FLUKE.
Biomedical

ESA620

Electrical Safety Analyzer

Getting Started Manual

PN 2814971
January 2008, Rev. 4, 8/23

Warranty and Product Support

Fluke Biomedical warrants this instrument against defects in materials and workmanship for one year from the date of original purchase OR two years if at the end of your first year you send the instrument to a Fluke Biomedical service center for calibration. You will be charged our customary fee for such calibration. During the warranty period, we will repair or at our option replace, at no charge, a product that proves to be defective, provided you return the product, shipping prepaid, to Fluke Biomedical. This warranty covers the original purchaser only and is not transferable. The warranty does not apply if the product has been damaged by accident or misuse or has been serviced or modified by anyone other than an authorized Fluke Biomedical service facility. NO OTHER WARRANTIES, SUCH AS FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSED OR IMPLIED. FLUKE SHALL NOT BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES OR LOSSES, INCLUDING LOSS OF DATA, ARISING FROM ANY CAUSE OR THEORY.

This warranty covers only serialized products and their accessory items that bear a distinct serial number tag. Recalibration of instruments is not covered under the warranty.

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Unpacking and Inspection

Follow standard receiving practices upon receipt of the instrument. Check the shipping carton for damage. If damage is found, stop unpacking the instrument. Notify the carrier and ask for an agent to be present while the instrument is unpacked. There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. Inspect the instrument for physical damage such as bent or broken parts, dents, or scratches.

Technical Support

For application support or answers to technical questions, please contact technical support at:
https://www.flukebiomedical.com/support/technical-support.

Claims

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.

Returns and Repairs

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 1-440-498-2560.

Repair and calibration:

For customers based in the U.S.A., please contact Fluke Biomedical at globalcal@flukebiomedical.com, or call 1-833-296-9420.

All other customers, please go to www.flukebiomedical.com/service to find the nearest service center.

To ensure the accuracy of the Product is maintained at a high level, Fluke Biomedical recommends the product be calibrated at least once every 12 months. Calibration must be done by qualified personnel. Contact your local Fluke Biomedical representative for calibration.

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.

Restrictions and Liabilities

Information in this document is subject to change and does not represent a commitment by Fluke Biomedical. Changes made to the information in this document will be incorporated in new editions of the publication. No responsibility is assumed by Fluke Biomedical for the use or reliability of software or equipment that is not supplied by Fluke Biomedical, or by its affiliated dealers.

Manufacturing Location

The ESA620 Electrical Safety Analyzer is manufactured at Fluke Biomedical, 6920 Seaway Blvd., Everett, WA, U.S.A.

Table of Contents

Introduction

The Fluke Biomedical ESA620 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 international (IEC 60601-1, EN 62353, AN/NZS 3551, IEC 61010, VDE 751) and domestic (ANSI/AAMI ES1, NFPA 99) electrical-safety standards. The integrated ANSI/AAMI ES1, IEC 60601-1, and IEC 61010 patient loads are easily selectable.

The Analyzer performs the following tests:

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

Table 1. Symbols

Symbol	Description
	WARNING.RISK OF DANGER.
	WARNING. HAZARDOUS VOLTAGE. Risk of electric shock.
CE	Conforms to European Union directives
	This product complies with the WEEE Directive and its marking requirements. The affixed label indicates that you must not discard this electrical/electronic product in domestic household waste. Do not dispose of this product as unsorted municipal waste. For information about take-back and recycling programs available in your country, see the Fluke website.
CAT II	Measurement Category II is applicable to test and measuring circuits connected directly to utilization points (socket outlets and similar points) of the low-voltage MAINS installation.
	Equipotential

Safety Information

In this manual, a **Warning** identifies conditions and procedures that are dangerous to the user. A **Caution** identifies conditions and procedures that can cause damage to the Product or the equipment under test.

⚠⚠ Warning

To prevent possible electrical shock or personal injury:

- **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 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.**
- **Do not use the 15-20 A adapter to power devices rated in excess of 15 A. Doing so may overload the installation.**

- **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.**
- **Use extreme caution when working with voltages above 30 volts.**
- **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 Analyzer is intended for use by trained service technicians to perform periodic inspections on a wide range of medical equipment. The testing procedures are menu-driven, and simple to operate.

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:

- ESA620
- Getting Started Manual
- Users Manual CD
- Carrying case
- Power cord
- 15 – 20 A Adapter (USA only)
- Test lead set
- TP1 Test probe set (USA, Australia, and Israel only)
- TP74 Test probe set (Europe only)
- Alligator clip set
- Null post adapter
- Data transfer cable

Instrument Familiarization

Figure 1 and Table 2 describe the top-panel controls and connections of the Analyzer.

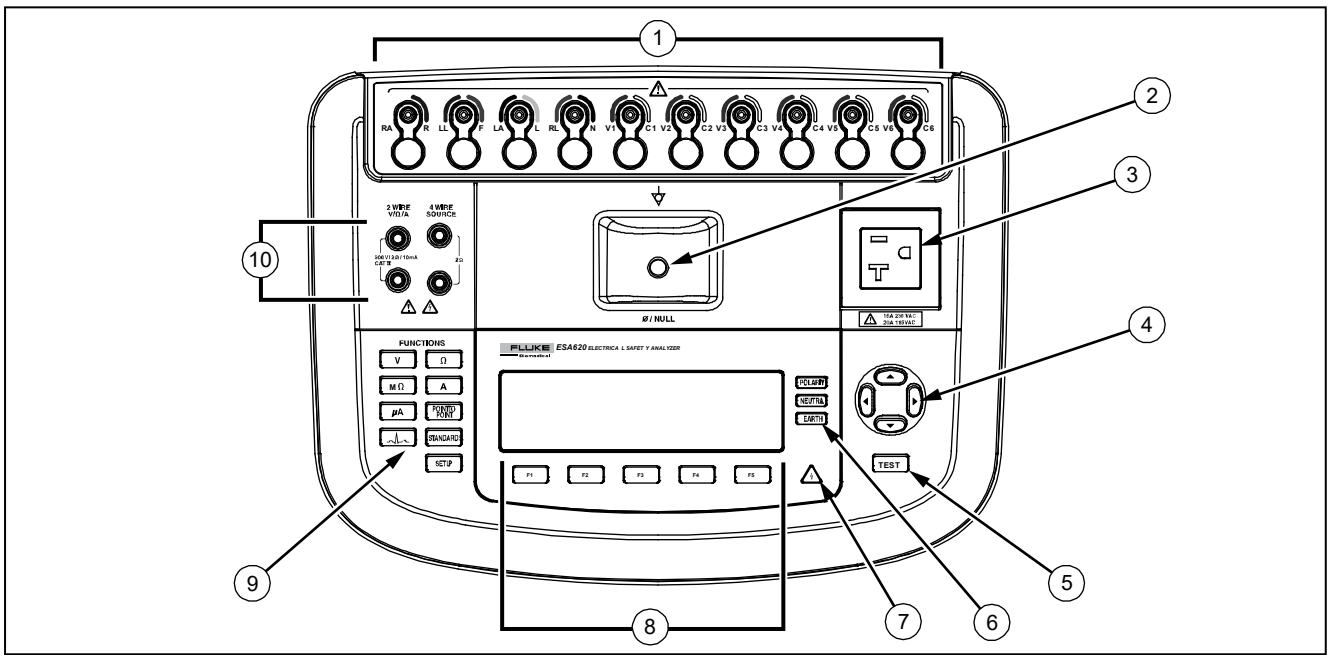

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Figure 1. Top-Panel Controls and Connections

Table 2. Top-Panel Controls and Connections

Item	Name	Description
①	ECG/Applied Parts Posts	Connection posts for Device Under Test (DUT) leads, like ECG leads. Used to test for leakage current through leads and to supply ECG signals and performance waveforms to a DUT.
②	Nulling Jack	Connection for zeroing test lead resistance. Use the probe attached to the test lead to put into the null jack. Use the null post adapter when you use the alligator clip attached to the test lead.
③	Equipment Outlet	Equipment outlet, specific to the version of the Analyzer, which provides a DUT connection.
④	Navigation Buttons	Cursor control buttons for navigating menus and lists.
⑤	Test Button	Initiates selected tests.
⑥	Equipment Outlet Configuration Buttons	Controls the wiring of the equipment outlet. Opens and closes the neutral and ground connection and reverses the polarity of the neutral and hot connection.
⑦	High Voltage Indicator	Indicates when high voltage is applied to the ECG/Applied Parts posts or L1 and L2 of the Test Receptacle.
⑧	Function Softkeys	Keys F1 through F5 are used to select from a number of selections that appear in the LCD display above each function softkey.
⑨	Test Function Buttons	Selects the various Analyzer test functions.
⑩	Input Jacks	Test lead connectors.

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

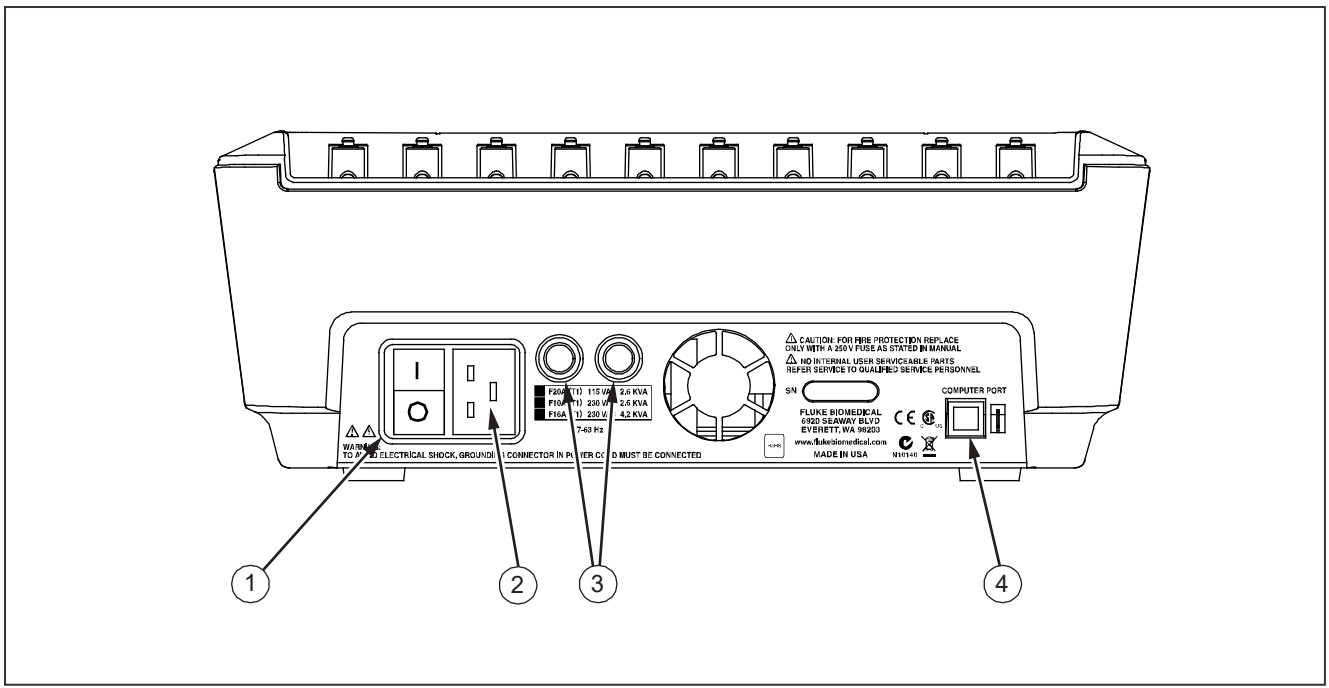

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Figure 2. Rear-Panel Connections

Table 3. Rear-Panel Connections

Item	Name	Description
①	AC Power Switch	Turns ac power on and off
②	AC Power Input Connector	A grounded male three-prong (IEC 320 C20) connector that accepts the line-power cord.
③	Line Power Fuse Holders	The line power fuses.
④	USB Device Port (B-style connector)	Digital connection for controlling the Analyzer from a PC or instrument controller.

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.

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 3 shows a DUT connected to the test receptacle, applied parts posts, and a separate connection to the DUT's enclosure or protected earth ground.

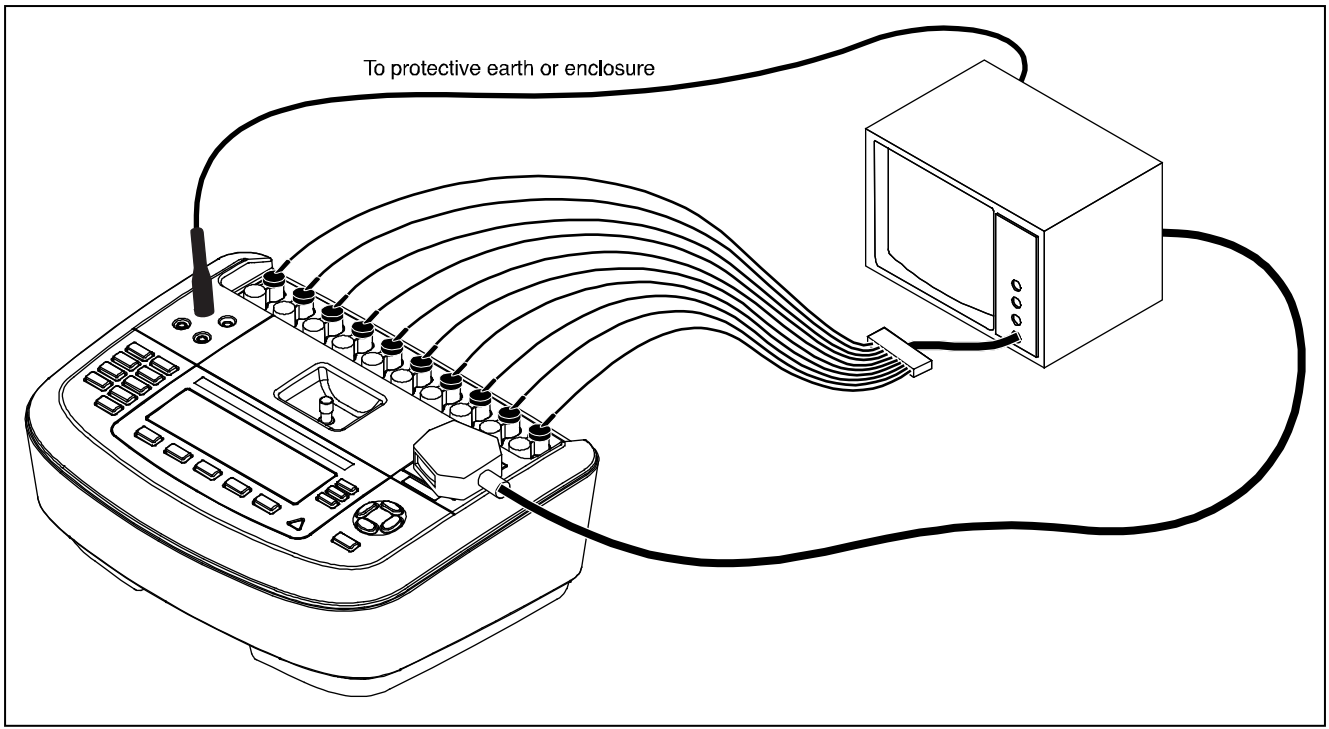

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Figure 3. DUT Connections to the Analyzer

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 rear 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.

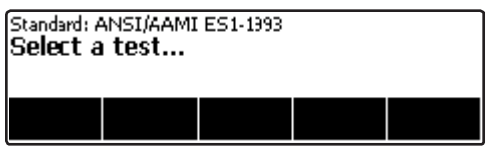

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Figure 4. Analyzer Ready for Operation

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 ESA620 power cycled off and then on again.

Adjusting the Display's Contrast

While the Analyzer displays the start-up menu shown in figure 4, press ▲ or ▼ 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 5, 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 F5) under a specific test will cause the analyzer to setup for or perform the selected test.

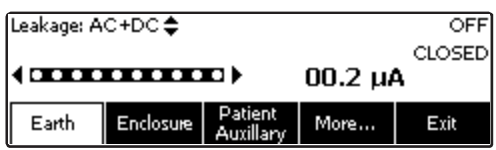

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Figure 5. Leakage Current Menu

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 ⬍ next to it. This icon indicates the selection is controlled by pressing ▲ or ▼. In this example, the leakage current measurement is switched between AC+DC, AC only, or DC only. The applied parts indicator has ◀ on the left end and ▶ on the right end. These icons indicate the use of ◀ and ▶ to select an applied part.

The three buttons along the right side of the display (POLARITY NEUTRAL EARTH) control the wiring 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.

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 protected earth ground or enclosure. To test the DUT ground using the 2-wire method with 200 mA test current:

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 the test lead to the 2-WIRE V/Ω/A jack.
4. Connect the other end of the test lead to the nulling jack in the middle of the top panel of the Analyzer.

   Note

   Use the supplied null post adapter when you null the test lead with the alligator clip.
5. Press the softkey labeled **Zero Leads**.
6. Move the test lead from the nulling post to the DUT's enclosure or protective earth connection. The resistance is displayed as shown in Figure 6.

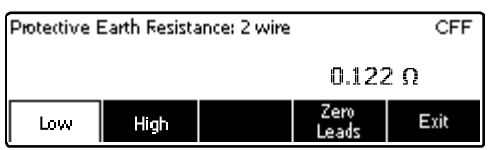

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Figure 6. DUT Ground Resistance Measurement

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 *ESA620 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.

Cleaning the Analyzer

⚠⚠ Warning

To prevent 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
ESA620 Getting Started Manual		2814971
ESA620 Users Manual CD		2814967
Power Cord	USA	2238680
	UK	2238596
	Australia	2238603
	Europe	2238615
	France/Belgium	2238615
	Italy	2238615
	Israel	2434122
Test Probe Set	USA, Australia, & Israel	650887
	Europe	1541649

Table 4. Replaceable Parts (cont.)

Item	Fluke Biomedical Part Number
Null Post Adapter	3326842
Carrying Case	2814980
Data Transfer Cable	1626219
⚠ T20A 250V Fuse (Time Lag), ¼ in x 1¼ in	2183691
⚠ T10A 250V Fuse (Time Lag), 5 mm x 20 mm	3046641
⚠ T16A 250V Fuse (Time Lag), 5 mm x 20 mm	3056494
15 – 20 A Adapter	2195732
⚠ 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
Kelvin Test Lead Set for 4-wire ground	2067864
Ground Pin Adapters	2242165
ESA620 USA/AUS/ISR Accessory Kit: Test Lead Set TP1 Test Probe Set AC285 Alligator Clip Set	3111008
ESA620 EUR Accessory Kit: Test Lead Set TP74 Test Probe Set AC285 Alligator Clip Set	3111024

Specifications

Temperature

Operating	10 °C to 40 °C (50 °F to 104 °F)
Storage	-20 °C to 60 °C (-4 °F to 140 °F)
Humidity	10 % to 90 % non-condensing
Altitude	To 5,000 meters @ 115 V ac mains and ≤150 V measurements To 2,000 meters @ 230 V ac mains and ≤300 V measurements
Display	LCD display
Communications	USB device port for computer control
Modes of Operation	Manual and remote

Power

120 Volt power outlet	90 to 132 V ac rms, 47 to 63 Hz, 20 A maximum
230 Volt power outlet	180 to 264 V ac rms, 47 to 63 Hz, 16 A maximum
Size (L x W x H)	32 cm x 23.6 cm x 12.7 cm (12.6 in x 9.3 in x 5 in)
Weight	4.7 kg (10.25 lb)
Safety	IEC 61010-1: Overvoltage category II, Pollution Degree 2 IEC 61010-2-030: Measurement 300 V, CAT II

Electromagnetic Compatibility (EMC)

International	IEC 61326-1: Controlled Electromagnetic Environment CISPR 11: Group 1, Class A *Group 1: Equipment has intentionally generated and/or uses conductively-coupled radio frequency energy that is necessary for the internal function of the equipment itself.*

Class A: Equipment is suitable for use in all establishments other than domestic and those directly connected to a low-voltage power supply network that supplies buildings used for domestic purposes. There may be potential difficulties in ensuring electromagnetic compatibility in other environments due to conducted and radiated disturbances.

Emissions that exceed the levels required by CISPR 11 can occur when the equipment is connected to a test object.

Korea (KCC) ..... Class A Equipment (Industrial Broadcasting & Communication Equipment)

Class A: Equipment meets requirements for industrial electromagnetic wave equipment and the seller or user should take notice of it. This equipment is intended for use in business environments and not to be used in homes.

USA (FCC)..... 47 CFR 15 subpart B. This product is considered an exempt device per clause.

Detailed Specifications

Voltage

Mains voltage

Ranges ..... 0.0 to 300 V ac rms

Accuracy ..... ±(2 % of reading + 1.0 V ac)

Accessible Voltage and Point to Point Voltage

Range ..... 0.0 to 300 V ac rms

Accuracy ..... ±(2 % of reading + 2 LSD)

Earth Resistance

Modes ..... Two terminal and four terminal

Test Current ..... >200 mA ac into 500 mΩ with open circuit voltage ≤24 V
25 A short circuit ±10 % (with open circuit voltage 6 V ac at nominal mains)

Range..... 0.0 to 2.0 Ω

Accuracy

Two Terminal Mode

Test current >200 mA ac into 500 mΩ .....±(2 % of reading + 0.015 Ω) for 0.0 to 2.0 Ω

Test current 1-16 A ac .....±(2 % of reading + 0.015 Ω) for 0.0 to 0.2 Ω
±(5 % of reading + 0.015 Ω) for 0.2 to 2.0 Ω

Four Terminal Mode

Test current >200 mA ac into 500 mΩ .....±(2 % of reading + 0.005 Ω) for 0.0 to 2.0 Ω

Test current 1-16 A ac .....±(2 % of reading + 0.005 Ω) for 0.0 to 0.2 Ω
±(5 % of reading + 0.005 Ω) for 0.2 to 2.0 Ω

Additional error caused by series inductance

Resistance	**Series Inductance**			
	0 µH	**100 µH**	**200 µH**	**400 µH**
0.000 Ω	0.000 Ω	0.030 Ω	0.040 Ω	0.050 Ω
0.020 Ω	0.000 Ω	0.025 Ω	0.030 Ω	0.040 Ω
0.040 Ω	0.000 Ω	0.020 Ω	0.025 Ω	0.030 Ω
0.060 Ω	0.000 Ω	0.015 Ω	0.020 Ω	0.025 Ω
0.080 Ω	0.000 Ω	0.010 Ω	0.015 Ω	0.020 Ω
0.100 Ω	0.000 Ω	0.010 Ω	0.010 Ω	0.015 Ω
>0.100 Ω	0.000 Ω	0.010 Ω	0.010 Ω	0.010 Ω

Equipment Current

Range	0 – 20 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 IEC 61010: Fig A-1
Crest factor	≤3
Ranges	0.0 to 199.9 μA 200 to 1999 μA 2.00 to 10.00 mA
Accuracy**	
DC to 1 kHz	±(1 % of reading + (1 μA or 1 LSD, whichever is greater))
1 to 100 kHz	±(2 % 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))

Mains on applied part test voltage ..... 110 % ±5 % of Mains, current limited to 7.5 mA ±25 % @ 230 V for IEC 60601
100 % ±5 % of Mains for AAMI, current limited to 1 mA ±25 % @ 115 V per AAMI
100 % ±5 % of Mains for 62353 current limited to 3.5 mA ±25 % @ 230 V per 62353

Note

For Alternative and Direct applied parts leakage tests, the leakage values are compensated for nominal mains as per 62353. Therefore, the accuracy specified for other leakages is not applicable. The actual leakage readings given during these tests will be higher.

Note

For all Map Voltage, additional residual leakage up to 5 μA @120 V ac, 9 μA @240 V ac applies on all measurements. Additional 2% error applies for all measurements within ±30 % of chosen current limit.

Differential leakage

Ranges ..... 50 to 199 μA
200 to 2000 μA
2.00 to 20.00 mA

Accuracy ..... ±10 % of reading ±(2 counts or 20 μA, whichever is greater)

Insulation resistance

Ranges ..... 0.5 to 20 MΩ
20 to 100 MΩ

Accuracy

20 MΩ Range ..... ±(2 % of reading + 2 counts)

100 MΩ Range ..... ±(7.5 % of reading + 2 counts)

Source test voltage ..... 500 V dc (+20 %, -0 %) 1.5 mA short-circuit current or 250 V dc selectable

ECG Performance Waveforms

Accuracy ..... ±2 %
±5 % for amplitude 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 and 2 Hz

Sine wave ..... 10, 40, 50, 60, and 100 Hz

Triangle wave ..... 2 Hz

Pulse (63 ms pulse width)..... 30 and 60 BPM