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An Accuracy Study of Defibrillator Performance Measurement at Songklanagarind Hospital, Thailand

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Abstract:

Objective: To assess and validate the accuracy and reliability of key parameters. The performance of manual external defibrillators (MEDs) at Songklanagarind Hospital was evaluated.

Material and Methods: This study sampled 60% of the defibrillators from various departments and brands within the hospital. Key performance parameters, including delivered energy output, charge time, and synchronized time, were evaluated against the specified tolerance limits outlined by manufacturer specifications and industry standards. The accuracy of delivered energy was assessed by integrating absolute error and %relative error, along with expanded uncertainty (U(E)). The acceptable charge time was defined as not exceeding 15 seconds, while the discharge in synchronized mode was required to occur within 60 milliseconds.

Results: The findings demonstrated that all the tested models showed a high degree of accuracy in delivered energy. Additionally, the mean charge time for all defibrillators followed the 15-second threshold established by both manufacturer specifications and universally recognized standards. Furthermore, the synchronized shock delivery capability of all 3 defibrillator models successfully met the critical 60-millisecond timeframe essential for clinical efficacy. These validated results confirm that the evaluated parameters consistently fell within acceptable ranges, thereby substantiating the reliability of these models in assessing defibrillator performance.

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Conclusion: These findings emphasize the significance of assessing the reliability and accuracy of the MEDs through calibration techniques for continuous monitoring and regular maintenance. These devices are imperative to guarantee adherence to the prescribed standards before medical practice.

Keywords: calibration technique, charge time, defibrillator, delivered energy, synchronized time and Songklanagarind Hospital

Introduction

In medical research and statistical analysis, a substantial percentage of individuals succumb to acute myocardial infarction, accounting for roughly 20–25% of global instances of ventricular fibrillation (VF) or ventricular tachycardia (VT)[1]. The most efficacious intervention for acute myocardial infarction is rapid cessation via an electric countershock, a procedure referred to as defibrillation[2]. Consequently, the application of defibrillation is critical for survival following acute myocardial infarction or sudden cardiac arrest, as the probability of successful intervention quickly declines with time.

The effectiveness of a defibrillator's performance is dependent upon several pivotal factors, including the accuracy of the energy delivered, the time required for charging, and the precision of its timing[3]. It is paramount that the defibrillator delivers an accurate magnitude of electrical energy to the heart. Delivering an energy level that is too low might prove inefficacious in defibrillating the heart, while an excessively high energy level could potentially cause damage to the heart tissue. Moreover, transthoracic impedance plays an essential role in determining current flow[4]. Upon reviewing the energy measurements of a defibrillator, it was discovered that approximately 14.91% of the defibrillator tests failed to meet the specified metrological requirements and periodic calibration standards. As a result, these defibrillators were excluded from the healthcare system or required corrective maintenance procedures to ensure their proper functioning and compliance with the established standards[5]. A systematic review of the literature revealed mean transthoracic impedance levels in humans ranging from 52 to 212 Ω[6]. Additionally, some studies suggest that approximately 4% of the transthoracic current traverses the myocardium during human transthoracic defibrillation[7]. The accuracy of defibrillator measurements necessitates meticulous examination through specialized calibration methodologies. Regular calibration is imperative for maintaining uniform standards and ensuring the reliable performance of equipment. Specifically, the calibration procedure for defibrillators is meticulously designed to ensure strict adherence to both manufacturer specifications and universally accepted defibrillation standards, such as IEC 60601-1[8] and IEC 60601-2-4[9]. This validation process ensures that defibrillators conform to the specified criteria for their safe and effective operation, thus guaranteeing their reliability and functionality in critical medical situations.

This study aimed to assess and validate the precision and confirmation of delivered energy accuracy, charge time, and synchronized timing. The investigation involved the routine evaluation of the performance of the MEDs at Songklanagarind Hospital, thereby contributing to the ongoing efficacy and adherence of these critical medical devices in order to establish standards.

Material and Methods

This research comprised 3 distinct studies designed to evaluate the accuracy of defibrillators. The studies were focused on assessing the precision of various defibrillator

brands and models that have undergone servicing from the Medical Equipment and Maintenance Center (MEMC) of Songklanagarind Hospital. The first study assessed the delivered energy by precisely measuring the defibrillators' energy output at specified usage levels (5, 50, 100, 150, and 200 Joules: J). Simultaneously, it investigated a range of resistance values (25, 50, 100, 125, and 150 ohm: Ω) to determine the impact of impedance on energy delivery. The second study evaluated the accuracy of the device's charge time test. The third study investigated the operation of the synchronized mode. This study collected samples from a total of 60% of defibrillators, representing 2 distinct brands: Brand AA (Models A1 and A2) and Brand BB (Model B1).

The delivered energy, charge time and synchronized time on defibrillators

The calibration of delivered energy, charge time and synchronized time accuracy in defibrillators was conducted in strict compliance with the guidelines stipulated by IEC 60601-2-4:2010-12 and ECRI Procedure Number 408-20210319. A comparison method was employed, utilizing standard defibrillators as the reference.

The evaluation of delivered energy was conducted using a defibrillator analyzer (standard device, STD) to assess the energy output of the defibrillator, referred to as the unit under calibration (UUC), across a range of impedance values. The procedure entailed setting the initial energy range of the UUC and adjusting the load resistance of the defibrillator's selectable load accessory from its minimum to maximum levels. During the assessment, the UUC was tasked with charging and discharging energy to the defibrillator analyzer as part of its defibrillation function. To enhance the reliability and precision of the measurements, all assessments, including the analysis of the effect of load resistance variations on the delivered energy error and the evaluation of uncertainty, were replicated 3 times.

The primary goal of the charge time test was to assess the accuracy and consistency of the defibrillators' charging mechanism and battery performance. The test was conducted by setting the energy value to the machine's maximum capacity (200 joules at 50 ohms). Subsequently, 10 consecutive charge and discharge cycles were implemented.

The synchronizer operation test evaluated the synchronization between the defibrillator's electrocardiogram (ECG) and the delivery of the electrical shock to ensure optimal timing and effectiveness. This test involved examining the operation in synchronized mode, requiring the device to discharge within 60 milliseconds upon receiving the R-wave signal at the maximum energy value of 200 joules and a resistance of 50 ohms. Both the charge time and synchronizer time measurements were repeated 3 times to verify consistency and accuracy.

Data analysis of delivered energy, charging time and synchronized time

To assess the defibrillator's accuracy, a series of measurements of the delivered defibrillation energy were conducted using a standardized calibration technique. Determining the accuracy of measurements is crucial, including any potential errors. An error value signifies a deviation or discrepancy from the expected result. Therefore, high accuracy is demonstrated when the measured value closely corresponds to the actual value. The absolute error value is computed as the difference between the mean measured energy value (E) acquired through the STD and the nominal delivered energy value (E_0) based on the various brands, utilizing Equation 1:

$$Absolute\ Error = E - Eo \quad (1)$$

In addition, a critical parameter to consider is the relative error, a metric that quantifies the magnitude of absolute error in relation to the true value of the

measurement. The relative error is defined as the ratio of the difference between the measured value and the true value, typically expressed as a percentage by multiplying it by 100. The formula for calculating the %relative error () is given in Equation 2.

$$\delta_{Er} = \left|\frac{E-E_o}{E_o}\right| \times 100\% \quad (2)$$

Additionally, the estimation of uncertainty was performed in accordance with the Guide to the Expression of Uncertainty in Measurement (GUM)[10]. The uncertainty components were derived either through statistical analysis of repeated measurements or from information provided in calibration certificates, system parameters, environmental conditions, and their respective probability distributions. Consequently, the standard uncertainties were collected using the combined uncertainty method, denoted as Uc(E). This process involved either summation in quadrature or the root-sum-of-squares approach, as represented by Equation 3.

$$\mathrm{Uc(E)} = \sqrt{C_i u_{std}^2 + C_i u_{std_{res}}^2 + C_i u_{rep}^2} \quad (3)$$

The combined uncertainty of energy, denoted as Uc(E), comprises several components that collectively contribute to the overall measurement uncertainty. These components include, which accounts for the uncertainty caused by the standard source, and, which represents the uncertainty arising from the resolution of the standard source. Additionally, addresses the uncertainty associated with the standard deviation of the mean values of the standard. For each delivered energy measurement, the standard deviation of the mean values was determined based on the variations observed in the energy readings. A critical aspect of uncertainty evaluation is the application of sensitivity coefficients (Ci). Since all input quantities or uncertainty contributors are expressed in the same unit, the Ci of 1 can be applied, ensuring that the calculation of uncertainty remains unaffected by unit conversion factors or scaling.

The Uc(E) is a widely utilized metric for quantifying measurement uncertainty. However, it is often necessary to report an expanded uncertainty, U(E), which defines an interval around the measurement result that encompasses a substantial portion of the distribution of values reasonably attributable to the measurand. The determination of U(E) constitutes the final step in the measurement uncertainty estimation process. To calculate U(E), the Uc(E) is multiplied by a coverage factor, *k*. In this study, *k* corresponds to an interval with a confidence level of approximately 95%, derived using the T-value of the student's t-distribution, which accounts for the associated probability and the effective degrees of freedom. The value of *k* is estimated to be 2. Consequently, the expanded uncertainty, U(E), can be determined by multiplying Uc(E) by *k*, as expressed in Equation 4.

$$\mathrm{U(E)} = \mathrm{Uc(E)} \cdot \mathrm{k} \quad (4)$$

In the validation process of the MEDs, the accuracy of delivered energy is evaluated by integrating the absolute error value at a 5-joule setting and the % relative error values at settings of 50, 100, 150, and 200 joules, in conjunction with the U(E). Therefore, the acceptable accuracy of delivered energy for MEDs must fall within the specified tolerance limits established for each brand and model, taking into account variations in load impedance. A summary of these tolerance limits is presented in Table 1.

To assess the performance of the test battery, the battery was subjected to a continuous cycle of charging and discharging, repeated 10 times. The final value, obtained by averaging the results of 3 independent experiments, was recorded as the test time ($T_{measured}$). According to the specified criteria (ECRI-Procedure-Number 408-20210319), a standard charging time (T_{std}) for the tenth cycle was not to exceed 10

seconds in this research. The time deviation for each model is quantified by calculating the difference between the $T_{measured}$ and T_{std}, as mathematically formulated in Equation 5.

$$\text{Time Deviation} = T_{measured} - T_{std} \quad (5)$$

To evaluate charging efficiency, 3 synchronized tests were conducted. The average values for the measured test time ($T_{measured}$) were obtained. The time deviation in the synchronized mode for each model was subsequently determined by comparing $T_{measured}$ with the standard time (T_{std}) of 60 milliseconds, as specified in the criteria (IEC 60601-2-4: 2010 (201.104) and ECRI-Procedure-Number 408-20210319). This calculation was performed using Equation 4.

In this study, the collected data regarding charging time and synchronized time were visually represented using box plot charts. The box plot charts are particularly valuable for conducting visual comparisons of data distributions across different groups or populations. They also facilitate the identification of outliers and the assessment of data distribution.

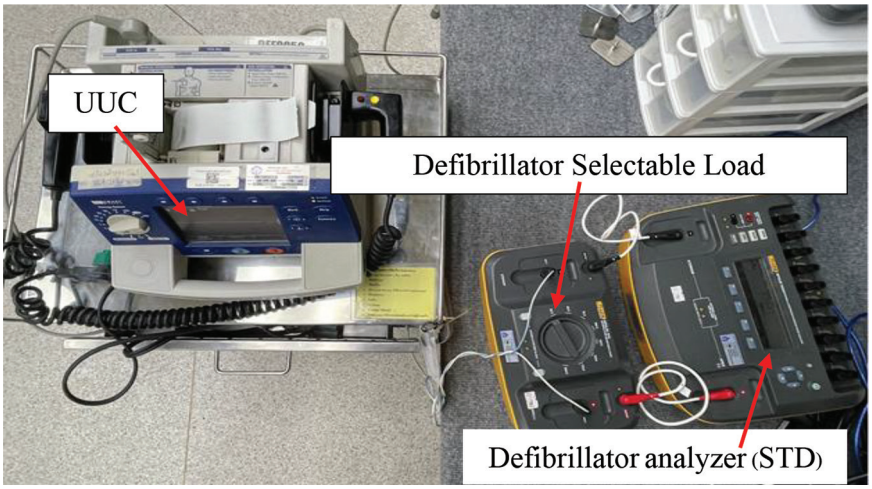
Experimental setup

This investigation into defibrillator accuracy included the measurement of delivered energy via the UUC, as assessed by the defibrillator analyzer (Fluke Biomedical, Impulse 7000DP Defibrillator Analyzer and Pacemaker Tester) with the first-class measurement accuracy ±1% of reading +0.1 joules. The analyzer was linked to the defibrillator's selectable load accessory (Fluke Biomedical, Impulse 7010 Defibrillator Selectable Load Accessory), as illustrated in Figure 1.

The measurements were conducted within the controlled environment of a calibration room (ISO/IEC 17025:2017, Accreditation No. Calibration 0433) situated at the MEMC, Songklanagarind Hospital. The calibration environment was implemented to maintain a consistent temperature of 25±2 °C and a relative humidity (RH) of 50±10%, ensuring optimal conditions for accurate measurements.

Table 1 A compaative analysis of defibrillator nominal delivered energy with variations in load impedance and tolerance

Brands	Models	Setting Energy (Joules)	Nominal delivered energy (Joules)					Tolerance
			Load resistance (Ohm)					
			25	50	100	125	150	
AA	A1	5	4.3	5.0	5.4	5.5	5.6	±1J
		50	43.0	50.0	54.0	550	56.0	±10%
		100	87.0	100.0	108.0	111.0.	111.0	±10%
		150	130.0	150.0	162.0	166.0	167.0	±10%
		200	173.0	200.0	216.0	222.0	223.0	±10%
	A2	5	4.7	5.0	5.4	5.4	5.2	±2J
		50	46.7	50.0	52.3	53.5	52.1	±15%
		100	93.5	100.0.	104.7	107.2	104.4	±15%
		150	140.3	1500	156.8	161.0	156.5	±15%
		200	187.0	200.0	209.3	214.6	208.6	±15%
BB	B1	5	3.0	5.0	6.0	6.0	6.0	±3J
		50	35.0	54.0	61.0	62.0	61.0	±15%
		100	71.0	109.0	122.0	125.0	123.0	±15%
		150	107.0	164.0	183.0	188.0	184.0	±15%
		200	142.0.	230.0	253.0	269.0	261.0	±15%



The UUC refers to unit under calibration and the STD refers to defibrillator analyzer (standard device)

Figure 1 Diagram of the calibration setup utilized for measuring defibrillator performance

Results and Discussion

The accuracy study of delivered energy

The findings of this study on the accuracy of delivered energy by the MEDs were presented through the integration of the absolute error at a 5-joule setting and the %relative error at 50, 100, 150, and 200 joules, in conjunction with the U(E). These measurements were evaluated against the specified tolerance limits defined for each brand and model, taking into account variations in load impedance.

At a 5-joule setting, the accuracy of delivered energy, represented by the mean of the absolute error combined with the U(E), varied among the tested brands. Brand A1 demonstrated an accuracy range of 0.2 to 0.3 joules, as shown in Figure 2A, while Brand A2 exhibited a range of 0.3 to 0.4 joules, as illustrated in Figure 2B. Brand B1 displayed a broader range of 0.4 to 0.6 joules, as depicted in Figure 2C. Notably, Brands A1, A2, and B1 exhibited consistent performance, with similar accuracy values across varying load resistances. There were no obvious trends indicating that accuracy values either increased or decreased with changes in resistance. This analysis suggests that the combined absolute error and the U(E) were not correlated with resistance variations, highlighting the stability of these devices under different load conditions. In the validation process of the MEDs, the acceptable accuracy of delivered energy for brands A1, A2, and B1, as determined by combining the absolute error value with the U(E) and represented by standard deviation bars, remained within the specified tolerance limits of ±1, ±2, and ±3 joules for brands A1, A2, and B1, respectively.

The accuracy of delivered energy, as assessed through the %relative error combined with the U(E), demonstrated variability across the tested brands. Brand A1 exhibited a slight increase in %relative error combined with the U(E) across varying resistance values, with recorded ranges of 4.4% to 5.0%, 4.8% to 5.2%, 4.4% to 5.1%, and 4.3% to 5.0% for energy settings of 50, 100, 150, and 200 joules, respectively, as shown in Figure 2A. In contrast, Brand A2 displayed a decreasing trend in %relative error combined with the U(E) as resistance values increased, with ranges of 4.4% to 3.6%, 4.9% to 3.9%, 5.0% to 4.0%, and 5.1% to 4.2% for the same energy settings, as illustrated

in Figure 2B. Brand B1, however, exhibited more variability in %relative error combined with U(E) across resistance levels, with recorded ranges of 5.1% to 7.4%, 4.7% to 3.8%, 4.0% to 3.7%, and 4.3% to 3.7% for energy settings of 50, 100, 150, and 200 joules, respectively, as shown in Figure 2C. Notably, all 3 brands—A1, A2, and B1—demonstrated consistent performance at the 5-joule setting, with similar accuracy values across varying load resistances. This observation suggests that the combined %relative error and U(E) were not significantly correlated with changes in load resistance, indicating that these devices maintain stability and reliability under different operational conditions. Additionally, during the validation process of the MEDs, the acceptable accuracy of delivered energy, determined by the %relative error and U(E) combined with standard deviation bars, remained within the specified tolerance limits of ±10%, ±15%, and ±15% for brands A1, A2, and B1, respectively. These results affirm the devices' compliance with established accuracy criteria, reinforcing their suitability for practical applications.

The analysis evaluated 3 brands—A1, A2, and B1—each characterized by distinct error margins. The accuracy of delivered energy was determined through the integration of absolute error and %relative error, combined with the U(E). The findings demonstrate that the accuracy of delivered energy by the MEDs is robust, maintaining consistent energy delivery despite variations in load impedance. This consistency emphasises their reliability for practical applications. Moreover, the results suggest that MEDs are well-suited for diverse operational environments, ensuring stable performance and energy efficiency across a range of conditions.

The accuracy study of charge time

One of the primary considerations regarding the charging time of MEDs is ensuring their complete readiness for immediate use in critical situations. These defibrillators typically offer adjustable energy settings, with the charging time corresponding to the selected energy level for defibrillation. Notably, recent technological advancements have enabled the majority of commercially available defibrillators to achieve a full battery charge[3,11,12], enabling rapid charging to 200 joules in manual mode.

In order to evaluate the precision of each brand's defibrillators, a comprehensive study was undertaken to scrutinize their respective charging durations. The box plot graph was employed for the analysis of the time deviation in charging energy. The minimum value of the time deviation indicates a longer charging duration, while the maximum value of the time deviation signifies a shorter charging period. The findings disclosed that the maximum charging power was -3.4 seconds (B1) and -7.5 seconds (A2), respectively. As a result, brand A2 demonstrated a more rapid charging duration in comparison to A1 and B1, as depicted in Figure 3. This data provides a comparative analysis of these brands under the same conditions. The results are significant in understanding the performance and reliability of these brands in terms of charge deviation over time. Moreover, A2 represents both the average and median values of the charging time, signifying the discrepancy between the actual measurement time and the specified time. These values are approximately -7.3 and -7.2 seconds respectively, thereby indicating that every B2 brand tested exhibits a prolonged charging duration, with no outlier values deviating from the majority of the data. Consequently, the median value is closely aligned with the mean value. Hence, the mean value can be considered as a representative charging time value for all devices. Despite the varying charging durations among the 3 brands, they all meet the acceptable performance requirements, fulfilling 100% of the established criteria. Extensive research has revealed that the average charging time for defibrillators varies significantly based on the particular model employed. Specific models have demonstrated charging

durations as short as 5 seconds, whereas others require intervals extending up to 10 seconds[13]. Furthermore, a comprehensive examination exploring the implications of charge time revealed a consistent survival rate among patients subjected to defibrillation between 5 and 10 seconds after device activation[14].

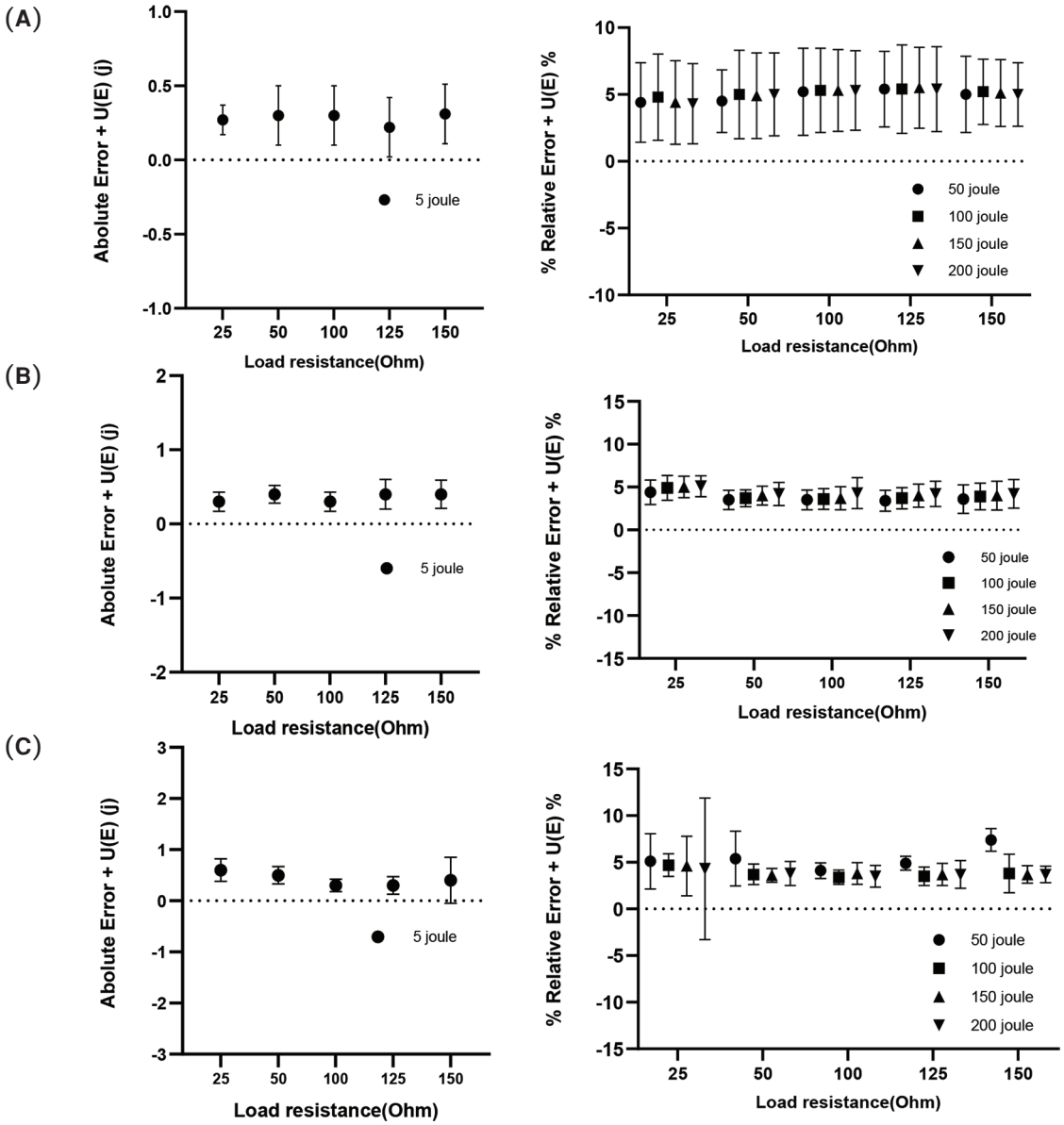


Figure 2 Illustration of delivered energy accuracy, combining the absolute error value at a 5-joule setting and the %relative error values at 50, 100, 150, and 200 joules, presented alongside the expanded uncertainty (U(E)) with standard deviation bars. The analysis is categorized by the following brands and models: (A) Brand A, Model A1; (B) Brand A, Model A2; and (C) Brand B, Model B1

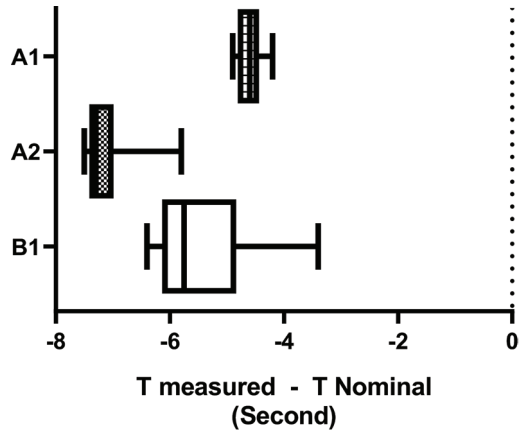


Figure 3 Illustration of the time deviation values for charge time across defibrillator models A1, A2, and B1

The accuracy study of synchronized time

In a defibrillator, synchronization accuracy is a crucial feature of the system. This is because the device operates synchronously, administering an electrical shock during the QRS complex. The QRS complex is a cardiac phase characterized by the heart muscle's increased susceptibility to defibrillation. This synchronized timing, termed the R-wave delay, refers to the interval between the shock's initiation and the end of the R-wave. Precisely timing the shock delivery within the cardiac cycle is imperative, necessitating the device's prompt activation within a predetermined time frame following the detection of the R-wave signal. According to established guidelines, the discharge should occur within 60 milliseconds of the R-wave's identification[15].

The synchronization time test was performed to assess the precision of defibrillators from 3 distinct brands, namely A1, A2 and B1. The box plot graph was utilized to illustrate the deviation in time, as shown in Figure 4. The minimum charging times for brands A1, A2 and B1 were -33.7, -27.1 and -46.2 milliseconds, respectively. In contrast, the maximum charging times were -24.3 milliseconds for A2 and -50.7 milliseconds for B1. Subsequent statistical analyses were conducted to ascertain whether the synchronization time accuracy of the 3 brands fell within the acceptable range, thereby finding the 100% performance requirements.

In investigations relating to synchronized time, the study demonstrated that synchronized shocks consistently registered a peak of the R-wave within 35 milliseconds of each QRS complex. These findings emphasise the importance of precise synchronization timing in optimizing outcomes during defibrillation procedures, ultimately contributing to the preservation of lives in critical cardiac scenarios.

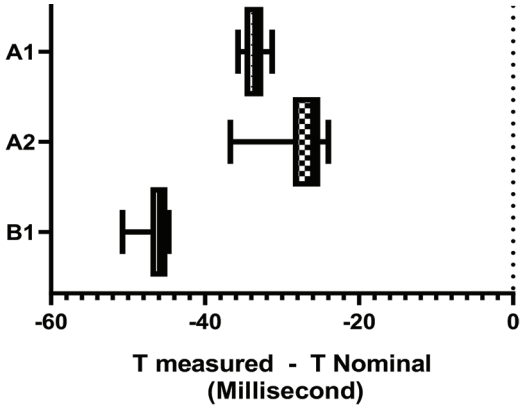


Figure 4 Illustration of the time deviation values during synchronized operation for defibrillator models A1, A2, and B1

To mitigate potential bias arising from the exclusion of defibrillators that fail to meet metrological requirements or require corrective maintenance, it is essential to examine the implications of such exclusions and adjust the analysis accordingly. Instead of excluding these devices, the analysis should incorporate failure rates, categorizing devices into

compliant and non-compliant groups. This approach allows for a comprehensive evaluation of how each group contributes to overall performance. Furthermore, determining the frequency of defibrillator calibrations is guided by established international standards and guidelines. These recommendations typically include daily functional checks, comprehensive testing every 6–12 months (depending on the manufacturer's instructions and usage intensity), and post-event inspections to ensure continued functionality after critical use. Standards such as the IEC 60601-2-4[9] and the European Resuscitation Council (ERC)[16] stress the necessity of routine testing and maintenance in order to guarantee device reliability in emergency situations. Despite the importance of regular calibration and maintenance, several challenges impede effective implementation. These challenges include variability in device designs across different manufacturers and models, a shortage of skilled personnel, and the financial burden associated with routine testing. Addressing these challenges requires the development of standardized maintenance protocols tailored to the specific needs of healthcare facilities, ensuring both the feasibility and consistency of maintenance practices.

Conclusion

This article provides a comprehensive summary of a study evaluating the accuracy of defibrillator performance in terms of delivered energy, charge time, and synchronized time across various MEDs. The analysis included brands A1, A2, and B1, each exhibiting distinct error margins. By integrating absolute error, %relative error, and the U(E), the study demonstrated that these devices maintain robust accuracy in delivered energy, ensuring consistent performance across varying load impedances. These findings underscore the stability, reliability, and suitability of MEDs for diverse operational environments, supporting their energy efficiency and functional reliability in practical applications. Furthermore, the study revealed that the time deviations for charge time did not exceed 10 seconds, conforming to accepted standards. Similarly, the time deviations in synchronized mode for all 3 defibrillator models remained well within the prescribed tolerance of 60 milliseconds. These results emphasize compliance with established benchmarks for performance.

The findings from the accuracy study of defibrillator performance at Songklanagarind Hospital highlight the importance of consistent monitoring and routine calibration to ensure the reliability of delivered energy, charge time, and synchronized time. Adherence to these standards enhances MED performance and strengthens preventive maintenance practices, ultimately contributing to improved patient safety and care quality.

Author Contributions

Dr. Mahdee Samae drafted the proposal, conducted experiments, contributed to conceptualization and methodology, performed statistical analyses, and interpreted the results. Asst. Prof. Dr. Theera Leeudomwong, Mr. Banyat Nualkaew, and Mr. Tassanai Sanponpute reviewed the proposal, interpreted certain results, provided critical feedback on the manuscript, and participated in its revision. All authors have read and approved the final manuscript.

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Conflict of interest

The authors declare no conflict of interest.

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