



Product Specification – Mediana A16 Core HeartOn AED

Product Information

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| REF: | 2941, 2942 |
| Supplier Model Numbers: | A16M-DS-0E Semi-automatic (2941) A16M-DF-0E fully automatic (2942) |
| Notes: | Models not compatible with optional CPR Module Models not Compatible with Pads Quality feature |
| Description: | Mediana A16 Core HeartOn AED |
| Distributor: | Reliance Medical LTD |
| Address: | West Avenue, Talke, Stoke-on-Trent, Staffordshire, ST7 1TL, United Kingdom. |
| Manufacturer: | Mediana Co. Ltd |
| Address: | Mediana Building 4F 53, Donggwang-ro (Bangbae-dong), Seocho-gu Seoul 06561, South Korea |
| Country of Origin: | South Korea |
| Commodity Code: | 9018.90.2090 |
| Product Weight: | 3.00kg |
| Characteristics: | Pace Pulse detection & rejection function Super fastest shock delivery time Adult/Pediatric Mode Switch Voice prompt, Action Icon (LED) Indicator, Status LCD Self-test: POST (Power On Self-Test), Periodic Test (Daily, Weekly, Monthly) BIST (Battery Insertion Self-Test) |
| Storage Conditions: | Operation: 0 to 43°C (32 to 109.4°F) Storage: 0 to 43°C (32 to 109.4°F) |



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| Warranty: | 60 months |
| Battery weight: | 250g |
| Battery composition: | LiMnO2 |
| WEE Weight: | 1860g |
| Medical device class: | IIb (MDD transitioning to MDR) |
| MHRA Registered: | yes |

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| EUDAMED Registered: | yes |
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Shipping Information

| UNIT | QUANTITY | PACKAGING DIMENSIONS | | | GROSS WEIGHT |
|---------------------|----------|----------------------|-----|-----|--------------|
| | | mmL | mmW | mmH | |
| Single Unit: | 1 | 350 | 320 | 170 | 3kg |

Physical Specifications

HeartOn A16 Automated External Defibrillator

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| Dimensions | 200 × 286.5 × 90 (mm) (W×H×D) |
| Weight | Approx. 1.95 kg including the battery |
| Degree of Protection against Electric Shock | Pads: Type |
| Environmental Conditions Operation/Standby | |
| Temperature | 0 to 43°C (32 to 109.4°F) |
| Relative Humidity | 5 to 95% RH (Non-condensing) |
| Altitude | 0 to 4,575 m |
| Shock | Acceleration: 100 G (+/- 10%) Time: 6 msec The number of shocks: 3 times/axis (6 axes (+/- X, Y, Z)) |
| Vibration | Frequency: 10Hz to 2000Hz Acceleration: 10 Hz to 100 Hz: 5,0 (m/s ²)/Hz 100 Hz to 200 Hz: -7 dB per octave 200 Hz to 2000 Hz: 1,0 (m/s ²)/Hz |
| Drop height | 0.75m |
| Water and dust resistance | IP55 (IEC60529) |
| Note: The Standby condition indicates that the self-test periodically runs with installed battery in the AED. | |
| Storage (in shipping container) | |
| Temperature | -20 to 60°C (-4 to 140°F) |
| Relative Humidity | 5 to 95% RH (Non-condensing) |
| Altitude | 0 to 12,192 m |
| Self-Test | |
| Temperature | 0 to 43°C (32 to 109.4°F) |
| Cycle | Every 24 hours, 1 week, 1 month Power on self-test, Battery insertion self-test |

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| Test result | Status LCD displays "O" / "X". |
| <u>Note: Only when the battery is installed, self-test will be activated.</u> | |
| Data Backup and Communication Standard | SD card (Option), Infrared communication port |
| Expected Service Life | 10 years |

Accessories Specifications

Pads Adult / Pediatric Pads

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| Reliance Medical Ref: | 2902 |
| Shelf life | 3 years |
| Electrodes | Disposable pads |
| Placement | Adult: Anterior-lateral Pediatric: Anterior-posterior |
| Minimum active gel area | 80 cm ² +/-5% |
| Cable length | About 1.8 m |
| Environmental Conditions | |
| Temperature | Operation: 0 to 43°C (32 to 109.4°F) Storage: 0 to 43°C (32 to 109.4°F) |
| Relative Humidity | 5 to 95% RH (Non-condensing) |

Battery

| | |
|---------------------------------------|---|
| Reliance Medical Ref: | 2905 |
| Type | LiMnO ₂ , Disposable, Long-Life Primary Cell |
| Voltage/Capacity | 15V, 3000 mAh |
| Shelf Life(in the original packaging) | 2 years from manufacture date |
| Standby Life (inserted in the AED) | 5 years from manufacture date |

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| Discharge | A minimum of 200 shocks (excepting the CPR period between the defibrillation therapy) or more than 6 hours of operating time at 20°C |
| Environmental Conditions | |
| Temperature | Operation: 0 to 43°C (32 to 109.4°F) Storage: 10 to 25°C (50 to 77°F) |
| Relative Humidity | 5 to 95% RH (Non-condensing) |

Defibrillation waveform

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| <p>Waveform parameters</p> | <p>Waveform parameters are automatically adjusted as a function of patient defibrillation impedance. In the diagram at left, A is the width of pulse 1 and B is the width of pulse 2 of the waveform, C is the inter-pulse delay, I_p is the peak current, and I_f the final current.</p> <p>The AED delivers shocks to load impedances from 25 to 200 ohm. The duration of each pulse of the waveform is dynamically adjusted based on delivered charge, in order to compensate for patient impedance variations, as shown below:</p> |
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| Adult defibrillation | | | |
|------------------------------|--------------------|--------------------|----------------------|
| Load Resistance (Ω) | Pulse width 1 (ms) | Pulse width 2 (ms) | Delivered Energy (J) |
| 25 | 3.3 | 3.1 | 195 |
| 50 | 4.7 | 4.1 | 190 |
| 75 | 6.7 | 4.7 | 185 |
| 100 | 8.3 | 5.9 | 195 |
| 125 | 9.7 | 6.7 | 190 |
| 150 | 11.3 | 7.9 | 185 |

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| 175 | 11.7 | 8.7 | 180 |
| 200 | 11.7 | 8.7 | 170 |
| Pediatric defibrillation | | | |
| Load Resistance (Ω) | Pulse width 1 (ms) | Pulse width 2 (ms) | Delivered Energy (J) |
| 25 | 3.3 | 3.1 | 51 |
| 50 | 4.7 | 4.1 | 50 |
| 75 | 6.7 | 4.7 | 49 |
| 100 | 8.3 | 5.9 | 51 |
| 125 | 9.7 | 6.7 | 50 |
| 150 | 11.3 | 7.9 | 49 |
| 175 | 11.7 | 8.7 | 47 |
| 200 | 11.7 | 8.7 | 44 |
| Charging Time | < 10 seconds typical (with new battery) | | |
| After 6 discharges, the maximum time from the initiation of rhythm analysis with a clear ECG signal to readiness for discharge | Approx. 12 seconds | | |
| After 6 discharges, initially switching power on to ready for discharge at maximum energy | Approx. 21 seconds | | |
| Shock Analysis Time | < 8 seconds typical Note: Shock analysis would take about 16seconds at maximum from the start to the completion of analysis if ECG signal is interfered by motion or others. | | |
| Disarm | The AED constantly detects ECG signals from after the ECG analysis to before delivering the shock.If the ECG rhythm changed to a nonshockable rhythm, the shock energy that is accumulated on the high-voltage capacitor will be disarmed through internal resistance.If the shock button is not pressed during 20 seconds, the shock energy that is accumulated on the high-voltage capacitor will be disarmed through internal resistance. | | |

ECG Analysis Performance

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| Rhythm class | AHA-DB | MIT-DB | CU-DB | VF-DB | VT-DB | Total number of sample size |
|--|--------|--------|-------|-------|--------|-----------------------------|
| VF-shockable : TP | 988 | 22 | 282 | 908 | - | 2200 |
| VF-shockable : FN | 44 | 0 | 7 | 23 | - | 74 |
| VF-shockable : sensitivity(%) | 95.74 | 100.00 | 97.58 | 97.53 | - | 96.75 |
| Adult mode VT-shockable : TP | - | - | - | 701 | - | 701 |
| Adult mode VT-shockable : FN | - | - | - | 66 | - | 66 |
| Adult mode VT-shockable : sensitivity(%) | - | - | - | 91.40 | - | 91.40 |
| Pediatric mode VT-shockable : TP | - | - | - | - | 18 | 18 |
| Pediatric mode VT-shockable : FN | - | - | - | - | 3 | 3 |
| Pediatric mode VT-shockable : sensitivity(%) | - | - | - | - | 81.82 | 81.82 |
| Non-shockable : TN | 32291 | 17518 | 1267 | 7062 | - | 58138 |
| Non-shockable : FP | 0 | 2 | 8 | 33 | - | 43 |
| Specificity(%) | 100.00 | 99.99 | 99.37 | 99.53 | - | 99.93 |
| Positive Predictive Value | 100.00 | 91.67 | 97.24 | 97.99 | 100.00 | 98.55 |

Database for ECG Analysis

- From AHA (American Heart Association) official database
- From MIT (Massachusetts institute Technology) official database(CU-DB: The Creighton University Sustained Ventricular Arrhythmia Database,VF-DB, VT-DB: MIT-BIH Malignant Ventricular Arrhythmia Database)

ECG rhythm to determine if a shock is appropriate

- Ventricular Fibrillation at a amplitude greater than or equal to 0.2mV.
- Ventricular Tachycardia at a heart rate greater than or equal to 150 bpm(Adult) / 180 bpm (Pediatric).

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