CER-S, an ECG Platform for the Management of Continuous ECG Recordings and Databases

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Abstract

We introduce three new databases of ambulatory Continuous ECG Recordings. The databases consist of 24-hour Holter records acquired in clinical practice from various acquisition devices, including longer recordings from new patch devices.

All cardiac events, both rhythm and beat annotations, have been manually reviewed and adjusted by an expert cardiologist with more than 25 years of experience on reviewing Holter data.

ECG recordings are organized in different categories based on the predominant arrhythmic events.

The databases (total of 1300 records) have been annotated and can be reviewed by CER-S, a software platform used to manage multi-vendor continuous ECG data. CER-S includes two automatic algorithms: 1) ABILE, for the detection of ECG beats and for arrhythmia assessment and 2) BRAVO for the quantitative measurement of the ECG waveforms), either at the beat level or on Time-averaged templates. CER-S has a rich graphical interface with several tools for optimal review and editing both at the ECG beat and arrhythmia level. The tool allows manual entry of other arrhythmia not yet automatically detected by ABILE algorithm and the customization of a clinical report.

1. Introduction

AAMI EC57 (Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms) specifies which standard public databases must be used during testing as reference data. These consist of the following two-channel Holter data databases from Physionet: AHA, MIT-BIH, ESC and NST Databases.

AHA and MIT-BIH accounts for several arrhythmic events including Atrial fibrillation, complex ventricular, junctional, and supraventricular arrhythmias and conduction abnormalities

The size of these database is limited, accounting to 128, 30-minute 2-lead recordings and were originally acquired in analog format and converted to digital years later.

Indeed, the major drawbacks of this database, as well as the other ECG database available on Physionet such as AHA, NST and ESC is the limited size/length and the original analog acquisition.

In this manuscript we will introduce three new databases of Continuous ECG recordings focusing on CER-S, the commercial and research ECG software that was used for the annotation effort of the three databases. A description CER-S embedded algorithm for beat detection and arrhythmia assessment and for the measurement of the ECG beats will also be provided.

2. AMPS Databases

AMPS-PMB This database consists of 1068 annotated continuous ECG recordings with a mean length of 23 hours; it includes selected records from clinically collected outpatients with challenging atrial tachyarrhythmias, including atrial fibrillation, atrial flutter, atrial tachycardia and all combinations of the three, which make the detection of AF particularly complex.

The raw ECG waveform data was acquired using Spiderview Holter recorder device (Sorin Group), with a sampling rate of 200 Hz and an amplitude resolution of 10 µV. Most of the recordings is 2-lead, few 3 and 12-leads recordings are also present.

A record was considered eligible for database enrolment only if the maximum noise level was 1 minute/hour, except for the beginning and end of the recording. The noise content (about 2% of the data) is most likely better than the average of some clinical context, but it still represents a realistic scenario.

Records are organized in different categories based on the predominant event/activity: 30 VTF (Ventricular Tachycardia / Ventricular Fibrillation, at least 1 event of

VT/VF or 15 or more consecutive ventricular beats), 6 Atrial Ventricular Block, 268 Atrial Tachyarrhythmia (1 or more events of Atrial Fibrillation/Atrial Tachycardia/Atrial Flutter and 0 VTF), 240 Premature Ventricular Contraction (extensive or predominant ventricular activity with at least 240 ventricular beats and 0 VTF/ATA), 6 pause (longer than 5s) and 518 Normal Sinus Rhythm (with sporadic Supraventricular or Ventricular activity and 0 VTF/ATA/PVC).

Supraventricular beats were not validated on this database.

AMPS-PDT A specific pediatric database has been created collecting different recordings acquired with Mortara H12+ recorders on real patients from an Italian pediatric Hospital.

The database has been created following the principles described in the guide "*Premarket Assessment of Pediatric Medical Devices Guidance for Industry and Food and Drug Administration Staff*", March 24 2014.

The database consists of 182 records of 2-hour, 12-lead recorded from 62 different patients.

No Atrial Fibrillation events are present in the database and the Supraventricular events are few to be statistically significant.

The record can be grouped in 4 different sub-categories, based on patients' age: 58 Newborn on 12 subjects, 28 Infant on 12 subjects, 54 Child on 20 subjects and 42 Adolescent on 18 subjects

AMPS-PCH A specific database has been created collecting records acquired with two different patch devices, consisting of 50 records of 2-hour, 1-lead, recorded at 128Hz. Amplitude resolution was 1µV for device A and 5.5 µV for the other.

The patches have been placed on the patient's chest in different positions, as required by device's manufacturers. Both devices declared equivalence to Holter-leads with the usage of the patch in specific locations. It is continuously updated with new recordings from different patches with length up to 30-day length

All arrhythmic events and beat annotations of these three databases were manually reviewed and adjusted by a highly experienced Cardiologist.

Table 1. Databases comparison, main characteristics. (*1) S beats have not been validated on AMPS-PMB; (*2) They are few to be considered statistically significant.

	MIT-BIH	AHA	NST	ESC	AMPS-PMB	AMPS-PDT	AMPS-PCH
Records	48	80	12	90	1068	182	50
Total Hours or Recording	24	47	6	180	24000	364	100
Channels	2	2	2	2	from 2 up to 12	12	1
Sample rate	360	250	360	250	200	180	128
Resolution	5 µV	2.5 µV	5 µV	5 µV	10 µV	6.25 µV	1 – 5.5 µV
# QRS	91300	182000	21500	750000	108 millions	2 millions	349000
# N Beats	82000	165000	18000	744000	105 millions	2 millions	335000
# V Beats	6100	16500	2300	4400	1,4 millions	200	12434
# S Beats	2800	0	500	1100	--- (*1)	--- (*2)	250
# Afib events	108	0	0	--- (*2)	2000	0	30
# Hours of Afib Events	2	0	0	--- (*2)	2500	0	21
# ST events	0	0	0	250	0	0	0
# Hours of ST Events	0	0	0	29	0	0	0

3. CER-S: the Continuous ECG Recording Suite

CER-S is a windows-based medical device software intended to analyze, edit, review and report digital continuous ECG recordings.

CER-S allows to load electrocardiographic tracings of different formats, including ISHNE, MIT-WFDB and EDF formats, from 1 to 15 leads and lasting from 30 seconds up to 30 days, regardless and seamlessly of the waveform sampling rate (100 to 1024 Hz) and amplitude resolution (anywhere less than 10 µV). CER-S also allows to load native ECG beat annotations, including beat position and labels and onset/offset of arrhythmic events, so that it can be used as a Continuous ECG viewer of previously analyzed and annotated data, for example for Physionet databases.

CER-S embeds two proprietary algorithms ABILE and BRAVO, respectively used for arrhythmia assessment and for quantitative waveform measurement.

3.1 ABILE Algorithm

ABILE is the CER-S core algorithm and is composed of several separate modules:

1) beat detection, beat labelling and templating. Identification of QRS complexes position and classification of normal, ventricular (V) and artifact,

pseudo beat that shall be considered as non-beat, is based on beat morphology and velocity. Each detected beat of a given beat type is compared against the previously defined templates, if the correlation is below a certain threshold for all templates, a new template is generated including only the latter ECG beat, otherwise, the beat will be included in the template maximizing the correlation.

Selectable options are the leads to be used for detection, a combination of available leads and one or more bipolar derived leads, CR, CL, CF (derived from I, II and V/V2); beat detection sensitivity; beat detection timeout, refractory period, minimum distance expressed in ms for the detection of a next contiguous beat

2) Arrhythmia detection for the reanalysis of normal beats and detect supraventricular (SV) beats based on a specified prematurity index, as the latter are beats with normal QRS morphology, but premature and detection of episodes of atrial fibrillation and other several arrhythmias using the listing of ECG Beat position and label, outputted by beat detection and labeling steps. For the identification of atrial fibrillation episodes, a detailed analysis of the segment prior QRS complexes if performed to ensure absence of P-waves. This module includes the detection of the following arrhythmias:

- Bradycardia Prolonged RR Interval, Pause and Sinus Tachycardia
- Isolated Supraventricular Beat, SV Couplet, Run, Bigeminy/Trigeminy and Supraventricular Tachycardia
- Atrial Fibrillation
- Isolated V Beats, V Couplet, Run, Bigeminy/Trigeminy and Ventricular Tachycardia

3) Analysis of the ST segment, defined as the ECG section that connects the end of the QRS complex (J point) and the onset of the T-wave which typically has a duration of 60-80 ms up to 150 ms.

The algorithm can assess the changes of amplitude in the ST segment at several equally distant points (e.g. with a 10 ms resolution), and detecting episodes where the amplitude difference between a user-defined point on the ST segment and the isoelectric level is greater than +/- 100uV. Finally, and the ST slope and ST area within the ST segment window are also computed.

4) Heart Rate Variability (HRV). Finally, ABILE algorithm can assess the following time domain and frequency domain HRV parameters: mean RR, SDNN, PNN50, RMSSD, LF, HF (the summed power of frequency components between 0.03-0.15 Hz, 0.15-0.40 Hz respectively for LF and HF) and the ratio LF/HF.

3.2 BRAVO Algorithm

BRAVO is used to provide automated measurements on rhythm ECG data (typically 10s long, but up to several minutes) or from single beat representative waveforms (averaged or median beats) [1-3].

The BRAVO algorithm automatically detects and let the user override the position of the following markers:

P-wave onset, P-wave peak, P-wave offset, isoelectric point, QRS onset, R-wave peak, J point, T-wave onset, T-wave peak and T-wave offset. From these markers, a set of intervals and amplitudes are then computed such as PP and RR intervals, P-wave duration, PR interval, QRS width, QT/QTc, QTp, JT, JTp/JTpc, TpTe intervals [4-5] P, R and T wave amplitudes.

When embedded in CER-S, BRAVO algorithm can measure the ECG parameters on individual beats (providing a beat-by-beat output matrix) or on computed time-averaged representative beats, at a user-based resolution (from a few seconds to a few minutes). Under this modality, only normal beats are used (artifact and Ventricular or paced are excluded), measuring the available leads or a derived RMS lead.

BRAVO is also used, in other scenarios, applied to standard 10s ECGs [1-3]. The software has the capability to add additional algorithms, developed by third parties so that it is easy to switch from native, BRAVO/ABILE-computed annotations and those from the third-party algorithm.

3.3 User Interface

CER-S includes a detailed graphical interface for the display and editing of beat and template annotations based on histograms, trends, and review of the detected arrhythmias, sorted by their severity.

The software is currently employed in many clinical settings in combination with different ECG devices, such as Holter and patches, and it is also widely used in research. In a notable example, it has been used in a study to validate an atrial fibrillation algorithm in patients simultaneous wearing a commercial patch and a Samsung smartwatch, with a total of 81,944 hours of collected data [6]. The software is also used as viewer for Intensive Care unit bedside monitors alarms annotations with the aim of generating a gold standard of correct/false arrhythmia alarms [7-8].

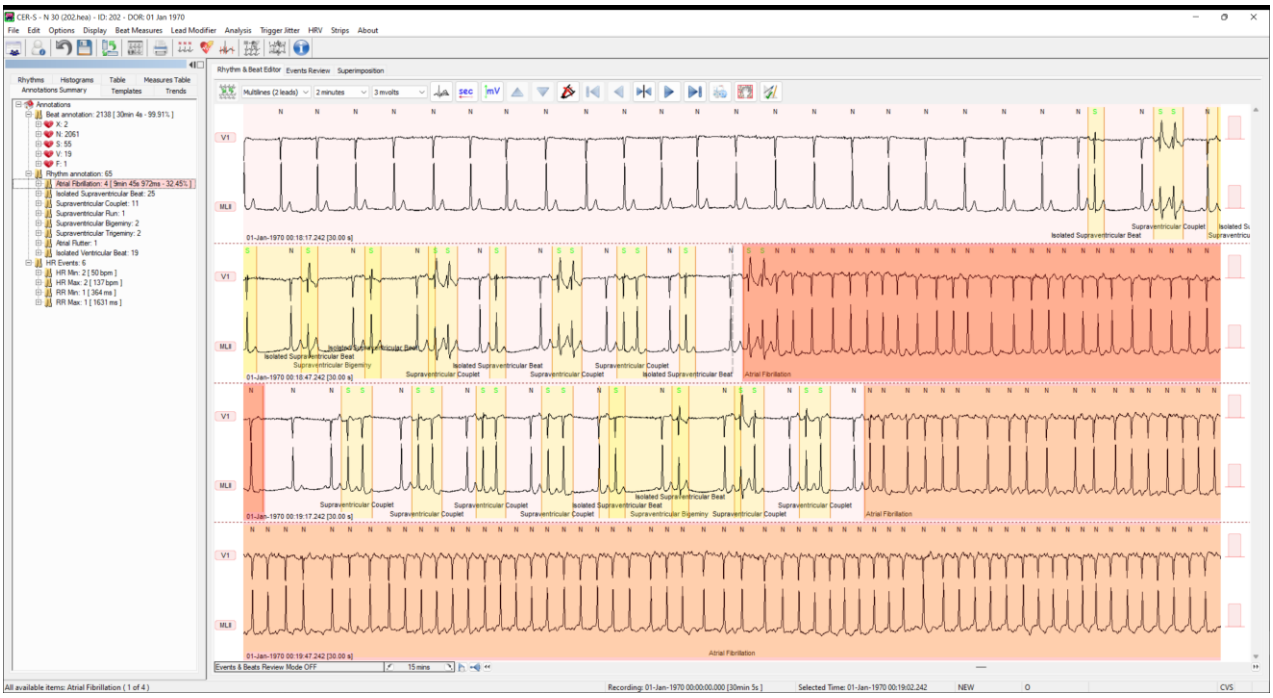

Figure 1. CER-S software displaying a recording from MIT-BIH database with significant Atrial Fibrillation activity.

3.4 CER-S Remote

In addition to its default stand-alone usage, CER-S has been developed to be easily "remotized". For example, the platform can be deployed using a standard Remote Desk Protocol (RDP) or via RemoteApp by Windows, where the entire application resides on a server but works as if it were installed on the user's machine.

Another option is to use the Remote Desktop Services Web Client where the remote application is made available directly through a web page.

In both implementations, users can access CER-S without the need to install any local application or to use a Windows-based machine.

References

[1] P. Kligfield, F. Badilini, I. Denjoy, S. Babaeizadeh, E. Clark, J .De Bie, B. Devine, F. Extramiana, G. Generali, R. Gregg, E. Helfenbein, J. Kors, R. Leber, P. Macfarlane, P. Maison-Blanche, I. Rowlandson, R. Schmid, M. Vaglio, G. van Herpen, J. Xue, B. Young, C. L. Green, "Comparison of automated interval measurements by widely used algorithms in digital electrocardiographs", Am. Heart J, 200 (2018): 110-113.

[2] F. Badilini, N. Sarapa, "Implications of methodological differences in digital electrocardiogram interval measurement", J. Electrocardiol, 39 (2006): S152-S156.

[3] G. K. Panicker, D. R. Karnad, P. Kadam, F. Badilini, A. Damle, S. Kothari, "Detecting moxifloxacin-induced QTc prolongation in thorough QT and early clinical phase studies using a highly automated ECG analysis approach", Br. J. Pharmacol, 173 (2016): 1373–1380.

[4] JP. Couderc, S. Ma, A Page, C BEsaw, J Xia, B Chiu, J De Bie, J Vincente, M Vaglio, F Badilini, S Babaeizadeh, CS Chien, M Baumert, "An evaluation of multiple algorithms for the measurement of the heart rate corrected JTpeak interval", J. Electrocardiol, 50 (2017): 769-775.

[5] F. Badilini, M. Vaglio, G. Libretti, "Automated JTpeak analysis by BRAVO", J. Electrocardiol, 50 (2017):752-757.

[6] R. Avram, M. Ramsis, A. D. Cristal, V. Nathan, L. Zhu, J. Kim, J. Kuang, A. Gao, E. Vittinghoff, L. Rohdin-Bibby, S. Yogi, E.Seremet, V. Carp, F. Badilini, M. J. Pletcher, G. M. Marcus, D. Mortara, J. E. Olgin, "Validation of an algorithm for continuous monitoring of atrial fibrillation using a consumer smartwatch", Heart Rhythm, 18 (2021): 1482-1490.

[7] M. M. Pelter, D. Mortara, F. Badilini, "Computer Assisted Patient Monitoring: Associated Patient, Clinical and ECG Characteristics and Strategy to Minimize False Alarms", Hearts 2 (2021): 459-471.

[8] L. K. Bawua, C. Miaskowski, S. Suba, F. Badilini, D. Mortara, X. Hu, G. W. Rodway, T. J. Hoffmanna, M. M. Pelter, "Agreement between respiratory rate measurement using a combined electrocardiographic derived method versus impedance from pneumography", J. Electrocardiol, 71 (2022):16-24.

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