

A Remote Diagnosis Service Platform for Wearable ECG Monitors

Jun Dong, *Suzhou Institute of Nano-Tech and Nano-Bionics, Chinese Academy of Sciences*

Jia-wei Zhang, *East China Normal University*

Hong-hai Zhu, *Suzhou Institute of Nano-Tech and Nano-Bionics, Chinese Academy of Sciences*

Li-ping Wang, *East China Normal University*

Xia Liu, *Shanghai Ruijin Hospital*

Zhen-jiang Li, *Institute of Automation, Chinese Academy of Sciences*

To provide real-time monitoring of cardiovascular patients' electrocardiogram data, the authors evaluate existing ECG monitors and diagnosis systems, and present a patient-location-independent and continuous ECG monitoring and diagnosis system.

To lessen increased pressures on hospitals and improve service quality for outpatients, China aims to provide a Basic Community Medical Insurance System (BCMIS) before 2020. By reducing face-to-face consultations and shortening hospitalization, the BCMIS could minimize strain on

healthcare resources, while maintaining and improving service quality.

Cardiovascular disease—one of the deadliest diseases in both China and the industrialized world—is among the major subjects the BCMIS is addressing. Almost two out of every 1,000 people in China die of stroke, heart attack, heart failure, or other cardiovascular problems each year. Nearly 70 percent of all deaths happen at home, in public places, in offices, or on the way to hospitals. The ability to continuously monitor the heart health status of patients who

suffer from cardiovascular problems is vital. Wearable systems track users' health status¹ through a real-time, belted, wearable electrocardiogram (ECG) monitor that supplies data for cardiovascular diagnosis, letting physicians quickly respond to potential heart health problems. More than 100,000 clinics are estimated to be in the BCMIS, and the market for monitors and diagnosis service platforms is predicted to be close to 2 billion renminbi (RMB) within four to five years.

Traditionally, two categories of ECG monitors exist. The first is the one used in hospitals,

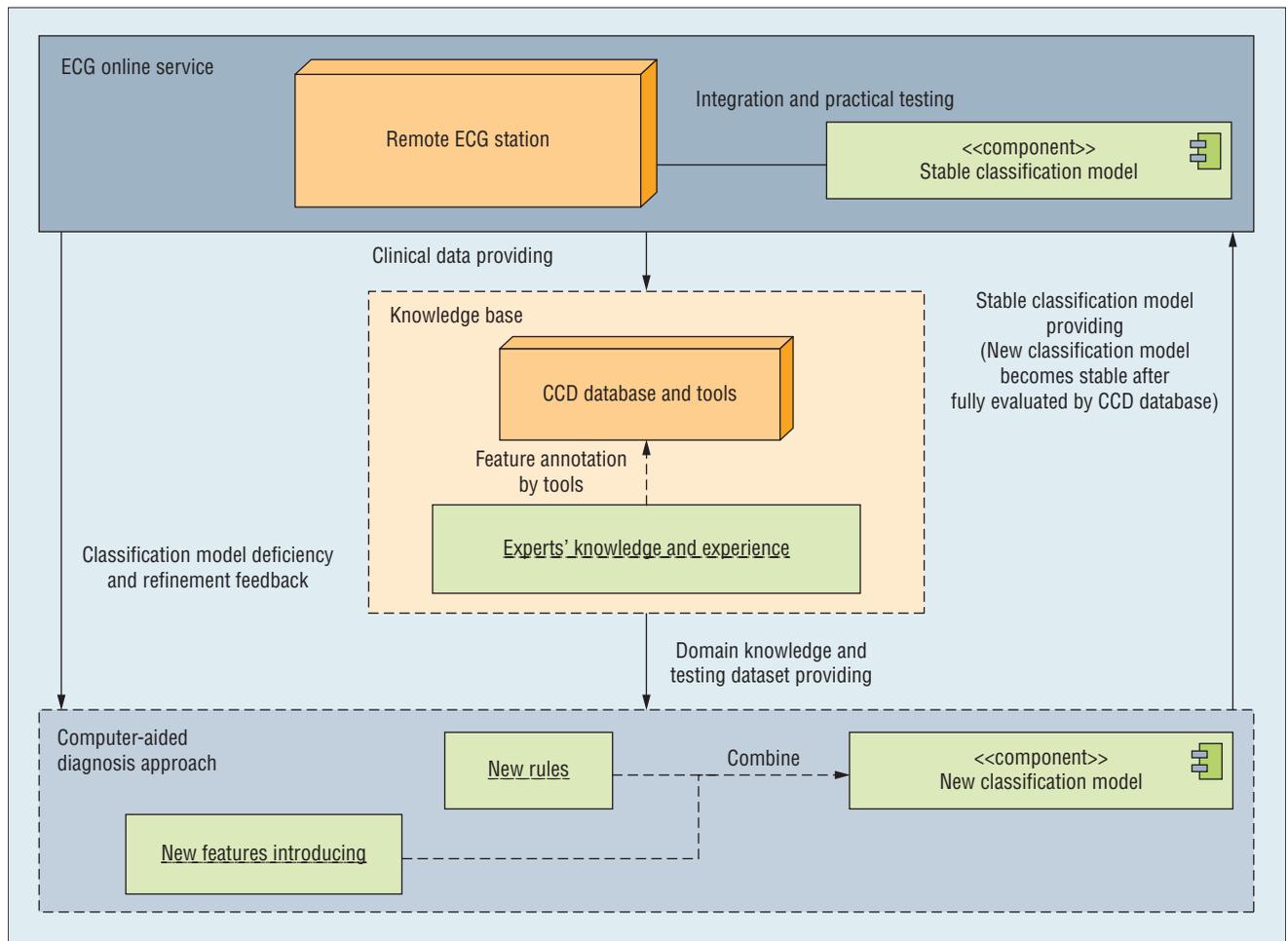


Figure 1. Platform architecture. The electrocardiogram (ECG) online service provides outpatients with remote ECG monitoring services. The knowledge base contains the Chinese Cardiovascular Diseases (CCD) database and experts' experiences.

and the other is the Holter telemonitoring system, which transmits ECG signals via telephone lines and can record data for more than 24 hours. Physicians can display and analyze the full ECG data in hospitals using custom computer software after data acquisition. This software isn't designed for real-time mobile applications, however, and simply recording data doesn't suffice. To capture heart abnormalities instantly, a device must provide monitoring at any time and in any place. Wearable mobile ECG monitors also need to be simple and cost-effective so that people can afford them. Smartphones play a key role in this because of their portability and ability to handle relatively complex computing loads. The ECG results can

help patients and other parties make informed decisions and allow closer cooperation between primary care doctors and hospital specialists.

One specific focus in designing wearable systems is to help people who suffer from arrhythmias. When arrhythmia patients wear such a system, no matter how far they are from a hospital, their ECG data is being monitored; data is sent to a diagnosis server continuously. One study discusses smartphone-based ECG diagnosis equipment and its incorporation into a real-time monitoring system at a medical center for high-risk arrhythmia patients.² However, the ECG recognition data concentrates only on a few limited uses. The author pointed out: "We have not been

able to find precise descriptions of the kind of ECG analysis performed in any of these systems."

Here, we present a patient location-independent and continuous ECG monitoring and diagnosis system. Our ECG recognition method is based on morphology and physicians' experiences with the Chinese Cardiovascular Diseases Database³ (CCD database or CCDD) we've developed (<http://58.210.56.164:9080/ccdd>).

Platform Architecture

As Figure 1 shows, we can divide our platform into three aspects: an *ECG online service* (ECG-OS), a *knowledge base* (KB), and a *computer-aided diagnosis approach* (CADA). The ECG-OS provides the remote

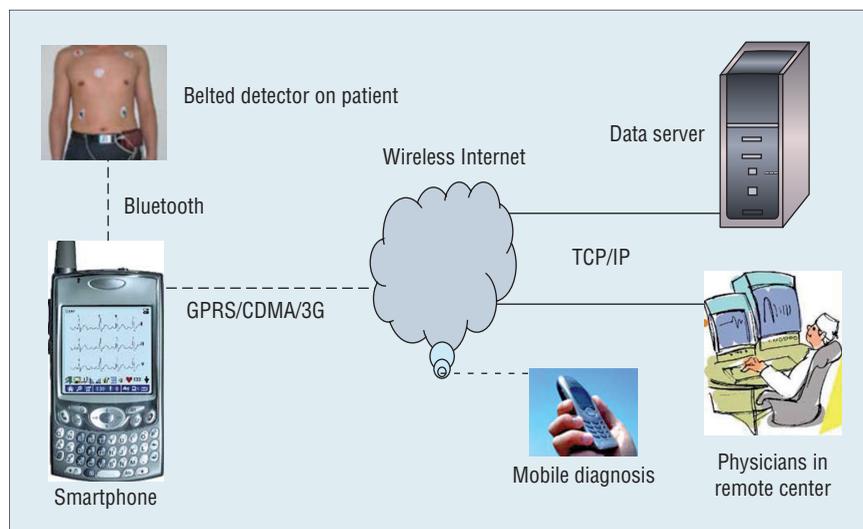


Figure 2. The remote diagnosis service system. Its basic components are a belted detector, a smartphone, a data server, a diagnosis terminal, and short- and long-distance wireless modules.

ECG checking services to outpatients through which the patient and physician are connected. CADA provides a *stable classification model* after the model is evaluated in the CCDD. This model assists physicians in improving their diagnosis efficiency and accuracy. Any deficiencies discovered in practical usage are fed back to CADA for further refinement. Those ECG cases that explore model deficiency are kept in the CCDD and arranged for detailed annotation, which is necessary for model correction and reevaluation.

The KB contains CCDD data and experts' experiences. The CCDD is a standard ECG database—that is, it doesn't directly support the ECG-OS, but it does support ECG-related algorithm evaluation. Such algorithms concentrate on ECG feature mining, feature extraction, disease classification, and so on, for which raw ECG data isn't enough. ECG features should also be annotated by qualified physicians, who not only do feature labeling work with given tools but also provide their knowledge and precious experience to guide the design and study CADA.

CADA introduces new ECG diagnosis features and corresponding

diagnosis rules, which can be executed using domain knowledge from physicians or data mining technologies based on CCDD. These features and rules help us design new classification modules that will be tested by the CCDD before the ECG-OS adopts them.

The primary difference between the CCDD and other databases is that its data content is dynamic—that is, the data is enhanced continuously on the basis of feedback from other parts of the platform and thus provides more useful annotation features. The ECG-OS's stable classification model does practical testing and puts forward refined requirements to CADA, which will ask the KB to collect relevant testing data from the ECG-OS and wait for physicians to label the indispensable information. To create a refined classification model in place of the original in the ECG-OS, we can introduce new feature-extraction methods and even incorporate new features and classification rules through incorporating physicians' advice, prior knowledge, and the testing dataset from the CCDD. This provides better support for physicians and better service for patients who are far away.

ECG-Online Service

The basic components of the ECG-OS are a belted detector, a smartphone, a data server, a diagnosis terminal, and short- and long-distance wireless modules. Figure 2 illustrates this system, which is one application of cyber-physical systems.⁴ The service uses Bluetooth—the widely used short-distance wireless communication protocol—for data communication between the detector and the smartphone.

The smartphone dynamically receives, stores, displays, and analyzes ECG data acquired from a 7-lead (for home use such as continuous or short-term monitoring) or 12-lead (for BCMIS) detector. Because the smartphone has limited memory, users can synchronize data to a PC.

The system uses GSM, GPRS, or 3G-based wireless communication to transmit the ECG data between the smartphone and a data server located in a hospital or service center. Physicians use remote diagnosis terminals with more features than the smartphone (for example, PCs) for data examination and diagnosis.⁵ An alternative diagnosis terminal is a mobile phone. When real-time ECG data arrives at the data server, the server informs an identified physician that some action is needed. If the physician isn't in the office, he or she can still receive the ECG data on a mobile phone, diagnose that data, and send back any treatment instructions. A different group of physicians is available 24 hours, 7 days a week in a remote medical center to ensure real-time abnormal ECG detection.

The online service provides the bridge between patients and physicians, and integrates the KB and CADA.

Knowledge Base

The CCDD is a better standard ECG database that can improve studies in

the field of automatic ECG diagnosis and is available for academic use. The recordings in the database are all 12-lead, high-quality clinical ECGs. More features are annotated in our database and compared with existing mainstream databases, including the onset and offset of P-QRS-T waves, the morphology features on all leads, and the beat diagnosis result. Figure 3 shows an example of our expert annotation.

The accuracy of ECG annotation is important to our researchers for validating algorithms. CCDD will import a huge amount of ECG recordings collected from the ECG-OS. Additionally, a selection step occurs to discard unqualified recordings (strong noise or broken data).

The next step is to distribute the selected records for annotation. Two cardiologists receive each record simultaneously. After they finish the task independently, another cardiologist helps reach consensus about their work.

The platform also provides tools for data management, task distribution, and feature annotation. The cardiologists use the feature annotation assistant tool to decrease their workloads and create the computer-readable annotations. The whole annotation job is divided into a series of detail-feature annotation work. Each channel has *QRS onset and offset*, *T onset and offset*, *P onset and offset*, *QRS morphology pattern and character*, *QRS baseline*, and *T morphology* components, along with *beat diagnosis*. The sequence of these jobs is settled according to their relationships with one another. For example, the QRS boundary should be decided before each channel's QRS morphology pattern and character have been labeled.

The physicians' experience includes two parts: one for CCDD (denotation),



Figure 3. One completed beat annotation. We can see the wave positions and normal/abnormal results.

and another for diagnosis (features definition and classification rules).

Computer-Aided Diagnosis Approach

A wide range of ECG recognition algorithms are available, including the wavelet, syntax analysis, mathematical morphology, hidden Markov models, neural networks, fuzzy logic, pattern matching, knowledge-based autoregressive modeling, and support vector machines (SVMs). Data mining and machine learning seem to offer new hope for finding rules in classifications, as with SwiftRule.⁶ In fact, computers can't summarize all practical diagnosis rules automatically; human experiences are too complex to be simulated exactly without human-computer interaction. However, these methods are insufficient for use in a clinical environment. Our morphology-feature-based ECG recognition approach presents a new method that simulates a physician's thinking with regard to diagnosis.

Morphology-Based Perception

Experts can perceive things that are invisible to the novice, given that it can take a decade or more to become an expert. Consequently, experiences and imagery thinking⁷ are key parts of our intelligent system. The system's major effort is to mine the implicit knowledge and inference rules from physicians' minds and represent them formally.

In terms of vision, humans can recognize an object at different levels. A face can be recognized as a face, but also more specifically as a male face, Tommy Zhang's face, or his smiling face. It's common in cognitive science to assume that the ability to recognize an object at different levels relies on different computational mechanisms. In particular, some have proposed that subordinate-level recognition (identification) comes from configurational judgments, whereas basic-level categorization ("face," "dog," or "car") relies on a qualitative representation formulated on the basis of the presence or absence of features.

When physicians extract features from the ECG data, no numerical computation is usually involved except for general recognition matching. The physician

- scans the ECG and locates the P-wave, QRS-complex wave, T-wave, and so on;
- measures the P-wave-to-P-wave (PP) and QRS-to-QRS (RR) intervals;
- estimates the altitude, slope, interval between adjacent QRS complex waves, and duration of one QRS complex;
- recognizes special morphology features; and
- compares the ECG with templates and prior experiences, and then makes a decision.

In other words, features directly perceived through the senses and

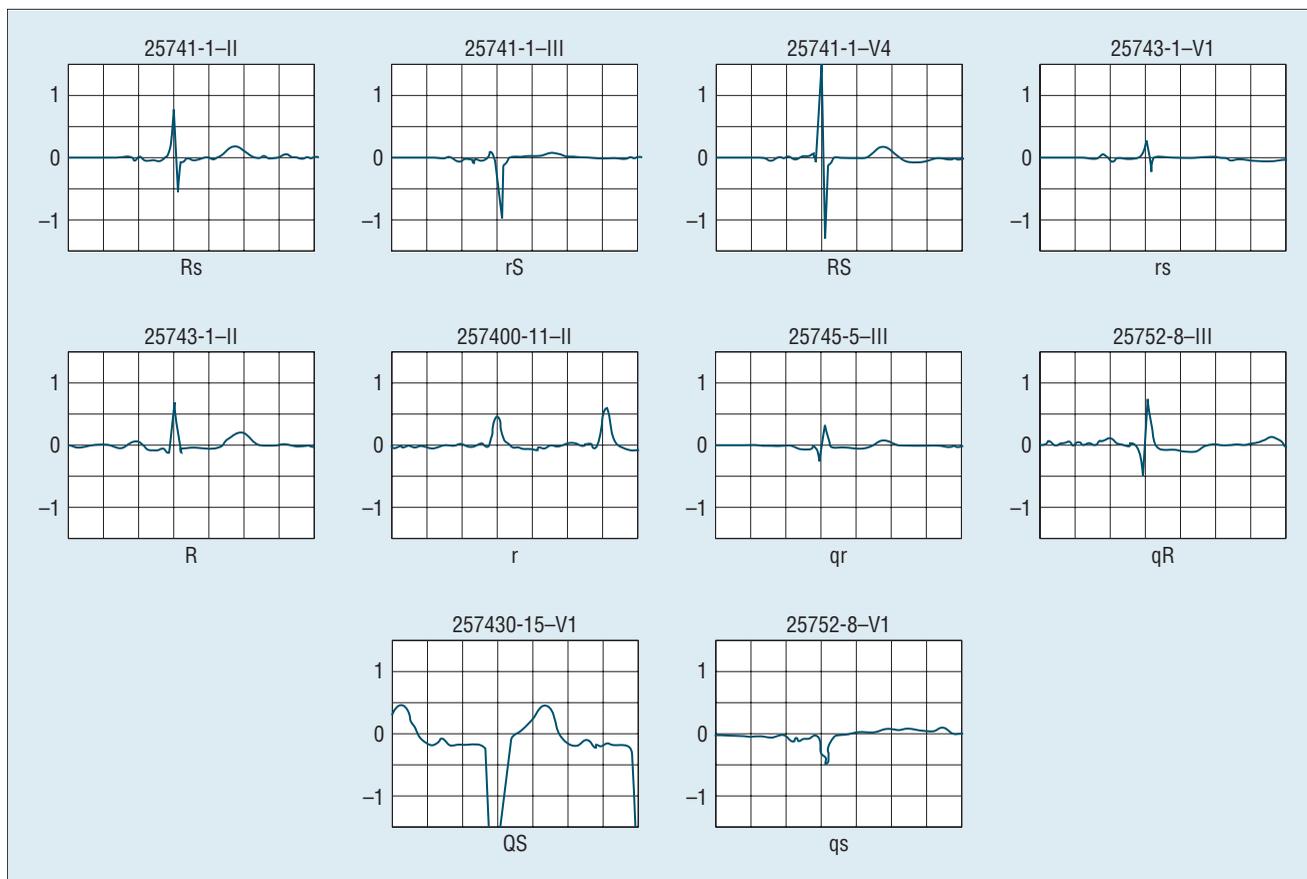


Figure 4. Ten real QRS morphology patterns. "Rs," "rS," and so on come from different ECG leads.

morphology features should be investigated as effortful,⁸ and deductive reasoning and inductive reasoning be combined.⁹

Figure 4 illustrates 10 QRS complex morphology patterns. If only a downside wave is present in a QRS complex wave, for example, it's named "QS wave," and q , r , and s are used respectively to represent relatively small altitudes of the QRS complex wave. Specialists can conduct the diagnosis process immediately by visually inspecting the ECG.

The ECG algorithm analyzes the ECG (especially a QRS complex) and signals an alarm when needed. To simplify, the algorithm uses the altitude, slope, and interval parameters of adjacent QRS complexes and ignores the ECG morphology features.

Features Recognition

The following features are ready for recognition: the start point, the end

point, the altitude of P, the QRS complex, T, the slope of the QRS complex, the interval of adjacent QRS complexes, the QT interval and ST slope, and morphology characters such as *incisure* and *blunt* for Q, R, S, R', S', P, T, and so on.

Among all points of inflection from the start point to the end point, the algorithm selects the trend wave trough and trend wave peak as the points of inflection from down to up and from up to down, respectively, as follows:

- **R-wave calculation.** Search the first trend wave peak above the baseline; if found, an R-wave is present, and relative altitude can be obtained.
- **Q-wave calculation.** If there is no R-wave, continue searching (special morphology exists). Otherwise, search the lowest trend wave

trough below the base line in $[start, R)$; if found, a Q-wave is present, and the relative altitude can be obtained.

- **S wave calculation.** If there is no R-wave, continue (special morphology exists). Otherwise, search the first trend wave trough below the base line in $(R, end]$; if found, an S-wave is present, and the relative altitude can be obtained.
- **R'-wave calculation.** No S-wave means no R' wave; continue. Otherwise, search the first trend wave peak above the baseline in (S, end) ; if found, an R' wave is present, and the relative altitude can be obtained.
- **S'-wave calculation.** No R'-wave means no S'-wave; continue. Otherwise, search the first trend wave trough above the baseline in (R', end) ; if found, an S'-wave is present, and the relative altitude can be obtained.

Such feature recognition is the most significant step for classification.

Binary Classification

Physicians at remote medical service centers evaluate the data from server requests and can spend considerable time distinguishing between abnormal and normal ECG data. Our approach aims to distinguish between normal and abnormal ECGs automatically and let physicians diagnose only the abnormal ECG data.

Many papers on ECG recognition and classification exist, but little of this research tested more than a standard dataset (the MIT/BIH database, or in some cases, just part of it), or satisfied a real application. Because the single classification approach isn't sufficient to meet real requirements, integrating a different approach is a promising alternative.

One area for data classification that's gaining increased interest is statistical learning approaches, such as the SVM. Researchers have conducted multiple SVM-based ECG classifications, including the multi-class SVM with error-correcting output codes, combining the SVM with preprocessing methods yielding two neural classifiers.

We tested data classification through Bayesian decision, certainty factor modeling, and SVM. Our tests showed that the SVM approach is better than others for abnormal versus normal ECG classification.¹⁰ We used both general and morphology features for classification. We introduce morphology features into SVM as nominal type (qR, qRs, and so on).

A detector can send ECG data out continuously and automatically or can first analyze a heart rate as "too fast" or "too slow." Then, a smartphone can send the ECG to a remote medical center only if preconditions

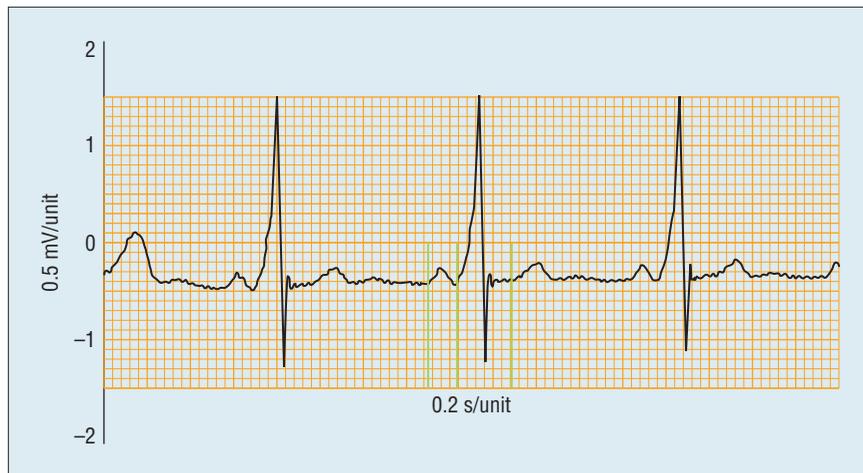


Figure 5. Abnormal reading. This reading registers as normal in the MIT/BIH database (record 230).

are met. That is, using our approach, diagnosis is completed through human-machine interaction, not totally by computer. Abnormal ECGs should still be diagnosed by physicians in remote medical centers.

Evaluation Results

The ECG recognition process software that uses the aforementioned rules is based on how morphology features work. The definitions of *true positive* (TP, the number of correctly detected events), *false positive* (FP, the number of falsely detected events), *true negative* (TN, the number of correctly rejected nonevents), and *false negative* (FN, the number of missed events) are standard for recognition process software. Accordingly, we can apply the following definitions when examining detection algorithm performance:

$$\text{Sensitivity, } Se = \frac{TP}{TP + FN} \%$$

$$\text{Specificity, } Sp = \frac{TN}{TN + FP} \%$$

We compared our approach's output to the standard results from the MIT/BIH database to obtain error and loss values. We calculated Se , Sp , and part of the results on *premature ventricular contraction* (PVC)

with MIT/BIH. Recognition results improve when morphology features are used. Our approach's successful recognition rate, in general, is about 95 percent. In addition, in working with physicians to formalize the rules set to determine which classes of heartbeats are normal, we found some of the normal heart beats or records in MIT/BIH to be abnormal. This discrimination resulted from MIT/BIH ignoring the abnormal appearances in T-wave and ST segments. For example, Figure 5 belongs to a normal set from MIT/BIH, but is in fact the pre-excitation syndrome. Each unit includes five small grids. This is another reason why implicit knowledge or experiences should be obtained from physicians continuously.

Table 1 concerns part of the binary classification results with general features and with general features plus morphology features, respectively. The table shows 23 general features; we calculated morphology features through independent component analysis. We used the open source tool ECGpuwave (www.physionet.org/physiotools/ecgpuwave/) to extract features, and we selected the open source SVM tool Libsvm for classification. We must first determine two parameters, C and σ , where

Table 1. Binary ECG classifications with different features.

Number	Features	Se (%)	Sp (%)	GCR (%)
1-1	General	95.03	99.24	98.55
1-2	General plus morphology	95.38	99.37	98.72
2-1	General	94.37	99.35	98.54
2-2	General plus morphology	94.66	99.53	98.74

* 1-1, 1-2: $C = 100$ and $\sigma = \frac{\sqrt{2}}{2}$; 2-1, 2-2: $C = 10$ and $\sigma = \frac{\sqrt{2}}{2}$

we calculate the *general correctness rate* as follows:

$$GCR = \frac{TP + TN}{TP + FN + TN + FP} \%$$

As we can see from the table, considering morphology features improves correctness. Clearly, the methods by which the physicians think do matter in our system. This indicates that the features we determined in collaboration with physicians are valuable and suitable. The characteristics of how physicians think with respect to ECG data classification have been neglected in relevant academic research and engineering applications, which is one major reason expert systems have always failed.

Before applying our wearable ECG monitor product to the real-world market, we performed and passed the following tests:

- tests against ECG signals generated by a hardware patient simulator, the PS-410 from Metron AS Norway;
- signal-recognition accuracy verified by the State Drug Administration Shanghai Center for Medical Equipment Quality Supervision and Testing; and
- clinical tests and comparisons with standard ECG equipment in hospitals, including China's top-tier hospital, the Peking Union Medical College Hospital.

Thus, the BCMIS and private physicians can use our product instead

of relying on ECG monitors installed in hospitals. We've deployed the system and terminals in places such as Shanghai, and the Fujian, Jiangsu, Guangdong, and Shandong provinces in China.

Wearable technology has a long-term potential to change the out-of-office workplace just as much as PCs have changed the office environment. When people get older, their hearts are subject to more strain. We have the technology to design ECG signal monitors that are wearable, handy to use, produced at low cost, and convenient for patients. The products have been licensed (numbers 2211301 and 2210232) by the Shanghai Food and Drug Administration.

In fact, we originally only imaged the wireless monitor. Later on, we designed the mobile diagnosis terminal simultaneously. To solve the service issue, we developed the remote platform. To help physicians distinguish between normal and abnormal ECGs, we investigated the ECG binary classification approach, which resulted from a real application requirement. Meanwhile, we're also focusing on a multiclassification algorithm for different diseases. The key AI technologies our product uses are the ECG measurement and recognition, paying close attention to ECG morphology features and classification rules on the basis of physicians' experience and thinking habits. We discussed features and rules repeatedly with experienced physicians, constructed the CCDD to test our classification algorithms and provide a public database, and combined statistical learning

with expert systems to get a better recognition rate. Our solution provides both background and application for AI, where theory and practice are smoothly interconnected.

In the future, we plan to focus on the following issues. First, we want to incorporate data representing more physiological signals for cardiovascular diseases—such as ECGs, pulse wave, and blood pressure readings—into the same detector while decreasing its size. We should also implement a data fusion algorithm to get more comprehensive cardiovascular situation evaluations.

Second, we will investigate morphology features and experienced-thinking progress to formalize them directly, and we'll combine several general classifiers to reach more precise classification results.

Third, we plan to integrate GPS into the detector so that users can be located and found in critical situations. Smartphones and the detector could be designed together in one board for more convenient use and lower cost. One trend is embedding the ECG detector as a service function in the smartphone.

Fourth, the MIT/BIH database isn't sufficient to test our diagnosis algorithm because it includes only a few records without full 12-lead information, and contains mistakes, some of which we pointed out previously. Therefore, completely annotated 12-lead ECG data from representative patients is necessary (CCDD). Like MIT/BIH, such a database will be open, but we need more responsible physicians to take part in labeling jobs.

Fifth, because different kinds of ECG detectors are available in the current clinical environment, sampled ECGs should be transformed into regular and standard formats for easy exchange and analysis within electronic medical records or health

THE AUTHORS

information systems. We've thus applied the ECG specification HL7 (www.hl7.org) to our application system.

Finally, although our R&D effort meets social demands to some degree, it still has a long way to go. ■

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Jun Dong is a professor in the interdisciplinary division at the Suzhou Institute of Nano-Tech and Nano-Bionics, Chinese Academy of Sciences. His research focuses on intelligence simulation, thinking patterns, and cognition modeling, including computer-aided medicine diagnosis methods, relative wearable terminals, and art creation simulation. Dong has a PhD in computer simulation from Zhejiang University, China. Contact him at jdong2010@sinano.ac.cn.

Jia-wei Zhang is a CT R&D software engineer at Siemens Shanghai Medical Equipment. His research focuses on ECG features recognition. Zhang has a PhD in computer application from East China Normal University. Contact him at zwei.jiawei@gmail.com.

Hong-hai Zhu is a PhD candidate in the interdisciplinary division at the Suzhou Institute of Nano-Tech and Nano-Bionics, Chinese Academy of Sciences. His research interests include wireless medical terminal and pattern recognition. Zhu has an MS in software engineering from East China Normal University. Contact him at hhzhu2010@sinano.ac.cn.

Li-ping Wang is a lecturer and PhD candidate in the school of software engineering at East China Normal University. Her research focuses on ECG diseases classification. Wang has an MS in computer software and theory from Northwest University, China. Contact her at lipingwang@sei.ecnu.edu.cn.

Xia Liu is chief physician at Shanghai Ruijin Hospital of Shanghai Jiaotong University, China. Her research interests include ECG diagnosis and cardiovascular diseases analysis. Liu has an MS in medicine from Shanghai Jiaotong University. Contact her at liuxia9110@yahoo.com.cn.

Zhen-jiang Li is an associate professor at the State Key Laboratory of Management and Control for Complex Systems, Chinese Academy of Sciences. His research focuses on embedded systems. Li has a PhD in pattern recognition and control engineering from the Institute of Automation, Chinese Academy of Sciences. Contact him at zhenjiang.li@ia.ac.cn.

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