Optimizing Frequency of AED Self-Tests for Enhanced Clinical Reliability

Weekly low-energy AED self-tests are shown to help minimize clinical risk and improve clinical reliability while maintaining battery longevity.

ZOLL MEDICAL CORPORATION

Automated external defibrillators (AEDs) have been widely accepted in the past two decades as a necessary device in public places in the event of cardia arrest. Currently, AEDs are a central component to the American Heart Association's "chain of survival" for the treatment of cardiac arrest due to strong scientific consensus (Berg et al, 2010). Several key publications have shown the critical value of performing high-quality chest compressions, ventilations, and defibrillation of lethal arrhythmias as early as possible to increase the likelihood of survival.

Recent data from the Resuscitation Outcomes Consortium (ROC) registry indicates that AED use in communities is associated with nearly a doubling of survival after out-of-hospital cardiac arrest and approximately 474 lives saved per year (Weisfeldt et al, 2010). As with any medical device, the frequency of testing to ensure proper functionality must be weighed against several factors. Currently, most AED devices perform a low-energy cost self-test every one to seven days, as well as a monthly high-energy cost self-test. Because all AED devices are battery powered, the frequency of self-tests must be weighed against the average failure rate, energy cost of performing self-tests, and subsequent battery longevity (which ultimately has associated maintenance and economic costs).

Investigating self-check frequency

The following document describes an analysis that investigates the frequency of low-energy self-checks in AED devices that would optimize clinical reliability given real-world failure rates. The analyses in this report are based on estimated probabilities of clinical events and field data collected by ZOLL Medical Corporation.

Regardless of how often a self-test is performed, the overall clinical reliability of AED devices over a five-year period is remarkably high (Shah and Maisel, 2006). Due to differences in definition and ascertainment of data, the reported incidence of rates of AED use for clinical events has not been clearly defined. However, monthly rates have been estimated to vary from 0.005% to 0.05% per AED. If it is assumed that AEDs have perfect maintenance (i.e., replacement of a device occurs immediately after a failure is observed), monthly rates of a clinical event are 0.01%, and the daily probability of latent failure equals 0.000125% (as approximated from field data), the five-year clinical reliability of an AED that self-tests each day is 99.9999992% (see Appendix – Calculation #1).

Under the same scenario, an AED device that self-tests every seven days has a five-year clinical reliability of 99.999997%, which equates to the odds of an undetected clinical failure being one in 32,876,710 during a five-year period. Consequently, the best case-scenario in which maintenance is done on time and all device failures are observed when they occur, the five-year clinical reliability as a function of self-test frequency declines linearly with increasing intervals, but reduces at a magnitude of questionable significance (0.0000004%/day).

Maintenance and replacements

In a real-world setting, however, it is unrealistic to presume perfect maintenance and same-day replacement of a faulty device occurring as part of common practice. Indeed, DeLuca and colleagues (2011) found that only 1.5% of adverse events with AEDs reported in the FDA's Manufacturer and User Facility Device Experience (MAUDE) database included documentation of any sort of device maintenance program or schedule.

In addition, the amount of time between when an AED is identified as needing maintenance and a replacement unit is requested, received, and installed will vary based on personnel at the site and availability of a replacement. This process could realistically take as little as one to two days or perhaps as long as five to seven days. Ultimately this replacement time represents the period in which the site has increased clinical risk or is "clinically exposed."

The risk and the time frame associated with it can be viewed as the intersection of a device failure, a maintenance lag, and a clinical event. This should not be confused with the unreliability of the device, because a device failure, although not a desirable event, does not necessarily result in a life lost. Consequently, any operational features of an AED that affect the rate of failure should be evaluated on whether they increase or decrease clinical risk.

Device failure

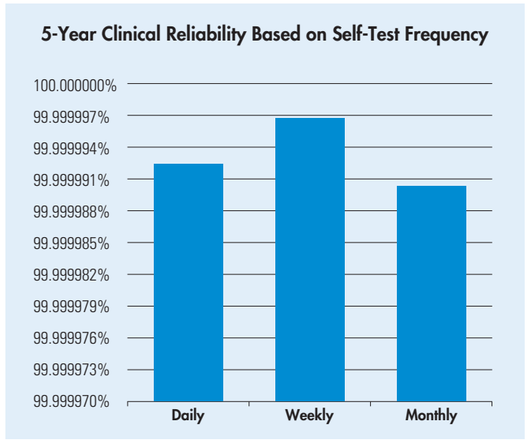
AEDs can be modifiable and potentially impact clinical risk. One such feature is automated self-tests. Reliabilty analyses have shown that the duration of a powered-on electronic device has a direct influence on device failure rate (MIL- HDBK-781; 1996). Furthermore, each time an electronic device is powered on, there is a small risk of failure in part due to power surge across internal circuits and components, as well as thermal fatigue associated with activation and deactivation (Anzawa et al, 2008).

The probability of device failure can comprise three components: device failure due to a random or unknown cause when the device is off; device failure due to the actual act of powering on the device; and the frequency of power cycles. The contribution of powering on the device to device failure will vary based on manufacturing processes, including the rigor of the high-accelerated life and stress test methods.

In an environment in which each device undergoes rigorous stress testing, the vast majority of faulty devices will be identified in factory testing and never reach the commercial sector. Consequently, the primary contributors to device failure are power cycling and the related time in which the AED device is powered on.

In Figure 1 below, a conservative estimate (25%) of the contribution of power cycling due to automated self-testing is used to determine the five-year clinical reliability (see Appendix – Calculation #2). As noted previously, it is unrealistic to expect that a failed AED device will be replaced immediately. Therefore, Figure 1 factors in an average delay of three days to replace the AED (see Appendix – Calculation #3).

Figure 1



This data illustrates the amount of time in which sites have increased clinical risk as a function of self-test frequency. More frequent self-tests will also compromise battery longevity and the subsequent need for battery change-out, which may also increase clinical risk. It is important to note that this analysis does not factor in differences related to the implied battery longevity and electrode/pad expiration. As the timeframe on either of these components shortens, the 'readiness' of the device will be reduced as the likelihood of failing to replace the battery or pads in a timely manner increases. AED devices that self-test frequently will therefore inherently have a greater time in which the site is clinically exposed or operating at increased clinical risk.

Upon first consideration, it may seem logical to conclude that AED self-tests should be performed on a daily basis to ensure proper device functionality. However, other factors such as real-world maintenance/replacement delays and increased failure rate due to unnecessary self-tests should be taken into consideration. A self-test frequency of approximately once per week provides an optimized clinical reliability and minimizes clinical risk without sacrificing battery longevity.

References

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Appendix

Calculation #1: Derivation of five-Year Clinical Reliability assuming perfect maintenance and change-out of a failed device immediately upon detection

- If the self-test interval is every day: the daily clinical reliability of a device for any given day is expressed as:
  $(1 - (a \times b))$
  a = daily probability of clinical event
  b = daily probability of latent failure

- If the self-test interval is every two days: a clinical event could occur on Day 1 and the device could fail on Day 1 $(a \times b)$, a clinical event could occur on Day 2 but the device could have failed on Day 1 $(a \times b)$, or a clinical event could occur on Day 2 and the device could fail on Day 2 $(a \times b)$. Resulting in: $3 \times (a \times b)$.

- Therefore, the daily clinical reliability could be expressed as:
  $\mathrm{j}1 - (\sum k) \times abk=1$
  Where j = frequency of self-test interval in days

- To determine five-year clinical reliability:
  $\mathrm{j}\,(1 - (\sum k) \times (ab)(5 \times 365 \div \mathrm{j})k=1$

Calculation #2: Derivation of five-year clinical reliability accounting for device power cycling.

- The daily probability of latent device failure was determined from field data obtained by ZOLL Medical Corporation.
- Presuming a 0.01% monthly clinical event rate and varying contributions of power- cycling towards the device failure rate used in Calculation #1; the clinical reliability is calculated as:
  j(1 – (∑ k) × a(b + (c × k=17(5 ×365÷j) j

Where a = daily probability of clinical event, b = daily probability of undetermined/unknown cause of failure, c = probability of device failure due to power cycle, and j = self-test frequency in days.

NOTE: It is assumed that b + c equals 0.000125% (the daily probability of latent failure as determined from field data collected by ZOLL Medical).

Calculation #3: Derivation of five-year clinical reliability accounting for device power cycling and clinical exposure (not having a functional AED) due to replacement delay.

- The daily probability of latent device failure was determined from field data obtained by ZOLL Medical Corporation.
- Presuming a 0.01% monthly clinical event rate and varying contributions of power- cycling towards the device failure rate used in Calculation #1; the clinical reliability is calculated as:

j7(5 ×365÷j) [(1 – (∑ k) + d) × a(b + (c × k=1))]j

Where a = daily probability of clinical event, b = daily probability of undetermined/unknown cause of failure, c = probability of device failure due to power cycle, d = number of days associated with replacement delay, and j = self-test frequency in days.

NOTE: It is assumed that b + c equals 0.000125% (the daily probability of latent failure as determined from field data collected by ZOLL Medical).