mysafety insight

Advanced ECG Monitoring

Clinical Information Leaflet

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Content & Preface

Cardiovascular diseases, leading to almost 17.9 million deaths each year, are the number one cause of mortality globally (Figure 1) [1]. ECG, as the most prevalent method to monitor the heart's status, is crucial to detect cardiovascular abnormalities and is irreplaceable in terms of efficiency and accessibility. As continuous ECG monitoring is helpful in capturing the changes in heart rate, rhythm, and waveform morphology, it is essential to ensure patient safety in various clinical scenarios, such as below:

Top 5 causes of death

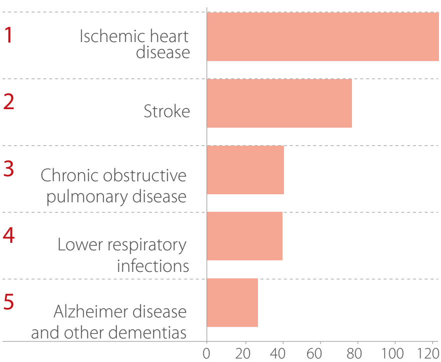


Figure 1. Sourced from WHO: 2016, for both sexes, all ages

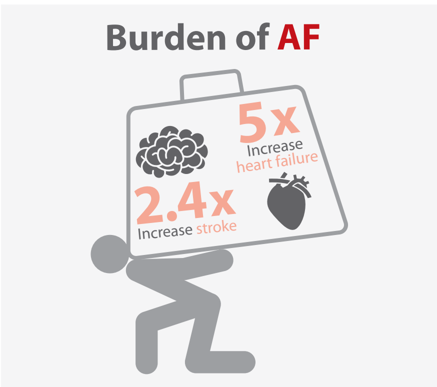
1. Alarm fatigue is a nonnegligible issue in ICU as it causes clinicians to get desensitized to alarms, which can directly affect patient safety. Also, some arrhythmias are not easy to be detected by computerized algorithms. Missing those alarms is dangerous. Mindray four-lead ECG analysis algorithm is an advanced technology that has been an achievement of researches and development for many years. By simultaneously analyzing four leads, it has strong abilities of anti-interference and arrhythmia detection. It effectively decreases false alarms and provides a comprehensive analysis for arrhythmia detection, thus contributing to patient safety.

2. Given complicated clinical scenarios, It is not always practical to adopt continuous 12-lead ECG monitoring. However, the need for a comprehensive view of different leads is still valid for patient moinitoring, especially for those with a high risk of cardiac ischemic events.

Mindray D12L algorithm reconstructs 12 leads using only six electrodes, which enables 12-lead ECG monitoring. It is also available for the functions of four-lead ECG analysis, ST Graphic, QT/QTc analysis, and AF detection.

3. Continuous ST monitoring is appreciated by clinicians as it assists in the early detection of myocardial ischemic events. Nevertheless, a gap exists between the expectation and clinical practice, because usually the ST deviation information is not well organized for display and notice. Mindray' s intuitive and ease of use "ST Graphic" can facilitate the diagnostic process, which contributes to better outcomes.

4. Since the prolongation of the QT interval is associated with an increased risk for potentially lethal arrhythmias such as Torsade de Pointes (TdP), precise QT interval measurement and real-time monitoring is of great significance for clinicians. Besides, QT prolongation is a powerful predictor of mortality in high-risk patients. Mindrays' advanced QT/QTc analysis algorithm combined with an intuitive graphical display tool "QT View" can provide timely notifications of QT intervals and contribute to patient safety.



5. Atrial fibrillation (AF) sometimes brings such mild symptoms that patients don' t give them a second thought. However, the patients could be in danger, since living with undiagnosed and uncontrolled AF can lead to a host of complications, including stroke. It is challenging to detect paroxysmal AF by doing an ECG test, if there is no AF episode occurring during the short test period.

To avoid the life-long burden of patients caused by AF and aim at early detection of AF, Mindray independently developed an advanced AF detection algorithm, which can perform well even in a signalnoisy environment.

In conclusion, with these advanced features, Mindray' s ECG monitoring solution could relieve the alarm fatigue burden, provide better user experience, improve clinical workflow, and ultimately ensure safety for patients.

1 Four-lead ECG Analysis Algorithm

AHA Guidance

"...monitors should be capable of simultaneously displaying and analyzing two and preferably three or more leads."

——American Heart Association, 1989 [2]

The ECRI 2020 executive report illustrates that clinicians have become overwhelmed by loads of alarms from medical devices, which disrupts their attention on direct patient care tasks and creates the potential for a clinically significant event to go unaddressed [3].

False arrhythmia alarms are the main source of alarm fatigue. A 31-day observational study of consecutive intensive care unit patients found that 45.1% of the alarms are sourced from arrhythmia [4]. In the study, clinicians annotated 12,671 arrhythmia alarms and concluded that 88.8% are false alarms.

The high false arrhythmia alarm rate has severe implications such as disruption of patient care, caregiver alarm cognitive overload, and desensitization from clinical staff to real life-threatening alarms [2,5]. Therefore, finding an effective way to relieve alarm fatigue becomes an essential task for all the manufactures of patient monitoring devices, which would greatly benefit the comfort of both patients and caregivers, as well patient safety.

Multi-lead algorithm can improve arrhythmia analysis by simultaneously processing up to four ECG leads

Most ECG algorithms utilize one or two leads to analyze heart rate and rhythm and generate alarms. Analyzing multiple leads (more than two) for arrhythmia detection can provide several benefits. Mindray arrhythmia analysis algorithm, that processes up to four ECG leads, is much less susceptible to noise and artifact (fewer false calls), offers better arrhythmia detection sensitivity (fewer missed calls), and guarantees continuous monitoring even when certain ECG electrodes have contact failure. It can thus provide a better quality of ECG monitoring.

Clinical value of four- lead ECG analysis

1. Free from ECG artifact

Compared with one-lead or two-lead systems, simultaneously analyzing more leads could increase the possibility to reduce the impact of artifacts resulting from the patient activity or nursing care, because artifacts often only contaminate certain leads (Figure 2) [6]. Unless the single or two-lead algorithm is configured to use the right leads, there is a risk of missing lethal arrhythmia alarms. Besides, contact failures often occur when electrodes are used for a prolonged periods of time or when they get partly detached during patient activity or when the patient is diaphoretic. When this occurs, on systems using one or two analysis leads, depending on the leads affected, ECG analysis will be suspended until the electrodes are replaced, and lethal rhythms could potentially be missed. When more leads can be used by the analysis algorithm, such failures can be better handled.

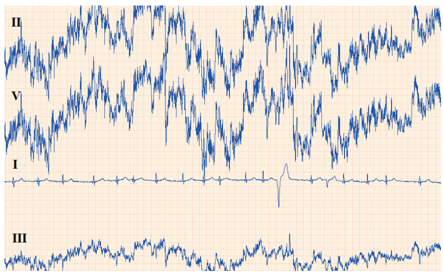


Figure 2. Example of artifact caused by patient movement

2. Enhanced arrhythmia detection

It is expected that automated ECG algorithms should not miss detecting lethal arrhythmia events like ventricular fibrillation

(V-Fib) and ventricular tachycardia (V-Tach) because patient safety is of utmost importance. However, detecting such rhythms is not always easy for computerized algorithms. For example, the morphological differences between successive PVCs in a run of polymorphic V-Tach could make it challenging to detect all the PVCs in one lead, as the amplitude could vary a lot from beat to beat. In Figure 3, significant differences in amplitude and morphology are seen among the beats that constitute the V-Tach event [6]. Single and two-lead analysis algorithms would have found it difficult to recognize all the PVCs using leads I and V, which would result in a missing V-Tach event. On the other hand, if four leads are analyzed simultaneously, the V-Tach event will be detected because the hard-to-define beats in the run are clearly seen on leads II and III.

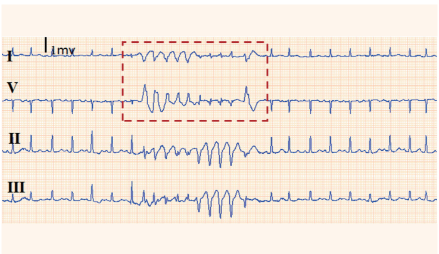


Figure 3. Example of V-Tach event

The four-lead algorithm has a stronger anti-interference ability and more accurate arrhythmia detection ability, which could reduce false alarms and missed lethal alarms effectively. Combined with intelligent alarm management technology, it could relieve the alarm fatigue, provide better user experience, and guarantee patient safety.

2 Derived 12-Lead ECG (D12L)

An easier way to monitor 12-lead ECG

The value of 12-lead ECG monitoring, which requires ten electrodes, is in its ability to detect arrhythmias and acute myocardial ischemia. More electrodes placed on the patient means more information provided to clinicians. However, different from the standalone ECG machine, continuous ECG monitoring has to consider patient comfort and clinicians' workload. Sometimes, it can even be impossible to be implemented because of therapy operations. For example, when a traditional 12-lead ECG is not practical because placing too many precordial leads on the patient' s chest skin may block the location of an echocardiographic transducer or defibrillator pads, D12L provides an alternative way for 12-lead ECG monitoring.

What is D12L technology?

Mindray D12L algorithm reconstructs 12-lead ECG with the Mason-Likar system, using four limb electrodes and two chest electrodes (Figure 4,5). The derived 12-lead ECG monitoring (D12L) provides comprehensive 12-lead information of the heart, including

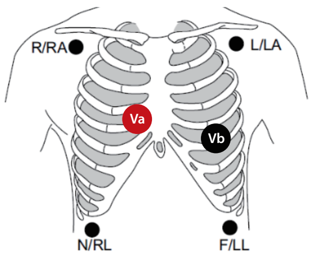


Figure 4. Mindray D12L chest electrodes can be selected from (V1 & V3), (V1 & V4), (V1 & V5), (v2 & v4), (V2 & V5), (V3 & V5), (V3 & V6)

arrhythmia detection, ST-segment analysis, and QT/QTc interval monitoring with only six electrodes in standard placement. The workflow for clinicians is simplified, but the real-time monitoring of the heart is uncompromised.

Figure 5. 12-lead ECG with 6 electrodes (the derived leads start with "d")

Since D12L uses the standard electrode positions, clinicians can easily switch from D12L to traditional 12-lead ECG with four extra chest electrodes. Where the current standard practice of patient monitoring is utilizing five electrodes, just adding one more chest electrode could obtain the benefits of 12-lead ECG monitoring. Therefore, compared with other novel methods of reduced electrode placement, the non-derived eight leads (I, II, III, aVL, aVR, aVF, Va, Vb) are still available for serial comparison.

3 Graphical Display of ST Changes

AHA Recommendation

"Reference to the anatomic location of the ischemic region, such as anterior or inferior, is recommended and is based on the leads that show the ST-segment alterations". [7]

ST Graphic helps visualize myocardial ischemia

Although myocardial ischemia is often accompanied by symptoms, such as chest pain or shortness of breath, some patients do not experience typical acute coronary syndrome (ACS) symptoms [8]. Therefore, continuous ST monitoring is critical for patients whose clinical conditions warrant ischemia monitoring, for example, ACS, myocardial infarction (MI), angina, and cardiac surgery. Also, research has shown that ST monitoring is an independent predictor of mortality [9].

ST-segment monitoring may be underused, although it is effective for assessing ongoing myocardial ischemia. A national random survey in the USA illustrated that nearly half of nurses in cardiac units did not use ST monitoring for the detection of myocardial ischemia in patients with ACS [10]. Possible reasons were high number of false ST alarms and lack of education about what to do in response to ST alarms.

The traditional display of ST changes on the bedside patient monitor is a list of the 12 leads with the corresponding numbers indicating the amount of ST elevation or depression. The display does not show the location of the ST changes (Figure 6), and it does not give any indication of the evolution of the changes over time.

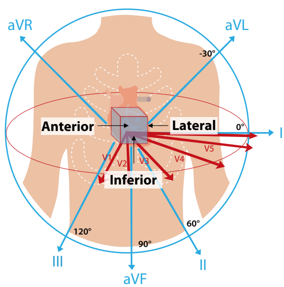


Figure 6.
The wall location of the heart

ST Baseline

ST change under limit

ST change over limit

Direction of green/yellow bars from baseline indicates elevation or depression.

Figure 7. The display of ST Graphic

Mindray's exclusive ST Graphic is an intuitive graphical representation of the ST changes in an easy to read histogram. It displays dynamic ST values from frontal (limb leads) and horizontal (chest leads) planes and divides them into three anatomic locations, helping medical staff easily monitor patients at risk for myocardial ischemia or infarction and identify the effectiveness of interventional therapy.

Striking yellow bars mean abnormal ST-segment deviation, while green bars mean there is a deviation but it is within the preset normal range (Figure 7). Such a feature shortens the time for caregivers to process information, and most importantly, its ease of use can facilitate the regular ST monitoring in cardiac units and even other departments.

The high-resolution ECG platform and false-alarm-suppression algorithms will dramatically increase the accuracy of ST monitoring and avoid extra false alarms. In addition, D12L can minimize the electrode placement work and is reliable

4 Intuitive QT/QTc Analysis

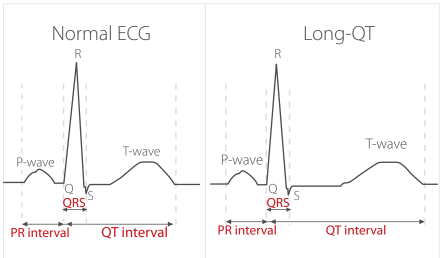


Figure 8. Interpretation of QT prolongation

Increased awareness of Long QT Syndrome

Nowadays, the types of patients that come to be seen by cardiologists and physicians are progressively changing. It is no longer exceptional to see a patient either suspected to be affected by the long QT syndrome (LQTS) or found to have a prolonged QT interval. The prevalence of congenital LQTS is estimated to be 1 in 2,000 live births, so it can no longer be regarded as a rare disease [11].

LQTS is a disorder of the cardiac electrical activity (Figure 8). It can cause sudden, uncontrollable and dangerous arrhythmias. Although many people with LQTS have no signs or symptoms, when sudden deteriorations and arrhythmias occur, they can be lethal.

Medications can induce and aggrazvate LQTS

While LQTS can be genetic, it can also be induced by a wide range of medications. More than 50% of commonly prescribed medications can lead to drug-induced LQTS [12]. The drugs include those frequently used in critical care, such as antibiotics, anti-arrhythmias and anti-psychotic agents. Acquired LQTS from medications is even more common than genetic LQTS. Besides, acquired LQTS may also aggravate genetic LQTS. Therefore, patients with acquired or genetic LQTS may be at an increased risk of developing lethal arrhythmias, such as R on T and Torsade de Pointes (TdP), which could lead to cardiac arrest.

QTc assessment is essential before initiating certain drugs

The QT interval changes in response to the heart rate. When the heart rate increases, the QT interval shortens. To account for this, QT interval can be corrected for heart rate (QTc) using a variety of mathematical formulas. Mindray patient monitors provide the four most commonly used formulas as options.

In the case of both inherited and acquired LQTS, the AHA' s guidelines recommend QTc monitoring to be performed [13]. Such an indication may include patients at risk for LQTS before initiating the drugs with a known risk of prolonging the QT intervals.

For instance, chloroquine or hydroxychloroquine, a debatable medication used for Covid-19, does prolong the QT interval and may thus be dangerous for those with LQTS. Therefore, before and after using such kind of QT-prolonging drugs, an assessment of the risk is essential [14].

Accurate QT/QTc monitoring

Technically, the onset of the QT is easy to mark, at the beginning of QRS complex. However, the end of T wave may be difficult to determine, as it merges smoothly with the baseline or even with a U wave. Mindray' s high-resolution-ECG platform and advanced algorithms provide an accurate determination of QT/QTc. Besides, an intuitive QT-view window is provided for caregivers to quickly notice and compare the QTc deviations (Figure 9).

Figure 9. QT View provides baseline and current ECG for comparison

5 Atrial Fibrillation Detection Algorithm

ESC Guidance

"Paroxysmal AF is often missed, as well as the best time for treatment. Extended continuous ECG monitoring has been validated for the detection of paroxysmal AF."

——European Society of Cardiology, 2016 [15]

The burden of Atrial Fibrillation

In the last 20 years, atrial fibrillation (AF) has become one of the most important public health problems and a significant cause of increasing health care costs in western countries. In Europe, AF is present in 0.12%–0.16% of those younger than 49 years, in 3.7%–4.2% of those aged 60–70 years, and in 10%–17% of those aged 80 years or older [16]. By 2030, it is expected that there will be 14 to 17 million patients with AF in Europe, and 120,000 to 215,000 new patients will be diagnosed each year [15].

AF can be silent, but it can lead to severe consequences like stroke and death. For patients with paroxysmal and self-terminating AF, it can be difficult to detect this kind of arrhythmia with ECG machine, because there may be no AF episode during the test. In contrast, recording of continuous ECG monitoring is an effective and cost-effective method to track AF. There is good evidence that continuous ECG monitoring can enhance the detection of undiagnosed AF, for example, 72-hour ECG monitoring after a stroke [17], or even for a longer period [18]. Also, a randomized controlled trial proved that active screening (ECG monitoring) for atrial fibrillation improved the AF detection performance in patients aged over 65 [19].

Benefits of AF Algorithm

1. Detecting silent and unknown AF;
2. Early treatment helps release life-long burden;
3. Evaluation of antiarrhythmic drug effects or catheter ablation for rhythm control.

Mindray's AF detection algorithm can be used in most clinical scenarios. It processes up to four leads of ECG simultaneously and can detect AF arrhythmia events accurately in a timely manner. It performs well even in signal noisy environment, and therefore effectively improves clinical outcomes and contributes to patient safety.

Mindray's ECG algorithm provides accurate and comprehensive monitoring functions for patient surveillance in the ECG, improving caregivers' workflow and contributing to patient safety.

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