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Measurement Uncertainty in Defibrillator Performance Testing: A Metrological Approach to Patient Safety

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ABSTRACT: *This study aims to design a calibration procedure to measure defibrillator efficiency, analyze it using the uncertainty calculation method, and compare output efficiency across different medical institutions. Performance testing was conducted using a specified defibrillator analyzer, with readings for each parameter recorded ten times. These results were then subjected to uncertainty measurement by combining Type-A statistical evaluations and Type-B non-statistical evaluations to determine if the critical care equipment's efficiency performance was in good condition. The collected data was analyzed using independent and paired sample t-tests for intergroup and intragroup comparisons, alongside one-way ANOVA and non-parametric Kruskal-Wallis tests depending on data normality, with a significance level of 0.05.The study's sample included functioning defibrillators from TVETMARA Ledang, Hospital Tangkak, and Hospital Muar. Specifically, the tested models were the Schiller Defigard 5000, Philips Efficia DFM100, and Nihon Kohden TEC5521K. Connected to the analyzer, the devices were tested for energy efficiency (J) and charge time (s). The results indicated an average energy value of 150.54 J. Furthermore, the statistical analysis revealed that the Muar 3, Tangkak 1, and Tangkak 3 defibrillators exhibited a significant difference in output efficiency between medical institutions when compared to the other defibrillators tested.*

Keywords: *defibrillator; measurement uncertainty; performance testing; calibration procedure; energy efficiency*

I. INTRODUCTION

The human heart functions as a vital circulatory pump, carefully regulated by intrinsic electrical activity originating at the sinoatrial node, which coordinates rhythmic cardiac contractions (Fish & Geddes, 2009). When these internal electrical pathways malfunction, patients can suffer from life-threatening cardiac arrhythmias, most notably ventricular tachycardia (VT) and ventricular fibrillation (VF) (Iaizzo, 2015). During these severe episodes, the heart's chambers beat erratically and fail to pump a sufficient volume of blood, a critical condition that contributes to approximately 135,000 deaths worldwide each year (Shao et al., 2016). For patients experiencing VF or pulseless VT, the only proven and effective medical intervention is early defibrillation.

Defibrillators are essential life-saving devices designed to deliver a controlled, therapeutic wave of electrical pulse energy directly to the patient's myocardium (Braga & Cooper, 2015). This electrical shock forces a synchronized depolarization of the cardiac muscle, ending the arrhythmia and allowing the heart to re-establish a normal sinus rhythm. Human tissue is highly sensitive to electrical currents where excessive or

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improper discharges can cause electrolysis, severe tissue burns, respiratory arrest, or even total cardiac arrest which is the absolute accuracy of a defibrillator's energy output is of paramount importance. Consequently, medical institutions utilize dedicated defibrillator analyzers to rigorously verify the exact energy content of the discharge pulse, ensuring it aligns perfectly with the clinical settings required for safe patient resuscitation (Rao & Guha, 2001).

However, securing the ongoing metrological reliability of these high-risk devices presents a significant challenge in modern clinical engineering. The primary problem lies in the fact that while the basic safety and physical performance of defibrillators are frequently evaluated during routine preventive maintenance, their true energy output efficiency is often not strictly maintained or rigorously validated over time (Golpaygani et al., 2019). Testing and calibrating medical instruments is a critical necessity to guarantee that the precision and accuracy of their measurements remain constant (Thongpance et al., 2017). If a defibrillator delivers a shock that deviates from the expected therapeutic threshold, it can result in fatal consequences in the emergency department or intensive care unit.

To overcome this diagnostic gap, the implementation of measurement uncertainty provides a robust metrological solution to quantify a defibrillator's true operational efficiency (Filho et al., 2015). Measurement uncertainty characterizes the dispersion of values that can be reasonably attributed to a measurement, offering a concrete level of confidence in the device's analytical precision (JGCM, 2008). By incorporating uncertainty calculations by combining statistical Type-A evaluations and non-statistical Type-B evaluations for biomedical engineers can accurately determine the acceptable range of energy output, allowing them to correct systematic errors and calibrate devices properly before clinical use. Understanding the critical need to eliminate diagnostic misreads and prevent equipment malfunctions, this research aims to optimize how high-risk cardiac devices are assessed. The aims of this study were to design a calibration procedure to measure the efficiency of the defibrillator, to analyze the energy efficiency of the defibrillator using the uncertainty calculation method, and to compare the output efficiency of defibrillators at different medical institutions.

II. METHODOLOGY

This study employs a cross-sectional experimental research design aimed at establishing a precise calibration procedure to measure and compare the energy efficiency of critical care equipment. The primary device under test (DUT) is the defibrillator, a high-risk medical device utilized in critical care units. The sampling framework employed a purposive strategy, selecting equipment from three distinct medical and educational institutions: TVETMARA Ledang, Hospital Muar, and Hospital Tangkak. To ensure comparative reliability, three different defibrillator models were selected: the Schiller Defigard 5000 (TVETMARA Ledang), the Philips Efficia DFM 100 (Hospital Muar), and the Nihon Kohden TEC 5521K (Hospital Tangkak). The inclusion criteria strictly dictated that all selected equipment must be actively functioning and in excellent working order. Any critical care equipment of different models, as well as devices that were no longer functional or lacked proper preventive maintenance, were excluded from the scope of this investigation.

The performance testing and data acquisition were conducted using a highly specialized defibrillator analyzer, specifically the Datrend PHASE 3 Defibrillator/Pacer Analyzer. This analyzer was explicitly chosen because it is designed to evaluate monophasic, biphasic, and pulsed multiphasic defibrillators, boasting an inherent measurement accuracy of 1 percent. The analyzer was physically connected to the DUT via external paddle plates, enabling hands-free, and high-precision testing. The evaluation focused on two primary operational parameters: the actual energy output measured in J (J) and the device’s charge time measured in seconds (s). To simulate various clinical intervention scenarios, the defibrillators were tested across a spectrum of energy settings, including 8, 10, 20, 30, 50, 90, 100, 150, 200, and up to 270 J, depending on the specific model's maximum capacity. To guarantee statistical validity, the testing procedure was designed so that the reading for each individual parameter and energy setting was recorded ten consecutive times.

A core element of this methodology is the application of measurement uncertainty, which acts as a stringent gauge for quantifying whether the medical equipment's performance falls within a safe, acceptable clinical range. A measurement result is achieved by approximating specific quantities subjected to two distinct

types of uncertainty evaluations: statistical methods (Type-A) and non-statistical means (Type-B). Type-A standard uncertainty (Ur) is determined by calculating the standard deviation of the ten repeated measurements for each energy setting, capturing the random uncertainty inherent in repeated clinical discharges.

$$Ur = \frac{\sigma}{\sqrt{N}}$$

where Ur = random uncertainty, σ = standard deviation, N = number of measurement

Conversely, Type-B standard uncertainty (Ub) evaluates variance utilizing existing data, such as manufacturer-published device specifications and master calibration certificates. Assuming a rectangular distribution, the Type-B component is subdivided into three specific categories: the innate uncertainty of the Datrend master analyzer (Ub1), the calculated uncertainty due to the specific defibrillator's accuracy (Ub2), and the uncertainty generated by the resolution limits of the Equipment under Test (Ub3).

$$Ub = \frac{a}{\sqrt{\ni}}$$

where a = semi range or half range between the upper and lower limits, and ∋ = standard uncertainty for Type B evaluation.

These individual variances are then synthesized using the Root Sum Square technique to calculate the Combined Standard Uncertainty (Uc), using the formula:

$$Uc = \sqrt{Ur^2 + Ub1^2 + Ub2^2 + Ub3^2}$$

where
Uc: Standard Uncertainty,
Ub1: Uncertainty of master equipment,
Ub2: Uncertainty due to accuracy,
Ub3: Uncertainty due to resolution

Finally, to provide an actionable metric for clinical engineers, an Expanded Uncertainty (U) is derived by multiplying Uc by a coverage factor (k=1.960), which provides a highly reliable 95% level of confidence regarding the true dispersion of the defibrillator's energy output.

$$Veff = \frac{Uc^4}{\frac{Ur^4}{V1} + \frac{Ub1^4}{V2} + \frac{Ub2^4}{V3} + \frac{Ub3^4}{V4}}$$

where
V1- degress of freedom for Type A evaluation
V2, V3, V4 - Degrees of Freedom for Type B evaluation.

$$U = k * Uc$$

$$X = x \pm U$$

where X: Measurand, x – True value, U – Expanded Uncertainty

Following the mathematical calculation of uncertainty, the resulting data was subjected to rigorous statistical analysis using Statistical Package for the Social Sciences (SPSS) version 17.0 software. Intergroup statistical comparisons which aimed at identifying variances in output efficiency across the different medical institutions which were conducted utilizing independent samples t-tests. Intragroup variables were analyzed using paired samples t-tests. Furthermore, a one-way Analysis of Variance (ANOVA) was utilized to analyze normally distributed data across the multiple institutions, whereas the non-parametric Kruskal-Wallis test was employed for any non-normal data sets. The significance level utilized across all statistical tests in this investigation was established at 0.05.

III. RESULT

A total of nine functioning defibrillator units were evaluated across three different medical and educational institutions around Muar district. The analyzed sample consisted of one Schiller Defigard 5000 unit from TVETMARA Ledang, five Philips Efficia DFM 100 units from Hospital Pakar Sultanah Fatimah (Hospital Muar), and three Nihon Kohden TEC 5521K units from Hospital Tangkak as showed in Table 1. Descriptive statistics obtained from the ten repeated measurements at various energy settings (ranging from 8 J to 270 J) revealed specific functional consistencies. For instance, at a low-energy setting of 10 J, the Tangkak 3 unit recorded the lowest standard deviation (SD) of 0.00632, demonstrating high precision, whereas the Tangkak 2 unit displayed the highest variance with an SD of 0.15951.

Table 1: Demographic of defibrillators used in Muar district

Identity	Medical Institution	Brand	Model	Serial no.	Location
L1	TVETMARA Ledang	Schiller	Defigard 5000	101991006257	Life Support Lab
M1	Hospital Pakar Sultanah Fatimah	Philips	Efficia DFM 100	CN32600578	Ward 4
M2	Hospital Pakar Sultanah Fatimah	Philips	Efficia DFM 100	CN32604354	Ward 18
M3	Hospital Pakar Sultanah Fatimah	Philips	Efficia DFM 100	CN326043144	Ward 16
M4	Hospital Pakar Sultanah Fatimah	Philips	Efficia DFM 100	CN32600577	ICU
M5	Hospital Pakar Sultanah Fatimah	Philips	Efficia DFM 100	CN32629301	ICU
T1	Hospital Tangkak	Nihon Kohden	TEC 5521K	09289	Ward 3
T2	Hospital Tangkak	Nihon Kohden	TEC 5521K	09287	Ward 2
T3	Hospital Tangkak	Nihon Kohden	TEC 5521K	01592	Ward 4

Analysis of discharge time and equipment responsiveness because defibrillators are critical life-support devices utilized in time-sensitive emergency scenarios, the duration required for the equipment to fully charge and discharge is a vital determinant of its clinical effectiveness as showed in Table 2. Discharge time testing was performed on all units at their respective maximum energy capacities 200 J for the TVETMARA Ledang and Hospital Muar units, and 270 J for the Hospital Tangkak units. The analysis identified the Hospital Tangkak 3 defibrillator as the most responsive, registering the fastest mean discharge time of just 5.077 seconds. Conversely, the TVETMARA Ledang 1 defibrillator recorded the slowest mean discharge time at 9.213 seconds. These findings indicate a notable variance in operational readiness depending on the age, make, and maintenance status of the specific equipment.

Table 2: Descriptive statistics of defibrillator discharge time

Defibrillator	Maximum Energy Level (J)	Minimum (s)	Maximum (s)	Mean (s)	Std. Deviation
TVETMARA Ledang 1	200	8.77	9.59	9.2130	.23027
Hospital Muar 1	200	6.42	6.58	6.4990	.04654
Hospital Muar 2	200	6.21	6.49	6,3200	.08628
Hospital Muar 3	200	5.98	6.52	6.3000	.18756
Hospital Muar 4	200	6.08	6.54	6.3330	.15093
Hospital Muar 5	200	6.21	7.09	6.5620	.34855
Hospital Tangkak 1	270	4.96	5.30	5.1420	.09508
Hospital Tangkak 2	270	4.69	5.36	5.1440	.21355
Hospital Tangkak 3	270	4.91	5.41	5,0770	.15992

To fulfill the core objective of analyzing true energy efficiency, uncertainty calculation methods were applied to evaluate measurements at a standard therapeutic threshold of 150 J, as well as at each unit's maximum capacity as showed in Table 3. The Expanded Uncertainty (U) incorporates both random statistical uncertainty (Type-A) and non-statistical variances such as equipment accuracy and analyzer resolution (Type-B). The data revealed that the Hospital Muar 2 defibrillator demonstrated the most reliable metrological performance.

At 150 J, it recorded the lowest Expanded Uncertainty of 17.122 J, establishing a 95% confidence interval that the true energy output lies between 133.418 J and 167.662 J. At its 200 J maximum, its uncertainty remained the lowest at 22.124 J. Conversely, the TVETMARA Ledang 1 defibrillator exhibited the highest degree of output uncertainty. At 150 J, its Expanded Uncertainty was calculated at 25.579 J (a range of 118.741 J to 169.899 J), and this uncertainty scaled up to 34.052 J when operating at its 200 J maximum capacity. These uncertainty budgets successfully established quantitative boundaries that define the acceptable operational range for each specific device.

Table 3: Uncertainty budget table defibrillator TVETMARA Ledang 1 with test value 150 J and 200 J

Type of uncertainty	Uncertainty source		Probability Distribution		Uncertainty Contribution		DOF (degree of freedom)	
	150 J	200 J	150 J	200 J	150 J	200 J	150 J	200 J
Ur (random uncertainty)	-	-	Normal	Normal	0.0059255	0.17075	9	9
Ub1 (defib analyzer uncertainty)	1.8	1.8	Normal	Normal	0.9	0.9	∞	∞
Ub2 (uncertainty due to accuracy)	22.55	30.05	Rectangular	Rectangular	13.0915	17	∞	∞
Ub3 (uncertainty due to EUT resolution)	0.05	0.05	Rectangular	Rectangular	0.028868	0.028868	∞	∞
Combined uncertainty Uc =	150 J	13.05049						
	200J	17.3736						
Effective degrees of freedom Veff=	150 J	∞						
	200J	∞						
Expanded uncertainty U=	150 J	25.5789604						
	200J	34.05226						

To ascertain whether the uncertainty calculation method highlighted significant deviations from conventional expected outputs, a One-Sample T-Test was conducted with the test value standardized at 150 J (the baseline energy achievable by all nine devices) as showed in Table 4. The TVETMARA Ledang 1 unit showed the most substantial negative mean difference (-5.6800), meaning it systematically under-delivered energy compared to the 150 J target. The Muar 2 unit showed the highest positive mean difference (+0.5400). Only the Hospital Muar 3 unit displaying no statistically significant deviation (p=0.541) from the targeted norm.

Table 4: One sample t-test with test value 150 J

Defibrillator	t	p-value	Mean Difference	95% Confidence Interval of the Difference	
				Lower	Upper
TVETMARA Ledang 1	-95.857	.000	-5.68000	-5.8140	-5.5460
Hospital Muar 1	-15.570	.000	-.87000	-.9964	-.7436
Hospital Muar 2	14.548	.000	.54000	.4560	.6240
Hospital Muar 3	.635	.541	.03000	-.0769	.1369
Hospital Muar 4	10.585	.000	.19000	.1494	.2306
Hospital Muar 5	6.194	.000	.18000	.1143	.2457
Hospital Tangkak 1	-3.801	.004	-2.16000	-3.4455	-.8745
Hospital Tangkak 2	-13.301	.000	-1.65000	-1.9306	-1.3694
Hospital Tangkak 3	-21.938	.000	-2.74000	-3.0225	-2.4575

Finally, to assess output efficiency discrepancies strictly between the different medical institutions, a One-Way ANOVA was utilized at the 150 J setting as showed in Table 5. The results exhibited statistically significant differences ($p<0.05$) in their output efficiency when compared across institutional lines. The Tangkak 1 defibrillator, in particular, displayed the highest variance between groups (Sum of Squares: 27.205), indicating that institutional protocols, varying device models, and localized maintenance environments actively contribute to distinct discrepancies in the energy delivery performance of critical cardiac equipment.

Table 5: One way ANOVA with test value 150 J

Defibrillator		Sum of Squares	Mean Square	F	p- value
Hospital Muar 1	Between Groups	0.123	0.061	2.725	0.133
	Within Groups	0.158	0.023	-	-
	Total	0.281	-	-	-
Hospital Muar 2	Between Groups	0.006	0.003	0.178	0.841
	Within Groups	0.118	0.017	-	-
	Total	0.124	-	-	-
Hospital Muar 3	Between Groups	0.139	0.069	7.847	0.016
	Within Groups	0.062	0.009	-	-
	Total	0.201	-	-	-
Hospital Muar 4	Between Groups	0.002	0.001	0.191	0.830
	Within Groups	0.028	0.004	-	-
	Total	0.029	-	-	-
Hospital Muar 5	Between Groups	0.006	0.003	0.300	0.750
	Within Groups	0.070	0.10	-	-
	Total	0.076	-	-	-
Hospital Tangkak 1	Between Groups	27.205	13.602	51.205	0.000
	Within Groups	1.859	0.266	-	-
	Total	29.064	-	-	-
Hospital Tangkak 2	Between Groups	0.329	0.165	1.093	0.386
	Within Groups	1.055	0.151	-	-
	Total	1.385	-	-	-
Hospital Tangkak 3	Between Groups	0.912	0.456	6.488	0.025
	Within Groups	0.492	0.070	-	-
	Total	1.404	-	-	-
TVETMARA Ledang 1	Between Groups	0.076	0.038	1.118	0.379
	Within Groups	0.240	0.034	-	-
	Total	0.316	-	-	-

IV. DISCUSSION

The primary goal of this research was to establish a robust calibration procedure, apply measurement uncertainty to analyze defibrillator energy efficiency, and compare outputs across different medical institutions. Defibrillation involves applying a therapeutic dose of electrical energy to an injured heart, making the reliable performance of these devices an absolute necessity in emergency and intensive care units (ICUs). Previous research by Filho et al. (2015) and Golpaygani et al. (2017) demonstrated the importance of evaluating delivered energy against manufacturer tolerance limits using specialized biomedical analyzers. Additionally, works by Shao et al. (2016) and Vijay et al. (2014) emphasized the necessity of traceable calibration systems and the inclusion of variables like calibrator accuracy and data resolution when verifying critical care parameters. Building upon these methodologies, this study utilized a Datrend Phase 3 Defibrillator Analyzer to assess three distinct models such as the Schiller Defigard 5000, Philips Efficia DFM 100, and Nihon Kohden TEC-5521K across three medical institutions. Ten repeated measurements were recorded at varying energy levels up to 270 J to ensure the statistical reliability required for an advanced calibration procedure.

A pivotal aspect of this study is the application of the measurement uncertainty method to determine true energy efficiency. Measurement uncertainty quantifies the inherent doubt regarding the validity of a measurement's result, characterizing the dispersion of values that can properly be attributed to the measurand. Instead of relying solely on conventional average output readings, this rigorous metrological approach combines statistical Type-A evaluations (random uncertainty, Ur, derived from the standard deviation of repeated measurements) with non-statistical Type-B standard uncertainties. In this study, Type-B contributions were meticulously synthesized, encompassing the intrinsic uncertainty of the Datrend master analyzer (Ub1, determined to be 1.8 J based on its calibration certificate), the uncertainty generated by the specific defibrillator's accuracy specifications (Ub2, varying from 10% to 15% depending on the manufacturer), and the uncertainty due to the equipment's inherent resolution (Ub3).

By calculating the expanded uncertainty (U) which utilizes a coverage factor to represent a 95% confidence interval where the study established highly precise acceptable operating boundaries for each specific device. For instance, while prior research by Thongpance (2017) noted an average tested energy of 152.04 J, this study recorded an average overall output of 150.54 J. More importantly, the uncertainty analysis revealed that the Philips Efficia DFM 100 located in Hospital Muar (Muar 2) demonstrated the highest metrological reliability, recording the lowest expanded uncertainty value of ±17.122 J at the 150 J setting, and ±22.124 J at its 200 J maximum capacity. Conversely, the Schiller Defigard 5000 (TVETMARA Ledang 1) exhibited the highest measurement uncertainty, reaching ±25.579 J at 150 J and ±34.052 J at 200 J. Quantifying this precise uncertainty budget is a critical clinical safeguard; it sets definitive boundaries for an acceptable energy range, proving a device's true energy efficiency and ensuring that the prescribed therapeutic shock will effectively stabilize arrhythmias without causing unintended harm to the myocardium.

Beyond individual device performance, the study highlighted vital statistical discrepancies in output efficiency across different medical institutions. Utilizing a one sample t-test standardized at the 150 J threshold, the analysis revealed significant statistical deviations for the majority of the tested devices when compared to conventional expected outputs except one (Muar 3). Furthermore, one-way ANOVA testing corroborated that specific units which namely the Muar 3 (Philips Efficia DFM 100), Tangkak 1, and Tangkak 3 (Nihon Kohden TEC 5521K) exhibited statistically significant differences in energy output efficiency strictly between the institutions. These cross-institutional variances can be attributed to several practical factors, including differences in intrinsic defibrillator brands, varying device age, and differing localized preventive maintenance and calibration protocols between the hospitals. Ultimately, these findings strongly advocate for the integration of rigorous measurement uncertainty calculations into standard biomedical safety and performance testing. Relying solely on conventional average readings is scientifically insufficient for high-risk critical care equipment. Determining the expanded uncertainty provides biomedical engineers with the concrete, metrological data necessary to calibrate these life-saving devices accurately, thereby reducing systematic errors and guaranteeing clinical dependability in the emergency department.

V. CONCLUSION

In conclusion, this study successfully achieved its primary objectives by designing a comprehensive calibration procedure and effectively applying the measurement uncertainty method to assess defibrillator energy efficiency. Defibrillators are essential life-saving devices, and any metrological ineffectiveness or deviation in their output can result in serious patient injury or death in the emergency department. The findings of this research conclusively demonstrate that relying on conventional average readings is insufficient for verifying the safety of high-risk medical equipment. The statistical analysis proved that there is a significant difference in energy efficiency evaluation when the metrological uncertainty approach is utilized instead of conventional methods. Through this rigorous calculation, the study successfully defined the acceptable operational boundaries for each device. Notably, the Philips Efficia DFM 100 (Muar 2) demonstrated the highest metrological reliability with the lowest expanded uncertainty, whereas the Schiller Defigard 5000 (TVETMARA Ledang 1) recorded the highest energy uncertainty. Furthermore, the investigation highlighted vital discrepancies in equipment performance depending on its location. The specific devices like Muar 3, Tangkak 1, and Tangkak 3 units confirms that there is a statistically significant difference in the output efficiency of defibrillators across different medical institutions. This underscores the critical need for standardized, stringent calibration protocols across all hospital environments.

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