

FLUKE®

Biomedical

ESA612

Electrical Safety Analyzer

Getting Started Manual

PN 3334511

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For application support or answers to technical questions, either email techservices@flukebiomedical.com or call 1-800- 648-7952 or 1-425-446-6945.

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Our routine method of shipment is via common carrier, FOB origin. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim. If the instrument is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact Fluke Biomedical or your local sales representative.

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Products returned within 30 days of original purchase are subject to a minimum restocking fee of 15 %. Products returned in excess of 30 days after purchase, but prior to 90 days, are subject to a minimum restocking fee of 20 %. Additional charges for damage and/or missing parts and accessories will be applied to all returns.

Return Procedure

All items being returned (including all warranty-claim shipments) must be sent freight-prepaid to our factory location. When you return an instrument to Fluke Biomedical, we recommend using United Parcel Service, Federal Express, or Air Parcel Post. We also recommend that you insure your shipment for its actual replacement cost. Fluke Biomedical will not be responsible for lost shipments or instruments that are received in damaged condition due to improper packaging or handling.

Use the original carton and packaging material for shipment. If they are not available, we recommend the following guide for repackaging:

- Use a double-walled carton of sufficient strength for the weight being shipped.
- Use heavy paper or cardboard to protect all instrument surfaces. Use nonabrasive material around all projecting parts.
- Use at least four inches of tightly packed, industry-approved, shock-absorbent material around the instrument.

Returns for partial refund/credit:

Every product returned for refund/credit must be accompanied by a Return Material Authorization (RMA) number, obtained from our Order Entry Group at 1-800-648-7952 or 1-425-446-6945.

Repair and calibration:

To find the nearest service center, go to www.flukebiomedical.com/service or

In the U.S.A.:

Cleveland Calibration Lab

Tel: 1-800-850-4606

Email: globalcal@flukebiomedical.com

Everett Calibration Lab

Tel: 1-888-99 FLUKE (1-888-993-5853)

Email: service.status@fluke.com

In Europe, Middle East, and Africa:

Eindhoven Calibration Lab

Tel: +31-402-675300

Email: ServiceDesk@fluke.com

In Asia:

Everett Calibration Lab

Tel: +425-446-6945

Email: service.international@fluke.com

Certification

This instrument was thoroughly tested and inspected. It was found to meet Fluke Biomedical's manufacturing specifications when it was shipped from the factory. Calibration measurements are traceable to the National Institute of Standards and Technology (NIST). Devices for which there are no NIST calibration standards are measured against in-house performance standards using accepted test procedures.

WARNING

Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazards or improper operation. Fluke Biomedical will not be responsible for any injuries sustained due to unauthorized equipment modifications.

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Manufacturing Location

The ESA612 Electrical Safety Analyzer is manufactured at Fluke Biomedical, 6920 Seaway Blvd., Everett, WA, U.S.A.

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Electrical Safety Analyzer








Introduction

The Fluke Biomedical ESA612 Electrical Safety Analyzer (hereafter the Analyzer) is a full-featured, compact, portable analyzer, designed to verify the electrical safety of medical devices. The Analyzer tests to domestic (ANSI/AAMI ES1, NFPA 99) and international (IEC62353, AN/NZS 3551, and parts of IEC 60601-1) electrical-safety standards. The integrated ANSI/AAMI ES1 and IEC60601-1 patient loads are easily selectable.

The Analyzer performs the following tests:

- Line (Mains) voltage
- Ground Wire (or Protective Earth) Resistance
- Equipment current
- Insulation resistance
- Ground (Earth) leakage
- Chassis (Enclosure) leakage
- Lead to Ground (Patient) and Lead to Lead (Patient Auxiliary) leakage
- Lead isolation (Mains on applied parts leakage)
- Differential leakage
- Direct equipment leakage
- Direct applied part leakage
- Alternative equipment leakage
- Alternative applied part patient leakage
- Point to point leakage, voltage, and resistance
- ECG simulation and performance waveforms

Table 1. Symbols

Symbol	Description
	Important information; refer to manual.
	Hazardous voltage
	Conforms to relevant Canadian and US standards
	Conforms to relevant Australian EMC requirements
	Conforms to European Union directives
	This product complies with the WEEE Directive (2002/96/EC) marking requirements. The affixed label indicates that you must not discard this electrical/electronic product in domestic household waste. Product Category: With reference to the equipment types in the WEEE Directive Annex I, this product is classed as category 9 "Monitoring and Control Instrumentation" product. Do not dispose of this product as unsorted municipal waste. Go to Fluke's website for recycling information.
CAT II	IEC Measurement Category II – CAT II equipment designed to protect against transients from energy-consuming equipment supplied from fixed installations.
	Accessible Functional Earth Terminal

Safety Information

In this manual, a **Warning** identifies hazardous conditions and actions that could cause bodily harm or death. A **Caution** identifies conditions and actions that could damage the Analyzer, the equipment under test, or cause permanent loss of data.

⚠️⚠️ Warning

To avoid possible electrical shock or personal injury, follow these guidelines:

- Use this Analyzer only in the manner specified by the manufacturer or the protection provided may be impaired.
- Read the Users Manual before operating the Analyzer.
- Do not connect the Analyzer to a patient or equipment connected to a patient. The Analyzer is intended for equipment evaluation only and should never be used in diagnostics, treatment or in any other capacity where the Analyzer would come in contact with a patient.
- Do not use the product in wet or damp locations, around explosive gases or dust.
- Inspect the Analyzer before using it. Do not use the Analyzer if abnormal conditions of any sort are noted (such as a faulty display, broken case, etc.)
- Inspect the test leads for damaged insulation or exposed metal. Check test lead continuity. Replace damaged leads before using the Analyzer.
- When testing, always be sure to keep your fingers behind the safety barriers on the test leads.
- Never open the Analyzer's case. Dangerous voltages are present. There are no user replaceable parts in the Analyzer.
- Have the Analyzer serviced only by qualified personnel.

- **The Analyzer must be properly earthed. Only use a supply socket that has a protective earth contact. If there is any doubt as to the effectiveness of the supply socket earth, do not connect the Analyzer. Do not use a two-conductor adapter or extension cord; this will break the protective ground connection.**
- **Do not use the 15-20 A adapter to power devices rated in excess of 15 A. Doing so may overload the installation.**
- **Use extreme caution when working with voltages above 30 V.**
- **Use the proper terminals, functions and ranges for the test being performed.**
- **Do not touch metal parts of the device under test (DUT) during analysis. The DUT should be considered an electrical shock hazard when connected to the Analyzer as some tests involve high voltages, high currents, and/or the removal of DUT earth bond.**

Intended Use

The Product is an electronic signal source and measurement device for verifying the electrical safety of medical devices. The Product also provides ECG

simulation and performance waveforms to verify patient monitors are performing within their operating specifications.

The Product provides the following function categories:

- ECG Functions
- ECG-Performance Testing

The intended user is a trained biomedical equipment technician who performs periodic preventative maintenance checks on patient monitors in service. Users can be associated with hospitals, clinics, original equipment manufacturers and independent service companies that repair and service medical equipment. The end user is an individual, trained in medical instrumentation technology.

This Product is intended to be used in the laboratory environment, outside of the patient care area, and is not intended for use on patients, or to test devices while connected to patients. This Product is not intended to be used to calibrate medical equipment. It is intended for over-the-counter use.

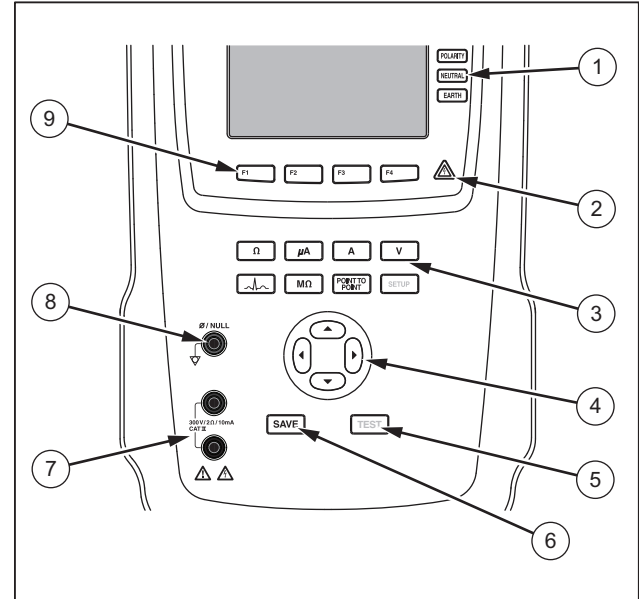
Unpacking the Analyzer

Carefully unpack all items from the box and check that you have the following items:

- ESA612
- Getting Started Manual
- Users Manual CD
- Carrying case
- Power cord
- 15 – 20 A Adapter (USA only)
- ESA USA Accessory Kit (USA, Australia, and Israel only)
- ESA EUR Accessory Kit
- Ansur demo CD
- Null Post Adapter
- 5-to-5 Banana to ECG Adapter (BJ2ECG)
- Data Transfer Cable

Instrument Familiarization

Figure 1 and Table 2 describes the front-panel controls and connections of the Analyzer.



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Figure 1. Front-Panel Controls and Connections

Table 2. Front-Panel Controls and Connections

Item	Name	Description
1	Equipment Outlet Configuration Buttons	Controls the configuration of the equipment outlet. Opens and closes the neutral and ground connection and reverses the polarity of the neutral and hot connection.
2	High Voltage Indicator	Indicates when high voltage is applied to the ECG/Applied Parts posts or L1 and L2 of the Test Receptacle.
3	Test Function Buttons	Selects the various Analyzer test functions.
4	Navigation Buttons	Cursor control buttons for navigating menus and lists.
5	Test Button	Initiates selected tests.
6	Save Button	Saves the measurement or ECG waveform to memory.
7	Input Jacks	Test lead connectors.

Item	Name	Description
8	Nulling Jack	Connection for zeroing test lead resistance.
9	Function Softkeys	Keys F1 through F4 are used to select from a number of selections that appear in the LCD display above each function softkey.

Figure 2 and Table 3 describe the side and top-panel connections of the Analyzer.

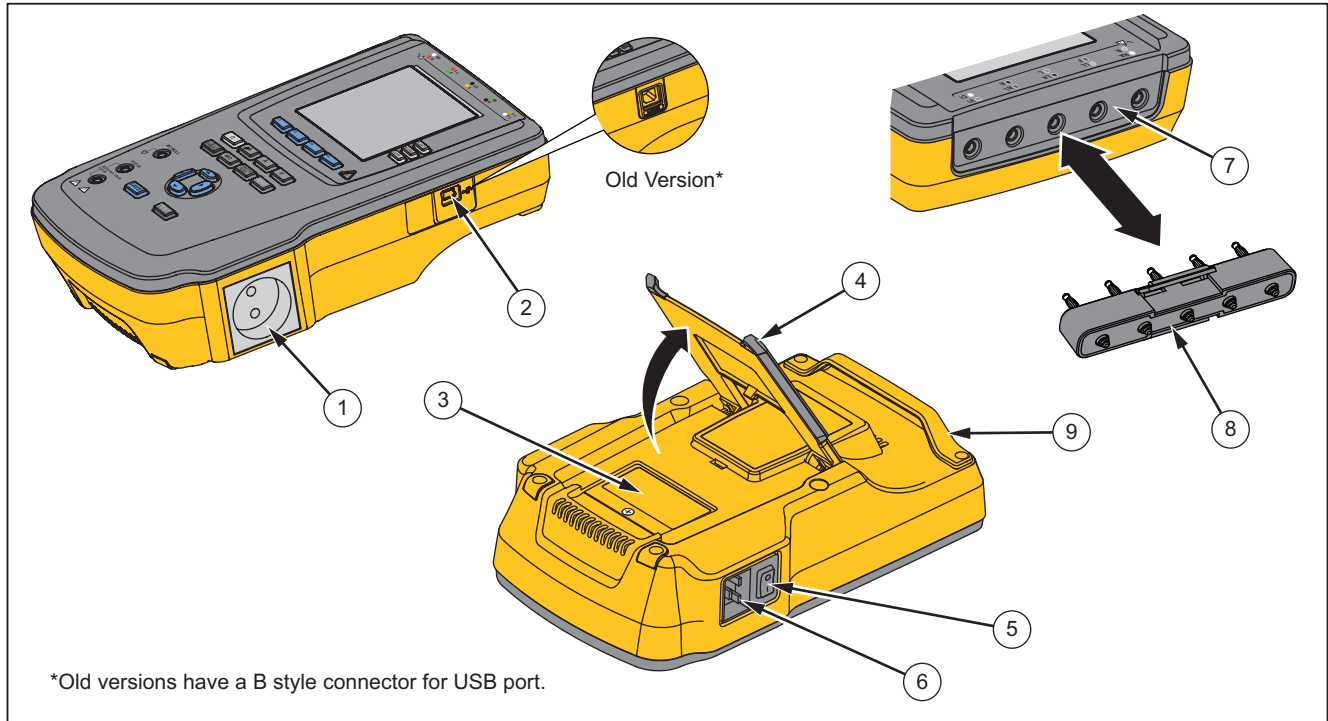


Figure 2. Side and Top-Panel Connections

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Table 3. Side and Top-Panel Connections

Item	Name	Description
1	Equipment Outlet	Equipment outlet, specific to the version of the Analyzer, which provides a DUT connection.
2	USB Device Port (Mini B-style connector) ¹	Digital connection for controlling the Analyzer from a PC or instrument controller.
3	Fuse Access Door	Covers the equipment outlet fuses.
4	Tilt Stand	Support for holding the Analyzer in a tilted position.
5	AC Power Switch	Turns ac power on and off.
6	Power Input Connector	A grounded male three-prong (IEC 60320 C19) connector that accepts the line-power cord.
7	ECG/Applied Parts Jacks	Connection posts for Device Under Test (DUT) applied parts, such as ECG leads. Used to test for leakage current through leads and to supply ECG signals and performance waveforms to a DUT.
8	Banana Jack to ECG Adapter	Adapter for connecting ECG snap leads to the Analyzer.
9	Carry Handle	Handle to transport Analyzer. Note: There is no handle on old versions of the analyzer.
<p>¹ Older versions of the Analyzer have a B-style USB port connector.</p>		

How to Hold the Product

When you move the Analyzer, use the handle in the bottom case to hold it. See Figure 3.

Note

There is no handle on old versions of the Analyzer.



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Figure 3. Product Handle

Connecting to Line Power

⚠️⚠️ Warning

To avoid shock hazard and for proper Analyzer operation, connect the factory supplied three-conductor line power cord to a properly grounded power outlet. Do not use a two-conductor adapter or extension cord; this will break the protective ground connection.

Connect the Analyzer to a properly grounded three-prong outlet. The Analyzer will not properly test a DUT when the ground lead is open.

The Analyzer is intended for use with single-phase, grounded power. It is not intended for dual, split-phase or three-phase power configurations. But it can be used with any power system that supplies the correct voltages for single-phase and is grounded, or is an isolated power system.

Connecting a DUT to the Analyzer

A Device Under Test (DUT) can be connected in a number of different ways depending on the device and the number of connections needed for a full electrical safety test. Figure 5 shows a DUT connected to the test receptacle, applied parts posts, and a separate connection to the DUT's enclosure or protective earth ground.

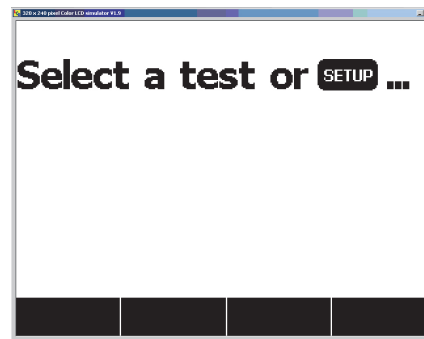
Turning the Analyzer On

Note

To ensure the high voltage indicator is working, look for it to illuminate during the power-up self test.

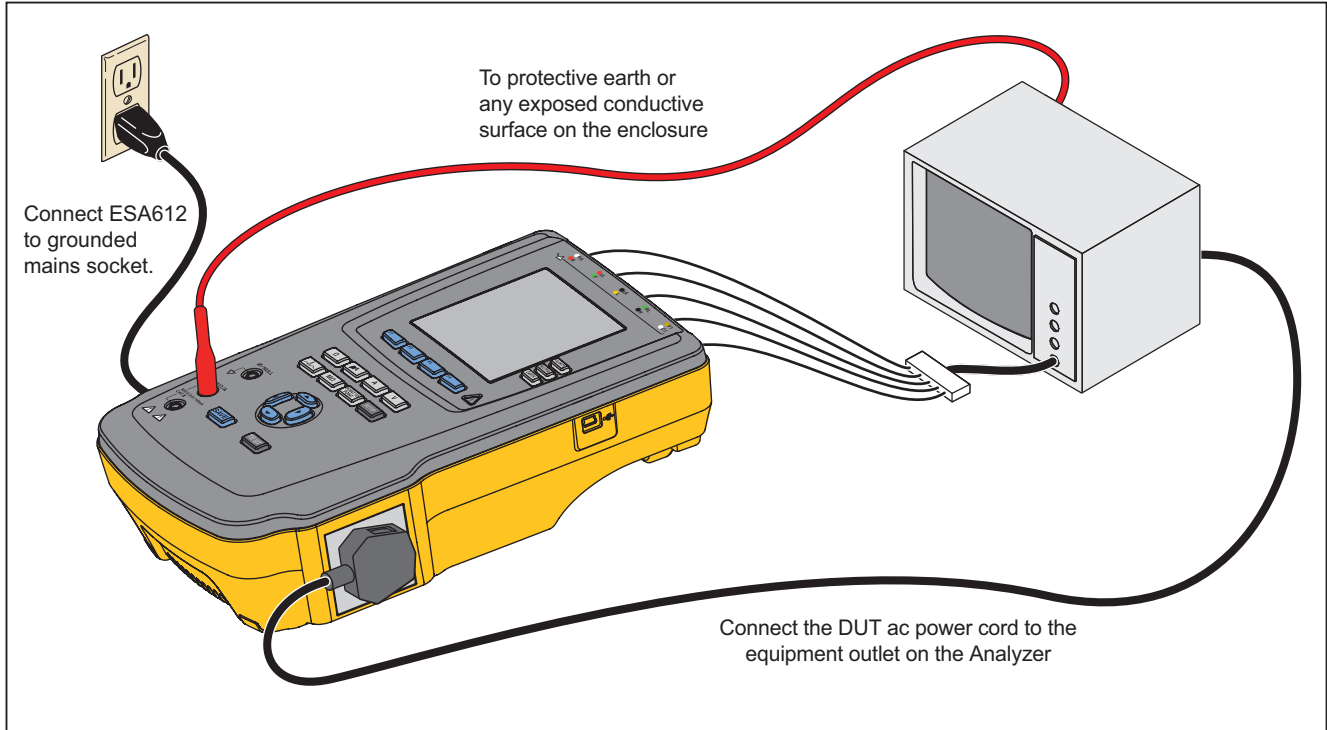
Press the power switch on the left-side panel so the "I" side of the ac power switch is depressed. The Analyzer

will perform a series of self tests and then display the message shown in Figure 4 when the self test has completed successfully.



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Figure 4. Analyzer Ready for Operation



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Figure 5. DUT Connected to the Analyzer

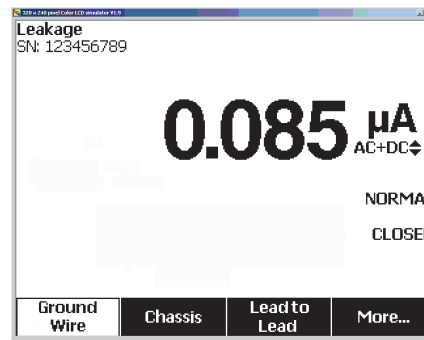
During the self-test, the Analyzer checks its ac mains input for proper polarity, ground integrity and voltage level. The high voltage indicator illuminates briefly during the self test. If the polarity is reversed, the Analyzer indicates this condition and allows the polarity to be reversed internally. If the ground is open, the Analyzer displays this fault. If the mains voltage is too high or too low, the Analyzer displays this fault and does not continue until the supply voltage is corrected and the Analyzer power cycled off and then on again.

Setting the Display's Contrast

Whenever the Analyzer displays the start-up menu shown in Figure 4, press \uparrow or \downarrow to increase or decrease the display's contrast. Press the softkey labeled **Done** to exit contrast setup.

Accessing the Analyzer's Functions

For each test and setup function, the Analyzer uses a series of menus to access various Analyzer tests and setup variables. As shown in Figure 6, the Analyzer indicates various leakage current tests along the bottom of the display. An Exit selection is also indicated as a way of backing out of the leakage current tests. Pressing a softkey (F1 through F4) under a specific test will cause the analyzer to setup for or perform the selected test.



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Figure 6. Leakage Current Menu

In addition to the function softkeys, the Analyzer test functions may require using the navigation buttons to select parameters as well. In the example above, the leakage selection has \leftrightarrow next to it. This icon indicates the selection is controlled by pressing \uparrow or \downarrow . In this example, the leakage current measurement is switched between AC+DC, AC only, or DC only. The applied parts indicator has \blacktriangleleft on the left end and \blacktriangleright on the right end. These icons indicate the use of \updownarrow and $\left\langle \right\rangle$ to select the number of applied parts.

The three buttons along the right side of the display (POLARITY NEUTRAL EARTH) control the configuration of the Analyzer's test receptacle for some electrical tests. The present state of these three buttons is displayed along the right edge of the display whenever these controls are active.

Figure 5 shows polarity is settable between normal, reversed, and off. Neutral is also settable to closed or open. Earth condition is not displayed, which indicates it can not be changed. However, earth is internally opened during this test.

Prior to conducting any leakage tests with the Analyzer, it is best to test the integrity of the ground connection between the Analyzer's test receptacle ground and the DUT's Protective earth ground or enclosure with this test.

To access the Ground Wire (Protective Earth) \emptyset /Null Resistance Test menu press Ω .

Note

The DUT is powered off for this test.

To perform a ground wire resistance test:

1. Ensure the power cord from the DUT is plugged into the Analyzer's test receptacle.
2. Press Ω to reveal the resistance function menu.
3. Connect one end of a test lead to the V/ Ω /A jack.
4. Connect the other end of the test lead to \emptyset /Null jack.

5. Press the softkey labeled **Zero Leads**. The Analyzer zeroes out the measurement to cancel the test lead resistance.
6. Connect the test lead coming from the \emptyset /Null jack to the DUT enclosure or protective earth connection.
7. The measured resistance is displayed as shown in Figure 7 after the DUT connection(s) is/are made.

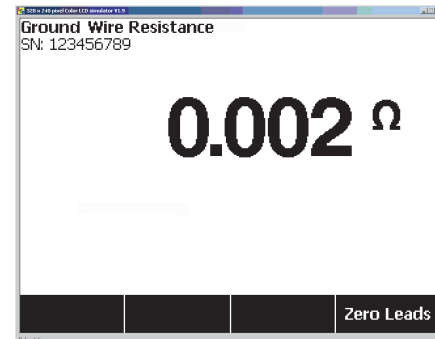


fig105.eps

Figure 7. DUT Ground Wire Resistance Measurement

A low resistance reading is required to confirm a good ground connection through the power cord. Refer to the appropriate electrical safety standard for the specific limit value to be followed.

At this point, the Analyzer is ready to test the electrical safety of the DUT.

What to Do Next

For more information on how to use the Analyzer, refer to the *ESA612 Users Manual* contained on the accompanying CD.

Maintenance

The Analyzer needs little maintenance or special care. However, treat it as a calibrated measuring instrument. Avoid dropping or other mechanical abuse that could cause a shift in the calibrated settings.

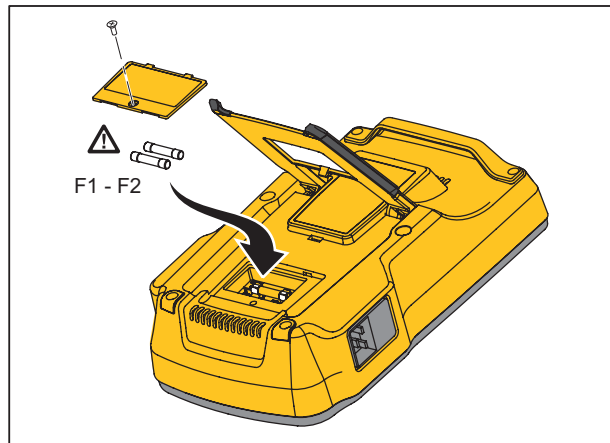
Testing and Replacing the Fuses

⚠⚠ Warning

To prevent electric shock, remove all power cords and test leads from the Analyzer before opening the fuse door.

For electrical protection of the equipment outlet, the Analyzer uses two fuses, one in the live (L1) line and one in the neutral (L2) line. To test the fuses, do the following while referring to Figure 8:

1. Turn the Analyzer so the case bottom is facing up.
2. Flip up the tilt stand.
3. Remove the fuse door from the Analyzer by removing the screw holding the fuse door with a #2 Phillips head screwdriver and lifting the fuse door from the Analyzer.
4. Remove the fuses from the Analyzer.



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Figure 8. Fuse Access

5. Using a multimeter, measure the continuity of each fuse.
If one or both fuses do not show continuity, replace the fuse(s) with fuses that have the same current and voltage rating. Appropriate fuse ratings are posted on the case bottom label of the Analyzer. Table 4 lists available fuses with Fluke Biomedical part numbers.
6. Reinstall the fuse door and secure it with the screw.

Cleaning the Analyzer

⚠⚠ Warning

To avoid electric shock, do not clean the Analyzer plugged into mains or attached to a DUT.

⚠ Caution

Do not pour fluid onto the Analyzer surface; fluid seepage into the electrical circuitry may cause the Analyzer to fail.

⚠ Caution

Do not use spray cleaners on the Analyzer; such action may force cleaning fluid into the Analyzer and damage electronic components.

Clean the Analyzer occasionally utilizing a damp cloth and mild detergent. Take care to prevent the entrance of liquids.

Wipe down the adapter cables with the same care. Inspect them for damage to and deterioration of the insulation. Check the connections for integrity before each use.

Replaceable Parts

Table 4 list the parts and part numbers of the replaceable parts.

Table 4. Replaceable Parts

Item		Fluke Biomedical Part Number
ESA612 Getting Started Manual		3334511
ESA612 Users Manual CD		3334509
Power Cord	USA	2238680
	UK	2238596
	Australia	2238603
	Europe	2238615
	France/Belgium	2238615
	Thailand	2238680
	Israel	2434122
	Switzerland	3379149
Null Post Adapter		3326842
Ansur, CD with demo version		2795488
5-to-5 Banana jack to ECG (BJ2ECG) adapter		3359538

Table 4. Replaceable Parts (cont.)

Item		Fluke Biomedical Part Number	
Carrying Case		2248650	
Data Transfer Cable		1626219	
Fuse	USA	⚠ T20A 250V Fuse (Time Lag), 1¼ in x ¼ in	2183691
	Australia, Switzerland	⚠ T10A 250V Fuse (Time Lag), 1¼ in x ¼ in	109298
	Europe, UK, Thailand, France/Belgium, Israel	⚠ T16A 250V Fuse (Time Lag), 6.3 mm x 32 mm	3321245
15 – 20 A Adapter		2195732	
ESA USA/AUS/ISR Accessory Kit: Test Lead Set TP1 Test Probe Set AC285 Alligator Clip Set		3111008	
ESA EUR Accessory Kit: Test Lead Set TP74 Test Probe Set AC285 Alligator Clip Set		3111024	
⚠ To ensure safety, use exact replacement only.			

Accessories

Table 5 lists available accessories for the Analyzer.

Table 5. Accessories

Item	Fluke Biomedical Part Number
Test Leads with Retractable Sheath	1903307
Ground Pin Adapters	2242165
1-to-10 ECG Adapter	3392119
Universal Snap to Banana Adapter	2462072
Ansur ESA612 Plug-In License	3454829

Specifications

Temperature

Operating10 °C to 40 °C (50 °F to 104 °F)

Storage.....-20 °C to 60 °C (-4 °F to 140 °F)

Humidity10 % to 90 % non-condensing

Altitude

120 V ac mains supply voltage5000 m

230 V ac mains supply voltage2000 m

DisplayLCD display

CommunicationsUSB device port for computer control

Modes of OperationManual and remote

Power

120 Volt power outlet90 to 132 V ac rms, 47 to 63 Hz, 20 A maximum

230 Volt power outlet180 to 264 V ac rms, 47 to 63 Hz, 16 A maximum

Weight1.6 kg (3.5 lb)

Size28.5 cm x 17.6 cm x 8.4 cm (11.2 in x 6.9 in x 3.3 in)

Safety Standards

CEIEC/EN61010-1 2nd Edition; Pollution degree 2

CSACAN/CSA-C22.2 No 61010-1; UL61010-1

Electromagnetic Compatibility Standards (EMC)

European EMC.....EN61326-1

Detailed Specifications

Test Standard Selections.....ANSI/AAMI ES-1, IEC62353, IEC60601-1, and AN/NZS 3551

Voltage

Ranges (Mains voltage)..... 90.0 to 132.0 V ac rms
 180.0 to 264.0 V ac rms

Range (Point-to-point voltage)..... 0.0 to 300.0 V ac rms

Accuracy±(2 % of reading + 0.2 V)

Earth Resistance

Modes Two terminal

Test Current >200 mA ac

Range 0.000 to 2.000 Ω

Accuracy ±(2 % of reading + 0.015 Ω)

Equipment Current

Range 0.0 to 20.0 A ac rms

Accuracy ±(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
 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: AC+DC, AC only, and DC only available for all leakages with exception of MAP that are available in True-rms (shown as AC+DC)

Patient Load Selection AAMI ES1-1993 Fig. 1
 IEC 60601: Fig. 15

Crest factor ≤3

Ranges0.0 to 199.9 μ A
200 to 1999 μ A
2.00 to 10.00 mA

Accuracy

DC to 1 kHz \pm (1 % of reading + (1 μ A or 1 LSD, whichever is greater))
1 to 100 kHz \pm (2 % of reading + (1 μ A or 1 LSD, whichever is greater))
1 to 5 kHz (current > 1.6 mA) \pm (4 % of reading + (1 μ A or 1 LSD, whichever is greater))
100 kHz to 1 MHz \pm (5 % of reading + (1 μ A or 1 LSD, whichever is greater))

Note

Accuracy for Isolation, MAP, Direct AP, Alternative AP, and Alternative Equipment leakage tests all ranges are:

- *At 120 VAC + (2.5 μ A or 1 LSD, whichever is greater)*
- *At 230 VAC additional \pm 3.0 % and + (2.5 μ A or 1 LSD, whichever is greater)*

For Alternative 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.

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

Ranges75 to 199 μ A
200 to 1999 μ A
2.00 to 20.00 mA

Accuracy \pm (10 % of reading + (2 counts or 20 μ A, whichever is greater))

Insulation resistance

Ranges0.5 to 20.0 M Ω
20.0 to 100.0 M Ω

Accuracy

20 M Ω Range.....	$\pm(2\%$ of reading + 0.2 M Ω)
100 M Ω Range.....	$\pm(7.5\%$ of reading + 0.2 M Ω)
Source test voltage	500 V dc (+20 %, -0 %) 2.0 \pm 0.25 mA short-circuit current or 250 V dc selectable
Maximum load capacitance	1 μ F

ECG Performance Waveforms

Accuracy

Frequency	$\pm 2\%$
Amplitude	$\pm 5\%$ of 2 Hz square wave only, fixed @ 1 mV Lead II configuration

Waveforms

ECG Complex	30, 60, 120, 180, and 240 BPM
Ventricular Fibrillation	
Square wave (50 % duty cycle)	0.125 Hz and 2 Hz
Sine wave	10, 40, 50, 60, and 100 Hz
Triangle wave.....	2 Hz
Pulse (63 ms pulse width).....	30 BPM and 60 BPM