

Arrhythmia Monitoring ST/AR Algorithm

Application Note

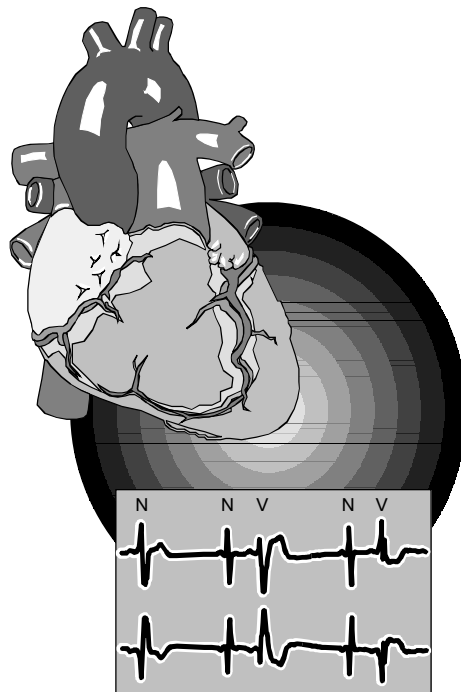
The ST/AR (ST and Arrhythmia) algorithm is a multi-lead ECG algorithm designed for arrhythmia, ST segment and QT monitoring. The arrhythmia algorithm can run as single-lead analysis or multi-lead analysis. This application note provides a detailed description of the arrhythmia monitoring portion of the ST/AR algorithm. This document also describes the arrhythmia system's alarm structure. The assessment of the arrhythmia algorithm's performance is described in a separate publication titled Assessing Arrhythmia Performance, Part Number 453564115641.

Introduction

Computerized arrhythmia monitoring is a valuable clinical tool in many patient areas. To be most effective, this tool requires a thorough knowledge of the system's features, how the computer processes the signals, as well as the proper application procedures.

The ST/AR arrhythmia monitoring algorithm is designed to process one or two simultaneous channels of surface ECG signals for detecting changes in the ECG rhythm while offering continuous patient surveillance and alarm generation.

Through a sophisticated computer algorithm, QRS complexes are detected, labeled and classified. Based on the classification, the computer then generates alarms. It is the intent of this application note to explain the fundamentals involved in each of these steps.



ST/AR Arrhythmia Algorithm

Arrhythmia Monitoring Algorithm

An algorithm is a set of rules and instructions that computers use to analyze data. The arrhythmia monitoring algorithm processes the ECG signals for both paced, non-paced, adult, pediatric and neonatal patients.

The algorithm performs several actions on the incoming ECG waveform, including filtering the signal, detecting and classifying the QRS, generating heart rate, identifying ectopic events and rhythms, and generating alarms if necessary.

Quality Check of the ECG Signal

Before monitoring begins, the ECG signal quality is checked for noise and inoperative (INOP) conditions.

Noisy ECG Signals

Noise refers to any degradation of the ECG signal that makes it difficult to accurately detect and classify beats. Causes of noise, such as artifact and electrical interference, should be avoided whenever possible.

The following are some possible causes of noisy ECG signals:

- Poor skin prep.
- Dried electrode gel.
- Detached electrodes.
- Broken lead wires.
- Muscle artifact caused by shivering, movement or tremors.
- Baseline wander caused by excessive chest movement, or the offset differences between two brands of electrodes.
- Respiration artifact caused by thoracic or abdominal movement of both spontaneous and ventilated breathing patterns.
- Equipment.

Prompt attention by the clinician to any of the above ECG interferences increases the accuracy of the algorithm and decreases the incidence of false alarms. The causes of noisy signals and possible corrective actions are shown in the table on the following page.

INOP Conditions

Inoperative conditions which interfere with or prevent monitoring the ECG signal can also interfere with arrhythmia monitoring. A leads off condition which results in the loss of ECG monitoring will also inhibit arrhythmia monitoring until the condition is corrected and a lead has been restored. If using a 5-wire leadset, whether doing standard or EASI lead placement or 6-wire leadset, a leads off condition does not necessarily result in the loss of monitoring. The arrhythmia algorithm will use whichever lead(s) are available for monitoring.

Multi-Lead Monitoring

While in most cases highly accurate results are obtained when monitoring two leads of ECG simultaneously, it is important to remember that both leads of ECG are being used for detection, classification and alarm generation. The quality of both signals will effect the accuracy of the arrhythmia algorithm in beat detection, classification, and alarm generation.

Even though a multi-lead arrhythmia algorithm has better ability in handling noisy signals than a single-lead algorithm, in order to achieve the maximum performance it is important that the two ECG leads selected for monitoring be free of noise.

In the following example, the second lead is extremely noisy, and therefore it provides little value to QRS detection. During classification both leads are used. The second noisy lead may impact negatively on the final beat classification. In addition, if the channel 1 ECG becomes inoperative, the second lead will be the only lead available for analysis; hence poor performance will result.

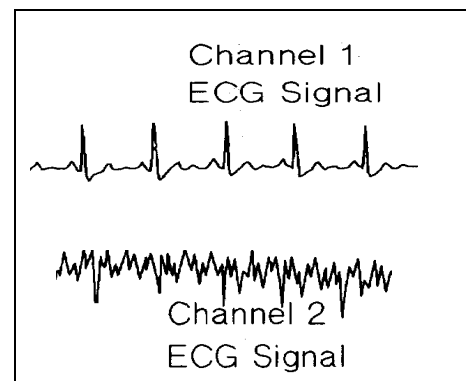





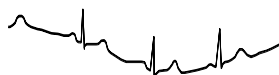
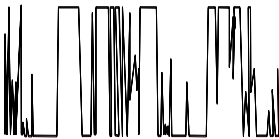
Figure 1 Two channels ECG

Although the ST/AR algorithm has an improved handling of noisy signals and the changing amplitudes caused by the loss of a good lead, it is still important to choose the best two leads available. If there are false alarms, examine both leads. You may need to select a different lead or change the electrodes or electrode position if there is excessive noise, unstable voltage, low amplitude or large P- or T-waves.

In cases where selecting a different lead or changing electrode position to correct the problem is not possible or practical, then it is better to select a lead with the best signal quality and use the single-lead analysis for monitoring.

ST/AR Arrhythmia Algorithm

Figure 2 Noisy ECG Problem Solving

<p>Power Line Interference (50 / 60-Cycle Interference)</p> 	<p>Regular sawtooth baseline with exactly 10 peaks every 5 mm at 25 mm/sec. (50 cycle) or 12 peaks every 5 mm at 25 mm/sec. (60 cycle).</p>	<p>Poor electrode placement.</p> <p>Possible non-grounded instrument near patient.</p>	<p>Reapply electrodes.</p> <p>Disconnect electrical appliances near patient (one at a time) by pulling wall plugs, to determine faulty grounding. Have engineer check grounding.</p>
<p>Muscle Artifact</p> 	<p>Fuzzy, irregular baseline.</p>	<p>Tense, uncomfortable patient.</p> <p>Poor electrode placement.</p> <p>Tremors.</p> <p>Diaphoresis.</p>	<p>Make sure patient is comfortable.</p> <p>Check that electrodes are applied on flat, non-muscular areas of the torso; reapply electrodes if necessary.</p>
<p>Irregular Baseline</p> 	<p>Rough, jagged baseline.</p>	<p>Poor electrical contact.</p> <p>Respiratory interference.</p> <p>Faulty electrodes.</p> <p>Dry electrodes.</p>	<p>Reapply electrodes, using proper technique.</p> <p>Move electrodes away from areas with greatest movement during respiration.</p> <p>Apply new electrodes.</p>
<p>Baseline Wander</p> 	<p>Rhythmic up-and-down movement of the ECG baseline.</p>	<p>Movement of the patient.</p> <p>Improperly applied electrodes.</p> <p>Respiratory interference.</p>	<p>Make sure the patient is comfortable.</p> <p>Reapply electrodes. Check that patient cable is not pulling on electrodes.</p> <p>Move electrodes away from areas with greatest movement during respiration.</p>
<p>Poor Electrode Contact</p> 	<p>Trace switching from high to low in steps.</p>	<p>Loose electrodes.</p> <p>Defective cables.</p>	<p>Change all electrodes, using good skin prep.</p> <p>Replace cables.</p>

ST/AR Arrhythmia Algorithm

ECG Analysis

Step 1: ECG Signal Filtering

Digital Sampling

The patient's incoming ECG waveforms are digitally sampled at 8000 samples/second. The ECG sampling rate of 500 samples/second is used to preserve the narrow pace pulses (spikes) for accurate pacing analysis. For QRS detection and ventricular fibrillation detection where high sampling rates are not needed, a lower sampling rate of 125 samples/second is used. For QRS classification, a sampling rate of 250 samples/second is used for analysis at the Information Center. The sample rate for the IntelliVue Monitors is 125 samples/second for QRS classification.

Pace Pulse Processing

With both bedside monitors and telemetry systems, detection of the pace pulse for patients with pacemakers occurs in the bedside monitor or the telemetry transmitter. This permits highly accurate pace pulse detection on the unfiltered ECG signal. Using the 500 samples/second data, the pace pulses are eliminated before the ECG waveforms are processed by the QRS detector. In this way the accidental detection of the pace pulse as a QRS is prevented.

Note: The removal of pace pulses is done only on the signals that are used by the algorithm for arrhythmia analysis. The pace pulses remain available for viewing on the display or recordings if the paced mode is active in the IntelliVue Patient Monitor.

Filtering

Next, the ECG waveform(s) are processed by two digital filters: a detection filter and a classification filter. These filters are optimized individually to enhance the performance of QRS detection and classification.

Detection Filter

The detection filter removes low frequency noise (baseline wander) and muscle artifact, and accentuates the QRS complexes. P-waves and T-waves are diminished. This filter makes it easier to accurately detect the QRS and helps avoid erroneously detecting tall T-waves or artifact as beats. Since it distorts the true shape of the QRS, the output from the detection filter is used only for beat detection.

A special filter is used for neonatal ECG processing. This filter improves detection sensitivity of narrow neonatal QRS complexes.

Classification Filter

The classification filter also removes signal irregularities, but it preserves the important features of the QRS. Since this filter does not distort the complex, the resulting ECG output can be used for feature measurements and beat classification.

Step 2: QRS Detection

The algorithm's challenge in QRS detection is to first locate R-wave peaks that become "candidate peaks" and then to make sure that they are not actually noise, P- or T-wave peaks.

ECG Amplitude

In order to comply with ANSI/AAMI EC-13 specification, ST/AR internally removes the gain adjustments before the signal is analyzed for detection and classification. The detection threshold for the QRS cannot be less than 0.15 millivolts. This specification is aimed at preventing the detection of P-waves or baseline noise as QRS complexes during complete heart block or asystole.

Thus increasing or decreasing gain at the point-of-care device has no effect on the ECG size used for QRS detection. The algorithm will analyze the ECG signal as it would appear at a gain $\times 1$. Therefore, for optimal performance and to prevent false alarms such as pause or asystole, it is important that the lead(s) selected for monitoring have adequate amplitude. This can be confirmed by comparing the ECG signal to the one-millivolt reference bar on the display and recordings

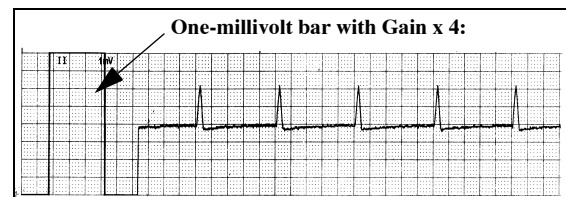


Figure 3 What the clinician sees on the display - gain applied to signal.

The bedside monitor and Information Center displays, as well as recordings, will show a waveform with the gain adjustments and a one-millivolt reference bar at the beginning of the waveform. Consequently the clinician can be looking at a waveform which appears large until compared to the one-millivolt reference. ST/AR sees a smaller waveform (gain $\times 1$) which it analyzes.

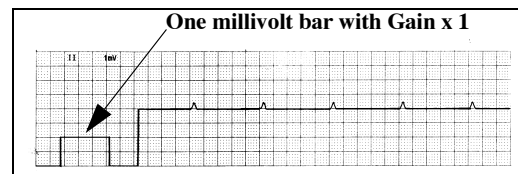


Figure 4 What the ST/AR algorithm sees after removing the gain

Combining Multiple Leads Into A Single Signal

With multi-lead analysis, after both ECG signals pass through the detection filter, they are combined into a single signal for QRS detection. The contribution from each ECG lead to the QRS detection signal is proportional to its measured quality based on the waveform amplitude, and the amount of muscle and baseline noise. The weighting factors are updated at least every 200 milliseconds to allow for quick adaptation to signal quality changes.

The QRS detection signal can dynamically adapt to the quality of the incoming ECG signal(s), thus the impact of noisy signals to QRS detection can be reduced. To further prevent a bad ECG signal (such as noise, large P- or T-waves) from corrupting the detection signal, the user has the option of using one of the two ECG signals for QRS detection while the beat classification is performed on both leads. This can only be done for telemetry and bedside other than the IntelliVue Patient Monitor at the Information Center. Selecting Manual in the QRS Detection box in the bottom of the Arrhythmia Analysis window allows the user to select the minimum threshold for single QRS detection.

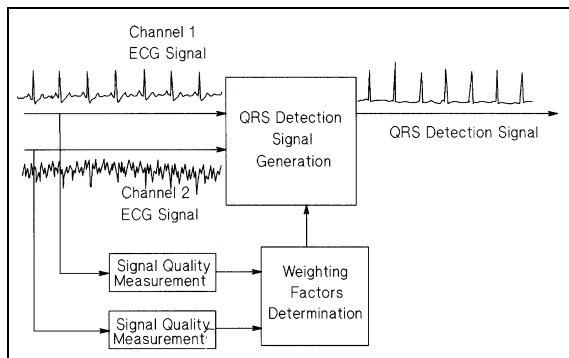


Figure 5 Generating the QRS Detection Signal Using Two ECG Signals

Locating Candidate R-Wave Peaks

The QRS detector checks the QRS detection signal for the presence of the peak of an R-wave. Searching begins after an absolute refractory period from the previously identified QRS complex. This helps prevent a T-wave from being identified as an R-wave. The value used for the absolute refractory period is 192 milliseconds for adult and pediatric patients. A smaller value, 160 milliseconds, is used for neonatal patients.

A moving search region is established at the end of the refractory period. For each search region, a new threshold is established based on:

- Noise around the search region.
- Distance from the previously detected R-wave.

- Averaged R-wave height.

The largest peak within the search region is considered a candidate R-wave.

Minimum Detection Threshold

To prevent the detection of P-waves or noise as QRS complexes during complete heart block or asystole, the detection threshold will never go below the larger of 1/5 of the average R-wave height or 0.15 millivolts. Any peak smaller than this value is not detected.

User Adjustable Minimum Detection Threshold

(For the IntelliVue Information Center only)

For monitoring signals with P-waves exceeding the minimum QRS detection threshold, the 0.15 millivolt limit can be increased manually by the user. When the manual adjustment is used, the QRS detection will be performed on only one ECG channel. If the arrhythmia analysis is in multi-lead mode, the single ECG channel used for QRS detection is user selectable with the primary lead (first displayed lead) as the default choice. If single lead arrhythmia analysis is used, the QRS detection threshold is on the primary lead.

Noise Rejection

After a candidate peak is detected, it is checked against a noise threshold to make sure that it is not a noise artifact or a QRS complex surrounded by noise. If the ECG lead(s) are determined to be noisy then a beat label "A" is assigned to the candidate peak and no classification is performed. With multi-lead, the noise check is performed on each lead independently. Only the lead that is identified as noisy will be excluded from subsequent analysis.

Peak Rejection

Before accepting the peak as a potential R-wave, there are two further tests which are carried out on each lead independently.

Potential False Identification of the P-Wave

To prevent a P-wave that is associated with a QRS from being counted as a QRS, it is checked against what is known about the previously identified P-waves. If it is found to be similar, the peak is rejected. In addition, to prevent P-waves from being erroneously counted as QRS complexes during complete heart block, three consecutive candidate peaks are further tested to see if they are actually consecutive P-waves. These peaks are rejected if they are found to be P-waves.

Potential False Identification of the T-Wave

If a candidate peak is found in close proximity to the preceding beat, it is tested to see if it might be a late T-wave. After a series of height and timing tests, the peak may be determined to be a T-wave and rejected.

If it is determined that the candidate peak is neither a P-wave or a T-wave, it is identified as a QRS complex and saved.

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P-Wave Detection

After a QRS complex is located, a search is made on each lead independently in the area prior to the beat to determine if there is an associated P-wave. This area is 200 milliseconds wide (104 milliseconds for neonate) and ends 120 milliseconds (56 milliseconds for neonate) before the R-wave peak. To be considered a P-wave, it must be at least 1/32 of the R-wave height and the P-R interval must be close to the average P-R interval.

In other words, the candidate P-wave must represent average characteristics in its relationship to the QRS. P-wave detection is used to differentiate between a Sinus Rhythm (normal QRS complexes with associated P-waves) and a Supraventricular (SV) Rhythm (normal QRS complexes without associated P-waves).

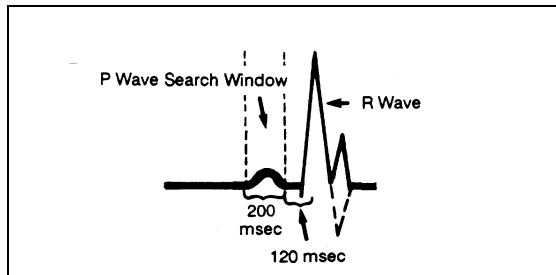


Figure 6 P-Wave Detection for Adult/Pedi

Step 3: Feature Measurement

After a beat is detected, it is measured in a number of ways to determine its features. These features represent beat characteristics which can be used to discriminate between different types of beats.

The features measured are: height, width, area, and timing (a series of R-R interval measurements). With multi-lead analysis, the height, width and area are measured for each lead independently.

Step 4: Beat Labeling

Once the signal quality is checked and verified, and the QRS is detected and measured, the beat is labeled. Labeling means the algorithm assigns the complex one of the following labels:

N	Normal
S	Supraventricular Premature
V	Ventricular Ectopic

P	Paced
?	Questionable
L	Learning

If the signal quality is not good, the algorithm assigns one of the following labels to the waveform.

I	Inoperative
A	Artifact

Another label used to label the ECG signal is:

M	No QRS
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Beat labeling involves three major concepts:

1. The use of template families to represent recurring morphologies.
2. The use of initial learning of the patient's normal morphology and/or paced morphology if the patient is paced.
3. The use of template families to aid classification of QRS complexes.

Grouping into Template Families

To aid the algorithm in labeling a new beat, previously detected beats that have similar shapes are grouped into "template families."

Each template family contains the following information:

- Template family classification: Normal, Ventricular, Paced, or Unclassified.
- Waveform template, generated by averaging all the beats that are considered similar enough to be included.
- The number of complexes having this shape.
- The length of time since this shape was last seen.
- Statistical information on the beats' feature measurements.
- If the patient is paced, pace pulse information associated with the beats.

For each patient, up to 16 different active template families can be created for each individual lead. To keep the template family information current, they are dynamically created and replaced as the patient's beat shapes change.

If the patient begins to display a new beat morphology, a new template family is created. Older template families from beats the patient is no longer experiencing are automatically deleted.

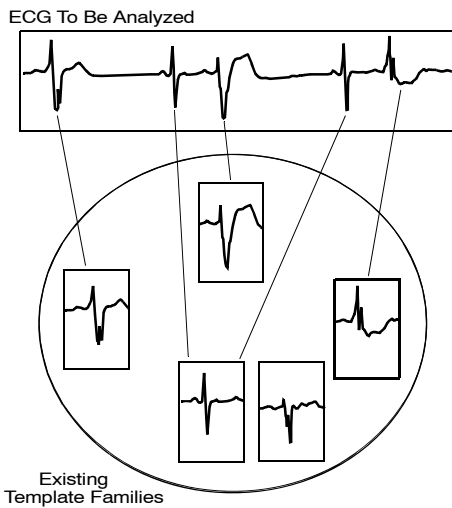


Figure 7 Example of Template Families

Template Matching

When a beat is detected, it is matched against the stored waveform templates for that patient. Matching means comparing the beat shape with a waveform template. This process involves overlaying the beat on the template and using a mathematical procedure to measure the differences between the two shapes

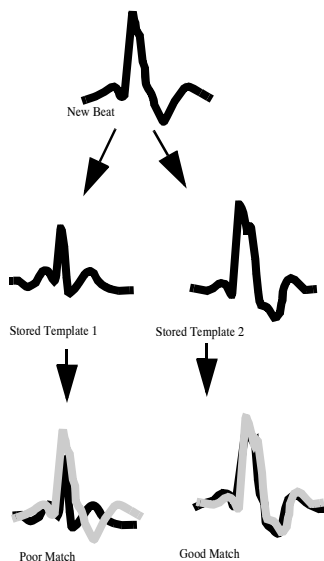


Figure 8 Template Matching

Learning

When arrhythmia monitoring starts, a learning process is initiated. The goal is to learn the patient's normal complexes and/or the paced complexes if the patient with a pacemaker is in paced rhythm. The learning process involves the first 15 valid (non-noisy) beats encountered during the learning phase.

The family selected to represent the "normal" includes the beat that is the most frequently seen, narrowest, on-time beat. For this reason, learning should not be initiated when the patient's rhythm is primarily ventricular.

A manual relearning should be initiated if beat detection is not occurring or if beat classification is incorrect, and results in a false alarm. Remember, however if the same signal condition exists which caused the algorithm to perform poorly, relearning will not be able to correct the problem. The problem can only be corrected by selecting a different lead.

The algorithm automatically relearns the ECG waveform(s) whenever:

- ECG monitoring is initiated with arrhythmia turned on. (including power on or restart or ECG on/off).
- Arrhythmia monitoring is turned on.
- Pacer status is changed.
- Patient category is change. A Profile change will cause a relearn if the patient category is different from the previous Profile.
- Exiting Standby
- Unpairing a bedside and telemetry device.
- Entering or exiting Demo mode at the bedside monitor.
- After a "Leads Off" INOP situation lasting longer than 60 seconds has reversed.

When multi-lead analysis is active, the algorithm learns both the Primary and Secondary ECG leads simultaneously when the above conditions occur and the "Learning ECG" message is displayed above the Primary ECG lead.

For minimum interruption of continuous monitoring the ST/AR algorithm provides the flexibility for learning each lead independent of another lead. The algorithm continues monitoring one ECG lead while the other lead is being learned. The unaffected lead will be analyzed continuously without interruption.

When single-lead analysis is active, the algorithm learns the Primary ECG lead and displays the learning message during the above conditions as well but will also automatically relearn when the Primary ECG lead or lead label is changed.

During a learning phase:

- Alarm timeout periods are cleared
- Stored arrhythmia templates are cleared

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- Asystole, Vfib, and HR alarms (when there are enough beats to compute the HR) are active. No other alarms are active.

Beat Labeling

Once the initial learning process is over and a normal template family is established, each newly detected beat is labeled:

1. If the beat matches a waveform template of a family which has already been classified:
 - The beat is labeled the same as the template family.
 - The template is updated, the population is increased, and the new beat features are added to the family's statistics.
2. If the beat matches a waveform template of a family which has not been classified:
 - The beat is labeled. using the beat labeling rules (described below).
 - The template family is updated, and when enough beats matching the template occur, the template family is classified using the template family classification rules (described below)
3. If the beat does not match any of the existing waveform templates:
 - The beat is labeled using the beat labeling rules.
 - A new template family is created with this beat as its first member.

Beat Labeling Rules

Every beat is analyzed using the "beat labeling rules." These rules determine a preliminary label for each beat:

N	Normal
S	Supraventricular Premature
V	Ventricular Ectopic
P	Paced
?	Questionable

To help avoid artifact being labeled V, a new beat shape may be labeled as "?" when initially seen.

The beat labeling rules use a combination of the following information:

- Feature measurements.
- Timing/Rhythm.
- Template matching.
- Morphology similarity to neighboring beats.
- Pace pulses associated with the beat (if paced patient).

The rules emulate the behavior a clinician uses when analyzing an ECG waveform. Even though the same rules are used for both the adult and neonate monitoring modes, several thresholds are adjusted for

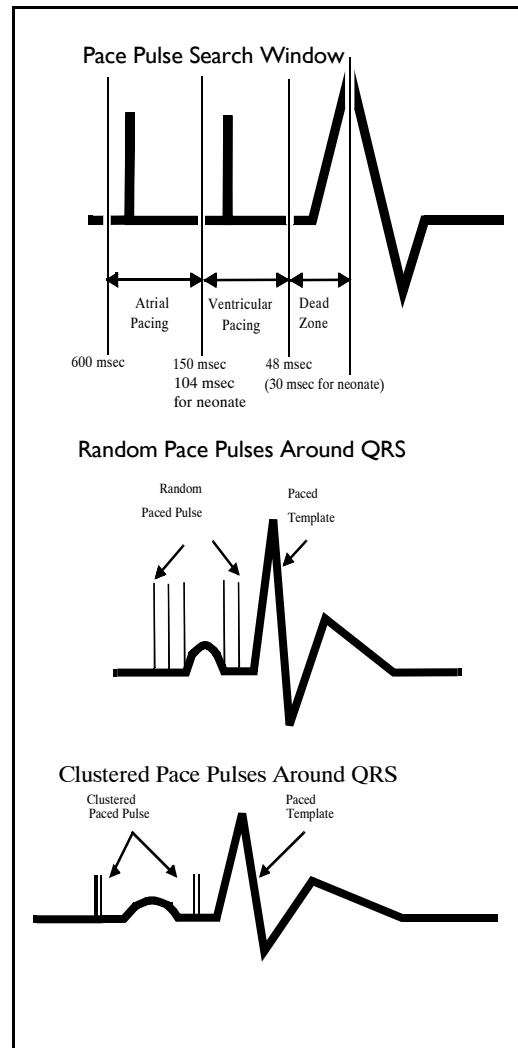
monitoring neonatal patients to account for their higher heart rate and narrower QRS complexes.

Pace Beat Classification

First, the algorithm searches for both atrial and ventricular pace pulses. To accomplish this, a "search window" is established prior to the QRS complex. Then, as pace pulses are seen in the search window, their distances from the beat are tracked.

For the algorithm to consider the new beat paced, the pace pulses to QRS distance must be similar to the pace pulses associated with the paced template.

If the pace pulses fall at random distances they are considered to have no effect on the beat. The distance that the pulses are found from the beat determines the type of pacing - atrial, ventricular or AV (atrial/ventricular) paced..



Template Family Classification Rules

After the normal family is initially learned, each newly created family remains unclassified until enough similar beats, usually less than five, are seen to classify it accurately.

Template families are classified as:

N	Normal
V	Ventricular Ectopic
P	Paced

The labels given to the beats using the beat labeling rules are used to determine the family classification.

A normal template can include N and S beats. For a template to be classified as V, a majority of members must be labeled V. By the ninth beat, if the template is not classified as V, the template is classified N.

A paced template is determined by statistical analysis of all the pace pulses detected within 600 milliseconds of the QRS complexes that are included in the template family. In order for the algorithm to consider the template paced, pace pulses must fall at a consistent distance from the QRS. Based on the number of consistent distances found and their values, the paced template is classified as atrially paced, ventricular paced or AV paced.

The template family classifications are continuously checked against labels given to the individual beats using the beat labeling rules. If many discrepancies are found, the template family is reclassified. In this way, the algorithm has a mechanism to correct inaccuracies made during template classification.

Beat labeling rules use current information to analyze ectopic activity, while template matching provides long term memory to the algorithm. By using this combination of beat features, timing, and template matching techniques, the algorithm flexibly manages a variety of conditions with a high degree of accuracy.

Step 5: Atrial Fibrillation Detection

If the Atrial Fibrillation (AF) alarm is present (available in IntelliVue Patient Monitor Release G.0 or higher or Information Center Release L or higher) and the Adult patient category is selected (AF analysis is not available for Pediatric or Neonatal patient categories), AF analysis is performed using both the RR intervals and the P waves. The algorithm uses three features for AF detection, including RR irregularity, PR interval variability, and P wave variability.

The RR interval analysis is performed when the interval beats are both classified as N or S beats. It updates for every valid RR interval found.

Every 15 seconds, an averaged beat is formed by using beats classified as N or S beats that match the dominant normal template. P wave detection is performed on the averaged beat. PR interval variability is calculated as the PR interval deviation between the current measurement and the running average. The P wave region variability is determined by matching the P wave region of the current and previous 15-second averaged beats.

For AF to be detected for the 15-second period the:

- Normal beat RR intervals must be irregular
- PR interval deviation must be large
- P-wave region must not match well

An AF alarm is detected if AF is present for four 15-second intervals.

Atrial fibrillation cannot be detected if beats are classified as PVCs or Paced beats. Since most atrial flutters have regular RR intervals, they cannot be detected by the atrial fibrillation algorithm.

An independent N-N interval analysis is performed to detect R-R interval changes greater than 12.5%. If a large number of such interval changes is detected an irregular HR alarm will be issued. This analysis is available for all patient categories.

Step 6: Ventricular Fibrillation Detection

Working in parallel with beat detection and labeling, a separate detector continuously examines the in-coming ECG signal(s) for ventricular fibrillation. If a flutter or sinusoidal wave pattern persists for more than four seconds in both ECG channels, the monitor alarms for ventricular fibrillation.

If single-lead arrhythmia monitoring has been selected, only the primary ECG is used for the detection of ventricular fibrillation.

Step 7: Rhythm and Alarm Detection

The results from beat labeling, atrial fibrillation detection, and ventricular fibrillation detection are used by the rhythm and alarm detector as it measures the heart rate, determines the patient's underlying rhythm, and identifies ectopic events.

Alarms are activated by the alarm generator. Higher priority alarms, such as asystole, take precedence and supersede lower priority alarms, such as low heart rate.

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Heart Rate Computation

Two different averages are used by the arrhythmia algorithm to determine the heart rate:

Normally, the heart rate is computed by averaging the most recent 12 R-R intervals. Beats N, S, P, and V are all included in the computation. This average gives a stable estimate of the underlying heart rate even when the rhythm is irregular.

When the heart rate drops below 50 bpm (80 bpm for neonates), the number of R-R intervals used in the average is dropped to four to improve the response time for the computed heart rate to reach the correct value during bradycardia.

Note: For the supraventricular and ventricular tachycardia alarms which have a user-definable PVC run length limit, the heart rate is computed based on the user selected PVC run length up to nine PVCs maximum (i.e. up to 8 R-R intervals). For instance, if the VT alarm is user-defined as five or more consecutive PVCs and heart rate greater than 100 bpm, then four R-to-R intervals will be used to compute the heart rate to see if the rate exceeds the limit of 100 bpm. Likewise, if the VT alarm is user-defined as ten or more consecutive PVCs and heart rate greater than 100 bpm, then eight R-to-R intervals will be used as that is the maximum possible.

Arrhythmia Monitoring for the Paced Patient

Detection of the pace pulse occurs at the point of care device (bedside monitor or telemetry transmitter). This permits highly accurate pace pulse detection on the unfiltered ECG signal.

Since the pace pulses are detected and eliminated BEFORE the ECG waveform is processed by the QRS beat detector, accidental detection of the pace pulse as a QRS is prevented. The pace pulses remain available for viewing on the display or recordings. The pace pulses are displayed at the point that they actually occurred.

Proper Application of the Paced Patient Algorithm

Careful observation during the arrhythmia system's analysis of the paced patient is vitally important. The clinician must always verify that paced pulse detection is indeed taking place.

First, paced patient select must be turned on. The monitor relearns the patient's rhythm using the paced patient algorithm.

While learning, the user should observe the delayed, annotated wave to be certain pace pulse tic marks are properly associated with pace pulses.

Up to two pace pulse tic marks are displayed regardless whether they are associated with the following beat or not. Thus for a dual-chamber paced beat there will be two separate marks (one for each pace pulse).

A double tic mark will be displayed when biventricular pace pulses are present.

Paced Alarms

Although not designed to detect pacemaker sensing problems, the alarm system incorporates two specific alarms for paced rhythms:

- "Pacer-Not-Capture" is determined when a QRS does not occur for 1.75 times the average R-to-R interval and a pace pulse is detected in the time interval.
- "Pacer-Not-Pace" is initiated if a QRS does not occur for 1.75 times the average R-to-R interval and no pace pulse is detected in the time interval.

Note: "M" beat label will appear when a QRS does not occur.

The following application points can greatly improve the results of the paced patient algorithm:

- Pacing detection should always be turned on when monitoring patients with any type of pacemaker.
- Paced complexes should be between 1 and 2 millivolts in size and taller than the pace pulse.
- Ventricular paced beats should be wider than the normal QRS complex.
- Pace pulses should not have visible repolarization (overshoot/undershoot). Repolarization causes increased width to the pace pulse and could result in the pace pulse being detected as a beat.
- Avoid pseudo fusion beats where the pace pulse falls inside the QRS complex. Pseudo fusion beats may cause a narrow QRS complex to be removed as part of the pace pulse removal process and result in false asystole alarms..



AVOID PACE PULSE REPOLARIZATION TAILS (NOTE WIDTH)

Special Concerns for Computerized Arrhythmia Monitoring

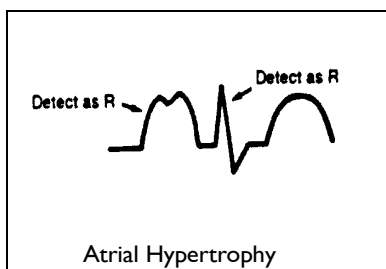
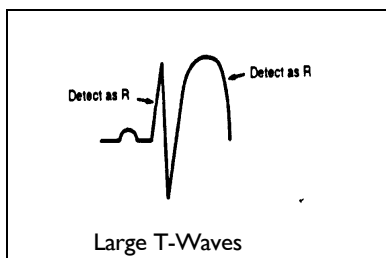
It is impossible to design a computerized arrhythmia algorithm that accurately analyzes 100% of all patients. In the following sections, several conditions that can cause difficulty for the algorithm are described.

Tall P- and T-waves

The algorithm is designed to selectively recognize and filter P- and T-waves to prevent classification as beats. However, if a T-wave is much larger than the R-wave's height, correct classification is difficult. The T-wave might be detected and incorrectly classified as a PVC, and an "R-on-T PVC" or "High Heart Rate" alarm could be activated.

Large P-waves may also be detected and incorrectly classified as an R-wave, causing the algorithm to generate incorrect high heart rate or PVC-related false alarms.

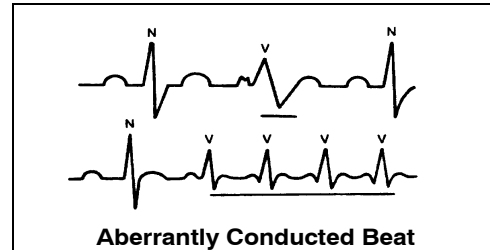
In most instances, large T- and P-waves can be addressed by selecting different leads. However, in conditions such as extreme atrial hypertrophy, hyperkalemia, or decreased ventricular voltage, the P- and T-waves may be as large as the R-wave despite careful lead selection. In these cases, instead of trying to select two leads with the proper P- and T-wave height, it is easier to just select the lead that shows the lowest P- and T-wave height and use the single lead arrhythmia monitoring option or the single lead QRS detection with adjustable minimum detection threshold option.



Aberrantly Conducted Beats

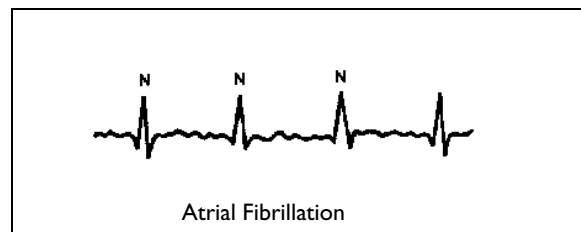
Since P-waves are not analyzed, it is difficult and sometimes impossible for a monitoring system to distinguish between an aberrantly

conducted supraventricular beat and a ventricular beat. If the aberrant beat resembles a ventricular morphology, it is classified as ventricular.



Atrial Fibrillation and Flutter

In some cases of atrial dysrhythmias, the erratic baseline fibrillations and flutters may be greater than the algorithm's detection threshold, causing erroneous detection and false alarms. This is another condition where single-lead arrhythmia monitoring or the single-lead QRS detection with adjustable minimum detection threshold option should be considered if it is difficult to select two leads that have low level erratic baseline.

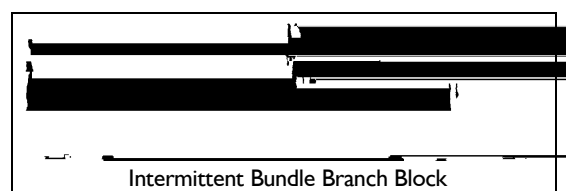


Sinus Arrhythmia

In some cases, during sinus arrhythmia, the P-wave cannot be detected reliably or the P-wave morphology is varying, may cause a false atrial fibrillation alarm.

Intermittent Bundle Branch Block

The phenomenon of bundle branch or any of the other fascicular blocks creates a challenge for the arrhythmia algorithm. If the QRS during the block changes considerably from the learned normal, the blocked beat may be incorrectly classified as ventricular, causing false PVC alarms..



ST/AR Arrhythmia Algorithm

Cardiotach Mode (Arrhythmia Off)

The ST/AR algorithm also provides a cardiotach function when the arrhythmia is turned off. The cardiotach algorithm can process one or two simultaneous ECG channels.

For IntelliVue Multi-measurement Server Release C.0 and higher when arrhythmia is off, the QRS detection is the same as when arrhythmia is turned on. This means that all the noise and rejection tests are performed. See pages 4-6 for a description.

From the beats detected, the heart rate is then calculated using the same formulas used in the arrhythmia algorithm. Working in parallel with beat detection, the asystole and ventricular fibrillation detection algorithms in arrhythmia analysis are used to detect the presence of asystole and ventricular fibrillation.

Cardiotach Alarms

The arrhythmia alarms available are a subset of the basic arrhythmia alarms. The alarms included are:

- Asystole
- V-fib/Tach
- Extreme Tachycardia
- Extreme Bradycardia
- High and Low Heart Rate.

The Arrhythmia System's Alarm Structure

Alarm Detection

The ST/AR arrhythmia monitoring algorithm is designed to analyze up to 23 rhythm disturbances and irregularities. Each of these must pass a set of tests before the alarm is declared. If the system has been configured to have Basic Alarms active, the system will declare only ten alarms. Systems that have been configured with Enhanced Alarms will have 23 alarms. See the charts on alarm chaining for the alarms in each group.

After an alarm sounds and a more serious alarm is detected, the lesser alarm message disappears and the higher priority alarm is activated.

The following two tables describe each alarm and the conditions required to generate the alarm.

Table 1: * Red Alarms**

Alarm	Condition Required to Generate Alarm
Asystole	No QRS detected for x seconds. Choices of > 2.5 to 4 seconds
Ventricular Fib/Tach	Fibrillatory wave (sinusoidal wave between 2-10 Hz) for 4 consecutive seconds
Ventricular Tachycardia	Consecutive PVCs \geq V-Tach Run limit and run HR > V-Tach HR limit
Extreme Tachycardia	Heart Rate greater than the Extreme Tachy limit
Extreme Bradycardia	Heart Rate less than the Extreme Brady limit

Table 2: *Yellow Alarms

Alarm	Condition Required to Generate Alarm
Non-Sustained VT	A run of Vs having ventricular HR > V-Tach HR limit, but lasting for less than the V-Tach Run limit
Ventricular Rhythm	A dominant rhythm of adjacent Vs > vent rhythm limit and ventricular HR < V-Tach HR limit
Run PVCs	Run of PVCs greater than 2
Pair PVCs	Two consecutive PVCs between non-PVCs
Pause	No QRS detected for x seconds. Choices of >1.5 to 2.5 seconds ^a
Pacer Not Capture	No QRS for 1.75 x the average R-R interval with Pace Pulse (paced patient only)
Pacer Not Pace	No QRS and Pace Pulse for 1.75 x the average R-R interval (paced patient only)
Missed Beat	No beat detected for 1.75 x average R-R interval for HR <120, or no beat for 1 second with HR >120 (non-paced patient only)
SVT	Run of SVPBs \geq SVT Run limit and SVT run Heart Rate > SVT HR limit

Alarm	Condition Required to Generate Alarm
R-on-T PVC	For HR <100, a PVC with R-R interval <1/3 the average interval followed by a compensatory pause of 1.25 x average R-R interval or 2 such Vs without a compensatory pause occurring within 5 min. of each other. (When HR >100, 1/3 R-R interval is too short for detection.)
Ventricular Bigeminy	A dominant rhythm of N, V, N, V, N (N=supraventricular beat, V=ventricular beat)
Ventricular Trigeminy	A dominant rhythm of N, N, V, N, N, V, N, N (N=supraventricular beat, V=ventricular beat)
PVCs>Limit	PVCs within one minute exceeded the PVCs /min limit
Multiform PVCs	The occurrence of two differently shaped Vs, each occurring at least twice within the last 300 beats as well as each occurring at least once within the last 60 beats
Heart Rate>Limit	Heart Rate greater than the upper HR limit
Heart Rate<Limit	Heart Rate lower than the lower HR limit
Atrial Fibrillation	Consistently irregular rhythm (irregular R-R intervals), P-R variability and P-wave variability (For Adult patients only)
Irregular Heart Rate	Consistently irregular rhythm (irregular R-R intervals).

a. When the setting for Pause and Asystole are both set at > 2.5 sec., if an event occurs of > 2.5 sec., the Asystole alarm will be annunciated.

Note: >= is greater than or equal to a number.

Alarm Activation and Graded Alarm Structure

The ST/AR arrhythmia system's alarm structure is based on priorities, with a system of *** Red, * /**Yellow and INOP alarms. Each type has a distinctive visual and audible alarm, enabling quick recognition of the severity of the alarm event.

Once an alarm is detected, it is immediately activated. An alarm message appears on the display, and a distinctive audible alarm activates.

*** Red Arrhythmia Alarms

Red alarms, the most critical and life-threatening, always take priority over lesser arrhythmia alarms.

They can never be individually turned off.

All red and yellow alarms will be turned off if:

- Alarms are suspended (Pause Alarms or Alarms off selected).
- ECG alarms are off (HR alarms off) at the bedside monitor.
- All red and yellow arrhythmia alarms are off for telemetry.

Red arrhythmia alarms generated from the Information Center for telemetry and IntelliVue Patient Monitors with Audible and Visual Latching On will:

- Have audible and visual alarms until silenced.
- If the condition has ceased when silenced, the audible and visual indicators will disappear.
- If the condition is still present when silenced, the audible sound will disappear and the visual message will continue.

With the IntelliVue Patient Monitors, if you have configured the system to have the Visual and Audible Latching Off, then the following behavior will apply when a red arrhythmia alarm occurs:

- While the alarm condition is present, but has not yet been silenced the condition will have an audible sound and visual message.
- If the condition should cease before the alarm has been "silenced" then the visual message and the audible sound will be turned off.
- If the condition is still present when the Silence key has been selected, the system will maintain the visual text message until the condition ceases.

Alarm Reminders (Re-Alarm)

If Alarm Reminder is configured on for your monitor, you will get an audible reminder of alarm conditions that remain active after you have acknowledged the alarm. This reminder may take the form of a repetition of the alarm tone for a limited time, or an unlimited repetition of the alarm tone (this is the same as a new alarm). In Configuration Mode, you can set the interval between silencing the alarm and sounding the reminder tone to one, two, or three minutes.

* Yellow Arrhythmia Alarms

Yellow alarms are considered lower in priority than red alarms, but still may indicate serious rhythm or rate disturbance. A arrhythmia yellow alarm can be superseded by a more serious yellow alarm event, or a red alarm.

Individual arrhythmia yellow alarms can be disabled. Disabling yellow arrhythmia alarms for a particular patient does not affect any alarms on any other patient.

Yellow arrhythmia alarms have a distinctive sound which is sounded for a fixed duration This means that the yellow alarm lamp and the tones are active for a configured number of seconds only, after which

ST/AR Arrhythmia Algorithm

the flashing numeric and the alarm message remain for up to three minutes. Alarm reminders are not provided for yellow arrhythmia alarms.

***Yellow arrhythmia alarms generated from the Information Center for telemetry or SDN bedside monitors or IntelliVue Patient Monitors will behave in the following manner:**

If silenced:

- And the condition ceases, the visual indicators will disappear.
- And the condition continues, the visual alarm message continues. When the timeout period ends, a realarm is announced both audibly and visually. A new alarm is not stored.

If not silenced:

- And the condition ceases, the visual indicators will disappear after 3 minutes.
- And the condition continues, the visual alarm indicators will continue. When the timeout period ends, a realarm is announced audibly. A new alarm is not stored. If the timeout period is configured to "0," no reminders will be issued.

Yellow arrhythmia alarms are always set to latch visually for three minutes.

**** Yellow HR Limit Alarms**

HR limits can be configured to be **Yellow limit alarms. If configured to be a limit alarm, they will be announced as a continuous yellow level alarm. **Yellow HR limit alarms will respond to the configured Latching settings configured in the host IntelliVue Patient Monitor - IntelliVue Patient Monitor or Information Center

Audible and Visual Latching On:

- Audible and visual alarms until silenced.
- If the condition has ceased when silenced, the audible and visual indicators will disappear.
- If the condition is still present when silenced, the audible sound will disappear and the visual message will continue.

Visual and Audible Latching Off:

- While the alarm condition is present, but has not yet been silenced, the condition will have an audible sound and visual message.
- If the condition should cease before the alarm has been "silenced," then the visual message and the audible sound will be turned off.
- If the condition is still present when the Silence key has been selected, the system will maintain the visual text message until the condition ceases.

Alarm Reminders (Re-Alarm)

Similar to the ***Red arrhythmia alarms, if Alarm Reminder is configured on for your monitor, you will get an audible reminder of alarm conditions that remain active after you have acknowledged the alarm. Alarm reminders if configured "ON" will issue a reminder tone every 1, 2, or 3 minutes or if set to re-alarm a continuous alarm tone will sound.

INOP Alarms

INOP alarms occur whenever the ECG signal cannot be properly analyzed due to noise or INOP conditions. If more than 2/3 of the time over the last 30 seconds beats are classified as either noisy or questionable, a "Cannot Analyze" INOP alarm is generated. When active, the INOP alarm continues, visually and audibly, as long as the condition exists, and stops automatically when the condition terminates.

Since the INOP alarm is a lower priority alarm it will not override a red or yellow alarm should it occur during the same time a red or yellow alarm is occurring. On the other hand, if an arrhythmia event is detected while the INOP alarm is active, the red or yellow arrhythmia alarm will override the INOP alarm.

Since the "Cannot Analyze" INOP alarm indicates that the effectiveness of the arrhythmia monitoring for the patient is compromised, a quick response to this alarm is recommended.

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Alarm Chaining

To prevent the confusion of redundant alarms or the activation of less important alarms while acknowledging serious alarms, the arrhythmia system sets alarm priorities through an “alarm chaining system.”

Related events, such as ventricular alarms, are grouped in a “chain.” The most critical alarms occupy the top of the chain and are followed by events in logical, descending order.

The manner in which the alarms are grouped and prioritized define how the alarms are announced. *** Red alarms having the highest priority are announced first if present. If there are no *** Red alarms detected, then the highest priority *Yellow alarm detected in any given alarm chain is announced. If alarms of the same priority in different alarm chains are detected, the alarm that occurred most recently is announced.

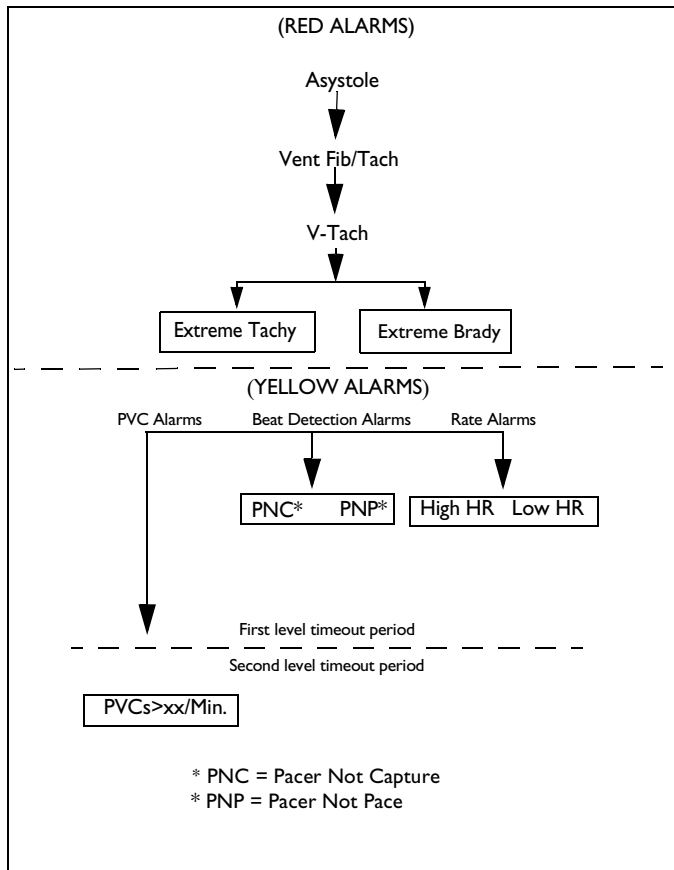


Figure 9 Alarm Chain for Basic Arrhythmia Monitoring

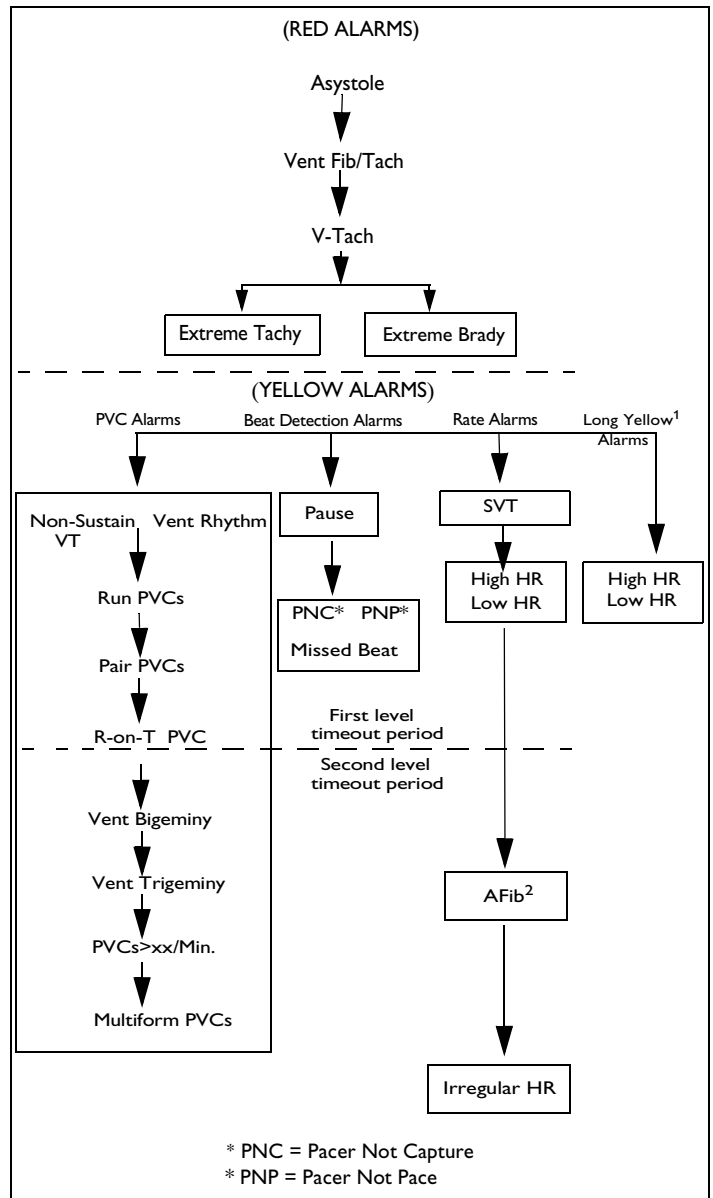


Figure 10 Alarm Chain for Enhanced Arrhythmia Monitoring

Note: For the IntelliVue Patient Monitors, when arrhythmia analysis is turned off the only available alarms are: Asystole, Ventricular Fibrillation, Extreme Tachycardia, Extreme Bradycardia, High HR and Low HR.

¹ HR High and HR Low limit alarms can be configured to be short arrhythmia alarms or long limit alarm sounds. If configured to long alarm limit alarm, there is no timeout period and no chaining of the Afib and irregular HR alarm.

² Atrial Fibrillation alarm only available for IntelliVue Patient Monitor Release G.0 or higher or Information Center Release L. or higher.

Alarm Behavior after Annunciation

Alarm Timeouts

To reduce the number of unnecessary alarms, at the time when a

* Yellow alarm is announced, a fixed non-extending timeout is initiated. The duration of the timeout period is user-configurable. **Red alarms have no timeouts.**

During the timeout period, this alarm and all lower priority alarms within the same chain (group) will not be announced. Higher priority alarms or alarms from a different chain will be announced if detected during the timeout.

The timeout period for first level yellow alarms can be configured for between 0 and 5 minutes. The timeout period for second level yellow alarms can be configured for between 0 and 15 minutes. Timeout periods will end once the configured amount of time has passed. They will also be cleared if any of the conditions that cause learning occur. (see Learning)

Points to Remember About Alarms

- Clinicians should acknowledge as many alarms as possible.
- If an alarm condition exists, it is always activated unless it is turned off, there is a higher priority alarm in effect, or the fixed timeout period is in effect.
- * Yellow alarms can individually be user-disabled.
- *** Red alarms never automatically reset with one exception. If the IntelliVue Patient Monitor is configured with the Visual and Audible Latching to OFF, any Red alarm will cease once the condition ceases.
- All arrhythmia alarms are disabled if alarms are suspended or ECG alarms are off (HR alarms off) at the bedside. All alarms can be turned off if the patient is being monitored via telemetry, by using the "All Red and Yellow Arrhythmia Alarms Off" button.

How to Get the Best Performance from Computerized Arrhythmia Monitoring

Steps to Better Arrhythmia Monitoring

1. Optimize Signal Quality

- Skin preparation is especially important when using gel electrodes.
- Change electrodes every 24 hours. Increased baseline wander is the first indication that electrodes are dry and need to be changed.
- Support cable and electrode wires. Artifact and wander may increase if the skin under the electrode is stretched. Taping the electrode may reduce this if your patient is active.

2. Choose the Best Lead(s)

- Choose a lead(s) where QRS amplitude is stable and has adequate amplitude (recommended amplitude greater than 0.5 millivolts).
- If the system can do multi-lead analysis but only one lead has adequate stable voltage, change arrhythmia analysis to single-lead analysis or use the single lead QRS detection feature.

3. Ensure the Best QRS Complex

Size and shape of the QRS are very important for proper beat detection and classification. Use the following guidelines to choose leads which produce the best QRS morphology for analysis by the arrhythmia system.

The Normal Beat

- R-wave is tall, not clipped or biphasic.
- T-wave is less than 1/3 the R-wave height.
- P-wave is smaller than 1/5 the R-wave height.

The Ectopic Beat

- Height is at least 1/5 the normal QRS height.
- Beat should not be clipped.
- Shape is distinctly different than the normal.

The Paced Beat

- Pace pulse not much larger than the QRS complex.
- Ventricular paced beat is wider than the normal QRS complex.
- Pace pulse has no visible re-polarization.
- Avoid pseudo fusion beats where the pace pulse falls inside the QRS complex.

4. Adjust Minimum Detection Threshold.

The size of the P-wave can impact the accurate detection of the QRS. When the P-wave is larger than 1/5 the height of the QRS or is larger than 0.15 millivolts, adjust the threshold level above the P-wave.

5. Adjust Alarms

Adjusting some alarms off, changing the alarm criteria or adjusting the timeout periods will:

- Reduce the number of alarms.
- Alert the clinician to alarms specific to the patient.
- Prevent redundant alarms for known or chronic conditions.

Conclusion

Computerized arrhythmia monitoring is a tool the clinician can use to continuously monitor and evaluate the progress of patients. In order to fully make use of this tool, it is important to understand the computer algorithm's capabilities and limitations.

