RIGEL
From SEAWARD

An Introduction to Defibrillator Testing (60601-2-4)

Agenda

History of Defibrillation

- Early 20th century 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.
- 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 counter shock.

Kouwenhoven's open-chest defibrillator

History of Defibrillation

- Beck was an expert in improving heart circulation. He had noticed that during cardiac surgery, the heart would occasionally go into VF.
- 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.
- In Moscow, 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.

Kouwenhoven's open-chest defibrillator

History of Defibrillation

- The 1950s-1960s led to improvements in defibrillator design.
  - Paul Zoll – a Boston cardiologist who experimented with external closed-chest cardiac pacing and AC defibrillation.
  - Dr. Bernard Lown – used DC for cardioversion, inventing the "cardioverter".
  - Bohumil Peleŝka – who optimized and improved Gurvich's DC defibrillation.
- From the 1960s to 1980s further advancements in technology paved the way for sophisticated defibrillators and pacemakers
- The final development in defibrillation was AEDs in the 1990s, a single-button automatic defibrillator that could be used by anyone, bettering the survival rate odds for OHCA patients

Kouwenhoven's open-chest defibrillator

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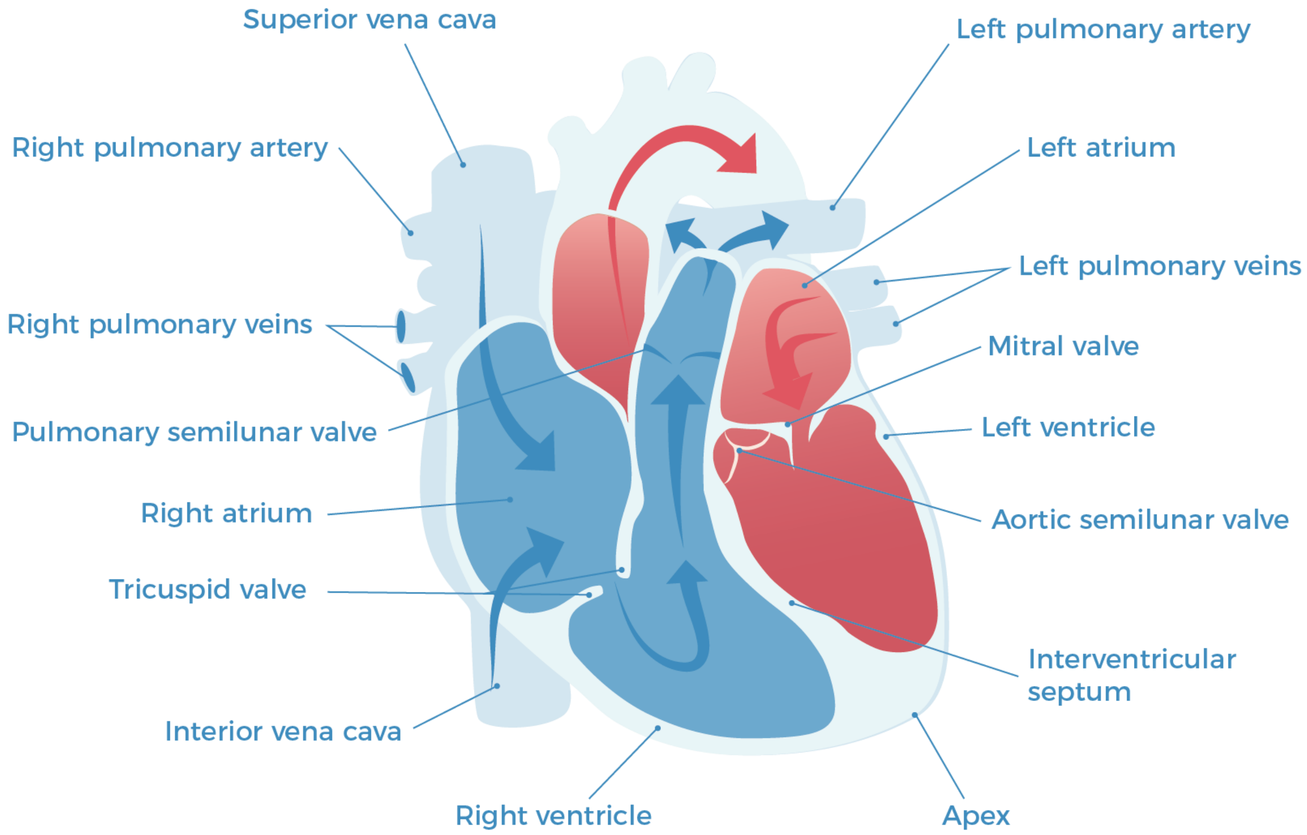
RIGEL From SEAWARD

1. Defibrillation - History and Theory
2. **Heart & Electrical Signals**
3. Definition & Use
4. Standard– IEC 60601-2-4
5. Defibrillator PM
6. Closing remarks

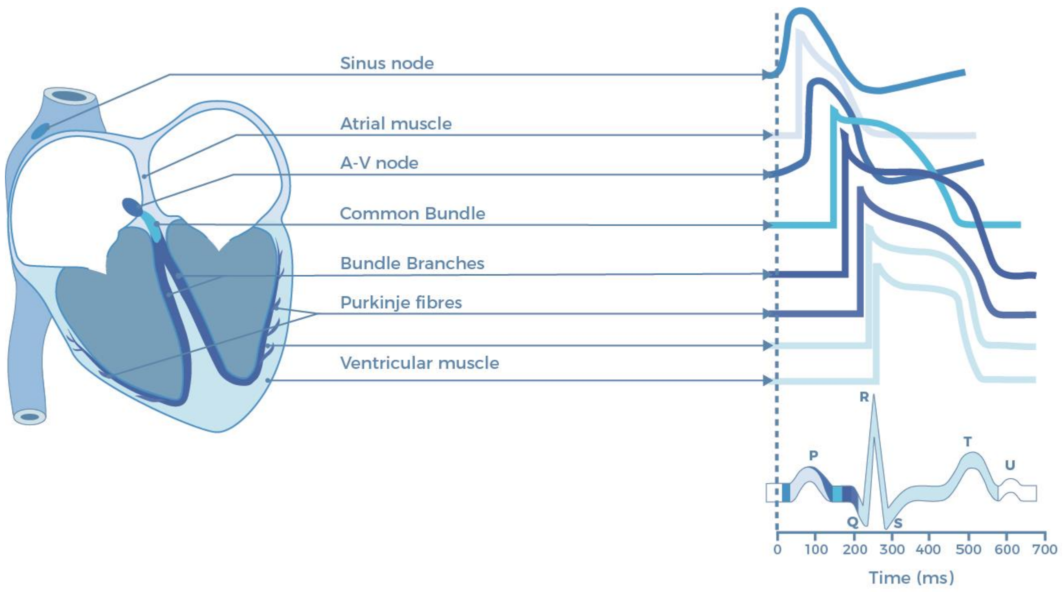
The Heart

- The heart has four chambers, the right and left atria, and the right and left ventricles comprised of cardiac muscle; myocardium.
- The electrical activity of the myocardium regulates the cardiac cycle.
    - The cardiac cycle is the simultaneous contraction (systole) of both atria's, followed by the contraction of both ventricles.
    - After ventricular systole the heart will relax (diastole) and the atria will fill with blood.
    - The right atrium returns deoxygenated blood from the upper and lower body to the right ventricle via the right atrioventricular (AV) valve.
    - As 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, the blood then passes the left AV valve to the left ventricle. When the left ventricle contracts, oxygenated blood is pumped past aortic semilunar valve, through the aorta to the upper and lower body

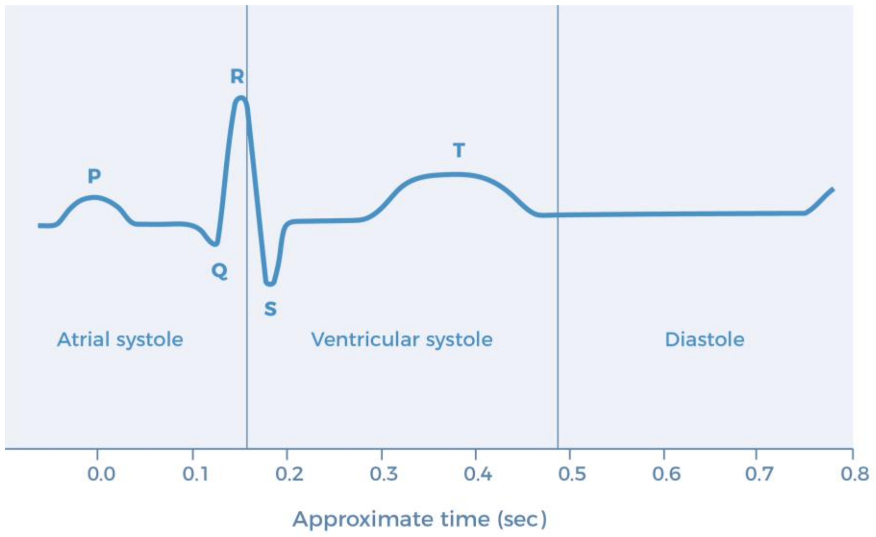
The Heart



Superior vena cava
Left pulmonary artery
Right pulmonary artery
Left atrium
Left pulmonary veins
Right pulmonary veins
Mitral valve
Pulmonary semilunar valve
Left ventricle
Right atrium
Aortic semilunar valve
Tricuspid valve
Interventricular septum
Interior vena cava
Right ventricle
Apex



Sinus node
Atrial muscle
A-V node
Common Bundle
Bundle Branches
Purkinje fibres
Ventricular muscle
R
P
T
U
Q
S
0 100 200 300 400 500 600 700
Time (ms)



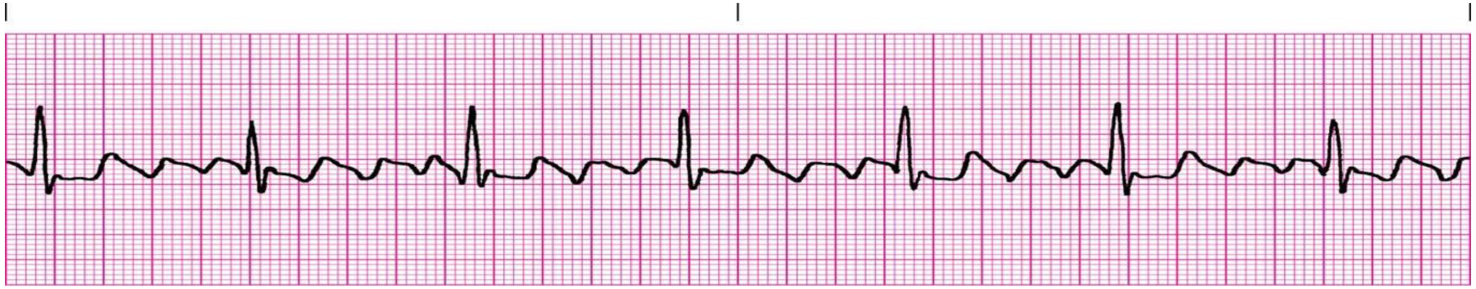
R
T
P
Q
S
Atrial systole
Ventricular systole
Diastole
0.0 0.1 0.2 0.3 0.4 0.5 0.6 0.7 0.8
Approximate time (sec)

Shockable Arrhythmias

- Ventricular Fibrillation (Fine) (VFF)
- Ventricular Fibrillation (Course) (VFC)
- Ventricular Tachycardia (VT)
  - (Pulseless)

The above produce no pulsating blood flow and require no synchronized defib pulse

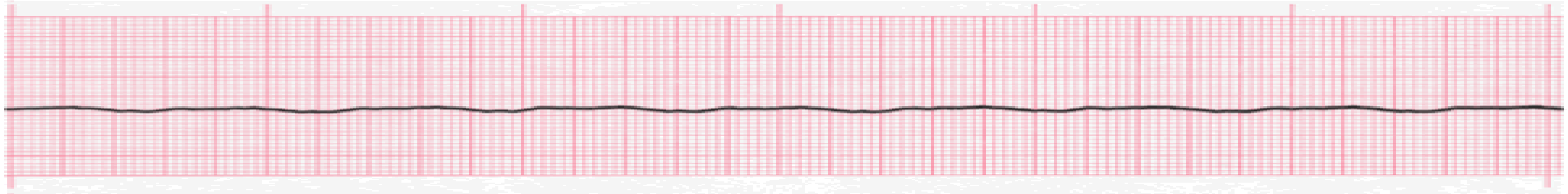
- Atrial Flutter (AFLT)
- Atrial Fibrillation (AFIB)
- Ventricular Tachycardia (VT)
  - (With pulse)



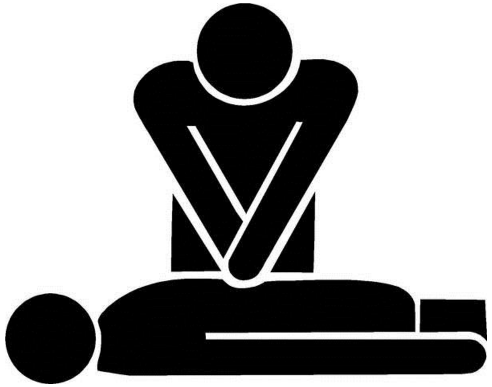
The above produce pulsating blood flow and require synchronized defib pulse

Non-Shockable Arrhythmias

- Asystole – the P-wave can still be present (flat line)

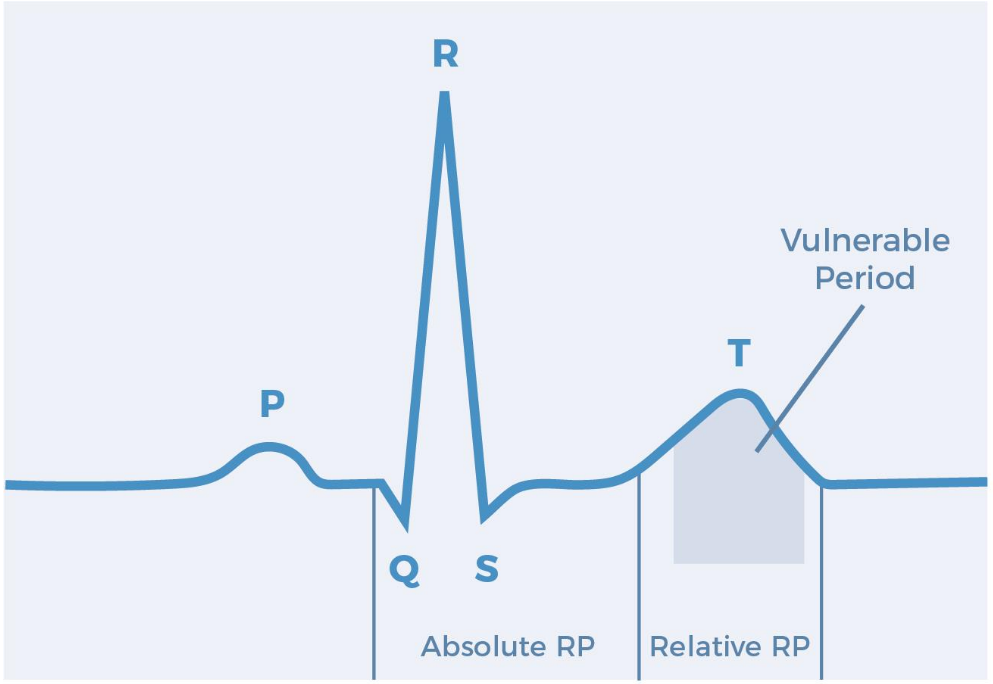


- Treatment possible through CPR and drugs to stimulate the heart into any electrical activity



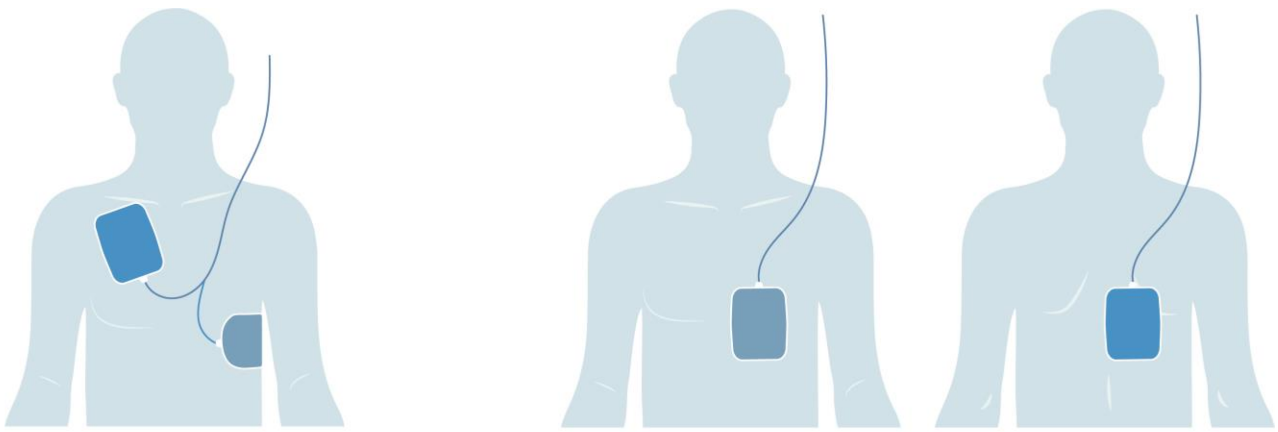
Cardiac Synchronization

- When the heart goes through a depolarization and repolarization process, it produces recognizable electrical cardiogram (ECG) wave forms, example shown below
- When a pulse is present, defibrillation shall not occur during the vulnerable period as this could lead to non-pulse fibrillation
- An electrical pulse must be delivered as close to the R-wave, thus synchronized.
- Delay typically between 10-30ms
- The defibrillator analyzer measures the delay between R-wave and energy delivery in milliseconds (ms)



Transcutaneous Pacing

- Applying a pulse of current up to 200mA non-invasively
- Typically for bradycardic patients
- Stimulate the myocardium
- Demand and non-demand (fixed)
- Anterior-Anterior, Anterior-Posterior placement



Anterior-Anterior Position

Anterior-Posterior Position

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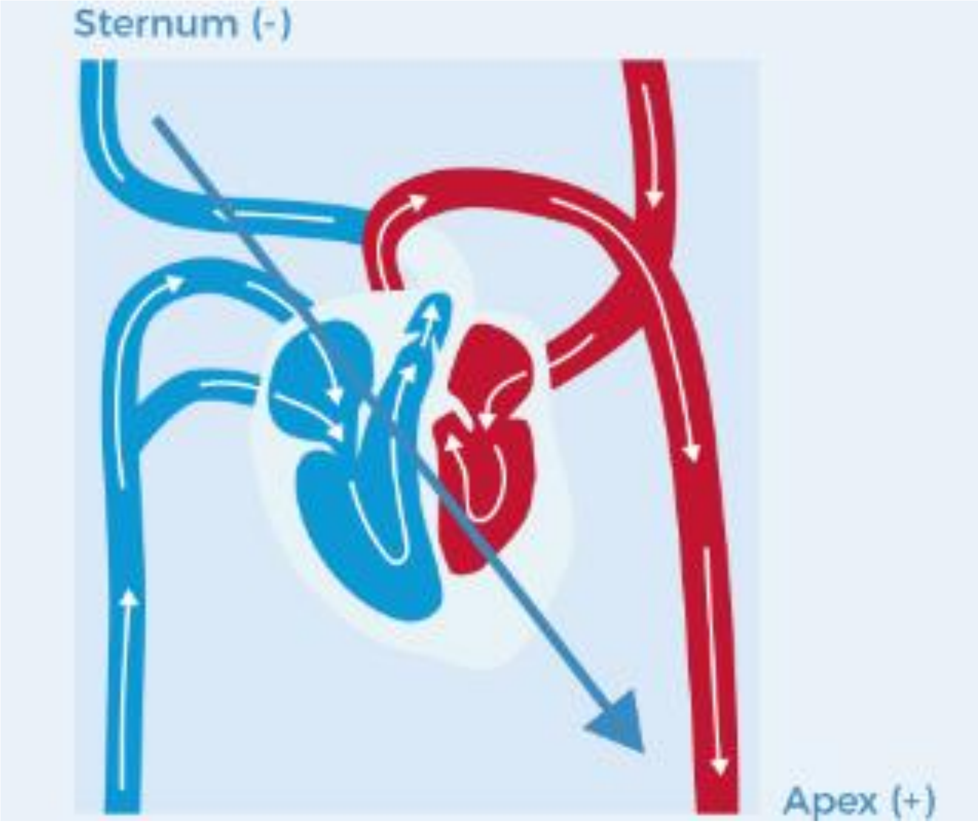
Definition

- **Defibrillation** is a treatment for life-threatening cardiac dysrhythmias, specifically ventricular fibrillation (VF) and non-perfusing ventricular tachycardia (VT). A **defibrillator** delivers a dose of electric current (often called a counter shock) to the heart.

What is Fibrillation?

- Uncontrolled (rapid) contractions of the heart muscles
- Atrial and Ventricular fibrillations
  - Atrial Fibrillation is not immediately life threatening
  - Ventricular Fibrillation severely affects or even stops the blood flow leading to cardiac arrest
- Rapid loss of consciousness, resulting in Asystole, followed by death if untreated immediately - window of opportunity up to 10 minutes!
- Atrial fibrillation can be treated with heart rate lowering drugs or electrical stimulation (defib – cardioversion)
- Ventricular fibrillation requires high energy source to “reset” the fibrillation (de-fibrillation)

What is defibrillation?



- Energy is across the heart, current flowing between the Atria to the Ventricles
- The paddles on an external defibrillator are placed from the sternum to 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

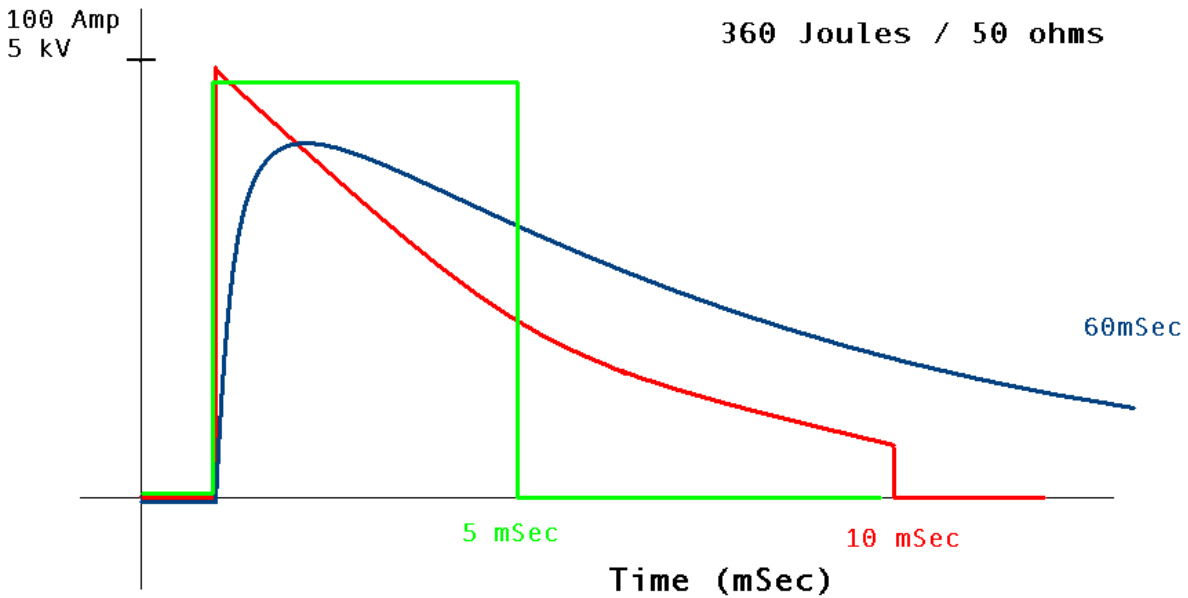
Defibrillation - Types of external defibrillators

- Advanced life support (ALS) – External defibs
  - All-in-one solution – pacing, vital signs monitoring, diagnostic ECG monitoring, and other optional features
  - Comprehensive medical devices used by emergency medical service (EMS) personnel
- Basic Life Support (BLS) – Automatic External Defibrillator (AED)
  - Can be operated by unskilled personnel
  - Basic functions
  - Algorithms to accurately evaluate cardiac rhythms
  - Will only shock VF or VT

Monophasic

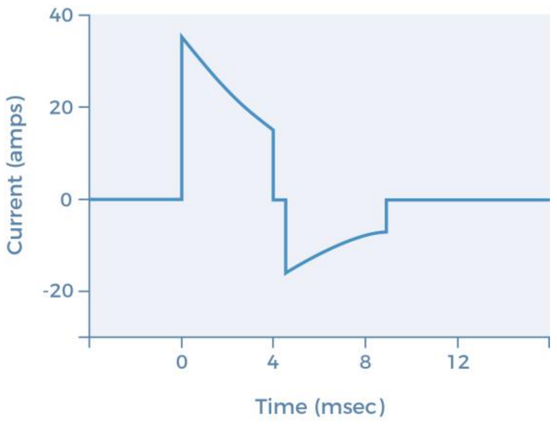
- Earlier type defibrillators
- Less effective
- Require higher energy
- Energy levels of 200 to 360J

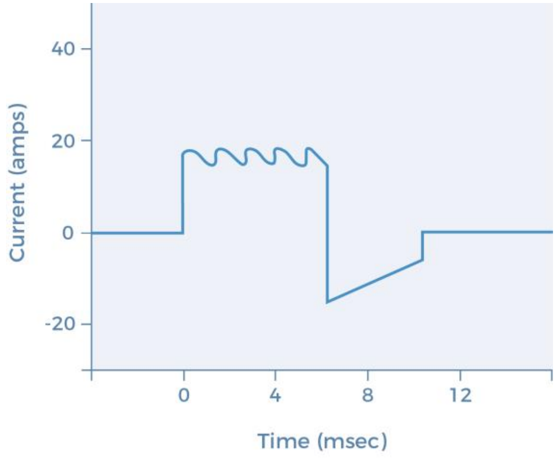
Different types of Monophasic waveforms

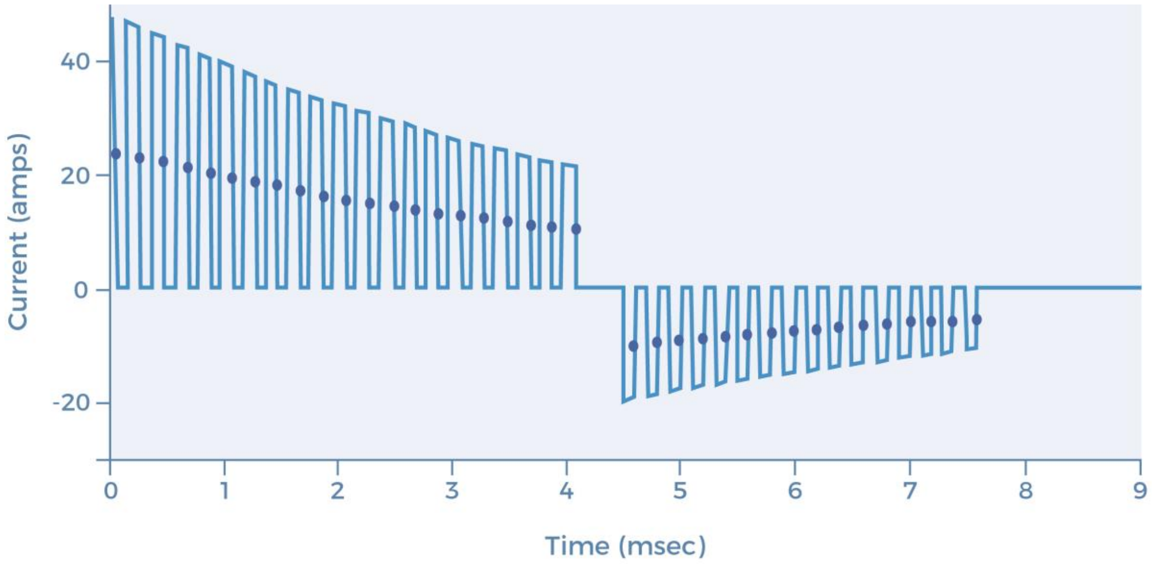


Biphasic

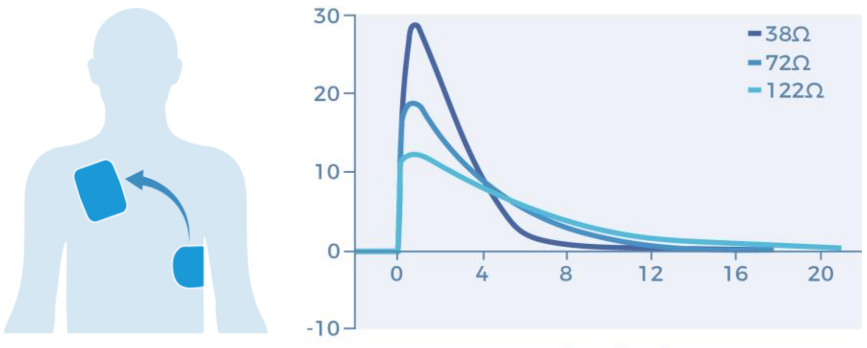
- More modern type defibrillators
- Energy levels up to 150-200J
- Manufacturers have their own patented biphasic technologies
    - Biphasic Truncated Exponential (BTE)
    - Rectilinear Biphasic Waveform (RBW)
    - Pulsed biphasic



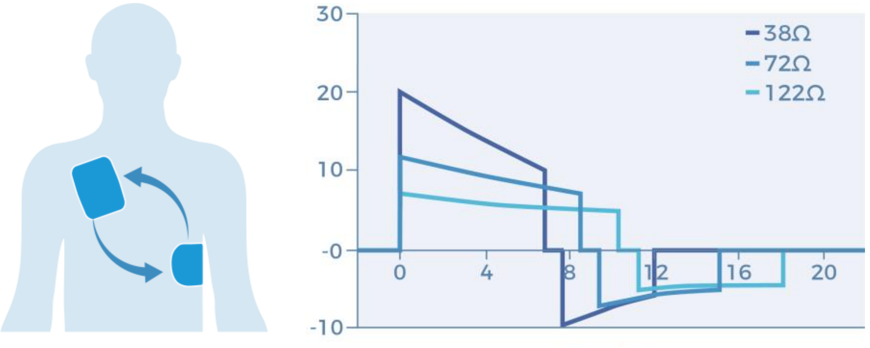




Monophasic vs Biphasic



Monophasic Waveform



Biphasic Waveform

Monophasic
- Damped sine wave with a high peak current
- 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
- Current flow is bidirectional
- Current waveforms adjust to maintain the delivered energy regardless of patient impedance - a patient will have equal chance of survival regardless of their impedance
- Lower energy delivered by biphasic devices can be as effective as higher energy monophasic devices
- Biphasic energy at 200 J or less can have equal or higher efficacy than monophasic energies of 200 to 360 J
- Using lower biphasic energy may result in less damage to the myocardium

Defibrillation

Myth

- Defibrillator starts the heart
- Used when flat-line

True

- A defibrillator briefly stops the heart
- Then the heart re-starts by itself
- Only possible when electrical activity is still present in the Myocardial muscles (i.e. no flat-line)

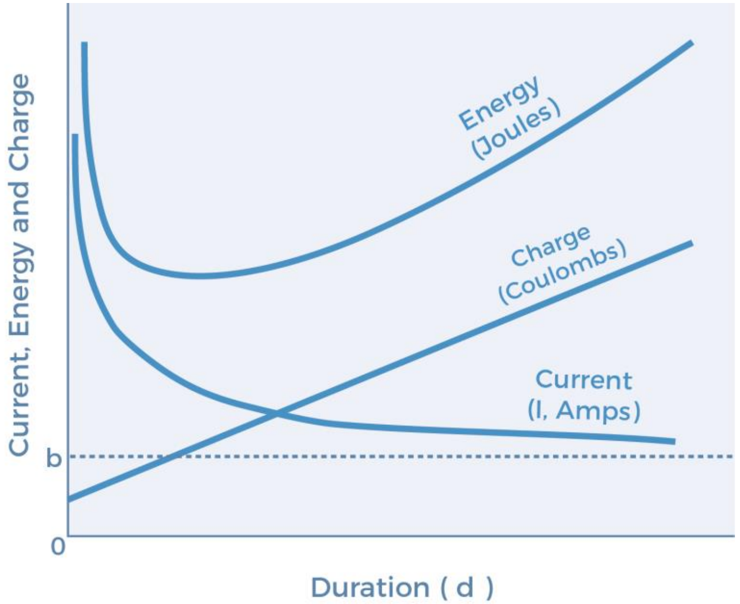
Joules of energy

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:

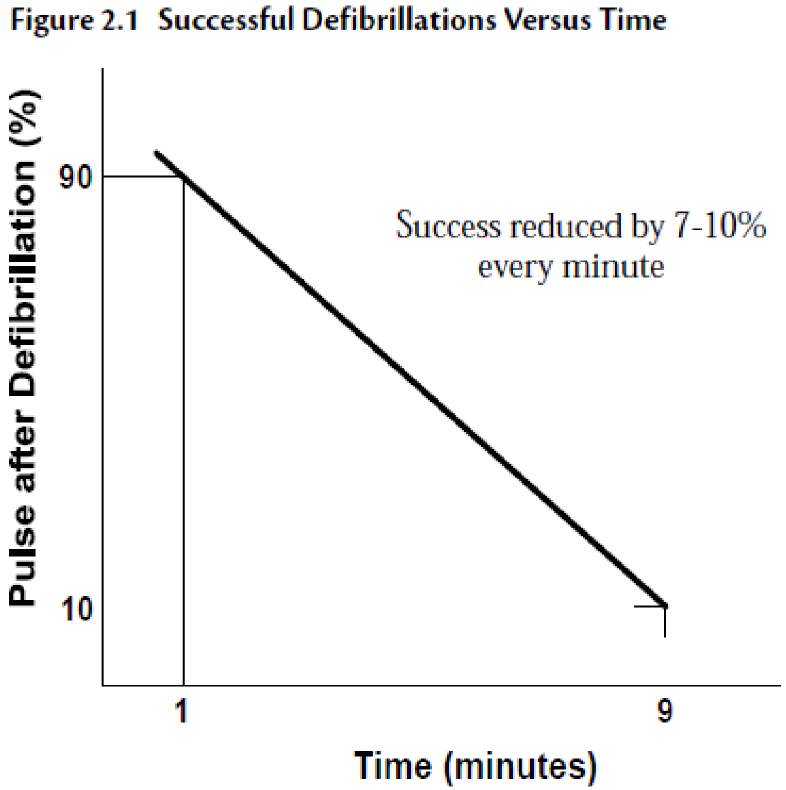
$$P = V \times I = \frac{V^2}{R} = I^2 \times R$$

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

$$\therefore 1\,joule = 1\,watt \times 1\,second$$



Time is of the essence



Source:

http://www.skillstat.com/PDF/mceElectric.pdf

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IEC 60601-2-4:2011

- 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 synchronized peak QRS complex to the peak delivered energy - differentiation and identification of shockable and non-shockable arrhythmia, and the accuracy of the pacing pulse rate, current and duration.

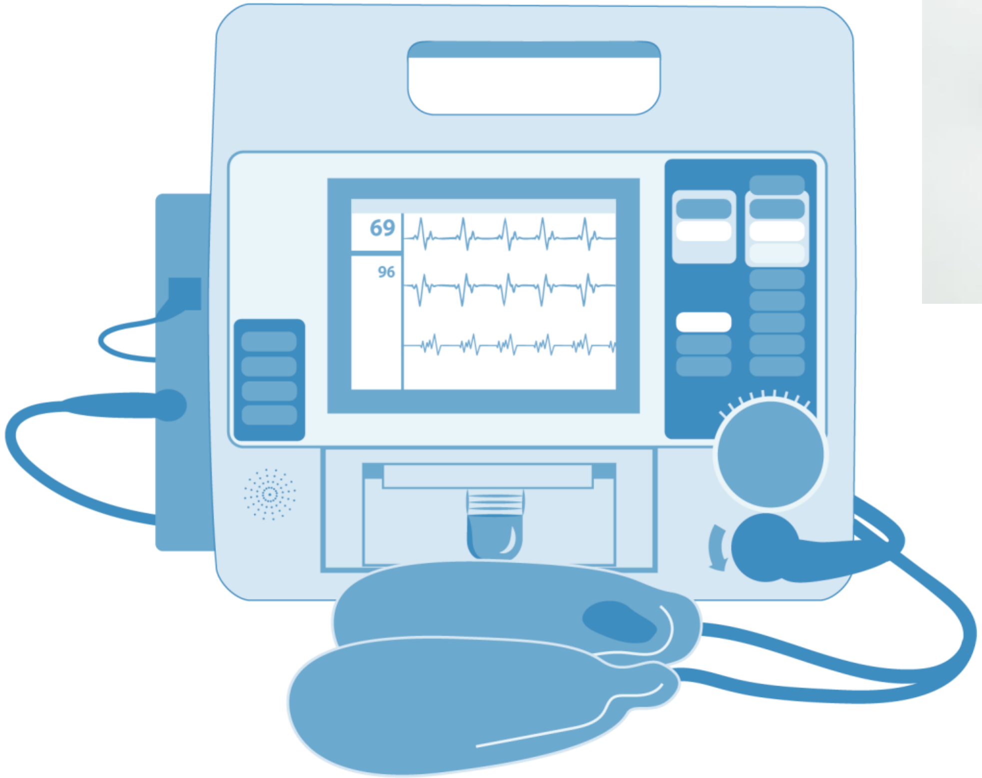
Agenda

Typical PM

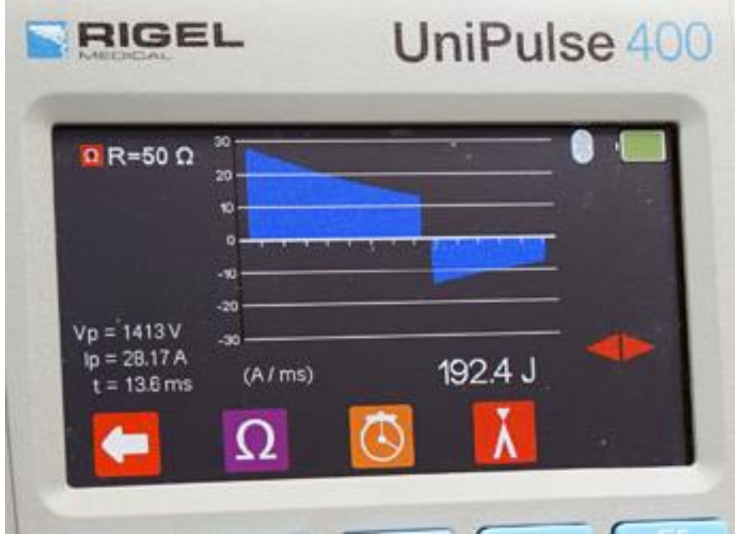
- Visual test
- Electrical safety Test
- Battery performance
- Alarms
- ECG performance
  - Amplitude gain
  - BPM rate verification
  - Frequency response
- Synchronization/cardioversion operation
  - Recording sync delay
- Energy output
  - Energy Linearity
  - Delivery after a specified time – typ. 1 minute @ max output
  - Charge time @ max output – typ. < 10 s
  - 10^{th} repetitive test @ max output
- Pacer output
  - Current linearity
  - Pulse width
  - PPM
- Paddle impedance check
- Printer
  - Paper speed
- Vital signs verification
  - SPO_2, NIBP, CO_2

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.

Video




RIGEL
UniPulse 400


RIGEL
MEDICAL
UniPulse 400
R=50 Ω
Vp = 1413 V
Ip = 28.17 A
t = 13.6 ms
(A / ms)
192.4 J

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Thank you for your time!

Q&A

Coming soon...
Guide to Defibrillator Testing

E-mail us at brittanys@rigelmedical.com for your e-copy

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