FLUKE®
Biomedical

Technical data

# ESA615
# Electrical Safety Analyzer

The ESA615 Electrical Safety Analyzer brings fast and simple automated testing to a portable analyzer for healthcare technology management professionals that perform electrical safety testing on medical equipment both in the field and in facilities. Whether it is simple testing or comprehensive analysis, the ESA615 can do it all. This multifaceted device performs all primary electrical safety tests, including line (mains) voltage, ground wire (protective earth) resistance, insulation resistance, device current, and lead (patient) leakage tests. It also offers ECG simulation and point–to-point voltage, leakage, and resistance tests. Versatile to global electrical safety standards of choice, ESA615 tests to ANSI/AAMI ES1, NFPA-99, IEC62353 (VDE751) IEC60601-1 (2nd and 3rd editions) and AS/NZS 3551. The ESA615 is an all-in-one solution with a safety analyzer and ECG simulator in a single test instrument.

## Key features

- Portable, ergonomic design with an integrated handle and tilt stand
- On-board automation with automated test sequences for easy compliance to key global electrical safety standards (ANSI/AAMI ES-1 (NFPA-99), IEC62353 (VDE751), IEC60601-1 2nd and 3rd editions, and AS/NZS 3551)
- User-friendly interface for streamlined testing
- ECG waveform tests and dual-lead measurements combine the functionality of a simulator and safety analyzer in a single test tool
- Five applied parts jacks and easy ECG snap connection; optional expander box for up to 12-lead ECG testing
- Easy data entry through barcode external keyboard or on-board keypad
- Wireless communication plus removable memory card for fast and convenient data storage and exchange
- 20 A at 120 V current capability
- Replaceable mains fuses keep your unit in the field and out of the repair shop
- Custom language selections include: English, French, German, Spanish, Italian and Portuguese
- Rigorously tested for rugged field applications with CE and CSA in addition to Fluke-quality-ruggedness for long-term reliability
- Two-year extended warranty (no-cost available after first-year calibration at any authorized Fluke Biomedical Service Center)
- Global support network delivering prompt service and peace of mind to Fluke Biomedical customers worldwide

**Automated:** Pre-set templates allow you to test to the global standard of your choices at the push of a button. Let the unit guide you through the test steps quickly and accurately in three simple steps:

1. Select the test sequence corresponding to your standard of choice

2. Initiate the automated test sequence.

3. Store the results on-board or wirelessly export to your PC in seconds.

It is that easy. The automated test sequences are easily customized to suit individual testing requirements.

**Portable:** The ESA615 is a small, lightweight analyzer with an integrated handle to carry from place to place for on-the-go field service. It is designed for operation in tight spaces, and is easy to fit on any cart. A light, protective carrying case makes it easy to store and transport.

**Simple:** A push-button interface allows quick access to highly-comprehensive functions and features, and an intuitive interface guides the user through tests. The ESA615 features a large display for clear indication of available functions, set-up criteria, device under test receptacle conditions, and test results. Data can be entered quickly with a plug–and-play keyboard, barcode scanner and/or on-board data entry interface. Data archival is fast and simple with wireless communication or through a removable memory card with capacity for thousands of test results.

## Specifications

| | | | |
|---|---|---|---|
| **Voltage** | | | |
| Range (mains voltage) | 90.0 V ac rms to 132.0 V ac rms | | |
| | 180.0 V ac rms to 264.0 V ac rms | | |
| Range (point-to-point voltage) | 0.0 V ac rms to 300.0 V ac rms | | |
| Accuracy | ± (2 % of reading + 0.2 V) | | |
| Voltage tests | Mains and point to point | | |
| **Earth resistance** | | | |
| Modes | Two-Wire | | |
| Test current/ranges/accuracy | > 200 mA ac | 0.000 Ω to 2.000 Ω | ± (2 % of reading + 0.015 Ω) |
| Resistance tests | Earth resistance and point to point | | |
| **Equipment current** | | | |
| Mode | AC rms | | |
| Range/Accuracy | 0.0 A to 20.0 A | ± (5 % of reading + (2 counts or 0.2 A, whichever is greater)) | |
| Duty cycle | 15 A to 20 A, 5 min. on/5 min. off<br>10 A to 15 A, 7 min. on/3 min. off<br>0 A to 10 A continuous | | |
| **Leakage current** | | | |
| Modes* | AC + DC (True-rms) | | |
| | AC only | | |
| | DC only | | |
| *Modes are available in all leakage tests with the exception of MAP leakages that are available only in true-rms | | | |
| Patient load selection (input impedance) | AAMI ES1-1993 Fig.1<br>IEC 60601: Fig 15 | | |
| Crest factor | ≤ 3 | | |
| Ranges | 0.0 µA to 199.9 µA | | |
| | 200 µA to 1999 µA | | |
| | 2.00 mA to 10.00 mA | | |

| | | |
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| Frequency response/accuracy | DC to 1 kHz | ± (1 % of reading + (1 µA or 1 LSD, whichever is greater)) |
| | 1 kHz to 100 kHz | ± (2 % of reading + (1 µA or 1 LSD, whichever is greater)) |
| | 1 kHz to 5 kHz (current > 1.6 mA) | ± (4 % of reading + (1 µA or 1 LSD, whichever is greater)) |
| | 100 kHz to 1 MHz | ± (5 % of reading + (1 µA or 1 LSD, whichever is greater)) |
| | Accuracy for Isolation, MAP, Direct AP, Alternative AP, and Alternative Equipment leakage tests all ranges are:<br>• At 120 V ac + (2.5 µA or 1 LSD, whichever is greater)<br>• At 230 V ac additional ± 3.0 % and + (2.5 µA or 1 LSD, whichever is greater)<br>For Alternative equipment, Alternative AP, and Direct AP leakage tests, the leakage values are compensated for nominal mains as per 62353. Therefore, the accuracy specified for other leakages is not applicable. | |
| Leakage tests | Ground wire (earth) | |
| | Chassis (enclosure) | |
| | Lead to ground (patient) | |
| | Lead to lead (patient auxillary) | |
| | Lead isolation (mains on applied part) | |
| | Direct equipment | |
| | Direct applied part | |
| | Alternative equipment | |
| | Alternative applied part | |
| | Point to point | |
| Mains on applied part test voltage | 100 % ± 7 % of Mains for AAMI, current limited to 1 mA ± 25 % per AAMI<br>100 % ± 7 % of Mains for IEC 62353 current limited to 3.5 mA ± 25 % per IEC 62353<br>100 % ± 7 % of Mains for IEC 60601-1 current limited to 7.5 mA ± 25 % per IEC 60601-1 | |
| Differential leakage | | |
| Ranges | 75 µ A to 199 µA | |
| | 200 µA to 1999 µA | |
| | 2.00 mA to 20.00 mA | |
| Accuracy | ± (10 % of reading + (2 counts or 20 µA, whichever is greater)) | |
| Insulation resistance | | |
| Ranges/accuracy | 0.5 MΩ to 20.0 MΩ | ± (2 % of reading + 0.2 MΩ) |
| | 20.0 MΩ to 100.0 MΩ | ± (7.5 % of reading + 0.2 MΩ) |
| Source test voltage | 500 V dc or 250 V dc (+20 %, -0 %) | |
| | 2.0 ± 0.25 mA short-circuit current | |
| Insulation resistance tests | Mains-PE, AP-PE, Mains-PE, Mains-NE (non-earthed accessible conductive part) and AP-NE (non-earthed accessible conductive part) | |

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| **ECG performance waveforms** | | |
| Accuracy | ± 2 % | |
| | ± 5 % for amplitude of 2 Hz square wave only, fixed at 1 mV lead II configuration | |
| Waveforms | Rates | |
| | ECG complex | 30 BPM, 60 BPM, 120 BPM, 180 BPM, and 240 BPM |
| | Ventricular fibrillation | |
| | Square wave (50 % duty cycle) | 0.125 Hz and 2 Hz |
| | Sine wave | 10 Hz, 40 Hz, 50 Hz, 60 Hz, and 100 Hz |
| | Triangle wave | 2 Hz |
| | Pulse (63 ms pulse width) | 30 BPM and 60 BPM |
| **Test standards** | | |
| Available selections | ANSI/AAMI ES-1, IEC62353, IEC60601-1, and AS/NZS 3551 | |
| **Built-in test sequences** | | |
| IEC60601-1 3rd Edition | Patient Monitor, Defibrillator, Infusion Pump, Ultrasound Device, Generic Device and System | |
| IEC62353 | Patient Monitor, Defibrillator, Infusion Pump, Ultrasound Device and Generic Device | |
| NFPA-99 (Hospital) | Patient Monitor, Defibrillator, Infusion Pump, Ultrasound Device and Generic Device | |
| ANSI/AAMI ES1 | Patient Monitor, Defibrillator, Infusion Pump, Ultrasound Device and Generic Device | |
| **Communications** | | |
| USB device upstream port | Mini-B connector for control by a computer | |
| USB host controller port | Type A, 5 V output, 0.5 A max load. Connector for keyboard and barcode reader | |
| Wireless | IEEE 802.15.4 for control by a computer | |
| Modes of operation | Manual and remote | |
| **Power ratings** | | |
| Mains voltage outlet | 120 V ac | 230 V ac |
| Mains voltage inlet power range | 90 V ac rms to 132 V ac rms | 180 V ac rms to 264 V ac rms |
| Maximum current | 20 A | 16 A |
| Hz | 47 to 63 Hz | 47 to 63 Hz |
| **Physical case** | | |
| Dimensions (WxDxH) | 17.6 cm x 8.4 cm x 28.5 cm (6.9 in x 3.3 in x 11.2 in) | |
| Weight | 1.6 kg (3.5 lb) | |

| Environmental | |
|---|---|
| Operating temperature | 10 °C to 40 °C (50 °F to 104 °F) |
| Storage temperature | -20 °C to 60 °C (-4 °F to 140 °F) |
| Operating humidity | 10 % to 90 % non-condensing |
| Altitude | 100/115 V ac mains supply voltage up to 5000 meters<br>230 V ac mains supply voltage up to 2000 meters |
| Warranty | Two-year extended warranty (no-cost, available after first-year calibration at any authorized Fluke Biomedical Service Center, otherwise standard one year warranty applies) |

## Ordering information

### Models/descriptions

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|---|---|
| 4132046 | ESA615 US, 115 V |
| 4162180 | ESA615 US, 115 V with Ansur automation software |
| 4132054 | ESA615-01 France/Belgium, 230V |
| 4162198 | ESA615 France/Belgium, 230 V with Ansur automation software |
| 4132093 | ESA615-02 Europe, 230 V |
| 4162211 | ESA615 Europe, 230 V with Ansur automation software |
| 4132101 | ESA615-03 Israel, 230 V |
| 4162227 | ESA615 Israel, 230 V with Ansur automation software |
| 4132112 | ESA615-05 Australia/China, 230 V |
| 4162230 | ESA615 Australia/China, 230 V with Ansur automation software |
| 4132120 | ESA615-06 UK, 230 V |
| 4162248 | ESA615 UK, 230 V with Ansur automation software |
| 4132135 | ESA615-07 Switzerland, 230 V |
| 4162253 | ESA615 Switzerland, 230 V with Ansur automation software |
| 4132147 | ESA615-08 Thailand, 230 V |
| 4162275 | ESA615 Thailand, 230 V with Ansur automation software |
| 4132158 | ESA615-09 Japan, 100 V |
| 4162282 | ESA615 Japan, 100 V with Ansur automation software |
| 4132164 | ESA615-10 North America 220V |
| 4162341 | ESA615 North America, 220 V with Ansur automation software |
| 4161125 | ESA615-11 Brazil 230V |
| 4162352 | ESA615 Brazil with Ansur automation software |
| 4161133 | ESA615-12 India 230V |
| 4162365 | ESA615 India with Ansur automation software |

## Standard accessories

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|---|---|
| 4105850 | Operator's Manual (multilingual CD-ROM) |
| 4105845 | Getting Started Guide, hard copy, multilingual |
| 4034393 | Data Transfer Cable |
| 3111008 | USA/AUS/ISR Accessory Kit: test lead set, TP1 test probe set, AC285 alligator clip set (ESA T/L kit, country-specific, see below) |
| 2195732 | 15 – 20 A Adapter (2719-0154) |
| 4151242 | USA/NEMA outlet to NBR14136 socket (Brazil only) |
| 3326842 | Null Post Adapter |
| 3359538 | 5-to-5 Banana Jack to ECG (BJ2ECG) Adapter (ESA612-2016) |
| 2248650 | Carrying Case |
| LINE CORD | Country-specific power cord |
| 4165219 | Ansur ESA615 Plug-in Software (Ansur automation software versions only) |

## Accessory kits (country specific)

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|---|---|
| 3111008 | USA/AUS/ISR Accessory Kit: test lead set, TP1 test probe set, AC285 alligator clip set (ESA T/L kit, USA) |
| 3111024 | EUR Accessory Kit: test lead set, TP74 test probe set, AC285 alligator clip set (ESA T/L kit, EUR) |

## Optional accessories

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|---|---|
| 1903307 | Retractable test leads (6358) |
| 2392639 | Ground pin adapter (US receptacle testing ground lug) (9503-0004) |
| 3392119 | 1-to-10 ECG adapter box assembly (1210 ECG) |
| 3341333 | ZigBee USB dongle |
| 3472633 | Ultrasound test cable adapter |
| 2462072 | Fix vertical alignment universal snap-to banana adapter |
| 4165219 | Ansur ESA615 Plug-In Software |
| 4200364 | ESA615, 1 Year Gold CarePlan |
| 4200373 | ESA615, 3 Year Gold CarePlan |
| 4200386 | ESA615, 1 Year Silver CarePlan |
| 4200399 | ESA615, 3 Year Silver CarePlan |
| 4200416 | ESA615, 1 Year Bronze CarePlan |
| 4200402 | ESA615, 3 Year Bronze CarePlan |

## About Fluke Biomedical

Fluke Biomedical is the world's leading manufacturer of quality biomedical test and simulation products. In addition, Fluke Biomedical provides the latest medical imaging and oncology quality-assurance solutions for regulatory compliance. Highly credentialed and equipped with a NVLAP Lab Code 200566-0 accredited laboratory, Fluke Biomedical also offers the best in quality and customer service for all your equipment calibration needs.

Today, biomedical personnel must meet the increasing regulatory pressures, higher quality standards, and rapid technological growth, while performing their work faster and more efficiently than ever. Fluke Biomedical provides a diverse range of software and hardware tools to meet today's challenges.

## Fluke Biomedical regulatory commitment

As a medical test device manufacturer, we recognize and follow certain quality standards and certifications when developing our products. We are ISO 9001 and ISO 13485 medical device certified and our products are:

- CE Certified, where required
- NIST Traceable and Calibrated
- UL, CSA, ETL Certified, where required
- NRC Compliant, where required

**Fluke Biomedical.**
*Trusted for the measurements that matter.*

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