FLUKE®
Biomedical

DALE601/601E
Electrical Safety Analyzer

Operators Manual

PN 2243573
August 2007

Warranty and Product Support

Fluke Biomedical warrants this instrument against defects in materials and workmanship for one year from the date of original purchase. 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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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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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.

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Cleveland Calibration Lab
Tel: 1-800-850-4606
Email: globalcal@flukebiomedical.com

Everett Calibration Lab
Tel: 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

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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 DALE 601/601E Electrical Safety Analyzer is manufactured in Everett, Washington by Fluke Biomedical, 6920 Seaway Blvd., Everett, WA, U.S.A.

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Introduction

The DALE601/601E Electrical Safety Analyzer, hereafter referred to singly as the Analyzer, is a simple, highly versatile, and portable instrument. The Analyzer is used to evaluate the basic electrical safety of electrical systems, medical devices, and physiological instrumentation, and a broad range of external measurements, as listed under *Key Features.*

Its compact handheld size makes it an ideal addition to a toolbox, as well as serving as a bench top instrument for the laboratory. The Analyzer does not sacrifice functions or accuracy, and its low cost permits putting one on each bench.

Simplicity

The Analyzer is simple to use, incorporating the following:

- A single, labeled master function switch that leads the user through a complete specific measurement procedure
- A single range meter for each measurement that minimizes the chance of erroneous readings
- Heavy-duty switches that change polarity, open and close the neutral, and select chassis or earth leakage current measurements
- A single slide switch that gives the user a choice of AAMI or IEC test load
- Five universal EKG lead connectors that allow for any type of lead connection
- Green and amber lights that indicate five power line conditions

The Analyzer uses sophisticated electronics for true rms measurement of current and voltage. Input impedance uses the manually selectable AAMI ES1-1993 or IEC601-1 test load to compensate for high frequency components in the measurement. Resistance measurements are made with a four-wire Kelvin bridge to eliminate errors resulting from cable length and connector resistance.

Versatility

The Analyzer has an additional unique capability to make a broad range of external measurements, including leakage current and/or voltage gradients and the resistance between two points. Providing the voltage and measuring function, the Analyzer can independently measure the isolation current of a device. Thus, the Analyzer can evaluate the electrical system; system installation; and, separately, the isolation of probes and transducers, in addition to conventional leakage current measurement.

General Safety Considerations

The Analyzer should be inspected and its related documentation reviewed for familiarization with safety markings and instructions before operation.

Symbols

Table 1-1 describes the symbols used in association with the Analyzer.

Table 1-1. Symbols

Symbol	Description
⚠	Hazardous voltage
⚠	Important information; refer to manual.
CE	Conforms to European Union directives
	Do not dispose of this product as unsorted municipal waste. Go to Fluke's website for recycling information.
CAT I	IEC Measurement Category I – CAT I equipment designed to protect against transients in equipment on circuits not directly connected to MAINS. Under no circumstances should the terminals of the Analyzer be connected to any MAINS voltage.

Warnings and Cautions

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:

- **Disconnect all patient connections before connecting the device to be tested to the Analyzer. Continued connection may jeopardize patient safety by possible application of measurement currents.**
- **Maintain care when making connections. Isolation test uses 120 or 230 V ac applied to patient leads or to external connections that are accessible to the tester. Although the voltage is current limited to 1 mA is safe for healthy intact skin contact, it can be felt and can result in a startle reaction.**
- **Ensure the mains installation current rating is adequate for the DUT (device under test). If the DUT requires 20 A, the Analyzer must be powered by a 20 A service to avoid overloading the mains installation.**

⚠ Caution

To avoid possible damage to the Analyzer, follow these guidelines:

- **Ensure that the DUT power requirements are within the capabilities of the Analyzer, labeled as 15 A or 20 A at 120 V ac (depending on model purchased) and 10 A at 230 V ac. While the analyzers are equipped with receptacles limiting access to devices of higher ratings, the replacement cord set may have been installed incorrectly.**

- **This device is sensitive to electromagnetic fields. If interference is encountered in measurements, reconfigure the test setup or contact the manufacturer.**
- **Do not leave the DUT connected and drawing high load current for extended periods. The Analyzer is not designed for continuous measurements and may overheat.**
- **Always pause in the OFF (middle) position when switching polarity from normal to reverse. Inductive loads of the DUT may create high voltage transients when trying to reverse the direction of current flow instantaneously.**

Key Features

- Small, lightweight, self-contained, portable, hand-held instrument
- 120 V and 230 V operation (DALE601 and DALE601E, respectively)
- Easy to use controls with master range meter for each test
- Five (5) universal EKG lead connectors
- True rms measurement of current and voltage
- Accurate resistance measurements with 4-wire Kelvin bridge
- Manually selectable ANSI/AAMI ES1-1993 or IEC601-1 test loads
- Measures the following:
  - Line (Mains) Voltage
  - Device Current
  - Earth Resistance
  - Leakage Current: Earth, Enclosure (Chassis), Patient Lead (Leakage Currents can be measured in Open/Closed Neutral, Normal/Reversed Polarity and Open/Closed Ground and are displayed directly in μA.)
  - Patient Auxiliary Current
  - M.A.P. (Patient Lead Isolation) Current
  - External Measurements: Leakage Current, Electrical Isolation, Resistance

Instrument Familiarity

The Analyzer is shown in Figures 1-1 and 1-2, and Table 1-2 describes its labeled components.

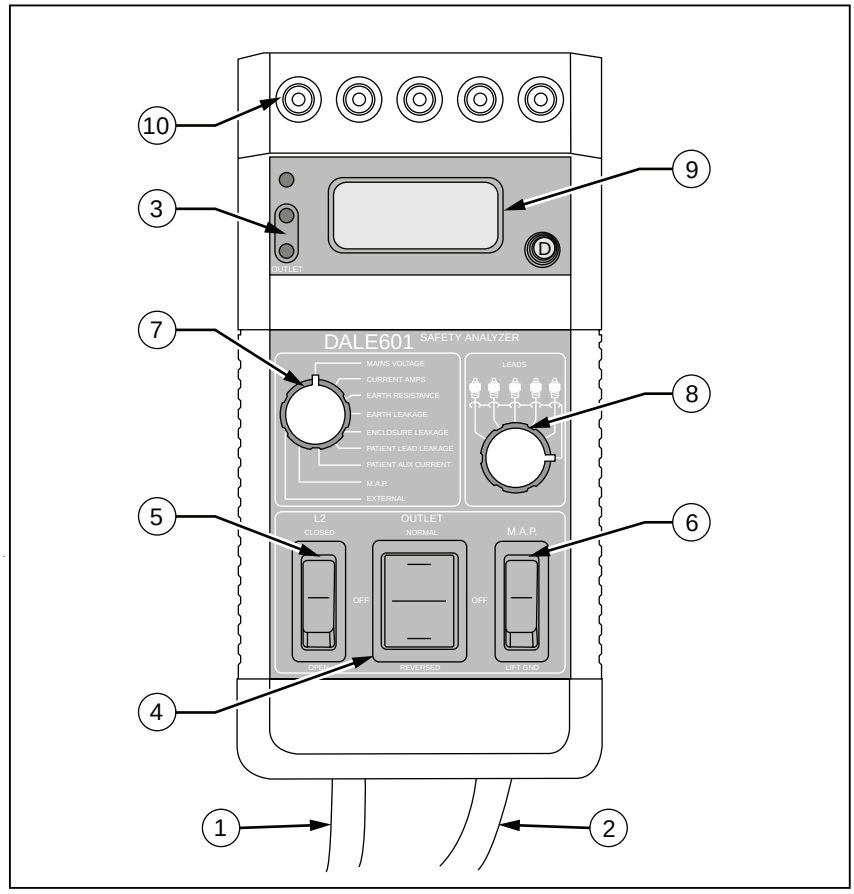

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Figure 1-1. Analyzer Front Panel Components and Controls

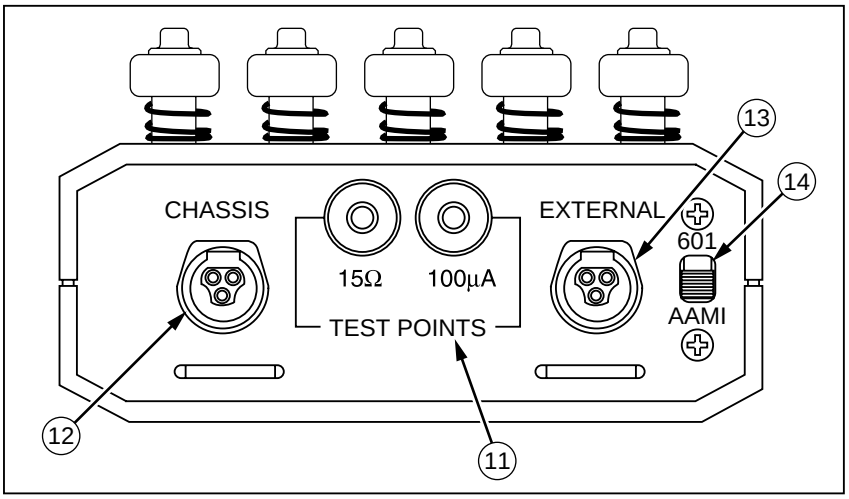

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Figure 1-2. Analyzer Top Panel Components and Controls

Table 1-2. Components and Controls of the Analyzer

Label	Name	Function
①	Power Cord	Supplies power to the Analyzer and to the DUT. The measurement circuits are energized when the power cord is plugged into an outlet. There is no on/off switch.
②	Test Receptacle	Supplies power to the DUT: DALE601, 15 A at 125 V or DALE601, 20A at 125V; and DALE601E, 10 A at 230 V.
③	Outlet Indicators (DALE601 only)	Verifies the polarity and wiring of the outlet to which the Analyzer is connected. Only correctly wired outlets should be used. Not applicable to isolated systems.
④	Outlet Switch	With the center OFF position, permits testing with both the NORMAL (forward) and REVERSED polarity of the line. It is recommended that the switch is paused in the center OFF position before changing polarity.

Table 1-2. Components and Controls of the Analyzer (cont.)

Label	Name	Function
⑤	L2 (Neutral) Switch	Permits making leakage current measurements under the OPEN neutral (L2) condition as required by UL and IEC.
⑥	Lift Ground / M.A.P. Switch	A dual function switch. The LIFT GROUND position will open ground to the device for leakage current measurements. The MAP test position will energize the selected patient lead at mains voltage, current limited, to measure the isolation current when the function switch is in the M.A.P. position. With the function switch in the EXTERNAL position, the isolation test voltage is supplied to the EXTERNAL connector for measuring the isolation current of a probe or transducer.
⑦	Function Switch	Provides direct one-step selection of the measurement to be made. The functions are: Mains voltage, instrument current, grounding (earth) resistance, earth and leakage currents and the patient lead currents. These include lead leakage, auxiliary current and mains on applied parts (M.A.P.) for isolation (sink) current. An external position is provided to measure leakage current between two points, or isolation current of probes and transducers, independent of their instruments.
⑧	Lead Switch	Directs the selected measurement to the desired patient lead. When testing a 10 lead device, a second pass is required for the C leads. The setting to the far right is the ALL lead position.
⑨	Meter (Display)	A large, ½ inch, high contrast 3½-digit display of the measured parameter. This can display 1999 with decimal points added where required
⑩	Universal Patient Leads	Provide means for the connection of the patient leads for leakage current measurement.

Table 1-2. Components and Controls of the Analyzer (cont.)

Label	Name	Function
⑪	Test Points	0.15 Ω and 100 µA; provided to check the Analyzer by clipping onto with the chassis cable and selecting appropriately, RESISTANCE or ENCLOSURE LEAKAGE, via the function switch.
⑫	Chassis Connector	Provides means for inputting the chassis cable with its clip for connection to the DUT chassis or enclosure. With the FUNCTION switch in the resistance position, the earth resistance is measured, and on the enclosure position, the enclosure leakage current is measured.
⑬	External Connector	Provided for making external measurement of resistance, voltage gradient, leakage current or isolation current of probes and transducers, when used in conjunction with the chassis cable for the other reference point.
⑭	Test Load	Selector switch between IEC601.1 and AAMI
	Chassis Cable (not shown)	A black coil cord with a clamp with black insulation for measurement of enclosure leakage and earth resistance. One is supplied with each Analyzer.

Specifications

The following are specifications for the Analyzer. Please contact your Fluke Biomedical service representative for more information regarding the device specifications.

Controls

Function Switch.....9 position rotary
Lead Switch.....6 position rotary
Neutral Switch .....2 position rocker (Open/Closed)
Polarity Switch.....3 position rocker (Normal/Off/Reversed)
Leakage Switch .....2 position rocker (Chassis/Earth)

MAP / Ground Switch	2 position rocker (Open Ground / Apply Mains on Applied Part test voltage)
DUT Power	15 A @ 120 V, 20 A @ 120 V, 10 A @ 230 V
Physical Size	4.0 x 7.8 x 1.6 in (102 x 196 x 41 mm)
Mains Voltage	
Range	Line Voltage
Accuracy	±2 % of reading, ±1 digit
Current Consumption	
Range	0 – 14.99 A (Dale601-1515) 0 – 19.99 A (Dale601-1520/2020) 0 – 9.99 A (Dale601E)
Accuracy	±5 % of reading, ±1 digit
Earth Resistance	
Range	0 – 19.99 Ω
Accuracy	±1 % of reading, ±1 digit (0 – 1.99 Ω) ±2 % of reading, ±1 digit (2 – 19.99 Ω)
Current Source	10 mA DC (four-wire bridge)
Leakage Current	
Range	0 – 1999 µA
Accuracy	
DC and 25 HZ to 1 KHz	±1 % of reading, ±3 LSD
1.0 KHz to 100 KHz	±2.5 % of reading, ±3 LSD
100 KHz to 1 MHz	±5 % of reading, ±3 LSD
Type Measurement	True rms
Test Load	AAMI or IEC601 – 1 (selectable)
Isolation Test (Mains on Applied Parts)	
Voltage	Mains voltage
Current	Limited @ 1 mA
Current Capacity	
DALE601-1515	15 A
DALE601E	10 A
DALE601-1520/2020	20 A, 20 % duty cycle (2 minutes on, 8 minutes off)
Environmental	
Operating Temperature	15 – 40 ºC
Storage Temperature	- 20 – 65 ºC
Relative Humidity	90 % max

Accessories

Standard accessories and part numbers are listed in Table 1-3. Optional accessories and part numbers are listed in Tables 1-4 and 1-5.

Table 1-3. Standard Accessories

Name	Description	Part Number
Chassis Cable: black coil cord, 8 ft extended length with clamp with black insulation	For measurement of earth resistance and enclosure leakage current. Also used as reference lead for external measurement.	2392409
Soft Carrying Case	Case to carry accessories and to protect the Analyzer when placed in a toolbox.	2392584
Operators Manual	This book	2243573

Table 1-4. Optional Accessories

Name	Description	Part Number
8-foot black cable- with large clamp with black insulation	Used for dual lead ~~leakage~~	2392409
Chassis Cable: black coil cord, 16 ft extended with clamp with black insulation	For measurement of earth resistance and enclosure leakage current. Also used as reference lead for external measurement.	2231563
Chassis Ground Probe: black coil cord with copper needle probe for testing receptacles and for tight spaces, 8 ft long extended	For measurement of earth resistance and enclosure leakage current. Also used for grounding saline baths for isolation testing of probes and transducers.	2392427

Table 1-4. Optional Accessories (cont.)

Name	Description	Part Number
External Leakage Cable: coiled cord is 8 ft, extended with a clamp with red insulation	Standard auxiliary cable for external measurements of leakage current and voltage gradient between two conductive surfaces.	~~2292409~~
External Leakage Cable: coiled cord is 16 ft extended with a clamp with red insulation	Standard auxiliary cable for external measurements of leakage current and voltage gradient between two conductive surfaces.	2261563
Hard Carrying Case	Case for carrying the Analyzer and accessories.	2231830

Table 1-5 lists optional probe adaptor cables needed for isolation testing. These make electrical contact with all terminals of an ultrasound probe connector.

Table 1-5. Optional Probe Adapter Cables

Description	Part Number
GEYMS probe (for GE product)	2392453
LOGIQ series probe (for GE product)	2392466
For Model 21369A probe (for HP/Agilent product)	2392482
For Model 21364A probe (for HP/Agilent product)	2392494
UNIVERSAL Ultrasound Transducer Probe	2231616

Chapter 2
Operation

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Preliminary Steps

The Analyzer measures electrical parameters, as described below. These voltages and currents are a natural phenomenon, and their presence within reasonable limits does not constitute a hazard. However, it is necessary to measure their values to determine if there is a significant change from previous measurements or from the device specifications.

Figure 2-1 is a block diagram of a typical line-operated instrument with patient connections. Measured parameters are labeled, and the discussions that follow are keyed to the labels in the diagram.

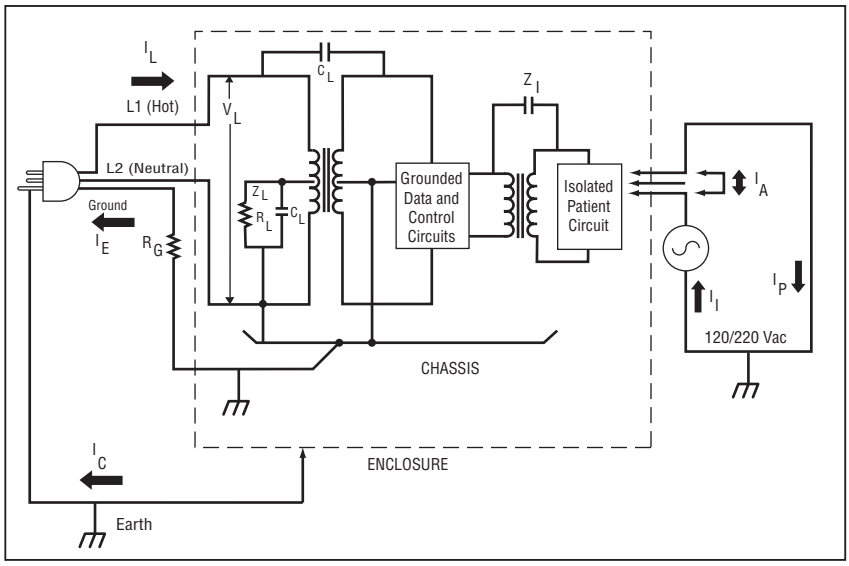

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Figure 2-1. Block Diagram of a Line-operated Instrument

Preparing the Analyzer for Use

⚠⚠ Warning

To avoid possible electrical shock or personal injury to the patient, disconnect all patient connections to the device to be tested before starting.

To prepare the Analyzer for use:

1. Place the Analyzer's switches in the following initial positions:

FUNCTION switch	**Mains Voltage**
NEUTRAL switch	**CLOSED**
OUTLET switch	**OFF** (center)

2. Plug the Analyzer into a properly-rated outlet.

⚠⚠ Warning

To avoid possible electrical shock or personal injury to the patient, plug the Analyzer only into a grounded, "Hospital Grade" power receptacle. Do not circumvent this precaution for any reason.

The Analyzer is equipped with a hospital-grade power plug. Grounding reliability can be achieved only when the Analyzer is connected to an equivalent power receptacle marked "Hospital Grade." Grounding is important for personnel safety and to make some of the tests offered by the Analyzer.

Note

This device is sensitive to electromagnetic fields. If interference is encountered in measurements, reconfigure the test setup or contact the manufacturer.

Verifying the Power Outlet Connections

Note

This section is not applicable to isolated power systems or to the 601E (230 V version).

Three neon lamps provide indication of the polarity and condition of the outlet used, as determined by the following chart.

REV	○	●	○	○	●
	●	●	●	○	○
OK	●	○	○	○	●
	Correct wiring	**Reverse polarity**	**Open ground**	**Open hot**	**Hot / ground reversed**

Note

Lamps do not check open neutral or neutral/ground reversal.

If the line is found faulty, correct the problem before proceeding. If the line checks OK, plug the device to be tested into the Analyzer's line receptacle.

⚠⚠ Warning

To avoid possible electrical shock or personal injury due to faulty device under test, follow these guidelines:

- **Do not touch the metal chassis, any accessible conductive part, or terminal of the DUT with mains power applied until all applicable tests have been completed and the product is verified as compliant.**
- **Keep fingers behind guards on supplied test accessories and/or if necessary remove power from the DUT before making necessary connections.**

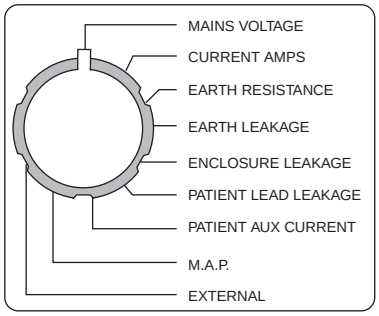
Measuring Line (Mains) Voltage

Line Voltage (V_L) is the mains power supplied by the electrical distribution system of the hospital. It is shown as a three-wire system of HOT, NEUTRAL (L2) and GROUND with NEUTRAL, like GROUND, returned to true earth at entry into the building.

Measurement is made between the HOT and NEUTRAL wires via transformer coupling to isolate the measuring circuits from the line.

To measure line voltage:

1. Set the **FUNCTION** switch to **MAINS VOLTAGE (**the recommended starting position).



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   The Analyzer displays the mains voltage with a resolution of 1 V.

2. Set the **OUTLET** switch to the **NORMAL** position and **POWER ON** the DUT.

3. The Analyzer displays mains voltage, but under the load of the device being tested. Depending on the DUT operating current and the electrical supply wiring, the voltage differential may be significant.

   Note

   The difference between the line voltages with the DUT powered off and powered on indicates whether the line is adequate for the device. A large drop may suggest that a dedicated, higher ampacity line should be run in for the device.

4. Check the value under load against the DUT ratings to be sure that the actual value remains within prescribed limits.

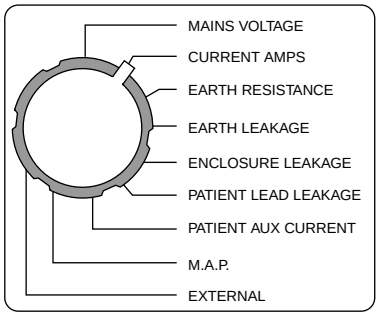
Measuring Device Current

Device Current (I_L) (instrument current) is that used by the DUT. When powered on, the DUT should be operated in its various modes to determine the worst condition to track. Verify that the DUT current is within the current rating of the Analyzer being used.

Measurement is made in the HOT wire via transformer coupling to ensure that the total current is measured, because it is possible that the NEUTRAL and GROUND wires share the return path

To measure device current.

1. Set the **FUNCTION** switch to **CURRENT AMPS**.



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   The Analyzer displays the DUT current to 19.99 A.

2. Set the **OUTLET** switch to **NORMAL** and **L2** to **CLOSED**.
3. **POWER ON** the DUT and place it in its maximum load condition to obtain the proper reading.
4. Log this data and note changes in values to help detect problems early.

Measuring Earth Resistance

Earth Resistance (R_G) (grounding resistance) is the resistance from the DUT conductive "grounded" chassis to the grounding terminal on the receptacle into which it is plugged. Maintaining a low resistance is important to protect the chassis from becoming "hot" with current as a result of an internal fault. The resulting voltage drop across the ground wire raises the potential of the chassis with respect to the local ground, creating a potential hazard.

The ground wire in the power cable is responsible for most of the resistance, which is proportional to the cable length. See Table 2-1 for typical values for a 10-foot cable. The resistance measurement also includes the junction resistance in connecting the wire at both ends and the bulk resistance of the chassis from the grounding point to the point of measurement.

Low resistance values are being measured between the clip on the black chassis cable and the grounding pin receptacle of the Analyzer. Therefore, the Analyzer uses a four wire Kelvin bridge to make the measurement, avoiding errors caused by the contact resistance of the cable connectors and the length of the test cable.

Table 2-1. Ground Resistance of a Ten-foot Power Cable

Wire Size (AWG)	Resistance (milliohms)
18	64
16	41
14	25

Note

Underwriters Laboratory (UL) limits the ground resistance for new products to 100 mΩ (0.1Ω), and the National Fire Protection Association (NFPA) limits ground resistance to 150 mΩ for new products and 500 mΩ for devices in the field.

To measure earth resistance:

Note

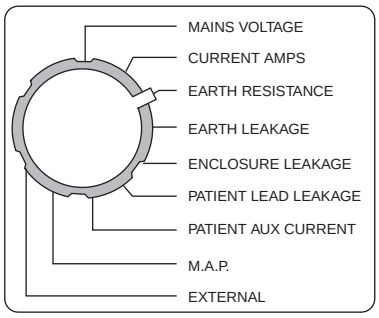
This test is applicable only to devices using three-wire (grounded) power cords.

1. Set the **OUTLET** switch to the **OFF** position.
2. Connect the standard cable (supplied with unit) that has a black coil cord cable with the clamp with black insulation to the **CHASSIS** connector on the top panel of the Analyzer.
3. Clamp the cable clip to the exposed chassis of the DUT or to the enclosure, if conductive.

Note

Ensure that bare metal is reached and that both jaws of the clip are in contact with the chassis. Do not use metal labels or incidental conductive hardware for this test.

4. Once connection is made, set the **FUNCTION** switch to **EARTH RESISTANCE**.



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The earth resistance value is displayed to 19.99 Ω.

Measuring Leakage Current

Leakage current is the flow of current through or over the surface of an insulating material or insulator. Leakage current is caused by the proximity of the hot wire or line potential components to the chassis. In Figure 2-1, this relationship is represented by Z_L, a combination of capacitance (C_L) and resistance (R_L) components. For example, if a person comes in contact with an operational device, leakage current flows from the contact point, through the person's body, and back to ground. Measurement of leakage current is required on all mains power products.

Earth Leakage Current

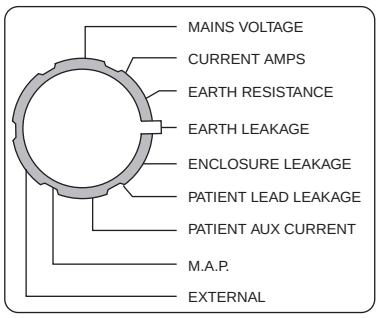
Earth Leakage Current (I_E) (internal chassis current) flows in the ground wire of the power cable to return the chassis leakage current to true earth ground. This current is not a hazard if the ground wire remains intact and the current does not become excessive. This leakage can occur if a major fault results in the ground wire sharing the load current with the neutral wire or in supplying the total return. The measurement is made using the 1000 Ω AAMI load placed directly in series with the ground wire. Open neutral usually represents the worst case.

To measure earth leakage current:

Note

Earth leakage current flows normally in the ground wire of the device. This test is applicable only to devices using three-wire (grounded) power cords.

1. Set the **FUNCTION** switch to **EARTH LEAKAGE**.



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The leakage current displays to 1999 µA.

2. Take measurements under all combinations of the **OUTLET** switch in **NORMAL** and **REVERSE**, the **L2 NEUTRAL** switch in **CLOSED** and **OPEN**, and the device power turned **ON** and **OFF**.

Note

Be sure to pause in the OFF (middle) position when switching from NORMAL to REVERSE.

Enclosure (Chassis) Leakage Current

Enclosure Leakage Current (I_C) flows between the accessible conductive chassis or enclosure and earth ground, as measured through a 1000 Ω impedance. Under the condition of an open ground, this current is the same as the earth current. With ground intact, the current should be very low, reflecting the mΩ impedance of the ground wire paralleling the 1000 Ω AAMI load.

Note

Differentiation is made between earth and chassis currents because the wide use of insulated enclosures makes a conductive chassis inaccessible. Under this condition, earth current represents total leakage.

To measure enclosure leakage current:

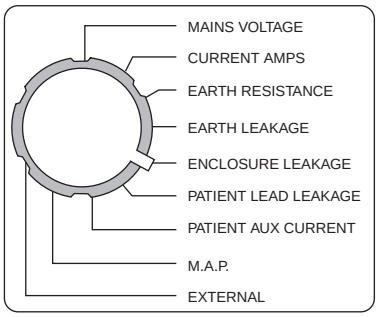
1. Connect the standard cable (supplied with unit) that has a black coil cord cable with the clamp with black insulation to the **CHASSIS** connector on the top panel of the Analyzer.

2. Clamp the cable clip to accessible conductive sections of the chassis and the enclosure.

Note

Ensure that bare metal is reached and that both jaws of the clip are in contact with the chassis. Do not use metal labels or incidental conductive hardware for this test.

3. Set the **FUNCTION** switch to **ENCLOSURE LEAKAGE**.



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The enclosure leakage displays in µA.

4. Take measurements under all combinations of the **OUTLET** switch in **NORMAL** and **REVERSE**, the **GROUND** switch **CLOSED** and **OPEN**, the **L2 NEUTRAL** switch in **CLOSED** and **OPEN**, and the device power turned **ON** and **OFF**.

Note

Be sure to pause in the OFF (middle) position when switching from NORMAL to REVERSE.

Patient Lead Leakage Current

Patient Lead Leakage Current (I_P) (source current) would flow through individual patient leads and all of the patient leads connected together, if the patient were to come into contact with earth ground. This test was originally required only for devices incorporating intra-cardiac electrodes or conductive

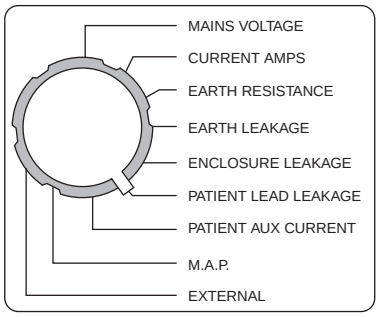
pathways directly to the heart, but it has become standard for all devices having any patient-applied parts.

This test simulates the condition of a patient with leads attached touching ground such as an electric bed. If the patient connections are not isolated, this current reflects the earth current when tested under the open ground condition, as this is its only path back to true earth. For devices incorporating isolated patient connections, this current is reduced by the patient isolating impedance Z_I, a combination of resistive and capacitive leakage.

Measurement is made to the lead selected by the lead selector switch, with the other side of the AAMI load connected to system ground.

To measure patient lead leakage:

1. Connect the patient leads to the corresponding universal connectors on the front of the Analyzer.
2. Set the **FUNCTION** switch to **PATIENT LEAD LEAKAGE.**



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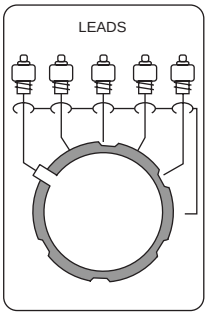
The leakage current displays in μA.

3. Select the lead to be tested by the **LEADS** switch.



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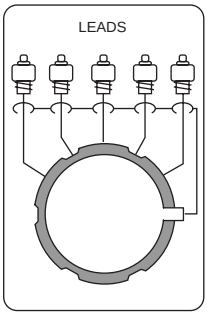
4. Take measurements for any combination of the **OUTLET** switch, the ground intact or lifted, and the DUT power **ON** or **OFF**.
5. Rotate the **LEADS** switch to test each lead individually, including the **ALL** position for testing all leads connected together.



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Current measured should be the same for all leads, including the **ALL** position, as the current represents the isolation impedance to the patient circuit.

Measuring Patient Auxiliary Current

Patient Auxiliary Current (I_A) (lead-to-lead current) flows from any patient lead to any other patient lead and to all other leads connected together, including:

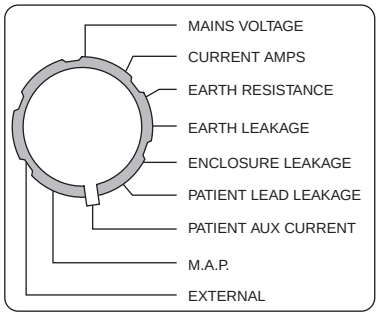
- Bias current of the input amplifier
- Reverse leakage current of input protection diodes
- Lead-off sensing current
- Impedance measurement current such as for respiration

The currents can be dc or ac or a combination of both. They are measured using a true rms to provide the common base necessary for accurate readout with a variety of common waveforms.

Measurement is made with a completely floating circuit to avoid extraneous leakage currents to ground introducing errors. Measurement is made from the selected lead to all other leads connected together, thus reducing the permutations required to cover all possibilities.

To measure patient auxiliary current:

1. Connect the patient leads to the universal connectors on the front of the analyzer.
2. Set the **FUNCTION** switch to **PATIENT AUX CURRENT**.



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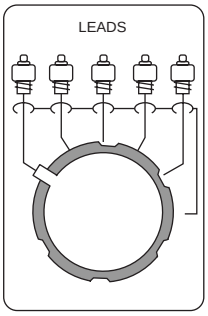
3. Select by the **LEADS** switch to test individual leads.



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4. Make measurements under all combinations of the **OUTLET** switch, **NORMAL** and **REVERSE**; **GROUND CLOSED** and the **LIFT GROUND** switch **OPEN**; and the device power turned **ON** and **OFF**.

   Under normal conditions, the current is primarily input bias current, measuring current or leadoff sensing current. The worst case condition is measured from the individual lead to all other leads connected together.

   The single lead carrying the most current is generally considered the reference lead (RL) because it acts as the return for the other leads. Therefore, the leads can be taken in groups of four with the common reference lead (RL) and then summed.

Measuring MAP (Patient Lead Isolation) Current

MAP (Mains on Applied Parts) Current (I_l) (patient lead isolation current) is that which would flow into the DUT if the patient were to come into contact with full line voltage. An example is an electric patient bed that has become ungrounded and has a short to the frame.

Measurement is made in each individual leads, but a common value is found for all leads, as well as for the **ALL** position, as this is the measurement for the isolation of the patient circuit. To assure proper reading, the test should be run with ground intact. For additional safety, the current is applied to the patient leads only when the **ISO TEST** switch is pressed.

For this test, the Analyzer provides a specially shielded line voltage secondary on its power transformer that minimizes internal leakage currents from the

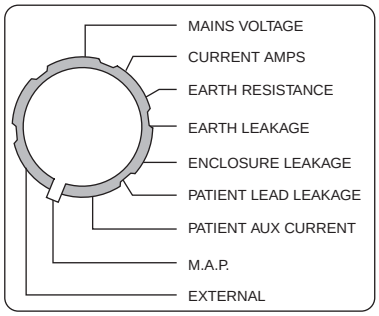
measuring circuit. This avoids the necessity of measuring the current and subtracting it from all readings. The current is limited with a 120 KΩ resistor for user protection.

⚠⚠ Warning

To avoid possible electrical shock or personal injury to the patient, take care when handling the patient leads. High voltage, 120/230 volts with respect to earth ground, is accessible at the patient connections during part of this test.

To measure lead isolation sink current:

1. Connect the patient leads to the universal lead connectors on the front of the analyzer.
2. Set the **FUNCTION** switch to **M.A.P**.



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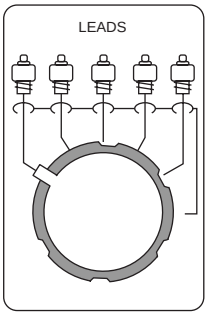
3. Select the individual lead to be tested by the **LEADS** switch.



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4. Press the **ISO TEST** switch to safely apply the high voltage to the leads.
5. While the **ISO TEST** is energized, read the isolation current in µA.
6. Take measurements for all combinations of the **OUTLET** in **both NORMAL** and **REVERSE** and **L2** switch **CLOSED** and with the DUT **ON** and **OFF**.

External Measurements

The Analyzer provides the extended capability of making leakage current and isolation current measurements between selected points, performing as follows:

- An ohmmeter capable of measuring resistance in the mΩ range for chassis bonding measurements.
- A low impedance (1000 Ω) voltmeter as specified by the NFPA, with a range to 1999 mV.
- A 1000 µA ammeter to measure the leakage current between two devices or between the DUT and a local ground reference. Range is to 1999 µA.
- An isolation tester for testing ultrasound probes and other transducers independently from the device in which it is used.

Note

Additional optional accessory cables must be purchased to perform these tests.

Leakage Current

Leakage Current and Voltage Gradients between two points are also measured for permanently installed equipment as additional verification of the integrity of the installation. These measurements are equivalent, because the relationship between volts and current across 1000 Ω is one mV per µA.

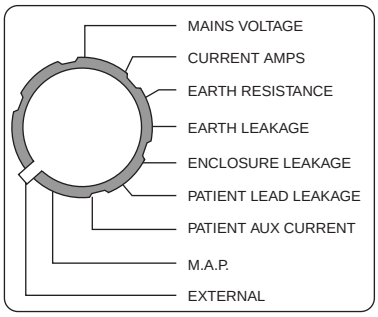
To measure leakage current and voltage gradient between two points:

1. Connect the black coil cord cable with the clamp with black insulation to the **CHASSIS** connector and the black cable with the clamp with red insulation to the **EXTERNAL** connector on the top panel of the Analyzer.

   Note

   Do not plug a device into the Analyzer. The measurement circuit must remain isolated from ground.

2. Set the **FUNCTION** switch to **EXTERNAL.**



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3. Clip the cables to the two points for which leakage current is to be measured.

   The Analyzer displays the leakage current between the two points to 1999 µA. The number displayed is also the voltage gradient in mV between the two points, based on a voltmeter with an input impedance of 1000 Ω.

Electrical Isolation

Isolation testing of probes and transducers that make internal contact to a patient is provided to assure the reliability of the isolation barrier. Such devices incorporate electrical circuits that can introduce or sink hazardous currents to a patient who comes into contact with line potential or who becomes grounded.

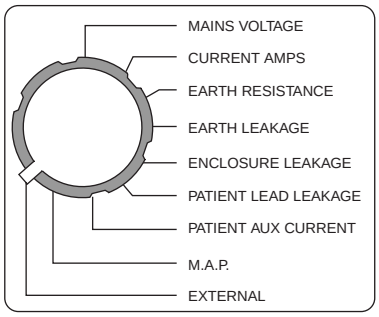
Note

For devices that require sterilization before use, testing before sterilization is recommended.

To measure electrical isolation of a probe or transducer:

1. Connect the black coil cord cable with the clamp with black insulation to the **CHASSIS** connector and the black cable with the clamp with red insulation to the **EXTERNAL** connector on the top panel of the Analyzer.

2. Set the **FUNCTION** switch to **EXTERNAL**.



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3. Press the **ISO TEST** switch.

   This action applies isolated line voltage between the two sides. The Analyzer displays the isolation current that flows.

Note

The method for making connection to either side of the isolation barrier varies with the device to be tested.

⚠⚠ Warning

To avoid possible electrical shock or personal injury take care when handling the cables. High voltage, 110 percent of line volts, will be accessible between the two cables when the LIFT GROUND/ISO TEST switch is in the ISO TEST position.

Resistance

Resistance measurements between two points are made to verify the integrity of permanently installed equipment whose ground cannot be broken to measure the chassis leakage current. These are usually high power devices, which can have high leakage currents and depend on the bonding of all chassis to a common point for safety. It is recommended that these devices be powered off for testing.

Measurement is made with a 10 mA dc current and is highly resistant to ac currents flowing between the measurement points as a result of chassis leakage current from either or both devices. However, such leakage current may have a dc component from rectification within the instrument. This dc current adds and subtracts from the measurement current, resulting in some error that can be corrected for by reversing the connections, remeasuring, and averaging the two readings.

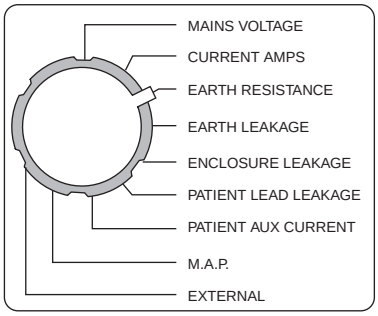
To measure resistance between two points:

1. Connect the two black chassis cables with clamps with black insulation to the **CHASSIS** and **EXTERNAL** connectors on the top panel of the Analyzer.
2. Clip the cables onto the two points to be measured.

Note

Do not plug a device into the Analyzer. Ensure that ground connections do not provide parallel measurement circuits causing erroneous results.

3. Set the **FUNCTION** switch to **EARTH RESISTANCE**.



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The display shows the resistance between the two points.

Chapter 3
Maintenance and Service

Contents **Page**

Maintenance

The Analyzer requires little maintenance or special care; however, it is a calibrated measuring instrument and should be treated as such. Store the Analyzer in its optional carry case, and ensure that the storage environment is free from vibration.

Avoiding Damage

Do not drop the instrument or subject it to any mechanical abuse that could cause a shift in the calibrated settings.

⚠ Caution

To avoid damage to the Analyzer or adverse affects on its performance, do not expose the system to temperature extremes. Ambient temperatures should remain between 15 °C and 40 °C, with a relative humidity less than 90 %.

Cleaning

Clean the exterior of the Analyzer occasionally with a cloth dampened with a mild detergent solution.

⚠ Caution

To avoid damage to the Analyzer or adverse affects on its performance, do not spray liquid directly on or immerse the unit.

Carefully wipe down the cables and inspect them for damage and deterioration of the insulation. Check the cable connections for integrity of the cable clamp and strain relief.

Verifying Analyzer Performance

The general performance of the Analyzer can be verified, using the procedures summarized in Table 3-1 and the parameters in Table 3-2. If the Analyzer does not perform correctly, contact the Fluke Biomedical Service Center immediately.

Table 3-1. Performance Verification Parameters

Parameter	Procedure	Desired Reading
Mains Voltage	Use a multimeter.	Volts
Current	Connect a lamp with a standard incandescent bulb to the DUT receptacle and set the OUTLET switch to NORMAL.	Amps, approximately as shown in Table 3-2
Resistance	Connect the black chassis cable with black insulation to the CHASSIS connector and clip it to the 0.15 Ω test point.	0.15 ±0.02 Ω
Enclosure Leakage	Connect the black chassis cable with a clamp with black insulation to the CHASSIS connector and clip it to the 100 µA test point.	100 ±2 µA
Patient Lead Leakage	Attach a clip lead to the 100 µA test point and the other end to the LEAD snap selected.	100 ±2 µA
Patient Aux. Leakage	Attach a clip lead to the 100 µA test point and the other end to the LEAD snap selected.	100 ±2 µA

Table 3-1 Performance Verification Parameters (cont.)

Parameter	Procedure	Desired Reading
M.A.P. (lead isolation current)	Connect the black chassis cable with a clamp with black insulation to the EXTERNAL connector and the clip to the lead selected. Press ISO TEST.	1000 ±15 %, depending on line voltage
External; for leakage current measurement	Connect the black external cable with a clamp with red insulation to the EXTERNAL connector and the clip to the 100 µA test point.	100 ±2 µA
Isolation	Clip the black external cable with a clamp with red insulation to the black chassis cable and press the ISO TEST switch.	1000 ±15 %, depending on the line voltage
Calibration	Do not attempt.	Not Applicable

Table 3-2. Current Verification Parameters

Bulb (Watts)	Current (Amps)	
	120 V Line	**230 V line**
60	0.50	0.30
75	0.63	0.35
100	0.83	0.45
150	1.25	0.70

Service and Calibration

If the new Analyzer fails to operate properly or if it needs a recommended yearly calibration, please contact the Fluke Biomedical Service Center immediately, as indicated under *Warranty and Product Support*.

⚠ Caution

To avoid damage to the Analyzer or adverse affects on its performance, allow only qualified technical personnel to service the Analyzer.

Packing

If repairs or calibration are required, return the Analyzer to the factory or the nearest service center.

1. Before returning the Analyzer for factory service, contact Fluke Biomedical Service Center for a required Return Authorization Number.
2. Provide the following information:
   - The Analyzer serial number
   - The specific steps that reproduce your problem
   - A daytime phone number
   - Your name / company
   - A fax number (if available)
3. Pack the instrument carefully, using the original shipping container and packing materials supplied by Fluke Biomedical. If the original packing materials are not available, refer to *Return Procedures* for a list of preferred materials or contact Fluke Biomedical for replacement packing.

Note

Failure to pack the instrument properly could void your warranty.

Shipping

1. Place the Return Authorization Number in a prominent place on the outside of the packing box, and refer to the number in any correspondence with Fluke Biomedical Service.
2. Enclose your return address and Return Authorization Number.
3. Insure the unit for full retail value and ship to the nearest Fluke Biomedical service center.