



Review of Defibrillator Efficacy and Patient Safety

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ABSTRACT: Defibrillators are indispensable life-saving devices engineered to deliver a precise, therapeutic electrical shock to patients suffering from fatal cardiac arrhythmias, such as ventricular fibrillation and ventricular tachycardia. While these high-risk medical devices are essential for restoring normal sinus rhythm by delivering energy directly to the myocardium, an improperly calibrated shock presents severe multi-systemic hazards. The human body's extreme sensitivity to electrical currents means that inaccurate discharges can induce painful electrolysis, thermal tissue burns, and lethal respiratory or total cardiac arrest. Consequently, ensuring exact metrological reliability is a paramount clinical safety imperative. This comprehensive review bridges the physiological principles of cardiac resuscitation with the rigorous clinical engineering required for equipment performance testing. We evaluate the operational circuitry of modern defibrillators, including the transition from monophasic to biphasic waveforms, and systematically analyze recent advancements in metrological traceability. By synthesizing recent quality control audits and evaluating modern calibration methodologies specifically the implementation of digitally sampling analyzers and mathematical measurement uncertainty frameworks where this paper demonstrates that conventional preventive maintenance is inherently insufficient. We conclude that integrating standardized, traceable uncertainty budgets into routine biomedical testing is essential to prevent equipment malfunction and safeguard patients during critical resuscitation events.

Keywords: defibrillator; cardiac arrhythmia; metrological; performance testing; measurement uncertainty

I. INTRODUCTION

The human heart is a complex, vital muscle pump responsible for continuously circulating oxygen-rich blood and essential compounds throughout the body while simultaneously removing metabolic wastes (Weinhaus, 2005). This highly coordinated, rhythmic mechanical activity is intrinsically governed by the sinoatrial node (SAN), a specialized cluster of pacemaker cells located within the right atrium as showed in Figure 1. In a healthy individual, the SAN is uniquely capable of adjusting the heart rate in response to physiological demands, maintaining a normal sinus rhythm that typically ranges between 50 and 90 beats per minute (Fish & Geddes, 2009). However, when these intrinsic electrical pathways malfunction, patients can develop severe, life-threatening cardiac arrhythmias. Ventricular tachycardia (VT) occurs when the heart rate abnormally accelerates past 100 beats per minute, causing the heart's chambers to pump inefficiently because they lack sufficient time to adequately fill with blood (Othman et al., 2016). Collectively, these severe arrhythmic episodes contribute to approximately 300,000 fatalities globally each year (Faramarz & José, 2001).

Defibrillators are high-risk critical care devices engineered to deliver a precise, therapeutic wave of electrical pulse energy directly to the patient's myocardium (Mahmoodi, 2026; Rao, 2001). By charging a large

internal capacitor and discharging it via external paddles or remote pads, the device forces a synchronized depolarization of the cardiac muscle, effectively terminating the arrhythmia and allowing the heart to restore its natural automaticity. Despite their life-saving capabilities, the application of massive electrical currents to human tissue carries profound physiological hazards if the energy output is inaccurate.

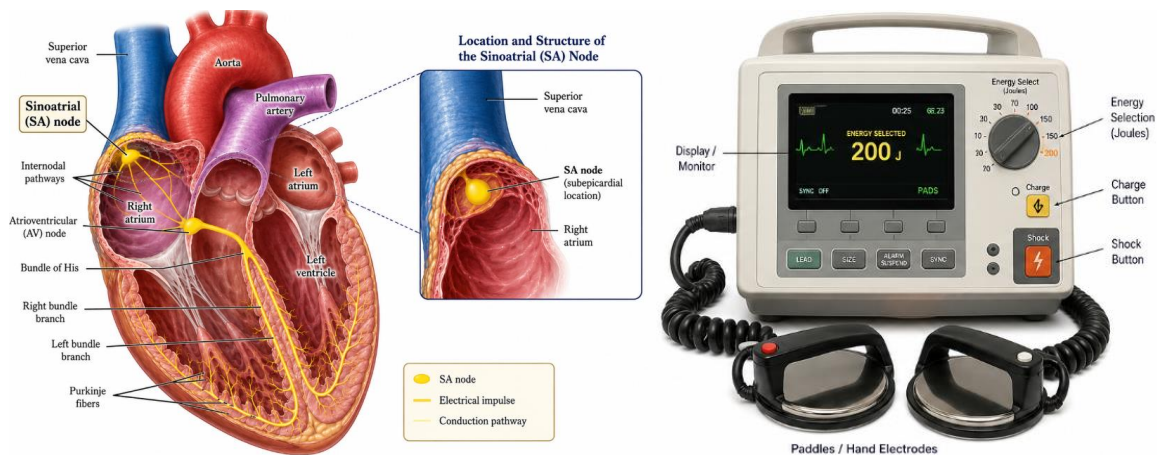


Figure 1: Sinoatrial node location (left) and conventional defibrillator (right)

Consequently, ensuring the precise metrological reliability of a defibrillator is a non-negotiable patient safety imperative. While modern healthcare facilities routinely evaluate basic device safety during standard preventive maintenance, the true energy output efficiency is frequently not rigorously validated against strict traceability standards over time. Therefore, there is an urgent need to bridge the gap between clinical application and rigorous metrological testing using advanced, highly accurate defibrillator analyzers (Golpaygani et al., 2017). This review paper aims to comprehensively explore this intersection, transitioning from the physiological principles of cardiac arrhythmias to a critical evaluation of modern defibrillator safety, equipment calibration methodologies, and the indispensable role of metrological traceability in preventing equipment malfunction during critical resuscitation events.

II. CARDIAC PHYSIOLOGY AND THE PATHOGENESIS OF ARRHYTHMIAS

The human heart is a vital organ of the circulatory system, anatomically situated in the middle mediastinum between the two lungs, featuring a left-angled apex (Shah et al., 2009). It functions as a highly efficient, involuntary muscle pump comprising four distinct interior chambers: the right and left atria, and the right and left ventricles. The structural integrity and mechanical force of the heart are maintained by three specialized tissue layers: the epicardium acts as a thin protective outer layer; the myocardium provides the powerful muscular force necessary to eject blood into the arteries; and the endocardium lining ensures the rapid and smooth flow of blood through the internal cavities (Weinhaus & Roberts, 2005).

This highly coordinated rhythmic mechanical activity is intrinsically regulated by the sinoatrial node (SAN), which serves as the heart's natural pacemaker (Iaizzo, 2015). Located in the right atrium, the SAN consists of specialized pacemaker cells capable of generating spontaneous electrical action potentials. These electrical impulses propagate through distinct conduction pathways by traveling from the SAN to the atrial tissue, and subsequently through the atrioventricular node (AVN), the Bundle of His, and the Purkinje fibers. This signal propagation results in the perfectly synchronized contraction and relaxation of the cardiac chambers, a cycle that dictates the heart rate and rhythm (Tripathi, 2011). The SAN is unique in its capacity to adapt the heart rate to physiological demands, maintaining a normal resting sinus rhythm of 50 to 90 beats per minute in a healthy adult (Kalyanasundaram et al., 2023; Iaizzo, 2015).

However, when these intrinsic electrophysiological pathways malfunction, patients can develop severe cardiac arrhythmias. Ventricular tachycardia (VT) is a critical arrhythmia frequently observed in individuals with structural heart disease and heart failure (Tang et al., 2018). VT occurs when the heart rate

abnormally accelerates beyond 100 beats per minute. During a VT episode, the rapid firing of the ventricles severely limits the time available for the chambers to adequately fill with blood, resulting in vastly insufficient cardiac output to the lungs and body. Identified on an electrocardiogram (ECG) by a broad QRS complex, VT can quickly degenerate into sudden cardiac arrest, a potentially fatal medical emergency. A more extreme and consistently lethal progression of this electrical dysfunction is ventricular fibrillation (VF) as showed in Figure 2. VF is characterized by highly erratic, uncoordinated contractions of the ventricular myocardium (Othman et al., 2016). Instead of producing a forceful, synchronized pump, the ventricles essentially quiver, leading to an immediate cessation of effective blood circulation and profoundly impaired cardiac pump performance. The ECG waveform during VF is entirely chaotic, marked by uneven amplitudes, rates, and shapes (Imnadze, 2019). Globally, sudden arrhythmic events such as VT and VF account for approximately 300,000 deaths annually (Faramarz & José, 2001) because the spontaneous conversion from VF back to a normal sinus rhythm is exceptionally rare, the application of early electrical defibrillation is an absolute clinical imperative to restore automaticity and save the patient's life.

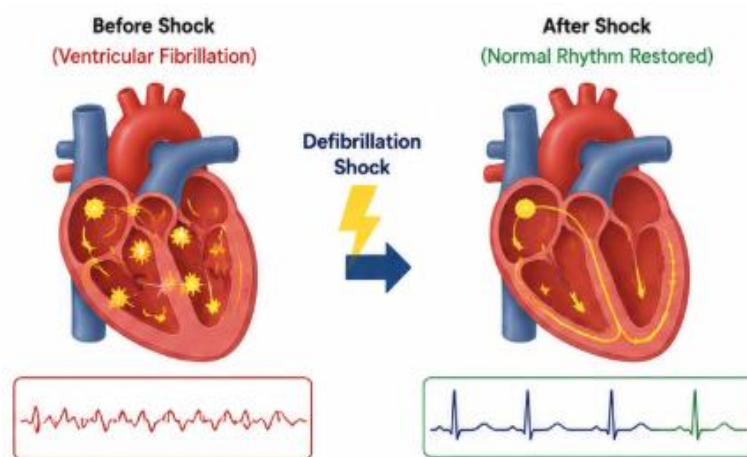


Figure 2: Ventricular Fibrillation (left) and normal rhythm (right)

III. OPERATIONAL MECHANISMS OF DEFIBRILLATORS

The fundamental operational principle of a defibrillator is to deliver a precisely controlled, therapeutic dose of electrical current directly to the patient's myocardium (Mahmoodi, 2026). The core mechanism relies on a large internal capacitor, which acts as the primary energy storage unit as showed in Figure 3. This capacitor is charged over a period of several seconds, drawing massive amounts of power either from a direct line source or specialized rechargeable batteries (Chaudari & Baker, 2005). An integral visible or audible indicator signals to the clinician when the capacitor has reached the desired energy threshold and is fully prepared for discharge. When activated, the stored electrical pulse energy is released through an inductor, which helps shape the current waveform before it reaches the patient's chest.

Clinically, these high-risk devices are engineered with three primary modes of operation: external defibrillation, internal defibrillation, and synchronized cardioversion (Link et al., 2010). External defibrillation utilizes standard paddle electrodes or disposable adhesive pads applied to the chest typically in a sternum-apex configuration, while internal defibrillation employs specialized small concave paddles applied directly to the exposed heart during surgical procedures. Synchronized cardioversion, however, is a highly specialized operational mode specifically engineered to correct organized arrhythmias, such as ventricular tachycardia (VT). In this mode, the defibrillator's sophisticated control circuits continuously monitor the patient's electrocardiogram (ECG) to detect the presence of an R wave. This precise synchronization is a vital safety safeguard designed to explicitly avoid delivering a shock during the vulnerable period of ventricular repolarization, which could inadvertently precipitate lethal ventricular fibrillation.

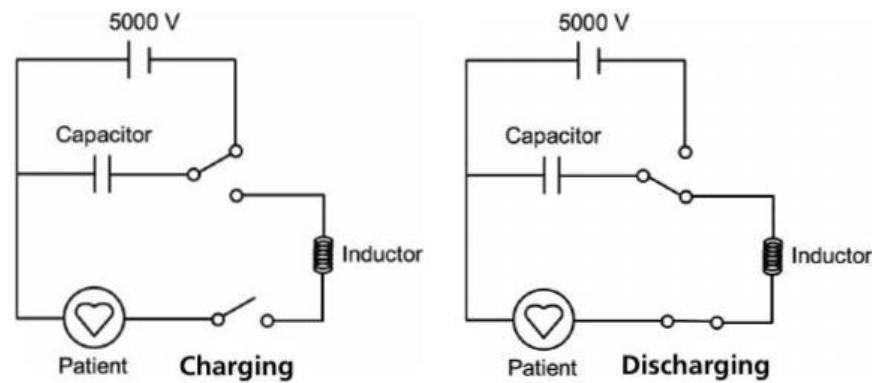


Figure 3: Defibrillator circuit diagram for charging (left) and discharging (right)

Furthermore, the therapeutic efficacy of the shock is deeply influenced by the type of electrical waveform delivered (Niebauer et al., 2004; Tuite & George, 2005). Historically, traditional defibrillation relied on a monophasic waveform, characterized by a single pulse of electrical energy flowing in only one continuous direction between the electrodes. However, modern clinical engineering has largely transitioned to biphasic waveforms. Originally developed for automated external defibrillators (AEDs) and implanted cardioverter-defibrillators, biphasic technology is now the standard for manual hospital defibrillators. In a biphasic discharge, the electrical current initially flows in one direction and then rapidly reverses its path through the heart. Despite this complex internal electrical delivery, the external clinical application for medical personnel remains functionally identical to older monophasic models, maintaining the traditional sternum-apex positioning (JCGM, 2008; Tuite & George, 2005). To verify the effectiveness of the therapy, the defibrillator is inherently integrated with an ECG monitor, and modern units frequently include supplementary diagnostic features such as pulse oximetry and non-invasive blood pressure monitoring. Because these operational mechanics rely on storing and releasing massive amounts of electrical power, ensuring the exact energy discharged matches the selected clinical setting is paramount.

IV. PHYSIOLOGICAL HAZARDS OF INACCURATE ELECTRICAL CURRENTS

While the precise application of electrical energy is the definitive and often sole treatment for lethal cardiac arrhythmias, the human body remains profoundly sensitive to external electrical forces. Electric shock is clinically defined as a powerful and immediate physiological reaction to the passage of an electric current through any portion of a person's body (Fish & Geddes, 2009). Because a defibrillator is purposely designed to deliver massive surges of electrical energy directly to the myocardium, an improperly calibrated device that discharges inaccurate currents poses a severe, multi-systemic hazard to the patient as showed in Figure 4.

To fully grasp the clinical gravity of these hazards, it is essential to recognize the human body's extraordinarily low threshold for electrical tolerance. The physiological consequences of alternating current (AC) operating at a standard 50 Hz frequency perfectly illustrate this vulnerability. Human perception of an electrical current begins at a minuscule threshold of approximately 0.5 mA. However, as the current increases, the physiological effects rapidly escalate from mere perception to lethal shock; exposure to an electrical current of merely 20 mA can be entirely fatal under certain circumstances (Vucenovic & Setrajic, 2017). Given that therapeutic defibrillation utilizes significantly higher concentrated energy levels, the margin for metrological error is incredibly narrow. When an inaccurate or excessive electrical current is delivered to a patient, it forcefully acts upon the body's tissues and fluids, precipitating several distinct physiological injuries. Additionally, severe thermal burns are a highly prevalent physical hazard. As electric current flows through bodily materials possessing high electrical resistance, it rapidly dissipates power as thermal heat.

Current (50–60 Hz AC)	Physiological Effect	Current Through Body (mA)	Effect	Current to Heart (μ A)	Effect
1 mA	Threshold of perception (tingling)	1 – 5	Sensation	10	Potential hazard
5 mA	Slight shock, generally harmless	10 – 20	Muscle contraction	50 – 100	Ventricular fibrillation possible
10 – 20 mA	Pain, muscle contraction	50 – 100	Respiratory arrest	> 100	High risk of cardiac arrest
20 – 50 mA	Loss of muscular control (let-go threshold exceeded)	100 – 300	Ventricular fibrillation		
50 – 100 mA	Respiratory paralysis, severe pain	> 1 A	Cardiac arrest, severe injury		
100 – 300 mA	Ventricular fibrillation likely				
> 1 A	Cardiac arrest, severe burns, tissue damage				

MACROSHOCK

MICROSHOCK

Figure 4: Physiological effect of electrical hazard in defibrillator

Poorly regulated electrical currents severely disrupt the neuromuscular system by inducing intense muscular cramps or tetanus (Beinart & Nazarian, 2013). Tetanus occurs when muscles contract involuntarily and continuously in response to a sustained external electrical input. Most critically, an inaccurate defibrillator discharge can completely halt the very organ it is intended to save. The heart is a highly specialized muscular organ that relies on a continuous, uninterrupted cycle of contraction and relaxation to act as an effective blood pump. If an excessive or improperly dosed current induces tetanus within the cardiac musculature itself, the heart is effectively paralyzed in a state of contraction. This inhibits all pumping action, resulting in total cardiac arrest.

V. ADVANCEMENTS IN DEFIBRILLATOR PERFORMANCE TESTING AND CALIBRATION

To prevent the catastrophic physiological hazards associated with inaccurate electrical discharges, the medical equipment industry relies on highly specialized defibrillator analyzers. The fundamental purpose of these analyzers is to guarantee that the therapeutic energy delivered by the defibrillator precisely matches the energy level selected by the clinician. In early testing models, such as the defibrillator energy tester developed by Thongpance, Kaewgun, and Petprapaset (2015), the calorimetric principle was employed. This method calculates the electrical pulse discharged into a water-submerged copper coil by carefully monitoring temperature fluctuations using thermocouple sensors. While their functional testing yielded average percentage errors ranging from 3.34% to 6.04% across different waveforms, modern clinical engineering has largely transitioned toward high-speed digital sampling methodologies for greater precision.

A persistent challenge in biomedical testing is ensuring strict metrological traceability. Zhao et al. (2015) highlighted that many commercial measurement standards used by metrological agencies are incapable of ensuring an unbroken calibration traceability chain, leading to unreliable hospital inspections. To resolve this, researchers have focused on developing robust standard measuring units. For instance, Shao et al. (2016) developed a highly advanced calibration system using an integral source-meter configuration. By utilizing a resistive divider to attenuate pulse voltage, a current transducer, and synchronous dual data A/D converters, their system continuously generated and measured both monophasic and biphasic waveforms up to 360 Joules. This architecture achieved an impressive pulse energy measurement uncertainty of merely 0.2%. Similarly, Yang et al. (2018) established traceable calibration frameworks using digital sampling techniques in Hong Kong, proving that analyzers could routinely achieve expanded measurement uncertainties of less than 1%.

Beyond equipment design, modern performance testing heavily integrates the mathematical framework of measurement uncertainty. Validating medical parameters requires factoring in multiple compounding error variables (Vijay, Akila, & Sabitharamakrishnan, 2014). In a comprehensive evaluation of

hospital defibrillators in Brazil, Filho et al. (2015) demonstrated the necessity of establishing an "Uncertainty Budget." Rather than relying on simple averages, this rigorous procedure synthesizes statistical variance from repeated shock discharges (Type-A uncertainty) with non-statistical equipment limitations, such as the master analyzer's inherent accuracy and data resolution (Type-B uncertainty). By calculating this combined expanded uncertainty, engineers can establish definitive metrological boundaries to verify if a device operates within the manufacturer's safe tolerance limits. The clinical urgency of adopting these advanced calibration procedures is best illustrated by real-world quality control audits. Golpaygani et al. (2017) conducted extensive performance testing on twenty active defibrillators across ten different public and private hospitals. Their quantitative analysis revealed alarming fail rates; a significant number of the clinical devices failed to meet basic metrological accuracy requirements for energy delivery, particularly when operating under weak battery conditions. Ultimately, these combined studies underscore a critical conclusion for biomedical engineering: standard, visual preventive maintenance is inherently insufficient. To guarantee patient safety during critical resuscitation events, medical institutions must mandate stringent periodic verifications governed by traceable measurement uncertainty protocols.

VI. CONCLUSION

Early electrical defibrillation remains the single most effective, life-saving intervention for terminating lethal cardiac arrhythmias, such as ventricular fibrillation and ventricular tachycardia. However, as this review has demonstrated, the very mechanism that saves a life by the delivery of a massive, concentrated electrical current to the myocardium which inherently carries profound physiological risks. If a defibrillator discharges an inaccurate or improperly calibrated energy pulse, the patient is exposed to severe clinical hazards, ranging from localized thermal burns and electrolysis to catastrophic outcomes like involuntary muscular tetanus, respiratory failure, and total cardiac arrest. Consequently, the metrological reliability of these high-risk critical care devices cannot be taken for granted. While standard preventive maintenance protocols serve a foundational administrative purpose, recent advancements in biomedical testing reveal that visual inspections and basic functional checks are inherently insufficient to guarantee precise energy delivery. To bridge this critical gap in patient safety, modern clinical engineering must transition toward advanced, mathematically rigorous performance testing frameworks. It is imperative that medical institutions mandate the use of highly accurate, digitally sampling defibrillator analyzers capable of ensuring an unbroken chain of metrological traceability. By establishing definitive metrological boundaries through expanded measurement uncertainty, healthcare facilities can scientifically guarantee that every defibrillator operates strictly within safe manufacturer tolerances. Ultimately, standardizing these advanced calibration protocols is not merely a technical upgrade; it is an absolute clinical safeguard necessary to prevent equipment malfunction, mitigate systematic errors, and ensure optimal life-saving performance during the most critical resuscitation events.

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