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An Introduction to Defibrillation and Transcutaneous Pacing

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CONTENTS

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Foreword

This booklet is written as a guideline for people involved in testing medical defibrillator devices. All reasonable care has been taken to ensure that the information, reference figures and data are accurate and have been taken from the latest versions of various standards, guidance notes and recognised best practices to establish the recommended testing requirements. Rigel Medical, their agents and distributors, accept no responsibility for any error or omissions within this booklet or for any misinterpretations by the user.

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Author: Michael James Walton, MSc.

Introduction

A cardiac arrest happens when the heart cannot pump blood around the body. In the UK there are an estimated 30,000 out-of-hospital cardiac arrests (OHCA) annually; in the USA 350,000. The chances of surviving an OHCA are 1 in 10; this increases to a 1 in 5 chance of survival if the cardiac arrest occurs within a hospital. Unless there is immediate intervention from cardiopulmonary resuscitation (CPR) and defibrillation, death will follow within minutes. Survival rates fall at a rate of 10% per minute without the intervention of CPR and defibrillation. [1] [2] [3]

Defibrillators are medical devices that are commonly used to treat irregular heartbeats known as cardiac arrhythmias. External defibrillators can be used to treat serious life-threatening cardiac rhythm conditions like ventricular fibrillation (VF) as well as the lesser ominous rapid rhythms of atrial fibrillation (AF), atrial flutter (AFL), and ventricular tachycardia (VT) that require elective procedures. Defibrillators apply a countershock (a strong electric shock) to a patient with the purpose of converting a patient's rapid, ineffective, and uncoordinated heart rhythm disorder to a more organised, normal and slower rhythm - allowing the heart to efficiently pump blood around the body. [4] [1]

There are two types of defibrillator: external and internal.

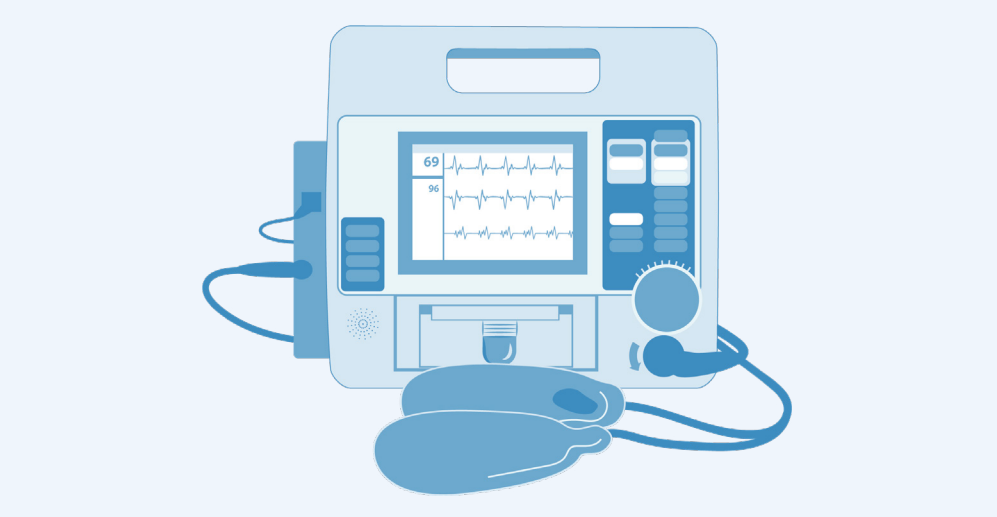

Figure 1 – Advanced life support external defibrillator

Internal defibrillators – implantable cardioverter defibrillators (ICD) - are similar to pacemakers, monitoring the heart's electrical activity to deliver a shock if needed.

An external defibrillator can be operated to deliver a shock, either monophasic or biphasic, to the patient by a physician, a paramedic, or an untrained bystander. Automated external defibrillators (AEDs) - often referred to as public access defibrillators (PADs) - are easy to use and are becoming increasingly common, typically found in many public places. AEDs offer basic life support (BLS). Advanced life support (ALS) units are used by healthcare professionals. They include advanced monitoring parameters, which go beyond delivering electrical shock, offering external pacing and optional vital sign monitoring. [5] [6]

The Medicines and Healthcare products Regulatory Agency (MHRA) reported that more than 10,000 AEDs across the UK may not deliver a sufficient electrical shock and advised that AEDs should be subject to routine testing. [7] Defibrillators are critical life support and resuscitation devices that must be tested to ensure full functionality is available at all times to establish reliability and effective performance.

Defibrillator analysers are a must in any clinical engineering department. They are specialised devices that test a defibrillator's performance characteristics, and include a test load with impedance similar to a human's thorax that can absorb the dissipated energy without overheating. Both monophasic and biphasic energy delivered from the defibrillator across the simulated load can be measured by the defibrillator analyser. [8] [9]

History

With the advances in medicine at the turn of the 20th century, heart disease was a serious health concern due to people living longer, and became the leading cause of death. People had usually died from infectious diseases before reaching an age where heart problems could threaten their health. Around this period, Swiss researchers Jean-Louis Prévost and Frédéric Batelli brought about the paradox that electric current could lead to fibrillation of the cardiac chambers, and more importantly defibrillation, when experimenting on a dog's heart. [9] [10]

In the 1920s engineering professor William B. Kouwenhoven began research on electric defibrillation at John Hopkins University, Baltimore. His pioneering work with surgeon Claude S. Beck led to open chest and clinical defibrillation. In 1933, Kouwenhoven had restored a dog's normal sinus rhythm (NSR) using an AC surge of electricity he called a countershock. This was a radical advancement in cardiac care - defibrillation was born.

Beck was an expert in improving heart circulation. He had noticed that during cardiac surgery, the heart would occasionally go into VF. Massaging the heart did not always work and the patient would die from the fibrillation. In 1947, Beck applied open chest defibrillation to a human heart in VF during surgery, successfully reviving the patient using Kouwenhoven's team's AC biphasic electric defibrillator (*Figure 2*).

In Moscow, during 1938-39, Naum L. Gurvich began work on a less dangerous DC monophasic device to deliver transthoracic defibrillation. Gurvich discharged between 2 kV – 6 kV from a capacitor across the chest of animals to restore cardiac function. AC defibrillation requires bulky generators, and the strong chest contractions could break ribs. DC discharge was less likely to cause fibrillation and was more likely to spontaneously restart the heart without artificial intervention.

During the 1950s-1960s there were big improvements in defibrillator design. Gurvich and Kouwenhoven were not alone in the fields of their research. There were advancements by Boston cardiologist Paul Zoll, who experimented with external closed chest cardiac pacing and AC defibrillation, Dr. Bernard Lown who used DC for cardioversion, inventing the "cadioverter" and Bohumil Peleska – who optimised and improved Gurvich's DC defibrillation. All of this research contributed to the creation of a portable, safe and external transthoracic defibrillator we are familiar with today.

From the 1960s to 1980s, further advancements in technology paved the way for sophisticated defibrillators and pacemakers that could work together inside the human body, sustaining heart rhythms. The subfields of defibrillation - cardioverters and cardiac pacing merged, which led to the development of ICDs.

The final development in defibrillation was AEDs in the 1990s, a single-button automatic defibrillator that could be used by the public, bettering the survival rate odds for OHCA patients. [10] [11] [12]

Figure 2: Kouwenhoven's open chest defibrillator [10]

Heart

The heart is located in the thoracic cavity. It pumps blood, creates blood pressure, and circulates oxygen, nutrients and other substances we absorb around our body. The heart has four chambers: the right and left atria, and the right and left ventricles. The chambers are made up of cardiac muscle known as myocardium. The electrical activity of the myocardium regulates the mechanical sequence of events known as the cardiac cycle (Figure 3).

In its simplest form, the cardiac cycle is the simultaneous contraction (systole) of the right and left atria, followed by the contraction of the right and left ventricles. After ventricular systole the heart (Figure 4) will relax (diastole) and the aria will fill with blood. The right atrium returns deoxygenated blood from the upper and lower body to the right ventricle via the tricuspid valve. When the right ventricle contracts, deoxygenated blood is pumped past the pulmonary semilunar valve, through the pulmonary artery to the lungs. The lungs perform a gas exchange expelling the waste product, carbon dioxide, from blood to air, and taking in the nutrient, oxygen, from air to blood. The left atrium receives oxygenated blood from the lungs via the pulmonary veins, which then passes the mitral valve to the left ventricle. When the left ventricle contracts, oxygenated blood is pumped past the aortic semilunar valve, through the aorta to the upper and lower body. [13]

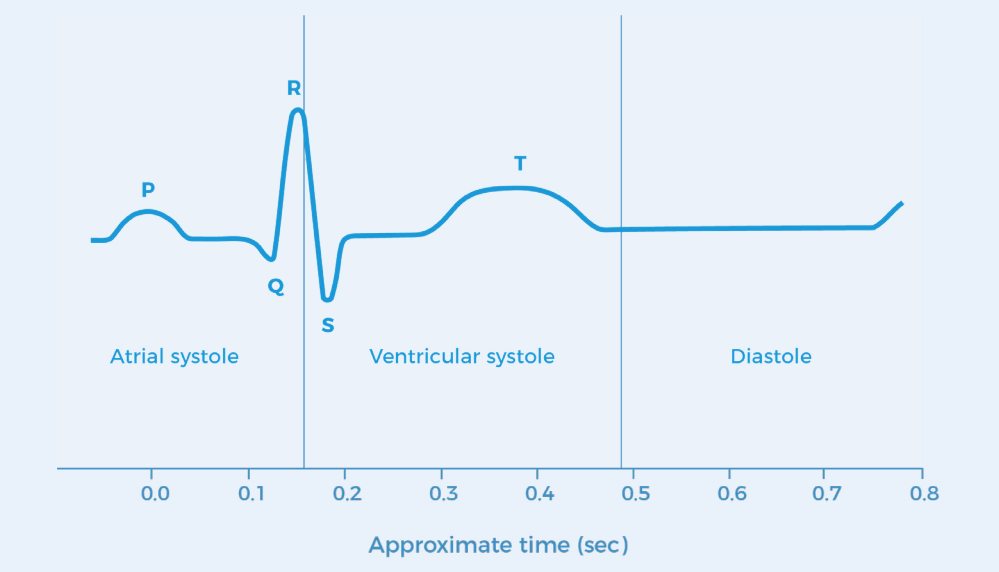

Figure 3: Cardiac cycle

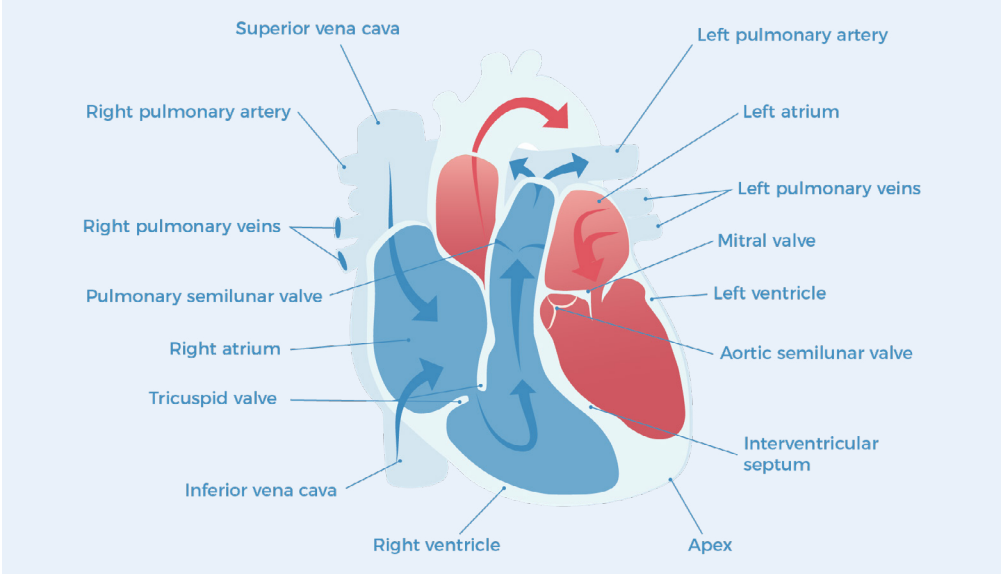

Figure 4: The Heart [13]

Electrical activity of the heart

Cardiac muscle cells can spontaneously contract without nerve impulses. The heart generates its own beat, and its natural pacemaker is the sinoatrial (SA) node – a cluster of highly conductive cells located in the right atrium. The SA node initiates the heartbeat with rapid depolarisation. Impulses from the SA node follow a conductive path to the AV node and atrial myocardium; this transmission brings about atrial contraction. The cardiac conductive pathway continues from the AV node, sending an impulse to the AV bundle (bundle of His) which branch off to the right and left bundle branches, further travelling to the Purkinje fibres and the rest of the ventricular myocardium (causing the ventricles contract). [13]

Action potential is a chemical reaction that changes the electrical charge potential of the cell membrane in response to stimulus.

Depolarisation reverses an electrical charge of a cell membrane causing muscle fibres to contract.

Repolarisation follows depolarisation and restores the electrical charge of the cell membrane. The muscle fibres are now able to respond to stimulus.

[13]

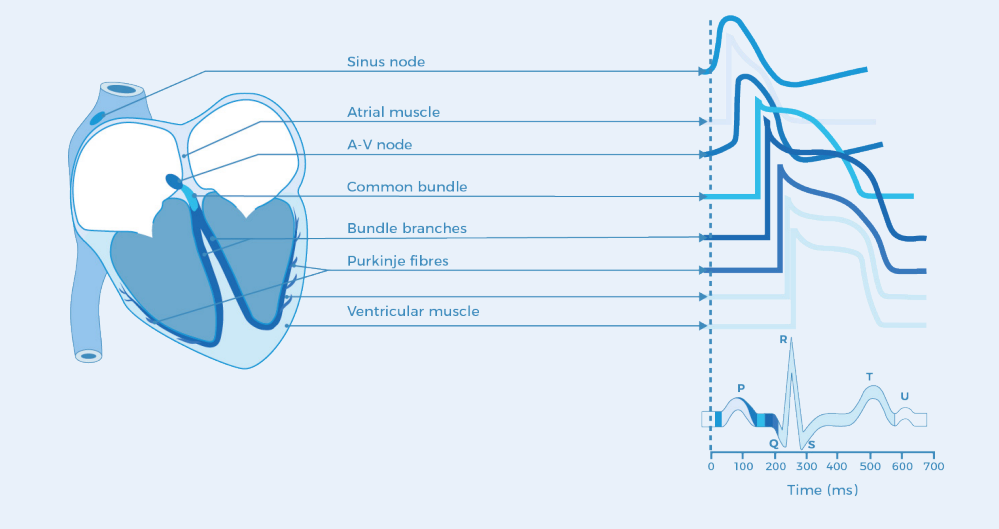

Figure 5: ECG electrical activity

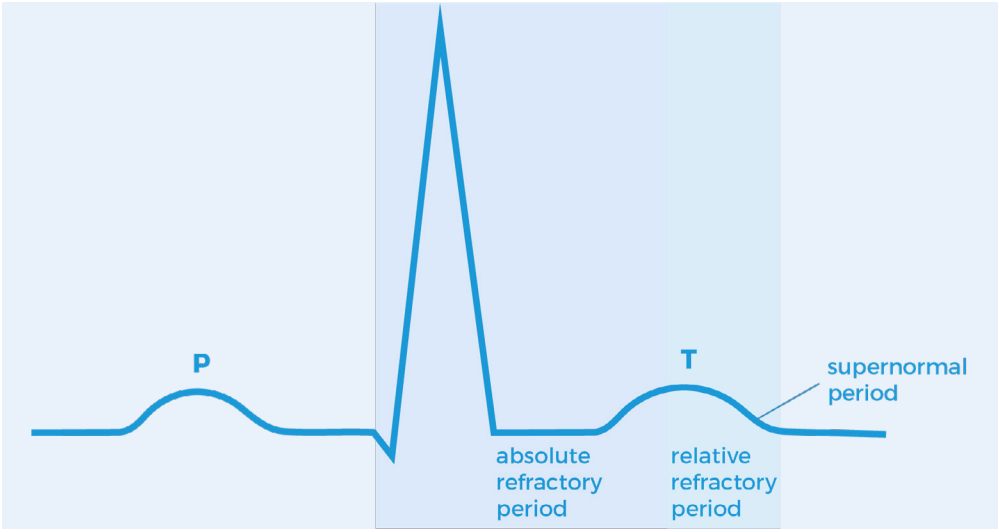

Figure 6: Refractory period

Electrocardiogram

The series of electrical events generated by the myocardium can be depicted using an electrocardiogram (ECG) monitor when electrodes are attached to the skin across the chest, arms and legs. A typical ECG (Figure 5) consists of: the P wave, representing SA node depolarisation of the atria; the QRS complex, representing depolarisation on the ventricles as the impulses distribute through the ventricular myocardium; and the T wave, representing the repolarisation of the ventricles. Atria repolarisation is masked by the QRS complex, therefore, it does not have its own wave. [13] [14]

Absolute and relative refractory

There are periods during the cardiac cycle where the myocardial cells are resting, this is called refractory (Figure 6). The cells are unable to respond to stimulus as they are recharging for another beat. Absolute refractory period (APR) is the period of ventricular depolarisation from the start of the QRS complex to the repolarisation phase near the peak of the T wave. The myocardial cells cannot respond to strong stimulus during this period. Relative refractory period (RRP) is the duration of ventricular repolarisation from the peak to the end of the T wave. The cells will respond to strong stimulus. [15] [16]

Arrhythmias

An irregular heartbeat is known as an arrhythmia, which is caused by damage to the cardiac conductive pathway. The electrical impulses may be too fast, too slow, or erratic. Therefore, the heart will not pump blood effectively around the body, causing damage.

Types of arrhythmia are:

- **Atrial Fibrillation (AF)** - rapid irregular contraction of the atria
- **Atrial Flutter (AFL)** - similar to AF but not irregular
- **Bradycardia** - slow resting heart rate <60bpm
- **Ventricular Tachycardia (VT)** - fast resting heart rate >100bpm
- **Ventricular Fibrillation (VF)** - disorganised electrical signals cause the ventricles to rapidly quiver

[35] [13]

Flutter is a regular but very rapid heartbeat that can cause contractions of 300 times per minute. AF is not immediately life threatening as atrial pumping is not crucial. Ventricular flutter is usually a short transitional period between VT and VF.

Fibrillation is very rapid, uncoordinated contractions that cause a sudden reduction in cardiac output (the amount of blood pumped by the ventricles per minute). The ventricles then do not pump the necessary blood via the arteries to the rest of the body – this is known as a cardiac arrest.

A heart attack - myocardial infarction (MI) - is the sudden interruption of the blood supply to the body and can cause VF. If the heart is in VF, intervention is required to prevent death. [17] [13]

Defibrillation

Defibrillation is the corrective measure to stop VF or, to simplify, convert arrhythmia to a NSR. A defibrillator can deliver a strong electric shock to the heart, simultaneously depolarising the cardiac cells so they contract. The cells then simultaneously repolarise themselves to a relaxed state. A normal heart beat will "restart" if the first part of the heart to recover is the SA node.

The energy delivered to a patient must be adequate to affect the heart cells. In general, short duration shocks require larger currents, and longer duration shocks require smaller currents. This relationship is shown in Figure 7.

In use, shockable energies from the electrodes of a defibrillator to a patient's chest range from 1 to 360 joules (J), with the intensity of tens of amps and a few thousand volts over a duration of between 3-10ms. Typical impedance values of a patient's transthoracic cavity can range between 25 to180Ω. Influencing factors on impedances include body/tissue mass, age, disease, and skin resistance. Only a fraction of the current delivered to the transthoracic cavity will reach the heart. [18] [13] [4] [6]

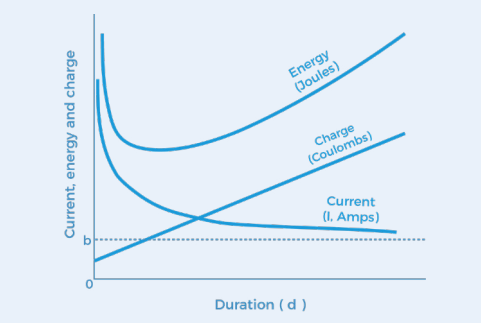

Figure 7: Shock duration vs current [4]

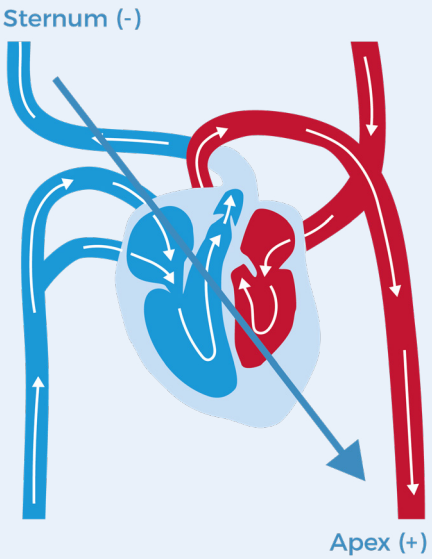

Figure 8: Energy is dissipated across the sternum to apex

- **Energy is across the heart, current flowing between the atria to ventricles**
- **The paddles on an external defibrillator are placed from the sternum to the apex**
- **Placement of the paddles can be anterior to anterior or anterior to posterior**
- **Defibrillators clearly identify their paddles as Apex (+) and Sternum (-) to guide placement**

Shockable and Non-shockable Arrhythmias

Non-shockable arrhythmias include pulseless electrical activity (PEA), and asystole.

- PEA: A condition where an ECG is present but there are no signs of a palpable pulse or other signs of circulation
- Asystole: The absence of ventricular contraction. The ECG is almost a flat line, sometimes with the occasional P wave

[19]

Shockable arrhythmias include VF, VT, AFL, and AF. Shockable rhythms can be divided in two parts: no cardiac synchronised defibrillation and cardiac synchronised defibrillation.

No synchronisation

- VF and VT (pulseless)

Synchronisation

- AF, AFL and VT (with a pulse)

Synchronisation or synchronised electrical cardioversion is used by defibrillators to sense the QRS complex. This is to prevent the inadvertent shock during T wave of the ECG, known as the vulnerable period (Figure 9). A shock during the T wave of the ECG can produce VF. The defibrillator will measure the timing of the R wave and synchronise to the patient's heart rate, delivering the energy close to the R wave period. [20] [4]

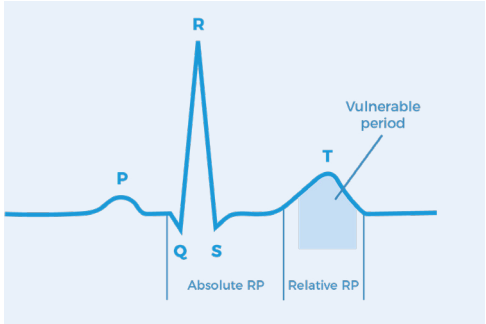

Figure 9: Absolute and relative refractory periods. T wave - vulnerable period

Energy

The joule is the standard unit (SI) of energy used in scientific applications to measure and express the work done. The energy or work required to produce one watt of power (P) for one second (s) is a joule (J). The relationship between energy (E), voltage (V), current (I), resistance (R), power (P) and time (t) is as follows:

Different defibrillator manufacturers output various waveforms. The electrical energy output by a defibrillator can be measured based on the following equation:

$$E = \int_0^T p(t)dt = \int_0^T v(t)i(t)dt$$

Across a resistor (R) or transthoracic cavity the total energy dissipated is expressed as:

$$E = \frac{1}{R}\int_0^T [v(t)]^2 dt$$

$$P = V \times I = \frac{V^2}{R} = I^2 \times R$$

$$E = V \times I \times t = P \times t = \frac{V^2}{R} \times t = I^2 \times R \times t$$

$$\therefore 1 \text{ joule} = 1 \text{ watt} \times 1 \text{ second}$$

Typical Energy Dosage

Arrhythmia	Biphasic	Monophasic
Adult VF, VT (pulseless)	120 – 200J	360J
Adult AF	120 – 200J	Up to 200J
Adult SVT, AFL	50J stepwise increases	Up to 100J
Adult VT (with pulse)	100J stepwise increases	Up to 200J
Paediatric VF, VT (pulseless)	2J/kg - 4-10J/kg	Biphasic equivalent
Paediatric tachycardia	0.5J/kg - 2J/kg	Biphasic equivalent

Figure 10: AHA's recommended energy dosage [21] [22] [23]

Defibrillator Devices

Modern external defibrillators being manufactured today are robust, portable, and comprehensive medical devices used by emergency medical service (EMS) personnel, offering an all-in-one life support solution. Defibrillator technologies provide the necessary emergency care to adults, paediatrics, and neonates. Higher specified, top of the range defibrillators in the market have AED, manual defibrillation, non-invasive transcutaneous pacing, and synchronised electrical cardioversion. Other optional advancements include vital sign monitoring capabilities such as:

- SpO2 – to monitor blood oxygen saturation levels; 1 to 100%*, 300 bpm*
- Non-invasive blood pressure (NIBP) – automatically measuring BP via a cuff; -400 to 400 mmHg*
- Invasive blood pressure (IBP) – measuring BP invasively; -50 to 300 mmHg*
- Temperature – using thermistors to measure body temperatures, 400/700 series, 0 to 50˚C*
- ECG – up to 12-lead ECG to display and record diagnostics measurements; including STEMI detection; 15-300 bpm*
- Respiration – measuring rpms across the transthoracic cavity; 0.1 to 3Ω*, 200 rpm*
- Capnography – monitoring carbon dioxide levels; 0 to 99 mmHg*, 0 to 150 rpm*
- CPR support – offering advisory audible guidance and a metronome to improve resuscitation outcomes

*Typical values

Defibrillator manufacturers must conform to a multitude of IEC standards. Primarily, IEC 60601-2-4:2011 Particular requirements for safety of cardiac defibrillators is of essential adherence; other standards include IEC 60601 -1, IEC 60601-8, IEC 60601-12, IEC 60601-2-27, IEC 60601-2-30, IEC 60601-2-34, IEC 60601-2-49, ISO 80601-2-6, EN 6010-3 covering the plethora of extra monitoring possibilities modern defibrillators use to provide advanced life support.

Typically, defibrillators are internally battery powered and can be charged and powered using AC mains power (100-240V) or a DC adaptor. The energy output from the paddles ranges from 1 to 200J, or 1 to 360J in to an impedance typically ranging between 25 to 200Ω. Biphasic is now the waveform of choice by many manufacturers over monophasic.

Defibrillator Waveforms

The first commercial defibrillators available were biphasic. However, for 30 years the western world adopted monophasic until the mid-1990s when there was a general acceptance that biphasic technology increased the success of defibrillation.

Monophasic (Figure 11) is a damped sine wave with a high peak current; the current flows in one direction across the heart. Current decreases as bodily impedance increases – the heart may not receive enough current to defibrillate if impedance is high.

Biphasic (Figure 12) current flow is bidirectional. Current waveforms adjust to maintain the delivered energy regardless of patient impedance. Therefore, a patient will have equal chance of survival regardless of their impedance.

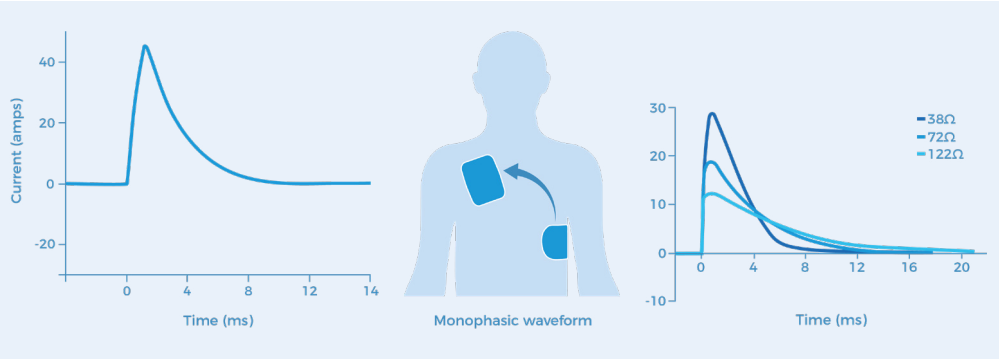

Figure 11: Monophasic waveform, current flow, and changes in impedance @ 38Ω, 72Ω, and 122Ω

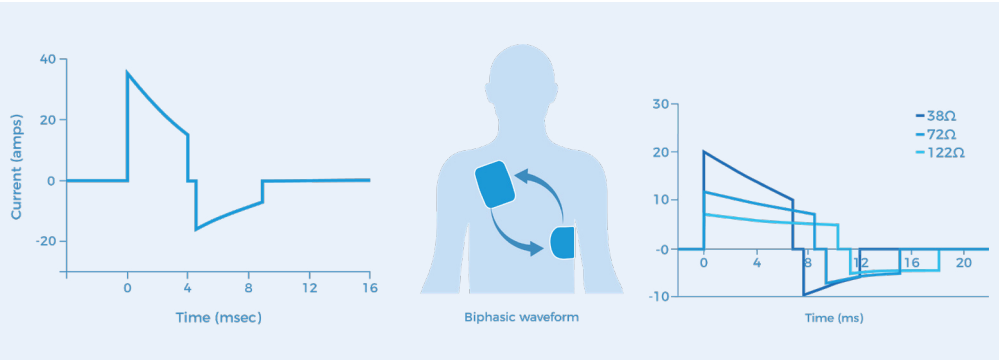

Figure 12: Biphasic waveform, current flow, and changes in impedance @ 38Ω, 72Ω, and 122Ω

Biphasic devices have advantages over monophasic. Lower energy delivered by biphasic devices can be as effective as higher energy monophasic devices. Biphasic energy at 200J or less can have equal or higher efficacy than monophasic energies of 200 to 360J. Using lower biphasic energy may result in less damage to the myocardium and a reduction of post-shock dysrhythmias, skin burns, and contractility. [24] [25] [26]

Biphasic waveforms are not homogeneous from device to device. Manufacturers have their own patented biphasic technologies. There are three patented technologies: biphasic truncated exponential (BTE) (Figure 13), rectilinearbiphasic waveform (RBW) (Figure 14), and pulsed biphasic (Figure 15). [27] [28]

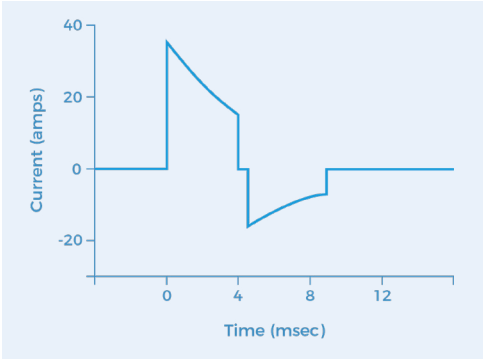

Figure 13: Biphasic truncated exponential

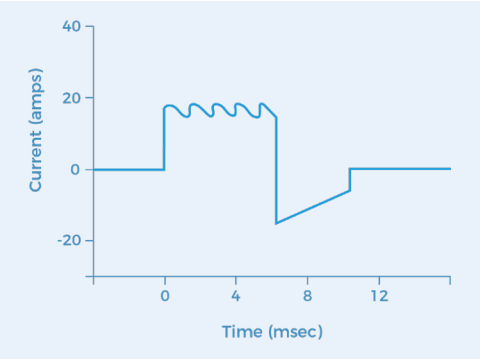

Figure 14: Rectilinear biphasic waveform

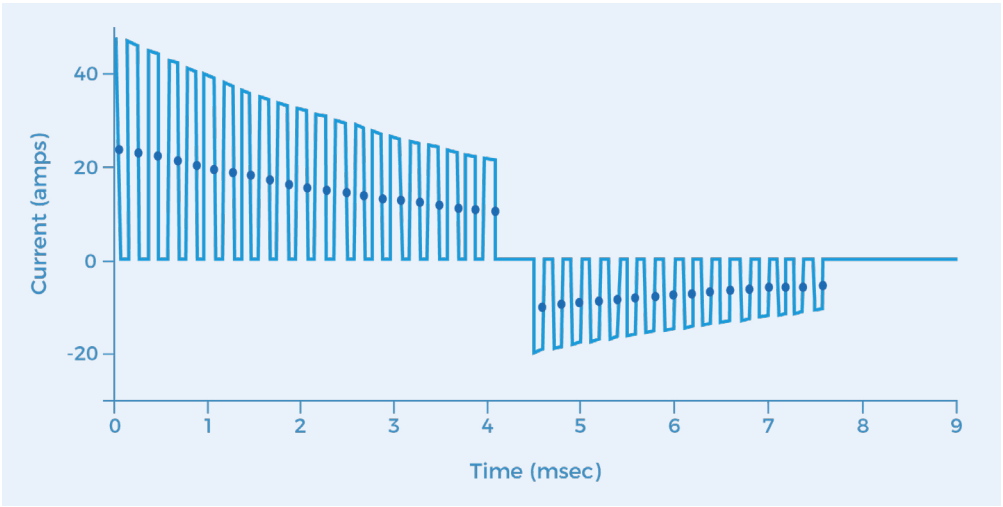

Figure 15: Pulsed biphasic

Automatic External Defibrillators

AEDs use algorithms to accurately evaluate cardiac rhythms and deliver the appropriate countershock if an arrhythmia is present. The AEDs differentiate between shockable and non-shockable rhythms and will only deliver energy to patients showing signs of VF or VT (pulseless) with specific peak-to-peak ECG amplitudes in accordance with American Heart Association (AHA) guidelines. AEDs can be semi-automatic, where the operator must push the shock button to deliver the shock. AEDs that are fully automatic require no operator action when a shock is required.

PADs have become widely available for non-medical, unskilled personnel to operate AEDs with a first person response to improve OHCA outcomes. [29] [30]

Figure 16: An AED device

Modern AEDs determine ECG signal quality, contact integrity, and measure patient impedance. Typically, AEDs deliver biphasic energy at fixed levels between 120 to 200J for adults, and 50J for paediatrics, but some manufacturer's devices can deliver a full range of energy from 20 to 360J.

Implantable Cardioverter Defibrillators
Implantable Cardioverter Defibrillators (ICDs) are invasive devices placed under a patient's collarbone that are an important part of arrhythmia management. ICDs monitor the electrical activity of the heart by attaching electrodes directly to the myocardium. Modern ICDs can provide the following:

- **Defibrillation** - delivering a large shock to restore an NSR
- **Cardioversion** - deliver one or several small shocks to restore an NSR
- **Transvenous Pacing** - fast low voltage impulses to correct a slow heart rhythm

Transcutaneous Pacing
Non-invasive transcutaneous pacing externally stimulates the heart with electrical impulses via self-adhesive electrodes placed anterior to posterior or anterior to anterior (Figure 17), with the purpose of creating cardiac depolarisation and myocardial contraction. The stimulus is intended to treat patients with dangerously slow bradycardic rhythms.

The intervention of pacing can increase cardiac output and mean arterial pressure whilst decreasing systemic vascular resistance.

Non-invasive transcutaneous pacing has two modes:

Non-demand (asynchronous or fixed rate) – a clinician will set a pacing rate regardless of the patient's intrinsic heart rate. This is a preferable option if an ECG signal is hard to detect due to noise or motion artefacts or a less common termination of tachyarrhythmia by overdriving a patient's intrinsic heart rate. The danger of non-demand pacing is when the QRS complex is not sensed; potentially this could trigger VF as the T wave could be paced.

Demand (synchronous) – the patient's intrinsic heart rate is sensed by the pacer. Pacing will provide the electrical stimulus if the sensed patient's heart rate is slower than the clinician's set rate, and inhibit pacing if the sensed heart rate is faster than the set rate. The advantage of this is to minimise the competition between pacer stimuli and the patient's intrinsic heart rate, decreasing the chance of pacing the T wave.

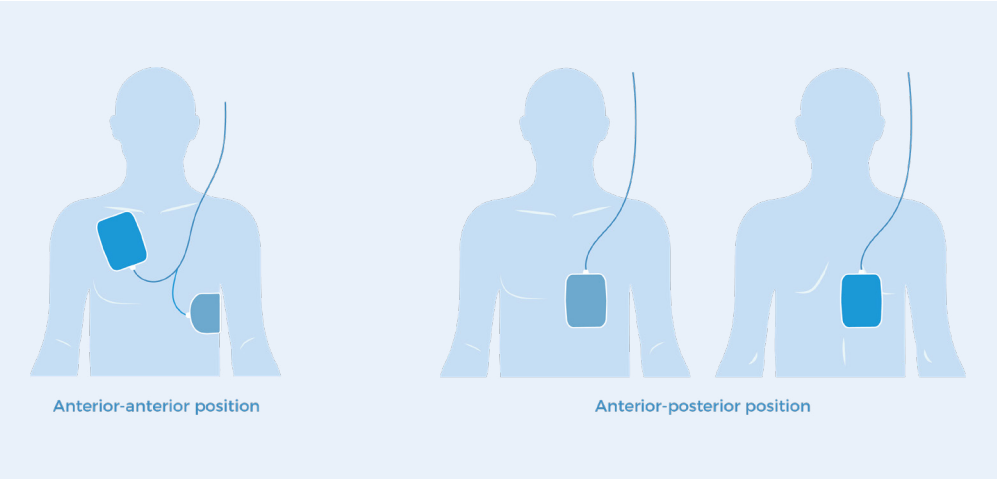

Figure 17 – Transcutaneous electrode placement

The paced refractory period is the time after the delivered paced pulse; in this period the pacer will not sense. The refractory period can be between 200 to 350ms. The period shortens as the pacing rate is increased.

Pacemakers have a sensitivity adjustment measured in millivolts (mV). The sensing determines the threshold at which the pacemaker can detect the impulses of a patient's intrinsic cardiac activity. Appropriate sensing levels need to be set to differentiate between the desired R wave and T wave, and muscle artefacts. [33] [32] [34]

Typical transcutaneous pacemakers deliver a pulse, the characteristics are as follows:

- Current output - 0 to 200mA
- Pulse rate - 20 to 200ppm
- Pulse width - 20 to 50ms
- Refractory period - 200 to 350ms

Standard
The current in-use standard for external defibrillators is IEC 60601-2-4:2011 Particular requirements for safety of cardiac defibrillators. The purpose of the standard is to establish particular basic safety and essential requirements for cardiac defibrillators for manufacturers' adherence.

The standard stipulates the accuracy of:

- Defibrillator energy output into various loads
- Maximum delay time from the synchronised peak QRS complex to the peak delivered energy
- Differentiating and identification of shockable and non-shockable arrhythmia
- The accuracy of the pacing pulse rate, current and duration.

Defibrillator Testing

A typical test procedure to ensure electrical safety and performance of an external defibrillator can consist of the following tests:

- Visual test
  - Line cord, chassis, cables, electrodes, switches, fuses, paddles
- Battery performance
- Alarms
- ECG performance
  - Amplitude gain
  - Bpm rate verification
  - Frequency response
- Synchronisation/cardioversion operation
  - Recording sync delay
- Energy output
  - Energy linearity
  - Deliver after a specified time - typ. 1 minute @ max output
  - Charge time @ max output - typ. <10s
  - 10th repetitive test @ max output
- Pacer output
  - Current linearity
  - Pulse width
  - PPM
- Paddle impedance check
- Printer
  - Paper speed
- Vital signs verification
  - SPO2, NIBP, CO2
- Electrical safety test

Note: When testing a defibrillator it is crucial to understand the operation of the device under test. The output energy from defibrillators is extremely hazardous; precautions must be followed to ensure the device is tested under safe conditions only. Always ensure that all tests are carried out by a competent suitably trained individual.

UniPulse 400

The UniPulse 400 from Rigel Medical is designed to comprehensively test all defibrillators accurately and efficiently. The UniPulse 400 is capable of analysing all monophasic, biphasic, standard and pulsating waveforms. This unrivalled functionality and our new comprehensive pacer function makes the UniPulse 400 the ultimate defibrillator analyser on the market. The dedicated fast keys and simple to use operating system enables test engineers to select the relevant test function in seconds. The icon based fast keys make test selection easy with the UniPulse 400.

Figure 18

Analysing Defibrillator Energy

The UniPulse 400 can accurately analyse energy from 0 to 360J on all monophasic, biphasic, standard and pulsating waveforms across a non-inductive 50Ω fixed load, and accommodate external variable loads if required. E - energy (J), Vp - peak voltage (V), Ip - peak current (I), and t - pulse duration (ms) can all be displayed on-screen. There is no need for an oscilloscope to view captured waveforms – the UniPulse 400 displays a Y (Ip, A) and X (t, ms) axis graphical on-screen representation of the dissipated pulse.

The time response of the defibrillator's cardiac synchronisation can be measured in ms by the analyser. The defibrillator will synchronise with the R wave of the ECG. The heart rate can be varied by the UniPulse 400; the timing from the synchronised R wave and delivered energy pulse will be measured.

A requirement of IEC 60601-2-4 is to record battery recovery. The UniPulse 400 has a stopwatch feature to determine the duration of the charge time which is typically set at the maximum charge. The charge time is measured from the prompting of the charge on the defibrillator to the discharging of the energy across the analyser's load.

Figure 19

AED Testing

The UniPulse 400 can simulate arrhythmias across its test load for an AED to analyse and differentiate an ECG that is shockable against a non-shockable ECG; the AED will discharge across the test load accordingly.

E - energy (J), Vp - peak voltage (V), Ip - peak current (I), and t - pulse duration (ms) can all be displayed on-screen. A graphical on-screen representation of the dissipated pulse is also captured.

ECG Simulation

The analyser has a categorised range of more than 40 ECG simulations. Sinus rhythms, ventricular arrhythmias, atrial conduction and arrhythmias, pacer waveforms and performance waveforms can be simulated with ease using the UniPulse 400's intuitive fast key approach. The analyser provides a visual representation of each ECG waveform on-screen so there is no need to look at service manuals to determine the shape of waveforms. Adjustable parameters are available to verify the defibrillator's patient monitoring capabilities. Included parameters are:

- Amplitude - 0.5 – 5 mV (10 mV performance)
- Frequency - 0.1 – 300 Hz
- Heart rate - 20 – 300 BPM
- Noise 50 or 60 Hz 0.1 – 10 mV (that superimposes commercial frequency interference to the ECG signal).

Transcutaneous Pacer Measurement

Pacer Pulse Mode

Pacemaker manufacturers' pulse shapes vary from brand to brand. The UniPulse 400 covers many manufacturers' algorithms to correctly measure the current delivered by the pacemakers. In pacer pulse mode, rate - heart rate (ppm), PW - pulse-width (ms), Ip – peak current (mA) and E – energy (mJ or µJ) can all be displayed on-screen, and a graphical on-screen representation of the pulse is captured. Further current measurements are also available; Iavg – RMS measurement, Ilead – leading edge, and Itrail – trailing edge. A lock feature enables the user to pause readings. Pacing can be delivered into a fixed non-inductive 50Ω load (defibrillation input) or a variable 50 to 1600Ω load (pacer input).

The UniPulse 400 will measure all the pacer parameters in demand or in asynchronous (non-demand) mode. In demand mode, the pacemaker can be verified by interacting with the ECG signal. Underdrive (85% of selected bpm) and overdrive (115% of selected bpm) presets can be selected from a soft key. The pacer should stop pacing when overdrive is enabled.

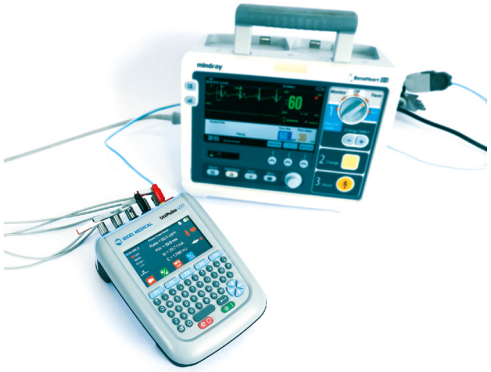

Figure 20

Refractory Period

The paced refractory period (PRP) is the time at which the pacemaker delays the pacer pulse output due to a sensed incoming QRS signal introduced by the UniPulse 400.

The test starts with the pacer in demand mode and the UniPulse 400 providing no stimulation. The pacer will pace at the set rate and the UniPulse 400 will produce a QRS blip a short time after the received pacer pulse has ended. If this QRS blip falls within the PRP, the pacer doesn't see the blip and keeps pacing at the set rate. However, as soon as the QRS blip falls outside the PRP, the pacer will delay the pacer pulse. As soon as this happens, the analyser records the PRP in ms.

Sensed Refractory Period

The sensed refractory period (SRP) is the time at which the pacer delays the pacer pulse output due to a sensed PRP event introduced by the UniPulse 400. The sensed refractory period (SRP) is measured using a second QRS blip which is generated immediately after the first "blip" (at the PRP point).

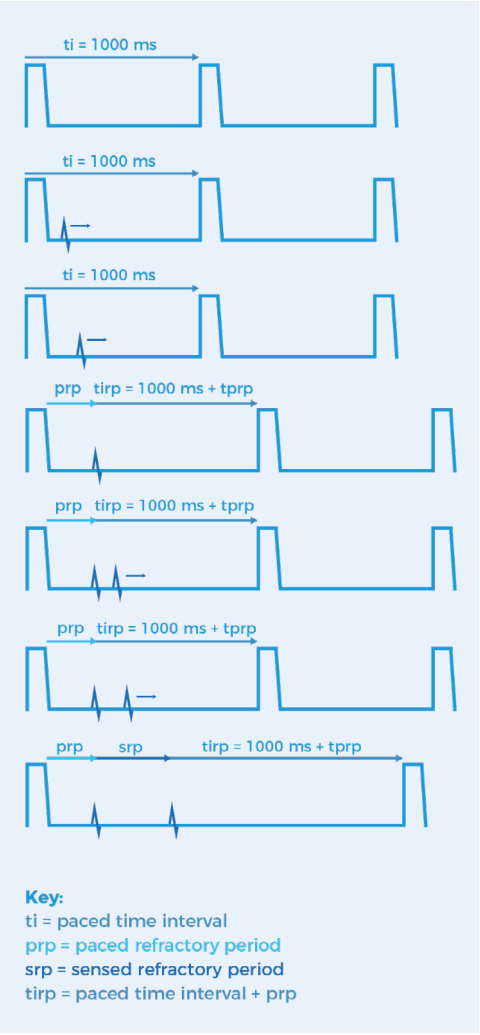

Figure 21: PRP and SRP relationship

Sensitivity Test

The sensitivity test increases the amplitude of the R wave simulation until the pacemaker under test senses the simulation and inhibits output. Pace makers in demand mode will not output any pulses when a heart rate is detected above the set pacer rate. The UniPulse 400 will automatically set to a heart rate greater than the pacer rate, the simulated R wave output waveform will also increase its mV amplitude automatically until the pacer detects the heart rate and stops pacing. A soft key makes it possible to toggle positive and negative polarity of the R wave prior to the sensitivity test.

Noise Immunity

The UniPulse 400 superimposes a 50 Hz or 60 Hz sinusoidal waveform, with a variable amplitude (0.0 to 15 mV), onto the output waveform verifying the pacemaker's filtering capabilities.

Conclusion

Defibrillators have an important role to play providing the necessary intervention required for successful CPR procedures. Advancements in technology give EMS staff the tools to deliver ALS solutions reducing potentially fatal outcomes. AEDs are also improving OHCA outcomes, and can be found globally in most public places for layman's use.

Defibrillators are hazardous medical devices, and are certainly not without risk. With this in mind, regular performance and safety tests of defibrillators will further improve patient safety by ensuring the devices meet manufacturers' specifications, are accurate, and meet their intended purpose of use.

When considering the purchase of a defibrillator/transcutaneous analyser, ensure that you fully understand the manufacturer's requirements and the technical capabilities.

The Rigel Medical UniPulse 400 is a small, compact, intuitive instrument offering safer, faster and more accurate testing of defibrillators. Enabling you to meet international and manufacturer specific test requirements simply and efficiently.

We hope you have found the information in this booklet useful and interesting. We welcome your feedback.

If you need any assistance with testing electrosurgical devices please visit **rigelmedical.com/support** and raise a support ticket.

European Office
T: +44 (0)191 586 3511

USA Office
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European Office

15 -18 Bracken Hill, South West Industrial Estate,
Peterlee, County Durham, SR8 2SW. United Kingdom

T: +44 (0) 191 586 3511 **E:** sales@rigelmedical.com

USA Office

6304 Benjamin Road, Suite 506, Tampa, FL 33634, United States

T: +1 813 886 2775 **E:** sales@rigelmedical.com

rigelmedical.com