

# Technical data

**Biomedical** 

**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-qualityruggedness 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

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**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 ever is greater))	counts or 0.2 A, which-
Duty cycle	15 A to 20 A, 5 min. on/5 min. off 10 A to 15 A, 7 min. on/3 min. off 0 A to 10 A continuous		
Leakage current			
Modes*	AC + DC (True-rms)		
	AC only		
	DC only		
*Modes are available in all leak true-rms	age tests with the excep	tion of MAP leakages t	hat are available only in
Patient load selection (input impedance)	AAMI ES1-1993 Fig.1 IEC 60601: Fig 15		
Crest factor	≤ 3		
Ranges	0.0 μA to 199.9 μA		
	200 μΑ to 1999 μΑ		
	2.00 mA to 10.00 mA		
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Frequency response/accuracy	DC to 1 kHz	$\pm$ (1 % of reading + (1 $\mu A$ or 1 LSD, whichever is greater))	
	1 kHz to 100 kHz	$\pm$ (2 % of reading + (1 $\mu A$ or 1 LSD, whichever is greater))	
	1 kHz to 5 kHz (current > 1.6 mA)	$\pm$ (4 % of reading + (1 $\mu A$ or 1 LSD, whichever is greater))	
	100 kHz to 1 MHz	$\pm$ (5 % of reading + (1 $\mu A$ or 1 LSD, whichever is greater))	
	Accuracy for Isolation, MAP, Direct AP, Alternative AP, and Alternative Equipment leakage tests all ranges are: • At 120 V ac + (2.5 $\mu$ A or 1 LSD, whichever is greater) • At 230 V ac additional ± 3.0 % and + (2.5 $\mu$ A or 1 LSD, whichever is greater) 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 (patie	ent)	
	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 % $\pm$ 7 % of Mains for AAMI, current limited to 1 mA $\pm$ 25 % per AAMI 100 % $\pm$ 7 % of Mains for IEC 62353 current limited to 3.5 mA $\pm$ 25 % per IEC 62353 100 % $\pm$ 7 % of Mains for IEC 60601-1 current limited to 7.5 mA $\pm$ 25 % per IEC 60601-1		
Differential leakage			
Ranges	75 μ Α to 199 μΑ		
	200 μΑ to 1999 μΑ		
	2.00 mA to 20.00 mA		
Accuracy	± (10 % of reading + (2	2 counts or 20 μA, whichever is greater))	
Insulation resistance			
Ranges/accuracy	0.5 MΩ to 20.0 MΩ	$\pm$ (2 % of reading + 0.2 M $\Omega$ )	
,	20.0 MΩ to 100.0 MΩ	$\pm$ (7.5 % of reading + 0.2 M $\Omega$ )	
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 %	± 2 %		
	$\pm5\%$ 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, IEC6	0601-1, 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 con	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)			



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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 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

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
	4162180 4132054 4162198 4132093 4162211 4132101 4162227 4132112 4162230 4132120 4162248 4132135 4162253 4132147 4162275 4132158 4162282 4132164 4162341 4161125 4162352 4161133



### Standard accessories

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)**

3111008	
3111000	LIC A /ALIC /ICD A   /:1. 1 1 1 1 TD4
	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**

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



