

FLUKE®

Biomedical

ESA620

Electrical Safety Analyzer

Getting Started Manual

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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, either email techservices@flukebiomedical.com or call 1-800- 648-7952 or 1-425-446-6945.

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.

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Please note that only serialized products and their accessory items (i.e., products and items bearing a distinct serial number tag) are eligible for partial refund and/or credit. Nonserialized parts and accessory items (e.g., cables, carrying cases, auxiliary modules, etc.) are not eligible for return or refund. Only products returned within 90 days from the date of original purchase are eligible for refund/credit. In order to receive a partial refund/credit of a product purchase price on a serialized product, the product must not have been damaged by the customer or by the carrier chosen by the customer to return the goods, and the product must be returned complete (meaning with all manuals, cables, accessories, etc.) and in “as new” and resalable condition. Products not returned within 90 days of purchase, or products which are not in “as new” and resalable condition, are not eligible for credit return and will be returned to the customer. The Return Procedure (see below) must be followed to assure prompt refund/credit.

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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 ESA620 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 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, EN62353, AN/NZS 3551, IEC61010, VDE 751) and domestic (ANSI/AAMI ES1, NFPA 99) electrical-safety standards. The integrated ANSI/AAMI ES1, IEC60601-1, and IEC61010 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
	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
	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. Under no circumstances should the terminals of the Analyzer be connected to any MAINS voltage.

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 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 because 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 15-20A adapter to power devices rated in excess of 15A. Doing so may overload the installation.**
- **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.

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 (US, Australia, and Israel only)
- TP74 Test probe set (Europe only)
- Ansur demo CD
- Alligator clip set

Instrument Familiarization

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

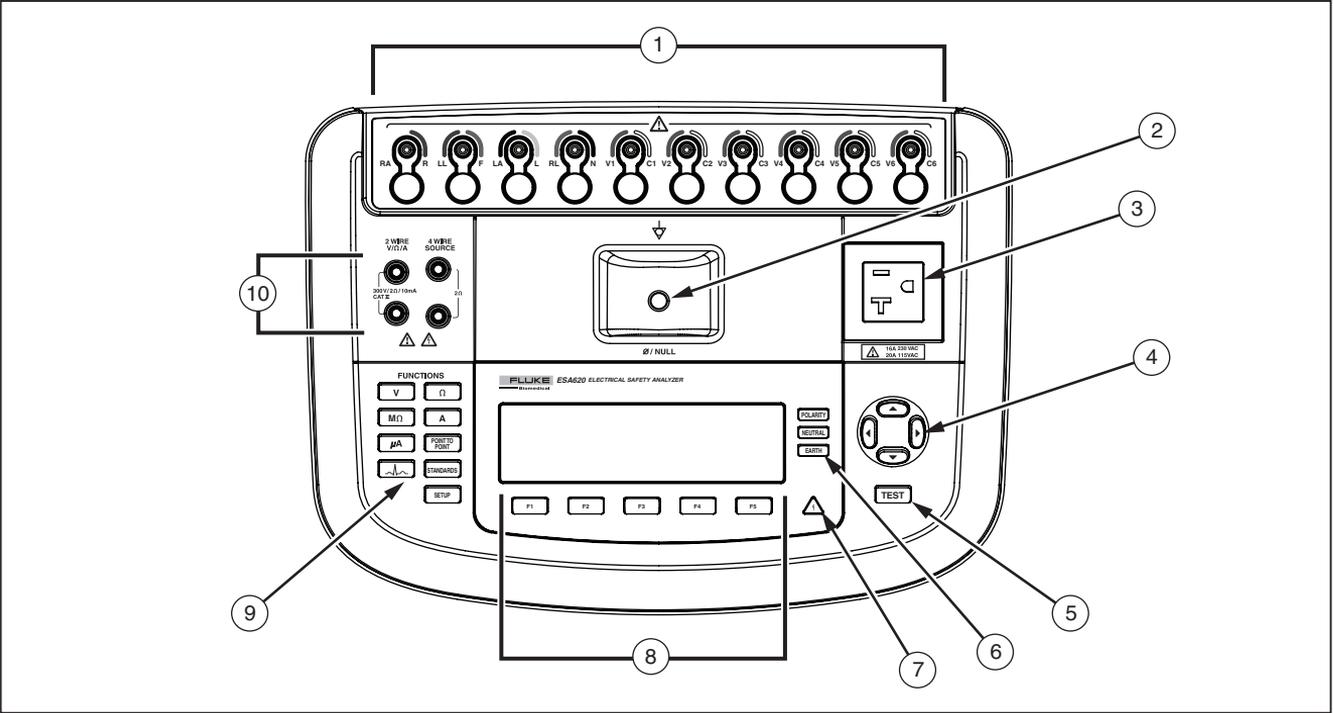


Figure 1. Top-Panel Controls and Connections

faw02.eps

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 Post	Connection for zeroing test lead resistance.
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 describes the rear-panel connections of the Analyzer.

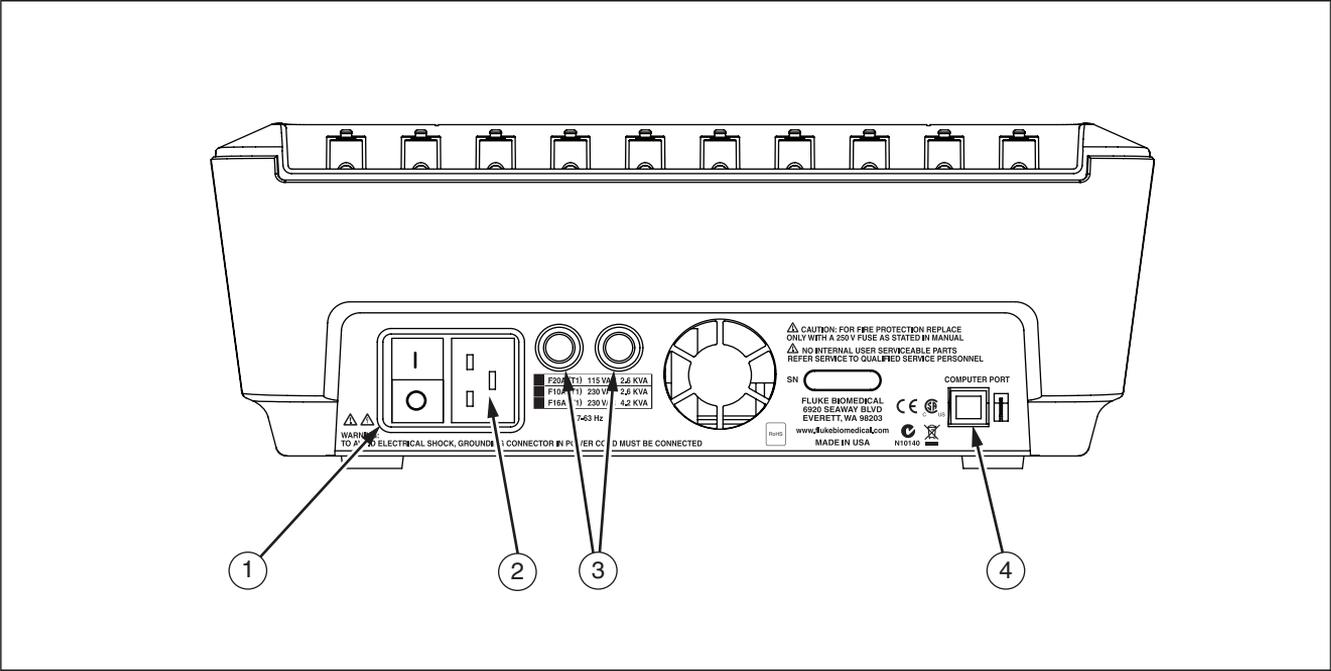


Figure 2. Rear-Panel Connections

faw01.eps

Table 3. Rear-Panel Connections

Item	Name	Description
1	AC Power Switch	Turns Analyzer 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.

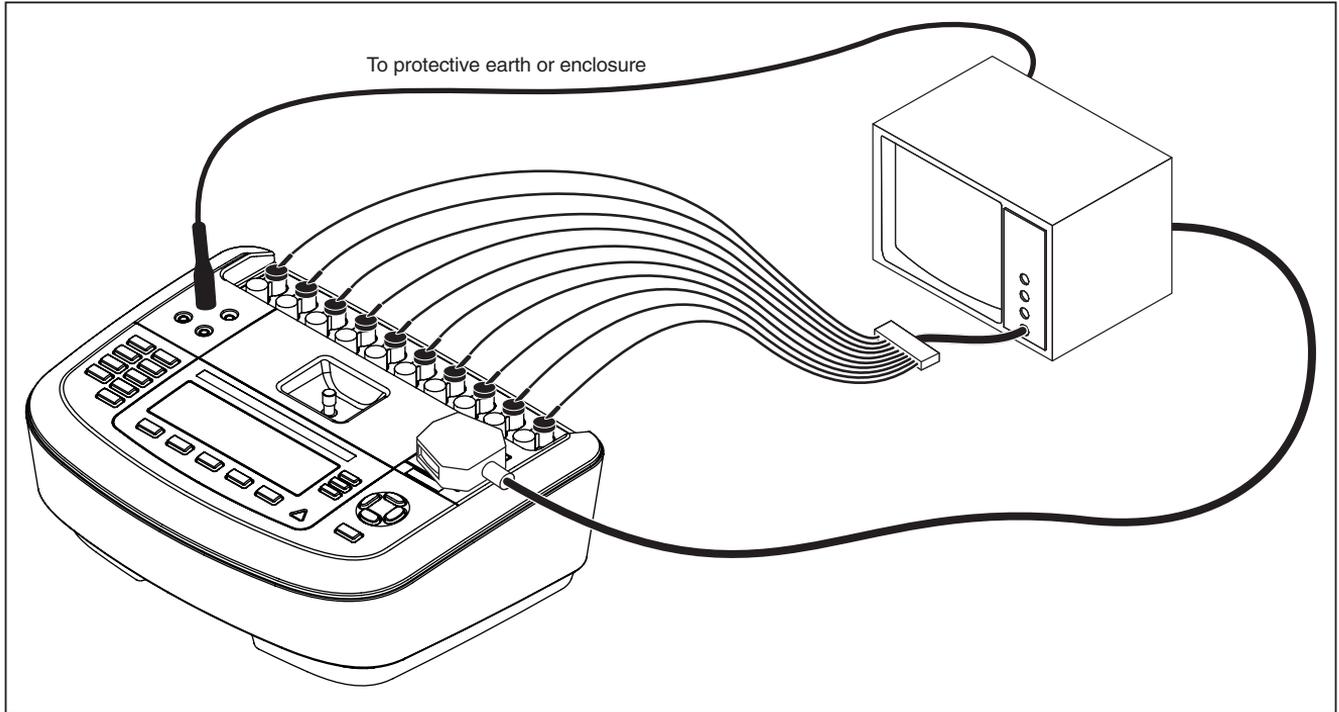


Figure 3. DUT Connected to the Analyzer

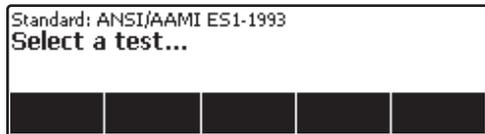
faw03.eps

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

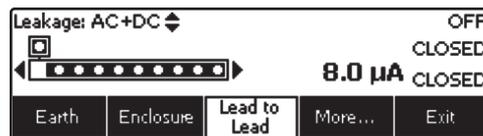
low, the Analyzer displays this fault and does not continue until the supply voltage is corrected and the ESA620 power cycled off and then on again.

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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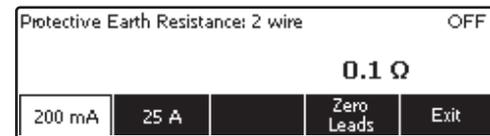
Figure 5. Leakage Current Menu

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 (  ) 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  to reveal the resistance function menu.
3. Connect a test lead between the 2-WIRE V/ Ω /A red jack and the nulling post in the middle of the Analyzer's top panel.
4. Press the softkey labeled **Zero Leads**.
5. 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.



faw06.eps

Figure 6. DUT Protective Earth 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 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
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
Ansur Plug-in, CD with demo version		2795488
Test Probe Set	USA, Australia, & Israel	650887
	Europe	1541649

Table 4. Replaceable Parts (cont.)

Item	Fluke Biomedical Part Number
Carrying Case	2814980
Data Transfer Cable	1626219
T20A 3AB 250V Fuse (SLO-BLO), 1¼" x ¼"	2183691
13 A BS 1362 Fuse, 1" x ¼"	3095769
T10A 250V Fuse (Time Lag), 5 x 20 mm	3046641
T16A 250V Fuse (Time Lag), 5 x 20 mm	3056494
15 – 20 A Adapter	2195732

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

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 (H x W x L) 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 Standards

CE IEC/EN61010-1 2nd Edition; Pollution degree 2

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

Electromagnetic Compatibility Standards (EMC)

European EMC..... EN61326-1

Detailed Specifications

Voltage

Ranges (Mains voltage) 90 to 132 V ac rms
180 to 264 V ac rms

Range (Accessible voltage) 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
10 – 25 Aac (with open circuit voltage <6 Vac)
Ranges0.0 to 0.2 Ω
Accuracy.....±(2 % of reading + 0.005 Ω)

Equipment Current

Range.....0 – 20 A ac rms
Accuracy.....5 % of reading ± (2 counts or 0.2 A, whichever is greater)

Leakage Current

Modes.....AC+DC (True-rms)
AC only
DC only
Patient Load SelectionAAMI ES1-1993 Fig. 1
IEC 60601: Fig 15
IEC 61010: Fig A-1

Crest factor.....≤3
Ranges0.0 to 199.9 μA
200 to 1999 μA
2.00 to 10.00 mA

Accuracy

0.0 to 199.9 μA.....±(1 % of reading + 1 μA) from DC to 1 kHz
200 to 1999 μA.....±(2 % of reading + 1 μA) from 1 to 100 kHz
2.00 to 10.00 mA.....±(5 % of reading + 1 μA) from 100 kHz to 1 MHz
Mains on applied part test voltage110 % ±5 % of Mains, current limited to 7.5 mA ±25 % @ 230 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

Differential leakage

Ranges.....	10 to 199 μ A 200 to 2000 μ A 2.00 to 20.00 mA
Accuracy	\pm 10 % of reading \pm (2 counts or 20 μ A, whichever is greater)

Insulation resistance

Ranges.....	0.5 to 20 M Ω 20 to 100 M Ω
Accuracy	
20 M Ω Range.....	\pm (2 % of reading + 2 counts)
100 M Ω Range.....	\pm (5 % of reading + 2 counts)
Source test voltage	500 V dc (+20 %, -0 %) 1.5 mA short-circuit current or 250 V dc selectable when AN/NZS 3551 standard selected

ECG Performance Waveforms

Accuracy	\pm 2 % \pm 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
Sine wave.....	10, 40, 50, 60, and 100 Hz
Triangle wave.....	2 Hz
Pulse (63 ms pulse width)	30 and 60