# Evaluation of a Shock Advisory System with Non-Shockable Pediatric Rhythms

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### Abstract

*This study aims at validation of the specificity (Sp) of a shock advisory system (SAS) in automatic external defibrillators (AED) with non-shockable pediatric ECGs.*

*Own pediatric ECG database is collected including lead II holter recordings from 46 children - healthy and cardiac patients. A number of 10301 ten-second samples of non-shockable (N) rhythms are analysed. Adult ECG database (MIT-vfdb) is used to show the reference SAS criteria values for N(>18) and shockable S(>18) rhythms.*

*Specific ECG criteria of an AED SAS are evaluated: heart rate, slope uniformity of positive vs. negative peaks, deflections from signal extrema and signal mean in a narrow frequency band for QRS complexes enhancement.*

*Pediatric N rhythms, age: (1-4), (5-8), (9-12) vs. adult N(>18) show significant differences in all criteria, shifting in beneficial direction further away from S(>18) when combined criteria are used. The SAS validation for N(1-4), N(5-8), N(9-12) present respectively Sp=100%, 99.8%, 100%, higher than N(>18) with 99.6%.*

## 1. Introduction

Ventricular fibrillation (VF) or ventricular tachycardia (VT), once thought to be rare in children, occur in 25% of in-hospital and at least 7% of out-of-hospital pediatric cardiac arrests [1]. Patients with an initial rhythm VF/VT have better survival than those with asystole/pulseless electrical activity [2], therefore prompt VF/VT treatment improves the survival rate. Since 2005, the European Resuscitation Council Guidelines for pediatric life support [3] recommend the use of pediatric pads and lower energy levels in automated external defibrillators (AED) for children aged 1 to 8 years. Due to insufficient information for safety and efficacy in infants younger than 1 year, the AED use in this age group is not advised.

Recent efforts are spent to assess the performance and to adapt AED algorithms designed for adults to achieve high accuracy also for pediatric rhythms. There are evidences for significant differences between pediatric vs. adult electrocardiogram (ECG) [4]. Reports show that heart rate is sensitive to age groups and thus rate-dependent ECG morphology parameters are significantly affected, particularly in pediatric non-shockable rhythms [5-7]. Insignificant differences are reported for some morphology parameters in shockable pediatric rhythms [5] and spectral parameters in both shockable and non-shockable rhythms [7]. The technical implication of these studies is AEDs that should implement either separated pediatric and adult decision system [8-9] or a unique solution [5,10,11].

The purpose of the present study is to create an ECG database of non-shockable pediatric rhythms and to use this database for assessment of specific ECG criteria in different pediatric age groups. Differences among the ECG criteria between pediatric non-shockable rhythms and a reference adult database are studied. Verification of the safety of a commercial AED in children is aimed by validating the specificity of its shock advisory system embedding the same ECG criteria settings as validated for adults.

## 2. Materials and methods

### 2.1. Pediatric ECG database

Pediatric rhythms were collected retrospectively from Holter recordings of children with various cardiac diseases, who underwent annual examinations in the Pediatric Cardiac Unit of the National Heart Hospital, Sofia, Bulgaria. Rhythms were acquired with standard ECG electrodes in modified lead II position and bandwidth (0.5-30)Hz. The ECG holter recordings format is: 250Hz as sampling rate, 12bit resolution, 4.9µV/bit dynamics. The database including 46 children – 6 healthy and 40 cardiac patients, age 1 to 12 years old, consisted only of non-shockable samples without lethal ventricular arrhythmias. Selected 10-second samples from the non-shockable (N) recordings were annotated by three cardiologists into two categories – normal sinus rhythm (NSR) and other non-shockable arrhythmia (ONS). This group includes premature ventricular contractions, supra-ventricular tachycardia (SVT), sinus bradycardia, SA/AV and bundle branch blocks (BBB), atrial fibrillation. The rhythm type assigned to each sample reflects the consensus decision of the three annotators. The presence of noise was also indicated. The study followed the AHA guidelines [12] for rhythm annotation and analysis of noise-free episodes only. More than one sample per patient and per rhythm type were involved, representing the different heart rates and ECG morphologies seen in 46 pediatric subjects with diagnosis like healthy control, supraventricular arrhythmia, Tetralogy of Fallot (before and after correction), SA/AV block, prolonged AV or ventricular conduction, atrial or ventricular ectopy, cardiomyopathy, atrial fibrillation, etc.

A total number of 10301 non-shockable samples divided into 3 age groups N(1–4), N(5–8), N(9–12), were identified for analysis. Details are presented in Table 1.

Table 1. Summary of the pediatric database in age groups.

| Age Group, (years) | Nb patients | NSR samples | ONS samples |
|---|---|---|---|
| N(1–4) | 9 | 1487 | 309 |
| N(5–8) | 27 | 1318 | 3250 |
| N(9–12) | 10 | 1932 | 2005 |

## 2.2. Reference Adults ECG database

Reference adult ECG samples were extracted from the MIT-BIH Malignant Ventricular Arrhythmia Database, MIT-vfdb [13], recognized as standard in ECG testing. Subsets were chosen as they contain a wide variety of transitions to lethal arrhythmias. The rhythm classification process followed the recommendations in [12]. In this study, non-shockable (N) and shockable (S) rhythm categories are considered: (i) N(>18) including NSR and ONS rhythms as specified for pediatric patients; (ii) S(>18) including coarse ventricular fibrillation (VF) and rapid ventricular tachycardia (VT) with rate above 150 $min^{-1}$. The number of 10-second samples in each rhythm group is presented in Table 2.

Table 2. Summary of the MIT-vfdb database.

| Rhythm Group | Nb recordings | NSR samples | ONS samples | VF/VT samples |
|---|---|---|---|---|
| N(>18) | 20 | 1023 | 1425 | - |
| S(>18) | 18 | - | - | 510 |

## 2.3. Shock advisory system

The study evaluated a shock advisory system (SAS) of a commercial AED (Fred Easy, Schiller Médical, France) with settings validated for adults [14]. Four ECG criteria were studied being basic for the two main SAS branches:

- Branch 1 for detection of significant peaks in ECG provided information for heart rate (HR) and slope uniformity of positive vs. negative peaks (SU). These are illustrated by the examples in Fig.1-5 (top trace), with asterisks marking the detected significant peaks.
- Branch 2 with narrow pass-band adjusted for QRS complexes enhancement provided information for deflections from signal extrema (SE) and signal mean (SM). The bottom trace of Fig.1-5 illustrates the SE threshold (dotted bold line) and the SM range (the highlighted area).

The criteria were calculated within each 10-second sample from the pediatric and reference adult databases. Several examples illustrate these calculations for an adult S-rhythm and various pediatric N-rhythms (see Fig.1-5).

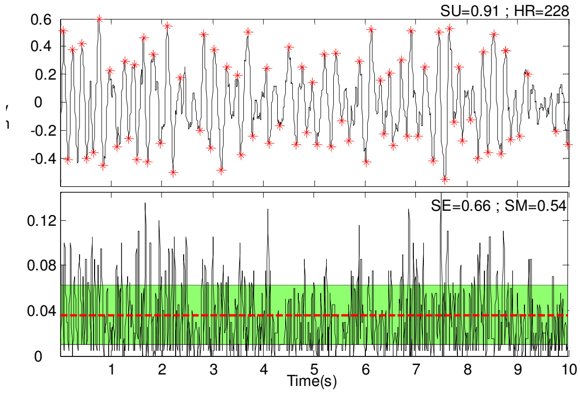


Figure 1. VF signal from the reference file 423 of MIT-vfdb. The values of HR, SU, SE, SM are typical for the S-rhythms: high HR matching the expectedly rapid VF frequency ($min^{-1}$); high SU correlated to the symmetrical slope of positive and negative VF waves; high SE and low SM corresponding to the uniform filtered signal distribution.

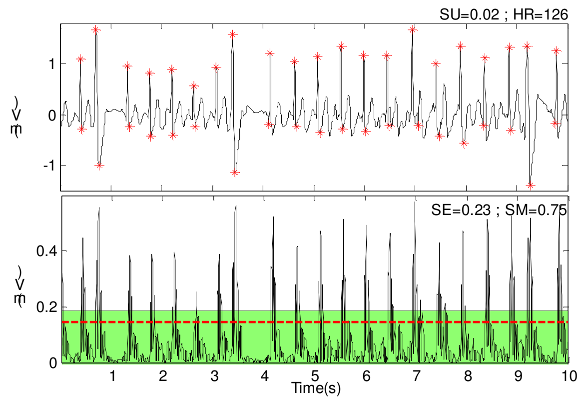


Figure 2. Pediatric ONS rhythm, with sinus rhythm interrupted by 3 ventricular ectopic beats. The HR, SU, SE, SM values are typical for the N-rhythms: low SU identifying the lack of slope symmetry in QRS; low SE and high SM due to the narrow peaks under QRS.

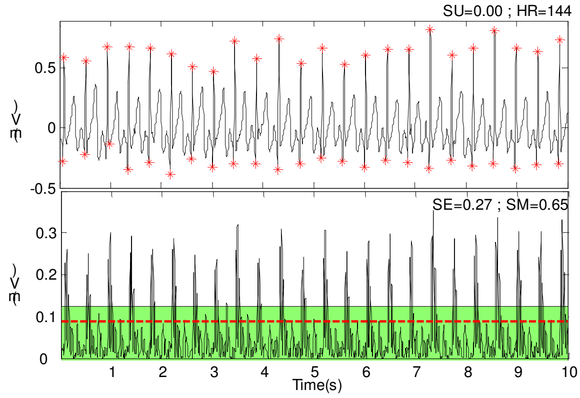


Figure 3. Pediatric ONS rhythm with SVT identified with HR=144 min$^{-1}$. The values of the other criteria SU, SE, SM show insensitivity to the HR.

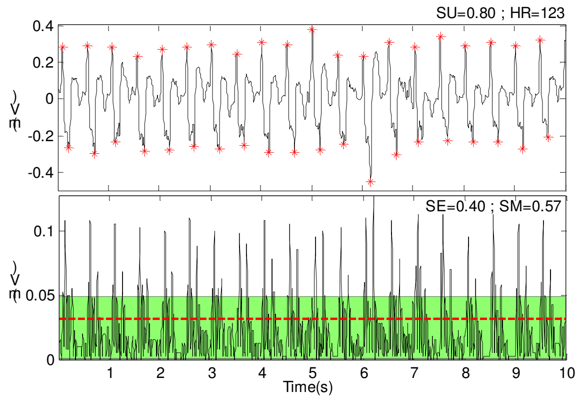


Figure 4. Dilated cardiomyopathy Pediatric ONS rhythm shows sensitivity of SU, SE, SM to the QRS morphology: increased SU due to the symmetrical QRS patterns with S-wave slurring; increased SE and decreased SM due to the doubled peaks at R and S waves (see bottom trace).

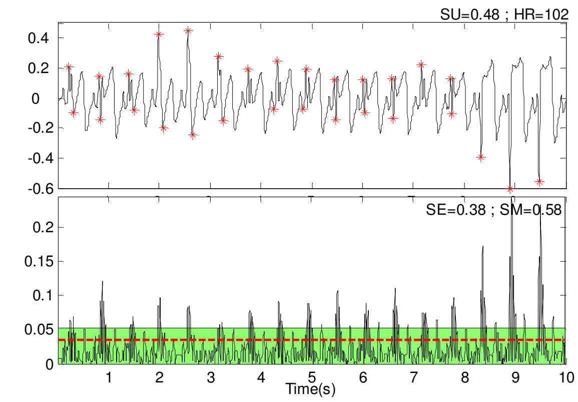


Figure 5. Pediatric ONS rhythm with left BBB and variable QRS morphology. The alternating wide and narrow complexes result in SU rise. The deficit of high frequency components in wide-QRS and low-amplitude QRS complexes shifts down the thresholds towards higher SE and lower SM.

# 3. Results

Statistical analysis of the SAS criteria HR, SU, SE, SM was expressed as mean±standard deviation (SD) for the different rhythm groups N(1-4), N(5-8), N(9-12), N(>18), S(>18) (Fig.6). Student's t-test was used to compare the means between groups. A 2-tailed *p*-value <0.05 was considered as statistically significant. The distributions of all criteria in Fig.6 showed significant difference between the shockable and all non-shockable groups. Significant differences were found in all criteria between the adult non-shockable (N>18) vs some pediatric N-groups.

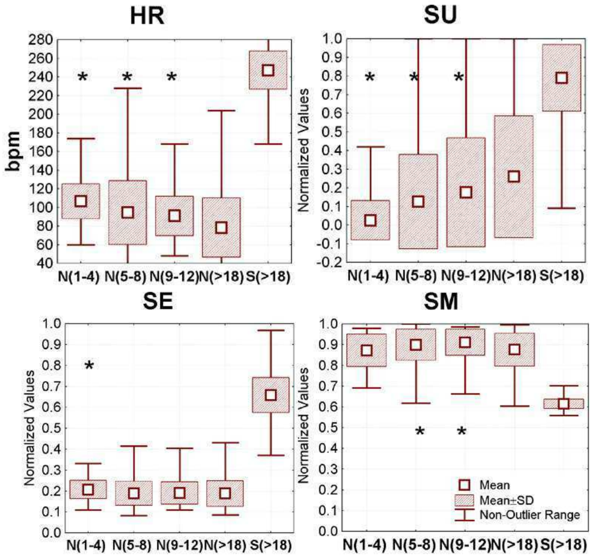


Figure 6. Box-plots (Mean, ±SD, Non-Outlier range) of the 4 SAS criteria for the pediatric and adult rhythms.
Comparison of N(X-Y) to N(>18)*: p<0.05
Comparison of N(X-Y,>18) to S(>18): p<0.05 in all cases

Once the differences found above (adult vs. pediatrics) in each criterion were noted, the synergistic influence of all criteria on the non-shockable detection accuracy was assessed. For that aim, a discriminant analysis was applied for calculation of the Mahalanobis distance for each pair of groups (S(>18) vs. N(1-4), N(5-8), N(9-12), N(>18)) in the multivariate space defined by the 4 criteria HR, SU, SE, SM (Table 3).

Table 3. Mahalanobis distances between N vs. S groups derived by the joint use of HR, SU, SE, SM criteria.

| Group Pair | N(1-4) vs. S(>18) | N(5-8) vs. S(>18) | N(9-12) vs. S(>18) | N(>18) vs. S(>18) |
|---|---|---|---|---|
| Mahalanobis distance | 106 p<0.0001 | 70 p<0.0001 | 68 p<0.0001 | 55 p<0.0001 |

The SAS specificity (Sp) for pediatric and adult N-groups, the sensitivity (Se) for the adult S-group and a reference to the AHA goal are presented in Table 4.

Table 4. SAS accuracy with pediatric and adult ECGs.

| Rhythm Group | Sp % NSR samples | Sp % ONS samples | Se % VF/VT samples |
|---|---|---|---|
| N(1–4) | 100% (1487/1487) | 100% (309/309) | - |
| N(5–8) | 100% (1318/1318) | 99.7% (3239/3250) | - |
| N(9–12) | 100% (1932/1932) | 100% (2005/2005) | - |
| N(>18) | 99.9% (1022/1023) | 99.4% (1417/1425) | - |
| S(>18) | - | - | 97.8% (499/510) |
| AHA goal | >99% | >95% | >90% |

## 4. Limitations

Due to access to a limited amount of data, this study concerns multiple samples from single patients. Shockable cases of pediatric patients were not available, and thus have not been tested.

## 5. Discussion and conclusions

A pediatric ECG database composed of non-shockable samples was collected to study differences between children and adult ECGs. Specific criteria embedded in the SAS of a commercial AED were studied. Although the AED use related to children concerns only patients 1 to 8 years old, our database was composed of 3 pediatric age groups – N(1-4), N(5-8), N(9-12), the last group extending the validity of the tests.

The presented examples of ECG arrhythmia (Fig.1-5) aimed to show that the SAS criteria SU, SE, SM have a stronger dependance to the ECG morphology than the heart rate. The t-tests confirmed the well-known fact that HR in children is significantly higher than in adults (Fig.6) thus increasing the probability for inappropriate shock, if a decision is based on HR only. Conversely, SU for pediatric subjects was significantly lower than adults which contributes to safety improvement in youngers. The synergistic influence of the 4 criteria on the level of safety was ranked by comparison of the Mahalanobis distances for each shockable vs non-shockable group pair (S(>18) vs. N(1-4), N(5-8), N(9-12), N(>18)) (Table3). The trend of increasing distance with decreasing age can be interpreted as beneficial for the younger group safety when the SAS combined criteria are used.

The non-shockable pediatric ECG database was used to validate the specificity of the Fred Easy AED analysis system in children with the same settings as validated for adults. The results (Table 4) showed a specificity for all age groups that exceeds the AHA performance goal for adults, which indicates that the analysis algorithm is safe with pediatric non-shockable rhythms.

## References


[1] Sahu S, Kishore K, Lata I. Better outcome after pediatric resuscitation is still a dilemma. J Emerg Trauma Shock 2010;3(3):243–250.

[2] Herlitz J, Svensson L, Engdahl J, et al. Characteristics of cardiac arrest and resuscitation by age group: an analysis from the Swedish Cardiac Arrest Registry. Am J Emerg Med 2007;25:1025–1031.

[3] Biarent D, Bingham R, Richmond S, et al. European Resuscitation Council Guidelines for Resuscitation 2005 Section 6. Paediatric life support. Resuscitation 2005; 67(1):S98.

[4] Chan T, Sharieff G, Brady W. Electrocardiographic manifestations: Pediatric ECG. J Emerg Med. 2008;35(4):421–430.

[5] Cecchin F, Jorgenson D, Berul C, et al. Is arrhythmia detection by automatic external defibrillator accurate for children? Circulation 2001;103:2483–2488.

[6] Rustwick B, Geheb F, Brewer J, Atkins D. Electrocardiographic characteristics for automated external defibrillator algorithms are different between children and adults. Circulation 2007;116:II_926.

[7] Aramendi E, Irusta U, Pastor E, Bodegas A, Benito F. ECG spectral and morphological parameters reviewed and updated to detect adult and pediatric life-threatening arrhythmia. Physiologicam Measurement 2010;31:749-761.

[8] Irusta U, Ruiz J, Ruiz de Gauna S, Aramendi E. A pediatric shock advice algorithm based on the regularity of the detected beats. Computers in Cardiology 2008;35:1033–1036.

[9] Atkins L, Scott W, Blaufox A, et al. Sensitivity and specificity of an automated defibrillator algorithm designed for pediatric patients. Resuscitation 2008;76:168–174.

[10] Irusta U, Ruiz J. An algorithm to discriminate supraventricular from ventricular tachycardia in automated external defibrillators valid for adult and pediatric patients. Resuscitation 2009;80:1229–1233.

[11] Atkinson E, Mikysa B, Conway J, et al. Specificity and sensitivity of automated external defibrillator rhythm analysis in infants and children. Ann Emerg Med 2003;42(2):185–196.

[12] Kerber R, Becker L, Bourland J, et al. Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety. Circulation 1997; 95:1677-1682.

[13] MIT-VFDB http://physionet.org/physiobank/database/vfib.

[14] Jekova I, Krasteva V, Ménétré S, Stoyanov T, Christov I, Fleischhackl R, Schmid JJ, Didon JP. Bench study of the accuracy of a commercial AED arrhythmia analysis algorithm in the presence of electromagnetic interferences. Physiol Meas 2009;30:695–705.



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