KPR Institute of Engineering and Technology
Learn Beyond
(Autonomous, Affiliated to Anna University)

KPR Center for Biomedical Equipment Testing and Calibration

Defibrillator Safety & Performance Testing

DUT (Device Under Test): _____

Objective: To collaboratively test and verify the safety and performance of a Defibrillator in various modes (Manual, Synchronized Cardioversion, Pacing) using a defibrillator analyzer, adhering to electrical safety and procedural standards.

Pre-settings: Ensure the analyzer and DUT are prepared and set ready for testing. Confirm electrical safety, proper lead connections, and correct analyzer mode selection.

Part A: Electrical Safety Tests (IEC 60601-1)

DUT Details: Model: _____ Serial No.: _____

Test Leads: Patient Cable Type: _____ Test Load: 50Ω

Test	Parameter / Mode on DUT	Measurement from Impulse D6000	Expected Range / Limit	Pass/Fail
Energy Accuracy Test	Manual Mode: Set: 50J, 100J, 200J Charge & Deliver	Measured Energy (J): 50J: _____ J 100J: _____ J 200J: _____ J	Tolerance: ±15% or ±4J (whichever is greater)	[ ] Pass [ ] Fail
Synchronized Cardioversion	Sync Mode: Set: 50J Sync to R-wave & Deliver	Energy Delivered: _____ J Sync Delay: _____ ms	Energy: ±15% Delay: < 60 ms from R-wave	[ ] Pass [ ] Fail

Team Observations & Troubleshooting Notes:

_____
_____
_____
_____
_____
_____

Charge Time Test

Time taken to charge to selected energy

Energy Setting	Maximum Allowable Charge Time	Measured Charge Time	Pass/Fail
50 J	15 seconds	_____ sec	[ ] Pass [ ] Fail
100 J	15 seconds	_____ sec	[ ] Pass [ ] Fail
150 J	15 seconds	_____ sec	[ ] Pass [ ] Fail
200 J	20 seconds	_____ sec	[ ] Pass [ ] Fail

Custom ECG Waveform Generation for performance test

Test	Custom Waveform Parameters (Generated in Impulse D6000)	Expected Result	Pass/Fail
1. VF Detection - Fine Fibrillation	Amplitude: **0.2-0.5 mV**	Shock Advised = **Yes** Time < 15 sec	[ ] Pass [ ] Fail
2. VF Detection - Coarse Fibrillation	Amplitude: **1.0-2.0 mV**	Shock Advised = **Yes** Appropriate energy	[ ] Pass [ ] Fail
3. VT with Pulse Simulation	Rate: **180 bpm**	Manufacturer dependent (Often "No Shock")	[ ] Pass [ ] Fail
4. Asystole Detection	Flatline: **< 0.1 mV**	"No Shock Advised" CPR Prompt = Yes	[ ] Pass [ ] Fail
5. Sinus Rhythm + Artifact	NSR 80 bpm + **Motion Artifact**	Should NOT advise shock	[ ] Pass [ ] Fail

AED Algorithm Performance Scoring

Rate the AED's performance on each custom waveform (1=Poor, 5=Excellent)

Waveform Type	Detection Accuracy	Analysis Speed	Overall Score
Fine VF	[1] [2] [3] [4] [5]	[1] [2] [3] [4] [5]	_____ / 10
Coarse VF	[1] [2] [3] [4] [5]	[1] [2] [3] [4] [5]	_____ / 10
Any other arrhythmia	[1] [2] [3] [4] [5]	[1] [2] [3] [4] [5]	_____ / 10
Noisy Signal	[1] [2] [3] [4] [5]	[1] [2] [3] [4] [5]	_____ / 10
TOTAL			**_____ / 40**

Post-Test Analysis & Reporting

Data Analysis:

Did any test point fail? If yes, what could be the potential causes?

Error Sources:

List three potential sources of error in defibrillator testing:

Clinical Significance:

Why is energy accuracy (±15%) critical in defibrillation?

Team Handover & Summary:

- Defibrillator model tested: _____
- Overall result (All Pass / Fail at X test): _____
- One key challenge faced and how it was resolved: _____