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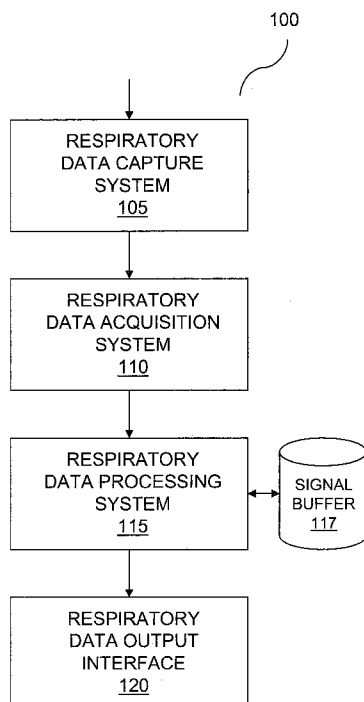
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[Continued on next page]

(54) Title: DEVICE AND METHOD FOR CONDITIONING DISPLAY OF PHYSIOLOGICAL PARAMETER ESTIMATES ON CONFORMANCE WITH EXPECTATIONS

FIG. 1



(57) Abstract: Method and device for continual physiological monitoring in which the display of physiological parameter estimates is conditioned on conformance of the estimates with expectations. Current estimates of physiological parameters are compared with expectations for the current estimates determined using prior estimates of the physiological parameters. Nonconformance with expectations can result in display of information indicating present unavailability of an estimate for the physiological parameter. The method and device are adaptable for use with various types of monitored physiological parameters and various expectation metrics.

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

DESCRIPTION

TITLE OF INVENTION: DEVICE AND METHOD FOR
CONDITIONING DISPLAY OF PHYSIOLOGICAL PARAMETER
ESTIMATES ON CONFORMANCE WITH EXPECTATIONS

5

TECHNICAL FIELD

The present invention relates to a device and method for
conditioning display of physiological parameter estimates on
conformance with expectations.

10

BACKGROUND ART

This invention relates to physiological monitoring and,
more particularly, to reducing unreliable physiological
parameter output in physiological monitoring applications.

15

Continual monitoring of the physiological state of people
who suffer from chronic diseases is an important aspect of
chronic disease management. By way of example, continual
respiratory monitoring is in widespread use in managing
respiratory diseases, such as asthma. Continual monitoring of
physiological state is also widely used in other contexts, such
as elder care.

20

One serious problem encountered in continual
physiological monitoring is parameter estimation error.
Continual monitoring is often performed using a portable (e.g.

wearable) device that continually acquires and analyzes a physiological signal, such as a signal that includes heart and lung sounds, as a person wearing the device goes about his or her daily life. The physiological signal acquired by the device can be rendered temporarily unreliable due to, for example, noise effects, motion effects, poor network connection and sensor malfunction. This can result in erroneous estimation of physiological parameters by the device and outputting of erroneous estimates. Reliance on these erroneous estimates can have serious adverse consequences on the health of the person being monitored. For example, erroneous estimates can lead the person or his or her clinician to improperly interpret physiological state and cause the person to undergo treatment that is not medically indicated, or forego treatment that is medically indicated.

Such conventional physiological monitoring device and method are described in the following patent literatures: US7,585,680B2, US7,383,070,070 B2, US2009/0058636 A1, and US7,006,856 B2.

SUMMARY OF THE INVENTION

The present invention provides a method and device for continual physiological monitoring in which the display of physiological parameter estimates is conditioned on conformance of the estimates with expectations. Current

estimates of physiological parameters are compared with expectations for the current estimates determined using prior estimates of the physiological parameters. Nonconformance with expectations can result in display of information indicating present unavailability of an estimate for the physiological parameter. The method and device are adaptable for use with various types of monitored physiological parameters and various expectation metrics.

In one aspect of the invention, a method for continual physiological monitoring comprises acquiring by a physiological monitoring device a physiological signal; calculating by the device a current estimate of a physiological parameter from the physiological signal; evaluating by the device conformance of the current estimate with expectations for the current estimate determined by the device using one or more prior estimates of the physiological parameter calculated by the device from the physiological signal; and displaying by the device information regarding the current estimate determined by the device based at least in part on the evaluation.

In another aspect of the invention, a physiological monitoring device comprises a physiological data capture system; a physiological data acquisition system communicatively coupled with the capture system; a physiological data processing system communicatively

coupled with the acquisition system; and

a physiological data output interface communicatively coupled with the processing system, wherein the processing system receives a physiological signal from the capture system via the acquisition system, calculates a current estimate of a physiological parameter from the physiological signal, evaluates conformance of the current estimate with expectations for the current estimate determined using one or more prior estimates of the physiological parameter calculated from the physiological signal, and transmits to the output interface information regarding display of the current estimate determined based at least in part on the evaluation, whereupon information regarding the current estimate is displayed on the output interface.

These and other aspects of the invention will be better understood by reference to the following detailed description taken in conjunction with the drawings that are briefly described below. Of course, the invention is defined by the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a physiological monitoring device in some embodiments of the invention.

FIG. 2 shows consecutive sampling windows of a physiological signal in some embodiments of the invention.

FIG. 3 shows a normal distribution for a current estimate in some embodiments of the invention.

FIG. 4 shows a method for continual physiological monitoring in some embodiments of the invention.

5 FIGS. 5A-5C show display screens for displaying information regarding physiological parameter estimates in some embodiments of the invention.

FIG. 6 shows an explanation of the evaluating step in some embodiments of the invention.

10 DESCRIPTION OF EMBODIMENTS

FIG. 1 shows a physiological monitoring device 100 in some embodiments of the invention. Monitoring device 100 includes a physiological data capture system 105, a physiological data acquisition system 110, a physiological data processing system 115 and a physiological data output interface 120 communicatively coupled in series. Processing system 115 is also communicatively coupled with a signal buffer 117.

20 Capture system 105 detects body sounds, such as heart and lung sounds, at a detection point, such as a trachea, chest or back of a person being monitored and transmits a physiological signal to acquisition system 110 in the form of an electrical signal generated from detected body sounds.

25 Capture system 105 may include, for example, a sound

transducer positioned on the body of a human subject.

Acquisition system 110 amplifies, filters, performs analog/digital (A/D) conversion and automatic gain control (AGC) on the physiological signal received from capture
5 system 105, and transmits the physiological signal to processing system 115. Amplification, filtering, A/D conversion and AGC may be performed by serially arranged pre-amplifier, band-pass filter, final amplifier, A/D conversion and AGC stages, for example.

10 Processing system 115, under control of a processor executing software instructions, processes the physiological signal to continually estimate one or more physiological parameters of the subject being monitored. Monitored physiological parameters may include, for example, heart rate
15 and respiration rate. To enable continual estimation of physiological parameters, processing system 115 continually buffers in signal buffer 117 and evaluates samples of the physiological signal, wherein the length of each sample is equal to a sampling window length. Processing system 115
20 under control of the processor transmits to output interface 120 format and content information for displaying information regarding recent estimates of the monitored physiological parameters.

Output interface 120 includes a user interface having a
25 display screen for displaying information in accordance with

format and content information received from processing system 115 regarding recent estimates of physiological parameters. The displayed information may include, for example, the most recent prior estimate, the current estimate, trend arrows and indications that estimates are presently unavailable (e.g. question marks). Output interface 120 may also have a data management interface to an internal or external data management system that stores the information and/or a network interface that transmits the information to a remote monitoring device, such as a monitoring device at a clinician facility.

In some embodiments, capture system 105, acquisition system 110, processing system 115 and output interface 120 are part of a portable ambulatory monitoring device that monitors a person's physiological well-being in real-time as the person performs daily activities. In other embodiments, capture system 105, acquisition system 110, processing system 115 and output interface 120 may be part of separate devices that are remotely coupled via wired or wireless links.

FIG. 2 shows consecutive sampling windows (W_{N-1} , W_N) of a physiological signal in some embodiments of the invention. Each of the illustrated windows 200 is rectangular, such that data within the window is given equal weight. Moreover, the illustrated windows 200 are non-overlapping, although in other embodiments windows may be overlapping.

Additionally, the illustrated windows 200 are of fixed length, although in other embodiments processing system 115 may dynamically adjust window length. Processing system 115 under control of a processor analyzes the signal data in windows (W_{N-1} , W_N) 200 to generate the most recent prior estimate E_{N-1} and the current estimate E_N , respectively, for one or more physiological parameters, such as heart rate or respiratory rate. The most recent prior estimate E_{N-1} and earlier prior estimates (e.g. E_{N-2} , E_{N-3} , E_{N-4} , etc.) are used by processing system 115 to determine expectations for the current estimate E_N , and the current estimate E_N is compared with its expectations to determine its acceptance and display status.

By way of example, one element of expectations for the current estimate E_N is conformance with a confidence interval for the current estimate calculated assuming a normal distribution. FIG. 3 shows a normal distribution $P(E_N)$ for a current estimate E_N in some embodiments of the invention. The normal distribution $P(E_N)$ is a bell-shaped curve having a midpoint at an expected mean for the current estimate E_N and a confidence interval having a range of plus or minus two standard deviations ($+2\sigma$) from the expected mean. If the current estimate E_N falls within the confidence interval, the current estimate E_N conforms to expectations and is accepted; otherwise, the decision of whether to accept the current

estimate E_N is deferred pending additional analysis. For purposes of calculating the confidence interval for the current estimate E_N , the expected mean is set to the value of the most recent prior estimate E_{N-1} , and the standard deviation σ is set to a value calculated using the variance of a predetermined number of prior estimates (e.g. E_{N-1} , E_{N-2} , E_{N-3} , etc.) from their respective expected means (e.g. E_{N-2} , E_{N-3} , E_{N-4} , etc.).

FIG. 4 shows a method for continual physiological monitoring in some embodiments of the invention. In these embodiments, the method is performed by processing system 115 under control of a processor that executes software instructions in conjunction with output interface 120 which displays information on a display screen in accordance with format and content information received from processing system 115 regarding recent estimates of a physiological parameter.

At Step 400, the next sample N is acquired and processing system 115 calculates the current estimate (E_N) from signal data in the sampling window (W_N).

At Step 405, processing system 115 calculates confidence intervals for the current estimate (E_N). The confidence intervals include a first confidence interval having a range of plus or minus two standard deviations ($+2\sigma$) from an expected mean at the most recent prior estimate (E_{N-1}), and a second confidence interval having a range of plus or

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minus two standard deviations ($+2\sigma$) from an expected mean at the second most recent prior estimate (E_{N-2}). In other embodiments, the ranges may span a smaller or larger number of standard deviations.

5 At Step 410, processing system 115 determines whether the current estimate (E_N) falls within the first confidence interval. That is, processing system 115 determines whether the current estimate (E_N) is within two standard deviations of the most recent prior estimate (E_{N-1}). If this condition is met,
10 the current estimate (E_N) conforms to expectations and the flow proceeds to Step 415. If this condition is unmet, the flow proceeds to Step 420 for further analysis.

 At Step 415, processing system 115 sets the acceptance status of the most recent prior estimate (E_{N-1}) to accepted (if
15 not already set to accepted), sets the acceptance status of the current estimate (E_N) to accepted, and transmits information to output interface 120 instructing output interface 120 to contemporaneously display the most recent prior estimate (E_{N-1}) and the current estimate (E_N) in the format shown in FIG.
20 5A. The flow then returns to Step 400 where the next sample is considered.

 At Step 420, processing system 115 determines whether the most recent prior estimate (E_{N-1}) has been accepted. If so, the decision on acceptance of the current estimate (E_N) is
25 deferred and the flow proceeds to Step 425. If not, the flow

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proceeds to Step 430 for further analysis.

At Step 425, processing system 115 transmits information to output interface 120 instructing output interface 120 to contemporaneously display the most recent prior estimate (E_{N-1}) and a trend arrow in the format shown in FIG. 5B. The trend arrow is up if the current estimate (E_N) is greater than the most recent prior estimate (E_{N-1}) and the trend arrow is down if the current estimate (E_N) is less than the most recent prior estimate (E_{N-1}). The flow then returns to Step 400 where the next sample is considered.

At Step 430, processing system 115 determines whether the second most recent prior estimate (E_{N-2}) has been rejected. If so, the most recent prior estimate (E_{N-1}) will also be rejected and the flow proceeds to Step 450. If not, the flow proceeds to Step 435 for further analysis.

At Step 435, processing system 115 performs a sustained trend check to determine whether the current estimate (E_N) conforms with expectations even though it is outside the first confidence interval. In this check, processing system 115 determines whether either the current estimate (E_N) is part of a sustained upward trend in which the current estimate (E_N) is greater than the most recent prior estimate (E_{N-1}) which is in turn greater than the second most recent prior estimate (E_{N-2}) or, alternatively, the current estimate (E_N) is part of a sustained downward trend in which the current

estimate (E_N) is less than the most recent prior estimate (E_{N-1}) which is in turn less than the second most recent prior estimate (E_{N-2}). If the current estimate (E_N) is part of a sustained upward or downward trend, the current estimate
5 (E_N) conforms to expectations and the flow proceeds to Step 415. If the current estimate (E_N) is not part of a sustained upward or downward trend, the flow proceeds to Step 440 for further analysis.

At Step 440, processing system 115 performs a self-
10 correction check to determine whether the current estimate (E_N) conforms to expectations even though it is outside the first confidence interval and is not part of a sustained upward or downward trend. In this check, processing system 115 evaluates whether the reason for nonconformance of the
15 current estimate (E_N) with the first confidence interval is that the most recent prior estimate (E_{N-1}) was affected by a temporary adverse condition from which monitoring device 100 has since recovered, such as a temporary spike in signal noise or temporary sensor malfunction. Processing system
20 115 thus determines whether the current estimate (E_N) falls within the second confidence interval calculated in Step 405. That is, processing system 115 determines whether the current estimate (E_N) is within two standard deviations of the second most recent prior estimate (E_{N-2}). If this condition is
25 met, the current estimate (E_N) conforms to expectations and

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the flow proceeds to Step 415 after recalculating the most recent prior estimate (E_{N-1}) at Step 445 as the average of the current estimate (E_N) and the second most recent prior estimate (E_{N-2}). If this condition is unmet, the flow proceeds to Step 450.

At Step 450, processing system 115 sets the acceptance status of the most recent prior estimate (E_{N-1}) to rejected, and transmits information to output interface 120 instructing output interface 120 to display an indication that the most recent prior estimate (E_{N-1}) and the current estimate (E_N) are presently unavailable as shown in FIG. 5C. The flow then returns to Step 400 where the next sample is considered.

FIG. 6 shows an explanation of the evaluating step of the present invention. This invention relates to statistical treatment of physiological readings, such as a person's heart rate or breathing rate. When autocorrelating measurements such as the interval between heartbeats or respiration rate ("RR" in the figure on p. 11), the results sometimes exhibit more than a single peak, causing doubt about which one of, perhaps, two different values is correct. If a second correlated measurement yields one value within a defined confidence interval, and another outside the confidence interval, the first value is probably correct. If both values are outside the confidence interval, there is uncertainty about which is correct. The invention helps select the probably correct value

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of a prior reading based on a comparison of recent past readings and a current reading.

The example on Fig.6 shows readings in Box 1 of a prior reading $(N-1) = 16$ and the one before that $(N-2) = 15$. The current reading, in Box 2 (time "N," where the arrow is), is uncertain. The measurements produce autocorrelation peaks that make the value in Box 2 (where the arrow is), at time N, either 22, the left number in Box 3, or 14, the left number in Box 4. The question is, which is the probable correct reading at time N, 22 or 14. The invention provides a method of selecting between those values based on the next $(N+1)$ reading, which is the right number appearing in Boxes 3 and 4. If the $N+1$ reading is 28, as shown in Box 3, then the probable correct reading for N is 22. If the $N+1$ reading is 18, shown in Box 4, then the probable correct reading for N is 14. By adjusting a prior uncertain reading based on a current reading, the invention allows for increasing the confidence level of physiological readings over time. Box 5 is the case where no good value is measured at $N+1$, so the correct value of the prior N reading remains uncertain, too.

In some embodiments, conformance of the current estimate with the expectations is determined based at least in part on whether the current estimate falls within a confidence interval for the current estimate.

In some embodiments, the confidence interval is a range

whose midpoint is the most recent prior estimate.

In some embodiments, the confidence interval is a range whose midpoint is the second most recent prior estimate.

5 In some embodiments, the method further comprises recalculating by the device the most recent prior estimate as an average of the current estimate and the second most recent prior estimate.

10 In some embodiments, conformance of the current estimate with the expectations is determined based at least in part on whether the current estimate is higher than the most recent prior estimate and whether the most recent prior estimate is higher than the second most recent prior estimate.

15 In some embodiments, conformance of the current estimate with the expectations is determined based at least in part on whether the current estimate is lower than the most recent prior estimate and the most recent prior estimate is lower than the second most recent prior estimate.

20 In some embodiments, the displaying step comprises contemporaneously displaying by the device the current estimate and the most recent prior estimate.

In some embodiments, the displaying step comprises contemporaneously displaying by the device the most recent prior estimate and a trend arrow.

25 In some embodiments, the displaying step comprises displaying by the device an indication that the most recent

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prior estimate and the current estimate are presently unavailable.

It will be appreciated by those of ordinary skill in the art that the invention can be embodied in other specific forms without departing from the spirit or essential character hereof. The present description is therefore considered in all respects to be illustrative and not restrictive. The scope of the invention is indicated by the appended claims, and all changes that come with in the meaning and range of equivalents thereof are intended to be embraced therein.

CLAIMS

1. A physiological monitoring device, comprising:

a physiological data capture system;

5 a physiological data acquisition system
communicatively coupled with the capture system;

 a physiological data processing system
communicatively coupled with the acquisition system; and

 a physiological data output interface
10 communicatively coupled with the processing system, wherein
the processing system receives a physiological signal from the
capture system via the acquisition system, calculates a
current estimate of a physiological parameter from the
physiological signal, evaluates conformance of the current
15 estimate with expectations for the current estimate
determined using one or more prior estimates of the
physiological parameter calculated from the physiological
signal, and transmits to the output interface information
regarding display of the current estimate determined based at
20 least in part on the evaluation, whereupon information
regarding the current estimate is displayed on the output
interface.

2. The device of claim 1, wherein conformance of the
25 current estimate with the expectations is determined based at

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least in part on whether the current estimate falls within a confidence interval for the current estimate.

3. The device of claim 2, wherein the confidence interval
5 is a range whose midpoint is the most recent prior estimate.

4. The device of claim 2, wherein the confidence interval
is a range whose midpoint is the second most recent prior
estimate.

10 5. The device of claim 4, wherein the processing system
recalculates the most recent prior estimate as an average of
the current estimate and the second most recent prior
estimate.

15 6. The device of claim 1, wherein conformance of the
current estimate with the expectations is determined based at
least in part on whether the current estimate is higher than
the most recent prior estimate and whether the most recent
20 prior estimate is higher than the second most recent prior
estimate.

25 7. The device of claim 1, wherein conformance of the
current estimate with the expectations is determined based at
least in part on whether the current estimate is lower than

the most recent prior estimate and the most recent prior estimate is lower than the second most recent prior estimate.

8. The device of claim 1, wherein the processing system
5 contemporaneously displays the current estimate and the most recent prior estimate.

9. The device of claim 1, wherein the processing system
10 contemporaneously displays the most recent prior estimate and a trend arrow.

10. The device of claim 1, wherein the processing system displays an indication that the most recent prior estimate and the current estimate are presently unavailable.

11. A method for continual physiological monitoring,
comprising:

acquiring by a physiological monitoring device a physiological signal; calculating by the device a current
20 estimate of a physiological parameter from the physiological signal;

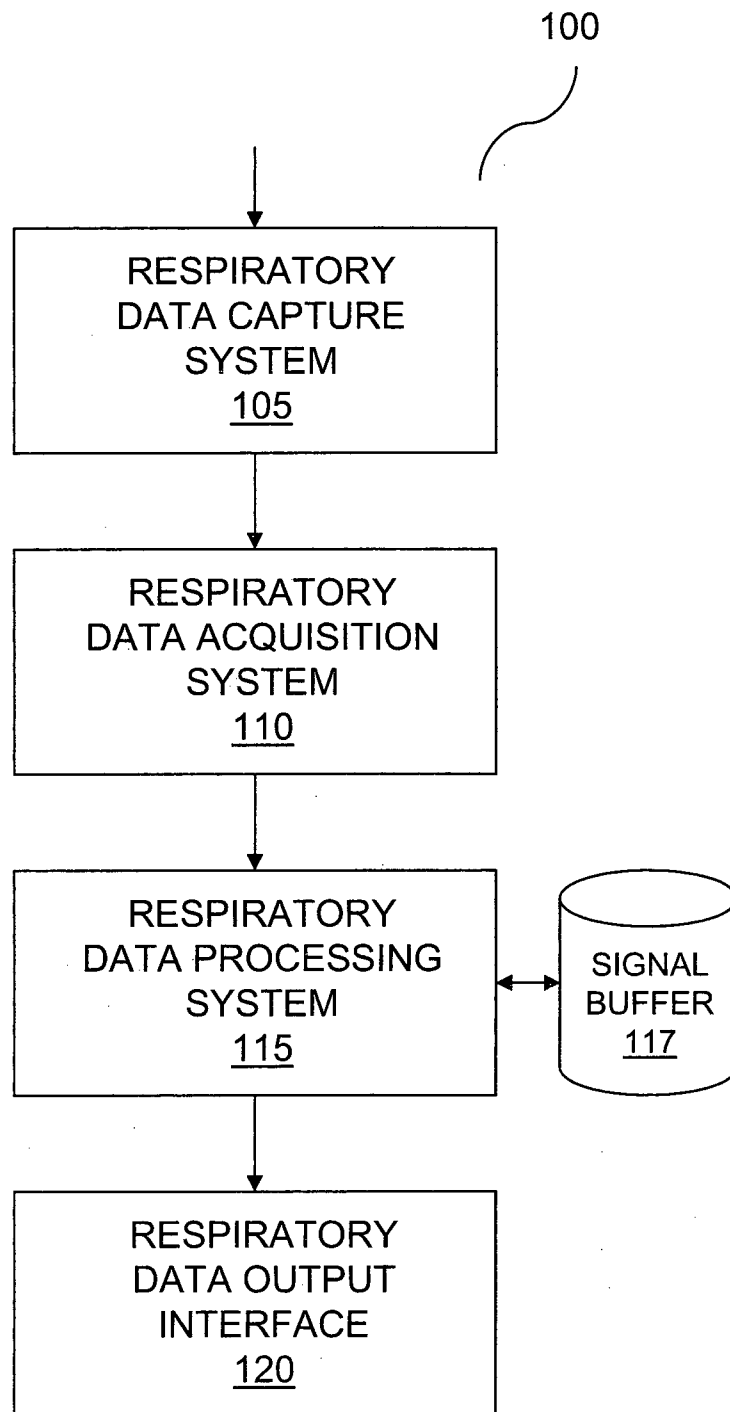
evaluating by the device conformance of the current estimate with expectations for the current estimate determined by the device using one or more prior estimates of
25 the physiological parameter calculated by the device from the

physiological signal; and

displaying by the device information regarding the current estimate determined by the device based at least in part on the evaluation.

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FIG. 1



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FIG. 2

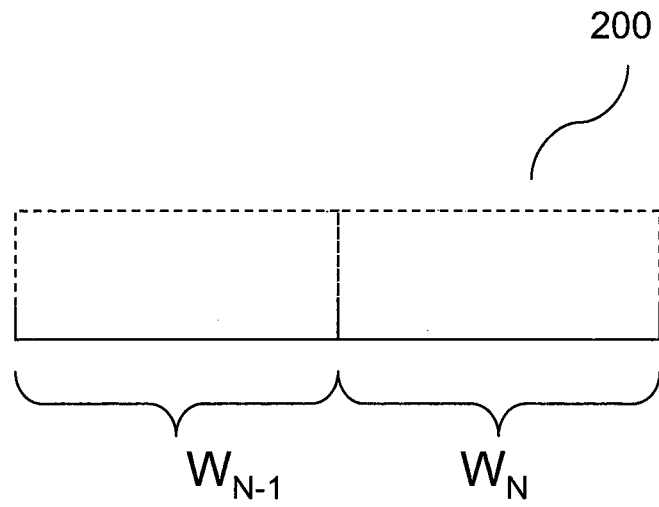
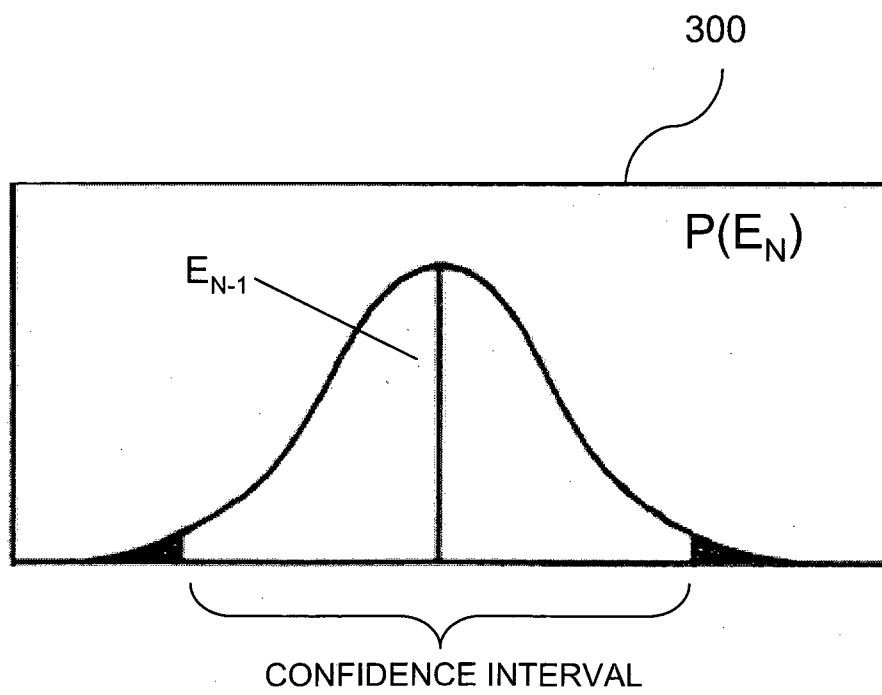


FIG. 3



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FIG. 4

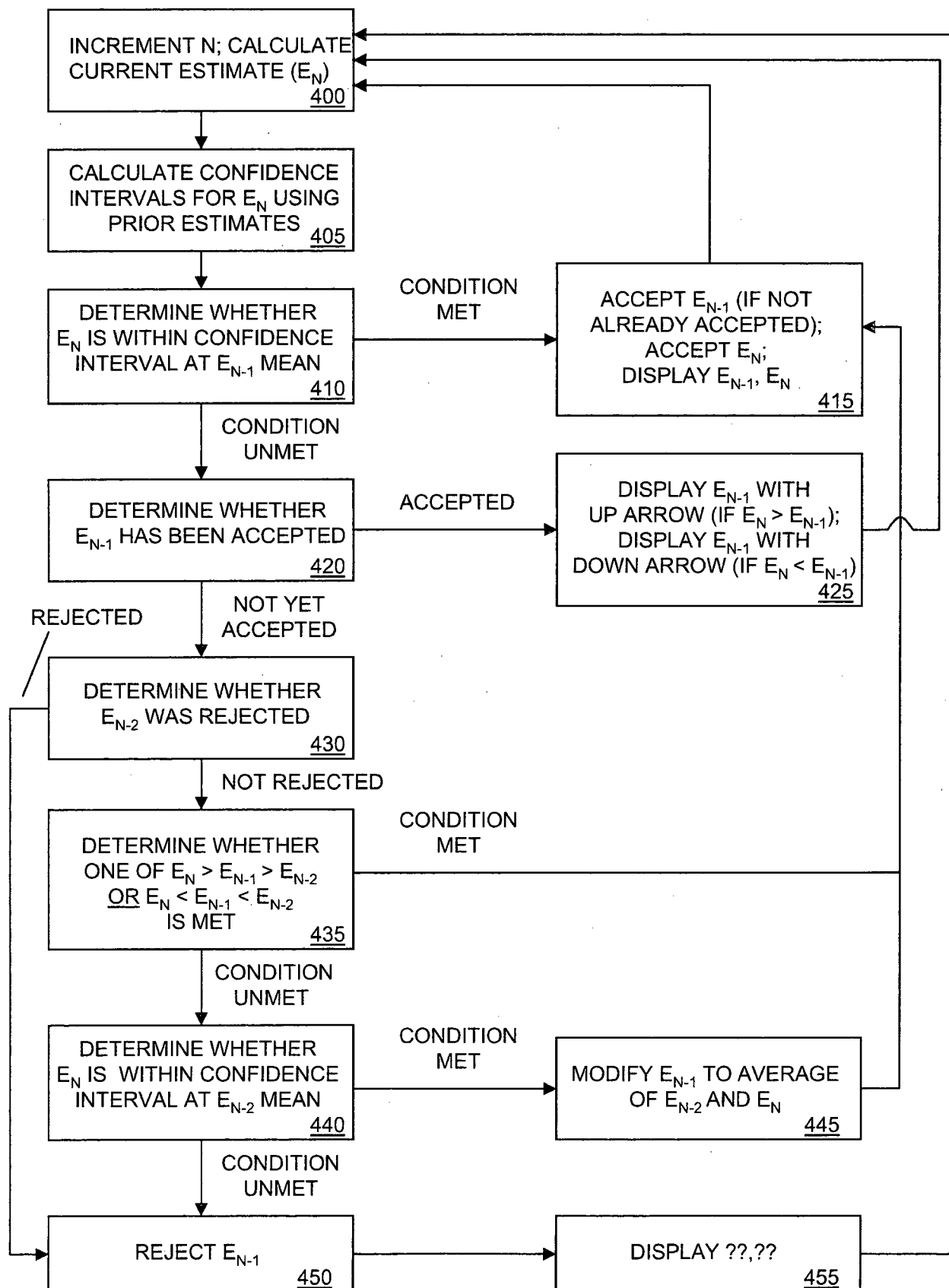


FIG. 5A

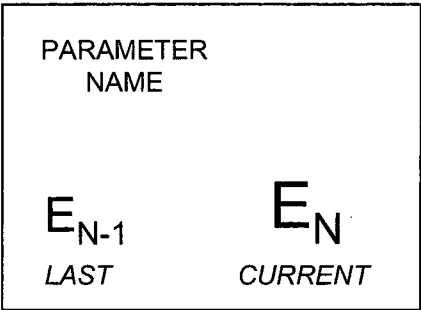


FIG. 5B

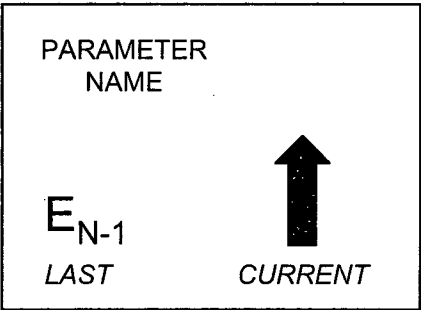
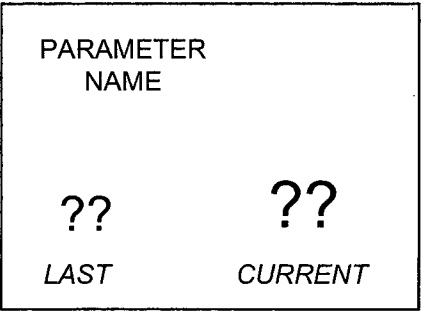
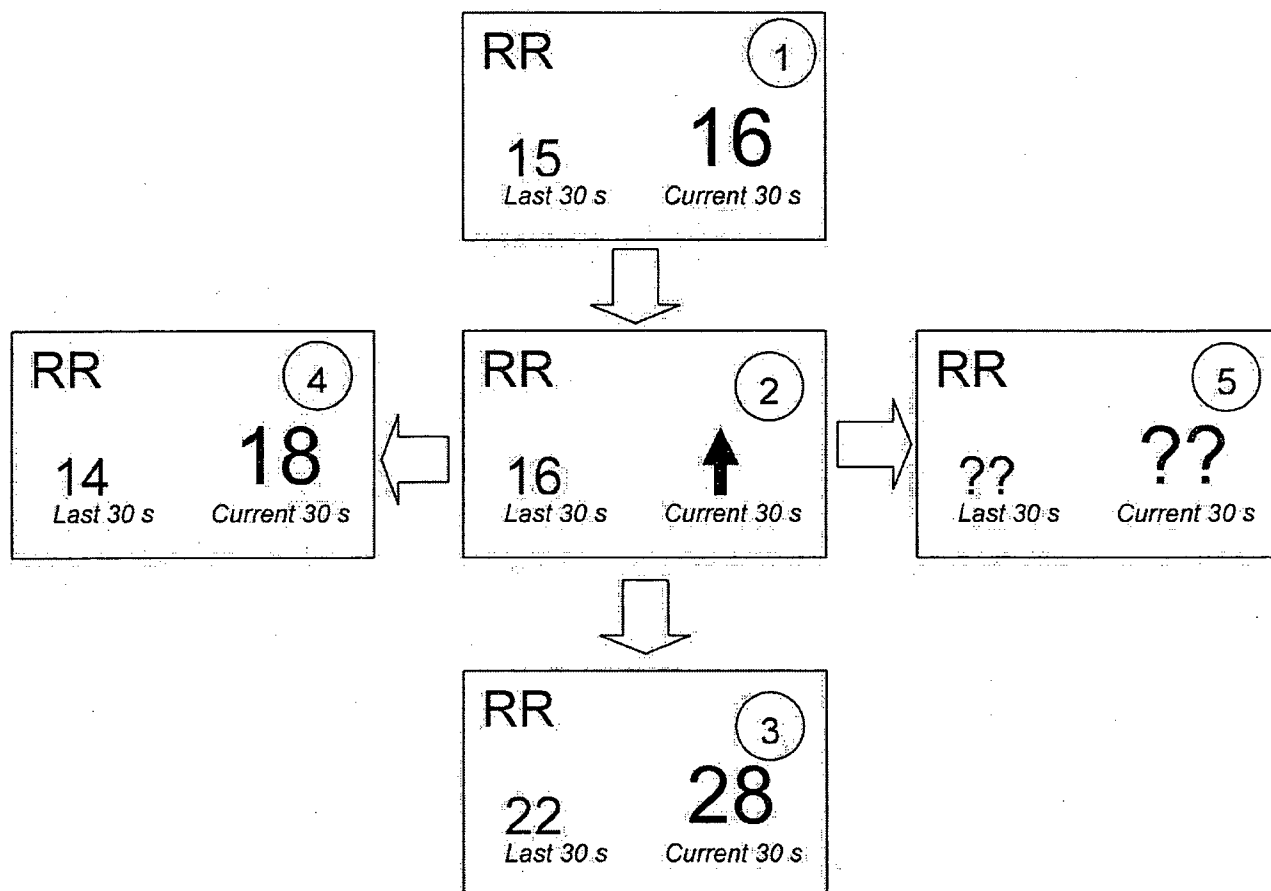


FIG. 5C



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FIG. 6



INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2011/063299

A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl. A61B5/0245 (2006.01) i, A61B5/11 (2006.01) i

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)

Int.Cl. A61B5/0245, A61B5/11

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

Published examined utility model applications of Japan 1922-1996
 Published unexamined utility model applications of Japan 1971-2011
 Registered utility model specifications of Japan 1996-2011
 Published registered utility model applications of Japan 1994-2011

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y A	US 2009/0112111 A1 (Shimizu Hideki) 2009.04.30, full sentence, all figures & JP 4458436 B & WO 2007/032226 A1 & CN 101262815 A	1, 2, 11 8-10 3-7
X Y A	JP 2002-191569 A (Seiko Co., Ltd.) 2002.07.09, full sentence, all figures (Family: none)	1-4, 11 8-10 5-7
Y	JP 09-81101 A (Seiko Co., Ltd.) 1997.03.28, claim4, figure9 & US 5795301 A & EP 761163 A2 & DE 69615115 D & DE 69615115 T	8
Y	JP 2005-341990 A (Noritz Co., Ltd.) 2005.12.15, 【0040】, figure11 (Family: none)	9



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

“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

02.09.2011

Date of mailing of the international search report

13.09.2011

Name and mailing address of the ISA/JP

Japan Patent Office

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Kazuyoshi Kuki

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2011/063299

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	JP 2002-65618 A (Olympus Co., Ltd.) 2002.03.05, 【0027】 , figure8 (Family:none)	1 0
A	JP 07-236617 A (Nihon Korin Co., Ltd.) 1995.09.12, 【0014】 & US 5649536 A & US 5836888 A & US 6045510 A & US 2002/0120199 A1 & US 6413224 B1	1 - 1 1
A	JP 2001-017403 A (Alpine electronics company Co., Ltd.) 2001.01.23, Claim11 (Family:none)	1 - 1 1
A	JP 2005-80712 A (Medical Bridge Co., Ltd.) 2005.03.31, figure18 (Family:none)	1 - 1 1

INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2011/063299

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

(Invention1) Claim1-5,11 (Invention2) Claim 6 (Invention3) Claim 7 (Invention4)
Claim 8 (Invention5) Claim 9 (Invention6) Claim 10

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☒ No protest accompanied the payment of additional search fees.