LL (-);
5. Lead aVL: electrode LA (+) to electrodes RA & LL (-);
6. Lead aVF: electrode LL (+) to electrodes RA & LA (-);
7. Lead V1: electrode V1;
8. Lead V2: electrode V2;
9. Lead V3: electrode V3;
10. Lead V4: electrode V4;
11. Lead V5: electrode V5; and
12. Lead V6: electrode V6.

ECG leads 30 are connected to electrocardiograph 40 via cables (not shown) attached to the electrodes as known in the art to conduct electrical activity of heart 11 of patient 10 to electrocardiograph 40.

Electrocardiograph 40 is structurally configured as known in the art to process ECG leads 30 for measuring and recording an electrocardiogram 41 of heart 11 of patient 10. For embodiments of the inventions of the present disclosure incorporating a segregation of electrocardiograph 40 and ECG quality controller 50, electrocardiograph 40 may employ a digital signal processor (not shown) or a central processing unit (not

shown) for streaming processed ECG leads 30 to ECG quality controller 50 or ECG quality controller 50 may employ known modules (not shown) for processing ECG leads 30. For embodiments of the inventions of the present disclosure incorporating an integration of electrocardiograph 40 and ECG quality controller 50, electrocardiograph 40 may employ a digital signal processor (not shown) or a central processing unit (not shown) for processing ECG leads 30 on behalf of ECG quality controller 50.

As shown in FIG. 1A, ECG quality controller 50 executes a high frequency noise evaluation 51a and a low frequency noise evaluation 51b of processed ECG leads 30 for respectively estimating a high-frequency noise level and a low-frequency noise level of each individual ECG lead 30 on an electrocardiogram segmentation basis.

For high frequency noise evaluation 51a, ECG quality controller 50 analyzes each segment of electrocardiogram 41 in sequence to estimate a high-frequency noise level of each individual ECG lead 30 including, but not limited to, any muscle artifact and any electrode motion artifact. In practice, ECG quality controller 50 may analyze any parameter(s) of each segment of electrocardiogram 41 suitable for estimating the high-frequency noise level of each individual ECG lead 30. In one embodiment, ECG quality controller 50 analyzes a standard deviation of a short segment of electrocardiogram 41 outside of the areas of high amplitude signal from the heart for estimating the high-frequency noise level of each individual ECG lead 30 as will be further described herein and illustrated in FIG. 2. Alternative embodiments for measuring high frequency noise in a narrow (in time) window include, but are not limited to, (1) a high pass filter followed by a root mean square (RMS) calculation in a sliding window, (2) a first difference or derivative estimator followed by a RMS calculation in a sliding window, and (3) high frequency filters from a filter bank with a smoothed envelope calculation at the output of each filter.

For low frequency noise evaluation 51b, ECG quality controller 50 analyzes each segment of electrocardiogram 41 in sequence to estimate a low-frequency noise level of each individual ECG lead 30 including, but not limited to, any baseline wander of each segment of electrocardiograph 41. In practice, ECG quality controller 50 may analyze any parameter(s) of each segment of electrocardiogram 41 suitable for estimating the low-frequency noise level of each individual ECG lead 30. In one embodiment, ECG quality controller 50 analyzes each change in baseline levels of each

segment of electrocardiogram 41 for estimating the low-frequency noise level of each individual ECG lead 30 as will be further described herein and illustrated in FIG. 2.

For both high/low-frequency noise evaluations 51a and 51b, ECG quality controller 50 controls a display of a signal quality indication for each segment of the electrocardiogram 41 resulting from the respective noise level analysis of each segment of electrocardiogram 41. In practice, ECG quality controller 50 may generate signal quality indication in any form suitable for communicating the resulting from the respective noise level analysis of each segment of electrocardiogram 41. In one embodiment, ECG quality controller 50 generates a textual signal quality indicator, a graphical signal quality indicator and/or a color-coded signal quality indicator for concurrent segment display with each ECG lead 30 as will be further described herein and illustrated in FIG. 2.

The result of high/low-frequency noise evaluations 51a and 51b is a capability of monitoring device 20 and/or an operator thereof to discard any low-quality segments of cardiogram 41 and to maintain good-quality leads among ECG leads 30 while resolving corrupted leads among ECG leads 30 as indicated by the evaluation of the high/low frequency signal quality of each individual ECG lead 30. This is beneficial to an accurate interpretation and diagnosis of electrocardiogram 41.

Referring to FIG. 1B, a defibrillator 21 employing electrocardiograph 40 and ECG quality controller 50 of monitoring device 20 as described in FIG. 1A, and further employs a shock source 60 structurally configured as known in the art to store electric energy for delivery of a defibrillation shock 61 via electrode pads 31 to heart 11 of patient 10. In practice, defibrillation shock 61 may have any waveform as known in the art. Examples of such waveforms include, but are not limited to, a monophasic sinusoidal waveform (positive sine wave) 61a and a biphasic truncated waveform 61b as shown in FIG. 1B.

In one embodiment, shock source 60 employs a high voltage capacitor bank (not shown) for storing a high voltage via a high voltage charger and a power supply upon a pressing of a charge button. Shock source 60 further employs a switching/isolation circuit (not shown) for selectively applying a specific waveform of an electric energy charge from the high voltage capacitor bank to electrode pads 31.

Electrode pads 31 are structurally configured as known in the art to be conductively applied to a patient 10 in an anterior-apex arrangement as shown in FIG. 1 or in an anterior-posterior arrangement (not shown). Electrode pads 31 conduct a defibrillation shock from shock source 60 to a heart 11 of patient 10, and are connected to electrocardiograph 40 via cables (not shown) attached to the electrodes as known in the art to conduct electrical activity of heart 11 of patient 10 to electrocardiograph 40 and for establishing ECG leads 32.

Electrocardiograph 40 is structurally configured as known in the art to process ECG leads 32 for measuring and recording an electrocardiogram 42 of heart 11 of patient 10. For embodiments of the inventions of the present disclosure incorporating a segregation of electrocardiograph 40 and ECG quality controller 50, electrocardiograph 40 may employ a digital signal processor (not shown) for streaming processed ECG leads 32 to ECG quality controller 50 or ECG quality controller 50 may employ known modules (not shown) for processing ECG leads 32. For embodiments of the inventions of the present disclosure incorporating an integration of electrocardiograph 40 and ECG quality controller 50, electrocardiograph 40 may employ a digital signal processor (not shown) or a central processing unit (not shown) for processing ECG leads 32 on behalf of ECG quality controller 50.

As shown in FIG. 1B, ECG quality controller 50 executes high frequency noise evaluation 51a and low frequency noise evaluation 51b as previously described herein of processed ECG leads 32 for respectively estimating a high-frequency noise level and a low-frequency noise level of each individual ECG lead 32 on an electrocardiogram segmentation basis. This is beneficial to an accurate interpretation and diagnosis of electrocardiogram 42.

To facilitate a further understanding high frequency noise evaluation 51a and low frequency noise evaluation 51b in accordance with the inventive principles of the present disclosure, a flowchart 70 representative of a monitoring method of the present disclosure as executed by application modules 51-55b of an exemplary embodiment of ECG quality controller 50 as illustrated in FIG. 2 will now be described herein in the context of ECG leads 30 and electrocardiogram 40 as illustrated in FIG. 1A. From this description, those having ordinary skill in the art will appreciate how to apply the inventive principles of the present disclosure in structurally configuring various

embodiments of ECG quality controller 50 in implementing various embodiments of high frequency noise evaluation 51a and low frequency noise evaluation 51b.

Referring to FIG. 2, a stage S72 of flowchart 70 encompasses an activity monitor 51 of ECG quality controller 50 computing an activity level of electrocardiogram 40. In practice, activity monitor 51 divides electrocardiogram 40 into segments of a specified duration and for each segment, computes an activity function for each sample across all ECG leads 30.

In one embodiment, activity monitor divides electrocardiogram 50 into ten (10) second ECG recording segments, which are further divided into one (1) second sections, and computes the activity function at each sample across all leads in an ECG segment is in accordance with the following equation [1]:

$$A_i = \sum_{leads} (ECG_i - ECG_{i-1})^2 \qquad [1]$$

where A_i is the activity function,

where ECG_i is the current ECG sample, and

wherein ECG_{i-1} is the previous ECG sample.

Activity monitor 51 low-pass filters the computed values activity function A_1 and detects local minima of activity function A_1 by a short-term sliding window for each section of the ECG segment.

For example, FIG. 3 illustrates a ten (10) second ECG segment 90 of ECG leads 30 subdivided into ten (10) one (1)-second sections, and FIG. 4 illustrates monitor 51 activity function 91 computed by activity monitor 41 within one of the sections of the ECG segment whereby activity monitor 41 detects a local minimum activity function A_1 as represented by the X for evaluating the high-frequency noise level and the low-frequency noise level for each ECG lead 30 in a small window around the local minimum.

Referring back to FIG. 2, a stage S74 of flowchart 70 encompasses a high-frequency noise ("HFN") estimator 52a of ECG quality controller 50 for estimating a high-frequency noise level for a current ECG segment of each individual ECG lead 30. In practice, HFN estimator 52a computes a standard deviation of a short segment for

each individual ECG lead 30 per segment section as an estimation of high-frequency noise level for each individual ECG lead 30. In one embodiment, HFN estimator 52a computes a standard deviation of each individual ECG lead 30 per segment section is in accordance with the following equation [2]:

$$\sigma_{lead} = \sqrt{E[(ECG_{lead} - E[ECG_{lead}])^2]} \quad [2]$$

where σ_{lead} is the standard deviation of a particular ECG lead 30,

where ECG_{lead} is the particular ECG lead 30, and

wherein E is an average or expected value of standard deviation σ_{lead} of the particular ECG lead 30.

Upon computation of standard deviation σ_{lead} for each ECG lead 30 over each segment section, a stage S76 of flowchart 70 encompasses a HFN scorer 53a computing a HFN score for individual ECG lead 30 for the current ECG segment. In practice, HFN scorer 53a computes the HFN score of each individual ECG lead 30 per segment section as a function of the estimated high-frequency noise levels per segment section during stage S74. In one embodiment, HFN scorer 53a computes a HFN score in accordance with the following equation [3]:

$$NS_{HF} = \alpha . median(\sigma_{lead}) \quad [3]$$

where NS_{HF} is the HFN score for a particularly ECG lead 30,

where $median(\sigma_{lead})$ is the median of the computed standard deviations across sections of a time segment of a particular ECG lead 30, and

where α is a weighting factor for all ECG leads 30.

Still referring to FIG. 2, stage S74 of flowchart 70 further encompasses a low-frequency noise ("LFN") estimator 52b of ECG quality controller 50 for estimating a low-frequency noise level for a current ECG segment of each individual ECG lead 30. In practice, LFN estimator 52b computes a baseline wander per segment section as an estimation of low-frequency noise level for each individual ECG lead 30. In one

embodiment, LFN estimator 52b computes baseline wander of each individual ECG lead 30 per segment section around the local minimum of activity function A_i is in accordance with the following equations [4a] and [4b]:

$$BW_{1,lead} = \begin{cases} \text{Baseline}[ECG_k] - \text{Baseline}[ECG_{k-1}], & k \neq 1 \\ 0, otherwise \end{cases} \quad [4a]$$

$$BW_{2,lead} = \begin{cases} \text{Baseline}[ECG_k] - \text{Baseline}[ECG_{k-2}], & k \neq 1,2 \\ 0, otherwise \end{cases} \quad [4b]$$

where $BW_{1,lead}$ is the baseline wander of a current segment for a particular ECG lead 30,

where $BW_{2,lead}$ is the baseline wander of the previous segment for a particular ECG lead 30,

where ECG_k is the current section of the current ECG segment (e.g., current 1-second section of the current 10-sec ECG segment), and

wherein ECG_{k-1} is previous section of the current ECG segment (e.g., previous 1-second section of the current 10-sec ECG segment).

Note equations [4a] and [4b] facilitate a location of a time point which does not include high amplitude physiological signal from the heart, but rather a quiet time for the heart, in absence of physiological signal.

Upon computation of the baseline wander for each ECG lead 30 over segments, stage S76 of flowchart 70 further encompasses a LFN scorer 53b computing a LFN score for each individual ECG lead 30 for the current ECG segment. In practice, LFN scorer 53b computes the LFN score of each individual ECG lead 30 per segment section as a function of the baseline wander computed during stage S74. In one embodiment, LFN scorer 53b computes a LFN score in accordance with the following equation [5]:

$$NS_{BW} = \beta.(|BW_{1,lead}| + |BW_{2,lead}|) \quad [5]$$

where NS_{BW} is the LFN score for a particularly ECG lead 30; and

where β is a weighting factor for all ECG leads 30.

Still referring to FIG. 2, a stage S78 of flowchart 70 encompasses a HFN comparator 54a of ECG quality controller 50 comparing the HFN score of each individual ECG lead 30 to one or more signal quality threshold differentiating two or more signal quality zones, and a LFN comparator 54b of ECG quality controller 50 comparing the LFE score of each individual ECG lead 30 to the signal quality threshold(s) differentiating the signal quality zones. In practice, the signal quality threshold(s) may be selected in a validation process by training an algorithm with an annotated database and optimizing the performance of noise quality classification for classifying the HFN score in multiple signal quality zones. In one embodiment, two (2) thresholds were utilized to classify the HFN score of each individual ECG lead 30 into one of three (3) categories including (1) good, (2) fair, and (3) poor quality.

For example, the signal quality zones are summarized in the following TABLE 1 and illustrated in FIG. 5:

TABLE 1

Signal quality zones	Criteria
Good	$0 \leq$ Noise Score $\leq$ Threshold1
Fair	Threshold1 $<$ Noise Score $\leq$ Threshold2
Poor	Threshold2 $<$ Noise Score $\leq$ UpperLimit

Referring back to FIG. 2, upon determining the HFN and LFN signal quality of each ECG lead for the current ECG segment, a stage S80 of flowchart 70 encompasses a HFN indicator 55a and a LFN indicator 55b generating a signal quality indication representative of the signal quality. In practice, the signal quality indication may take any form suitable for communicating the HFN and LFN signal quality for each ECG lead including a textual signal quality indication and/or a graphical signal quality

indication, both of which may be coded by various features including color and font. Additionally in practice, the signal quality indication may be displayed with the current ECG segment of ECG leads 30 or the representative beat of the current ECG segment.

In one embodiment, HFN indicator 55a and LFN indicator 55b normalize the respective HFN score and the LFN score to integers in on a scale of 0 to 10 where Threshold1 and Threshold2 are located at 2.5 and 4.5, respectively, and the UpperLimit is 10 as shown in in accordance with the following TABLE 2 :

TABLE 2

Signal quality zones	Criteria
Good	Noise Score = 0, 1, 2
Fair	Noise Score = 3,4
Poor	Noise Score = 5, 6, 7, 8, 9, 10

From the normalization, a color-coded textual indicator for each ECG lead may be concurrently displayed with the ECG leads 30 as exemplary shown in FIGS. 6, 7 and 9. Alternatively, the ECG lead waveforms may be color-coded as exemplary shown in FIG. 10.

Referring to FIG. 6, the following exemplary HFN scores and LFN scores are exemplary displayed adjacent an exemplary current ECG segment of ECG leads 30:

1. Good HFN/LFN Scores (green color-coded): Leads V3 and V4;
2. Fair HFN/LFN Scores (yellow color-coded): Leads aVL, V1, V2, V5 and V6; and
3. Poor HFN/LFN Scores (red color-coded): Leads I, II, III, aVR and aVF.

Referring to FIG. 7, the following exemplary HFN scores and LFN scores are exemplary displayed in boxes above an exemplary current ECG segment of ECG leads 30:

1. Good HFN/LFN Scores (green color-coded): Leads V3 and V4;
2. Fair HFN/LFN Scores (yellow color-coded): Leads aVL, V1, V2, V5 and V6; and
3. Poor HFN/LFN Scores (red color-coded): Leads I, II, III, aVR and aVF.

Referring to FIG. 8, the following exemplary HFN scores and LFN scores are exemplary displayed adjacent an exemplary color-coded current ECG segment of ECG leads 30:

1. Good HFN/LFN Scores (green wave): Leads V3 and V4;
2. Fair HFN/LFN Scores (yellow wave): Leads aVL, V1, V2, V5 and V6; and
3. Poor HFN/LFN Scores (red wave): Leads I, II, III, aVR and aVF.

Referring to FIG. 9, the following exemplary HFN scores and LFN scores are exemplary displayed in boxes above an exemplary representative beats of the current ECG segment of ECG leads 30:

1. Good HFN/LFN Scores (green color-coded): Leads V3 and V4;
2. Fair HFN/LFN Scores (yellow color-coded): Leads aVL, V1, V2, V5 and V6; and
3. Poor HFN/LFN Scores (red color-coded): Leads I, II, III, aVR and aVF.

Referring back to FIG. 2, note one of the purposes of stage S76 as described herein is to equalize the HFN score and the LFN score for comparisons to the same signal quality thresholds of stage S78. Nonetheless, in practice, the HFN score and the LFN score do not have to be equalized and may be compared to different signal quality thresholds.

Upon completion of stage S80, flowchart 70 returns to stage S72 to repeat stages S72-S80 for the next ECG segment and continues to loop until terminated.

Referring to FIGS. 1-9, those having ordinary skill in the art will appreciate numerous benefits of the present disclosure including, but not limited to, the novel and unique evaluating and visually displaying high-frequency and low-frequency noise levels within electrocardiogram segments of each ECG lead in an ECG recording during a continuous ECG monitoring of a patient. More generally, the inventions of the present disclosure applies to a variety of monitoring devices for displaying segments of a single lead or multi-lead continuous physiological waveform, which are often disturbed by noise or artifact that limits the interpretation and analysis of the physiological waveform, whereby the inventions of the present disclosure provides an evaluation and display of a level of noise from different sources in each individual lead. The benefits being a capability of the monitoring device and/or an operator thereof to discard any low-quality segments of the physiological waveform and to maintain good-quality leads while resolving corrupted leads as indicated by the evaluation of the high/low frequency signal quality of each individual lead.

Furthermore, as one having ordinary skill in the art will appreciate in view of the teachings provided herein, features, elements, components, etc. described in the present disclosure/specification and/or depicted in the FIGS. 1-9 may be implemented in various combinations of electronic components/circuitry, hardware, executable software and executable firmware and provide functions which may be combined in a single element or multiple elements. For example, the functions of the various features, elements, components, etc. shown/illustrated/depicted in the FIGS. 1-9 can be provided through the use of dedicated hardware as well as hardware capable of executing software in association with appropriate software. When provided by a processor, the functions can be provided by a single dedicated processor, by a single shared processor, or by a plurality of individual processors, some of which can be shared and/or multiplexed. Moreover, explicit use of the term "processor" should not be construed to refer exclusively to hardware capable of executing software, and can implicitly include, without limitation, digital signal processor ("DSP") hardware or other central processing unit ("CPU"),, memory (e.g., read only memory ("ROM") for storing software, random access memory ("RAM"), non-volatile storage, etc.) and virtually any

means and/or machine (including hardware, software, firmware, circuitry, combinations thereof, etc.) which is capable of (and/or configurable) to perform and/or control a process.

Moreover, all statements herein reciting principles, aspects, and embodiments of the invention, as well as specific examples thereof, are intended to encompass both structural and functional equivalents thereof. Additionally, it is intended that such equivalents include both currently known equivalents as well as equivalents developed in the future (e.g., any elements developed that can perform the same or substantially similar function, regardless of structure). Thus, for example, it will be appreciated by one having ordinary skill in the art in view of the teachings provided herein that any block diagrams presented herein can represent conceptual views of illustrative system components and/or circuitry embodying the principles of the invention. Similarly, one having ordinary skill in the art should appreciate in view of the teachings provided herein that any flow charts, flow diagrams and the like can represent various processes which can be substantially represented in computer readable storage media and so executed by a computer, processor or other device with processing capabilities, whether or not such computer or processor is explicitly shown.

Furthermore, exemplary embodiments of the present disclosure can take the form of a computer program product or application module accessible from a computer-usable and/or computer-readable storage medium providing program code and/or instructions for use by or in connection with, e.g., a computer or any instruction execution system. In accordance with the present disclosure, a computer-usable or computer readable storage medium can be any apparatus that can, e.g., include, store, communicate, propagate or transport the program for use by or in connection with the instruction execution system, apparatus or device. Such exemplary medium can be, e.g., an electronic, magnetic, optical, electromagnetic, infrared or semiconductor system (or apparatus or device) or a propagation medium. Examples of a computer-readable medium include, e.g., a semiconductor or solid state memory, magnetic tape, a removable computer diskette, a random access memory (RAM), a read-only memory (ROM), flash (drive), a rigid magnetic disk and an optical disk. Current examples of optical disks include compact disk – read only memory (CD-ROM), compact disk – read/write (CD-R/W) and DVD. Further, it should be understood that any new

computer-readable medium which may hereafter be developed should also be considered as computer-readable medium as may be used or referred to in accordance with exemplary embodiments of the present disclosure and disclosure.

Having described preferred and exemplary embodiments of novel and inventive high/low-frequency noise evaluations of an electrical connection to an electrocardiograph, it is noted that modifications and variations can be made by persons having ordinary skill in the art in light of the teachings provided herein, including the FIGS. 1-9. It is therefore to be understood that changes can be made in/to the preferred and exemplary embodiments of the present disclosure which are within the scope of the embodiments disclosed herein.

Moreover, it is contemplated that corresponding and/or related systems incorporating and/or implementing the device or such as may be used/implemented in a device in accordance with the present disclosure are also contemplated and considered to be within the scope of the present disclosure. Further, corresponding and/or related method for manufacturing and/or using a device and/or system in accordance with the present disclosure are also contemplated and considered to be within the scope of the present disclosure.

CLAIMS:

1. A monitoring device, comprising:

an electrocardiograph (40) operable to derive an electrocardiogram from at least one of ECG lead (30) responsive to a connection of the electrocardiograph (40) to the at least one ECG lead (30); and

an ECG quality controller (50) operable, in response to the connection of the electrocardiograph (40) to the at least one ECG lead (30), to control separate evaluations of a high-frequency noise level and a low-frequency noise level of an individual ECG lead (30) on an electrocardiogram segmentation basis.

2. The monitoring device of claim 1, wherein the high-frequency noise level evaluation of the individual ECG lead (30) by the ECG quality controller (50) further includes:

the ECG quality controller (50) being operable to ascertain the standard deviation of the individual ECG lead (30) relative to a specified activity level of each electrocardiogram segment.

3. The monitoring device of claim 2, wherein a high-frequency noise level evaluation of the individual ECG lead (30) by the ECG quality controller (50) includes:

the ECG quality controller (50) being operable, during each electrocardiogram segment, to derive a high-frequency noise score for the individual ECG lead (30) from a standard deviation of the individual ECG lead (30).

4. The monitoring device of claim 2, wherein a high-frequency noise level evaluation of the individual ECG lead (30) by the ECG quality controller (50) further includes:

the ECG quality controller (50) being operable, during each electrocardiogram segment, to scale the standard deviation of the individual ECG lead (30) by a weighting factor to thereby derive the high-frequency noise score for the individual ECG lead (30).

5. The monitoring device of claim 2, wherein the high-frequency noise level evaluation of the individual ECG lead (30) by the ECG quality controller (50) further includes:

the ECG quality controller (50) being operable, during each electrocardiogram segment, to compare the high-frequency noise score to at least one signal quality threshold differentiating a plurality of distinct signal quality zones.

6. The monitoring device of claim 1, wherein a low-frequency noise level evaluation of the individual ECG lead (30) by the ECG quality controller (50) includes:

the ECG quality controller (50) being operable, during each electrocardiogram segment, to derive a low-frequency noise score for the individual ECG lead (30) from any change in a baseline level of the individual ECG lead (30).

7. The monitoring device of claim 6, wherein the low-frequency noise level evaluation of the individual ECG lead (30) by the ECG quality controller (50) further includes:

the ECG quality controller (50) being operable, during each electrocardiogram segment, to scale any change in the baseline level of the individual ECG lead (30) by a weighting factor to thereby derive the low-frequency noise score of the individual ECG lead (30).

8. The monitoring device of claim 6, wherein the low-frequency noise level evaluation of the individual ECG lead (30) by the ECG quality controller (50) further includes:

the ECG quality controller (50) being operable to ascertain any change in the baseline level of the individual ECG lead (30) measured at a specified activity level of each electrocardiogram segment.

9. The monitoring device of claim 6, wherein the low-frequency noise level evaluation of the individual ECG lead (30) by the ECG quality controller (50) further includes:

the ECG quality controller (50) being operable to compare the low-frequency noise score to at least one signal quality threshold differentiating a plurality of distinct signal quality zones.

10. The monitoring device of claim 1, wherein the ECG quality controller (50) is further operable to control a display of the separate evaluations of the high-frequency noise level and the low-frequency noise level of the individual ECG lead (30) on an electrocardiogram segmentation basis.

11. The monitoring device of claim 10, wherein a display of the high-frequency noise level evaluation and the low-frequency noise level evaluation of the individual ECG lead (30) by the ECG quality controller (50) includes:

the ECG quality controller (50) being operable to display one of the individual ECG lead (30) or a representative beat of the ECG lead (30) concurrently with a signal quality indication of the separate evaluations of the high-frequency noise level and the low-frequency noise level of the individual ECG lead (30),

wherein each signal quality indication is at least one of a textual signal quality indication and a graphical signal quality indication.

12. The monitoring device of claim 1, wherein the ECG quality controller (50) includes:

a high-frequency noise estimator operable to compute a median of standard deviations of the individual ECG lead (30) measured at specified activity levels during an electrocardiogram segment; and

a high-frequency noise scorer operable to derive a high-frequency noise score from a computation by the high-frequency noise estimator of the median of standard deviations for the individual ECG lead (30); and

a high-frequency noise comparator operable to compare a computation by the high-frequency noise scorer of the high-frequency noise score to at least one signal quality threshold differentiating a plurality of distinct signal quality zones.

13. The monitoring device of claim 12, wherein the ECG quality controller (50) further includes:

a high-frequency noise indicator operable to derive a signal quality indication of the evaluation of the high-frequency noise level of the individual ECG lead (30) from a comparison by the high-frequency noise comparator of the high-frequency noise score to at least one signal quality threshold,

wherein each signal quality indication is at least one of a textual signal quality indication and a graphical signal quality indication.

14. The monitoring device of claim 1, wherein the ECG quality controller (50) includes:

a low-frequency noise estimator operable to compute any change in a baseline level of the individual ECG lead (30) at specified activity level within an electrocardiogram segment; and

a low-frequency noise scorer operable to derive a low-frequency noise score from a computation by the low-frequency noise estimator of any change in the baseline level of the individual ECG lead (30); and

a low-frequency noise comparator operable to compare a computation by the low-frequency noise scorer of the low-frequency noise score to at least one signal quality threshold differentiating a plurality of distinct signal quality zones.

15. The monitoring device of claim 14, wherein the ECG quality controller (50) further includes:

a low-frequency noise indicator operable to derive a signal quality indication of the evaluation of the low-frequency noise level of the individual ECG lead (30) from a comparison by the low-frequency noise comparator of the low-frequency noise score to at least one signal quality threshold,

wherein each signal quality indication is at least one of a textual signal quality indication and a graphical signal quality indication.

16. A monitoring method, comprising

an electrocardiograph (40) deriving an electrocardiogram from at least one ECG lead (30) responsive to a connection of the electrocardiograph (40) to the at least one ECG lead (30); and

an ECG quality controller (50) controlling separate evaluations of a high-frequency noise level and a low-frequency noise level of an individual ECG lead (30) on an electrocardiogram segmentation basis.

17. The monitoring method of claim 16, wherein the high-frequency noise level evaluation of the individual ECG lead (30) by the ECG quality controller (50) includes:

during each electrocardiogram segment, the ECG quality controller (50) deriving a high-frequency noise score for the individual ECG lead (30) from a standard deviation of the individual ECG lead (30); and

the ECG quality controller (50) comparing each high-frequency noise score to at least one signal quality threshold differentiating a plurality of distinct signal quality zones.

18. The monitoring method of claim 16, wherein the low-frequency noise level evaluation of the individual ECG lead (30) by the ECG quality controller (50) includes:

during each electrocardiogram segment, the ECG quality controller (50) deriving a low-frequency noise score for the individual ECG lead (30) from any change in a baseline level of the individual ECG lead (30); and

the ECG quality controller (50) comparing each low-frequency noise score to at least one signal quality threshold differentiating a plurality of distinct signal quality zones.

19. The monitoring method of claim 16, further comprising:

the ECG quality controller (50) controlling a display of the separate evaluations of the high-frequency noise level and the low-frequency noise level of the individual ECG lead (30) on the electrocardiogram segmentation basis.

20. The monitoring method of claim 19, wherein the display of the high-frequency noise level evaluation and the low-frequency noise level evaluation of the individual ECG lead (30) by the ECG quality controller (50) includes:

the ECG quality controller (50) displaying the individual one of the individual ECG lead (30) or a representative beat of the ECG lead (30) concurrently with a signal quality indication of the separate evaluations of the high-frequency noise level and the low-frequency noise level of the individual ECG lead (30),

wherein each signal quality indication is at least one of a textual signal quality indication and a graphical signal quality indication.

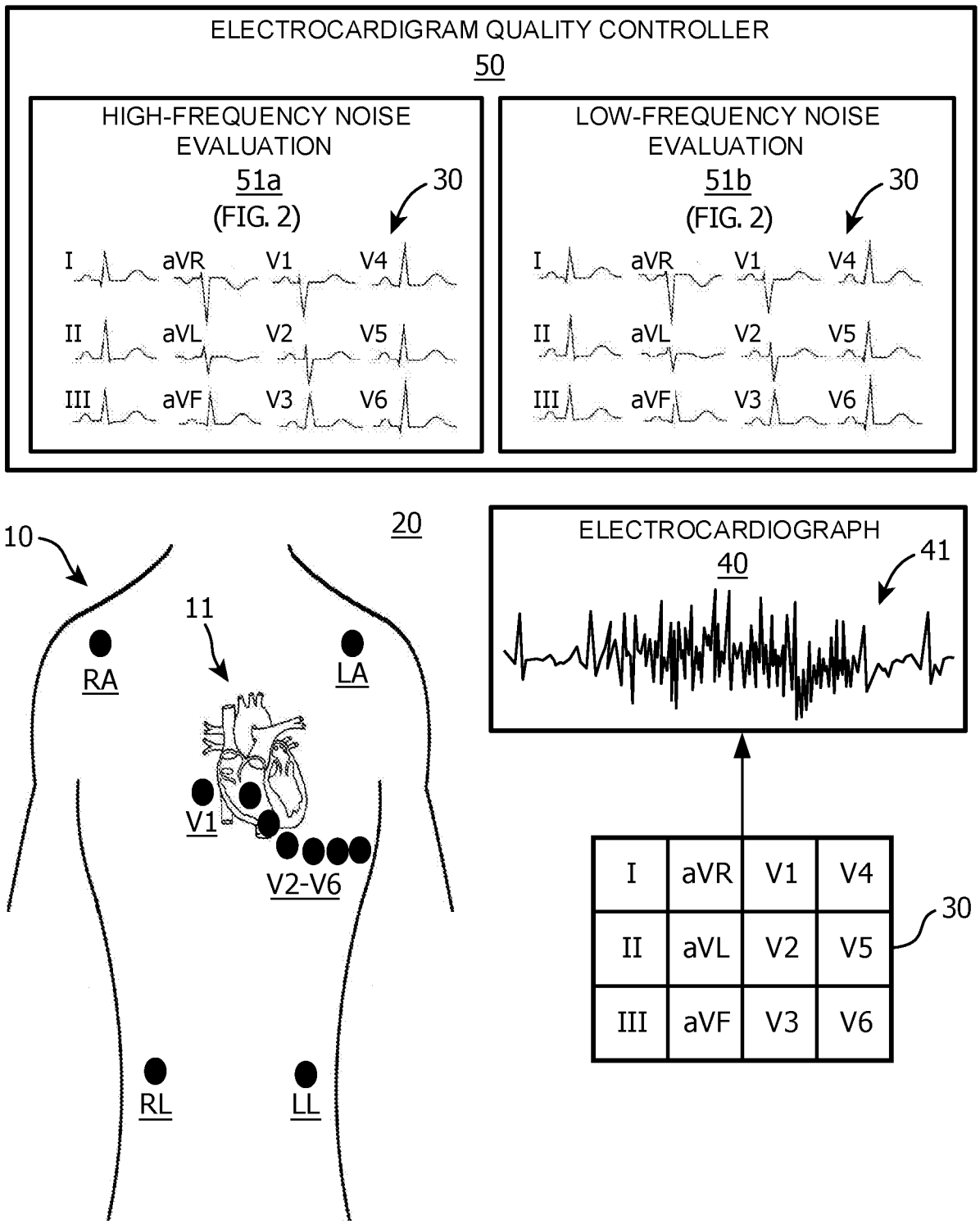
ELECTROCARDIGRAM QUALITY CONTROLLER
50
HIGH-FREQUENCY NOISE EVALUATION
51a
(FIG. 2)
30
I aVR V1 V4
II aVL V2 V5
III aVF V3 V6
LOW-FREQUENCY NOISE EVALUATION
51b
(FIG. 2)
30
I aVR V1 V4
II aVL V2 V5
III aVF V3 V6
10
20
11
RA
LA
V1
V2-V6
RL
LL
ELECTROCARDIOGRAPH
40
41
I aVR V1 V4
II aVL V2 V5
III aVF V3 V6
30

FIG. 1A

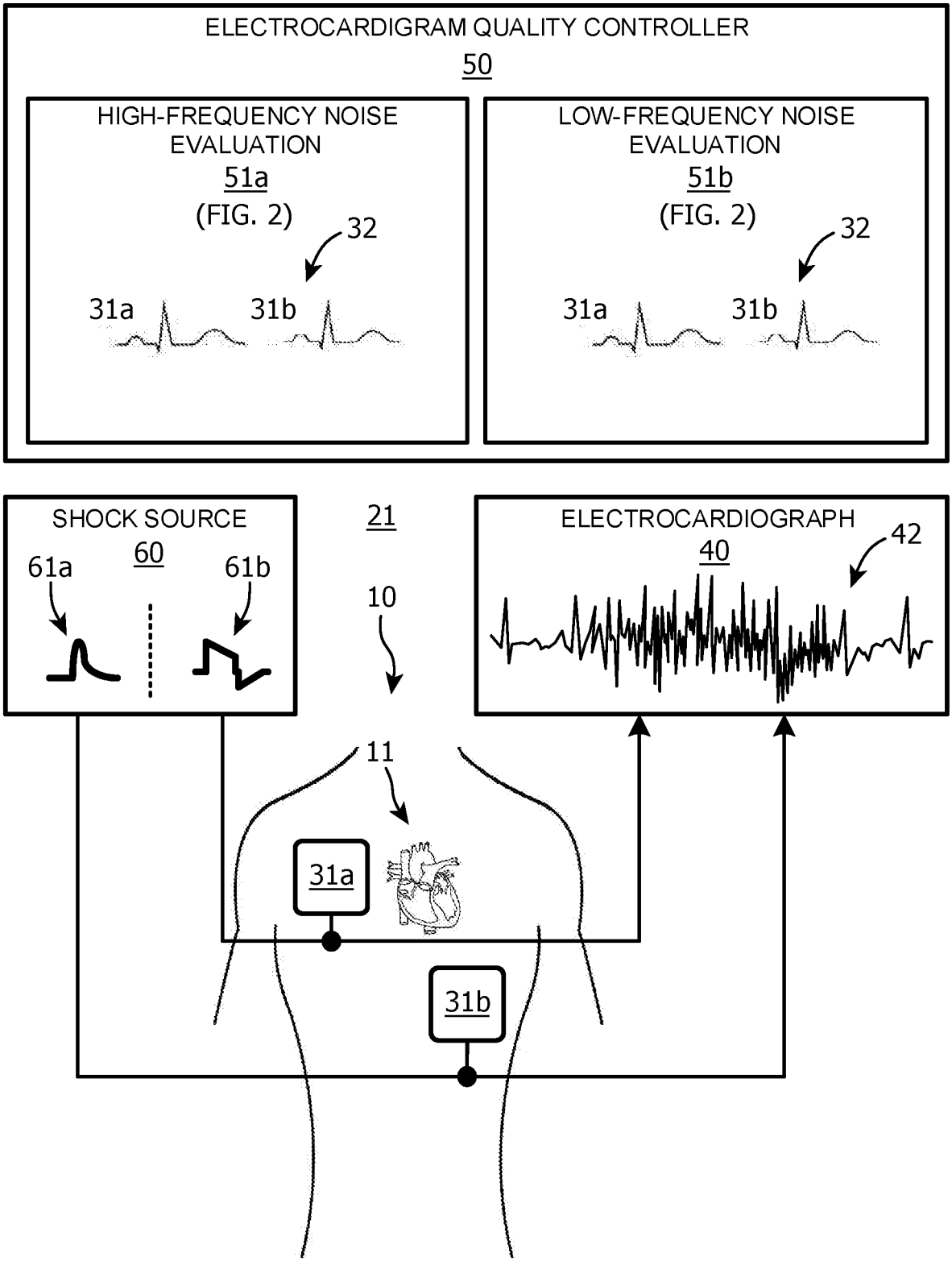
ELECTROCARDIGRAM QUALITY CONTROLLER
50
HIGH-FREQUENCY NOISE EVALUATION
51a
(FIG. 2)
32
31a
31b
LOW-FREQUENCY NOISE EVALUATION
51b
(FIG. 2)
32
31a
31b
SHOCK SOURCE
60
61a
61b
21
10
ELECTROCARDIOGRAPH
40
42
11
31a
31b

FIG. 1B

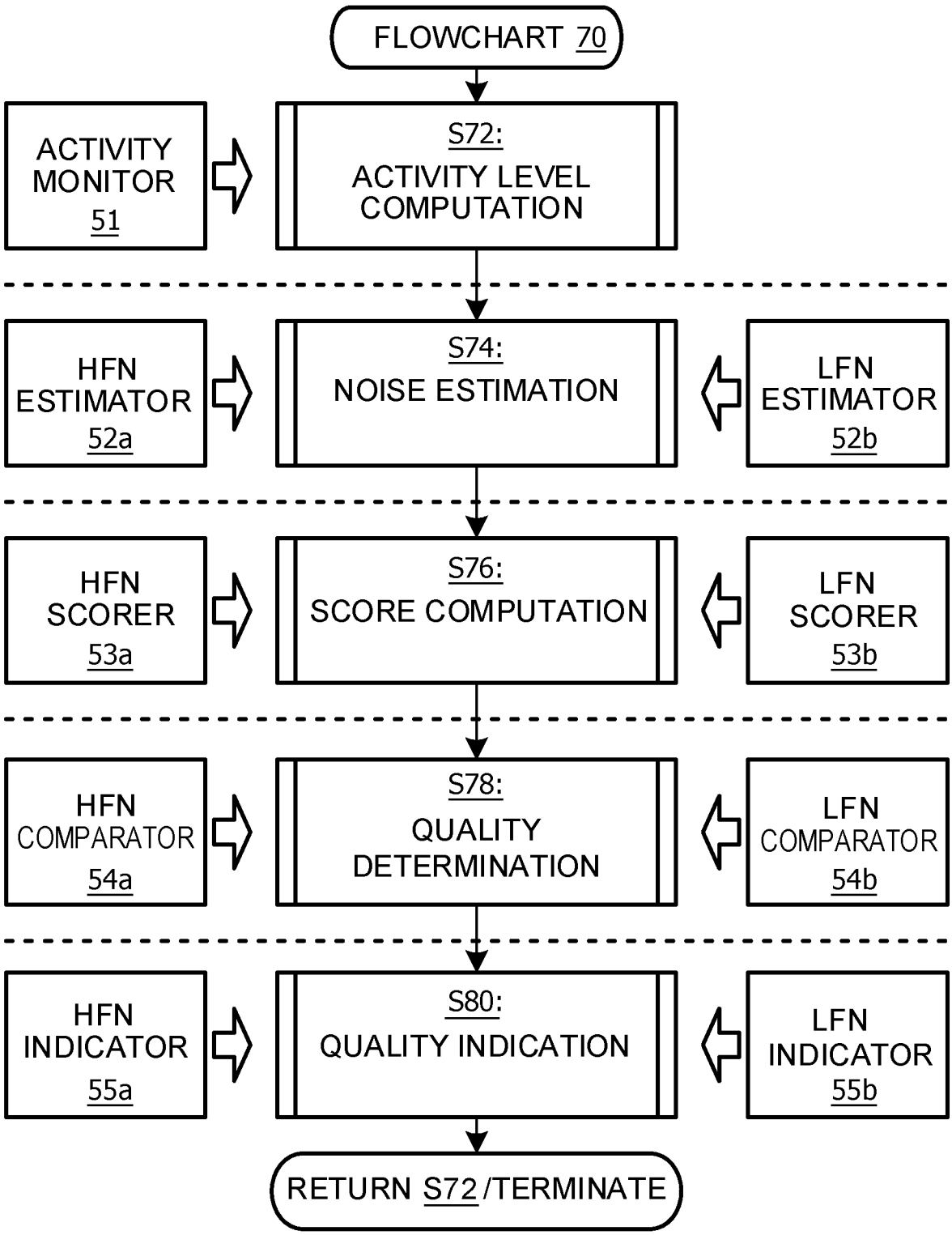
FLOWCHART 70
ACTIVITY MONITOR 51
S72: ACTIVITY LEVEL COMPUTATION
HFN ESTIMATOR 52a
S74: NOISE ESTIMATION
LFN ESTIMATOR 52b
HFN SCORER 53a
S76: SCORE COMPUTATION
LFN SCORER 53b
HFN COMPARATOR 54a
S78: QUALITY DETERMINATION
LFN COMPARATOR 54b
HFN INDICATOR 55a
S80: QUALITY INDICATION
LFN INDICATOR 55b
RETURN S72/TERMINATE

FIG. 2

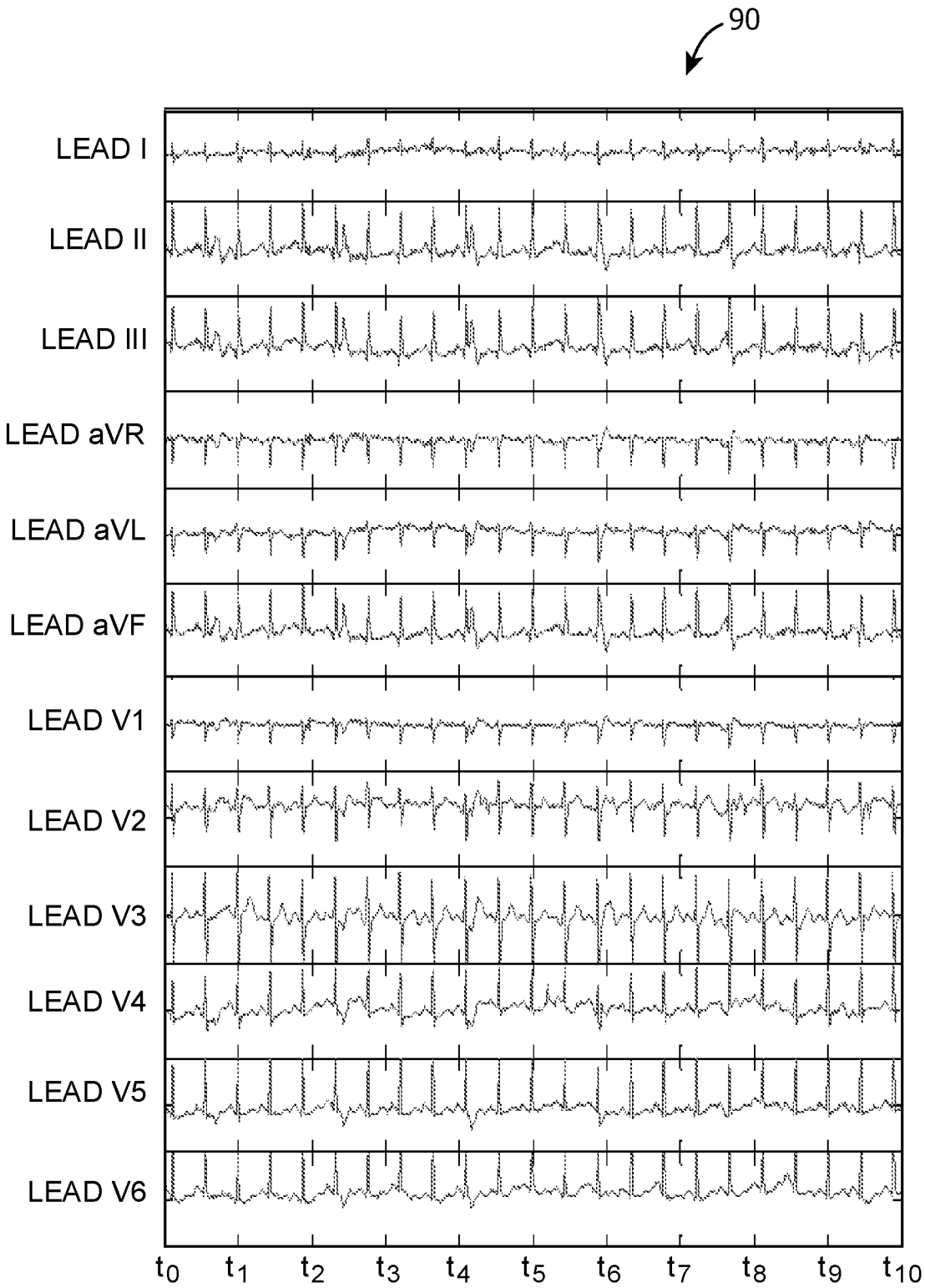
90
LEAD I
LEAD II
LEAD III
LEAD aVR
LEAD aVL
LEAD aVF
LEAD V1
LEAD V2
LEAD V3
LEAD V4
LEAD V5
LEAD V6
t0 t1 t2 t3 t4 t5 t6 t7 t8 t9 t10

FIG. 3

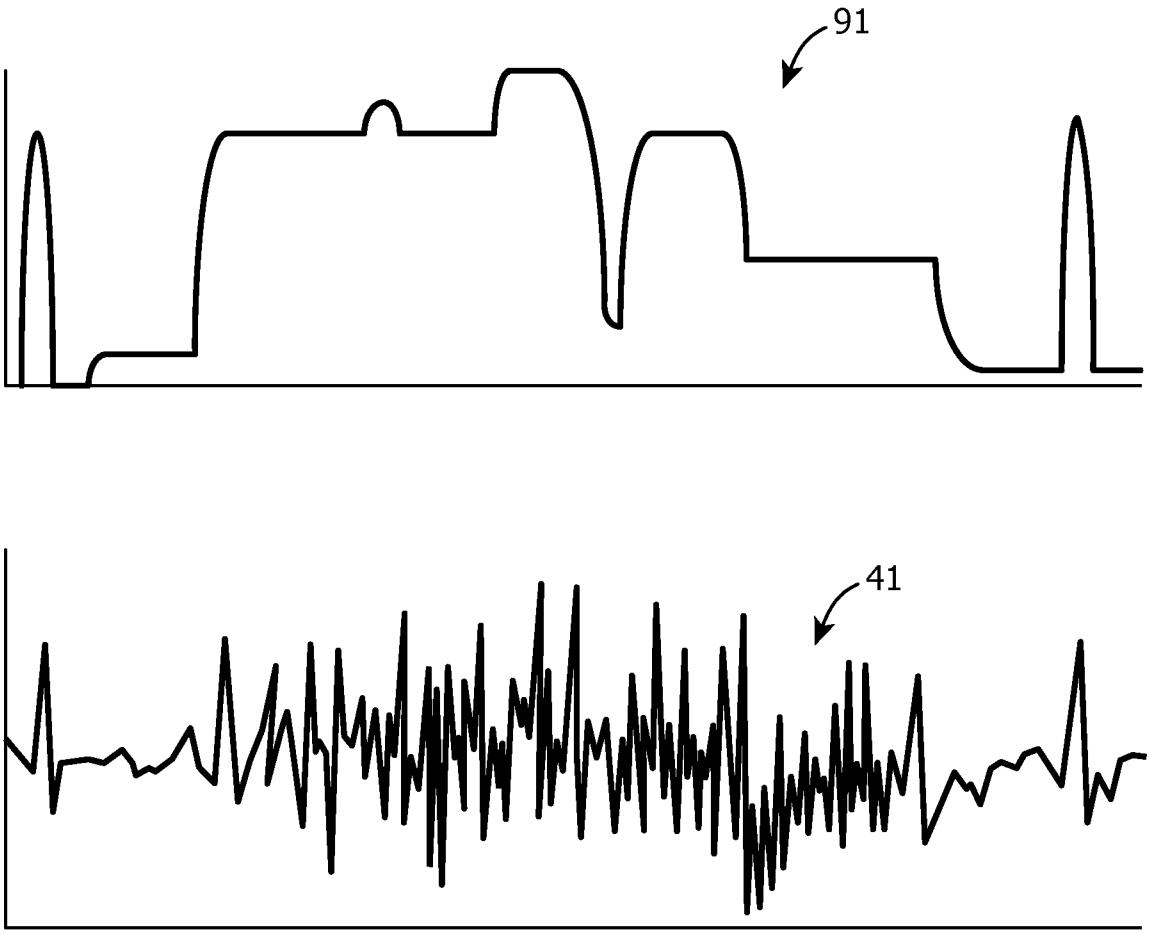

FIG. 4

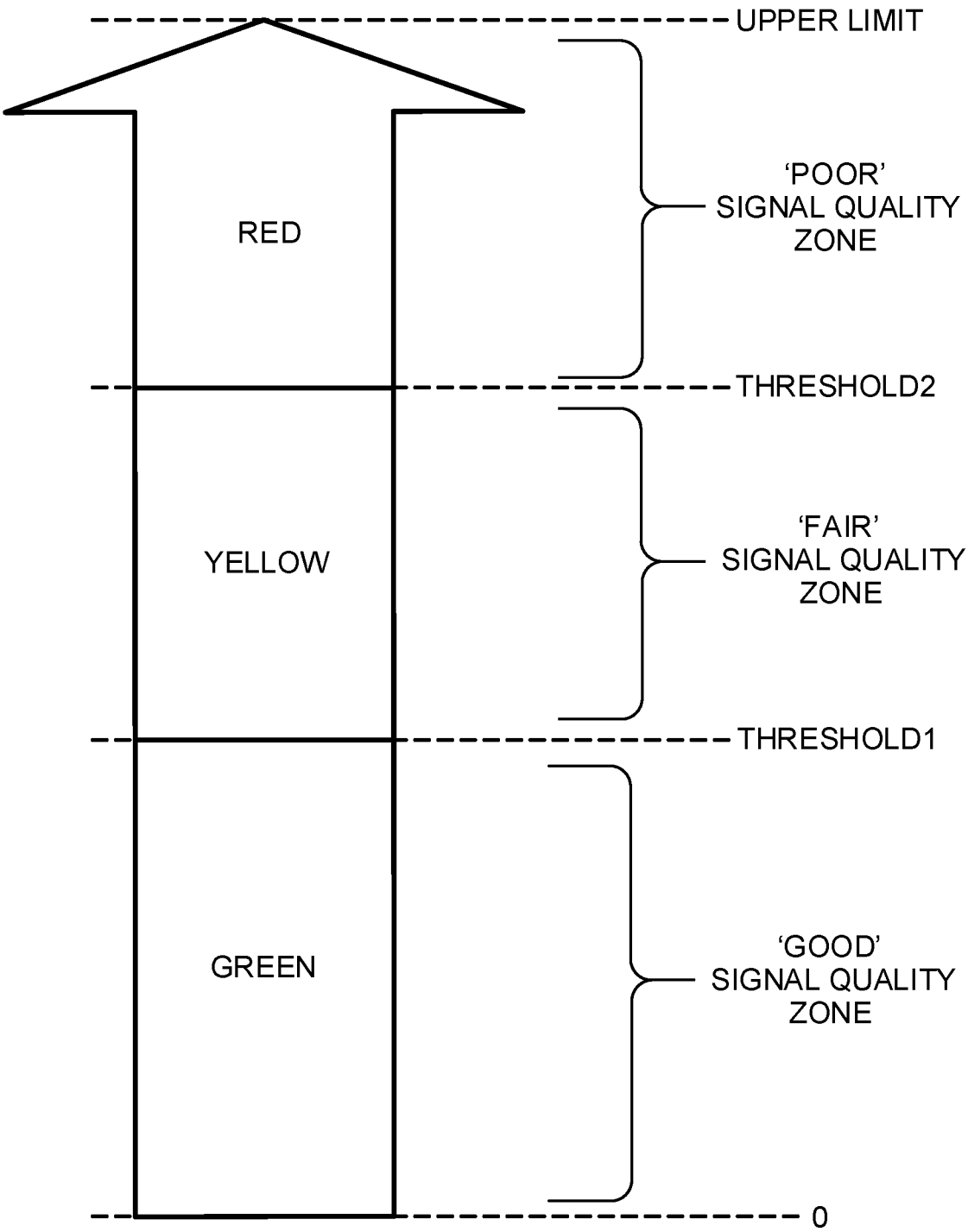
UPPER LIMIT
RED
'POOR' SIGNAL QUALITY ZONE
THRESHOLD2
YELLOW
'FAIR' SIGNAL QUALITY ZONE
THRESHOLD1
GREEN
'GOOD' SIGNAL QUALITY ZONE
0

FIG. 5

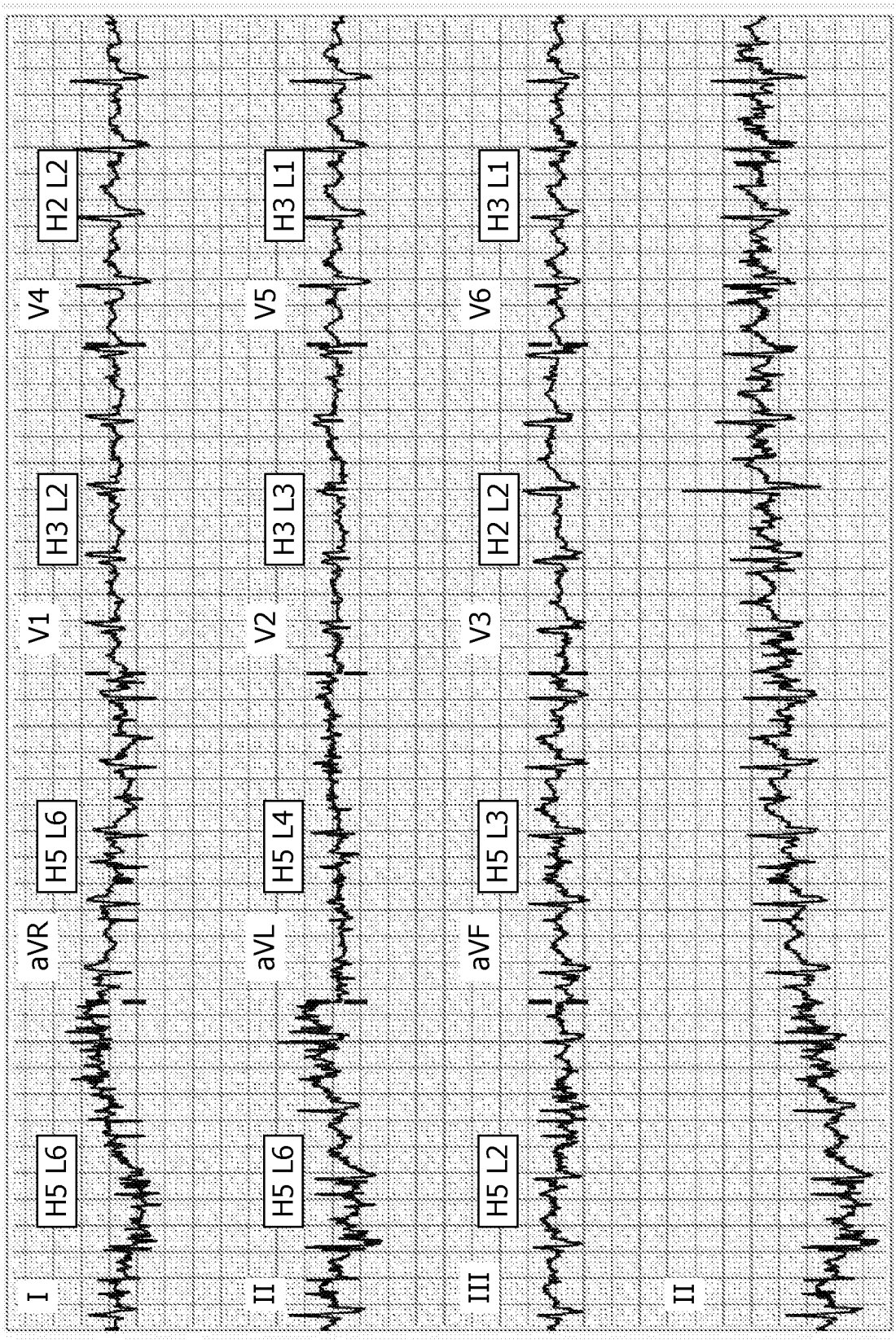
I
H5 L6
aVR
H5 L6
V1
H3 L2
V4
H2 L2
II
H5 L6
aVL
H5 L4
V2
H3 L3
V5
H3 L1
III
H5 L2
aVF
H5 L3
V3
H2 L2
V6
H3 L1
II

FIG. 6

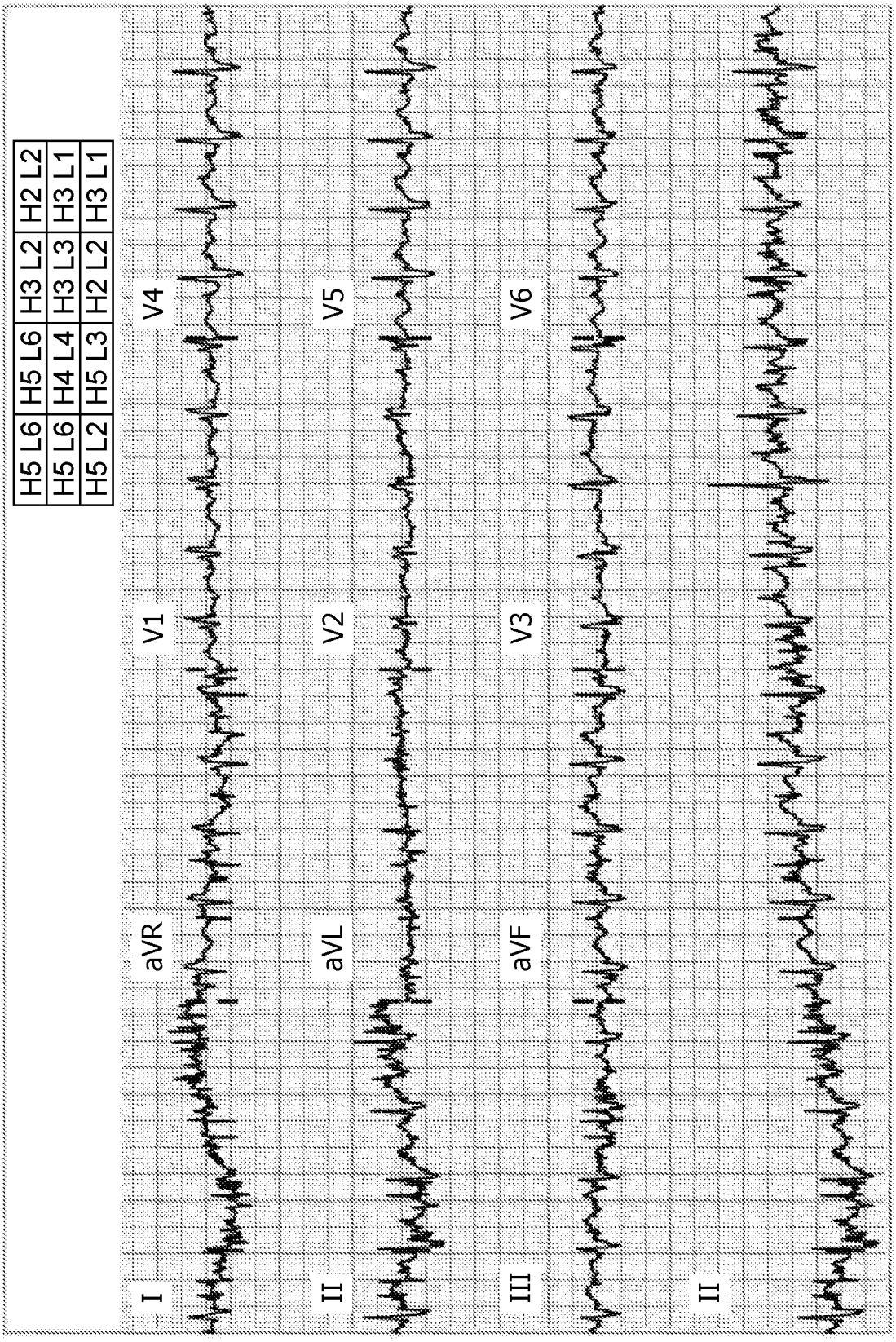
H5 L6 H5 L6 H3 L2 H2 L2
H5 L6 H4 L4 H3 L3 H3 L1
H5 L2 H5 L3 H2 L2 H3 L1
I
aVR
V1
V4
II
aVL
V2
V5
III
aVF
V3
V6
II

FIG. 7

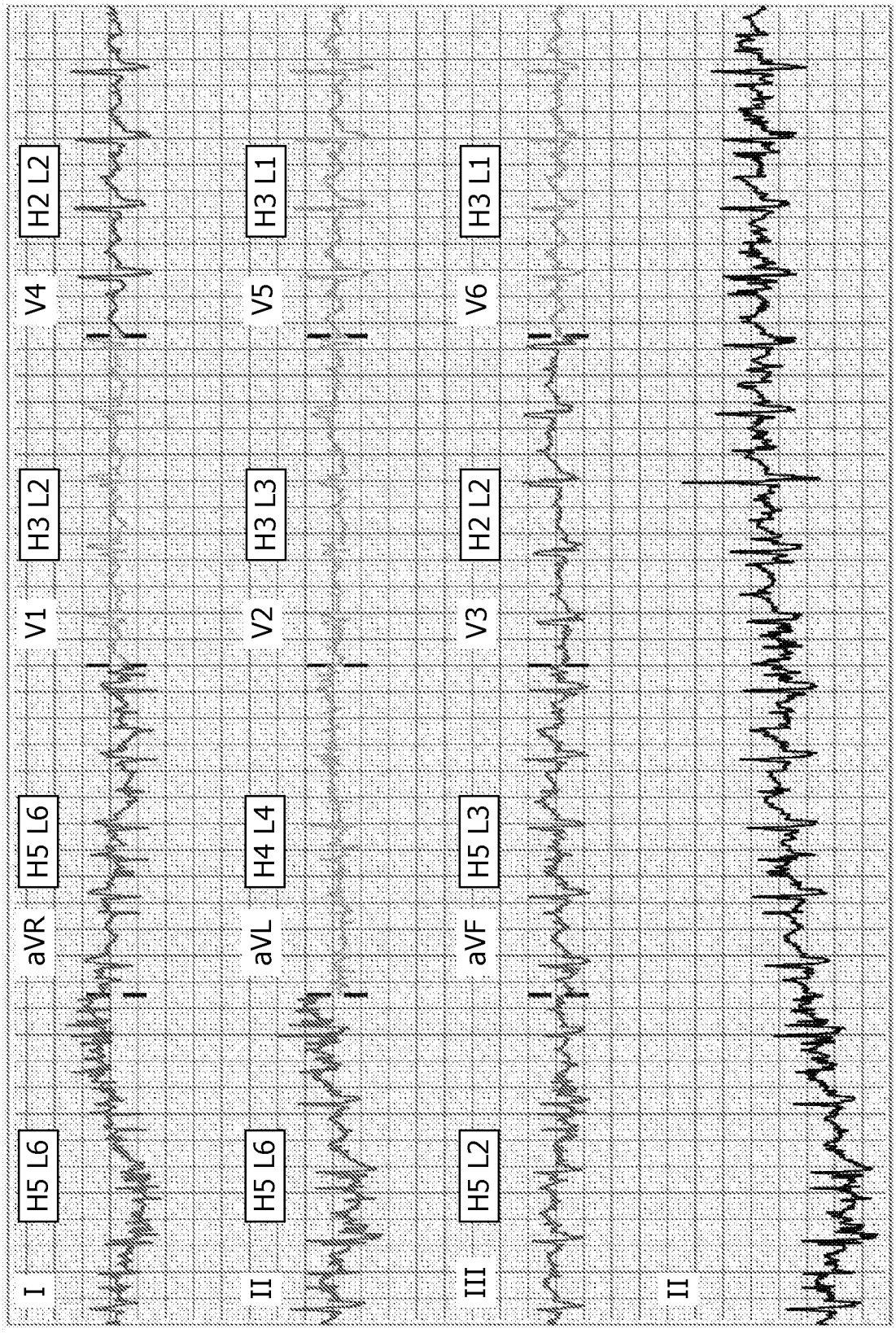
I
H5 L6
aVR
H5 L6
V1
H3 L2
V4
H2 L2
II
H5 L6
aVL
H4 L4
V2
H3 L3
V5
H3 L1
III
H5 L2
aVF
H5 L3
V3
H2 L2
V6
H3 L1
II

FIG. 8

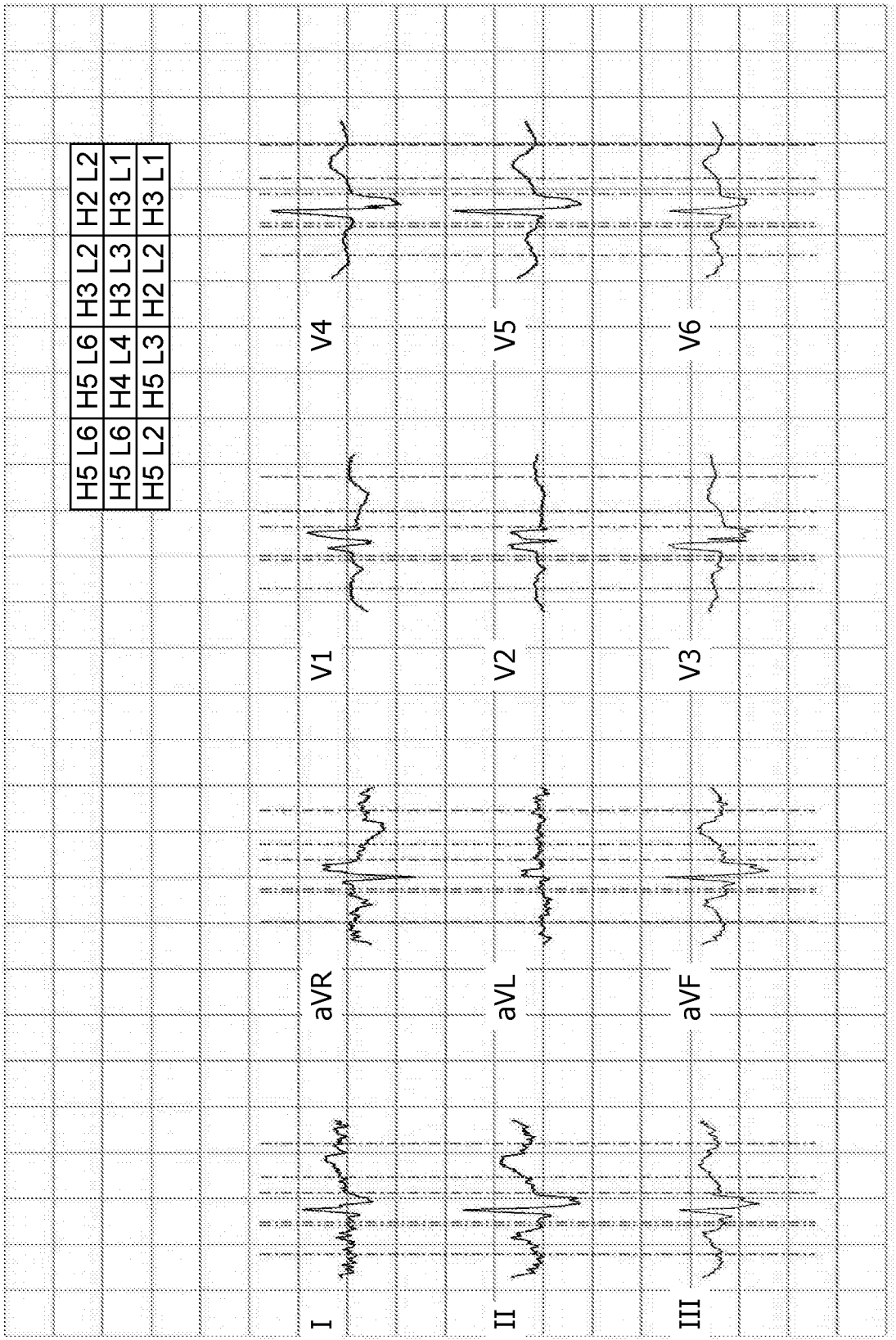
H5 L6 H5 L6 H5 L2
H5 L6 H4 L4 H5 L3
H3 L2 H3 L3 H2 L2
H2 L2 H3 L1 H3 L1
I
II
III
aVR
aVL
aVF
V1
V2
V3
V4
V5
V6

FIG. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2016/055061

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/0402 A61B5/00
ADD. A61B5/04 A61B5/044

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/022903 A1 (SITZMAN DAVID A [US] ET AL) 28 January 2010 (2010-01-28) abstract paragraphs [0008], [0009], [0022], [0027], [0043] - [0049], [0056] figure 2	1-7, 9-11, 16-20
X	US 5 827 196 A (YEO CHEUW LEE [US] ET AL) 27 October 1998 (1998-10-27) column 5, line 22 - column 6, line 52 column 10, line 17 - column 12, line 58	1,6,8, 12-16
X	US 2014/249437 A1 (ZONG WEI [US] ET AL) 4 September 2014 (2014-09-04) paragraphs [0046] - [0058]	1,16

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 December 2016	22/12/2016

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

2

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

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	SATIJA UDIT ET AL: "A simple method for detection and classification of ECG noises for wearable ECG monitoring devices", 2015 2ND INTERNATIONAL CONFERENCE ON SIGNAL PROCESSING AND INTEGRATED NETWORKS (SPIN), IEEE, 19 February 2015 (2015-02-19), pages 164-169, XP032768817, DOI: 10.1109/SPIN.2015.7095425 [retrieved on 2015-04-24] page 164, right-hand column, line 10 - page 166, left-hand column, line 28 -----	1,16

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2016/055061

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		EP 2744402 A1	25-06-2014
		JP 2014528342 A	27-10-2014
		US 2014249437 A1	04-09-2014
		WO 2013054242 A1	18-04-2013