Test Sequence

Defibrillator Functional – IEC 60601-2-4 (v1.0)

Template	Defibrillator Functional – IEC 60601-2-4
Version	1.0
Created	2025-10-02 11:02
Created By	Seed

Test Steps

#	Step / Instruction	Type	Limits	Unit	Actual / Pass
1	**Visual Inspection** Inspect casing, leads, electrodes, controls, and labels for integrity. Ref: IEC 60601-2-4 / Manufacturer	Yes/No Check	-	-	_____
2	**Protective Earth Continuity** Measure resistance from earth pin to accessible conductive parts. Ref: IEC 60601-1 / IEC 62353	Measurement	0.2 Ω ±0.2	Ω	_____
3	**Enclosure Leakage Current (NC)** Measure enclosure leakage in normal condition. Ref: IEC 60601-1	Measurement	500 µA ±500	µA	_____
4	**Enclosure Leakage Current (SFC)** Apply single fault condition per test regime and measure leakage. Ref: IEC 60601-1	Measurement	1000 µA ±1000	µA	_____
5	**Applied-Part Leakage (NC)** Measure patient/applied-part leakage in normal condition. Ref: IEC 60601-1	Measurement	100 µA ±100	µA	_____
6	**Applied-Part Leakage (SFC)** Simulate single fault condition (e.g., open PE) and measure leakage. Ref: IEC 60601-1	Measurement	500 µA ±500	µA	_____
7	**Insulation Resistance** Measure insulation resistance between mains and applied parts. Ref: IEC 60601-1	Measurement	2 MΩ ±0	MΩ	_____
8	**Delivered Energy @ 200 J** Charge to 200 J and discharge into analyzer; record delivered energy. Ref: IEC 60601-2-4:2010 §201.12.4.101	Measurement	200 J ±15% ±1	J	_____
9	**Delivered Energy @ Maximum** Charge to maximum selectable energy (e.g., 360 J) and verify delivered energy. Ref: IEC 60601-2-4:2010 §201.12.4.101	Measurement	360 J ±15% ±1	J	_____
10	**Charge Time @ 200 J** Measure time to charge to 200 J. Ref: Manufacturer / IEC 60601-2-4	Measurement	10 s ±10	s	_____
11	**Charge Time @ Maximum** Measure time to charge to maximum energy (e.g., 360 J). Ref: Manufacturer / IEC 60601-2-4	Measurement	15 s ±15	s	_____
12	**Charge Cancel / Disarm** Verify charge cancellation and safe disarm into the load. Ref: IEC 60601-2-4	Yes/No Check	-	-	_____
13	**Sync Function (R-Wave Delay)** Verify synchronisation to R-wave; measure sync delay. Ref: IEC 60601-2-4	Measurement	60 ms ±60	ms	_____
14	**Energy Accuracy Across Loads** Verify delivered energy remains within tolerance across 25–175 Ω loads. Ref: IEC 60601-2-4	Yes/No Check	-	-	_____
15	**Maximum Energy Verification** Confirm maximum selectable energy output meets tolerance across specified loads. Ref: IEC 60601-2-4	Yes/No Check	-	-	_____
16	**Defibrillator Proof Test** Verify device withstands defibrillator proof test pulses as specified. Ref: IEC 60601-2-4	Yes/No Check	-	-	_____
17	**Pacing Output Current (if equipped)** Set nominal pacing current and measure output.	Measurement	4 mA ±10%	mA	_____

Test Sequence

Defibrillator Functional – IEC 60601-2-4 (v1.0)

#	Step / Instruction	Type	Limits	Unit	Actual / Pass
	Ref: IEC 60601-2-31 / Manufacturer				
18	**Pacing Rate Accuracy (if equipped)** Set pacing rate (e.g., 60 bpm) and verify measured rate. Ref: IEC 60601-2-31 / Manufacturer	Measurement	60 bpm ±5%	bpm	_____
19	**ECG Display Calibration** Verify ECG amplitude calibration using a standard calibration signal. Ref: IEC 60601-2-4 / -2-27	Measurement	1 mV ±0.1	mV	_____
20	**Heart Rate Accuracy** Simulate ECG at known rates and verify displayed heart rate. Ref: IEC 60601-2-27	Measurement	60 bpm ±5%	bpm	_____
21	**Arrhythmia Detection** Simulate VF/VT/asystole/brady/tachy and verify correct detection/alarms. Ref: IEC 60601-2-27 / Manufacturer	Yes/No Check	-	-	_____
22	**Alarm Functionality** Verify audible/visual alarms activate appropriately for critical conditions. Ref: IEC 60601-2-4 / -2-27	Yes/No Check	-	-	_____
23	**Impedance / Lead-Off Detection** Verify patient impedance checks and lead-off detection operate correctly. Ref: IEC 60601-2-4	Yes/No Check	-	-	_____
24	**Battery Performance** Verify charge/discharge behaviour and runtime under load per manufacturer spec. Ref: Manufacturer	Yes/No Check	-	-	_____
25	**Data Logging / Printer Output** Verify event logs and printed outputs are complete and accurate. Ref: Manufacturer	Yes/No Check	-	-	_____