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(54) **APPARATUS AND METHOD FOR CARDIAC SIGNAL NOISE DETECTION AND DISPOSITION BASED ON PHYSIOLOGIC RELEVANCE**

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(52) **U.S. Cl.**

CPC **A61B 5/7207** (2013.01); **A61B 5/0402** (2013.01); **A61B 5/04017** (2013.01)

(57) **ABSTRACT**

(58) **Field of Classification Search**

CPC .. A61N 1/3704; A61N 1/3718; A61B 5/7207; A61B 5/04017; A61B 5/0428

See application file for complete search history.

An apparatus comprises an input configured to receive electrocardiogram (ECG) data detected by a patient monitoring device, the ECG data containing a physiologic signal and one or more segments of noise within the ECG data. A scrubber comprises a plurality of scrubbing modules each configured to process the ECG data and noise in a manner differing from other scrubbing modules. The scrubber is configured to filter the one or more noise segments that overlap with the physiologic signal, and consolidate the ECG data to eliminate the one or more noise segments that are non-overlapping with the physiologic signal. An output is configured to output scrubbed ECG data.

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20 Claims, 17 Drawing Sheets

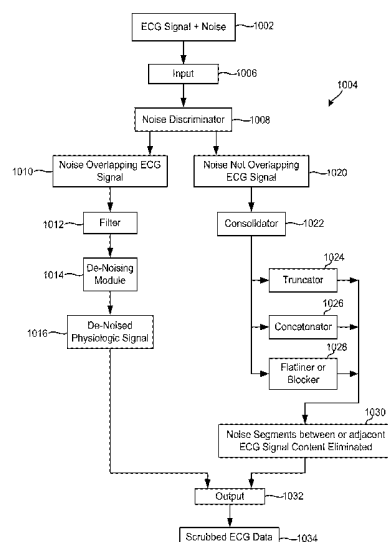


FIGURE 1

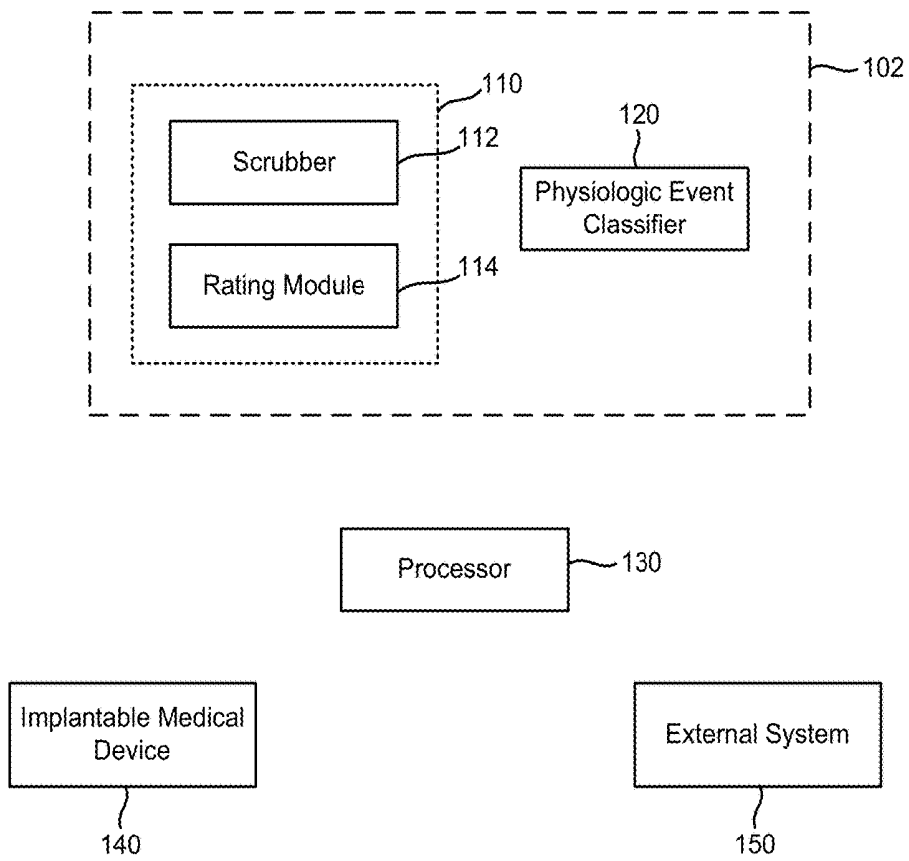


FIGURE 2

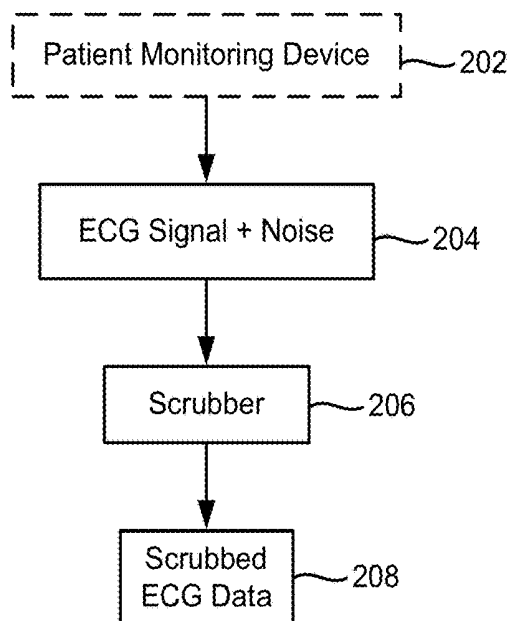


FIGURE 3

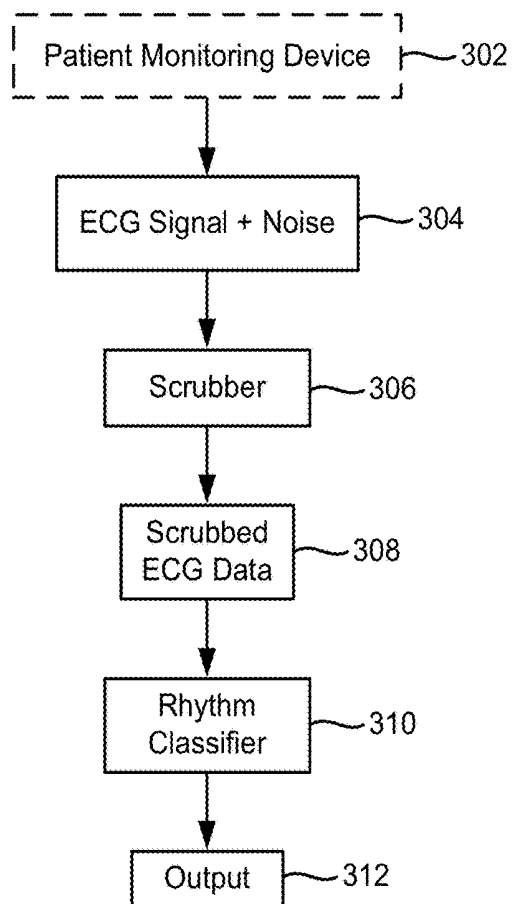


FIGURE 4

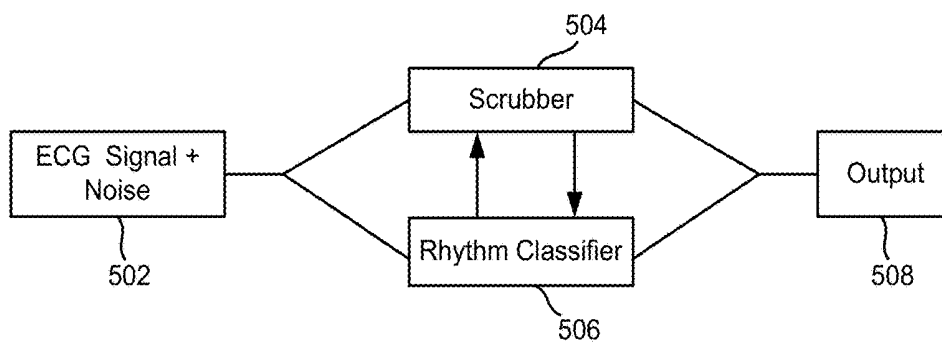
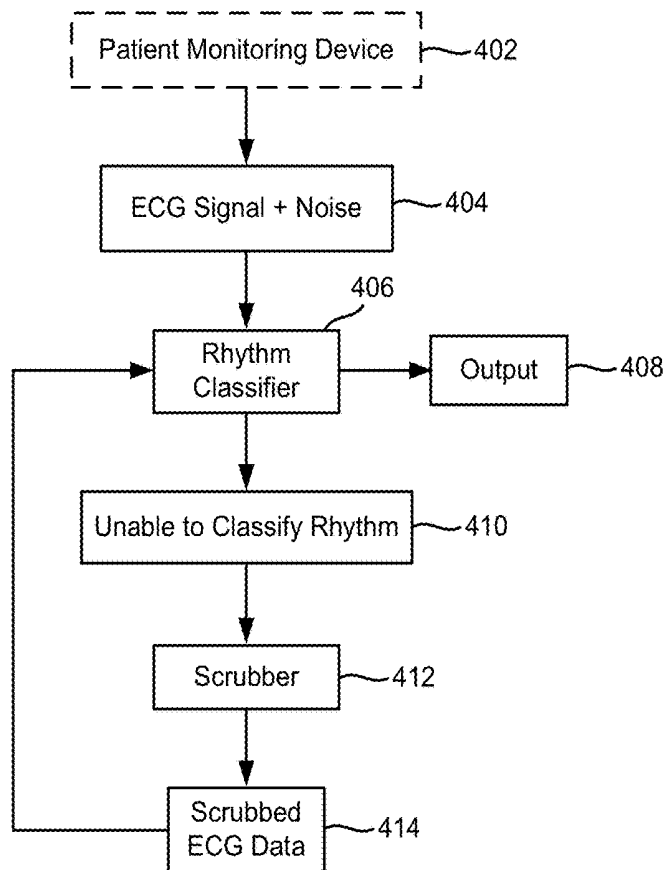


FIGURE 5

FIGURE 6

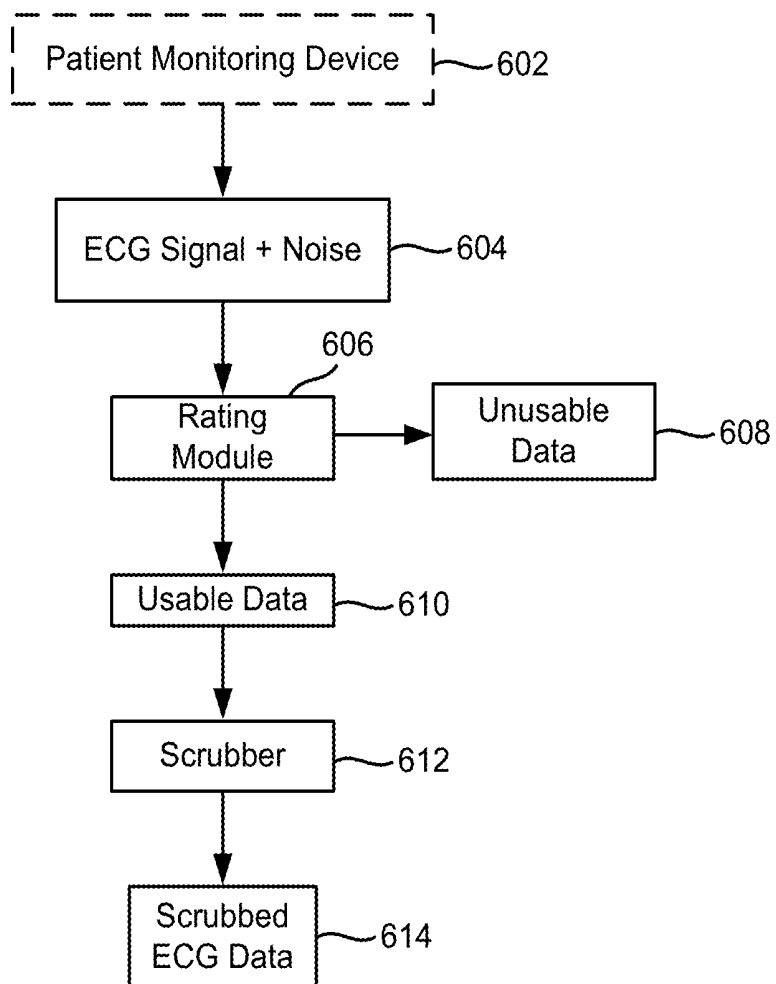
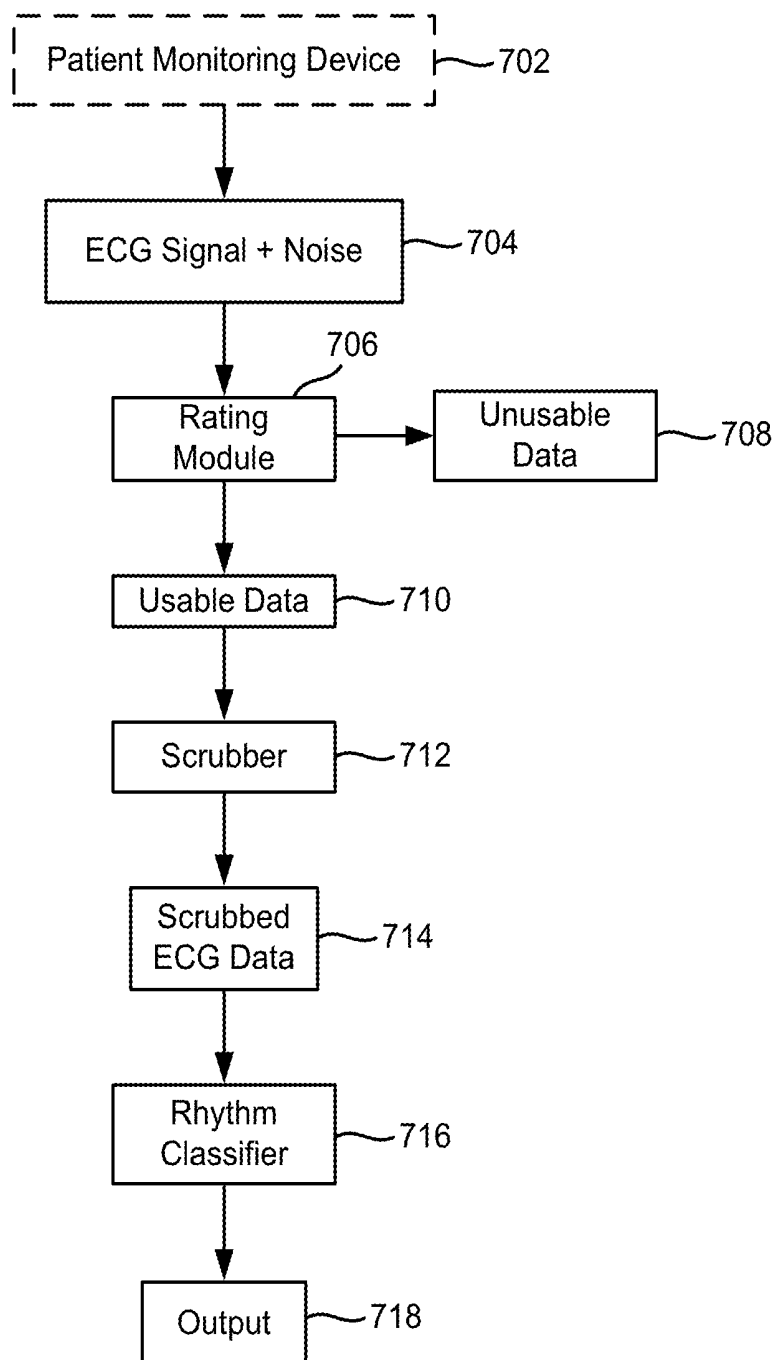


FIGURE 7



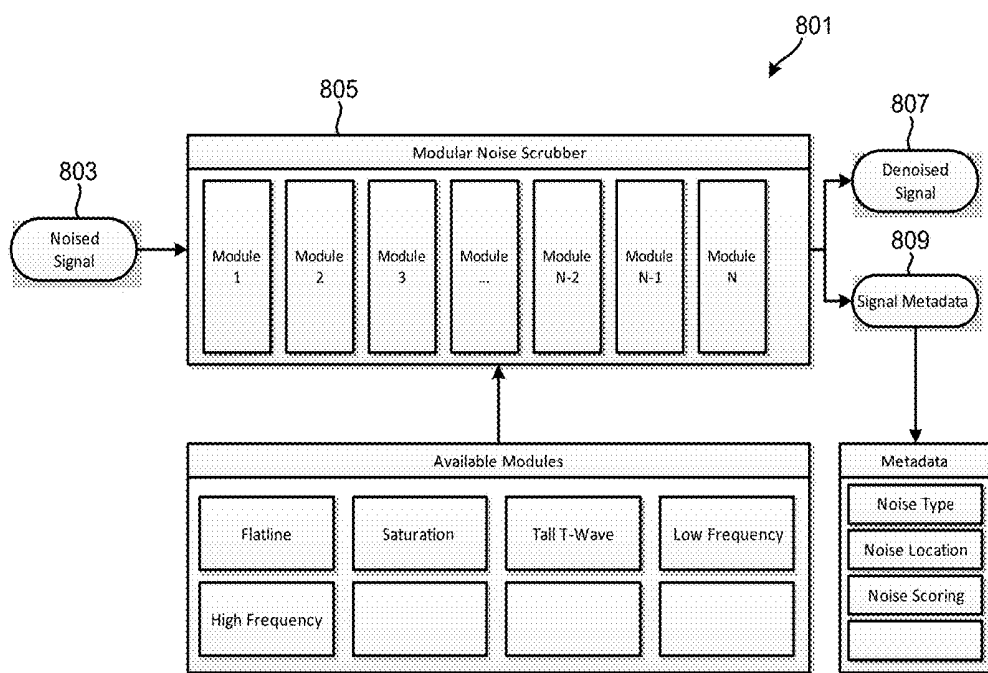


FIGURE 8A

FIGURE 8B

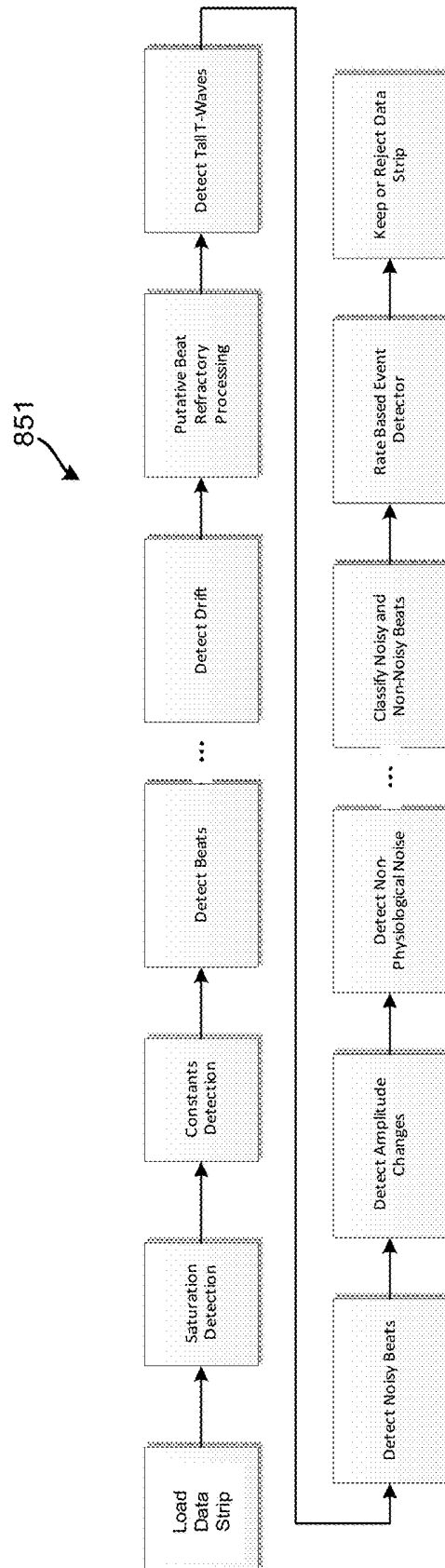


FIGURE 8C

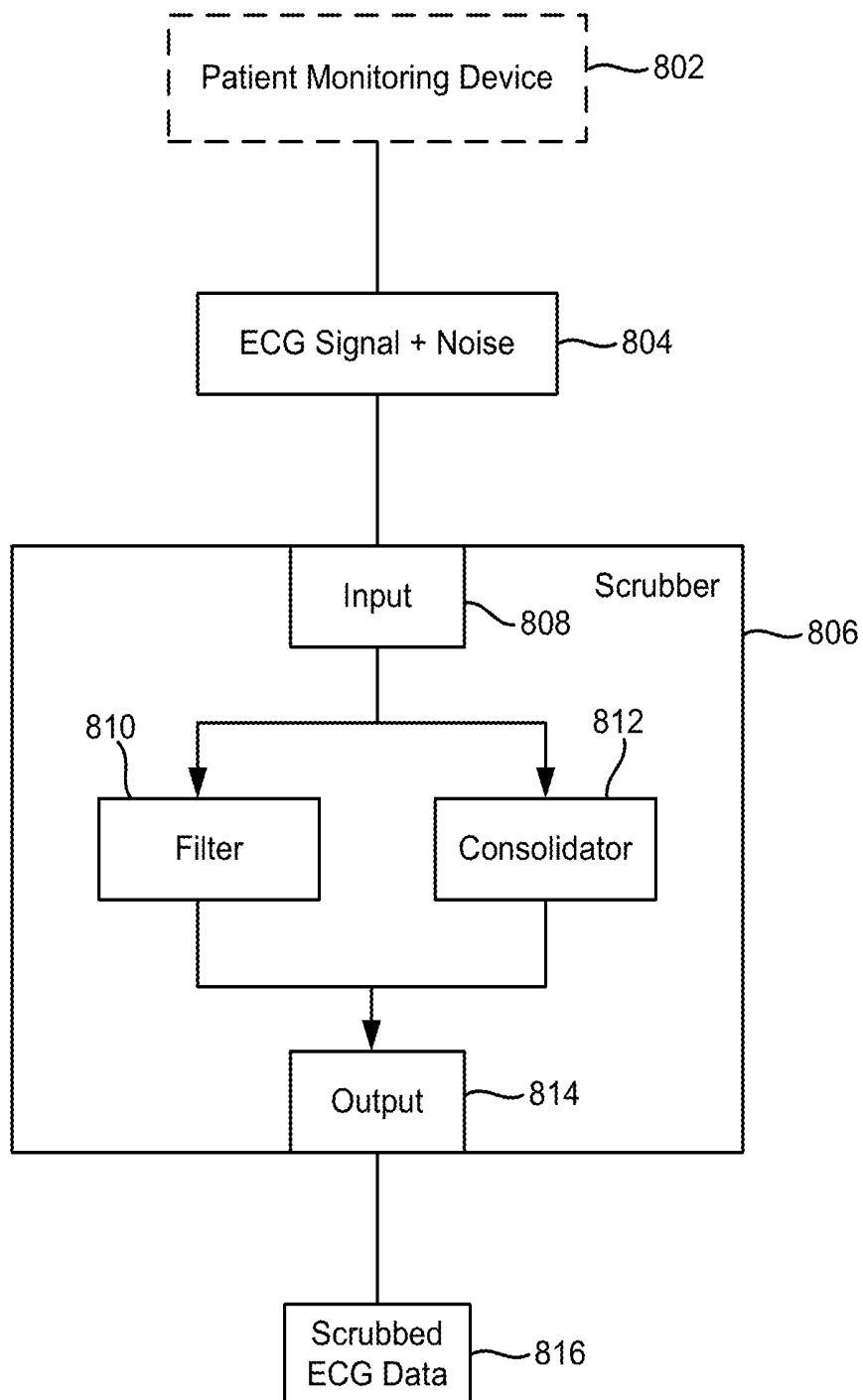


FIGURE 9

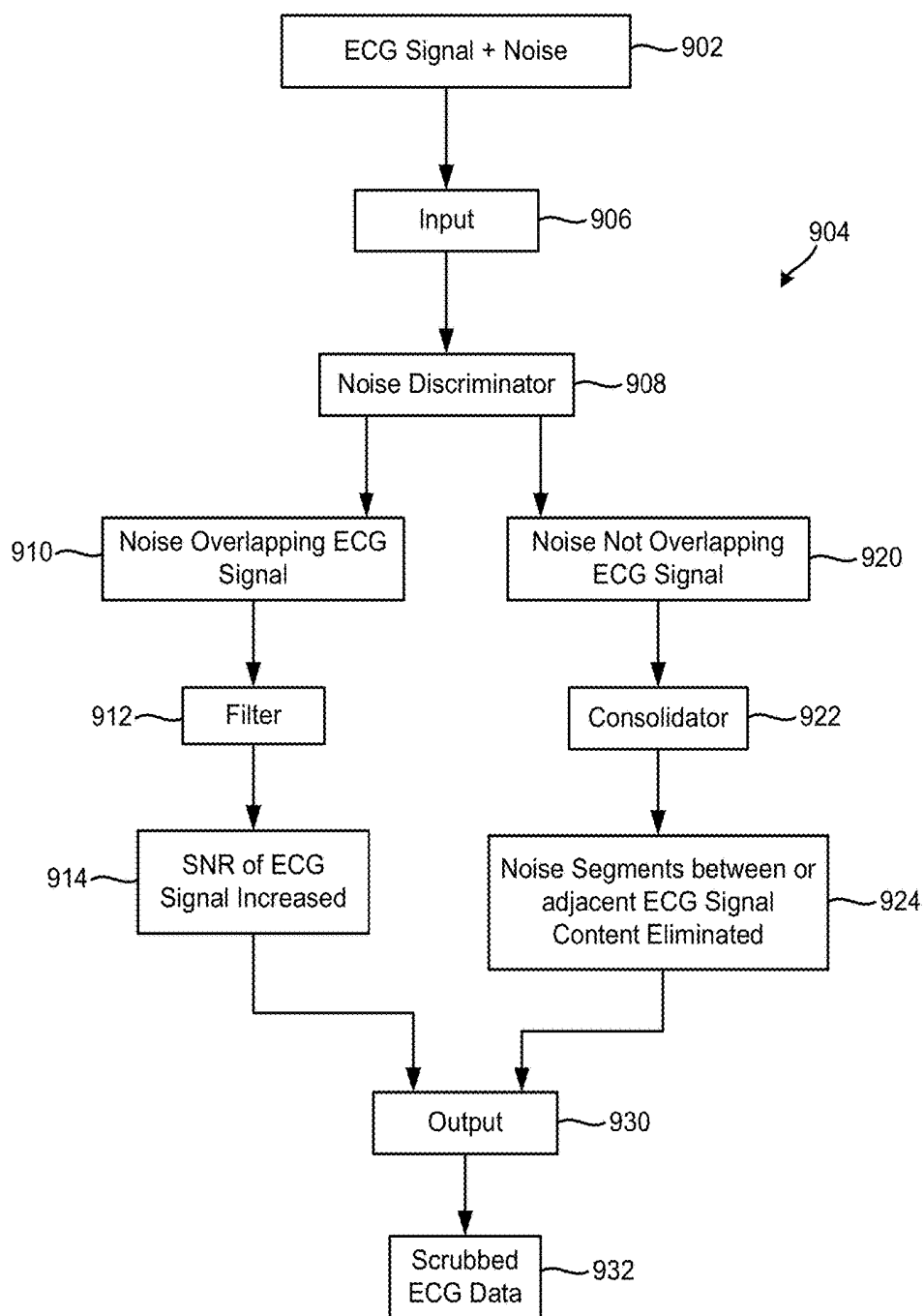
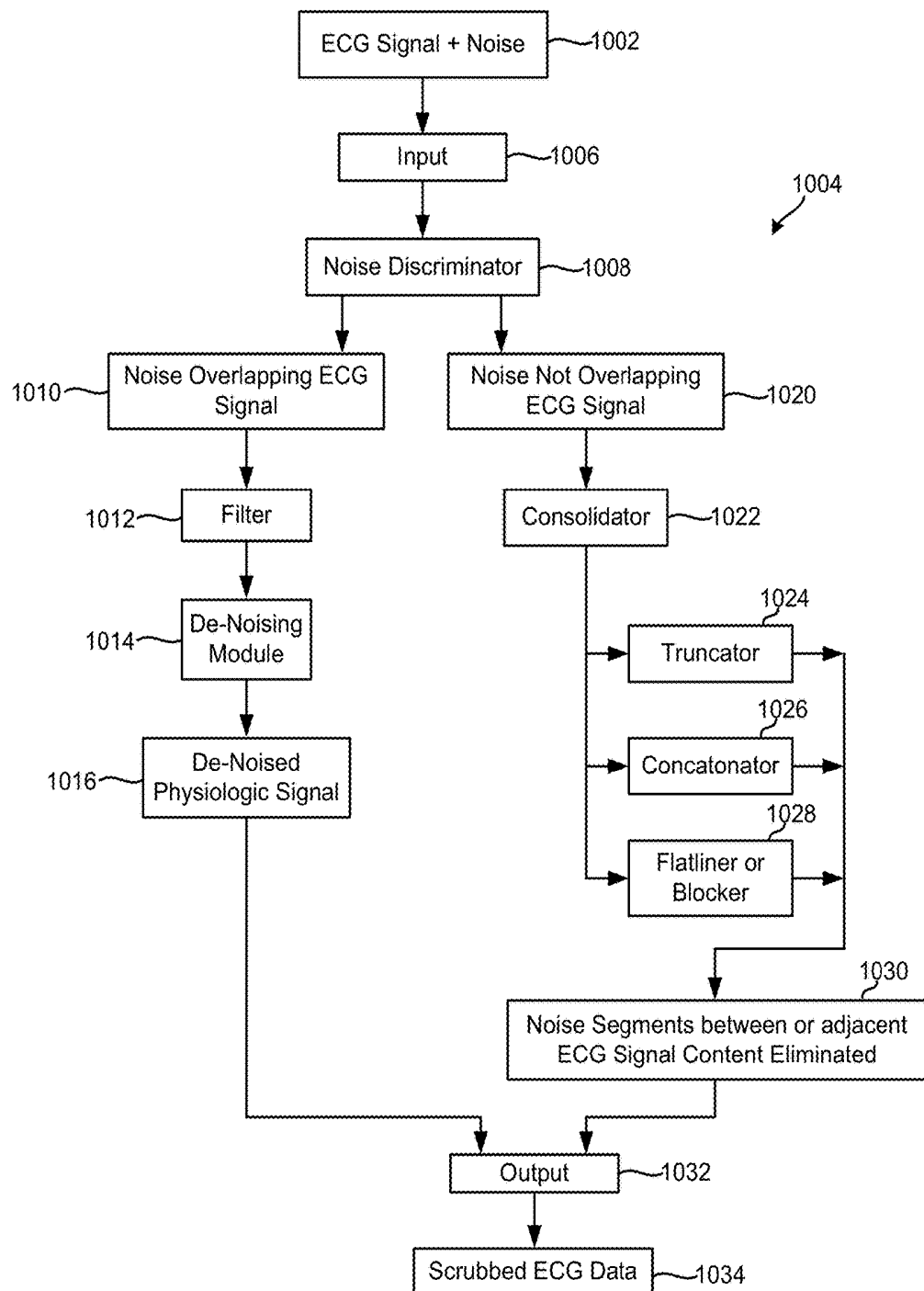


FIGURE 10A



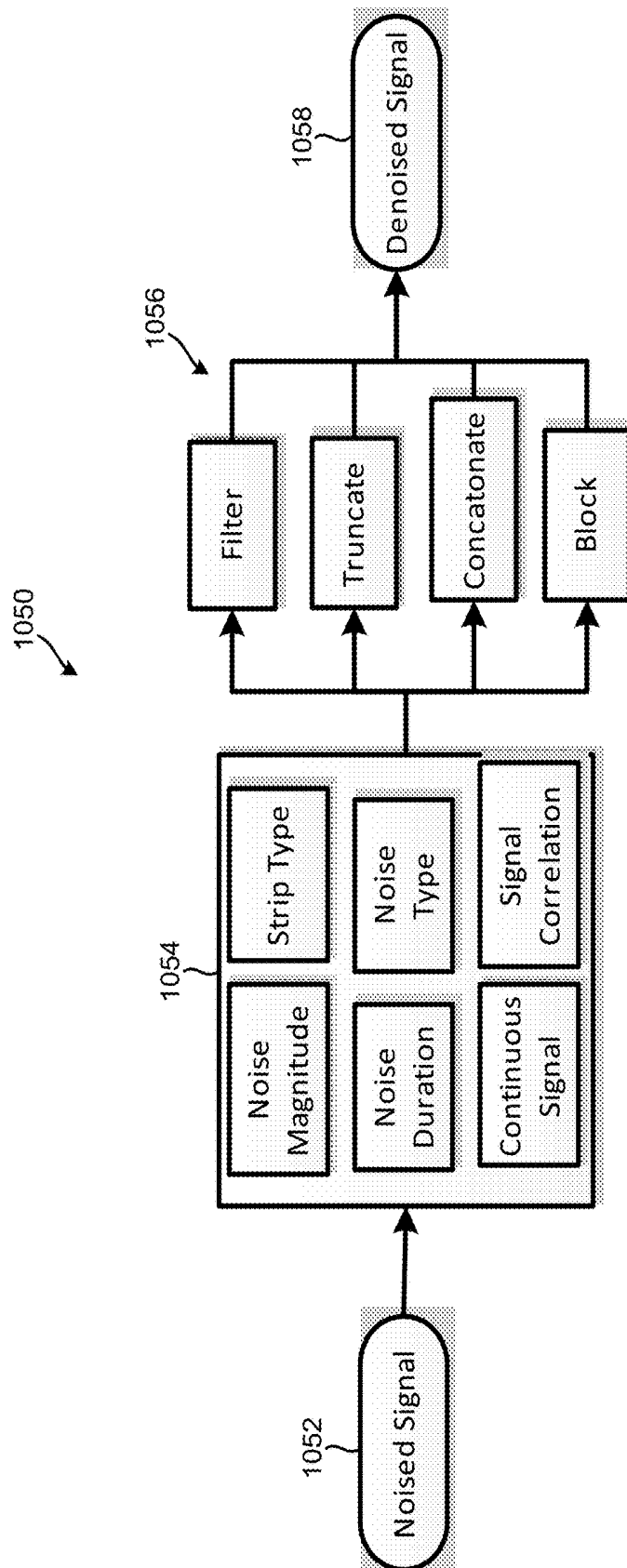
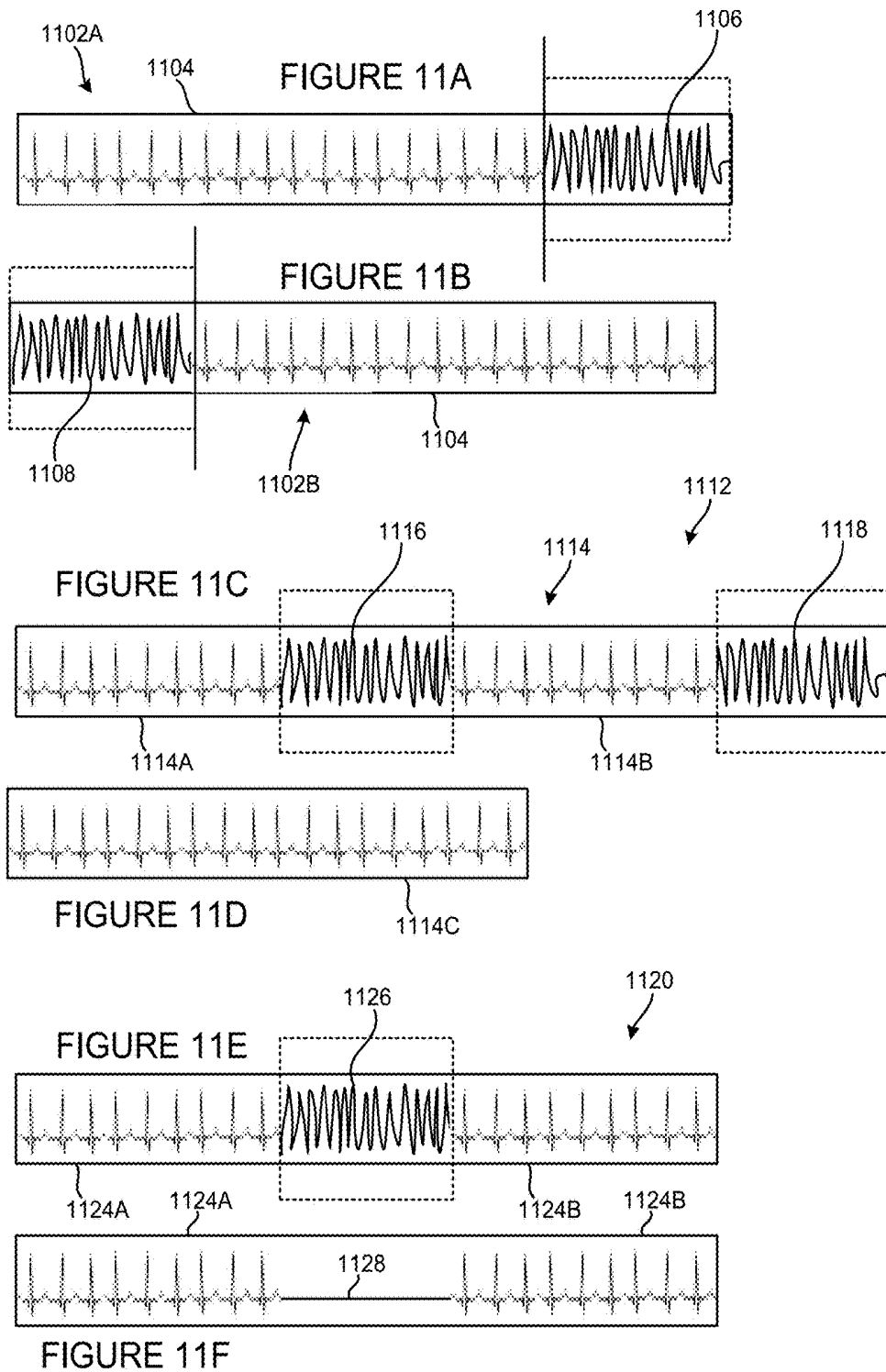
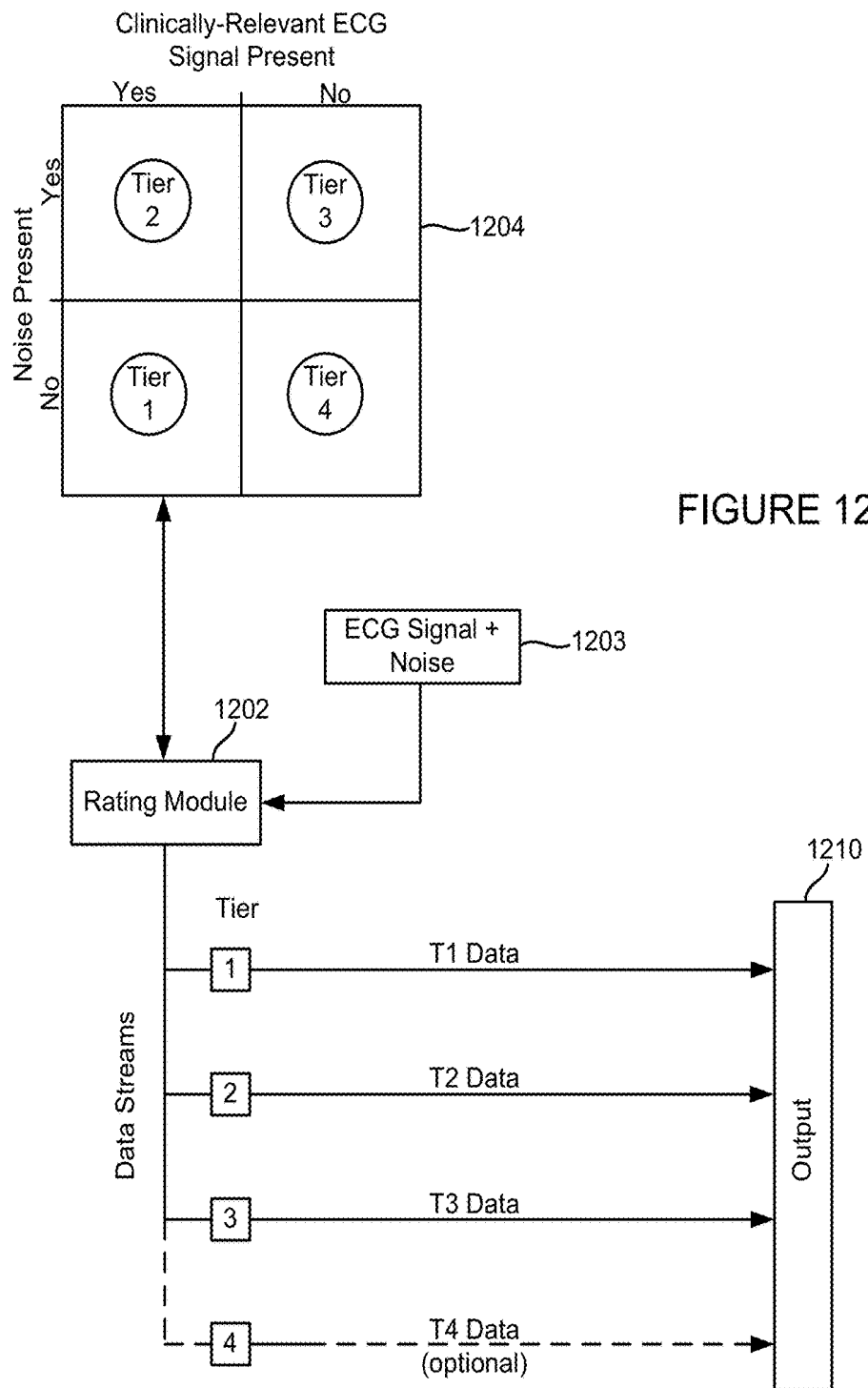


FIGURE 10B



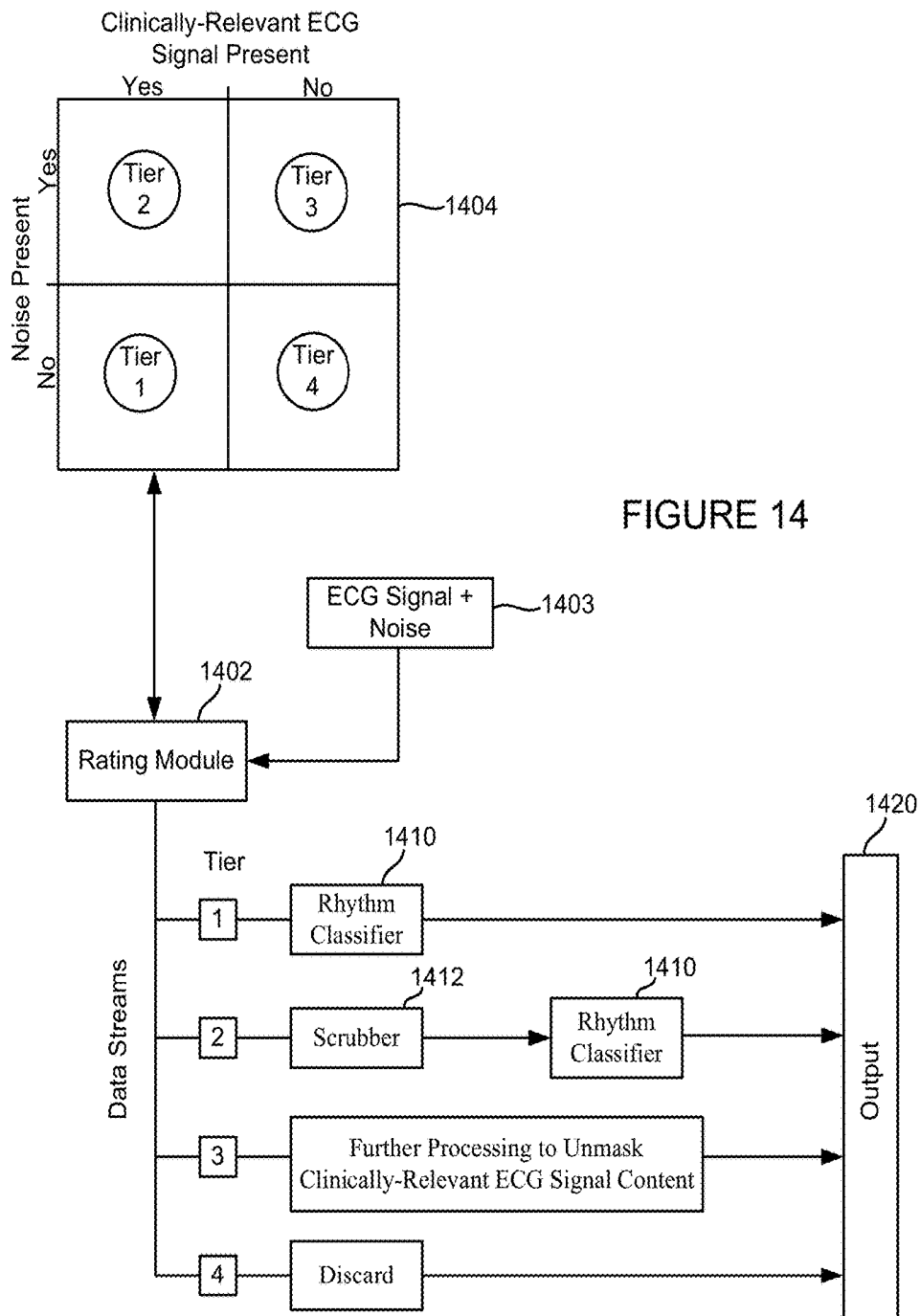


Clinically-Relevant ECG
Signal Present

		Yes	Maybe	No
Noise Present	Yes	Tier 2	Tier 3	Tier 4
	Maybe	Tier 3	Tier 3	Tier 4
	No	Tier 1	Tier 3	Tier 4

1304

FIGURE 13



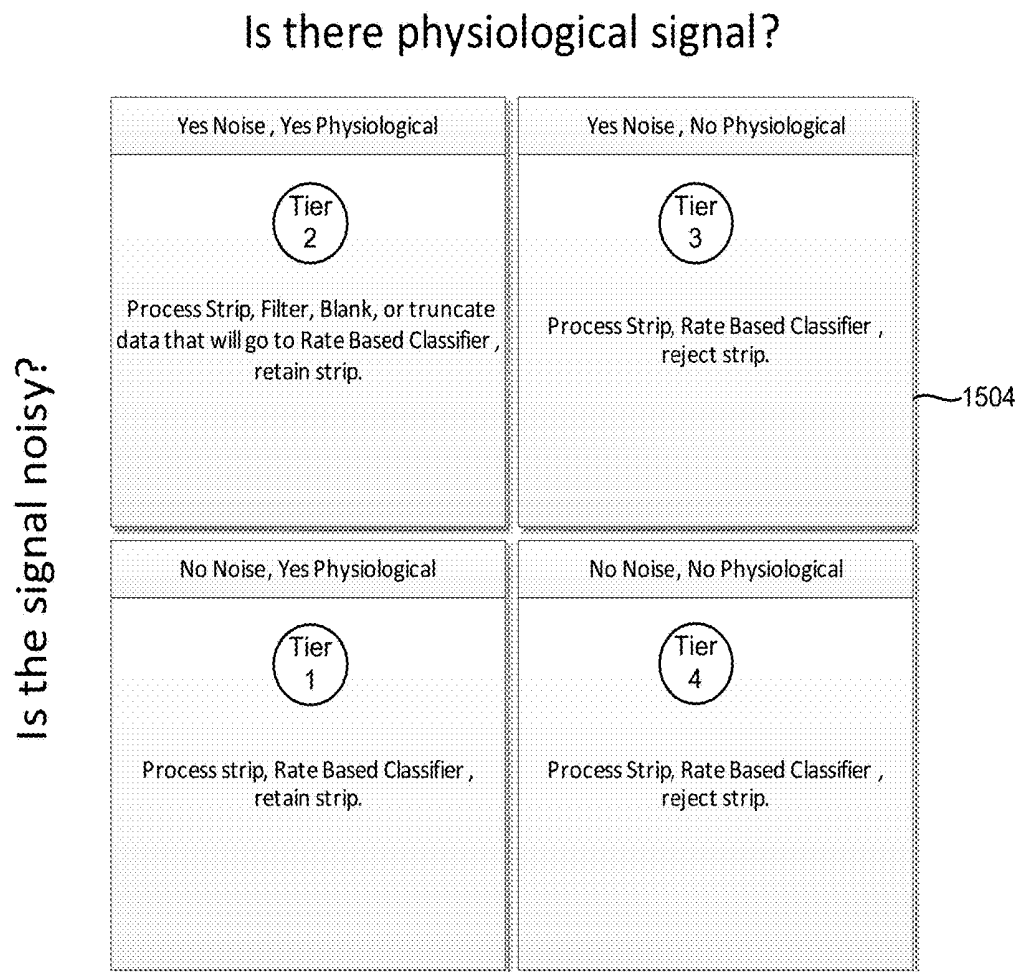
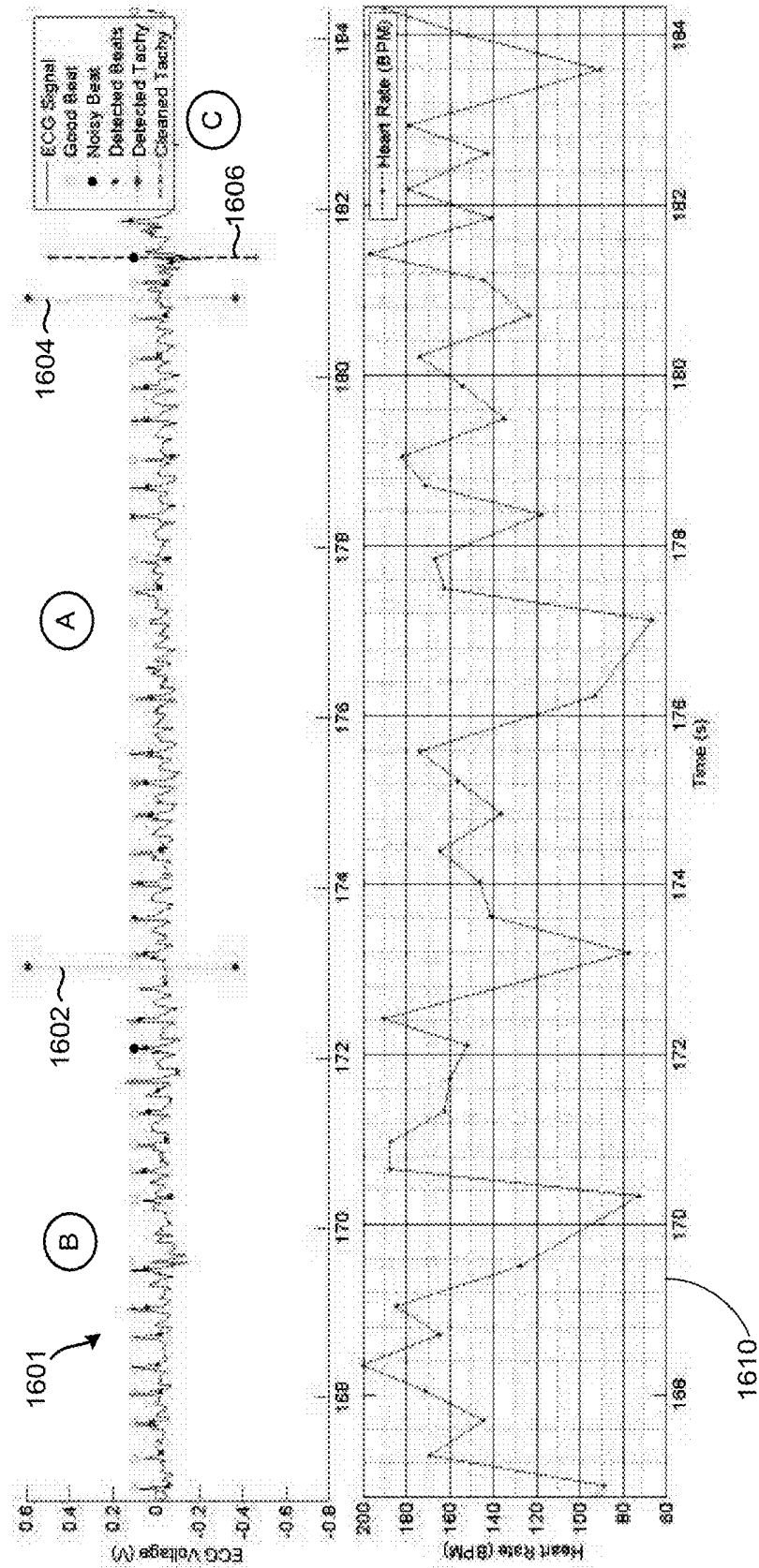


FIGURE 15

FIGURE 16



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APPARATUS AND METHOD FOR CARDIAC SIGNAL NOISE DETECTION AND DISPOSITION BASED ON PHYSIOLOGIC RELEVANCE

TECHNICAL FIELD

This patent document pertains generally to noise detection and more particularly, but not by way of limitation, to noise detection in a cardiac signal.

BACKGROUND

Noise in signals can be problematic. This can be especially true with cardiac signals. In some instances, noise sources can cause false triggers of arrhythmia recording devices leading to high false positive rates. In some instances, one or more noise sources in a cardiac recording can conceal or completely eliminate a relevant cardiac signal. Recording excessive amounts of noise in addition to cardiac signal content can be wasteful, in terms of processing time, memory usage, and time required to evaluate cardiac signal information (e.g., electrocardiogram data or strips) by a clinician.

SUMMARY

Embodiments of the disclosure are directed to a method comprising receiving electrocardiogram (ECG) data detected by a patient monitoring device, the ECG data containing a physiologic signal and sporadic noise. The method also comprises identifying a temporal occurrence of the ECG data and a temporal occurrence of one or more segments of noise within the ECG data. The method further comprises scrubbing the ECG data by filtering the one or more noise segments that overlap with the physiologic signal, and consolidating the ECG data to eliminate the one or more noise segments that are non-overlapping with the physiologic signal. The method also comprises generating an output comprising scrubbed ECG data.

Other embodiments are directed to an apparatus comprising an input configured to receive electrocardiogram (ECG) data detected by a patient monitoring device, the ECG data containing a physiologic signal and one or more segments of noise within the ECG data. A scrubber comprises a plurality of scrubbing modules each configured to process the ECG data and noise in a manner differing from other scrubbing modules. The scrubber is configured to filter the one or more noise segments that overlap with the physiologic signal, and consolidate the ECG data to eliminate the one or more noise segments that are non-overlapping with the physiologic signal. An output is configured to output scrubbed ECG data.

The above summary is not intended to describe each disclosed embodiment or every implementation of the present disclosure. The figures and the detailed description below more particularly exemplify illustrative embodiments

BRIEF DESCRIPTION OF THE DRAWINGS

Throughout the specification reference is made to the appended drawings, where like reference numerals designate like elements, and wherein:

FIG. 1 is a block diagram of a system for processing physiologic signals and noise in accordance with various embodiments;

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FIG. 2 illustrates an embodiment of a physiologic signal processor configured to receive ECG data from a patient monitoring device in accordance with various embodiments;

FIG. 3 illustrates an embodiment of a physiologic signal processor configured to receive ECG data from a patient monitoring device in accordance with various embodiments;

FIG. 4 illustrates an embodiment of a physiologic signal processor configured to receive ECG data from a patient monitoring device in accordance with various embodiments;

FIG. 5 illustrates an embodiment of a physiologic signal processor which involves parallel processing between a noise scrubber and a rhythm classifier in accordance with various embodiments;

FIG. 6 illustrates an embodiment of a physiologic signal processor which includes a rating module in accordance with various embodiments;

FIG. 7 illustrates an embodiment of a physiologic signal processor which includes a rating module, a noise scrubber, and a rhythm classifier in accordance with various embodiments;

FIG. 8A illustrates an embodiment of a noise scrubber in accordance with various embodiments;

FIG. 8B illustrates an embodiment of a noise scrubber in accordance with various embodiments;

FIG. 8C illustrates an embodiment of a noise scrubber in accordance with various embodiments;

FIG. 9 illustrates various details of a noise scrubber in accordance with various embodiments;

FIG. 10A illustrates various details of a noise scrubber in accordance with other embodiments;

FIG. 10B illustrates de-noising signal flow through a scrubber in accordance with some embodiments;

FIGS. 11A-11F illustrate different ECG data containing noise subject to consolidation by a noise scrubber in accordance with various embodiments;

FIG. 12 illustrates various details of a rating module in accordance with various embodiments;

FIG. 13 illustrates a decision matrix included in or coupled to a rating module in accordance with various embodiments;

FIG. 14 is a diagram showing combined use of a rating module, a decision matrix, a noise scrubber, and a rhythm classifier in accordance with various embodiments;

FIG. 15 illustrates a decision matrix which can be coupled to a rating module in accordance with various embodiments; and

FIG. 16 is an output of a scrubber according to various embodiments.

The figures are not necessarily to scale. Like numbers used in the figures refer to like components. However, it will be understood that the use of a number to refer to a component in a given figure is not intended to limit the component in another figure labeled with the same number.

DETAILED DESCRIPTION

The present inventors have recognized, among other things, that noise in a cardiac signal is generally undesirable and have sought to lessen if not eliminate noise in a cardiac signal. The present inventors have recognized that it is desirable to provide an apparatus or method for cardiac signal noise detection and disposition based on physiologic relevance, through noise reduction in conjunction with characterization and tiered prioritization of data.

In the following detailed description, reference is made to the accompanying drawing which form a part hereof, and in which is shown by way of illustration specific examples in

which the present description may be practiced. These examples are described in sufficient detail to enable those skilled in the art to practice the present subject matter, and it is to be understood that other examples may be utilized and that structural changes may be made without departing from the scope of the present description. Therefore, the following detailed description is not to be taken in a limiting sense.

In this document, the terms “a” or “an” are used, as is common in patent documents, to include one or more than one, independent of any other instances or usages of “at least one” or “one or more.” In this document, the term “or” is used to refer to a nonexclusive or, such that “A or B” includes “A but not B,” “B but not A,” and “A and B,” unless otherwise indicated. In this document, the terms “including” and “in which” are used as the plain-English equivalents of the respective terms “comprising” and “wherein.” Also, the terms “including” and “comprising” are open-ended, that is, a system, device, article, or process that includes elements in addition to those listed after such a term are still deemed to fall within the scope of the description. Moreover, the terms “first,” “second,” and “third,” etc. are used merely as labels, and are not intended to impose numerical requirements on their objects.

FIG. 1 is a block diagram of a system for processing physiologic signals and noise in accordance with various embodiments. The system shown in FIG. 1 includes a physiologic signal processor **102** configured to receive physiologic signal data containing a physiologic signal and one or more artifactual segments of noise confounding the physiologic signal. In various embodiments, the physiologic signal data received by the physiologic signal processor **102** is produced by a patient monitoring device, such as an implantable or external device that monitors a patient's electrocardiogram (ECG). For example, the ECG data received by the physiologic signal processor **102** can be equivalent in signal content to that which is presented on an ECG strip. Although embodiments disclosed herein are described as being implemented to process ECG data, it is understood that other forms of physiologic signal data are contemplated (e.g., electrogram (EGM), electroencephalogram (EEG), electromyogram (EMG)). The physiologic signal processor **102** includes a noise processor **110**. In some embodiments, the physiologic signal processor **102** also includes a physiologic rate and/or rhythm classifier **120**, it being understood that the classifier **120** may be excluded in various embodiments.

The term ECG signal or data is used throughout the disclosure and, in particular, in the context of noise that can obscure or mask the presence of ECG signal content that is clinically relevant (e.g., usable for diagnostic purposes). It is understood that the term ECG signal or data used herein generally refers to an ECG signal or data that contains clinically-relevant content. In some portions of the disclosure, the term clinically-relevant ECG signal or data is explicitly used, while in others this connotation of the term is implicit.

According to some embodiments, the noise processor **110** includes a noise scrubber **112**. The scrubber **112** typically comprises a multiplicity of noise scrubbing modules each configured to process the physiologic signal and noise in a manner differing from other scrubbing modules. For example, the scrubber **112** includes one or more scrubbing modules that are designed to operate on noise segments that overlap with a physiologic event. The scrubber **112** also includes one or more scrubbing modules that are designed to operate on noise segments that are non-overlapping with a

physiologic event. A scrubbed physiologic signal (e.g., a scrubbed ECG signal) is produced at the output of scrubber **112**. The scrubber **112** may be the exclusive component of the noise processor **110** or, in accordance with various embodiments, may be combined with other components.

In other embodiments, the noise processor **110** includes a rating module **114**, which may be the exclusive component of the noise processor **110** or, in some embodiments, may be combined to operate with the scrubber **112**. The rating module **114** is configured to rate the physiologic signal data input to the noise processor **110** based on the presence or absence of both the physiologic signal and noise, as well as input from other sources external to the rating module **114**, such as patient activated markers. The rating module **114** analyzes the physiologic signal data for noise content that would render the physiologic signal either undetectable or unusable. The rating module **114** employs a decision matrix to distinguish physiologic signal data that can be readily processed from physiologic signal data that requires scrubbing or further processing. The rating module **114** can be configured to flag or annotate the physiologic signal data, such as by adding noise markers to the data. The rating module **114** can facilitate the production of a multiplicity of data streams that differ in terms of noise content. The different data streams can be processed in a manner appropriate for each data stream in accordance with various embodiments.

According to further embodiments, the physiologic signal processor **102** includes a physiologic event classifier **120**. In general terms, the physiologic event classifier **120** is configured to detect and classify physiologic events based on pre-specified criteria within the physiologic signal data. In various embodiments disclosed herein, the physiologic event classifier **120** is implemented as a general rhythm classifier. In various embodiments disclosed herein, the physiologic event classifier **120** is implemented solely as a rate classifier. In some embodiments, the physiologic event classifier **120** is implemented to operate in cooperation with the scrubber **112**. In other embodiments, the physiologic event classifier **120** is implemented to operate cooperatively with both the scrubber **112** and the rating module **114**.

A physiologic event classifier **120** implemented as a rhythm classifier, according to various embodiments, is configured to classify a cardiac rhythm based on ECG data received by the physiologic signal processor **102**. In some embodiments, the rhythm classifier implements a known rate classification algorithm for classifying cardiac rhythms, such as bradycardia, tachycardia, and asystole. In other embodiments, the rhythm classifier uses algorithms that analyze the morphology of ECG signals for classifying cardiac rhythms. Various known template matching and processing algorithms can be employed for analyzing the morphology of ECG signals for purposes of classifying cardiac rhythms. Other algorithms can be implemented by the rhythm classifier when classifying cardiac rhythms, such as pattern-based and wavelet-based algorithms.

The system shown in FIG. 1 can include a processor **130** which can be configured to coordinate the operations of the physiologic signal processor **102** and the flow of data through the physiologic signal processor **102** and other system components. In some embodiments, some or all of the components of the physiologic signal processor **102** can be implemented in an implantable medical device **140**, such as a loop recorder or a cardiac rhythm management device. In other embodiments, some or all of the components of the physiologic signal processor **102** can be implemented in an external system **150**, such as a system that includes a

desktop or laptop computer. For example, a patient monitoring device (e.g., implantable or external) can be implemented to monitor and store ECG data. The ECG data can be communicated in batch mode or in real-time to an external system **140** which includes one or more of the components of the physiologic signal processor **102**. The received ECG data can be processed by the external system **150** according to the embodiments described herein.

FIGS. **2** through **15** illustrate various embodiments or aspects of a physiologic signal processor that incorporates one or a combination of the components shown in FIG. **1**. FIG. **2** illustrates an embodiment of a physiologic signal processor configured to receive ECG data from a patient monitoring device **202**. The ECG data **204** contains an ECG signal and one or more segments of noise. A scrubber **206** is configured to operate on the ECG data in a manner discussed herein. Scrubbed ECG data is produced at an output **208** of the scrubber **206**.

FIG. **3** illustrates an embodiment of a physiologic signal processor configured to receive ECG data **304** from a patient monitoring device **302**. The ECG data **304**, which includes an ECG signal and noise, is input to a scrubber **306** which produces scrubbed ECG data **308** at its output. The scrubbed ECG data **308** is input to a rhythm classifier **310**, which is configured to classify cardiac rhythms based on the scrubbed ECG data **308**. Either the scrubber **306** or the rhythm classifier **310** is configured to determine if a sufficient amount of ECG signal content is present in the scrubbed ECG data **308** to properly classify cardiac rhythms. Data produced by the rhythm classifier **310** is provided at an output **312**. For example, data output from the rhythm classifier **310** may include an indication of normal sinus rhythm, bradycardia, tachycardia, and asystole, for example. The data output by the rhythm classifier **310** or the scrubber **306** may also include various cardiac event markers and/or noise markers that can be used to annotate ECG data provided at the output **312**.

In general, the duration and number of ECG data recordings produced by the patient monitoring device **302** can vary. In some cases, the ECG data produced by the patient monitoring device **302** resulted as a response to a patient-initiated command issued to the patient monitoring device **302**. For example, a patient may be able to initiate recording of cardiac activity for a period of 7 minutes by actuating a control on an external medical device or on an external communication device that interfaces with an implantable medical device (e.g., a loop recorder). In some cases, device triggered recording of ECG data can result in ECG recordings of 1 minute in duration, based on preset criteria for triggering such as a minimum heart rate or a certain type of rhythm, for example. In other cases, a trending algorithm can be implemented by an external or implantable medical device, wherein 20 second ECG recordings are regularly obtained, based on a specific time lapse. In these scenarios involving different amounts of ECG data, the rhythm classifier **310** (or the scrubber **306**) is configured to evaluate whether a sufficient amount of ECG data is available after scrubbing to allow for proper classification of various cardiac rhythms, it being understood that different cardiac rhythms may require a different minimum amount of ECG data to be accurately classified by the rhythm classifier **310**.

FIG. **4** illustrates an embodiment of a physiologic signal processor configured to receive ECG data **404** from a patient monitoring device **402**. In this embodiment, ECG data **404** is initially communicated to a rhythm classifier **406**. If the ECG data **404** is suitable for classification, the rhythm classifier **406** generates an output **408** indicating the classi-

fied cardiac rhythm. If the ECG data cannot be classified **410**, such as due to the presence of noise, the ECG data is communicated to a scrubber **412**. Scrubbed ECG data **414** is communicated back to the rhythm classifier **406** which, once again, attempts to classify the cardiac rhythm using the scrubbed ECG data **414**. If the rhythm classifier **406** is unable to classify the rhythm after repeated attempts, the ECG data **414** is discarded and processing is terminated, with a specific annotation to the nature of the data classification failure provided at the output **408** to indicate such failure.

FIG. **5** illustrates an embodiment of a physiologic signal processor which involves parallel processing between a scrubber **504** and a rhythm classifier **506**. According to the embodiment shown in FIG. **5**, ECG data **502** is received by the scrubber **504** and the rhythm classifier **506** concurrently, with different portions of the ECG data **502** being distributed to the two components **504** and **506**. As such, each of the scrubber **504** and rhythm classifier **506** operates on different portions of ECG data **502** simultaneously.

The following is a description of ECG data processing that originates at the rhythm classifier **506**. For ECG data portions that can be classified by the rhythm classifier **506**, these portions are classified then communicated to the output **508**, thereby bypassing the scrubber **504**. For ECG data portions that cannot be classified by the rhythm classifier **506**, these portions are communicated to the scrubber **504** for processing. After scrubbing the ECG data portions, the scrubber **504** communicates the scrubbed portions back to the rhythm classifier **506** for classification. Assuming the scrubbed portions are successfully classified, these portions are communicated to the output **508**. If the scrubbed portions cannot be successfully classified, these portions of the ECG signal data are discarded or passed on so that they can be evaluated manually by a clinician.

The following is a description of ECG data processing that originates at the scrubber **504**. For ECG data portions that do not need to be scrubbed, these portions are communicated to the rhythm classifier **506** for classification. For ECG data portions that require scrubbing, the scrubber **504** processes these portions. The scrubbed ECG data portions are then communicated back to the rhythm classifier **506** for classification. Assuming the scrubbed portions are successfully classified, these portions are communicated to the output **508**. If the scrubbed portions cannot be successfully classified, these portions of the ECG data are discarded or passed on so that they can be evaluated manually by a clinician. In some embodiments, the scrubber **504** and the rhythm classifier **506** conduct parallel processing on data **502**, such that the concurrently processed output of the scrubber **504** and the rhythm classifier **506** gates the output **508**. If in the course of parallel processing, the scrubber **504** or the rhythm classifier **506** flag the physiologic signal **502** according to certain preset criteria, the parallel processing modality terminates and the flow of data processing switches to serial processing based on the nature of the flag, such as scrubber processing first followed by rhythm classification, or rhythm classification first followed by scrubbing, as proposed in previous embodiments of outlined in FIG. **3** and FIG. **4**. The data flow switching described herein, would be conducted in real-time as dictated by the nature of physiologic signal **502** being processed. The data flow would then revert back to parallel processing for the following incoming physiologic signal **502**.

FIG. **6** illustrates an embodiment of a physiologic signal processor which includes a rating module **606**. The rating module **606** receives ECG data **604** produced by a patient

monitoring device **602**. As was discussed previously, the rating module **606** is configured to rate the ECG data based on the presence or absence of both an ECG signal and noise. In some cases, the rating module **606** determines that some of the ECG data is unusable **608**. The unusable data **608** may be discarded or, in some embodiments, stored for later review by a clinician. ECG data **610** determined by the rating module **606** to be usable is communicated to a scrubber **612**, which produces scrubbed ECG data **614**. The rating module **606** can use preset thresholds for determining data usability. These thresholds could be static or adaptive over time, as well as utilizing parametric or non-parametric input, such as allowances for certain signal to noise levels, provided by the healthcare provider.

FIG. 7 illustrates an embodiment of a physiologic signal processor which includes a rating module **706**, a scrubber **712**, and a rhythm classifier **716**. In the embodiment shown in FIG. 7, ECG data **704** is received from a patient monitoring device **702**, and communicated to a rating module **706**. The rating module **706** determines which ECG data **704** is usable **710** or unusable **708**. The usable data **710** is communicated to a scrubber **714**, which produces scrubbed ECG data **714**. The scrubbed ECG data **714** is communicated to the rhythm classifier **716**, which classifies the cardiac rhythm. The scrubbed ECG data along with classification data is communicated to an output **718**. It is also anticipated that the order of data scrubbing and rhythm classification can be conducted in the reverse order where classification occurs first followed by data scrubbing, or using a parallel processing scheme as described previously.

Noise sources can cause false triggering of arrhythmia recording devices, potentially leading to high false positive rates. Conversely, noise can also cause missed detections of arrhythmias by masking the underlying triggers, leading to high false negative rates. In some examples, a modularized noise detection algorithm can be used to lessen, if not eliminate, noise from a signal, such as a cardiac signal. By modularizing each of the n-dimensional noise modules, in some examples, the algorithm can be optimized for different data types and noise sources, which can be specific to a certain medical device, a specific implanting location, a specific electrode configuration, or a specific patient disease or characteristic, for example.

Referring to FIG. 8A, an algorithm, apparatus, system, and/or method can include one or more noise scrubber modules and outputs according to various embodiments. In some examples, a cardiac signal recorder can record three data types: scheduled trending, device detected arrhythmias, and patient triggered recordings. In some examples, data strips of these data types can be transmitted to a wireless communication device and sent to a third party cardiac monitoring center to be analyzed. False positives triggered by signal noise can be problematic, for instance, by increasing the data burden. In some examples, a noise cleaning algorithm can allow monitoring centers to scrub the incoming data and flag (reject) strips that only contain noise and no real arrhythmias, thereby decreasing the data burden.

As is shown in the embodiment illustrated in FIG. 8A, a scrubber **801** can comprise a number of different modules configured to operate on different types of noise. The representative scrubber **801** shown in FIG. 8A can include modules configured to detect a flatline signal, amplifier saturation, a tall T-wave, low frequency signal content, high frequency content, signal drift, signal amplitude attenuation, non-physiological noise, and intermittent burst noise patterns, to name a few. Other and different noise scrubbing modules are contemplated, and those shown in FIG. 8A are

for non-limiting illustrative purposes. A noised ECG signal is provided at an input **803** of the scrubber **801**, which is processed by a number of different scrubber modules **805**. A de-noised signal is provided at an output **807** of the scrubber **801**. The scrubber **801** also produces signal metadata at an output **809**, according to some embodiments.

The signal metadata provided at output **809** can be a file containing information about the scrubbing modules used, the noise characteristics, and the noise location and duration as percentage of total data, for example. The metadata file can be used to improve the functionality of the scrubber **801**. Perhaps more importantly, this flagging or notation provided by the metadata file can be critical in notifying the physician about what was done to the raw noisy data and the confidence he or she should have when reviewing that data. For example, very noisy data that underwent significant processing could be at risk of misrepresenting an arrhythmia due to over-filtration. Any clinical inferences made from this data may need to weigh that fact. Alternatively, if there was little truncation or filtration that was done to the raw signal, the physician could have much higher confidence in the signal. The metadata can be represented as an output in a file that can be separately accessed by the physician if they are interested in looking at that or as a symbol flag on the display screen that can indicate if the data is reliable (e.g., the color green), if moderately reliable (e.g., the color yellow), and if marginal (e.g., the color red), for example.

FIG. 8B shows a number of sequential processing steps **851**, each step implicating a different scrubbing algorithm or module in accordance with some embodiments. A typical scrubber includes a noise scrubber function, a beat detection function, and a rate-based classification function that can be interwoven, but are largely modular and functionalized. Some or all of the processing steps **851** shown in FIG. 8B can be incorporated in a scrubber according to various embodiments. The processing steps **851** shown in FIG. 8B include data strip loading, saturation detection, constants detection, beat detection, drift detection, putative beat refractory processing, tall T-wave detection, noisy beat detection, amplitude changes detection, non-physiological noise detection, noisy and non-noisy beat detection, rate based event detection, and a keep or rejection data strip function. According to some embodiments, four processing steps or functions define the majority of the logic for the scrubber algorithm: user interface, signal processing and beat detection, scrubber core functionality, and classifying arrhythmias. Several of the processing steps shown in FIG. 8B can be considered modularized support functions for the four major processing steps or functions identified above according to some embodiments.

FIG. 8C illustrates an embodiment of a scrubber in accordance with various embodiments. The scrubber **806** shown in FIG. 8C receives ECG data **804** produced by a patient monitoring device **802**. The scrubber **806** includes an input **808** configured to receive the ECG data **804**, and includes a filter **810** and a consolidator **812**. The filter **810** is configured to operate on ECG data **804** for which one or more noise segments overlap the ECG signal. The consolidator **812** is configured to operate on ECG data **804** for which one or more noise segments are non-overlapping with the ECG signal. Scrubbed ECG data **816** is provided at an output **814** of the scrubber **806**.

FIG. 9 illustrates various details of a scrubber in accordance with various embodiments. The scrubber **904** shown in FIG. 9 receives ECG data **902** at an input **906**, which communicates this data to a noise discriminator **908**. The noise discriminator **908** is configured to analyze the ECG

data **902** for the presence and location of noise within the ECG data **902**. More particularly, the noise discriminator **908** is configured to distinguish between noise **910** that is overlapping with the physiologically relevant ECG signal from noise **920** that is non-overlapping with the physiologically relevant ECG signal. The ECG signal containing overlapping noise **910** is processed by a filter **912** configured to increase the signal-to-noise ratio (SNR) **914** of the ECG signal. The ECG signal containing non-overlapping noise **920** is processed by a consolidator **922**. The consolidator **922** is configured to eliminate noise segments between or adjacent to the physiologically relevant ECG signal content. Scrubbed ECG data **932** produced by the filter **912** and the consolidator **922** is provided at an output **930** of the scrubber **904**.

FIG. **10A** illustrates various details of a scrubber in accordance with other embodiments. The scrubber **1004** shown in FIG. **10A** receives ECG data **1002** at an input **1006**, which is communicated to a noise discriminator **1008**. For an ECG signal with overlapping noise **1010**, a de-noising module **1014** of a filter **1012** is configured to attenuate or eliminate the overlapping noise from the ECG signal to produce de-noised ECG data **1016**. For example, the de-noising module **1014** can be configured to remove or attenuate one or more noise segments within the ECG data to a level that allows for classification of the overlapping physiologic signal. The de-noising module **1014** can also be configured to scale one or more noise segments within the ECG data to allow for detection of physiologically relevant signal content.

For an ECG signal with overlapping noise **1020**, a consolidator **1022** can employ one of several different modules to eliminate the noise based on the location of the noise relative to the ECG signal content. The consolidator **1022** is configured to identify the location of noise within the ECG data, determine if the location is suitable for consolidation, and determine which of several available noise consolidation modules can be used to eliminate the noise based on its temporal location.

The embodiment of the consolidator **1022** shown in FIG. **10A** includes three modules, a truncator **1024**, a concatenator **1026**, and a flatliner or blocker **1028**. These three modules **1024**, **1026**, **1028** can operate individually or in combination on the ECG signal with overlapping noise **1022** to eliminate noise segments between or adjacent the ECG signal content **1030**. Scrubbed ECG data **1034** is provided on an output **1032** of the scrubber **1004**. In some embodiments, the scrubbed ECG data **1034** is evaluated to determine if the ECG data, after consolidation, comprises contiguous physiologic signal data of at least a predefined minimum duration or amount, or is sufficient to classify a physiological event. If sufficient physiologic signal data is present in the scrubbed ECG data **1034**, this data can be communicated to a rhythm classifier, for example, for further processing.

The truncator **1024** is configured to operate on ECG data where the noise (e.g., noise segment) allows for truncation of the noise from the ECG signal **1104**. FIGS. **11A** and **11B** illustrate ECG data **1102A**, **1102B** that can be subject to truncation by the truncator **1024**. In FIG. **11A**, the ECG data **1102A** contains a noise segment **1106** located at the end of an ECG signal **1104**. In FIG. **11B**, the ECG data **1102B** contains a noise segment **1108** located at the beginning of the ECG signal **1104**. Because the noise segments **1106** and **1108** are located at the end and beginning of the ECG signal **1104**, respectively, these noise segments **1106**, **1108** can be eliminated without degrading the ECG signal **1104**, since

segments **1102A** and **1102B** are adequate to complete rhythm classification or further processing.

The concatenator **1026** is configured to operate on ECG data where the noise segments can be eliminated and viable portions of the ECG signal can be concatenated. FIG. **11C** illustrates ECG data containing noise segments to be processed by the concatenator **1026**. FIG. **11D** illustrates the ECG data of FIG. **11C** following concatenation by the concatenator **1026**. In FIG. **11C**, the ECG data **1112** contains two noise segments **1116** and **1118** interspersed within the ECG signal **1114**. Although the noise segment **1118** can be truncated (e.g., by the truncator **1024**), the noise segment **1116** cannot be truncated without losing a significant portion of the ECG signal **1114** (i.e., ECG segment **1114A** or ECG segment **1114B**). The concatenator **1026** is configured to eliminate the intervening noise segment **1116** and the truncator **1014** is configured to eliminate the noise segment **1118** located at the end of the ECG signal **1114**. Elimination of the noise segment **1116** results in two temporally-spaced ECG signal segments **1114A** and **1114B**. The concatenator **1026** concatenates the two ECG signal segments **1114A** and **1114B** to produce a contiguous ECG signal segment **1114C** shown in FIG. **11D**. While the new signal segment **1114C** cannot be used for temporal analysis due to concatenation, the new signal segment **1114C** would contain valuable data to complete other types of analysis such as morphologic analysis, for example.

The flatliner or blocker **1028** is configured to operate on the ECG data where one or more noise segments interspersed within the ECG signal can be replaced by flatlined signal content, such as a DC signal. FIG. **11E** shows ECG data **1120** that contains a noise segment **1126** located between two ECG signal segments **1124A** and **1124B**. The flatliner or blocker **1028** is configured to replace the noise segment **1126** with a flatlined signal segment **1128** of equal time duration, as is shown in FIG. **11F**. By replacing the noise segment **1126** with the flatlined signal segment **1128**, the original timing of the ECG data is preserved, allowing for temporal analyses, such as cardiac rate classification and periodicity for example.

In some embodiments, portions of the ECG data that have been modified by the filter **1012** and consolidator **1022** can be accentuated in some manner so as to be readily perceivable by a clinician. For example, de-noised segments, deleted noise segments, and flatlined segments can be highlighted using annotation, flags, and/or colorization to allow for easy review by a clinician when the ECG data is presented on a user interface (e.g., monitor of a computer). In other embodiments, the original ECG data prior to processing by the filter **1012** and consolidator **1022** can be preserved for later review by a clinician or technician, such as for evaluating the efficacy of the noise processing algorithms. Preservation of original ECG data is preferably an optionally requested feature, since it would result in an increase, rather than a decrease, in total ECG data.

FIG. **10B** illustrates de-noising signal flow through a scrubber in accordance with other embodiments. Based on the input data, parameters, and noise detected, in some examples, algorithms implemented by the scrubber **1050** can attempt to de-noise the data using one or more of the available methods. In some examples, de-noising can be based on strip type and/or strip duration. In some examples, strip data can be used to inform how to properly clean and present data. It is noted that processing data on a strip type level (inter-strip) makes decisions for whether to keep or reject (or flag for rejection) an entire strip. This results in reduction of data burden. It is further noted that processing

data within a strip (intra-strip) makes decisions on noise magnitude and duration to allow for de-noising. This results in cleaning the data to support better clinical decision making, but does not reduce data burden.

The scrubber **1050** shown in FIG. **10B** receives a noised ECG signal at an input **1052**, which is communicated to a noise discriminator **1054**. The noise discriminator **1054** includes a number of modules each configured to process the noised ECG signal in a different manner. Representative modules of the noise discriminator **1054** shown in FIG. **10B** include modules configured to detect noise magnitude, noise duration, noise type, strip type, signal continuousness, and signal correlation. Other modules **1056** of the scrubber **1050** shown in FIG. **10B**, and as discussed previously, include modules configured to filter, truncate, concatenate, and block noise in the noised ECG signal. A scrubbed signal is provided at an output **1058** of the scrubber **1050**.

FIG. **12** illustrates various details of a rating module in accordance with various embodiments. The rating module **1202** is configured to receive ECG data **1203** produced from a patient monitoring device. The rating module **1202** includes or is coupled to a decision matrix **1204**. The decision matrix **1204** is configured to analyze the ECG data **1203** and rate the ECG data **1203** based on the presence or absence of an ECG signal and noise in the ECG data. In the embodiment shown in FIG. **12**, the decision matrix **1204** is a 2x2 matrix that is used to rate the ECG data **1203** according to four tiers. The two columns of the decision matrix **1204** indicate the presence (Yes) and absence (No) of a clinically-relevant ECG signal within the ECG data **1203**, such as rate-based arrhythmias like tachycardia, or rhythm-based arrhythmias like atrial fibrillation, as examples. The two rows of the decision matrix **1204** indicate the presence (Yes) and absence (No) of noise (e.g., one or more segments of noise) within the ECG data **1203**, as assessed independently or through a scrubber module as described previously.

Tier 1 (T1) data is indicated in the decision matrix **1204** as ECG data **1203** in which a clinically-relevant ECG signal is present (Yes) in the absence of noise (No). Tier 2 (T2) data is indicated in the decision matrix **1204** as ECG data **1203** in which a clinically-relevant ECG signal is present (Yes) and noise is present (Yes). Tier 3 (T3) data is indicated in the decision matrix **1204** as ECG data **1203** in which a clinically-relevant ECG signal is absent (No) and noise is present (Yes). Lastly, Tier 4 (T4) data is indicated in the decision matrix **1204** as ECG data **1203** in which an ECG signal is absent (No) and noise is also absent (No).

In some embodiments, the rating module **1202** is configured to rate the ECG data **1203** in a manner described above, and indicate the tier level of the data **1203**, such as by the use of flags or annotation. In other embodiments, the rating module **1202** is configured to facilitate the production of separate data streams for each of the different tier levels. As is shown in FIG. **12**, for example, four data streams (T1 Data, T2 Data, T3 Data, T4 Data) are produced, each associated with one of the tier levels T1 through T4. The disparate data streams are communicated to an output **1210** for subsequent use by other components of the system. It is noted that, in some embodiments, the T4 data stream can be discarded by the rating module **1202** and not communicated to the output **1210**. In such embodiments, the T4 data stream is deemed to be a clean signal, having little or no noise, with no clinically-relevant ECG signal content that would warrant further processing. In other embodiments, the T4 data stream can be communicated to the output **1210**, and be subject to evaluation by a clinician to confirm the absence of

clinically-relevant ECG signal content or to evaluate the efficacy of the rating module **1202**.

In some embodiments, the rating module **1202** can solely use the decision matrix **1204** to triage the ECG signal based on preset parameters, which can be static or adaptive over time. In some embodiments, the rating module **1202** can use the decision matrix **1204** in conjunction with other parametric or non-parametric input to triage the ECG signal. These additional inputs can be patient-activated, through an external mechanism, when a patient feels the onset and termination of certain symptoms, for example. In some embodiments, the external mechanism could include a patient activator peripheral device with an input capability, or a magnet swiped over the patient monitoring device, for example. In some embodiments, the additional inputs can be driven by a healthcare provider, through an external mechanism, such as when the healthcare provider wants to be notified urgently when a specific rhythm classification or noise pattern is detected, for example. The external mechanism for the healthcare provider can include web-based dedicated portal access to the patient's monitoring device or a wired/wireless mode of communication with said device, for example.

In the embodiment shown in FIG. **12**, the decision matrix **1204** is a 2x2 matrix as discussed above. FIG. **13** illustrates a decision matrix **1304** that is generally representative of an nxn matrix, where n in this illustrative embodiment is equal to three. It is understood that more sophisticated decision matrices can be developed beyond 2x2 and 3x3 matrices. In the decision matrix **1304** shown in FIG. **13**, three columns are used to indicate the presence (Yes), possible presence (Maybe), and absence (No) of a clinically-relevant ECG signal in the ECG data. The three rows shown in FIG. **13** are used to indicate the presence (Yes), possible presence (Maybe), and absence (No) of noise in the ECG data. Each of the combinations of columns and rows has an associated tier level ranging between T1 and T4. It is noted that the tier levels T1-T4 assigned to the boxes in the decision matrix **1204** are representative levels. It is also noted that the tier level range may include fewer or greater than four distinct levels. In a manner similar to that described in FIG. **12**, the output from the decision matrix **1304** can be used to flag or annotate the ECG data according to tier level or, in other embodiments, can be used to produce disparate data streams each associated with a different tier level.

FIG. **14** is a diagram showing combined use of a rating module, decision matrix, scrubber, and rhythm classifier in accordance with various embodiments. In the embodiment illustrated in FIG. **14**, a rating module **1402** receives ECG signal data **1403** as an input, typically from a patient monitoring device. The rating module includes or is coupled to a decision matrix **1404**, which can be a 2x2 matrix (as shown) or an nxn matrix for example. FIG. **14** shows that the tier 1 (T1) data stream is directed to the rhythm classifier **1410** without need for scrubbing. This is because the tier 1 data rated by the rating module **1402** was found to include clinically-relevant ECG signal content and has an absence of noise. As such, the rhythm classifier **1410** can operate on the tier 1 data stream without additional processing.

FIG. **14** shows that the tier 2 (T2) data stream is directed to a scrubber **1412**. This is because the tier 2 data rated by the rating module **1402** was found to include clinically-relevant ECG signal content and noise. The scrubber **1412** operates on the tier 2 data stream in a manner previously described so as to increase the signal-to-noise ratio (e.g., filter) or eliminate (e.g., consolidate) the noise of the tier 2 data. The scrubbed ECG data produced at the output of the

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scrubber **1412** is input to the rhythm classifier **1410**, which classifies cardiac rhythms in a manner previously described. The ECG data produced at the output of the rhythm classifier **1410** can include cardiac event markers and/or noise markers.

The tier **3** (T3) data shown in FIG. **14** can be subject to further processing by the rating module **1402**. In some cases, ECG data that does not appear to contain clinically-relevant ECG signal content but contains noise can be subject to further processing in an attempt to recover ECG signal content that might be hidden or not readily recoverable due to the presence of noise. The tier **4** (T4) data can be discarded by the rating module **1402**, since this data is not noisy to require further processing and does not contain any clinically-relevant ECG signal content.

FIG. **15** illustrates a representative 2x2 decision matrix **1504** that shows additional processing performed for each of the four tiers T1-T4 of the matrix **1504**. In general, logic can be implemented to complement the scrubbing process and efficiently and intelligently accept or flag (reject) data strips. Such logic is based on the outcome of two questions: 1) is there physiological signal (e.g., Tiers T1 and T2), and 2) is the signal noisy (e.g., Tiers T2 and T3). The decision matrix **1504** illustrated in FIG. **15** represents a strip flagging matrix that indicates various steps for different permutations of the answers to these two questions posed above.

In some examples, the two no-noise cases (Tiers **1** and **4**) are relatively simple algorithmically. In the case of a physiological signal and no noise (Tier **1**), in some examples, the strip can be classified and retained for further processing or storage. In the case of no physiological signal and no noise (Tier **4**), in some examples, the classification rules will not be met and the strip will be flagged (rejected).

In some examples, the two cases with noise (Tiers **2** and **3**) can include additional algorithm logic to streamline the classification process. In the case of no physiological signal and noise (Tier **3**), in some examples, the signal can be scrubbed to verify the lack of physiological signal, and the strip can then be flagged (rejected) either because the classification rule is not met or because there is not enough contiguous data to allow for classification. In some examples, the final case where there is physiological signal and also noise (Tier **2**) allows for strip flagging at several points in the scrubbing process.

Referring now to FIG. **16** (top panel), an output of a scrubber includes a plot of data **1601** with clean beats, noisy beats, arrhythmias, and noise graphically presented as well as the decision to flag the data according to various embodiments. In FIG. **16**, open circles indicate clean (good) beats, solid circles indicate noisy beats, Xs show electrocardiogram (ECG) monitor beats, dotted vertical lines (e.g., lines **1602** and **1604**) show tachycardia, dashed lines shows ECG monitor tachycardias, and dashed lines through solid circles (e.g., line **1606**) show scrubber tachycardias. The ECG monitor **1610** (bottom panel) is flagging tachycardias that are noise artifacts.

The ECG monitor **1610** (bottom panel) shows the measured heart rate. The ECG monitor hardware is reporting tachycardias that are from noisy beats. In various examples, the scrubber can take into account noisy beats to lower false positives and improve true positives. In some examples, the ECG monitor **1610** can include an external device. In other examples, the ECG monitor **1610** can include an internal device. In further examples, the ECG monitor **1610** can include an implantable loop recorder (ILR). In other examples, other implantable ECG monitors can be used.

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With reference again to the top panel of FIG. **16**, the plot of data **1601** between dotted vertical lines **1602** and **1604** represents a zone (Zone A) of detected tachycardia. The data **1601** of Zone A represents clean data, which would be deemed acceptable by a decision matrix according to various embodiments. The portion of the data **1601** (Zone B) preceding the dotted vertical line **1602** includes one or more noisy beats and would be flagged and rejected by a decision matrix according to various embodiments. The flagged data (Zone B) of the plot of data **1601** shown in FIG. **16** would be excluded from the data **1601** output from the decision matrix.

Vertical line **1606** represents a cleaned tachycardia beat that was incorrectly detected by the ECG monitor hardware as a noisy beat. Processing of the noisy beat by a scrubber revealed clinically-relevant ECG data that was subsequently and correctly detected as a tachycardia beat. As such, the data **1601** of Zone C subsequent to the vertical line **1604** which includes the cleaned tachycardia beat **1606** can be included in the accepted data of Zone A.

CONCLUSION

The above description is intended to be illustrative, and not restrictive. For example, the above-described examples (or one or more aspects thereof) may be used in combination with each other. Other examples may be used, such as by one of ordinary skill in the art upon reviewing the above description. Also, in the above Detailed Description, various features may be grouped together to streamline the disclosure. This should not be interpreted as intending that an unclaimed disclosed feature is essential. Rather, inventive subject matter may lie in less than all features of a particular disclosed example.

What is claimed is:

1. A method, comprising:

receiving electrocardiogram (ECG) data detected by a patient monitoring device, some of the ECG data containing a cardiac signal and some of the ECG data containing the cardiac signal and noise;

rating the ECG data based on presence or absence of both the cardiac signal and the noise, wherein rating the ECG data comprises:

rating, as a first tier, the ECG data in which the cardiac signal is present and the noise is absent;

rating, as a second tier, the ECG data in which the cardiac signal is present and the noise is present;

rating, as a third tier, the ECG data in which the cardiac signal is absent and the noise is present; and

rating, as a fourth tier, the ECG data in which the cardiac signal is absent and the noise is absent;

identifying a temporal occurrence of the ECG data and a temporal occurrence of one or more segments of noise within the ECG data, the one or more noise segments comprising one or more first noise segments and one or more second noise segments;

scrubbing the ECG data by two separate operations comprising:

filtering the one or more first noise segments that overlap with the cardiac signal; and

consolidating the ECG data to eliminate the one or more second noise segments, wherein consolidating the ECG data comprises determining a location of the one or more second noise segments relative to the cardiac signal, the one or more second noise segments rendering cardiac signal content at the location unusable for diagnostic purposes; and

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generating an output comprising scrubbed ECG data, the scrubbed ECG data comprising the filtered cardiac signal and the consolidated ECG data.

2. The method of claim 1, wherein consolidating the ECG data comprises one or more of:

truncating the one or more second noise segments;
concatenating two or more of the second noise segments;
and
blocking or flattening the one or more second noise segments.

3. The method of claim 1, wherein:
consolidating the ECG data comprises determining if the location is suitable for consolidation.

4. The method of claim 1, further comprising determining if the ECG data, after consolidating, comprises contiguous cardiac signal data of at least a predefined minimum duration or amount or is sufficient to classify a cardiac event.

5. The method of claim 1, wherein filtering the one or more first noise segments comprises at least one of:

removing or attenuating the one or more first noise segments to a level that allows for classification of the overlapping cardiac signal; and

scaling the one or more first noise segments to allow for detection of detectable cardiac signal content.

6. The method of claim 1, further comprising:
marking the one or more first and second noise segments;
and

generating the output comprising the scrubbed ECG data annotated with noise markers and cardiac event markers.

7. The method of claim 1, further comprising performing rhythm classification on the scrubbed ECG data.

8. The method of claim 1, further comprising rating the ECG data as usable or unusable based on the presence or absence of both the cardiac signal and noise, wherein a manner of scrubbing the ECG data is based at least in part on the ECG data rating.

9. The method of claim 1, further comprising rating the ECG data as usable or unusable based on the presence or absence of both the cardiac signal and noise, wherein:

the method further comprises generating a plurality of output data streams each corresponding to one of the ECG rating tiers.

10. The method of claim 1, further comprising:
rating the ECG data as usable or unusable based on the presence or absence of both the cardiac signal and noise; and

flagging or annotating the ECG data based on a rating indicating presence of noise in the ECG data.

11. An apparatus, comprising:

an input configured to receive electrocardiogram (ECG) data detected by a patient monitoring device, some of the ECG data containing a cardiac signal and some of the ECG data containing the cardiac signal and noise, the noise comprising one or more first noise segments and one or more second noise segments;

a rating module configured to:

rate, as a first tier, the ECG data in which the cardiac signal is present and the noise is absent;

rate, as a second tier, the ECG data in which the cardiac signal is present and the noise is present;

rate, as a third tier, the ECG data in which the cardiac signal is absent and the noise is present; and

rate, as a fourth tier, the ECG data in which the cardiac signal is absent and the noise is absent;

a scrubber comprising a plurality of scrubbing modules each configured to process the ECG data and the noise

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in a manner differing from other scrubbing modules, the scrubber configured to implement two separate operations that:

filter the one or more first noise segments that overlap with the cardiac signal; and

consolidate the ECG data to eliminate the one or more second noise segments, the scrubber configured to determine a location of the one or more second noise segments relative to the cardiac signal, the one or more second noise segments rendering cardiac signal content at the location unusable for diagnostic purposes; and

an output configured to output scrubbed ECG data, the scrubbed ECG data comprising the filtered cardiac signal and the consolidated ECG data.

12. The apparatus of claim 11, wherein:

at least some of the scrubbing modules are configured to receive parameters that are pre-configured, automatically adaptive, or physician modifiable; and

operation of at least some of the scrubbing modules is established or adjusted based on the parameters.

13. The apparatus of claim 11, wherein the scrubber is configured to consolidate the ECG data by one or more of:

truncating the one or more second noise segments;
concatenating two or more of the second noise segments;
and

blocking or flattening the one or more second noise segments.

14. The apparatus of claim 11, wherein the scrubber is configured to determine if the location is suitable for consolidation.

15. The apparatus of claim 11, further comprising a rhythm classifier configured to classify a cardiac rhythm using the scrubbed ECG data.

16. The apparatus of claim 15, wherein the rhythm classifier is configured to determine if a remaining duration or amount of the scrubbed ECG data is sufficient to allow for classification of a cardiac event depending on the nature of the cardiac event.

17. The apparatus of claim 11, wherein the scrubber is configured to filter the one or more first noise segments by at least one of:

removing or attenuating the one or more first noise segments to a level that allows for classification of the overlapping cardiac signal; and

scaling the one or more first noise segments to allow for detection of detectable cardiac signal content.

18. The apparatus of claim 11, wherein the scrubber is configured to:

mark the one or more first and second noise segments; and
generate an output comprising the scrubbed ECG data annotated with noise markers and cardiac event markers.

19. The apparatus of claim 11, wherein the rating module is configured to rate the ECG data as usable or unusable based on the presence or absence of both the cardiac signal and noise, wherein a manner of scrubbing the ECG data by the scrubber is based at least in part on a rating accorded the ECG data by the rating module.

20. The apparatus of claim 11, wherein the rating module is configured to:

rate the ECG data as usable or unusable based on the presence or absence of both the cardiac signal and noise; and

flag or annotate the ECG data based on a rating indicating presence of noise in the ECG data.

* * * * *

专利名称(译)	用于基于生理相关性的心脏信号噪声检测 and 处置的装置和方法		
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[标]发明人	KATRA RODOLPHE CHAKRAVARTHY NIRANJAN		
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摘要(译)

一种装置包括：输入，被配置为接收由患者监测设备检测的心电图（ECG）数据，该ECG数据包含生理信号和ECG数据内的一个或多个噪声区段。洗涤剂包括多个洗涤模块，每个洗涤模块被配置为以不同于其他洗涤模块的方式处理ECG数据和噪声。擦洗器被配置为过滤与生理信号重叠的一个或多个噪声段，并合并ECG数据以消除与生理信号不重叠的一个或多个噪声段。输出配置为输出擦洗的ECG数据。

