Automated external defibrillator and operator performance in out-of-hospital cardiac arrest
ABSTRACT

Aim: An increasing number of failing automated external defibrillators (AEDs) is reported: AEDs not giving a shock or other malfunction. We assessed to what extent AEDs are ‘failing’ and whether this had a device-related or operator-related cause.

Methods: We studied analysis periods from AEDs used between January 2012 and December 2014. For each analysis period we assessed the correctness of the (no)-shock advice (sensitivity/specificity) and reasons for an incorrect (no)-shock advice. If no shock was delivered after a shock advice, we assessed the reason for no-shock delivery.

Results: We analyzed 1114 AED recordings with 3310 analysis periods (1091 shock advices; 2219 no-shock advices). Sensitivity for coarse ventricular fibrillation was 99% and specificity for non-shockable rhythm detection 98%. The AED gave an incorrect shock advice in 4% (44/1091) of all shock advices, due to device-related (n=15) and operator-related errors (n=28) (one unknown). Of these 44 shock advices, only 2 shocks caused a rhythm change. One percent (26/2219) of all no-shock advices was incorrect due to device-related (n=20) and operator-related errors (n=6). In 5% (59/1091) of all shock advices, no shock was delivered: operator failed to deliver shock (n=33), AED was removed (n=17), operator pushed ‘off’ button (n=8) and other (n=1). Of the 1073 analysis periods with a shockable rhythm, 67 (6%) did not receive an AED shock.

Conclusion: Errors associated with AED use are rare (4%) and when occurring are in 72% caused by the operator or circumstances of use. Fully automatic AEDs may prevent the majority of these errors.
5.1 INTRODUCTION

To increase early defibrillation, automated external defibrillator (AED) programs have been introduced, including traditional first responder AED programs,\textsuperscript{1,2} public access defibrillation programs,\textsuperscript{3–7} and AED programs where the dispatcher plays the key role in guiding lay rescuers to the cardiac arrest patients.\textsuperscript{8–10}

In the Netherlands, the percentage of connected AEDs in patients with an out-of-hospital cardiac arrest (OHCA) has almost tripled between 2006 and 2012, from 21\% to 59\%.\textsuperscript{11} Studies about AED performance in cases of OHCA are scarce. One study reviewed AED performance of currently available AEDs operated by emergency medical service (EMS) personnel.\textsuperscript{12} Since AEDs are increasingly used by first responders and lay rescuers, who may use an AED only rarely and may therefore have difficulties operating the AED, it is important to evaluate first responder and lay rescuer AED performance.

The aims of this study were (1) to determine diagnostic performance of AEDs in rhythm detection in OHCA patients, (2) to study the rescuers’ performance to deliver the advised shocks, and (3) to identify possible causes for inappropriate shock delivery or no-shock delivery after a shock advice.

5.2 METHODS

Study regions and data collection

This study is part of the AmsteRdam REsuscitation STudies (ARREST), an ongoing prospective registry of all OHCAs in three regions within the Netherlands (province of North-Holland, Twente and the municipality of Breda) with a mixed urban and rural population with total 3.28 million inhabitants.

From all OHCAs we collected patient and resuscitation-related data according to standard procedures in the ARREST-study and to Utstein recommendations that are described elsewhere.\textsuperscript{13} If an AED was connected, study personnel retrieved the stored electrocardiograms (ECGs).

We included the recordings of all AEDs that were connected to patients treated for OHCA. Police officers and firefighters are first responders that almost exclusively used LIFEPAK 1000 (Physio Control, Redmond, WA) AEDs. All other AEDs are used by local rescuers; either on-site or alerted with a text-message.\textsuperscript{10} We analyzed all AED recordings that were collected between January 2012 and December 2012. Because the number of AED recordings from rescuers with LIFEPAK 1000 was higher than recordings from other AED types, we extended the study period for other AEDs to December 2014.

The Medical Ethics Review Board of the Academic Medical Center in Amsterdam approved the ARREST data collection and gave a waiver for the requirement of informed consent.
Definitions

We defined coarse ventricular fibrillation (VF) as VF with a peak-to-peak amplitude of \( \geq 0.2 \) mV, in accordance with the American Heart Association (AHA) 1997 Task Force.\(^1,4\) We defined fine VF as VF with a peak-to-peak amplitude of \(< 0.2 \) mV but exceeding the AED manufacturers’ lower threshold. The peak-to-peak amplitude of the VF waveform ranged from \( \geq 0.08 \) mV to 0.2 mV between manufacturers (Supplemental Table 5.1). Ventricular tachycardia (VT) was defined according to the manufacturers’ definition with broad QRS-complexes (>120 ms or \( \geq 160 \) ms with no clear p-waves) and rates varying from >120 beats per minute (bpm) to >180 bpm. All other rhythms were defined as non-shockable. We defined an analysis period as the period from the start of the rhythm analysis to the end of the AED’s rhythm analysis; marked on the ECG recording and the voice prompt to deliver a shock or to resume cardiopulmonary resuscitation (CPR). If a shock was advised, the delivery of that shock was also included in the analysis period. We excluded analysis periods that were not completed due to AED disconnection and analysis periods that were not assessable because of prolonged movement of the patient or because prolonged uninterrupted chest compressions (CC) prevented rhythm assessment. A device-related failure was defined as an incorrect rhythm analysis, not attributed to human error: a voice prompt to either deliver a shock to a non-shockable rhythm (false positive) or failure to recognize a rhythm as shockable (false negative). Operator-circumstance related failures were those situations where a voice prompt to deliver a shock was not followed and a shock was not delivered. Not delivering a shock was also considered a failure in cases where our post-resuscitation analysis determined that there was a false positive shock advice, unless there was sufficient circumstantial evidence that either the patient had signs of life or EMS overruled the operator.

A semi-automatic AED requires rescuer action to push the shock button. A fully automatic AED delivers the shock without the requirement of rescuer action. Automatic external defibrillators are never used by EMS personnel.

Data analysis and statistics

All AED recordings were analyzed with specific software from each manufacturer. All assessments were done by visual inspection of the rhythm on screen, with the calibration as shown on the background grid. For each analysis two authors (JAZ and LEB) determined the rhythm during the analysis period and the AED advice associated with that analysis period.

If a shock was incorrectly advised, we also determined the most likely reason for this incorrect advice. If a shock was advised, we noted whether the shock was delivered and if not, the reason for no-shock delivery. If a shock was not advised while the patient had a shockable rhythm, we assessed the reason for the incorrect advice. For these assessments, we used information from the impedance signal (if available),
which allowed us to distinguish CC from other movements. If there was doubt concerning the assessments, MH and RWK reassessed the decision to consensus.

For our analyses we included all (in)correct advices within one AED recording. Such analysis may bias towards repeated errors of a single cause in one patient. To address such bias we also analyzed only the first analysis periods of the AED recordings, irrespective if more analysis periods in that AED recording were available. Results from this analysis are presented in Supplemental Table 5.2 and Supplemental Figures 5.1–5.4.

Sensitivity for coarse VF detection was calculated, for all AED brands together and for AED brands separately if >100 analysis periods were available. Because of the limited number of analysis periods with fine VF and VT, we only calculated overall sensitivity for fine VF and VT detection. Specificity for non-shockable rhythm detection was calculated, for all AED brands together and for AED brands separately if >100 analysis periods were available. We also calculated the proportion of delivered shocks after a shock advice, for all AEDs together and for each AED brand individually.

We calculated if individual AED brands performed significantly different from overall AED performance regarding to the delivery of a shock after a shock was advised. In addition, we tested whether the proportion of recommended shocks that were not delivered by first responders was different from shocks not delivered by lay rescuers. We calculated false positive and false negative rates for shock advice on coarse VF and assessed if this was caused by device-related or operator-related errors. For all analysis periods where a shock advice was given but no shock was delivered, we calculated the delay to the next shock.

The Chi-Square statistic was used to test differences in proportions. Time delay to the next shock was expressed as median (25th–75th percentile). The Adjusted Wald method was used to calculate 95% confidence intervals (CIs). A P-value of <0.05 was considered statistically significant and the Bonferroni correction applied for multiple testing of AEDs. All data were analyzed using SPSS (SPSS for Mac, version 20.0, IBM SPSS Inc.).

5.3 RESULTS

In the study period, AED recordings of 1119 patients were obtained. Cases excluded from final analysis are shown in Figure 5.1. Our study population included 3310 analysis periods from 1114 AEDs; on average three analysis periods per AED recording. Patient, baseline and AED characteristics of all 1114 patients are shown in Table 5.1. Table 5.2 provides an overview of the number of analysis periods and the number of shock advices for each rhythm category, irrespective of the question if this advice was determined by algorithm performance or interference of artefacts.
AED analysis: sensitivity and specificity

A shock was recommended for 984 of 998 analysis periods with coarse VF: sensitivity 99% (95% CI 98–99) and between 97% and 100% for the individual AED brands (Figure 5.2). Fine VF was detected in 46 of 52 analysis periods: sensitivity 88% (95% CI 81–97). A shock was recommended for 17 of 23 analysis periods with rapid VT: sensitivity 74% (95% CI 56–90). No shock was recommended for 2193 of 2237 analysis periods with a non-shockable rhythm: specificity 98% (95% CI 97–99) and between 97% and 100% for individual AED brands.

Shock advice and shock delivery

The AED gave a shock advice in 1091 of 3310 (33%) analysis periods. In 1047 of 1073 (98%) analysis periods with a shockable rhythm, the AED gave an advice to shock (Figure 5.3, left panel). The AED gave an incorrect shock advice in 44 of 1091 shock advices (false positive rate: 4%). Fifteen incorrect shock advices were caused by device-related errors and 28 were caused by operator-related errors, such as movement of the patient due to CC. Three examples of device-related incorrect shock
Table 5.1  Patient, baseline and AED characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>n=1114</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age in years (SD)</td>
<td>65 (15)</td>
</tr>
<tr>
<td>Male gender, n (%)</td>
<td>815 (73)</td>
</tr>
<tr>
<td>Cardiac arrest of presumed cardiac origin, n (%)</td>
<td>1011 (91)</td>
</tr>
<tr>
<td>Collapse at public location, n (%)</td>
<td>479 (43)</td>
</tr>
<tr>
<td>Witnessed collapse, n (%)</td>
<td>801 (72)*</td>
</tr>
<tr>
<td>Shockable rhythm at any time, n (%)</td>
<td>579 (52)†</td>
</tr>
<tr>
<td>AED use</td>
<td></td>
</tr>
<tr>
<td>Lay rescuer, n (%)</td>
<td>602 (54)</td>
</tr>
<tr>
<td>Dispatched first responder, n (%)</td>
<td>512 (46)</td>
</tr>
<tr>
<td>AED brand used‡</td>
<td></td>
</tr>
<tr>
<td>Physio Control, n (%)</td>
<td>595 (53)</td>
</tr>
<tr>
<td>Fully automatic, n (%)</td>
<td>27 (5)§</td>
</tr>
<tr>
<td>Defibtech, n (%)</td>
<td>153 (14)</td>
</tr>
<tr>
<td>Fully automatic, n (%)</td>
<td>5 (3)</td>
</tr>
<tr>
<td>Cardiac Science, n (%)</td>
<td>141 (13)</td>
</tr>
<tr>
<td>Fully automatic, n (%)</td>
<td>107 (77)</td>
</tr>
<tr>
<td>Philips, n (%)</td>
<td>114 (10)</td>
</tr>
<tr>
<td>Zoll, n (%)</td>
<td>63 (6)</td>
</tr>
<tr>
<td>Samaritan, n (%)</td>
<td>27 (2)</td>
</tr>
<tr>
<td>Welch Allyn, n (%)</td>
<td>8 (&lt;1)</td>
</tr>
<tr>
<td>Schiller, n (%)</td>
<td>5 (&lt;1)</td>
</tr>
<tr>
<td>CardiAid, n (%)</td>
<td>3 (&lt;1)</td>
</tr>
<tr>
<td>Primedic, n (%)</td>
<td>3 (&lt;1)</td>
</tr>
<tr>
<td>Nihon Kohden, n (%)</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Telefunken, n (%)</td>
<td>1 (&lt;1)</td>
</tr>
</tbody>
</table>

AED indicates automated external defibrillator; and SD, standard deviation. Percentages were calculated on the basis of the total number of patients, excluding those with missing data.
* Data of 6 patients were missing.
† In 24 patients the shockable rhythm was not the initial rhythm.
‡ All AEDs are semi-automatic, unless classified as fully automatic.
§ Data of 3 AEDs were missing.
|| Data of 2 AEDs were missing.

Table 5.2  Number of observations per rhythm category

<table>
<thead>
<tr>
<th>Rhythms</th>
<th>Number of analysis periods</th>
<th>Shock advice by AED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shockable</td>
<td>1073</td>
<td>1047</td>
</tr>
<tr>
<td>Coarse VF</td>
<td>998</td>
<td>984</td>
</tr>
<tr>
<td>Fine VF</td>
<td>52</td>
<td>46</td>
</tr>
<tr>
<td>Rapid VT</td>
<td>23</td>
<td>17</td>
</tr>
<tr>
<td>Non-shockable</td>
<td>2237</td>
<td>44</td>
</tr>
<tr>
<td>Asystole</td>
<td>1060</td>
<td>24</td>
</tr>
<tr>
<td>AF, SB, SVT, heart block, idioventricular, PVCs</td>
<td>933</td>
<td>12</td>
</tr>
<tr>
<td>Normal sinus rhythm</td>
<td>208</td>
<td>2</td>
</tr>
<tr>
<td>No rhythm diagnosis due to noise</td>
<td>27</td>
<td>6</td>
</tr>
<tr>
<td>Other VT*</td>
<td>9</td>
<td>0</td>
</tr>
</tbody>
</table>

AED indicates automated external defibrillator; AF, atrial fibrillation/flutter; PVC, premature ventricular contractions; SB, sinus bradycardia; SVT, supraventricular tachycardia; VF, ventricular fibrillation; and VT, ventricular tachycardia.
* Did not meet the rate criteria for VT in a specific AED.
Figure 5.2 Sensitivity for coarse ventricular fibrillation detection and specificity for non-shockable rhythm detection. VF indicates ventricular fibrillation. Only AED brands with >100 completed periods of analysis were included, except in the overall group. Error bars indicate 95% confidence interval.

* The number of analysis periods with coarse VF.
† The number of analysis periods with a non-shockable rhythm.

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>Physio Control</th>
<th>Defibtech</th>
<th>Cardiac Science</th>
<th>Philips</th>
<th>Zoll</th>
<th>Samaritan</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>998</td>
<td>452</td>
<td>164</td>
<td>158</td>
<td>109</td>
<td>64</td>
<td>26</td>
</tr>
<tr>
<td>† n</td>
<td>2237</td>
<td>1205</td>
<td>297</td>
<td>252</td>
<td>249</td>
<td>123</td>
<td>76</td>
</tr>
</tbody>
</table>

Figure 5.3 Reasons for erroneously detecting a (non)-shockable heart rhythm (AED analysis, left part) and reasons for no-shock delivery after a shock advice (operator performance, right part). AED indicates automated external defibrillator; PVC, premature ventricular contraction; VF, ventricular fibrillation; and VT, ventricular tachycardia.

The numbers between brackets indicate in how many individual patients the errors occurred.
* VF <0.2 mV but always above the VF detection threshold of AED manufacturers.
† In one case, signs of life were present and CPR was withheld according to the guidelines.
‡ All in patients with a shockable rhythm.
## AED analysis

### Analysis periods with assessable rhythm
- n=3310

<table>
<thead>
<tr>
<th>Shock advice</th>
<th>No shock advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=1091</td>
<td>n=2219</td>
</tr>
</tbody>
</table>

### Shock advice

- Correct advice: n=1047
- No correct advice: n=44

### No shock advice

- Correct advice: n=2193
- No correct advice: n=26

### Operator performance

### Analysis periods with assessable rhythm
- n=3310

<table>
<thead>
<tr>
<th>Shock advice</th>
<th>No shock advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=1091</td>
<td>n=2219</td>
</tr>
</tbody>
</table>

### Shock advice

- Shock delivered: n=1032
- No shock delivered: n=59

### No shock advice

- No shock delivered: n=2219

### Operator performance

### 15 Device-related (10)
- Narrow complex tachycardia: n=5
- Bradycardia: n=4
- Asystole: n=3
- Normal sinus rhythm: n=2
- Multiple PVCs: n=1

### 28 Operator-related (22)
- Movement due to chest compressions: n=21
- Movement due to other cause: n=7
- Unknown: n=1

### 20 Device-related (16)
- VF, \( \geq 0.2 \text{ mV} \): n=7
- VT: n=6
- VF, \(< 0.2 \text{ mV}\): n=5
- VF with pacemaker spikes: n=2

### 6 Operator-related (5)
- Movement due to chest compressions: n=5
- Movement due to other cause: n=1

### 59 Operator-circumstance related (46)
- ‘Failure’ to deliver shock: n=33
- Shockable rhythm: n=19
- Non-shockable rhythm: n=14
- AED removed prior to shock delivery: n=17
- Shockable rhythm: n=13
- Non-shockable rhythm: n=4
- Pushed off button instead of shock button: n=8
- Closed the lid of the AED: n=1

*VF, \(< 0.2 \text{ mV}\)*

†Non-shockable rhythm

‡Shocked while lid is closed

§Pushed off button instead of shock button
Figure 5.4 Performance of AED operators.
Panel A: Percentages of correctly delivered shocks after a shock advice, overall and by the different AED brands.
* The number of correctly delivered shocks.
Panel B: Reasons for no-shock delivery, overall and by the different AED brands.
AED indicates automated external defibrillator.
† The number of not delivered shocks after a shock advice, including false positives.
advices are shown in Supplemental Figures 5.5–5.7. In one case, we could not find the cause of the incorrect shock advice. In 26 of 44 (59%) incorrect shock advices, a shock was delivered. In 24 of these delivered shocks, the rhythm did not change after shock delivery and were considered not harmful. In one case, the rhythm probably converted from a low-voltage regular rhythm to asystole (Supplemental Figure 5.7). In a second case, the rhythm converted from a supraventricular tachycardia to asystole. In 18 of 44 analysis periods where a shock was advised, the shock was not delivered. In 2237 of 3310 (68%) analysis periods there was a non-shockable rhythm. In 2219 of 3310 (67%) analysis periods the AED gave a no-shock advice. The AED gave incorrectly a no-shock advice in 26 of 2219 (false negative rate: 1%) analysis periods. Twenty incorrect no shock advices were caused by device-related errors and six were caused by operator-related errors, such as movement of the patient. Two examples of device-related incorrect no-shock advices are shown in Supplemental Figures 5.8 and 5.9.

In 1032 of 1091 (95%) analysis periods, the operator correctly executed the AED’s shock advice (Figure 5.3, right panel). In 59 (5%) analysis periods, a shock advice was given but the AED operator did not deliver the shock. The most important reasons for no-shock delivery were failure to deliver a shock (n=33) and AED removal prior to shock delivery (n=17).

We compared the baseline characteristics of 46 patients where the shock was not delivered with the 1068 other patients. Patients who did not receive a shock after a shock advice collapsed more often in public than all other patients (67% vs. 42%, P=0.001). Overall, errors associated with AED use occurred in 129 of 3310 analysis periods (4%). In 93 of the 129 cases (72%), these errors were caused by operator and circumstance-related factors.

Consequences of no-shock delivery

In the 18 cases where the operator failed to deliver the shock or the AED was removed, the rhythm was non-shockable. In 16 of these cases, EMS continued CPR but all patients died on scene in asystole. In two cases, return of spontaneous circulation (ROSC) could be the reason to ignore the (incorrect) shock advice (example in Supplemental Figure 5.5).

Of all 1073 analysis periods with a shockable rhythm, in 67 (6%) analysis periods (in 52 patients) no shock was advised or delivered. In 26 of these cases, the AED did not give a shock advice and in 41 cases the rescuer did not follow the AED’s shock advice. In 31 cases, a shock was subsequently given by the AED after a next rhythm analysis and in 32 cases a shock was given by EMS. The median delay to subsequent shock delivery was 2.7 minutes (25th–75th percentile: 1.0–4.8 minutes). In four cases, no further shock advice was given at all due to dissolution of the VF signal to asystole. Of the 52 patients (with total 67 analysis periods), 15 died on scene and 37 were transported with ROSC to the hospital.
Operator performance

Figure 5.4A shows the overall percentage of correctly delivered shocks after a shock advice was given and for each AED brand separately. Successful shock delivery rates ranged between 91% and 99%. None of these AED brands performed significantly different from the overall performance (P=0.009 with Bonferroni correction; the critical new P-value for six comparisons is 0.008). Reasons for no-shock delivery per AED brand are shown in Figure 5.4B.

We found no significant difference between the proportion of operator-(circumstance) related errors that were caused or influenced by lay rescuers compared to first responders (2.5% and 2.2% respectively, P=0.51).

5.4 DISCUSSION

This study describes experience with AED use in OHCA in the Netherlands and shows that in more than 95% of the analysis periods, AEDs are used correctly and deliver shocks when indicated. Errors associated with AED use are rare (4%) and if they do occur, are related to the operator and circumstances in 72% of cases. When repeating the same analyses on patient level, these percentages are similar, 3% and 72% respectively. These rates are true incidence rates of failure, as the dataset of our study included all AED use in the study regions. We were able to separate device-related errors from operator and circumstance-related errors, which are commonly also perceived as AED failures and offer a broader perspective of AED use than the assessment derived from ECG databank testing.

About 25% of errors were caused by movement of the patient during AED rhythm analysis, mainly from the continuation of CC despite AED prompts to discontinue CC. These movements could lead either to an inappropriate shock advice or to failure to recognize a shockable rhythm because the analysis algorithm aborted. An important second operator-circumstance related error was failure to deliver the shock when advised. In most cases, the rescuer did not respond to the audible and/or visual prompts or the AED was disconnected by EMS before shock delivery. Premature AED removal by EMS during rhythm analysis or just before shock delivery, occurred in 17 cases and resulted in further delay in shock delivery by EMS as shown previously.16 EMS should be instructed to await the AED’s assessment and shock delivery before disconnecting the AED. Failure to deliver a recommended shock was observed only once in AEDs from Cardiac Science and multiple times in all other AEDs. In our dataset, 77% of the Cardiac Science AEDs were fully automatic. This may explain the high percentage of correctly delivered shocks with this AED. In two studies the safety, speed and operator-device interactions of fully automatic versus semi-automatic defibrillation by untrained rescuers were compared.17,18 Both studies showed that
fully-automatic AEDs are safe when used by untrained rescuers and result in increased compliance with the protocol and reduced variability in time to deliver shocks.

In 18 of the 50 analysis periods where the operator did not deliver the shock, the rhythm in fact was not shockable. This may have been related to the combination of two errors: first not hearing the voice prompt to stop CPR for rhythm analysis and subsequently not responding to the voice prompt to deliver a shock.

We analyzed all events, including repetition of the same errors in one patient. We performed a secondary analysis of the same data, only including the first analysis period from each AED recording (Supplemental Table 5.2 and Supplemental Figures 5.1–5.4). The results of these analyses did not essentially alter our findings and conclusions.

All AED brands exceeded the minimum AHA performance standards for coarse VF and non-shockable rhythm detection in a combination of AED performance and the presence of noise (e.g. movement artifacts). The AHA performance statement requires a minimum test sample size of at least 50 VT cases in order to calculate VT performance. Shockable VT occurred in only 2% of all shockable rhythms. Based on this low observed proportion of shockable VT rhythms, it would require more than 2500 AED analysis periods with a shockable rhythm for OHCA to comply with the AHA requirement of a VT sample size.

### 5.5 RECOMMENDATIONS

Many operator-related errors can be prevented, such as movement due to CC. Paying strict attention to AED voice prompts should be emphasized during basic life support training. This can be enhanced by reducing the voice prompts to only key messages, make voice prompts louder and use prominent visual prompts such as a flashing shock button. To prevent ignoring a correct shock advice or prevent rescuers to push the off button instead of the shock button, fully automatic AEDs may be useful. Finally, AED software that can analyze the rhythm during CC may avoid false positive shock decisions or disruption of the analysis process.

### 5.6 LIMITATIONS

We followed the amplitude thresholds for VF and VT as defined by each AED brand but several AED analysis algorithms were more complex than only measuring VF peak-to-peak amplitude. The added value of these more complex algorithms, however, is not demonstrated. The modest quality of the AED review software of several AED brands to allow precise amplitude measurement was also a limiting factor.
We have not reported on AED maintenance failures due to empty or frozen batteries, the absence of electrodes, or failure to switch on due to an AED defect, because under such circumstances we would not have received any AED recordings. Between 1993 and 2008, the Food and Drug Administration received 40,787 AED-related events in their Manufacturer and User Device Experience database, of which 1150 (3%) were failed defibrillation events. Of these, 23% could be attributed to battery/power problems and another 23% to pads/connector problems. However, in this database there is no known denominator of AED use and a failure rate cannot be derived.

5.7 CONCLUSION

All studied AEDs comply with the accepted diagnostic rhythm performance standards in real OHCA. Errors associated with AED use are infrequent and if they do occur, the majority appears to be caused by the operator or circumstances of use. Inappropriate AED shocks almost never have adverse consequences. Fully automatic AEDs may contribute to correct AED shock delivery when indicated.

CONFLICTS OF INTEREST STATEMENT

Data collection of the ARREST-study is made possible by an unconditional grant from Physio Control (Redmond, WA, USA), and conditional grants for another study from Cardiac Science (Waukesha, WI, USA), Defibtech (Guilford, CONN, USA), Philips Nederland B.V. (Eindhoven, the Netherlands) and Zoll Medical (Chelmsford, MA, USA). The funders had no access to the data and did not contribute to the manuscript. RWK is the recipient of the funding mentioned above and is an unpaid advisor to Physio Control and HeartSine. He also received financial support for unrelated studies of mechanical chest compression devices from Physio Control/Jolife AB and Zoll Medical. JAZ is supported by a grant from the Dutch Heart Foundation (#2010T083). MH is supported by a personal grant from the Dutch Heart Foundation (#2013T034). LEB and SGB report no conflicts.

DEDICATION

We dedicate this paper to the memory of our friend and eminent researcher Richard E. Kerber, who passed away on November 8, 2016. Among his many important contributions to resuscitation science was the publication of 1997.
with recommendations for AED algorithm performance. This publication was an inspiration to perform our current study.

ACKNOWLEDGEMENTS

We thank Paulien Homma and Remy Stieglis for expert data management. We are grateful for all participating dispatch centers, EMS, first responders and text-message responders for their cooperation and support. Special thanks to Irmgard Maassen, Jeanet Glas, Gerard Kamphuis, Ron Regoort, Babette Hendriks, Desiree Graumans, Piet Mattheeuwsen and all medical students who helped to collect the data of the used AEDs.
REFERENCES


### SUPPLEMENTAL TABLES

#### Supplemental Table 5.1  Shockable rhythm detection threshold of all included AED brands

<table>
<thead>
<tr>
<th>AED brand</th>
<th>Peak-to-peak VF/VT detection threshold</th>
<th>VT detection rate with QRS-complex &gt;120 ms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physio Control</td>
<td>≥0.08 mV*</td>
<td>&gt;120 bpm†‡</td>
</tr>
<tr>
<td>Defibtech</td>
<td>≥0.20 mV*</td>
<td>&gt;180 bpm*</td>
</tr>
<tr>
<td>Cardiac Science</td>
<td>≥0.16 mV*</td>
<td>&gt;160 bpm*§</td>
</tr>
<tr>
<td>Philips</td>
<td>≥0.10 mV†</td>
<td>&gt;135 bpm†</td>
</tr>
<tr>
<td>Zoll</td>
<td>≥0.10 mV*</td>
<td>&gt;150 bpm*</td>
</tr>
<tr>
<td>Samaritan</td>
<td>≥0.20 mV†</td>
<td>&gt;180 bpm†</td>
</tr>
<tr>
<td>Welch Allyn</td>
<td>≥0.10 mV*</td>
<td>&gt;160 bpm*</td>
</tr>
<tr>
<td>Schiller</td>
<td>≥0.15 mV†</td>
<td>&gt;180 bpm†</td>
</tr>
<tr>
<td>CardiAid</td>
<td>≥0.16 mV†</td>
<td>Unknown</td>
</tr>
<tr>
<td>Primedic</td>
<td>≥0.20 mV*</td>
<td>Based on morphology†</td>
</tr>
<tr>
<td>Nihon Kohden</td>
<td>≥0.10 mV†</td>
<td>&gt;180 bpm†</td>
</tr>
<tr>
<td>Telefunken</td>
<td>≥0.16 mV†</td>
<td>pVT &gt;120 bpm; mVT &gt;150 bpm; mVT &gt;120 bpm+ amplitude &gt;3.5 mV†</td>
</tr>
</tbody>
</table>

AED indicates automated external defibrillator; mVT, monomorphic ventricular tachycardia; pVT, polymorphic ventricular tachycardia; VF, ventricular fibrillation; and VT, ventricular tachycardia.

* Information retrieved from AED manual specifications.
† Information retrieved from AED manufacturer’s communicated information.
‡ QRS-complex must be ≥160 ms with no clear p-waves.
§ This rate is programmable between 120 bpm and 240 bpm via MDLink Software by the Medical Director. The default detection rate is 160 bpm.

#### Supplemental Table 5.2  Number of observations per rhythm category including first analysis periods only

<table>
<thead>
<tr>
<th>Rhythms</th>
<th>Number of analysis periods</th>
<th>Shock advice by AED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shockable</td>
<td>548</td>
<td>538</td>
</tr>
<tr>
<td>Coarse VF</td>
<td>519</td>
<td>512</td>
</tr>
<tr>
<td>Fine VF</td>
<td>22</td>
<td>19</td>
</tr>
<tr>
<td>Rapid VT</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Non-shockable</td>
<td>559</td>
<td>7</td>
</tr>
<tr>
<td>Asystole</td>
<td>314</td>
<td>6</td>
</tr>
<tr>
<td>AF, SB, SVT, heart block, idioventricular, PVCs</td>
<td>192</td>
<td>1</td>
</tr>
<tr>
<td>Normal sinus rhythm</td>
<td>46</td>
<td>0</td>
</tr>
<tr>
<td>No rhythm diagnosis due to noise</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Other VT*</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

AED indicates automated external defibrillator; AF, atrial fibrillation/flutter; PVC, premature ventricular contractions; SB, sinus bradycardia; SVT, supraventricular tachycardia; VF, ventricular fibrillation; and VT, ventricular tachycardia.

* Does not meet the rate criteria for VT in a specific AED.
Supplemental Figure 5.1  Description of the data collection process, including first analysis periods only.
AED indicates automated external defibrillator; and ECG, electrocardiogram.
Supplemental Figure 5.2  Sensitivity for coarse ventricular fibrillation detection and specificity for non-shockable rhythm detection, including first analysis periods only. Error bars indicate 95% confidence interval. VF indicates ventricular fibrillation.

* The number of analysis periods with coarse VF.
† The number of analysis periods with a non-shockable rhythm.
Supplemental Figure 5.3 Reasons for erroneously detecting a (non)-shockable heart rhythm (AED analysis, left part) and for no-shock delivery after a shock advice (operator performance, right part), including first analysis periods only. AED indicates automated external defibrillator; PVC, premature ventricular contraction; VF, ventricular fibrillation; and VT, ventricular tachycardia.

* The number of analysis periods with coarse VF.
† The number of analysis periods with a non-shockable rhythm.
Supplemental Figure 5.4  Performance of AED operators, including first analysis periods only.
Panel A: Percentages of correctly delivered shocks after a shock advice, overall and by the different AED brands, including first analysis periods only.
* The number of correctly delivered shocks.
Panel B: Reasons for no-shock delivery, overall and by the different AED brands, including first analysis periods only. AED indicates automated external defibrillator.
† The number of not delivered shocks after a shock advice, including false positives.
Supplemental Figure 5.5  For legend see next page
Supplemental Figure 5.5  Example of an incorrect shock advice (narrow complex tachycardia) caused by a device-related error in combination with an operator-circumstance related error ('failure' to deliver shock). The patient probably regained consciousness after receiving a shock on ventricular fibrillation first, then had return of an organized rhythm. He survived to hospital discharge without having received further chest compressions. The line below the ECG strip shows the signal of the sternum transducer. No chest compressions are given in the full recording except for the first three seconds. CPR indicates cardiopulmonary resuscitation; and ECG, electrocardiogram.

Supplemental Figure 5.6  Example of an incorrect shock advice (bradycardia) due to a device-related cause, probably from electrical interference. The shock was delivered on sinus bradycardia. After the shock short-lasting atrial arrhythmias are visible. CPR indicates cardiopulmonary resuscitation.
Supplemental Figure 5.7  Example of an incorrect shock advice caused by a device-related error. The rhythm is a low voltage regular rhythm with a rate of 80–90/min. After the shock, chest compressions obscure reliable assessment of the post-shock rhythm, but the rhythm appears to be asystole. CPR indicates cardiopulmonary resuscitation.
Supplemental Figure 5.8  Example of an incorrect no shock advice (wide-complex tachycardia, rate 200/minute, VT) cause by a device-related error.
Supplemental Figure 5.9  Example of an incorrect no shock advice caused by a device-related error. The amplitude of the VF waveform exceeds the manufacturer’s threshold of 0.15 mV. VF indicates ventricular fibrillation.