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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 February 2016 (18.02.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/024081 A1

(51) International Patent Classification:
A61B 5/04 (2006.01) *A61B 5/00* (2006.01)
A61B 5/0452 (2006.01) *A61N 1/37* (2006.01)

(21) International Application Number:
PCT/GB2015/052190

(22) International Filing Date:
29 July 2015 (29.07.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
1414330.9 13 August 2014 (13.08.2014) GB

(72) Inventor; and
(71) Applicant : **SAUMAREZ, Richard C.** [GB/GB]; 21 Greenside, Waterbeach, Cambridge, Cambridgeshire CB25 9HW (GB).

(74) Agents: **TOLFREE, Adam** et al.; TPT Cambridge, Toll Drove, Manea, Cambridgeshire PE15 0JX (GB).

(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).

Declarations under Rule 4.17:

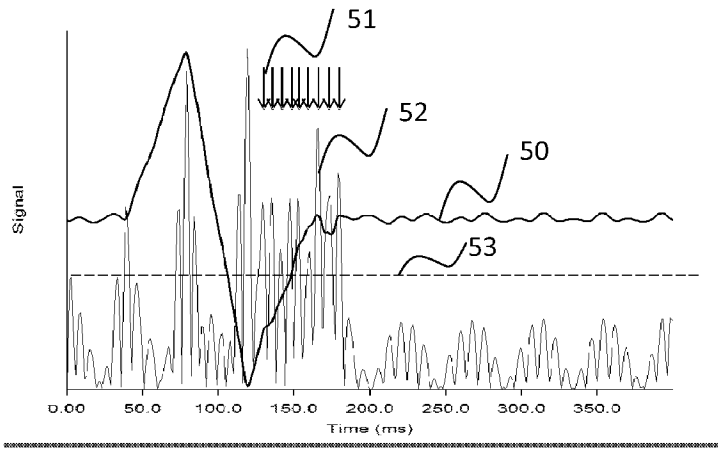
— *of inventorship (Rule 4.17(iv))*

Published:

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

(54) Title: IMPROVEMENT TO ANALYSING PHYSIOLOGICAL ELECTROGRAMS

Figure 14



(57) Abstract: Previous research has shown that the risk of sudden death due to cardiac arrhythmias can be predicted by observing the shape of recorded endocardial electrograms in response to pacing, and in particularly detecting certain small deflections in the recorded electrogram following early stimulation of the heart.A long standing problem has been the reliable detection of these small individual potentials because of the presence of noise in the recorded electrical signals created by other electrical equipment within a typical catheter laboratory. The solution described involves deriving a model of noise from a first portion of the electrogram in which a physiological signal is presumed to be absent,and transforming a second portion of the electrogram, presumed to contain a physiological signal,into the model of noise. The physiological signal can then be identified by identifying portions of signal within the second portion of the electrogram that do not conform to the model of noise.

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Improvement to Analysing Physiological Electrograms

The present invention relates to the analysis of physiological electrograms, in particularly but not exclusively for identifying pathological cardiac conditions.

Previous research has shown that the risk of sudden death due to cardiac arrhythmias can be predicted by observing the shape of recorded endocardial electrograms in response to pacing.

The diagnostic change in electrograms consists of small deflections in the recorded electrogram following early stimulation of the heart. The heart is stimulated with apparatus that generates a stimulation sequence at one site in the heart and records electrograms from other sites within the heart.

The pacing sequence comprises of a number of stimuli at a constant rate, known as S1 stimuli. After a pre-set number of S1 stimuli an early stimulus is introduced known as the S2 stimulus or 'extra-stimulus'. The sequence is repeated. Typically the interval between S1 and S2 stimuli is reduced on each occasion until the interval is so short that the heart is no longer able to respond to the S2 stimulus.

The interval between the S2 stimulus and the following S1 stimulus is the same as the S1-S1 interval.

The predictive method depends on demonstrating that the electrogram following an extra-stimulus becomes prolonged and contains more peaks. This effect in patients that are at high risk of sudden death becomes more pronounced as the interval between the S1 and S2 stimuli is reduced.

Each individual potential of the electrogram following an extrastimulus is identified together with its delay after the extra stimulus. These data can subsequently be analysed to predict the risk of sudden cardiac death.

A long standing problem with this method has been the reliable detection of small individual potentials within the response to an extra stimulus. This stems from the presences of noise in the recorded electrical signals that may be created by other electrical equipment within a typical catheter laboratory. The electrical noise may vary widely between different laboratories. The problem is that of reliably distinguishing between potentials in the electrogram that are of physiological origin as opposed to spurious potentials caused by electrical interference.

GB2439562 describes a method of processing date from electrograms to reduce noise. The method comprises correlating an electrogram signal with several templates to produce a correlator output associated with each template. The electrogram signal may be passed through a high pass filter beforehand.

The correlator output from trace 1 is compared with the traces produced from the other templates. The selected trace that is considered most similar is used.

A fundamental problem is that any series of templates that purport to represent a physiological signal will be correlated, and therefore the results of each correlated trace will not be independent of each other. This creates considerable difficulties in to how to combine the various correlator outputs to give optimal signal detection and avoid spurious over detection and under detection of physiological potentials within the signal.

The noise can be reduced further by identifying the peak-to-peak amplitude of the correlated output within a period of the electrogram when no physiological signal is presumed to occur. This is used to create a threshold in which any peak having an amplitude below this threshold is considered to be noise. However, signals of

physiological origin may have amplitudes which are close to the threshold, as a consequence is if the threshold is set too low, the physiological derived peaks will be detected but many other peaks will also be detected due to noise. Conversely, if the amplitude threshold is too high, physiologically important features of the signal may not be detected.

An object of the invention is to overcome or at least ameliorate the above problems.

According to first aspect of the invention there is provided a method of analysing an electrogram, for example a cardiac electrogram, to distinguish a physiological signal from noise; the method comprising:

deriving a model of noise from a first portion of the electrogram in which a physiological signal is presumed to be absent; and

transforming a second portion of the electrogram, presumed to contain a physiological signal, into the model of noise, and wherein the physiological signal is identified by identifying portions of the signal that do not conform to the model of noise.

This provides an improvement over using the amplitude method because detected potentials are more likely to be genuinely physiological in origin and so subsequent analysis is greatly simplified.

In a preferred embodiment, the model of noise is derived from multiple portions of the electrogram in which a physiological signal is presumed to be absent. This provides a more accurate means of representing the noise thereby enabling improved detection of physiological signals from the noise.

It is favourable that the model of noise is derived by cross-correlation of the first portion of the electrogram in which a physiological signal is presumed to be absent

with multiple templates that represent features of the presumed physiological signal to produce a number of template correlated signals.

The number and form of the templates will depend on the signal in question and can be determined by experiment. In the context of cardiac electrograms, a set of time dilated templates are used that correspond to different local conduction velocities in the region of the recording electrodes.

It is preferred that a co-variance matrix is derived from the template correlated signals for each portion of the electrogram in which a physiological signal is presumed to be absent. By deriving covariance matrices that are inherently symmetric, the eigenvectors thence derived are wholly real and orthogonal (and thus independent), and the eigenvalues are real. In this way it is possible to differentiate a signal from noise because the signal will have significant components in eigenvectors where the noise is very small or non-existent.

The method preferably comprises deriving a mean co-variance matrix from the co-variances matrices derived for each portion of the cardiac electrogram in which a physiological signal is presumed to be absent. The mean covariance matrix provides a better estimate of the behaviour of the noise throughout the entire recording.

It is preferred that the model of noise is expressed by deriving eigenvectors and eigenvalues from the mean co-variance matrix.

It is preferred that the second portion of the electrogram is correlated with multiple templates that represent features of the presumed physiological signal to produce a set of template correlated signals, and additionally favourable that a vector is derived from a first time sample of each template correlated signal of the set, and further vectors from further time samples of each template correlated signal of the set.

It is preferred that the vectors are represented as points in the model of noise by projecting each vector onto each eigenvector thereby representing the original signal as a trajectory in the model of noise, and so allows comparison of the signal and the noise.

The physiological signal is preferably identified by determining points that lie outside the limits of the model of noise thereby discriminating the signal from the noise.

The invention can also be expressed in terms of apparatus and thus according a further aspect of the invention there is provided apparatus for analysing an electrogram to distinguish a physiological signal from noise; the apparatus comprising:

means for deriving a model of noise from a first portion of the cardiac electrogram in which a physiological signal is presumed to be absent; and

means for transforming a second portion of the electrogram presumed to contain a physiological signal into the model of noise, and where the physiological signal is identified by identifying portions of the signal that do not conform to the model of noise.

The invention will now be described by example with reference to the following Figures in which:

Figure 1 is a schematic representation of apparatus for pacing a heart, recording an electrogram and subsequent analysis;

Figure 2 is schematic representation of a paced cardiac electrogram sequence;

Figure 3 is schematic representation similar to Fig 1 illustrating the regions of the signal used to evaluate noise;

Figure 4 is a schematic illustrating the principle of the analysis technique;

Figure 5 is a schematic of time domain representation of the templates;

Figure 6 illustrates a correlation matrix of the templates showing correlation therebetween;

Figure 7 is a flow diagram illustrating the steps for creation of a noise model;

Figure 8 is a graphical illustration of the noise model for three templates;

Figure 9 is a flow diagram illustrated the steps for identification of potentials the noise model;

Figure 10 is a graphical illustration of the noise model for three templates showing trajectory of one noise record within the noise model illustrating that it remains within the limits of the model;

Figure 11 a graphical illustration of the noise model for three templates showing a trajectory of a signal that is derived from a physiological signal;

Figure 12 is a graphically illustrates a normalised noise model for three templates;

Figure 13 illustrates a simulated electrogram to which noise and small potentials have been added; and

Figure 14 illustrates the simulated electrogram of Fig 13 with the time domain output signal of the model superimposed.

The apparatus comprises amplifiers 1 that are connected to recording electrodes 2 within the heart 3 and electronics and associated software 4. A pacing and recording

program 5 issues signals to a pacing signal generator 6 that is switched onto one selected electrode 2 by multiplexer 7 to stimulate the heart 3. The signals sensed by the other electrodes 2 are amplified and digitised by an ADC 8 and stored in memory 9. Subsequently the data is retrieved and analysed by analysis program 10.

All subsequent analysis is with sampled signals, care having been taken to conform to the Nyquist sampling theorem.

The use of the multiplexer 7 allows the heart to be stimulated at different sites 3.

The functions and arrangement described above can be derived, in conjunction with the teaching within this document by the person skilled in the art.

Figure 2 illustrates a pacing sequence applied at one electrode 2, showing the constant rate stimuli S1 and extra-stimuli S2. The intervals between S1-S1 stimuli and the S2-S1 stimuli remain constant, in this example with an interval of 500ms. The interval between the S1 and S2 stimuli varies, and typically reduces by one 1ms on each occasion.

Figure 3 illustrates the regions 11 preceding S1 stimuli that are used for evaluating noise on the premise that no physiological signals occur in these regions 11. Also shown are regions 12 that are analysed to identify physiological signals resulting from S2 stimuli.

As illustrated in Fig 4, the noise regions 11 are extracted from the recorded signal and correlated with templates 13, generated by the analysis program 10, to create a model 14 with independent eigenvectors. The templates 13 are representations of potentials of varying widths that are likely to be the result of a physiological event.

Subsequently, the portions 12 of the recorded signal are correlated to templates 13 and projected into model 14 that provides an output 15 that is indicative of whether the sample being analysed is signal or noise.

Figure 5 illustrates the fifteen templates 13 that are correlated with the signals 11 12. Template number one 13A has the longest time duration while template number fifteen 13B has the shortest. The intermediate template numbers 13C shorten progressively.

In practice the templates are always used in their frequency domain representations, i.e. their discrete Fourier transform, for computational efficiency.

The correlation between templates 13 is shown as a correlation matrix, see Fig 6, in which each element is the correlation between template n and template m where n and m are the template numbers. This shows that the templates 13 are not independent since if they were all non-diagonal elements would be equal to zero.

Referring to Figure 7, the templates 13 are computed in the frequency domain 20. A record of each noise region 11 is transformed into the frequency domain by Fast Fourier transform 21 and correlated 22 with each template by multiplication. The result is summed to form the mean cross-correlation spectrum 23. A mean noise co-variance matrix is derived 24 from the cross-correlation spectrum. The co-variance matrix is decomposed 25 into its eigenvectors and eigenvalues, thus forming a noise model 14.

Figure 8 illustrates a noise model for three templates only (because of the difficulties of showing high dimensional models). The three eigenvectors $\Lambda 1$, $\Lambda 2$, $\Lambda 3$ are at rights angles, i.e. orthogonal. The limits of the noise model is shown by the shaded area 40 as defined by the eigenvalues.

Referring to Fig 9, every signal identification region 12 is processed individually. The individual signal portion 26 is transformed into the frequency domain 27 and correlated 28 with templates 13 and the result expressed 29 in the time domain. The resultant signal template correlation records are projected 30 into the eigenvector space of the noise model 14 as a trajectory.

Figure 10 is an illustration of the trajectory 41 of a signal within region 11 illustrating that it remains within the limits 40 of the model 14 as defined by the eigenvectors/eigenvalues.

Fig 11 illustrates the trajectory 42 of a signal within the region 12 showing that it exceeds the limits 40 of the noise model 14 and thus is likely to be attributed to a physiological origin.

A convenient method of determining whether the signal exceeds the noise is to reduce the trajectory to a single time domain signal. To achieve this, the resultant trajectory is normalised by division of each eigenvector by its eigenvalue so that the noise model becomes a spheroid 43 as illustrated in Figure 12. The norm 45 of the trajectory vector in this space 44 is computed to give the one-dimensional time domain signal.

Any peak in the time domain signal that is above of the noise is considered to be physiologically significant.

Figure 13 shows a portion of a simulated electrogram 50, corresponding to a single S1-S2 interval. Noise has been added to the electrogram together with small potentials expected from a physiological response. The small potentials have the same peak-to-peak amplitude of the noise; the positions of the small potentials are indicated by arrows 51.

Figure 14 shows the electrogram of Fig 13 with a time domain signal output 52 derived using the method described above superimposed. The time domain signal output shows clear peaks that exceed the noise threshold 53 corresponding to the limit of the noise model, at the positions that the small potentials were inserted into the signal with a significant increase in signal to noise ratio.

Claims

1 A method of analysing an electrogram to distinguish a physiological signal from noise; the method comprising:

deriving a model of noise from a first portion of the electrogram in which a physiological signal is presumed to be absent;

transforming a second portion of the electrogram presumed to contain a physiological signal into the model of noise, and wherein the physiological signal is identified by identifying portions of the second portion of the electrogram that do not conform to the model of noise.

2. A method according to claim 1 wherein the model of noise is derived from multiple portions of the electrogram in which a physiological signal is presumed to be absent.

3. A method according to claim 1 or 2 in which the model of noise is derived by cross-correlation of the first portion of the electrogram in which a physiological signal is presumed to be absent with multiple templates that represent features of the presumed physiological signal to produce a number of template correlated signals.

3. A method according to claim 2 comprising deriving a co-variance matrix from the template correlated signals for each portion of the electrogram in which a physiological signal is presumed to be absent.

4. A method according to claim 3 comprising deriving a mean co-variance matrix from the co-variances matrixes derived for each portion of the electrogram in which a physiological signal is presumed to be absent.

5. A method according to claim 4 wherein the model of noise is expressed by deriving Eigenvectors and Eigen values from the mean co-variance matrix.

6. A method according to any previous claim comprising correlating the second portion of the electrogram with multiple templates that represent features of the presumed physiological signal to produce a set of template correlated signals.

7. A method according to claim 6 comprising deriving a vector from a first time sample of each template correlated signal of the set; and further vectors from further time samples of each template correlated signal of the set.

8 A method according to claim 7 comprising representing the vectors as points in the model of noise by projecting each vector onto each eigenvector thereby representing the original signal as a trajectory in the model of noise.

9. A method according to claim 8 wherein a physiological signal is identified by determining points that lie outside the limits of the model of noise.

10. A method of analysing a cardiac electrogram according to any previous claim.

11. Apparatus for analysing an electrogram to distinguish physiological signal from noise; the apparatus comprising:

means for deriving a model of noise from a first portion of the cardiac electrogram in which a physiological signal is presumed to be absent; and

means for transforming a second portion of the electrogram presumed to contain a physiological signal into the model of noise, and where the physiological signal is identified by identifying portions of the second portion of the electrogram that do not conform to the model of noise.

12. Apparatus according to claim 11 wherein comprising means to derive the model of noise from multiple portions of the electrogram in which a physiological signal is presumed to be absent.

13. Apparatus according to claim 11 or 12 comprising means to derived the model of noise by cross-correlation of the first portion of the cardiac electrogram in which a physiological signal is presumed to be absent with multiple templates that represent features of the presumed physiological signal to produce a number of template correlated signals.

14. Apparatus according to claim 13 comprising means for deriving a co-variance matrix from the template correlated signals for each portion of the cardiac electrogram in which a physiological signal is presumed to be absent.

15. Apparatus according to claim 14 comprising means for deriving a mean co-variance matrix from the co-variance matrices derived for each portion of the cardiac electrogram in which a physiological signal is presumed to be absent.

16. Apparatus according to claim 15 comprising means for expressing the model by deriving Eigenvectors and Eigen values from the mean co-variance matrix.

17. Apparatus according to any claim 11 -16 comprising means for correlating the second portion of the cardiac electrogram with multiple templates that represent features of the presumed physiological signal to produce a set of template correlated signals.

18. Apparatus according to claim 17 comprising means for deriving a vector from a first time sample of each template correlated signal of the set; and further vectors from further time samples of each template correlated signal of the set.

19 Apparatus according to claim 18 comprising means for expressing the vectors as points in the model of noise by projecting each vector onto each eigenvector thereby representing the original signal as a trajectory in the model of noise.

20. Apparatus according to claim 19 comprising for identifying a physiological signal by determining points that lie outside the limits of the model of noise.

21. Apparatus according to any claim 11-20 for analysing a cardiac electrogram.

22. Apparatus for analysing an electrogram to distinguish a physiological signal from noise; the apparatus comprising a processor, responsive to executing computer instructions, to perform operations comprising:

deriving a model of noise from a first portion of the cardiac electrogram in which a physiological signal is presumed to be absent; and

transforming a second portion of the electrogram presumed to contain a physiological signal into the model of noise, and identifying a physiological signal by identifying portions of the signal that do not conform to the model of noise.

23. A method of analysing an electrogram to distinguish a physiological signal from noise; the method comprising:

deriving a model of noise from a first portion of the electrogram in which a physiological signal is presumed to be absent;

transforming a second portion of the electrogram presumed to contain a physiological signal into the model of noise, and wherein the physiological signal is identified by identifying portions of the signal that do not conform to the model of noise.

Figure 1

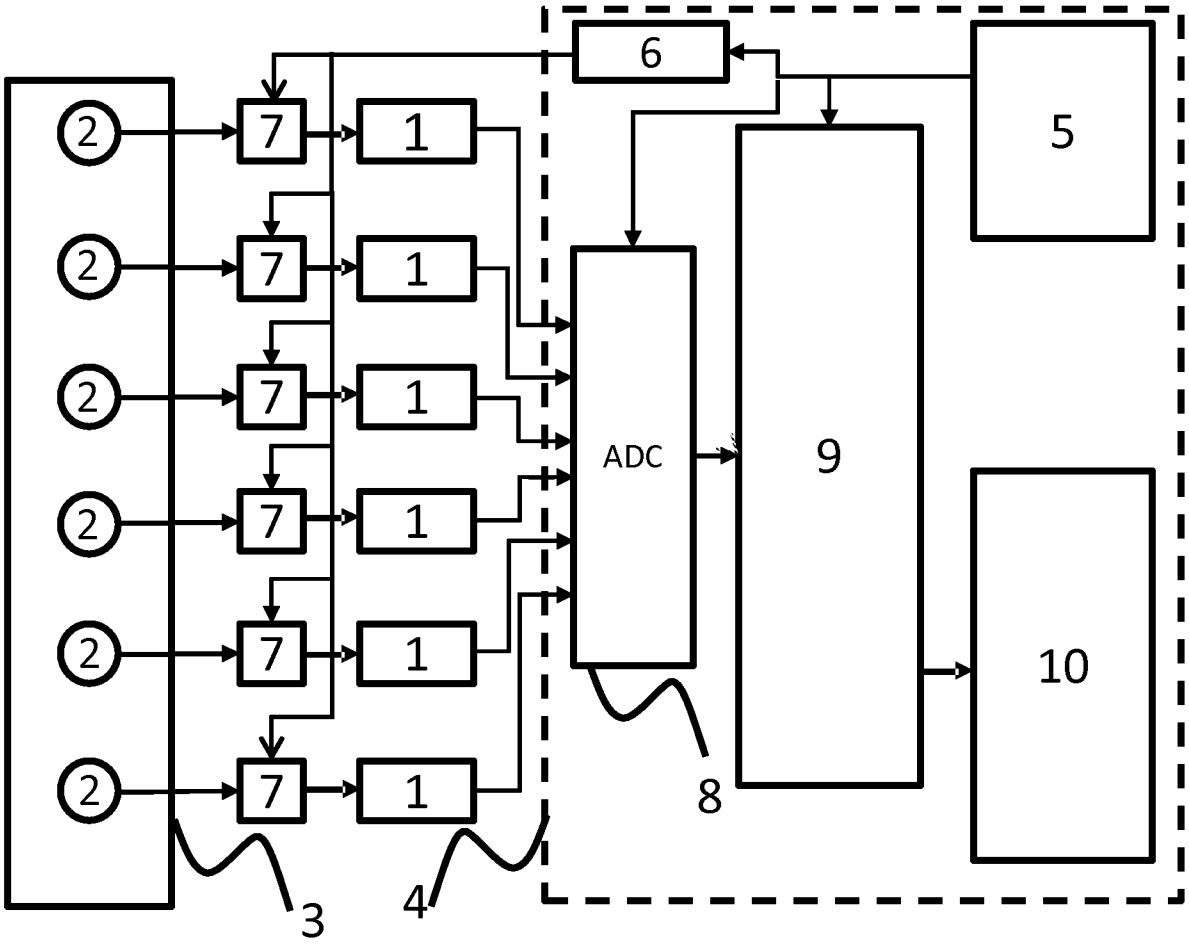


Figure 2

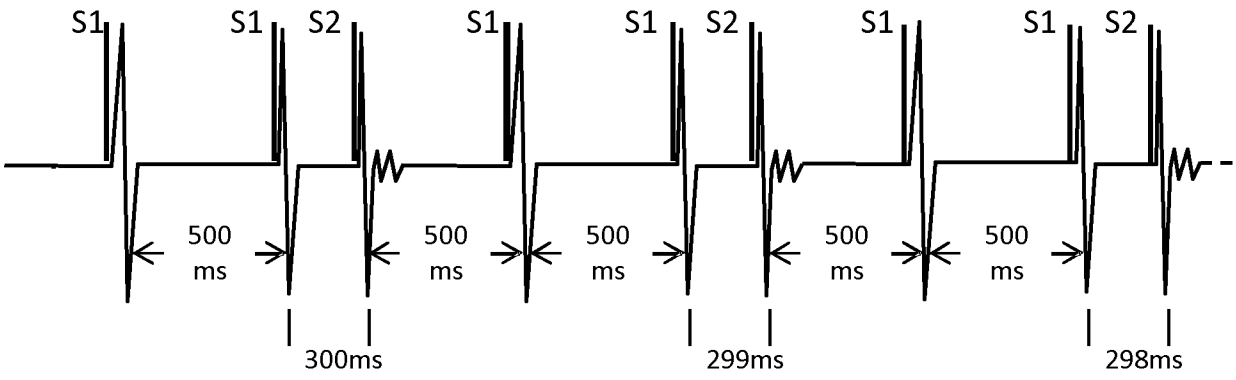

S1
S1
S2
S1
S1
S2
S1
S1
S2
500 ms
500 ms
500 ms
500 ms
500 ms
300ms
299ms
298ms

Figure 3

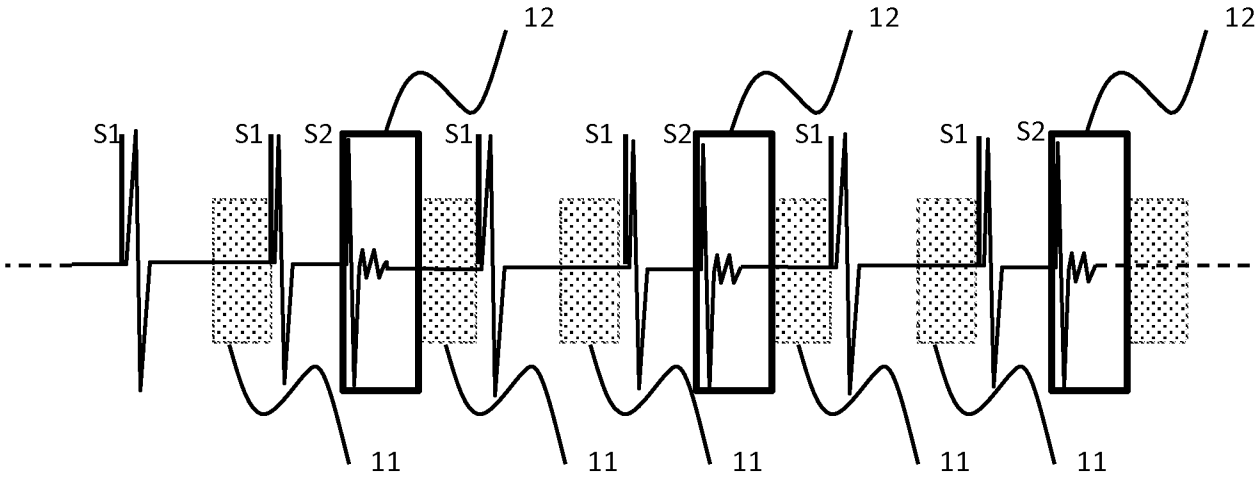


Figure 4

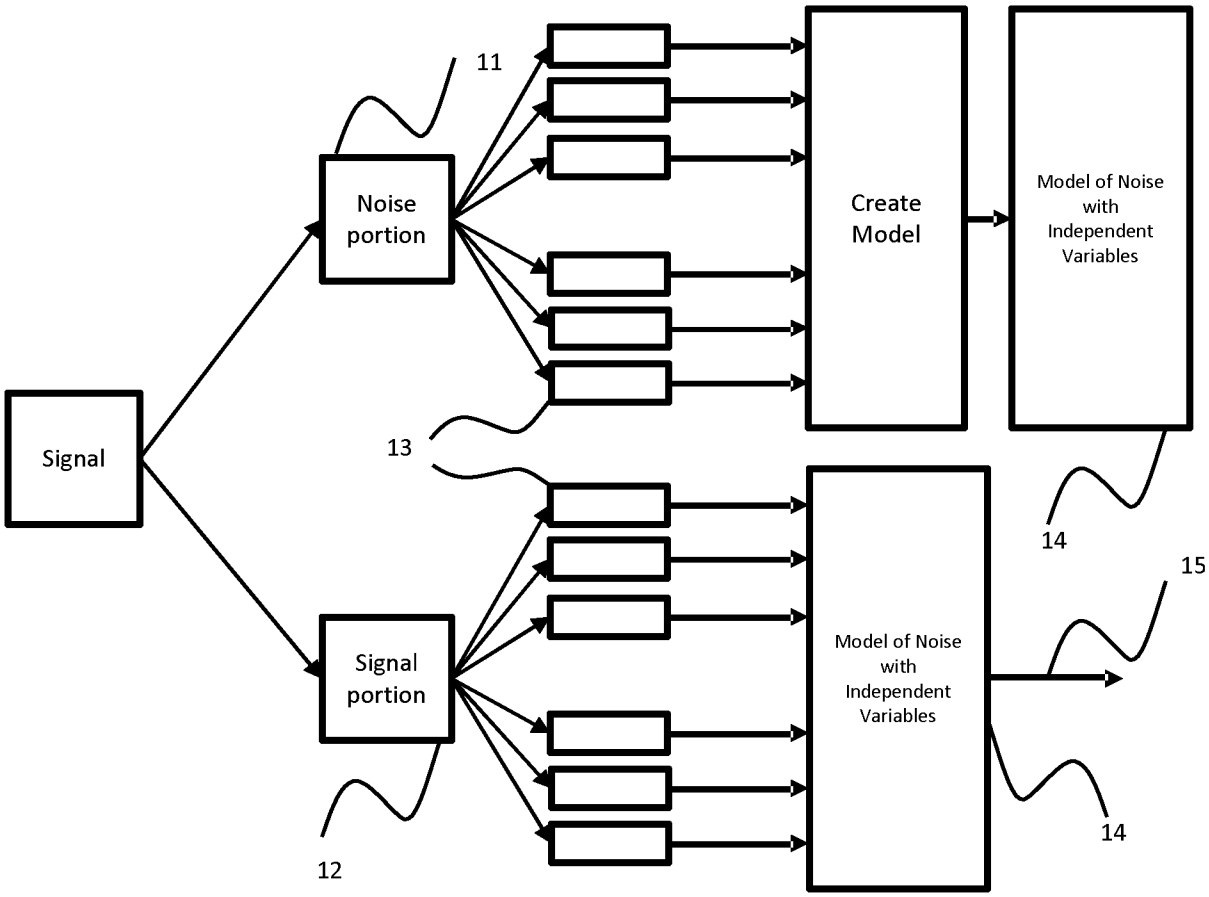

Signal
Noise portion
Signal portion
11
12
13
Create Model
Model of Noise with Independent Variables
14
15
Model of Noise with Independent Variables
14

Figure 5

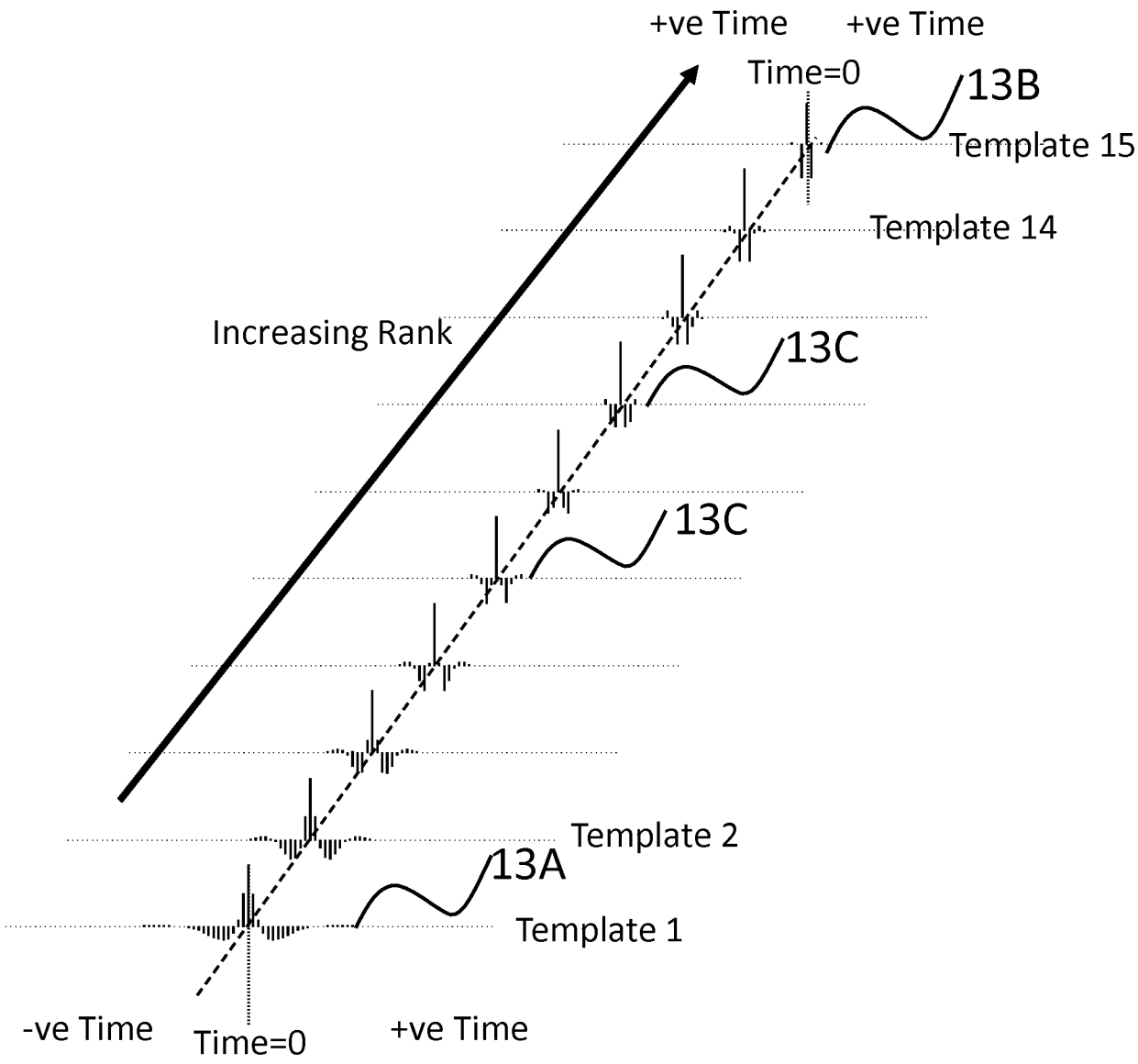

+ve Time
+ve Time
Time=0
13B
Template 15
Template 14
Increasing Rank
13C
13C
Template 2
13A
Template 1
-ve Time
Time=0
+ve Time

Figure 6

$$r_{n,m}$$

1.00	0.87	0.69	0.55	0.45	0.37	0.31	0.27	0.24	0.22
0.87	1.00	0.91	0.76	0.63	0.53	0.45	0.39	0.35	0.32
0.69	0.91	1.00	0.94	0.83	0.72	0.62	0.55	0.49	0.45
0.55	0.76	0.94	1.00	0.96	0.88	0.79	0.71	0.65	0.60
0.45	0.63	0.83	0.96	1.00	0.97	0.91	0.84	0.78	0.73
0.37	0.53	0.72	0.88	0.97	1.00	0.98	0.94	0.89	0.84
0.31	0.45	0.62	0.79	0.91	0.98	1.00	0.99	0.95	0.92
0.27	0.39	0.55	0.71	0.84	0.94	0.99	1.00	0.99	0.97
0.24	0.35	0.49	0.65	0.78	0.89	0.95	0.99	1.00	0.99
0.22	0.32	0.45	0.60	0.73	0.84	0.92	0.97	0.99	1.00

Figure 7

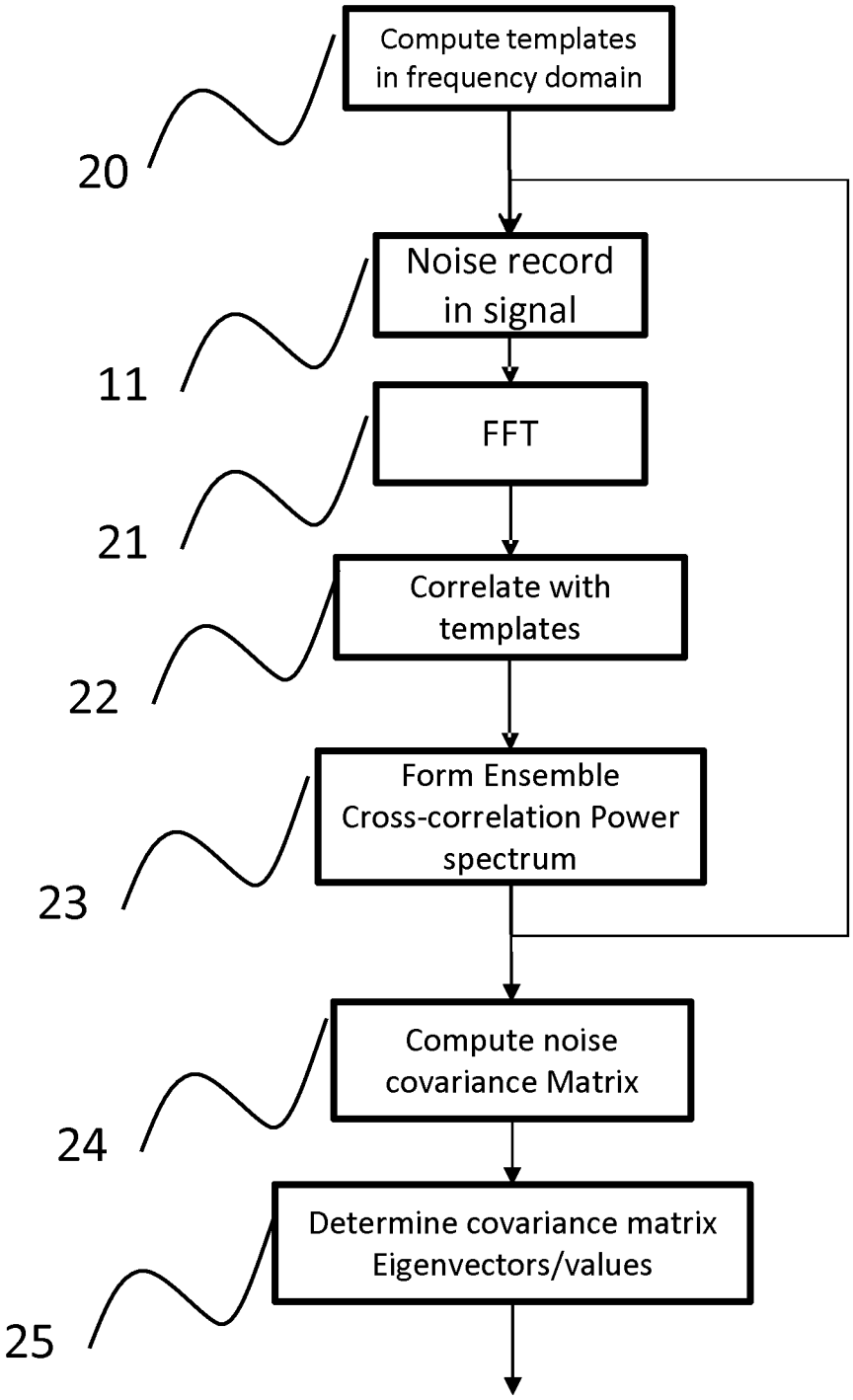

Compute templates in frequency domain
20
Noise record in signal
11
FFT
21
Correlate with templates
22
Form Ensemble Cross-correlation Power spectrum
23
Compute noise covariance Matrix
24
Determine covariance matrix Eigenvectors/values
25

Figure 8

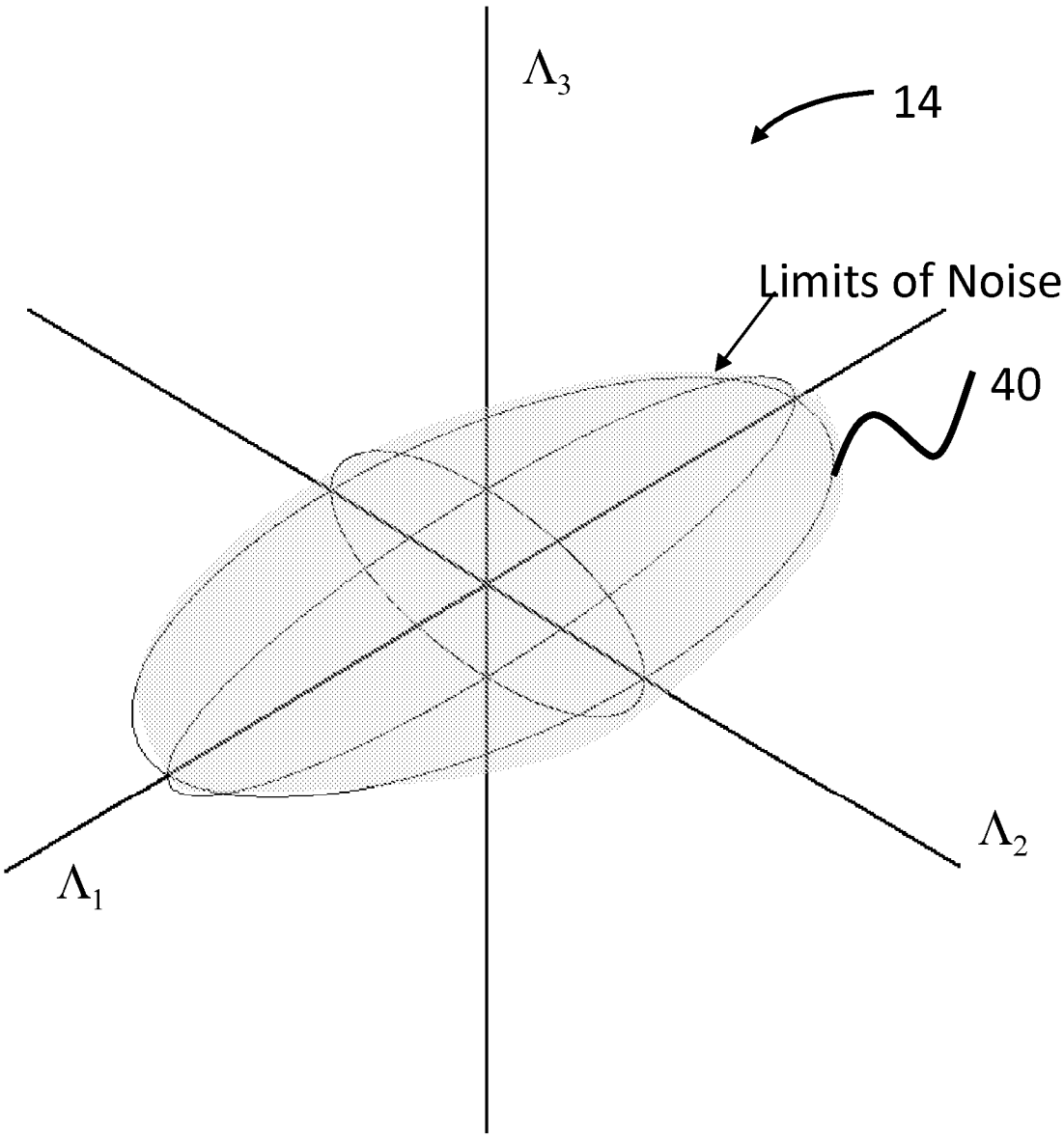


Figure 9

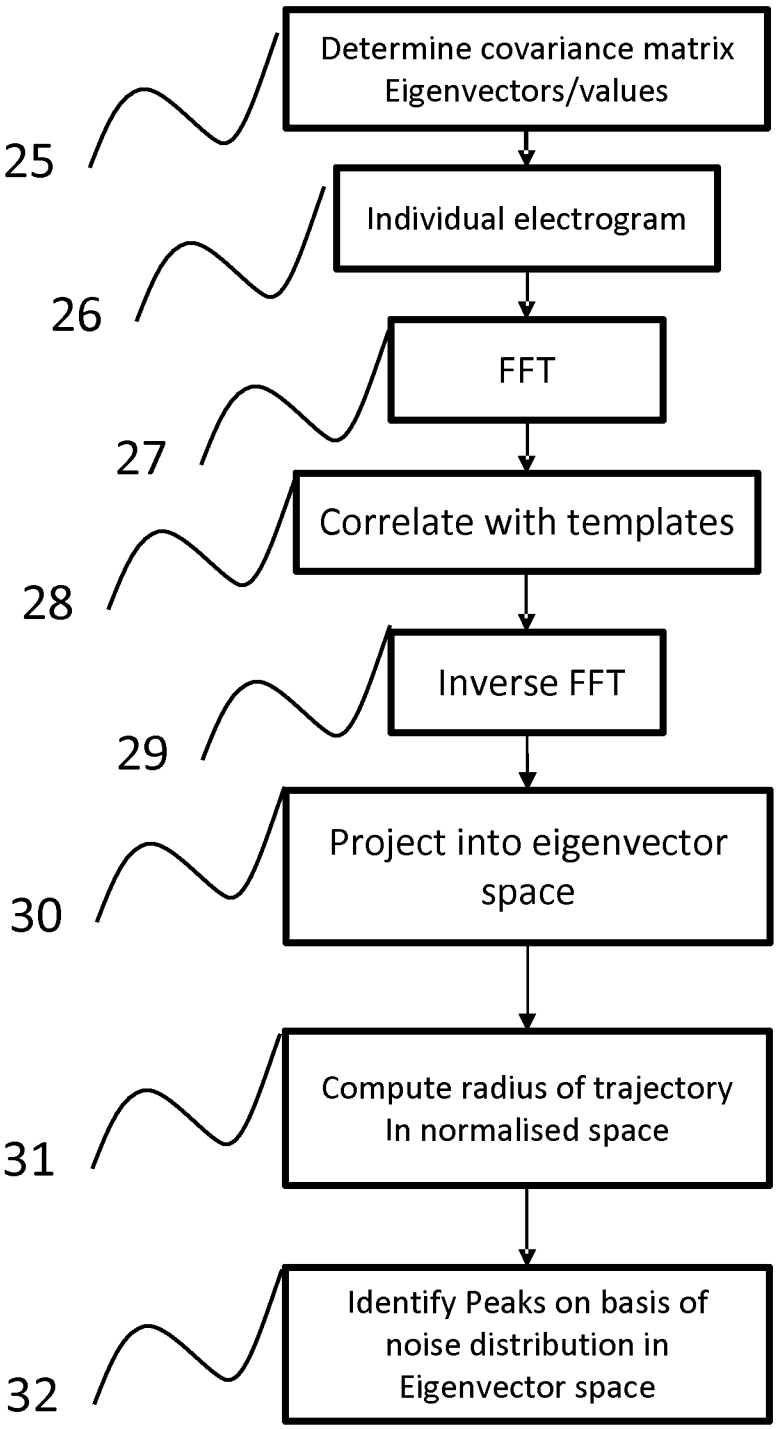

Determine covariance matrix Eigenvectors/values
25
Individual electrogram
26
FFT
27
Correlate with templates
28
Inverse FFT
29
Project into eigenvector space
30
Compute radius of trajectory In normalised space
31
Identify Peaks on basis of noise distribution in Eigenvector space
32

Figure 10

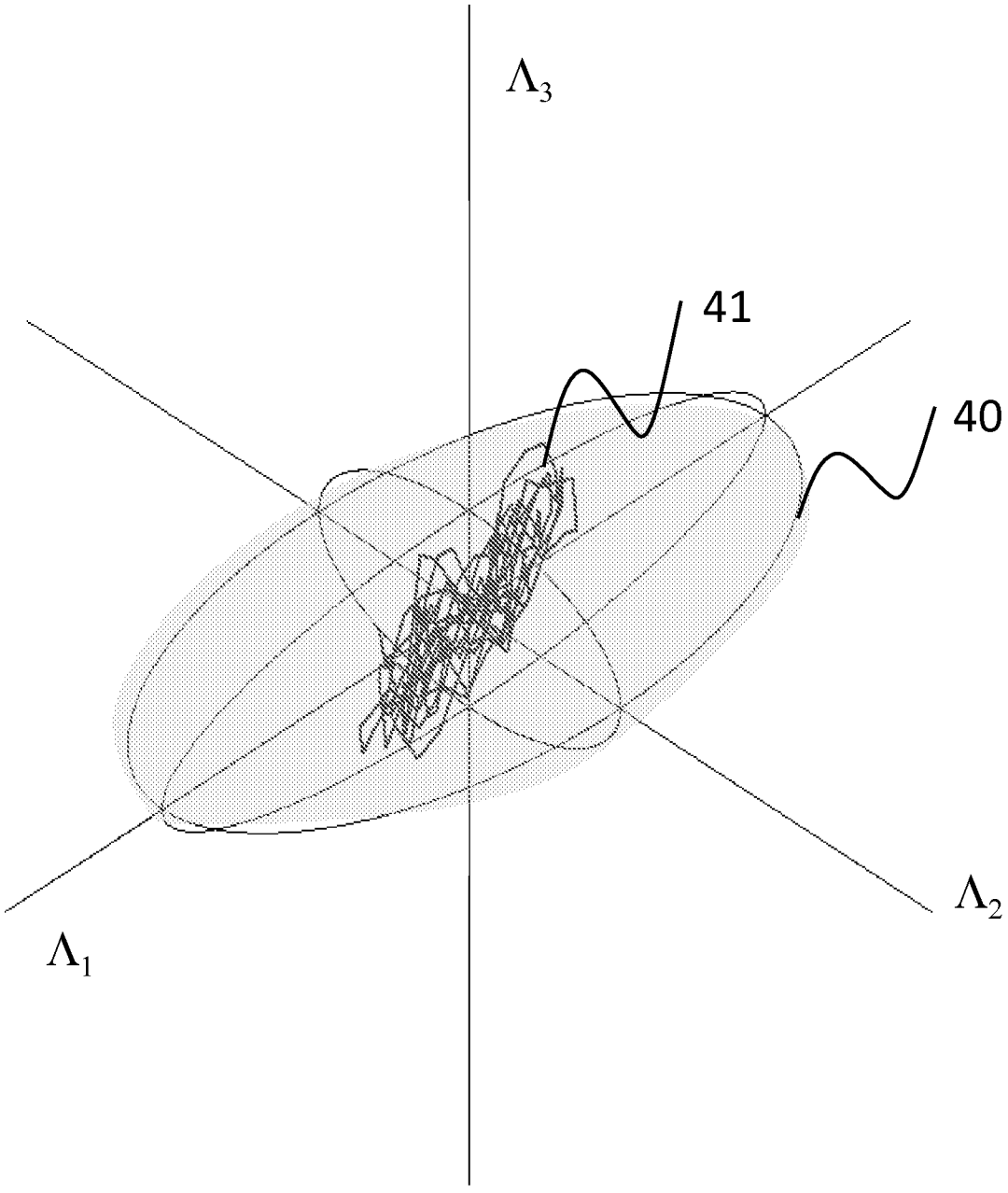


Figure 11

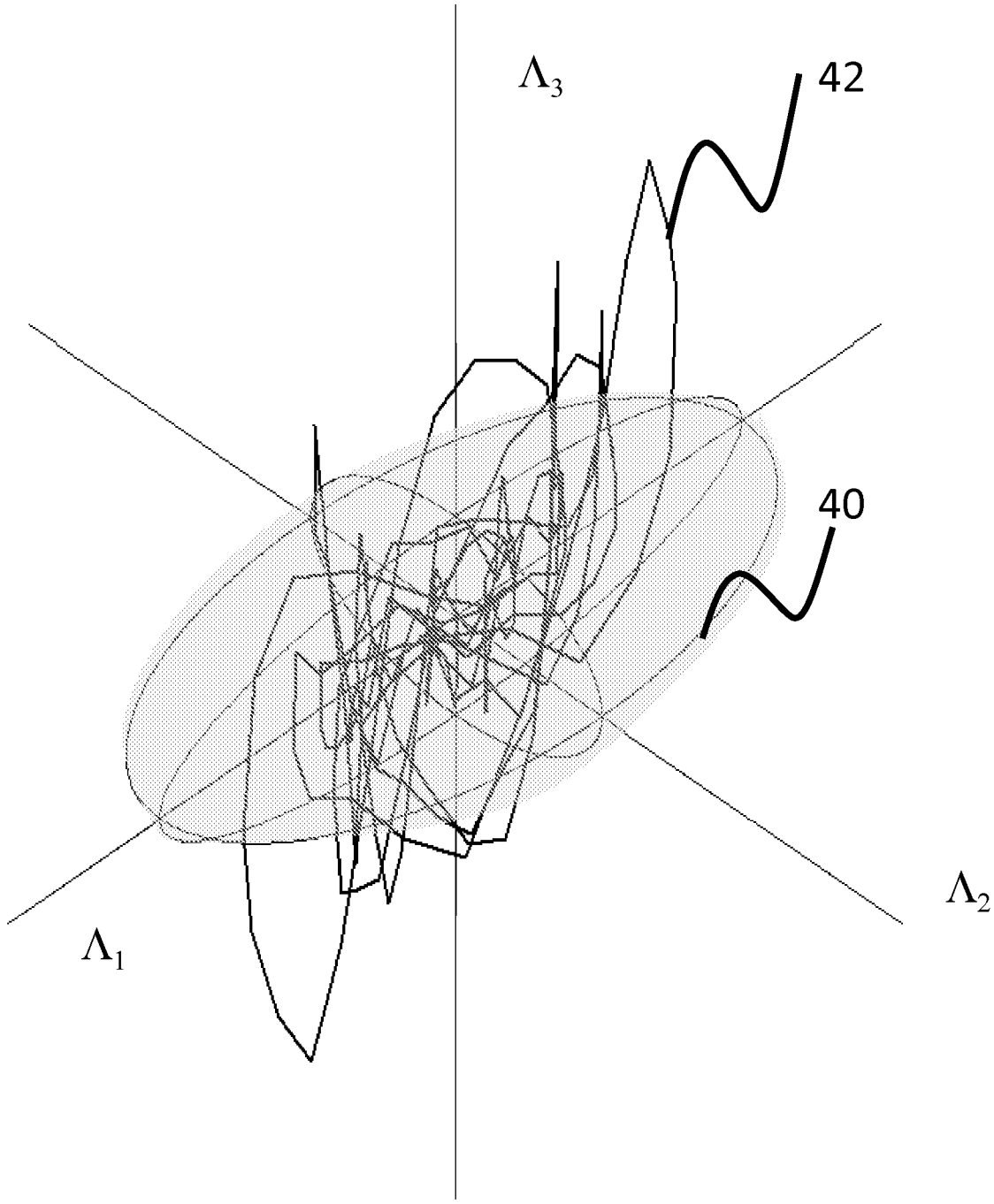


Figure 12

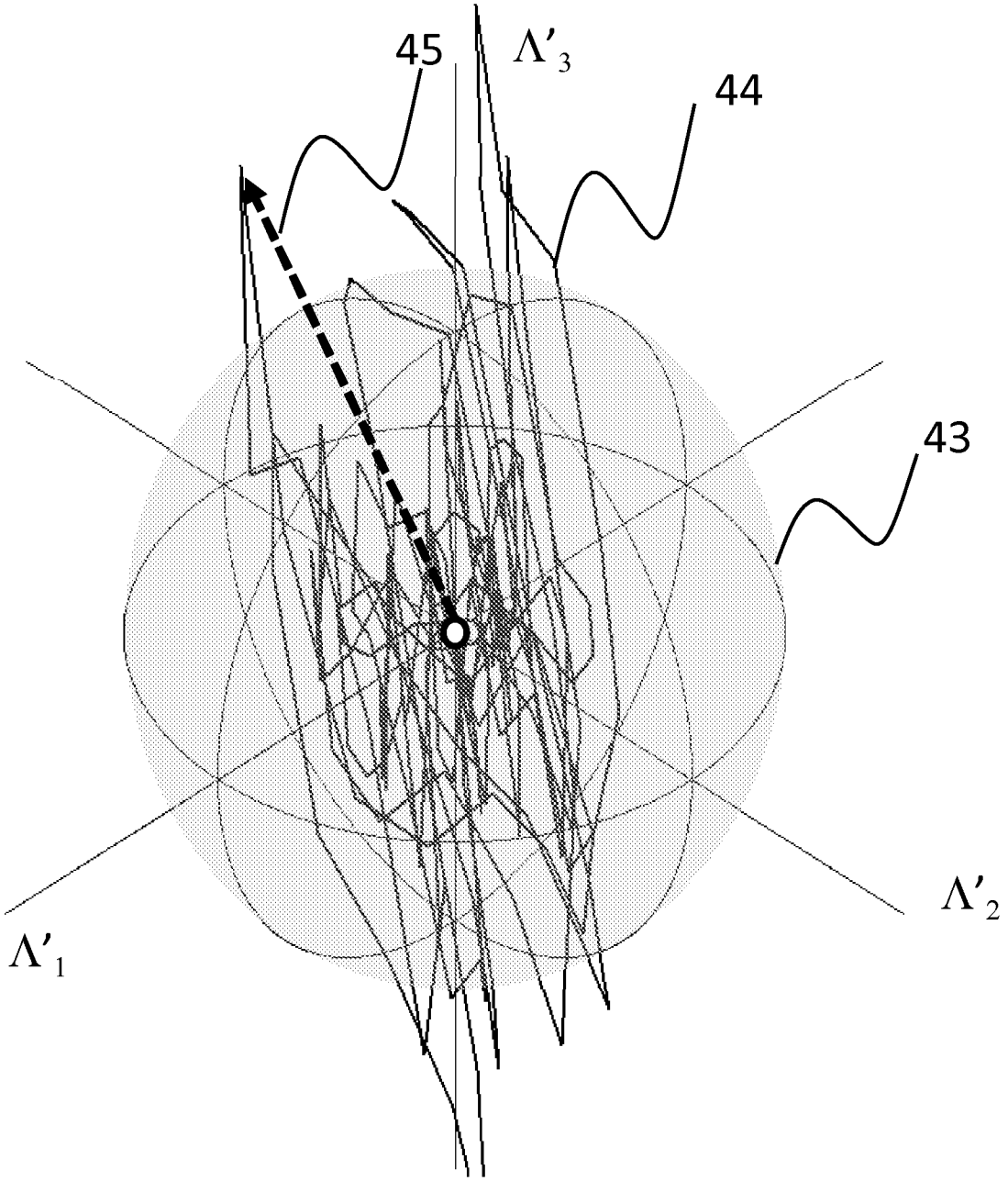


Figure 13

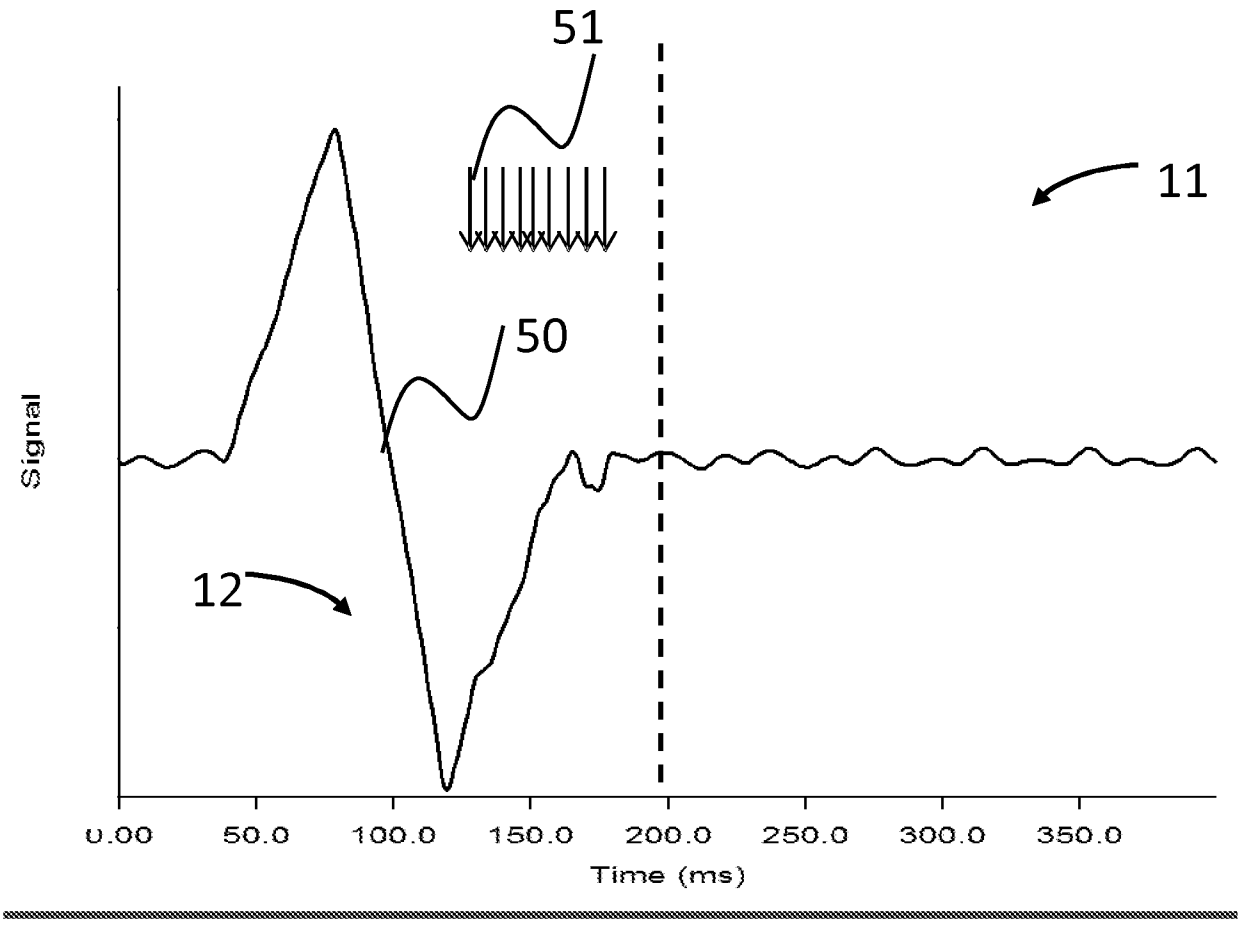
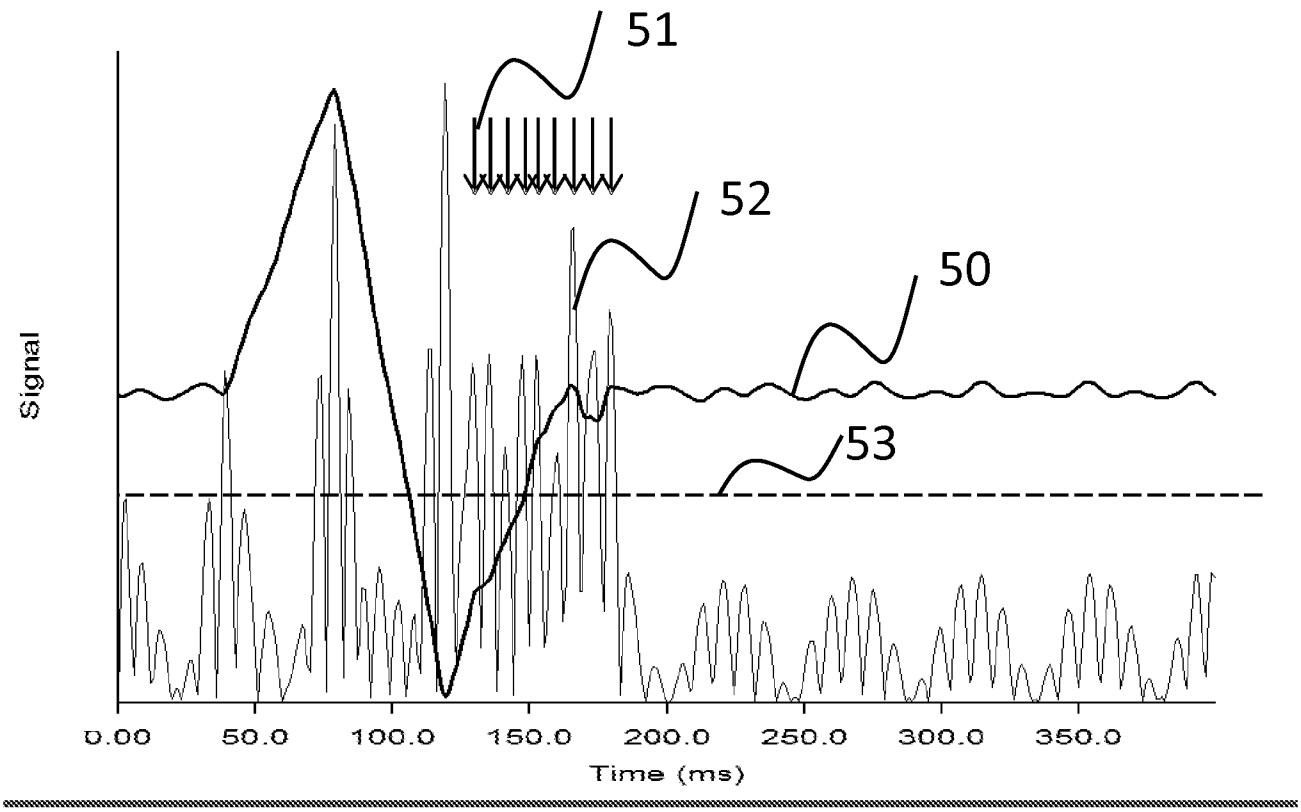

51
11
50
12
Signal
0.00
50.0
100.0
150.0
200.0
250.0
300.0
350.0
Time (ms)

Figure 14


51
52
50
53
Signal
0.00
50.0
100.0
150.0
200.0
250.0
300.0
350.0
Time (ms)

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2015/052190

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/04 A61B5/0452 A61B5/00 A61N1/37
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61N

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 Y	GB 2 439 562 A (MEDILEC LTD [GB]) 2 January 2008 (2008-01-02) cited in the application page 10, lines 4-6 page 17, line 25 - page 20, line 31 figures -----	1-3,6, 10-13, 17,21-23 3-5,7-9, 14-16, 18-20
Y	US 2006/253044 A1 (ZHANG YI [US] ET AL) 9 November 2006 (2006-11-09) paragraphs [0102] - [0105] figure 8 -----	3-5,7-9, 14-16, 18-20
A	US 2005/149134 A1 (MCCABE AARON [US] ET AL) 7 July 2005 (2005-07-07) the whole document -----	1-23

☐ Further documents are listed in the continuation of Box C.

☒ 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

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"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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 September 2015	05/10/2015

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	Bataille, Frédéric

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2015/052190

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2439562 A	02-01-2008	GB 2439562 A	02-01-2008
		US 2009227884 A1	10-09-2009
		WO 2008000821 A2	03-01-2008
US 2006253044 A1	09-11-2006	US 2006253044 A1	09-11-2006
		US 2011137192 A1	09-06-2011
US 2005149134 A1	07-07-2005	NONE	

专利名称(译)	分析生理电图的改进		
公开(公告)号	EP3179905A1	公开(公告)日	2017-06-21
申请号	EP2015747189	申请日	2015-07-29
[标]申请(专利权)人(译)	FEN EP LTD		
[标]发明人	SAUMAREZ RICHARD C		
发明人	SAUMAREZ, RICHARD C.		
IPC分类号	A61B5/04 A61B5/0452 A61B5/00 A61N1/37		
CPC分类号	A61B5/04012 A61B5/0402 A61B5/04525 A61B5/7203 A61B5/7217 A61B5/7246 A61B5/7275 A61N1/3627		
优先权	2014014330 2014-08-13 GB		
外部链接	Espacenet		

摘要(译)

先前的研究表明，心律失常导致猝死的风险可以通过观察记录的心内膜电图的形状来预测，以响应起搏，特别是在心脏早期刺激后检测记录的电图中的某些小的偏转。由于在典型的导管实验室中由其他电气设备产生的记录的电信号中存在噪声，因此常设问题是对这些小的个体电位的可靠检测。所描述的解决方案涉及从电图的第一部分导出噪声模型，其中假定生理信号不存在，并且将假定包含生理信号的电描记图的第二部分变换为噪声模型。然后可以通过识别电图的第二部分内不符合噪声模型的信号部分来识别生理信号。