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Defibrillator

Technical Specification

1. SYSTEM OVERVIEW

Equipment

Portable defibrillator with integrated:

- Manual Defibrillation
- Automated External Defibrillator (AED)
- Synchronized Cardioversion
- External Non-Invasive Pacing
- Multi-parameter Patient Monitoring
- Integrated Thermal Recorder

Intended Patient Population

Suitable for adult and pediatric patients. Vendors shall declare any patient limitations.

Clinical Applications

Suitable for:

- Emergency Department
- ICU/CCU
- Operating Theatre
- Ambulance and Patient Transport

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2. DEFIBRILLATION

The device shall provide:

- Biphasic waveform technology with automatic impedance compensation
- Manual Defibrillation
- AED mode with voice and visual prompts
- Synchronized Cardioversion
- Monitoring mode

Performance

- Energy range: 1 J (or lower) to at least 270 J
- User-selectable energy levels
- Configurable escalating energy protocol
- Charge time to maximum energy: ≤5 seconds from a fully charged battery
- Automatic impedance measurement and compensation across a minimum range of 25–175 Ω
- Delivered energy accuracy: within ±15% or ±4 J of selected energy

Safety

- Automatic discharge of stored energy
- Shock-ready indication
- Audible and visual charging indicators

- ECG synchronization marker
- Continuous internal self-test
- Event logging of all shocks

Accessories

- Reusable adult paddles
- Pediatric paddles or attenuation system
- Multifunction disposable pads suitable for defibrillation, cardioversion, pacing, and ECG monitoring

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3. PATIENT MONITORING

Display

- Minimum 6.5-inch high-resolution color TFT/LCD display
- Adjustable brightness
- Sunlight-readable
- Minimum resolution 800 × 480
- Minimum four simultaneous waveforms
- Freeze, trend, and waveform review

ECG

- 3- and 5-lead ECG monitoring
- Heart rate display
- Pacemaker detection
- Lead-off detection
- Defibrillation-protected ECG inputs with signal recovery within 5 seconds of a maximum-energy shock
- 12-lead ECG acquisition, interpretation, and ST analysis (preferred)
- Frequency response: 0.05–150 Hz (diagnostic mode); 0.5–40 Hz (monitoring mode)
- CMRR: ≥89 dB at 50/60 Hz
- Input impedance: ≥10 MΩ at 10 Hz

SpO_2

- Range: 0–100%
- Motion and low-perfusion tolerant technology preferred

NIBP

- Automatic, Manual, and STAT modes
- Adult, pediatric, and neonatal capability
- Accuracy: ±3 mmHg

Alarms

Audible and visual alarms for physiological limits, lead/pad disconnection, battery status, technical faults, and sensor faults with adjustable alarm volume and silence function.

4. EXTERNAL PACING

- Demand and Fixed pacing modes
- Adjustable pacing rate: minimum 30–180 ppm
- Adjustable output current: minimum 0–200 mA
- Adjustable pulse width: minimum range 20–40 ms
- Vendor shall declare pacing waveform shape (monophasic or biphasic)
- Visual pacing capture indication on display waveform

- Pacing via multifunction pads

5. CPR ASSISTANCE (Preferred)

- Real-time CPR feedback
- Compression rate and depth monitoring
- CPR metronome
- CPR quality review

6. DATA MANAGEMENT

Recorder

- Integrated thermal printer
- Continuous and event recording
- Paper width: 50 mm or 80 mm (vendor to declare)

Storage

- Minimum 500 event memory
- Waveform and trend storage
- Event timestamps including shock delivery time, selected energy, delivered energy, and patient impedance

Connectivity

- USB (minimum USB 2.0)
- Ethernet
- Wireless connectivity preferred
- PDF/Event data export
- HL7 compatibility preferred

7. USER INTERFACE

- Dedicated hard keys for critical functions
- Rotary control and/or touchscreen
- AED voice and visual guidance
- English language interface

8. POWER SUPPLY

AC Power

- 100–240 V AC, 50/60 Hz
- Hospital-grade BS 1363 (Type G) plug

Battery

- Rechargeable Lithium-ion battery
- Minimum 4 hours continuous monitoring or 200 maximum-energy shocks
- Battery status and charging indicators
- Low battery alarm
- Hot-swappable battery preferred
- Recharge time ≤4 hours

9. PHYSICAL REQUIREMENTS

- Compact, lightweight, and portable
- Durable impact-resistant housing
- Suitable for transport trolley and ambulance mounting
- IP44 or higher ingress protection rating
- Weight ≤8 kg including battery (preferred)

- Operating temperature: minimum 15°C to +40°C

10. SELF-TEST

Automatic daily self-test including:

- Defibrillation circuitry
- Battery status and capacity
- Charging system
- ECG acquisition
- Internal memory
- System integrity

11. STANDARD ACCESSORIES

Supply shall include:

- Adult reusable paddles – 1 set
- Pediatric paddles or attenuation system – 1 set
- Adult multifunction defibrillation/cardioversion/pacing/ECG electrodes – minimum 10 pairs
- Pediatric multifunction defibrillation/cardioversion/pacing electrodes – minimum 2 pairs (if applicable)
- ECG patient cable – 1
- Adult reusable SpO_2 sensor – 1
- Adult NIBP cuff and hose – 1
- Rechargeable battery – 1 installed
- AC power cord – 1
- Thermal paper – minimum 50 rolls
- Carry case or transport trolley – 1 (where applicable)

Optional:

- Pediatric SpO_2 sensor
- Pediatric NIBP cuff
- Pediatric multifunction pads
- Additional battery

12. CLEANING

- Reusable accessories compatible with hospital disinfectants
- Disposable accessories supplied sterile where applicable

13. STANDARDS & REGULATORY COMPLIANCE

The equipment shall comply with the latest applicable versions of:

- ISO 13485 — Quality management systems for medical devices
- ISO 14971 — Risk management for medical devices
- IEC 60601-1 — General safety and essential performance
- IEC 60601-1-2 — Electromagnetic compatibility
- IEC 60601-1-6 — Usability
- IEC 60601-1-8 — Alarm systems
- IEC 60601-2-4 — Cardiac defibrillators
- IEC 62366 — Usability engineering

The device shall be CE marked under EU MDR 2017/745 and/or US FDA 510(k) cleared.

14. TRAINING

- Supplier shall provide:
- Clinical user training covering all operational modes
- Biomedical engineering training covering preventive maintenance, calibration, and fault diagnosis
- Operational checks and preventive maintenance procedures training
- Training documentation in English

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15. WARRANTY & SUPPORT

- Minimum 12-month comprehensive warranty covering parts, labor, and software
- Preventive maintenance during warranty period at intervals declared by vendor
- Software updates provided at no cost during warranty period
- Local technical support with declared maximum response time for breakdown
- Spare parts availability guaranteed for a minimum of 10 years from date of supply

16. DOCUMENTATION

The following shall be supplied in English:

- User Manual
- Service Manual
- Preventive Maintenance Procedures
- Electrical Safety Test Report
- Calibration Certificate
- Spare Parts Catalogue
- Compliance Certificates

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17. INSTALLATION

Supplier shall provide delivery, installation, commissioning, functional testing, user acceptance testing, and demonstration of operational readiness.