

Rhythm Recognition Performance Welch Allyn AED 10™

Standards

The Welch Allyn AED 10 algorithm exceeds the requirements of ANSI/AAMI DF39-1993 section 3.3.18 and the sensitivity and specificity levels recommended by the AHA Automated External Defibrillators for Public Access Use: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance. The test database includes shockable rhythms consisting of ventricular fibrillation rhythms (> 99 V) and wide-complex ventricular tachycardia at a rate greater than 160 BPM. Non-shockable rhythms include various sinus rhythms including supraventricular tachycardia, atrial fibrillation, atrial flutter, sinus rhythm with PVC's, asystole, pacemaker rhythms, and ventricular tachycardia with a rate less than 160 BPM and/or narrow complexes.

Performance

Rhythm Class	ECG Test Sample Size	Performance Goal	90% one-sided lower confidence level	Conclusion
Shockable: VF	90	>90% sensitivity	97.2%	Meets the AAMI DF39 requirement and AHA recommendation
Shockable: VT	33	>75% sensitivity	84.6%	Meets the AAMI DF39 requirement and AHA recommendation
Nonshockable: NSR	349	>99% specificity (AHA)	100%	Meets the AAMI DF39 requirement and AHA recommendation
Nonshockable: asystole	10	>95% specificity	100%	Meets the AAMI DF39 requirement and AHA recommendation
Nonshockable: all other rhythms	242	>95% specificity	97.8%	Meets the AAMI DF39 requirement and AHA recommendation