CER-S, an ECG platform for the management of continuous ECG database

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Abstract

We introduce a new database of ambulatory Continuous ECG Recordings. The database mainly consists of 24-hour Holter records acquired in clinical practice and it is being constantly updated with new recordings 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.

Only recordings with minimal noise (1 minute/hour maximum, except for the very beginning and end of the recording) were considered eligible for database enrolment.

ECG recordings (total 1068) are organized in different categories based on the predominant event/activity: Ventricular Tachycardia (#30), Atrial Ventricular Block (#6), Atrial Tachyarrhythmia, including Atrial Fibrillation, Atrial Flutter and Atrial Tachycardia (#268), Premature Ventricular Contraction (#240), Premature Atrial Contraction (#1), Pause (#6) and Normal Sinus Rhythm (#517).

In addition, we will introduce CER-S, a software platform used to manage multi-vendor continuous ECG data that was used for the annotation of the database and which is used as a viewer for the recordings. The platform also includes two automatic algorithms ABILE, for the detection/classification of ECG beats based on morphology and for arrhythmia assessment (including Atrial fibrillation, main Ventricular and Supraventricular activity, VT, SVT, Pause, Bradycardia and Sinus Tachycardia), BRAVO for the measurement of the ECG beats (including standard time interval annotations and ST displacement, both at a beat-to-beat level and Time-averaged) and 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.

2. Outline

The present paper in the first part will present three new databases of Continuous ECG recordings then will focus on CER-S, a Continuous ECG software that can be used to review and edit ECG beat annotations which includes two automatic algorithms, one for beat detection and arrhythmia assessment and the second for the measurement of the ECG beats.

2. AMPS DBs

AMPS-PMB This database consists of 1067 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 devices (Sorin Group), with a sampling rate of 200 Hz and an amplitude resolution of 10 uV. Most of the recordings is 2-lead, few 3 and 12-leads recordings are also present.

A record was considered eligible for database enrollment 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 in an Italian University 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 1uV for device A and 5.5uV 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.

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	1056	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 uV	2.5 uV	5 uV	5 uV	10 uV	6.25 uV	1uV – 5.5uV
# QRS	91300	182000	21500	750000	108 milions	2 milions	349000
# N Beats	82000	165000	18000	744000	105 milions	2 milions	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, Continuous ECG Recording Suite

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

CER-S allows to load electrocardiographic tracings of different formats, including ISHNE and MIT-WFDB format, from 1 to 15 leads and lasting from a few minutes

up to 30 days. It is also flexible regarding supported sampling rate (100 to 1024 Hz) and amplitude resolution (anywhere less than 10uV). It 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, for example for Physionet databases.

CER-S comes with two proprietary algorithms:

ABILE is designed to provide ECG analysis, including:

1) beat detection, beat labeling and templating: identification of QRS complexes position and beat classification between normal, ventricular (V) and artifact, pseudo beat that shall be considered as non-beat, 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. Note that for identification of atrial fibrillation episodes, a detailed analysis of the segment prior QRS complexes if performed to ensure absence of P-wave.

It 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 Beat, V Couplet, Run, Bigeminy/Trigeminy and Ventricular Tachycardia

3) The ST segment is the part of the ECG that connects the end of the QRS complex (J point) and the onset of the T-wave and typically has a duration of 60-80 ms up to 150 ms. Changes in height/amplitude of the ST segment can be linked to significant cardiac diseases such as transmural myocardial infarction, myocarditis, pericarditis and hyperkalemia in case of ST elevation, myocardial ischemia or infarction, unstable angina and hypokalemia in case of ST depression.

The algorithm can assess the changes of amplitude in the ST segment, detecting episodes where the amplitude difference between a user-defined point on the ST segment and the isoelectric level is greater than +/- 100uV.

4) 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.

BRAVO, providing automated measurements for rhythm ECG data (typically 10s long, but up to several minutes) or single beat representative waveforms (averaged or median beats) [1-5].

The BRAVO algorithm can detect and place the following fiducial points on a beat:

Position of QRS-complex, P-wave onset, P-wave peak (for P-wave amplitude), P-wave offset, Isolectric line, QRS onset, R-wave amplitude, J point, T-wave onset, T-wave peak (for T-wave amplitude) and T-wave offset. From these points, the following intervals can be easily derived: PP, RR, P-wave duration, PR, QRS width, QT, QTp, JT, JTp [6-7], TpTe and the following amplitudes R-wave, T-wave and ST-displacement.

When embedded in CER-S, Bravo algorithm can measure the ECG on a beat-to-beat fashion or on computed time-averaged representative beats [9], at a resolution spanning between few seconds to few minutes, using only normal beats, excluding artifact and Ventricular or paced beats, measuring the available leads or a derived RMS lead.

BRAVO is also used, in other scenarios, applied to standard 10s ECGs [1-5].

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.

In addition of the algorithms described, the software comes with a detailed graphical interface for the display of the ECG signal, beat annotations and overlying arrhythmias. A series of interactive tools to review and edit beats label and arrhythmias are available, such as Trends, Poincaré plot, histograms and more.

The software is currently used in clinical settings throughout the world in combination with different ECG devices, such as Holter and patches. Software can also be used via command-line with or without the graphical interface.

It has been used to validate Atrial fibrillation algorithm in Samsung smartwatch [8], where simultaneous recordings from BioTel ePatch and smartwatch were acquired. 81,944 hours of data was analyzed by CER-S and the sections with automatically detected Atrial

fibrillation episodes were overread by a technician and a board-certified cardiologist. Ultimately estimation of the sensitivity and specificity of the smartwatch algorithm for continuous detection of AF from sinus rhythm in a free-living setting was assessed.

The software is also used as viewer for bedside ICU monitors alarms annotations [9-10].

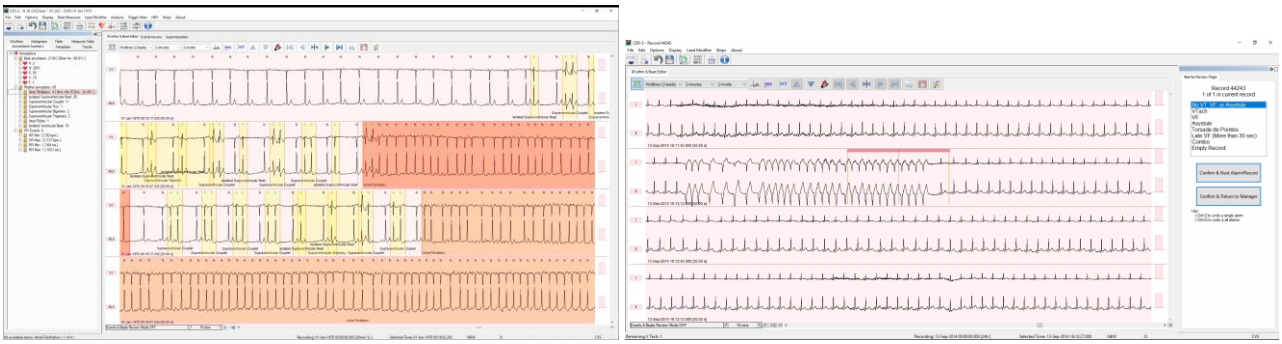

Figure 1. CER-S software displaying a recording from MIT-BIH database with significant Atrial Fibrillation activity (left), CER-S used in Intensive Care Unit Alarm review (right).

3.1 CER-S Remote

In addition to the stand-alone usage, the software can be used remotely via standard RDP or Remote App where the application resides on a server but works as if it were installed on the user's machine.

Other options are RDS Web Client where the remote application is made available through a web page at a specific link or RDP with Apache Guacamole allowing to use a remote app within another web application capable via a simple link. The generation and management of this link is done through the Apache Guacamole component, running on Linux). The possibility of accessing the remote apps via a link allows the integration of the remote app into a larger and more complex system capable of managing a well-defined data flow.

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