EK-Pro

The choice for quality ECG arrhythmia monitoring

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Clinical care environments rely heavily on technology to facilitate patient care and increase efficiency. One such technology is the computerized arrhythmia analysis utilized in patient monitoring systems. This article presents the latest enhancements in GE Healthcare's EK-Pro arrhythmia detection algorithm.

EK-PRO – ADVANCING SIMULTANEOUS, MULTI-LEAD ARRHYTHMIA MONITORING FOR OVER THREE DECADES

EK-Pro, an advanced software algorithm, is the result of more than three decades of development, design and testing. EK-Pro can simultaneously process up to five independent ECG leads for arrhythmia detection and up to 12 ECG leads for morphology analysis. The reason for analyzing multiple leads is quite simple. Unless cardiac monitors can acquire and analyze lead data that faithfully represents several different "views" of the heart, there is a very real risk of failure to detect clinically significant cardiac events. Conversely, because artifacts are often not evident in all leads, it is important to allow the algorithm to continue to recognize the patient's normal rhythm even when substantial artifact is present. Consider some of the important clinical benefits provided by the simultaneous analysis of three or more leads.

- **Event Notification.** By analyzing data from the inferior, anterior, and lateral walls of the heart, multi-lead algorithms can detect cardiac events that might otherwise go unnoticed.
- **Artifact Discrimination.** Simultaneous multi-lead analysis enables algorithms to better distinguish extraneous, random signals from true beats. Such artifacts can frequently cause lesser systems to exhibit faulty beat detection and interpretation, which then most often result in false and nuisance alarms.
- **Uninterrupted Monitoring.** Simultaneous, multi-lead analysis provides redundancy, so that monitoring can continue in the event of a contact failure. While such electrode issues should always be corrected at the first opportunity, it is important that arrhythmia algorithms be able to handle such failures so that the analysis function continues uninterrupted. Single and sometimes even dual-lead systems cannot provide this safety benefit.
- **Multi-Lead ST Analysis.** ST-segment monitoring has become a valuable tool clinicians can use for real-time assessment of myocardial ischemia in patients with unstable angina[1], patients treated with percutaneous transluminal coronary angioplasty (PTCA)[2], and patients with acute myocardial infarction treated with thrombolytics[3]. In addition, a consensus statement[4] by the ST-Segment Monitoring Practice Guideline International Working Group recommends using ST-segment monitoring in patients with chest pain that prompts emergency department visits, in patients after cardiac surgery, and in patients at risk for postoperative cardiac complications after non-cardiac surgery. Since cardiac ischemia can often be localized to specific areas of the myocardium, there is a clear need to use an ST analysis algorithm that processes multiple leads representing the inferior, anterior, and lateral views of the heart.

The American Hospital Association for many years has likewise affirmed the need for simultaneous multi-lead arrhythmia analysis[5], and the technologies at the core of EK-Pro have been meeting that need for over three decades. In today's demanding care environments, a high-quality arrhythmia analysis algorithm should provide nothing less.

CLINICAL BENEFITS OF MULTI-LEAD ARRHYTHMIA MONITORING

Multi-lead monitoring for arrhythmias has a variety of documented clinical benefits, as illustrated by these examples:

- **Continuous monitoring when it counts.** Some algorithms simply stop analyzing when they encounter artifacts. EK-Pro continues monitoring via leads that still exhibit good signal quality. Below is an example of a patient with postoperative cardiac standstill after heart surgery. Prior to the event the patient felt pain resulting in significant artifact in a majority of the leads. If this patient would have been monitored with an algorithm that did not continue monitoring in leads with good signal quality, this event may not have been detected.

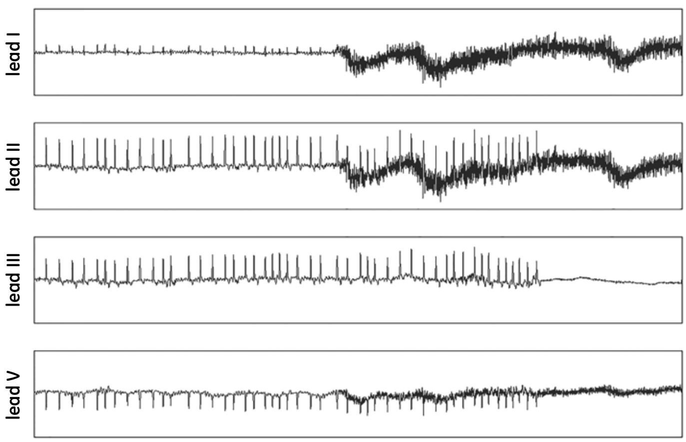

Figure 1. Cardiac standstill and artifact

- **Detecting arrhythmias in different leads.** The leads that best show normal rhythms are not always the same leads that best show an arrhythmia event. This example shows a significant change in morphology in leads I and III, but not in leads II and V.

Figure 2. A patient with ventricular tachycardia.

- **More consistent and accurate interval measurements** Measurements of QRS duration and QT interval can be different in the various leads. Thus, the American Heart Association recommends using global versus lead-specific measurements for consistency and accuracy[6]. In the arrhythmia event in Figure 3, the QRS duration is relatively narrow in leads I and V, but significantly wider in leads II and III. Since QRS duration is a key feature in beat interpretation and arrhythmia detection, the importance of using multiply leads to obtain an accurate measurement is clear.

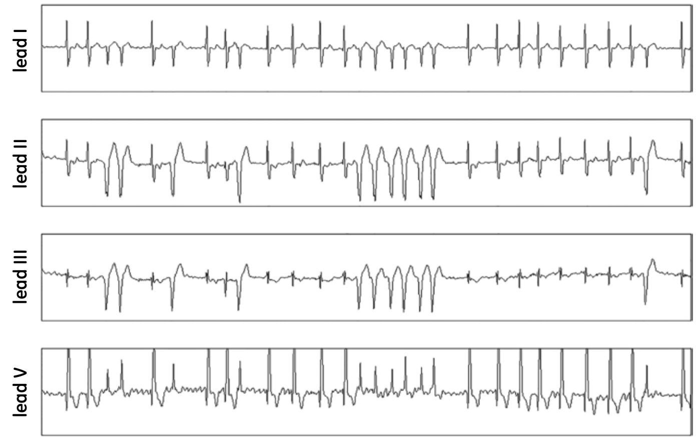

Figure 3. Duration of QRS during arrhythmia differs from lead to lead

- **Finding the "Best Lead".** Some algorithms are configured to use a single "best lead" for the duration of monitoring. However, arrhythmias can often cause that "best lead" to exhibit low QRS amplitude or morphologies that are hard to distinguish. The example in Figure 4 show the importance of analyzing multiple leads and not just the "best" one or two. During arrhythmia there is low amplitude in leads I and V and relatively normal amplitude in leads II and III.

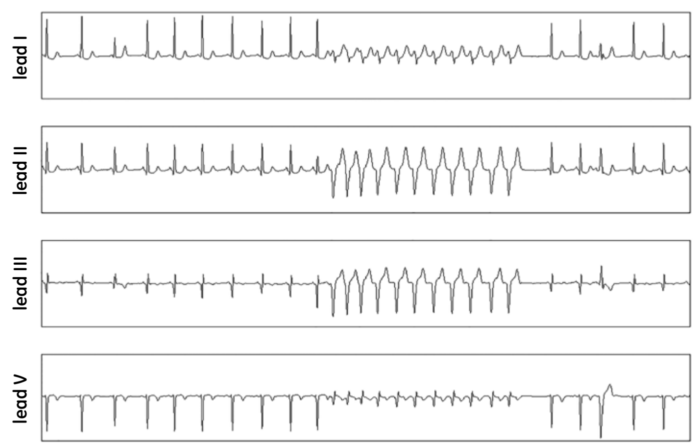

Figure 4. Low amplitude and changes in beat morphology during arrhythmia events.

ACCURATE DETECTION OF VENTRICULAR TACHYCARDIA IN PEDIATRIC PATIENTS

Continuous development of the EK-Pro has achieved excellent performance for the relatively narrow beat morphologies common to ventricular tachycardia in pediatric patients – a factor that frequently pose a challenge to algorithms designed primarily for adult patients. To verify this accuracy, the EK-Pro algorithm was evaluated on waveform data representing 100 pediatric patients from the cardiac units of several pediatric hospitals. The ECG recordings in this proprietary GE database were selected by the hospitals as representative of patients having arrhythmias that were the especially challenging for monitors to detect. Results for the detection of ventricular tachycardia are shown in Table 1.

Auth Alarm Type	Total Events	Events Detected
VTACH (long run)	11	11
VTACH (short run)	29	25

Table 1. Results for the detection of ventricular tachycardia in 100 pediatric patients from a database enriched with challenging arrhythmias

SUPRAVENTRICULAR TACHYARRHYTHMIA

Atrial fibrillation is the most common arrhythmia that results in hospitalization in the United States[7]. To aid clinicians in developing an effective patient management plan that may prevent atrial fibrillation from becoming chronic,[8] the EK-Pro algorithm also provides analysis for the detection and trending of this arrhythmia.

In addition, supraventricular tachyarrhythmias are a common cause of morbidity after cardiac surgery. They may decrease diastolic filling and cardiac output and increase myocardial oxygen consumption, resulting in hypotension and myocardial ischemia. These arrhythmias may also cause a dramatic increase in pulmonary pressures, especially in patients with diastolic dysfunction. The latest version of EKPro supports the detection of three supraventricular tachyarrhythmias:

- Supraventricular tachycardia
- Atrial fibrillation
- Frequent supraventricular beats

Table 2 shows the performance of the algorithm in detecting atrial fibrillation and supraventricular tachycardia in publically available[9] MIT databases for arrhythmia[10], atrial fibrillation[11] and supraventricular arrhythmia[12].

Alarm Type	Total Events	Sensitivity
AFIB	268	92%
SVT	43	93%

Table 2. Measured sensitivity for the detection of atrial fibrillation and supraventricular tachyarrhythmia.

MISSING BEAT

EK-Pro also supports the detection of “missing beats”. As an example, a missing beat may indicate second decree AV block from which especially type II may progress rapidly to a complete heart blockage and sudden cardiac death. Detecting a missing beat early can help in identifying the patients who potentially benefit from an implanted pacemaker.

FALSE ALARM RATES

Since 2012, ECRI Institute has placed clinical alarm hazards at the top of their list of Top 10 Health Technology Hazards[13]. In clinical devices that monitor ECG, it is acknowledged that alerts for arrhythmias are responsible for the majority of ECG-related alarms. To ensure high levels of performance, every major version of the EK-Pro algorithm is extensively evaluated using proprietary ECG waveform data collected from multiple clinical units. This commitment to thorough evaluation, a hallmark of the EK-Pro algorithm, means that test results accurately reflect actual clinical performance. Examples of the very low false alarm rates provided by the EK-Pro algorithm are shown in Tables 3-5.

Alarm	False Alarm Rate
ASYSTOLE	1 per 75 hours
VFIB	1 per 571 hours
VTACH	1 per 75 hours
VT > 2	1 per 8 hours

Table 3. Measured false alarms from EK-Pro V13 in 8000 hours of monitoring data from a telemetry environment notable for its noisy data conditions. The data was collected from a GE customer hospital.

Alarm Type	False Alarm Rate
ASYSTOLE	1 per 254 hours
VFIB	1 per 2367 hours
VTACH	1 per 38 hours
VT > 2	1 per 8 hours

Table 4. Measured false alarms from EK-Pro V13 in 7100 hours of Holter recordings collected from 284 patients. The data is notable for high levels of artifact.[14]

Alarm Type	False Alarm Rate
ASYSTOLE	1 per 64 hours
VFIB	1 per 1600 hours
VTACH	1 per 106 hours
VT > 2	1 per 15 hours

Table 5. Measured false alarms from EK-Pro V13 in 4800 hours of multi-lead data collected from 200 ICU patients including 48 with pacemakers and LVADs. The data was collected from a GE customer hospital.

ADVANCED TECHNOLOGIES USED BY THE EK-PRO ALGORITHM

The EK-Pro algorithm takes advantage of several special advanced processing techniques that help contribute to its high performance levels.

- **Continuous Correlation** causes the incoming multi-lead waveforms to be continuously compared to the beat “templates” as part of the QRS detection process. This method greatly improves beat detection and recognition in the presence of interfering noise or artifact and is extremely advantageous amid the challenging signal conditions encountered in the clinical setting.
- **Incremental Template Updating** is a process by which the multi-lead waveform templates used for beat classification and measurement accurately track subtle, progressive changes in beat shapes. With this technology, automated measurements can be made consistently and accurately, since waveform artifact is effectively minimized in the waveform templates by this updating process.
- **Contextual Analysis** enables the algorithm to use information gained from neighboring beats, both before and after the beat undergoing analysis, for its identification of arrhythmia events. This allows the algorithm to consider the beats in the patient’s rhythm in a manner highly similar to that used by a clinician.
- **Configurability for neonatal and pediatric patients** allows each of the aforementioned techniques to be automatically adapted for the unique waveform features presented by neonatal and pediatric patients. In addition, certain criteria for QRS detection and arrhythmia alarms are adjusted to account for the normally higher heart rates and narrower QRS widths associated with younger patient populations.

NOTES ON OTHER PERFORMANCE MEASUREMENTS

It is common for device manufacturers to test and evaluate arrhythmia detection algorithms on commercially available collections of recorded ECG signals. The two most common of these collections are frequently referred to as the MIT/BIH[15] and AHA databases[16]. These databases consist of two-channel Holter recordings and make possible a convenient method for estimating and comparing the performance of arrhythmia detection algorithms. Unfortunately, standard testing that uses these two test databases reflects only 61 total hours of monitoring time for both databases combined. This stands in stark contrast to the more than 2000 hours of clinical evaluation that is applied to each major release of the EK-Pro algorithm.

The minimum performance specification for EK-Pro algorithm for these databases is provided in Table 6. However, it is extremely important to understand that these databases should never be considered a "gold standard" by which the arrhythmia algorithm should be judged. As noted by the American Heart Association,

"...There are problems, however, with these databases, as all ECG patterns are not included. Specifically, the AHA database includes ventricular abnormalities only and excludes abnormalities such as supraventricular arrhythmias and atrioventricular block that are clinically important in the acute myocardial infarction setting ..."[17]

Because of the limited scope of these databases, they can provide only a partial estimate of how accurately algorithms can really detect ventricular arrhythmias in actual care environments. Also noted by the American Heart Association,

"...These databases are also collections of rhythms recorded primarily for the evaluation of diagnostic algorithms of ambulatory ECG systems under environmental conditions and with methods that differ significantly from those used, for example, in the coronary care unit. Errors may be significant. ..."[17]

It is inappropriate to assume that algorithm performance as measured on Holter databases will accurately predict the performance in acute patient monitoring. It is for these reasons the EK-Pro algorithm is always extensively tested and validated on ECG data from clinical care units, and not simply on convenient databases.

	AHA/MIT
QRS Detection Sensitivity	>97.5%
QRS Positive Predictivity	>97.5%
VEB Detection Sensitivity	>90%
VEB Positive Predictivity	>90%

Table 6. The EK-Pro algorithm exceeds these performance specifications on AHA and MIT databases.

CONCLUSIONS

GE Healthcare has more than three decades of experience in developing and testing simultaneous, multi-lead arrhythmia monitoring algorithms. While the user is reminded to always refer to the User Manual that accompanies the ECG monitor for detailed arrhythmia monitoring instructions, cautions, and warnings, GE Healthcare has presented here the some of the key advantages of the latest EK-Pro algorithm. This vital technology can help improve detection of cardiac events that might otherwise go unnoticed. It delivers reliable and accurate ST monitoring, helps to reduce false alarm rates and helps to assure uninterrupted monitoring. Building on this core technology, the latest version of the EK-Pro algorithm provides improved detection of narrow complex ventricular tachycardia especially with pediatric patients and brings new technology to the detection of supraventricular tachyarrhythmia.

REFERENCES

1. Langer, A. *et al.* ST segment shift in unstable angina: pathophysiology and association with coronary anatomy and hospital outcome. *J Am Coll Cardiol.* **13**, 1495-1502 (1989).
2. Krucoff, M. W. *et al.* Stability of multilead ST-segment "fingerprints" over time after percutaneous transluminal coronary angioplasty and its usefulness in detecting reocclusion. *Am J Cardiol.* **61**, 1232-1237 (1988).
3. Drew, B. J. and Tisdale, L. A. ST-segment monitoring for coronary artery reocclusion following thrombolytic therapy and coronary angioplasty: identification of optimal bedside monitoring leads. *Am J Crit Care.* **2**, 280-292 (1993).
4. Drew, B. J. and Krucoff, M. W. for the ST-Segment Monitoring Practice Guidelines International Working Group. Multilead ST-segment monitoring in patients with acute coronary syndromes: a consensus statement for healthcare professionals. *Am J Crit Care.* **8**, 372-388 (1999).
5. Mirvis, D. M. *et al.* Instrumentation and practice standards for electrocardiographic monitoring in special care units. A report for health professionals by a Task Force of the Council on Clinical Cardiology. *American Heart Association* **79**, 464-471 (February 1989).
6. Kligfield, P., *et al.* (2007). "Recommendations for the Standardization and Interpretation of the Electrocardiogram. Part I: The Electrocardiogram and Its Technology. A Scientific Statement from the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society. Endorsed by the International Society for Computerized Electrocardiology." Circulation.
7. Baily, D. *et al.* Hospitalizations for arrhythmias in the United States: Importance of atrial fibrillation, (abstr.) *J Am Coll Cardiol.* **19**, 41A (1992).
8. Franz, M. R. *et al.* Electrical remodeling of the human atrium: Similar effects in patients with chronic atrial fibrillation and atrial flutter. *J Am Coll Cardiol.* **30**, 1785-92, (1997).
9. Goldberger AL, Amaral LAN, Glass L, Hausdorff JM, Ivanov PCh, Mark RG, Mietus JE, Moody GB, Peng C-K, Stanley HE. PhysioBank, PhysioToolkit, and PhysioNet: Components of a New Research Resource for Complex Physiologic Signals. Circulation 101(23):e215-e220 Circulation Electronic Pages; 2000 (June 13). http://circ.ahajournals.org/cgi/content/full/101/23/e215
10. Moody GB, Mark RG. The impact of the MIT-BIH Arrhythmia Database. *IEEE Eng in Med and Biol* **20(3)**:45-50 (May-June 2001). (PMID: 11446209)
11. Moody GB, Mark RG. A new method for detecting atrial fibrillation using R-R intervals. Computers in Cardiology. 10:227-230 (1983).. http://ecg.mit.edu/george/publications/afib-cinc-1983.pdf
12. Greenwald SD. Improved detection and classification of arrhythmias in noise-corrupted electrocardiograms using contextual information. Ph.D. thesis, Harvard-MIT Division of Health Sciences and Technology, 1990
13. ECRI Institute. "Top 10 Health Technology Hazards for 2014." *Health Devices*, **Vol 42**, Issue 11, Nov 2013.
14. Young, B & Brodnick, D & Rowlandson, I. (1993). Performance characteristics of a real-time arrhythmia analysis program on different databases. *Journal of electrocardiology*, **26** Suppl.
15. The Massachusetts Institute of Technology — Beth Israel Hospital Arrhythmia Database.
16. The American Heart Association Database of Evaluation of Ventricular Arrhythmia Detectors.
17. Mirvis, D. M. *et al.*

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